

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

Assistive devices  
eHealth solutions  
Medical devices  
Other technologies  
Technologies for outbreaks



2011-2014

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The call, evaluation, and compilation of submissions for the Compendium were managed by the World Health Organization (WHO) Medical Devices team, Policy Access and Use unit of the Essential Medicines and Health Products department under the coordination of Ms Adriana Velazquez Berumen and supervision of Dr Gilles Bernard Forte and Mr Cornelis de Joncheere.

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# Introduction

One of the cornerstones of the Universal Health Coverage (UHC) initiative is access to health technologies. Medical devices, assistive devices and eHealth solutions are health technologies that save lives or improve quality of life. However, too many people worldwide suffer unnecessarily because they lack access to affordable health technology. In low- and middle-income countries the problem is even more acute and high-quality, appropriate, available, accessible and affordable medical technologies are severely needed to fill this gap.

The objective of the compendium series of innovative medical devices, assistive devices and eHealth solutions is to provide a neutral platform for technologies which are likely to be suitable for use in less resourced settings. It presents a snapshot of several health technologies which might have the potential to improve health outcomes and the quality of life, or to offer a solution to an unmet medical/health technology need. It is released to acknowledge some success stories and at the same time, to raise awareness of the pressing need for appropriate and affordable design solutions and to encourage more innovative efforts in the field. This effort also aims to encourage greater interaction among ministries of health, procurement officers, donors, technology developers, manufacturers, clinicians, academics and the general public to ensure greater investment in health technology and to move towards universal access to essential health technologies.

All submissions to the 'Call for Innovative Health Technologies for Low-Resource Settings' underwent an evaluation process; technologies were assessed by an expert panel based on the material and evidence provided by the applicant as well as publicly available information.

Note that for a selected technology, the 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 one page summarizing the health problem addressed, the proposed solution and product specifications, based on data, information, and images provided by the developers of the technologies concerned.

Due to the Ebola outbreak, the 2014 call was extended to include medical devices for outbreaks, including disinfection technologies. Many innovations are in the way and are being tested in the field; we look forward to increasingly list new technologies that can be affordable, easy to use, safe and of good quality, which can be available for low resource settings especially in case of emergencies, outbreaks and for non-communicable diseases.

This volume now includes 127 Technologies from 36 Countries, on the following areas: Assistive devices, Basic equipment for health facilities, Devices for infectious diseases and for infection prevention, Healthcare management, Medical imaging, Laboratory, Monitoring, Non-communicable diseases, Reproductive, maternal, neonatal and child health, Respiratory support and Surgery.

Every year the process became increasingly selective; the parameters of evaluation more stringent and more evidence had to be made available or requested from the manufacturer. This compendium is another step in the ongoing process to better target global health needs and priorities. It is important to note that while many technologies are being marketed, the quality and safety are doubtful.

Important is to highlight that academia, innovators and medical devices industries innovate and find ways to target the priority diseases with affordable, good quality and safe technologies. Additionally, delivery systems must allow medical devices to reach their final destination, whether being used by health care workers or patients. Challenges in regulatory approval, selection, procurement, evaluation, distribution channels, delivery, user training and maintenance until decommissioning should be remembered at all times. WHO guidance regarding this process is available in the Medical Devices Technical series, at [http://www.who.int/medical\\_devices/management\\_use/en/](http://www.who.int/medical_devices/management_use/en/)

The distribution channels should also guarantee that there will be effective maintenance and spare parts available, so that these technologies remain useful at the point of care.

It is imperative that innovative, affordable and good quality health technologies are being used by the base of the pyramid, that is, the majority of population, to have access to better and most appropriate technologies to match their health needs; this will enable disease prevention, early diagnostics, effective treatment and assistive care as appropriate. In cases where there are low availabilities of supplies, infrastructure or specialized human resources, innovative technological solutions should be envisaged for low resource settings in order to empower health care staff with better tools.

Many challenges lie ahead. Both the unfinished MDG agenda and the new Sustainable Development Goals that were approved this year hope to bring universal health coverage to all populations. To achieve this goal it is essential that scientific and technological advances, research and development as well as innovative technologies have a substantial supportive role in health care; this will best place us to reach the highest attainable level of global health.

# Terms, conditions and disclaimers

Compendium for innovative health technologies: Ebola relief technologies, medical devices, eHealth solutions and In-Vitro diagnostics for low-resource settings 2011, 2012, 2013 and 2014

WHO reserves the right not to select any application or to annul the solicitation process at any time, without thereby incurring any liability or any obligation to inform the applicants of the grounds for the 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, in 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, in 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 to submit 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 as such. The submission of applications, the subsequent selection process and outcome of the selection process will not be subject to any claim of any kind whatsoever, or appeal. Each applicant will be notified in writing by WHO (by e-mail) whether or not the 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 complementary information and/or a more detailed proposal, if so requested by WHO) 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 at drawing stakeholders' attention to innovative technologies with a view to furthering development and availability of, and access to such innovative health technologies.

The mention of specific companies or of 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 the 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.

# eHealth solutions 2014



# Doctor assistant app

Country of origin | Mauritius

## Health problem addressed

Disorganized healthcare systems is a drawback in low and middle income countries. Paper-based systems are known to promote an erratic performance. The aim of this app has been to harness the computational power of smart devices to build a simple EMR for daily usage

## Product description

Simple, easy to use and free EMR for tablets and smartphones. The software is an Android based application that runs an SQLite Database in background overlaid by a beautiful user-friendly interface. The digital footprint of the application is approximately 1 MB only but allows unlimited data entry for patients. Doctor assistant app has been launched in March 2014 but already count 1800 users worldwide.



## Developer's claims of products benefits

The application runs on a stable Android platform. Despite having 1.5 million apps on Google Play, none have resembled the app so far. No actual maintenance is required and it is readily accepted by users. The app requires minimal resources but the output is massive in terms of making healthcare practices become paperless.

## Operating steps

The application is freely available on Google Play and can be installed easily. The usage is straightforward and resemble most of the software currently available for Android. No specialized knowledge is required. The app can easily input data by typing, handwriting recognition or even speech to text. Data can be saved to Google Drive, Dropbox or email attachment

## Effectiveness for Low-Resource Settings

The software is being used by about 70 doctors in Mauritius. Here the paper-based system is a major problem. The market penetration of smartphones in the Island has been 200% over the past two years. So, it is the right environment for the expansion of the app. Moreover, making it freely available on the Google Play suits the current economical setting perfectly

## Evaluation

The evaluation has been carried out through questionnaires, online surveys and direct interview. Customer satisfaction is as high as 90%. In addition, all the feedbacks received are used to make the application better through regular updates. The application is being used worldwide keeping in mind that we never did any commercial advertisement or marketing. Every week 100 new users are received worldwide.

## Future work and challenges

This company has paired up with local software company to expand the software in collaboration with Mauritius Research Council and University of Mauritius. The more advanced version of the software includes cloud capabilities, picture management, Google Print and integration with the Mauritius National ID card via NFC technology

## Use and environment

**User:** physician, technician, nurse, midwife, family member, medical students or patients

**Training:** Minimal training required, system is self-explanatory and easy to use.

**Setting:** Any Health Care Settings

## Solution specifications

**Software, Hardware Requirements:** Android System, requires 1 MB free space

**Date of Commercialization:** 2014

**Retail price (USD):** Freely Available

**Country used in:** Worldwide

# e-Health software for NCD health education

Country of origin | South Africa

## Health problem addressed

It addresses NCD at individual level, community and primary health care level. Target audience: Global population, people between 30-70 years. Specific emphasis on the developing world which is hit the hardest with 86% of NCD related deaths occurring in the developing world, where 29% of deaths occur among people under the age of 60. Progress to date on NCDs has been vastly inadequate. The size and complexity of the epidemic and its universal impact makes NCDs everyone's problem.



## Product description

Internet-based, cell phone-enabled application, works with or without internet to deliver a retooled and re-engineered Primary health care model that is nurse driven, patient-centred and NCD orientated. Acute patients serve as a source and feeder to the unobtrusive perpetual universal screening for NCD. Seeking out individuals who have established NCD, qualify their NCD status and quantify their risk of developing complications. NCD free individuals are assessed for risk of developing NCD, risk factors that drive such risk are identified. System generated health education tools that are based on international guidelines

## Developer's claims of products benefits

This is a new approach that integrates multiple disjointed approaches currently out there in the market. The best private initiated NCD program in South Africa by the Centre for Diabetes and Endocrinology, is largely paper based, serves only diabetic patients belonging to the medical aid industry. Some of the best internationally acclaimed chronic disease management organizations in South Africa are largely concerned with cost containment and not disease containment and are not open to the general public

## Suitability for low-resource settings

The application has various modules that are PC, cell phone and web-based, provided free to end users such as the general public, wellness organisations, and NGOs who do NCD screenings. Nurses who work in poorly resourced settings are able to deliver specialist level NCD diagnosis and care through access to real-time support by a doctor or specialist at a remote location. This functionality maximises the use of scarce human resources often faced in the developing world.

## Evaluation

This application is designed to meet HIPAA and HL7 best practices, has been tested in a primary healthcare setting and within a community of secondary school teachers in Benoni, South Africa. Based on the positive feedback received from the test sites, the application has been enhanced by adding new and ground breaking features such as a personal portable health records and virtual consultation functionality, as well as a re-engineered community outreach module.

## Future work and challenges

Future challenges are expected in making the application available to the general population and greater medical industry including research organisations. Funding and financial support for up-scaling the solution and making accessible to a wider audience in various languages

## Use and environment

**User:** Self Use/Patient, Physician, Nurse, Family Member

**Training:** Training requirements are based on the level of use. individual users have simple self-explanatory modules, clinics will be supplied with user interphase, electronic user manuals and video demonstrations

**Settings:** Rural, Urban, Outdoor and Indoor Settings, at home or any level of healthcare centre.

## Solution specifications

**Solution is used to support:** Electronic Health Records/ Electronic Medical Record, mHealth

**Software, Hardware Requirements:** Internet, Cellular Phone Network, laptop

**Software Specifics:** The software is designed in modules, the modules that provide the widest possible impact on NCD awareness, risk assessment, diagnosis and health education are free to the general public NGOs and Nurses. Modules that are intended for the insurance industry and medical practice management will be made available at a stipulated price for the specific industry.

**Availability:** Patients can download a free clinical grade NCD android app from the website. Nurses and doctors can access the free NCD software by creating clinics with own corporate image from this website. Diabetics and hypertensive patients may subscribe to the Premium NCD still to be priced. Larger clinics also purchase this new re-engineered primary healthcare application designed for NCD, HIV/AIDS and Ante Natal care orientated primary healthcare centers

**Country used in:** South Africa

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# Electronic Health Record (EHR) solution

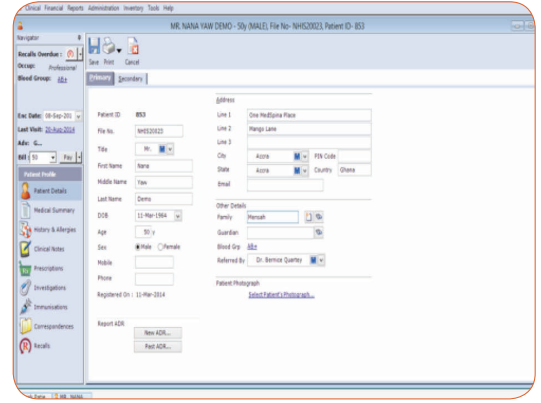
Country of origin | Ghana and India

## Health problem addressed

According to the WHO, about 80% of NCD deaths occur in low and middle income countries. Considering the fact that about 70% of people with diabetes and hypertension do not show symptoms, periodic monitoring is important for the early detection of these diseases as well as their prevention and control. Currently there are limitations on the data available to monitor NCDs.

## Product description

The Electronic Health Record (EHR) solution presented has the capability to improve the quality, safety, and efficiency of patient care. Its use can assist with medication safety, tracking, and reporting and eliminate concerns about the legibility of paper medical records. Its other advantages include the facilitation of improved communication between health care providers and the promotion of quality of care through optimized compliance with guidelines. Despite obstacles to widespread adoption in resource poor settings, use of the EHR as a real-time, evidence-based support tool can help busy healthcare providers increase the quality of the care they provide through improved care coordination, communication, and documentation.



## Developer's claims of products benefits

The state of patient safety and drug data management in low resource environments is one of an inefficient, paper driven, improperly documented business process. Where conversion to an electronic record has been attempted, the solutions have usually been complex, not customized for the local environment and generally difficult to adopt. This EHR brings a comprehensive, well designed, easy to configure and manage solution to these problems. This software solution is template based, with flexibility to adjust the business process to suit the existing flow and cause very little disruption.

## Suitability for low-resource settings

This ERH solution is ideal for public health clinics with little or no funding to afford such a technology on their own. Some of which include the HIV ART Clinic in Nigeria, HIV Clinic in Ghana, Chronic Care Clinic at the Korle-Bu Polyclinic, The Malaria Control Programme Clinics, The EPI Clinics. These are resource limited settings with weak and poorly linked health management and referral systems. Patient medical records are largely housed in a poorly coordinated file room which is usually very full and some patient medical records binders can be seen lying on the floors due to lack of space. Processes are largely manual, not properly documented and error prone. Patient health data is incompletely and inaccurately recorded, leading to inefficient decision making and poor program monitoring and evaluation.

## Operating steps

Pre-installation Readiness Assessment. Implementation Planning and Software Requirements Specification. Hardware requirements assessment. EHR installation and network configuration. Data Integration. Ongoing Training and Support. Continuous quality improvement

## Regulatory status

Adheres to HL7 and ICD10 standards.

## Future work and challenges

The intent is to make the EHR solution more available to health facilities and clinics in rural and low resource areas with little access to technology. This will require providing both the computers and software to run the system. The usage locations should have a continuous power supply or enough power to charge laptops to allow usage during work hours. Users should be computer literate as a pre-requisite and will be trained on the use and support of the system

## Use and maintenance

**User:** Patient, Physician, Technician, Nurse, Midwife, Pharmacist or Lab Technician

**Training:** Training by experienced product support team. Basic computer usage ability is a pre-requisite. Training will take approximately 5 days to become an expert user.

**Maintenance:** Scheduled, automated data backup by any trained support person

## Environment of use

**Setting:** To be used in Rural or Urban Indoor Settings and in Primary, Secondary and Tertiary Levels of Health Care

**Power source requirements:** Requires 240 V continuous power supply or for min 1.5 hrs to charge battery (battery life is 9 hrs)

## Solution specifications

**Software Requirements:** Runs on basic laptop or desktop computer.

**Retail price (USD):** It is sold at \$5000 per license which covers up to ten integrated users.

**Other features:** The software is configurable to the local

terminology of most intended users and uses. Supports English, Hindi, Bengali, Tamil

**Year of commercialization:** 2003

Currently sold in: Ghana, Tanzania, Uganda, Zimbabwe, Kenya, India

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

# Smartphone-powered cloud-enabled portable Electrocardiograph (ECG)

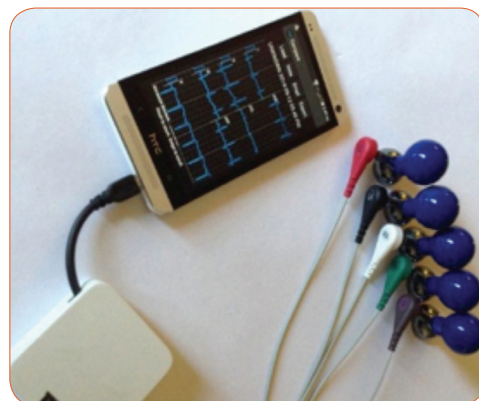
Country of origin | United States of America

## Health problem addressed

Thirty-two percent of all deaths are due to cardiovascular disease, 80% of which occur in low- to mid-income countries. By enabling remote telemedicine diagnostics, these smartphone-powered devices connect patients living in rural areas with cardiologists in urban settings. These higher quality diagnostics can enable physicians to make better decisions, leading to better outcomes.

## Product description

The technology is a low-cost portable electrocardiograph device that allows medical professionals to acquire ECG readings of patients with symptoms of cardiovascular disease. Medical professionals can then send readings to colleagues in remote facilities via a secure tele-cardiology system that allows doctors to view the ECG on their phones and laptops. The device is small enough to fit in the hand and weighs 40g; this extreme portability eases use for physicians who need to travel long distances and enables health workers to obtain ECGs when in remote locations lacking access to large traditional devices.



## Developer's claims of product benefits

The current 12-lead electrocardiographs are usually large, difficult to use, and require a stable source of electricity and expensive disposable electrodes. This device is 10X smaller, 10X cheaper, uses reusable electrodes and is powered by a smartphone or tablet. This system also enables remote telecardiology diagnoses.

## Suitability for low-resource settings

The device is intended for use in rural settings without access to stable electrical infrastructure, disposable electrodes, or even physicians who can interpret ECGs. The device is powered by the provider's smartphone, which can be recharged either beforehand or with solar panels, uses reusable suction electrodes and allows for secure telemedicine communication with remote physicians who are able to interpret the ECG.

## Evaluation

This technology was deployed in the Kisoro District Hospital in Uganda and was recently deployed to a hospital in Malawi. The device has been used by 10 physicians to diagnose 50 patients. The Kisoro Hospital suffers frequent power outages, and does not have access to disposable electrodes; however, the hospital does have physicians trained to interpret ECG results.

## Future work and challenges

Making and distributing these devices on a large scale will be a key challenge to improving global accessibility to ECGs. Building automated diagnostic algorithms and improving telemedicine features (such as MD crowdsourcing) could be useful in rural areas. Willingness to reduce the price of this device even further and support a larger range of devices by using Bluetooth wireless technology. These devices could be even smaller and lighter and would work with a larger range of smartphones (i.e. Android, iOS, Windows, Nokia).

## Use and environment

**User:** Physician, Technician, Nurse

**Training:** N/A

**Settings:** Rural, Urban, Outdoor and Indoor Settings and Primary, Secondary, and Tertiary level health centres

## Solution specifications

**Software, Hardware Requirements:** Access to a cellular network enables telemedicine features, but is not necessary for use

**Software Specifics:** smartphone app

**Currently sold in:** Uganda and Malawi

**Retail price (USD):** 300 USD

**Year of commercialization:** 2014



# Medical devices

## 2014

# Anaesthesia delivery for low resource setting

Country of origin | China

## Health problem addressed

Unsafe anaesthesia causes morbidity/mortality with the problem being more pronounced in developing countries. In developed markets, anaesthesia related mortality is approx. 11,700/yr. for a population of 1B and 138M surgeries. For developing nations, the anaesthesia related mortality is approx. 45,000/yr. for a population of 6B and 96.2 surgeries. A 6 times increase in population, but the number of surgeries is less by 40%. So there is still a large % of population with no access to hospitals with OTs.

## Product description

The proposed anaesthesia machine is a compact, integrated, and intuitive anaesthesia delivery system. The machine provides general inhalation anaesthesia and ventilatory support for patients during surgery as well as monitoring and displaying various patient parameters. The anaesthesia machine is composed of the anaesthetic breathing system, anaesthetic gas transfer and receiving systems, anaesthetic vapour delivery devices, anaesthetic ventilator, and accessories. The machine is lightweight and compact for easy manoeuvrability. The anaesthesia machine also offers enhanced monitoring capabilities (SpO2 monitoring) and advance ventilation that includes WYSIWYG (What You Set Is What You Get) Tidal Volume setting



## Developer's claims of products benefits

The offerings from the leading vendors are primarily targeted for use in areas where resources, both physical and economical, are not constrained. Also, they are targeted to address a broad range of health cases thus driving up the costs of the equipment & increasing the complexity of the equipment. Local players focus on cost reduction, more often than not, at the expense of quality, safety and reliability. In all these areas, this equipment outcores them

## Suitability for low-resource settings

**Infrastructure:** compact frame designed for mobility throughout the hospital. Extended battery life of up to 360 minutes, which allows continued work, even during extended procedures in unstable power environments.

**Training Effort:** decreases training effort with its intuitive design, straightforward User Interface, and an in-depth clinical training package that helps new users quickly acclimate to the machine's advanced features

## Regulatory status

The equipment is CE certified.

## Future work and challenges

Field trials are taking place in each of the target country/region. Anticipated challenges are in terms of underdeveloped infrastructure and personnel with reduced skill levels. The strategy to overcome the latter challenge is to educate the end user thoroughly about the product via focused trainings - both in theory and practice. The former challenge will be addressed feeding the learnings from the field trials into the next iteration of the product. Apart from this, there will be focused effort to train the personnel in the target areas on safe surgery practices and how the equipment enables them to perform the same

## Use and maintenance

**User:** Intended to be used by a physician or technician.

**Training:** The manufacturer's representative in the region where the equipment is planned to be used will provide the training. The manufacturer will provide all the equipment required. Time required is 2 days.

**Maintenance:** Calibration required at time of use, along with scheduled annual maintenance.

## Environment of use

**Setting:** Designed for use in indoor rural or urban settings in primary, secondary or tertiary levels of healthcare facilities

**Energy and Other Requirements:** Runs off either batteries or continuous power supply of 100-120V. Requires proprietary software, which ensures reliable working of the Anesthesia machine. Key functionality includes display, monitoring, ventilation, leak tests, self-tests & diagnostics. There is no specific license fee associated with the software. Necessary software for proper functioning of the machine is provided with every machine.

Pipeline input range: 280 kPa to 600 kPa/41 psi to 87 psi

## Product specifications

**Weight (kg):** 70

**Dimensions:** 1480mm x 900mm x 700mm

**Consumables:** Inhalation Agents, Delivery gases - O2, N2O

**Retail price (USD):** 10 000

**Other features:** The software, along with user manuals, is available in following languages:

English, French, Spanish, Portuguese, Turkish, Russian, and

Vietnamese & Indonesian. Breathing system auto-clavable at 134 °C

**Year of commercialization:** 2012

**Currently sold in:** India, Vietnam, Philippines, Malaysia, Indonesia, Singapore, Algeria, Nigeria, Kenya, Morocco, Senegal, Tanzania, Togo, Uganda, Cote D'ivoire, Honduras, Paraguay, Lebanon, Pakistan, Bangladesh

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



# Cooling mattress for neonates

Country of origin | India

## Health problem addressed

Birth asphyxia is the medical condition resulting from lack of oxygen in a newborn infant. It is a major cause of Hypoxic Ischemic Encephalopathy and consequential brain damage or even death. According to WHO data of 2012, birth asphyxia accounted for 10% of the deaths of children under 5 years old. Statistics of each country for 2010 is enclosed. Therapeutic hypothermia induced by cooling to around 33 °C for three days after birth is the prescribed treatment.

## Product description

The Cooling Device for Neonates is a low cost technology to induce therapeutic hypothermia among newborn infants suffering from birth asphyxia. It is a non-invasive, whole body passive cooling device, which works via conduction of heat from the newborn by a cool surface maintained at a constant temperature. The working principle behind the device is use of phase change materials (PCM) designed to melt/freeze at the temperatures which would ensure a temperature regulation of the infant between 33 and 34°C for up to 72 hours. PCMs do this by the virtue of their latent enthalpy at their melting/freezing temperatures. PCMs absorb heat from the baby thereby cooling the baby. The device uses two PCMs which has a melting/freezing temperature of 29°C and 21°C and an insulated cradle to place these PCMs. A gel bed is placed above the PCMs to give a comfortable surface for the baby.



## Developer's claims of products benefits

Several control instruments are used to cool the neonate currently and maintain the temperature between 33-34°C. These offer high accuracy but are very expensive. The proposed technology is 1/10th price of the servo control devices and still offers the same accuracy with the added advantage of portability, ease of use as no electronic components are involved. Ice packs are also used to cool the baby but they tend to overcool the baby leading to adverse side effects.

## Suitability for low-resource settings

The majority of deaths from birth asphyxia, occur in developing countries where the main resource constraint is money and availability of electricity. With the proposed technology, the cost has been reduced by 90%. The device cools passively using PCMs so makes access to a constant power source unnecessary. PCMs can be pre-cooled and stored for use when power is available.

## Operating steps

Pre-cool the PCMs FS-29 and FS-21 in a refrigerator for a period of 6-8 hours. Place the 3 pre-cooled PCM FS-29 slabs in the insulated cradle. On top, place 2 slabs of PCM FS-21. Place the gel bed above the PCMs. Place the complete set in the bassinet of a standard infant warmer. Place the baby over the gel bed. Use a rectal probe to measure the temperature continuously. If temperature decrease below 33°C, use warmer to increase temperature.

## Regulatory status

Although currently in India neither is required, the company has started the process of ISO 13485 and CE certification and is expected to receive both in the next 3-5 months.

## Future work and challenges

The major challenge is to bring acceptability and develop confidence for the product among the medical community. The company has adopted a three point strategy to make the product available across the globe. Products are being given free of cost to established hospitals/doctors locally and the results are being shared in medical journals so as to establish confidence. The company is setting up an effective distributor network across the Indian sub-continent, South East Asia and Africa to utilize the distributors already widespread reach in hospitals. Partnership with NGOs are being pursued so that treatment of birth asphyxia can be taken up as a social issue. Simultaneous pursuit of above paths will lead to quick accessibility.

## Use and maintenance

**User:** physician or nurse only

**Training:** no additional training required, follow user instructions provided with technology

**Maintenance:** No maintenance is required.

## Environment of use

**Setting:** Designed for use in rural or urban settings at primary, secondary or tertiary levels of health care facilities

**Facility and Energy requirements:** A domestic refrigerator is required for freezing the PCM; the temperature of NICU should be maintained above 25°C. Also requires basic facilities for monitoring the vital parameters of the newborn during treatment.

## Product specifications

**Weight (kg):** 13 kg

**Dimensions:** 620mm x 460mm

**Consumables:** None

**Lifetime:** 3 years

**Retail price (USD):** 1200

**Other features:** Able to maintain temp of 33.5 °C for a period of 72 hours as required

**Year of commercialization:** 2014

**Currently sold in:** India

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

# Infant radiant warmer for primary care

Country of origin | India

## Health problem addressed

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

## Product description

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



## Developer's claims of products benefits

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

## Suitability for low-resource settings

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

## Operating steps

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

## Regulatory status

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

## Future work and challenges

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

## Use and maintenance

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

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

**Maintenance:** No scheduled maintenance required

## Environment of use

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

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

## Product specifications

**Weight (kg):** 37

**Dimensions:** 1500mm x 800mm x 800mm

**Consumables:** heat reflector skin patch

**Lifetime:** 7 years

**Retail price (USD):** 1 500

**Other features:** mobile

**Year of commercialization:** 2014

**Currently sold in:** India, Malaysia, Indonesia, Vietnam

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# Infant resuscitation and suctioning device

Country of origin | India

## Health problem addressed

Nearly 2/3 of all newborn deaths (4 million annually) occur in 10 countries. Birth asphyxia is a leading contributor of neonatal deaths (23% of total neonatal deaths). Low birth weight & premature babies are especially prone to the same. Limited access to quality resuscitation devices & skilled care in low resource settings are big challenges. Urgent action is needed to address the issue of neonatal deaths and progress on MDG4, since 40% of under the age of 5 deaths are in newborns.

## Product description

Effective suction. Controlled resuscitation. One solution. The resuscitation and suctioning device is a compact solution for suctioning and resuscitation needs immediately after delivery. The device is completely gas driven and doesn't require electricity and suctioning works on the gas Venturi technique. The compact design doesn't allow for gas leakage and doesn't use any gas when switched off. It is mountable on the Infant warmer thereby providing a complete neonatal care solution with thermoregulation and resuscitation. One baby-One bed.

## Developer's claims of products benefits

The current standard of care includes bag & mask devices (no accurate pressure control), gas powered devices (not comprehensive). For suctioning the devices are manual (no clinical efficacy) or electrically operated and are bulky. This prohibits users from effectively delivering care to the patient. The device presented here is a compact unit that combines suctioning and resuscitation in a single unit making it really easy to use. It doesn't require electricity so is well adapted to low resource settings.

## Suitability for low-resource settings

An ideal solution for low-resourced clinical settings with poor infrastructure low skilled nurses, lack of space, low purchasing power. The compact technology combines suctioning and resuscitation in a single unit making it easy to use. It doesn't require electricity so is well adapted to low resource settings. It is affordable with low maintenance & service costs and also comes with the option of a reusable bag & mask accessories.

## Operating steps

Mount and fasten the unit onto (the dovetail rail) of an infant warmer. Keep the device in 'OFF' condition and fasten the oxygen hose to the backside of the device. Connect the suction tubing to the suction port; connect the oxygen tubing and bag & mask to the oxygenation port on the front of the device. Check the functioning of the device by switching it 'ON' and occluding the ends of the tubing and bag & mask devices. Use for suctioning & resuscitation as needed.

## Regulatory status

CE Certificate Number: CE01236. Notified Body Number:0086. ISO certification (ISO13485), EN ISO:10993. RoHS compliant.

## Future work and challenges

One of the obstacles is government specifications and tenders. The documents need to be updated with new technologies so that the product can reach the markets it is actually meant for. Product adoption, awareness, education, training, distribution to penetrate market

## Use and maintenance

**User:** Nurse or Physician

**Training:** Minimal training. Operator manual and product videos included with technology.

**Maintenance:** No scheduled maintenance required.

## Environment of use

**Setting:** Rural and urban indoor setting for all levels of health care in primary, secondary and tertiary levels of care

**Energy requirements:** Gas powered, oxygen supply of 40-80psi at 70 LPM

**Facility requirements:** e\Required an ambient environment within the ranges of 18-41°C and 0-90% RH

## Product specifications

**Weight (kg):** 3 kg

**Dimensions:** 140mm x 222mm x 195mm

**Consumables:** Adapters to connect oxygen hose, oxygen hose, dovetail mount, suction canister, bag & mask, oxygen tubing, infant masks.

**Lifetime:** 7 years

**Retail price (USD):** 600

**Price of consumables (USD):** 100

**Other features:** Adapters to connect oxygen hose, oxygen hose, dovetail mount, suction canister, bag & mask, oxygen tubing, infant masks.

**Year of commercialization:** 2014

**Currently sold in:** India and Countries in Africa and ASEAN



# Infant T-piece resuscitator

Country of origin | India

## Health problem addressed

Nearly 2/3 of all newborn deaths (4 million annually) occur in 10 countries. Birth asphyxia is a leading contributor of neonatal deaths (23% of total neonatal deaths). Low birth weight & premature babies are especially prone to the same. Limited access to quality resuscitation devices & skilled care in low-resourced settings are big challenges. Urgent action is needed to address the issue of neonatal deaths and progress on MDG4, since 40% of under 5 deaths are in newborns.

## Product description

T-piece resuscitation that is easy, economical to use and is designed for safety. The compact, T-piece resuscitation device with in-built air-oxygen blende is gas powered and allows for precise control of delivery pressures and accurate blending of air-oxygen to deliver to the patient. The compact design doesn't allow for gas leakage and doesn't use any gas when switched off. Being extremely easy to use (single PIP knob operation, etc.), the caregiver can focus his/her attention on the baby rather than managing equipment.

### Developer's Claims of Product Benefits

The devices available offering the current standard of care do not provide a comprehensive resuscitation solution. The bag & mask device is manually operated and doesn't provide accurate control of pressures and gas flows. Other gas-operated devices require additional components & accessories (e.g. blender, flowmeter, connectors) to operate efficiently. The Infant T-Piece Resuscitator is an integrated and compact device with a built in blender and flowmeter with simpler controls making it really easy to use and operate.



## Suitability for low-resource settings

This resuscitator works well in government district hospital that has semi-skilled nurses and limited infrastructure (frequent power outages, etc.). The Resuscitator is fully gas driven and doesn't need any electricity to operate. It is easy to use and is rugged & reliable thus making it very usable in low resource settings. It comes with a Quick reference guide that makes for quick reading and quick understanding for the operator. So far, the unit has been successfully deployed and tested across many pilot sites in India and in Malaysia. These range from small private clinics, district hospitals, mother & child hospitals. Clinicians found that the clinical outcomes were favorable and that their workflow became simpler compared to existing devices. Clinicians appreciated that the product would be exceptionally useful in rural settings.

## Operating steps

Ensure that the ON/ OFF the switch located on the front of the unit, is OFF. Connect the air and oxygen supplies to the rear of the device via hoses. Connect the T-piece to the gas port on the front of the device. Turn ON the ON/OFF switch and adjust the PIP and flow rate via the knobs to the required value. Resuscitate the patient.

## Regulatory status

CE Certificate Number: CE01236. Notified Body Number:0086. ISO certification (ISO13485), EN ISO:10993. RoHS compliant

## Future work and challenges

One of the obstacles is government specifications and tenders. The documents need to be updated with new technologies so that the product can reach the markets it is intended for. Product adoption, awareness, education, training, distribution to penetrate market are all part of the process to taking this product to market.

## Use and maintenance

**User:** Intended for use by physician or nurse

**Training:** Minimal training required, device is accompanied by operator manual and videos.

**Maintenance:** Will require blender calibration every 2 years

## Environment of use

**Setting:** Designed for use in rural and urban indoor settings for secondary and tertiary levels of health care facilities

**Energy and facility requirements:** Gas powered ( compressed oxygen and air)requires 40-80 psi, 70 LPM , also requires environment to be in eth ranges of 16-41°C and 0-90% humidity

## Product specifications

**Weight (kg):** 5 kg

**Dimensions:** 145mm x 313 mm x 222mm

**Consumables:** T piece apparatus

**Lifetime:** 7 years

**Retail price (USD):** 1 600

**Price of consumables (USD):** 100

**Year of commercialization:** 2014

**Currently sold in:** India, Malaysia, Brunei and Countries in Africa and ASEAN.

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# Infusion pump

Country of origin | United States of America

## Health problem addressed

Infusion pumps are in widespread use in clinical settings such as hospitals, nursing homes, and in the home for the delivery of nutrients, medications or fluids. A rugged and portable infusion pump can be a life-saving difference for those in need of infusions especially for areas of natural disaster or low-resource settings.

## Product description

Ruggedized rotary peristaltic design pushes fluid around a rotor providing positive pressure. Bag can be anywhere. All other pumps are linear peristaltic pumps, which require IV bag above the pump. Can be used in any axis, even upside down. All others break frequently and cannot take remote site abuse or extreme heat, cold or moisture.

## Developer's claims of products benefits

This pump is economic, doesn't break, can be in any position, bag can be anywhere, is simple to operate and lasts a very long time. Others have had many recalls, bag must be vertically above the pump, and often need repair.

## Suitability for low-resource settings

This device is economic, needs not maintenance, never breaks. Well suited for use in remote environments (for example in the North Slope oil well platforms, a doctor was able to use this technology to treat herself for cancer in Antarctic). Customers include Doctors Without Borders in Chad, and in Haiti by NYC Fire Department after the 2010 earthquake.

## Operating steps

According to the results of the Homeland Security test, the pump requires little training. Simply open the rotor door, insert the tubing, rotate the rotor and close the door. At this point the pump is ready for use.

## Regulatory status

The technology has had trials at Temple University (accuracy), Butterworth Hospital (accuracy & blood haemodialysis), Ohio State (accuracy), Navy Submarine Station (hyperbaric chambers, Genentech (TPA clinical trial)

## Future work and challenges

This current pump is ideal and proven for emerging market countries (ruggedness, simplicity, always works). Now working to come out with a modular three channel unit, much smaller in size (2lbs), modular pump in 2015 with added wireless and a drug library

## Use and maintenance

User: Can be used by the patient, physician, technician, nurse, midwife or family member

Training: Can be done by film, operating instructions or by company representative

Maintenance: Regular maintenance not required, the manufacturer, engineer or technician must do repairs.

## Environment of use

**Setting:** Designed to work in any healthcare setting or for home use

**Energy Requirements:** Runs off of either batteries which require 220V for recharging, or 12-24 DC.

**Software Requirements:** Proprietary Software required, used to operate the pump

## Product specifications

**Weight (kg):** 2

**Dimensions:** 110mm x 110mm x 180mm

**Retail Price (USD):** 2 500

**Price of Consumables (USD):** 6.50

**Other Features:** Works in temperature range of -10 to 120°C

**Year of Commercialization:** 1984

**Currently sold in:** US, Canada, Jordan, Syria, Egypt, Chad, Costa Rica, Brazil, Dubai



# Integrated respiratory blower & humidifier

Country of origin | New Zealand

## Health problem addressed

This technology aims to help irregularly breathing patients from infants, paediatrics, adults and the elderly requiring varying degrees of respiratory support in the forms of additional oxygen, pressure support, humidification, improving breathing efficiency, and or tolerance to therapy. This includes but not limited to: hypoxia, pneumonia, bronchiectasis, mucocytus, COPD, and other forms of chronic or acute respiratory illness.



## Product description

The device is a humidifier with an integrated flow generator that delivers a wide range of flow rates (2-60 L/min) delivering warmed and humidified respiratory gases, with or without supplementary oxygen, to spontaneously breathing patients through a variety of patient interfaces. The motor entrains room air and supplemental oxygen, if required. The integrated humidifier heats and humidifies these dry gases. A heated breathing tube connects to the device and carries warmed and humidified gases to the patient via nasal cannula or tracheostomy interface. Software controls flow and heating, adjustable by the user.

## Developer's Claims of Product Benefits

Typically respiratory supports in high acuity patients involve a ventilator with a humidifier and gas sources for air and oxygen. The new technology removes the need for a ventilator and air source by combining a blower and humidifier to support the patients across the acuity spectrum. It can also be used in low acuity settings providing O<sub>2</sub> therapy with the added benefit of humidification and the display of delivered O<sub>2</sub> fraction, which is only estimated in current practice

## Suitability for low-resource settings

The minimum requirement for the device to provide respiratory support via delivery of warmed and humidified air is electricity supply and clean water for the humidifier. No air supply is required.

## Operating steps

The user slides the water chamber onto matching ports and connects the breathing tube via a simple sleeve locking mechanism onto the device. Supplemental oxygen may be connected if required. The water level in the water chamber is automatically controlled via a float mechanism. The patient is fitted with a nasal cannula/tracheostomy interface to receive the warmed and humidified gases. The user sets the desired flow and temperature using push buttons to navigate the menu on the colour display

## Regulatory status

Complies with ISO 14971-risk management, ISO 8185 respiratory humidifiers, IEC 60601-1 electrical safety, IEC 60601-1-2 electromagnetic compatibility, ISO 10993-1 biocompatibility

## Future work and challenges

New therapies require time for market awareness in distribution channels and government recognition for reimbursement in each country's medical system. Increasing regulations and burden to comply are some of the challenges in making this device available in the market. Further education on awareness and benefits of new therapy and continued publications on therapy efficacy are some of the ways to make the technology more accessible

## Use and maintenance

**User:** Patient, Physician, Nurse or Family Member

**Training:** User manuals are sufficient for use of the device, however in home, and self-users, medical professional may be needed to provide some assistance

**Maintenance:** No routine maintenance required.

## Environment of use

**Setting:** To be used indoors either at home or in any level of health care facility

**Energy or Facility requirements:** Requires a continuous power supply of 230V. Also requires special software, which is proprietary and embedded within the device to control the device heating, flow, alarms, and display/menu settings. There is no software license fee. The facility must also have a clean water supply and if the patient requires, a wall supply of Oxygen.

## Product specifications

**Weight (kg):** 2

**Dimensions:** 295mm x 170mm x 175mm

**Consumables:** Breathing tube, humidification chamber, nasal cannula, air filter

**Lifetime:** 5 years

**Retail price (USD):** 3 000

**Price of consumables (USD):** 100

**Other features:** It is possible to change factory defaults for flow rate, temperature, oxygen alarm limits and a choice of 27 languages.

**Year of commercialization:** 2010

**Currently sold in:** Australia, New Zealand, USA, Canada, EU, China. Selected countries in South East Asia, Middle East.

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# Low-cost computed tomography scanner

Country of origin | China

## Health problem addressed

The Computerized Tomography Scanner is a front line modality for general imaging of multiple anatomical organs like brain, chest, abdomen, spine, blood vessels, and joints etc. It offers high spatial resolution along with the ability to complete a scan within seconds in most use cases that is vital to imaging time critical patients such as trauma and stroke.

## Product description

This low-cost innovation is a compact 16-slice CT scanner designed to provide exceptional image quality for all routine CT imaging needs and support advanced applications such as CT Angiography, Colonoscopy and Perfusion. With 0.35mm isotropic resolution and an array of dose reduction technologies the scanner delivers detailed visualization of patient anatomy and pathology at lower patient dose. The scanner is equipped with a console computer and dual monitors that hosts a simple user interface and essential advanced applications for 3D visualization, post processing, filming, and reporting.



## Developer's claims of products benefits

With Emergency Mode & Digital Tilt technologies, operators can position and scan patients much quicker on a CT385 scanner. Compared to previous designs, this CT scanner with digital tilt can be up to 23% faster for brain CT scans. Higher spatial resolution helps doctors see more detail and improve their diagnostic confidence. With a small footprint and minimal siting requirement of 10.1m<sup>2</sup>, this is one of the most compact 16-slice CT design systems and 16% smaller than previous 2-slice CT. An ecomagination rated product with Energy Save mode helps reduce power consumption by up to 41%. Lower powers input requirement by 20% compared to previous generation of 16-slice CT scanners. Remote service tools allow global service engineer online access to diagnose up to 30% of issues in a timely manner.

## Suitability for low-resource settings

The compact, 16-slice CT scanner that can fit in a minimal site space of 10.2m<sup>2</sup>. This is lower than previous generation and other 16-slice CT systems. A ecomagination rated product that consumes 40% lower power using an Energy Save mode. With broadband network the CT system can be connected to a remote service center for expert service engineers and applications support.

## Operating steps

This CT scanner has a one time power-up procedure after which patients are loaded on the patient table and operator positions the patient using the gantry control panel. The CT host computer allows the operator to select a scan, set scan parameters and complete the scan. The console software also allows viewing, post-processing, and reporting.

## Regulatory status

CE Compliant (IEC 60601-1-2), ROHS compliant, Japan Ministry of Health Approved, Regulatory clearance for sale in 146 countries as of July 2014.

## Future work and challenges

The business strategy is continued investment in developing more affordable CT scanners through new technical advancements in areas like detector, power electronics, and gantry mechanical design to name a few. In addition, we continue to address ease of use through simpler user interface and workflow development working with target users in tier II/III areas of emerging markets.

## Use and maintenance

**User:** Physician, Technician or Radiologist

**Training:** Initial training by manufacturer, and operator manuals

**Maintenance:** Requires regular maintenance 3 times annually by trained engineer, technician or manufacturer

## Environment of use

**Setting:** Intended to be used in secondary or tertiary levels of Health Care Facility

**Energy requirements:** Continuous power supply of 420V

**Facility requirements:** The CT scanner room temperature requirement is 18C to 26C and 30% to 60% RH. The scanner room size and shielding for X-rays should be as per local regulations

**Software Requirements:** The system includes standard operating software that is installed on a control computer. There are several software clinical applications that are optional and individual licenses are sold based on customer need.

## Product specifications

**Weight (kg):** 1700

**Dimensions:** 1783mm x 1741 mm x 921mm

**Retail price (USD):** 300 000

**Other features:** The user interface and workflow software is available in several regional languages. Dutch, French, German, Italian, Norwegian, Spanish, Swedish, Portuguese, Korean, Japanese, Turkish

**Year of commercialization:** 2012

**Currently sold in:** Many countries. Emerging market countries include Egypt, Morocco, Nigeria, Rwanda, Pakistan, Philippines, India, Myanmar, Cambodia, Vietnam, Bangladesh, Indonesia, Afghanistan, Turkey, Mexico, Columbia, Argentina, Ukraine (partial list)

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# Low pressure anaesthetic machine with pneumatic ventilator

Country of origin | United Kingdom

## Health problem addressed

Two billion people globally have no access to emergency or surgical care and conditions treatable by surgery account for 11% of the global burden of disease. In remote or rural locations and low-income countries anaesthesia machines may be non-existent, unreliable or unaffordable, preventing essential surgery. Anaesthesia is vital for surgical treatment of traumas, hernias, tumours, burns, infections, congenital deformities, and for life saving emergency obstetric care such as Caesarean sections.

## Product description

This complete anesthesia machine has been specifically designed to provide reliable inhalational anesthesia in difficult environments. It is easy to operate, economical to run and needs minimal maintenance. It can continue to function, without interruption, if either the oxygen or electricity supply fails. It consists of a versatile breathing system; a pneumatically driven ventilator; an oxygen concentrator (that supplies oxygen & air to the patient and to drive the ventilator); and an uninterruptible power supply for voltage stabilization and battery backup. It can be used in the operating theatre for anesthesia or in intensive care as a ventilator or as a source of pre and postoperative oxygen. The machine is suitable for both pediatrics and adults.

## Developer's claims of products benefits

Conventional anesthetic machines are designed for use in well-equipped hospitals in wealthy countries. Hospitals in many parts of the world have limited resources, no oxygen, electricity or technical support. In these circumstances, sophisticated anesthetic machines are unable to function. This machine has been designed to overcome all these problems and deliver safe, affordable anesthesia in the difficult conditions of low-resource settings. No expensive consumables of compressed gases are needed.

## Suitability for low-resource settings

The machine is designed to function in the most challenging low-resource settings including where supplies of electricity and compressed gases are unreliable or absent, there is no skilled technical support, environmental conditions are hostile (eg temperature, humidity, dust) and infrastructure is limited. The design incorporates many specific features to overcome all these problems. This machine is based upon an established anesthesia system that is known and respected worldwide as a safe and reliable machine for low-resource settings and which has proved itself by more than ten years of service in some of the most difficult locations around the world. Numerous publications refer to the successful application of this machine in low resource settings.

## Operating steps

Utilizing medical gases from the inbuilt oxygen concentrator, the patient can be anaesthetized and ventilated using the simple set up instructions. It is suitable for nurse anesthetists or anesthetic clinical officers.

## Regulatory status

Produced in an ISO 13485 certified factory. The product is tested to ISO 60601 -1 and is in the process of conformity assessments and CE marking.

## Future work and challenges

The technology will be demonstrated at forthcoming conferences in Africa, Asia and Europe. We will be co-authoring papers for publication in peer-reviewed journals.

## Use and maintenance

**User:** physician, nurse, anaesthetic clinical officer

**Training:** Machine comes with manual and training DVD films providing full instructions for operation and maintenance

**Maintenance:** Minimal maintenance required, can be performed on-site by technician or trained personnel

## Environment of use

**Setting:** Designed for use in rural, or urban, indoors settings and suited to use in primary, secondary and tertiary levels of health care facilities.

**Energy requirements:** The machine options based on resources available. It can run off batteries, which require a 160-290 V power supply for recharging or continuous power supply of 110-290 V.

## Product specifications

**Weight (kg):** 98 kg

**Dimensions:** 420mm x 660mm x 1450mm

**Consumables:** Anaesthetic agent only. Can be used with isoflurane and halothane, or sevoflurane

**Lifetime:** 10 years

**Shelf life:** 5 years

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**Retail price (USD):** 24 650

**Price of consumables (USD):** Based on chosen anaesthesia agent.

**Other features:** mobile

**Currently sold in:** more than 60 countries worldwide



# Mobile-enabled non-invasive measure-through motion and low perfusion pulse oximeter

Country of origin | United States of America

## Health problem addressed

Globally, 19% of all under-five deaths are caused by pneumonia, while 26% of neonatal deaths are caused by severe infections during the neonatal period, including pneumonia or the serious blood-borne bacterial infection sepsis. From a global perspective, approximately 7% of all neonatal deaths are attributable to major congenital malformations of which at least 25% are due to severe forms of CHD. Early recognition of these diseases could potentially improve and save many lives.

## Product description

The proprietary technology uses adaptive filters for real-time physiologic monitoring to accurately calculate arterial saturation and pulse rate. While other pulse oximetry technologies employ one, or sometimes two algorithms to attempt to measure a patient's arterial oxygen saturation, the non-invasive device uses multiple signal processing algorithms and is the world's first Measure-through Motion and Low Perfusion™ pulse oximeter for medical use, allowing clinicians to noninvasively track and trend oxygen saturation (SpO2), pulse rate, and perfusion index with select Android and iOS devices.



## Developer's claims of products benefits

Flexible and easy-to-use for spot-check of the following parameters: oxygen saturation, pulse rate, and perfusion index using a mobile smart device. Ability to use compatible reusable and adhesive sensors (for Adult and Pediatric patients). Display and share information using e-mail and smart phones and facilitates remote assessment and management of patients.

## Suitability for low-resource settings

Effective, affordable, and scalable pulse oximetry evaluation of adults and paediatrics, along with reliable follow-up in low-resource countries can significantly reduce infection-related paediatric death rates. The ease of usability and low maintenance can arm front-line health care providers with the most effective pulse oximeter that is accurate in challenging conditions of patient movement (common in paediatrics) and low perfusion.

## Operating steps

Insert the iSpO2 Rx connector into the power port of the smart device. Attach the sensor to the patient. The measurements will display on the smart device as a waveform measurement and numeric display. More details about attachment types and operational procedures can be found in the user manual accompanying the technology.

## Regulatory status

CE Marked in France, Italy, Germany, Spain, United Kingdom and other European countries.

## Future work and challenges

Increase functionality to a wider range of smart mobile devices, and develop new non-invasive parameter capabilities that can be easily accessed in low-resource settings. Continue to partner with health ministries to raise awareness and improve access to technologies, develop universal standardized training for end-users, and drive further adoption of mobile devices in low-resource settings.

## Use and maintenance

**User:** Can be used by patient or by any health care professional

**Training:** Group training by a local health partner (clinician, technician, nurse, other community health worker).

**Maintenance:** Prior to each use clean the sensor, cable and connector by wiping with a 70% isopropyl alcohol pad.

## Environment of use

**Setting:** Intended to be used in any setting or healthcare facility

**Energy requirements:** draws power from attached mobile device

**Software Requirements:** The Masimo iSpO2 Rx app for Android may be downloaded from the Google Play Store, and the app for iOS may be downloaded from the App Store

## Product specifications

**Weight (kg):** 0.07

**Dimensions:** 87mm x 3 mm x 2 mm

**Consumables:** disposable batteries, cable with sensor

**Lifetime:** 5 years

**Retail price (USD):** 490

**Year of commercialization:** 2014

**Currently sold in:** France, Italy, Germany, Spain, United Kingdom and other European countries

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# Neonatal bag-mask

Country of origin | Norway

## Health problem addressed

Around 10 million babies born annually need assistance to breathe, and for approximately 6 million of these babies basic resuscitation such as bag-mask ventilation is sufficient, without need for more advanced measures. Low-income countries account for over two-thirds of the world's neonatal deaths, and a large number of birth attendants need to be trained and have access to effective, affordable and therapeutic tools.

## Product description

The proposed solution is a reusable bag-mask for use in developing countries. It can ventilate newborns and babies up to 10 kg who need help breathing. It makes it easier to obtain mask seal and provide effective ventilations, with a new mask design and an upright stance of the bag. The bag volume is 330 ml and includes a pop-off valve, which limits the applied airway pressure to 30 to 45 cmH<sub>2</sub>O.



## Developer's claims of products benefits

The product has 7 parts including the mask (compared to 9 to 12 parts for current manual reusable bag-masks), which makes reprocessing faster, easier, and less prone to errors. The loop tab on the bag makes it easier to remove from the valve during disassembly compared to current bag-masks. Other technological improvements include improved mask sealing, larger bag volume, added convenience to storage and transport, and high-level disinfection in low-resource setting.

## Suitability for low-resource settings

The product can be used in any setting, and does not require any electricity or automated equipment. The product can be high-level disinfected by boiling with clean water, chemical disinfection, or steam autoclaving. The product was designed with 7 parts including the mask to improve speed and ease of reprocessing between uses.

## Operating steps

The Directions for Use (DFU) explains disassembly and reassembly, cleaning and disinfection, and testing before use. The bag-mask disassembles into 7 parts, reducing room for error with reassembly compared to other available products with more parts. After disassembly and cleaning, boiling, chemical solution, or autoclaving can disinfect the bag-mask. Before the bag-mask is ready for use, 4 steps must be performed to ensure that components are functioning correctly.

## Regulatory status

Meets ISO 10651-4:2002/EN ISO 10651-4:2009, Lung ventilators – Particular requirements for operator-powered resuscitators, for babies up to 10 kg. Newborn Mask - Snap design, fits connectors in accordance with ISO 5356-1:2004 - Anesthetic and respiratory equipment.

## Future work and challenges

This year, the CE marked product will be field tested in India by PATH ([www.path.org](http://www.path.org)) as well as in Tanzania at Haydom Lutheran Hospital. The product will be offered on a not-for-profit basis for use in 75 focus countries relative to the UN Millennium Development goals. In order to achieve sufficient implementation every user should be trained or re-trained and receive follow-up support in newborn resuscitation.

## Use and maintenance

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

**Training:** The product should only be used by persons who have received sufficient training in newborn resuscitation. This could be a one-day training program such as Helping Babies Breathe.

**Maintenance:** The product must be disinfected between patients.

## Environment of use

**Setting:** Designed for use in indoor urban and rural settings at all levels of health care facilities.

**Facility requirements:** The technology requires a clean water supply, temperature range of between -18 to 50 °C, and availability of some sterilization method, either boiling, chemical glutaraldehyde solution or steam autoclaving can be used.

## Product specifications

**Weight (kg):** 0.19

**Dimensions:** 72mm x 85mm x 217mm

**Consumables:** none required, reusable system

**Lifetime:** 5 years

**Shelf life:** 5 years

**Retail price (USD):** 20

**Other features:** reusable

**Year of commercialization:** 2014

**Currently sold in:** offered on not for profit basis to the 75 countries listed as focus countries relative to the UN MDGs.



# Non-invasive haemoglobin monitoring device

Country of origin | United States of America

## Health problem addressed

Anaemia affects more than 2 billion people globally, resulting in 1million deaths per year. Iron deficiency anaemia, is one of the top 10 risk factors contributing to the global burden of disease. It impacts quality and length of human life along with a country's social and economic development costing \$50 billion annually in GDP losses worldwide. Children, infants & women are most susceptible to anaemia, yet typically this population group has the least access to services & timely intervention.

## Product description

This device is an easy-to-use, lightweight, ruggedly designed handheld device that provides non-invasive and quick measurement of haemoglobin, oxygen saturation, pulse rate and perfusion index in approximately 1 minute, in virtually any environment. It takes only four simple steps to obtain all measurements. This device measures haemoglobin using similar principles as pulse oximetry with additional wavelengths of light. The device uses a sensor with multi-wavelengths of light to calculate functional oxygen saturation, haemoglobin concentration and pulse rate.



## Developer's claims of products benefits

Current devices require painful blood draw exposing workers to blood borne pathogens, calibration/QC testing, numerous supplies requiring special storage/handling, disposal of hazardous waste, & special training/certification. The monitor is a simple easy to use multi-parameter device that doesn't require special training, supplies, or calibration to measure SpO2, pulse rate and Hg all of which it does in approximately 1 minute without drawing blood. It can be used with infants, children & adults in any setting.

## Suitability for low-resource settings

This device is a small lightweight rugged handheld battery powered monitor designed to screen adults, children and infants for anaemia without painful blood draw virtually anywhere. Non-invasive measurement reduces fear of painful blood draws, no special handling/storage of supplies, helps addresses religious cultures concerns of blood draws, no special training required, & eliminates exposure to hazardous waste.

## Operating steps

Connect sensor to the monitor and turn the device ON. Select sensor size using finger size guide. Place sensor on finger, thumb or great toe (for infants). The Monitor will automatically provide SpO2, pulse rate, and perfusion index first. Press the SpHb (non-invasive haemoglobin) button when tone is heard. Haemoglobin measurement will be displayed. Record measurements.

## Regulatory status

CE Marked in France, Italy, Germany, Spain, United Kingdom, Sweden, Netherlands, Belgium, Finland, Austria, Poland, Portugal, Czech Republic, Latvia, Croatia, Slovakia, Greece, Slovenia, Romania, Hungary, Malta, Luxemburg, Ireland, Bulgaria, Denmark, and other European countries

## Future work and challenges

Noninvasively measuring haemoglobin empowers healthcare workers & patients across the globe, enabling them to easily identify & manage anaemia more proactively at the point of care anywhere, any time without a lab, technician or clinician. This allows a community screenings and permits health workers to focus to develop programs to address anaemia more effectively. Future work will also include education and training for both community members and health care workers of the importance of recognizing anaemia.

## Use and maintenance

**User:** Intended for self-use by patient, or by any health care provider

**Training:** Training can be accomplished individually or in groups. Material available: Operator's Manual, Quick reference guides, videos and webinars. Training takes approximately 30 minutes.

**Maintenance:** Prior to each use clean the sensor, cable and connector by wiping with a 70% isopropyl alcohol pad.

## Environment of use

**Setting:** Designed to be used in any setting, including outdoor use

**Energy requirements:** Battery operated

## Product specifications

**Weight (kg):** 0.37

**Dimensions:** 158mm x 76mm x 36mm

**Consumables:** Disposable batteries and sensor

**Lifetime:** 5 years

**Retail price (USD):** 600

**Price of consumables (USD):** 6

**Year of commercialization:** 2014

**Currently sold in:** France, Italy, Germany, Spain, United

Kingdom, Central and South America, Sweden, Switzerland, Turkey, Argentina, Australia, Canada, China, Japan, Finland, Guam, Hong Kong, India, Iraq, Israel, Italy, Jordan, Kenya, Kuwait, New Zealand, Nigeria, Qatar, Africa, Spain, US, Saudi Arabia, Belgium, Singapore, Norway, Sri Lanka

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# Oxygen reservoir filling system

Country of origin | United Kingdom

## Health problem addressed

Oxygen is essential in hospital wards and operating theatres, but a reliable supply is often lacking in low-resource settings. Oxygen is used in treating pneumonia, the biggest killer of children in the developing world, and other respiratory diseases. Access to oxygen can reduce mortality from childhood pneumonia by up to 35%. Oxygen is also essential for anesthesia, emergency medicine, shock, severe bleeding, and can be crucial to the survival of mothers with complications in labor

## Product description

A low cost solution for back up oxygen supply for use in the event of power failure and absence of cylinder or piped oxygen.

## Product functionality

The technology consists of a compressor pump designed to fill a reservoir vessel with oxygen from an oxygen concentrator. Oxygen concentrators generate oxygen from atmospheric air, a free and inexhaustible resource. The system enables this oxygen to be stored in either a 20 liter or 100 liter reserve tank to a pressure of 5 bar (75psi) giving 100 or 500 liters of usable oxygen. This can be used in the event of power failure or absence of oxygen cylinders for direct supply to patients. It can also be used to provide up additional back up supply to run the Glostavent® Anesthesia Machine.



## Developer's claims of products benefits

Hospitals in low-resource settings rarely have piped oxygen. Oxygen cylinders are expensive, difficult to transport, and run out. The only other alternative is oxygen concentrators that generate low-cost oxygen from air, but depend on electrical power that is notoriously unreliable in low-resource settings. This technology for the first time enables storage of oxygen generated by a concentrator when power is available for use during power cuts, thus ensuring essential oxygen is always available.

## Operating steps

The system is designed to be easy to use and does not require a skilled operator.

Connect the oxygen concentrator to the compressor pump inlet. Connect the compressor pump to reservoir vessel inlet. Plug in and run the concentrator, set flow to maximum. Switch on pump to fill reservoir vessel. Store oxygen in the reservoir vessel until it is needed.

### Regulatory Approval

In-house technical evaluation by manufacturer, an ISO 13485 certified factory.

### Evaluation in Low Resource Settings

This technology is intended for use in low-income countries and remote locations where gas cylinders are expensive and difficult to transport, and where electrical power supply is unreliable. An oxygen reservoir filling system, with four 100 litre storage vessels, was supplied to Bansang Hospital, in rural Gambia. The hospital reports the equipment is functioning well and is supporting critically ill patients in the Paediatric and Female wards. The hospital is keen to obtain further storage vessels, and the management report that the equipment is making an important contribution to improving the quality of care and reducing operational costs.

## Future work and challenges

The technology will be demonstrated at forthcoming conferences in Africa, Asia, the Middle East and Europe. We are co-authoring a paper for publication in peer-reviewed journals.

## Use and maintenance

**User:** Physician or Nurse

**Training:** Device comes with manual with full instructions for operation and maintenance, and a training DVD film

**Maintenance:** Minimal maintenance which can be performed on site

## Environment of use

**Setting:** rural and urban settings, indoors and in primary, secondary and tertiary levels of health care

**Energy requirements:** Requires a steady power supply of 12V for 2 hours in order to recharge.

## Product specifications

**Weight (kg):** 13kg

**Dimensions:** 20mm x 20mm x 330mm

**Consumables:** No consumables required

**Lifetime:** 5 months

**Shelf life:** 5 months

**Retail price (USD):** 2635

**Other features:** mobile

**Year of commercialization:** 2012

**Currently sold in:** So far sold for use in Benin, Burkina Faso, Gambia, Liberia, Malawi, and Nigeria.

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

# Pulse oximeter

Country of origin | Taiwan, China

## Health problem addressed

Each year, 31 million operations take place in low-resource countries without access to anaesthesia monitoring with pulse oximeters. The high cost and unsuitability of the oximeter models traditionally available have resulted in 70,000 operating rooms in these countries not having access to this technology, which is in standard use across high-income countries. In addition, 2.7 million children die each year in low-resource countries due to congestive diseases that result in hypoxemia. Early detection of hypoxemia is essential in reducing mortality and morbidity.

## Product description

A pulse oximeter is the most important monitoring tool in modern anaesthesia practice. It is a non-invasive device that checks the level of oxygen in a patient's bloodstream and sounds an alarm as soon as it detects the slightest unsafe change, thus avoiding hypoxia. This model is a robust hand-held device designed for use in low-resource settings where there is no access to constant electricity, biomedical engineering, consumables or replacement parts. It runs on rechargeable battery (as well as power), is available with reusable probes suitable for all ages, has a rotating screen for maximum clarity, as well as visual and audio alarms.



## Developer's claims of products benefits

Unlike other models, this has been developed specifically for use in low-resource settings. It is robust and reliable, and can be operated using either electricity (when available) or the rechargeable battery supplied with the oximeter. On a full charge, the battery will last for more than 14 hours. Unlike the devices traditionally available, this model is compatible with Nellcor probes and is very simple to use at low-cost. No calibration or servicing is required, making it ideal for settings where biomedical engineers and service personnel are non-existent.

## Suitability for low-resource settings

This model has been specifically designed for use in low-resource settings. It is robust and reliable, and can be operated using either mains electricity (when available) or the rechargeable battery supplied with the oximeter. On a full charge, the battery will last for more than 14 hours. Unlike the devices traditionally available, it is compatible with Nellcor probes and is very simple to use at low-cost. No training, calibration or servicing is required.

## Operating steps

This model offers a solution to the problem of how to effectively measure blood oxygen saturation and avoid hypoxia from anaesthesia and childhood pneumonia throughout the hospital in low-resource settings. Generic probes ranging from neonatal to adult provide accurate saturation levels, as well as heart rate monitoring (Quick Start Guide attached).

## Regulatory status

This model is CE marked (0434), meets FDA standards and conforms to IEC 60601-1 and ISO 9919, the international standard for pulse oximetry. In addition, the manufacturer must produce the units under conditions that meet the international standard ISO 13485:2003. The product and manufacturer have been independently examined by DNV GL and found to meet these standards.

## Future work and challenges

Reinforcing education will be one of the priorities for the future to make sure that the devices are used effectively. We are also looking at ways to strengthen the spare parts model to make sure that every hospital using a pulse oximeter will be able to procure the devices locally.

## Use and maintenance

**User:** Intended for use by physician, technician, midwife or nurse

**Training:** No additional training required

**Maintenance:** No scheduled maintenance required

## Environment of use

**Setting:** Can be used in rural and urban settings at any level of healthcare facility

**Energy requirements:** Requires a 100/220V power supply for recharging. Recharge time approximately 4 hours

## Product specifications

**Weight (kg):** 0.2

**Dimensions:** 123mm x 58.5mm x 28mm

**Consumables:** None

**Lifetime:** 2-5 years

**Shelf life:** >5 years

**Retail price (USD):** 250

**Price of consumables (USD):** 25 for probes, 10 for batteries

**Year of commercialization:** 2010

**Currently sold in:** Available for use in any country classified by the World Bank as low- or middle-income

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

# Trans-oral nasopharynx brush biopsy-quantitative PCR for epstein barr virus DNA detection

Country of origin | United of States of America

## Health problem addressed

Nasopharyngeal cancer (NPC) affects over 80,000 individuals a year globally with the vast majority in southern China, Southeast Asia, Arctic, and the Middle East/North Africa, most living in rural, less developed areas. NPC originates in obscure location of the head; lacks early signs and symptoms and often present to medical care very late with abysmal prognosis. Currently there is no suitable simple, inexpensive, non-invasive, field utilizable screening test for early detection



## Product description

The technology is a noninvasive early stage nasopharynx cancer (NPC) screening test that can be used in rural locations by trained healthcare workers. A sample of NP epithelial cells is collected painlessly by means of a swab of the upper throat area. The sample can then be preserved in room temperature and is analyzed for the presence of Epstein Barr virus DNA in the nuclear region of the cells. This technology is presently the only direct NPC screening test that is 99% accurate; specific in correlation with the diagnosis and able to identify NPC at its earliest stages, when treatment is most effective. Samples are easily collected and stored in remote communities, without a need for a visit to a medical specialist in a major city.

## Developer's claims of products benefits

Currently, non-specific blood tests to detect the presence of antibodies to EBV or EBV DNA in the blood are used. These tests simply measure the levels of a tumor marker indirectly; have much lower sensitivity and specificity and only detect cancer when tumor is large and therefore has no value for early stage cancer detection. In addition, these methods require specific sample preservations methods such as refrigeration that is not practical for testing of patients from rural areas.

## Future work and challenges

Cancer screening is an important public health measure. A major challenge to screening efforts is public education and awareness about the importance of screening, especially in the absence of obvious symptoms. Education and risk-awareness are crucial to success and provides a strategic platform for Oral Cancer (HPV) screening, which has a higher at-risk population. If the test is made available to a broader user group, it can be a model for simple, accurate, testing for virally-triggered cancers of the oral cavity of susceptible individuals in developing nations.

## Regulatory status

The ambulatory early stage screening test for nasopharyngeal cancer has been approved for sale under CLIA/FDA, in the USA, based on its 99% accuracy rate for detection of the disease (less than 1% false positive or negative). The test provides a direct measurement of whether or not epithelial cells from the nasopharynx have been infected with EBV and contain EBV DNA, indicating that the cells have been malignantly transformed. The DNA-based genetic assay is sold as a Laboratory Developed Test under CLIA (Clinical Laboratory Improvement Amendment- FDA) in USA, Canada and Hong Kong. Additionally, a Pre-Submission for Market Approval has already been filed with the FDA in the USA. This was submitted in order to establish further precedence for the virally-triggered cancer detection platform, so that it can be made applicable for other diseases.

## Suitability for low-resource settings

The circumpolar Inuit, Polynesians and rural North African villagers are at high-risk for nasopharyngeal cancer. A sparse population base, inaccessibility to medical specialists and low-availability of health care resources makes healthcare delivery impossible for these patients. This technology would allow early stage cancer screenings for patients in these remote locations at a fraction of health care cost and minimal dependency on specialists and health care infrastructures. The test is used in a number of primary care settings, both in Canada and Hong Kong. In addition, basic standards for training front-line healthcare workers, sampling methodology, and test procedures have been worked out for community hospital settings and doctor's offices in these locations, in anticipation of staging into more low-resource settings. The sample preservative technology is robust, eliminating the need for sophisticated temperature requirement such as dry ice or refrigeration.

## Use and maintenance

**User:** Intended to be used by a physician, technician, nurse or ENT specialist

**Training:** Persons required to use the tool will already have been trained on how to take samples.

## Environment of use

**Setting:** Designed for use in health care facility at all levels of care.

**Facility Requirements:** Requires an ambient environment to be within range of -30 to 40 °C, and requires mail/courier service

## Product specifications

**Lifetime:** single use

**Shelf Life:** 10 Months

**Retail Price (USD):** 300

**Price of Consumables (USD):**

**Year of Commercialization:** 2010

**Currently sold in:** US, Canada, Hong Kong

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

# Z-arm digital x-ray

Country of origin | People's Republic of China

## Health problem addressed

It provides state-of-the-art image quality, image post-processing, operator control, dose reporting and auto system check. These features make the system reliable and easy to use while providing high-quality radiographic images in a digital environment.

## Product description

This patented digital detector, which captures radiographic images in digital form, is an X-ray generator/power unit. An acquisition and review workstation for image post-processing, short-term storage, and quick in-room parameter setting are included. Images may be transferred manually or automatically via DICOM network for printing, archive and view.

## Developer's claims of products benefits

Z-shaped arm positioner allows for faster positioning and better reliability with a built in angle meter. This technology requires a lower patient dosage than other x-ray machines. It also had easy installation and less space requirements than traditional x-ray machines.

## Suitability for low-resource settings

The device is specifically designed for low resource settings. It is designed to be rugged: e.g. all mechanical movement are tested for over 200 thousand times to survive for 10 years, severe shipping test to simulate over 1200 miles truck transportation. Smaller size and room requirement. Full functionality and perfect DR image quality. It could get benefit for rural market, which has low resource condition.

## Regulatory status

Conforms to the requirements of Medical Devices Regulatory. Also certified ISO 13485&9001

## Future work and challenges

Future developments will include continue improving product quality, and looking for more opportunity to reduce product price and contribute to more basic healthcare areas and wish more countries could gain benefit from this innovative technology. The challenge is now to implement these strategies for a lower cost.

## Use and maintenance

**User:** Intended for by physician or technician.

**Training:** Application engineer of GEHC, for normal DXR, 8 hours of training required. 4 hours training for Z-arm Digital X-ray which is much shorter than other normal DXR product.

**Maintenance:** Annual maintenance required for proper functionality assurance.

## Environment of use

**Setting:** Intended to be used at all levels of health care facility

**Energy requirements:** Required 380V of continuous power supply

**Software Requirements:** Application software is designed base on Linux system by GEHC. Open source, no license fee needed. APP software could provide work list management, simplified auto protocol assistant and patient information management more than 600 User programmable APR which have improvements that make it easier to use by poorly trained technicians

Environment Requirements: +10°C- +35°C humidity range: 30% to 75%.

**Facility requirements:** Facility must have radiation Isolation capabilities and ability to the system to connect to a laptop or computer. Recommended minimum room area 25m<sup>2</sup>

## Product specifications

**Weight (kg):** 770

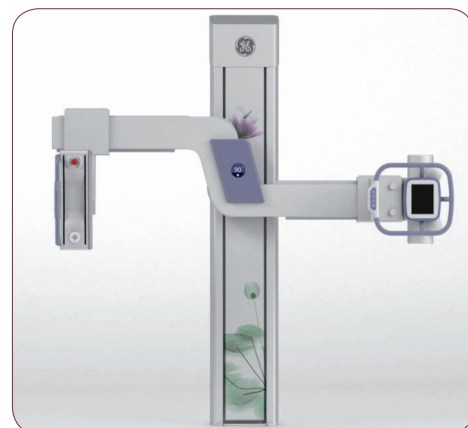
**Dimensions:** 2400mm x 2000mm x 2300mm

**Retail price (USD):** 150 000

**Other features:** The Software can be customized for local use including English and Chinese languages.

**Year of commercialization:** 2013

**Currently sold in:** China, Thailand, Myanmar, Malaysia, and Australia





# Other technologies

## 2014



# Breastfeeding simulator

Country of origin | People's Republic of China

## Health problem addressed

Breastfeeding is one of the most effective ways to ensure child health and survival. Globally, about 800 000 children could be saved annually if every child were optimally breastfed. Globally, less than 40% of infants under six months of age are exclusively breastfed.

## Product description

The product is intended to be worn by people. Along with an abstract exterior, the design enables both male and female health workers and trainers to feel comfortable while allowing an interactive role-play and “hands-on” demonstrations and practice.

When the user performs manual milk expression techniques, the breastfeeding simulator provides positive feedback by releasing droplets of water. The product contains two 500 ml bags in a skin-like neoprene textile that the user refills with water between sessions. These bags supply the liquid for the feedback mechanism and provide a realistic feeling of postpartum breasts.

## Developer's claims of product benefits

Existing solutions provide realism and feedback relative to the learning goals, but are costly (> 500 USD) and not portable. There are textile models that enable communication training through role-play, but are lacking in realism and feedback when the correct technique is applied. This solution provides anatomical realism, feedback, and training on communication skills through role-play at an affordable cost for large-scale implementation of training programs.

## Suitability for low-resource settings

The product is intended for large-scale deployment of maternal and child health education programs. It is highly affordable so that NGOs can purchase large quantities for large-scale classroom learning. It is not only a demonstration tool, but also meant for individuals to role-play and practice. It is designed to be highly mobile, so that trainers can easily move it to different training sites and facilities for teaching.

## Operating steps

Fill bags with 500ml of water each. Use belt straps to secure to body. Practice skin-to-skin care or manual milk expression. Let the simulator be available for retraining, or empty water bags for convenient transport.

## Regulatory status

Although the simulator does not require regulatory approval, it has been tested according to the manufacturer's and developers' internal requirements and quality standards (lifetime testing, durability, material compatibility, etc.).

## Future work and challenges

Future work involves large-scale deployment of maternal and child health education programs

## Use and maintenance

**User:** Intended to be used by Physician, Midwife or Nurse for Training Purposes

**Training:** Various NGOs will provide training, integrated as part of larger maternal and child health training programs.

**Maintenance:** Wipe down, and filling of water tank, after and before each day of use.

## Environment of use

**Setting:** Can be used in any setting or level of healthcare facility

**Facility requirements:** Clean water supply

## Product specifications

**Weight (kg):** 300mm x 270mm x 170mm

**Dimensions:** 0.29

**Consumables:** None

**Lifetime:** 3 years (at least 3,000 cycles)

**Retail price (USD):** 58

**Year of commercialization:** 2014

**Currently sold in:** It is offered on a not-for-profit price to the 75 countries that have been identified by UN as focus countries relative to MDG 4 and 5.



# Healthy newborn kit

Country of origin | India

## Health problem addressed

Every year, four million infants die in the neonatal period (within 28 days of birth). Of these, three million new-borns die in the first week of life. In many high neonatal mortality settings, mothers and new-borns do not have access to the basics of post-partum newborn care (thermal care, infection prevention, and feeding support), increasing risk for preventable but life-threatening infection. India has the highest number of under-five deaths



## Product description

This simple, low-cost technology addresses the main preventable causes of newborn mortality (hypothermia, infection and asphyxia) by providing a “one stop shop” for basic tools and education to ensure health of baby during the early neonatal period. The kit contains essential commodities recommended by the WHO to ensure infection reduction (e.g., bath soap, mucous extractor, Chlorhexidine gel for cord care) and thermal care (e.g., thermometer, receiving blanket, hat). The kit also includes educational tools for both the mother and health worker (e.g., pictorial newborn care guide, tips on kangaroo care and breastfeeding)

## Developer's claims of product benefits

Currently, no convenient, comprehensive or cost-effective newborn kit on the market exists that meets the unique needs of resource-poor settings, and specifically promotes globally recognized best practices. Due to staff/supply shortages in healthcare facilities, individual components are often unavailable, forgotten, or reused without proper sterilization. This customizable kit addresses local/cultural/facility-based needs, providing ALL essentials tools together in the right place, right time.

## Suitability for low-resource settings

This kit addresses major barriers to proper newborn care, while taking into consideration local factors ranging from harmful traditional practices to institutional bureaucracy. The kit simplifies procurement for health facilities and is more affordable compared to purchasing components separately. This educational tools address specific cultural issues that deter parents and health workers proper, recommended care (e.g., using old rags to cloth baby, applying oil/mud on the cord, etc.).

## Operating steps

Open kit; find all tools needed for essential neonatal care. Use soap to clean baby; thermometer to check for hypothermia; Chlorhexidine to rub on the umbilical cord, clean hat and blanket to keep baby warm, etc. (all basic tools familiar to health workers). Check pictorial guide/mobile phone training for instructions on product use if needed. Health worker gives educational tools to mother.

## Regulatory status

The Healthy Newborn Kit was recently accepted as a commitment to the Every Newborn Action Plan. The UN Health Envoy has recognized the kit as a “high-impact commodity that can improve newborn health and survival.

## Future work and challenges

A large need exists for awareness and advocacy around best practices, particularly the use of Chlorohexidine (given the Indian policy on dry cord care and other traditional practices such as using oil and mud). This kit is accompanied as well, by a mobile phone training program intend to be use as a method for educating health workers and mothers on recommended best practices.

## Use and maintenance

**User:** Intended for use by mother with explanation and training from a Physician, Nurse or Midwife

**Training:** Pictorial guide, Mobile voice message training (optional)

## Environment of use

**Setting:** Intended to be used in primary and secondary health care facilities

**Facility requirements:** Clinical Waste Disposal Facilities to dispose of products with blood. Access to mobile phone network is ideal but not required.

## Product specifications

**Weight (kg):** 1

**Dimensions:** 300mm x 170mm x 90mm

**Consumables:** Underpad, mucous extractor, scalpel, cord clamp

**Retail price (USD):** 5.99

**Price of consumables (USD):** xx

**Year of commercialization:** 2015

**Currently sold in:** India

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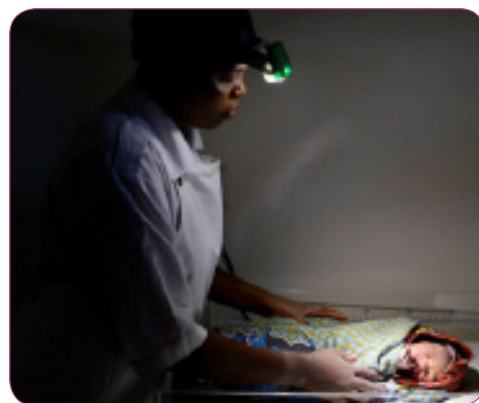
[http://www.who.int/medical\\_devices](http://www.who.int/medical_devices)

# Task and room light for health workers

Country of origin | People's Republic of China

## Health problem addressed

Health workers working in resource limited settings struggle with poor illumination while performing critical duties like delivering new-borns and emergency care for new-borns and mothers. They often rely on sources like candles and gas lamps or cheap electric torches which often are unreliable, unsuitable and in need of assistance. There is also a need for a focused beam of light for birth-related activities like vaginal inspection, noting cervical dilatation, etc.



## Product Description

A compact, rechargeable light with a narrow focused task light, and ambient light with three brightness levels each. Shine times range between 4 to 70 hours on full charge and selected mode of brightness level. Lamp can be worn on head, neck, hung from roof or as a table lamp with simple accessories. It is rechargeable from main grid or solar panel through a micro USB port. When charged, it can also be used to as battery boost to the mobile phone. Lithium ion battery allows for long shelf life and a large number of recharge cycles.

## Developer's claims of products benefits

This product is more robust, easier to use, and more affordable to maintain than other lights available in low-resource settings. This model does not require dry cell batteries. It can survive a 1m-drop. The bright focused light and hands free usage make it appropriate for lighting during medical procedures. It can be also used as an emergency power source to charge cell phones

## Suitability for low-resource settings

Li-ion batteries with long shelf life, provides a maximum burn time of 70 hours. It is easy to recharge through grid using a micro USB port (even intermittent supply) and solar panel. This also can prove useful for emergency recharge of mobile phone battery. This light is easy to use with multiple light modes and usability features. Durable and robust casing for weather resistance.

## Regulatory status

Is CE-marked.

## Future work and challenges

A distribution channel that works to get the lights in the hands of the intended target users is the biggest challenge. It may happen through government procurements for its public health workers or through organised channel partners in the domain. Customs duty for imports into certain nations may add to the cost of the product.

## Use and maintenance

**User:** This task light is designed for all health care personnel

**Training:** None

**Maintenance:** Requires only regular cleaning and charging

## Environment of use

**Setting:** The task light can be used anywhere, in any setting

**Energy Requirements:** Required power supply to recharge: 100V for 3 hours. If by solar power, requires 4 hours sunlight. Or continuous power supply of 5V. Expected battery life is 70 hours.

## Product specifications

**Weight (kg):** 0.3

**Dimensions:** 70mm x 70mm x 35mm

**Consumables:** None

**Lifetime:** 5 years

**Retail Price (USD):** 19

**Other Features:** can be wall mounted, attached to a head/strap or table/mounted

**Year of Commercialization:** 2014

**Currently sold in:** Rwanda, India

# Technologies for outbreaks

## 2014

# Alcohol & chlorine free sanitizer

Country of origin | United Kingdom

## Health problem addressed

This sanitizer is a highly technical sanitizer that aims to address the problems such as Norovirus, C-diff, Ebola, Flu, Swine Flu, MERS etc.

## Product description

An alcohol and chlorine free sanitizer consisting of a blend of technical quaternary ammonium compounds, biguanides and surfactants. It comes in many different formats, such as wipes, hand hygiene, sprays and air fogging. It is safe to use on all surfaces, and has a residual barrier of up to 18 hours.

## Developer's claims of products benefits

This sanitizer could be more beneficial over chlorine and alcohol. Chlorine is very harmful to the environment, skin, and health and is also very costly, hard to store and transport. Also once mixed it has a short shelf life. Alcohol causes skin irritation, can't be used in prisons, mental health institutes etc. It is widely documented that alcohol isn't effective against most viruses. This sanitizer was independently tested against Ebola.

## Suitability for low-resource settings

No training or skill set required to use, easy to store, easy to apply, and both chlorine and alcohol free, effective and reasonably priced.

## Operating steps

Little explanation required, use according to product package instructions.

## Regulatory status

Tested by BluLab, ALcontrol Laboratories, BluScientific, and other laboratories.

## Future work and challenges

This product has been fully developed tested and is on the market. Future steps will be expanding the market.

## Use and maintenance

**User:** This product is intended to be used by anyone in a medical setting

**Training:** none required

**Maintenance:** none required

## Environment of Use

**Setting:** The sanitizer can be used in any setting and at any level of care

**Energy or Facility Requirements:** None

## Product specifications

**Shelf Life:** 3 years

**Available Products:** surface spray, wipes and fogging agents.

**Retail price (USD):** 600 mL hand sanitizer- 9.20 Bulk Surface Wipes - 56.80, Surface Spray - 11.65

**Year of commercialization:** 2014

**Currently sold in:** United Kingdom





# Autoclave powered by solid fuel

Country of origin | United States of America

## Health problem addressed

Surgical Site Infections (SSIs) are the most common type of infection experienced by patients. In rural settings, electric autoclaves help prevent these infections, but are expensive or impractical for hospitals to buy, maintain and use. This autoclave ensemble addresses the needs of patients and practitioners for clean medical supplies in off-the-grid health centres or emergency locations. The ensemble can also be used for the sterilization of medical waste for a cleaner environment.

## Product description

The stove is fitted with an adapter ring that allows the autoclave to be powered by this super-efficient, institutional-sized, biomass-burning stove. The autoclave sits within the stove-body receiving heat simultaneously from both below and 360 degrees around the sides the unit by a biomass fire in the combustion chamber below. Super-efficient combustion of biomass produces a minute amount of smoke. Further, any smoke produced is expelled through an attached chimney that can be configured for both indoor and outdoor use. The stove remains safe to touch at full temp. As little as 1 kg of wood is enough to power the stove ensemble for a cycle. Ensemble is easily transportable.

## Developer's claims of products benefits

Most existing autoclaves use electricity, making them expensive for off-the-grid health centers that must use a generator to run them. Furthermore, most waste is burned or unhygienically disposed-off. This system harnesses the most fuel-efficient, institutional rocket stove on earth and uses one tenth the fuel to complete a sterilization cycle in under an hour. It is faster, safer, more efficient, and more environmentally-sound than alternative technologies for sterilizing equipment or waste.

## Suitability for low-resource settings

This autoclave uses solid fuel as an energy source (e.g. wood, briquette, other biomass) and is appropriate as a primary autoclave system for rural healthcare centers (hospitals, clinics), or as a backup system for urban centers. Its fuel-flexibility, efficiency, ease of use, dependability, minimal environmental impact and minimal operating costs make it appropriate for any low-resource situation.

## Operating steps

Insert adaptor ring on stove, prepare and load autoclave for sterilization cycle. Start fire in combustion chamber. Insert sterilizer, bring to pressure, following venting protocol. Time sterilization cycle. Remove sterilizer from stove. Vent remaining steam from unit.

## Regulatory status

FDA Registered (Food and Drug Administration)  
And ISO 13485 (Medical Device)

## Future work and challenges

The biggest challenge is overcoming mind-sets: that burning is an appropriate waste-management practice, that electrical technology is the best in developing world settings, and that environmental health should be a consideration of any health centre.

## Use and maintenance

User: Any trained personnel

Training: Training is possible either by watching a video or by reading the instruction manual and following directions

Maintenance: Combustion chamber cleaned of ash after each use

## Environment of use

**Setting:** To be used in rural or urban settings, either indoor or outdoor at any level of healthcare facility

**Facility Requirements:** Clean water supply and access to solid fuel

## Product specifications

**Weight (kg):** 56 kg

**Dimensions:** 880mm x 610mm x 980mm

**Consumables:** biomass fuel (firewood, coal, pellets, etc.)

**Lifetime:** 10 years

**Retail price (USD):** 1600

**Price of consumables (USD):** variable

**Other features:** mobile

**Year of commercialization:** 2011

**Currently sold in:** Worldwide



# Bleach dilution gauge

Country of origin | United Kingdom

## Health problem addressed

A fundamental aspect of managing Ebola within healthcare facilities is the daily preparation of bleach solutions: a 1:10 bleach solution for disinfecting bodies; a 1:10 solution for surfaces, medical devices and personal protection equipment. Current WHO guidance advocates the use of a cup measurement system or scratch-marking of levels inside buckets. This simple device reduces variance in practice, minimises human error and improves process efficiency.

## Product description

A Bleach Dilution Gauge to aid the rapid measurement of 1:100 & 1:10 bleach concentrations for disinfecting bodies, surfaces and personal protective equipment

## Product functionality

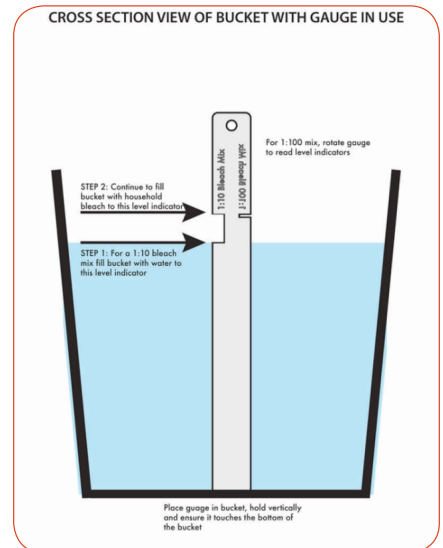
A single component product, laser cut from 3mm PE plastic sheet.

A 'flat' product to minimize associated supply and distribution costs.

A minimal product to minimize associated production costs

Flexible manufacturing allows for production of bespoke gauges/ calibrations to match procurement contracts, variance in buckets & draft angles etc.

Product's 'indentations' provides a visual indicator of water and bleach fill levels for 1:10 & 1:100 dilution mixes.



## Developer's claims of products benefits

The tool standardises practice, improves accuracy and reduces repetition. The Dilution gauge is an improvement over current WHO recommendations as it eliminates the following current problems with the cup-measurement system:

1. reduces variance of infection prevention practices.
2. first attempt is likely to be unsuccessful as container size requires judgement to ensure that full capacity of bucket is reached
3. accurate measurement of a 10th of a cup is problematical for a 1:100 mix
4. reduces the repetition of filling a bucket using a small capacity container

## Future work and challenges

Variance in bucket dimensions and their capacities has been identified as a potential challenge but deliberately responded to through the selection of a flexible manufacturing process to accommodate customer needs: differing bucket sizes, capacities etc.

## Use and maintenance

**User:** physician, technician, nurse, midwife, family member

**Training:** none required

**Maintenance:** none required

## Environment of use

**Setting:** Designed for use in rural, urban, indoor, outdoor and at primary, secondary and tertiary levels of care

**Energy and Facility Requirements:** Clean water supply, and a bucket with minimal taper

## Product specifications

**Dimensions:** 300mmx 30 mmx3 mm

**Consumables:** none

**Retail price (USD):** 1 USD

**Year of commercialization:** 2014

**Currently sold in:** New to Market

# Disposable patient transfer sheet

Country of origin | United Kingdom

## Health problem addressed

During a typical shift, on average a hospital staff nurse will lift 20 patients into bed, and transfer 5-10 patients from bed to a chair. Lightweight and inexpensive but high quality and immensely strong - as well as assisting in the prevention of cross infection, the Disposable Patient Transfer sheet has been designed to make patient handling both easy and safe, helping prevent back strain and injury to the staff transferring patients and is single-use thus reducing cross-contamination



## Product description

This product is a single use patient transfer slide sheet ideal for departments across the hospital and to help reduce cross-contamination. This can be used in a hospital, nursing home or community setting to avoid lifting patients manually any more. It is acceptable to give a patient some support, or to perform horizontal moves with a sliding aid, if this is done according to agreed safer handling principles.

## Developer's claims of products benefits

A few reports in the literature have suggested that textiles may have been the source of patient infections, including staphylococcal and Bacillus cereus colonization, infection in newborns and antibiotic-resistant organisms. Single-use textiles are used daily as protective barriers in a majority of hospitals. In today's healthcare environment, safety, barrier qualities, cost and infection prevention are key words of supreme importance in patient care. Single-use products meet these challenges.

## Suitability for low-resource settings

The RCN looked at the relative expense to introduce such devices into everyday practice. They found that hospitals have traditionally assumed that it would be far too expensive to provide enough handling equipment to even consider a radical change in lifting policy. In fact, costs are not that great and the cost of not tackling the issue is likely to be much greater. There are additional and potentially very high costs associated with the problems of reusable linen used for manual handling.

## Operating steps

Start with single use transfer sheet under supine patient. Two staff stand on one side, roll the patient onto the side, staff at the opposite side to insert the patslide under sheet. With a walking stance, two staff push supine patient to the middle only. Two staff pull supine patient over to the receiving surface.

## Regulatory status

The product is produced in an ISO-9001 registered facility. It holds CE certificates and technical files. The product, registered with the Department of Health and this CE number with the MHRA is CA 012543. The European Declaration of Conformity Certificate is attached.

## Product functionality

No one working in a hospital, nursing home or community setting to avoid lifting patients manually. It is acceptable to give a patient some support, or to perform horizontal moves with a sliding aid, if this is done according to agreed safer handling principles. The use of transfer assist devices must be considered as a possible source of infection or contamination of workers' hands; consequently, these devices should be suitably designed and made of appropriate materials. This product is single-patient use to reduce cross-contamination.

## Future work and challenges

Supply of product to low-resource settings requires activities of transportation, procurement, inventory control, distribution management, and customer service. Distributors will only make a limited commitment to creating the new product market, because at some point the supplier may choose a different distributor or go direct. Therefore the new product markets are never fully developed in this route to market. The distributor simply delivers other companies ideas and generally only reacts if someone else has already done so. They can be reactive and expensive and do not necessarily add value for the end customer

## Use and maintenance

**User:** Intended for use by physician, technician, nurse, or midwife

**Training:** Minimal training required as device is easy to use and understand

**Maintenance:** None

## Environment of use

**Setting:** Rural, Urban, Outdoors, Indoors, and in Primary, Secondary and Tertiary Levels of Care

**Energy and Facility Requirements:** Incineration Facilities

## Product specifications

**Weight (kg):** 0.1kg

**Dimensions:** 850mm x 1000mm x 1mm

**Lifetime:** 10 years

**Shelf Life:** 10 years

**Retail price (USD):** 3

**Other features:** Single-use technology

**Year of commercialization:** 2013

**Currently sold in:** Europe

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# Formaldehyde gas sterilizer

Country of origin | Japan

## Health problem addressed

It is common knowledge that the sterilization of medical equipment parts is very important in infection control. Sterilization is mainly performed using Autoclave. Non-heat-resistant items such as endoscopes must be sterilized using low temperature gas sterilization such as ethylene oxide (ETO) gas. However, ETO gas must aerate over a long period of time to secure safety. It requires 24 hours or more, and in some countries its emission is the subject of regulations due to toxicity.

## Product description and functionality

This device sterilizes using formaldehyde gas produced by vaporising 12% aqueous formalin solution in a chamber set to 50 degrees Celsius and adjusting pressure from -0.08 Mpa to -0.01 Mpa. The residual gas after the sterilization is decomposed and detoxified by the oxidation reaction of the catalyst. It uses the ammonia which vaporized it as a purification accelerant in this process. Therefore, it does not directly emit formaldehyde gas into the environment after sterilization



## Developer's claims of product benefits

Non-heat-resistant items must be sterilized with a low temperature sterilizer. But, ETO gas and H<sub>2</sub>O<sub>2</sub> gas are expensive, and difficult to obtain in some regions and countries. Above all, It must aerate over a long period of time to secure safety. It requires 24 hours or more. This product uses formalin, which is cheap and can be obtained easily in many countries and areas, as a sterilization medium. The processing time is 310min. It can be operated several times in a day. It doesn't require special training

## Suitability for low-resource settings

The formalin solution used as a sterilization medium is cheap and easy to obtain, as is the ammonia used as a purification accelerant for the gas decomposition. The device is powered only by electricity, so it does not need steam or water supply and drainage. Therefore, installation is extremely simple. It requires a stable electric supply, but the device is sealed in case of a blackout, and has infallible gas leak safety measures.

## Operating steps

Push the power button, Open the door of chamber, Close the door after putting the sterilizing objects in the chamber, Push the start switch of the touch panel. After the processing, open the door and take the sterilizing objects.

## Regulatory approval

It is approved by Ministry of Health, Labour and Welfare Government of Japan and ISO-13485

## Future work and challenges

A small-sized 100V formaldehyde gas sterilizer is planned, and we intend to make it operable by battery.

## Use and maintenance

**User:** Nurse, Midwife, Cleaning Staff

**Training:** The distributor performs simple handling explanation at the setting place for about 15 minutes.

**Maintenance:** NA

## Environment of use

**Setting:** Rural and Urban Settings, Indoors, Primary, Secondary and Tertiary levels

**Energy requirements:** Continuous power supply of 200V for 6 hour recharging

**Facility Requirements:** System requires an air exhaust duct

## Product specifications

**Weight (kg):** 460kg

**Dimensions:** 840mm x 940mm x 1745mm

**Consumables:** Formalin 12% solution and Ammonia 9% solution

**Lifetime:** 10 years

**Shelf Life:** 10 years

**Retail price (USD):** 161,000

**Price of consumables (USD):** 3

**Other features:** Once installed, can be a mobile unit

**Year of commercialization:** August, 2008

**Currently sold in:** Russia, Saudi Arabia, United Arab Emirates, Vietnam. Malaysia, Singapore, China, Korea and India



# Inexpensive cleaning and sterilization kit

Country of origin | United Kingdom

## Health problem addressed

Decontamination should begin as soon as the medical instrument has been removed from the patient. This system comprises of an all-in-one Channel Cleanser and gauze designed for the initial flush and wipe of an instrument in a sachet and tub. It also combines a sachet of detergent for a thorough manual clean, with a cleaning brush, together with a sachet of peracetic acid for the disinfection of the equipment. All you need to do is just add water!

## Product description

This system combines all the elements required to completely clean and disinfect a medical instrument and consists of a number of sachets and cleaning brushes to achieve this in a simple and cheap way. During clinical use, medical instruments are contaminated by multiple microorganisms, and failure to appropriately reprocess and handle such equipment can result in nosocomial outbreaks and serious infections. The system offers the ability to pre-clean, manually clean and finally to disinfect such equipment in an easy and affordable way. The system is simple, and only requires the user to add water to activate the three stages of total cleaning and disinfection.



## Developer's claims of products benefits

The system provides a high level of standardization and repeatability for the handling of medical devices and other delicate equipment and fills an important gap in the device reprocessing cycle offering a total product solution when only manual systems can be employed and no automated reprocessing machines are available. It has the features of providing a complete cleaning and sterilization cycle at an advantageous price.

## Suitability for low resource settings

With the number of procedures growing around the world, it is vital that medical devices are processed correctly in order to keep patients and staff safe from the spread of infection. Along with adhering to rigorous cleaning and decontamination practices, proper cleaning and sterilization of expensive, delicate instruments are crucial to ensure patient and staff safety and maintain optimal function. This product provides a cost-effective solution for the safe cleaning of medical instrumentation.

## Operating Steps

Open first sachet and put wipe in tub. Add water to activate the detergent concentrate. Wipe and flush the instrument as appropriate. Place instrument into a sink and empty the contents of the detergent sachet. Manually clean the instrument with the brush provided. Rinse the instrument. Empty peracetic acid sachet into a fresh sink of water. Disinfect the instrument for the prerequisite amount of time.

## Regulatory status

The product is manufactured in the UK providing high quality products and enabling close control of the manufacturing process. It is produced in an ISO-9001 registered facility and holds a CE mark number MHRA is CA 012543.

## Future work and challenges

Supply of product to low-resource settings requires activities of transportation, procurement, inventory control, distribution management, and customer service. Distributors will only make a limited commitment to creating the new product market, because at some point the supplier may choose a different distributor or go direct. Therefore the new product markets are never fully developed in this route and the market route can sometimes be expensive without adding value to the customer.

## Use and maintenance

**User:** physician, technician, nurse

**Training:** intended users will already be familiar with cleaning and sterilization protocol

**Maintenance:** single use, therefore no maintenance required

## Environment of use

**Setting:** Rural, Urban. Indoors, and in Primary, Secondary and Tertiary Levels of Care

**Energy and Facility Requirements:** clean water supply and incineration facilities

## Product specifications

**Weight (kg):** 0

**Dimensions:** 150mm x 200mm x 70mm

**Consumables:** None

**Lifetime:** 2 years

**Shelf Life:** 2 years

**Retail price (USD):** 30

**Price of consumables (USD):** None

**Year of commercialization:** 2014

**Currently sold in:** New Product

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# Medical device transfer and storage system

Country of origin | United Kingdom

## Health problem addressed

BSE (Bovine Spongiform Encephalopathy) crisis has led to heightened concerns that the human form, Creutzfeldt - Jakob disease (CJD), may be transmitted by contaminated instruments or their detachable parts. The recent re-emergence of Ebola also presents a threat of cross-contamination in areas where devices are being used and transported. Many International guidelines state that medical devices should be covered during the transportation process between the procedure room and the cleaning room.

## Product description

Colour coded tamper-proof bag and tag system offers a protective environment and clear identification that the equipment is 'clean' or 'contaminated'. During clinical use, instruments are contaminated by multiple microorganisms, and failure to appropriately reprocess and handle devices both contaminated and clean can result in nosocomial outbreaks and serious infections. The system offers a protective environment for the newly disinfected device, the green tag providing clear identification that the equipment is 'clean'. After the procedure, the device is returned to the bag, the red tag attached and the medical device can be safely and hygienically transported back to the cleaning room, with the red tag clearly showing it as contaminated. All parts of the system are single-use to reduce cross-contamination. The system is also sterilized.



## Developer's claims of products benefits

The system provides a high level of standardization for the handling of medical devices and other delicate equipment and fills an important gap in the device reprocessing cycle offering a total product solution when used in combination with manual or automated reprocessing systems. It has the features of keeping the instrument safe, sealed and has a tamper-proof design at an advantageous price.

## Suitability for low-resource settings

With the number of procedures growing around the world, it is vital that medical devices are processed correctly in order to keep patients and staff safe from the spread of infection. Along with adhering to rigorous cleaning and decontamination practices, proper transport and storage of expensive, delicate endoscopes are crucial to ensure patient and staff safety and maintain optimal function. This product provides a cost-effective solution for the safe handling of medical instrumentation.

## Operating steps

Take bag out of box, 1 green tag and 1 red tag. Place bag in a tray with red tag in base of tray. Put clean device in bag and tray. Close bag and twist. Place green tag round bag and seal. Transport device to location and use. Put dirty device in the bag. Close bag and twist. Place red tag round bag and seal. Transport device to location and clean

## Regulatory status

The product is manufactured in the UK providing high quality products and enabling close control of the manufacturing process. It is produced in an ISO-9001 registered facility.

The system is registered with the Department of Health and this CE number with the MHRA is CA 012543. It has European Declaration of Conformity Certificate.

## Future work and challenges

Supply of product to low-resource settings requires activities of transportation, procurement, inventory control, distribution management, and customer service. Distributors will only make a limited commitment to creating the new product market, because at some point the supplier may choose a different distributor or go direct. Therefore the new product markets are never fully developed in this route to market, and end product is often expensive.

## Use and maintenance

**User:** physician, technician, nurse

**Training:** no training required

**Maintenance:** single use, no maintenance required

## Environment of use

**Setting:** Intended for use in any health care facility

**Facility Requirements:** Requires availability of incinerator

## Product specifications

**Weight (kg):** 6

**Dimensions:** 625mm x 400mm x 115mm

**Consumables:** none

**Lifetime:** 10 years

**Shelf Life:** 10 years

**Retail price (USD):** 1

**Price of consumables (USD):** NA

**Other features:** single use

**Year of commercialization:** 2012

**Currently sold in:** US and Europe

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# Portable, power-free medical instrument sterilizer

Country of origin | United States of America

## Health Problem Addressed

Conditions that can be addressed by basic surgery account for 25% of the world's disease burden by some estimates (includes NCDs, injuries, obstetric complications). Surgery is a cost-effective means of saving lives and preventing disability, yet 2 billion people do not have access to this care. The ability to sterilize instruments without power eliminates a barrier to providing essential procedures to the 1.2 billion people who live without electricity.

## Product description

A rugged case equipped with a timer and a simple valve for a cartridge of nitrogen dioxide (NO<sub>2</sub>) gas sterilizes a wide range of medical equipment. A scrubber safely absorbs the gas at the end of the cycle, and is then disposed of with regular non-hazardous waste. NO<sub>2</sub> is a common, well-understood gas that has been proven and patented as a room-temperature sterilant that effectively kills bacteria, viruses, and spores.



## Developer's claims of products benefits

Recently published literature review found sterilizers were available at only 64% of hospitals in LMICs, and anecdotal evidence suggests that available sterilizers are usually in disrepair and cannot be used. Boiling/chemical immersion is used for disinfection, but does not eliminate all biological contaminants. Single-use, disposable "kits" can be used, but supply and waste disposal costs are unsustainable. New technology allows for equipment to be safely re-used without any existing infrastructure.

## Suitability for low-resource settings

The sterilizer is designed for use in rural health clinics and temporary medical response units that have either no access, or unreliable access, to electricity and clean water. The nitrogen dioxide sterilization technology has been commercialized in the American industrial sterilization market, but has now been adapted to a simplified, rugged form that is appropriate for all settings due to its lack of reliance on electricity or other infrastructure.

## Operating steps

Equipment is placed inside the case along with a gas scrubber and chemical indicator. The case is closed and locked, the valve cap is removed, gas cartridge is inserted, and the cap is screwed back on. Sterilization cycle begins; timer indicates process progress and completion. Sterilization cycle is complete, the valve cap unlocks, and the empty cartridge can be removed, unlocking the box. Chemical indicator is checked for successful exposure.

## Regulatory status

The sterilizer holds a CE mark, as is currently being evaluated in low-resource settings.

## Future work and challenges

An entity has been established with a Ugandan partner for distribution of the product throughout East Africa. The company has already received a purchase order from Uganda for their Ministry of Health, and has been in talks with the Ministry of Health in Tanzania. The primary challenge lies in speeding the validation, regulatory, and production processes forward so that the need for the product can begin to be met. Supply chain design for resupply of consumables is another challenge, but the company is in the process of developing a comprehensive inventory and resupply strategy through local and international partnerships.

## Use and Maintenance

**User:** physician, technician, nurse, midwife

**Training:** Less than 1 hour program offered by Jhpiego

**Maintenance:** As needed by nurses or technicians

## Environment of use

**Setting:** Rural Settings, Urban Settings, Outdoors, Indoors, Primary, Secondary and Tertiary levels

**Energy requirements:** Timer-Safety locking mechanism runs on battery with 5 year lifetime

## Product specifications

**Weight (kg):** < 5

**Dimensions:** 502mm x 400mm x 188mm

**Consumables:** Cartridge of NO<sub>2</sub> Gas, scrubber, chemical indicator

**Lifetime:** 5 years

**Retail price (USD):** 500

**Price of consumables (USD):** 5

**Other features:** portable,

**Year of commercialization:** March, 2015

**Currently sold in:** NA

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# Innovative work 2014

The 2014 Compendium of innovative health technologies for low-resource settings included a new section of ebola relief innovations to encourage the development of health solutions for the regions experiencing this health crisis. Although not formally accepted to the 2014 Compendium due to not yet being commercialized or regulatory approved, the following technologies showed great potential and the medical devices team wish to show case them to further acknowledge the level of innovative work being put forth to bring medical technology to those who most need it.

# Safi-safe water drops

Country of origin | Haiti and the United States of America

## Health problem addressed

We intend to target Africa, Asia, Latin America, and the Caribbean using Safi as a health prevention to confront the outbreak of Cholera, Zika, Ebola, Schistomaisis, Chickunguyna, Marburg.

## Product description

The product has been shown in laboratory tests and field studies to be effective against bacteria, viruses and parasites in a solution containing only one drop of Safi treatment per gallon (or 3.78 liters) from a 100 ml Safi bottle, and 35 ml of Safi treatment for a bucket of water. Shake or stir and wait 30 minutes. After this the water is purified and safe to drink

## Developer's claims of product benefits

Low cost, effective Water Treatment for low/resource settings.

## Suitability for low-resource settings

Safi-Safe Water Drops is a revolutionary approach at the molecular level of water purification resulting in a persistent and cumulative solution to a country's water supply. In a single treatment we can effectively eliminate childhood dysentery, stop Cholera outbreaks right away, and neutralize E. coli contamination in a targeted environment.

## Operating steps

Safi-Safe Water Drops is a non-toxic tasteless and odorless alternative to traditional water purifying treatments. The important advantage of Safe-Safe Water drops, is that it remains in solution indefinitely so water stored in dirty containers or contaminated by dirty hands or cups will continue to be disinfected

## Regulatory status

Safi was evaluated and approved in 2012 by the Minister of Health in Haiti.

## Future work and challenges

The intent is to conduct several studies relating to zinc and copper deficiency

## Use and maintenance

**User:** Intended for use by everyone

## Environment of use

**Setting:** Designed for use in rural and urban settings at in primary and secondary level of health care facilities

**Other requirements:** Requires access to a fresh water supply and sterilization procedures.

## Product specifications

**Year of commercialization:** 2012

**Currently sold in:** Haiti





# U-sterilize

Country of origin | Italy

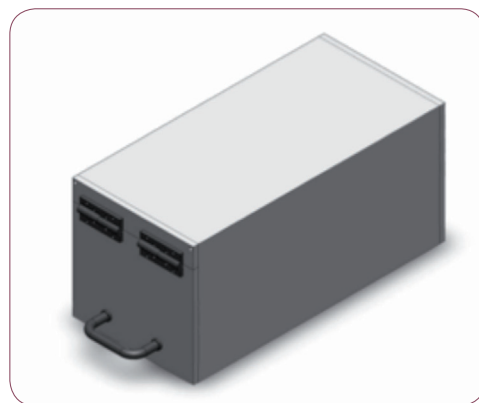
## Health problem addressed

One of the main problems of poorer countries is the lack of sterilization systems. Sterilization is important for everyday life in particular to have clean water, as well as to make medical treatments efficient and safe, avoiding viruses and bacteria transmission and proliferation. This system represents a power saving, easy to use and portable solution to sterilize surgical instruments and water.

## Product description

Ultraviolet-C light at particular wavelengths (250-280 nm) can provide an efficient and economic means to create a portable, programmable and safe system to sterilize surgery and hospital tools, but also water and physiological solutions in suitable and compatible containers (neither polymeric nor organic material are compatible). This sterilizer is basically composed of an UVC lamp capable of inducing most of bacteria and virus death and degeneration.

The inside of the case is in aluminium to maximize efficiency. It is possible to connect a control system by USB port which calculates the most efficient exposure time.



## Developer's claims of product benefits

UVC systems have been largely developed to sterilize water. There are also some sterilizers for dentists and podiatrists, for example, because their tools are quite small. The strengths of this sterilizer are the optimization from the power consumption point of view and the possibility of using battery and solar energy. Furthermore it is completely open source and easily reproducible at low cost.

## Suitability for low-resource settings

The sterilizer is designed to provide low energy consumption with the best compromise between efficacy and power efficiency. The control algorithm optimizes the exposition time to reach a good SAL (Sterility Assurance Level, typically  $10^{-3}$  -  $10^{-6}$ ) saving much energy. The use of aluminium for the internal case increases the efficiency by 70%.

The system can be equipped with solar panels and batteries in lieu of main power.

## Operating steps

Without system control: open the case, put the object inside, close the door. After having plugged in the power supply, turn it on. Some standard exposure times are given. A homogeneous exposure needs to turn the system off and upside down the object. With system control: you can set some parameters; the display automatically shows the exposure time and turns on and off the lamp, indicating when eventually to turn the object.

## Regulatory status

Still requires regulatory approval.

## Future work and challenges

The University of Pisa is developing this sterilizer with a particular attention to the optimization of energy consumption to improve the efficiency of the system: future studies will be spent in finding energy autonomy solutions, using also natural and available forms of energy as well as solar and mechanical. Furthermore UVC diodes are now starting to be commercialized: these represent a very efficient system which will be able to drastically reduce power consumption, but in this moment they still are a research tool.

## Use and maintenance

**User:** Can be operated by any trained personnel

**Maintenance:** Requires annual maintenance, which can be done on-site

## Environment of use

**Setting:** Designed for use in indoor health care facilities.

**Energy requirements:** Requires a continuous power supply of 220v

**Software requirements:** This sterilizer is intended to be completely open source and easily reproducible, so that the system control has been implemented in C language with Arduino support, but it can identically be used with other platforms.

## Product specifications

**Weight (kg):** 2

**Dimensions:** 240mm x 120mm x 120mm

**Lifetime:** 1 year

**Retail price (USD):** 300

**Price of Consumables (USD):** 30

**Other features:** The software, being open source, can be customized. For example it can be developed with sensors for Ozone and temperature control: these can easily be integrated in the system, intervening on the software too.

**Year of commercialization:** Still in Development

**Currently sold in:** Still in Development

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# Assistive devices

## 2013

# Artificial prosthetic knee joint

Country of origin | Canada

## Health problem addressed

Over 25 million people living in developing countries require the use of prosthetic and orthotic devices. Individuals who have had their leg(s) amputated above the knee joint due to trauma, disease or a congenital reasons and are unable to walk without the use of a lower-limb prostheses are the target population for this product. With an above-knee prosthesis, people with above-knee amputations will be able to walk, remain independent, productive and healthy.

## Product description

The artificial knee joint is an integral part of the above-knee prostheses. The knee unit is simple in design and made of fiber-reinforced polymer construction. The lower end connects to a modular prosthetic system, which ultimately connects to an artificial foot. The upper end connects to a prosthetic socket with an attachment.



## Product functionality

The knee unit utilizes a proprietary stance-phase control mechanism, termed the 'Automatic Stance-Phase Lock (ASPL)'. It is composed of a knee lock that is automatically engaged as the knee becomes fully extended thus preventing the knee from bending. A combination of a hip flexion moment and loading of the forefoot unlocks the knee. This is a natural sequence of events that occurs at each step of walking and allows the knee to be stable as needed while facilitating natural swing-phase flexion.

The knee joint is fitted by a trained technician during the fabrication of the above-knee prostheses.

## Developer's claims of products benefits

One of the most common types of knee joints used in low resource settings is the manually locking knee that requires walking with either a straight leg or an unlocked one that is very unstable. This product provides a high level of stability during weight bearing and at the same time a high level of mobility. It is easy to assemble, can be used in water and wet environments without being damaged and is also low-cost.

## Development stage

Independent product evaluations and clinical trials have been conducted in Canada, Chile, El Salvador, Germany, India and Myanmar. It was tested as part of the ISO 10328 standard-Prosthetics structural testing of lower-limb prostheses.

## Future work and challenges

There is a need to establish a partnership with an international distributor. In addition, finalization of negotiations in regards to production is required in order to decrease further the product cost while ensuring high and consistent quality.

## Use and maintenance

**User:** Self-use

**Training:** Not required

**Maintenance:** On-site as needed

## Environment of use

**Settings:** Rural, urban, ambulatory, at home

**Requirements:** A facility with tools and materials and trained clinical/technical personnel to fit the product into a prosthesis

## Product specifications

**Dimensions (mm):** 60 x 80 x 180

**Weight (kg):** 0.7

**Consumables:** None

**Life time (years):** 3-5

**Shelf life (years):** 10

**Retail price (USD):** NA

**List price (USD):** 100

**Other features:** Reusable

**Year of commercialization:** Premarket launch 2013

**Currently sold in:** Germany and used in Chile, Myanmar, Tanzania, India, Nicaragua and Canada.

# Child wheelchair

Country of origin | Israel

## Health problem addressed

About 70 million people have different health conditions ranging from spinal cord injury to birth defects requiring a wheelchair for mobility. Among them, only 5-15% have access to one and out of this population, 25% are children with disabilities. Wheelchairs can assist these children to be mobile, independent and healthy.



## Product description

The wheelchair consists of two large rear wheels with pushrims, two small swiveling front wheels (castors), a metallic frame, plastic seat, footrest and a cushion. It is modular in design, its components come in three separate boxes and need to be assembled as per the need of the child.

## Product functionality

The user sits in the wheelchair and can move around manually by pushing the pushrims. It fosters independence and social integration and allows the child to leave the house, access education, and be like other children.

## Developer's claims of products benefits

Most of the available wheelchairs in the world are for adults. Available child wheelchairs are often the miniature size of adult wheelchairs without valuing children's needs and preferences. This product has been specifically designed for children. The wheelchair is light-weight but durable, low-cost and can be assembled locally. It requires low maintenance and is very attractive to children due its design and colour.

## Development stage

The wheelchair was developed and assessed according to DIN ISO 7176 and the WHO "Guidelines on the provision of manual wheelchairs in less-resourced settings".

## Future work and challenges

To establish collaboration with local NGOs and governmental organizations to support training and distribution, to provide training to rehabilitation teams and to raise funds to support the wheelchair's production and distribution.

## Use and maintenance

**User:** Self-use

**Training:** 1 day training by physiotherapist, occupational therapist or rehabilitation teams

**Maintenance:** Monthly adjustments of screws

## Environment of use

**Settings:** Rural, urban, ambulatory, at home, primary (health post, health center), secondary (general hospital), tertiary (specialized hospital)

**Requirements:** Trained clinical/technical personnel to assemble the wheelchair

## Product specifications

**Dimensions (mm):** 800 x 400 x 740

**Weight (kg):** 11 with tubeless wheels, 9.5 with pneumatic tube

**Consumables:** Cushion, accessories

**Life time (years):** 3

**Retail price (USD):** 95

**List price (USD):** 95

**Other features:** Continuous-use, mobile

**Year of commercialization:** Anticipated 2014

# Hollow mattress

Country of origin | Bangladesh

## Health problem addressed

People with spinal cord injuries often develop pressure sores due to prolonged sitting or lying without changing position. Sitting or lying on hard surfaces makes the situation worse. Many people while sitting in a wheelchair use a pressure relief cushion but do not have the capacity to afford a pressure relief mattress. As a result they often develop pressure sores, which are difficult to manage and expensive to treat, especially in low and middle income countries.



## Product description

The product is a mattress with an opening to accommodate the pressure relief seat cushion of the patient's wheelchair.

## Product functionality

By having the space to accommodate the pressure relief seat cushion in the mattress, the pressure is relieved at the usual pressure points, such as in the tailbone and hip bones, while in the supine position. The wheelchair seat cushion is placed in the hole of the mattress to make a full mattress. The whole mattress is covered with water resistant fabrics.

## Developer's claims of products benefits

This modified pressure relieving mattress prevents development of pressure sores in the supine position. It saves on unnecessary health care expenditures to heal/manage the pressure sores. It also helps to reduce the time needed for full rehabilitation. It can be made locally with easily available and accessible resources such as an ordinary foam mattress. It is affordable and water resistant.

## Development stage

The product has been used in a rehabilitation centre for people with spinal cord injuries. This product has been approved by the multidisciplinary team of the specialized Spinal Cord Injury Unit of the largest paraplegic centre of Bangladesh.

## Use and maintenance

**User:** Self-use, family member, care-giver

**Training:** Not required

**Maintenance:** Not required

## Environment of use

**Settings:** Rural, urban, ambulatory, at home, primary (health post, health center), secondary (general hospital), tertiary (specialized hospital)

## Product specifications

**Dimensions (mm):** Variable

**Weight (kg):** 7-8

**Consumables:** No

**Life time (years):** 5

**Shelf life (years):** 5

**Retail price (USD):** 25 (without the cost of cushion)

**List price (USD):** 25 (without the cost of cushion)

**Other features:** Mobile, continuous-use

**Year of commercialization:** 2008

**Currently sold in:** Bangladesh

# Magnetic prosthetic suspension system

Country of origin | Malaysia

## Health problem addressed

A prosthesis is used as part of amputee rehabilitation and the suspension system is an important feature that affects prosthesis users' quality of life. Individuals with lower limb amputation need to wear prosthesis to perform activities of daily life, especially walking.

## Product description

The magnetic suspension system is a magnetic coupling device, which holds the residual part of the limb (stump) inside the prosthesis (artificial limb). It consists of three parts: a metal plate inside the socket, which is attached to a prosthetic soft liner; a magnetic assembly (the source of magnetic power), which remains outside of the socket - positioned between the prosthetic socket and the pylon (internal frame of the prosthetic leg); and a switch, which connects or disconnects the coupling device. The soft liner acts as a sort of "second skin" between the movable soft tissue of the stump and the hard shell of the socket. The soft liner provides comfort and holds the stump inside the prosthesis with the help of the magnetic coupling device.



## Product functionality

After donning the prosthetic soft liner, the user puts the stump inside the prosthesis. The mechanical switch is positioned in the "On" mode. The magnetic field will hold and retain the stump within the prosthesis. While removing, the user needs to position the switch to the "Off" mode, which will then allow the user to withdraw the stump from the prosthesis. The system comes with an optional acoustic safety alarm, which can warn the user about imminent possibilities of suspension failure.

## Developer's claims of products benefits

The system is easy to fabricate, cheaper than other suspension systems, more durable and easy to use. It requires less maintenance, reduces pain in the residual limb, decreases interface pressure and reduces pistoning.

## Development stage

The system patent is pending both in Malaysia (PI2012700220) and the US (13/865,677). The technical aspects have been approved by the University of Malaya Medical Ethics Committee and the product has been clinically tested by lower limb amputees. The findings of a technical evaluation have been published in the Institute for Scientific Information (ISI) journals. A paper on the biomechanical evaluation of the system was awarded with the best research in the field of "Advancing technologies" in the 14th International Society for Prosthetics and Orthotics (ISPO) world congress.

## Future work and challenges

Future work includes implementation of large scale manufacturing and worldwide distribution.

## Use and maintenance

**User:** Self-use

**Training:** Not required

**Maintenance:** On-site once a year

## Environment of use

**Settings:** Rural, urban, ambulatory, at home

**Requirements:** A trained prosthetist to fit the product into a prosthesis

## Product specifications

**Dimensions (mm):** 30 x 30 x 30

**Weight (kg):** 0.25

**Consumables:** Batteries, if used with safety alarm

**Life time (years):** 5

**Retail price (USD):** 500

**List price (USD):** 250

**Other features:** Reusable

**Year of commercialization:** Ready to be commercialized



# Pen-mounted CCTV camera

Country of origin | India

## Health problem addressed

Persons with very low vision due to age related macular degeneracy or advanced glaucoma have difficulty in reading their own writing due to the small size of the written font.

## Product description

The closed-circuit television (CCTV) camera is mounted on a pen and connected to a computer/monitor, which shows the camera picture (written font) magnified to the extent necessary on the screen.

## Product functionality

A person can see on the screen what he or she writes on paper with the camera-equipped pen. The magnification of the font size is adjustable using a switch on the system.



## Developer's claims of products benefits

This camera enables persons with very low vision to see what they write. Local production is possible with easily available accessible low-cost CCTV cameras.

## Development stage

The product has been tested by patients at one of the largest eye-hospitals in India.

## Future work and challenges

The idea is simple and made freely available at low cost to anyone who wishes to use it. Drawings and production details may be requested from the contact person.

## Use and maintenance

**User:** Self-use

**Training:** Not required

**Maintenance:** Not required

## Environment of use

**Settings:** Rural, urban settings, at home

**Requirements:** Continuous power supply for the PC, laptop, or monitor and camera

## Product specifications

**Dimensions (mm):** 200 x 20 x 20

**Weight (kg):** 0.5 (whole system excluding monitor)

**Consumables:** No

**Life time (years):** 5

**Shelf life (years):** 5

**Retail price (USD):** 20

**List price (USD):** 20

**Other features:** Portable, continuous-use

**Year of commercialization:** Ready to be commercialized

# Polycentric prosthetic knee joint

Country of origin | United States of America

## Health problem addressed

Around 9.5 million people with an above-knee amputation living in low and middle income countries need a prosthesis to regain mobility for livelihood, employment and social integration. Most of the amputations are due to injuries, especially road traffic crashes, diabetes, and other health conditions. Modern above-knee prosthesis are prohibitively expensive, especially due to the cost of the knee joint, which is the most complex component of an above-knee prosthesis.

## Product description

It is a polycentric prosthetic knee joint, which mimics the movement of a normal knee joint while walking. At the same time, it provides stability during the weight-bearing phase to ensure the person can walk with their artificial limb without falling.



## Product functionality

A prosthetic knee joint is the connector between below and above knee prosthetic components to provide knee movement like a normal knee. It usually gets attached to a modular component or a pylon at the lower end which ultimately connects to a prosthetic foot. On the other end, it connects to a prosthetic socket again through a modular attachment.

## Developer's claims of products benefits

Prosthetic clinics in the developing world typically recycle used donated prosthetic knees or use locally made single-axis knees. Donated knees are cost prohibitive to maintain and perform poorly in rugged environments. Single-axis knees are unstable and can buckle, especially when walking on uneven surfaces. The polycentric prosthetic knee joint provides increased stability for uneven and unpaved terrain, withstands high usage by using an oil-filled nylon polymer which self lubricates with use, it can be used in humid and wet environments and it is low cost. It provides 165° range of motion at the knee, which is critical for low and middle income countries, especially for kneeling, squatting, biking and agricultural work.

## Development stage

The knee has been fit on over 4,600 patients, primarily in India. In 2013, the latest version of the product was tested to ISO 10328 - Prosthetics structural testing of lower-limb prostheses.

## Future work and challenges

Successful outcomes depend on availability of trained prosthetists who can fabricate a custom socket to fit over the patient's residual limb. Scaling is currently limited to areas with established prosthetic clinics capable of providing a proper fitting.

## Use and maintenance

**User:** Self-use

**Training:** Instructions for use comes with the product, fitting training is required for prosthetists

**Maintenance:** Not required

## Environment of use

**Settings:** Rural, urban settings, at home

**Requirements:** A trained prosthetist to fit the product

## Product specifications

**Dimensions (mm):** 60 x 80 x 140

**Weight (kg):** 0.68

**Consumables:** None

**Life time (years):** 5

**Retail price (USD):** 80

**List price (USD):** 80

**Other features:** Single-use, portable

**Year of commercialization:** 2008

**Currently sold in:** India

# Polypropylene endoskeletal lower limb prosthetic system

Country of origin | Switzerland

## Health problem addressed

Due to road traffic injuries, wars and conflicts, non-communicable diseases and other health conditions, many people with disabilities have limited mobility and are in poor health. Nearly 35 million people in the world are in need of orthopaedic (prosthetic/orthotic) devices to improve mobility and their overall health. Among them, only 5-15% in low and middle income countries have access to one.

## Product description

The system is a set of specially designed polypropylene components to fabricate/fit lower limb prosthesis (artificial limb) for people with lower limb amputation. Usually, it comes in two varieties: 1) Trans-tibial (below-knee) and 2) Trans-femoral (above knee) amputation. The system consists of a foot piece, convex ankle, two concave cylinders, convex disc, cylindrical TT cup, flat steel washer and countersunk head bolt, lock washer and a knee unit in case of Trans-femoral (above knee) prosthesis.



## Product functionality

The modular endoskeletal components are mostly made out of polypropylene and available in different sizes. It also comes with a prosthetic foot and other necessary materials for fabrication of the socket and cosmetic cover. A trained prosthetist fabricates the socket, selects the needed components, assembles those to make the prosthesis as per measurement and then does the fitting.

## Developer's claims of products benefits

The product is affordable, durable, comfortable, easy to use and to maintain. It has a long shelf life and at the same time, recyclable. It is compatible with different climatic regions of the world.

## Development stage

Products are available on the market and are being used in more than 100 projects all around the world. The product has the ISO Norm 10328 certificate by C.E.R.A.H. The product has been evaluated by the International Society for Prosthetics and Orthotics (ISPO).

## Future work and challenges

Future work includes development of an advanced prosthetic foot, knee and a hip joint.

## Use and maintenance

**User:** Self-use

**Training:** Short training on use and maintenance

**Maintenance:** On-site every 1-2 years

## Environment of use

**Settings:** Rural, urban, at home; for indoor and outdoor use.

## Product specifications

**Dimensions (mm):** Components come with different sizes to accommodate all age groups.

**Weight (kg):** Trans-tibial 2 kg; Trans-femoral 5 kg

**Consumables:** Polypropylene sheets, assembly items

**Life time (years):** 3

**Shelf life (years):** Feet 18 months. Remaining components between 3-5 years depending on storage quality

**Retail price (USD):** Trans-tibial 150, trans-femoral 275

**List price (USD):** Trans-tibial 150, trans-femoral 275

**List price of consumables (USD):** Foot+consumables 80

**Other features:** Portable, continuous-use

**Year of commercialization:** Concept emerged in 1993, developed further since then and the development work on prosthetic foot, knee and hip is still ongoing.

**Currently sold in:** 72 low, middle and high income countries

# Prefabricated components for lower limb orthoses

Country of origin | India

## Health problem addressed

Despite polio eradication drives, 0.5% of the those affected by polio or other neuromuscular conditions in India and low-income countries require some kind of orthoses. Among this population, 75% live in rural areas with the majority unable to access an orthoses due to its cost and inappropriateness for the rural environment and lifestyle.

## Product description

The prefabricated plastic Knee-Ankle-Foot Orthotic (PF-KAFO) system consists of two plastic thermoformed shells - one for below the knee and one for above the knee - a pair of orthotic knee joints with drop-lock and uprights which connect the below-knee and above-knee shells, and accessories such as straps/fasteners and rivets. The prefabricated plastic shells are available in nine sizes for the left and right leg. Orthotic knee joints are available in two sizes for children and adults.



## Product functionality

Lower limb orthoses facilitate mobility and prevent secondary deformities. Components of suitable sizes are selected from the available range, assembled as per measurement of the individual and then fitted to the user. The user attaches the orthosis to the leg by means of straps/fasteners. Locked knee joints facilitates stability during the weight bearing phase and assists in walking despite having weak/paralysed legs. Unlocked knee joints allow the user to bend his or her knee, while sitting.

## Developer's claims of products benefits

It is comfortable, cost-effective and very appropriate for low and middle income countries. It requires a minimum of time, tools and machineries for assembly. It is suitable for a rapid fitting in remote locations. It is water proof and has the possibility of using it with or without footwear making the orthosis more culturally appropriate, especially inside the house or temple.

## Development stage

The product has been evaluated by the International Society for Prosthetics and Orthotics (ISPO) in 2003-2004. The second ISPO evaluation was done in Ethiopia during trials in 2005. The third ISPO evaluation was completed in 2006 after more of ten months of use in Ethiopia. The findings were presented during ISPO 2007 in Vancouver. Based on the feedback, better shells and new sets of orthotic knee joints have been developed and the new product was launched during the 7th International Conference of the Federation of African Orthopaedic Technologists (FATO), Ivory Coast, 30 September - 5 October 2013.

## Future work and challenges

Future work includes development of an ankle joint, introduction of the technology in the Prosthetics and Orthotics Course curriculum, and introduction of the PF-KAFO system under the assistance to disabled persons of India programme, sponsored by the Government of India.

## Use and maintenance

**User:** Self-use

**Training:** Short training on assembly and use

**Maintenance:** Daily cleaning and checking for broken straps

## Environment of use

**Settings:** Rural, urban, ambulatory, at home, primary (health post, health center), secondary (general hospital), tertiary (specialized hospital)

**Requirements:** A facility with tools, stable power supply and gait training materials

## Product specifications

**Dimensions (mm):** Vary by size

**Weight (kg):** 2-4

**Consumables:** Velcro fasteners, rubber soles, adhesives, padding foams, stockinette, rivets, screws, nuts

**Life time (years):** 3-5

**Shelf life (years):** 10

**Retail price (USD):** 60 for the PF-KAFO shells and 60 for the knee joints.

**List price (USD):** 60 for the PF-KAFO shells and 60 for

the knee joints.

**Other features:** Portable, continuous-use

**Year of commercialization:** Concept was introduced in 2003, it developed further based on the feedback and evaluations, and development work on the knee joints was finalized in 2013. The whole system was launched on 30 September 2013.

**Currently sold in:** Bangladesh, Ethiopia, India, Kenya, Nepal, Nigeria, Sri Lanka, Tanzania

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# eHealth solutions 2013



# Blood pressure eReader

Country of origin | Canada and Kenya

## Health problem addressed

High blood pressure (HBP) is the leading risk factor for mortality globally (WHO); 1 in 6 in developing countries has HBP (CDC). A “silent killer”, symptomless unless measured, leads to heart attack, stroke and disability. In sub-Saharan Africa, it’s underdiagnosed, poorly managed and lacks community-wide preventive strategies (AJH).

## Solution description

The self-measured blood pressure (SMBP) e-reader positioned in social points (e.g. posho mills, bars) will be accessed by community members who want to check their blood pressure. The digital SMBP machine will capture one’s blood pressure, interpret the reading, and transmit the reading to health centers through cloud information services. Community members



will anonymously take readings, however, they will provide a phone number which will only be used to follow-up readings deemed at risk. Community members can check their readings as many times as they wish within the period of the project. This is an opportunity for those unaware they have high blood pressure to know and seek treatment.

## Functionality

Using a provided step-by-step guide, the user will measure blood pressure, the machine will automatically interpret the results digitally and verbally to the user in the local language and automatically wirelessly transmit the blood pressure reading with the phone number as the only identifying information.

## Developer’s claims of solution benefits

Self-administered ease of use, a step-by-step guide and use of the local language reduces training requirements. It is cost-effective in high blood pressure management by capturing asymptomatic and pre-event at-risk users. It is population-based, thus labor saving for health providers by screening only those at risk and provides public health epidemiological surveillance of patterns in populations.

## Future work and challenges

Technology will be available in public areas distributed through local entrepreneurs who can use the screen platform to advertise their products thus contributing to local economies and leading to sustainability.

## User and environment

**User:** Self-use/patient

**Training:** A point of contact community based worker for a 30 minute training

**Settings:** Rural, social settings

## Reviewer’s comments

Blood pressure self monitoring is a good way for biosensors to help patients in optimal self-management. Several studies have demonstrated that this approach improves blood pressure simply through self-monitoring, even without medications. This intervention at rural and underserved areas of the countries, having the device solar powered and sending the signals to the cloud to monitor, is a good approach to capture data. Having patients being able to access the results by phone is reasonable, although being able to access results through the same computer may be more useful, especially in understanding the longitudinal changes. Therefore, even though this approach is not novel, its practical applicability in low resource settings is an advantage.

Another additional benefit would be using this to track population level data to understand the prevalence and incidence of hypertension in different regions, and whether monitoring longitudinally would reduce these rates and improve outcome of decreased sequelae of hypertension (e.g. stroke, heart attacks, etc.).

## Solution specifications

**Solution is used to support:** Decision support systems, Diagnosis and treatment, Electronic Health Record, eLearning/mLearning, Public health surveillance

**Software/Hardware requirements:** The facility will require access to the Internet, access to a mobile phone, use of a computer and a stable power supply which will be solar powered

**Standards:** ICD10

**Currently used in:** Canada

**Evaluation:** The technology has been validated through independent, published clinical trials. The research has determined that the equipment conforms to AAMI (US-FDA) and BHS (UK) guidelines for device accuracy. Software will be developed to be used with the device to interpret readings in local language and transmit the readings in the local language to the health provider.

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<http://www.who.int/ehealth>

# ePharmacyNet system

Country of origin | Benin

## Health problem addressed

This technology is designed to solve the poor accessibility of medicine in pharmacies for patients in developing countries like Benin. It is often difficult for people in rural, as well as urban areas, to buy all medicine on a prescription in only one pharmacy. Usually they have to try several pharmacies.

## Solution description

The system intends to help a patient to discover available pharmacies in his area with a list of available medicine in stock. The patient can use any 2G/3G enabled device to communicate with the EpharmacyNet system. That system contains a localisation-based database with a real time description of available stock of all pharmacies within a region. Then the system replies back to the patient's request with the pharmacies in an area of 10km of diameter that have the target list. Interactions between both parties in the mobile network can be done via USSD, SMS, voice or data connection depending on the patient device. The system aims to provide home delivery and online payment.

## Functionality

A patient gets a prescription from a physician. He/she uses the ePharmacyNet system to enter all the medicine listed on that prescription. The physician can also use the system to check availability. The system uses the central database to help the patient find the nearest pharmacy with all medicine available in stock.

## Developer's claims of solution benefits

Using the system, patients in villages or living far from a pharmacy may receive a prescribed medicine within two days. We can thus reduce the waiting time by up to 90%. Also the transport expenses can be reduced. The system would help to increase the quality of care provision by improving the access to pharmaceutical products.

## Future work and challenges

Future work includes spreading the system to all African countries and working with the pharmaceutical industry in developed countries to increase access to orphan medicines (with regards to the African market).

Furthermore, we plan to manage logistics problems by developing a RFID based transport box thereby increasing security (for the patient and products) and avoid fraud during the transportation of medicine. The box can also help to keep medicine at the right temperature during transportation.

## User and environment

**User:** Physician, nurse, midwife, self-use/patient, family member

**Training:** Local EpharmacyNet system IT professionals can deliver required training within a one week period

**Settings:** Rural, urban, at home, ambulatory, primary (health post, health center), secondary (general hospital), tertiary (specialized hospital)

## Solution specifications

**Solution is used to support:** Decision support systems, diagnosis and treatment, Electronic Health Record/Electronic Medical Record, Geographic Information System, Health research, mHealth, Management of patient information, Telemedicine

**Software/Hardware requirements:** Internet access. Mainly, open source solutions will be implemented and no licence fees. Mobile device uses USSD, SMS or specific SIM menu to interact with the database. Additional software to include localisation in the request will be used on smartphones, tablets or equivalent. The platform uses PostgreSQL, MySQL database and Linux OS. The system is not proprietary.

**Standards:** HL7

**Currently used in:** Benin

**Evaluation:** The study has been conducted in Benin in Jan, 2010. In total, 434 people had taken part in the project in the 3 test areas. The tests took 2 weeks simultaneously in all areas. More than 95 per cent were women. The participants were satisfied with the experience. The results also demonstrated that the system is easy to use by those with limited reading and writing skills.

# Health and hospital information system

Country of origin | Spain

## Health problem addressed

Health centers in resource poor locations have deficiencies in the management of patient and hospital information. This solution provides a platform that optimizes and improves the patient and hospital information management using free software.

## Solution description

It is free software and is designed to be multi-platform, so it can be installed in different operating systems (GNU/Linux, FreeBSD, MS Windows). It uses Python as the programming language, PostgreSQL as the Database engine and Tryton as the development framework.

## Functionality

The health documentation portal explains how the solution works and is available at:

[http://en.wikibooks.org/wiki/GNU\\_Health](http://en.wikibooks.org/wiki/GNU_Health)

## Developer's claims of solution benefits

It is an eco-friendly solution (100% paperless). Its free software policy is a warranty of cost reduction and sustainability - basic features needed in emerging economies

## Future work and challenges

The main challenge of the project is to continue raising awareness for the use of free software in public health.

## User and environment

**User:** Physician, nurse, midwife, self-use/patient, family member, technician

**Training:** United Nations University IIGH will deliver training in a 5-day duration course.

**Settings:** Rural, urban, at home, ambulatory, primary (health post, health center), secondary (general hospital), tertiary (specialized hospital)

## Reviewer's comments

This solution is applicable for low-resource settings as it is free; works in different operating systems, and with the modular approach is customizable to the local needs of hospitals and health centers. It is available in English, French, Spanish and can be easily translated to local languages via the tryton module translator.

## Solution specifications

**Solution is used to support:** Decision support systems, Diagnosis and treatment, Electronic Health Record/Electronic Medical Record, Geographic Information System, Management of patient information, Management of hospital information, Public health surveillance

**Standards:** ICD10, ICD10-PCS

**Country used in:** partial list of government portals, organizations and health centers involved with GNU Health: <http://health.gnu.org/community.html>

**Software/Hardware requirements:** Server and client workstation, laptop, mobile devices and stable continuous supply power supply. Free Software licensed under GNU Public License.

# Hearing screen eRecord

Country of origin | South Africa

## Health problem addressed

15-20% of the world's population suffers from hearing loss, yet only fewer than 10% seek professional help due to the inaccessibility and high cost of treatment. (WHO 2012) Hearing loss has also been described to be the most prevalent disability in developed countries (Davis, 1997).

## Solution description

The technology seamlessly integrates:

1. Optimised screening enabled by an application that provides an accurate, accessible and affordable audiogram screen;
2. Optimised diagnosis enabled by effective data management, analytics, automated reports and remote review;
3. Optimised care enabled by patient remote review, e-referral, tracking, engagement and eLearning.

## Functionality

Instructions on the touchscreen are intuitive, clear and simple.

## Developer's claims of solution benefits

Audiology services currently rely largely on unwieldy, expensive, dedicated equipment requiring skilled personnel to conduct testing. Few devices used 'in the field' for screening are web-enabled. This device offers improvements in that it uses existing, widely available touch screen mobile phones, or tablets - thus vastly reducing the cost of screening equipment. It is very simple to operate. eHealth records are immediately captured.

## Future work and challenges

Adoption of technology requires regulatory approval. Initial capital for handsets or computer tablets, and headphones needs to be raised. Local policy and remote evaluation of screening outcomes needs to be developed.

## User and environment

**User:** Physician, nurse, technician, self-use/patient

**Training:** Minimal training is required

**Settings:** Rural, urban, primary (health post, health center), secondary (general hospital), tertiary (specialized hospital)

## Solution specifications

**Solution is used to support:** Decision support systems, Diagnosis and treatment, Electronic Health Record, eLearning, mHealth, Patient monitoring, Telemedicine.

**Software/Hardware requirements:** A touchscreen device, headphones. Screening Apparatus: iOS (plan to add Android); platform: developed using open source software

**Standards:** HL7

**Currently used in:** South Africa

**Evaluation:** International Journal of Audiology Vol. 51, No. 8, p 606-610 August 2012

# Maternal and child health mobile services

Country of origin | India

## Health problem addressed

Mobile services were developed to address some of the highest rates of maternal neonatal and infant mortality (MMR 305/100,000, NMR 35/1000, IMR 55/1000) in India by helping community health workers (CHWs) in Bihar to communicate crucial information on health behaviours to pregnant women and mothers of infants.

## Solution description

CHWs refresh and expand their knowledge of family health using an Interactive Voice Response (IVR) training course that they can bookmark and complete at their own pace over a period of up to one year. Additionally, CHWs use a second mobile service, a job aid, which is complemented by a deck of colour coded and illustrated cards bearing life saving information, to reinforce the information that they share with families on routine visits. The services are available on any mobile handset and any network in the state, are voice-based and are accessible via common mobile short codes that bring listeners directly to training content and job aid.



## Functionality

**Job aid:** When the CHW counsels family members, she dials a unique short code listed on any of the 40 cards while showing the illustrated card to the family. The call takes her to the voice of a doctor character who reinforces the health message on the card. She plays the message to the family. **Training aid:** CHW completes mobile course at her own pace.

## Developer's claims of solution benefits

Training is cheaper (\$1.50 for full course) and more accessible than face to face training, the content is specifically designed for local context, in simple and suitable language, and therefore more engaging and easy to remember. The services use available, cheap mobile phones that are light and easy to carry, and an accompanying deck of cards containing dial codes and additional information is light and waterproof. The services are easy to use by anyone who can dial out on a mobile phone.

## Future work and challenges

There is interest in taking the mobile services to other Indian states and countries. The technology is scalable, however, a challenge in taking the services to new regions is the additional investment required to adapt the content to new cultural and language contexts.

## User and environment

**Users:** Nurse, midwife, self-use/patient, community health worker

**Training:** CHWs are trained by a local NGO partner for approximately 4 days

**Settings:** Rural, primary (health post), at home

## Solution specifications

**Solution is used to support:** eLearning/mLearning, mHealth

**Software/Hardware requirements:** The infrastructure required is the same as required for access to basic mobile phone functions i.e. relatively stable power supply and access to a cellular/mobile network. It is available on any mobile handset and across all the six major network providers in the state. It uses open source software, MOTECH.

**Currently used in:** India

**Evaluation:** The services deliver health education, rather than clinical services, thus clinical trials are not applicable. However extensive user-testing was carried out to assess the usability and accessibility of the services with CHWs across Bihar (100 health workers in four batches over six months). The technical health messages in the content were approved by the Government of Bihar and developed with input from a range of medical experts and institutions in line with WHO guidelines.



# Mobile supply chain management tool

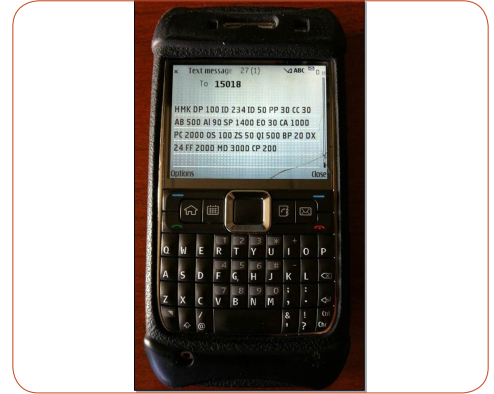
Country of origin | United States of America

## Health problem addressed

Stockouts and other supply chain disruptions pose real challenges in low-resource communities. According to a WHO report, the problem is in getting staff, medicines, vaccines, and information on time, reliably, and in sufficient, sustained and affordable quantities to those who need them.

## Solution description

The solution is an open-source turnkey product designed to strengthen logistics management through the use of mobile technology. Its purpose is to support health workers and other mobile agents who manage commodities in low-resource settings. It has been proven at scale, through real-world deployments, to provide reliable, real-time, and actionable information to improve the performance of new and existing supply chains.



## Functionality

Users report stock through SMS, an app running on Java, Androids, or tablets, or the web. They report data such as stock levels, receipts, and orders. This is analyzed to infer indicators e.g. monthly consumption, lead times, and order fill rates. Appropriate actors are notified of impending stockouts, reorder quantities, deliveries, etc.

## Developer's claims of solution benefits

The proposed system provides real-time, reliable, and accurate information directly to those with decision-making capabilities. It streamlines logistics systems with targeted, actionable information to supervisors and managers; it improves quality of reliable, real-time stock information to decision-makers at all levels; it facilitates detection, resolution, and prevention of stock outs; and it reduces lead times through improved supervision of requisition and delivery, and identification of bottlenecks.

## Future work and challenges

In the future, partnerships with local telecom companies will be sought in order to bring SMS costs down. Improvements to the system will also be made with inclusion of advanced stock level forecasting and optimal reorder point calculation. As more and more deployments launch, the body of open source technology behind the system will continue to grow, allowing each individual deployment to benefit.

## User and environment

**User:** Nurse, midwife, technician, pharmacy worker, supply officer, laboratory staff, immunization teams

**Training:** Training sessions of 1-2 days are provided by implementers, programs, and the Ministry of Health

**Settings:** Rural, urban, ambulatory, primary (health post, health center), secondary (general hospital), tertiary (specialized hospital), medical stores

## Reviewer's comments

The system is simple and meeting a well known challenge in the health system in low-resource settings. The system has been piloted in three relevant countries and is now in use.

## Solution specifications

**Solution is used to support:** Decision support systems, Geographic Information System, mHealth, Management of hospital information, Logistics and supply chain management

**Software/Hardware requirements:** Mobile workers require a mobile phone with SMS capability or a mobile application (and network coverage). Supervisors use a personal computer with an internet connection. As open source software, anyone is free to download and modify the code.

Additionally, the hosted version provides a reports customization layer which allows any developer to generate custom views, reports, dashboards, and forms, while at the same time leveraging the common shared software repository used by a community of other projects.

**Currently used in:** Ghana, India, Malawi, Tanzania, Uganda

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<http://www.who.int/ehealth>

# Remote healthcare solution

Country of origin | India

## Health problem addressed

70% of the rural population in India has very poor access to healthcare. 76% of the medical facilities are concentrated in urban areas, and there is an overall shortage of medical personnel. Thus rural patients are left to semi- and non-qualified practitioners, creating a huge disease burden.

## Solution description

The technology enables rural patients to reach urban doctors through a telemedicine solution. This comprises of a modular data analysis unit (MDAU) - a USB powered multiparameter diagnostic device which captures ECG, temperature, heart & lung sounds, SPO2 and BP, and communicates with the remote doctor through a low bandwidth audio/video/data conferencing. The solution allows for the integration of the whole healthcare delivery ecosystem to provide meaningful service. The solution also captures the workflow of delivery processes and enables resource optimization by capturing and analysing operational service delivery data.



## Functionality

A rural operator carries out remote consultation for the patient at the village using the internet with a doctor sitting anywhere in the world. Doctors remotely control the MDAU device to obtain medical parameters, provide a prescription to the patient, and store medical records. The solution also supports supply-chain management, lab reports and referrals.

## Developer's claims of solution benefits

This solution works at extremely low bandwidths (32 kilobits/s onwards) for real-time audio/video/data teleconsultation, thereby reaching places where other existing solutions cannot reach. It is very easy to use by a village operator, is extremely power efficient, and works out of USB power, and comprehensive solution linking multiple providers (doctors / pharmacies / labs / hospitals), and addresses 75% of healthcare needs at the point-of-care at a fee of less than 1 USD.

## Future work and challenges

Future work includes working closely with healthcare service delivery partners and e-governance players to define and implement large scale projects; enhancing the technology with further diagnostics as well as ground-level delivery processes to capture them better; identifying and building relations with partners having complementary solutions (hardware and software); integrating a mobile based bluetooth enabled telemedicine solution, as even 32 kilobits/s bandwidth is not available in all of rural India; and changing the business model to include software-as-a-service.

## User and environment

**User:** Physician, nurse, midwife, technician, community health worker, self-use/patient

**Training:** On-site individual/group training, video-conferencing/desktop sharing application based e-training that takes 2 to 4 hours

**Settings:** Rural, urban, primary (health post, health center), secondary (general hospital, at home)

## Solution specifications

**Solution is used to support:** Decision support systems, Diagnosis and treatment, Electronic Health Record/ Electronic Medical Record, eLearning/mLearning, Health research, mHealth, Patient monitoring, Telemedicine

**Software/Hardware requirements:** Medical device connected to USB port of PC/Laptop. Windows operating system on the PC/Laptop, an internet connection for telemedicine. Minimum 32 kilobits/s internet speed for real-time audio / video / data tele-consultation. Fixed static IPs at both ends for professional edition, and at server in enterprise edition.

The specific software that comes as part of the solution, is proprietary. It has been optimized for usage in low-

resource and low-skillset environment (e.g. video conferencing and real-time data transfer can work at a bandwidth as low as 32 Kbps). The license fee depends on number of clients and scale of the network.

**Standards:** HL7, ICD10

**Currently used in:** Primarily in India, few countries in Africa, Central & South America and Southeast Asia

**Evaluation:** IEC60601-1 compliance completed, ISO13485:2008 AC 2010 and ISO9001:2008 manufacturing process compliance. CE marking process underway.

# SMS-DMCare

Country of origin | United States of America

## Health problem addressed

Diabetes is now a major health concern in low- and middle-income countries. Patient education and training is a cornerstone of effective diabetes care yet is rarely available in low-resource settings. Many providers lack basic training in diabetes and health systems are poorly equipped to provide nutrition, exercise, and medication education.

## Solution description

The product provides patients with diabetes a mobile phone-based coaching program. Patients receive automated SMS messages on their cell phones that provide education and reminders about diabetes self-care and SMS back responses to questions. Their responses help dynamically tailor the program to meet their individual needs and enable remote health workers to monitor their adherence and health needs.

## Functionality

Patients are enrolled over the phone by a remote health worker using a web-based system. The following day patients begin receiving automated SMS messages on their phone tailored to their health condition. If patients' responses suggest the need for more individual attention, an alert is sent to a remote health worker who then calls the patient.

## Developer's claims of solution benefits

The product has several advantages over existing solutions. It leverages a commonly used platform for communication, SMS, as a means of health education. As a software solution, it provides a low-cost, scalable model for improving diabetes self-management in low-resource settings. The product is based on a novel model for behavior change that has been developed by researchers at the University of Chicago, and is currently being evaluated in a clinical trial.

## Future work and challenges

The biggest barrier to this product is that it requires trained health workers to provide exception based care by telephone. Training and supervision of these health workers may be challenging in low-resource settings. Another challenge is in adapting the product to other languages and customs. The behavioral model was developed in a specific cultural context, inner-city Chicago, and may not fully translate to other settings. Finally, while SMS is an increasingly common mode of communication between health workers in low-resource settings, their use in provider-patient communication is largely unexplored.

## User and environment

**User:** Self-use/patient, low-skilled health worker

**Training:** Patients require no training. Remote health workers need training in diabetes coaching (4 weeks).

**Settings:** Rural, urban, at home.

## Solution specifications

**Solution is used to support:** Patient monitoring, Telemedicine, Treatment compliance

**Software/Hardware requirements:** Remote health workers require a computer with an Internet connection and stable power supply. However, patients only need access to a cellular phone and mobile network. The software is proprietary but will be licensed freely to public and nonprofit health organizations for use in low-resource settings.

**Currently used in:** Pilot study conducted in 2010 demonstrated the feasibility and acceptability of the product in low-income African-Americans in the U.S. Currently, a single-arm clinical trial is underway at the

University of Chicago in which 70 patients with diabetes are receiving the intervention for 6 months. Although the results are not yet published, preliminary analysis demonstrates an improvement in glycemic control (hemoglobin A1c) and in diabetes self-care activities such as treatment compliance.

**Evaluation:** Dick JJ, Nundy S, Solomon MC, Bishop KN, Chin MH, Peek ME. Feasibility and usability of a text message-based program for diabetes self-management in an urban African-American population. *J Diabetes Sci Technol.* 2011 Sep 1;5(5):1246-54.

# SMS service

Country of origin | Kenya

## Health problem addressed

Globally, 33.4 million people are infected with HIV/AIDS. While treatment scale-up in sub-Saharan Africa has had dramatic public health impacts, including reducing mortality, sub-optimal medication adherence is a barrier to maximizing health outcomes.

## Solution description

The solution involves a weekly short message service (SMS) to check-in on how patients are doing and provide them the opportunity to identify whether assistance is required. Once a week, an automated text message is sent to patients asking "Mambo?" (Swahili for "How are you?"). Participants indicate within 48 hours of receiving the message either that they are well (e.g. "OK" or "Sawa") or that they have a problem (e.g. "Problem" or "Shida"). Clinicians follow-up all participants who identify a problem to provide triage, advice, or general support. Participants who do not indicate a problem, but fail to respond within two weeks, are called by a clinician to inquire as to their status.

## Functionality

A health care worker registers patients in the system (on a laptop at the clinic). The system sends registered patients a weekly text message. A clinician reviews the incoming text messages and instances of non-response. The clinician calls patients who responded indicating a problem. Non-responders are contacted after two weeks.

## Developer's claims of solution benefits

One of the advantages of the proposed text-message support is that it has a strong evidence-base. In a randomized controlled trial, it demonstrated effectiveness at improving self-reported treatment adherence and viral load suppression at 12-months. Other advantages of the service include its use of existing technology, its simplicity, low-cost, and proven health care provider and patient acceptability in the local context.

## Future work and challenges

Part of our strategy includes the development of a sustainable business model to scale-up the service, which we are doing in our ongoing project "Moving from Evidence to Action". Challenges in making the technology available to our intended user group include: i) despite high cell phone penetration in the region, not everybody who may benefit from the service has cell phone access; ii) ensuring interoperability with existing clinic systems; and iii) despite low costs, securing sustainable financing in resource limited settings.

## User and environment

**Users:** Nurse, self-use/patient

**Training:** A clinician will instruct the patient on using the system upon registration (10 min)

**Settings:** Rural, urban, primary (health post), ambulatory

## Reviewer's comments

Although the given mHealth solution is not unique and similar SMS solutions have been implemented in low-resource settings, this implementation in Kenya has been successful based on the evaluation that has been done. It uses the existing infrastructure, is a simple, and a low-cost intervention that has proved effective in a low-resource setting.

## Solution specifications

**Solution is used to support:** Diagnosis and treatment, Health research, Patient monitoring

**Software/Hardware requirements:** The service requires a stable power supply, cellular network, a clinician to operate the system, and a cell phone for the clinician. A laptop or desktop computer is required, with the WelTel platform (Smartphone application to stay in touch with patients taking antiretroviral medications to treat HIV/AIDS) installed, a SMS gateway, and a GSM (Global System for Mobile Communications) modem connected to the computer to send and receive messages. The application is open source, customized software.

**Currently used in:** Canada, Kenya

**Evaluation:** 1) Lester R et al. Effects of a mobile phone short message service on antiretroviral treatment adherence in Kenya (WelTel Kenya1): a randomised trial. *Lancet*. 2010;376(9755):1838-1845.

2) Horvath T et al. Mobile phone text messaging for promoting adherence to antiretroviral therapy in patients with HIV infection. *Cochrane Database Syst Rev*. 2012.



# T1D system (Type I Diabetes system)

Country of origin | Spain

## Health problem addressed

People with diabetes have to eat according to a fixed pattern depending on the insulin dose prescribed by the doctor. Any change in intake, sport or other daily event, cannot be safely managed by patients.

## Solution description

This is a mobile technology to better self-manage type 1 diabetes mellitus (T1D).

Factors, like food intake and exercise, are logged into the system by the patient. The T1D system takes the insulin pattern determined by their doctor and recalculates the recommended insulin dose based on the parameters introduced by the patient in their individual daily context. By personalizing data management, the system can prevent, for example, hypoglycemia during sleep. Patients gain flexibility over their diet and security in their treatment. Patients and their doctors can connect via the system and monitor the evolution of their disease remotely.

## Functionality

Download APP interface to mobile or computer. Enter personal information (once): height, weight etc. Enter control blood sugar/glucose levels. Enter food/drink ingested. Recommended insulin is calculated. Information is synced in real-time between diabetic and doctor. Alerts are sent to both when a potential problem is flagged.

## Developer's claims of solution benefits

Existing solutions do not take into account individual differences in people with diabetes. The T1D system does and it creates preventive actions before problems occur. Other options focus on the now. The system focuses on the past, present and future. T1D and T2D costs healthcare systems \$471 billion/year, often in response to complications. Our T1D system is a call to action for the person with diabetes to self-manage their disease and let their doctor be more time- and cost-effective. This can lead to fewer complications so less face time will be needed.

## Future work and challenges

The T1D system uses metric weights and measures but the United States uses avoirdupois and imperial so there is a potential need to additionally develop to address the US users satisfactorily. Future development work includes port to iOS/iPhone and an interface with glucometers.

The T1D system puts insulin dosage adjustment and control into the hands of the person with diabetes. They become the primary monitor, not their doctor. Their disease reacts and responds to them, the individual. It does not act generically. So the T1D system treats the individual as such by reacting and responding to them, the individual. It's a fundamental shift in responsibility to self-manage a unique life and lifestyle.

## User and environment

**User:** Physician, self-use/patient

**Training:** Training is not needed. The system is very user-friendly but training videos are being produced

**Settings:** Rural, urban, at home, ambulatory

## Reviewer's comments

This software, available for free or at an additional cost with the premium version, can help motivate patients' behavioural change in several ways:

1. By tracking food intake and caloric intake, it helps patients to understand the type of food that they eat vis-a-vis the caloric count - something health professionals cannot be too specific about. For example, a doctor in Spain would be hard pressed to articulate what a 1500 Calorie diet for his/her African or Asian patients. Patients can take responsibility and fully understand their intake and sensibly alter patterns. Recent studies suggest that the general population has difficulty accurately estimating their food intake, and this applies both to adults and even more so to teenagers.
2. Tracking food intake and setting goals are powerful ways to motivate patients to change. This system would encourage that.
3. Being able to have communication with their doctors, providing support and the ability to take the power of control of how much insulin to use gives the motivated patients incentive change take to make positive changes.

## Solution specifications

**Solution is used to support:** Diagnosis and treatment, Electronic Health Record/Electronic Medical Record, Health research, Management of patient information, Patient monitoring, Public health surveillance, Telemedicine

**Software/Hardware requirements:** Access to a cellular/mobile network via mobile, personal computer, tablet or SmartTV. Android platform.

App is free. Premium version license at \$19.25/year

**Currently used in:** Worldwide

**Evaluation:** Currently 2,900 active users. Rating for ease of use and effectiveness between 4.51 - 5.0 (highest satisfaction=5.0 out of 5.0).

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<http://www.who.int/ehealth>



# TeleOphthalmology aided primary eye care

Country of origin | India

## Health problem addressed

1% of the population are blind and 80% of these cases are treatable or preventable. As with other health care, eye care services also have significant variations across regions and between rural and urban settings. There is a challenge of access. A shortage of ophthalmologists restricts the provision of services in rural areas.

## Solution description

It is a web-based comprehensive software solution for primary eye care services that records the registration of patients, records systemic diseases and clinical findings, captures images, and integrates teleconsulting equipment so a base hospital ophthalmologist can review the findings and discuss the problem. It also generates prescriptions, manages the inventory of optical and medical supplies, includes financial details and tracks the patients referred to the base hospital to ensure compliance with the recommended treatment. Ophthalmologists have access to the medical record entered at the rural centre from the base hospital, and interact with the patient and provide consultancy services to the patient.

## Functionality

The rural centre coordinator registers the patient by asking their demographic and systemic condition details and generates an ID Card. A vision technician examines the patient, enters the findings and passes a message to the base hospital ophthalmologist to come online for a consultation. The ophthalmologist consults and advises on the treatment accordingly.

## Developer's claims of solution benefits

Community outreach programs have been the traditional approach to reach the rural community. As per the referred research, only 6.8% of the population who need eye care attend eye camps - a temporary service offered a maximum of twice per year.

Primary eye care centres in rural areas are a permanent setup to provide primary eye care, diagnostic services and delivery of the services. They helped to reach 25% of the community in 4 years in support of universal coverage. Using tele-ophthalmology will enable services to treat 90% of the patients visiting the centre without any visits to the base hospital.

## Future work and challenges

As such there are no major challenges in the technology. Today, the majority of the eye care providers are concentrating on secondary and tertiary eye care services. This tool will enable the promotion of primary eye care. In order to implement this system, the service should be designed in such a way that the primary eye care centres are connected to secondary and tertiary centres in order to handle the patients that could not be handled at their level.

## User and environment

**User:** Technician, ophthalmic technician

**Training:** Trained users handle training either onsite or remotely for 3 to 7 days

**Settings:** Rural, primary (health post, health centre)

## Solution specifications

A Primary Eye Care Centre offers the following facilities:

1. 400 sq ft of space to accommodate various examination rooms
2. Trained vision technician and coordinator of ophthalmic equipment, like slitlamp, refraction trial set and drum
3. Computer, 512 Kbps Internet connectivity, webcam

The only functionality of the tool is to transmit video and audio. Any software could be designed around this tool like our auroPECS.

# Medical devices

## 2013

# Bedside newborn phototherapy

Country of origin | United States of America

## Health problem addressed

Global health experts estimate 10% of all newborn mortality can be attributed to jaundice. An excess of the chemical bilirubin in the blood approaches dangerous levels in more than 10% of all newborns. The result can be kernicterus, lifelong disability, severe brain damage, and death, placing an extreme burden on families and communities. Every year in South Asia and Sub-Saharan Africa, more than 5.7 million jaundiced infants need treatment, but do not receive simple phototherapy. There currently is no durable and easy-to-use phototherapy device for rural facilities, so newborn jaundice accounts for 20-33% of admissions to national-level hospitals in developing countries.



## Product description

Bedside Newborn Phototherapy is a device designed to treat jaundice in the mother's room in rural clinics. The double-sided, high-power LED lighting cures the most severe cases of jaundice and dramatically reduces treatment time.

## Developer's claims of products benefits

The device is compact, intuitive, and durable enough to function in the mother's room in a rural clinic, reducing staff workload and promoting breastfeeding. The reduction in treatment time allows resources to be used to treat more infants and allows the family to go home sooner. This can decrease the cost of care, reduce loss of income, reduce exposure to infection, and return mother and baby to the safer home environment to breastfeed. Bedside Newborn Phototherapy's design uses energy-efficient light emitting diodes (LEDs) that last 5 years. It is completely sealed against dust and bugs and has no moving parts, drastically increasing product life.

## Suitability for low-resource settings

In low-resource settings, jaundiced infants referred from rural to higher-level hospitals risk developing permanent brain damage or dying en route. Jaundiced infants are isolated from their mothers in crowded neonatal ICUs, hindering breastfeeding in the critical first days. Bedside phototherapy enables rural hospitals to treat jaundice, which reduces the burden on national-level hospitals to treat more serious conditions. It is produced locally in Vietnam.

## Operating steps

Plug it in and press the button. Fixed two-sided lighting, one intensity setting, and an easy to clean, removable single-infant bassinet make this device hard to use improperly, thereby reducing incidence of ineffective treatment and cross-infection.

## Regulatory status

Used IEC 60601-1:2005 and IEC 60601-2-50:2009 standards to guide the design. Pending assessment by Ministry of Health in Vietnam, recognized by the ASEAN countries. Expected date November 2013.

## Future work and challenges

Production of the first 200 Bedside devices is nearing completion. The first devices were delivered to hospitals in northern Vietnam during Fall 2013; over the following year the remainder will be distributed to Vietnam, Myanmar, Cambodia, Laos, East Timor, the Philippines, Thailand, Malaysia, and Ghana. The plan is to expand to a total of 1,000 Bedside devices, reaching at least 250,000 newborns. The next big challenge is to connect with additional organizations who wish to purchase and distribute the devices worldwide to reach millions of beneficiaries.

## Use and maintenance

**User:** Physician, nurse, family member

**Training:** Provided by supplying organization

**Maintenance:** None

## Environment of use

**Settings:** Rural, urban settings, primary (health post, health center), secondary (general hospital), tertiary (specialized hospital)

**Requirements:** Continuous power supply (90-264VAC), or a 12VDC input typical of car batteries and solar power systems.

## Product specifications

**Dimensions (mm):** 660 x 380 x 495

**Weight (kg):** 11.8

**Consumables:** None

**Life time:** 5 years

**Shelf life:** 5+ years

**Retail Price (USD):** N/A

**List price (USD):** 1500

**Other features:** Mobile, capital equipment

**Year of commercialization:** 2011

**Currently sold in:** Cambodia, East Timor, Ghana, Laos, Malaysia, Myanmar, Philippines, Thailand and more.

# Compact portable ultrasound

Country of origin | United States of America

## Health problem addressed

The device addresses the issues of maternal death, maternal near misses, newborn death, and stillbirths. Obstetric complications that may be detected by ultrasound include: placenta previa, fetal malposition, multiple gestations, ectopic pregnancy, retained placental products, fetal anomalies, and fetal demise.

## Product description

As a compact portable visualization tool with ultrasound technology this device provides a non-invasive look inside the body for immediate visual validation of what a clinician can feel or hear. The additional information facilitates optimization of the course of treatment for the patient and reduces time required for diagnosis, thereby reducing patient wait times and improving clinical workflow. The device is small and lightweight, which makes it easy to carry and its battery capacity provides over one hour of scanning on a single charge, giving it enough power for a full day's worth of patient exams.



## Developer's claims of products benefits

While ultrasound forms an integral part of pregnancy management in developed nations, the technology is highly inaccessible and underused in resource poor settings. The need for trained health professionals, a certain level of infrastructure and a continuous power source limits ultrasound access in many regions. Unlike most available ultrasound devices, this compact ultrasound device is portable, easy to use and is battery operated. The device can also be charged with solar power to enable its use in areas that do not have regular grid power supply.

## Suitability for low-resource settings

The technology is suitable for use in health centres in low-resource settings where electricity is irregular or unavailable. It is ideal for attracting more mothers to the formal health system increasing antenatal attendance and institutional delivery. The device has been used in low resource settings by health paraprofessionals in Indonesia, Tanzania, Ghana and Bangladesh. These users were competent performing limited obstetric ultrasound in rural and peri-urban health centers.

## Operating steps

To start the device: open the flap and the device will start automatically. Select the OB preset and apply gel on the transducer to start scanning. Increase or decrease depth with the up and down arrows and auto optimize by pressing and holding the central button. Close the device after use and put on the docking station for recharging.

## Regulatory status

The device is both FDA approved and CE marked.

## Use and maintenance

**User:** Physician, technician, nurse, midwife

**Training:** Limited obstetric training is conducted by local trainers usually in the country's capital city.

**Maintenance:** Limited routine maintenance that can be performed by a nurse, physician, technician, or manufacturer.

## Environment of use

**Settings:** Rural, urban settings, ambulatory, at home, primary (health post, health center), secondary (general hospital), tertiary (specialized hospital)

**Requirements:** Some source of power, even if intermittent, for charging the device.

## Product specifications

**Dimensions (mm):** 135 x 73 x 28

**Weight (kg):** 0.39

**Consumables:** Ultrasound gel, cleaning supplies

**Life time:** 7 years

**Retail Price (USD):** 7900 USD with considerable variation between countries

**List price (USD):** 12,000

**Other features:** Software use, portable, capital equipment

**Year of commercialization:** 2010

**Currently sold in:** More than 40 countries



# Dry blood spot screening

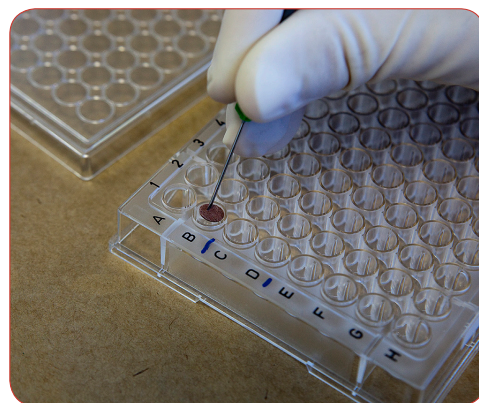
Country of origin | Spain and Brazil

## Health problem addressed

Early diagnosis and prevention are widely promoted by national health systems, international organizations and NGOs, because they have been shown to represent significant savings for health systems and the patients themselves. Despite this, access to these benefits by the poor is limited due to challenges in getting blood to labs for analysis.

## Product description

The test analyzes specific biochemistry parameters - uric acid, cholesterol, triglycerides, glucose, creatinine - in dried blood samples, using standard laboratory equipment. Blood samples are obtained by a single-use lancet or pin prick. The system does not require special conditions for storage or transportation and it requires only minimal investment in training the personnel that handle the samples. Using the device only requires a finger-prick.



## Developer's claims of products benefits

The current blood diagnosis industry, which is based mainly on venous puncture, is oriented towards developed markets where costs of logistics (refrigeration and transportation) are expensive but do not represent the highest burden. However, in developing economies, these costs are unaffordable for the system or individuals and families. This test eliminates cold chain requirements, which results in major cost savings and makes a step towards universal lab blood service coverage. It also makes it possible to remove the key impediments to population monitoring through massive screening to inform health policies. The strategy is based on maintaining a solution at very low cost so that it can be offered to all people, including those that have very limited financial resources.

## Suitability for low-resource settings

The test has been implemented in several countries. It has been used successfully in the favelas of Rio, where only 30% of the pregnant women have access to a antenatal care to prevent vertical transmission. However, with the device, samples were collected in the hospital and sent to a lab, with 100% coverage of the 84,000 women in the catchment area ensuring that there was no vertical transmission from these women to their children. The system has also been tested in In Alta Verapaz, Guatemala, with coverage for 1,500 pregnant women who live in the forest.

## Operating steps

A few drops of blood, are dried on filter paper at room temperature (1 - 1.30 hrs). Once dried, the sample can be transported by any means to the lab - no need for cold chain. In the lab, a 3mm sample is cut. With a single drop two to four parameters (HIV, Syphilis, Hepatitis, Cholesterol, Glucose, etc.) can be analyzed, using an appropriate solvent which extracts the biological material that is required for the test. This room-temperature extraction (stove & shaker) occurs inside a micro plate and read-out is done on an ELISA's reader.

## Regulatory status

Reagents for infectious diseases and non-communicable diseases have approval for use by authorities such as ANVISA in Brazil. It has a CE mark for its biochemistry reagents.

## Future work and challenges

The business model for this product is based on high volume, high quality and affordable cost. For this reason the product needs the collaboration of governments that seek data to reduce the burden of disease. One way to obtain this data is from large-scale blood screening and analysis.

## Use and maintenance

**User:** Self-use/patient, physician, nurse, midwife, family member

**Training:** One week for laboratory technicians, one hour for personnel in the field

**Maintenance:** None

## Environment of use

**Settings:** Rural, urban settings, ambulatory, at home, primary (health post, health center), secondary (general hospital), tertiary (specialized hospital)

**Requirements:** Water. At field level: lancet and filter paper; at the local laboratory: an ELISA reader.

## Product specifications

**Dimensions (mm):** Not provided

**Weight (kg):** Not provided

**Consumables:** Specific reagents

**Life time:** Not provided

**Shelf life:** Not provided

**Retail Price (USD):** 5

**List price (USD):** 5

**Other features:** Mobile, single-use

**Year of commercialization:** 2008

**Currently sold in:** Brazil, Guatemala, India, Spain



# Electro-hyperthermia

Country of origin | Germany

## Health problem addressed

In 2008 there were 715,000 new cases (95% in advanced stages) and 542,000 deaths from cancer in Africa. The available treatments are limited and the increasing incidence of cancer is a huge burden on the struggling economies in Sub-Saharan Africa. Heating tumours increases chemo-/radiotherapy efficacy, improves survival and lowers healthcare costs.

## Product description

A 13.56 MHz low radiofrequency electric field is applied using capacitive coupling between two electrodes. The electric field passes through the patient's body moving through the pathways with the lowest impedance. The malignant tissue has lower impedance due to the increased ion concentration in the highly metabolic tumours (as seen on PET scans). The tumour acts as a capacitor; it stores a charge and is safely and selectively heated, sensitizing it to the chemotherapy or radiation therapy treatment. Hyperthermia damages the cell walls; slows protein, DNA and RNA synthesis/repair; increases blood flow, drug delivery, oxygen, metabolism and drug reaction rate; and sensitizes hypoxic tumours to radiation.



## Developer's claims of products benefits

The only technique other than electro-hyperthermia used in the region is interstitial hyperthermia (South Africa). Although effective, interstitial hyperthermia is complex, expensive, has high risks, and requires specialized staff and facilities. Various technologies are available internationally but they are expensive and impractical for Africa. It is safer (even for the brain) due to non-invasive, selective and deep heating. The safety, simplicity and practicality of the device make it more cost-effective to use, with a capital price as much as 10 times lower than some devices. It is far more practical in limited resource settings as the treatments are only 30-90 minutes and dedicated/specialized staff/facilities are not required (unlike other devices which require bunkers, MRIs, etc). It is reliable and easy to maintain with a 10 year life span.

## Suitability for low-resource settings

In oncology, funding, resources, staff and facilities are limited. The device is safe for patients and staff; easy to use and very reliable (10 year life span). It does not require specialized facilities/equipment/consumables/staff. It comes with a UPS (protects against power surges in the region) and it is affordable and cost effective to run and maintain (only 2 services a year). It can improve treatment efficacy and lower the costs of the treatment. It has been in use in a private facility in South Africa for four months. Reports from doctors and patients confirm the safety, feasibility and practicality of the device.

## Operating steps

Switch on the device. Let the self-test run. Choose the correct size electrode. Fix the electrode to the adjustable arm and plug in the cable to the bed. Lay the patient on the bed. Place the electrode over the treatment area. Set the treatment parameters (time/power). Press start. Device will signal end of treatment. Press stop, remove electrode, and assist patient off the bed.

## Regulatory status

Approved by European Union (EU) - European Medical Device Directive (CE), Germany - Technischer Überwachungs-Verein (TUV), Australian Registrar of Therapeutic Goods, South Africa - Department of Health: Directorate of Radiation and Hazardous substances, Russia, Korea (KFDA), Turkey, Canada - Health Canada.

## Future work and challenges

The economic instability in the region is the largest challenge. The most unstable countries do not have oncology facilities offering radiation and chemotherapy, thus these countries will not be included in the target market until such time as facilities are available and technical staff are able to move safely in the countries. In countries in which facilities are available, the public health sector will be targeted as this is where the most benefit will be gained from the technology.

## Use and maintenance

**User:** Physician, nurse, radiation therapist

**Training:** One day, on site conducted by distributor

**Maintenance:** Every 6 months by local distributor technical staff.

## Environment of use

**Settings:** Rural, urban settings, secondary (general hospital), tertiary (specialized hospital)

**Requirements:** The work area should be 4m x 4m (safe for consulting areas, no shielding required). The electricity supply should be 230V/50Hz (device includes surge protector and 30 minute battery back-up). The device should be kept within +10°C to +30°C, 20% - 60% humidity, and 700 hPa - 1060 hPa.

## Product specifications

**Dimensions (mm):** 585 x 2062 x 920

**Weight (kg):** 500

**Consumables:** None

**Life time:** 10 years

**Retail Price (USD):** 303,000

**List price (USD):** 303,000

**Other features:** Software use, installed stationary, capital equipment

**Year of commercialization:** 1996

**Currently sold in:** Australia, Austria, Belgium, Canada, China, Denmark, Germany, Greece, Hungary, Israel, Italy, Japan, Jordan, Lebanon, Netherlands, Poland, Romania, Russia, South Korea, Turkey, Ukraine, South Africa

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

# Fecal occult blood test

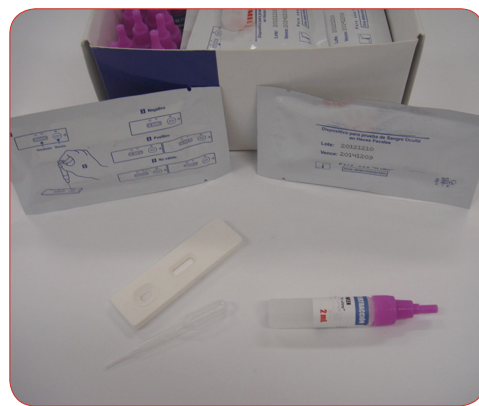
Country of origin | Cuba

## Health problem addressed

Cancer is one of the main causes of death in the world. It is expected that death by cancer worldwide will grow to reach 13,1 million in 2030. Colon cancer is among those with the highest death rate. However, the success rate of treatment is also high when detected at early stages and properly treated.

## Product description

The device enables fast qualitative detection of occult blood in feces. It consists of a sandwich type chromatographic immunoassay and makes use of a combination of monoclonal and polyclonal antibodies for the detection of human hemoglobin with a high degree of sensitivity. In five minutes, levels of human hemoglobin as small as 0.2 Qg/mL can be spotted in feces and positive results are visually evident. The test is used for annual screening of colorectal cancer in people above age 50 and it is useful for the early diagnosis and follow-up treatment of gastrointestinal disorders that cause bleeding. The product is supplied in boxes of 20 cassettes and 20 collector flasks.



## Developer's claims of products benefits

The test can provide highly sensitive and rapid detection of human blood in the feces. The technology uses a detection method that is specific to human hemoglobin, so the patient does not need to stop eating meat two or three days earlier as there is no interference with animal hemoglobin.

## Suitability for low-resource settings

Standard (household) refrigeration is the only requirement. It has been used successfully in Cuba.

## Operating steps

A small amount of feces should be taken as a sample by using the applicator incorporated to the top of the collector flask. Afterwards, the top is wound and the flask content agitated. A diluted sample will be placed on the cassette by using the collector flask dropper. In five minutes, the result can be read from the device.

## Regulatory status

The test is registered in Cuba and Peru and is GMP compliant. It has been evaluated by Cuba's CECMED (Centro Estatal para el Control de Equipos Médicos y Medicamentos) and Peru's DIGEMID (Dirección General de Medicamentos, Insumos y Drogas).

## Future work and challenges

The strategy is to provide a stable supply of consumables (diagnostic kits), a stable after sales service, and technological renewal as soon as improved diagnostic kits are developed.

## Use and maintenance

**User:** Physician, technician

**Training:** None

**Maintenance:** None

## Environment of use

**Settings:** Rural, urban settings, ambulatory, primary (health post, health center), secondary (general hospital)

**Requirements:** Product should be stored in a standard (household) refrigerator between 2-8 °C.

## Product specifications

**Dimensions (mm):** 160 x 115 x 80 (per box of 20 cassettes and 20 collector flasks)

**Weight (kg):** 0.3 (per box of 20 cassettes and 20 collector flasks)

**Consumables:** None

**Life time:** 2 years

**Shelf life:** 2 years

**Retail Price (USD):** 2 (per test)

**List price (USD):** 2 (per test)

**Other features:** Portable, single-use

**Year of commercialization:** 2013

**Currently sold in:** Cuba

# Infant radiant warmer

Country of origin | India

## Health problem addressed

In under-resourced settings, hypothermia at birth is one of the most important risk factors for newborn morbidity and mortality. 99% of newborns that die globally are in such settings. It is vital to keep newborns warm and help them achieve thermoregulation in order to prevent and minimize morbidities and mortalities due to hypothermia.

## Product description

The device consists of a biocompatible bed on which to place the infant, and an overhead heater that delivers radiant heat. A skin temperature probe monitors infant temperature. Heat output can be controlled manually or through baby mode (feedback mode) for thermoregulation. Visual and audio alarms are present for safety. An APGAR timer helps to efficiently take APGAR scores post-delivery.



## Developer's claims of products benefits

Current radiant warmers have heaters typically made from quartz or ceramic. These heaters tend to breakdown faster as well as take a much longer time to heat up - up to 13 minutes in some cases. Each additional minute of cold stress can lead to increased morbidity for an infant. This device gives better clinical results because it provides uniform heating across the bed as well as a much faster warmup time (4 minutes only) that reduces the time to warm a hypothermic infant. Furthermore, the lower power consumption and long life of the heating element (Calrod heater) lead to considerable cost savings.

## Suitability for low-resource settings

The device uses less power at startup and during operation compared to other radiant warmers. It is designed for infection control (e.g. non-stitch biocompatible mattress for no infections in stitches plus no need for a mattress cover). It has a faster warmup time for high volume environments with little pre-warming. Over 1500 warmers have been deployed in low-resource settings.

The device has been designed, developed and manufactured in India based on extensive customer input in India and similar countries. It has been adopted in Tier 2 and 3 towns in India, as well throughout the country of Myanmar by the Ministry of Health. Testing of the device includes protocols that try to simulate low-resource setting issues such as voltage fluctuations, high humidity etc.

## Operating steps

The device is usually pre-warmed in manual mode for at least four minutes. The infant is then placed on the bed mattress and the skin temperature probe is attached. The operator then switches to baby mode (feedback) and enters the desired baby temperature. The APGAR timer and observation light can be switched on as needed.

## Regulatory status

It conforms with the requirements of Medical Devices Directive 93/42/EEC - BSI CE 0086 mark. It is also certified ISO 13485. It has US FDA 510K clearance (K121625), and it is ROHS compliant.

## Use and maintenance

**User:** Physician, nurse, midwife

**Training:** Initial training by manufacturer, and operator manual

**Maintenance:** Annually by technician, engineer, or manufacturer

## Environment of use

**Settings:** Rural, urban settings, primary (health post, health center), secondary (general hospital), tertiary (specialized hospital)

**Requirements:** Continuous power supply (100-240V). Can withstand some fluctuations in voltage and occasional spikes, but stable power supply is strongly recommended. General cleaning supplies to disinfect after every infant are needed.

## Product specifications

**Dimensions (mm):** 1120 x 655 x 1800 (minimum height), can be ordered at different settings from factory

**Weight (kg):** 72

**Consumables:** Reflector patches to cover the sensor are recommended in order to provide an accurate reading

**Life time:** 7 years

**Shelf life:** 2 years (6 months without any operation)

**Retail Price (USD):** 3000, with considerable variation between countries

**List price (USD):** 3500

**Other features:** Software use, mobile, capital equipment

**Year of commercialization:** 2009

**Currently sold in:** 115 countries. Emerging market countries include Albania, Algeria, Brazil, Bulgaria, Cambodia, Chile, Dominican Republic, Egypt, Gabon, India, Indonesia, Iraq, Jordan, Kazakhstan, Kenya, Lebanon, Macedonia, Nigeria, Palestinian Territory, Philippines, Syria, South Africa, Vietnam.

# Infant warmer

Country of origin | United States of America

## Health problem addressed

There are over 20 million premature and low birth weight babies born each year globally, with more than 95% born in developing countries. Three million babies die within the first 28 days of their life, with more than a quarter of these deaths occurring in India alone. Those who survive often grow up to have lifelong problems such as low IQ, early onset of diabetes, and heart diseases. Hypothermia is a significant problem faced by many of these babies.

## Product description

The infant warmer works without a constant supply of electricity. It has no moving parts, and is safe and easy to use. It is also portable, enabling newborns to be kept warm during transport. One of the other big advantages of the device is that it complements Kangaroo Mother Care (KMC). It consists of three parts - a sleeping bag to place the baby, a pouch of phase change material and an electric heater. The pouch is heated for 30 mins in the heater (second version uses boiling water instead of electricity to heat) and then placed in the sleeping bag. It maintains the WHO recommended temperature of 37 deg C for 4-6 hours, after which it can be reheated.



## Developer's claims of products benefits

In low resource areas in developing countries, common infant warming methods include blankets, hot water bottles, hot coals & light bulbs. These methods are ineffective and unsafe, often causing burns on babies. Some hospitals use a device called a radiant warmer which is expensive, needs a constant supply of electricity and is complicated to use. This innovative infant warmer is much lower cost (less than half) of other devices (mostly radiant warmers) available to treat hypothermia in low birthweight infants. It also has much lower running costs since it does not require a constant supply of electricity and faces a much lower incidence of breakdowns (almost zero). In addition, it is much easier to use and reduces the load of nurses/doctors. In comparison to make-shift solutions such as light bulbs, this is safer and effective.

## Suitability for low-resource settings

The technology is meant for use in low-resource and remote primary and secondary healthcare facilities. These facilities have intermittent access to electricity and very low doctor/nurse to patient ratio. With just 10-20 beds, these facilities may administer over 200 deliveries a month. This infant warmer works well with intermittent electricity in these settings, reduces the load of nurses/doctors due to ease of use and quicker monitoring, and does not occupy much physical space. The device has been deployed in more than 50 low-resource and remote primary/secondary government healthcare facilities across India. Doctors and nurses have given extremely positive feedback about the device's ease of use resulting in reduced workload and high quality healthcare that may otherwise not be easily available in these settings. The device has been functioning well in these settings and is in frequent use. The technology is currently being produced locally. The heater requires basic electronic components which are readily available locally. The sleeping bag is made locally using a tailor. The pouch of phase change material is also packaged locally.

## Operating steps

Sanitize all 3 components. Insert the phase change material pouch into the heater. Close the lid of the heater and push button. In 30 minutes, the alarm will ring. A green light indicates that the phase change material pouch is ready and remains lit to indicate that the heater is keeping the pouch warm.

Remove pouch, check temperature indicator, and use only if indicator bar is in OK region. Place the pouch of phase change material correctly into the sleeping bag. Wrap the newborn and tighten straps to prevent the newborn from slipping. Monitor the newborn's temperature once every hour for the next 4-6 hours. When the temperature indicator on the pouch slips into the TOO COLD region, remove the newborn. Remove the pouch and reheat as needed.

## Regulatory status

A draft CE Mark has been received. Internal processes are ISO:13485 certified.

## Future work and challenges

The target users are neonatologists and pediatricians (including those in government hospitals) who will use the warmer as a critical component of providing neonatal care for low birth weight infants, starting with those in India. Different strategies have been implemented to reach out to these practitioners including establishing a direct sales team and partnerships with pharmaceutical/medical device companies for distribution.

## Use and maintenance

**User:** Physician, nurse

**Training:** No intensive training required. Basic instructions included with device in pictorial form.

**Maintenance:** None

## Environment of use

**Settings:** Rural, urban settings, ambulatory, primary (health post, health center), secondary (general hospital), tertiary (specialized hospital)

**Requirements:** Intermittent supply of electricity, limited supply of water and sanitizer (to clean the sleeping bag before placing newborns). Second version of the warmer, meant for in-home use, uses boiling water instead of electricity.

## Product specifications

**Dimensions (mm):** 440 x 290 x 70

**Weight (kg):** 4.1

**Consumables:** None

**Life time:** 3 years

**Retail Price (USD):** 250

**List price (USD):** 250

**Other features:** Portable, reusable

**Year of commercialization:** 2011

**Currently sold in:** India



# Infrared ear thermometer

Country of origin | China

## Health problem addressed

Body temperature measurement is used to assist in disease diagnosis.

## Product description

The device has a sensor inside that detects infrared emitted from the tympan. It provides the body temperature based on the calculation of the amount of emittance. This ear thermometer does not require a protective cover for the sensor, and the sensor can be cleaned by wiping it directly with ethanol.

## Developer's claims of products benefits

Other body temperature measurement options take a long time, and other ear thermometers usually require a protective cover to prevent the invasion of foreign matter. These covers may affect the accuracy of the measurement, cause infection when inappropriately used, and increase maintenance costs. The design of this device enables fast measurement (only one to two seconds), requires no protective cover, allows for easy cleaning of the sensor (wiping directly with ethanol), and has a low maintenance cost. The compact design allows for portability.

## Suitability for low-resource settings

This device is suited for use in areas where the healthcare system is less developed given its ease of use and low maintenance costs. It is also designed for home use (especially for infants). This device is already registered and well accepted in China.

## Operating steps

Switch on the power and check the display. Pull the ear backwards, insert the ear thermometer straight into the ear path, make sure the sensor reaches the tympan, and press the start button to measure. Measurement is complete when an audible beep is heard and the indicator is on. Read the result. Clean the sensor after use.

## Regulatory status

The device has a Republic of China Measuring Device Manufacturing License and a Republic of China Medical Device Registration.

## Future work and challenges

The price of this device is still quite high compared with normal thermometers, which limits its distribution. However, the production cost will decrease with an increase in production quantity.

## Use and maintenance

**User:** Self-use/patient, physician, technician, nurse, midwife, family member

**Training:** None

**Maintenance:** Cleaning of probe at fixed intervals

## Environment of use

**Settings:** Rural, urban settings, ambulatory, at home, primary (health post, health center), secondary (general hospital), tertiary (specialized hospital)

**Requirements:** Requires batteries of type CR2032, with an environment of use between 16 and 35 degrees Celsius and 30-85% relative humidity without condensation.

## Product specifications

**Dimensions (mm):** 105 x 32 x 25

**Weight (kg):** 0.038

**Consumables:** None

**List price (USD):** 76

**Other features:** Portable, reusable

**Year of commercialization:** 2012

**Currently sold in:** China





# LED phototherapy for neonatal jaundice

Country of origin | India

## Health problem addressed

Neonatal jaundice (hyperbilirubinemia) occurs in at least 60% of term infants. If untreated, it can cause irreversible brain damage. Phototherapy equipment for treatment currently available have frequent bulb replacement needs, expensive bulb replacement costs and experience frequent breakdown in remote, rural areas.

## Product description

The device emits light through an array of high-powered light emitting diodes (LEDs). These LEDs have been specifically selected to emit a narrow wavelength of blue light (dominant wavelength 458nm) that maximises the rate of bilirubin breakdown. The arrangement of the LEDs along with the optics have been designed to provide uniformity of light on the patient, while minimizing unwanted spill and glare outside the treatment surface. The device provides the ability to cater the treatment to the patient by allowing the caregiver to choose a high intensity ( $45\mu\text{W}/\text{nm}/\text{cm}^2$ ) or low intensity ( $22\mu\text{W}/\text{nm}/\text{cm}^2$ ) setting.



## Developer's claims of products benefits

Most phototherapy devices on the market use tubelights or compact fluorescent (CFL) bulbs to provide phototherapy. Many of these do not provide adequate intensity or uniform coverage. Moreover, these tubelights have to be replaced frequently - every 1000 hours. This is often not feasible due to high replacement costs and availability in markets.

This device is easy to use for the caregiver, has a low total cost of ownership, is designed to be rugged and reliable, and provides excellent clinical outcomes. The uniformity, intensity and wavelength of emitted light results in a 28% increase in bilirubin breakdown. It utilizes only 20W of power, which is great for electricity savings as well as for the environment. It can be used with most commercially available photovoltaic systems, or potentially car batteries connected to inverters. It is simple to use with only two buttons - on/off and high/low. Lamps last for 50,000 hours, which provides 6 years of night and day use.

## Suitability for low-resource settings

The device is specifically designed for low resource settings. It is designed to be rugged: e.g. all moving mechanical parts such as fans have been removed from the lamphead. The cost of ownership is highly minimized by having LEDs that last 50,000 hours - 6 years of night & day use, and 50 times that of bulbs. It also uses only 20W of power. Over 2000 units have been deployed in low-resource settings.

Almost one third of the device's sales in India have been to Tier 2 or 3 towns. It has been awarded the Oxford Analytica validation Healthymagination certificate for product that improves access, better quality and reduces cost of care. The Federation of Indian Chambers of Commerce and Industry have awarded it the prestigious Healthcare Excellence Award in 2012 for innovation to solve pressing healthcare challenges in India.

## Operating steps

The device is simple to use. After installation, it has to be plugged into mains power (100-240V). There are then only two buttons - On/Off and High/Low to vary the intensity. Black screws on top can be unfastened to remove the lamp head for placement on an incubator. The height of the lamp can be adjusted by unscrewing a ring in center of the pole.

## Regulatory status

It conforms with the requirements of Medical Devices Directive 93/42/EEC - BSI CE 0086 mark. It is also certified ISO 13485. It has US FDA 510K clearance (K120168). It is ROHS compliant and a WEEE certificate is available.

## Use and maintenance

**User:** Physician, nurse, midwife

**Training:** None

**Maintenance:** None

## Environment of use

**Settings:** Rural, urban settings, primary (health post, health center), secondary (general hospital), tertiary (specialized hospital)

**Requirements:** Continuous power supply (100-240V)

## Product specifications

**Dimensions (mm):** 530 x 550 x 1700 (maximum height)

**Weight (kg):** 10

**Consumables:** None

**Life time:** 7 years

**Shelf life:** 2 years (6 months without any operation)

**Retail Price (USD):** 1200 with considerable variation between countries

**List price (USD):** 1500

**Other features:** Mobile, capital equipment

**Year of commercialization:** 2011

**Currently sold in:** 122 countries. Emerging market countries include Bahamas, Bolivia, Costa Rica, Czech Republic, Ecuador, Egypt, Gabon, Ghana, Hungary, India, Indonesia, Mexico, Moldova, Myanmar, Peru, Philippines, Poland, Romania, South Africa, Thailand, Tunisia, Vietnam.

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# Low pressure anaesthesia machine

Country of origin | United Kingdom

## Health problem addressed

More than 2 billion people lack access to adequate emergency surgical services and receive just 4% of 234 million surgical procedures performed each year. A major deficiency is the lack of appropriate anaesthesia equipment which can operate despite power outages and shortages of compressed oxygen, both of which are required for conventional machines.

## Product description

This device allows oxygen from multiple sources, includes an integrated concentrator, pipeline, and cylinder, and can also draw in room air if no other source of oxygen is available. It can work without power during long outages without any reconfiguration during surgery. It is designed for adult, pediatric and neonatal patients. All disposables are generic.



## Developer's claims of products benefits

Conventional anaesthesia machines require compressed oxygen to create the anaesthetic gas mixture. Most machines also need electrical power to operate. Without compressed gas or power there is no general anesthesia other than the use of ketamine. This device, however, works at ambient pressure and can adapt to loss of compressed gas or electric power. If power is available, the device creates its own oxygen supply and acts like a conventional machine (though saving money on compressed gas.) If no power or compressed gas is available, it automatically draws in room air and continues to safely deliver anaesthetic gas. Battery operated patient monitoring provides safe delivery under any circumstances.

## Suitability for low-resource settings

Many low-resource hospitals experience power outages and stock outs of compressed gas. This device works at ambient pressure and can adapt to loss of compressed gas or electric power.

## Operating steps

When the device is operated, the oxygen flow rate automatically matches the patient minute volume demand. If required, room air is introduced. To deliver the anaesthetic agent, ambient pressures are sufficient and compressed medical gas is not required. When required, patient ventilation is performed with bellows.

## Regulatory status

The machine is CE marked and is produced in an ISO certified factory.

## Future work and challenges

The organization providing the device operates as a non-profit and sells the device to non-profit and government hospitals at a discounted price that covers manufacturing cost and delivery. It is distributed through NGOs, government tenders, sales to donor organizations and direct sales and donations to hospitals. The challenges include cost-effective distribution in low income countries, cost of training users ranging from anesthesia assistants to consultant anaesthetists, and provision of service to remote locations. The focus is on training users and local technicians and providing backup support when necessary.

## Use and maintenance

**User:** Physician, anaesthesia clinical office, nurse anaesthetist

**Training:** Training provided by local or international medical doctor anaesthetists and biomedical technicians

**Maintenance:** Daily checklist for user with occasional replacement of the oxygen sensor and air filter

## Environment of use

**Settings:** Rural, urban settings, primary (health post, health center), secondary (general hospital), tertiary (specialized hospital)

**Requirements:** Intermittent access to electrical power to charge battery. Stable power connection to use optional oxygen concentrator

## Product specifications

**Dimensions (mm):** 1460 x 530 x 690

**Weight (kg):** 130

**Consumables:** 80 USD/year including 60 USD for oxygen fuel cell replacement every 12 to 18 months and 20 USD for primary air filter replacement every year.

**Life time:** 15 years

**Shelf life:** 15 years

**Retail Price (USD):** 15,000

**List price (USD):** 15,000

**Other features:** Software use, mobile, capital equipment

**Year of commercialization:** 2010

**Currently sold in:** Ghana, Haiti, Jordan, Kenya, Malawi, Nepal, Nigeria, Rwanda, Sierra Leone, Somaliland, South Africa, Tanzania, Uganda, United Kingdom, Zambia

# Mandibular repositioning device

Country of origin | United States of America

## Health problem addressed

Over 20 million people in the U.S. have obstructive sleep apnea (OSA), yet 85% have not received treatment. The condition is even less frequently treated in developing countries. Continuous positive airway pressure (CPAP) is the usual treatment but it is expensive and requires electricity. People with untreated OSA are many times more likely to die of a stroke, heart attack, or car crash because of chronic severe sleep deprivation.

## Product description

For decades, dental devices called mandibular repositioning devices (MRDs) have been an effective treatment option for OSA. They need no electricity but are typically fabricated in a dental lab and fitted by a dentist, making them expensive. This device is an MRD that may be fitted with nothing more than boiling water. Its mechanism of action is the same as any other MRD and can therefore treat OSA.



## Developer's claims of products benefits

CPAP machines are typically used to treat obstructive sleep apnea but they are expensive, have poor patient compliance, and require an electrical outlet, frequent maintenance and disposable supplies. MRDs enjoy good patient compliance, are smaller, lighter, tougher, and they don't require electricity, maintenance or supplies. However, most are individually fabricated and therefore very expensive. This device is a mass-produced MRD that is custom-fitted with nothing more than boiling water.

## Suitability for low-resource settings

MRDs such as this device require no electricity, and unlike most other MRDs which must be individually fabricated in a manually-intensive process, the device is inexpensively mass-produced and may be custom-fitted using nothing more than a pot of boiling water and a spoon. The device may be produced anywhere, using basic injection molding equipment available worldwide.

## Operating steps

After immersing the device in boiling water for a minute, remove and allow it to cool a bit. Then while holding the jaw forward, bite down, molding it to the teeth. To use, merely put the device in the mouth at bedtime and it holds the jaw in the same "forward" position, opening the airway and allowing more unobstructed breathing.

## Regulatory status

It has been cleared by the FDA (K113022) as a Class II medical device for the treatment of obstructive sleep apnea (OSA) as well as snoring.

## Future work and challenges

The challenge is to familiarize the requisite agencies with the device so that they understand how it can help many people.

## Use and maintenance

**User:** Self-use/patient, physician, technician, nurse

**Training:** None

**Maintenance:** None

## Environment of use

**Settings:** Rural, urban settings, at home, secondary (general hospital), tertiary (specialized hospital)

**Requirements:** Boiling hot water

## Product specifications

**Dimensions (mm):** 50 x 50 x 20

**Weight (kg):** 0.014

**Consumables:** None

**Life time:** 1 year

**Shelf life:** 5 years

**Retail Price (USD):** 60

**List price (USD):** 60

**Other features:** Portable, reusable

**Year of commercialization:** 2007

**Currently sold in:** Canada, USA

# Oscillometric ankle-arm measurement

Country of origin | Switzerland

## Health problem addressed

Peripheral artery disease (PAD) is on the rise in developing countries due to an increase in diabetes mellitus. PAD increases cardiovascular risk and is associated with chronic venous ulcers.

## Product description

The device is an automated oscillometric blood pressure monitor designed for clinical use. The device allows for screening of three major cardiovascular risks: PAD, AF, and hypertension. It is equipped with two cuffs for simultaneous double arm measurements and ankle brachial index (ABI) assessment, both of which are recommended screening methods for detection of peripheral arterial disease (PAD). The ABI is automatically calculated by the device. The device can also be used as a regular clinical blood pressure monitor. Since it is also equipped with an atrial fibrillation (AF) detection system, it automatically screens for AF during routine blood pressure measurement.



## Developer's claims of products benefits

The procedure to test for PAD is commonly performed with Doppler which requires skill, is liable to observer bias and is time consuming. This device is easy to use, the procedure is conducted faster and is less liable to observer bias. The device can also be used with minimal training.

## Suitability for low-resource settings

The device is portable and can also be used as a regular blood pressure monitor. Because of its relative low price and multiple configurations (with and without software), it is suitable to be used in small hospitals or healthcare centers. Once fully charged, many measurements can be taken making the device portable and easy to travel with (e.g. to screen in small villages). The device can diagnose PAD, hypertension and atrial fibrillation in a small amount of time. Only limited training is required.

## Operating steps

First, a patient is measured simultaneously at both arms in the supine position to determine the arm with the highest BP. Thereafter, a cuff is placed around the arm and ankle to perform the ankle-arm measurement simultaneously. The ankle-cuff is then placed on the other ankle and the procedure repeated.

## Regulatory status

The device is both FDA approved and CE marked.

## Future work and challenges

Challenges include making doctors and nurses aware that this device is an automated oscillometric device that can reliably assess ABI, convincing them that general use of this device will improve awareness of peripheral artery disease, and convincing them that cardiovascular screening will lead to the prevention of cardiovascular disease and reduce overall healthcare costs.

## Use and maintenance

**User:** Physician, nurse, technician

**Training:** Can be conducted in 20 minutes by the organization/company providing the device

**Maintenance:** None

## Environment of use

**Settings:** Rural, urban settings, primary (health post, health center), secondary (general hospital), tertiary (specialized hospital)

**Requirements:** The device can work on a rechargeable battery, but also with electricity. When the user has access to a PC, the device can be controlled from the PC and a report produced. The device can be used with and without the PC software which is included free of charge. Ambient temperature for device storage and use should be between 10 and 40 degrees Celsius.

## Product specifications

**Dimensions (mm):** 200 x 125 x 90

**Weight (kg):** 1.1 (including batteries)

**Consumables:** None

**Life time:** 5 years

**Shelf life:** 10 years

**Retail Price (USD):** 1100

**Other features:** Software use, mobile, portable, capital equipment

**Year of commercialization:** 2008

**Currently sold in:** Canada, Netherlands, Spain, United Kingdom, United States, and some countries in Asia



# Oscillometric blood pressure measurement

Country of origin | Switzerland

## Health problem addressed

Pre-eclampsia and eclampsia is the second cause of maternal death (10-15% of all maternal deaths) in low and middle income countries.

## Product description

This device provides automated oscillometric blood pressure measurement. It measures the mean arterial pressure by which the systolic and diastolic blood pressure are then calculated using an algorithm.

## Developer's claims of products benefits

The device is accurate in identifying pre-eclampsia and requires limited training. Studies have shown that it is user-friendly and leads to better adherence to measurement at home.



## Suitability for low-resource settings

The device only requires batteries and has been validated for use among pregnant women and women with pre-eclampsia. In addition, cuffs are available in S, M, L, L-XL sizes in both reusable and disposable varieties.

## Operating steps

Place the cuff on the upper arm, press the on/off button and the device automatically measures blood pressure and presents the measured blood pressure value on the LCD screen.

## Regulatory status

The device is both FDA approved and CE marked.

## Future work and challenges

Challenges include making doctors and nurses aware that this device is an automated oscillometric device that can reliably measure pregnant women with high blood pressure and pre-eclampsia and that patients can screen themselves at home with this device.

## Use and maintenance

- User:** Self-use/patient, physician, nurse, midwife, technician
- Training:** Only in the case of patient self-use. Training can be provided by the midwife, nurse or physician
- Maintenance:** None

## Environment of use

- Settings:** Rural, urban settings, ambulatory, at home, primary (health post, health center), secondary (general hospital), tertiary (specialized hospital)
- Requirements:** The device can work on batteries but also with an adapter and electricity. When the user has access to a PC, the device can be used as a telemedicine device and the data uploaded to the PC and transferred via the internet to a hospital or general practitioner. However, this is optional. Ambient temperature for device storage and use should be between 10 and 40 degrees Celsius.

## Product specifications

- Dimensions (mm):** 150 x 100 x 50
- Weight (kg):** 0.385
- Consumables:** None
- Life time:** 5 years
- Shelf life:** 10 years
- Retail Price (USD):** 110
- Other features:** Software use, portable, capital equipment, telemedicine solution
- Year of commercialization:** 2008
- Currently sold in:** All of Europe (except for some Eastern European countries), Canada, United States and many countries in Asia



# Oxygen concentrator-driven bubble CPAP

Country of origin | United Kingdom

## Health problem addressed

In 2011, 1.8 million children under five died from respiratory complications, most in developing countries. CPAP (Continuous Positive Airway Pressure), a form of oxygen therapy for respiratory distress, could save many infants and preterm babies. However, the cost of conventional CPAP is prohibitive in poor countries; as a result it is often unavailable, even in lifesaving situations.

## Product description

Treatment of serious breathing difficulties requires the continuous delivery of a mixture of oxygen and air to the lungs. This device generates and delivers a safe, easily controllable mixture of humidified oxygen and air for CPAP treatment. It is driven by an oxygen concentrator that generates oxygen from atmospheric air, eliminating the need for expensive cylinders of compressed gases. The device delivers flows of up to 8L/min of both oxygen and air. Pressure in the system is controlled by a bubble bottle that depends on the depth of tubing under water, and is set by a simple dial on the bottle top. An oxygen/air mixing chart provided means there is no need for an oxygen analyzer.

## Developer's claims of products benefits

Most CPAP devices available are designed for use in resource-rich countries and are inappropriate for low-resource settings. A few devices have been designed to make CPAP more widely available in low-resource settings, but these still require an external oxygen source, making them expensive to run. This device is unique in being driven by its own oxygen concentrator, a cost-efficient method of generating oxygen. This makes it possible to deliver low-cost reliable CPAP treatment in low-resource or remote areas where gas cylinders are not an affordable or practical option. The model of oxygen concentrator used in this CPAP device was selected for its durability and performance in tests. The device is robust, simple to operate and requires only minimal maintenance.

## Suitability for low-resource settings

The device is intended for use in low-income countries and remote areas where gas cylinders are expensive and difficult to transport. The device needs no compressed gases. It delivers both oxygen and air at 8 L/min and costs just 70 pence per day. Equivalent use of compressed gas costs £70 per day. It delivers safe, affordable, reliable CPAP.

## Operating steps

Plug in and run oxygen concentrator. Fill the bubble bottle with boiled, cooled water and connect the breathing circuit. Adjust the level of CPAP required using a simple dial control on the bottle. Flow of air and oxygen can be seen in the bottle as bubbles in the water. Connect nasal prongs or mask to the patient and continue to monitor signs of respiratory distress.

## Regulatory status

The oxygen concentrator and CPAP system incorporated in this device have CE mark and FDA approval. The device is provided by an ISO 13485 registered company.

## Future work and challenges

The device will be demonstrated at forthcoming exhibitions and conferences in Africa, Asia and the Middle East. Peer reviewed clinical trials are underway in Papua New Guinea. Intention is to co-author papers for publication in peer-reviewed journals.

## Use and maintenance

**User:** Physician, nurse

**Training:** Not required. Device comes with a manual with full instructions for operation and maintenance. It has successfully been used by medical staff, without any additional special training, in low-resource settings in rural hospitals in Kenya, Papua New Guinea, Sierra Leone, the Solomon Islands and Uganda.

**Maintenance:** Minimal maintenance by nurse/physician or technician

## Environment of use

**Settings:** Rural, urban settings, primary (health post, health center), secondary (general hospital), tertiary (specialized hospital)

**Requirements:** The device requires a stable electricity supply to run. Nasal prongs and tubes are reusable and autoclavable, thus they need to be sterilized between patients. Boiled water for the bubble bottle valve is required.

## Product specifications

**Dimensions (mm):** 390 x 440 x 840

**Weight (kg):** 26

**Consumables:** None

**Life time:** > 5 years

**Shelf life:** > 5 years

**Retail Price (USD):** 2400

**List price (USD):** 2400

**Other features:** Mobile, reusable

**Year of commercialization:** 2012

**Currently sold in:** Sold in the United Kingdom for use in Afghanistan, Congo, Kenya, Malawi, Papua New Guinea, Sierra Leone, Solomon Islands, Uganda.



# Telecardiology

Country of origin | France

Health problem addressed \_\_\_\_\_

Chronic cardiovascular disease

Product description \_\_\_\_\_

The system consists of a 12-lead electrocardiograph (ECG) that transmits its recordings via satellite or any solution available on site: 2G, 3G, ADSL, WiFi, to a web platform where data is accessible. An elastic belt facilitates operation by eliminating the installation of 10 ECG electrodes.

Developer's claims of products benefits \_\_\_\_\_

This device is easy to use and can even be operated by the patient without the support of a health professional. It also provides quick medical advice through the development of an online medical file that simplifies the relationship between health professionals.

Suitability for low-resource settings \_\_\_\_\_

The device prevents the need for patient transport when monitoring chronic cardiovascular disease and it allows for specialist advice in areas far from specialized healthcare facilities.

Operating steps \_\_\_\_\_

The stretch belt equipped with the pre-placed electrodes is placed on the patient's chest. The recorded data is directly sent to a specialist. The data is stored remotely and the cardiologist performs the reading on a smartphone or computer via the Internet.

Regulatory status \_\_\_\_\_

The product is CE marked and manufactured by an ISO 13485 certified company. Data transfer is secure and compatible according to Telemedicine laws.

Future work and challenges \_\_\_\_\_

Future work includes the addition of new sensors (e.g. spirometry, SpO2, blood pressure, balance, thermometer) and the generalization of the service platform to meet the increased need for prevention and management of chronic diseases, while allowing a reduction in health care costs.

Use and maintenance \_\_\_\_\_

**User:** Self-use/patient, physician, nurse, family member

**Training:** The training can be done by locals familiar with the device. Training time is about 15 minutes.

**Maintenance:** Yearly maintenance by technician

Environment of use \_\_\_\_\_

**Settings:** Rural, urban settings, ambulatory, at home, primary (health post, health center), secondary (general hospital), tertiary (specialized hospital)

**Requirements:** Power supply for recharging and access to the internet

Product specifications \_\_\_\_\_

**Dimensions (mm):** 270 x 150 x 140

**Weight (kg):** 1.54

**Consumables:** None

**Life time:** 10 years

**Shelf life:** 5 years

**Retail Price (USD):** 2000

**List price (USD):** 1500

**Other features:** Software use, portable, capital equipment, telemedicine solution

**Year of commercialization:** 2011

**Currently sold in:** France and in Francophone African countries.



# Umbilical artery doppler analyser

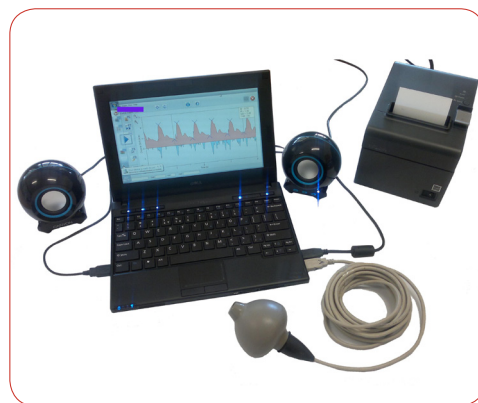
Country of origin | South Africa

## Health problem addressed

Placental insufficiency is a major cause of intrauterine growth restriction. Doppler ultrasound to assess the flow velocity of the umbilical artery of the fetus with poor growth is the only method of antenatal surveillance that has significantly improved perinatal outcome, but Doppler technology is often unavailable at the primary care level.

## Product description

The technology uses Doppler waveform analysis for reliable and cost-effective antenatal screening in low-resource environments. The technology measures blood flow in the umbilical artery of the fetus at greater than 24 weeks gestation. From such a measurement, decisions can be made about the ability for the placenta to provide sufficient nutrients and oxygen in order to sustain adequate fetal development. The ultrasonic Doppler probe connects to the USB port of a standard Pentium PC or laptop on which proprietary software is installed. The product consists of a graphic user interface, operational software and the physical mechanical parts of the probe (hosing, acoustic nose, etc.). The external speakers, printer, and notebook are off the shelf products. The system allows for a database facility, serial monitoring, plotting and printing of results, quality assurance and remote expert support. A 3G data connection (integrated SIM card) is necessary if remote expert support is desired.



## Developer's claims of products benefits

2D ultrasound with Doppler mode are available at secondary and tertiary care facilities in South Africa but operation requires sonography skills and training. Sonographers are expensive and scarce in South Africa. This system is based on continuous-wave technology, which is easier to use and already proven to be as reliable as the more expensive and larger duplex mode machines found in ultrasound units. By introducing the simple-to-use Doppler to primary antenatal care, it is anticipated that this device could significantly reduce the numbers of referrals to a higher level of care.

## Suitability for low-resource settings

The system requires little management and few consumables apart from the gel to operate the probe and thermal printer paper if maternity case records are to be maintained. The system is rugged as well as water and acid resistant. It has demonstrated that simple PC-based, continuous wave Doppler ultrasound device operated by a midwife at the antenatal study clinic is effective in identifying patients at risk for placental insufficiency and in excluding pregnant women from additional tests for fetal well-being.

## Operating steps

Enter patient details, palpate to determine fetal orientation, apply gel to probe and move it across the abdomen to detect umbilical blood flow with good audible signal. Record measurement, review waveform diagram and plotted indices, follow clinical management suggestions. Save patient file, print result and staple into the maternity case record.

## Regulatory status

Two external audits for ISO 13485 are scheduled for November and December 2013. The audit for CE marking is scheduled for February 2014.

## Future work and challenges

Future work and challenges include training device operators in conducting waveform Doppler measurement, establishing a medical device management system to support devices in the field, developing a reliable remote expert support (telemedicine) feature for quality assurance and assistance of clinical personnel in the field, and pursuing liability insurance system accreditation and tender-based procurement by Departments of Health.

## Use and maintenance

**User:** Nurse, midwife

**Training:** Yes

**Maintenance:** Daily cleaning/removal of any gel from keypad and probe by the nurse

## Environment of use

**Settings:** Rural, urban settings, primary (health post, health center), secondary (general hospital)

**Requirements:** Access to electricity to charge the battery of the notebook because the probe is powered directly from the computing device via USB connection. A lockable treatment or storage room against theft protection during hours when the clinic is closed. 3G connection if remote expert support is desired.

## Product specifications

**Dimensions (mm):** 300 x 250 x 70

**Weight (kg):** 2.2 (includes notebook, probe, speakers, charger, and thermal printer)

**Consumables:** Transmission gel, thermal printer paper

**Life time:** 10 years

**Shelf life:** 1 year

**Retail Price (USD):** 2400

**List price (USD):** 1100

**Other features:** Software use, telemedicine capability, mobile, capital equipment

**Year of commercialization:** Anticipated 2014

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# Other technologies

## 2013



# Postpartum uterus trainer

Country of origin | Norway

## Health problem addressed

There is a large unmet need for family planning and postpartum uterus care. 95,000 maternal deaths can be prevented annually if women who desired to postpone or avoid childbearing had used effective family planning. The intrauterine device (IUD) is an effective, safe and reversible long acting family planning method, and can be safely inserted immediately after delivery of the placenta.

## Product description

The product represents an anatomically correct postpartum uterus from 10 minutes up to 48 hours after the delivery of the placenta, enabling the teaching and practice of the insertion of the postpartum IUD and balloon/condom tamponade, among other practices such as cervical and vaginal inspection, gauze packing, bimanual compression and removal of placental parts. Due to its size and simplicity, the instructor can actively interact with the learners and observers during hands-on practices, obtaining instant feedback from the uterine cavity and the vagino-uterine angle. It works as a stand-alone product and also in combination with a birthing simulator.



## Developer's claims of products benefits

Current models of IUD placement trainers are expensive, heavy, require additional accessories and are not durable enough. Their vague anatomical features causes misinterpretations and malpractice (such as too low IUD placements, resulting in increased expulsion rates). Their high cost prevents large-scale implementation as well as "high-frequency, low-dosage" training.

There are no other solutions in the market that can provide high-fidelity training in various postpartum uterine interventions.

## Suitability for low-resource settings

The product was developed to facilitate efficient training in low-resource settings for important, lifesaving postpartum interventions. The simplicity and durability allows it to be used in any setting and also facilitates that it can be purchased and distributed in large quantities, so that health providers in even the most rural areas can access it for the important frequent refresher training that will enable them to maintain skills learnt during the initial training course. The device was designed to be highly realistic where essential (particularly in feeling of the fundus and cervical-vaginal angle), culturally adapted, flat packed for easy transport and storage, highly affordable, durable and easy to use. In addition, it is designed to facilitate role play and efficient training.

## Operating steps

The product is easily prepared for use by one quick step and is fully manually operated.

## Regulatory status

Not applicable. It is classified as a training device.

## Future work and challenges

In order to achieve efficient implementation of better quality postpartum uterus care and postpartum IUD insertion, the product should be available for health care workers during their initial training - and importantly - also for subsequent regular refresher training. Ideally, there should be a simulator available in every health facility. The greatest barriers for widespread implementation are believed to be financing (although highly affordable, funding may be needed from governments or aid organizations) and distribution (due to bureaucracy and often prohibitive customs rates).

## Use and maintenance

**User:** Physician, nurse, midwife, instructors and students in courses for postpartum interventions

**Training:** None

**Maintenance:** General cleaning of training product after use by wiping with a moist cloth and drying.

## Environment of use

**Settings:** Rural, urban settings, ambulatory, primary (health post, health center), secondary (general hospital), tertiary (specialized hospital)

**Requirements:** The product is operational in any setting and environment. There is no need for electricity or other advanced infrastructure.

## Product specifications

**Dimensions (mm):** 350 x 200 x 175

**Weight (kg):** 0.65

**Consumables:** None

**Life time:** 3 years

**Shelf life:** 3 years

**Retail Price (USD):** 50

**List price (USD):** 50

**Other features:** Portable, reusable

**Year of commercialization:** 2013

**Currently sold in:** It is offered on a not-for-profit price to the 75 countries that have been identified by UN as focus countries relative to MDG 4 and 5.



# Pressure cooker autoclave

Country of origin | United States of America

## Health problem addressed

Healthcare associated infections are the most frequent threat to patient safety worldwide, and Surgical Site Infections (SSIs) are the most common type of infection. The effects of SSIs on patients and health-systems are both severe and underestimated, and the burden of infections falls on the patient population with the highest level of need.

## Product description

The pressure cooker autoclave is an affordable, easy to use autoclave. An electronic sterilization monitor connects to a pressure cooker via an integrated thermal sensor. The monitor provides verbal instructions to health post employees in their native language. It notifies them when their attention is required and guarantees whether or not instruments were fully sterilized at the end of each cycle. Information regarding frequency, features used, and rates of successful sterilization cycles is sent via cellular networks to an online database where location and usage information can be viewed and analyzed.



## Developer's claims of products benefits

Medical instrument boilers and autoclaves are available in some regions. Boilers are the most common sterilization method used, but are ineffective and can leave instruments contaminated. The low-cost autoclaves that are currently available require electricity, which is often intermittent at best, and therefore they often go unused.

The principal benefits of the pressure cooker autoclave are convenience and efficacy. Pressure cookers can completely sterilize medical instruments whereas boilers cannot. Spoken instructions in the local language facilitate use for health post employees, enhance staff efficiency, reduce training costs, and ensure that the sterilization protocol is followed correctly. Remote monitoring helps health administrators to measure the impact of the devices and know they are used regularly.

## Suitability for low-resource settings

The pressure cooker autoclave is intended for use in remote and resource-constrained clinics in lower and middle-income countries. By removing the dependency on electricity and featuring a built-in instructor, it is suitable for areas without regular electricity and addresses education and training challenges faced by normal autoclaves.

## Operating steps

Users select how the medical instruments are packaged (wrapped in linen or not) on the cycle monitor. Verbal instructions then help users complete a successful sterilization cycle. At the end of the cycle, the monitor notifies users whether sterilization was successful, and how to maintain the instruments clean until use.

## Regulatory status

Meets CDC standards for sterilization by exposure to high temperature and pressure. The manufacturers hold ISO 9001:2008, ISO 13485:2003 QMS certifications and UL certifications. CE mark certification is in progress.

## Future work and challenges

Remote clinics typically do not have the funds necessary to purchase their own equipment. In order to reach the intended users, governments or other health administration bodies will first purchase the autoclaves to distribute to intended consumers. Governments often have little incentive to be early adopters of new technology. Finding the correct strategy to move the product to the intended users is the primary challenge facing the pressure cooker autoclave.

## User and environment

**User:** Nurse, health post employee

**Training:** None

**Maintenance:** None

## Environment of use

**Settings:** Rural, urban settings, primary (health post, health center), secondary (general hospital), tertiary (specialized hospital)

**Requirements:** Almost no infrastructure requirements are necessary to operate this autoclave. Fresh water should be used each time new instruments are sterilized. A heat source capable of boiling water must be employed. Whatever is typically used to cook food can be used, including gas, coal, electric or solar.

## Product specifications

**Dimensions (mm):** 300 x 300 x 500

**Weight (kg):** 3

**Consumables:** None

**Life time:** 10 years

**Shelf life:** 15 years

**Retail Price (USD):** 250

**List price (USD):** -

**Other features:** Software use, mobile, capital equipment

**Year of commercialization:** Awaiting CE mark

# Assistive devices

## 2012

# Solar charger for hearing aid

Country of origin | Botswana & Brazil

## Health problem addressed

7% of the world's population is hearing impaired. That is a total of 312 million people, of whom two-thirds are living in developing countries. The extent of hearing loss leads to unnecessary poverty and hardship in the families and communities affected, and by extension, to the larger society. It also costs governments up to 3% of their GNP.

## Product description

Rechargeable hearing aid, solar charger and rechargeable hearing aid battery.

## Product functionality

This device has a rechargeable hearing aid battery which costs \$1 and lasts 2-3 years. To charge the battery, a novel, but not patented, solar powered battery recharger was developed, which can be recharged via the sun, household light or plug in using a Nokia cell phone electrical recharger.



## Developer's claims of product benefits

This device is the only low-cost rechargeable analogue and digital hearing aid on the market.

## Operating steps

During the day a solar panel charges 2 AA rechargeable batteries. Once or twice a week, one takes out the rechargeable hearing aid battery and puts them in the charger. The next morning these batteries are ready to use again. One can also charge the batteries using a household light or plug-in. The batteries fit into 85% of all hearing aids.

## Development stage

Countries that receive these rechargeable hearing aids, solar charger and rechargeable batteries to do not require FDA or CE approval, but all of these component suppliers have FDA, CE and are ISO approved.

## Future work and challenges

The technology is offered for free to like-minded non-profit organizations. In addition, the company helps write the business plans, raise money, and set up manufacturing operations for others for free.

## User and environment

**User:** Self-use/patient

**Training:** None

**Maintenance:** Yes, 3-5 years change batteries

## Environment of use

**Settings:** Rural, urban, at home

**Requirements:** Sunlight

## Product specifications

**Dimensions (mm):** 40 x 20 x 15

**Weight (kg):** 0.3

**Consumables:** Rechargeable AA and rechargeable hearing aid battery

**Life time:** 10 years

**Shelf life:** 5 years

**Retail Price (USD):** 48

**List price (USD):** 24

**Other features:** Portable, reusable

**Year of commercialization:** 2002

**Currently sold in:** 39 developing countries

# eHealth solutions 2012

# Biometric technology in healthcare

Country of origin | India

## Health problem addressed

Tuberculosis (TB) is one of the biggest public health problems in India. The country holds one-fifth of the global TB burden with nearly 2 million new cases and 330,000 TB-caused deaths every year. Patients who do not complete the entire course of treatment often develop drug resistance.

## Solution description

The system utilizes a simple interface with minimal text and color coding for ease of use in low-literacy areas. The system synchronizes up-to-date reports with a central Electronic Medical Record (EMR) database located at the office headquarters. The application uses .NET Framework and runs locally on any Windows machine. Primarily an offline application, it sends daily attendance reports through SMS to an online server, through the USB modem. When the patient registers onto the system they provide a fingerprint, which is used throughout their course of treatment to track their treatment schedule. If a patient misses a dose, an SMS is sent to their counselor by the end of the day.

## Functionality

Patients registered at the terminal log their visit to a TB center on a fingerprint reader. At the end of each day, the attendance record is compressed into a text message and sent to an online server. If a patient misses a dose, the counselor receives a text message and must follow up with the patient within 48 hours to take their medication.

## Developer's claims of solution benefits

The eCompliance initiative is the first to apply biometric attendance monitoring to tuberculosis treatment. No other TB control system can provide verifiable evidence to back up their TB statistics. The innovation's transparency and accountability are two of its strongest aspects. While other TB programs have digitized their systems, these programs rarely cater to impoverished areas, relying on the Internet or 3G networks to relay information.

## Future work and challenges

Funding is needed for operations of the system and the ever-changing field of technology.

## User and environment

**User:** technician, counselors.

**Training:** training on the system takes 3-4 hours and is given by one of the biometric team members.

**Settings:** rural, urban, home, ambulatory, primary, secondary, and tertiary.

## Solution specifications

**Solution is used to support:** Electronic Health Record/ Electronic Medical Record; mHealth.

**Software/Hardware requirements:** Netbooks for use in the treatment centers and access to SMS network to work with the netbook. The software is open-source and can be downloaded from the website for free.

**Country used in:** India

**Evaluation:** There has been one pilot study at the treatment centers, and a follow up of a qualitative study in 25 centers in two states. Over 2,300 patients have been registered. The qualitative study interviewed 8 health workers, 4 center owners and 23 patients. Findings suggest that the terminal helps draw patients to the center by incentivizing health workers and convincing patients to come.



# Case-based smartphone messaging platform

Country of origin | United States of America

## Health problem addressed

This technology is focused on addressing the diagnostic/treatment support and information resource needs of healthcare providers in Botswana, a country with the 2nd highest prevalence of HIV and 4th highest prevalence of TB. There are about 40 physicians per 100,000 people and access to physician care outside of city centers remains challenging.

## Solution description

A mobile medical platform that 1) connects resident physicians to their peers & faculty for timely team-based case consultations related to patient care; 2) provides access to a global network of physicians (via Swinfen Charitable Trust's Telemedicine programme) for external referrals; and 3) enables easy, centralized access to important medical resources relevant to Botswana.

Users can:

- Complete case forms, including images & videos, and send to colleagues for consultation
- Send messages to the entire team or individuals
- Search message history
- Share geographic location
- Search and share references such as local treatment guidelines and PubMed.

## Functionality

Users sign-on and set their status as "on call" or "online" and indicate their location. They can see others' status and location. Users complete a case consult form, attach media such as photos or videos, and share with team members for comments. Users are notified of news messages & replies via notifications on their device and in the app.

## Developer's claims of solution benefits

The application provides an integrated platform for physicians to communicate efficiently about patient care and to access and share reference information through a single app on a mobile device. Users benefit from telemedicine consults & searchable message threads (thereby learning through a shared case-based model) and have access to country-specific guidelines & journal abstracts. The product captures usage data allowing for analysis and is designed for low-resource/marginal-connectivity settings.

## Future work and challenges

The challenges - and the opportunities for solutions - are spread across a number of categories: namely, Software -> Hardware -> Personnel -> Programs. Given that each of these category silos have their own unique set of issues (e.g., design & development of information architectures optimized for low-bandwidth settings; procurement at a cost-effective price of smart devices for Sub-Saharan Africa; recruitment, training, & engagement of field pilot professionals; and administrative management of multiple groups through protocols, feedback & study design) it is essential to operate across categories in an integrated and iterative manner.

## User and environment

**User:** physician

**Training:** an initial two-hour training session, including demonstrations and cases.

**Settings:** rural, urban, home, ambulatory, primary, secondary, and tertiary.

## Solution specifications

**Solution is used to support:** Telemedicine; eLearning/ mLearning; mHealth; Geographic Information System

**Software/Hardware requirements:** Use of this product requires an Android mobile device and access to mobile Internet or WiFi connection for full-access to all the features of the system. However, users without a data connection can still prepare and save case information using an "offline mode" for later uploading. Software is proprietary developed specifically for deployment by the Botswana-UPenn Partnership and its physician teams.

The product is still in Field Pilot / R&D phase and has not yet been commercialized.

**Standards:** It adheres to HIPAA security & privacy rules for PHI data.

**Currently used in:** Botswana

**Evaluation:** No studies have been conducted on the technology yet, but the team is in the process of designing a study to evaluate the technology with local partners.

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<http://www.who.int/ehealth>

# Cervical cancer screening information system

Country of origin | Argentina

## Health problem addressed

In Argentina, cervical cancer is the second most common cause of death by tumours, in women from 35 to 64 years old, there is a death rate of 7.1 / 100,000 and an incidence of 23.2 / 100,000. Each year, in Argentina, 1,800 women die and a further 3,000 new cases are diagnosed. Women of low socioeconomic status are more vulnerable due to lack of access to screening.

## Solution description

The national information online system of screening allows for the monitoring and appropriate treatment of affected women by providing nominalized lists of women included in the national prevention programme. The national information system identifies women with pathological paps for their diagnosis and treatment. It also provides indicators to monitor and evaluate the prevention programme.



## Functionality

The national online information system allows for coordination of health services that are involved with uterine cervical cancer prevention, serving as a support of the monitoring of health services. It is used at the primary care level, cytology laboratories, gynaecology services and central level.

## Developer's claims of solution benefits

It is an online information system that links services and users so that the information related to screening, diagnosis and treatment supports the management of the service network. It allows for the flow of information among different health services and country areas, allowing the monitoring of women in all stages of prevention, even those living in remote areas. It has an alert system that allows for faster detection of problems with women in need of diagnosis and treatment.

## Future work and challenges

Incorporation of modules on breast and colon cancer screening, diagnosis and treatment.

## User and environment

**User:** physician, technician, nurse, midwife, administrative staff.

**Training:** none

**Settings:** rural, urban, ambulatory, primary, tertiary.

## Reviewer's comments

This system is deployed nationally for cervical cancer screening, treatment and capturing of data. It is also being developed and used locally and requires very low resources. A formal evaluation of this program would be helpful to contribute evidence, and this would form a basis upon which other countries might want to consider adopting it.

## Solution specifications

**Solution is used to support:** Decision Support Systems; Electronic Health Record/Electronic Medical Record

**Software/Hardware requirements:** Access to a computer connected to the Internet. It uses the database engine SQL- Server, ASP programming language. The ministry of health has licenses for using them, so it was decided to develop the described tool on this platform. The software development is an open source and it belongs to the ministry of health.

**Standards:** ICD-10; Bethesda

**Currently used in:** Argentina

**Evaluation:** Arrossi, S; Paolino, M: Proyecto para el mejoramiento del Programa Nacional de Prevención de Cáncer de Cuello Uterino en Argentina - Informe Final: Diagnóstico de situación del Programa Nacional y Programas Provinciales. Buenos Aires. Organización panamericana de la Salud; 2007, page 33.

# Computer-aided detection for Tuberculosis

Country of origin | The Netherlands

## Health problem addressed

Tuberculosis is the second deadliest infectious disease in the world. With early detection and proper treatment, most people with tuberculosis can fully recover. Combined efforts and investment in Tuberculosis detection can help to save millions of lives worldwide.

## Solution description

Digital X-rays can efficiently make large numbers of chest radiographs at low cost. Computer Aided Detection software (CAD) can immediately analyse these digital images. The CAD software gives a probability percentage normal vs. abnormal consistent with TB.

CAD follows the processing steps:

- Lung shape analysis
- Clavicle detection
- Texture analysis.

Texture within the lung fields and the shape of the extracted lung fields are compared with a training database obtained from thousands of training images. Based on this analysis a grade for the image is computed. Based on the grade and the expected prevalence in the population, the probability that the image contains signs of TB is calculated.

## Functionality

The software can be configured to run automatically after a digital X-ray has been made: the image is sent automatically to a separate computer on which the CAD software is installed, the program performs the quality check and the image analysis steps and the result is stored on disk.

## Developer's claims of solution benefits

Present technologies are time consuming and quality/temperature sensitive or costly for hundreds of tests. With a portable digital X-ray even remote groups can be screened at low cost as the incremental costs of digital X-ray and CAD are very low. Studies done by universities and Zambart show that the sensitivity and specificity of the software to diagnose culture positive TB from chest radiograph is the same as done by clinical officers and CRRS certified human observers (no significant difference in performance).

## Future work and challenges

Challenges ahead:

1. Creating a computerized decision support by combining X-ray signs with clinical symptoms.
2. Evaluate CAD with GeneXpert (cartridge-based, automated diagnostic test ) as an efficiency "filter" in TB screening to determine who gets GeneXpert.
3. Regulatory approval.

## User and environment

**Users:** physician, technician

**Training:** a 3-hours training is provided on a laptop or PC.

**Settings:** rural, urban, ambulatory, primary, and secondary.

## Solution specifications

**Solution is used to support:** Telemedicine; Electronic Health Record/Electronic Medical Record; mHealth; Health Research.

**Software/Hardware requirements:** Laptop or computer with MS Windows, Intel Pentium preferably i7, 8 GB RAM 120 GB HDD, Calculation time depends on amount of RAM and type of processor. CAD4TB is proprietary software that runs on any laptop or PC that meets the above specifications.

**Standards:** DICOM, HL7

**Currently used in:** Zambia, South Africa, The Gambia

**Evaluation:** The CAD software is currently used prospectively in clinical trial to make a selection with TB suspects should undergo other more expensive and time-consuming further testing.

The partners CIDRZ and Zambart in Zambia are using the CAD software as a "filter" in TB screening to determine who gets GeneXpert.

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<http://www.who.int/ehealth>

# Electronic consultation register

Country of origin | Burkina Faso

## Health problem addressed

In Burkina Faso, 1 in 6 children die before the age of 5. The Integrated Management of Childhood Illness (IMCI) protocol was developed by WHO to reduce child mortality but its implementation is difficult due to an insufficient number of trained health workers and because arduous working conditions increase the lack of rigor and motivation.

## Solution description

The registre électronique de consultation (REC) is an offline web application that guides the health professionals throughout the consult to help them strictly apply the IMCI. A step-by-step approach allows for determining in real-time the illnesses of the patients as the health worker identifies the symptoms. Once the diagnostic is established, the REC identifies the appropriate treatment and the medicines to be prescribed with their dosages. The diagnostic and treatment data are centralized and restored via a secured synchronization procedure via USB drives. The REC allows agents to easily create a personal file for each patient with the history of diagnostics and treatments administered.



## Functionality

Users launch the REC or synchronization process through a single main menu.

The diagnosis is in 3 simple steps:

1. Search - if the patient already has a file in the system
2. Evaluate - each question of the IMCI protocol is answered sequentially
3. Treat - follow the identified treatment and medicines.

## Developer's claims of solution benefits

The REC addresses key problems of the implementation of the IMCI protocol. The guided step-by-step approach ensures that the protocol is correctly applied. It avoids diagnostic errors as long as symptoms are correctly identified. Since little computer training is required to use the application, even health workers without IMCI training can safely apply the protocol. The user interface also allows for a quick data entry, reducing the time of consult per patient.

## Future work and challenges

The global user experience could be improved by porting the REC to tactile devices. It would ease the learning curve and limit the number of devices to one for easier maintenance. With the improvement of the telecommunication networks a wireless data synchronization would make data centralization seamless and ease the integration of the REC to national health systems.

## User and environment

**User:** nurse, physician, midwife.

**Training:** a 2-day session to learn the use of the computer and the REC.

**Settings:** rural, urban, ambulatory, primary.

## Reviewer's comments

IMCI is known to be difficult to implement in primary care settings and this tool provides guidance and learning opportunities for healthcare professionals, and improves continuity of care thanks to a basic electronic medical record module.

## Solution specifications

**Solution is used to support:** Decision Support Systems; Electronic Health Record/Electronic Medical Record; eLearning/mLearning. providing the environment necessary to run a web server locally.

**Software/Hardware requirements:** Netbook, The REC operates in rural areas with a solar panel. Electricity is required for at least a couple of hours per day in order to recharge the batteries of the netbook.

The REC was developed exclusively with open source software. The operating system is a customized Linux

**Currently used in:** Burkina Faso

**Evaluation:** The pilot implementation period Oct 2010 - Oct. 2011 was documented by the University of Geneva. A baseline study is currently in progress with the London School of Hygiene and Tropical Medicine in order to monitor the extension to 75 health centres in 2012.

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<http://www.who.int/ehealth>

# Health workforce information systems

Country of origin | United States of America

## Health problem addressed

The 2006 World Health Report identified 57 countries with human resources for health crises that have less than 2.3 health workers per 1000 population. It is estimated that more than a billion people do not have access to a health worker. Associated challenges include health workforce planning, policy, training, deployment, management and retention.

## Solution description

The software is an open source LAMP-architecture solution (Linux, Apache, MySQL, PHP) that, once established, may be accessed via a web browser on the same computer the software is deployed, or via a LAN, or from anywhere on the World Wide Web. The software supports easy configuration of key variables (such as job titles, cadres, competencies and job structures). Information is then collected on the health workforce, either through a centralized national architecture, or a decentralized subnational architecture that can then be aggregated for national analysis. The software supports easily customized reports and charts, or the exporting of data in many common formats.

## Functionality

Typical steps for setting up and using the software include:

- Adding Geographical Areas
- Configure database 'drop-downs'
- Create a job structure
- Create positions
- Enter employee information including identifying information, contact information, dependents, position, qualifications, trainings, employment and education history
- Create and run reports as needed.

## Developer's claims of solution benefits

A free and open source solution is designed to support full country adoption and ownership. The software is cost effective, easy to configure and is supported with strong documentation, eLearning, and other resources. This solution also support countries to avoid vendor lock-in. All data can be exported in a variety of formats at any time for migration to a new solution if desired.

## Future work and challenges

The biggest challenge remains whether the users have enough access to the Internet to learn about and access the technology and associated resources. As infrastructure continues to strengthen and this situation improves, a cloud-based version can be offered to minimize initial configuration and set-up challenges. It is also part of the future plan to move from an HR 'Information' System to an HR 'Management' System, which is less about collecting and reporting on workforce data, and more on taking consistent and high-quality management actions.

## User and environment

**User:** health managers, supervisors, workforce planners and regulators.

**Training:** administrator training is currently available online, and user training is under development.

**Settings:** rural, urban, secondary, tertiary, district management offices, Ministry of Health.

## Solution specifications

**Solution is used to support:** Decision Support Systems; mHealth; eLearning/mLearning; Health Research.

**Software/Hardware requirements:** At minimum, a computer running Linux with Apache, MySQL and PHP installed is required. The solution offers a preconfigured 'appliance' that has everything ready to plug into a LAN. It can also be run from a flash drive, or freely downloaded and configured as a Linux install package. LAN, WAN or Internet access is needed for remote data entry or reports.

**Standards:** SDMX-HD

**Currently used in:** Botswana, Ghana, India, Kenya, Lesotho, Mali, Nigeria, Rwanda, Sierra Leone, Tanzania, Togo, Uganda.

**Evaluation:** An extensive independent evaluation has not been done.

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# Integrated smartreader & cloud services

Country of origin | Canada

## Health problem addressed

Two of the biggest problems in infectious diseases are inadequate diagnosis and case management at point of care (POC) by health workers and inadequate resource allocation and monitoring by health managers and funders.

## Solution description

The smartreader is a rugged, companion device for use by health workers at POC that captures and transmits a broad range of data to the cloud via local cell networks. The reader currently interprets commercially-available malaria rapid diagnostic tests (RDTs). Additional infectious disease targets are to follow in rapid succession, e.g. HIV, dengue, hepatitis.

Via standard web browsers, the portal provides health managers and funders with a host of cloud information services, including data management and reporting, mapping and surveillance, based on data captured by smartreaders. Managers can connect with workers in the field to implement quality control measures, and disseminate clinical and operational guidelines.



## Functionality

Smartreader software guides the user through RDT processing steps and data entry, interprets test results, and automatically transmits patient and worker activity data, GPS, image of RDT over cell networks to the cloud. Managers log into the portal to view/create reports, query real-time data, disseminate messages and content to readers.

## Developer's claims of solution benefits

This solution transforms infectious disease healthcare delivery and healthcare management by enabling:

- high-quality healthcare delivery by minimally trained health workers at point of care
- real-time monitoring and analysis of point-of-care data for resource management and timely response to outbreaks
- evidence-based resource allocation and investment decisions by healthcare funders and industry.

## Future work and challenges

Distribution via franchises with local entrepreneurs, thus not only contributing to local economies and skill development, but also accelerating sales.

## User and environment

**User:** physician, nurse, midwife, technician, community health worker.

**Training:** optional training will be provided by qualified local distributors.

**Settings:** rural, urban, ambulatory, primary, and secondary.

## Reviewer's comments

The innovation of the project is mostly related to the hardware (smart reader for rapid diagnostic tests). However, its information components are very well integrated into a coherent set of tools, which represents the state-of-the-art.

## Solution specifications

**Solution is used to support:** Decision Support Systems; mHealth; Geographic Information System; Health Research.

**Software/Hardware requirements:** Smartreader at POC: minimally trained health worker. Data transmission from POC to cloud: any local cell network. Cloud information services: health program manager with standard web browser on any computer. Smartreader functions for 4 days on internal battery rechargeable by electric outlet, solar panel, handcrank.

The software is proprietary and is charged on a pay per use basis. The system hosts third-party mHealth applications.

**Standards:** Upcoming releases will support HL7 and HIPAA.

**Currently used in:** Colombia, Ecuador, Kenya, Tanzania, Ghana.

**Evaluation:** Performance was validated for 7000 patients by 50 health workers at 30 sites in four countries. Diagnostic accuracy studies fully blinded and expected to be submitted for publication in peer-reviewed journals in 2012.

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# Maternal health Tanzania

Country of origin | Tanzania

## Health problem addressed

Maternal and neonatal healthcare in Africa faces well-documented challenges, including: 1) Limited qualified health staff, 2) Ineffective referral systems for triage to urban/higher facilities, 3) Inadequate diagnostics at point of care, 4) Limited community-level data and connectivity, 5) Uninformed patients, 6) Limited Public Private Partnership (PPP) financial models.

## Solution description

The platform is accessed through the Internet by a netbook computer, smartphone, or other modern web device. Users submit patient data, which is validated before being sent via encrypted connection to a central database. The platform features sending / receiving SMS to patients and clinicians, portable ultrasound integration, dynamic filter-based patient cohorts for targeted follow-up, scheduling of return visits or patient referrals in a central calendar, and recording of orders and payments made during a clinic visit. An additional continuing medical education module allows online creation and publication of multimedia courses and informal clinician accreditation.

## Functionality

1) User registers mother at clinic. 2) User submits outcome of clinical examination and schedules follow-up visit. 3) Specialist conducts portable ultrasound examination and saves image to the mother's record. 4) Upon referral, user at another facility accesses mother's full record. 5) Mother receives targeted educational and reminder SMS.

## Developer's claims of solution benefits

Validate data instantly and track user performance to identify areas of weakness for retraining.

Enable community-based care outside of clinic setting using networked computers.

Retain a full record of mother's information in health system.

Generate system-wide clinical and operational reports without tedious data collection/aggregation.

Enable portable obstetric-ultrasound screenings: better diagnosis, early intervention.

Browser-based platform overcomes limitations of phone-based platforms.

## Future work and challenges

A large portion of active deployment costs come from the Internet usage and SMS costs for follow-up with patients. Deployment on a large scale would be greatly facilitated by partnership with mobile operators (e.g. corporate social responsibility initiative or volume-based pricing).

Emphasis on the importance of record-keeping and the power of data will help highlight the advantages of the platform's various modules working together and motivate adoption (e.g. targeted SMS follow-up based on early identification of high-risk mothers, accreditation of health workers through online training to assess quality of human resources, detailed reports to assist management in budget allocation).

## User and environment

**User:** physician, nurse, midwife, technician, facility or health system administrator.

**Training:** one week hands-on training.

**Settings:** rural, urban, ambulatory, primary, secondary and tertiary.

## Solution specifications

**Solution is used to support:** Telemedicine; Electronic Health Record/Electronic Medical Record; eLearning/mLearning; mHealth; Reporting, portable diagnostics, facility management.

**Standards:** Format of structured data adheres to the Tanzania Ministry of Health maternal health card.

**Currently used in:** Tanzania

**Software/Hardware requirements:** The server-side component of the platform requires specific software running on a secure Internet-connected data centre. The software is being made available on an international free-for-use license. Customization of data forms for use outside Tanzania may require modest technical development investment.

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# Medical cloud

Country of origin | United States of America

## Health problem addressed

Picture Archiving and Communication Systems (PACS) represent the integration of medical diagnostic images and records playing a critical role in patient diagnosis and outcome. Traditionally only medical centres in developed countries have been benefactors leaving a significant disconnect globally for resource-poor locations to also benefit.

## Solution description

Patient information regardless of the imaging modality (ultrasound, x-ray and beyond) and/or digital medical records are scanned and uploaded by an authorized medical professional. Automatically the information is sent through a secure Digital Imaging and Communications in Medicine (DICOM) process over a standard web browser from a digital device the user is accustomed to using such as any smart phone or mobile computer. Physicians, teams of specialists and qualified medical professionals across the globe have on-the-go access through a log in user name and password with access to review patient medical information providing accurate diagnosis and second opinion reports.



## Functionality

The DICOM sender module offers a zero foot print viewer system that allows for images to be viewed on the web. This cloud based approach requires no additional hardware or software to be purchased. Native studies are sent directly to fully functioning PACS systems or viewed through a log in user name and password over any personal digital device.

## Developer's claims of solution benefits

Physicians will have access to images and reports allowing them to take their services to patients who could not be reached previously. Informed patient care decisions allow for a faster accurate diagnosis from anywhere in the world that has access to the Internet. Statistics show there are 2.2 billion mobile phones in the developing world while some parts have a patient-doctor ratio of one in 20,000. A mobile cloud service enables better care to be provided to more patients at a lower cost. The fundamental financial and operational model has a primary focus on the healthcare industry, one known to be cautious with technology.

## Future work and challenges

Confusion hinders adoption and there is some confusion about what Cloud computing can do.

## User and environment

**User:** physician, nurse, technician, authorized medical professionals and health care providers.

**Training:** remote training is provided. The service team is accessible online through a live chat feature.

**Settings:** rural, urban, home, ambulatory, primary, secondary, tertiary.

## Reviewer's comments

This proposed iCloud Web PACS, having been tried by several countries, can conceivably be built up over time to facilitate more exchanges. The affordability of this technology in underserved communities depends largely on the company's case use fees. This is an important consideration for prospective countries when considering this system.

Crossing jurisdictional governance between countries could hamper some privacy and confidentiality issues.

## Solution specifications

**Solution is used to support:** Telemedicine; Electronic Health Record/Electronic Medical Record; RIS (Radiology Information Systems).

**Software/Hardware requirements:** Access to the Internet is required with a recommended minimum bandwidth of 512K. Medical images are uploaded and viewed over personal PC or PDA's. Medical images need to be in the DICOM format.

**Standards:** HL7, DICOM, HIPAA (The Health Insurance Portability and Accountability Act).

**Currently used in:** Technology is used globally. The service has been originated in the USA. The current focus is throughout the Caribbean, and Central/South American markets.

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# mHealth platform for community health workers

Country of origin | United States of America

## Health problem addressed

High infant and maternal mortality in developing countries are a major public health concern. Community health programmes have been effective in reducing mortality but their effectiveness is limited due to lack of sufficient training, absence of performance evaluation and feedback, absence of standardized protocols and ineffective care coordination.

## Solution description

The platform has a mobile app and a Health Insurance Portability and Accountability Act (HIPAA) compliant cloud-based platform with web interface. Community health workers (CHW) use mobile phones in the field to capture data, educate patients and provide case management. The web interface is used for monitoring the program and generating reports. In the field, patient data can be stored on the phone or sent to the server. The platform supports audio, images, video data and also uses GPS and bar code data. The platform can also send reminder SMS messages, emails or generate other alerts required in the workflow. Through active monitoring of data, timely, interpretable reports and targeted follow up actions can be created for CHWs and the supervisors.



## Functionality

The CHW logs into CommCare using a username and password. The CHW selects the module (e.g. Pregnant Women) and the form (e.g. Pre-Natal) for this type of visit. The form guides the CHW through a series of questions and education prompts to provide patient specific referrals and counseling. The form is submitted to the web interface for monitoring.

## Developer's claims of solution benefits

This technology improves care across four areas: access to care through client lists on the CHWs' phones and SMS reminders when visits are due; client engagement through audio and video clips and improved credibility of the CHW; quality of care through checklists, decision support, and delivery of sensitive information through recorded voices; and data-driven management through real-time monitoring of the CHWs activities.

## Future work and challenges

The success of this platform is contingent on availability of funding for community health worker programmes. Using this platform has demonstrated return on investment. A dollar-for-dollar effectiveness ratio of 3.48 is anticipated. This will be confirmed through randomized controlled evaluations.

## User and environment

**User:** physician, nurse, midwife, community health worker.

**Training:** our team of field engineers deliver training using field-tested methodologies over a two day period.

**Settings:** rural, urban, home.

## Solution specifications

**Solution is used to support:** mHealth

**Software/Hardware requirements:** The mobile component of the software runs on either simple Nokia phones or Android Smartphones. Cellular data plan is required to transmit data from the field. The cloud-based platform can be accessed through a web browser via any internet connected computer.

The software platform is open source and is available to anyone at no cost. Organizations with less than 20 users are offered hosting, implementation and support for free. After 20 users, the charge is \$0.75 per user / month. In case the clients want customized project design, deployment and support they pay standard software development rates.

**Standards:** HL7

**Currently used in:** India, Tanzania, Zambia, Malawi, Bangladesh, Mexico, South Africa, Afghanistan, USA, Mozambique, Nicaragua, Benin, Guatemala.

**Evaluation:** A recent randomized controlled trial in Tanzania showed that a reminder system incorporated into the system with eventual escalation to supervisor notification generated significant results, with 85% more timely visits for the groups that received SMS reminders. Also, a preliminary controlled trial in Tanzania found increased adherence to protocols by over 20% compared to traditional methods.

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# New media to train health workers

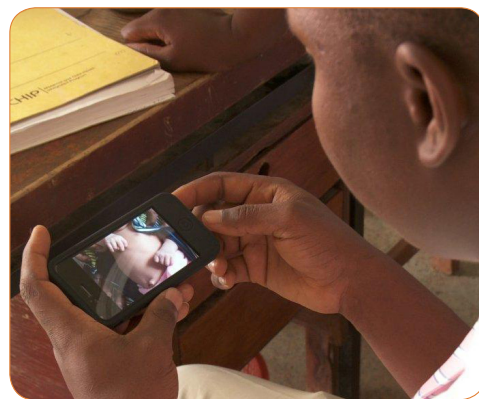
Country of origin | United States of America

## Health problem addressed

Frontline health workers need more and better training. Current methods—lectures and written materials—are not effective, and often fail to consider the reality of resource-poor settings. Health worker shortages make it difficult and costly for them to spend time in workshops. Current approaches are not able to reach the large numbers who need training.

## Solution description

The new media consists of videos that combine live footage with animated segments, and are designed and created for playback on portable devices. The films are brief vignettes that “bring alive” international clinical guidelines. They cover topics in a simple and concise way with “need-to-know” information. They are carefully scripted to provide step-by-step instruction that is easy to understand and put into action. They are voiced over to enable narration in different languages, and shot and formatted for the small screen of mobile devices.



## Functionality

Operation consists of standard procedures for video viewing. Varies based on available technology: 1) offline on video-capable phones using memory cards or computers (where the Internet connectivity or electricity is limited); 2) on basic video equipment (portable players or TVs) using DVDs; 3) on smartphones or computers with live streaming.

## Developer's claims of solution benefits

New media can deliver step-by-step instruction on clinical skills and procedures in an effective and efficient way. With expansion of the Internet access and the proliferation of mobile devices, this solution can reach far more people with better health care information than was conceivable only a few years ago. New media for medical training is still in its infancy in resource-poor countries, but it is readily scalable and can help better train providers at much lower cost than traditional methods.

## Future work and challenges

The intention is to make this new media accessible to any and all frontline health workers who need better training; thus, the plan is for an open-access model that makes the videos freely available to users. The challenge is to obtain funding that will make this goal feasible. Other challenges related to its adoption include: 1) environmental and hardware constraints: access to viewing devices, power supply, and the Internet; 2) modification of the videos for use across many regions: accurate translation of languages and effective voice over.

## User and environment

**User:** self-use/patient, physician, nurse, midwife, family member, technician, community health worker.

**Settings:** rural, urban, home, ambulatory, primary, secondary, schools and training programmes.

## Solution specifications

**Solution is used to support:** eLearning/mLearning; mHealth.

**Software/Hardware requirements:** A basic viewing device is required, for example a battery-powered DVD player. As access to more sophisticated devices, the Internet, and stable power supply increases, more options for viewing the videos become available.

**Currently used in:** India, South Africa.

**Evaluation:** Videos have been shown to be effective instructional tools and are commonly used to teach medical practices and skills in high-income countries; however, they remain vastly underutilized and unavailable in the developing world. The content is based on best practice standards and is subjected to rigorous review by global content experts. Content is field tested for effectiveness in teaching, and for comprehension and relevance.



# Primary health care continuous quality improvement (CQI) tools

Country of origin | Australia

## Health problem addressed

Lack of data on care processes and outcomes in primary care is an on-going problem for applying evidence-based practice. CQI approaches have potential to address this challenge. The approach presented provides a flexible and tailored solution, facilitating use of local level data and targeted CQI appropriate to the burden of disease.

## Solution description

A CQI process developed to assist primary health care services to improve their clinical services and client outcomes by collecting data using specially developed audit tools and protocols. The tools are based on best practice standards and recommended scheduled services for a range of clinical services i.e. child and maternal care. Audit data are entered onto a web-based database which provides automated real-time analysis and generation of a quality improvement report for use at the local health centre level. In addition to the audit data, qualitative data are collected from the primary health care team through a facilitated discussion using a system's assessment tool for action planning.

## Functionality

Training in applied continuous quality improvement and clinical auditing. Data collected through clinical audits. The primary health care team participates in a system's assessment to collect quantitative data. All data are entered into a web-based database and reports are generated. The team sets goals and action plans for the next 12 months.

## Developer's claims of solution benefits

This approach comprehensively addresses the development of capacity to apply CQI in a health service context starting at the stage where the health service is at. It embeds ownership of the process by the health service staff. It uses systems currently in place to collect health data. It provides tools to measure health service practice against accepted best practice. It encourages the process of quality improvement in steps to address areas identified as priorities by the health service.

## Future work and challenges

The existing technology is modelled on Australian terminology and best practice for disease which is not necessarily suitable for other settings. Recommended changes include: tools abbreviated to include key disease outcomes, and corresponding modification to electronic database interface including capacity for local users to edit specific field options (e.g. drug doses, ethnicity) and download/upload capacity to support off-line use. Coordinators should be trained and supported to maintain the technology locally.

## User and environment

**User:** physician, nurse, midwife, technician, health workers, indigenous/other health workers.

**Training:** training is required and is given initially by an Australian team who can build more sustainable capacity among local trainers.

**Settings:** rural, urban, primary, secondary, and tertiary.

## Reviewer's comments

The continuous quality improvement (CQI) system is an innovative approach developed to support high-quality primary health care for Aboriginal and Torres Strait Islanders. CQI can be adapted and used with limited IT equipment.

## Solution specifications

**Solution is used to support:** Decision Support Systems; Continuous Quality Improvement(CQI).

**Software/Hardware requirements:** In the Australian context, it uses customised software to support web-based clinical audit tools for the collection of data to allow reporting of key performance indicators against best practice guidelines. The technology is not dependent on this specific software solution.

Microsoft SQL, Microsoft ASP.Net, Menzies proprietary code.

**Standards:** Clinical Guideline Standards for Chronic Disease, Maternal, Preventive, Child Health, and Mental Health.

**Currently used in:** Australia

**Evaluation:** Rumbold A et al. Delivery of maternal health care in Indigenous primary care services: baseline data for an on-going quality improvement initiative. BMC Pregnancy and Childbirth 2011, 11:16 doi:10.1186.

Gardner KL, Dowden M, Togni S, Bailie R. Understanding uptake of continuous quality improvement in Indigenous primary health care: lessons from a multi-site case study of the Audit and Best Practice for Chronic Disease project. Implement Sci. 2010;5:21

# Rapid SMS providing availability of essential medicines

Country of origin | United States of America, Tanzania, Malawi

## Health problem addressed

Many public health supply chains in Africa suffer chronic shortages and stock out of essential medicines, contributing to high morbidity and mortality rates. Decision makers have little access to stock levels, rendering them unable to monitor stock availability and address stock outs.

## Solution description

At pre-scheduled time intervals, facility/community users send text messages with key data to a toll-free short code using their personal mobile phones. Data is used to calculate resupply quantities, which are sent via SMS to resupply facilities to enable prepacking of orders. Reported data items, such as stock on hand, as well as monthly email summary reports and supply management reports are displayed on an interactive web-based interface, with varying access levels, to enable decision making. The solution also alerts higher level staff via SMS if stock levels are limited or depleted.

## Functionality

Refer to solution description.

## Developer's claims of solution benefits

In Tanzania, evaluation results indicated that 88% of facilities improved on-time stock report submission rates, and 93% improved stock counting exercises because of receiving routine mobile alerts; 45% of facilities reported improved product availability. In Malawi, community health worker(CHW) logistics reporting rates grew to 97% from 43%; and lead times were reduced. The group messaging feature enables managers to reinforce skills and procedures.

## Future work and challenges

Some challenges include maintaining the system and solving software problems when they occur. Timely resolution of problems is key to maintaining user confidence in the system. Common human resources challenges also can occur such as turnover of trained staff. Additionally, transitioning the system to full Ministry of Health ownership can be a challenge if they are not engaged from the outset in the technology development. Future challenges include how to continue to ensure increased product availability, use of data for decision making and determining to what extent it can supersede the existing paper-based system rather than be a supplement.

## User and environment

**User:** community health worker, health facility staff, district health staff, and national health staff.

**Training:** training is conduct by trained trainers using phones and training manuals for one or two days.

**Settings:** rural, urban, primary, secondary, tertiary and national level.

## Reviewer's comments

Very good use of SMS, a well-used feature by cell phone users, to trace medication stock, and also analyse their use and distribution. The pilot of this tool has shown promising results, with high comfort of use and also good results not only on replenishing medications but also tracking usage and reminders to restock.

## Solution specifications

**Solution is used to support:** Decision Support Systems; mHealth; Supply Chain Data.

**Software/Hardware requirements:** Requirements include simple mobile phones for health workers and access to network coverage, and electricity to recharge phones. Health centre and district staff reviewing the data dashboard online need regular access to a computer with the Internet access.

The software is open-source and built on the rapid SMS platform. The source code is available for any user that would like to adopt and adapt the system for their use.

**Standards:** HL7

**Currently used in:** Tanzania, Malawi.

**Evaluation:** In Tanzania, of the 5 district users and 17 facility users surveyed, 100% indicated that they preferred SMS based reporting, and 88% of the facility users further said that the stock reporting system has also helped improve their reporting rates and adherence to reporting groups. At the facility level, the stock reporting system has increased the attention of health workers on their reproductive health commodities and as a result, improved the timeliness of ordering and stock management.

# Real-time measurement of meteorological events on public health

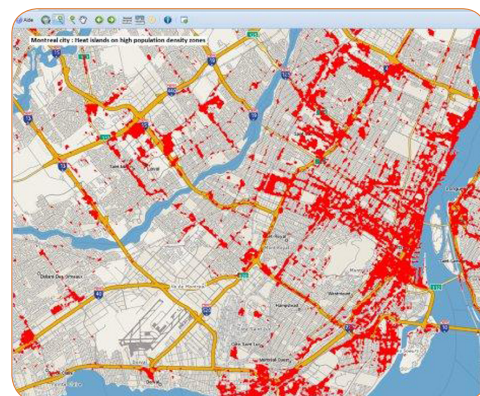
Country of origin | Canada

## Health problem addressed

A changing climate leads to changes in the frequency and intensity of extreme weather events. Deaths, injuries, diseases, and mental health problems related to extreme weather events result from the exposure and vulnerability of human systems. The average number of people killed by natural disasters for 1972-1996 was about 123,000/year worldwide.

## Solution description

The objective of this integrated web application system is to provide in real-time a complete meteorological picture (actual conditions, forecasts and alerts) and population's health status on relevant indicators. Other environmental and spatial information is also provided for preventive purposes and for supporting emergency preparedness. The system comprises four functions: F1 - Data acquisition and integration, F2 - Risk analysis and alerts, F3 - Cartographic application, and F4 - Climate change and health information.



## Functionality

The system is available through a secure web information portal and provides access to weather forecasts, historic and real-time health and weather indicators, alerts, and various cartographic data for conducting prevention and emergency measures. Currently the heat wave function is fully developed, and the floods function will be completed in 2012.

## Developer's claims of solution benefits

No other system is known to offer a dynamic cartographic application showing the urban heat islands and having tools for identifying vulnerable areas using a combination of numerous user-selected and user-controlled indicators. Furthermore, all the cartographic layers are available as Web Map Services (WMS), ensuring better access to the data since they can be reused within other OGC-compliant systems without any development effort.

## Future work and challenges

As this is not a commercial product, the strategy to make the product accessible has been through publications and presentations, notably through webinars organized by the Pan American Health Organization, the Public Health Agency of Canada, etc. The implementation of the system in two less developed countries will also serve as a case study in using such a system in countries where the basic data may be less widely available than in Canada. Indeed, availability of data probably represents the main challenge for such a system. Currently, the system allows for any type of georeferenced data to be published as a layer of information. Other data are also used for automatic charts and reports.

## User and environment

**User:** physician, nurse, technician, public health or municipal officers.

**Training:** training by developer through the Internet and simple means such as Beam my Screen; duration 1-4 hours.

**Settings:** rural, urban, home, ambulatory, primary, secondary, tertiary, municipalities, and civil protection.

## Reviewer's comments

This innovative approach, especially if and when coupled with disease surveillance systems like [www.healthmap.org](http://www.healthmap.org), can start to uncover known and unknown correlations of disease outbreaks as they relate to weather. The requirement of technologies is not onerous and easy to learn which makes the use and sustainability of the system very achievable.

## Solution specifications

**Solution is used to support:** Decision Support Systems; Geographic Information System; Health Research; Health Surveillance.

**Software/Hardware requirements:** personal computer or laptop or network and access to the Internet. The application can be installed on a single computer, no need for a network. It can also be installed on a server and accessed over a Local Area Network, the Internet or a cellular/mobile network.

**Standards:** Open Geospatial Consortium (OGC) standards.

**Currently used in:** Canada.

**Evaluation:** Bustinza R, Toutant S, Bélanger D, Gosselin P. Système intégré des données de vigilance et surveillance des aléas hydrométéorologiques et géologiques: Évaluation de l'utilisation du volet chaleur au cours de l'été 2010.

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<http://www.who.int/ehealth>

# Smart phones for supportive supervision for TB

Country of origin | United States of America

## Health problem addressed

Nigeria ranks 4th among the 22 high TB burden countries in the world. The TB burden is further compounded by the high HIV/AIDS prevalence. The HIV prevalence for Nigeria is 4.4% (2005 National sentinel survey). There is low capacity to provide high-quality TB-DOTS and TB-HIV services in public and private sector facilities.

## Solution description

Introduced Smartphones for data collection and analysis. Built a real-time feedback mechanism on Android Smartphones platform coded on Pendragon Forms and EpiSurveyor. Created an excel-based tool that allows transfer of forms from one mHealth tool to another; Created forms and connected the forms to the users; Distributed the forms wirelessly via Wi-Fi or SIM cards; Uploaded to centralized web database; Built and deployed database that: Provides online data aggregation for analysing and disseminating data in real-time; Provided quality control system for data including online government approvals of data; Enabled access to the data along with operational and quality of care indicators.

## Developer's claims of solution benefits

Supervisors have indicated that the system is enabling them to monitor and assess performance of the TB health delivery system, identify problems and opportunities, and in many cases take immediate action for improvements. For example, the rate of drug stock-outs has significantly decreased, and external quality control is easily obtained for quality service with far less delay.

## Future work and challenges

Scale up of initial training to Lagos and Abia States to nationwide implementation requires careful needs analysis and planning.

## User and environment

**User:** technician, clinic supervisor.

**Training:** some level of training is required and will be provided by Ministry of Health officials.

**Settings:** rural, urban, primary.

## Solution specifications

**Solution is used to support:** Decision Support Systems; mHealth.

**Software/Hardware requirements:** Access to a cellular network; access to the Internet to link to the online database. Android OS coded with Pendragon (proprietary - 1 license) with open source EpiSurveyor software.

**Currently used in:** Ethiopia, Nigeria.

# Telemedicine for HIV/AIDS care

Country of origin | Belgium

## Health problem addressed

The policy of scaling-up antiretroviral therapy for HIV patients coupled with the increasing availability of generic HIV drugs have been effective in achieving the target of four million HIV patients under treatment in developing countries. However one of the main obstacles to that has been the workforce shortage and lack of training and continuing professional development (CPD).

## Solution description

The HIV/AIDS telemedicine referrals are managed through a web site discussion forum (<http://telemedicine.itg.be>) based on a free, open-source package, which allows registered users to follow and contribute to discussion of referrals, both online and by email.

Topic	Author	Replies	Read	Last Post	Page
QID 1514: HIV test results (new)	Isabella	0	0	04/02/2013 08:33:17	1 of 1
QID 1517: Access on AZT	Isabella	0	2	04/02/2013 10:05:07	1 of 1
QID 1532: Link data on this box	Isabella	1	3	04/02/2013 10:05:07	1 of 1
QID 1529: Patients changed to TDF while failing	Isabella	4	10	04/02/2013 10:05:07	1 of 1
QID 1527: Third Line in Resource Limited Settings	Isabella	2	15	04/02/2013 10:05:07	1 of 1
QID 1521: Provider Report	Isabella	4	28	04/02/2013 10:05:07	1 of 1
QID 1528: Malawi: hyperactive malawi.telemedicine.itg.be	Isabella	0	3	04/02/2013 10:05:07	1 of 1
QID 1522: Seroneversion?	Isabella	1	10	04/02/2013 10:05:07	1 of 1
QID 1514: CASE REVIEW	Isabella	2	14	04/02/2013 10:05:07	1 of 1
QID 1510: use of Isotretinoin	Isabella	1	15	04/02/2013 10:05:07	1 of 1
QID 1500: Kuvuini plus Cratic	Isabella	5	40	04/02/2013 10:05:07	1 of 1
QID 1480: Avelis	Isabella	3	26	04/02/2013 10:05:07	1 of 1

## Functionality

The patient's history, physical examination, non-identifying pictures, laboratory findings and questions to be answered are posted on the <http://telemedicine.itg.be> discussion forum, using an electronic format available on the telemedicine website.

## Developer's claims of solution benefits

ITM Telemedicine is one of the very few long-running telemedicine networks delivering humanitarian services to physicians working in resource-limited settings. Telemedicine is a possible way to offer support, mentorship and supervision to physicians working in developing countries. A web-based approach helps to learn from others' experiences, submitting cases and questions and to be aware of other ways to manage patients.

## Future work and challenges

Telemedicine is a powerful educational method. A follow up users' survey showed that telemedicine advice was valuable in the management of specific cases, and significantly influenced the way that clinicians managed other similar cases subsequently. Despite this success, a trend of decline in use of service has been recognised. Sustaining the interest of users remains a key challenge and further information is required about users' satisfaction and network performance. In addition, anchoring the service to partner institutions or regional partnerships needs to be explored. Collaboration with larger groups to address these challenges has begun.

## User and environment

**User:** physician (Alumni of the Institute of Tropical Medicine in Antwerp).

**Settings:** rural, urban, home, primary, secondary, tertiary.

## Solution specifications

**Solution is used to support:** Telemedicine

**Software/Hardware requirements:** Personal computers with access to the Internet.

**Standards:** DICOM

**Currently used in:** 42 countries

**Evaluation:** Telemedicine in HIV/AIDS care: a users' satisfaction survey: Proceedings\_Med\_e\_tel\_2011.



# Telemedicine network

Country of origin | Switzerland

## Health problem addressed

Continuing education of healthcare professionals and access to specialized advice are keys to improve the quality, efficiency and accessibility of health systems. In developing countries, these activities are usually limited to capitals, and remote professionals do not have access to such opportunities.

## Solution description

A suite of software tools specifically designed to work in low-bandwidth, low-infrastructure settings, to provide distance education ("Dudal" module) and tele-expertise consultations ("Bogou" module). These software modules are developed in Java, and deployed using Java Web Start technology.

## Functionality

For distance education, slide presentations are converted using open-source office automation software (OpenOffice) into a webcastable format. The webcasting environment includes an instant messaging tool for interactivity.

The tele-expertise environment uses a PKI infrastructure to secure information exchange, and a forum interaction paradigm.

## Developer's claims of solution benefits

Most existing tools are not designed and optimized to work in low-infrastructure environments. They lack the ability to connect to medical information sources (e.g., DICOM) and have insufficient security for exchanging sensitive medical information.

## Future work and challenges

The main limiting factor for mainstreaming is the availability of the Internet connectivity in remote settings. The situation is rapidly evolving with the deployment of mobile networks and related GPRS/3G/4G connections, in particular in East Africa. In West Africa, satellite connections are still needed, and remain expensive thus limiting the economic sustainability of these tools to larger hospitals.

Other challenges include the necessity to anchor these services in the institutional framework of each country, which is facilitated if countries have a eHealth strategy and related policies and coordination structures.

## User and environment

**User:** physician, nurse, midwife, technician.

**Training:** training is required and is provided by online documentation and through the support of national coordination teams.

**Settings:** rural, urban, secondary and tertiary.

## Solution specifications

**Solution is used to support:** Telemedicine; eLearning/ mLearning.

**Software/Hardware requirements:** The software tools require low-bandwidth Internet access, which can be provided by DSL, 3G or satellite links. Uplink bandwidth of 20 kbps and downlink bandwidth of 40 kbps are sufficient to run all services.

Dudal and Bogou modules are Java applications based on open-source libraries, freely available with no license fee.

**Standards:** DICOM

**Currently used in:** Mali, Mauritania, Senegal, Burkina Faso, Niger, Ivory Coast, Chad, Cameroon, Congo, DRC, Guinea, Madagascar, Liberia, Ghana, Tanzania, Egypt, Tunisia, Morocco, Bolivia, Laos.

**Evaluation:** Bagayoko CO et al. Deploying portable ultrasonography with remote assistance for isolated physicians in Africa: lessons from a pilot study in Mali. *Stud Health Technol Inform.* 2010;160:554-8.

Bagayoko CO et al. Can ICTs Contribute to the Efficiency and Provide Equitable Access to the Health Care System? *Year Med Inform.* 2011;6(1):33-8.

# Tele-ophthalmology software application

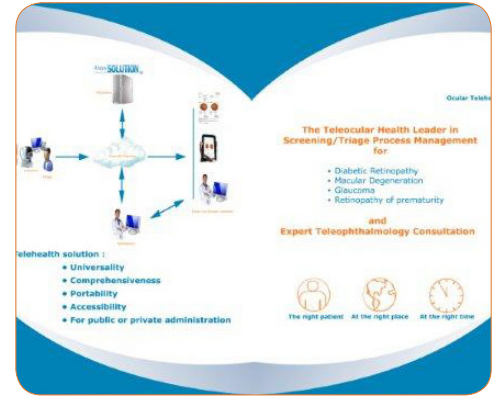
Country of origin | Canada

## Health problem addressed

Diabetic retinopathy (DR) is a leading cause of blindness and visual disability in the world. Diabetes affects 8 to 10% of the population in the developed countries. Approximately 2% of people become blind after 15 years of diabetes.

## Solution description

The online screening management application collects captured fundus images, patients personal data, clinical data, and transfers the data for reading and reporting medical follow-ups. This online screening application also provides yearly management recall and scheduling, quality control and inter-professional consultation. It maintains complete trackability, security, confidentiality and easy access to data (with/without immediate access to the Internet).



## Functionality

New patient file: nominal and clinical data, visual acuity are added.  
 Patient's eyes are imaged, the images added to the file and uploaded to the server.  
 A doctor accesses and reads the file.  
 Medical report are generated.  
 Patient is given follow-up or put on recall list.  
 Overview of process with alerts.  
 Quality control.  
 Data organized at will.

## Developer's claims of solution benefits

This solution integrates all aspects of the screening process, from the initial appointment, uploading of data and fundus images to reading, reporting, follow-up and automated recall scheduling. Access to full history. It further sets itself apart by the comprehensiveness of its flow management, health result analysis and reading tools, and its automated medical quality control. It allows e-consultation. Can be used in situations with/without immediate access to the Internet.

## Future work and challenges

Ways to promote global adoption and integration and to motivate people to increase the use of teleophthalmology for DR need to be found as it is a proven strategy to improve the quality of health care and collaboration among professionals worldwide. The biggest obstacle is not that of attitude or that of access to the equipment, but that of the will and of carrying out its organization to provide systematic screening for diabetic retinopathy to all diabetics.

## User and environment

**User:** physician, nurse, technician.

**Training:** intuitive solution with instructions for every step are provided; no training needed.

**Settings:** rural, urban, primary, secondary, and tertiary.

## Reviewer's comments

Well-organized, integrated system for managing tele-consultations for ophthalmology, mostly for the screening of diabetic retinopathy, which is also becoming a significant issue in developing countries.

The innovation lies mostly in the comprehensive integration of the whole process, and includes quality control. The solution has been validated in rural settings in Canada but not in developing countries.

## Solution specifications

**Solution is used to support:** Telemedicine; Electronic Health Record/Electronic Medical Record; Health Research.

**Software/Hardware requirements:** Any facility with access to a fundus imaging camera and a computer. Solution is a web-based software application; it is proprietary and subject to a license fee.

**Standards:** HL7, DICOM

**Currently used in:** Canada

**Evaluation:** Can J Ophthalmol 2008;43:658-68.

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<http://www.who.int/ehealth>

# Teletrauma

Country of origin | Ukraine

## Health problem addressed

Trauma is the main cause of death for people younger than 40 years old worldwide. There are 2 million injured persons per year in Ukraine (4% of population). Polytrauma due to industrial disasters and motor vehicle accidents (MVAs) are a critical problem for Donetsk's large industrial region, because 70% are lethal or result in extremely high level of disabilities.

## Solution description

Web-platform: open source iPath secure server. Server allows to upload and download clinical data and images, perform discussions, upload additional information as evidence-base for recommendations, send/receive e-mail alerts.

Scheme "E-mail+SMS": referral doctor prepares anonymous clinical data, sends it via e-mail to the expert hospital and sends SMS as alert about urgent request. Doctor on duty after receiving SMS opens e-mail and reads the case; sends answer immediately via e-mail.

Perform discussion, upload additional information as evidence base for recommendations, send/receive e-mail alerts.

## Functionality

Telemedicine service is provided by both synchronous and asynchronous telemedicine methods. Patient confidentiality and security achieved by: patient's consent, secure server, VPN-lines, anonymity, sending data in DICOM or SCP-ECG.

## Developer's claims of solution benefits

Cost effective and available, based on existing IT infrastructure, easy to introduce and use, clinically effective, do not need technicians or long preparation.

## Future work and challenges

Integration of digital signature tools. Development of tele-assistance based on low-cost devices for transmission of video from arthroscopy and ultrasound devices. Randomised trials for evaluation.

## User and environment

**User:** physician, nurse.

**Training:** training is required on basic computer skills, medical data preparation skills, security skills - 3-6 academic hours.

**Settings:** rural, urban, primary and secondary.

## Reviewer's comments

The organizational aspects for using ICT meaningfully to address the management of trauma patients are good, and have demonstrated convincing results.

## Solution specifications

**Solution is used to support:** Telemedicine; eLearning; mHealth.

**Software/Hardware requirements:** standardized equipment (PC, digital camera, printer, web-camera) and IP data transfer protocol (based on principles of low-resource telemedicine); iPath.

**Standards:** DICOM

**Currently used in:** Ukraine, Russia

**Evaluation:** Vladzomyrsky A.V., Klymovytskyy V.G., Kalinovsky D.K. et al. Clinical Efficiency of Telemedicine in Trauma and Orthopaedics / Med-e-Tel 2008.-Luxembourg,2008.-P.87-88.

# Medical devices

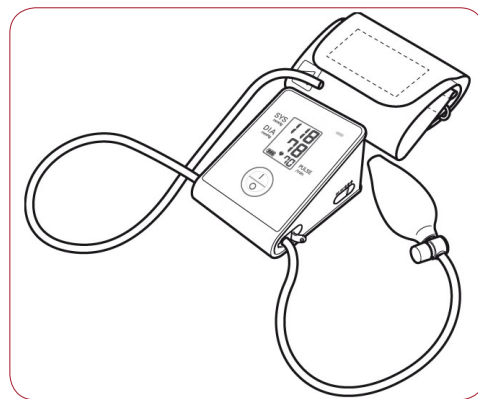
## 2012

# Automated solar-powered blood pressure monitor

Country of origin | Japan

## Health problem addressed

There is a progressive increase in the prevalence of cardiovascular diseases resulting in approximately 8 million deaths annually worldwide which can be attributed to high blood pressure. Low- and middle-income countries shoulder 80% of the cardiovascular disease burden, more than half of which occurs in people of working age and pregnant women.



## Product description

This electronic automated blood pressure monitor operates with solar power alone, as well as AC adapter and regular dry battery. It is also equipped with ultraviolet-tolerant plastic parts and dust-preventive structure to bare direct sunlight exposure for battery charge.

## Product functionality

Functions as a standard blood pressure monitoring system.

## Developer's claims of product benefits

With progressive integrated circuit technology, the electronic circuit of the device consists of an ultimately small number of components resulting in very low energy consumption which can be supplied with a solar panel. The chassis of the device is made of ultraviolet-tolerant plastic which bare direct sunlight. To the best of the submitters' knowledge, this is the world's first product according to WHO's specifications, including solar power and accuracy.

## Operating steps

Charge battery by exposing the device to strong light, such as direct sunlight. Attach blood pressure cuff to upper arm. Inflate the cuff by pumping bulb up to estimated systolic blood pressure, then the device starts measurement. Remove the pressure entirely by pressing release button when the device displays the results.

## Development stage

The product underwent field tests in Uganda and Zambia. In the evaluation, healthcare providers used the product in 700 patients and in comparison with conventional method (auscultation), 95% of the providers preferred the product with the reasons of easiness, solar power, and automated measurement. The product is approved as medical equipment in Japan, Europe and the US based on respective regulatory systems.

## Future work and challenges

Currently, the price of the product is set relatively high level because of little manufacturing quantity. When the product sells more, the unit price aims to be much lower.

## User and environment

**User:** Self-use/patient, physician, technician, nurse, midwife, family member, care person

**Training:** None

**Maintenance:** None

## Environment of use

**Settings:** Rural settings, urban settings, ambulatory, at home, primary (health post, health center), secondary (general hospital), tertiary (specialists hospital)

**Requirements:** None

## Product specifications

**Dimensions (mm):** 90 x 75 x 125

**Weight (kg):** 0.2

**Life time:** 5 years

**Retail Price (USD):** 100

**List price (USD):** 100

**Other features:** Portable (hand-held), reusable

**Year of commercialization:** 2009

**Currently sold in:** Japan, EU Nations



# Interventional cardiovascular lab

Country of origin | India

## Health problem addressed

Cardiovascular diseases (CVDs) are the number one cause of death globally. An estimated 17.3 million people died from CVDs in 2008. Out of that, more than 80% of CVD deaths take place in low and middle-income countries due to lack of access to affordable equipment for diagnosis and treatment.

## Product description

The catheterization lab has a high power 80 KW generator digital X-ray system, a patient table, and a gantry stand with varying degrees of movements, and different X-ray modes.

## Product functionality

The X-ray system provides real time images which help to visualize and identify blocks in blood vessels and makes it possible to treat them by means of stenting, coiling, etc. The patient table and gantry stand allows imaging that makes it possible to view blood vessels in different parts of body in real time. Different X-ray modes facilitate the imaging.



## Developer's claims of product benefits

The economy catheterization lab is tailored for the economy section as it has the flexibility to perform a wide variety of procedures. Infrastructure requirements are also lesser as the system has a small footprint which makes it possible to fit it in even small hospitals emerging economies. Low cost of ownership/maintenance makes the product ideal for low and middle-income sections. The lab requires less training to operate as it has an intuitive user interface and simple workflow. User manual and localized software interface helps ensure the product is well-suited for different countries. Overall, it is a robust product and withstands high workload demand, which is typical for resource-constrained countries. Configurable options and mobile table allow a variety of procedures in cardiac and vascular areas.

## Operating steps

The principle of operation is that of a general x-ray system. For specifics, the user manual reference needed.

## Development stage

Internal verification and validation testing completed. External evaluations done at hospitals globally. CE marked product. Compliance to European Medical Devices Directive MDD/93/42EEC. Manufacturing facility is ISO13485 certified. The catheterization lab has been commercially released and is in use in various markets like India, Nepal, Egypt, Turkey, Latin America and Eastern Europe.

## Future work and challenges

Availability of trained interventional cardiologist and radiologist is one of the major challenges and targeting this would be the next step.

## User and environment

**User:** Interventional cardiologist and interventional radiologist

**Training:** Required

**Maintenance:** Annually

## Environment of use

**Settings:** Rural settings, urban settings, secondary (general hospital), tertiary (specialists hospital)

**Requirements:** Stable 120 kVA power supply and good earthing. Procedure room should be semi-sterile. Lead shielding on doors and windows should be present to protect from scattered radiation. Technician operating the system needs to be trained. Temperature range is 15-35°C and humidity range is 30-75%.

## Product specifications

**Dimensions (mm):** 2000 x 1000 x 2000

**Weight (kg):** 300

**Retail Price (USD):** 180000 - 250000

**List price (USD):** 180000 - 250000

**Other features:** Software use, installed stationary, reusable

**Year of commercialization:** 2010

**Currently sold in:** India, Nepal, Egypt, Turkey, Chile, Columbia, Peru, Poland

# Intramedullary nail and interlocking screw system

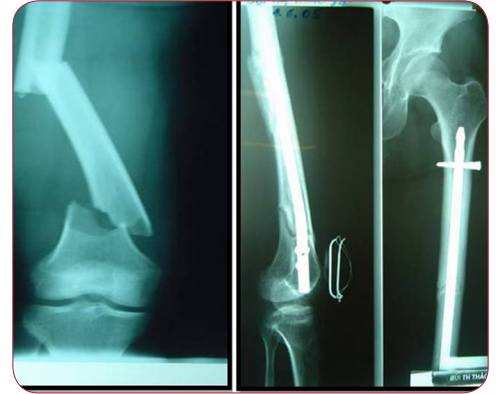
Country of origin | United States of America

## Health problem addressed

According to WHO statistics, road traffic accidents (RTAs) cause about 25.4 million severe injuries per year. RTAs are projected to become the third leading cause of DALYs lost worldwide by 2020. Developing countries lack the surgical tools to treat severe fracture injuries effectively. Those who live in poverty cannot afford the cost of surgical implant they need in order to quickly recover and provide for their dependents.

## Product description

The intermedullar (IM) nail and interlocking screw system is designed to be used without electricity or x-ray imaging in the operating room. The system consists of stainless steel nails which are placed down the middle of the bones with screws that are placed through the bone and nail to stabilize the fracture.



## Product functionality

This method allows patients to walk using crutches the day after surgery and be discharged usually three days after surgery. The same instruments and implants of different sizes are used to treat fractures of the femur, tibia, and humerus. Results are recorded on an online database to ensure the proper technique is being followed and to learn more about fracture healing.

## Developer's claims of product benefits

The IM nail and interlocking screw system's cost effectiveness is reflected in less disability after the fracture, ability to return sooner to work, and more efficient utilization of hospital beds. The IM nail interlocking screw technique is globally recognized as the preferred treatment for long bone fractures. This system makes it possible for surgeons to use this treatment on patients who couldn't afford it otherwise. Total cost is less than other systems of equivalent quality.

## Operating steps

During surgery, the fracture is reduced and the stainless steel IM nail is placed through the canal of the bone. A target arm and special instruments are used to place screws through the slots in the nail and through the bone to stabilize the tibia, femur, or humerus fracture. No electricity or x-ray imaging is necessary for the surgery.

## Development stage

FDA cleared for use in the USA. The stainless steel alloy composition is approved for implantation in humans. The associated online database has over 50,000 entries and is the largest database of treatment of long bone fractures in the world. This has been reviewed by surgeons and reported in peer reviewed medical journals. Biomechanical tests have been obtained as noted in listed articles.

## Future work and challenges

Though the product is comparatively low-cost and available on a not-for-profit basis, it is a challenge to keep up with the increasing number of requests for the IM nail and interlocking screw system as financing is limited. Continual updating of technique is also a challenge due to the increasing number of hospitals which have this system.

## User and environment

**User:** Physician, orthopaedic surgeon

**Training:** Yes; training and tools are given by surgeons familiar with the technique (over 10+ surgeries)

**Maintenance:** Yes; periodic replenishments (by nurse, technician, manufacturer, physician)

## Environment of use

**Settings:** Rural, urban, secondary (general hospital), tertiary (specialists hospital)

**Requirements:** Operating room with sterile conditions, anesthesia personnel and machines, well trained nurses, and sterilizing personnel are all required

## Product specifications

**Dimensions (mm):** 8-12 x 8-12 x 280-420

**Weight (kg):** 0.118-0.389

**Consumables:** Surgical supplies

**Retail Price (USD):** Varies

**List price (USD):** Varies

**Other features:** Portable

**Year of commercialization:** 2002

**Currently sold in:** United States, Vietnam, Iran, Guatemala, & Indonesia. Donated to 48 other countries

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

# Mobile ECG with web-based telemedicine platform

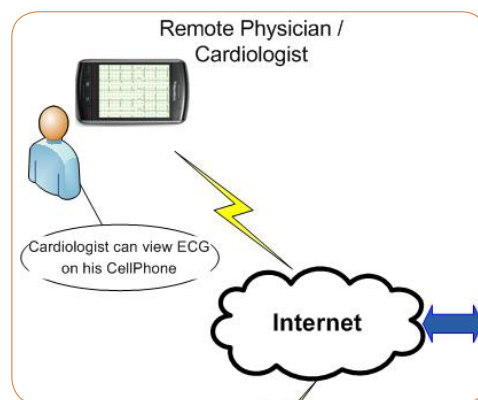
Country of origin | India

## Health problem addressed

Coronary heart disease is one of the leading causes of death across the globe. Every second in some part of the world a person suffers from chest pain or has a heart attack with lack of early warning systems. The problem gets compounded by the fact that the ratio of doctors attending patients is far less in lower and middle income regions.

## Product description

The system has been designed to provide a telecardiology platform for remote ECG analysis and real time reporting from the doctor for the attending paramedic or the general practitioner. The portable system gives specialists the possibility to interpret ECG's from their mobiles, thus bridging the gap between the patient and the specialist. Also the system gives an auditable trail of all the reports right from acquisition to reporting of the patient ECG.



## Product functionality

Patient details are entered in the device along with taking their ECG. 20 ECG's can be stored in the device. Each patient details can be transmitted to the doctor in real time.

## Developer's claims of product benefits

Prevalent solutions use facsimile and dual-tone multi-frequency solutions to implement transmission of ECG's to the remote doctors. These are one way communications without proper platform for digital reporting of diagnosis from the doctor. This has been overcome with comprehensive auditable online storage. This device has been so designed keeping in view the ease of use, adaptability and scalability. The device can be used not only as an emergency single point of care, but with its local and cloud printing capabilities, it also means that the same device can replace a conventional ECG machine.

## Operating steps

1. Connect the patient cable to the ECG connector at the bottom of the device.
2. Clean the skin surface before/after applying electrodes.
3. Connect the electrodes to the patient.
4. Attach the patient cable leads to the electrodes placed on the patient's skin surface.
5. Switch on.
6. Follow the process on device as mentioned in section 7.2 in manual.

## Development stage

The unit was tested and deployed at a renowned 800 bedded multi-specialty hospital and a cardiac critical care center in Mumbai. Further in the first 12 months the devices has been used in cardiac screening camps at multiple remote rural locations within India with more than 10000 ECGs being taken and reported in this period. Certified for CE - 1293.

## Future work and challenges

- 1) Availability of: reliable communication networks, electrical power for device charging in remote rural locations, doctors to report the ECGs on timely basis.
- 2) Seamless integration of various emergency response teams to take follow actions.
- 3) Developing and managing software clients for various different smartphones.
- 4) Slow adoption by medical professional / local administration agencies.

## User and environment

**User:** Patient, physician, technician, nurse

**Training:** 3 hrs; delivered by company technician

**Maintenance:** Preventative; once per year

## Environment of use

**Settings:** Urban, rural, ambulatory, at home, primary (health post, health center), secondary (general hospital), tertiary (specialists hospital)

**Requirements:** Access to cellphone network, power supply for recharging

## Product specifications

**Dimensions (mm):** 140 x 97 x 43

**Weight (kg):** 0.65

**Consumables:** ECG gel, reporting paper

**Life time:** 7 years

**Shelf life:** 5 years

**Retail Price (USD):** 1000-1200

**List price (USD):** 1400

**Other features:** Portable, reusable, uses software

**Year of commercialization:** 2010

**Currently sold in:** India, Mauritius

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

# Multi-parameter remote diagnostic kit

Country of origin | India

## Health problem addressed

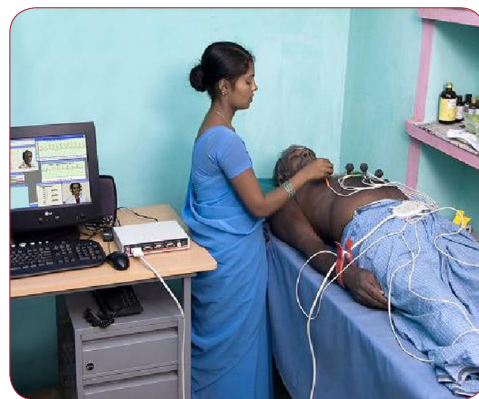
70% of the rural population in India has very poor access to health care. 76% of the medical facilities are concentrated in the urban areas, and there is an overall shortage of medical personnel.

## Product description

The technology comprises of a USB powered multiparameter diagnostic device which captures ECG, temperature, heart & lung sounds, SPO2 and BP, and communicates with the remote doctor through a low bandwidth audio/video/data conferencing.

## Product functionality

The technology enables rural patients to reach urban doctors through a telemedicine solution that integrates the whole healthcare delivery ecosystem to provide meaningful services. The solution also captures the workflow of delivery processes, and enables resource optimization by capturing and analysing operational data in service delivery.



## Developer's claims of product benefits

Infrastructure (bandwidth) and skillset limits the reach of technological solutions. This solution works at extremely low bandwidths (32 kilobits/s onwards) for real-time audio/video/data tele-consultation, thereby reaching places where other existing solutions can't reach. It is very easy to use by a village operator and is extremely power efficient (works on USB power). Further, it is a comprehensive solution linking multiple providers (doctors/pharmacies/labs/hospitals), and addresses 75% of healthcare needs at the point-of-care at sub USD 1.0 fees.

## Operating steps

A rural operator carries out remote consultation for the patient at the village with a doctor sitting anywhere with an internet connection. The doctor remotely controls the device to obtain medical parameters, and to provide prescription to the patient, while medical records are stored. The solution also supports supply-chain, lab reports, and referrals.

## Development stage

More than 850 devices have been operational in the rural areas of India with low bandwidths (mostly over 64 kilobits/s bandwidth) and semi-skilled village operators, and more than 100,000 tele-consultations have been carried out successfully. IEC60601-1 compliance and ISO13485 manufacturing process compliance have been completed. CE marking process is underway.

## Future work and challenges

Implement large scale projects with healthcare service delivery partners and e-governance players. Enhance technology with further diagnostics and better ground level delivery processes. Develop mobile Bluetooth based solution for places lacking 32 kilobits/s bandwidth. Build relations with partners having complementary solutions. Modify business model to include software-as-a-service.

## User and environment

**User:** Self-use/patient, physician, technician, nurse, midwife, family

**Training:** On-site individual/group training, videoconferencing/teamviewer based e-training, 2-4 hrs

**Maintenance:** Annual, Preventive. To be conducted by Manufacturer.

## Environment of use

**Settings:** Rural settings, urban settings, at home, primary (health post, health center), secondary (general hospital)

**Requirements:** USB 1.0 connection to a desktop or laptop computer. Windows XP/Vista operating system on the desktop or laptop. Minimum 32 kilobits/s internet speed for real-time audio / video / data tele-consultation. Fixed static IPs at both ends for professional edition, and at server for enterprise edition.

## Product specifications

**Dimensions (mm):** 225 x 165 x 40

**Weight (kg):** 0.61

**Consumables:** ECG Gel

**Life time:** 5 years

**Shelf life:** 2 years

**Retail Price (USD):** 1800

**List price (USD):** 1800

**Other features:** Software use, installed stationary, reusable

**Year of commercialization:** 2008

**Currently sold in:** Primarily in India, some countries in Africa and South East Asia



# Non-invasive hypothermia indicator for newborns

Country of origin | United Kingdom/United States of America

## Health problem addressed

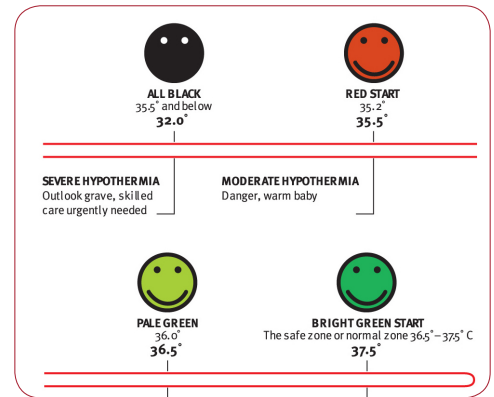
The problem of detecting hypothermia exists throughout the “disadvantaged world” where up to 4 million newborns die within their first 28 days of life from either disease, malnutrition or a combination of both. Preterm, sick and low birth weight babies are especially at risk. The effect for a newborn that has suffered from hypothermia and survived is poorly researched and is in need of urgent attention.

## Product description

The hypothermia indicator is a 12mm diameter disc with a black ‘face’ with two small white “dots” on one side, the other side has a self-adhesive facility. This device comes in a strip of 5 units. Liquid crystal technology provides function for it to perform reliably and accurately within an operating tolerance of +/- 0.5 degree Celsius.

## Product functionality

When in situ on a healthy newborn (temperature 36.5 -37.5° C), the device shows a ‘bright green’ background with a smiling ‘face’ clearly visible which is the ‘safe-zone’ for the average ‘normal’ temperature. Should the temperature drop below 36.5° C, the color fades to a ‘pale green’ before a ‘red/brown’ color is displayed. At 35.5° C the ‘black’ color shows.



## Developer's claims of product benefits

A naked newborn exposed to an environmental temperature of 23° C suffers the same heat loss as a naked adult at 0° C. This heat loss is even greater for preterm, sick and low birth weight babies, especially if left wet and uncovered at birth. Hypothermia in the newborn can occur in all climates due to a lack of knowledge and/or procedure. The availability of a very simple, low cost device placed either in an axilla, above the liver or the great vessels of the neck would empower to maintain “the warm chain” immediately following birth. The device has been designed so that also illiterate mothers can understand and safely use it.

## Operating steps

1. Choose site under an arm or on the right side of the abdomen. 2. Clean site with an alcohol. 3. Press device firmly into site, white “dots” upright. 4. Provided the body temperature is within the “safe-zone”, a smiling face will appear on a bright-green background. Observe every two hours. 5. Mothers should seek advice if the “smiling face” begins to fade or reverts to “black”. 6. The device remains attached for up to a week and can be reused.

## Development stage

Published, tested, clinical trials conducted. Commercially available. CE No: 0434.

## Future work and challenges

Currently, the device is difficult to read in poor light and in the dark. Getting the device widely established has been unexpectedly slow.

## User and environment

**User:** Physician, nurse, midwife, family member

**Training:** None

**Maintenance:** None

## Environment of use

**Settings:** Rural, urban, ambulatory, at home, primary (health post, health center), secondary (general hospital), tertiary (specialists hospital)

**Requirements:** Storage in cool, dark location (out of direct sunlight)

## Product specifications

**Dimensions (mm):** 80 x 20 x 0.001

**Weight (kg):** 0.002

**Consumables:** Disposable alcohol wipes, transparent medical tape

**Life time:** 5 years

**Shelf life:** 2+ years

**List price (USD):** 0.40

**Other features:** Portable, reusable

**Year of commercialization:** 2010

**Currently sold in:** India, Russia, USA, UK, Haiti. Australia, Canada, Cyprus, Egypt, Kenya, Netherlands, Papua New Guinea, Peru, Tanzania, Zimbabwe

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# Non-invasive vascular age risk prediction

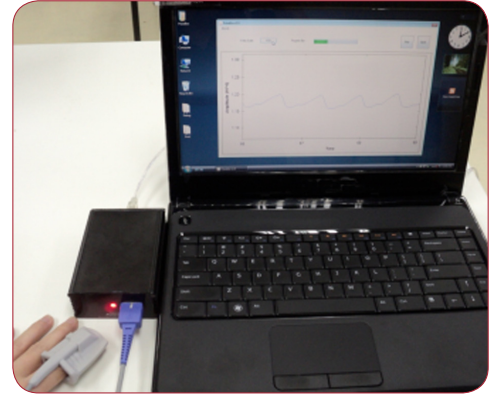
Country of origin | Malaysia

## Health problem addressed

According to WHO 17.3 million people died from cardiovascular diseases (CVD) in 2008 and over 80% of CVD deaths are in low and middle income countries. Over the past 10 years, the trend of hospitalizations and death due to cardiovascular and circulatory diseases has increased from 13% in 2008 to 16% in 2009 as reported by Malaysian Ministry of health.

## Product description

Photoplethysmography (PPG) is a non-invasive technique to detect blood volume changes. Analysis of the PPG signal can provide sufficient information on the cardio-vascular related performance. The proposed simple, user friendly and operator independent vascular risk prediction method is a non-invasive quantification of hemodynamic vascular properties.



## Product functionality

The system utilizes PPG to assess cardiovascular health in a non-invasive, inexpensive manner.

The advancement of the Information Technology enables the medical personnel access the clinical data irrespective to the geographical location and reduces the number of visits to hospital as well as consultation costs. The portability and server-based processing features allow its use in low-resources settings.

## Developer's claims of product benefits

The conventional technique to assess the cardiovascular health is to measure the thickness of the carotid artery wall (CIMT). The CIMT technique is ultrasound-based, costly and requires expertise in measurements. PPG is a non-invasive and low-cost optical technique to detect blood volume changes in the micro vascular bed of tissue. The system can be a part of standard health screenings in public and private medical sectors for general vascular risk assessment and as a cost effective and efficient alternative to current methods of screening. The system is applicable in rural and mobile clinics due to its convenience and portability.

## Operating steps

a. Upon arrival, verify patients fasting status. b. The patients need to rest for 10 minutes before data recording. c. PPG signal will be recorded for a duration of 90 seconds at a room temperature of 24-25° C. Recording is done at a sampling rate of 50 Hz and saved in ASCII format. d. Subject to be in supine position with arms rested on pillows during the data recording session. PPG to be obtained from tip of the left index finger.

## Development stage

In 2010, the clinical trials and community health screening program have been conducted in several places including universiti kebangsaan Malaysia medical center (UKMMC), Taman Melewar Gombak (urban) and Felda Sungai Tinggi Kuala Kubu Baru (sub-urban). Approximately 370 subjects participated. The study was granted the Ethical Committee approval from the UKMMC Research Ethical Committee.

## Future work and challenges

Vascular age is a newly develops concept and technology which have a great potential to improve the health care services especially in CVD screening. The main challenge is the acceptance among the medical personals. The vascular age model is the ethnic and population dependent. Therefore, data acquisition across the nations would help to establish and improve the existing model.

## User and environment

**User:** Patient

**Training:** None

**Maintenance:** None

## Environment of use

**Settings:** Urban, rural, at home, primary (health post, health center)

**Requirements:** Laptop, access to Internet

## Product specifications

**Dimensions (mm):** 80 x 110 x 40

**Weight (kg):** 0.3

**Consumables:** None

**Life time:** 3 years

**Shelf life:** 3 years

**Retail Price (USD):** 2000

**List price (USD):** 2000

**Other features:** Mobile, reusable, uses software

**Year of commercialization:** 2010

**Currently sold in:** Malaysia

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# Non-surgical male circumcision device

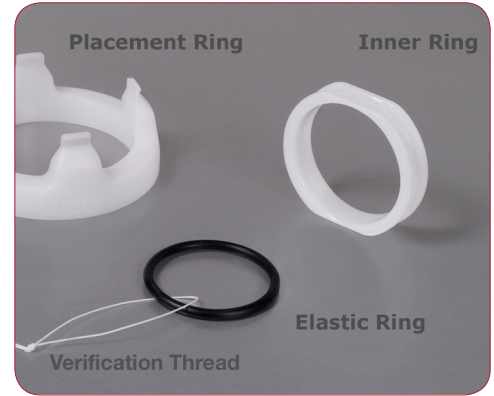
Country of origin | Israel

## Health problem addressed

Three randomized controlled clinical trials in Africa showed that male circumcision can reduce risk of HIV transmission among heterosexual men by as much as 60%. Public health leaders aim to circumcise 20 million men by 2015 in 14 nations in Sub-Saharan Africa; Africa has reached less than 5% of its goal with existing surgical methods.

## Product description

The device consists of an Inner Ring, Elastic Ring and Applicator. The device applies controlled radial elastic pressure to compress the foreskin and cut off circulation. The distal foreskin becomes necrotic and is removed after 5-7 days. The procedure takes less than 5 minutes, is bloodless, requires no injected anesthesia, no sutures, no sterile settings and can be conducted by low cadre nurses, as validated scientifically by the Government of Rwanda.



## Product functionality

This simple and scalable device was specifically developed to provide voluntary circumcision to men, ages 15 to 49, living in 14 priority nations in Sub-Saharan Africa where there are high rates of HIV transmission and limited healthcare infrastructure.

## Developer's claims of product benefits

Currently, the only WHO recommended method for circumcision is surgery, which entails skills and infrastructure that are hard to attain in resource-scarce settings. Other devices that were not specifically designed for resource-poor settings entail blood (albeit less than surgery), require injected anesthesia, cutting of live tissue and a sterile setting. Compared to surgery, this device is safer, simpler (no sutures, 3 vs 10 days of training, and with low cadre, non-surgically trained nurses, significantly reducing burden to health system), and more scalable (done in less than 5 minutes vs. over 20). It is the only non-surgical device in market --bloodless, no injected anesthesia, no sterile settings--offering a viable solution for resource poor settings.

## Operating steps

Clients are measured to select ring size. The circumcision line is marked based on WHO guidelines. The inner ring is inserted. An elastic ring is aligned with the inner ring to compress the foreskin and stop blood flow. Verification thread is then cut. Ischemic necrosis is initiated. Device remains in situ for 5-7 days, and is then removed.

## Development stage

The device is FDA cleared (K103695) and certified CE Mark Class IIa and is manufactured using USP Class VI biocompatible elastomeric materials compliant to ISO 13485 Medical Devices (Quality Management systems) and FDA, 21 CFR177. 2600. The device is currently undergoing clinical trials by the government of Zimbabwe and Rwanda. To date the device was studied in 3 independent clinical trials in Rwanda on over 880 subjects.

## Future work and challenges

The challenges are scalability, uptake and government commitment. If governments have a viable and sustainable solution with minimal burden to the health system, they are more likely to commit resources, enable task shifting policies, and achieve the national and regional HIV prevention goals.

## User and environment

**User:** Nurse, community health workers

**Training:** Yes; will be provided by Rwandan Centers of Excellence

**Maintenance:** None

## Environment of use

**Settings:** Rural, urban, primary (health post, health center), secondary (general hospital)

**Requirements:** Clean (though nonsterile) setting, trained healthcare provider, bed, biologics disposal box

## Product specifications

**Dimensions (mm):** 22 x 60 x 60

**Weight (kg):** 0.011

**Consumables:** Gauze pads, scissors, spatula, forceps, dressing, betadine, anesthetic cream

**Life time:** 5 years

**Shelf life:** 2 years

**List price (USD):** 15-20

**Other features:** Portable

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

# Oral syringe dosing clip

Country of origin | United States of America

## Health problem addressed

Studies show that 40-60% of parents make errors when giving children liquid medication. Misdosing medication can have serious consequences. For example, with liquid Anti-Retroviral Medications (ARVs) for HIV-positive infants and children, inaccurate doses can lead to drug resistance, which can be fatal.



## Product description

The oral syringe dosing clip is a small, plastic clip that fits into the barrel of an oral syringe and acts as a stopping mechanism for the plunger, ensuring that the correct dose of medication is drawn into the syringe. The clips are color-coded by dose and can be pre-set by a physician, do not come into contact with the medication and can be reused.

## Product functionality

The oral syringe dosing clip enables caregivers and patients to deliver accurate doses of liquid medication when using an oral syringe.

## Developer's claims of product benefits

It was found in laboratory and community settings that inserting the clip into the syringe enables a greater proportion of users to deliver an accurate dosage of liquid medication when compared to a syringe without a clip and a teaspoon. The clips are inexpensive and can be used by caregivers to improve dosing of liquid medication, regardless of literacy and numeracy skills, manual dexterity, and visual acuity. The clip may therefore be particularly beneficial in low-resource settings.

## Operating steps

Pull back plunger. Insert clip into syringe barrel. Push plunger into barrel. Twist and lock clip into place. Draw liquid medication into the syringe until the clip stops the plunger, preventing further intake of liquid. Dispense dose of medication with syringe as normal.

## Development stage

The dosing clips are being used by the Swaziland Ministry of Health in its national Prevention of Mother to Child Transmission of HIV/AIDS (PMTCT) program. More than 213,000 clips have been distributed to mothers participating in the program to ensure that infants receive the proper dose of liquid anti-retroviral medication.

## Future work and challenges

The clip has been licensed and is available globally for purchase. A preferred pricing structure for Global Alliance for Vaccines and Immunisation (GAVI) countries has been established. Challenges ahead include identifying new non-governmental, governmental, and corporate partners to scale up dissemination of the clip.

## User and environment

**User:** Self-use/patient, family member

**Training:** Healthcare provider can demonstrate clips and syringe to user in less than 2 minutes.

**Maintenance:** None

## Environment of use

**Settings:** Rural, urban, ambulatory, at home

**Requirements:** None

## Product specifications

**Dimensions (mm):** 53 x 14 x 3

**Weight (kg):** 0.001

**Consumables:** None

**Life time:** 1 year

**Shelf life:** 2 years

**Retail Price (USD):** 0.10-0.25

**List price (USD):** 0.10-0.25

**Other features:** Portable and reusable

**Year of commercialization:** 2011

**Currently sold in:** Swaziland

# Point of care diagnostic device for total WBC

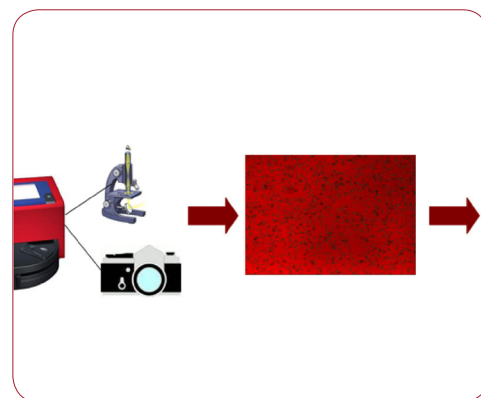
Country of origin | Sweden

## Health problem addressed

Measuring white blood cells (WBC) can provide information which may aid in the diagnosis of infection, inflammatory diseases or leukemia and aid in judicious prescription of antibiotics. A WBC POC will be beneficial in rural settings to increase access of a vital test. The system is designed as a portable device to be used in rural settings or where near patient testing for WBC is of benefit. As only a small blood volume is needed it is useful also for small children and anemic patients.

## Product description

The system consists of an analyzer and single use cuvettes. One drop (10µL) of capillary or venous blood is drawn into the cuvette by capillary action. The portable analyzer consists of a microscope and a camera and the cells are counted by image analysis.



## Product functionality

The microcuvette serves as pipette, mixing and reaction chamber and the correct specimen volume is obtained by capillary action.

## Developer's claims of product benefits

No similar system exists which can be used by the intended user/environment. Automated cell counters or manual microscopy technologies are available at laboratories but requires laboratory educated staff and requires specimen to be transported. The suggested solution is performed as near patient testing. The WBC system will provide rural areas with increased availability to one of the most frequently used lab parameters. Instant results of the white blood cell count will facilitate more well informed decisions in several clinical situations and facilitate monitoring of diseases and treatment (for example in infections, HIV, inflammatory diseases etc.). Making the WBC more rapidly accessible to rural settings will improve healthcare as well as save costs and transportation time.

## Operating steps

1. Fill the cuvette. 2. Place it in the analyzer. 3. Result is available < 3 min.

## Development stage

The device is CE-marked and FDA 510(k) cleared. Besides internal evaluations, the accuracy of the device has been validated in 2 published studies: a study by Osei-Bimpong et al (Osei-Bimpong; Int Journal of Laboratory Hematology; 2008) and a study by Casey et al (Casey et al; Clinical Pediatrics, 2009).

## Future work and challenges

The company will use its well established distribution network to make the system available to the intended user. Through an extensive network the hemoglobin systems have been made widely available in developing regions, and has proved experience in bringing POC tests to rural settings including set up and local training. The main challenge lies in introducing and getting local acceptance of a new test and challenges regarding local decision making policies.

## User and environment

**User:** Physician, technician, nurse, midwife

**Training:** Required; provided by device distributors

**Maintenance:** Minimal; cleaning

## Environment of use

**Settings:** Rural, urban, ambulatory, primary (health post, health center), secondary (general hospital), tertiary (specialists hospital)

**Requirements:** Power supply

## Product specifications

**Dimensions (mm):** 120 x 135 x 183

**Weight (kg):** 0.6

**Consumables:** Yes

**Life time:** >7 years

**Shelf life:** >7 years

**List price (USD):** 624.50

**Other features:** Portable, single use consumables and reusable device

**Year of commercialization:** 2008

**Currently sold in:** US, Europe

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# Portable anaesthesia machine

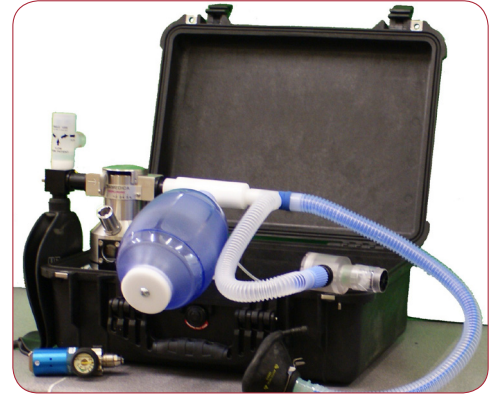
Country of origin | United Kingdom

## Health problem addressed

In remote locations, anaesthesia may be non-existent or unreliable which can prevent emergency surgery. For instance, millions of mothers and babies die from birth complications; many of which could be saved by C-sections if safe anaesthesia were available. Anaesthesia is also vital for treatment of traumas, hernias, animal bites, burns, infections, and congenital deformities.

## Product description

This device is a complete inhalational anaesthesia system that is suitable for a variety of settings. It includes a valve with a circuit removing the valve, a reservoir unit for pre-oxygenation, a vaporiser for consistency over a wide temperature range, and is calibrated for Halothane/Isoflurane or Sevoflurane to overcome possible supply problems.



## Product functionality

The device is used for spontaneous breathing or assisted ventilation, and drawover or continuous flow inhalational anaesthetics.

## Developer's claims of product benefits

Most anaesthetic machines are designed to function in high-resource environments by specialized operators and require skilled technical support and maintenance. Current solutions require compressed gases and stable electricity supplies, which are not suitable for rapid response in austere environments. This device is robust, affordable, lightweight and easily transportable. It is easy to operate and virtually maintenance free, making it suitable for use by local personnel. It is extremely cost-effective and economic to use as there is no requirement for expensive consumables. Supremely safe, it can be used where supply of electricity and medical gases are unreliable or non-existent.

## Operating steps

Following the rapid assembly of the three principal components: vaporiser, reservoir, and breathing system, the product is ready for use. The product is intended for use by medical personnel trained in delivery of draw-over anaesthesia (e.g. anaesthesia physician, nurse or officer). It is designed to be easy to operate and require little maintenance.

## Development stage

The product was developed at the request of and with feedback from those operating in the field. The product is in use in 15 low-income countries and feedback from operators confirms its ease of use.

## Future work and challenges

This product will be promoted at existing training courses for anaesthetists in North America, UK, Africa and Australia. It will be demonstrated at exhibitions worldwide, and published in international peer-reviewed journals.

## User and environment

**User:** Anaesthesia physician, nurse, officer

**Training:** None

**Maintenance:** None

## Environment of use

**Settings:** Rural settings, ambulatory, primary (health post, health center), secondary (general hospital), tertiary (specialists hospital)

**Requirements:** None

## Product specifications

**Dimensions (mm):** 470 x 330 x 170

**Weight (kg):** 9.5

**Consumables:** Inhalational anaesthetic agent

**Life time:** >10 years

**Shelf life:** >10 years

**Retail Price (USD):** 4589

**List price (USD):** 4589

**Other features:** Portable and reusable

**Year of commercialization:** 2010

**Currently sold in:** Sold from UK for use in Australia, Bangladesh, Burma, Canada, Democratic Republic of Congo, Fiji, Gabon, Guatemala, Haiti, Honduras, India, Kenya, Mexico, Nepal, New Zealand, Rwanda, Sudan, Togo, Uganda, Zambia.

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# Sputum mobilization device

Country of origin | United States of America

## Health problem addressed

Obtaining a proper deep lung specimen is a critical step in the diagnosis and management of respiratory tuberculosis; both for the adult community and pediatric community. Neither spontaneous samples, which result in many false negatives, nor sputum induction using hypertonic saline are practical or optimal.

## Product description

A low frequency acoustic wave is generated at the mouth, travels retrograde into the lower airways and increases mucociliary clearance. This device, which is FDA approved, produces such a wave with vigorous exhalation to aid in secretion clearance.



## Product functionality

The patient simply needs to blow repeatedly into the device with the same effort as blowing out a candle. The secretions mobilizes within 5-15 minutes after the therapy session ends. Its simple design and operation result in high compliance.

## Developer's claims of product benefits

Existing technology is a spontaneous sputum sample. This does not produce the deep lung secretion required. The preferred method is hypertonic saline sputum induction. This method, though effective, is not widely used in the field because of complications and discomfort to the patient. Reducing the number of inadequate sputum samples and thus the frequency of false negatives. The device presented here is highly effective at producing a deep lung secretion sample, which saves times, and is very easy to use with no counter indications.

## Operating steps

The patient sits upright, leaning forward slightly. The device works in 2 blow repetitions: blow out with enough force to activate the reed, and repeat steps to complete 2 repetitions. After two blow repetitions, the patient removes the mouthpiece, inhales normally, and repeats the above steps to perform up to 20 cycles. After 5-10 minutes, the patient coughs and collects sputum.

## Development stage

As published in a 2009 study, use of this device enabled rapid diagnosis of TB in 47% of confirmed TB patients, who had produced no sputum prior to using the device. The device was user-friendly as assessed by a questionnaire completed by the patients.

## Future work and challenges

This device could be manufactured at considerably lower cost with locally available materials, technologies and labor.

## User and environment

**User:** Self-use/patient

**Training:** Healthcare professional delivers training, written instructions are provided, training takes 3-5 min

**Maintenance:** None

## Environment of use

**Settings:** Rural, urban, primary (health post, health center)

**Requirements:** None

## Product specifications

**Dimensions (mm):** 350 x 60 x 30

**Weight (kg):** 0.25

**Consumables:** None

**Year of commercialization:** 2006

**Currently sold in:** Australia, Austria, Canada, Germany, Greece, India, Italy, Japan, Lebanon, Malaysia, Philippines, Singapore, South Korea, Switzerland, Turkey, United States

# Urine albumin test

Country of origin | Sweden

## Health problem addressed

Chronic kidney disease (CKD) is common and harmful yet can be easily treated if detected early through a simple urine test and the measurement of low levels of albumin in the urine. If not detected, it may escalate to end stage renal disease (ESRD) which requires expensive treatment and risk of poverty due to inability to work.

## Product description

This device uses a quantitative rapid turbidimetric immunoassay of albumin in human urine using a specially-designed analyzer.

## Product functionality

The system can be used for the quantitative determination of low levels of albumin in human urine for the purpose of screening, diagnosing, monitoring and to supplement the clinical evidence in the treatment of microalbuminuria.

## Developer's claims of product benefits

Current devices are semiquantitative dipsticks, some with visual reading only. In comparison, this new system provides lab equivalent results in 90 seconds, and is easy to use by anyone. It requires minimal maintenance since it is factory calibrated, does not require any further recalibration, and results can be compared between sites. The system makes it possible to perform large screening programs in rural settings as long as power supply is available.

## Operating steps

The microcuvette serves as pipette, mixing and reaction chamber and the correct specimen volume is obtained by capillary action. First, the cuvette is filled, then it is placed in the analyzer. The result can then be read.

## Development stage

The system has not been part of any clinical studies, but has been evaluated. The system has been used during a World Kidney Day screening event in Kenya, in hospitals in Kenya, in a large screening program in Morocco and Mexico, in the Nordic Countries, in the US, and in Europe.

## Future work and challenges

The scope of the problem and the need is huge, but the awareness of it and the priority on health care are limited. The subjects who are not detected early may face a devastating future as the treatment in the later stages, such as dialysis and transplantation, is not available or very expensive. However, through early detection and cost-effective treatment, a near normal life can be lived.

## User and environment

**User:** Physician, technician, nurse, midwife, anyone also without laboratory education

**Training:** Easy to follow documentation is provided with the analyzer. Distributors can support training.

**Maintenance:** Minimal maintenance - cleaning.

## Environment of use

**Settings:** Rural, urban, ambulatory, primary (health post, health center), secondary (general hospital)

**Requirements:** Continuous power supply

## Product specifications

**Dimensions (mm):** 170 x 115 x 66

**Weight (kg):** 0.350

**Consumables:** Urine Albumin Microcuvettes

**Life time:** >7 years

**Shelf life:** >7 years

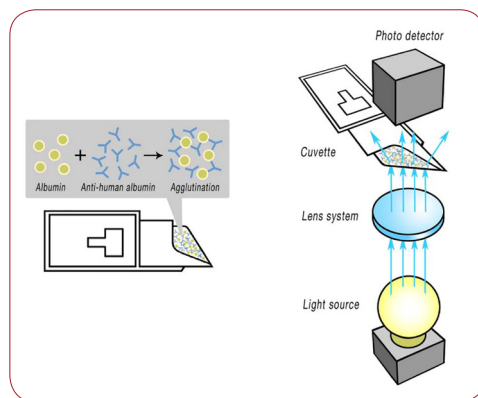
**Retail Price (USD):** N/A

**List price (USD):** 600 (device) 2.99-3.99 (consumables)

**Other features:** portable, single-use

**Year of commercialization:** 2006

**Currently sold in:** US, Europe, Mexico, Kenya, South Africa, Russia



# Other technologies

## 2012

# Auto stop electrochlorinator

Country of origin | United States of America

## Health problem addressed

Over 1 billion people worldwide do not have access to safe water. Furthermore, 1.8 million children under the age of 5 years die annually from diarrheal disease caused by unsafe water in places with poor sanitation. The auto stop chlorinator produces chlorine, which is a highly effective disinfectant for drinking water. Treating drinking water with chlorine has been shown to reduce rates of diarrhea in children by up to 29%.

## Product description

The electrochlorinator consists of a salt brine bottle where the salt and water is poured. It also consists of power leads to connect to a battery source as well as a control panel at the base of the brine bottle to start and stop the chlorination process.



## Product functionality

The auto stop electrochlorinator localizes chlorine production, eliminating shelf life and inventory management issues experienced with liquid chlorine and water filters while requiring little maintenance. The intended kiosk model centralizes water treatment to trained operators and can treat water for 200 people per day.

## Developer's claims of product benefits

Drinking water can be treated by many methods, including boiling, chemical disinfection, filtration, and UV light. All methods have their advantages and drawbacks, mostly related to cost, ease of use, and appropriateness for the source water conditions. This device is innovative because of its low capital and recurring costs, income generation potential, and its relative ease of use. The chlorinator is durable, has no moving parts, and very minimal maintenance requirements. Disinfection of clothing, hard surfaces and medical equipment is greatly simplified. With a low wholesale price and high chlorine generation rate, it is an excellent candidate for microloan-supported entrepreneurial programs. The kiosk model also provides financial incentives to operators.

## Operating steps

Add salt and water to the indicated lines in the salt brine bottle. Shake until all salt is dissolved. Attach the power leads to a 12 V battery. Fill the device with 50 mL of salt brine and press start. Wait about 5 minutes until the device beeps and the light flashes. Dose chlorine into drinking water storage containers.

## Development stage

The device has been proven for its simplicity and has undergone many field trials without incident. In field trials, random checks of participating households showed a 2-3 log E. coli reduction against controls. Lab testing found greater than 4 log reduction of virus and 6 log reduction of bacteria. Device conforms to US EPA guide standard and protocol for microbiological water purifiers, as tested in-house.

## Future work and challenges

Challenges include cost, distribution, and appropriate support. Efficient manufacturing process that reduces costs and ensures high quality is required to reach target sale price. Partnerships with local and international NGOs implementing water and health programs is required to develop implementation support materials to ensure successful, sustainable use of technology in different scenarios.

## User and environment

**User:** Self-use/patient, physician, technician, nurse, midwife, shop owner

**Training:** Training can be conducted programmatically in under 30 minutes with instruction manual and device.

**Maintenance:** None

## Environment of use

**Settings:** Rural settings, Urban settings, primary (health post, health center), secondary (general hospital), tertiary (specialists hospital)

**Requirements:** This product requires a minimally trained operator and a charged 12V battery. It also requires a power supply for recharging.

## Product specifications

**Dimensions (mm):** 100 x 77 x 122

**Weight (kg):** 0.2

**Consumables:** Salt, Water, Battery Power

**Life time:** 20 years

**Shelf life:** 10 years

**List price (USD):** 100

**List price of consumables (USD):** 0.05/1000 liters of water treated

**Other features:** Software use, Installed stationary, Reusable

**Year of commercialization:** 2012

**Currently sold in:** Worldwide

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

# Birthing simulator for training

Country of origin | Norway

## Health problem addressed

Appropriately skilled birth attendants could save the majority of the annual 350,000 maternal deaths, 99% of which occur in low-resource settings. In order to reduce the high number of unnecessary maternal and newborn deaths on the day of birth, there is an urgent need to train birth attendants and other "Frontline Health Workers" in Basic Emergency Obstetric and Newborn Care (BEmOC).

## Product description

The birthing simulator supports training in BEmOC in developing countries. It enables the instructor to create very compelling simulations of normal to more complex birthing scenarios, and is particularly suitable for training control of post-partum hemorrhage, the leading cause of maternal deaths.



## Product functionality

Behind the birthing suit, the instructor can manually control: cervical dilation, position of the baby, delivery of the baby, delivery of placenta, bleeding (amount and nature), uterus condition, and fetal heart sounds.

## Developer's claims of product benefits

The simulator is distinctively different from other birthing simulators available on the market. It aims to respond to the needs of a supportive device that can improve quality of BEmOC as presented in "International Journal of Gynecology & Obstetrics" by being highly realistic where essential (particularly in simulating post-partum hemorrhage and uterus contraction), and culturally adapted. It facilitates effective communication training and integrated training with newborn routine care and resuscitation. It is flat packed for easy transport and storage, highly affordable, durable, and easy to use.

## Operating steps

The simulator is strapped onto the instructor, who acts as the mother, and creates and controls the various scenarios and situations directly with his/hers hands.

## Development stage

It is offered on a not-for-profit price to the 68 countries that have been identified by UN as focus countries relative to MDG 4 and 5. It has been field tested in several countries including USA, Norway, Tanzania, and Ethiopia.

## Future work and challenges

**Financing:** Although the product is available on a not-for-profit basis, healthcare facilities and educational institutions in low and middle income countries often have limited financial resources.

**Distribution channels:** bureaucracy and often prohibitive customs rates in importing such material to the countries where the need for these products is greatest.

## User and environment

**User:** Family member, midwife, nurse, physician

**Training:** None required

**Maintenance:** Instructor in courses

## Environment of use

**Settings:** Rural, urban, health post, health center, general hospital, specialists hospital

**Requirements:** No specific infrastructure requirements. Access to 3-4 liters of water would be desirable to create simulated blood and to fill the newborn simulator with water.

## Product specifications

**Dimensions (mm):** 500 x 350 x 200

**Weight (kg):** 4.5 (filled with simulated blood), 3.5 (empty)

**Consumables:** None

**Life time:** 3 years

**Shelf life:** 3 years

**Retail Price (USD):** 100

**List price (USD):** 100

**Other features:** Portable and reusable

**Year of commercialization:** 2011

**Currently sold in:** 68 countries that have been identified by UN as focus countries relative to MDG 4 and 5.

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



# Low smoke stove

Country of origin | India

## Health problem addressed

Total world deaths from indoor air pollution due to burning solid fuels are estimated at 1,619,000 each year. India accounts for 25% of such deaths.

## Product description

The stove has a bypass duct for efficient draft, soot collector and chimney connector.

## Product functionality

The stove can be easy to use and maintain, and can be used with indigenous biomass as fuel. Cooking time is reduced by 1.5 hours per day and fuel consumption (wood and cow dung) is reduced by 60-70%.



## Developer's claims of product benefits

Most people in the targeted areas don't use a stove, but have a 'three-stone' cooking setup without any form of ventilation. Traditional stoves sold in these regions (e.g. India) are monolithic (in one piece), which makes them more difficult to transport and expensive to replace. The developers therefore added a chimney and designed a modular solution. It has been designed with respect to Indian cooking needs and in order to accommodate different culinary habits. The design of the stove allows the chimney to take exhaust fumes out of the kitchen area. As the stove is locally produced and distributed, it is relatively cheap and easily available. Stove production uses local materials and processes, and also allows for easy installation.

## Operating steps

Operates like a traditional stove.

## Development stage

This product has been used successfully, mostly in India, but also in countries like Kenya and Laos. It's technical performance has been assessed and certified by the College of Engineering, Pune and Approvecho, Pondicherry, India.

## Future work and challenges

To take the next step in empowering local entrepreneurship and enabling NGOs to implement the solution, the company has set up a webpage. The corresponding online platform aims to support the dissemination of the stove by free distribution of the design specifications. It also enables networking with other involved stakeholders and facilitates transfer of knowledge.

## User and environment

**User:** Self-use/patient

**Training:** Training can be conducted by local entrepreneurs who produce and install the stove and explain about use and cleaning.

**Maintenance:** Chimney and soot collector cleaning once per month.

## Environment of use

**Settings:** Rural settings

**Requirements:** Low tech manufacturing using only cement and clay.

## Product specifications

**Dimensions (mm):** 800 x 450 x 270

**Weight (kg):** 90

**Consumables:** Biomass fuel (wood or cow dung)

**Retail Price (USD):** Approximately 20 including product, transportation and installation.

**List price (USD):** Approximately 20 including product, transportation and installation.

**Other features:** Installed stationary, reusable

**Year of commercialization:** 2008

**Currently sold in:** India, Kenya, Laos, Guatemala, Peru

# Assistive devices 2011

# Manual wheelchairs and mobility devices

Country of origin | United Kingdom

## Health problem addressed

An estimated 20 million people in need of a wheelchair in low-income countries do not have one. Many donated wheelchairs are unsuitable for the local terrain, do not fit properly and do not provide adequate comfort or postural support. These factors can restrict a person's mobility, hinder their health and well-being and even cause life threatening secondary complications such as pressure sores.

## Product description

The technology encompasses a range of 3-wheel and 4-wheel wheelchairs, sports wheelchairs, supportive seating and tricycles specifically designed for use in less resourced settings. The products are available in a range of sizes and have many adjustable features. Each product is flat-packed, requires local assembly and must be distributed through a wheelchair service.



## Product functionality

Products in the range require assembly by trained local staff. Basic hand tools are required and pictorial assembly instructions for each product are provided. Once assembled to the client's prescription, the client is fitted comfortably and given instructions on how to use the product safely and carry out basic maintenance. The products are manual and easy to maneuver by the client or an attendant.

## Developer's claims of product benefits

The complete product range can be uniquely shipped in any volume to service centres around the world and provides a mean to facilitate and expedite the provision of appropriate manual wheelchairs in low-income countries. Providing a range promotes choice for people with disabilities and ensures they receive a product that is most suited to their need and aids their rehabilitation. The products are affordable, high in quality and durable and use locally available components. The adjustable features optimize comfort. The majority of products are supplied with a pressure relieving cushion, a life saving device that is often not provided with other donated wheelchairs. Training is provided to local staff to ensure they have the skills to assemble, fit and adjust the products correctly and competently.

## Operating steps

The products are assembled according to the assembly instructions. Once set up the client is fitted with the wheelchair or mobility device. If necessary, adjustments can be made to maximize comfort, for example the footrest, backrest height or seat depth can be altered. Once the client is happy, he or she is then able to self-propel manually or can be assisted by an attendant.

## Development stage

The first product commercialized is the wheelchair for rough terrain, on the market since 2005. However, design reviews and upgrades are carried out periodically. Studies were carried out in South Africa to measure the impact the product has had on the quality of life of users. Two international NGOs have performed their own successful trials in Angola and the Philippines over a six and two months period respectively. The product is distributed to over 20 countries. The range includes other commercialized mobility devices and accessories. The product has regulatory approval.

## Future work and challenges

Challenges include: Provision of products to the end user (client) is heavily dependent on donated funds; competition from other products on the market that are donated to organizations and end users free of charge; capital to maintain stock of products to enable quicker dispatch from factory.

## User and environment

**User:** Patient, family member, clinician, technician

**Training:** Training is required to assess the client and assemble the product. Training for the full product range is a minimum of three days. Basic workshop hand tools and clinical equipment such as a therapy bed and foot blocks are required. **Maintenance:** Patient, technician

## Environment of use

**Requirements:** The product must be distributed through a service centre where local staff has been trained to assess wheelchair users and assemble and fit the products. A workshop and clinical assessment are required. The centre will act as a point for clients to return to for follow up and product maintenance or repairs. The products are manual and do not have any special operational requirements. The ease of use of the product can depend on the local infrastructure i.e. often buildings are inaccessible so may prevent the user from independently accessing the building.

## Product specifications

**Dimensions (mm):** approx. 1212 x 740 x 865

**Weight (kg):** 22

**Life time:** 5 years

**Retail Price (USD):** 171

**Year of commercialization:** 2005

**Currently sold in:** Argentina, Australia, East Timor, Ethiopia, Ghana, India, Kiribati, Lebanon, Lesotho, Liberia, Malawi, Nepal, Pakistan, Papua New Guinea, Serbia, Sierra Leone, Solomon Islands, South Africa, Sri Lanka, Sudan, Thailand, Uganda, Zimbabwe

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<http://www.who.int/disabilities/technology>

# eHealth solutions 2011

# Medical data communication system

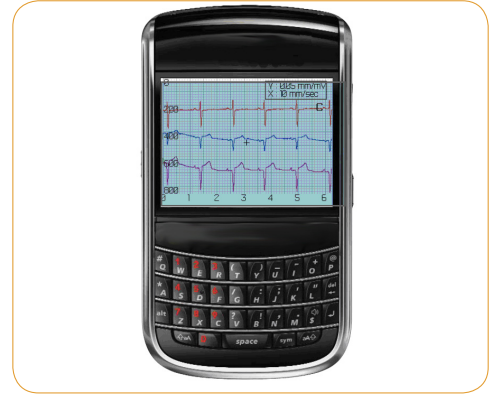
Country of origin | United States of America

## Health problem addressed

Access to medical opinion by cardiovascular specialists can be difficult to obtain in rural or poor areas. As a result, medical data obtained at the point of care such as EKG's, medical images, lab results or any other type of information cannot be adequately reviewed by the required clinicians and appropriate treatment cannot be prescribed.

## Product description

The medical communication system is a technology that allows any type of medical data to be transmitted from the point of care to the desired specialist(s). The data is transmitted securely and rapidly for delivery to mobile devices or computers so that physician's can review the data and provide opinions.



## Product functionality

The system is a proprietary push delivery and review platform allowing remote review using the internet and cell phone network of EKG's/medical images. Medical data is recorded at the point of care and then uploaded to the system's server from which it is then delivered to a physician's smartphone or PC. The transaction is fully traceable and secure.

## Developer's claims of product benefits

Current practice includes mailing video tapes, DVD's or faxing data to desired physician. These methods suffer from systematic insufficiencies and are slow and non-traceable. Instead, this system offers a technically sound and more accessible solution. Given the prevalence of cell phone networks and the internet it is easily reachable.

## Operating steps

Data is acquired at the point of care and uploaded to a secure server. Physician reviews data and has the option to respond back to the point of care or forward to a colleague. Physician can review data on their smartphone or PC as convenient.

## Development stage

Has been in technically evaluated. Has been in production for over two years. System is classified as a hospital IT product. System conforms to DICOM standards.

## Future work and challenges

Product is commercialized.

## User and environment

**User:** Nurse, physician, technician.

**Training:** Web based and/or self training CD.

**Maintenance:** Technician, engineer, manufacturer.

## Environment of use

**Requirements:** Sending side: EKG and/or imaging systems and connectivity to internet/ phone line, connection to a laptop preferred;

Receiving side: access to cell phone network on a smartphone and/or access to internet and PC.

## Product specifications

**Dimensions (mm):** N/A

**Weight (kg):** N/A

**Consumables:** none.

**Retail Price (USD):** Base \$50,000 (depends on configuration) + customization and other charges may apply.

**Other features:** Portable and reusable. Uses software. Telemedicine system.

**Year of commercialization:** 2009

**Currently sold in:** USA



# Mobile technology to connect patients to remote doctors

Country of origin | United States of America

## Health problem addressed

The bottom of the pyramid population in the developing world continues to face fundamental challenges in healthcare, due to lack of access, low affordability, low quality and exploitative care, and a reactive, emergency-driven system. Existing solutions lack financial and human resources and show sub-optimal use of limited resources.

## Product description

This product is an Integrated Mobile Health Technology Platform that enables frontline health providers (community health workers, rural nurses and doctors) to connect patients to remote doctors in order to obtain timely medical diagnosis and administer effective treatment for underserved patients. Selected awards: Winner at the 2008 MIT 100K Entrepreneurship Competition and Best Telemedicine Innovation at the 2009 World Health Care Congress.

## Product functionality

Frontline health providers use the mobile application to perform health risk screening and medical triage to identify health concerns. The diagnostics application on the phone instructs health providers with immediate actions to care for the patient, or transmits the case to remote doctors for further diagnosis and treatment advice.

## Developer's claims of product benefits

This solution is cost-effective as it requires no additional equipment or infrastructure by using available mobile phones, mobile connectivity and local health providers. Training for local health providers takes less than an hour because all users are already familiar with the use of mobile phones. Maintenance is minimal as local phone stores are capable of maintaining the mobile devices. The service reduces travel costs, minimizes time to obtain treatment (from weeks to minutes), and is accessible locally to underserved patients via health workers or close-by rural clinics.

## Operating steps

Frontline health providers use mobile phones to access the diagnostics application. They enter patient symptoms information by going through a series of decision-tree based medical algorithm. For cases requiring remote doctor consultation, the phone transmits the patient symptoms information via mobile broadband or SMS/MMS to the remote doctor.

## Development stage

The product was technically evaluated and tested for clinical effectiveness via concordance rates between in-person and mobile-transmitted remote diagnosis in Egypt, Ghana, Botswana, the US. We pursue various partnerships. Partners include mHealth Alliance, BRAC, Sajida Foundation, Mobinil Egypt, Orange Botswana, University of Pennsylvania Medical School, Harvard, MIT, American Academy of Dermatology.

## Future work and challenges

These applications and corresponding business models were tested through pilots in over 10 countries. The basic technology proposition was proven and patient acceptability demonstrated. Commercial scalability is now ready to be tested by 1) improving the technology platform to support large scale usage from current ~500,000 beneficiaries to >1 million, 2) expanding distribution channels, 3) refining service models to suit our markets.

## User and environment

**User:** Patient, family member, nurse, midwife, physician

**Training:** 30-60 min walk-through of the mobile application

**Maintenance:** Technician, engineer, manufacturer

## Environment of use

**Requirements:** Mobile connectivity, access to a power source to charge mobile phones.

## Product specifications

**Dimensions (mm):** 110 x 47 x 14 (approx.)

**Weight (kg):** 0.008

**Life time:** Varies by phone model

**Retail Price (USD):** Varies

**Year of commercialization:** 2009

**Currently sold in:** US, Botswana, Bangladesh

# Treatment response software application

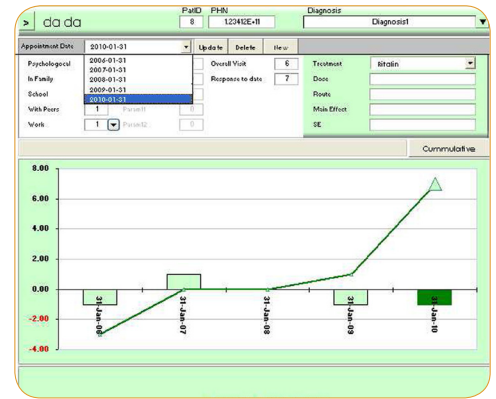
Country of origin | Canada

## Health problem addressed

Tracking patient response to specific treatments other than measurable physiological changes (laboratory test results), survival or death remain a matter of clinical judgment. Diagnostic validity and reliability is an ongoing problem in applying evidence-based practice. The system application presented here provides a gold RCT standard to this problem.

## Product description

This application may be used to track and graphically represent individual patient responses to treatments over time. Additionally, patients may be assigned to up to four specific treatment groups (RCT) to compare treatments. Students can compare the diagnostic accuracy of their assessments and interventions with experts.



## Product functionality

Download and open - this is an Excel/VBA based application. It may be used to track and represent individual patient responses to treatments over time. Additionally, patients may be assigned to specific treatment groups. User defined variables representing treatment and response parameters may be defined across clinically relevant domains.

## Developer's claims of product benefits

The application is intended to support physicians or nurses in tracking patients responses to treatment. It will permit outcome measurement for any treatment for any disease or health concern. The application and manual are available free of charge.

## Operating steps

This is a Microsoft Excel software program that is user completed.

## Development stage

The current program is complete and self-contained.

Regulatory approval status of the product is completed. Conformity assessment has been carried out in Canada.

## Future work and challenges

Since posted on the web approximately 1000 individuals have either visited or downloaded the application. Future versions will have more robust operability (e.g. automated amalgamation of data from individual cases).

## User and environment

**User:** Nurse, midwife, physician

**Training:** Manual - 1 hour

**Maintenance:** None

## Environment of use

**Requirements:** A compatible computer is required. Visual Basic for Applications, Microsoft Excel 11.0 Object Library, OLE Automation, Microsoft Office 11.0 Object Library, Microsoft Forms 2.0 Object Library, Microsoft Calendar Control 11.0.

## Product specifications

**Consumables:** None

**Retail Price (USD):** 0

**List price (USD):** 0

**Year of commercialization:** 2010

**Currently sold in:** Available for all

# Medical devices

## 2011

# Fetal heart rate monitor

Country of origin | United Kingdom

## Health problem addressed

Every year, 1 million babies die during childbirth. Complications during childbirth kill half a million mothers, and a further 1 million babies within a month of birth. Over 99% of these deaths occur in the developing world and many are preventable with timely detection of complications.

## Product description

Using advanced Doppler ultrasound technology, the monitor detects and measures the fetal heart rate. This vital indicator of fetal stress allows rural healthcare workers to make life-saving decisions during childbirth. Destined for use in low resource settings, its design focuses on simplicity of use, durability and electrical power independence.



## Product functionality

The fetal heart rate monitor is designed for ruggedness and simplicity of use, but its most distinguishing element is the human-powered electricity solution. By using the self-powered technology, simply winding a handle will charge the batteries. Each minute of winding provides about 10 minutes of monitoring time.

## Developer's claims of product benefits

Fetal monitoring methods in low income countries are limited to Pinard fetal stethoscopes. Current availability of monitoring in the majority of primary and district care facilities in middle and especially low income countries being limited makes this monitoring unreliable. The accuracy of the Pinard is without much evidence indicating improved outcomes in situations of fetal distress. Doppler ultrasound fetal heart rate monitors are recommended but only 1 % of these devices worldwide are available in low income countries. This device aims at a reduction in perinatal mortality and neonatal encephalopathy. The majority of the midwives who used the monitor preferred it to the Pinard as the device was easy to charge; it was very easy to obtain a reading and quick to identify the fetal heart rate within 30 seconds.

## Operating steps

The powerful narrow beam Doppler head is placed on a pregnant woman's abdomen. The fetal heart rate is delivered as an audio signal and displayed as a number in beats per minute.

## Development stage

This fetal heart rate monitor won the Index Global Design Award in 2009 and has the potential to dramatically improve health outcomes especially for babies. Pilot field testing was carried out in 9 South African primary care maternity facilities run only by midwives (without doctors).

## Future work and challenges

The fetal heart rate monitor is currently available and in production.

## User and environment

**User:** Nurse, midwife, physician

**Training:** None

**Maintenance:** Technician

## Environment of use

**Setting:** Rural, primary (health post, health center), secondary (general hospital)

**Requirements:** None

## Product specifications

**Dimensions (mm):** 170 x 85 x 75

**Weight (kg):** 0.7

**Consumables:** None

**Life time:** 5 years

**Shelf life:** 3 years

**List price (USD):** 350

**Other features:** Portable and reusable. Runs on batteries. Uses software.

**Year of commercialization:** 2010

**Currently sold in:** United Kingdom, South Africa and other African countries.

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

# Isothermal nucleic acid amplification system for POC diagnosis

Country of origin | China

## Health problem addressed

One major limitation of effective tuberculosis control is the lack of a suitable diagnostic technology. Current technologies, such as sputum smear microscopy, are insensitive; immuno tests are indirect, and the available molecular tests are complex and expensive. It is the responsibility of scientific and business communities to provide rapid, simple, accurate and affordable technologies and products.

## Product description

This TB diagnostic is based on 5 core technologies: 1. Glass transition of reagents for ambient temperature transport/storage; 2. Instrument free sample preparation; 3. Isothermal Nucleic-acid amplification; 4. Visual read-out: a DNA lateral-flow device (LFD); 5. Cross-contamination control device. The TB DNA test with these integrated technologies can be delivered and performed at almost any location.

## Product functionality

Sample preparation: using syringe and a membrane unit, no centrifugation; Amplification: proprietary Cross Priming Amplification (CPA) technology, water bath is the only instrument needed; Lateral-flow strip detection: visual readout in an enclosed device, cross contamination proof; Glass transition of reagents: the entire kit can be transported/stored at ambient temperature.

## Developer's claims of product benefits

The amplification method (CPA) and cross-contamination proof detection device are the primary inventions. The glass transition method and sample preparation device are improvements on existing technology: Cost effectiveness: No setup cost, almost no instrument cost; Ease of use and Maintenance: Single test package, simple operation; Reduced training Requirements: No highly trained personnel required; Labour and time saving: Sample to result in 2 hours; Reduced resource Requirements: The only equipment needed is a water bath maintaining a temperature around 63°C; Technical superiority: Detected 10 or less pathogens with high specificity; Better accessibility: Shipped and stored at ambient temperatures; Cross-contamination control: Sealed cartridge ensuring amplicon is never exposed.

## Operating steps

Step 1: Sample preparation - Use our instrument-free nucleic acid extraction device. The process takes 15 minutes after sputum specimen liquefied and boiled; Step 2: Amplification - Amplification can be accomplished with any incubator that keeps a constant temperature. CPA takes 60 minutes at 63°C. Step 3: Detection and read-out - Place the CPA reaction tube into the cartridge and lock. Read result in 10 minutes.

## Development stage

The Isothermal Amplification Diagnostic Kit was approved by TUV for CE marking. Our manufacturing facilities are EN ISO 9001:2000 and EN ISO 13485+AC:2007 approved. One example of product trials conducted was at Taipei Medical University, Municipal Wan Fang hospital - sensitivity: 99%, specificity: 94%, PPV: 97%, and NPV: 97%.

## Future work and challenges

Market education: The technologies are new and little known. It requires significant effort to educate users, promote products and gain acceptance. Regulatory approval: The CE mark has been obtained for the TB tests. Entry approval from individual governments is still needed requiring time and resources. Network: A network for distribution and demonstration, covering health centers in developing countries, needs to be established.

## User and environment

**User:** Nurse, physician, technician

**Training:** Product brochure, instruction for use, actual testing kits. Training takes about 3 hours.

**Maintenance:** Nurse, physician

## Environment of use

**Setting:** Rural and urban health care facilities.

**Requirements:** The assays can be used at community health centers with minimal or no lab infrastructure, and can be performed by personnel with minimal training; water and method to boil for bacteria decontamination, water-bath to maintain temperature between 58 to 65°C, and temporary electricity (battery/solar) are required. Long-term storage at larger clinics would need to transport the devices to hard-to-reach areas.

## Product specifications

**Weight:** 500g/20 tests

**Shelf time:** 1 year

**Consumables:** Pipette tips

**Retail Price (USD):** \$6 (including sample preparation, amplification and detection)

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**Other features:** The diagnostic test is portable and single-use.

**Year of commercialization:** 2009

**Currently sold in:** China, Thailand, Singapore, Taiwan, Canada and USA (research only)



# Non-pneumatic anti-shock garment

Country of origin | United States of America

## Health problem addressed

Postpartum hemorrhage (PPH) in developing countries continues to be the single most common cause of maternal morbidity and mortality, accounting for approximately 25 percent of maternal deaths globally. Over 90 percent of these deaths occur in developing countries.

## Product description

For women suffering from uncontrollable PPH, a method to control the bleeding, reverse the shock, and stabilize the patient for safe transport to a comprehensive obstetric care facility could be lifesaving. One method to manage PPH is the use of a non-pneumatic anti-shock garment (NASG).

## Product functionality

The NASG is a lightweight neoprene garment that is made up of five segments that close tightly with Velcro. The NASG applies pressure to the lower body and abdomen, thereby stabilizing vital signs and resolving hypovolemic shock. When fitted correctly, the reusable NASG forces blood to the essential organs - heart, lungs, and brain.

## Developer's claims of product benefits

This garment provides an improvement over existing products in that it is a validated, low-cost, high-quality garment. This is achieved by providing direct access to qualified manufacturers who can supply the garment at the price of US\$54 (purchaser is responsible for freight forward from China and import regulations, minimum order is 1,000 units).

## Operating steps

1. Place NASG under woman; 2. close segments 1 tightly around the ankles; 3. close segments 2 tightly around each calf; 3. close segments 3 tightly around each thigh, leave knees free; 4. close segment 4 around pelvis; close segment 5 with pressure ball over the umbilicus; 6. Finish closing the NASG using segment 6. Segments 1, 2, 3 can be applied by two persons simultaneously, segments 4, 5, 6 should only be applied by one.

## Development stage

Clinical trials led by Suellen Miller at the University of California, San Francisco are on-going. Currently, the large-size device is cleared by the US Food and Drug Administration and has been tested in low-income settings. The device is ready for manufacturing and sale in China.

## Future work and challenges

**NASG Sizes:** The NASG is not a one-size-fits-all PPH tool. Three sizes (small, medium, and large) of NASG have been developed to accommodate the significant population-dependent anthropomorphic variations around the world. In our interviews in Nigeria, it was also clear that an extra-large-size NASG was desired to accommodate larger women in that region. Only the large-size NASG has been qualified with manufacturers.

**Cleaning of the NASG:** Cleaning is another challenge. There is no established method of accurately tracking the number of uses and cleanings, thus it is difficult to identify when sufficient degradation has occurred to retire the NASG and replace it with a new one.

## User and environment

**User:** Family member, nurse, midwife, physician, technician

**Training:** Pathfinder International has developed course curriculum and training materials which vary in length depending on target audience, and whether the intended user is applying or removing the garment.

**Maintenance:** Hospital orderlies are generally responsible for cleaning.

## Environment of use

**Setting:** At home and in health care facilities in rural or urban settings.

**Requirements:** Water and bleach for cleaning.

## Product specifications

**Life time:** Approx. 40 uses

**List price (USD):** 53.76

**Other features:** Portable and reusable

**Currently sold in:** United States of America



# Oxytocin in prefilled auto-disable injection system

Country of origin | United States of America

## Health problem addressed

Postpartum hemorrhage (PPH) is the leading cause of maternal death worldwide. Women delivering outside of health facilities or in facilities with constrained resources may not receive the WHO-recommended dose of 10 IU of oxytocin for the prevention of PPH. There is a need for an easy-to-use delivery system for oxytocin that increases access.

## Product description

A compact, prefilled, auto-disable injection system is used to deliver Oxytocin. A time-temperature indicator on each package indicates heat exposure. Oxytocin in this device can enable minimally trained health workers to provide the PPH prevention dose in low- resource facilities, emergency situations, or remote locations.



## Product functionality

As a prefilled system the easy-to-use device allows caregivers to safely inject drugs or vaccines with minimal training. The system prefilled with Oxytocin ensures that an accurate dose is delivered to a patient with minimal preparation, minimum waste, and a guarantee that the syringe and needle will not be used again.

## Developer's claims of product benefits

Current practice is to use a syringe and two 5-IU ampoules or one 10-IU ampoule of Oxytocin. Oxytocin in described injection system is prefilled with 10 IU and ensures an accurate dose by minimally skilled health workers. It is individually packaged and sterile in an injection-ready format, optimal for low-resource settings. It is compact and prefilled so generates minimal waste.

## Operating steps

1. Check the time-temperature indicator; 2. Open the foil pouch; 3. Activate the device; 4. Remove the needle shield; 5. Continue to hold the injection device by the port and insert the needle into the patient; 6. Squeeze the reservoir to inject the oxytocin; 7. Do not re-cap; 8. Dispose according to medical waste procedures.

## Development stage

Oxytocin in conjunction with described injection device is currently being produced in Argentina and India. Oxytocin in Uniject is commercially registered in Argentina, Guatemala, Honduras, Paraguay, and India. Additional registrations in Latin America and Africa are being pursued.

## Future work and challenges

The value of oxytocin in conjunction with described injection system has been demonstrated in the field. More and more countries are recognizing the need to reduce maternal mortality, and the easy and safe delivery of oxytocin has been identified as an important tool, but more must be done to raise awareness. The next phase of work will include efforts to raise awareness, increase demand, and ensure a sustainable supply.

## User and environment

**User:** Nurse, midwife, physician, technician

**Training:** User instructions are included in the box and on the primary packaging. Training requires no more than 1 day.

## Environment of use

**Setting:** At home and in health care facilities in rural and urban settings.

**Requirements:** Cold chain is ideal, but the time-temperature indicator on the package allows for brief excursions outside the cold chain, like to low-resource health posts or to a woman's home.

## Product specifications

**Dimensions (mm):** (foil pouched product) 148 x 56 x 10 (reservoir height)

**Weight (kg):** 0.0025 (filled, excluding pouch)

**Shelf life:** 24 months

**Retail Price (USD):** Varies by country

**Other features:** Portable and single-use.

**Year of commercialization:** 2009

**Currently sold in:** Argentina, Guatemala, India



# Phototherapy for neonatal jaundice treatment

Country of origin | Brazil

## Health problem addressed

Neonatal Jaundice (Hyperbilirubinemia) is a frequent issue in newborns. Approximately 60% of newborns become clinically jaundiced. It is a clinical condition generally benign and reversible if properly treated, but its exacerbated intensification may generate serious sequelae into the central nervous system, which may lead patient to death.

## Product description

Phototherapy is an efficient mean to treat Hyperbilirubinemia. By emitting blue light over the patient's skin, it converts toxic bilirubin molecules in the blood into less toxic isomeric forms, by photo-oxidation and photoisomerization. The device uses high power LEDs for treatment and negligible emission of UV / IR radiation.



## Product functionality

The phototherapy uses a set of 5 high power LEDs, positioned 30 cm above the patient. The treatment uses high radiation emitted at the blue range of the spectrum, from 400 to 550 nm (the most recommended for Jaundice treatment). The device also provides extra functions, such as integrated radiometer and treatment time counter.

## Developer's claims of product benefits

Traditional devices use fluorescent or halogen lamps, or many conventional LEDs. Lamps may require filters to attenuate UV / IR rays and have a low life expectancy (around 2.000h). Conventional LEDs are low power devices. To work effectively, hundreds of LEDs must be used, making the phototherapy complex and prone to failure. The proposed technology uses only 5 high power LEDs, which is equivalent to more than 250 conventional LEDs. The result is a compact, highly efficient, long life time (20.000 h) and low cost phototherapy. It provides new resources: output radiation level adjustment, embedded radiometer and irradiance measurement reports. In addition, it is compact, saving space in the intensive care unit.

## Operating steps

Place the device over the newborn, 30 cm away. Turn it on and press 'Menu' to go to the irradiance level screen. Set the irradiance using the 'up'/'down' keys and press 'Enter' to confirm. Be sure the newborn is exposed to the light at the chest and abdomen area. Protect the newborn's eyes.

## Development stage

The product is being manufactured and commercialized. It has been fully validated and clinically tested. Studies verify that the blue high power LEDs are more efficient for Jaundice treatment. The market confirms those studies. It has the Brazilian ANVISA regulatory approval, the CE marking and it is currently obtaining the UL recognition approval.

## Future work and challenges

Promoting the technology's ease-of-use, efficient treatment system and affordable cost in low and middle income countries is the greatest challenge. Assistance herein is required, e.g. through workshops by professionals to explain the importance and advantages and to make users familiar with new functions that improve the treatment quality, like the embedded radiometer and the timer.

## User and environment

**User:** Nurse, physician

**Training:** Concept presentation (2 hours training).

**Maintenance:** Technician

## Environment of use

**Setting:** Secondary (general hospital), tertiary (specialists hospital)

**Requirements:** Power supply (100 to 240 Vac), 50 or 60Hz; ambient temperature between 18°C and 28°C; air humidity between 10% and 95%; eye protection for the patient.

## Product specifications

**Dimensions (mm):** 230 x 116 x 50

**Weight (kg):** 1

**Consumables:** Eye protector

**Other features:** Portable and reusable. It utilizes software.

**Year of commercialization:** 2005

**Currently sold in:** Algeria, Australia, Bolivia, Brazil, Colombia, Costa Rica, Ecuador, Spain, Finland, France, Indonesia, Iran, Iraq, Jamaica, Lithuania, Malaysia, Mexico, Nicaragua, Paraguay, Peru, Poland, Portugal, Russia, Syria, Sudan, Sweden, Uruguay, Venezuela, Vietnam, Yemen.

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



# Portable haemoglobin meter

Country of origin | Brazil

## Health problem addressed

Anemia is one of the most common blood disorders globally. Iron deficiency anemia is the most prevalent nutritional disorder in the world. Anemia diagnosis is frequently not performed or the test results are delayed, causing aggravations or even sequels in the most vulnerable population, children and pregnant women.

## Product description

Portable hemoglobin meters that are user-friendly can be a great aid to change the global anemia scenario. Avoiding the displacement of patients and shortening the diagnostic process, this solution can spread this clinical test to people with low access to health services.



## Product functionality

The portable hemoglobin meter is a micro processed photometer. In a disposable vial, containing Drabkin's reagent, 10 uL of blood sample are dropped. Reaction follows inside the vial, also used as the lecture cuvette. Hemoglobin content is read and calculated by a microprocessor and proprietary software. Results are presented in a LCD display.

## Developer's claims of product benefits

The reagents are stable for a long periods and extreme environmental conditions. The use of the injection vial, containing the reagent, as a cuvette, reduces the number of operations, reduces costs, speeds lecture and allows portability. The equipment is battery (rechargeable) driven allowing the use in any environment.

## Operating steps

After cleaning the skin, a puncture is done and a 10 uL blood sample is collected with a micropipette and transferred to the reagent vial. After 30 seconds of mixing, the vial is inserted in the equipment and a button is pressed. The sample hemoglobin content is exhibited in the display in g/dL.

## Development stage

The device is fully developed and extensively tested (over 20,000 patients). In Brazil validation was performed by PP-SUS program, a governmental trial of innovative technologies for public health care. PAHO and IPTI are performing tests (process n° BR/LOA/1000065.001). Researchers from São Paulo University and FIOCRUZ Foundation are performing tests in anemia trials.

## Future work and challenges

For the moment, it is commercialized only in Brazil, in compliance with the standards from Brazilian national regulatory legal demands (ANVISA). International certifications need to be performed. Additionally, there exists a need for investors and/or commercial partners interested in business improvement.

## User and environment

**User:** Nurse, physician, technician

**Training:** One to two days, blood collection practice by puncture and pipette

**Maintenance:** Manufacturer

## Environment of use

**Requirements:** Powered by batteries and designed for a global environment use, there are no special requirements. The tests are disposable and previously sterilized.

## Product specifications

**Dimensions (mm):** 167 x 108 x 37

**Weight (kg):** 0.358

**Consumables:** Hemoglobin meter reagent vial, tips

**Life time:** several years

**Retail Price (USD):** 1500

**List price (USD):** 1500

**List price of consumables (USD):** 1.0/vial

**Other features:** Portable and reusable. Runs on batteries, uses software.

**Year of commercialization:** 2010

**Currently sold in:** Brazil



# Portable ventilator

Country of origin | United States of America

## Health problem addressed

Patient groups most likely to benefit include those with COPD, Cardiogenic Pulmonary Edema, Immunocompromised patients (e.g. HIV), and COPD patients weaning from mechanical ventilation. COPD is one of the fastest growing causes for death today worldwide. Over the next 20-30 years, it is poised to become the 3rd or even 2nd leading causes of death.

## Product description

The device is a small size, portable, versatility and can run on batteries.

## Product functionality

The device's primary innovation is owed to its use of micro-blower technology and unique gas control algorithms. In combination the device is able to meet the needs of a wide variety of ventilatory demands, including high leaks seen in noninvasive ventilation while still maintaining patient-ventilator synchrony.

## Developer's claims of product benefits

By costing a third of other ICU ventilators and offering both invasive and noninvasive capabilities, the device is ideally suited for patients in respiratory distress, no matter what their location or severity.

## Operating steps

The device employs a micro-blower to generate airflow and connects directly to oxygen supplies to provide between 21-100% oxygen enriched, pressurized gas. Pressure and flow sensors provide signals to a very sophisticated controls algorithm to precisely meter pressure, flow and volume even in leak prone, noninvasive applications.

## Development stage

The device was market released July 2010 and is sold worldwide. Several investigators have compared the device's performance to other ventilators, in various patient populations, and under different clinical conditions such as leak-prone noninvasive applications. The results of such studies show the relative superiority of the device's design elements and precise gas delivery. One bench study demonstrates the unique ability of the device to maintain accurate volume control mode delivery even while using cheap and simple intentional leak breathing circuits.

## Future work and challenges

None

## User and environment

**User:** Nurse, physician, technician

**Training:** Interactive CD-ROM (self paced), User's Manual (reference material), various slide presentations.

**Maintenance:** Technician, engineer, manufacturer

## Environment of use

**Settings:** Ambulatory, secondary, and tertiary health care facilities.

**Requirements:** Basic electrical power 100 - 240 VAC, 50/60 Hz, 2.1 A, 5-40C temperature range and high pressure oxygen source (40-87 psi) via compressed gas tanks or wall outlets. Optional: available equipment to disinfect breathing circuits if reusable circuits are preferred.

## Product specifications

**Dimensions (mm):** 21.3 x 28.5 x 23.5

**Weight (kg):** 5.6 (including batteries)

**Consumables:** Breathing circuit and patient interface (artificial airway or facemask)

**Life time:** Several years

**Retail Price (USD):** 11,500

**List price (USD):** 11,500

**List price of consumables (USD):** 80 (Std. Adult reusable circuit), 14 (disposable circuit)

**Other features:** Portable and reusable. Runs on batteries, uses software and is compatible with telemedicine systems.

**Year of commercialization:** 2010

**Currently sold in:** US, Eastern and Western Europe, all Scandinavia, most countries in Asia/Pacific, India, Africa, Japan, Latin America and Middle East.



# Prefilled auto-disable injection system

Country of origin | United States of America

## Health problem addressed

Solutions are needed in low-resource settings to increase access to drug and vaccine delivery. It is also necessary to prevent reuse of syringes, helping to prevent transmission of bloodborne disease and to minimize waste in these settings.

## Product description

The device developed to address this health problem is a compact, sterile, prefilled, nonreusable injection system for delivery of vaccines or drugs.

## Product functionality

The prefilled, sterile injection system may allow minimally trained health workers to accurately inject drugs or vaccines that they would not otherwise be allowed to deliver. The auto-disable feature prevents reuse, helping prevent transmission of bloodborne disease between patients. The compact, prefill device also minimizes waste.



## Developer's claims of product benefits

Compared with standard syringes and ampoules (depending on the drug delivered), the developed injection system is prefilled ensuring an accurate dose by minimally skilled health workers. It is individually packaged and sterile in an injection-ready format, optimal for low-resource settings. It is compact and prefilled so generates minimal waste.

## Operating steps

1. Open the foil pouch; 2. Push the needle shield into the port; 3. Push until you close the gap between needle shield and port; 4. Remove the needle shield; 5. Hold the device by the port and insert needle into patient; 6. Squeeze reservoir firmly to inject; Discard according to medical waste procedures.

## Development stage

The injection system was developed around 15 years ago, and as a viable container for drugs is fully developed. The availability of important drugs in the injection device for use in low-resource settings is established in some areas and developing in others. Oxytocin, hepatitis B vaccine, and tetanus Toxoid vaccine are available in some countries; other drugs and vaccines are in early stage development. Injectable contraceptives are in their final stage of regulatory approval. Betamethasone and gentamicin are still in research stages.

The unfilled device is available for purchase by pharmaceutical manufacturers worldwide.

## Future work and challenges

The injection system itself is designed to be portable and requires minimal resources for preparation. Depending on the drug or vaccine applied, cold chain may be needed. Some applications can include a time-temperature indicator which allows brief excursions out of the cold chain, like to low-resource health posts or for rural/home delivery.

## User and environment

**User:** Patient, family member, nurse, midwife, physician

**Training:** User instructions are included in the box and on the primary packaging.

## Environment of use

**Setting:** At home and in health care facilities in rural and urban settings.

**Requirements:** The device itself is designed to be portable and requires minimal resources for preparation. Depending on the drug or vaccine applied, cold chain may be needed.

## Product specifications

**Dimensions (mm):** max.100 (excl. pouch) x 23 x 10 (reservoir height)

**Weight (kg):** 0.002 - 0.0025 (filled, excluding pouch)

**Shelf life:** 5 years

**Retail Price (USD):** Varies by drug/vaccine and country

**Other features:** Portable and single-use.

**Year of commercialization:** 1998

**Currently sold in:** Indonesia, India, Argentina, Belgium

# Reusable neonatal suction device

Country of origin | Norway

## Health problem addressed

Nearly 1 million newborns in developing countries die from birth asphyxia each year. A similar number are disabled due to compromised breathing at birth. To stimulate spontaneous breathing, or bag-mask ventilate effectively, an open airway is mandatory. Often this requires clearing the mouth and nose of mucous and meconium using vacuum.

## Product description

The proposed solution is a bulb suction device that is particularly suitable for use in developing countries. It is easy to use and reusable when disinfected in accordance with instructions, over the product's lifespan.

## Product functionality

The product benefits newborns suffering from birth asphyxia and in need of clearing the upper airways. Squeezing the bulb generates vacuum so that the birth attendant can extract mucus and meconium from the baby's mouth and nostrils.

## Developer's claims of product benefits

This product is clinically effective, easy and safe to use. It is an improvement over the neonatal suction devices typically used in low-resource settings (i.e., mouth suction or hand bulb suction, available in non-cleanable versions and mainly intended for single patient use) as it can be easily opened, cleaned and boiled for disinfection after use, it is made of very durable silicone and withstands several hundred times of reuse. The transparent material makes it easy for the user to see whether it has been cleaned since last use situation; the price (available on a not-for-profit basis) combined with number of use situations dramatically reduces the cost per use compared to existing products.

## Operating steps

Ensure that the device is clean before use on patient. Squeeze bulb to generate vacuum, and place the nozzle tip into the newborn's oral or nasal cavity. Slowly release bulb squeeze to extract the mucus, discharge contents into a water container, towel or similar. For repetitive suctioning, keep the body squeezed until suctioning again.

## Development stage

The product has been available on a not-for-profit basis for newborn resuscitation projects in developing countries since April 2010. It has been FDA device listed, and is developed to applicable standards and regulation required for CE-marking. Self-declaration for CE-marking is imminent within March 2011.

## Future work and challenges

**Financing:** Although the products is highly affordable and available on not-for-profit basis, individual health care facilities and educational institutions in low-and middle income countries often have limited financial resources and may need to obtain funding from governments or international aid organizations.

## User and environment

**User:** Family member, midwife, nurse, physician

**Training:** None

**Maintenance:** Any person responsible for disinfection.

## Environment of use

**Requirements:** The only requirement is that it must be possible to clean and disinfect the device (before first use and between patient uses). Cleaning can be performed by boiling the one-piece device in water, or by more advanced methods.

## Product specifications

**Dimensions (mm):** 40 x 40 x 130

**Weight (kg):** 0.06

**Consumables:** None

**Life time:** 5 years

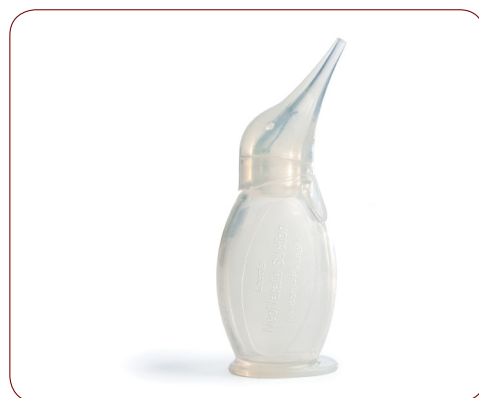
**Retail Price (USD):** 3

**List price (USD):** 3

**Other features:** Portable and reusable.

**Year of commercialization:** 2010

Currently available in: 68 countries identified by UN as focus countries relative to UN Millennium.



# Self-powered pulse oximeter

Country of origin | United Kingdom

## Health problem addressed

10.8 million children die every year. 99% of these deaths are in developing countries and 2.7 million are due to congestive diseases that result in hypoxemia. Early detection of hypoxemia is essential in reducing mortality and morbidity. SPO2 monitoring facilitates this. SPO2 monitoring is also essential during anesthesia. It is called the 5th vital sign.

## Product description

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



## Product functionality

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

## Developer's claims of product benefits

This is a monitor specifically designed for use in low resource settings or where electricity supply is a problem. The SPO2 monitor is rugged and reliable and has its own on-board power generator. Human energy is converted into electricity and saved in rechargeable batteries. The monitor gives 10-15 minutes of monitoring per minute of winding. The monitor may also be recharged using grid power when available. The pulse oximeter is designed to be compatible with a wide range of probes to take advantage of generic offerings when available. Unlike monitors designed for mainstream medical markets, it is very simple to use at low cost.

## Operating steps

The SPO2 monitor is a solution to the problem of measuring blood oxygen saturation in developing world health environments. By turning the crank human energy is efficiently converted into electricity and stored in rechargeable batteries. Generic probes ranging from pediatric to adult provide accurate pulse and saturation levels.

## Development stage

The pulse oximeter is currently available and in production. It is manufactured in India. Pilot field testing was carried out in South African secondary hospitals and its performance was congruent with "gold standard" high-end pulse oximeters.

Regulatory approval is completed.

## Future work and challenges

Product is commercialized.

## User and environment

**User:** Nurse, midwife, physician.

**Training:** None

**Maintenance:** Nurse, physician, technician

## Environment of use

**Setting:** Rural. Ambulatory, primary (health post, health center), secondary (general hospital)

**Requirements:** none

## Product specifications

**Dimensions (mm):** 170 x 85 x 75

**Weight (kg):** 0.7

**Consumables:** None

**Life time:** 5 years

**Shelf life:** 3 years

**List price (USD):** 600

**Other features:** Portable and reusable. Runs on batteries. Uses software.

**Year of commercialization:** 2011

**Currently sold in:** South Africa

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



# Transcutaneous bilirubin measurement system for infants

Country of origin | United States of America

## Health problem addressed

Hyperbilirubinaemia is a common condition in many newborns, affecting nearly 1 in 10 newborns and nearly 90% of premature infants in the first week of life. If undetected and untreated the levels of bilirubin may rise high enough to pass through the blood brain barrier and is deposited in the brain causing kernicterus and brain damage.

## Product description

The device provides a numerical measurement of predicted bilirubin count in mg/dL or  $\mu\text{mol/L}$  within a clinically beneficial range that has been correlated with total serum bilirubin concentration measured by High Pressure Liquid Chromatography (HPLC).



## Product functionality

The device works by directing white light into the skin of the newborn and measuring the intensity of the specific wavelengths that are returned. By knowing the spectral properties of the components within the skin, one can subtract out the interfering components and determine the concentration of bilirubin.

## Developer's claims of product benefits

The technology of the device evaluates melanin, collagen, hemoglobin and bilirubin in a patient's subcutaneous tissues through a proprietary algorithm and optics system. Existing technologies measure the yellowness of the skin as it relates to jaundice.

## Operating steps

Simple button push for calibration, place on infants head or sternum and press the measurement button 5 times in succession and the results appears on the screen. Test taken in minutes.

## Development stage

This product has been sold globally since 2002. To date over 5000 units have been delivered to hospitals, clinics, physicians and community health workers.

Technical evaluation and health technology assessment review: FDA 510K # k010052.

Regulatory approval complete. Conformity assessment has been carried out (USA).

## Future work and challenges

The product is not registered as a medical device in all countries. Depending on the country of use, the product may need to be registered before it is used.

## User and environment

**User:** Nurse, midwife, physician

**Training:** Technique education on how to properly take a measurement.

**Maintenance:** Manufacturer

## Environment of use

**Setting:** Rural and urban health care facilities.

**Requirements:** Power supply to charge the battery, disposal of calibration tip and cleansing products for pre-patient use.

## Product specifications

**Dimensions (mm):** 2045 x 50.23 x 59.4

**Weight (kg):** 0.346

**Consumables:** Disposable calibration tip (per test)

**Life time:** 5 years

**Shelf life:** 20 months

**Retail Price (USD):** 3500

**List price (USD):** 4295

**List price of consumables (USD):** approx. 360 (bag of 50)

**Other features:** Portable and reusable. Runs on batteries and uses software.

**Year of commercialization:** 2009 (first version in 1996)

**Currently sold in:** Most of Europe, as well as in Australia and several African, Asian, North- and South-American countries (65 countries)



# Ventilator using continuous positive airway pressure

Country of origin | Vietnam

## Health problem addressed

Every year hundreds of thousands babies die because of respiratory failure. Infant mortality could be reduced by application of CPAP — relatively simple therapy addressing 90% of cases. Diseases treated: pneumonia, apnea, hypoxia, and respiratory failure - main cause of infant mortality worldwide.

## Product description

CPAP is one of the methods used to support infants with respiratory distress and assist them in maintaining continuous positive airway pressure while breathing on their own. This solution is customized for the use in hospitals with basic infrastructure and limited resources. It is simple in use with only short training required.



## Product functionality

CPAP provides mixed gas flows down the inspiratory limb to nasal cannula while expired gas returns via the expiratory limb to the pressure bottle. The medical staff is able to control appropriate mix of gases as well as desired temperature, humidity and flow.

## Developer's claims of product benefits

The Complete CPAP system is designed to be used in the low resources settings. The only requirement is power supply and oxygen. The system provides its own air compressor, humidifier, oxygen and air blender, air heater. All the functions can be controlled by the user through simple interface requiring minimum training. The system is fully reusable and washable limiting the need for consumable parts to nasal connectors. It allows the user to keep running expenses at very low level keeping the treatment costs at less than a few dollars per patient.

## Operating steps

Connect the system to oxygen and power source; Connect the tube circuit to the patient; Turn the system on, Set the desired oxygen concentration and flow rate; set the temperature and humidity.

## Development stage

The device is based on the concept of the CPAP technology developed by Colin Sullivan at Royal Prince Alfred Hospital, Australia, 1981. To this, the adaptation element to low resource settings was added. The system has been proven by extensive use in countries such as Vietnam, Laos, Cambodia and East Timor following initial studies at National Hospital of Pediatrics in Hanoi in 2006/2007. By now it is a national standard in countries mentioned above being used in over 200 public hospitals treating thousands of patients every year.

## Future work and challenges

Due to a lack of funds in public healthcare barring commercial ventures, the strategy is to introduce the technology using charity money and leverage from such demonstration in the future. The biggest challenge is to convince local authorities to start spending public funds on such solutions which could make the whole system sustainable.

## User and environment

**User:** Nurse, physician

**Training:** CPAP set, 3 days

**Maintenance:** Nurse, physician, technician

## Environment of use

**Settings:** Rural as well as urban secondary and tertiary health care facilities

**Requirements:** Stable power supply, oxygen supply (wall, cylinder, concentrator)

## Product specifications

**Dimensions (mm):** 330 x 330 x 1400

**Weight (kg):** 15

**Consumables:** None

**Life time:** 5 years

**Retail Price (USD):** 2,500

**List price (USD):** 2,300

**Other features:** Reusable. Uses software.

**Year of commercialization:** 2006

**Currently sold in:** Vietnam, Laos, Cambodia, East Timor

# Other technologies

## 2011

# Newborn simulator for resuscitation training

Country of origin | Norway

## Health problem addressed

UN Millennium Development Goal (MDG) 4 aims at reducing child mortality by 2/3 from 1990-2015. To date, the improvement is far from sufficient, particularly for neonatal mortality. To reach MDG 4, there is an urgent need to train large numbers of birth attendants in developing countries in neonatal routine care and resuscitation.

## Product description

The proposed solution is a highly realistic and affordable newborn simulator. The baby's status can be simulated as desired to facilitate role playing in relevant scenarios covering basic newborn care as well as standard resuscitation measures. The simulator is available with therapeutic tools.



## Product functionality

By squeezing the bulbs connected to the simulator, an instructor can simulate three vital signs: Crying; spontaneous breathing; and palpable umbilical pulse. Depending on how the learner assesses the situation and acts, the instructor can easily provide feedback to the learner by changing the vital signs.

## Developer's claims of product benefits

The simulator facilitates effective and affordable simulation training in low-resource settings that can improve quality of neonatal resuscitation as it is: Very low cost (available at USD 50); Allows assessment of key competencies (e.g. ability of trainee to ventilate adequately); Durable, easy to take apart/reassemble/transport; Culturally sensitive (available in dark or light complexion).

The simulator is also highly realistic. It has the size and appearance of a newborn baby, and natural weight, feel and touch when filled with water. As it comes deflated in a compact container and can be emptied between uses, distribution and transport of the simulator is convenient.

## Operating steps

The simulator is easily prepared for use by filling the body with 2 liters of water (alternatively by air). An instructor can simulate vital signs by squeezing the simulation bulbs. The simulator facilitates practice in effective bag-mask-ventilation as the chest only will rise with correct technique.

## Development stage

The product was introduced in 2009. It is available on a not-for-profit basis for projects in the 68 developing countries identified by UN as focus countries for MDG4. The use of the Simulator was validated in pilot tests in Kenya, Tanzania, Pakistan and India and is today a fundamental part of several courses in developing countries in basic newborn resuscitation.

## Future work and challenges

**Financing:** Although the product is available on not-for-profit basis, individual health care facilities and educational institutions in low-and middle income countries often have limited financial resources and may need to obtain funding from governments or international aid organizations.

**Distribution channels:** Bureaucracy and often prohibitive customs rates render import to countries where the need is greatest difficult.

## User and environment

**User:** Nurse, midwife, physician, course instructors, students, all other health care personnel needing refresher training

**Maintenance:** Any user

## Environment of use

**Setting and Requirements:** The product can be used in any setting, there are no specific requirements to the infrastructure.

## Product specifications

**Dimensions during transport (mm):** 300 x 200 x 70  
(simulator deflated in a kit with accessories)

**Dimensions in use (mm3):** 480 x 230 x 120

**Weight during transport (kg):** 0.8

**Weight filled (kg):** 2.2

**Life time:** 3 years

**Retail Price (USD):** 50

**Other features:** The simulator is portable and reusable.

**Year of commercialization:** 2009

**Currently available in:** 68 countries identified by UN as focus countries relative to UN Millennium Development Goal 4.

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

# Point-of-use water disinfection system

Country of origin | United States of America

## Health problem addressed

Worldwide, gastrointestinal illness (GI) is estimated to cause over 1.5 million deaths annually. In addition, an estimated 4 billion cases every year make GI the third highest cause of morbidity globally. Unsafe drinking water is recognized as one of the major pathways responsible for the transmission of GI causing pathogens.

## Product description

The UV tube is easy to operate and maintain point-of-use water disinfection system that uses ultraviolet light to inactivate pathogens at a fast flow rate of 5 liters per minute, without producing unpleasant or harmful disinfection by-products. The UV Tube is appropriate for households, schools, clinics, and small communities.



## Product functionality

The UV tube uses a 15 watt germicidal lamp to deliver a UV-C (254nm) dose of 900 J/m<sup>2</sup> to inactivate virus, protozoa, and bacteria suspended in water.

## Developer's claims of product benefits

The UV tube was developed by an interdisciplinary team of students and professors, who recognize that a wide array of safe water options are urgently needed in order to address the severe and widespread health problems caused by drinking water contaminated with pathogens. Through rigorous laboratory and extensive field testing, the UV Tube was designed to be an effective, easy to use, low-cost, and adaptable point-of-use safe water solution. The dose is more than twice the minimum recommended by the US NSF/ANSI Standard 55, providing a safety factor that guarantees its effectiveness even in certain non-ideal conditions.

## Operating steps

To disinfect water, a user has to: (1) turn on the switch; (2) confirm that the lamp is on; (3) open the water valve; (4) wait for the safe storage container to fill up, 1 minute for each 5 liters; (5) close the water valve; (6) drain the system; (7) turn off the switch. No consumables required, but every 1-3 years some components need replacement.

## Development stage

The product was validated in the laboratory and a prototype tested in 24 households in Mexico in 2005. Positive water quality and user acceptance results led to piloting the technology in 150 households, 3 schools and 13 communities between 2007 and 2008. Successful results motivated the development of a scalable model in 2009. In 2010, 450 household systems were installed in Mexico as part of a stepped-wedge cluster randomized trial. In 2011 the UV tube will be installed in at least 8 schools and 38 community systems serving approx. 10,000 people.

## Future work and challenges

As most water treatment technologies seeking to make real improvements, the device must be implemented as part of a program that allows for needs assessment; adaptation to local conditions; hygiene education; operation and maintenance training. For this reason, we see the UV tube being scaled up through partnerships with institutions, organizations, and/or companies that have local presence and are committed to improving the health of the populations they serve.

## User and environment

**User:** Self-user, family member, nurse, technician

**Training:** Although the system is easy to use and most people can learn how to operate it from a manual, it is recommended that they participate in a basic (20-30 minute) training session

**Maintenance:** Trained nurse / community member, technician

## Environment of use

**Requirements:** Access to electricity. The product consumes 20 watts. To disinfect 1,000 liters it only uses 0.1 kilo watt hours of electricity. The source can be direct current (e.g. 12-24 volts from a solar powered battery) or alternate current (e.g. 110-220 volts from the grid). If water is turbid or contaminated, pre-disinfection filtration is required.

## Product specifications

**Dimensions (mm):** 600 x 150 x 150

**Weight (kg):** 3

**Life time:** 3-5 years

**Retail Price (USD):** 45

**Other features:** Reusable, can run on batteries.

**Year of commercialization:** 2009

**Currently sold in:** Mexico, but projects can be established in new countries.



# Water filter

Country of origin | United States of America

## Health problem addressed

"Infectious diseases caused by pathogenic bacteria, viruses, protozoa and helminthes are the most common and widespread health risk associated with drinking water." (WHO, 2004). In Ghana where the ceramic pot filter is made, 50% of people lack access to improved water supply. Ghana has the 4th lowest worldwide rate of sanitation coverage.

## Product description

The filter unit consists of a fired clay pot filter element, a plastic bucket storage unit, a "ring lid" to support the ceramic pot, a tap and a cover lid. These filters are made from red clay and wood saw-dust or rice-husk which gets mixed, pressed in mold and fired in a kiln.



## Product functionality

Particles, bacteria, guinea worm cyclops and protozoa are removed by physical straining, and also by the mechanisms of sedimentation, adsorption, diffusion, inertia, and turbulence. The filter element is treated with colloidal silver which may act as a bactericide and viricide.

## Developer's claims of product benefits

The ceramic pot filter, made of terracotta clay, can be produced in most countries around the world because of the simple component parts and the universality of clay and combustible material inputs. Moreover, there is the potential to create local, self-sustaining businesses from this endeavor.

## Operating steps

1. Settle turbid water in a storage vessel before filling the ceramic pot; 2. Keep the ceramic pot filled to the top. This will improve filtration rate; 3. Clean filter with brush provided when flow rate becomes too slow; 4. Clean storage unit with soap and filtered water if necessary. Disinfect with chlorine bleach, iodine or boiling water.

## Development stage

The product is being manufactured in >20 countries. In Ghana, in 2007, it has been approved by UNICEF and the government for emergency distribution during a flood emergency. In 2008, it was approved for emergency distribution during a guinea worm outbreak. The product is being locally manufactured and sold in the region with the highest rates of diarrhea in Ghana. The technology has become known through efforts of several international aid organizations and the work of several renowned academic institutions.

## Future work and challenges

In Ghana, the current challenge is to build a self-sustaining enterprise. This effort has taken 6 years, and there are still struggles to reach those who lack improved water at an affordable price. Willingness to pay ranges from \$2 - \$15, but the product price is \$25. Moreover, emergency distribution of the product is free, which distorts the market further, even while making the product familiar to a wider customer base. There is a need for a reliable stream of buyers, support for technical training, human resources and financial management and support for further R&D to improve the product.

## User and environment

**User:** Self-user, family member

**Training:** Each filter comes with an educational sticker. Hands-on demonstration training takes 1 hour in groups.

**Maintenance:** Self-user

## Environment of use

**Requirements:** This filter removes microbes from unclean water. It does not require any power supply, internet, cell phone, etc. . There is no specialized personnel needed to operate the filter.

## Product specifications

**Dimensions (mm):** 500 x 42 (diameter)

**Weight (kg):** 7

**Consumables:** The ceramic pot filter element needs replacement after 2-3 years.

**Life time:** 3 years

**Retail Price (USD):** 25

**List price of consumables (USD):** 8 (to replace the pot

element after three years)

**Other features:** Portable and reusable.

**Currently sold in:** The filter is commercialized in certain countries (Guatemala, Cambodia, and largely promoted by NGOs in other countries)

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# Appendix

# Appendix

All submissions to the call for innovative health technologies for low-resource settings underwent an evaluation process. The technologies were reviewed by WHO, WHO collaborating centres, members of EUROSCAN and other relevant stakeholders. However, no in-depth assessments of the technologies were performed, and no pre-qualification process was done. The evaluation relied solely on the material and evidence provided by the applicant as well as publicly available information that served to analyze the potential of the technology to improve health outcome in low-resource regions. Furthermore, prior to 2013, the fact sheets did not include information on regulatory status. This appendix provides references and regulatory information for medical devices submitted in 2012 and 2011.

## 2012

For further reading about technologies and respective health problems: refer to references provided in the submission documents.

Pg	Name	Regulatory	References
79	<b>Auto stop electrochlorinator</b>	Conforms to US EPA guide standard and protocol for microbiological water purifiers, as tested in-house.	<ul style="list-style-type: none"> <li>Arnold BF, Colford JM Jr. Treating water with chlorine at point-of-use to improve water quality and reduce child diarrhea in developing countries: a systematic review and meta-analysis. <i>Am J Trop Med Hyg</i> February 2007 vol. 76 no. 2 354-364</li> </ul>
65	<b>Automated solar-powered blood pressure monitor</b>	The product is approved as medical equipment in Japan, Europe and the US based on respective regulatory system	<ul style="list-style-type: none"> <li>Gianfranco Parati, Eoin O'Brien, et al. A New Solar-Powered Blood Pressure Measuring Device for Low-Resource Settings. <i>Hypertension</i> Nov. 8, 2010</li> </ul>
80	<b>Birthing simulator for training</b>		<ul style="list-style-type: none"> <li>Hofmeyr GJ, Haws RA, Bergström S, Lee ACC, Okong P, Darmstadt GL, Mullany LC, Oo EKS, Lawn JE. Obstetric care in low-resource settings: What, who, and how to overcome challenges to scale up? <i>IJGO</i> 2009;107:s21-s45.</li> <li>The portable Glostavent: a new anaesthetic machine for use in difficult situations. R Tully, R Eltringham, IA Walker, AJ Bartlett. <i>Anaesthesia and Intensive Care</i>, 2010, 38(6): 1085-9</li> <li>The Diamedica Draw-Over Vaporizer: a comparison of a new vaporizer with the Oxford Minature Vaporizer. WA English, R Tully, GD Muller &amp; RJJ Eltringham. <i>Anaesthesia</i> 2009, 64: 84-92.</li> <li>Modification of a draw over vaporizer for use with sevoflurane. T Payne, R. Neighbour &amp; R.Eltringham. <i>British Journal of Anaesthesia</i> 2012, 108(5):763-72012</li> <li><a href="http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(10)60518-1/abstract">http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(10)60518-1/abstract</a></li> </ul>
66	<b>Interventional cardiovascular lab</b>	CE marked product. Compliance to European Medical Directive Directive MDD/93/42 EEC. Manufacturing facility is ISO 13485 certified.	<a href="http://www.who.int/mediacentre/factsheets/fs317/en/">http://www.who.int/mediacentre/factsheets/fs317/en/</a>
67	<b>Intramedullary nail and interlocking screw system</b>	FDA cleared for use in the USA, Regulation Number 888.3020.	<ul style="list-style-type: none"> <li>WHO Global Status Report on Road Safety, 2009,</li> <li>WHO Global Burden of Disease Study, 2004.</li> <li>Ikem IC, Ogunlusi JD, Ine HR. Achieving interlocking nails without using an image intensifier. <i>SICOT</i> 2007 31:487-490.</li> <li>Calafi LA, Antkowiak T, Curtiss S, et al. A biomechanical comparison of the Surgical Implant Generation Network (SIGN) tibial nail with the standard hollow nail. <i>Injury</i> 41 (2010) 753-757.</li> <li>Young S, Lie SA, Hallan G, Zirkle LG, et al. Low infection rates after 34,361 intramedullary nail operations in 55 low-and middle-income countries. <i>Acta Orthopaedica</i> 2011; 82(6) 727-743.</li> <li>Sekimpi P, Okike K, Zirkle L, Jawa A. Femoral fracture fixation in developing countries: an evaluation of the Surgical Implant Generation Network (SIGN) intramedullary nail. <i>J Bone Joint Surg Am.</i> 2011 Oct; 93(19):1811-8.</li> </ul>
68	<b>Mobile ECG with web-based telemedicine platform</b>	Certified for CE - 1293	
69	<b>Multi-parameter remote diagnostic kit</b>	IEC60601-1 compliance completed, ISO13485 manufacturing process compliance. CE marking process underway.	
70	<b>Non-invasive hypothermia indicator for newborns</b>	CE No: 0434	<ul style="list-style-type: none"> <li>Green.D.A, Kumar.A,Khanna.R. Neonatal hypothermia detection by ThermoSpot in Indian urban slum dwellings. <i>Arch Dis Child Fetal Neonatal</i> Ed 2006;91:f96-F98. doi:10.1136/adc.2005.078410</li> <li><a href="http://www.who.int/reproductivehealth/publications/maternal_perinatal_health/MSM_97_2/en/index.html">http://www.who.int/reproductivehealth/publications/maternal_perinatal_health/MSM_97_2/en/index.html</a> ("Thermal protection of a newborn")</li> </ul>

Pg	Name	Regulatory	References
71	<b>Non-invasive vascular age risk prediction</b>		<ul style="list-style-type: none"> <li>Yusuf, S, Reddy, S, Ounpuu, S &amp; Anand, S. 2001. Global burden of cardiovascular diseases: Part 1: General considerations, the epidemiologic transition, risk factors and impact of urbanization. <i>Circulation</i>, 104(22):2746-53.</li> <li>Vintro, IB. 2004. Control and prevention of cardiovascular disease around the world (Editorials). <i>Rev Esp Cardiol</i>, 57(6):487-94.</li> <li>Yusuf, S, Hawken, S, Öunpuu, S, et al. 2004. Effect of potentially modifiable risk factors associated with myocardial infarction in 52 countries (the INTERHEART Study): Case-control study. <i>Lancet</i>, 364(9438):937-52.</li> <li>Allen, J. &amp; Murray, A. 2000a. Similarity in bilateral photoplethysmographic peripheral pulse wave characteristics at the ears, thumbs and toes. <i>Physiological Measurement</i> 21:369-377.</li> <li>Bots ML., Carotid intima-media thickness as a surrogate marker for cardiovascular disease in intervention studies. <i>Curr Med Res Opin</i>. 2006 Nov;22(11):2181-90.</li> <li>Bots ML, Dijk JM, Oren A, Grobbee DE. Carotid intima-media thickness, arterial stiffness and risk of cardiovascular disease: current evidence. <i>J Hypertens</i>. 2002 Dec;20(12):2317-25.</li> <li>Allen, J., Photoplethysmography and its application in clinical physiological measurement. <i>Physiol. Meas.</i> 2007, 28 R1</li> <li>Zahedi E., Chellappan K., Mohd Ali M.A. &amp; Singh H. Analysis of the Effect of Ageing on Rising Edge Characteristics of the Photoplethysmogram using a Modified Windkessel Model. <i>Cardiovascular Engineering</i>. 2007. 7(4):172-181.</li> </ul>
72	<b>Non-surgical male circumcision device</b>	FDA cleared (K103695) Certified CE Mark Class IIa Compliant to ISO 13485 Medical Devices (Quality Management systems) and FDA, 21 CFR177. 2600.	<ul style="list-style-type: none"> <li>Auvert B, Taljaard D, Lagarde E, Sobngwi- Tambekou J, Sitta R, Puren A. — Randomized, controlled intervention trial of male circumcision for reduction of HIV infection, risk: the ANRS 1265 Trial. <i>PLoS Med</i>. 2005 Nov;2(11):e298. Erratum in: <i>PLoS Med</i>. 2006 May;3(5):e298.</li> <li>Bailey RC, Moses S, Parker CB, et al. —Male circumcision for HIV prevention in young men in Kisumu, Kenya: a randomised controlled trial. <i>Lancet</i>. 2007 Feb 24;369(9562):643-56.</li> <li>Gray RH, Kigozi G, Serwadda D, et al. —Male circumcision for HIV prevention in men in Rakai, Uganda: a randomised trial. <i>Lancet</i>. 2007 Feb 24;369(9562):657-66.</li> <li>World Health Organization. —Progress in scale-up of male circumcision for HIV prevention in Eastern and Southern Africa: Focus on service delivery. 2011. Accessed online 2/3/2012: <a href="http://whqlibdoc.who.int/publications/2011/9789241502511_eng.pdf">http://whqlibdoc.who.int/publications/2011/9789241502511_eng.pdf</a></li> <li>Bitega, Jean. —Safety and Efficacy of the PrePex Device for Rapid Scale-Up of Male Circumcision for HIV Prevention in Resource-Limited Settings. <i>JAIDS Journal of Acquired Immune Deficiency Syndromes</i>: 15 December 2011 - Volume 58 - Issue 5 - p e127-e134. Accessed online 2/4/2012: <a href="http://journals.lww.com/jaids/Fulltext/2011/12150/Safety_and_Efficacy_of_the_PrePex_Device_for_Rapid.16.aspx">http://journals.lww.com/jaids/Fulltext/2011/12150/Safety_and_Efficacy_of_the_PrePex_Device_for_Rapid.16.aspx</a></li> </ul>
73	<b>Oral syringe dosing clip</b>		<ul style="list-style-type: none"> <li>Yin HS, Dreyer BP, Van Schaick L, Foltin GL, Dinglas C, Mendelsohn AL. Randomized controlled trial of a pictogram-based intervention to reduce liquid medication dosing errors and improve adherence among caregivers of young children. <i>Arch Pediatr Adolesc Med</i>. 2008; 162(9):814- 822.</li> <li>Yin HS, Wolf MS, Dreyer BP, Sanders LM, Parker RM. Evaluation of consistency in dosing directions and measuring devices for pediatric nonprescription liquid medications. <i>JAMA</i>. 2010;304(23)(doi:10.1001/jama/2012.1797)</li> </ul>
74	<b>Point of care diagnostic device for total WBC</b>	Medical products Agency, FDA 510(k) Clearance Ref 7 Certificate of Registration (LV) Ref 8 k 053253	<ul style="list-style-type: none"> <li>Point-of care method for total white blood count; An evaluation for the Hemocue WBC device A Osei Bimpong, C Jury R McLean, S.M Lewis <i>Int Jnl. Lab.Hem</i> 2009 31 657-664</li> <li>A Comparison of 2 White Blood Cell Count Devices to Aid Judicious Antibiotic Prescribing, Janet R. Casey and Michael E. Pichichero <i>Clin Pediatr (Phila)</i> 2009; 48; 29</li> </ul>
43	<b>Solar charger for hearing aid</b>		<ul style="list-style-type: none"> <li>World Health Organization, 2001, Guidelines for Hearing Aids and Services</li> </ul>
76	<b>Sputum mobilization device</b>	USFDA 501(k): K091557, K060439; Class I CE mark	<ul style="list-style-type: none"> <li>Novel method for sputum induction using the Lung Flute in patients with suspected pulmonary tuberculosis Fujita et al, <i>Respirology</i>, 2009</li> </ul>
77	<b>Urine albumin test</b>	CLIA waiver certificate Ref 7 k530253 -A002 Medical products Agency, FDA 510(k) Clearance Ref 9 Certificate of Registration (LV) Ref 10 k 053253	<ul style="list-style-type: none"> <li>Sarafidis PA, Riehle J, Bogojevic Z, Basta E, Chugh A, Bakris GL. A comparative evaluation of various methods for microalbuminuria screening. <i>Am J Nephrol</i>. 2008;28(2):324-9. Epub 2007 Nov 29.</li> </ul>

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For further reading about technologies and respective health problems: refer to references provided in the submission documents.

Pg	Name	Regulatory	References
90	<b>Isothermal nucleic acid amplification system for POC diagnosis</b>	CE Mark Our current manufacturing facility (capable of 1 million tests per year) has been approved by TUV for ISO 9001 and ISO 13485, and our TB tests are CE qualified	<ul style="list-style-type: none"> <li>Neglected diagnostics", Nature Methods - 4, 877 - 878 (2007).</li> <li>Reference(s): Fang, R., Li, X., Hu, L., You, Q., Li, J., Wu, J., Xu, P., Zhong, H., Luo, Y., Mei, J. et al. (2009) Cross-priming amplification for rapid detection of Mycobacterium tuberculosis in sputum specimens. J Clin Microbiol, 47, 845-847.</li> </ul>
83	<b>Manual wheelchairs and mobility devices</b>	ISO standard 7176, including fire retardant foam and fabric and is ISO 9001 (2008- 2013) and ISO 13845 (2008- 2013) certified	<ul style="list-style-type: none"> <li>WHO Guidelines on the provision of Manual Wheelchairs in less resourced settings.</li> </ul>
103	<b>Newborn simulator for resuscitation training</b>		<ul style="list-style-type: none"> <li>Lawn, J.E, Lee, A.C, Kinney, M., Sibley, L., Carlo, W.A., Paul, V.K., Pattinson, R., Darmstadt, G.L. Two million intrapartum-related stillbirths and neonatal deaths: Where, why, and what can be done? IJGO 2009; 107: s5-19.</li> <li>Stephen N. Wall , Anne CC Lee, Susan Niermeyer, Mike English , William J. Keenan , Wally Carlo, Zulfiqar A. Bhutta , Abhay Bang , Indira Narayanan, Iwan Ariawan, Joy E. Lawn. (2009). Neonatal resuscitation in low-resource settings: What, who, and how to overcome challenges to scale up? IJGO 2009; 107: s47-64.</li> </ul>
91	<b>Non-pneumatic anti-shock garment</b>		<ul style="list-style-type: none"> <li>World Health Organization (WHO) Department of Reproductive Health and Research. Maternal Mortality in 2000: Estimates Developed by WHO, UNICEF, and UNFPA. Geneva: WHO; 2004.</li> <li>Hensleigh PA. Antishock garment provides resuscitation and haemostasis for obstetric haemorrhage. BJOG. December 2002;109:1377-1384.</li> <li>Miller S, Ojengbede A, Turan J, Ojengbede O, Butrick E, Hensleigh P. Antishock garments for obstetric hemorrhage. Current Women's Health Reviews, 2007; 3:3-11.</li> <li>Miller S, Martin HB, Morris JL. Antishock garment in postpartum haemorrhage. Best Practice &amp; Research Clinical Obstetrics and Gynaecology. 2008; 22(6):1057-1074.</li> </ul>
92	<b>Oxytocin in prefilled auto-disable injection system</b>		<ul style="list-style-type: none"> <li>Tsu VD, Sutanto A, Vaidya K, Coffey P, Widjaya A. Oxytocin in prefilled Uniject injection devices for managing third-stage labor in Indonesia. International Journal of Gynaecology and Obstetrics. 2003;83(1):103-111.</li> </ul>
93	<b>Parasitological test system</b>	ISO 9001-2008 / ISO 13485-2003 CE mark / FDA	
94	<b>Phototherapy for neonatal jaundice treatment</b>	CE mark	<ul style="list-style-type: none"> <li>Martins BM, de Carvalho M, Moreira ME, Lopes JM. Efficacy of new microprocessed phototherapy system with five high intensity light emitting diodes (Super LED). J Pediatr (Rio J). 2007;83(3):253-258.</li> </ul>
104	<b>Point-of-use water disinfection system</b>	A cluster randomized control trial was carried out by UC Berkeley in 2009-2010 in 450 households using the UV Tube. The results are expected to be published in 2011 or 2012	<ul style="list-style-type: none"> <li>WHO. Diarrhoeal disease. Programmes and projects. Media center. Fact sheets. Vol. 2010, 2009.</li> <li>Brownell, Sarah A., Alicia R. Chakrabarti, Forest M. Kaser, Fermin Reygadas, Micah J. Lang, Lloyd G. Connelly, Rachel L. Peletz, Daniel M. Kammen, and Kara L. Nelson. 2008. Assessment of a low-cost, point-of-use, ultraviolet water disinfection technology. Journal of Water and Health 6, no. 1 (3): 53.</li> </ul>
95	<b>Portable haemoglobin meter</b>	BPF ANVISA / Brazil registration number: 80431950001 ( <a href="http://www.anvisa.gov.br/datavisa/Consulta_Produto_correlato/rconsulta_produto_detalhe.asp">http://www.anvisa.gov.br/datavisa/Consulta_Produto_correlato/rconsulta_produto_detalhe.asp</a> )	<ul style="list-style-type: none"> <li>Stoltzfus R.J. J. Defining Iron-Deficiency Anemia in Public Health Terms: A Time for Reflection. J. Nutr. 131: 565S-567S, 2001.</li> <li>Juliana, C.T et al. Prevalence of anemia among preschoolers and response to iron supplementation. Jornal de Pediatria, vol 87(1), 2011.</li> </ul>

Pg	Name	Regulatory	References
96	<b>Portable ventilator</b>	IEC 60601-1 Medical electrical equipment, Part 1: General requirements for safety  IEC 60601-1-2 General requirements for safety - collateral standard Electromagnetic compatibility- requirements and tests  IEC 60601-2-12 Medical electrical equipment Part 2-12: Particular requirements for the safety of lung ventilators -Critical Care ventilator	
97	<b>Prefilled auto-disable injection system</b>		<ul style="list-style-type: none"> <li>Tsu VD, Sutanto A, Vaidya K, et al. Oxytocin in prefilled Uniject injection devices for managing third-stage labor in Indonesia. <i>International Journal of Gynaecology and Obstetrics</i>. 2003;83(1):103-111.</li> <li>Bahamondes L, Marchi NM, Nakagave HM, et al. Self-administration with Uniject of the once-a-month injectable contraceptive Cyclofem. <i>Contraception</i>. 1997;56:310-304.</li> <li>Otto B, Suarnawa IM, Stewart T, et al. At-birth immunisation against hepatitis B using a novel pre-filled immunisation device stored outside the cold chain. <i>Vaccine</i>. 2000;18:498-502.</li> <li>Sutanto A, Suarnawa IM, Nelson CM, et al. Home delivery of heat-stable vaccines in Indonesia: outreach immunization with a prefilled, single-use injection device. <i>Bulletin of the World Health Organization</i>. 1999;77(2):119-126.</li> </ul>
98	<b>Reusable neonatal suction device</b>	The Product is FDA device listed and CE-marked.  The product has been developed in accordance with ISO 9001 and ISO 13485	<ul style="list-style-type: none"> <li>Lawn, J.E, Lee, A.C, Kinney, M., Sibley, L., Carlo, W.A., Paul, V.K., Pattinson, R., Darmstadt, G.L. Two million intrapartum-related stillbirths and neonatal deaths: Where, why, and what can be done? <i>IJGO</i> 2009; 107: s5-19.</li> <li>WHO, <i>Managing Newborn Problems: A guide for doctors, nurses, and midwives</i>. WHO, Geneva, 2003.</li> <li>Stephen N. Wall , Anne CC Lee, Susan Niermeyer, Mike English , William J. Keenan , Wally Carlo, Zulfiqar A. Bhutta , Abhay Bang , Indira Narayanan, Iwan Ariawan, Joy E. Lawn. (2009). Neonatal resuscitation in low-resource settings: What, who, and how to overcome challenges to scale up? <i>IJGO</i> 2009; 107: s47-64.</li> </ul>
100	<b>Transcutaneous bilirubin measurement system for infants</b>	FDA 510K # k010052	
105	<b>Water filter</b>		<ul style="list-style-type: none"> <li>WHO, <i>Guidelines for Drinking Water Quality</i>, 3rd Ed. 2004. <a href="http://www.who.int/water_sanitation_health/dwq/GDWQ2004web.pdf">http://www.who.int/water_sanitation_health/dwq/GDWQ2004web.pdf</a></li> </ul>













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

Assistive devices  
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