# Design for reliability: Ideal product requirement specifications for oxygen concentrators for children with hypoxemia in low-resource settings

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# Acronyms

| | |
|---|---|
| ATF | Advanced Technology Fractionator |
| °C | degrees Celsius |
| DC | direct current |
| FDA | United States Food and Drug Administration |
| IEC | International Electrotechnical Commission |
| ISO | International Organization for Standardization |
| L | liter(s) |
| m | meter |
| OCSI | oxygen concentration status indicator |
| SLPM | standard liter(s) per minute |
| LRS | low-resource settings |
| VAC | volts of alternating current |
| V | volt(s) |
| W | watt(s) |

# Introduction

## Problem statement

Hypoxemia is the major fatal complication of pneumonia, the leading infectious cause of death in children under the age of five years worldwide. In 2013, pneumonia killed 935,000 children—about 2,600 children every day—and accounted for more childhood deaths than HIV/AIDS, malaria, and tuberculosis combined.[1] Although it affects children worldwide, pneumonia mortality associated with hypoxemia is highest in LRS. In addition, child deaths that result from other common serious conditions such as birth asphyxia, low birth weight, meningitis, sepsis, acute asthma, and malaria add to the substantial burden of hypoxemia in LRS. Administration of supplemental oxygen is essential for the management of hypoxemia in acute patient care. However, the availability of oxygen is poor in settings where resources are limited, and many hypoxemic patients still do not receive oxygen. A survey of 22 low- and middle-income countries reported that less than half of all health facilities had uninterrupted access to oxygen and 35 percent had no oxygen.[2]

## Specification need

The reliable operation of oxygen concentrators in low-resource settings (LRS) is limited by intermittent and poor-quality power, a lack of access to replacement parts, and an absence of trained maintenance personnel. The hot, humid, and often dusty environments found in LRS serve to further exacerbate these issues and shorten the useful life of these devices. This document lists ideal product requirements for the development of a reliable, robust, and scalable oxygen concentrator platform appropriate for use in LRS for the treatment of children under five years of age with hypoxemia. PATH has defined performance characteristics and recommended specifications for feedback and action by manufacturers, developers, and innovators of oxygen supply technologies.

# Purpose and scope

The ideal product requirement specifications addresses the performance requirements and potential design approaches for oxygen concentrators intended for use in LRS that are characterized by intermittent power and minimal maintenance capacities. The purpose of this document is to provide guidance to developers and manufacturers in the development of a reliable, robust, and scalable oxygen concentrator that is appropriate for treatment of pediatric patients with hypoxemia in LRS. The suggested design approaches to meet these requirements are intended to serve as discussion points with oxygen concentrator developers and manufacturers. Their invaluable expertise and recommendations on the technical feasibility of these requirements and design strategies will be crucial to the development of a suitable product that meets the global public health need, end-user needs, and environment of use.

# Use case

The product design specifications for the proposed oxygen concentrator were developed to address the intended patient indication, user profile, and environment of use.

## Intended patient population

The use case for the proposed oxygen concentrator design is built on the assumed oxygen needs necessary for the treatment of infants and children with uncomplicated hypoxic respiratory illness. Pediatric patients less than five years of age with hypoxic pneumonia typically require continuous oxygen therapy for two to five days, with flow rates between 0.5 and 2.0 standard liters per minute (SLPM). In hospitals where hypoxic respiratory illnesses are prevalent, simultaneous treatment of multiple patients is needed. Thus, the system must be able to deliver at least 5 SLPM to support treatment for at least two pediatric patients simultaneously. While recognizing seasonality of pneumonia admissions, our use case does not consider variations in need beyond the desire to have capacity to treat up to two pediatric patients at any one time.

## User profile and environment of use

The described oxygen concentrator is intended for use in lower-level health care facilities in LRS that are capable of admitting and overseeing a patient overnight. Clinically trained staff are on site; however, technical maintenance staff or engineers are rarely available. Lack of assigned or otherwise sufficiently trained personnel to conduct maintenance, high staff turnover, and lack of training programs translates to most devices not receiving the preventative maintenance required to function properly. Furthermore, replacement parts are often in scarce supply, and supply and maintenance infrastructure are rarely present, resulting in device underutilization or failure. Although pulse oximetry is an essential tool for early detection of hypoxemia and in guiding oxygen therapy, its availability and widespread use is often scarce in LRS.

Intermittent and unstable power as well as harsh hot and humid environments present challenging operating conditions that often cause premature failure of oxygen concentrators in LRS. The power quality at these facilities is poor and characterized by the occurrence of frequent power fluctuations and surges. Voltage sags and spikes often occur for a few minutes each time. Backup power sources are also often unreliable. We assume a minimum of 4 hours of power outages frequently encountered each day, which may last up to 22 hours. In addition, the majority of health care facilities above sea level to as high as 2,000 meters often experience harsh ambient conditions, including high temperatures (up to 40°C) and high humidity (up to 95%) simultaneously. Average low temperatures can fall between 5°C and 10°C. Health care facilities at altitudes above 2,000 meters experience cooler temperatures, lower atmospheric oxygen levels, reduced barometric pressures, and less humid conditions. Lastly, very dusty or sooty environments and unhygienic conditions are also common to LRS.

# Method and inputs

The recommended specifications were proposed after careful review and analysis of the current market and state of oxygen concentrator technologies. These specifications were informed by international standards (Table 1); a literature review; interviews with subject-matter experts; and, where appropriate, primary research to include engineering evaluation of currently available oxygen concentrators.

Table 1. References.

| | |
|---|---|
| **International standards** | • ISO 13485:2003 Medical devices – Quality management systems -- Requirements for regulatory purposes.<br>• ISO 14971:2007 Medical devices – Application of risk management to medical devices.<br>• ISO 80601-2-69:2014 Medical electrical equipment – Part 2-69: Particular requirements for basic safety and essential performance of oxygen concentrator equipment.<br>• ISO 62366-1:2015 Medical devices – Part 1: Application of usability engineering to medical devices.<br>• IEC 60601-1:2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.<br>• IEC 60601-1-2:2014 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests.<br>• IEC 60601-1-6:2013 Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability.<br>• IEC 60601-1-8:2012 Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral Standard: General requirements, tests, and guidance for alarm systems in medical electrical equipment and medical electrical systems.<br>• IEC 60601-1-9:2013 Medical electrical equipment – Part 1-9: General requirements for basic safety and essential performance – Collateral Standard: Requirements for environmentally conscious design.<br>• IEC 60601-1-11:2010 Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home health care environment. |
| **Regulations** | United States regulations:<br>• 21 CFR part 820 Quality System Regulation.<br>• 21 CFR section 868.5440, Portable Oxygen Generator.<br>Japan regulations:<br>• MHLW Ordinance No.169 Quality System Regulation.<br>European Union regulations:<br>• Medical Device Directive 93/42/EEC. |

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|---|---|
| **Other** | • ANSI/AAMI HE75:2009 – American National Standard for Human Factors Engineering – design of medical devices (Chapter 5.6: Task analysis; Chapter 4: Heuristics).<br>• Duke T. *The Clinical Use of Oxygen in Hospitals With Limited Resources: Guidelines for health care workers, hospital engineers, and managers*. World Health Organization; 2012.<br>• FDA Draft Guidance for Industry – Applying Human Factors Engineering to Optimize Medical Device Design (June 22, 2011).<br>• UMDNS 12873 – World Health Organization/ECRI General information on hospital medical equipment – oxygen concentrators (2012).<br>• World Health Organization (WHO). *Pocket Book of Hospital Care for Children: guidelines for management of common childhood illnesses*. 2nd ed. Geneva: WHO; 2013.<br>• Zhang J, *et al*. Using usability heuristics to evaluate patient safety of medical devices. *Journal of Biomedical Informatics*. 2003;36(1-2):23–30. |

## Failure modes and effects

Current oxygen concentrators often fail with normal wear over time in the target environment of use. The PATH team conducted a gap analysis, including a review of the literature and current technologies, to analyze the gap between existing oxygen concentrators and the desired targets. The ideal product requirement specifications focus on key attributes to address or mitigate the common failure modes related to oxygen concentrators in LRS and their causes and effects. Though objective measures are sought whenever possible, data on the frequency and severity of failure modes is largely unavailable or incomplete. The PATH team has prioritized five key underlying causes that affect proper operation and reliability of oxygen concentrators in LRS worth further examination and discussion based on the gap analysis and earlier censuses with subject-matter experts. The list of underlying causes of failures considered below is neither exhaustive nor are the causes mutually exclusive.

Table 2. Underlying causes of failure modes encountered in LRS.

| Underlying cause | Desired target |
|---|---|
| Frequent power outages stops oxygen delivery immediately, interrupting therapy.[3] Backup power systems are often too expensive for health centers to acquire and maintain. | Provide uninterrupted oxygen flow to a minimum of two pediatric patients by integrating a backup solution for oxygen delivery during power outages. |
| Harsh operating environments can cause damage to internal electrical components (e.g., valves, compressor, sieve beds, and printed circuit boards), rendering the oxygen concentrator inoperable until serviced by skilled technicians who can access replacement parts, which may take an indefinite period of time.[4] | Operate under harsh environments characterized by high temperature, humidity, and dust. |

| Underlying cause | Desired target |
|---|---|
| Frequent power spikes, power sags, and distortions, also known as "dirty power," can cause damage or stop oxygen concentrators from operating, which interrupts oxygen therapy.[5,6] | Include power conditioning and protection against regular power outages and voltage fluctuations (e.g., surges, sags, and spikes). |
| Oxygen concentrators often fail in routine use when they do not receive annual preventive maintenance by skilled technicians.[7] Infrastructure and support for maintenance are often not available in LRS. | Easy to maintain and repair, requiring minimal technical training, replacement parts, and tools. |
| Acquisition and ongoing costs of the oxygen concentrator plus a backup system are prohibitively expensive. | Cost-efficient and include a minimum 5-year warranty. |

# Technical requirements

The purpose of the ideal product requirement specifications is to define a device that meets the intended use, the needs of the users and other stakeholders, and is safe. It organizes the high-level attributes for the design of oxygen concentrators and suggests design approaches to meet the desired targets. Developers and manufacturers may identify appropriate design approaches to fulfill the identified targets. The PATH team recognizes that manufacturer input is critical to assessing the feasibility of these specifications.

Table 3. Detailed specifications.

| Attribute | Minimum requirement | Desired target | Rationale |
|---|---|---|---|
| **Oxygen flow** | | | |
| **Maximum flow rate** | 5 SLPM. | ≥ 5 SLPM. | The technology must be able to support treatment for a minimum of two pediatric patients simultaneously, with each patient requiring flow rates between 0.5–2.0 SLPM. Larger units may support additional patients and/or other applications. |
| **Time to reach 95% of specified performance** | 5 minutes. | < 5 minutes. | Minimizing the time required to deliver concentrated oxygen reduces any delay in care to the patient. |
| **Flow control** | Flow limiter to prevent user from overdrawing | Same. | Users are known to overdraw oxygen flow, which can reduce sieve bed performance. |

| Attribute | Minimum requirement | Desired target | Rationale |
|---|---|---|---|
| | oxygen. | | |
| **Flow meter(s)** | One built-in flow meter 0–5 SLPM and continuously adjustable in minimum increments of 0.5 SLPM. | At least two oxygen outlets, where flow in each is controlled by separate pediatric flow meters, 0–2 SLPM, each continuously adjustable in minimum increments of 0.25 SLPM. | The intent is to create a product that eliminates the need to purchase additional flow splitters and supports the delivery of treatment for at least two pediatric patients simultaneously. |
| **Patient monitoring** | Standalone pulse oximeter available. | Pulse oximeter available with oxygen concentrator. | Pulse oximeters can make the use of oxygen supplies more efficient and improve delivery and monitoring of oxygen therapy to the patient. |
| **Design and user interface** | | | |
| **Oxygen outlet** | Recessed, replaceable metal or plastic threads or barbs. | Recessed, replaceable metal barbs. | Outlets are known to break upon being snagged or bumped. Metal barbed outlets are preferred since there are several variations of threaded outlets. |
| **Oxygen monitor** | Visual and audible oxygen concentration status indicator (OCSI), indicating three ranges of oxygen concentration. | OCSI with red, yellow, and green lights for concentrations < 85%, 70%–85%, and < 70%, respectively. | The intent is to design a product that provides a simple, reliable way to indicate proper functioning of the technology. |
| **Indicators** | User interface is easy to understand; numbers and displays are clearly visible. | All components the user interacts with are clearly labeled or marked with appropriate pictures and language. Where possible, audible alerts and diagnostic indicators | The intent is to deliver a product that minimizes the need for literacy and numeracy and is culturally appropriate. |

| Attribute | Minimum requirement | Desired target | Rationale |
|---|---|---|---|
| | | informing necessary action(s) are desirable. | |
| **Audible alarms** | Audible and/or visual alarms for high temperature, low/high/no flow rate, and low/high pressure. | Same. | The intent is to alert users of a device malfunction and a high-priority alarm condition requiring immediate response. |
| **User instructions** | Instruction manual including use of the device with additional flow meters provided in the shipping package of the device. | User instructions attached with reference to labels and markings on the device. It should include pictograms and local language text where possible. | The intent is to provide clear user instructions despite lost instruction manuals to reduce the margin of error, yielding improved delivery of oxygen therapy. |
| **Weight** | N/A. | Compact and lightweight (< 27 kg) for ease of portability and transport. | Whole unit to be easily portable by a single person. The suggested weight value is based on the average weight of existing devices. |
| **Mobility** | Four antistatic swivel castors, two with brakes. Integrated handle. | Same. | Whole unit to allow easy moving and positioning by a single person. |
| **Sound level** | 50 decibels. | ≤ 50 decibels. | Minimizing noise prevents disruptions or distractions during the provision of care as well as increases patient comfort and acceptability of the device. |
| **Power** | | | |
| **Power efficiency** | ≤ 55 watts (W)/SLPM. | ≤ 40 W/SLPM. | The intent is to deliver a product with a power efficiency that is at least comparable to existing technologies. |
| **Power** | ≤ 275 W at 5 | Scales with | The intent is to reduce the power |

| Attribute | Minimum requirement | Desired target | Rationale |
|---|---|---|---|
| **consumption** | SLPM. | delivery output — i.e., consumes less power at lower flow rates. | requirements and prevent blackouts aggravated by high power draw. |
| **Electrical plug** | Compatible with the local power outlet and rated above the device's amperage and voltage requirements. | Universal conversion power adapter compatible with and rated above the device's amperage and voltage requirements. | The intent is to deliver a product that is compatible with the power input requirements of the socket to be used. |
| **Power conditioning** | | | |
| **Surge protection** | External. | Integrated. | The intent is to protect against regular voltage fluctuations to prevent damage to the oxygen concentrator and interruption of oxygen therapy. |
| **Voltage input tolerance at rated maximum capacity** | ± 20% of volts of alternating current (VAC) input. | 85–264 VAC. | |
| **Uninterrupted backup supply during power outages** | | | |
| **Backup duration provided at maximum flow** | External. Supplies ≥ 2 hours at 5 SLPM or 600 liter(s) (L) oxygen. | Integrated. Supplies ≥ 4 hours at 5 SLPM or 1,200 L oxygen. | The intent is to deliver a product that can provide a continuous supply of oxygen during power outages lasting greater than two hours each day. |
| **Down time required to refill or recharge (> 90%) each day** | ≤ 2 hours for every 2 hours of continuous backup provided. | < 2 hours for every 4 hours of continuous backup provided. | The intent is to provide an uninterruptible and inexhaustible supply of oxygen during frequent power outage. |
| **Maintenance and reliability** | | | |
| **Filters** | All replaceable. Coarse filter is washable and reusable. | Same. | The intent is to reduce the requirements for routine maintenance of replacement parts. |
| **Cleaning interval** | Weekly cleaning of external course filter. | None required. | The intent is to reduce the requirements for routine maintenance. Concentrators often underperform due to a lack of regular cleaning of the coarse filters. |

| Attribute | Minimum requirement | Desired target | Rationale |
|---|---|---|---|
| **Hour meter** | Non-resettable digital or analog meter displaying cumulative hours of operation. | Same. | The intent is to indicate routine maintenance required for proper functioning. |
| **User care skill level** | Trained user. | Minimal to none. | The intent is to reduce the requirements for training clinical and technical staff, especially since high staff turnover can disrupt safe and effective use. |
| **Decontamination** | Easy to clean flat surfaces and compatible with common disinfecting agents. | Reduce recessed areas and need for specialized cleaning procedures or products. | The intent is to deliver a product that can be cleaned similarly to existing oxygen concentrators, with a mild disinfecting cleaning agent or a diluted solution of bleach. |
| **Technical skill for maintenance** | Trained technician with training in basic operation and maintenance. | Minimally trained user. | The intent is to minimize the requirements for specialized repair or advanced maintenance tasks. Concentrators can fail in routine use when not sent to skilled technicians for annual preventative maintenance. |
| **Preventive maintenance interval** | Every 24 months. | Minimal to none for the lifetime of the device is desirable. | The intent is to minimize the maintenance requirements for the duration of the warranty period. |
| **Tools required** | Minimal specialized tools required for sieve bed and filter replacement. | No specialized tools required. | The intent is to increase user serviceability and minimize the requirements for specialized tools. |
| **Replacement parts and consumables** | None required for 24 months. | None required for lifetime of device is desirable. | Replacement parts and consumables are often in scarce supply, and supply and maintenance infrastructures are rarely present. |
| **High durability and robustness** | Operate continuously in temperatures of 10° to 40°C, relative humidity of 15% to 95%, simultaneously at | Operate continuously in a broad range of harsh ambient conditions, including temperatures of 5° | The intent is to deliver a product that demonstrates high durability and robustness in harsh operating environments frequently encountered in LRS. |

| Attribute | Minimum requirement | Desired target | Rationale |
|---|---|---|---|
| | elevations up to 2,000 meters. | to 45°C, relative humidity of 15% to 95%, and very dusty air, simultaneously at elevations above sea level to ≥ 2,000 meters. | |
| **System warranty** | ≥ 3 years. | ≥ 5 years. | The intent is to deliver a product that is at least comparable to existing technologies. |
| **Applicability and scalability** | | | |
| **Documentation requirements** | User, technical, and maintenance manuals to be supplied in the English language. Include list of all spare or replacement parts, lifetime, and costs for the life cycle of the product. | User, technical, and maintenance manuals to be supplied in the appropriate language. Include local contact details for the manufacturer, supplier, and local service agent. | The intent is to provide information regarding technical support to increase the probability of successful and sustainable implementation. |
| **Costs** | ≤ US$750. | Must confirm desired target for pricing. If the cost is higher, the added value of the technology should be clear (e.g., reduced maintenance, lower power requirements, increased reliability). | The intent is to reduce the cost and burden to procurement. The total cost should be equivalent or less than the cost of existing concentrators and demonstrate high affordability of the total package including operating costs and rates of consumption of consumables or replacement parts during the life cycle of the product. |
| **Scalability** | Manufacturer demonstrates supply capacity, scalability, and sustainability. | The product demonstrates fit and adaptability to reach urban, rural, regional, or global scale. | The intent is to deliver a reliable, robust, and scalable product that could provide an uninterruptible and inexhaustible supply of oxygen for use by lower-level health care facilities in LRS. |

| Attribute | Minimum requirement |
|---|---|
| **Quality and safety** | |
| **International Organization for Standardization (ISO)** | The technology shall have a comparable quality and safety profile to existing oxygen concentrators and comply with ISO 80601-2-69:2014 Medical electrical equipment – Part 2-69: Particular requirements for basic safety and essential performance of oxygen concentrator equipment, or its equivalent. |
| **Regulatory approval(s)** | The technology shall obtain US Food and Drug Administration 510(k) approval [USA], declare compliance with Conformité Européenne (CE) marking [EU], or have approval from any regulatory member of the International Medical Device Regulatory Forum [Australia, Brazil, Canada, China, the EU, Japan, and USA] in addition to appropriate local regulations from the countries in which the concentrator will be sold. |

# Suggested design approach

The ideal oxygen concentrator to serve pediatric patient populations in LRS that are characterized by unreliable power and maintenance could contain an integrated battery pack that provides enough energy during a power outage lasting at least four hours. Further investigation is needed to identify more cost-effective and immediate solutions and backup power approaches to address longer durations of power outages commonly experienced in LRS. Recognizing that there is often a trade-off between energy storage capacity and physical size, the PATH team suggests that incorporating design elements to maximize power efficiency and reduce maintenance requirements are key.

### Incorporate a power-efficient sieve bed design with a variable-speed direct current (DC) compressor, or similar improved oxygen concentrator system, that can deliver at least 5 SLPM.

Technological solutions to significantly reduce the power consumption of oxygen concentrators can enable efficient integration with a battery backup supply. A continuous flow oxygen concentrator integrating a power-efficient sieve bed design with a DC compressor (e.g., SeQual eQuinox™), or similar improved oxygen concentrator system, may provide a promising and immediate solution to significantly reduce the power demand of oxygen concentrators.

### Incorporate a variable-speed DC compressor.

DC compressors can address the damaging effects caused by dirty AC power, allow for integration with battery packs, and reduce thermal loading. DC compressors accommodate larger voltage input tolerances at rated maximum capacity and enable an integrated surge protection solution against power fluctuations. The use of a variable-speed DC compressor further improves power efficiency by enabling consumption of power that scales with delivery output —i.e., consumes less power at lower flow rates.

### Integrate a Lithium Iron Phosphate or Lithium Carbon Oxide battery pack.

With the increased energy efficiency offered by an improved oxygen concentrator system, integrated battery packs can provide a solution for delivering an uninterrupted oxygen supply during power outages. Compared to the commonly used lead-acid battery, these battery chemistries demonstrate improved cycle lifetimes, lower discharge depths, and greater stability at high temperatures.

### Incorporate an Advanced Technology Fractionator (ATF) sieve bed design or similar improvements to reduce the requirements for maintenance and replacement parts.

The ATF sieve bed module eliminates several mechanical valves and other components that are typical of other oxygen concentrators, thus reducing the maintenance and replacement requirements compared to concentrators with conventional sieve bed designs.

### Eliminate the external coarse filter, design modular parts with clear instructions for user to service, and provide access to user-serviceable external sieve beds.

Recent models of commercialized oxygen concentrators reduce the requirements for cleaning, training, maintenance, and specialized tools. Eliminating the need for coarse filter cleaning (e.g., AirSep VisionAire™) would be a major improvement, as this is often neglected in LRS, causing early failure. Employing a modular system enables a trained user to replace worn components, and providing access to user-serviceable external sieve beds facilitates improved serviceability and reparability without the need for specialized tools (e.g., Inogen at Home™). The ideal concentrator would require no repairs within the warranty of the device (5 years) and preventative maintenance at no more than annual intervals. Based on claimed performance of existing devices, such a warranty lifetime seems achievable.

## Proposed actions

Overall, PATH believes that an improved oxygen concentrator system with improved power efficiency, reduced maintenance requirements, and capacity to address unavailable and poor quality power could have significant benefits in LRS where the current alternatives are inappropriate or unreliable. Recognizing that the market for oxygen concentrators is continually improving and shifting toward developing more power-efficient and easy-to-use devices, the PATH team seeks to identify manufacturers with the potential to innovate or adapt devices to meet the minimum requirements and desired targets defined in this document. Despite significant improvements in the safety and performance of oxygen concentrators, the feasibility of adapting technologies to the target use case must be further investigated to understand whether affordable and effective solutions to the unique needs of LRS may be satisfied by continued research and development. The PATH team suggests that three lines of technical inquiry be explored with a manufacturer to fully understand the feasibility of the recommended specifications and suggested design approaches:

1. What are the reliability ratings and failure modes?

    a. What components are failing in field use, and what are their modes of failure?
    b. How many hours of use, and how many years of annual maintenance are anticipated before major service is required?
    c. Could minimally trained users be sufficient to maintain and service the device?
2. What is the scope of adapting state-of-the-art technologies into a 5 SLPM oxygen concentrator?
    a. What are the trade-offs for maintaining power efficiency of < 40 W/SLPM for a 5 SLPM unit?
    b. What design approaches can be used to eliminate the preventive maintenance requirements (i.e., large filters and alarm capacitor)?
    c. What are the cost and safety implications of increasing the size of the battery cell to achieve 4 hours or more of backup power?
    d. Is the technical scope of effort or projected system cost significantly reduced if the scale-up target is less than 5 SLPM?
3. Can the cost of an improved oxygen concentrator system be reduced to be more affordable for LRS?
    a. What is the projected cost of goods sold at higher volumes that can be achieved from accessing LRS markets?
    b. Is global access pricing available for select LRS countries?

# References


1. World Health Organization, United Nations Children's Fund. *Ending Preventable Child Deaths From Pneumonia and Diarrhoea by 2025*. Geneva, Switzerland: World Health Organization; 2013.

2. Vo D, Cherian MN, Bianchi S, et al. Anesthesia capacity in 22 low- and middle-income countries. *Journal of Anesthesia and Clinical Research*. 2012;3(4):207.

3. Kingham TP, Kamara TB, Cherian MN, et al. Quantifying surgical capacity in Sierra Leone: a guide for improving surgical care. *Archives of Surgery*. 2009;144(2):122–127.

4. Peel D, Neighbour R, Eltringham RJ. Evaluation of oxygen concentrators for use in countries with limited resources. *Anaesthesia*. 2013;68(7):706–712.

5. Bradley BD, Qu S, Cheng YL, Peel D, Howie SRC. Options for medical oxygen technology systems in low-resource settings: A framework for comparison. *Proceedings - 2012 IEEE Global Humanitarian Technology Conference, GHTC 2012*. 2012:356–362.

6. Enarson PM, head of the Child Lung Health Division for the International Union Against Tuberculosis and Lung Disease, personal communication, August 2014.

7. Enarson P. Implementation of an oxygen concentrator system in district hospital paediatric wards throughout Malawi. *Bulletin of the World Health Organization*. 2008;86(5):344–348.