Ventilator, with extended battery time

Country of origin Primary function Category

United States of America Supporting or sustaining life Medical device

Commercial information.

List price (USD): \$15,0001

Year of commercialization: 20181 Number of units distributed: 101-1.0001

Currently marketed in: Sub-Saharan Africa and Southeast Asia²

Brand: Gradian Health Systems¹

Model: Gradian CCV1

Health problem addressed.

Mechanical ventilators, when operated by a trained medical professional, provide respiratory support to patients who cannot breathe or require assistance to breathe due to illnesses, such as pneumonia, COPD, and COVID-19, trauma, or other complications. They are essential to sustaining life while patients undergo treatment or until treatment can be accessed. A major factor inhibiting access is inadequate infrastructure to support delivery of critical care in facilities and during transport.1

Product description.

A comprehensive care ventilator can assist or replace the breathing of a patient requiring respiratory support, in any care setting. Gas is drawn from compressed sources of oxygen and medical air, or entrained from room air by an in-built compressor, and mixed by an integrated gas blender to an oxygen concentration prescribed by the care provider. A closed-loop control system regulates the delivery of breath through a breathing circuit, according to the prescribed mode and settings.1

Product details

Accessories: Rolling stand, bag of 3 extra filters, kit - handle, swivel hooks, stand mount, external battery, extra exhalation valve, reusable adult and pediatric breathing circuits, SpO2 monitor, HMEs, test lung, air and oxygen hoses, power cords, reservoir cylinder, humidifier and accessories.³

Consumables: It is recommended that the device be used with bacterial/viral filters in order to avoid cross-contamination. When using the device without an active humidifier, a Heat and Moisture Exchanging Filter (HMEF) is recommended.1

Other required products: Patient interfaces such as endotracheal tubes and non-invasive ventilation masks are required to use the device. The device should only be used in the presence of and in conjunction with other monitoring and life-supporting equipment required for administration of adequate critical care.1

Warranty duration: 3 years1

Lifetime: 10-15 years1

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- Reported by manufacturer on 14 August 2020
- Reported by manufacturer on 8 January 2020
- Reported by manufacturer on 15 December 2020

WHO ASSESSMENT

WHO specification comparison

This device partially complies with the WHO technical specifications for transport ventilators.

Compliant relevant characteristics: There is the option for using external low-pressure oxygen (approx. 20 psi) as a source. However, the instructions of use indicate that "Proper tidal volumes may not be provided with a gas source not providing a minimum of 80 LPM at 280 kPa (40 psi)". The device includes non-invasive ventilation, an oxygen conservation feature, and IP22 degree of protection. The device can be used continuously in battery operating mode with standard ventilation for up to 21 hours total (7 hours on internal battery and 14 hours on external battery).

Non-compliant: The oxygen-air mixture accuracy is 12% as opposed to the WHO specification of 4%. The inspiratory pressure is 15 - 55 cmH2O instead of the WHO specified range of 0-40 cmH2O. The device does not have minute volume alarms and single limb circuits cannot be connected. Additionally, the device does not measure leak percentage or display/monitor minute volume and spontaneous minute volume. The display shows numerical indicators but no waveforms for all ventilation parameters.

Aspects that could not be verified: Minute volume alarms

Regulatory assessment



Pre-market assessment



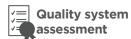
Proceed



Post-market assessment



Proceed





Proceed

All WHO requested information and documentation for all three Regulatory and Quality Assessment categories was provided. At the time of this report creation, the product was both EU CE Marked under the MDD and US FDA 510(k) cleared. The regulatory status for the various accessories was provided. The product's manufacturer (Allied Health) has obtained an MDSAP ISO 13485:2016 certificate. Gradian provided all top-level SOPs for their regulatory and quality system responsibilities for the WHO countries. Gradian must also ensure they comply with local country import and pre-market regulations

Technology evidence assessment

Domains

Evidence assessment Risk/benefit Impact

Innovation



Medical







Safety







Economy





















Social

Green

environ-











The ventilator provides basic configuration for volume control assistance. It is a me-too ventilator without innovative approaches. The price includes additional tools. Local production options seem to be available in some low- and middle-income countries, but there must be compliance with local country regulations. Maintenance is also offered locally.

Summary

Transferability



Technology readiness level

Evidence (according to GRADE)

Technology evidence Recommended assessment

Health technology and engineering management

Domains

Appropri-

Domains

Appropriateness

Target setting: Hospitals and transport

This product is a mechanical ventilator





Durability



Ease of maintenance



Infrastructure requirements







Ease of Use

Affordability

Engineering

minimization

resources

Cultural

and social





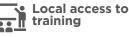












support







production

use within target setting

Locations of

Local









intended for a variety of settings, including austere environments with unreliable access to oxygen and or electricity. It incorporates a pulse oximeter and provides for 3 years of parts and service warranty. It can function on internal battery power for up to 7 hours and on an external battery source for up to 14 hours. It is also a portable device that can be used for patient transport. Video-based user and support training is provided. Although judged to be easy to use, technical support is dependent on adequate availability of vendor training and spare parts.





Aesthetics

Ease of cleaning









