Accelerated Emergency Ventilator Development
Apollo XIII - Case Study

MATLAB Expo 2021

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Introduction
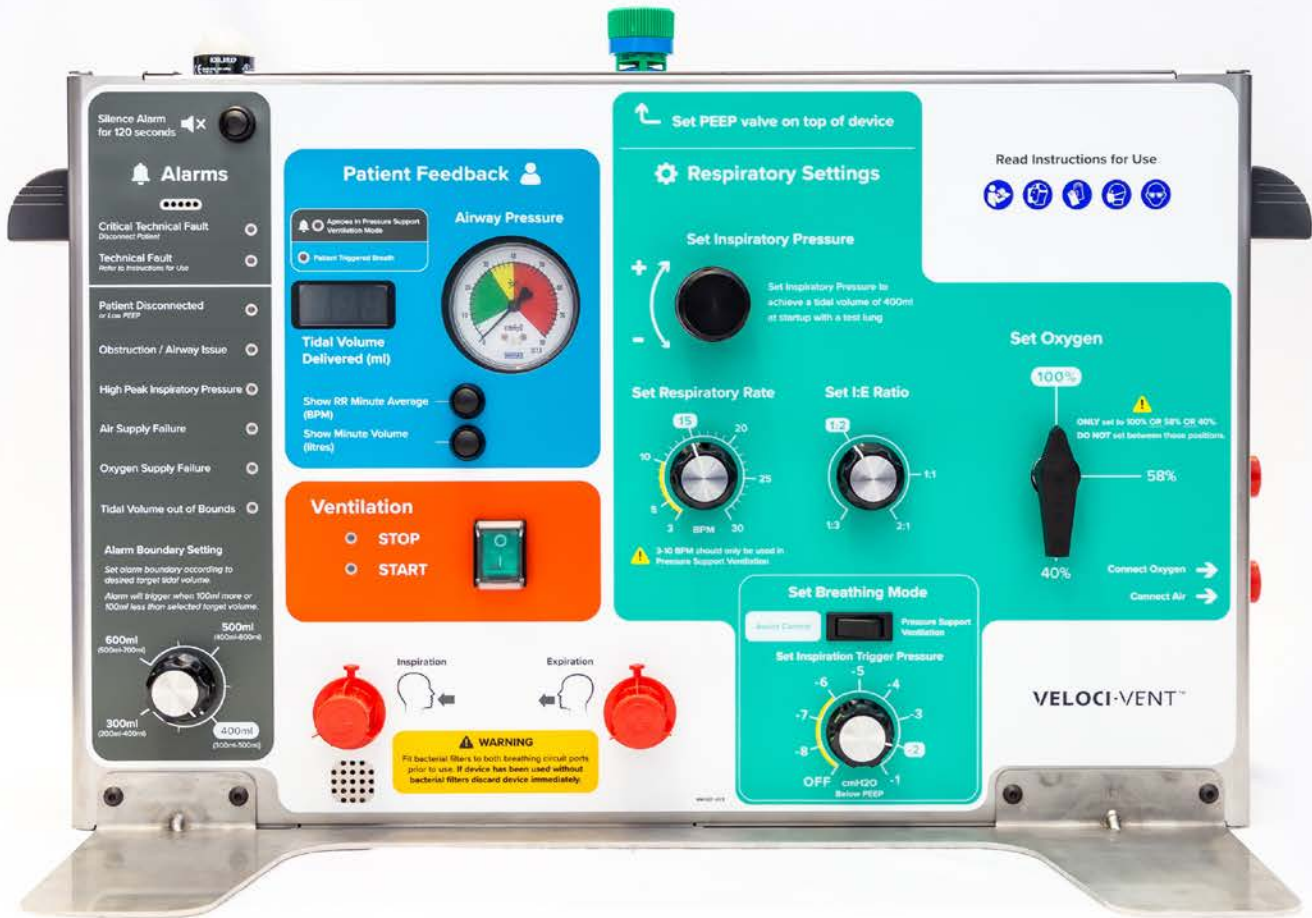
Alarms

Critical Technical Fault
Disconnect Patient

Technical Fault
Refer to Instructions for Use

Patient Disconnected
or Low PEEP

Obstruction / Airway Issue

High Peak Inspiratory Pressure

Air Supply Failure

Oxygen Supply Failure

Tidal Volume out of Bounds

Alarm Boundary Setting
Set alarm boundary according to
desired target tidal volume.

Alarm will trigger when 100ml more or
100ml less than selected target volume.

500ml
(400ml-600ml)

600ml
(500ml-700ml)

300ml
(200ml-400ml)

400ml
(300ml-500ml)

Patient Feedback 👤

Approx in Pressure Support
Ventilation Mode

Patient Triggered Breath

Airway Pressure

Tidal Volume
Delivered (ml)

Show RR Minute Average
(BPM)

Show Minute Volume
(litres)

Ventilation

○ STOP

○ START

Inspiration

Expiration

⚠ WARNING
Fit bacterial filters to both breathing circuit ports
prior to use. If device has been used without
bacterial filters discard device immediately.

↰ Set PEEP valve on top of device

⚙ Respiratory Settings

Set Inspiratory Pressure

+

−

Set Inspiratory Pressure to
achieve a tidal volume of 400ml
at startup with a test lung

Set Respiratory Rate

15

20

10

25

5

3   30
BPM

⚠ 3-10 BPM should only be used in
Pressure Support Ventilation

Set I:E Ratio

1:2

1:1

1:3

2:1

Set Breathing Mode

Assist Control   Pressure Support
Ventilation

Set Inspiration Trigger Pressure

−6   −5

−7   −4

−8   −3

−2

OFF   cmH2O   −1
Below PEEP

Read Instructions for Use

Set Oxygen

100%

⚠ ONLY set to 100% OR 58% OR 40%.
DO NOT set between these positions.

58%

40%

Connect Oxygen →

Connect Air →

VELOCI·VENT™

Background to the Apollo project

- In March 2020, the UK government approached Cambridge Consultants and other companies to help manufacture, design and build ventilators for the National Health Service in the fight against COVID-19

  - *Worst-case scenario planning had identified a shortfall of tens of thousands of ventilators*

  - *There was recognition that commercial ventilators supplies could not fill the gap*

  - *Multiple options were being pursued in parallel – from adapting existing designs to ground up development*

Development progressed at an extremely rapid pace

| 17th March 2020 | 26th March 2020 | 6th April 2020 | 10th April 2020 | 25th April 2020 |
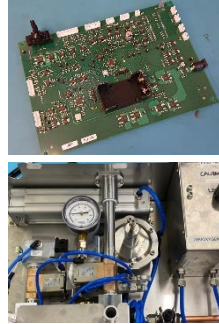
Proof of Concept

- Realised 1 day after architecture concept identified

- Off the shelf parts

- Matched top level pneumatic architecture

- Delivered core functional performance with representative values

First generation modules

- Rev 1 electronics hardware

- Pneumatics

First full integration

- Core software functions present

  - Hooks for advanced functions

- Not designed for manufacture

- Not final components

Second full integration

- Rev.2 electronics hardware

- Advanced software functions

  - Basic alarms

  - Breath triggering

- Uncontrolled build

Final build

- Rev. 3 electronics hardware

- Final mechanic

- Final alarms

- Integrated gas blender

- GMP compliant

- O2 safe build

MathWorks reached out to help

- MathWorks reached out to us with an offer of support. They kindly provided us with a number of licenses and time with an application engineer.

- Furthermore, MathWorks had previously published a ventilator and lung example model that we went on to use as a starting point in our own models.

- We'd really like to acknowledge their contribution to this project and thank them for all their support.

Pneumatic Circuit Development

System architecture options were rapidly assessed

- Five possible architecture concepts were rapidly mapped out and one leading approach chosen
  - *Criteria included*
    - *Component availability*
    - *Technical risk*
    - *Ability to meet all requirements*
    - *Reliability and safety*

- Pressure controlled approach selected
  - *Common pneumatic components used in industrial automation for reliability and availability*
  - *Initial basic functionality achieved with pure electronics*
  - *Minimal moving parts*
  - *Ability to simply meet all must-have and nice-to-have requirements*
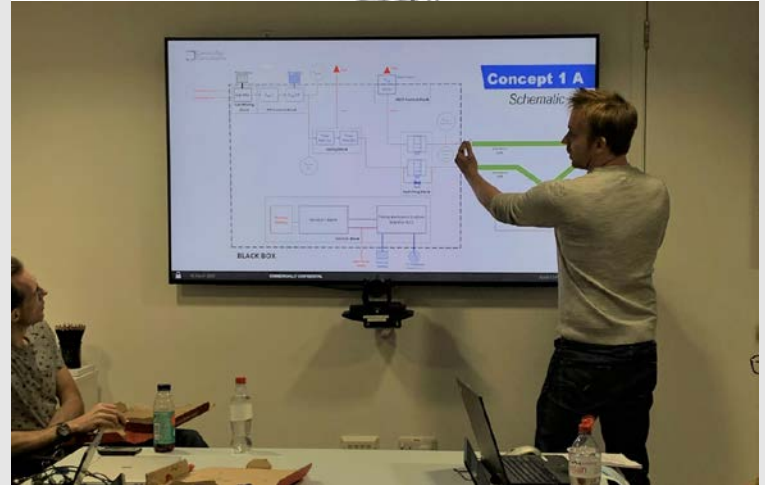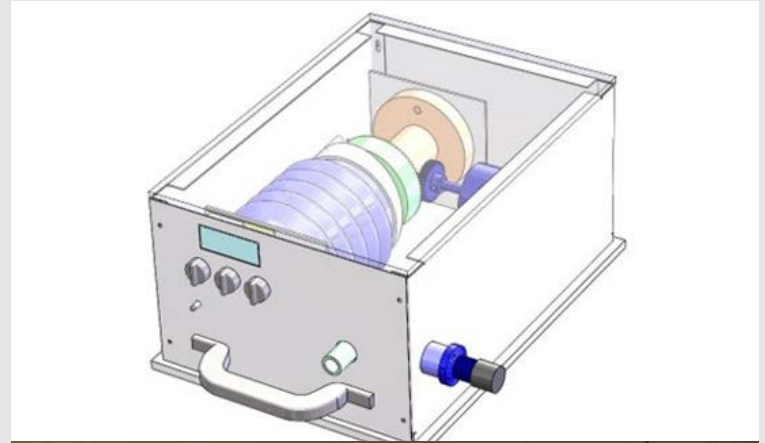
Robust and flexible modular system architecture

- Emerging requirements such as advanced breathing modes and sophisticated alarms drove the need for software-based control

- A key challenge was the gas mixing unit
  - *Not clear that an off-the-shelf module would be available*
  - *We drew a 'black box' around the gas mixer, defining interfaces but not worrying about the solution until more information was available.*
  - *This enabled progress to be made on the design of the rest of the system*
  - *Our own custom gas mixer was later integrated, once it was clear that no stock of commercial units was available.*

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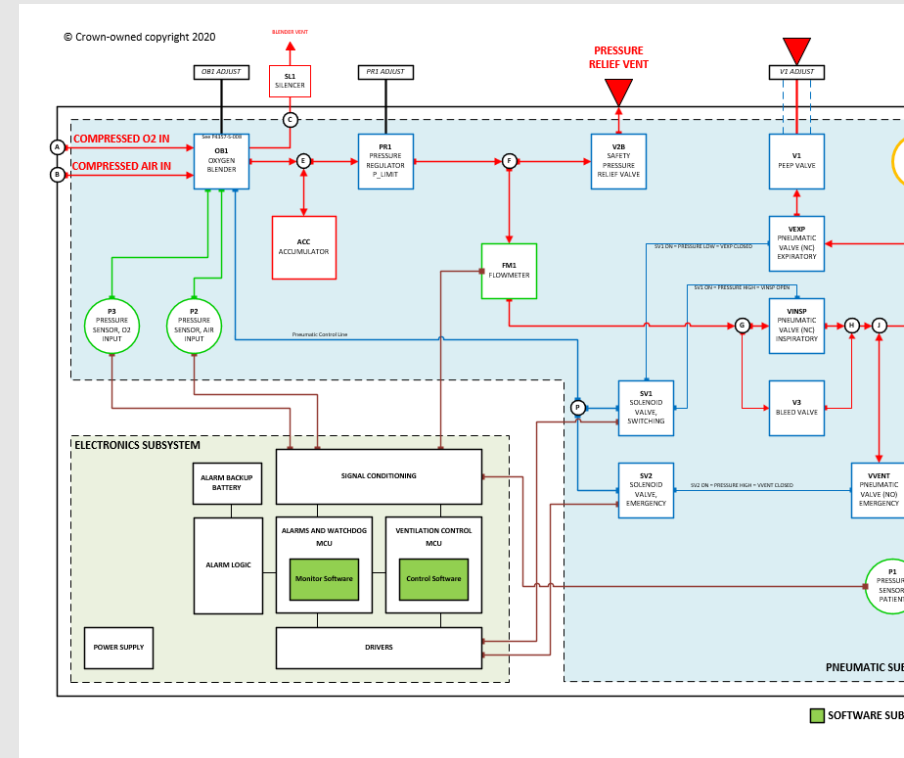
Pneumatic System Model

- A complete and detailed model of the pneumatic domain of the ventilator was developed.

- This allowed us to:
  - Simulate failure modes and assess the efficacy of related mitigations
  - Respond instantly to supply chain issues by evaluating the performance of alternative components
  - Identify and understand the effect of ambiguity in the hospital and ventilator specification and requirements
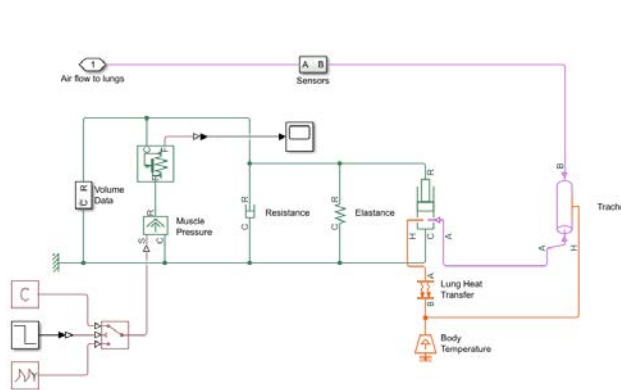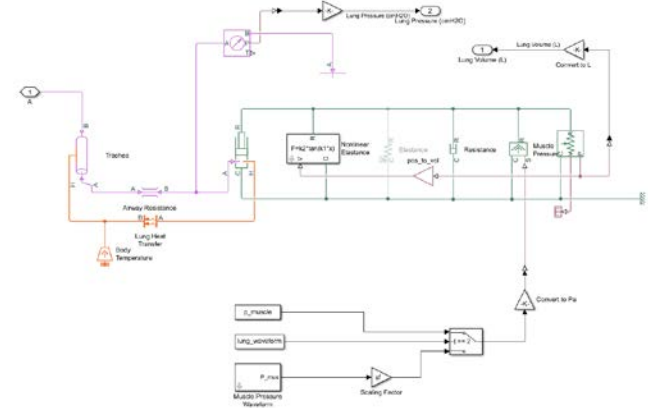 - Capture the requirements for the custom gas blender sub-assembly
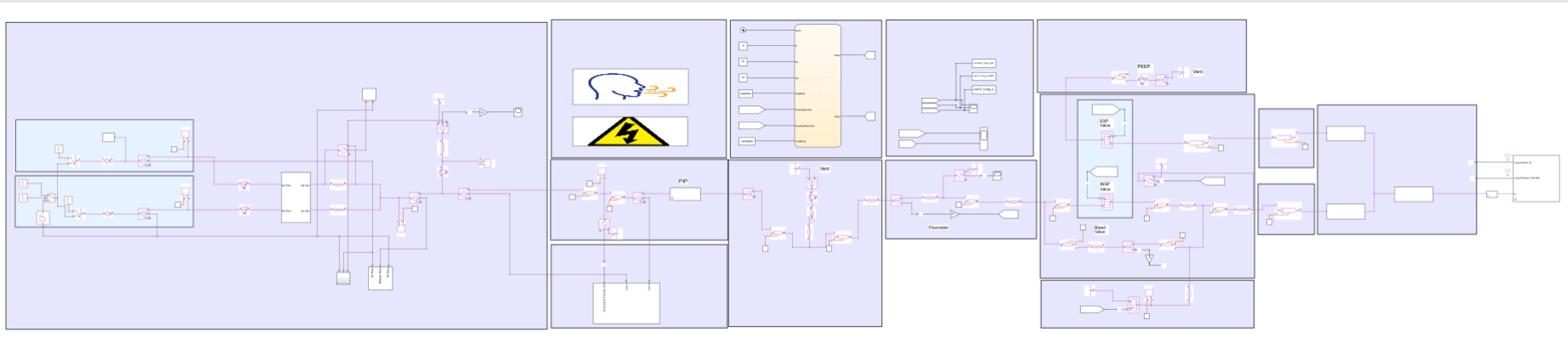
Lung Models

▪ Over the course of the project, three models of a human lung were used each at different levels of fidelity, and each was used to achieve different goals.
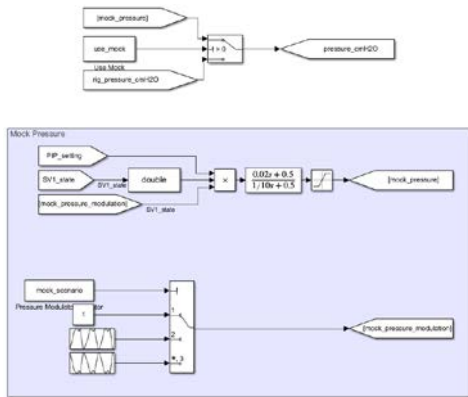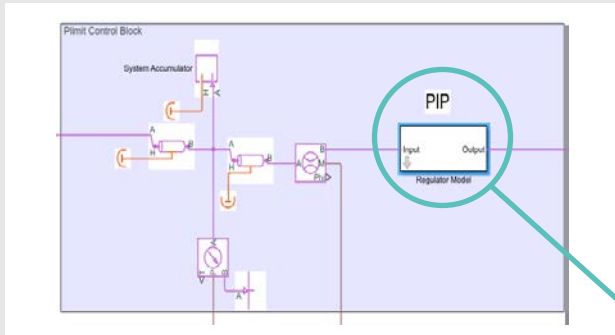

Laplace domain
Passive Breathing

Domain specific, linear parameters
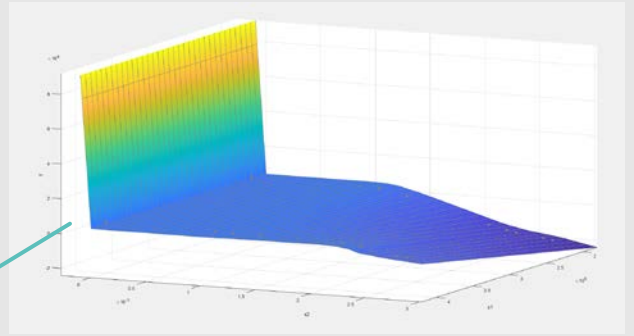**Simple Active Breathing**

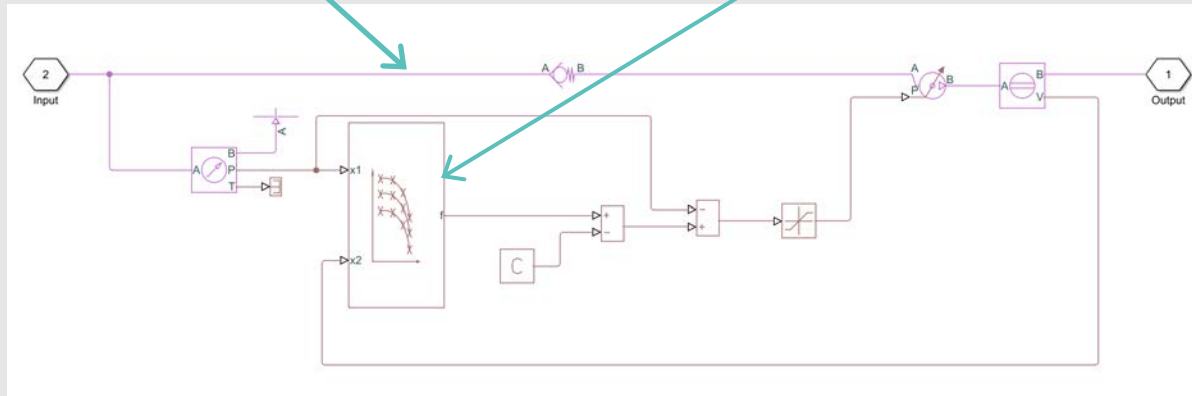**Domain specific, non-linear parameters**
Advanced Active Breathing

Specific component behaviour was added to the model

Device performance from datasheet

PIP regulator in pneumatic circuit

Non-ideal regulator model

Clinical Alarms Development

Ventilator Alarms

- Alarms are visual-audio cues for healthcare professionals to acknowledge and intervene if necessary

- Risk assessment and typical (mandatory) alarms guided the requirements and ventilator design

- Most alarms are mainly based on air Pressure and Volume signals:
  – Patient disconnection
  – Airway obstruction
  – Overpressure
  – Tidal volume out of bounds
  – Technical faults (i.e. leaks)

- Commercial ventilators have multiple sensors to base their algorithms, but we algorithms. Our design had one pressure sensor and one flow sensor.

AIRWAY OBSTRUCTION

PATIENT DISCONNECTION

HEALTHY
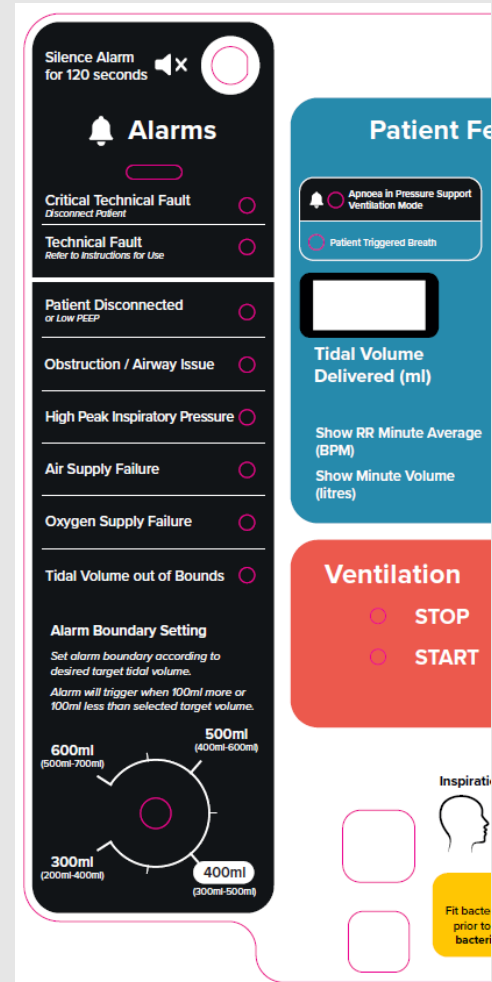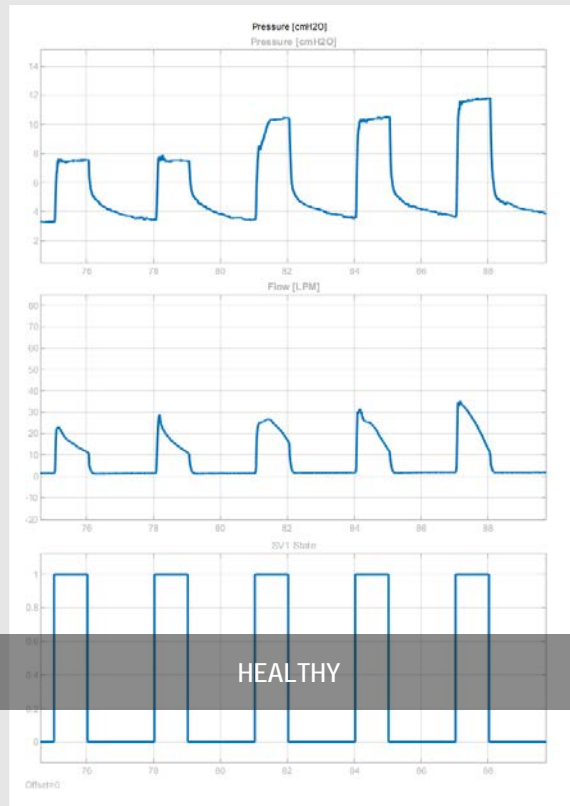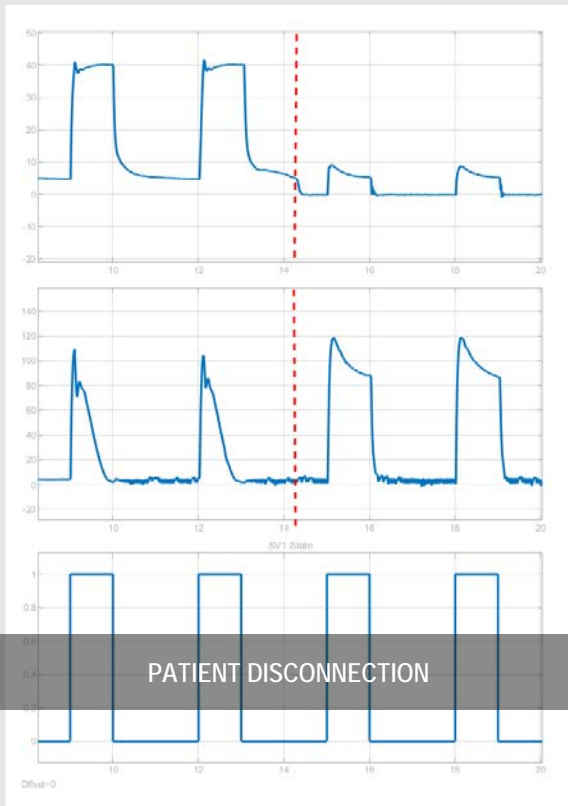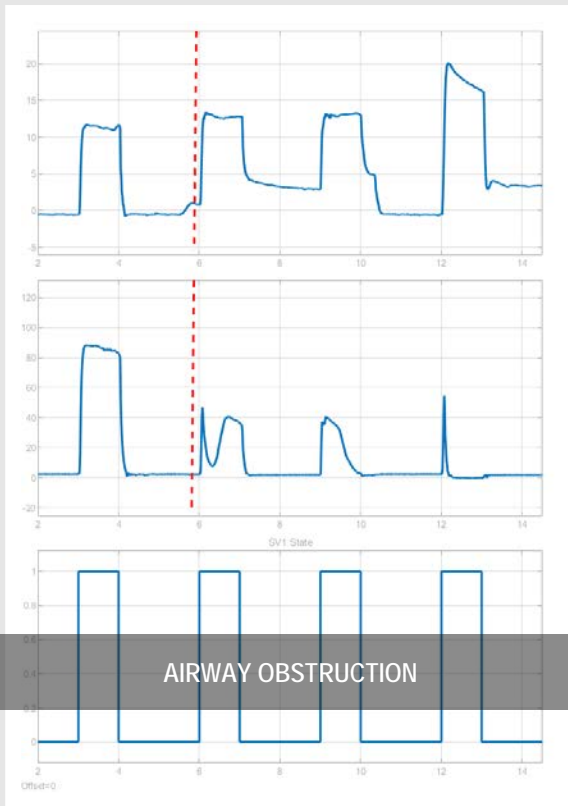
How MathWorks tools accelerated algorithm development

- **Simulink Desktop Real-Time** allowed using a high performance DAQ and run our model in real time at the same rate (500-1000Hz) as the expected embedded software.
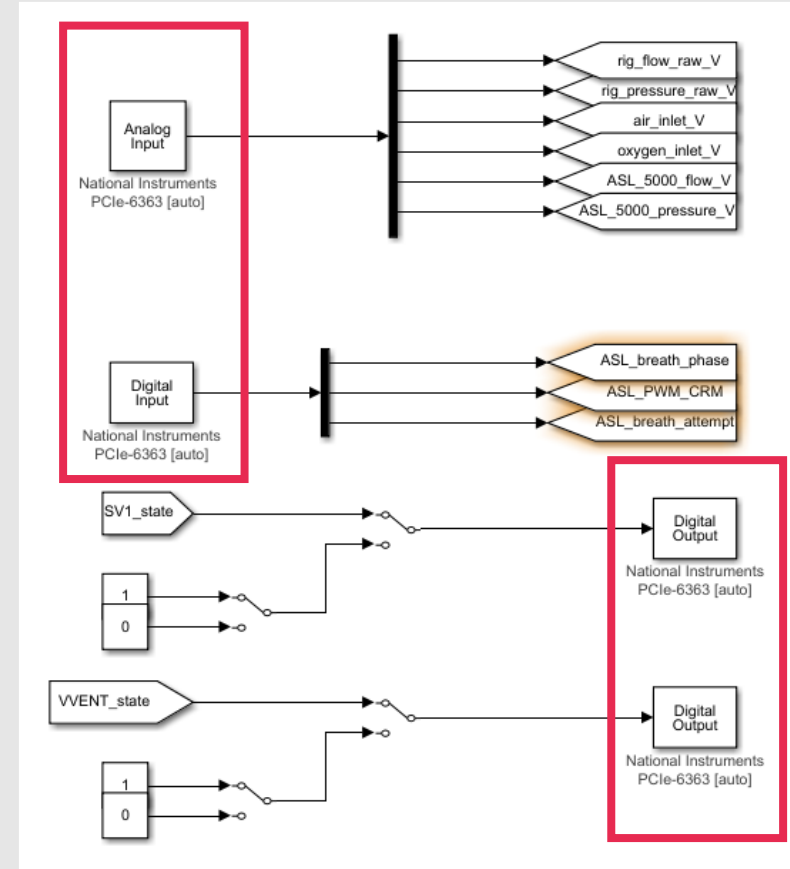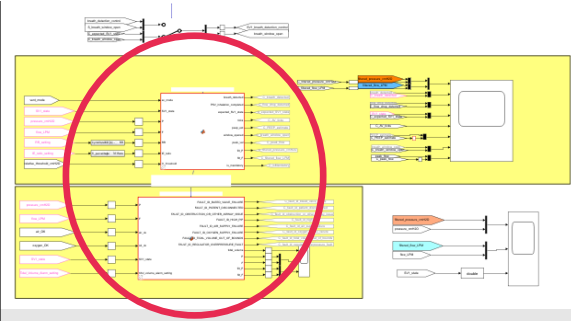
How MathWorks tools accelerated algorithm development

Simulink to prototype numerical and logical algorithms, visualise live data
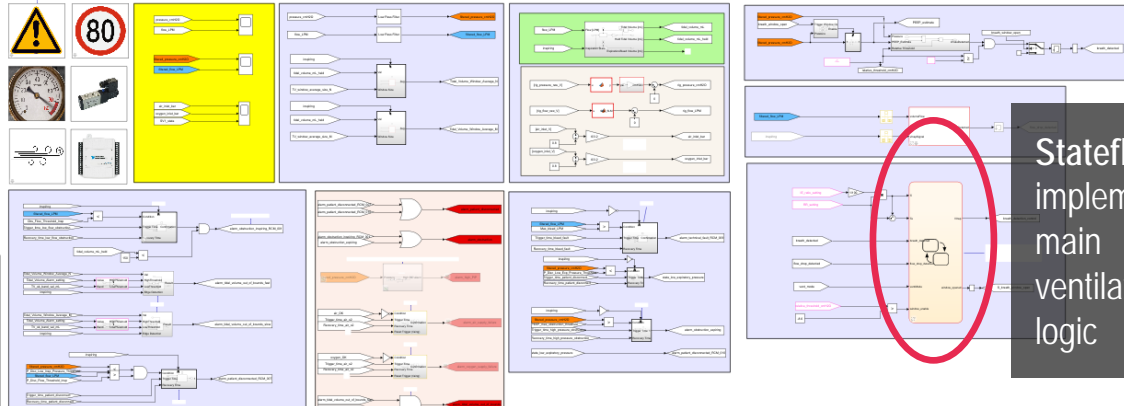
Stateflow to implement the main ventilation logic

Simulink Coder to execute the hand-coded algorithms in parallel and verify a 1:1 performance match
Fixed point designer to match MCU precision

# How MathWorks tools accelerated algorithm development

- **Simulink Dashboard** was fundamental to implement a like for like interface to mimic the ventilator panel features so that people who never used MATLAB/Simulink could still "play" with the ventilator

- Great to demonstrate the expected performance to the UK Medicine and Healthcare products Regulatory Agency (MHRA)
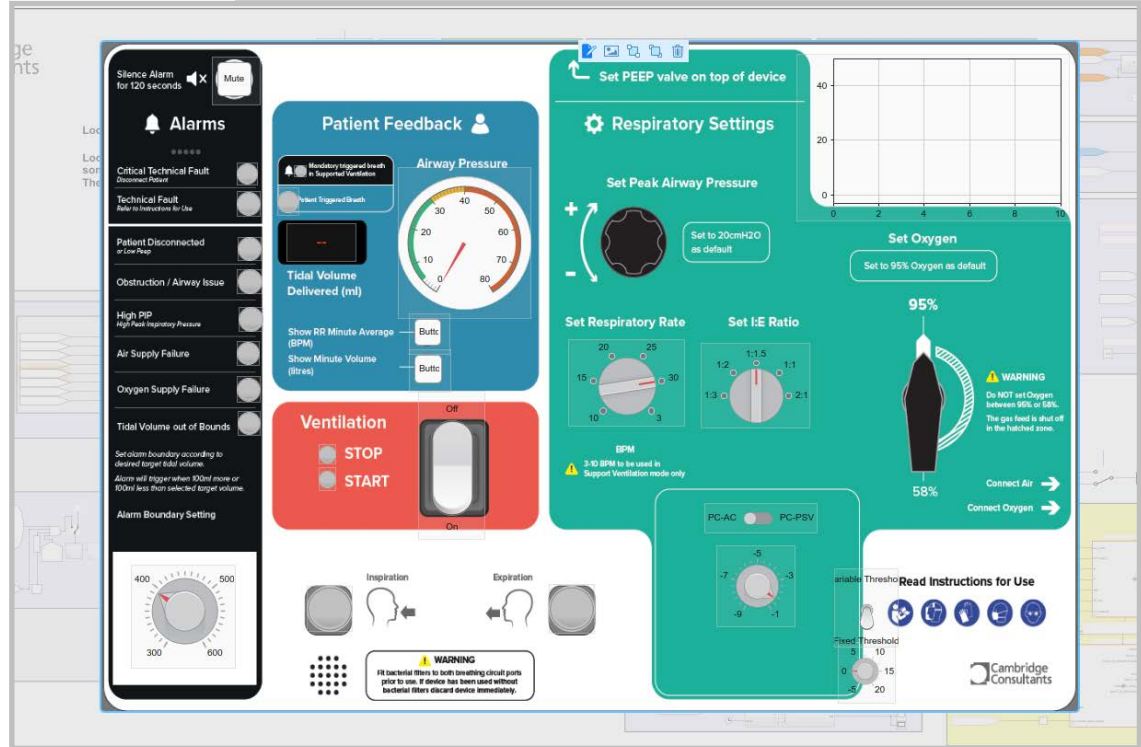
Spontaneous Breathing Algorithm

Spontaneous Breathing Algorithm

- On the 6th of April, we were invited to develop a so-called 'Spontaneous Breathing Algorithm' in response to new requirements from the Medicines and Healthcare products Regulatory Agency (MHRA). This feature would allow the ventilator to detect when a patient was attempting to breathing in or out and deliver a breath to them in response, rather than simply breathing on a timer.

- This new feature was deemed critical to the viability of the ventilator.

- The timelines for this were extremely tight.

- To achieve this, we would have to rely heavily upon the simulations and Hardware-In-the-Loop rig we had implemented earlier in the project.
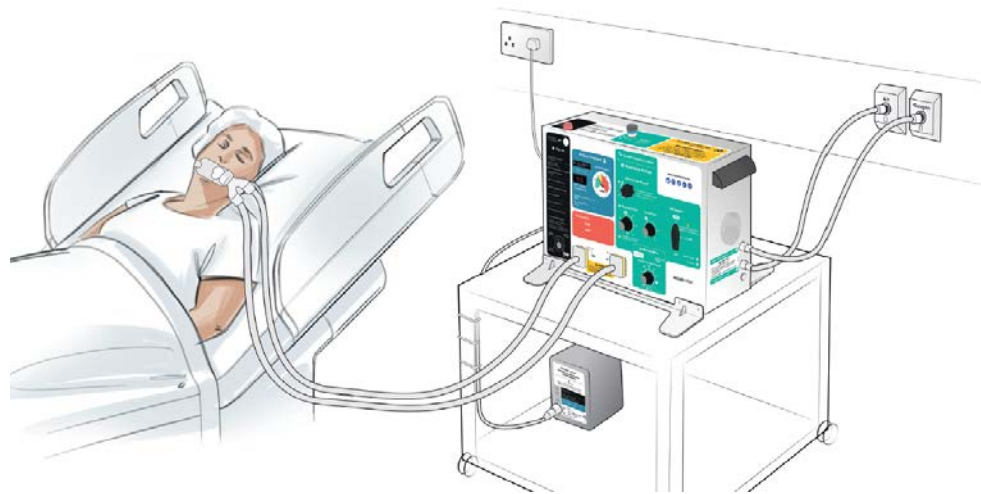
Sensing Challenges – Requirements Change

- The system architecture was designed and set in place against the initial set of requirements from the MHRA. Due to the need for the minimum viable product, the simplest sensor architecture was selected to enable the specified clinical alarms.

- We needed to understand how the architecture choices that had been decided (only days previously) but could not be changed were going to impact our ability to implement this algorithm.

RMVS

[303283] System Requirements Specification (P4357-RS-002)

Client:
MHRA

Prepared by: Duncan Bishop, Marco Rizzardo, Alex Joseph
Date: 11 June 2020
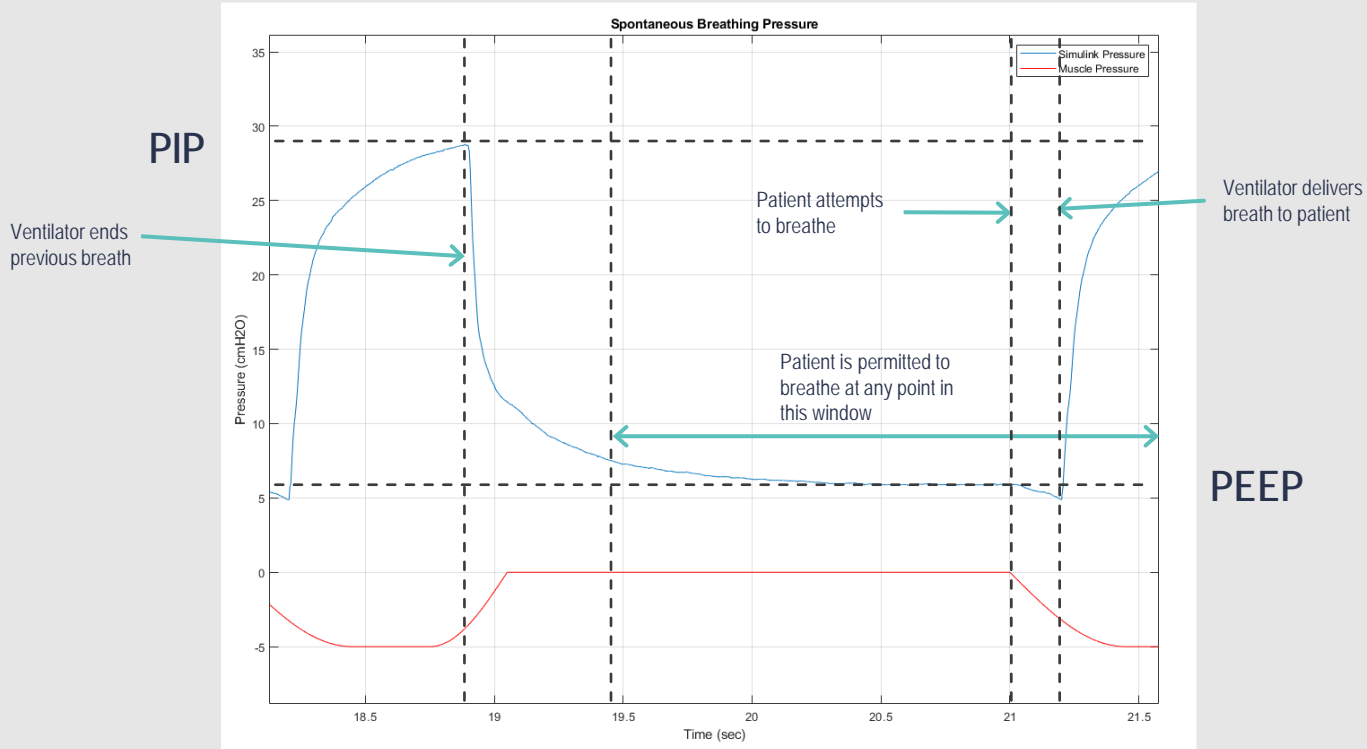**Doc Ref:** P4357-RS-002 v5.0

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Sensing Challenges – Pressure Sensing and Pressure Controlled Ventilation

Approach

- Our approach was to leverage the fact that the simulation and HIL work had been implemented in the same development environment: Simulink.

- The initial algorithm draft was developed in simulation using the pneumatic circuit model. The algorithm was placed in a shared library with the HIL model, allowing it be seamlessly integrated into our test setup.

- We were able to demonstrate a successful implementation of the algorithm deployed to the actual production hardware within 2 days of receiving our initial instructions.
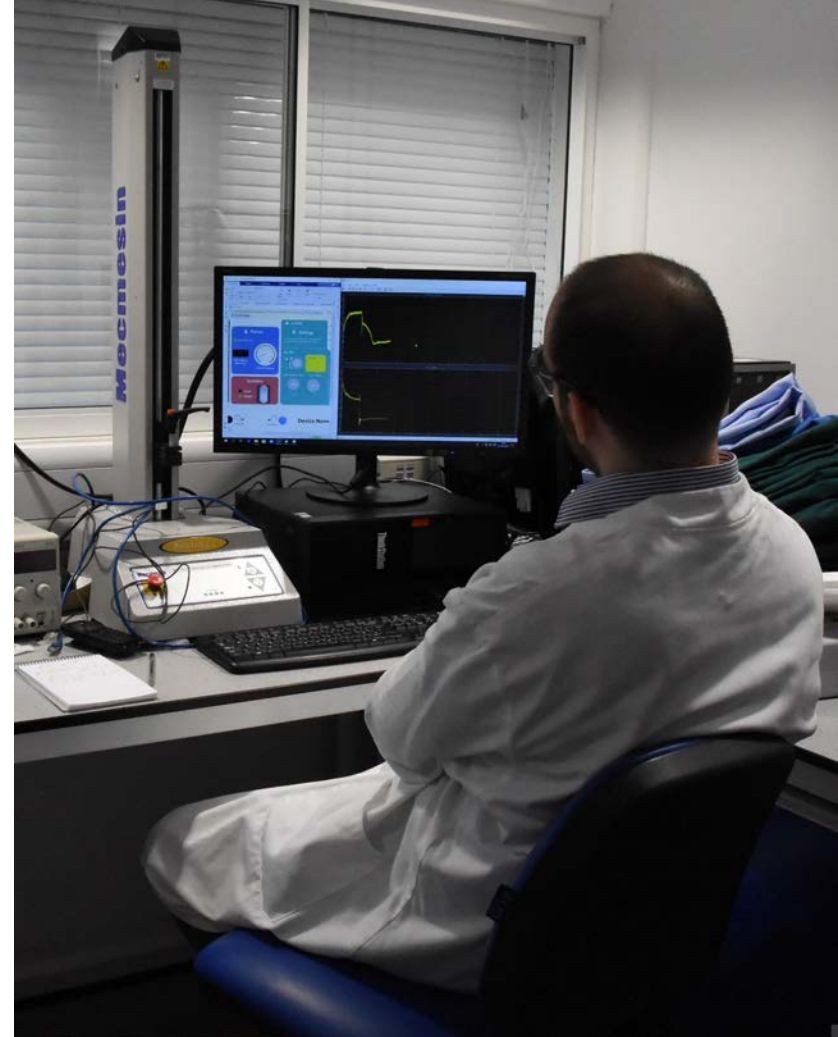
First Draft Algorithm Performance
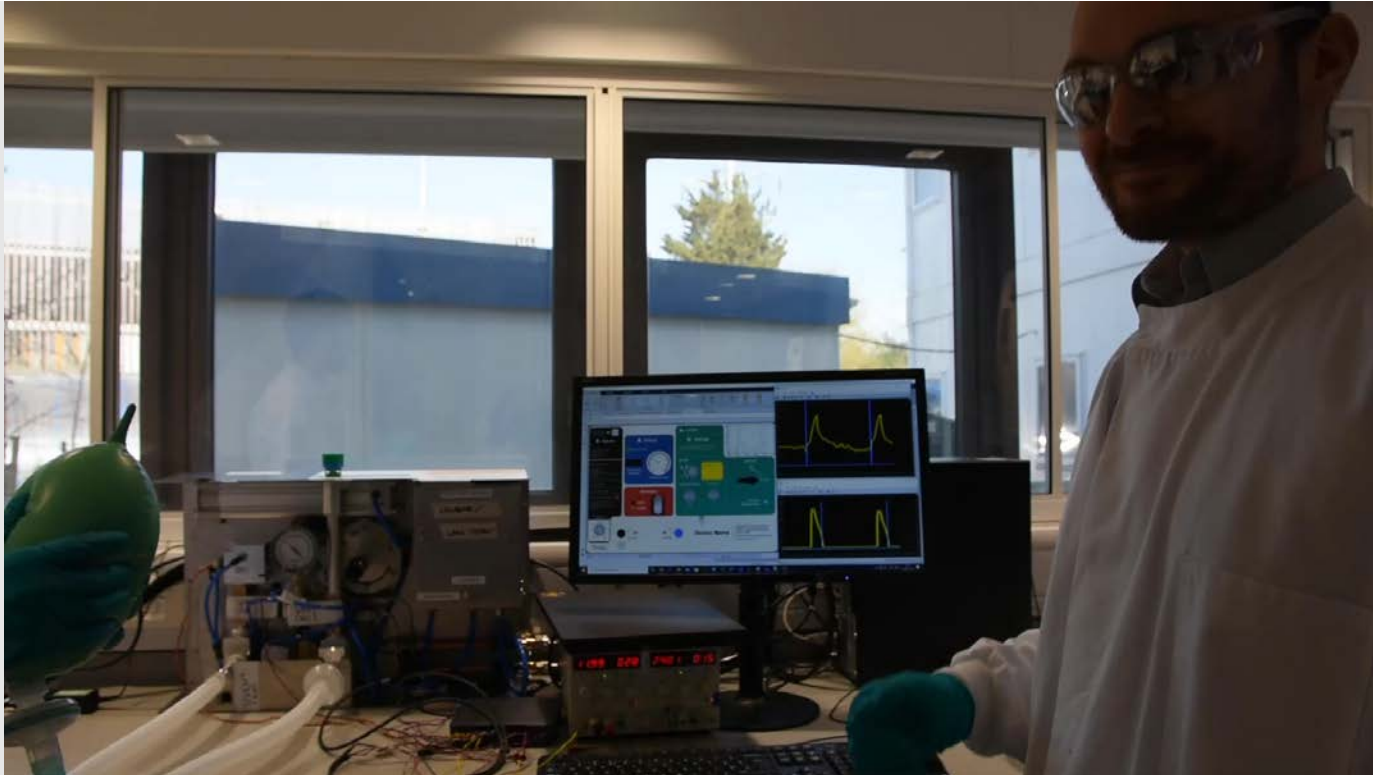
Rapid Algorithm Prototyping Rig - Hardware

- The image here shows the rapid prototyping rig that was used for most of the development and testing.

- The ASL 5000 simulated the patient, capable of imitating a wide range of lung conditions and performing active inhalation and exhalation.

- The rig could operate the algorithms using Simulink Fixed point Designer which allowed the evaluation of algorithm performance on a processor without a floating-point unit.
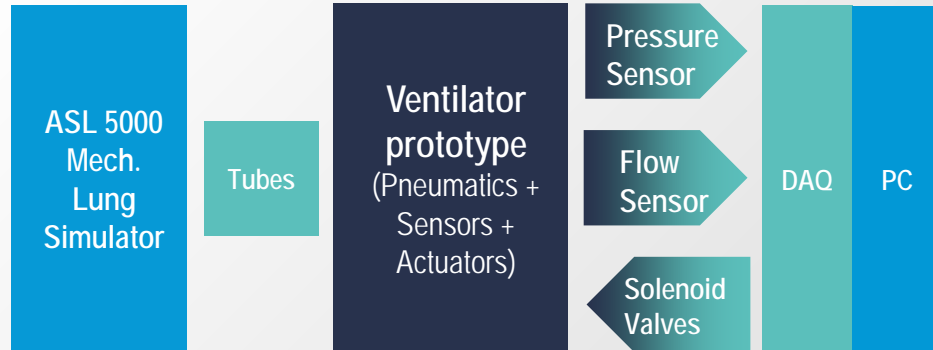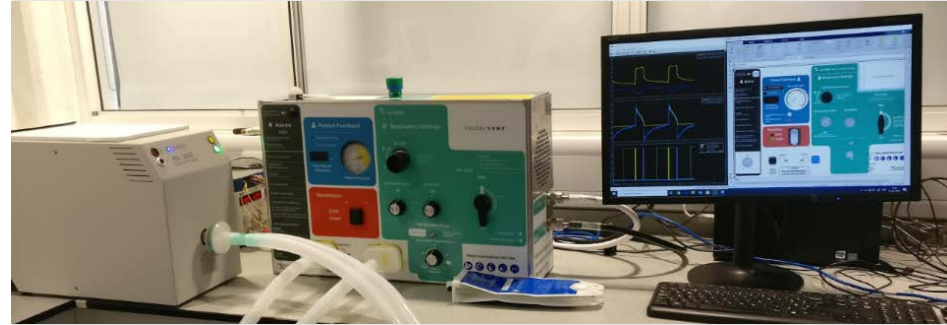
Building Confidence and Deploying to Code-base

- Having started on the 6th of April, we handed off the final algorithm specification to the software team by 13th of April. By the 20th of April, the MHRA's ventilator consultant reported that the Class III software implementation of the SBA worked.
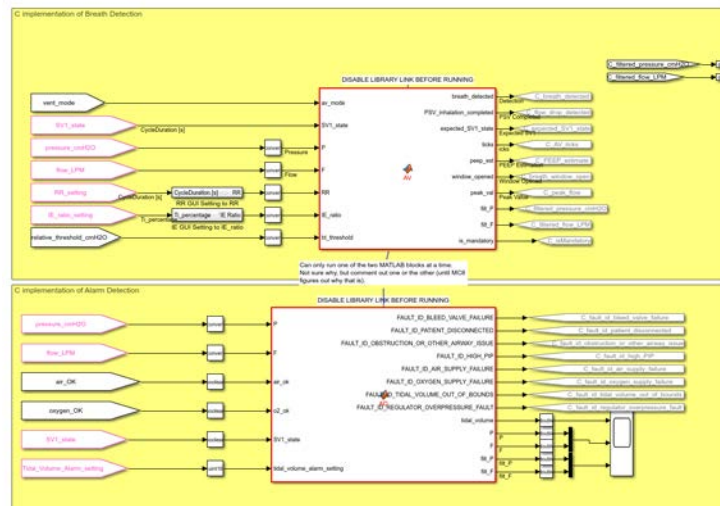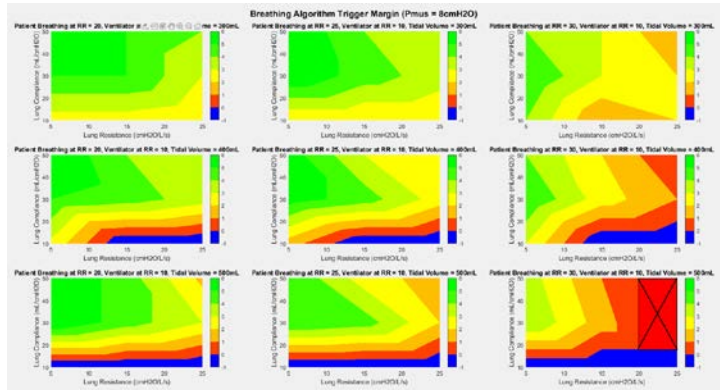
Conclusions

Summary

- Simulink and a wider set of MathWorks tools were effectively employed to provide deep insights into many aspects of the design and guide decision making.

- Although we have different technical backgrounds, by collaborating in the same environment to solve different types of problems, we built the infrastructure to rapidly design more complex functions such as the SB algorithms.

- These tools alone didn't make us ventilator experts overnight. However, they did allow us to draw powerfully on the expertise of many experts on the team and guide it together into a single tapestry of design that we were able to deploy to excellent effect in a way that would have been difficult to achieve otherwise.

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