Code Life Ventilator Challenge

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VENTILATION FEATURES AND SPECIFICATIONS (SUITABLE FOR INVASIVE VENTILATION)

1. Pressure controlled; inspiratory pressure up to 40cmH2O, expiratory pressure up to 25cm H2O
2. Respiratory rate 6-40 breaths/ minute
3. Adjustable inspiratory time or I:E ratio
4. Tidal volume measurement (Y piece/other, considering aerosolization risk vs. ease, cost of flow/VT circuit location)
5. Capacity to control circuit humidity and temperature (HME, inline or combination)
6. FiO_2 from 21% to 100% in 10% increments; vs./ or room air, 30, 40, 60 and 100%
7. **Optional** O_2 concentration readout
8. Triggering—timed and/or patient-triggered
9. Can be connected to standard masks, tubes and standard oxygen connectors
10. Accuracy (within <10% for volume/pressure, 1 breath a minute for rate)
11. Dual circuit with non-rebreathing valve

PATIENT SAFETY

ALARMS OR LIMITS

1. Minute Ventilation (low/high) alarm, peak and low expiratory pressure (or peak + other disconnection alarm).
2. **Optional** Oxygen concentration high and low threshold alarms
3. 40cm H20 mechanical failsafe value to limit maximum airway pressure

DEVICE SAFETY

1. Preliminary considerations for patient safety, operator safety, and device efficacy (with more detailed requirements for adherence to medical device standards coming at a further stage of the competition)

INFECTION CONTROL

1. Device incorporates expiratory flow contamination to environment (HEPA or another filter, other device).
2. Controlled 'stand-by' or on/off function to stop flow during disconnection of ETT from vent without aerosolization.
3. Total disinfection capacity (surface-all models-and consider circuit disinfection time/safety vs. disposable ventilator)

DESIGN REQUIREMENTS

USER INTERACTION

1. Simple, intuitive user interface
2. **Optional** configuration wizard to guide a first-time user through the settings.
3. **Optional** Sequential screen instructions to allow an inexperienced operator to use the ventilator, with a ‘go directly to settings’ bypass for ventilator-trained carers)
4. Preferably modular, with known failure potential (modular component/other)
5. Easy to service (per module if modular)
6. Settings legible (at 1m or as per relevant standard), clear markings with standard pictograms especially for critical functions

MATERIAL AND MANUFACTURABILITY

1. Available material (e.g. 3D printable filaments, plastic/metal sheets) biocompatible with inhaled gas

OPERATIONAL REQUIREMENTS

1. 120V and 240V operation
2. Can work without power source for >180 min.

TESTING, CALIBRATION, AND MAINTENANCE REQUIREMENTS

1. Tests to calibrate and validate volume and pressure settings, verify limits and alarms.
2. Illustrated and clear diagram for taking apart, replacing, and rebuilding the device safely.
3. Clearly described and practicable maintenance, diagnostic, and verification test procedures, including routine functional checks.
4. Should be easy to change the battery when necessary.

LIFETIME AND RELIABILITY

1. All components must survive a 14-day 100% duty cycle usage, without replacement.
2. Expected failure rate for all functions (particularly critical ones) shall be estimated using a known methodology.
3. Alarm related functions shall have an expected failure rate, as per relevant standard
4. Design shall be modular and time to repair by module replacement shall be quantified.