Besoin mondial de dispositifs médicaux pour COVID-19
Oxymètre de Pouls-Saturomètre

World Health Organization

Adriana Veláquez Berumen- WHO

Gabriela Jimenez Moyao-WHO

Oxymètre de pouls

Les oxymètres de pouls sont des équipements indispensables et critiques à utiliser lorsque l'oxygène est administré à un patient.

Informations de référence
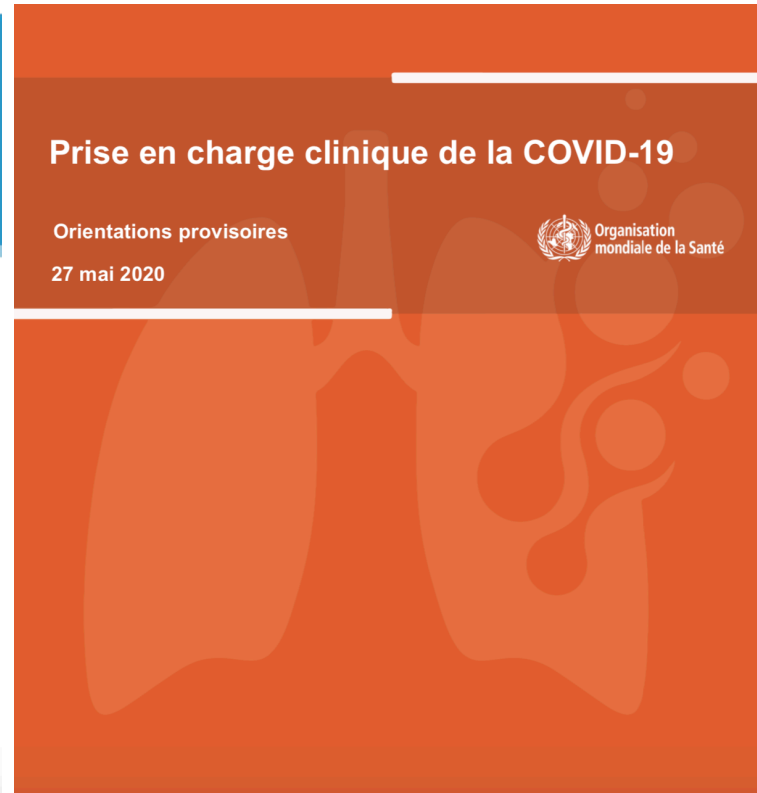
Oxymètre de pouls dans la liste de disposifs medicaux prioritaires

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 outpatient; second level includes general hospitals and laboratories; and third level, includes specialized hospitals with intensive care units and SARI units. The technologies listed are for the interventions 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 SARI Units, procurement and regulatory agencies and Ministries of Health. Recommend to involve Biomedical Engineer in the selection and verification of installation of the equipment and ensure training of health care workforce.

Considerations

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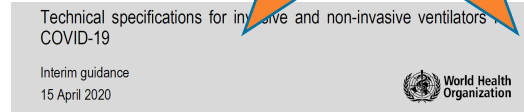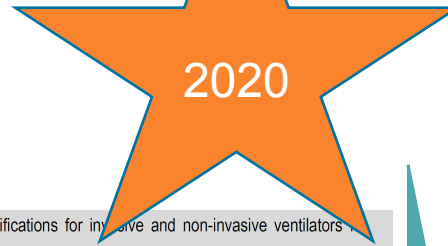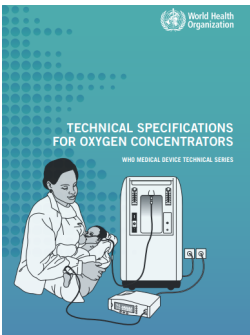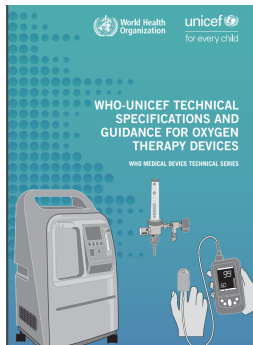* Extended warranty of at least one year and additional spare parts for maintenance should be also aggregated, according to the health care capacity.
Note: Training is indispensable for invasive ventilation.

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
	Monitoring	-	Infrared thermometer	x			•		
		Option 1 - Desirable.	Pulse oximeter - portable handheld, with cables and sensor		x	x		•	•
		Option 2.	Pulse oximeter - fingertip	x	x	x	•	•	•
		Option 3.	Pulse oximeter - table top, with cables and sensor		x			•	•
		Option 1 - Desirable.	Patient monitor, multiparametric, including EKG, non invasive blood pressure (NIBP), oxygen saturation (SpO2), respiratory rate (RR), temperature (TEMP), with sensors and cables			x		•	•
		Option 2.	Patient monitor, multiparametric, NIBP, SpO2, TEMP, respiratory rate (RR) with sensors and cables, (without EKG)		x	x		•	•
		It is recommended that the device							

Sheet1

Spécifications techniques pour l´approvisionement

2019

2020

2020

World Health Organization

WHO Technical specifications of Neonatal Resuscitation Devices

WHO-UNICEF TECHNICAL SPECIFICATIONS AND GUIDANCE FOR OXYGEN THERAPY DEVICES

WHO MEDICAL DEVICE TECHNICAL SERIES

TECHNICAL SPECIFICATIONS FOR OXYGEN CONCENTRATORS

WHO MEDICAL DEVICE TECHNICAL SERIES

Technical specifications for invasive and non-invasive ventilators for COVID-19

Interim guidance
15 April 2020

These technical specifications describe the minimum requirements that invasive and non-invasive ventilators must comply with to ensure quality, safety and effectiveness when used for the management of COVID-19.

All these ventilators require a source of air and oxygen to operate their internal blenders. Some of the equipment includes an internal air compressor, but all these pieces of equipment require either a low-flow oxygen source (e.g. oxygen concentrator) or a high-flow oxygen source (e.g.

Definitions and intended use

1.1 Invasive ventilators

1.1.1 Patient ventilators for intensive care unit: Designed to provide temporary ventilatory and respiratory assistance to adult and paediatric patients who cannot breathe on their own or who require assistance to maintain adequate ventilation. This equipment is usually connected to a 50-psi gas supply. Some ventilators have their own air compressor but still need

Medical Devices

Medical devices for patient management

This page refers only to the specific **priority medical devices for clinical management**, including: diagnostic imaging, monitoring equipment; oxygen supply therapy and equipment for intensive care units.

This is a subset of the complete priority medical devices list which can be found here.

Technical specifications for the medical devices for clinical management are listed below:

These technical specifications describe the minimum requirements that the medical devices must comply with to ensure quality, safety and effectiveness when used for the management of COVID-19.

Access technical specifications for invasive and non-invasive ventilators (15 April 2020)

COVID-19 Technical specifications of invasive and non invasive ventilators V2 . (Draft 11 August 2020)

Technical specifications for pressure-swing-adsorption (PSA plants)

⬇ COVID-19 Technical specifications for procurement of oxygen therapy and ⬇ monitoring devices (final draft 10 July 2020)
   pdf, 828kb

⬇ COVID-19 Technical specifications for infusion devices (final draft 10 July 2020)
   ⬇ pdf, 429kb

⬇ COVID-19 Technical specifications for imaging devices: portable ultrasound;
   ⬇ mobile radiographic digital equipment; computed tomography (CT) scanning
      system (4 August 2020)
      docx, 146kb

The draft specifications will be integrated in a single publication along with other sets that are being updated.

3. Technical specifications for oxygen therapy and monitoring devices
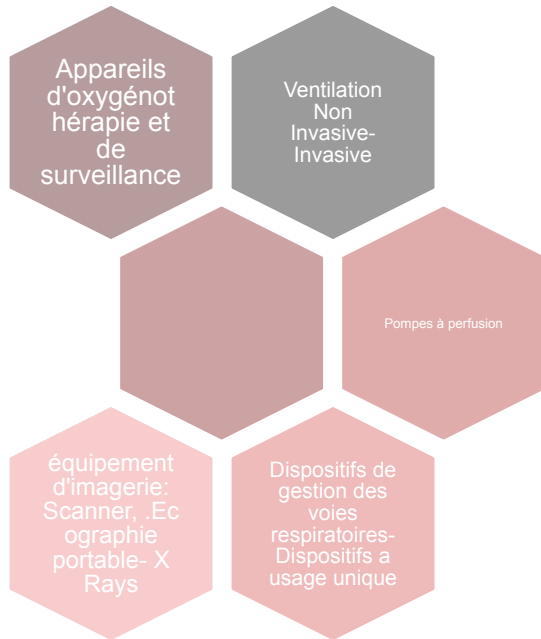
oxygen source devices – oxygen concentrator, oxygen cylinder; oxygen delivery devices – nasal oxygen cannula with prongs, mask with reservoir bag, Venturi mask; devices for oxygen regulation and conditioning – flowmeter Thorpe tube, flow splitter, non-heated bubble humidifier; tubing (for medical gases); manual ventilation devices – self-inflating resuscitation bag with mask, heat and moisture exchanger filter (HMEF), colourimetric end-tidal CO2 (EtCO2) detector; patient monitoring devices – pulse oximeter (handheld, tabletop, fingertip), patient monitor multiparametric (basic, intermediate, advanced)

https://www.who.int/medical_devices/priority/COVID-19_medequipment/en

Spécifications techniques pour l´approvisionement

World Health Organization

DISPONIBLE BIENTÔT

Appareils d'oxygénot hérapie et de surveillance

Ventilation Non Invasive- Invasive

Pompes à perfusion

équipement d'imagerie: Scanner, .Ec ographie portable- X Rays

Dispositifs de gestion des voies respiratoires- Dispositifs a usage unique

3. Technical specifications for oxygen therapy and monitoring devices

5. Technical specifications for infusion devices

https://www.who.int/medical_devices/priority/COVID-19_medequipment/en/

Publication 2019 WHO-UNICEF

World Health Organization

https://www.who.int/medical_devices/publications/tech_specs_oxygen_therapy_devices/en/

WHO-UNICEF TECHNICAL SPECIFICATIONS AND GUIDANCE FOR OXYGEN THERAPY DEVICES

WHO MEDICAL DEVICE TECHNICAL SERIES
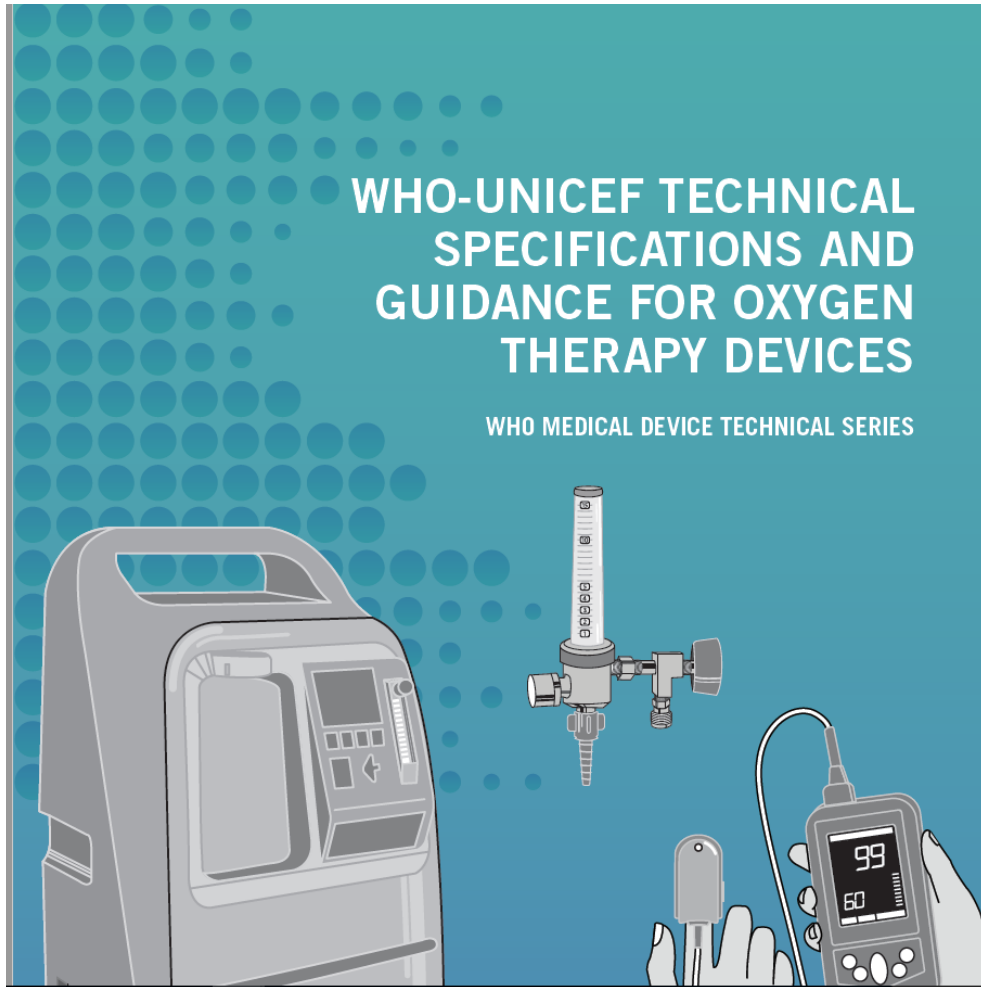
Les Systèmes d'oxygène ont besoin d´oxymètres de pouls pour la surveillance du patient
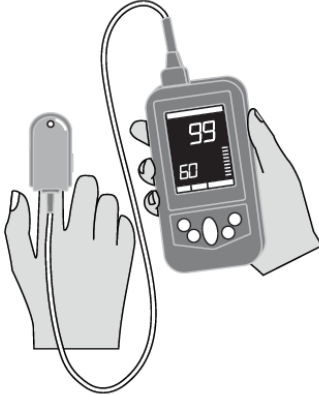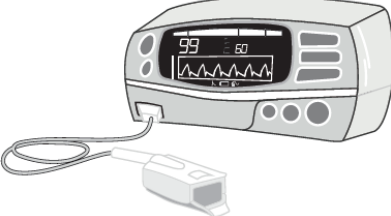
Fig. 2.2 Oxygen systems components

OXYGEN SYSTEMS

Oxygen source	Distribution	Regulation and conditioning	Delivery	Patient monitoring
• Concentrator • Cylinder • Plant • Liquid oxygen	• Central or sub-central piping • Tubing • Transport (for cylinders)	• Regulator • Flowmeter • Flowmeter stand (flow splitter) • Humidifier (heated and non-heated) • Blender • CPAP • Ventilator	• Nasal cannula • Nasal catheter • Masks • Tubing	• Pulse oximeter • Multiparameter monitor

Power supply
- Voltage stabilizers
- Surge suppressors
- Backup power supply

Maintenance
- Oxygen analysers
- Tools and spare parts for maintenance of all devices

Types d'oxymètres de pouls

Table 6.1 Description and comparison of pulse oximeters

	au doigt	portable	de table
	Self-contained fingertip	**Portable handheld**	**Tabletop**
General characteristics			
Illustration/image			
Description	Portable device that has the sensor, analyser and display contained in a single unit.	Handheld portable device with display screen and attached sensor probe and cable.	Stationary device for continuous operation/monitoring. Some can be wall- or pole-mounted.
Clinical application and/or use case	Measurement of pulse rate and SpO$_2$ to detect hypoxaemia, supporting the diagnosis of respiratory disorders. Almost always designed for adults.	Measurement and/or ongoing monitoring of pulse rate and SpO$_2$ to detect hypoxaemia, supporting the diagnosis of respiratory disorders.	Monitoring of pulse rate, SpO$_2$ and plethysmography waveform to detect hypoxaemia, supporting the diagnosis of respiratory disorders.

8.27 x 11.69 in

Caractéristiques

	Au doigt	Portable	De table
Paramètres surveillés	SpO2 Rythme cardiaque	SpO2 Rythme cardiaque (respiratory rate)	SpO2 Rythme cardiaque (respiratory rate)
Accesoires requis	Batteries Cable USB	Sonde (adult, pediatric, neonatal) a remplace chaque annes Batteries de remplacement Cable	Sonde (adult, pediatric, neonatal) a remplace chaque annes Batteries de remplacement Cable
Avantages	Faible coùt initial Portable Unité autonome	Portable Alarme et plus grande memoire Capacite operationel superior a 12 heures sur batterie, moins de 4 heures pour la recharge Port WiFi	Peut être monté sur support Grande memoire interne Port WiFI Plus precis en general

Conditions d´utilisation

World Health Organization

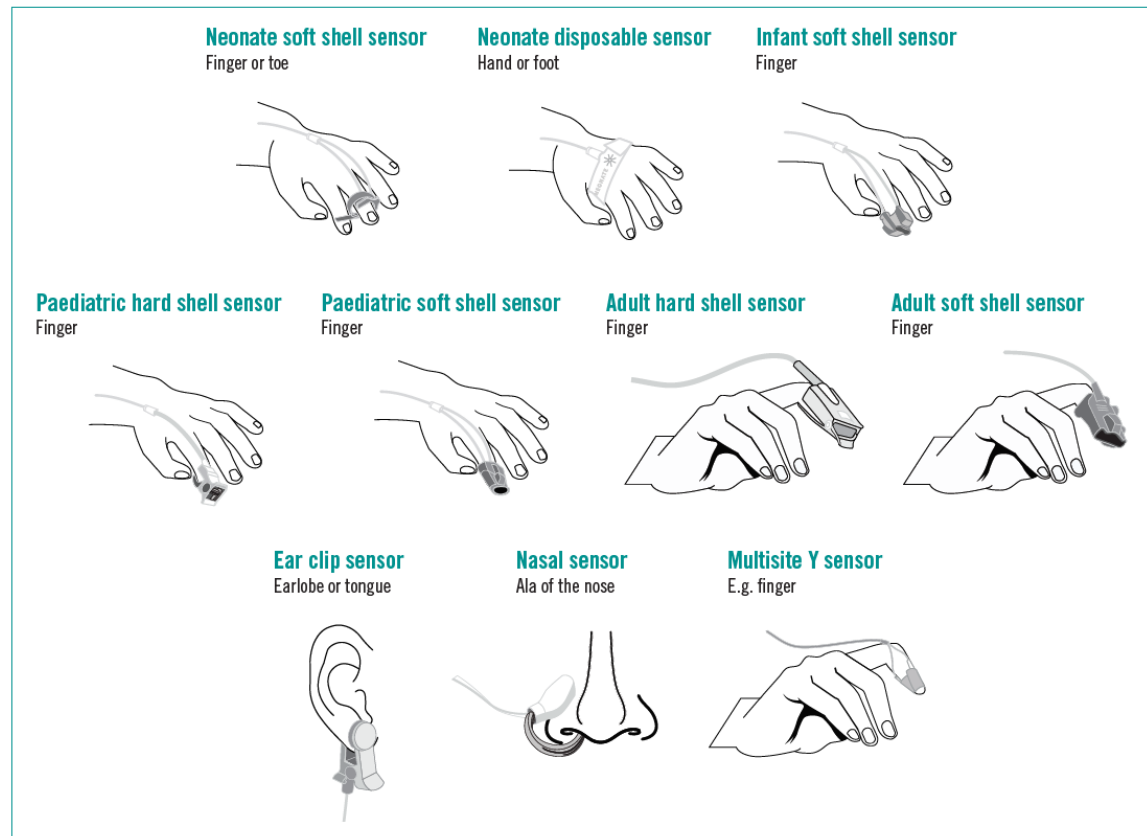|	Au doigt	Portable	De table
Inconvenients	• Non recommande pour utilisations neonatales • Pas de memoire interne • Peut être fragile • Probable remplacement de la unité complete en cas de defaillance • Peut être perdú facilement • Peu precis	• Cher et approvisionement compliqué (particulierement pour les postes avancés) si utilisation de sonde a usage unique • Sonde reutilisable peut être fragile	• Coût initial elevé • Pas facile a transporter • Cher et approvisionement compliqué (particulierement pour les postes avancés) si utilisation de sonde a usage unique • Sonde reutilisable peut être fragile • •
Alimentation	Piles	Batterie (usage uique ou rechargeable) ou secteur	Batterie et/ou secteur

Table 6.1 Description and comparison of pulse oximeters (continued)

Types de sondes

Fig. 6.1 SpO$_2$ sensor/probe cable types

Neonate soft shell sensor
Finger or toe

Neonate disposable sensor
Hand or foot

Infant soft shell sensor
Finger

Paediatric hard shell sensor
Finger

Paediatric soft shell sensor
Finger

Adult hard shell sensor
Finger

Adult soft shell sensor
Finger

Ear clip sensor
Earlobe or tongue

Nasal sensor
Ala of the nose

Multisite Y sensor
E.g. finger

56   WHO-UNICEF Technical specifications and guidance for oxygen therapy devices

Spécifications techniques

6.5 Technical specifications for tabletop pulse oximeters

6.5.1 Overview of specifications

For complete specifications see Annex 1, Table A1.11. The content in the specifications focuses on commercially available technologies; however, it was written with the understanding that innovations in manufacturing, products, infrastructure and clinical practice will advance the field of oxygen supply and delivery. The specifications do not preclude appropriate upcoming products and/or technologies.
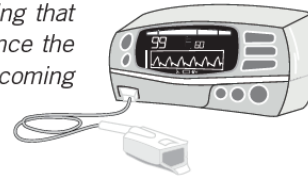
Operational characteristics
- Continuously monitors SpO_2, plethysmography waveform and pulse rate for adults, children, infants and neonates, for all skin pigmentations. Weight range for each patient category must be stated.
- SpO_2 detection range to include: 70–100%.
- SpO_2 resolution: 1% or less.
- 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 range: 30–240 bpm.
- Pulse rate resolution: 1 bpm or less.
- Pulse rate accuracy: within ± 3 bpm.
- Data update period for valid data display ≤ 10 s.
- Display with main parameters: SpO_2, pulse rate, plethysmographic waveform, 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 as per tests in

- SPO2 Precision +-2%
- Fréquence d`actualisation des données <-10 s
- Adapté au conditions de faible perfusion- faible débit sanguin.
- Résistant au conditions difficiles

Règlements et normes

International standards applicable to the manufacturer and the manufacturing process are listed below. Compliance to the latest available version is recommended.

- ISO 13485 Medical devices – Quality management systems – Requirements for regulatory purposes.
- ISO 14971 Medical devices – Application of risk management to medical devices.
- IEC 80001-5-1, Application of risk management for IT-networks incorporating medical device – Safety, effectiveness and security in the implementation and use of connected medical devices or connected health software – Part 5-1: Activities in the product life cycle.

International standards applicable to the product are listed below. Compliance to the latest available version is recommended.

- 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.

WHO-UNICEF Technical specifications and guidance for oxygen therapy devices

- ISO 80601-2-61; Exigences particulières pour la sécurité de base et les performances essentielles pour les oxymètres de pouls
- ISO 60601-1 Exigences générales pour la sécurité de base et les performances essentielles des appareils électromédicaux
- ISO 13485 Gestión de la qualité

Catalogue des produits COVID, y compris les EPI, (pour 120 pays) Le portail d'approvisionnement COVID-19, comprend dispositifs médicaux prioritaires: Dx. Tx, EPI

Site Internet COVID medical devices

https://www.who.int/medical_devices/priority/COVID-19/en/

Outil d'inventaire-COVID 19

Biomedical Equipment for COVID-19 Case Management
Interim guidance

Inventory tool for facility readiness and equipment re-allocation

07 April 2020

World Health Organization

Introduction

Oxygen is an essential medicine for COVID-19, it is therefore very important to assess availability of different sources of oxygen, as well as the delivery and supply systems to the patient, in order to prioritize, reallocate and compare with calculated numbers to define the needs. As of April 4, 2020, global supply-chain issues remain extremely disrupted as a result of the COVID-19 pandemic. It is strongly recommended that Ministries of Health leverage existing supplies and resources, where possible, in order to enable an immediate response.

This is the first edition of guidance on conducting a rapid inventory assessment to determine readiness of a health facility, as well as capacity to re-allocate biomedical equipment, for COVID-19 case management. This tool will comprise a survey (paper or digital) along with a a set of product/device showcards. This tool is to be used in-line with WHO's emergency disease commodities package (DCP) for COVID-19 [1], the WHO Priority List of medical devices for COVID, as well as Technical specifications for oxygen delivery systems[2], Resuscitation devices [3] and Oxygen concentrators[4]. This tool is intended for health facility administrators, clinical decision-makers, procurement officers, planning officers, biomedical engineers, or infrastructure engineers to identify readily available biomedical equipment for immediate use and/or re-allocation.

Please note that WHO will update these recommendations as new evidence and information becomes available.

Instructions

The tool has been developed to facilitate a rapid assessment of facility readiness and existing device availability to accelerate decision making with response-plan roll-out. It will be available for use in both digital and paper format at this time.

1. **Paper format**
   A word document follows this introduction sheet, which requires customization of a few fields prior to printing and completing by hand. An excel file is to be used as part of this package to help support with data "roll-up" or help to aggregate findings from paper surveys after data entry. Another component of carrying out this survey are "showcards", which are images to help data collectors by facilitating correct identification of equipment under assessment that is appropriate for use for COVID-19 case management.

2. **SurveyCTO**
   An electronic data collection software is also available for use on smartphone and tablet (Android or iOS) using an application ("app"). Data is captured digitally, even when offline, and then pushed to a central server when networks become available. As data is already digitized, it can be immediately analysed and reported using any data collection software (e.g. Excel, SPSS, Stata, R, etc.).

Consideration should be given to starting data collection at all higher-level facilities pre-identified for COVID-19 case management,

References

1. World Health Organisation, *Disease commodity package - Novel Coronavirus (COVID-19)*. 2020.
2. World Health Organization - UNICEF, *Technical specifications and guidance for oxygen therapy devices*. 2019: p. 164.
3. World Health Organisation, *WHO Technical Specifications of Neonatal Resuscitation Devices*. 2016.
4. World Health Organization, *Technical specifications for oxygen concentrators*. 2015.

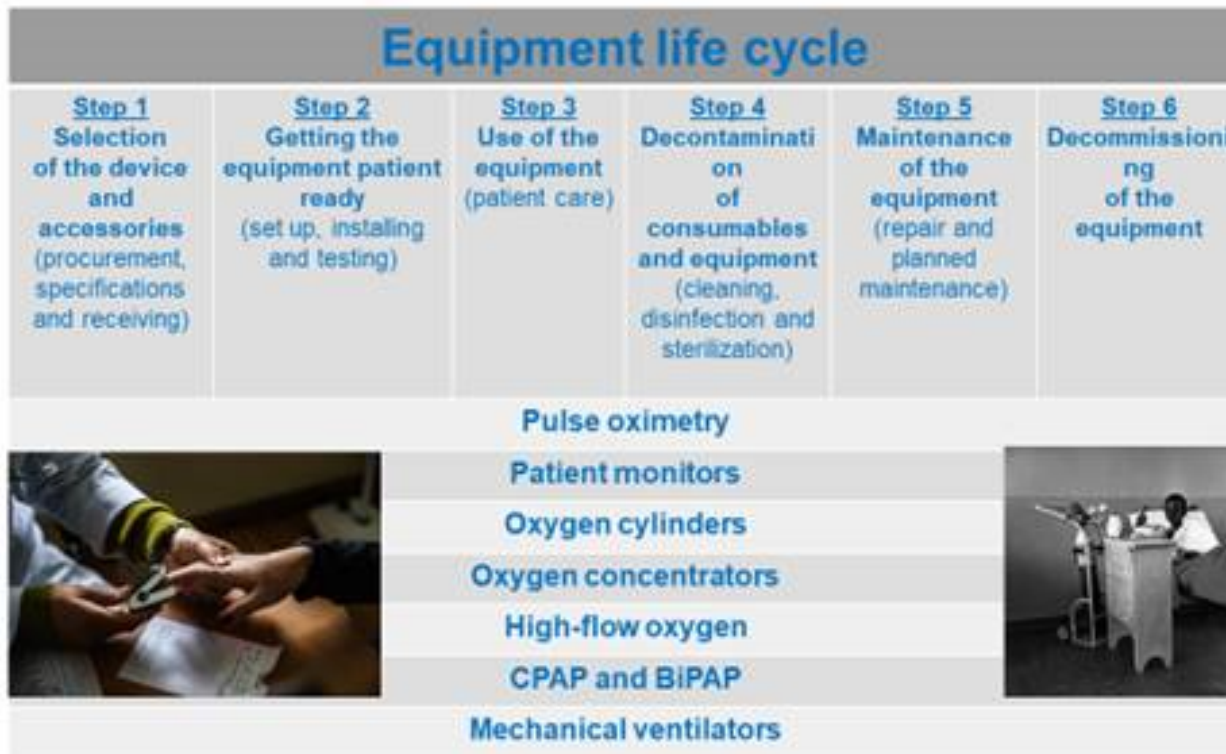© **World Health Organization 2020**. All rights reserved. WHO continues to monitor the situation closely for any changes that may affect this interim guidance. Should any factors change, WHO will issue a further update. Otherwise, this interim guidance document will expire 2 years after the date of publication.

INSTRUCTIONS TO DOWNLOAD AND CONFIGURE SURVEYCTO APP ON SMARTPHONE OR TABLET (ANDROID OR IOS)

Formation WHO-plateforme éducative

World Health Organization

DISPONIBLE BIENTÔT

COVID-19 educational platform for WHO Academy and openWHO:

World Health Organization

Equipment life cycle

Step 1	Step 2	Step 3	Step 4	Step 5	Step 6
Selection of the device and accessories (procurement, specifications and receiving)	Getting the equipment patient ready (set up, installing and testing)	Use of the equipment (patient care)	Decontamination of consumables and equipment (cleaning, disinfection and sterilization)	Maintenance of the equipment (repair and planned maintenance)	Decommissioning of the equipment

Pulse oximetry

Patient monitors

Oxygen cylinders

Oxygen concentrators

High-flow oxygen

CPAP and BiPAP

Mechanical ventilators

Les dispositifs médicaux sont utilisés pour diagnostiquer, traiter les patients et protéger le personnel de santé
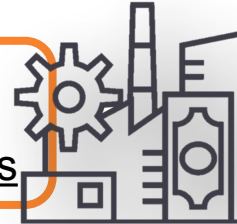
Medical devices, IVDs and PPEs required. Local Biomedical engineers are needed to manage.

Pour garantir un meilleur accès à des dispositifs médicaux sûrs et de qualité

World Health Organization

R&D

- Industrie et universitaires: la recherche et le développement devraient être basés <u>sur les besoins</u>

Évaluation

- Évaluation de la technologie de la santé
- Listes de DM pour remboursement (systeme de sante) ou marchés publics

Element Commun

Regulations

- Processus de réglementation des dispositifs médicaux
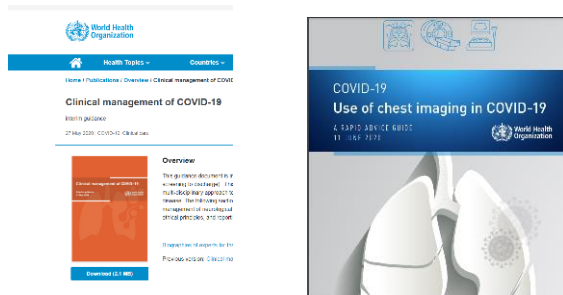- Listes des appareils approuvés pour la commercialisation dans le pays.

Management

- Évaluation des besoins
- Selection
- Incorporation: (approvisionement, donations, prêt…)
- Utilisation sûre,
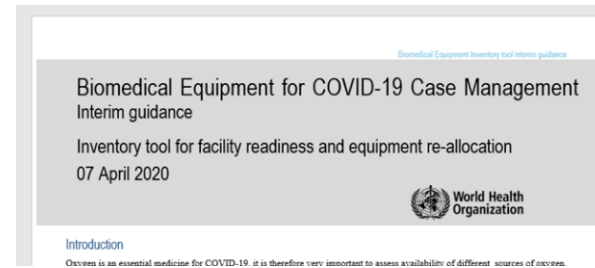- Suivi post commercialisation et notification des évènements indésirables
- Mise hors service,

Bulletin d'information de l'OMS sur les dispositifs médicaux

https://www.who.int/medical_devices/publications/Medical_Devices_Newsletter/en/

Nouveaux guides de l'OMS,

WHO enquête

Biomedical Equipment for COVID-19 Case Management
Interim guidance

Inventory tool for facility readiness and equipment re-allocation
07 April 2020

WHO postes vacants

For Biomedical/ Clinical engineers or related disciplines, with more than 4 years' experience Postgraduate degree and experience working in hospitals or clinics.
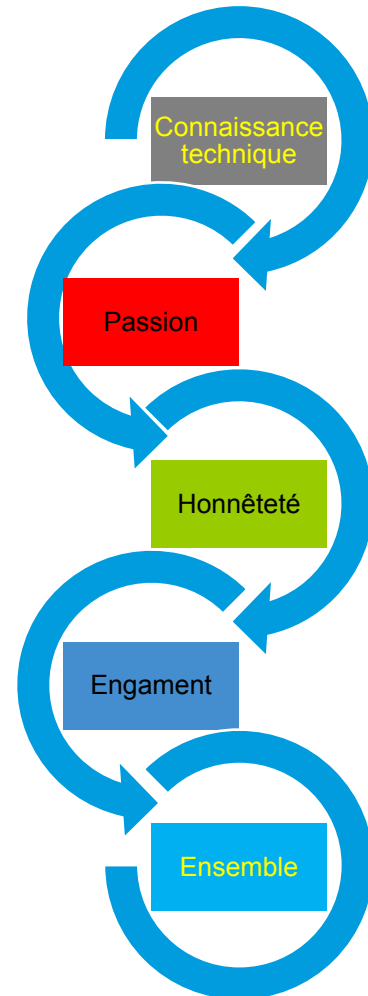
Timeline requested 2 months: 20th October to 20th December, 2020.

Please send email to COVID-MEDDEVICES@who.int

Evènements

PPE-Bridging the Standardization Gap

Supply-Chain Challenges and WHO's Contributions

EXECUTIVE BOARD
145th session
Provisional agenda item 5.1

EB145/3
30 April 2019

Standardization of medical devices nomenclature

International classification, coding and nomenclature of medical devices

Report by the Director-General

N'oubliez pas qu'un patient est à la fin de toutes nos activités, il mérite notre

Connaissance technique

Passion

Honnêteté

Engament

Ensemble

La technologie innovante doit être:
Sûr
Bonne qualité!
Facile à utiliser
Facile à maintenir
Adaptable
Abordable
Disponible
Accessible
Acceptable

Gracias
Thank you
Merci
Shokran

World Health Organization

WHO

20, Avenue Appia
1211 Geneva

Switzerland

www.who.int/medical_devices

Adriana Velazquez Berumen

velazquezberumena@who.int