AutoMedx

SAVe II+ Operator's Manual

INSTRUCTIONS FOR USE

SAVe II+™

Notice to Operators

Please note all indications for use and other applicable contraindications in this Manual. This manual describes how to operate and maintain the SAVe II+ ventilator. It is intended to inform responsible parties of the requirements associated with the safe and effective use of the device.

Federal law (U.S.A) restricts this device to sale by or on the order of a licensed medical practitioner. Outside the United States check local laws for any restrictions that may apply.

Read and understand the instructions contained in this manual before operating the ventilator.

DOCUMENT VERSION

M42110 Rev 5.9 (3/24); **Firmware Version R2.0.0 and R2.1.0.** Both versions are valid depending on the device's specific hardware configuration.

Revisions are expected to be made to this document as the COVID-19 situation evolves. Please go to www.automedx.com/support to find current product literature.

The information contained in this manual is applicable to the product with which it was shipped. Product specifications and features are subject to change without notice. Always verify the firmware version of this manual (in bold above) matches the associated device. User environments in which multiple versions of the ventilator are used must avoid mis-matching manuals.

MANUFACTURER

Manufacturer of record:

AutoMedx, LLC
4553 Westgrove Dr.
Addison, TX, 75001
1-886-617-2904
www.automedx.com

TRACKING REQUIREMENTS

U.S. Federal Law (21 CFR 821) requires the tracking of ventilators. Under this law, owners of this ventilator must notify AutoMedx LLC if this product is:

- Received
- Lost, stolen or destroyed
- Donated, resold, or otherwise distributed to a different organization

If any of the above apply, please visit www.automedx.com/register to register the device.

AUTOMEDX WILL SEND NOTIFICATION OF SAFETY UPDATES, A RECALL OR SOFTWARE UPDATES TO THE REGISTERED EMAIL ADDRESS ASSOCIATED WITH THE DEVICE. THE REGISTERED ORGANIZATION SHOULD UPDATE THE REGISTRATION WHEN OWNERSHIP IS TRANSFERRED, OR THE PRODUCT IS DESTROYED.

SOFTWARE/FIRMWARE LICENSE

The software/firmware ("Software") included in the SAVe II+ product ("Product") is owned by AutoMedx and is protected by U.S. and international copyright and other intellectual property laws and treaties. Your rights to use the Software are subject to such laws and treaties and the following terms. Your purchase and/or use of the Product signifies your agreement to these terms.

1) **Ownership**: All rights to the Software are owned by AutoMedx. The Software is licensed and not sold. AutoMedx reserves all rights not expressly granted by these terms.

2) **License:** AutoMedx grants you a limited, non-exclusive license to use the Software solely with, and as incorporated into, the Product.

3) **Express Limitations:** You may not, directly or indirectly, make or distribute copies of the Software, attempt to discover or gain access to the source code for the Software, or modify, create derivative works of, disassemble or reverse engineer the Software.

4) **Transfer:** You may transfer the Software solely with, and as incorporated into, the Product, provided that the acquirer of the Product is subject to these terms.

Device Warnings

GENERAL

ALTERNATIVE VENTILATION – Always have immediate access to an alternative means of ventilation, which is ready to use, to reduce the possibility of patient death or serious deterioration of health.

PATIENT MONITORING – This ventilator is intended to be continuously attended to by an operator. Failure to be in close proximity to this ventilator can contribute to patient death or serious injury. Such personnel should be prepared to troubleshoot alarms, address equipment malfunctions and circumstances where equipment experiences problems.

EXPIRED VOLUME & EXPIRATORY END-TIDAL CO_2 MONITORING –This device is not equipped with expired volume monitoring or CO_2 monitoring equipment for measurement of the expiratory carbon dioxide concentration. The device must be equipped with suitable expired volume monitoring or CO_2 monitoring equipment (complying with ISO 80601-2-55) before being put into service.

PULSE OXIMETRY MONITORING – This device is not equipped with Pulse Oximetry (SpO2) monitoring. This device is not equipped with oxygen monitors to confirm the fractional oxygen concentration (FiO2) being delivered to the patient. The device must be used in conjunction with such while in use.

SINGLE USE ACCESSORIES – Do not reuse accessories that are marked as single use, such as the patient breathing circuit. Such accessories are not designed for cleaning or reuse and could result in incorrect therapy delivery, or other risk of harm or death to the patient. Only approved, new, and properly packaged single-use accessories have been tested and verified to function properly with the SAVe II+.

EQUIPMENT COMPATIBILITY - Do not add any attachments or accessories to the ventilator that are not listed as intended for use in combination with the ventilator in the instructions for use of the ventilator or accessory, as the ventilator might not function correctly leading to the risk of patient death or additional serious deterioration of health. For more information refer to www.automedx.com/accessories.

INLET GASSES - The ventilator shall not be used with inlet gases, which are not specified for use (e.g. helium or helium mixtures). Such use might cause the ventilator to not function correctly, causing patient death or serious deterioration of health. The ventilator shall not be used with nitric oxide.

NEBULIZATION / HUMIDIFICATION – When using nebulization or humidification, the breathing system filters can require more frequent replacement to prevent increased. resistance and blockage. These products are not approved for use with the SAVe II+.

VOLUME ACCURACY - The ventilator accuracy can be affected by the gas added to the ventilator breathing system by use of a pneumatic nebulizer.

PREVENTATIVE MAINTENANCE - Failure to follow preventative maintenance procedures could result in device malfunction. For more information refer to www.automedx.com/service

NOT MRI COMPATIBLE - Do not put the SAVe II+, any components, or accessories inside an MRI machine.

NO HYPOBARIC CHAMBER - The ventilator shall not be used in a hyperbaric chamber. Such use might cause the ventilator to not function correctly, causing patient death or serious deterioration of health.

STORAGE ENVIRONMENT - Storage of the SAVe II+ outside the specified storage environment may materially impact device performance and permanently damage and/or shorten the life of the device.

TRANSPORT OF LITHIUM-ION BATTERIES - Regulations govern the transportation of lithium-ion batteries and devices that have lithium-ion batteries. Check the appropriate statutes to ensure compliance before transporting the device and / or the batteries.

UNCERTAIN POWER SOURCES / AUTOMOBILE POWER OUTLETS - Verify the SAVe II+ internal battery is in good condition and fully charged before connecting the SAVe II+ AC power supply to uncertain power input sources. Connecting to an improperly rated power source may damage the AC power supply, preventing the SAVe II+ battery from charging.

If using a multiple socket-outlet, the outlet shall (1) not be placed on the floor, (2) an additional multiple socket-outlet or extension cord shall not be used, and (3) the maximum current load for the MAINS electrical circuit shall not be exceeded – each SAVe II+ power supply may require up to 0.9A at 100-240V at 50-60Hz.

PRIOR TO & AFTER EACH DEPLOYMENT

CHARGING BATTERY / EXTERNAL POWER - Only use the battery charger specified for use with the SAVe II+. The battery should be charged in accordance with the instructions.

BATTERY - If you suspect the internal battery is damaged, take the unit out of service immediately. Contact AutoMedx for disposition instruction. DO NOT SHIP DAMAGED LITHIUM-ION BATTERIES.

RISK OF INFECTION - A patient treated by mechanical ventilation is highly vulnerable to the risks of infection. Dirty or contaminated equipment is a potential source of infection. Clean the ventilator and its accessories regularly and systematically before and after each use and following any maintenance procedure to reduce the risks of infection.

SAND/DUST/DEBRIS INSIDE MANIFOLD – Do not operate the SAVe II+ if sand, dust, or other debris have entered the ports.

AUTOCLAVE/STERILIZATION - Never place any part of the SAVe II+ or its accessories in an autoclave. Unless otherwise indicated, the SAVe II+ and its accessories are shipped clean, but not sterile.

CONTAMINATED ENVIRONMENT - Take appropriate precautions. The debris filter is designed to stop particulates, not chemical or biological agents.

IMMEDIATELY PRIOR TO USE

PRE-USE CHECK - Verify functionality of the alarms before connecting the patient to the ventilator.

CROSS CONTAMINATION - Do not reuse single use accessories. This may cause cross contamination between patients.

USE OUTSIDE SPECIFIED NORMAL OPERATING CONDITIONS - The performance of the SAVe II+ may be materially affected if it is used outside of the specified normal operating conditions.

VENTILATOR PRESETS - Ventilator HEIGHT PRESETS may only be used on adult patients. Do not use presets when ventilating children. Presets are intended to aid operators with the initial setup but may not be appropriate for extended periods or in all situations. Operators should consult their medical director to determine the suitability of device presets for a given situation.

DURING USE

PATIENT MONITORING – This ventilator is intended to be continuously attended to by an operator. Failure to be in close proximity to this ventilator can contribute to patient death or serious injury. Such personnel should be prepared to troubleshoot alarms, address equipment malfunctions and circumstances where equipment experiences problems. Operators should observe the patient for non-obvious physiological effects such as hyperventilation, hypoventilation, and excessive airway pressure (overpressure).

ALARM INDICATORS – DO NOT OBSTRUCT AUDIBLE OR VISUAL ALARM INDICATORS. Audible indicators may be difficult to hear in noisy environments or if operator is wearing hearing protection. Do not allow the ventilator's alarm speaker port to become covered or obstructed in any way by stickers, labels, clothing, sand, mud, debris, or other equipment. Take extra precautions to closely monitor the patient and ventilator in these environments. Verify audible alarm indicators can be heard in the environment of use.

VISUAL ALARM INDICATORS - DO NOT COVER OR OBSTRUCT VISUAL ALARM INDICATORS IN ANY WAY. ALWAYS HAVE THE USER INTERFACE IN VIEW. When an alarm condition is triggered, or there is evidence of a patient-ventilator fault or problem, examine the patient first before examining the ventilator.

RESPONSE TO ALARMS – When an alarm condition is triggered, or there is evidence of a patient-ventilator fault or problem, examine the patient first before examining the ventilator.

AIRWAY OBSTRUCTIONS - Vomitus and other debris may obstruct the patient end of the patient breathing circuit. Refer to instructions on clearing debris from the patient breathing circuit.

SECURE DEVICE - Failure to properly secure the SAVe II+ could damage the device and could harm the patient by dislodging the breathing circuit or airway. DO NOT COVER THE VENTILATOR or placed in a position that affects proper operation, for example by placing the ventilator under a blanket or in a position where tension is placed on the Patient Circuit that may cause it to become dislodged.

FIRE HAZARD - Avoid open flames if using supplemental oxygen.

WET ENVIRONMENTS - If using the SAVe II+ in a wet environment take precautions and protect the device by covering it with a protective barrier.

UNINTENTIONAL CHANGES - To avoid accidental changes to the settings or inadvertently shutting off the device, verify the user interface is protected from unintentional contact.

MAINTAINING AND SERVICING

DO NOT SERICE WHILE DEVICE IS IN USE – The SAVe II+ shall not be serviced or maintained while in use with a patient.

SERVICE PERSONNEL QUALIFICATIONS - All servicing and repair of the SAVe II+ must be performed by a service technician qualified by AutoMedx. To request a SAVe II+ SERVICE MANUAL (P/N: M42147) and for qualification requirements visit www.automedx.com/service

BATTERY REPLACEMENT & DISPOSAL - The SAVe II+ battery should only be replaced by qualified service personnel. Replacement of Lithium-Ion batteries by inadequately trained personnel could result in an unacceptable risk or a HAZARDOUS SITUATION including, but not limited to, excessive temperatures, fire or explosion. Batteries must be disposed of according to local environmental legislation. Refer to SAVe II+ SERVICE MANUAL (P/N M42147).

PERSONAL INJURY AND ELECTRICAL SHOCK - Do not open the enclosure casing and do not use batteries, ac adapters, cables, or external power supplies with visible signs of damage. Only use power supplies approved by AutoMedx. Refer to http://automedx.com/accessories for more information.

LIQUIDS – To avoid inadvertent damage, do not pour or spray liquids directly on the SAVe II+. If liquid cleaners are used, spray on a lint free cloth, then use the cloth to clean the SAVe II+ and its accessories.

AUTOCLAVE/STERILIZATION - Never place any part of the SAVe II+ or its accessories in an autoclave. Unless otherwise indicated, the SAVe II+ and its accessories are shipped clean, but not sterile.

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Overview

INDICATIONS FOR USE

The SAVe II+™ is intended to provide short-term ventilatory support to adults during CPR or when Positive Pressure Ventilation (PPV) is required to manage Acute Respiratory Failure (ARF). The SAVe II+™ is appropriate for adults that weigh at least 45 kg. It is intended to be used in pre-hospital, field hospitals, and transport environments.

℞only Federal law restricts this device to sale (or use) on the order of a licensed practitioner.

CONTRAINDICATIONS

- Should not be used on patients weighing less than 45 kg (99 lbs.)
- Should not be used in situations where Positive Pressure Ventilation (PPV) is contraindicated.
- Do not use the device for extended periods without monitoring blood gases. As duration of use increases, the need for close monitoring of CO_2 and O_2 levels also increases. This is especially true for patients over 6' 9."
- Spontaneously breathing patients may not synchronize with ventilator. If spontaneously breathing patient has difficulty synchronizing with the device, consider discontinuing use.
- Do not set PEEP above zero (0) when performing CPR.

ENVIRONMENTS OF USE

The SAVe II+ is intended to be used in pre-hospital, field hospitals, and transport environments.

Normal Use Environment

The SAVe II+ is intended for use in emergency medical services and healthcare environment. Performance specifications are based on use in environments with ambient temperatures of 5 to 45°C (41 to 113°F), relative humidity from 15 to 95%, and atmospheric pressures from 70 to 110 kPa.

Extreme Operating Environments

Attempting to operate the ventilator outside the temperatures range of -20°C to 50°C (-4°F to 122°F) may result in ventilator failure and harm to the patient. The extreme operating environment is when you take the device from a room temperature environment into an extreme environment and immediately use the device.

TRAINING REQUIREMENTS

The device is intended for use by and under the supervision of trained healthcare professionals, e.g., doctors, nurses, emergency medical technicians, respiratory therapists and those certified to perform CPR. All operators regardless of experience or training must be familiar with the contents of this manual and be prepared to provide primary response to a respiratory emergency. The most up to date information related to training for operating the SAVe II+ is available at www.automedx.com.

RISKS & BENEFITS

The SAVe II+ is designed to enable providers with limited training to deliver life-sustaining ventilation to adult patients suffering from Acute Respiratory Failure. The device is easy to use, lightweight, and intended to be used in any healthcare environment that requires the use of a ventilator. The operator simply selects the height of the patient and the device dials in a lung protective Tidal Volume of 6 ml/kg of ideal body weight, PIP limit of 30 cmH2O and no PEEP. These presets may not be appropriate for all patients or all conditions. Most ARDS patients will require some level of PEEP. The operator must continue to monitor the patient and adjust as necessary.

The SAVe II+ offers a breath-to-breath consistency not achievable with a bag valve mask (BVM). This is especially important in high stress situations where studies have demonstrated rescuers are prone to hyperventilating patients. The SAVe II+ delivers a consistent tidal volume at a consistent rate. In an urgent first-responder situation, the SAVe II+, unlike a BVM, frees up the responder to address other injuries, attend to other patients or further assist in transporting the patient. The SAVe II+ at the 5'9" preset values will provide 8.5 to 9.25 hours of ventilation on a full charge. The time varies depending on settings, patient condition, and battery capacity. The SAVe II+ will detect a patient's inspiratory effort and automatically trigger a breath.

Unlike pneumatic resuscitators, the SAVe II+ does not require compressed air to operate, however it will accept low-pressure supplemental oxygen when a higher FIO_2 is needed. If in a combat zone, relying on high-pressure oxygen tanks poses a fire and explosion hazard. These tanks tend to be large and only ventilate for a brief period. If supplemental oxygen is available and desired, refer to the instructions on page 26.

The operator administering care must monitor the patient to ensure adequate gas exchange is occurring. The SAVe II+ is designed with multiple system checks to monitor proper operation of the device and safety of the patient. If an alarm condition occurs, the SAVe II+ will emit both a visual and audible alarm. In addition, depending on what triggered the alarm, the SAVe II+ will limit functionality as necessary to avoid patient injury. For example, the device will trigger an alarm and cutoff power to the pump when the delivery of additional air exceeds the PEAK INSPIRATORY PRESSURE (PIP) limit. This safety feature is designed to prevent over inflation and alerts the medic to fix the fault that triggered the alarm. An alarm troubleshooting label is attached to the bottom of the device.

The SAVe II+ has adjustable tidal volume (200-800 ml), respiratory rate (8-30 BPM), peak inspiratory pressure limit (10-60 cmH2O) and positive end expiratory pressure (0-20 cmH2O). However, the I:E ratio is fixed at 1:2 and it does not have an intermittent mandatory ventilation mode. The max flow rate is 40 LPM and the max minute ventilation is 12.5 LPM. The device is not intended to be used on patients less than 45 kg.

SAVe II+ Ventilator

The AutoMedx SAVe II+ ventilator is a small, extremely durable, portable mechanical ventilator designed to provide lifesaving mechanical ventilation in prehospital, aeromedical, field hospital and hospital settings. The SAVe II+ is not a full featured ICU ventilator, however, it can play a significant role in extending a hospital's surge capabilities during a pandemic or mass casualty situation.

Figure 1: Device Overview

VISUAL INDICATORS

Green LED indicators communicate the current normal operating status of the device. Green numerical parameter displays communicate device parameter settings and measured pressures. Like blinking indicators, blinking parameter displays are intended to signal that operator action is needed to confirm a setting. If the CONFIRM button (see above) is pressed when all the parameter displays are solid, then measured pressures (PIP & PEEP) will be displayed for 3 seconds. The CONFIRM button also blinks for LOW PEEP ALARM and must be pressed to acknowledge the alarm.

Red alarm codes and the audible alarm indicator signal an alarm condition. Solid indicators communicate the current device settings or past alarm conditions. Blinking indicators are intended to signal that operator intervention is needed due to a control change requiring confirmation or an active alarm condition.

FRONT PANEL

For rapid setup and troubleshooting device controls, indicators and displays are located on the front panel of the device and are organized based on task.

The device is controlled using membrane buttons. Except for POWER ON/OFF, MUTE and MANUAL TRIGGER, control changes require confirmation to prevent inadvertent changes to device settings. Parameter adjustments require operators to select (press) the appropriate HEIGHT PRESET or the +/- parameter control buttons until the desired setting is reached then press CONFIRM. The parameter display will blink with the prospective setting for 10 seconds or until the CONFIRM button is pressed. If not confirmed, the device will revert to the current device setting and the numerical parameter displays will turn solid.

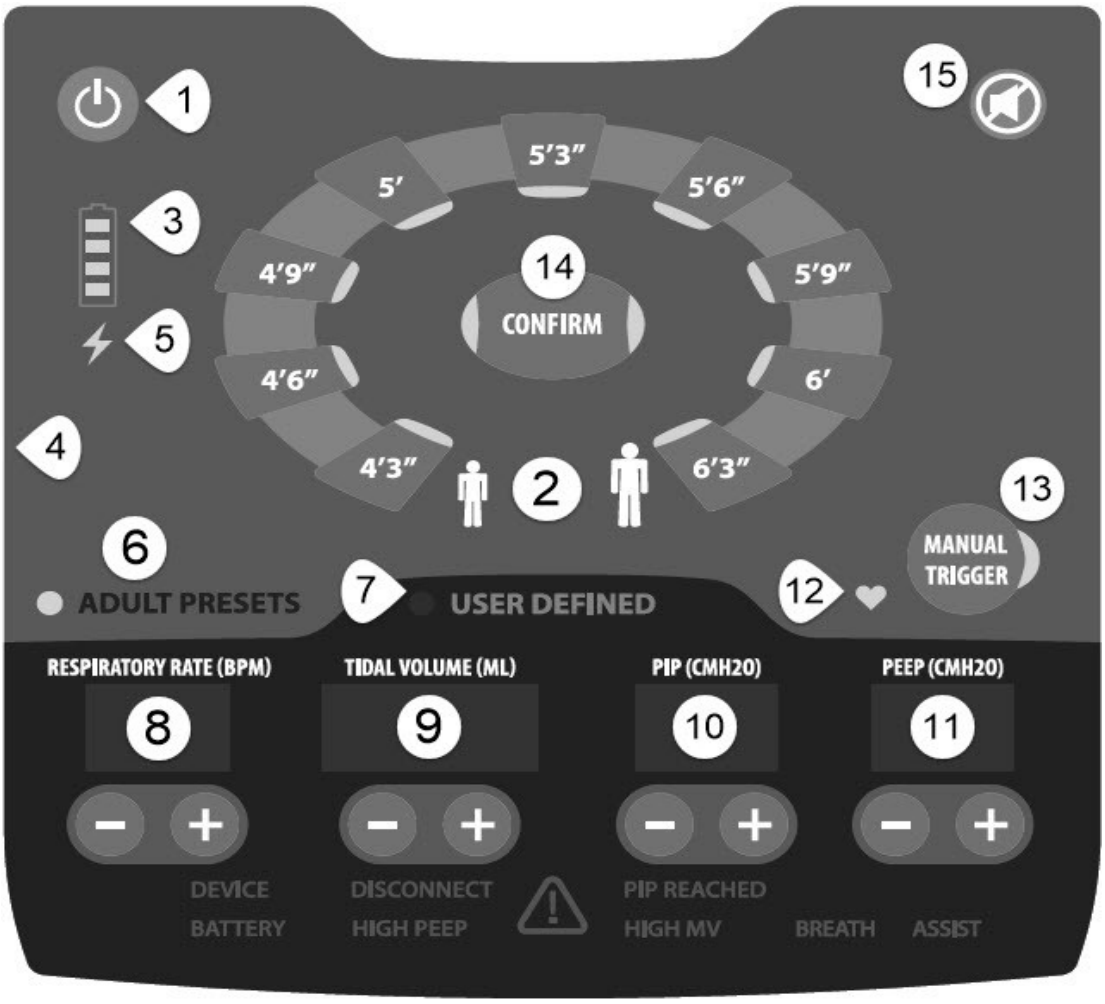


Figure 2: Front Panel

Table 1: User Interface Overview

REF	Name	Description
1	POWER ON/OFF	Control used to turn device On and Off. Press for 1 second to turn it on. Hold for 3 seconds to turn it off. The high priority audible alarm indicator will activate 1 second prior to shut down.
2	ADULT HEIGHT PRESETS	Control and indicator used to set default ventilator parameters based on patient height and monitor current setting.
3	BATTERY LIFE	Indicates remaining battery life.
4	AUDIBLE ALARM INDICATOR	Indicates an active alarm condition.
5	EXTERNAL POWER	Indicates external power is connected.
6	ADULT HEIGHT PRESETS	Indicates device set using preset patient height parameters.
7	USER DEFINED	Indicates device set to user defined parameters.
8	RESPIRATORY RATE	Control and display used to set the RESPIRATORY RATE (RR) and monitor the set number of breaths delivered each minute
9	TIDAL VOLUME	Control and display used to set the TIDAL VOLUME (TV) and monitor the set volume in milliliters of gas delivered each breath.
10	PIP	Control and display used to set the PEAK INSPIRATORY PRESSURE (PIP) limit (pressure cutoff). Once the setting is confirmed the display stays fixed, however, the device measures the peak pressure breath to breath. To see the last measured PEAK INSPIRATORY PRESSURE at the Patient Connection Port press the CONFIRM button.
11	PEEP	Control and display used to set the POSITIVE END-EXPIRATORY PRESSURE (PEEP) and display the <u>set</u> PEEP of each breath. By pressing the CONFIRM button during normal operation, the device will display the <u>measured</u> PEEP maintained in the breathing circuit at the end of exhalation.
12	COMPRESSION RATE	Indicator blinks at a rate of 100/minute to aid users performing chest compressions when the device is in MANUAL / CPR mode (RR set to zero [0]).
13	MANUAL TRIGGER	Control used to deliver a breath at the set tidal volume.
14	CONFIRM	Control and indicator used to prevent unintended changes. Blinking indicates the ventilator parameter settings must be confirmed to become active. When all parameter settings are confirmed (solid) and no changes are pending, pressing the CONFIRM button will cause the most recent measured PIP and PEEP values to be displayed in the PIP and PEEP parameter displays for 3 seconds.
15	MUTE	Silences an active audible alarm for 120 seconds. The new alarm will override MUTE. If an alarm condition is still present after 120 seconds, the audible alarm will resume.

ALARM DASHBOARD

The alarm dashboard identifies alarm conditions.

Figure 3: Alarm Dashboard

WARNING:
DO NOT BLOCK VIEW OF THE ALARM DASHBOARD. The operator must always have a clear view of the alarm dashboard when the device is connected to the patient, especially in noisy environments where caregiver may not hear alarms.

ALARM	DESCRIPTION
DEVICE	The device is outside its temperature range or a software, mechanical or electrical issue has been detected.
DISCONNECT	The minimum pressure threshold has not been reached during an inhalation. Most likely caused by a disconnection of the Breathing Circuit tubing or patient airway.
PIP REACHED	The set Peak Inspiratory Pressure Limit has been reached. Possible causes include blockage of Breathing Circuit or airway, low lung compliance (stiff lungs), excessive tidal volume, and tension pneumothorax.
BATTERY	Low battery alarm. Audible priority escalates as low battery thresholds reached.
HIGH PEEP	The measured PEEP is 5 cmH2O above set PEEP. Most likely causes are blockage of the exhalation port or the patient actively exhaling during the exhalation phase.
LOW PEEP	The measured PEEP is 5 cmH2O below set PEEP.
HIGH MV	The combination of TV/RR requires a flow rate that exceeds the pump's ability to deliver at an I:E ratio of 1:2. The device will not permit operator to select these TV/RR combinations.
BREATH	More than 30 seconds have passed since the last manually triggered breath. Only active in MASK CPR MODE (RR set to zero).
BREATH ASSIST	Indicates a patient inspiratory effort has been detected and a patient triggered breath has been delivered.

BACK PANEL

The SAVe II+ back panel has two labels. These labels are intended as a reference to users who have read this manual and the Quick Start Guide. The Basic Setup label lists the steps to setup the device and includes a table that lists the tidal volumes for males and females based on height. The Quick Alarm Troubleshooting label lists the most common conditions associated with each alarm.

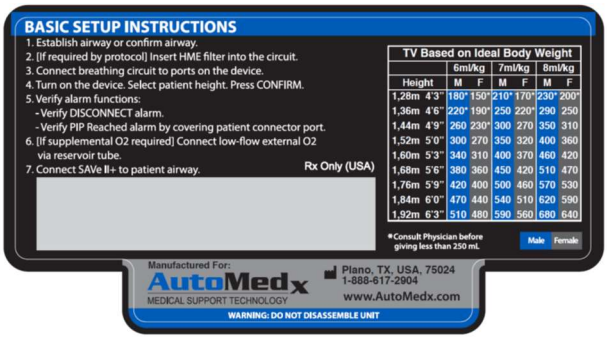


Figure 4: Basic Setup

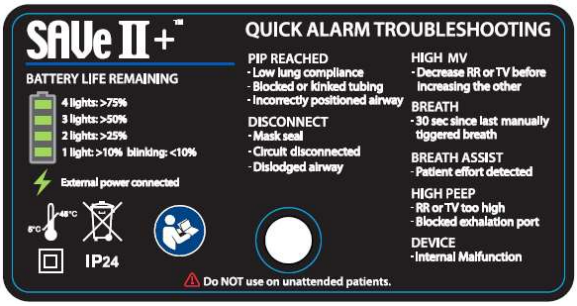


Figure 5: Quick Troubleshooting

PORT AND DC JACK

The SAVe II+ has a label over the ports and next to the DC Jack. These labels are intended as a reference to users who have read this manual and the Quick Start Guide.

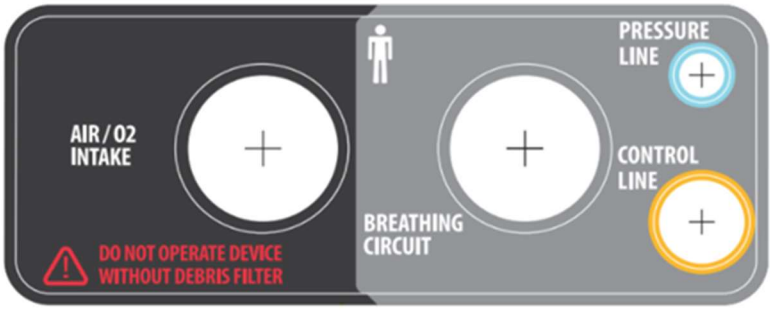


Figure 6: Port Label (Inside Port Cover)

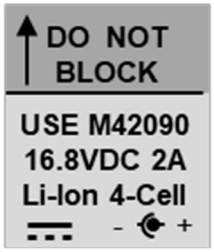


Figure 7: DC Jack Label

Device Accessories & Accompanying Documents

The SAVe II+ is kitted with the following accessories and single-use items.

Part Name:	Qty per Kit	Description
Breathing Circuit (PN: M40105)	1 EA 	Channels air to and from the patient's airway. Actuates the external control valve and monitors pressure.
Extendable O_2 Reservoir Tube (PN: F20072)	1 EA	Connects to air intake port and flow regulated oxygen source. Enables delivery of up to 100% FIO_2 using flow rates up to 12.5 LPM.
Noise Attenuator (PN: M41112)	1 EA	Mitigates device noise when the oxygen reservoir or air intake cap is not in use. Fits over intake port.
Debris Filter - Air intake (PN: F20053)	2 EA (Installed)	Spongey material inside intake port that protects pump manifold from dust, dirt, and other particles.
Intake Cap - Air Intake (PN: F20059)	1 EA (Installed)	Black cap that protects the debris filter and intake port from direct exposure to particles and water.
AC Power Supply (PN: M42090)	1 EA	Supplies the device and battery with external power.
Mains Power Cord with Ferrite Bead	1 EA	Type A (PN: M41125), C (PN: M41126), and/or G (PN: M41127) based on customer location.
Hard Carrying Case (PN: F20065)	1 EA	Water and dust proof case that protects the system during transport and storage.
Quick Setup Guide, SAVe II+ (PN: M42148)	1 EA	Aids the operator's initial setup by outlining basic setup instructions and use of the device.
Operator's Manual, SAVe II+ (PN: M42110)	1 EA	Instructions for use, storage, and maintenance.

WARNING:

ONLY USE AUTHORIZED ACCESSORIES. Do not add any attachments or accessories to the ventilator breathing system that are not listed as intended for use in combination with this ventilator, as the ventilator might not function correctly leading to the risk of patient death or additional serious deterioration of health. For information on device accessories refer to www.automedx.com

PATIENT BREATHING CIRCUIT

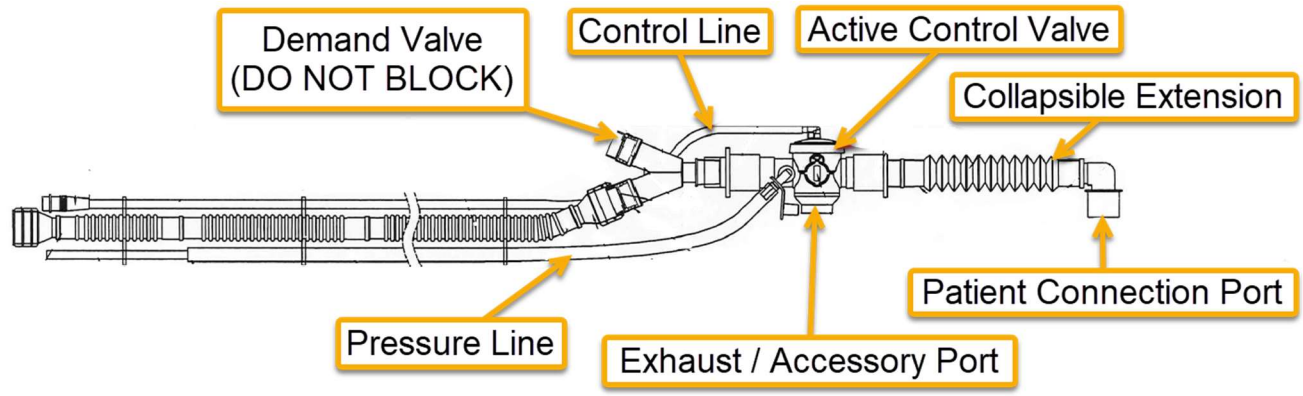


Figure 8: Patient Breathing Circuit Diagram

OXYGEN RESERVOIR TUBE

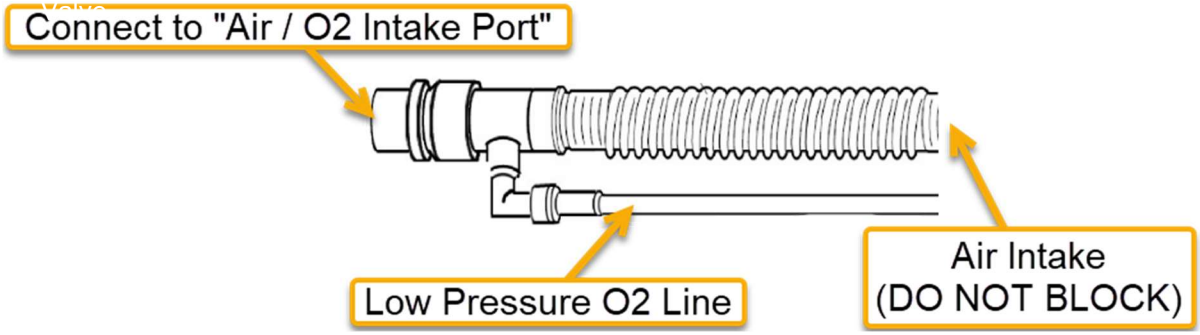


Figure 9: Oxygen Reservoir Tube

AC POWER SUPPLY / BATTERY CHARGER

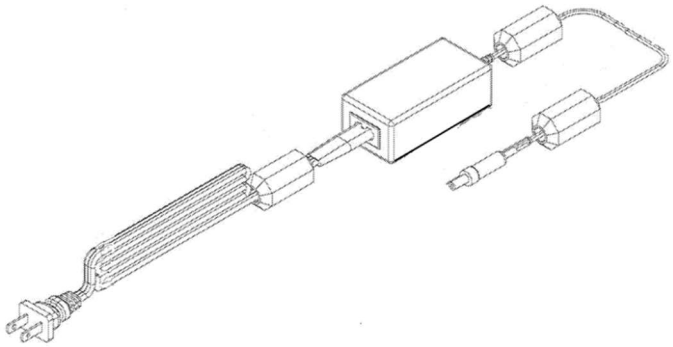


Figure 10: AC Power Supply / Battery Charger

HARD CARRYING CASE

Figure 11: Hard Carrying Case

Prepare for Use

To prepare the SAVe II+ for deployment the operator must:

1) Unpack device
2) Verify required contents are packaged in kit
3) Verify Patient Circuit
4) Verify Debris Filter Installation
5) Verify battery has adequate charge and charge as necessary

STEP 1: UNPACK DEVICE

Carefully remove the ventilator and all accessories from the transport container. Confirm you have received all items listed on the packing slip. Unless otherwise indicated, the SAVe II+ and its accessories are provided clean, not sterile. It is best to keep all accessories packaged until needed.

STEP 2: VERIFY KIT INCLUDES THE FOLLOW REQUIRED CONTENTS:

1) SAVe II+, (PN: M50016)
2) Breathing Circuit, (PN: M40105 or F20066)
3) AC Power Supply, (PN: M42090) and Mains Power Cord (Types A/C/G)
4) Extendable O_2 Reservoir Tubing, (PN: F20072 or M40092)
5) Operator's Manual, (PN: M42110)

STEP 3: VERIFY PATIENT CIRCUIT

Prior to use, verify the Breathing Circuit (PN: M40105 or F20066) is new and packaged with original labeling. Confirm there are no visible signs of damage. Verify shelf life has not expired.

STEP 4: VERIFY DEBRIS FILTER INSTALLATION

The Debris Filter (P/N: F20053) is intended to protect the patient and the internal components of the SAVe II+ system from dust, dirt, and other particles. If used in extremely dusty or dirty environments two debris filters must always be placed inside the Air/ O_2 intake port of the SAVe II+.

Replace the debris filter after each use if there is any risk of contamination. Inspect the debris filter prior to each patient use and replace if there is any sign of exposure to moisture, dust, sand, or other debris.

The Air Intake Cap (PN: F20059) protects the debris filter from direct exposure to particles and water when the O_2 reservoir is not in use. The Intake Cap will not obstruct airflow to the patient. The notches on the intake port permit sufficient air to be drawn into the pump.

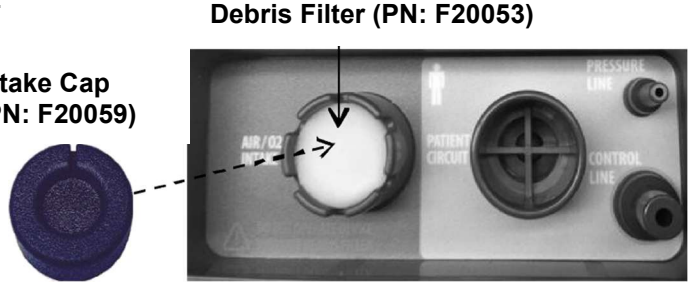


Figure 12: Air Intake Port & Debris Filters

WARNING:

- **DELIVERED TIDAL VOLUME MAY DECREASE SIGNIFICANTLY WITHOUT ALARMING IF FINE PARTICULATES (SAND) ENTERS THE DEVICE MANIFOLD.**
- **NEVER USE A WET OR MOIST DEBRIS FILTER.** The debris filter is not designed to filter chemical or biological agents and will not protect the patient from contaminated environments.
- **NEVER OPERATE THE UNIT WITHOUT A DEBRIS FILTER IN PLACE.** Immediately take the device out of service if dust, sand, or other debris have entered the internal SAVe II+ system.
- **ONLY USE DEBRIS FILTERS DESIGNED FOR THE SAVE II+.** Using other debris filters may impact device performance by either allowing fine particulates into the device manifold or increasing resistance at the air intake port of the ventilator.

STEP 5: CHARGE BATTERY

The battery is recharged by connecting the SAVe II+ to external power (100 – 240 VAC, 50 – 60 Hz) via the AC POWER SUPPLY (PN: M42090). The SAVe II+ will simultaneously run and charge the internal lithium-ion battery. It takes a little over 1 hour to fully charge the SAVe II+. The required time to fully charge increases by 15 – 40% if the device is recharged while ventilating.

Table 2: Battery Capacity

Illuminated LEDs	Usable Battery Capacity
4 LEDs	> 75%
3 LEDs	> 50%
2 LEDs	> 25%
1 LED	> 10%
1 LED (Blinking)	< 10%

TO CHARGE THE BATTERY:

1) Connect AC Power Supply to appropriate power source (See power input specifications) and the power input port of the SAVe II+

2) Verify charge indicator light (lightning bolt icon) is illuminated

3) Monitor charge status using the Battery Level Indicator

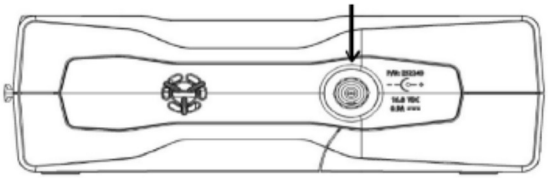


Figure 13: Power Input Port

Setup for Use

The SAVe II+ creates positive pressure by creating a seal between the Ventilator Breathing System and the patient airway. Establish the appropriate airway based on your facilities established protocols.

1) Establish and confirm airway
2) [Optional] Install Heat and Moisture Exchanger (HME) filter into breathing circuit
3) Connect patient breathing circuit to ventilator
4) Turn on. Select adult patient height. Hit Confirm
5) Verify Disconnect alarm
6) Verify PIP Reached alarm
7) Connect breathing circuit to airway

STEP 1: ESTABLISH AND CONFIRM AIRWAY

Follow established protocols to establish and confirm airway placement and seal.

STEP 2: [OPTIONAL] INSTALL HMEF INTO BREATHING CIRCUIT

A heat and moisture exchanger filter (HMEF) may be added to the SAVe II+ patient circuit between the active control valve and the patient connection port. The HMEF provides heat and moisture to the inspired gas by recycling the heat and moisture contained in the patient's exhaled gas and acts as a bacterial and viral filter. Be sure to follow all instructions provided by the manufacturer. Only HMEFs that have been approved by AutoMedx should be used.

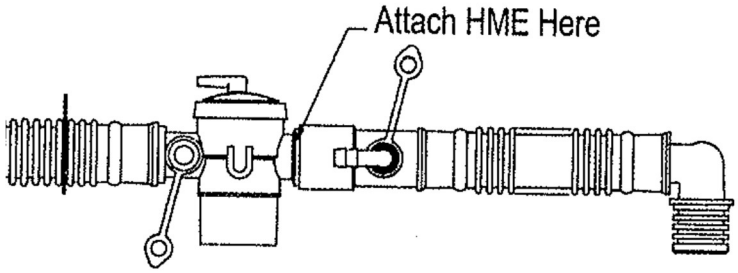


Figure 14: Breathing Circuit with HMEF

WARNING:

Inserting an HME or HMEF will increase the resistance and dead space of the Patient Circuit. Only use HMEs and HMEFs approved by AutoMedx. Nebulizers can increase the resistance of the HME / HMEF.

STEP 3: CONNECT PATIENT BREATHING CIRCUIT

Locate an unused SAVe II+ Patient Breathing Circuit in its original packaging. Remove patient circuit from packaging and connect to the appropriate SAVe II+ Manifold Port.

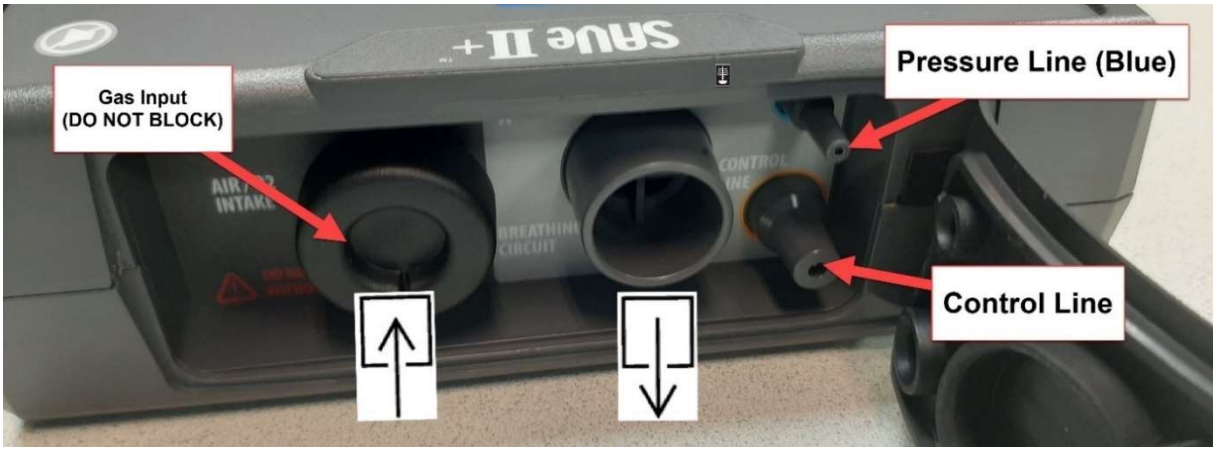


Figure 15: Air/ O_2 Intake Port and Breathing Circuit Connection Ports

Figure 16: Breathing Circuit Connected

STEP 4: TURN ON. SELECT PATIENT HEIGHT. PRESS CONFIRM.

The Adult Height Presets default to 6 ml/kg of ideal body weight for a male. There is a look up chart in the Quick Start Guide and on the bottom of the device that lists the tidal volume for male and females which can be used to make adjustments. At 6 ml/kg of ideal body weight females receive 30 ml less volume than males of the same height. Do not forget to add PEEP if it is indicated.

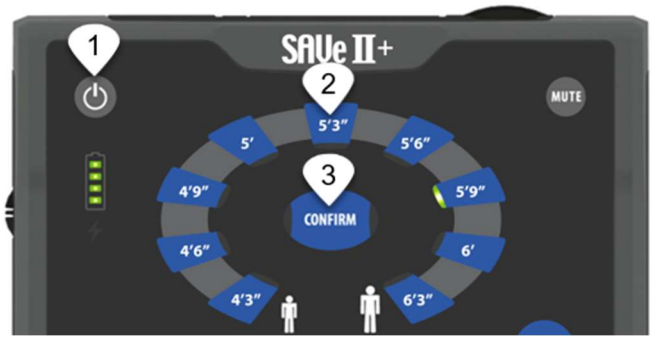


Figure 17: Setup Using Adult Height Presets

Table 3: Adult Height Preset Values

Height	Rate (BPM)	Tidal volume (ml)	Minute Ventilation (LPM)	PIP Limit (cmH2O)	PEEP (cmH2O)
4’ 3” (129 cm)	20	250	5.0	30	0
4’ 6” (137 cm)	21	250	5.3	30	0
4’ 9” (145 cm)	21	260	5.5	30	0
5’ 0” (152 cm)	20	300	6.0	30	0
5’ 3” (160 cm)	18	340	6.1	30	0
5’ 6” (168 cm)	16	380	6.1	30	0
5’ 9” (175 cm)	15	420	6.3	30	0
6’ 0” (183 cm)	14	470	6.6	30	0
6’ 3” (191 cm)	13	510	6.6	30	0

STEP 5: VERIFY DISCONNECT ALARM

PROCEDURE	PASS CRITERIA
Simulate a disconnect by leaving circuit disconnected from Patient’s airway	- DISCONNECT visual alarm indicator begins blinking within 2 breaths - Audible alarm indicator can be clearly heard - Pump continues to operate normally (cycle)

STEP 6: VERIFY PIP REACHED ALARM

PROCEDURE	PASS CRITERIA
Completely block patient connection port with your hand	- PIP REACHED visual alarm indicator begins blinking within 1 breath - Pump turns off for a few seconds and then turns on briefly again until PIP limit is reached again

WARNING:

Always verify the Disconnect and PIP Reach patient alarms prior to connecting the SAVe II+ to the patient and following any change to device’s configuration such as by adding or removing an accessory to the Ventilator Breathing System.

DO NOT USE if the device fails the checkout.

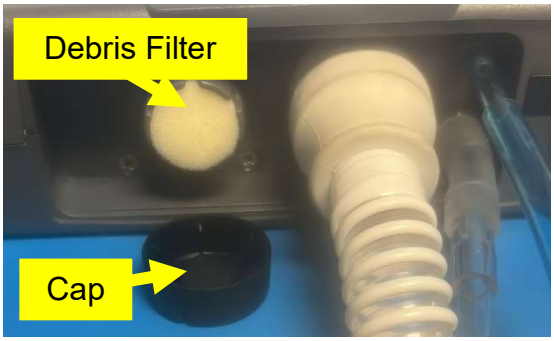
Step 7: Connect Breathing Circuit to Airway

Connect SAVe II+ breathing circuit to the patient airway. This should cause the audio disconnect alarm to stop and for the DISCONNECT visual alarm to stop blinking and stay lit for 30 seconds. The PIP Reached visual alarm should also stop blinking and stay lit for 30 seconds.

Verify air is being delivered to patient by adequate chest rise.

SUPPLEMENTAL OXYGEN

If medically indicated, connect supplemental oxygen. To titrate supplemental oxygen to the patient, remove the black Intake Cap covering the Air/O_2 Intake. See figures 12 and 14. Leave the debris filters in place. Fully expand the reusable Oxygen Reservoir tube and connect as pictured. Actual O_2 reservoir may have clear connector instead of the green cuff. Connect the low pressure O_2 line to flow regulated oxygen source.



Remove and store the black cap, leave the debris filters in place.

Connect the expandable O2 reservoir tube to the AIR/ O2 intake port.

Connect Oxygen tubing to Oxygen flow source

Figure 18: Supplemental Oxygen Connection

To set the desired FIO_2, calculate the minute ventilation by multiplying the set tidal volume by the respiratory rate and find the column below that reflects the liters per minute being delivered (See A). Slide down the column to the desired FIO_2 (See B) and slide to the far right to see the corresponding setting for the O_2 flow rate. You can achieve 100% FIO_2 by matching the oxygen supply flow rate delivered to the minute ventilation. For example, to achieve 100% FIO_2 when the patient is receiving a minute ventilation of 7 LPM set the flow regulator to 7 LPM. The O_2 will accumulate in the reservoir during the exhale and be delivered to the patient during the next breath.

A → Calculated Minute Ventilation

Desired FIO2 (%)	2 LPM	3 LPM	4 LPM	5 LPM	6 LPM	7 LPM	8 LPM	9 LPM	10 LPM	11 LPM	12 LPM	Set O2 flow rate (L/min) to:
60%	50%	40%	40%	35%	30%	30%	30%	30%	30%	30%	1	
100%	75%	60%	55%	50%	45%	40%	40%	40%	35%	35%	2	
	100%	80%	70%	60%	55%	50%	50%	45%	45%	40%	3	
		100%	85%	75%	65%	60%	55%	55%	50%	50%	4	
			100%	90%	80%	70%	65%	60%	60%	55%	5	
				100%	90%	80%	75%	70%	65%	60%	6	
					100%	90%	80%	75%	70%	70%	7	
						100%	90%	85%	80%	75%	8	
							100%	90%	85%	80%	9	
								100%	95%	90%	10	
									100%	95%	11	
										100%	12	

B → Desired FIO2 (%)

C → Set O2 flow rate (L/min) to:

Figure 19: FIO_2 by O_2 Flow Rate and Minute Volume

NOTE:

1) FIO_2 values assume the O_2 tank or concentrator is delivering 100% oxygen.
2) Setting the oxygen source flow rate higher than the minute ventilation of the ventilator will unnecessarily deplete oxygen supply faster.
3) Specified FIO_2 values require a fully expanded oxygen reservoir tube. Failing to fully extend the tube may materially decrease FIO_2 values for a given O_2 flow rate.
4) Many variables impact delivered FIO_2 values. If the concentration of delivered oxygen is critical, then it should be measured with a calibrated oxygen analyzer that features a minimum and maximum concentration alarm.
5) As altitude increases, the fractional concentration of oxygen in ambient air decreases. It may be necessary to increase oxygen flow rates to compensate.

WARNING:

- If using supplemental oxygen, avoid smoking or open flames. Leaks at oxygen connections can cause dangerous O_2 levels in the vicinity of the leak. To avoid the risk of ignition, visually inspect oxygen connections before and after connecting supplemental O_2 and take measures to properly ventilate the area.

- 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.

- Do not block the air intake port of the O_2 reservoir tube.

- Place the end of oxygen reservoir tube in a location that will prevent sand or dust from entering. The oxygen supply must be shut off when ventilation is interrupted.

- The line connecting the ventilator to the oxygen source must be designed exclusively for use with medical-grade oxygen. Under no circumstances should the user modify the low pressure O_2 line. In addition, the line must be attached without the use of lubricants.

- Take required precautions when using oxygen. Do not use in an explosive atmosphere or near an open flame.

- It is the responsibility of the responsible organization to ensure that the oxygen source is compatible with the rated range of pressure, flowrate and oxygen concentration as marked on the ventilator 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.

- The ventilator does not monitor the oxygen source. Ensure that there is an adequate and working source for the volume of oxygen that is needed.

- Equip the ventilator with O2 monitoring equipment (in compliance with IEC 80601-2-55:2018) for the measurement of the inspiratory oxygen concentration (at the patient connection port).

NOISE ATTENUATOR

If you are not using supplemental oxygen, consider attaching the noise attenuator to the device to mitigate the sound. The reusable ATTENUATOR (P/N: M41112) is a U-shaped tube designed to mitigate the noise of the device. The attenuator is connected to the air intake port as shown in Figure 20. The attenuator is meant to be U-shaped. Do not cut the fastener that holds the shape.

To keep the SAVe II+ small the attenuator has been developed as an external reusable accessory rather than an internal component. It is not required for operation but can be used to significantly dampen the noise. Remove the black air intake cap and connect the female end of the attenuator over the air intake port, which contains the debris filter (do not remove the debris filter) and position the nipple to sit inside the port well so that it is not easily occluded. If the nipple becomes occluded, air will not be delivered to the patient and a disconnect alarm will trigger. If the attenuator is exposed to sand or dust wash it with water between uses. Make sure it is dry before reusing. In a dust or sandstorm, the black air intake port cap will do a better job than an attenuator at guarding against particulates getting into the pump.

Attach the attenuator by:

1) Remove the black Intake Cap from air intake port. See Figure 12.
2) Attach the attenuator to air intake port. Leave the debris filter in place.
3) To avoid blocking the nipple at the end of the attenuator, orient the end so that it faces into the port well.

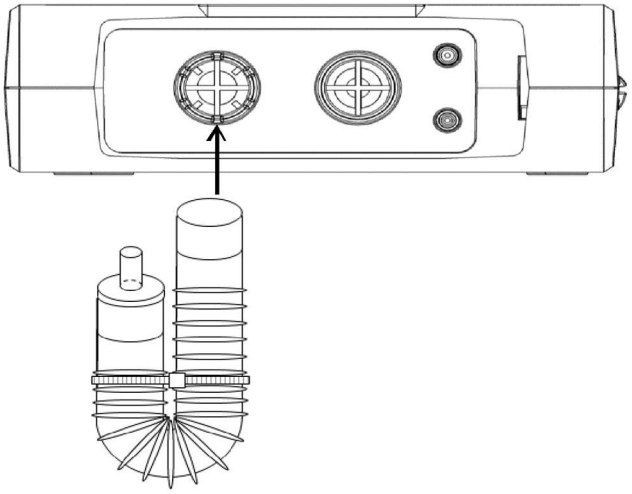


Figure 20: Attenuator Attachment

WARNING:

- Do not occlude small nipple as this will dramatically decrease tidal volume.
- Leave the debris filter in place. You can see picture of debris filter in Figure 18: Supplemental Oxygen Connection.
- In particularly sandy or dusty conditions use the air intake port cap instead of the attenuator.

Refining Ventilator Parameters

Once the SAVe II+ is setup and running refine the parameters as necessary based on ventilation protocols of your facility.

Table 4: Ventilator Settings

PARAMETER	RANGE	INCREMENTS
RESPIRATORY RATE (RR)	0, 8 - 30	1 breath / min
TIDAL VOLUME (TV)	200 - 800	10 ml
PEAK INSPIRATORY PRESSURE (PIP) LIMIT	10 - 60	5 cmH_2O
POSITIVE END EXPIRATORY PRESSURE (PEEP)	0 – 20	1 cmH_20

RESPIRATORY RATE (RR)

The RESPIRATORY RATE controls the number of breaths delivered to the patient in a minute. When the RR is set to 0 and confirmed, this will place the SAVe II+ into MANUAL / CPR Mode. While in this mode, the operator is in full control of when a breath is delivered to the patient. The operator controls the respiratory rate by pressing the MANUAL TRIGGER button. The heart indicator will blink 100 times / min to guide the compression rate.

WARNING:

- If the RESPIRATORY RATE is set to zero, the patient will only receive a breath when the operator provides one. The breath assist function (see breath assist section) is disabled when in MANUAL/CPR Mode to prevent false triggering caused by chest compressions.

TIDAL VOLUME (TV)

The TIDAL VOLUME controls the volume of air delivered to the patient with each breath. To maintain a desired Minute Ventilation (TV x RR), the TV may be decreased (to avoid reaching the PIP Limit) and the RR may be increased.

NOTE: The SAVe II+ delivers the stated tidal volume at ambient air temperature and pressure (ATP). Most ICU ventilators calculate volume and flow taking into consideration that the air will expand or contract based on the difference between ambient temperature, humidity, and pressure from that of the body (BTPS). For example, if the ambient air is 20C, 50% relative humidity and at sea level at standard pressure the air will expand 11.5%. The cooler the ambient air, the higher the altitude (lower the pressure) and lower the humidity the more the air expands inside the patient's lungs. As a rule of thumb, the ambient volume in an air-conditioned hospital will expand by 8-12% inside the patient's lungs. Please consult with your medical director to decide whether to adjust the SAVe II+ tidal volume accordingly.

WARNING:

- If the PIP limit is reached, the SAVe II+ will stop the inspiratory phase and less TV than indicated will be delivered to the patient. Consider increasing respiratory rate and decreasing tidal volume.

RR & TV COMBINATIONS

The SAVe II+ supports minute ventilation up to 12.5 LPM at a fixed I:E ratio of 1:2. The cells marked “not allowable combinations” are TV and RR combinations that exceed the pump’s minute ventilation capabilities and therefore are not permitted. If an operator wanted to change the settings from 600 ml at 20 BPM to 400 ml at 30 BPM (both of which are permitted) the user would first decrease the TIDAL VOLUME to 400 ml before increasing the RESPIRATORY RATE to 30 BPM. Trying to increase the RESPIRATORY RATE first is not possible because the device does not support 30 BPM RESPIRATORY RATE at a 600 ml TIDAL VOLUME.

A visual (no audible) MV HIGH alarm indicator will activate if the operator selects a RR/TV combination that results in minute ventilation >12.5 LPM. If +/- controls appear to not work, it is likely that the operator has attempted to select a RR/TV combination that is not supported. AutoMedx recommends that the operators experiment with this during training so that it does not come as a surprise during actual use.

Table 5: Supported TV & RR Combinations and Resulting LPM of Minute Ventilation

Respiratory Rate BPM	Tidal Volume (TV) in milliliters (mL)												
	200	250	300	350	400	450	500	550	600	650	700	750	800
8	1.6	2.0	2.4	2.8	3.2	3.6	4.0	4.4	4.8	5.2	5.6	6.0	6.4
9	1.8	2.3	2.7	3.2	3.6	4.1	4.5	5.0	5.4	5.9	6.3	6.8	7.2
10	2.0	2.5	3.0	3.5	4.0	4.5	5.0	5.5	6.0	6.5	7.0	7.5	8.0
11	2.2	2.8	3.3	3.9	4.4	5.0	5.5	6.1	6.6	7.2	7.7	8.3	8.8
12	2.4	3.0	3.6	4.2	4.8	5.4	6.0	6.6	7.2	7.8	8.4	9.0	9.6
13	2.6	3.3	3.9	4.6	5.2	5.9	6.5	7.2	7.8	8.5	9.1	9.8	10.4
14	2.8	3.5	4.2	4.9	5.6	6.3	7.0	7.7	8.4	9.1	9.8	10.5	11.2
15	3.0	3.8	4.5	5.3	6.0	6.8	7.5	8.3	9.0	9.8	10.5	11.3	12.0
16	3.2	4.0	4.8	5.6	6.4	7.2	8.0	8.8	9.6	10.4	11.2	12.0	
17	3.4	4.3	5.1	6.0	6.8	7.7	8.5	9.4	10.2	11.1	11.9		
18	3.6	4.5	5.4	6.3	7.2	8.1	9.0	9.9	10.8	11.7			
19	3.8	4.8	5.7	6.7	7.6	8.6	9.5	10.5	11.4	12.4			
20	4.0	5.0	6.0	7.0	8.0	9.0	10.0	11.0	12.0				
21	4.2	5.3	6.3	7.4	8.4	9.5	10.5	11.6					
22	4.4	5.5	6.6	7.7	8.8	9.9	11.0	12.1					
23	4.6	5.8	6.9	8.1	9.2	10.4	11.5						
24	4.8	6.0	7.2	8.4	9.6	10.8	12.0						
25	5.0	6.3	7.5	8.8	10.0	11.3							
26	5.2	6.5	7.8	9.1	10.4	11.7							
27	5.4	6.8	8.1	9.5	10.8	12.2							
28	5.6	7.0	8.4	9.8	11.2								
29	5.8	7.3	8.7	10.2	11.6								
30	6.0	7.5	9.0	10.5	12.0								

Unsupported RR / TV Combinations

Minute Ventilation LPM

Table 6: MaxIMUM Tidal Volume supported for each respiratory rate

BPM	Max TV	LPM	BPM	Max TV	LPM
0-15	800	12.0	23	530	12.2
16	780	12.5	24	510	12.2
17	730	12.4	25	490	12.3
18	690	12.4	26	470	12.2
19	650	12.4	27	450	12.2
20	620	12.4	28	430	12.0
21	590	12.4	29	420	12.2
22	560	12.3	30	400	12.0

PEAK INSPIRATORY PRESSURE (PIP)

The PIP limit controls the maximum pressure during the inspiratory phase before the pump shuts off and the PIP REACHED alarm activates. When the PIP limit is reached, the pump will stop to prevent over inflation and the unit will enter the exhalation phase. An audible and visual alarm indicator will activate. All the Adult Height Presets default to a PIP limit of 30 cmH_2O. The PIP limit is automatically set to 20 cmH_2O when RR is set to zero (MANUAL / CPR Mode). This is to help prevent insufflating the stomach during CPR.

WARNING:

- If the PIP limit is reached, the SAVe II+ will stop the inspiratory phase short and less TV than indicated will be delivered to the patient.
- Before increasing the PIP Limit, consider increasing respiratory rate and decreasing tidal volume.
- Do not increase the preset PIP limit unless directed to do so by personnel with the required level of training.

POSITIVE END EXPIRATORY PRESSURE (PEEP)

The SAVe II+ has the internal capability to maintain a set positive end expiratory pressure (PEEP). The SAVe II+ is designed to safely reach targeted PEEP value by slowly incrementing PEEP with each breath until it reaches the selected PEEP value. This typically takes 22 to 24 breaths.

WARNING:

- PEEP is contraindicated during CPR

DISPLAYING MEASURED PIP AND PEEP

To view the measured Peak Inspiratory Pressure (PIP) or measured Peak End Expiratory Pressure “PEEP”, press the Confirm button during normal operation when no changes are pending (i.e. indicators are not blinking).

The most recent measured PIP and PEEP values to be displayed for 3 seconds. During this time, the RR and TV displays are cleared to help indicate that the device is displaying measured values.

The PIP and PEEP measurements are taken at the patient airway at the end of their respective breath phases. The displays show the most recently measured values prior to pressing the CONFIRM button.

It is recommended that you check these measured values every time you check on the patient. Understanding how the pressure is changing over time is an important consideration in managing the patient.

The user may revert the display back to the active ventilator settings prior to the 3 second automatic transition by pressing the CONFIRM button again. The user may also begin to make changes to the ventilator settings without returning to the active settings display; pressing a HEIGHT PRESET or “+” or “-” control button will be handled as normal and will cause the device to show the pending ventilator settings.

The SAVe II+ does not have an inspiratory hold feature so plateau pressure cannot be measured. The peak inspiratory pressure will be slightly higher than the corresponding plateau pressure.

MANUALLY TRIGGERED BREATHS

If a temporary increase in respiratory rate is desired during normal operation, the operator may press the MANUAL TRIGGER Button to deliver the set TIDAL VOLUME. To avoid stacking breaths, the MANUAL TRIGGER button is only active during the expiratory phase of the breath cycle. If the operator wants to only deliver manual breaths set the respiratory rate to zero.

MANUAL / CPR MODE

MANUAL / CPR MODE allows operators performing CPR to give the specified number of compressions and then manually trigger breaths as directed by the American Heart Association (AHA) guidelines. In MANUAL / CPR Mode, the PEEP and BREATH ASSIST are disabled. The PIP limit defaults to 20 cmH_2O to reduce the risk of gastric insufflation (air directed to stomach) and the COMPRESSION RATE INDICATOR (heart icon) and BREATH ALARM become active. To avoid stacking breaths, the button will only trigger a breath after the minimum exhalation time has elapsed.

NOTE:

- This mode is primarily intended to support 30:2 CPR when using a mask.
- **The default PIP Limit is decreased to 20 cmH_2O** for all heights in MANUAL / CPR Mode but is still adjustable. This is intended to avoid air being directed to the stomach (gastric insufflation) during use with a mask or other unprotected airway.
- Heart Icon LED blinks at compression rate of 100 per minute.
- If the MANUAL TRIGGER button is not pressed for 30 seconds “Breath” alarm will trigger indicating a breath needs to be delivered.
- To exit MANUAL / CPR Mode, the user can select and CONFIRM a HEIGHT PRESET or non-zero RESPIRATORY RATE.

ACTION	**EXPECTED DEVICE RESPONSE**
1) Set TIDAL VOLUME	TV indicator blinks
2) Decrease RESPIRATORY RATE to zero (0)	MANUAL TRIGGER and RR indicators blink PEEP disabled (set to zero) PIP defaults to 20 cmH2O
3) Press CONFIRM	TV, RR and MANUAL TRIGGER lights stop blinking. Compression rate light (heart icon) flashes at 100/min
4) Press MANUAL TRIGGER to deliver breath	Single breath delivered at stated settings

Follow AHA Guidelines or protocol as directed by your Medical Director. The device will only deliver breaths when the MANUAL TRIGGER button is pressed.

WARNING:

- Operators must press the MANUAL TRIGGER control button for ventilator to deliver breath.
- Increasing PIP limit to above 20 cmH2O when using an airway other than a properly placed ET tube may result in gastric insufflation.

Special Procedures

HOW TO CHANGE THE HMEF

AutoMedx recommends placing the HMEF between the exhalation control valve and the patient connection port. See Figure 14 on page 23. AutoMedx recommends using the procedure outlined below when the HME filter needs to be changed while the patient requires PEEP. This procedure is intended to limit the amount of PEEP lost by the patient when the HME filter needs to be added, exchanged, or removed.

1) Unwrap the new HME filter.
2) Reduce the RESPIRATORY RATE on the SAVe II+ to 0 and CONFIRM. The heart rate icon will begin to blink.
3) Close off the patient airway using your current protocols.
4) Disconnect the HME filter from the patient circuit (between the control valve and the flex segment that connects to airway).
5) Connect the new HME filter in place slowly. Connecting quickly may trigger a HIGH PEEP alarm. If the HIGH PEEP alarm triggers while connecting the HME:
   a. Disconnect one end of the HME.
   b. Press the MANUAL TRIGGER button on the SAVe II+ (This will trigger a disconnect alarm. Ignore this alarm for the time being).
   c. Reconnect the HME to the breathing circuit less abruptly.
   d. Repeat as needed so that the HIGH PEEP alarm is not flashing - solidly illuminated is permissible.
6) If the HIGH PEEP alarm is not flashing, open the patient airway per your healthcare center protocol.
7) Administer one manual breath to provide immediate respiration.
8) Set the desired RESPIRATORY RATE on the SAVe II+ and CONFIRM, the SAVe II+ should begin administering breaths at the set rate and volume.
9) Verify the patient is being correctly ventilated.

To display the last measured values for the PIP and PEEP press the CONFIRM button when no setting changes are pending.

If the patient airway remains blocked, the "PIP Reached" alarm will indicate when breaths are administered, and the PEEP algorithm will reset. The PEEP will slowly rise from 0 cmH_2O to the set value when normal operation resumes. This happens over 22 to 24 breaths.

If a breath is delivered (manually or automatically) while the HIGH PEEP alarm is active (flashing) the PEEP algorithm may reset, slowly raising the PEEP from 0 cmH_2O to the set value once the disconnect alarm has been cleared.

This procedure could also be used to exchange the entire patient circuit as needed while minimizing the PEEP lost by the patient.

How To Clear Debris or Excess Fluid From Breathing Circuit

The SAVe II+ breathing circuit is for a single patient use. If the patient aspirates during use and the circuit needs to be cleared of debris, follow the steps below.

1) Disconnect circuit from patient airway.
2) Replace the active circuit with a new circuit if one is available. If a new circuit is not available, consider ventilating the patient by other means.
3) If that is not possible, remove the flexible elbow and any other piece of the circuit as necessary to empty contents then reassemble. Make sure there is no debris or fluid in the control or pressure line.
4) Verify if proper operation of the circuit by blocking the patient connection port to see if you get a PIP alarm.
5) Reattach the circuit to the patient's airway. Verify adequate chest rise and monitor the patient closely.
6) Reattach the circuit to the patient's airway. Verify adequate chest rise and monitor the patient closely.

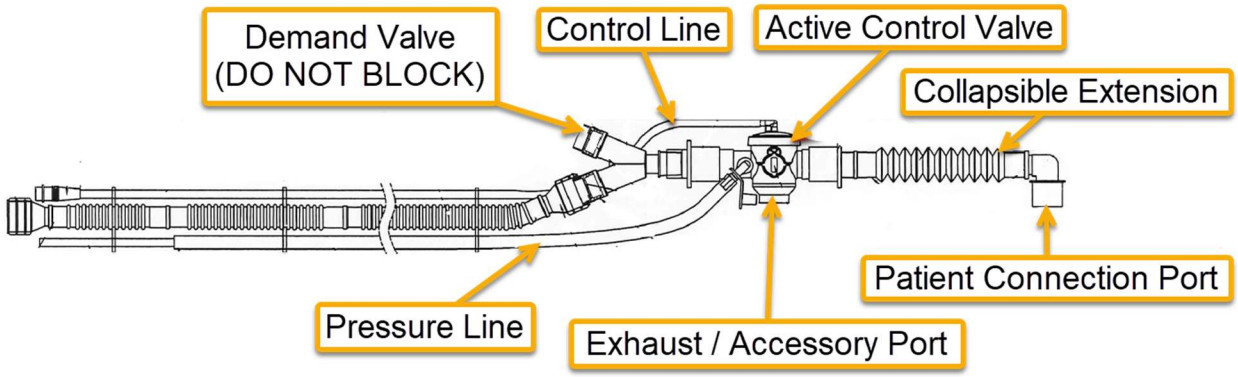


Figure 21: Patient Breathing Circuit

WARNING:

- Operators must verify the breathing circuit has been reassembled correctly.
- If the demand valve is removed or modified, the operator MUST reassemble with the one-way valves oriented in the correct direction.
- Verify the Active Control Valve's cap where the Control Line connects to the valve body is securely attached with the diaphragm properly seated.

Responding to Alarms

ALARM OVERVIEW

The SAVe II+ has alarms to alert the operator to potentially unsafe conditions. These alarms are triggered by monitoring internal device parameters and airway pressures.

The device will continue delivering breaths during most alarms; however, if it detects a condition that may cause direct harm to the patient by delivering another breath, the device will enter a safe mode and stop delivering breaths until the problem is resolved. Once the problem is resolved, the device will resume normal operation.

When an alarm condition occurs:

1) A visual alarm indicator flashes on and off and an audible alarm sound (except the "HIGH MV" Alarm which is strictly a visual alarm and Low PEEP which is an audible alarm).
2) Depending on the alarm, the SAVe II+ may take other actions, such as terminating an inspiration or opening the exhalation valve.
3) Pressing MUTE will silence the audio alarm for 120 seconds.

When an alarm condition clears:

1) The audible alarm ceases.
2) The visual alarm indicator stops flashing and turns solid for 30 seconds after which the indicator turns off.

WARNING:

- FAILURE TO RESPOND TO ALARMS CAN RESULT IN SERIOUS HARM OR DEATH. Alarms must always be monitored, and the operator must be prepared to ventilate with an alternative method of ventilation.
- THE ABSENCE OF AN ALARM DOES NOT INDICATE THE PATIENT IS RECEIVING ADEQUATE VENTILATION. If the SAVe II+ is used for extended periods, the operator must monitor blood gases to ensure adequate gas exchange.

AUDIBLE ALARM INDICATOR

To help operators prioritize multiple simultaneous alarms, the audible alarm indicator of the SAVe II+ is divided into three levels of priority. The easiest way to distinguish between the priorities is how quickly the alarm repeats.

Table 7: Audible Alarm Indicator

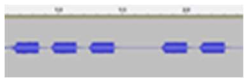
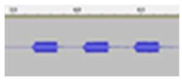
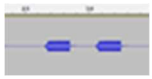
Priority	Audible Description	Alarms Conditions
High	Three closely spaced beeps with a short pause followed by two closely spaced beeps. Repeats every 2.5 seconds. 	- Disconnect - PIP Reached - Device - High PEEP - Breath - Device powering off (no visual component) - Battery < 5% capacity
Medium	Three closely spaced beeps Repeats every 7.5 seconds. 	- Breath Assist - Battery <10% capacity - Low PEEP / Target not achieved
Low	Two closely spaced beeps Repeats every 20 seconds. 	- Battery <15% capacity

Table 8: Alarm Sound Pressure

High Priority	58-65 dB	60.0 dB A-weighted average
Medium Priority	51-61 dB	54.8 dB A-weighted average
Low Priority	44-54 dB	47.4 dB A-weighted average

DISCONNECT ALARM

The DISCONNECT alarm triggers when the minimum pressure threshold has not been reached during the inspiratory phase of the ventilator. The ventilator will continue to cycle and alarm until the condition is resolved.

Triggered when airway pressure is < 1.0 cmH_2O/110 ml of TV at end of inhalation or pressure increase during last 250ms of inhale is < 1cmH_2O/120ml.

Device response:

1) Continue active cycling (i.e. delivery breaths).
2) Activating the “DISCONNECT” visual alarm indicator.
3) Activating the High Priority audible alarm indicator.

WARNING:

- The absence of an alarm does not indicate the patient is receiving adequate ventilation. It is recommended the operator monitor oximetry and blood gases to ensure adequate gas exchange.
- Failure to respond to alarms can result in serious harm or death. Alarms should always be monitored, and the operator should be prepared to ventilate with alternative method.

What to do:

1) Verify all three patient circuit tubes are firmly connected to the ventilator.
2) Verify breathing circuit is firmly attached to airway.
3) Verify all sections of the breathing circuit are firmly connected to one another.
4) Verify placement and seal of airway (Endotracheal tube, mask, etc.).
5) Verify the ventilator’s air intake is not blocked.
6) Verify there is no fluid or debris in the control valve, control line or pressure line.
7) Replace breathing circuit if available.
8) Ventilate by alternative means.

Note: It is possible that an internal problem in the device could trigger a DISCONNECT alarm which the operator may not be able to resolve.

PIP REACHED ALARM

The PIP REACHED alarm activates when the pressure measured at the patient airway exceeds the PIP Limit setting. When this alarm occurs, any inspiration in progress is terminated and the Exhalation Valve is opened to prompt an exhale. Except in MANUAL/CPR MODE, the next breath will begin after the appropriate expiration time has passed. In MANUAL/CPR MODE, the next breath will initiate when the operator presses the MANUAL TRIGGER button. The alarm is resolved when a full breath is delivered without reaching the set PIP Limit.

Device response:

1) Activate “PIP REACHED” visual alarm and high priority audible alarm.
2) End the inhalation cycle and enter the exhalation phase.
3) After exhalation attempts to deliver the next breath cycle.

NOTE: If the next breath is delivered without hitting the PIP limit, then the alarm is resolved.

WARNING:

- SAVe II+ will stop the inspiratory phase and less than the set TV will be delivered to patient if the set PIP Limit is reached.
- Failure to respond to alarms can result in serious harm or death.
- Alarms must always be monitored.
- Operator must be prepared to ventilate with alternative method.

What to do:

1) ***Full Blockage*** - Activation in the first half of inspiratory cycle suggests a full blockage of the gas path. If alarm is activated in the first half of inspiratory phase:
    a. Verify no kinks or narrow bends in breathing circuit.
    b. Verify correct placement of the airway and that it is clear of obstructions.
    c. Check to see if patient has tension pneumothorax.

2) ***Low Lung Compliance*** - If the alarm is activated in the second half of the inspiratory phase this suggests low lung compliance and/or high airway resistance.
    a. First consider decreasing the SET Tidal Volume. Compensate for the lower Minute Ventilation by increasing the SET Respiratory Rate if necessary.
    b. Increasing the SET PIP Limit may avoid triggering the alarm condition and prematurely terminating the inhale. Decreasing the amount of PEEP will have a similar effect. Both approaches should only be considered under a physician’s instruction.

If the above does not resolve the alarm, disconnect the Patient Circuit from the Patient’s Airway. If the “PIP Reach” alarm condition continues then remove the Patient Circuit and SAVe II+ Ventilator from service and ventilate by alternative means.

WARNING:

- Avoid setting the PIP Limit above 35 cmH2O to avoid patient injury.

BATTERY ALARM

The BATTERY low-priority alarm activates when less than 15% of battery capacity remains. To resolve connect the SAVe II+ to an appropriate external power source.

Device response:

Less than 15% of capacity:

- Low priority audible indicator activates for 30 seconds.
- Last battery LED begins to flash.

Less than 8% of capacity:

- Medium priority audible indicator activates for 30 seconds.
- Last battery LED continues flashing.

At or below 5% of capacity:

- High priority audible indicator activates for 30 seconds.
- Last battery LED continues flashing.

At or below 0% of capacity (Reserve Capacity):

- Device will go into low battery mode for at least 5 minutes:
- Discontinue breaths.
- Open exhalation valve
- Therapy control indicators are cleared.
- Alarm continues to sound.
- All button presses (except MUTE and POWER) are disabled.

What to do:

1) Connect to an external power source using the SAVe II+ AC Power Supply. Verify the charge indicator illuminates.
2) If unable to perform Step #1 then prepare to ventilate by alternative means. The remaining battery capacity can be extended by ventilating at lower minute volumes and reducing the SET PEEP.
3) If the battery duration was shorter than expected after charging for at least 1 hour consider if the battery needs to be replaced.

NOTE: If the system has been running and the battery becomes disconnected or suddenly fails, ONLY the Hazard indicator will illuminate (Triangle in the center of the Alarm Dashboard. See Figure 3 on Page 16), and the audible alarm will sound for at least 2 minutes until all power reserves are drained.

DEVICE ALARM

The SAVe II+ software monitors multiple components to ensure they are operating within the expected parameters. The DEVICE alarm is triggered when the device is outside of specified temperature range OR a non-field correctible malfunction is detected.

Device responds by:

1) Activating “DEVICE” visual alarm indicator and high priority audible alarm indicator.
2) Stops ventilating (cycling).
3) Opens the exhaust valve to allow patient to spontaneously breathe with minimal resistance.
4) Displays a device error code in the TIDAL VOLUME (TV) display.

What to do:

If an error code is observed turn the device off, then on to clear transient alarms. If this does not address the problem, then begin ventilating using another method.

See if the error code corresponds to one of the following potentially field correctable issues:

- **E13**: Most likely caused by operating at temperatures below -10C. Increase device temperature to above 0C.
- **E15**: Most likely caused by a loose battery connection or battery that has entered a safe mode due to a malfunction. Verify the battery connection. If the device still produces error code, then replace battery.
- **E16**: Most likely caused by operating at temperatures above 60C. Decrease device temperature to below 50C.

For all other device codes or if the error is not field correctable then immediately take the device out of service. Make a note of the error code and contact an authorized service provider.

HIGH PEEP ALARM

Alarm is triggered when measured PEEP is 5.0 cmH2O above the SET PEEP.

Potential Cause:

1) Patient is not synchronizing with the ventilator.
2) Exhalation valve port is blocked or occluded.
3) Patient is not completely exhaling during the expiratory phase of the breath.

Device responds by:

1) Activating “HIGH PEEP” visual and high priority audible alarm indicators.
2) Opening the exhaust valve.
3) Stopping ventilation (cycling).

The alarm is resolved when the measured PEEP is < 2.0 cmH_2O above SET PEEP.

What to do:

1) Inspect the exhale gas pathway for blockages or increased resistance.
2) Consider removing any accessories that increase Expiratory Resistance. For example, remove or change the HME or HMEF if installed.
3) Increase the duration of the Expiratory Cycle by reducing the Respiratory Rate. This may resolve the alarm by providing the patient more time to fully exhale.
4) Note: Verify Minute Volume requirements are still being met. If the patient is asynchronous with ventilator, consider sedating patient or discontinuing ventilation as medically directed.

LOW PEEP ALARM

When the PEEP as measured at the end of the exhale remains 2 cmH2O below the set PEEP for 40 consecutive breaths, the Low PEEP alarm will be activated.

Alarm Behavior:

1) The medium priority audible alarm is activated.
2) The RR/TV/PIP displays will blink (1 second on, 1 second off).
3) The PEEP display alternates between the set value and the measured value (1 second for each phase).
4) The Confirm button blinks (1 second on, 1 second off; the "on" phase is synchronized with the display of the measured PEEP).

The alarm is cleared when the measured PEEP reaches the set PEEP or when the user presses the Confirm button. When the alarm clears, the Confirm button will stop blinking, and the user interface will go back to displaying the set parameters.

HIGH MINUTE VENTILATION

A High Minute Ventilation alarm triggers when the TV/RR combination requires a minute ventilation that exceeds 12.5 LPM. The device will not permit the operator to select these TV/RR combinations. See Table 6 on page 31 to see the max tidal volume supported by each respiratory rate.

Device responds by:

1) Activating “High MV” visual alarm. There is no audible alarm.
2) Device will not let you increase the setting you are trying to increase.

What to do:

1) Make sure the TV/RR combination results in minute ventilation of no more than 12.5 LPM.
2) If one parameter is being adjusted up and the other down, start by adjusting the parameter moving down.

BREATH ALARM

A breath alarm activates when the device is set to 0 breaths per minute, and it has been 30 seconds since the last manually triggered breath was delivered to the patient.

Device responds by activating the BREATH visual alarm and high priority audible alarm.

What to do:

1) Press MANUAL TRIGGER if a breath is indicated.
2) Increase RR above 0 to exit MANUAL / CPR mode if indicated.

BREATH ASSIST ALARM

This alarm is triggered when the device detects inspiratory effort from the patient.

Potential Cause:

1) Patient inspiratory effort was detected (spontaneous breathing) and triggered breath assist.
2) Chest wall recoil during CPR chest compressions triggered breath assist.

Device responds by:

1) Activating “BREATH ASSIST” visual alarm and medium priority audible alarm.
2) The SAVe II+ will trigger a breath to assist the patient’s inspiratory effort.
3) The SAVe II+ will deliver the SET TV at the max pump flow rate which is 40 LPM.
4) The SAVe II+ will resume normal mandatory ventilation following delivery of the single triggered breath.

What to do:

1) If the patient is asynchronous with ventilator, consider removing patient from ventilator if patient can breathe adequately or if appropriate sedate patient.
2) If performing chest compressions, consider putting the ventilator into MANUAL/CPR Mode by setting RR to 0.

TO DISCONTINUE USE

Follow local protocols and care provider guidance before discontinuing therapy with the SAVe II+. Turning off the SAVe II+ may result in harm to the patient if ventilation is still required and not provided by another means.

When the patient no longer requires the SAVe II+ for ventilatory support, ventilation can be stopped by holding the power button for 3-5 seconds. All LED indicators (other than the power charger if connected) will turn off, and the unit will cease to deliver breaths to the patient.

Detach the breathing circuit from the Endotracheal tube or mask. The breathing circuit and, if applicable, the HMEF, cannot be reused and should be properly disposed of as medical waste.

Clean the SAVe II+ and accessories as described below.

Review the condition of the debris filters on the SAVe II+ intake port. If the filters appear damaged or soiled, replace the filters before next use. Failure to do so may result in incorrect tidal volume delivery to the patient, reduced battery operation time, or other potential injuries to the patient. Ensure the intake cap is properly placed and secured over the intake port (Figure 6 on page 17).

The Attenuator or Oxygen Reservoir, if used, should be evaluated for damage or other indications of dirt or debris. These parts, if undamaged, once cleaned, may be returned to their packaging, and returned to the SAVe II+ Kit Case for future use.

- The Attenuator, once sealed in the resealable plastic packaging, is generally placed into the top pocket of the case.
- The Oxygen reservoir must be carefully coiled within its resealable packaging such that the coiled reservoir, in the bag, can fit into the cutout used for the ventilator unit, below the ventilator, such that the reservoir and ventilator when placed into the packaging do not protrude above the foam packing of the cutout.

Replace a new, properly packaged, patient breathing circuit into the SAVe II+ Kit Case pocket. The bag may need to be compressed and folded to reduce the size of the packaged circuit to fit. The patient breathing circuit is generally placed diagonally into the case pocket from the lower left corner to the upper right corner.

MAINTENANCE

The SAVe II+ ventilator is designed to operate with minimal maintenance. However, the battery charge should be verified every 6 months, and the calibration should be verified annually by an authorized service representative. To learn more or to schedule your service please visit www.automedx.com/service.

BATTERY MAINTENANCE

All batteries degrade over time. If the battery will be stored at elevated temperatures or for an extended period, store it with a 50% charge (2-3 bars).

Runtime on a single battery charge depends on multiple factors: battery capacity, tidal volume, respiratory rate, PEEP, patient compliance, environmental temperature, number of charge/discharge cycles, previous storage conditions, depth of discharge and age of battery. When a new, fully charged 2800mAh battery is used, the SAVe II+ will run for 9.25 hours (or about 8.5 hours with a 2600mAh battery) when set to 5'9" Adult Preset.

CLEANING

Always keep the SAVe II+ and its accessories clean. The SAVe II+ ventilator should never be disassembled in the field. The following components may be cleaned as needed between uses:

- SAVe II+ Ventilator
- O_2 Reservoir
- Attenuator
- Carrying Case

All SAVe II+ external surfaces must be cleaned before and after each patient use and as may be required. Disinfect the exterior surfaces of SAVe II+ (including the inside of the port cover) according to hospital / site infection control guidelines. At a minimum, wipe the control unit with a clean damp cloth. If available to you, the use of methylated spirits is accepted. Wipe away any residual cleaner. See caution statement regarding cleaning agents.

Do not clean any portion of the SAVe II+ or its accessories with abrasives or chlorinated hydrocarbon cleansers.

Do not allow dirt, sand, debris, grease, oil, or caustic chemicals to enter or coat the unit or its accessories. To prevent debris from entering the SAVe II+, the Debris Filters should always be securely in place and the port cover should be closed when the unit is not in use. If the debris filter becomes saturated with dust or sand, turn the unit upside down when removing the filter so any loose debris falls out rather than in the unit. If sand or dust gets into the unit, service the unit before using as particulates may significantly impact tidal volume.

Clean the port well and port cover prior to removing the debris filter. It is recommended the SAVe II+ be stored in its carrying case when not in use.

WARNING:

- Sand or dust inside the pump may significantly decrease the volume of gas delivered to the patient.
- Do not attempt to clean single-use accessories.
- To avoid damaging SAVe II+ plastic components and user interface, do not use cleaning agents containing ammonium chloride, other chloride compounds, more than 2% glutaraldehyde, phenols, or abrasive cleaners.

- Under no circumstances should the SAVe II+ or its accessories be immersed in liquid. If the SAVe II+ becomes wet, the unit should be dried using a lint-free cloth immediately, or once the unit is no longer in use. If the SAVe II+ becomes immersed, discontinue use. Air dry with port door open and patient ports facing down so water that may have entered the pump can drip out. Return to appropriate service facility for inspection. DO NOT expose the switch, external power jack, or audible alarm port directly to liquids.
- Never expose to an autoclave.

REPLACE CONSUMABLES

Single-use accessories must be replaced after each use. Other accessories should be replaced Replace the following after each patient use:

- Patient breathing circuit
- Debris filter
- Mask
- Heat and moisture exchanger (HME or HMEF)

Reordering information is available at http://www.automedx.com

BREATHING CIRCUIT

The SAVe II+ breathing circuit is single use. Examine the breathing circuit tubes for cracking, discoloration, sharp edges, or other signs of damage. DO NOT attempt to use or repair damaged breathing circuits. Damaged breathing circuits must be replaced. If necessary, exterior walls of tubing may be cleaned with a damp cloth and dried using a lint-free cloth. The breathing circuit has a three-year shelf life from the date of manufacture.

DEBRIS FILTER

The debris filter should be evaluated following each patient use. If the debris filter appears soiled or damaged, it should be replaced. Failure to do so may result in incorrect tidal volume delivery to the patient, damage to the SAVe II+ unit, reduced battery operation time, or other potential injuries to the patient. If the debris filter becomes damaged or soiled during use, replace it with a new debris filter and as appropriate reattach extendable oxygen reservoir tube attenuator, or Intake Cap.

AIRWAY

Airways and masks must be replaced following use.

STORAGE

The SAVe II+ should be stored as a complete kit in a state of readiness. The SAVe II+ CARRYING CASE (P/N: F20065) is designed to protect the SAVe II+ and its accessories during transport, shipping overseas and storage. This case is rated IP67 indicating complete protection from dust, sand, and protection from immersion in water up to 1 m. In addition, the case is designed to float to avoid immersion.

For short-term storage, the temperature can range from 0 to 40°C (32 to 104°F).

For extended storage periods, the SAVe II+ should be stored indoors, out of direct sunlight, and in a clean environment. The best storage temperature is between 10 and 30°C (50 to 80°F). The relative humidity in the storage facility should be low.

If the device will be stored for more than 6 months at temperatures above 21°C (70°F) then the battery should be stored at a state of charge of 50% or less to maintain a higher level of recoverable charge. The storage state of charge is most important when the device will be exposed to elevated temperatures for extended durations.

SCHEDULED MAINTENANCE

The SAVe II+ should have an annual calibration check to verify the device continues to operate within specification. There should be a dated calibration sticker on the side of each device. Failure to verify calibration each year increases the risk of harm to the patient and may void warranty. If the device is used in extreme environments or is exposed to dust, sand, or water then maintenance should be performed more frequently. If you have any reason to believe the device is not within specification, arrange for service. For more service information please visit www.automedx.com/service.

The battery should be checked and recharged to between 50% and 75% at least every six months. This can vary depending on the storage temperature.

PROPER DISPOSAL

Used patient breathing circuits, HME filters, patient masks, endotracheal tubes, and accessories that have been damaged with biologic residue should be disposed of after each use in accordance with local protocols and regulations as medical waste.

Packaging materials, and other accessories such as the oxygen reservoir and attenuator, if no longer suitable for reuse and if not contaminated with biologic residue should be properly disposed of as trash or recycling in accordance with local protocols and regulations.

The SAVe II+ contains electronic components and a Lithium-Ion battery and, if no longer serviceable, must be disposed of properly in accordance with local regulations.

Appendix A: Specifications

GENERAL			
Mode	Continuous Mandatory Ventilation		
Control	Time-cycled, volume targeted, pressure-limited		
AC Power Supply	Input: 100 – 240 VAC / 50-60 Hz Shock Protection: Class II		
Battery Duration[1]	8.5 to 9.25		
Time to Full Charge[2]	1.4 hours (Typical)		
Dimensions	Ventilator: 6.5" x 6.25" x 2.0” | Storage-case: 13.8” x 12.1” x 6.8”		
Weight	Ventilator: 2.8 LBS (1.3 kg) | Storage-case: 9.9 LBS (4.5 kg)		
ENVIRONMENTAL			
Ingress Protection	Ventilator: IP44 Storage-case: IP67		
Humidity	Operating: 15 – 95% Storage/Transport: 15 – 85% (non-condensing)		
Atmospheric Pressure	700 – 1100 hPa		
Operating Temperature[3]			
- Normal	5 to 45°C (41 to 113°F)		
- Transient	- 20 to 50°C (-4 to 122°F)		
Storage Temperature[4]			
- Short Term and Transport	0 to 40°C (32 to 104°F)		
- Long Term	0 to 30°C (32 to 86°F)		
PARAMETERS	**RANGE**	**RESOLUTION**	**TOLERANCE**
Inspiratory Time (Seconds)	0.667 to 2.500	N/A	± .100
Rate (Breaths per Minute)	0, 8 to 30	1	± 1 BPM
Tidal Volume (ml)[5]	200 to 800	10	± 10 + 10% of set value
Pressure Limit (cmH_2O)	10 to 60	5	± 4.0 + 5% of set value
PEEP (cmH_2O)[6]	0 to 20	1	± 2.0 + 10% of set value
Measured Airway Pressure (cmH2O)	0 – 70.0	1	± 2.0 + 8% of actual reading
FiO_2[7]	21 to 100%	See chart	± 10% of set value
Sound Pressure (A-weighted)	Up to 73.5 dB	N/A	N/A
OTHER SPECIFICATIONS		**PERFORMANCE**	
Flow (LPM)		Up to 40	
I:E Ratio		FIXED 1:2	
Minute Ventilation		1.6 – 12.5	
Auto PEEP		< 2.0 cmH_2O	
Inspiratory Trigger		2.0 cmH_2O	
Dead space (ml)[8]		45 – 115	
Inspiratory Resistance (cmH_2O/L/sec)		< 3.0 @ 30 LPM	
Expiratory Resistance (cmH_2O/L/sec)		< 3.0 @ 30 LPM	

[1] Ventilator set to simulate 5'9" patient with moderate ARDs at room temperature. The 8.5 hours is with a 2600 mAh battery and 9.25 hours is with a 2800 mAh battery. Changes in settings, patient condition, and temperature will affect run time.
[2] Operating the ventilator while it is charging will increase time to full charge. Full charge is 96% capacity or greater. Above that, to protect the battery, the charging rate slows down.
[3] If stored at room temperature (15 – 20C) prior to use the ventilator will continue normal operation for up to 1.5 hours at the lower temperature extreme of -20 C.
[4] To maximize the useful life of the device's lithium-ion battery, store at temperature in lower range of the specified long-term storage range with 40 – 60% of charge (2 battery lights)
[5] Gas volumes are specified at ambient temperatures and pressure (ATP). Critical care ventilators often quote the volume of the gas as it is in the patient's lungs (BTPS) where the higher temperature and more humid environment make the gas expand.
[6] Allow up to 40 breaths to reach set PEEP.
[7] Declared tolerance with 100% oxygen input. FiO2 should be adjusted if the medical gas supply or oxygen concentrator outputs less than 100% oxygen. O2 concentrators and hospital supply lines may supply a lower value and flow rates should be adjusted accordingly.
[8] Value depends on if the extendable airway connector is collapsed or fully extended. If ventilating with low tidal volumes or adding accessories such as an HMEF it is recommended to collapse the extension as much as possible to limit dead space in the circuit.

REGULATORY INFO / CLASSIFICATION

Electrical Shock

Protection Class	Class II
Degree of protection	B
Applied Parts	Patient breathing circuit (Type B)
Power	Internally Powered ME Equipment
Battery Charger	Mascot Type 2541
Input ratings	100-240Vac, 50-60Hz, max. 0.9A.

Electromagnetic Compatibility

The SAVe II+ is suitable for the electromagnetic environment of pre-hospital, field hospitals, outpatient environments, hospitals, ICU's and transport environment settings.

During the immunity testing described below the SAVe II+ continued to ventilate normally. If the device is exposed to disturbances beyond that specified in the immunity testing below the device will alarm. If this happens, we suggest you reorient equipment and observe for proper operation.

WARNINGS:

- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the SAVe II+ System, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result."
- The SAVe II+ should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the SAVe II+ should be observed to verify normal operation. If operation is not normal, the SAVe II+ or the other equipment should be moved.
- Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions

or decreased electromagnetic immunity of this equipment and result in improper operation.

- Avoid exposure to known sources of EMI (electromagnetic interference) such as diathermy, lithotripsy, electrocautery, RFID (Radio Frequency Identification), and electromagnetic security systems such as anti-theft/electronic article surveillance systems, metal detectors. Note that the presence of RFID devices may not be obvious. If such interference is suspected reposition the equipment, if possible, to maximize distances.

Electromagnetic Emissions

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF Emissions CISPR 11	Group 1	The SAVe II+ 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 II+ 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	

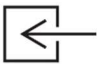
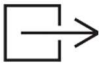
*Harmonic emissions (IEC 61000-3-2) and Voltage fluctuations, and flicker (IEC 61000-3-3) are not applicable for devices operating at 120VAC, the Mains power in USA.

Electromagnetic Immunity

Immunity Test	Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	± 8 Contact ±2, 4, 8 and 15 kV Air	Complies	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Radiated RF IEC 61000-4-3	10 V/m 80MHz to 2.7GHz	Complies	The SAVe II+ is suitable for the electromagnetic environment of typical hospital settings.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms ISM and amateur band	Complies	
Electrical fast transient IEC 61000-4-4	±2kV power line	Complies	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV line to line	Complies	
Power frequency magnetic field IEC 61000-4-8	30 A/m	Complies	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Voltage dips, short interrupts and voltage variations on power supply input lines IEC 61000-4-11	0% U_T, 0.5 cycle 0% U_T 1 cycle 70% U_T 30 cycles100%U_T 300 cycles	Complies	MAINS power quality should be that of a typical commercial or hospital environment. If the user of the SAVe II+ Portable Ventilator requires continued operation during power mains interruptions, it is recommended that the SAVe II+ Portable Ventilator be powered from an uninterruptible power supply
NOTE: U_T is the A/C. mains voltage prior to application of the test level.			

Appendix B: Symbols Glossary

Symbol	Explanation of Symbol
	Manufactured By. The full name, address and phone number of the legal manufacturer appears next to this symbol.
	European Authorized Representative. The full name and address of the Authorized Representative appears next to this symbol. This is the official contact for complaints when manufacturer is located outside EU.
	CE Mark, 4 digits after the CE or underneath the CE refer to Notified Body number. Numbers should be ½ the height and equal boldness and font to CE.
	Important instructions inside
	Refer to instruction manual/ booklet. Follow instructions for use.
	Do not re-use
	Non-sterile
	Caution
	Date of manufacture
	Federal law restricts this device to sale (or use) on the order of a licensed practitioner.
	On/Off Power Button
	Class II Equipment

	Type BF Applied Part
	Waste Container – use proper disposal
	Biological risks
	One-way Valve
	Input (airflow)
	Output (airflow)
	Alternating Current
	Direct Current
	Catalog
	Serial Number
	Lot Number
	Use-by Date
	Do Not use if package is damaged
	Fragile
	Temperature Limit

	Pressure limit
	Humidity limit
IP24	Ingress Protection IP2x – The first digit represents solid particle protection, with “2” representing effective against object > 12.5mm, fingers or similar. IPx4 – The second digit represents liquid ingress protection, with “4” representing effective against splashing water.
	Not made with natural rubber latex
	Mute
	Battery Level
	Charge
	Compression Rate (CPR)
	Decrease Parameter
	Increase Parameter
	Patient Height

Appendix C: Re-Order Information

ITEM	MFG PN
Ruggedized Patient Circuit, Single-use, Adult	M40105
Patient Circuit, Single-use, Adult	F20066
Resupply Kit, Intake Filter x2 and cap	M41113
Extendable O_2 Reservoir Tube	F20072
Noise Attenuator	M41112
Battery Replacement Kit, 2800 mAh	M40116
AC Power Supply and Battery Charger, SAVe II+	M42090
Mains Power Cord with Ferrite Bead, Type A Plug (USA)	M41125
Mains Power Cord with Ferrite Bead, Type C Plug (Europe)	M41126
Mains Power Cord with Ferrite Bead, Type G Plug (UK/ME)	M41127
Hard Case, SAVe II+	F20065

Appendix D: Principles of Operation

The SAVe II+ is a completely self-contained, small, lightweight, 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 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 control valve which opens and closes 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 [CMH_2O] 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 one (1) 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 pump's 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 stop the pump and switch to 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 one (1) 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 cmH_2O 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 cmH_2O (as opposed to 30 cmH_2O 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 FIO_2 to the patient. This is done using a low-flow oxygen source (up to 15 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. Figure 19 on page 26 in this manual guides the user to an appropriate oxygen flow rate depending on the TV, RR and FIO_2 desired.

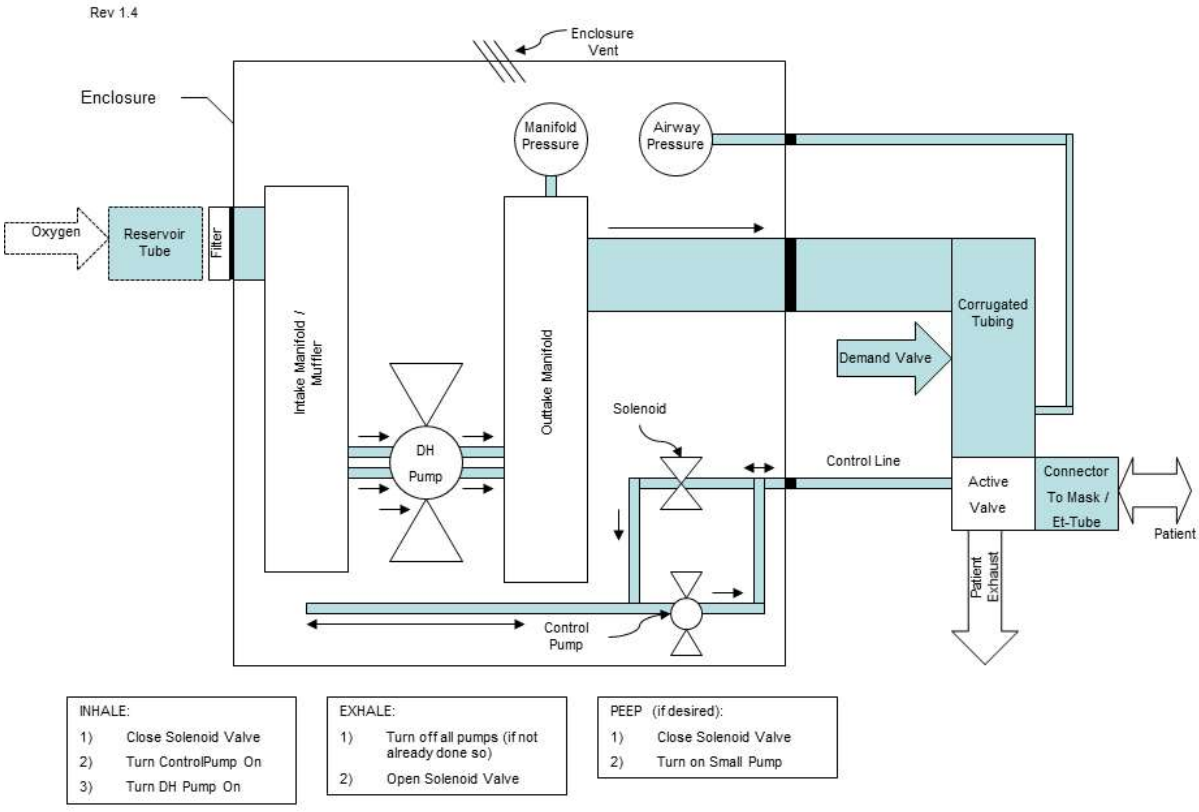


Figure 22: Pneumatic Diagram

ESSENTIAL PERFORMANCE

The Essential Performance criteria established for the SAVe II+ is as follows:

1. Delivery a set volume of respiratory gas within a set range and tolerance to the patient,
2. Deliver respiratory gas to the patient at a set rate withing a set range and tolerance,
3. Limit the maximum pressure of the respiratory gas delivered to the patient to a preset value within a set range and tolerance,
4. When delivering PEEP therapy, maintain a minimum pressure in the patient's airway within a set range and tolerance,
5. Permit adequate time for the patent to exhale respiratory gas between respiratory cycles,
6. Permit the operator to set a target tidal volume appropriate to the patient population,
7. Permit the operator to set a pressure limit,
8. Permit the operator to set a respiratory rate appropriate to the patient population,
9. Permit the operator to set a minimum airway pressure when PEEP therapy is indicated,
10. Provide an alarm to notify the operator for anomalous operations or failure to operate, and
11. Operate without the use of external power for a period of time.

Appendix E: Limited Warranty

Limited Warranty Applicable to the SAVe II+

AutoMedx warrants to the original purchaser ("Customer") of the SAVe II+ that if there is a defect in material or workmanship in the SAVe II+ and AutoMedx is notified of such defect within three (3) years 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 is materially affected by many factors. As such, AutoMedx warrants to the Customer of the SAVe II+ that, if there is a defect in material or workmanship in the battery contained in the SAVe II+ 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 battery at no charge to the Customer.

Sole Remedy

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

Limited Liability

To the maximum extent permitted by applicable law, in no event shall AutoMedx or its Suppliers be liable for any special, incidental, indirect, physical or consequential damages whatsoever arising out of the use or inability to use the SAVe II+ product and or accessories. In any case, AutoMedx's entire liability shall be limited to the amount actually paid for the purchase of the SAVe II+ product. Valid proof of purchase required.

Disclaimer

Some countries, states, or provinces do not allow the exclusion or limitation of implied warranties or the limitation of incidental or consequential damages for certain products supplied to consumers, or the limitation of liability for personal injury, so the above limitations and exclusions may be limited in their application to you. When the implied warranties are not allowed to be excluded in their entirety, they will be limited to the duration of the applicable written warranty. This warranty gives you specific legal rights, which may vary depending on local law.

Appendix F: Software Release History

Software revisions of 2.0.x and 2.1.x are both valid software revisions. The difference relates to a change in an internal component.

Release	Effective Date	Description of Change
R2.0.0	May 15, 2020	Initial release
R2.1.0	July 17, 2020	Software updated for a hardware specific change


M42110:5.9