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The scramble to reinvent the ventilator

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As Smiths Group delays its split partly so it can focus on ventilator production, the US FDA grants emergency authorisation to other breathing devices to treat Covid-19.

The lack of mechanical ventilators to treat Covid-19 patients is a pressing problem across the world. A wide variety of efforts are being made by medtechs and non-medtech companies, regulators and academic researchers to accelerate production of approved devices, repurpose other breathing systems for emergency use, and to build new ventilators from scratch.

The engineering conglomerate Smiths Group today said it would delay the separation of its medtech unit, which had been scheduled for mid-year, partly so it can focus on the delivery of ventilators and other critical care devices. The company is part of the VentilatorChallengeUK alliance, from which the UK government has ordered 10,000 units.

The VentilatorChallengeUK consortium also includes Airbus, BAE Systems, Ford, Rolls-Royce, McLaren and Siemens, and is working to source and assemble parts for two ventilator designs, one of which is from Smiths Group. This device, made in the UK, is a portable ventilator usually used in ambulances and not typically used for long-term intensive care.

This consortium is only one of many deals in which engineering groups outside the medtech sector are retooling facilities to build breathing equipment. The US diversified company General Electric is working with Ford, which is to manufacture a simplified GE ventilator with the aim of producing 50,000 units by early July. Separately GE said it was adding manufacturing lines to its own ventilator production sites and increasing the number of shifts so the devices can be produced around the clock.

Even so, workers at GE's aviation factory in Lynn, Massachusetts staged a protest yesterday, demanding that the company reconfigure its aircraft manufacturing facilities to make ventilators there, too.

Other groups including Mercedes and Dyson are also developing their own breathing devices more or less from scratch, in collaboration with various academic groups. And Medtronic has made the design schematics of one of its ventilators available for free, to allow other manufacturers to build and release the device.

Emergency

Even so, other initiatives will be necessary. Aware that US demand for ventilators will explode within days, the FDA is allowing breathing devices and their accessories not normally used in hospital contexts to be deployed

in the fight against Covid-19.

Last week the agency issued an emergency use authorisation – a temporary permission that exists as long as America is in a state of emergency – for devices including anaesthesia gas machines and positive pressure breathing devices that have been modified for use as ventilators.

The devices that are eligible for inclusion under this EUA are those that are not currently marketed in the US, or that are currently marketed but have been subject to an alteration that would usually need a new 510(k) clearance application.

So far EUAs have been granted to ventilators made by two Chinese companies, Beijing Aeonmed and Mindray, and by the US group Vyaire Medical.

But many other companies could benefit. The table below summarises the companies with the most US approvals, from 2014 to date, of the kinds of respiratory devices now eligible for emergency authorisation, once they have been modified to work as ventilators.

Makers of modifiable devices eligible for EUAs	
Company	**No of approvals**
Resmed	24
Philips	12
Fisher & Paykel Healthcare	8
Getinge	6
General Electric	6
Hill-Rom	5
Hamilton Company	5
Mindray Medical International	4
3B Medical	4
Vyaire Medical	3
Drägerwerk	3
Medtronic	3
Thornhill Medical	3
Apex Medical	3
Drive Devilbiss Healthcare	3
Note: includes only manufacturers with at least 3 approved devices. Source: EvaluateMedTech, FDA.	

It is no surprise to see Resmed way out in front. A large part of the company's business is the manufacture of continuous positive airway pressure (CPAP) machines, which force air into sleep apnoea patients' lungs as they sleep. CPAP machines would not be used as standard therapy for hospitalised patients who cannot breathe on their own, but ought to be reasonably easy to tweak so as to work in that way.

Resmed also makes ventilators for use when patients are awake, but this business is almost entirely focused on home care rather than the large machines found in hospitals; but again, these devices could be repurposed for the ICU. Resmed has said it is doing all it can to increase production of its ventilators and other respiratory devices and intends to double or triple its ventilator output, and scale up ventilation mask production more than tenfold.

The Philips devices that fall into the FDA's categories came entirely though its 2008 acquisition of Respironics. One example is the Trilogy Evo portable ventilator, designed to be used initially in the hospital setting but then to be taken home by patients once they recover. The Dutch group also plans to double production of its hospital ventilators by mid-May and quadruple it by the third quarter of 2020.

These efforts are praiseworthy, but it still takes time to build these machines, and whether the overwhelming

short-term demand can be met is in doubt. Some in industry insiders have been particularly sceptical about non-specialists attempting to develop their own ventilators without expert assistance.

And even the established respiratory tech developers could run into difficulty since the global supply chains for the components used in ventilator manufacture have been disrupted by the pandemic – as has staffing. Time will tell how much the obvious determination on the part of these various players can accomplish.