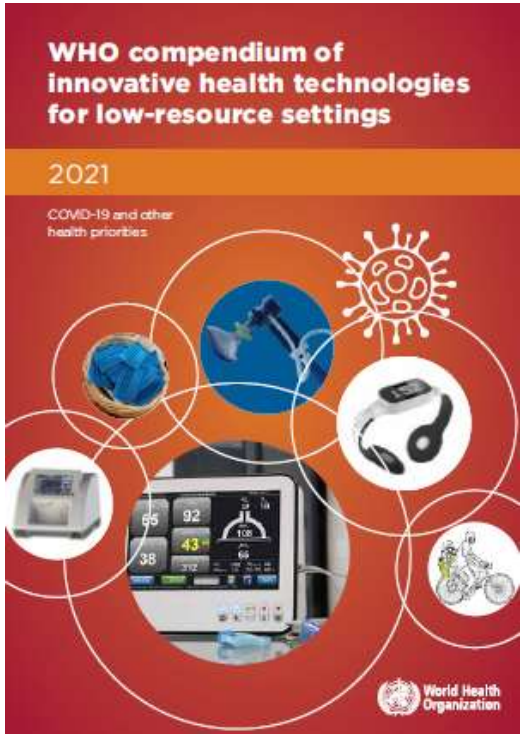
Innovation Medical Devices

Compendium of Innovative Health Technologies COVID-19 edition

World Health Organization



Adriana Velázquez Berumen- WHO

Agenda

31st August, 16:00 to 17:30 hrs CEST

Webinar 2021 Compendium of innovative technologies for low resource settings

Welcome session	Mariangela Simao, ADG, WHO
2021 Compendium of innovative tech	Adriana Velazquez, WHO
Technology assessments	Gabriela Jimenez, Caroline Soyars, Cesar Burgi, Hans Peter Dauben, Inaki Gutierrez, Yadin David and Tom Judd and collaborators
Interdisciplinary work and innovation	Janet Diaz, Louise Agersnap,WHO
Case studies: Oxygen, Ventilator and PPE	Innovators, funders, regional colleagues, WHO staff
C-TAP and dissemination of compendium	Erika Duenas, WHO Mariela Machado, E4C

Goal 3. Good health and well being
Goal 9. Innovation

World Health Organization

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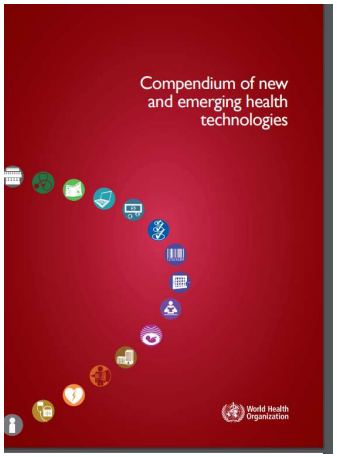
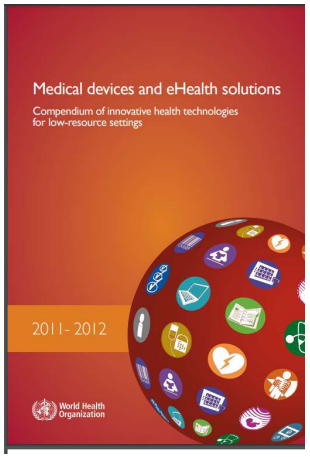
13th WHO Global Programme of Work:

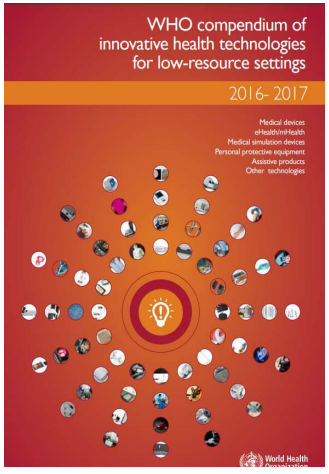
"Triple Billion" targets

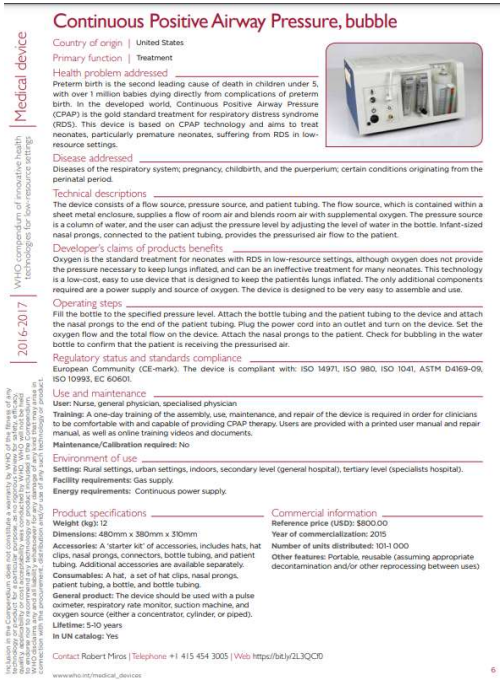
WHO Assessing innovative technologies for use in low resource settings, since 2010

Formats and process is more stringent every year . Prototypes considered









List of compendia and downloads

Name of the publication	Year of publication	Number of Technologies per book	Number of Downloads per book (accessed 25.08.2021)
Compendium of new and emerging health technologies	2011	44	10,310
Compendium of innovative health technologies for low-resource settings	2014	86	11,235
WHO compendium of innovative health technologies for low resource settings, 2011-2014	2015	119	22,312
WHO compendium of innovative health technologies for low-resource settings, 2016- 2017	2018	71	12,913
WHO compendium of innovative health technologies for low-resource settings, 2021. COVID-19 and other health priorities.	2021	24	
	TOTAL	344	56,770

To ensure improved access of safe, quality medical devices for COVID-19

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R&D

- Academia - Innovation
- Industry production

Regulations

- Regulatory clearance, conformity

Assessment (HTA)

- Priority medical devices list for COVID-19, or others

Management

- Procurement
- Safe use
- Post market surveillance
- Decommissioning

Sequence of process to ensure access to appropriate and safe health technologies

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Health technology regulation

Safety
performance
and quality

Health technology assessment

Clinical
effectiveness
Ethics
Social issues
Organizational

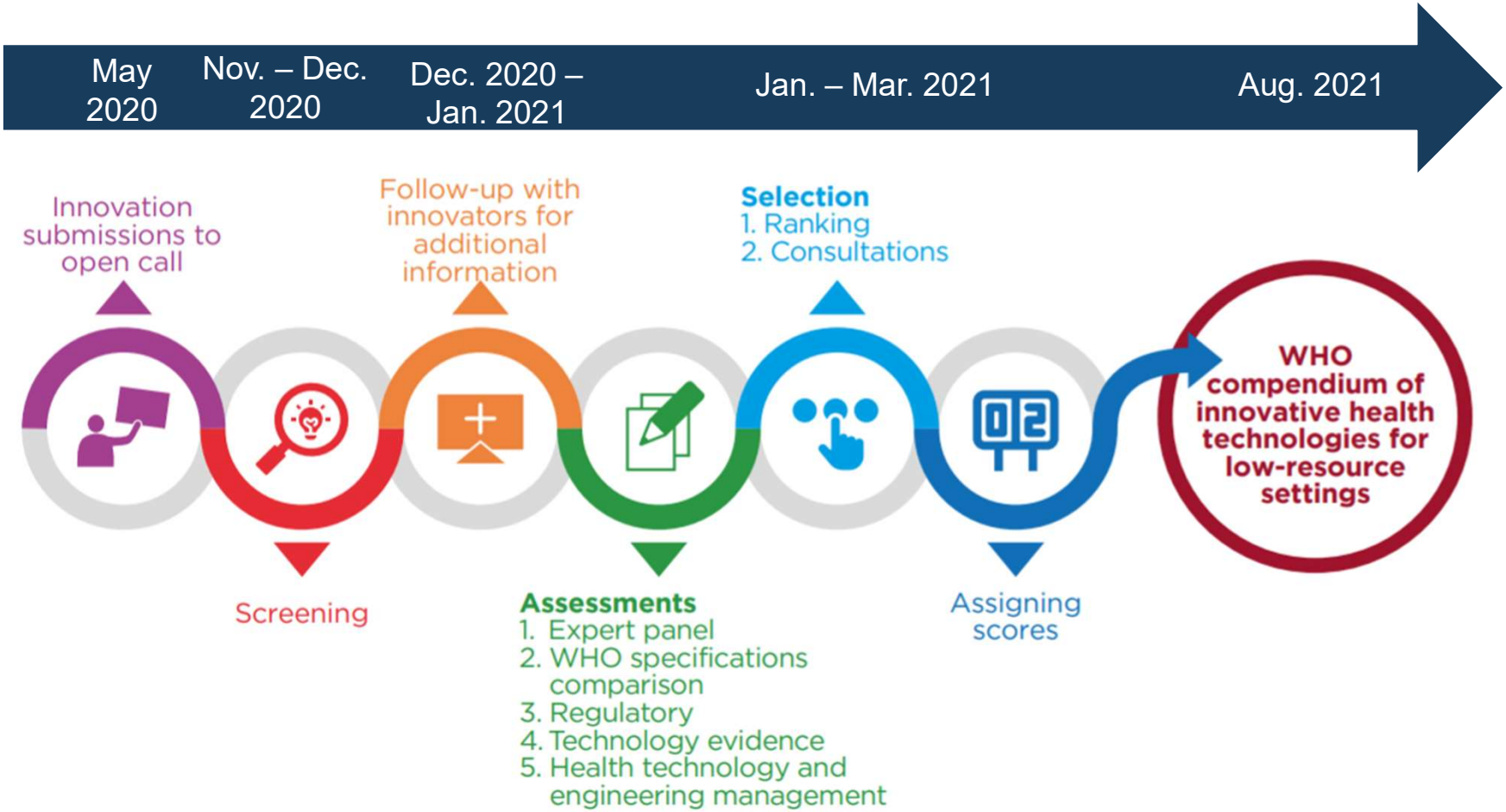
Health technology management

Procurement
Selection
Training
Use

2020 On line submission format for assessment includes: 5 sections:

Documents need to be submitted for review

Evaluation Process and Timeline



Submissions to the call

42 submissions out of ≈280 that were considered to have relevant details after screening and were contacted for additional information

33 complete submissions after innovator follow-up that underwent full assessment

24 products selected to be in the compendium

9 prototypes

15 commercially available

Innovator information per submission

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WHO compendium of innovative health technologies for low-resource settings

COMMERCIALLY AVAILABLE | 2021 |

s of any technology or product
lity or cost acceptability was
nology or product included in
of any kind that may arise in
or product.

Newborn heart rate meter

Country of origin | Norway

Primary function | Monitoring

Commercial information

List price (USD)[1]: $150
Year of commercialization[1]: 2018
Number of units distributed[1]: 101-1,000
Currently marketed in[2]: Europe, Australia, New Zealand, and Tanzania
Brand[1]: Laerdal Medical AS
Model[1]: NeoBeat Newborn Heart Rate Meter

Health problem addressed[3]

An estimated 10 million newborns are born every year that are not breathing and require resuscitation. Due to insufficient oxygenation of the newborn, 0.7 million newborns died and 1.15 million newborns suffered permanent brain injury. To address this issue, there is a need for immediate provision of newborn's heart rate to support health care workers in performing effective ventilations, by application of a reusable ECG heart rate meter onto the wet newborn's chest and quick continuous display of the newborn's ECG heartrate.

Product description[3]

ECG signals from newborn's wet chest are picked up by dry stainless-steel electrodes that are embedded in one spring-elastic plastic buckle. A housing includes a rechargeable battery, signals processor, and a bright-LED display.

Product details[3]

Accessories[1]: USB 5V power supply (charger), AC plug kit to fit various global electrical systems
Warranty Duration[1]: 1 year
Lifetime[1]: 2-5 years
Energy requirements[4]: Continuous power supply (AC powered, 110V/220V, 5W)
Facility requirements[4]: Disinfection with 70% ethanols

Contact: Frode Liland | Email frode.liland@laerdal.com | Telephone +47 91106093 | Web https://bit.ly/3hzpDFh

[1] Reported by manufacturer on 5 May 2020 | [2] Reported by manufacturer on 7 Jan 2020 | [3] Reported by manufacturer on 18 Jan 2020. | [4] Reported by manufacturer on 20 Jan 2020.

Disclaimer and Regulatory Assessment

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WHO specification comparison

At the time of report creation, WHO technical specifications are not available to compare against for this type of technology.

Regulatory assessment

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

Some WHO requested information and documentation for all three Regulatory and Quality Assessment categories is absent. Therefore, a thorough review of this product was not possible at this time. Laerdal has obtained an EU MDD CE Mark for the AS NeoBeat Newborn Heart Rate Meter. The regulatory status for the various accessories is currently unclear. Laerdal has obtained an ISO 13485:2016 certificate. Laerdal must also ensure they comply with local country import and pre-market regulations.

- A regulatory & quality system requirements checklist was created for each device type
- EU & US device regulatory & quality system requirements were used as benchmarks for all devices, to ensure consistency & objectivity for each device assessment

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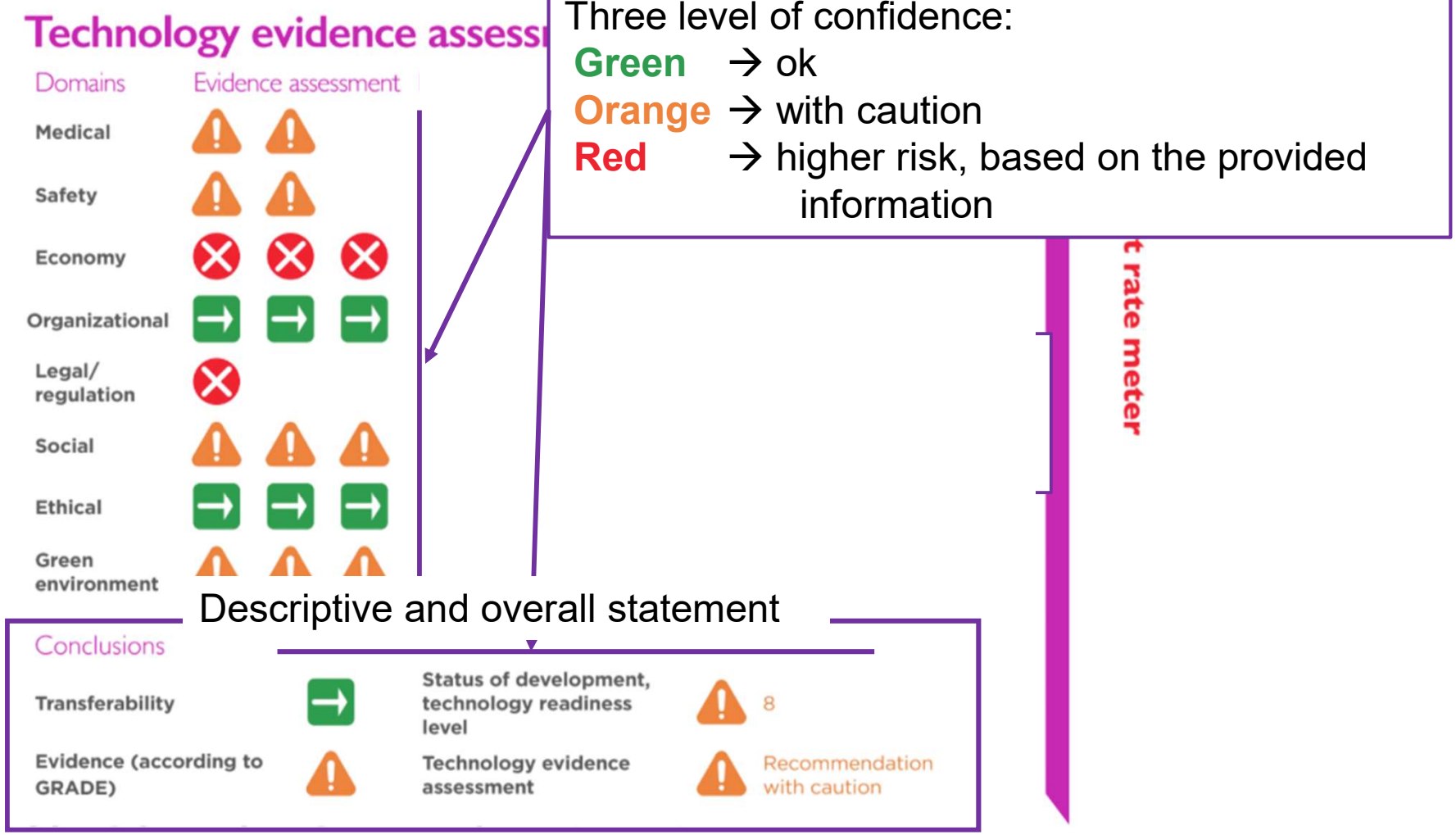
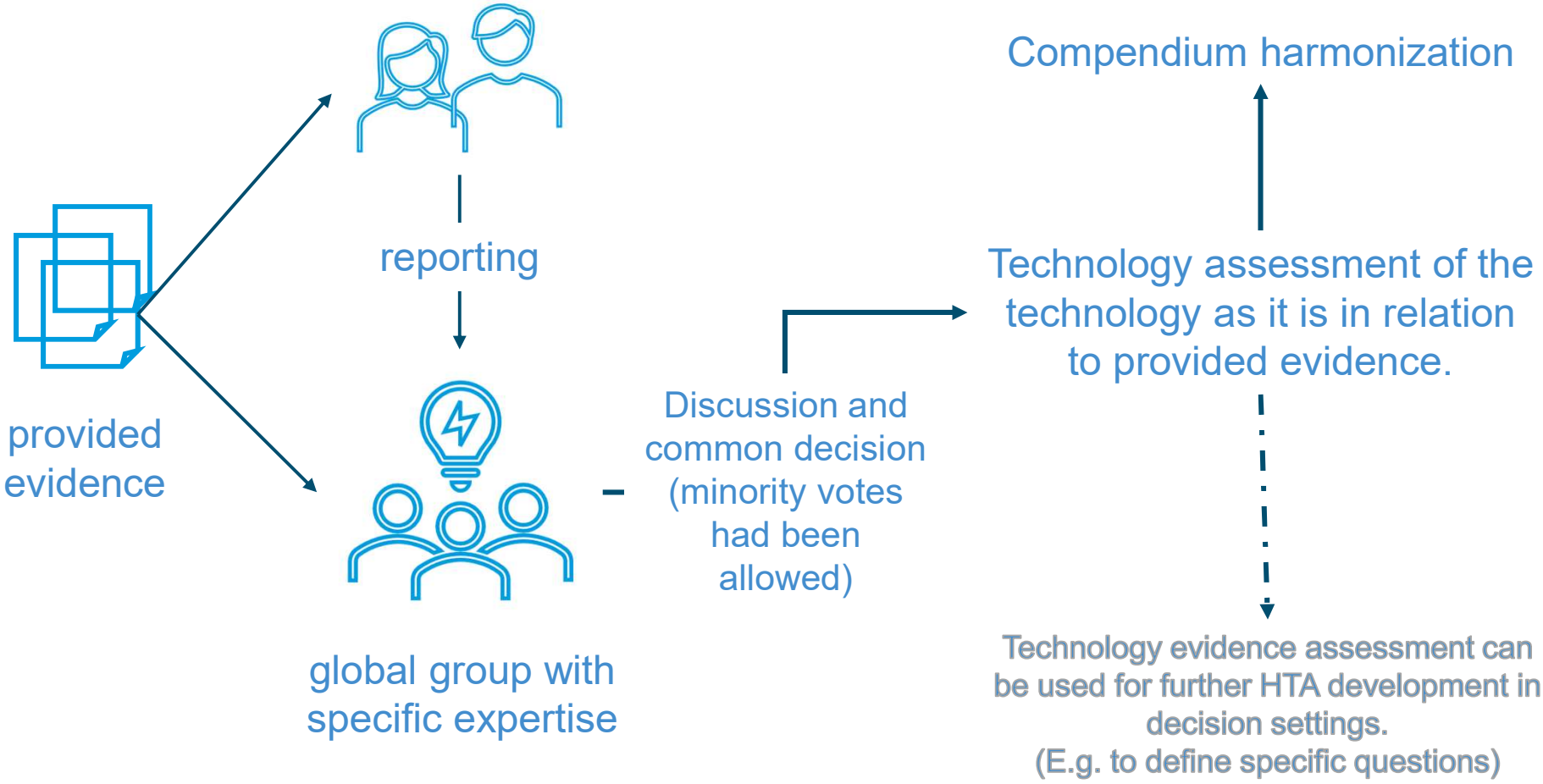


Technology evidence assessment



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Health technology and engineering management

	Appropriateness for low-resource settings		Appropriateness for low-resource settings
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:
Neonatal ICU

This product is a heart monitor for newborns. It is applied to the newborn's chest with an elastic spring and buckle and dry stainless-steel electrodes make contact with the skin. A housing with a rechargeable battery, signal processor, and LED display is on the center of the buckle. The device includes a charging stand. The device must be attached to the newborn skin up to two minutes in order for the pulse oximetry readings to appear. Although the product is easy to apply, there are concerns about pressure and skin irritation on the fragile newborn chest due to the long duration of use. The manufacturer suggests that the product can assist during emergencies, however, it would obstruct a chest x-ray or cardiac resuscitation if urgently needed. The product requires minimal maintenance, is easy to cleaning, and seems to be well supported by sales and technical staff.

Health technology & engineering management

Field-Based Evaluation

- Purpose: To review and assess technological attributes and engineering management of Health Technologies submitted to WHO to address needs of low resource settings (LRS).
- Methodology: Through collaboration between the IFMBE Clinical Engineering Division (CED) and the Global Clinical Engineering Alliance (GCEA), we engaged our international network of field-based practitioners, mostly from LRS. The group validated the Survey tool and participated in grading the attributes shown on the previous slide.
- Results: Data collection evidence included multiple responses for each of the submissions and validation through senior Clinical Engineering experts. The data included 102 inputs from 50 practitioners in 37 countries. This is the first WHO Innovation Compendium with the benefits from Engineering field-based Evaluation.

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Key for Icons

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Regulatory assessment	Proceed	Proceed with caution	Not acceptable
Technology evidence assessment - risk/ benefit ratio	High	Medium	Low
Technology evidence assessment - Impact	High	Medium	Low
Innovation		Innovation aspect in the domain	
Summary:			
Transferability	Fully transferable	Partly transferable	Not transferable
Evidence (according to GRADE)	High	Medium	Low
Technology evidence assessment	Recommended	Recommend with caution	Not recommended
Health technology and engineering management	High appropriate-ness for low-resource settings	Moderate appropri-ateness for low-resource settings	Low appro-priateness for low-resource setting

N/A

Not Applicable

Hospitals

Clinic

Health care facilities

Public and home settings

Patient transport

Health care systems

Health care providers

Neonatal care

Neonatal ICU

Screening tool at public and clinical sites

ICU

Radiology

2021 Innovative Technologies

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Panel 1: Oxygen innovations

OXYGEN INNOVATIONS

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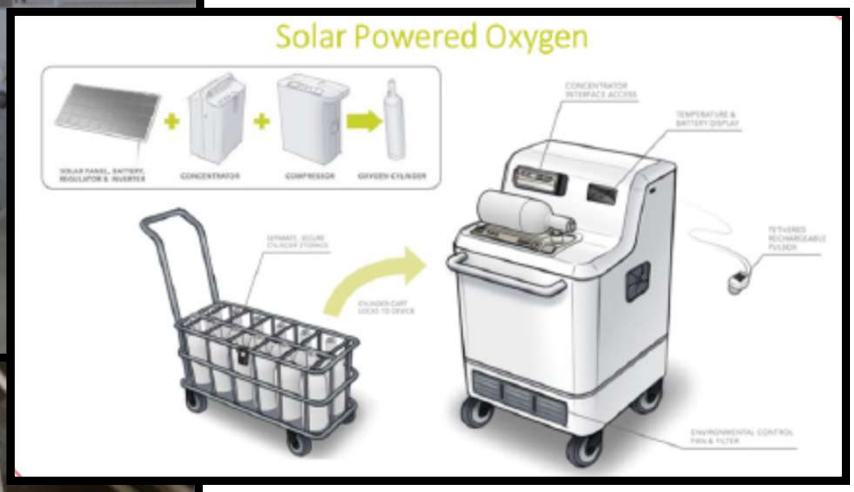


Innovation in health begins and ends with a life saved…

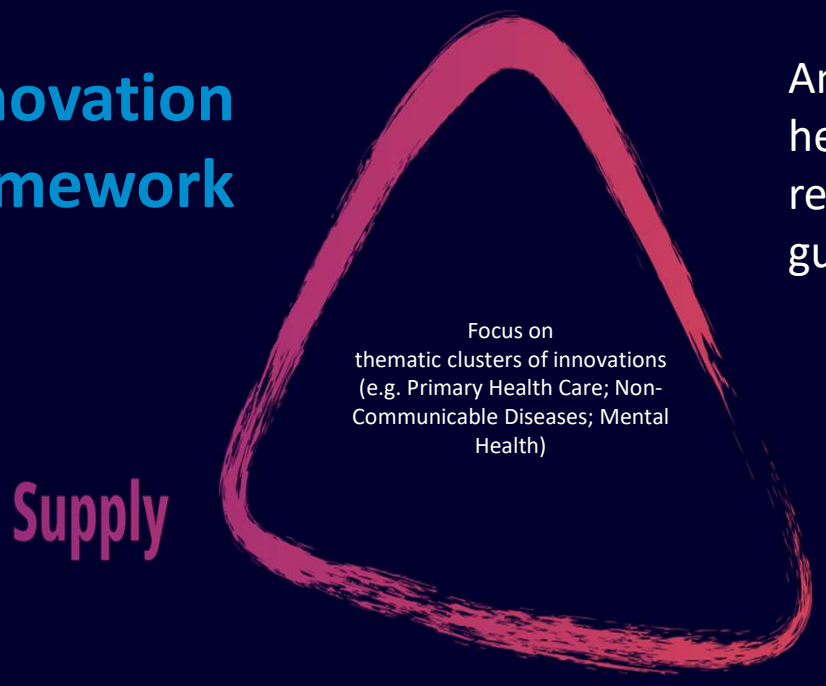
This child is receiving oxygen through a solar-powered oxygen concentrator – an innovative solution that can save lives in places with frequent power cuts, such as this hospital in Somalia

Key facts:

- Installed thanks to a new WHO Innovation Scaling framework – a WHO facilitated multi-partner approach to innovation scaling
- Since then many more lives have been saved (and counting)
- Pneumonia kills 800,000 people each year. 20-40% could be saved with medical oxygen
- COVID19 has accelerated global demand for oxygen
- Barriers exist for conventional oxygen systems

Innovation
Accelerate impact in health
World Health Organization

WHO Innovation Scaling Framework



An approach to matching country health demands with supply of ready-to-scale innovations, guided by assessment

Lessons learned from Innovation Matchmaking & Scaling

- Demand drives scaling
- WHO can add value by ‘unlocking demand’
- WHO and UN Country Reps → the ‘salesforce’
- Assessment – a double edged sword
- Heavy process – need match-making platform
- Supply pipeline: Wholesale approach
- Understand and engage audiences
- Horizontal scaling through peer-to-peer learning

Scaling

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Panel 2: Innovative ventilators

INNOVATIVE VENTILATORS

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Gradian Health Systems

At Gradian, we believe medical equipment is a catalyst — not a sole solution — for overcoming inequitable access to healthcare service. The impact of medical equipment on patient outcomes can only be realized with robust, comprehensive, and sustained technical support and training.

WHO WE ARE

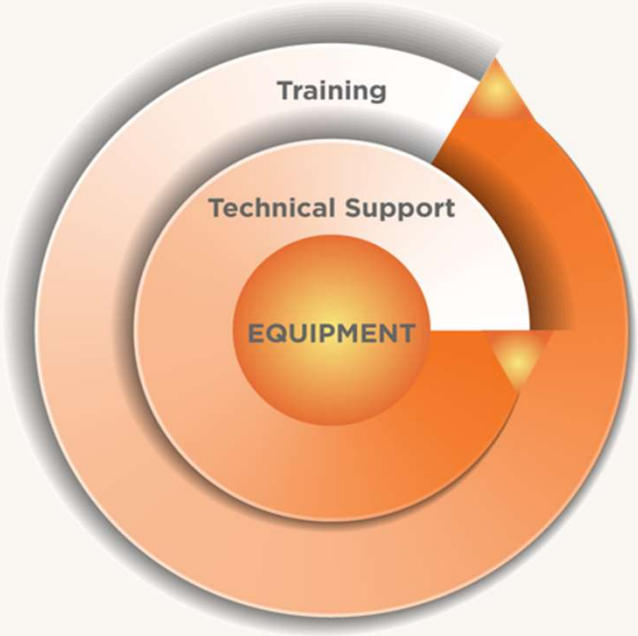
Nonprofit medical technology company focused on resource-constrained settings

WHAT DO WE

Develop, distribute & sustain world-class medical technology with local customer service & user-centered training

WHY WE DO IT

Every patient deserves access to high-quality healthcare, which means every provider needs access to high-quality medical technology and training



Equipment | Gradian CCV

The Gradian CCV offers management options for post-op, intensive, critical care, and facilitates ventilation during transport within and between hospitals

Portability Features
Bed hooks, handle, and shoulder strap for convenient use and transportation in any setting

Fully-Automatic Ventilator
Pneumatically-driven mechanical ventilator with 7 hours of rechargeable internal battery

Internal Compressor
Built-in air compressor that uses room air to supplement existing oxygen sources or ventilate patients when medical oxygen is unavailable

Oxygen Reservoir
Reservoir enabling use with low-flow oxygen sources like a concentrator or flowmeter

External Battery
Hot-swappable, rugged battery providing additional 14 hours of operating time (up to 21 hours in total)

Technical Support | Proactive & In-person

Gradian has extensive service operations infrastructure — managed from our service and operations hub in Nairobi, Kenya — to best better serve our customers where they are

- 3-year service and spare parts warranty with every purchase carried out by Gradian certified engineers and technicians
- On-site preventive maintenance annually and corrective maintenance, as needed
- Spare parts stored locally for rapid deployment
- 24/7 customer service for remote troubleshooting via WhatsApp, phone, email

Training | Building Capacity for the Long-Term

Trainings are designed and led by teams of certified local clinical trainers with deep experience in the specialties of anesthesia and critical care medicine and are:

- ✓ **User centric**
- ✓ **Rapid-cycle, deliberate practice**
- ✓ **Modular**
- ✓ **Accessible**
- ✓ **Locally contextualized**

Since the start of COVID-19, Gradian has supported COVID-19 responses in Kenya, Uganda, Nepal, Sierra Leone, Tanzania, Zambia, and Benin among other countries with Gradian CCVs as well as the training of more than 2,000 healthcare providers.

Training | Uganda Spotlight

The Government of Uganda has taken on an ambitious effort to increase critical care capacity by fully equipping ICUs at all regional referral hospitals across the nation – as such, Gradian is working with the Association of Anesthesiologists of Uganda and Joint Medical Store to support nationwide scale up of ventilation capabilities

- 109 CCVS installed at 17 hospitals representing all regional referral hospitals in the country
- 698 clinical providers trained, amounting to 850+ hours of training

"In every hospital that we've trained, we've covered the basics of critical care or the fundamentals of critical care. Things to do with definition of what a critical care bed is, what a critical patient needs, and different interventions and therapies that can be provided in a critical care unit. We've also trained on therapies like oxygen therapy, fluid therapy."

- Dr. Fred Bulamba

World Health Organization

Panel 3: personal protective equipment (PPE)

INNOVATIVE PPE

World Health Organization

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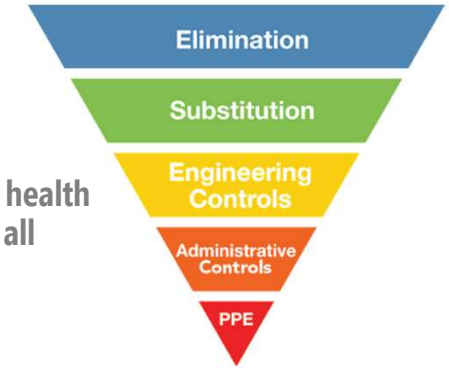
Personal Protective Equipment

Innovations in the context of COVID-19

Madison Moon
WHO Health Emergencies Programme
Infection Prevention and Control

WHO Compendium of Innovative Technologies for Low-Resource Settings Launch
31 August 2021

An Animated HD PowerP



- In the context of COVID-19 the use of PPE (and masks in particular) has increased substantially, leading to global shortages in availability of PPE
- In most instances, the use of masks has been elevated to be a primary control strategy in both health care and community settings, as an inability to identify and isolate all suspected cases renders all persons as potential cases
- Environmental and engineering controls remain extremely important, particularly in instances where there is a need to ration personal protective equipment (including extended use, alternatives, reprocessing). PPE conservation carries risk, as deviations from standard and transmission-based precautions can result in widespread surface contamination and self-contamination
- In health care settings, any strategy to maintain hygienic care conditions must contend with the wide variety of possible organisms that transmit in health care. Although it is relatively easy to kill SARS-CoV-2 with standard cleaning and disinfection practices; difficult to ensure full decontamination of items (including PPE) potentially contaminated with C. difficile, norovirus, C. auris, etc.

The PPE ecosystem needs to change

- Single use PPE contributes to enormous generation of waste (both infectious and normative waste streams)
- Lack of focused research attention on comfort, harms, effectiveness, and self-contamination risks despite being relied upon daily by millions of health workers worldwide
- There are now more untrained users of PPE and masks than ever before, often well-intended but inconsistently or incorrectly implemented
- Reliance on global market rather than local production and testing capacities creates disparities in cost and availability
- Beyond COVID-19, antimicrobial resistance is increasing, additional respiratory infection variants are being identified, occasional concerning cases of viral hemorrhagic fever occurring with smaller intervals between cases. PPE must meet the challenges of today and tomorrow.

RESOURCES ON PERSONAL PROTECTIVE EQUIPMENT IN THE CONTEXT OF COVID-19

World Health Organization

- Rational use of personal protective equipment for coronavirus disease (COVID-19) and considerations during severe shortages: https://www.who.int/publications/i/item/rational-use-of-personal-protective-equipment-for-coronavirus-disease-(covid-19)-and-considerations-during-severe-shortages
- Mask use in the context of COVID-19:https://www.who.int/publications/i/item/advice-on-the-use-of-masks-in-the-community-during-home-care-and-in-healthcare-settings-in-the-context-of-the-novel-coronavirus-(2019-ncov)-outbreak
- Technical specifications of personal protective equipment for COVID-19: https://www.who.int/publications/i/item/WHO-2019-nCoV-PPE_specifications-2020.1
- Infection prevention and control during health care when coronavirus disease (COVID-19) is suspected or confirmed: https://www.who.int/publications/i/item/WHO-2019-nCoV-IPC-2021.1
- COVID-19 Essential Supplies Forecasting Tool: https://www.who.int/publications/i/item/WHO-2019-nCoV-Tools-Essential_forecasting-Overview-2020.1
- COVID-19 Supply Chain System: https://www.who.int/emergencies/diseases/novel-coronavirus-2019/covid-19-operations
- OpenWHO Training: Standard precautions: The role of personal protective equipment (PPE): https://openwho.org/courses/IPC-SP-PPE-EN
- WHO Academy: Augmented reality personal protective equipment training (AR PPE): https://www.who.int/about/who-academy/the-who-academy-s-covid-19-mobile-learning-app#:~:text=New!,while%20they%20care%20for%20patients

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C-TAP (Technology Access Pool)

C-TAP

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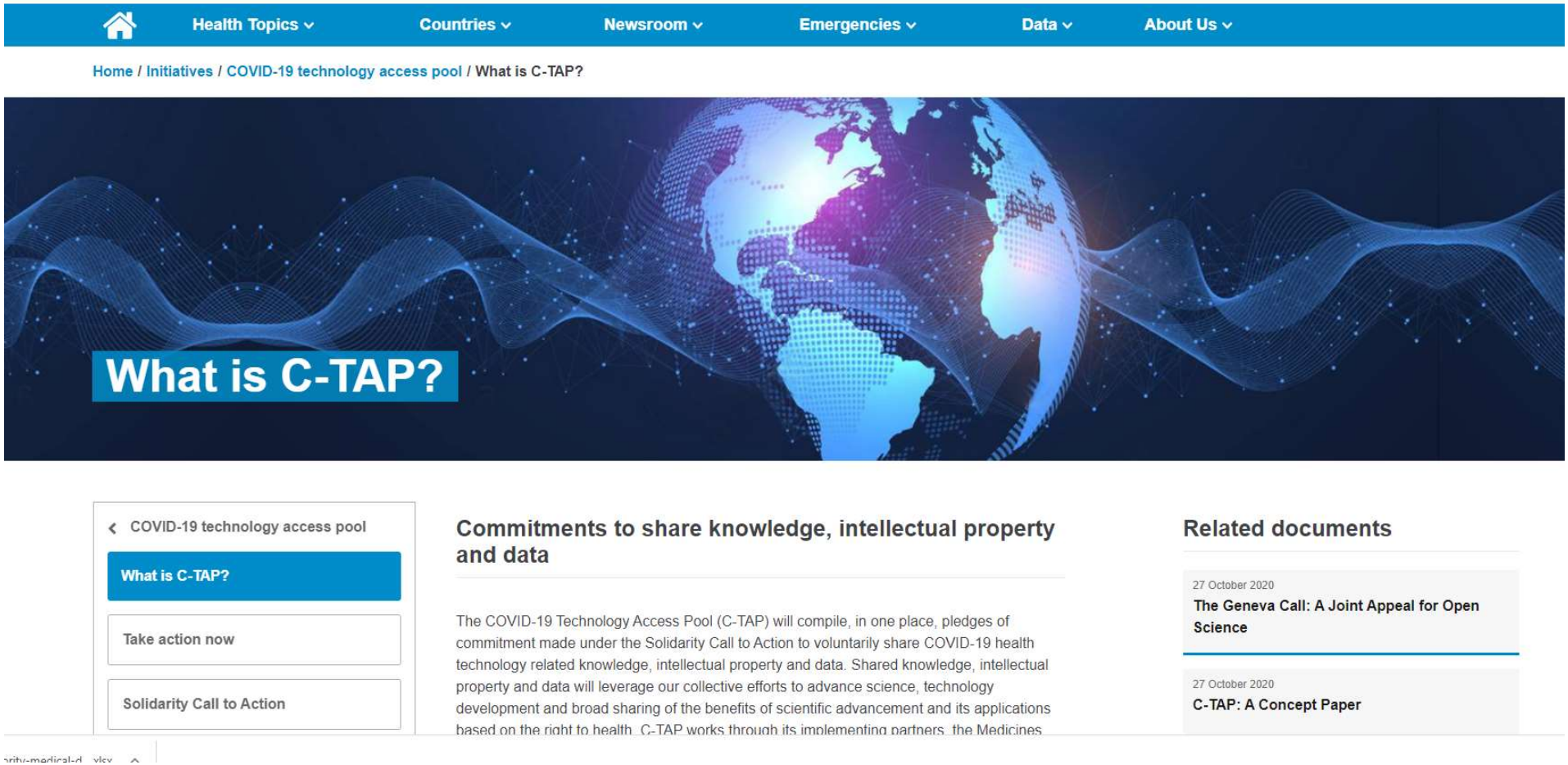


https://www.who.int/emergencies/diseases/novel-coronavirus-2019/global-research-on-novel-coronavirus-2019-ncov

Engineering Global Development
Engineering for change “4FC” disseminates technical information from WHO compendia
August 2021

engineering FOR CHANGE

ASME
SETTING THE STANDARD

E4C is on a mission is to prepare, educate and activate the international engineering workforce to improve the quality of life of underserved communities around the world.

We do this by providing resources, programs and platforms that accelerate the development of impactful solutions and cultivate change agents.

www.engineeringforchange.org

ASME SETTING THE STANDARD engineering FOR CHANGE

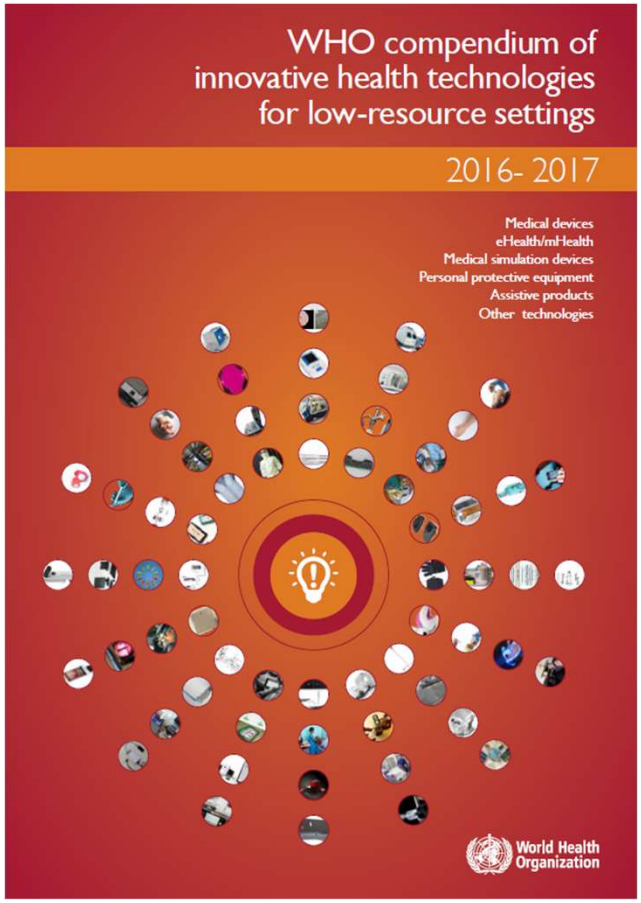
E4C Solutions Library

Living database of products and services (1,000+) intended to be accessible and appropriate for those living in resource-constrained environments.

- Codified framework and taxonomy
- Technical performance, market and compliance information, evaluation methods and standards
- Neutral information that is normalized across all products
- Side-by-side comparison and analysis of market influences

Relevant resource for engineers, designers, manufacturers and implementers of tech4good

E4C >< WHO



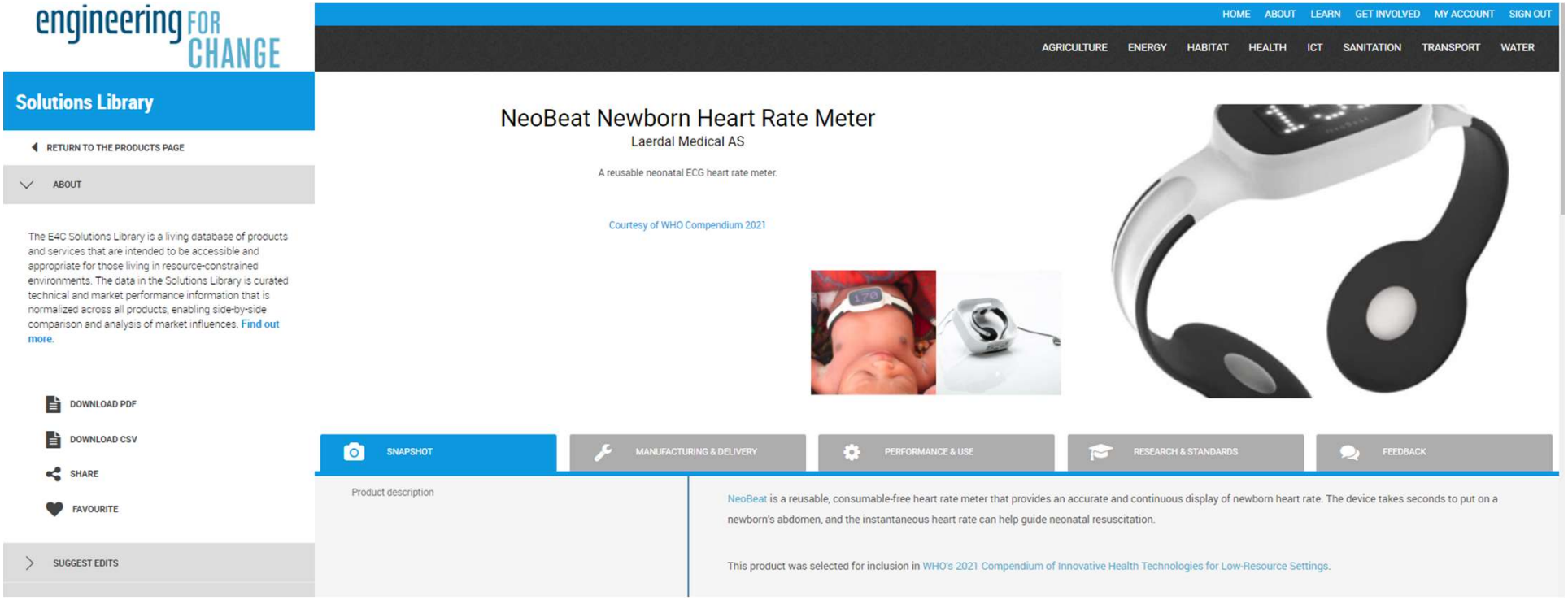
2016 - Data disclosure framework, taxonomy harmonization and integration of ~10 products from the Compendium, promotion to network

2018 - Harmonization of eHealth/mHealth product classification

2021 - Integration of 24 new products in three technology categories (invasive ventilators, non-invasive ventilators, and oxygen systems) +

Targeted promotion to E4C's network via research briefs and signal boosts

Solutions Library><WHO Compendium



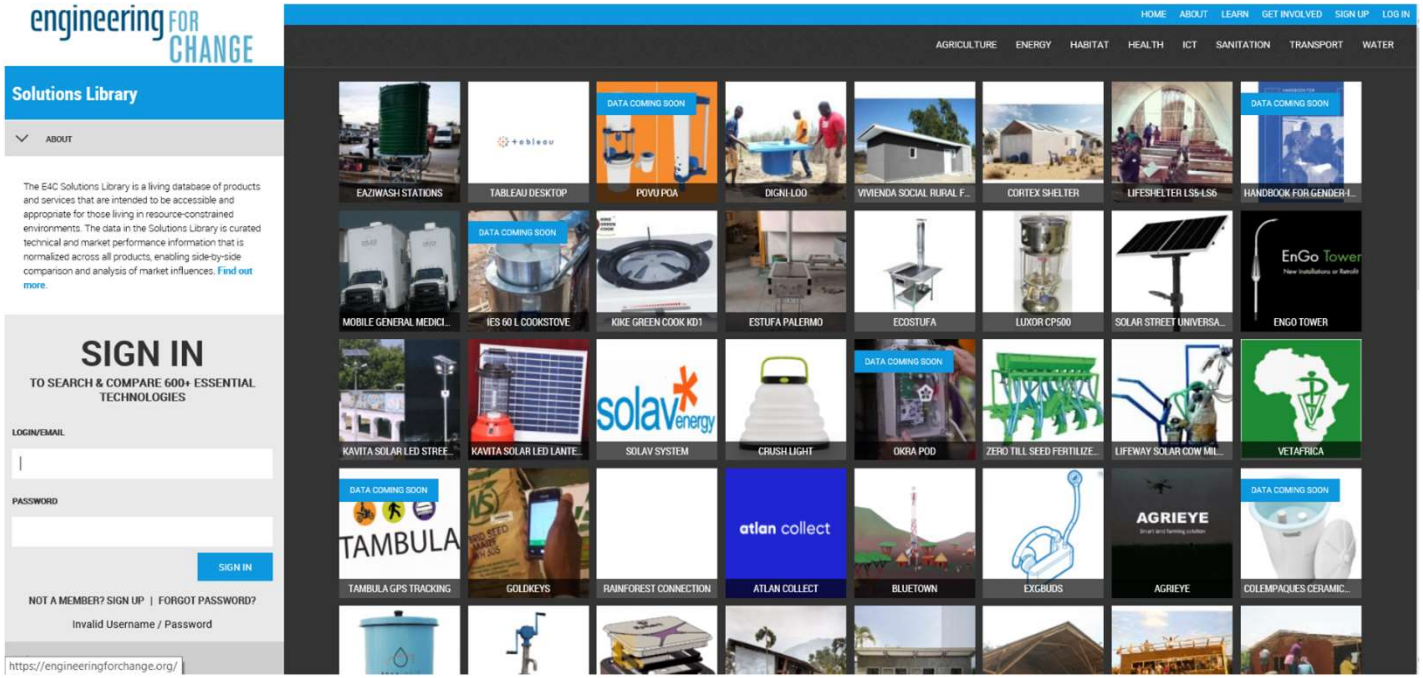
Solutions Library><WHO Compendium

SNAPSHOT | MANUFACTURING & DELIVERY | PERFORMANCE & USE | RESEARCH & STANDARDS | FEEDBACK

Fields marked ✔ are sourced values that have been evaluated by the manufacturer or a third party, all others are design specifications.

Consumables	None
Indispensable equipment for function	No
Power Supply Type	Rechargeable battery
Maintenance or calibration required by user at time of use?	No
Alert mechanism	No
Clinical measurements monitored	Heartrate
Patient population	Newborns
Maximum duration of consecutive usage	Unknown

Elevating the WHO Compendium



www.engineeringforchange.org/solutions/products

THANK YOU!

arandai@asme.org

machadom@asme.org

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Next call open during September, to be published early 2022

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To review previous submissions with more evidence and to add new ones.

Submission for Compendium of innovative health technologies for low-resource settings 2021 vol 2 (ID 396376)

https://extranet.who.int/dataformv3/index.php/396376?lang=en

Gracias
Thank you
Merci
Shokran
Xie xie
Spasiva

World Health Organization

WHO

20, Avenue Appia
1211 Geneva

Switzerland

Adriana Velazquez Berumen

velazquezberumena@who.int

www.who.int/medical_devices