PROTOTYPE PRODUCT/ NEWLY COMMERCIALIZED

2022

High oxygen peep device

Country of origin | South Africa
Primary function | Supporting or sustaining life
Category | Medical device

Commercial information

List price (USD): 165
Year of commercialization: 2021
Number of units distributed: 10,000-50,000
Currently marketed in: African Region
Brand: Gabler Medical (Pty) Ltd
Model: OxERA

Product description

It comprises a custom main housing, incorporating an adjustable PEEP valve (5 – 15 cm H2O), anti-asphyxiation valve (for safety), and oxygen supply via a hose and accumulator bag. The oxygen hose can be connected to any available source of oxygen. Commercial medical devices such as an anesthetic mask and viral filter complete the package together with simple but effective elastic head straps. The snug fit and accumulator maximises oxygen efficiency and the PEEP valve provides PEP.

Product details

Consumables: Viral / bacterial respiratory filter
Facility requirements: pathological waste, sharps, chemicals, etc (Device requires disposal as medical waste as it comes into contact with the patient's skin, expired air and secretions); Gas supply (Oxygen)

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NOTE: Information reported by manufacturer before 17 December 2021

WHO ASSESSMENT

WHO assessed some newly commercialized products as a prototypes considering they had limited production, availability and evidence.

Clinical assessment

Acute viral pneumonia that progresses to acute respiratory distress syndrome is the leading cause of morbidity and mortality from COVID-19. Supplemental oxygen therapy and increased respiratory support are required as patients' respiratory status deteriorates. A trial of a high-flow nasal cannula or non-invasive ventilation may be used in selected patients with COVID-19 and mild acute respiratory distress syndrome, according to WHO clinical guidelines.

The OxERA device is intended for use as a step-up strategy on adult hypoxemic patients in hospital settings who require additional respiratory therapy in the form of Positive Expiratory End-Pressure (PEEP). The device is an oxygen accumulator with an adjustable PEEP valve (5-15 cmH2O) that allows exhalation while delivering high levels of oxygen at ambient pressure. If the oxygen supply is insufficient, as expected in certain rural areas with inadequate infrastructure, an anti-asphyxiation valve can be used to draw in supplementary ambient air.

This device may be more beneficial in low-resource environments, such as district-level hospitals or during transportation, where non-rebreather face masks would be the only viable option. However, continuous monitoring of the patient's respiratory status must be ensured for patients undergoing clinical deterioration, as well as prompt referrals to higher-level facilities.

WHO specification comparison

This device is reported to be a "High Oxygen Peep device". Consequently, at the time of report creation, WHO technical specifications are not available to compare this type of technology.

Regulatory assessment

Pre-market assessment
Post-market assessment
Quality system assessment

Proceed with caution
Not acceptable
Proceed

Pre-Market - A Human Factors/Usability report was provided. The manufacturer stated that the product was incompliance with EN ISO 15223-1:2016, Iso 18562-1:2017, ISO 20789:2018, and ISO 17510:2015 but performance and/or safety data was not provided to enable a Pre-market Assessment. Adequate documentation was not provided to perform a medical device Regulatory or Quality System review on this product. Design verification and validation reports were not submitted for pre-market assessment, see list below for applicable standards. They do have a current Licence to Manufacture Medical Devices from the South African Health Products Regulatory Authority.

Post-maket - No documents or data provided.

A current ISO 13485:2016 certificate was provided.

Missing safety and performance data:

- ISO 5356-1 Third edition 2004-05-15 Anaesthetic and respiratory equipment - Conical connectors: Part 1: Cones and sockets
- ISO 10651-4 First edition 2002-03-01 Lung ventilators - Part 4: Particular requirements for operator powered resuscitators
- ISO 18562-1 First edition 2017-03 Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 1: Evaluation and testing within a risk management process
- ISO 18562-2 First edition 2017-03 Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 2: Tests for emissions of particulate matter
- ISO 18562-3 First edition 2017-03 Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 3: Tests for emissions of volatile organic compounds
- ISO 18562-4 First edition 2017-03 Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 4: Tests for leachables in condensate
- ISO 10993-1:2018 Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process - needed for the mask material

Technology evidence assessment

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

The device is an all-in-one, single-use, high oxygen peep prototype device. It consists of an oxygen accumulator bag, anaesthetic mask, adjustable mechanical peep valve, anti-asphyxiation valve, and oxygen supply via the hose. It is intended for use by trained health professionals in hospitals or clinical settings, in general, to provide a supportive oxygen supply for respiratory diseases. According to the manufacturer, phase one safety study data showed no CO_2 retention and good tolerance to the mask in healthy volunteers. Referring documents are available but have not been submitted and peer-reviewed yet. Phase 2 and 3 trials are in the planning stage. According to the manufacturer, local production is possible but not currently planned. The entire device is a single-use product. Information on environmental compatibility, recycling, and disposal is not provided. Considering that the device is intended for single use only, the intended price does not support affordability in low-resource settings. In conclusion, a recommendation could only be made with caution, especially given the lack of clinical evidence, pending regulation, questionable affordability, and missing data on environmental compatibility.

Summary

Innovation		Technology evidence assessment	Recommend with caution
Technology readiness level	7		

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: Rural, Urban, Ambulance, Primary & Secondary level

This commercially available product is an Oxygen Efficient Respiratory Aid (OxERA), which is designed to assist patients by providing a high percentage of oxygen while maintaining a slight pressure to prevent the lungs from collapsing during expiration. The product contains an anesthetic-like mask, oximetry set with a hose, filter, rebreathing bag, anti-asphyxiation valve, and mechanically hand adjusted PEEP valve. The face mask has an inflatable edge that allows it to be fitted to the patient's face shape and size by adding/removing air from the edge with a syringe. The product cost is about US$165, which positions it above alternative used products. The product benefit is that it offers more efficient use of oxygen sources; an important feature in setting where Oxygen supply is an issue. The product design is durable and easy to use.

Intellectual property and local production

Technology transferability	✓
Openly access intellectual property	✗
Local production	✓

Intellectual property – The device has registered trademarks. Clearance is required to use this technology. Proceed with due diligence.

Local production – Technical complexity for local production is low to moderate. Market fluctuations can impact production feasibility.

WHO related guidance material

- Living guidance for clinical management of COVID-19 - https://www.who.int/publications/i/item/WHO-2019-nCoV-clinical-2021-2
- Coronavirus disease (COVID-19) technical guidance: Patient management - https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/patient-management
- Therapeutics and COVID-19: living guideline - https://www.who.int/publications/i/item/WHO-2019-nCoV-therapeutics-2021.3
- WHO Coronavirus (COVID-19) Dashboard - https://covid19.who.int/