Priority medical devices list for the COVID-19 response and associated technical specifications

INTERIM GUIDANCE

19 NOVEMBER 2020

World Health Organization

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Abbreviations

AC	alternating current
ANSI	American National Standards Institute
AP	anteroposterior
APAP/AutoPAP	automatic positive airway pressure
BiPAP/BPAP	bi-level positive airway pressure
B-mode	brightness mode
bpm	beats per minute
BS	British Standard
CAD	computer assisted detection
CDI	colour Doppler imaging
CE	Conformité Européenne
CGA	Compressed Gas Association (USA)
CMR	common mode rejection
CPAP	continuous positive airway pressure
CSA	Canadian Standards Association
CT	computed tomography
CTDI	CT dose index
CTDIvol	volumetric CT dose index
CTDIw	weighted CT dose index
DAP	dose area product
dB(A)	decibels (A-weighted)
DCP	Disease Commodity Package
DDR	direct digital radiography
DICOM	Digital Imaging and Communications in Medicine
DISS	Diameter Index Safety System
DLP	Dose Length Product
DSA	digital subtraction angiography
ECG	electrocardiogram
EEG	electroencephalogram
EQA	external quality assessment
ET	endotracheal
$EtCO_2$	colourimetric end-tidal CO_2
EU	European Union
FAT	factory acceptance test
FDA	Food and Drug Administration (USA)
FiO_2	fraction of inspired oxygen
FOV	field of view
FSC	free sales certificate
GB	gigabytes

GHS	Globally Harmonized System of Classification and Labelling of Chemicals
GMP	good manufacturing practice
HD	high definition
HDMI	high-definition multimedia interface
HFNC	high-flow nasal cannula
HFNO	high-flow nasal oxygen
HHHF	heated humidified high-flow
HIS	hospital information system
HME	heat moisture exchanger
HMEF	heat and moisture exchanger filter
HU	heat unit
IAEA	International Atomic Energy Agency
IBP	invasive blood pressure
ICU	intensive care unit
IFMBE	International Federation of Medical and Biological Engineering
IMDRF	International Medical Device Regulators Forum
IPC	infection prevention and control
IQC	internal quality control
IR	infrared
ISO	International Organization for Standardization
IV	intravenous
KAP	Kerma area product
kHU	kilo heat unit
kPa	kilopascal
kV	kilovolt
kVA	kilovolt-ampere
KVO	keep vein open
kVp	kilovoltage peak
kW	kilowatt
LAN	local area network
LCD	liquid crystal display
LDT	low dose tip
LED	light-emitting diode
L/min	litres per minute
LIS	laboratory information system
mA	milliampere
MAP	mean arterial pressure
mAs	milliampere seconds
MHz	megahertz
MinIP	minimum intensity projection
MIP	maximal intensity projection
M-mode	motion mode
MPR	multiplanar reformation
MRI	magnetic resonance imaging

MSK	musculoskeletal
MTF	Modulation Transfer Function
NAAT	nucleic acid amplification test
NFPA	National Fire Protection Association (USA)
NIBP	non-invasive blood pressure
NIST	National Institute of Standards and Technology (USA)
PA	posteroanterior
PAC	pressure assisted control
PACS	picture archiving and communication system
PC	pressure control
PCV	pressure control ventilation
PDI	power Doppler imaging
PE	polyethylene
PEEP	positive end-expiratory pressure
POC	point-of-care
PP	polypropylene
PRVC	pressure regulated volume control
PS	polystyrene
psi	pounds per square inch absolute
PSV	pressure support ventilation
PVC	polyvinyl chloride
RH	relative humidity
RIS	radiology information system
RR	respiratory rate
s/sec	second(s)
SARI	severe acute respiratory infection
SAT	site acceptance test (on-site)
SID	source to image receptor distance
SIMV	synchronized intermittent mandatory ventilation
SOPs	standard operating procedures
SpO_2	haemoglobin oxygen saturation
SPR	scan projection radiograph
TENS	transcutaneous electrical nerve stimulation
TFT	thin film transistor
TFT LCD	thin-film transistor liquid-crystal display
UL	Underwriters Laboratories (global certification scheme)
UPS	uninterruptible power supply
USB	universal serial bus
VCV	volume control ventilation
VRT	volume rendering technique
VTBI	volume to be infused selector
W	watt(s)
WHO	World Health Organization

1. Introduction

The WHO Priority Medical Devices project started in 2011, defining the methodology to select medical devices required by disease or by clinical intervention for diagnostic use, treatment or rehabilitation. The list has grown to include more diseases and health conditions. The final objective of the priority medical devices lists are that Member States use them as a reference to inform or develop their national lists, in order to ensure access, procurement, availability in health care settings and appropriate use. These lists are to be adapted by countries and settings, according to the available infrastructure, health workforce, financial resources and local priorities. In the past 5 years WHO has developed lists of priority devices required for reproductive, maternal, newborn and child health *(1)*, and for specific diseases such as cancer *(2)* and Ebola, and is developing lists for diabetes and cardiovascular diseases, and this publication to address priority medical devices for the current pandemic *(3)*.

1.1 Objective

In response to the global pandemic crisis and the need for a model reference list of basic and priority medical devices required for the COVID-19 response, this project was developed by the World Health Organization (WHO), following the latest available evidence on COVID-19 clinical management and infection prevention and control (IPC). The first version of the WHO list of priority medical devices for COVID-19 response, was published 9 April 2020 *(4)*. The present second version was drafted following the updated clinical guidelines in clinical management, use of diagnostic imaging and

rational use of personal protective equipment (PPE) as well as input from WHO regional offices *(5)* and expert review.

The first version, therefore, has been updated and is presented in this publication, along with most of the associated technical specifications describing quality and performance characteristics of the priority medical devices in order to support the incorporation, procurement, lease or donation of these products.

The priority medical devices list informed the Disease Commodity Package (DCP) *(6)*, the Emergency Global Supply Chain System (COVID-19) Catalogue *(7)* and the COVID-19 Partners Platform and Supply Portal, as well as other regional, and international agencies supporting the pandemic response.

On 3 March, WHO issued a call to industry and governments to increase production of PPE to meet the rising demand and to overcome the shortage of protection devices. On 8 April, the United Nations COVID-19 Supply Chain Taskforce was launched to scale up the procurement and distribution of PPE, in vitro diagnostics, oxygen and other related medical equipment.

Since then the Health Emergencies and Medical Devices units of WHO have defined technical specifications of priority medical devices, including PPE, to be procured by WHO and countries. The latest publications on PPE and technical specifications of oxygen concentrators and oxygen delivery therapy devices were considered.

In order to facilitate access to the priority medical devices selected, technical specifications were drafted to allow procurement or donations of these technologies and to ensure good quality products. These technical specifications are provided in the following chapters.

The list of priority medical devices *(4)* and DCP *(6)* were published on the WHO COVID-19 website so that countries, nongovernmental organizations, partners and funding agencies can determine the technologies needed. Several iterations of the specifications and lists have taken place, responding to the latest available evidence on transmission, diagnostics and clinical management of the disease, while awaiting a vaccine and medicines targeted to the treatment of severe cases.

The Medical Devices unit produces a WHO medical devices newsletter and advises stakeholders on the priority devices lists and technical specifications available, to raise awareness and support information dissemination, to ensure access of these priority devices.

Current and future situation

Knowledge on the origins, symptoms, method of contagion and many other specificities of COVID-19 are constantly evolving, as new studies and developments emerge every day, affecting the way COVID-19 is perceived and tackled. The global spread of SARS-CoV-2 has created the need for this consolidated medical device guidance, which will be updated if new evidence is available, otherwise a revision will be foreseen in 2 years, as new technologies are also developed.

1.2 Target audience

This document is recommended to support decision-making regarding the selection, incorporation, allocation and use of medical devices in the context of COVID-19 and is intended for health care providers, managers of severe acute respiratory infection (SARI) units, procurement and regulatory agencies, policy-makers and planning officers in ministries of health. It also informs biomedical engineering professionals, the private health sector, medical device industry and intergovernmental and international agencies on the characteristics of the products required.

WHO recommends involving biomedical or clinical engineers, along with clinical doctors, physician assistants, nurses, diagnostic and laboratory technicians, radiographers, respiratory therapists, and intensive care nurses in the selection of the medical devices requested, according to clinical needs and local infrastructure, and for verification of installation and operation of the equipment and to ensure training of the health care workforce.

1.3 Methodology

In order to select the devices and to describe the characteristics, different methodologies were used and outcomes produced, therefore this publication is divided into two parts:

- Part A: List of priority medical devices for COVID-19
- Part B: Technical specifications

Each of these parts had a different procedure which is described below:

Part A: Methodology to develop the list of priority devices in the context of COVID-19

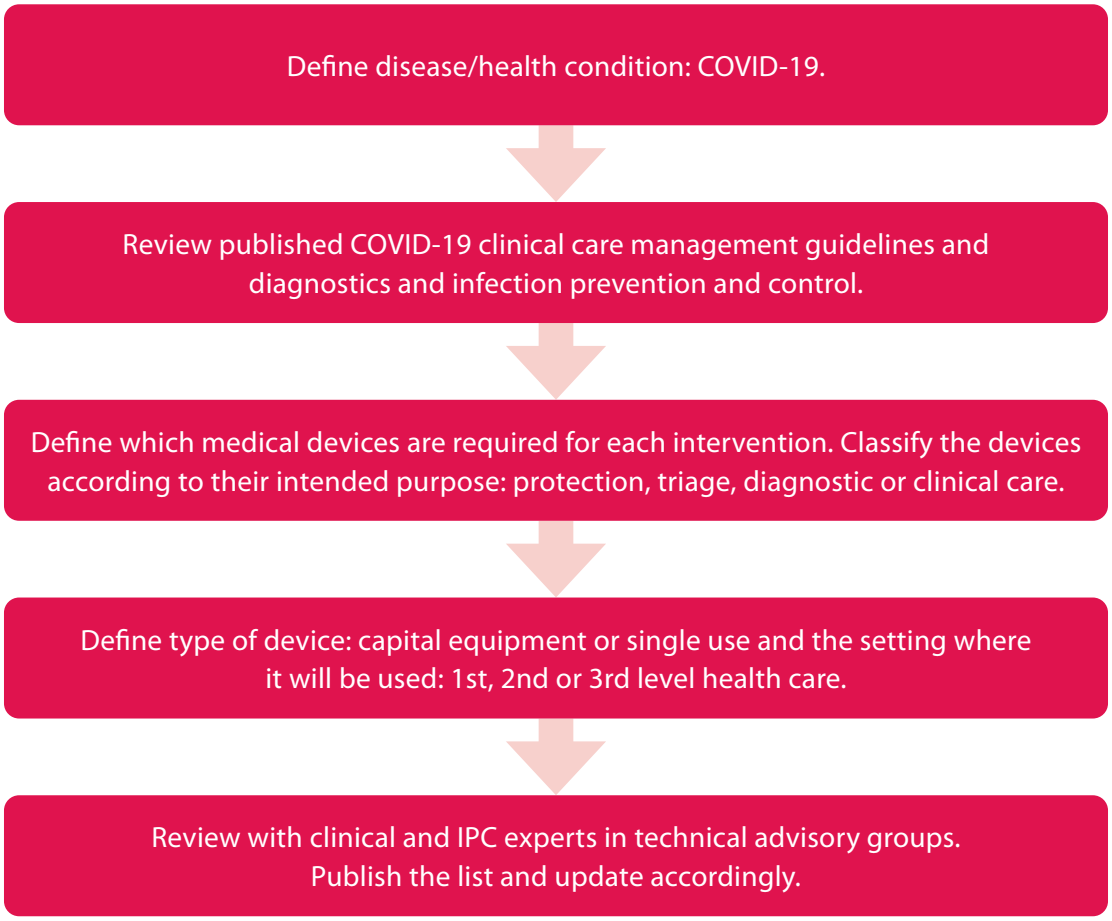
Considering the WHO COVID-19 clinical management guideline *(8)* and the rational use of PPE guidance *(9)*, as well as recent technical specifications on ventilators, on oxygen delivery systems, and the use of chest imaging in COVID-19: a rapid advice guide *(10)*, the WHO Secretariat drafted the second version of the list of priority medical devices to be used for COVID-19.

The list was based on the clinical management guidelines and the definitions of the technologies needed for those interventions. The present revised second version was updated according to the most recent evidence, reviewed with WHO regional advisors and by the members of the Technical Advisory Group of experts of Respiratory Clinical Panel established in May 2020. Fig. 1.1 describes the steps followed.

The main differences between the first and second version of the list are inclusion of:

- Three types of invasive ventilators, including the sub-acute ventilator besides the intensive care and transport ones.
- Imaging equipment: ultrasound, X-ray and CT scanner.
- Automated polymerase chain reaction (PCR) and antigen diagnostics.
- Medical mask level 2 for health care workers.

Fig. 1.1 Methodological steps



Part B: Methodology to develop the technical specifications for the priority medical devices

This part defines the technical characteristics developed to define the minimum requirements for the product to ensure good quality, safety and efficacy. The process to develop these specifications included: a review of recent publications of WHO technical specifications for medical devices; analysis of the technologies required to perform the clinical management of COVID-19 *(11)*; analysis of existing products in the market, based on approval from the regulatory agencies; analysis of international, regional and country standards; device overviews, specifications and comparative data published by ECRI *(12)*, an evidence-based practice centre, which is a non-profit, independent organization that conducts independent medical device evaluations; revision and comments from the WHO Respiratory Experts ad hoc panel, and clinical engineer experts from the International Federation of Medical and Biological Engineering (IFMBE) Clinical Engineering Division ad hoc panel. It should be noted that all members of both panels provided Conflict of Interest documents, which were reviewed by WHO and no conflicts of interest were found.

In the case of the three imaging devices, the development was done jointly with the IAEA Division of Human Health: Nuclear Medicine and Diagnostic Imaging and Dosimetry and Medical Radiation Physics sections and discussed with specialized professional organizations in official relations with WHO, including International Society of Radiology, International Society of Radiographers & Radiological Technologists, International Organization for Medical Physics, IFMBE, and the Global Diagnostics Imaging Healthcare IT & Radiation Therapy Trade Association.

1.4 Considerations

An assessment of the health facility is required prior to choosing equipment from the list in order to have a fully functional unit. For more details consult the technical specifications per equipment in the subsequent chapters. Quantities of accessories and consumables for starting operation are not disaggregated in this list. These should be provided with the purchase of the equipment, enough for at least 3 months of operation. An extended warranty of at least 1 year and additional spare parts for maintenance should be also aggregated, according to the health care capacity. Note: Training is indispensable for many of the medical devices listed, but especially important for invasive ventilation.

Most of the priority devices listed in this publication have been considered in the WHO Emergency global supply chain system (COVID-19) catalogue *(7)*.

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PART A:
LIST OF PRIORITY MEDICAL DEVICES IN THE CONTEXT OF COVID-19

2. Priority medical devices in the context of COVID-19

2.1 Interventions by clinical area

Considering the latest evidence-based WHO COVID-19 clinical care management, diagnostics and IPC guidelines, the clinical interventions are listed, to be able to define the medical devices requested.

Table 2.1 describes the interventions and levels of health care and clinical area. The first level is for outpatients, including home care; the second level includes general hospitals and laboratories; and the third level includes specialized hospitals with intensive care units (ICUs) and SARI units. The technologies listed are for the interventions and should be adapted to the caregiver, health care workforce, IPC, infrastructure and technological resources available.

Table 2.1 Interventions by clinical area

Clinical area	Intervention	Triage	Severe patients	Critical patients	1st level	2nd level	3rd level
Clinical assessment	Body temperature assessment	●	●	●	●	●	●
	Oxygen saturation assessment	●	●	●	●	●	●
Medical imaging	Ultrasound scan		●	●		●	●
	CT scan		●	●		●	●
	X-ray scan, chest		●	●		●	●
Clinical laboratory	Blood gas analysis		●	●		●	●
	RT-PCR test	●	●	●	○	●	●
	Antigen test	●	●	●	●	●	●
Clinical care	Multiparametric monitoring		●	●		●	●
	Oxygen therapy		●	●	●	●	●
	Airway management and intubation		●	●		●	●
	Non-invasive ventilation		●	●		●	●
	Invasive ventilation			●		●	●
	Infusion therapy		●	●		●	●
	Intensive care treatment			●		●	●
	Central venous catheter placement			●			●
	Gastroenteral feeding			●			●
	Urine collection		●	●		●	●
Protective equipment	General	●	●	●	●	●	●
	Personal protection	●	●	●	●	●	●
	Sterilization	●	●	●	●	●	●

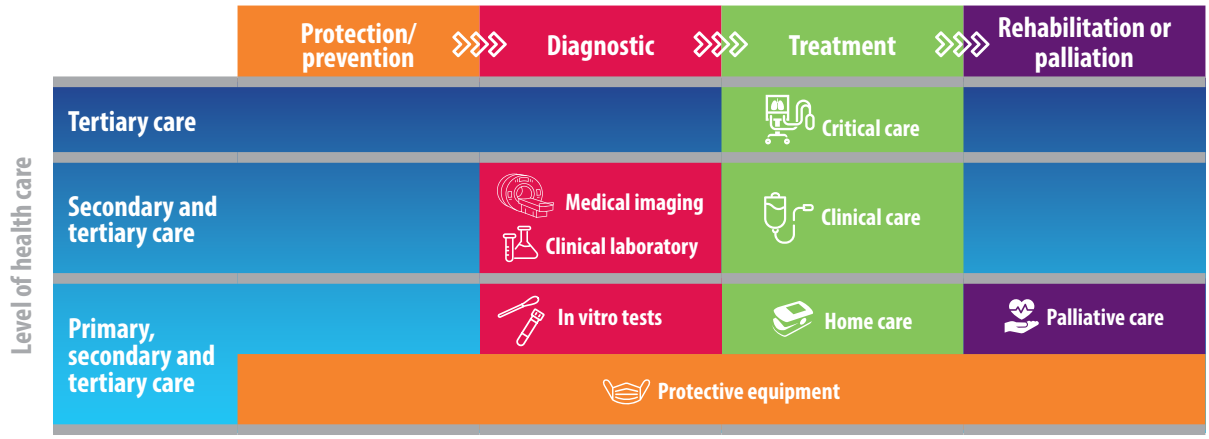
Note: ○ – sample collection

2.2 Navigation diagram

The list of priority medical devices in the context of COVID-19 provides descriptions for clinical management at different levels of health care provision.

Considering the site for the clinical intervention, the use of priority medical devices in the protection, diagnosis, treatment and palliative care of COVID-19 is described. Following the table above on the clinical interventions in the clinical units, a navigation diagram is presented in Fig. 2.1.

Fig. 2.1 Navigation diagram



Early diagnosis can take place in primary health care; obtaining samples from the community and sending them to national reference laboratories and laboratories in specialized hospitals. The treatment of severe and critical patients is mostly done in inpatient wards in general and specialized hospitals in secondary and tertiary levels and the critically ill are treated in intensive care units (ICU). The management of cases in each setting depends on the health workforce available, and technologies available, which can be adapted in every country as needed.

Home care for patients with suspected or confirmed COVID-19, requires that the caregiver should have appropriate PPE and adopt IPC measures. A home pulse oximeter is an important tool to identify hypoxia before the patient shows worsening symptoms that might require hospital care. Palliative care can also take place at home, where patients should have access to a caregiver, along with medicines, medical equipment and social support.

As in vitro diagnostics are developed, sampling and diagnostics could change and it should be considered that the clinical management of patients may change with future research evidence and depending on the availability of a vaccine or specific therapeutics. The following section 2.3 lists the devices by clinical area.

2.3 Priority medical devices by clinical area

Clinical assessment

Intervention	Medical device generic name	
Body temperature assessment	Infrared thermometer	
	Digital thermometer	
Oxygen saturation assessment	Pulse oximeter	Portable handheld, with cables and sensor Fingertip Tabletop, with cables and sensor

Medical imaging

Intervention	Medical device generic name
Ultrasound scan	Ultrasound, portable with linear and phased array transducers for basic cardiac and lung studies, wheeled cart or trolley
CT scan	Computed tomography (CT) system (multi-slice) with control console and indipendent workstation
X-ray scan, chest	General purpose mobile digital radiography system

Clinical laboratory

Intervention	Medical device generic name	Accessories/consumables/single-use devices
Blood gas analysis	Blood gas analyser, portable	Cartridges Control solutions Arterial blood sample kits (syringes with dry lithium heparin [23.5 IU/mL])
Nucleic acid amplification test (NAAT)	Real-time PCR detection systems PCR work stations Nucleic acid extraction systems Vortex Centrifuge Biosafety cabinet Refrigerator (to store specimens if applicable) Freezer (to store kits/reagents if applicable)	PPE (mask, gloves and protective goggles) Sterile sampling swabs Viral transport media Amplification reagents and controls Micropipettes Sterile, nuclease-free disposable pipette tips with filters Nucleic acid extraction reagents and controls Additional reagents and controls as required by the test Biohazardous waste bags/rigid containers
Antigen test	Rapid diagnostic test device/kit Dedicated analyser for reading/ interpretation of results (if applicable) Refrigerator (to store kits and/or specimens if applicable)	PPE (mask, gloves, protective goggles) Sterile sampling swabs Viral transport media (if applicable) Reaction tubes Extraction buffer Micropipette Dispensing tips Timer Rack for reaction tubes Biohazardous waste bags/rigid containers

Clinical care

Intervention	Medical device generic name	Accessories/consumables/single-use devices
Multiparametric monitors have many accessories and you find those, to be included per category, here in the last column	Advanced: for ECG, CO_2, invasive blood pressure (IBP), non-invasive blood pressure (NIBP), oxygen saturation (SpO_2), respiratory rate (RR) and temperature (TEMP) (with accessories)	Lead ECG cable: 2 per equipment Lead ECG cable (if option offered): 2 per equipment Sets of ECG connection electrodes (if reusable type): 5 sets Tubes electrode gel (if required): 5 tubes Reusable SpO_2 probes adult: 3 probes Reusable SpO_2 probes paediatric use: 3 probes Blood pressure – non-invasive: 3 paediatric reusable cuffs; 3 adult reusable cuffs Blood pressure – invasive: 1 sensor for each channel offered External skin temperature probes: 2 probes If CO_2 mainstream technology: tube adapter: 3 per equipment; sensor: 3 per equipment If CO_2 side stream technology: sample lines: 100 lines; water traps: 10 per equipment Battery: 1 set
	Intermediate: for ECG, non-invasive blood pressure (NIBP), oxygen saturation (SpO_2), respiratory rate (RR) and temperature (TEMP) (with accessories)	Lead ECG cables Sets of ECG connection electrodes Tubes electrode gel Reusable SpO_2 probes for adult and paediatric Blood pressure – non-invasive adult and paediatric reusable cuffs External skin temperature probes If CO_2 mainstream technology: tube adapters and sensors If CO_2 side stream technology: sample lines and water traps Set of batteries
	Basic: for non-invasive blood pressure (NIBP) and oxygen saturation (SpO_2) (with accessories)	Reusable SpO_2 probes for adult and paediatric Blood pressure – non-invasive adult and paediatric reusable cuffs Set of batteries
Oxygen therapy	Concentrator O_2, 10 L/min, with accessories	Non-heated bubble humidifier Tubing, medical gases, int. diam. 5 mm Flow splitter, 5 flowmeters 0–2 L/min, for paediatric use Catheter, nasal, 40 cm, with lateral eyes, sterile, single use; different sizes: 10 Fr, 12 Fr, 14 Fr, 16 Fr, 18 Fr Nasal oxygen cannula, with prongs, adult and paediatric Venturi mask, with percent O_2 lock and tubing, adult and paediatric
	Medical gas cylinder, portable, for oxygen, fitted with a valve and a pressure and flow regulator	Non-heated bubble humidifier Tubing, medical gases, int. diam. 5 mm Flow splitter, 5 flowmeters 0–2 L/min, for paediatric use Flowmeter, Thorpe tube, for oxygen 0–15 L/min Catheter, nasal, 40 cm, with lateral eyes, sterile, single use; different sizes: 10 Fr, 12 Fr, 14 Fr, 16 Fr, 18 Fr Nasal oxygen cannula, with prongs, adult and paediatric Mask, oxygen, with connection tube, reservoir bag and valve, high-concentration, adult and paediatric non-sterile, single use Venturi mask, with percent O_2 lock and tubing, adult and paediatric

Clinical care (continued)

Intervention	Medical device generic name		Accessories/consumables/single-use devices	
Airway management and intubation	Laryngoscope	Fibre optic, diameter 28 mm, with blades *or* Video-laryngoscope, with blades and accessories	Compressible self-refilling ventilation bag for adult, capacity > 1500 mL, with masks (small, medium, large) Airway, nasopharyngeal, sterile, single use, set with sizes of: 20 Fr, 22 Fr, 24 Fr, 26 Fr, 28 Fr, 30 Fr, 32 Fr, 34 Fr, 36 Fr Airway, oropharyngeal, Guedel, set with sizes of: No. 2 (70 mm), No. 3 (80 mm), No. 4 (90 mm), No. 5 (100 mm) Colourimetric end tidal CO_2 detector, adult and paediatric, single use Cricothyrotomy, set, emergency, 6 mm, sterile, single use Syringe, Luer slip, 10 mL, sterile, single use	
			Endotracheal tube introducer	Stylet, sterile, single use, sizes: 10 Fr, 30 to 45 cm and 14 Fr, 30 to 45 cm
				Bougie, sterile, single use, sizes: 10 Fr, 60 cm and 15 Fr, 70 cm
			Tube, endotracheal	No. 2, No. 2.5, No. 3, No. 3.5, No. 4, No. 5, without cuff, sterile, single use
				No. 4, No. 5, No. 6, No. 7, No. 8, No. 9, with cuff, sterile, single use
			Laryngeal mask airway (LMA), size 2, size 3, size 4, sterile, single use Lubricating jelly Forceps Magill, 24 cm	
Non-invasive ventilation	Continuous positive airway pressure (CPAP), for adult and paediatric, with accessories			
	Bilevel positive airway pressure unit (BiPAP), for adult and paediatric, with accessories			
	High-flow nasal cannula, with accessories			
Invasive ventilation	Ventilator for intensive care unit, for adult and paediatric with accessories			
	Ventilator for transport, for adult and paediatric with accessories			
	Ventilator for sub-acute care, for adult and paediatric with accessories			
Infusion therapy	Electronic drop counter, IV fluids			
	Infusion pump, with accessories			
Intensive care treatment	Electrocardiograph, portable, with accessories			
	Suction pump	Electrical, with accessories		
		Manual		
Central venous catheter placement	Central venous catheters kit with: finder needle, syringe, wire, dilator, lidocaine, scalpel, needle, thread			
	Transparent adhesive plasters, wash proof, 5 × 5 cm			

Clinical care (continued)

Intervention	Medical device generic name	Accessories/consumables/single-use devices
Gastroenteral feeding	Basin kidney, stainless steel, 825 mL	Syringe, feeding, LDT, ENFit, sterile, single use, sizes: 1 mL, 2.5 mL, 5 mL Syringe, feeding, ENFit, sterile, single use, sizes: 10 mL, 20 mL, 60 mL Tube, feeding, nasogastric, ENFit tip, sterile, single use, sizes: 6 Fr, 50 cm / 8 Fr, 50 cm / 10 Fr, 50 cm / 12 Fr, 90 cm / 14 Fr, 90 cm Stethoscope, binaural, adult/child, single use Lubricating jelly Pad, absorbent
Urine collection		Bag, collecting, urine, with outlet tap, with non-return valve, 2000 mL, adult, non-sterile, single use Catheter, urethral, Foley, 2-way, sterile, single use, set of sizes of: 10 Fr, 12 Fr, 14 Fr, 16 Fr, 18 Fr

Protective equipment

Intervention	Medical device generic name	Accessories/consumables/single-use devices
General		Antiseptic wipe with alcohol and chlorhexidine Compress, gauze, 10 × 10 cm, 8–12 ply, sterile, single use Tape, surgical, hypoallergenic, .025 × 5 m Drape, surgical, non-woven, sterile, single use
Personal protection		Medical/surgical mask Respirator Face shield, single use Protective goggles, wraparound, soft frame, indirect vent Surgical gowns/isolation gowns, non-sterile Apron, plastic, single use Gloves, examination, nitrile, powder-free, large, medium, small, non-sterile, single use
Sterilization	Autoclave, 40–60 L, with accessories	Blood sample kits (syringes, tags, tubes)

2.4 Medical devices for case management of severe and critical patients by health facility level

Type	Medical purpose	Medical device generic name	Triage	Treatment of severe patients	Treatment of critical patients	1st level	2nd level	3rd level	For the latest technical guidance, please refer to: https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance-publications
Medical equipment	**Screening and monitoring**	Infrared thermometer	●			■	■	■	Screening – mass casuality
		Digital thermometer		●	●	■	■	■	Patient care
		Pulse oximeter – fingertip	●				■	■	Option 1
		Pulse oximeter – portable handheld (with accessories)		●	●	■	■	■	Option 2
		Pulse oximeter – tabletop (with accessories)		●	●		■	■	Option 3
		Stethoscope, binaural, adult/child, single use		●	●	■	■	■	
		Electrocardiograph, portable (with accessories)		●	●		■	■	Equipment per ward
		Patient monitor multiparametric: basic – for non-invasive blood pressure (NIBP) and oxygen saturation (SpO_2) (with accessories)		●	●		■	■	Option 1 – basic
		Patient monitor multiparametric: intermediate – for ECG, non-invasive blood pressure (NIBP), oxygen saturation (SpO_2), respiratory rate (RR) and temperature (TEMP) (with accessories)		●	●		■	■	Option 2 – intermediate
		Patient monitor multiparametric: advanced – for ECG, CO_2, invasive blood pressure (IBP), non-invasive blood pressure (NIBP), oxygen saturation (SpO_2), respiratory rate (RR) and temperature (TEMP) (with accessories)			●		■	■	Option 3 – advanced

Medical devices for case management of severe and critical patients by health facility level (continued)

Type	Medical purpose	Medical device generic name	Triage	Treatment of severe patients	Treatment of critical patients	1st level	2nd level	3rd level	For the latest technical guidance, please refer to: https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance-publications
Medical equipment (continued)	**Oxygen therapy** Oxygen source to be selected according to capability of the health facility (i.e. power supply, pipeline oxygen network)	Concentrator O_2, portable (with accessories)		●	●	■	■	■	Option 1 – recommended that the device provides at least 5 L/min and has electrical protection (power surge)
		Medical gas cylinder, portable, for oxygen, fitted with valve, and pressure and flow regulator		●	●	■	■	■	Option 2 – sizes, labelling and connections are according to international regulations; and refilling and transport are according to manufacturer's quality procedures
		Other sources of oxygen, such as pressure swing adsorption (PSA) plants, liquid oxygen thermos can be added		●	●		■	■	Require special infrastructure and piped lines inside health facility
	Airway management and intubation	Laryngoscope, fibre optic, diameter 28 mm (with blades)			●		■	■	Option 1 – to be chosen by the clinician
		Video-laryngoscope (with blades and accessories)			●		■	■	Option 2 – to be chosen by the clinician according to training skills and infrastructure capabilities
	Mechanical ventilation To perform invasive ventilation requires trained staff	Ventilator for ICU, for adult and paediatric (with accessories)			●			■	Option 1 – two sub-options depending of the oxygen inlet (only high pressure or both high and low pressure)
		Ventilator for transport, for adult and paediatric (with accessories)			●		■	■	Option 2 – transport ventilator
		Ventilator for sub-acute care, for adult and paediatric (with accessories)			●		■	■	Option 3 – sub-acute care ventilator (mainly non-invasive but can provide invasive ventilation)

Medical devices for case management of severe and critical patients by health facility level (continued)

Type	Medical purpose	Medical device generic name	Triage	Treatment of severe patients	Treatment of critical patients	1st level	2nd level	3rd level	For the latest technical guidance, please refer to: https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance-publications
Medical equipment (continued)	**Non-invasive ventilation** Clinical decision according to the management of patient; generated aerosols require special protective equipment measures to minimize the risk of contagion	Continuous positive airway pressure (CPAP), for adult and paediatric (with accessories)			●		■	■	Requires special mask for patient, special protection for health care worker and oxygen flow and pressure
		Bilevel positive airway pressure (BiPAP) unit, for adult and paediatric (with accessories)			●		■	■	Requires special mask for patient, special protection for health care worker and oxygen flow and pressure
		High-flow nasal cannula (HFNC), with tubing and patient interfaces for adult and paediatric (with accessories)			●		■	■	Option to be chosen by the clinician; the device can provide more than 50 L/min
	IV infusion	Electronic drop counter, IV fluids		●	●		■	■	
		Infusion pump (with accessories)		●	●		■	■	
	Blood chemistry	Blood gas analyser, portable, with cartridges and control solutions		●	●		■	■	Consider some options that may be already available (e.g. automated clinical chemistry analysers)
	Imaging To support diagnostics and follow up of COVID-19 patients, but these equipment are to serve many other patients/units in the facility	Ultrasound, portable (with accessories)		●	●		■	■	Medical equipment that requires trained staff
		Radiographic mobile digital equipment		●	●		■	■	Medical equipment that requires trained staff
		Computed tomography (CT) scanning system			●			■	Medical equipment that requires trained staff and special infrastructure
	Suction pump	Suction pump, electrical (with accessories)			●		■	■	Option 1 – desirable
		Suction pump, manual			●		■	■	Option 2

Medical devices for case management of severe and critical patients by health facility level (continued)

Type	Medical purpose	Medical device generic name	Triage	Treatment of severe patients	Treatment of critical patients	1st level	2nd level	3rd level	For the latest technical guidance, please refer to: https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance-publications
Accessories and consumables associated with medical equipment	**Oxygen delivery devices** Accessories for ventilator equipment listed above	Bubble humidifier, non-heated		●			■	■	Ensure compatibility with equipment connector
		Tubing, medical gases, internal diameter 5 mm		●	●	■	■	■	
		Flow splitter, 5 flowmeters, 0–2 L/min, for paediatric use		●		■	■	■	
		Flowmeter, Thorpe tube, for oxygen, 0–15 L/min		●	●	■	■	■	For piped oxygen; it should be adapted for the type of oxygen outlet available in the country
Consumables (single-use devices) Some of the generic consumables may be available in the health facility. They are disaggregated according to medical procedure	**Airway management and intubation**	Catheter, nasal, 40 cm, with lateral eyes, sterile, single use; different sizes: 10 Fr, 12 Fr, 14 Fr, 16 Fr, 18 Fr		●	●		■	■	—
		Nasal oxygen cannula, with prongs, adult and paediatric		●	●	■	■	■	Recommended for flows 1–6 L/min
		Mask, oxygen, with connection tube, reservoir bag and valve, high-concentration, adult and paediatric non-sterile, single use		●	●	■	■	■	Recommended for flows 10–15 L/min
		Venturi mask, with percentage O_2 lock and tubing, adult and paediatric		●	●	■	■	■	FiO_2 can be regulated
		Compressible self-refilling ventilation bag for adult, capacity > 1500 mL, with masks (small, medium, large)		●	●	■	■	■	
		Airway, nasopharyngeal, sterile, single use, set with sizes of: 20 Fr, 22 Fr, 24 Fr, 26 Fr, 28 Fr, 30 Fr, 32 Fr, 34 Fr, 36 Fr		●	●		■	■	

Medical devices for case management of severe and critical patients by health facility level (continued)

Type	Medical purpose	Medical device generic name	Triage	Treatment of severe patients	Treatment of critical patients	1st level	2nd level	3rd level	For the latest technical guidance, please refer to: https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance-publications
Consumables (single-use devices) (continued)	**Airway management and intubation**	Airway, oropharyngeal, Guedel, set with sizes of: No. 2 (70 mm), No. 3 (80 mm), No. 4 (90 mm), No. 5 (100 mm)		●	●		■	■	
		Colourimetric end tidal CO_2 detector, adult and paediatric, single use			●		■	■	
		Cricothyrotomy, set, emergency, 6 mm, sterile, single use			●		■	■	
		Syringe, Luer slip, 10 mL, sterile, single use			●		■	■	
		Endotracheal tube introducer, stylet, sterile, single use, sizes: 10 Fr, 30–45 cm and 14 Fr, 30–45 cm			●		■	■	Option 1 – to be chosen by the clinician
		Endotracheal tube introducer, bougie, sterile, single use, sizes: 10 Fr, 60 cm and 15 Fr, 70 cm			●		■	■	Option 2 – to be chosen by the clinician
		Tube, endotracheal, No. 2, No. 2.5, No. 3, No. 3.5, No. 4, No. 5, without cuff, sterile, single use			●		■	■	Option 1 – to be chosen by the clinician
		Tube, endotracheal, No. 4, No. 5, No. 6, No. 7, No. 8, No. 9, with cuff, sterile, single use			●		■	■	
		Laryngeal mask airway (LMA), size 2, size 3, size 4, sterile, single use			●		■	■	Option 2 – to be chosen by the clinician
		Lubricating jelly			●		■	■	
	Blood chemistry	Arterial blood sample kits (syringes with dry lithium heparin [23.5 IU/mL])		●	●		■	■	Sample to be sent to laboratory

Medical devices for case management of severe and critical patients by health facility level (continued)

Type	Medical purpose	Medical device generic name	Triage	Treatment of severe patients	Treatment of critical patients	1st level	2nd level	3rd level	For the latest technical guidance, please refer to: https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance-publications
Consumables (single-use devices) (continued)	**Central venous line**	Central venous catheters kit with: finder needle, syringe, wire, dilator, lidocaine, scalpel, needle, thread			●			■	
		Transparent adhesive plasters, wash proof, 5 × 5 cm		●	●		■	■	
	Gastroenteral feeding	Syringe, feeding, LDT, ENFit, sterile, single use, sizes: 1 mL, 2.5 mL, 5 mL			●			■	
		Syringe, feeding, ENFit, sterile, single use, sizes: 10 mL, 20 mL, 60 mL			●			■	
		Tube, feeding, nasogastric, ENFit tip, sterile, single use, sizes: 6 Fr, 50 cm / 8 Fr, 50 cm / 10 Fr, 50 cm / 12 Fr, 90 cm / 14 Fr, 90 cm			●			■	
		Conductive gel, container		●	●		■	■	For ECG and ultrasound
		Antiseptic wipe with alcohol and chlorhexidine	●	●	●	■	■	■	
		Compress, gauze, 10 × 10 cm, 8–12 ply, sterile, single use		●	●	■	■	■	
		Tape, surgical, hypoallergenic, .025 × 5 m		●	●	■	■	■	
		Drape, surgical, non woven, sterile, single use		●	●	■	■	■	
	Urine collection	Bag, collecting, urine, with outlet tap, with non-return valve, 2000 mL, adult, non-sterile, single use		●	●		■	■	
		Catheter, urethral, Foley, 2-way, sterile, single use, set of sizes of: 10 Fr, 12 Fr, 14 Fr, 16 Fr, 18 Fr		●	●		■	■	

Medical devices for case management of severe and critical patients by health facility level (continued)

Type	Medical purpose	Medical device generic name	Triage	Treatment of severe patients	Treatment of critical patients	1st level	2nd level	3rd level	For the latest technical guidance, please refer to: https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance-publications
Instruments and utensils		Forceps Magill, 24 cm			●		■	■	
		Basin kidney, stainless steel, 825 mL		●	●		■	■	
Personal protective equipment	**Health worker personal protection**	Medical/surgical mask	●	●	●	■	■	■	https://www.who.int/publications/i/item/WHO-2019-nCoV-PPE_specifications-2020.1
		Medical mask	●	●	●	■	■	■	
		Respirator masks (i.e. N95, FPP2)		●	●		■	■	Reserve for aerosol-generating procedures
		Face shield, single use	●	●	●	■	■	■	
		Protective goggles	●	●	●	■	■	■	
		Surgical gowns (sterile)		●	●		■	■	
		Isolation gowns (non-sterile)	●	●	●	■	■	■	
		Apron, plastic, single use			●		■	■	
		Gloves surgical (sterile, powder free)		●	●	■	■	■	
		Gloves, medical examination (non -sterile), single use	●	●	●	■	■	■	
In vitro diagnostics tests		Triple packaging boxes for transport	●	●	●	■	■	■	https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/laboratory-guidance
		Sample collection kit: swag and transport medium	●	●	●	■	■	■	
		Extraction kit	●	●	●	■	■	■	
		Thermocyclers for RT-PCR, manual (open system)		●	●		■	■	
		Thermocyclers for RT-PCR automated (closed system)		●	●		■	■	https://www.who.int/diagnostics_laboratory/200710_eul_sars_cov2_product_list.pdf?ua=1

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PART B:
TECHNICAL SPECIFICATIONS

3. Technical specifications for oxygen therapy and monitoring devices

3.1 Context and considerations

Approximately 14% of people with COVID-19 develop severe disease requiring hospitalization and oxygen support and 5% require admission to an intensive care unit. A complete oxygen system must consist of the following elements: oxygen sources; delivery devices; regulation and conditioning devices; and patient monitoring devices.

The aim of this chapter is to provide a compilation of the technical specifications for devices for oxygen supply, delivery, regulation and conditioning, and patient monitoring included in the WHO List of priority medical devices for COVID-19 case management. The technical specifications do not entail treatment options or IPC aspects.

The content of the technical specifications has been directly sourced from the publication WHO-UNICEF Technical specifications and guidance for oxygen therapy devices *(1)* for some of the products. Additionally, other technical specifications of products included in the WHO List of priority medical devices for COVID-19 case management, have been included.

Supplementary equipment for electrical safety purposes and inspection quality control must be purchased accordingly when delivering oxygen, such as:

- oxygen analyser;
- voltage corrector/stabilizer/UPS, depending on the local electrical supply availability and quality;
- strong chain or strap, rack wall, work bench or hand trolley capable of preventing cylinders from falling or being knocked over.

In WHO-UNICEF Technical specifications and guidance for oxygen therapy devices *(1)*, further harmonized product specifications for a wide range of oxygen products, and extensive guidance on selection, procurement, use and maintenance, can be found.

All medical equipment must be purchased with:

- consumables required to operate for a minimum 3 months;
- user care instructions and protocols, including guidance for replacement of accessories and consumables and safe decontamination of reusable parts, indicating if they are generic or brand related;
- technical maintenance protocols; and
- training for users and technical teams (provided in an online format, if possible).

3.2 Definitions and intended use

Oxygen supply devices

Oxygen concentrator: An electrically powered medical device designed to concentrate oxygen from ambient air. Used to deliver oxygen at the bedside, typically through an attached nasal cannula (or prongs), to a patient requiring oxygen therapy. The intended use or clinical purpose is the delivery of low-flow, continuous, clean and concentrated oxygen (> 82%) from room air (21%).

Oxygen cylinder: Compressed oxygen and medical air cylinders are dedicated refillable containers for holding oxygen/medical gases in a high-pressure, non-liquid state. They are fitted with a valve and a pressure regulator, that also includes a flow regulator in the integral valve version, for supplying 50 psi oxygen and medical air to other medical devices, or low-pressure supply to the patient if an integral valve is installed. The cylinders are available in various standard sizes and are supplied with regulators and fittings for all international standards.

The oxygen supply devices included in this section are only those that are located at the bedside of the patient. Oxygen sources at scale (e.g. cryogenic tanks or pressure swing adsorption generator plants) are not considered in this document.

Table 3.1 Cylinder sizes common in health facilities

Cylinder size	D	E	F	G	J
Nominal content/ oxygen capacity (L)	340	680	1360	3400	6800
Water capacity (L)	2.3	4.7	9.4	23.6	47.2
Dimensions (height × diameter) (mm)	535 × 102	865 × 102	930 × 140	1320 × 178	1520 × 229
Approximate full weight (kg)	3.9	6.5	17	39	78
Valve outlet connection (and specification)	Pin index (ISO 407)	Pin index (ISO 407)	Bullnose (BS 341)	Bullnose (BS 341)	Pin index side spindle (ISO 407)
Nominal service pressure (kPa/bar/psi)	13 700 kPa (137 bar/1987 psi)	13 700 kPa (137 bar/1987 psi)	13 700 kPa (137 bar/1987 psi)	13 700 kPa (137 bar/1987 psi)	13 700 kPa (137 bar/1987 psi)
Health facility use	Emergency and ambulance transport	Emergency and ambulance transport	Stand-alone	Stand-alone	Manifold connection and stand-alone

Notes: BS – British Standard; ISO – International Organization for Standardization; psi – pounds per square inch absolute.
Source: WHO-UNICEF Technical specifications and guidance for oxygen therapy devices *(1)*.

Oxygen delivery devices

Nasal oxygen cannula with prongs: Plastic tubes shaped as two prongs used to deliver air/oxygen mixture into the nasal cavities, when connected to an oxygen source. This is a single-use, non-sterile device.

Mask with reservoir bag: Face mask and tubing used to deliver medical oxygen directly to the upper airway of the patient. It allows the administration of a high oxygen concentration.

Venturi mask: Also known as air-entrainment masks, this device is able to provide total inspiratory flow at a specified fraction of inspired oxygen (FiO_2).

Table 3.2 Guidance on oxygen delivery devices

Oxygen delivery devices (single use)	Typical flow rate range	FiO_2 delivered	Considerations	Advantages/ disadvantages	Can be used with		
					Oxygen concentrator	Compressed oxygen cylinder	Piped supply oxygen
Nasal cannula, adult and paediatric (single use) 	1–6 L/min	24–44% oxygen Increases by approximately 4% with each litre of oxygen per minute The actual value depends on the patient's inspiratory peak flow	Technically, it is possible to deliver higher flows with this device, however, the oxygen source should deliver the desired flow; it can dry the nasal mucosa and disturb sleeping patterns; humification might be required according to clinical guidance. For paediatric patients with a flow > 4 L/min humidification is necessary (WHO)	**Advantages** Easy to use Patient can eat and talk **Disadvantages** Can be easily dislodged and is not as effective in patients with deviated septum or polyps	**Yes**	**Yes**	**Yes**
Mask with reservoir bag; adult	> 10 L/min	80–95% oxygen FiO_2 depends on the patient's pattern of breathing	Non-rebreather mask with reservoir bag	**Advantages** Delivers high concentration of oxygen **Disadvantages** Oxygen flow should be > 10 L/min; less can cause the bag to collapse during inspiration	**No**	**Yes**	**Yes**
Venturi mask; adult, paediatric 	2–15 L/min	24–60% oxygen, according to the type of mask	Allows precise measurement of FiO_2 delivered Utilizes different sized ports to change the FiO_2 delivered (24–50%) Some brands relate a colour to a flow rate and FiO_2 delivered, e.g. blue = 2–4 L/min = 24%; white = 4–6 L/min = 28%; yellow = 8–10 L/min = 35%; red = 10–12 L/min = 40%; green = 12–15 L/min = 60%.	**Advantages** Precise measurement of FiO_2 delivered Does not dry mucous membranes **Disadvantages** Is confining for some patients It interferes with talking and eating	**Yes** with some hesitation, as some studies demonstrate they deliver lower concentrations than expected	**Yes**	**Yes**

Disclaimer: This table is intended to provide information from the technical point of view about oxygen delivery devices, including flow rate ranges, achievable FiO_2, and possible oxygen sources that can be used with each device. Clinical decisions should determine the methods of administration of oxygen therapy and device selection.

Devices for oxygen regulation and conditioning

Flowmeter, Thorpe tube: In oxygen therapy systems, flowmeters are needed to measure and control the rate of oxygen flow to a patient, either from a high-pressure cylinder or a terminal unit of a piped system.

Table 3.3 Models of flowmeters

Oxygen models availability (minimum requirements for accuracy, graduation and flood flow)	**Medical air models availability** (minimum requirements for accuracy, graduation and flood flow)
0–200 mL/min, accuracy 10%, single taper graduations 25 mL/min in the range 25–200 mL/min, 0.5–1 L/min flood flow.	**0–3 or 3.5 L/min,** accuracy 10%, dual taper graduations 0.25 L/min (0–1 L/min range) and 0.5 L/min (1 L/min – maximum range) or single taper graduations 0.25 L/min full range, 8–10 L/min flood flow.
0–1000 mL/min, accuracy 10%, single taper, 0.1 L/min graduations in the range 0.1–1000 mL/min, 2.5–5 L/min flood flow.	**0–7 or 8 L/min,** accuracy 10%, dual taper graduations 0.5 L/min (0–5 L/min range) and 1 L/min (5 L/min – maximum range), 25 L/min flood flow.
0–3 or 3.5 L/min, accuracy 10%, dual taper graduations 0.25 L/min (0–1 L/min range) and 0.5 L/min (1 L/min – maximum range), or single taper graduations 0.25 L/min full range, 8–10 L/min flood flow.	**0–16 L/min,** accuracy 10%, dual taper graduations 0.5 L/min (0–5 L/min range) and 1 L/min (5 L/min – maximum range), 70 L/min flood flow.
0–7 or 8 L/min, accuracy 10%, dual taper graduations 0.5 L/min (0–5 L/min range) and 1 L/min (5 L/min – maximum range), 25 L/min flood flow.	**0–70 L/min,** accuracy 10%, single taper graduations 5 L/min full range, 85 L/min flood flow.
0–16 L/min, accuracy 10%, dual taper graduations 0.5 L/min (0–5 L/min range) and 1 L/min (5 L/min – maximum range), 70 L/min flood flow.	
0–70 L/min, accuracy 10%, single taper graduations 5 L/min full range, 85 L/min flood flow.	

Flow splitter: The flow splitter is a tabletop or wall-mounted device composed of an inlet valve that delivers oxygen to multiple independent flowmeters, each one providing an outlet. Up to five independent Thorpe tube pressure-compensated flowmeters, that can be calibrated to multiple flow ranges, are installed in the flowmeter stand housing. It can be connected to concentrators or to any standard pressure oxygen source, like cylinders and central system, according to device version.

Non-heated bubble humidifier: A bottle that reduces the dryness of oxygen by bubbling the gas through distilled water (or water that has been boiled).

Consult clinical guidelines to determine if humidification is needed. Humidification may not be necessary when oxygen is delivered in tropical climates by a concentrator rather than a cylinder, since concentrators provide oxygen at room temperature whereas cylinders deliver cold oxygen.

Tubing (for medical gases): Tubing (interior diameter 5 mm) made of medical grade silicone, designed for external connection of an oxygen delivery source (i.e. oxygen concentrators or pressure regulators and flowmeters connected to oxygen cylinders or central supply system).

Manual ventilation devices

Self-inflating resuscitation bag with mask: Handheld device used to provide positive pressure ventilation to patients who are not breathing or not breathing adequately. The device is used during resuscitation or intubation procedures. Antiviral filter should be used to reduce the risk of contamination of reusable components.

Heat and moisture exchanger filter (HMEF): Heat and moisture exchanging filters are intended both to conserve a portion of the patient's exhaled heat and moisture and condition inspired gas by warming and humidifying it, and to reduce the transmission of microbes and other particulate matter in breathing systems. This is a single-use device.

Colourimetric end-tidal CO_2 ($EtCO_2$) detector: This device is used to monitor the non-invasive measurement of exhaled CO_2. This equipment is commonly used for the verification of endotracheal tube placement. The colourimetric $EtCO_2$ detector changes its colour depending on the CO_2 percentage in exhaled gases measured using a numerical scale semi-quantitatively. End-tidal CO_2 detectors are able to provide objective evidence of the tube position in the trachea. In addition to quickly revealing the misplaced oesophageal intubations, it can prevent unnecessary re-intubations. This is a single-use device.

Patient monitoring devices

For COVID-19 patients two patient monitoring devices are considered in the priority medical devices list: pulse oximeter and patient monitor for continuous monitoring of physiological parameters.

Pulse oximeter: This is a medical device designed to monitor the haemoglobin oxygen saturation (SpO_2) through transcutaneous measurements using plethysmography. There are various types as described below:

- **Handheld:** A portable, battery-powered device that displays the SpO_2 value and can display pulse rate.
- **Tabletop:** An electrically powered bedside device that displays the SpO_2 value, pulse rate, and may detect, calculate and display other parameters.
- **Fingertip:** A portable, battery-powered device used on a patient's finger. It displays the SpO_2 value.

Patient monitor multiparametric: basic; intermediate; advanced

These are medical devices that continuously measure, calculate and display physiological parameters designed to monitor patients. They can be basic, measuring one or two vital signs; or advanced, with multiple parameters which are used for critical patients in intensive care units and specialized surgeries. There are portable versions which are battery powered or electrically powered at the bedside. The devices include patient cables, sensors and accessories, depending on the parameters to be measured (e.g. ECG, blood pressure, heart rate, temperature, respiratory rate and respiratory gas concentrations), according to configuration, so that clinicians can be informed of changes in a patient's condition.

3.3 Technical specifications for procurement

3.3.1 Oxygen supply devices

3.3.1.1 Oxygen concentrator

Oxygen concentrator		
1	**General technical requirements**	Provides a continuous flow of concentrated oxygen (> 82%) (preferably > 90%) from room air through one oxygen outlet. Continuous flow up to 5 L/min or 8 L/min or 10 L/min. Contains oxygen monitor to verify concentration. Requires continuous AC power source to operate. Power efficiency ≤ 70 W/L/min (preferable). User interface to be easy to operate; numbers and displays clearly visible and easily readable in low ambient light and sunlight. Digital or analogue meter that displays cumulative hours of device operation. Oxygen outlet(s) with 6 mm (1/4 inch) barbed fitting or equivalent. Oxygen outlet to be securely mounted and sheltered to reduce risk of being broken or bent. 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. Noise level < 60 dB(A). Capable to be disinfected with hospital grade detergents. At least IP11 degree of protection to the harmful ingress of water (fluid spill resistance), preferable up to IP21. Mechanical shock resistance, mechanical vibration, electromagnetic compatibility and electrical safety testing. 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.
2	**Displayed parameters**	Oxygen flow rate (on flowmeter). Cumulative hours of operation.
3	**User adjustable settings**	Oxygen flow rate.
4	**Alarms**	Audible and/or visual alarms for: • Low oxygen concentration (< 82%). • Power supply failure. • High temperature. • Low battery (preferable). • Low high/no flow (preferable). • Low/high output pressure.
5	**Accessories (included and mentioned in a disaggregated list)**	• 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. • Humidifier included, bubble, non-heated, single use is preferred (3 months' supply required). Reusable may be acceptable with appropriate disinfection protocols.
6	**Spare parts (included and mentioned in a disaggregated list)**	1-year spare parts kit as per preventive maintenance programme. Including: • Internal and external mounted filters for cleaning the air intake. • Spare battery set for alarm system (if applicable). • Spare mains power cable length ≥ 2.5 m (if applicable). • Replacement sets of spare fuses (if non-resettable fuses are used). • Sieve beds. Bidder must give a complete list of the specific spare parts included in their bid. Other spares that may be needed: circuit breaker, printed circuit board, sieve beds, compressor service kit, valves, wheels, motor capacitor, flowmeters and fan.
7	**Mobility, portability**	Whole unit to be movable with wheels on at least two castors. Unit weight to be < 27 kg.

Oxygen concentrator		
8	**Power supply, voltage, frequency and plug vary across countries**	Equipment must be connected to a reliable and continuous source of energy. Operates from AC power electric line: 100–240 V/50–60 Hz. Main power cable and plug adapted for various countries. Mains power cable length ≥ 2.5 m. 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.
9	**Documentation requirements (English language mandatory)**	Set: user and maintenance manuals, hard and soft copies, in English (mandatory) and other languages (preferable). Certificate of calibration and inspection. Troubleshooting, calibration and routine maintenance. List of all spare parts and accessories, with part numbers and contact details for parts supply. Document with contact details of manufacturer, supplier and local service agent.
10	**Primary packaging label**	Name and/or trademark of the manufacturer. Electrical power input requirements (voltage, frequency and socket type) and safety use and storage (keep away from oil, grease and petroleum-based or flammable products as well as smoking or open flames). Model or product reference. Information for particular storage conditions (temperature, pressure, light, humidity).
11	**Standards, for the manufacturer**	Certified quality management system for medical devices (e.g. ISO 13485). General quality management (e.g. ISO 9001). Application of risk management to medical devices (e.g. ISO 14971).
12	**Regulatory approval/ certification**	Free sales certificate (FSC) or certificate for exportation of medical device provided by the authority in manufacturing country. Proof of regulatory compliance, as appropriate, per the product's risk classification (e.g. Food and Drug Administration [FDA] and/or Conformité Européenne [CE]).
13	**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) for: ISO 80601-2-69:2014 Medical electrical equipment – Part 2-69: Particular requirements for basic safety and essential performance of oxygen concentrator equipment. IEC 60601-1:2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance. 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. IEC 60601-1-6:2013 Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability. 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. 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. 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. Compliance with ISO 8359 may be considered.
14	**Warranty**	2 years with regards efficiency and quality of the product. Availability of accessories and spare parts for at least 2 years.
Any variation to be indicated in the offer.		

3.3.1.2 Oxygen cylinder

Oxygen cylinder		
1	**General technical requirements**	Oxygen and medical air cylinders are refillable containers for such gas, in a compressed form, available in international standard capacity/pressure and dimensions. The cylinders can be made of steel, aluminium/alloy, carbon fibre or other composite material. Nominal pressure should be 13 700 kPa (137 bar, 1987 psi) for standard cylinders and 23 000 or 30 000 kPa (230 or 300 bar, 3336 or 4351 psi) for cylinders fitted with integral valves. Each cylinder is fitted and supplied with a valve. Multiple options for pressure regulators, various fitting and outlets, and integral valves should be available separately. Specific ISO, American National Standards Institute (ANSI) and other international colour coding for oxygen and medical air should be available. Accessories like holders, racks and trolleys should be available separately. **Oxygen cylinders:** • Refillable cylinders for compressed oxygen (oil-free and compliant to ISO standards) or air (compliant to ISO standards) for medical use. • Fitted with a primary valve, standard (pin index or bullnose) or integral, refillable. • Nominal pressure 13 700 kPa (137 bar, 1987 psi), for standard valve cylinders, or 23 000–30 000 kPa (230–300 bar, 3336–4351 psi) depending on the cylinder model, for integral valve cylinders. • Compressed Gas Association (CGA) approved seamless steel/aluminium alloy/composite body, colour coding according to ISO/ANSI/CGA/NFPA, sizes ISO/US standard. • Cylinders supplied with optional pressure regulators, multiple fitting according to all the international standards. • Safety over-pressure release valve (if not built-in in the integral valve fitted cylinders). **Primary valve and pressure regulator assemblies:** • Pin index or bullnose primary valve and compatible pressure regulators, providing pressure regulated supply of oxygen (oil-free and compliant to ISO standards) or medical air (compliant to ISO standards). • Steel/plated brass/aluminium casing, brass valve. • Pin index and bullnose primary valve versions, handle/key operated, supplied with tools. • Nominal inlet pressure 13 700 kPa (137 bar, 1987 psi), maximum 20 000 kPa (200 bar, 2901 psi). • Outlet pressure 345 kPa (3.5 bar, 50 psi). • Integrated manometer, 0–20 000 kPa (0–200 bar, 0–2901 psi). • Safety over-pressure release valve. • Pressure regulator supplied with flowmeter, if required – see configurations/options for specifications. **Integral valves:** • All-in-one cylinder valve for oxygen (oil-free and compliant to ISO standards) or medical air (compliant to ISO standards), providing direct attachment to the cylinder, pressure regulation and supply of medical gas with adjustable flow rate. • Steel/plated brass/aluminium casing, brass valve. • 6 mm barbed and BS 5682 Schrader (if applicable depending on the size of the cylinder) outlets. • Integrated open/close valve, outlet nominal pressure 400 kPa (4 bar, 58 psi). • Inlet pressure 23 000–30 000 kPa (230–300 bar, 3336–4351 psi), depending on the cylinder model. • Integrated refill valve ISO 5145/CGA 540 compliant. • Integrated manometer, covering the full nominal pressure range of the cylinder, standard 23 000–30 000 kPa (230–300 bar, 3336–4351 psi), for integral valve cylinders, or whatever applicable. • Integrated flowmeter. • Safety over-pressure release valve. Capable of being stored in ambient temperature of at least 5–50 °C, relative humidity of at least 15–95% non-condensing. Suitable for continuous operation in ambient temperature of at least 5–45 °C, relative humidity of at least 15–90% non-condensing. Specific requirements for altitude may be required, depending on the installation site. Applicable regulations on transport and storage of cylinders may vary if the cylinders are empty or partially/fully filled. Compliance with regulations on hazardous goods, flammable, explosive, compressed gas, according to the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) and international standards, is mandatory.

Oxygen cylinder		
2	**Configurations/options**	**Oxygen cylinder configurations/versions/options:** Standard and MRI-compatible versions. Specific ISO/ANSI/CGA/NFPA colour coding for oxygen and medical air. Seamless cylinders made of steel, aluminium/alloy, carbon fibre or other composite material (CGA approved and compliant to ISO applicable standards). Pin index/bullnose and integral valve options. OXYGEN and MEDICAL AIR cylinders with STANDARD VALVE available in all the ISO international standard sizes, including size AZ, C, D, E, F, G, H, J, and also US sizes M2 to M 265 (not all sizes apply to both oxygen and medical air). The type of standard valve has to be compliant to international ISO and US standards, i.e. pin index ISO 407/BS 850/CGA 870 valve, CGA 540 valve, 5/8 inch BSP (F) Bullnose BS 341 valve, also according to the size/pressure of the cylinder and to any applicable regulation. OXYGEN cylinders should be available also with INTEGRAL VALVE (with manometer and flow regulator, 400 kPa (4 bar) nominal outlet pressure, 6 mm barbed and BS 5682 Schrader outlets), in all the ISO international standard sizes, including size ZA, CD, ZD, HX and ZX, and also US sizes in M coding system. **Regulator/integral valve configurations/versions:** Standard and MRI-compatible versions. Oxygen and medical air versions. Pressure regulators and integral valves should be available with DISS and 6 mm barbed outlet. Pressure regulators should be available in basic open/close model and fitted with integrated flowmeter, Thorpe tube or Bourdon gauge. *Pressure regulators and integral valves with Thorpe or Bourdon flowmeter should be available at least in the following flow ranges, for oxygen and medical air:* • Low flow 0–3 or 4 L/min (only for oxygen), discrete (dial) flow setting (indicative steps 0, 0.03, 0.06, 0.12, 0.25, 0.50, 0.75, 1.0, 1.5, 2.0, 3.0, 4.0), accuracy 10%. • Standard flow 0–15 L/min, discrete (dial) flow setting (indicative steps 0, 0.25, 0.5, 1.0, 2.0, 3.0, 4.0, 5.0, 6.0, 8.0, 10.0, 12.0, 15.0), accuracy 10%. • High flow 0–25 L/min minimum, discrete (dial) flow setting (indicative steps 0, 0.25, 0.50, 1.0, 2.0, 3.0, 4.0, 6.0, 8.0, 10.0, 15.0, 25.0), accuracy 10%. *Pressure regulators and integral valves with Thorpe or Bourdon flowmeter should be available at least in the following flow ranges, for oxygen and medical air:* • Low flow 0–3 or 4 L/min (only for oxygen), accuracy 10%, indicative graduation (L/min) 0.03, 0.06, 0.12, 0.25, 0.5, 0.75, 1.0, 1.5, 2.0, 3.0, 4.0. • Standard flow 0–7 or 8 and 0–15 or 16 L/min, accuracy 10%, graduation 0.5 L/min (0.5–3 range) and 1 L/min (3–max range). • High flow 0–25 L/min minimum, accuracy 10%, graduation 0.5 L/min first increment and 1 L/min full range. Cylinder body, primary valve and pressure regulator or integral valve assembly, outlet connectors, safety pressure release valve, valve/regulator knob, manometer and flowmeter (for integral valve). Portable or stationary (depending on the size of the cylinder). Brass valve assemblies. Cylinders made of steel, aluminium/alloy, carbon fibre or compound material. Bronze/brass/synthetic sealings. All materials in contact with air certified for medical use.
3	**Displayed parameters**	Pressure and flow (for integral valve cylinders only).
4	**User adjustable settings**	Open/close control, pressure and flow (for integral valve cylinders only).
5	**Accessories**	Cylinder holding, carts, trolleys. Supplied with keys and tools to operate valves and regulators. Complete set of tubing and adapters to use the pressure regulator and the integral valve with all common international standard fittings, for medical gas sources, patient circuits and other medical devices.

Oxygen cylinder		
6	**Spare parts**	Common and frequently used spare parts, sensors/transducers/actuators, reusable probes/cables/patient connection accessories, periodic maintenance and calibration kits/materials, renewables that should be procured together with the equipment and in quantity sufficient for 2 years recommended (1 year at least) of typical use. These items should be supplied to each department where the equipment is installed and also to central and local maintenance department. Sealing set, maintenance kit, regulating unit (knob), adapters and connectors, keys and tools to operate the valves. Items in the above-mentioned categories that are not frequently needed or require specialized skills to be used/replaced. The need and the quantity of these items should be assessed by technical staff before procuring the main medical devices, and procured together. It is recommended to store and use them in central and local maintenance department. Primary valve assembly, regulator valve assembly, pressure safety valve, inlet/outlet connectors, full set of sealings, integral valve assembly, manometer and flowmeter (for integral valves).
7	**Mobility, portability (if relevant)**	Portable or stationary (depending on the size of the cylinder).
8	**Documentation requirements (English language mandatory)**	Set: user and maintenance manuals, hard and soft copies, in English (mandatory) and other languages (preferable). Certificate of calibration and inspection. Troubleshooting, calibration and routine maintenance. List of all spare parts and accessories, with part numbers and contact details for parts supply. Document with contact details of manufacturer, supplier and local service agent.
9	**Transportation and storage and primary packaging labelling**	Applicable regulations on transport and storage of cylinders may vary if the cylinders are empty or partially/fully filled. Compliant with regulations on hazardous goods, flammable, explosive, compressed gas, according with GHS and international standards is mandatory. Sealed container. Capable of being transported and stored in ambient temperature of at least 5–50 °C, relative humidity of at least 15–95% non-condensing. Specific requirements for altitude may be required, depending on the installation site. Hazardous goods, flammable, explosive, compressed gas labelling according with GHS and international standards and regulations. Primary packaging: Unit of use: one (1) cylinder or valve/regulator in a box or case with manufacturer's instruction for use, spare parts and accessories (when applicable). Cylinder type and content in litres, tare weight (weight when empty), maximum cylinder pressure, cylinder size code. Labelling on the primary packaging: Name and/or trademark of the manufacturer; manufacturer's product reference; type of product and main characteristics; lot number prefixed by the word "LOT" (or equivalent harmonized symbol) (if applicable); information for particular storage conditions (temperature, pressure, light, humidity, etc.), as appropriate (or equivalent harmonized symbol); information for handling, if applicable (or equivalent harmonized symbol). Over packaging: Packaging unit. Labelling on the packaging unit: Labelling to be the same as primary packaging. Extra information required: number of units.
10	**Standards, for the manufacturer**	Certified quality management system for medical devices (e.g. ISO 13485). General quality management (e.g. ISO 9001). Application of risk management to medical devices (e.g. ISO 14971).
11	**Regulatory approval/ certification**	Free sales certificate (FSC) or certificate for exportation of medical device provided by the authority in manufacturing country. Proof of regulatory compliance, as appropriate, per the product's risk classification (e.g. Food and Drug Administration [FDA] and/or Conformité Européenne [CE]).

Oxygen cylinder		
12	**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) for: Colour coding ISO or ANSI for medical gases. Conforms to ISO, NFPA and/or CGA standards, and/or UL or CSA approved. ISO 11114 Gas cylinders – Compatibility of cylinder and valve materials with gas contents. ISO 10524 Pressure regulators for use with medical gases. ISO 15002 Flow-metering devices for connection to terminal units of medical gas pipeline systems. ISO 15245 Gas cylinders – Parallel threads for connection of valves to gas cylinders. ISO 10297 Gas cylinders – Cylinder valves – Specification and type testing. ISO 17871 Gas cylinders – Quick-release cylinder valves – Specification and type testing. ISO 17879 Gas cylinders – Self-closing cylinder valves – Specification and type testing. ISO 407 Small medical gas cylinders – Pin-index yoke-type valve connections. ISO 5145 Cylinder valve outlets for gases and gas mixtures – Selection and dimensioning. ISO 11117 Gas cylinders – Valve protection caps and valve guards – Design, construction and tests. ISO 11363 Gas cylinders – 17E and 25E taper threads for connection of valves to gas cylinders. ISO 12209 Gas cylinders – Outlet connections for gas cylinder valves for compressed breathable air. ISO 14246 Gas cylinders – Cylinder valves – Manufacturing tests and examinations. ISO 22435 Gas cylinders – Cylinder valves with integrated pressure regulators. ISO 7866 Gas cylinders – Refillable seamless aluminium alloy gas cylinders – Design, construction and testing. ISO 20701 Gas cylinders – Refillable welded aluminium-alloy cylinders – Design, construction and testing. ISO 9809 Gas cylinders – Refillable seamless steel gas cylinders – Design, construction and testing. ISO 11119 Gas cylinders – Refillable composite gas cylinders and tubes – Design, construction and testing. ISO 13341 Gas cylinders – Fitting of valves to gas cylinders. ISO 32 Gas cylinders for medical use – Marking for identification of content. ISO 7225 Gas cylinders – Precautionary labels. ISO 10461 Gas cylinders – Seamless aluminium-alloy gas cylinders – Periodic inspection and testing. ISO 11623 Gas cylinders – Composite construction – Periodic inspection and testing. ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements. ISO 15996 Gas cylinders – Residual pressure valves – Specification and type testing of cylinder valves incorporating residual pressure devices. ISO 15001 Anaesthetic and respiratory equipment – Compatibility with oxygen.
13	**Warranty**	5 years recommended for the cylinders, 3 years recommended for the pressure regulators and valves (2 years at least).
Any variation to be indicated in the offer.		

3.3.2 Oxygen delivery devices

3.3.2.1 Nasal oxygen cannula with prongs

Nasal oxygen cannula with prongs		
1	**Specifications**	Cannula with nasal prongs designed for easy administration of medicinal oxygen through patient nostrils; single use. 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. 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). The harness is fully adjustable (over the patient's ear) with a double tubing (right and left side), interlinked through a moulded Y-connector to the oxygen supply line. All tubing is soft and flexible, kink resistant, with star lumen, and with proximal end with a universal, funnel-shaped connector to oxygen source. 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. Individually packed in a sealed plastic envelope. Non-sterile. Box of 50 or 100 units.
2	**Sizes**	Adult: outer diameter of the prong: 6 mm; tube length: 1.5–2 m. Paediatric: outer diameter of the prong: 3.7 mm; tube length: 1.5–2 m.
3	**Material**	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).
4	**Primary packaging label**	Single use. Name and/or trademark of the manufacturer. Model or product reference. Information for particular storage conditions (temperature, pressure, light, humidity).
5	**Standards, for the manufacturer**	Certified quality management system for medical devices (e.g. ISO 13485). General quality management (e.g. ISO 9001). Application of risk management to medical devices (e.g. ISO 14971).
6	**Regulatory approval/ certification**	Free sales certificate (FSC) or certificate for exportation of medical device provided by the authority in manufacturing country. Proof of regulatory compliance, as appropriate, per the product's risk classification (e.g. Food and Drug Administration [FDA] and/or Conformité Européenne [CE]).
7	**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) for: ISO 11712:2009 Anaesthetic and respiratory equipment – Supralaryngeal airways and connectors. ISO 15001 Anaesthetic and respiratory equipment – Compatibility with oxygen. ISO 18562 Biocompatibility evaluation of breathing gas pathways in healthcare applications. ISO 18190 Anaesthetic and respiratory equipment – General requirements for airways and related equipment. ISO 18562-1 Biocompatibility evaluation of breathing gas pathways in healthcare applications Part 1: Evaluation and testing within a risk management process. ISO/DIS 23368 Anaesthetic and respiratory equipment – Low flow nasal cannula for oxygen therapy. ISO/DIS 17256 Anaesthetic and respiratory equipment – Respiratory therapy tubing and connectors. ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements.
Any variation to be indicated in the offer.		

3.3.2.2 Mask with reservoir bag

Mask with reservoir bag		
1	**Specifications**	Non-rebreather mask with reservoir bag, used to deliver medical oxygen directly to the upper airway of the patient; single use. 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). Mask is soft, transparent, well-fitting moulded, with two side vents. The nose clip is soft, malleable and adjustable. The tubing (oxygen line) is non-kinking, well-fitted. 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. Individually packed. Non-sterile. Box of 50 or 100 units.
2	**Sizes**	Adult. Paediatric: tube length: 1.5–2 m.
3	**Material**	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).
4	**Primary packaging label**	Single use. Name and/or trademark of the manufacturer. Model or product reference. Information for particular storage conditions (temperature, pressure, light, humidity).
5	**Standards, for the manufacturer**	Certified quality management system for medical devices (e.g. ISO 13485). General quality management (e.g. ISO 9001). Application of risk management to medical devices (e.g. ISO 14971).
6	**Regulatory approval/ certification**	Free sales certificate (FSC) or certificate for exportation of medical device provided by the authority in manufacturing country. Proof of regulatory compliance, as appropriate, per the product's risk classification (e.g. Food and Drug Administration [FDA] and/or Conformité Européenne [CE]).
7	**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) for: ISO 11712:2009 Anaesthetic and respiratory equipment – Supralaryngeal airways and connectors. ISO 15001 Anaesthetic and respiratory equipment – Compatibility with oxygen. ISO 18562 Biocompatibility evaluation of breathing gas pathways in healthcare applications. ISO 18190 Anaesthetic and respiratory equipment – General requirements for airways and related equipment. ISO 18562-1 Biocompatibility evaluation of breathing gas pathways in healthcare applications Part 1: Evaluation and testing within a risk management process. ISO/DIS 23368 Anaesthetic and respiratory equipment – Low flow nasal cannula for oxygen therapy. ISO/DIS 17256 Anaesthetic and respiratory equipment – Respiratory therapy tubing and connectors. ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements.
Any variation to be indicated in the offer.		

3.3.2.3 Venturi mask

Venturi mask		
1	**Specifications**	Also known as an air-entrainment mask (with percent O_2 lock). It delivers oxygen, with a specific concentration from 24–60% minimum. The mask has an adjustable nose clip. The kit of the mask includes the tubing, humidity cup and multiple jets, which are colour-coded and indicating the percentage of oxygen. Individually packed. Non-sterile. Box of 50 or 100 units.
2	**Sizes**	Adult. Paediatric: tube length: 1.5–2 m.
3	**Material**	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).
4	**Primary packaging label**	Single use. Name and/or trademark of the manufacturer. Model or product reference. Information for particular storage conditions (temperature, pressure, light, humidity).
5	**Standards, for the manufacturer**	Certified quality management system for medical devices (e.g. ISO 13485). General quality management (e.g. ISO 9001). Application of risk management to medical devices (e.g. ISO 14971).
6	**Regulatory approval/ certification**	Free sales certificate (FSC) or certificate for exportation of medical device provided by the authority in manufacturing country. Proof of regulatory compliance, as appropriate, per the product's risk classification (e.g. Food and Drug Administration [FDA] and/or Conformité Européenne [CE]).
7	**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) for: ISO 11712:2009 Anaesthetic and respiratory equipment – Supra-laryngeal airways and connectors. ISO 15001 Anaesthetic and respiratory equipment – Compatibility with oxygen. ISO 18562 Biocompatibility evaluation of breathing gas pathways in healthcare applications. ISO 18190 Anaesthetic and respiratory equipment – General requirements for airways and related equipment. ISO 18562-1 Biocompatibility evaluation of breathing gas pathways in healthcare applications Part 1: Evaluation and testing within a risk management process. ISO/DIS 23368: Anaesthetic and respiratory equipment – Low flow nasal cannula for oxygen therapy. ISO/DIS 17256 Anaesthetic and respiratory equipment – Respiratory therapy tubing and connectors. ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements.
Any variation to be indicated in the offer.		

3.3.3 Devices for oxygen regulation and conditioning

3.3.3.1 Flowmeter, Thorpe tube

Flowmeter, Thorpe tube		
1	**General technical requirements**	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. 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. Transparent, clearly readable and graduated (metric system) column, shatter-resistant polymer certified for medical use. Clearly visible graduation, 270 or more degrees of visibility. Needle valve and body constructed of brass or aluminium. Calibrated at 345–380 kPa (3.4–3.8 bar, 50–55 psi) inlet gauge pressure. 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). Pressure-compensated design to give specified accuracy for whole range of input pressures. Minimum flow rate to be zero, i.e. fully closed. Maximum flow rate when fully open to be stated. Anti-slip knob. Available in international ISO and ANSI colour-coding systems for oxygen and medical air. Disinfectable with hospital grade detergents. Availability of various outlet adapters (tubing nipples/Christmas trees), with ISO, ANSI and generic colour-coding and suitable for all international standard outlet fittings, including (but not limited to) threaded, non-threaded, 6 mm barbed and 9/16 inch UNF female thread for oxygen and medical air. Brass/steel/aluminium/polymers/hard plastic body and valve, certified for medical use. Material: polypropylene, polycarbonate, acrylic or transparent equivalent biocompatible plastic/polymer certified for medical use, unbreakable or shatter resistant, for the column.
2	**Primary packaging label**	Name and/or trademark of the manufacturer. Model or product reference. Information for particular storage conditions (temperature, pressure, light, humidity). Gas type, calibration temperature and pressure should be specified on the label.
3	**Standards, for the manufacturer**	Certified quality management system for medical devices (e.g. ISO 13485). General quality management (e.g. ISO 9001). Application of risk management to medical devices (e.g. ISO 14971).
4	**Regulatory approval/ certification**	Free sales certificate (FSC) or certificate for exportation of medical device provided by the authority in manufacturing country. Proof of regulatory compliance, as appropriate, per the product's risk classification (e.g. Food and Drug Administration [FDA] and/or Conformité Européenne [CE]).
5	**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) for: Colour coding ISO or ANSI for medical gases. Conforms to ISO, NFPA, and/or CGA standards, and/or UL or CSA approved. ISO 15001 Anaesthetic and respiratory equipment – Compatibility with oxygen. ISO 15002 Flow-metering devices for connection to terminal units of medical gas pipeline systems. ISO 18562 Biocompatibility evaluation of breathing gas pathways in healthcare applications. ISO 10524 Pressure regulators for use with medical gases. ISO 18082 Anaesthetic and respiratory equipment – Dimensions of non-interchangeable screw-threaded (NIST) low-pressure connectors for medical gases. ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements. ISO 5359 Low-pressure hose assemblies for use with medical gases. ISO 32 Colour coding for medical gases.
6	**Warranty**	2 years with regards efficiency and quality of the product. Availability of accessories and spare parts for at least 2 years.
Any variation to be indicated in the offer.		

3.3.3.2 Flow splitter

Flow splitter		
1	**General technical requirements**	Flow splitter from a single or double oxygen supply. Equipped with four or five independent, pressure-compensated, Thorpe tube flowmeters, to regulate the flow of medical gas. Suitable for tabletop and/or wall mount. Flowmeters capacity: 0.125–2 L/min. Accuracy: ± 10%. 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. 6 mm barbed outlet as standard – availability of adapters and outlet options to match all the international standards for oxygen fittings to be stated. Transparent, clearly readable and graduated (metric system) column, shatter-resistant polymer certified for medical use. Needle valve and body constructed of brass or aluminium. Adjustment knobs to have rough surface to prevent slipping. Colour-coded flowmeter preferable, e.g. to ISO 32. Flowmeter stand hard plastic or metal epoxy painted. Capable to be disinfected with hospital grade detergents.
2	**Primary packaging label**	Name and/or trademark of the manufacturer. Model or product reference. Information for particular storage conditions (temperature, pressure, light, humidity). Gas type, calibration temperature and pressure should be specified on the label.
3	**Standards, for the manufacturer**	Certified quality management system for medical devices (e.g. ISO 13485, or good manufacturing practice [GMP]). General quality management (e.g. ISO 9001). Application of risk management to medical devices (e.g. ISO 14971).
4	**Regulatory approval/ certification**	Free sales certificate (FSC) or certificate for exportation of medical device provided by the authority in manufacturing country. Proof of regulatory compliance, as appropriate, per the product's risk classification (e.g. Food and Drug Administration [FDA] and/or Conformité Européenne [CE]).
5	**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) for: Colour coding ISO or ANSI for medical gases. Conforms to ISO, NFPA, and/or CGA standards, and/or UL or CSA approved. ISO 15001 Anaesthetic and respiratory equipment – Compatibility with oxygen. ISO 15002 Flow-metering devices for connection to terminal units of medical gas pipeline systems. ISO 18562 Biocompatibility evaluation of breathing gas pathways in healthcare applications. ISO 10524 Pressure regulators for use with medical gases. ISO 18082 Anaesthetic and respiratory equipment – Dimensions of non-interchangeable screw-threaded (NIST) low-pressure connectors for medical gases. ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements. ISO 5359 Low-pressure hose assemblies for use with medical gases. ISO 32 Colour coding for medical gases.
6	**Warranty**	2 years with regards efficiency and quality of the product. Availability of accessories and spare parts for at least 2 years.
Any variation to be indicated in the offer.		

3.3.3.3 Non-heated bubble humidifier

Non-heated bubble humidifier		
1	**General technical requirements**	Non-heated bubble humidifier. Graduated, transparent humidification bottle. Graduation should show minimum and maximum water level. Detachable metal or rigid durable polymer cap with gas. DISS inlet connector. 6 mm barbed (or specify alternate style) outlet. Humidification chamber working volume available between 150–500 mL. Graduation options available in metric, imperial and both units. Flow rate capacity up to 15 L/min. Pressure relief safety valve ≥ 14 kPa (0.14 bar, 2 psi). All components to be capable of disinfection including: bottle, diffuser, tubing, O-ring/seals, inlet and outlet connectors, cover lid in between patients. Supplier must define decontamination procedure. Bottle, diffuser and tubes made of polypropylene, polycarbonate or equivalent biocompatible plastic/polymer certified for medical use, unbreakable or shatter resistant. Cap and connectors made of brass/steel/other biocompatible metal or polymer certified for medical use. Pressure valve made of brass chromium plated or equivalent metal certified for medical use.
2	**Primary packaging label**	Name and/or trademark of the manufacturer. Model or product reference. Information for particular storage conditions (temperature, pressure, light, humidity).
3	**Standards, for the manufacturer**	Certified quality management system for medical devices (e.g. ISO 13485). General quality management (e.g. ISO 9001). Application of risk management to medical devices (e.g. ISO 14971).
4	**Regulatory approval/ certification**	Free sales certificate (FSC) or certificate for exportation of medical device provided by the authority in manufacturing country. Proof of regulatory compliance, as appropriate, per the product's risk classification (e.g. Food and Drug Administration [FDA] and/or Conformité Européenne [CE]).
5	**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) for: Conforms to ISO, NFPA and/or CGA standards, and/or UL or CSA approved. ISO 15001 Anaesthetic and respiratory equipment – Compatibility with oxygen. ISO 18562 Biocompatibility evaluation of breathing gas pathways in healthcare applications. ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements. ISO 18190 Anaesthetic and respiratory equipment – General requirements for airways and related equipment. ISO 18562-1 Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 1: Evaluation and testing within a risk management process. ISO 8185 Respiratory tract humidifiers for medical use – Particular requirements for respiratory humidification systems.
Any variation to be indicated in the offer.		

3.3.3.4 Tubing (for medical gases)

Tubing (for medical gases)		
1	**General technical requirements**	Medical grade tubing (interior diameter 5 mm) used for the circulation of medical gases. Translucent, flexible and soft plastic tubing of uniform diameter. Anti-kink tubing, non-permanent deformation if kinked or bent too tight. Oxygen and air/oxygen mixture compatibility, as per ISO 15001. Round shape section, internal diameter range 3–5 mm (1/8–3/16 inch), compatible with standard 6 mm barbed fitting. Length: 25 m (preferable). Connectors/adapters for oxygen therapy/respiratory support circuits (preferable).
2	**Material**	Rubber or soft plastic tubing, semi-rigid, PVC or other material, FDA Title 21/USP VI compliant and certified for medical use, hardness > 60 Shore A (ASTM D-2240).
3	**Primary packaging label**	Name and/or trademark of the manufacturer. Model or product reference. Information for particular storage conditions (temperature, pressure, light, humidity).
4	**Standards, for the manufacturer**	Certified quality management system for medical devices (e.g. ISO 13485). General quality management (e.g. ISO 9001). Application of risk management to medical devices (e.g. ISO 14971).
5	**Regulatory approval/ certification**	Free sales certificate (FSC) or certificate for exportation of medical device provided by the authority in manufacturing country. Proof of regulatory compliance, as appropriate, per the product's risk classification (e.g. Food and Drug Administration [FDA] and/or Conformité Européenne [CE]).
6	**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) for: Conforms to ISO, NFPA and/or CGA standards, and/or UL or CSA approved. ISO 15001 Anaesthetic and respiratory equipment – Compatibility with oxygen. ISO 18562 Biocompatibility evaluation of breathing gas pathways in healthcare applications. ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements. ISO 18190 Anaesthetic and respiratory equipment – General requirements for airways and related equipment. ISO 18562-1 Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 1: Evaluation and testing within a risk management process. ISO/DIS 17256 Anaesthetic and respiratory equipment – Respiratory therapy tubing and connectors. ISO 5359:2014 Anaesthetic and respiratory equipment – Low-pressure hose assemblies for use with medical gases.
Any variation to be indicated in the offer.		

3.3.4 Self-inflating resuscitation bag with mask (Manual resuscitator)

Self-inflating resuscitation bag with mask		
1	**General technical requirements**	Hand-operated resuscitator used for mechanical ventilation of adult and paediatric patients. Easy to disassemble and reassemble. Easy to clean and disinfect. Reusable. All parts must be manufactured from high-strength, long-life materials and require no special maintenance or storage conditions. Ventilation can be done with ambient air or with oxygen. Resuscitator shall be supplied as a complete set with: • Compressible self-refilling ventilation bag with maximum capacity not less than 1300 mL. Dead volume: < 7 mL. • 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 cmH_2O) when squeezed normally with one hand. • Patient connector, outside diameter: 22 mm; inside diameter: 15 mm. • Inlet valve with nipple for oxygen tubing. • Oxygen reservoir bag capacity according to patient size.
2	**Sizes**	Adult: for small adult, adult standard, and large adult. Infant: for small infant, infant standard, and large infant.
3	**Material**	Compressible self-refilling ventilation bag: silicone rubber, or other materials specified in ISO10651-4 or equivalent. 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. Oxygen reservoir bag: bag is made of silicone and valve of polycarbonate/polysulfone or any materials fulfilling ISO10651-4 or equivalent. Oxygen masks: silicone rubber, transparent or equivalent. Materials must be compatible with steam sterilization.
4	**Primary packaging label**	Name and/or trademark of the manufacturer. Model or product reference. Information for particular storage conditions (temperature, pressure, light, humidity, etc.) as appropriate (or equivalent harmonized symbol). If the packaging is not transparent, it must bear a diagram (preferably actual size) showing the essential parts of the product and indicating the position of the product in the packaging. Lot number prefixed by the word "LOT" (or equivalent harmonized symbol). Information for handling, if applicable (or equivalent harmonized symbol).
5	**Documentation requirements (English language mandatory)**	Set: user manuals, hard and soft copies, in English (mandatory) and other languages (preferable).
6	**Standards, for the manufacturer**	Certified quality management system for medical devices (e.g. ISO 13485). General quality management (e.g. ISO 9001). Application of risk management to medical devices (e.g. ISO 14971).
7	**Regulatory approval/ certification**	Free sales certificate (FSC) or certificate for exportation of medical device provided by the authority in manufacturing country. Proof of regulatory compliance, as appropriate, per the product's risk classification (e.g. Food and Drug Administration [FDA] and/or Conformité Européenne [CE]).
8	**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) for: 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). ISO 10993-1:2009 Biological evaluation of medical devices – Part 1: Evaluation and testing for mask. ISO 10993-5:2009 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity. ISO 10993-10:2010 Biological evaluation of medical devices – Part 10: Tests for irritation and delayed-type hypersensitivity (or classified as USP class V).
9	**Warranty**	1 years with regards efficiency and quality of the product.
Any variation to be indicated in the offer.		

3.3.5 Heat and moisture exchanger filter (HMEF)

Heat and moisture exchanger filter (HMEF)		
1	**General technical requirements**	Heat and moisture exchanger filters (HMEF) for respiratory breathing systems (i.e. endotracheal tube); single use. 99.9% efficiency; humidification level > 30 mg H_2O/L; dead space < 40 mL.
2	**Sizes**	Adult: 22 Fr/15 mm; transparent cover; maximum tidal volume (breathing filter): adapted for adult patient. Paediatric: connector 22 Fr/15 mm; transparent cover; maximum tidal volume (breathing filter): adapted for paediatric patient.
3	**Primary packaging label**	Name and/or trademark of the manufacturer. Model or product reference. Information for particular storage conditions (temperature, pressure, light, humidity). If the packaging is not transparent, it must bear a diagram (preferably actual size) showing the essential parts of the product and indicating the position of the product in the packaging. Lot number prefixed by the word "LOT" (or equivalent harmonized symbol). Shelf life: 3 years.
4	**Standards, for the manufacturer**	Certified quality management system for medical devices (e.g. ISO 13485). General quality management (e.g. ISO 9001). Application of risk management to medical devices (e.g. ISO 14971).
5	**Regulatory approval/ certification**	Free sales certificate (FSC) or certificate for exportation of medical device provided by the authority in manufacturing country. Proof of regulatory compliance, as appropriate, per the product's risk classification (e.g. Food and Drug Administration [FDA] and/or Conformité Européenne [CE]).
5	**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) for: ISO 9360-2:2001 Anaesthetic and respiratory equipment – Heat and moisture exchangers (HMEs) for humidifying respired gases in humans – Part 2: HMEs for use with tracheostomized patients having minimum tidal volumes of 250 ml. ISO 5367:2014 Anaesthetic and respiratory equipment – Breathing sets and connectors.
Any variation to be indicated in the offer.		

3.3.6 Colourimetric end-tidal CO_2 ($EtCO_2$) detector

Colourimetric end-tidal CO_2 ($EtCO_2$) detector		
1	**General technical requirements**	CO_2 detection device for verification of correct endotracheal tube placement; single use. Usage time: up to 2 hours preferable. Connector port adapted to standard patient circuit (22 Fr/15 mm). Colour chart for different ranges of $EtCO_2$.
2	**Sizes**	Adult: internal volume: 25 cc approximately. Paediatric: internal volume: 3 cc approximately.
3	**Primary packaging label**	Name and/or trademark of the manufacturer. Model or product reference. Information for particular storage conditions (temperature, pressure, light, humidity). If the packaging is not transparent, it must bear a diagram (preferably actual size) showing the essential parts of the product and indicating the position of the product in the packaging. Lot number prefixed by the word "LOT" (or equivalent harmonized symbol). Shelf life: 3 years.
4	**Standards, for the manufacturer**	Certified quality management system for medical devices (e.g. ISO 13485). General quality management (e.g. ISO 9001). Application of risk management to medical devices (e.g. ISO 14971).
5	**Regulatory approval/ certification**	Free sales certificate (FSC) or certificate for exportation of medical device provided by the authority in manufacturing country. Proof of regulatory compliance, as appropriate, per the product's risk classification (e.g. Food and Drug Administration [FDA] and/or Conformité Européenne [CE]).
6	**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) for: ISO 5367:2014 Anaesthetic and respiratory equipment – Breathing sets and connectors.
Any variation to be indicated in the offer.		

3.3.7 Pulse oximeter

3.3.7.1 Pulse oximeter: handheld

Pulse oximeter: handheld		
1	**General technical requirements**	SpO_2 and pulse rate monitor, for adults, children, for all skin pigmentations. Plethysmography waveform (preferable). SpO_2 detection to include the range: 70–100%. SpO_2 resolution: 1% or less. SpO_2 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. If equipment capable of a wider SpO_2 detection range, accuracy over that wider range shall be stated. Pulse rate detection to include the range: 30–240 bpm. Pulse rate resolution: 1 bpm or less. Pulse rate accuracy within ± 3 bpm. Data update period for valid data displayed ≤ 10 s. Display with main parameters: % SpO_2, pulse rate, plethysmography waveform (preferable) (and possibly other indicators of signal quality), alarm messages, battery state indication. Suitable for detection in low perfusion conditions (as per ISO 80601-2-61, test method must be described). Automatic correction for movement and ambient light artefacts (as per ISO 80601-2-61, test method must be described). Design must enable use in demanding environments, e.g. shock, vibration and free fall tests as per tests in ISO 80601-2-61. Capable of working with adult, paediatric and neonatal reusable probes. Enclosure to have ingress protection level IPX2 or better. Overall device and probe weight < 400 g. Any aspects of usability as per IEC 62366-1 must be described. Suitable for cleaning and disinfection. Continuous operation within specification in ambient temperature of at least 5–40 °C, relative humidity of at least 10–85% non-condensing (90% preferable). Function for continuous monitoring. Internal data storage for patient trends and event log (preferable).
2	**Displayed parameters**	Display with main parameters: % SpO_2, pulse rate, plethysmography waveform (preferable) (and possibly other indicators of signal quality), alarm messages, battery state indication. Display must allow easy viewing in all ambient light levels.
3	**User adjustable settings**	Audio-visual adjustable alarms: high/low SpO_2 and high/low pulse rate (operator variable settings). Alarm override and temporary silencing.
4	**Alarms**	Audible and visual alarms for low/high saturation and pulse rate, threshold set by user. Audible and visual alarms for sensor error or disconnected, system errors, low battery. Alarm temporary silencing function.
5	**Accessories**	Carry case: 1 per equipment. Reusable probes, adult (finger clip): 2 per equipment. Reusable probes, paediatric: 2 per equipment. Extender cable to achieve probe cable length > 1 m (if applicable): 3 per equipment. Battery charger (if applicable): 1 per equipment.
6	**Spare parts**	1-year spare parts kit as per preventive maintenance programme.
7	**Portability**	Portable handheld.
8	**Power supply, voltage, frequency and plug vary across the countries**	Operated by replaceable battery power supply, either rechargeable or single use. Rechargeable batteries are preferred. External or built-in AC battery charger, if rechargeable type. Power connection requirements as per local power supply. Charger, if used, to have protection against over-voltage and over-current line conditions, and preferably to be certified to IEC 60601-1. Protection against defibrillator discharges and electrosurgical units. Automatic switch between battery and mains powered modes, when recharging or in mains power failure (preferable). The display shall show which power source is in use. Running time on battery only ≥ 12 hours. Operates from AC power electric line: 100–240 V~/50–60 Hz. Main power cable and plug adapted for various countries.

Pulse oximeter: handheld		
9	**Documentation requirements (English language mandatory)**	Set: user and maintenance manuals, hard and soft copies, in English (mandatory) and other languages (preferable). Certificate of calibration and inspection (other means of assurance may be considered). Troubleshooting, calibration and routine maintenance. List of all spare parts and accessories, with part numbers and contact details for parts supply. Document with contact details of manufacturer, supplier and local service agent.
10	**Primary packaging label**	Name and/or trademark of the manufacturer. Electrical power input requirements (voltage, frequency and socket type) and safety use and storage (keep away from oil, grease and petroleum-based or flammable products as well as smoking or open flames). Model or product reference. Information for particular storage conditions (temperature, pressure, light, humidity).
11	**Standards, for the manufacturer**	Certified quality management system for medical devices (e.g. ISO 13485). General quality management (e.g. ISO 9001). Application of risk management to medical devices (e.g. ISO 14971).
12	**Regulatory approval/ certification**	Free sales certificate (FSC) or certificate for exportation of medical device provided by the authority in manufacturing country. Proof of regulatory compliance, as appropriate, per the product's risk classification (e.g. Food and Drug Administration [FDA] and/or Conformité Européenne [CE]).
13	**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) for: IEC 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance. IEC 60601-1-1 Medical electrical equipment – Part 1-1: General requirements for safety – Collateral standard: Safety requirements for medical electrical systems. 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. ISO 80601-2-61 Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment. ISO/IEEE 11073-10404 Health informatics – Personal health device communication – Part 10404: Device specialization – Pulse oximeter.
14	**Warranty**	2 years with regards efficiency and quality of the product. Availability of accessories and spare parts for at least 2 years.
Any variation to be indicated in the offer.		

3.3.7.2 Pulse oximeter: tabletop

Pulse oximeter: tabletop		
1	**General technical requirements**	Continuously monitors SpO_2, plethysmography waveform and pulse rate for adults and children. SpO_2 detection to include the range: 70–100%. SpO_2 resolution: 1% or less. SpO_2 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. If equipment is capable of a wider SpO_2 detection range, the accuracy over that wider range shall be stated. Pulse rate detection to include the range: 30–240 bpm. Pulse rate resolution: 1 bpm or less. Pulse rate accuracy within ± 3 bpm. Data update period for valid data displayed ≤ 10 s. Suitable for detection in low perfusion conditions (as per ISO 80601-2-61, test method must be described). Automatic correction for movement and ambient light artefacts (as per ISO 80601-2-61, test method must be described). Design must enable use in demanding environments, e.g. shock, vibration and free fall tests as per tests in ISO 80601-2-61. Internal data storage for patient data and trends and for event log. Capable of working with, adult, paediatric and neonatal reusable probes. Enclosure to have ingress protection level IPX2 or better. Any aspects of usability as per IEC 62366-1 must be described. Disinfectable with hospital grade detergents. Continuous operation within specification in ambient temperature of at least 5–40 °C, relative humidity of at least 10–85% non-condensing (90% preferable).

Pulse oximeter: tabletop		
2	**Displayed parameters**	Display with main parameters: % SpO_2, pulse rate, plethysmography waveform (and possibly other indicators of signal quality), alarm messages, battery and system messages/state indication. Display must allow easy viewing in all ambient light levels.
3	**User adjustable settings**	Audio-visual adjustable alarms: high/low SpO_2 and high/low pulse rate (operator variable settings). Alarm override and temporary silencing.
4	**Alarms**	Audible and visual alarms for low/high saturation and pulse rate, threshold set by user. Audible and visual alarms for sensor error or disconnected, system errors, low battery. Alarm override and temporary silencing function.
5	**Accessories**	Reusable probes, adult (finger clip): 2 per equipment. Reusable probes, paediatric: 2 per equipment. Extender cable to achieve probe cable length > 1 m: 3 per equipment. Battery charger (if applicable): 1 per equipment.
6	**Spare parts**	1-year spare parts kit as per preventive maintenance programme.
7	**Portability**	Tabletop.
8	**Power supply, voltage, frequency and plug vary across the countries**	Operated by line electrical power supply with internal replaceable rechargeable battery backup. Protection against defibrillator discharges and electrosurgical units. Battery charger integrated in the main unit. Automatic switch between battery and mains powered modes, when recharging or in mains power failure. The display shall show which power source is in use. Running time on battery only ≥ 6 hours. Operates from AC power electric line: 100–240 V~/50–60 Hz. Main power cable and plug adapted for various countries. Mains power cable length ≥ 2.5 m.
9	**Documentation requirements (English language mandatory)**	Set: user and maintenance manuals, hard and soft copies, in English (mandatory) and other languages (preferable). Certificate of calibration and inspection (other means of assurance may be considered). Troubleshooting, calibration and routine maintenance. List of all spare parts and accessories, with part numbers and contact details for parts supply. Document with contact details of manufacturer, supplier and local service agent.
10	**Primary packaging label**	Name and/or trademark of the manufacturer. Electrical power input requirements (voltage, frequency and socket type) and safety use and storage (keep away from oil, grease and petroleum-based or flammable products as well as smoking or open flames). Model or product reference. Information for particular storage conditions (temperature, pressure, light, humidity).
11	**Standards, for the manufacturer**	Certified quality management system for medical devices (e.g. ISO 13485). General quality management (e.g. ISO 9001). Application of risk management to medical devices (e.g. ISO 14971).
12	**Regulatory approval/ certification**	Free sales certificate (FSC) or certificate for exportation of medical device provided by the authority in manufacturing country. Proof of regulatory compliance, as appropriate, per the product's risk classification (e.g. Food and Drug Administration [FDA] and/or Conformité Européenne [CE]).
13	**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) for: IEC 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance. IEC 60601-1-1 Medical electrical equipment – Part 1-1: General requirements for safety – Collateral standard: Safety requirements for medical electrical systems. 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. ISO 80601-2-61 Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment. ISO/IEEE 11073-10404 Health informatics – Personal health device communication – Part 10404: Device specialization – Pulse oximeter.
14	**Warranty**	2 years with regards efficiency and quality of the product. Availability of accessories and spare parts for at least 2 years.
Any variation to be indicated in the offer.		

3.3.7.3 Pulse oximeter: fingertip

Pulse oximeter: fingertip		
1	**General technical requirements**	SpO_2 and pulse rate monitor integrated into finger/toe clip. Configurations required to apply to adults and children, and all skin pigmentations. Suitable for spot check. SpO_2 detection to include the range: 70–99%. SpO_2 resolution: 1% or less. SpO_2 accuracy (in the range at least 70–99%): within ± 3%. If equipment is capable of a wider SpO_2 detection range, the accuracy over that wider range shall be stated. Pulse rate detection to include the range: 30–240 bpm. Pulse rate resolution: 1 bpm or less. Pulse rate accuracy within ± 3 bpm. Suitable for detection in low perfusion conditions (as per ISO 80601-2-61, test method must be described). Design must enable use in demanding environments, e.g. shock, vibration and free fall tests as per tests in ISO 80601-2-61. Available probe sizes must accommodate finger/toe thicknesses at least including the range 8–25 mm. Automatic correction for movement, ambient light artefacts (as per ISO 80601-2-61, test method must be described). Display shows % SpO_2, pulse rate, signal quality, sensor error or disconnect and low battery status. Enclosure to have ingress protection level IPX2 or better. Any aspects of usability as per IEC 62366-1 must be described. Disinfectable with hospital grade detergents. Automatic power-off. Hours of continuous use, or number of tests, per battery set shall be stated. Batteries must allow at least 2500 spot checks calculated at 30 s per spot check, or at least 12 hours of operation, or better. Operated by internal battery. If rechargeable, batteries may be charged via USB connector or by external AC charger. Rechargeable batteries are preferred.
2	**Displayed parameters**	SpO_2, pulse rate, battery and system status and preferably signal quality.
3	**Alarms**	Audible and visual alarms for sensor error or disconnected, system errors, low battery. Audible and visual alarms for low/high saturation and pulse rate.
4	**Consumables**	Rechargeable and/or non rechargeable batteries: 2 sets
5	**Accessories**	Battery charger (AC or USB if relevant): 1 per equipment. Replacement flexible cover for patient finger contact (if removable): 2 per equipment. Carry case and/or lanyard.
6	**Documentation requirements (English language mandatory)**	User: manuals, hard and soft copies, in English (mandatory) and other languages (preferable). Certificate of calibration and inspection (other means of assurance may be considered). Troubleshooting separate manual or as part of the user manual.
7	**Primary packaging label**	Name and/or trademark of the manufacturer. Electrical power input requirements (voltage, frequency and socket type) and safety use and storage (keep away from oil, grease and petroleum-based or flammable products as well as smoking or open flames). Model or product reference. Information for particular storage conditions (temperature, pressure, light, humidity).
8	**Standards, for the manufacturer**	Certified quality management system for medical devices (e.g. ISO 13485). General quality management (e.g. ISO 9001). Application of risk management to medical devices (e.g. ISO 14971).
9	**Regulatory approval/ certification**	Free sales certificate (FSC) or certificate for exportation of medical device provided by the authority in manufacturing country. Proof of regulatory compliance, as appropriate, per the product's risk classification (e.g. Food and Drug Administration [FDA] and/or Conformité Européenne [CE]).

Pulse oximeter: fingertip		
10	**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) for: IEC 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance. IEC 60601-1-1 Medical electrical equipment – Part 1-1: General requirements for safety – Collateral standard: Safety requirements for medical electrical systems. 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. ISO 80601-2-61 Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment. 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). IEC 60068-2-31 Environmental testing – Part 2-31: Tests –Test Ec: Rough handling shocks, primarily for equipment-type specimens. IEC 62366-1 Medical devices – Part 1: Application of usability engineering to medical devices. 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.
11	**Warranty**	2 years with regards efficiency and quality of the product. Availability of accessories and spare parts for at least 2 years.
Any variation to be indicated in the offer.		

3.3.8 Patient monitor multiparametric

3.3.8.1 Patient monitor multiparametric: basic – for non-invasive blood pressure (NIBP) and oxygen saturation (SpO_2) (with accessories)

Patient monitor multiparametric: basic – for non-invasive blood pressure (NIBP) and oxygen saturation (SpO_2) (with accessories)		
1	**General technical requirements**	Continuous display of non-invasive blood pressure and SpO_2. Display of calculated heart rate, respiratory rate are optional. Operator can set audio-visual alarm levels for low or high levels of each parameter independently. Operates from mains voltage or from internal rechargeable battery. • Heart rate measurement range to be at least 30–250 bpm, with accuracy better than ± 5 bpm and minimum gradation 1 bpm. • SpO_2 measurement range at least 70–99%, with accuracy better than ± 3% and minimum gradation 1%. • Blood pressure monitoring range at least 30–270 mmHg, minimum gradation 1 mmHg. • Internal pump for cuff inflation for non-invasive blood pressure measurement, with over pressure protection. Liquid crystal display (LCD) or thin-film transistor (TFT) screen with: • numerical values visualization; • settable limits for the measured variables; • all parameters can be shown. Design must enable use in demanding environments, e.g. shock, vibration and free fall tests as per tests. Protections of all the functions against defibrillator discharges and electrosurgical units. Capable of operating continuously in ambient temperature of 10–40 °C and relative humidity of 15–85% (90% preferable). Automatic and programmable memory (preferable). Storage of continuous monitoring data (preferable). Trend display of each parameter over a timeframe possible (preferable). Enclosure to have ingress protection level IPX1 or better.
2	**Alarms**	Alarm override and temporary silence facility to be included. Audio-visual alarms required: high and low levels for each parameter (operator variable settings), sensor/wire/probe disconnected, low battery, cuff leak, cuff disconnect, hose leak, inflation/deflation errors, failure to take successful reading. Power failure.
3	**Accessories**	All the cables, sensors and connectors needed for full monitor functionality are to be included in the bid. Reusable SpO_2 probes adult: 2 probes. Reusable SpO_2 probes paediatric use: 2 probes. Blood pressure – non-invasive: 3 paediatric reusable cuffs; 3 adult reusable cuffs. Battery: 1 set.
4	**Spare parts**	1-year spare parts kit as per preventive maintenance programme, including but not exclusively: sets of spare fuses (if non-resettable fuses used) and battery.
5	**Power supply, voltage, frequency and plug vary across the countries**	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. Operates from AC power electric line: 100–240 V~/50–60 Hz. Main power cable and plug adapted for various countries. Mains power cable length ≥ 2.5 m. Protections against over-voltage and over-current line conditions. Protection against defibrillator discharges and electrosurgical units. Automatic switch between battery and mains powered modes, when recharging or in mains power failure. The display shall show which power source is in use. Compliance with electrical standards and regulations.
6	**Documentation requirements (English language mandatory)**	Set: user and maintenance manuals, hard and soft copies, in English (mandatory) and other languages (preferable). Certificate of calibration and inspection. Troubleshooting, calibration and routine maintenance. List of all spare parts and accessories, with part numbers and contact details for parts supply. Document with contact details of manufacturer, supplier and local service agent.

Patient monitor multiparametric: basic – for non-invasive blood pressure (NIBP) and oxygen saturation (SpO_2) (with accessories)		
7	**Primary packaging label**	Name and/or trademark of the manufacturer. Electrical power input requirements (voltage, frequency and socket type) and safety use and storage (keep away from oil, grease and petroleum-based or flammable products as well as smoking or open flames). Model or product reference. Information for particular storage conditions (temperature, pressure, light, humidity).
8	**Standards, for the manufacturer**	Certified quality management system for medical devices (e.g. ISO 13485). General quality management (e.g. ISO 9001). Application of risk management to medical devices (e.g. ISO 14971).
9	**Regulatory approval/ certification**	Free sales certificate (FSC) or certificate for exportation of medical device provided by the authority in manufacturing country. Proof of regulatory compliance, as appropriate, per the product's risk classification (e.g. Food and Drug Administration [FDA] and/or Conformité Européenne [CE]).
10	**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) for: IEC 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance. IEC 60601-1-1 Medical electrical equipment – Part 1-1: General requirements for safety – Collateral standard: Safety requirements for medical electrical systems. 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. IEC 60601-1-8 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). IEC 80601-2-49 Medical electrical equipment – Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment. IEC 80601-2-30 Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers. ISO 80601-2-61 Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment. 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. *Preferable if tested for*: IEC 62366-1 Medical devices – Part 1: Application of usability engineering to medical devices. IEC 60068-1:2013 Environmental testing – Part 1: General and guidance. IEC 60068-2-31 Environmental testing – Part 2-31: Tests: Rough handling shocks, primarily for equipment-type specimens.
11	**Warranty**	5 years with regards efficiency and quality of the product (software upgrades included). Availability of accessories and spare parts for at least 5 years.

3.3.8.2 Patient monitor multiparametric: intermediate – for ECG, non-invasive blood pressure (NIBP), oxygen saturation (SpO_2), respiratory rate (RR) and temperature (TEMP) (with accessories)

Patient monitor multiparametric: intermediate – for ECG, non-invasive blood pressure (NIBP), oxygen saturation (SpO_2), respiratory rate (RR) and temperature (TEMP) (with accessories)		
1	**General technical requirements**	Continuous display on screen of patient ECG, respiration rate and heart rate, non-invasive blood pressure, body temperature and SpO_2. Dynamic digital display that can show all active parameters. Unwanted parameters can be deselected from display. Operator can set audio-visual alarm levels for low or high levels of each parameter independently. Operates from mains voltage or from internal rechargeable battery. ECG patient connectors that are sterilizable and reusable are preferred. Hard copy printout of traces will not be required. • Minimum 3 leads (and up to 12 leads) ECG measurement and selectable display; an extra option for simple five-lead connection preferred. • Heart rate measurement range to be at least 30–250 bpm, with accuracy better than ± 5 bpm and minimum gradation 1 bpm. • SpO_2 measurement range at least 70–99 %, with accuracy better than ± 3% and minimum gradation 1%. • Blood pressure monitoring range at least 30–270 mmHg, minimum gradation 1 mmHg. Cuff sizes neonatal/paediatric and adult. User selectable measurement intervals. • Internal pump for cuff inflation for non-invasive blood pressure measurement, with over pressure protection. • Temperature probe to be reusable, external skin contact type, but consumable to protect between patients or disinfection method explained. • Temperature range at least 30–40 °C, minimum gradation 0.1 °C. • Respiration rate measurement range at least 0–100 bpm, minimum gradation 1 bpm. Automatic and programmable memory. Storage of continuous monitoring data. Trace signal velocity of at least 25 mm/s. LCD or TFT screen with: • analogue shape signals and numerical values visualization; • settable limits for the measured variables. Design must enable use in demanding environments, e.g. shock, vibration and free fall tests as per tests. Protections of all the functions against defibrillator discharges and electrosurgical units. Pace-maker detection. Data management functions (preferable). Capable of operating continuously in ambient temperature of 10–40 °C and relative humidity of 15–85% (90% preferable). Enclosure to have ingress protection level IPX1 or better.
2	**Displayed parameters**	Trend display of each parameter.
3	**User adjustable settings**	Alarm override and temporary silence facility to be included. Audio-visual alarms required: high and low levels for each parameter (operator variable settings), sensor/wire/probe disconnected, low battery.
4	**Alarms**	Alarm override and temporary silence facility to be included. Audio-visual alarms required: high and low levels for each parameter (operator variable settings), sensor/wire/probe disconnected, low battery, cuff leak, cuff disconnect, hose leak, inflation/deflation errors, failure to take successful reading, low battery notice. Power failure.
5	**Consumables**	ECG electrodes (if applicable): 100 sets.
6	**Accessories**	All the cables, sensors and connectors needed for full monitor functionality are to be included in the bid. Lead ECG cable: 2 per equipment. Lead ECG cable (if option offered): 2 per equipment. Sets of ECG connection electrodes (if reusable type): 5 sets. Tubes electrode gel (if required): 5 tubes. Reusable SpO_2 probes adult: 2 probes. Reusable SpO_2 probes paediatric use: 2 probes. Blood pressure – non-invasive: 3 paediatric reusable cuffs; 3 adult reusable cuffs. External skin temperature probes: 2 probes. Battery: 1 set.

Patient monitor multiparametric: intermediate – for ECG, non-invasive blood pressure (NIBP), oxygen saturation (SpO_2), respiratory rate (RR) and temperature (TEMP) (with accessories)		
7	**Spare parts**	1-year spare parts kit as per preventive maintenance programme, including but not exclusively: sets of spare fuses (if non-resettable fuses used) and battery.
8	**Power supply, voltage, frequency and plug vary across the countries**	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. Operates from AC power electric line: 100–240 V~/50–60 Hz. Main power cable and plug adapted for various countries. Mains power cable length ≥ 2.5 m. Protections against over-voltage and over-current line conditions. Protection against defibrillator discharges and electrosurgical units. Automatic switch between battery and mains powered modes, when recharging or in mains power failure. The display shall show which power source is in use. Compliance with electrical standards and regulations.
9	**Documentation requirements (English language mandatory)**	Set: user and maintenance manuals, hard and soft copies, in English (mandatory) and other languages (preferable). Certificate of calibration and inspection. Troubleshooting, calibration and routine maintenance. List of all spare parts and accessories, with part numbers and contact details for parts supply. Document with contact details of manufacturer, supplier and local service agent.
10	**Primary packing label**	Name and/or trademark of the manufacturer. Electrical power input requirements (voltage, frequency and socket type) and safety use and storage (keep away from oil, grease and petroleum-based or flammable products as well as smoking or open flames). Model or product reference. Information for particular storage conditions (temperature, pressure, light, humidity).
11	**Standards, for the manufacturer**	Certified quality management system for medical devices (e.g. ISO 13485). General quality management (e.g. ISO 9001). Application of risk management to medical devices (e.g. ISO 14971).
12	**Regulatory approval/ certification**	Free sales certificate (FSC) or certificate for exportation of medical device provided by the authority in manufacturing country. Proof of regulatory compliance, as appropriate, per the product's risk classification (e.g. Food and Drug Administration [FDA] and/or Conformité Européenne [CE]).
13	**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) for: IEC 60601-1 Medical electrical equipment– Part 1: General requirements for basic safety and essential performance. IEC 60601-1-1 Medical electrical equipment – Part 1-1: General requirements for safety – Collateral standard: Safety requirements for medical electrical systems. 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. IEC 60601-1-8 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). IEC 80601-2-49 Medical electrical equipment – Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment. IEC 80601-2-30 Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometer. ISO 80601-2-61 Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment. IEC 60601-2-27 Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment. *Preferable if tested for*: IEC 62366-1 Medical devices – Part 1: Application of usability engineering to medical devices. IEC 60068-1:2013: Environmental testing – Part 1: General and guidance. IEC 60068-2-31 Environmental testing – Part 2-31: Tests: Rough handling shocks, primarily for equipment-type specimens.
14	**Warranty**	5 years with regards efficiency and quality of the product (software upgrades included). Availability of accessories and spare parts for at least 5 years.

3.3.8.3 Patient monitor multiparametric: advanced – for ECG, CO_2, invasive blood pressure (IBP), non-invasive blood pressure (NIBP), oxygen saturation (SpO_2), respiratory rate (RR) and temperature (TEMP) (with accessories)

Patient monitor multiparametric: advanced – for ECG, CO_2, invasive blood pressure (IBP), non-invasive blood pressure (NIBP), oxygen saturation (SpO_2), respiratory rate (RR) and temperature (TEMP) (with accessories)		
1	**General technical requirements**	Continuous display on screen of patient ECG, respiration rate and heart rate, invasive and non-invasive blood pressure, body temperature, SpO_2 and CO_2 mainstream or side stream. Dynamic digital display that can show all active parameters. Unwanted parameters can be deselected from display. Operator can set audio-visual alarm levels for low or high levels of each parameter independently. Operates from mains voltage or from internal rechargeable battery. ECG patient connectors that are sterilizable and reusable are preferred. Hard copy printout of traces will not be required. • Multichannel (up to 12 leads) ECG measurement and selectable display; an extra option for simple five-lead connection preferred. • Heart rate measurement range to be at least 30–250 bpm, with accuracy better than ± 5 bpm and minimum gradation 1 bpm. • SpO_2 measurement range at least 70–99%, with accuracy better than ± 3% and minimum gradation 1%. • Blood pressure monitoring range at least 30–270 mmHg, minimum gradation 1 mmHg. Cuff sizes neonatal/paediatric and adult. User selectable measurement intervals. • Internal pump for cuff inflation for non-invasive blood pressure measurement, with over pressure protection. • Temperature probe to be reusable, external skin contact type, but consumable to protect between patients or disinfection method explained. • Temperature range at least 30–40 °C, minimum gradation 0.1 °C. • Respiration rate measurement range at least 0–100 bpm, minimum gradation 1 bpm. • CO_2 monitoring capabilities. • Invasive blood pressure (IBP) monitoring capabilities. Automatic and programmable memory. Storage of continuous monitoring data. Trace signal velocity of at least 25 mm/s. LCD or TFT screen with: • analogue shape signals and numerical values visualization; • settable limits for the measured variables; • not less than 10″ wide. Design must enable use in demanding environments, e.g. shock, vibration and free fall tests as per tests. Protections of all the functions against defibrillator discharges and electrosurgical units. Pace-maker detection. Data management functions (preferable). Capable of operating continuously in ambient temperature of 10–40 °C and relative humidity of 15–85% (90% preferable). Enclosure to have ingress protection level IPX1 or better.
2	**Displayed parameters**	Trend display of each parameter.
3	**User adjustable settings**	Alarm override and temporary silence facility to be included. Audio-visual alarms required: high and low levels for each parameter (operator variable settings), sensor/wire/probe disconnected, low battery.
4	**Alarms**	Alarm override and temporary silence facility to be included. Audio-visual alarms required: high and low levels for each parameter (operator variable settings), sensor/wire/probe disconnected, low battery, cuff leak, cuff disconnect, hose leak, inflation/deflation errors, failure to take successful reading, low battery notice. Power failure.
5	**Consumables**	ECG electrodes (if applicable): 100 sets.

Patient monitor multiparametric: advanced – for ECG, CO_2, invasive blood pressure (IBP), non-invasive blood pressure (NIBP), oxygen saturation (SpO_2), respiratory rate (RR) and temperature (TEMP) (with accessories)		
6	**Accessories**	All the cables, sensors and connectors needed for full monitor functionality are to be included in the bid. Lead ECG cable: 2 per equipment. Lead ECG cable (if option offered): 2 per equipment. Sets of ECG connection electrodes (if reusable type): 5 sets. Tubes electrode gel (if required): 5 tubes. Reusable SpO_2 probes adult: 2 probes. Reusable SpO_2 probes paediatric use: 2 probes. Blood pressure – non-invasive: 3 paediatric reusable cuffs; 3 adult reusable cuffs. Blood pressure – invasive: 1 sensor for each channel offered. External skin temperature probes: 2 probes. If CO_2 mainstream technology: tube adapter: 3 per equipment; sensor: 3 per equipment. If CO_2 side stream technology: sample lines: 100 lines; water traps: 10 per equipment. Battery: 1 set.
7	**Spare parts**	1-year spare parts kit as per preventive maintenance programme including but not exclusively, sets of spare fuses (if non-resettable fuses used) and battery.
8	**Power supply, voltage, frequency and plug vary across the countries**	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. Operates from AC power electric line: 100–240 V~/50–60 Hz. Main power cable and plug adapted for various countries. Mains power cable length ≥ 2.5 m. Protections against over-voltage and over-current line conditions. Protection against defibrillator discharges and electrosurgical units. Automatic switch between battery and mains powered modes, when recharging or in mains power failure. The display shall show which power source is in use. Compliance with electrical standards and regulations.
9	**Documentation requirements (English language mandatory)**	Set: user and maintenance manuals, hard and soft copies, in English (mandatory) and other languages (preferable). Certificate of calibration and inspection. Troubleshooting, calibration and routine maintenance. List of all spare parts and accessories, with part numbers and contact details for parts supply. Document with contact details of manufacturer, supplier and local service agent.
10	**Primary packaging label**	Name and/or trademark of the manufacturer. Electrical power input requirements (voltage, frequency and socket type) and safety use and storage (keep away from oil, grease and petroleum-based or flammable products as well as smoking or open flames). Model or product reference. Information for particular storage conditions (temperature, pressure, light, humidity).
11	**Standards, for the manufacturer**	Certified quality management system for medical devices (e.g. ISO 13485). General quality management (e.g. ISO 9001). Application of risk management to medical devices (e.g. ISO 14971).
12	**Regulatory approval/ certification**	Free sales certificate (FSC) or certificate for exportation of medical device provided by the authority in manufacturing country. Proof of regulatory compliance, as appropriate, per the product's risk classification (e.g. Food and Drug Administration [FDA] and/or Conformité Européenne [CE]).

Patient monitor multiparametric: advanced – for ECG, CO_2, invasive blood pressure (IBP), non-invasive blood pressure (NIBP), oxygen saturation (SpO_2), respiratory rate (RR) and temperature (TEMP) (with accessories)		
13	**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) for: IEC 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance. IEC 60601-1-1 Medical electrical equipment – Part 1-1: General requirements for safety – Collateral standard: Safety requirements for medical electrical systems. 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. IEC 60601-1-8 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). IEC 80601-2-49 Medical electrical equipment – Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment. IEC 80601-2-30 Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometer. IEC 60601-2-34 Particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment). ISO 80601-2-55 Particular requirements for the basic safety and essential performance of respiratory gas monitors). ISO 80601-2-61 Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment. IEC 60601-2-27 Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment. Preferable if tested for: IEC 62366-1 Medical devices – Part 1: Application of usability engineering to medical devices. IEC 60068-1:2013 Environmental testing – Part 1: General and guidance. IEC 60068-2-31 Environmental testing – Part 2-31: Tests: Rough handling shocks, primarily for equipment-type specimens.
14	**Warranty**	5 years with regards efficiency and quality of the product. Availability of accessories and spare parts for at least 2 years.

Reference

1. WHO & UNICEF. WHO-UNICEF Technical specifications and guidance for oxygen therapy devices. Geneva: World Health Organization and Copenhagen: United Nations Children Fund; 2019 (https://www.who.int/medical_devices/publications/tech_specs_oxygen_therapy_devices/en/, accessed 18 May 2020).

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4. Technical specifications for invasive and non-invasive ventilators

4.1 Context and considerations

This chapter is an update of the version first published on 13 April 2020. The updates have been discussed and agreed with specifically appointed panels of experts (respiratory care, biomedical engineering and procurement) in order to respond to:

- New information and updates regarding COVID-19 clinical management of critical and non-critical patients.
- Specific procurement issues concerning the availability of ventilators and their compliance to the technical requirements requested.
- The technical specifications are the minimum requirements with which invasive and non-invasive ventilators used for the management of COVID-19 patients must comply to ensure quality, safety and effectiveness.

All these ventilators require a source of medical grade oxygen and a source of medical grade air. Some equipment has internal turbines/pistons/compressors and can be used with high-pressure oxygen (e.g. oxygen tank, piped oxygen) and/or low-pressure oxygen source (e.g. oxygen concentrator). **Oil-based external air compressors can ruin ventilator sensors because of the vapour produced.**

All these ventilators should be provided with accessories, consumables and spare parts, as required to operate for at least 6 months. The maintenance guidance for replacement of accessories and consumables and safe decontamination of reusable parts provided by the manufacturer must be followed.

Important considerations:

- Invasive ventilators require highly trained medical staff to perform intubation and to set the pressure settings, controls and alarms. Provision must also be made in terms of infrastructure, especially, if available, concerning high-pressure oxygen and/or air sources, environmental temperature and humidity control, and availability of technical staff to perform troubleshooting protocols, maintain the equipment, and for decontamination procedures. Many ventilators may require oxygen concentrations > 80% for functioning without constantly alarming and many ventilators may require oxygen supply pressure greater than that which can be delivered by an oxygen concentrator or other low-pressure source.
- The non-invasive ventilators, mainly continuous positive airway pressure (CPAP), bilevel positive airway pressure (BiPAP/BPAP) and high-flow nasal cannula (HFNC), require high attention in terms of infection control to reduce the risk of contagion of health care providers by the aerosol generated. And HFNC and CPAP may require extremely large supplies of oxygen.

A HFNC can provide a higher flow (up to 50–70 L/min) than a nasal cannula connected to a standard flowmeter (up to approximately 15 L/min).

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

4.2 Definitions and intended use

Invasive ventilators

Ventilator for intensive care unit: This is designed to provide temporary ventilatory and respiratory assistance to adult and paediatric intensive care patients who cannot breathe on their own or who require assistance to maintain adequate ventilation. The equipment is usually connected to a 50 psi (4 bar/345 kPa) gas supply. Some ventilators have an in-built air compressor and still need an oxygen source. The mixed, heated and humidified gas is delivered to the patient using a double-limb breathing circuit (one for inspiratory and one for expiratory phases). Different parameters can be controlled by the user and displayed on a screen (e.g. fraction of inspired oxygen [FiO_2], trigger, respiratory rate [RR], positive end-expiratory pressure [PEEP], control modes).

Ventilator for transport: This is designed to provide temporary ventilatory assistance with a full degree of portability (weight and manageability). Battery life is an important consideration – the equipment should have the ability to operate on an external battery for 4 hours. It should also minimize oxygen consumption and operate without any compressed gas source (e.g. by a turbine). It should work when connected to a 35 psi (2.4 bar) or a low-flow oxygen supply. Simplicity of use and low cost are advantages to consider ahead of advanced ventilatory features, including invasive ventilation modes and capabilities.

Ventilator for sub-acute care: Designed to provide mainly non-invasive ventilation, but in case of an emergency, it can also provide temporary invasive ventilation to patients who cannot breathe on their own or who require assistance to maintain adequate ventilation. The equipment should be capable of operating on an external battery for an extended period and minimize oxygen consumption. It should work when connected to a 35 psi (2.4 bar) or a low-flow oxygen supply. Simplicity of use and low cost are advantages to consider ahead of advanced ventilatory features.

Non-invasive ventilators

Continuous positive airway pressure (CPAP): This is designed to apply CPAP to non-intubated adult or paediatric patients. It is commonly used in spontaneously breathing patients who require short-term mechanical assistance. These units can deliver air or a mixture of air and oxygen at high flow rates and a single set pressure, typically 3–20 cmH_2O, through a circuit and patient interface. The effectiveness of the treatment is closely related to the proper sealing of the nasal or oral-nasal mask to the patient's face.

Bilevel positive airway pressure (BiPAP/BPAP): This is designed to apply CPAP to non-intubated adult or paediatric patients, allowing clinicians to adjust two different pressures during the inspiratory and expiratory phases of a breath. It is commonly used in spontaneously breathing patients who require short-term mechanical assistance.

These units can deliver air or a mixture of air and oxygen at high flow rates. The higher inspiratory pressure reduces the patient's breathing effort while the lower pressure helps to preserve an adequate alveolar volume and prevent collapse of unstable alveolar units during expiration. The effectiveness of the treatment is closely related to the proper sealing of the nasal or oral-nasal mask to the face of the patient.

High-flow nasal cannula (HFNC) also known as heated humidified high-flow (HHHF) therapy or high-flow nasal oxygen (HFNO): Designed to deliver high flow rates with heated humidification to non-intubated adult or paediatric patients. Warm and humidified gas decreases airway inflammation and reduces the caloric expenditure in acute respiratory failure. The maximum flow varies according to manufacturer, going up to 50–70 L/min. A specialized flowmeter and a heated humidifier are incorporated into the unit to deliver heated and humidified gases, through a circuit and patient interface. There is a low level of positive pressure at the patient's airway. The FiO_2 can be set by the clinician. The effectiveness of the treatment is related to the high flow generated rather than the proper sealing of the nasal mask to the patient's face (reduced exhaled air dispersion).

4.3 Technical specifications for procurement

4.3.1 Invasive ventilators

4.3.1.1 Invasive ventilator – intensive care unit

Ventilator for intensive care unit (adult and paediatric)		
1	**General technical requirements**	Medical oxygen and air high-pressure input ports (> 35 psi [2.4bar]) provide a means to limit reverse gas flowrate (leakage). Each high-pressure input port with a filter and water trap, if applicable, for air input port. Medical air compressor or turbine in-built preferred, alternatively external air compressor. Possibility for using external low-pressure oxygen (approx. 20 psi), as source (preferable). Mechanical safety valve. Internal function testing/leak testing. At least IP21 degree of protection to the harmful ingress of water (fluid spill resistance). Mechanical shock resistance, mechanical vibration, electromagnetic compatibility and electrical safety testing. Compatible active humidifying system. Event log for errors traceability (preferable). Operating temperature and humidity 5–40 °C and 0–95% relative humidity (RH). Storage temperature and humidity -20–60 °C, 0–95% RH.
2	**Ventilation modes**	Pressure control ventilation (PCV). Volume control ventilation (VCV). Pressure support ventilation (PSV). Synchronized intermittent mandatory ventilation (SIMV) (preferable). Pressure regulated volume control (PRVC) or similar (preferable). Non-invasive ventilation (CPAP or BiPAP).
3	**Monitored and controlled parameters (by user)**	FiO_2: 21–100%. Tidal volume: 20–1500 mL. Pressure setting: 0–40 cmH_2O. I:E ratio. I:E inverse ratio. RR: 10–60 breaths/min, minimum. Inspiratory pause manoeuvre capability to measure plateau pressure. Adjustable peak pressure limitation/pressure-cycling mechanism above measured peak pressure. Internal PEEP capability/range: 0–20 cmH_2O, minimum.
4	**Displayed parameters (colour and graphics preferable)**	Display easily readable in low ambient light and sunlight. 3 scalar waveforms: pressure, volume and flow (preferable). Loop (axis) displays: pressure-volume, flow-volume and pressure-flow (preferable). Status indicators for ventilator mode, battery status, patient data, alarm settings. FiO_2. Airway pressures (peak, plateau mean and PEEP). Tidal volume (expired and inspired preferable). Minute volume (inspired and expired). I:E ratio. RR (spontaneous and mechanical). End-tidal CO_2.
5	**Alarms, related to gas delivered (adjustable, visual and audible)**	High/low FiO_2. High/low inspiratory pressure and PEEP. High/low tidal volume (not achieved or exceeded). Apnoea. High/low RR. Continuously high pressure/occlusion. Breathing circuit disconnect. Low minute volume.

Ventilator for intensive care unit (adult and paediatric)		
6	**Alarms, related to equipment operation (visual and audible)**	Gas supply failure. Power failure. Low battery. Self-diagnostics failure alarm.
7	**Consumables, labelled "single use" (included and mentioned in a disaggregated list)**	Breathing circuits for adult: double-limb with standard outlet/inlet connectors with 22 mm outside diameter (at least 60). Breathing circuits for paediatric (if needed): double-limb with standard outlet/inlet connectors with 22 mm outside diameter (at least 40). Exhaled gas filter (when applicable). Heat moisture exchanger filters (HMEF) (at least 90). Non-invasive ventilation masks, for adult (at least 50 in different sizes). Non-invasive ventilation masks, for paediatric (if needed) (at least 12). Viral/bacterial filters 99.99% efficiency minimum; inspiratory and expiratory, as applicable (at least 180).
8	**Reusable accessories (included and mentioned in a disaggregated list)**	Breathing circuits for adult: double-limb with standard outlet/inlet connectors with 22 mm outside diameter (at least 2). Breathing circuits for paediatric (if needed): double-limb with standard outlet/inlet connectors with 22 mm outside diameter (at least 2). Expiratory housing with in-built bacteria filters; as well as the possibility to accommodate heat moisture exchangers (HMEs). Exhalation valve. CO_2 sensors. Active humidifier with relevant connectors. Air compressor if external to the unit. Standard hoses and connectors (i.e. DISS/NIST as applicable for the country) for oxygen and medical air wall outlets and cylinders. Pressure regulators (from wall outlet to ventilator) to avoid damaging ventilator, as required to operate.
9	**Spare parts (included and mentioned in a disaggregated list)**	1 year's spare parts kit as per preventive maintenance programme (preferable).
10	**Portability**	Mounting tray and support stand (cart for transport with at least 2 castors fitted with breaks).
11	**Power supply (voltage, frequency and plug vary across the countries)**	Operates from AC power electric line: 100–240 V AC ± 10% / 50–60 Hz ± 10% of nominal value. In-built rechargeable battery. Automatic switch from AC power electric-line mode to battery operating mode and vice versa. Continuous in battery operating mode with standard ventilation not less than 1 hour. Total re-charging time not greater than 6 hours. Equipment must be connected to a reliable and continuous source of energy.
12	**Documentation (included)**	Instruction for use; service manual and product information to be provided in English language, at least.
13	**Primary packaging label**	Name and/or trademark of the manufacturer. Model or product reference. Information for particular storage conditions (temperature, pressure, light, humidity).
14	**Standards, for the manufacturer**	Certified quality management system for medical devices (e.g. ISO 13485). Application of risk management to medical devices (e.g. ISO 14971).
15	**Regulatory approval/ certification**	Free sales certificate (FSC) or certificate for exportation of medical device provided by the authority in manufacturing country. Proof of regulatory compliance, as appropriate, per the product's risk classification (e.g. Food and Drug Administration [FDA] and/or Conformité Européenne [CE]).

Ventilator for intensive care unit (adult and paediatric)		
16	**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) for (latest version recommended but compliance to previous standards versions could be accepted): IEC 60601-1:2005 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance. 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. ISO 80601-2-12:2020 Medical electrical equipment – Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators. ISO 80601-2-74:2017 Medical electrical equipment – Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment. ISO 80601-2-79:2018 Medical electrical equipment – Part 2-79: Particular requirements for basic safety and essential performance of ventilatory support equipment for ventilatory impairment. 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). ISO 20789:2018 Anaesthetic and respiratory equipment – Passive humidifiers (if applicable).
17	**Warranty**	Minimum 2 years. Availability of accessories, consumables and spare parts for at least 2 years.
Any variation to be indicated in the offer.		

4.3.1.2 Invasive ventilators – transport

Ventilator for transport (adult and paediatric)		
1	**General technical requirements**	Medical air compressor integral to unit, with inlet filter, or high performance turbines, or Venturi systems. External low-flow oxygen (preferable). Oxygen high-pressure input port (> 35 psi). Oxygen-air mixture accuracy of not higher than 10%. Oxygen conserve feature (preferable). Internal function testing/leak testing. Event log for errors traceability (preferable). All parts withstand high disinfection procedures. At least IP21 degree of protection to the harmful ingress of water. Polyvinyl chloride (PVC) materials must be avoided in the patient gas pathway.
2	**Ventilation modes**	Pressure control ventilation (PCV). Volume control ventilation (VCV). Synchronized intermittent mandatory ventilation (SIMV) (preferable). Pressure support ventilation (PSV) (preferable). Pressure regulated volume control (PRVC) (or similar preferable). Non-invasive ventilation (CPAP/ BiPAP).
3	**Monitored and controlled parameters (by user)**	Air and externally supplied oxygen mixture ratios fully controllable. FiO_2: at least from 40% (or less) to at least 97% (or more). Tidal volume: 20–1000 mL (preferable). Inspiratory pressure: 0–40 cmH_2O. I:E ratio. RR: 10–60 breaths/min, minimum.

Ventilator for transport (adult and paediatric)		
4	**Displayed parameters (colour and graphics preferable)**	Display easily readable in low ambient light and sunlight. Real-time scalar waveforms for flow, volume and pressure, at least two simultaneously (preferable). Status indicators for ventilator mode, battery status, patient data, alarm settings. Airway pressures (peak and PEEP). Tidal volume (expired). Minute volume (expired). I:E ratio. Inspiration time. RR. FiO_2. Occlusion pressure detection or combination of apnoea and high-pressure alarms. Air and/or oxygen pressure. Spontaneous ventilation. Leak. Gas availability/time remaining (preferable).
5	**Alarms, related to gas delivered (visual and audible)**	High/low FiO_2 (preferable). High/low minute volume. High/low inspiratory pressure. Breathing circuit disconnect. Apnoea.
6	**Alarms, related to equipment operation (visual and audible)**	Gas supply failure. Power failure. Low battery.
7	**Consumables, labelled "single use" (included and mentioned in a disaggregated list)**	Breathing circuits for adult: single or double-limb (prefered) with standard outlet/inlet connectors with 22 mm outside diameter (at least 60). Breathing circuits for paediatric (if needed): single or double-limb (preferred) with standard outlet/inlet connectors with 22 mm outside diameter (at least 40). Exhaled gas filter (when applicable). Heat moisture exchanger filters (HMEF) (at least 90). Non-invasive ventilation masks, for adult (at least 50 of different sizes). Non-invasive ventilation masks, for paediatric (if needed) (at least 12). Viral/bacterial filters 99.99% efficiency minimum; inspiratory and expiratory, as applicable (at least 180).
8	**Accessories, reusable (included and mentioned in a disaggregated list)**	Breathing circuits for adult: double-limb with standard outlet/inlet connectors with 22 mm outside diameter (at least 2). Breathing circuits for paediatric (if needed): double-limb with standard outlet/inlet connectors with 22 mm outside diameter (at least 2). Exhalation valve if applicable. CO_2 sensors (preferable). Standard hoses and connectors (i.e. DISS/NIST as applicable for the country) for oxygen wall outlets and cylinder, as required to operate.
9	**Spare parts (included and mentioned in a disaggregated list)**	1 year's spare parts kit as per preventive maintenance programme (preferable).
10	**Portability**	Portable equipment with mechanical strength to lever rough handling.
11	**Power supply (voltage, frequency and plug vary across countries)**	Operates from AC power electric line: 100–240 V AC ± 10% / 50–60 Hz ± 10%. In-built rechargeable battery. Automatic switch from AC power electric-line mode to battery operating mode and vice versa. Continuous in battery operating mode with standard ventilation not less than 4 hours. Total re-charging time not greater than 6 hours.
12	**Documentation (included)**	Instruction for use; service manual and product information to be provided in English language, at least.
13	**Primary packaging label**	Name and/or trademark of the manufacturer. Model or product reference. Information for particular storage conditions (temperature, pressure, light, humidity).
14	**Standards, for the manufacturer**	Certified quality management system for medical devices (e.g. ISO 13485). Application of risk management to medical devices (e.g. ISO 14971).

Ventilator for transport (adult and paediatric)		
15	**Regulatory approval/ certification**	Free sales certificate (FSC) or certificate for exportation of medical device provided by the authority in manufacturing country. Proof of regulatory compliance, as appropriate, per the product's risk classification (e.g. Food and Drug Administration [FDA] and/or Conformité Européenne [CE]).
16	**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) for (latest version recommended but compliance to previous standards versions could be accepted): IEC 60601-1:2005 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance. 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. ISO 10651-3:1997 Lung ventilators for medical use – Part 3: Particular requirements for emergency and transport ventilators. ISO 80601-2-12:2011 – Particular requirements for basic safety and essential performance of critical care ventilators. 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. 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). ISO 20789:2018 Anaesthetic and respiratory equipment – Passive humidifiers (if applicable). N 13718-1:2015 Medical vehicles and their equipment – Air ambulances – Part 1: Requirements for medical devices used in air ambulances (preferable). RTCA DO-160G Environmental conditions and test procedures for airborne equipment (preferable). DIN EN 794-3 Lung ventilators – Part 3: Particular requirements for emergency and transport ventilators (preferable). IEC 60601-1-8:2006 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 (preferable).
17	**Warranty**	Minimum 2 years. Availability of accessories, consumables and spare parts for at least 2 years.
Any variation to be indicated in the offer.		

4.3.1.3 Invasive ventilators – sub-acute care

Ventilator for sub-acute care (adult and paediatric)		
1	**General technical requirements**	Medical air compressor or turbine in-built, with inlet filter. Possibility for using external low-pressure oxygen (approx. 20 psi) as source (preferable). If oxygen, high pressure input port (> 35 psi [2.4bar]). Oxygen-air mixture accuracy of 4%. Oxygen conserve feature (preferable). Internal function testing/leak testing. Event log for errors traceability (preferable). At least IP21 degree of protection to the harmful ingress of water (higher preferable). Capability to work with dual-limb breathing circuits. Capability to connect to an active humidifying system.
2	**Ventilation modes**	Non-invasive ventilation. It must include at least one mandatory and invasive ventilation mode. Pressure control ventilation (PCV). Volume control ventilation (VCV). Pressure support ventilation (PSV). Synchronized intermittent mandatory ventilation (SIMV) (preferable). Pressure regulated volume control (PRVC) (or similar preferable).

Ventilator for sub-acute care (adult and paediatric)		
3	**Monitored and controlled parameters (by user)**	Air and externally supplied oxygen mixture ratios fully controllable. FiO_2: 21–100%. Tidal volume: 50–1000 mL (preferable). Inspiratory pressure: 0–40 cmH_2O. I:E ratio. RR: 10–60 breaths/min, minimum. PEEP: at least 0–20 cmH_2O.
4	**Displayed parameters (colour and graphics preferable)**	Display easily readable in low ambient light and sunlight. 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). Tidal volume (expired). Minute volume (expired). I:E ratio. Inspiration and expiration times. RR. FiO_2. Occlusion pressure detection. Air and oxygen pressure. Spontaneous ventilation. Leak. Spontaneous minute volume (preferable).
5	**Alarms, related to gas delivered (visual and audible)**	High/low FiO_2. High/low minute volume. High/low inspiratory pressure. Breathing circuit disconnect. Low minute volume (preferable). Apnoea.
6	**Alarms, related to equipment operation (visual and audible)**	Gas supply failure. Power failure. Self-diagnostics failure alarm. Low battery.
7	**Consumables, labelled "single use" (included and mentioned in a disaggregated list)**	Single-limb breathing circuit for adult with standard connector with 22 mm outside diameter (at least 60). Single-limb breathing circuit for paediatric (if needed) with standard connector with 22 mm outside diameter (at least 40). Double-limb breathing circuits for adult with standard outlet/inlet connectors with 22 mm outside diameter (preferable) (at least 60). Double-limb breathing circuits for paediatric (if needed) with standard outlet/inlet connectors with 22 mm outside diameter (preferable) (at least 40). Non-invasive ventilation masks, for adult (at least 50 in different sizes). Non-invasive ventilation masks, for paediatric (if needed) (at least 12). Viral/bacterial filters 99.99% efficiency minimum; inspiratory and expiratory as applicable (at least 180). Exhaled gas filter, when applicable. Heat and moisture exchanger filters (HMEF) (at least 90).
8	**Accessories, reusable (included and mentioned in a disaggregated list)**	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). Exhalation valve (if applicable). CO_2 sensors (preferable). Standard hoses and connectors (i.e. DISS/NIST as applicable for the country) for oxygen wall outlets and cylinder, as required to operate. Compatible active humidifier provided.
9	**Spare parts (included and mentioned in a disaggregated list)**	1 year's spare parts kit as per preventive maintenance programme, including exhalation valves and also oxygen sensors (if applicable).

Ventilator for sub-acute care (adult and paediatric)		
10	**Portability**	Preferable: portable equipment with mechanical strength to lever rough handling. Alternative option: mounted on a mobile cart with at least 2 castors fitted with breaks.
11	**Power supply (voltage, frequency and plug vary across the countries)**	Operates from AC power electric line: 100–240 V AC ± 10% / 50–60 Hz ± 10%. In-built rechargeable battery. Automatic switch from AC power electric-line mode to battery operating mode and vice versa. Continuous in battery operating mode with standard ventilation not less than 4 hours. Total re-charging time not greater than 6 hours.
12	**Documentation (included)**	Instruction for use; service manual and product information to be provided in English language, at least.
13	**Primary packaging label**	Name and/or trademark of the manufacturer. Model or product reference. Information for particular storage conditions (temperature, pressure, light, humidity).
14	**Standards, for the manufacturer**	Certified quality management system for medical devices (e.g. ISO 13485). Application of risk management to medical devices (e.g. ISO 14971).
15	**Regulatory approval/ certification**	Free sales certificate (FSC) or certificate for exportation of medical device provided by the authority in manufacturing country. Proof of regulatory compliance, as appropriate, per the product's risk classification (e.g. Food and Drug Administration [FDA] and/or Conformité Européenne [CE]).
16	**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), for (latest version recommended but compliance to previous standards versions could be accepted): IEC 60601-1:2005 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance. 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. ISO 10651-5:2006 Lung ventilators for medical use – Particular requirements for basic safety and essential performance – Part 5: Gas-powered emergency resuscitators. ISO 80601-2-74:2017 Medical electrical equipment – Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment. 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). ISO 20789:2018 Anaesthetic and respiratory equipment – Passive humidifiers (if applicable).
17	**Warranty**	Minimum 2 years. Availability of accessories, consumables and spare parts for at least 2 years.
Any variation to be indicated in the offer.		

4.3.2 Non-invasive ventilators

4.3.2.1 Non-invasive ventilators – continuous positive airway pressure (CPAP)

Continuous positive airway pressure (CPAP) (adult and paediatric)		
1	**General technical requirements**	Maintains continuous positive pressure in airway. Easy to operate user interface, numbers and displays to be clearly visible. Leakage compensation capability (preferable). In-built air compressor or turbine. Oxygen inlet. Capability to connect to an active humidifier system (preferable). Noise level < 35 dB at mid pressure range. Expiratory relief features that reduce the pressure slightly at the end of each breath to make it easier for the patient to exhale (preferable). Pressure ramp option that starts pressure at low level and slowly increases over a period (preferable). All parts withstand high disinfection procedures. Inspiration trigger for auto start. Class I or Class II or internally powered. Protection IP21 required (IP22 preferable).
2	**Ventilation modes**	Non-invasive CPAP.
3	**Monitored and controlled parameters (by clinical user)**	FiO_2: 21–100% (preferable). Pressure: 4–20 cmH_2O.
4	**Displayed parameters (colour and graphics preferable)**	Display easily readable in low ambient light and sunlight. Pressure: cmH_2O. FiO_2 (%) (preferable). Flow (preferable). Air leak (%) (preferable). RR (preferable).
5	**Alarms, related to gas delivered (visual and/or audible)**	High/low pressure and/or minute ventilation. High/low oxygen (preferable). Breathing circuit disconnection.
6	**Alarms, related to equipment operation (visual and/or audible)**	Lack of water (preferable). System failure. Air filter to be replaced. Power failure (preferable). Low battery (preferable).
7	**Consumables, labelled "single use" (included and mentioned in a disaggregated list)**	Inlet bacteria filters, if applicable (at least 180). Expiratory filters, high efficiency. Full face mask with tubing (for paediatric and universal fit for adult), alternative oral-nasal mask for adult and paediatric with tubing (at least 12 adult in different sizes). Helmet for adult and paediatric with tubing (preferable).
8	**Accessories, reusable (included and mentioned in a disaggregated list)**	Full face mask with tubing (for paediatric and universal fit for adult), alternative oral-nasal mask for adult and paediatric with tubing (at least 2 adult and 2 paediatric); withstands high-level disinfection and sterilization. Helmet for adult and paediatric with tubing (preferable); withstands high-level disinfection and sterilization (preferable). Humidifier accessory if not integrated. Standard hoses and connectors (i.e. DISS/NIST, barb, as applicable for the country) for oxygen wall outlets and cylinder, as required to operate. Mains power cable ≥ 2 m, as required to operate.
9	**Spare parts (included and mentioned in a disaggregated list)**	1 year's spare parts kit as per preventive maintenance programme (or as part of a service level agreement).
10	**Portability**	Portable equipment with mechanical strength to lever rough handling.

Continuous positive airway pressure (CPAP) (adult and paediatric)		
11	**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%. 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. Automatic switch from AC power electric-line mode to battery operating mode and vice versa, if applicable.
12	**Documentation (included)**	Instruction for user and clinical guidance; service manual and product information to be provided in English language, at least.
13	**Primary packaging label**	Name and/or trademark of the manufacturer. Model or product reference. Information for particular storage conditions (temperature, pressure, light, humidity).
14	**Standards, for the manufacturer**	Certified quality management system for medical devices (e.g. ISO 13485). Application of risk management to medical devices (e.g. ISO 14971).
15	**Regulatory approval/ certification**	Free sales certificate (FSC) or certificate for exportation of medical device provided by the authority in manufacturing country. Proof of regulatory compliance, as appropriate, per the product's risk classification (e.g. Food and Drug Administration [FDA] and/or Conformité Européenne [CE]).
16	**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), for (latest version recommended but compliance to previous standards versions could be accepted): IEC 60601-1 Medical electric equipment – Part 1: General requirements for basic safety and essential performance. 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. ISO 80601-2-70 Medical electrical equipment – Part 2-70: Particular requirements for basic safety and essential performance of sleep apnoea breathing therapy equipment. 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. ISO 60601-1-1-8 Medical electrical equipment – Part 1-8: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems. If applicable, for the accessories and consumables: ISO 18562-1:2017 Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 1: Evaluation and testing within a risk management process. ISO 80601-2-74:2017 Medical electrical equipment – Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment. ISO 17510:2015 Medical devices – Sleep apnoea breathing therapy – Masks and application accessories.
17	**Warranty**	Minimum 2 years. Availability of accessories, consumables and spare parts for at least 2 years.
Any variation to be indicated in the offer.		

4.3.2.2 Non-invasive ventilators – bilevel positive airway pressure (BiPAP/BPAP)

Bilevel positive airway pressure (BiPAP/BPAP) (adult and paediatric)		
1	**General technical requirements**	Maintains continuous positive pressure in airway at high flow rate. Easy to operate user interface, numbers and displays to be clearly visible. Leakage compensation capability. Provides a higher positive pressure airway upon inhalation than upon exhalation. In-built air compressor or turbine. Oxygen inlet. Capability to connect to an active humidifier system (preferable). Noise level < 35 dBA at mid pressure range. Expiratory relief features that reduce the pressure slightly at the end of each breath to make it easier for the patient to exhale (preferable). Pressure ramp option that starts pressure at low level and slowly increases over a period. All parts withstand high disinfection procedures. Class I or Class II or internally powered. Protection IP21 required (IP22 preferable).
2	**Ventilation modes**	CPAP (spontaneous). T (timed). Pressure assisted control/pressure control (PAC/PC) (preferable). Automatic positive airway pressure (also called APAP or AutoPAP) (preferable).
3	**Monitored and controlled parameters (by clinical user)**	FiO_2: 21–100% (preferable). Pressure: 4–25 cmH_2O. Spontaneous timing. Trigger sensitivity range: 1–10 cmH_2O, increments of 1 or automatic.
4	**Displayed parameters (colour and graphics preferable)**	Display easily readable in low ambient light and sunlight. Inspiratory and expiratory pressure. Inspiratory and expiratory time. FiO_2 (%) (preferable). Mean airway pressure (MAP) (preferable). Air leak (%).
5	**Alarms, related to gas delivered (visual and audible)**	High/low pressure and/or minute ventilation. High/low oxygen (preferable). Breathing circuit disconnect.
6	**Alarms, related to equipment operation (visual and/or audible)**	Lack of water (preferable). System failure. Air filter to be replaced. Power failure (preferable). Low battery (preferable).
7	**Consumables, labelled "single use" (included and mentioned in a disaggregated list)**	Inlet bacteria filters, if applicable (at least 180). Expiratory filters, high efficiency. Full face mask with tubing (for paediatric and universal fit for adult), alternative oral-nasal mask for adult and paediatric with tubing (at least 12 adult in different sizes). Helmet for adult and paediatric with tubing (preferable).
8	**Accessories, reusable (included and mentioned in a disaggregated list)**	Full face mask with tubing (for paediatric and universal fit for adult), alternative oral-nasal mask for adult and paediatric with tubing (at least 2 adult and 2 paediatric); withstands high-level disinfection and sterilization. Humidifier accessory, if not integrated. Standard hoses and connectors (i.e. DISS/NIST, barb, as applicable for the country) for oxygen wall outlets and cylinder, as required to operate. Mains power cable ≥ 2 m, as required to operate.
9	**Spare parts (included and mentioned in a disaggregated list)**	1 year's spare parts kit as per preventive maintenance programme.
10	**Portability**	Mounting tray and support stand with at least 2 castors fitted with breaks.

Bilevel positive airway pressure (BiPAP/BPAP) (adult and paediatric)		
11	**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%. 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. Automatic switch from AC power electric-line mode to battery operating mode and vice versa, if applicable.
12	**Documentation (included)**	Instruction for use; service manual and product information to be provided in English language, at least.
13	**Primary packaging label**	Name and/or trademark of the manufacturer. Model or product reference. Information for particular storage conditions (temperature, pressure, light, humidity).
14	**Standards, for the manufacturer**	Certified quality management system for medical devices (e.g. ISO 13485). Application of risk management to medical devices (e.g. ISO 14971).
15	**Regulatory approval/ certification**	Free sales certificate (FSC) or certificate for exportation of medical device provided by the authority in manufacturing country. Proof of regulatory compliance, as appropriate, per the product's risk classification (e.g. Food and Drug Administration [FDA] and/or Conformité Européenne [CE]).
16	**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), for (latest version recommended but compliance to previous standards versions could be accepted): IEC 60601-1 Medical electric equipment – Part 1: General requirements for basic safety and essential performance. 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. ISO 80601-2-70 Medical electrical equipment – Part 2-70: Particular requirements for basic safety and essential performance of sleep apnoea breathing therapy equipment. 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. ISO 60601-1-1-8 Medical electrical equipment – Part 1-8: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems. If applicable, for the accessories and consumables: ISO 18562-1:2017 Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 1: Evaluation and testing within a risk management process. ISO 80601-2-74:2017 Medical electrical equipment – Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment. ISO 17510:2015 Medical devices – Sleep apnoea breathing therapy – Masks and application accessories.
17	**Warranty**	Minimum 2 years. Availability of accessories, consumables and spare parts for at least 2 years.
Any variation to be indicated in the offer.		

4.3.2.3 Non-invasive ventilators – high-flow nasal cannula (HFNC)

High-flow nasal cannula (HFNC) (adult and paediatric)		
1	**General technical requirements**	Capability to generate a high flow of mixed room air and oxygen. Capability to use oxygen from an oxygen concentrator or cylinder. In-built air compressor/turbine/piston or similar. Easy to operate user interface, with displayed parameters clearly visible. The mixed room air and oxygen should be warmed up to 37 °C and 100% RH. Controls to be easy to operate, numbers and displays to be clearly visible. It should have a humidity compensation system. Noise level < 35 dB at mid pressure range. Protection IP21 required (IP22 preferable).
2	**Monitored and controlled parameters (by clinical user)**	FiO_2: 21–100% (preferable). Flow up to: 50 L/min (minimum).
3	**Displayed parameters (colour and graphics preferable)**	Display easily readable in low ambient light and sunlight. Gas temperature (°C). Flow (L/min). Air leak (%) (preferable). FiO_2 (%) (preferable).
4	**Alarms, related to gas delivered (visual and audible)**	Incorrect temperature/humidity. System leakage or blockage. High/low FiO_2 (preferable).
5	**Alarms, related to equipment operation (visual and audible)**	Lack of water. System failure. Air filter to be replaced. Power failure. Low battery (if applicable).
6	**Consumables, labelled "single use" (included and mentioned in a disaggregated list)**	Housing and patient interface for adult and paediatric: at least 30 per equipment (different sizes). Inlet bacteria filters, if applicable: 30 per equipment. Expiratory filters: high efficiency.
7	**Accessories, reusable (included and mentioned in a disaggregated list)**	Flowmeter, graduated in L/min, as required to operate. Humidifier, as required to operate. Water chamber, as required to operate. Standard hoses and connectors (i.e. DISS/NIST, barb, as applicable for the country) for oxygen wall outlets and cylinder, as required to operate. Mains power cable ≥ 2 m.
8	**Spare parts (included and mentioned in a disaggregated list)**	1 year's spare parts kit as per preventive maintenance programme.
9	**Portability**	Mounting tray and support stand with at least 2 castors fitted with breaks.
10	**Power supply (voltage, frequency and plug vary across the countries)**	Operates from AC power electric line: 100–240 V AC ± 10% / 50–60 Hz ± 10%. 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. Automatic switch from AC power electric-line mode to battery operating mode and vice versa.
11	**Documentation (included)**	Instruction for use; service manual and product information to be provided in English language, at least.
12	**Primary packaging label**	Name and/or trademark of the manufacturer. Model or product reference. Information for particular storage conditions (temperature, pressure, light, humidity).
13	**Standards, for the manufacturer**	Certified quality management system for medical devices (e.g. ISO 13485). Application of risk management to medical devices (e.g. ISO 14971).

High-flow nasal cannula (HFNC) (adult and paediatric)		
14	**Regulatory approval/ certification**	Free sales certificate (FSC) or certificate for exportation of medical device provided by the authority in manufacturing country. Proof of regulatory compliance, as appropriate, per the product's risk classification (e.g. Food and Drug Administration [FDA] and/or Conformité Européenne [CE]).
15	**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), for (latest version recommended but compliance to previous standards versions could be accepted): IEC 60601-1:2005 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance. 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. ISO 18562-1:2017 Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 1: Evaluation and testing within a risk management process. ISO 17510:2015 Medical devices – Sleep apnoea breathing therapy – Masks and application accessories.
16	**Warranty**	Minimum 2 years. Availability of accessories, consumables and spare parts for at least 2 years.
Any variation to be indicated in the offer.		

5. Technical specifications for infusion devices

5.1 Context and considerations

This chapter will define the basic technical characteristics of infusion devices – infusion pump, syringe pump and drop counter – for accurate administration of medicines to patients. The decision on appropriate clinical use of each of these devices is reserved for medical staff.

In many contexts technical-mechanical performance will no longer be the main focus when selecting this type of device but the interoperability with other devices and hospital systems/servers, the access to drug libraries, and log events record and editor access. However, for all contexts basic criteria in all cases should be considered:

- Consumable costs, availability and compatibility (administration sets/infusion sets used to connect the drug supply and the patient) and licence fees. Buying a pump generally involves establishing a long-term relationship with the pump supplier.
- User training required – ease of use.
- Calibration and maintenance requirements.

5.2 Definitions and intended use

Infusion pump: Infusion pumps are devices used to accurately deliver liquids through intravenous (IV) or epidural routes for therapeutic or diagnostic purposes. They provide greater accuracy than gravity administration sets, and higher pressures. They are calibrated in flow settings of mL per hour ranging from 0.1 to 3600 mL/hr. Most pumps have a drug dose calculator that permits programming of the flow according to the physician dose order.

It should be noted that infusion pumps are of high risk to patients and special care should be taken in the delivery of the medication or IV solution. Mistakes when setting the infusion rate or volume can damage the patient. All infusion devices should be used under close monitoring of patients. Special considerations for COVID-19 or other highly infectious patients is the length of the infusion IV tubing, which can cause higher resistance in the delivery of the infusion solution, and alarms that will pause the infusion.

Box 1. Use of extension sets to position infusion pumps outside COVID-19 patients' rooms

At high flow rates (e.g. 300 mL/hour), increasing resistance to fluid flow because of the microbore tubing extensions can result in frequent occlusion alarms, making the pump unusable.

For more information:
Institute for Safe Medication Practices: https://ismp.org
ECRI Institute: https://assets.ecri.org/PDF/COVID-19-Resource-Center/COVID-19-Clinical-Care/COVID-Alert-Large-Vol-Infusion-Pumps-3.pdf

Syringe pump: Syringe pumps administer highly concentrated drugs or antibiotics from a syringe. They are designed to precisely drive the plunger of a syringe down its barrel to infuse a solution when it must be administered with a high degree of volume accuracy and rate consistency. They are commonly used for neonatal and paediatric patients because of the mentioned characteristics and for management of small volumes (≤ 60 mL). A syringe containing medication is securely mounted on the drive arm. The drive arm infuses the medication at a steady, programmed rate.

Drop counter: This device counts the number of drops according to the number of drops previously memorized and selected by the operator. This device is rarely used today because of its poor accuracy and limited or non-existent market availability.

5.3 Technical specifications for procurement

5.3.1 Infusion pump

Infusion pump		
Naming: EMDN nomenclature: infusion pumps (code: Z12030301). Alternative names: infusion multi-therapy pumps; injection pumps		
1	**General technical requirements**	One channel (at least). Capable of accepting any kind of fluids (solutions and medications preferable). Pump capabilities: • flow range 0.1 to ≥ 999 mL/hr • increments 0.1–100 mL/hr • keep vein open (KVO) rate 1–5 mL/hr • volume to be infused selector (VTBI) 1–9999 mL • flow rate accuracy of ± 5% or better • when multiple channel automatic piggybacking. Ingress protection not less than IPX2. Front panel lockout. Self-check carried out on powering on. Events stored system – log book. Pause infusion facility required. Anti-bolus system to reduce pressure on sudden release of occlusion. IV set: • free-flow protection • air trapping capability • needleless IV connection. "Dose error" reduction system (preferable). Drug library software available, including updates (free during warranty). Air bubble detector with single and cumulative functions (preferable). Clearly visible optical alarms. Acoustic alarms not less than 45dB. Easy set up and operation. Large easy to read display. Real-time display. Availability of a nurse call system connectable to a staff alerting system, 24 V/0.2 A; static or dynamic (preferable). Compatibility with standard infusion sets commonly distributed in the market (desirable at least by the leading brands). Equipment provided "ready to use". Continuous operation within specification in ambient temperature of at least 5–40 °C, relative humidity of at least 10–90% non-condensing. A limit of 85% relative humidity will be possibly considered as "acceptable" in the current COVID-19 pandemic context. Any accessory or dedicated device necessary to the proper functioning and utilization of the equipment is included. Shock-fall protection.
2	**Monitored and displayed parameters (colour and graphics preferable)**	Flow. Pressure. Dose. Availability of software to monitor the delivery of drugs (preferable).
3	**Alarms**	Audible alarm required with volume control. Momentary silence less than 2 min. Occlusion upstream. Occlusion downstream. Air in line. System malfunction. Set loaded improperly. Door open. Infusion complete. Loss of mains power. Low battery. Depleted battery (preferable). Clinical advisory messages.
4	**Consumables, labelled "single use", (included and mentioned in a disaggregated list)**	Compatible administration sets: 100. Compatible administration sets microbore and macrobore: 100. Compatible long administration sets both microbore/small and macrobore or long extension sets: 100.

Infusion pump		
5	**Accessories, reusable (included and mentioned in a disaggregated list)**	Clamp for mounting pump on IV stand. Clamp for external transportation (preferable) (if applicable).
6	**Spare parts (included and mentioned in a disaggregated list)**	As per manufacturer. Include calibration software and hardware (kit). Include list of spare parts with their part numbers and costs.
7	**Portability**	Data port required, at least RS232 and/or USB interface. Log analysis software and updates provided for free during warranty period. Wireless connectivity (preferable). Event log required and recording, 1 week at least of operations. Software upgrade required. Software to diagnose and calibrate the equipment with access to calibration settings.
8	**Power supply (voltage, frequency and plug vary across the countries)**	Operates from AC mains power: 100–240 V~/50–60 Hz. In-built rechargeable battery. Battery with operating time at least 4 hours at 25 mL/hr. Automatic switch from AC mains power mode to battery operating mode and vice versa. Total re-charging time not greater than 6 hours. Appropriate external device to protect the equipment against over-voltage and over-current line conditions (between plug and socket). 12 V DC socket for recharging during outside transportation (preferable). **Equipment must be connected to a reliable and continuous source of energy.**
9	**Documentation (included)**	Instruction for use; service manual and product information to be provided in English, at least. Certification of calibration. List of procedures for calibration and routine maintenance.
10	**Primary packaging label**	Name and/or trademark of the manufacturer. Model or product reference. Information for particular storage conditions (temperature, pressure, light, humidity).
11	**Standards, for the manufacturer**	Certified quality management system for medical devices (e.g. ISO 13485). General quality management (e.g. ISO 9001). Application of risk management to medical devices (e.g. ISO 14971).
12	**Regulatory approval/ certification**	Free sales certificate (FSC) and certificate for exportation of medical device provided by the authority in manufacturing country. Proof of regulatory compliance, as appropriate, per the product's risk classification (e.g. Food and Drug Administration [FDA] and/or Conformité Européenne [CE]) National local regulatory approval (of recipient country, as applicable).
13	**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) for: Standards specific for infusion equipment: ISO 8536-8:2004 Infusion equipment for medical use – Part 8: Infusion equipment for use with pressure infusion apparatus. ISO 8536-9:2004 Infusion equipment for medical use – Part 9: Fluid lines for use with pressure infusion equipment. ISO 8536-10:2004 Infusion equipment for medical use – Part 10: Accessories for fluid lines for use with pressure infusion equipment. ISO 8536-11:2004 Infusion equipment for medical use – Part 11: Infusion filters for use with pressure infusion equipment. ISO 8536-12:2007 Infusion equipment for medical use – Part 12: Check valves. IEC 60601-2-24 Ed. 2.0:2012 (b) Medical electrical equipment – Part 2-24: Particular requirements for the basic safety and essential performance of infusion pumps and controllers. Other general standards for medical equipment: IEC 60601-1:2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance. IEC 60601-1-1:2000 Medical electrical equipment – Part 1-1: General requirements for safety – Collateral standard: Safety requirements for medical electrical systems. IEC 60601-1-2:2007 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests.
14	**Warranty**	Minimum 2 years. Availability of accessories, consumables and spare parts for at least 5 years.
Any variation to be indicated in the offer.		

5.3.2 Syringe pump

Syringe pump		
Naming: EMDN nomenclature: syringe pumps (code: Z12030302). Alternative names: infusion pumps, syringe; syringe drivers; drivers, syringe		
1	**General technical requirements**	Capable of accepting any kind of fluids (as solutions and medicines). Capable of working with the commonly available 20, 50 and 60 mL syringes (with at least the leading brands of syringes). Volumetric flow rate accuracy with dedicated syringes better than +/- 2%, and +/- 5% with common syringes. Maximum pressure generated ≤ 20 psi. Automatic detection of syringe size and proper fixing. Must provide alarm for incorrect loading of syringe. Clearly visible optical alarms. Acoustic alarms not less than 45dB. Anti-bolus system to reduce pressure on sudden release of occlusion. Pause infusion facility required. Self-check carried out on powering on. Event logging system. Capability of recording of dose units, default values, bolus settings, technical values. KVO rate configurable; deactivation possible. Pump based priming feature available to reduce lag time (preferable). "Dose error" reduction system. Allow the user to enter dose rate rather than volume rate. Availability of a medications database with at least 250 medications selectable for download to pump. Easy to clean equipment. Large and easy to read display. Ingress protection not less than IPX2. Nurse call: connectable to a staff alerting system, 24 V/0.2 A. Continuous operation within specification in ambient temperature of at least 5–40 °C, relative humidity of at least least 10–85% non-condensing. 90% RH relative humidity (is preferable). Equipment provided "ready to use". Any accessory or dedicated device necessary to the proper functioning and utilization of the equipment is included. Shock-fall protection.
2	**Monitored and controlled parameters (by user)** **Displayed parameters (colour and graphics preferable)**	Control panel. Flow rate programmable range at least from 0.1–200 mL/hr, in steps of 0.1 mL/hr; and at least from 100–1200 mL/hr in steps of 1 mL/hr. Flow rate or volume limit to administer at least from 0.1–999.9 mL. Saves last infusion rate even when the AC power is switched off. Bolus rate should be programmable at least in the range from 0.1–1000 mL/hr, with infused volume display. Selectable occlusion pressure trigger levels selectable at least from 300, 500 and 900 mmHg. Availability of software to monitor the delivery of drugs (preferable).
3	**Alarms**	Comprehensive alarm package required, including at least: • occlusion alarm • plunger disengaged • syringe loading error • flow error • syringe unlocked • infusion complete • near/end of infusion pre-alarm/alarm • volume limit pre-alarm and alarm • low battery pre-alarm and alarm • AC power failure. Maintenance required (preferable).
4	**Consumables, labelled "single use", (included and mentioned in a disaggregated list)**	Disposable syringes of different volumes.

Syringe pump		
5	**Accessories, reusable (included and mentioned in a disaggregated list)**	Clamp for mounting pump on IV stand. Clamp for out of hospital transport, preferable (if applicable).
6	**Spare parts (included and mentioned in a disaggregated list)**	As per manufacturer. Include calibration software and hardware. Include list of spare parts with their part numbers and costs.
7	**Portability**	At least RS232 and/or USB interface for data transmission. Wireless connectivity, preferable.
8	**Power supply (voltage, frequency and plug vary across the countries)**	Operates from AC mains power: 100–240 V~/50–60 Hz. Built-in rechargeable battery. Automatic switch from AC mains power mode to battery operating mode and vice versa. Internal rechargeable battery having at least 5 hours backup for 10 mL/hr flow rate with 50 mL syringe. Battery-powered alarm for power failure or disconnection. Total battery re-charging time not greater than 6 hours. 12 V DC socket for recharging during outside transportation (preferable). Appropriate external device to protect the equipment against over-voltage and over-current line conditions (between plug and socket). **Equipment must be connected to a reliable and continuous source of energy.**
9	**Documentation (included)**	Instruction for use; service manual and product information to be provided in English, at least.
10	**Primary packaging label**	Name and/or trademark of the manufacturer. Model or product reference. Information for particular storage conditions (temperature, pressure, light, humidity).
11	**Standards, for the manufacturer**	Certified quality management system for medical devices (e.g. ISO 13485). General quality management (e.g. ISO 9001). Application of risk management to medical devices (e.g. ISO 14971).
12	**Regulatory approval/ certification**	Free sales certificate (FSC) or certificate for exportation of medical device provided by the authority in manufacturing country. Proof of regulatory compliance, as appropriate, per the product's risk classification (e.g. Food and Drug Administration [FDA] and/or Conformité Européenne [CE]). National local regulatory approval (of recipient country, as applicable)
13	**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): specific to infusion equipment for: ISO 7886-2:1996 Sterile hypodermic syringes for single use – Part 2: Syringes for use with power-driven syringe pumps. ISO 8536-8:2004 Infusion equipment for medical use – Part 8: Infusion equipment for use with pressure infusion apparatus. ISO 8536-9:2004 Infusion equipment for medical use – Part 9: Fluid lines for use with pressure infusion equipment. ISO 8536-10:2004 Infusion equipment for medical use – Part 10: Accessories for fluid lines for use with pressure infusion equipment. ISO 8536-11:2004 Infusion equipment for medical use – Part 11: Infusion filters for use with pressure infusion equipment. ISO 8536-12:2007 Infusion equipment for medical use – Part 12: Check valves. ISO 9626:1991 Stainless steel needle tubing for the manufacture of medical devices. General for medical equipment: IEC 60601-1:2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance. IEC 60601-1-1:2000 Medical electrical equipment – Part 1-1: General requirements for safety – Collateral standard: Safety requirements for medical electrical systems. IEC 60601-1-2:2007 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility - Requirements and tests. IEC 60601-2-24 Ed. 2.0:2012 (b) Medical electrical equipment – Part 2-24: Particular requirements for the basic safety and essential performance of infusion pumps and controllers.
14	**Warranty**	Minimum 2 years. Availability of accessories, consumables and spare parts for at least 5 years.
Any variation to be indicated in the offer.		

5.3.3 Drop counter

Drop counter		
Naming: Not specifically classified with EMDN (infusion instruments with code Z120303, and infusion instruments – others with code: Z12030399 are linkable codes). Alternative names: drops monitor; infusion rate monitor.		
1	**General technical requirements**	Capable to monitor the flow rate of IV fluids by monitoring the drops through the drip chamber of a standard IV administration set. Equipment provided already calibrated (if necessary) and "ready to use". Provided with display for data and settings easy visualization, LCD preferable. Equipment capable to work with most common tubing sets and drips (adult and paediatric). Ingress protection not less than IP22. Continuous operation within specification in ambient temperature of at least 5–40 °C, relative humidity of at least 10–85% non-condensing. 90% relative humidity (preferable). Equipment with adjustable flow rate (mL/hr) and/or drops per minute and/or total volume administered. Treatment time adjustable (preferable).
2	**Monitored and controlled parameters (by user)** **Displayed parameters (colour and graphics preferable)**	At least the following parameters can be displayed: • calculated flow rate • fluid volume • drops per minute • treatment time (preferable).
3	**Alarms**	At least the following video and/or audio alarms available: • battery low • flow rate and/or volume and/or drops per minute set values has been reached • set rate changes (preferable) • empty bag/bottle (preferable).
4	**Consumables, labelled "single use", (included and mentioned in a disaggregated list)**	Intravenous compatible tubing set for both adult and paediatric: quantity to be defined.
5	**Accessories, reusable (included and mentioned in a disaggregated list)**	As per manufacturer proposal.
6	**Spare parts (included and mentioned in a disaggregated list)**	As per manufacturer proposal. Include calibration software and hardware, if applicable. Include list of spare parts with their part numbers and costs.
7	**Portability**	N/A
8	**Power supply (voltage, frequency and plug vary across the countries)**	Operates with built-in rechargeable battery and/or AC mains power: 100–240 V~/50–60 Hz. Automatic switch from AC mains power mode to battery operating mode and vice versa (if applicable). Internal rechargeable battery with at least 24 hours working time. Battery charger provided. Built-in battery charger (preferable). Low battery alarm available.
9	**Documentation (included)**	Instruction for use; service manual and product information to be provided in English, at least.
10	**Primary packaging label**	Name and/or trademark of the manufacturer. Model or product reference. Information for particular storage conditions (temperature, pressure, light, humidity).
11	**Standards, for the manufacturer**	Certified quality management system for medical devices (e.g. ISO 13485). General quality management (e.g. ISO 9001). Application of risk management to medical devices (e.g. ISO 14971).
12	**Regulatory approval/ certification**	Free sales certificate (FSC) or certificate for exportation of medical device provided by the authority in manufacturing country. Proof of regulatory compliance, as appropriate, per the product's risk classification (e.g. Food and Drug Administration [FDA] and/or Conformité Européenne [CE]). National local regulatory approval (of recipient country, as applicable)

Drop counter		
13	**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) for: General medical equipment: IEC 60601-1:2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance or ANSI/AAMI ES60601-1:2005+A2 (R2012) Medical electrical equipment – Part 1: General requirements for basic safety and essential performance. IEC 60601-1-1:2000 Medical electrical equipment – Part 1-1: General requirements for safety – Collateral standard: Safety requirements for medical electrical systems. IEC 60601-1-2:2007 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests.
14	**Warranty**	Minimum 2 years. Availability of accessories, consumables and spare parts for at least 5 years.
Any variation to be indicated in the offer.		

Resources

ECRI. Evaluation & Guidance – Infusion pump integration: why is it needed, and what are the challenges? 1 July 2013 (https://www.ecri.org/components/HDJournal/Pages/hd201307guid_InfusionPumpIntegration.aspx?tab=1, accessed 27 June 2020).

ECRI. Evaluation & Guidance – Four key questions about syringe infusion pumps. 16 July 2014 (https://www.ecri.org/components/HDJournal/Pages/Four-Key-Questions-about-Syringe-Infusion-Pumps.aspx, accessed 27 June 2020).

ECRI. Evaluation & Guidance – Dose error reduction systems: features and functions. 4 April 2014, updated 25 February 2015 (https://www.ecri.org/components/HDJournal/Pages/Dose-Error-Reduction-Systems-Features-and-Functions.aspx?tab=1, accessed 27 June 2020).

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ECRI. Evaluation & Guidance – Evaluation background: infusion pump quality analytics software and services. 4 May 2016, updated 18 March 2020 (https://www.ecri.org/components/HDJournal/Pages/Eval-Background-Infusion-Pump-Quality-Analytics.aspx, accessed 27 June 2020).

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6. Technical specifications for complementary medical equipment to support COVID-19 management

6.1 Context and considerations

This chapter will define the basic technical characteristics of complementary medical equipment required in the management of COVID-19 patients. Most of these devices will be used in relation to those listed in the previous chapters on medical equipment.

The devices listed below do not require installation, maintenance or other technical aspects, therefore the format only includes the name, description and the standards they should comply to in order to ensure good quality. Any comments on sizes or variations would require further consideration.

As per the rest of the devices, they require to be selected according to the setting and intended use.

In this chapter the following devices are described:

- Infrared thermometer
- Digital thermometer
- Electrocardiograph, portable
- Laryngoscope
- Video-laryngoscope
- Suction pump, electric
- Suction pump, manual
- Venous blood pH and gas (pCO_2)
- Blood gas analyser, portable.

6.2 Technical specifications for procurement

6.2.1 Infrared thermometer

Infrared thermometer		
i	**Version no.**	2
ii	**Date of initial version**	13/6/2012
iii	**Date of last modification**	15/7/2020
iv	**Date of publication**	13/11/2020
v	**Completed/submitted by**	WHO working group
Name, category and coding		
1	**WHO category/code**	(under development)
2	**Generic name**	Thermometer, infrared, skin
3	**Specific type or variation (optional)**	Skin
4	**CND code (https://ec.europa.eu/health/md_topics-interest/overview_en)**	V03010102
5	**CND nomenclature**	ELECTRONIC THERMOMETERS AND END CAPS
Purpose of use		
6	**Clinical or other purpose**	Estimate the temperature of a site on the skin.
7	**Level of use (if relevant)**	Health post, health centre, district hospital, provincial hospital, specialized hospital, outreach (mobile clinics).
8	**Clinical department/ward (if relevant)**	Emergency room (ER), neonatal intensive care unit (NICU), surgery, outpatient, intensive care unit (ICU), hospital triage and other departments.
9	**Overview of functional requirements**	Displays patient temperature by measurement of infrared radiation from the skin. Device must be reusable, with sterilizable surface. Display should be easily readable in all levels of ambient light.
Technical characteristics		
10	**Detailed requirements**	Specified accuracy to be not higher than 0.2–0.3 °C. Measurement range at least from 30–43 °C. High/low patient temperature display feature preferred. Auto power off required after minimum of 1 minute. Out of range indication required. Response (measurement) time not higher than 3 sec. Ready-to-use after switch-on in a time not higher than 10 sec. Infrared (IR) spectral response 6000–14 000 nm. Optimal measuring distance approximately 8–12 cm/4–6 inch. Equipment factory calibrated and pre-set emissivity data for all skin types. Automatic self-test on switch-on. Video and/or audio alert/signal at least for the following cases: switch-on, ready-to-use and measurement completed.
11	**Displayed parameters**	Display graded in 0.1/0.3 °C steps. High/low patient temperature. Low battery. Malfunction. °F or °C measurement units.

Infrared thermometer		
12	**User adjustable settings**	None.
Physical/chemical characteristics		
13	**Components (if relevant)**	Supplied in protective case for clean storage and safe transport. Unit case should be hard and splashproof. Must be lightweight and comfortable to hold. There must be no sharp edges on the unit.
14	**Mobility, portability (if relevant)**	Easy and safe transport to be possible by hand.
15	**Raw materials (if relevant)**	N/A
Utility requirements		
16	**Electrical, water and/or gas supply (if relevant)**	Powered by internal, rechargeable, replaceable battery. Battery cover to be secure but simple to open. Battery to allow at least 4000 measurements between charges. Battery charger to operate from input supply 110–220 V, 60–50 Hz, ± 10% (battery charger built-in or external).
Accessories, consumables, spare parts, other components		
17	**Accessories (if relevant)**	Full range of any adaptors required to allow for measurement of all ages of patient.
18	**Sterilization process for accessories (if relevant)**	Not required.
19	**Consumables/reagents (if relevant)**	Not required.
20	**Spare parts (if relevant)**	Replacement battery pack, supplied empty of charge.
21	**Other components (if relevant)**	
Packaging		
22	**Sterility status on delivery (if relevant)**	N/A
23	**Shelf life (if relevant)**	N/A
24	**Transportation and storage (if relevant)**	Unit shall be supplied protectively packed for safe transportation and delivery.
25	**Labelling (if relevant)**	N/A
Environmental requirements		
26	**Context-dependent requirements**	Capable of being stored continuously in ambient temperature of 0–50 °C and relative humidity of 15–85%, preferably 90%. Capable of operating continuously in ambient temperature of 10–40 °C and relative humidity of 15–85%, preferably 90%.
Training, installation and utilization		
27	**Pre-installation requirements (if relevant)**	Not required.
28	**Requirements for commissioning (if relevant)**	Safety and operation checks before handover.

Infrared thermometer		
29	**Training of user/s (if relevant)**	Training of users in operation and technicians in basic maintenance.
30	**User care (if relevant)**	The whole unit is to be cleanable with alcohol or chlorine wipes or with any standard hospital disinfection procedure/material.
Warranty and maintenance		
31	**Warranty**	Not less than 2 years. Specific inclusions and exclusions to be listed. Contact details of manufacturer, supplier and local service agent to be provided.
32	**Maintenance tasks**	List of procedures required for local routine maintenance should be provided.
33	**Type of service contract**	Costs and types of post-warranty service contract available should be described (when needed).
34	**Spare parts availability post-warranty**	Guaranteed time period of availability of spare parts post-warranty should be pointed out.
35	**Software/hardware upgrade availability**	Not required.
Documentation		
36	**Documentation requirements**	User/technical manual to be supplied in English (provision of versions in other UN languages, if available, will be an asset). Certificate of calibration and inspection to be provided. List to be provided of equipment and procedures required for local calibration, if necessary, and routine maintenance. Battery disposal according local laws.
Decommissioning		
37	**Estimated life span**	Not less than 5 years.
Safety and standards		
38	**Standards, for the manufacturer and the equipment**	Certified quality management system for medical devices (e.g. ISO 13485:2016 Medical devices – Quality management systems – Requirements for regulatory purposes). General quality management (e.g. ISO 9001:2015 Quality management systems – Requirements). Application of risk management to medical devices (e.g. ISO 14971:2019 Medical devices – Application of risk management to medical devices).
39	**Regulatory approval/ certification**	Free sales certificate (FSC). Certificate for exportation of medical device provided by the authority in manufacturing country. Proof of regulatory compliance, as appropriate, per the product's risk classification (e.g. Food and Drug Administration [FDA] and/or Conformité Européenne [CE]).
40	**International standards**	Compliance to the following international standards, when applicable, or to regional or national equivalent (including the technical tests for safety and performance from accredited laboratory or third party). Reference to the last available version is recommended but compliance to previous standards versions could be considered. IEC 60601-1:2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance. IEC 60601-1-2:2007 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests. ISO 80601-2-56:2009 Medical electrical equipment – Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement. IEC 80601-2-59 Ed. 1.0:2008 (b) Medical electrical equipment – Part 2-59: Particular requirements for the basic safety and essential performance of screening thermographs for human febrile. EN ISO 15223-1 (EN 980) Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements. ASTM E1104-98(2016) Standard specification for clinical thermometer probe covers and sheaths. ASTM E1112-00(2018) Standard specification for electronic thermometer for intermittent determination of patient temperature.

6.2.2 Digital thermometer

Digital thermometer		
i	**Version no.**	2
ii	**Date of initial version**	25/6/2013
iii	**Date of last modification**	21/7/2020
iv	**Date of publication**	13/11/2020
v	**Completed/submitted by**	WHO working group
Name, category and coding		
1	**WHO category/code**	(under development)
2	**Generic name**	Thermometer, digital
3	**Specific type or variation (optional)**	Clinical thermometer, non-mercury
4	**CND code(https://ec.europa.eu/health/md_topics-interest/overview_en)**	V03010102
5	**CND nomenclature**	ELECTRONIC THERMOMETERS AND END CAPS
Purpose of use		
6	**Clinical or other purpose**	Designed to measure patient body temperature, used to take periodic body temperature measurements as primary diagnostic indicators.
7	**Level of use (if relevant)**	Health post, health centre, district hospital, provincial hospital, specialized hospital and outreach (mobile clinics).
8	**Clinical department/ward (if relevant)**	Emergency room (ER), neonatal internsive care unit (NICU), surgery, outpatient, intensive care unit (ICU), hospital.
9	**Overview of functional requirements**	Thermistor/thermocouple designed to measure patient body temperature.
Technical characteristics		
10	**Detailed requirements**	Digital thermometer °C or °F scales available. Safe to use, no glass, no mercury. Measurement range at least from 33–43 °C. Accurate measurement not higher than: ± 0.2 °C between 35–41°C. Liquid crystal display, easy to read. Beep sound and switch off. Response time < 90 sec required. Water proof for ease of cleaning. Supplied with battery. Supplied with clear instructions for use/preventive maintenance. Automatic self-test on switch-on. Ready-to-use after switch-on in a time not higher than 10 sec. Equipment factory calibrated. Auto power off capability required.
11	**Displayed parameters**	Temperature displayed in steps not higher than 0.3 °C. High/low patient temperature. Low battery indication. Malfunction. °F or °C measurement units.
12	**User adjustable settings**	N/A

Digital thermometer		
Physical/chemical characteristics		
13	**Components (if relevant)**	Supplied in protective case for clean storage and safe transport. Unit case should be hard and splashproof. Must be lightweight and comfortable to hold. There must be no sharp edges on the unit. Provided with at least 2 probes (1 spare) capable to be used with any patient and depending on the specific product design.
14	**Mobility, portability (if relevant)**	Easy and safe transport to be possible by hand.
15	**Raw materials (if relevant)**	N/A
Utility requirements		
16	**Electrical, water and/or gas supply (if relevant)**	Powered by internal, rechargeable, replaceable battery. Battery cover to be secure but simple to clean. Battery to allow at least 4000 measurements between charges. Provided with battery charger to operate from input supply 110–220 V, 60–50 Hz, ± 10% (battery charger built-in or external).
Accessories, consumables, spare parts, other components		
17	**Accessories (if relevant)**	Full range of any adaptors required to allow for measurement of all ages of patient, if necessary. Supplied in protective case for clean storage and safe transport.
18	**Sterilization process for accessories (if relevant)**	Not required.
19	**Consumables/reagents (if relevant)**	Single-use probe cover caps (if applicable, depending on the product design).
20	**Spare parts (if relevant)**	Replacement battery pack, supplied empty of charge. At least 1 probe capable to be used with any patient, depending on the design of the product (probes cover included when available and applicable).
21	**Other components (if relevant)**	N/A
Packaging		
22	**Sterility status on delivery (if relevant)**	Equipment preferably provided with a probe cover by a single-use cap.
23	**Shelf life (if relevant)**	N/A
24	**Transportation and storage (if relevant)**	Primary packaging: unit of use. One (1) thermometer in storage case with manufacturer's instructions for use. Labelling on the primary packaging: name and/or trademark of the manufacturer. Manufacturer's product reference. Type of product and main characteristics. If the packaging is not transparent, it must bear a diagram (preferably actual size) showing the essential parts of the product and indicating the position of the product in the packaging. Lot number prefixed by the word "LOT" (or equivalent harmonized symbol) (if applicable). Information for particular storage conditions included (temperature, pressure, light, humidity, etc.), as appropriate (or equivalent harmonized symbol). Information for handling, if applicable (or equivalent harmonized symbol). Secondary packaging: protected unit. × clinical thermometers in a box. Labelling on the secondary packaging: labelling to be the same as primary packaging. Extra information required: number of units per secondary packaging.
25	**Labelling (if relevant)**	N/A

Digital thermometer		
Environmental requirements		
26	**Context-dependent requirements**	Capable of being stored continuously in ambient temperature of 0–50 °C and relative humidity of 15–85%, preferably 90%. Capable of operating continuously in ambient temperature of 10–40 °C and relative humidity of 15–85%, preferably 90%.
Training, installation and utilization		
27	**Pre-installation requirements (if relevant)**	Not required.
28	**Requirements for commissioning (if relevant)**	Local clinical staff to affirm completion of installation. Supplier to perform installation, safety and operation checks before handover.
29	**Training of user/s (if relevant)**	Training of users in operation and technicians in basic maintenance shall be provided.
30	**User care (if relevant)**	The whole unit is to be cleanable with alcohol or chlorine wipes or with any standard hospital disinfection procedure/material.
Warranty and maintenance		
31	**Warranty**	Not less than 2 years. Specific inclusions and exclusions to be listed. Contact details of manufacturer, supplier and local service agent to be provided.
32	**Maintenance tasks**	List of equipment and procedures required for local routine maintenance should be provided.
33	**Type of service contract**	Costs and types of post-warranty service contract available should be described (when needed).
34	**Spare parts availability post-warranty**	Guaranteed time period of availability of spare parts post-warranty should be pointed out (when applicable).
35	**Software/hardware upgrade availability**	Not required.
Documentation		
36	**Documentation requirements**	User/technical manual to be supplied in English (provision of versions in other UN languages, if available, will be an asset). Certificate of calibration and inspection to be provided. List to be provided of equipment and procedures required for local calibration, if necessary, and routine maintenance. Battery disposal according local laws.
Decommissioning		
37	**Estimated life span**	Not less than 5 years.
Safety and standards		
38	**Standards, for the manufacturer and the equipment**	Certified quality management system for medical devices (e.g. ISO 13485:2016 Medical devices – Quality management systems – Requirements for regulatory purposes). Application of risk management to medical devices (e.g. ISO 14971:2019 Medical devices – Application of risk management to medical devices).
39	**Regulatory approval/ certification**	Free sales certificate (FSC). Certificate for exportation of medical device provided by the authority in manufacturing country. Proof of regulatory compliance, as appropriate, per the product's risk classification (e.g. Food and Drug Administration [FDA] and/or Conformité Européenne [CE]).

Digital thermometer		
40	**International standards**	Compliance to the following international standards, when applicable, or to regional or national equivalent (including the technical tests for safety and performance from accredited laboratory or third party). Reference to the last available version is recommended but compliance to previous standards versions could be considered. IEC 60601-1:2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance. IEC 60601-1-2:2007 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests. ISO 80601-2-56:2009 Medical electrical equipment – Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement. IEC 80601-2-59 Ed. 1.0:2008 (b) Medical electrical equipment – Part 2-59: Particular requirements for the basic safety and essential performance of screening thermographs for human febrile. EN ISO 15223-1 (EN 980) Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements. ASTM E1104-98(2016) Standard specification for clinical thermometer probe covers and sheaths. ASTM E1112-00(2018) Standard specification for electronic thermometer for intermittent determination of patient temperature.

6.2.3 Electrocardiograph, portable

Electrocardiograph, portable		
i	**Version no.**	2
ii	**Date of initial version**	13/6/2012
iii	**Date of last modification**	13/11/2020
iv	**Date of publication**	13/11/2020
v	**Completed/submitted by**	WHO working group
Name, category and coding		
1	**WHO category/code**	(under development)
2	**Generic name**	Electrocardiograph
3	**Specific type or variation (optional)**	multi-channel
4	**CND code (https://ec.europa.eu/health/md_topics-interest/overview_en)**	Z120503, Z12050301
5	**CND nomenclature**	ELECTROCARDIOGRAPHS, GENERAL PURPOSE ELECTROCARDIOGRAPHS
Purpose of use		
6	**Clinical or other purpose**	Detect, measure, and display a patient's electrocardiogram (ECG) through leads and sensors attached to the patient.
7	**Level of use (if relevant)**	Health centre, district hospital, provincial hospital, specialized hospital and outreach (mobile clinics).
8	**Clinical department/ward (if relevant)**	Emergency room (ER), intensive care unit (ICU), surgery, outpatient, hospital.
9	**Overview of functional requirements**	Recorder of patient ECG and heart rate with printing and displaying capabilities. 12 electrographic standard leads measuring with simultaneous acquisition. Settable alarms for low or high heart rate, ventricular fibrillation and other cases. Operates from mains voltage or from internal rechargeable battery. Patient connectors that are sterilizable and reusable are preferred, though reusable cables that attach to disposable connection patches are also acceptable. Hard copy printout of traces will be included. Display to be either clear screen, readable in direct sunlight, and/or durable paper printout.

Electrocardiograph, portable		
Technical characteristics		
10	**Detailed requirements**	Automatic equipment calibration. 12 electrographic standard leads measuring with simultaneous acquisition. Visualization of at least one group of 3 leads simultaneously. At least 1 rest ECG patient cable with at least 5 terminals. LCD or TFT colour monitor display of at least 7 inches with visualization of analogical curves, alphanumeric values measured and the related physiological limits. Frequency response range at least: 0.05–150 Hz. Equipment compatible with patients with pacemakers. Protection against defibrillation. Automatic internal data storing up to at least 40 ECG records. Input impedance not less than 5 MΩ (preferably higher than 10 MΩ). Patient leakage current not higher than 10 uA. Common mode rejection (CMR) not less than + 100 dB (preferably + 120 dB). ECG signal measurement range not smaller than -2 mV to +2 mV. At least the following adjustable alarms: a) heart failure b) ventricular fibrillation c) tachycardia d) bradycardia e) electrode disconnection. Equipment provided with filters at least for: baseline instability, AC 50/60 Hz interference, rumours, low-pass, etc. Equipment provided with at least the following software applications: a) arrhythmias detection and analysis b) ventricular fibrillation detection and analysis c) ventricular tachycardia detection and analysis d) ST segment analysis. Integrated printer using standard A4 format paper. Selectable printing paper speed at least of 5, 25 and 50 mm/sec.
11	**Displayed parameters**	Arrhythmia detection basic. Numeric display. Graphical and numerical trends and physiological curves display (preferable).
12	**User adjustable settings**	
Physical/chemical characteristics		
13	**Components (if relevant)**	There must be no sharp edges on the unit. Equipment provided with data management capabilities: RS232 or USB port for PC connection and data transmission. Provided with case for transport when available.
14	**Mobility, portability (if relevant)**	Easy and safe portable equipment
15	**Raw materials (if relevant)**	N/A

Electrocardiograph, portable		
Utility requirements		
16	**Electrical, water and/or gas supply (if relevant)**	Powered by both mono-phase electrical source and internal, rechargeable, replaceable batteries. 110–220 V, 60–50 Hz, ± 10% mono-phase electrical source with line-conection plug type in compliance with specific national standards and regulations. Rechargeable batteries with at least the following characteristics: a) automatic switch from electric-line mode to battery operating mode and vice-versa b) battery capacity: at least 30 ECGs or 30 min of continuous recording c) low battery visual alarm d) 100% high capacity batteries with re-charging time not greater than 6 hours e) battery charger to operate from input supply 110–220 V, 60–50 Hz, ± 10% (battery charger built-in or external). Appropriate external device to protect the equipment against over-voltage and over-current line conditions (between plug and socket). Voltage corrector/stabilizer to allow operation at ± 30% of local rated voltage.
Accessories, consumables, spare parts, other components		
17	**Accessories (if relevant)**	12 leads ECG patient cable. Sets of disposable electrodes for adult and paediatric patients. Sets of reusable electrodes (suction ball-type chest electrodes and/or extremity clamp type). Set of Limb electrodes. Rest ECG patient cable with at least 5 terminals. Any accessory or dedicated device necessary to the proper functioning and utilization of the equipment is included. Any accessory, consumable and/or part needed to the proper equipment installation, calibration, training, testing and commissioning is included.
18	**Sterilization process for accessories (if relevant)**	Not required.
19	**Consumables/reagents (if relevant)**	Bottle/tubes of conductive gel for body-connection electrodes. Pocket/sets of recording thermal paper.
20	**Spare parts (if relevant)**	Sets of rechargeable batteries, supplied empty of charge. Sets of spare fuses.
21	**Other components (if relevant)**	
Packaging		
22	**Sterility status on delivery (if relevant)**	N/A
23	**Shelf life (if relevant)**	N/A
24	**Transportation and storage (if relevant)**	
25	**Labelling (if relevant)**	N/A
Environmental requirements		
26	**Context-dependent requirements**	Capable of being stored continuously in ambient temperature of 0–50 °C and relative humidity of 15–85%, preferably 90%. Capable of operating continuously in ambient temperature of 10–40 °C and relative humidity of 15–85%, preferably 90%.

Electrocardiograph, portable		
Training, installation and utilization		
27	**Pre-installation requirements (if relevant)**	Not required.
28	**Requirements for commissioning (if relevant)**	Local clinical staff to affirm completion of installation. Supplier to perform installation, safety and operation checks before handover.
29	**Training of user/s (if relevant)**	Training of users in operation and technicians in basic maintenance shall be provided.
30	**User care (if relevant)**	The unit has to be cleanable and disinfectable with alcohol or chlorine wipes.
Warranty and maintenance		
31	**Warranty**	Not less than 2 years. Specific inclusions and exclusions to be listed. Contact details of manufacturer, supplier and local service agent to be provided.
32	**Maintenance tasks**	List of equipment and procedures required for local routine maintenance should be provided. Advanced maintenance tasks required shall be documented.
33	**Type of service contract**	Costs and types of post-warranty service contract available shall be described.
34	**Spare parts availability post-warranty**	Guaranteed time period of availability of spare parts post-warranty should be pointed out.
35	**Software/hardware upgrade availability**	Software updates Included during warranty. Upgradable device with additional programs and software fuctions (when available). Guaranteed time period of support and updates (when necessary) availability post-warranty shall be described.
Documentation		
36	**Documentation requirements**	User/technical manual to be supplied in English (provision of versions in other UN languages, if available, will be an asset). Certificate of calibration and inspection to be provided. List to be provided of equipment and procedures required for local calibration, if necessary, and routine maintenance. Battery disposal according local laws. Contact details of manufacturer, supplier and local service agent to be provided.
Decommissioning		
37	**Estimated life span**	Not less than 7 years.
Safety and standards		
38	**Standards, for the manufacturer and the equipment**	Certified quality management system for medical devices (e.g. ISO 13485:2016 Medical devices – Quality management systems – Requirements for regulatory purposes). General quality management (e.g. ISO 9001:2015 Quality management systems – Requirements). Application of risk management to medical devices (e.g. ISO 14971:2019 Medical devices – Application of risk management to medical devices).
39	**Regulatory approval/ certification**	Free sales certificate (FSC). Certificate for exportation of medical device provided by the authority in manufacturing country. Proof of regulatory compliance, as appropriate, per the product's risk classification (e.g. Food and Drug Administration [FDA] and/or Conformité Européenne [CE]).

Electrocardiograph, portable		
40	**International standards**	Compliance to the following international standards, when applicable, or to regional or national equivalent (including the technical tests for safety and performance from accredited laboratory or third party). Reference to the last available version is recommended but compliance to previous standards versions could be considered (as/when applicable). IEC 60601-1:2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance. IEC 60601-1-2:2007 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests. 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. IEC 60601-2-25:2011 Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs. IEC 60601-2-27:2011 Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment. IEC 60601-2-49:2011 Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment.

6.2.4 Laryngoscope

Laryngoscope		
i	**Version no.**	2
ii	**Date of initial version**	23/6/2020
iii	**Date of last modification**	22/7/2020
iv	**Date of publication**	13/11/2020
v	**Completed/submitted by**	WHO working group
Name, category and coding		
1	**WHO category/code**	Under development
2	**Generic name**	Laryngoscope (rigid)
3	**Specific type or variation (optional)**	rigid, curved/straight
4	**CND code (https://ec.europa.eu/health/md_topics-interest/overview_en)**	Z12021003
5	**CND nomenclature**	LARYNGOSCOPES
Purpose of use		
6	**Clinical or other purpose**	To manipulate the tongue and enable a clear view of the trachea for surgical/mechanical ventilation/intubation procedures.
7	**Level of use (if relevant)**	Health centre, district hospital, provincial hospital, specialized hospital.
8	**Clinical department/ward (if relevant)**	Outpatients, ear, nose and throat (ENT), operating theatre, emergency room (ER), intensive care unit (ICU).
9	**Overview of functional requirements**	A light source on or via the blade illuminates the larynx to allow viewing and tube passage. The unit is handheld with internal batteries and has interchangeable, rigid blades of different sizes.
Technical characteristics		
10	**Detailed requirements**	LED technology light bulb. Fibre optic direct transmission of the light. Equipment provided with compatible stinless steel autoclavable reusable set of blades with illumination included.
11	**Displayed parameters**	N/A
12	**User adjustable settings**	User shall be able to vary intensity of light in addition to powering on/off.
Physical/chemical characteristics		
13	**Components (if relevant)**	The system/equipment provided is composed at least by the following components/parts: handheld unit, single piece (with external diameter preferable not less than 25 mm); on/off switch to be robust and easy to use; external material to be non-ferrous; compatible set of blades; protective case for clean storage and safe transport. Unit case should be hard and splashproof. There must be no sharp edges on the unit.
14	**Mobility, portability (if relevant)**	Easy and safe transport to be possible by hand.
15	**Raw materials (if relevant)**	Blades to be made of surgical grade stainless steel material or any equivalent or better quality material.

Laryngoscope		
Utility requirements		
16	**Electrical, water and/or gas supply (if relevant)**	Powered by internal, rechargeable, replaceable battery. Battery cover to be secure but simple to open and battery compartment to be sealed against liquid ingress. Battery charger to operate from input supply 110–220 V, 60–50 Hz, ± 10% (battery charger built-in, preferably, or external) with protection against over-voltage and over-current line conditions.
Accessories, consumables, spare parts, other components		
17	**Accessories (if relevant)**	Protective case for clean storage and safe transport (with dedicated space to transport at least: the handle, set of batteries and 3 blades). At least the following 4 autoclavable blades-sets for adult and paediatric applications: Macintosh, size 2 (paediatric); Macintosh, size 4 (adult); Macintosh size 3 (preferable); Miller, size 2 (paediatric); Miller, size 3 (adult); Miller size 1 (preferable).
18	**Sterilization process for accessories (if relevant)**	Supplier to describe any sterilisation process required for accessories, if any.
19	**Consumables/reagents (if relevant)**	Tongue depressors, single use. Supplier to describe any additional necessary consumables, detailing shelf life and number of uses.
20	**Spare parts (if relevant)**	Replacement battery pack, supplied empty of charge. Spare light bulb compatible with the device provided.
21	**Other components (if relevant)**	
Packaging		
22	**Sterility status on delivery (if relevant)**	N/A
23	**Shelf life (if relevant)**	N/A
24	**Transportation and storage (if relevant)**	Unit shall be supplied protectively packed for safe transportation and delivery.
25	**Labelling (if relevant)**	N/A
Environmental requirements		
26	**Context-dependent requirements**	Capable of being stored continuously in ambient temperature of 0–50 °C and relative humidity of 15–85%, preferably 90%. Capable of operating continuously in ambient temperature of 10–40 °C and relative humidity of 15–85%, preferably 90%.
Training, installation and utilization		
27	**Pre-installation requirements (if relevant)**	Not required.
28	**Requirements for commissioning (if relevant)**	Local clinical staff to affirm completion of installation. Supplier to perform installation, safety and operation checks before handover.
29	**Training of user/s (if relevant)**	Training of users in operation and technicians in basic maintenance shall be provided.
30	**User care (if relevant)**	The whole unit is to be cleanable with standard disinfectants usually used in hospitals.

Laryngoscope		
Warranty and maintenance		
31	**Warranty**	Not less than 2 years with specific inclusions and exclusions to be clearly listed. Contact details of manufacturer, supplier and local service agent to be provided.
32	**Maintenance tasks**	List shall be provided of equipment and procedures required for local calibration and routine maintenance.
33	**Type of service contract**	Costs and types of post-warranty service contract available shall be described.
34	**Spare parts availability post-warranty**	Guaranteed time period of availability of spare parts post-warranty shall be described.
35	**Software/hardware upgrade availability**	N/A
Documentation		
36	**Documentation requirements**	User/technical manual to be supplied in English (provision of versions in other UN languages, if available, will be an asset). Certificate of calibration and inspection to be provided, when applicable. List to be provided of equipment and procedures required for local calibration, if necessary, and routine maintenance. Battery disposal according local laws.
Decommissioning		
37	**Estimated life span**	Not less than 5 years.
Safety and standards		
38	**Standards, for the manufacturer and the equipment**	Certified quality management system for medical devices (e.g. ISO 13485:2016 Medical devices – Quality management systems – Requirements for regulatory purposes). General quality management (e.g. ISO 9001:2015 Quality management systems – Requirements). Application of risk management to medical devices (e.g. ISO 14971:2019 Medical devices – Application of risk management to medical devices).
39	**Regulatory approval/ certification**	Free sales certificate (FSC). Certificate for exportation of medical device provided by the authority in manufacturing country. Proof of regulatory compliance, as appropriate, per the product's risk classification (e.g. Food and Drug Administration [FDA] and/or Conformité Européenne [CE]).
40	**International standards**	Compliance to the following international standards, when applicable, or to regional or national equivalent (including the technical tests for safety and performance from accredited laboratory or third party). Reference to the last available version is recommended but compliance to previous standards versions could be considered. IEC 60601-1:2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance. IEC 60601-1-2:2007 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility - Requirements and tests. ISO 7376-1:1994 Laryngoscopic fittings – Part 1: Conventional hook-on type handle-blade fittings. IEC 60601-2-18 Ed. 3.0:2009 (b) Medical electrical equipment – Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment. ISO 8600-1:2013 Endoscopes – Medical endoscopes and endotherapy devices – Part 1: General requirements. ISO 8600-4:1997 Optics and optical instruments – Medical endoscopes and certain accessories – Part 4: Determination of maximum width of insertion portion. ISO 8600-7:2012 Endoscopes – Medical endoscopes and endotherapy devices – Part 7: Basic requirements for medical endoscopes of water-resistant type.

6.2.5 Video-laryngoscope

Video-laryngoscope		
i	**Version no.**	1
ii	**Date of initial version**	23/6/2020
iii	**Date of last modification**	22/7/2020
iv	**Date of publication**	13/11/2020
v	**Completed/submitted by**	WHO working group
Name, category and coding		
1	**WHO category/code**	(under development)
2	**Generic name**	Video-Laryngoscope, rigid
3	**Specific type or variation (optional)**	Bladed video laryngoscope
4	**CND code (https://ec.europa.eu/health/md_topics-interest/overview_en)**	Z12021004
5	**CND nomenclature**	VIDEOLARYNGOSCOPES
Purpose of use		
6	**Clinical or other purpose**	To manipulate the tongue and enable a clear view of the trachea for surgical/mechanical ventilation/intubation procedures.
7	**Level of use (if relevant)**	Health centre, district hospital, provincial hospital, specialized hospital.
8	**Clinical department/ward (if relevant)**	Outpatients, ear, nose and throat (ENT), operating theatre, emergency room (ER), intensive care unit (ICU).
9	**Overview of functional requirements**	Video laryngoscope rigid equipment used to establish a direct line-of-sight between the practitioner's eye and the larynx using a digital monitors. The system is composed by an handle, reusable or single use blades with included a video-camera function and a monitor/display mounted on the device's handle.
Technical characteristics		
10	**Detailed requirements**	Safe intubation of paediatrics and adults. Highly curved d-blade and paediatric d-blade or better for particularly difficult airway. TFT/LCD or equivalent or better technology. Colour display/monitor attached to the handle or built-in or external. If the display is attached to the handle, the dimension should be not less than 2 inch; if the monitor is external the size should be not less than 7 inch. High definition video processor. With white balance adjustment, preferable. Quick-shot camera button which makes it easy to operate or similar system for digital still images recording. Sizes: neonates (preferable), paediatric and adult. CMOS/CCD full-colour camera with integrated LED or better light source.
11	**Displayed parameters**	N/A
12	**User adjustable settings**	User shall be able to vary intensity of light in addition to powering on/off.

Video-laryngoscope		
Physical/chemical characteristics		
13	**Components (if relevant)**	The system/equipment provided is composed at least by the following components/parts: handheld unit; on/off switch to be robust and easy to use; monitor/display integrated or external; compatible set of reusable or disposable blades; protective case for clean storage and safe transport. Unit case should be hard and splashproof. There must be no sharp edges on the unit.
14	**Mobility, portability (if relevant)**	Easy and safe transport to be possible by hand.
15	**Raw materials (if relevant)**	Reusable blades or disposable blades to be made of surgical grade material or better quality material.
Utility requirements		
16	**Electrical, water and/or gas supply (if relevant)**	Powered by internal, rechargeable, replaceable battery. Battery cover to be secure but simple to open and battery compartment to be sealed against liquid ingress. Battery charger to operate from input supply 110–220 V, 60–50 Hz, ± 10% (battery charger built-in, preferably, or external) with protection against over-voltage and over-current line conditions.
Accessories, consumables, spare parts, other components		
17	**Accessories (if relevant)**	The equipment is provided complete of the set of accessories and/or consumables for adult and paediatric, depending on which one of the following alternative configurations requested will be offered: Configuration 1) At least three compatible Macintosh blades of different measures (adult and paediatric) and at least two compatible Miller reusable blades (adult and paediatric). OR Configuration 2) One reusable blade with an adjustable length to be used with different adult and paediatric patients; in this case the blade should be provided with a complete set of disposable blade covers or tips. OR Configuration 3) Complete set of disposable blades with at least three different measures for adult and paediatric, and compatible with the system provided. Protective case for clean storage and safe transport (with dedicated space to transport at least: the handle, the monitor, a set of batteries and 2 blades, when applicable).
18	**Sterilization process for accessories (if relevant)**	Supplier to describe any sterilization process required for accessories, if any.
19	**Consumable /reagents (if relevant)**	Tongue depressors, single use. Complete set for adult and paediatric of fully compatible single-use blades (or blade covers) (if necessary to operate and when applicable). Supplier to describe any additional necessary consumables, detailing shelf life and number of uses.
20	**Spare parts (if relevant)**	Replacement battery pack, supplied empty of charge. Spare light bulb compatible with the device provided.
21	**Other components (if relevant)**	
Packaging		
22	**Sterility status on delivery (if relevant)**	N/A
23	**Shelf life (if relevant)**	N/A
24	**Transportation and storage (if relevant)**	Unit shall be supplied protectively packed for safe onward shipping. Labelling on the primary packaging under local regulations.
25	**Labelling (if relevant)**	N/A

Video-laryngoscope		
Environmental requirements		
26	**Context-dependent requirements**	Capable of being stored continuously in ambient temperature of 0–50 °C and relative humidity of 15–85%, preferably 90%. Capable of operating continuously in ambient temperature of 10–40 °C and relative humidity of 15–85%, preferably 90%.
Training, installation and utilization		
27	**Pre-installation requirements (if relevant)**	Not required.
28	**Requirements for commissioning (if relevant)**	Local clinical staff to affirm completion of installation. Supplier to perform installation, safety and operation checks before handover.
29	**Training of user/s (if relevant)**	Training of users in operation and technicians in basic maintenance shall be provided.
30	**User care (if relevant)**	The whole unit is to be cleanable with standard disinfectants usually used in hospitals.
Warranty and maintenance		
31	**Warranty**	Not less than 2 years with specific inclusions and exclusions to be clearly listed. Contact details of manufacturer, supplier and local service agent to be provided.
32	**Maintenance tasks**	List shall be provided of equipment and procedures required for local calibration and routine maintenance.
33	**Type of service contract**	Costs and types of post-warranty service contract available shall be described.
34	**Spare parts availability post-warranty**	Guaranteed time period of availability of spare parts post-warranty shall be described.
35	**Software/hardware upgrade availability**	Software updates included during warranty. Upgradable device with additional programs and software fuctions (when available). Guaranteed time period of support and updates (when necessary) availability post-warranty shall be described.
Documentation		
36	**Documentation requirements**	User/technical manual to be supplied in English (provision of versions in other UN languages, if available, will be an asset). Certificate of calibration and inspection to be provided, when applicable. List to be provided of equipment and procedures required for local calibration, if necessary, and routine maintenance. Battery disposal according local laws.
Decommissioning		
37	**Estimated life span**	Not less than 5 years.
Safety and standards		
38	**Standards, for the manufacturer and the equipment**	Certified quality management system for medical devices (e.g. ISO 13485:2016 Medical devices – Quality management systems – Requirements for regulatory purposes). General quality management (e.g. ISO 9001:2015 Quality management systems – Requirements). Application of risk management to medical devices (e.g. ISO 14971:2019 Medical devices – Application of risk management to medical devices).
39	**Regulatory approval/ certification**	Free sales certificate (FSC). Certificate for exportation of medical device provided by the authority in manufacturing country. Proof of regulatory compliance, as appropriate, per the product's risk classification (e.g. Food and Drug Administration [FDA] and/or Conformité Européenne [CE]).

Video-laryngoscope		
40	**International standards**	Compliance to the following international standards, when applicable, or to regional or national equivalent (including the technical tests for safety and performance from accredited laboratory or third party). Reference to the last available version is recommended but compliance to previous standards versions could be considered. IEC 60601-1:2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance. IEC 60601-1-2:2007 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests. ISO 7376-1:1994 Laryngoscopic fittings – Part 1: Conventional hook-on type handle-blade fittings. IEC 60601-2-18 Ed. 3.0:2009 (b) Medical electrical equipment – Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment. ISO 8600-1:2013 Endoscopes – Medical endoscopes and endotherapy devices – Part 1: General requirements. ISO 8600-4:1997 Optics and optical instruments – Medical endoscopes and certain accessories – Part 4: Determination of maximum width of insertion portion. ISO 8600-7:2012 Endoscopes – Medical endoscopes and endotherapy devices – Part 7: Basic requirements for medical endoscopes of water-resistant type.

6.2.6 Suction pump, electric

Suction pump, electric		
i	**Version no.**	2
ii	**Date of initial version**	25/6/2013
iii	**Date of last modification**	22/7/2020
iv	**Date of publication**	13/11/2020
v	**Completed/submitted by**	WHO working group
Name, category and coding		
1	**WHO category/code**	(under development)
2	**Generic name**	Electric hand/foot operated portable suction machine/pump
3	**Specific type or variation (optional)**	Portable, reusable
4	**CND code(https://ec.europa.eu/health/md_topics-interest/overview_en)**	Z120105
5	**CND nomenclature**	SURGICAL ASPIRATORS
Purpose of use		
6	**Clinical or other purpose**	Mobile equipment used for blood, secretions and other liquids suction by means of an integrated vacuum pump; mainly used to evacuate gas, fluid, tissue, or foreign materials from the high airways by means of vacuum suction but also for medium level surgery interventions. Single or double bottle.
7	**Level of use (if relevant)**	Health centre, district hospital, provincial hospital, specialized hospital.
8	**Clinical department/ward (if relevant)**	Emergency medicine, gynaecology, intensive care units, nursing services, obstetrics and paediatrics, operating theatres.
9	**Overview of functional requirements**	Generates suction by hand- or foot-operated pump electric action. AC line power operated (battery operated optionally). Maximum negative pressure generated not less than 450 mmHg.
Technical characteristics		
10	**Detailed requirements**	Oil free vacuum pump. Maximum vacuum not less than 450 mmHg (adjustable by control). Maximum suction capacity not less than 15 L/min. Collection bottle (1 or 2, preferably 2): at least 1 L capacity each bottle (disposable bag or collection jar), preferably 2 L. Bottle(s) to have an automatic cut off when full to prevent ingress of fluid to pump. Filter and overflow valve incorporated to prevent cross-contamination (e.g. shatterproof material, over flow protection system). It should be disposable or autoclavable. Equipment control: manual on/off power switch and, preferably also foot switch. Air line to pump to incorporate bacterial filter. Tubing to patient to be minimum 1.5 m long, non-collapsible type. All parts are manufactured from high-strength, durable material, that does not require specific maintenance or storage conditions. Pump can be disassembled entirely, is easy to clean, disinfect and sterilize. Equipment provided complete with dedicated trolley/cart or housing with castor wheels for easy movement. Sound level not higher than 60 dBA. System integrated holder for suction cannulas/tubing easy and safe positioning. Any necessary greasing/oiling to be simple, accessible and possible by health users.
11	**Displayed parameters**	Pressure gauge shall display suction generated.

Suction pump, electric		
12	**User adjustable settings**	User settable valve shall allow adjustment of suction delivered to patient.
Physical/chemical characteristics		
13	**Components (if relevant)**	Supplied mounted on robust board or cart or trolley, movable on castors, with carrying handle. There must be no sharp edges on the unit surface is to be hard and corrosion resistant. Pump handle and/or pedal to be spring loaded to return to "up" position after each stroke.
14	**Mobility, portability (if relevant)**	Portable, movable equipment.
15	**Raw materials (if relevant)**	N/A
Utility requirements		
16	**Electrical, water and/or gas supply (if relevant)**	Powered by mono-phase electrical source, AC line 110–220 V, 60–50 Hz, ± 10% with line connection plug compatible with local standards. Protections against over-voltage and over-current line conditions. Powered preferably also by internal, rechargeable, replaceable battery. Battery to allow at least 45 minutes of operation at a standard vacuum pressure. Battery charger to operate from input supply 110–220 V, 60–50 Hz, ± 10% (battery charger built-in or external).
Accessories, consumables, spare parts, other components		
17	**Accessories (if relevant)**	The equipment should be provided with all accessories necessary to have a "ready to start" system. Equipment supplied with at least all standard accessories and consumables (jars, cover, overflow valves, tubes and filters). Supplier should specify any accessories required for normal operation, stating any extra cost.
18	**Sterilization process for accessories (if relevant)**	Supplier should describe the specific sterilization process required/compatible with accessories and components provided.
19	**Consumables/reagents (if relevant)**	Complete set of suction tubing should be provided in agreement with the number of interventions planned by the contracting authority (if single use/consumable tubing sets are used/requested); the sets of suction tubing should be complete of all connectors and cannulas necessary to operate. Complete set of bacteria filters should be provided (single use or preferably autoclavable). Supplier to describe any necessary consumables, detailing shelf life and number of uses. Complete set of consumables should be provided with the equipment. Patient contact devices (e.g. handpiece/tip, mask), when necessary/required and applicable.
20	**Spare parts (if relevant)**	Complete sets of spare filters if autoclavable filters provided. Spare suction bottles. Spare seals for each storage jar, when applicable. List to be provided of other spare parts anticipated during one year's operation, with costs.
21	**Other components (if relevant)**	N/A
Packaging		
22	**Sterility status on delivery (if relevant)**	N/A
23	**Shelf life (if relevant)**	N/A
24	**Transportation and storage (if relevant)**	Unit shall be supplied protectively packed for safe onward shipping. Labelling on the primary packaging under local regulations.
25	**Labelling (if relevant)**	N/A

Suction pump, electric		
Environmental requirements		
26	**Context-dependent requirements**	Capable of being stored continuously in ambient temperature of 0–50 °C and relative humidity of 15–85%, preferably 90%. Capable of operating continuously in ambient temperature of 10–40 °C and relative humidity of 15–85%, preferably 90%.
Training, installation and utilization		
27	**Pre-installation requirements (if relevant)**	Not required.
28	**Requirements for commissioning (if relevant)**	Local clinical staff to affirm completion of installation (when applicable). Supplier to perform installation (when applicable), safety and operation checks before handover.
29	**Training of user/s (if relevant)**	Training of users in operation and technicians in basic maintenance shall be provided.
30	**User care (if relevant)**	Unit layout to enable easy cleaning and sterilization of all surfaces. Storage container easy to remove, empty, sterilize and reconnect. Collection canisters should be monitored and emptied if they come close to capacity; suction regulators must be accurate; suction levels that are too high can cause tissue damage; a pump containing aspirated fluid can be a source of contamination; changing or cleaning the suction tip during surgeries or other use can help reduce infection risk; operators should follow universal precautions, including wearing gloves, face shields or masks and gowns. After dismantling and cleaning, the pump must be reassembled and tested to make sure that it works correctly.
Warranty and maintenance		
31	**Warranty**	Not less than 2 years. Specific inclusions and exclusions to be listed. Contact details of manufacturer, supplier and local service agent to be provided
32	**Maintenance tasks**	List of equipment and procedures required for local routine maintenance should be provided. Advanced maintenance tasks required shall be documented.
33	**Type of service contract**	Costs and types of post-warranty service contract available shall be described.
34	**Spare parts availability post-warranty**	Guaranteed time period of availability of spare parts post-warranty should be pointed out.
35	**Software/hardware upgrade availability**	Not required.
Documentation		
36	**Documentation requirements**	User/technical manual to be supplied in English (provision of versions in other UN languages, if available, will be an asset). Certificate of calibration and inspection to be provided (when applicable). List to be provided of equipment and procedures required for local calibration, if necessary, and routine maintenance. Battery disposal according local laws.
Decommissioning		
37	**Estimated life span**	Not less than 5 years.
Safety and standards		
38	**Standards, for the manufacturer and the equipment**	Certified quality management system for medical devices (e.g. ISO 13485:2016 Medical devices – Quality management systems – Requirements for regulatory purposes). General quality management (e.g. ISO 9001:2015 Quality management systems – Requirements). Application of risk management to medical devices (e.g. ISO 14971:2019 Medical devices – Application of risk management to medical devices).

Suction pump, electric		
39	**Regulatory approval/ certification**	Free sales certificate (FSC). Certificate for exportation of medical device provided by the authority in manufacturing country. Proof of regulatory compliance, as appropriate, per the product's risk classification (e.g. Food and Drug Administration [FDA] and/or Conformité Européenne [CE]).
40	**International standards**	Compliance to the following international standards, when applicable, or to regional or national equivalent (including the technical tests for safety and performance from accredited laboratory or third party). Reference to the last available version is recommended. IEC 60601-1 Ed. 3.1:2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance. IEC 60601-1-2 Ed. 3.0:2007 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests. ISO 10079-1:1999 Medical suction equipment – Part 1: Electrically powered suction equipment – Safety requirements. ISO 10079-3:1999 Medical suction equipment – Part 3: Suction equipment powered from a vacuum or pressure source (if applicable). ISO 5359:2008 Low-pressure hose assemblies for use with medical gases (if applicable).

6.2.7 Suction pump, manual

Suction pump, manual		
i	**Version no.**	2
ii	**Date of initial version**	27/8/2012
iii	**Date of last modification**	22/7/2020
iv	**Date of publication**	13/11/2020
v	**Completed/submitted by**	WHO working group
Name, category and coding		
1	**WHO category/code**	(under development)
2	**Generic name**	Suction system, manual
3	**Specific type or variation (optional)**	Emergency use, portable, reusable
4	**CND code(https://ec.europa.eu/health/md_topics-interest/overview_en)**	R050103
5	**CND nomenclature**	AIRWAY MUCUS CLEARING DEVICES
Purpose of use		
6	**Clinical or other purpose**	To aspirate fluids, secretions, or other foreign materials from a patient's airway by means of suction.
7	**Level of use (if relevant)**	Health centre, district hospital, provincial hospital, specialized hospital, mobile clinics.
8	**Clinical department/ward (if relevant)**	Ambulance service, emergency department, nursing services, obstetrics and paediatrics, minor surgical theatres.
9	**Overview of functional requirements**	Generates suction by hand- or foot-operated pump manual action.
Technical characteristics		
10	**Detailed requirements**	Able to generate a maximum vacuum of at least 0.75 bar (570 mmHg). Minimum open tube flow rate at least 1 L liquid per minute. Single or twin suction bottles, minimum size 0.5 L each. Bottle(s) to have an automatic cut off when full, to prevent ingress of fluid to pump. Filter and overflow valve incorporated to prevent cross-contamination. Air line to pump to incorporate bacterial filter. Tubing to patient to be minimum 0.5 m long, non-collapsible type. Equipment provided with any necessary greasing/oiling to be simple and accessible by users. Reusable and sterilizable (autoclavable) equipment components.
11	**Displayed parameters**	Pressure gauge should display the level of suction generated.
12	**User adjustable settings**	User settable valve should allow adjustment of suction pressure level delivered to patient.
Physical/chemical characteristics		
13	**Components (if relevant)**	Must be lightweight and comfortable to hold. There must be no sharp edges on the unit surface is to be hard and corrosion resistant. Pump handle/pedal to be spring loaded to return to "up" position after each stroke. Supplied mounted on robust board with carrying handle.
14	**Mobility, portability (if relevant)**	Easy and safe transport to be possible by hand.

Suction pump, manual		
15	**Raw materials (if relevant)**	N/A
Utility requirements		
16	**Electrical, water and/or gas supply (if relevant)**	N/A
Accessories, consumables, spare parts, other components		
17	**Accessories (if relevant)**	The equipment should be provided with all accessories necessary to have a "ready to start" system. Supplier should specify any accessories required for normal operation, stating any extra cost.
18	**Sterilization process for accessories (if relevant)**	Supplier should describe the specific sterilization process required/compatible with accessories and components provided.
19	**Consumables/reagents (if relevant)**	Complete set of suction tubing should be provided in agreement with the number of interventions planned by the contracting authority (if single use/consumable tubing sets are used/requested). Supplier to describe any necessary consumables, detailing shelf life and number of uses. Complete set of consumables should be provided with the equipment. Patient contact devices (e.g. handpiece/tip, mask), when necessary/required and applicable.
20	**Spare parts (if relevant)**	Complete sets of spare filters (i.e. bacterial, etc.) Spare suction bottles. Spare seals for each storage jar. Suction tubing spare sets should be provided (if reusable tubings are requested). List to be provided of other spare parts anticipated during one year's operation, with costs.
21	**Other components (if relevant)**	
Packaging		
22	**Sterility status on delivery (if relevant)**	N/A
23	**Shelf life (if relevant)**	N/A
24	**Transportation and storage (if relevant)**	Unit shall be supplied protectively packed for safe onward shipping. Labelling on the primary packaging under local regulations.
25	**Labelling (if relevant)**	N/A
Environmental requirements		
26	**Context-dependent requirements**	Capable of being stored continuously in ambient temperature of 0–50 °C and relative humidity of 15–85%, preferably 90%. Capable of operating continuously in ambient temperature of 10–40 °C and relative humidity of 15–85%, preferably 90%.
Training, installation and utilization		
27	**Pre-installation requirements (if relevant)**	Not required.
28	**Requirements for commissioning (if relevant)**	Local clinical staff to affirm completion of installation (when applicable). Supplier to perform installation (when applicable), safety and operation checks before handover.
29	**Training of user/s (if relevant)**	Training of users in operation and technicians in basic maintenance shall be provided.

Suction pump, manual		
30	**User care (if relevant)**	Unit layout to enable easy cleaning and sterilization of all surfaces. Storage container easy to remove, empty, sterilize and reconnect. Collection canisters should be monitored and emptied if they come close to capacity; suction regulators must be accurate; suction levels that are too high can cause tissue damage; a pump containing aspirated fluid can be a source of contamination; changing or cleaning the suction tip during surgeries or other use can help reduce infection risk; operators should follow universal precautions, including wearing gloves, face shields or masks and gowns. After dismantling and cleaning, the pump must be reassembled and tested to make sure that it works correctly.
Warranty and maintenance		
31	**Warranty**	Not less than 2 years. Specific inclusions and exclusions to be listed. Contact details of manufacturer, supplier and local service agent to be provided.
32	**Maintenance tasks**	List of equipment and procedures required for local routine maintenance should be provided. Advanced maintenance tasks required shall be documented.
33	**Type of service contract**	Costs and types of post-warranty service contract available shall be described.
34	**Spare parts availability post-warranty**	Guaranteed time period of availability of spare parts post-warranty should be pointed out.
35	**Software/hardware upgrade availability**	Not required.
Documentation		
36	**Documentation requirements**	User/technical manual to be supplied in English (provision of versions in other UN languages, if available, will be an asset). Certificate of calibration and inspection to be provided (when applicable). List to be provided of equipment and procedures required for local calibration, if necessary, and routine maintenance.
Decommissioning		
37	**Estimated life span**	Not less than 5 years.
Safety and standards		
38	**Standards, for the manufacturer and the equipment**	Certified quality management system for medical devices (e.g. ISO 13485:2016 Medical devices – Quality management systems – Requirements for regulatory purposes). General quality management (e.g. ISO 9001:2015 Quality management systems – Requirements). Application of risk management to medical devices (e.g. ISO 14971:2019 Medical devices – Application of risk management to medical devices).
39	**Regulatory approval/ certification**	Free sales certificate (FSC). Certificate for exportation of medical device provided by the authority in manufacturing country. Proof of regulatory compliance, as appropriate, per the product's risk classification (e.g. Food and Drug Administration [FDA] and/or Conformité Européenne [CE]).
40	**International standards**	Compliance to the following international standards, when applicable, or to regional or national equivalent (including the technical tests for safety and performance from accredited laboratory or third party). Reference to the last available version is recommended. ISO 10079-2:1999 Medical suction equipment – Part 2: Manually powered suction equipment or equivalent.

6.2.8 Blood gas analyser, portable

Blood gas analyser, portable		
i	**Version no.**	1
ii	**Date of initial version**	30/1/2020
iii	**Date of last modification**	22/7/2020
iv	**Date of publication**	13/11/2020
v	**Completed/submitted by**	WHO working group
Name, category and coding		
1	**WHO category/code**	(under development)
2	**Generic name**	Arterial whole blood pH and gases (pO_2, pCO_2) analyser
3	**Specific type or variation (optional)**	Blood
4	**EMDN code**	W0201069002
5	**EMDN nomenclature**	BLOOD GAS PORTABLE ANALYSERS
Purpose of use		
6	**Clinical or other purpose**	Measurement of arterial blood gases and pH. Blood gas measurements are requested in respiratory, metabolic or kidney disease, especially if there is respiratory distress, to evaluate the amount of oxygen and the acid/base balance.
7	**Level of use (if relevant)**	Health post, health centre, district hospital, provincial hospital, specialized hospital and outreach (mobile clinics).
8	**Clinical department/ ward (if relevant)**	Emergency room (ER), neonatal internsive care unit (NICU), surgery, outpatient, intensive care unit (ICU), hospital.
9	**Overview of functional requirements**	The equipment tests arterial whole blood samples or capillary whole blood samples; must be anti-coagulated (balanced lithium heparin). Blood gas/pH analysers use reagents kits or specific consumables or are cartridge-based systems. They have sensors for assessing pH, pO_2, and pCO_2, in anticoagulated blood samples. Once a proprietary cartridge is inserted into a point-of-care (POC) blood gas/pH device or a specific reagent kit is used, the pH, pO_2, and pCO_2 values are reported. Temperature changes affect measured values, test cartridges in particular are inserted into a temperature-controlled block within a POC blood gas/pH analyser that is maintained at 37 °C (normal body temperature). Cartridges are disposed as biohazardous garbage after testing.

Blood gas analyser, portable		
Technical characteristics		
10	**Detailed requirements**	Point-of-care equipment, easy to be moved between different hospital departments. Analytical performance/accuracy should remain stable throughout the measurement of the analyte and can be monitored using internal quality controls (ICQ) which are performed automatically by the analyser; frequency will depend on manufacturer. The assay is linear across at least the measuring ranges: pH 6.75–7.85; pO_2 1.33–73.3 kPa; pCO_2 1.6–14.7 kPa. Analytical specificity (interferences): method should be evaluated and demonstrate no interference from ascorbate, bilirubin, haemoglobin, lipid, acetaminophen, acetylsalicylic acid. Blood gas analysis should have bias from the reference method not higher than 5%. Potentiometric measurement principle on a dedicated blood gas analyser, quality equivalent measurement principles can be considered. The equipment should have a LCD (or equivalent technology) monitor/display to easy visualize data and to manage parameters settings. Sample volume will vary by instrument but is typically not higher than 195 µl for a complete assay. Values reported are quantitative, results should be reported at least in pH units, kilo Pascals (kPa; O_2 and CO_2) and mmol/L (bicarbonate). Bicarbonate is calculated from the Henderson-Hasselbalch equation. Availability of other additional and selectable pressure measurement units, is preferable. Time to result not higher than 3 minutes. Specimen throughput not lower than 20 specimens per hour. The manufacturer should precisely state the tests limitations, if any. Quality control checks will be automatically performed at intervals defined by manufacturer. External quality assessment (EQA) material should be provided with the equipment (when necessary, and available). The equipment should use specific/proprietary or preferably non-branded (commonly available in the market) test kits/reagents or dedicated cartridges. The shelf life of kit/reagents or cartridges upon delivery should not be less than 6 months. The equipment should be provided with automatic calibration function. The equipment should be provided with a built-in or external compatible printer. Equipment preferably provided with bar-code reader for both reagents/kits/cartridges and samples. The equipment should have the capability of data storage (at least 300 patient results and 50 control results) and transfer to external PC through an interface (hardware and software necessary for data transfer should be provided with the equipment). Equipment provided with all components, consumables and accessories necessary for having a "ready to start" device and for performing the required quality control (QC) and calibration tests.
11	**Displayed parameters**	At least the following paramentes displayed: PO_2, PCO_2 and pH.
12	**User adjustable settings**	Depending on the manufacturer and models.
Physical/chemical characteristics		
13	**Components (if relevant)**	Equipment supplied with dedicated case for safe transport (preferably, when available). Equipment supplied with a dedicated dust cover (preferably, when available). There must be no sharp edges on the unit.
14	**Mobility, portability (if relevant)**	Easy and safe to be transported from different departments.
15	**Raw materials (if relevant)**	N/A

Blood gas analyser, portable		
Utility requirements		
16	**Electrical, water and/or gas supply (if relevant)**	Powered by mono-phase electrical source, AC line 110–220 V, 60–50 Hz, ± 10% with line connection plug compatible with local standards. Power should preferably be delivered via an online uninterruptable power supply (UPS) providing the same output as local electric supply. Protections against over-voltage and over-current line conditions. Powered preferably also by internal, rechargeable, replaceable battery. Battery capacity at least 1 hour of battery power when analyser is in "ready mode", or approximately 25 samples. Battery charger to operate from input supply 110–220 V, 60–50 Hz, ± 10% (battery charger built-in or external).
Accessories, consumables, spare parts, other components		
17	**Accessories (if relevant)**	Trolley or cart with brakes, able to carry the analyser and his UPS (when necessary, preferable). Equipment provided with any accessory or dedicated device necessary to the proper functioning and utilization of the equipment included (e.g. batteries, mounting kit, first test kit).
18	**Sterilization process for accessories (if relevant)**	N/A
19	**Consumables/reagents (if relevant)**	Complete reagent kits /cartridges with replacement electrodes if bundled. Complete self-calibration and quality controls kits/cartridges. All reagents and consumables should be provided by manufacturer; components should be clearly listed.
20	**Spare parts (if relevant)**	Replacement battery pack, supplied empty of charge. List to be provided of other spare parts anticipated during 1 year's operation, with costs.
21	**Other components (if relevant)**	N/A
Packaging		
22	**Sterility status on delivery (if relevant)**	N/A
23	**Shelf life (if relevant)**	N/A
24	**Transportation and storage (if relevant)**	Unit shall be supplied protectively packed for safe onward shipping. Labelling on the primary packaging under local regulations.
25	**Labelling (if relevant)**	N/A
Environmental requirements		
26	**Context-dependent requirements**	Capable of being stored continuously in ambient temperature of 0–50 °C and relative humidity of 15–85%, preferably 90%. Capable of operating continuously in ambient temperature of 10–40 °C and relative humidity of 15–85%, preferably 90%.
Training, installation and utilization		
27	**Pre-installation requirements (if relevant)**	Not required
28	**Requirements for commissioning (if relevant)**	Local clinical staff to affirm completion of installation. Supplier to perform installation, safety and operation checks before handover.
29	**Training of user/s (if relevant)**	Training of users in operation and technicians in basic maintenance shall be provided.
30	**User care (if relevant)**	The whole unit is to be cleanable with standard disinfectants usually used in hospitals.

Blood gas analyser, portable		
Warranty and maintenance		
31	**Warranty**	Not less than 2 years with specific inclusions and exclusions to be clearly listed. Contact details of manufacturer, supplier and local service agent to be provided.
32	**Maintenance tasks**	List of equipment and procedures required for local calibration and routine maintenance should be provided.
33	**Type of service contract**	Costs and types of post-warranty service contract available shall be described.
34	**Spare parts availability post-warranty**	Guaranteed time period of availability of spare parts post-warranty shall be described.
35	**Software/hardware upgrade availability**	Software updates included during warranty. Guaranteed time period of support and updates (when necessary) availability post-warranty shall be described.
Documentation		
36	**Documentation requirements**	User/technical manual to be supplied in English (provision of versions in other UN languages, if available, will be an asset). Certificate of calibration and inspection to be provided, when applicable. List to be provided of equipment and procedures required for local calibration, if necessary, and routine maintenance. Battery disposal according local laws.
Decommissioning		
37	**Estimated life span**	Not less than 5 years.
Safety and standards		
38	**Standards, for the manufacturer and the equipment**	Certified quality management system for medical devices (e.g. ISO 13485:2016 Medical devices – Quality management systems – Requirements for regulatory purposes). General quality management (e.g. ISO 9001:2015 Quality management systems – Requirements). Application of risk management to medical devices (e.g. ISO 14971:2019 Medical devices – Application of risk management to medical devices).
39	**Regulatory approval/ certification**	Free sales certificate (FSC). Certificate for exportation of medical device provided by the authority in manufacturing country. Proof of regulatory compliance, as appropriate, per the product's risk classification (e.g. Food and Drug Administration [FDA] and/or Conformité Européenne [CE]).
40	**International standards**	Compliance to the following international standards, when applicable, or to regional or national equivalent (including the technical tests for safety and performance from accredited laboratory or third party). Reference to the last available version is recommended. ISO 23640: In vitro diagnostic medical devices – Evaluation of stability of in vitro diagnostic reagents. ISO 18113-1: In vitro diagnostic medical devices – Information supplied by the manufacturer (labelling) – Part 1: Terms, definitions and general requirements.

Resources

AAMI. AAMI offers free standards and resources to help fight coronavirus. Association for the Advancement of Medical Instrumentation; 2020 (https://www.aami.org/detail-pages/press-release/aami-offers-free-standards-and-resources-to-help-fight-coronavirus, accessed 12 August 2020).

ISO. COVID-19 response: freely available ISO standards. International Organization for Standardization; 2020 (https://www.iso.org/covid19, accessed 29 August 2020).

7. Technical specifications for airway and ICU consumables and single-use medical devices

7.1 Context and considerations

This chapter describes the basic technical characteristics of consumables and single-use medical devices required in the management of COVID-19 patients. Most of these devices will be used in relation to those listed in the previous chapters on medical equipment.

The devices listed below do not require installation, maintenance or other technical aspects, therefore the format only includes the name, description and the standards they should comply to in order to ensure good quality. Any comments on sizes or variations would require further consideration.

The devices require to be selected according to the setting and intended use.

7.2 Technical specifications for procurement

7.2.1 List of airway and ICU consumables and single-use medical devices

Item no.	WHO item name	Required technical specifications
1	**Compress, gauze net, with paraffin, 10 × 10 cm, sterile, single use**	Used in the treatment of wounds, especially to dress and protect burns; prevents gauze dressings from adhering to the wound; allowing enabling serum, exudation or suppuration; it has cicatrising properties. Large-mesh netting impregnated with a soft paraffin-based material (with or without balsam of Peru). Radiolucent. Hypoallergenic. The paraffin compress is placed between two papers (parchment type) in a polyethylene or aluminium peel pack. Individually peel-packed in sterile heat-welded wrapping (it is preferred to metal boxes since it has better resistance to heat exposure). To be stored below 25–26 °C and in horizontal position.
2	**Electro-conductive gel**	Preferably capable to be used in applications such as electrocardiogram (ECG), electroencephalogram (EEG), ultrasound, transcutaneous electrical nerve stimulation (TENS).
4	**Airway, nasopharyngeal, sterile, single use. Sizes from 20 Fr to 36 Fr (with 2 Fr increments)**	A nasopharyngeal airway is recommended for use as an airway adjunct in the semi-conscious or unconscious patient with an intact gag reflex. Individually packaged sterile with a conveniently attached surgical lubricant for quick access to facilitate ease of insertion. Flexible and soft material for maximum patient comfort. Rounded tip allows for gentle insertion. Trumpet design for secure placement. Diameter and size labelled according to standards.
5	**Airway, oropharyngeal, Guedel, adolescent, size 3 (80 mm), autoclavable**	One-piece, semi-rigid, curved plastic tube, used to be inserted through the oropharynges to facilitate airway management. Guedel type. Flange surface is permanently marked with tube size/length in mm, and the manufacturer or supplier's name. It is bite resistant. Proximal (or buccal) end straight and reinforced. Distal end semi-rigid, curved, with atraumatic soft rounded edges.
6	**Airway, oropharyngeal, Guedel, adult, size 4 (90 mm), autoclavable**	One-piece, semi-rigid, curved plastic tube, used to be inserted through the oropharynges to facilitate airway management. Guedel type. Flange surface is permanently marked with tube size/length in mm, and the manufacturer or supplier's name. It is bite resistant. Proximal (or buccal) end straight and reinforced. Distal end semi-rigid, curved, with atraumatic soft rounded edges.
7	**Airway, oropharyngeal, Guedel, adult, size 5 (100 mm), autoclavable**	One-piece, semi-rigid, curved plastic tube, used to be inserted through the oropharynges to facilitate airway management. Guedel type. Flange surface is permanently marked with tube size/length in mm, and the manufacturer or supplier's name. It is bite resistant. Proximal (or buccal) end straight and reinforced. Distal end semi-rigid, curved, with atraumatic soft rounded edges.
8	**Airway, oropharyngeal, Guedel, child, size 2 (70 mm), autoclavable**	One-piece, semi-rigid, curved plastic tube, used to be inserted through the oropharynges to facilitate airway management. Guedel type. Flange surface is permanently marked with tube size/length in mm, and the manufacturer or supplier's name. It is bite resistant. Proximal (or buccal) end straight and reinforced. Distal end semi-rigid, curved, with atraumatic soft rounded edges.
9	**Laryngeal mask airway (LMA), size 2, sterile, single use**	Standard laryngeal mask airway used for patients undergoing general anaesthesia or as a resuscitation device in ICU departments. Maximum cuff volume: 10 mL.

Item no.	Dimensions/sizes/ presentation	Material	Standards for product safety, performance and quality assurance, as requested or equivalent
1	Width: 10 cm. Length: 10 cm.	Compress: 100% cotton fabric, wide meshed tulle (threads every 2–3 mm). Paraffin substance: 100–180 g/m^2. Mixture of balsam of Peru (approximately 1 g) and soft paraffin q. suff. (approximately 100 g). Initial sterilization method: ethylene oxide gas or ionizing radiation or equivalent method.	EN 14079: Dressing gauze thread count. EN 868 (1 to 7) and EN-10993-10 for biologic evaluation.
2	1000 mL.	Medical grade conductive gel.	ISO 10993-1:2018 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.
4	Sizes: 20, 22, 24, 26, 28, 30, 32, 34, 36 Fr.	Latex-free.	ISO 5364:2016(en) Anaesthetic and respiratory equipment – Oropharyngeal airways ISO 4135:2001(en) Anaesthetic and respiratory equipment
5	Size/length /ISO graduation/inner diameter/ colour code/patient: no. 3/80 mm/8/4.5 mm/green/ for small adult.	Polyethylene vinyl acetate (EVA) and polyvinyl chloride (PVC); siliconized; transparent; medical grade. Hygienically clean for medical use. It must resist steam sterilization at 121 °C or 134 °C.	EN 12181 or ISO 5364: Oropharyngeal airways. ISO 10993-1: Biological safety testing.
6	Size/length/ISO graduation/inner diameter/ colour code/patient: no. 4/90 mm/9/4.5 mm/ yellow/for adult.	Polyethylene vinyl acetate (EVA) and polyvinyl chloride (PVC); siliconized; transparent; medical grade. Hygienically clean for medical use. It must resist steam sterilization at 121 °C or 134 °C.	EN 12181 or ISO 5364: Oropharyngeal airways. ISO 10993-1: Biological safety testing.
7	Size/length/ISO graduation/inner diameter/ colour code/patient: no. 5/100 mm/10/5.0 mm/red/ for large adult.	Polyethylene vinyl acetate (EVA) and polyvinyl chloride (PVC); siliconized; transparent; medical grade. Hygienically clean for medical use. It must resist steam sterilization at 121 °C or 134 °C.	EN 12181 or ISO 5364: Oropharyngeal airways. ISO 10993-1: Biological safety testing.
8	Size/length/ISO graduation/inner diameter/ colour code/patient: no. 2/70 mm/7/4.0 mm/white/ for young adult.	Polyethylene vinyl acetate (EVA) and polyvinyl chloride (PVC); siliconized; transparent; medical grade. Hygienically clean for medical use. It must resist steam sterilization at 121 °C or 134 °C.	EN 12181 or ISO 5364: Oropharyngeal airways. ISO 10993-1: Biological safety testing.
9	Mask size 2: children 10–20 kg.	Flexible medical grade PE. Latex-free.	ISO 11712:2009(en) Anaesthetic and respiratory equipment – Supralaryngeal airways and connectors.

Item no.	WHO item name	Required technical specifications
10	**Laryngeal mask airway (LMA), size 3, sterile, single use**	Standard laryngeal mask airway used for patients undergoing general anaesthesia or as a resuscitation device in ICU departments. Maximum cuff volume: 20 mL.
11	**Laryngeal mask airway (LMA), size 4, sterile, single use**	Standard laryngeal mask airway used for patients undergoing general anaesthesia or as a resuscitation device in ICU departments. Maximum cuff volume: 30 mL.
12	**Syringe, 10 mL, three pieces, Luer type, sterile, single use**	Three pieces syringe: barrel with Luer nozzle, piston, and stopper. Barrel: permanent and legible graduated scale in mL with intervals of 0.20 or 0.50 mL. Increment of each mL to be numbered. Concentric or eccentric Luer lock or Luer slip nozzle. Length with a maximum usable capacity of at least 10% more than the nominal capacity. Plunger stopper with backstop. Double sealing ring on plunger. Initial sterilization method: ethylene oxide gas or equivalent. Individually peel-packed in paper and/or plastic.
13	**Catheter, nasal, 40 cm, with lateral eyes, sterile, single use. Set with different sizes**	Nasal catheter for the administration of medical oxygen. Open distal end with multiple lateral holes , or a central eye and distal cross perforation. Proximal end features a straight conical connector available. Each set include different sizes. At least the following sizes provided in each set: 10 Fr, 12 Fr, 14 Fr, 16 Fr, 18 Fr.
14	**Endotracheal tube introducer, bougie, sterile, single use**	To assist with endotracheal intubations is used to guide the tube properly into the airway. Blue or yellow tube with graduated marking. Curved tip with distal rounded smooth tip. Initial sterilization method: ethylene oxide gas or Gamma radiation or equivalent as appropriate and applicable. Individually peel-packed in paper and/or plastic. At least the following sizes included in the set provided: 10 and 15 Fr.
15	**Endotracheal tube introducer, stylet, sterile, single use, 10 Fr**	Flexible and malleable guide (stylet) to be inserted into the endotracheal tube to guide it properly during the intubation. It has a soft and round end-tip. It can be shaped as needed. It has graduated marking. Manufacturer name and tube size are indicated on the tube. Initial sterilization method: ethylene oxide gas or Gamma radiation or equivalent as appropriate and applicable. Individually peel-packed in paper and/or plastic.
16	**Endotracheal tube introducer, stylet, sterile, single use, 14 Fr**	Flexible and malleable guide (stylet) to be inserted into the endotracheal tube to guide it properly during the intubation. It has a soft and round end-tip. It can be shaped as needed. It has graduated marking. Manufacturer name and tube size are indicated on the tube. Initial sterilization method: ethylene oxide gas or Gamma radiation or equivalent as appropriate and applicable. Individually peel-packed in paper and/or plastic.

Item no.	Dimensions/sizes/ presentation	Material	Standards for product safety, performance and quality assurance, as requested or equivalent
10	Mask size 3: children/adult 30–50 kg.	Flexible medical grade PE. Latex-free.	ISO 11712:2009(en) Anaesthetic and respiratory equipment – Supralaryngeal airways and connectors.
11	Mask size 4: adult 50–70 kg.	Flexible medical grade PE. Latex-free.	ISO 11712:2009(en) Anaesthetic and respiratory equipment – Supralaryngeal airways and connectors.
12	Barrel nominal capacity: 10 mL.	Barrel: polyethylene (PE) or polypropylene (PP) or polystyrene (PS); sufficiently transparent. Piston: polypropylene (PP) or equivalent. Latex-free/PVC-free.	Barrel graduation: ISO 7886-1:2017: Sterile hypodermic syringe for single use: Part 1: syringe for manual use. Needle, Luer type: ISO 80369-7:2016: Small-bore connectors for liquids and gases in healthcare applications – Part 7: Connectors for intravascular or hypodermic applications. Sterilization method: ISO 11135:2014: Sterilization of health-care products – Ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices.
13	Length: 40 cm. ID: 10 Fr, 12 Fr, 14 Fr, 16 Fr and 18 Fr.	PVC. Proximal end: polyester piece of foam.	ISO/DIS 23368: Anaesthetic and respiratory equipment – Low flow nasal cannula for oxygen therapy. ISO/DIS 17256: Anaesthetic and respiratory equipment – Respiratory therapy tubing and connectors.
14	Standard size: 10 Fr and 15 Fr, approximately 60–70 cm long.	Flexible, medical grade, radiopaque, braided polyester base with a resin coating.	ISO 5361:2016: Anaesthetic and respiratory equipment – Tracheal tubes and connectors. ISO 10993-1:2018: Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.
15	Size 1: For endotracheal tube with internal diameter of 3.5–4.5 mm. Length: 30–45 cm, approximately. Diameter: 10 Fr (3.3 mm).	Stylet: malleable metal alloy covered by polyvinyl chloride (PVC) coated, latex-free; white; disinfectant resistant; withstand steam sterilization.	ISO 5361:2016: Anaesthetic and respiratory equipment – Tracheal tubes and connectors. ISO 10993-1:2018: Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.
16	Size 2: For endotracheal tube with internal diameter of 4.5–6.0 mm. Length: 30–45 cm, approximately. Diameter: 14 Fr (4.6 mm).	Stylet: malleable metal alloy covered by polyvinyl chloride (PVC) coated, latex-free; white; disinfectant resistant; withstand steam sterilization.	ISO 5361:2016: Anaesthetic and respiratory equipment – Tracheal tubes and connectors. ISO 10993-1:2018: Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.

Item no.	WHO item name	Required technical specifications
17	**Tube, endotracheal, No. 2, with cuff, sterile, single use**	Endotracheal tube designed to be introduced into the trachea via the mouth or nose, ensuring an unobstructed upper airway to convey gases and vapours to and from the lungs during anaesthesia, resuscitation and other situations where the patient is not properly ventilated. It consists in a thin, flexible, transparent and single hollow cylinder, with an anatomical curvature Magill-type of 37.5°, black and legibly depth markings and graduation in cm, with radio-opaque continuous line mark, with cuff and pilot balloon, with a standard connector in the proximal end. The proximal end of the tube safely fits the connector from which size is selected according to the tube size. The connector is straight and double-ended, with the proximal end being an outer, standard 15 mm internal diameter, conical tip that allows the tube to be connected to the ventilation system (breathing circuit or manual resuscitator). The distal end of the tube is open and bevelled (obliquely cut), atraumatic, with Murphy's eye. The endotracheal tubes are standard in all aspects: dimension, markings and connectors. Initial sterilization method: ethylene oxide gas or Gamma radiation. Individually peel-packed in paper and/or plastic.
18	**Tube, endotracheal, No. 2.5, with cuff, sterile, single use**	Endotracheal tube designed to be introduced into the trachea via the mouth or nose, ensuring an unobstructed upper airway to convey gases and vapours to and from the lungs during anaesthesia, resuscitation and other situations where the patient is not properly ventilated. It consists in a thin, flexible, transparent and single hollow cylinder, with an anatomical curvature Magill-type of 37.5°, black and legibly depth markings and graduation in centimetres, with radio-opaque continuous line mark, with cuff and pilot balloon, with a standard connector in the proximal end. The proximal end of the tube safely fits the connector from which size is selected according to the tube size. The connector is straight and double-ended, with the proximal end being an outer, standard 15 mm internal diameter, conical tip that allows the tube to be connected to the ventilation system (breathing circuit or manual resuscitator). The distal end of the tube is open and bevelled (obliquely cut), atraumatic, with Murphy's eye. The endotracheal tubes are standard in all aspects: dimension, markings and connectors. Initial sterilization method: ethylene oxide gas or Gamma radiation. Individually peel-packed in paper and/or plastic.
19	**Tube, endotracheal, No. 3, with cuff, sterile, single use**	Endotracheal tube designed to be introduced into the trachea via the mouth or nose, ensuring an unobstructed upper airway to convey gases and vapours to and from the lungs during anaesthesia, resuscitation and other situations where the patient is not properly ventilated. It consists in a thin, flexible, transparent and single hollow cylinder, with an anatomical curvature Magill-type of 37.5°, black and legibly depth markings and graduation in cm, with radio-opaque continuous line mark, with cuff and pilot balloon, with a standard connector in the proximal end. The proximal end of the tube safely fits the connector from which size is selected according to the tube size. The connector is straight and double-ended, with the proximal end being an outer, standard 15 mm internal diameter, conical tip that allows the tube to be connected to the ventilation system (breathing circuit or manual resuscitator). The distal end of the tube is open and bevelled (obliquely cut), atraumatic, with Murphy's eye. The endotracheal tubes are standard in all aspects: dimension, markings and connectors. Initial sterilization method: ethylene oxide gas or Gamma radiation. Individually peel-packed in paper and/or plastic.
20	**Tube, endotracheal, No. 3.5, with cuff, sterile, single use**	Endotracheal tube designed to be introduced into the trachea via the mouth or nose, ensuring an unobstructed upper airway to convey gases and vapours to and from the lungs during anaesthesia, resuscitation and other situations where the patient is not properly ventilated. It consists in a thin, flexible, transparent and single hollow cylinder, with an anatomical curvature Magill-type of 37.5°, black and legibly depth markings and graduation in cm, with radio-opaque continuous line mark, with cuff and pilot balloon, with a standard connector in the proximal end. The proximal end of the tube safely fits the connector from which size is selected according to the tube size. The connector is straight and double-ended, with the proximal end being an outer, standard 15 mm internal diameter, conical tip that allows the tube to be connected to the ventilation system (breathing circuit or manual resuscitator). The distal end of the tube is open and bevelled (obliquely cut), atraumatic, with Murphy's eye. The endotracheal tubes are standard in all aspects: dimension, markings and connectors. Initial sterilization method: ethylene oxide gas or Gamma radiation. Individually peel-packed in paper and/or plastic.

Item no.	Dimensions/sizes/ presentation	Material	Standards for product safety, performance and quality assurance, as requested or equivalent
17	Tube: Size: 2. Internal diameter: 2.0 mm. External diameter: 3.0 mm. Length: 160 mm, minimum. Connector: Proximal end: standard internal diameter: 15 mm. Distal end (fits the tube): length: 9 mm, minimum.	Tube: polyvinyl chloride (PVC) or polyurethane; medical grade; transparent. Connector: polyvinyl chloride (PVC); medical grade; transparent or blue.	ISO 5361:2016: Anaesthetic and respiratory equipment – Tracheal tubes and connectors. ISO 10993-1:2018: Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.
18	Tube: Size: 2.5. Internal diameter: 2.5 mm. External diameter: 3.5 mm. Length: 140 mm, minimum. Connector: Proximal end: standard internal diameter: 15 mm. Distal end (fits the tube): length: 9 mm, minimum.	Tube: polyvinyl chloride (PVC) or polyurethane; medical grade; transparent. Connector: polyvinyl chloride (PVC); medical grade; transparent or blue.	ISO 5361:2016: Anaesthetic and respiratory equipment – Tracheal tubes and connectors. ISO 10993-1:2018: Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process. ISO 11135:2014: Sterilization of health-care products – Ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices.
19	Tube: Size: 3. Internal diameter: 3 mm. External diameter: 4.2 mm. Length: 160 mm, minimum. Connector: Proximal end: standard internal diameter: 15 mm. Distal end (fits the tube): length: 9 mm, minimum.	Tube: polyvinyl chloride (PVC) or polyurethane; medical grade; transparent. Connector: polyvinyl chloride (PVC); medical grade; transparent or blue.	ISO 5361:2016: Anaesthetic and respiratory equipment – Tracheal tubes and connectors. ISO 10993-1:2018: Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process. ISO 11135:2014: Sterilization of health-care products – Ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices.
20	Tube: Size: 3.5. Internal diameter: 3.5 mm. External diameter: 4.8 mm. Length: 140 mm, minimum. Connector: Proximal end: standard internal diameter: 15 mm. Distal end (fits the tube): length: 9 mm, minimum.	Tube: polyvinyl chloride (PVC) or polyurethane; medical grade; transparent. Connector: polyvinyl chloride (PVC); medical grade; transparent or blue.	ISO 5361:2016: Anaesthetic and respiratory equipment – Tracheal tubes and connectors. ISO 10993-1:2018: Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process. ISO 11135:2014: Sterilization of health-care products – Ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices.

Item no.	WHO item name	Required technical specifications
21	**Tube, endotracheal, No. 4, with cuff, sterile, single use**	Endotracheal tube designed to be introduced into the trachea via the mouth or nose, ensuring an unobstructed upper airway to convey gases and vapours to and from the lungs during anaesthesia, resuscitation and other situations where the patient is not properly ventilated. It consists in a thin, flexible, transparent and single hollow cylinder, with an anatomical curvature Magill-type of 37.5°, black and legibly depth markings and graduation in cm, with radio-opaque continuous line mark, with cuff and pilot balloon, with a standard connector in the proximal end. The proximal end of the tube safely fits the connector from which size is selected according to the tube size. The connector is straight and double-ended, with the proximal end being an outer, standard 15 mm internal diameter, conical tip that allows the tube to be connected to the ventilation system (breathing circuit or manual resuscitator). The distal end of the tube is open and bevelled (obliquely cut), atraumatic, with Murphy's eye. The endotracheal tubes are standard in all aspects: dimension, markings and connectors. Initial sterilization method: ethylene oxide gas or Gamma radiation. Individually peel-packed in paper and/or plastic.
22	**Tube, endotracheal, No. 5, with cuff, sterile, single use**	Endotracheal tube designed to be introduced into the trachea via the mouth or nose, ensuring an unobstructed upper airway to convey gases and vapours to and from the lungs during anaesthesia, resuscitation and other situations where the patient is not properly ventilated. It consists in a thin, flexible, transparent and single hollow cylinder, with an anatomical curvature Magill-type of 37.5°, black and legibly depth markings and graduation in cm, with radio-opaque continuous line mark, with cuff and pilot balloon, with a standard connector in the proximal end. The proximal end of the tube safely fits the connector from which size is selected according to the tube size. The connector is straight and double-ended, with the proximal end being an outer, standard 15 mm internal diameter, conical tip that allows the tube to be connected to the ventilation system (breathing circuit or manual resuscitator). The distal end of the tube is open and bevelled (obliquely cut), atraumatic, with Murphy's eye. The endotracheal tubes are standard in all aspects: dimension, markings and connectors. Initial sterilization method: ethylene oxide gas or Gamma radiation. Individually peel-packed in paper and/or plastic.
23	**Tube, endotracheal, No. 4, with cuff, sterile, single use**	Endotracheal tube designed to be introduced into the trachea via the mouth or nose, ensuring an unobstructed upper airway to convey gases and vapours to and from the lungs during anaesthesia, resuscitation and other situations where the patient is not properly ventilated. It consists in a thin, flexible, transparent and single hollow cylinder, with an anatomical curvature Magill-type of 37.5°, black and legibly depth markings and graduation in cm, with radio-opaque continuous line mark, with cuff and pilot balloon, with a standard connector in the proximal end. The proximal end of the tube safely fits the connector from which size is selected according to the tube size. The connector is straight and double-ended, with the proximal end being an outer, standard 15 mm internal diameter, conical tip that allows the tube to be connected to the ventilation system (breathing circuit or manual resuscitator). The distal end of the tube is open and bevelled (obliquely cut), atraumatic, with Murphy's eye. The cuff, situated at the distal end of the tube, provides an airtight seal between the tube and the tracheal wall. It seals the lungs against the liquid secretions sloshing around in the upper airway. And, it ensures that the environment below the cuff can be pressurised and ventilated with a carefully controlled gas mixture. The cuff has a low pressure in order to avoid inadequate pressure on the tracheal mucous membrane to prevent damage or even necrosis. It typically has a capacity of 10 mL. The cuff is inflated via a small-bore inflation tube welded to the outside of the tracheal tube or built into its wall. The pilot balloon indicates the cuff distension. One end is connected to the cuff through a thin inflation tube located close to the proximal end. The other end has a spring-loaded, one-way valve that maintains a pre-set pressure in the circuit, and has Luer tip connector for syringes. The endotracheal tubes are standard in all aspects: dimension, markings and connectors. Initial sterilization method: ethylene oxide gas or Gamma radiation. Individually peel-packed in paper and/or plastic.

Item no.	Dimensions/sizes/ presentation	Material	Standards for product safety, performance and quality assurance, as requested or equivalent
21	Tube: Size: 4. Internal diameter: 4 mm. External diameter: 5.4 mm. Length: 200 mm, minimum. Connector: Proximal end: standard internal diameter: 15 mm. Distal end (fits the tube): length: 11 mm, minimum.	Tube: polyvinyl chloride (PVC) or polyurethane; medical grade; transparent. Connector: polyvinyl chloride (PVC); medical grade; transparent or blue.	ISO 5361:2016: Anaesthetic and respiratory equipment – Tracheal tubes and connectors. ISO 10993-1:2018: Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process. ISO 11135:2014: Sterilization of health-care products – Ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices.
22	Tube: Size: 5. Internal diameter: 5.0 mm. External diameter: 6.9 mm. Length: 250 mm, minimum. Connector: Proximal end: standard internal diameter: 15 mm. Distal end (fits the tube): length: 12 mm, minimum.	Tube: polyvinyl chloride (PVC) or polyurethane; medical grade; transparent. Connector: polyvinyl chloride (PVC); medical grade; transparent or blue.	ISO 5361:2016: Anaesthetic and respiratory equipment – Tracheal tubes and connectors. ISO 10993-1:2018: Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process. ISO 11135:2014: Sterilization of health-care products – Ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices.
23	Tube: Size: 4. Internal diameter: 4.0 mm. External diameter: 6.7 mm. Length: 210 mm, minimum. Connector: Proximal end: standard internal diameter: 15 mm. Distal end (fits the tube): length: 11 mm, minimum. Cuff: Diameter: 10.5 mm.	Tube: polyvinyl chloride (PVC) or polyurethane; medical grade; transparent. Connector: polyvinyl chloride (PVC); medical grade; transparent or blue. Cuff: siliconized rubber, or siliconized polyvinyl chloride (PVC). Pilot balloon: siliconized latex, or siliconized polyvinyl chloride (PVC).	ISO 5361:2016: Anaesthetic and respiratory equipment – Tracheal tubes and connectors. ISO 10993-1:2018: Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process. ISO 11135:2014: Sterilization of health-care products – Ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices.

Item no.	WHO item name	Required technical specifications
24	**Tube, endotracheal, No. 5, with cuff, sterile, single use**	Endotracheal tube designed to be introduced into the trachea via the mouth or nose, ensuring an unobstructed upper airway to convey gases and vapours to and from the lungs during anaesthesia, resuscitation and other situations where the patient is not properly ventilated. It consists in a thin, flexible, transparent and single hollow cylinder, with an anatomical curvature Magill-type of 37.5°, black and legibly depth markings and graduation in cm, with radio-opaque continuous line mark, with cuff and pilot balloon, with a standard connector in the proximal end. The proximal end of the tube safely fits the connector from which size is selected according to the tube size. The connector is straight and double-ended, with the proximal end being an outer, standard 15 mm internal diameter, conical tip that allows the tube to be connected to the ventilation system (breathing circuit or manual resuscitator). The distal end of the tube is open and bevelled (obliquely cut), atraumatic, with Murphy's eye. The cuff, situated at the distal end of the tube, provides an airtight seal between the tube and the tracheal wall. It seals the lungs against the liquid secretions sloshing around in the upper airway. And, it ensures that the environment below the cuff can be pressurised and ventilated with a carefully controlled gas mixture. The cuff has a low pressure in order to avoid inadequate pressure on the tracheal mucous membrane to prevent damage or even necrosis. It typically has a capacity of 10 mL. The cuff is inflated via a small-bore inflation tube welded to the outside of the tracheal tube or built into its wall. The pilot balloon indicates the cuff distension. One end is connected to the cuff through a thin inflation tube located close to the proximal end. The other end has a spring-loaded, one-way valve that maintains a pre-set pressure in the circuit, and has Luer tip connector for syringes. The endotracheal tubes are standard in all aspects: dimension, markings and connectors. Initial sterilization method: ethylene oxide gas or Gamma radiation. Individually peel-packed in paper and/or plastic.
25	**Tube, endotracheal, No. 6, with cuff, sterile, single use**	Endotracheal tube designed to be introduced into the trachea via the mouth or nose, ensuring an unobstructed upper airway to convey gases and vapours to and from the lungs during anaesthesia, resuscitation and other situations where the patient is not properly ventilated. It consists in a thin, flexible, transparent and single hollow cylinder, with an anatomical curvature Magill-type of 37.5°, black and legibly depth markings and graduation in cm, with radio-opaque continuous line mark, with cuff and pilot balloon, with a standard connector in the proximal end. The proximal end of the tube safely fits the connector from which size is selected according to the tube size. The connector is straight and double-ended, with the proximal end being an outer, standard 15 mm internal diameter, conical tip that allows the tube to be connected to the ventilation system (breathing circuit or manual resuscitator). The distal end of the tube is open and bevelled (obliquely cut), atraumatic, with Murphy's eye. The cuff, situated at the distal end of the tube, provides an airtight seal between the tube and the tracheal wall. It seals the lungs against the liquid secretions sloshing around in the upper airway. And, it ensures that the environment below the cuff can be pressurised and ventilated with a carefully controlled gas mixture. The cuff has a low pressure in order to avoid inadequate pressure on the tracheal mucous membrane to prevent damage or even necrosis. It typically has a capacity of 10 mL. The cuff is inflated via a small-bore inflation tube welded to the outside of the tracheal tube or built into its wall. The pilot balloon indicates the cuff distension. One end is connected to the cuff through a thin inflation tube located close to the proximal end. The other end has a spring-loaded, one-way valve that maintains a pre-set pressure in the circuit, and has Luer tip connector for syringes. The endotracheal tubes are standard in all aspects: dimension, markings and connectors. Initial sterilization method: ethylene oxide gas or Gamma radiation. Individually peel-packed in paper and/or plastic.

Item no.	Dimensions/sizes/ presentation	Material	Standards for product safety, performance and quality assurance, as requested or equivalent
24	Tube: Size: 5. Internal diameter: 5.0 mm. External diameter: 6.7 mm. Length: 250 mm, minimum. Connector: Proximal end: standard internal diameter: 15 mm. Distal end (fits the tube): length: 12 mm, minimum. Cuff: Diameter: 13 mm.	Tube: polyvinyl chloride (PVC) or polyurethane; medical grade; transparent. Connector: polyvinyl chloride (PVC); medical grade; transparent or blue. Cuff: siliconized rubber, or siliconized polyvinyl chloride (PVC). Pilot balloon: siliconized latex, or siliconized polyvinyl chloride (PVC).	ISO 5361:2016: Anaesthetic and respiratory equipment – Tracheal tubes and connectors. ISO 10993-1:2018: Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process. ISO 11135:2014: Sterilization of health-care products – Ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices.
25	Tube: Size: 6. Internal diameter: 6.0 mm. External diameter: 8.0 mm. Length: 290 mm, minimum. Connector: Proximal end: standard internal diameter: 15 mm. Distal end (fits the tube): length: 13 mm, minimum. Cuff: Diameter: 18.5 mm.	Tube: polyvinyl chloride (PVC) or polyurethane; medical grade; transparent. Connector: polyvinyl chloride (PVC); medical grade; transparent or blue. Cuff: siliconized rubber, or siliconized polyvinyl chloride (PVC). Pilot balloon: siliconized latex, or siliconized polyvinyl chloride (PVC).	ISO 5361:2016: Anaesthetic and respiratory equipment – Tracheal tubes and connectors. ISO 10993-1:2018: Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process. ISO 11135:2014: Sterilization of health-care products – Ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices.

Item no.	WHO item name	Required technical specifications
26	**Tube, endotracheal, No. 9, with cuff, sterile, single use**	Endotracheal tube designed to be introduced into the trachea via the mouth or nose, ensuring an unobstructed upper airway to convey gases and vapours to and from the lungs during anaesthesia, resuscitation and other situations where the patient is not properly ventilated. It consists in a thin, flexible, transparent and single hollow cylinder, with an anatomical curvature Magill-type of 37.5°, black and legibly depth markings and graduation in cm, with radio-opaque continuous line mark, with cuff and pilot balloon, with a standard connector in the proximal end. The proximal end of the tube safely fits the connector from which size is selected according to the tube size. The connector is straight and double-ended, with the proximal end being an outer, standard 15 mm internal diameter, conical tip that allows the tube to be connected to the ventilation system (breathing circuit or manual resuscitator). The distal end of the tube is open and bevelled (obliquely cut), atraumatic, with Murphy's eye. The cuff, situated at the distal end of the tube, provides an airtight seal between the tube and the tracheal wall. It seals the lungs against the liquid secretions sloshing around in the upper airway. And, it ensures that the environment below the cuff can be pressurised and ventilated with a carefully controlled gas mixture. The cuff has a low pressure in order to avoid inadequate pressure on the tracheal mucous membrane to prevent damage or even necrosis. It typically has a capacity of 10 mL. The cuff is inflated via a small-bore inflation tube welded to the outside of the tracheal tube or built into its wall. The pilot balloon indicates the cuff distension. One end is connected to the cuff through a thin inflation tube located close to the proximal end. The other end has a spring-loaded, one-way valve that maintains a pre-set pressure in the circuit, and has Luer tip connector for syringes. The endotracheal tubes are standard in all aspects: dimension, markings and connectors. Initial sterilization method: ethylene oxide gas or Gamma radiation. Individually peel-packed in paper and/or plastic.
27	**Tube, endotracheal, No. 7, with cuff, sterile, single use**	Endotracheal tube designed to be introduced into the trachea via the mouth or nose, ensuring an unobstructed upper airway to convey gases and vapours to and from the lungs during anaesthesia, resuscitation and other situations where the patient is not properly ventilated. It consists in a thin, flexible, transparent and single hollow cylinder, with an anatomical curvature Magill-type of 37.5°, black and legibly depth markings and graduation in cm, with radio-opaque continuous line mark, with cuff and pilot balloon, with a standard connector in the proximal end. The proximal end of the tube safely fits the connector from which size is selected according to the tube size. The connector is straight and double-ended, with the proximal end being an outer, standard 15 mm internal diameter, conical tip that allows the tube to be connected to the ventilation system (breathing circuit or manual resuscitator). The distal end of the tube is open and bevelled (obliquely cut), atraumatic, with Murphy's eye. The cuff, situated at the distal end of the tube, provides an airtight seal between the tube and the tracheal wall. It seals the lungs against the liquid secretions sloshing around in the upper airway. And, it ensures that the environment below the cuff can be pressurised and ventilated with a carefully controlled gas mixture. The cuff has a low pressure in order to avoid inadequate pressure on the tracheal mucous membrane to prevent damage or even necrosis. It typically has a capacity of 10 mL. The cuff is inflated via a small-bore inflation tube welded to the outside of the tracheal tube or built into its wall. The pilot balloon indicates the cuff distension. One end is connected to the cuff through a thin inflation tube located close to the proximal end. The other end has a spring-loaded, one-way valve that maintains a pre-set pressure in the circuit, and has Luer tip connector for syringes. The endotracheal tubes are standard in all aspects: dimension, markings and connectors. Initial sterilization method: ethylene oxide gas or Gamma radiation. Individually peel-packed in paper and/or plastic.

Item no.	Dimensions/sizes/ presentation	Material	Standards for product safety, performance and quality assurance, as requested or equivalent
26	Tube: Size: 9. Internal diameter: 9.0 mm. External diameter: 12.0 mm. Length: 350 mm, minimum. Connector: Proximal end: standard internal diameter: 15 mm. Distal end (fits the tube): length: 16 mm, minimum. Cuff: Diameter: 28 mm.	Tube: polyvinyl chloride (PVC) or polyurethane; medical grade; transparent. Connector: polyvinyl chloride (PVC); medical grade; transparent or blue. Cuff: siliconized rubber, or siliconized polyvinyl chloride (PVC). Pilot balloon: siliconized latex, or siliconized polyvinyl chloride (PVC).	ISO 5361:2016: Anaesthetic and respiratory equipment – Tracheal tubes and connectors. ISO 10993-1:2018: Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process. ISO 11135:2014: Sterilization of health-care products – Ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices.
27	Tube: Size: 7. Internal diameter: 7.0 mm. External diameter: 9.3 mm. Length: 320 mm, minimum. Connector: Proximal end: standard internal diameter: 15 mm. Distal end (fits the tube): length: 16 mm, minimum. Cuff: Diameter: 24 mm.	Tube: polyvinyl chloride (PVC), or polyurethane; medical grade; transparent. Connector: polyvinyl chloride (PVC); medical grade; transparent or blue. Cuff: siliconized rubber, or siliconized polyvinyl chloride (PVC). Pilot balloon: siliconized latex, or siliconized polyvinyl chloride (PVC).	ISO 5361:2016: Anaesthetic and respiratory equipment – Tracheal tubes and connectors. ISO 10993-1:2018: Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process. ISO 11135:2014: Sterilization of health-care products – Ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices.

Item no.	WHO item name	Required technical specifications
28	**Tube, endotracheal, No. 8, with cuff, sterile, single use**	Endotracheal tube designed to be introduced into the trachea via the mouth or nose, ensuring an unobstructed upper airway to convey gases and vapours to and from the lungs during anaesthesia, resuscitation and other situations where the patient is not properly ventilated. It consists in a thin, flexible, transparent and single hollow cylinder, with an anatomical curvature Magill-type of 37.5°, black and legibly depth markings and graduation in cm, with radio-opaque continuous line mark, with cuff and pilot balloon, with a standard connector in the proximal end. The proximal end of the tube safely fits the connector from which size is selected according to the tube size. The connector is straight and double-ended, with the proximal end being an outer, standard 15 mm internal diameter, conical tip that allows the tube to be connected to the ventilation system (breathing circuit or manual resuscitator). The distal end of the tube is open and bevelled (obliquely cut), atraumatic, with Murphy's eye. The cuff, situated at the distal end of the tube, provides an airtight seal between the tube and the tracheal wall. It seals the lungs against the liquid secretions sloshing around in the upper airway. And, it ensures that the environment below the cuff can be pressurised and ventilated with a carefully controlled gas mixture. The cuff has a low pressure in order to avoid inadequate pressure on the tracheal mucous membrane to prevent damage or even necrosis. It typically has a capacity of 10 mL. The cuff is inflated via a small-bore inflation tube welded to the outside of the tracheal tube or built into its wall. The pilot balloon indicates the cuff distension. One end is connected to the cuff through a thin inflation tube located close to the proximal end. The other end has a spring-loaded, one-way valve that maintains a pre-set pressure in the circuit, and has Luer tip connector for syringes. The endotracheal tubes are standard in all aspects: dimension, markings and connectors. Initial sterilization method: ethylene oxide gas or Gamma radiation. Individually peel-packed in paper and/or plastic.
29	**Syringe, feeding, 1 mL, LDT, ENFit, sterile, single use**	Low dose tip (LDT) syringe used for the administration of oral medication or delivery of enteral nutrition by connection to an enteral administration device. It consists of a calibrated hollow barrel (cylinder) made of plastic and a moveable plunger. The tip is designed to mate only with enteral administration devices and is specifically incompatible with Luer (6%) connectors and intravenous devices. Initial sterilization method: ethylene oxide gas. Individually peel-packed in paper and/or plastic.
30	**Syringe, feeding, 10 mL, ENFit, sterile, single use**	Syringe used for the administration of oral medication or delivery of enteral nutrition by connection to an enteral administration device. It consists of a calibrated hollow barrel (cylinder) made of plastic and a moveable plunger. The tip is designed to mate only with enteral administration devices and is specifically incompatible with Luer (6%) connectors and intravenous devices. Initial sterilization method: ethylene oxide gas. Individually peel-packed in paper and/or plastic.
31	**Syringe, feeding, 2.5 mL, LDT, ENFit, sterile, single use**	Low dose tip (LDT) syringe used for the administration of oral medication or delivery of enteral nutrition by connection to an enteral administration device. It consists of a calibrated hollow barrel (cylinder) made of plastic and a moveable plunger. The tip is designed to mate only with enteral administration devices and is specifically incompatible with Luer (6%) connectors and intravenous devices. Initial sterilization method: ethylene oxide gas. Individually peel-packed in paper and/or plastic.
32	**Syringe, feeding, 20 mL, ENFit, sterile, single use**	Syringe used for the administration of oral medication or delivery of enteral nutrition by connection to an enteral administration device. It consists of a calibrated hollow barrel (cylinder) made of plastic and a moveable plunger. The tip is designed to mate only with enteral administration devices and is specifically incompatible with Luer (6%) connectors and intravenous devices. Initial sterilization method: ethylene oxide gas. Individually peel-packed in paper and/or plastic.

Item no.	Dimensions/sizes/ presentation	Material	Standards for product safety, performance and quality assurance, as requested or equivalent
28	Tube: Size: 8. Internal diameter: 8.0 mm. External diameter: 10.7 mm. Length: 340 mm, minimum. Connector: Proximal end: standard internal diameter: 15 mm. Distal end (fits the tube): length: 16 mm, minimum. Cuff: Diameter: 26 mm.	Tube: polyvinyl chloride (PVC), or polyurethane; medical grade; transparent. Connector: polyvinyl chloride (PVC); medical grade; transparent or blue. Cuff: siliconized rubber, or siliconized polyvinyl chloride (PVC). Pilot balloon: siliconized latex, or siliconized polyvinyl chloride (PVC).	ISO 5361:2016: Anaesthetic and respiratory equipment – Tracheal tubes and connectors. ISO 10993-1:2018: Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.
29	Barrel: 1 mL; graduations every 0.1 mL.	Barrel: transparent polypropylene, ending with a female ENFit tip, LDT to decrease the dead space. Plunger: polypropylene or polyethylene coloured to be distinguished from injection syringes. Gasket: synthetic elastomer (latex-free).	ISO 80369-3:2016: Small-bore connectors for liquids and gases in healthcare applications – Part 3: Connectors for enteral applications. ISO 18250-3:2018: Medical devices – Connectors for reservoir delivery systems for healthcare applications – Part 3: Enteral applications.
30	Barrel: 10 mL; graduations every 0.5 mL.	Barrel: transparent polypropylene, ending with a female ENFit tip. Plunger: polypropylene or polyethylene coloured to be distinguished from injection syringes. Gasket: synthetic elastomer (latex-free).	ISO 80369-3:2016: Small-bore connectors for liquids and gases in healthcare applications – Part 3: Connectors for enteral applications. ISO 18250-3:2018: Medical devices – Connectors for reservoir delivery systems for healthcare applications – Part 3: Enteral applications.
31	Barrel: 2.5 to 3 mL; graduations every 0.1 mL.	Barrel: transparent polypropylene, ending with a female ENFit tip, LDT to decrease the dead space. Plunger: polypropylene or polyethylene coloured to be distinguished from injection syringes. Gasket: synthetic elastomer (latex-free).	ISO 80369-3:2016: Small-bore connectors for liquids and gases in healthcare applications – Part 3: Connectors for enteral applications. ISO 18250-3:2018: Medical devices – Connectors for reservoir delivery systems for healthcare applications – Part 3: Enteral applications.
32	Barrel: 20 mL; graduations every 0.5 mL.	Barrel: transparent polypropylene, ending with a female ENFit tip. Plunger: polypropylene or polyethylene coloured to be distinguished from injection syringes. Gasket: synthetic elastomer (latex-free).	ISO 80369-3:2016: Small-bore connectors for liquids and gases in healthcare applications – Part 3: Connectors for enteral applications. ISO 18250-3:2018: Medical devices – Connectors for reservoir delivery systems for healthcare applications – Part 3: Enteral applications.

Item no.	WHO item name	Required technical specifications
33	**Syringe, feeding, 5 mL, LDT, ENFit, sterile, single use**	Low dose tip (LDT) syringe used for the administration of oral medication or delivery of enteral nutrition by connection to an enteral administration device. It consists of a calibrated hollow barrel (cylinder) made of plastic and a moveable plunger. The tip is designed to mate only with enteral administration devices and is specifically incompatible with Luer (6%) connectors and intravenous devices. Initial sterilization method: ethylene oxide gas. Individually peel-packed in paper and/or plastic.
34	**Syringe, feeding, 60 mL, ENFit, sterile, single use**	Syringe used for the administration of oral medication or delivery of enteral nutrition by connection to an enteral administration device. It consists of a calibrated hollow barrel (cylinder) made of plastic and a moveable plunger. The tip is designed to mate only with enteral administration devices and is specifically incompatible with Luer (6%) connectors and intravenous devices. Initial sterilization method: ethylene oxide gas. Individually peel-packed in paper and/or plastic.
35	**Tube, feeding, nasogastric, 12 Fr and 14 Fr, 90 cm, ENFit tip, sterile, single use**	Used for short-term gastro-enteral feeding and drug administration when connected to feeding syringes; or, for ventricular lavage. It is intended mainly for newborn and infant patients. The nasogastric tube is introduced via the nasopharynx into the gastrointestinal (GI) tract. It consists in a thin, flexible, transparent and single hollow cylinder with radio-opaque line marked from the distal end. The distal end is a soft and rounded closed-ended tip, with two laterals opposite alternated eyelets. The proximal end with a connector, ENFit tip, and a stopper, allows the tube to be connected to feeding syringes. Visible international-recognized colour code on cup connector. Initial sterilization method: ethylene oxide gas. Individually peel-packed in paper and/or plastic.
36	**Tube, feeding, nasogastric, 6 Fr, 8 Fr and 10 Fr, 50 cm, ENFit tip, sterile, single use**	Used for short-term gastro-enteral feeding and drug administration when connected to feeding syringes; or, for ventricular lavage. It is intended mainly for newborn and infant patients. The nasogastric tube is introduced via the nasopharynx into the gastrointestinal (GI) tract. It consists in a thin, flexible, transparent and single hollow cylinder with radio-opaque line marked from the distal end. The distal end is a soft and rounded closed-ended tip, with two laterals opposite alternated eyelets. The proximal end with a connector, ENFit tip, and a stopper, allows the tube to be connected to feeding syringes. Visible international-recognized colour code on cup connector. Initial sterilization method: ethylene oxide gas. Individually peel-packed in paper and/or plastic. Each set provided is composed by at least the following sizes: 6 Fr, 8 Fr and 10 Fr.
37	**Stethoscope, binaural, adult/child**	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. Sensitivity 3.2dB in a range from 50–500 Hz for cardiology. The Y tube treated rubber with large diameter of 10 mm. Binaural device, with non-folding smooth spring frame. Double head chest piece. Plain spring non-folding frame. Plastic ear tips. Ear clips included. Vinyl stethoscope tubing. Combined bell and diaphragm sprague type. Approximate length of 1 m.

Item no.	Dimensions/sizes/ presentation	Material	Standards for product safety, performance and quality assurance, as requested or equivalent
33	Barrel: 5 mL; graduations every 0.2 mL.	Barrel: transparent polypropylene, ending with a female ENFit tip, LDT to decrease the dead space. Plunger: polypropylene or polyethylene coloured to be distinguished from injection syringes. Gasket: synthetic elastomer (latex-free).	ISO 80369-3:2016: Small-bore connectors for liquids and gases in healthcare applications – Part 3: Connectors for enteral applications. ISO 18250-3:2018: Medical devices – Connectors for reservoir delivery systems for healthcare applications – Part 3: Enteral applications.
34	Barrel: 60 mL; graduations every 1 mL.	Barrel: transparent polypropylene, ending with a female ENFit tip. Plunger: polypropylene or polyethylene coloured to be distinguished from injection syringes. Gasket: synthetic elastomer (latex-free).	ISO 80369-3:2016: Small-bore connectors for liquids and gases in healthcare applications – Part 3: Connectors for enteral applications. ISO 18250-3:2018: Medical devices – Connectors for reservoir delivery systems for healthcare applications – Part 3: Enteral applications.
35	Sizes: 12 Fr and 14 Fr. Length: 90 cm.	Polyvinyl chloride (PVC); medical grade.	ISO 80369-3:2016: Small-bore connectors for liquids and gases in healthcare applications – Part 3: Connectors for enteral applications. ISO 18250-3:2018: Medical devices – Connectors for reservoir delivery systems for healthcare applications – Part 3: Enteral applications. ISO 11135:2014: Sterilization of health-care products – Ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices.
36	Sizes: 6 Fr, 8 Fr and 10 Fr. Length: 50 cm.	Polyvinyl chloride (PVC); medical grade.	ISO 80369-3:2016: Small-bore connectors for liquids and gases in healthcare applications – Part 3: Connectors for enteral applications. ISO 18250-3:2018: Medical devices – Connectors for reservoir delivery systems for healthcare applications – Part 3: Enteral applications. ISO 11135:2014: Sterilization of health-care products – Ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices.
37	Length: approximately 1 m.	As appropriate to guarantee flexibility in use.	No specific product standard for stethoscopes.

Item no.	WHO item name	Required technical specifications
38	**Bag, collecting, urine, with outlet tap, with non-return valve, 2000 mL, adult, non-sterile, single use**	Used to fit gastric tube (aspirating/feeding tube) or incontinence condom. Drainable bag for collecting urine with permanent and legible graduations every 100 mL. With reinforced eyelets for hanging. With a drainage valve (outlet tap) which permits the bag to be emptied without disconnecting, maintaining sterility. It is fitted to an outlet tube. With a non-return valve, located inside the urine collector bag at the upper part (urine entry point), which prevents urine backflow into the indwelling urinary catheter. It is fitted with a kink resistant, transparent plastic inlet tube, with universal connector and protective cap.
39	**Catheter, urethral, Foley, 2-way, sterile, single use, different sizes**	A soft thin rubber tube with a balloon at the nelaton tip, designed for insertion in the bladder cavity, via the urethra, in order to drain off urine, instil a liquid or irrigate the bladder. A standard catheter consists of a hollow 2-way cylindrical tube with one central channel for urinary drainage; bladder side ending, Foley type, with a rounded atraumatic end tip (nelaton tip), with two opposing eyelets and one balloon; collector side ending that is a universal and hollow truncated cone (funnel) to connect the urine bag, spigot, syringe or irrigating device; and the balloon port, side channel ending with a non-return valve and a Luer tip connector. Catheter size is expressed in French gauge or Charrier (Fr or CH) and colour coded; balloon expansion capacity is expressed in mL. Dimensions and colour code must be legible and visible on the connectors. Preferable intended use for this size: children, medium- or long-term catheterization. Initial sterilization method: ethylene oxide gas or equivalent if applicable. Individually peel-packed in paper and/or plastic. Double-packaged: protected with an interior layer and an outer peel pack. Each set provided is composed by at least the following external diameter sizes: 10 Fr, 12 Fr, 14 Fr, 16 Fr and 18 Fr.
40	**Cricothyrotomy, set, emergency, 6 mm, sterile, single use**	Set/kit to apply an incision made through the skin and cricothyroid membrane to establish a patent airway during specific life-threatening situations, such as airway obstruction. The cricothyrotomy set should be composed at least by the following devices: • One 6.0 mm, cuffed cricothyroidotomy tube • One cricothyroidotomy, tube holder • One dilator • One scalpel blade, No. 15 preferably, for handle No. 3 preferably, sterile, single use • One suture, surgical, synthetic, non absorbable, monofilament, DEC 3.5 (0), 45 cm, with needle, 3/8 circle, 29.9 mm, cutting point • One syringe, 10 mL, two or three pieces, Luer type, sterile, single use • One HME filter.
41	**Lubricating jelly**	Lubricating jelly is a sterile, water-soluble, latex-free, alcohol-free gel intended for use on intact skin, on mucous membranes and in natural body orifices. Sterile, greaseless lubricating jelly used in many clinical procedures such as: nasopharyngeal airway insertion, feeding tube insertion, endoscopy and ultrasound intracavitary examinations. Great viscosity for better resolution.
42	**Central venous catheters kit, single use, sterile**	Central venous catheters kit with: finder needle, syringe, wire, dilator, lidocaine, scalpel, needle, thread.
43	**Tape, surgical, hypoallergenic, .025 × 5 m**	Hypoallergenic surgical tape is designed to be commonly used in any operating theatre, in emergency departments (i.e during first aid to hold a bandage) and ICU departments. It should be made to firmly adhere to the skin or dressing materials and at the same time to be easily removed without the risk of damaging sensitive skin. Moreover, the surgical tape should be designed to permit the air to reach the skin (to be "breathable"). Hypoallergenic tape is usually more (but not exclusively) used in infants and elderly management, and for post-surgery application. Hypoallergenic Surgical tapes should be tested and proved not to cause any skin reactions. Surgical tape should be also preferably water-resistant.

Item no.	Dimensions/sizes/ presentation	Material	Standards for product safety, performance and quality assurance, as requested or equivalent
38	Capacity, bag: 2000 mL. Length, tube: 85–95 cm. Diameter, tube: 6.5 mm, approximately.	Bag: polyvinyl chloride (PVC), polypropylene or ethylene vinyl acetate (EVA); medical grade. Tube, connector and protective cap: polyvinyl chloride (PVC); medical grade.	ISO 8669-2:1996: Urine collection bags – Part 2: Requirements and test methods.
39	Length: 30 cm. External diameter sizes provided: 10 Fr, 12 Fr, 14 Fr, 16 Fr and 18 Fr. Balloon expansion capacity: 3 to 5 mL.	Silicone-coated natural latex.	ISO 20696:2018: Sterile urethral catheters for single use. ISO 11135:2014: Sterilization of health-care products – Ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices.
40	Many.		
41	Available in different formats and different tubes volume capacity.		
42	Kit.	Different materials, including polyurethane.	ISO 10555-6:2015(en) Intravascular catheters – Sterile and single-use catheters.
43	Width: 2.5 cm. Roll length: 500 cm.	Different materials, latex-free and up to at least 90% allergens free.	ASTM F2258 - 05(2015) Standard test method for strength properties of tissue adhesives in tension.

Item no.	WHO item name	Required technical specifications	
44	**Drape, surgical, non-woven, sterile, single use**	Single-use sterile device used to maintain aseptic conditions in an operative area. Should be made of two or three layers, non-woven fabric material. Easy to be draped and traction resistant material. Designed with or without a hole, depending on use.	
45	**Forceps Magill, 24 cm**	Angled forceps designed to guide a tracheal tube into the larynx or a nasogastric tube into the esophagus. They could be also used to remove foreign bodies. Devices used mainly in emergency and ICU departments.	
46	**Basin kidney, stainless steel, 825 mL**	Basin with a kidney-shaped base and sloping walls used in medical and surgical wards to receive soiled dressings and other medical waste. Reusable, autoclavable kidney dish.	

Item no.	Dimensions/sizes/ presentation	Material	Standards for product safety, performance and quality assurance, as requested or equivalent
44	Different sizes available, depending on exigencies and request. Most common measures are (approximately): 50 × 70 cm; 70 × 90 cm; 90 × 140 cm; 140 × 250 cm.	Non-woven fabric, made of synthetic fibres, typically cellulose and/or polyester and/or polyethylene.	ISO 22610:2006(en) Surgical drapes, gowns and clean air suits, used as medical devices, for patients, clinical staff and equipment – Test method to determine the resistance to wet bacterial penetration.
45	Length approximately 24 cm.	Stainless steel.	ASTM F899 - 20 Standard specification for wrought stainless steels for surgical instruments ISO 7153-1:2016 Surgical instruments – Materials – Part 1: Metals.
46	Volume capacity approximately 825 mL.	Stainless steel.	ISO 7153-1:2016 Surgical instruments – Materials – Part 1: Metals.

Resources

AAMI. AAMI offers free standards and resources to help fight coronavirus. Association for the Advancement of Medical Instrumentation; 2020 (https://www.aami.org/detail-pages/press-release/aami-offers-free-standards-and-resources-to-help-fight-coronavirus, accessed 12 August 2020).

ISO. COVID-19 response: freely available ISO standards. International Organization for Standardization; 2020 (https://www.iso.org/covid19, accessed 29 August 2020).

8. Technical specifications for imaging equipment

In June 2020, WHO published a rapid advice guide on the use of medical imaging in the context of the COVID-19 pandemic.[1] The guide makes recommendations for the use of chest imaging in the acute care of adult patients with suspected, probable or confirmed COVID-19, based on available evidence. The imaging modalities considered are ultrasound, radiography and computed tomography (CT), for use within the care pathway.

In view of the urgency to produce a complementary document of technical specifications of equipment to support the rapid advice guide, a working group was established with staff and consultants on imaging technologies from WHO and the International Atomic Energy Agency (IAEA). The draft was sent to experts and nongovernmental organizations for review and comment.

The final chapter presented here considers the conditions of COVID-19 patients and the best types of technologies to address them. Nevertheless, these technologies can also be used as diagnostic imaging tools for many other health conditions and diseases. Therefore, the accessories and software packages listed in these specifications are detailed in order to have equipment that can be used not only for COVID-19 but for co-morbidities and for future use for other pathologies.

It should be noted that the selection of the imaging device to be procured or used is made considering clinical and technical perspectives and depends on the resources available in a specific

[1] WHO. Use of chest imaging in COVID-19: a rapid advice guide, 11 June 2020. Geneva: World Health Organization; 2020 (https://apps.who.int/iris/handle/10665/332336, accessed 26 June 2020).

setting: human, technical, infrastructure and financial. Use is dependent on the clinical judgement of medical professionals and the condition of individual patients.

All three equipment categories require a trained health care workforce and, in the case of CT, special infrastructure. All the equipment detailed requires specialized care and maintenance; accessories can be purchased in the future to further enhance functionality.

The references and resources sections for each technology provide further guidance and specific information for the selection, protection and use of these imaging technologies.

This chapter is a joint publication between WHO and IAEA for use in the procurement of imaging technology devices for COVID-19.

8.1 Portable ultrasound scanner

8.1.1 Context and considerations

This section describes the basic technical characteristics of ultrasound portable scanners, also called cart-based point-of-care ultrasound scanners or portable ultrasound scanners.[1]

The decision on appropriate clinical use of each of these devices is reserved for medical staff.

Diagnostic ultrasound scanners are medical imaging devices that use high-frequency sound waves to permit users to collect information on normal and pathologic appearances of patients' internal and external organs and tissues.

Portable ultrasound scanners are designed for point-of-care (POC) applications. They can be battery operated, are relatively easy to use, and have capabilities and features designed for imaging assessments at the POC. However, since diagnostic ultrasound is a highly operator-dependent imaging modality, proper training is required to make optimum use of the equipment, produce diagnostic quality images, and interpret them correctly to make reliable diagnostic judgements.

Portable ultrasound scanners can speed patient management decision-making, providing more time-efficient and effective patient care. Diagnostic applications include examinations which can be performed externally (transcutaneously) or endoscopically (endocavitary or endoluminal) for visualization of abdominal and pelvic organs, the lungs, cardiovascular and musculoskeletal [MSK] systems, and small parts and obstetric imaging. In addition to its diagnostic applications, portable ultrasound is also used to guide interventional procedures such as intravascular injection of medications, drainage of collections, and for a range of other applications performed by various health care providers.

[1] CND/EMDN nomenclature code Z11040103.

8.1.2 Definitions and intended use

Laptop-style scanners: These take the shape of a laptop, notebook or tablet computer and often have most of the functionality of a conventional full-size scanner, but in a smaller package. Cart-based portable ultrasound scanners are included in this category.

Other type of ultrasound scanners not in the scope of this chapter:

Handheld scanners: These can be held in one hand, while the attached transducer or probe is held in the other. They lack many of the features of other types of scanners.

USB-powered scanners: This category describes self-contained transducers that can be plugged into the universal serial bus (USB) port of a user-supplied computer-based device (e.g. laptop, tablet, smartphone) either directly or through an adapter.

This chapter only refers to the laptop-style portable scanners category (both touchscreen and/or standard laptop equipment and cart-based), which are also referred to as cart-based point-of-care ultrasound scanners or portable ultrasound scanners.

Regarding the ongoing COVID-19 pandemic and, in particular, COVID-19 related lung damage and associated complications, ultrasound technology offers benefits in imaging pneumonia, assessing pleural complications and evaluating the condition of the heart *(1, 2)*.

Ultrasound does not expose the patient to radiation, is portable and fairly inexpensive to perform in isolation settings such as for COVID-19.

The portable ultrasound unit will be primarily used in emergency and critical care units, but can also be used in other health care centres and acute respiratory units and treatment centres and will serve for general purposes after the pandemic. The unit will be used to (but not limited to) investigate thoracic, abdominopelvic, obstetrics/gynaecological and vascular diseases and to perform, if needed, interventional procedures.

The infection prevention and control precautions and, in particular, the level of decontamination of the probes, differ according to procedure, for example, whether the transducers used are in contact with intact skin or body fluids *(3)*.

8.1.3 Technical specifications for procurement

Portable ultrasound scanner		
Naming: Cart-based point-of-care ultrasound scanners, also called portable ultrasound scanners (both touchscreen and/or standard laptop equipment and cart-based)		
1	**General technical requirements**	Capable of generating imaging procedures involving lungs, heart, abdomen, pelvis, blood vessels, musculoskeletal and soft tissue. Console: laptop style console design, optional touchscreen combined with conventional user-control panel. Total weight of the equipment 5–10 kg (preferable). Dimensions, approximately: 35–45 cm (L); 35–45 cm (H); 5–10 cm (D). Battery duration: minimum 2 hours under normal use conditions. Clear protective control panel cover for infection control. Imaging focusing: adjustable focal depth, either manually or automatically synchronized to the selected scanning depth. Zooming capability with automated image optimization. Depth range selection: capable of multiple depth range selection, synchronized with automatic focal zone selection. Field of view: imaging depth at least 20 cm. Image orientation: capable of lateral and vertical inversion (in B-mode). Image modes at least: • 2-D imaging • M-mode • B/M mode • dual 2-D/colour image mode with cine loop • pulsed wave Doppler, colour Doppler imaging (CDI), power Doppler imaging (PDI), duplex, continuous wave Doppler, triplex mode (optional). Needle enhancement ability. Software applications that include at least: • obstetrics/gynaecological measurements and calculations, including gestational sac mean diameter, femur length, crown-rump length, biparietal diameter and abdominal circumference, enabling estimation of gestational age and foetal weight (preferable); • small parts/soft tissues; • lung; • vascular/basic cardiac quantification; • easy selection of callipers; • measurements capabilities (distance, area and circumference by ellipse and trace method); • capability to be upgraded with additional software applications. Probe-dependant applications with factory-default pre-sets at least: cardiac, peripheral vascular, abdominal adult, abdominal paediatric, small parts, lung, MSK-general, MSK-superficial, obstetrics/gynaecological, trans-vaginal. Equipment with zoom functionality available. Screen annotations capture patient data, date and time, scanning protocols, probes. Text annotations and body markers and image orientation indicator. Transducer ports: at least two active transducer ports permanently available; capability of electronic (preferable) or manually switch between probes.
2	**Monitor and display**	Screen monitor: high-definition (HD) digital black and white and colour liquid-crystal display (LCD) monitor of at least 25 cm diagonal (across), equivalent to 10 inches (at least 15 inches preferable), with reflection filter or adequate alternative. Screen monitor protection available. Laptop monitor fold-down and lock mechanism of the screen for safe and easy transportation (if applicable). User-friendly control panel: easy to use, logical and orderly control panel: for quick and easy location of most common functions. Back lighting or highlighting of application knobs/buttons/controls.

Portable ultrasound scanner		
3	**Communication and storage**	Data communication, storage and transfer interface: USB minimum, high-definition multimedia interface (HDMI) preferable. DICOM 3.0 conformity. Digital image storage capacity: at least 64 GB of cine memory for static images and dynamic clips. Cine loop: freeze and cine-loop functions. Image grey scale: 256 shades of grey and video output of 625 lines/frame 150 dB full time dynamic range. Capability for database of patient images and information.
4	**Consumables**	Ultrasound transmission gel for 1000 patients' exams. Cleaning and disinfection products for 1000 patients' exams. Compatible printing paper for 3 months' operation (when printer available).
5	**Accessories (included)**	Transducers: • Phased-array 2–5 MHz for basic cardiac and lung studies. • Phased-array up to 8 MHz for paediatric patients. • Broadband curvilinear at least 2–5 MHz for general abdominal, obstetrics/gynaecological and lung ultrasound applications. This should have colour, power and spectral Doppler capabilities. M-mode is desirable for obstetrics. • Linear-array high frequency broadband at least 5–10 MHz, with colour, power and spectral Doppler capabilities for vascular and small parts. • Capability to connect endocavitary transducers. Dedicated probes covers should be provided. If applicable, matching trolley (compact and lightweight) or compatible wheeled cart, with gel bottle holders, drawer, or dedicated space for accessories, as well as a place for scanner positioning and easy orientation. Cables and other connection accessories. Storage security lock/chain and key Wheeled cart or dedicated trolley (if applicable) with gel bottle holders, drawer or dedicated space for accessories, place for scanner positioning and easy orientation. Equipment provided with necessary quality assurance and control testing tools.
6	**Power supply (voltage, frequency and plug vary across countries)**	Equipment must be connected to a reliable and continuous source of energy. Operates from AC power electric line: 100–240 V ~, 50/60 Hz. Built-in rechargeable battery included. Automatic switch from AC power electric line mode to battery operating mode and vice versa. Power supply: power supply may vary according to country. Working time in battery mode and standard operations not less than 2 hours. Battery recharging time not more than 4 hours.
7	**Documentation (included, minimum in English language)**	Hard and soft copies in English (provision of versions in other UN languages, if available, will be an asset). Certificate of calibration and inspection. User manual with specific protocols for cleaning, disinfection, troubleshooting. Service manual with calibration and routine maintenance. Contact details for after sales service. Contact details of manufacturer, supplier and local service agent.
8	**Primary packaging label**	Labelling on the primary packaging to include: • Name and/or trademark of the manufacturer. • Model or product reference. • Information for particular storage conditions (temperature, pressure, light, humidity).
9	**Standards, for the manufacturer and the equipment**	Certified quality management system for medical devices (e.g. ISO 13485:2016 Medical devices – Quality management systems – Requirements for regulatory purposes). General quality management (e.g. ISO 9001:2015 Quality management systems – Requirements). Application of risk management to medical devices (e.g. ISO 14971:2019 Medical devices – Application of risk management to medical devices).

Portable ultrasound scanner		
10	**Regulatory approval/ certification**	Free sales certificate (FSC) or certificate for exportation of medical device provided by the authority in manufacturing country. Proof of regulatory compliance, as appropriate, per the product's risk classification (e.g. Food and Drug Administration [FDA] and/or Conformité Européenne [CE]).
11	**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). Reference to the last available version is recommended but compliance to previous standards versions could be considered (as/ when applicable). • ISO 29821:2018 Condition monitoring and diagnostics of machines – Ultrasound – General guidelines, procedures and validation. • IEC 60601-1:2005+AMD1:2012 Consolidated version – Medical electrical equipment – Part 1: General requirements for basic safety and essential performance. • 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. • 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. • IEC 61157:2007+AMD1:2013 Consolidated version – Standard means for the reporting of the acoustic output of medical diagnostic ultrasonic equipment. • IEC 60601-1-4 Medical electrical equipment – Part 1-4: General requirements for safety – Collateral standard: Programmable electrical medical systems.
12	**Warranty**	The system shall be covered by a warranty of at least 1 year including parts and labour, including the probes, starting as of the date of successful on-site acceptance, as per testing and acceptance. Spare parts availability for the equipment lifespan (not less than 7 years). Warranty shall include all necessary spare parts, shipment to site, cost of replacement work, personnel, disposal of faulty parts, and software (patches, upgrades and updates).
Any variation to be indicated in the offer.		

Additional services required

Testing and acceptance

- The system, prior to shipment, shall be tested by designated agents for conformity with manufacturer's performance specifications and the minimum requirements specified.
- The results of the testing of the system shall be documented by the contractor in an acceptance protocol that shall be signed by the end user.

Training and manuals

- User care instructions and protocols (manuals) to be provided, including guidance for replacement of accessories and consumables and safe decontamination of reusable parts (if applicable), indicating if they are generic or brand related.
- Technical maintenance protocols and manuals to be provided.
- Trainings for users and technical maintenance teams (provided also in online format, if available). Trainings shall include topics related to the use of quality assurance and control tools provided for testing.

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8.2 Mobile digital radiography system

8.2.1 Context and considerations

The WHO developed a rapid advice guide on the use of medical imaging in the context of the COVID-19 pandemic *(1)*. Subsequently, these technical specifications for mobile digital radiography system have been developed.

This section describes the requirements for a mobile radiographic unit to be used as a complete standalone solution for acquisition, review, presentation, display, storage and transfer of radiographic images in a resource-limited setting. It aims to define the minimum technical characteristics of mobile digital radiography system (also called: X-ray mobile equipment; general radiographic X-ray mobile equipment).

The decision as to the appropriate clinical use of these devices is reserved for medical staff.

Mobile radiographic digital equipment encompasses medical imaging devices that use X-ray technology to permit users to collect information on normal and abnormal features of different body sections. The mobile radiographic digital equipment is mainly used for radiographic imaging of patients who cannot be moved to the radiology department and are in hospital departments, such as intensive care units (ICUs) or operating and emergency rooms, that are missing standard, fixed radiographic equipment. Mobile equipment is designed to be used mainly when patient transport is contraindicated for any reason. Mobile radiographic digital equipment should not be used for patients whose condition/isolation status does not prevent them from being transported to the radiology department. These devices are commonly used for general 2-D radiographic studies (predominantly for chest X-rays) as well as for orthopaedic imaging.

The mobile radiographic digital equipment described here requires a direct digital radiography (DDR) technology with a flat-panel detector. The equipment consists of a wheeled cart that transports an X-ray generator, an X-ray tube, a tube telescopic arm support, collimators, on-board computer and a flat-panel digital detector. The equipment is a battery-powered unit, with a battery and charging system and a motor drive that is powered by the battery. The main AC line voltage is used to charge the batteries and, in some models, to power the equipment during standard operations (this dual power supply reduces the unit's downtime by permitting the equipment to operate while recharging the batteries).

8.2.2 Definitions and intended use

With regard to the ongoing COVID-19 pandemic and, in particular, COVID-19 related lung damage and connected complications, mobile radiographic digital technology offers benefits in chest imaging and assessing levels of COVID-19 probability and disease severity *(1)*.

The "user" is defined as the counterpart in the destination territory, as on the purchase order.

The mobile radiographic digital equipment is primarily used in the emergency unit and critical care unit/ICU of district general hospitals, specialized hospitals and health care centres. However, it can

also be used in outreach operations (i.e. mobile clinics). This equipment will serve for orthopaedic and other general purposes after the pandemic.

With regard to COVID-19 infection prevention and control (IPC) precautions, the level of decontamination (cleaning and disinfection protocols) of the radiographic unit components applied depends on the clinical procedures used and on the brand/model indications provided together with the user and technical manuals.

8.2.3 Technical specifications for procurement

Mobile digital radiography system		
Naming: X-ray mobile equipment, mobile; general radiographic X-ray mobile equipment		
1	**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. Equipment: mobile, motorized, battery and AC power operated (AC mandatory for charging and, preferably, for standard working operations too). Digital Imaging and Communications in Medicine (DICOM) 3.0 compatible image storage and transfer required. The system should be capable of storing at least 2000 images with comprehensive post-processing options (Dose Area Product [DAP] meter to be integrated). 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). Integrated Ethernet connectivity required. At least 20 anatomical programmes shall be available. Software for COVID-19 detection should be included (preferable) (if available). An integrated image review monitor to be included in the configuration. Anti-scatter grid or software for scatter correction (preferable) (if available). Equipment provided with DAP device/capability to record the patient dose.
2	**Detailed technical requirements**	kVp range at least 40–120 kVp, digitally displayed. mAs range at least 0.5–200 mAs or more. Minimum exposure time is 8.0 msec or less. Maximum exposure time 4 sec. Automatic exposure control facility (preferable) (if available). Tube power rating at least 20 kW (measured at 100 kVp). Rotating anode with dual focal spots and the maximum focal spot not higher than 1.3 mm (equivalent output/technology could be considered). Heat storage capacity of the anode at least 120 000 HU. Cooling rate not less than 14 000 HU/min. Total filtration at least of 2.5 mm aluminium equivalent. 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. Capability for alphanumeric annotation of images. Equipment total weight in the range 100–500 kg.
3	**Digital detector**	Image quality: spatial resolution better than 3 lp/mm. Pixel pitch: < 150 x 150 µm. Grayscale: at least 4096 (12-bit). Preview image access time: less than 10 sec after X-ray exposure.

Mobile digital radiography system		
Naming: X-ray mobile equipment, mobile; general radiographic X-ray mobile equipment		
4	**Displayed and user-adjustable parameters and settings**	Image to be displayed immediately after exposure. Digital display of mAs, kV, KAP/DAP and an electronic timer. Low battery indicator/alarm. Exposure status lights on main control and/or collimator (standby, ready up, exposure). Image display to be contrast- and brightness-adjustable, at least 18 inches diagonal size. Exposures by remote control should also be possible, with operating distance higher than approximately 10 m. The exposure release switch n the imaging suite should be detachable, with a cord of at least 5 m long.
5	**System components and other physical characteristics**	An X-ray tube support with telescopic arm. The tube stand must be fully counter-balanced for rotation in all directions. Articulated arm for imaging with any patient position. Source to image receptor distance (SID) range not less than 100–200 cm. Frame with column/arm rotation range not less than ± 180 degrees. Adjustable multi-leaf collimator, rotatable ± 90 degrees, with patient centring light. All cables shall be concealed in the arm system. Collimation light to confirm the radiation field size. Unit base wheels must be easily accessible for cleaning.
6	**Mobility and portability**	When motor or battery is non-functional, free movement by pushing must be possible. Equipment speed capacity not less than approximately 1.5 km/hr. Motorized movement capable of ascending slope of up to at least 7 degrees from horizontal. The unit must have an effective system for parking, transport and emergency braking. Unit base wheels must be easily accessible for cleaning.
7	**Power supply (voltage, frequency and plug vary across countries)**	AC power input to be 120 and/or 220 V ± 10%, 50–60 Hz, single phase, fitted with compatible mains plug. X-ray exposures without power supply (battery mode exposure) preferable (if available). Motor battery to be sealed lead-acid type, recharged by main unit power connection and recharging time not higher than 8 hours. Battery total energy capacity up to at least 20 000 mAs. Resettable overcurrent breaker to be fitted on both live and neutral supply lines. Voltage corrector/stabilizer to allow safe and stable operations at ± 20% of local rated voltage (if necessary).
8	**Accessories and spare parts**	Must be supplied with protective dust cover at least for control panel. To be supplied with at least 1 adult-size protective lead apron and 1 thyroid shield. Portable radiation hazard warning signs to be supplied with unit. List of important spares and accessories to be provided with their part numbers and cost. Spare parts availability for the equipment lifespan (not less than 7 years). 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.
9	**Packaging, transport and environmental requirements**	The system, for the shipment by air to end users, shall be packed in accordance with international standards that are applicable for the shipment by air of this kind of equipment. Capable of being stored continuously in ambient temperature of 0–50 °C and relative humidity (RH) of 15–90%. Capable of operating continuously in ambient temperature of 10–40 °C and RH 15–90%. Labelling on the primary packaging to include: • Name and/or trademark of the manufacturer. • Production year. • Model or product reference. • Information for particular storage conditions (temperature, pressure, light, humidity).

Mobile digital radiography system		
Naming: X-ray mobile equipment, mobile; general radiographic X-ray mobile equipment		
10	**Standards, for the manufacturer and the equipment**	Certified quality management system for medical devices (e.g. ISO 13485:2016 – Medical devices – Quality management systems – Requirements for regulatory purposes). General quality management (e.g. ISO 9001:2015 – Quality management systems – Requirements). Application of risk management to medical devices (e.g. ISO 14971:2019 – Medical devices – Application of risk management to medical devices).
11	**Regulatory approval/ certification**	Free sales certificate (FSC) or certificate for exportation of medical device provided by the authority in manufacturing country. Proof of regulatory compliance, as appropriate, per the product's risk classification (e.g. Food and Drug Administration [FDA] and/or Conformité Européenne [CE]).
12	**Standards, for product performance**	Compliance to the following international standards or to regional or national equivalent, as applicable (including the technical tests for safety and performance from accredited laboratory or third party). Reference to the last available version is recommended but compliance to previous standards versions could be considered (as/when applicable). • IEC 60601-1:2005+AMD1:2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance. • 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. • IEC 60336:2005 X-ray tube assemblies for medical diagnosis – Characteristics of focal spots. • 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. • 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. • 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 fluoroscopy.
13	**Warranty and post-warranty**	The system shall be covered by a warranty of at least 1 year, including all spare parts and labour, starting as of the date of successful on-site acceptance, as per testing and acceptance. Warranty shall include all necessary spare parts, shipment to site, cost of replacement work, personnel, disposal of faulty parts, and software (patches, upgrades and updates). Specific warranty inclusions and exclusions shall be clearly listed. At least two service visits per year shall be made under warranty. List to be provided of important spares and accessories, with their part numbers and cost. Spare parts availability for the equipment lifespan (not less than 7 years). List of equipment and procedures required for local calibration and routine maintenance shall be provided. Advanced maintenance tasks required shall be documented. Costs and types of post-warranty service contract available shall be described. The guaranteed time-period of support and software upgrade (if relevant) availability post-warranty shall be described.
Any variation to be indicated in the offer.		

Additional services required

Testing and acceptance

- Factory acceptance test (FAT): the system, prior to shipment, shall be tested for conformity of the system with the manufacturer's performance specifications and the minimum requirements specified. The FAT report shall be provided by the supplier.
- Supplier shall perform, when applicable: installation, calibration, safety and operation checks before handover.
- On-site acceptance test (SAT): the system, after delivery, shall be tested by the contractor together with the user to demonstrate that the performance meets the manufacturer's performance specifications and the minimum requirements specified as determined by WHO, IAEA and users. The results of the SAT shall be documented in an acceptance test protocol that shall be signed by the end user (after consultation with the hospital medical physicist) and the manufacturer.
- The results of the testing of the system shall be documented by the contractor in an acceptance protocol that shall be signed and dated by the user.

Training and manuals

- User, technical and maintenance manuals, hard and soft copies, to be supplied in English language (provision of versions in other UN languages, if available, will be an asset). Supplier has to describe any materials contained in the device that are classified as hazardous under local regulations.
- Specific cleaning and disinfection instructions for IPC included (preferable).
- Training of users in operation (including basic radiation protection topics and the use of quality assurance/control tools provided for testing), and training to technicians for basic maintenance shall be provided (provided also in an online format, if available).
- Contact details of manufacturer, supplier and lists of local service agents to be provided together with the documentation.

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8.3 Computed tomography (CT) scanning system

8.3.1 Context and considerations

Publication by WHO of a rapid advice guide on the use of chest imaging in the context of the COVID-19 pandemic *(1)* motivated the development of computed tomography (CT) scanning system technical specifications, described here and co-authored by WHO, the International Atomic Energy Agency (IAEA) and external experts.

This section details the requirements for a CT scanning system to be used as a complete standalone solution for acquisition, review, display, storage (CT console and workstation) and transfer of images in resource-limited settings.

The section will define the minimum technical requirements of a CT scanning system (also called CT scanner, computed tomography unit, CT system, helical CT scanner, multi-detector row CT scanner, spiral CT scanner, volume CT scanner) recommended when incorporating new equipment.

Computed tomography is an imaging technique that combines a series of X-ray images to produce cross-sectional images of the human body. The result of a CT exam is generally a set of axial slices which can be processed through different software/hardware platforms to render sagittal/coronal image slices and/or 3-D image reconstructions.

A CT scanning system mainly consists of: an X-ray system, a patient table, a gantry and a PC control. A high-voltage X-ray generator supplies power to the X-ray tube, which usually has a rotating anode and is capable of withstanding high heat loads generated during multi-detector acquisition. The gantry includes the X-ray generator, detector system, X-ray tube, collimators and rotational frame.

Computed tomography technology figures centrally in evidence-based patient care algorithms for many clinical indications, but the scope of this chapter is to outline the optimal technical specifications of a CT scanner appropriate for COVID-19 imaging. For appropriate detection and characterization of COVID-19 induced lung changes and other multisystemic complications, 64-slice CT machines are necessary; high-resolution units can be also applied broadly and appropriately after the pandemic. Applications of a 64-slice unit range from the complex imaging of manifestations of other infections like tuberculosis, to cardiovascular conditions, chronic lung diseases, trauma, diabetes complications, the most common types of cancer, and other pathologies.

Appropriate patient referral to CT for COVID-19 and the manner in which the CT exam, itself, is protocolled and performed are ultimately the responsibility of qualified medical staff, tailored to the patient and clinical context, and in compliance with resources, best practices, and available guidelines *(2)*.

8.3.2 Definitions and intended use

Computed tomography (CT) scanning allows the assessment of COVID-19 related lung damage and known comorbidities of COVID-19 such as pulmonary embolism/thromboembolism or extra-thoracic disease manifestations. Pulmonary disease severity of COVID-19 can be evaluated by CT imaging *(1)*.

In the establishment or improvement of access to CT scanning systems during the pandemic, deployed CT systems are anticipated to be used primarily in imaging departments of district general hospitals and specialized hospitals. These units will serve multiple other general and specific purposes after the pandemic; for example, the imaging of trauma, infections, cancer staging, and more, including minimally invasive CT-guided procedures such as biopsies. 64-slice units (as opposed to fewer slice systems) are recommended due to the quality of images needed to detect subtle lung abnormalities of COVID-19. Moreover, the procured 64-slice CT units have the capacity to be used for a broader array of multi-purpose applications than lower number of detector rows (e.g. 16, 32, etc.) units which could not be used appropriately in the CT evaluation of, for example, coronary artery disease *(3, 4)*.

With regard to COVID-19 infection prevention and control (IPC) precautions, the level of decontamination (cleaning and disinfection protocols) of the CT system components shall be specific to the clinical procedures undertaken and dependent upon the brand/model specifications detailed in the accompanying user and technical manuals *(1)*. Moreover, health centres shall also follow the institutional and/or national guidelines, when available.

8.3.3 Technical specifications for procurement

Computed tomography scanning system		
Naming: CT scanner, computed tomography unit, CT system, helical CT scanner, multi-detector CT scanner, spiral CT scanner, volume CT scanner		
1	**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. The CT scanner should be suitable for all relevant cross-sectional imaging requirements in diagnostic radiology. Number of actual slices per 360° rotation should be not less than 64 slices at all speeds. Reconstructed slice width options range from at least 0.625 mm to 10 mm. Minimum rotation time (360°) not higher than 0.5 sec. Retrospective reconstruction should be possible of raw data files with the capacity to modify parameters such as field of view (FOV). At least the following scanning modes should be possible: scan projection radiograph (SPR), axial and spiral. 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. Multiple volumetric studies capability. 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. The CT scanner should have conventional built-in lasers or light beams, which indicate the coincidence of the centre of rotation and scan position. 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. Dose computation and display: the system should display CT dose index (CTDI) – volumetric (CTDIvol) or weighted (CTDIw) – and dose-length product (DLP) and have the capacity to transfer this information to the exam record. Dose optimization tools should be available.
2	**Patient table**	The CT scanner should have a tabletop made of resistant and radiotransparent material. Table with minimum dimensions of 235 x 40 cm (preferable). Vertical moving minimum range 44–90 cm (preferable). The speed of horizontal movement must be variable with a maximum speed of at least 100 mm per sec. The scannable range should be at least 160 cm. Maximum loading capacity of not less than 200 kg without any change in stated performance technical specifications (such as the positioning accuracy). Capability of automatic patient isocentring (preferable).
3	**Gantry**	Number of rows not less than 64. A gantry aperture of at least 70 cm. Scan FOV of at least 50 cm. Balancing system and laser lights to support centring. Preferable: gantry tilt at least ± 30 degrees (preferable), controllable by the console; also (remote).

Computed tomography scanning system		
Naming: CT scanner, computed tomography unit, CT system, helical CT scanner, multi-detector CT scanner, spiral CT scanner, volume CT scanner		
4	**X-ray system (tube and generator) and detectors**	High-frequency generator with gantry implanted microprocessor. The X-ray tube shall have dual focal spots. The contractor shall state the size of the focal spots. Tube focal spots not higher than 0.9 x 0.8 mm and 1.1 x 1.2 mm. Power rating of at least 70 kW. kVp range of at least 80 kV to 135 kV. mA range of at least 20 mA to 550 mA. Maximum anode cooling rate of at least 1000 kHU/min. Anode heat storage capacity of not less than 7 MHU. High performance, low noise, high data density, active response data acquisition system. Solid state detectors. At least 38 mm detector coverage with no less than 64 rows Free from repeated calibrations. 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. High detection efficiency (to be specified by the contractor). High discharging speed (to be specified by the contractor).
5	**Hardware, console and software for console and independent workstation**	Raw data reconstruction hardware: • Latest generation system with high performance processors. • 4 GB of RAM. • Raw data hard disk of at least 300 GB. • High multi-tasking level. Double monitor acquisition (operation) console with at least the following characteristics: • Capability for simultaneous scanning and reconstruction. • 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. • Last generation processor. • At least two 19″ thin-film transistor liquid-crystal display (TFT LCD or equivalent or better technologies) colour monitors medical safety requirements compliant. • Keyboard and mouse. • At least 2 GB of RAM. • At least 250 GB image storage hard disk. • CD/DVD driver with integrated CD reviewing software for DICOM stored images. • 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. • DICOM compliance statement should be provided. • DICOM data high transmission speed to and from the workstation. • Verbal/audio bi-directional communication system must be provided between the operator and the patient. • At least local area network (LAN) connection driver. Acquisition (operation) console's software at least with the following functions: • Easy access software interface. • Positioning digital radiography with a length of at least 160 cm. • Initial definition of the exam's protocol with real-time availability to modify it. • List of defined exam's protocols. • Spiral and axial (preferable) scan. • For contrast-enhanced exams, scan synchronization with the arrival of the administered contrast (bolus test and bolus tracking).

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5	**Hardware, console and software for console and independent workstation** (continued)	• Multi-perspective and cardiovascular examination software with at least the following requirements: – best reconstruction timing choice; – electrocardiogram (ECG) tracing and image-gating procedure; – automatic multi-phase reconstruction of cardiac kinetic function. • Software for low dose protocols included. Independent double (preferable) monitor workstation with at least the following characteristics: • High-performance workstation for post-processing and advanced clinical applications. • Latest generation processor. • One (preferably two) monitor, at least 21", LCD or equivalent or better technologies, medical safety requirements compliant. • Keyboard and mouse. • At least 4 GB of RAM. • Not less than 1 TB image storage hard disk. • 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. • CD/DVD driver with integrated CD reviewing software for DICOM stored images. • 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. • DICOM compliance statement should be provided. • DICOM data high transmission speed to and from the workstation. • At least LAN connection driver. Software features for the independent workstation described in the previous point: • Volume, partial, package or radial maximal intensity projection (MIP) and minimum intensity projection (MinIP). • Volume, partial, package or radial volume rendering technique (VRT). • Volume, package, radial multiplanar reformation (MPR). • Single curve, package or radial MPR. • Surface 3-D. • Dynamic scan with or without patient table movement. • Angio package with bolus-CT capability. • 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. • Vessel structure analysis package with 2-D and 3-D measurement (angio-CT software) (preferable). • CT neuro package (neuro digital subtraction angiography [DSA] CT and neuro perfusion CT)(preferable). • Lung examination/analysis full package provided. Moreover, software for COVID-19 detection/assessment should be considered as an option, if available. • CT oncology package (lung nodules detection with computer assisted detection [CAD] capability and colonography with CAD capability) (preferable). • Automatic bones subtraction package (preferable). • Analysis and comparison of tumours for serial exams on the same patient (preferable). • 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.

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6	**Image quality**	The reconstruction matrix should be at least 512 x 512 pixel. Display matrix not less than 1024 x 1024 pixel. In plane spatial resolution values shall be provided by the contractor to be evaluated. Low-contrast detectability (or resolution) 5 mm or less at 0.3% at no more than 20 mGy. High-contrast spatial resolution: at least 18 lp/cm at 0% modulation transfer function (MTF). Metal artefacts reduction algorithm (preferable). Reconstruction index of at least 190 slice/sec (3 frames/sec). 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. Table and bone removal (image subtraction) function available. Virtual endoscopic view available (preferable).
7	**Power supply (voltage, frequency and plug vary across countries)**	Power input to be approximately 380 V, 50/60 Hz, 90 kVA, triphasic electrical source. 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. Protectors against power surge (over-voltage and over-current) line conditions. UPS provided: online UPS with maintenance-free batteries for the backup of the entire system for at least 30 minutes.
8	**Accessories and spare parts**	Patient table provided with complete accessories set for patient positioning for any exam type. Necessary quality assurance phantoms to check the image quality and calibration of the CT scanner should be provided. Phantom holder provided. Contrast injector system. 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.[1] List of important spares and accessories to be provided with their part numbers and cost. Spare parts availability for the equipment lifespan (not less than 10 years).
9	**Packaging, transport and environmental requirements**	The system should have all safety markings in English. System packaging: for the shipment by air to the end user, should be packed in accordance with international standards that are applicable for the shipment by air of this kind of equipment. Capable of being stored continuously in ambient temperature of 0–50 °C and relative humidity (RH) of 15–90%. Capable of operating continuously in ambient temperature of 10–40 °C and RH of 15–90% (preferable). Labelling on the primary packaging to include: • Name and/or trademark of the manufacturer. • Production year. • Model or product reference. • Information for particular storage conditions (temperature, pressure, light, humidity).
10	**Standards, for the manufacturer and the equipment**	Certified quality management system for medical devices (e.g. ISO 13485:2016). General quality management (e.g. ISO 9001). Application of risk management to medical devices (e.g. ISO 14971).

[1] If image-guided interventional procedures will be performed, all the protection devices listed must be considered "mandatory". This list is dependent on specific site/location and planned work type.

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11	**Regulatory approval/ certification**	Free sales certificate (FSC) or certificate for exportation of medical device provided by the authority in manufacturing country. Proof of regulatory compliance, as appropriate, per the product's risk classification (e.g. Food and Drug Administration [FDA] and/or Conformité Européenne [CE]).
12	**Standards, for product performance**	Compliance with the following international standards or to regional or national equivalent, as applicable (including the technical tests for safety and performance from accredited laboratory or third party). Reference to the last available version is recommended but compliance to previous standards versions could be considered . • IEC 60601-1:2005+AMD1:2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance. • 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. • IEC 60601-2-44 Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography. • 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. • IEC 60336:2005 X-ray tube assemblies for medical diagnosis – Characteristics of focal spots. • 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. • IEC 60613:2010 Electrical and loading characteristics of X-ray tube assemblies for medical diagnosis.
13	**Warranty and post-warranty**	The system should be covered by at least 1 year's warranty including spare or replacement parts, tube and labour, starting as of the date of successful on-site acceptance, as per testing and acceptance below. Warranty should include all necessary spare parts, X-ray tube, shipment to site, cost of replacement work, personnel, disposal of faulty parts and software (patches, upgrades and updates). Specific warranty inclusions and exclusions should be clearly listed. At least two service visits per year should be made under warranty. List to be provided of important spares and accessories, with their part numbers and cost. Spare parts availability for the equipment lifespan (not less than 10 years). List of equipment and procedures required for local calibration and routine maintenance should be provided, if any. Expected life of the tube, as dependent upon utilization and local conditions, to be specified by the contractor *(2)*. Advanced maintenance tasks required should be documented. The contractor should provide detailed annual costs related to up to 5 additional years of preventive and corrective maintenance services, following the initial year of full warranty, including parts, X-ray tube and labour costs.
Any variation to be indicated in the offer.		

Additional services required

Installation requirements

- The contractor should install the system at the site requested in the contract.
- The contractor will supply direct electric connection of the equipment to the three-phase power supply network. The connection will be effectuated directly to the network with thermomagnetic disconnecting switch.
- The contractor will connect the equipment to the radiology DICOM network, when available.
- The contractor should review the site layout room to ensure compliance to the technical requirements before supplying the system.
- The contractor should communicate with the beneficiary/user and verify the appropriateness of the designated area for the installation of the system. Furthermore, the contractor should provide timely drawings detailing all electrical, structural or any additional requirement to be performed by the beneficiary for the installation of the system.
- The completion date of the site preparation will be communicated by the contracting authority to the contractor in due time to start the execution of the contract activities.
- Notwithstanding any authorization given by the contracting authority, the contractor should visit, inspect and ascertain that all necessary conditions are met at the beneficiary/user site before starting any activities. Any comments or suggestions as regards the conditions of the site should be made at least 4 weeks before initiating installation activities.

Testing and acceptance

- Factory acceptance test (FAT): the system, prior to shipment, should be tested for conformity of the system with the manufacturer's performance specifications and the minimum requirements specified. The FAT report should be provided by the supplier.
- The supplier should perform, when applicable: installation, calibration, safety and operation checks before handover.
- On-site acceptance test (SAT): the system, after delivery, shall be tested by the contractor together with the user to demonstrate that the performance meets the manufacturer's performance specifications and the minimum requirements specified as determined by WHO, IAEA and users. The results of the SAT shall be documented in an acceptance test protocol that shall be signed by the end user (after consultation with the hospital medical physicist) and the manufacturer.
- Recommended constancy checks provided.
- The results of the testing of the system should be documented by the contractor in an acceptance protocol that should be signed and dated by the user.

Training and manuals

- User manuals, hard and soft copies, to be supplied in English (provision of versions in other UN languages, if available, will be an asset; manuals shall be provided in a language understandable to the user). The supplier has to describe any materials contained in the device that are classified as hazardous under local regulations.
- Technical and maintenance manuals, hard and soft copies, to be supplied in English (provision of versions in other UN languages, if available, will be an asset; manuals shall be provided in a language understandable to the user). Supplier has to describe any materials contained in the device that are classified as hazardous under local regulations.
- Specific cleaning and disinfection instructions for IPC should be also included.

- Training of users in operation should include at least the following topics (a detailed training programme should be provided):
  - CT technology;
  - description of all settings, parameters;
  - optimization procedures of protocols on a patient selective basis;
  - dose considerations for different patient sizes, in particular for paediatric patients;
  - image quality and techniques to be used for different clinical indications;
  - steps on how to adapt to different noise textures;
  - CT dose quantities;
  - relevance of CT diagnostic reference levels (DRLS);
  - warning and reference levels in CT;
  - CT dose metrics and patient dose estimation;
  - quality assurance and quality control tests;
  - radiation safety issues;
  - importantly, a specific training on the "dose optimization methods" available should be provided.
- Training to technical and specifically appointed staff for basic maintenance should be provided (provided also in an online format, if available).
- The training provided for user will last not less than 40 hours. The training sessions will be organized for not fewer than four persons/staff. A follow-up training phase should be scheduled.
- The training for maintenance staff will last not less than 30 hours. The training session will be organized for not fewer than four persons/staff. A follow-up training phase should be scheduled.
- Contact details of manufacturer, supplier and lists of local service agents to be provided together with the documentation.

Maintenance requirements

- The contractor should include full maintenance services during the standard warranty period. Full maintenance services during the warranty period should include:
  - preventive maintenance;
  - on-call interventions;
  - any software update/upgrade for the system that will be become available;
  - all necessary replacement and spare parts.
- As part of the on-site acceptance, the contractor should provide to the local engineer and to the hospital medical physicist a plan for preventative maintenance and the name and contacts of a service representative/office for on-call maintenance intervention.
- Intervention time should be clearly defined and should comply with the uptime requirements defined as follows:
  - The contractor should guarantee that the CT scanner will have an uptime of at least 95% (excluding outages for maintenance or causes external to the system).
  - Uptime is calculated on a basis of 250 operating days per year (weekly working days).
  - Should the downtime exceed 2 working days cumulative on a 6-month basis (i.e. summing up the hours), then the warranty and/or maintenance (as applicable) will be extended for a corresponding period.
  - The records of downtime of the CT scanner will be kept by a representative of the beneficiaries/users; the contractor should have the right to request copies of such records.
- The contractor should provide an offer up to 5 additional years of preventive and corrective maintenance services as part of the main contract, following the initial year of full warranty, including parts, X-ray tube and labour costs. The related annual costs should be stated in the offer.

- The contractor shall ensure that a suitable qualified person can be on-site within 48 hours following an unexpected breakdown and to resolve any problem within 5 working days, throughout the warranty period.
- The contractor should preferably include, when available, in the maintenance proposal (separating the periods during warranty and post-warranty) the feature related to remote diagnosis of the equipment. The costs of this option should be separately detailed and fully described in the offer.

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