Ventilators I – not 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 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) Integrated 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: • patient disconnection • high and low respiratory frequency • min and max pressure • min volume minutes • 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

No	Type	Minimum requirements		
		Description/Features	EU legislation	Reference standards[1] (non-obligatory)
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 paediatric 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	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 ISO

		• 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)		