The development of the SAVe II (Simplified Automated Ventilator) was funded by DARPA, and 510k cleared by the FDA in 2014. The SAVe II was designed to be fully operational in the rough terrain of the battlefield. By simply selecting the height of the patient, minimally trained medics are able to dial in a neuro and lung protective tidal volume derived from the ARDSnet protocol of 6 ml/kg of ideal body weight. This removes the guesswork and operator error associated with bagging a patient or using overly sophisticated ventilators especially in high stress environments. By pressing two buttons medics can deliver ventilation that follows best practices even on the battlefield. The SAVe II has been deployed worldwide with NATO militaries.

The SAVe II+ was developed specifically for the Strategic National Stockpile. It received Emergency Use Authorization in early 2020. 510k clearance is expected in 2021. The SAVe II+ uses a more capable motor, improved electrical system and software to deliver up to 12.5 LPM of air and to generate up to 20 cmH2O of PEEP. In comparison the SAVe II generated up to 8 LPM of air and up to 10 cmH2O of PEEP. Given the average ventilated COVID-19 patient receives 9.1 LPM of air and between 8-12 cmH_2O of PEEP, these improvements are significant.[1]

Ventilator Settings	Average COVID Settings	SAVe II+ Range
PEEP (cmH_20)	10 (8-12)	0 - 20
FIO_2 (%)	.7	.21 - 1.0
V_E (L/min)	9.1	1.6 - 12.5
Tidal Volume	450	200 - 800
PIP (cmH_20)	21 (19-26)	10 - 60
Breaths per Minute	20.5	8 - 30

Figure 1: Average Ventilator Settings based on MGH COVID-19 Report[1]

ARDS or acute respiratory distress syndrome occurs in 42% of patients presenting with COVID-19 pneumonia, and 61–81% of those requiring intensive care.[2] COVID-19 ARDS follows a predictable time course over days, with median time to intubation of 8.5 days after symptom onset. In these cases, full mechanical support is needed. It is now well recognized that lung protective strategies using low tidal volumes, PEEP $\leq$20cmH2O and higher FiO2 are preferred. These patients require the highest level of critical care using the most advanced mechanical ventilators managed by physicians that are board certified in critical care medicine. It should be recognized that even with this level of sophisticated care, the mortality associated with severe ARDS from COVID-19 is high.

[1] American Journal of Respiratory and Critical Care Medicine Vol 201 Number 12, June 15, 2020
[2] Med J Aust. 2020 Jun 22: 10.5694/mja2.50674.

The SAVE II+ is not a replacement for full featured critical care ventilators when these advanced devices are available. However, since at least 2008 there has been a well described role for an easy to use, affordable transport ventilate that could be deployed in large numbers during mass casualties such as pandemics. The SAVe II and II+ performance characteristics were modeled after the requirements laid out in *Surge Capacity Mechanical Ventilation* paper published in the Journal of Respiratory Care[3]. This paper also discusses the merit of using height to dial in 6 ml/kg of ideal body weight.

	Mandatory Capabilities laid out in 2008 paper	**SAVe II+ Performance Characteristics**
Dimensions	Small enough to carry	Hand sized 6.5x6.25x2 inches
Weight	Less than 22 lbs. (10kg)	2.8 lbs. (1.3 kg)
Flow Rate	Not specified	0 - 40 LPM
I:E Ratio	Not specified	1:2
Respiratory Rate	6-35 BPM	8 - 30 BPM
Tidal Volume	250-750 mL	200 - 800 ml
Peak Inspiratory Pressure	Less than 30 cmH2O	10 - 60 cmH_2O
Peak End Expiratory Pressure	5-15 cmH_2O	0 - 20 cmH_2O
Battery Duration	4+ Hours	8.25-9.25 Hours
FIO2	.21-1.0	Yes
Controls	Separate TV & RR controls Monitor airway pressure	Yes Yes
Meets ARDS Network Guidelines	Yes	Yes
Price	Less than $10,000	Yes
Mode	Volume Control Ventilation	Yes
Country	USA	USA
Alarms	Circuit Disconnect High airway pressure Low airway pressure Loss of electrical power Loss of high-pressure gas	Yes Yes Yes Yes Not applicable (uses low pres)
Ease of Use	Body-weight prediction based on height	Yes, simply select height and device dials in tidal volume representing 6 ml/kg of IBW

Figure 2: Desired Surge Performance Characteristics[3] compared to SAVe II+

Limits of the SAVe II+

The SAVe II+ does not support the low tidal volumes (lower than 200 ml) or the high respiratory rates (higher than 30) demanded by small children. The SAVe II+ does not support the flow requirements of conscious patients spontaneously breathing nor does it have the controls to synchronize with patient triggered breaths. Most COVID-19 patients will be sedated and for the vast majority of these patients the SAVe II+ will have the range of controls (TV, RR, PIP, PEEP, Alarms) desired.

[3] Surge Capacity Mechanical Ventilation, Respiratory Care, Jan 2008 Vol 53 No 1, Branson et al

Deploying the SAVe II+

The SAVe II+ can be used on patients that do not demand the capabilities of a full featured critical care ventilator. This frees up critical care ventilators for small children or other patients that require the advanced features. This is a cost-effective way to optimize resources. The SAVe II+ is also well adapted to be used in situations where there is a shortage of highly skilled staff, in field hospital situations when there are no longer enough ICU beds.

In surge situations difficult decisions on how to allocate equipment and staff must be made. As staff that doesn't normally operate ventilators are forced to manipulate ventilator controls and as surge equipment that isn't normally used is deployed training and ease of use become key considerations. As equipment shortage mount patients advanced in age or with comorbidities that make survival unlikely may receive no mechanical ventilation. The SAVe II+ can play an important role in addressing these challenges during a mass casualty event like a pandemic.

Manual ventilation following hurricane Katrina[4]

About AutoMedx

Founded in 2004, AutoMedx is a veteran owned small business focused on the design and manufacture of improved mechanical ventilation devices. AutoMedx specializes in cost-effective field ventilators that require little training and are simple to set up and operate.

[4] deBoisblanc BP. Black Hawk, please come down: reflections on a hospital's struggle to survive in the wake of Hurricane Katrina. Am J Respir Crit Care Med 2005;172(10):1239–1240