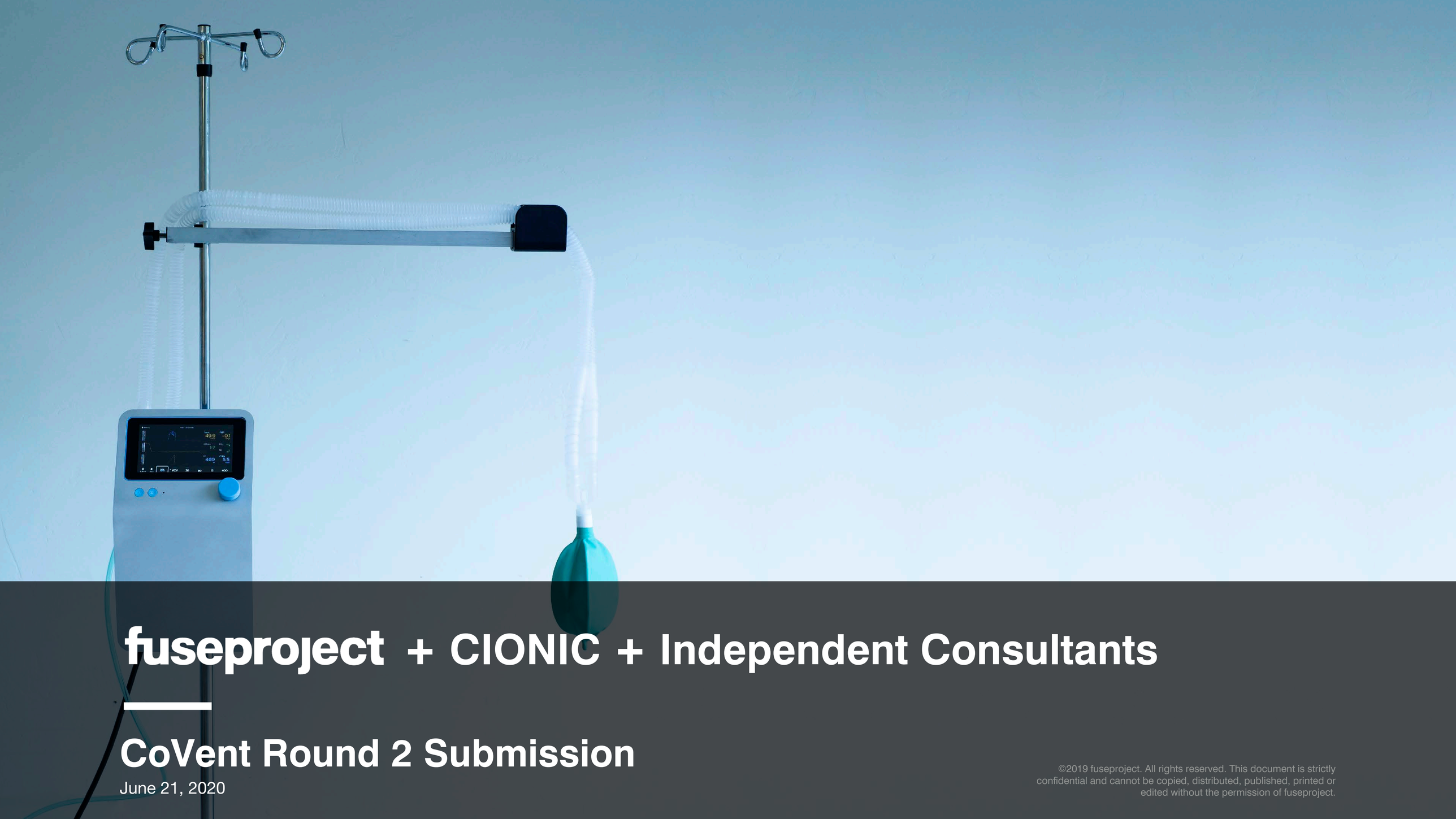

fuseproject + CIONIC + Independent Consultants

CoVent Round 2 Submission

June 21, 2020

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History has proven that in times of crisis, innovation can flourish.

Penicillin was first used as a lifesaving antibiotic on a patient in 1942. Facing the casualties of World War II, the US government called on pharmaceutical companies across the country to chip in on the war effort by making penicillin product a priority.

Traditionally slow and intensive to produce, Pfizer combined its knowledge of fermentation with the specific conditions of penicillin to discover a rapid production method that treated an estimated 100,000 soldiers.

Collaboration is the **key** to effective response in crisis.

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Penicillium spp. growing on a variety of Petri dishes

The modern ventilator is a sophisticated device. At it’s most complex, it enables precision tailoring for a wide-range of ventilation needs.

With Covid-19, medical system around the world are overburdened. Access to this lifesaving device presents a challenge for health care settings experience peak surges as well as low resourced hospitals with limited ventilator supply.

The global ventilator supply is not enough. The medical community has issued a call to action to designers and engineers.

A team of designers and engineers banded together to optimize the ventilator for an overburdened supply chain constraining health care capacity.

fuseproject

Design & Innovation

CIONIC

Medical Device Technology

Independent Consultants

Mechanical Engineering

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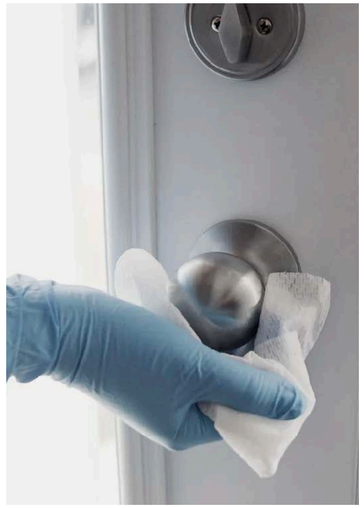
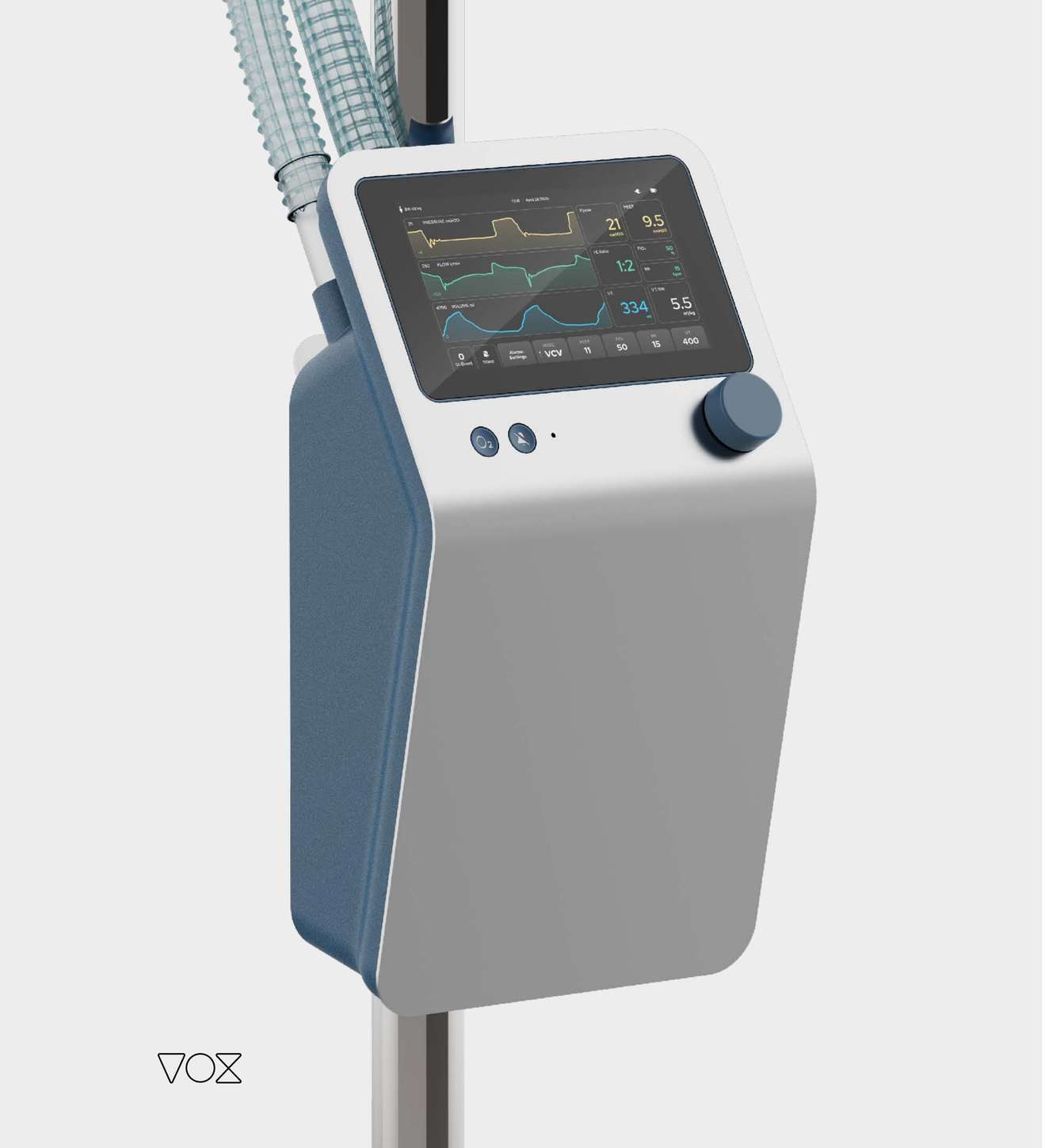
Our approach stems from a fundamental belief that innovation starts with human insight.



Our design is the result of **continual collaboration with health care professionals** in order to ensure an intuitive, improved experience for those working with the life-saving device.



Introducing

VOX

A pneumatically-driven ventilator, optimized for a Covid-19 health care context and assembled in under 4 hours

We looked to the context for innovation clues

With accidents down and elective surgeries canceled, hospitals are operating at as low as 50% capacity.

VOX leverages the ubiquitous IV pole enabling speedy manufacturability, adjustable placement in use, easy transport, and simple storage.

Designed for safe & accurate delivery

Ventilation, while lifesaving, introduces additional dangers of lung injury from volume or pressure trauma – especially true for long term use of bag valves (also known as ambu bag) as a ventilation device which present the potential of air valve collapse.

A pneumatic valve ventilation system offers the safest delivery of lifesaving ventilation.

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Round 2 Addition

Eliminating unnecessary exposure to our health workers

Health workers around the world are going to great lengths to limit their personal exposure. VOX's dashboard functionality allows health workers to monitor and even operate multiple ventilators from a single desktop computer or tablet, drastically limiting personal exposure to the disease.

Leveraging the best of 3D printing to simplify assembly

Our design maximizes use of Stratasys’ advanced polyjet printing technologies and library of materials for optimized assembly.

Combining outer shell and housing, the unit leverages multi-material and multi-color printing functionality to include venting, fasteners for assembly, Venturi tubes and even exterior UI details like buttons and icons.

Round 2 Addition

Adaptable for each unique care setting

Each hospital is unique in design, workflows, and built environment. The refinement of our design focused on flexibility and adaptation, including a customizable UI flow.

Additionally, VOX's multi-device dashboard capability opens up the possibility of a screen-free device. Low-resource contexts can opt to remove the built-in screen and leverage external mixing, thus minimizing materials and processes and reducing the overall cost of the device.

VOX is the integration of many solutions optimizing for flexibility, manufacturing & assembly while delivering a best-in-class user experience.

Intuitive User Experience

Intelligent Manufacturing

Simplified Architecture

© and confidential

Intuitive User Experience

There’s no time to learn a new machine. VOX was designed with affordance to leverage existing user behaviors, while enabling a customizable UI tailored to each hospital’s unique work flow.

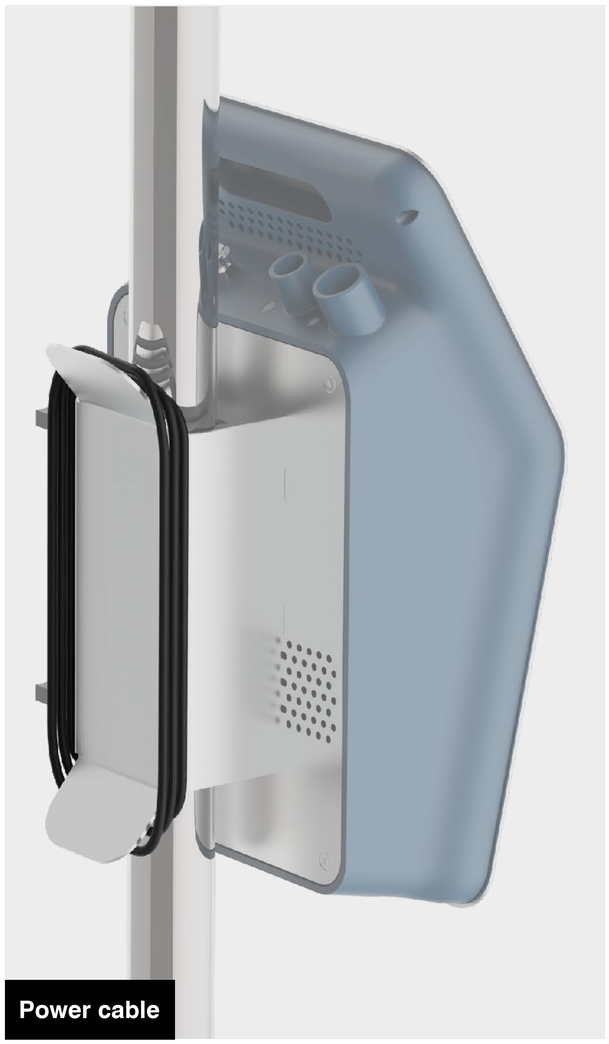
© and confidential

Pole attachment

Ease of installation, transport & storage

- Simple attachment mechanism for variably sized poles, additionally allowing user to adjust height for comfort
- Leverages built-in mobility of IV poles for easy transport
- Detaches from poles for space-saving storage

Tube support arm

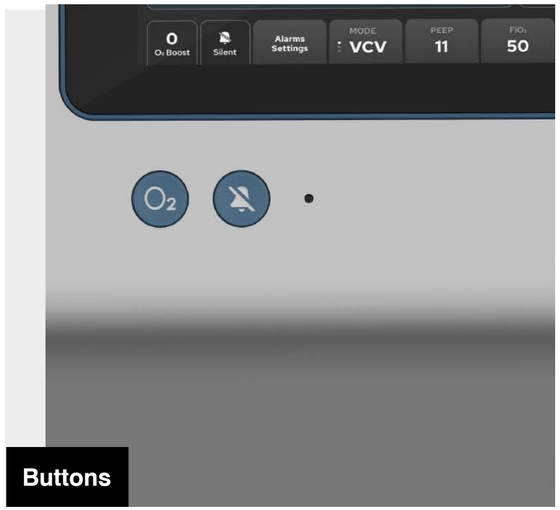


Power cable

Organized tube and cable management

- Tube support arm improves angle of tube-to-patient connection, reducing accidental disconnections
- The cable management back cover provides a clean storage solution for he power cable while also hiding the pole clamps.

Rotary dial



Buttons

Ergonomic interface

Intuitive navigation and legibility

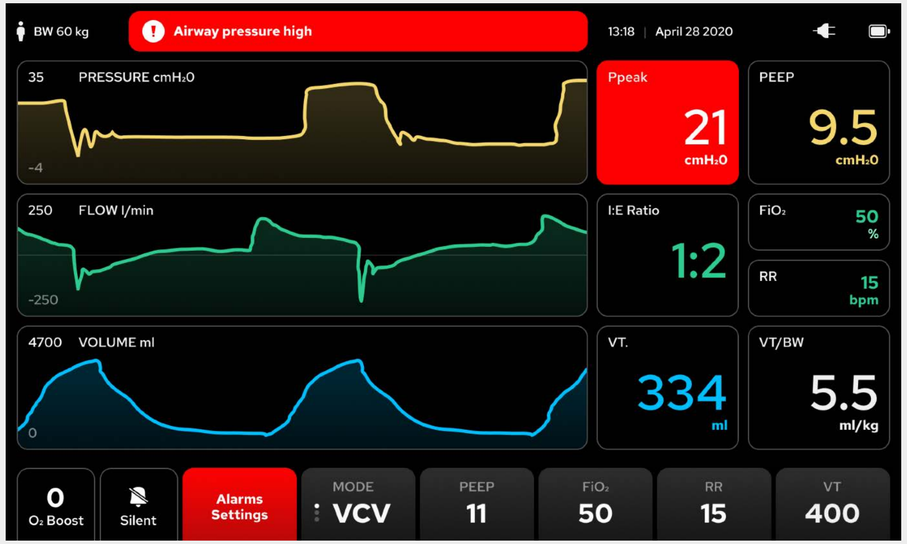
- Simple rotary dial for menu navigation and incremental adjustments
- Two easy to identify main buttons for of critical function oxygen boost and alarm silencing
- Angled face to improve ergonomics of the device

Familiar UI and controls

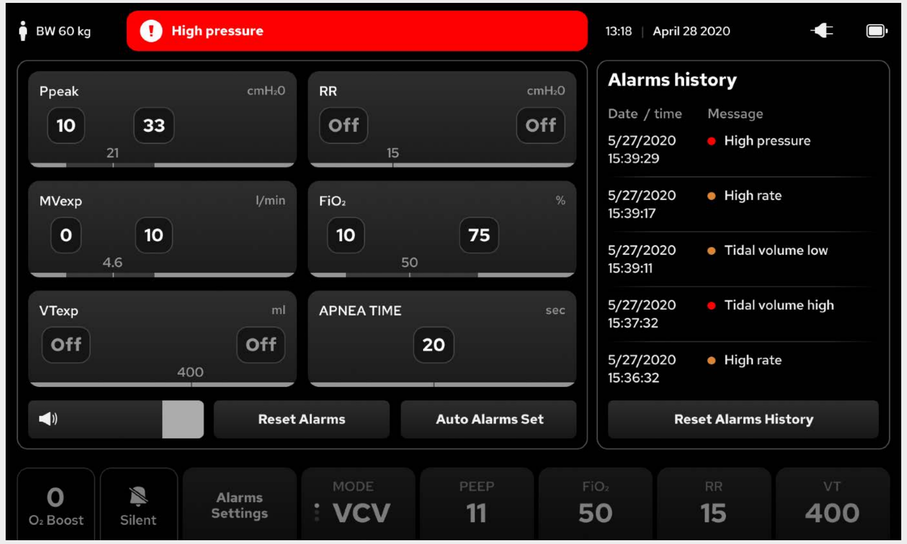
- Valuable waveform monitoring for pressure, flow and volume
- Simplified interpretation with grouped inputs and outputs
- Color coding to distinguish key inputs and outputs

Round 2 Refinement:

- Customizability to tailor sequencing of inputs and outputs to each hospital's unique workflow



Alarm settings



Alarm controls

Simple alert states with streamlined management

- A highlighted alert area pairs with messaging on the top of the screen to allow for quick scanning and comprehension.

Round 2 Refinement:

- Volume control and sound signatures by alarm type
- “Auto alarm set” with a pre-programmed parameters standard for coronavirus patients

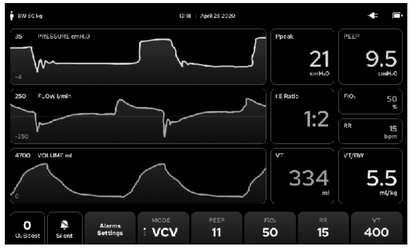
Round 2 Addition

A multi-device dashboard

- A single dashboard view for monitoring up to 4 ventilator devices on a single desktop computer, tablet or smart phone device
- Additional capabilities to operate ventilator include alarm management, O2 boost, and ventilation settings

World Wide Web (W3C) Accessibility Consortium

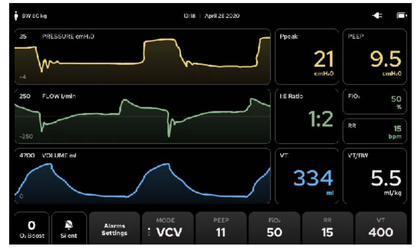
Our product’s accessibility enhance the usability for all users, including those with low vision.
Our UI meet (W3C) AAA grade contrast ratio and works across color blindness visions.



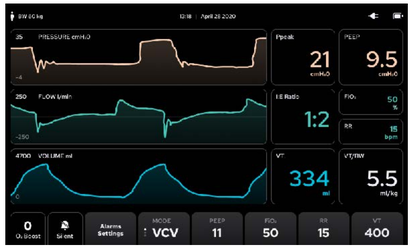
Achromatopsia vision

Deuteranomaly vision

Deuteranopia vision

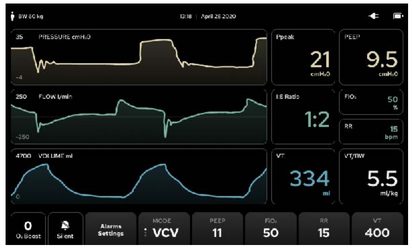


Protanomaly vision



Tritanomaly vision

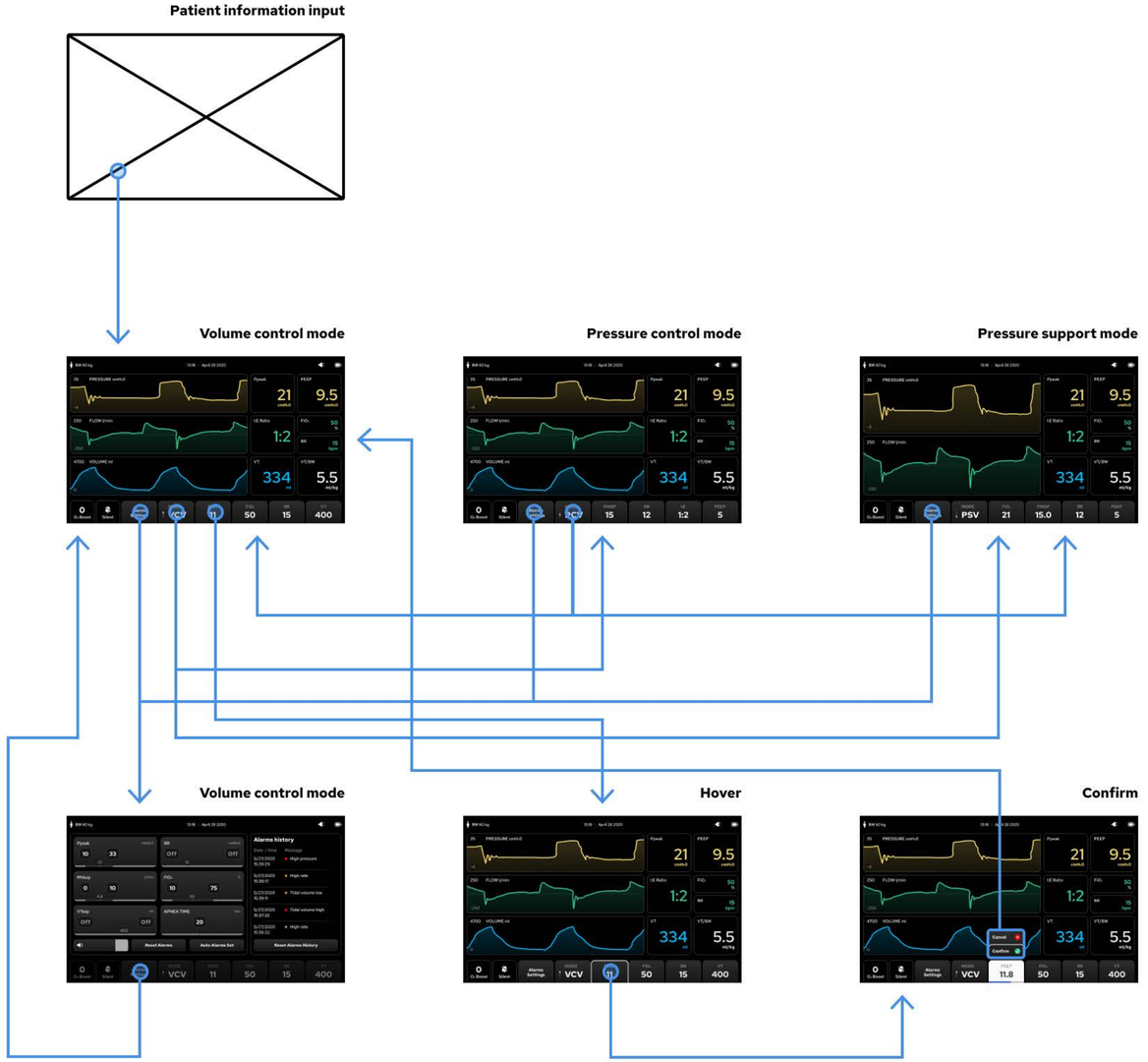
Tritanopia vision



Achromatomaly vision

Protanopia vision

UI flow


Patient information input
Volume control mode
Pressure control mode
Pressure support mode
Volume control mode
Hover
Confirm

Intelligent Manufacturing

Great ventilator models exist. The real opportunity here is getting this made fast, reducing time-to-market with simple manufacturing processes that scale globally.

Base materials

Plug in wall mount air supply

Educated material selection

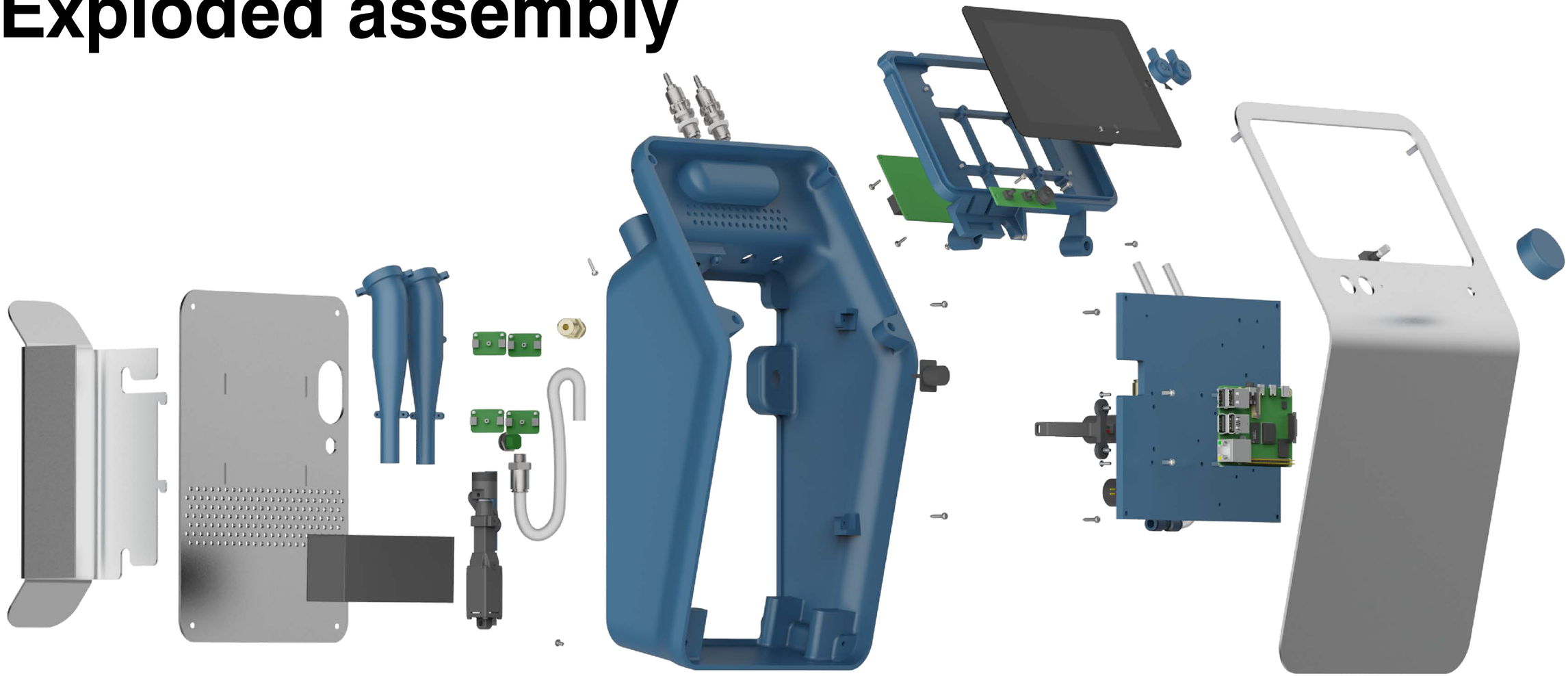
- Leveraging Stratasys 3D printing technology for multi-material, multi-color in a single print to eliminate labelling, assembly and post-processing, streamlining processing and production time.
- Optimized size, form and material of aluminum for durability and protection
- Single bend aluminum front plate which can be fabricated cheaply at most metal fabricators
- Virus persists on aluminum for 2-8 hours, compared to 48 hours on steel.

Exploded view - Sub-assemblies mount to 3D printed body

Simplified assembly

- Fewer parts minimize need for fasteners.
- Design without adhesives cuts assembly time.
- Reduction in components significantly reduces assembly errors.
- Self-tapping screws remove the need for threaded inserts, speeding up assembly time.
- Removable pneumatic and screen sub-assemblies are designed to modularize production workflow.

Exploded assembly



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IV Poles from empty rooms in hospital wards

Standard Pole clamp

Plug in wall mount air supply

Leveraging hospital equipment

- Due to the decline in ER visits and elective surgeries, precious ER equipment including IV poles sits unused.
- Flexible clamping mechanism can adapt to other pole attachments in a hospital setting.

Simplified Architecture

Ventilators can have an incredible range of capabilities and features. Explore alternative technologies to focus on what’s most necessary for Covid-19.

Pneumatics

Venturi Tubes

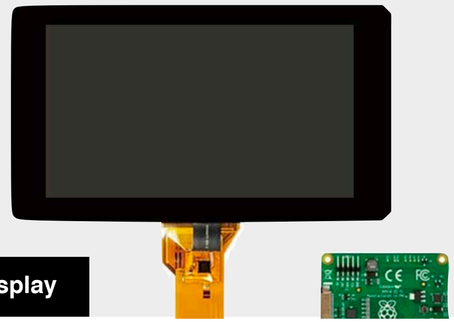
Standard Connections

Pneumatic operation system

- Leverages existing pressurized air system in hospitals instead of mechanical actuation.
- Lighter more manageable form factor.
- Sensors mounted directly to Venturi tubes
- Built-in overpressure relief valve for safety.
- Simple variable timing and flow control.
- Spontaneous mode supports patient triggered ventilation.
- Components with proven long-term reliability.

Off The Shelf Sensors

Single Board Computer

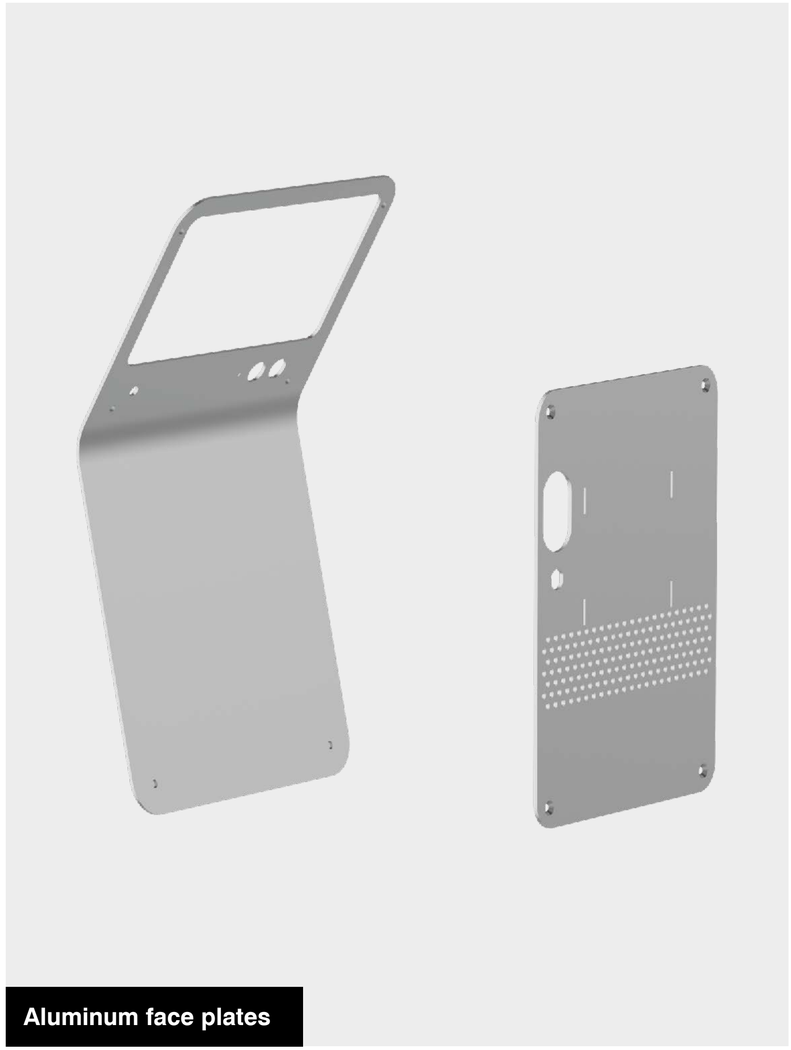


Standard Display

Proportional Solenoid Valves

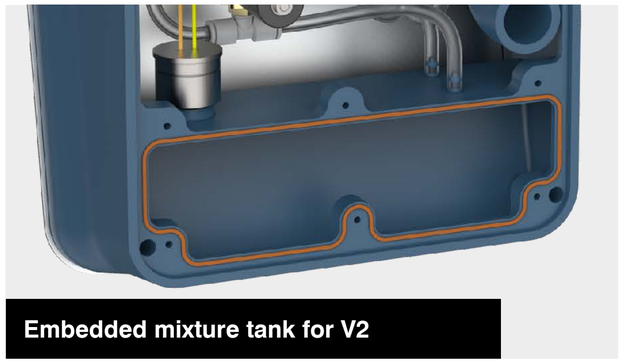
Maximizing OTS + serviceability of parts

- Subassemblies allow for easy serviceability
- Open hardware and open software
- Highly responsive solenoids



Aluminum face plates

Venturi tubes



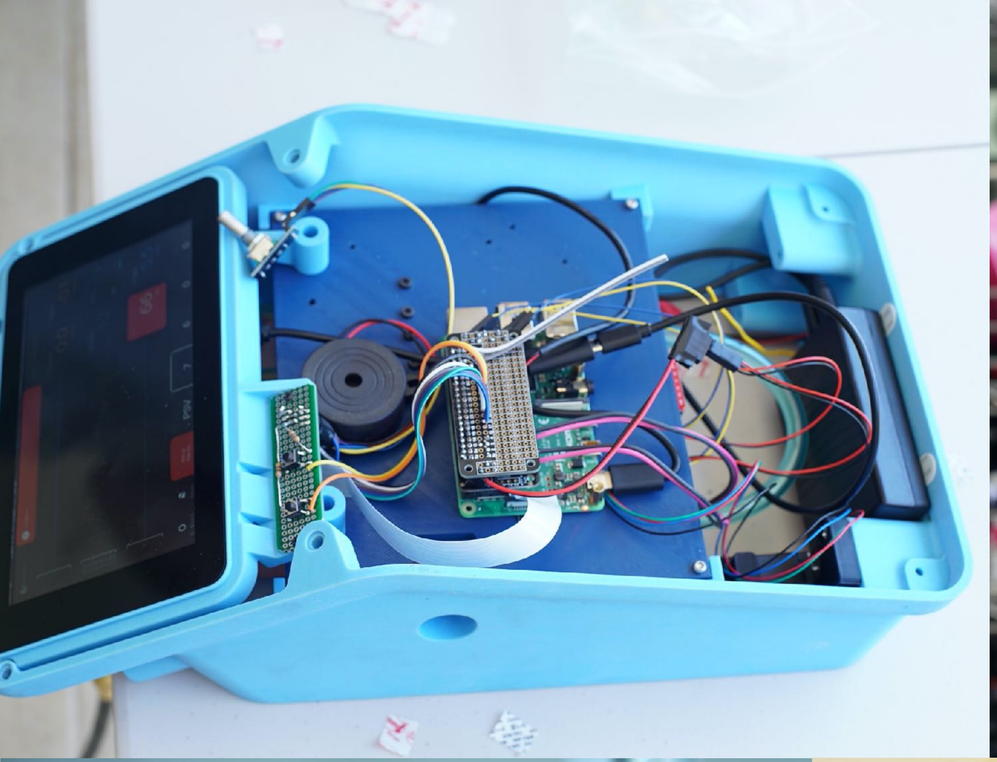
Embedded mixture tank for V2

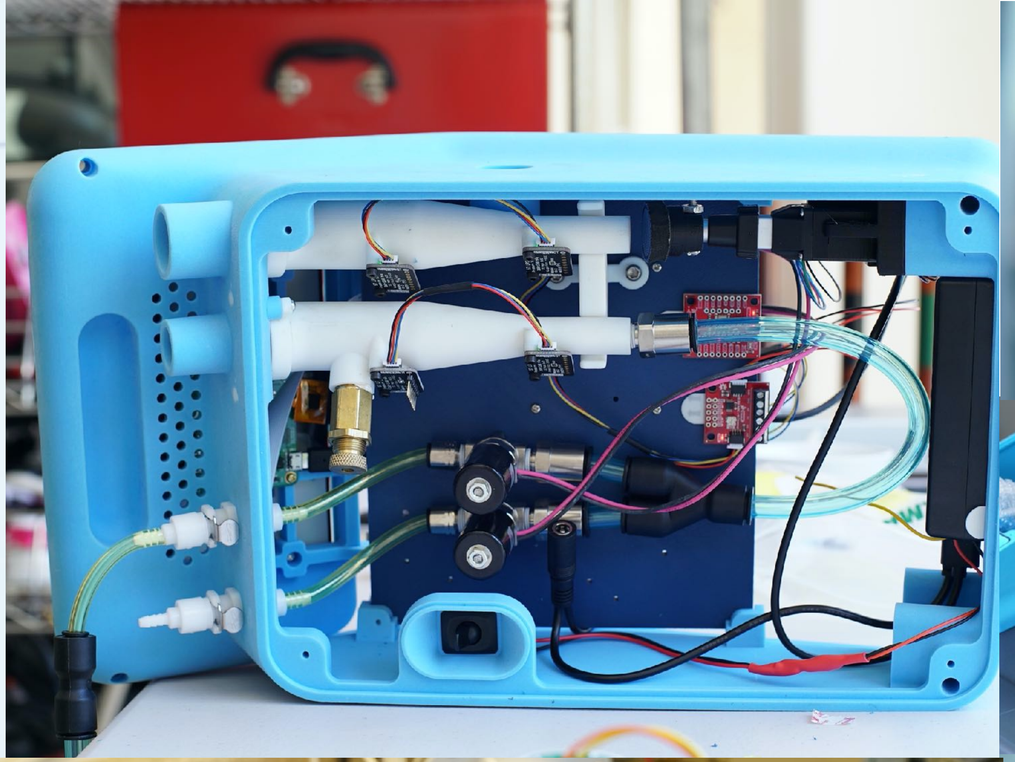
Simple design, sophisticated functionality

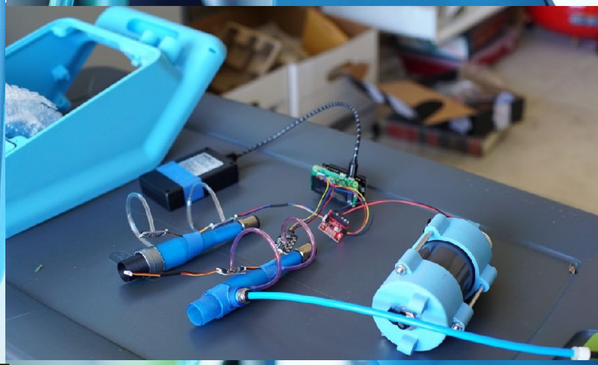
- Pneumatic approach simplifies entire system size and complexity compared to a mechanical design.
- Hidden fasteners built into aluminum face plate for simplified sterilization.
- Embedded air mixture tank and Venturi tubes are 3D printed to reduce cost and manufacturing time.
- Leverages standard IV poles for mounting.

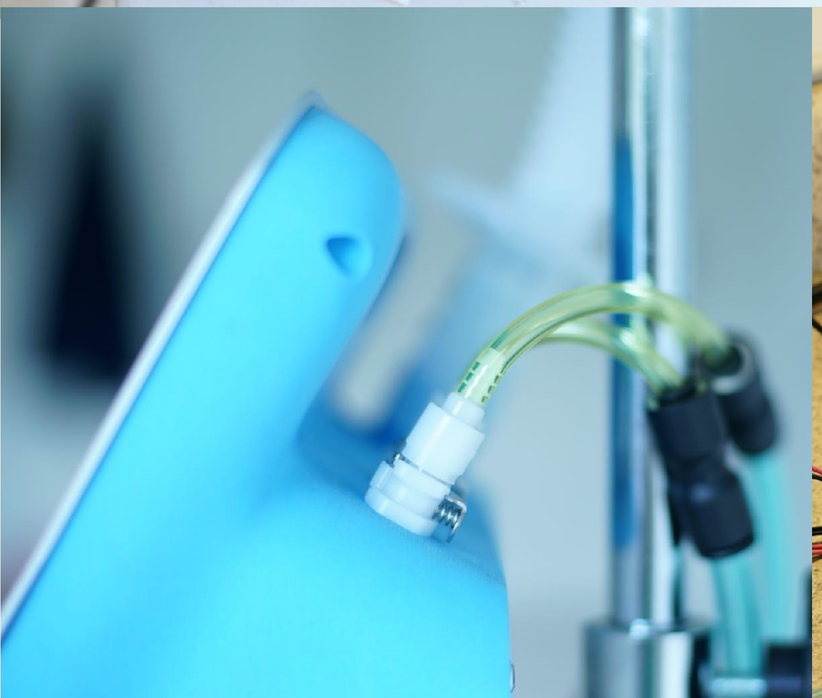
Putting it all together

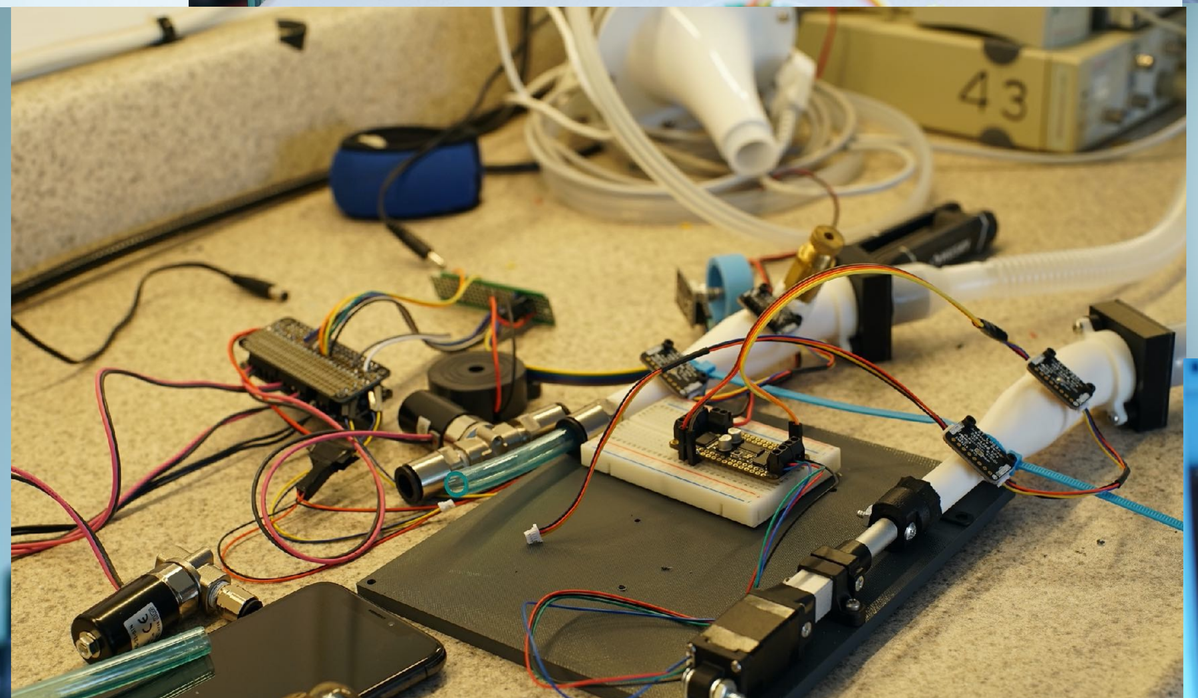
This last sprint has been about putting together more than just a ventilator that looks good on paper, but a ventilator that works.







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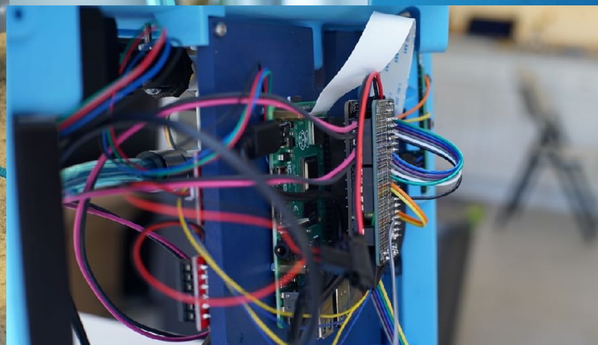

Assembly video

VOX

Intuitive user experience, intelligent manufacturing, simplified architecture

Last Thoughts

Thank you to our medical experts…

Rob Bautista
ICU Respiratory Therapist, UCSF

Lindsay Ryan
Emergency Physician, San Francisco VA Medical Center ER

Robb Johnson
Chief Perfusionist, Saint Joseph Mercy Oakland Michigan

Bob Hankins
Ventilator Expert, Nordson Medical

John Feiner
Professor, UCSF Department of Anesthesia and Perioperative Care

Dave Holtzclaw
Anesthesiologist, Mills Peninsula Medical Center

Fiona Holtzclaw
BS, BSN, RN, PCCN, Stanford Hospital

Ayla Pelleg
Professor, Icahn School of Medicine at Mount Sinai

Amanda Foote
ICU RN, Hospital of the University of Pennsylvania

Bryan Hahn
ICU RN, Summit Medical

…and all of our frontline workers.

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Next Steps

- Develop Assembly Instructions to support final assembly of prototype
- Consult with Ximedica on completion of the Design History File
- Continued develop of UI flows, including onboarding and multi-device desktop dashboard
- Partnership with the African Federation for Emergency Medicine to conduct primary research focusing on the care context and user experience of Nigerian hospitals in order to identify additional design opportunities

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CIONIC

Independent
Consultants

Requirements met by VOX

IDENTIFIER	COMPONENT	REQUIREMENT TEXT	VERIFICATION METHODS	CLOSEOUT REFERENCES	VERIFICATION STATUSES	VERIFICATION COMMENTS	STATUS	# CHILDREN VERIFIED	COMPLIANCE	ATTACHMENTS
SR-01-385	InVent	Operation shall support mandatory Ventilation (Primary function / minimum)	Review		Verified	Review Req	1/1	N/A	...	+ Add Attachment
SR-02-386	InVent	Operation shall support spontaneous Ventilation (Secondary function / design goal)	Test		Verified	Video Verific	1/1	N/A	...	spontaneous_compressed + Add Attachment
SR-03-387	InVent	Volume Control (Primary function / minimum)	Test		Verified	See Files for	1/1	N/A	...	+ Add Attachment
SR-04-388	InVent	Pressure Control (Secondary function / design goal) 5-60 +/- 5 cmH2O	Test		Verified	...	1/1	N/A	...	ISO_PCV1 ISO_PCV2 + Add Attachment
SR-05-389	InVent	Pressure Support 1.0-15+/-5 cmH2O, may be either flow- or pressure-triggered (Secondary function / design goal)	Test		Verified	...	1/1	N/A	...	spontaneous_compressed + Add Attachment
SR-06-390	InVent	Apnea back-up shall kick in at 30 or 60 seconds (+/-5sec) (Secondary function / design goal)	Test		Verified	Video Verific	1/1	N/A	...	spontaneous_compressed + Add Attachment
SR-07-391	InVent	flow rate shall be > 60 liters per minute	Test		Verified	Testing sho	1/1	N/A	...	103.009 l/min (ISO) + Add Attachment
SR-08-392	InVent	PEEP Pressure: 5-15 cmH2O in increments of 5 cmH2O (+/-5 cmH2O)	Test		Verified	5 cm H20	2/2	N/A	...	5 cm H20 (ISO) 10 cm H20 (ISO) 15 cm H20 (P15) + Add Attachment
			Test		Verified	10 cm H20				
			Test		Verified	15 cm H20				
			+ Add							
SR-09-393	InVent	Inspiratory:Expiratory ratio during Mandatory Ventilation: 1:2, 1:3, and 1:4 options shall be available (click stop)	Test		Verified	1:2	4/4	N/A	...	IE = 1:2 (ISO) IE = 1:3 (ISO) IE = 1:4 (ISO) IE = 1:5 (P15) + Add Attachment
			Test		Verified	1:3				
			Test		Verified	1:4				
			Test		Verified	1:5				
			+ Add							
SR-10-394	InVent	The respiratory rate shall deliver 10-30 breaths per minute in increments of 2 bpm	Test		Verified	10bpm	8/8	N/A	...	10bpm (P15) 12bpm (ISO) 15bpm (ISO) 20bpm (ISO) 30bpm (P30) + Add Attachment
			Test		Verified	12bpm				
			Test		Verified	15bpm				
			Test		Verified	20bpm				
			Test		Verified	30bpm				
			+ Add							
SR-11-395	InVent	Tidal volume options available shall be as followingOption #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: 200-600cc adjustable in 100cc increments (+/- 10% or 10mL)	Test		Verified	200cc	6/6	N/A	...	200cc (C200) 300cc (C300) 400cc (C400) 500cc (C500) 600cc (C600) + Add Attachment
			Test		Verified	300cc				
			Test		Verified	400cc				
			Test		Verified	500cc				
			Test		Verified	600cc				
			+ Add							
SR-12-455	DISS_Air	Gas connectors shall be compatible with high pressure (~50psi) gas source (i.e., pipeline supply) OR low-flow inlet	Rules		1/1 Edit Rules	Verified	1/1	N/A	...	+ Add Attachment
			+ Add							
SR-12-456	DISS_02	Gas connectors shall be compatible with high pressure (~50psi) gas source (i.e., pipeline supply) OR low-flow inlet	Rules		1/1 Edit Rules	Verified	1/1	N/A	...	+ Add Attachment
			+ Add							
SR-13-517	InVent	Oxygen delivery options shall be as following Option #1: FiO2 (21%+10%, 50%+/- 10%, 100% -10%)Option #2: adjustable between room air (21%) and 100% (+/-10%)	Test		Verified		1/1	N/A	...	SR13 FiO2 50 SR13 FiO2 100 + Add Attachment
			+ Add							
SR-15-515	Patient_Circuit	All components coming in contact with the patients breath must be disposable OR sterilizable (e.g., autoclavable)	Review		Verified	Patient circ	1/1	N/A	...	+ Add Attachment
			+ Add							
SR-16-516	Patient_Circuit	0.22um or smaller filter shall be on patient inspiration and expiration pathway	Rules		1/1 Edit Rules	Verified	1/1	N/A	...	+ Add Attachment
			+ Add							
SR-17-462	Contact_Surfaces	Viral filter must be installed on ventilator inlet gas to allow filtration	Rules		1/1 Edit Rules	Verified	1/1	N/A	...	+ Add Attachment
			+ Add							
SR-18-461	Contact_Surfaces	All external surfaces must not degrade with application of standard agents for disinfection (e.g. bleach solution)	Review		Verified	Clear anodiz	1/1	N/A	...	+ Add Attachment
			+ Add							
SR-19-338	Buzzer_Transducer	Inlet Gas (02) or Power supply failure shall trigger alarm	Test		Verified	Video Verific	1/1	N/A	...	SR19, SR23, SR24 Alarm + Add Attachment
			+ Add							

IDENTIFIER	COMPONENT	REQUIREMENT TEXT	VERIFICATION METHODS	CLOSEOUT REFERENCES	VERIFICATION STATUSES	VERIFICATION COMMENTS	STATUS	# CHILDREN VERIFIED	COMPLIANCE	ATTACHMENTS
SR-20-339	Buzzer_Transducer	Alarm shall trigger when inspiratory airway pressure exceeded limits:Polat <30 35 cmH20Peak ?> no more than 2 cmH20 greater than PpatFail safe valve opens at 60cmH20 (powered or un-powered)	Test		Verified	Video Verific	1/1	N/A	...	SR23 Alarm + Add Attachment
			+ Add							
SR-21-340	Buzzer_Transducer	Alarm shall trigger when apnea (i.e. patient not breathing) on spontaneous mode (secondary)	Test		Verified	...	1/1	N/A	...	spontaneous_compressed + Add Attachment
			+ Add							
SR-22-341	Buzzer_Transducer	Alarm shall trigger when inspiratory and PEEP pressure not achieved (i.e. disconnection)	Test		Verified	Video Verific	1/1	N/A	...	SR22 Alarm + Add Attachment
			+ Add							
SR-23-342	Buzzer_Transducer	Alarm shall trigger when tidal volume not achieved or exceeded (with ~23% tolerance)	Test		Verified	...	1/1	N/A	...	SR19, SR23, SR24 Alarm + Add Attachment
			+ Add							
SR-24-343	Buzzer_Transducer	Alarm shall trigger when O2 disconnection occurs	Test		Verified	Video Verific	1/1	N/A	...	SR19, SR23, SR24 Alarm + Add Attachment
			+ Add							
SR-25-544	Buzzer_Transducer	Alarm Volume shall be 60 to 80 dBA at one meter (+/- 5 dBA)	Rules		1/1 Edit Rules	Verified				
			Test		Verified	Video Video	2/2	N/A	...	SR25 SP... + Add Attachment
			+ Add							
SR-26-412	InVent	Actual Value (TV, RR, PEEP, FiO2, Flow Rate, PIP) shall be monitored	Review		Verified	Video Verificat	1/1	N/A	...	SR26 UI Monitoring + Add Attachment
			+ Add							
SR-27-510	InVent	Vent shall be able the function at +/-10,000 ft Altitude	Test		Not veri...	...	0/1	N/A	...	+ Add Attachment
			+ Add							
SR-28-511	InVent	Durability of the ventilator shall ~2,000 hours	Test		Not veri		0/1	N/A	...	+ Add Attachment
			+ Add							
SR-29-512	InVent	Ventilator shall be compatible with readily available patient circuits, (ISO 5356-1 fittings)	Review		Verified	Patient Tubing	1/1	N/A	...	+ Add Attachment
			+ Add							
SR-30-513	InVent	Ventilator shall comply with FDA Ventilator Guidance Standards (i.e. ISO 80601-2-12)	Review		Verified	...	1/1	N/A	...	+ Add Attachment
			+ Add							
SR-31-514	InVent	Ventilator shall comply with general Medical Device Guidance Standards (e.g. ISO 13485, ISO 14971, ISO 62304, ISO 62366)	Review		In progr...	...	0/1	N/A	...	+ Add Attachment
			+ Add							
SR-32-404	Electronics	Ventilator shall be powered by 120VAC	Rules		1/1 Edit Rules	Verified	1/1	N/A	...	+ Add Attachment
			+ Add							
SR-33-405	Electronics	Electrical components shall comply with IEC 60601-1 and IEC 60601-1-2	Review		In progr...	...	0/1	N/A	...	+ Add Attachment
			+ Add							
SR-34-406	Electronics	None with labeling (primary function)	Review		Verified	...	1/1	N/A	...	+ Add Attachment
			+ Add							
SR-35-407	Electronics	Ventilator shall have 1 hour (secondary function / design goal) of battery back - up	Rules		1/1 Edit Rules	Verified	1/1	N/A	...	+ Add Attachment
			+ Add							

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BOM

- Common off-the-shelf parts.
- Parts researched to ensure inventory is available.

QTY	Description	P/N
1	ENCLOSURE	TBD
2	QUICK DISCONNECT AIR CONNECT ADAPTER	5012K320
2	HIGH-PURITY POLYPROPYLENE TUBING, 0.25" OD	4218N11
2	CHECK VALVE	AKH07B-N01S
2	PROPORTIONAL SOLENOID VALE	PVQ31-6G-16-01-F
1	PUSH TO CONNECT WYE	5779K264
1	HIGH-PURITY POLYPROPYLENE TUBING, 3/8" OD	4218N13
3	PUSH TO CONNECT TUBE FITTING	5779K116
1	02 SENSOR MOUNT	TBD
1	O2 SENSOR	SS26
1	VENTURI, INSPIRATION	TBD
4	PRESSURE SENSOR	LPS33HW
1	PRESSURE RELIEF VALVE	48935K250
1	VENTURI, EXPIRATION	TBD
1	LINEAR ACTUATOR PEEP CAP	TBD
1	LINEAR ACTUATOR	S20-15-30-B
1	LINEAR ACTUATOR MOUNT	TBD
1	PLATE, ABS, VALVE MOUNTING	TBD
1	BRACKET, CABLE MANAGEMENT	TBD
1	COVER PANEL, FRONT	TBD
6	STAINLESS STEEL STAND-OFF	TBD
10	SCREW, M2.63 x 8mm, RH TORX, THREAD FORMING	99397A415
4	IMU BREAKOUT	BNO080

QTY	Description	P/N
1	DISPLAY MOUNT	TBD
1	RASPBERRY PI 7IN LCD	8997466
1	BUTTON PCBA	TBD
2	TACTILE SWITCH SPST-NO	B3F-1020
1	MAGNETIC BUZZER TRANSDUCER	CEM-1203_42
1	BUTTON PCB	TBD
4	SCREW, M3 x 5mm, PH PHILLIPS	90116A150
2	BUTTON COVER, COSMETIC	TBD
1	PI DISPLAY PCBA	TBD
3	IV POLE C-CLAMP	BK-IVP-8950
1	TUBE GUIDE, PATIENT CIRCUIT	TBD
1	RASPBERRY PI 4 MODEL B	RPI4B
6	SCREW, M2.63 x 5mm, RH TORX, THREAD FORMING	99397A413
4	SCREW, M3 x 12mm, PH THREAD FORMING	96817A912
1	BARREL JACK, 2.1mm, DC	610 ADAFRUIT
1	COVER PANEL, REAR	TBD
6	SCREW, M5 x 8mm, PH TORX	90304A218
8	SCREW, M4 x 8mm, FH THREAD FORMING	STP41040-0080
1	ROTARY ENCODER	PEC11R-4015F-S0024
1	POWER BUTTON	IPR1SAD2
1	BATTERY BACKUP	GP37+
2	STEPPER MOTOR BONNET	4280

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About fuseproject

Building “firsts” and category leaders

fuseproject is an integrated design and innovation firm founded by world- renowned Swiss designer, Yves Behar. We are most known for creating "firsts" and category leaders. We take a human-centered, sustainable approach to design to improve the way people go about their everyday lives. We approach every step in the design process with an eye towards executing the offering successfully in market.

Our globally diverse team of 100 experts, based in San Francisco, brings a range of backgrounds and expertise that bridges disciplines and spans industries—including retail, automotive, robotics, consumer, software, technology, telecommunications, finance, and many more. Our capabilities include innovation strategy, sustainability, branding, industrial design & packaging, environment design and activations.

Fuseproject Team

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Lead Creative Technologist

VOX

About Cionic

Building precision bionics to enable a world without limitation.

Despite the incredible progress of the digital age, we have made very few advances in improving mobility for individuals suffering from neuromuscular disease. Inspired to help his daughter navigate her diagnosis of cerebral palsy, Jeremiah Robison founded Cionic on the belief that technology could offer more than crutches, canes, walkers, and wheelchairs.

Cionic builds wearable solutions that provide comprehensive analysis and precise augmentation to enhance human performance and improve quality of life. Our devices push the limits of integrated hardware, predictive modeling, and software design, emphasizing functional wearability and personalized intelligence.

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