



**Homeland
Security**

Science and Technology

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System Assessment and Validation for Emergency Responders

The U.S. Department of Homeland Security (DHS) established the System Assessment and Validation for Emergency Responders (SAVER) Program to assist emergency responders making procurement decisions.

Located within the Science and Technology Directorate (S&T) of DHS, the SAVER Program conducts objective assessments and validations on commercial equipment and systems, and provides those results along with other relevant equipment information to the emergency responder community in an operationally useful form. SAVER provides information on equipment that falls within the categories listed in the DHS Authorized Equipment List (AEL).

The SAVER Program is supported by a network of technical agents who perform assessment and validation activities. Further, SAVER focuses primarily on two main questions for the emergency responder community: "What equipment is available?" and "How does it perform?"

For more information on this and other technologies, contact the SAVER Program Support Office.

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Summary

Pre-Hospital Ventilators

(AEL reference number 09ME-02-VENT)

Ventilators are positive pressure devices that deliver regulated volumes of air and supplemental oxygen to patients requiring respiratory support. The concentration of air and oxygen can be adjusted as needed with each breath and with the number of breaths per minute. Pre-hospital ventilators are used during emergency response operations and for ground or air transport.

In order to provide responders with information on currently available pre-hospital ventilators, Science Applications International Corporation conducted a comparative assessment of these devices for the System Assessment and Validation for Emergency Responders (SAVER) Program in May 2012. Detailed findings are provided in the *Pre-Hospital Ventilators Assessment Report*, which is available by request at <https://www.rkb.us/saver>.

Assessment Methodology

Prior to the assessment, eight emergency medical technicians and paramedics were chosen from various jurisdictions to participate in a focus group. The group identified evaluation criteria and recommended product selection criteria and possible scenarios for assessment.

After identifying evaluation criteria, the focus group assigned each criterion to one of five SAVER categories, and then assigned a weight for its level of importance. Once the criteria were weighted, the five SAVER categories were assigned a percentage value to represent the level of each category's importance relative to the other categories.

Based on focus group recommendations, market research, and system availability, the following pre-hospital ventilators were selected for assessment:

- AutoVent™ 3000, Allied Healthcare Products Inc.;
- Simplified Automated Ventilator (SAVe™), AutoMedx Inc.;
- AEV® Automatic Emergency Ventilator, Impact Instrumentation Inc.; and
- MCV200 Portable Ventilator, Allied Healthcare Products Inc.



Eight responders served as evaluators for this assessment. All evaluators had received Emergency Medical Technician—Intermediate or Paramedic certification or licensure by a national or state agency, and had at least 8 years of professional experience providing advanced adult and pediatric patient airway management.

During the assessment, evaluators rated the pre-hospital ventilators based on evaluation criteria established by the focus group. The assessment was separated into two phases: the specification assessment and the operational assessment. Evaluators assessed the systems based on vendor-provided information during the specification assessment. Hands-on experience using the pre-hospital ventilators during four scenarios served as the basis for the operational assessment. Mannequins were used to simulate adult patients during each of the scenarios.

Assessment Results

Table 1 displays the composite assessment scores as well as the category scores for each pre-hospital ventilator. Higher scores indicate a higher rating by evaluators. For specifications, see table 2. The advantages and disadvantages of each pre-hospital ventilator, as identified by evaluators, are listed in table 3. To view how each pre-hospital ventilator scored against the evaluation criteria assigned to the SAVER categories, see table 4.

An analysis of evaluator comments and scores revealed the following common observations concerning the assessed pre-hospital ventilators:

- Evaluators placed a high value on pre-hospital ventilators that are intuitive and easy to use.
- Evaluators expressed a strong preference for pre-hospital ventilators capable of operating in a wide range of environments.
- Evaluators preferred pre-hospital ventilators with dual settings that allow the unit to be used on both adult and pediatric patients.
- Evaluators placed a high value on pre-hospital ventilators that are sensitive to changes in airway pressure.
- Evaluators expressed a strong preference for pre-hospital ventilators that can be easily deployed due to being compact, lightweight, and/or mountable.
- Evaluators preferred pre-hospital ventilators that are reasonably priced and have low maintenance costs.
- Evaluators placed a high value on pre-hospital ventilators that can be easily cleaned.
- Evaluators expressed a strong preference for pre-hospital ventilators that include a warranty.
- Evaluators placed a high value on pre-hospital ventilators that have lengthy run times and reduced charge times.
- Evaluators expressed a strong preference for pre-hospital ventilators that include audio and visual alarms.

Responder agencies considering the purchase of a pre-hospital ventilator should review the detailed findings in the *Pre-Hospital Ventilators Assessment Report* and carefully consider each device’s overall capabilities and limitations in relation to their jurisdiction’s operational needs. All reports in this series, as well as reports on other technologies, are available in the SAVER section of the Responder Knowledge Base (RKB) website, <https://www.rkb.us/saver>.

SAVER Category Definitions
Affordability groups criteria related to life-cycle costs of a piece of equipment or system.
Capability groups criteria related to the power, capacity, or features available for a piece of equipment or system to perform or assist the responder in performing one or more relevant tasks.
Deployability groups criteria related to the movement, installation, or implementation of a piece of equipment or system by responders at the site of its intended use.
Maintainability groups criteria related to the maintenance and restoration of a piece of equipment or system to operational condition by responders.
Usability groups criteria related to the quality of the responders’ experience with the operational employment of a piece of equipment or system. This includes the relative ease of use, efficiency, and overall satisfaction of the responders with the equipment or system.

Table 1. Pre-Hospital Ventilator Assessment Results

Product	Composite Score	Affordability (15% Weighting)	Capability (25% Weighting)	Deployability (10% Weighting)	Maintainability (10% Weighting)	Usability (40% Weighting)
AutoVent™ 3000	3.6	3.1	3.3	4.3	3.0	4.0
SAVe™	3.6	2.9	3.3	4.5	3.0	4.0
AEV®	3.3	2.7	3.8	3.2	3.0	3.3
MCV200	3.0	2.9	3.3	2.6	2.7	3.0

Table 2. Pre-Hospital Ventilator Specifications¹

Specifications	AutoVent™ 3000	SAVe™	AEV®	MCV200
Flow rate	16 to 48 L/min	6 L/min	0 to 100 L/min	12 to 36 L/min
Tidal volume	400 to 1,200 mL	600 mL	50 to 1,500 mL	200 to 1,200 mL
FIO ₂ (percentages)	100	21, 65, 100	21 to 100	21, 65, 100
Frequency	8 to 20 bpm	10 bpm (preset)	1 to 60 bpm	8 to 20 bpm
Dimensions (L x W x H)	3.5 x 6.0 x 1.8 in.	6.5 x 6.3 x 2.5 in.	8.0 x 12.5 x 4.5 in.	14.5 x 10.3 x 3.5 in.
Weight	1.5 lbs	3.0 lbs	9.5 lbs	17.2 lbs
FDA approval	November 1993	September 2007	April 2011	May 2009

Notes:

¹ Information was provided by manufacturers and has not been independently verified by the SAVER Program.

bpm = beats per minute

FDA = U.S. Food and Drug Administration

FIO₂ = fraction of inspired oxygen

H = height

in. = inches

L = length

lbs = pounds

L/min = liters per minute

mL = milliliter

W = width

Table 3. Pre-Hospital Ventilator Advantages and Disadvantages





Product	Advantages	Disadvantages
 <p>AutoVent™ 3000 Composite Score: 3.6</p>	<ul style="list-style-type: none"> • Can be used on both adult and pediatric patients • Well suited for emergency response and transport • Simplistic use • Minimal training required for use • All pneumatic; no battery or electronic power source required • Rugged, lightweight, and compact • Rugged circuit; difficult to kink • PEEP valve available as an assembly • Reasonable initial cost • Low maintenance costs • Easily deployed 	<ul style="list-style-type: none"> • Labeling of control knobs • Unable to operate without oxygen • Minimal alarms; no low pressure alert or notification • No extended warranty available; no replacement or loaner units provided

Table 3. Pre-Hospital Ventilator Advantages and Disadvantages (Continued)

Product	Advantages	Disadvantages
 <p>SAVe™ Composite Score: 3.6</p>	<ul style="list-style-type: none"> Well suited for pre-hospital response Simplistic use Small learning curve Battery powered with 5.5-hour run time Will operate without compressed gas Durable; designed for forward combat life-savers Automatic shutoff; prevents overpressure or over insufflations Tactical mode; allows user to turn off audible and visual alarms Inexpensive initial cost 1-year warranty; extended warranty available Loaner units available Low maintenance costs Lightweight, compact, portable Rapid deployment time Easily decontaminated No software updates needed 	<ul style="list-style-type: none"> Fixed ventilator; only for apneic patient Preset settings; unable to change or customize (e.g., tidal volume, rate, etc.) Only administers 600 mL; cannot be used on patients weighing less than 100 pounds 14-hour charge time; slow trickle charge
 <p>AEV® Composite Score: 3.3</p>	<ul style="list-style-type: none"> Well suited for critical care transport Capable of operating without a compressed gas source Sensitive to change in airway pressure Easy to troubleshoot 10-hour battery life High operating temperatures Audible and visual alarms Customizable settings Allows for spontaneous breathing Extra features (e.g., waveform display, safety features, multi-step processes) Good in-service training/DVD 	<ul style="list-style-type: none"> Requires moderate level of training; not an entry level unit Selector knob slippage CPAP mode required for manual breath to work Initial cost Carrying case not included Operating manual not included; \$27 additional cost Loaner unit provided based on availability Maintenance costs Extended warranty costs Poor handle; no straps to tie to stretcher
 <p>MCV200 Composite Score: 3.0</p>	<ul style="list-style-type: none"> Operates independently on compressed gas or will operate on battery with room air Automatically changes to room air if compressed gas is depleted Audio and visual alarms Can be used on both adult and pediatric patients Will accept CBRNE air filter/cartridge; can be used in hazardous environments Straps included to secure unit to stretcher 	<ul style="list-style-type: none"> Labels for adult settings should be larger and brighter Heavy and cumbersome No security locks; controls easily unintentionally adjusted Lag time in adjustment knobs No values on electronic control knobs Difficult to read color on pressure gauge No legend on screen; difficult to see in low light Slow to respond to changes in air pressure High pressure alarm reads from 0 to 80 psi; only works from 0 to 20 psi; does not alarm between 20 and 80 psi Straps not attached or durable; can be easily lost Initial cost

Notes:

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|-------|---|--|------|---|----------------------------------|
| CBRNE | = | chemical, biological, radiological, nuclear, and explosive | mL | = | milliliter |
| CPAP | = | continuous positive airway pressure | PEEP | = | positive end expiratory pressure |
| DVD | = | Digital Versatile Disc | psi | = | pounds per square inch |

Table 4. Pre-Hospital Ventilator Criteria Ratings¹

KEY					
Least Favorable		Most Favorable			
	    	AutoVent™ 3000	SAVe™	AEV®	MCV200
Affordability					
Value for cost					
Replacement parts costs					
Accessory costs					
Maintenance costs					
Capability					
Decontamination capability					
Power supply options					
System durability					
System alarms					
Oxygen adjustments					
System features					
Multifunctional ventilation					
Initial implementation					
Equipment compatibility					
Deployability					
Ease of transport					
Ease of site setup					
Maintainability					
Ease of decontamination					
User serviceability					
Warranty					
Software updates ²		Not applicable	Not applicable		
Usability					
Ease of use					
User-friendly controls					
Easy-to-read display					
Functional component connections					

Note:

- ¹ Averaged criteria ratings for each assessed product are graphically represented by colored and shaded circles. Highest ratings are represented by full green circles.
- ² This criterion was not assessed for the AutoVent 3000 or the SAvE as it was not applicable. This did not affect the products' final scores.