ximedica

CoVent-19 Challenge and Ximedica

Overview

24 MAR 2020

Overview

Goal and challenge overview

Immersion

- Ventilator Workflow Overview
- COVENT System Architecture
- Requirements table
- Design guidelines

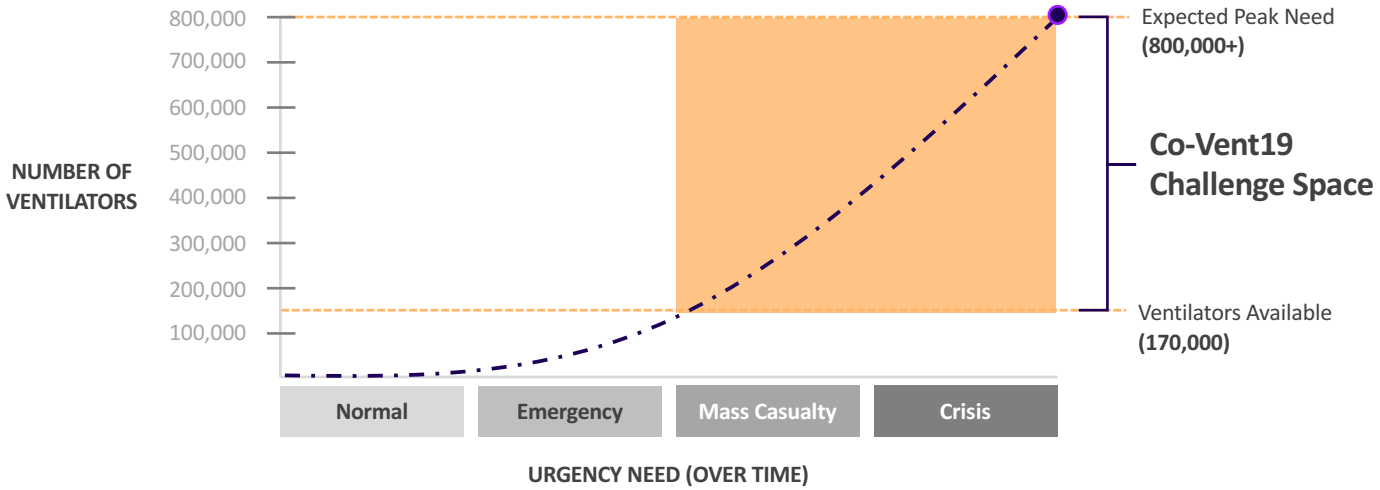
CoVent-19 Goal and Overview

GOAL

Solve for the ventilator shortage:

- At the peak there will be a need for 800k+ ventilators
- Only 170k ventilators in the US
- Increase the capacity of hospitals to provide mechanical ventilation around the world
- Rapidly deployable solution
- Strive for a complete mechanical system
  - Note: electronics and software add development and regulatory risk

CHALLENGE IS FOCUSED ON NEEDS OF **MASS CASUALTY** AND **CRISIS** MODES



COVENT | Goal and challenge overview

The CoVent Process

A Virtual Co-Development and Innovation Challenge
Founded by residents at Massachusetts General Hospital, the CoVent-19 Challenge is a completely virtual open moonshot challenge hosted on GrabCAD to develop a rapidly deployable mechanical ventilation solution

Survive the peak

Curve: let's all aim to flatten the curve with hygiene and social distancing, but we also need to survive the peak.

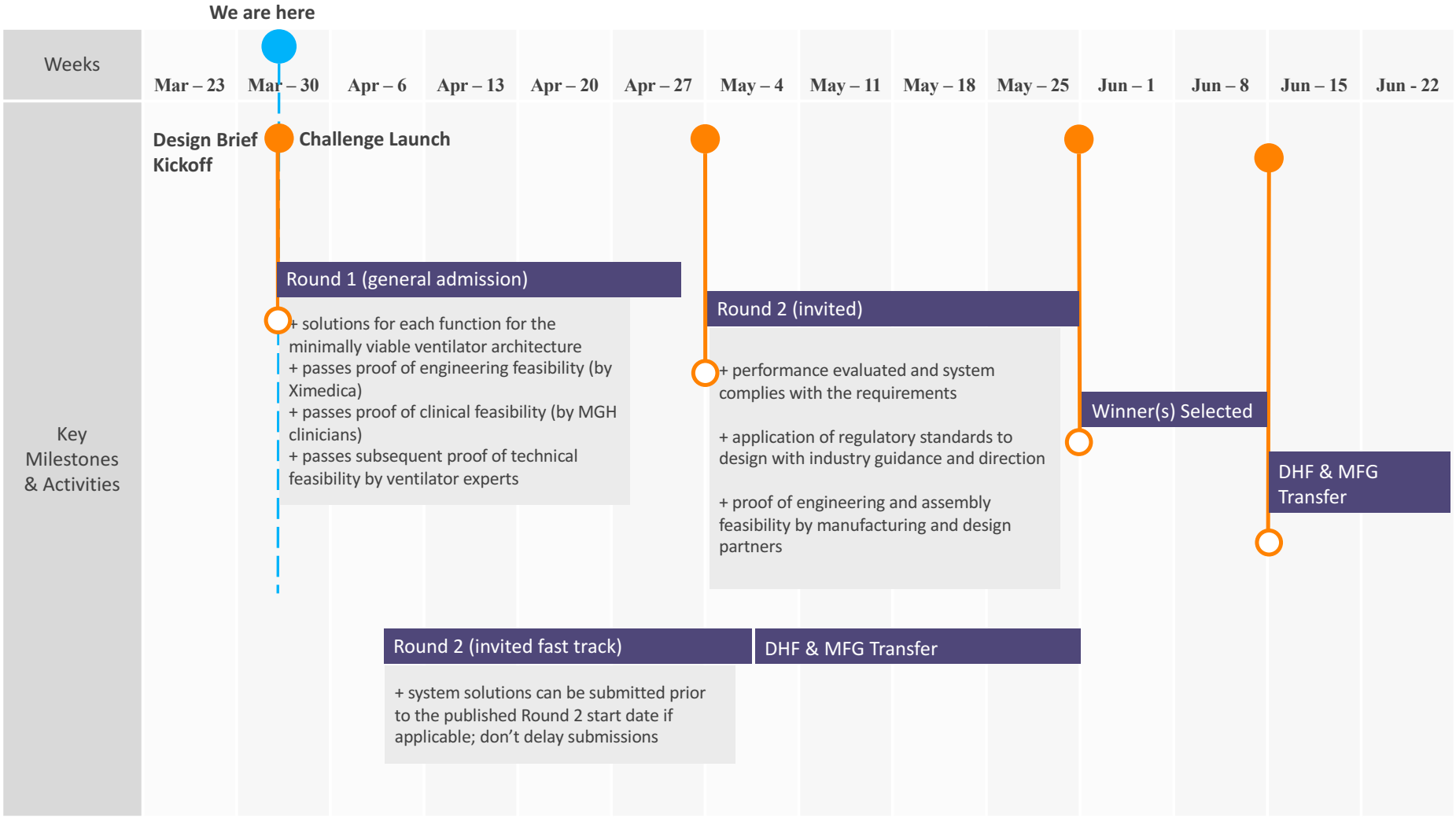
Open: we need to commit to open minds and open access in order to take on this enormous effort to survive COVID-19.

Ventilation: we all ventilate to breathe, but during respiratory failure sometimes we need assistance. This project aims to give everyone access to life-saving mechanical ventilation when they need it.

Innovation: we will count on the best engineers, innovators, designers and makers to bring innovative, rapidly deployable designs to reality.

Deploy: additive manufacturing and rapid prototyping tools have made rapid deployment possible.

Project Overview | **Estimated Timeline - Baseline**



Immersion

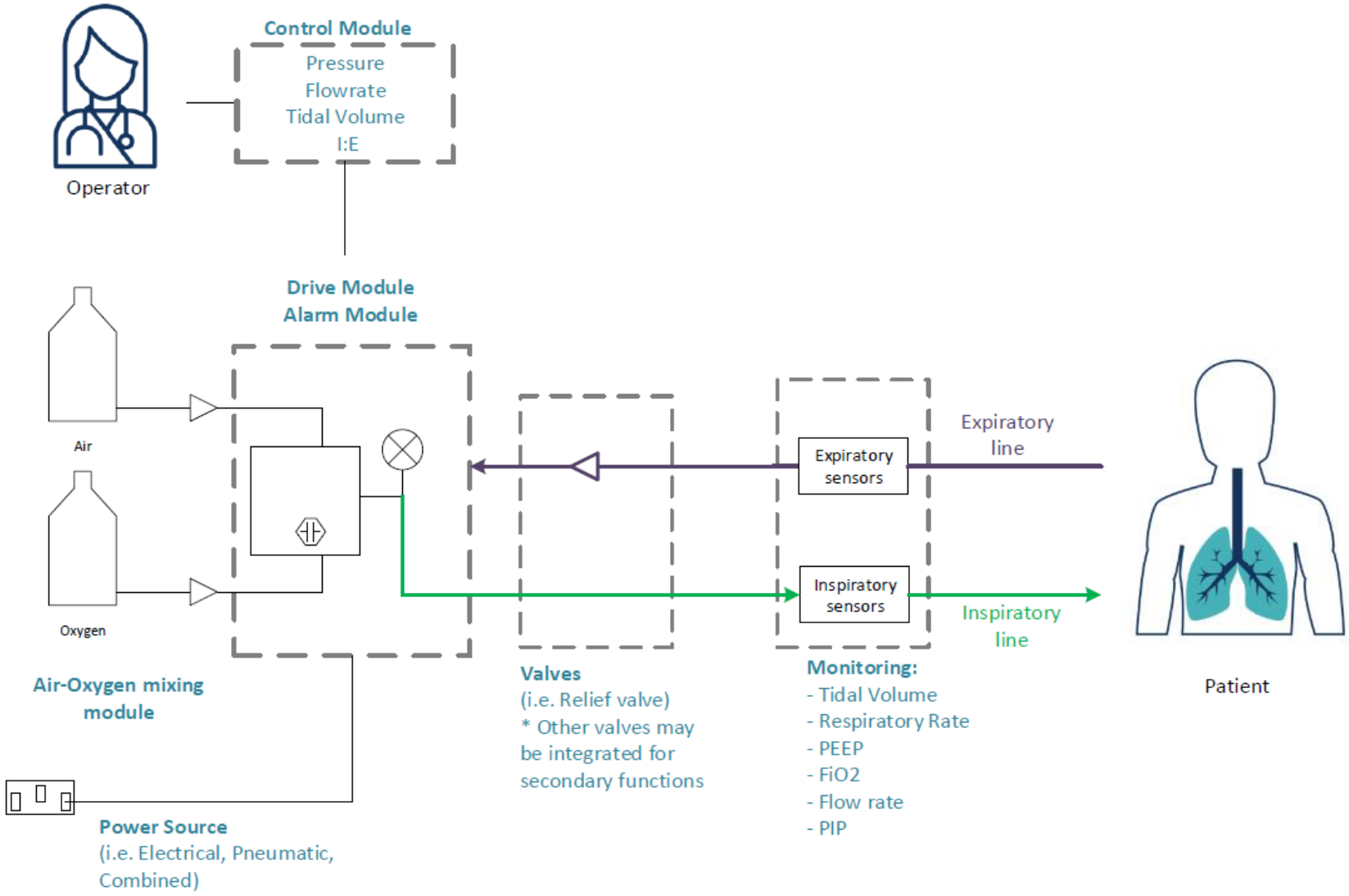
Immersion | Ventilator Workflow Overview

1. Prep					2. Treatment	
1.1 Ventilation Decision Make decision about whether to put the patient on ventilator	**1.2 Ventilator Set-Up** Set up ventilator and breathing circuit	**1.3 Anesthesia** Anesthetize patient	**1.4 Endotrachial Intubation** Intubate patient	**1.5 Placement Confirmation** Ensure that endotrachial tube is placed correctly	**2.1 Mode Selection** Select between mandatory and spontaneous ventilation modes	**2.2 Settings** Set parameters like tidal volume and respiratory rate.

3. Monitor and Adjust			4. Ventilator Weaning		5. Dissasembly	
3.1 Monitored Values Monitor values like tidal volume and respiratory rate	**3.2 Adjustments** Adjust parameters like tidal volume and respiratory rate.	**3.3 Alarms** See and/or hear relevant alarms	**4.1 Weaning** Adjust settings to determine if patient can tolerate removal from ventilator	**4.2 Extubation** Remove endotrachial tube	**5.1 Dissasembly** Dismantle ventilator and breathing circuit	**5.1 Disposal and Reprocessing** Disinfect reusable parts and dispose of disposables

Primary focus areas

Immersion | **Ventilator Architecture**



Immersion | **System Requirements**

	Description	Identifier	Inputs (Requirements)	Module Allocation
General Perform-ance	Modes of Operation	SR-01	Mandatory Ventilation (Primary function / minimum)	Control Module
		SR-02	Spontaneous Ventilation (Secondary function / design goal)	Control, Monitoring Module
	Control	SR-03	Volume Control (Primary function / minimum)	Control Module
		SR-04	Pressure Control (Secondary function / design goal) 5-60 +/- 5 cmH2O	Control Module
		SR-05	Pressure Support 10-15+/-5 cmH2O; may be either flow- or pressure-triggered (Secondary function / design goal)	Control Module
		SR-06	Apnea back-up kicks in at 30 or 60 seconds (+/-5sec) (Secondary function / design goal)	Control, Monitoring Module
	Flow Rate	SR-07	> 60 liters per minute	Drive Module
	PEEP	SR-08	Pressure: 5-15 cmH2O in increments of 5 cmH20 (+/-5 cmH2O)	Control Module
	Inspiratory : Expiratory (I:E) Ratio	SR-09	Mandatory Ventilation: 1:2, 1:3, and 1:4 options available (click-stop)	Control Module
	Respiratory Rate	SR-10	10-30 breaths per minute in increments of 2 bpm	Control Module
	Tidal Volume	SR-11	Option #1: Input height and gender for 6cc/kg TV (+/- 10% or 10mL) Option #2: 350cc (for average woman) and 450cc (for average man) (+/- 10% or 10mL) Option #3: 400cc only (+/- 10% or 10mL) Option #4: 300-600cc adjustable in 100cc increments (+/- 10% or 10mL)	Control Module
Gas	Gas Connectors	SR-12	Compatible with high pressure (~50psi) gas source (i.e., pipeline supply) OR low-flow inlet	Air-Oxygen Mixing Module
	Oxygen delivery	SR-13	Option #1: FiO2 (21%+10%, 50%+/- 10%, 100% -10%) Option #2: adjustable between room air (21%) and 100% (+/-10%)	Control Module

Immersion | **System Requirements**

	Description	Identifier	Inputs (Requirements)	Module Allocation
Infection Control	Reusability	SR-15	All components coming in contact with the patients breath must be disposable OR sterilizable (e.g., autoclavable)	Breathing Circuit
	Viral Filters	SR-16	0.22um or smaller filter on patient inspiration and expiration pathway	Breathing Circuit
		SR-17	Ventilator inlet gas to allow filtration	Air-Oxygen Mixing Module
	Cleanable	SR-18	All external surfaces must not degrade with application of standard agents for disinfection (e.g. bleach solution)	All reusable touchpoints
Alarms & Monitoring	Critical	SR-19	Inlet Gas (O2) or Power supply failure	Alarm, Air-Oxygen Mixing, and Power Source Modules

		SR-20	• Inspiratory airway pressure exceeded limits
			  • Pplat <30-35 cmH2O
			  • Peak P no more than 2 cmH2O greater than Pplat
			  • Fail-safe valve opens at 60cmH2O (powered or un-powered)
				Alarm and Monitoring Modules

		SR-21	Apnea (i.e. patient not breathing) on spontaneous mode (secondary)	Alarm and Monitoring Modules
		SR-22	Inspiratory and PEEP pressure not achieved (i.e. disconnection)	Alarm and Monitoring Modules
		SR-23	Tidal volume not achieved or exceeded (with ~20% tolerance)	Alarm and Monitoring Modules
		SR-24	O2 disconnection	Alarm and Air-Oxygen Mixing Modules
		SR-25	Alarm Volume 60 to 80 dBA at one meter (+/- 5 dBA)	Alarm Module
	Monitoring	SR-26	Actual Value (TV, RR, PEEP, FiO2, Flow Rate, PIP)	Monitoring Module

Immersion | **System Requirements**

	Description	Identifier	Inputs (Requirements)	Module Allocation
Ventilator Specific Standards / Misc.	Ventilator Specific	SR-27	Vent performance for </=10,000 ft Altitude,	Guidance provided in Round 2
		SR-28	Durability =2,000 hours	Guidance provided in Round 2
		SR-29	Compatibility with readily available patient circuits, (ISO 5356-1 fittings)	Guidance provided in Round 2
		SR-30	Comply with FDA Ventilator Guidance Standards (i.e. ISO 80601-2-12)	Guidance provided in Round 2
	Medical Device Generic	SR-31	Comply with general Medical Device Guidance Standards (e.g. ISO 13485, ISO 14971, ISO 62304, ISO 62366)	Guidance provided in Round 2
Electric (if applicable)	Power	SR-32	120VAC	Power Module
	Electrical Safety	SR-33	Comply with IEC 60601-1 and IEC 60601-1-2	Guidance provided in Round 2
	Battery Backup	SR-34	None with labeling (primary function)	Power Module
		SR-35	1 hour (secondary function / design goal)	Power Module

Immersion | **Design Brief**

Engineering and design for manufacturing Strategy – The effort is predicated on speed! Design solutions to the greatest extent possible should identify and leverage the fastest possible methods that will maximize ease of assembly and function

1) Additive manufacturing (particularly Stratasys) is preferred
    - Consider different Stratasys material options

2) Tolerances and material finish –
    - Design parts and clearance considering this process

3) Post processing – Sanding / smoothing
    - While post processing is possible it should be avoided

4) RAW Materials –
    - Incorporating cut tubing extrusions as sleeves to achieve smooth surfaces
    - Die cutting 2D shapes from flat stock

5) Assembly –
    - Snap fits – consider material properties (%deflection)
    - Snap fits – require overtravel to engage
    - Bayonets – A good AM technique but should be avoid for multiple actuations
    - Thread forming screws – Plastite
    - Avoid – adhesives if possible
    - Avoid - Ultrasonic welding or heat staking