AutoMedx
BREATHING NEW LIFE INTO RESUSCITATION

SAVe II Operation Manual

SAVe II™

12478

Preamble

Trademark Information

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Document Version

M40100 Rev 4.2 (12/18); Firmware Version R1.0.5

If more than 1 year has elapsed since the date above contact AutoMedx to determine if there have been any updates to the product or to this manual.

Notice to Operators

The detailed information and instructions contained within this Operation Manual are designed to ensure the safe and effective setup, use, and field maintenance of the SAVe II™. The SAVe II must be setup, operated, maintained and repaired in accordance with the instructions provided in this manual, accompanying labels and inserts.

It is important that this manual is read and understood in its entirety before operating the ventilator. Operating or servicing this device without a complete understanding of its characteristics may cause harm to the patient or user and may permanently damage the device.

The SAVe II is designed for use by trained personnel under the direction of a physician and in accordance with applicable laws and regulations. This manual describes how to operate and respond to the ventilator, but does not include instructions on how to respond to the patient. Please contact AutoMedx if the instructions in this manual conflict with your protocols. 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.

Service procedures, including annual calibration verification tests, routine and non-routine maintenance operations are described separately in the SAVe II™ SERVICE MANUAL (P/N: M40101). For service information contact: service@AutoMedx.com

FDA Tracking Requirements

U.S. Federal Law (21 CFR 821) requires the tracking of ventilators. Under this law, owners of this ventilator are required to register the device and to inform AutoMedx if the device is sold or given to another organization or destroyed. This allows AutoMedx to notify you of safety updates, a recall or software updates.

Please send the following information to register@automedx.com:

Contact name
Title
Organization name
Street address
City, State, Zip
Contact phone number
Email address
Model Number and Serial Number
Disposition of the device

TABLE OF CONTENTS

Safety Information

Operators **MUST** read and understand the following information about Warning and Caution and statements **BEFORE** operating the SAVe II™. General warnings and cautions are listed below. Specific warnings appear throughout the manual where pertinent.

WARNING

"WARNING" statements alert the reader to potentially hazardous situations, which, if not avoided, could result in death or serious injury.

CAUTION

"CAUTION" statements alert the reader to potentially hazardous situations, which, if not avoided, could result in equipment damage. These situations could indirectly cause death or serious injury if the equipment damage causes the ventilator to operate improperly.

General Warning Statements

Restricted Use - The SAVe II is a restricted device that must be used according to its intended use by properly trained and qualified personnel under the direction of a physician and in accordance with applicable laws and regulations.

Patient Monitoring - Qualified personnel must constantly monitor patients. Such personnel should be prepared to troubleshoot alarms, address equipment malfunctions and circumstances where equipment becomes inoperative.

Alternative ventilation - An alternative means of ventilating the patient should be available at all times.

Pre-Use Functional Check - The operator should perform a quick functional check to ensure proper operation before connecting to a patient.

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 refer to appropriate guidelines or their medical director to determine the suitability of these presets for a given situation.

Sand/Dust/Debris Inside Manifold – Do not operate the SAVe II if sand, dust or other debris have entered the ports.

Equipment Damage/Malfunction - Do not operate the SAVe II, any components, or accessories that appear to be damaged, fail Checkout tests, or malfunction in any way. Discontinue use and immediately contact an authorized service technician or AutoMedx. If equipment is damaged or behaves in a way that is inconsistent with normal operation, stop use of the device immediately, unplug, power off the device, and disconnect external oxygen.

Preventative Maintenance - Failure to follow Preventative Maintenance procedures described in this manual could result in device malfunction. Refer to information on page 45.

Battery - If you suspect the internal battery is damaged, take the unit out of service immediately.

Accessories - Serious harm to the patient may result from the use of unauthorized parts or accessories. Only use accessories approved by AutoMedx. Refer to information on page 19.

Use with Oxygen Concentrator - Oxygen concentrators are not intended as a primary source of oxygen and a back- up oxygen source should always be available.

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

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. Refer to information on page 12.

Contaminated Environment - Do not use the SAVe II in contaminated environments. The debris filter is designed to stop particulates, not chemical or biological agents.

Cross Contamination - Do not reuse the Breathing Circuit as it may cause cross contamination between patients. A patient treated by mechanical ventilation is at risk 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 risk of infection.

Audible Indicators - 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.

Noisy Environments - Alarms may be difficult to hear in noisy environments. Take extra precautions to closely monitor the patient and ventilator in these environments.

Visual Alarm Indicators - Do not cover or obstruct visual alarm indicators in any way. Always have the user interface in view.

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 on page 35.

Unintentional Changes - In order to prevent accidental changes to the settings or inadvertently shutting off the device, verify the user interface is protected from unintentional contact.

Secure Device - During evacuation or transport, it is strongly recommended that the SAVe II be secured to the patient or litter. Failure to properly secure the SAVe II could damage the device and could harm the patient by dislodging the Breathing Circuit or airway.

Fire Hazard - 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.

Personal Injury and Electrical Shock - To avoid electric shock hazard, 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 information on page 22.

Caution Statements

Risk of Equipment Interference - Potential electromagnetic interference may occur at levels greater than 20 V/m. Avoid use of the device in environments that may have high electromagnetic levels. The AC Adapter (Battery Charger) and its associated cables are in compliance with the requirements of IEC 60601-1-2.

Service Personnel Qualifications - All servicing and repair of the SAVe II must be performed by a service technician qualified by AutoMedx. Contact AutoMedx at service@AutoMedx.com for a SAVE II SERVICE MANUAL (P/N: M40101) and qualification requirements.

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 on page 22.

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

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.

Battery Replacement & Disposal - The SAVe II battery should only be replaced by qualified service personnel Batteries should be disposed of according to local environmental legislation. Refer to SAVE II SERVICE MANUAL (P/N: M40101).

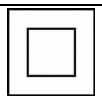
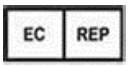
Transport of Lithium-Ion Batteries - Regulations govern the transportation of lithium ion batteries and devices that have lithium ion batteries. Check the appropriate statutes to ensure compliance before transporting the device and / or the batteries.

Uncertain Power Sources / Automobile Power Outlets - Before connecting the SAVe II AC Power Supply to uncertain power input sources, verify the SAVe II internal battery is in good condition and fully charged. Connecting to an improperly rated power source may damage the AC Power Supply, preventing the SAVe II battery from charging.

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.

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.

Use of Symbols

Symbol	Title & Usage	Symbol	Title & Usage
	CAUTION		ON/OFF POWER BUTTON
	CONSULT INSTRUCTION FOR USE		MUTE
	DO NOT REUSE		CLASS II EQUIPMENT
	DATE OF MANUFACTURE		TYPE BF APPLIED PART
	MANUFACTURER		ONE-WAY VALVE
	AUTHORIZED REP (EUROPE)		ALTERNATING CURRENT
	WASTE CONTAINER		DIRECT CURRENT
	CATALOGUE NUMBER		CONTAINS OR PRESENCE OF PHTHALATE
	SERIAL NUMBER		LATEX FREE
	BATCH CODE		CE MARKED PRODUCT
	USE-BY DATE		BATTERY LEVEL
	DO NOT USE IF PACKAGE IS DAMAGED		CHARGE
	NON-STERILE		COMPRESSION RATE
	FRAGILE, HANDLE WITH CARE		DECREASE PARAMETER
	TEMPERATURE LIMIT		INCREASE PARAMETER
IP24	ENCLOSURE PROTECTION RATING		PATIENT HEIGHT

INTRODUCTION

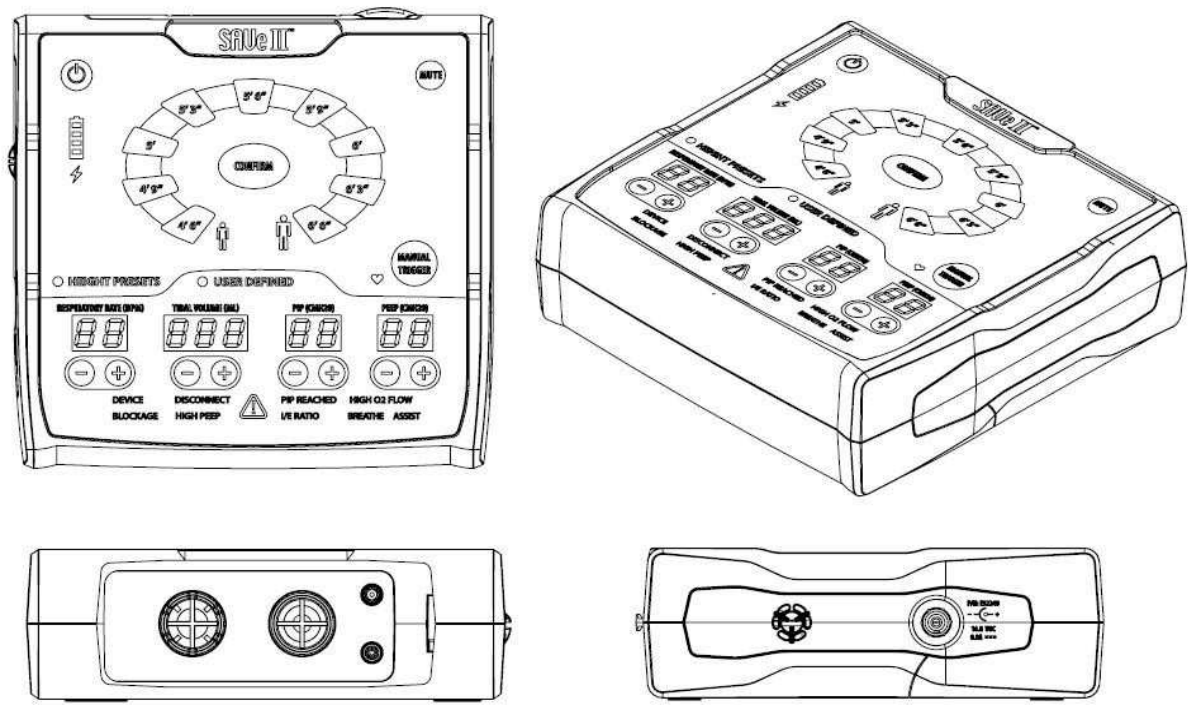


FIGURE 1: MULTIPLE VIEWS OF SAVe II

Device Overview

The SAVe II is designed to be used in lieu of a Bag Valve Mask (BVM) in the pre-hospital environment or during inter-and intra-hospital transport. It is meant to remove the guesswork and reduce the operator error associated with BVMs and overly sophisticated transport ventilators.

The SAVe II uses a battery-powered compressor to deliver air to a patient for up to 10 hours on a single charge. To support use in austere environments, where compressed oxygen is unavailable or ill advised, the device does not require compressed oxygen. However, FiO_2 can be increased if compressed oxygen or an oxygen concentrator is available.

Responders can quickly deploy the SAVe II by selecting the patient's height. The unit dials in a preliminary tidal volume and respiratory rate appropriate for adults of that size. After initial setup, users with an appropriate level of training can fine-tune the settings. To mitigate the risk of patient injury, airway pressure is monitored and users are alerted to potentially dangerous low and high pressure situations. In a high pressure situation, the pump will stop if the pressure reaches the peak inspiratory pressure (PIP) cutoff. The PIP setting is adjustable but defaults to 30 cmH_2O. Visual alarm indicators located at the bottom of the user interface help the user quickly troubleshoot issues.

Indications for Use

The SAVe II series 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 series is appropriate for adults that weigh at least 45 kg (approximately 99 lbs.). It is intended to be used in the pre-hospital, field hospitals and transport environments.

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

Contra-Indications

ABSOLUTE CONTRA-INDICATIONS

The SAVe II should not be used in situations where Positive Pressure Ventilation (PPV) is contra-indicated.

RELATIVE CONTRA-INDICATIONS

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.

Do not set PEEP above zero (0) when performing CPR.

Spontaneously breathing patients may not synchronize with ventilator. Consider discontinuing use if a spontaneously breathing patient has difficulty synchronizing with the device.

Use Environment

NORMAL OPERATING ENVIRONMENT

The SAVe II is intended for use in pre-hospital and in-hospital settings. Performance specifications are based on use in environments with ambient temperatures of 0 to 50°C (32 to 122°F), relative humidity from 15 to 95%, and atmospheric pressures from 70 to 110 kPa.

EXTREME OPERATING ENVIRONMENT

Attempting to operate the ventilator outside the temperatures range of -10 to 50°C (14 to 122°F) may result in ventilator failure and harm to the patient.

WARNING: The performance of the SAVe II may be materially affected if it is used outside of the specified NORMAL OPERATING CONDITIONS. If at the discretion of the medical director, the device is used outside of the specified NORMAL OPERATING CONDITIONS, but within specified EXTREME OPERATING CONDITIONS, the Operator must practice extra patient vigilance. Do NOT at any time operate or store the Device in environments outside specified EXTREME OPERATING ENVIRONMENTS. This may result in ventilator failure and/or harm to the patient.

Training Requirements

Operators must be familiar with the contents of this manual and trained to provide primary response to a respiratory emergency.

Features

- Height based presets enable rapid setup
- Presets dial in lung protective ARDSnet based parameters based on ideal body weight (6 ml/kg)
- Small size and weight make it one of the most portable ventilators on the market
- Ventilate a patient on the internal battery for 10 hours (runtime varies based on settings)
- Adjustable tidal volume (TV), respiratory rate (RR), peak inspiratory pressure (PIP) and positive end expiratory pressure (PEEP)
- Alarm Dashboard simplifies troubleshooting
- No compressed gas tank required
- Deliver FiO_2 up to 100% using included oxygen reservoir and flow regulated oxygen source
- Displays breath to breath PEEP and PIP measurements

Risks & Benefits

The SAVe II is designed to enable a medic or other first responder with limited training to provide life-sustaining ventilation until the patient can be evacuated to a higher level of care. The device is easy to use, lightweight, and intended to be used on the battlefield, in the pre-hospital environment or during transport. The operator simply selects the height of the patient and the device dials in an ARDSnet Protocol recommended tidal volume of 6 ml/kg of ideal body weight. These presets may not be appropriate for all patients or all conditions. The operator must continue to monitor the patient and make adjustments as necessary.

The SAVe II has a number of benefits over a bag-valve-mask (BVM). First, it offers a breath-to-breath consistency not achievable with a 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. Second, the SAVe II, unlike a BVM, frees up the responder to address other injuries, attend to other patients or further assist in the evacuation. Third, the SAVe II will provide up to 10 hours of ventilation on a full charge (time varies depending on settings). It is impractical to expect a medic to manually ventilate a patient for that duration with a BVM. 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 if a higher FiO2 is needed. Devices relying on high-pressure oxygen tanks in a combat zone pose a fire and explosion hazard, tend to be large and only ventilate for a short period of time.

The medic 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.

DEVICE DESCRIPTION

- ✓ User Interface
- ✓ Device Labels
- ✓ Alarm Dashboard
- ✓ Device Disposables & Accessories

User Interface

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

The device is controlled using buttons. With the exception of Power On/Off, Mute and Manual Trigger, control changes require confirmation to prevent inadvertent changes. Controls requiring confirmation are associated with adjusting ventilator parameters and require operators to select (press) the appropriate Height Preset or +/- parameter control button 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 back to the current device setting and the numerical parameter displays will turn solid.

Green LED indicators communicate the current normal operating status of the device. Red alarm codes and the audible alarm indicator signal an alarm condition. Solid indicators are intended to only communicate information such as a 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.

Green numerical parameter displays communicate device parameter settings and measured pressures. Similar to 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 of the parameter displays are solid then measured pressures (PIP & PEEP) will be displayed for 3 seconds.

SECTION	DESCRIPTION
UPPER UI PANEL (Gray)	Primary indicators, displays and controls generally used during initial setup.
LOWER UI PANEL (Black)	Secondary indicators, displays and controls generally used to monitor and fine tune ventilator parameters.
ALARM PANEL (Black – Bottom of UI Panel)	Alerts operator to potential issues with operation of device.

Description of Controls, Indicators and Displays

REFERENCE & NAME		DESCRIPTION
1	**Power On/Off**	Control used to turn device On and Off. Press for 1 second to turn on. Hold for 3 seconds to turn 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 Indictor**	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[1].
11	**PEEP**	Control and display used to set the POSITIVE END-EXPIRATORY PRESSURE (PEEP) and display the set PEEP of each breath. By pressing the confirm button during normal operation, the device will display the measured PEEP maintained in the BREATHING CIRCUIT at the end of exhalation[1].
12	**Compression Rate**	Indicator blinks at a rate of 100/minute to aid users performing chest compressions when device is in MASK 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 (Refer to instructions on page 29)[1].
15	**Mute**	Silences an active audible alarm for 120 seconds. New alarm will override. If alarm condition still presents after 120 seconds the audible alarm will resume.

[1] Feature available in devices programmed with firmware release R1.0.4 or later

Device Labeling

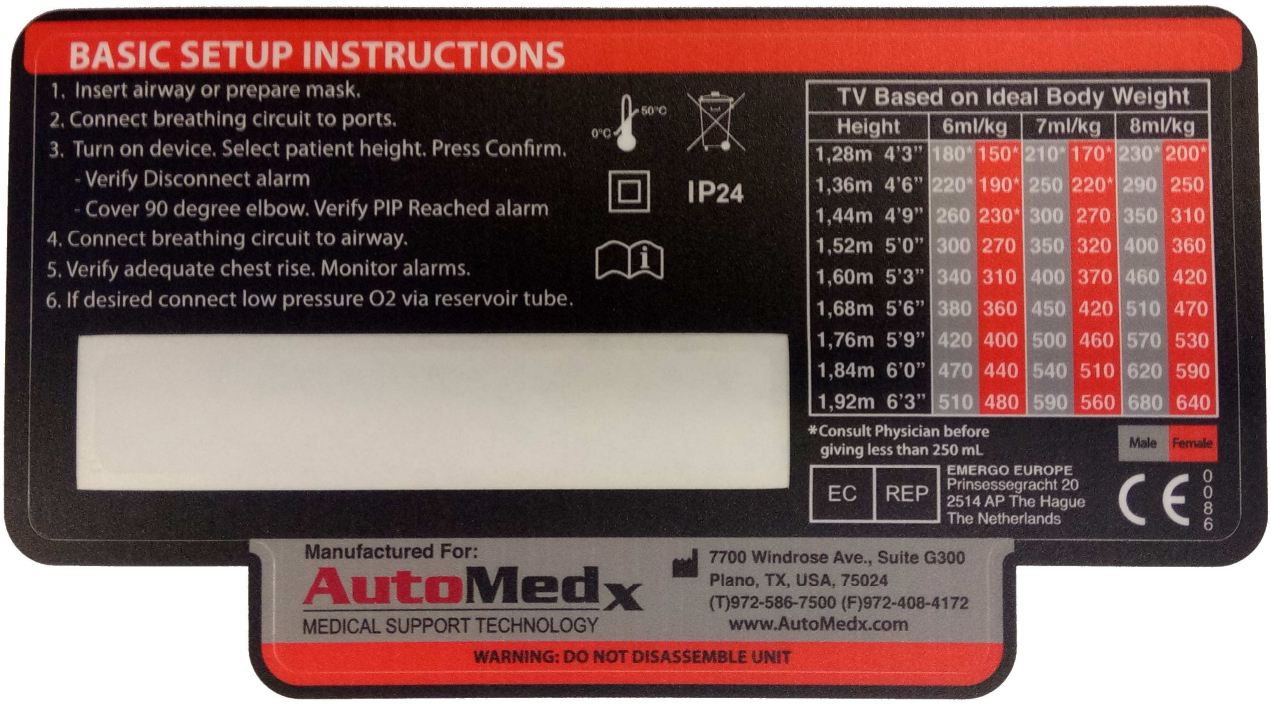
FRONT PANEL LABEL / USER INTERFACE

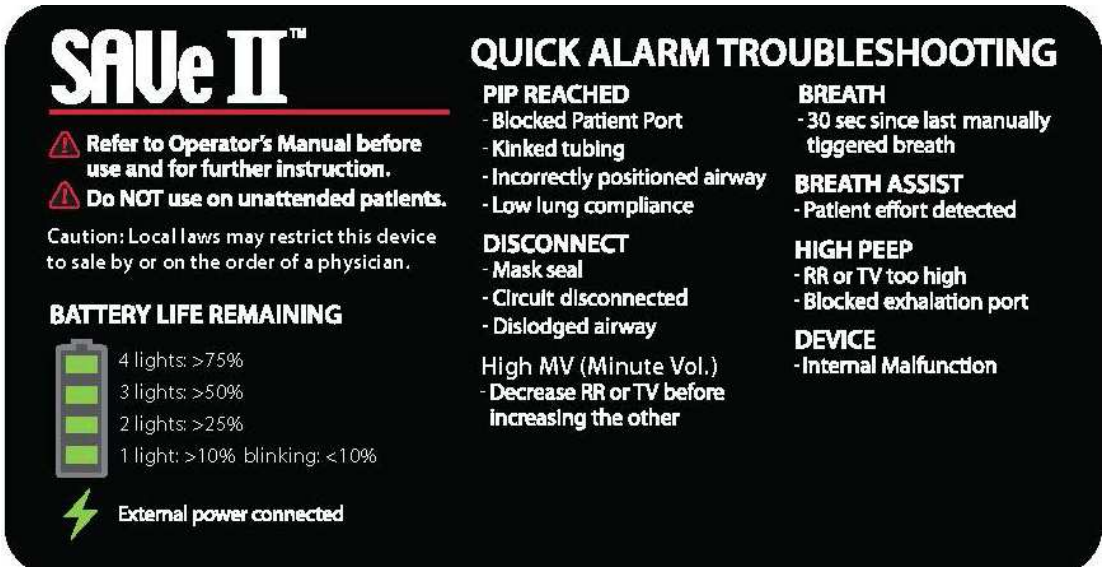
FIGURE 2: USER INTERFACE

BACK PANEL LABELS

The SAVe II back panel has two labels. These labels are intended as a reference to users who have read this manual. The back panel device labels include information concerning:

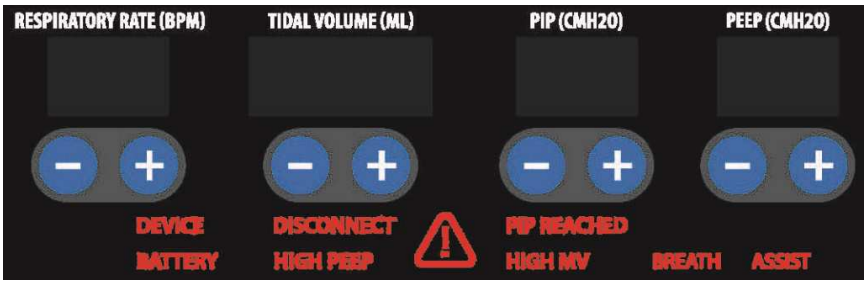
- Basic setup instructions
- Tidal volume reference table for advanced users
- Device Serial Number
- Quick alarm troubleshooting information
- Battery capacity reference





Alarm Dashboard

The Alarm Dashboard is located at the bottom of the user interface. Alarm codes will illuminate in red to alert the operator of various conditions:



Warning: Never cover or obstruct the alarm panel. Operator must have a clear view of the panel at all times when the device is connected to the patient, especially in noisy environments where caregiver may not hear alarms.

ALARM CODE	DESCRIPTION AND LIKELY CAUSE	RESPONSE
DEVICE	The device is outside its temperature range or a software, mechanical or electrical issue has been detected.	**Page 43**
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.	**Page 40**
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.	**Page 41**
BATTERY	Less than 10% of battery capacity remains. The unit must be connected to an appropriate external power source.	**Page 42**
HIGH PEEP	The measured PEEP is 5 cmH_2O above set PEEP. Most likely causes are blockage of the exhalation port or the patient actively exhaling during the exhalation phase.	**Page 43**
HIGH MV (Minute Vol.)	The combination of TV/RR requires a flow rate that exceeds the pumps ability to deliver at an I:E ratio of 1:2. The device will not permit operator to select these TV/RR combinations. Refer to information on page 30.	**Page 44**
BREATH (CPR Mode)	More than 30 seconds have passed since the last manually triggered breath. Only active in MASK CPR MODE (RR set to zero).	**Page 44**
BREATH ASSIST	Indicates a patient inspiratory effort has been detected and a patient triggered breath has been delivered.	**Page 44**

Refer to information on page 40 for instructions detailing how to respond to alarms.

The Hazard indicator will illuminate for all errors and alarms; however, it may be the only indicator if the battery is disconnected or there is a major malfunction.

Device Disposables & Accessories

ITEM	PART #	DESCRIPTION
Breathing Circuit	M40105	Channels air to and from the patient's airway.
Air Intake Debris Filter	F20053	Protects internal components from dust, dirt and other particles.
Air Intake Cap	F20059	Protects the Debris Filter from direct exposure to particles and water during storage or use when the Attenuator or Oxygen Reservoir is not being used.
Oxygen Reservoir	M40092	Allows delivery of up to 100% FiO_2 using a flow regulated oxygen source.
Noise Attenuator	M41112	Mitigates device noise when the Oxygen Reservoir or Air Intake Cap is not in use.
AC Power Supply	E52240 / M40090	Supplies device and battery with external power.
Power Cable (Type A)	E11021	Connects the AC Power Supply to external power.
Hard Carrying Case	F20055	Protects the system during transport and storage.
Head Harness[1]	E11001	Assists user in securing mask to patient.
Mask[1]	E11000	Basic non-invasive interface between Breathing Circuit and patient.
Mask Inflation Syringe[1]	E10996	Used to re-inflate mask if necessary.

[1] Items provided for convenience of user and may not be included in all kits. Please check with your distributor.

PREPARE FOR USE

To prepare the SAVe II for rapid deployment, operator must:

1. Unpack device
2. Verify required contents are packaged in kit
3. Verify debris filter is installed
4. Verify battery has adequate charge

Step 1: Unpack Device

Inspect the transport container for evidence of damage during transit. If damaged, notify the delivery service immediately. Carefully remove the ventilator and all accessories from the transport container. Confirm you have received all items listed on the packing slip. Notify an authorized sales representative or AutoMedx of any discrepancies. Examine the ventilator and accessories for visible damage. If damaged, notify AutoMedx. 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 Contents

INCLUDED IN SAVE II KIT		
QTY	**DESCRIPTION**	**PART NUMBER**
1 EA	Ventilator	M50012
1 EA	Breathing Circuit, Ruggedized, Disposable, Single- Use	M40105
1 EA	Air Intake Debris Filter, Disposable	F20053
1 EA	AC Power Supply / Battery Charger	E52240
1 EA	Power Cable (Type A)	E11021
1 EA	Mask and Inflation Syringe (included in some kits)	M40106
1 EA	Head Harness (4 point) (included in some kits)	E11001
1 EA	Attenuator (Sound Dampening U Shaped Tube), Reusable	M41112
1 EA	Oxygen Reservoir, Reusable	M40092
1 EA	Air Intake Cap	F20059
1 EA	Operator's Manual	M40100

Note: An airway is required for use but may not be included with kit. Operators must identify an airway appropriate for the situation and have it ready for use. The SAVe II should always be packaged with an airway that is appropriate based on the training of the provider and needs of the patient. Consult your medical director. Only use accessories approved by AutoMedx for use with the SAVe II. To verify if an airway is approved for use with the SAVe II, contact info@AutoMedx.com

The above list describes the configuration of the Standard, 70100H-US, Kit. The specifics of your configuration may vary based on the country or region of use and the specific requirements of your organization.

Step 3: Verify Debris Filter Installation

The DEBRIS FILTER (P/N: F20053) is intended to protect the internal components of the SAVe II system from dust, dirt and other particles. Two debris filters must be placed inside the "Air/O2 Intake" port of the SAVe II at all times.

The AIR INTAKE CAP (P/N: F20059) protects the Debris Filter from direct exposure to particles and water during storage and use when the Attenuator or O2 Reservoir is not being used. The notched edges of the air intake port allow air to flow to the patient even when the Air Intake Cap is in place. In particularly dusty or sandy environments the air intake cap should be used instead of the Attenuator.

Inspect the Air Intake Debris Filter prior to each patient use and replace if there is any sign of exposure to moisture, dust, sand or other debris. AutoMedx recommends replacing the debris filter after each patient use due to the austere environments in which the SAVe II is often used. The debris filter may require replacement less often if the device is not being used in particularly dirty or dusty environments.

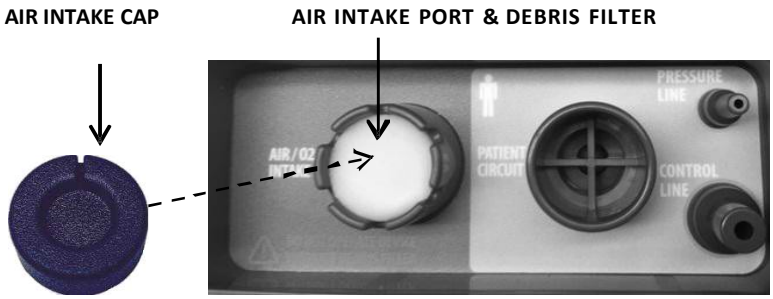


FIGURE 3: AIR INTAKE PORT, DEBRIS FILTER & PORT CAP

WARNING:

- Failure to properly maintain the debris filter can decrease delivered tidal volumes to the patient as well as lower the life expectancy of the unit due to increased workload on the pump motor.
- Immediately take device out of service if dust, sand or other debris have entered the internal SAVe II system. The delivered tidal volume may decrease significantly without alarming.
- Never operate the unit without a filter in place. Two clean Debris Filters must be in place at all times
- 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.
- Only use filters designed for the SAVe II. Using other filters may impact device performance.
- The AIR INTAKE CAP should be used when the Attenuator or O_2 reservoir is not being used.

Step 4: Charge Battery

The SAVe II is primarily powered by an internal lithium-ion battery. The battery is re-charged by connecting the SAVe II to external power (100 – 240 VAC, 50 – 60 Hz) via the AC POWER SUPPLY (P/N: E52240). When the SAVe II is connected to external power by the AC Power Supply it can simultaneously run and charge the internal lithium-ion battery. Please note that if the battery is completely discharged that in rare instances it may take a few minutes of charging before device has enough power to run.

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

TO OPERATE FROM EXTERNAL POWER AND RECHARGE THE BATTERY:	
1	Connect AC Power Supply to appropriate power source. (See POWER INPUT specifications on
2	Connect other end of AC Power Supply to Power Input Port. (See Illustration below)
3	Verify charge indicator light (lightning bolt icon) is illuminated.
4	Monitor charge status using Battery Level Indicator. Approximate charging time for a battery that is empty ➢ **1 hour** – 30% charged, ➢ **2 hours** – 60% charged, ➢ **3 hours** – 85% charged, ➢ **3:45 hours** – 100% charged. If the SAVe II is running, the charge time will increase 15% to 40% depending on the device settings. The unit is fully charged when the LED on the Power Supply turns green.

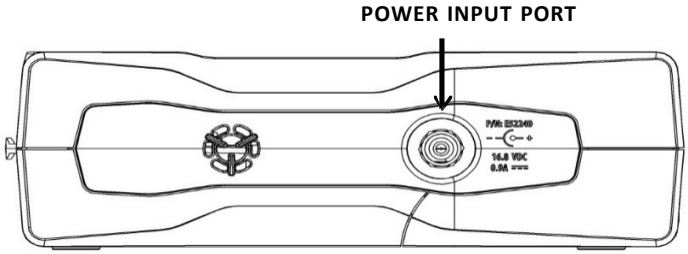


FIGURE 4: POWER INPUT PORT

CAUTION:

- The battery should only be replaced by qualified biomedical equipment technicians.
- Only use AC Power Supplies from AutoMedx or its authorized distributors. The SAVe II AC Power Supply has been carefully selected to meet all required standards for a medical device as well as for safely charging the SAVe II lithium ion battery.
- Use caution when connecting to unreliable power sources. When connecting the AC Power Supply, follow power input specifications of 100 – 240 VAC, 50 – 60 Hz.

USING THE SAVE II

- ✓ Setup for Use
- ✓ Manual Trigger Breaths
- ✓ Clear Breathing Circuit of Debris
- ✓ Alarms

Setup for Use

1. Connect Patient Breathing Circuit to unit
2. Verify proper operation
3. Connect Patient Breathing Circuit to Airway
4. Select ventilator parameters
5. Optional: Connect Supplemental Oxygen or Noise Attenuator
6. Monitor patient and respond to alarms (Refer to info on page 40)

Step 1: Attach Breathing Circuit

Prior to use, inspect the circuit to verify it has been assembled correctly (pictured below) with no visible signs of damage. Verify a Debris Filter has been placed inside the Breathing Circuit Demand Valve if using in particularly sandy or dusty environment. Do not "jam" the Debris Filter into the one-way valve of the Demand Valve. This may increase the inspiratory resistance of spontaneously breathing patients. The Demand Valve is meant to allow a patient to draw in ambient air if they begin to breathe spontaneously.

CONNECT THE SAVe II PATIENT BREATHING CIRCUIT BY:	
1	Locate an unused SAVE II PATIENT BREATHING CIRCUIT (P/N: M40105) in its original
2	Remove Patient Breathing Circuit from packaging.
3	Verify circuit is properly assembled with the Active Control Valve cap securely attached and no visible signs of damage.
3	Open the "Breathing Circuit Port Cover" located on the ventilator.
4	The three ports grouped together are different sizes. Work from largest to smallest. Connect the large grey tube to the port labeled Breathing Circuit. Connect the tube with a white end to the port labeled Pressure Line. Connect the small blue tube to the smallest port which is labeled Control Line.

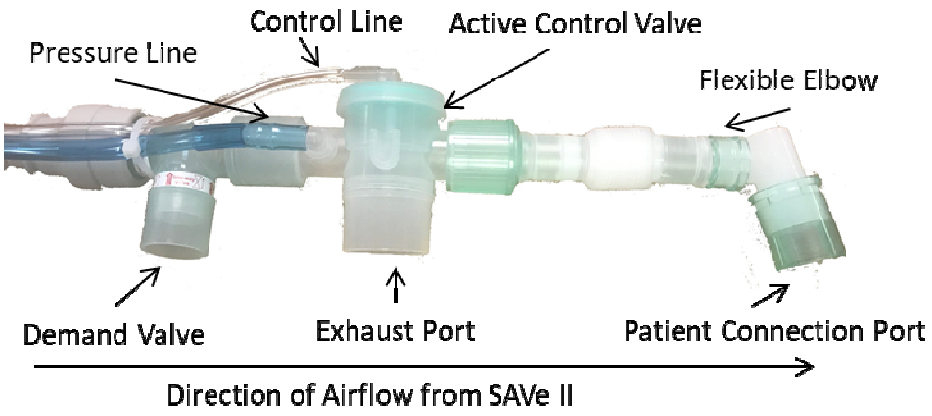


FIGURE 5: BREATHING CIRCUIT

WARNING:

- Do not block the BREATHING CIRCUIT EXHAUST PORT.
- If the Demand Valve is improperly connected the patient will not be able to breath spontaneously.
- The Demand Valve's two internal one-way valves must be oriented in the direction of airflow.
- Failure to properly connect the Breathing Circuit and accessories may materially impact device performance.
- Only use Breathing Circuits expressly approved by AutoMedx for use with the SAVe II Ventilator.
- Do not disassemble Patient Breathing Circuit unless required to do so to clear debris.
- Do not use damaged or misassembled Breathing Circuits.
- Always dispose of the circuit after each patient use following the institutional guidelines for biologically contaminated material. Reusing the circuit can result in cross contamination between patients.
- The Control and Pressure Lines of the SAVe II Breathing Circuit contain phthalates. These lines are not in the air pathway so the patient does not come into contact with phthalates.

Step 2: Verify Proper Operation

Verify basic functionality and safety of the SAVe II prior to each mission or immediately prior to use.

Test	Procedure	Acceptance Criteria
Verify Disconnect Alarm	1. Connect circuit to unit. **Do not connect to airway.** 2. Turn device on 3. Select and confirm any height preset	• Disconnect visual alarm indicator activates within 2 breaths and starts blinking • Audible alarm indicator activates • Pump continues to operate normally
Verify PIP Reached Alarm	4. Completely block "Patient Connection Port"	• PIP Limit visual alarm indicator activates within 1 breath and starts blinking • Pump turns off for a few seconds and then turns on briefly again until PIP Limit is reached again

WARNING: If the device fails the checkout, do not use and have it serviced immediately.

Step 3: Attach Airway

An airway is necessary to channel air from the Patient Breathing Circuit to the patient's lungs. The Breathing Circuit can be connected to a variety of airways using the standard 22mm O.D. / 15mm I.D. patient connection port. The SAVe II should always be packaged with an airway (Mask, King-LT, ET Tube, etc.) that is appropriate based on the training of the provider and needs of the patient. Read and follow separate airway Instructions for Use.

ATTACH AIRWAY BY:	
1	Attach/Secure airway to patient by following Instructions For Use of selected airway.
2	Attach Patient Breathing Circuit to Airway by connecting Patient Connection Port to Airway.
3	Verify the rise and fall of the chest as well as the absence of ALARMS.

FIGURE 6: PATIENT BREATHING CIRCUIT

WARNING: Do not use a mask with a filter and make sure any ports on the mask are sealed with a cap.

Step 4A: Select Adult Patient Height

Height presets were designed to enable minimally trained providers, who may otherwise use a BVM, to deliver a more targeted and consistent therapy than can be achieved with a BVM in the pre-hospital or transport environment. The provider simply selects the patient's height. Preset parameters are automatically dialed in as outlined in the below chart. This Basic Setup is quick and removes the guesswork and operator error associated with bagging patients in high stress environments or attempting to setup a more complex ventilator.

OPERATOR ACTION		EXPECTED DEVICE RESPONSE
1	Verify Proper Operation	See previous section
2	Select and confirm appropriate Preset based on patient height	Device activates using Preset Height parameters
3	Verify adequate chest rise and monitor Patient and Alarms	No active alarms (blinking). Refer to information on page 40 for details on how to respond to alarms.

Note:

- An alternate Height Preset button may be selected and confirmed at any time.
- Ventilator height presets may only be used on adult patients. Height presets are only a guide and do not replace clinical decision making. Ventilator parameters may need to be adjusted.
- MANUAL TRIGGER is always active. Be careful to avoid inadvertent operation.

HEIGHT (FT' IN")	HEIGHT (cm)	RR (BPM)	TV[1] (ml)	Minute Volume (LPM)	PIP (cmH_2O)	PEEP (cmH_2O)
4' 3"	129	20	250	5.0	30	0
4' 6"	137	21	250	5.3	30	0
4' 9"	145	21	260	5.5	30	0
5' 0"	152	20	300	6.0	30	0
5' 3"	160	18	340	6.1	30	0
5' 6"	168	16	380	6.1	30	0
5' 9"	175	15	420	6.3	30	0
6' 0"	183	14	470	6.6	30	0
6' 3"	191	13	510	6.6	30	0

[1] The Tidal volume presets were calculated using 6 ml/kg of a male patient's ideal body weight (IBW). The respiratory rate was set to achieve minute volumes between 5 and 6.6 liters depending on the size of the patient. Females receive on average 6.5 ml/kg of ideal body weight. The presets do not go below 250 ml so patients at 4'3" and 4'6" are receiving higher relative tidal volumes. Refer to the specifications on page 49 for the tolerances of each parameter. There is a look up table on the back of the device to help provider make further adjustments. This label is also included on page 17 of this manual.

Step 4B – Dial in Parameters (Advanced Users Only)

While the height presets enable Basic providers the ability to deliver a more targeted and consistent therapy than is possible with BVMs, an Advanced User can adjust the settings as necessary.

OPERATOR ACTION		EXPECTED DEVICE RESPONSE
1	Setup based on patient height	See previous section
2	Adjust ventilator parameters using +/- control buttons	The adjusted settings blink until the Confirm button is pressed. Until the Confirm button is pressed the unit operates at previously
3	Confirm selection	Display of desired setting transitions from blinking to solid and new settings become
4	Monitor patient and alarms	No active alarms (blinking). Refer to information on page 40 for details on how to respond to

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 – 10	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 MASK 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 a patient will only receive a breath when the caregiver provides one. The breath assist function (see page 41) is disabled when in Mask 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 Volume (TV x RR), the TV may be decreased (to avoid reaching the PIP Limit) and the RR may be increased.

WARNING: If PIP limit is reached, the SAVe II will cut the inspiratory phase short and less TV than indicated will be delivered to patient.

RR & TV Combinations

The SAVe II supports minute volumes of up to 8 LPM at an I:E ratio of 1:2. The cells marked with an "X" are combinations that exceed the pump's capabilities and therefore are not permitted. If an operator wanted to change the settings from 500 ml at 15 BPM to 400 ml and 17 BPM (both of which are permitted) the user would first decrease the tidal volume to 400 ml before increasing the respiratory rate to 17 BPM. Trying to increase the respiratory rate first isn't possible because the device does not support 17 BPM respiratory rate at a 500 ml tidal volume.

A visual (no audible) MV HIGH alarm indicator will activate if operator selects a RR/TV combination that results in I:E ratio of less than 1:2. 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 2: ALLOWED RR AND TV COMBINATIONS

RR / TV:	200	250	300	350	400	450	500	550	600	650	700	750	800
8													
9													
10													
11												X	X
12											X	X	X
13										X	X	X	X
14									X	X	X	X	X
15								X	X	X	X	X	X
16								X	X	X	X	X	X
17							X	X	X	X	X	X	X
18							X	X	X	X	X	X	X
19						X	X	X	X	X	X	X	X
20						X	X	X	X	X	X	X	X
21					X	X	X	X	X	X	X	X	X
22					X	X	X	X	X	X	X	X	X
23					X	X	X	X	X	X	X	X	X
24				X	X	X	X	X	X	X	X	X	X
25				X	X	X	X	X	X	X	X	X	X
26				X	X	X	X	X	X	X	X	X	X
27			X	X	X	X	X	X	X	X	X	X	X
28			X	X	X	X	X	X	X	X	X	X	X
29			X	X	X	X	X	X	X	X	X	X	X
30			X	X	X	X	X	X	X	X	X	X	X

Peak Inspiratory Pressure (PIP)

The PIP LIMIT controls the maximum acceptable pressure during the Inspiratory Phase before the pump shuts off and the PIP Reached alarm activates. When the PIP pressure limit is reached, the pump will cutoff to prevent over inflation and the unit will enter the exhalation phase. An audible and visual alarm indicator will active. The PIP limit is automatically set to 20 cmH_2O when entering RR is set to zero (MASK CPR Mode).

WARNING: Do not increase the preset PIP limit unless directed to do so by personnel with the required level of training. This is very important when using a mask, LMA or supraglottic airway devices because excessive airway pressure may direct air into the stomach causing gastric insufflation or serious complications.

WARNING: If PIP limit is reached, the SAVe II will cut the inspiratory phase short and less TV than indicated will be delivered to patient.

Positive End Expiratory Pressure (PEEP)

The SAVe II has the internal capability to maintain a set Positive End Expiratory Pressure (PEEP). The device may take up to 1 minute to reach the desired PEEP level after a confirmed change. The SAVe II is designed to safely reach targeted PEEP value by slowly incrementing PEEP with each breath. The SAVe II may take up to a minute to reach targeted PEEP value. PEEP is disabled in MASK CPR Mode.

WARNING: PEEP is contraindicated during CPR

DISPLAYING MEASURED PIP AND PEEP

When settings are confirmed and no changes are pending (i.e. the Confirm Indicators are not blinking), pressing the Confirm button will cause 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 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 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.

Step 5A: Connect Supplemental Oxygen (Optional)

The reusable OXYGEN RESERVOIR (P/N: M40092) allows the SAVe II to deliver up to 100% FiO_2 using a low flow supplemental oxygen source. The reservoir avoids wasting O_2 delivered by the low flow O_2 source during the device's exhalation phase by accumulating it for delivery in the inhalation phase. Simply connect the Oxygen Reservoir to the device as described below and then connect the low flow line to a flow regulated oxygen tank, a low-flow wall source or an oxygen concentrator capable of delivering between 0 and 10 LPM. Given the max minute volume of the SAVe II is 8 LPM any additional oxygen flow would spill out of the reservoir tube into the ambient air. The Oxygen Reservoir will also dampen the noise produced by the ventilator.

Do not delay therapy to connect supplemental O_2. Connect reservoir tube only after the ventilator is providing air to the patient.

Connect Low Flow Oxygen Source by:	
1	Remove Air Intake Cap from the "Air/ O_2 Intake" port. Store for later use. Do not remove
2	Attach reservoir's green connector to "Air/ O_2 Intake" port then fully extend the collapsible
3	Attach reservoir's low pressure O_2 line to flow regulated oxygen source.
4	Set flow regulated oxygen source to deliver between 0 – 10 LPM. Reference FiO_2 look up table below.

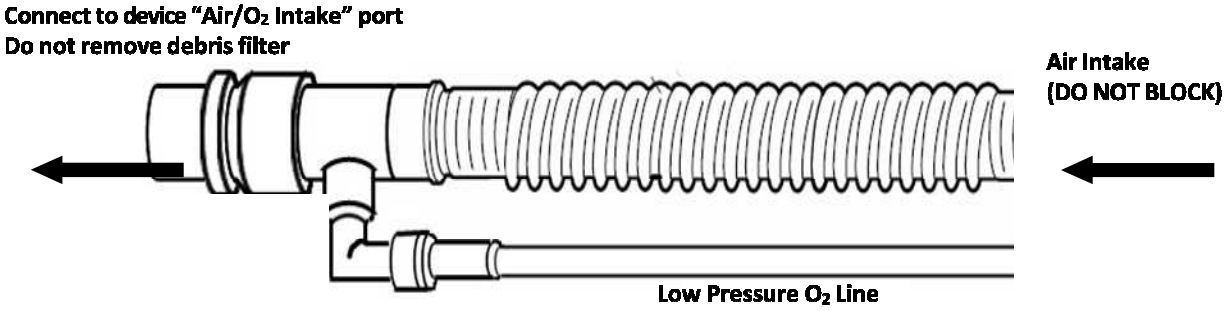


FIGURE 7: OXYGEN RESERVOIR

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

WARNING:

- The hose 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 explosive atmospheres or near open flame.
- Do not use flow rates greater than 10 LPM.

The desired FIO_2 is achieved by regulating the amount of O_2 delivered relative to the minute volume being produced by the ventilator. Use Table 3 below to determine the delivered FIO_2 % based on Minute Volume (RR x TV) and oxygen supply flow rate. For instance at a respiratory rate of 10 BPM and a tidal volume of 500 ml the device is delivering 5 LPM. Setting the O_2 source to deliver 3 LPM would result in a FIO_2 of approximately 68% (3L*100% + 2L*21%)/5LPM = 68%. The oxygen reservoir tube must be fully expanded to achieve the O_2 concentrations listed below. As a rule of thumb if you're ventilating a patient using any of the presets on the user interface delivering 2 LPM of O_2 will result in 40-50% FIO_2 and if 100% FIO_2 set the flow to 6.6 LPM.

Note:

- Setting the oxygen source flow rate higher than the minute volume of the ventilator will unnecessarily deplete oxygen supply faster.
- The below values are predicated on a fully expanded oxygen reservoir tube. Failing to fully extend the tube may material decrease FiO_2 values for a given O_2 flowrate.
- 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.

TABLE 3: DELIVERED FIO_2 % BASED ON MINUTE VOLUME AND SUPPLEMENTAL O_2 FLOW RATE

Minute Volume: O_2 Flow Rate:	2 L	3 L	4 L	5 L	6 L	7L	8L
1	60	47	40	36	33	31	**30**
2	100	74	60	52	46	43	**40**
3	100	100	80	68	59	54	**50**
4	100	100	100	84	74	66	**60**
5	100	100	100	100	87	77	**70**
6	100	100	100	100	100	89	**80**
7	100	100	100	100	100	100	**90**
8	100	100	100	100	100	100	**100**
9	100	100	100	100	100	100	**100**
10	**100**	**100**	**100**	**100**	**100**	**100**	**100**

Note: These values assume the O_2 tank or concentrator is delivering 100%.

Step 5B: Connect NOISE ATTENUATOR (Optional)

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 8. The attenuator is meant to be U shaped. Do not cut the fastener that holds the shape.

In order to keep the SAVe II small the attenuator which mitigates the sound of the ventilator 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. The attenuator is a small U shaped tube that has a small nipple on the end. 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 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. Do not cut the small cord holding the attenuator in a U shape. 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 sand storm the black Air Intake Port Cap will do a better job than an attenuator at guarding against particulates getting into the pump.

ATTACH ATTENUATOR BY:	
1	Remove the black Air Intake Port Cap (See Figure 3) from Air Intake Port.
2	Attach the Attenuator to Air Intake Port. Leave Debris Filters in place.
3	To avoid blocking the nipple at the end of the attenuator, orient it so that it faces into the port well.

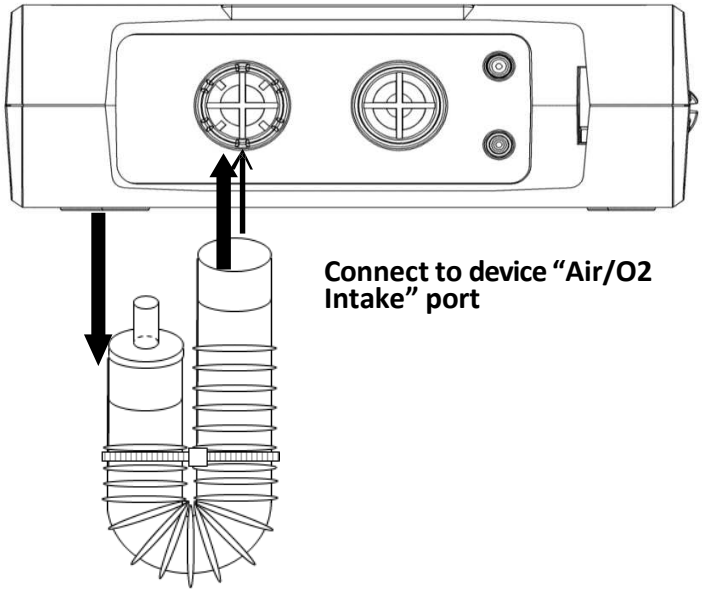


FIGURE 8: CONNECTING ATTENUATOR

WARNING: Do not occlude small nipple as this will dramatically decrease tidal volume.

WARNING: In particularly sandy or dusty conditions use the Air Intake Port Cap instead of the Attenuator.

Step 6: Monitor Patient and Respond to Alarms

Monitor the patient and verify adequate chest rise. Refer to information on page 37 for information on how to respond to alarms.

Manually Triggered Breaths

The Respiratory Rate of the device can be controlled manually by pressing the MANUAL TRIGGER button.

MANUALLY TRIGGERED BREATHS DURING NORMAL OPERATION

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.

MASK CPR MODE

MASK CPR MODE allows operators performing MASK CPR to give the specified number of compressions and then manually trigger breathes as directed by the American Heart Association guidelines. In MASK CPR MODE, the PEEP and PATIENT TRIGGERED BREATHS 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 and BREATH ALARM become active. To avoid stacking breaths, the button will only trigger a breath after the minimum exhalation time has elapsed.

Note:

- Heart LED blinks at compression rate of 100 per minute.
- Default PIP Limit is decreased to 20 cmH_2O for all heights in Mask CPR Mode but is still adjustable. This is intended to avoid air being directed to the stomach (gastric insufflation).
- If the Manual Trigger button is not pressed for 30 seconds “Breath” alarm will trigger indicating a breath needs to be delivered.
- To exit MASK CPR Mode, the user can select and confirm a height preset or non-zero respiratory rate.

	Operator 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 cmH_2O
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
5	Follow AHA Guidelines or protocol as directed by your Medical Director	➢ Device will only deliver breaths when MANUAL TRIGGER button is pressed ➢ BREATH ALARM indicator activates if breath not delivered for 30 seconds

WARNING:

- Operators must press 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.

Clearing Debris 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 then follow steps below.

CLEAR DEBRIS FROM BREATHING CIRCUIT BY:	
1	If an appropriate replacement circuit is available then replace active circuit with new circuit.
2	If a replacement circuit is not available then consider ventilating patient by other means.
3	Clear debris by removing Flexible Elbow and any other piece of the circuit as necessary to empty contents then reassemble and verify proper orientation. (See Figure 9)
4	Verify proper operation.
5	Reattach circuit to patient. Verify adequate chest rise and monitor pulse oximeter if available.

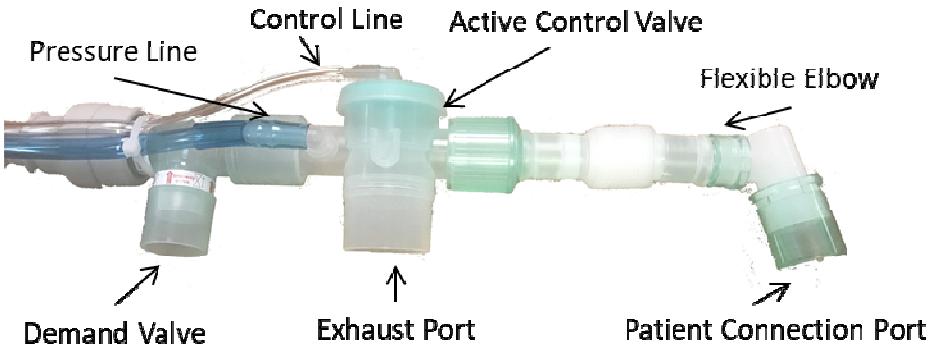


FIGURE 9: CLEANING A PATIENT BREATHING CIRCUIT

WARNING:

- Operators must verify Breathing Circuit has been reassembled correctly.
- If the Demand Valve is removed or modified it MUST be reassembled with the one-way valves oriented in the correct direction.
- Verify the Control Valve cap (connected to Control Line) is securely attached with the diaphragm properly seated.

Alarm Overview

The SAVe II has a number of alarms to alert the operator to potentially unsafe conditions. These alarms trigger 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:

- A Visual Alarm indicator flashes on and off and an Audible Alarm sounds (except the MV HIGH Alarm which is strictly a visual alarm).
- Depending on the alarm, the SAVe II may take other actions, such as terminating an inspiration or opening the exhalation valve.
- Pressing Mute will silence the Audio Alarm for 120 seconds.

When an Alarm condition clears:

- The AUDIBLE ALARM ceases.
- 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 should always be monitored and the operator should be prepared to ventilate with alternative method of ventilation.
WARNING: The absence of an alarm does not indicate the patient is receiving adequate ventilation. If the SAVe II is used for extended periods, it is recommended the operator monitor blood gases to ensure adequate gas exchange.

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. The high priority alarms repeat every 2.5 seconds.

LEVEL	AUDIBLE CHARACTERISTICS	ALARMS
High	*Beep*, Pause 100ms, *Bee*p, Pause 100ms, *Beep*, Pause 300ms, *Beep*, Pause 100ms, *Beep*, Pause 500ms…. Repeats every 2.5 seconds	➢ Disconnect ➢ PIP Reached ➢ Device ➢ High PEEP ➢ Battery < 5% capacity ➢ Breath
Medium	*Beep*, Pause 200ms, *Beep*, Pause 200ms…. Repeats every 7.5 seconds	➢ Breath Assist ➢ Battery <10% capacity
Low	*Beep*, Pause 200ms… Repeats every 20 seconds	➢ Battery <15% capacity

Alarm Quick Reference Guide

ALARM	CAUSE/TRIGGER	RESOLUTION	DEVICES RESPONSE
Disconnect	Inadequately connected circuit tubing Inadequate seal between patient and airway Blocked Intake Port or Attenuator Leak in Patient Breathing Circuit Dust, sand or debris inside device manifold	Pressure > 1 cmH_2O/110 ml of TV at end of inhalation AND Pressure increase during last 250ms of inhale is >= 1cmH_2O/120ml (*only when inhale flow rate is > 14Lpm and end inspiratory pressure is < 5cm*H_2O)	High Priority Alarm Continues to deliver breaths

ALARM	CAUSE/TRIGGER	RESOLUTION	DEVICES RESPONSE
PIP Reached	Patient airway pressure reached Peak Inspiratory Pressure Limit during inhalation	Full inhalation of the patient without reaching set PIP limit. Usually requires operator to increase PIP Limit or decrease tidal volume. To maintain constant minute volume offset any decrease in TV by increasing respiratory rate.	High Priority Alarm Enter exhalation phase when pressure limit reached Continues to deliver breaths
Battery	Various low battery thresholds (see Battery Indicator section)	Connect the device to approved external battery charger	At 15% of capacity last battery LED begins to flash. Low Priority Alarm for 30 seconds. At 8% of capacity Medium Priority Alarm for 30 seconds At or below 5% of capacity High Priority Alarm for 30 secs At 0% of capacity (running on Reserve Capacity) device will go into Low Battery Mode: - Discontinue breaths - Open Exhalation Valve - Therapy control indicators are cleared All button presses (except mute and power) are disabled The high priority audible alarm will sound.

ALARM	CAUSE/TRIGGER	RESOLUTION	DEVICES RESPONSE
Device	Device is outside of allowable temperature range OR Internal malfunction	Turn off unit and then back on. If the condition that triggered the alarm is still present, the alarm will reactivate. Refer to Device Alarms on page 43	High Priority Alarm Opens exhaust port Discontinues Ventilation
High PEEP	Measured PEEP > 5 cmH2O above set PEEP	Measured PEEP < 2 cmH2O above set PEEP level	High Priority Alarm Open exhaust port Discontinue breaths until condition cleared
MV High	A TV or RR increment button is pushed to a TV/RR combination that is not permitted	The device settings will not allow the selected TV or RR to change If changing TV & RR start with the one which is decreasing	MV High Visual Alarm No Audio Alarm Will not allow TV/RR combination
Breath **(Manual)**	30 seconds has elapsed since last manually triggered breath when RR is set to 0 (MASK CPR Mode)	Manually trigger a breath OR Increase RR to non-zero value	High Priority Alarm “Breath” alarm indicator activates
Breath Assist	Measured Airway Pressure > 2 cmH2O below set PEEP (Patient is spontaneously breathing)	None	“Breath Assist” alarm indicator activates. Patient’s inspiratory effort immediately triggers breath Deliver set TV at max pump flow rate

RESPONDING TO ALARMS

DISCONNECT ALARM

The Disconnect Alarm indicates the minimum pressure threshold has not been reached during the Inspiratory Phase of the ventilator. The ventilator will continue to operate and alarm until the condition is resolved.

Triggered when Airway Pressure is <1cmH_2O/110 ml of TV at end of inhalation or pressure increase during last 250ms of inhale is < 1cmH_2O/120ml (only checked when inhale flow is > 14LPM and end inspiratory pressure < 5cmH_2O).

Device responds by:

- Activating DISCONNECT visual alarm indicator and high priority audible alarm indicator
- Device will continue to actively ventilate

WARNING:

- The absence of an alarm does not indicate the patient is receiving adequate ventilation. It is recommended the operator monitor 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.

POSSIBLE CAUSE	WHAT TO DO
➢ Inadequately connected circuit tubing ➢ Inadequate seal between patient and airway ➢ Blocked Intake Port or Attenuator ➢ Leak in Patient Breathing Circuit ➢ Dust, sand or other debris inside device manifold	1. Verify Breathing Circuit tubing connections between SAVe II control unit and airway. 2. Verify mask or airway is tightly sealed to patient. Adjust seal pressure if necessary. 3. Verify nothing is blocking the device air intake which could prevent device from drawing in ambient air. 4. Replace Breathing Circuit (if available). 5. Ventilate by alternative means. 6. If 4 and 5 are not possible, listen/feel Breathing Circuit for leaks. Patch leak if found.

Resolved when measured pressure is > 1 cmH_2O/110 ml of TV at end of inhalation AND pressure increase during last 250ms of inhale is >= 1cmH_2O/120ml (only when inhale flow rate is > 14Lpm and end inspiratory pressure is < 5cmH_2O)

PIP REACHED ALARM

The PIP REACHED alarm will activate if 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. Except in MASK CPR MODE, the next breath will begin after the appropriate expiration time has expired. In MASK 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 responds by:

- Activating PIP REACHED visual alarm and high priority audible alarm
- Entering exhalation phase (cycling) when set pressure limit is reached

WARNING:

- If PIP limit is reached, the SAVe II will cut the inspiratory phase short and less than the stated TV will be delivered to patient.
- 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 of ventilation.

POSSIBLE CAUSE	WHAT TO DO
➢ Kinked Breathing Circuit ➢ Blocked airway ➢ Low patient lung compliance ➢ High patient airway resistance ➢ Vomitus in airway ➢ Tension pneumothorax ➢ Patient is actively exhaling during the inspiratory phase of the device (may be accompanied by Breath Assist and/or HIGH PEEP alarm)	1. Verify Breathing Circuit does not have kinks. 2. Verify correct placement of airway and that it is clear of obstructions. (See Page 33 for instructions on clearing debris). 3. Verify PIP limit and TV setting are appropriate. To maintain Minute Volume consider offsetting any decrease in TV by increasing the respiratory rate. 4. Verify patient does not have a tension pneumothorax. 5. Disconnect Breath Circuit from the patient airway. If alarm condition continues (blinking PIP REACHED indicator) then take the device out of service.

BATTERY ALARM

The BATTERY alarm activates when less than 10% of battery capacity remains. To resolve the alarm connect to an appropriate external power source.

Device response:

- At 10% of capacity:
  - Low Priority audible indicator activates for 30 seconds
  - Last battery LED begins to flash
- At 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 second
  - Last battery LED continues flashing
- At or below 0% of capacity (Reserve Capacity):
  - Device will go into Low Battery Mode for 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

POSSIBLE CAUSE	WHAT TO DO
➢ The battery charge has been depleted ➢ Battery has been stored for extended periods at high temperatures. ➢ Battery has reached the end of its useful life	1. Connect device to an external power source using SAVe II AC Power Supply. 2. Prepare to ventilate by alternative means if an external power source is not available. 3. Verify that the battery has been maintained properly. Refer to information on page 45.

Note: If the battery is disconnected, ONLY the Hazard indicator will illuminate 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 expected parameters. The Device Alarm is triggered when device is outside of specified temperature range OR a non-field correctible malfunction is detected.

Device responds by:

- Activating DEVICE visual alarm indicator and high priority audible alarm indicator.
- Stops ventilating (cycling)
- Opens the Exhaust Valve to allow patient to spontaneously breath with minimal resistance
- Displays a Device error code in the tidal volume (TV) Display

If an error code is observed turn the device off then on to clear transient alarms. If this does not address the problem 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 cmH2O above set PEEP. Alarm is resolved when measured PEEP is < 2 cmH2O above set PEEP level.

POSSIBLE CAUSE	WHAT TO DO
➢ Exhalation Port blocked ➢ Patient not synchronizing with ventilator	1. Clear blockage from Exhalation Port. 2. Adjust RR or consider manually trigger breaths 3. If Patient is spontaneously breathing consider sedating patient or stopping ventilation as directed by medical director. 4. Disconnect Breath Circuit from the patient airway. If alarm condition continues take the device out of service.

MV HIGH ALARM

The combination of TV/RR requires a flow rate that exceeds the pumps ability to deliver at an I:E ratio of 1:2. The device will not permit operator to select these TV/RR combinations. Refer to information on page 27.

POSSIBLE CAUSE	WHAT TO DO
➢ Attempted to select RR & TV combination that would have resulted in a minute volume greater than 8 LPM	1. Select TV/RR combination that results in minute volume of no more than 8 LPM see Table 2. 2. If one parameter is being adjusted up and the other down, start by adjusting the parameter moving down. For instance, if moving to higher respiratory rate (10 → 16 BPM) and lower volume (600 → 400 ml), reduce TV before increasing RR. Otherwise the device will not let you increase the RR beyond 13 BPM because that is the highest rate supported at 600 ml.

BREATH ALARM

POSSIBLE CAUSE	WHAT TO DO
➢ Device is in MASK CPR mode (RR = 0) and 30 seconds have elapsed since last manually triggered breath	1. Press MANUAL TRIGGER if a breath is indicated. 2. Increase RR above 0 to exit MASK CPR mode if indicated.

BREATH ASSIST ALARM

POSSIBLE CAUSE	WHAT TO DO
➢ Patient inspiratory effort was detected (spontaneous breathing) and triggered breath assist ➢ CPR chest compressions have triggered breath assist	1. If patient is not synchronizing with ventilator, consider removing patient from ventilator if patient is able to breathe adequately. 2. If performing chest compressions, consider putting the ventilator into MASK CPR Mode.

MAINTENANCE

- ✓ Maintenance Schedule
- ✓ Battery Maintenance
- ✓ Cleaning
- ✓ Replace Consumables
- ✓ Storage
- ✓ Scheduled Maintenance

WARNING: Failure to follow maintenance instructions could result in damage to the ventilator. This could reduce the life of the unit or lead to potential harm to the patient.

Maintenance Schedule

The SAVe II ventilator is designed to operate with minimal maintenance. However, the device should be annually calibrated by an authorized service representative.

	PERFORMED BY:		WHEN:		
PROCEDURE	MEDIC	BMET	BEFORE USE	AFTER USE	ANNUALLY
Charge	x	x	x	x	x
Clean	x	x	x	x	x
Verify Functionality	x	x			x
Verify Performance		x			x

Battery Maintenance

Runtime on a single battery charge depends on multiple factors: 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 battery is fully charged, the SAVe II will run for 10 hours when set to 500 ml and 10 BPM.[1]

BATTERY CHARGE RETENTION	21°C (70°F)	45°C (113°F)
1 Month	97%	92%
3 Months	94%	87%
6 Months	93%	83%
12 Months	90%	76%

[1] Test conditions: Lung Resistance 5 $cmH_2O/L/sec.$, Compliance 0.02 L/cmH_2O, Settings: Respiratory rate 10, Tidal Volume 500 ml, Peak Inspiratory Pressure 40 cmH_2O, PEEP 0 cmH_2O, at room temperature and humidity on a 2400mAh battery is 10 hours and on the 2800 mAh battery 12 hours.

All batteries degrade over time. The below chart shows you how much of the battery's potential can be recovered after a period of storage. If the battery will be stored at high temperatures store with 50% charge.

CHARGE RECOVERED	100% STORAGE CHARGE		50% STORAGE CHARGE	
Storage Temperature	**6 Months**	**12 Months**	**6 Months**	**12 Months**
21°C (70°F)	98%	96%	99%	99%
45°C (113°F)	92%	87%	97%	97%

CLEANING

Keep the SAVe II and its accessories clean at all times. The SAVe II ventilator should never be disassembled in the field. The following components may be cleaned as needed between uses:

- Control Unit
- O_2 Reservoir
- Attenuator
- Carrying Case

CONTROL UNIT

All SAVe II external surfaces should be cleaned before and after each patient use and as may be required. Wipe the exterior surfaces of SAVe II (including the inside of the port cover) with a clean, damp cloth. The use of methylated spirits is acceptable. Be sure to 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 delivered to the patient.

Single-Use Accessories – Do not attempt to clean or re-use single use accessories.

Outside Accessories – Refer to accessories instructions for use for cleaning procedures.

Cleaning Agents – 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.

Immersion – 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 and return to appropriate service facility for inspection. DO NOT expose the switch, external power jack, or audible alarm port directly to liquids.

Auto-Clave – Never expose to an autoclave.

REPLACE CONSUMABLES

The following SAVe II Accessories are intended for use on a single patient and should be replaced following each use:

- Patient Breathing Circuit
- Debris Filter
- Mask (If used)

WARNING: Serious harm to the patient may result from the use of unauthorized parts or accessories. To ensure proper performance of the ventilator, only use accessories approved by AutoMedx.

WARNING: Serious harm to the patient may result from the use of unauthorized parts or accessories. To ensure proper performance of the ventilator, only use accessories approved by AutoMedx.

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.

DEBRIS FILTER

The debris filter should be replaced with a new filter following each use. If the debris filter becomes damaged or soiled during use, replace it with a new debris filter and reattach Intake Port Cap, Attenuator or O_2 Reservoir. If the debris filter is soiled remove the filter while the device is upside down so that any loose debris falls out instead of in the unit. If sand or dust get past the debris filter discontinue use and have it serviced.

MASK

The mask included in the SAVe II Kit (P/N: 70100) should be replaced following each use.

STORAGE

The SAVe II should be stored as a complete kit in a state of readiness. AutoMedx recommends storing in the device's hard case which is water, dust and sand proof. The SAVe II CARRYING CASE (P/N: F20055) is designed to protect the SAVe II and its accessories during transport, shipping overseas and storage especially in sandy, dusty or wet environments. This case is rated IP67 indicating complete protection from dust and protection from immersion in water up to 1 m. In addition, the case is designed to float to avoid immersion.

FIGURE 10: CARRYING CASE

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 high temperatures for extended durations.

SCHEDULED MAINTENANCE

Automedx recommends performing service annually to verify the device continues to operate within specification. If the device is used in Extreme Environments or is exposed to dust, sand or water then maintenance should be performed more frequently.

APPENDIX A– SPECIFICATIONS[1]

Ventilator Parameters		Operating Modes:	Continuous Mandatory Ventilation (CMV)
		Primary Control:	Time
		Secondary Control:	Pressure
		Breath Target:	Volume
	Rate	Flow Rate (LPM):	Up to 24
		Breath Rate (BPM):	8 – 30
	Pressure (cmH_2O)	Peak Inspiratory Pressure (PIP) Limit	10 - 60
		Positive End Expiratory Pressure (PEEP)	0 - 10 (±2cmH_2O)
		Inspiratory Trigger Pressure	2
		Inadvertent PEEP	< 2
		Sensor Range	-60 to +60
	Volume (ml)	Tidal Volume	200 – 800
		Minute Volume	1600 – 8000
		Dead Space	< 100
	Time (Seconds)	Inspiratory	0.67 – 2.50
		Expiratory	1.30 – 5.00
		I:E Ratio	1:2
	Resistance (cmH_2O)	Inspiratory	< 6.0 cmH_2O/L/sec
		Expiratory	< 6.0 cmH_2O/L/sec
	Supplemental Oxygen	Input Flow Rate:	0 – 10 LPM
		FIO_2:	21-100%
	Operating Time[3]:	TV=500, RR=10, PEEP=0	2400 mAh battery 10 hours | 2800 mAh battery 12 hours
		TV=600, RR=10, PEEP=0	2400 mAh battery 8.5 hours | 2800 mAh battery 10 hours
Measured Values	Pressure	Peak Inspiratory Pressure (PIP)	0 – 60 (±2 cmH_2O, or 10%)
		Positive End Expiratory Pressure (PEEP)	0 – 60 (±2 cmH_2O, or 10%)
Power	External Battery Charger	Input:	100 – 240 VAC / 50-60 Hz
		Output (Li-Ion charger):	16.8 VDC @ 0.9A
	Control Unit	Input:	16.8 VDC @ 0.9A
Environmental	Temperature Ranges	Operating – Normal:	0 to 50°C (32 to 122°F)
		Operating – Extreme:	-10 to 50°C (23 to 122°F)
		Storage - Short-Term:	0 to 40°C (32 to 104°F)
		Storage - Long-Term:	0 to 30°C (32 to 86°F)
		Charging	0 to 45°C (32 to 113°F)
	Humidity	Operating:	15% – 95% RH (non-condensing)
		Storage:	15% to 85% RH (non-condensing)
	Atmospheric Pressure		700 – 1100 hPa
	Shock & Vibration		IEC 60068-2-6 and 60068-2-36
	Ingress	Unit only without protection	IP24
		Within Hard Case	IP67
Other	Audible Alarm		Meets 60601-1-8 IEC Standard
	Dimensions:	Size:	6.5" x 6.25" x 2.0" (81 in^3)
		Weight (Unit Only):	2.6 lbs. (1.2 kg)
		Weight (Kit with Hard Case)	9.7 lbs. (4.4 kg)
	Product Life	Control Unit	5 years
		Breathing Circuit	1 year
		Other Accessories	See accessory labeling
	Warranty:	Device	3 years
		Battery	1 year

Footnote

[1] All specifications include a tolerance of ±10% of nominal value unless stated otherwise. Test conditions available upon request.
[2] Delivered Tidal Volume may be materially affected by very low lung compliance (< 0.01 L/cmH_2O)
[3] Change to higher capacity battery was made in July 2016. The 5'9" preset will run approximately 10 hours with the new battery.

APPENDIX B – REGULATORY INFO/CLASSIFICATION/ LIMITED WARRANTY

Protection/Insulation class (electric shock)	Class II
Medical device directive classification	Class IIb
Degree of protection against risk of electric	BF
Power	External (AC – mains) or internal (DC – battery)
Operation mode	Continuous Operation

ELECTROMAGNETIC EMISSIONS AND IMMUNITY

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The SAVe II Portable Ventilator is intended for use in the electromagnetic environment specified below. The customer or the user of the SAVe II Portable Ventilator should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment – Guidance**
RF Emissions CISPR 11	Group 1	The SAVe 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	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The SAVe II Portable Ventilator is intended for use in the electromagnetic environment specified below. The customer or the user of the SAVe II Portable Ventilator should assure that it is used in such an environment.			
Immunity Test	**IEC60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	±6kV Contact ±8kV 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	20 V/m 80MHz to 2.5GHz	Complies	Field strengths outside the shielded location from fixed RF transmitters, as determined by an electromagnetic sit survey, should be less than 3 V/m. Interference may occur in the vicinity of equipment marked with the following symbol:
Conducted RF IEC 61000-4-6	3Vrms 150kHz to 80MHz	Complies	
Electrical fast transient IEC 61000-4-4	±2kV power line ±1kV I/O lines	Complies	 Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV Differential ±2kV common	Complies	
Power frequency magnetic field IEC 61000-4-8	3 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	>95% dip 0.5 cycle 60% dip 5 cycles 70% dip 25 cycles 95% dip 5 sec.	Complies	Mains power quality should be that of a typical commercial or hospital environment. If the user of the SAVe II requires continued operation during power mains interruptions, it is recommended that the SAVe II be powered from an uninterruptible power supply or battery.

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, as noted above, 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.

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.

APPENDIX C – PRINCIPLES OF OPERATION

The SAVe II is a completely self-contained, small, light-weight, rechargeable battery powered device intended to provide controlled, positive pressure ventilation to a patient. It is a time cycled pressure limited volume targeted ventilator. The SAVe II will monitor the patient's airway pressure and provide alarms for key events such as but not limited to: disconnect, high pressure, and device malfunction. The SAVe II uses a single-patient-use breathing circuit to connect to the device on one end and to the patient interface on the other end. The breathing circuit on the patient end uses an industry standard 15/22 mm connector to facilitate connection with an appropriate breathing mask, airway, or tracheal (breathing) tube. On the ventilator end, the breathing circuit has 3 connections: 1) The main tube to deliver air to the patient; 2) The pressure line to monitor the patient pressure; and 3) the control line to activate the exhaust port. The SAVe II user interface is intended to provide as few user interactions as possible. Quick selection buttons are organized in an arc-shaped graphic which allows quick selection of appropriate default ventilator settings based on the patient's height, ranging from 4'3" to 6'3". After selecting the patient's height, pressing the Confirm button will start the device in "Ventilation" mode. This "Adult Presets" section is intended both for Basic Users as well as making initial setup minimal. When desired an Advanced 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 "MASK CPR" mode by setting the RR to zero (0). In "MASK CPR" mode, the ventilator will only deliver a breath to the patient after the user has pressed the Manual Trigger button.

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

When the PIP Limit is reached, the SAVe II will automatically cut the pump off and move into the exhalation phase of the breathing cycle to prevent harm to the patient. When desired by an Advanced User, expiration pressure is also regulated to provide a slightly positive end expiratory pressure (PEEP). The SAVe II will also provide a breath if the patient spontaneously inspires (Spontaneous Breath). The device detects patient inspiratory effort by monitoring airway pressure. The device will respond in less than 250 ms to a pressure drop greater than 2 cmH_2O below set PEEP.

In "MASK 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 it is expected that a mask may be used as the

airway of choice and 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 MASK 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 through the use of a low-flow oxygen source (less than 10 L/min) and a 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. A chart on page 30 guides the user to an appropriate oxygen flow rate depending on the TV, RR and FIO_2 desired.

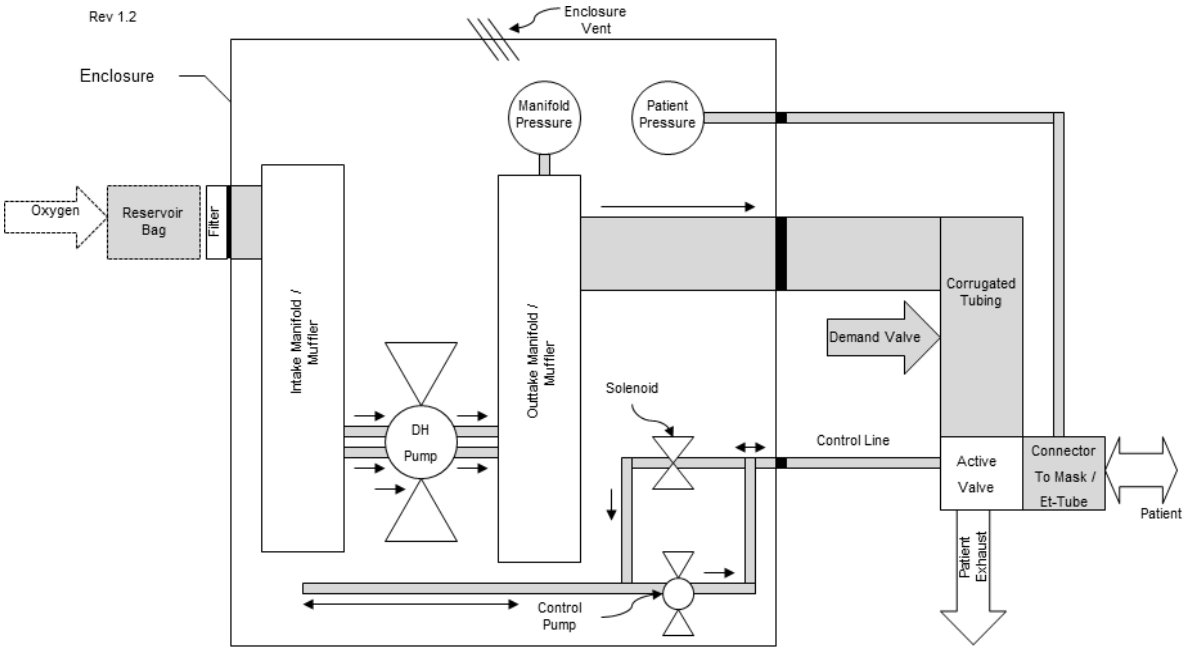


FIGURE 11: PNEUMATIC DIAGRAM

APPENDIX D - RE-ORDER INFORMATION

Item	Part Number	Per Package
SAVe II Kits[1]:		
SAVe II Kit with Hard Case, English, Type A Plug (USA)	70100H-US	1
SAVe II Kit with Hard Case, Metric, English, Type A Plug (Canada/Mexico)	70100H-CA	1
SAVe II Kit with Hard Case, Metric, English, Type C Plug (Europe)	70100H-EU	1
SAVe II Kit with Hard Case, Metric, Danish, Type C Plug (Denmark)	70100H-DK	1
SAVe II Kit with Hard Case, Metric, Swedish, Type C Plug (Sweden)	**70100H-SE**	**1**
SAVe II Kit with Hard Case, Metric, English, Type G Plug (UK/ME/Africa)	70100H-UK	1
SAVe II Kit with Hard Case, Metric, English, Type G Plug (Singapore)	70100H-SG	1
SAVe II Unit[2]	M50012	N/A
SAVe II Unit[2], Metric	M50013	N/A
Consumables:		
Patient Ventilator Circuit, Disposable, Single-Use, SAVe II, Case of 10[3]	M40105-10	10
Mask and Inflation Syringe, Adult Medium, Case of 10[4, 5, 6]	M40106-10	10
Head-harness, Case of 10[6]	E11001-10	10
Resupply Kit, Incl. 2ea Debris Filter and 1ea Intake Cover, SAVe II, Package of 5	M41113-5	5
Oxygen Reservoir, SAVe II, Package of 5[3]	M40092-5	5
Noise Attenuator, SAVe II, Package of 5[3]	M41112-5	5
Air Intake Debris Filter, Disposable, SAVe II, Package of 50	F20053-50	50
Battery Replacement Kit, SAVe II[7, 8]	M40116	1
Accessories:		
AC Power Supply / Battery Charger, SAVe II, Type A Plug	M40090-A	1
AC Power Supply / Battery Charger, SAVe II, Type C Plug	M40090-C	1
AC Power Supply / Battery Charger, SAVe II, Type G Plug	M40090-G	1
Power Cord, Type A, (USA, Canada, Mexico, Japan) SAVe II	E11021	1
Power Cord, Type C, (Europe, Asia, South America, Iran) SAVe II	E11106	1
Power Cord, Type G, (UK, Middle East, Malaysia, Singapore) SAVe II	E11105	1
Hard Case, SAVe II	F20055	1
Labelling:		
Operation Manual, English, SAVe II	M40100-EN	1
Operation Manual, Swedish, SAVe II	M40101-SE	1
Operation Manual, Danish, SAVe II	M40101-DK	1
Preventive Maintenance Manual, English, SAVe II	M40101-EN	1

[1] The standard SAVe II kit includes 1ea SAVe II, 1ea SAVe II Patient Circuit, 1ea Hard Case, 1ea AC / Battery Charger, 1ea Oxygen Reservoir, 1ea Noise Attenuator, 1ea Patient Mask, 1ea Mask Inflation Syringe, 1ea Universal Head harness, 1ea Operator Manual
[2] The SAVe II unit is only available for sale in a kit
[3] Labeling in English unless specified otherwise
[4] Mask labelling indicates alternative manufacturer part number 1055
[5] The mask and syringe are only resupplied as a set
[6] Item provided for convenience of user and may not be available in certain markets
[7] Includes battery and required replacement hardware
[8] **Shipments of lithium-ion batteries without equipment:** Domestic shipments by ground only. International air shipments limited to quantity 4ea per shipment.

APPENDIX E – SOFTWARE RELEASE HISTORY

Release	Effective Date	Description of Change
R1.0.2	June 12, 2015	➢ Initial release
R1.0.3	November 9, 2015	➢ Removed device alarm when battery temperature is below 0 (zero) degrees C
R1.0.4	June 10, 2016	➢ Displays software version on start-up ➢ PIP & PEEP Display by hitting Confirm ➢ Improve fault tolerance ➢ Chirp when powering off ➢ Improve recovery from low battery ➢ Improve "Charge Level" reporting of Battery Charger LED
R1.0.5	July 20, 2016	➢ Improves device ease of use by automatically releasing PEEP (if enabled) when the device is switched into Manual Trigger mode.