The European Commission has asked CECIMO to help in this time of need.

The COVID-19 outbreak is causing severe shortages of critical equipment needed in hospitals, in particular valves or ventilators.

Therefore, they asked us to check with AM companies about the possibility to help in the production of such pieces of equipment.

In case any company within the AITA network would be willing to contribute to such task, the European Commission kindly request you to fill out the template (which you can find in attachment).

All template should be sent to CECIMO, as the European Commission asked us to coordinate this action.

Once received the information, the competent authorities at both European and national level will get in touch with the companies based on the info provided.

You can find below the description of the equipment needed.

Ventilators I - non-invasive

No
Type
Minimum requirements
Description/Features
EU legislation
Reference standards[1]
(non-obligatory)
1
Ventilators I - non-invasive
Pressure and volumetric ventilation, of latest generation, controlled by microprocessor
Wide a
availability of ventilation methods, such as CPAP, PSV, PCV, PAV, BILEVEL (PAP + EPAP), and at least CPAP, PCV and BILEVEL) particularly oriented for non-invasive ventilation (but may in addition be suitable for invasive ventilation)
Integra ted turbine with good performance for compensation of possible (potentially large) leaks in the mask-circuit/patient interface -maintenance of high capacity fluxes (preferably up to 200 l/min)
Backup ventilation for apnea
* Mixing with oxygen from 21% to 100%

* Wide availability of adjustable alarms - at least the following alarms must be present:
o patient disconnection
o high and low respiratory frequency
o min and max pressure

o min volume minutes
o battery
* Visualization of volumes in real time
* Power supply and with rechargeable battery with good autonomy (at least 30 minutes)
* Easy to use, ergonomic, with first level maintenance and easy to perform checks by the operator
* Easy to disinfect contaminated parts
* With flexible tubes, accessories and junctures to connect with plugs with AFNOR terminal
* Trolley with wheels

Documentation and languages
* * User manual, describing also maintenance needs (at least description of the activity and frequency)
* * Documents (e.g.: Instructions for Use, User Manual) at least in English
* * Serigraphs in English
* * Possibility to set the software language (English shall be the standard setting)

* Directive 93/42/EEC on medical devices *
EN 60601-1-1:2001 Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems
*
Ventilators II - invasive
Ventilators under this lot comply with the following minimum quality requirements:
No
Type
Minimum requirements
Description/Features
EU legislation
Reference standards[2]
1
Ventilators II - invasive
* * Tidal volume up to 1,000 mL
* * Pressure (inspiratory) up to 80 cm H20
* * Volume (inspiratory) up to 120 L/min
* * Respiratory rate: up to 60 breaths per minute.
* * SIMV Respiratory Rate: up to 40 breaths per minute.
* * CPAP/PEEP up to 20 cm H2O.
* * Pressure support up to 45 cm H2O.
* * FiO2 between 21 to 100 %
* * Inspiratory and expiratory times up to at least 2 sec and 8 sec respectively
* * I:E Ratio at least from 1:1 to 1:3.
*
* Additional elements
* * Lung ventilator suitable for adult and pediatric ventilation (without the need to modify the machine's circuit)
* * Monitoring of respiratory parameters such as: static and dynamic compliance, resistance, P01, EtCO2, FiO2

*
* * Presence of expiratory trigger and inspiratory trigger at pressure and flux with high sensitivity , at least 0.3 l/min
*
* Modes of ventilation:
* * Volume controlled (VC).
* * Pressure controlled (PC).
* * Biphasic pressure support (PS).
* * Synchronized intermittent mandatory ventilation (SIMV) with pressure support.
* * Assist / control mode
* * Continuous Positive Airway Pressure (CPAP) / Positive End Expiratory Pressure (PEEP)
*

* Alarms
* * Alarms required: FiO2, minute volume, pressure, PEEP, apnoea, occlusion, high respiration rate, disconnection
* * System alarms required: power failure, gas disconnection, low battery, vent inoperative, self-diagnostics
* * If alarm silencing feature is incorporated, it must be temporary and clearly displayed when activated

General requirements
* * Air and externally supplied oxygen mixture ratios fully controllable
* * Inlet gas supply (O2) pressure range at least 35 to 65 psi
* * Medical air compressor integral to unit, with inlet filter
* * Power supply 220 - 240 V AC, 50 - 60 Hz
* * Rechargeable battery (back up time at least 30 minutes)
* * Complete with connection to oxygen distribution, compressed air: junctions with medical gas distribution system, compatible with existing distribution equipment, should be provided and installed by the chosen supplier
*
* Documentation and languages
* * User manual, describing also maintenance needs (at least description of the activity and frequency)
* * Documents (e.g.: Instructions for Use, User Manual) at least in English
* * Serigraphs in English
* * Possibility to set the software language (English shall be the standard setting)

* Directive 93/42/EEC on medical devices *
** EN 60601-1:2006 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
* EN 60601-1-1:2001 Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems
* EN 60601-2-12:2006 Medical electrical equipment - Part 2-12: Particular requirements for the safety of lung ventilators - Critical care ventilators