May 7, 2020

Emergency Use Authorization (EUA) for AutoMedx SAVe II and SAVe II+ Series

On February 4, 2020, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that involves the virus that causes COVID-19. The Secretary of HHS then declared on March 24, 2020, that circumstances exist justifying the authorization of emergency use of medical devices, during the COVID-19 pandemic.

On March 24, 2020, FDA authorized the emergency use of ventilators and other related technology subject to certain criteria established by FDA for safety, performance and labeling for emergency use in healthcare settings to treat patients during the COVID-19 pandemic. On April 24, FDA authorized SAVe II Series Ventilator models M50012 and M50013 and further expanded EUA coverage on May 7, 2020 to the SAVe II+ models M50016, M50017 for emergency use in healthcare settings to treat patients during the COVID-19 pandemic, subject to the conditions set forth in the EUA. Models M50012, M50013, M50016, and M50017 have been added to the FDA's list of authorized devices contained in Appendix B of the EUA[1]. The emergency use of the SAVe II and SAVe II+ Ventilators under respective EUA's are consistent with the terms of each EUA, including the Scope of Authorization (for use in healthcare settings to treat patients during the COVID-19 pandemic emergency), Conditions of Authorization (inclusive of authorized labeling and manufacturer's processes for collecting and reporting adverse events etc), and Criteria for Safety, Performance and Labeling (inclusive of conformance with standards and device specifications).

The SAVe II and the SAVe II+ Ventilator series were originally cleared for transport use and have now been modified to allow for conditions which may include longer term use. The original and new intended uses are provided below. Additionally, to allow for use in COVID patients, the PEEP maximum setting has been adjusted to allow for an upper limit of 20 cmH20 ± 2 cmH2O and a procedure for changing the heat and moisture exchanger filter has been developed and is provided in the EUA supplement to the user's manual.

Authorized labeling for the Save II series includes:

1. Quick Start Guide
2. Operations Manual
3. Fact Sheet for Healthcare Providers: Emergency Use of Ventilators During the COVID-19 Pandemic
4. Fact Sheet for Patients: Emergency Use of Ventilators During the COVID-19 Pandemic

[1] FDA list of Authorized Ventilators, Appendix B: https://www.fda.gov/media/136528/download

Originally cleared Intended Use (modified from K131877 with respect to EUA 200336, issued on April 24, 2020):

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

Intended Use (modified from K131877 under EUA 200336):

The SAVe II™ series are intended to provide ventilatory support for adults during CPR or when Positive-Pressure Ventilation (PPV) is required to manage Acute Respiratory Failure (ARF) or other situations where mechanical ventilation is needed. The SAVe II™ series are appropriate for adults that weigh at least 45 kg. It is intended to be used in pre-hospital, field hospitals, outpatient environments, hospitals, ICU's, transport environments or any other healthcare environment requiring the use of a ventilator.