Project Name	Code Life Ventilator Challenge	GOV.UK: Coronavirus (COVID-19): ventilator supply specification	Open Source Ventilator - OpenLung BVM Ventilator
Project Link	https://www.agorize.com/en/challenges/code-life-challenge?lang=en	https://www.gov.uk/government/publications/coronavirus-covid-19-ventilator-supply-specification	https://gitlab.com/open-source-ventilator/OpenLung/
Specification Link	https://cdn.fs.agorize.com/iiw25RXxSkuSKzIVNVQQ	https://www.gov.uk/government/publications/coronavirus-covid-19-ventilator-supply-specification/rapidly-manufactured-ventilator-system-specification	https://gitlab.com/open-source-ventilator/OpenLung/-/tree/master/requirements
Pressure Inspiratory	up to 40 cmH2O	up to 35 cmH2O Plateau pressure should adapt to achieve volume and be limited to peak. Peak pressure should be not more than 2 cmH2O greater than plateau Ideally a mechanical failsafe valve at 40 cmH2O	up to 35 cmH2O Default: 30 cmH2O Plateau (Paw): ??? to 35 cm H2O
Pressure Expiratory (PEEP)	up to 20 cmH2O	5 to 25 cmH2O in increments of 5 Patient breathing system must remain pressurised to at least the PEEP level setting at all times	5 to 24 cmH2O
Respiratory Rate	5 to 20 bpm	10 to 30 bpm Increments of 2 (only in mandatory mode)	15 to 35 bpm Setting: +/- 2 bpm Default: <30 cm H2O
I:E Breathing Ratio, Inspiratory:Expiratory	not specified	2.0 (expiration lasts twice as long as inspiration) Adjustable to 1.0 to 3.0	1:1 to 1:2
FiO2 (Inhaled O2 %)	20% to 100%, in 10% steps	Minimum 50% to 100% Preferred 30% to 100% in 10% steps	
Ventilation Triggering	Timed or patient-effort triggered	Must have mandatory ventilation mode. Optional pressure support mode (ex. BIAP) Must have automated fallback from pressure support mode to mandatory ventilation	
Tidal Volume (Vt)		Must have at least one setting of 400ml +/- 10 ml Ideally 350ml and 450 ml options Optionally Range 250 to 600 ml in steps of 50ml Even more optionally up to 800 ml Optionally the ability to input body weight and have volume calculated as, for example, 6ml/kg of ideal body weight	205ml to 530ml Setting: ±1ml/Kg(35ml)
Supports O2 concentrator?	Recommended	Optional	
Tube/Patient Connectivity	Standard connections	Must present a 22mm (OD) male connector to interface with 22mm female (patient side).	

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O2 Connectivity	Standard O2 connections	Standard non-interchangeable connectors and be colour coded according to current standards. If fixed O2 hose: Must support wall pipeline Schrader valve BS 5682 If not fixed O2 hose: Must support NIST screw-thread, ISO 10802 Can support backup O2 cylinder Must support cylinder operation: 1 to 137 bar (no regulator), or 4 bar (with regulator) Must incorporate a pressure regulator (from <137 to 4 bar) (Additional parameters included in specification text) Must have over-pressure failsafe (40 cmH2O).	
Humidifier-warmer	not specified	Optional ultrasonic	
Accuracy	<10% for volume and pressure, 1 breath/min		
Primary Power	110v and 220v AC (60Hz!!)	240v AC	
Aux Power	Battery	Battery (See **NOTE**) Optional hot-swap support. Optional extended battery support (ex. 2Hrs for hospital transfer) **NOTE**: There is leeway here for a non-battery design, but a battery is “expected”. Logistical issues of locating thousands of batteries is considered in the “Battery Backup” section of the specification.	
Aux Power Duration	>180min	>20min	
Patient Safety, monitoring and alarms			
Alarm – Minute Ventilation	Yes, Low/High		
Alarm – Peak Pressure	Yes	Yes	
Alarm – Low expiratory pressure	Yes		

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Alarm – O2 Disconnection	Yes	Yes	
Alarm – PEEP pressure (disconnection)	Yes	Yes	
Alarm – Power Loss		Yes	
Alarm – Manual off when in mandatory mode		Yes	
Alarm – Tidal Volume		Yes, Low/High	
Monitoring – Tidal Flow	Yes (Measure of tidal flow at the Y piece)	Yes (continuously displayed)	
Monitoring – Respiratory Rate		Yes (continuously displayed)	
Monitoring – PEEP		Yes (continuously displayed)	
Monitoring – Plateau Pressure		Yes (continuously displayed)	
Monitoring – O2 Concentration (FiO2)	Yes	Yes (continuously displayed)	
Monitoring – Realtime monitoring		Yes, if in pressure support mode	
Safety – Electrical Safety	ISO 80601-2-12:2020 Standard for Medical electrical equipment —Part 2-12.	Must avoid RF or EM emissions	
Safety – Fire Safety	Yes		
Infection Control – HEPA	Yes, HEPA Filtered inlet and outlet	HMEF bacterial/viral filter on patient side Filter may impact air-flow through resistance Product must be designed with this resistance in mind with an included offset.	
Infection Control – Easy Clean Surfaces	Yes	Yes (see specifics in text)	
Infection Control – Gas Pathways		All elements in the gas pathway must meet biological safety and oxygen safety standards, especially to minimise risk of fire or contamination of the patient's airway.	
Infection Control – Patient Side		All parts coming into contact with the patient's breath must be either disposable or decontaminatable between patients	

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Design Requirements			
Reliability		100% duty-cycle for up to 14 days. Expected durability must be specificed. Should be robust.	
Simplicity	"Simple to use, must not require specialized training"	"must not require more than 30 minutes training for a doctor with some experience of ventilator use"	
Modularity	"Modular, with known failure potential for each component"		
Maintenance	"Easy to maintain (related to modularity)"		
Visibility	"Settings legible from 1m"		
Instruction	"Clear flow directions"	Must be intuitive Instructions must be included All critical functions labelled with standard terms, images and colours.	
Design		"Must have transparent design, supply chain, manufacture and testing processes..."	
Usability		Must not be cumbersome Can be floor-standing Should be mountable on patient bed	
Materials	1.Widely available material (e.g. 3D printable filaments, plastic/metal sheets) 2.Can be built locally using either simple tools or rapid prototyping (i.e. 3D printing, CNC, etc.) 3.Only eligible material allowed (see list to exclude)	"Must be made from materials and parts readily available in the UK supply chain (anticipating increasing global restrictions on freight movement)."	
Testing, calibration, maintenance	1.Tests to calibrate and validate volume and pressure settings 2.Tests to verify limits and alarms 3.Illustrated and clear diagram for taking apart, replacing, and rebuilding the device safely		

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Standards		Standards exist, not formal regulatory, consider as helpful in this situation. BS EN 794-3:1998 +A2:2009: Particular requirements for emergency and transport ventilators ISO 10651-3:1997: Lung ventilators for medical use – emergency and transport BS ISO 80601-2-84:2018: Medical electrical equipment. Part 2 to 84. Particular requirements for basic safety and essential performance of emergency and transport ventilators – especially the parts on 'patient gas pathway' safety (very similar to IEC 60601) BS ISO 19223:2019: Lung ventilators and related equipment. Vocabulary and semantics	