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COVID-19 Technical Specifications for Invasive and Non-Invasive Ventilators

The Technical Specifications are the minimum requirements that Invasive and Non-Invasive Ventilators used for the management of COVID-19 must comply to ensure quality, safety and effectiveness.

All these equipment require a source of air and oxygen to operate the internal blenders. Some of the equipment has internal air compressor but all of them require either a low flow oxygen source (e.g. oxygen concentrator) or a high flow oxygen (e.g. oxygen tank, piped oxygen). External air compressors that are oil-based, can ruin ventilator sensors because of the produced vapor.

All these equipment should be provided with accessories, consumables and spare parts as required to operate for minimum 3 months. Follow the Maintenance Guidance for replacement of accessories and consumables and safe decontamination of the reusable parts provided by the manufacturer.

Important considerations:

1. Invasive Ventilators require a highly trained medical staff to perform the intubation and to set the pressure settings controls and alarms of the equipment. Provision must also be made in terms of infrastructure specially if available high pressure oxygen and / or air sources, controlled temperature and humidity of the environment, and availability of technical staff to perform troubleshooting protocols and maintain the equipment and finally for the decontamination procedures.
2. The Non-Invasive Ventilators, mainly CPAP, BPAP and High Flow oxygen systems require high controls in terms of Infection Control to reduce the risk of contagion of the health care providers by the aerosol generated, for example used of airborne precautions with respirators.

Some advantages of Non-Invasive Ventilators are avoiding intubation and easier and decontamination processes. In the case of the High Flow Nasal Cannula, it 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 selection of equipment for treatment of critical and severe patients in the context of COVID-19 [link].

1. 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. The equipment is usually connected to a 50 psi gas supply. Some ventilators have their own air compressor but still need the 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 an Intensive Care Ventilator, it is capable to provide temporary ventilatory assistance by controlling flow, rate, FiO_2 and PEEP. The degree of portability (including weight and manageability), as well as is battery life are important considerations. The equipment should have the ability to operate on external battery for four hours, minimise 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 front of advanced ventilatory features.

1.2 Non-Invasive Ventilators.

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

These units can deliver air or a mixture of air and oxygen (O_2) 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. Commonly used in spontaneously-breathing patients who require short term mechanical assistance.

These units can deliver air or a mixture of air and oxygen (O_2) at high flow rates. The higher inspiratory pressure off-loads the patients 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 interface.

1.2.3 High Flow Nasal Cannula (HFNC); or, Heated Humidified High Flow (HHHF) therapy; or, High Flow Nasal Oxygen (HFNO): Designed to deliver high flow rates with heated humidification to non-intubated adult or paediatric patient. Warm and humidify gas decreases airway inflammation and reduce the caloric expenditure in acute respiratory failure. The maximum flow varies according to the manufacturers going up to 50 to 70 L/min. A specialized flowmeter and a heated humidifier are incorporated into the unit to

deliver heated and humidified gases, through a circuit and patient interface. 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 mask to the face of the patient (reduced exhaled air dispersion).

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2. Technical specifications for procurement.

2.1 Invasive Ventilators.

	2.1.1	Intensive-Care Patient Ventilator, for adult and paediatric
1	General technical requirements	Inlet gas: From Internal Air Compressor + External low pressure Oxygen (concentrators), preferable . ➔ If two high-pressure input ports (50 psi), to 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 having a pore size <=100 µm. 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. Polyvinyl chloride (PVC) materials must be avoided in the patient gas pathway.
2	Ventilation modes	Continuous Mandatory ventilation (CMV) pressure regulated volume control, or with Pressure Control (PC) or volume control (VC); Synchronized Intermittent Mandatory Ventilation (SIMV) with VC/PC capacity and 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; ➔ At least one setting of 400 mL +/- 10 mL; alternative settings from 250 to 800 mL, increments of 50 mL. Inspiratory flow: 1 - 160 [L/min]; Inspiratory pressure: 0 – 40 [cmH_2O], increments of 5 [cmH_2O]; I:E ratio: 1:1, 1:2, 1:3; RR: 10 to 60 [breaths/min]; Inspiratory pause manoeuvre capability to measure plateau pressure Peak pressure limited to 2 [cmH_2O] below Plateau Pressure; PEEP: 5 to 20 [cmH_2O], increments of 5 [cmH_2O]. Pressure Control/Pressure Support with an adjustable driving pressure range between 0 to 50 cmH_2O (i.e. 0 cmH_2O during PSV allows for CPAP, whereas during PCV at maximum PEEP of 20 cmH_2O can achieve a peak pressure of 70 cmH_2O.
4	Displayed parameters (colour and graphic are preferable)	3 scalar waveforms: Pressure, Volume and Flow. 3 loop (axis) displays: Pressure-Volume, Flow-Volume and Pressure-Flow. 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)

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		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 built-in 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. 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)		
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. 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 1 hour. Total re-charging time not greater than 6 hours. **Equipment must be connected to a reliable and continues source of energy.**	

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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 healthcare 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.
		Any variation to be indicated in the offer.

	2.1.2	**Patient Ventilators for Transport/Mass-casualty Care, for adult and paediatric**
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 to 50 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.

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		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	Continuous Mandatory ventilation (CMV) with Volume Control (VC) and Pressure Control (PC); Synchronized Intermittent Mandatory Ventilation (SIMV) with VC/PC capacity and Pressure Support Ventilation (PSV); CPAP/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; ➔ At least one setting of 400 mL +/- 10 mL; alternative settings from 250 to 800 mL, increments of 50 mL. Inspiratory pressure: 15 – 40 [cmH_2O], increments of 5 [cmH_2O]; I:E ratio: 1:2; RR: 10 to 60 [breaths/min].	
4	Displayed parameters (colour and graphic are preferable)	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 pressure (Mean). 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	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.

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	mentioned in a disaggregated list)		
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 built-in bacteria filters. Exhalation valve. CO_2 sensors. 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)		
10	Portability	Portable equipment with mechanical strength to lever rough handling.	
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. 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 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 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 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.
		Any variation to be indicated in the offer.

2.2 Non-Invasive Ventilators.

	2.2.1	Continuous Positive Airway Pressure (CPAP), for adult and paediatric	
1	General requirements	Maintains low flow and continuous positive pressure in airway. Controls to be easy to operate, numbers and displays to be clearly visible. Inspiration trigger for auto start. Leakage compensation capability. Servo control of the warming, preferable. Humidity compensation system, preferable. FiO_2: 21 to 100 %. Flow: 4 to 40 L/min. Pressure: 4 to 20 mbar. Pressure support: 0 - 45 [cmH_2O]. Monitoring of the air temperature: precision ± 1 °C. Noise level to be less than 35 dbA at mid pressure range. In built air compressor. All parts withstand high disinfection procedures.	
2	Displayed parameters (colour and graphic are preferable)	Gas temperature; FiO_2; Tidal volume; Inspiratory pressure; Inspiratory and Expiratory time; I:E ratio.	
3	Alarms, related to gas delivered	Visual and audible for: High/Low Temperature; Breathing circuit disconnect.	
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 "single use",** (included and mentioned in a	Inlet bacteria filters, if applicable.	30 per equipment.

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	disaggregated list)		
6	Accessories, reusable (included and mentioned in a disaggregated list)	Nasal mask for adult and paediatric; withstands high level disinfection and steam sterilization. Helmet for adult and paediatric; withstands high level disinfection and steam sterilization. Flowmeter, graduated in L/min. Humidifier. Connectors for air and oxygen.	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)		
8	Portability	Portable equipment with mechanical strength to lever rough handling.	
9	Power supply, **Voltage, Frequency and Plug vary across the countries**	Operates from AC power electric line: 220 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. **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.	

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		Any variation to be indicated in the offer.

	2.2.2	Bi-Level Positive Airway Pressure Unit (BiPAP), for adult and paediatric	
1	General requirements	Maintains low flow and continuous positive pressure in airway. Provides a higher positive pressure airway upon inhalation than upon exhalation. Controls to be easy to operate, numbers and displays to be clearly visible. Oxygen inlet port cable to enter 15 L/min, preferable. Pressure ramp function required to assist falling asleep. Servo control of the warming, preferable. Humidity compensation system, preferable. Spontaneous timing (S/T). CPAP (Spontaneous), T (Timed), Pressure Assisted Control/Pressure Control (PAC/PC), Volume Assured Pressure Support (VAPS), preferable. FiO_2: 21 to 100 %. Flow: 4 to 40 L/min. Pressure: 3 to 25 mbar. Pressure support: 0 - 45 [cmH_2O]. Trigger sensitivity range: 1-10, increments of 1 or automatic. Monitoring of the air temperature: precision ± 1 °C. Noise level to be less than 25 dbA at 10 cm H_2O. In built air compressor. All parts withstand high disinfection procedures.	
2	Displayed parameters (colour and graphic are preferable)	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 Temperature; High/Low Pressure; Breathing circuit disconnect; Inlet air filter to be fitted.	
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 "single use",** (included and	Inlet bacteria filters, if applicable.	30 per equipment.

	mentioned in a disaggregated list)		
6	Accessories, reusable (included and mentioned in a disaggregated list)	Nasal mask for adult and paediatric; withstands high level disinfection and steam sterilization. Helmet for adult and paediatric; withstands high level disinfection and steam sterilization. Flowmeter, graduated in L/min. Humidifier. Connectors for air and oxygen.	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)		
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: 220 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. **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.
		Any variation to be indicated in the offer.

	2.2.3	High Flow Nasal Cannula (HFNC), for adult and paediatric	
1	General requirements	Ability to generate flow from room air and mix with oxygen. The oxygen source could be an oxygen concentrator or cylinder. 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 dbA at mid pressure range. Trigger sensitivity range: 1-10 cmH_2O, increments of 1 cmH_2O or automatic. Monitoring of the air temperature: precision ± 1 °C. Noise level to be less than 25 dbA at 10 cmH_2O. In built air compressor. All parts withstand high disinfection procedures.	
2	Displayed parameters (colour and graphic are preferable)	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 "single use",** (included and mentioned in a disaggregated .list)	Air filters.	30 per equipment.
6	Accessories , reusable	Housing and patient interface for adult and paediatric; withstands high level disinfection and steam sterilization.	10 per equipment.

	(included and mentioned in a disaggregated list)	Flowmeter, graduated in L/min. Humidifier. Water chamber. Connectors for air and oxygen. Internal air compressor capacity.	5 per equipment. 2 per equipment. 2 per equipment. As required to operate.
7	Spare parts (included and mentioned in a disaggregated list)		
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: 220 to 240 V~ / 50 to 60 Hz. In built 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), 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.	
		Any variation to be indicated in the offer.	