

## MADVent Mark V PRODUCT LABELING

The **MADVent Mark V** is a single-mode continuous, mandatory, closed-loop pressure controlled time-terminated emergency ventilator meant for sedated, intubated patients being cared for in a professional healthcare facility **only**. It employs an FDA-recognized single-use and disposable, automatically self-inflating manual (“ambu”) ventilator bag with attached positive end-expiratory pressure (PEEP) valve.

**It is only an emergency use ventilator, for use only in a professional healthcare facility when *both* other ventilators are unavailable *and* patient survival depends upon having access to a ventilator during the Coronavirus Disease 2019 (COVID-19) pandemic. This product cannot be presumed to be safe or effective for the prevention or treatment of COVID-19.**

Healthcare providers administering the device must consult the [Fact Sheet for Healthcare Providers: Emergency Use of Ventilators During the COVID-19 Pandemic](#).

Patients and/or their guardian(s) must be provided the FDA [Fact Sheet for Patients: Emergency Use of Ventilators During the COVID-19 Pandemic](#)

**NOTE:** This ventilator is for use only with intubated patients. It is not for use with masks nor nasal appliances.

**WARNING:** Do not use this ventilator without first ensuring the included emergency backup battery has been fully charged. Do not attempt to use the ventilator only on battery power for more than 20 minutes. Doing either can possibly lead to ventilator stoppage, and to patient death or serious deterioration of health.

**WARNING:** Do not cover or position the ventilator in a manner that prevents its motion, could potentially pinch or trap the ventilation tubes, or produce a safety hazard to the patient or others.

**WARNING:** Always have immediate access to an alternative means of ventilation, which is ready for use, in order to reduce the possibility of patient death or serious deterioration of health.

**WARNING:** The ventilator shall not be used in a hyperbaric chamber. Such use may cause ventilator malfunction, patient death, or serious deterioration of health.

**WARNING:** The ventilator shall not be used with inlet gases not specified for use with the bag ventilator (standard BVM-bags, for example an Ambu-bag). Such use may cause ventilator malfunction, patient death, or serious deterioration of health.

**WARNING:** The ventilator accuracy can be affected by the gas added to the ventilator breathing system by use of a pneumatic nebulizer.

**WARNING:** It is the responsibility of the responsible organization to ensure that the oxygen source is compatible with the rated range of pressure, flow rate, and oxygen concentration as marked on the ventilator bag and indicated in the instructions for use, as this can affect the performance of the ventilator that can consequently result in patient death or serious deterioration of health.

**WARNING:** The healthcare professional operator should carefully consider the *dead space* in the ventilation tubing between the ventilator and the patient. The dead space is the volume within the tubing from the patient's lungs to the ventilator bag, and during ventilation this can be cycled back and forth into and out of the patient without removal from the ventilation system. The healthcare professional operator must shorten the inspiratory tubing as much as practical, include appropriate valving, and provide expiratory flow ventilator tubing to minimize the dead space and risk of inadequate oxygenation, particularly in patients with compromised lung volume from acute respiratory distress syndrome (ARDS) and similar conditions.

**WARNING:** It is the responsibility of the responsible organization to ensure that the manual ventilator bag (standard BVM-bags, for example an Ambu-bag), its parts, other parts and accessories used in the ventilation system are all compatible with the **Mark V ventilator**. Incompatible parts can result in degraded performance that could consequently result in patient death or serious deterioration of health.

**WARNING:** When using nebulization or humidification, breathing system filters and heat and moisture exchangers can require more frequent replacement or prevent increased resistance and blockage.

The **Mark V ventilator** mounts the manual ventilator bag in a motor-driven, programmable bag squeezing mechanism designed to compress and release the bag according to a set respiratory rate and defined high and low pressure thresholds. An integrated electronic pressure sensor provides feedback to the bag squeezing mechanism and controller to reduce the risk of overpressure lung injury or air leakage leading to failed ventilation. Alarms are also provided to alert the clinician to overheating of the device, sensor failure, or mechanical malfunction. A display screen is provided to inform the clinician of the current settings of the ventilator.

**WARNING:** As with any continuous, mandatory ventilator, the patient will need to be sedated to avoid dyssynchronous breathing and system alarming from bucking and coughing. The healthcare provider must be aware of the risks of sedation.

**WARNING:** This Resuscitator has not been tested for electromagnetic compatibility (EMC). It may produce electromagnetic disturbances that will affect the performance of other equipment. It may fail to perform as expected in the presence of electromagnetic disturbances from other equipment.

**WARNING:** Due to the rapid development cycle for this emergency use device, all efforts were made to verify the software, but defects may still exist. The consequences of these defects are unknown and may pose a risk to the patient.

## **Mark V ventilator capabilities:**

MADVent Mark V is a single-mode continuous, mandatory, closed-loop pressure controlled time-terminated emergency ventilator intended to be operated by the healthcare professional operator for sedated ventilator-dependent patients.

- Ventilation mode: single-mode continuous mandatory pressure-controlled and time terminated operation
- Single arm inspiration/expiration tube extending from the valve at the exit of the bag. Expiration from the patient goes through a filter and PEEP valve.
- Target pressure 10-35 cm H<sub>2</sub>O (increment 1 cm H<sub>2</sub>O)
- Respiratory rate 6-35 bpm (increment 1 bpm)
- Inspiratory time 1-3 sec (increment 0.1 s)
- High volume threshold 200-1000 cc (increment 20 cc)
- Low volume threshold 200-1000 cc (increment 20 cc)
- High pressure threshold 35-40 cm H<sub>2</sub>O (increment 1 cm H<sub>2</sub>O)
- PEEP 0-20 cm H<sub>2</sub>O (increment 5 cm H<sub>2</sub>O)

**Documentation** provided with the system include the following:

1. **MADVent Mark V product labeling** for the healthcare professional provider and other individuals to consult regarding the product.
2. **MADVent Mark V operating instructions** for the healthcare professional provider to test and operate the product.
3. **MADVent Mark V ventilator parts and detailed assembly procedure** for the healthcare professional provider to assemble the product.
4. **MADVent Mark V ventilator technical description** for additional details and information for the healthcare professional provider to consult as desired or needed.

**Alarms** provided with the system serve to monitor patient health and mechanical failure as follows:

1. **High volume alarm:** In the event of a high volume condition, the system flashes a red light and triggers an audible alarm to alert the healthcare provider. The system returns to the zero position and then continues ventilation with lower tidal volumes. This could happen in the event of a leak in the tube connecting the patient and the ventilator.
2. **Low volume alarm:** In the event of a low volume condition, the system flashes a red light and triggers an audible alarm to alert the healthcare provider. This could happen in the event of a constriction or blockage in the tube that causes pressure build up but no appreciable volume change.
3. **High pressure alarm:** In the event of a high pressure condition the system will flash a red light, and trigger an audible alarm to alert the healthcare provider, and indicate the alarm on the LCD screen. This could happen in the event of a cough or other high pressure event.
4. **Overheating alarm:** The system is equipped with two temperature sensors, to be mounted on the motor controller and the motor. These sensors continually monitor temperature and flashes a red light and triggers an audible alarm to alert the healthcare provider if the system overheats.

5. **Mechanical malfunction:** In the event of a mechanical malfunction, such as the lanyard from motor and spool to the bag compression arm losing tension or breaking, or the motor fails to rotate for an unknown reason, the system is equipped with sensors to trigger an alarm, flashing a red light and triggering an audible alarm to alert the healthcare provider.
6. **Emergency battery usage:** In the event of a power failure to the main power supply, the system resorts to drawing power from the back-up power supply. In this case, a red light flashes and alerts the healthcare provider to the power failure. This includes the case when the on-off switch is switched off, to alert the healthcare provider if the switch was operated inadvertently.
7. **Start-up error:** The system executes an automated start-up procedure to ensure that the lights, sensors, and motor are detected. If any of the components are missing, the system does not allow the healthcare provider to proceed and displays an error on the LCD screen and flashes a red light.

The **sensors and calibration procedure** that enable the detection of the faults outlined above include:

1. **Pressure sensor:** The system is equipped with a differential pressure sensor (Honeywell SSCMRRN060MDSA5 or equivalent) that records ambient air pressure and in-line pressure.
2. **Calibration protocol for volume:** The system has been calibrated to calculate volume delivered to the patient based on **ISO80601-2-12:2020** section 201.12.1.102.
3. **Optical switch:** The system tracks the position of the lever arm used to compress the bag using an optical switch.
4. **Rotary encoder:** The device uses a motor to rotate a spool attached to its shaft. The rotary encoder (Cui Devices C14D32P-A3 or equivalent) is attached to the same shaft to continually monitor its rotation position. The spool collects and releases a lanyard by rotation, and the lanyard pulls and releases a lever arm against the bag-based ventilator.
5. **Thermistors:** Temperature sensors (Daburn electronics 2200/22SWH-100) continually monitor the temperature of the motor and the motor controller.

**WARNING: As an emergency ventilator system, the Mark V ventilator does NOT include the ability to connect to a distributed alarm system or electronic health record system.**

**The liquid crystal display (LCD)** screen provides information on the currently set values of the high and low volume alarm limits, high pressure alarm limit, target pressure, cumulative run time, inspiration time, and respiratory rate.

- The peak pressure is set by the healthcare professional provider and the system operates based on this set value.
- The high and low volume alarm limits and the high pressure alarm limit are set by the healthcare professional provider.
- The inspiration time is the time taken by the system to reach the peak pressure defined by the healthcare professional provider.
- The respiratory rate is the number of breaths per minute.
- Cumulative runtime is the total time the unit has been in ventilation mode over its lifetime.

The **emergency operation battery** included with the system is a BP1.2-12-T1 battery (BB Tech), and conforms to **IEC 61056-1**. It is a 12V, 1.2Ah maintenance-free lead acid rechargeable battery mounted to the side of the frame. The battery can be easily removed for recharging using the hook and loop straps. The battery is designed to provide at least 30 minutes of backup power in case of mains (wall) power failure. While the battery is being used, an LED labeled “battery” will flash red indicating the mains power is disconnected. The battery must be removed to be charged, and the system should not be used without a charged emergency operation battery.

The **manual ventilation bag** patient connector has both a 22 mm male and a 15 mm female connection per **ISO 5356-1** and can connect to a single limb ventilation line with passive exhalation.

The **manual ventilation bag** expiratory connector is 30 mm female per **ISO 5356-1**. It is intended for use with a PEEP valve attachment.

The **manual ventilation bag** oxygen inlet line conforms with **ISO 5359**.

**Expected service life** is two weeks. The healthcare professional operator must inspect the system, including compression lanyard, ventilator connections, and ventilator bag for visible wear or damage every six hours of operation at a minimum. Any system with visible wear or damage must be taken out of service and replaced or repaired.

**Cleaning, disinfection, and sterilization.** The manual ventilator bag should be changed or cleaned according to its instructions. In compliance with clinical guidelines for ventilators, the **Mark V ventilator** should be wiped clean as necessary using either 70% ethanol or bleach-free disinfecting wipes. Non-corrosive spray disinfectant is compatible with the ventilator, but the healthcare professional operator must consult the manual ventilator bag instructions regarding safe sterilization procedures for that component. Invasive components will have to be sterilized and are not a part of the components included with the **Mark V ventilator**.

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