WHO compendium of innovative health technologies for low-resource settings

2021

COVID-19 and other health priorities

World Health Organization

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Contents

Acknowledgements iv
Glossary of terms v
Objectives xii
Methodology xiii
Terms, conditions and disclaimers for the call xxiii
Key for icons xxv

COMMERCIALLY AVAILABLE PRODUCTS 1

Bleach additive, colourized 2
Deployable facility, for emergencies, shipping container based . . . 4
e-voucher, vaccination management 6
Heart rate meter, for newborn 8
Infrared thermography camera 10
MP3 radio, solar, wind-up powered 12
Oxygen generation plant, deployable 14
Oxygen, portable rebreathing 16
Respiratory monitoring system, portable 18
Solar-powered oxygen concentrator 20
Tele-education, for COVID-19 22
Ventilator, for low oxygen inlet pressure 24
Ventilator, mechanical, pressure control 26
Ventilator, with extended battery time 28
X-ray detector, dual energy, portable 30

PROTOTYPE PRODUCTS 33

Face mask, reusable, polypropylene based 34
Microfluidic based, COVID-19 test 36
Optical screeing jaundice device, neonatal 38
Pediatric automated ultrasound 40
Personal protective equipment, biodegradable, jute cellulose based . 42
Personal protective equipment suit reusable, ventilated 44
Solar Powered Oxygen Concentrator & Compressor (SPOCC) . . . 46
Ventilator, resuscitator bag based 48
Ventilator, ICU with waveform display 50

Non-listed products 52
Discussion 53

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Glossary of terms

Term	Definition
Affordability	"Health facilities, goods [including medical devices], and services must be affordable for all. Payment for healthcare services, as well as services related to the underlying determinants of health, must be based on the principle of equity, ensuring that these services [and goods], whether privately or publicly provided, are affordable for all, including socially disadvantaged groups. Equity demands that poorer households [settings and countries] should not be disproportionately burdened with health expenses as compared to richer households [settings or countries]." CESCR (Committee on Economic, Social and Cultural Rights) General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12). This refers to securing a standard of living (e.g., housing, education, or health) at a price that does not impose, in the eyes of a third party (usually government), an unreasonable burden on household incomes. In the context of this report, it is the extent to which the intended recipients of a service can pay for it, be it a public, governmental, or private service.
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	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. 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.
Certificate to Foreign Government	An FDA certificate that is required by some countries to prove that an exported medical device from the US is legally marketed in the US 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.

Term	Definition
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 EU's MEDical DEVices Documents (MEDDEV) 2.7.1 Rev. 3 guidelines and the Medical Device Regulation provide manufacturers with guidance regarding how to properly evaluate the clinical safety and performance of their devices.
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.
Declaration of interest (DOI)	To ensure the highest integrity and public confidence in its activities, WHO requires that experts serving in an advisory role disclose any circumstances that could give rise to a potential or reasonably perceived conflict of interest related to the subject of the activity in which they will be involved. The term "conflict of interest" means any interest declared by an expert that may affect or reasonably be perceived to (1) affect the expert's objectivity and independence in providing advice to WHO and/or (2) create an unfair competitive advantage for the expert or persons or institutions with whom the expert has financial or business interests (such as adult children or siblings, close professional colleagues, administrative unit or department).
Design control	Design controls are 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.

Term	Definition
Digital health	The field of knowledge and practice associated with the development and use of digital technologies to improve health. Digital health expands the concept of eHealth to include digital consumers, with a wider range of smart-devices and connected equipment. It also encompasses other uses of digital technologies for health such as the Internet of things, artificial intelligence, big data and robotics.
Ease of use	A concept that describes how easily users can deploy a product safely and effectively.
Environmental conditions	The ability of specific technology to fulfill its intended use in extreme conditions present in the surroundings where it is expected to be used, such as power variability, temperature, humidity, or blowing particles and sand.
Grading of Recommendations, Assessment, Development and Evaluation (GRADE)	Describes a process of rating the quality of the best available evidence and developing healthcare recommendations following the approach proposed by the GRADE working group.[1]
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.[2]
Health Technology Management (HTM)	A service 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.

1 Schünemann H, Borzek J, Guyatt G (2013): Handbook for grading the quality of evidence and the strength of recommendations using the GRADE approach. GRADE Working group Mar,2017 https://gdt.gradepro.org/app/handbook/handbook.html.

2 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
Instructions for use (IFU)	A document required for medical products for communication of instructions for the safe operation and application of medical products.
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.
In vitro Diagnostics (IVD)	IVDs are tests that can detect disease, conditions, and infections. *In vitro* means "in glass," meaning these tests are typically conducted in test tubes and similar equipment, as opposed to in vivo tests, which are conducted in the body itself. *In vitro* tests may be done in laboratories, healthcare facilities, or the home. The tests can be performed on a variety of instruments ranging from small, handheld tests to complex laboratory instruments. They allow doctors to diagnose patients effectively and provide appropriate treatments.
IVD Directive (IVDD)	The EU Directive (98/79/CE) that describes the requirements that IVDs must meet before they can be sold in the EU market.
In vitro Diagnostic Regulation (IVDR)	The new regulation [(EU) 2017/746] in the EU/EFTA that will replace the IVDD. The new rules will apply to all IVDs on the market from May 2022.
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.
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.
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 $1,035 or less in 2019; lower middle-income economies are those with a GNI per capita between $1,036 and $4,045; upper middle-income economies are those with a GNI per capita between $4,046 and $12,535.[3]

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

Term	Definition
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	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: • 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.
Medical Device Directive (MDD)	Legislation (Councl 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.
PICO	Describes a search tool for devising a search strategy. The tool focuses on population, intervention, comparison, and outcomes. It is commonly used to identify components of clinical evidence for systematic reviews in evidence-based medicine.[4]
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.

4 Methley AM, Campbell S, Chew-Graham C, McNally R, Cheraghi-Sohi S (2014): PICO, PICOS and SPIDER: a comparison study of specificity and sensitivity in three search tools for qualitative systematic reviews. BMC Health Serv Res.14:579. Published November 21, 2014. doi:10.1186/s12913-014-0579-0.

Term	Definition
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.
Post-market regulatory 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.
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.
Premarket regulatory 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.
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.
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 strong 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.
Survey	A set of activities that aims to discover new knowledge through the use of a data collection tool.

Term	Definition
Technology Evidence Assessment (TEA)	Within the Compendium, the different technologies have different types of evidence sources. To offer added value, the evidence was assessed without an available PICO question and based on a risk/benefit ratio with additional impact assessment. It is a part of the HS process.
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.[5]
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.

5 Junye Wang, Hualin Wang, Yi Fan, Techno-Economic Challenges of Fuel Cell Commercialization, Engineering, Volume 4, Issue 3, 2018, Pages 352-360, https://doi.org/10.1016/j.eng.2018.05.007.

Objectives

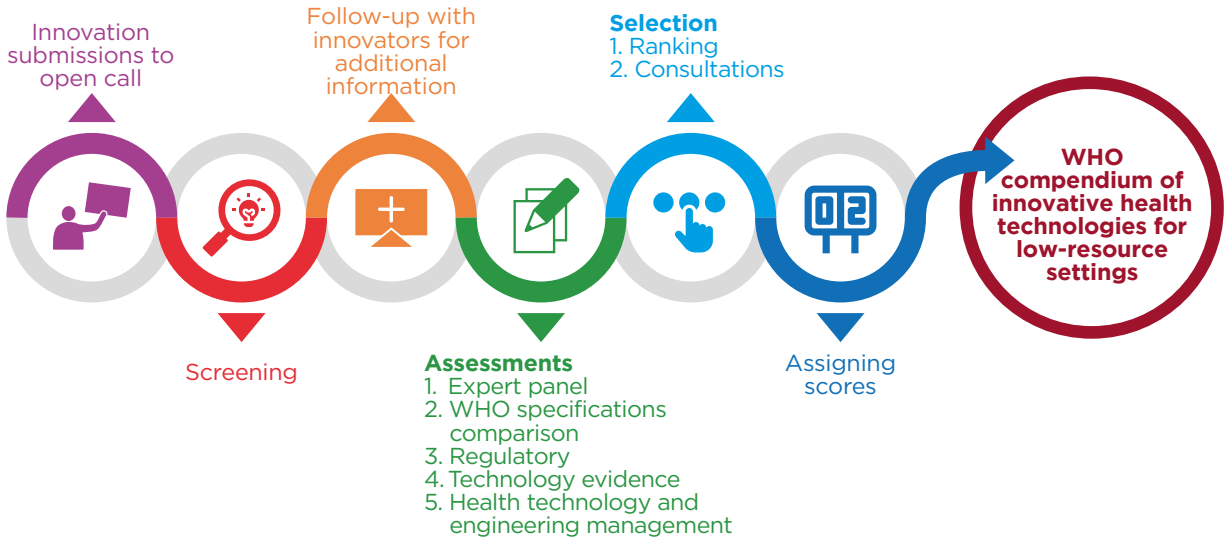
The response to the global COVID-19 pandemic crisis has exacerbated the need for rapid evidence-based assessments of innovative health technologies to ensure safe and appropriate use. Thus, the objectives of the 2021 compendium are to:

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. Shed light on advantages and challenges associated with the adoption of innovative health technologies in low-resource settings.
3. Acknowledge some success stories and, at the same time, raise awareness of the pressing need for appropriate and affordable design solutions and encourage more innovative efforts in the field.
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.

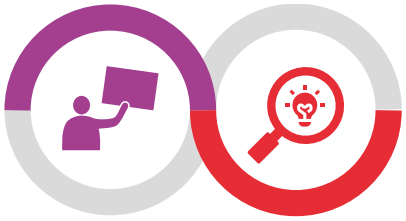
Methodology

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

Figure 1. Overall evaluation process



Innovation submissions to open call and screening



Following the 2010, 2011, 2012, 2013, 2014, and 2016 calls, the last one was launched in May 2020 in response to an influx of innovations being developed to address technology needs during the COVID-19 pandemic. The format of the online submission form was modified from the 2016 call to incorporate questions about the applicability of technologies to COVID-19. 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, oxygen 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. Additionally, technologies were identified from business-to-business channels (innovations coming from innovation contests and grants) and invited to submit an application. A total of 42 submissions were received and contained relevant details to be considered for further assessment.

Figure 2. Assessment domains of the submission form.

Follow-up with innovators for additional information

The materials from the 42 submissions were reviewed by a senior, core team of experts, with experience in regulatory and quality systems, health technology assessment, and clinical engineering, to ensure that sufficient information was available to perform the assessments. If missing information was identified, the innovators were contacted and asked to provide additional documentation to complete their applications and continue the process. A total of nine products were withdrawn at this stage, leaving 33 complete submissions that were considered for the full assessment.

Assessments

The 33 complete submissions underwent 5 separate assessments that were led by the core team of experts with assistance from 96 external reviewers from 46 countries, who presented no conflict of interest. The technologies were assessed based only on the material and evidence provided by the applicant.

Expert panel

Experts panels were convened in different sessions during May, June, July, November, and December 2020 and January 2021 to exercise their judgment and give an opinion whether the technology should be included in the Compendium.

The three expert panels were:

1. A respiratory expert panel comprised of physicians, respiratory therapists, anesthesiologists, and clinical engineers involved in the COVID-19 response.
2. A technical advisory group on Personal Protective Equipment (PPE) for COVID-19 comprised of infection control experts, public health experts, members of UN agencies in charge of procurement, regulatory affairs experts, materials engineers, members of organizations such as the Global Fund, Clinton Health Access Initiative (CHAI) and Centers for Disease Control and Prevention (CDC) and WHO consultants and staff involved in the technical guidance development and procurement of PPE.
3. Consultants on medical devices selected and hired by WHO, from November 2020 to February 2021, to work on different topics related to access to medical devices during COVID-19, such as donations, local production, training videos, and medical devices information systems.

It is important to note that these expert panels were not only convened for innovation assessment purposes, but also for other objectives, such as the development of training and technical guidance.

Innovators were called to present their technology in a five- to seven-minute presentation, followed by a question-and-answer session, with the objective of assessing whether the solution was appropriate or unique to a well-defined health problem and the technology was an innovation that had potential and was suitable for use in low-resource settings.

At the end of each presentation, opinions were gathered through a poll using the software SLIDO. The poll had the following questions:

1. In what type of setting does ***the technology*** target a well-defined and substantial health problem/ condition? (Low-resource settings, middle-resource setting, high-resource setting)
2. In what ways is ***the technology*** unique or superior to existing solutions (innovative)?
3. Should ***the technology*** be listed in the WHO Compendium?

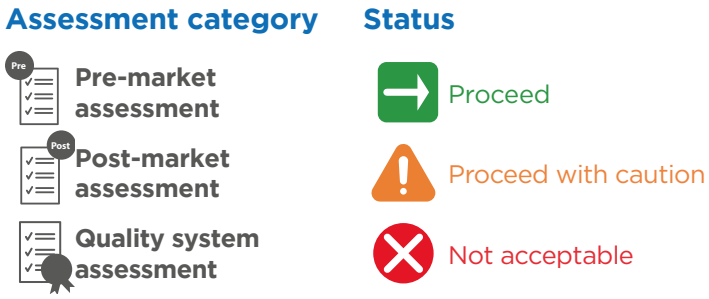
The expert panel expressed their opinions in a multiple answer setup. The panel members' opinions were taken into account to build a final ranking. This was then used to support Compendium inclusion and exclusion decisions.

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. Each technical characteristic was reviewed against the technical specifications specified 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, and not verified technical characteristics in the applicable technologies. The opinion of the technical evaluator was given to contribute to the final selection and scoring system.

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.



Technology evidence assessment

Based on the invitation by WHO, EuroScan adapted health technology assessment (HTA) and horizon scanning (HS) methods to create a technology related evidence-based assessment. 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 8 weeks for 33 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 on 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:

Topic 1: the classical-specific HTA-related domains were used to identify the relevant questions in each domain. Due to the special low-resource settings, COVID-19-related topics, 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: transferability, level of evidence provided (modified according to GRADE requirements, as no systematic evidence search was prepared), technology readiness level (TRS) (according to EU classification), and the overall evidence-based technology assessment.

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

- no systematic evidence search (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 processes)
- no comparator and, therefore, no PICO question(s).

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.

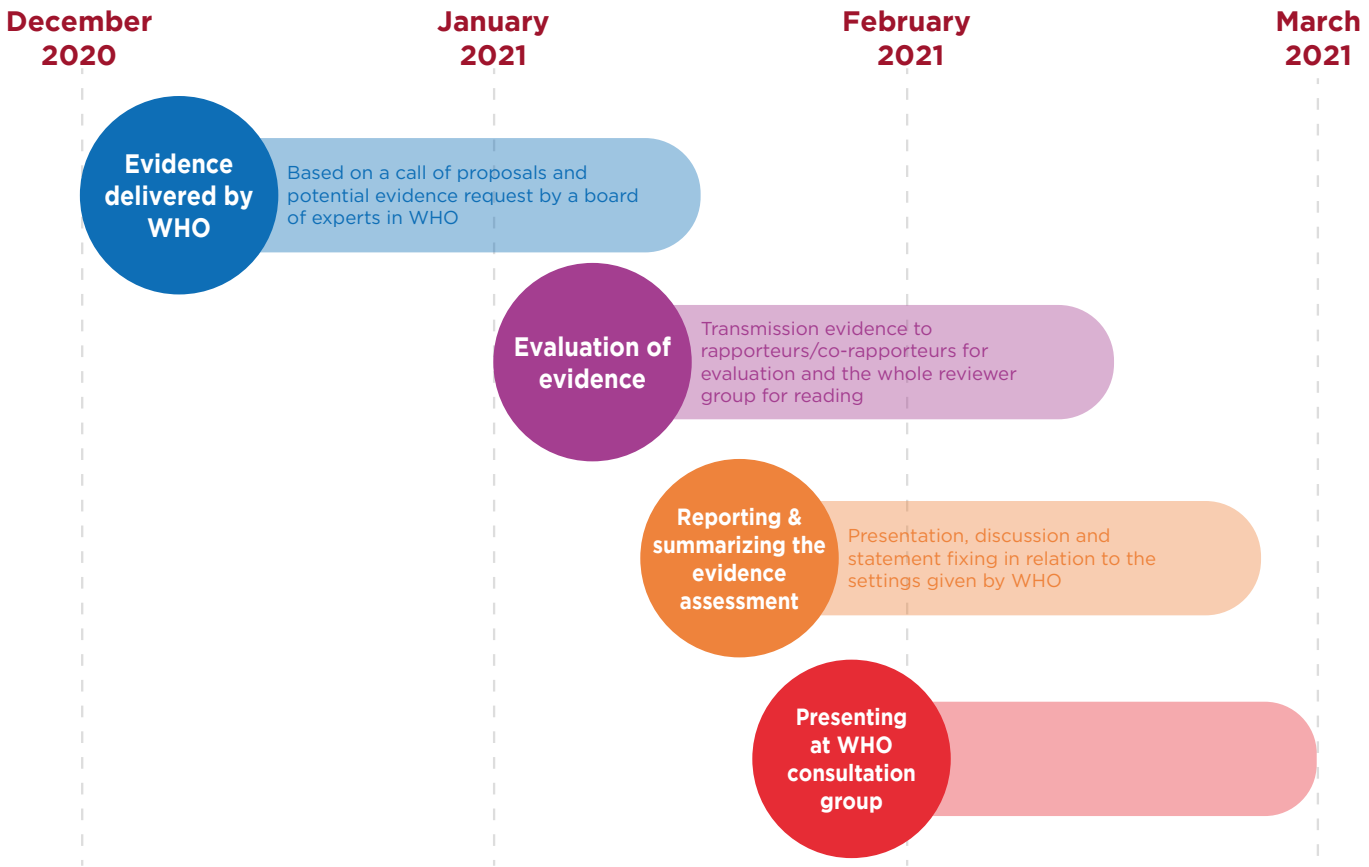
After a short pre-evaluation phase, including the adaptation of HTA and HS methodologies, EuroScan established a working group of reviewers from eight countries, mainly from public institutions or publicly funded organizations. All participants signed the required DOI and had a professional background 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. It was done by EuroScan internally and prepared by a rapporteur and a co-rapporteur who provided an overview to the group of reviewers. Within this process, all reviewers could bring their expertise, and the rapporteur and co-rapporteur could answer the questions based on the evidence. By also including people from LMICs, special expertise on requirements in these countries was included.

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, four 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



First phase of evaluation

For each technology, a rapporteur had to summarize the provided evidence and assign to HTA domains (including the focus on clinical outcomes). Then, a co-rapporteur had to comment and/or add 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 (medical/health, safety, efficacy, 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 special, 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).

In addition, the following three statements were included in the report as a summary of the evidence assessment:

- the transferability assessment
- the evidence-level assessment
- the overall TA regarding the implementation of a technology.

The LMIC transferability topic was rated as:

Fully transferable (if the production, license, and good manufacturing practice could be assured)

Partly transferable (if the technology was, for example, produced in other countries, but maintenance or specific parts could be performed in the LMIC)

Not transferable (if the technology had to be entirely bought in other countries, and and the maintenance services have to be provided by other manufacturing country)..

The evidence level was adopted based on GRADE recommendations (https://www.gradeworkinggroup.org/). It must be mentioned that the reviewers had no chance to request additional evidence or prepare any kind of systematic knowledge retrieval. Therefore, the GRADE recommendations had to be adapted to the amount and quality of evidence provided to the group. 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).

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

The TA was performed as 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. For this reason, all evidence was stored and can be shared with comments and explanations on request to euroscan.int.net.

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.

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 2020 cycle of innovation submissions. The submissions were initially reviewed for completeness of needed technological information by Senior Clinical Engineering Experts (SCEE), who had 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. 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 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 assessment, the CEE submitted their evaluations by completing an online survey tool designed by the SCEE. 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 other similar technology. Acceptability questions related to aesthetics and social acceptance of a product, while robustness related to the quality of a product's construction. Environmental conditions examined the effects of extreme humidity, temperature, sand, and storing conditions on product performance. The effect of deploying a product on the need for additional engineering or supplies resources and 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 facilitated feedback from remote and central locations around the world. A total of 102 completed surveys were received from 50 CEEs representing 37 countries across all WHO regions. Of the 50 CEE reviewers, 68% were male and 32% were female.

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 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 average values for each submission are presented in a colour-coded format. A feature presented in red indicates low appropriateness for low-resource settings, which is defined as product characteristics with responses that were typically weak, without evidence, or unsupported. Orange indicates moderate appropriateness for low-resource settings, which is defined as product characteristics with average responses and 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 target settings for each product were also determined by the SCEE based on the information provided with the submission and survey response.

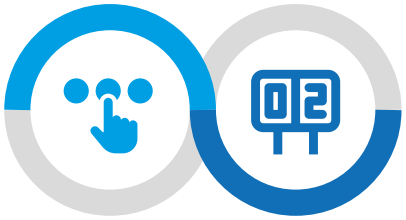
High appropriateness for low-resource settings
Product characteristics that have strong or above average evidence

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

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

Selection and scoring



Once the assessments were completed, the core team including the multidisciplinary team of consultants representing the technical specifications, the regulatory oversight, the technology assessment and the technology management, synthesized their findings and selected the technologies to be included in the 2021 Compendium. This step consisted of a ranking process and team consultation sessions. The ranking process consisted of each of the five assessment teams assigning a score to each submission based on their findings. The following 4-point scale was used: 1) *listed*: sufficient evidence, 2) *conditional*: additional evidence requested, 3) *resubmit*: submission incomplete, and 4) reject: no evidence of utility or evidence of harm.

Each assessment team's rankings were then presented and discussed during a series of core team consultation sessions. During the meetings, the team confirmed acceptance of technologies with 100% consensus rankings of 1 or 2 and rejection of technologies with 100% consensus rankings of 3 and 4. If there were conflicting rankings for a submission, each assessment team gave a brief presentation of their findings to the rest of the core team and then discussed questions. Once the discussion had concluded, these submissions were put to a team vote and accepted if there was a 75% consensus of rankings 1 or 2.

Once the evaluations were received and compiled, a total of nine prototypes and 15 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 two pages summarizing the results from the WHO assessments and describing information provided by the manufacturers (commercial information, health problem addressed, product description, product details).

Medical devices, personal protective equipment, oxygen systems, eHealth/mHealth solutions for consistency with classifications listed in product reports and others are health technologies that have the potential to save lives and improve quality of life and well-being. However, 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 some innovative technologies that are in the pipeline and others that are available to empower healthcare workers and potentially help people and patients to 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 assessment of data and information submitted in the developers' applications and, where available, additional sources of evidence, such as literature search results or other publicly available information. 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 information 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

Below is an easy to read legend for all the icons in their category.

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

Target settings

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

Hospitals

Health care systems

ICU

Clinic

Health care providers

Radiology

Health care facilities

Neonatal care

Public and home settings

Neonatal ICU

Patient transport

Screening tool at public and clinical sites

COMMERCIALLY AVAILABLE PRODUCTS

COMMERCIALLY AVAILABLE | 2021

Bleach additive, colourized

Country of origin | United States of America
Primary function | Prevention
Category | Other technology

Commercial information

List price (USD): $5[1]
Year of commercialization: 2017[1]
Number of units distributed: 10,000-50,000[1]
Currently marketed in: Globally[1]
Brand/Model: Kinnos Highlight for Liquid Bleach[1]

Health problem addressed

Less than 50% of critical surfaces in healthcare settings are adequately disinfected due to human error and poor training. Contaminated surfaces lead to 5-6x higher risk of getting an infection, and the threat of healthcare-associated infections (HAIs) is several-fold higher in low-resource settings compared to high-income countries. Although COVID-19 is thought to be primarily transmitted through the air, surface disinfection plays an important role in preventing HAIs as a complicating factor.[1]

Product description

The product is a colorized bleach additive in the form of blue powder that improves visibility and coverage of sprayed areas. It enables real-time visual colorization so healthcare workers can see exactly what surfaces they have covered to eliminate guesswork from the disinfection process. The color automatically fades away to colorless after a few minutes to prevent staining. Peer-reviewed studies have demonstrated quantifiable improvements in disinfection technique and that the additive is safe to use.[2]

Product details

Lifetime: Single use[1]

Contact: Jason King | Email: jason@kinnos.us | Website: https://bit.ly/3agSxXs

1 Reported by manufacturer on 27 November 2020
2 Reported by manufacturer on 25 January 2021

WHO ASSESSMENT

WHO specification comparison

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

Regulatory assessment

Regulatory and quality system assessment

Proceed — No regulatory or quality system objections.

Technology evidence assessment

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

This substance reduces the use of toxic (chlorine based) material. The product helps inform citizens about how to correctly use disinfection materials, thus reducing contamination and improving safety. It is an additive and therefore does not require extra infrastructure. It can be handled by trained people.

Summary

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

Health technology and engineering management

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

Target setting: Public and home settings

The purpose of this product is to aid in infection prevention. It uses a patented colorized bleach additive that combines with standard bleach and thus enables real-time visualization of surfaces where the disinfectant was already applied. The user combines the color additive to the bleach and chlorine disinfectant. The product has a shelf life of up to 2 years and does not require any additional resources. The manufacturer provided study outcomes demonstrating that surface coverage is improved. However, there is no evidence that cleaning efficiency improves when using the product.

Deployable facility, for emergencies, shipping container based

Country of origin | United States of America
Primary function | Treatment
Category | Other technology

Commercial information

List price (USD): $195k-485k based on the type of unit (pharmacy vs. clinic vs. isolation clinic vs BSL 3 lab) and add-ons such as vaccine freezers, hardware/software for telemedicine, negative pressure rooms, etc.[1]
Year of commercialization: 2020[2]
Number of units distributed: 0-100[2]
Currently marketed in: Globally[2]
Brand: Xploration Health Solutions, LLC (a spin off company from Baylor College of Medicine)[3]
Model: Emergency SmartPod[3]

Health problem addressed

The technology addresses care provision during natural disasters and outbreaks as well as the provision of care in under-resourced and difficult-to-reach geographies. It is designed to provide a nimble and flexible healthcare solution that is dual purpose: day-to-day community-based care with easy and rapid deployability during natural disasters, outbreaks or emergencies. The technology addresses all health problems, including respiratory pathogens (COVID-19), Ebola, mental health, primary care, and other non-communicable diseases.[4]

Product description

The SmartPod is an ISO standard 8 X 20 container with aluminum panels and a steel frame that expands manually (< 4 people, < 20 minutes) into a 400 SF facility. It can be transported by train, truck, helicopter, ship or plane and is designed for use in conditions where the ground is uneven, power or water may be off grid and wind/weather conditions are adverse (withstands winds up to 116 MPH). The units come equipped with GPS tracking and hardware/software for connectivity as well as training apps.[3]

Product details

Accessories: Generator and Water Tank (if there is no power supply or running water in the community)[3]
Warranty duration: 1 year[3]
Lifetime: 15-20 years[3]
Energy requirements: Continuous power supply, solar power[3]
Facility requirements: Clean water supply, Healthcare waste disposal facilities[3]

Contact: Brodus A.Franklin | Email: Brodus.Franklin@bcm.edu | Telephone: +001 281 788-5985 | Website: https://bit.ly/3iwXRK0

1 Reported by manufacturer on 4 January 2021
2 Reported by manufacturer on 13 January 2021
3 Reported by manufacturer on 25 November 2020
4 Reported by manufacturer on 20 January 2021

WHO ASSESSMENT

WHO specification comparison

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

Regulatory assessment

Regulatory and quality system assessment

Proceed — No regulatory or quality system objections.

Technology evidence assessment

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

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

Summary

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

Health technology and engineering management

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

Target setting: Public and home settings

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

e-voucher, vaccination management

Country of origin | Japan
Primary function | Electronic health/medical records
Category | eHealth/mHealth solution

Commercial information

List price (USD): Initial cost of $400,000-$600,000 and recurring cost of $500,000-$600,000 per year. Initial and recurring costs depend on the number of beneficiaries, outlets, and registrars.[1]

Year of commercialization: 2015[1]

Number of units distributed: 56,000 IC cards have been distributed by 90 outlets and registrars[1]

Currently marketed In: Angola, Ethiopia, Lesotho, Madagascar, Malawi, Mozambique, Rwanda, Senegal, Tanzania, Uganda, Zambia, Zimbabwe, Ivory Coast, Eswatini, Ghana, Kenya, Nigeria, Botswana, Gabon, Mauritius, Namibia, South Africa[1]

Brand: NEC Corporation[2]

Health problem addressed

The technology can be used by patients, hospitals and clinics, pharmacies, and vaccine management authorities (Ministry of Health) to support vaccination and prevention efforts for COVID-19 and other infectious diseases.[1]

Product description

The technology is a Cloud service system with a Front-end to Back-end, End to End solution that can be used Online and Offline. It enables hospitals and clinics to track the beneficiary's enrollment, identification (face recognition, PIN or other options), new vaccine registration, and past vaccination records with an IC card that is given to the beneficiary. The beneficiary can use the system to purchase sanitation items, such as masks and hand sanitizer, from pharmacies by e-voucher. The vaccine management authority (Ministry of Health) can monitor and analyze transaction records as well as register and manage products sold by pharmacies with e-voucher. API enables integration with other IT systems subject to technical clarification and requirements.[1]

Product details

Other required products: For beneficiary: IC card; For the registrar and outlet: A Tablet PC or Smartphone (Android OS, NFC interface) and External IC card reader/writer if NFC interface Tablet PC is not available; For the vaccine management authority (Ministry of Health): PC accessible to internet.[1]

Lifetime: 20+ years[2]

Energy requirements: Rechargeable battery (AC powered, 110V/220V, 10W, 24-hour battery life, 1-hour battery recharge cycle)[2]

Facility requirements: Access to internet, access to cellular phone network[2]

Contact: Miyawaki Kazuhiko | Email: kmiyawaki@nec.com | Telephone: +81-80-1338-4967 | Website: https://bit.ly/2Z0D2O6

1 Reported by manufacturer on 05 February 2021
2 Reported by manufacturer on 22 June 2020

WHO ASSESSMENT

WHO specification comparison

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

Regulatory assessment

Regulatory and quality system assessment — Proceed — No regulatory or quality system objections.

Technology evidence assessment

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

The system is based on RFID cards and a cloud-based system. It can be used without internet for a specific situation, but is in need of regular updates as otherwise the data are too old. The system is not compatible with existing systems and requires a specific new card. There is no clear solution on how data are protected on the local settings after downloading information. Within the cloud general cyber security standards are mentioned. Regarding the offered evidence the actual system could not be recommended for LMICs.

Summary

Transferability	✕	Technology readiness level	9
Evidence (according to GRADE)	!	Technology evidence assessment	Not recommended

Health technology and engineering management

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

Target setting: Healthcare systems

This product is an electronic health/ medical records operating system application for the management of vaccine distribution and related population records secured archiving. The system is intended to be used with delivery of oxygen treatment to persons. The system is an internet based proprietary software application supported by cloud computing and uses face recognition algorithm to identify patients and accept transactions. The system requires access to the internet and/or cellular phone network.
The product can be compared with other similar systems currently being used. One of our senior clinical engineering reviewers who went through the process of receiving the COVID-19 vaccination commented that the face recognition feature on a different program was disabled due to the use of face masks that curtailed the application. In addition, the benefits-to-investment ratio is not clear as the upfront costs and the on-going subscription and support costs are significant, and no data of benefits was presented.
Our reviewer, with digital health experience in South America, noted concerns with cyber security and card privacy issues as well as impact of individual smart phone loss or stolen.

Heart rate meter, for newborn

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

Commercial information

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

Health problem addressed

An estimated 10 million newborns are born every year that are not breathing and require resuscitation. Due to insufficient oxygenation of the newborn, 0.7 million newborns died and 1.15 million newborns suffered permanent brain injury. To address this issue, there is a need for immediate provision of newborn's heart rate to support health care workers in performing effective ventilations, by application of a reusable ECG heart rate meter onto the wet newborn's chest and quick continuous display of the newborn's ECG heartrate.[2]

Product description

ECG signals from newborn's wet chest are picked up by dry stainless-steel electrodes that are embedded in one spring-elastic plastic buckle. A housing includes a rechargeable battery, signals processor, and a bright-LED display.[1]

Product details

Accessories: USB 5V power supply (charger), AC plug kit to fit various global electrical systems[3]
Warranty duration: 1 year[1]
Lifetime: 2-5 years[1]
Energy requirements: Continuous power supply (AC powered, 110V/220V, 5W)[1]
Facility requirements: Disinfection with 70% ethanols[1]

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

1. Reported by manufacturer on 26 November 2020
2. Reported by manufacturer on 11 January 2021
3. Reported by manufacturer on 16 December 2020

WHO ASSESSMENT

WHO specification comparison

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

Regulatory assessment

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

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

Technology evidence assessment

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

This portable device is clinically useful for timely monitoring of critical newborns that require resuscitation. There is no need for extra workers other than the health care personnel resuscitating the newborn. The device is battery-powered, simple, and easy to use. Decontamination is necessary after each use. The manufacturer provides the device to low-resource settings at a subsidized cost. Spare parts can be procured through the manufacturer's website. Additional safety and regulation documentation is needed and further clarity is required for labeling.

Summary

Transferability	→	Technology readiness level	8
Evidence (according to GRADE)	⚠	Technology evidence assessment	Recommended with caution

Health technology and engineering management

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

Target setting: Neonatal ICU

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

Infrared thermography camera

Country of origin | Japan
Primary function | Prevention
Category | Other technology

Commercial information

List price (USD): $15,000[1]
Year of commercialization: 2015[1]
Number of units distributed: 1,001-10,000[1]
Currently marketed in: Ivory Coast, Senegal, Burkina Faso, Liberia, Ghana, Nigeria, Cape Verde, Guinea, Guinea Bissau, Sierra Leone, Gambia, Gabon, DRC, Zambia, Ethiopia, Uganda, Botswana, Mexico, South Korea.[2]
Brand: Nippon Avionics Co., Ltd[1]
Model: R450-D[1]

Health problem addressed

The technology is a countermeasure against Ebola hemorrhagic fever at border posts in African countries.[3]

Product description

The technology detects infrared energy from a radiating object surface and indicates 2D temperature distribution. The infrared thermographs are installed in locations such as international airports and border checkpoints to measure the body surface temperatures of many individuals at once without making physical contact. The technology is used to screen feverish individuals.[3]

Product details

Accessories: Rechargeable lithium ion battery[3]
Warranty duration: 3 years[1]
Lifetime: 5-10 years[1]
Energy requirements: Rechargeable battery (AC powered, 110V/220V, 2.5-hour battery life)[1]

Contact: Name: Yosuke Koide | Email: ykoide@nec.com | Telephone: +81 8088794584 | Website: https://bit.ly/354yMkj

1 Reported by manufacturer on 2 June 2020
2 Reported by manufacturer on 9 December 2020
3 Reported by manufacturer on 12 January 2020

WHO ASSESSMENT

WHO specification comparison

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

Regulatory assessment

Pre-market assessment	Do not proceed
Post-market assessment	Do not proceed
Quality system assessment	Do not proceed

Nippon states that this product is not medical equipment. However, by their own admission in their response to WHO's request for additional information, this product meets the definition of a medical device. Adequate documentation was not provided by Nippon to perform a medical device regulatory or quality system review. Additionally, Nippon did not provide performance data per the internationally recognized standard IEC 80601-2-59 Edition 2.0 2017-09 Medical electrical equipment - Part 2-59: Particular requirements for the basic safety and essential performance of screening thermographs for human febrile temperature screening. Nippon should provide the regulatory and quality system documents requested in order for them to be included in a procurement process. Nippon must also ensure they comply with local country import and pre-market regulations.

Technology evidence assessment

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

This device is used to detect high body temperature. It is easy to set up and use in various environments. There are grants offered for some low- and middle-income countries through which maintenance can be provided locally. There is no indication that using thermography to screen for diseases in public areas is beneficial. In fact, the use of such technologies only raises awareness. The technology presents organizational challenges because personnel are expected to perform the scanning and manage detected individuals. It is not a medical device with a proven benefit.

Summary

Transferability	→	Technology readiness level	8
Evidence (according to GRADE)	⚠	Technology evidence assessment	Recommended with caution

Health technology and engineering management

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

Target setting: Screening tool at public and clinical sites

This product is a high body temperature screening tool for COVID-19 infected persons. It is a portable camera based on infrared sensor technology and a software processing application. The manufacturer proposes that the camera can be used to assist with identifying persons at border posts suspected of having high body temperature. It uses an AC adaptor or battery as an energy source and can support up to 2.5 hours of operation on a single battery charge. The required rechargeable battery is readily available. Maintenance for the device is offered with an additional cost. The product must be returned to the manufacturing for servicing during the 3 years warranty period. The camera costs $15,000 USD which may be challenging for low-resource locations. Access to local operator training is also limited.

MP3 radio, solar, wind-up powered

Country of origin | United Kingdom
Primary function | Communication, safety, training
Category | Other technology

Commercial information

List price (USD): $44.94[1]
Year of commercialization: 2013[2]
Number of units distributed: 50,000+[1]
Currently marketed in: Globally[1]
Brand: Freeplay Energy[1]
Model: Encore Player MP3[1]

Health problem addressed

The radio provides communities in harsh, off-grid environments with access to information live via radio, recorded from voice or radio, and downloaded information onto SD card. 34,000 units were shipped to schools and communities during the Ebola crisis broadcasts so that children could continue learning whilst schools were closed and families could stay informed with vital health updates. Content can be stored on any subject or language. Community listening clubs facilitate dialogue for individuals and groups and have proved to be an efficient way for rural and isolated communities to access information and engage in group communication, which leads to action. The radio is used in both UNFPA and FAO programs.[2]

Product description

The radio is used by both small and larger groups of people. It features a mobile phone charger which will fully charge a mobile phone. For reading or close work after dark, there is a bright task light. The radio delivers over 24 hours of playtime from a full charge and is powered by a solar panel backed up by a patented fail-safe winding mechanism to ensure that even in times of extended bad weather power is always available.[1]

Product details

Warranty duration: 2 years[1]
Lifetime: 5-10 years[1]
Energy requirements: Mechanical energy, rechargeable battery, continuous power supply, solar power (DC powered, 5V USB, 1W, 30-hour battery life, 10-hour battery recharge cycle, 5-hour solar recharge cycle)[1]

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1 Reported by manufacturer on 2 June 2020
2 Reported by manufacturer on 28 January 2021

WHO ASSESSMENT

WHO specification comparison

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

Regulatory assessment

Regulatory and quality system assessment — Proceed — No regulatory or quality system objections.

Technology evidence assessment

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

The device can be used within Public Health interventions to inform people also in rural areas with low need on electricity.

Summary

Transferability	✕	Technology readiness level	9
Evidence (according to GRADE)	⚠	Technology evidence assessment	Recommended with caution

Health technology and engineering management

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

Target setting: Public and home settings

This product is a radio "designed for use in harsh, off-grid environments. Freeplay Energy has a Long-Term Arrangement with UNICEF for the supply of three solar radios including Encore Player. Freeplay shipped 34,000 Encore Player radios during the Ebola crisis providing schools and communities with access to information live via radio, recorded from voice or radio and downloaded information onto SD card. Both UNFPA and FAO piggy-back onto the LTA so that they can use the radios in their programs. The radio is used by both small and larger groups of people. It features a mobile phone charger which will fully charge a mobile phone. For reading or close work after dark, there is a bright task light. The radio delivers over 24 hours of playtime from a full charge and is powered by a solar panel backed up by a patented fail-safe winding mechanism to ensure that even in times of extended bad weather power is always available." The connection to accessories such as external solar panel, external battery, and the player functionality dependence on the insertion of an SD card present a challenge over time for use in inclement environment conditions. The capacity to sustain listeners' attention to education sessions is limited in time duration due to product's ability to deploy only audio presentation.

COMMERCIALLY AVAILABLE | 2021

Oxygen generation plant, deployable

Country of origin | United States of America
Primary function | Supporting or sustaining life
Category | Oxygen system

Commercial information

List price (USD): $163,800[1]
Price of consumables per use (USD): $2,357List price (USD): $10,000
Year of commercialization: 1984List price (USD): $10,000
Number of units distributed: 101-1,000List price (USD): $10,000
Currently marketed in: GloballyList price (USD): $10,000
Brand: Pacific Consolidated Industries - PCI GasesList price (USD): $10,000
Model: DOCS 80 / 200 / 500List price (USD): $10,000

Health problem addressed

In developed countries with fully functional infrastructure, medical oxygen is often supplied as liquid or in cylinders. In most LMICs this is either unreliable or impossible. The alternatives are on-site oxygen generation plants (OGP) requiring only power and ambient air to secure medical oxygen supply.[2]

Product description

The technology utilizes state-of-the-art Vacuum Swing Adsorption (VSA) technology. These systems secure an uninterrupted supply of life saving medical oxygen to patients abrogating the need for unreliable cylinder logistics. The technology is recognized as a reliable, secure, low maintenance source of on-site medical oxygen.[1]

Product details

Consumables: Annual change of filter[1]
Warranty duration: 3 years[1]
Lifetime: 15-20 years[1]
Energy requirements: Continuous power supply (AC powered, 220V/380V, 18,000W)[1]

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1 Reported by manufacturer on 21 May 2020
2 Reported by manufacturer on 29 January 2021

WHO ASSESSMENT

WHO specification comparison

WHO technical Specifications are available for PSA plants but not for VSA plants. For this reason, there are few applicable WHO specifications for this product because an air compressor and air receiver tank are not needed. The oxygen production process for VSA plants is different than PSA plants.

Compliant: The manufacturer claims that their product eliminates the need for process valves, feed air compressors, and associated dryers and feed air filtering systems. By removing these components, the lifetime of the parts and mechanism could be extended and less energy consumption may be required. The manufacturer offers a 10-year warranty. The manufacturer also states that VSA plants are not as susceptible to humid environments as PSA plants.

Some aspects that couldnt be verified: Some aspects could not be verified including accessories such as PSA O2, alarms, the control panel, and software and firmware property rights.

Regulatory assessment

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

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

Technology evidence assessment

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

The system facilitates O2 delivery in rural areas with minimal effort. It requires electricity.

Summary

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

Health technology and engineering management

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

Target setting: Hospitals

This product utilizes Vacuum Swing Adsorption (VSA) technology for a deployable oxygen concentration system. The product provides an uninterrupted supply of medical oxygen to patients. It is considered to be easier to use and more robust in contrast to similar technologies used in extreme weather conditions such as high humidity and poor air quality. Its plug and play features are advantageous for installation. The maintenance support and replacement parts required over the product's lifetime are reasonable. Product limitations include maximum oxygen flow requirements and a high demand of electrical power.

Oxygen, portable rebreathing

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

Commercial information

List price (USD): $2,640[1]
Price of consumables per use (USD): $66List price (USD): $10,000
Year of commercialization: 2020List price (USD): $10,000
Number of units distributed: 0-100List price (USD): $10,000
Currently marketed in: Europe, Africa, Asia/Pacific[2]
Brand: Mirola Rescue ABList price (USD): $10,000
Model: FIDOList price (USD): $10,000

Health problem addressed

More than 95% of COVID-19 patients do not require a ventilator with continuous monitoring, in which cases, patients need low consumption of O2 combined with warm moist inhalation air.[2]

Product description

FIDO delivers 50% oxygen level in default mode and can go up to 89% oxygen level. This should be compared with free-flowing oxygen systems that deliver 72% oxygen level at best. FIDO increases the oxygen level mechanically if the treated person consumes higher levels of oxygen. It generates warm return air to the patient of about 33 degrees Celsius and <95% humidity. Patients can use the device by themselves.[2]

Product details

Accessories: A breathing mask, a bio-filter and an oxygen bottle[1]
Consumables: Oxygen[1]
Warranty duration: 1 year[1]
Lifetime: 15-20 years[1]

Contact: Christophe Galan | Email: christophe.galan@mirola.se | Telephone: +44 7969 100 942 | Website: https://bit.ly/3rAT0M2

1 Reported by manufacturer on 06 May 2020
2 Reported by manufacturer on 11 January 2021

WHO ASSESSMENT

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	Proceed with caution
Quality system assessment	Proceed with caution

Some requested information and documentation for all three Regulatory and Quality Assessment categories is absent. Therefore, a thorough review of this product was not possible at this time. At the time of this report creation, Mirola has obtained an EU MDD CE Mark for the Rescue AB FIDO Rebreathing System. The regulatory status for the various accessories is currently unclear. Mirola has obtained an ISO 13485:2016 certificate. Mirola must also ensure they comply with local country import and pre-market regulations.

Technology evidence assessment

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

As a portable rebreathing device, FIDO claims to be clinically useful as a transportation device. According to the manufacturer, it is easy to use in field settings. The manufacturer declares that the device must be maintained annually in the production facility. As a result, due to the long return transport to Sweden, large transport costs are to be expected. In addition, the acquisition costs seem very high for low resource settings. The CO2 cartridges, the oxygen mask, and the biofilters have to be considered also as consumables per case.

Summary

Transferability	✗	Technology readiness level	8
Evidence (according to GRADE)	⚠	Technology evidence assessment	Recommended with caution

Health technology and engineering management

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

Target setting: Patient transport

This product is a portable rebreathing system for delivering oxygen treatment to patients in transit (up to one hour). The mechanical system contains a patented mixing valve where rebreathed air mixes with oxygen after passing through a soda lime absorbing cartridge that is connected to a collection bag and oxygen feed from a tank. The mixing occurs prior to delivering treatment through bio filters and a breathing mask. The oxygen tank supply attaches to the patented mixing valve through a pressure regulator and can be adjusted. A manometer indicator provides the user with oxygen supply pressure measurements. The product is comparable to other systems, with the key advantage of enabling efficient consumption of oxygen resources. An oxygen flash button activates a momentary increase in oxygen delivery. The mask must be properly fitted to the patient in order for the system to be effective. Product cleaning is simple process, however there is not sufficient instruction about use with COVID-19 patients. Servicing and proprietary spare parts are only available from the vendor in Sweden.

Respiratory monitoring system, portable

Country of origin | United States of America
Primary function | Monitoring
Category | Medical device

Commercial information

List price (USD): $12,000[1]
Price of consumables per use (USD): $47[1]
Year of commercialization: 2020[1]
Number of units distributed: 0-100[1]
Currently marketed in: United States, Canada[2]
Brand: MediPines Corporation[List price (USD): $15,000]
Model: AGM100[List price (USD): $15,000]

Health problem addressed

This technology instantly detects changes in pulmonary gas exchange in disease states such as COPD, pneumonia, influenza, and Acute Respiratory Distress Syndrome (ARDS), caused by COVID-19. As a result, premature mortality from respiratory disease can be prevented. Its intended use is for any patient aged 18+ suffering from respiratory distress. WHO states that 3.17 million deaths were caused by just COPD alone in 2016, while 34+ million people are infected by COVID-19 globally in 2020.[1]

Product description

The device samples a patient's normal breathing in a 2-minute test (which is performed through provided breathing circuits) while wearing a pulse oximeter. With the SpO^2 value and end-tidal breath sampling, the oxygen dissociation curve is calculated in conjunction with the Bohr effect. The device then outputs clinically valuable, numerical measurements including PaO^2, $PETCO^2$, O^2 deficit (A-a gradient equivalent), and more in real time.[1]

Product details

Accessories: SpO^2 sensor[1]
Consumables: Single patient use breathing circuit kit, nose clip[1]
Warranty duration: 1 year[1]
Lifetime: 0-2 years[1]
Energy requirements: Rechargeable battery, continuous power supply (AC powered, 120V/240V, 15W, 2-hour battery life, 4-hour battery recharge cycle)[1]
Facility requirements: Specific temperature and/or humidity range

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1 Reported by manufacturer on 13 October 2020
2 Reported by manufacturer on 8 January 2020

WHO ASSESSMENT

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
Post-market assessment	Proceed
Quality system assessment	Proceed

Adequate documentation was provided to perform a medical device regulatory and quality system review but there are some deficiencies noted in the review. At the time of this report creation, MediPines has obtained US FDA 510(k) clearance (K180902) and Health Canada Medical Device COVID-19 Authorization (IO313459) for the AGM100. The regulatory status for the various accessories was provided. MediPines has a MDSAP ISO 13485:2016 certificate. MediPines must also ensure they comply with local country import and pre-market regulations.

Technology evidence assessment

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

The monitor is useful for various tests and can be quickly moved to different locations for testing. The costs are high. Due to vague manufacturing and maintenance description, transferability is low.

Summary

Transferability	✕	Technology readiness level	9
Evidence (according to GRADE)	⚠	Technology evidence assessment	Recommended with caution

Health technology and engineering management

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

Target setting: Health care facilities

This product detects changes in pulmonary gas exchange in disease states such as COPD and ARDS caused by COVID19. It uses a disposable breathing circuit to sample patient end-tidal breath. Using the oxygen disassociation curve, the product software calculates numerical measurements such as PaO^2, $PetCO^2$, and O^2 deficit that are clinically valuable. Testing involves about 2 minutes of patient breathing through mouthpiece tubing along with the use of a pulse oximeter and blocking nose clip. The use of proprietary software limits local support. The product operates on an internal battery and is portable. The product requires consumables such as SpO^2 sensors and the vendor's single patient breathing circuit and nose clip. The vendor estimated shelf life is 2 years and carries 1-year warranty. The product costs $12,000 USD and an additional $47 per use which may limit the benefit of its use in low-resource settings.

Solar-powered oxygen concentrator

Country of origin | Canada
Primary function | Treatment
Category | Oxygen system

Commercial information

List price (USD): $10,000[1]
Year of commercialization: 2020[1]
Number of units distributed: 0-100[1]
Currently marketed in: Uganda, Somalia, DRC, Kenya[2]
Brand: DeVilbiss[3]
Model: 525DS[3]

Health problem addressed

Pneumonia is the leading cause of childhood mortality worldwide with over 900,000 deaths annually. Most of these deaths are concentrated in low-resource countries in Africa and Asia where reliable access to oxygen is limited. The WHO has added oxygen to its Model List of Essential Medicines, given its importance in treating pneumonia and other hypoxemic diseases such as COVID-19. Studies have demonstrated that reliable access to oxygen can reduce deaths due to pneumonia in children by up to 35%.[1]

Product description

The technology is a solar-powered oxygen system to address limited access to oxygen in LMICs. These systems consist of a commercially available oxygen concentrator, connected through a charge controller to a battery bank and solar panels, producing medical grade oxygen without access to the power grid. The system can be designed to draw power from the grid when available and switch to solar/battery power during outages, or to draw solar/battery power only.[1]

Product details

Accessories: Pulse oximeter[1]
Consumables: Filters/sieve beds[1]
Lifetime: 5-10 years[1]
Energy requirements: Rechargeable battery, solar power (AC powered, voltage can be adapted, 400W, 72-hour battery life)[1]

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1 Reported by manufacturer on 28 August 2020
2 Reported by manufacturer on 8 December 2020
3 Reported by manufacturer on 18 January 2021

WHO ASSESSMENT

WHO specification comparison

The oxygen concentrator used in this oxygen system partially complies with the WHO technical specifications.

Compliant: The oxygen concentrator in the system is designed for the same intended use as other concentrators.

Some aspect that could not be verified: Some aspects that could not be verified such as power efficiency and EMC compliance for TUV 50 Hz and 1500-400 M at 230 V. The batteries proposed for the system are valve-regulated stationary lead-acid batteries. From a technical perspective, sealed gel or lithium batteries are preferred in an oxygen rich environment. This is a good concentrator; however, it is expensive and spare parts are not available everywhere as specified by the manufacturer.

Regulatory assessment

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

Some requested information and documentation for all three Regulatory and Quality Assessment categories is absent. Therefore, a thorough review of this product was not possible at this time. At the time of report creation, DeVilbiss has obtained an EU MDD CE Mark and US FDA 510(k) clearance. The regulatory status for the various accessories is currently unclear. DeVilbiss has obtained an ISO 13485:2016 certificate. DeVilbiss concentrator with extra solar power system must also ensure they comply with local country import and pre-market regulations.

Technology evidence assessment

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

This solar powered oxygen system provides reliable and sustainable access to oxygen. Components are commercially available. The system and its associated components are tailored to the unique needs of a health facility. The solar charging speed and backup battery supply varies based on the panels and batteries used and the number of sunlight hours at a given location. Tests are being performed to evaluate the system's clinical benefit in treating pediatric pneumonia. Clinical training and supervision are provided to ensure effective implementation.

Summary

Transferability	→	Technology readiness level	8
Evidence (according to GRADE)	⚠	Technology evidence assessment	Recommended with caution

Health technology and engineering management

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

Target setting: Clinics and secondary hospitals

This product is intended for delivering oxygen therapy and managing hypoxia in young patients. The system consists of an oxygen concentrator powered by a solar energy system. The solar energy system stores excess energy collected during the daytime that can be used to operate the device at night or during power outages. The system delivers between 1-5 LPM of oxygen captured from the surrounding air, which is then subjected to filtration and sieve pads within the concentrator. As a result, the nitrogen is absorbed thereby increasing the concentration of the oxygen delivered via a cannula or face mask. The oxygen concentrators are two models manufactured by DeVilbiss Healthcare. There are 10 years of established post market data for these models. The product is similar to other similar oxygen concentrator systems with the added advantage of being energized by solar power. The solar panels must be installed in an area with sun exposure and connected to the inside of the facility with electrical wires. Batteries must be installed within the facility to collect the excess power. There is significant installation and system costs of about $10,000 USD per unit. Semi-annual maintenance by a technician is required in order to inspect and replace panel and battery parts and components within the concentrator.

Tele-education, for COVID-19

Country of origin | United States of America
Primary function | Provider training & education
Category | ehealth/mHealth solution

Commercial information

List price (USD): Product $0; Service: $22,000/course[1]
Year of commercialization: 2020[2]
Number of units distributed: 101-1,000
Currently marketed in: Global. Current program is has participants from 128 countries.
List price (USD): $10,000
Brand: Assist International
Model: Tele-Education Platform (using the Project ECHO model)[2]

Health problem addressed

Few providers in low- and middle- income countries (LMICs) are trained in critical care medicine, and there is a dearth of training opportunities that are appropriately tailored to healthcare providers working in low-resource settings. This has proven a challenge historically, now amplified during the COVID-19 pandemic. As COVID-19 cases surge globally, and the ability to facilitate in-person education remains limited, novel tele-mentoring programs are needed. Thus, a unique partnership has been developed to create and facilitate a virtual clinical and technical education program, with a curriculum that is tailored to the unique constraints of low-resource settings and supports healthcare workers to provide safe and effective lifesaving care to patients in need.[1]

Product description

The technology is a mentoring model that uses videoconferencing (e.g. Zoom), an online course platform (e.g. the Learning Resource Center), and social media (e.g. WhatsApp) to connect experts to clinicians and healthcare workers at low-resource health facilities in the Global South. Our COVID-19 Tele-Education programming includes series on: (i) clinical best practices for providing oxygen therapy and critical care medicine; and (ii) health technology management (e.g. maintenance and repair of key equipment used in critical care). Sessions include live interpretation in multiple languages selected according to participant demand.[1]

Product details

Lifetime: 0-2 years[2]
Energy requirements: Anyone with access to a smartphone, tablet or laptop with an internet connection can access the COVID-19 Tele-Education series. Thus, energy is required in the sense that the devices used to access our series will require some form of battery/power supply.[2]
Facility requirements: Access to internet, access to a cellular phone network, connection to a laptop/computer.[2]

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1 Reported by manufacturer on 7 February 2021
2 Reported by manufacturer on 5 June 2020

WHO ASSESSMENT

WHO specification comparison

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

Regulatory assessment

Regulatory and quality system assessment

Proceed — No regulatory or quality system objections.

Technology evidence assessment

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

The training platform can be used without physical connection. The content can be adapted to local needs and regional development. It can be used as an input for training people adjusted to their requirements. Hence, the tool can help to increase knowledge. The tool is not COVID specific and data on patient related outcome, quality assurance are missing.

Summary

Transferability	→	Technology readiness level	8
Evidence (according to GRADE)	⚠	Technology evidence assessment	Recommended with caution

Health technology and engineering management

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

Target setting: Healthcare providers

This product is an educational platform that uses video conferencing to connect experts world-wide to clinicians and healthcare workers at low resource health facilities. It includes clinical best practices, oxygen therapy, and health technology management. The educational sessions are provided with interpretation in several languages with the vendor stating that Spanish and Portuguese are coming. Participation requires registration on-line and the session includes didactic lecture, video demonstration, and facilitation of a Q&A period. The application focus on COVID19-related technological subjects is given priority on this product. Participants are able to join the application via laptop, tablet, or SmartPhone with an Internet connection. We could not find quality control or freedom from commercial promotion in the tele-education content. The participant cost and minimal technological requirements from servicing and training facilitates wide use of this product.

Ventilator, for low oxygen inlet pressure

Country of origin | Viet Nam
Primary function | Supporting or sustaining life
Category | Medical device

Commercial information

List price (USD): $4,500[1]
Price of consumables per use (USD): $10[1]
Number of units distributed: 0-100[2]
Currently marketed in: All countries that recognize and accept CE Mark and do not have their own regulatory requirements.[2]
Brand: Impala[1]
Model: V1[1]

Health problem addressed

The principal indications for technology are airway protection and respiratory failure. A compromised airway, or an airway at risk of compromise, may be identified by physical examination and ancillary testing. The technology is indicated for use with a wide range of patients such as acute lung injury, apnea, acute respiratory acidosis, hypoxemia, COPD, hypotension including sepsis, shock, congestive heart failure, and neurological diseases, requiring respiratory support for a wide range of clinical conditions in hospital, hospital type facilities.[2]

Product description

The technology is an intensive-care ventilator that provides continuous or intermittent positive pressure ventilation for the care of individuals who require mechanical ventilation. The device contains a built-in pump to generate positive end-expiratory pressure (PEEP) and Peak Inspiratory Pressure (PIP) without necessity of any external air sources. An integrated blender and oxygen monitoring function also allows oxygen-rich (>21% O^2) air with accurate fraction of inspired oxygen (FiO^2) to be safely delivered to the patient. It may be used for both invasive and non-invasive ventilation.[2]

Product details

Accessories: Control unit with 12V adaptor, reusable breathing circuit, single use HME-HEPA filter, silicon masks, oxygen hose, oxygen hose connector, stand, AC cord, and user manual[3]
Consumables: Nasal masks[1]
Warranty duration: 1 year[2]
Lifetime: 5-10 years[1]
Energy requirements: Rechargeable battery, continuous power supply, solar power (AC powered, 110V/220V, 60W, 3-hour battery life, 1-hour battery recharge cycle, 3-hour solar recharge cycle)[1]

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1 Reported by manufacturer on 5 June 2020
2 Reported by manufacturer on 10 January 2021
3 Reported by manufacturer on 23 December 2020

WHO ASSESSMENT

WHO specification comparison

This device partially complies with the WHO technical specifications for intensive care ventilators.
Compliant: The device allows for use of an external low-pressure oxygen (approx. 20 psi) source. The user manual states that "the gas sources must provide pressure within the range of 10 to 60 psi (0.7 to 4.1 bar)". If the gas sources are outside of this range, the device may not be able to produce the desired $\%FiO^2$. However, the oxygen inlet for all pressure ranges is CGA 1240.
Non-compliant: The device does not comply with the WHO specifications for operating temperature and humidity. While the WHO specifications state that the required operating temperature is 5–40 °C and the required humidity range is 0–95% relative humidity (RH), the manufacturer states that this device can only operate between 19°C to 37°C and 30%RH to 90%RH. There is no apnea alarm explicitly specified and the gas supply failure and power failure alarms are indirect. Overall, the alarms should be revised. The inspiratory pressure setting starts at 5 cmH2O instead of 0cmH20 as required. The continuous battery-operating mode is 3 hours instead of the requested 4 hours.
Some aspects of the device could not be verified such as the means for limiting reverse gas flowrate (leakage), the filter and water trap filter for input post, and the mechanical safety valve. The inspiratory pause maneuver capability to measure plateau pressure could also not be verified. It is unclear if there is an adjustable peak pressure limitation/pressure-cycling mechanism above measured peak pressure. Additional unverifiable features include the I: E inverse ratio, loop (axis) displays, display of minute volume (expired), occlusion pressure detection, and spontaneous ventilation.

Regulatory assessment

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

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

Technology evidence assessment

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

The system may be used for a limited time during transport for controlled breathing scenarios (up to 3h). The cost is comparable to similar devices. Maintenance must be performed by trained personnel such as a technician or nurse. Use of the device on COVID patients may be restricted due to potential additional risk.

Summary

Transferability	→	Technology readiness level	8
Evidence (according to GRADE)	!	Technology evidence assessment	Recommended with caution

Health technology and engineering management

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

Target setting: ICUs and patient transport

This product is indicated for continuous or intermittent mechanical ventilation support of patients weighing at least 5 Kg as prescribed by the attending physician. The device can operate on AC power or by a 6x rechargeable battery source when a continuous power supply is not available, such as during a power outage. A fully charged battery can support up to 3 hours of operation and the battery can be recharged within 1 hour. A software provides several operation modes as well as troubleshooting for the user. Parameter tolerances of +/- 10% may be questionable for small patients. The manufacturer states that a trained technician is required to perform maintenance and repairs. The recommended servicing frequency is between 6-12 months. The air filter needs to be cleaned or replaced every 6 months and the oxygen sensor needs to be replaced every 12-18 months. The listed price of $4,500 USD plus $10 USD per use is reasonable. There are concerns regarding the availability of local access to sales and technical support, but it is possible this type of support may improve as the company grows.

Ventilator, mechanical, pressure control

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

Commercial information

List price (USD): $6,000[1]
Price of Accessories Per Unit: $600[1]
Price of Consumables Per Use (USD): $60[1]
Year of Commercialization: 2020[2]
Number of Units Distributed: 101-1,000[1]
Currently Marketed In: Canada, United States[1]
Brand: Mechanical Ventilator Milano (MVM)[1]
Model: Basic-0010[1]

Health problem addressed

The large number of people affected by SARS-CoV-2 created an urgent demand for ventilators on a global scale. The demand exceeds the capacity of existing supply chains, especially in some regions where cross-border supply has been disrupted. This need motivated the development of a reliable, fail-safe, and easy to operate mechanical ventilator that can be quickly produced at a large scale with readily available parts.[2]

Product description

The electronically-controlled mechanical ventilator can be operated in two modes: pressure controlled ventilation (PCV) and pressure support ventilation (PSV). The system connects directly to a line of pressurized medical oxygen or medical air, and relies on regulation of the flow to deliver gas to the patient at a pressure in the range suitable for treatment. Pressure regulation of the end-expiratory cycle is achieved by discharging the expiratory flow through a valve to set the desired PEEP.[1]

Product details

Accessories: Gas blender, gas blender hoses, catheter mount, power supply, reducing adapter, device stand[2]
Consumables: Patient respiratory circuit, respiratory circuit flow meter, breathing system filter, tracheal tube, PEEP valve[2]
Warranty Duration: 1 year[2]
Lifetime: 5-10 years[1]
Energy Requirements: Rechargeable battery, continuous power supply (AC powered, 110V/220V, 60W, 24-hour battery recharge cycle, 2-hour battery life)[1]
Facility Requirements: Specific temperature and/or humidity range, gas supply[1]

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1 Reported by manufacturer on 18 May 2020
2 Reported by manufacturer on 27 January 2021

WHO ASSESSMENT

WHO specification comparison

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

Compliant: The device only provides pressure support modes. All requested alarms and most of the requested display parameters are present. The device has IP22 degree of protection and an internal testing/leak function. The operating temperature range is 10-40°C although the battery charging is only guaranteed in an ambient temperature range of 10-35°C.

Non-compliant: The device does not have volume control and non-invasive ventilation modes. The continuous operating mode is 2 hours rather than the specified 4 hours. Using an external low-pressure oxygen source is not possible. The tidal volume range is 50 mL to 1500 mL rather than 20-1500 mL as stated in the WHO specifications.

Some aspects could not be verified such as a mechanical safety valve, loop axis, and spontaneous ventilation. The air and oxygen pressure and leak display could also not be verified. The time required to fully recharge the battery is unknown.

Regulatory assessment

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

Some requested information and documentation for all three Regulatory and Quality Assessment categories is absent. Therefore, a thorough review of this product was not possible at this time. At the time of this report creation, MVM has obtained an US FDA Emergency Use Authorization and Health Canada Medical Device COVID-19 Authorization (IO319627). The regulatory status for the various accessories is currently unclear. MVM has an ISO 13485:2016 certificate. MVM must also ensure they comply with local country import and pre-market regulations.

Technology evidence assessment

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

This pressure-controlled ventilator has a basic design and is mainly built with generally available products. The software is open source. GMP practice must be ensured in order to guarantee safety. Even though local production is available in some low- and middle-income countries, they must also ensure compliance with local country regulations.

Summary

Transferability	→	Technology readiness level	8
Evidence (according to GRADE)	!	Technology evidence assessment	Recommended

Health technology and engineering management

Target setting: Hospitals

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

This product is a mechanical ventilator that can operate in 2 modes: pressure controlled and pressure support ventilation. It is connected directly to pressurized oxygen or medical air and relies on the regulation of the flow to deliver gas to the patient. It has a user operation control allowing for setting parameters and alarm levels. The vendor suggests that the routine maintenance requirement is limited to cleaning and disinfection between uses. The product relies on external sources of gas rather than an internal turbine. Although the vendor states that many of the parts used in the construction of the product are off the shelf, perceived lack of technical support and spare parts limit the locations of use.

Ventilator, with extended battery time

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

Commercial information

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

Health problem addressed

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

Product description

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

Product details

Accessories: Rolling stand, bag of 3 extra filters, kit – handle, swivel hooks, stand mount, external battery, extra exhalation valve, reusable adult and pediatric breathing circuits, SpO^2 monitor, HMEs, test lung, air and oxygen hoses, power cords, reservoir cylinder, humidifier and accessories.[3]

Consumables: It is recommended that the device be used with bacterial/viral filters in order to avoid cross-contamination. When using the device without an active humidifier, a Heat and Moisture Exchanging Filter (HMEF) is recommended.[1]

Other required products: Patient interfaces such as endotracheal tubes and non-invasive ventilation masks are required to use the device. The device should only be used in the presence of and in conjunction with other monitoring and life-supporting equipment required for administration of adequate critical care.[1]

Warranty duration: 3 years[1]

Lifetime: 10-15 years[1]

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

WHO ASSESSMENT

WHO specification comparison

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

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

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

Aspects that could not be verified: Minute volume alarms

Regulatory assessment

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

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

Technology evidence assessment

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

The ventilator provides basic configuration for volume control assistance. It is a me-too ventilator without innovative approaches. The price includes additional tools. Local production options seem to be available in some low- and middle-income countries, but there must be compliance with local country regulations. Maintenance is also offered locally.

Summary

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

Health technology and engineering management

Target setting: Hospitals and transport

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

This product is a mechanical ventilator intended for a variety of settings, including austere environments with unreliable access to oxygen and or electricity. It incorporates a pulse oximeter and provides for 3 years of parts and service warranty. It can function on internal battery power for up to 7 hours and on an external battery source for up to 14 hours. It is also a portable device that can be used for patient transport. Video-based user and support training is provided. Although judged to be easy to use, technical support is dependent on adequate availability of vendor training and spare parts.

X-ray detector, dual energy, portable

Country of origin | Canada
Primary function | Diagnosis
Category | Medical device

Commercial information

List price (USD): $125,000[1]
Year of commercialization: 2020[2]
Number of units distributed: 0-100[3]
Currently marketed in: United States, Canada[1]
Brand: KA Imaging Reveal™ 2
Model: 35C Flat Panel Detector[2]

Health problem addressed

The technology addresses screening of and aids the diagnosis of pulmonary health issues including tuberculosis, lung cancer, COPD, pneumonia and COVID-19 infection. Pulmonary health issues are a dominant health concern in low- and middle-income countries.[1]

Product description

The technology uses a three-layer stacked sensor design to acquire three spectrally different X-ray images using only a single conventional chest X-ray exposure. The three different spectral X-ray images can then be used to generate a conventional digital radiography, a bone subtracted and a soft tissue subtracted X-ray image to see lung disease better. The device can also generate lateral view dual energy X-ray images using a lateral X-ray exposure.[1]

Product details

Accessories: IO Cable, battery and charger, laptop[2]
Warranty duration: 1 year[3]
Lifetime: 5-10 years[1]
Energy requirements: Replaceable batteries, rechargeable battery, continuous power supply (AC powered, 110V/220V, 63W, 8-hour battery life, 5-hour battery recharge cycle)[1]
Facility requirements: Specific temperature and/or humidity range, radiation isolation, connection to a laptop/computer[1]

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1 Reported by manufacturer on 16 June 2020
2 Reported by manufacturer on 21 December 2020
3 Reported by manufacturer on 11 January 2021

WHO ASSESSMENT

WHO specification comparison

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

Regulatory assessment

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

Some requested information and documentation for all three Regulatory and Quality Assessment categories is absent. Therefore, a thorough review of this product was not possible at this time. At the time of this report creation, KA Imaging has obtained a US FDA 510(k) clearance (K201591) and a Canadian Medical Device Licence (105205) for the Reveal 35C X-Ray System. The regulatory status for the various accessories was provided. KA Imaging has obtained an ISO 13485:2016 certificate. KA Imaging must also ensure they comply with local country import and pre-market regulations.

Technology evidence assessment

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

This alternative technology provides the radiologists with unobstructed views of the lungs. Soft tissues and bone images are clearly visible raising diagnostic sensitivity. The device is portable and can integrate with existing technologies. It is durable and easy to maintain. Clinical investigations and clinical performance studies have been conducted and some are currently ongoing. Training is required for the healthcare staff. The device has been found to be safe and effective for intended users and the circumstances of use.

Summary

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

Health technology and engineering management

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

Target setting: Radiology

This product is intended to improve the clinical benefits of conventional X-ray systems by obtaining higher quality images through a detector plate structured with multiple energy absorbing materials. This novel approach offers several advantages over a single radiation shot, such as reducing motion artifacts and exposure, while simultaneously obtaining clinical information from various tissues. The detector is powered by a battery that needs to be recharged every 8 hours of use. The device also requires Wi-Fi connectivity. The detector must be calibrated by the manufacturer every 6 months. The operational temperature range is 10-35^{0} C. The detector costs $125,000 USD which may be challenging for low-resource locations.

COMMERCIALLY AVAILABLE | 2021

PROTOTYPE PRODUCTS

Face mask, reusable, polypropylene based

Country of origin | United States of America
Primary function | Prevention
Category | Personal protective equipment

Commercial information

List price (USD): $4.50[1]
Development Stage: The masks are currently sold at cost to select health facilities in the United States. It is not openly distributed. Protocols and manufacturing methods are intended to be distributed as widely as possible so that the device can be reproduced.[2]
Brand: Recyclablu[3]
Model: BluMask[3].

Health problem addressed

During the COVID-19 pandemic, there has been a lack of PPE in healthcare settings across the globe due to supply chain shortages. Additionally, 7,000 tons of medical waste is produced daily in the US alone. This solution attempts to find a viable and safe alternative to produce face masks from recycled waste material that will not only protect the health of communities but also protect the health of the planet.[1]

Product description

The technology is recycled surgical sterilization wraps repurposed into face masks. The repurposed material is currently used and produced globally for sterilization of surgical instruments. The material is 2-ply polypropylene with a tested filtration efficiency of 87%. It is trilaminated nonwoven fabric treated with electrostatic charge similar to N95 masks.[1]

Product details

Consumables: Surgical steel wire[1]
Lifetime: 0-2 years[1]
Facility Requirements: Clean water supply, sterilization[1]

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1 Reported by manufacturer on 25 January 2021
2 Reported by manufacturer on 24 December 2020
3 Reported by manufacturer on 4 November 2020

WHO ASSESSMENT

WHO specification comparison

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

Regulatory assessment

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

Significant work is needed on developing robust pre-market regulatory, post-market regulatory, and quality system plans to ensure this prototype will be able to be successfully brought to market. BluMask should develop their medical device support documentation and data. BluMask should share their collection protocol and manufacturing process with WHO to enable both groups to facilitate this distribution process to most effectively help LIMCs and facilities.

Technology evidence assessment

Domains	Evidence assessment: Risk/benefit ratio	Evidence assessment: Impact	Innovation
Medical	⚠	→	
Safety	✕	✕	
Economy	✕	✕	
Organizational	⚠	⚠	
Legal	✕	✕	
Social	→	→	
Ethical	→	→	
Green environment	⚠	⚠	⚡

The technology is under development. Based on current evidence, the level of filtration and protection is unclear. The cleaning and reuse process is uncertain.

Summary

Transferability	→	Technology readiness level	6
Evidence (according to GRADE)	⚠	Technology evidence assessment	Not recommended

Health technology and engineering management

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

Target setting: Public and home settings

This product uses sterile surgical fabric that is formed and cut into face masks. The vendor claims that its performance is similar to N95 masks, however, the evidence that was reviewed does not provide clear indications to support this claim. There is a need to collect such fabrics and reformat their shape into face masks in localities with shortages of PPE. However, no evidence was provided to support safe individual use due to lack of insufficient identification of material in the tests.

Microfluidic based, COVID-19 test

Country of origin | Sweden
Primary function | Diagnosis
Category | In vitro diagnostic

Commercial information

List price (USD): $500[1]
Price of Consumables Per Use (USD): $10[1]
Development Stage: The prototype has been developed for emergency use and has been tested clinically. The manufacturer is in process of applying regulatory approval in Mexico.[2]
Brand: KTH Royal Institute of Technology[1]
Model: Lamp on a Disc[2].

Health problem addressed

According to the Foundation for Innovative New Diagnostics, an estimated 500 million COVID-19 diagnostic tests will be needed in in low- and middle-income countries over the next 12 months, 75% of which will be in decentralized settings. PCR is currently the gold standard for COVID testing, however, it is complex and expensive. The use of rapid antigen tests has been encouraged in the context of resource-limited settings, however, the clinical sensitivity is not yet satisfying the WHO standards. Nucleic acid amplification tests are expected to provide higher sensitivity and potentially higher specificity than antigen rapid tests, thus being the ideal solution for low-resource settings if costs and equipment complexity can be kept low.[2]

Product description

The technology is a fully integrated, cost-effective and scalable microfluidics-based platform for COVID-19 test based on loop mediated isothermal amplification (LAMP). The clinically validated method takes the swab sample and delivers results of 20 tests simultaneously using a smartphone within 30 min. In addition to precise fluid control, the technology features a novel agarose bead-based sample processing strategy to stop the reaction and improve the signal reaction response by approximately 30x signal enhancement. As a result, the user can make a visual by naked eye or smartphone-based detection. The operating steps involve the user adding a 1 uL swab sample to LAMP mastermix, heating the LAMP mastermix at 65C for 30 min and obtaining the readout using any smartphone.[2]

Product details

Accessories: Cartridge, USB cable, AC power adapter, portable battery pack (optional)[3]
Consumables: Lamp mastermix reagent[1]
Lifetime: 5-10 years[1]
Energy Requirements: Replaceable batteries, continuous power supply, rechargeable batteries (AC powered, 12V, 60W, 2-2.5-hour battery life, 1-1.5-hour battery recharge cycle). We have a second-generation prototype that uses 9V batteries, but no clinical data yet.[2]
Facility Requirements: Clean water supply, specific temperature or humidity range[1]

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1 Reported by manufacturer on 27 November 2020
2 Reported by manufacturer on 8 February 2021
3 Reported by manufacturer on 17 January 2021

WHO ASSESSMENT

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	Proceed with caution
Quality system assessment	Proceed with caution

Significant work is needed on developing robust pre-market regulatory, post-market regulatory, and quality system plans to ensure this prototype will be able to be successfully brought to market. The KTH Royal Institute of Technology should develop their medical device support documentation and data.

Technology evidence assessment

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

The test is a qualitative COVID-19 Anti-RNA test with high level of sensitivity and specificity. The diagnostic window is unclear. Up to eighteen test can be done in parallel as a screening before a more expensive PCR test is being done. However, it is also actually unclear whether the test can be used as a screening tool in point-of-care environment.

Summary

Transferability	→	Technology readiness level	5
Evidence (according to GRADE)	⚠	Technology evidence assessment	Recommended with caution

Health technology and engineering management

Target setting: Hospitals

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

This prototype IVD intends to provide a high volume, low-cost diagnostic tool to test individuals for COVID19 exposure. Its operation principle requires the collection of a sample by swab and intervention by lab technicians to provide precise dilutions with reactive agent and thermal heating to fix the solution. At this point, the sample contains dead virus and is inserted into a microfluidic disc channel that can process up to 20 different samples at a time and is placed into an additional instrument that provides the isothermal reaction. The process takes about 35 minutes and the submitter claims that the expected nucleic acid amplification-based test provides acceptable sensitivity and specificity as recommended by WHO. While considered by the submitter as an alternative to the PCR diagnostic tool, there is insufficient evidence to validate associations with various viral loads and environmental conditions and to demonstrate predictable outcomes. The results are provided by communication with a smartphone. Comparative results using this LAMP product did not provide sufficient information about the cohort of subjects participating in studies at various LMIC locations. Although the user manual notes that regular maintenance is not required, in our opinion, an instrument that spins, heats, and uses optical components should have preventive maintenance procedures described, service personnel, training, and spare parts support.

Optical screeing jaundice device, neonatal

Country of origin | Norway
Primary function | Monitoring
Category | eHealth/mHealth solution

Commercial information

List price (USD): $100[1]
Development Stage: Prototype is tested and waiting regulatory approval.[2]
Brand: Picterus[1]
Model: 1.0[3]

Health problem addressed

A global estimation reported that extreme neonatal jaundice (NNJ) affected 481,000 late-preterm and term newborns during 2010. Failure to detect and manage it resulted in 114,100 avoidable neonatal deaths and 63,000 infants with severe disabilities. The global burden was extremely higher for the poorest countries and 75% of mortality occurred in Sub-Saharan Africa and South Asia, attributing this outcome to lack of preventive services and effective treatment.[1]

Product description

The technology is based on biomedical optics and photonics further complemented with machine learning algorithms that facilitates accurate remote diagnostics by taking a simple picture with a Smartphone. A medical worker or parents puts the color calibration card on the newborn´s chest, the Smartphone recognizes the card, and the App automatically takes a few pictures. The pictures are analyzed through algorithms and provide a bilirubin estimate.[1]

Product details

Consumables: Color calibration card[1]
Other Required Products: Smart phone[1]
Lifetime: 0-2 years[1]
Energy Requirements: Energy to charge the smart phone[1]
Facility Requirements: Access to internet (offline version will be available at a later stage)[1]

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1 Reported by manufacturer on 26 November 2020
2 Reported by manufacturer on 5 February 2021
3 Reported by manufacturer on 9 February 2021

WHO ASSESSMENT

WHO specification comparison

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

Regulatory assessment

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

Significant work is needed on developing robust pre-market regulatory, post-market regulatory, and quality system plans to ensure this prototype will be able to be successfully brought to market. Picterus should develop their medical device support documentation and data.

Technology evidence assessment

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

This technology is not connected to COVID-19 requirements. As a prototype, there might be some impact on diagnostic tools for the future, but there are many open issues such as different skin colors, potential outcome related evidence. There are also some discrepancies between printed and presented description (based on the actual development phases). Also the diagnostic cards are quite expensive and not feasible for areas with higher humidity. The clinical effect is to be proven by relevant evidence.

Summary

Transferability	✕	Technology readiness level	5
Evidence (according to GRADE)	!	Technology evidence assessment	Recommended with caution

Health technology and engineering management

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

Target setting: Neonatal care

This product is based on software App that uses SmartPhone to measure the yellowness of subcutaneous tissue in neonates by pointing the camera at the neonate chest and contrasting it with a color-coded calibration card. The software according to the submitter can estimate bilirubin concentrations in newborns in a few minutes. The submitter stated the equipment is intended to support a healthcare provider assessment of neonatal bilirubin but not as a stand-alone diagnostic device. The measurement is dependent upon the quality of the SmartPhone camera, the retention of the colors on the card, and the accuracy of the software application. An important comment is made that this App can be used only with the Samsung Galaxy S7 SmartPhone. Overall, this product is highly mobile and easy to use, but lacks evidence for availability of technical support, training, spare parts, and appropriate operation under various environmental conditions.

Pediatric automated ultrasound

Origin | China, Hong Kong SAR
Primary function | Diagnosis
Category | Medical device

Commercial information

List Price (USD): $600[1]

Price of Consumables Per Use (USD): Less than $0.02 USD for ultrasonic gel or $0.08 USD for ultrasound gel patches.[1]

Development Stage: The automated ultrasound technology is in the rapid prototyping phase of design and development. Imaging trials commenced in Q2 of 2020 and are ongoing during 2021, with bench top lab testing and field MVP testing slated for Q2 2021.[2]

Brand: Bloom Standard limited Kaaria[1]

Model: 1111[1]

Health problem addressed

Despite progress in reducing the size and cost of pediatric ultrasound and echocardiography, the lack of trained sonographers contributes to poor access – often resulting in delayed diagnosis and referral of children with serious medical conditions. The technology being developed automates ultrasound image acquisition and interpretation, eliminating the need for medically-trained sonographers to screen + diagnose infants/children at the point of care to support: (i) early diagnosis of heart and lung conditions, (ii) appropriate, timely referrals and treatment pathways, (iii) lower device and associated skill costs, expanded access to essential non-radiating imaging for young patients with pneumonia/lung conditions (including COVID-19) and cardiac conditions.[2]

Product description

The Automated Ultrasound device is composed of a constellation of CMUT (chip-based) sensors embedded onto a wearable, reusable device and positioned over preset ultrasonic windows on the body to provide relevant images within the thoracic cavity. With an onboard SDK-connected processor the device leverages machine-learning algorithms to map, rank and compare images, sifting through image artifact to interpret physical markers associated with cardiac conditions and lung A/B and pleural lines. Operators are provided simple decision/referral support based on normal vs abnormal findings, requiring no additional knowledge or skill in guided acquisition or interpretation.[2]

Product details

Accessories: Charging port, charging appliance, ultrasonic gel or gel patch, cleaning spirits/supplies.[1]

Consumables: Ultrasound gel or gel patches (working on a design solution that might eliminate this).[1]

Other Required Products: None[1]

Lifetime: 2-5 years[1]

Energy Requirements: Rechargeable battery (DC powered, USB 5V, 4W, 24-hour battery life, 3-hour battery recharge cycle)[1]

Facility requirements: Mobile phone/tablet for running accompanying app. Access to internet only required for firmware updates and special operations such as saving data to the cloud.[1]

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1 Reported by manufacturer on 4 December 2020
2 Reported by manufacturer on 28 January 2021

WHO ASSESSMENT

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	Proceed with caution
Quality system assessment	Proceed with caution

Significant work is needed on developing robust pre-market regulatory, post-market regulatory, and quality system plans to ensure this prototype will be able to be successfully brought to market. Bloom Standard should develop their medical device support documentation and data.

Technology evidence assessment

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

The device is in need of internet access to cloud solution for artificial intelligence (AI) based advice. The general development is still a prototype. The technology is not COVID specific. There is missing evidence regarding safety (diagnostic support), data protection and any kind of evidence regarding patient related outcome.

Summary

Transferability	✗	Technology readiness level	6
Evidence (according to GRADE)	⚠	Technology evidence assessment	Recommended with caution

Health technology and engineering management

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

Target setting: Healthcare facilities

This product provides an innovative approach to accommodate cardiac screening for low resource countries. While evidence from clinical studies is limited, the incorporation of AI-driven application allows this screening to be conducted by locally trained clinical personnel. The images can be transmitted remotely through the internet for specialist confirmation of findings. We could not find evidence for support of both probe replacement as well as technical issues in the intended locations of use.

Personal protective equipment, biodegradable, jute cellulose based

Country of origin | Bangladesh
Primary function | Prevention
Category | Personal protective equipment

Commercial information

List price (USD): $4[1]

Development Stage: The team has developed the prototype and will soon begin trial among medical professionals for user-friendliness, feasibility, and acceptability. The team performed some tests recommended by WHO and other tests in laboratory but need test verification from accredited independent laboratory.[2]

Brand: International Centre for Diarrhoeal Disease Research, Bangladesh and Bangladesh Jute Mill Corporation (BJMC)[1]

Health problem addressed

The current conventional PPE is often single-use. Single-use PPE contributes to unaccounted environmental pollution globally and leads to more manufacturing of PPE that is often non-biodegradable. In well-regulated countries, incineration is commonly used for terminal medical waste management. However, there is oftentimes injudicious PPE disposal into the environment within ill-regulated waste management systems.[2]

Product description

The jute-based cellulose is liquid proof and air proof. Its molecular composition of cellulose can be altered to withstand fluid for various lengths of time. Jute is a native leafy plant that grows in abundance in Bangladesh and South Asia. Jute holds about 72% - 75% cellulose, of which, 50% - 55% could be extracted.[2]

Product details

Lifetime: Single use[1]

Facility Requirements: Specific temperature and/or humidity range[1]

1 Reported by manufacturer on 4 December 2020
2 Reported by manufacturer on 27 January 2021

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WHO ASSESSMENT

WHO specification comparison

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

Regulatory assessment

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

Significant work is needed on developing robust pre-market regulatory, post-market regulatory, and quality system plans to ensure this prototype will be able to be successfully brought to market. BJMC and icddr,b should develop their medical device support documentation and data.

Technology evidence assessment

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

This PPE is based on organic material and can be produced in LMICs at low cost and in low resource settings. The environmental protection is not finally clear as there is no information about the use of needed chemicals during the process of preparing the needed substance. The cost per unit is low. The potential impact could be high. There is the need of support to collect the evidence needed and to assure that the process to develop the product is in line with social, ethical, and environmental goals.

Summary

Transferability	→	Technology readiness level	6
Evidence (according to GRADE)	!	Technology evidence assessment	Recommended with caution

Health technology and engineering management

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

Target setting: Public and home settings

This innovative product is a personal protection gown made of jute cellulose polymers and shellback natural fibrous materials. The inventor stated that the material is biodegradable and non-toxic offering advantages over chemical-based polymer PPE. Several characteristics of the gown need to be established such as protection offered by the product in extreme environmental conditions such as high humidity and high temperature. In addition, the comfort of the wearer using the product over long periods needs to be established. Evidence to support local production needs to be provided. The advantage of protection to the environment after disposal of the product is noted.

Personal protective equipment suit reusable, ventilated

Country of origin | Switzerland
Primary function | Prevention
Category | Personal protective equipment

Commercial information

List price (USD): $1,000[1]

Development Stage: The development of the suit has reached a design approval stage where performance testing and eventually field tests to validate the robustness and appropriateness for the staff and the existing protocols.[2]

Brand: Ecole Polytechnique Federale de Lausanne (EPFL), Medecins Sans Frontieres (MSF) Switzerland, and Hôpitaux Universitaires de Genève (HUG)[1]

Model: SmartPPE[1]

Health problem addressed

Most of the personal protective equipment (PPE) used during the 2013-2016 Ebola outbreak in West Africa provided unbearable working conditions and restricted empathic relationships with the patients. The primary requirement of the PPE is safety, as the healthcare workers must be protected against any contamination from the Ebola virus. The main improvement is to provide improved working conditions in extreme environments characterized with high temperatures and high humidity.[2]

Product description

The technology is a reusable full body ventilated suit designed to withstand multiple decontamination cycles in a 0.5% solution of chlorine. It is composed of a single-piece garment fully integrating the body except for the hands and the feet allowing use of reusable gloves and standard boots. The suit is equipped with a large face shield. The design simplifies donning and doffing procedures and the internal air flow increases the comfort of healthcare workers allowing for longer shifts in the hot zones.[2]

Product details

Accessories: Full ventilation system with blower and air diffuser headset, indicator cable with LED,storage and charger box, multiple (10) battery charger box, battery, reusable filters.[2]

Lifetime: 0-2 years[1]

Energy Requirements: The system is powered with a 21.6V 70.2Wh Li-Ion battery pack. The autonomy of the ventilated PPE is 4 hours. The charger is plugged on standard 220V outlets.[2]

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1 Reported by manufacturer on 19 May 2020
2 Reported by manufacturer on 1 February 2021

WHO ASSESSMENT

WHO specification comparison

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

Regulatory assessment

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

Significant work is needed on developing robust pre-market regulatory, post-market regulatory, and quality system plans to ensure this prototype will be able to be successfully brought to market. EPFL, MSF, and HUG should develop their medical device support documentation and data.

Technology evidence assessment

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

This PPE is reusable and thus protective. Still it is a prototype and there is no daily life evidence how often it can be reused. Cleaning (inside and outside) is not described and hence the environmental impact is unclear as well as the acceptance by the user. The cost per device is high (USD 1000) and the transferability to LMIC as well as handling after it is no longer used is unclear.

Summary

Transferability	✗	Technology readiness level	5
Evidence (according to GRADE)	!	Technology evidence assessment	Recommended with caution

Health technology and engineering management

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

Target setting: Public and home settings

This product is a personal protection one-piece suit intended for individual protection in infection sites. The suit is designed with large visibility at the head level between the care provider and patient and a ventilation system that creates airflow away from the face (anti-fogging). Having a design of one garment as compared with conventional shirt and pant suits is an advertised advantage making it easier to don and doff lessening post-procedure infection of the care giver. It is advertised as reusable up to 100 times and easily cleaned. The suit lends itself to facilitate local production and ease of wear, however, its stated cost may be limiting.

Solar Powered Oxygen Concentrator & Compressor (SPOCC)

Country of origin | United States of America
Primary function | Treatment
Category | Oxygen systems

Commercial information

List Price (USD): 7000[1]

Development Stage: The prototype is currently undergoing system testing. In parallel, a field ready version (Fast Track) that does not require regulatory approvals is planned for testing in Q1 2021.[2]

Brand: Lean Med LLC[1]

Model: 02 Cube[1]

Health problem addressed

Low-resource settings are vulnerable to pneumonias (PNA), including pandemics like COVID-19, due to inadequate access to O2. For instance, 99% of all pediatric PNA deaths occur in developing regions. Improved community case management is thought to reduce pediatric PNA mortality by up to 70%, as an estimated 81% of deaths occur outside of the hospital setting. The SPOCC system makes O2 available in pre-hospital care, including in rural health centers and during patient referral to the hospital.[1]

Product description

The SPOCC system is a solar powered, supplemental oxygen system that generates oxygen regardless of the surroundings. It fills cylinders with oxygen for use in health centres and during transportation of patients from a rural health centre to a referral centre. The technology is designed with proven technology that has been repackaged for ease of use and durability. The Fast-Track version of the technology does not require FDA or CE approvals because it employs medical devices already approved for their intended use donated by supportive equipment donors. The components of the system are: solar panel, concentrator, compressor, cylinders and pulse oximeter.[2]

Product details

Other Required Products: Stethoscope[1]

Lifetime: 5-10 years[1]

Energy Requirements: Solar power (4-9 hour recharge cycle, 7-18 hour battery life)[2]

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1 Reported by manufacturer on 18 July 2020
2 Reported by manufacturer on 13 January 2021

WHO ASSESSMENT

WHO specification comparison

The oxygen concentrator used in this oxygen system partially complies with the WHO technical specifications. The system as a whole was not technically assessed.

Positive: The oxygen concentrator in the system is designed for the same intended use as other concentrators.

To pay attention: The operating temperature is 12-32ºC instead of 10-40 ºC as required by the WHO specifications. Important features include an OPI unit and an alarm that is triggered when there is a low oxygen condition. However, the threshold for the alarm is not specified for this concentrator. Additionally, the concentrator is IPX1 instead of IP11 so there is no degree of protection against solid foreign objects.

Some aspects that could not be verified including the power efficiency and display of cumulative hours of operation.

Regulatory assessment

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

Significant work is needed on developing robust pre-market regulatory, post-market regulatory, and quality system plans to ensure this prototype will be able to be successfully brought to market. Lean Med should develop their medical device support documentation and data.

Technology evidence assessment

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

The design ensures that the product cannot be tampered with. The device complies with the specifications for the components of oxygen supply devices, including gas specificity. Tests specify that the oxygen concentration must be greater than 82% at 40 C and 95% RH. A continuous supply of oxygen is maintained through contingencies. The system enables provision of oxygen at health centers and during patient transport. The system can function without being connected to an electric grid and does not require cylinders. Drawbacks include the need for trained technicians, servicing, and spare parts. A phased development program has been planned.

Summary

Transferability	→	Technology readiness level	8
Evidence (according to GRADE)	!	Technology evidence assessment	Recommended with caution

Health technology and engineering management

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

Target setting: Health facilities and transport

This product is a solar-powered oxygen concentrator and compressor (SPOCC). The product consists of four components: oxygen concentrator, oxygen compressor and filling station, solar panel, and pulse oximeters. Together the product provides the ability to generate and refill small O2 cylinders and provide oxygen treatment in rural and harsh environments. The product includes indicators that provide feedback to the user about the oxygen volume status. The integration of traditionally separate components into a single system provides an innovative solution in difficult environments. The product seems to require periodic maintenance such as changing sensors and air filters and replacing rechargeable batteries. The initial unit cost is somewhat prohibitive. In addition, local production of this product may be challenging. Management of the pneumatics and oxygen creates a potential fire hazard that must also be considered.

Ventilator, resuscitator bag based

Country of origin | Norway
Primary function | Treatment
Category | Medical devices

Commercial information

List price (USD): 6000[1]

Price of consumables per use (USD): 50[1]

Development Stage: The product development is completed, the technical file has been assessed for conformity with MDD. A clinical investigation trial is in planning phase to create pivotal data necessary to support the product claims.[2]

Brand: Laerdal Medical[1]

Model: Laerdal Servi Ventilator[1]

Health problem addressed

In emergency situations where normal ventilators are unavailable, manual ventilation is the only alternative. Manual ventilation is not a good alternative because each patient occupies both hands of a health worker. Furthermore, ventilations are delivered inconsistently and inaccurately. Such emergency situations happen when there is a surge in patients needing ventilation or when existing ventilators are unavailable due to damaged infrastructure or lack of infrastructure, supplies or spare parts.[2]

Product description

The device is intended for ventilatory and respiratory assistance for monitored and intubated adult patients with normal healthy lungs, or with mild to moderate respiratory failure, requiring ventilation volumes of 200 – 800 ml when it can be used on patients under direct observation by healthcare professionals. It provides capacity in cases where more advanced critical care ventilators are unavailable. The technology functions with a processor-controlled stepper motor that compresses a self-inflatable silicone bag. The controlled and display parameters are tidal volume, rate, and I:E. Supplemental oxygen is possible through a bottle or an oxygen concentrator in order to achieve FiO2 0.21-1.0. The device has an adjustable PEEP on expiration diverter as well as a battery backup.[2]

Product details

Accessories: Laerdal Silicone Resuscitator adult bag with inlet valve, oxygen reservoir bag, oxygen tube, Laerdal Silicone Resuscitator patient valve, exhalation port, manometer connector, pressure sensor tube[3]

Consumables: HME filter, adjustable PEEP valve, patient tube, patient tube connector[1]

Lifetime: 5-10 years[1]

Energy Requirements: Continuous power supply (AC powered, 220V, 270W).[1] Device is also equipped with a backup battery. Maximum time to charge a fully depleted battery is 8h. Battery life in use is typically 5h for normal patient lungs and approximately 1h for very demanding patient lungs. Minimum battery life is 30 min.[2]

Facility requirements: Specific temperature and/or humidity range[1]

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1 Reported by manufacturer on 02 December 2020
2 Reported by manufacturer on 05 February 2021
3 Reported by manufacturer on 04 January 2021

WHO ASSESSMENT

WHO specification comparison

This Device cannot be considered in the criteria of ventilators used for Intensive Care as described in the WHO specifications the intended use of which is "to provide short-term (up to 48 hours) ventilatory and respiratory assistance to monitored patients who are under constant observation by healthcare professionals".

Compliant: Possibility for using external low-pressure oxygen (approx. 20 psi), as source. An oxygen concentrator can be connected in order to provide supplemental oxygen. The only ventilation mode available is volume control.5.5 hours of operational time of the ventilator.

Non-compliant: There are many non-applicable aspects because of the nature of the device, this ventilator is not intended to be connected to a Medical Oxygen and air high-pressure input port therefore some characteristics are not needed. The product has not been tested for compatibility with active humidifying systems and does not have pressure control ventilation, noninvasive ventilation or pressure support ventilation. FiO2 input is indirectly set by the user based on user setting of input O2 flow in relation to output minute volume of gas. The "Assisted Ventilation Mode" is not intended for patients in need of FiO2 > 0.21. Inspiratory pause cannot be set. Plateau pressure can be estimated manually – see pg 15 of User Guide. Only single limb proprietary circuit can be connected.

There are some aspects that couldn't be verified such as: Display parameters (Minute volume and status indicators for battery status, patient data, alarm settings,)

Regulatory assessment

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

Significant work is needed on developing robust pre-market regulatory, post-market regulatory, and quality system plans to ensure this prototype will be able to be successfully brought to market. Laerdal should develop their medical device support documentation and data.

Technology evidence assessment

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

The principle of this tool is very simple and easy to train. The equipment can also be used and maintained in LMIC if the cost per device will be lower. There are missing studies on clinical evidence regarding safety and nosocomial infections as this is stated as a benefit for this technology. The medical use is limited (volume-based ventilation).

Summary

Transferability	→	Technology readiness level	6
Evidence (according to GRADE)	!	Technology evidence assessment	Recommended with caution

Health technology and engineering management

Target setting: Hospitals

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

This product is a mechanical ventilator for use in hospitals that is well supported by vendor sales and technical personnel. In addition, the vendor further supports the product with on-line video training. It is well constructed, easy to clean and operate with some limitation for its deployment in extreme environmental conditions. The product is suitable for use in intensive care units in low resource countries.

Ventilator, ICU with waveform display

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

Commercial information

List Price (USD): $3000[1]

Price of Consumables Per Use (USD): $65[1]

Development Stage: The device is currently at demonstrator level. A collaboration is in place to develop a full software and hardware package to optimise the design for production in OECD-DAC countries.[2]

Brand: CERN[1]

Model: HEV/HPLV V2[2].

Health problem addressed

The infectious nature of the COVID 19 disease and the number of patients who develop serious respiratory problems, requiring a long period of treatment, has highlighted the need for various items of key medical equipment such as ventilators. The device is designed as a high-quality, low-cost ventilator to provide artificial support for lung function of patients using technologies developed by the particle physics community for pressure and gas regulation. There is a collaboration in place that will optimise the design for low-resource settings, where aspects such as robustness, independence from hospital compressed air supply and remote training and post market surveillance are particularly important.[2]

Product description

The device is a high-quality ventilator designed to support treatment and management of patients suffering from pulmonary lung disease and in particular in the context of the COVID-19 pandemic. It is controlled via a touchscreen with a sophisticated display of parameters and pressure/volume/flow curves. The supported ventilation modes are Pressure Control (including PRVC), Volume Control, Pressure Support and CPAP. The ventilator is designed to be low cost and easily assembled from readily available components. It is suitable for hospital use in or out of the ICU and is adaptable to a wide range of geographical settings.[2]

Product details

Accessories: For invasive ventilation: Endotracheal tube, double limb respiratory circuit ended by Y piece, two filters, HME filter at the Y piece. For non-invasive ventilation: facemask in addition to the above.[1]

Consumables: All contaminated pieces are exchanged between patients; tube/facemask, filters and HME.[1]

Other required products: All mandatory ICU monitoring, in particular patient oximeter.[1]

Lifetime: 5-10 years[1]

Energy requirements: Rechargeable battery, continuous power supply, solar power (AC powered, 110V/220V, 60W, 3-hour battery life, 1-hour battery recharge cycle, 3-hour solar recharge cycle)[1]

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1 Reported by manufacturer on 03 June 2020
2 Reported by manufacturer on 03 February 2020

WHO ASSESSMENT

WHO specification comparison

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

Compliant: Display easily readable, provide the information of 3 scalar waveforms, loop and parameters required in the technical specifications, alarms for FiO2, inspiratory pressure, apnea and others required. The oxygen is continuously measured via meter which takes a small continuous flow from the buffer.

Non-compliant: Medical air compressor or turbine in built not present; the manufacturers claim this is going to be considered for future prototypes, "the team has planned to include a separate multi-stage turbine to generate pressurized air independently of other infrastructure" ETHZ_HEV_Report Page 3. Volume control modes are not included but can be added if needed, only CPAP non-invasive mode is included. The RR allowed is 10-30 breaths/min, adjustable in increments of 2 , arxiv document page 4 vs the 10-60 breaths/min. System is currently designed to be used with disposable PEEP valves which can be manually interchanged to provide, typically 5 mbar adjustments of the PEEP. An upgrade to this system is under investigation (Compiled Info Request by the Manufacturer page 10)

Some aspects that could not be verified: Tidal Volume range, Adjustable peak pressure limitation/pressure-cycling mechanism above measured peak pressure, operating temperature and humidity, IP protection among others.

Regulatory assessment

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

Significant work is needed on developing robust pre-market regulatory, post-market regulatory, and quality system plans to ensure this prototype will be able to be successfully brought to market. CERN should develop their medical device support documentation and data.

Technology evidence assessment

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

The product shows how low cost ventilators can be developed. Beside this there are open issues regarding the intended group of users, the good manufacturing practice and potential safety topics. The actual model seems to be at an early stage without any kind of design to be useful in clinical settings. Especially issues such as PEEP adjustments are too complex for daily life usage.

Summary

Transferability	→	Technology readiness level	5
Evidence (according to GRADE)	!	Technology evidence assessment	Recommended with caution

Health technology and engineering management

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

Target setting: Hospitals

This product is an innovative, high energy ventilator that was designed with a vision for local production in low resource countries by using standard available parts, open-source software controlling the operation and display. The ventilator provides typical ventilation support modes such as PRVC, SIMV-PC, and CPAP. The ventilator design deployed software-controlled solenoids, mechanical valves, and storage for buffering pressured air mixed with oxygen. The design dependence on pressurized vessels requires measurement and alarms relating to any possible system leaks. In addition, dependency on high-pressure gas input, may limit the applicability of the product to locations that have centralized piped-in gas. We could not find evidence for oxygen level measurements within the system as well as for supporting the product in the field.

Non-listed products

The non-listed products that are kindly invited to collect more evidence for future calls are:

Generic Name	Brand (company/ affiliation)	Model
Antiviral Protective Face Mask	Virustatic Shield Limited	AVM 96
Continuous Positive Airway Pressure (CPAP) Device	UCLVentura CPAP Device	
Ventilator Splitter System	Combilift	Combi-Ventilate
Broad Spectrum Pathogen Blood Filter	ExThera Medical Corporation	Seraph® 100 Microbind® Affinity Blood Filter
Face Shield	Charmant	Clarishield
Mask Brace	Fix the Mask	V3
Powered Air-Purifying Respirator (PAPR)	Tiki	Tiki
Patient Ventilator	Vestech Medical Pty Ltd	CoVida Ventilator
UV-C Air Flow Disinfection Device	Planika/Sayoli	Sayoli 300 Pro

Discussion

This publication provides a general overview and rapid evaluation of innovative health technologies for low-resource settings. Multiple assessments were performed to assess the safety, quality, acceptability, affordability, and appropriateness of each innovation when considering low-resource contexts. 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.

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.

Given the stated objectives of this publication, the methodological approach and evaluation criteria focused on the technology's potential for adoption within low-resource settings rather than the innovator's business model and scaling plans, which is typically the emphasis of other global health innovation initiatives. Future work should consider how to integrate the results of this product innovation evaluation with assessments of business innovations.

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 should include an in-depth collection of end-user feedback and an assessment of the best approach for gathering input from end users that is efficient and a genuine representation of how a 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 only with evidence provided by the manufacturer for the sake of expediency. Data was especially limited for prototypes given their early stage of development. Future work should include a comprehensive review of the evidence available for each technology, including comparisons to existing solutions.

For further reading

WHO has published several documents and interim guidance to support the response to COVID-19. The relevant ones for this publication are the following:

1. WHO. Priority medical devices list for the COVID-19 response and associated technical specifications. Geneva: World Health Organization, 2020. https://apps.who.int/iris/bitstream/handle/10665/336745/WHO-2019-nCoV-MedDev-TS-O2T.V2-eng.pdf?sequence=1&isAllowed=y.
2. WHO Technical specifications for Personal protective equipment , COVID-19. Geneva: World Health Organization, 2020. https://www.who.int/publications/i/item/WHO-2019-nCoV-PPE_specifications-2020.1

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

WHO is also working with other NGOs to promote innovation.

Engineering for change

Engineering for change is a knowledge organization dedicated to preparing the global workforce to deliver solutions that improve the quality of life of under served communities. This NGO has considered the health technologies in the WHO compendia and described them in their solutions library, to be accessed and compared in an on line searchable database.
https://www.engineeringforchange.org/

IFMBE Clinical Engineering Division

International Federation of Medical and Biological engineering, Clinical Engineering Division develops webinars and disseminates WHO information on innovation and health technology management.
https://ifmbe.org

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