COVID-19

List of Priority Medical Devices in the context of COVID-19

(provisional recommendations, 11 May 2020)
4th Version

Overview

This document updates PAHO's interim recommendations for case management of COVID-19 in health services*.

Objective of the document:

The fourth version† of the list of priority medical devices in the context of COVID-19 provides technical descriptions and specifications for the management of patients with suspected and/or confirmed COVID-19 infection at different levels of healthcare in the following stages of care:

- Triage and initial care.
- Sampling for diagnosis.
- Early supportive therapy and monitoring of severe acute respiratory infections (SARI) when COVID-19 infection is suspected.
- Treatment of acute hypoxemic respiratory failure (AHRF), acute respiratory distress syndrome (ARDS) and septic shock.

Please note that the list included in this document should be adapted to the context of each country in the Region, according to the needs and capacities of each health system.

Target audience:

This document is recommended to support decision-making by medical health care providers, managers of intensive care units, and ministries of health in the Region, for the selection and use of medical devices in the context of COVID-19, for proper management of patients with suspected or confirmed COVID-19 in medical care settings.

*A description of the methodology used is available at: https://www.paho.org/en/documents/methodology-list-priority-medical-devices-context-covid-19

† This 4th version updates the recommendations on the following medical devices: Patient ventilators for transport / Mass-casualty Care; Patient ventilators for intensive care unit; Swabs for respiratory sample collection and viral transport medium (VTM); Triple packaging system; Alcohol-based hand rub solution; Face shields; Gloves, examination, non-sterile; Gloves, surgical, sterile; Googles, protective; Gown; Medical mask; and Respirator (Grade N95 / FFP2 or higher). Additionally, the following devices are included for non-invasive ventilation: Bi-Level positive airway pressure unit (BiPAP); Continuous positive airway pressure (CPAP) and; High-flow nasal cannula (HFNC).

Priority Medical Devices List in the context of COVID-19

Table 1. List of medical devices, organized by COVID-19 attention stages and levels of care

Category	Medical device	Triage and initial care	Sampling diagnosis	Early supportive therapy and monitoring	Treatment of AHRF, ARDS and septic shock	1st level	2nd level	3rd level
Accessories & consumables	Carbon dioxide detector				x		•	•
	Heimlich maneuver assist device			x	x		•	•
	Flow splitter			x	x		•	•
	Fit test kit				x			•
	Humidifier, non-heated				x		•	•
	Resuscitator, adult			x	x	•	•	•
	Resuscitator, child			x	x	•	•	•
Single use devices/ disposables/ medical supplies	Endotracheal tube introducer, Bougie or Gum elastic Bougie				x		•	•
	Endotracheal tube introducer, Stylet type				x		•	•
	Intercostal catheter (ICC) / chest tube				x		•	•
	Intravenous infusion set with macrodrip			x	x	•	•	•
	Laryngeal mask (LMA)				x		•	•
	Nasal catheter, flexible			x	x			•
	Nasopharyngeal airway				x	•	•	•
	NIV mask: full face or oronasal				x			•
	Oxygen mask			x	x	•	•	•
	Percutaneous tracheostomy set				x			•
	Swabs for respiratory sample collection and viral transport medium (VTM)		x			•	•	•
	Set of laryngoscope blades				x	•	•	•

Category	Medical device	Triage and initial care	Sampling diagnosis	Early supportive therapy and monitoring	Treatment of AHRF, ARDS and septic shock	1st level	2nd level	3rd level
	Venturi mask				x		•	•
Single use devices/ disposables/ medical supplies	Bags for medical waste		x	x	x	•	•	•
	Disposable towel for hand drying (paper or tissue)	x	x	x	x	•	•	•
	Endotracheal tube, with cuff				x	•	•	•
	Endotracheal tube, without cuff				x	•	•	•
	Oropharyngeal airway, Guedel				x	•	•	•
	Oxygen prongs, nasal			x	x	•	•	•
	Oxygen tube, extension			x	x	•	•	•
	Sharps container boxes		x	x	x	•	•	•
	Triple packaging system		x			•	•	•
Personal protective equipment (PPE)	Apron	x	x	x	x	•	•	•
	Face shields		x	x	x	•	•	•
	Gloves, cleaning	x	x	x	x	•	•	•
	Gloves, surgical, sterile	x	x	x	x	•	•	•
	Gloves, examination, non-sterile		x	x	x	•	•	•
	Goggles, protective		x	x	x	•	•	•
	Gown	x	x	x	x	•	•	•
	Medical mask	x	x	x	x	•	•	•
	Respirator (Grade N95 / FFP2 or higher)				x	•	•	•
Medical equipment	Bi-Level positive airway pressure unit (BiPAP)				x		•	•
	Cardiovascular ultrasound imaging system				x			•
	Continuous positive airway pressure (CPAP)				x		•	•
	Conventional X-ray equipment	x		x	x		•	•

Category	Medical device	Triage and initial care	Sampling diagnosis	Early supportive therapy and monitoring	Treatment of AHRF, ARDS and septic shock	1st level	2nd level	3rd level
Medical equipment	Electrocardiogram, 12-Lead			x	x	•	•	•
	External defibrillator			x	x	•	•	•
	Flowmeter, Thorpe tube			x	x		•	•
	High-flow nasal cannula (HFNC)				x		•	•
	Portable aspirator/ Suction system				x	•	•	•
	Patient ventilators for transport / Mass-casualty Care			x	x		•	•
	Patient ventilators for intensive care unit			x	x			•
	Portable ultrasound scanner with probes				x		•	•
	Portable X-ray equipment				x		•	•
	Pulse oximeter			x	x	•	•	•
	Sphygmomanometer, with cuffs (adult / children)	x		x	x	•	•	•
	Stethoscope	x		x	x	•	•	•
	Vital signs monitor				x	•	•	•
Instrumental	Digital thermometer	x		x	x	•	•	•
	Laryngoscope, adult/children				x	•	•	•
Medical furniture	Foot-operated waste bin	x	x	x	x	•	•	•
Solutions and reagents	Alcohol-based hand rub solution	x	x	x	x	•	•	•
	Chlorine	x	x	x	x	•	•	•
	Liquid plain soap for hand hygiene	x	x	x	x	•	•	•

**** The following equipment should be considered according to the context of use and the capacity of the health system***

Medical equipment	Computed tomography (CT) system				x			•

Technical description and specifications

Table 2: Technical description and specifications of the recommended medical devices* for COVID-19

**(PPE's are shown on Table 3)*

MEDICAL DEVICE	TECHNICAL DESCRIPTION AND SPECIFICATIONS	
Computed Tomography (CT) scanner, 16-Slice	Computed tomography equipment with a full rotation helical and axial tracking time of 360 degrees at 0,8 seconds or less, applicable to all regions of the body. · 16 slices in a full 360° full body turn. · Gantry: angulation of +/- 30 degrees or greater. 70 cm opening. or greater. · X-Ray tube: with anode heat storage capacity of 5 MHU or greater. With 3.5 MHU or greater anode heat storage capacity with iterative reconstruction. · With a thickness of cut less than or equal to 0,75 mm x 16 spiral cuts. · Real-time image reconstruction of 6 images or greater per second. · Spatial resolution with a minimum of 15 lp/cm. or greater than 0% MTF. · Acquisition station: - 19" or larger color monitor, 1024x1024 or larger display matrix. - Storage capacity of images on hard disk of 140 Gb or greater. - CD or DVD. - DICOM media (viewer or removable), print, query / retrieve, storage and worklist. - Software for dose modulation and saving in real time. - Automatic bolus tracking. - UPS for the computer equipment. · Reconstruction of a set of three-dimensional or 3D cuts. · MPR image reconstruction in real time. · MIP image reconstruction. · Accessories - Set of phantoms for quality control. - Accessories for positioning of pediatric tomographic studies.	
Bi-Level positive airway pressure unit (BiPAP)	General requirements	For adult and pediatric use. 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 H2O, 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.
	Monitored and controlled parameters	· FiO2: 21 to 100 %. · Pressure: 4 to 25 [cmH2O].
	Displayed parameters (color and graphic are preferable)	Display easily readable in low ambient light and sunlight. · Inspiratory and Expiratory pressure; · Inspiratory and Expiratory time; · FiO2 [%]; · Mean Airway Pressure (MAP); · Air leak [%].

MEDICAL DEVICE	TECHNICAL DESCRIPTION AND SPECIFICATIONS	
	Alarms, related to gas delivered	Visual and audible for: · High/Low Temperature; · High/Low Pressure; · Breathing circuit disconnect.
	Alarms, related to equipment operation	Visual and audible for: · Lack of water; · System failure; · Air filter to be replaced. · Power failure; · Low battery.
	Consumables, labelled *"single use"*	· Inlet bacteria filter, if applicable. · Expiratory filters high efficiency. · Nasal mask for adult and pediatric, with tubing. · Oral/nasal mask for adult and pediatric, with tubing. · Helmet for adult and pediatric, with tubing.
	Accessories, reusable	· Nasal mask for adult and pediatric use with tubing; withstands high level disinfection and sterilization. · Oral/nasal mask for adult and pediatric use with tubing; withstands high level disinfection and sterilization. · Helmet for adult and pediatric 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.
	Portability	Mounting tray and support stand with at least 2 castors fitted with breaks.
	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.
	Documentation (included)	All supporting documentation, operation, service and user manuals must be presented in the official language of the country in which the equipment will be used.
	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).
	Standards, for manufacturer	Certified quality management system for medical devices (e.g. ISO 13485, or good manufacturing practice (GMP)).
	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 (not 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 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: Anesthetic and respiratory equipment — Passive humidifiers. · ISO 17510:2015 Medical devices - Sleep apnea 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.

MEDICAL DEVICE	TECHNICAL DESCRIPTION AND SPECIFICATIONS	
		· 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.
	Warranty	Minimum 2 years. Availability of accessories, consumables and spare parts for at least 2 years.
	According to: *WHO- Technical specifications for invasive and non-invasive ventilators for COVID-19*	
Carbon dioxide detector	· Disposable. · Colorimetric. · Sizes compatible with child and adult endotracheal tube.	
Cardiovascular ultrasound imaging system	An assembly of devices designed for extracorporeal and/or intracorporeal (endosonographic or endoscopic) imaging procedures involving the heart and blood vessels. · Scanner and software, several single- or multifrequency transducers, a TEE probe, color Doppler, M-mode, CFM, cardiac analysis software. · Phased array transducers required. · Frequency range covered by probes supplied to be at least 1 - 15 mHz . · Transesophageal echocardiogram - TEE scanning capability. · Penetration depth of at least 30 cm. · Digital and caliper measurement functions required for both distance and area. · Alphanumeric annotation to be possible. · Connection port for image printing to be included (printer specified separately). · Measurement accuracy to be better than 2% over 10cm distance. · Doppler display to indicate blood flow both numerically and in color. · System that is DICOM compatible for communication efficiency. 3D or 2D image for cardiac studies in adults, children and infants. · Zoom in real time at least 4X and zoom for frozen image at least 20X. · Equipment dynamic range, at least, 180 dB. · The hardware and software included in the offer will allow the following application: (i) cardiac and stress echo; (ii) tissue differentiation to clearly show the walls of the left ventricle and regional wall motion abnormalities; (iii) left ventricle wall abnormalities software; (iv) abdominal; (v) obstetrical and gynecological; (vi) peripheral and deep vascular; (vii) tissue imaging synchronization or equivalent technique. Must include all consumables required for its optimal operation (e.g. conductive gel)	
Continuous positive airway pressure (CPAP)	General requirements	For adult and pediatric use. 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. O2 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.
	Monitored and controlled parameters	· FiO2: 21 to 100 %. · Pressure: 3 to 20 [cmH2O].
	Displayed parameters (color and graphic are preferable)	· Display easily readable in low ambient light and sunlight. · Pressure [cmH2O]. · FiO2 [%]. · Flow, preferable. · Air leak [%], preferable.

MEDICAL DEVICE	TECHNICAL DESCRIPTION AND SPECIFICATIONS	
		• RR, preferable.
	Alarms, related to gas delivered	Visual and audible for: • High/Low Temperature; • Breathing circuit disconnection.
	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.
	Consumables, labelled *"single use"*	• Inlet bacteria filter, if applicable. • Expiratory filters high efficiency. • Nasal mask for adult and pediatric, with tubing. • Oral/nasal mask for adult and pediatric, with tubing. • Helmet for adult and pediatric, with tubing.
	Accessories, reusable	Nasal mask for adult and pediatric with tubing; withstands high level disinfection and sterilization. Oral/nasal mask for adult and pediatric use with tubing; withstands high level disinfection and sterilization. Helmet for adult and pediatric 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.
	Portability	Portable equipment with mechanical strength to lever rough handling.
	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.
	Documentation (included)	All supporting documentation, operation, service and user manuals must be presented in the official language of the country in which the equipment will be used.
	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).
	Standards, for the manufacturer	Certified quality management system for medical devices (e.g. ISO 13485, or good manufacturing practice (GMP)).
	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: Anesthetic and respiratory equipment — Passive humidifiers.

MEDICAL DEVICE	TECHNICAL DESCRIPTION AND SPECIFICATIONS
	· ISO 17510:2015 Medical devices - sleep apnea 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.
	Warranty: Minimum 2 years. Availability of accessories, consumables and spare parts for at least 2 years.
	According to: *WHO- Technical specifications for invasive and non-invasive ventilators for COVID-19*
Conventional X-ray equipment	Digital X-ray system that allows taking radiographic imaging plates. · Must have a digital display of mAs and kV, and an electronic timer. - kV range at least 50kV to 150kV, digitally displayed. - mA range at least 0 to 600 mA. - Exposure time range at least 1 ms to 5 s. · Automatic exposure control facility required. · Tube power rating at least 60 kW. · Resolution to be better than 5 lines pairs / mm. · Must have a rotating anode with focal spot size less than 1mm. · Heat storage capacity of the anode at least 350,000 HU. · Adjustable multileaf collimator, rotatable ±90 deg with patient centering light. · Alphanumeric annotation of images required. · Image display to be contrast- and brightness- adjustable, at least 18 inches diagonal size. · Image to be displayed immediately after exposure. · The system should be capable of storing at least 3000 images, with capacity for removable media storage. · Connectivity to hospitals RIS-PACS systems. · Must comply with the DICOM standard. All specific technical characteristics must be in accordance with each health system guidelines.
Electrocardiogram, 12-Lead	Equipment used to detect electrical signals associated with cardiac activity. It is used for diagnosis and to assist in the treatment of some types of cardiorespiratory diseases. · Include the electrodes and wires for the 12-lead socket. · Must be able to display 3 simultaneous waves. · Able to obtain P, QRS, and T waveforms. · Include uninterruptible power supply and backup battery. · With automatic calibration function. Must include all consumables required for its optimal operation (e.g. electrodes, conductive gel, etc.)
Endotracheal tube introducer (Bougie or gum elastic Bougie)	For oral intubation when the view of the larynx is suboptimal or endotracheal tube exchange. · Multiple or single use. · Length 60 cm to 70 cm. · Diameter: 14 - 15 Fr. · For ET tubes from 6 to 11 mm of internal diameter. · 30 degrees tip angle.
Endotracheal tube introducer, Stylet type	Flexible and malleable guide (stylet type). · The end of the guide should be smooth and round, as required. · Graduated marking. · The tube must be marked with the manufacturer's name and tube's size. · Sterile, single use. · Diameter 10 Fr. and 14 Fr. · Length from 30 cm to 45 cm.
Endotracheal tube, with cuff	· Endotracheal tube with cuff. · Open distal end and Magill-type point with oral angle of 37.5°.

MEDICAL DEVICE	TECHNICAL DESCRIPTION AND SPECIFICATIONS
	· Standard connector (external diameter 15mm) at the proximal end enabling the tube to be connected to the ventilation system. · Radio opaque mark. · With Murphy's eye. · Graduations. · Internal diameter size: 6.5mm, 7mm, 7.5mm, 8mm or 8.5mm. · Material: polyvinyl chloride (PVC). · Disposable / sterile.
Endotracheal tube, without cuff	· Endotracheal tube without cuff. · Open distal end and Magill-type point with oral angle of 37.5°. · Standard connector (external diameter 15mm) at the proximal end enabling the tube to be connected to the ventilation system. · Radio opaque mark. · With Murphy's eye. · Graduations. · Internal diameter size: 3mm or 3.5mm. · Material: Polyvinyl chloride (PVC). · Disposable / Sterile. · Initial sterilization method: Ethylene oxide gas or Gamma radiation.
External defibrillator	· Manual and semi-automated operating modes. · Biphasic waveform operation. · Maximum energy to be at least 220 Joules. · Conductive area for paddles shall be >50cm^2 for adult, >15cm^2 for pediatric. · ECG analysis time to be < 15 s. · Charge time to full energy to be < 10 s. - 30 full energy discharges to be possible solely off battery operation. · Voice prompting function included for operator direction. · Number of discharges (total lifetime and on current battery) to be displayed. · Self-test facility to be included. · Automatic impedance compensation. · External defibrillation discharging start control just only by pressing both buttons on the external paddles. · One set of reusable adult external paddles and related pediatric adapters compatible with the equipment. · Displayed parameters - indicator for power and battery state required.
Fit test kit	To evaluate effectiveness of seal for tight-fitting respiratory protection devices. OSHA 29 CFR 1910.134 Appendix A.
Flow splitter	Splitter of oxygen flow provided by a single oxygen supply (e.g. oxygen concentrator). Each flow can be adjusted individually via its flow meter, range: 0.125 to 2 l/min (liter per minute). The output nozzle can either be fit with tubing or left blank. Input pressure: 50 to 350 kPa.
Flowmeter, Thorpe tube	The Thorpe tube flowmeter consists of inlet and outlet ports, a regulator, a valve, and a clear conical metering tube. · It is suitable for connecting various sources of medicinal gases, such as centralized systems, gas cylinders, concentrators or compressors. · Flowmeter measurements (absolute and uncompensated) must be adjusted for specific flow ranges.
Foot-operated waste bin	Foot-operated waste bin for hospital use. Must be properly labeled for easy identification.
Heimlich maneuver assist device	Portable suction device. · Manual. · Non-invasive.

MEDICAL DEVICE	TECHNICAL DESCRIPTION AND SPECIFICATIONS	
High-flow nasal cannula (HFNC)	General requirements	For adult and pediatric use. 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. FiO2: 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 cmH2O, increments of 1 cmH2O or automatic. In-built air compressor. All parts withstand high disinfection procedures.
	Displayed parameters (color and graphic are preferable)	Display easily readable in low ambient light and sunlight. Gas temperature; FiO2; Tidal volume; Inspiratory pressure; Inspiratory and Expiratory time; I:E ratio; Mean Airway Pressure (MAP); Air leak [%].
	Alarms, related to gas delivered	Visual and audible for: ・ High/Low FiO2; ・ Incorrect Temperature/Humidity; ・ System leakage or blockage.
	Alarms, related to equipment operation	Visual and audible for: ・ Lack of water; ・ System failure; ・ Air filter to be replaced; ・ Power failure; ・ Low battery.
	Consumables, labelled *"single use"*	・ Inlet bacteria filter, if applicable. ・ Expiratory filters high efficiency. ・ Housing and patient interface for adult and pediatric use.
	Accessories, reusable	・ Housing and patient interface for adult and pediatric 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.
	Portability	Mounting tray and support stand with at least 2 castors fitted with breaks.
	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.
	Documentation (included)	All supporting documentation, operation, service and user manuals must be presented in the official language of the country in which the equipment will be used.
	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).

MEDICAL DEVICE	TECHNICAL DESCRIPTION AND SPECIFICATIONS	
	Standards, for the manufacturer	Certified quality management system for medical devices (e.g. ISO 13485, or good manufacturing practice (GMP)).
	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 (not 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 tests 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: Anesthetic and respiratory equipment — Passive humidifiers. · ISO 17510:2015 Medical devices - Sleep apnea 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.
	Warranty	Minimum 2 years. Availability of accessories, consumables and spare parts for at least 2 years.
	According to: *WHO- Technical specifications for invasive and non-invasive ventilators for COVID-19*	
Humidifier, non-heated	The humidifier is inserted in the inspiratory line of a breathing circuit to add moisture to the breathing gases for administration to a patient. The bubbling bottle humidifier is a sealed container filled with water and connected inline into the breathing circuit. The medical gas mixture flows through the water inside the bottle and is enriched in humidity. This type of humidifier does not heat the gas. To be compatible with oxygen concentrator, including necessary hose connectors.	
Intercostal catheter (ICC) / chest tube	· Sterile, single use. · Straight and right-angle versions in various sizes (12-40 Fr). · Bold depth marks and radiopaque mark.	
Intravenous infusion set with macrodrip	Sterile for single use. Components of the device: · Driller: sharp drilling device with protective cap. · Air inlet: with integrated bacteriological filter. · Drop count chamber: clear drip chamber, calibrated to 20 drops/ml, with 15-20 µm fluid filter. · Tube: transparent tube, minimum length 150cm, with latex or latex-free injection space (or Y injection port), with distal connector preferably Luer Lock connector. · Precision flow regulator: smooth roller clamp for easy and safe control and adjustment of fluid rates. ISO 8536-4 Infusion sets for medical use.	
Laryngeal mask (LMA)	· Reusable medical grade silicone rubber. · Include main components: airway tube, inflatable mask, and mask inflation line. · Slightly curved, semi-rigid and semi-transparent tube with a longitudinally black line. · Available in eight sizes, from neonates to large adults, 1 to 6 and two medium sizes 1.5 and 2.5	
Laryngoscope, adult/child	A hand-held device (i.e., non-endoscopic rigid type) intended to be used by anesthesia/emergency service personnel to manipulate the tongue, preventing it from obstructing the oropharynx and enabling a clear view of the trachea for the insertion of an endotracheal (ET) tube prior to the delivery of inhalation anesthesia and/or ventilation. · Handle is 28 mm diameter and battery powered with two standard alkaline dry cell batteries (1.5 V, type C (LR14)). · Large hollow, cylindrical, slightly ribbed handle. · Handle made of either chromium-plated or stainless steel. · Stud contact, fitting various sizes and types of blades. · Include Macintosh and Miller type blades, as described in *"Set of laryngoscope blades".*	

MEDICAL DEVICE	TECHNICAL DESCRIPTION AND SPECIFICATIONS
	Complies with ISO 7376:2009 or equivalent.
Nasal Catheter, Flexible	· Flexible nasal catheter with multiple holes (6 to 12 lateral eyes) at distal end. · Oxygen and air/oxygen mixture compatibility, as per ISO 15001. · Proximal end with connector. · Sterile, single use. · Diameter: 8 Fr. Length: 40 cm.
Nasopharyngeal airway	A Nasopharyngeal Airway is recommended for use as an airway adjunct in the semi-conscious or unconscious patient with an intact gag reflex. · Sterile, single use. Individually packaged sterile with a conveniently attached surgical lubricant for quick access to facilitate ease of insertion. · Flexible and soft material for maximum patient comfort. · Rounded tip allows for gentle insertion. · Trumpet design for secure placement. · Diameter and size labelled according to standards. · Range of sizes from 20 Fr to 36 Fr.
NIV mask: full face or oronasal	Only to be used if other forms of ventilation are exhausted. · Nasal and full face: BiPAP mask or BiPAP full face mask. · Includes: 4-point helmet. · Compatible to single and dual limb circuit. · Size: S, M, L and XL.
Oropharyngeal airway, Guedel	One-piece, semi-rigid, curved plastic tube. To be inserted through the oropharynges to facilitate airway management. Guedel type. · Child sizes: 00, 0, 1. · Adult sizes: 2, 3, 4. · Semi-rigid, transparent. · Proximal (or buccal) end straight and reinforced. · Flange color coded and/or marked with corresponding size number. · Sizes: (size 00, approximately 40mm); (size 0, approximately 50mm); (size 1, approximately 60 mm); (size 2, approximately 70mm); (size 3, approximately 80 mm); (size 4, approximately 90mm) · Material: Polyethylene/vinyl acetate (EVA) - Polyvinyl chloride (PVC). · Sterile, single patient use. · ISO10651-4; EN12181 or equivalent.
Oxygen mask	· Connection tube, reservoir bag and valve. High concentration. · Non-sterile, single use. · Different sizes: adult, pediatric.
Oxygen prongs, nasal	Consists of a plastic tube which fits behind the ears, and a set of two prongs which are placed in the nostrils, connected with an oxygen administration circuit. · Soft twin prongs nasal tips to ensure equal oxygen flow to both. · Star lumen main tube to avoid accidental blockage. · Adjustable, smoothly finished, nasal tips for maximum patient comfort. · Soft funnel shaped connector to facilitate easy connection to oxygen source. · Nonsterile, single use. · Cannulae designed for low-flow applications (0–15 L/min range) or high flow (> 15 L/min). · Oxygen and air/oxygen mixture compatibility, as per ISO 15001. · Oxygen tube length: approximately 2m. · Different sizes: adult, pediatric and neonatal
Oxygen tube, extension	Tube used to deliver oxygen through the nose. · Material: PVC. · Automatic, open distal (patient) end, with 6 to 12 lateral eyes. · Proximal end with connector enabling the tube to be connected to an oxygen supply tube of any diameter (e.g. Serrated male conical tip). · Sterile, for single patient use. · Diameter: CH 10. Length: 40cm. · Shelf life: minimum 10 years. · Bag and hands should be white color.

MEDICAL DEVICE	TECHNICAL DESCRIPTION AND SPECIFICATIONS	
Patient ventilators for intensive care unit	General technical requirements	The medical oxygen and air 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. Medical air compressor integral to unit. Air turbine, alternative. Possibility for using external low-pressure oxygen, as source, preferable. Mechanical safe valve that opens at 80 cm H2O. 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.
	Ventilation modes	Pressure regulated volume control (PRVC), or similar. Pressure control ventilation (PCV) Volume control ventilation (VCV) Synchronized intermittent mandatory ventilation (SIMV) Pressure support ventilation (PSV) Non-Invasive ventilation capability
	Monitored and controlled parameters (by user)	FiO2: 21% - 100% Tidal volume: 20 - 2000 mL Inspiratory flow: 1 -160 L/min Inspiratory pressure: 0 - 40 cmH2O I:E ratio; I:E inverse ratio; RR: 10 to 60 [breaths/min] Inspiratory pause maneuver capability to measure plateau pressure; Peak pressure limitation/pressure-cycling mechanism adjustable range of 5 - 20 cmH2O above measured peak pressure PEEP: 0 to 20 [cmH2O], minimum.
	Displayed parameters (color 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 FiO2. Airway pressures (peak, plateau mean and PEEP). Tidal volume (inspired and expired). Minute volume (inspired and expired). I:E ratio RR (spontaneous and mechanical)
	Alarms, related to gas delivered	High/low FiO2; High/low inspiratory pressure and PEEP; High/low tidal volume (not achieved or exceeded); Apnea, adjustable from 10-30 sec; High/low respiratory rate; Continuously high pressure/occlusion; Breathing circuit disconnect.
	Alarms, related to equipment operation	Gas supply failure; Power failure; Low battery; Self-diagnostics failure alarm.
	Consumables, labelled “single use”	Breathing circuits: double limb with standard outlet/inlet connectors with 22 mm of outside diameter. Bacterial/Viral filters. Exhaled gas filter

MEDICAL DEVICE	TECHNICAL DESCRIPTION AND SPECIFICATIONS	
	Accessories, reusable	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. CO2 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.
	Portability	Mounting tray and support stand (cart for transport with at least 2 castors fitted with breaks).
	Power supply and battery	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.
	Standards for the manufacturer	Certified Quality Management System for medical devices (e.g. ISO 13485, or Good Manufacturing Practice (GMP)).
	Standards for the product performance	・ ISO 18562-1 Biocompatibility evaluation of breathing gas pathways in healthcare applications ・ ISO 20789:2018 Anesthetic and respiratory equipment ・ ISO 80601-2-12 Medical Electrical Equipment - Part 2-12: Particular requirements for the Safety of Lung Ventilators - Critical Care Ventilators. ・ IEC 60601-1-2 Medical Electrical Equipment Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Alternative national equivalent tests are acceptable.
	Warranty	Minimum 2 years. Availability of accessories, consumables and spare parts for at least 2 years.
	According to: *WHO- Technical specifications for invasive and non-invasive ventilators for COVID-19*	
Patient ventilators for transport / Mass-casualty Care	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. O2 - air mixture accuracy of 4%. O2 consumption with 660 L (E) tank: ・ 104 minutes with 16 L/min, FiO2 50%. ・ 280 minutes with 6 L/min, FiO2 50%. O2 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.
	Ventilation modes	Pressure regulated volume control (PRVC), or similar. Pressure control ventilation (PCV) Volume control ventilation (VCV) Synchronized intermittent mandatory ventilation (SIMV) Pressure support ventilation (PSV) Non-Invasive ventilation capability
	Monitored and controlled	FiO2: 21% - 100% Tidal Volume: 20 - 1000 mL, ideally Air and externally supplied oxygen mixture ratios fully controllable.

MEDICAL DEVICE	TECHNICAL DESCRIPTION AND SPECIFICATIONS	
	parameters (by user)	Inspiratory pressure: 0 – 40 [cmH2O]; I:E ratio; RR: 10 to 60 [breaths/min], minimum
	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. Inspiration and expiration times. Status indicators for ventilator mode, battery status, patient data, alarm settings. FiO2. Airway pressures (Peak, Mean and PEEP). Tidal volume (Expired). Minute volume (expired, spontaneous). Air and oxygen pressure; Occlusion pressure detection; I:E ratio. RR.
		Spontaneous ventilation Leak percentage.
	Alarms, related to gas delivered	High/Low FiO2; High/Low Inspiratory pressure; High/Low Flow; Apnea; Breathing circuit disconnect.
	Alarms, related to equipment operation	Gas supply failure; Power failure; Low battery. Self diagnostics failure alarm.
	Consumables, labelled “single use”	Breathing circuits: double-limb with standard outlet/inlet connectors with 22 mm of outside diameter. Bacterial/Viral filters. Exhaled gas filter
	Accessories, reusable	Breathing circuits: double-limb with standard outlet/inlet connectors with 22 mm of outside diameter. Expiratory housing with in-built bacteria filters. Exhalation valve. CO2 sensors, preferable. Internal air compressor capacity (or high-performance turbines). Standard connectors to air and oxygen wall pipelines.
	Portability	Portable equipment with mechanical strength to lever rough handling.
	Power supply and battery	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.
	Standards for the manufacturer	Certified Quality Management System for medical devices (e.g. ISO 13485, or Good Manufacturing Practice (GMP)).
	Standards for the product performance	• ISO 18562-1 Biocompatibility evaluation of breathing gas pathways in healthcare applications • ISO 20789:2018 Anesthetic and respiratory equipment • ISO 80601-2-12 Medical Electrical Equipment - Part 2-12: Particular Requirements for the Safety of Lung Ventilators - Critical Care Ventilators. • IEC 60601-1-2 Medical Electrical Equipment Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Alternative national equivalent tests are acceptable.
	Warranty	Minimum 2 years.

MEDICAL DEVICE	TECHNICAL DESCRIPTION AND SPECIFICATIONS
	Availability of accessories, consumables and spare parts for at least 2 years. According to: *WHO- Technical specifications for invasive and non-invasive ventilators for COVID-19*
Percutaneous tracheostomy set	· Sterile, single dilator. · With tracheostomy tube, cuff and introducer. · Dilator with ergonomic handle design. · 15 mm tube connector which allows connection to the breathing system or heat and moisture exchanger.
Portable aspirator/ Suction system	Portable suction device (aspiration pumps) used to evacuate secretions and liquids from de nasal cavity or from high airways. · Adults and pediatric suction catheters should be less than half the internal diameter of the tracheal tube. · Vacuum adjustment: continuous. · Must be able to generate a vacuum of at least 0.85 bar (650mmHg). · Maximum vacuum: 700 mmHg. · Minimum open tube flow rate at least 5 liters liquid per minute. · Twin suction bottles, minimum size 3 liters each. · Bottles to have an automatic cut off when full to prevent ingress of fluid to motor. · Airline to pump to incorporate bacterial filter. · Tubing to patient to be minimum 3m long, non-collapsible type · Pedal and manual equipment suction function activation. · Sound Level: < 70 dB. · Castors: 75 mm diameter, unidirectional, anti-static.
Portable ultrasound scanner with probes	An assembly of devices designed to be used in a wide variety of both extracorporeal and/or intracorporeal (endosonographic or endoscopic) ultrasound imaging procedures. · High performance ultrasound scanner. · System integrates scanner, 2 probes, matching trolley and video-printer. · Compact and lightweight, easy to transport and position. · Alphanumeric keyboard with trackball and time gain control (TCG). · Piezoelectric probes, electronically scanned: convex and linear. · Sectorial transducer (which is used in the BLUE protocol). · Linear transducer that covers frequencies between 5-10 mHz and one sectorial (2-5 mHz). So that the evaluation of "pulmonary sliding" is available (pulmonary point in case of pneumothorax). · Imaging display modes: B, dual B, M, B and M. · Adjustable field-of-view, 6 level zooms. · Imaging technologies: dynamic frequency imaging, multi-stage focusing, aperture control. · Depth range selection: convex sector image and linear image, 3 steps. · Image orientation: lateral and vertical inversion (in B mode). · Freeze function with storage of approx. 25 images measurements and analysis. · Caliber control: trackball. · B-mode image: distance, area and circumference by ellipse and trace method, volume, ratio, gestational age, fetal weight. · Angle gestational table: user programmable. · M-mode: velocity, time interval, depth, heart rate, LV function Alpha-numeric & graphics. · Text annotations and body markers. · Automatic display of date and time, focal point setting, image orientation indicator, image scrolled position, distance scale mark, M-mode time mark, grey scale for calibration. · High resolution B/W monitor, approx. 25 cm diagonal (across), equals to 10 inches, fit with reflection filter. · Image grey scale: 256 levels. · Video output: 625 lines/frame. · Two transducer ports leave 2 probes permanently available, electronic switch between probes. · Data communication interface: RS232, BNC, IEEE, USB or equivalent. Power supply may vary according to countries. Must include all consumables required for its optimal operation (e.g. conductive gel)

MEDICAL DEVICE	TECHNICAL DESCRIPTION AND SPECIFICATIONS
Portable X-ray equipment	Portable X-ray system that allows taking radiographic imaging plates. · With the ability to connect to the RIS-PACS system. · Must comply with the DICOM standard. · It must show the parameters mAs, kV and exposure time. - kV within the range 40kV - 125kV. - mA within the range 0.5-200 mA. - Exposure times within the range of 1ms to 5 s. · Automatic exposure control facility required. · Must have a rotating anode with focal spot size less than 1 mm. · Heat storage capacity of the anode at least 200,000 HU. · Adjustable multileaf collimator, rotatable ±90 deg with patient centering light. · Alphanumeric annotation of images required. · DICOM compatible image storage and transfer required. Last image hold facility required, displayed on clear, movable screen. · The system should be capable of storing at least 3000 images, with capacity for removable media storage. Other technical characteristics must be in accordance with the health system guidelines.
Pulse oximeter	Compact portable device measures arterial blood oxygen saturation (SpO_2), heart rate and signal strength. · Finger-tip or tabletop. · Measuring range: SpO_2 30 to 100% (minimum graduation 1%). Resolution: 1% or less. · Heart rate 20 to 250 bpm (minimum graduation 1bpm). Resolution: 1 bpm or less. · Line powered or battery powered. Complies with ISO 80601-2-61:2011 or equivalent.
Resuscitator, adult	Resuscitator to ventilate adult (body weight over 30kg). · Manual (operated by hand), ventilation with ambient air. · With compressible self-refilling ventilation bag. · Capacity: 1475-2000 ml. · Mask, silicon, in 3 sizes: adult small, adult medium and adult large. · Resuscitator shall be easy, to disassemble and reassemble, to clean and disinfect, and be autoclavable. · All parts must be manufactured from high-strength, long-life materials and require no special maintenance or storage conditions.
Resuscitator, child	Resuscitator to ventilate child (body weight 7-30kg). · Manual (operated by hand), ventilation with ambient air. · With compressible self-refilling ventilation bag. · Child capacity: 500-700ml and non-rebreathing valve with pressure limiting valve, patient connector. · Mask, silicon, for infants. · Resuscitator shall be easy, to disassemble and reassemble, to clean and disinfect, and be autoclavable. · All parts must be manufactured from high-strength, long-life materials and require no special maintenance or storage conditions.
Swabs for respiratory sample collection and viral transport medium (VTM)	Dacron or polyester flocked swabs should be used. Vials containing 1 to 3 ml of VTM. Commercial or in house VTM can be used. Additionally, sterile saline might be used if VTM is not available.
Set of laryngoscope blades	Macintosh type (curved): · Curved Nr 2, length 90 - 110 mm, for child. · Curved Nr 3, length 110 - 135 mm, for small adult. · Curved Nr 4, length 135 - 155 mm, for adult. Miller type (straight): · Straight Nr 1, length approx. 100 mm.
Sharps container boxes	Puncture resistant container for collection and disposing of used, disposable and auto-disable syringes, needles.

MEDICAL DEVICE	TECHNICAL DESCRIPTION AND SPECIFICATIONS
	· 5 L capacity or equivalent to 100 syringes. · Containers must be properly identified. · Must comply with WHO performance specification E10/IC.1 or WHO/UNICEF standard E10/IC.2 or equivalent.
Sphygmomanometer, with cuffs (adult / children)	Aneroid sphygmomanometer used in the physical examination, diagnosis, and monitoring of hypertension. Measures blood pressure non-invasively by displaying the pressure in a cuff wrapped around a patient's arm. · It should include a method of fixing the arm cuff to facilitate its use, cleaning and little accumulation of dirt. · The manometer must allow the reading of blood pressure with an accuracy of 2 mmHg. · Maximum pressure of 300 mmHg. · Gauge body to allow recalibration of readings, yet in normal operation be sealed and secure.
Stethoscope	A mechanical listening device designed for listening to sounds from the heart and lungs. It typically comprises a membrane at the listening head connected by a split "Y" tube to the headgear with ear olives that are placed into the user's ears. · Binaural device, with non-folding smooth spring frame. · Double stent chest piece. · Plain spring non-folding frame. · Plastic ear tips. Ear clips included. · Vinyl stethoscope tubing. · Combined bell and diaphragm sprague type. · Approximate length of 1 m.
Thermometer	Digital thermometer that allows the measurement of the patient's temperature. · Resolution of 0,1 °C. · Measurement range to include 32.2 to 42.2°C · Response time < 90 s required.
Triple packaging system	Any triple packaging system used to contain an infectious substance must comprise three layers: → a primary, watertight receptacle containing the infectious substance (the primary receptacle must be wrapped in enough absorbent material to absorb all the fluid in the event of a breakage or leakage); → a second, watertight and leakproof or sift proof packaging to enclose and protect the primary receptacle; and → a third, outer layer of packaging that is used to protect the secondary packaging from physical damage while in transit. For air shipments, follow Packing instruction P650 for "Biological Substances, Category B".
Venturi Mask	· Disposable, single patient use. · Non-Sterile packed sealed in Pouch. · 210 cm long star lumen tubing to ensure continuous flow of oxygen. · Different sizes: adult and pediatric.
Vital signs monitor	Electrocardiogram monitoring, non-invasive blood pressure, respiratory rate, temperature, oxygen saturation, among others. With the ability to connect to a central monitoring station. · Modular or configured monitor with a minimum 10-inch screen. · Able to connect to a monitoring network. · Defibrillator discharge protection. · Pacemaker detection. · Graphic and numerical trends of at least 24 hours of all parameters, user selectable. · Display of physiological curves on screen: - At least 4 simultaneous curves. - ECG, which allows the simultaneous display of at least 2 curves to choose from among 3 leads or more. - Plethysmography. - Breathing. · Numerical display of: - Heart rate. - Breathing frequency. - Oxygen saturation.

MEDICAL DEVICE	TECHNICAL DESCRIPTION AND SPECIFICATIONS
	- Non-invasive pressure (systolic, diastolic and mean). - Temperature. · Unwanted parameters can be deselected from display. · With internal rechargeable battery lasting at least one hour, with built-in charger and low-level indicator on screen. · Audible and visible alarms, prioritized in at least three levels with a function that allows reviewing and modifying the upper and lower limits of the following parameters: - Oxygen saturation. - Heart rate. - Non-invasive blood pressure (systolic, diastolic). - Temperature. - Breathing frequency. - Apnea alarm. · Covering use from newborn to adult.

Table 3: Technical description and specifications of personal protective equipment (PPE)

MEDICAL DEVICE	TECHNICAL DESCRIPTION AND SPECIFICATIONS
Alcohol-based hand rub solution	Bottles of 100 ml to 500 ml. Hand rub formulations containing 75% isopropanol or 80% ethanol. · Required: ASTM E2755 or EN 1500 · Optional: ASTM E1115 or ASTM E1174
Apron	Heavy duty apron, reusable, waterproof. · Fabric: polyester with PVC coating or 100% PVC or 100% rubber. · Minimum basis weight: 250 g/m2. · Adjustable neck strap (reusable) and back fastening. · Covering size: 70-90 cm (width) x 120-150cm (height), standard adult size. Compliance with: · EN ISO 13688 · EN 14126-B and partial protection (EN 13034 or EN 14605) · EN 343 for water and breathability or equivalent.
Bags for medical waste	Disposal bag for bio-hazardous waste, 30x50cm, with "Biohazard" printed legend, autoclavable polypropylene. Thickness between 50-70 micra.
Chlorine	NaDCC, granules, 1kg, 65 to 70% + dosage spoon.
Disposable towel for hand drying (paper or tissue)	50 to 100m roll.
Face shields	Made of clear plastic and provides good visibility to both the wearer and the patient. Adjustable band to attach firmly around the head and fit snuggly against the forehead, fog resistant (preferable). Completely covers the sides and length of the face. May be re-usable (made of robust material which can be cleaned and disinfected) or disposable. Compliance with: · EU PPE Regulation 2016/425, CE Notifying Body must be declared · EN 166 · ANSI/ISEA Z87.1 or demonstrate equivalent set of standards
Gloves, cleaning	Outer glove should have long cuffs, reaching well above the wrist, ideally to mid-forearm. · Minimum 280 mm total length. · Sizes: S, M, L. · Reusable. · Puncture-resistant, FDA compliant.
Gloves, surgical, sterile	Gloves, surgical, latex or nitrile, powder-free, sterile, single-use. Gloves should have long cuffs, reaching well above the wrist, ideally to mid-forearm. Sizes: S, M, L. Minimum thickness 0.10mm. Compliance with: · EU MDD (directive) 93/42/EEC Class IIa. · EU PPE Regulation 2016/425 Category III, CE Notifying Body must be declared. · FDA Class 1. · EN 455. · ASTM D3577. · Sterility according to USP. · EN ISO 11607 or demonstrate equivalent set of standards
Gloves, examination, non-sterile	Gloves, examination, latex or nitrile, powder-free, non-sterile, single-use. Gloves should have long cuffs, reaching well above the wrist, ideally to mid-forearm. Sizes: small, medium, large. Minimum thickness 0.05mm. Compliance with: · EU MDD (directive) 93/42/EEC Class I. · EU PPE Regulation 2016/425 Category III, CE Notifying Body must be declared. · FDA Class 1. · EN 455.

MEDICAL DEVICE	TECHNICAL DESCRIPTION AND SPECIFICATIONS
	· EN 374. · ASTM D6319. or equivalent set of standards
Goggles, protective	Good seal with the skin of the face: flexible PVC frame to easily fit with all face contours with even pressure. Enclose eyes and the surrounding areas, accommodate wearers with prescription glasses. Clear plastic lens with fog and scratch resistant treatments. Adjustable band to secure firmly so as not to become loose during clinical activity; Indirect venting to avoid fogging. May be re-usable (provided appropriate arrangements for decontamination are in place) or disposable. Compliance with: · EU PPE Regulation 2016/425 Category III, CE Notifying Body must be declared. · EN 166. · ANSI/ISEA Z87.1. or equivalent
Gown	Single use, fluid resistant, disposable, length mid-calf to cover the top of the boots. Light colors preferable to better detect possible contamination. Thumb/finger loops or elastic cuff to anchor sleeves in place. Compliance with: · EU PPE Regulation 2016/425 Category III, CE Notifying Body must be declared. · EU MDD (directive) 93/42/EEC Class I. · FDA class 1. · EN 13795 any performance level, or AAMI PB70 all levels acceptable, or ASTM F3352.
Liquid plain soap for hand hygiene	Liquid soap.
Medical mask	Medical/surgical mask, high fluid resistance, good breathability. Internal and external faces should be clearly identified. Structured design that does not collapse against the mouth (e.g. duckbill, cup-shaped). Compliance with: · EU MDD (directive) 93/42/EEC Class I. · EU PPE Regulation 2016/425 Category III, CE Notifying Body must be declared. · FDA Class 2. · EN 14683 Type II, IIR. · ASTM F2100 minimum Level 1 or equivalent.
Respirator (Grade N95 / FFP2 or higher)	N95 or FFP2 respirator, or higher. Good breathability with a design that does not collapse against the mouth (e.g. duckbill, cup-shaped). Compliance with: · EU PPE Regulation 2016/425 Category III, CE Notifying Body must be declared · EU MDD (directive) 93/42/EEC Class I. · FDA Class 2. · Minimum "N95" respirator according to CDC NIOSH 42 CFR 84. · Minimum "FFP2" according to EN 149, or demonstrate equivalent set of standards.

PAHO/IMS/HSS/COVID-19/20-0015