Commercially available - 2023 Call for innovative health technologies for low-resource settings

A. Contact details (for the submitter and one additional contact)

Affiliation:

A1. Please complete the information of one **ADDITIONAL CONTACT** that we can reach in case the submitter is unavailable:

First name:
Last name:
Organization:
Email:

C. Technology details

Generic name for the technology:

Country of origin:

Primary function:

Category:

List price (USD):

Year of commercialization:

Number of units distributed:

Currently marketed in which countries:

Afghanistan
Angola
Albania
Andorra
United Arab Emirates
Argentina
Armenia
Antigua and Barbuda
Australia
Austria
Azerbaijan
Burundi
Belgium
Benin
Burkina Faso
Bangladesh
Sierra Leone
Bahrain
Bahamas
Bosnia and Herzegovina
Belarus
Belize
Bolivia (Plurinational State of)
Brazil
Barbados
Brunei Darussalam
Bhutan

Botswana
Central African Republic
Canada
Switzerland
Chile
China
Côte d'Ivoire
Cameroon
Democratic Republic of the Congo
Congo
Cook Islands
Colombia
Comoros
Cabo Verde
Costa Rica
Cuba
Cyprus
Czechia
Germany
Djibouti
Dominica
Denmark
Dominican Republic
Algeria
Ecuador
Egypt
Eritrea
Spain
Estonia
Ethiopia
Finland
Fiji
France
Micronesia (Federated States of)
Gabon
United Kingdom of Great Britain and Northern Ireland
Georgia
Ghana
Guinea
Gambia
Guinea-Bissau
Equatorial Guinea
Eswatini
Grenada
Guatemala
Guyana
Honduras
Croatia
Haiti
Hungary
Indonesia
India
Ireland
Iran (Islamic Republic of)
Iraq
Iceland
Israel
Italy
Jamaica
Jordan
Japan
Kazakhstan
Kenya
Kyrgyzstan
Cambodia
Kiribati

Saint Kitts and Nevis
Republic of Korea
Kuwait
Lao People's Democratic Republic
Lebanon
Liberia
Libya
Saint Lucia
Sri Lanka
Lesotho
Lithuania
Luxembourg
Latvia
Morocco
Monaco
Republic of Moldova
Madagascar
Maldives
Mexico
Marshall Islands
North Macedonia
Mali
Malta
Myanmar
Montenegro
Mongolia
Mozambique
Mauritania
Mauritius
Malawi
Malaysia
Namibia
Niger
Nigeria
Nicaragua
Niue
Netherlands
Norway
Nepal
Nauru
New Zealand
Oman
Pakistan
Panama
Peru
Philippines
Palau
Papua New Guinea
Poland
Democratic People's Republic of Korea
Portugal
Paraguay
Qatar
Romania
Russian Federation
Rwanda
Saudi Arabia
Sudan
Senegal
Singapore
Solomon Islands
El Salvador
San Marino
Somalia
Serbia
South Sudan

Sao Tome and Principe
Suriname
Slovakia
Slovenia
Sweden
Seychelles
Syrian Arab Republic
Chad
Togo
Thailand
Tajikistan
Turkmenistan
Timor-Leste
Tonga
Trinidad and Tobago
Tunisia
Türkiye
Tuvalu
United Republic of Tanzania
Uganda
Ukraine
Uruguay
United States of America
Uzbekistan
Saint Vincent and the Grenadines
Venezuela (Bolivarian Republic of)
Viet Nam
Vanuatu
Samoa
Yemen
South Africa
Zambia
Zimbabwe

Brand:

Model:

Short product description:

Accessories:

Consumables:

Warranty duration:

Lifetime:

Energy requirements:

Facility requirements:

Contact name:

Contact email:

Phone:

Website:

Please add an image of the technology:

D. Public health problem or clinical condition addressed by the technology

D1. Please provide a summary of the public health problem(s) or clinical condition(s) that the technology aims to address:

D2. Describe the beneficiaries of the technology/target population:

D3. Please describe the current standard of care that your technology intends to replace:

D4. Can you provide any relevant documentation with :

- Latest WHO statistics related to the health problem
- Additional metrics related to the health problem (peer-reviewed studies of the burden of disease or similar)

D5. If you have documentation on a public website, please provide URL(s):

D6. Please provide any additional comments relevant to the sections above (Public health problem/clinical condition addressed by the technology):

E. Technical specifications part 1

E0. Do the technical specifications of this technology align with the technical specifications of any international (WHO, MSF, UNICEF) or national (MoH) organization?

E1. Name and coding

E1a. Name and coding

EMDN name:
EMDN code:
GMDN name:
GMDN code:
UMDNS name:
UMDNS code:
Alternative name/s (optional):
Alternative code/s (optional):
Keywords (optional):

E1b. GMDN/UMDNS definition (optional):

E2. Purpose of use

E2a. Clinical or other purpose:

E2b. Please provide a concise technical explanation of the technology and how it operates:

E2c. Level of use (if relevant):

Community services (Community-based services, including home-based and school-based care, as part of primary care)
Pre-hospital emergency services (Emergency scene and emergency transport prior to admission to a health facility)
General outpatient services (Health posts, health centres, standalone general outpatient clinics, and outreach services for primary care)
First-level hospitals (Inpatient and/or outpatient services of district or general hospitals)
Second-level or third-level hospitals or specialized outpatient services (Inpatient and/or outpatient services of second-level or third-level hospitals and standalone specialized outpatient clinics)

E2d. Clinical department/ ward/ healthcare unit (if relevant):

E3. Technical characteristics

E3a. Key features:

E3b. Features

Displayed parameters (if relevant):
User adjustable settings (if relevant):
Alarms (if relevant):
Sound level of the alarms (db) (if relevant):

E4. Physical/chemical characteristics

E4a. Characteristics

Please list the length of the technology (mm):
Please list the width of the technology (mm):
Please list the height of the technology (mm):
Please list the weight of the technology (kg):
Please list the components of the technology (if relevant):
Is the technology portable (if relevant):
Please list the main materials (raw materials) used to construct the technology:
Physical space recommended for installation of device (if relevant):

E4b. Do you have any additional comments on the technical specifications section above?

- Name and coding
- Purpose of use
- Technical characteristics
- Physical/chemical characteristics

E. Technical specifications part 2

E5. Utility requirements (Infrastructure requirements)

E5a. Are any of the following required?

Electricity
Connectivity (WiFi)
Water
Gas

E6. Accessories, consumables, spare parts, other components

E6a. Is sterilization needed for accessories (if relevant)?

E6b. Please list the consumables / reagents needed (if relevant):

E6c. Are any spare parts included (if relevant)?

E6d. Are additional components needed for the correct functioning of the technology (if relevant)?

E6e. Options for alternative power (if relevant):

E7. Packaging

E7a. What is the sterility status on delivery (if relevant)?

E7b. Please specify the shelf life in months (if relevant):

E7c. Please specify the transportation and storage requirements (if relevant):

E7d. Please attach a labelling example (if relevant):

E7e. Please share any photo/image of packaging

E8. Documentation

E8a. Do you have any of the documentation below to support the technical specifications assessment?

User manual or instructions for use (English)
User manuals (or instructions for use) in other languages
Maintenance manual (English)
Installation manual, if separate from user manual (English)
Training manual
Spare parts manual
Example of certificate of calibration
Example of certificate of inspection
Example of document with contact details of manufacturer, supplier and service agent

E8b. Please list the languages available for the manuals:

Arabic
Chinese
English
French
Russian
Spanish
Other

E9. Do you have any additional comments on the technical specifications section above?

- Utility requirements (infrastructure requirements)
- Accessories, consumables, spare parts, other components
- Packaging
- Documentation

F. Regulatory section part 1

F1. Pre-market assessment

F1a. Risk classification

EU
USA
Other

F1b. Did the technology undergo testing for verification and validation?

F1c. Did the technolgy undergo any pre-clinical studies?

F1d. Did the technolgy undergo any clinical studies?

F1e. Do you have any of the documentation below to support your pre-market assessment?

Design verification and validation (Test reports)
Pre-clinical studies (used for regulatory processes)
Clinical evaluation (used for regulatory processes)
Other reports (used for regulatory processes)

F2. Post-market assessment

F2a. Do you keep record of customer complaints?

F2b. Do you have a field safety corrective action plan?

F2c. Have adverse events been reported?

F2d. Did the technology undergo a recall?

F2e. Did you obtain any regulatory approval for the technology from any regulatory body/agency?

F2f. Do you have any of the documentation below to support your post-market assessment?

Distribution records
Post-market studies
On-going post-market report
Record of customer complaints
Product registration
All regulatory approvals including marketing authorizations
Other

F2g. Do you have any additional comments on the regulation section:

- Pre-market assessment
- Post-market assessment

F. Regulatory section part 2

F3. Quality Management System (QMS)

F3a In how many sites is the technology currently being manufactured?

F3b. Please provide a list of all relevant international/regional/national certifications and standards for the **manufacturing of this product** and the current period of certification:

F3c. Please provide a list of all relevant international/regional/national certifications and standards for this **product's performance** and the current period of certification:

F3d. Do you have any of the following documentation to support the QMS assessment?

Establishment registration
Establishment license
ISO 13485:2016
Compliant certification for the manufacturer
Compliant certification for the product

F4. Security

F4a. Does the technology pose any biosecurity risk?

F4c. Does the technology pose any cybersecurity risk?

F4e. Did the technology undergo testing for Electromagnetic compatibility (EMC) (if relevant)?

F4f. Do you have any additional comments on the QMS or Security sections?

G. Health Technology Assessment (HTA)

G1. Medical

G1a. Please provide a summary of the best available evidence that demonstrates that the technology is at least as effective as the standard of care:

G1b. Please state if a clinical trial(s) has/have been undertaken:

G1c. Please summarize which aspects of this technology are better than the standard of care:

G1d. Please highlight the innovative aspects of this technology compared to the standard of care:

G1e. Do you have any of the documentation below to support the medical assessment?

- Testing reports
- Pre-clinical studies
- Clinical trial publication
- Clinical studies
- Other peer-reviewed evidence
- Independent performance evaluation reports
- Field studies
- Biocompatibility reports

G2. Safety

G2a. Please provide a summary of the **best available** evidence that demonstrates that the technology is as safe or safer than the current standard of care:

G2b. Compared to the standard of care, does the technology introduce any additional risk?

G2d. Please describe the process you are using for identifying, assessing, and controlling RISK FOR PATIENTS associated with this technology:

G2e. Please describe the process you are using for identifying, assessing, and controlling RISK FOR USERS associated with this technology:

G2f. Do you have any of the documentation below to support the safety assessment?

- Safety testing reports
- Risk assessment
- ISO 14971:2019— Application of risk management to medical devices
- Mitigation strategy

If yes, then please upload file(s)

If you have documentation on a public website, please provide URL(s):

G3. Economy

G3a. Please provide a summary of the evidence that demonstrates that the technology is cost-effective?

G3b. Could you provide an estimate for the budget impact when incorporating the technology in a new environment?

G3c. Do you have any of the documentation below to support the financial assessment?

Cost effective analysis or similar
Pricing list

G3d. Please provide any additional comments on the sections above:

- Medical
- Safety
- Economy

G. Health Technology Assessment (HTA) part 2

G4. Organizational

G4a. Compared to the current standard of care, what are the operational benefits of using this technology?

G4b. Does the introduction of the new technology and its use in place of the current comparator(s) require organizational changes?

G4c. What are the work force requirements for using this technology?

G4d. Is the device interoperable with other devices?

G4e. Which compatibility standards does the technology use? (e.g., HL7, DICOM)

G4f. Does the technology have any compatibility limitations?

G4g. Is there are any specific training needed to use or manage the technology?

G4h. Do you have any of the documentation or interoperability reports?

G5. Legal

G5a. Can the technology be introduced using the same legal framework as the standard of care?

G5b. Does the use of the technology require new legislation or a publication of a ministerial/administrative act?

G6. Social

G6a. Compared to the current standard of care, is the technology as socially acceptable?

G6b. Compared to the standard of care is the technology as culturally acceptable?

G6c. Have you ever faced any cultural or social issues while introducing the technology in a specific context?

G6d. Please provide a summary of the qualitative studies related to end user acceptability, and other social or cultural aspects

G6e. Has the technology ever faced reluctance for its use by healthcare staff or patients?

G6f. Do you have any documentation or qualitative peer-reviewed studies to support the social assessment?

G. Ethical

G7a. Have ethical approval for this technology been obtained from any organization?

G7c. Compared to the standard of care, is the technology introducing any ethical challenge? Please consider Beauchamp and Childress's four principles. autonomy, non-maleficence, beneficence, and justice.

G7d. Do you have any documentation on ethical approval?

G8. Green environment

G8a. Compared to the standard of care, is the technology greener in any aspect?

G8b. Compared to the standard of care, is the technology more sustainable?

G8c. Are there any considerations to reduce the CO2 foot print for producing, using or disposing of this device?

G8d. Please describe how to dispose of the device:

G8e. Can the device be reused, reprocessed, remanufactured?

G8f. Can any of the materials be recycled?

G9. Please provide any additional comments that may be useful for the assessments above:

- Organizational
- Legal
- Social
- Ethical
- Green environment

H. Health Technology Management (HTM) part 1

H1. Durability

H1a. Did you perform any physical durability testing for this technology?

H1b. Did you perform any chemical resistance testing for common disinfection solutions?

H1c. Please specify the IP code or ingress protection code for the technology:

H2. Ease of use

H2a. Step-by-step explanation of the operation of your technology so that potential users can understand the operation level of difficulty

H2b. How is this technology appropiate for low-resource settings?

H2c. Has the technology been successfully implemented in low-resource setting?

H2d. Do you have any of the documentation below to support the ease-of-use assessment?

Video showing the operation of the technology (mandatory)
Available online training
Field studies
Case studies
Other

H3. Ease of maintenance (if relevant)

H3a. Does the technology require preventative maintenance?

H3c. Who should provide **PREVENTATIVE** maintenance?

H3d. Who should provide **CORRECTIVE** maintenance?

H3e. Is there available online training for planned preventive maintenance and corrective maintenance?

H3f. Does the technology include a warranty plan?

H3g. Are spare parts available post-warranty?

H3h. Is there availability for software/hardware of the upgrades?

H3i. Please include any additional comments on the sections above:

- Durability
- Ease of use
- Ease of maintenance

H. Health Technology Management (HTM) part 2

H4. Environmental conditions

H4a. Please specify the humidity range in which the technology operates?

H4b. Please specify the temperature range in which the technology operates?

H4c. Is the technology in any way adapted for working in extreme environments (e.g. intermittent power supply, sand-proof, for use in very humid environments, etc.)?

H5. Affordability

H5a. Compared to the standard of care is this technology in any way more affordable? Please explain.

H5b. Please enumerate the list prices in all countries where the technology is commercialized:

H6. Local access to technical support

H6a. Is there access to local commercial teams? In which countries?

H6b. Which distribution channel are you using to distribute the technology globally and/or locally?

H6c. How do you provide training to users?

H6d. How do you provide training for maintenance?

H6e. Do you provide troubleshooting software or procedure, to help users diagnose and solve the malfunctioning?

H6f. Are replacement components for the technology available globally and/or locally? In which countries?

H7. Ease of cleaning

H7a. Please describe how to clean and disinfect the technology:

H7b. Please list any chemicals needed for cleaning and disinfecting (if relevant):

H8. Infrastructure requirements

H8a. Are there any infrastructure requirements needed to introduce the technology (Floor type, isolation of walls, ceiling, etc.)? (Additional to the ones in the technical specification section). Describe them if any.

H9. Please include any additional comments on the sections above:

- Environmental conditions
- Affordability
- Local access to technical support
- Ease of cleaning
- Infrastructure requirements

I. Local production and intellectual property (IP)

I1. Local production and technology transfer

I1a. In which countries is the technology currently manufactured?

I1b. Is the technology produced in the area in which it is intended to be used?

I1c. Please provide a short assessment of the feasibility of local production of the technology and list challenges and problems that you foresee. What type of infrastructure would be required?

I1d. What is your existing manufacturing approach? (completely in-house or in-house critical parts manufacturing & final assembly or only semi-knock-down kit assembly or final packaging alone or completely contract manufactured)

I2. Intellectual property and open access

I2a. Do you or your institution own **knowledge and/or data** related to this technology?

I2f. Please indicate the **intellectual property rights** covering the technology (e.g., Patents, copyright, trade secret, utility models, trademarks).

I2g. Do you or your institution hold the **intellectual property rights** for the production and sale of the technology?
If any of the intellectual property rights are owned by a third party, please indicate the name of the legal owner and the relationship with the applicant.

I2h. Address of the Legal Owner of the intellectual property rights. Please provide the registered details.

I2i. If applicable, please list and provide information on the relevant **patent(s), or patent-application(s)** covering the device (scope, status, patent number/application number, title, countries, and expiry date).

I2j. If applicable, please list and provide information on any **other REGISTERED intellectual property rights** (scope, status, expiry date and registration number).

I2k. If applicable, please list and provide information on any **UNREGISTERED intellectual property rights** (e.g., trade secret, copyright). Please indicate the scope, status, and registration number.

I2l. Does the medical device use any kind of software?

I2m. Please indicate if any of the intellectual property is available as **open access** or **open source**.

I2n. Are any third-party-owned intellectual property rights necessary for the production and sale of the Medical Device (e.g., patents, machinery, software). If applicable, please list and provide information on such rights.

I2o. If applicable, please provide the name of the legal owner and the legal relationship between the applicant and the owner of such third-party owned intellectual property rights.

I2p. Please indicate if there are any existing licensing agreements related to the technology.
Please provide a copy of the agreement(s) or any details that you are prepared to share in confidence with WHO.

I2q. Do you have any of the documentation below to support the intellectual property/open access assessment?

Intellectual property documents
Agreements

I2r. Please include any additional comments on the sections above:

- Local production and technology transfer
- Open-access and intellectual property

I3. Thank you for completing the survey, after you click "submit", you will have the option to 'Save as a PDF' for your survey responses. We recommend doing this for your reference. If you have any questions or technical difficulties please contact techinnovation@who.int (mailto:techinnovation@who.int).