Respiratory monitoring system, portable

Country of origin | United States of America
Primary function | Monitoring
Category | Medical device

Commercial information

List price (USD): $12,000[1]
Price of consumables per use (USD): $47[1]
Year of commercialization: 2020[1]
Number of units distributed: 0-100[1]
Currently marketed in: United States, Canada[2]
Brand: MediPines Corporation[List price (USD): $15,000]
Model: AGM100[List price (USD): $15,000]

Health problem addressed

This technology instantly detects changes in pulmonary gas exchange in disease states such as COPD, pneumonia, influenza, and Acute Respiratory Distress Syndrome (ARDS), caused by COVID-19. As a result, premature mortality from respiratory disease can be prevented. Its intended use is for any patient aged 18+ suffering from respiratory distress. WHO states that 3.17 million deaths were caused by just COPD alone in 2016, while 34+ million people are infected by COVID-19 globally in 2020.[1]

Product description

The device samples a patient's normal breathing in a 2-minute test (which is performed through provided breathing circuits) while wearing a pulse oximeter. With the SpO^2 value and end-tidal breath sampling, the oxygen dissociation curve is calculated in conjunction with the Bohr effect. The device then outputs clinically valuable, numerical measurements including PaO^2, $PETCO^2$, O^2 deficit (A-a gradient equivalent), and more in real time.[1]

Product details

Accessories: SpO^2 sensor[1]
Consumables: Single patient use breathing circuit kit, nose clip[1]
Warranty duration: 1 year[1]
Lifetime: 0-2 years[1]
Energy requirements: Rechargeable battery, continuous power supply (AC powered, 120V/240V, 15W, 2-hour battery life, 4-hour battery recharge cycle)[1]
Facility requirements: Specific temperature and/or humidity range

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1 Reported by manufacturer on 13 October 2020
2 Reported by manufacturer on 8 January 2020

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
Post-market assessment	Proceed
Quality system assessment	Proceed

Adequate documentation was provided to perform a medical device regulatory and quality system review but there are some deficiencies noted in the review. At the time of this report creation, MediPines has obtained US FDA 510(k) clearance (K180902) and Health Canada Medical Device COVID-19 Authorization (IO313459) for the AGM100. The regulatory status for the various accessories was provided. MediPines has a MDSAP ISO 13485:2016 certificate. MediPines must also ensure they comply with local country import and pre-market regulations.

Technology evidence assessment

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

The monitor is useful for various tests and can be quickly moved to different locations for testing. The costs are high. Due to vague manufacturing and maintenance description, transferability is low.

Summary

Transferability	✕	Technology readiness level	9
Evidence (according to GRADE)	⚠	Technology evidence assessment	Recommended with caution

Health technology and engineering management

Domains	Appropriateness	Domains	Appropriateness
Durability	⚠	Ease of maintenance	→
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	⚠		

Target setting: Health care facilities

This product detects changes in pulmonary gas exchange in disease states such as COPD and ARDS caused by COVID19. It uses a disposable breathing circuit to sample patient end-tidal breath. Using the oxygen disassociation curve, the product software calculates numerical measurements such as PaO^2, $PetCO^2$, and O^2 deficit that are clinically valuable. Testing involves about 2 minutes of patient breathing through mouthpiece tubing along with the use of a pulse oximeter and blocking nose clip. The use of proprietary software limits local support. The product operates on an internal battery and is portable. The product requires consumables such as SpO^2 sensors and the vendor's single patient breathing circuit and nose clip. The vendor estimated shelf life is 2 years and carries 1-year warranty. The product costs $12,000 USD and an additional $47 per use which may limit the benefit of its use in low-resource settings.