

MADVent Mark V OPERATING INSTRUCTIONS

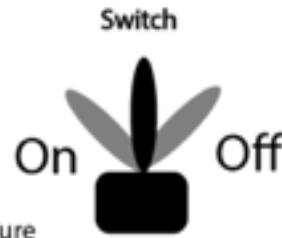
The **MADVent Mark V** is a single-mode continuous, mandatory, closed-loop pressure controlled time-terminated emergency ventilator meant for sedated, intubated patients being cared for in a professional healthcare facility **only**. It employs an FDA-recognized single-use and disposable, automatically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

Healthcare Operator Interface

LED Alarms

	Temperature	➔	motor is overheating
	Mechanical	➔	lever arm has stopped
	Pressure sensor	➔	sensor disconnected, or high pressure
	High volume	➔	High volume threshold has been exceeded
	Low volume	➔	Low volume threshold has been exceeded
	Battery	➔	back-up battery not connected or running low
	Wall power	➔	power no longer available from wall

Failure Modes if Red



Parameters

Rate(RR)		➔	6 - 35 breaths per minute
Pressure(P,T)		➔	10 - 35 cm H2O peak pressure
Insp time(I)		➔	1.0 - 3.0 seconds of inspiration per breath
High(H)		➔	200 - 1000 cc, when "High volume" alarm will go off
Low(L)		➔	200 - 1000 cc, when "Low volume" alarm will go off
High P(P,A)		➔	35 - 40 cm H2O, when "High pressure" alarm will go off

Volume thresholds

LCD Display

```
"RR: ##/min I: #.#s "
```

```
"P: T:## A:## M:## cm"
```

```
"V: L:#### H:#### mL "
```

```
"RT: ##:##:## -----"
```

↑
Error messages here

(RT) total runtime of the unit over its lifetime in hours

(P,M) indicates the measured pressure, current PEEP during inhale and current Peak during exhale

Assembly, start-up and functional test procedure by healthcare professional operator (13 total steps)

Step 1: Ventilator assembly procedure: consult the separate documents **MADVent Mark V ventilator parts and detailed assembly procedure guide** and **MADVent Mark V product labeling** provided with these instructions, and the Healthcare Operator Interface figure above. If needed, additional technical information is provided in the separate document **Mark V ventilator technical description**.

Step 2: Plug the ventilator power supply into a standard 120V 60Hz wall outlet (USA Standard). Verify charge status of integrated rechargeable battery, on start up an LED will appear either green if the battery is sufficiently charged or red if on low charge. The integrated battery is solely for use as an emergency or temporary backup for disconnection or loss of mains (wall) power. It is not to be used as the primary method to power the ventilator.

NOTE: Place ventilator at least 3 feet away from other electromagnetically active equipment. 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.

Step 3: Choose and prepare a bag-valve resuscitator (colloquially known as a BVM e.g. an “Ambu Bag”) for use. The MADVent has been calibrated for use with the Ambu SPUR II (adult size).

Step 4: Attach the provided hook and loop fasteners as shown in the separate document MADVent Mark V Parts and Detailed Assembly Procedure to the bag-valve resuscitator.

Step 5: Place the bag-valve resuscitator into the cradle. Be sure the hook and loop fastener on the bag-valve resuscitator securely attaches to the corresponding hook and loop fastener in the cradle.

Step 6: Note arrow indicating manual rotation direction to rotate the spool and loop the lanyard around the spool. Continue manually rotating the spool in the direction indicated by the arrow and wind the lanyard around it until the lever arm just begins to compress the bag of the bag-valve resuscitator. Approximately 4 to 5 turns is sufficient.

Step 7: Place the ventilator system as close to the patient as practically possible.

Step 8: Attach the patient inspiration line to the ventilator output. 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 may be cycled back and forth into and out of the patient without removal from the ventilation system, with decrease in oxygen and increase in carbon dioxide in that volume. 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 patient oxygenation.

Step 9: Turn on the ventilator by plugging the barrel jack and the battery cable into the corresponding sockets on the control box. An automated startup procedure will begin and proceed for a few seconds.

- During startup, the system first automatically tests the auditory and visual alarm indicators. The **alarm buzzer** will sound and all seven light emitting diodes (LED) will turn **red**. If ANY of these indicators do not occur, there is a fault in the system and the healthcare professional operator should not proceed past this step to move forward with using the system. To begin the rest of the set up the healthcare professional operator must flip the toggle switch from off to on and back to off.
- During startup, the system then automatically tests the wall power, battery, pressure sensor, temperature sensors, motor, motor controller, the rotary encoder on the motor shaft, and the optical switch used to detect the motion of the lever arm. At each check, an **LED corresponding to each component will turn green to confirm its presence and safe operation** in sequence. If the corresponding LED turns **red**, the component is missing or not functioning as intended. In this case the healthcare professional operator should not progress beyond this step nor use the system. If this fails, the system should be taken out of service and replaced.
- The testing of the motor and rotary encoder, and the optical switch requires input by the healthcare professional operator. The system will alert the healthcare professional operator on the screen to flip the toggle switch from

off to on and back to off to indicate the system is ready to test. The motor and arm will move a small amount as part of the test.

- **Seven LEDs illuminated green and the word “READY” in the bottom right corner of the screen indicate the system is ready to be used.** Continue to the next step.

Step 10: Once the startup procedure has successfully completed (denoted by seven LEDs illuminated green), the healthcare professional operator should set the intended ventilation values: respiratory rate, peak pressure, inspiration time, and minimum and maximum volume alarm volumes and the high pressure limit. These settings are made by adjusting the knobs on the controller. If any respiratory settings are flashing on the LCD screen, it means that the ventilation parameters are in conflict and must be reconciled before the ventilator will operate.

Step 11: Enable the ventilator using the **ventilator enable** switch from **off** to **on**.

Ventilation should begin immediately. Monitor the first few ventilation cycles to ensure the ventilation parameters are being reasonably met.

Step 12: Continue to monitor the ventilator screen and indicators for any errors that appear. If an LED has turned **red**, the corresponding label indicates the type of error detected. The screen may also flash the value related to the error. In addition, the ventilator may also take the additional following actions:

- If a **high volume error** is detected, the system will flash a red light, trigger an audible alarm to alert the healthcare provider, and will immediately stop. This alarm indicates the volume entering the inspiratory line has increased above a set value. This may occur if there is an issue with the patient or there is a leak in the system. This issue *must* be resolved before ventilation may continue. If the high volume error remains **DO NOT CONTINUE WITH OPERATION**.
- If a **low volume error** is detected, the system will flash a red light and trigger 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. If the low volume error remains **DO NOT CONTINUE WITH OPERATION**.
- If a **high pressure error** is detected the system will flash a red light, trigger an audible alarm to alert the healthcare provider, and indicate the alarm on the

LCD screen. This alarm indicates the pressure in the inhalation line exceeds the set value.

- **Other errors** (temperature, lanyard arm position error, motor rotation error, integrated circuit (IC) fault) may not require changes in operation, but instead indicate cautious observance of the system by the healthcare professional provider is necessary. If the system appears to function incorrectly **DO NOT CONTINUE WITH OPERATION**, follow the correct shutdown procedures provided below, and replace the system.

Step 13: In the event an error is detected and corrected, disable then re-enable the system by switching the **ventilator enable** switch to **off** then **on**. This will clear the error. The system will begin to function as normal. Note the power loss alarm will be active while the **ventilator enable** switch is in the **off** position. This is intentional as a safety measure to inform the healthcare provider if the switch is inadvertently activated.

Shutdown by healthcare professional operator (6 total steps)

Step 1: Stop the ventilator by switching the **ventilator enable** switch from **on** to **off**.

Note the power loss alarm may be deactivated by toggling the **ventilator enable** switch **off-on-off** a second time.

Step 2: Disconnect the patient inspiratory line from the ventilator output.

Step 3: Turn off the ventilator by unplugging the battery and wall power. The screen and LEDs should turn off.

Step 4: Remove the bag-valve resuscitator by rotating the lever arm away from the bag and pulling the bag up and away from the hook and loop fasteners.

Step 5: Unplug the ventilator power supply from the wall outlet.

Step 6: Clean, disinfect, sterilize, and discard the components of the ventilator according to the **cleaning, disinfection, and sterilization** instructions provided below.

Pressure values

1. Maximum limited pressure, $P_{LIM, max} = 50 \text{ cm H}_2\text{O}$.
2. Rated range of maximum working pressure that may be set by the provider: $P_{W, max} = 10 \text{ cm H}_2\text{O}$ to $50 \text{ cm H}_2\text{O}$, as defined by pressure limiting operation of the ventilator breathing system.
3. The rated range of inspiratory gas pathway resistance, over which the accuracies of the set and monitored pressure settings are maintained, is between 5 and $50 \text{ cm H}_2\text{O}/(\text{L-s})$.
4. The rated range of compliance, over which the accuracies of the set and monitored pressure settings are maintained, is between 0.02 and $0.1 \text{ L/cm H}_2\text{O}$.

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 clorox wipes. Non-corrosive spray disinfectant is compatible with the ventilator.

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.

Additional technical information

Additional technical information is provided in the separate document **Mark V Ventilator Technical Description**, including the following parts:

1. Method for checking the function of the alarm system by healthcare professional operator.
2. Uncertainty for each disclosed tolerance.
3. Pneumatic diagram of the ventilator.
4. Summary description of the filtering or smoothing techniques for all measured or computer variables that are displayed or used for control.
5. Summary description of the means of initiating and terminating the inflation phase in each ventilation mode of the ventilator.

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