Technical specifications for invasive and non-invasive ventilators for COVID-19

Interim guidance

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World Health Organization

These technical specifications describe the minimum requirements that invasive and non-invasive ventilators must comply with to ensure quality, safety and effectiveness when used for the management of COVID-19.

All these ventilators require a source of air and oxygen to operate their internal blenders. Some of the equipment includes an internal air compressor, but all these pieces of equipment require either a low-flow oxygen source (e.g. oxygen concentrator) or a high-flow oxygen source (e.g. oxygen tank, piped oxygen). O*il-based external air compressors produce vapour that can damage ventilator sensors.*

All these ventilators should be provided with accessories, consumables and spare parts as required to operate for minimum duration of 3 months. It is advisable to follow the maintenance guidance for the replacement of accessories and consumables, and for the safe decontamination of the reusable parts provided by the manufacturer.

Important considerations:

1. Invasive ventilators require well-trained medical staff to perform the intubation and to manage the pressure setting controls and alarms. Provision must also be made in terms of the following infrastructure, particularly high-pressure oxygen or air sources, controlled temperature and humidity of the environment, and availability of technical staff to perform troubleshooting protocols, maintain the equipment and for decontamination procedures.
2. The non-invasive ventilators, mainly continuous positive airway pressure (CPAP), bilevel positive airway pressure (BPAP) and high-flow oxygen systems require health workers to take infection control measures to reduce the risk of becoming infected with COVID-19 by the generation of aerosols, for example, by wearing respirators and implementing airborne precautions.
3. Some advantages of non-invasive ventilators are that they avoid intubation and are easier to use once the right interface is applied.
4. In addition, use of high-flow nasal cannula and non-invasive ventilators can provide a higher flow (up to 50 to 70 L/min) than a nasal cannula connected to a standard flowmeter, which is up to about 15 L/min.

Follow the clinical guidelines for the selection of equipment for the treatment of critically and severely patients in the context of COVID-19.

Definitions and intended use

1.1 Invasive ventilators

1.1.1 Patient ventilators for intensive care unit: Designed to provide temporary ventilatory and respiratory assistance to adult and paediatric patients who cannot breathe on their own or who require assistance to maintain adequate ventilation. This equipment is usually connected to a 50-psi gas supply. Some ventilators have their own air compressor but still need an oxygen source. The mixed, heated and humidified gas is delivered to the patient using a double-limb breathing circuit (one for inspiratory and one for expiratory phases). Different parameters can be controlled by the user and displayed in a screen (e.g. fraction of inspired oxygen (FiO_2), trigger, respiratory rate (RR), positive end-expiratory pressure (PEEP), control modes).

1.1.2 Patient ventilators for transport/mass-casualty care: Similar to intensive care ventilators, these devices are capable of providing temporary ventilatory assistance by controlling flow, rate, FiO_2 and PEEP. The degree of portability (including weight and manageability), as well as battery life, are important considerations. The equipment should have the ability to operate on an external battery for 4 hours, minimize the oxygen consumption, and operate without any compressed gas source (e.g. by a turbine). It should work when connected to a 50 psi or a low-flow oxygen supply. Simplicity of use and low cost are advantages, in addition to advanced ventilatory features.

1.2 Non-invasive ventilators

1.2.1 Continuous positive airway pressure (CPAP): Designed to apply continuous positive airway pressure to the non-intubated adult or paediatric patient. Can be used in spontaneously breathing patients who require short-term mechanical assistance.

These units can deliver air or a mixture of air and oxygen at high flow rates and a single set pressure, typically between 3 and 20 cmH_2O, through a circuit and patient interface. The effectiveness of the treatment is closely related to the proper sealing of the nasal or oral-nasal mask to the face of the patient.

1.2.2 Bi-level positive airway pressure (BiPAP or BPAP): Designed to apply continuous positive airway pressure to non-intubated adult or paediatric patient, allowing clinicians to adjust two different pressures during the inspiratory and expiratory phases of a breath. Can be used in spontaneously breathing patients who require short-term mechanical assistance.

These units can deliver air or a mixture of air and oxygen at high flow rates. The higher inspiratory pressure off-loads the patient's breathing effort while the lower pressure helps to preserve an adequate alveolar volume and prevent collapse of unstable alveolar units during expiration. The effectiveness of the treatment is closely related to the proper sealing of the nasal or oral-nasal mask to the face of the patient. There are also more novel helmets that can be used as an interface.

1.2.3 High-flow nasal cannula (HFNC), heated humidified high-flow (HHHF) therapy or high-flow nasal oxygen (HFNO): Designed to deliver high flow rates with heated humidification to the non-intubated adult or paediatric patient. The maximum flow varies according to the manufacturer and can go up to 50 to 70 L/min. A specialized flowmeter and a heated humidifier are incorporated into the unit to deliver warm, humidified gases through a patient interface (nasal cannula). There is a low level of positive pressure at the patient's airway. The FiO_2 can be set by the clinician. The effectiveness of the treatment is related to the high flow generated rather than the proper sealing of the nasal cannula (reduced exhaled air dispersion).

Technical specifications for procurement

2.1 Invasive ventilators

2.1.1		Intensive-care patient ventilator for adult and paediatric patients
1	General technical requirements	The medical oxygen and air high-pressure input ports (50 psi) provide a means to limit reverse gas flowrate (leakage) and cross leakage when flowrate is < 100 mL/min. Each high-pressure input port with a filter should have a pore size ≤ 100 µm. Medical air compressor is integral to unit. Air turbine is an alternative. Possibility of using external low-pressure oxygen, as source, preferable. Mechanical safe valve that opens at 80 cm H_2O. Internal function testing/leak testing. Event log for errors traceability, preferable. All parts withstand high disinfection procedures. At least IP21 degree of protection to the harmful ingress of water (fluid spill resistance). Polyvinyl chloride (PVC) materials must be avoided in the patient gas pathway. Mechanical shock resistance, mechanical vibration, electromagnetic compatibility and electrical safety testing. Operating temperature and humidity 5 to 40 °C and 0 to 95% RH. Storage temperature and humidity -20 to 60 °C, 0 to 95% RH.
2	Ventilation modes	Pressure regulated volume control (PRVC), or similar. Pressure control (PC) Volume control (VC) Synchronized intermittent mandatory ventilation (SIMV) Pressure support ventilation (PSV) Non-Invasive ventilation capability
3	Monitored and controlled parameters (by user)	FiO_2: 21 to 100%; Tidal Volume: 20 - 2,000 mL, ideally; Inspiratory flow: 1 - 160 [L/min]; Inspiratory pressure: 0 – 40 [cmH_2O]; I:E ratio; I:E inverse ratio; RR: 10 to 60 [breaths/min], minimum; Inspiratory pause manoeuvre capability to measure plateau pressure; Peak pressure limitation/pressure-cycling mechanism adjustable range of 5 - 20 cmH_2O above measured peak pressure. PEEP: 0 to 20 [cmH_2O], minimum.
4	Displayed parameters (colour and graphic are preferable)	Display easily readable in low ambient light and sunlight. 3 scalar waveforms: pressure, volume and flow. 3 loop (axis) displays: pressure-volume, flow-volume and pressure-flow, preferable. Status indicators for ventilator mode, battery status, patient data, alarm settings. FiO_2. Airway pressures (peak, plateau mean and PEEP). Tidal volume (inspired and expired). Minute volume (inspired and expired). I:E ratio RR (spontaneous and mechanical) End-tidal CO_2.
5	Alarms, related to gas delivered	Adjustable, visual and audible for: High/low FiO_2; High/low inspiratory pressure and PEEP;

		High/low tidal volume (not achieved or exceeded); Apnoea, adjustable from 10-30 sec; High/low respiratory rate; Continuously high pressure/occlusion; Breathing circuit disconnect.	
6	Alarms, related to equipment operation	Visual and audible for: Gas supply failure; Power failure; Low battery.	
7	Consumables, labelled "single use", (included and mentioned in a disaggregated list)	Breathing circuits: double-limb with standard outlet/inlet connectors with 22 mm of outside diameter. Bacteria filters, if applicable.	30 per equipment. 30 per equipment.
8	Accessories, reusable (included and mentioned in a disaggregated list)	Breathing circuits: double-limb with standard outlet/inlet connectors with 22 mm of outside diameter. Expiratory housing with in-built bacteria filters; as well as the possibility to accommodate heat moisture exchangers (HMEs). Flex adapters for placement between the circuit way-adapter and the ETT (protects from unnecessary trauma from eve small circuit repositioning. Exhalation valve. CO_2 sensors. Servo-controlled heated humidifier; alternatively access to HMEs. Internal air compressor capacity (or high-performance turbines). Connector 30 mm, if required for the gas exhaust port. Standard connectors to air and oxygen wall pipelines.	10 per equipment. 10 per equipment. 10 per equipment. 1 per equipment. 1 per equipment. As required to operate.
9	Spare parts (included and mentioned in a disaggregated list)	1-year spare parts kit as per preventive maintenance programme, preferable.	
10	Portability	Mounting tray and support stand (cart for transport with at least 2 castors fitted with breaks).	
11	Power supply, Voltage, frequency and plug vary across the countries	Operates from AC power electric line: 100 to 240 V~ / 50 to 60 Hz. Built-in rechargeable battery. Automatic switch from AC power electric-line mode to battery operating mode and vice versa. Continuous in battery operating mode with standard ventilation not less than 1 hour. Total re-charging time not greater than 6 hours. Equipment must be connected to a reliable and continues source of energy.	
12	Documentation (included)	Instruction for use; service manual and product information to be provided in English language, at least.	
13	Primary packaging	Labelling on the primary packaging to include: name and/or trademark of the manufacturer. Model or product's reference. Information for particular storage conditions (temperature, pressure, light, humidity).	
14	Standards, for the manufacturer	Certified quality management system for medical devices (e.g. ISO 13485, or good manufacturing practice (GMP)).	
15	Standards, for the product performance	Free sales certificate (FSC) provided by any of the following countries: Australia, Canada, Japan, USA and European Community (e.g. FDA and/or CE certificate given by a third certified party for the specific medical devices proposed (no only declaration of conformity). If the FSC comes from other national regulatory agencies, it should be supported by the following certificates of quality performance, while alternative national equivalent tests are acceptable: ISO 18562-1:2017: Biocompatibility evaluation of breathing gas pathways in health-care applications — Part 1: Evaluation and testing within a risk management process. ISO 20789:2018: Anaesthetic and respiratory equipment — passive humidifiers. ISO 80601-2-12:2020 Medical electrical equipment — Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators. ISO 80601-2-74:2017 Medical electrical equipment — Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment. ISO 80601-2-79:2018 Medical electrical equipment — Part 2-79: Particular requirements for basic safety and essential performance of ventilatory support equipment for ventilatory impairment.	

		IEC 60601-1-1:2015 Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems. IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.
16	Warranty	Minimum 2 years. Availability of accessories, consumables and spare parts for at least 2 years.

2.1.2		**Patient ventilators for transport/mass-casualty care for adult and paediatric use**	
1	General technical requirements	Medical air compressor integral to unit, with inlet filter. External low-flow oxygen, preferable. ➔ If oxygen high-pressure input port (≥ 35 psi). ➔ Each high-pressure input port with a filter having a pore size ≤ 100 µm. O_2 - air mixture accuracy of 4%. O_2 consumption with 660 L (E) tank: ➔ 104 minutes with 16 L/min, FiO_2 50%. ➔ 280 minutes with 6 L/min, FiO_2 50%. O_2 conserve feature, preferable. Internal function testing/leak testing. Event log for errors traceability, preferable. All parts withstand high disinfection procedures. At least IP21 degree of protection to the harmful ingress of water. Polyvinyl chloride (PVC) materials must be avoided in the patient gas pathway.	
2	Ventilation modes	Pressure Regulated Volume Control (PRVC), or similar Pressure Control (PC) Volume Control (VC) Synchronized Intermittent Mandatory Ventilation (SIMV) Pressure Support Ventilation (PSV) Non-Invasive Ventilation capability	
3	Monitored and controlled parameters (by user)	Air and externally supplied oxygen mixture ratios fully controllable. FiO_2: 21 to 100%; Tidal Volume: 20 - 1,000 mL, ideally; Inspiratory pressure: 0 – 40 [cmH_2O]; I:E ratio; RR: 10 to 60 [breaths/min], minimum.	
4	Displayed parameters (colour and graphic are preferable)	Display easily readable in low ambient light and sunlight. Real time scalar waveforms for flow, volume and pressure at least 2 simultaneously. Status indicators for ventilator mode, battery status, patient data, alarm settings. Airway pressures (Peak, Mean and PEEP). Tidal volume (Expired). Minute volume (Expired). I:E ratio. Inspiration and expiration times. Spontaneous Minute Volume. RR. FiO_2. Occlusion pressure detection; Air and oxygen pressure; Spontaneous ventilation; Leak percentage.	
5	Alarms, related to gas delivered	Visual and audible for: High/Low FiO_2; High/Low Flow; High/Low Inspiratory pressure; Breathing circuit disconnect; Apnoea.	
6	Alarms, related to equipment operation	Visual and audible for: Gas supply failure; Power failure; Low battery.	
7	Consumables, labelled “single use”, (included and mentioned in a disaggregated list)	Breathing circuits: double-limb with standard outlet/inlet connectors with 22 mm of outside diameter. Bacteria filters, if applicable.	30 per equipment. 30 per equipment.

8	Accessories, reusable (included and mentioned in a disaggregated list)	Breathing circuits: double-limb with standard outlet/inlet connectors with 22 mm of outside diameter. Expiratory housing with in-built bacteria filters. Exhalation valve. CO_2 sensors, preferable. Internal air compressor capacity (or high-performance turbines). Standard connectors to air and oxygen wall pipelines.	10 per equipment. 10 per equipment. 1 per equipment. 1 per equipment. As required to operate.
9	Spare parts (included and mentioned in a disaggregated list)	1-year spare parts kit as per preventive maintenance program, preferable.	
10	Portability	Portable equipment with mechanical strength to lever rough handling.	
11	Power supply Voltage, frequency and plug vary across countries	Operates from AC power electric line: 100 to 240 V~ / 50 to 60 Hz. In-built rechargeable battery. Automatic switch from AC power electric-line mode to battery operating mode and vice versa. Continuous in battery operating mode with standard ventilation not less than 4 hours. Total re-charging time not greater than 6 hours. Equipment must be connected to a reliable and continuous source of energy.	
12	Documentation (included)	Instruction for use; service manual and product information to be provided in English language, at least.	
13	Primary packaging	Labelling on the primary packaging to include: Name and/or trademark of the manufacturer. Model or product's reference. Information for particular storage conditions (temperature, pressure, light, humidity).	
14	Standards, for the manufacturer	Certified quality management system for medical devices (e.g. ISO 13485, or good manufacturing practice (GMP)).	
15	Standards, for the product performance	Free Sales Certificate (FSC) provided by any of the following countries: Australia, Canada, Japan, USA and European Community (e.g. FDA and/or CE certificate given by a third certified party for the specific medical devices proposed (no only declaration of conformity) If the FSC comes from other national regulatory agency, it should be supported by the following certificates of quality performance, alternative national equivalent test are acceptable: ISO 18562-1:2017: Biocompatibility evaluation of breathing gas pathways in health-care applications — Part 1: Evaluation and testing within a risk management process. ISO 20789:2018: Anaesthetic and respiratory equipment — Passive humidifiers. ISO 10651-5:2006: Lung ventilators for medical use — Particular requirements for basic safety and essential performance — Part 5: Gas-powered emergency resuscitators. ISO 80601-2-74:2017 Medical electrical equipment — Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment. IEC 60601-1-1:2015 Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.	
16	Warranty	Minimum 2 years. Availability of accessories, consumables and spare parts for at least 2 years.	

2.2 Non-invasive ventilators

2.2.1		**Continuous positive airway pressure (CPAP) for adult and paediatric use**
1	General requirements	Maintains continuous positive pressure in airway at high flow rate User interface to be easy to operate, numbers and displays to be clearly visible. Inspiration trigger for auto start. Leakage compensation capability. Servo-controlled heated humidifier Noise level to be less than 35 dbA at mid pressure range. In-built air compressor. O_2 inlet All parts withstand high disinfection procedures. Expiratory relief features that reduce the pressure slightly at the end of each breath to make it easier for the patient to exhale, preferable Pressure ramp option that starts pressure at low level and slowly increases over a period, preferable

		Automatic positive airway pressure, also called AutoPAP or APAP, preferable.	
2	Monitored and controlled parameters (by user)	FiO_2: 21 to 100 %. Pressure: 3 to 20 [cmH_2O].	
3	Displayed parameters (colour and graphic are preferable)	Display easily readable in low ambient light and sunlight. Pressure [cmH_2O]. FiO_2 [%]. Flow, preferable. Air leak [%], preferable. RR, preferable.	
4	Alarms, related to gas delivered	Visual and audible for: High/Low Temperature; Breathing circuit disconnection.	
5	Alarms, related to equipment operation	Visual, audible and clearly indicating the problem for: Lack of water; System failure; Air filter to be replaced; Power failure; Low battery.	
6	Consumables, labelled “single use”, (included and mentioned in a disaggregated list)	Inlet bacteria filter, if applicable. Expiratory filters high efficiency. Nasal mask for adult and paediatric, with tubing. Oral/nasal mask for adult and paediatric, with tubing. Helmet for adult and paediatric, with tubing.	30 per equipment. 30 per equipment. 30 per equipment. 30 per equipment. 30 per equipment.
7	Accessories, reusable (included and mentioned in a disaggregated list)	Nasal mask for adult and paediatric with tubing; with stands high level disinfection and sterilization. Oral/nasal mask for adult and paediatric use with tubing; withstands high level disinfection and sterilization. Helmet for adult and paediatric patients with tubing; withstands high level disinfection and sterilization. Humidifier accessory if not integrated in-built. Connectors for air and oxygen outlets, adaptable for most connectors including barb, NF, DISS and NIST. Mains power cable to have length ≥2.	10 per equipment. 5 per equipment. 10 per equipment. 2 per equipment. As required to operate.
8	Spare parts (included and mentioned in a disaggregated list)	1-year spare parts kit as per preventive maintenance programme, preferable.	
9	Portability	Portable equipment with mechanical strength to lever rough handling.	
10	Power supply, Voltage, Frequency and Plug vary across the countries	Operates from AC power electric line: 100-240 V ~, 50/60 Hz. in-built rechargeable battery. Automatic switch from AC power electric-line mode to battery operating mode and vice versa. **Equipment must be connected to a reliable and continues source of energy.**	
11	Documentation (included)	Instruction for use; service manual and product information to be provided in English language, at least.	
12	Primary packaging	Labelling on the primary packaging to include: Name and/or trademark of the manufacturer. Model or product’s reference. Information for particular storage conditions (temperature, pressure, light, humidity).	
13	Standards, for the manufacturer	Certified quality management system for medical devices (e.g. ISO 13485, or good manufacturing practice (GMP)).	
14	Standards, for the product performance	Free sales certificate (FSC) provided by any of the following countries: Australia, Canada, Japan, USA and European Community (e.g. FDA and/or CE certificate given by a third certified party for the specific medical devices proposed (no only declaration of conformity) If the FSC comes from other national regulatory agency, it should be supported by the following certificates of quality performance, alternative national equivalent test are acceptable: ISO 18562-1:2017: Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 1: Evaluation and testing within a risk management process. ISO 20789:2018: Anaesthetic and respiratory equipment — Passive humidifiers. ISO 17510:2015 Medical devices - sleep apnoea breathing therapy - masks and application accessories.	

		IEC 60601-1-1:2015 Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems. IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.
15	Warranty	Minimum 2 years. Availability of accessories, consumables and spare parts for at least 2 years.

2.2.2		**Bi-Level positive airway pressure unit (BiPAP) for adult and paediatric use**	
1	General requirements	Maintains continuous positive pressure in airway at high flow rate User interface to be easy to operate, numbers and displays to be clearly visible. Provides a higher positive pressure airway upon inhalation than upon exhalation. Built-in air compressor. Oxygen inlet Servo-controlled heated humidifier Spontaneous timing (S/T). CPAP (Spontaneous), T (Timed), Pressure Assisted Control/Pressure Control (PAC/PC), preferable. Trigger sensitivity range: 1-10 cm H_2O, increments of 1 or automatic. Noise level to be less than 35 dBA at mid pressure range. Expiratory relief features that reduce the pressure slightly at the end of each breath to make it easier for the patient to exhale, preferable Pressure ramp option that starts pressure at low level and slowly increases over a period Automatic positive airway pressure, also called AutoPAP or APAP, preferable All parts withstand high disinfection procedures.	
2	Monitored and controlled parameters (by user)	FiO_2: 21 to 100 %. Pressure: 4 to 25 [cmH_2O].	
3	Displayed parameters (colour and graphic are preferable)	Display easily readable in low ambient light and sunlight. Inspiratory and Expiratory pressure; Inspiratory and Expiratory time; FiO_2 [%]; Mean Airway Pressure (MAP); Air leak [%].	
4	Alarms, related to gas delivered	Visual and audible for: High/Low Temperature; High/Low Pressure; Breathing circuit disconnect.	
5	Alarms, related to equipment operation	Visual and audible for: Lack of water; System failure; Air filter to be replaced. Power failure; Low battery.	
6	Consumables, labelled “single use”, (included and mentioned in a disaggregated list)	Inlet bacteria filter, if applicable. Expiratory filters high efficiency. Nasal mask for adult and paediatric, with tubing. Oral/nasal mask for adult and paediatric, with tubing. Helmet for adult and paediatric, with tubing.	30 per equipment. 30 per equipment. 30 per equipment. 30 per equipment. 30 per equipment.
7	Accessories, reusable (included and mentioned in a disaggregated list)	Nasal mask for adult and paediatric use with tubing; withstands high level disinfection and sterilization. Oral/nasal mask for adult and paediatric use with tubing; withstands high level disinfection and sterilization. Helmet for adult and paediatric use with tubing; withstands high level disinfection and sterilization. Humidifier accessory, if not integrated in-built. Connectors for air and oxygen outlets, adaptable for most connectors including barb, NF, DISS and NIST. Mains power cable to have length ≥2.	10 per equipment. 5 per equipment. 10 per equipment. 2 per equipment. 2 per equipment.

			As required to operate.
8	Spare parts (included and mentioned in a disaggregated list)	1-year spare parts kit as per preventive maintenance programme, preferable.	
9	Portability	Mounting tray and support stand with at least 2 castors fitted with breaks.	
10	Power supply, Voltage, Frequency and Plug vary across the countries	Operates from AC power electric line: 100-240 V ~, 50/60 Hz. Built-in rechargeable battery. Automatic switch from AC power electric-line mode to battery operating mode and vice versa. **Equipment must be connected to a reliable and continues source of energy**.	
11	Documentation (included)	Instruction for use; service manual and product information to be provided in English language, at least.	
12	Primary packaging	Labelling on the primary packaging to include: Name and/or trademark of the manufacturer. Model or product's reference. Information for particular storage conditions (temperature, pressure, light, humidity).	
13	Standards, for the manufacturer	Certified quality management system for medical devices (e.g. ISO 13485), or good manufacturing practice (GMP)).	
14	Standards, for the product performance	Free sales certificate (FSC) provided by any of the following countries: Australia, Canada, Japan, USA and European Community (e.g. FDA and/or CE certificate given by a third certified party for the specific medical devices proposed (no only declaration of conformity) If the FSC comes from other national regulatory agency, it should be supported by the following certificates of quality performance, alternative national equivalent test are acceptable: ISO 18562-1:2017: Biocompatibility evaluation of breathing gas pathways in health-care applications — Part 1: Evaluation and testing within a risk management process. ISO 20789:2018: Anaesthetic and respiratory equipment — Passive humidifiers. ISO 17510:2015 Medical devices - Sleep apnoea breathing therapy - Masks and application accessories. IEC 60601-1-1:2015 Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems. IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.	
15	Warranty	Minimum 2 years. Availability of accessories, consumables and spare parts for at least 2 years.	

2.2.3		**High-flow nasal cannula (HFNC) for adult and paediatric use**	
1	General requirements	Ability to generate flow from room air and mix with oxygen. The oxygen source could be an oxygen concentrator or cylinder. User interface to be easy to operate, numbers and displays to be clearly visible. The mixed gas of air and oxygen is warmed up to 37 °C and 100% relative humidity. FiO_2: 21 to 100 %. Flow: 2 to 50 L/min (minimum). Controls to be easy to operate, numbers and displays to be clearly visible. Digital display of Temperature [°C], Flow [L/min], Oxygen concentration [%]. Humidity compensation system. Noise level to be less than 35 dB A at mid pressure range. Trigger sensitivity range: 1-10 cmH_2O, increments of 1 cmH_2O or automatic. In-built air compressor. All parts withstand high disinfection procedures.	
2	Displayed parameters (colour and graphic are preferable)	Display easily readable in low ambient light and sunlight. Gas temperature; FiO_2; Tidal volume; Inspiratory pressure; Inspiratory and Expiratory time; I:E ratio; Mean Airway Pressure (MAP); Air leak [%].	
3	Alarms, related to gas delivered	Visual and audible for: High/Low FiO_2; Incorrect Temperature/Humidity; System leakage or blockage.	
4	Alarms, related to equipment operation	Visual and audible for: Lack of water; System failure; Air filter to be replaced; Power failure; Low battery.	
5	Consumables, labelled	Inlet bacteria filter, if applicable.	30 per equipment.

	"single use", (included and mentioned in a disaggregated .list)	Expiratory filters high efficiency. Housing and patient interface for adult and paediatric use.	30 per equipment. 30 per equipment.
6	Accessories , reusable (included and mentioned in a disaggregated list)	Housing and patient interface for adult and paediatric use; withstands high level disinfection and sterilization. Flowmeter, graduated in L/min. Humidifier. Water chamber. Connectors for air and oxygen outlets, adaptable for most connectors including barb, NF, DISS and NIST. Mains power cable to have length ≥ 2. Internal air compressor capacity.	10 per equipment. 5 per equipment. 2 per equipment. 2 per equipment. As required to operate.
7	Spare parts (included and mentioned in a disaggregated list)	1-year spare parts kit as per preventive maintenance program, preferable.	
8	Portability	Mounting tray and support stand with at least 2 castors fitted with breaks.	
9	Power supply, Voltage, Frequency and Plug vary across the countries	Operates from AC power electric line: 100-240 V ~, 50/60 Hz. Built-in rechargeable battery: 12 or 24 V. Automatic switch from AC power electric-line mode to battery operating mode and vice versa. Continuous in battery operating mode withstands at least 1 hour. Equipment must be connected to a reliable and continues source of energy.	
10	Documentation (included)	Instruction for use; service manual and product information to be provided in English language, at least.	
11	Primary packaging	Labelling on the primary packaging to include: Name and/or trademark of the manufacturer. Model or product's reference. Information for particular storage conditions (temperature, pressure, light, humidity).	
12	Standards, for the manufacturer	Certified Quality Management System for medical devices (e.g. ISO 13485), or Good Manufacturing Practice (GMP)).	
13	Standards, for the product performance	Free Sales Certificate (FSC) provided by any of the following countries: Australia, Canada, Japan, USA and European Community (e.g. FDA and/or CE certificate given by a third certified party for the specific medical devices proposed (no only declaration of conformity) If the FSC comes from other national regulatory agency, it should be supported by the following certificates of quality performance, alternative national equivalent test are acceptable: ISO 18562-1:2017: Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 1: Evaluation and testing within a risk management process. ISO 20789:2018: Anaesthetic and respiratory equipment — Passive humidifiers. ISO 17510:2015 Medical devices - Sleep apnoea breathing therapy - Masks and application accessories. IEC 60601-1-1:2015 Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems. IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.	
14	Warranty	Minimum 2 years. Availability of accessories, consumables and spare parts for at least 2 years.	

Methodology and references

Technical specifications define the minimum requirements for the product to ensure quality, safety and efficacy. The process to develop these specifications included:

1. Analysis of the technologies required for clinical management of COVID-19 patients https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/patient-management.
2. Analysis of products that meet requirements based on regulatory agency approvals, including information published by the International Medical Device Regulators Forum (IMDRF).
3. Rapidly manufactured ventilator system (RMVS) document RMVS001 - specification issued by MHRA: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/876167/RMVS001_v3.1.pdf.
4. Device overviews, specifications and comparative data published by ECRI: Evidence-based Practice Center, a non-profit, independent organization that conducts independent medical device evaluations: https://www.ecri.org/.

5. Revision and comments from WHO Respiratory Experts, ad hoc panel, and Clinical Engineers Experts, ad hoc panel. All members have provided conflict of interest declarations to WHO; no relevant conflicts have been identified.

WHO continues to monitor the situation closely for any changes that may affect this interim guidance. Should any factors change, WHO will issue a further update. Otherwise, this interim guidance document will expire 2 years after the date of publication.

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