

RESPONDING TO COVID-19

A blog series with Technology Scotland members

wideblue
making technology happen

Responding to COVID-19: Wideblue

As the situation regarding COVID-19 continues to develop, some of our Technology Scotland members have been able to respond to the calls for assistance we have been seeing across Scotland, and the UK. These responses have taken a variety of forms, from tailoring pre-existing products to provide support in these unprecedented times to innovating business procedures and practices to provide more relevant and efficient services.

We're proud that those of our members who have been able to provide support, have offered their support in such unprecedented and uncertain times.

As a result, we'll be bringing you a brand new, weekly blog series in which we'll be talking to these members, finding out what they've been doing and understanding how they have been responding to COVID-19.

This week, we're hearing from Russell Overend, Managing Director at Wideblue.

TS: Hi Russell, thanks for chatting with us today! Firstly, can you tell us a little bit about Wideblue and what you do there?

RO: Wideblue are a new product design and development company specialising in optical / photonics products and new medical devices. We did a management buy out of Polaroid's European Design centre in 2006 and now we apply our optics, electronics, firmware, software, mechanical engineering skills to a wide variety of new products. In 2018 we were partly acquired by US product design and manufacturing company Pivot International. Pivot have a large supply chain operation in USA, Europe and the Far East and have in house manufacturing in USA and Philippines. We are therefore able to design, develop and manufacture new technology products using readily available materials and manufacturing methods and ease the transition from development into full scale manufacturing.

TS: Due to the current and ongoing situation regarding COVID-19, there's been a huge shift and change in demand for assistance of all kinds - especially within the product design and development sectors. How did Wideblue first become involved in developing this latest solution?

RO: I attended an Innovate UK briefing session in 2015 for a "Photonics for Health" competition and bumped into an old work colleague from Thales - Des Gibson. Des was the founder and CEO of Gas Sensing Solutions who make industrial Infra Red CO2 sensors. Wideblue were experienced and accredited for the development of medical devices. We thought it would be a good idea to combine GSS sensors into a medical device to make a personal capnometer. We needed a company to carry out the clinical trials and analyse the patient data so we invited Cambridge Respiratory Innovations (CRI) to join the consortium. We applied and won funding. Wideblue led the consortium and we solved all the technical problems and developed the first version of the personal capnometer.

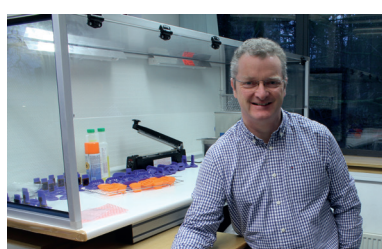
Wideblue and GSS developed a low volume manufacturing process for a data collector version of the product and CRI ran clinical trials on COPD, Asthma, Congestive Heart Failure patients. Each patient was issued with a personal device, replacement mouthpieces and replacement AA batteries. They breathed into the device 3 times a day and kept a diary. The data was collected and the results showed measurable changes in the patients CO2 breath profile long before they had an Asthma attack or COPD exacerbation. On the basis of this result we developed the current version with a replaceable mouthpiece / breath tube added 2G comms, internal rechargeable battery, improved the appearance and improved the ergonomics of the design.

The new product was called the N-Tidal and was used while breathing normally in and out through the device. The breath data is automatically transmitted through the mobile phone network to a secure server where the data is analysed. We agreed that the new N-Tidal product would be marketed by Cambridge Respiratory Innovations (CRI) and the product won gold award at the European product design awards in 2019. Wideblue built 200 N-Tidal devices for use in further clinical trials with COPD and Asthma patients.

Early in 2020 it became clear that clinicians needed a new way to assess the health of a patients lungs. Spirometry, peak flow meters and forced expiratory volume measurements were shown to generate aerosols of virus when used with Covid-19 patients and so their use was prohibited. Clinicians were looking for a new way to assess who was suitable for ventilators, when to take a patient off a ventilator and how to monitor the recovery of a patient. Because the N-Tidal was used with normal relaxed breathing it was the perfect candidate. The 200 units already built have been repurposed for Covid-19 use. CRI have generated Covid-19 use protocols and expect to have trials underway in London and New Jersey within days. Wideblue are already ordering parts for a forecast scale up.

TS: Can you tell us about the solution you've developed; the personal capnometer?

RO: The N-Tidal product uses a GSS CO₂ sensor incorporated into a new medical device. Wideblue optimised the optical design to allow breath to pass in and out through the sensor using a Wieblue designed custom low cost replaceable infra red transmitting breath tube without making contact with the N-Tidal device. We developed the electronics and firmware to control the device, control the user interface and transmit the data to a secure server. We developed and tooled the housing, chassis, breath tubes and mouthpiece parts for injection moulding. We carried out device testing both formally (ISO testing) and informally (30 "friends and family" trials). We set up a pilot manufacturing line to assemble, test and package the devices (where necessary in a clean room). Using our parent company Pivot International we set up the supply chain to include sourcing of plastic parts, optical infra red parts, batteries, membrane switch panels, cables etc from low cost sources. For critical items such as main PCBA (from EMA), certification of clean rooms(Assured Micro) and regulatory certification (Eurofins and Compliance Solutions) we use local suppliers.



TS: As there's such a high demand to get products like this designed, developed and manufactured so quickly; how has the business had to adapt in order to be able to deal with these tighter timescales?

RO: Normally at this stage in the scale up of a new medical device we would carry out a technology transfer to a suitable high volume medical device manufacturer with ISO13485 certification. This would normally require multiple trips for training, checking new suppliers, auditing and device validation and verification but with the travel restrictions this will not be possible. We have therefore taken the decision to scale this product up in house. We are reconfiguring our labs, taking on additional staff and renting additional space to allow this scale up to happen. Wideblue are certified to ISO13485 for the design, development and associated manufacturing of new medical devices so our certification allows us to carry out this additional work. Luckily we already have the quality and regulatory procedures and approved suppliers in place to handle this additional work.

TS: How do you envisage the product design & development landscape will change coming out of COVID-19?

RO: Wideblue have been working on collaborative R+D projects like this with other companies, Universities and Research organisations for many years. We understand the benefits of these types of collaborative projects for all involved. In this project Wideblue worked closely with GSS and CRI and all three companies have benefited from the interaction and produced a product that none would have been capable of producing alone. We are seeing the same collaborative approach working with the VentilatorChallengeUK consortium and with many other projects. I hope that when people see what can be achieved by new product design and manufacturing engineers there will be an increase in innovative collaborative projects, we will inspire a load of young people and generate a surge of interest in this career path.

Finally, I would also hope that there will be shift in the general public's attitude away from celebrity and sports culture as people appreciate the good work done by clinicians, carers, scientists and engineers.