

SAVe II + – PRINCIPLES OF OPERATION

The SAvE II+ is a completely self-contained, small, light-weight, rechargeable battery powered device intended to provide controlled, positive pressure ventilation to a patient. It is a time-cycled pressure-limited volume-targeted ventilator. The SAvE II+ will monitor the patient's airway pressure and provide alarms for key events such as but not limited to: disconnect, high inspiratory pressure, and device malfunction. The SAvE II+ uses a single-patient-use breathing circuit to connect to the device on one end and to the patient interface on the other end. The breathing circuit on the patient end uses an industry standard 15/22 mm connector to facilitate connection with an appropriate breathing mask, airway, or tracheal (breathing) tube. On the ventilator end, the breathing circuit has 3 connections: 1) The main tube to deliver air to the patient; 2) The pressure line to monitor the patient pressure; and 3) the control line to activate the exhaust port. The SAvE II+ user interface is intended to provide as few user interactions as possible. Quick selection buttons are organized in an arc-shaped graphic which allows quick selection of appropriate default ventilator settings based on the patient's height, ranging from 4'3" to 6'3". After selecting the patient's height, pressing the CONFIRM button will start the device in "Ventilation" mode. This "Adult Presets" section is intended to make initial setup minimal. When desired a User may adjust key variables, such as: RESPIRATORY RATE (RR) [Breaths Per Minute], TIDAL VOLUME (TV) [Milliliters/Breath], POSITIVE END-EXPIRATORY PRESSURE (PEEP) [CMH₂O], and PEAK INSPIRATORY PRESSURE (PIP) limit [CMH₂O] in the "User Defined" section of the user interface. In certain situations (like during CPR), the user may desire to control when a breath is delivered. For these situations, the user may switch from "Ventilation" mode to MANUAL / CPR mode by setting the RR to zero (0). In MANUAL /CPR mode, the ventilator will only deliver a breath to the patient after the user has pressed the MANUAL TRIGGER button.

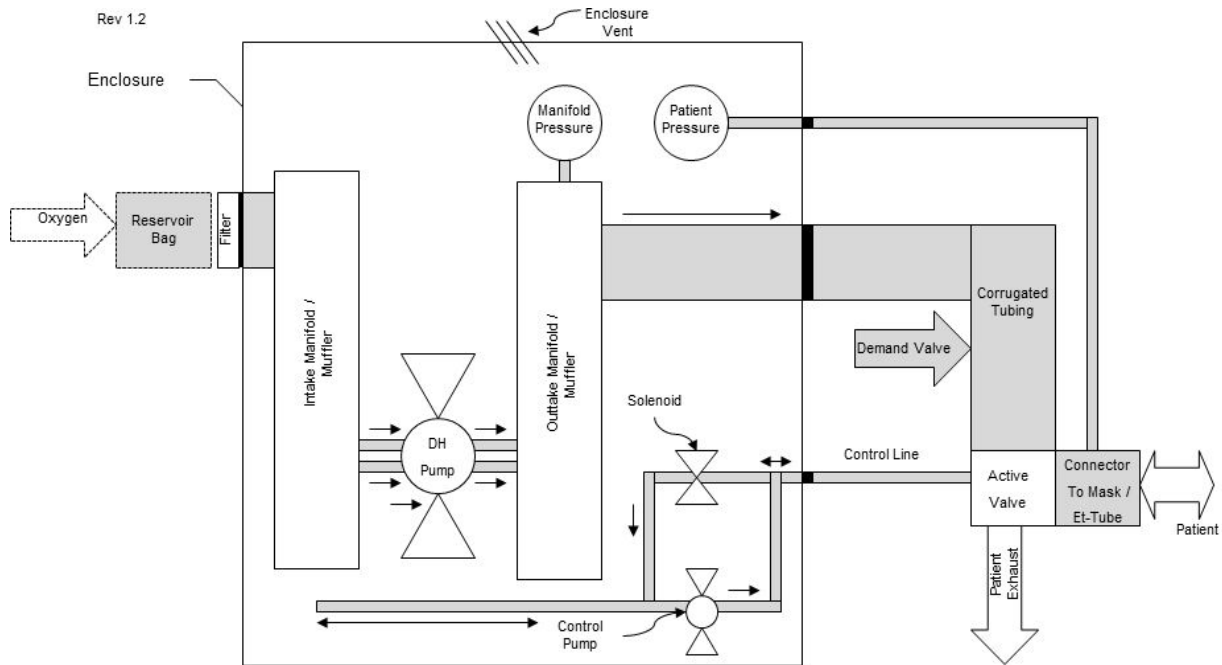
The flow rate of the delivered breath is determined by the combination of the selected TV and RR as well as the I:E ratio. The I:E ratio is fixed at 1:2. TV and RR combinations that require flow rates greater than the pumps ability to deliver the breaths and still maintain an I:E ratio of 1:2 are not permitted. For patient safety purposes, the target TV may not be reached if the patient airway pressure reaches the PEAK INSPIRATORY PRESSURE (PIP) Limit.

When the PIP Limit is reached, the SAvE II+ will automatically cut the pump off and move into the exhalation phase of the breathing cycle to prevent harm to the patient. When desired, expiration pressure is also regulated to provide a slightly positive end expiratory pressure (PEEP). The SAvE II+ will also provide a breath if the patient spontaneously inspires (Spontaneous Breath). The device detects patient inspiratory effort by monitoring airway pressure. The device will respond in less than 250 ms to a pressure drop greater than 2 cmH₂O below set PEEP.

In MANUAL / CPR mode, the user has control over when a breath is delivered to the patient. As this mode will commonly be used during CPR, a Heart icon on the User Interface will flash at a rate of 100/minute, which is the presently recommended

compression rate by the American Heart Association for CPR. In this mode the PIP Limit will automatically be set to 20 cmH₂O (as opposed to 30 cmH₂O in “Ventilation” mode), as in the event that a mask is used as the airway of choice, this setting will decrease the likelihood of gastric insufflation. While the RR is set to zero an alarm will sound if more than 30 seconds elapse since the last breath. To keep the patient safe, in MANUAL / CPR mode, the PEEP option is disabled so that the patient airway pressure returns to 0 after the delivered breath. Also, to prevent false triggering due to compressions, the Breath Assist feature is disabled.

In addition to delivering ambient air to the patient, the SAVE II+ also accepts supplemental oxygen to increase the FIO₂ to the patient. This is done through the use of a low-flow oxygen source (less than 12 L/min) and an extendable oxygen reservoir tube that connects between the oxygen source and the intake port of the ventilator. During an exhalation phase, the reservoir tube will begin to fill with oxygen from the oxygen source. During the inhalation phase, the SAVE II+ will draw from the reservoir tube, thus pulling in oxygen to deliver to the patient. The amount of oxygen delivered to the patient is dependent on the flow rate of the oxygen source, which is set by the user. Table 2 in this manual guides the user to an appropriate oxygen flow rate depending on the TV, RR and FIO₂ desired.



PNEUMATIC DIAGRAM