

## Technical specifications of medical devices for the case management of COVID-19 in healthcare settings

PAHO/PHE/IM/Covid-19/20-001 (interim recommendations, 3 March 2020)

## **Key considerations**

- In December 2019 a novel coronavirus (SARS-CoV-2) was identified as the causative agent of pneumonia (COVID-19) among people exposed to a seafood market in Wuhan, China.\*
- There are gaps in the knowledge about the natural history of COVID-19, including viral shedding, reservoirs and patterns of transmission. On February 17, 2020, the Chinese Center for Disease Control and Prevention published a study with 72,314 recorded cases, of which 44,672 (62%) were confirmed for COVID-19. Among the confirmed cases, 31.2% were over 60 years of age and accounted for 81% of the total deaths. The overall case-fatality rate was 2.3%. The most prevalent comorbid conditions were hypertension, diabetes, and cardiovascular disease. The spectrum of disease included 81% of mild cases (non-pneumonia and mild pneumonia cases), 14% severe (dyspnea, respiratory frequency higher than ≥) 30/min, blood oxygen saturation lesser than ≤ 93%, PaO<sub>2</sub>/FiO<sub>2</sub> ratio lesser than ≤ 300, and/or lung infiltrates > 50% within 24–48 hours), and 5% of critically ill patients, with respiratory failure, septic shock, and/or multiple organ dysfunction or failure.<sup>†</sup>
- The implementation of timely, effective, and safe supportive therapies (oxygen, antibiotics, hydration & fever/pain relief) is the cornerstone of therapy for patients that develop severe manifestations of COVID-19.<sup>‡</sup>
- At the moment, there is no specific treatment for COVID-19, such as antivirals. There have been anecdotal reports on the use of these agents; however, its efficacy and safety are yet to be determined.

## Objectives

- The medical devices listed in this document provide minimum standards and technical description and specifications of medical devices for supportive treatment of COVID-19.§
- These medical devices are not limited, and to be adaptable to all countries in the region irrespective of their different health care systems and socioeconomic disparities. In addition, they are recommended for:
  - Early supportive therapy and monitoring of severe acute respiratory illness (SARI) when COVID-19 infection is suspected;
  - Management of hypoxemic respiratory failure and Acute Respiratory Distress Syndrome (ARDS) in COVID-19 patients;
  - Management of septic shock in COVID-19 patients;

\* For the most updated information related to the COVID-19, please consult: <a href="https://www.who.int/emergencies/diseases/novel-coronavirus-2019">https://www.who.int/emergencies/diseases/novel-coronavirus-2019</a>. These recommendations are preliminary and subject to review as new evidence becomes available.

<sup>&</sup>lt;sup>†</sup> Chinese Center for Disease Control. [The epidemiological characteristics of an outbreak of 2019 novel coronavirus diseases (COVID-19) in China]. Zhonghua Liu Xing Bing Xue Za Zhi. 2020 Feb 17;41(2):145-151. doi: 10.3760/cma.j.issn.0254-6450.2020.02.003. [Epub ahead of print] 
<sup>†</sup> World Health Organization. (2020). Clinical management of severe acute respiratory infection when novel coronavirus (nCoV) infection is suspected: interim guidance, 25 January 2020. World Health Organization. <a href="https://apps.who.int/iris/handle/10665/330854">https://apps.who.int/iris/handle/10665/330854</a>. License: CC BY-NC-SA 3.0 IGO

<sup>§</sup> The mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or recommended by the Pan American Health Organization in preference to others of a similar nature that are not mentioned. This document is not intended to provide guidance on the class of drugs and dosage required for the supportive care of COVID-19 patients.



## Target audience

• The list of medical devices identified in this document is the minimum required to support health care providers, intensive care unit managers and Ministries of Health to appropriately manage a suspected or confirmed COVID-19 patient in a health care setting.

Technical description and specifications of medical devices for supportive treatment of COVID-19 in healthcare settings

Table 1: Technical description and specifications of medical devices for supportive treatment of COVID-19 in healthcare settings

Item	Technical description and specifications
	Child sizes: 00, 0, 1; Adult sizes: 2, 3, 4.
Airway, Guedel, sterile, single use (range of sizes)	Oro-pharyngeal airway, Guedel type.
	Semi-rigid, transparent.
	Proximal (or buccal) end straight and reinforced.
	Flange color coded and/or marked with corresponding size number.
	Size: Airway Guedel, size 00, approximately 40mm; size 0, approx. 50mm; size 1,
	approx. 60 mm; size 2, approx. 70mm; size 3 approx. 80 mm; size 4 approx. 90mm
	Material: Polyethylene/vinyl acetate (EVA) - Polyvinyl chloride (PVC).
	Sterile, single patient use.
	ISO10651-4: Lung ventilators - Part 4: Particular requirements for operator-powered
	resuscitators.
	Disposable
Carbon dioxide detector	Colorimetric
	Sizes compatible with child and adult endotracheal tube
	Manual and semi-automated operating modes.
	Biphasic waveform operation.
	Maximum energy to be at least 220 Joules.
	• Conductive area for paddles shall be >50cm² for adult, >15cm² for pediatric.
	ECG analysis time to be < 15 sec.
	Charge time to full energy to be < 10 sec.
	30 full energy discharges to be possible solely off battery operation.
External defibrillator	Voice prompting function included for operator direction.
	Number of discharges (total lifetime and on current battery) to be displayed
	Self-test facility to be included.
	Automatic impedance compensation.  Statement of the illustrated in the illustrated in the statement of the illustrated in the statement of the illustrated in the illustrated
	External defibrillation discharging start control just only by pressing both buttons on
	the external paddles.
	One set of reusable adult external paddles and related pediatric adapters compatible  with the equipment.
	<ul> <li>with the equipment.</li> <li>Displayed parameters - Indicator for power and battery state required.</li> </ul>
	Single use
	<ul> <li>Double-lumen tube with two cuffs: syringes primed with the correct inflation volumes</li> </ul>
Esophageal tracheal airway	Each lumen able to be connected to a breathing system (distal lumen and proximal)
(Combitube)	lumen)
	Not for pediatric use
	<ul> <li>Scanner and software, several single- or multifrequency transducers, a TEE probe,</li> </ul>
	color Doppler, M-mode, CFM, cardiac analysis software.
Cardiovascular ultrasound	Phased array transducers required.
imaging system	<ul> <li>Frequency range covered by probes supplied to be at least 1 – 15 mhz.</li> </ul>
	Transesophageal Echocardiogram - TEE scanning capability.
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Item	Technical description and specifications
	Penetration depth of at least 30 cm.
	Digital and caliper measurement functions required for both distance and area.
	Alphanumeric annotation to be possible.
	<ul> <li>Connection port for image printing to be included (printer specified separately).</li> </ul>
	<ul> <li>Measurement accuracy to be better than 2% over 10cm distance.</li> </ul>
	Doppler display to indicate blood flow both numerically and in color.
	<ul> <li>System that is DICOM compatible for communication efficiency. 3D or 2D image for</li> </ul>
	cardiac studies in adults, children and infants.
	<ul> <li>ZOOM in real time at least 4X and ZOOM for frozen image at least 20X.</li> </ul>
	Equipment dynamic range, at least, 180 db.  The hardware and seftware included in the effect will allow the following applications.
	The hardware and software included in the offer will allow the following application:  (i) conding and strong policy (ii) tissue differentiation to clearly show the walls of the left.
	(i) cardiac and stress echo; (ii) tissue differentiation to clearly show the walls of the left
	ventricle and regional wall motion abnormalities; (iii) left ventricle wall abnormalities
	software; (iv) abdominal; (v) obstetrical and gynecological; (vi) peripheral and deep
	vascular; (vii) tissue imaging synchronization or equivalent technique.  • Open distal end and Magill-type point with oral angle of 37.5º
	<ul> <li>Standard connector (ext. Ø 15mm) at the proximal end enabling the tube to be</li> </ul>
	connected to the ventilation system.
	Radio opaque mark.
	With Murphy's eye.
Endotracheal tube, with cuff	Graduations.
	Endotracheal tube without cuff.
	Size: Ø internal 6.5mm, 7mm, 7.5mm, 8mm or 8.5mm. Material: Polyvinyl chloride
	(PVC).
	Disposable / Sterile.
	Open distal end and Magill-type point with oral angle of 37.59
	Standard connector (ext. Ø 15mm) at the proximal end enabling the tube to be
	connected to the ventilation system.
	Radio opaque mark.
	With Murphy's eye.
Endotracheal tube, without cuff	Graduations.
	Endotracheal tube without cuff.
	Size: Ø internal 3mm or 3.5mm
	Material: Polyvinyl chloride (PVC).
	Disposable / Sterile.
	Initial sterilization method: Ethylene oxide gas or Gamma radiation.
Heimlich Maneuver Assist device	Manual, non-invasive, portable suction device
	Sterile single use.
	Device components:
	Perforator: Sharp piercing device with protective cap. Air inlet: With integrated
Infusion giving set, sterile, single	bacteriological filter. Drop counting chamber: Transparent drip chamber, calibrated at
use	20 drops/ml, with 15-20μm fluid filter.
	Tubing: Transparent tubing, minimum length 150cm, with injection site latex or latex-
	free (or Y-injection port), with distal connector preferably Luer Lock connector.
	Precision flow regulator: Smooth roller clamp to facilitate easy, safe control and adjustment of fluid rates, ISO 9536. A Infusion agricument for medical use.
	adjustment of fluid rates. ISO 8536-4 Infusion equipment for medical use.
Intercostal catheter (ICC)/ Chest	• Sterile, single use.
tube	Straight and right-angled versions in varied sizes (12-40 Fr).      The state of the state
	Bold Depth Markings and Radiopaque Stripe.
	Reusable, medical grade silicone rubber.
Laryngeal mask (LMA)	3 main components: 1. Airway tube 2. Inflatable mask 3. Mask inflation line.
, , , , , , , , , , , , , , , , , , , ,	Slightly curved, semirigid and semitransparent airway tube with a longitudinally black
	line.



Item Technical description and specifications		
	• Available in eight sizes, from neonates to large adults, 1 to 6 and two half sizes 1.5 and 2.5.	
Laryngoscope**	<ul> <li>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. It has a handle containing batteries to power its light (a small built-in light bulb or fiber-optic light) for airway illumination, and a curved or straight blade of various designs and lengths that can be hinged/interchanged or integral. Some types can be magnetic resonance imaging (MRI) compatible.</li> <li>Large hollow, cylindrical, slightly ribbed handle.</li> <li>Handle made of either chromium-plated or stainless steel</li> <li>Can be opened to insert two batteries (type LR14, size C, 1.5 V).</li> <li>Stud contact, fitting various sizes and types of depressors.</li> <li>ISO 7376:2009.</li> <li>Anesthetic and respiratory equipment — Laryngoscopes for tracheal intubation.</li> </ul>	
NIV Mask: Full Face or Oronasal	Nasal & Full face bipap mask Or Total Face bipap mask	
Mask	• Includes: 4-point headgear/single and dual limb circuit compatible/size: S, M, L and XL	
Non-invasive ventilator (BiPAP)	<ul> <li>CPAP/PEEP: 4 to 25 cm H2O</li> <li>IPAP: 4 to 40 cm H2O</li> <li>I-time (inspiratory time): 0.30 to 3.00 sec</li> <li>Max P (AVAPS maximum IPAP): 6 to 40 cm H2O</li> <li>Min P (AVAPS minimum IPAP): 5 to 30 cm H2O</li> <li>O2 (oxygen percent): 21 to 100%</li> <li>Ramp Time: Off, 5 to 45 min</li> <li>Rate (respiratory rate): 4 to 60 BPM</li> <li>Rise (rise time): 1 to 5</li> <li>Auto-adaptive leak compensation</li> <li>Modes of ventilation:</li> <li>CPAP – Continuous positive airway pressure</li> <li>S/T – Spontaneous with timed backup</li> <li>PCV – Pressure control ventilation</li> <li>Alarms required: Power Failure Alarm; gas disconnection; low battery, vent inoperative; minute volume, pressure, PEEP, apnea, occlusion, high respiration rate</li> </ul>	
Oxygen concentrator; Flow splitter	<ul> <li>Splitter of oxygen flow provided by an oxygen concentrator. Each flow can be adjusted individually via its flow meter, range: 0.125 to 2LPM (Liter Per Minute). The output nozzle can either be fit with tubing or left blank. Input pressure: 50 to 350kpa.</li> </ul>	
Oxygen concentrators****	Device concentrates oxygen from ambient air. On 4 antistatic swivel castors, 2 with brakes. Integrated handle allows for easy moving and positioning. Oxygen sensing device is integrated and measures concentration at flow meter entrance. Four-step filtering of air-intake, including bacterial filter. All filters replaceable, coarse filter washable/reusable. Continuous monitoring with visual and audible alerts, on low 'high output pressure, low oxygen concentration, power failure and battery test. Operating conditions: Temperature between 5 to 45 degrees Celsius, Relative humidity max. 90% without condensation. Spare parts should be required for operating at least one year.	

http://apps.who.int/iris/bitstream/handle/10665/199326/9789241509886\_eng.pdf;jsessionid=9A022BB1EEBA492F1F4EBB784449458C?sequence=1

<sup>\*\*</sup> WHO: https://www.who.int/medical\_devices/management\_use/mde\_tech\_spec/en/

<sup>††</sup> WHO Core: Concentrator, Oxygen: <a href="http://www.who.int/medical\_devices/innovation/hospt\_equip\_11.pdf">http://www.who.int/medical\_devices/innovation/hospt\_equip\_11.pdf</a>

<sup>&</sup>lt;sup>‡‡</sup> Oxygen Concentrator Technical Guidelines:



Item	Technical description and specifications	
Oxygen prongs, nasal, nonsterile, single use	<ul> <li>Consists of a plastic tube which fits behind the ears, and a set of two prongs which are placed in the nostrils.</li> <li>Soft twin prongs nasal tips to ensure equal oxygen flow to both.</li> <li>Star lumen main tube to avoid accidental blockage.</li> <li>Adjustable, smoothly finished, nasal tips for maximum patient comfort.</li> <li>Soft funnel shaped connector to facilitate easy connection to oxygen source.</li> <li>Oxygen tube length: approximately 2m.</li> <li>Adult and Pediatric sizes.</li> </ul>	
Oxygen tube, extension	• Tube used to deliver oxygen through the nose. Material: PVC. Automatic, open distal (patient) end, with 6 to 12 lateral eyes. Proximal end with connector enabling the tube to be connected to an oxygen supply tube of any diameter (e.g. Serrated male conical tip). Sterile, for single patient use. Diameter: CH 10. Length: 40cmshelf life: minimum 10 years. Bag and hands should be of white color.	
Percutaneous tracheostomy set	<ul> <li>Sterile, single dilator</li> <li>With Blue Line Ultra® Tube and Soft Seal® cuff</li> <li>Unique Blue Line Ultra® introducer</li> <li>Ergonomic handle design single dilator</li> <li>Tube 15 mm connector allows connection to breathing system or heat and moisture exchanger</li> </ul>	
Portable aspirator/ Suction system	<ul> <li>Adults and pediatric suction catheters should be less than half the internal diameter of the tracheal tube</li> <li>Vacuum Adjustment: Continuous</li> <li>Must be able to generate a vacuum of at least 0.85 bar (650mmhg)</li> <li>Maximum vacuum: 700 mmhg</li> <li>Minimum open tube flow rate at least 5 liters liquid per minute</li> <li>Twin suction bottles, minimum size 3 liters each</li> <li>Bottles to have an automatic cut off when full to prevent ingress of fluid to motor</li> <li>Airline to pump to incorporate bacterial filter</li> <li>Tubing to patient to be minimum 3m long, non-collapsible type</li> <li>Pedal and manual equipment suction function activation</li> <li>Sound Level: &lt; 70 dba.</li> <li>Castors: 75 mm diameter, unidirectional, anti-static</li> </ul>	
Portable transport ventilator	Same specifications as for ventilators	
Portable ultrasound probes, included with scanner	Convex abdominal probe, frequency range: 2.5 / 3.5 / 5.0 mhz	
Portable ultrasound scanner	<ul> <li>High performance ultrasound scanner.</li> <li>System integrates scanner, 2 probes, matching trolley and video-printer.</li> <li>Compact and lightweight, easy to transport and position.</li> <li>Alphanumeric keyboard with trackball and time gain control (TCG).</li> <li>Piezoelectric probes, electronically scanned: convex and linear.</li> <li>Sectorial transducer (which is used in the BLUE protocol).</li> <li>Linear transducer that covers frequencies between 5-10 mhz and one sectorial (2-5 mhz). So that the evaluation of "pulmonary sliding" is available (pulmonary point in case of pneumothorax).</li> <li>Imaging display modes: B, dual B, M, B and M.</li> <li>Adjustable field-of-view, 6 level zooms.</li> <li>Imaging technologies: dynamic frequency imaging, multi-stage focusing, aperture control.</li> <li>Depth range selection: convex sector image and linear image, 3 steps.</li> <li>Image orientation: lateral and vertical inversion (in B mode) Freeze function with storage of approx. 25 images Measurements and analysis:</li> <li>Caliber control: trackball.</li> </ul>	



Item	Technical description and specifications	
	<ul> <li>B-mode image: distance, area and circumference by ellipse and trace method, volume, ratio, gestational age, fetal weight, angle Gestational table: user programmable.</li> <li>M-mode: velocity, time interval, depth, heart rate, LV function Alpha-numeric &amp; graphics:</li> <li>Text annotations and body markers</li> <li>Automatic display of date and time, focal point setting, image orientation indicator, image scrolled position, distance scale mark, M-mode time mark, grey scale for calibration.</li> <li>High resolution B/W monitor, approx. 25 cm diagonal (across), equals to 10 inches, fit with reflection filter.</li> <li>Image grey scale: 256 levels.</li> <li>Video output: 625 lines/frame.</li> <li>Two transducer ports leave 2 probes permanently available, electronic switch between probes Data communication interface: RS232, BNC, IEEE, USB or equivalent Power supply may vary according to countries.</li> </ul>	
Portable ventilator	<ul> <li>Tidal volume up to 1,000 ml.</li> <li>Pressure (inspiratory) up to 80 cm H20.</li> <li>Volume (inspiratory) up to 120 L/min.</li> <li>Respiratory rate: up to 60 breaths per minute.</li> <li>SIMV Respiratory Rate: up to 40 breaths per minute.</li> <li>CPAP/PEEP up to 20 cm H2O.</li> <li>Pressure support up to 45 cm H2O.</li> <li>Fio2 between 21 to 100 %</li> <li>Inspiratory and expiratory times up to at least 2 sec and 8 sec respectively.</li> <li>I:E Ratio at least from 1:1 to 1:3.</li> <li>Modes of ventilation: a) Volume controlled. b) Pressure controlled. c) Pressure support. d) Synchronized intermittent mandatory ventilation (SIMV) with pressure support. e) Assist / control mode f) CPAP/PEEP.</li> <li>Alarms required: fio2, minute volume, pressure, PEEP, apnea, occlusion, high respiration rate, disconnection.</li> <li>System alarms required: power failure, gas disconnection, low battery, vent inoperative, self-diagnostics.</li> <li>If alarm silencing feature is incorporated, it must be temporary and clearly displayed when activated.</li> <li>Air and externally supplied oxygen mixture ratios fully controllable.</li> <li>Inlet gas supply (O2) pressure range at least 35 to 65 psi.</li> </ul>	
Pulse Oximeter	<ul> <li>Medical air compressor integral to unit, with inlet filter.</li> <li>Compact portable device measures arterial blood oxygen saturation (spo2), heart rate and signal strength. Measuring range: spo2 30 to 100% (minimum graduation 1%), Heart rate 20 to 250 bpm (minimum graduation 1bpm). Line-powered, or Extrabatteries/rechargeable batteries are required at least one year.</li> <li>ISO 80601-2-61:2011or equivalent.</li> </ul>	
Resuscitator, adult	<ul> <li>Resuscitator to ventilate adult (body weight over 30kg), with compressible self-refilling ventilation bag, capacity: 1475-2000ml Resuscitator operated by hand, Ventilation with ambient air. Resuscitator shall be easy, to disassemble and reassemble, to clean and disinfect, and be autoclavable. All parts must be manufactured from high-strength, long-life materials and require no special maintenance or storage conditions.</li> </ul>	
Resuscitator, child	long-life materials and require no special maintenance or storage conditions.  Resuscitator to ventilate child (body weight 7-30kg).  With compressible self-refilling ventilation bag, child, capacity: 500-700ml and non-rebreathing valve with pressure limiting valve, patient connector. Resuscitator operated by hand, Ventilation with ambient air.  Resuscitator shall be easy, to disassemble and reassemble, to clean and disinfect, and be autoclavable.	



Item	Technical description and specifications	
	All parts must be manufactured from high-strength, long-life materials and require no special maintenance or storage conditions	
Set of stainless-steel depressors	<ul> <li>Miller type:</li> <li>Straight Nr 1, length approx. 100 mm macintosh type:</li> <li>Curved Nr 2, length approx. 110 mm</li> <li>Curved Nr 3, length approx. 135 mm</li> <li>Curved Nr 4, length approx. 155 mm</li> </ul>	
Tracheal Tube Introducer (Bougie or Gum elastic Bougie)	<ul> <li>For oral intubation when the view of the larynx is suboptimal or endotracheal tube exchange</li> <li>Multiple or single use</li> <li>70 cm in length</li> <li>14 – 15 Fr in diameter</li> <li>For ET tubes from 6 to 11 mm of internal diameter</li> <li>30 degrees tip angle</li> </ul>	
Venturi Mask	Venturi mask system, oxygen inflow is connected to a specific color-coded entrainment device at the base of the mask that provides a set fio2 at a set oxygen inflow rate. Various entrainment devices can provide an fio2 of 0.24 to 0.5, with an oxygen inflow of 4 to 15 l/min and a total flow delivered to the patient (including entrained air) of 35 to 45 l/min. Disposable Single patient use. Non-Sterile packed sealed in Pouch. 210 cm long star lumen tubing to ensure continuous flow of oxygen.	



Table 2: Checklist for Medical Material for the case management of COVID-19 according to the level of care.

	Material checklist			
Level of care	Item	Verif	Verification	
	itelli	Yes	No	
	External defibrillator			
Infusion giving set, sterile, single use				
ъ	Heimlich Maneuver Assist device			
Early supportive therapy and monitoring	Oxygen concentrators			
aby	(Oxygen concentrator) Flow splitter			
heri	Oxygen prongs, nasal, nonsterile, single use - Adult			
e tl	Oxygen prongs, nasal, nonsterile, single use - Pediatric			
Ę	Oxygen tube, extension			
Early suppo monitoring	Portable ventilator			
sul	Pulse Oximeter			
arly ioni	Resuscitator, adult			
<u>й</u> Е	Resuscitator, child			
	Airway, Guedel, sterile, single use (range of sizes)			
	Carbon dioxide detector			
	Cardiovascular ultrasound imaging system			
	Endotracheal tube, without cuff			
	Endotracheal tube, with cuff			
	Esophageal tracheal airway (Combitube)			
	External defibrillator			
	Heimlich Maneuver Assist device			
	Infusion giving set			
~	Intercostal catheter (ICC)/ Chest tube			
اعور	Laryngeal mask (LMA)			
c sł	Laryngoscope – Adult			
èpti	Laryngoscope – Pediatric			
β Q	Non-invasive ventilator (BiPAP)		П	
ano	NIV Mask: Full Face or Oronasal Mask (S, M, L and XL)			
SDS	Oxygen concentrators			
Ą	(Oxygen concentrator) Flow splitter			
ure	Oxygen prongs, nasal, nonsterile, single use - Adult			
fail	Oxygen prongs, nasal, nonsterile, single use - Pediatric			
piratory failure, ARDS and Septic shock	Oxygen tube, extension	П	П	
ratı	Portable aspirator/ Suction system	П		
	Percutaneous tracheostomy set	П		
S S	Portable ultrasound scanner	П		
emi	Portable ultrasound probes, included with scanner			
Management of hypoxemic res	Portable ventilator			
hyr	Pulse Oximeter			
o	Resuscitator, adult			
ent	Resuscitator, adult			
me	Set of stainless-steel depressors			
nag	· · · · · · · · · · · · · · · · · · ·			
Aa	Tracheal Tube Introducer (Bougie or Gum elastic Bougie)  Venturi Mask			