WHO, WIPO, WTO Workshop on innovation in, and Access to, COVID-19 Technologies

World Health Organization

Equitable access for diagnostics, Therapeutics and

other COVID-19 Health Technologies.

Adriana Velazquez, Team Lead Medical devices and in vitro diagnostics,

27 September 2021.

Health technologies includes thousands of types of Medical Devices.

They have no pharmacological action.

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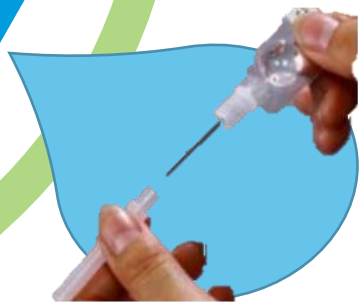
Self –used

Patients

Doctor/ Nurse/ Technician

- Medical Equipment including all imaging
- IVDs: POC & lab testing
- Medical Software CAD
- **Medical Devices**
- Implantable Medical Devices
- Single Use Medical Devices including PPE
- Surgical Instruments



COVID-19 requires many types of medical devices. Biomedical engineers need to ensure technology is safe, effective, good quality and appropriate to the settings.

Personal protective equipment, in vitro diagnostics and medical equipment

https://www.who.int/health-topics/medical-devices#tab=tab_1

Value chain to ensure improved access of safe, quality medical devices,

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Tech transfer

R&D

Assessment

Regulations

Management

Nomenclature

- Academia and
- Medical devices industry

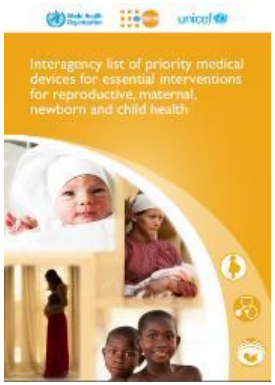
- Health Technology Assessment
- Priority medical devices lists and Essential in vitro diagnostics

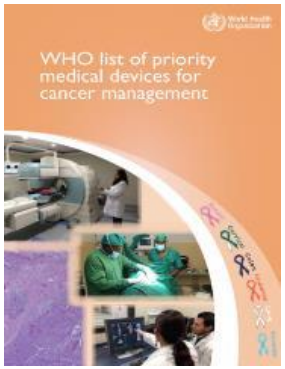
- Regulation process of medical devices
- Lists of approved MD for marketing in country.

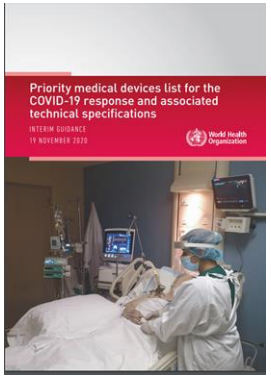
- Technical specifications, procurement and supply
- Installation, inventories, training, maintenance, operations
- Post market surveillance and adverse event report
- Decommissioning, Replacement
- Safe use

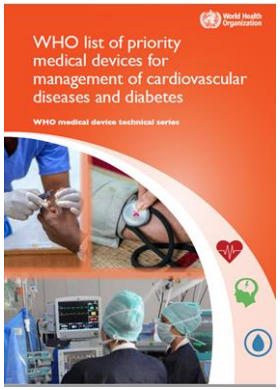
WHO Publications of priority medical devices and essential in vitro diagnostics and related technical specifications of quality and safety to be available, affordable, acceptable, appropriate.

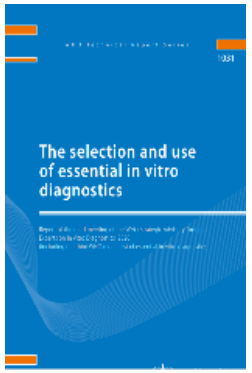
List of essential/ priority



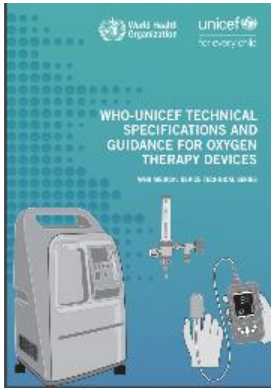


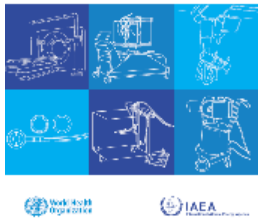






Technical specifications

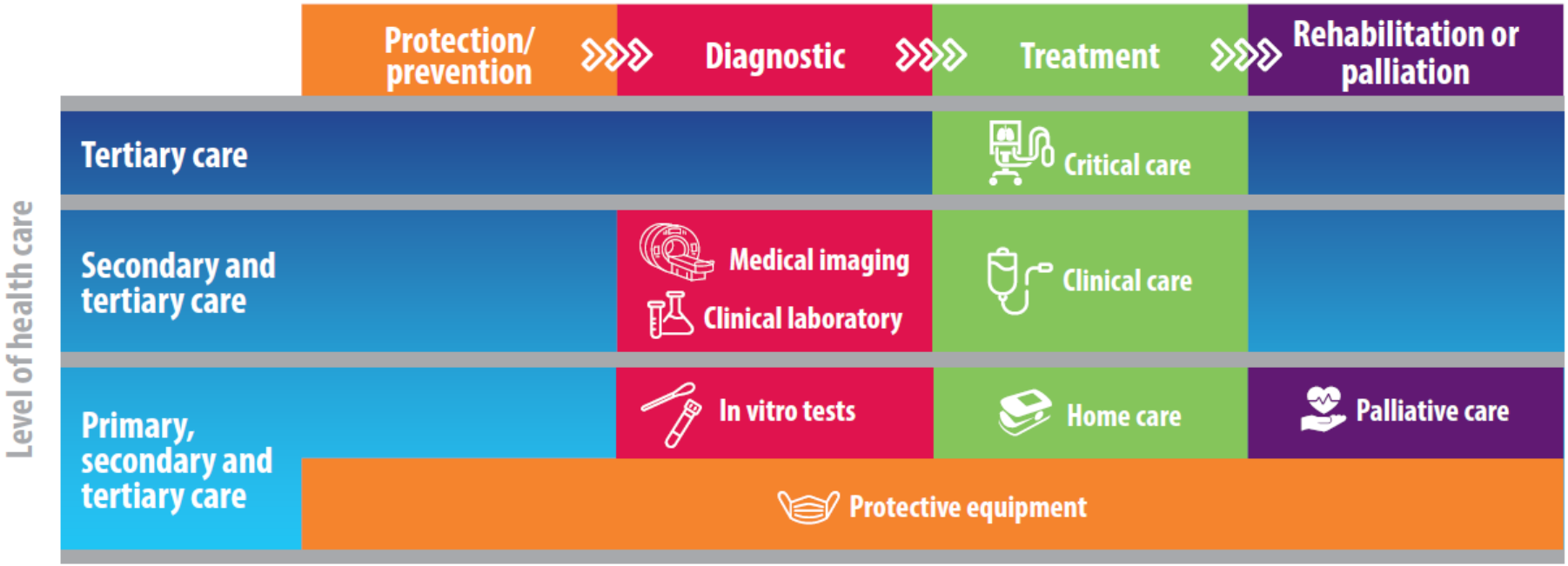




Technical specifications including quality and safety requirements

https://www.who.int/publications/i/item/WHO-2019-nCoV-PPE_specifications-2020.1 and https://www.who.int/publications/i/item/WHO-2019-nCoV-MedDev-TS-O2T.V2

Medical devices including in vitro diagnostics and personal protective equipment are used along the care pathway



Medical equipment should include consumables, accessories, that should comply with local needs and required trained staff

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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	For the latest technical guidance, please refer to: https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance-publications
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
		Video-laryngoscope (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)

Ie. Standards and regulatory compliance

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Bilevel positive airway pressure (BiPAP/BPAP) (adult and paediatric)		
11	**Power supply (voltage, frequency and plug vary across the countries)**	Operates from AC power electric line: 100–240 V AC ± 10% / 50–60 Hz ± 10%. In-built rechargeable battery (preferable); if the equipment does not have an internal battery, an external battery or uninterruptible power supply should be included to provide battery back up in the case of AC power failure. Automatic switch from AC power electric-line mode to battery operating mode and vice versa, if applicable.
12	**Documentation (included)**	Instruction for use; service manual and product information to be provided in English language, at least.
13	**Primary packaging label**	Name and/or trademark of the manufacturer. Model or product reference. Information for particular storage conditions (temperature, pressure, light, humidity).
14	**Standards, for the manufacturer**	Certified quality management system for medical devices (e.g. ISO 13485). Application of risk management to medical devices (e.g. ISO 14971).
15	**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]).
16	**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), for (latest version recommended but compliance to previous standards versions could be accepted): IEC 60601-1 Medical electric equipment – Part 1: General requirements for basic safety and essential performance. IEC 60601-1-2:2014 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests. ISO 80601-2-70 Medical electrical equipment – Part 2-70: Particular requirements for basic safety and essential performance of sleep apnoea breathing therapy equipment. ISO 80601-2-80 Medical electrical equipment – Part 2-80: Particular requirements for basic safety and essential performance of ventilatory support equipment for ventilator insufficiency. ISO 60601-1-1-8 Medical electrical equipment – Part 1-8: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems. If applicable, for the accessories and consumables: ISO 18562-1:2017 Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 1: Evaluation and testing within a risk management process. ISO 80601-2-74:2017 Medical electrical equipment – Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment. ISO 17510:2015 Medical devices – Sleep apnoea breathing therapy – Masks and application accessories.
17	**Warranty**	Minimum 2 years. Availability of accessories, consumables and spare parts for at least 2 years.
Any variation to be indicated in the offer.		

LMIC receiving TECH TRANSFER require: Local regulation, production, testing, maintenance and training.

Innovation

Tech transfer: Local production , local testing, local supply

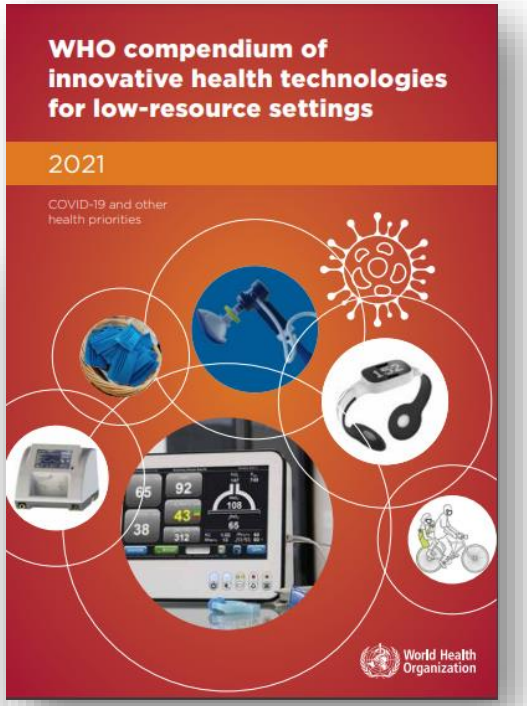
Regulation approvals

HTM: Assessments needs and supply

HTA: Priority medical devices

WHO Compendium of Innovative Technologies for Low Resource Settings

searching for tech that can be transferred to LMIC



https://www.who.int/activities/accelerating-impact-for-innovations-for-health

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Evaluation for the compendium of innovative technologies for Low resource settings.

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Assessments

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Ventilator, with extended battery time

Country of origin | United States of America
Primary function | Supporting or sustaining life
Category | Medical device

Commercial information

List price (USD): $15,000[1]
Year of commercialization: 2018[2]
Number of units distributed: 101-1,000[3]
Currently marketed in: Sub-Saharan Africa and Southeast Asia[2]
Brand: Gradian Health Systems[1]
Model: Gradian CCV[1]

Health problem addressed

Mechanical ventilators, when operated by a trained medical professional, provide respiratory support to patients who cannot breathe or require assistance to breathe due to illnesses, such as pneumonia, COPD, and COVID-19, trauma, or other complications. They are essential to sustaining life while patients undergo treatment or until treatment can be accessed. A major factor inhibiting access is inadequate infrastructure to support delivery of critical care in facilities and during transport.[1]

Product description

A comprehensive care ventilator can assist or replace the breathing of a patient requiring respiratory support, in any care setting. Gas is drawn from compressed sources of oxygen and medical air, or entrained from room air by an in-built compressor, and mixed by an integrated gas blender to an oxygen concentration prescribed by the care provider. A closed-loop control system regulates the delivery of breath through a breathing circuit, according to the prescribed mode and settings.[1]

Product details

Accessories: Rolling stand, bag of 3 extra filters, kit – handle, swivel hooks, stand mount, external battery, extra exhalation valve, reusable adult and pediatric breathing circuits, SpO_2 monitor, HMEs, test lung, air and oxygen hoses, power cords, reservoir cylinder, humidifier and accessories.[1]
Consumables: It is recommended that the device be used with bacterial/viral filters in order to avoid cross-contamination. When using the device without an active humidifier, a Heat and Moisture Exchanging Filter (HMEF) is recommended.[1]
Other required products: Patient interfaces such as endotracheal tubes and non-invasive ventilation masks are required to use the device. The device should only be used in the presence of and in conjunction with other monitoring and life-supporting equipment required for administration of adequate critical care.[1]
Warranty duration: 3 years[1]
Lifetime: 10-15 years[1]

Contact: Lina Sayed | Email: lsayed@gradianhealth.org | Telephone: +1 917 685 4066 | Website: https://bit.ly/37wRM1H

1 Reported by manufacturer on 14 August 2020
2 Reported by manufacturer on 8 January 2020
3 Reported by manufacturer on 15 December 2020

WHO ASSESSMENT

WHO specification comparison

This device partially complies with the WHO technical specifications for transport ventilators.

Compliant relevant characteristics: There is the option for using external low-pressure oxygen (approx. 20 psi) as a source. However, the instructions of use indicate that "Proper tidal volumes may not be provided with a gas source not providing a minimum of 80 LPM at 280 kPa (40 psi)". The device includes non-invasive ventilation, an oxygen conservation feature, and IP22 degree of protection. The device can be used continuously in battery operating mode with standard ventilation for up to 21 hours total (7 hours on internal battery and 14 hours on external battery).

Non-compliant: The oxygen-air mixture accuracy is 12% as opposed to the WHO specification of 4%. The inspiratory pressure is 15 - 55 cmH2O instead of the WHO specified range of 0-40 cmH2O. The device does not have minute volume alarms and single limb circuits cannot be connected. Additionally, the device does not measure leak percentage or display/monitor minute volume and spontaneous minute volume. The display shows numerical indicators but no waveforms for all ventilation parameters.

Aspects that could not be verified: Minute volume alarms

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Regulatory assessment

Pre-market assessment	Proceed
Post-market assessment	Proceed
Quality system assessment	Proceed

All WHO requested information and documentation for all three Regulatory and Quality Assessment categories was provided. At the time of this report creation, the product was both EU CE Marked under the MDD and US FDA 510(k) cleared. The regulatory status for the various accessories was provided. The product's manufacturer (Allied Health) has obtained an MDSAP ISO 13485:2016 certificate. Gradian provided all top-level SOPs for their regulatory and quality system responsibilities for the WHO countries. Gradian must also ensure they comply with local country import and pre-market regulations

Ventilator, with

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Technology evidence assessment

Domains	Evidence assessment: Risk/benefit ratio	Evidence assessment: Impact	Innovation
Medical	✗	→	?
Safety	✗	→	?
Economy	✗	!	
Organizational	✗	!	?
Legal	!	!	
Social	!	!	
Ethical	!	!	
Green environment	✗	→	?

During emergencies, the technology has a dual purpose of regular clinic use and deployment. The pod has a continuous power supply and can use solar energy. It is robust and usable during severe weather and on uneven terrains. In terms of deployment, training is required for which video instruction is provided. It is easy to use, maintain, and decontaminate.

Summary

Transferability	→	Technology readiness level	9
Evidence (according to GRADE)	!	Technology evidence assessment	Recommended

Health technology and engineering management

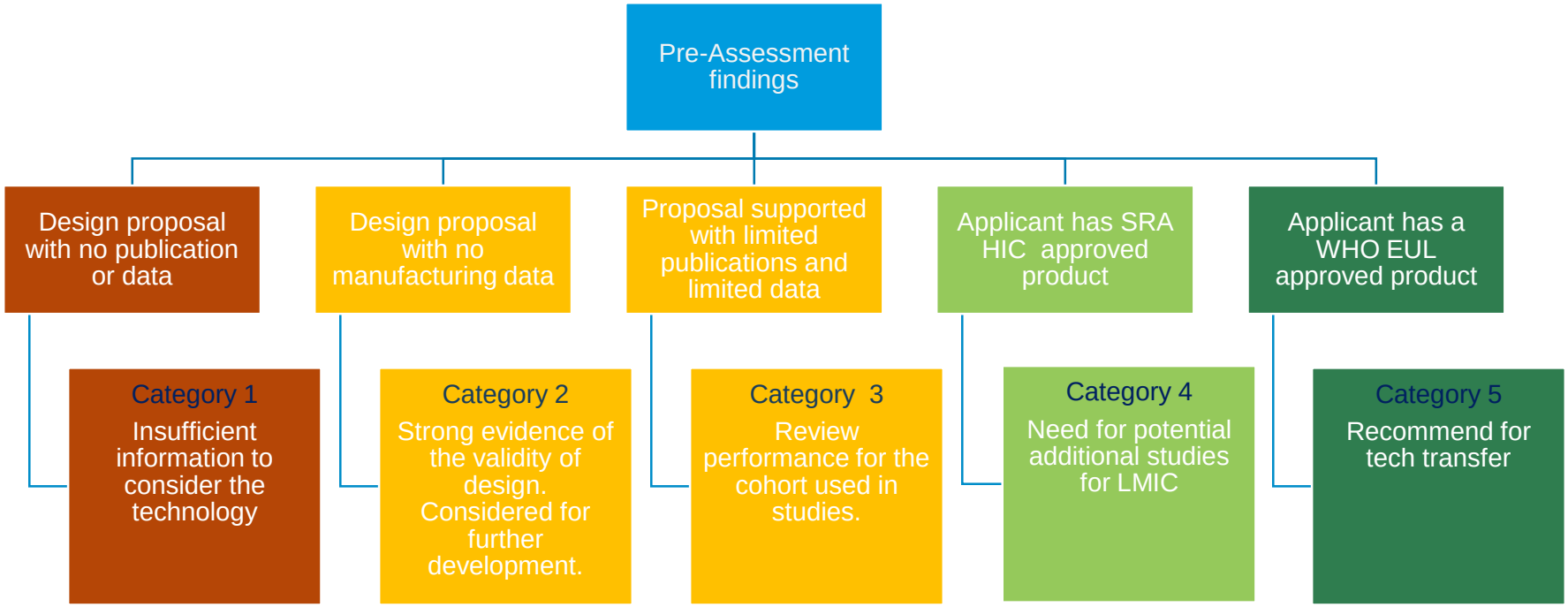
Domains	Appropriateness	Domains	Appropriateness
Durability	→	Ease of maintenance	→
Ease of Use	→	Infrastructure requirements	!
Positive impact on clinical outcomes	!	Local access to sales support	!
Affordability	✗	Local access to technical support	!
Engineering resources minimization	!	Local access to training	!
Cultural and social acceptability	→	Local access to spare parts	!
Environmental conditions	!	Local production	!
Aesthetics	!	Locations of use within target setting	✗
Ease of cleaning	→		

Target setting: Public and home settings

This product is a mobile, deployable facility for providing temporary clinical services. It is durable, easy to set up, use and maintain, and socially and culturally acceptable. The facility requires utilities such as electricity and compressed air in order to support various equipment. It is not clear if this product provides significant innovation over similar commercially available products.

Deployable facility, for emergencies, shipping container based

C-TAP
Before tech transfer need to know the level of the technology through Pre-Assessment Decision Outcomes



https://www.who.int/initiatives/covid-19-technology-access-pool

Working together with biomedical engineers to solve local, regional and global health problems

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Goal: To ensure access to medical devices that will support better patient care.

It is not about the technology but about the patient behind the technology

Different settings, where we can make a difference

Gracias
Thank you
Merci
Shokran
Xie xie
Spasiva

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https://www.who.int/health-topics/medical-devices#tab=tab_1

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