AutoMedx
MEDICAL SUPPORT TECHNOLOGY

SAVe Ventilator

Simplified Automated Ventilator

Operator's Manual

Model 600x10

REF	70000

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This product is protected by issued and pending US and PCT patents.

Caution: Federal law (U.S.A.) restricts this device to sale by or on the order of a physician (or properly licensed practitioner).

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Glossary

CO_2	Carbon Dioxide
ET-Tube	Endotracheal Tube
O_2	Oxygen
PEEP	Positive End Expiratory Pressure
SAVe	Simplified Automated Ventilator
PIP	Peak Inspiratory Pressure
BVM	Bag Valve Mask

Apneic Patient – Patient that is not breathing.

Automatic Time-Cycle Resuscitator – Resuscitator in which the cycling between the inspiratory phase and expiratory phase is controlled automatically at time intervals determined by the control setting.
Source: ISO 10651-5:2006 Lung ventilators for medical use – Particular requirements for basic safety and essential performance – Part 5: Gas-powered emergency resuscitators

Emergency and Transport Ventilator – Portable active medical device for lung ventilation intended for emergency use and/or transportation.
Source: EN 764-3:1998+A2:2009 Lung Ventilators – Part 3: Particular requirements for emergency and transport ventilators

First Responder – Individual who has been trained to provide primary response to a respiratory emergency.
Source: ISO 10651-5:2006 Lung ventilators for medical use – Particular requirements for basic safety and essential performance – Part 5: Gas-powered emergency resuscitators

SPECIFICATION OVERVIEW

Model 600x10

BATTERY LIFE:	up to 5.5 hours
UNIT WEIGHT:	3.1 lbs (1.4 kg)
UNIT SIZE:	6.75” x 6.25” x 2.5” (17 x 16 x 6 cm)
TIDAL VOLUME:	600 mL/breath
RESPIRATORY RATE:	10 BPM
PIP LIMIT:	38 cmH_2O

FEATURES

- Consistent tidal volume and respiratory rate
- Ease Of Use: Single knob operation
- Does NOT require compressed gas source
- System can accept supplemental O_2
- Pressure limited to avoid over-pressurization of lungs
- Fail-safe mechanisms and visual/audible alarms
- High-pressure alarm detects airway blockage
- Compatible with colorimetric detector for $ETCO_2$ in patient exhale
- Rechargeable battery last for up to 5.5 hours per charge

ADVANTAGES

- Fills an underserved need in emergency resuscitation
- More consistent tidal volume and breath rate than manual resuscitator (BVM)
- Compact design makes it highly portable
- Reduced training requirements
- Quick turnaround between patients
- Disposables avoid cross contamination
- Long shelf life and durability
- Designed for remote/austere locations
- The SAVe will run over 4 times longer on a single charge than a pneumatic ventilator running on a D tank

Introduction & Background

Properly ventilating a patient is a difficult task, even under ideal conditions. The need for an easy-to-use reliable automated ventilatory device is highlighted by the fact that the first time many medics ventilate a human patient will be on the battlefield.

The SAVe was built to save lives by improving the triage capabilities of medics and elevating the standard of care in the far forward environment by replacing bag valve masks (BVM) with a simplified automated ventilation device.

Utilizing a BVM to ventilate has been the standard of care in the pre-hospital environment for the last 50 years. In the civilian pre-hospital sector, two trained medical responders typically attend a single patient and transport times average only 11 minutes. However, on the battlefield a single medic is often required to triage multiple casualties with life threatening injuries for several hours. BVMs completely incapacitate the medic from performing other critical duties. In multiple casualty situations like those caused from IEDs or RPGs, a medic cannot neglect other patients with life threatening injuries while bag-valve ventilating a non-breathing patient. Triage priorities dictate the medic help other patients. As such, the apneic patient is unlikely to receive adequate care in time.

The SAVe can be deployed by a medic in less than 30 seconds. If triage priorities dictate the medic help other patients, a combat life-saver who is trained to keep the patient's head tilted and how to hold a two handed seal can remain with the patient. This frees up the medic to apply a tourniquet, start fluids, administer drugs or attend other patients with life threatening wounds. A mask can be used to supply initial breaths immediately after the onset of respiratory failure; however, an airway device such as an ET-Tube should be inserted by an appropriately trained individual as soon as possible. Using a mask in the field or a given airway device is dependent on training issues. Always defer to the direction of a medical officer or your chain of command.

In addition to the manpower issues associated with bag valve ventilation, there is a growing body of evidence that links ventilating with a BVM to hyperventilation and gastric insufflation. Ventilating a patient using a bag valve device requires significant concentration and skill in stressful situations. With every squeeze of the bag, the rescuer is selecting the respiratory rate and tidal volume. Providing the appropriate amount of air at the appropriate intervals can be extremely difficult for even the most highly trained professional. Keeping artificial ventilation rates low is difficult due to the high-adrenaline state of the rescuer which alters time perception, and the rapidly refilling bag ventilation systems prompts a reflex in which rescuers are inclined to deliver breaths as soon as the bag inflates. Peer reviewed published studies have demonstrated that civilian paramedics who bag patients on a routine basis and in much less stressful situations tended to deliver between 22 and 33 breaths per minute rather than the target of 10 to 12. Hyperventilating a patient adversely affects hemodynamics, especially in patients in shock and with

traumatic brain injuries, both of which represent a high percentage of the preventable causes of combat death.

Equipment that improves a medic's remote triage capabilities, mitigates the potential for additional injury, reduces operator error and requires very little training is critically needed. To that end, AutoMedx developed the SAVe for combat medics.

SAVe Overview

The SAVe is a time cycled, constant flow, volume-targeted device with a peak inspiratory pressure limit of 38 cmH_2O designed as a safety measure to prevent barotrauma. The SAVe delivers a set tidal volume at a set respiratory rate. It is at the discretion of the prescribing physician to determine if the SAVe's preset settings are appropriate for the patient.

Figure 1: SAVe Unit

The SAVe does not require a compressed gas source to operate. Instead, it uses a rechargeable battery driven pump to deliver ambient air to the patient. Actual runtime depends on many factors including the patient's lung compliance, ambient temperature when it is being used, the storage temperature and time since it was last charged. When the battery is low, the unit can be connected to an external power supply. This will run the unit as well as recharge the battery.

When the SAVe Should be Used / Indication for Use Statement

The SAVe is intended to provide short-term ventilatory support for individuals during CPR or when positive-pressure ventilation is required to manage acute respiratory failure. The SAVe is appropriate for individuals that weigh at least 45 kilograms (approximately 100 lbs.). It is intended to be used in field hospitals, transport and pre-hospital environments.

When the SAVe Should Not be Used

The SAVe is not intended for long-term use. The SAVe is not intended for children or adults weighing less than 45 kilograms (approximately 100 lbs.). Extreme care should be practiced when using the SAVe on patients that have non-compliant lungs as the pressure cut off may be reached before the targeted tidal volume is delivered. The SAVe should not be used on patients that are still spontaneously breathing.

Training Requirements

The SAVe should only be used by individuals who have been trained to provide primary response to respiratory distress.

Risks and Benefits

The SAVe is designed to enable a medic or other first responder with limited training to provide life-saving ventilation until the patient can be evacuated to a higher level of care. The device is easy to use, lightweight, and is intended to be used on the battlefield, during transport and other pre-hospital environments. The SAVe utilizes a single Tidal Volume and Respiratory Rate. This eliminates guesswork and reduces the operator error associated with bag-valve ventilation.

The SAVe has a number of benefits over a bag-valve-mask (BVM). First, it offers a breath-to-breath consistency that is not achievable with a BVM. This is especially important during high stress situations. The SAVe will ensure the patient receives a consistent tidal volume at a consistent rate. Second, the SAVe, unlike a BVM, frees up the medic to address other injuries, attend to other patients or further assist in the evacuation. Third, the SAVe will provide up to 5 1/2 hours of ventilation on a full charge. It is impractical to expect a medic to be able to provide resuscitation manually for that duration with a BVM.

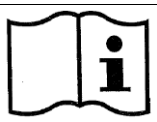
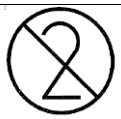
The SAVe uses a rechargeable battery-driven pump to deliver ambient air to the patient and does not need compressed air to operate. The SAVe accepts low pressure supplemental oxygen but it is not required. Devices that rely on high-pressure oxygen tanks pose a fire and explosion hazard, tend to be large and only provide air for a short period of time.

Although the SAVe automates the task of delivering breaths, the medic administering care must monitor the patient to ensure adequate gas exchange is taking place. The SAVe is designed to prevent immediate harm to the patient if a problem should occur. In addition to sounding an alarm, the unit will cut off power to the pump when the delivery of additional air may cause harm to the patient. Although this is a safety feature that protects the patient, a medic must respond quickly to fix the fault that triggered the alarm or the patient may suffer serious harm from a lack of air.

The SAVe is not designed to provide definitive care. The patient should be evacuated to a higher level of care as quickly as possible and connected to fully-featured ventilator by an individual with an appropriate level of training.

General Warnings and Cautions

Failure to adhere to the WARNINGs and CAUTIONS below as well as to all of the instructions given in the manual could lead to death or serious injury to the user and/or to the patient.

	WARNING: Read the instructions contained within this manual BEFORE operating the SAVe.
	WARNING: If using supplemental oxygen, avoid smoking or naked flames. To avoid the risk of ignition, do not use oil, grease, or combustible lubricants (only those approved for oxygen use) in contact with any part of the ventilator, regulator, or cylinder.
	WARNING: The device may deliver tidal volumes outside of the stated range if stored or operated in extreme temperatures outside of those identified within the Product Specification. CAUTION: When operating the SAVe in wet environments, users should take precautions and protect the device by covering it with a protective barrier (e.g. small tarp, etc.). CAUTION: Use of the SAVe outside of normal operating conditions may materially impact device performance and may permanently damage and/or shorten life of the device. CAUTION: Storage of the SAVe outside of normal storage conditions may materially impact device performance.
	WARNING: Electric shock hazard. Do not open the enclosure casing. CAUTION: Internal components are susceptible to damage from static discharge. CAUTION: Potential electromagnetic interference may occur at levels greater than 20 V/m. Avoid use of the device in unknown environments that may have high electromagnetic levels. CAUTION: Portable and mobile RF communications equipment can affect Medical Electrical Equipment.
	CAUTION: Reuse of patient circuit may cause cross contamination. Do not reuse the patient circuit.

WARNING: The SAVe should not be used on unattended patients.

WARNING: The SAVe should only be used by individuals who have received training to provide primary response to a respiratory emergency.

WARNING: Federal law (USA) restricts the use or sale of the SAVe by, or on the order of, a physician.

WARNING: The use of a mask increases the risk of gastric insufflation.

WARNING: An alternative method of ventilating the patient should be available in the unlikely event the SAVe malfunctions.

WARNING: Correct operation of the ventilator does not guarantee required blood gas levels; these should be monitored independently.

WARNING: Do not obstruct the air intake or patient exhaust ports of the patient circuit valve.

WARNING: If a mask is being used, a less than stated tidal volume may be delivered to the patient if an adequate seal is not maintained or if patient airway is compromised.

WARNING: The use of accessories not approved for use by AutoMedx could result in unsatisfactory performance.

WARNING: The debris filter will not protect the patient from contaminated environments. Do not use the SAVe in contaminated environments.

WARNING: If the unit's PIP limit is reached, the pump will enter an expiratory phase and deliver less than stated tidal volume at a greater than stated respiratory rate.

WARNING: Alarm suppression should **ONLY** be utilized in situations where audible or visual alarms would compromise the safety of human life. Alarms should be immediately returned to a fully functional state (audible and visual) as soon as safely possible.

WARNING: Be aware that if using an $ETCO_2$ detector, vomitus may obstruct the airway.

WARNING: Any unit that does not pass all checks during normal use or regular maintenance should be taken out of service and reported to AutoMedx immediately.

WARNING: Pre-use checks should be performed prior to every use.

CAUTION: The SAVe may not be appropriate for someone with ARDS-type symptoms.

CAUTION: If the SAVe is used on a patient that exhibits a low compliant lung, an advanced airway (ET-Tube or Supraglottic Airway) should be used.

CAUTION: Only use AutoMedx-approved power supplies with the SAVe.

CAUTION: Do not allow water, oil, grease, sand or other particulates to enter the ports.

CAUTION: Operation of the SAVe without the debris filter properly installed may damage the unit.

CAUTION: Service is to be performed by qualified biomedical equipment technicians only. Internal components should not be touched unless ESD precautionary procedures are used. It is recommended that all technicians involved with servicing be trained to ESD precautionary procedures.

Importance of the Need to Adhere to Instructions

The SAVe is a life-supporting medical device. Improper use of the device could lead to harm of the patient. Suppressing, neglecting or otherwise not responding quickly to alarms may cause serious harm or death.

Pre-Deployment Checkout Procedure

The procedures outlined below should be performed prior to using the SAVe. Ideally, this should be done prior to deploying the SAVe on a mission. These procedures are modified from full preventative maintenance procedures such that they may be performed quickly in the field by the end user. Please refer to the Maintenance section of this manual and the SAVe Preventative Maintenance Manual (P/N: M40060, available upon request) for complete maintenance and troubleshooting instructions.

Step	Procedure	Description
1	**Kit Contents**	Verify the SAVe kit is complete and contents are in proper working order. At a minimum, the SAVe should be packaged with a new patient circuit, debris filter and mask or airway.
2	**Debris Filter**	Verify that a debris filter is installed.
3	**Battery Life**	Turn the control knob to the first ON (|) position. Verify that the unit has adequate battery life. Charge the unit as necessary. Unit should be charged after each use.
4	**High Pressure Alarm**	Turn the control knob to the first ON (|) position. Verify operation of the high pressure alarm by closing the "Patient Circuit Port Cover." The patient alarm should activate and the pump should quickly cycle between the inspiratory and expiratory phases.
5	**Low Pressure Alarm**	Turn the control knob to the first ON (|) position. Open the patient circuit port cover. The patient alarm should continue to activate but the pump should deliver a full cycle.

STEP 1 – Verify Kit Contents

The SAVe is typically kitted with the contents in the table below.

At a minimum, the SAVe unit must be packaged with a new patient-circuit, debris filter, and airway such as a mask or ET-Tube.

If kitted with a mask, verify that the mask is fit for use. The inflation of inflatable masks with an inflation valve may be adjusted by inserting a standard male syringe. Please see the separate mask instructions for details.

Kit	P/N	NSN	Picture
SAVe Kit with Hard Case	70000H	6515-01-581-8155	

Item*	P/N	NSN	Qty.	Picture
SAVe Unit	M50000	N/A	1	
Patient Circuit w/ Debris Filter	M40003	6515-01-580-0768	2	
External Power Supply	E10478	6515-01-580-3522	1	
Head Strap	E11001	N/A	1	
Patient Mask	E11000	N/A	1	
Syringe	E10996	N/A	1	N/A
Supplemental O_2 Tubing	E10365	6515-01-580-3532	1	
Hard Case**	F20020	6515-01-588-8198	1	

**Configurations vary depending on kit type.*

***Some units may be kitted with a soft-case instead of a hard case or no case at all.*

STEP 2 – Debris Filter

It is necessary for a filter to be installed into the ventilator's air intake port to prevent dirt, sand, or other debris and contaminates from entering the ventilator and potentially damaging the ventilator or harming the patient.

The air intake port is located on the right side of the ventilator (**Figure 2**). The debris filter is a foam disk approximately 1.6 inches in diameter and 0.375 inches thick. A picture of a correctly installed debris filter is provided in **Figure 3**.

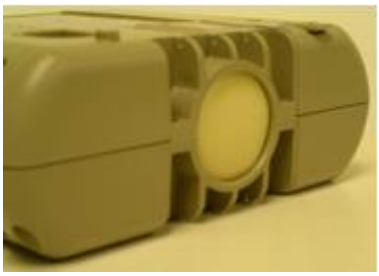


Figure 2: Installed Filter

Figure 3: Air Intake Port

Never use the SAVe without the debris filter installed. Only use debris filters manufactured by AutoMedx.

The debris filter will not protect the patient from harm due to contaminated environments. Do not use the SAVe in contaminated environments.

Once the debris filter has been properly installed, it should appear flush against the side of the ventilator housing. The debris filter should be cleaned or replaced whenever visible buildup of dirt is observed or it has been exposed to biomaterial such as blood or vomitus. AutoMedx recommends cleaning or replacing the debris filter after each patient use.

STEP 3 – Battery Life

The battery life of the SAVe should be verified prior to deployment. Turn the control knob to the first ON (|) position and determine how many lights are illuminated. Use the chart below to estimate remaining battery life.

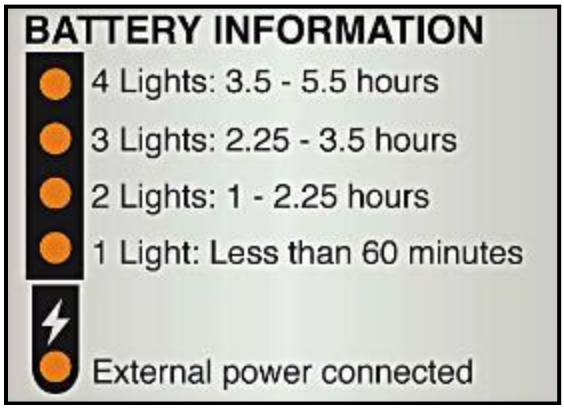


Figure 4: Battery Information

If the SAVe unit has insufficient battery life remaining, refer to the Maintenance section for instruction on how to charge the battery. Please note that even if all charge indicator lights are illuminated the device may last as little as 3.5 hours. A fully depleted battery requires 14 hours to fully recharge.

STEP 4 – High Pressure Alarm

The high pressure alarm is a critical safety feature that detects a blockage of the air pathway. Verify the operation of the high pressure alarm by using the patient circuit port cover to block the patient circuit port and then turn the device to the first ON (|) position as illustrated in Figure 5. When testing, make sure the patient circuit port is adequately blocked by the patient circuit port cover. The SAVe should **quickly** cycle between the inspiratory and expiratory phases and the visual and audible patient alarms should activate.

Figure 5: High Pressure Alarm Test

Figure 6: Low Pressure Alarm Test

STEP 5 – Low Pressure Alarm

The low pressure alarm is another critical safety feature of the SAVe that detects a disconnection of the patient circuit or severe leak in the air pathway. Verify the correct operation of the low pressure alarm by opening the patient circuit port cover and turning the device to the first ON (|) position as indicated in Figure 6. The SAVe should cycle normally with the exhalation phase lasting twice as long as the inspiratory phase and the patient visual and audible alarms should activate within 3 breath cycles.

Operating the SAVe

Control Knob Positions

All switch positions other than the OFF (O) position will activate the ventilator (see **Figure 7**). Because battlefield use may require suppression of audible or visual alarms, additional alarm configurations are provided. The ON (**|**) position will activate the ventilator and both visual and audible alarms. The following position to the right of the ON (**|**) position will operate

visual alarms and audible alarms will be suppressed. The following switch position to the right will activate audible alarms and suppress visual alarms. The final setting suppresses all audible and visual alarms. **Alarms should only be fully suppressed when absolutely necessary**. Icons at each position have been provided as a visual reminder.

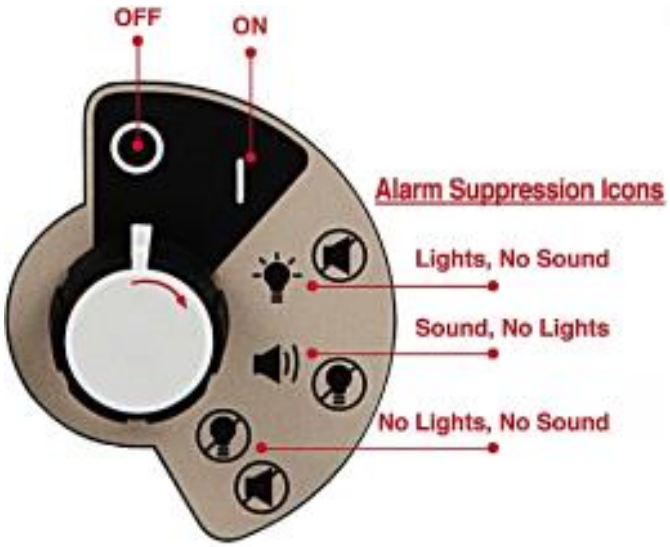


Figure 7: Control Knob Positions

When operating with all alarms suppressed, the patient must be constantly monitored since there is no means for the SAVe to alert nearby personnel of a patient-related or device-related error condition. This is especially true if using a mask as the airway could become compromised by the head tilting forward or if the seal is lost. If an alarm condition should occur, the status of the various LEDs will help the user troubleshoot the problem. Please see Indicators, Errors and Alarms section for further details.

Patient Circuit (Valve)

The SAVe Patient Circuit is intended to connect the SAVe control unit to the airway device or mask. When the pump is not pushing air, the patient circuit valve allows the patient to exhale to the ambient environment through the valve's exhalation port. The design of the breathing circuit allows the patient to breathe ambient air with minimal resistance from the valve through the exhaust port if a spontaneous breath occurs during the ventilator's exhale state or even if the unit is powered off. A properly assembled patient circuit is illustrated in **Figure 8** below. If debris or patient vomitus enters the valve, replace the entire breathing circuit. If a new patient circuit is not available, remove debris or patient vomitus by disconnected the patient circuit valve from patient breathing circuit and shaking it to remove debris or vomitus. The valve may be cleaned with a damp cloth. If the debris or vomitus cannot be adequately removed and a replacement breathing circuit is unavailable, an alternative means of ventilation should be used.

It may be necessary to remove the patient valve from the circuit and clear any debris which may be blocking the airway. Reconnect patient connection port to valve once cleared.

Do NOT block valve ports.

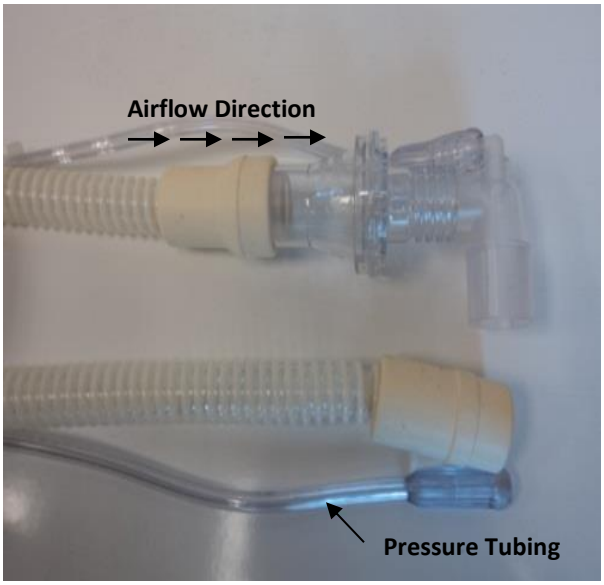


Figure 8: Correctly Assembled Patient Circuit

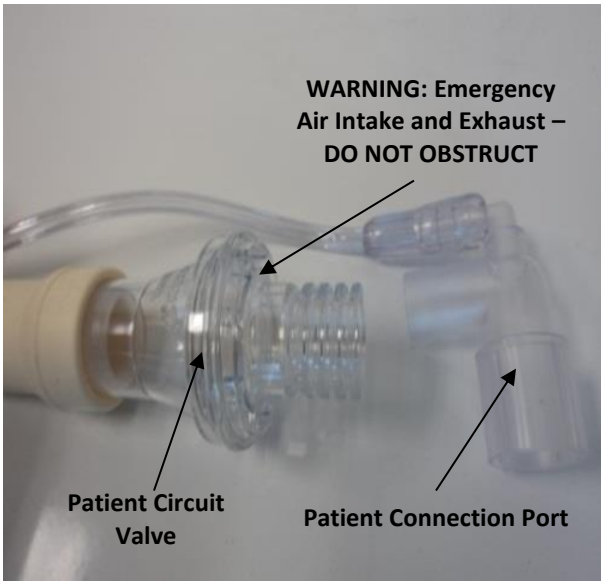
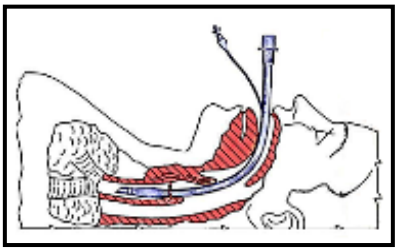
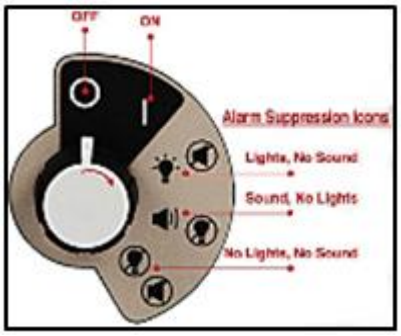
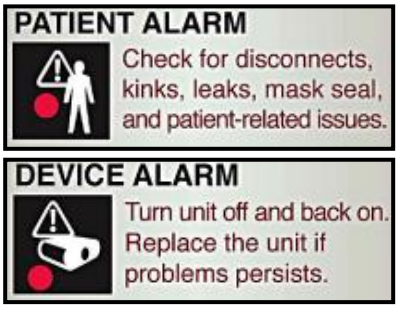


Figure 9: Patient Connection Port Removed

Using the SAVe

Step	Procedure	
1	Look, listen and feel for breathing and pulse. ⚠ Do not connect the SAVe to spontaneously breathing patient who may become out of sync with, or "buck", the ventilator.	
2a	Verify the airway is not blocked.	
2b	Clear any visible debris or excess fluids from the patient's mouth. If additional personnel are available, instruct them to begin rescue breathing.	
3	Open cover labeled "Patient Breathing Circuit" and connect patient circuit main tube and pressure tube to the appropriate ports. ⚠ Make sure the main tube and pressure tube are securely attached.	
4	Insert airway device (if using advanced airway).	

(continued)

Step	Procedure	
5	Connect the patient connection port to the airway device or mask. Only use masks approved by AutoMedx. Never use a mask with a pop-off valve or filter.	
6	Turn the SAVe ON by rotating the knob one position from (O) to (I). Do not turn past first ON (I) position unless absolutely necessary to suppress the alarms.	
7a	If using a mask, use the "head tilt chin lift" or if neck injury is suspected the "jaw thrust maneuver" to open and maintain the airway.	
7b	Use two hands to maintain the seal of the mask. Verify adequate chest rise, feel for leaks, and listen for exhale at the valve.	
8	Verify battery level and that no patient or device alarms are activating.	

(continued)

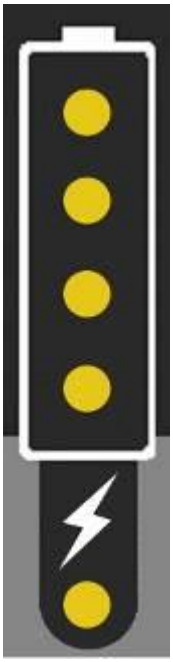
Step	Procedure
9	Supplemental O_2 may be connected to the patient if necessary. The use of supplemental O_2 may slightly increase delivered volume. The FiO_2 chart indicates the oxygen concentration delivered to the patient within ±10%.  FLOW RATE (L/min) / FIO_2 (%) 0 / 21 1 / 33 2 / 40 4 / 51 6 / 62
10	Secure SAVe to the patient. When operating the SAVe in wet environments, users should take precautions and protect the device by covering it with a protective barrier (small tarp, plastic sheet, etc.). 
11	Evacuate to a higher level of care and transfer to a more capable device as quickly as possible. 

Importance of the Need to Monitor the Activity of the Device

The SAVe is a life-supporting medical device. DO NOT leave the patient unattended, especially if a mask is being used. Improper use of the device could ultimately lead to harm of the patient. Neglecting alarms and not responding in a timely manner could leave the patient without ventilation, potentially causing severe harm or death.

Indicators and Alarms

Battery Level Indicator



The SAVe operates primarily from an internal, rechargeable battery. Located on the front panel of the SAVe is a battery icon with four power level indicators. The bottom LED (below the lightning bolt) is the external power supply indicator. During operation when the visual alarms and indicators have not been suppressed, the battery icon estimates the remaining charge in the battery.

The chart below gives the approximate run time remaining for a given battery level. When the SAVe is connected to an external power supply, the external power indicator (below the lightning bolt) will illuminate, indicating the unit is being powered externally and the battery is recharging.

Battery Level	Model 600x10
4 Lights	3.5 – 5.5 hours
3 Lights	2.25 – 3.5 hours
2 Lights	1 – 2.25 hours
1 Light (blinking)	Less than 60 min

NOTE: Operation time is materially affected by the following factors:

- Time since last charge
- Temperature conditions during storage
- Temperature of the environment where SAVe is used
- Age of battery and number of charge / discharge cycles
- Patient specific factors such as lung compliance and airway resistance (i.e. higher resistance decreases operation time as does lower lung compliance)

For more detailed battery specifications, contact AutoMedx.

Low Battery Alarm

Once the bottom battery LED begins to blink, the ventilator has approximately 45-60 minutes of battery life remaining. Connect the unit to a charger, if available, and be

prepared to replace the unit or ventilate the patient by other means. If the device alarm is engaged with the low battery alarm, little or no air is being delivered to the patient. Immediately plug in the device to external power or manually resuscitate.

High Temperature Alarm

The four battery lights will begin to blink when the internal temperature of the SAVe reaches 60°C. This indicates the internal temperature is too high and the ventilator may not operate properly. Replace unit if possible. If another unit is unavailable, ventilate patient by other means or begin rescue breathing.

Patient-Related (Correctable) Alarm

The patient alarm will activate to indicate low pressure, high pressure or if a positive pressure is maintained through several breath cycles.

Alarm Trigger	Likely Indicates
Low Pressure	Disconnect of main tube or pressure tube Severe leak
High Pressure	Patient-related Blockage Blockage somewhere in air pathway
Constant Pressure	Valve malfunction

There are a number of conditions that may trigger the patient alarm, including:

<u>Low Pressure</u>

- A disconnected patient circuit anywhere between the ventilator and the mask or ET-Tube
- A broken or punctured patient circuit
- A poor seal between the patient and breathing mask. **The absence of an alarm does not indicate a proper seal has been created.**

<u>High Pressure</u>

- The patient airway is compromised
- Tension pneumothorax
- The patient is improperly intubated
- A blockage of the intake port (where debris filter is located)
- A blockage of the patient connection port (where patient circuit connects to the mask or ET-Tube)
- The patient is capable of breathing sufficiently enough to fight the ventilator's function

Constant Pressure

- A blockage of the exhaust air flow ports (patient circuit valve)
- Malfunction of the patient circuit valve

Please see the Troubleshooting section for information on responding to the patient alarms. In the event that corrective action does not resolve the alarm condition, ventilate by alternative means as quickly as possible.

Device (Non-Field Serviceable) Alarm

In the event of a device-related error, indicated by the flashing red indicator light next to the device alarm icon, immediately begin ventilating the patient by other means. The SAVe is not field-serviceable for device-related errors unless it is in conjunction with a low battery alarm which will require connecting the device to an external power source. Some possible failures that may lead to a device alarm include the failure of internal components that control the inhalation and exhalation timing, a fully depleted battery or pump failure.

Please see the Troubleshooting section for more information.

Instructions on Use of Accessories

The SAVe can be used with a number of accessories including a mask, head strap, ET-Tube, $ETCO_2$ detector, and/or supplemental O_2. Please contact AutoMedx to determine if an accessory is compatible with the SAVe.

The SAVe has been kitted for immediate use situations; however, the mask, head strap and $ETCO_2$ detector which may be included with the kit are not manufactured by AutoMedx. Please refer to their instructions for use.

This manual includes instructions and information on accessories manufactured by AutoMedx and instructions for those accessories not manufactured by AutoMedx.

All accessories should be kept in their original packaging until they are to be used. Any accessory in an open or torn bag should not be used and should be discarded. All accessories are for single patient use. The SAVe is only to be used with accessories pre-approved by AutoMedx.

Use of Mask

It is at the discretion of the prescribing physician or user to determine if application of the device and any accessories are appropriate for a given patient. The SAVe kit includes a face mask that can be used with the SAVe. This face mask is intended to fit a broad range of patients but may not be ideal for all patients. It may be difficult or impossible to achieve a proper seal on patients with significantly smaller or larger than average faces or individuals with facial hair. If using an inflatable face mask, always check the cushion's inflation for appropriate fit and seal to the patient's face. Medium inflation generally provides the best

fit and seal. The mask may be inflated using the accompany syringe or any standard male syringe without a needle by inserting the syringe into the inflation valve located on the side of the mask.

Whether you use a mask or an airway is a training issue. Follow the instructions of your medical director or chain of command. When a mask is used, two hands should be used to perform a head tilt chin lift or jaw thrust maneuver. This will open the patient's airway and enable the user to hold the seal of the mask. Special care must be given to ensure the head remains tilted and chin lifted. If the head tilts forward, the airway may become compromised. Most leaks will occur around the mouth and chin. Listen for air from the patient to exhaust through the valve and watch for adequate chest rise.

When using a mask, there is a greater risk of gastric insufflation.

Do not use damaged or deformed masks which may cause an incomplete seal and leak.

Always assume that a mask is going to leak. Remember to watch for the rise of the patient's chest, listen for the patient's exhale at the valve, feel for leaks and visually verify the corners of the mouth are inside the seal of the mask.

Do not suppress the alarms unless absolutely necessary, especially while using a mask.

Only use masks approved by AutoMedx. Under no circumstances should a mask equipped with any type of filter, one way valve, or open oxygen/air port be used.

Over-inflating the mask bladder or using excessive pressure to hold the mask in place may restrict the usable surface area or close the patient's airway.

Once the SAVe is turned on, it will alarm until the mask is applied to the patient's face. Tilt the head and lift the chin. Hold the mask around the patient's face using two hands as shown in **Figure 10**. If a spinal injury is suspected, the jaw thrust maneuver is usually the preferred technique.

Figure 10: Proper Use of Mask with the SAVe

Maintaining a seal is a skill that can be easily learned but requires practice. It is recommended to use a pulse oximeter to monitor the patient's oxygen saturation. A head strap that may be used to help secure the mask to the patient is included with the SAVe kit. This head strap is intended to aid the operator and does not replace the need for the use of two hands.

Use of ET-Tube

The SAVe may be attached directly to an ET-Tube which has been properly inserted into the patient. Always ensure the ET-Tube is properly inserted into the patient before connecting the patient circuit. Refer to **Figure 11** and **Figure 12** below.

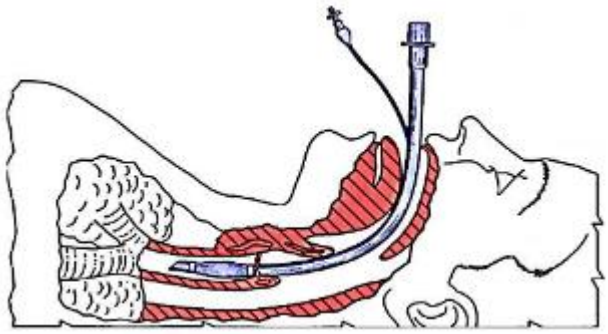


Figure 11: ET-Tube Insertion

Figure 12: ET-Tube Connection

Use with $ETCO_2$ Detector

An $ETCO_2$ detector may be inserted in-line between the patient elbow and ET-Tube as shown in **Figure 13**. To ensure compatibility and proper operation, only use $ETCO_2$ detectors approved by AutoMedx. All instructions and directions included with the sensor should be followed. An ETCO2 detector can be used to confirm airway placement and detect approximate ranges of end-tidal CO_2.

Be aware that if using an $ETCO_2$ detector, vomitus may obstruct the airway.

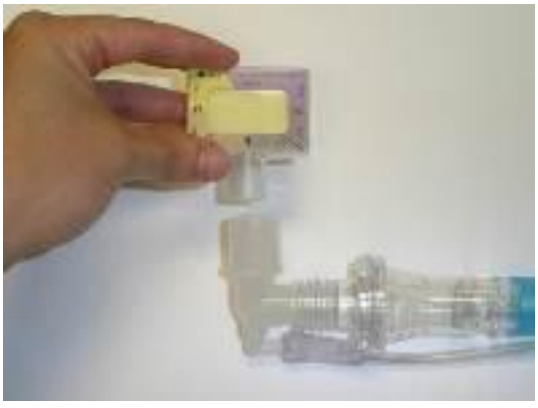


Figure 13: $ETCO_2$ Detector Connection

Use with Supplemental O_2

The SAVe has the capability to accept low pressure supplemental air or oxygen. Standard medical grade tubing is connected from the air source's flow-regulated output valve to the supplemental O_2 port on the SAVe (see **Figure 14**). The O_2 must be regulated at the source. The use of supplemental oxygen may slightly increase the delivered tidal volume of the SAVe.

Figure 14: SAVe Supplemental O_2 Port

The oxygen flowing through the supplemental port is blended with the ambient air being drawn in through the air intake port. Changing the flow rate of the oxygen from the source will change the concentration of oxygen delivered to the patient. The maximum acceptable flow rate from the air source is 6 liters per minute. The associated fraction of inspired oxygen (FIO_2) at different flow rates is shown in the following table. Values may vary by several percentage points.

Never deliver more than 6 LPM as it could cause harm to the device and patient. Delivering more than 6 LPM may inadvertently create positive end expiratory pressure (PEEP) and / or stacking breathes.

Flow Rate (L/min)	Oxygen Concentration (%)
0	21
1	33
2	40
4	51
6	62

Accuracy: ± 10% of stated FIO_2

Securing the SAVe to the Patient

During evacuation or transport, it is strongly recommended that the SAVe be secured to the patient or litter. AutoMedx recommends using rolled gauze (ex: Kerlix) to wrap the SAVe and patient together, generally using an arm.

When securing the SAVe to the patient, keep in mind the following:

1. Be aware of the flexibility and length of the patient breathing circuit between the SAVe and the patient mask or endotracheal tube. This tubing should retain some flexibility of movement once the SAVe has been secured.
2. Do not block the air intake port (on the side of the unit behind the debris filter) or the patient circuit's exhaust valve (reference **Figure 8** and **Figure 9** above).
3. Do not secure the SAVe to an injured limb.
4. Keep visual access to the error alarm icons and battery indicator LEDs.
5. Ensure the switch is oriented such that it cannot be accidentally moved.

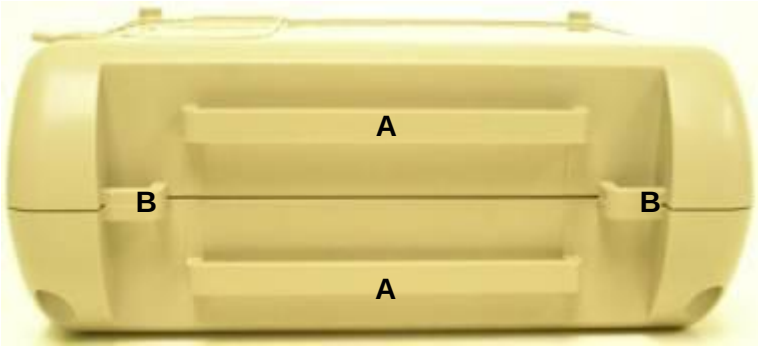


Figure 15: View of Attachment Points (Rear Panel) for SAVe

The SAVe also provides two alternative methods of secure attachment. First, two belt loops (Section A of **Figure 15**) are attached to the rear panel of the SAVe. A belt or strap may be positioned through these loops and used to tighten the SAVe against the patient. Second, two cord attachment (Section B of **Figure 15**) loops are provided. To attach a cord (**Figure 16**) (shoelace, etc.) to this loop, pass the center of the cord through the loop on the SAVe and then pass the ends of the cord through the loop of cord created. Tighten the cords by pulling on both ends. The free ends of the cord may now be used to tie or secure the unit.

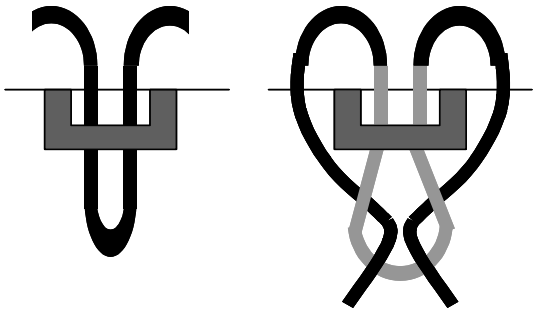


Figure 16: Connecting an Attachment Cord

Maintenance

The procedures contained within this manual are intended to be performed in the field by the end user. A Preventative Maintenance Manual containing complete maintenance information is available. To request this manual, please contact AutoMedx at 972-586-7500 or email at service@automedx.biz.

Regular Maintenance

Prior to Use

Please see Pre-use Checkout Procedure.

After Use

After the SAVe is used on a patient, the following tasks should be completed to prepare the SAVe for the next patient.

1. Single-use items including the ET-Tube, patient circuit, mask, debris filter, supplemental O_2 tubing, and head strap should be disposed of properly.
2. The pressure tube port on the SAVe should be wiped with a damp, soapy cloth and thoroughly dried with a lint-free cloth between patient uses.
3. The SAVe should be visually inspected for any damage that may affect operation. Do not use a damaged ventilator. Dirt and debris should be cleaned from the unit.
4. A new single-use patient breathing circuit, and a new ET-Tube or patient mask should be packaged and stored with the SAVe.
5. The SAVe should be fully charged.

Charging

If the SAVe has insufficient battery power, use the external power supply (P/N: E10478) to recharge the unit. The external power supply can be used to simultaneously recharge the battery and power the unit, if necessary.

Ensure the external power indicator light, which is below the lightning bolt, is illuminated to verify the unit is properly charging.

Take care to ensure the power cord is not inadvertently detached from the external power jack. By design it requires very little pressure to detach.

The Power Supply can accept an AC voltage between 100 and 240V at frequencies of 50-60 Hz. The battery will lose a portion of its charge every month. A completely depleted battery requires approximately 14 hours to fully re-charge. Always recharge the device after it is used. Storing the device with a low charge may shorten the life of the battery. To ensure the SAVe retains at least 65% of its charge, follow the following guidelines.

Storage Temperature	Interval of charge (refresh charge)
Below 68°F (20°C)	9 Months
68°F (20°C) to 86°F (30°C)	6 Months
86°F (30°C) to 104°F (40°C)	3 Months

NOTE: The SAVe internal battery is not field replaceable. Please contact AutoMedx for further instructions if the battery must be replaced.

Cleaning

Keep the SAVe and its accessories clean at all times. Under no circumstances should the SAVe unit be disassembled. Do not clean any portion of the SAVe or its accessories with abrasives or chlorinated hydrocarbon cleansers

Do not allow dirt, sand, debris, grease, oil, or caustic chemicals to enter, coat, or otherwise contaminate its components. To prevent debris from entering the SAVe, the patient breathing circuit port cover should always be securely in place when the unit is not in use or being cleaned.

Under no circumstances should the SAVe or its accessories be immersed in liquid or exposed to an autoclave. Should the SAVe become wet, the unit should be dried using a lint-free cloth immediately, or once the unit is no longer in use. Should the SAVe become immersed, discontinue use and return to manufacturer for refurbishing and testing. DO NOT expose the switch, external power jack, or audible alarm port directly to liquids.

Exterior

The exterior housing of the SAVe may be cleaned as necessary using a damp cloth and dried using a lint-free cloth. The front panel of the SAVe should be cleaned as necessary using only a lint-free cloth.

Carefully clean the port covers with a damp cloth and dry using a lint-free cloth. Examine the insides of patient circuit tubing ports for dirt or debris. Removal of objects, if required, may be attempted using forceps or similar non-sharp objects. Cleaning may be attempted, if required, using a dry lint-free cloth. If the insides of the patient circuit tubing ports cannot be cleaned, DO NOT attempt to use the SAVe. Return the SAVe to AutoMedx for refurbishment and testing.

Debris Filter

The debris filter should be replaced with a new filter following each use. If the debris filter becomes damaged or soiled during use, replace it with a new debris filter.

Patient Circuit

Examine the patient circuit tubes for cracking, discoloration, sharp edges, or other signs of damage. DO NOT attempt to use or repair damaged patient circuits. Damaged patient

circuits must be replaced. If necessary, exterior walls of tubing may be cleaned with a damp cloth and dried using a lint-free cloth.

Only a new patient circuit freshly removed from its packaging should be used. Do not re-use any portion of the patient circuit.

Annual Maintenance

After 2000 hours of use or 1 year, whichever comes first, the SAVe must complete a testing inspection to ensure continued operation within the specifications. The testing must be completed by an AutoMedx authorized facility. There are a number of approved biomedical testing sites within the U.S. military. Please contact AutoMedx by email at service@automedx.biz or by phone at (972) 586-7500 for details.

Storage

Prior to storing the SAVe unit, ensure that the unit is fully charged. Storing the unit in a discharged state will reduce the life of the internal battery.

For extended storage periods, the SAVe should be stored indoors, out of direct sunlight, and in a clean environment. The best storage temperature is between 0 and 30°C (32 to 86°F). For short-term storage, the temperature can range from -15 to 40°C (5 and 104°F). In both cases, the relative humidity in the storage facility should be low. It is recommended that if the device is to be stored for extended periods that it be kept in the hard case manufactured by AutoMedx.

To ensure optimum performance it is recommended that the SAVe is recharged at regular intervals as follows:

Storage Temperature	Interval of charge (refresh charge)
Below 68°F (20°C)	9 Months
68°F (20°C) to 86°F (30°C)	6 Months
86°F (30°C) to 104°F (40°C)	3 Months

Expected Failure Time and Mode and the Effect on the Patient

The internal pump of the SAVe is the first expected component to fail over the life of the unit due to normal wear and tear. This is expected to occur following 2,000 to 3,000 hours of ventilator use. When the pump fails, the device alarm will be triggered (reference section regarding Device Errors above) and the ventilator will cease pumping air to the patient. The medic should replace the unit immediately or begin ventilating by other means.

Instructions on How to Safely Dispose of the Device

If the SAVe unit is no longer in use, please return the unit to AutoMedx's facilities for proper disposal. Please contact AutoMedx for packaging and mailing instructions.

Troubleshooting

The SAVe has three alarm types as described below. Ensure that the light indicators are not suppressed while troubleshooting.

Alarm Overview

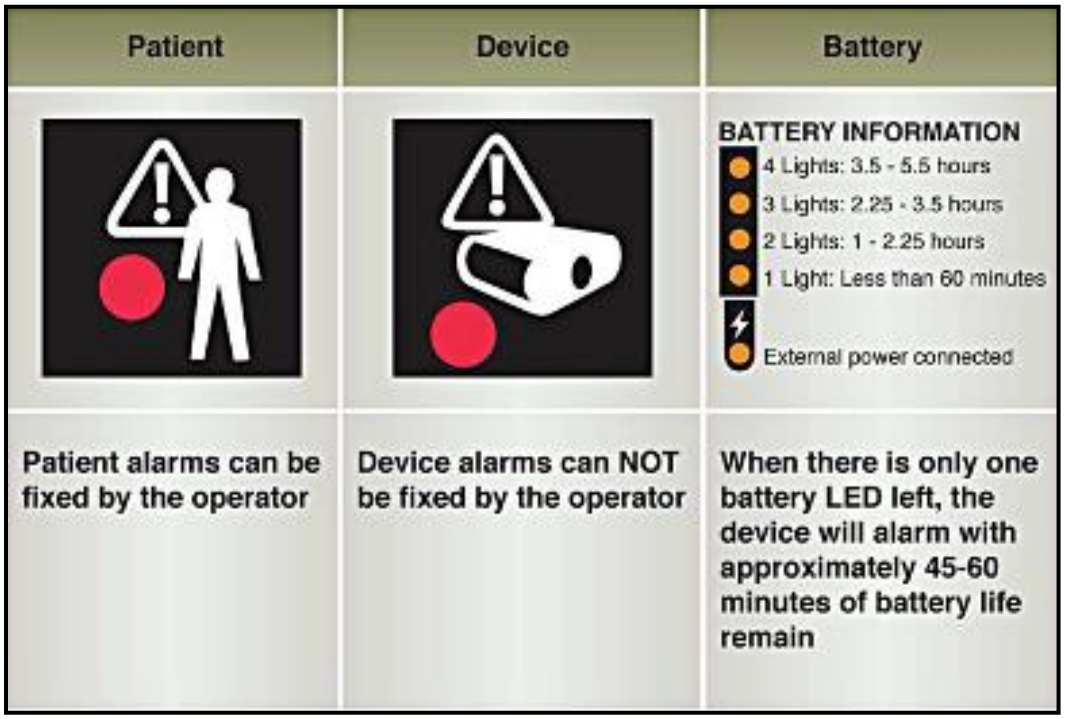


Figure 17: Alarm Overview

Patient Alarms

The patient alarm may be triggered by one of the events listed below. Please note once the problem that triggered the alarm is fixed, the alarm will cease and the ventilator will begin proper operation on its own.

Troubleshooting patient alarms may involve clearing debris from the patient.

Situation	The ventilator motor repeatedly attempts to start but quickly stops
Likely Source	Blockage
Possible Solution	Begin troubleshooting with the patient and work towards the ventilator 1. If the problem cannot be addressed quickly, consider ventilating by other means or begin rescue breathing. 2. If using a mask: • Ensure head is tilted back and chin is lifted • Ensure there is no debris or vomitus in mouth, mask, or valve 3. If using an ET-Tube: • Ensure tube is properly placed in trachea • If $ETCO_2$ detector is being used, verify that it has indicated proper intubation of the patient • Ensure there is no debris or vomitus in the airway adjunct 4. Ensure there is no debris in the patient circuit valve 5. Ensure air intake port is not blocked 6. Ensure patient tubing is not kinked 7. If problem is not identified, replace patient circuit.

Situation	The ventilator motor turns on for a couple of seconds and then turns off for a couple of seconds. Aside from the alarm, the device seems to function normally.
Likely Source	A leak or disconnect
Possible Solution	1. If the problem cannot be addressed quickly, consider ventilating patient by other means or begin rescue breathing. 2. Ensure both tubes leading to patient are properly connected to the ventilator. 3. If using a mask, ensure there is a tight seal to the patient's face. 4. If using an ET-Tube, ensure it is not dislodged. 5. Ensure the patient circuit is properly connected to the ET-Tube or mask. 6. Ensure there is no hole or leak in the patient breathing circuit. If a leak is found, replace patient circuit immediately. 7. If problem is not identified, replace patient breathing circuit.

Situation	The ventilator cuts off for more than 10 seconds.
Likely Source	A malfunctioning exhaust valve.
Possible Solution	Replace patient breathing circuit immediately.

Situation	The alarm is intermittent. The alarm sounds and the pump turns off for several seconds and as air is released, the alarm ceases and the pump resumes again, repeating every several breaths.
Likely Source	Breath stacking (insufficient amount of air is being exhaled from the lungs between breaths).
Possible Solution	1. Ensure valve on patient circuit is parallel/horizontal to the ground (i.e. patient circuit valve is not upright or vertical to the ground). 2. If the problem cannot be addressed quickly, ventilate patient by other means or begin rescue breathing. 3. Ensure that the patient circuit exhaust valve is not blocked. 4. If problem is not identified, replace patient circuit.

Device Alarms

1. If the battery indicator has only one LED lit and a device alarm comes on, plug the device into an electrical outlet immediately. If alarm continues, ventilate by other means or begin rescue breathing. These two alarms together indicate little or no air is being delivered to the patient due to low power.
2. For all other device related alarms, ventilate patient by other means or begin rescue breathing.

Low Battery Alarm

Once the bottom battery LED begins to blink, the ventilator has approximately 45-60 minutes of battery life remaining. Connect the unit to a charger, if available, and be prepared to replace the unit or ventilate the patient by other means. If the device alarm is engaged during a low battery, little or no air is being delivered to the patient. Immediately plug in the device or manually resuscitate.

High Temperature Alarm

The four battery lights will begin to blink when the internal temperature of the SAVe reaches 60°C. This indicates the internal temperature is too high and the ventilator may not operate properly. Replace unit if possible. If another unit is unavailable, ventilate patient by other means or begin rescue breathing.

Limited Warranty

Limited Warranty Applicable to the SAVe

AutoMedx warrants to the original purchaser ("Customer") of the SAVe that if there is a defect in material or workmanship in the SAVe and AutoMedx is notified of such defect within one (1) year of Customer's original purchase, AutoMedx shall, in its sole and absolute discretion, repair or provide a replacement of such defective part(s) at no charge to the Customer, provided that this warranty provision is not applicable to batteries or used consumables.

Limited Warranty Applicable to the Battery

The life of the battery, as noted above, is materially affected by many factors. As such, AutoMedx warrants to the Customer of the SAVe that, if there is a defect in material or workmanship in the battery contained in the SAVe and AutoMedx is notified of such defect within ninety (90) days of Customer's original purchase, AutoMedx shall, in its sole and absolute discretion, repair or provide a replacement of such defective battery at no charge to the Customer.

Sole Remedy

The sole remedy for a defect in materials or workmanship of the SAVe (or the battery or any other component of the SAVe) shall be, at AutoMedx's sole and exclusive discretion, repair or replacement of the defective SAVe or component thereof, as the case may be.

Exclusions

AutoMedx's warranty shall not apply to defects or conditions resulting from: (a) repairs by an unauthorized party; (b) improper maintenance; (c) modifications made without written permission of AutoMedx; (d) damage by accident, abuse, misuse, or misapplication; or (e) operation otherwise than in accordance with this manual or other instructions furnished by AutoMedx.

AutoMedx's warranty shall not apply if the unit has been disassembled.

AutoMedx's warranty shall not apply to: (a) any Product if the serial number of such Product has been altered, defaced or removed or (b) any used consumables.

AutoMedx's warranty is neither assignable nor transferable.

All warranty repairs shall be subject to return postage billing.

Disclaimer of Warranty and Limitation on Remedies

THE WARRANTY AND REMEDIES SET FORTH ABOVE ARE EXCLUSIVE AND IN LIEU OF ALL OTHERS, WHETHER ORAL OR WRITTEN, EXPRESS OR IMPLIED. AUTOMEDX SPECIFICALLY DISCLAIMS ANY AND ALL IMPLIED WARRANTIES, INCLUDING WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

AUTOMEDX IS NOT RESPONSIBLE FOR DIRECT, INDIRECT, SPECIAL, INCIDENTAL, CONSEQUENTIAL OR EXEMPLARY DAMAGES WHETHER BASED ON CONTRACT, TORT, OR ANY OTHER LEGAL THEORY.

Electromagnetic Emissions and Immunity

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The SAVe Portable Ventilator is intended for use in the electromagnetic environment specified below. The customer or the user of the SAVe Portable Ventilator should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF Emissions CISPR 11	Group 1	The SAVe Portable Ventilator uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The SAVe Portable Ventilator is suitable for use in all establishments including domestic and those directly connected to the public low-voltage power supply network power supply that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Class B	
Voltage Fluctuations / Flicker Emissions	Complies	

<table>
<tr><th colspan="4">Guidance and Manufacturer's Declaration – Electromagnetic Immunity</th></tr>
<tr><td colspan="4">The SAVe Portable Ventilator is intended for use in the electromagnetic environment specified below. The customer or the user of the SAVe Portable Ventilator should assure that it is used in such an environment.</td></tr>
<tr><th>Immunity Test</th><th>IEC60601 Test Level</th><th>Compliance Level</th><th>Electromagnetic Environment - Guidance</th></tr>
<tr><td>Electrostatic Discharge (ESD)
IEC 61000-4-2</td><td>±6kV Contact
±8kV Air</td><td>Complies</td><td>Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.</td></tr>
<tr><td>Radiated RF
IEC 61000-4-3</td><td>20 V/m
80MHz to 2.5GHz</td><td>Complies</td><td rowspan="2">Field strengths outside the shielded location from fixed RF transmitters, as determined by an electromagnetic sit survey, should be less than 20 V/m. Interference may occur in the vicinity of equipment marked with the following symbol:
  </td></tr>
<tr><td>Conducted RF
IEC 61000-4-6</td><td>3Vrms
150kHz to 80MHz</td><td>Complies</td></tr>
<tr><td>Electrical fast transient
IEC 61000-4-4</td><td>±2kV power line
±1kV I/O lines</td><td>Complies</td><td rowspan="2">Mains power quality should be that of a typical commercial or hospital environment.</td></tr>
<tr><td>Surge
IEC 61000-4-5</td><td>±1kV differential
±2kV common</td><td>Complies</td></tr>
<tr><td>Power frequency magnetic field
IEC 61000-4-8</td><td>3 A/m</td><td>Complies</td><td>Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.</td></tr>
<tr><td>Voltage dips, short interrupts and voltage variations on power supply input lines
IEC 61000-4-11</td><td>>95% dip 0.5 cycle
60% dip 5 cycles
70% dip 25 cycles
95% dip 5 sec.</td><td>Complies</td><td>Mains power quality should be that of a typical commercial or hospital environment. If the user of the SAVe Portable Ventilator requires continued operation during power mains interruptions, it is recommended that the SAVe Portable Ventilator be powered from an uninterruptible power supply or battery.</td></tr>
</table>

Technical Overview

The SAVe's pneumatic subsystem uses an internal air pump to deliver ambient air to the patient. During the inhalation cycle, ambient air is drawn into the pump through the air input port. If needed, supplemental O_2 may be connected to an additional port.

As air is pushed from the pump into the internal manifold, a pneumatically connected pressure sensor monitors the pressure of the air delivered to the patient. The air manifold interfaces to the patient breathing circuit by way of a standard 22mm (outer diameter) port. The patient breathing circuit contains a bi-directional valve that directs air to the patient when the pump is running. When the pump is not pushing air, the valve allows the patient to exhale to the ambient environment through the valve's exhalation port. The design of the breathing circuit allows the patient to breathe ambient air with minimal resistance from the valve through its exhaust port if a spontaneous breath occurs during the ventilator's exhale state or even if the unit is powered off.

The second pressure sensor is connected through tubing to a sampling port between the bi-directional valve and the patient. This second pressure sensor monitors the patient's airway pressure, assuring the patient's airway pressure during the entire breathing cycle is within expected limits. An optional colorimetric $ETCO_2$ detector to detect approximate ranges of end-tidal CO_2 in intubated patients may be connected in-line between the patient connection port and ET-Tube.

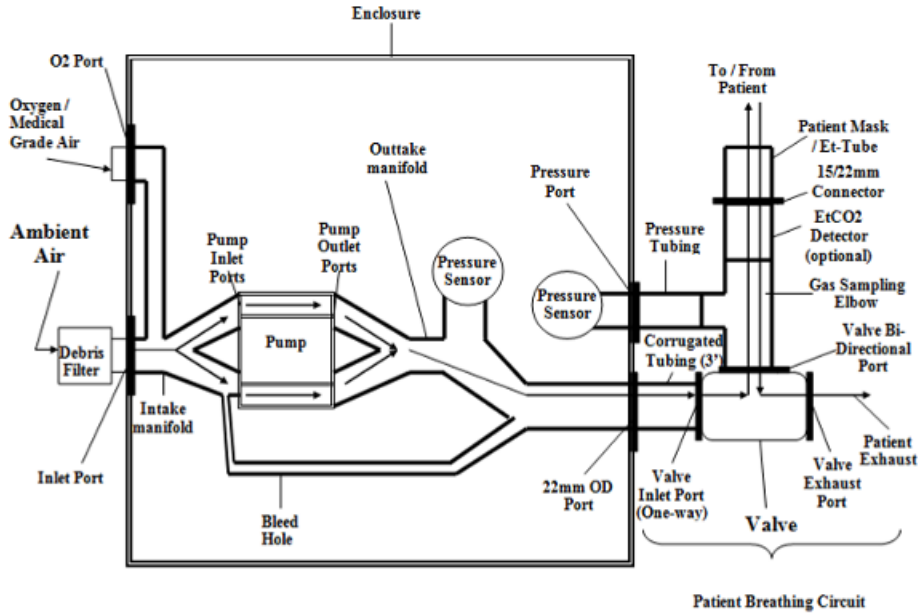


Figure 18: SAVe Technical Overview

The SAVe consists of numerous safety and alarm features to prevent harm to the patient and alert the medic immediately of a problem. These features include monitoring for a disconnection of the patient circuit, a blockage in the airway, exhaust valve malfunction, and excessive Positive End-Expiratory Pressure (PEEP). If the patient's lung pressure reaches the Peak Inspiratory Pressure (PIP) limit during inhalation, the SAVe immediately

enters into an exhale cycle. If it reaches that limit quickly, it triggers an alarm suggesting there is a blockage. The audible alarm sounds at a minimum decibel level of 70 db. The SAVe is an FDA Class II device. The patient breathing circuit and accompanying accessories are all “Type B” parts classified under IEC 60601-1 (i.e. applied parts not conductive and can immediately be released from the patient).

Product Specification[1]

Operating Modes:		Dual Control Continuous Mandatory Ventilation (DC-CMV)
Primary Control:		Time
Secondary Control:		Pressure
Breath Target:		Volume Targeted
Flow Rate:		18 LPM
Breath Rate[2]:		10 BPM
Minute Volume[2]:		6 LPM
Tidal Volume[2] Airway Resistance = 5 $cmH_2O/L/sec$	Lung Compliance = 50 mL/cmH_2O	600 mL/breath
	Lung Compliance = 20 mL/cmH_2O	560 mL/breath
Inspiratory to Expiratory Time (I:E ratio):		1:2
FIO_2:		21 – 62%
Inadvertent PEEP:		<2 cmH_2O
Peak Inspiratory Pressure (PIP) Limit:		38 cmH_2O
Oxygen Input Flow:		0 – 6 LPM
SAVe Unit Input Voltage:		15VDC
External Power Supply	Input:	100 – 240VAC/ 55 Hz/ 700 mA
	Output:	15VDC / 2A
Operating Time:		4 – 5.5 Hours at max charge
Audible Alarm Characteristics:		minimum 70 dB at 30 cm
Pressure Sensor Range:		0 – 40 cmH_2O
Dead Space:		20 mL (Excluding Accessories)
Patient Circuit Valve Resistance:		Spontaneous Breath – 3.5 $cmH_2O/L/sec$ Exhalation – 1 $cmH_2O/L/sec$
Temperature Ranges	Normal Operating:	0 to 40°C (32 to 104°F)
	Extreme Operating:	-15 to 50°C (5 to 122°F)
	Short-Term Storage:	-15 to 40°C (5 to 104°F)
	Long-Term Storage:	0 to 30°C (32 to 86°F)
Size:		6.75” x 6.25” x 2.5” (17 x 16 x 6 cm)
Weight:		3.1 lbs. (1.4 kg)
Warranty:		1 Year Limited

[1] All measurements include a tolerance of ±10% of nominal value unless stated otherwise. Test conditions available upon request.

[2] Delivered Tidal Volume is materially affected by low lung compliance. At a compliance of 10 mL/cmH_2O and airway resistance of 5 $cmH_2O/L/sec$ the SAVe is pressure limited. Due to an abbreviated inspiratory and expiratory phase, the resultant Tidal Volume is 325 mL/br and the Respiratory Rate is 15 breaths/minute which calculates to a Minute Volume of 5 L/min.

Accessory Order Information

Please contact AutoMedx at 972-586-7500 to order any accessory.

The SAVe is only to be used with accessories pre-approved by AutoMedx.

Part #	Description	NSN	Weight	Dimensions
M40003	Ruggedized Patient Breathing Circuit w/ Debris Filter	6515-01-580-0768	2 oz	3.25'L x 2"W x 1"D
E11000	Mask	N/A	2 oz	4"L x 3"H x 5"W
E10478	Power Supply	6515-01-580-3522	10 oz	13.5'L x 3.5"H x 2.5"W
E11001	Head-strap	N/A	1 oz	24"L x 1/16"H x 15.25"W
E10996	Syringe	N/A	.5 oz	5"L x 1"H x 1"W
E10365	Supplemental O_2 Tubing	6515-01-580-3532	2 oz	6.75'L x 5"H x .25"W
M40037	Debris Filter (5 pack)	6515-01-580-0972	.25 oz	1.5"x .25"
F20020	Hard Case	6515-01-588-8198	5 lbs	16"L x 12"W x 7"D
E10477	$ETCO_2$ Detector	N/A	.5 oz	2"L x 2"W x 1.5"D

Registering the SAVe

To ensure that you are eligible to take advantage of the product warranty and that you are notified of any changes in the Operator's Manual or Training Materials, please take a minute to register your SAVe unit by going to www.automedx.biz/products.

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