

Oxygen, portable rebreathing

Country of origin		Sweden
Primary function		Treatment
Category		Medical device

Commercial information

List price (USD): \$2,640¹

Price of consumables per use (USD): \$66^{List price (USD): \$10,000}

Year of commercialization: 2020^{List price (USD): \$10,000}

Number of units distributed: 0-100^{List price (USD): \$10,000}

Currently marketed in: Europe, Africa, Asia/Pacific²

Brand: Mirola Rescue AB^{List price (USD): \$10,000}

Model: FIDO^{List price (USD): \$10,000}



Health problem addressed

More than 95% of COVID-19 patients do not require a ventilator with continuous monitoring, in which cases, patients need low consumption of O2 combined with warm moist inhalation air.²

Product description

FIDO delivers 50% oxygen level in default mode and can go up to 89% oxygen level. This should be compared with free-flowing oxygen systems that deliver 72% oxygen level at best. FIDO increases the oxygen level mechanically if the treated person consumes higher levels of oxygen. It generates warm return air to the patient of about 33 degrees Celsius and <95% humidity. Patients can use the device by themselves.²

Product details

Accessories: A breathing mask, a bio-filter and an oxygen bottle¹

Consumables: Oxygen¹

Warranty duration: 1 year¹

Lifetime: 15-20 years¹

Contact: Christophe Galan | **Email:** christophe.galan@mirola.se | **Telephone:** +44 7969 100 942 | **Website:** <https://bit.ly/3rAT0M2>

¹ Reported by manufacturer on 06 May 2020

² Reported by manufacturer on 11 January 2021

WHO ASSESSMENT

WHO specification comparison

At the time of report creation, WHO technical specifications are not available to compare this type of technology.

Regulatory assessment

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

Some requested information and documentation for all three Regulatory and Quality Assessment categories is absent. Therefore, a thorough review of this product was not possible at this time. At the time of this report creation, Mirola has obtained an EU MDD CE Mark for the Rescue AB FIDO Rebreathing System. The regulatory status for the various accessories is currently unclear. Mirola has obtained an ISO 13485:2016 certificate. Mirola must also ensure they comply with local country import and pre-market regulations.

Technology evidence assessment

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



As a portable rebreathing device, FIDO claims to be clinically useful as a transportation device. According to the manufacturer, it is easy to use in field settings. The manufacturer declares that the device must be maintained annually in the production facility. As a result, due to the long return transport to Sweden, large transport costs are to be expected. In addition, the acquisition costs seem very high for low resource settings. The CO2 cartridges, the oxygen mask, and the biofilters have to be considered also as consumables per case.

Summary

Transferability		Technology readiness level	8
Evidence (according to GRADE)		Technology evidence assessment	Recommended with caution

Health technology and engineering management

Domains	Appropriateness	Domains	Appropriateness	Target setting: Patient transport
Durability		Ease of maintenance		<p>This product is a portable rebreathing system for delivering oxygen treatment to patients in transit (up to one hour). The mechanical system contains a patented mixing valve where rebreathed air mixes with oxygen after passing through a soda lime absorbing cartridge that is connected to a collection bag and oxygen feed from a tank. The mixing occurs prior to delivering treatment through bio filters and a breathing mask. The oxygen tank supply attaches to the patented mixing valve through a pressure regulator and can be adjusted. A manometer indicator provides the user with oxygen supply pressure measurements. The product is comparable to other systems, with the key advantage of enabling efficient consumption of oxygen resources. An oxygen flash button activates a</p>
Ease of Use		Infrastructure requirements		
Positive impact on clinical outcomes		Local access to sales support		
Affordability		Local access to technical support		
Engineering resources minimization		Local access to training		
Cultural and social acceptability		Local access to spare parts		
Environmental conditions		Local production		
Aesthetics		Locations of use within target setting		
Ease of cleaning				

momentary increase in oxygen delivery. The mask must be properly fitted to the patient in order for the system to be effective. Product cleaning is simple process, however there is not sufficient instruction about use with COVID-19 patients. Servicing and proprietary spare parts are only available from the vendor in Sweden.