World Health Organization

WHO/2020-nCoV/MedDev/TS/O2T.V1 17 June -2020
Final draft 10-07-2020 pending integration to a single publication with all other technical specifications

COVID-19 Technical specifications for procurement of oxygen therapy and monitoring devices

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Abbreviations

AC	alternating current
ANSI	American National Standards Institute
bpm	beats per minute
BS	British Standard
CE	Conformité Européenne
CGA	Compressed Gas Association (USA)
CSA	Canadian Standards Association
dB(A)	decibels (A-weighted)
DISS	Diameter Index Safety System
ECG	electrocardiogram
$EtCO_2$	colourimetric end-tidal CO_2
FDA	Food and Drug Administration (USA)
FiO_2	fraction of inspired oxygen
FSC	free sales certificate
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
GMP	good manufacturing practice
HMEF	heat and moisture exchanger filter
IBP	invasive blood pressure
IFMBE	International Federation of Medical and Biological Engineering
IMDRF	International Medical Device Regulators Forum
IPC	infection prevention and control
ISO	International Organization for Standardization
kPa	kilopascal
LED	light-emitting diode
L/min	litres per minute
NFPA	National Fire Protection Association (USA)
NIBP	non-invasive blood pressure
psi	pounds per square inch absolute
s	second(s)
SpO_2	haemoglobin oxygen saturation
UL	Underwriters Laboratories (global certification scheme)
W	Watt(s)

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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 document is to provide a compilation of the technical specifications for devices for oxygen supply, delivery, regulation and conditioning, and patient monitoring included in the *List of priority medical devices for COVID-19 case management.* The technical specifications do not entail treatment options or infection prevention and control (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* (WHO & UNICEF, 2019) for some of the products. Additionally, other technical specifications of products included in the *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* (WHO & UNICEF, 2019), 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).

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2. Definitions and intended use

2.1 Oxygen sources 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.

Table 2.1 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 (WHO & UNICEF, 2019).

2.2 Oxygen delivery devices

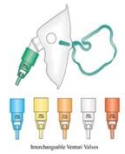
Nasal oxygen cannula with prongs: Plastic tubes shaped as two prongs used to deliver air/oxygen mixture into the nasal cavities, when connected to an oxygen source. This is a single-use, non-sterile device.

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 2.2 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	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**

		pattern of breathing					
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.

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2.3 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 2.3 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. **0–1000 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.** **0–3 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.** **0–7 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.** **0–16 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.**	**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. **0–7 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. **0–16 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 5mm) 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).

2.4 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.

2.5 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.

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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. Technical specifications for procurement

3.1 Oxygen sources devices

		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.

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		Oxygen concentrator
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 and 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.
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]).

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		Oxygen concentrator
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.

		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.

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		Oxygen cylinder
		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.

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		Oxygen cylinder
		• 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.
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 dial style 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%.

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		Oxygen cylinder
		• 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.
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).

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		Oxygen 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]).

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		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.

		Oxygen cylinder
		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.

3.2 Oxygen delivery devices

		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).

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		Nasal oxygen cannula with prongs
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.

		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.

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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.

		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 Devices for oxygen regulation and conditioning

		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.

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		Flowmeter, Thorpe tube
		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.

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		Flowmeter, Thorpe tube
		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.

		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.

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		Flow splitter
		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.

		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 psig). 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.

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		Non-heated bubble humidifier
		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.

		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.

3.4 Manual ventilation devices

		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, maximum capacity: 1300 mL. Dead volume: < 5 m.

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		Self-inflating resuscitation bag with mask
		• 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: 2000–2600 mL.
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

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		Self-inflating resuscitation bag with mask
		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.

		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.

		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.

3.5 Patient monitoring devices

		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 is capable of a wider SpO_2 detection range, the accuracy over that wider range shall be stated.

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		Pulse oximeter: handheld
		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): 3 per equipment. Reusable probes, paediatric: 3 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.

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		Pulse oximeter: handheld
		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.
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.

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		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).
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): 3 per equipment. Reusable probes, paediatric: 3 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.

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		Pulse oximeter: 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.

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		Pulse oximeter: tabletop
		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.

		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.

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		Pulse oximeter: fingertip
		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]).
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.

COVID-19 Technical specifications for procurement of oxygen therapy and monitoring devices

		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. Pace-maker detection. 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: 3 probes. Reusable SpO_2 probes paediatric use: 3 probes. Blood pressure – non-invasive: 3 paediatric reusable cuffs; 3 adult reusable cuffs. Battery: 1 set.

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

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

		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.

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		Patient monitor multiparametric: intermediate – for ECG, non-invasive blood pressure (NIBP), oxygen saturation (SpO_2), respiratory rate (RR) and temperature (TEMP) (with accessories)
		• 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	User operated 1 mV ECG test marker function required. 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.

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		Patient monitor multiparametric: intermediate – for ECG, non-invasive blood pressure (NIBP), oxygen saturation (SpO_2), respiratory rate (RR) and temperature (TEMP) (with accessories)
		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: 3 probes. Reusable SpO_2 probes paediatric use: 3 probes. Blood pressure – non-invasive: 3 paediatric reusable cuffs; 3 adult reusable cuffs. External skin temperature probes: 2 probes. 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 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).

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

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		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).

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		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)
		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	User operated 1 mV ECG test marker function required. 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: 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 tramps: 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.

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		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)
		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]).
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.

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		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)
		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.

4. Methodology

Technical specifications define the minimum requirements for the product to ensure good quality, safety and efficacy. The process to develop these specifications included:

- Review of recent publications of WHO technical specifications for medical devices
- Analysis of the technologies required to perform the clinical management of COVID-19 patients: https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/patient-management
- Analysis of existing products in the market, based on approval from the regulatory agencies
- Devices overviews, specifications and comparative data published by ECRI – an evidence-based practice centre – which is a non-profit, independent organization that conducts independent medical device evaluations: https://www.ecri.org/
- 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. All members of both panels have provided Conflict of Interest documents, which have been reviewed by WHO and no conflict of interests were found.
- International experts drafted the document (WHO consultants: Laura Alejandra Velez Ruiz Gaitan, Gabriela Jimenez Moyao, Francesco Ribolzi).
- Expert input from UNICEF (Beverly Bradley) and consultant (Andrew Gammie).
- Development coordinated by Adriana Velazquez, Group Lead Medical Devices and In Vitro Diagnostics, WHO.

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