

WHO compendium of innovative health technologies for low-resource settings

2022



WHO compendium of innovative health technologies for low-resource settings

2022

WHO compendium of innovative health technologies for low-resource settings 2022

ISBN 978-92-4-004950-5 (electronic version)

ISBN 978-92-4-004951-2 (print version)

© **World Health Organization 2022**

Some rights reserved. This work is available under the Creative Commons Attribution-NonCommercial-ShareAlike 3.0 IGO licence (CC BY-NC-SA 3.0 IGO; <https://creativecommons.org/licenses/by-nc-sa/3.0/igo>).

Under the terms of this licence, you may copy, redistribute and adapt the work for non-commercial purposes, provided the work is appropriately cited, as indicated below. In any use of this work, there should be no suggestion that WHO endorses any specific organization, products or services. The use of the WHO logo is not permitted. If you adapt the work, then you must license your work under the same or equivalent Creative Commons licence. If you create a translation of this work, you should add the following disclaimer along with the suggested citation: "This translation was not created by the World Health Organization (WHO). WHO is not responsible for the content or accuracy of this translation. The original English edition shall be the binding and authentic edition".

Any mediation relating to disputes arising under the licence shall be conducted in accordance with the mediation rules of the World Intellectual Property Organization (<http://www.wipo.int/amc/en/mediation/rules/>).

Suggested citation. WHO compendium of innovative health technologies for low-resource settings 2022. Geneva: World Health Organization; 2022. Licence: [CC BY-NC-SA 3.0 IGO](https://creativecommons.org/licenses/by-nc-sa/3.0/igo).

Cataloguing-in-Publication (CIP) data. CIP data are available at <http://apps.who.int/iris>.

Sales, rights and licensing. To purchase WHO publications, see <http://apps.who.int/bookorders>. To submit requests for commercial use and queries on rights and licensing, see <https://www.who.int/copyright>.

Third-party materials. If you wish to reuse material from this work that is attributed to a third party, such as tables, figures or images, it is your responsibility to determine whether permission is needed for that reuse and to obtain permission from the copyright holder. The risk of claims resulting from infringement of any third-party-owned component in the work rests solely with the user.

General disclaimers. The designations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of WHO concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement.

The mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or recommended by WHO in preference to others of a similar nature that are not mentioned. Errors and omissions excepted, the names of proprietary products are distinguished by initial capital letters.

All reasonable precautions have been taken by WHO to verify the information contained in this publication. However, the published material is being distributed without warranty of any kind, either expressed or implied. The responsibility for the interpretation and use of the material lies with the reader. In no event shall WHO be liable for damages arising from its use.

Graphic design and layout: Genève Design.

Contents

Acknowledgements	iv
Glossary of terms.....	v
Executive summary.....	x
Objectives.....	xi
Methodology	xii
Terms, conditions and disclaimers for the call.....	xxiv
Key for icons.....	xxvi

Commercially available

Cool packs for blood transportation 2
Face mask 5
Fetal monitor - wireless, mobile 8
High flow nasal cannula with CPAP 11
High flow nasal cannula 14
Intensive care ventilator 17
Multipoint suction breathing tube 20

Prototype products

Continuous positive airway pressure device 24
Fetal monitor 27
Filling station and multiple oxygen tanks 30
High oxygen peep device 33
Medical imaging analyzer 36
Mechanical ventilator 39
Oxygen concentrator 42
Oxygen concentrator and storage 45

Non-listed products	48
Discussion.....	49
For further reading	50

Acknowledgements

The call, compilation, and evaluation of submissions for the Compendium of Innovative Health Technologies for Low-Resource Settings (hereinafter referred to as the Compendium) were managed by the World Health Organization (WHO) under the coordination of Adriana Velazquez Berumen, Team Lead of Medical Devices and In vitro Diagnostics from the Health Product Policy and Standards Department under the Access to Medicines and Health Products Division.

WHO acknowledges and is most grateful to the consultants and reviewers who dedicated their time and expertise to help identify potential health technology solutions for global health priorities, as well as the German Federal Ministry of Education and Research for their financial support.

Special acknowledgement is given to the WHO consultants listed below who were specially dedicated to the different phases of the project: Daniela Rodriguez Rodriguez, Switzerland/Mexico for initiating the call, organizing the information required by external and internal reviewers and supporting the logistics of the selection process, Debjani Basu Mueller, India/South Africa/Germany for compiling the information for the publication. Jillian Reichenbach Ott, Switzerland/New Zealand for designing the assessment tool, Maria de Lourdes Aguirre Algara, Mexico, for reviewing the intellectual property, Einstein Albert Kesi, India on local production, Francesco Ribolzi, Italy for review of technical specifications, Sasikala Thangavelu, Malaysia and Kimberly Walker, USA for reviewing the regulatory section, Cesar Vieira, Portugal for providing clinical input, from EuroScan International Network (EuroScan): Iñaki Gutiérrez-Ibarluzea, Spain and Maximilian Otte, Germany for providing the technology assessment reviews, and from the Global Clinical Engineering Alliance: Yadin David and Tom Judd, USA for providing health technology management and engineering analysis. Acknowledgment is extended to Nicolò Binello (WHO) for conducting the clinical assessment of all submissions and ensuring clinical alignment with WHO guidelines, recommendations, and resources.

WHO acknowledges the following international external reviewers of the technologies engaged through the Global Clinical Engineering Alliance. The reviewers provided declaration of interest (DOI) documents, which were assessed by the WHO secretariat, and no conflicts of interest were found.

Maliki Seidou Adjaratou, Benin; Mohammad Ameen, India; Md Ashrafuzzaman, Bangladesh; Tazeen Saeed Bukhari, Pakistan; Dan Clark, United Kingdom of Great Britain and Northern Ireland; Eunice Conceicao, Portugal; Maombi Edison, Chad; Riad Farah, Lebanon; Luis Fernandez, Mexico; Keiko Fukuta, Japan; German Gilles, Argentina; Jingying Gao, China; Nur Aqilah Ismail, Brunei; Peck Ha Tan, Singapore; Anwar Hossain, Bangladesh; Ashenafi Hussein, Ethiopia; Ivan Joubert, South Africa; Baset Khalaf, Canada/South Africa; Karen Kulp, USA; Zheng Kun, China; Marcelo Lencina, Argentina; Anne-Marie Lugossy, Canada; Isabel Watanabe Ortega, Mexico; Maurice Page, France; Nicolas Pallikarakis, Greece; Ledina Picari, Albania; Damas Magesa, United Republic of Tanzania; Claudio Meirovich, Spain; Mulugeta Mideksa, Ethiopia; Martha Mulerwa, Uganda; Shauna Mullally, Canada; Umberto Nocco, Italy; Busola Oronti, Nigeria; Leandro Pecchia, Italy; Tashi Penjore, Bhutan; Mladen Poluta, South Africa; K Siddique-e Rabbani, Bangladesh; Barun Kumar Rauniyar, Nepal; Rossana Rivas, Peru; Alfonso Rosales, Costa Rica; Erica Schmidt, Canada; Ricardo Silva, Venezuela; Letizia Songia, Italy; Kallirroï Stavrianou, Greece; Alison Syrett, United Kingdom/Luxembourg; Ichiko Watanabe, Japan; Anna Worm, the Netherlands; Lou Xiaomin, China.

Furthermore, WHO acknowledges the following international external reviewers of the technologies engaged by EuroScan: Syaquirah Akmal, Malaysia; Gaizka Benguria-Arrate, Spain; Lorena Aguilera Cobos, Spain; Agnieszka Dobrzynska, Spain; Li Ying (Grace) Huang, Taiwan, China; Mei-Chi (Joanne) Lai, Taiwan, China; Ingrid Lara, El Salvador; Linda Mundy, Australia; Nurfarah Aqilah Ahmad Nizam, Malaysia; Roza Sarimin, Malaysia. The reviewers provided declaration of interest (DOI) documents, which were assessed by the WHO secretariat, and no conflicts of interest were found.

WHO also acknowledges the following WHO staff for their contribution: Ying Ling Lin and Madison Moon on assessments for PPE and Garreth Mehl for digital health solutions.

Glossary of terms

Term	Definition
Biocompatibility	Biocompatibility is a general term describing the property of a material being compatible with living tissue. Biocompatible materials do not produce a toxic or immunological response when exposed to the body or bodily fluids. The internationally recognized standard for general medical device biocompatibility is ISO 10993. There are many other standards that cover various aspects of biocompatibility testing and/or biocompatibility issues specific to particular types of medical devices.
510(k) Boundary Conditions	The elements of an FDA cleared 510(k) that characterize the device and demonstrate substantial equivalence, such as descriptions, predicate comparisons, labeling, performance characteristic data, and evaluation criteria.
510(k) Clearance	<p>A 510(k) is a notification submitted to the FDA to demonstrate that a medical device to be marketed in the USA is “substantially equivalent” to a legally marketed device. There are different types of 510(k) submissions (traditional, abbreviated, or special), depending on whether the device is new or already on the market and has been modified.</p> <p>Clearance is granted to devices that receive marketing permission from the FDA through the 510(k) process. The 510(k) process is not an approval process.</p>
Certificate to Foreign Government	An FDA certificate that is required by some countries to prove that an exported medical device from the USA is legally marketed in the USA and in compliance with the requirements of the Federal Food, Drug, and Cosmetic Act (FD&C Act).
Certificate of Free Sale (CFS)	Many countries require a CFS, sometimes called a Certificate for Export. It is evidence that goods, such as medical devices, are legally sold or distributed in the open market, freely without restriction, and approved by the regulatory authorities in the country of origin.
Clinical engineer	A trained professional who supports and advances patient care outcomes by applying engineering, life sciences, and managerial skills to optimize healthcare technology life cycles.
Clinical engineering	An application of engineering, life sciences, and management attributes to optimally deploy and safely manage technological tools, risk management techniques, and system challenges associated with the provision of healthcare services, especially in the clinical environment.
Clinical Evaluation Report (CER)	This documents the conclusions of a clinical evaluation of a medical device. A CER consists of analyzed clinical data that was collected from a clinical investigation of a device or the results of other studies on substantially equivalent devices. A CER demonstrates that a device achieves its intended purpose without exposing users and patients to further risk. The European Union’s MEDical DEVICES documents (MEDDEV), 2.7.1 Rev. 3 guidelines and the Medical Device Regulation provide manufacturers with guidance regarding how to evaluate the clinical safety and performance of their devices properly.
Clinical outcomes	Measurable changes in health or quality of life as result of specific healthcare delivery interventions.
CE marking	European Conformity (Conformité Européenne) mark. A mandatory European mark for products (including medical devices) to indicate conformity with essential health and safety requirements set out in the EU directives and regulations.

Term	Definition
Design control	Design control is an interrelated set of practices and procedures that are incorporated into the design and development process, i.e., a system of checks and balances. Design controls make systematic assessment of the design an integral part of development. As a result, deficiencies in design input requirements and discrepancies between proposed designs and requirements are made evident and corrected earlier in the development process. Design controls increase the likelihood that a design transferred to production will translate into a device that is appropriate for its intended use.
Design validation	Testing that aims to ensure that a product or system fulfills the defined user needs and requirements under specified operating conditions and establishing by objective evidence that device specifications conform to user needs and intended uses.
Design verification	Testing that aims to ensure that a product as designed is the same product as intended. Design verification is confirmation by examination and provision of objective evidence that specified requirements have been fulfilled, i.e., the design output meets the design input requirements.
Global Clinical Engineering Alliance (GCEA)	An international not-for-profit organization of national and regional clinical engineering associations and groups of other collaborating stakeholders within the healthcare field.
Good Manufacturing Practices (GMP)	The quality system requirements for FDA regulated products. Medical device GMPs are found in 21 CFR (Code of Federal Regulations) 820 (see QSR below).
Health innovation	Health innovation aims to develop and deliver new or enhanced health policies, systems, products, technologies, services, and delivery methods to improve people's health.
Health technology	The WHO definition is the application of organized knowledge and skills in the form of (medical) devices, medicines, vaccines, procedures, and systems developed to solve a health problem and improve quality of care and/or life.
Health Technology Assessment (HTA)	A multidisciplinary process that uses explicit methods to determine the value of a health technology in comparison to others at different points in its lifecycle. The purpose is to inform decision-making to promote an equitable, efficient, and high-quality health system. ¹
Health Technology Management (HTM)	A process focusing on health-related devices and their usage within clinical procedures and systems.
Horizon Scanning (HS)	Set of method and a concept to identify early available knowledge on health-related innovations or innovative usage as an input for further evaluations, public awareness or decision support as for example, within procurement.
Human factors	The application of knowledge about human behavior, abilities, limitations, and other characteristics of medical device users to the design of a device, including mechanical- and software-driven user interfaces, systems, tasks, user documentation, and user training to enhance and demonstrate safe and effective use.
Instructions for use (IFU)	A document required for medical products for communication of instructions for the safe operation and application of medical products.

¹ O'Rourke B, Oortwijn W, Schuller T; International Joint Task Group. The new definition of health technology assessment: A milestone in international collaboration. *Int J Technol Assess Health Care*. 2020 Jun;36(3):187-190. doi: 10.1017/S0266462320000215.

Term	Definition
ISO 14971 – Medical devices – Application of risk management to medical devices	The international standard that specifies a process for a manufacturer to identify the hazards associated with medical devices, estimate and evaluate the associated risks, control these risks, and monitor the effectiveness of the controls.
ISO 13485 – Medical devices – Quality management systems – Requirements for regulatory purposes	The international standard that specifies requirements for the quality management system for organizations involved with medical devices (manufacturers, distributors, etc.). Organizations must follow this standard to demonstrate their ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements. The standard applies to organizations involved with medical devices at any point in their lifecycle.
Label	Any display of written, printed, or graphic matter on or affixed to the immediate container or package of any article.
Labeling	All written, printed, or graphic matter accompanying an article at any time while such article is in interstate commerce or held for sale after shipment in interstate commerce. It includes user manuals, instructions for use, brochures, advertising, websites, and verbal communications.
Lifecycle	The period of time from idea and concept phase to commercial product, clinical application, upgrade, allocation, and retirement phase of a medical device.
Low- and middle-income countries (LMICs):	According to the World Bank, low-income economies are defined as those with a GNI (Gross National Income) per capita of USD1,035 or less in 2019; lower middle-income economies are those with a GNI per capita between USD1,036 and USD4,045; upper middle-income economies are those with a GNI per capita between USD4,046 and USD12,535. ²
Low-resource settings	Any place with limited infrastructure (e.g., no running water, unstable or unavailable electricity, few or no specialized health professionals, low accessibility, located far from a hospital).
Maintenance	A set of activities (including repair, planned, preventive, and/or predictive maintenance) that help to sustain the availability of safe and calibrated patient-ready products.
Manufacturer	The entity that builds a (medical) product manually or mechanically and is legally responsible for it.
Medical device	<p>The definition of the medical device is as follows and based on IMDRF/GHTF/SG1/N071:2012:</p> <p>A medical device is defined as any instrument, apparatus, appliance, software, implant, reagent, material, or other item intended by a manufacturer to be used alone or in combination for human beings for one or more of the following specific medical purposes:</p> <ul style="list-style-type: none"> • diagnosis, prevention, monitoring, prediction, prognosis, treatment, or alleviation of disease • diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability • investigation, replacement, or modification of the anatomy or of a physiological or pathological process or state • providing information by means of in vitro examination of specimens derived from the human body, including organ, blood, and tissue donations.

² World Bank. World Bank Country and Lending Groups. <https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-bank-country-and-lending-groups>.

Term	Definition
Medical Device Directive (MDD)	Legislation (Council Directive 93/42/EEC) that sets the general requirements relating to the design and construction of medical devices and their accessories, excluding in vitro and active implantable devices. Provides the legislative framework within which EU/EFTA Member State Competent Authorities and Notified Bodies regulate the CE marking process for placing and maintaining medical devices on the market in the EU.
Medical Device Regulation (MDR)	The new regulation [(EU) 2017/745] in the EU/EFTA that will replace the MDD. The new rules apply to all medical devices on the market from May 2021.
Performance Evaluation Reports (PER)	Assessment and analysis of data to establish or verify the performance of an IVD medical device. This is the CER equivalent requirement for EU IVDs.
Periodic Safety Update Report (PSUR)	A report that summarizes the results and conclusions of analyses of post-market surveillance data gathered as a result of a post-market surveillance plan together with a rationale and description of any preventive and corrective actions taken. Throughout the lifetime of the device concerned; required for EU MDR Class IIa, IIb, and III, and IVDR Class C and D devices.
Point-of-care (POC)	A location, usually in a healthcare delivery setting, where patient and provider interact. Technology can often be found in such interactions.
Post-Market Surveillance (PMS)	Manufacturers with economic operators participate in a pro-active systematic procedure to collect and review the experiences of marketed products. This is a global regulatory and quality system requirement. The FDA defines PMS activities as including tracking systems; reporting of device malfunctions, serious injuries, or deaths; registering the establishments where devices are produced or distributed; post-market surveillance studies; and post-approval studies.
Post-Market Surveillance Report (PMSR)	Required for EU MDR Class I and IVDR Class A and B devices.
Quality System Regulation (QSR) 21 CFR 820	The federal regulation that specifies the good manufacturing practices required for medical device companies. Manufacturers must establish and follow quality systems to help ensure that their products consistently meet applicable requirements and specifications.
Repair	A series of activities, on demand by qualified individuals, to return a medical product to its original performance and condition.
Risk management	The systemic application of management policies, procedures, and practices to the tasks of analyzing, evaluating, controlling, and monitoring risk.
Robustness	The quality of being resilient or having the ability to withstand adverse conditions.
Software validation	The process of evaluating software during or at the end of the development process to determine whether it satisfies specified business requirements.
Spare parts	Component to be used when replacing a defective original component of a product.

Term	Definition
Survey	A set of activities that aims to discover new knowledge through the use of a data collection tool.
Technical Readiness Level (TRL)	TRL is a system used to estimate technology maturity. TRL is based on a scale from 1 to 9, with 9 being the most mature technology. ³
Technical service	The planned or on demand application of activities that sustain or return a medical or dental product to its patient-ready condition.
Technical specification	These define the minimum requirements for a product to ensure good quality, safety, and efficacy.
Technical training	In clinical engineering, an educational strategy that aims to promote safe, optimal, and compliant maintenance and repair services of medical devices.

³ https://ec.europa.eu/research/participants/data/ref/h2020/other/wp/2016_2017/annexes/h2020-wp1617-annex-g-trl_en.pdf

Executive summary

Access to innovations in health technologies is one of the pillars of the Universal Health Coverage (UHC) strategy. Health innovation aims to develop and deliver new or enhanced health policies, systems, products, technologies, services, and delivery methods to improve people's health. Medical devices, oxygen sources, and personal protective equipment (among others) are all health technologies that have the potential to improve quality of life and health outcomes. However, access to high quality, safe, appropriate, and affordable health technology is not equitable, with the situation being most severe in low resource settings. Furthermore, the COVID-19 pandemic has heightened the need for new and innovative health technologies, especially in low-resource settings. Therefore, a timely and evidence-based assessments for such emerging technologies is a pressing need. The first Compendium of innovative technologies was published in 2011. Since then, WHO has been regularly publishing new volumes of the Compendium. For the volumes in 2021 and 2022 the Compendium focused on identifying health technologies that support the COVID-19 response and other health priorities. Detail information on all volumes of the Compendium of innovative technologies for low resource settings are available at <https://www.who.int/activities/accelerating-impact-for-innovations-for-health>.

The objective of the 2022 Compendium is to compile and highlight emerging innovative health technologies for low-resource settings. It presents a snapshot of technologies that are solutions to an unmet medical/health technology need or are likely to improve health outcomes and the quality of life. Health technologies in the Compendium underwent WHO rapid evidence-based assessments focused on the life cycle of health technology innovations for low-resource settings. The evaluation included:

- clinical assessment
- WHO specification comparison
- regulatory assessment
- technology evidence assessment
- health technology and engineering management assessment
- intellectual property and local production

The process for selecting health technologies for the Compendium is based on a multidisciplinary assessment methodology. It begins with a call for submission, which undergoes an initial review for completeness. Based on the material and evidence submitted by the applicant, assessments were conducted followed by synthesis of the findings, deliberation and selection of technologies to be included in the Compendium.

The submission and screening process to eliminate technologies that do not fulfil the basic criteria for health technologies, the assessment method for ranking technologies, and the review of the results are continuously being monitored and improved.

The WHO Compendium of innovative technologies for low-resource settings - 2022 presents manufacturer-reported information and WHO assessment results of fifteen health technologies. Health technologies were classified as either commercially available (seven technologies) or prototypes (eight technologies). Each technology in the Compendium is presented in three pages summarizing the product specifications provided by the developers, the synthesis of all WHO assessments, and related WHO guidance material.

The Compendium sheds light on advantages and challenges associated with implementing innovative health technologies in low-resource settings and can be used by governments, NGOs and other stakeholders to support procurement decisions. It also aims to foster greater collaboration between ministries of health, procurement officers, donors, technology developers, manufacturers, clinicians, academics, and the public to ensure increased investment in appropriate health technology and a move toward universal access to essential health technologies.

Objectives

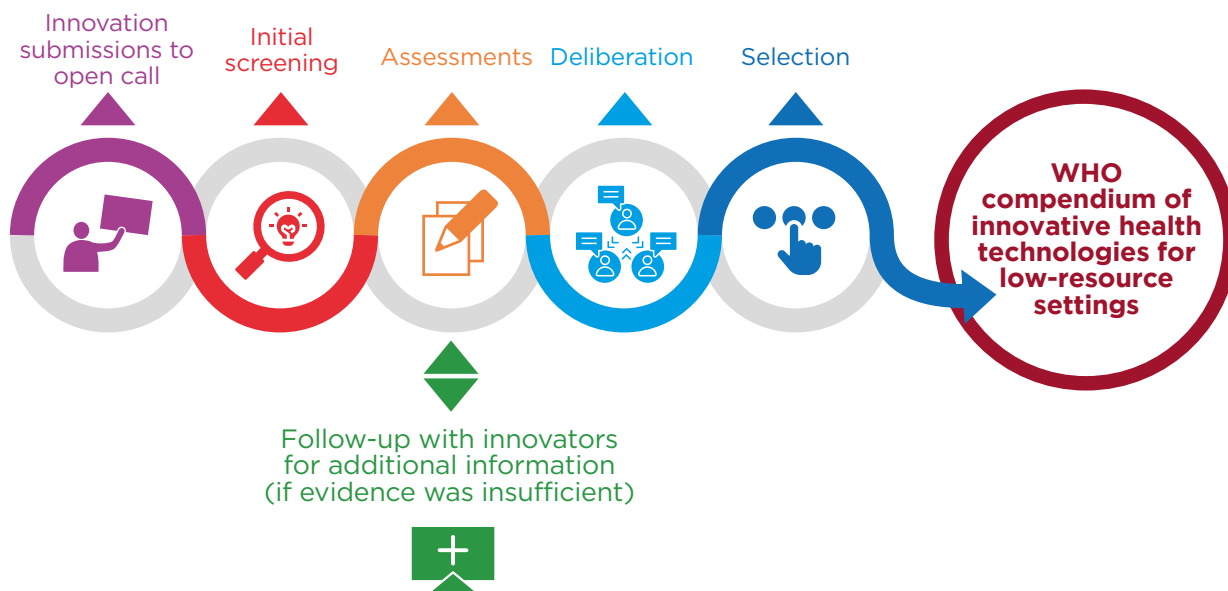
The response to the global COVID-19 pandemic crisis has exacerbated the need for rapid evidence-based assessments of innovative health technologies to ensure safe and quality health impact. The 2021 volume included 24 technologies, and many more were received for assessment, therefore this present volume aligns and expands from the 2021 Compendium. The objectives of the 2022 Compendium are to:

1. Select innovative technologies that can have an immediate or future impact on the COVID-19 preparedness and response, have the potential to improve health outcomes and quality of life, and/or offer a solution to an unmet medical/health technology need by evaluating their appropriateness, quality, and safety.
2. Select innovative technologies that might have the potential of being locally produced or subject to technology transfer for submission to the [COVID technology access pool \(C-TAP\)](#).
3. Provide technical information onto the prototypes presented for appropriate and affordable design solutions to meet the clinical outcomes.
4. Encourage greater interaction among ministries of health, procurement officers, donors, technology developers, manufacturers, clinicians, academics, and the general public to ensure greater investment in appropriate health technology and a move toward universal access to essential health technologies.
5. Support informed procurement decisions by NGOs, governments, and other stakeholders.

Methodology

The overall evaluation and selection process is shown in Figure 1. The stages include innovation submissions to an open call, initial screening, varied assessments, deliberation, and selection.

Figure 1. Overall evaluation process



Innovation submissions to open call and screening



Following the success of the earlier calls (2010-2014, 2016 and 2020), a new call for the Compendium was opened in 2021. These calls respond to the influx of innovations being developed to address technology needs for the COVID-19 response and other health priorities. The format of the online submission form was the same as that of the 2020 call. The sections of the survey are shown in Figure 2. Two categories of products based on the state of development were considered: prototypes and commercially available health technologies. The possible types of technologies to submit were medical devices, personal protective equipment, IVDs medical devices, medical gas systems, e-health solutions (including medical device interfaces), and other digital technologies.

The call for submissions was open to the public and posted on the WHO website (<https://www.who.int/activities/accelerating-impact-for-innovations-for-health>). The submissions underwent an initial screening process to ensure that the forms were complete. The total number of full submissions reviewed for this compendium volume were 34. Other submissions received in the call were duplicates or not full submissions, therefore were not assessed. It should be clarified that the technologies presented for COVID-19 are not specific to COVID-19 but also to other respiratory diseases, such as pneumonia.

Figure 2. Assessment domains of the submission form.



Follow-up with innovators for additional information



The materials from the submissions were reviewed by a senior, core team of experts, with experience in regulatory and quality systems, intellectual property and local production, health technology assessment, and clinical engineering, to ensure that sufficient information was available to perform the assessments. If any relevant missing information was identified, the innovators were contacted and asked to provide additional documentation so that the assessment process could continue. Two products were excluded at this stage, leaving 32 submissions that were considered for the full assessment.

Assessments



The 32 complete submissions underwent 6 separate assessments that were led by the core team of experts with assistance from 57 external reviewers from 37 countries. All experts and external reviewers provided a Disclosure of Interest (DoI) form and no conflicts of interest were identified. The technologies were assessed based primarily on the material and evidence provided by the applicant; in some specific cases, publicly available information was consulted. After the assessment 15 technologies were included in the compendium and 17 were not listed. The accepted technologies include 8 prototypes and 7 commercially available technologies.

Clinical assessment

A clinical assessment was conducted on each medical device submitted through the WHO application process. All clinical characteristics linked to the use of the device, including the health problem addressed, the medical indications and the intended clinical use, were reviewed based on the information provided by the user manuals, clinical guidance materials, technical manuals, and brochures of the devices. For this purpose, WHO clinical recommendations or related documents were used as a reference. The clinical and epidemiological data were compiled using the most recent WHO materials and resources. The perspective and expertise of the evaluators from clinical settings was also factored into the final selection of the technology.

WHO specification comparison

A WHO specification comparison was conducted on the devices submitted whose generic names fell into the List of Priority Medical Devices in the context of COVID-19, or that had been listed in any of the other [WHO lists of priority medical devices](#), or to the [WHO technical specifications for medical devices](#). Each technical characteristic was reviewed against the technical specifications in the user manuals, clinical guidance, technical manuals, and brochures of the devices. This was further summarized in the technology report as relevant compliant characteristics, non-compliant characteristics, or not verified technical characteristics in the applicable technologies. The technical evaluation contributed towards the final selection of the technology.

Regulatory assessment

Pre- and post-market regulatory and quality system assessments were conducted on each device submitted through the WHO application process. Each supporting document was reviewed and benchmarked against current US FDA and EU regulatory and quality system requirements. If gaps were identified, each applicant was given the opportunity to provide documentation to further support the assessment. A final report was created for each device, which provided details on the suitability of each device to be placed on the market in LMICs. This report was further summarized for inclusion in the Compendium with the intended purpose of assisting healthcare providers with their purchasing decisions. This summary includes coloured icons for each assessment category to help purchasers understand the regulatory and quality system status for each device.

Status



Proceed



Proceed with caution



Not acceptable

Technology evidence assessment

EuroScan adapted health technology assessment (HTA) and horizon scanning (HS) methods to create a technology related evidence-based assessment, which was used in the 2021 Compendium. The evidence that was evaluated was provided by the WHO secretariat, which collected the evidence from the submission forms innovators had completed and contacted the innovators if further information was required for the analysis. The time to do the evaluation was limited to 6 weeks for 32 technologies.

The technology related evidence-based assessment was used to answer different HTA-related questions related to the use of the technology in LMICs as well as to evaluate the transferability of a technology's production or maintenance. Finally, the evidence assessment helped to decide whether a technology would be listed in the Compendium.

The evidence assessment was divided into different topics:

The classical-specific HTA-related domains were used to identify the relevant questions in each domain. Due to the special low-resource settings and green environmental policies, the domains also included special topics on the organizational requirements to use the technology and a green environmental assessment, which included the production, maintenance, use of a technology, and waste associated with a product.

Additional topics were included in the evidence assessment: technology readiness level (TRL) (according to EU classification), and the overall evidence-based technology assessment.

The entire evaluation had limitations according to HTA methodology, including:

- no systematic evidence literature review (only evidence that WHO collected from the innovator, in the survey call, was considered)
- limited time offered to complete the evaluation (a maximum of eight weeks including all results)

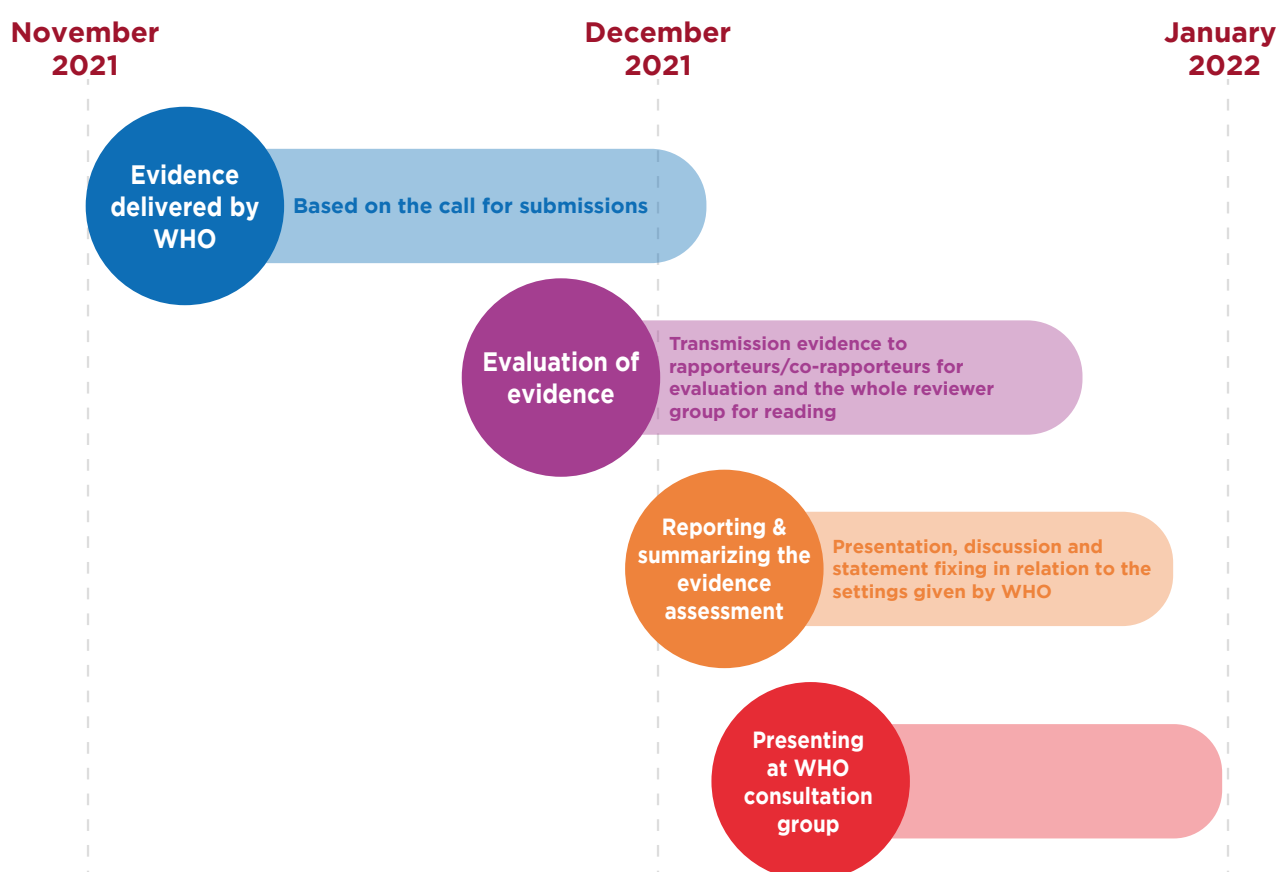
The entire evaluation was linked to HTA but is not a final HTA. Nevertheless, the evidence evaluation can be used and should be extended taking context specificities and point of care (POC) requirements into account to support the decision-making process as defined by the HS concept.

After a short pre-evaluation phase, including the adaptation of HTA and HS methodologies, EuroScan established a working group of reviewers from five countries, mainly from public institutions or publicly funded organizations. All participants signed the required DOI and had a professional background in medical device evaluations and training in the HTA method (including general evidence-based medicine expertise and knowledge management in health-related technologies). Professionals with different backgrounds were involved, including engineers, health economists, medical doctors, biochemists, information specialists, and epidemiologists.

The process was divided into two phases:

The first phase comprised the evaluation of the evidence based on a given evaluation background. It was done by EuroScan internally and prepared by a rapporteur and a co-rapporteur who provided an overview to the group of reviewers. All reviewers could contribute their expertise to this process, and the rapporteur and co-rapporteur could respond to questions based on the evidence. Specific expertise on requirements in LMICs was incorporated by involving professionals from these countries.

In the second phase, there was a transfer into a WHO required schema and final judgement assessment within the WHO consultation group. For the second phase, two senior HTA experts were included to summarize the presentation and discussion and fill in the WHO evaluation schema.

Figure 3. Step-by-step process description

For each technology, a rapporteur summarized the provided evidence and assigned it to HTA domains (including the focus on clinical outcomes). Then, a co-rapporteur commented and/or added to the first rapporteur's report. All provided evidence was delivered to everyone in the reviewer group. After the presentation of the assigned rapporteurs, all reviewers discussed the report, the options for LMIC settings, and the HTA-related domains (clinical effectiveness, economic, social, ethical, legal, and organizational issues). The assessment of the domain-related evidence was divided into a risk/benefit ratio, the potential impact of the technology in the domain area, and whether the technology had an innovation aspect in the domain.

The evidence related to the HTA domains was assessed against a risk/benefit ratio by giving a combined answer on whether:

- the evidence supported the proposed intended use
- the evidence described an acceptable risk/benefit ratio
- the evidence showed a high-level risk within the risk/benefit ratio assessment
- the technology could have a potential impact on the domain area
- the evidence suggested a potential positive impact
- the evidence described a moderate impact
- the evidence highlighted a potential negative impact on the desired outcome
- the technology had an innovative aspect (yes/no).

Every domain was evaluated separately:

- The medical/health domain had to describe the value related to patient-related outcome with a specific, but not exclusive, focus on COVID-19 treatment.
- The safety aspects were evaluated against the safety toward a patient and related staff.
- The economic evaluation was done only in relation to the direct costs of the technology and the provided pricings. The limitation was the absence of a deeper analysis due to a lack of knowledge about the environment of usage and a final statement of costs.
- The ethical and social aspects were related to a higher level of abstraction, as local/contextual aspects could not be considered. General global beliefs were taken into consideration. Specific local aspects could not be included in the assessment. The same limitation exists due to specific sets of values and local social structures.
- The legal aspects mainly included regulatory or human rights aspects.
- The green environment assessment was done separately from the safety aspects to describe the impact of a technology and the risk to a green environment. This included manufacturing, transportation of the technology and related equipment, and the maintenance and waste related to the use of a technology.

The summary of the assessment was divided into four statements (see Figure 3). The reviewers checked whether it was a prototype or a ready-for-market technology (TRL level according to EU standards; <https://bit.ly/3rUUEY7>).

Four levels were used to classify the evidence level:



High: the provided evidence fulfilled all requirements, and no further data was needed.



Medium: the level of evidence was of sufficient quality to ensure that conclusions were properly based on data even though further evidence could be required.



Low: a significant amount of evidence was lacking, especially on health-related information (outcome-related).



Not applicable

Poor: the evidence provided did not meet any kind of reliable review option.

The TA was performed on a snapshot of the evidence. The assessment is risk/benefit assessment, which has to be re-evaluated in a given setting and considering newly published evidence.

The TA was grouped into:



Recommended: recommended for use without any known limitations.



Recommend with caution: limitations could be identified, and the implementation of the technology in a specific context should be done with caution.



Not recommended: enough evidence to support the non-implementation of a technology.



Not applicable

This final assessment was transferred into a graphical and text-based summary for the Compendium.

Health technology and engineering management assessment

The GCEA engaged an international community of clinical engineering experts (CEE) to review and assess the technological attributes of health technologies submitted to WHO during the 2021 cycle of innovation submissions. The submissions were initially reviewed for completeness of needed technological information by Senior Clinical Engineering Experts (SCEE), who has experience of conducting global clinical engineering surveys, including in low-resource countries, and publishing findings in engineering literature. Once completed, the submissions were forwarded to the international CEE for their review and feedback. Its members were selected based on their technical area of expertise, clinical setting experience, and location of practice. Specific criteria for the experts' qualifications included working experience in a healthcare delivery system, a practical understanding of HTM principles, a match between their technological experience and the categories of the submissions assigned for their review, prior or current clinical engineering practice in low-resource settings, and the acceptance of WHO's terms of participation.

Following the qualification of experts, at least two reviewers were assigned to each submission. The submissions were matched to CEE reviewers according to their area of expertise and location of practice, along with the technological nature of the submission. To meet the goals of the engineering assessment, the CEE submitted their evaluations by completing an online survey tool designed by the SCEE for this purpose. The survey tool consisted of 26 multiple-choice questions on various technological characteristics identified as relevant to evaluating the appropriateness of innovative health technologies for low-resource settings. Evaluated parameters, examined from the Point of Care (POC) perspective, included product outcomes, acceptability, robustness, environment of use conditions, resource requirements, availability of local support, and ease of operational use. Product outcomes included questions related to the potential impact from use of innovative product as compared with alternative technology. Acceptability questions are related to aesthetics and usability of the product in the intended locality, while robustness is related to the quality of a product's construction and its durability. Environmental conditions examined the effects of extreme humidity, temperature, sand, power fluctuations, and storing conditions on product performance. The effect of deploying the product on the need for additional engineering or supplies resources and the extent for sufficient local sales and technical support were also included. The survey tool was designed to align with the experts' working knowledge of related nomenclature. Each multiple-choice question was coupled with a section for comments to enable CEEs to provide additional reasons to support their responses.

The online tool was tested previously and deployed during the evaluation process of submissions received during the previous 2021 Compendium. The online format of the tool facilitated timely feedback collection from remote and central locations around the world. A total of 52 filled surveys were received from 50 CEEs representing 34 countries from across all of WHO regions. Over 38% of these countries are from LMIC regions. Of the 50 CEE reviewers, 54% were male and 46% were female.* (the list of reviewers is in the acknowledgement section)

Results from the survey were collated, analyzed, and compiled by the SCEE team. For each completed survey, the SCEE reviewed all multiple-choice questions and their corresponding comments. The SCEE then converted the responses to each question into a score of 1, 3, or 5. A value of 1 indicated a lack of evidence or evidence of negative impact to support the feature in the question. A value of 3 indicated partial evidence and a need for additional information to address concerns. A value of 5 indicated sufficient evidence to support the feature in question. For every submission, a mean score of CEE responses was calculated for each question in the survey. Mean scores between 1–2.99, 3–3.99, and 4–5 were classified as product characteristics with low, moderate, and high appropriateness for low-resource settings, respectively. The SCEE team used their expertise to complete ratings for features where inconclusive field data was collected.

The average values for each submission are presented in a color-coded format. A feature presented in red indicates low appropriateness for low-resource settings, which is defined as product characteristics having responses that were typically weak, without evidence, or unsupported. Orange indicates moderate appropriateness for low-resource settings, which is defined as product characteristics having average responses and contains caution for further need of evidence. Green represents high appropriateness for low-resource settings, which is defined as product characteristics that have strong or above average evidence. The intended target settings for each product were also determined by the SCEE based on the information provided with the submission and the survey responses.



High appropriateness for low-resource settings

Product characteristics that have strong or above average evidence



Moderate appropriateness for low-resource settings

Product characteristics with average responses and caution for further need of evidence



Low appropriateness for low-resource setting

Product characteristics with responses that were typically weak, without evidence, or unsupported



Not applicable

The results, which are based on an assessment from 50 international field-based CEEs, provide evidence for the engineering and technology management assessment of each of the submissions. For each product, the SCEE summarized the responses into a final ranking to support Compendium inclusion or exclusion decisions. The classification of technological properties for each accepted submission is presented into the final format.

Intellectual property and local production

The methodology for assessing the intellectual property (IP) of the innovations submitted to WHO consisted in identifying the IP rights associated to or protecting each innovation, determining their ownership, and evaluating their accessibility and transferability.

Several steps were followed to identify the IP rights (copyrights, patents, design registrations or design patents, trade secrets, and trademarks) accurately. First, the information and evidence provided by the innovators was reviewed. The IP rights mentioned in the submissions were noted in a report. Subsequently, a more comprehensive research was performed to verify the evidence provided and identify further IP rights. International IP searches were performed using numerous IP open databases. IP laws from the relevant countries were reviewed to verify the scope of the identified IP rights. In some cases, further information was required, and innovators were given the opportunity to provide additional documentation. After their identification, a brief description of each IP right and their current legal status was added. For each technology, IP rights were categorized into registered or unregistered, granted or pending, open access or not, proprietary or open source (software), and relevant or irrelevant to the present IP assessment.

Following the identification stage, it was determined whether all of the IP rights identified were in fact owned by the applicant, and if not, who was the legal owner. Further, the nature of the ownership was determined (sole or joint ownership, license, assignment, amongst others). A background search on the applicant (individual or company and its subsidiaries) was performed at this stage to clarify what the applicant's position was regarding the ownership of the IP rights.

For the next step of the assessment, a brief infringement check was performed to verify whether the IP rights identified were or could be subject to infringement by others. A limited check was also performed to verify if any assets or IP rights were infringed upon, or if the products used, were licensed or in the public domain.

Subsequently, all the available agreements that could have an impact on the transferability of the technology were reviewed. These included any existing licensing (exclusive or non-exclusive), manufacturing, and distribution agreements. At a later stage, a thorough research was executed to assess if the IP of each technology was fully open access, limited open access or no open access and if the owners of the IP rights retained any rights and control over the distributed material.

Lastly, to reach a conclusion on the transferability of the technology, the following points were considered:

- Identification of the IP rights and their legal status
- Ownership of the IP rights
- Possibility of infringement of third-party owned rights
- Existing agreements
- Willingness of the IP owner to transfer the IP

The transferability was rated as:



Fully transferable



Partly transferable



Not transferable



Not applicable

Local production assessment

Since local production is a business case that is influenced by a number of factors ranging from technology to regional policies and global competition, the methodology for local production was designed to assess overall maturity of LMIC's to manufacture the specific product. The availability of regional resources vs. import was used as the basis since the variability and the diversity in production capabilities (including both MICs and LICs), across LMIC member states is too complex.

The methodology ensures that aspects contributing to Affordability, Accessibility, and Availability (including long-term supply of spares irrespective of economic sanctions) are also considered. A uniform and unbiased evaluation was used to verify that these requirements are met. Man, Material, Machine, Method, and Money, the 5M's^{4,5} of production management, were used to analyse the potential for local production. These were subdivided in to sub parameters as seen in table below.

Product		TEMPLATE	TEMPLATE
Compendium code		HIC	LMIC
Local production - Analysis of 5M's		HIC	LMIC
Man (HR)	Resources for manufacturing		
	Resources for quality		
	Resources for regulatory		
Material	Raw/base material (regional/import)		
	Semi finished material (regional/import)		
	Semi-knocked-down kit units (regional/import)		
	Packaging material (regional/import)		
	Material complexity (low - medium- high)		
Machine	Supply chain cluster		
	Inhouse manufacturing		
	Testing equipment/Rigs		
	3rd party validating labs		
Methods	Processes needed		
	Quality control		
Money	Regional Market & exports		
	CAPEX/investment vs returns case		
	Unit production cost		
Conclusion on local production			

4 Bradley E. Reliability Engineering: A Life Cycle Approach. Taylor & Francis Limited; 2021. (21st Century Business Management).

5 Weeden MM. Failure Mode and Effects Analysis (FMEA) for Small Business Owners and Non-Engineers: Determining and Preventing What Can Go Wrong. American Society for Quality; 2015. _____

A conclusion was reached for the Compendium based on the evaluation of these sub parameters: Low-Moderate-High. The “Unit Production Cost” (under Money in the table above) is determined by considering the analysis of all other sub parameters as well as the evidence gathered from open sources and the assessment results on the technology obtained by the other experts. Thus, it is not quantifiable; rather, it provides insight on the increase or decrease in production costs due to local production.

Based on the above analysis, the most prevalent and sensitive areas of concern and maturity needed for the specific product are listed in the comments to ensure successful manufacturing. As a result, the points listed are not comprehensive but rather the most important aspects specific to that product that must be examined first before proceeding on to other aspects of local production.



High potential for local production



Moderate potential for local production



Low potential for local production



Not applicable

WHO related guidance material

WHO clinical recommendations, management guidelines, and other relevant resources that were used as a reference to conduct the clinical evaluation were included in this section.

Selection



Once the assessments were completed, the core team including the multidisciplinary team of consultants representing the clinical assessment, WHO specification comparison, regulatory assessment, technology evidence assessment, health technology and engineering management assessment and intellectual property assessment synthesized their findings and selected the technologies to be included in the 2022 Compendium. This step consisted of the team deliberation sessions and a selection process.

Each assessment team recorded their findings and recommendations in a pre-designed web-template developed for capturing input and comments from the team. During the deliberation session, each of the six assessment teams provided a summary of their findings, discussed, and weighed the rationale for inclusion or exclusion of each product in the Compendium. In addition, clinical experience with similar technologies in a real-world scenario was taken into consideration. The final decision on the technology was postponed to a later session, if the need for additional information from the manufacturer was raised. Each team assigned a confirmation to each submission based on the deliberation during the selection process. The following scale was used: 1) listed: sufficient evidence 2) not listed: submission incomplete or no evidence of utility or evidence of harm. During the meetings, the team confirmed acceptance of technologies with 75% consensus rankings of one and rejection of technologies with 75% consensus rankings of two.

After the selection process was completed, a total of eight prototypes, and seven commercially available products were selected and are presented in this Compendium. It should be noted that for any selected technology, inclusion in the Compendium does not constitute a warranty for fitness of the technology for a particular purpose.

All innovative solutions in the Compendium are presented in three pages summarizing the results from the WHO assessments and describing information provided by the manufacturers (commercial information, product description, product details).

The innovative solutions in the Compendium include the following types of products: medical devices, personal protective equipment, medical gas systems and eHealth solutions. In many low-resource settings, too many people suffer because they do not have access to appropriate, good quality health technologies to support the prevention, diagnosis, or treatment of a disease or disability. This Compendium illustrates innovative technologies (in the pipeline and available) to empower healthcare workers and potentially help people and patients enjoy a healthier life.

Terms, conditions and disclaimers for the call

WHO reserves the right not to select any application or to annul the solicitation process at any time without incurring any liability or any obligation to inform the applicants of the grounds for WHO's action. WHO reserves the right, at any time during the solicitation process, to modify the scope of the call. At any step in the evaluation process, WHO reserves the right to issue an amendment to the call detailing the change to only those applicants who have not been officially eliminated at that point in time. Applications will be evaluated by WHO, in collaboration with partner experts and institutions, at its sole discretion, taking into account the criteria outlined above. There is no obligation by WHO to reveal or discuss with any applicant how a submission was assessed or to provide any other information relative to the selection process.

Incomplete applications and applications submitted after the deadline will, in principle, be disregarded unless WHO, at its sole discretion, decides otherwise in respect of such incomplete or late application. WHO may request applicants to submit complementary or additional information as a condition for consideration. Any possible requests to submit complementary information and/or a more detailed application, as well as any discussions ensuing therefrom, will be exploratory only, and do not mean that the applicant concerned will be selected.

WHO will not be held to offer applicants any explanation or justification as to why their proposal has been rejected and/or why they have not been selected. The list of selected applications will not necessarily be made public. The submission of applications, the subsequent selection process, and the outcome of the selection process will not be subject to any claim of any kind whatsoever or appeal. Each applicant will be notified by WHO in writing (by e-mail) whether or not their submission has been selected.

Any and all costs and expenses incurred in relation to, or ensuing from, the submission of an application (including the possible request by WHO for complementary information and/or a more detailed proposal) will not be subject to claims for financial compensation of any kind whatsoever.

WHO does not warrant that any medical devices, innovations, concepts, or products that may be used, identified, or otherwise developed from selected proposals will be successfully commercialized in target countries, or that WHO will finance or otherwise support the development or commercialization of any product. By selecting applications, WHO will not be held to endorse any product but will solely aim to draw stakeholders' attention to innovative technologies with a view to furthering the development and availability of and access to such innovative health technologies.

The mention of specific companies or certain manufacturers' products at any stage of the selection process or subsequently will not imply that they are endorsed or recommended by WHO in preference to others of a similar nature that are not mentioned, nor that they have been found to be safe and efficacious.

Without WHO's prior written approval, selected applicants shall not, in any statement of an advertising or promotional nature, refer to their selection under this call for innovative health technologies. In no case shall selected applicants use the name or emblem of the World Health Organization, or any abbreviation thereof, in relation to their business or otherwise. The same applies to all applicants during the selection process and thereafter.

Disclaimer for the results

Eligibility for inclusion in the Compendium has been evaluated by WHO and the external technical advisers listed in the Acknowledgements. However, the evaluation has been solely based on a limited assortment of data including information submitted in applications and when available additional identified public sources. There has been neither physical testing nor rigorous review for safety, efficacy, quality, applicability, or cost acceptability of any of the technologies. Therefore, inclusion in the Compendium does not constitute a warranty of the fitness of any technology for a particular purpose. Besides, the responsibility for the quality, safety, and efficacy of each technology remains with the developer and/ or manufacturer and/or user.

The decision to include a particular technology in the Compendium is subject to change on the basis of new evidence that may subsequently become available to WHO. WHO will not be held to endorse or recommend any technology included in the Compendium. Inclusion in the Compendium solely aims to draw stakeholders' attention to innovative health technologies, either existing or under development, with a view to fostering the development and availability of and/or access to new and emerging technologies that are likely to be accessible, appropriate, and affordable for use in low-and middle-income countries.

WHO does not warrant or represent that:

1. The list of innovative health technologies is exhaustive or error free.
2. The technologies that are included in the Compendium will be embodied in future editions of the Compendium.
3. The use of the technologies listed is, or will be, in accordance with the national laws and regulations of any country, including but not limited to patent laws.
4. Any product that may be developed from the listed technologies will be successfully commercialized in target countries, or that WHO will finance or otherwise support the development or commercialization of any such product.

WHO disclaims any and all liability and responsibility whatsoever for any injury, death, loss, damage, use of personal data, or other prejudice of any kind that may arise as a result of, or in connection with, the procurement, distribution, and/or use of any technology embodied in the Compendium, or of any resulting product and any future development thereof. Developers whose technology has been included in the Compendium shall not, in any statement of an advertising, commercial, and/ or promotional nature, refer to their participation and/or inclusion in the Compendium. In no case shall the latter use the WHO name and/or emblem, or any abbreviation thereof, in relation to their business or otherwise.

Key for icons

This section includes three keys for icons. The first key (below) is an easy to read legend for all the icons in their category. The second key includes the icons used to describe target settings (next page). The third key is an example of the profile used to depict assessment results for each technology. This example depicts a complete list of icons and their definitions in the order they appear for all technologies.

				
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

Target settings

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

Primary level



Home settings



Urban



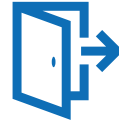
Secondary level



Ambulance



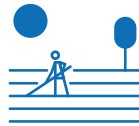
Outdoors



Tertiary level



Rural



Indoors



Generic name of type of technology

Country of origin | Country name

Primary function | Prevention; Treatment; Electronic health/medical records; Monitoring; Communication, safety, training; Supporting or sustaining life; Diagnosis; Alleviation of disease; Disinfection of medical devices; Control of conception

Category | Medical Device; Other technology; Medical gas system; eHealth/mHealth solution; Personal protective equipment

Image of
technology

Commercial information

List price (USD):

Year of commercialization:

Number of units distributed:

Currently marketed in:

Brand:

Model:

Product description

A concise technical explanation including the underlying functional mechanisms of the technology is provided.

Product details

Accessories:

Consumables:

Warranty duration:

Lifetime:

Energy requirements:

Facility requirements:

Contact name: | Email: | Phone: | Web:

WHO ASSESSMENT

Clinical assessment

This section provides a brief report on the clinical assessment that was performed. Based on the information provided by the user manuals, clinical guidance materials, technical manuals, and brochures of the devices all clinical characteristics related to the use of the device, including the health problem addressed, the medical indications and the intended clinical use, were reviewed.

WHO specification comparison

This summarizes relevant compliant and non-compliant characteristics, as well as technical characteristics that could not be verified. The comparison was conducted on the devices submitted whose generic names appear in the List of Priority Medical Devices in the context of COVID-19, or other WHO medical devices lists. The technical characteristics were reviewed against the technical specifications specified in the user manuals, clinical guidance, technical manuals, and brochures of the devices.

Regulatory assessment

Each device submitted through the WHO application process was subjected to pre- and post-market regulatory and quality system evaluations. For each device, a final report was generated that detailed the device's readiness for placement on the market in LMICs.



Pre-market assessment

Review of all plans, documents, and data required to support a medical device or IVD medical device premarket submission. US FDA and EU MDR/IVDR CE Mark requirements are used as a benchmark representative for all global regulatory requirements.



Post-market assessment





Review of all plans, documents, and data required to ensure support of a medical device or IVD medical device after a manufacturer or market authorization holder has received premarket clearance or approval. US FDA and EU MDR/IVDR CE Mark requirements are used as a benchmark representative for all global regulatory requirements.







Quality system assessment

Review of all plans, documents, and data required to support a medical device or IVD medical device quality system of a manufacturer and/or market authorization holder. US FDA and EU MDR/IVDR CE Mark requirements are used as a benchmark representative for all global regulatory requirements.

Technology evidence assessment











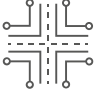



Domains	Description	Innovation
 Medical	The health benefit of using a technology, program, or intervention to address a specific problem.	Improvement of the health benefit against the standard of care
 Safety	A judgment concerning the acceptability of the risk (a measure of the probability of an adverse outcome and its severity) associated with using a technology in a given situation (e.g. for a patient with a particular health problem) by a clinician with certain training, or in a specified treatment setting.	Improvement of the safety profile of the technology against the standard of care if any
 Economy	The comparative analysis of the costs and consequences of applying the technology in the context against the current standard of care, in this case, applied to the affordability of the costs in low resource settings	Reduction of the overall costs of managing the patient against the current standards if any
 Organizational	The needed structure, skills and behaviours that are involved in the management and safe delivery of patient care with the implementation of the proposed technology	Improvement of the structure, skills and behaviours with the inclusion or implementation of the proposed technology against the standard of care that suppose an opportunity for systems.

Domains	Description	Innovation
 Legal	<p>The impact of the technology on national, regional, and local law, rules, regulations and other jurisprudence among providers, payers and vendors to the health care industry and its patients, and delivery of health care services, with an emphasis on operations, regulatory and transactional issues</p>	<p>Enhancement of the impact on legal aspects of the proposed technology in comparison to the existing alternatives if any</p>
 Social	<p>It relates to unique perspectives about experiences, attitudes, preferences, values, and expectations concerning health, illness, service delivery and treatments. The burden of living with the condition being studied. Experiences of current used health technologies. Experiences with and expectations of the health technology being studied</p>	<p>Enhancement of the experiences, attitudes, preferences, values, and expectations that could improve the intended effect of the analysed technology in comparison to the standard of care if any</p>
 Ethical	<p>The dilemmas that the technology could trigger around: a) the use of the technology, b) the conduct of research to generate evidence that supports technology use and c) the allocation of resources</p>	<p>Partial or complete resolution of the ethical dilemmas that the current standard of care trigger on health systems.</p>
 Green environment	<p>The impact of the technology design and materials, production, packaging, transportation, distribution, storage, maintenance, destruction, recyclability, on the environment and its influence on climate change and people's health</p>	<p>Reduction of the undesirable or unintended effects that the technology could generate in the environment</p>

Summary



Item	Definition
Innovation	Health innovation is to develop new or improved health policies, systems, products and technologies, and services and delivery methods that improve people's health, with a special focus on the needs of vulnerable populations.
Technology Readiness Level	Originally defined by NASA in the 1990's as a means for measuring or indicating the maturity of a given technology. The TRL spans over nine levels. ⁶
Technology Evidence Assessment	Final recommendation according to the ponderation of the different domains assessed and their relative importance.

Health technology and engineering management

Domains	Appropriateness
 Durability	A measure of expected ability to withstand environmental and use conditions at the target location
 Ease of Use	A concept that describes how easily users can deploy a product safely and effectively
 Positive impact on clinical outcomes	A measure of the extent of expected change in clinical outcomes when a specific brand of technology is deployed in comparison with another brand of the same technology
 Affordability	It is the extent to which the intended recipients of a service can pay for it be it a public, governmental, or private service
 Engineering resources minimization	Indicator of the ratio between increased operational benefits and demands for additional operational resources such as logistics, technical management, risk prevention, spare parts or test tools, and dependency on technical Labor competency or support
 Cultural and social acceptability	A measure of suitability of a product to operate as intended in the designated locality
 Environmental conditions	The ability of specific technology to fulfil its intended use extreme conditions present in the surroundings where it is expected to be used, such as power variability, temperature, humidity, or blowing particles and sand
 Aesthetics	A feature of the external presentation and appearance of a product
 Ease of cleaning	A measure reflecting lack of difficulty and/or unique burden to accomplish proper cleaning of product
 Ease of maintenance	The intensity of lack of difficulty or required technical effort in sustaining product intended use at the level when acquired
 Infrastructure requirements	The extent of additional functional demands presented when the product introduces to the local location of use, such as space, utilities, communication, system integration, and staff technical competency
 Local access to sales support	Measure of availability of sales or marketing personnel associated with the evaluated product as resources to support the intended deployment of their product and its continuous level of deployment at patient readiness level
 Local access to technical support	Measure of availability of technical resources associated with the evaluated product at the intended deployment of their product to warrant its continuous level of deployment at patient readiness level
 Local access to training	In clinical engineering, availability at the target deployment of a product of educational program that aims to promote safe, optimal, and compliant maintenance and repair services of medical devices.

Domains

Appropriateness




	Local access to spare parts	A measure of the immediacy and affordability of a clinical engineering service team to access the parts needed to sustain the operation of a technology at its intended safe and effectiveness levels
	Locations of use within target setting	Determination of settings of use for a product based on information provided with the submission and survey response from intended users

Intellectual property and local production

This provides a summary of IP rights associated with the product as well as determination of ownership, analysis of their accessibility, evaluation of local transferability and potential for local production.

Domains

Appropriateness

	Technology transferability	Indicates the feasibility and willingness to transfer technical information, tacit know-how, performance skills, technical material or equipment, jointly or as individual elements, with the intent of enabling the technological or manufacturing capacity of the recipients. ⁷
	Openly access intellectual property	The extent of intellectual property that is freely available online to successfully produce the product.
	Local production	The possibility to successfully and sustainably produce a product locally in compliance with the applicable regulations and as per the technology transfer instructions.

WHO related guidance

WHO clinical recommendations, management guidelines and other relevant resources that were used as a reference to conduct the clinical evaluation were included in this section.

⁷ World Health Organization. (2012). Local production and technology transfer to increase access to medical devices: addressing the barriers and challenges in low- and middle-income countries.

LIST OF DEVICES

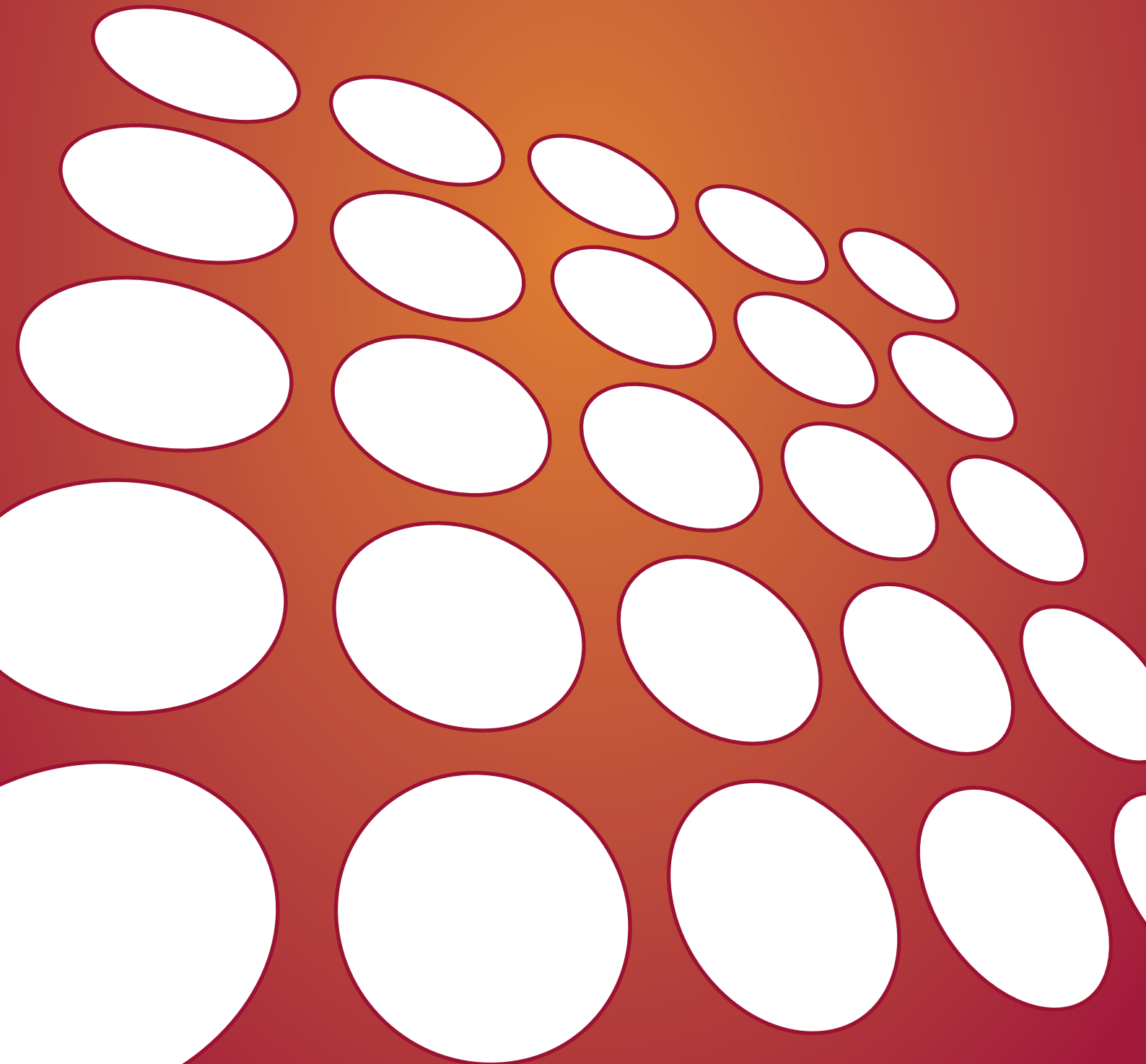
Commercially available

Cool packs for blood transportation	2
Face mask	5
Fetal monitor - wireless, mobile	8
High flow nasal cannula with CPAP	11
High flow nasal cannula	14
Intensive care ventilator	17
Multiport suction breathing tube	20

Prototype products

Continuous positive airway pressure device	24
Fetal monitor	27
Filling station and multiple oxygen tanks	30
High oxygen peep device	33
Medical imaging analyzer	36
Mechanical ventilator	39
Oxygen concentrator	42
Oxygen concentrator and storage	45

COMMERCIALY
AVAILABLE



Cool packs for blood transportation

Country of origin | Japan
 Primary function | Alleviation of disease
 Category | Other technology

Commercial information

List price (USD): 100
Year of commercialization: 2016
Number of units distributed: 10,000-50,000
Currently marketed in: Japan, Myanmar and Thailand
Brand: Daido Industries, INC.
Model: PC CONSTARII Model: 22062/ RBC CONSTARII Model:04062/ FFP CONSTAR Model:-2860



Product description

Red blood cells are to be transported at 2-6°C and platelets at 20-24°C. In order to keep the temperature within these ranges, this product uses chemicals. The solidification temperature stabilizes at the blood storage temperature. Thus, the temperature retention performance is high. Furthermore, when using this product you need to pre-cool it within the range of blood storage temperature, therefore you can place blood products directly on the cold storage material.

Product details

Accessories: Optional : Vacuum Insulated panel transportation box
Warranty duration: 1 year
Lifetime: 2-5 years
Facility requirements: Pre-cooling

Contact: Ogiri Shinsuke | **Email:** shinsuke_ogiri@daido-ind.co.jp | **Phone:** +81 6 6746 7141 |
Web: <http://www.daido-ind.co.jp/en/>

NOTE: Information reported by manufacturer before 17 December 2021

WHO ASSESSMENT

Clinical assessment

In resource-limited settings, safe blood and its transfusion are critical components of good-quality healthcare provision. Severe hemorrhage as a result of pregnancy or trauma, surgical operations, or severe anemia are all clinical indications for blood transfusion. As expected, the COVID-19 pandemic had a significant impact on Africa's blood supply, with about seven million patients requiring blood each year.

To ensure their safety and quality, blood and blood components must be stored under special conditions. After collection, plasma components should be frozen within a certain time window (preferably within 8 hours for fresh frozen plasma, or within 24 hours). Platelets should be stored at 20-24 °C under agitation and whole blood and RBCs should be refrigerated (at 1-6 °C).

The manufacturer's cool packs for blood transportation address the shortcomings of using frozen ice by allowing the blood product to be pre-cooled within the range of blood storage temperature before being placed directly on the surface material. If given technical clearance, such an approach appears innovative and promising and deserves further field-based evaluations.

WHO specification comparison

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

Regulatory assessment

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

RBC Constar, PC Constar and FFP Constar are the three models of cold packs listed in the application.

Pre-market - This product is a Class I medical device in the USA and EU (MDR). Minimal pre-market documentation was available and was limited to temperature maintenance reports. Puncture resistance and performance should have been demonstrated after repeated freeze/thaw cycles.

Post-market - No data or documents were provided. QS - A current ISO 13485:2016 certificate was provided and it expires in 2024.

Technology evidence assessment

Domains	Evidence assessment	
	Risk/benefit ratio	Impact
Medical		
Safety		
Economy		
Organizational		
Legal		
Social		
Ethical		
Green environment		

The technology is already available in low and middle-income countries, and it is used to transport different types of blood products safely and reliably, regardless of environmental temperature. It is simple to maintain and does not require any further training. Except for the cool packs, which will be produced only in Japan, the device can be manufactured locally. Its affordability and durability are attributed to the fact that it can be used over 1000 times. There was no information available on the materials used, especially in the cold packs. In low-resource settings, recycling may be an issue depending on the materials used. Despite this, the device should be recommended due to the critical need for alternative cooling systems in low-resource settings.

Summary

Innovation	Technology evidence assessment	Recommend with caution
Technology readiness level 9		

Health technology and engineering management

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

Target settings:
Rural, Urban, Outdoors, Indoors, Ambulance, Primary, Secondary & Tertiary level



This commercially available solution can help protect Fresh Frozen Plasma and other blood products in need of distribution and relocation against climate-related damage over time. The product's package contains a chemical substance that surrounds the FFP/blood product package, maintaining the contents within at the desired low temperature for a longer period of time (submitter claims up to 24 hours). The manufacturer provided evidence to substantiate the claims made, but no independent laboratory verification was included. In low-resource settings, the product's ability to prevent damage from exposure to temperature rise over time while transporting blood components is important. This product does not require any additional engineering or technology support to operate.

Intellectual property and local production

Technology transferability		Intellectual property - The company owns registered trademarks. Clearance is required to use this technology. Proceed with due diligence.
Openly access intellectual property		Local production - All key materials and technology need to be imported.
Local production		

WHO related guidance material

- WHO Expert Committee on Biological Standardization. 67th report - <https://www.who.int/publications/i/item/9789241210133>
- Safe blood and blood products: manual on the management, maintenance and use of blood cold chain equipment - <https://apps.who.int/iris/handle/10665/43359>
- Guidance on increasing supplies of plasma-derived medicinal products in low- and middle-income countries through fractionation of domestic plasma - <https://www.who.int/publications/i/item/9789240021815>
- Maintaining a safe and adequate blood supply and collecting convalescent plasma in the context of the COVID-19 pandemic: interim guidance, 17 February 2021 - <https://apps.who.int/iris/handle/10665/339793>
- World Blood Donor Day 2021 - <https://www.afro.who.int/regional-director/speeches-messages/world-blood-donor-day-2021>

Face mask

Country of origin | United Kingdom of Great Britain and Northern Ireland

Primary function | Prevention

Category | Medical device

Commercial information

List price (USD): 2.5

Year of commercialization: 2021

Number of units distributed: Unknown

Currently marketed in: United Kingdom

Brand: Triple 1 Group LTD UK

Model: Transparent Face Mask



Product description

A certified medical transparent face mask for adults and children conforming to the standard EN14683 medical device. Approved by the Medical Health Regulatory Agency [MHRA].

Product details

Facility requirements: Healthcare waste disposal facilities (disposal of face mask), disposal guidance provided by the manufacturer

Contact: Bibi Kausar | **Email:** kausar@triple1group.co.uk | **Phone:** +44 79 8400 0000 | **Web:** <https://triple1group.co.uk/>

NOTE: Information reported by manufacturer before 17 December 2021

WHO ASSESSMENT

Clinical assessment

In community settings where SARS-CoV-2 transmission is known or suspected, WHO advises that the general population use a non-medical mask indoors or outdoors if physical distancing of at least one meter cannot be maintained. Unless appropriate ventilation is ensured, WHO also advises that the general public wear a non-medical mask indoors, regardless of whether physical distancing can be maintained.

In healthcare settings, WHO recommends that healthcare practitioners that provide care to suspected or confirmed COVID-19 patients wear a medical mask in the absence of aerosol-generating procedures (AGPs). In contrast, respirators (N95 or FFP2 or FFP3 standards) are recommended where AGPs are performed if they are widely available.

This transparent face mask could be utilized best as a non-medical mask in community settings, where it may represent a single-use option for facilitating communication between mask wearers and patients with disabilities or special needs. Its use in resource-limited environments would be contingent upon non-clinical factors, including costs and ease of distribution.

WHO specification comparison




This device is a “Face mask” that can be used by nurses, physicians, and other health staff. The most similar WHO technical specifications that could be used for any compliance evaluation could be the “Medical mask” and/or the “Surgical Face mask”.

This device complies with the “Medical Mask” (fluid resistant) and the “Surgical Face Mask” WHO technical specifications. It is restricted for community and emergency use. The product is not a respirator and should not be worn for extended use.

Compliance: Medical mask, good breathability, internal and external faces clearly identified, Bacterial Filtration Efficiency (BEF) higher than 98%, fluid resistance, and EN 14683 Type IIR compliant (test report provided).

Non-compliance: To EN 149 or NIOSH 42 CFR Part 84.

Regulatory assessment

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

Pre-maket - The validation report is not comprehensive for the medical-grade mask.; conforms to the standard EN14683 medical device and is approved by MHRA.

WHO specification: compliance: Bacterial Filtration Efficiency (BFE):

Fluid resistant masks (surgical masks):

- EN 14683 Type IIR
- ASTM F2100 Level 1, 2 or 3
- YY 0469, with at least 98% bacterial droplet filtration

Non-fluid resistant mask:

- EN 14683 Type II
- YY/T 0969, with at least 98% bacterial droplet filtration USFDA; 6-406 ASTM F1862/F1862M-17

Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity)

























- 6-425 ASTM F2100-19 Standard Specification for Performance of Materials Used in Medical Face Masks
- 6-427 ASTM F2101-19 Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus

Non-compliance: to EN 149 or NIOSH 42 CFR Part 84.

Post-maket - documentation not provided

QMS - Is based on ISO 9001 Adequate documentation was not provided to perform a medical device Regulatory or Quality System review.

Technology evidence assessment

Domains	Evidence assessment		Summary
	Risk/benefit ratio	Impact	
 Medical			<p>The device is commercially available. According to the information provided, it is intended for use in community and hospital settings. The test results indicate a protective potency in the community. There is a lack of evidence on clinical settings, particularly in high contagious areas, so sufficient effectiveness in this area is uncertain. From a social standpoint, it should be noted that the device appears to be useful for gathering information about facial expressions in social interactions as well as in the treatment of mental illness due to the mask design. Given that the mask is intended for single use only, the intended price per mask appears to be quite high for low-resource settings. As a result, affordability and environmental friendliness are both questioned. To summarize, the device should be included but only for community use.</p> <hr/> <p>Innovation</p> <p>Technology evidence assessment</p> <p>Technology readiness level 9</p> <p>Recommend with caution</p>
 Safety			
 Economy			
 Organizational			
 Legal			
 Social			
 Ethical			
 Green environment			

Health technology and engineering management

Domains	Appropriateness	Domains	Appropriateness	Target settings: Rural, Urban, Outdoors & Home
Durability		Ease of cleaning		<p>The transparent mask properties are difficult to evaluate due to the limited information available for this product. More data is needed to determine the product's disposition and effectiveness in prevention. Although the submission claims to have a fog-resistance clear window to facilitate better communications, evidence for its effectiveness and durability was not provided. Currently, disposable masks are available on the market at a reasonable price.</p>
Ease of Use		Ease of maintenance		
Positive impact on clinical outcomes		Infrastructure requirements		
Affordability		Local access to sales support		
Engineering resources minimization		Local access to technical support		
Cultural and social acceptability		Local access to training		
Environmental conditions		Local access to spare parts		
Aesthetics		Locations of use within target setting		

Intellectual property and local production

Technology transferability		Intellectual property - Protected by trade secret. Clearance to use this technology is required.
Openly access intellectual property		Local production - Local production will reduce costs, but regional product demand has to be high enough to justify the business case.
Local production		

WHO related guidance material

- 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](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)
- Rational use of personal protective equipment for coronavirus disease (COVID-19) and considerations during severe shortages: interim guidance, 23 December 2020 - [https://www.who.int/publications/i/item/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)
- Infection prevention and control during health care when coronavirus disease (COVID-19) is suspected or confirmed: interim guidance, 12 July 2021 - <https://apps.who.int/iris/handle/10665/342620>
- WHO Standard precautions in health care - <https://www.who.int/publications/m/item/standard-precautions-in-health-care>
- WHO Coronavirus (COVID-19) Dashboard - <https://covid19.who.int/>

Fetal monitor - wireless, mobile

Country of origin | Japan
 Primary function | Monitoring
 Category | Medical device

Commercial information

List price (USD): 8000
Year of commercialization: 2019
Number of units distributed: 101-1,000
Currently marketed in: South East Asia Region
Brand: Melody International Ltd.



Product description

The fetal monitor iCTG ensures proper care of pregnant women and their fetuses. iCTG graphically displays the fetal heart rate and uterine contractions in 20 minutes to several hours. The iCTG is comparable in performance to conventional CTGs but is ultra-compact, completely wireless, and mobile. The widespread use of this device will enable the early transfer of pregnant women to secondary or tertiary hospitals in areas where there is a shortage of doctors or poor access to medical care.

Product details

Consumables: Ultrasound gel, 2 x CTG belts
Warranty duration: 5 year
Lifetime: 2-5 years
Energy requirements: Rechargeable battery, AC, 110V, 220V, 1-hour battery recharge cycle, 6-hour battery life
Facility requirements: Access to a cellular phone network, Storage temperature -10 to 45°C, relative humidity 10-90%, atmospheric pressure 700-1060hPA

Contact: Emi Sogo | **Email:** sogo@melodyinternational.com | **Phone:** +81 87 813 7362 | **Web:** www.melodyi.net

NOTE: Information reported by manufacturer before 17 December 2021

WHO ASSESSMENT

Clinical assessment

In 2017, around 295,000 women died during and after pregnancy and delivery, with the vast majority of deaths (94%) occurring in low-resource settings. In 2019, an estimated 1.9 million babies were stillborn at 28 weeks or later, with three-quarters of all cases occurring in Sub-Saharan Africa and South Asia. With better monitoring and availability of emergency obstetric care, a large proportion of these deaths could be avoided.


Cardiotocography enables the evaluation of fetal health during pregnancy by examining fetal heart rate patterns. The primary goal of antepartum and intrapartum fetal monitoring is to identify fetuses at risk of hypoxia and allow for a timely intervention to lower the risk of hypoxic injury or death while also avoiding unneeded interventions in well-oxygenated fetuses.

The manufacturer's iCTG offers a paperless, wireless, portable solution for both antepartum and intrapartum monitoring, which should only be used by a trained healthcare provider. It is intended to enable real-time visualization of relevant clinical data and facilitate remote diagnosis. The device does not support fetal heart rate measurement in multiple pregnancies, despite of the possibility of monitoring more than one foetus, caution must be exercised in the use of this device in low-resource settings, as it is not clear how it behaves in unidentified multiple pregnancies.

WHO specification comparison

The Melody International CTGi - Cardiotocograph MI1001A device is claimed to be a "Foetal heart detector" and not a "Monitor". Consequently, at the time of report creation, WHO technical specifications are not available to perform a compliance evaluation with this type of technology.

























Regulatory assessment


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

Pre-maket - A safety and EMC report, as well as a usability assessment based on IEC 60601-1-6/IEC 62366, was provided, but no protocol or test report was submitted. Report on biocompatibility and clinical performance or ultrasound testing and wireless and alarm validation were not included. The software validation is based on JIS T 2304:2017 certificate.

Post-maket - Documents were not provided. The ISO 13485 certificate expires in 2023. It has a MHLW manufacturing certificate.

Technology evidence assessment

Domains	Evidence assessment		
	Risk/benefit ratio	Impact	
 Medical			Melody-i is already commercially available as a cardiotocography device that detects fetal heart rate using an ultrasound Doppler method and uterine contraction using a strain gauge from mid-pregnancy to birth. The device can be used in areas with unstable power supplies since it has a built-in battery that provides 6-10 hours of usage. The battery can be charged using a small solar charger. It is durable, easy to produce and maintain. There is a high medical need. High implementation costs prevent the device from being affordable for low-resource settings. If the costs cannot be reduced significantly, the device is not recommendable.
 Safety			
 Economy			
 Organizational			
 Legal			
 Social			
 Ethical			
 Green environment			

Summary		
Innovation		Technology evidence assessment
Technology readiness level	9	Not recommended

Health technology and engineering management

Domains	Appropriateness	Domains	Appropriateness	Target settings:
Durability		Ease of cleaning		Primary, Secondary & Tertiary level, Ambulance
Ease of Use		Ease of maintenance		
Positive impact on clinical outcomes		Infrastructure requirements		
Affordability		Local access to sales support		
Engineering resources minimization		Local access to technical support		<p>This product, available commercially, offers added observation of expecting mother and their baby condition while away from the hospital. Although it is not a replacement for a clinically acceptable fetal monitoring system, it delivers information that can help manage mother and baby vital conditions during pregnancy. The sensors, to be placed on the mother's abdomen, detect the baby's heart movement using ultrasound detectors (doppler effect) and convert the information into a heart rate while a second force-based sensor detects the mother's contractions. Since the baby heartbeat sensing sensor uses quartz substance to create and sense changes in the ultrasound wave pitch - the handling of the iCTG must be gentle in order to prevent damage to the quartz (i.e. from dropping).</p>
Cultural and social acceptability		Local access to training		
Environmental conditions		Local access to spare parts		
Aesthetics		Locations of use within target setting		

The product is powered by a rechargeable Lithium battery that must be charged after 6 hours of operation. The charging time is an hour. This condition may require patients to obtain an additional backup unit for use during the battery depletion or charging period, which may increase the cost of the overall product. Additionally, the submission notes that an iPhone or iPad is required, while the Android devices have not yet been tested for connectivity.

Intellectual property and local production

Technology transferability		Intellectual property - It is patent-protected and the design is registered. There are registered trademarks for the device. Clearance to use this technology is required.
Openly access intellectual property		Local production - Innovator does not want to consider producing locally. There is also a high dependency on imports for local production.
Local production		

WHO related guidance material

- Maternal mortality: evidence brief - <https://apps.who.int/iris/handle/10665/329886>
- Trends in maternal mortality 2000 to 2017: estimates by WHO, UNICEF, UNFPA, World Bank Group and the United Nations Population Division - <https://apps.who.int/iris/handle/10665/327595>
- Managing complications in pregnancy and childbirth: a guide for midwives and doctors - 2nd ed. - <https://apps.who.int/iris/handle/10665/255760>
- WHO recommendations on antenatal care for a positive pregnancy experience - <https://apps.who.int/iris/handle/10665/250796>
- WHO recommendations on maternal health: guidelines approved by the WHO Guidelines Review Committee - <https://apps.who.int/iris/handle/10665/259268>
- Recurrence of adverse perinatal outcomes in developing countries - <https://dx.doi.org/10.2471/BLT.12.111021>

High flow nasal cannula with CPAP

Country of origin | New Zealand
 Primary function | Treatment
 Category | Medical device

Commercial information

Year of commercialization: 2021
Number of units distributed: 101-1,000
Currently marketed in: New Zealand
Brand: Company: Fisher & Paykel Healthcare Ltd. Brand: Optiflow
Model: Airvo 3



Product description

Airvo 3 delivers Nasal High Flow therapy (HFNC). High humidified room air flows provide respiratory support (reducing anatomical dead space & giving positive airway pressure). If needed, O₂ can also be delivered via Airvo 3, but O₂ is not required to provide respiratory support or a high flow of air. The gas is heated/humidified to provide patient comfort and therapy compliance. Airvo 3 can also provide bubble CPAP (Junior model) and CPAP/NIV therapy (Adult Acute model).

Product details

Consumables: Heated breathing tube & chamber, Optiflow Nasal Cannula - comes in three sizes for Adults and six sizes for Paediatrics or Bubble CPAP or Non-invasive ventilation Masks

Warranty duration: 2 years

Lifetime: 5 years

Energy requirements: Rechargeable battery, Continuous power supply, AC, 110V, 220V, 6-hour battery recharge cycle, 0.67-hour battery life

Facility requirements: Specific temperature and/or humidity range, Operating conditions: Temperature: 18-28 C°, Humidity: 10-95% (RH), Altitude: 0-3000 m (9840 ft), Storage temperature: -10 to 50C° and Humidity: 10% to 95% Relative Humidity

Contact: Varun Purushotham | **Email:** varun.purushotham@fphcare.fr | **Phone:** +33 63 412 7493 | **Web:** www.fphcare.co.nz

NOTE: Information reported by manufacturer before 17 December 2021

WHO ASSESSMENT

Clinical assessment

In low-resource settings, the COVID-19 pandemic has worsened and further exacerbated the long-standing need for accessible and reliable oxygen supplies. Lower respiratory tract infections are a leading cause of morbidity and mortality in low and lower-middle income countries and often necessitate supplemental oxygen therapy and/or non-invasive ventilation.

Airvo™3 allows for the delivery of high-flow nasal cannula oxygen (it retains all Airvo™2 features) and for C-PAP non-invasive ventilation among infants and adults. These characteristics contribute to making it a device of interest to treat severely hypoxemic patients in low-resource environments. Its use and application should be limited to secondary or tertiary healthcare facilities, where monitoring of the patient's clinical status can be ensured.

WHO specification comparison

AIRVO™3 compliance evaluation has been done using both the WHO "HFNC - High Flow Nasal Cannula" and "CPAP - Continuous Positive Airway Pressure" technical specifications.

This device fully complies with the "HFNC adult and paediatric" and "CPAP" WHO technical specifications

COMPLIANCE WITH "HFNC" and "CPAP": adult/paediatric. User/service draft manual provided. In-built turbine. Capability to generate a high flow of mixed room air and oxygen. Flow up to 60 L/min. Temperature of the warmed air. FiO₂ % available 21-100%. Pressure range compliant (up to 45 cmH₂O). Graphical display and user interface with all required parameters available to be displayed. All required alarms provided. Trolley with wheels, brakes and dedicated spaces for accessories. Compliant power supply characteristics and possibility to use it in combination with an UPS to provide battery back

























up in the case of AC power failure. IP22 protection level. RH% range. Automatic switch from AC power electric-line mode to battery operating mode. Compliant length of the main power cable (≥ 2 m). Necessary accessories and consumables are available. More than 10 languages available including English. Two years of warranty provided. Environmental requirements for storage/operations available.


NON-COMPLIANCE WITH “HFNC” and “CPAP”: None.

Regulatory assessment

 Pre-market assessment	 Proceed with caution	This product is commercially available in New Zealand and not distributed globally. Reports on pre-market design verification and validation have not been submitted. The clinical evaluation report and post-market documentation were not available. Adequate documentation should be provided to conduct regulatory and quality system reviews to demonstrate safety and efficacy of the device.
 Post-market assessment	 Proceed with caution	
 Quality system assessment	 Proceed	

Technology evidence assessment

Domains	Evidence assessment		
	Risk/benefit ratio	Impact	
 Medical			Airvo3 is innovative due to its technical features. Similar to the predecessor model Airvo2, a recommendation can only be made with caution. This is mainly due to the questionable affordability. This cannot be conclusively assessed on the basis of the documents submitted.
 Safety			
 Economy			
 Organizational			
 Legal			
 Social			
 Ethical			
 Green environment			

Summary		
Innovation		Technology evidence assessment
Technology readiness level	9	Recommend with caution

Health technology and engineering management

Domains	Appropriateness	Domains	Appropriateness	Target settings: Secondary & Tertiary level
Durability		Ease of cleaning		 Both the User and Technical manuals claim that the product life cycle is 5 years, with a shelf life of 0-2 years. These are ranges that are much shorter than users and industry are accustomed to for comparable products. This product contains software, motor, electronic display, alarm speaker, heating plate, and sensor but yet the manuals claim that preventive maintenance is not required. For a product that is expected to be subjected to fluid spills, electrical power instability, software glitches controlling a heating plate all operating around oxygen lines - there is a need for guidance on the frequency and process for testing and maintaining such a product on regular basis. The statement that PM is not required places patients and users in otherwise preventable hazard.
Ease of Use		Ease of maintenance		
Positive impact on clinical outcomes		Infrastructure requirements		
Affordability		Local access to sales support		
Engineering resources minimization		Local access to technical support		
Cultural and social acceptability		Local access to training		
Environmental conditions		Local access to spare parts		
Aesthetics		Locations of use within target setting		

Intellectual property and local production

Technology transferability		Intellectual property - It is patent-protected with registered industrial designs and trademarks. The use of all intellectual property will require clearance. The use of patented compatible third-party products may also require clearance.
Openly access intellectual property		Local production - Current regional volumes are significantly low, creating a poor business case for dedicated local production.
Local production		

WHO related guidance material

- WHO Global Health Estimates (the top 10 causes of death) - <https://www.who.int/news-room/fact-sheets/detail/the-top-10-causes-of-death>
- WHO Coronavirus (COVID-19) Dashboard - <https://covid19.who.int/>
- Coronavirus disease (COVID-19) technical guidance: Patient management - <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/patient-management>
- Living guidance for clinical management of COVID-19 - <https://www.who.int/publications/i/item/WHO-2019-nCoV-clinical-2021-2>
- Therapeutics and COVID-19: living guideline - <https://www.who.int/publications/i/item/WHO-2019-nCoV-therapeutics-2021.3>
- WHO recommendations on newborn health: guidelines approved by the WHO Guidelines Review Committee - <https://www.who.int/publications/i/item/WHO-MCA-17.07>
- WHO-ICRC Basic Emergency Care: approach to the acutely ill and injured - <https://www.who.int/publications/i/item/basic-emergency-care-approach-to-the-acutely-ill-and-injured>
- Emergency care - <https://www.who.int/emergencycare/systems/en/>
- WHO Medical Emergency Checklist - <https://www.who.int/publications/i/item/who-medical-emergency-checklist>
- Guidelines for essential trauma care - <https://www.who.int/publications/i/item/guidelines-for-essential-trauma-care>
- WHO Oxygen website - https://www.who.int/health-topics/oxygen#tab=tab_2
- Oxygen therapy for children: a manual for health workers - <https://apps.who.int/iris/handle/10665/204584>
- Oxygen sources and distribution for COVID-19 treatment centres: interim guidance, 4 April 2020 - <https://apps.who.int/iris/handle/10665/331746>

High flow nasal cannula

Country of origin | New Zealand
 Primary function | Treatment
 Category | Medical device

Commercial information

List price (USD): 3500
Year of commercialization: 2012
Number of units distributed: 50,000+
Currently marketed in: Globally
Brand: Company: Fisher & Paykel Healthcare. Brand: Optiflow
Model: Airvo 2



Product description

The Airvo 2 delivers Nasal High Flow therapy (HFNC). The delivery of high flows of humidified air provides respiratory support. Washout of anatomical dead space and positive airway pressure are two advantages. Supplemental oxygen can also be delivered via Airvo 2 if needed.

Heating/humidified gases, minimized condensation, and comfortable interfaces are used to ensure patient comfort and therapy compliance.

Product details

Consumables: 1. Heated breathing tube & chamber 2. Optiflow Nasal Cannula - comes in three sizes for Adults and two sizes for Paediatrics

Warranty duration: 2 years

Lifetime: 5-10 years

Energy requirements: Continuous power supply, AC, 110V, 220V, 165W

Facility requirements: Storage temperature: -10C to 60C°, humidity: 10% to 95% Relative Humidity

Contact: Varun Purushotham | **Email:** varun.purushotham@fphcare.fr | **Phone:** +33 63 412 7493 | **Web:** www.fphcare.co.nz

NOTE: Information reported by manufacturer before 17 December 2021

WHO ASSESSMENT

Clinical assessment

In low-resource settings, the COVID-19 pandemic has worsened and further exacerbated the long-standing need for accessible and reliable oxygen supplies. Lower respiratory tract infections are a leading cause of morbidity and mortality in low and lower-middle income countries and often necessitate supplemental oxygen therapy.

High-flow nasal cannula oxygen can be employed in a variety of conditions, including respiratory distress syndrome in premature newborns, and hypoxemic respiratory failure in children and adults. High-flow oxygen devices have several advantages over traditional oxygen delivery systems, including increased comfort, more accurate delivery of fraction of inspired oxygen, warming and humidification of secretions to facilitate expectoration, washout of upper airway dead space, and a positive airway pressure effect. Compared to oxygen face masks, high-flow nasal cannulas have been linked to a decreased need for mechanical ventilation (but not mortality) in observational studies and randomized clinical trials.

Patients who require high-flow nasal cannula oxygen are at high risk of severe respiratory failure or mechanical ventilation. Hence, Airvo™ 2 may be best used in a monitored setting, such as an intensive or critical care unit, and may be applied in selected resource-limited contexts with comparable features.







WHO specification comparison

AIRVO 2 Optiflow System has been evaluated by comparing the technical documents provided with the High Flow Nasal cannula WHO technical specifications currently used and updated on November 2020. This device COMPLIES with the “HFNC adult and paediatric” WHO technical specifications.

























compliance: adult/paediatric. User manual/instructions for use provided. Built-in turbine. Capability to generate a high flow of mixed room air and oxygen. Flow up to 60 L/min. The temperature of the warmed air. FiO₂ % available 21-100%. Graphical display and user interface. Trolley with wheels, brakes, and dedicated spaces for accessories. Compliant power supply characteristics and the possibility to use it in combination with a UPS to provide battery backup in the case of AC power failure. Necessary accessories and consumables are available. More than ten languages are available, including English. Two years of warranty provided. Environmental requirements for storage/operations available. IP22 certified. Compliant RH% range. Displayed parameters and alarms required are available. The length of the main power cable is longer than 2m.

Non-compliance: None.

Regulatory assessment

 Pre-market assessment	 Proceed with caution	There was insufficient documentation to perform a pre-market and post-market medical device regulatory review. AIRVO-2 had received approvals from Australia, the USA, Canada, Japan, India, China, Yemen, South Africa, Russia, and Nigeria at the time of this report.
 Post-market assessment	 Proceed with caution	
 Quality system assessment	 Proceed	

Technology evidence assessment

Domains	Evidence assessment		
	Risk/benefit ratio	Impact	
 Medical			The device is commercially available in up to 120 countries, including LMICs. The device has a good safety profile based on the given clinical data provided. It is easy to operate and maintain. Transferability is provided. The device is used in accordance with prescribed guidelines. In high-income settings, cost-effectiveness has been demonstrated. Transfer to LMI settings based on provided documents however, is not possible. To provide robust statements on affordability in LMICs, additional documents are required.
 Safety			
 Economy			
 Organizational			
 Legal			
 Social			
 Ethical			
 Green environment			

Summary		
Innovation	Technology evidence assessment	Recommend with caution
Technology readiness level	9	

Health technology and engineering management

Domains	Appropriateness	Domains	Appropriateness	Target settings: Urban, Indoors, Secondary & Tertiary level
Durability		Ease of cleaning		<p>The Nasal High Flow System is integrated with UPS-supported gas heating and humidification. The system's portability and usability are clearly demonstrated. The unit and accessory (i.e. parts) costs for this application appear to be high, with a product life expectancy of 5 years. Maintenance is required with insufficient guidance for changing filters, heating element functionality, fluid spills damage, and attending to the UPS on a frequent basis. Field-based evaluation is pending.</p>
Ease of Use		Ease of maintenance		
Positive impact on clinical outcomes		Infrastructure requirements		
Affordability		Local access to sales support		
Engineering resources minimization		Local access to technical support		
Cultural and social acceptability		Local access to training		
Environmental conditions		Local access to spare parts		
Aesthetics		Locations of use within target setting		

Intellectual property and local production

Technology transferability		Intellectual property - It is patent-protected with registered industrial designs. AIRVO, MY AIRVO, and OPTIFLOW have trademark registrations.
Openly access intellectual property		The use of all intellectual property will require clearance. The use of patented compatible third-party products may also require clearance.
Local production		Local production - Due to the low volume of current regional demand, there is a weak business case for dedicated local production.

WHO related guidance material

- WHO Global Health Estimates (the top 10 causes of death) - <https://www.who.int/news-room/fact-sheets/detail/the-top-10-causes-of-death>
- WHO Coronavirus (COVID-19) Dashboard - <https://covid19.who.int/>
- Coronavirus disease (COVID-19) technical guidance: Patient management - <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/patient-management>
- Living guidance for clinical management of COVID-19 - <https://www.who.int/publications/i/item/WHO-2019-nCoV-clinical-2021-2>
- Therapeutics and COVID-19: living guideline - <https://www.who.int/publications/i/item/WHO-2019-nCoV-therapeutics-2021.3>
- WHO recommendations on newborn health: guidelines approved by the WHO Guidelines Review Committee - <https://www.who.int/publications/i/item/WHO-MCA-17.07>
- WHO-ICRC Basic Emergency Care: approach to the acutely ill and injured - <https://www.who.int/publications/i/item/basic-emergency-care-approach-to-the-acutely-ill-and-injured>
- Emergency care - <https://www.who.int/emergencycare/systems/en/>
- WHO Medical Emergency Checklist - <https://www.who.int/publications/i/item/who-medical-emergency-checklist>
- Guidelines for essential trauma care - <https://www.who.int/publications/i/item/guidelines-for-essential-trauma-care>
- WHO Oxygen website - https://www.who.int/health-topics/oxygen#tab=tab_2
- Oxygen therapy for children: a manual for health workers - <https://apps.who.int/iris/handle/10665/204584>
- Oxygen sources and distribution for COVID-19 treatment centres: interim guidance, 4 April 2020 - <https://apps.who.int/iris/handle/10665/331746>

Intensive care ventilator

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

Commercial information

List price (USD): 2500
Brand: World Ventilator Foundation
Model: WorldVent

Product description

This emergency use ventilator utilizes the following proven approaches. Solenoid operated inspiratory and expiratory valve control typical of modern ICU vent designs; few moving parts
 Entrainment of room air via venturi action with all O₂ delivered to the patient without waste
 Standard silicon piezoresistive pressure sensors with a fixed orifice, airway flow sensor
 Commercial component controller using compiled SW without operating systems
 Commercial AC/DC power supply with standard Li-Ion battery

Product details

Accessories: Flow Sensor: Single piece molded component that creates a differential pressure signal as a function of airway flow.

Consumables: Generic versions of: Patient Breathing Circuit, Airway Pressure Sense Line, Inspiratory Filter

Lifetime: 5-10 years

Energy requirements: Rechargeable battery, continuous power supply, DC, 12V, 24W, 1-hour battery recharge cycle, 0.5-hour battery life

Facility requirements: Gas supply (Oxygen)

Contact: Ronald Tobia | **Email:** rtobia@worldvent.org | **Phone:** +1 608 825 4882 | **Web:** www.worldvent.org

NOTE: Information reported by manufacturer before 17 December 2021



WHO ASSESSMENT

Clinical assessment

Lower respiratory tract infections and respiratory diseases are a major source of morbidity and mortality in many resource-limited settings, ranking among the top ten causes of death in low- and lower-middle-income countries. The COVID-19 pandemic has heightened the global demand for high-quality, safe, and affordable medical equipment to treat patients with respiratory failure, particularly those who require mechanical ventilation.

In intensive care and critical care settings, the WorldVent ventilator could provide an easy-to-use alternative to traditional ventilators. Single-level controls and a simple interface may aid the user's familiarization with the ventilator, assuming that appropriate training is provided and reliable power supply is ensured (even though the ventilator has a backup battery).

WHO specification comparison



The WORLDVENT ventilator does NOT comply with the "ICU VENTILATOR" WHO technical specifications.

The following main non-compliances and non-verifiable (or not specified) requirements are listed:

Non-compliances: External low-pressure source compatible (< 35 psi). Pressure Control Ventilation (PCV) mode not available. NIV modes not provided (CPAP or BiPAP). FiO₂ range 21-100% not provided (60-100 discrete values). Tidal Volume range required at least 20 - 1500 ml (300 - 900 ml is available). Minimum RR requested is 10-60 breaths/min (10-34 bpm range provided). PEEP range: 0-20 cmH₂O required (5-20 cmH₂O provided). Real-time scalar waveforms, at least two simultaneously, not available. Loop (axis) displays for pressure-volume and flow-volume not available. Expiration time, Minute volume and End-Tidal CO₂ parameters not displayed. "High/Low FiO₂", "High/Low RR", "Low Minute Volume" and "Low PEEP" alarms not available. Power supply requirements (100-240 V AC 3 10% required).

Not possible to be verified: If paediatric patient could be treated. Oxygen-air mixture accuracy. Internal function testing/leak testing. “IP” protection level certification. If “PLATEAU and MEAN airway pressure” parameters can be displayed and if “adjustable peak pressure limitation/pressure-cycling mechanism above measured peak pressure” is available. Availability of single-limb and double-Limb breathing circuits for adult/paediatric are available.

Regulatory assessment

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

This is an FDA EUA authorized ventilator under product code QOT. Adequate documentation was not provided to perform a medical device Regulatory or Quality System review on this product. A summary document of the design verification and validation reports was submitted but did not provide the actual test reports for pre-market assessment. Documentation on the quality management system ISO 13485:2016 for quality system assessment is not available. Documentation was not provided on post-market activities.

























This product was assessed as prototype.

This product is classified as an EU MDR class IIb and USA FDA class II (product code CBT or MNT, depending on the specific claims).

The following are the FDA’s Recognized Consensus Standards for this product type:

ISO 5356-1 ;2004 ISO 80601-2-12 ;2011, ISO 5359 ;2014, ISO 18082 ;2014 [Including AMENDMENT 1 (2017)], ISO 18562-1 ; 2017, ISO 18562-2;2017, ISO 18562-3 ;2017, ISO 18562-4;2017, ISO 80601;2017, ISO 80601;2020

Technology evidence assessment

Domains	Evidence assessment		The device is a prototype ventilation system developed to meet the needs of low-resource settings to address COVID-19 related needs. Also suitable for patients requiring short-term supportive care. It requires minimal training, is easy to use and manufacture, and has a low operating cost. The maintenance requirement is also minimal. Due to the device’s durability, implementation and running costs seem affordable in LMICs. It is also portable and works in case of disruption of power supply with backup battery (0.5 hours). As a result of its simplistic design, this product meets basic safety and performance standards for critical care ventilation. Local production may be possible but not planned currently. The device is patent-protected. In summary, this device shows high potential to be beneficial in saving lives in LMICs and therefore could be recommended.
	Risk/benefit ratio	Impact	
 Medical			<p>Summary</p> <p>Innovation</p> <p>Technology readiness level 7</p> <p>Technology evidence assessment Recommended</p>
 Safety			
 Economy			
 Organizational			
 Legal			
 Social			
 Ethical			
 Green environment			

Health technology and engineering management

Domains	Appropriateness	Domains	Appropriateness	Target settings: Secondary & Tertiary level
Durability		Ease of cleaning		<p>The mechanical ventilator prototype is a well-designed product with attention to low-resource settings condition, but we could not find enough evidence to evaluate the financial aspects (i.e. initial cost, maintenance, battery replacement, and spare parts cost). Manufacturer claims that internal battery will support the ventilator operation for over 30 minutes facilitating protection for patient care during power disruption or transport. However, while the product's features support clinical needs, the maintenance requirement, guidance for testing gear needed and for performing functionality tests, as well as access to technical training for critical life support product are lacking.</p>
Ease of Use		Ease of maintenance		
Positive impact on clinical outcomes		Infrastructure requirements		
Affordability		Local access to sales support		
Engineering resources minimization		Local access to technical support		
Cultural and social acceptability		Local access to training		
Environmental conditions		Local access to spare parts		
Aesthetics		Locations of use within target setting		

Intellectual property and local production

Technology transferability		Intellectual property - The software is proprietary. The device is under trade secret and patent protection. The design of the device is also protected. The status of the patent applications is pending. The status of the trademark application for WORLDVENT is also pending. The use of all intellectual property, including any third-party-owned rights, will require clearance. Caution advised due to pending patent application.
Openly access intellectual property		
Local production		Local production - It is not ready for production since it is in the prototype phase. The production knowledge is with the contract manufacturer. Local production will suit only regions with considerable product demand. Good QMS, an established electronics assembly industry and testing capability are also required.

WHO related guidance material

- WHO Global Health Estimates (the top 10 causes of death) - <https://www.who.int/news-room/fact-sheets/detail/the-top-10-causes-of-death>
- WHO Coronavirus (COVID-19) Dashboard - <https://covid19.who.int/>
- Coronavirus disease (COVID-19) technical guidance: Patient management - <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/patient-management>
- Living guidance for clinical management of COVID-19 - <https://www.who.int/publications/i/item/WHO-2019-nCoV-clinical-2021-2>
- Therapeutics and COVID-19: living guideline - <https://apps.who.int/iris/handle/10665/345356>
- WHO-ICRC Basic Emergency Care: approach to the acutely ill and injured - <https://www.who.int/publications/i/item/basic-emergency-care-approach-to-the-acutely-ill-and-injured>
- Emergency Care - <https://www.who.int/emergencycare/systems/en/>
- Guidelines for essential trauma care - <https://www.who.int/publications/i/item/guidelines-for-essential-trauma-care>
- Severe Acute Respiratory Infections Treatment Centre - <https://www.who.int/publications/i/item/10665-331603>

Multiport suction breathing tube

Country of origin | United States of America

Primary function | Prevention

Category | Medical device

Commercial information

List price (USD): 18

Year of commercialization: 2019

Number of units distributed: 10,000-50,000

Currently marketed in: Globally

Brand: NeVap Inc

Model: Aspire Subglottic Suction Endotracheal Tube



Product description

The NeVap Aspire is the only suction breathing tube with a tissue spacer and 24 suction ports, which prevent tissue blockage and allow for effective, non-traumatic subglottic removal of pathogenic fluids that contribute to increased mechanical ventilation time, antibiotic use, ventilator-associated pneumonia, and mortality.

Product details

Facility requirements: Healthcare waste disposal facilities (medical waste), Gas supply (Oxygen and anesthetic gas), Source of Ventilation and suctioning, Dry and cool storage

Contact: Benjamin Wang MD | **Email:** Benjaminwang@gmail.com | **Phone:** +1 408 398 5159 | **Web:** www.nevap.co

NOTE: Information reported by manufacturer before 17 December 2021

WHO ASSESSMENT

Clinical assessment

In many resource-limited settings, lower respiratory tract infections, along with COVID-19 and respiratory diseases, are a major source of morbidity and mortality, ranking among the top 10 causes of death in low- and lower-middle-income countries. The COVID-19 pandemic has heightened the global demand for high-quality, safe, and affordable medical equipment to treat patients with respiratory failure, particularly those who require mechanical ventilation. The NeVap Inc multi-port subglottic suction endotracheal tube may offer a suitable solution for enhanced secretion removal in mechanically ventilated patients with respiratory failure, provided that the healthcare workforce receives appropriate, relevant training in its clinical use. The device's use may result in a lower risk of ventilator-associated pneumonia and a shorter period of stay in the intensive care unit.



WHO specification comparison

The "Aspire multiport suction breathing tube" has been compared with the "Endotracheal tube, with cuff" WHO technical specifications currently available in WHO publications. This device complies with the WHO technical specifications mentioned.

compliance: An endotracheal tube designed to maintain an unobstructed upper airway in order to transport gases and vapors to and from the lungs during anaesthesia, resuscitation, and other situations in which the patient is not properly ventilated. The Endotracheal Tube is designed with anatomical Magill Curve, Murphy Eye, and radiopaque markings. It includes a Pilot Balloon and inflation tube, a Cuff Balloon, a standard 15mm connector, and a preloaded "stylet." The cuff is inflated with a small-bore inflation tube that is included. The material is PVC. There are various sizes and lengths available. The Endotracheal Tube is individually packaged and sterile.

Non-compliance: None

Regulatory assessment

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

The product has obtained CE marking. The USA FDA 510(k) clearance is only for the tracheal tube and removal of secretions claim and not the pneumonia prevention claimed in the labeling provided. PMS report has no date and data collected was only in 2018; the report itself is not robust. The post-market documentation should be provided to complete the assessment of this device.

They need to explain their relationship with Omnimate; CE Mark for Production QA & MDD expired April 2021 & ISO 13485:2003


























expired Nov 2017; should have ISO 13485:2016.

Taiwan GMP certificate expired July 2019.


Animal study provided for COVID-19 claims; the report acknowledged that the suction at the end of the study was measuring higher than the original suction settings. This could be a patient safety issue and this was not discussed or justified in the report or with any corresponding risk analysis.

The 510(k) summary mentions several performance data reports but none were provided in this submission: ISO 5361:2016, ISO 5356_1:2015, ISO 10993:2018, IEC 62366_1:2015, ISO 14971:2019, Suction Patency Test, Fluid Recovery Rates determination, Suction_T Pull Test (Shear and Tensile Force) and Isolated Suction_T Material Pull Test.

Technology evidence assessment

Domains	Evidence assessment		Summary
	Risk/benefit ratio	Impact	
 Medical			<p>This innovative device is used to remove accumulated subglottic secretion and pathogens. According to the documents submitted, its efficacy was demonstrated in randomized control trials as well as its effectiveness in up to 30,000 cases in three different countries and in low and middle-resource settings. Its use is simple, and because the device is integrated into the tube, no additional training on the process of endotracheal intubation is required. The device is only intended for single use. Even though the device has the potential to reduce healthcare costs, the price per unit in LMIC settings appears to be too high. This is an IP-protected product. There are no plans to produce on-site. However, given the medical benefits, a recommendation can be made.</p> <p>Innovation </p> <p>Technology evidence assessment Recommended</p> <p>Technology readiness level 9</p>
 Safety			
 Economy			
 Organizational			
 Legal			
 Social			
 Ethical			
 Green environment			

Summary

Innovation 

Technology evidence assessment **Recommended**

Technology readiness level **9**

Health technology and engineering management

Domains	Appropriateness	Domains	Appropriateness	Target settings: Secondary & Tertiary level
Durability		Ease of cleaning		 Airway support tube for mechanically ventilated patients that incorporates delivery of breathing gas, trachea suctioning, and visualization in an innovative way. It is reasonably priced. Clinical use training is correctly required due to the tissue sensitivity to the placement of the tube edge and pressurizing balloon inside the airway. This disposable product does not require the use of engineering resources or product maintenance.
Ease of Use		Ease of maintenance		
Positive impact on clinical outcomes		Infrastructure requirements		
Affordability		Local access to sales support		
Engineering resources minimization		Local access to technical support		
Cultural and social acceptability		Local access to training		
Environmental conditions		Local access to spare parts		
Aesthetics		Locations of use within target setting		

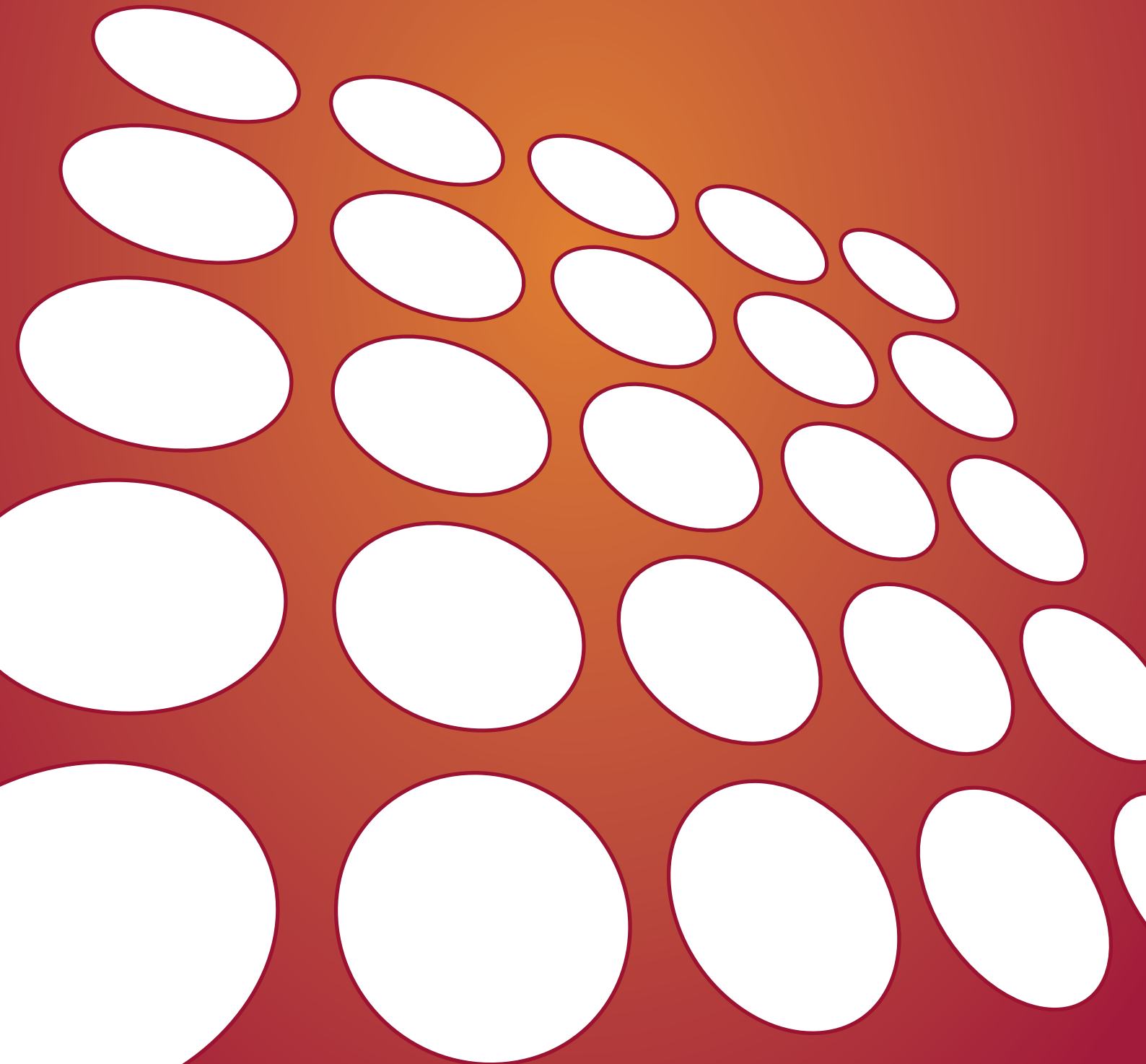
Intellectual property and local production

Technology transferability		Intellectual property - It is patent-protected. To use this technology, authorization from the patent owner or the assignee is required.
Openly access intellectual property		Local production - For LMICs, the current product price is high and market demand is low. Currently, dedicated local production for only this product is not feasible. As demand grows, an existing LMIC manufacturer of the same product line can explore licensing options.
Local production		

WHO related guidance material

- WHO Global Health Estimates (the top 10 causes of death) - <https://www.who.int/news-room/fact-sheets/detail/the-top-10-causes-of-death>
- WHO Coronavirus (COVID-19) Dashboard - <https://covid19.who.int/>
- Coronavirus disease (COVID-19) technical guidance: Patient management - <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/patient-management>
- Living guidance for clinical management of COVID-19 - <https://www.who.int/publications/i/item/WHO-2019-nCoV-clinical-2021-2>
- Therapeutics and COVID-19: living guideline - <https://apps.who.int/iris/handle/10665/345356>
- WHO-ICRC Basic Emergency Care: approach to the acutely ill and injured - <https://www.who.int/publications/i/item/basic-emergency-care-approach-to-the-acutely-ill-and-injured>
- Emergency Care - <https://www.who.int/emergencycare/systems/en/>
- Guidelines for essential trauma care - <https://www.who.int/publications/i/item/guidelines-for-essential-trauma-care>
- Severe Acute Respiratory Infections Treatment Centre - <https://www.who.int/publications/i/item/10665-331603>
- Nosocomial pneumonia: risk factors, rates and trends - <https://apps.who.int/iris/handle/10665/117465>

PROTOTYPE PRODUCTS



Continuous positive airway pressure device

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

Commercial information

List price (USD): 3000
Year of commercialization: 2021
Number of units distributed: 0-100
Currently marketed in: India, under evaluation in Ethiopia, Sri Lanka
Brand: InnAccel
Model: Saans Neonatal CPAP



Product description

Saans is an infrastructure-independent, low-skill breathing support system that can provide multiple therapy options (CPAP, HFNC, resuscitation), across multiple settings (hospitals of all levels and transport). The device has an in-built flow generator and air-oxygen blending and incorporates sensors and simple digital controls/displays for flow, FiO₂, and pressure output. In addition, Saans is portable, has an in-built battery backup, and alarm system.

Product details

Accessories: For long-term use, accessories required are: 1. Servo-controlled humidifier 2. Trolley
Consumables: Circuits and patient interfaces
Warranty duration: 1 year
Lifetime: 2-5 years
Energy requirements: Rechargeable battery, Continuous power supply, AC, 110V, 220V, 36W, 6-hour battery recharge cycle, 5-hour battery life
Facility requirements: Specific temperature and/or humidity range, Gas supply (Oxygen), Operating: 0 to 45 C°, Storage: 0 to 50 C° and Humidity: 25-95% non-condensing

Contact: Shaunak Patel | **Email:** shaunak@innaccel.com | **Phone:** +91 98 1060 2033 |
Web: <https://innaccel.com/products/saans/>

NOTE: Information reported by manufacturer before 17 December 2021

WHO ASSESSMENT

WHO assessed some newly commercialized products as a prototypes considering they had limited production, availability and evidence.

Clinical assessment

In 2019, 2.4 million newborns died worldwide, with sub-Saharan Africa carrying the highest neonatal mortality rate at 27 deaths per 1,000 live births, followed by Central and Southern Asia with 24 deaths per 1,000 live births. According to recent estimates, the primary causes of neonatal death include pre-term birth, intrapartum-related complications (birth asphyxia or lack of breathing at birth), infections, and birth defects. Similarly, the highest under-five mortality rate is recorded in the WHO African Region (74 per 1000 live births), around 9 times higher than that in the WHO European Region (8 per 1000 live births). Among under-five children, infectious diseases, including pneumonia and malaria, remain a leading cause of death.

Saans is a breathing support device that aims to address a substantial source of mortality among newborns and children by offering multiple therapy options, including continuous positive airway pressure (CPAP) and resuscitation therapy for newborns and high-flow nasal cannulas for pediatric patients. It requires minimal infrastructure support, has several built-in features, including an air-oxygen blender, digital control of flows and FiO₂, and relevant alarm systems, and can be employed by appropriately trained physicians in secondary or tertiary hospital settings as well as during the transportation.

WHO specification comparison

At the time of report creation, WHO technical specifications available are related to CPAP and HFNC devices ONLY for adults and paediatric applications, and NOT for neonates/infant. Consequently, the specific requirements cannot be compared to finalize a compliance evaluation.

Regulatory assessment

	Pre-market assessment		Proceed with caution	<p>Pre-market - The manufacturer provided an Oxygen Gas Monitoring test report per ISO 8573, USP, and EP requirements, and EMC/EMI safety test report based on IEC 6100. Three articles were provided to demonstrate clinical performance. However, other significant pre-market assessment data and documents were missing; please see the list below.</p> <p>Post-market - No data or documents were provided.</p> <p>GSA - A current ISO 13485:2016 certificate was provided.</p>
	Post-market assessment		Not acceptable	
	Quality system assessment		Proceed	

The following data and documents were not provided and should be included for the Pre-market assessment and to demonstrate the safety and efficacy of the device:

- IEC 62366: 2007, IEC 60601
- IEC 60601-1-8: 2012, ISO 5356-1 ;2004
- ISO 18562-1;2017
- ISO 18562-2;2017
- ISO 18562-3;2017
- ISO 18562-4;2017

Cleaning and Disinfection of a reusable medical device validation referencing :

- AAMI TIR12
- AAMI TIR30
- ASTM D543
- ASTM EI 837-96
- ISO 17664-1:2021

Technology evidence assessment

Domains	Evidence assessment		Saans is a low-skill breathing support system that can provide multiple therapy options. It provides CPAP and resuscitation therapy with the appropriate oxygen blend in all hospital settings (labor room, NICU, SNCU) and during transport. It is portable, has a built-in battery backup, an alarm system, and is compatible with various oxygen sources such as central oxygen lines, cylinders, and even oxygen concentrators. The device can entrain atmospheric air at high pressures in the absence of oxygen. The device is durable, but the battery and oxygen sensors should be checked annually. Control and alarm software is built-in. Clinical data were mentioned but were not provided. The manufacturer provides evidence on the effectiveness of the technology in general, but not specifically on the submitted device. The manufacturer mentioned several certificates but did not submit them. Given the lack of evidence, the device should be used with caution.
	Risk/benefit ratio	Impact	
Medical			<p>Summary</p> <p>Innovation </p> <p>Technology evidence assessment Recommend with caution</p> <p>Technology readiness level 7</p>
Safety			
Economy			
Organizational			
Legal			
Social			
Ethical			
Green environment			

Health technology and engineering management

Domains	Appropriateness	Domains	Appropriateness	Target settings: Primary, Secondary & Tertiary level, Ambulance
Durability		Ease of cleaning		 This commercially available CPAP device is intended to provide short-term support to babies suffering from RDS who are not in an ICU setting. The product's ease of use and ability to be powered by a variety of power sources (AC, battery, gas, and manually with Ambu bag) is an attractive feature especially for rural settings. Maintenance service is required for addressing, blender parts replacement, battery condition verification, compressor parts, filter condition/replacement, and oxygen sensor replacement, as with any mechanical product used in critical conditions. The submission includes a description from a paper presented at an Indian conference, but there is no performance data or identification of all maintenance services periodicity. Finally, the submission includes three (3) different versions
Ease of Use		Ease of maintenance		
Positive impact on clinical outcomes		Infrastructure requirements		
Affordability		Local access to sales support		
Engineering resources minimization		Local access to technical support		
Cultural and social acceptability		Local access to training		
Environmental conditions		Local access to spare parts		
Aesthetics		Locations of use within target setting		

of the product, each with a different user interface and features, making it difficult to determine which is the actual submitted product. The following information is required to resolve engineering assessment challenges: the final version of the product being offered, maintenance services requirements for the filter, sensors, compressor, other mechanical components (Ambu bag), and valves. Where will the spare parts be available to support servicing in low-resource settings? Recommend inclusion with caution.

Intellectual property and local production

Technology transferability		Intellectual property - The device is patent-protected and it has proprietary software. Clearance is required to use this technology.
Openly access intellectual property		Local production - The product is most likely in the field trial phase and will require regulatory approval. Manufacturing know-how is most likely to be with contract manufacturers. The licensee must have experience with electronic assembly/manufacturing and related QMS.
Local production		Existing manufacturing line is currently in a region suitable for low volume production, this, in addition to low volume of market demand is less likely to provide further commercial advantages through local production.

WHO related guidance material

- Newborns: improving survival and well-being - <https://www.who.int/news-room/fact-sheets/detail/newborns-reducing-mortality>
- Child mortality and causes of death - <https://www.who.int/data/gho/data/themes/topics/topic-details/GHO/child-mortality-and-causes-of-death>
- Guidelines on basic newborn resuscitation - <https://apps.who.int/iris/handle/10665/75157>
- Oxygen therapy for children: a manual for health workers - <https://apps.who.int/iris/handle/10665/204584>
- WHO recommendations on newborn health: guidelines approved by the WHO Guidelines Review Committee - <https://www.who.int/publications/i/item/WHO-MCA-17.07>

Fetal monitor

Country of origin | India
 Primary function | Monitoring
 Category | Medical device

Commercial information

List price (USD): 2000
Year of commercialization: 2019
Number of units distributed: 0-100
Currently marketed in: Commercially available in India.
 Under evaluation in Poland, Israel, ASEAN, Ghana
Brand: InnAccel
Model: Fetal Lite



Product description

Fetal Lite (FL) is based on non-invasive aECG/EMG signal capture and analysis, a next-gen technology in fetal monitoring. FL uses patented hi-sensitivity electrodes for data capture, and machine learning algorithms to derive fetal & maternal heart rate and uterine activity with high accuracy. FL is designed for low-resource settings, being portable, battery-powered, cloud-enabled for remote monitoring, with an AI-driven risk detection engine to detect fetal distress, and requires minimal user skill.

Product details

Consumables: Electrodes
Warranty duration: 1 year
Lifetime: 5-10 years
Energy requirements: Rechargeable battery, DC, 5V, 5W, 4-hour battery recharge cycle, 8-hour battery life
Facility requirements: Specific temperature and/or humidity range, Storage: 0 to 50 C°, Operation: 10 to 50 C°, Dry storage

Contact: Shaunak Patel | **Email:** shaunak@innaccel.com | **Phone:** +91 98 19602033 | **Web:** www.innaccel.com/products/fetal-lite

NOTE: Information reported by manufacturer before 17 December 2021

WHO ASSESSMENT

WHO assessed some newly commercialized products as a prototypes considering they had limited production, availability and evidence.

Clinical assessment

In 2019, an estimated 1.9 million babies were stillborn at 28 weeks or later, with a global stillbirth rate of 13.9 stillbirths per 1,000 total births and three-quarters of all cases occurring in sub-Saharan Africa and South Asia. With better monitoring during pregnancy and access to obstetric care, a large proportion of these deaths could be prevented.

The Fetal Lite electronic fetal monitor is designed for non-invasive intermittent monitoring of fetal heart rate, maternal heart rate, and uterine contractions during labor in singleton pregnancies at term and should be used by a qualified healthcare professional. The fetal heart rate pattern aids in identifying fetuses that do not tolerate the recurrent transitory disruptions of fetal oxygenation caused by uterine contractions. The sensor unit of the device is a single portable, wireless probe with six ECG electrodes that need to be positioned over the umbilicus to capture both fetal heart rate and uterine activity. This concept could partly circumvent the limitations of a conventional cardiotocograph, which requires fetal heart localization and does not allow for mother's movements. However, before utilizing it, the user should know whether the woman has multiple pregnancies, which raises some concerns about its applicability in resource-limited settings.

WHO specification comparison

The Fetal Lite device complies with the “Foetal Cardiac Monitor” WHO technical specifications currently available.

Non-compliances: None. Specific features such as headphones, additional probes and extended warranty can be provided as “options”.

Not possible to be verified/not specified: Not clear if the optional probe that could be provided and claimed to be a “probe for pre 36 weeks monitoring in singleton pregnancies” is compliant with the 10-12 weeks foetus required. Not clear if the following accessories required can be provided with the equipment: compatible headphones. Not clear which is the ultrasound working frequency (required in the range 2MHz -10% to 3MHz +10%). Not clear if other probes with compliant MHz specifications could be available since the requirement is to have “at least two high sensitivity equipment compatible probes provided: 2 and 3 MHz”.

Regulatory assessment

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

Pre-market - The product has an EC certificate. The manufacturer provided software validation and electrical safety test reports. An IEEE article was provided to demonstrate clinical performance. However, other significant pre-market assessment data and documents were missing.

Post-market - No documents were provided. A current ISO 13485:2016 certificate was provided.

The following data and documents were not provided and should be included for the pre-market assessment and to demonstrate the safety and efficacy of the device:

- IEC 60601-1-2:2014
- IEC 60601-1-11;2015

FDA Guidance for Industry and FDA Staff: Radio Frequency Wireless Technology in Medical Devices or equivalent wireless validation

- Use Life Testing
- Battery Life Testing
- Battery Indicator Testing
- Acoustic output measurement methodology as recommended in FDA

Cleaning and Disinfection of a reusable medical device validation referencing :

- AAMI TIR12 ,AAMI TIR30,ASTM D543 ,ASTM EI 837-96 ,ISO 17664-1:2021

Technology evidence assessment

Domains	Evidence assessment		
	Risk/benefit ratio	Impact	
Medical			<p>The device is already commercialized in India as non-invasive intermittent monitoring of Maternal Heart Rate (MHR), Fetal Heart Rate (FHR), and Uterine Activity (UA) during labour. It is still under evaluation in several other countries. The device is portable, easy to use for trained clinicians and nurses, and has a multilingual interface. The submitted documentation on safety confirmed a high accuracy of the device compared to CTG for FHR and CTG for UA. In LMICs usability tests, in hospital settings were performed. Affordability may be an issue based on cost data submitted. Cost-benefit analyses in LMICs were not submitted. The manufacturer does not provide information on handling twin pregnancies. Nevertheless, in summary, the device can be recommended with caution.</p>
Safety			
Economy			
Organizational			
Legal			
Social			
Ethical			
Green environment			
			<p>Summary</p> <p>Innovation </p> <p>Technology evidence assessment Recommend with caution</p> <p>Technology readiness level 9</p>

Health technology and engineering management

Domains	Appropriateness	Domains	Appropriateness	Target settings: Primary, Secondary & Tertiary level
Durability		Ease of cleaning		<p>Submission of portable fetal monitoring product that is commercially available in India. Presently undergoing clinical trials (Israel and Ghana), but no technical data was provided other than a paper presented at an Indian conference. In that paper, a total of 1053 fetal heart rate samples were compared with conventional fetal heart monitoring and estimated to be at almost 94% accurate. Similar data for comparison of the mother's contraction measurement during motion is missing. The product is powered by a rechargeable battery with a life of 8 hrs. It wirelessly connects to a detachable tablet to display results and archiving. Submitter claims benefit from A.I. deployment, however no evidence for benefits over conventional fetal heart monitors are described. User interface experience, the effect of mother/fetal movement, or when mother carries multiple fetuses on product performance, are missing. So is data on sensors resistance to product drops and user abuse. Product contains software and should have a start-up test and error code reporting, but none were identified. Use data is also missing about battery life/charging/replacement, error code interpretation of operational issues such as device dropped, loss of wireless communication, sensor failure alarm, and loss of data during use. Recommendation inclusion with caution.</p>
Ease of Use		Ease of maintenance		
Positive impact on clinical outcomes		Infrastructure requirements		
Affordability		Local access to sales support		
Engineering resources minimization		Local access to technical support		
Cultural and social acceptability		Local access to training		
Environmental conditions		Local access to spare parts		
Aesthetics		Locations of use within target setting		

Intellectual property and local production

Technology transferability		<p>Intellectual property - The device has proprietary software and patent protection. The status of the patent application is pending. Clearance to use this technology is required. Caution advised due to pending patent applications.</p> <p>Local production - Contract manufacturers are likely to have manufacturing know-how. Electronics assembly, manufacturing and related QMS experience are required. Existing manufacturing line is currently in a region suitable for low volume production, hence local production is less likely to provide further commercial benefits.</p>
Openly access intellectual property		
Local production		

WHO related guidance material

- Maternal mortality: evidence brief - <https://apps.who.int/iris/handle/10665/329886>
- Trends in maternal mortality 2000 to 2017: estimates by WHO, UNICEF, UNFPA, World Bank Group and the United Nations Population Division - <https://apps.who.int/iris/handle/10665/327595>
- Managing complications in pregnancy and childbirth: a guide for midwives and doctors - 2nd ed. - <https://apps.who.int/iris/handle/10665/255760>
- WHO recommendations on antenatal care for a positive pregnancy experience - <https://apps.who.int/iris/handle/10665/250796>
- WHO recommendations on maternal health: guidelines approved by the WHO Guidelines Review Committee - <https://apps.who.int/iris/handle/10665/259268>
- Recurrence of adverse perinatal outcomes in developing countries - <https://dx.doi.org/10.2471/BLT.12.111021>

Filling station and multiple oxygen tanks

Country of origin | United Kingdom of Great Britain and Northern Ireland

Primary function | Supporting or sustaining life

Category | Medical gas

Commercial information

List price (USD): 2500

Brand: GCE, GH labs

Product description

Air2O2 comprises a filling station and multiple oxygen tanks. The filling station uses an oxygen concentrator, compressor, control system, and user interface to fill the tanks with 15 bar oxygen. The filling station is operated with a single push button, monitors the fill (with indicators of the status and alerts), and connects to the tank with a specific fitting. The lightweight oxygen tank is portable and has two flow selectors each providing 0-15 lpm of flow.



Product details

Consumables: Cannula

Lifetime: 5-10 years

Energy requirements: Continuous power supply, AC, 110V, 220V, 1200W

Facility requirements: Indoor storage

Contact: Gareth Pemberton | **Email:** gareth.pemberton@gcegroup.com | **Phone:** +44 77 1 300 0000 | **Web:** gcegroup.com

NOTE: Information reported by manufacturer before 17 December 2021

WHO ASSESSMENT

WHO assessed some newly commercialized products as a prototypes considering they had limited production, availability and evidence.

Clinical assessment

Lower respiratory tract infections, in addition to COVID-19, and tuberculosis are a major cause of hypoxemia and a significant source of morbidity and mortality in many resource-limited settings, ranking among the top ten causes of death in low- and lower-middle-income countries. There, fewer than half of all health facilities have continuous oxygen supply. The lack of accessible oxygen supply contributes to preventable deaths, with an estimated 122 000 deaths from pediatric pneumonia that could be prevented each year if oxygen supplies were strengthened. Moreover, the COVID-19 pandemic has further increased the demand for oxygen at the global level.

To address this problem, the manufacturer offers an oxygen storage device that links to a concentrator and ensures continuous oxygen delivery to patients in settings characterized by potential power outages or oxygen supply interruptions. It consists of a gas filling station that uses oxygen from a concentrator and can fill multiple low-pressure oxygen tanks, making it a lightweight, portable solution for hypoxemic patients that requires little additional training.

WHO specification comparison

Air2O2 is a filling station with one or multiple Oxygen tank/s. The filling station uses an Oxygen concentrator/ compressor, control system and user interface to fill the tanks. Based on these information, at the time of report creation, WHO technical specifications are not available to compare this type of technology.

Regulatory assessment

























 Pre-market assessment	 Not acceptable
 Post-market assessment	 Not acceptable
 Quality system assessment	 Not acceptable

Adequate documentation was not provided to perform a medical device Regulatory or Quality System review on this product. Design verification and validation reports were not submitted for pre-market assessment. No documentation is available on the quality management system, ISO 13485:2016 for quality system assessment. No documentation was provided on post-market activities. As such this product is in the prototype stage.

The pre-market and QS requirements for this medical device are as follows:

- USFDA Recognized Consensus Standards: ISO 80601-2-69 , ISO 18562-1, ISO 18562-2 , ISO 18562-3 , ISO 18562-4 , ISO 80601-2-69
- WHO Technical specifications for oxygen concentrators :ISO 80601-2-69:2014 ,IEC 60601-1:2012 ,IEC 60601-1-2:2014, IEC 60601-1-6:2013 ,IEC 60601-1-8:2012 ,IEC 60601-1-9:2013 ,IEC 60601-1-11:2010
- ISO 13485:2003 Medical devices – Quality management systems – Requirements for regulatory purposes
ISO 14971:2007 Medical devices – Application of risk management to medical devices.
- Oxygen cylinder marking based on ISO 32
- Purity of oxygen based on International Pharmacopoeia

Technology evidence assessment

Domains	Evidence assessment		The device is designed to provide supplemental oxygen to people who require oxygen therapy using approved oxygen concentrators. It improves the standard of care for hypoxemic patients by providing them with uninterrupted oxygen. The device can be used for two patients in parallel. Based on usability studies conducted in hospital settings in low resource areas, it is portable, easy to use, and maintain. Durability is also provided. The device appears to be quite expensive for the respective settings and in comparison to other available oxygen concentrators. As a result, the device’s affordability is questioned. The manufacturer did not provide any information on integrated batteries or solar-energy-based power supply. The required continuous power supply is presumed. Additional tests, particularly to obtain CE certification, are still being conducted. Given the device’s costs and ongoing regulation, it can only be recommended with caution.
	Risk/benefit ratio	Impact	
 Medical			<p>Summary</p> <p>Innovation</p> <p>Technology evidence assessment</p> <p>Technology readiness level 7</p> <p>Recommend with caution</p>
 Safety			
 Economy			
 Organizational			
 Legal			
 Social			
 Ethical			
 Green environment			

Summary

Innovation

Technology evidence assessment

Technology readiness level **7**

Recommend with caution

Health technology and engineering management

Domains	Appropriateness	Domains	Appropriateness	Target settings: Rural, Urban, Home & Primary level
Durability		Ease of cleaning		This submission describes a prototype system consisting of medium pressure reservoir (MPR) oxygen delivery system intended to supplement oxygen provisioning for persons requiring oxygen therapy. It contains a filling station that is a combination of oxygen concentrator device supported by a compressor that feed tank mounted on two trolleys. This system requires two persons to move it between locations of use. It is heavy and even with its moveable mounts, a physically strong persons are needed for it safe relocation. The system generates noise level during the concentrator and compression operation that maybe annoying for patients and staff. Mechanical devices like concentrator and compressor do require periodical maintenance services as well as the valves and gauges on the filling station. However, no data was provided to facilitate engineering (maintenance) support evaluation that is needed for such a system.
Ease of Use		Ease of maintenance		
Positive impact on clinical outcomes		Infrastructure requirements		
Affordability		Local access to sales support		
Engineering resources minimization		Local access to technical support		
Cultural and social acceptability		Local access to training		
Environmental conditions		Local access to spare parts		
Aesthetics		Locations of use within target setting		

Intellectual property and local production

Technology transferability		Intellectual property - It has proprietary software. The design of the device is protected by a number of design registrations. Global Health Labs (GH Labs) and GCE Healthcare have a licensing agreement for technology transfer. Clearance to use this technology is required. The use of patented compatible third-party products will also require clearance.
Openly access intellectual property		
Local production		Local production - The product is not yet ready for production; it is currently undergoing advanced product testing. Once approved by a stringent regulatory agency, this is a promising product for local production.

WHO related guidance material

- WHO Oxygen website - https://www.who.int/health-topics/oxygen#tab=tab_2
- Oxygen therapy for children: a manual for health workers - <https://apps.who.int/iris/handle/10665/204584>
- Oxygen sources and distribution for COVID-19 treatment centres: interim guidance, 4 April 2020 - <https://apps.who.int/iris/handle/10665/331746>
- Coronavirus disease (COVID-19) technical guidance: Patient management - <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/patient-management>
- Living guidance for clinical management of COVID-19 - <https://www.who.int/publications/i/item/WHO-2019-nCoV-clinical-2021-2>
- WHO-ICRC Basic Emergency Care: approach to the acutely ill and injured - <https://www.who.int/publications/i/item/basic-emergency-care-approach-to-the-acutely-ill-and-injured>
- Emergency care - <https://www.who.int/emergencycare/systems/en/>
- WHO Medical Emergency Checklist - <https://www.who.int/publications/i/item/who-medical-emergency-checklist>
- Guidelines for essential trauma care - <https://www.who.int/publications/i/item/guidelines-for-essential-trauma-care>
- WHO recommendations on newborn health: guidelines approved by the WHO Guidelines Review Committee - <https://www.who.int/publications/i/item/WHO-MCA-17.07>
- Revised WHO classification and treatment of childhood pneumonia at health facilities - <https://www.who.int/publications/i/item/9789241507813>
- WHO Global Health Estimates (the top 10 causes of death) - <https://www.who.int/news-room/fact-sheets/detail/the-top-10-causes-of-death>
- WHO Coronavirus (COVID-19) Dashboard - <https://covid19.who.int/>

High oxygen peep device

Country of origin | South Africa
 Primary function | Supporting or sustaining life
 Category | Medical device

Commercial information

List price (USD): 165
Year of commercialization: 2021
Number of units distributed: 10,000-50,000
Currently marketed in: African Region
Brand: Gabler Medical (Pty) Ltd
Model: OxERA



Product description

It comprises a custom main housing, incorporating an adjustable PEEP valve (5 - 15 cm H₂O), anti-asphyxiation valve (for safety), and oxygen supply via a hose and accumulator bag. The oxygen hose can be connected to any available source of oxygen. Commercial medical devices such as an anesthetic mask and viral filter complete the package together with simple but effective elastic head straps. The snug fit and accumulator maximises oxygen efficiency and the PEEP valve provides PEP.

Product details

Consumables: Viral / bacterial respiratory filter

Facility requirements: pathological waste, sharps, chemicals, etc (Device requires disposal as medical waste as it comes into contact with the patient's skin, expired air and secretions); Gas supply (Oxygen)

Contact: Craig Parker | **Email:** craig@craigparker.co.za | **Phone:** +27 84 5655022 | **Web:** www.umoya.org.za & www.gablermedical.com

NOTE: Information reported by manufacturer before 17 December 2021

WHO ASSESSMENT

WHO assessed some newly commercialized products as a prototypes considering they had limited production, availability and evidence.

Clinical assessment

Acute viral pneumonia that progresses to acute respiratory distress syndrome is the leading cause of morbidity and mortality from COVID-19. Supplemental oxygen therapy and increased respiratory support are required as patients' respiratory status deteriorates. A trial of a high-flow nasal cannula or non-invasive ventilation may be used in selected patients with COVID-19 and mild acute respiratory distress syndrome, according to WHO clinical guidelines.

The OxERA device is intended for use as a step-up strategy on adult hypoxemic patients in hospital settings who require additional respiratory therapy in the form of Positive Expiratory End-Pressure (PEEP). The device is an oxygen accumulator with an adjustable PEEP valve (5-15 cmH₂O) that allows exhalation while delivering high levels of oxygen at ambient pressure. If the oxygen supply is insufficient, as expected in certain rural areas with inadequate infrastructure, an anti-asphyxiation valve can be used to draw in supplementary ambient air.

This device may be more beneficial in low-resource environments, such as district-level hospitals or during transportation, where non-rebreather face masks would be the only viable option. However, continuous monitoring of the patient's respiratory status must be ensured for patients undergoing clinical deterioration, as well as prompt referrals to higher-level facilities.

WHO specification comparison

This device is reported to be a "High Oxygen Peep device". Consequently, at the time of report creation, WHO technical specifications are not available to compare this type of technology.

Regulatory assessment

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

Pre-Market - A Human Factors/Usability report was provided. The manufacturer stated that the product was in compliance with EN ISO 15223-1:2016, ISO 18562-1:2017, ISO 20789:2018, and ISO 17510:2015 but performance and/or safety data was not provided to enable a Pre-market Assessment. Adequate documentation was not provided to perform a medical device Regulatory or Quality System review on this product. Design verification and validation reports were not submitted for pre-market assessment, see list below for applicable standards. They do have a current Licence to Manufacture Medical Devices from the South African Health Products Regulatory Authority.

Post-market - No documents or data provided.

A current ISO 13485:2016 certificate was provided.

Missing safety and performance data:

- ISO 5356-1 Third edition 2004-05-15 Anaesthetic and respiratory equipment - Conical connectors: Part 1: Cones and sockets
- ISO 10651-4 First edition 2002-03-01 Lung ventilators - Part 4: Particular requirements for operator powered resuscitators
- ISO 18562-1 First edition 2017-03 Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 1: Evaluation and testing within a risk management process
- ISO 18562-2 First edition 2017-03 Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 2: Tests for emissions of particulate matter
- ISO 18562-3 First edition 2017-03 Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 3: Tests for emissions of volatile organic compounds
- ISO 18562-4 First edition 2017-03 Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 4: Tests for leachables in condensate
- ISO 10993-1:2018 Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process - needed for the mask material

Technology evidence assessment

Domains	Evidence assessment		The device is an all-in-one, single-use, high oxygen peep prototype device. It consists of an oxygen accumulator bag, anaesthetic mask, adjustable mechanical peep valve, anti-asphyxiation valve, and oxygen supply via the hose. It is intended for use by trained health professionals in hospitals or clinical settings, in general, to provide a supportive oxygen supply for respiratory diseases. According to the manufacturer, phase one safety study data showed no CO ₂ retention and good tolerance to the mask in healthy volunteers. Referring documents are available but have not been submitted and peer-reviewed yet. Phase 2 and 3 trials are in the planning stage. According to the manufacturer, local production is possible but not currently planned. The entire device is a single-use product. Information on environmental compatibility, recycling, and disposal is not provided. Considering that the device is intended for single use only, the intended price does not support affordability in low-resource settings. In conclusion, a recommendation could only be made with caution, especially given the lack of clinical evidence, pending regulation, questionable affordability, and missing data on environmental compatibility.
	Risk/benefit ratio	Impact	
Medical			
Safety			
Economy			
Organizational			
Legal			
Social			
Ethical			
Green environment			

Summary		
Innovation	Technology evidence assessment	Recommend with caution
Technology readiness level 7		

Health technology and engineering management

Domains	Appropriateness	Domains	Appropriateness	Target settings: Rural, Urban, Ambulance, Primary & Secondary level
Durability		Ease of cleaning		<p>This commercially available product is an Oxygen Efficient Respiratory Aid (OxERA), which is designed to assist patients by providing a high percentage of oxygen while maintaining a slight pressure to prevent the lungs from collapsing during expiration. The product contains an anesthetic-like mask, oximetry set with a hose, filter, rebreathing bag, anti-asphyxiation valve, and mechanically hand adjusted PEEP valve. The face mask has an inflatable edge that allows it to be fitted to the patient's face shape and size by adding/removing air from the edge with a syringe. The product cost is about US\$165, which positions it above alternative used products. The product benefit is that it offers more efficient use of oxygen sources; an important feature in setting where Oxygen supply is an issue. The product design is durable and easy to use.</p>
Ease of Use		Ease of maintenance		
Positive impact on clinical outcomes		Infrastructure requirements		
Affordability		Local access to sales support		
Engineering resources minimization		Local access to technical support		
Cultural and social acceptability		Local access to training		
Environmental conditions		Local access to spare parts		
Aesthetics		Locations of use within target setting		

Intellectual property and local production

Technology transferability		Intellectual property - The device has registered trademarks. Clearance is required to use this technology. Proceed with due diligence.
Openly access intellectual property		Local production - Technical complexity for local production is low to moderate. Market fluctuations can impact production feasibility.
Local production		

WHO related guidance material

- Living guidance for clinical management of COVID-19 - <https://www.who.int/publications/i/item/WHO-2019-nCoV-clinical-2021-2>
- Coronavirus disease (COVID-19) technical guidance: Patient management - <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/patient-management>
- Therapeutics and COVID-19: living guideline - <https://www.who.int/publications/i/item/WHO-2019-nCoV-therapeutics-2021.3>
- WHO Coronavirus (COVID-19) Dashboard - <https://covid19.who.int/>

Medical imaging analyzer

Country of origin | United Kingdom of Great Britain and Northern Ireland

Primary function | Diagnosis

Category | Medical device

Commercial information _____

List price (USD): 1

Year of commercialization: 2021

Number of units distributed: 0-100

Currently marketed in: Globally

Brand: Envisionit Deep AI Limited

Model: Radify



Product description _____

RADIFY incorporates AI, deep learning techniques & algorithms in order to analyze medical images and provide suggested pathologies detected in those images. RADIFY incorporates cloud, on-premise and virtualization technologies to deliver its solutions anywhere. All components of the RADIFY platform are containerized and exposed as a comprehensive set of microservices that incorporate the latest digital technologies in information security, data protection, and storage, scalability, robustness, and disaster recovery.

Product details _____

Lifetime: 5-10 years

Energy requirements: Rechargeable battery, Continuous power supply, Solar power, DC, 120V, 240V, 400W, 4-hour battery recharge cycle, 6-hour solar recharge, 8-hour battery life

Facility requirements: Access to the Internet is required for cloud-based deployments, and enhance on-premise deployments. RADIFY stand-alone units can be connected directly to X-Ray units, connection to a laptop/computer

Contact: Jaishree Naidoo | **Email:** jaishree@envisionitgroup.net | **Phone:** +27 82 464 8518 | **Web:** www.edai.africa

NOTE: Information reported by manufacturer before 17 December 2021

WHO ASSESSMENT

WHO assessed some newly commercialized products as a prototypes considering they had limited production, availability and evidence.

Clinical assessment

Radify is a medical image analyzer that employs artificial intelligence and can serve as a clinical decision support tool for medical practitioners working in the field. It may be used for X-ray images, including mammography, and ultrasound scans, thereby assisting the clinician in the management and interpretation of radiographic images. Given its technical requirements, it might be more easily operationalized in tertiary hospitals or facilities with advanced infrastructure rather than last-mile primary healthcare settings. However, a specific application for use on mobile devices can be connected to a portal ultrasound probe (via USB cable or Bluetooth), providing an additional point-of-care solution.

WHO specification comparison

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

Regulatory assessment

 Pre-market assessment	 Not acceptable
 Post-market assessment	 Not acceptable
 Quality system assessment	 Not acceptable

























Adequate documentation was not provided to perform a medical device Regulatory or Quality System review on this product. Design verification and validation reports were not submitted for pre-market assessment. No documentation is available on the quality management system, ISO 13485:2016 for quality system assessment. No documentation was provided on post-market activities.

As such this product is considered as a prototype as less than 100 have been commercialized.

The following pre-market data and documentation was missing:

- Specific performance test data should be provided.
- FDA's Guidance for Content of Pre-market Submissions for Software contained in Medical Devices
- IEC 62366-1:2015
- NEMA UD 2-2004 (R2009)
- IEC 61391-2 Edition 1.0 2010-01
- NEMA XR 22-2006 (R2020)
- NEMA XR 23-2006 (R2020)
- ISO IEC 10918-1;1994
- NEMA PS 3.1 3.20 (2016)
- IEC 62127-1 Edition 1.1 2013-02
- IEC 62127-03 Edition 1.1 2013-05
- IEC 62127-2 Edition 1.2 2017-03 CONSOLIDATED VERSION
- IEEE Std 3333.2.1-2015
- IEC 60601-2-37 Edition 2.1 2015
- IEC 61391-1 Edition 1.1 2017-07 CONSOLIDATED VERSION
- IEC 62359 Edition 2.1 2017-09 CONSOLIDATED VERSION Ultrasonics

Technology evidence assessment

Domains	Evidence assessment		
	Risk/benefit ratio	Impact	
 Medical			<p>The device is very innovative. It is part of the clinical picture archiving and communication system (PACS) and is already commercialized. To use this system, additional digital infrastructure (e.g. digitally connected modalities, clinical information system), as well as an internet connection and a continuous power supply, are required. The system seems affordable. However, given the additional infrastructure required for operationality, affordability could be unlikely. Furthermore, the system has not yet been tested in low-resource settings, making its suitability and feasibility in those settings questionable. The device is difficult to use and maintain. It should also be recognized that additional training is necessary. Based on the documents provided, the sensitivity in detecting seems low. To summarize, the device is unsuitable for low-resource settings and should not be recommended.</p>
 Safety			
 Economy			
 Organizational			
 Legal			
 Social			
 Ethical			
 Green environment			
Summary			
Innovation			Technology evidence assessment Not recommended
Technology readiness level			
9			

Health technology and engineering management

Domains	Appropriateness	Domains	Appropriateness	Target settings: Primary, Secondary & Tertiary level
Durability		Ease of cleaning		An A.I. supported product that augments and transmits post examined scan images by a learned algorithm that able to read X-rays, mammography, and ultrasound images and responds with a diagnosis of about 20 pathologies. Developed for emergency use and incorporates machine learning, augmented scans review, and recorded expertise of radiologists to improve its performance of time. However, more data is needed to validate its clinical appropriateness for its intended use and for technical support this application requires. The system proposed can facilitate the reduction of time between taking an image and providing a report back to the referring radiologist. Thus, improving care outcomes. The computing power, power stability, and communication bandwidth requirements need to be reported for further assessment.
Ease of Use		Ease of maintenance		
Positive impact on clinical outcomes		Infrastructure requirements		
Affordability		Local access to sales support		
Engineering resources minimization		Local access to technical support		
Cultural and social acceptability		Local access to training		
Environmental conditions		Local access to spare parts		
Aesthetics		Locations of use within target setting		

Intellectual property and local production

Technology transferability		Intellectual property - Protected by trade secret. It has proprietary software and registered trademarks. The use of all intellectual property, including any rights owned by third parties, will require clearance. Please note that, in response to the COVID-19 outbreak, RADIFY® is being made available “free of charge” to any public or private organization that uses X-rays in the diagnosis and treatment of COVID-19 pneumonia. Proceed with due diligence.
Openly access intellectual property		
Local production		Local production - This is a software product - no manufacturing involved.

WHO related guidance material

- Generating evidence for artificial intelligence-based medical devices: a framework for training, validation and evaluation - <https://apps.who.int/iris/handle/10665/349093>
- Use of chest imaging in COVID-19: a rapid advice guide: web annex A: imaging for COVID-19: a rapid review - <https://apps.who.int/iris/handle/10665/332326>
- Diagnostic imaging : what is it? when and how to use it where resources are limited? / Harald Ostensen - <https://apps.who.int/iris/handle/10665/66703>

Mechanical ventilator

Country of origin | United States of America

Primary function | Treatment

Category | Medical device

Commercial information

List price (USD): 4000

Year of commercialization: N/A

Number of units distributed: N/A

Currently marketed in: N/A

Brand: OneBreath, Inc.



Product description

OneBreath's ventilator addresses the need for continuous ventilation in the absence of compressed gas or electricity and provides a range of settings utilizing a portable O₂ concentrator. Preventative maintenance is minimal and a simple and intuitive user interface controls state-of-the-art clinical features including Volume Targeted Pressure Control (VTPC), spontaneous breath support modes, programmable PEEP, neonatal ventilation, and accurate blending and sensing capabilities.

Product details

Accessories: Includes AC power cord and oxygen sensor

Consumables: The disposable breathing circuits, endotracheal tubes, bacterial filters (optional)

Lifetime: 2-5 years

Energy requirements: Rechargeable battery, Continuous power supply, AC, 110V, 220V, 4-hour battery recharge cycle, 24-hour battery life

Contact: Matthew Callaghan | **Email:** info@onebreathventilators.com | **Phone:** +1 650 646 4984 |

Web: www.onebreathventilators.com

NOTE: Information reported by manufacturer before 17 December 2021

WHO ASSESSMENT

Clinical assessment

In many resource-limited settings, lower respiratory tract infections, along with COVID-19 and respiratory diseases, are a major source of morbidity and mortality, ranking among the top 10 causes of death in low- and lower-middle-income countries. The COVID-19 pandemic has heightened the global demand for high-quality, safe, and affordable medical equipment to treat patients with respiratory failure, particularly those who require mechanical ventilation. Pending regulatory and technical evaluation, OneBreath may provide a suitable solution for mechanical ventilation for patients with respiratory failure, provided that the healthcare workforce receives appropriate, relevant training in its clinical use and maintenance.

WHO specification comparison







OneBreath ventilator partially complies with "Transport ventilator", "Sub-acute ventilator" and "ICU ventilator" WHO technical specifications.

The following main non-compliances and non-verifiable (or not specified) requirements are listed:

























Non-compliance: Volume Control Ventilation (VCV) mode is required. Real-time scalar waveform for volume not available. Tidal Volume expired not displayed. ONLY FOR "ICU VENTILATORS": Tidal Volume range required at least 20-1500 ml, while only 20-1000 ml is available. Three scalar waveforms are required to be displayed at the same time while only two are simultaneously available. Loop (axis) displays for pressure-volume and flow-volume not available. Expiration time and End-Tidal CO₂ parameters not displayed

Not possible to be verified: Oxygen-air mixture accuracy. Internal function testing/leak testing. "IP" protection level certification. Display brightness and contrast control capabilities. Not clear if "Inspiratory pause manoeuvre capability to measure plateau pressure" is available. Not clear if "PEAK, PLATEAU and MEAN airway pressure" and "RR (spontaneous and mechanical)" parameters can be displayed and if "adjustable peak pressure limitation/pressure-cycling mechanism above measured peak pressure" is available. "High/Low FiO₂", "High/Low RR", "High/Low Tidal Volume" and "Low PEEP" alarms availability. Availability of single-limb breathing circuits for adult/paediatric.

Regulatory assessment

































 Pre-market assessment	 Not acceptable	Adequate documentation was not provided to perform a medical device Regulatory or Quality System review on this product. Design verification and validation reports were not submitted for pre-market assessment. No documentation available on quality management system, ISO 13485:2016 for quality system assessment. No documentation was provided on post-market activities. As such, this product is in the prototype stage.
 Post-market assessment	 Not acceptable	
 Quality system assessment	 Not acceptable	

Technology evidence assessment

Domains	Evidence assessment		
	Risk/benefit ratio	Impact	
 Medical			The device is a patent-pending prototype made in the United States and Singapore. There is no provision for local manufacture. According to manufacturer tests, the device is simple to use and maintain in rural locations. It is portable and can be used in multiple settings, including ICUs, Emergency rooms, and transportation. Despite this, the device has yet to receive regulatory approval, and the manufacturer has not provided any clinical study data. The unit costs appear to be reasonable, yet they are not inexpensive. In this aspect, affordability is unlikely to be guaranteed in LMI settings. The device is a prototype. In conclusion, a recommendation could not be made based on the current level of evidence.
 Safety			
 Economy			
 Organizational			
 Legal			
 Social			
 Ethical			
 Green environment			

Summary		
Innovation		Technology evidence assessment Not recommended, still a prototype
Technology readiness level	5	

Health technology and engineering management

Domains	Appropriateness	Domains	Appropriateness	Target settings:
 Durability		 Ease of cleaning		Rural, Urban, Indoors, Ambulance, Secondary & Tertiary level
 Ease of Use		 Ease of maintenance		
 Positive impact on clinical outcomes		 Infrastructure requirements		The core design is based on proven innovation (turbine). The user interface is intuitive. Internal disinfection of the ventilator between patients' use is not addressed. The manufacturer mentions periodic maintenance, however, there is no information on training or parts availability in the submission. Disposables that are not proprietary are indicated. A field evaluation is pending.
 Affordability		 Local access to sales support		
 Engineering resources minimization		 Local access to technical support		
 Cultural and social acceptability		 Local access to training		
 Environmental conditions		 Local access to spare parts		
 Aesthetics		 Locations of use within target setting		

Intellectual property and local production

 **Technology transferability**

 **Openly access intellectual property**

 **Local production**



Intellectual property - It is patent-protected. Some patents are owned by third parties. All applicable patents will require clearance before they can be used. The breath delivery and ventilator management code is proprietary. For the user interface, third-party authorisation is also necessary. Proceed with due diligence.

Local production - It is not yet ready for production; it is still in the prototype stage.

WHO related guidance material

- WHO Global Health Estimates (the top 10 causes of death) - <https://www.who.int/news-room/fact-sheets/detail/the-top-10-causes-of-death>
- WHO Coronavirus (COVID-19) Dashboard - <https://covid19.who.int/>
- Coronavirus disease (COVID-19) technical guidance: Patient management - <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/patient-management>
- Living guidance for clinical management of COVID-19 - <https://www.who.int/publications/i/item/WHO-2019-nCoV-clinical-2021-2>
- Therapeutics and COVID-19: living guideline - <https://apps.who.int/iris/handle/10665/345356>
- WHO-ICRC Basic Emergency Care: approach to the acutely ill and injured - <https://www.who.int/publications/i/item/basic-emergency-care-approach-to-the-acutely-ill-and-injured>
- Emergency Care - <https://www.who.int/emergencycare/systems/en/>
- Guidelines for essential trauma care - <https://www.who.int/publications/i/item/guidelines-for-essential-trauma-care>
- Severe Acute Respiratory Infections Treatment Centre - <https://www.who.int/publications/i/item/10665-331603>

Oxygen concentrator

Country of origin | Bangladesh

Primary function | Treatment

Category | Medical gas

Commercial information _____

List price (USD): 400

Brand: OxyNLife

Model: OxyNLife

Product description _____

The developed device selectively removes nitrogen from the air to produce a high purity oxygen stream by utilizing a state-of-the-art porous adsorbent. The device continuously draws in air and generates a steady stream of high-purity oxygen.

Product details _____

Accessories: The device requires propriety software that comes with the device for it to function and achieve the target performance. Additionally, the device also needs filters (air, bacteria filters) as accessories.

Consumables: Face mask/nasal cannula for patients during use. The filter has to be changed every 6 months of use.

Warranty duration:

Lifetime: 2-5 years

Energy requirements: Continuous power supply, AC, 110V, 220V, 340W

Facility requirements: Healthcare waste disposal facilities (disposal of oxygen face mask, nasal canula and filters), disposal guidance provided by the manufacturer

Contact: Lutful Kabir | **Email:** lutfulkabar@iict.buet.ac.bd | **Phone:** +880 1819 276 951 |

Web: www.eng.nus.edu.sg/chbe/staff/chesf/

NOTE: Information reported by manufacturer before 17 December 2021



WHO ASSESSMENT

Clinical assessment

Hypoxemia is a condition in which the blood oxygen level is abnormally low. It can be caused due to various mechanisms and diseases and can lead to respiratory failure and the need for supplemental oxygen therapy. In many resource-limited settings, lower respiratory tract infections and tuberculosis, in addition to COVID-19, are a leading cause of hypoxemia and a significant source of morbidity and mortality, ranking among the top ten 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.

The COVID-19 pandemic has further increased the demand for oxygen worldwide, and the OxyNLife device intends to address this global health concern as a prototype oxygen concentrator. The device's inventive potential, however, is debatable based on the information supplied.

WHO specification comparison

OxyNLife device only partially complies with the related WHO requirements. Even if no non-compliance was found, the following device parameters and technical specifications could not be verified or were not included in the documents:

The type of oxygen outlet (required with 6 mm, or 1/4 inch, barbed fitting or equivalent) and how it is secured and shielded to avoid being broken or bent. The ability to continuously supply the specified oxygen concentration at elevations ranging from 0 to at least 2000 m (along with performance characteristics at altitudes higher than 2000 m) must be stated. The main power cable should be longer than 2.5 meters. It's unclear whether the DISS and barbed adaptors are included in the accessories list (for each outlet, if applicable). Storage and operating conditions related to temperature and humidity apply to the entire device, not just the sensor.

Mechanical shock resistance, mechanical vibration, electromagnetic compatibility, and electrical safety tests were all performed. The displayed parameters, display characteristics, and user-adjustable settings are all available. IP protection is provided.

Regulatory assessment

 Pre-market assessment	 Not acceptable
 Post-market assessment	 Not acceptable
 Quality system assessment	 Not acceptable

Adequate documentation was not provided to perform a medical device Regulatory or Quality System review. Design verification and validation reports were not submitted for pre-market assessment. No documentation available on quality management system, ISO 13485:2016 for quality system assessment. No documentation was provided on post-market activities.

As such, this product is in the prototype stage.

























USA FDA Recognized Consensus Standards:

- ISO 80601-2-69:2014
- ISO 18562-1:2017
- ISO 18562-2 :2017
- ISO 18562-3 :2017
- ISO 18562: 2017
- ISO 80601-2-69:2020

WHO technical specifications for oxygen concentrators :

- ISO 80601-2-69:2014,
- IEC 60601-1:2012,
- IEC 60601-1-2:2014,
- IEC 60601-1-6:2013,
- IEC 60601-1-8:2012,
- IEC 60601-1-9:2013,
- IEC 60601-1-11:2010,
- ISO 13485:2003,
- ISO 14971:2007

Technology evidence assessment

Domains	Evidence assessment		
	Risk/benefit ratio	Impact	
 Medical			<p>The device is a prototype that was developed specifically for COVID-19. It has been tested in two hospitals with two patients, and it complies with the WHO oxygen concentrator guidelines. All used components are low-cost, according to the documents provided. As a result, the system's affordability in LMIC appears credible. It is simple to manufacture, use, and maintain the device. The information about the shelf life (0-2 years) raises questions. More information about medical, safety and cost-effectiveness is needed for further evaluation and recommendation.</p> <p style="text-align: center;">Summary</p> <p>Innovation</p> <p>Technology readiness level 6</p> <p>Technology evidence assessment Not recommended, still a prototype</p>
 Safety			
 Economy			
 Organizational			
 Legal			
 Social			
 Ethical			
 Green environment			

Health technology and engineering management

Domains	Appropriateness	Domains	Appropriateness	Target settings: Primary, Secondary & Tertiary level
Durability		Ease of cleaning		<p>The submission includes a description of a prototype product that is not accompanied by an independent testing laboratory certificate. The technical specification is insufficient for a thorough engineering evaluation. User or technical manuals were not included. As a result, there are no instructions for use, maintenance, warnings, or contraindications listed. By design, this product's application and use are limited to a maximum output of 5 LPM, restricting its use to areas where oxygen flow limitation is not a concern.</p>
Ease of Use		Ease of maintenance		
Positive impact on clinical outcomes		Infrastructure requirements		
Affordability		Local access to sales support		
Engineering resources minimization		Local access to technical support		
Cultural and social acceptability		Local access to training		
Environmental conditions		Local access to spare parts		
Aesthetics		Locations of use within target setting		

Intellectual property and local production

Technology transferability		Intellectual property - Protected by trade secret. It uses proprietary software, which can be licensed to the manufacturer. The use of all intellectual property and third-party products will require clearance.
Openly access intellectual property		Local production - The device is in early prototype phase and is not ready for production.
Local production		

WHO related guidance material

- WHO Oxygen website - https://www.who.int/health-topics/oxygen#tab=tab_2
- Oxygen therapy for children: a manual for health workers - <https://apps.who.int/iris/handle/10665/204584>
- Oxygen sources and distribution for COVID-19 treatment centres: interim guidance, 4 April 2020 - <https://apps.who.int/iris/handle/10665/331746>
- Coronavirus disease (COVID-19) technical guidance: Patient management - <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/patient-management>
- Living guidance for clinical management of COVID-19 - <https://www.who.int/publications/i/item/WHO-2019-nCoV-clinical-2021-2>
- WHO recommendations on newborn health: guidelines approved by the WHO Guidelines Review Committee - <https://www.who.int/publications/i/item/WHO-MCA-17.07>
- WHO-ICRC Basic Emergency Care: approach to the acutely ill and injured - <https://www.who.int/publications/i/item/basic-emergency-care-approach-to-the-acutely-ill-and-injured>
- Emergency care - <https://www.who.int/emergencycare/systems/en/>
- WHO Medical Emergency Checklist - <https://www.who.int/publications/i/item/who-medical-emergency-checklist>
- Guidelines for essential trauma care - <https://www.who.int/publications/i/item/guidelines-for-essential-trauma-care>
- WHO Global Health Estimates (the top 10 causes of death) - <https://www.who.int/news-room/fact-sheets/detail/the-top-10-causes-of-death>
- WHO Coronavirus (COVID-19) Dashboard - <https://covid19.who.int/>

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 | **Phone:** +61 43 144 0820 | **Web:** www.freo2.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 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		
	Risk/benefit ratio	Impact	
 Medical			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.
 Safety			
 Economy			
 Organizational			
 Legal			
 Social			
 Ethical			
 Green environment			
			<p style="text-align: center;">Summary</p> <p>Innovation</p> <p>Technology evidence assessment Recommended, but still a prototype</p> <p>Technology readiness level 9</p>

Health technology and engineering management

Domains	Appropriateness	Domains	Appropriateness	Target settings: Rural, Urban, Indoors, Home, Primary, Secondary & Tertiary
Durability		Ease of cleaning		<p>The system consists of 5 subsystems - Oxylink, LPOS, Oxypump, FREO2 Solar and SIPHON. Some of the subsystems are more sensitive to misuse and damage. Given the importance of storage subsystems for oxygen flow, extra evidence for durability, environmental conditions, maintenance requirements, and cleaning should be provided. Beyond the initial site, performance testing is inconclusive. Krober/OxyLink oxygen concentrator system, which was recently included in this submission, describes a design that is appropriate for low-resource settings and is cost-effective, however no technical support or access to required spare parts is provided.</p>
Ease of Use		Ease of maintenance		
Positive impact on clinical outcomes		Infrastructure requirements		
Affordability		Local access to sales support		
Engineering resources minimization		Local access to technical support		
Cultural and social acceptability		Local access to training		
Environmental conditions		Local access to spare parts		
Aesthetics		Locations of use within target setting		

Intellectual property and local production

Technology transferability		Intellectual property - It is protected by trade secret and patents. The patent applications are still pending.
Openly access intellectual property		It has been stated that they are willing to provide access to their intellectual property. Caution advised due to pending patent applications.
Local production		Local production - It is not yet ready for production; it is still in the prototype stage.

WHO related guidance material

- WHO Oxygen website - https://www.who.int/health-topics/oxygen#tab=tab_2
- Oxygen therapy for children: a manual for health workers - <https://apps.who.int/iris/handle/10665/204584>
- Oxygen sources and distribution for COVID-19 treatment centres: interim guidance, 4 April 2020 - <https://apps.who.int/iris/handle/10665/331746>
- Coronavirus disease (COVID-19) technical guidance: Patient management - <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/patient-management>
- Living guidance for clinical management of COVID-19 - <https://www.who.int/publications/i/item/WHO-2019-nCoV-clinical-2021-2>
- WHO recommendations on newborn health: guidelines approved by the WHO Guidelines Review Committee - <https://www.who.int/publications/i/item/WHO-MCA-17.07>
- WHO-ICRC Basic Emergency Care: approach to the acutely ill and injured - <https://www.who.int/publications/i/item/basic-emergency-care-approach-to-the-acutely-ill-and-injured>
- Emergency care - <https://www.who.int/emergencycare/systems/en/>
- WHO Medical Emergency Checklist - <https://www.who.int/publications/i/item/who-medical-emergency-checklist>
- Guidelines for essential trauma care - <https://www.who.int/publications/i/item/guidelines-for-essential-trauma-care>
- WHO Global Health Estimates (the top 10 causes of death) - <https://www.who.int/news-room/factsheets/detail/the-top-10-causes-of-death>
- WHO Coronavirus (COVID-19) Dashboard - <https://covid19.who.int/>

Non-listed products

The following non-listed products require more evidence, and can be resubmitted in the future. The assessments are not published in this compendium but have been sent to the innovators as confidential feedback, for their consideration.

Generic name	Brand (company/affiliation)	Model
Telemedicine Vital Sign Monitoring	Black Space Technology Ltd	Rapid Telemed System
Powered air purifier respirator (PARP)	Vihelm Co, Ltd	Vihelm
Powered air purifier respirator (PARP)	Vihelm Co, Ltd	Vihood
Face mask	Rexa Designs	SS 3/2V Mask and AV 1 exhaust cap
Face mask	Narratek, Inc	Prolexus
Pressurized Steam Disinfection Chamber	Ideal Flow Control Pvt Ltd	CoAyrSteam
Nanotechnology filter coating protects	JBS Group USA Inc	
Air Purifier	Elite Technology & Innovation	Nutri Air
Virucidal plasma coating technology	Molecular Plasma Group SA	Not applicable*
Mobile health app	seeCOLe, LLC	
Multi-modal Patient Monitor	Freepulsemed	FreePulse
Pediatric Automated Ultrasound	Bloom Standard Limited	Kaaria / Product: 1111
Radar based contact-free continuous, autonomous monitoring of vital signs	Xander Kardian	XK300
Air purifier	Shreia Scalene Therapeutics LLC- USA/ Scalene Cybernetica Ltd India	Shycocan-Shcc-915
Mask Brace	Fix the Mask	V3

The following products have been rejected

These products did not comply with WHO guidelines.

Generic name	Brand (company/affiliation)	Model
UV-C Air Flow disinfection device**	Planika Sp. Z. O. O.	Sayoli 300 PRO
Individualized system for Augmenting Ventilator Efficacy***	Project Prana, NFP	iSave

* This technology involves applying a citric acid coating to the outside surface of PPE meant to inactivate the virus to minimize cross-contamination. The CE-certified coating is already commercialized on some medical and FFP2 masks. The submission to the compendium intended to increase visibility and availability in low resource settings, but it could not be included since the technology is a process (plasma coating) rather than a product. WHO welcomes a future submission for the assessment of finalized PPE product

** WHO do not recommend the use of mercury in healthcare settings

*** WHO do not recommend multiplexing ventilators in low resource settings

Discussion

This publication provides a general overview of the multidisciplinary methodology and rapid evaluation process of innovative health technologies in low-resource settings. A total of thirty-two submissions were assessed, out of which eight prototypes and seven commercially available products supported by adequate clinical/technological evidence were identified to be included in the Compendium. Multidisciplinary assessments were performed to assess the safety, serviceability, quality, acceptability, affordability, and appropriateness of each innovation when considering low-resource contexts. Furthermore, the evaluation shed insight on the intellectual property protection of the innovations as well as overall maturity of the countries' for manufacturing locally. An extended network of reviewers was leveraged to provide domain expertise and assess the potential of the innovations to meet the needs and realities on the ground, and to promote potential for future local manufacturing.

Stakeholders often do not have access to robust assessments of innovations that capture the practical considerations associated with use in resource-constrained environments. As a result, innovation uptake in these settings is delayed or pursued with incomplete evidence. This publication aims to bridge this information gap by providing considerations specifically tailored to use cases and decision makers in low-resource clinical environments to enable more informed decision making by stakeholders and, ultimately, accelerate the adoption of innovations to improve health outcomes.

It is important to note that successful adoption of these technologies is context dependent. Not all low-resource settings are the same and therefore not all technologies included in the Compendium will be appropriate for all low-resource settings. Each environment will have its own unique set of capabilities and constraints. Stakeholders must decide what technologies are appropriate for their context and use the information provided to help decide whether to adopt a specific technology. Factors that can be considered include the target setting; policy and financing; availability of human resources, training options, and local technical capacities; infrastructure, regulatory, and quality systems; risk/benefit ratio; and other available alternatives.

The processes and different methods used for selecting the technologies for the compendium are being evaluated and monitored on a regular basis. The online submission form is being modified in order to accurately represent the assessment results. Furthermore, in the future a pre-assessment screening process will be introduced to eliminate technologies that do not fulfil the criteria for health technologies allowing the process to be streamlined.

An extensive network of field and subject matter experts reviewed the innovations and provided valuable insights on implementation considerations in low-resource contexts. However, because the uptake of innovations is inherently limited, most reviewers did not have hands-on experience with the specific brands and products being assessed. Therefore, the results from this report should be viewed as a general perspective on each innovation's adoption potential within low-resource settings. Future work will include an in-depth collection of end-user feedback and an evaluation of the best approach for gathering input from end-users that is efficient and a genuine representation of how technology operates in the field. Another limitation was that the final decision-making discussion was limited to the core team of experts. The assessments were performed mostly with evidence provided by the manufacturer for the sake of expediency. Data was especially limited for those submissions identified as prototypes given their early stage of development.

Given the stated objectives of this publication, the methodological approach and evaluation criteria emphasized the technology's potential for adoption within low-resource settings as well as the possibility for future scaling for selected innovative products. The reviewers and core team members provide guidance and detailed comments to innovators of products that were not selected for inclusion in the Compendium, giving them the opportunity to improve their products further and resubmit their innovations in the next call.

For further reading

WHO is continuously searching for innovations to address needs, especially in low resource settings, please find the past compendia and other innovation initiatives in the following WHO webpage: <https://www.who.int/activities/accelerating-impact-for-innovations-for-health>.

For more information, please contact:

Medical Devices and in vitro diagnostics team
Health Product and Policy and Standards Department
Access to Medicines and Health Products Division

World Health Organization
20 Avenue Appia,
CH-1211 Geneva 27
Switzerland

Email: techinnovation@who.int
Web: www.who.int/activities/accelerating-impact-forinnovations-for-health

