

Oxygen concentrator and storage

Country of origin | Germany
 Primary function | Treatment
 Category | Medical device

Commercial information

List price (USD): 850

Year of commercialization: 2021

Number of units distributed: 0-100

Currently marketed in: We are initially targeting Uganda, Kenya and Tanzania for first sales. We will subsequently focus on the The Pacific.

Brand: FREO2 Foundation Australia and Kröber Medical Devices Germany

Model: Oxylink

Product description

A rugged concentrator with easy 'swap-n-go' unit exchange: heavy-duty, externally mounted filter and power stabilization. Even amid power fluctuations and surges, it continues to operate safely. During blackouts, cylinder integration guarantees oxygen flow.

*Options LPOS stands for low-pressure oxygen storage with automatic delivery during a power outage.

ODS: low-cost oxygen delivery system that delivers oxygen to patients directly through low-pressure rubber piping and bed-side flow meters, making HCW workflow easier.

Product details

Consumables: Nasal prongs

Warranty duration: 2 years

Lifetime: 2-5 years

Energy requirements: Continuous power supply, Solar power, AC,180-260 V, 600W

Facility requirements: Specific temperature and/or humidity range, 5 to 40 C° 15% to 93% relative humidity (non-condensing)

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NOTE: Information reported by manufacturer before 17 December 2021



WHO ASSESSMENT

Clinical assessment

Hypoxemia is a condition in which blood oxygen level is abnormally low (i.e., low partial oxygen tension). It can result in respiratory failure and the need for supplementary oxygen therapy due to various mechanisms and diseases. In resource-limited settings, lower respiratory tract infections and tuberculosis, in addition to COVID-19, are a major cause of hypoxemia and a primary source of morbidity and mortality, ranking among the top 10 causes of death in low- and lower-middle-income countries.

Furthermore, it is estimated that only fewer than half of all health facilities have continuous oxygen supply in low-resource contexts. A lack of accessible oxygen, in particular, leads to preventable deaths, with an estimated 122,000 deaths from pediatric pneumonia each year that could be avoided if oxygen supplies and delivery systems were improved. Moreover, the COVID-19 pandemic has further increased the demand for oxygen at the global level.





FREO2 - Oxylink system may thus provide a suitable alternative for oxygen concentration, storage, and delivery in healthcare settings lacking adequate infrastructure and experiencing short-term power fluctuations.

WHO specification comparison

The FreeO2 OXYLINK device has been evaluated by comparing the technical documents provided with the WHO “Oxygen Concentrator” technical requirements currently available.

This device partially complies with the “Oxygen Concentrator” WHO technical specifications due to the fact that the following aspects of the device could not be verified or were not specified: oxygen outlet(s) type (requested with 6 mm, or 1/4 inch, barbed fitting or equivalent) and how the oxygen outlet is mounted to be secure and sheltered to reduce risk of being broken or bent. Mechanical shock resistance, mechanical vibration, electromagnetic compatibility and electrical safety tests performed. Capability of supplying the specified oxygen concentration continuously with elevation from 0 to at least 2000 m (besides, performance characteristics at altitudes higher than 2000m must be stated). Length of the main power cable to be higher than 2.5 m. Not clear if in the accessories list is also included the DISS and barbed adaptors (for each outlet, if applicable).

Regulatory assessment

 Pre-market assessment	 Not acceptable
 Post-market assessment	 Not acceptable
 Quality system assessment	 Proceed with caution

It is a prototype model and has not been tested.

























Pre-market - full design verification and validation documentation required for oxygen storage, pipeline system, filter, safety valve, pressure regulator/switch, and alarm system

Post-market - complete documentation required for distribution, adverse event reporting, recall, field safety action, and complaint handling.

QMS - quality manual, risk management based on ISO 14971:2019, audit reports are required

The documentation provided is insufficient to undertake the assessment required to confirm the FREO2 system’s safety and performance in order for it to be included in the compendium.

Technology evidence assessment

Domains	Evidence assessment		
	Risk/benefit ratio	Impact	
 Medical			The device is designed to be simple, usable, and locally maintainable. Deployability was also assessed in low-resource settings based on the evidence presented. Local assembly and long-term manufacturing are being explored by the manufacturer. It can work successfully with a variable power supply or energy swings. Solar energy can be used to provide energy. The system is operating in a high-relative-humidity environment. The device appears to be inexpensive in LMI settings, based on the information provided.
 Safety			
 Economy			
 Organizational			
 Legal			
 Social			
 Ethical			
 Green environment			
			Summary
		Innovation	Technology evidence assessment Recommended, but still a prototype
		Technology readiness level 9	

Health technology and engineering management

Domains	Appropriateness	Domains	Appropriateness	Target settings: Rural, Urban, Indoors, Home, Primary, Secondary & Tertiary
Durability		Ease of cleaning		<p>The system consists of 5 subsystems - Oxylink, LPOS, Oxypump, FREO2 Solar and SIPHON. Some of the subsystems are more sensitive to misuse and damage. Given the importance of storage subsystems for oxygen flow, extra evidence for durability, environmental conditions, maintenance requirements, and cleaning should be provided. Beyond the initial site, performance testing is inconclusive. Krober/OxyLink oxygen concentrator system, which was recently included in this submission, describes a design that is appropriate for low-resource settings and is cost-effective, however no technical support or access to required spare parts is provided.</p>
Ease of Use		Ease of maintenance		
Positive impact on clinical outcomes		Infrastructure requirements		
Affordability		Local access to sales support		
Engineering resources minimization		Local access to technical support		
Cultural and social acceptability		Local access to training		
Environmental conditions		Local access to spare parts		
Aesthetics		Locations of use within target setting		

Intellectual property and local production

Technology transferability		Intellectual property - It is protected by trade secret and patents. The patent applications are still pending.
Openly access intellectual property		It has been stated that they are willing to provide access to their intellectual property. Caution advised due to pending patent applications.
Local production		Local production - It is not yet ready for production; it is still in the prototype stage.

WHO related guidance material

- WHO Oxygen website - https://www.who.int/health-topics/oxygen#tab=tab_2
- Oxygen therapy for children: a manual for health workers - <https://apps.who.int/iris/handle/10665/204584>
- Oxygen sources and distribution for COVID-19 treatment centres: interim guidance, 4 April 2020 - <https://apps.who.int/iris/handle/10665/331746>
- Coronavirus disease (COVID-19) technical guidance: Patient management - <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/patient-management>
- Living guidance for clinical management of COVID-19 - <https://www.who.int/publications/i/item/WHO-2019-nCoV-clinical-2021-2>
- WHO recommendations on newborn health: guidelines approved by the WHO Guidelines Review Committee - <https://www.who.int/publications/i/item/WHO-MCA-17.07>
- WHO-ICRC Basic Emergency Care: approach to the acutely ill and injured - <https://www.who.int/publications/i/item/basic-emergency-care-approach-to-the-acutely-ill-and-injured>
- Emergency care - <https://www.who.int/emergencycare/systems/en/>
- WHO Medical Emergency Checklist - <https://www.who.int/publications/i/item/who-medical-emergency-checklist>
- Guidelines for essential trauma care - <https://www.who.int/publications/i/item/guidelines-for-essential-trauma-care>
- WHO Global Health Estimates (the top 10 causes of death) - <https://www.who.int/news-room/factsheets/detail/the-top-10-causes-of-death>
- WHO Coronavirus (COVID-19) Dashboard - <https://covid19.who.int/>