# List of priority medical devices in the context of COVID-19

*(provisional recommendations, August 13, 2020)*
*5th Version*

## Overview

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

**Objective of the document:**

The **list of priority medical devices in the context of COVID-19** provides technical descriptions and specifications for the medical devices recommended 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.

Compared to the previous version, this fifth version updates the recommendations as indicated in the Annex I.

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

## 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 | | | • |
| | Non-heated bubble humidifier | | | | x | | • | • |
| | Resuscitation bag with mask | | | 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 | | | • |
| | Mask with reservoir bag | | | x | x | • | • | • |
| | Percutaneous tracheostomy set | | | | x | | | • |
| | Swabs for respiratory sample collection and viral transport medium (VTM) | | x | | | • | • | • |
| | Set of laryngoscope blades | | | | x | • | • | • |
| | Venturi mask | | | | x | | • | • |
| | Bags for medical waste | | x | x | x | • | • | • |
| | Disposable towel for hand drying (paper or tissue) | x | 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 |
|---|---|---|---|---|---|---|---|---|
| **Single use devices/ disposables/ medical supplies** | Endotracheal tube, with cuff | | | | x | • | • | • |
| | Endotracheal tube, without cuff | | | | x | • | • | • |
| | Oropharyngeal airway, Guedel | | | | x | • | • | • |
| | Nasal oxygen cannula with prongs | | | 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 | • | • | • |
| | Gloves, examination, non-sterile | x | x | x | x | • | • | • |
| | Goggles, glasses protective | | x | x | x | • | • | • |
| | Gown, surgical | x | x | x | x | • | • | • |
| | Medical mask, healthcare worker | x | x | x | x | • | • | • |
| | Medical mask, patient | x | x | x | x | • | • | • |
| | Particulate respirator | | | | x | • | • | • |
| **Medical equipment** | Bi-Level Positive Airway Pressure unit (BiPAP) | | | x | x | | • | • |
| | Computed tomography (CT) system | | | | x | | | • |
| | Continuous Positive Airway Pressure unit (CPAP) | | | x | x | | • | • |
| | Electrocardiogram, 12-Lead | | | x | x | • | • | • |
| | External defibrillator | | | x | x | • | • | • |
| | Flowmeter, Thorpe tube | | | x | x | | • | • |
| | High-Flow Nasal Cannula (HFNC) | | | 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** | Oxygen concentrator | | | x | x | • | • | • |
| | Portable aspirator/ Suction system | | | | x | • | • | • |
| | Portable ultrasound | | | x | x | • | • | • |
| | Portable X-ray equipment | | | x | x | • | • | • |
| | Pulse oximeter, fingertip | x | | x | x | • | • | • |
| | Pulse oximeter, handheld | | | x | x | • | • | • |
| | Pulse oximeter, tabletop | | | x | x | | • | • |
| | Sphygmomanometer, with cuffs (adult / children) | x | | x | x | • | • | • |
| | Stethoscope | x | | x | x | • | • | • |
| | Ventilator for Intensive Care Unit | | | | x | | • | • |
| | Ventilators for Sub-Acute Care | | | | x | | • | • |
| | Ventilators for Transport | | | | x | | • | • |
| | Patient monitor multiparametric, basic | | | x | | • | • | • |
| | Patient monitor multiparametric, intermediate | | | x | x | • | • | • |
| | Patient monitor multiparametric, advanced | | | | x | | • | • |
| **Instrumental** | Thermometer, digital | x | | x | x | • | • | • |
| | Thermometer, infrared | 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 | • | • | • |

## 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 | |
|---|---|---|
| Bi-Level Positive Airway Pressure unit (BiPAP) | General requirements | Maintains continuous positive pressure in airway at high flow rate.<br>Easy to operate user interface, numbers and displays to be clearly visible.<br>Leakage compensation capability.<br>Provides a higher positive pressure airway upon inhalation than upon exhalation.<br>In-built air compressor or turbine.<br>Oxygen inlet.<br>Capability to connect to an active humidifier system (preferable).<br>Noise level < 35 dBA at mid pressure range.<br>Expiratory relief features that reduce the pressure slightly at the end of each breath to make it easier for the patient to exhale (preferable).<br>Pressure ramp option that starts pressure at low level and slowly increases over a period.<br>All parts withstand high disinfection procedures.<br>Class I or Class II or internally powered.<br>Protection IP21 required (IP22 preferable). |
| | Ventilation modes | CPAP (spontaneous).<br>T (timed).<br>Pressure assisted control/pressure control (PAC/PC) (preferable).<br>Automatic positive airway pressure (also called APAP or AutoPAP) (preferable). |
| | Monitored and controlled parameters | FiO2: 21–100 % (preferable).<br>Pressure: 4–25 cmH2O.<br>Spontaneous timing.<br>Trigger sensitivity range: 1–10 cmH2O, increments of 1 or automatic. |
| | Displayed parameters (color and graphic are preferable) | Display easily readable in low ambient light and sunlight.<br>Inspiratory and expiratory pressure.<br>Inspiratory and expiratory time.<br>FiO2 (%) (preferable).<br>Mean airway pressure (MAP) (preferable).<br>Air leak (%). |
| | Alarms, related to gas delivered | Visual and audible for:<br>· High/low pressure and/or minute ventilation.<br>· High/low oxygen (preferable).<br>· Breathing circuit disconnect. |
| | Alarms, related to equipment operation | Visual and audible for:<br>· Lack of water (preferable).<br>· System failure.<br>· Air filter to be replaced.<br>· Power failure (preferable).<br>· Low battery (preferable). |
| | Consumables, single use | Full face mask with tubing (for paediatric and universal fit for adult), alternative oral-nasal mask for adult and paediatric with tubing<br>Helmet for adult and paediatric with tubing (preferable)<br>Inlet bacteria filters, if applicable<br>Expiratory filters high efficiency |

| MEDICAL DEVICE | TECHNICAL DESCRIPTION AND SPECIFICATIONS | |
|---|---|---|
| | Accessories, reusable | Full face mask with tubing (for paediatric and universal fit for adult), alternative oral-nasal mask for adult and paediatric with tubing; withstands high-level disinfection and sterilization.<br>Helmet for adult and paediatric with tubing (preferable); withstands high-level disinfection and sterilization.<br>Humidifier accessory, if not integrated.<br>Standard hoses and connectors (ie. DISS/NIST, barb, as applicable for the country) for oxygen wall outlets and cylinder.<br>Mains power cable ≥ 2 m. |
| | Spare parts | 1-year's spare parts kit as per preventive maintenance program (preferable) |
| | 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 AC±10 % / 50–60 Hz ±10 %<br>In-built rechargeable battery (preferable); if the equipment does not have an internal battery, an external battery or uninterruptible power supply should be included to provide battery back up in the case of AC power failure.<br>Automatic switch from AC power electric-line mode to battery operating mode and vice versa, if applicable. |
| | Standards, for manufacturer | Certified quality management system for medical devices (e.g. ISO 13485).<br>Application of risk management to medical devices (e.g. ISO 14971). |
| | Regulatory approval / certification | Free sales certificate (FSC) or certificate for exportation of medical device provided by the authority in manufacturing country.<br>Proof of regulatory compliance, as appropriate, per the product's risk classification (e.g. Food and Drug Administration [FDA] and/or Conformité Européenne [CE]). |
| | Standards, for product performance | Compliance to the following international standards or to regional or national equivalent, (including the technical tests for safety and performance from accredited laboratory or third party). Latest version recommended but compliance to previous standards versions could be accepted:<br>· IEC 60601-1 Medical electric equipment – Part 1: General requirements for basic safety and essential performance.<br>· IEC 60601-1-2:2014 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requir1w3qements and tests.<br>· ISO 80601-2-70 Medical electrical equipment – Part 2-70: Particular requirements for basic safety and essential performance of sleep apnoea breathing therapy equipment.<br>· ISO 80601-2-80 Medical electrical equipment – Part 2-80: Particular requirements for basic safety and essential performance of ventilatory support equipment for ventilator insufficiency.<br>· ISO 60601-1-8 Medical electrical equipment – Part 1-8: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems.<br>If applicable, for the accessories and consumables:<br>· ISO 18562-1:2017 Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 1: Evaluation and testing within a risk management process.<br>· ISO 80601-2-74:2017 Medical electrical equipment – Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment.<br>· ISO 17510:2015 Medical devices – Sleep apnoea breathing therapy – Masks and application accessories. |
| | Warranty | Minimum 2 years. |
| | According to: COVID-19 Technical specifications for invasive and non-invasive ventilators (link) | |

| MEDICAL DEVICE | TECHNICAL DESCRIPTION AND SPECIFICATIONS | |
|---|---|---|
| Carbon dioxide detector | · Disposable.<br>· Colorimetric.<br>· Sizes compatible with child and adult endotracheal tube. | |
| Computed Tomography (CT) scanner, 16-Slice | Functional and performance requirements and scanning parameters | CT scanning system with at least 64 slices suitable to perform a wide range of scans in patients of all ages and a diverse range of diseases, with a special focus on lung diseases.<br>The CT scanner should be suitable for all relevant cross-sectional imaging requirements in diagnostic radiology.<br>Number of actual slices per 360° rotation should be not less than 64 slices at all speeds.<br>Reconstructed slice width options range from at least 0.625 mm to 10 mm.<br>Minimum rotation time (360°) not higher than 0.5 sec.<br>Retrospective reconstruction should be possible of raw data files with the capacity to modify parameters such as field of view (FOV).<br>At least the following scanning modes should be possible: scan projection radiograph (SPR), axial and spiral.<br>The SPR length should be at least 1500 mm and the minimum width 500 mm. It must be possible to obtain the SPR from anteroposterior (AP) or posteroanterior (PA) or left to right or right to left directions.<br>Multiple volumetric studies capability.<br>The system must have automated dose control and milliampere (mA) control software that automatically adjusts mA for patient size, adjusts mA along the z-axis, and modulates mA during rotation.<br>The CT scanner should have conventional built-in lasers or light beams, which indicate the coincidence of the centre of rotation and scan position.<br>The system should be interconnected (all the workstations, any laser systems, printers etc.) and the CT scanner should be able to be networked at the site to allow transfer of CT data sets in Digital Imaging and Communications in Medicine (DICOM) format to a hospital information system (HIS), radiology information system (RIS) and picture archiving and communication system (PACS) system.<br>Dose computation and display: the system should display CT dose index (CTDI) – volumetric (CTDIvol) and weighted (CTDIw) – and dose-length product (DLP) and have the capacity to transfer this information to the exam record.<br>Dose optimization tools should be available. |
| | Patient table | The CT scanner should have a tabletop made of resistant and radiotransparent material.<br>Table with minimum dimensions of 235 x 40 cm (preferable).<br>Vertical moving minimum range 44–90 cm (preferable).<br>The speed of horizontal movement must be variable with a maximum speed of at least 100 mm per sec.<br>The scannable range should be at least 160 cm.<br>Maximum loading capacity of not less than 200 kg without any change in stated performance technical specifications (such as the positioning accuracy).<br>Capability of automatic patient isocentring (preferable). |
| | Gantry | Number of rows not less than 64.<br>A gantry aperture of at least 70 cm.<br>Scan FOV of at least 50 cm.<br>Balancing system and laser lights to support centring.<br>Preferable: gantry tilt at least ± 30 degrees (preferable), controllable by the console; also (remote). |
| | X-ray system (tube and | High-frequency generator with gantry implanted microprocessor.<br>The X-ray tube shall have dual focal spots. The contractor shall state the size of the focal spots. |

| MEDICAL DEVICE | TECHNICAL DESCRIPTION AND SPECIFICATIONS | |
|---|---|---|
| | generator) and detectors | Tube focal spots not higher than 0.9 x 0.8 mm and 1.1 x 1.2 mm.<br>Power rating of at least 70 kW.<br>kVp range of at least 80 kV to 135 kV.<br>mA range of at least 20 mA to 550 mA.<br>Maximum anode cooling rate of at least 1000 kHU/min.<br>Anode heat storage capacity of not less than 7 MHU.<br>High performance, low noise, high data density, active response data acquisition system.<br>Solid state detectors.<br>At least 38 mm detector coverage with no less than 64 rows<br>Free from repeated calibrations.<br>There shall be at least 600 elements per row and 64 or more detectors for acquisition of a minimum of 64 slices at a time.<br>High detection efficiency (to be specified by the contractor).<br>High discharging speed (to be specified by the contractor). |
| | Hardware, console and software for console and independent workstation | Raw data reconstruction hardware:<br>• Latest generation system with high performance processors.<br>• 4 GB of RAM.<br>• Raw data hard disk of at least 300 GB.<br>• High multi-tasking level.<br>Double monitor acquisition (operation) console with at least the following characteristics:<br>• Capability for simultaneous scanning and reconstruction.<br>• At least the following functions should be available: simultaneous scanning and routine analysis, simultaneous scanning and archiving and/or hard copying and simultaneous scanning and transfer to second console/workstation.<br>• Last generation processor.<br>• At least two 19'' thin-film transistor liquid-crystal display (TFT LCD or equivalent or better technologies) colour monitors medical safety requirements compliant.<br>• Keyboard and mouse.<br>• At least 2 GB of RAM.<br>• At least 250 GB image storage hard disk.<br>• CD/DVD driver with integrated CD reviewing software for DICOM stored images.<br>• The CT system should be fully DICOM compliant. The DICOM should support at least the following: DICOM 3.0 print, storage, send/receive, and query/retrieve.<br>• DICOM compliance statement should be provided.<br>• DICOM data high transmission speed to and from the workstation.<br>• Verbal/audio bi-directional communication system must be provided between the operator and the patient.<br>• At least local area network (LAN) connection driver.<br>Acquisition (operation) console's software at least with the following functions:<br>• Easy access software interface.<br>• Positioning digital radiography with a length of at least 160 cm.<br>• Initial definition of the exam's protocol with real-time availability to modify it.<br>• List of defined exam's protocol.<br>• Spiral and axial (preferable) scan.<br>• For contrast-enhanced exams, scan synchronization with the arrival of the administered contrast (bolus test and bolus tracking).<br>• Multi-perspective and cardiovascular examination software with at least the following requirements:<br>o best reconstruction timing choice;<br>o electrocardiogram (ECG) tracing and image-gating procedure;<br>o automatic multi-phase reconstruction of cardiac kinetic function.<br>• Software for low dose protocols included. |

| MEDICAL DEVICE | TECHNICAL DESCRIPTION AND SPECIFICATIONS | |
|---|---|---|
| | | Independent double (preferable) monitor workstation with at least the following characteristics:<br>• High-performance workstation for post-processing and advanced clinical applications.<br>• Latest generation processor.<br>• One (preferably two) monitor, at least 21", LCD or equivalent or better technologies, medical safety requirements compliant.<br>• Keyboard and mouse.<br>• At least 4 GB of RAM.<br>• Not less than 1 TB image storage hard disk.<br>• In the hard disk for image storage, the number of uncompressed 512 x 512 pixel images that can be stored should be at least 200 000. The maximum possible hard disk capacity should be provided.<br>• CD/DVD driver with integrated CD reviewing software for DICOM stored images.<br>• The CT system should be fully DICOM compliant. The DICOM should support at least the following: DICOM 3.0 print, storage, send/receive, and query/retrieve.<br>• DICOM compliance statement should be provided.<br>• DICOM data high transmission speed to and from the workstation.<br>• At least LAN connection driver.<br>Software features for the independent workstation described in the previous point:<br>• Volume, partial, package or radial maximal intensity projection (MIP) and minimum intensity projection (MinIP).<br>• Volume, partial, package or radial volume rendering technique (VRT).<br>• Volume, package, radial multiplanar reformation (MPR).<br>• Single curve, package or radial MPR.<br>• Surface 3-D.<br>• Dynamic scan with or without patient table movement.<br>• Angio package with bolus-CT capability.<br>• CT cardiovascular package, with at least the following functions available: calculation of the calcium density/quantity in the coronaries, functional/anatomic and morphologic analysis of cardiac system (coronaries and left ventricle) and coronary plaques characterization software.<br>• Vessel structure analysis package with 2-D and 3-D measurement (angio-CT software) (preferable).<br>• CT neuro package (neuro digital subtraction angiography [DSA] CT and neuro perfusion CT)(preferable).<br>• Lung examination/analysis full package provided. Moreover, software for COVID-19 detection/assessment should be considered as an option.<br>• CT oncology package (lung nodules detection with computer assisted detection [CAD] capability and colonography with CAD capability) (preferable).<br>• Automatic bones subtraction package (preferable).<br>• Analysis and comparison of tumours for serial exams on the same patient (preferable).<br>• All the software should be provided for reporting procedure with DICOM, pdf, rtf format export availability to enable transfer of images for tele-radiology to electronic health records, to other medical facilities or to others as warranted. |
| | Image quality | The reconstruction matrix should be at least 512 x 512 pixel.<br>Display matrix not less than 1024 x 1024 pixel.<br>In plane spatial resolution values shall be provided by the contractor to be evaluated.<br>Low-contrast detectability (or resolution) 5 mm or less at 0.3% at no more than 20 mGy.<br>High-contrast spatial resolution: at least 18 lp/cm at 0% modulation transfer function (MTF). |

| MEDICAL DEVICE | TECHNICAL DESCRIPTION AND SPECIFICATIONS | |
|---|---|---|
| | | Metal artefacts reduction algorithm (preferable).<br>Reconstruction index of at least 190 slice/sec (3 frames/sec).<br>Reconstruction speed, in both spiral and axial scan, with 512 x 512 pixel matrix, with every artefact correction, of at least 16 images/sec VRT.<br>Table and bone removal (image subtraction) function available.<br>Virtual endoscopic view available (preferable). |
| | Power supply (voltage, frequency and plug vary across countries) | Power input to be approximately 380 V, 50/60 Hz, 90 kVA, triphasic electrical source.<br>The provider will supply direct electric connection to the three-phase power supply network and the connection will be effectuated directly to the network with thermomagnetic disconnecting switch.<br>Protectors against power surge (over-voltage and over-current) line conditions.<br>UPS provided: online UPS with maintenance-free batteries for the backup of the entire system for at least 30 minutes. |
| | Accessories and spare parts | Patient table provided with complete accessories set for patient positioning for any exam type.<br>Necessary quality assurance phantoms to check the image quality and calibration of the CT scanner should be provided.<br>Phantom holder provided.<br>Contrast injector system.<br>At least two complete sets of necessary protective equipment for the staff/users. Each set will include lead: apron, thyroid collar, specific gloves, glasses and a mask.<br>List of important spares and accessories to be provided with their part numbers and cost.<br>Spare parts availability for the equipment lifespan (not less than 10 years). |
| | Standards for the manufacturer | Certified quality management system for medical devices (e.g. ISO 13485).<br>Application of risk management to medical devices (e.g. ISO 14971). |
| | Regulatory approval / certification | Free sales certificate (FSC) or certificate for exportation of medical device provided by the authority in manufacturing country.<br>Proof of regulatory compliance, as appropriate, per the product's risk classification (e.g. Food and Drug Administration [FDA] and/or Conformité Européenne [CE]). |
| | Standards for the product performance | Compliance to the following international standards or to regional or national equivalent, (including the technical tests for safety and performance from accredited laboratory or third party). Latest version recommended but compliance to previous standards versions could be accepted:<br>· IEC 60601-1:2005+AMD1:2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.<br>· 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.<br>· IEC 60601-2-44 Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography.<br>· IEC 60601-1-3:2008+AMD1:2013 Part 1-3: General requirements for basic safety and essential performance – Collateral standard: Radiation protection in diagnostic X-Ray equipment.<br>· IEC 60336:2005 X-ray tube assemblies for medical diagnosis – Characteristics of focal spots.<br>· IEC 60601-2-28:2010 Part 2-28 Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis.<br>· IEC 60613:2010 Electrical and loading characteristics of X-ray tube assemblies for medical diagnosis. |

| MEDICAL DEVICE | TECHNICAL DESCRIPTION AND SPECIFICATIONS | |
|---|---|---|
| | Warranty | The system should be covered by at least 1 year's warranty including spare or replacement parts, tube and laborxx, starting as of the date of successful on-site acceptance, as per testing and acceptance below. |
| | According to: *COVID-19 Technical specifications for imaging devices: portable ultrasound; mobile radiographic digital equipment; computed tomography (CT) scanning system* (link) | |
| Continuous Positive Airway Pressure unit (CPAP) | General requirements | Maintains continuous positive pressure in airway.<br>Easy to operate user interface, numbers and displays to be clearly visible.<br>Leakage compensation capability (preferable).<br>In-built air compressor or turbine.<br>Oxygen inlet.<br>Capability to connect to an active humidifier system (preferable).<br>Noise level < 35 dB at mid pressure range.<br>Expiratory relief features that reduce the pressure slightly at the end of each breath to make it easier for the patient to exhale (preferable).<br>Pressure ramp option that starts pressure at low level and slowly increases over a period (preferable).<br>All parts withstand high disinfection procedures.<br>Inspiration trigger for auto start.<br>Class I or Class II or internally powered.<br>Protection IP21 required (IP22 preferable). |
| | Ventilation modes | Non-invasive CPAP |
| | Monitored and controlled parameters | $FiO_2$: 21 to 100 %, preferable<br>Pressure: 4 to 20 [$cmH_2O$]. |
| | Displayed parameters (color and graphic are preferable) | Display easily readable in low ambient light and sunlight.<br>Pressure: cmH2O.<br>FiO2 (%) (preferable).<br>Flow (preferable).<br>Air leak (%) (preferable).<br>RR (preferable). |
| | Alarms, related to gas delivered | Visual and audible for:<br>· High/low pressure and/or minute ventilation.<br>· High/low oxygen (preferable).<br>· Breathing circuit disconnection. |
| | Alarms, related to equipment operation | Visual, audible for:<br>· Lack of water (preferable).<br>· System failure.<br>· Air filter to be replaced.<br>· Power failure (preferable).<br>· Low battery (preferable). |
| | Consumables, single use | Inlet bacteria filters, if applicable<br>Expiratory filters, high efficiency<br>Full face mask with tubing (for paediatric and universal fit for adult) alternative oral-nasal mask for adult and paediatric with tubing.<br>Helmet for adult and paediatric with tubing (preferable) |
| | Accessories, reusable | Full face mask with tubing (for paediatric and universal fit for adult), alternative oral-nasal mask for adult and paediatric with tubing; withstands high-level disinfection and sterilization<br>Helmet for adult and paediatric with tubing (preferable); withstands high-level disinfection and sterilization (preferable)<br>Humidifier accessory if not integrated |

| MEDICAL DEVICE | TECHNICAL DESCRIPTION AND SPECIFICATIONS | |
|---|---|---|
| | | Standard hoses and connectors (i.e. DISS/NIST, barb, as applicable for the country) for oxygen wall outlets and cylinder as required to operate.<br>Mains power cable ≥ 2 m. As required to operate. |
| | Spare parts | 1-year's spare parts kit as per preventive maintenance program (preferable). |
| | 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 AC ±10 % / 50–60 Hz ±10 %<br>In-built rechargeable battery (preferable); if the equipment does not have an internal battery, an external battery or uninterruptible power supply should be included to provide battery back up in the case of AC power failure.<br>Automatic switch from AC power electric-line mode to battery operating mode and vice versa, if applicable. |
| | Standards, for manufacturer | Certified quality management system for medical devices (e.g. ISO 13485).<br>Application of risk management to medical devices (e.g. ISO 14971). |
| | Regulatory approval / certification | Free sales certificate (FSC) or certificate for exportation of medical device provided by the authority in manufacturing country.<br>Proof of regulatory compliance, as appropriate, per the product's risk classification (e.g. Food and Drug Administration [FDA] and/or Conformité Européenne [CE]). |
| | Standards, for the product performance | Compliance to the following international standards or to regional or national equivalent, (including the technical tests for safety and performance from accredited laboratory or third party). Latest version recommended but compliance to previous standards versions could be accepted:<br>· IEC 60601-1 Medical electric equipment – Part 1: General requirements for basic safety and essential performance.<br>· 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.<br>· ISO 80601-2-70 Medical electrical equipment – Part 2-70: Particular requirements for basic safety and essential performance of sleep apnea breathing therapy equipment.<br>· ISO 80601-2-80 Medical electrical equipment – Part 2-80: Particular requirements for basic safety and essential performance of ventilatory support equipment for ventilator insufficiency.<br>· IEC 60601-1-8 Medical electrical equipment – Part 1-8: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems.<br>If applicable, for the accessories and consumables:<br>· ISO 18562-1:2017 Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 1: Evaluation and testing within a risk management process.<br>· ISO 80601-2-74:2017 Medical electrical equipment – Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment.<br>· ISO 17510:2015 Medical devices – Sleep apnea breathing therapy – Masks and application accessories. |
| | Warranty | Minimum 2 years. |
| | According to: COVID-19 Technical specifications for invasive and non-invasive ventilators (link) | |
| 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.<br>· Include the electrodes and wires for the 12-lead socket.<br>· Must be able to display 3 simultaneous waves.<br>· Able to obtain P, QRS, and T waveforms. | |

| MEDICAL DEVICE | TECHNICAL DESCRIPTION AND SPECIFICATIONS |
|---|---|
| | · Include uninterruptible power supply and backup battery.<br>· With automatic calibration function.<br>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.<br>· Multiple or single use.<br>· Length 60 cm to 70 cm.<br>· Diameter: 14 - 15 Fr.<br>· For ET tubes from 6 to 11 mm of internal diameter.<br>· 30 degrees tip angle. |
| Endotracheal tube introducer, Stylet type | Flexible and malleable guide (stylet type).<br>· The end of the guide should be smooth and round, as required.<br>· Graduated marking.<br>· The tube must be marked with the manufacturer's name and tube's size.<br>· Sterile, single use.<br>· Diameter 10 Fr. and 14 Fr.<br>· Length from 30 cm to 45 cm. |
| Endotracheal tube, with cuff | · Endotracheal tube with cuff.<br>· Open distal end and Magill-type point with oral angle of 37.5°.<br>· Standard connector (external diameter 15mm) at the proximal end enabling the tube to be connected to the ventilation system.<br>· Radio opaque mark.<br>· With Murphy's eye.<br>· Graduations.<br>· Internal diameter size: 6.5mm, 7mm, 7.5mm, 8mm or 8.5mm.<br>· Material: polyvinyl chloride (PVC).<br>· Disposable / sterile. |
| Endotracheal tube, without cuff | · Endotracheal tube without cuff.<br>· Open distal end and Magill-type point with oral angle of 37.5°.<br>· Standard connector (external diameter 15mm) at the proximal end enabling the tube to be connected to the ventilation system.<br>· Radio opaque mark.<br>· With Murphy's eye.<br>· Graduations.<br>· Internal diameter size: 3mm or 3.5mm.<br>· Material: Polyvinyl chloride (PVC).<br>· Disposable / Sterile.<br>· Initial sterilization method: Ethylene oxide gas or Gamma radiation. |
| External defibrillator | · Manual and semi-automated operating modes.<br>· Biphasic waveform operation.<br>· Maximum energy to be at least 220 Joules.<br>· Conductive area for paddles shall be >50cm$^2$ for adult, >15cm$^2$ for pediatric.<br>· ECG analysis time to be < 15 s.<br>· Charge time to full energy to be < 10 s.<br>1. 30 full energy discharges to be possible solely off battery operation.<br>· Voice prompting function included for operator direction.<br>· Number of discharges (total lifetime and on current battery) to be displayed.<br>· Self-test facility to be included.<br>· Automatic impedance compensation.<br>· External defibrillation discharging start control just only by pressing both buttons on the external paddles.<br>· One set of reusable adult external paddles and related pediatric adapters compatible with the equipment.<br>· Displayed parameters - indicator for power and battery state required. |

| MEDICAL DEVICE | TECHNICAL DESCRIPTION AND SPECIFICATIONS |
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| Fit test kit | To evaluate effectiveness of seal for tight-fitting respiratory protection devices.<br>OSHA 29 CFR 1910.134 Appendix A. |
| Flow splitter | Flow splitter from a single or double oxygen supply.<br>· Equipped with four or five independent, pressure-compensated, Thorpe tube flowmeters, to regulate the flow of medical gas.<br>· Suitable for tabletop and/or wall mount.<br>· Flowmeters capacity: 0.125–2 L/min.<br>· Accuracy: ± 10%.<br>· Inlet port to be compatible with all the international standards for oxygen fittings, including DISS, threaded and non-threaded, 6 mm barbed – availability of different ports and/or adapters to be stated.<br>· 6 mm barbed outlet as standard – availability of adapters and outlet options to match all the international standards for oxygen fittings to be stated.<br>· Transparent, clearly readable and graduated (metric system) column, shatter-resistant polymer certified for medical use.<br>· Needle valve and body constructed of brass or aluminum.<br>· Adjustment knobs to have rough surface to prevent slipping.<br>· Color-coded flowmeter preferable, e.g. to ISO 32.<br>· Flowmeter stand hard plastic or metal epoxy painted.<br>· Capable to be disinfected with hospital grade detergents.<br><br>Standards for product performance:<br>· Color coding ISO or ANSI for medical gases.<br>· Conforms to ISO, NFPA, and/or CGA standards, and/or UL or CSA approved.<br>· ISO 15001 Anesthetic and respiratory equipment – _Compatibility with oxygen.<br>· ISO 15002 Flow-metering devices for connection to terminal units of medical gas pipeline systems.<br>· ISO 18562 Biocompatibility evaluation of breathing gas pathways in healthcare applications.<br>· ISO 10524 Pressure regulators for use with medical gases.<br>· ISO 18082 Anesthetic and respiratory equipment – _Dimensions of non-interchangeable screw-threaded (NIST) low-pressure connectors for medical gases.<br>· ISO 15223-1 Medical devices – _Symbols to be used with medical device labels, labelling and information to be supplied – _Part 1: General requirements.<br>· ISO 5359 Low-pressure hose assemblies for use with medical gases.<br>· ISO 32 Color coding for medical gases. |
| Flowmeter, Thorpe tube | Thorpe tube flowmeter, to measure and regulate the flow of medical gas is composed of inlet and outlet ports, a regulator, a valve and a clear tapered measuring tube. It is suitable for connection with various medical gas sources, such as a centralized system, cylinders or compressors.<br>· DISS style inlet and outlet, or if required by end-user other international standard fittings, e.g. 1/8 inch FNPT female, 3/8 inch BSP female, UNI EN 737, DIN, DISS, AFNOR, Ohmeda, Chemtron, Puritan Bennet, Schrader.<br>· Transparent, clearly readable and graduated (metric system) column, shatter-resistant polymer certified for medical use.<br>· Clearly visible graduation, 270 or more degrees of visibility.<br>· Needle valve and body constructed of brass or aluminium.<br>· Calibrated at 345–380 kPa (3.4–3.8 bar, 50–55 psi) inlet gauge pressure.<br>· Inlet gauge pressure (nominal) > 380–413 kPa (3.8–4.1 bar, 55–60 psi), peak gauge inlet pressure 690 kPa (6.9 bar, 100 psi).<br>· Pressure-compensated design to give specified accuracy for whole range of input pressures.<br>· Minimum flow rate to be zero, i.e. fully closed.<br>· Maximum flow rate when fully open to be stated.<br>· Anti-slip knob.<br>· Available in international ISO and ANSI colour-coding systems for oxygen and medical air. |

| MEDICAL DEVICE | TECHNICAL DESCRIPTION AND SPECIFICATIONS | |
|---|---|---|
| | Standards for product performance:<br>· Color coding ISO or ANSI for medical gases.<br>· Conforms to ISO, NFPA, and/or CGA standards, and/or UL or CSA approved.<br>· ISO 15001 Anesthetic and respiratory equipment – Compatibility with oxygen.<br>· ISO 15002 Flow-metering devices for connection to terminal units of medical gas pipeline systems.<br>· ISO 18562 Biocompatibility evaluation of breathing gas pathways in healthcare applications.<br>· ISO 10524 Pressure regulators for use with medical gases.<br>· ISO 18082 Anesthetic and respiratory equipment – Dimensions of non-interchangeable screw-threaded (NIST) low-pressure connectors for medical gases.<br>· ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements.<br>· ISO 5359 Low-pressure hose assemblies for use with medical gases.<br>· ISO 32 Color coding for medical gases. | |
| 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.<br>· Manual.<br>· Non-invasive. | |
| High-Flow Nasal Cannula (HFNC) | General requirements | Capability to generate a high flow of mixed room air and oxygen.<br>Capability to use oxygen from an oxygen concentrator or cylinder.<br>In-built air compressor/turbine/piston.<br>Easy to operate user interface, with displayed parameters clearly visible.<br>The mixed room air and oxygen should be warmed up to 37 °C and 100% RH.<br>Controls to be easy to operate, numbers and displays to be clearly visible.<br>It should have a humidity compensation system.<br>Noise level < 35 dB at mid pressure range.<br>Protection IP21 required (IP22 preferable). |
| | Monitored and controlled parameters | FiO2: 21–100 % (preferable).<br>Flow up to: 50 L/min (minimum). |
| | Displayed parameters (color and graphic are preferable) | Display easily readable in low ambient light and sunlight.<br>Gas temperature (°C).<br>Flow (L/min).<br>Tidal volume (L).<br>Inspiratory pressure (cmH2O).<br>Air leak (%) (preferable).<br>FiO2 (%) (preferable). |
| | Alarms, related to gas delivered | Visual and audible for:<br>· Incorrect temperature/humidity.<br>· System leakage or blockage.<br>· High/low FiO2 (preferable). |
| | Alarms, related to equipment operation | Visual and audible for:<br>· Lack of water.<br>· System failure.<br>· Air filter to be replaced.<br>· Power failure.<br>· Low battery (if applicable). |
| | Consumables, single use | Housing and patient interface for adult and paediatric.<br>Inlet bacteria filters, if applicable<br>Expiratory filters high efficiency |

| MEDICAL DEVICE | TECHNICAL DESCRIPTION AND SPECIFICATIONS | |
|---|---|---|
| | Accessories, reusable | Flowmeter, graduated in L/min as required to operate<br>Humidifier as required to operate<br>Water chamber as required to operate<br>Standard hoses and connectors (i.e. DISS/NIST, barb, as applicable for the country) for oxygen wall outlets and cylinder as required to operate.<br>Mains power cable ≥ 2 m. |
| | Spare parts | 1-year's spare parts kit as per preventive maintenance program (preferable) |
| | 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 AC ±10 % / 50–60 Hz ±10 %<br>In-built rechargeable battery (preferable); if the equipment does not have an internal battery, an external battery or uninterruptible power supply should be included to provide battery back up in the case of AC power failure.<br>Automatic switch from AC power electric-line mode to battery operating mode and vice versa. |
| | Standards, for manufacturer | Certified quality management system for medical devices (e.g. ISO 13485).<br>Application of risk management to medical devices (e.g. ISO 14971). |
| | Regulatory approval / certification | Free sales certificate (FSC) or certificate for exportation of medical device provided by the authority in manufacturing country.<br>Proof of regulatory compliance, as appropriate, per the product's risk classification (e.g. Food and Drug Administration [FDA] and/or Conformité Européenne [CE]). |
| | Standards, for the product performance | Compliance to the following international standards or to regional or national equivalent, (including the technical tests for safety and performance from accredited laboratory or third party). Latest version recommended but compliance to previous standards versions could be accepted:<br>· IEC 60601-1:2005 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance<br>· 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.<br>· ISO 18562-1:2017 Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 1: Evaluation and testing within a risk management process.<br>· ISO 20789:2018 Anaesthetic and respiratory equipment – Passive humidifiers.<br>· ISO 17510:2015 Medical devices – Sleep apnoea breathing therapy – Masks and application accessories. |
| | Warranty | Minimum 2 years. |
| | According to: COVID-19 Technical specifications for invasive and non-invasive ventilators (link) | |
| Intercostal catheter (ICC) / chest tube | · Sterile, single use.<br>· Straight and right-angle versions in various sizes (12-40 Fr).<br>· Bold depth marks and radiopaque mark. | |
| Intravenous infusion set with macrodrip | Sterile for single use. Components of the device:<br>· Driller: sharp drilling device with protective cap.<br>· Air inlet: with integrated bacteriological filter.<br>· Drop count chamber: clear drip chamber, calibrated to 20 drops/ml, with 15-20 µm fluid filter.<br>· Tube: transparent tube, minimum length 150cm, with latex or latex-free injection space (or Y injection port), with distal connector preferably Luer Lock connector.<br>· 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.<br>· Include main components: airway tube, inflatable mask, and mask inflation line. | |

| MEDICAL DEVICE | TECHNICAL DESCRIPTION AND SPECIFICATIONS |
|---|---|
| | · Slightly curved, semi-rigid and semi-transparent tube with a longitudinally black line.<br>· 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.<br>· Handle is 28 mm diameter and battery powered with two standard alkaline dry cell batteries (1.5 V, type C (LR14)).<br>· Large hollow, cylindrical, slightly ribbed handle.<br>· Handle made of either chromium-plated or stainless steel.<br>· Stud contact, fitting various sizes and types of blades.<br>· Include Macintosh and Miller type blades, as described in *"Set of laryngoscope blades".*<br>Complies with ISO 7376:2009 or equivalent. |
| Mask with reservoir bag | Non-rebreather mask with reservoir bag, used to deliver medical oxygen directly to the upper airway of the patient. Non-sterile, single use.<br>· It includes two unidirectional valves, one that closes during inspiration to prevent room air mixing with oxygen in a reservoir bag; and one that closes during exhalation to prevent exhaled respiratory gases from entering the reservoir bag (non-rebreathing oxygen face mask).<br>· Mask is soft, transparent, well-fitting molded, with two side vents.<br>· The nose clip is soft, malleable and adjustable.<br>· The tubing (oxygen line) is non-kinking, well-fitted.<br>· Tubing compatibility with standard oxygen connection tubing, 3–5 mm internal diameter and 7–8 mm external diameter, and 15/22 mm diameter ventilation tubing; available with "standard" and "universal" hose end connector.<br>· Individually packed.<br>Sizes:<br>· Adult.<br>· Pediatric: tube length: 1.5–2 m.<br><br>Material:<br>· Mask and tubing PVC or other material, FDA Title 21/USP VI compliant and certified for medical use, hardness > 60 Shore A (ASTM D-2240).<br>Standards for product performance:<br>· ISO 11712:2009 Anesthetic and respiratory equipment – Supralaryngeal airways and connectors.<br>· ISO 15001 Anesthetic and respiratory equipment – Compatibility with oxygen.<br>· ISO 18562 Biocompatibility evaluation of breathing gas pathways in healthcare applications.<br>· ISO 18190 Anesthetic and respiratory equipment – General requirements for airways and related equipment.<br>· ISO 18562-1 Biocompatibility evaluation of breathing gas pathways in healthcare applications Part 1: Evaluation and testing within a risk management process.<br>· ISO/DIS 23368 Anesthetic and respiratory equipment – Low flow nasal cannula for oxygen therapy.<br>· ISO/DIS 17256 Anesthetic and respiratory equipment – Respiratory therapy tubing and connectors.<br>· ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements. |
| Nasal Catheter, Flexible | · Flexible nasal catheter with multiple holes (6 to 12 lateral eyes) at distal end.<br>· Oxygen and air/oxygen mixture compatibility, as per ISO 15001.<br>· Proximal end with connector.<br>· Sterile, single use.<br>· Diameter: 8 Fr. Length: 40 cm. |
| Nasal oxygen cannula with prongs | Cannula with nasal prongs designed for easy administration of medicinal oxygen through patient nostrils; single use. |

| MEDICAL DEVICE | TECHNICAL DESCRIPTION AND SPECIFICATIONS |
|---|---|
| | · Low-resistance tubing, round shape section, designed for low-flow procedures, typically 0–15 L/min, where the delivered gas does not meet all the inspiratory demand and entrains ambient air.<br>· The twin prongs nasal tips are soft and smoothly finished to ensure equal oxygen flow to both nostrils. They are connected to a lip support and harness (one tube right/left side).<br>· The harness is fully adjustable (over the patient's ear) with a double tubing (right and left side), interlinked through a molded Y-connector to the oxygen supply line.<br>· All tubing is soft and flexible, kink resistant, with star lumen, and with proximal end with a universal, funnel-shaped connector to oxygen source.<br>· Tubing compatibility with standard oxygen connection tubing, 3–5 mm internal diameter and 7–8 mm external diameter, and 15/22 mm diameter ventilation tubing; available with "standard" and "universal" hose end connector.<br>· Individually packed in a sealed plastic envelope.<br>· Non-sterile.<br><br>Sizes:<br>· Adult: outer diameter of the prong: 6 mm; tube length: 1.5–2 m.<br>· Pediatric: outer diameter of the prong: 3.7 mm; tube length: 1.5–2 m.<br><br>Material:<br>· Rubber or soft plastic tubing and prongs, semi-rigid and allowing freedom of movement, PVC or other material, FDA Title 21/USP VI compliant and certified for medical use, hardness > 60 Shore A (ASTM D-2240).<br><br>Standards for product performance:<br>· ISO 11712:2009 Anesthetic and respiratory equipment – Supralaryngeal airways and connectors.<br>· ISO 15001 Anesthetic and respiratory equipment – Compatibility with oxygen.<br>· ISO 18562 Biocompatibility evaluation of breathing gas pathways in healthcare applications.<br>· ISO 18190 Anesthetic and respiratory equipment – General requirements for airways and related equipment.<br>· ISO 18562-1 Biocompatibility evaluation of breathing gas pathways in healthcare applications Part 1: Evaluation and testing within a risk management process.<br>· ISO/DIS 23368 Anesthetic and respiratory equipment – Low flow nasal cannula for oxygen therapy.<br>· ISO/DIS 17256 Anesthetic and respiratory equipment – Respiratory therapy tubing and connectors.<br>· ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements. |
| 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.<br>· Sterile, single use. Individually packaged sterile with a conveniently attached surgical lubricant for quick access to facilitate ease of insertion.<br>· Flexible and soft material for maximum patient comfort.<br>· Rounded tip allows for gentle insertion.<br>· Trumpet design for secure placement.<br>· Diameter and size labelled according to standards.<br>· 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.<br>· Nasal and full face: BiPAP mask or BiPAP full face mask.<br>· Includes: 4-point helmet.<br>· Compatible to single and dual limb circuit.<br>· Size: S, M, L and XL. |
| Non-heated bubble humidifier | Non-heated bubble humidifier.<br>· Graduated, transparent humidification bottle.<br>· Graduation should show minimum and maximum water level.<br>· Detachable metal or rigid durable polymer cap with gas connectors.<br>· DISS inlet connector. |

| MEDICAL DEVICE | TECHNICAL DESCRIPTION AND SPECIFICATIONS | |
|---|---|---|
| | · 6 mm barbed (or specify alternate style) outlet.<br>· Humidification chamber working volume available between 150–500 mL. Graduation options available in metric, imperial and both units.<br>· Flow rate capacity up to 15 L/min.<br>· Pressure relief safety valve ≥ 14 kPa (0.14 bar).<br>· All components to be capable of disinfection including: bottle, diffuser, tubing, O-ring/seals, inlet and outlet connectors, cover lid in between patients.<br>· Supplier must define decontamination procedure.<br>· Bottle, diffuser and tubes made of polypropylene, polycarbonate or equivalent biocompatible plastic/polymer certified for medical use, unbreakable or shatter resistant.<br>· Cap and connectors made of brass/steel/other biocompatible metal or polymer certified for medical use.<br>· Pressure valve made of brass chromium plated or equivalent metal certified for medical use.<br><br>Standards for product performance:<br>· Conforms to ISO, NFPA and/or CGA standards, and/or UL or CSA approved.<br>· ISO 15001 Anesthetic and respiratory equipment – Compatibility with oxygen.<br>· ISO 18562 Biocompatibility evaluation of breathing gas pathways in healthcare applications.<br>· ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements.<br>· ISO 18190 Anesthetic and respiratory equipment – General requirements for airways and related equipment.<br>· ISO 18562-1 Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 1: Evaluation and testing within a risk management process.<br>· ISO 8185 Respiratory tract humidifiers for medical use – Particular requirements for respiratory humidification systems. | |
| Oropharyngeal airway, Guedel | One-piece, semi-rigid, curved plastic tube. To be inserted through the oropharynges to facilitate airway management. Guedel type.<br>· Child sizes: 00, 0, 1.<br>· Adult sizes: 2, 3, 4.<br>· Semi-rigid, transparent.<br>· Proximal (or buccal) end straight and reinforced.<br>· Flange color coded and/or marked with corresponding size number.<br>· 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)<br>· Material: Polyethylene/vinyl acetate (EVA) - Polyvinyl chloride (PVC).<br>· Sterile, single patient use.<br>· ISO10651-4; EN12181 or equivalent. | |
| Oxygen concentrator | General technical requirements | Provides a continuous flow of concentrated oxygen (> 82%) (preferably > 90%) from room air through one oxygen outlet.<br>Continuous flow up to 5 L/min or 8 L/min or 10 L/min.<br>Contains oxygen monitor to verify concentration.<br>Requires continuous AC power source to operate.<br>Power efficiency ≤ 70 W/L/min (preferable).<br>User interface to be easy to operate; numbers and displays clearly visible and easily readable in low ambient light and sunlight.<br>Digital or analogue meter that displays cumulative hours of device operation.<br>Oxygen outlet(s) with 6 mm (1/4 inch) barbed fitting or equivalent.<br>Oxygen outlet to be securely mounted and sheltered to reduce risk of being broken or bent.<br>Flowmeter minimum flow rate of 0.5 L/min or less. Flowmeter adjustable, within minimum gradation intervals of 0.5 L/min for 5 L/min models, and 1 L/min for larger models. |

| MEDICAL DEVICE | TECHNICAL DESCRIPTION AND SPECIFICATIONS | |
|---|---|---|
| | | Noise level < 60 dB(A).<br>Capable to be disinfected with hospital grade detergents.<br>At least IP11 degree of protection to the harmful ingress of water (fluid spill resistance), preferable up to IP21.<br>Mechanical shock resistance, mechanical vibration, electromagnetic compatibility and electrical safety testing.<br>Capable of supplying the specified oxygen concentration continuously in ambient temperature from 10–40 °C, relative humidity from 15–85% (preferably up to 95%), and elevation from 0 to at least 2000 m. For operation at elevations higher than 2000 m, environmental requirements are less stringent; performance characteristics at such altitudes must be stated. |
| | Displayed parameters | Oxygen flow rate (on flowmeter).<br>Cumulative hours of operation. |
| | User adjustable settings | Oxygen flow rate. |
| | Alarms | Audible and/or visual alarms for:<br>· Low oxygen concentration<br>· Power supply failure.<br>· High temperature.<br>· Low battery (preferable).<br>· Low high/no flow (preferable).<br>· Low/high output pressure. |
| | Accessories | DISS and 6 mm barbed adaptor for each outlet (interchangeable between devices of different brands and models) (if applicable): 1 package of 20 per equipment.<br>Humidifier included, bubble and non-heated, single use is preferred (3 months' supply required). Reusable may be acceptable with appropriate disinfection protocols. |
| | Spare parts | 1-year spare parts kit as per preventive maintenance program. Including:<br>· Internal and external mounted filters for cleaning the air intake.<br>· Spare battery set for alarm system (if applicable).<br>· Spare mains power cable length ≥ 2.5 m (if applicable).<br>· Replacement sets of spare fuses (if non-resettable fuses are used).<br>· Sieve beds.<br>Bidder must give a complete list of the specific spare parts included in their bid.<br>Other spares that may be needed: circuit breaker, printed circuit board, sieve beds, compressor service kit, valves, wheels, motor capacitor, flowmeters and fan. |
| | Portability | Whole unit to be movable with wheels on at least two castors.<br>Unit weight to be < 27 kg. |
| | Power supply and battery | Equipment must be connected to a reliable and continuous source of energy.<br>Operates from AC power electric line: 100–240 V/50–60 Hz.<br>Main power cable and plug adapted for various countries.<br>Mains power cable length ≥ 2.5 m.<br>Electrical protection by resettable circuit breakers or replaceable fuses, fitted in both neutral and live lines. Single fuse in live line may be considered but is less preferable. |
| | Standards for the manufacturer | Certified quality management system for medical devices (e.g. ISO 13485).<br>Application of risk management to medical devices (e.g. ISO 14971). |
| | Regulatory approval / certification | Free sales certificate (FSC) or certificate for exportation of medical device provided by the authority in manufacturing country.<br>Proof of regulatory compliance, as appropriate, per the product's risk classification (e.g. Food and Drug Administration [FDA] and/or Conformité Européenne [CE]). |

| MEDICAL DEVICE | TECHNICAL DESCRIPTION AND SPECIFICATIONS | |
|---|---|---|
| | Standards for the product performance | Compliance to the following international standards or to regional or national equivalent, (including the technical tests for safety and performance from accredited laboratory or third party). Latest version recommended but compliance to previous standards versions could be accepted:<br>· ISO 80601-2-69:2014 Medical electrical equipment – Part 2-69: Particular requirements for basic safety and essential performance of oxygen concentrator equipment.<br>· IEC 60601-1:2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.<br>· IEC 60601-1-2:2014 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests.<br>· IEC 60601-1-6:2013 Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability.<br>· IEC 60601-1-8:2012 Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems.<br>· IEC 60601-1-9:2013 Medical electrical equipment – Part 1-9: General requirements for basic safety and essential performance – Collateral standard: Requirements for environmentally conscious design.<br>· IEC 60601-1-11:2010 Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home health-care environment.<br>· Compliance with ISO 8359 may be considered. |
| | Warranty | Minimum 2 years. |
| | According to: *COVID-19 Technical specifications for procurement of oxygen therapy and monitoring devices (link)* | |
| Oxygen tube, extension | Tube used to deliver oxygen through the nose.<br>· Material: PVC.<br>· Automatic, open distal (patient) end, with 6 to 12 lateral eyes.<br>· Proximal end with connector enabling the tube to be connected to an oxygen supply tube of any diameter (e.g. Serrated male conical tip).<br>· Sterile, for single patient use.<br>· Diameter: CH 10. Length: 40cm.<br>· Shelf life: minimum 10 years.<br>· Bag and hands should be white color. | |
| Patient monitor multiparametric, advanced | General technical requirements | Advanced models are designed for continuous display of patient ECG, CO2, invasive blood pressure (IBP), non-invasive blood pressure (NIBP) and oxygen saturation (SpO2), respiratory rate (RR), heart rate (HR) and temperature (TEMP)<br>Dynamic digital display that can show all active parameters.<br>Unwanted parameters can be deselected from display.<br>Operator can set audio-visual alarm levels for low or high levels of each parameter independently.<br>Operates from mains voltage or from internal rechargeable battery.<br>ECG patient connectors that are sterilizable and reusable are preferred.<br>Hard copy printout of traces will not be required.<br>Multichannel (up to 12 leads) ECG measurement and selectable display; an extra option for simple five-lead connection preferred. |

| MEDICAL DEVICE | | TECHNICAL DESCRIPTION AND SPECIFICATIONS |
|---|---|---|
| | | Internal pump for cuff inflation for non-invasive blood pressure measurement, with over pressure protection.<br>Temperature probe to be reusable, external skin contact type. Disinfection method must be explained.<br>CO2 monitoring capabilities.<br>Invasive blood pressure (IBP) monitoring capabilities.<br>Automatic and programmable memory.<br>Storage of continuous monitoring data.<br>Trace signal velocity of at least 25 mm/s.<br>LCD or TFT screen with:<br>· analogue shape signals and numerical values visualization;<br>· settable limits for the measured variables;<br>· not less than 10" wide.<br>Design must enable use in demanding environments (e.g. shock, vibration and free fall tests).<br>Protections of all the functions against defibrillator discharges and electrosurgical units.<br>Pace-maker detection.<br>Data management functions (preferable).<br>Capable of operating continuously in ambient temperature of 10–40 °C and relative humidity of 15–85% (90% preferable).<br>Enclosure to have ingress protection level IPX1 or better. |
| | Displayed parameters | Trend display of each parameter.<br>Heart rate measurement range to be at least 30–250 bpm, with accuracy better than ± 5 bpm and minimum gradation 1 bpm.<br>SpO2 measurement range at least 70–99 %, with accuracy better than ± 3% and minimum gradation 1%.<br>Blood pressure monitoring range at least 30–270 mmHg, minimum gradation 1 mmHg. Cuff sizes neonatal/paediatric and adult. User selectable measurement intervals.<br>Temperature range at least 30–40 °C, minimum gradation 0.1 °C.<br>Respiration rate measurement range at least 0–100 bpm, minimum gradation 1 bpm. |
| | Alarms | Alarm override and temporary silence facility to be included.<br>Audio-visual alarms required:<br>· high and low levels for each parameter (operator variable settings),<br>· sensor/wire/probe disconnected,<br>· low battery,<br>· cuff leak, cuff disconnect,<br>· hose leak,<br>· inflation/deflation errors,<br>· failure to take successful reading,<br>· low battery notice.<br>Power failure. |
| | Consumables | ECG electrodes (if applicable) |
| | Accessories | All the cables, sensors and connectors needed for full monitor functionality are to be included in the bid.<br>Lead ECG cable<br>Lead ECG cable (if option offered)<br>Sets of ECG connection electrodes (if reusable type)<br>Tubes electrode gel (if required)<br>Reusable SpO2 probes adult<br>Reusable SpO2 probes paediatric use<br>Blood pressure – non-invasive: paediatric reusable cuffs and adult reusable cuffs. |

| MEDICAL DEVICE | TECHNICAL DESCRIPTION AND SPECIFICATIONS | |
|---|---|---|
| | | Blood pressure – invasive: 1 sensor for each channel offered.<br>External skin temperature probes<br>If CO2 mainstream technology: tube adapter and sensor.<br>If CO2 side stream technology: sample lines and water tramps.<br>Battery |
| | Spare parts | 1-year spare parts kit as per preventive maintenance program including but not exclusively, sets of spare fuses (if non-resettable fuses used) and battery. |
| | Power supply and battery | Operated by line electrical power supply with internal replaceable rechargeable battery backup allows operation for at least 1 hour in the event of power failure.<br>Operates from AC power electric line: 100–240 V~/50–60 Hz.<br>Main power cable and plug adapted for various countries.<br>Mains power cable length ≥ 2.5 m.<br>Protections against over-voltage and over-current line conditions.<br>Protection against defibrillator discharges and electrosurgical units.<br>Automatic switch between battery and mains powered modes, when recharging or in mains power failure.<br>The display shall show which power source is in use.<br>Compliance with electrical standards and regulations. |
| | Standards for the manufacturer | Certified quality management system for medical devices (e.g. ISO 13485).<br>Application of risk management to medical devices (e.g. ISO 14971). |
| | Regulatory approval / certification | Free sales certificate (FSC) or certificate for exportation of medical device provided by the authority in manufacturing country.<br>Proof of regulatory compliance, as appropriate, per the product's risk classification (e.g. Food and Drug Administration [FDA] and/or Conformité Européenne [CE]). |
| | Standards for the product performance | Compliance to the following international standards or to regional or national equivalent, (including the technical tests for safety and performance from accredited laboratory or third party). Latest version recommended but compliance to previous standards versions could be accepted:<br>· IEC 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.<br>· IEC 80601-2-49 Medical electrical equipment – Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment.<br>· IEC 80601-2-30 Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometer.<br>· IEC 60601-2-34 Particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment).<br>· ISO 80601-2-55 Particular requirements for the basic safety and essential performance of respiratory gas monitors).<br>· ISO 80601-2-61 Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment.<br>· IEC 60601-2-27 Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment.<br>Preferable if tested for:<br>· IEC 62366-1 Medical devices – Part 1: Application of usability engineering to medical devices.<br>· IEC 60068-1:2013 Environmental testing – Part 1: General and guidance.<br>· IEC 60068-2-31 Environmental testing – Part 2-31: Tests: Rough handling shocks, primarily for equipment-type specimens. |
| | Warranty | 2 years with regards efficiency and quality of the product (software upgrades included). |

| MEDICAL DEVICE | TECHNICAL DESCRIPTION AND SPECIFICATIONS | |
|---|---|---|
| | According to: *COVID-19 Technical specifications for procurement of oxygen therapy and monitoring devices (link)* | |
| Patient monitor multiparametric, basic | General technical requirements | Basic models are designed for continuous display of non-invasive blood pressure (NIBP) and oxygen saturation (SpO2).<br>Display of calculated heart rate, respiratory rate is optional.<br>Operator can set audio-visual alarm levels for low or high levels of each parameter independently.<br>Operates from mains voltage or from internal rechargeable battery.<br>Heart rate measurement range to be at least 30–250 bpm, with accuracy better than ± 5 bpm and minimum gradation 1 bpm.<br>SpO2 measurement range at least 70–99%, with accuracy better than ± 3% and minimum gradation 1%.<br>Blood pressure monitoring range at least 30–270 mmHg, minimum gradation 1 mmHg.<br>Internal pump for cuff inflation for non-invasive blood pressure measurement, with over pressure protection.<br>Liquid crystal display (LCD) or thin-film transistor (TFT) screen with:<br>· numerical values visualization;<br>· settable limits for the measured variables;<br>· all parameters can be shown.<br>Design must enable use in demanding environments (e.g. shock, vibration and free fall tests).<br>Protections of all the functions against defibrillator discharges and electrosurgical units.<br>Pace-maker detection.<br>Capable of operating continuously in ambient temperature of 10–40 °C and relative humidity of 15–85% (90% preferable).<br>Automatic and programmable memory (preferable).<br>Storage of continuous monitoring data (preferable).<br>Trend display of each parameter over a timeframe possible (preferable).<br>Enclosure to have ingress protection level IPX1 or better. |
| | Alarms | Alarm override and temporary silence facility to be included.<br>Audio-visual alarms required:<br>· High and low levels for each parameter (operator variable settings).<br>· Sensor/wire/probe disconnected.<br>· Low battery.<br>· Cuff leak, cuff disconnect.<br>· Hose leak.<br>· Inflation/deflation errors.<br>· Failure to take successful reading.<br>· Power failure. |
| | Accessories | All the cables, sensors and connectors needed for full monitor functionality are to be included in the bid.<br>Reusable SpO2 probes adult.<br>Reusable SpO2 probes pediatric use.<br>Blood pressure – non-invasive: pediatric and adult reusable cuffs.<br>Battery |
| | Spare parts | 1-year spare parts kit as per preventive maintenance program, including but not exclusively: sets of spare fuses (if non-resettable fuses used) and battery. |
| | Power supply and battery | Operated by line electrical power supply with internal replaceable rechargeable battery backup allows operation for at least 1 hour in the event of power failure.<br>Operates from AC power electric line: 100–240 V~/50–60 Hz.<br>Main power cable and plug adapted for various countries. |

| MEDICAL DEVICE | TECHNICAL DESCRIPTION AND SPECIFICATIONS | |
|---|---|---|
| | | Mains power cable length ≥ 2.5 m.<br>Protections against over-voltage and over-current line conditions.<br>Protection against defibrillator discharges and electrosurgical units.<br>Automatic switch between battery and mains powered modes, when recharging or in mains power failure.<br>The display shall show which power source is in use.<br>Compliance with electrical standards and regulations. |
| | Standards for the manufacturer | Certified quality management system for medical devices (e.g. ISO 13485).<br>Application of risk management to medical devices (e.g. ISO 14971). |
| | Regulatory approval / certification | Free sales certificate (FSC) or certificate for exportation of medical device provided by the authority in manufacturing country.<br>Proof of regulatory compliance, as appropriate, per the product's risk classification (e.g. Food and Drug Administration [FDA] and/or Conformité Européenne [CE]). |
| | Standards for the product performance | Compliance to the following international standards or to regional or national equivalent, (including the technical tests for safety and performance from accredited laboratory or third party). Latest version recommended but compliance to previous standards versions could be accepted:<br>· IEC 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.<br>· IEC 80601-2-49 Medical electrical equipment — Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment.<br>· IEC 80601-2-30 Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers.<br>· ISO 80601-2-61 Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment.<br>· IEC 62133 – Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells. Part 1: Nickel, Part 2: Lithium.<br>Preferable if tested for:<br>· IEC 62366-1 Medical devices – Part 1: Application of usability engineering to medical devices.<br>· IEC 60068-1:2013 Environmental testing – Part 1: General and guidance.<br>· IEC 60068-2-31 Environmental testing – Part 2-31: Tests: Rough handling shocks, primarily for equipment-type specimens. |
| | Warranty | 2 years with regards efficiency and quality of the product (software upgrades included). |
| | According to: *COVID-19 Technical specifications for procurement of oxygen therapy and monitoring devices (link)* | |
| Patient monitor multiparametric, intermediate | General technical requirements | Intermediate models are designed for continuous display of patient ECG, non-invasive blood pressure (NIBP) and oxygen saturation (SpO2), respiratory rate (RR), heart rate (HR) and temperature (TEMP)<br>Dynamic digital display that can show all active parameters.<br>Unwanted parameters can be deselected from display.<br>Operator can set audio-visual alarm levels for low or high levels of each parameter independently.<br>Operates from mains voltage or from internal rechargeable battery.<br>ECG patient connectors that are sterilizable and reusable are preferred.<br>Hard copy printout of traces will not be required.<br>Internal pump for cuff inflation for non-invasive blood pressure measurement, with over pressure protection. |

| MEDICAL DEVICE | TECHNICAL DESCRIPTION AND SPECIFICATIONS | |
|---|---|---|
| | | Temperature probe to be reusable, external skin contact type. Disinfection method must be explained.<br>Automatic and programmable memory.<br>Storage of continuous monitoring data.<br>Trace signal velocity of at least 25 mm/s.<br>LCD or TFT screen with:<br>· analogue shape signals and numerical values visualization;<br>· settable limits for the measured variables.<br>Design must enable use in demanding environments (e.g. shock, vibration and free fall tests).<br>Protections of all the functions against defibrillator discharges and electrosurgical units.<br>Pace-maker detection.<br>Data management functions (preferable).<br>Capable of operating continuously in ambient temperature of 10–40 °C and relative humidity of 15–85% (90% preferable).<br>Enclosure to have ingress protection level IPX1 or better. |
| | Displayed parameters | Trend display of each parameter.<br>Minimum 3 leads (and up to 12 leads) ECG measurement and selectable display; an extra option for simple five-lead connection preferred.<br>Heart rate measurement range to be at least 30–250 bpm, with accuracy better than ± 5 bpm and minimum gradation 1 bpm.<br>SpO2 measurement range at least 70–99 %, with accuracy better than ± 3% and minimum gradation 1%.<br>Blood pressure monitoring range at least 30–270 mmHg, minimum gradation 1 mmHg. Cuff sizes neonatal/pediatric and adult. User selectable measurement intervals.<br>Temperature range at least 30–40 °C, minimum gradation 0.1 °C.<br>Respiration rate measurement range at least 0–100 bpm, minimum gradation 1 bpm. |
| | Alarms | Alarm override and temporary silence facility to be included.<br>Audio-visual alarms required:<br>· high and low levels for each parameter (operator variable settings),<br>· sensor/wire/probe disconnected,<br>· low battery,<br>· cuff leak, cuff disconnect,<br>· hose leak,<br>· inflation/deflation errors,<br>· failure to take successful reading,<br>· low battery notice.<br>· Power failure. |
| | Consumables | ECG electrodes (if applicable) |
| | Accessories | All the cables, sensors and connectors needed for full monitor functionality are to be included in the bid.<br>Lead ECG cable.<br>Lead ECG cable (if option offered).<br>Sets of ECG connection electrodes (if reusable type).<br>Tubes electrode gel (if required).<br>Reusable SpO2 probes adult.<br>Reusable SpO2 probes paediatric use.<br>Blood pressure – non-invasive: paediatric and adult reusable cuffs.<br>External skin temperature probes.<br>Battery. |

| MEDICAL DEVICE | TECHNICAL DESCRIPTION AND SPECIFICATIONS | |
|---|---|---|
| | Spare parts | 1-year spare parts kit as per preventive maintenance programrg, including but not exclusively: sets of spare fuses (if non-resettable fuses used) and battery. |
| | Power supply and battery | Operated by line electrical power supply with internal replaceable rechargeable battery backup allows operation for at least 1 hour in the event of power failure.<br>Operates from AC power electric line: 100–240 V~/50–60 Hz.<br>Main power cable and plug adapted for various countries.<br>Mains power cable length ≥ 2.5 m.<br>Protections against over-voltage and over-current line conditions.<br>Protection against defibrillator discharges and electrosurgical units.<br>Automatic switch between battery and mains powered modes, when recharging or in mains power failure.<br>The display shall show which power source is in use.<br>Compliance with electrical standards and regulations. |
| | Standards for the manufacturer | Certified quality management system for medical devices (e.g. ISO 13485).<br>Application of risk management to medical devices (e.g. ISO 14971). |
| | Regulatory approval / certification | Free sales certificate (FSC) or certificate for exportation of medical device provided by the authority in manufacturing country.<br>Proof of regulatory compliance, as appropriate, per the product's risk classification (e.g. Food and Drug Administration [FDA] and/or Conformité Européenne [CE]). |
| | Standards for the product performance | Compliance to the following international standards or to regional or national equivalent, (including the technical tests for safety and performance from accredited laboratory or third party). Latest version recommended but compliance to previous standards versions could be accepted:<br>· IEC 60601-1 Medical electrical equipment– Part 1: General requirements for basic safety and essential performance.<br>· IEC 80601-2-49 Medical electrical equipment – Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment.<br>· IEC 80601-2-30 Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometer.<br>· ISO 80601-2-61 Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment.<br>· IEC 60601-2-27 Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment.<br>Preferable if tested for:<br>· IEC 62366-1 Medical devices – Part 1: Application of usability engineering to medical devices.<br>· IEC 60068-1:2013: Environmental testing – Part 1: General and guidance.<br>· IEC 60068-2-31 Environmental testing – Part 2-31: Tests: Rough handling shocks, primarily for equipment-type specimens. |
| | Warranty | 2 years with regards efficiency and quality of the product (software upgrades included). |
| | According to: *COVID-19 Technical specifications for procurement of oxygen therapy and monitoring devices (link)* | |
| Percutaneous tracheostomy set | · Sterile, single dilator.<br>· With tracheostomy tube, cuff and introducer.<br>· Dilator with ergonomic handle design.<br>· 15 mm tube connector which allows connection to the breathing system or heat and moisture exchanger. | |

| MEDICAL DEVICE | TECHNICAL DESCRIPTION AND SPECIFICATIONS | |
|---|---|---|
| Portable aspirator/ Suction system | Portable suction device (aspiration pumps) used to evacuate secretions and liquids from de nasal cavity or from high airways.<br>· Adults and pediatric suction catheters should be less than half the internal diameter of the tracheal tube.<br>· Vacuum adjustment: continuous.<br>· Must be able to generate a vacuum of at least 0.85 bar (650mmHg).<br>· Maximum vacuum: 700 mmHg.<br>· Minimum open tube flow rate at least 5 liters liquid per minute.<br>· Twin suction bottles, minimum size 3 liters each.<br>· Bottles to have an automatic cut off when full to prevent ingress of fluid to motor.<br>· Airline to pump to incorporate bacterial filter.<br>· Tubing to patient to be minimum 3m long, non-collapsible type<br>· Pedal and manual equipment suction function activation.<br>· Sound Level: < 70 dB.<br>· Castors: 75 mm diameter, unidirectional, anti-static. | |
| Portable ultrasound | General technical requirements | Capable of generating imaging procedures involving lungs, heart, abdomen, pelvis, blood vessels, musculoskeletal and soft tissue.<br>Console: laptop style console design, optional touchscreen combined with conventional user-control panel.<br>Weight of the console: 5–8 kg.<br>Dimensions: 35–45 cm (L); 35–45 cm (H); 5–10 cm (D).<br>Clear protective control panel cover for infection control.<br>Imaging focusing adjustable focal depth, synchronization of focal zone to the selected scanning depth.<br>Zooming capability with automated image optimization.<br>Depth range selection: capable of multiple depth range selection. Synchronized with automatic focal zone selection.<br>Field of view: deep (> 15 cm).<br>Image orientation: capable of lateral and vertical inversion (in B-mode).<br>Image modes at least:<br>· 2D imaging<br>· M-mode<br>· B/M mode<br>· dual 2D/colour image mode with cine loop<br>· Doppler, color Doppler imaging (CDI), power Doppler imaging (PDI), duplex, continuous wave Doppler, triple mode (optional).<br>Needle enhancement ability.<br>Software applications that include at least:<br>· small parts<br>· lung<br>· vascular/basic cardiac quantification<br>· easy selection of callipers<br>· measurements capabilities (distance, area and circumference by ellipse and trace method)<br>· capability to be upgraded with additional software applications.<br>Probe-dependant applications with factory-default presets at least: cardiac, peripheral vascular, abdominal adult, abdominal pediatric, small parts, lung, MSK-general, and MSK-superficial.<br>Equipment with write-zoom function available.<br>Screen annotations capture patient data, date and time, scanning protocols, probes.<br>Text annotations and body markers and image orientation indicator. |

| MEDICAL DEVICE | TECHNICAL DESCRIPTION AND SPECIFICATIONS | |
|---|---|---|
| | | Transducer ports: at least two active transducer ports permanently available; capability of electronic switch between probes. |
| | Monitor and display | Screen monitor: high-definition (HD) digital black and white and color liquid crystal display (LCD) monitor of at least 25 cm diagonal (across), equivalent to 10 inches, with reflection filter.<br>Screen monitor protection. Laptop monitor fold-down and lock mechanism of the screen for safe and easy transportation (if applicable).<br>User-friendly control panel: easy to use, logical and orderly control panel: for quick and easy location of most common functions.<br>Back lighting of application knobs/buttons. |
| | Communication and storage | Data communication, storage and transfer interface: USB minimum, high-definition multimedia interface (HDMI) preferable.<br>DICOM 3.0 conformance.<br>Digital image storage: Image and cine memory of at least 64 GB of cine memory.<br>Cine loop: freeze and cine-loop functions.<br>Image grey scale: 256 shades of grey and video output of 625 lines/frame 150 dB full time dynamic range.<br>Capability for database of patient images and information. |
| | Consumables | Ultrasound transmission gel for 3 months operation.<br>Disinfectants for 3 months operation.<br>Compatible printing paper for 3 months operation. |
| | Accessories | Transducers:<br>· Phased-array 1–5 MHz for basic cardiac and lung studies and phased array up to 8 MHz for pediatric patients.<br>· Broadband curvilinear at least 5–2 MHz for general abdominal, and lung ultrasound applications. This should have color, power and spectral Doppler capabilities. M-mode is desirable for obstetrics.<br>· Linear-array high frequency broadband at least 12–5 MHz, with color, power and spectral Doppler capabilities for vascular and small parts.<br>· Capability to connect endo-cavitary transducers.<br>Matching trolley compact and lightweight, easy to transport.<br>Cables and other connection accessories.<br>Storage security lock/chain and key<br>Wheeled cart (if applicable) with gel bottle holders, drawer or dedicated space for accessories, place for scanner positioning and easy orientation. |
| | Power supply | Equipment must be connected to a reliable and continuous source of energy.<br>Operates from AC power electric line: 100–240 V AC ± 10% / 50–60 Hz ± 10%<br>In-built rechargeable battery shall be included.<br>Automatic switch from AC power electric line mode to battery operating mode and vice versa.<br>Power supply: power supply may vary according to countries.<br>Working time in battery mode and standard operations not less than 1 hour.<br>Battery recharging time not more than 4 hours. |
| | Standards for the manufacturer | Certified quality management system for medical devices (e.g. ISO 13485).<br>Application of risk management to medical devices (e.g. ISO 14971). |
| | Regulatory approval / certification | Free sales certificate (FSC) or certificate for exportation of medical device provided by the authority in manufacturing country.<br>Proof of regulatory compliance, as appropriate, per the product's risk classification (e.g. Food and Drug Administration [FDA] and/or Conformité Européenne [CE]). |
| | Standards for the product performance | Compliance to the following international standards or to regional or national equivalent, (including the technical tests for safety and performance from accredited laboratory or third party). Latest version recommended but compliance to previous standards versions could be accepted: |

| MEDICAL DEVICE | TECHNICAL DESCRIPTION AND SPECIFICATIONS | |
|---|---|---|
| | | · ISO 29821:2018-Condition monitoring and diagnostics of machines – Ultrasound – General guidelines, procedures and validation.<br>· IEC 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.<br>· IEC 60601-1-2 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests.<br>· IEC 60601-2-37:2007 Medical electrical equipment – Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment.<br>· IEC 61157:2007/AMD1:2013 Amendment 1 – Standard means for the reporting of the acoustic output of medical diagnostic ultrasonic equipment.<br>· IEC 60601-1-4 Medical electrical equipment – Part 1-4: General requirements for safety – Collateral standard: programmable electrical medical systems. |
| | Warranty | 2 years recommended, at least 1-year mandatory. |
| | According to: *COVID-19 Technical specifications for portable ultrasound (link)* | |
| Portable X-ray equipment | General technical requirements | Equipment easy to assemble/install/set up and be fully functional and operational as a complete standalone solution for acquisition, review, presentation, display, storage and transfer of radiographic images in a resource-limited setting.<br>Equipment: mobile, motorized, battery and AC power operated (AC mandatory for charging and, preferably, for standard working operations too).<br>Digital Imaging and Communications in Medicine (DICOM) 3.0 compatible image storage and transfer required.<br>The system should be capable of storing at least 2000 images with comprehensive post-processing options (dose area product [DAP] meter to be integrated).<br>Capacity for removable media storage, to transfer data through different options (CD, DVD and/or USB), to send images through existing network port, and, preferably, to have wireless transfer of images through hospital wireless network (wireless and cable connections shall be provided).<br>Integrated Ethernet connectivity required.<br>At least 20 anatomical programs shall be available. Software for COVID-19 detection should be included (preferable) (if available).<br>An integrated image review monitor to be included in the configuration.<br>Anti-scatter grid or software for scatter correction (preferable) (if available).<br>Equipment provided with DAP device/capability to record the patient dose. |
| | Detailed technical requirements | kVp range at least 40–120 kVp, digitally displayed.<br>mAs range at least 0.5–200 mAs or more.<br>Exposure time range not less than 8.0 msec to 4 sec and minimum exposure time not higher than 8.0 msec.<br>Automatic exposure control facility (preferable) (if available).<br>Tube power rating at least 20 kW (measured at 100 kVp).<br>Rotating anode with dual focal spots and the maximum focal spot not higher than 1.3 mm (equivalent output/technology could be considered).<br>Heat storage capacity of the anode at least 120 000 HU.<br>Cooling rate not less than 14 000 HU/min.<br>Total filtration at least of 2.5 mm aluminium equivalent.<br>An integrated/paired digital radiography flat-panel detector: wireless and/or with cable (wireless flat detector preferable); sub mm pixel size, active detector area not less than 35 x 43 cm. |

| MEDICAL DEVICE | TECHNICAL DESCRIPTION AND SPECIFICATIONS | |
|---|---|---|
| | | Capability for alphanumeric annotation of images.<br>Equipment total weight in the range 100–500 kg. |
| | Digital detector | Image quality: spatial resolution better than 3 lp/mm.<br>Pixel pitch: < 150 x 150 µm.<br>Grayscale: at least 4096 (12-bit).<br>Preview image access time: less than 10 sec after X-ray exposure. |
| | Displayed and user-adjustable parameters and settings | Image to be displayed immediately after exposure.<br>Digital display of mAs and kV, KAP/DAP and an electronic timer.<br>Low battery indicator/alarm.<br>Exposure status lights on main control and/or collimator (standby, ready up, exposure).<br>Image display to be contrast- and brightness-adjustable, at least 18 inches diagonal size.<br>Exposures by remote control should also be possible, with operating distance higher than approximately 10 m.<br>The exposure release switch should be detachable, with a cord of at least 5 m. |
| | System components and other physical characteristics | An X-ray tube support with telescopic arm.<br>The tube stand must be fully counter-balanced for rotation in all directions.<br>Articulated arm for imaging with any patient position.<br>Source to image receptor distance (SID) range not less than 100–200 cm.<br>Frame with column/arm rotation range not less than ± 180 degrees.<br>Adjustable multi-leaf collimator, rotatable ± 90 degrees, with patient centring light.<br>All cables shall be concealed in the arm system.<br>Collimation light to confirm the radiation field size.<br>Unit base wheels must be easily accessible for cleaning. |
| | Mobility and portability | When motor or battery is non-functional, free movement by pushing must be possible.<br>Equipment speed capacity not less than approximately 1.5 km/hr.<br>Motorized movement capable of ascending slope of up to at least 7 degrees from horizontal.<br>The unit must have an effective system for parking, transport and emergency braking. |
| | Power supply | AC power input to be 120 and/or 220 V ± 10%, 50–60 Hz, single phase, fitted with compatible mains plug.<br>X-ray exposures without power supply (battery mode exposure) preferable (if available).<br>Motor battery to be sealed lead-acid type, recharged by main unit power connection and recharging time not higher than 8 hours.<br>Battery total energy capacity up to at least 20 000 mAs.<br>Resettable overcurrent breaker to be fitted on both live and neutral supply lines.<br>Voltage corrector/stabilizer to allow safe and stable operations at ± 20% of local rated voltage (if necessary). |
| | Accessories and spare parts | Must be supplied with protective dust cover at least for control panel.<br>To be supplied with at least 1 adult-size protective lead apron and 1 thyroid shield.<br>Portable radiation hazard warning signs to be supplied with unit.<br>List of important spares and accessories to be provided with their part numbers and cost.<br>Spare parts availability for the equipment lifespan (not less than 7 years).<br>Equipment provided with necessary quality assurance phantoms to check the image quality and calibration of the mobile radiography device. Phantom holder should be also provided as any quality assurance/control necessary tool. |

| MEDICAL DEVICE | TECHNICAL DESCRIPTION AND SPECIFICATIONS | |
|---|---|---|
| | Standards for the manufacturer | Certified quality management system for medical devices (e.g. ISO 13485).<br>Application of risk management to medical devices (e.g. ISO 14971). |
| | Regulatory approval / certification | Free sales certificate (FSC) or certificate for exportation of medical device provided by the authority in manufacturing country.<br>Proof of regulatory compliance, as appropriate, per the product's risk classification (e.g. Food and Drug Administration [FDA] and/or Conformité Européenne [CE]). |
| | Standards for the product performance | Compliance to the following international standards or to regional or national equivalent, (including the technical tests for safety and performance from accredited laboratory or third party). Latest version recommended but compliance to previous standards versions could be accepted:<br>· IEC 60601-1:2005+AMD1:2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.<br>· 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.<br>· IEC 60336:2005 X-ray tube assemblies for medical diagnosis – Characteristics of focal spots.<br>· IEC 60601-1-3:2008+AMD1:2013 Part 1-3: General requirements for basic safety and essential performance – Collateral standard: Radiation protection in diagnostic X-ray equipment.<br>· IEC 60601-2-28:2017 Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis.<br>· IEC 60601-2-54:2009+AMD1:2015+AMD2:2018 Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy. |
| | Warranty | 2 years recommended, at least 1-year mandatory. |
| | According to: *COVID-19 Technical specifications for imaging devices: portable ultrasound; mobile radiographic digital equipment; computed tomography (CT) scanning system* (enlace) | |
| Pulse oximeter, fingertip | | |
| | General technical requirements | SpO2 and pulse rate monitor integrated into finger/toe clip.<br>For use in adults and children, and all skin pigmentations<br>Suitable for spot check.<br>Suitable for detection in low perfusion conditions<br>Design must enable use in demanding environments (e.g. shock, vibration)<br>Enclosure to have ingress protection level IPX2 or better.<br>Suitable for cleaning and disinfection. |
| | Operational characteristics | SpO2 detection to include the range: 70–99%.<br>SpO2 resolution: 1% or less.<br>SpO2 accuracy (in the range at least 70–99%): within ± 3%.<br>Pulse rate detection to include the range: 30–240 bpm.<br>Pulse rate resolution: 1 bpm or less.<br>Pulse rate accuracy within ± 3 bpm.<br>Internal data storage, and/or external data download, for patient trends and event log optional.<br>Adult, pediatric configurations required. |
| | Display parameters | SpO2<br>Pulse rate<br>Signal quality<br>Plethysmography waveform (optional)<br>Battery and system status |
| | Alarms | Visual and audible (preferred with volume control)<br>· High/low SpO2 |

| MEDICAL DEVICE | TECHNICAL DESCRIPTION AND SPECIFICATIONS | |
|---|---|---|
| | | · High/low Pulse rate<br>· Sensor off or sensor failure<br>· Low battery |
| | Power supply and battery | Operated by internal battery.<br>Batteries must allow at least 2500 spot checks calculated at 30 s per spot check, or at least 21 hours of operation.<br>Batteries may be single use, or rechargeable with external AC battery charger, or by USB connection. Rechargeable batteries are preferred.<br>If rechargeable, operation must be possible while charging.<br>Charger, if used, must have protection against over-voltage and over-current line conditions, and be certified to IEC 60601-1.<br>Automatic power-off. |
| | Portability | Portable |
| | Accessories | Carry/storage case.<br>Spare sets of batteries, if single use type (separately packed).<br>Neck lanyard for carrying.<br>Replacement flexible cover for patient finger contact (if removable). |
| | Standards for the manufacturer | Certified quality management system for medical devices (e.g. ISO 13485).<br>Application of risk management to medical devices (e.g. ISO 14971). |
| | Regulatory approval / certification | Free sales certificate (FSC) or certificate for exportation of medical device provided by the authority in manufacturing country.<br>Proof of regulatory compliance, as appropriate, per the product's risk classification (e.g. Food and Drug Administration [FDA] and/or Conformité Européenne [CE]). |
| | Standards for the product performance | Compliance to the following international standards or to regional or national equivalent, (including the technical tests for safety and performance from accredited laboratory or third party). Latest version recommended but compliance to previous standards versions could be accepted:<br>· IEC 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.<br>· IEC 60601-1-2 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests.<br>· ISO 80601-2-61 Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment.<br>· ISO/IEEE 11073-10404 Health informatics – Personal health device communication – Part 10404: Device specialization – Pulse oximeter (if capacity for data connection to a computer is included).<br>· IEC 60068-2-31 Environmental testing – Part 2-31: Tests –Test Ec: Rough handling shocks, primarily for equipment-type specimens.<br>· IEC 62366-1 Medical devices – Part 1: Application of usability engineering to medical devices.<br>· IEC 62133 – Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells. Part 1: Nickel, Part 2: Lithium. |
| | Warranty | 2 years recommended, at least 1-year mandatory. |
| | According to: *COVID-19 Technical specifications for procurement of oxygen therapy and monitoring devices (link)* | |
| Pulse oximeter, handheld | | |
| | General technical requirements | SpO2 and pulse rate monitor, with plethysmography waveform, for adults, children and neonates, for all skin pigmentations.<br>Weight range for each patient category must be stated.<br>Suitable for detection in low perfusion conditions |

| MEDICAL DEVICE | | TECHNICAL DESCRIPTION AND SPECIFICATIONS |
|---|---|---|
| | | Automatic correction for movement and ambient light artefacts<br>Design must enable use in demanding environments (e.g. shock, vibration)<br>Capable of working with, and supplied with, adult, pediatric and neonatal reusable probes.<br>Enclosure to have ingress protection level IPX2 or better.<br>Overall device and probe weight < 400 g.<br>Suitable for cleaning and disinfection. |
| | Operational characteristics | SpO2 detection to include the range: 70–100%.<br>SpO2 resolution: 1% or less.<br>SpO2 accuracy (in the range at least 70–100%): within ± 2% under ideal conditions of use, and within ± 3% for all patients and perfusion/movement conditions.<br>If equipment is capable of a wider SpO2 detection range, the accuracy over that wider range shall be stated.<br>Pulse rate detection to include the range: 30–240 bpm.<br>Pulse rate resolution: 1 bpm or less.<br>Pulse rate accuracy within ± 3 bpm.<br>Data update period for valid data displayed ≤ 10 s.<br>Internal data storage for patient trends and event log (optional).<br>Data interface, suitable for exporting data to external software (optional).<br>Automatic power-off function enabling/disabling, to allow continuous monitoring use. |
| | Display parameters | %SpO2<br>Pulse rate<br>Plethysmography waveform (and possibly other indicators of signal quality)<br>Alarm messages<br>Battery state indication. |
| | Alarms | Visual and audible (preferred with volume control)<br>· High/low SpO2, threshold set by user.<br>· High/low Pulse rate, threshold set by user.<br>· Sensor off or sensor failure<br>· Low battery<br>· Alarm override and temporary silencing function. |
| | Power supply and battery | Operated by replaceable battery power supply, either rechargeable or single use. Devices that operate from rechargeable or both battery types will be preferred.<br>External or built-in AC battery charger, if rechargeable type. Plug style as per local supply.<br>Suitable for operation by battery and by mains power supply, if connected and/or recharging.<br>Automatic switch between battery and mains powered modes, when recharging or in mains power failure.<br>The display shall show which power source is in use.<br>Running time on battery only ≥ 12 hours. |
| | Portability | Portable, handheld. |
| | Accessories | Carry case.<br>To be supplied with reusable probes, adult, pediatric and neonatal sizes (depending on the intended use), recommended 2 or 3 probes of the needed type, probe cable length (including extender if supplied) > 1 m.<br>The catalogue shall include various sizes, fitting all patients, of clip and wrap-up (silicone, woven fabric, adhesive and other material/design) probes. |
| | Standards for the manufacturer | Certified quality management system for medical devices (e.g. ISO 13485).<br>Application of risk management to medical devices (e.g. ISO 14971). |
| | Regulatory approval / | Free sales certificate (FSC) or certificate for exportation of medical device provided by the authority in manufacturing country. |

| MEDICAL DEVICE | TECHNICAL DESCRIPTION AND SPECIFICATIONS | |
|---|---|---|
| | certification | Proof of regulatory compliance, as appropriate, per the product's risk classification (e.g. Food and Drug Administration [FDA] and/or Conformité Européenne [CE]). |
| | Standards for the product performance | Compliance to the following international standards or to regional or national equivalent, (including the technical tests for safety and performance from accredited laboratory or third party). Latest version recommended but compliance to previous standards versions could be accepted:<br>· IEC 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.<br>· IEC 60601-1-2 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests.<br>· ISO 80601-2-61 Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment.<br>· ISO/IEEE 11073-10404 Health informatics – Personal health device communication – Part 10404: Device specialization – Pulse oximeter. |
| | Warranty | 2 years recommended, at least 1-year mandatory. |
| | According to: *COVID-19 Technical specifications for procurement of oxygen therapy and monitoring devices (link)* | |
| Pulse oximeter, tabletop | General technical requirements | Continuously monitors SpO2, plethysmography waveform and pulse rate for adults and children.<br>Suitable for detection in low perfusion conditions.<br>Automatic correction for movement and ambient light artefacts.<br>Design must enable use in demanding environments, e.g. shock, vibration and free fall tests.<br>Capable of working with, adult, pediatric and neonatal reusable probes.<br>Enclosure to have ingress protection level IPX2 or better.<br>Suitable for cleaning and disinfection. |
| | Operational characteristics | SpO2 detection to include the range: 70–100%.<br>SpO2 resolution: 1% or less.<br>SpO2 accuracy (in the range at least 70–100%): within ± 2% under ideal conditions of use, and within ± 3% for all patients and perfusion/movement conditions.<br>If equipment is capable of a wider SpO2 detection range, the accuracy over that wider range shall be stated.<br>Pulse rate detection to include the range: 30–240 bpm.<br>Pulse rate resolution: 1 bpm or less.<br>Pulse rate accuracy within ± 3 bpm.<br>Data update period for valid data displayed ≤ 10 s.<br>Internal data storage for patient data and trends and for event log. |
| | Display parameters | Display must allow easy viewing in all ambient light levels.<br>· %SpO2<br>· Pulse rate<br>· Plethysmography waveform (and possibly other indicators of signal quality)<br>· Alarm messages<br>· Battery state indication. |
| | Alarms | Audible and visual alarms for: |

| MEDICAL DEVICE | TECHNICAL DESCRIPTION AND SPECIFICATIONS | |
|---|---|---|
| | | · Low/high saturation, threshold set by user.<br>· Low /high pulse rate, threshold set by user.<br>· Sensor error or disconnected, system errors, low battery.<br>· Alarm override and temporary silencing function. |
| | Power supply and battery | Operated by line electrical power supply with internal replaceable rechargeable battery backup.<br>Protection against defibrillator discharges and electrosurgical units.<br>Battery charger integrated in the main unit.<br>Automatic switch between battery and mains powered modes, when recharging or in mains power failure.<br>The display shall show which power source is in use.<br>Running time on battery only ≥ 6 hours.<br>Operates from AC power electric line: 100–240 V~/50–60 Hz.<br>Main power cable and plug adapted for various countries.<br>Mains power cable length ≥ 2.5 m. |
| | Portability | Tabletop |
| | Accessories | Reusable probes, adult (finger clip)<br>Reusable probes, pediatric<br>Extender cable to achieve probe cable length > 1 m.<br>Battery charger (if applicable). |
| | Standards for the manufacturer | Certified quality management system for medical devices (e.g. ISO 13485).<br>Application of risk management to medical devices (e.g. ISO 14971). |
| | Regulatory approval / certification | Free sales certificate (FSC) or certificate for exportation of medical device provided by the authority in manufacturing country.<br>Proof of regulatory compliance, as appropriate, per the product's risk classification (e.g. Food and Drug Administration [FDA] and/or Conformité Européenne [CE]). |
| | Standards for the product performance | Compliance to the following international standards or to regional or national equivalent, (including the technical tests for safety and performance from accredited laboratory or third party). Latest version recommended but compliance to previous standards versions could be accepted:<br>· IEC 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.<br>· IEC 60601-1-2 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests.<br>· ISO 80601-2-61 Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment.<br>· ISO/IEEE 11073-10404 Health informatics – Personal health device communication – Part 10404: Device specialization – Pulse oximeter. |
| | Warranty | 2 years recommended, at least 1-year mandatory. |
| | According to: *COVID-19 Technical specifications for procurement of oxygen therapy and monitoring devices (link)* | |
| Resuscitation bag with mask | Hand-operated resuscitator used for mechanical ventilation of adult and pediatric patients. Easy to disassemble and reassemble.<br>Easy to clean and disinfect.<br>Reusable. All parts must be manufactured from high-strength, long-life materials and require no special maintenance or storage conditions.<br>Ventilation can be done with ambient air or with oxygen. Resuscitator shall be supplied as a complete set with:<br>· Compressible self-refilling ventilation bag, maximum capacity: 1300 mL. Dead volume: < 5 mL. | |

| MEDICAL DEVICE | TECHNICAL DESCRIPTION AND SPECIFICATIONS |
|---|---|
| | · One-way valve with or without pressure limiting. Pressure-limiting system: the elasticity of the bag's outer cover limits the airway pressure to approximately 7 kPa (70 cmH2O) when squeezed normally with one hand.<br>· Patient connector, outside diameter: 22 mm; inside diameter: 15 mm.<br>· Inlet valve with nipple for oxygen tubing.<br>· Oxygen reservoir bag, capacity: 2000–2600 mL.<br>Sizes:<br>· Adult: for small adult, adult standard, and large adult.<br>· Infant: for small infant, infant standard, and large infant.<br>Material:<br>· Compressible self-refilling ventilation bag: silicone rubber, or other materials specified in ISO10651-4 or equivalent.<br>· One-way valve: polycarbonate; polysulfide; silicone, or any other material fulfilling ISO 10651-4 or equivalent. Inlet valve: polycarbonate; polysulfide, or any other material fulfilling ISO 10651-4 or equivalent.<br>· Oxygen reservoir bag: bag is made of silicone and valve of polycarbonate/polysulfone or any materials fulfilling ISO10651-4 or equivalent.<br>· Oxygen masks: silicone rubber, transparent or equivalent. Materials must be compatible with steam sterilization.<br><br>Standards for product performance:<br>· ISO 10651-4:2002* Lung ventilators – Part 4: Particular requirements for operator- powered resuscitators (*EN 13544-2 implied), oxygen related clauses are optional for face mask (if not made of silicone).<br>· ISO 10993-1:2009 Biological evaluation of medical devices – Part 1: Evaluation and testing for mask.<br>· ISO 10993-5:2009 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity.<br>· ISO 10993-10:2010 Biological evaluation of medical devices – Part 10: Tests for irritation and delayed-type hypersensitivity (or classified as USP class V). |
| Set of laryngoscope blades | Macintosh type (curved):<br>· Curved Nr 2, length 90 - 110 mm, for child.<br>· Curved Nr 3, length 110 - 135 mm, for small adult.<br>· Curved Nr 4, length 135 - 155 mm, for adult.<br>Miller type (straight):<br>· 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.<br>· 5 L capacity or equivalent to 100 syringes.<br>· Containers must be properly identified.<br>· 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.<br>· It should include a method of fixing the arm cuff to facilitate its use, cleaning and little accumulation of dirt.<br>· The manometer must allow the reading of blood pressure with an accuracy of 2 mmHg.<br>· Maximum pressure of 300 mmHg.<br>· 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.<br>· Binaural device, with non-folding smooth spring frame.<br>· Double stent chest piece. |

| MEDICAL DEVICE | TECHNICAL DESCRIPTION AND SPECIFICATIONS |
|---|---|
| | · Plain spring non-folding frame.<br>· Plastic ear tips. Ear clips included.<br>· Vinyl stethoscope tubing.<br>· Combined bell and diaphragm sprague type.<br>· Approximate length of 1 m. |
| 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. |
| Thermometer, digital | Digital thermometer that allows the measurement of the patient's temperature.<br>· Resolution of 0,1 °C.<br>· Measurement range to include 32.2 to 42.2°C<br>· Response time < 90 s required. |
| Thermometer, infrared | A hand-held, battery-powered, medical device designed to estimate the temperature of a site on the skin (e.g., axilla, forehead) by measurement of body infrared emissions at this particular point.<br>· Measurement range at least from 30 at 43 degrees C°<br>· Specified accuracy to be not higher than 0.3 degrees C°<br>· High / low patient temperature display feature, preferable<br>· Auto power off required after 1 minute<br>· Must include indication of *"out of range"* measurement<br>· Response time not higher than 2 seconds<br>· Ready to use after switch-on in a time not higher than 5 seconds<br>· IR spectral response 6,000 – 14,000 nm<br>· Optimal measuring distance approximately 8 – 12 cm (4 – 6 inch)<br>· Equipment factory calibrated and pre-set emissivity data for all skin types<br>· Automatic self-test on switch-on<br>· Video and/or audio alert/signal at least to the following cases: switch-on, ready-to-use and measurement completed.<br>Powered by internal, rechargeable, replaceable battery. Battery to allow at least 5,000 measurements between charges. Battery charger to operate from input supply 110-220 V, 60-50 Hz ±10% (battery charger built-in or external). |
| Triple packaging system | Any triple packaging system used to contain an infectious substance must comprise three layers:<br>→ 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);<br>→ a second, watertight and leakproof or sift proof packaging to enclose and protect the primary receptacle; and<br>→ a third, outer layer of packaging that is used to protect the secondary packaging from physical damage while in transit.<br>For air shipments, follow Packing instruction P650 for "Biological Substances, Category B". |
| Ventilator for Intensive Care Unit | General technical requirements: Medical oxygen and air high-pressure input ports (> 35 psi [2.4bar]) provide a means to limit reverse gas flowrate (leakage).<br>Each high-pressure input port with a filter and water trap, if applicable, for air input port.<br>Medical air compressor or turbine in-built preferred, alternatively external air compressor.<br>Possibility for using external low-pressure oxygen (approx. 20 psi), as source (preferable).<br>Mechanical safety valve.<br>Internal function testing/leak testing.<br>At least IP21 degree of protection to the harmful ingress of water (fluid spill resistance). |

| MEDICAL DEVICE | TECHNICAL DESCRIPTION AND SPECIFICATIONS | |
|---|---|---|
| | | Mechanical shock resistance, mechanical vibration, electromagnetic compatibility and electrical safety testing.<br>Compatible active humidifying system.<br>Event log for errors traceability (preferable).<br>Operating temperature and humidity 5–40 °C and 0–95% relative humidity (RH).<br>Storage temperature and humidity -20–60 °C, 0–95% RH. |
| | Ventilation modes | Pressure control ventilation (PCV).<br>Volume control ventilation (VCV).<br>Pressure support ventilation (PSV).<br>Synchronized intermittent mandatory ventilation (SIMV) (preferable).<br>Pressure regulated volume control (PRVC) or similar (preferable).<br>Non-invasive ventilation (CPAP or BiPAP). |
| | Monitored and controlled parameters (by user) | FiO2: 21–100%.<br>Tidal volume: 20–1500 mL.<br>Pressure setting: 0–40 cmH2O.<br>I:E ratio.<br>I:E inverse ratio.<br>RR: 10–60 breaths/min, minimum.<br>Inspiratory pause manoeuvre capability to measure plateau pressure.<br>Adjustable peak pressure limitation/pressure-cycling mechanism above measured peak pressure.<br>Internal PEEP capability/range: 0–20 cmH2O, minimum. |
| | Displayed parameters (color and graphic are preferable) | Display easily readable in low ambient light and sunlight.<br>3 scalar waveforms: pressure, volume and flow (preferable).<br>Loop (axis) displays: pressure-volume, flow-volume and pressure-flow (preferable).<br>Status indicators for ventilator mode, battery status, patient data, alarm settings.<br>FiO2.<br>Airway pressures (peak, plateau mean and PEEP).<br>Tidal volume (expired and inspired preferable).<br>Minute volume (inspired and expired).<br>I:E ratio.<br>RR (spontaneous and mechanical).<br>End-tidal CO2. |
| | Alarms, related to gas delivered | Adjustable, visual and audible:<br>· High/low FiO2.<br>· High/low inspiratory pressure and PEEP.<br>· High/low tidal volume (not achieved or exceeded).<br>· Apnea.<br>· High/low RR.<br>· Continuously high pressure/occlusion.<br>· Breathing circuit disconnect.<br>· Low minute volume. |
| | Alarms, related to equipment operation | Adjustable, visual and audible:<br>· Gas supply failure.<br>· Power failure.<br>· Low battery.<br>· Self-diagnostics failure alarm. |
| | Consumables, single use | Breathing circuits: double-limb with standard outlet/inlet connectors with 22 mm outside diameter.<br>Viral/bacterial filters 99.99% efficiency minimum; inspiratory and expiratory, as applicable. |

| MEDICAL DEVICE | TECHNICAL DESCRIPTION AND SPECIFICATIONS | |
|---|---|---|
| | Accessories, reusable | Breathing circuits: double-limb with standard outlet/inlet connectors with 22 mm outside diameter. Expiratory housing with in-built bacteria filters; as well as the possibility to accommodate heat moisture exchangers (HMEs).<br>Exhalation valve.<br>CO2 sensors.<br>Active humidifier with relevant connectors.<br>Air compressor if external to the unit.<br>Standard hoses and connectors (i.e. DISS/NIST as applicable for the country) for oxygen and medical air wall outlets and cylinders.<br>Pressure regulators (from wall outlet to ventilator) to avoid damaging ventilator. As required to operate. |
| | Spare parts | 1-year's spare parts kit as per preventive maintenance program (preferable) |
| | 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: 100–240 V AC ±10% / 50–60 Hz ±10% of nominal value.<br>In-built rechargeable battery.<br>Automatic switch from AC power electric-line mode to battery operating mode and vice versa.<br>Continuous in battery operating mode with standard ventilation not less than 1 hour.<br>Total re-charging time not greater than 6 hours.<br>Equipment must be connected to a reliable and continuous source of energy. |
| | Standards for the manufacturer | Certified quality management system for medical devices (e.g. ISO 13485).<br>Application of risk management to medical devices (e.g. ISO 14971). |
| | Regulatory approval / certification | Free sales certificate (FSC) or certificate for exportation of medical device provided by the authority in manufacturing country.<br>Proof of regulatory compliance, as appropriate, per the product's risk classification (e.g. Food and Drug Administration [FDA] and/or Conformité Européenne [CE]). |
| | Standards for the product performance | Compliance to the following international standards or to regional or national equivalent, (including the technical tests for safety and performance from accredited laboratory or third party). Latest version recommended but compliance to previous standards versions could be accepted:<br>· IEC 60601-1:2005 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.<br>· 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.<br>· ISO 80601-2-12:2020 Medical electrical equipment – Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators.<br>· ISO 80601-2-74:2017 Medical electrical equipment – Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment.<br>· 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.<br>· ISO 18562-1:2017 Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 1: Evaluation and testing within a risk management process (if applicable).<br>· ISO 20789:2018 Anesthetic and respiratory equipment – Passive humidifiers (if applicable). |
| | Warranty | Minimum 2 years. |

| MEDICAL DEVICE | TECHNICAL DESCRIPTION AND SPECIFICATIONS | |
|---|---|---|
| | According to: COVID-19 Technical specifications for invasive and non-invasive ventilators (link) | |
| Ventilators for Sub-Acute Care | General technical requirements | Medical air compressor or turbine in-built, with inlet filter.<br>Possibility for using external low-pressure oxygen (approx. 20 psi) as source (preferable).<br>If oxygen high pressure input port (> 35psi [2.4bar]).<br>Oxygen-air mixture accuracy of 4%.<br>Oxygen consumption with 660 L I tank:<br>· 104 minutes with 16 L/min, FiO2 50%.<br>· 280 minutes with 6 L/min, FiO2 50%.<br>Oxygen conserve feature (preferable).<br>Internal function testing/leak testing.<br>Event log for errors traceability (preferable).<br>At least IP21 degree of protection to the harmful ingress of water (higher preferable).<br>Capability to work with dual-limb breathing circuits.<br>Capability to connect to an active humidifying system. |
| | Ventilation modes | Non-invasive ventilation.<br>It must include at least one mandatory and invasive ventilation mode.<br>· Pressure control ventilation (PCV).<br>· Volume control ventilation (VCV).<br>· Pressure support ventilation (PSV).<br>· Synchronized intermittent mandatory ventilation (SIMV) (preferable).<br>· Pressure regulated volume control (PRVC) (or similar preferable). |
| | Monitored and controlled parameters (by user) | Air and externally supplied oxygen mixture ratios fully controllable.<br>FiO2: 21–100%.<br>Tidal volume: 50–1000 mL (preferable).<br>Inspiratory pressure: 0–40 cmH2O.<br>I:E ratio.<br>RR: 10–60 breaths/min, minimum.<br>PEEP: at least 0–20 cmH2O. |
| | Displayed parameters (color and graphic are preferable) | Display easily readable in low ambient light and sunlight.<br>Real-time scalar waveforms for flow, volume and pressure at least two simultaneously.<br>Status indicators for ventilator mode, battery status, patient data, alarm settings.<br>Airway pressures (peak, mean and PEEP).<br>Tidal volume (expired).<br>Minute volume (expired).<br>I:E ratio.<br>Inspiration and expiration times.<br>RR.<br>FiO2.<br>Occlusion pressure detection.<br>Air and oxygen pressure.<br>Spontaneous ventilation.<br>Leak percentage.<br>Spontaneous minute volume (preferable). |
| | Alarms, related to gas delivered | Adjustable, visual and audible:<br>· High/low FiO2.<br>· High/low flow.<br>· High/low inspiratory pressure.<br>· Breathing circuit disconnect.<br>· Low minute volume (preferable).<br>· Apnea. |

| MEDICAL DEVICE | TECHNICAL DESCRIPTION AND SPECIFICATIONS | |
|---|---|---|
| | Alarms, related to equipment operation | Adjustable, visual and audible:<br>· Gas supply failure.<br>· Power failure.<br>· Self-diagnostics failure alarm.<br>· Low battery. |
| | Consumables, single use | Single-limb breathing circuit with standard connector with 22 mm outside diameter. Double-limb breathing circuits with standard outlet/inlet connectors with 22 mm outside diameter (preferable).<br>Viral/bacterial filters 99.99% efficiency minimum; inspiratory and expiratory as applicable.<br>Exhaled gas filter, when applicable. |
| | Accessories, reusable | Single-limb breathing circuit with standard connector with 22 mm outside diameter. Double-limb breathing circuits with standard outlet/inlet connectors with 22 mm outside diameter (preferable).<br>Exhalation valve (if applicable).<br>CO2 sensors (preferable).<br>Standard hoses and connectors (ie. DISS/NIST as applicable for the country) for oxygen wall outlets and cylinder as required to operate.<br>Compatible active humidifier provided. |
| | Spare parts | 1-year's spare parts kit as per preventive maintenance program, including exhalation valves and also oxygen sensors (if applicable). |
| | Portability | Preferable: portable equipment with mechanical strength to lever rough handling.<br>Alternative option: mounted on a mobile cart with at least 2 castors fitted with breaks. |
| | Power supply and battery | Operates from AC power electric line: 100–240 V AC ±10 % / 50–60 Hz ± 10%<br>In-built rechargeable battery.<br>Automatic switch from AC power electric-line mode to battery operating mode and vice versa.<br>Continuous in battery operating mode with standard ventilation not less than 4 hours.<br>Total re-charging time not greater than 6 hours. |
| | Standards for the manufacturer | Certified quality management system for medical devices (e.g. ISO 13485).<br>Application of risk management to medical devices (e.g. ISO 14971). |
| | Regulatory approval / certification | Free sales certificate (FSC) or certificate for exportation of medical device provided by the authority in manufacturing country.<br>Proof of regulatory compliance, as appropriate, per the product's risk classification (e.g. Food and Drug Administration [FDA] and/or Conformité Européenne [CE]). |
| | Standards for the product performance | Compliance to the following international standards or to regional or national equivalent, (including the technical tests for safety and performance from accredited laboratory or third party). Latest version recommended but compliance to previous standards versions could be accepted:<br>· IEC 60601-1:2005 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.<br>· 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.<br>· ISO 10651-5:2006 Lung ventilators for medical use – Particular requirements for basic safety and essential performance – Part 5: Gas-powered emergency resuscitators.<br>· ISO 80601-2-74:2017 Medical electrical equipment – Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment. |

| MEDICAL DEVICE | TECHNICAL DESCRIPTION AND SPECIFICATIONS | |
|---|---|---|
| | | · ISO 18562-1:2017 Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 1: Evaluation and testing within a risk management process (if applicable).<br>· ISO 20789:2018 Anesthetic and respiratory equipment – Passive humidifiers (if applicable). |
| | Warranty | Minimum 2 years. |
| | According to: COVID-19 Technical specifications for invasive and non-invasive ventilators (link) | |
| Ventilator for Transport | General technical requirements | Medical air compressor integral to unit, with inlet filter or high performance turbines.<br>External low-flow oxygen (preferable).<br>If oxygen high-pressure input port (> 35 psi).<br>Each high-pressure input port with a filter having a pore size ≤ 100 µm. Oxygen-air mixture accuracy of 4%.<br>Oxygen consumption with 660 L (E) tank:<br>· 104 minutes with 16 L/min, FiO2 50%.<br>· 280 minutes with 6 L/min, FiO2 50%.<br>Oxygen conserve feature (preferable).<br>Internal function testing/leak testing.<br>Event log for errors traceability (preferable).<br>All parts withstand high disinfection procedures.<br>At least IP21 degree of protection to the harmful ingress of water.<br>Polyvinyl chloride (PVC) materials must be avoided in the patient gas pathway. |
| | Ventilation modes | Pressure control ventilation (PCV).<br>Volume control ventilation (VCV).<br>Synchronized intermittent mandatory ventilation (SIMV) (preferable).<br>Pressure support ventilation (PSV) (preferable).<br>Pressure regulated volume control (PRVC) (or similar preferable).<br>Non-invasive ventilation (CPAP/ BiPAP). |
| | Monitored and controlled parameters (by user) | Air and externally supplied oxygen mixture ratios fully controllable.<br>FiO2: 21–100%.<br>Tidal volume: 20–1000 mL (preferable).<br>Inspiratory pressure: 0–40 cmH2O.<br>I:E ratio.<br>RR: 10–60 breaths/min, minimum. |
| | Displayed parameters (color and graphic are preferable) | Display easily readable in low ambient light and sunlight.<br>Real-time scalar waveforms for flow, volume and pressure at least two simultaneously. Status indicators for ventilator mode, battery status, patient data, alarm settings. Airway pressures (peak, mean and PEEP).<br>Tidal volume (expired).<br>Minute volume (expired).<br>I:E ratio.<br>Inspiration and expiration times.<br>Spontaneous minute volume.<br>RR.<br>FiO2.<br>Occlusion pressure detection.<br>Air and oxygen pressure.<br>Spontaneous ventilation.<br>Leak percentage. |
| | Alarms, related to gas delivered | Adjustable, visual and audible:<br>· High/low FiO2.<br>· High/low flow.<br>· High/low inspiratory pressure.<br>· Breathing circuit disconnect. |

| MEDICAL DEVICE | TECHNICAL DESCRIPTION AND SPECIFICATIONS | |
|---|---|---|
| | | · Apnea. |
| | Alarms, related to equipment operation | Adjustable, visual and audible:<br>· Gas supply failure.<br>· Power failure.<br>· Low battery. |
| | Consumables, single use | Breathing circuits: double-limb with standard outlet/inlet connectors with 22 mm outside diameter.<br>Viral/bacterial filters 99.99% efficiency minimum; inspiratory and expiratory, as applicable |
| | Accessories, reusable | Breathing circuits: double-limb with standard outlet/inlet connectors with 22 mm outside diameter.<br>Exhalation valve if applicable<br>CO2 sensors (preferable).<br>Standard hoses and connectors (ie. DISS/NIST as applicable for the country) for oxygen wall outlets and cylinder as required to operate. |
| | Spare parts | 1-year's spare parts kit as per preventive maintenance program (preferable). |
| | Portability | Portable equipment with mechanical strength to lever rough handling. |
| | Power supply and battery | Operates from AC power electric line: 100–240 V AC ±10 % / 50–60 Hz ±10 %<br>In-built rechargeable battery.<br>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.<br>Total re-charging time not greater than 6 hours.<br>Equipment must be connected to a reliable and continuous source of energy. |
| | Standards for the manufacturer | Certified quality management system for medical devices (e.g. ISO 13485).<br>Application of risk management to medical devices (e.g. ISO 14971). |
| | Regulatory approval / certification | Free sales certificate (FSC) or certificate for exportation of medical device provided by the authority in manufacturing country.<br>Proof of regulatory compliance, as appropriate, per the product's risk classification (e.g. Food and Drug Administration [FDA] and/or Conformité Européenne [CE]). |
| | Standards for the product performance | Compliance to the following international standards or to regional or national equivalent, (including the technical tests for safety and performance from accredited laboratory or third party). Latest version recommended but compliance to previous standards versions could be accepted:<br>· IEC 60601-1:2005 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.<br>· 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.<br>· ISO 10651-5:2006 Lung ventilators for medical use – Particular requirements for basic safety and essential performance – Part 5: Gas-powered emergency resuscitators.<br>· ISO 80601-2-74:2017 Medical electrical equipment – Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment.<br>· ISO 18562-1:2017 Biocompatibility evaluation of breathing gas pathways in health-care applications – Part 1: Evaluation and testing within a risk management process (if applicable).<br>· ISO 20789:2018 Anesthetic and respiratory equipment – Passive humidifiers (if applicable). |
| | Warranty | Minimum 2 years. |

According to: COVID-19 Technical specifications for invasive and non-invasive ventilators (link)

| MEDICAL DEVICE | TECHNICAL DESCRIPTION AND SPECIFICATIONS |
|---|---|
| Venturi Mask | Also known as an air-entrainment mask (with percent O2 lock).<br>· It delivers oxygen, with a specific concentration from 24–60% minimum.<br>· The mask has an adjustable nose clip.<br>· The kit of the mask includes the tubing, humidity cup and multiple jets, which are color-coded and indicating the percentage of oxygen.<br>· Individually packed.<br>· Non-sterile.<br><br>Sizes:<br>· Adult.<br>· Pediatric: tube length: 1.5–2 m.<br><br>Material:<br>· Mask and tubing PVC or other material, FDA Title 21/USP VI compliant and certified for medical use, hardness > 60 Shore A (ASTM D-2240).<br><br>Standards for product performance:<br>· ISO 11712:2009 Anesthetic and respiratory equipment – Supra-laryngeal airways and connectors.<br>· ISO 15001 Anesthetic and respiratory equipment – Compatibility with oxygen.<br>· ISO 18562 Biocompatibility evaluation of breathing gas pathways in healthcare applications.<br>· ISO 18190 Anesthetic and respiratory equipment – General requirements for airways and related equipment.<br>· ISO 18562-1 Biocompatibility evaluation of breathing gas pathways in healthcare applications Part 1: Evaluation and testing within a risk management process.<br>· ISO/DIS 23368: Anesthetic and respiratory equipment – Low flow nasal cannula for oxygen therapy.<br>· ISO/DIS 17256 Anesthetic and respiratory equipment – Respiratory therapy tubing and connectors.<br>· ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements. |

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

| MEDICAL DEVICE | TECHNICAL DESCRIPTION AND SPECIFICATIONS |
|---|---|
| Alcohol-based hand rub solution | Bottle of 100ml & 500ml, at least 80% ethanol or 75% isopropyl alcohol (v/v)<br><br>Compliance with:<br>· ASTM E2755, or<br>· EN 1500<br>or alternative equivalent set of standards<br><br>Optional:<br>· ASTM E1115, or<br>· ASTM E1174 |
| Apron | Straight apron with bib.<br>Fabric: 100% polyester with PVC coating, or 100% PVC, or 100% rubber, or 100% reusable and biodegradable material, or other fluid resistant coated material.<br>Waterproof, sewn strap for neck and back fastening or single-material cut film.<br>Minimum basis weight: 300 g/m2.<br>Thickness: 200-300 microns, optional.<br>Covering size: 70 - 90 cm (width) x 120 - 150 cm (height).<br>Reusable (provided appropriate arrangements for decontamination are in place) or biodegradable.<br><br>Compliance with:<br>· EN ISO 13688<br>· EN 14126 and partial protection (EN 13034 or EN 14605)<br>· EN 343 for water and breathability<br>or alternative equivalent set of standards<br><br>If biodegradable;<br>· EN 13432<br>· ASTM D6400 |
| Bags for medical waste | Disposable autoclavable bag for biohazard waste.<br>Material: High Density Polyethylene (HDPE) or Polypropylene (PP).<br>Colour: red or yellow.<br>Autoclave ability (temperature resistant up to 121°C).<br>Printed with a sterilization patch that darkens when subject to steam.<br>Puncture, tear and leak resistant.<br>Leak proof flat bottom seal.<br>Black imprint "Biohazard" and tri-sickle logo according U+2623 on one side.<br>Capacity: Approximately 20L or 50L.<br>Thickness: min 0.038mm (1.5mil).<br>Sizes:<br>- width (45 cm), length (50 cm) (±10%)<br>- width (60 cm), length (82 cm) (±10%)<br><br>Compliance with:<br>· Puncture resistant meets ASTM D1709 (dart impact test).<br>· Tear resistant meets ASTM D1922 or ISO 6383-2.<br>· Temperature Resistance test at 121°C. |
| Chlorine | NaDCC, granules, 1kg, 65 to 70% + dosage spoon. |
| Disposable towel for hand drying (paper or tissue) | 50 to 100m roll. |

| MEDICAL DEVICE | TECHNICAL DESCRIPTION AND SPECIFICATIONS |
|---|---|
| Face shields | Made of clear plastic and providing 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 cover the sides and length of the face. May be re-usable (made of robust material which can be cleaned and disinfected) or disposable.<br><br>Compliance with:<br>· EN 166 (if reusable).<br>· ANSI/ISEA Z87.1 (if reusable).<br>or alternative equivalent set of standards. |
| Gloves, cleaning | Glove should have long cuffs, reaching well above the wrist, ideally to mid-forearm.<br>Minimum 280 mm total length.<br>Sizes S, M, L.<br>Reusable, heavy duty gloves, high cracking, puncture and abrasion resistant.<br>Powder free, seamless, and entirely waterproof.<br>Made of nitrile, synthetic rubber (no latex).<br>Knit inner lining facilitates slide-in and removal.<br>Cleanable with water and disinfectant (resisting both ethanol solutions 70% and chlorine solutions 0.5% or 500ppm).<br>Material thickness, at level of the fingers, not less than: 0.38 mm.<br>Length not less than: 30cm.<br>Supply co-packed as one left/right pair.<br><br>Compliance with:<br>· EN 388<br>· ANSI 105<br>· EN 374-1, EN 374-2 (at least Level 2)<br>· EN 374-4 and EN 374-5<br>· EN 420 + A1<br>or alternative equivalent set of standards. |
| Gloves, surgical, sterile | Gloves, surgical, nitrile (preferable), latex, polyisoprene, or polychloroprene, sterile, powder-free, single use.<br>Gloves should have long cuffs, reaching well above the wrist, ideally to mid-forearm.<br>Minimum thickness 0.10mm.<br>Sizes ranging 5.0 - 9.0<br><br>Compliance with:<br>· EN 455<br>· ASTM D3577<br>Sterility:<br>· United States Pharmacopeia<br>· EN ISO 11607<br>or alternative equivalent set of standards. |
| Gloves, examination, non-sterile | Gloves, examination, nitrile (preferable), latex, polychloroprene or PVC, powder-free, non-sterile. (e. g., minimum 230mm total length).<br>Minimum thickness 0.05mm.<br>Sizes S, M, L.<br><br>Compliance with:<br>· EN 455<br>· EN 374, optional additional:<br>· ASTM D6319, D3578, D5250, D6977<br>Or alternative equivalent set of standards. |

| MEDICAL DEVICE | TECHNICAL DESCRIPTION AND SPECIFICATIONS |
|---|---|
| Goggles, glasses protective | Good seal with the skin of the face, Flexible PVC frame to easily fit with all face contours with even pressure.<br>Enclose eyes and the surrounding areas, accommodate wearers with prescription glasses.<br>Clear plastic lens with fog and scratch resistant treatments.<br>Adjustable band to secure firmly so as not to become loose during clinical activity.<br>Indirect venting to avoid fogging.<br>May be re-usable (provided appropriate arrangements for decontamination are in place) or disposable.<br><br>Compliance with:<br>· EN 166<br>· ANSI/ISEA Z87.1<br>or alternative equivalent set of standards |
| Gown, surgical | Single use, disposable, nonwoven material, length mid-calf, sterile or non-sterile. Critical zones may be more fluid resistant than non-critical zones.<br>or<br>Single use, woven material, length mid-calf, sterilizable. Critical zones may be more fluid resistant than non-critical zones.<br><br>Reusable gowns should meet the minimum performance requirements after maximum suggested laundering cycles.<br><br>Compliance with:<br>· AAMI PB70 and ASTM F2407<br>· EN 13795<br><br>· EN 13034 - Type PB [6] (stitched gown), with minimum hydrostatic head of 50 cm H2O<br><br>· YY/T 0506<br>or alternative equivalent set of standards<br><br>EN 556, if sterile,<br>or alternative equivalent set of standards |
| Liquid plain soap for hand hygiene | Liquid soap. Bottle of 100ml & 500ml<br><br>· EN 1499<br>· ASTM E1174 |
| Medical mask, healthcare worker | Medical mask, good breathability, internal and external faces should be clearly identified, 98% droplet filtration, preferably fluid resistance.<br><br>Fluid resistant masks (surgical masks):<br>· EN 14683 Type IIR<br>· ASTM F2100 Level 1, 2 or 3<br>· YY 0469, with at least 98% bacterial droplet filtration<br>or alternative equivalent standard<br><br>Non-fluid resistant mask:<br>· EN 14683 Type II<br>· YY/T 0969, with at least 98% bacterial droplet filtration<br>or alternative equivalent standard |
| Medical mask, patient | Medical mask, good breathability, internal and external faces should be clearly identified<br><br>Compliance with:<br>· EN 14683 Type I,<br>· YY 0469 or YY/T 0969, if bacterial droplet filtration is below 98% |

| MEDICAL DEVICE | TECHNICAL DESCRIPTION AND SPECIFICATIONS |
|---|---|
| | or alternative equivalent standard |
| Particulate respirator | Good particle filtration (minimum 94% or 95%), good breathability with design that does not collapse against the mouth (e.g. duckbill, cup-shaped). May be tested for fluid resistance (NIOSH/FDA surgical N95, EN 149 FFP2+Type IIR, GB 19083 Grade/Level 1)<br><br>Fluid resistant respirator:<br>· Minimum NIOSH approved (42 CFR Part 84) and FDA cleared "surgical N95".<br>· EN 149, minimum "FFP2" and EN 14683 Type IIR<br>· GB 19083, minimum "Grade/Level 1"<br>or alternative equivalent standards<br><br>Non-fluid resistant respirator:<br>· Minimum NIOSH approved"N95" according to 42 CFR Part 84<br>· EN 149, minimum "FFP2"<br>· GB 2626, minimum "KN95"<br>or alternative equivalent set of standards |

## Annex I -

***Table 4: Description of main changes in this fifth version of the list of priority medical devices in the context of COVID-19***

| MEDICAL DEVICE | ACTION |
|---|---|
| Apron | Standards updated and harmonized with WHO's Disease Commodity Packages, v5. (link) |
| Bi-Level Positive Airway Pressure unit (BiPAP) | Specifications updated and harmonized with WHO's COVID-19 Technical specifications for invasive and non-invasive ventilators (link) |
| Computed tomography (CT) system | Specifications updated and harmonized with *COVID-19 Technical specifications for imaging devices: portable ultrasound; mobile radiographic digital equipment; computed tomography (CT) scanning system* (link) |
| Continuous Positive Airway Pressure unit (CPAP) | Specifications updated and harmonized with WHO's COVID-19 Technical specifications for invasive and non-invasive ventilators (link) |
| Face shields | Standards updated and harmonized with WHO's Disease Commodity Packages, v5. (link) |
| Flow splitter | Specifications updated and harmonized with WHO's COVID-19 Technical specifications for procurement of oxygen therapy and monitoring devices (link) |
| Flowmeter, Thorpe tube | Specifications updated and harmonized with WHO's COVID-19 Technical specifications for procurement of oxygen therapy and monitoring devices(link) |
| Gloves, cleaning | Specifications updated and harmonized with WHO's Disease Commodity Packages, v5. (link) |
| Gloves, examination, non-sterile | Standards updated and harmonized with WHO's Disease Commodity Packages, v5. (link) |
| Gloves, surgical, sterile | Standards updated and harmonized with WHO's Disease Commodity Packages, v5. (link) |
| Goggles, glasses protective | Specifications updated and harmonized with WHO's Disease Commodity Packages, v5. (link) |
| Gown, surgical | Standards updated and harmonized with WHO's Disease Commodity Packages, v5. (link) |
| High-Flow Nasal Cannula (HFNC) | Specifications updated and harmonized with WHO's COVID-19 Technical specifications for invasive and non-invasive ventilators (link) |
| Mask with reservoir bag | (Previously: oxygen mask). Specifications updated and harmonized with WHO's Disease Commodity Packages, v5. (link) |
| Medical mask, healthcare worker | Standards updated and harmonized with WHO's Disease Commodity Packages, v5. (link) |
| Medical mask, patient | New device. Harmonized with WHO's Disease Commodity Packages, v5. (link) |
| Nasal oxygen cannula with prongs | (Previously: oxygen prongs, nasal). Specifications updated and harmonized with WHO's Disease Commodity Packages, v5. (link) |
| Non-heated bubble humidifier | (Previously: Humidifier, non-heated). Specifications updated and harmonized with WHO's COVID-19 Technical specifications for procurement of oxygen therapy and monitoring devices (link) |
| Oxygen concentrator | New device. Specifications harmonized with WHO's COVID-19 Technical specifications for procurement of oxygen therapy and monitoring devices (link) |
| Particulate respirator | (Previously: respirator grade N95/FFP2) Specifications updated and harmonized with WHO's Disease Commodity Packages, v5. (link) |
| Patient monitor multiparametric, advanced | (Previously: vital signs monitor). Specifications updated and harmonized with WHO's COVID-19 Technical specifications for procurement of oxygen therapy and monitoring devices (link) |
| Patient monitor multiparametric, basic | (Previously: vital signs monitor). Specifications updated and harmonized with WHO's COVID-19 Technical specifications for procurement of oxygen therapy and monitoring devices (link) |
| Patient monitor multiparametric, intermediate | (Previously: vital signs monitor). Specifications updated and harmonized with WHO's COVID-19 Technical specifications for procurement of oxygen therapy and monitoring devices (link) |
| Portable ultrasound | (Previously: Portable ultrasound scanner with probes) Specifications updated and harmonized with WHO's, COVID-19 Technical specifications for portable ultrasound (link) |
| Portable X-ray equipment | Specifications updated and harmonized with *COVID-19 Technical specifications for imaging devices: portable ultrasound; mobile radiographic digital equipment; computed tomography (CT) scanning system* (link) |
| Pulse oximeter, fingertip | (Previously: pulse oximeter) Specifications updated and harmonized with WHO's COVID-19 Technical specifications for procurement of oxygen therapy and monitoring devices (link) |
| Pulse oximeter, handheld | (Previously: pulse oximeter) Specifications updated and harmonized with WHO's COVID-19 Technical specifications for procurement of oxygen therapy and monitoring devices (link) |
| Pulse oximeter, tabletop | (Previously: pulse oximeter) Specifications updated and harmonized with WHO's COVID-19 Technical specifications for procurement of oxygen therapy and monitoring devices (link) |
| Resuscitation bag with mask | (Previously: resuscitaror adult/pediatric) Specifications updated and harmonized with WHO's COVID-19 Technical specifications for procurement of oxygen therapy and monitoring devices (link) |
| Ventilator for Intensive Care Unit | Specifications updated and harmonized with WHO's COVID-19 Technical specifications for invasive and non-invasive ventilators (link) |
| Ventilators for Sub-Acute Care | Specifications updated and harmonized with WHO's COVID-19 Technical specifications for invasive and non-invasive ventilators (link) |
| Ventilators for Transport | Specifications updated and harmonized with WHO's COVID-19 Technical specifications for invasive and non-invasive ventilators (link) |
| Venturi mask | Specifications updated and harmonized with WHO's COVID-19 Technical specifications for procurement of oxygen therapy and monitoring devices (link) |

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