PROTOTYPE PRODUCT

Oxygen concentrator

Country of origin | Bangladesh
Primary function | Treatment
Category | Medical gas

Commercial information

List price (USD): 400
Brand: OxyNLife
Model: OxyNLife

Product description

The developed device selectively removes nitrogen from the air to produce a high purity oxygen stream by utilizing a state-of-the-art porous adsorbent. The device continuously draws in air and generates a steady stream of high-purity oxygen.

Product details

Accessories: The device requires propriety software that comes with the device for It to function and achieve the target performance. Additionally, the device also needs filters (air, bacteria filters) as accessories.

Consumables: Face mask/nasal cannula for patients during use. The filter has to be changed every 6 months of use.

Warranty duration:

Lifetime: 2-5 years

Energy requirements: Continuous power supply, AC, 110V, 220V, 340W

Facility requirements: Healthcare waste disposal facilities (disposal of oxygen face mask, nasal canula and filters), disposal guidance provided by the manufacturer

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NOTE: Information reported by manufacturer before 17 December 2021

WHO ASSESSMENT

Clinical assessment

Hypoxemia is a condition in which the blood oxygen level is abnormally low. It can be caused due to various mechanisms and diseases and can lead to respiratory failure and the need for supplemental oxygen therapy. In many resource-limited settings, lower respiratory tract infections and tuberculosis, in addition to COVID-19, are a leading cause of hypoxemia and a significant source of morbidity and mortality, ranking among the top ten 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.

The COVID-19 pandemic has further increased the demand for oxygen worldwide, and the OxyNLife device intends to address this global health concern as a prototype oxygen concentrator. The device's inventive potential, however, is debatable based on the information supplied.

WHO specification comparison

OxyNLife device only partially complies with the related WHO requirements. Even if no non-compliance was found, the following device parameters and technical specifications could not be verified or were not included in the documents:

The type of oxygen outlet (required with 6 mm, or 1/4 inch, barbed fitting or equivalent) and how it is secured and shielded to avoid being broken or bent. The ability to continuously supply the specified oxygen concentration at elevations ranging from 0 to at least 2000 m (along with performance characteristics at altitudes higher than 2000 m) must be stated. The main power cable should be longer than 2.5 meters. It's unclear whether the DISS and barbed adaptors are included in the accessories list (for each outlet, if applicable). Storage and operating conditions related to temperature and humidity apply to the entire device, not just the sensor.

Mechanical shock resistance, mechanical vibration, electromagnetic compatibility, and electrical safety tests were all performed. The displayed parameters, display characteristics, and user-adjustable settings are all available. IP protection is provided.

Regulatory assessment

Pre-market assessment	Not acceptable
Post-market assessment	Not acceptable
Quality system assessment	Not acceptable

Adequate documentation was not provided to perform a medical device Regulatory or Quality System review. Design verification and validation reports were not submitted for pre-market assessment. No documentation available on quality management system, ISO 13485:2016 for quality system assessment. No documentation was provided on post-market activities.

As such, this product is in the prototype stage.

USA FDA Recognized Consensus Standards:

- ISO 80601-2-69:2014
- ISO 18562-1:2017
- ISO 18562-2 :2017
- ISO 18562-3 :2017
- ISO 18562: 2017
- ISO 80601-2-69:2020

WHO technical specifications for oxygen concentrators :

- ISO 80601-2-69:2014,
- IEC 60601-1:2012,
- IEC 60601-1-2:2014,
- IEC 60601-1-6:2013,
- IEC 60601-1-8:2012,
- IEC 60601-1-9:2013,
- IEC 60601-1-11:2010,
- ISO 13485:2003,
- ISO 14971:2007

Technology evidence assessment

Domains	Evidence assessment: Risk/benefit ratio	Evidence assessment: Impact
Medical	!	→
Safety	!	→
Economy	→	→
Organizational	→	!
Legal	!	!
Social	!	!
Ethical	!	!
Green environment	✕	!

The device is a prototype that was developed specifically for COVID-19. It has been tested in two hospitals with two patients, and it complies with the WHO oxygen concentrator guidelines. All used components are low-cost, according to the documents provided. As a result, the system's affordability in LMIC appears credible. It is simple to manufacture, use, and maintain the device. The information about the shelf life (0-2 years) raises questions. More information about medical, safety and cost-effectiveness is needed for further evaluation and recommendation.

Summary

Innovation		Technology evidence assessment	Not recommended, still a prototype
Technology readiness level	6		

Health technology and engineering management

Domains	Appropriateness	Domains	Appropriateness
Durability	→	Ease of cleaning	→
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	N/A	Local access to training	✕
Environmental conditions	→	Local access to spare parts	✕
Aesthetics	→	Locations of use within target setting	!

Target settings: Primary, Secondary & Tertiary level

The submission includes a description of a prototype product that is not accompanied by an independent testing laboratory certificate. The technical specification is insufficient for a thorough engineering evaluation. User or technical manuals were not included. As a result, there are no instructions for use, maintenance, warnings, or contraindications listed. By design, this product's application and use are limited to a maximum output of 5 LPM, restricting its use to areas where oxygen flow limitation is not a concern.

Intellectual property and local production

Technology transferability	→
Openly access intellectual property	✕
Local production	N/A

Intellectual property – Protected by trade secret. It uses proprietary software, which can be licensed to the manufacturer. The use of all intellectual property and third-party products will require clearance.

Local production – The device is in early prototype phase and is not ready for production.

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/fact-sheets/detail/the-top-10-causes-of-death
- WHO Coronavirus (COVID-19) Dashboard - https://covid19.who.int/