

WHO Medical Devices May 2020, Newsletter

Dear colleagues,

Please find below information on related to COVID-19 technical documents
<https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance>

All technical guidance by topic

Critical preparedness, readiness and response actions for COVID-19	Surveillance, rapid response teams, and case investigation	National laboratories
Country-level coordination, planning, and monitoring	Clinical care	Infection prevention and control / WASH
The Unity Studies: Early Investigations Protocols	Essential resource planning	Guidance for schools, workplaces & institutions
Risk communication and community engagement	Virus origin/Reducing animal-human transmission	Points of entry / mass gatherings
Naming the coronavirus disease (COVID-19)	Humanitarian operations, camps, refugees/migrants in non-camps and other fragile settings	Health workers

1. Priority medical devices for COVID management

WHO has developed several tools, which can be found at:

<https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/covid-19-critical-items>

1. the List of **Priority Medical Devices for COVID**, describes the medical devices, the purpose and the settings where it can be used.

World Health Organization | **Priority Medical Devices in the context of COVID-19**
A. Medical Devices for Case Management

Objective
The list of priority medical devices in the context of COVID-19 provides descriptions for the management of patients with severe acute respiratory infection (SARI) when a COVID-19 virus infection is suspected at different levels of health care provision. The first level, for outpatients, second level includes general hospitals and laboratories, and third level, includes specialized hospitals with intensive care units and SAU units. The technologies listed are for the intermediate and should be adapted to the health care workforce, infrastructure and technological resources available.

Target Audience
This document is recommended to support decision-making regarding the allocation and use of medical devices in the context of COVID-19 and is intended for healthcare providers, managers of SAU Units, procurement and regulatory agencies and Ministries of Health. Recommendation to medical Biomedical Engineers in the selection and verification of installation of the equipment and ensure training of health care workforce.

Considerations
* An assessment of the health facility be required prior to checking equipment from the list in order to have a fully functional unit. If more details consult the technical specifications per equipment.
* Accessories and consumables for starting operation are not always specified in this list. They should be provided with the purchase of the equipment. For at least 3 months of operation.
* Estimated longevity of at least one year and additional spare parts for maintenance should be also appreciated, according to the health care capacity.
* Note: Training is indispensable for medical ventilation.

Table 1. Medical Devices for Case Management of severe and critical patients by health facility level.

Type	Medical Purpose	Remarks	Medical Device Generic Name	Triage	Treatment of severe patients	Treatment of critical patients	1st Level	2nd Level	3rd Level
Medical Equipment	Monitoring	Option 1 - Desirable	Infrared thermometer	x	x	x	-	-	-
		Option 2	Pulse oximeter - portable handheld, with cables and sensor	x	x	x	-	-	-
		Option 3	Pulse oximeter - finger tip	x	x	x	-	-	-
		Option 4 - Desirable	Patient monitor, multiparametric, including ECG, non invasive blood pressure (NIBP), oxygen saturation (SpO2), respiratory rate (RR), temperature (TEMP), with sensors and cables	x	x	x	-	-	-
	Oxygen therapy - Oxygen source to be selected according to capability of the health facility (i.e. power supply, pipeline oxygen network)	Option 1 - Desirable	Medical gas cylinder, portable, for oxygen, filled with a valve and a pressure and flow regulator	x	x	x	-	-	-
		Option 2	Concentrator O2, 10 L, with accessories	x	x	x	-	-	-
	Airway Management and Intubation	Option 1 - To be chosen by the clinician	Laryngoscope, P3, diameter 28 mm, with blades	x	x	x	-	-	-
		Option 2 - To be chosen by the clinician according to training skills and infrastructure capabilities	Videolaryngoscope, with blades and accessories	x	x	x	-	-	-
	Mechanical Ventilation - Invasive ventilation requires trained staff to be performed	Option 1 - Invasive ventilation in intensive care unit (ICU) or adult patient	Patient ventilator, intensive care, for adult and paediatric, with breathing circuits and patient interface	x	x	x	-	-	-
		Option 2 - Transport or Mass-Casualty: Invasive ventilation in non-ICU sites	Patient ventilator, transport, for adult and paediatric, with breathing circuits and patient interface	x	x	x	-	-	-
Non-invasive Ventilation - Critical decision according to the management of patients generated as a consequence of proper face fitting. The use of reserve or reuse mask are preferable to reduce the dead space generated as consequence of improper face fitting. Option to be chosen by the clinician	Option 1 - The use of reserve or reuse mask are preferable to reduce the dead space generated as consequence of improper face fitting. Option to be chosen by the clinician	CPAP, with tubing and patient interfaces for adult and paediatric, with accessories	x	x	x	-	-	-	
	Option 2 - The use of reserve or reuse mask are preferable to reduce the dead space generated as consequence of improper face fitting. Option to be chosen by the clinician	CPAP, with tubing and patient interfaces for adult and paediatric, with accessories	x	x	x	-	-	-	

2. Emergency supply catalogue

Emergency Global Supply Chain System (COVID-19)

Catalogue as of 22.04.2020

The items in this catalogue represent an initial prioritized selection of items and are subject to constant review. Nothing in this catalogue should be construed as offer or guarantee for allocation of supplies. Item costs are estimates only.

World Health Organization | **HEALTH EMERGENCIES programme**

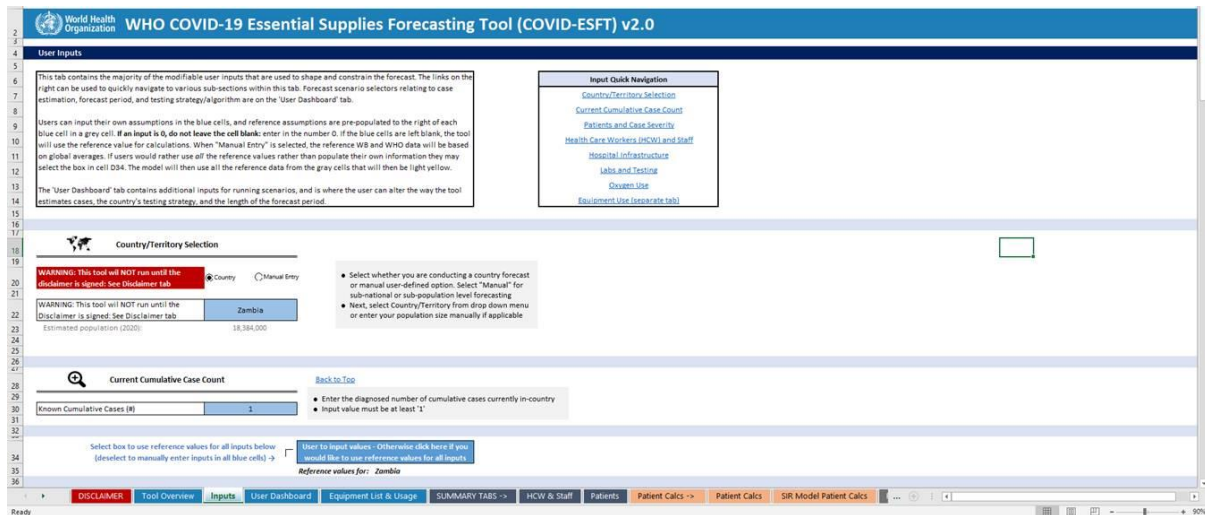
Emergency Global Supplies Catalogue(COVID-19)

Medical Purpose	Sample picture (not exhaustive)	Name	Covid19 Item Code	Indicative price* (USD unit)	UOM†
Oxygen delivery devices - Nasal cannula and catheters		Catheter, nasal, 40 cm, with lateral eyes, single-use, different sizes: 10 Ft, 12 Ft, 14 Ft, 16 Ft, 18 Ft	BIOCATN001	7.7	EA
		Nasal oxygen cannula, with prongs, adult	BIOCACX001	0.7	EA
		Nasal oxygen cannula, with prongs, pediatric	BIOCACX002	0.8	EA
Oxygen delivery devices - Masks		Mask, oxygen, with connection tube, reservoir bag and valve, high-concentration, adult, non-sterile, single use	BIOMASO001	1.8	EA
		Mask, oxygen, with connection tube, reservoir bag and valve, high-concentration, pediatric, non-sterile, single use	BIOMASO002	2.0	EA
		Venturi Mask, with percent O2 Lock and tubing, adult	BIOVMA001	1.3	EA
Monitoring		Infrared thermometer	BIOTHER001	4.0	EA
		Pulse oximeter - portable handheld, with cables and sensor	BIOPUX001	200	EA
		Pulse oximeter - finger tip	BIOPUX002	40	EA
		Pulse oximeter - table top, with cables and sensor	BIOPUX003	360	EA
		Patient monitor, multiparametric, including ECG, non invasive blood pressure (NIBP), oxygen saturation (SpO2), respiratory rate (RR), temperature (TEMP), with sensors and cables	BIOPAM001	7,601	EA
Oxygen therapy - Sources		Concentrator O2, 10 L, with accessories	BIOCOC001	883	EA
		Oxygen plant, pressure swing absorption (PSA)	BIOODPL001	NA	EA
Oxygen therapy - Accessories and consumables		Tubing, medical gases, int. diam. 5 mm	BIOTUB001	2.7	METER
		Bubble humidifier	BIOHUM001	3.5	EA
		Connector, bacterial, symmetric, int. diam. 7-13 mm	BIODCON001	1.1	EA
		Flow splitter, 5 flowmeters 0-2 L/min, for pediatric use	BIOPLOS001	137	EA
Oxygen therapy - Mechanical Ventilation		Patient ventilator, intensive care, for adult and paediatric, with breathing circuits and patient interface	BIOVENP001	28,384	EA
		Patient ventilator, transport, for adult and paediatric, with breathing circuits and patient interface	BIOVENP002	7,250	EA

* Directional prices for orientation only, status 22 April, refined prices will be included directly in the Covid-19 Supply Portal soon
† Unit of Measurement

World Health Organization | **HEALTH EMERGENCIES programme** | 2.

3. Recently launched the COVID-19 essential Supplies forecasting tool (1st May 2020)



4. For personal protective Equipment: Rational use of personal protective equipment for coronavirus disease (COVID-19)

This document summarizes WHO's recommendations for the rational use of personal protective equipment (PPE) in health care and home care settings, as well as during the handling of cargo; it also assesses the current disruption of the global supply chain and considerations for decision making during severe shortages of PPE. This updated version includes a section on considerations for decision making processes and a summary of temporary measures in the context of severe PPE shortage.

- [Access the publication](#) (6 April 2020)

Table with standards

Mask, medical Healthcare worker	Medical mask, good breathability, internal and external faces should be clearly identified	<ul style="list-style-type: none"> EN 14683 Type II, IIR ASTM F2100 minimum Level 1 or equivalent
Face shield	Made of clear plastic and provides good visibility to both the wearer and the patient, Adjustable band to attach firmly around the head and fit snugly against the forehead, Fog resistant (preferable), Completely cover the sides and length of the face, May be re-usable (made of robust material which can be cleaned and disinfected) or disposable.	<ul style="list-style-type: none"> EU PPE Regulation 2016/425, EN 166, ANSI/ISEA Z87.1, or demonstrate equivalent set of standards
Particulate respirator, grade N95/FFP2 or higher	N95 or FFP2 respirator, or higher Good breathability with design that does not collapse against the mouth (e.g. duckbill, cup-shaped)	<ul style="list-style-type: none"> Minimum "N95" respirator according to, under NIOSH 42 CFR 84, Minimum "FFP2" according to EN 149 or demonstrate equivalent set of standards

Please find attached latest guidance released by FDA on the types of masks, this supersedes the document released 25 of March, <https://www.fda.gov/media/136449/download>

5. For in vitro diagnostics

Laboratory testing guidance:

<https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/laboratory-guidance>

WHO Emergency Use Listing (EUL) for in vitro diagnostics.

Currently, the following IVDs are eligible for EUL submission:

- Assays for the detection of SARS-CoV-2 nucleic acid; and
- Rapid diagnostic tests for the detection of IgM/IgG to SARS-CoV-2
- All information can be found:

https://www.who.int/diagnostics_laboratory/EUL/en/

The EUL procedure is developed to expedite the availability of IVDs needed in public health emergency situations.

It is intended to assist interested procurement agencies and Member States on the suitability for use of a specific IVD, based on a minimum set of available quality, safety, and performance data.

Up to 24 of April the following products have been approved by WHO.



**World Health
Organization**

WHO Emergency Use Listing for SARS-CoV-2 in vitro diagnostic products

Last update: 24 April 2020

Date Listed	Product name	Product code(s)	Manufacturer
03 April 2020	cobas SARS-CoV-2 Qualitative assay for use on the cobas 6800/8800 Systems	09175431190 and 09175440190	Roche Molecular Systems, Inc.
07 April 2020	Primerdesign Ltd COVID-19 genesig Real-Time PCR assay	Z-Path-COVID-19-CE	Primerdesign Ltd.
09 April 2020	Abbott Realtime SARS-CoV-2	09N77-090 and 09N77-080	Abbott Molecular Inc.
24 April 2020	PerkinElmer SARS-CoV-2 Real-time RT-PCR Assay	SY580	SYM-BIO LiveScience Co., Ltd

Final Public Reports to be posted on the website once completed

End of document

6. Clinical Management of patients

<https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/patient-management>

7. For SARI treatment centers

- [Access the publication](#) (28 March 2020)

8. For manufacturers:

WHO is conducting a high-level market and risk assessment for respiratory equipment.

[link to participate in the survey.](#)

9. On Innovation

If you have Innovative product (approved for emergency use, or commercially available), that might help COVID, please complete the WHO SURVEY at:

<https://extranet.who.int/dataform/396376> so that your product could be assessed for COVID-19 compendia

Questions to: techinnovation@who.int, related past compendia of innovative technologies can be found at: https://www.who.int/medical_devices/innovation/en/
Other sites of interest for innovation, some will provide grants for development or :
Bill and Melinda Gates Foundation information

<https://www.gatesfoundation.org/TheOptimist/coronavirus>

Unitaid's Executive Board today approved up to US\$ 30 million for work against COVID-19, authorizing [Unitaid to contribute its expertise in innovative treatment, diagnostics and respiratory triage tools to a global pandemic response.](#)

Global innovations exchange <https://covid19innovations.org/>

Grand Challenges Canada <https://www.grandchallenges.ca/>

UN Innovation network <https://www.uninnovation.network/>

Innovation call Islamic Development Bank: <https://www.isdb-engage.org/en/challenge/call-for-innovation-via-transform-fund-2020>

10. Data update by country

For COVID

In the context of COVID-19, availability of essential equipment to provide oxygen and respiratory therapy to all countries, especially those that may have limitations in accessing global markets, is of utmost importance.

WHO has developed a COVID-19 Biomedical Equipment Inventory Tool (survey) whose aim is to collect facility data on the availability of biomedical equipment (oxygen, accessories and consumables) and ventilators at the country level. These data can serve to inform planning and readiness, at facilities and in-country, as well as to inform WHO's global COVID-19 Supply Chain System of existing capacity so that appropriate equipment gets sent to where it can be absorbed, and in an equitable manner.

WHO has a team assembled at HQ to support countries and willing participants to conduct the survey at facilities in-country, which can be completed electronically via the web or by using a free "app" (SurveyCTO platform), or using a paper survey with an excel spreadsheet "roll-up". We are encouraging countries to complete this survey in order help inform country-level planning, as well as to reduce burden on incredibly stretched global supply chain systems, which are in a current shift towards a WHO-led consortium.

The COVID-19 Biomedical Equipment Inventory Tool can be **found attached**. Of note, WHO is in full support of initiatives already under way to this effect, and encourages data sharing to HQ to ensure appropriate allocation.

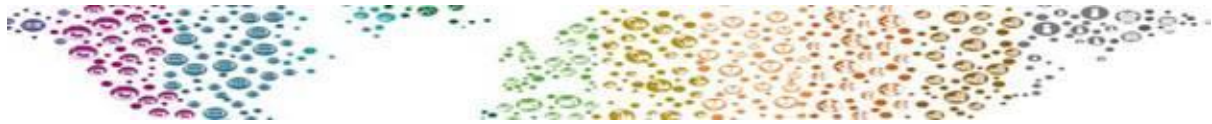
Please contact COVID-MED-DEVICES@who.int for support in implementing the survey, including leveraging existing survey initiatives, as well as if you are willing to participate.

Update of Global Atlas country data,

https://www.who.int/medical_devices/countries/en/

Update of the Global Atlas: The last version of the [Global Atlas for medical devices](#) was published in 2017, and the update of information for the next printed version is planned for 2020.

We kindly request your help to bring-up-to-date the figures of each country. Each request for edition needs to be sent to medicaldevices@who.int.



11. On-going work of WHO with NGOs in official relations in support of COVID

1. CED IFMBE WHO and CED are partnering together to host a series of COVID19 Critical Topic 1-hour Townhalls in May.

1. WHO - CED Critical COVID19 Topics Townhall: *Oxygen Delivery Systems, Tuesday, 5 May*, 2:00-3:00 pm CET Geneva time; first in a series of expected Critical Topic Townhalls throughout May

More information at <https://ced.ifmbe.org/blog/covid19-resources.html>

<https://ced.ifmbe.org/blog/who-ced-covid19-townhalls.html>



Register:

https://us02web.zoom.us/webinar/register/WN_MhkdUp9qOZClrpki5G_lw

Date	Topic
14:00-15:00 Geneva time	
Tuesday, May 5	Oxygen Systems
Friday, May 8	Masks, Respirators, and Face Shields
Tuesday, May 12	CPAP/BIPAP
Friday, May 15	Pulse oximeters
Tuesday, May 19	Ventilators

Other topics will follow

2. ISR. Guidance on the use of imaging for COVID



3. **Humatem**, has agreed to translate to French COVID documents and disseminate to member

5. **GMTA and DITTA** have been providing information of manufacturers to have discussions in WHO

4. **IFHE and IFMBE** are supporting the work on Respiratory care units

12 Severe Acute Respiratory Infections Treatment Centre

Practical manual to set up and manage a SARI treatment centre and a SARI screening - [Access the publication](#) (28 March 2020)

13. Global accelerator to increase access to diagnostics vaccines and treatment [WHO Access to COVID -19 Tools \(act\) Accelerator launch event transcript](#)

<https://www.who.int/news-room/detail/24-04-2020-global-leaders-unite-to-ensure-everyone-everywhere-can-access-new-vaccines-tests-and-treatments-for-covid-19>

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In case you want To join this list, , please send an email to: LISTSERV@listserv.who.int with the words: SUBSCRIBE WHOMEDICALDEVICES in the body of the message

You can access all [past newsletters](#).

Any questions please address to covid-med-devices@who.int

PLEASE STAY SAFE!!