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

28 June 2022
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
Process that led to the 2022 Compendium:
Call: October 2021. Screenings: March 2022. Publication: June 2022

WHO compendium of innovative health technologies for low-resource settings

Follow-up with innovators for additional information (if evidence was insufficient)
Value chain for medical devices = medical devices technical series.

- 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
Assessment domains of the submission form, v.2021

1. Innovative Health Technology

2. Health problem addressed and target population

3. Clinical assessment and WHO guidance

4. Description functionality and image

5. Operating steps

6. Developers claims of technology benefits

7. Use and environment

8. Technology specifications

9. Verification and validation

10. Regulatory status

11. Health Technology Assessment

12. Engineering evaluation in low resource settings

13. Market

14. Future work and challenges

15. Engineering & technology management

16. Intellectual property

17. Local production
Assessment values by topic

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<tr>
<th>Target settings</th>
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<td>Primary level</td>
<td>Home settings</td>
<td>Urban</td>
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<td>Ambulance</td>
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<td>Tertiary level</td>
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<td>Regulatory assessment</td>
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<td>Technology evidence assessment - risk/benefit ratio</td>
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<td>Technology evidence assessment - Impact</td>
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<td>Medium</td>
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<td>Moderate appropriateness for low-resource settings</td>
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<td>Technology transferability</td>
<td>Fully transferable</td>
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<td>Moderate appropriateness for low-resource settings</td>
<td>Low appropriateness for low-resource setting</td>
<td>Not applicable</td>
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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: Yes
We are initially targeting Uganda, Kenya, and Tanzania for first sales. We will subsequently focus on the Pacific region.
Brand: FREO2 Foundation Australia and Klober Medical Devices
Germany
Product: Floxygen

Product description
A rugged concentrator with easy ‘grab-and-go’ unit exchange; heavy-duty, externally mounted filter and power stabilization. Even amid power fluctuations and outages, it continues to operate safely. During blackouts, cylinder integration guarantees oxygen flow.
*Options: LPG 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 tubing and bedside flow meters, making HCW workflow easier.

Product details
Consumables: Nasal prongs
Warranty duration: 2 years
Life cycle: 2-5 years
Energy requirements: Continuous power supply, Solar power, AC 150-260 V, 600W
Facility requirements: Specific temperature and/or humidity range, 5 to 40 °C 15% 93% relative humidity (non-condensing)

Contact: Dyn Solar
Email: contact@freeso2.org
Phone: +41 43 144 0830
Website: www.freeso2.org

NOTE: Information reported by manufacturer before 17 December 2021

WHO ASSESSMENT

Clinical assessment
Hypoxemia is a condition in which blood oxygen level is abnormally low (i.e., low partial oxygen pressure). Hypoxemia is a result of 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 - Floxygen 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.

Areas assessed

WHO specification comparison
The FreO2 Floxygen device has been evaluated by comparing the technical documents provided with the WHO “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 (replaced with 6 mm, 0.4 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 3.5 m. Not clear if in the accessories list is also included the O2S and barbed adaptors (for each outlet, if available).

Regulatory assessment

- Pre-mark assessment: Not acceptable
- Post-market assessment: Not acceptable
- Quality system assessment: Proceed with caution
- OHS: 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 device’s safety and performance in order for it to be included in the compendium.
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
- Multisport 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
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

Health problem addressed: Nearly 2.5% of all newborn deaths (over 1 million annually) occur in 10 countries. India being the largest country with 875,000. Lack of skilled personnel, infrastructure and affordability are key challenges to providing primary care. Hypothermia at birth is one of the most significant risk factors of neonatal mortality irrespective of birth weight and gestational age. An urgent action is needed to address the issue of neonatal death and progress on MDG 4. Over 45% of under-5 deaths are in newborns.

Product description: Infant radiant warmer with uniform heating. The warmer features a patented ‘U-profile’ design that reflects heat uniformly to the best for more thermal stability. Reduced heat loss (heater is made with a patented C rallatek technology) is allowed for radiant warming of cold surfaces, thus helping to reduce cold stress for the babies. Safe contact with the patient. All contact point surfaces are made with biomedical materials—chosen to be gentle on the baby’s delicate skin. The warmer’s electrical system is engineered to operate without a voltage stabilizer and can withstand voltage fluctuations of up to 350V. Clear observation: With a LED-based observation lamp emitting a white light, the warmer allows for great patient observation.

Developers’ claims of product benefits: Many neonatal 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 hospitals. With C rallatek technology for the best clinical outcomes, ruggedness and reliability (survives 5 years warranty) and an extremely affordable price.

Suitability for low-resource settings: Designed for low-resource health facilities, with poor infrastructure (intermittent 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 350/Comes with 5 year warranty. The temperature probe is made of high-grade 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 ASAN with poor room air temperature control, constant power outages, rugged environment and a limited availability of skilled clinicians. The rugged and reliable design was 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 the mode to pre-heat, if needed. Place the baby on the matress in the basket and attach the skin probe to the baby. Toggle to the baby mode and set the control temperature for the thermoregulation.


Future work and challenges: The product is the past and means for low resource settings. One of the obstacles is government specifications and tenders. The device needs to be updated with new technologies so that the product can reach the markets. It is actually meant for low-income markets.

Used and maintenance: Ideal intended for use by obstetricians, nurses, or midwives. Training: Basic training manual (coded reference guide) provided and video available. Maintenance: Has scheduled maintenance required.

Environment of use: Setting: Designed for use in 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 220V and an environment within the range of 15°C-30°C. 

Product specifications:

- Weight (kg): 37
- Dimensions: 100cm x 80cm x 80cm
- Consumption: Heat reflector/skin patch
- Lifethis: 7 years

Contact: Sanjay Sanghavi | Email: info@sanjay sanghavi.com | Telephone: +101-2006506 | Website: www.babyhealthcare.com
From simple assessments to assessments along the value chain
Evolution of the assessment:
262 listed technologies, more than 300 evaluators

- **2011**: Respiratory diseases
- **2012**: Health product addressed
- **2013**: Ebola outbreak
- **2014**: Assistive technologies
- **2017**: COVID outbreak
- **2021**: COVID outbreak and other health conditions
- **2022**: NCDs

Time for a poll
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

Two electronic surveys:

| Innovators | Users of the Compendium |

If you know the Compendium, please complete the survey (Deadline 26 July).

Please share the survey.

2014 and 2015 WHO did studies for Local production and technology transfer in Ethiopia, Nigeria, Tanzania and South Africa
WHO promoting innovation and access to health technology

Share your intellectual property, knowledge or data
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
We need your help to assess the impact of the Compendium during the last 10 years.

Please complete the survey and share.

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!