

# WHO Medical Devices Newsletter

## November 2019

*Dear colleagues,*

*The year is about to finalize and we are pleased to announce the launching of two important publications, which we hope you will find useful and disseminate widely for implementation . This month we also need your kind input, so this newsletter includes 2 surveys and a request for information.*

*We count on you in order to know your preferences, needs and to reflect factual information as well as to disseminate WHO information .*

*Many thanks*

### 1. New publication: Technical specifications and guidance for oxygen therapy devices

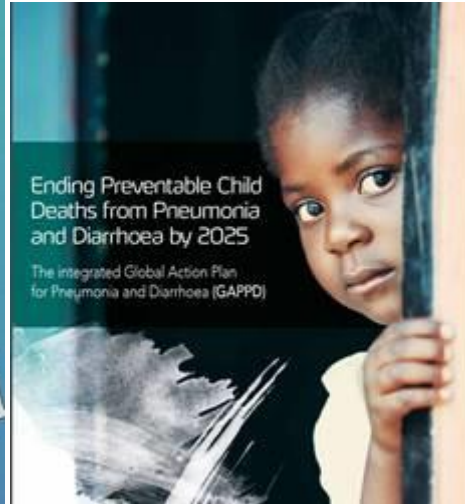
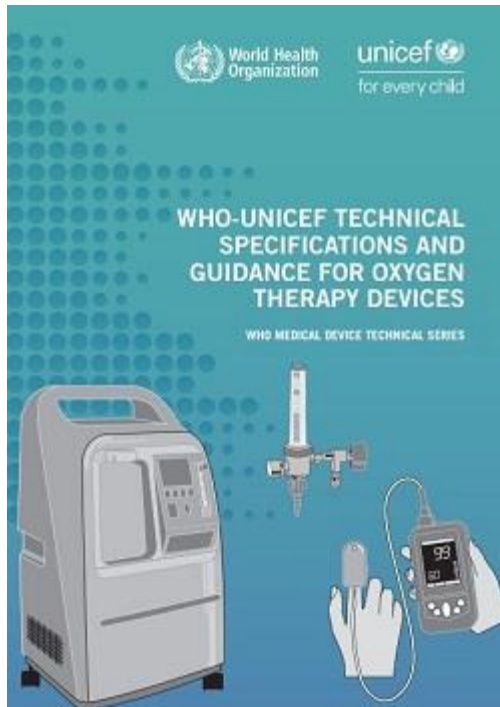
Next week, on the 12 of November, the World Pneumonia Day will take place.

Pneumonia accounts for 15% of all deaths of children under 5 years old and much work has to be done !.

#### Background:

Recognizing that Oxygen is an essential medicine that saves lives. This book is launched to support oxygen therapy for pneumonia patients,

acknowledging that Oxygen is also needed for surgery , trauma, respiratory and cardiac diseases among others.



In an effort to increase access to and utilization of oxygen therapy systems, WHO and UNICEF developed the technical specifications for a set of 15 essential devices.

It includes oxygen sources, pulse oximeters, devices to regulate flow and devices to deliver oxygen to patients.

#### Publication

To download the publication and specifications, visit [https://www.who.int/medical\\_devices/publications/tech\\_specs\\_oxygen\\_therapy\\_devices/en/](https://www.who.int/medical_devices/publications/tech_specs_oxygen_therapy_devices/en/).

The purpose of this interagency publication is to provide harmonized product specifications for a wide range of oxygen products, to provide guidance on the selection, procurement, use and maintenance of these products.

Funding for this project was provided by the Bill & Melinda Gates Foundation.

## 2. Review of the Global Atlas of Medical Devices for 2020



### Background:

In reference to WHA60.29 resolution, a survey was done in 2011, and updated 2014 and 2017 on Health technologies, specifically on medical devices which are essential for a functioning health system,

Considering that Medical devices are indispensable in the prevention, screening, diagnosis, monitoring, treatment and rehabilitation of disease or in different health conditions.

All country data retrieved so far can be found in [https://www.who.int/medical\\_devices/countries/en/](https://www.who.int/medical_devices/countries/en/).

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.

### Country profiles - Global atlas of medical devices (2017 update)

Global Atlas of medical devices book provides the global, regional and country data particularly on the availability of specific medical devices, policies, guidelines, standards and services.

Related links:

- [WHO Global Atlas of medical devices , 2017 \[pdf, 11.63mb\]](#)
- [WORD DOCUMENT TO UPDATE YOUR COUNTRY PROFILE](#)
- [Country profiles - Medical devices regulatory systems at country level](#)
- [Global Health Observatory \(GHO\) interactive maps on medical devices](#)
- [Global health observatory, data repository](#)

### Action requested:

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](mailto:medicaldevices@who.int) in the following format.

- a. Ministries of Health or public institutions of Member States can send updates of facts, websites or information or contacts at any time sending a message to [medicaldevices@who.int](mailto:medicaldevices@who.int)
- b. Information coming from other sources, like: Academia, NGOs, consultants, private sector, will be received and verified with Member States, as appropriate.
- c. For ease of keeping track of updates, ***please use track changes or highlight the sections that need to be updated with the new data***, using the “Global Atlas of Medical Devices Word document”.
- d. Please reference your source(s). (Without reference your changes WILL NOT be taken into consideration).
- e. The deadline for sending any edits is by the 13<sup>th</sup> of **December, 2019**.

### 3. Nomenclature of medical devices, survey for further analysis

#### Background:

- Nomenclature, coding and classification of medical devices has not been standardized globally and there are many systems that co-exist among countries and within countries and agencies.
- Information on this topic can be found in [https://www.who.int/medical\\_devices/priority/mde\\_nomenclature/en/](https://www.who.int/medical_devices/priority/mde_nomenclature/en/)
- In October 2018 WHO was requested to provide a report on medical devices nomenclature to be discussed in the WHO Executive Board in May 2019. ( [http://apps.who.int/gb/ebwha/pdf\\_files/EB145/B145\\_3-en.pdf?ua=1](http://apps.who.int/gb/ebwha/pdf_files/EB145/B145_3-en.pdf?ua=1))
- Due to the discussion in the Executive Board meeting, member states requested further analysis of nomenclature of medical devices.( <https://www.who.int/about/governance/executive-board/executive-board-145>)
- WHO has been having different consultations and will continue to do studies and analysis, in order to provide a report for the next Executive Board meeting of Member States in 2020.

#### Action requested:

If you use naming , classification, coding, nomenclature of any kind of medical devices including in vitro diagnostics, WHO will welcome your input in the following [SURVEY](#).

#### 4. Launch of the report of the Second WHO Model List of Essential In Vitro Diagnostics and survey for electronic version



#### Launch of the Report of the second meeting of the SAGE-IVD and Second WHO Model List of Essential In Vitro Diagnostics (EDL)

##### Background:

- The Essential Diagnostics List (EDL) is a compendium of priority in vitro diagnostics that form an integral component of the management of high burden and priority diseases and health conditions.
- The first edition of the list was released in 2018, and the second edition was released in July 2019.
- The second WHO model list of essential in vitro diagnostics was developed based on proposals made by a large number of stakeholders including academia, industry, and humanitarian organizations.
- The proposals were reviewed by a representative multidisciplinary group of experts known as the Strategic Advisory Group of Experts on In Vitro Diagnostics (SAGE IVD), who met in March 2019.
- The evidence reviewed by the SAGE, as well as the details of their deliberations, and final recommendations are now available in the form of a technical report. This report will be officially

launched in a live webcasted event on 5 November 2019 from 1400 to 1530 CST at WHO headquarters.

Event:

- The launch on 5<sup>th</sup> November, featured panel discussion among representatives from WHO regional and country offices, WHO headquarters, members of academia, implementing partners, professional organizations, and industry.
- The webcast link can be accessed from the following website.  
[https://www.who.int/medical\\_devices/diagnostics/selection\\_in-vitro/en/](https://www.who.int/medical_devices/diagnostics/selection_in-vitro/en/)
- [Agenda](#)  
pdf, 375kb

Publication :

- [Report of the second meeting of the SAGE IVD including Second EDL;](#)

Action requested:

- WHO requests your kind input to inform the design of an electronic version of the EDL, in order to access all information in a web-based platform.
- We are interested to know the use cases, if interested, please fill in **the survey by** 11 November, (no data is requested, only your preference on use of information)

Thank you very much for your kind input and please disseminate this information to the colleagues that might be interested.

Best regards,

Adriana, on behalf of medical devices, radiation safety , in vitro diagnostics teams.

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