

April 2020

## MedTech Quality Journal

*“Crises and deadlocks, when they occur, have at least this advantage—that they force us to think.”*  
- Jawaharlal Nehru (First Prime Minister of India)

The current Covid-19 crisis has created a tremendous stress on our healthcare system. There is an acute shortage of testing, PPE and ventilators. At the same time, we see examples of creative problem solving and rapid deployment of resources by the industry to solve these supply issues. The FDA is doing its part to authorize these devices quickly using the Emergency Use Authorization (EUA). It is great to see everyone doing their part to collectively solve this unprecedented crisis.



As a thank you to the healthcare workers, who put themselves at risk to combat the virus every day, we can all do our part by practicing social distancing and staying up to date with the rapidly evolving reports on COVID-19. We are all in this together!

This month's newsletter offers a quick overview of developments in these critical areas of need. These are videos you can watch to stay updated about key issues in the current Covid-19 crisis. Please [subscribe to our channel on Youtube](#) and let me know if there are other topics or questions of interest for future video updates by [contacting me here](#).

– Naveen Agarwal, Ph.D

### FEATURE VIDEO

## Overview of Coronavirus Testing



An overview of 3 types of tests that can be used to detect SARS-CoV2 infection.

**Insight: FDA has authorized many different tests from companies and commercial labs. They are now being deployed at mass scale.**

[Watch Video >>>](#)

### RISK MANAGEMENT

## N95 Respirator Decontamination



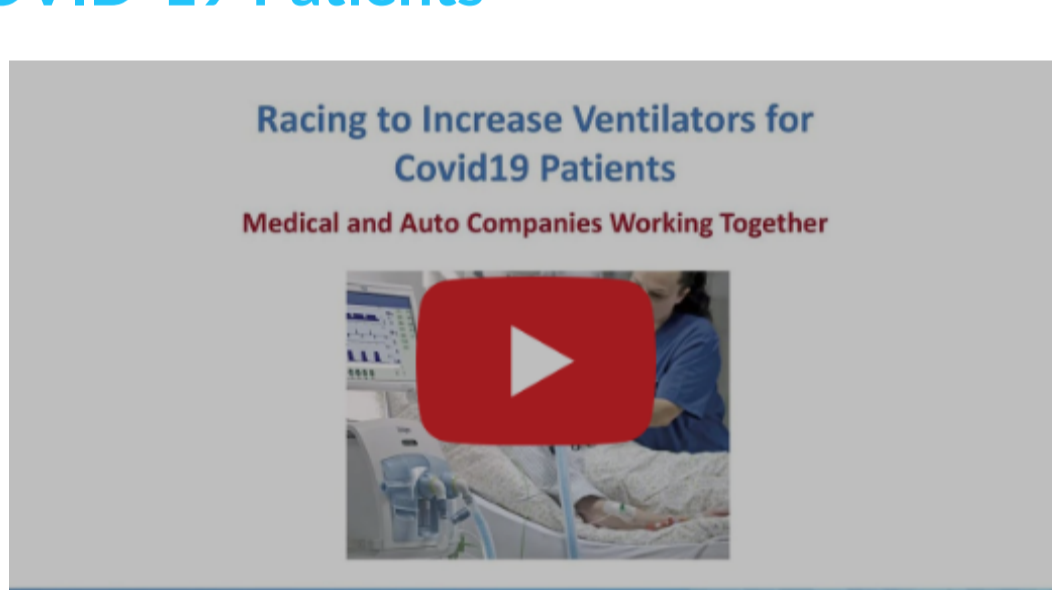
FDA has authorized 4 different systems for decontaminating N95 respirators.

**Insight: Benefit-risk of reusing decontaminated respirators is favorable as long as supply of fresh respirators lags behind the current demand.**

[Watch Video >>>](#)

### INDUSTRY NEWS

## Racing to Increase Ventilators for COVID-19 Patients



Overview of how medical and auto companies are working together to increase ventilator supply.

**Insight: This is a very interesting and promising development as two different industries collaborate to help solve this crisis.**

[Watch Video >>>](#)

## FDA EUA Granted to CytoSorb

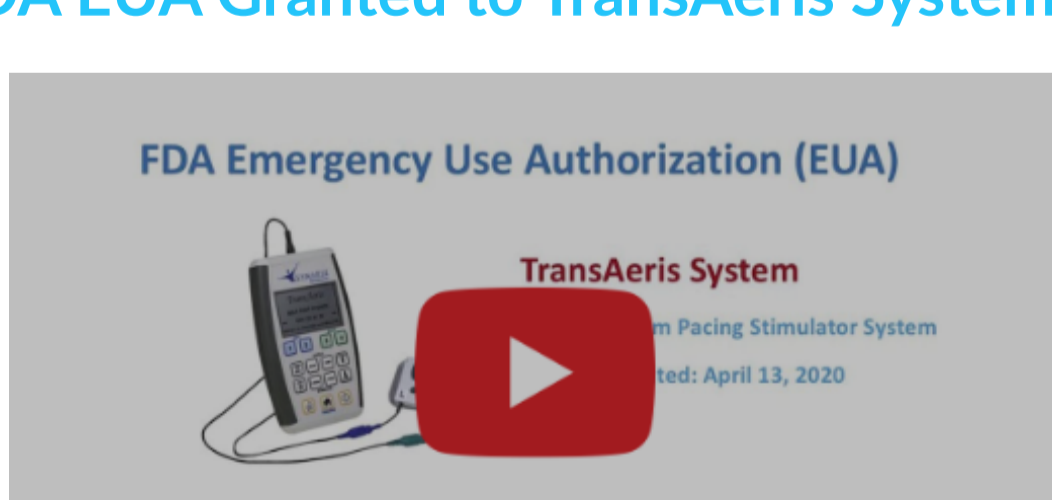


Learn details on the Blood Purification Device recently granted EUA by the FDA.

**Insight: The use of CytoSorb could help reduce the need to use a ventilator on ICU COVID-19 patients, but there are risks.**

[Watch Video >>>](#)

## FDA EUA Granted to TransAeris System



Learn details of a diaphragm pacing device recently granted an EUA by the FDA.

**Insight: Diaphragm pacing can help reduce the time on a ventilator.**

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Toll Free 1-833-MYEXEED | 1-833-693-9333

[info@ExeedQM.com](mailto:info@ExeedQM.com)

Creative Analytics Solutions, LLC  
2468 Atlantic Boulevard, Jacksonville, FL 32207

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