

Give-a-Breath Challenge | Munich Re & Fraunhofer

Specifications for non-invasive ventilators and O₂ concentrator device

Non-Invasive VENTILATION FEATURES needed for a COVID-19 Patient:

Technical relevant Information about a **COVID-19 patient:**

- Non-ICU patients:
 - o Need a higher O₂ concentration (21 – 50%)
 - o Need only low pressures (CPAP from 0 to max. 15mbar) in the mask
 - o Are breathing spontaneously (besides CPAP no additional inspiratory pressure support)
 - o Use their nose for humidification of the inhaled air (No HME necessary)
 - o Are not intubated
 - o Could cough a lot
 - o Could have a high exhaled amount of aerosol and secretion
- *[Intensive patients: Get worse rapidly and have to be intubated]* (IMPORTANT: OUT OF SCOPE OF THIS CHALLENGE)

Target Vision for a non-invasive ventilator // CPAP system:

- Aiming for a comprehensive device with fulfills all technical requirements
- Containing/ or combining with an O₂ concentrator unit for producing O₂ from ambient air
 - o Different O₂ concentration techniques possible¹
- Containing a positive pressure unit from 0 to max. 15 mbar
- Has connectors for a oronasal mask (Challenge II)
- O₂ flow 15 – 20 l/min needed to support/maintain desired CPAP levels
- Dilution needed via e.g. venturi or other techniques
- In case O₂ delivery system can not build up CPAP pressure supporting elements need to be added to system (e.g. turbine)
- Works either with line supply (110 – 240V) or with low voltage external power supply (12-24V) and >120min without direct access to electricity

¹ Membran Technologie [OTM (Oxygen Transport Membranes), ITM (Ion Transport Membranes)]

Adsorption Technologie [PSA (Pressure Swing Adsorption), Vacuum Pressure Swing Adsorption (VPSA), VSA (Vacuum swing adsorption)]

Technology Comparison:

https://www.ikts.fraunhofer.de/de/abteilungen/umwelttechnik_verfahrenstechnik/hochtemperaturseparation_katalyse/hochtemperaturmembranen_hochtemperaturspeicher/energiebedarf_von_sauerstoff-membrananlagen_technologievergleich.html

Scalability:

- The device can contain of stock products:
 - o Ensure the availability or self-production of these stock products in crisis period
 - o Deliver a list of all stock parts including all availabilities and supply chain
 - o Show how those stock products are connected or integrated exactly
- Scalability through 3D printing worldwide:
 - o The CAD Files have to be comprehensive after the challenge

Technical REQUIREMENTS for the devices: all ideas have to fulfill ALL requirements

Specification	Description
O2 concentrator from ambient air	Capable of 21-50% of O2 with a continuous flow of 15-20l/min
O2 concentration technique	Membran Technology OR Adsorption Technology ¹
Continuous Positive Airway Pressure (CPAP)	CPAP 0 – 12mbar with a continuous flow of 50l/min
Connector for Mask	Connector for Oronasal-Mask (covering mouth and nose) → Challenge II
Filter	Virus / Aerosol Filter between Mask and Tubes / Venturi systems

DEVICE SAFETY

- 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)

DESIGN REQUIREMENTS

USER INTERACTION

1. Simple, intuitive Ergonomic design
2. **Optional:** Sequential screen instructions to allow an inexperienced operator to use the CPAP ventilator, with a 'go directly to settings' bypass for ventilator-trained operator.
3. Preferably modular, with known failure potential for modules (that can easily be replaced)
4. Easy to service (per module if modular)
5. Settings legible (at 1m or as per relevant standard), clear markings with standard pictograms especially for critical functions

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 and as short as possible.