WHO Medical Devices November 2020 Newsletter

Dear colleagues,

We wish you and your families are doing well, stay safe.

Please find the following 3 sections:

1. New Interim guidance, publications and training material

2. Non- COVID Information

3. Ongoing projects on medical devices, November-December 2020 ;

- **1.On medical devices : https://www.who.int/publications/i/item/WHO-2019-nCoV-MedDev-TS-O2T.V2**

Table 2.1 Interventions by clinical area

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

clinical interventions in the clinical units, a navigation diagram is presented in Fig. 2.1.

Fig. 2.1 Navigation diagram

•Describes the medical devices required for the clinical management of COVID-19, selected and prioritized according to the latest available evidence and interim guidelines on clinical care. This includes: oxygen therapy, pulse oximeters, patient monitors, thermometers, infusion and suction pumps, X-ray, ultrasound and CT scanners as well as personal protective equipment, among others. In order to facilitate access to quality assured priority medical devices, the document also includes technical and performance characteristics, related standards, accessories and consumables. Itis intended for policy-makers and planning officers in Ministries of Health, procurement and regulatory agencies, intergovernmental and international agencies as well as the medical device industry.

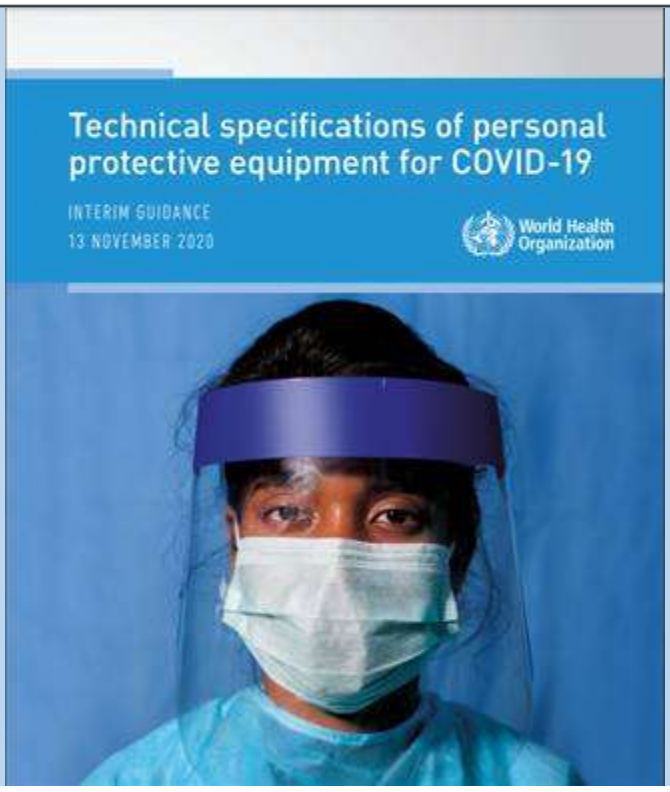
- More information can be found https://**www.who.int/medical_devices/priority/COVID-19_medequipment/en/**

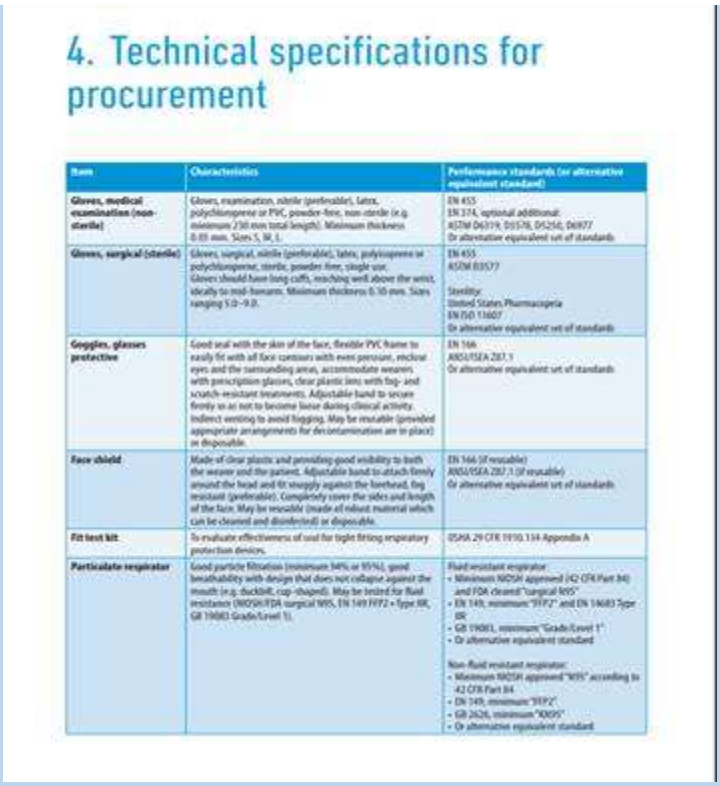
- Table including the products assessed by WHO for the pandemic global supply can also be found here.

2. **On the Personal protective equipment** **https://www.who.int/publications/i/item/WHO-2019-nCoV-PPE_specifications-2020.1**

This document provides interim guidance on the quality, performance characteristics and related standards of personal protective equipment (PPE) to be used in the context of COVID-19. This includes WHO Priority Medical Devices, specifically: surgical masks, non-surgical masks, gloves, goggles, face shields, gowns and N95 masks.

It is intended for procurement agencies, occupational health departments, infection prevention and control departments or focal points, health facility administrators, biomedical and materials engineering, PPE manufacturers and public health authorities at both national and facility levels.





4. Technical specifications for procurement

Item	Characteristics	Performance standards (or alternative equivalent standard)
Gloves, medical examination (non-sterile)	Gloves, examination, nitrile (preferable), latex, polychloroprene or PVC, powder-free, non-sterile (e.g. minimum 230 mm total length). Minimum thickness 0.05 mm. Sizes S, M, L.	EN 455 EN 374, optional additional: ASTM D6319, D5578, D5250, D6977 Or alternative equivalent set of standards
Gloves, surgical (sterile)	Gloves, surgical, nitrile (preferable), latex, polyisoprene or polychloroprene, sterile, powder-free, single use. Gloves should have long cuffs, reaching well above the wrist, ideally to mid-forearm. Minimum thickness 0.10 mm. Sizes ranging 5.0–9.0.	EN 455 ASTM D3577 Sterility: United States Pharmacopeia EN ISO 11607 Or alternative equivalent set of standards
Goggles, glasses protective	Good seal with the skin of the face, flexible PVC frame to easily fit with all face contours with even pressure, enclose eyes and the surrounding areas, accommodate wearers with prescription glasses, clear plastic lens with fog- and scratch-resistant treatments. Adjustable band to secure firmly so as not to become loose during clinical activity. Indirect venting to avoid fogging. May be reusable (provided appropriate arrangements for decontamination are in place) or disposable.	EN 166 ANSI/ISEA Z87.1 Or alternative equivalent set of standards
Face shield	Made of clear plastic and providing good visibility to both the wearer and the patient. Adjustable band to attach firmly around the head and fit snuggly against the forehead, fog resistant (preferable). Completely cover the sides and length of the face. May be reusable (made of robust material which can be cleaned and disinfected) or disposable.	EN 166 (if reusable) ANSI/ISEA Z87.1 (if reusable) Or alternative equivalent set of standards
Fit test kit	To evaluate effectiveness of seal for tight fitting respiratory protection devices.	OSHA 29 CFR 1910.134 Appendix A
Particulate respirator	Good particle filtration (minimum 94% or 95%), good breathability with design that does not collapse against the mouth (e.g. duckbill, cup-shaped). May be tested for fluid resistance (NIOSH/FDA surgical N95, EN 149 FFP2 + Type IIR, GB 19083 Grade/Level 1).	Fluid-resistant respirator: • Minimum NIOSH approved (42 CFR Part 84) and FDA cleared "surgical N95" • EN 149, minimum "FFP2" and EN 14683 Type IIR • GB 19083, minimum "Grade/Level 1" • Or alternative equivalent standard Non-fluid resistant respirator: • Minimum NIOSH approved "N95" according to 42 CFR Part 84 • EN 149, minimum "FFP2" • GB 2626, minimum "KN95" • Or alternative equivalent standard

- On the use of masks:
- Use of masks for children: https://www.who.int/publications/i/item/WHO-2019-nCoV-IPC_Masks-Children-2020.1

3. On in-vitro diagnostics,

- Information about emergency use listing, https://extranet.who.int/pqweb/vitro-diagnostics/coronavirus-disease-covid-19-pandemic-%E2%80%94-emergency-use-listing-procedure-eul-open (new website)
- Laboratory assessment https://www.who.int/publications/i/item/laboratory-assessment-tool-for-laboratories-implementing-covid-19-virus-testing (23 October 2020)
- More documents on Laboratories and diagnostics, can be found here

4. On the role of imaging diagnostics, (now available in 7 languages).

- You can find the role of ultrasound, chest X rays and CT scanners, here. https://www.who.int/publications/i/item/use-of-chest-imaging-in-covid-19
- And you can review chapter 8 of the Priority medical devices for COVID for the technical specifications **https://www.who.int/publications/i/item/WHO-2019-nCoV-MedDev-TS-O2T.V2**

5. **The Emergency Global Supply catalogue. Updated 11 November 2020.**

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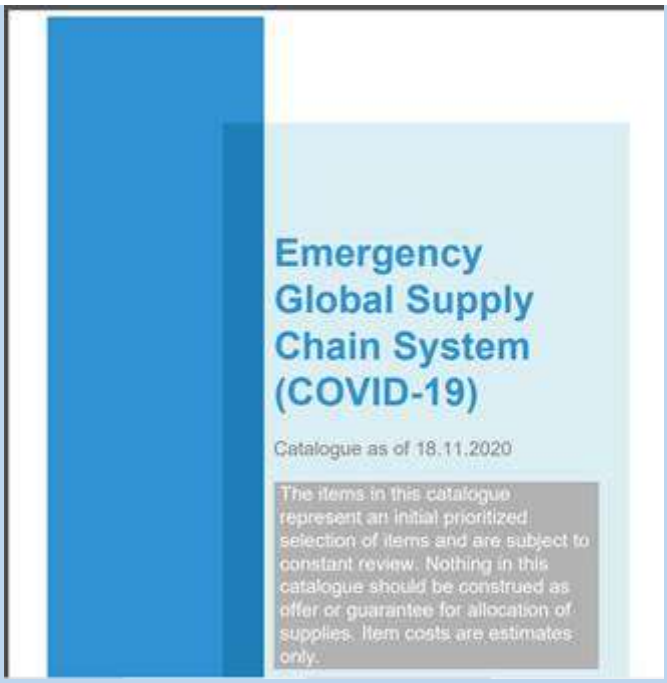
- 

2.3 Training and learning. Check for new courses on PPE and clinical management.

https://openwho.org/ \201C OpenWHO is WHO\2019 s interactive, web-based, knowledge-transfer platform offering online courses to improve the response to health emergencies. OpenWHO enables the Organization and its key partners to transfer life-saving knowledge to large numbers of frontline responders.\201D

https://www.who.int/about/who-academy/ \201C With COVID-19 science now doubling every 20 days and new guidance being published daily by WHO, the WHO Academy continues to improve its COVID - 19 mobile learning app so that health workers can keep up with the constantly evolving knowledge related to this disease.\201D

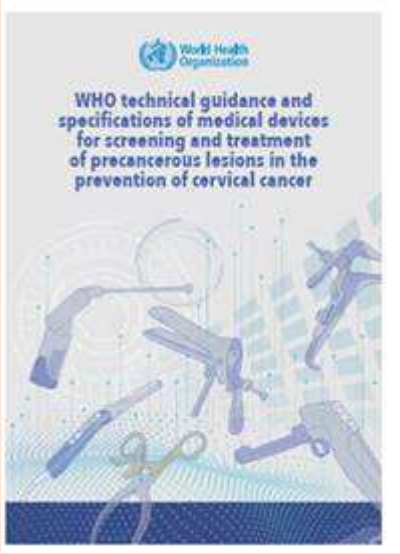
2. Cervical Cancer

2.1 Launch of the Global Strategy to accelerate the elimination of cervical cancer 17 November 2020

Information : https://www.who.int/news-room/events/detail/2020/11/17/default-calendar/launch-of-the-global-strategy-to-accelerate-the-elimination-of-cervical-cancer

https://www.who.int/health-topics/cervical-cancer#tab=tab_1

New technical guidance and specifications of medical devices for screening and treatment of precancerous lesions in the prevention of cervical cancer



other publications soon to be launched on Radiotherapy, post market surveillance..

3. Ongoing projects November-December 2020

Innovation submissions and country updates surveys close 30 November, for reporting 2020.

Thank you to many of you that applied! WHO has hired or finalizing process for 20 consultants for the following projects to be done November - December, please find information below. You might be contacted/ or you can contact us for any of this projects:

Project	Objective		Email contact
Nomenclature of medical devices	Follow up the 145/3 https://apps.who.int/gb/ebwha/pdf_files/EB145/B145_3-en.pdf	Will be followed by discussion in the Executive Board 148/11 in January 2021 https://apps.who.int/gb/ebwha/pdf_files/EB148/B148_1(draft)-en.pdf Member States consultation on 30 November 2030. More information will be available. (to come)	medicaldevices@who.int

Innovative technologies for low resource setting	b. Assess innovative technologies: specifications, regulations, HTA, in the intended settings	**LAST CALL** for Innovations to be included in the Compendium of Innovative Health Technologies for Low Resource Settings. Please submit your innovative technology **before 30th November**, 2020 at WHO SURVEY . The complete questionnaire is available in word for your reference here You can volunteer, as well, to be a reviewer of the submitted technologies if you have experience working in low and middle income settings. If you are interested in being a reviewer, please contact us or complete this survey, and your expertise and conflict of interest will be considered. 	**techinnovation@who.int**
Update of Global Atlas of medical devices, Updated of country data	b. support facility assessments of biomedical equipment including oxygen sources, (inventory survey listed above) support the provision of country information *for any of the surveys mentioned section 2 above*	1. Go to https://www.who.int/medical_devices/countries/en/ 2. Search for your country in the word version: **Atlas Word document to update your country profile** [Word, 4.62mb] 3. Related links: - WHO Global Atlas of medical devices , 2017 [pdf, 11.63mb] - Country profiles - Medical devices regulatory systems at country level - Global Health Observatory (GHO) interactive maps on medical devices - Global health observatory, data repository **Focal points of Global Atlas, will**	**medicaldevices@who.int**

		be contacted in November to provide updated information. 4. **Also MOH can send requests or changes to medicaldevices@who.int as needed before 30 NOVEMBER 2020.** 	
Facility surveys	To assess availability of health products, WHO has developed several tools, can be found	https://www.who.int/publications/i/item/WHO-2019-nCov-biomedical-equipment-inventory-2020.1: https://o2therapy.surveycto.com/collect/who_covid_oxygen_therapy_scto_open?caseid= Username:biomedequipment Password: facilityoxygen20 https://www.who.int/publications/i/item/WHO-2019-nCoV-HCF_assessment-Products-2020.1 https://www.who.int/publications/i/item/WHO-2019-nCoV-HCF_assessment-Safe_environment-2020.1	**COVID-MED-DEVICES@who.int**

		  	
Training on safe use, maintenance, of medical devices	Consolidate, assess and/ or develop training for best use and maintenance of medical devices	If you have publicly available training material willing to share, please send to covid-med-devices@who.int where it is being reviewed, assessed, and can become publicly available to support safe and appropriate use of Priority medical devices in general and specially for COVID-19,	**COVID-MED-DEVICES@who.int**

Donations of medical devices	Consolidate information on donated equipment status, use of guidance documents, and how to improve donations	https://www.who.int/medical_devices/management_use/manage_donations/en/ 	**medicaldevices@who.int**
Local production and technology transfer of: medical equipment, personal protective equipment, IVDs and other medical devices	Support C-TAP and Technology Access Partnership to increase access of essential and priority health products	https://www.who.int/emergencies/diseases/novel-coronavirus-2019/global-research-on-novel-coronavirus-2019-ncov/covid-19-technology-access-pool  https://techaccesspartnership.net/ 	**COVID-MED-DEVICES@who.int**

MEDEVIS	Priority Medical Devices Information system (to come)		**medicaldevices@who.int**

Many thanks!

Stay safe.

Best regards

Let\2019 s remember the importance of increasing access to affordable, appropriate, good quality medical devices, especially for those that need them the most!

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