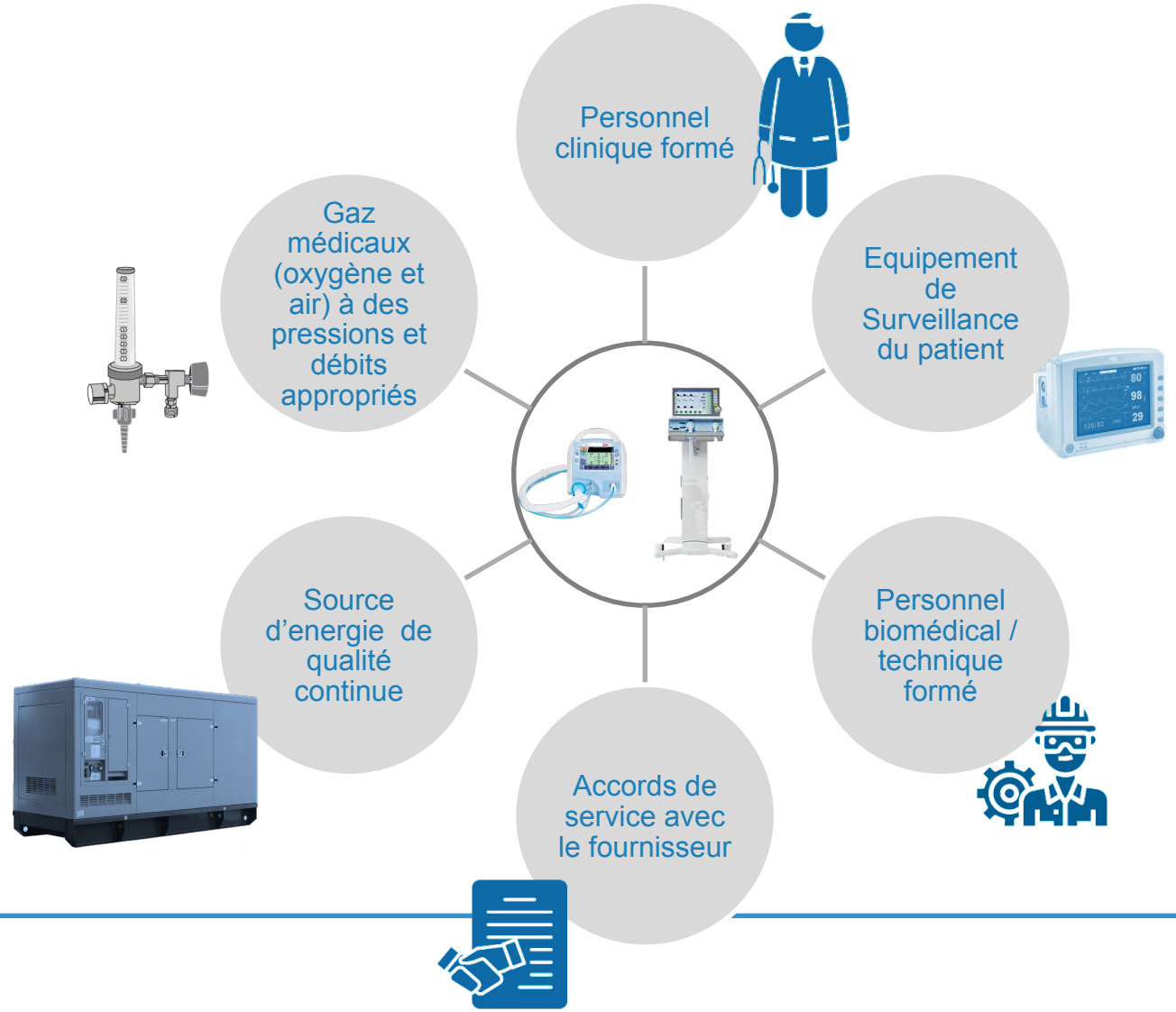
Ventilation
Invasive

World Health Organization

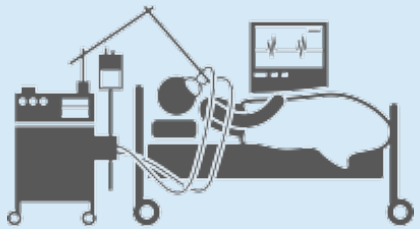
HEALTH EMERGENCIES programme

Considérations doivent être prises en compte lors de la sélection et de la mise en place des equipement pour garantir son fonctionnalité, sûrete efficace des equipements medicales



Prise en charge de la COVID-19: Px Avec état critique critical cases nécessitent des concentrations d'oxygène plus élevées ainsi que des débits à pression positive qui peuvent être fournis à l'aide d'un Ventilateur.

Il existe deux catégories de ventilateurs qui peuvent fournir une assistance ventilatoire aux cas critiques de COVID-19:



Ventilation Non Invasive (VNI)

- Px Avec état critique: syndrome de detresse respiratoire aiguË (SDRA)
- Traités avec des systèmes d'oxygénothérapie à haut débit (OHD) ou Ventilation non-invasive : Pression positive continue (PPC) / A deux niveaux de pression (BiPAP)
- Les patients sous VNI ne sont pas intubés

Ventilation Invasive

- Px Avec état critique: nécessitant une pression positive dans le voies respiratoire et une ventilation assitée
- Nécessite des prestataires de soins de santé hautement qualifiés pour l'intubation et la gestion des cas
- IMV nécessite une sédation du patient
- Peut également être utilisé de manière non invasive

Information de reference

Resources en Anglais

1. Outil de prevision d´équipements essentiels (resources humaine)

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

Information de reference

2. List of priority medical devices in the context of COVID-19

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

Medical devices for case management of severe and critical patients by health facility level (continued)

Type	Medical purpose	Medical device generic name	Triage	Treatment of severe patients	Treatment of critical patients	1st level	2nd level	3rd level	See WHO Medical devices: in vitro diagnostics for COVID-19 https://www.who.int/medical_devices/priority/COVID-19_Diagnostics/en/
Medical equipment (continued)	**Oxygen therapy** Oxygen source to be selected according to capability of the health facility (i.e. power supply, pipeline oxygen network)	Concentrator O_2, portable (with accessories)		●	●	■	■	■	Option 1 – recommended that the device provides at least 5 L/min and has electrical protection (power surge)
		Medical gas cylinder, portable, for oxygen, fitted with valve, and pressure and flow regulator							Option 2 – sizes, labelling and connections are according to international regulations; and refilling and transport are according to manufacturer's quality procedures
		Other sources of oxygen, such as pressure swing adsorption (PSA) plants, liquid oxygen thermos can be added		●	●		■	■	Require special infrastructure and piped lines inside health facility
	Airway management and intubation	Laryngoscope, fibre optic, diameter 28 mm (with blades)			●		■	■	Option 1 – to be chosen by the clinician
		Videolaryngoscope (with blades and accessories)			●		■	■	Option 2 – to be chosen by the clinician according to training skills and infrastructure capabilities
	Mechanical ventilation To perform invasive ventilation requires trained staff	Ventilator for ICU, for adult and paediatric (with accessories)			●			■	Option 1 – two sub-options depending of the oxygen inlet (only high pressure or both high and low pressure)
		Ventilator for transport, for adult and paediatric (with accessories)			●		■	■	Option 2 – transport ventilator
		Ventilator for sub-acute care, for adult and paediatric (with accessories)			●		■	■	Option 3 – sub-acute care ventilator (mainly non-invasive but can provide invasive ventilation)

World Health Organization

WHO/2020-nCoV/MedDev/TS/OZT.V1 09/04/20

Priority Medical Devices in the context of COVID-19

A. Medical Devices for Case Management

tive

st 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 nt 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 ologies listed are for the interventions and should be adapted to the health care workforce, infrastructure and technological resources available.

t Audience

locument 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 egulatory 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.

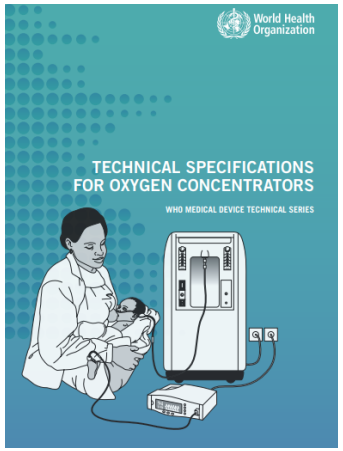
derations

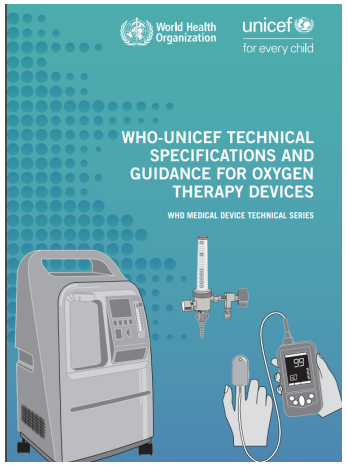
assessment of the health facility is required prior to choosing equipment from the list in order to have a fully functional unit. For more details consult the technical specifications per equipment.
essories and consumables for starting operation are not disaggregated in this list. They should be provided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

Specifications techniques pour le approvisionement





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

Interim guidance

15 April 2020

World Health Organization

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

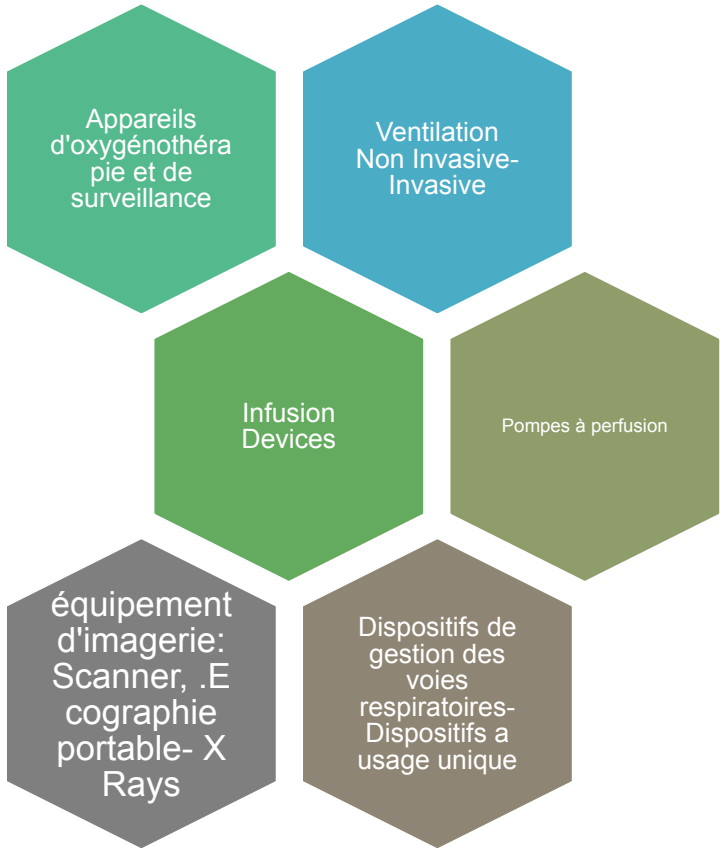
The draft specifications will be integrated in a single publication along with other sets that are being updated.

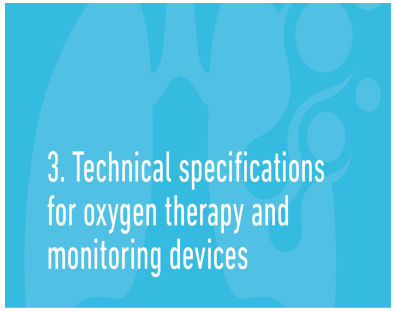
3. Technical specifications for oxygen therapy and monitoring devices

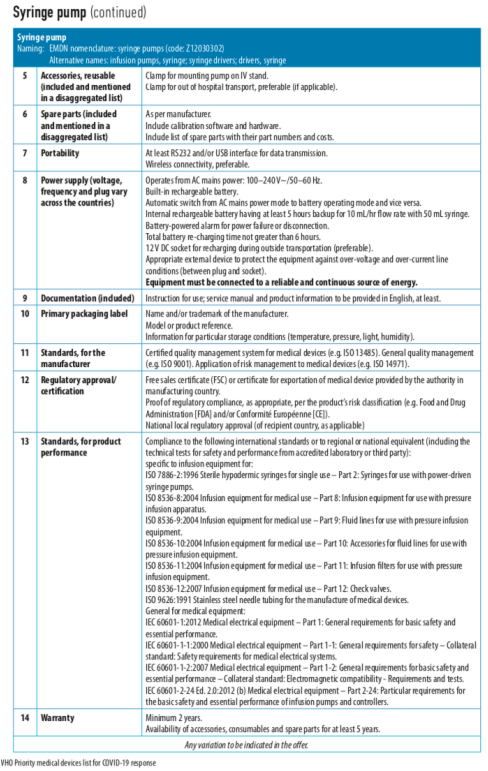
oxygen source devices – oxygen concentrator, oxygen cylinder; oxygen delivery devices – nasal oxygen cannula with prongs, mask with reservoir bag, Venturi mask; devices for oxygen regulation and conditioning – flowmeter Thorpe tube, flow splitter, non-heated bubble humidifier, tubing (for medical gases); 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)

Specifications techniques pour le approvisionement

DISPONIBLE BIENTÔT







Syringe pump (continued)

Syringe pump Naming: EMDN nomenclature: syringe pumps (code: Z12030302) Alternative names: infusion pumps, syringe; syringe drivers; drivers, syringe		
5	**Accessories, reusable (included and mentioned in a disaggregated list)**	Clamp for mounting pump on IV stand. Clamp for out of hospital transport, preferable (if applicable).
6	**Spare parts (included and mentioned in a disaggregated list)**	As per manufacturer. Include calibration software and hardware. Include list of spare parts with their part numbers and costs.
7	**Portability**	At least RS232 and/or USB interface for data transmission. Wireless connectivity, preferable.
8	**Power supply (voltage, frequency and plug vary across the countries)**	Operates from AC mains power: 100–240 V~/50–60 Hz. Built-in rechargeable battery. Automatic switch from AC mains power mode to battery operating mode and vice versa. Internal rechargeable battery having at least 5 hours backup for 10 mL/hr flow rate with 50 mL syringe. Battery-powered alarm for power failure or disconnection. Total battery re-charging time not greater than 6 hours. 12 V DC socket for recharging during outside transportation (preferable). Appropriate external device to protect the equipment against over-voltage and over-current line conditions (between plug and socket). **Equipment must be connected to a reliable and continuous source of energy.**
9	**Documentation (included)**	Instruction for use; service manual and product information to be provided in English, at least.
10	**Primary packaging label**	Name and/or trademark of the manufacturer. Model or product reference. Information for particular storage conditions (temperature, pressure, light, humidity).
11	**Standards, for the manufacturer**	Certified quality management system for medical devices (e.g. ISO 13485). General quality management (e.g. ISO 9001). Application of risk management to medical devices (e.g. ISO 14971).
12	**Regulatory approval/ certification**	Free sales certificate (FSC) or certificate for exportation of medical device provided by the authority in manufacturing country. Proof of regulatory compliance, as appropriate, per the product's risk classification (e.g. Food and Drug Administration [FDA] and/or Conformité Européenne [CE]). National local regulatory approval (of recipient country, as applicable)
13	**Standards, for product performance**	Compliance to the following international standards or to regional or national equivalent (including the technical tests for safety and performance from accredited laboratory or third party): specific to infusion equipment for: ISO 7886-2:1996 Sterile hypodermic syringes for single use – Part 2: Syringes for use with power-driven syringe pumps. ISO 8536-8:2004 Infusion equipment for medical use – Part 8: Infusion equipment for use with pressure infusion apparatus. ISO 8536-9:2004 Infusion equipment for medical use – Part 9: Fluid lines for use with pressure infusion equipment. ISO 8536-10:2004 Infusion equipment for medical use – Part 10: Accessories for fluid lines for use with pressure infusion equipment. ISO 8536-11:2004 Infusion equipment for medical use – Part 11: Infusion filters for use with pressure infusion equipment. ISO 8536-12:2007 Infusion equipment for medical use – Part 12: Check valves. ISO 9626:1991 Stainless steel needle tubing for the manufacture of medical devices. General for medical equipment: IEC 60601-1:2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance. IEC 60601-1-1:2000 Medical electrical equipment – Part 1-1: General requirements for safety – Collateral standard: Safety requirements for medical electrical systems. IEC 60601-1-2:2007 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility - Requirements and tests. IEC 60601-2-24 Ed. 2.0:2012 (b) Medical electrical equipment – Part 2-24: Particular requirements for the basic safety and essential performance of infusion pumps and controllers.
14	**Warranty**	Minimum 2 years. Availability of accessories, consumables and spare parts for at least 5 years.
Any variation to be indicated in the offer.		

VHO Priority medical devices list for COVID-19 response

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

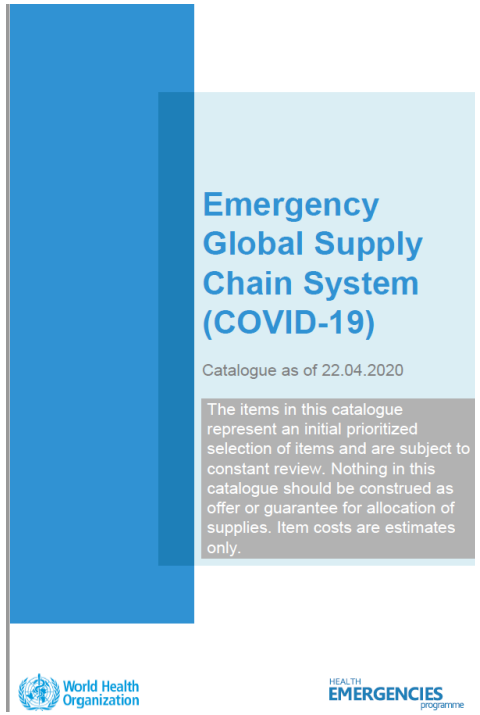
World Health Organization

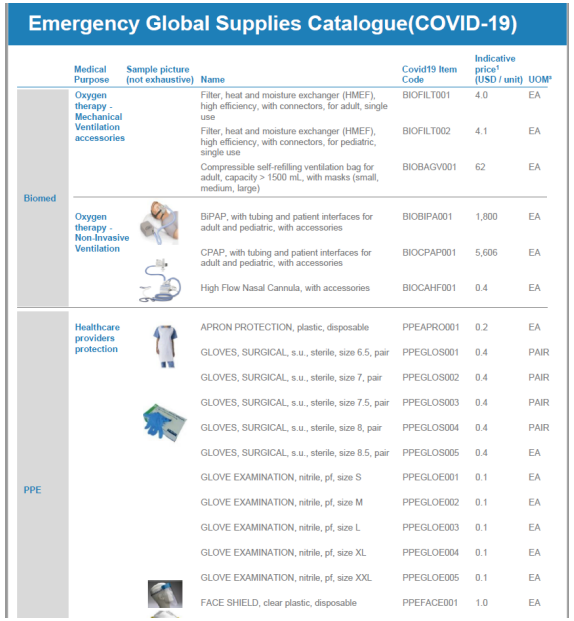
HEALTH EMERGENCIES programme

Catalogue COVID products, include PPE, (for 120 LMI countries) Supply portal COVID-19, includes all priority medical devices: Dx. Tx, PPE

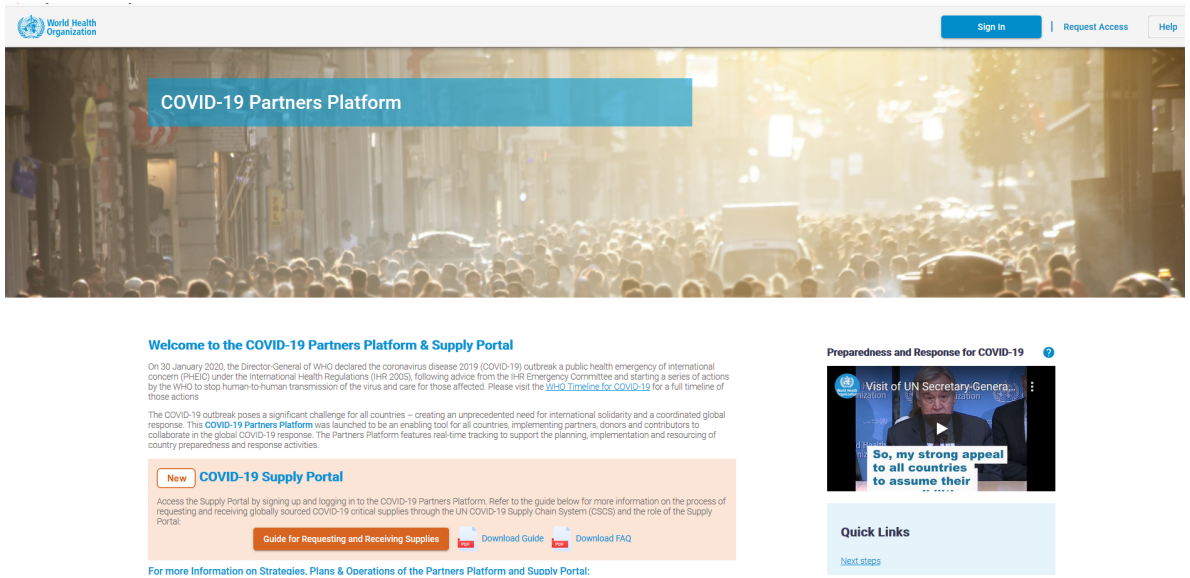
https://covid-19-response.org/

Catalogue



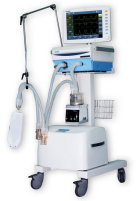


Supply portal



Specification technique

Intensive Care



Transport

Subacute (Non Invasive mais aussi invasive)

Regulation – Normes

Tubine /Compressor

Source d'oxygène haute ou basse pression

Mode de support ventilatoire

FIO2 (Concentration fractionelle de lóxygene dans l,air)

Volume Courant

Alarmes

Power Source

Display Parameters- Afficage

Parameters- Control

Humidification Active-Passive

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Utilisation potentielle dans
UNE CONTEXT COVID 19?

Pour votre considération

Accessoires et consommables	lié à la marque?	Quantification adecuate	Connector - d'oxygène et d'air
Formation/ entraînement	Clinique	Tecnique	WHO Academy Ventilator Training alliance
Disponibilité des pièces de rechange	Au moins 5 ans		
Mise en Place	Configuration des gaz selon les besoins- Dispositif		
Maintenance	Technique (Calibración)	Actualization du Logiciel	

Questions

1. Quantification des consommables: Comment quantifiez-vous les consommables pour l'achat de ventilateurs?
2. Sortie dóxygene et air medicale: Quel est le type le plus courant ou standard dans votre pays?

Merci

Merci