

# Webinar: 2022 compendium of innovative health technologies for low resource settings

28 June 2022



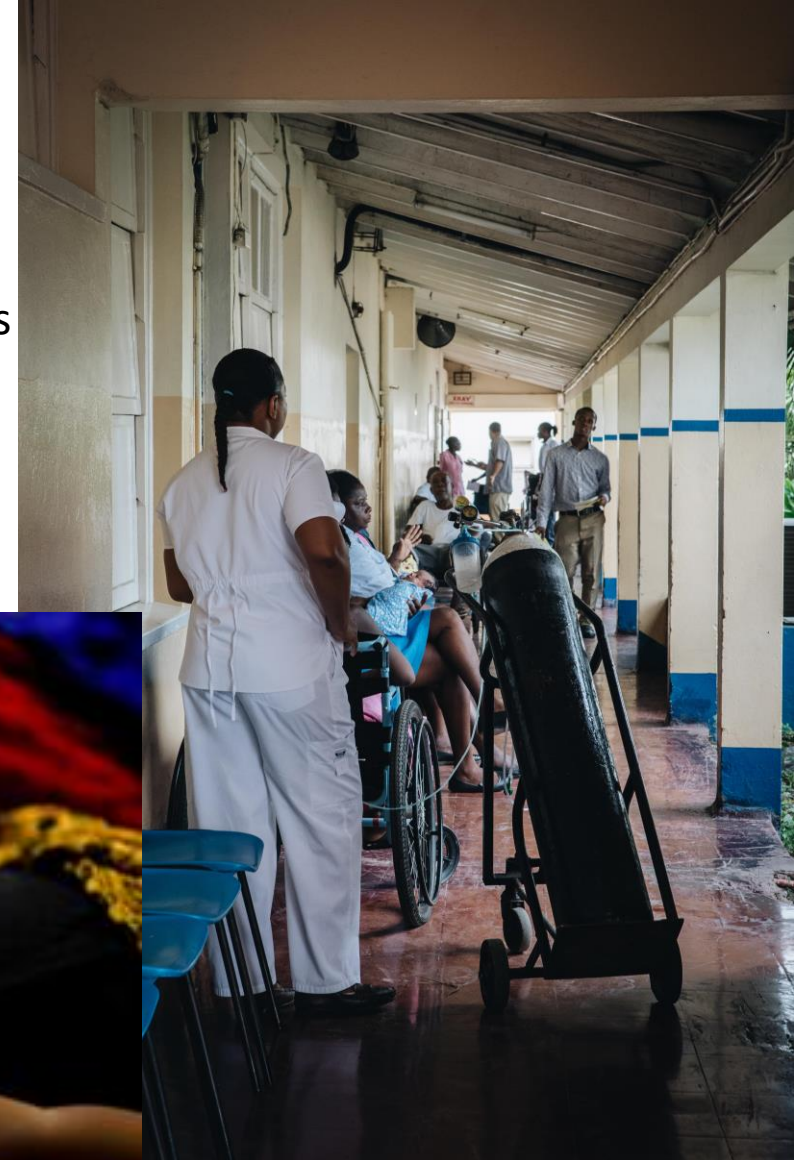
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# Agenda

2:00 PM – 2:05 PM	Opening remarks
2:05 PM – 2:10 PM	Introducing the 2022 WHO Compendium (WHO Secretariat)
2:10 PM – 2.30 PM	Experiences and perspectives from the field. Using health technologies in low-resource settings (Panel Discussion)
2:30 PM – 2:40 PM	Ten years of the Compendium (WHO Secretariat)
2:40 PM – 2:55 PM	WHO promoting innovation and access to health technology (Panel Discussion)
2:55 PM – 3:00 PM	Closing remarks



Low resource settings



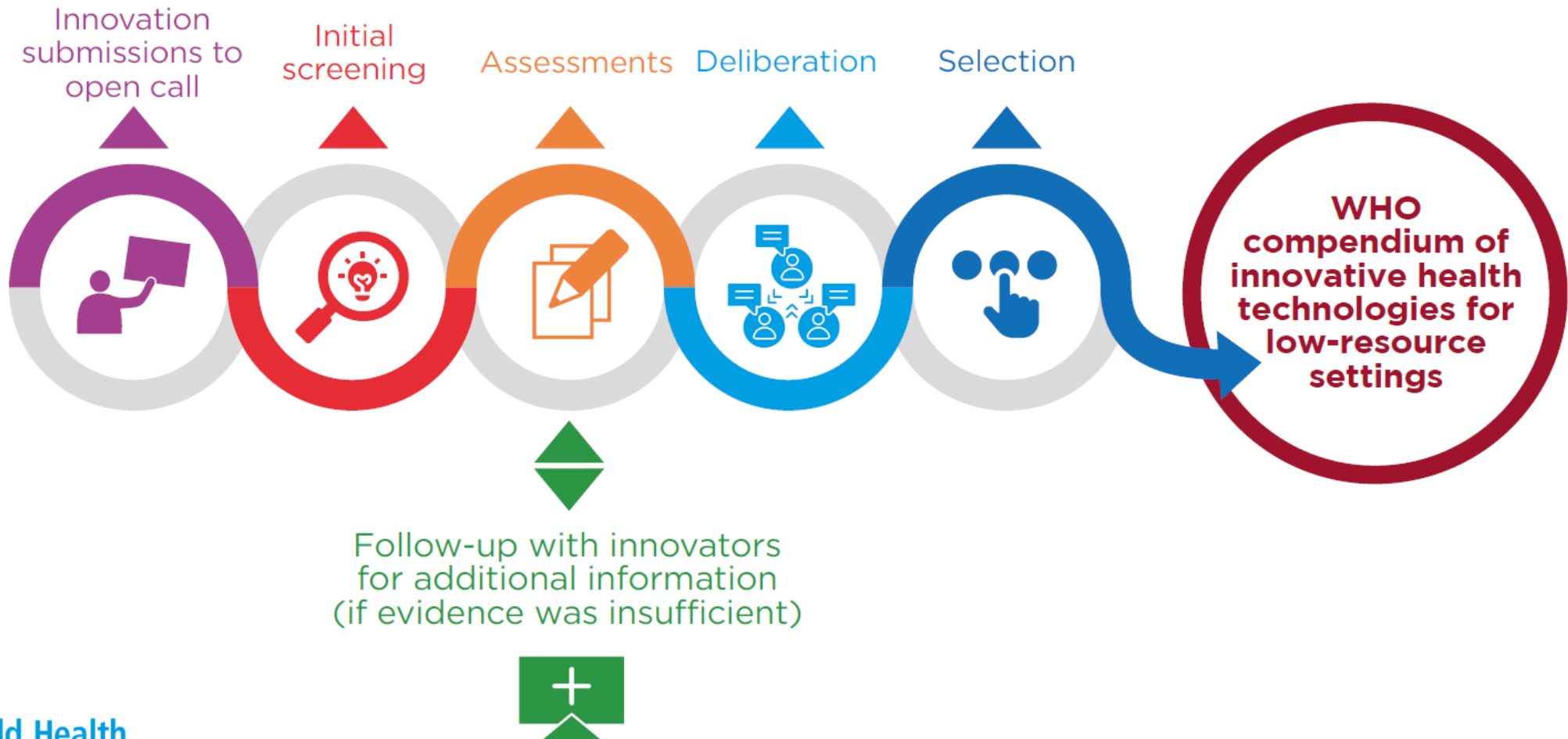


# 2022 Compendium

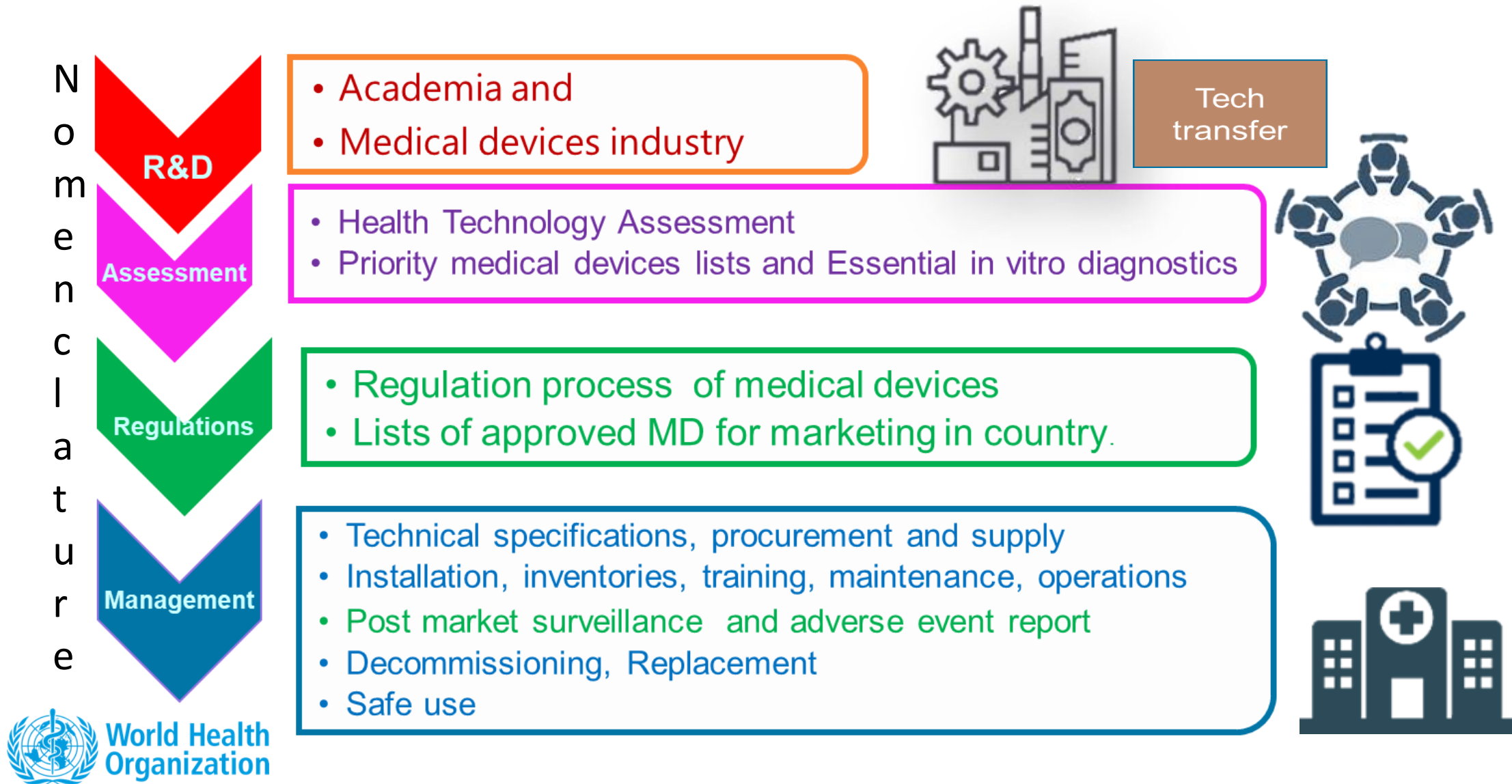


# Process that led to the 2022 Compendium:

Call: October 2021. Screenings: March 2022. Publication: June 2022



# Value chain for medical devices = medical devices technical series.



# Assessment domains of the submission form, v.2021



# Assessment values by topic

## Target settings

Icons for the target settings under 'Health technology and engineering management'.

Primary level



Home settings



Urban



Secondary level



Ambulance



Outdoors



Tertiary level



Rural



Indoors



## Regulatory assessment



Proceed



Proceed with caution



Not acceptable



Not Applicable

## Technology evidence assessment - risk/benefit ratio

High

Medium

Low

Not Applicable

## Technology evidence assessment - Impact

High

Medium

Low

Not Applicable

## Summary:

### Innovation



Innovation aspect in the domain

### Technology readiness level (TRL)

8-9

5-7

1-4

### Technology evidence assessment

Recommended

Recommend with caution

Not recommended

Not Applicable

## Health technology and engineering management

High appropriateness for low-resource settings

Moderate appropriateness for low-resource settings

Low appropriateness for low-resource setting

Not Applicable

## Technology transferability

Fully transferable

Partly transferable

Not transferable

Not Applicable

## Openly access intellectual property

Fully open access

Limited open access

No open access

Not Applicable

## Local production

High appropriateness for low-resource settings

Moderate appropriateness for low-resource settings

Low appropriateness for low-resource setting

Not Applicable



## Oxygen concentrator and storage

Country of origin | Germany  
Primary function | Treatment  
Category | Medical device

### Commercial information

List price (USD): 850  
Year of commercialization: 2021  
Number of units distributed: 0-100  
Currently marketed in: We are initially targeting Uganda, Kenya and Tanzania for first sales. We will subsequently focus on the The Pacific.  
Brand: FREO2 Foundation Australia and Kröber Medical Devices Germany  
Model: Oxylink

### Product description

A rugged concentrator with easy 'swap-n-go' unit exchange: heavy-duty, externally mounted filter and power stabilization. Even amid power fluctuations and surges, it continues to operate safely. During blackouts, cylinder integration guarantees oxygen flow.

\*Options LPOS stands for low-pressure oxygen storage with automatic delivery during a power outage.

ODS: low-cost oxygen delivery system that delivers oxygen to patients directly through low-pressure rubber piping and bed-side flow meters, making HCW workflow easier.

### Product details

Consumables: Nasal prongs  
Warranty duration: 2 years  
Lifetime: 2-5 years  
Energy requirements: Continuous power supply, Solar power, AC, 180-260 V, 600W  
Facility requirements: Specific temperature and/or humidity range, 5 to 40 °C 15% to 93% relative humidity (non-condensing)

Contact: Bryn Sobott | Email: [contact@freo2.org](mailto:contact@freo2.org) | Phone: +61 43 144 0820 | Web: [www.freo2.org](http://www.freo2.org)

NOTE: Information reported by manufacturer before 17 December 2021



## Areas assessed

## WHO ASSESSMENT

### Clinical assessment

Hypoxemia is a condition in which blood oxygen level is abnormally low (i.e., low partial oxygen tension). It can result in respiratory failure and the need for supplementary oxygen therapy due to various mechanisms and diseases. In resource-limited settings, lower respiratory tract infections and tuberculosis, in addition to COVID-19, are a major cause of hypoxemia and a primary source of morbidity and mortality, ranking among the top 10 causes of death in low- and lower-middle-income countries.

Furthermore, it is estimated that only fewer than half of all health facilities have continuous oxygen supply in low-resource contexts. A lack of accessible oxygen, in particular, leads to preventable deaths, with an estimated 122,000 deaths from pediatric pneumonia each year that could be avoided if oxygen supplies and delivery systems were improved. Moreover, the COVID-19 pandemic has further increased the demand for oxygen at the global level.

FREO2 - Oxylink system may thus provide a suitable alternative for oxygen concentration, storage, and delivery in healthcare settings lacking adequate infrastructure and experiencing short-term power fluctuations.

## WHO specification comparison

The FreeO2 OXYLINK device has been evaluated by comparing the technical documents provided with the WHO "Oxygen Concentrator" technical requirements currently available.

This device partially complies with the "Oxygen Concentrator" WHO technical specifications due to the fact that the following aspects of the device could not be verified or were not specified: oxygen outlet(s) type (requested with 6 mm, or 1/4 inch, barbed fitting or equivalent) and how the oxygen outlet is mounted to be secure and sheltered to reduce risk of being broken or bent. Mechanical shock resistance, mechanical vibration, electromagnetic compatibility and electrical safety tests performed. Capability of supplying the specified oxygen concentration continuously with elevation from 0 to at least 2000 m (besides, performance characteristics at altitudes higher than 2000m must be stated). Length of the main power cable to be higher than 2.5 m. Not clear if in the accessories list is also included the DISS and barbed adaptors (for each outlet, if applicable).

## Regulatory assessment

Pre-market assessment	Not acceptable
Post-market assessment	Not acceptable
Quality system assessment	Proceed with caution

It is a prototype model and has not been tested.

























**Pre-market** - full design verification and validation documentation required for oxygen storage, pipeline system, filter, safety valve, pressure regulator/switch, and alarm system

**Post-market** - complete documentation required for distribution, adverse event reporting, recall, field safety action, and complaint handling.

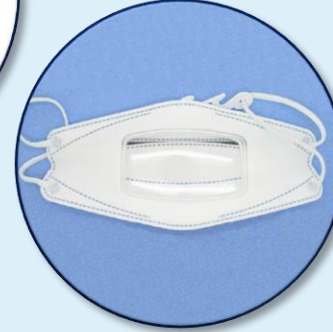
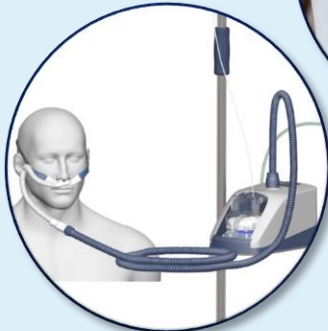
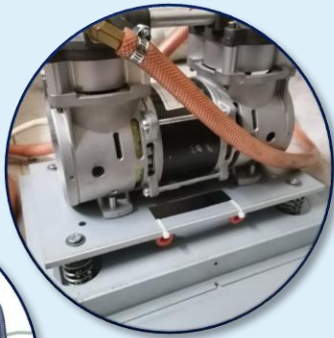
**QMS** - quality manual, risk management based on ISO 14971:2019, audit reports are required

The documentation provided is insufficient to undertake the assessment required to confirm the FREO2 system's safety and performance in order for it to be included in the compendium.

## Technology evidence assessment

Domains	Evidence assessment		Impact
	Risk/benefit ratio		
 Medical			<p>The device is designed to be simple, usable, and locally maintainable. Deployability was also assessed in low-resource settings based on the evidence presented. Local assembly and long-term manufacturing are being explored by the manufacturer. It can work successfully with a variable power supply or energy swings. Solar energy can be used to provide energy. The system is operating in a high-relative-humidity environment. The device appears to be inexpensive in LMI settings, based on the information provided.</p>
 Safety			
 Economy			
 Organizational			
 Legal			
 Social			
 Ethical			
 Green environment			
Summary			
Innovation			Technology evidence assessment Recommended, but still a prototype
Technology readiness level 9			

# Technologies listed



## Commercially available

- Cool packs for blood transportation
- Face mask
- Fetal monitor - wireless, mobile
- High flow nasal cannula with CPAP
- High flow nasal cannula
- Intensive care ventilator
- Multiport suction breathing tube

## Prototype products

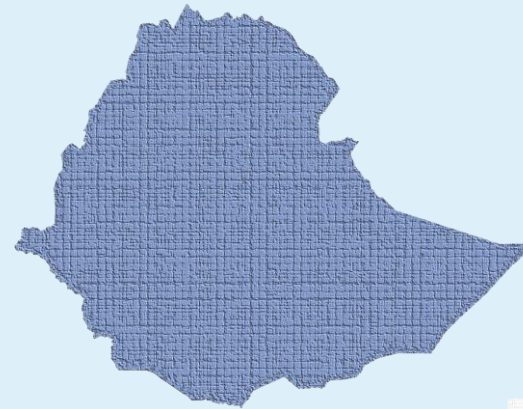
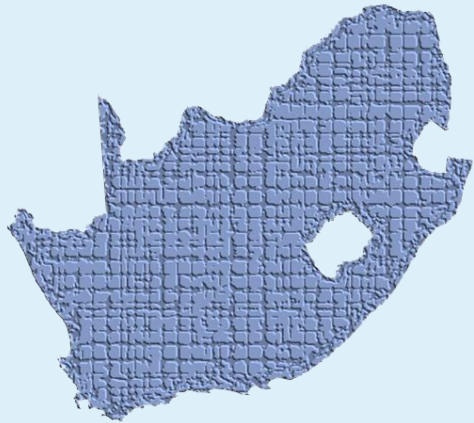
- Continuous positive airway pressure device
- Fetal monitor
- Filling station and multiple oxygen tanks
- High oxygen peep device
- Medical imaging analyzer
- Mechanical ventilator
- Oxygen concentrator
- Oxygen concentrator and storage





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# Experiences and perspectives from the field. Using health technologies in low-resource settings





# OxERA in South Africa

Oxygen accumulator with a PEEP valve

Intended for hospitalized adult hypoxemic patients requiring additional respiratory therapy in the form of PEEP

Published in the 2022 Compendium Edition

# OxERA in South Africa

**Dr John D Lotz**

Madwaleni Hospital

Eastern Cape Province

**Dr Jenny Nash**

Amathole District Clinical Specialist Team

Eastern Cape Province

# Neonatal C-PAP in Ethiopia

Oxygen concentrator with a bubble-driven C-PAP machine

Intended for use in neonatal intensive care units

Published in the 2011-2014 Compendium Edition



# Neonatal C-PAP in Ethiopia

**Gemechis Wari**

Head Nurse

St. Paul's Hospital Millennium Medical College

Addis Ababa





# Bedside Newborn Phototherapy in Myanmar

Phototherapy device with double-sided high-power LED

Designed to treat neonatal jaundice in rural settings

Published in the 2013 Compendium Edition



# Bedside Newborn Phototherapy in Myanmar

**Luciano Moccia**

CEO and Founder of Day One Health

Former Director of the Breath of Life Program of  
East Meets West Foundation



# Ten years of the Compendium!







## Infant warmer

Country of origin | United States of America, India

### Health problem addressed

20 million low-birth-weight babies are born yearly; 4 million die, and those that survive, grow up with severe problems, like low IQ, early onset of diabetes, heart disease. Incubators are costly and usually available in urban areas. Home solutions include wrapping hot water bottles around their bodies, placing them over hot coals or under light bulbs.

### Product description

We have developed a low-cost infant warmer that can work without electricity and provides heat to an infant at a constant temperature, the key factor needed for survival. Our product costs less than 1% of traditional incubators, has no moving parts, is portable and is safe and intuitive to use. It also complements skin to skin care.

### Product functionality

The re-usable warmer provides heat to infants weighing 1.5-3.0 kg. It is comprised of: a phase-change material (PCM) pouch; a heater that heats the pouch to 37°C; a sleeping bag that holds the infant and the pouch in adjacent compartments to promote sustained warming. The pouch will remain above 35°C for 4-6 hrs, providing heat to the infant.



## Self-powered pulse oximeter

Country of origin | United Kingdom

### Health problem addressed

10.8m children die every year. 99% of these deaths are in developing countries and 2.7m are due to congestive diseases that result in hypoxemia. Early detection of hypoxemia is essential in reducing mortality and morbidity.  $S_pO_2$  monitoring facilitates this.  $S_pO_2$  monitoring is also essential during anesthesia. It is called the 5th vital sign.

### Product description

Our pulse oximeter is a portable, easy to use monitor that measures blood oxygen saturation levels and the pulse rate. It is designed for use in low resource settings and is rugged, reliable and has its own on board human powered energy source.

### Product functionality

The oximeter offers the highest quality pulse oximetry on the market. It analyses the entire p'graphic wave form, locating the onset of a pulse and resulting in extreme pulse detection. It has excellent low perfusion and motion-compensating performance, warning the user and preventing inaccurate readings.

### Developer's claims of product benefits

This a monitor specifically designed for use in low resource settings or where electricity supply is a problem. The  $S_pO_2$  monitor is rugged and reliable and has its own on-board power generator. Human energy is converted into electricity and saved in rechargeable batteries. The monitor gives 10-15 minutes of monitoring per minute of winding. The monitor may also be recharged using wind power when available. The pulse oximeter is designed to be compatible with a



## Infant radiant warmer for primary care

Country of origin | India

### Health problem addressed

Nearly 2/3 of all newborn deaths (4 million annually) occur in 10 countries, India being largest contributor with 876,000. Lack of skilled personnel, infrastructure and affordability are big challenges to providing primary care. Hypothermia at birth is one of the most significant risk factors of neonatal mortality irrespective of birth weights and gestational ages. Urgent action is needed to address the issue of neonatal deaths and progress on MDG4, since 40% of under 5 deaths are in new-borns.

### Product description

Infant radiant warmer with uniform heating: the warmer features a patented "J-profile" design that reflects heat uniformly to the bed for more thermal stability. Reduced heat loss: the heater is made with a cartridge (Calrod-like) technology that allows for rapid warming of cold surfaces, thus helping to reduce cold stress for the babies. Safe contact with the patient: All patient contact surfaces are made with biocompatible materials—chosen to be gentle on the baby's delicate skin. Rugged: The warmer's electrical system is engineered to operate without a voltage stabilizer and can withstand voltage fluctuations of upto 390V. Clear observation: With a LED-based observation lamp emitting a white light, the warmer allows for great patient observation.

### Developer's claims of products benefits

Many cheap warmers available in the market are unreliable, break down frequently and do not deliver the desired level of clinical performance. There are others that are feature heavy and very highly priced and much beyond the buying capacity of primary care buyers. With Calrod technology for the best clinical outcomes, ruggedness and reliability (unique 5 years warranty) and at extremely affordable prices.

### Suitability for low-resource settings

Designed for a low resource health facility with poor infrastructure (intermittent power, power fluctuations, no electricity), low-skilled nurses, lack of space, low purchasing power. Easy to use: the device is plug-in and use requires minimal training. Rugged & Reliable: can withstand voltage fluctuations up to 390V. Comes with 5 year maintenance warranty. The temperature probe is made of Kevlar (material used to make bullet proof vests) Affordable: Low purchase price, low maintenance & service costs. So far, the warmer has been installed in many challenging environments across India and ASEAN with poor room air temperature control, constant power outages, rugged environment and a limited availability of skilled clinicians. The rugged and reliable design was well suited to the challenging environment and usage conditions.

### Operating steps

Plug in the assembled unit to a power source and switch on the device. The warmer performs a self test, then switch ON in the manual heating mode. Use this mode to pre-heat, if needed. Place the baby on the mattress in the bassinet and attach the skin probe to the baby. Toggle to the baby mode and set the control temperature for thermoregulation.

### Regulatory status

CE certified (CE 01236). Biocompatible: All surfaces coming in contact with the patient are biocompatible (EN ISO 10993-1:2009/AC:2010). EN 60601 regulations - Medical Electrical Equipment. The product conforms to RoHS requirements (residues of hazardous substances). Other: EN 62366 - Medical devices, EN 62304 - Medical Device software, EN ISO14971 - Application of risk management to medical devices, EN ISO 13485 - Quality Management Systems, EN 980 - Symbols for use in the labeling, EN 1041.

### Future work and challenges

The product is low cost and meant for low resource settings. One of the obstacles is government specifications and tenders. The documents need to be updated with new technologies so that the product can reach the markets it is actually meant for.

### Use and maintenance

User: Intended for use by a physician, nurse, or midwife

Training: Basic training manual (quick reference guide) provided and video available

Maintenance: No scheduled maintenance required

### Environment of use

Setting: Designed for rural and urban indoor settings and in primary, secondary and tertiary level health care facilities.

Energy and Facility requirements: Requires a continuous power supply of 230V and an environment within the range of 18-30 °C and 30-75%RH

### Product specifications

Weight (kg): 37

Dimensions: 1500mm x 800mm x 800mm

Consumables: heat reflector skin patch

Lifetime: 7 years

Retail price (USD): 1500

Other features: mobile

Year of commercialization: 2014

Currently sold in: India, Malaysia, Indonesia, Vietnam

Contact: Sumit Mehrotra | Email: lowresourcesetting@gmail.com | Telephone: 918040886511 | Web: www.gehealthcare.com

[http://www.who.int/medical\\_devices](http://www.who.int/medical_devices)



# From simple assessments to assessments along the value chain

2021

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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 (US\$):** \$5,000  
**Year of commercialization:** 2019  
**Number of units distributed:** 10-1000  
**Currently marketed in:** Sub-Saharan Africa and Southeast Asia  
**Brand:** Graden Health Systems  
**Model:** Graden GSV

**Health problem addressed:**  
 Respiratory ventilation, when initiated by a trained medical professional, provides respiratory support to patients who cannot breathe or require assistance to breathe due to illness, such as pneumonia, COVID-19, COVID-19, trauma, or other conditions. This is essential to continuing life while patients undergo treatment or until treatment can be accessed. A major factor limiting access is inadequate infrastructure to support delivery of critical care in facilities and during transport.

**Product description:**  
 A comprehensive care ventilator can assist or replace the breathing of a patient requiring respiratory support. In any care setting, this is drawn from compressed sources of oxygen and medical air or extracted 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.

**Product details:**  
**Accessories:** Raising stand, bag of 2 extra filters, kit - hands, nasal mask, stand mount, external battery, and external valve, reusable adult and pediatric breathing circuits, SpO<sub>2</sub> monitor, HPEL and lung, air and oxygen hoses, power cords, respiratory cylinder, humidifier and accessories.  
**Considerations:** 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.  
**Other required products:** Patient interface, such as ventilator tubes and non-invasive ventilator 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.  
**Warranty duration:** 2 years  
**Lifetime:** 10-15 years  
**Contact info:** Send email: [sales@gradenhealth.org](mailto:sales@gradenhealth.org) | Phone: +1-761-456-1000 | Email: [info@gradenhealth.org](mailto:info@gradenhealth.org)

2021

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**WHO ASSESSMENT**

### WHO specification comparison

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

**Compliance relevant characteristics:** There is the option for using external low pressure oxygen (up to 100 psi) as a source. However, the instructions of use indicate that "These instructions may not be available with a gas source not providing a minimum of 80 L/min at 360 psi (440 psi)". The device includes non-invasive ventilation, at oxygen concentrations between 21 and 100% degree of protection. The device can be used continuously in battery mode with up to 10 hours of operation for up to 10 hours total of hours on internal battery and 10 hours on external battery.

**Non-compliance:** The oxygen mixture accuracy is 5% as opposed to the WHO specification of 4%. The inspiratory pressure is 15-18 cmH<sub>2</sub>O instead of the WHO specified range of 5-40 cmH<sub>2</sub>O. The device does not have minute volume alarm and stops with disconnect cannot be corrected. Additionally, the device does not have a low battery alarm or display, however, the device stops and continuous minute volume. The display shows numerical indicators but no numerical for all ventilation parameters.

**Aspects that could not be verified:** Minute volume alarm

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### Regulatory assessment

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 not in EU CE marked under the MDD and did not have CE marking. The regulatory status for the various assessment was provided. The product's manufacturer (Graden Health) has obtained an ISO 13485:2016 certificate. Graden provided all top-level SOPs for their regulatory and quality system requirements for the WHO assessment. Graden must also ensure they comply with local country laws and are market regulations.

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## Assessments



2021

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### Technology evidence assessment

Domains	Evidence assessment (Target: 100%)	Score
Medical	100%	100%
Safety	100%	100%
Economic	100%	100%
Organizational	100%	100%
Legal	100%	100%
Social	100%	100%
Ethical	100%	100%
Green environment	100%	100%

During emergencies, the technology has a dual purpose of regular clinic use and deployment. The goal has a 100% proven power supply and can use solar energy. It is robust and stable during extreme weather and an uneven terrain. In terms of deployment, training is required for which video instruction is provided. It is easy to use, maintain, and disassemble.

**Summary**  
 Transferability: 100%  
 Evidence (according to GRADE): 100%  
 Technology readiness level: 100%  
 Technology evidence assessment: 100%

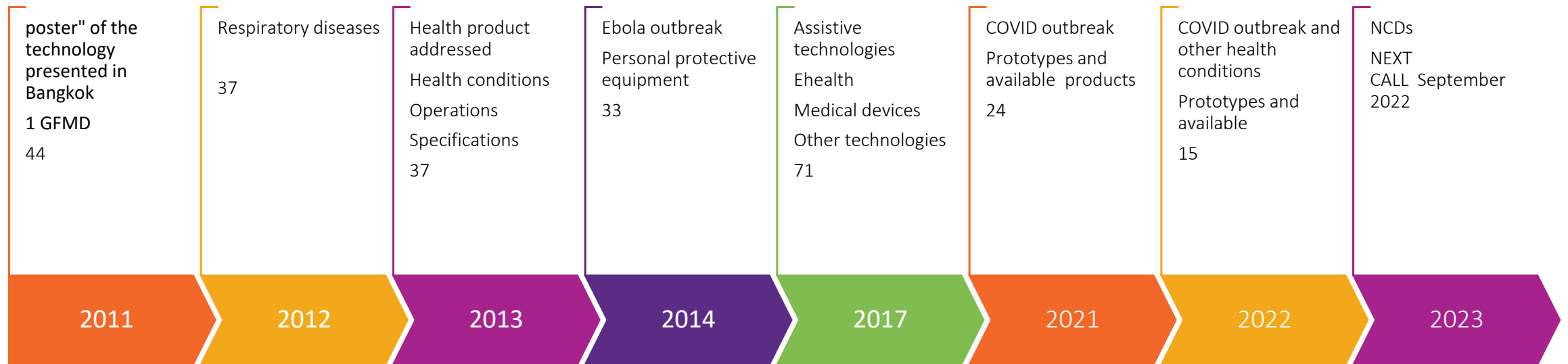
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**Health technology and engineering management**

Domains	Assessment	Domains	Assessment	Target setting (Risks and impact settings)
Duration	100%	Ease of maintenance	100%	This product is a mobile, deployable facility for providing temporary clinical services. It is durable, easy to set up, use and maintain, and locally and culturally acceptable. The facility requires utilities such as electricity and compressed air in order to support, connect equipment. It is not clear if this product provides significant innovation over similar commercially available products.
Ease of use	100%	Infrastructure requirements	100%	
Positive impact on clinical outcomes	100%	Local access to labor support	100%	
Affordability	100%	Local access to technical support	100%	
Engineering reliability and maintainability	100%	Local access to training	100%	
Cultural and social acceptability	100%	Local access to spare parts	100%	
Environmental conditions	100%	Local product line	100%	
Authorities	100%	Location of use within target setting	100%	

# Evolution of the assessment: 262 listed technologies, more than 300 evaluators



Time for a poll

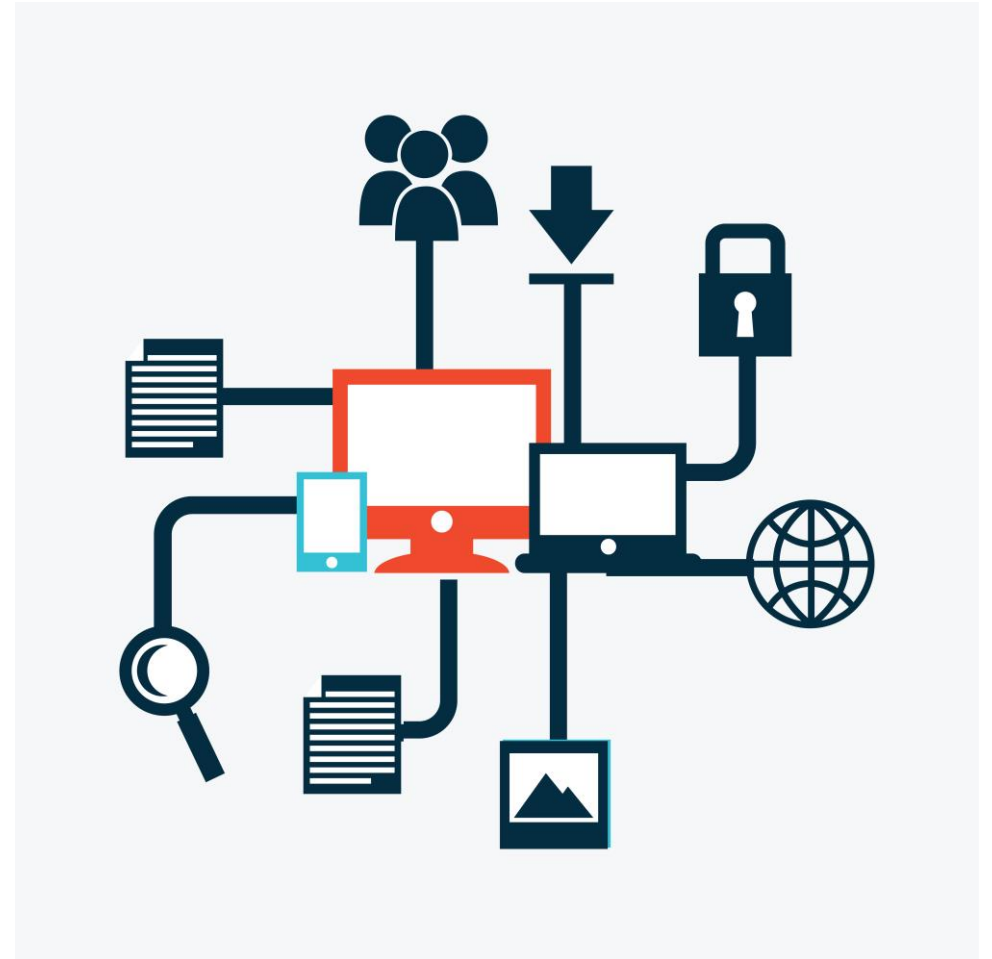
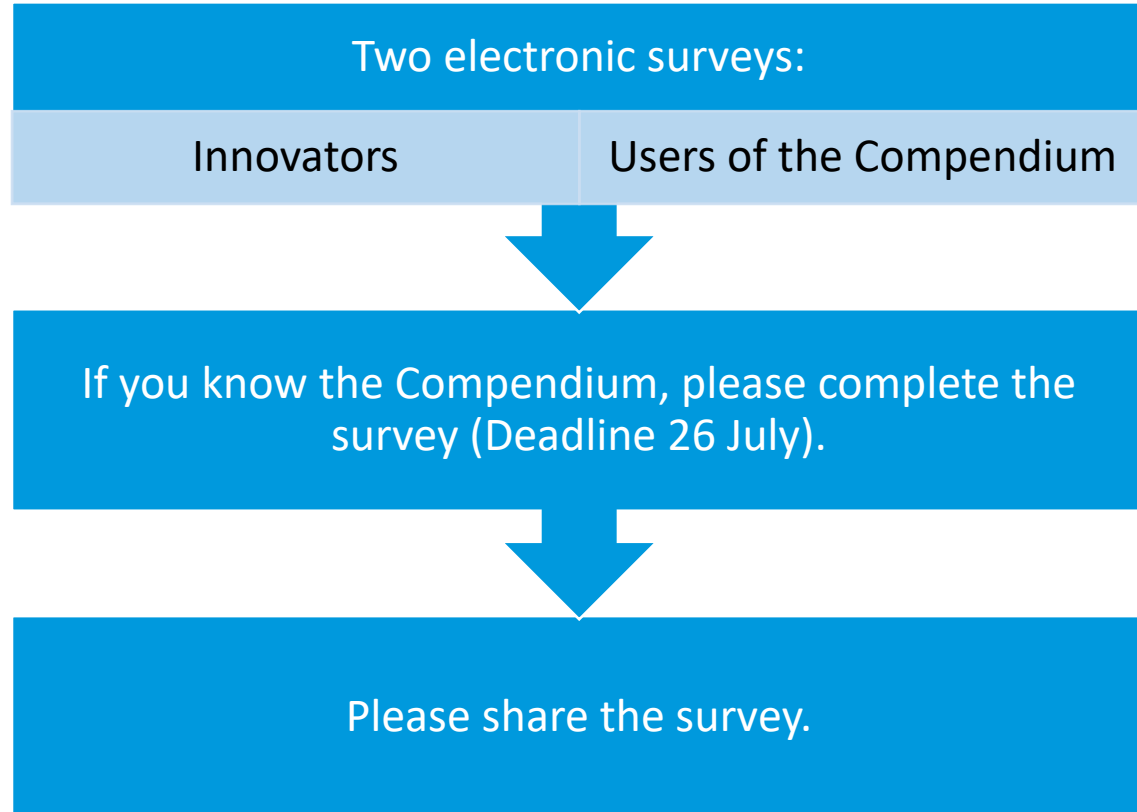
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## 2023 Compendium call announcement

- Noncommunicable diseases (NCDs) disproportionately affect people in low- and middle-income countries where more than three quarters of global NCD deaths – 31.4 million – occur.
- The next call of the Compendium will focus on technologies for NCDs
- It will open in Autumn 2022
- For more information visit:  
<https://www.who.int/activities/accelerating-impact-for-innovations-for-health>

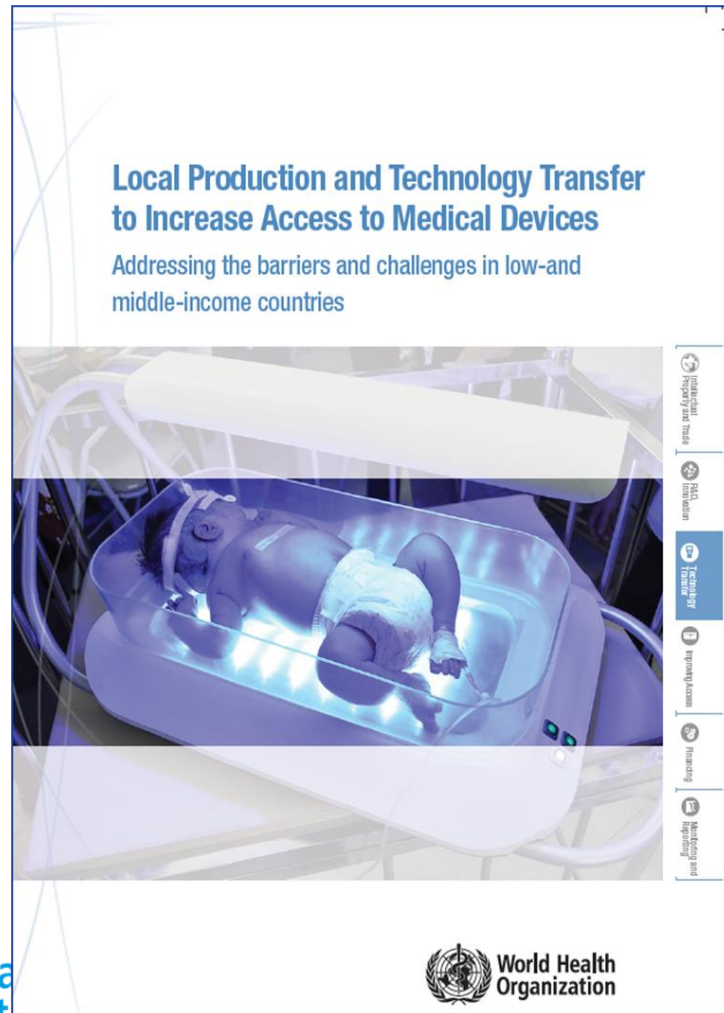


# Retrospective assessment of the Compendium 2011-2022





# 2014 and 2015 WHO did studies for Local production and technology transfer in Ethiopia, Nigeria, Tanzania and South Africa



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# WHO promoting innovation and access to health technology



**Share your intellectual property, knowledge or data**

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# WHO promoting innovation and access to health technology.

## C-TAP initiative

**Ms. Erika Dueñas Loayza,**

Head of the intellectual Property Unit, Access to Medicines, CTAP, WHO HQ

**Ms. Maria De Lourdes Aguirre**

Consultant, Intellectual Property of Medical Devices, CTAP

**Mr. Einstein Albert Kesi**

Consultant, Local Production of Medical Devices, CTAP

**Mr. Amol Karnick**

CEO, KA Imaging



Image Sources :

<https://www.who.int/initiatives/covid-19-technology-access-pool/take-action-now>

<https://www.who.int/initiatives/covid-19-technology-access-pool/solidarity-call-to-action>



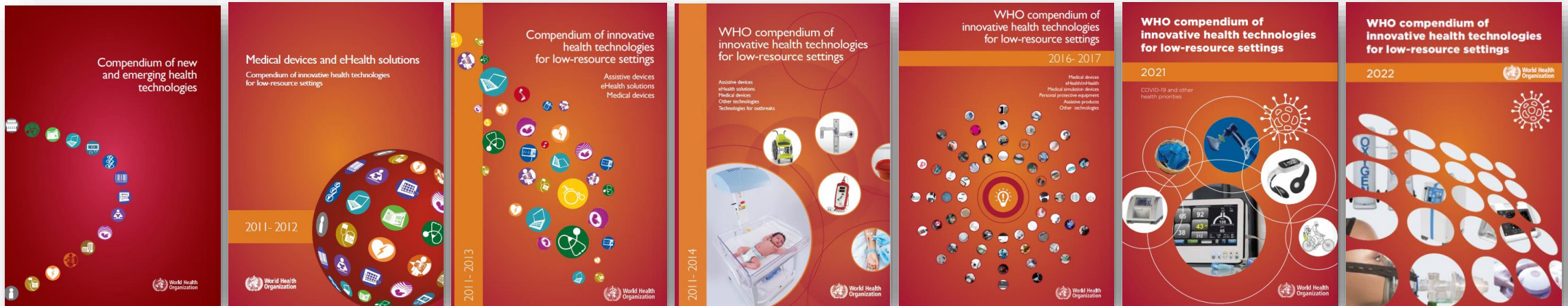
# We need your help to assess the impact of the Compendium during the last 10 years.



Please complete the survey and share.



<https://extranet.who.int/dataformv3/index.php/248639?lang=en>





# Closing Remarks

Innovative technologies to  
empower health care  
workers to diagnose,  
monitor and patients.

Increase access to  
population every where.



Innovative technology should be:

Safe

Good quality!

Easy to use

Easy to maintain

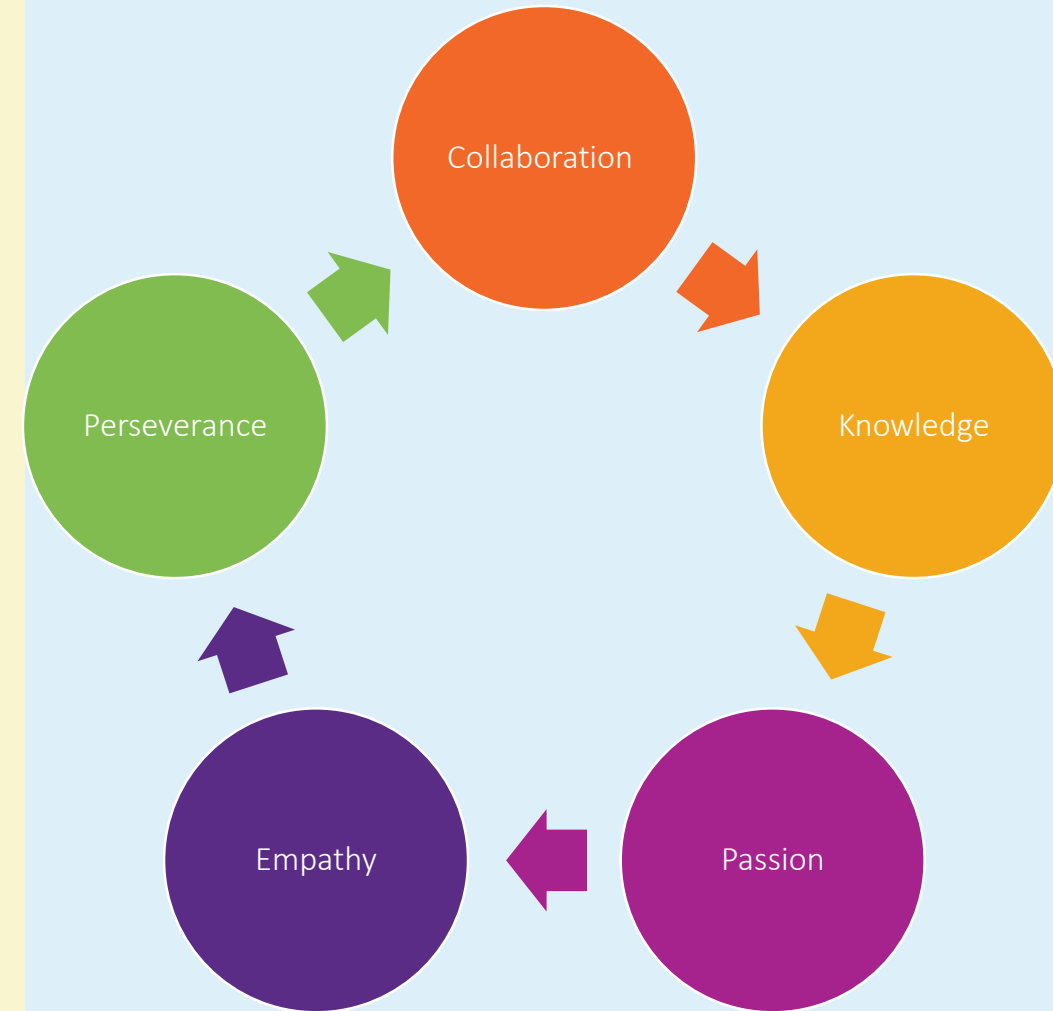
Adaptable

Affordable

Available

Accessible

Acceptable





# Thank you!



World Health  
Organization