IKUKU NDU VENTILATOR DESIGN CHALLENGE: DESIGN SPECIFICATION

Preliminary Requirements:

Considering the peculiar terrain of Nigeria, the preliminary requirement of the Ventilators should satisfy the following criteria:

1. Battery Powered
2. Portable
3. Electrical safety
4. Clinical Safety
5. Electro-magnetic compatibility (minimal interference and susceptibility)
6. Sterilization

Specifically, the following ISO standards apply would for the ventilators:

1) **ISO 80601-2-12:2020** Standard for Medical electrical equipment — Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators
2) **ISO 80601-2-80:2018** Medical electrical equipment – Part 2-80: Particular requirements for basic safety and essential performance of ventilatory support equipment for ventilatory insufficiency
3) **ISO 5367:2014** Anaesthetic and respiratory equipment – breathing sets and connectors

Ventilation Features and Specifications

1. Pressure controlled; inspiratory pressure up to 40cm H_2O, expiratory pressure up to 25cm H_2O
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; 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 H_20 mechanical failsafe value to limit maximum airway pressure

Patient Safety: 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. Preferably modular, with known failure potential (modular component/other)
3. Easy to service (per module if modular)
4. Settings legible (at 1m or as per relevant standard), clear markings with standard pictograms especially for critical functions

Design Requirements: Material and Manufacturability

1. Available material biocompatible with inhaled gas
    a. For materials that will not be exposed to gas pathways in direct contact with the patient, please consider that any mechanism with constant moving parts or motors will generate heat and thus might melt surrounding parts. Some properties to consider during material selection of parts that could be exposed to heat are the Heat Deflection Temperature (HDT, ASTM D648 or ISO 75) and the Coefficient of Linear Thermal Expansion (CLTE, ASTM E228).
    b. For materials that will be exposed to gas pathways in direct contact with the patient, you will have to verify if there are emissions of particulate matters (ISO 18562-2) or volatile organic compounds (ISO 18562-3). You will also need to validate the biocompatibility of the materials (ISO 10993 series). Another aspect to consider is the fact that 3D printing creates intrinsic porosities. A top layer or smoothing technique might be required to seal surfaces and limit leaching of components.

Operational Requirements

1. Battery Powered
2. Solar Panel for Recharging Battery

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.

Terms

HEPA – High-Efficiency Particulate Air
ETT – Endotracheal Tube
ASTM – American Society of Testing and Materials
ISO – International Standard Organization
FiO_2 – Fraction of Inspired Oxygen