Field oxygen rebreathing system*

Country of origin | Sweden
Primary use | Other
Category | Medical device (including in vitro diagnostics)

Year published in compendium: 2021

Commercial information

List price (USD): 2 870
Year of commercialization: 2020
Number of units distributed: 100-150
Currently marketed in: Democratic Republic of the Congo, France, Iceland, Israel, Spain, Sweden, United Kingdom
Model: FIDO

Product description

FIDO is a portable breathing apparatus that distributes oxygen. FIDO has the same technology as a diving rebreather, which absorbs the carbon dioxide from the exhaled breath to permit recycling of the unused oxygen. Extra oxygen is added to replace the amount metabolized by the user under treatment. The design of FIDO is compact, small, and lightweight, enabling it to be carried to the scene of the incident. The patented oxygen-air mixing valve provides an action time of around 1 h.

Product details

Accessories: FIDO is used with standard mask and bio filter similar to that used with the current system.
Consumables: FIDO is used with oxygen and also cartridges that collect the CO_2.
Warranty duration: 5 years
Lifetime: 5 years
Energy requirements: FIDO is 100% mechanical, requiring neither electricity or a battery
Facility requirements: None

Contact: Christophe Galan | Phone: +44 79 691 00942 | Web: https://bit.ly/4cPTlBc

*** Information reported by manufacturer, October 2023**

WHO assessment**

Clinical

Clinical → Proceed

Oxygen therapy is a cornerstone of medical care. Many conditions can cause type I respiratory failure, and supplemental oxygen is critical to patient outcomes. However, oxygen is not readily available in many parts of the world, especially in LMIC.

Type I respiratory failure causes hypoxaemia which can lead to patient death if not adequately managed. Supplemental oxygen is the only way to correct it. Conventional oxygen therapy can waste oxygen, as only a small fraction of it is extracted by the lungs. Carbon dioxide levels, however, rise about tenfold. This device allows for an extremely efficient use of supplemental oxygen, as the exhaled air is enriched and rebreathed. A chemical scrubber removes excess carbon dioxide, ensuring narcosis does not ensue. Oxygen use is reduced, and a more efficient use of oxygen is attained. Several safety features are built into this, making it an excellent solution for oxygen therapy in all settings.

**** This assessment was initiated November 2023**

Comparison with WHO technical specifications

Cannot be verified.

The manufacturer provides the necessary technical specifications supporting and detailing their declarations with appropriate and complete technical documentation (i.e., instructions and user manuals). At the time of this report's creation, WHO technical specifications were not available to compare this type of portable breathing and oxygen delivery apparatus.

Regulatory

Pre-market assessment	Proceed
Post-market assessment	Proceed with caution
Quality system assessment	Proceed
Security	Proceed

Pre-market: It has received CE certification. The manufacturers declared that they had conducted the design verification and validation of the product but did not submit these documentations. Consequently, full premarket assessments could not be conducted to ensure the safety and performance of the product.

Post-market: The manufacturers declared that they had the post-market documentation but did not submit the post-market surveillance and vigilance documentation. According to the submission, there have been no recalls or adverse events have been reported. Nevertheless, it is considered good regulatory practice to establish the complete post-marketing system before introducing the product to the market.

Quality management system (QMS): The manufacturing site is certified to ISO13485:2016.

Security: Introduction of this technology would not lead to biosecurity or cybersecurity risks. The manufacturer did not submit risk management systems documentation essential to ensure the safety and performance of the device.

Health technology assessment

Indicators	Evidence assessment	Innovation
Medical	!	✓
Safety	→	
Economy	−	
Organizational	!	
Legal	!	
Social	→	✓
Ethical	→	✓
Green environment	!	

This innovation uses a re-breathing technique and consumes much less oxygen than free-flowing oxygen treatment. In low-resource settings, where oxygen sources are limited, it can help with more judicious use of oxygen and greater accessibility.

Clinical evaluation, test reports, and a CE mark showcase the device's medical performance. However, peer-reviewed evidence is missing to assess its feasibility in LMICs. The innovation has a good safety profile, validated by test reports and risk assessments according to ISO 14971.

The overall usability of the device is acceptable, according to the provided report. An ultrasonic cleaner with adequate capacity for cleaning the FIDO house and a SpO2 oximeter should be used, if available in the facility. The innovation is subjected to routine maintenance. Additional costs and downtime should be expected if the device is to be sent to the innovator's site abroad.

The cost of the device without any accessories amounts to 2700 EUR, which may be too high for LMICs, while the cost of consumables is also not negligible. A 0.10 EUR cost reduction per minute of treatment compared to the standard of care is claimed; however, this is calculated by only taking into consideration only some consumables and oxygen cylinders purchased in a high-income country.

Technology readiness level 9

Technology evidence assessment Recommend with caution

Health technology management

Durability
Ease of Use
Ease of maintenance
Environmental conditions
Affordability
Local access to technical support
Ease of cleaning
Infrastructure requirements

Health-care delivery platform

The Mirola Fido is a portable, mechanical oxygen rebreathing system that generates warm return air to the patient at ~33°C and provides humid air at less than 95% while maximizing available oxygen. It is only meant to be used in patients weighing more than 40 kg. Durability, biocompatibility, usability, and chemical resistance testing have been conducted. Cleaning the system, recommended every three months or every 200 uses, requires an ultrasonic cleaner. Mirola advises against local maintenance and instead recommends annual service by the manufacturer or associated approved distributors. No local commercial teams are currently available in LMICs to provide this service; Mirola has, however, committed to the development of commercial teams and replacement part availability in Algeria and the Democratic Republic of the Congo.

The FIDO system involves high initial capital investment and ongoing operational costs, primarily due to its reliance on single-use components; each use of the system requires a new set of items, including an oxygen bottle, breathing mask, biofilter, and cartridge, the total cost of which is 37 euros per use. Given their single-use nature, cost, and the need for frequent replacements, health-care facilities will face challenges in maintaining an adequate stock of these components to effectively use the FIDO effectively The current absence of local commercial teams in LMICs also indicates that facilities might incur extra costs, delays, and logistical complexities in procuring these items. The Mirola FIDO system is an innovative solution that would maximize the delivery of comfortable oxygen therapy, but the system's high cost and manufacturer-specific maintenance requirements limits its usefulness.

Intellectual property and local production

Technology transferability
Open source/ access
Local production

Intellectual property: The technology is protected by patents, trademarks, and copyrights. The use of all intellectual property will require clearance.

Local production: The device has a compliant manufacturing process. The technology has a moderate business case for semi-knocked-down manufacture. Some of the manufacturing know-how is likely to be with manufacturing partners. End-to-end manufacture is highly import-dependent and requires a comparatively high level of technical and quality control expertise, and related infrastructure. The device can be considered for local production, with an anticipation for low volumes until the technology is widely accepted in the region. Moderate cost reductions can be achieved through local production.