WHO Medical Devices

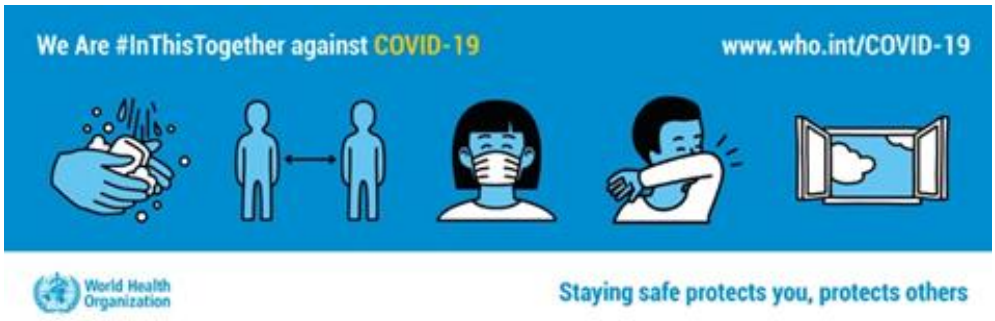
August 2021 Newsletter

Dear colleagues: this month we share with you 3 new publications, webinars.
Medical devices are indispensable for health care provision, please continue to support in every way you can, stay safe!

Find below the following information and please disseminate in your networks

1. **Technologies for COVID-19.**
2. **WHO List of Essential in vitro diagnostics and guidance for the implementation at country level**
3. **Other WHO webinars**

WHO August news:
Globally, as of **5:33pm CEST, 27 August 2021**, there have been **214,468,601 confirmed cases** of COVID-19, including **4,470,969 deaths**, reported to WHO.
As of **25 August 2021**, a total of **4,953,887,422 vaccine doses** have been administered.



1. Medical technologies for COVID-19 and other health priorities:

1.1. Consultations

International pharmacopeia, open for open consultation for GMP medical gases and Oxygen 93%

We invite you to review the following draft working document which is posted on the WHO Medicines website under
"*Monographs and general texts under review/revision for inclusion in The International Pharmacopoeia*"
(https://www.who.int/teams/health-product-and-policy-standards/standards-and-specifications/pharmaceuticals/current-projects):

Medicinal Oxygen
Draft proposal for revision in *The International Pharmacopoeia*"
qas20_867_rev2_medicinal_oxygen.pdf (who.int)

It is intended to revise the monograph on Oxygen in The International Pharmacopoeia:

- to clarify that WHO Member States, considering options for increasing the supply of medicinal oxygen to treat COVID-19 and other patients, can safely apply oxygen generated by:
    - Oxygen Generation Plants and concentrators, which use Pressure Swing Adsorption (PSA) or Vacuum Swing Adsorption (VSA) technologies to **generate 90 to 96% pure oxygen**, referred to in the draft revision as "Oxygen 93%; and/or
    - Air Separation Units, which use cryogenic technology to generate 99% pure oxygen, referred to in the draft revision as "Oxygen 99%;
- to define quality requirements for these products.

Please comment and send format to schmidth@who.int **by 10th September 2021**

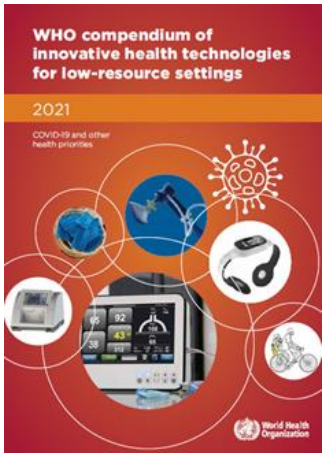
WHO good manufacturing practices for medicinal gases.
qas21_875_gmp_for_medical_gases.pdf (who.int)

Arising from an increased demand for medicinal gases, in particular the use of oxygen in the treatment of patients with Coronavirus disease 2019 (COVID-19), the World Health Organization (WHO) Health Products Policy and Standards Department and other departments involved in the supply of oxygen and the inspection of production sites of medicinal gases, raised the urgency for the preparation of the WHO good manufacturing practices for medicinal gases guidance text.

Please send your comments to Dr Steve Estevao Cordeiro, Technical Officer, Norms and Standards for Pharmaceuticals, Technical Standards and Specifications (estevaos@who.int), with a copy to Ms Sinéad Jones (jonessi@who.int) **before 31 August 2021.**

1.2. Webinar: 2021 Compendium of innovative technologies for low resource settings
When: 31 August 2021, 16:00 TO 17:30 hrs CEST

This event will launch a new WHO publication:



Registration and more information:
https://www.who.int/news-room/events/detail/2021/08/31/default-calendar/webinar-2021-compendium-of-innovative-health-technologies-for-low-resource-settings

1.3. Medical Technologies for Covid

1.3.1. PSA Plants and oxygen concentrators that need repair:

Please add your PSA plant that needs maintenance to: Every Breath Counts LMIC Oxygen Plant "FIX LIST" - Google Sheets

https://fdunn8.wixsite.com/website

Maintenance Challenge: https://drive.google.com/file/d/18URm59O_12t6ymjNqQ4pqxMvm0_YGv3I/view Email to connect: will@d-prize.org

WHO, UNICEF and other partners are working to support the repair of PSA plants, and increase availability of oxygen at country level.

Consultants available to support regional WHO offices on oxygen related equipment, that have more than 5 years expertise, please send CV to medicaldevices@who.int

1.3.2 NGOs very active on oxygen and medical equipment support

Every breath counts--- https://stoppneumonia.org/latest/covid-19/

PATH--- https://www.path.org/programs/market-dynamics/covid-19-oxygen-needs-tracker/

Clinton health access initiative--- https://www.clintonhealthaccess.org/our-programs/oxygen/

The Global Fund has opened another window for sending funding proposals mid September! Please find information below:

COVID-19 Response Mechanism to support countries to procure: in vitro Diagnostics, Personal Protective Equipment, Treatment and Oxygen Equipment. Requests can also be done for maintenance or local consultants.

1.4 C-TAP

Medical devices industry, academia, innovators are invited to share knowledge, IP or data, join C-TAP: The technology access pool, to increase access of COVID technologies globally.

Consultants interested to support C-TAP, that will have knowledge of technology transfer, local production, IP, innovation with more than 5 years of experience, please send CV to medicaldevices@who.int

1.5 Clinical management course

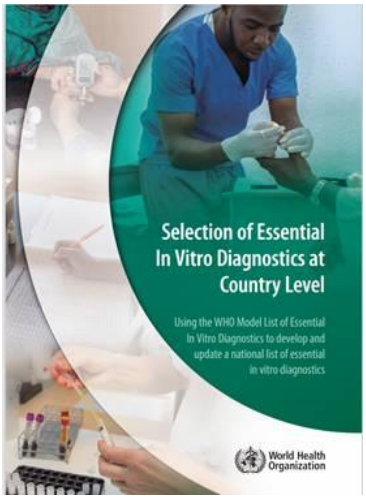
The Clinical management course is now live on OpenWHO: https://openwho.org/courses/clinical-management-COVID-19-mild-mod-severe

More information: https://www.who.int/emergencies/diseases/novel-coronavirus-2019

2. WHO List of Essential in vitro diagnostics and guidance for the implementation at country level

The EDL Secretariat is pleased to share with you the link for WHO new guidance document: "**Selection of essential in vitro diagnostics at country level using the WHO Model List of Essential In Vitro Diagnostics to develop and update a national list of essential in vitro diagnostics"**

Can be downloaded at: https://www.who.int/publications/i/item/9789240030923



This document is intended to provide guidance to countries on methods for developing and updating national lists of essential in vitro diagnostics (NEDL).

It describes the best practices for selecting categories of in vitro diagnostic tests for an NEDL, consistent with the evidence-based methods used to update the WHO EDL.

The document guides identification of the most relevant categories of IVDs listed in the WHO EDL for inclusion in the NEDL according to the country's context and needs.

It includes an overview of use of an NEDL for enabling and improving access to clinical laboratory services.

Visit the new IVD pages which provide EDL advocacy materials, the link to the eEDL, the report of last SAGE IVD meeting including EDL3, and information on SAGE IVD.

Your support for disseminating these materials and publications will be most welcome.

https://www.who.int/health-topics/in-vitro-diagnostics#tab=tab_1

https://www.who.int/teams/health-product-policy-and-standards/assistive-and-medical-technology/medical-devices/selection-access-and-use-in-vitro

3. Other WHO Webinars

3.1 **"Innovations in X-ray and Artificial Intelligence CAD Software for TB response"**
When: August 31st, from 12.00 to 13.30 CEST/Geneva time

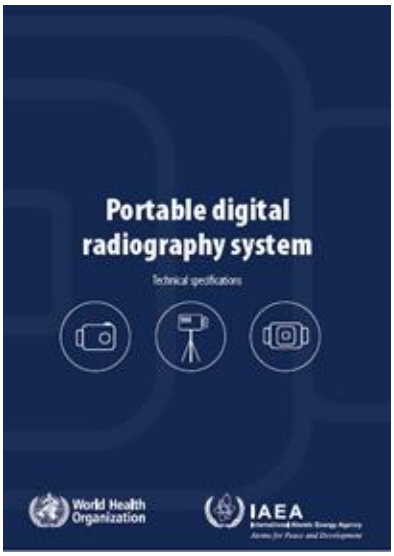
Register using the following link: https://primetime.bluejeans.com/a2m/live-event/zeyszvct

The aim of the webinar is to highlight the addition and the use of ultra-portable X-ray devices and computer-aided detection (CAD) software in the Stop TB's GDF catalogue and the release of Stop TB's ultra-portable X-ray and CAD implementation guide, and in the context

of the Global Fund's COVID-19 Response Mechanism (C19RM) which supports interventions to mitigate the impact of COVID-19 on TB services.

Objectives include:

- Providing the most up-to-date WHO policy on when, where, and how X-ray can be used in TB programmes for screening and triage, as well as insight on how new tools such as CAD solutions fit into these recommendations.
- Discussing the new ultra-portable digital X-ray systems and CAD software available in the Stop TB GDF's catalog for procurement and highlighting the newly released implementation guide as a resource for country programmes and implementing partners for further learning and discussion.
- Presenting the latest technical landscape of stationary, mobile and portable X-ray systems and the use of CAD software on analogue-converted digital radiographs.
- Spotlighting the experience of an early TB REACH implementer, including their advice and learnings from piloting these solutions.



The event will launch the latest WHO-IAEA technical specifications

3.2 **WHO COVID-19 Case Management Webinar Series**
When: 31st August 13:30 to 15:30 CET
Topic: Optimizing Care for Patients with Severe COVID-19 Disease.

More information and registration:
https://www.who.int/news-room/events/detail/2021/08/31/default-calendar/who-covid-19-case-management-webinar-series-optimising-care-for-patients-with-severe-covid-19-disease

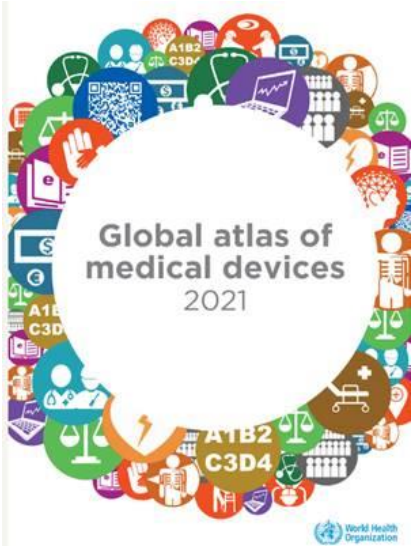
4. Global Atlas of medical devices 2021, for consultation during 4 weeks

The latest edition of the Global Atlas of Medical Devices, was published 5th August 2017, https://www.who.int/teams/health-product-policy-and-standards/assistive-and-medical-technology/medical-devices/global-atlas-of-medical-devices

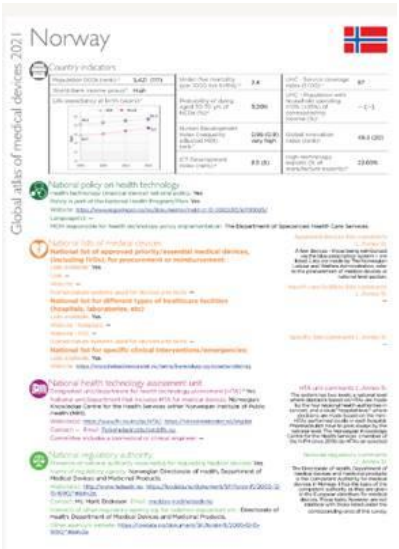
After many months of surveys, more than 1,000 email communications and desk reviews, WHO presents the Draft 2021 Global Atlas of medical devices for final consultation.

WHO welcomes and is very thankful to all that collaborated providing the information
This PDF document will be posted for consultation for 4 weeks, from today to 24th September 2021.

Please note, this is a **DRAFT PUBLICATION, still pending publication approval.**



Includes country profiles: i.e.



The PDF file for consultation and a word file template can be used to send to WHO the comments or changes required, to medicaldevices@who.int.

Please note that the edits can ONLY be submitted by governmental representatives of Ministry of Health, regulatory authorities or public institutions.

Thank you!