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BRIEF

FDA OKs anesthesia gas machines as ventilators amid coronavirus shortage fears

By Greg Slabodkin

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Dive Brief:

- FDA in an emergency use authorization this week allowed modifications to certain respiratory devices amid fears of a shortage in the supply and availability of agency-cleared ventilators for treating patients during the novel coronavirus outbreak.
- The policy for manufacturers authorizes the "emergency use of ventilators, anesthesia gas machines modified for use as ventilators, and positive pressure breathing devices modified for use as ventilators" as well as related ventilator tubing connectors and accessories.
- GE Healthcare, which has a global installed base of more than 100,000 anesthesia devices, noted on its website distinctions from ventilators but acknowledged the need during the pandemic. The company also said it doubled its ventilator production capacity since the start of the COVID-19 outbreak and plans to double it again by the end of the second quarter.

Dive Insight:

According to FDA's EUA, the "known and potential benefits" of anesthesia gas machines and positive pressure breathing devices modified for use as ventilators "when used to treat patients during the COVID-19 pandemic, outweigh the known and potential risks of such products."

The move is the latest effort by FDA to help supplement the nation's ventilator capacity and make ventilation capabilities more widely available for patients with respiratory failure or difficulty breathing caused by COVID-19. The agency on Sunday issued guidance permitting ventilator manufacturers to modify hardware and software without first submitting a premarket notification.

In particular, FDA's March 22 guidance stated the agency does not object to the use of anesthesia machines for patients requiring ventilation.

"Ventilators that are currently used by anesthesiologists, that are used in outpatient clinics and in other procedures, can be converted to be used as ventilators for people struggling with the effects of the coronavirus," said Vice President Mike Pence, chair of the White House Coronavirus Task Force, in a press briefing over the weekend. "We've confirmed that a particular screen in that device can be changed readily."

However, in a March 23 letter to customers, GE Healthcare warned "the use of an anesthesia machine is considered off-label use (not formally cleared or approved by any regulators)" and the company "does not in any way promote or recommend the use of anesthesia devices as ICU ventilators in any normal circumstances."

GE Healthcare emphasized in its customer communication "while an anesthesia device has a ventilator within it, the overall device is

not the same as an ICU ventilator, and it is critical to understand the differences in order to minimize risks to patients."

Nonetheless, given the "extreme circumstances" of the coronavirus pandemic, GE Healthcare said it also understands the "need to weigh the relative risks and benefits to support patients in these unprecedented times" and is only providing the information for consideration during the COVID-19 pandemic.

For the sickest COVID-19 patients in hospital ICUs, a shortage of the breathing machines could mean the difference between life and death. AdvaMed on Tuesday sent a letter to the Federal Emergency Management Agency asking for designation of a single agency to make allocation decisions to ensure the devices get to those who need them most.