

# Sagentia Innovation Ventilator



UK Government

## Rapid development of novel ventilator design for COVID-19 patients

Scientific modelling at the start of the coronavirus crisis predicted that the NHS was going to run out of ventilators, so the Government launched the Ventilator Challenge with a call to arms to manufacturers and medical device companies to step up production of existing designs and design new ventilators from scratch.

The Government received an overwhelming response, with over 5000 companies offering their support. Sagentia Innovation was one of the 25 companies commissioned to develop a Ventilator system for the UK Ventilator Challenge.

### Expertise and domain knowledge

- Human factors
- User experience
- Mechanical design
- VoC
- Rapid development
- Novel design
- Risk reduction
- Medical device regulation
- Transfer to manufacture
- Critical care environments



## Our client asked:

Sagentia Innovation was selected by the UK Government to develop a new ventilator design suitable for rapid manufacturing scale up with minimised supply chain risk. Sagentia Innovation deployed a cross functional team of 80 FTEs to go from specification to regulatory submission in rapid development.

## The project story:

The design philosophy was based on fabrication of parts rather than use of OTS components that were required by other ventilators to scale up their production lines at that time. We deployed a large, in-house team to work weekends and extended hours to fulfil the unprecedented development timescales for a medical device of its kind. There was collaboration with other local, and normally competing, consultancies that were all united in the common goal yet each developing their own ventilators in parallel. There was also intense, rapid part procurement from a large network of suppliers. To enable rapid development, no software was built into the system. We established an in-house manufacturing line which was assessed by a notified body, to ensure rapid transfer to manufacture. Finally, we completed the Technical File submission to UK Competent Authority (MHRA) for exceptional restricted use approval.

## Contact us

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## Results: deliverables and outcomes

- From specification to regulatory submission in 5 weeks and 3 days
- The system can ventilate stiff lungs of COVID-19 patients
- Low oxygen usage
- Volume controlled; pressure limited ventilation
- Control of FiO<sub>2</sub>, PEEP, PIP limit
- Alarms for safe use
- Simple and intuitive UI for non-specialists
- Assist mode for patients taking spontaneous breaths
- O<sub>2</sub> bypass adapter to use during suctioning
- Sagentia Ventilator was one of the 5 designs that remained in the final stage of development

“The Ventilator Challenge has proven just how much Britain can achieve when confronted with a difficult problem – bringing together the best minds in manufacturing, innovation and design. Thanks to these efforts, everyone who needed a ventilator has had access to one, and the NHS has the vital machines it needs to continue providing life-saving support against this deadly virus.”

**Borris Johnson, UK Prime Minister**