

# INNOVATIVE TECHNOLOGIES THAT ADDRESS GLOBAL HEALTH CONCERNS

OUTCOME OF THE CALL  
GLOBAL INITIATIVE ON HEALTH TECHNOLOGIES  
2010



World Health  
Organization

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Organization**

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# List of Abbreviations

WHO	World Health Organization
AGIT	Advisory Group for Innovative Technologies
PMD	Priority Medical Devices (project)
GBD	Global Burden of Disease (study)
MDGs	Millennium Development Goals
WHA	World Health Assembly
GDP	Gross Domestic Product

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# 1. Introduction

The World Health Assembly (WHA) Resolution 60.29 on Health Technologies recognizes that medical devices are indispensable tools in health care delivery for prevention, diagnosis, treatment and rehabilitation (1). It acknowledges that medical devices are essential to attain the internationally agreed health-related development goals, including those contained in the Millennium Declaration (2). It is widely accepted that the availability of, and access to appropriate and affordable health technologies in low- and middle-income countries are still insufficient.

In addition the WHA Resolution 61.21 on global strategy and plan of action on public health, innovation and intellectual property, acknowledges that (current) initiatives are not sufficient to surmount the challenges of ensuring access to, and innovation of, much needed health products and medical devices (3).

As a result of these resolutions, the World Health Organization (WHO) launched the Global Initiative on Health Technologies. Funded by the Bill and Melinda Gates Foundation, the initiative's goal is to make available the benefits of core health technologies at an affordable price particularly to communities in resource limited settings in order to effectively control important health problems. This initiative includes the development of guidelines and tools for health technology management, a call for innovative technologies (the results of which are discussed in this report), and the organization of a Global Forum on Medical Devices in Bangkok in September 2010.

The call for innovative technologies that took place from September 2009 to June 2010 sought to identify and evaluate innovative medical devices (including assistive devices) either existing or under development, which address global health concerns. A total of 84 submissions from 28 countries were received by the deadline of 31 January 2010.

Following an initial screening by WHO, 68 applications were sent for evaluation by external experts. From these, 15 were selected and posted on the web site<sup>1</sup> of the WHO Department of Essential Health Technologies in June 2010. This report discusses the selection process of the call and presents the 15 innovative technologies deemed to hold promise in reducing the global burden of disease. It is hoped this report will foster the development and availability of these technologies, particularly for those in low- and middle-income countries. Additional information about the call, including its guidelines and scope, is available in Annex 1.

Selection of these technologies does not imply WHO endorses any particular product; WHO solely aims to draw stakeholders' attention to innovative technologies to further their development, availability, and access. Interested parties should consider this report a call for further research and evaluation of not just the technologies selected, but all others submitted that can potentially reduce the burden of disease and disability worldwide.

The challenges faced by the applicants to succeed in getting their technologies into resource-limited settings are numerous and have been detailed in the WHO report *Medical devices: managing the mismatch* (4) as well as being discussed here. Once these challenges are met with the resources from industry, academia, and other stakeholders, these and many other innovative technologies can begin to ameliorate the health and well-being of all people. To this end, WHO will continue to work in search of appropriate, affordable, and available health technologies (in particular medical devices) that can reduce the global burden of disease.

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1 [http://www.who.int/medical\\_devices/call\\_selected\\_innovative\\_tech/en/index.html](http://www.who.int/medical_devices/call_selected_innovative_tech/en/index.html).

## 2. Background

### 2.1 Programme Objectives

Successful health care delivery requires effective medical devices to act as tools for the prevention, diagnosis, and treatment of diseases, as well as for rehabilitation purposes. Despite the exponential growth in scientific and technological development, low- and middle-income countries are still largely excluded from access to appropriate and affordable health technologies. Attainment of the health-related Millennium Development Goals (MDGs),<sup>1</sup> effective control of many diseases, and empowerment of those living with disabilities will not be possible without certain basic technologies.

The WHA Resolution 60.29 on health technologies emphasizes the role of medical devices and health technologies in health care, as well as their current suboptimal contribution to health outcomes:

“Understanding that health technologies, and in particular medical devices, represent an economic as well as a technical challenge to the health systems of many Member States, and concerned about the waste of resources resulting from inappropriate investments in health technologies that do not meet high-priority needs, are incompatible with existing infrastructures, are irrationally or incorrectly used, or do not function efficiently” (1).

A strategic objective of WHO’s plan for 2008–2013(5) is to ensure improved access, quality, and use of medical products including medical devices; this recognizes medical devices as tools with which to provide health care and enhance the health of people. In order to facilitate equitable access to the necessary core technologies, the WHO Department of Essential Health Technologies is tasked with identifying and promoting innovative technologies that address global health concerns and stimulating their further development.

### 2.2 Global investment in health technology

The Landscape analysis conducted by WHO (6) investigated the likelihood of any technology corporation developing or adapting technologies for global health purposes using their own funds. The following section summarizes some of the findings of that report relating to technology innovation.

Low- and middle-income countries bear a greater share of the global burden of disease than do high-income countries. In 2004, the regions of South-East Asia and Africa – comprising primarily low- and middle-income countries – bore 54% of the global disease burden, though they account for only about 40% of the world’s population. Despite this inequity, low- and middle-income countries spent much less on health as a percentage of gross domestic product (GDP) than did high-income countries (7).

Since 2002 an average of 200 new technologies per year have been added to the EuroScan database for innovative health technologies (8). A review of EuroScan’s public access database<sup>2</sup>, however, showed an apparent lack of information on technologies suitable for low-income countries.

1 [http://www.who.int/topics/millennium\\_development\\_goals/en/](http://www.who.int/topics/millennium_development_goals/en/).

2 <http://www.euroscan.org.uk/>

One common indicator of innovation activities is the number of new patents being registered. In terms of the country of origin the largest number of patent applications in the field of medical technology between 2001 and 2005 came from the United States of America (35%) and Japan (20%) although it is worth noting that several emerging economies such as Brazil, China, and India ranked high on the list (9).

As shown through patent activities and the EuroScan database, the focus of industry is not on innovative technologies for the developing world. In order to address this gap, new strategies are required to encourage investment in health technologies that deal with challenges specifically faced in low- and middle-income countries.

## 2.3 Global Initiative on Health Technologies

The Department of Essential Health Technologies initiated the Global Initiative on Health Technologies<sup>1</sup> in March 2008. The overall goal of the initiative is to help address important health problems associated with communities in resource-limited settings by making available the benefits of core health technologies, through equitable access and affordability. This requires technology innovation, either in the technologies themselves or in the processes designed to facilitate their dissemination, application, and utilization.

The two specific objectives of the initiative are to challenge the international community to establish a framework for the development of national health technology programmes that will lower the burden of disease and ensure effective use of resources; and challenge the business and scientific communities to identify and adapt innovative technologies that can have a significant impact on improving public health in developing countries.

### 2.3.1 Call for innovative technologies

The call for innovative technologies challenged manufacturers, institutions, universities, governments, individuals, and non-profit organizations which design, manufacture and/or supply any type of medical device to focus their activities towards addressing the global health concerns outlined below.

- Alcohol use disorders
- Birth asphyxia and birth trauma
- Cancer
- Cerebrovascular disease
- Chronic obstructive pulmonary disease
- Deficient maternal health
- Diarrhoeal diseases
- Disability
- HIV/AIDS
- Infant and child (under 5) mortality
- Ischaemic heart disease
- Lower respiratory infections
- Malaria
- Neonatal infections
- Prematurity and low birth weight
- Refractive errors
- Road traffic accidents
- Tuberculosis
- Unipolar depressive disorders

<sup>1</sup> [http://www.who.int/medical\\_devices/appropriate\\_use/en/](http://www.who.int/medical_devices/appropriate_use/en/).

The project aims to optimize public health outcomes by encouraging innovation through:

- increasing understanding among decision-makers about the critical role of health technologies and innovation in promoting public health;
- stimulating the development of new technologies;
- promoting the use of technologies that are safe and/or simpler to use than earlier solutions;
- promoting technologies that are more cost-effective than previous technologies;
- identifying new health-related uses of existing non-health technologies that can have a significant and immediate impact on improving public health; and
- facilitating the dissemination, application, and utilization of new technologies.

## 3. Call for innovative technologies

### 3.1 Key phases

The key phases of the call for innovative technologies consisted of the launch, outreach, deadline, and announcement of results; they are detailed below. Further information regarding the call can be found on the web site of the Department of Essential Health Technologies<sup>1</sup>.

#### 3.1.1 Launch

WHO launched the call for innovative technologies at the World Congress on Medical Physics and Biomedical Engineering in Munich on 11 September 2009. The health concerns to be addressed and the selection criteria to be used, which were developed with assistance of the Advisory Group on Innovative Technologies (AGIT) and WHO collaborating centres for health technologies, were also presented.

#### 3.1.2 Outreach

To disseminate the call WHO engaged in outreach activities including participation in MEDICA (the world's largest medical device trade fair), mailing information out to health technology stakeholders such as professional societies, manufacturers' umbrella organizations, and posting on health technology web sites.

#### 3.1.3 Deadline

The deadline for submissions was 31 January 2010. In total, 84 submissions were received from 28 countries.

#### 3.1.4 Announcement of results

A list of selected technologies was posted on the WHO web site<sup>2</sup> on 30 June 2010.

### 3.2 Screening and Selection Process

#### 3.2.1 Categories

The applicants had the opportunity to submit their technology into one of two categories, based on their level of maturity.

**Category 1** comprises commercialized products or products which are ready to be commercialized. This includes new products; products which have been commercialized for less than five years in high-income countries and which are not (yet) widely used in low- and middle-income countries; recent adaptation of existing non-health products for a health purpose; and/or recent adaptation of an existing medical device for low- and middle-income settings.

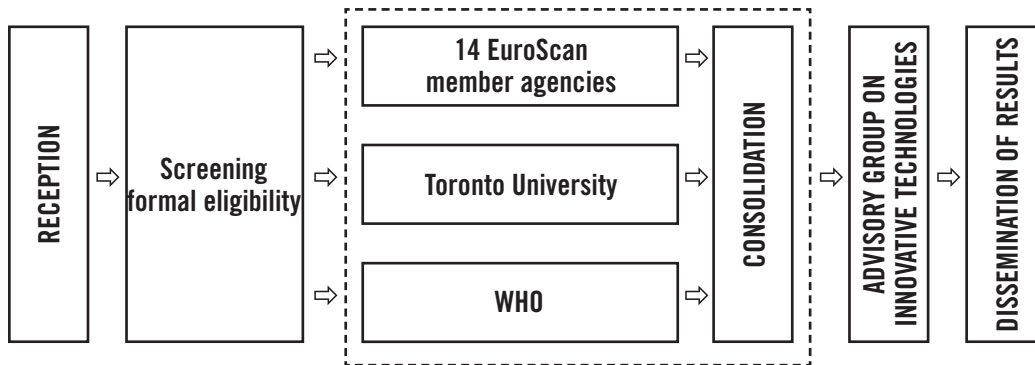
1 [http://www.who.int/medical\\_devices/call\\_selected\\_innovative\\_tech/en/index.html](http://www.who.int/medical_devices/call_selected_innovative_tech/en/index.html).

2 [http://www.who.int/medical\\_devices/call\\_selected\\_innovative\\_tech/en/index.html](http://www.who.int/medical_devices/call_selected_innovative_tech/en/index.html).

**Category 2** comprises products in a non-commercialized stage or that are not ready to be commercialized; it includes products which are under development or otherwise in a conceptual stage.

The process for screening, evaluation and selection is shown in Figure 1.

**Figure 1. Overview of the screening, evaluation and selection process**



### 3.2.2 Reception and screening of submissions

WHO only considered applications which were complete, within the scope of the call, and which were received by 31 January 2010. An identifier code was assigned to each application and all information about the applicant was removed to maintain confidentiality during the evaluation process.

### 3.2.3 Evaluation

The 68 anonymous applications that passed the initial screening by WHO in February 2010 were then sent to selected WHO collaborating institutions to determine how well they conformed to the selection criteria of the call and to assess their level of innovation.

The evaluation and grading process was undertaken by WHO staff, two teams of experts at Toronto University (appointed by WHO), and 14 member agencies of EuroScan during a period of approximately six weeks. All external evaluators signed confidentiality agreements. The evaluators were of different professional backgrounds including physicians, biomedical engineers, usability experts and health technology assessment specialists. The applications were graded on a scale from 1 to 5 by the evaluators solely based on the submission forms received without annexes. The grading was returned to the WHO Secretariat, which compiled the data to prepare for the selection process.

### 3.2.4 Recommendation for selection

The submission forms and the related grading were presented to the Advisory Group on Innovative Technologies (AGIT) by the WHO Secretariat. The AGIT was composed of experts in the field of health technologies representing a wide panel of competencies and geographical origins. Its members declared any conflicts of interest prior to participation; expert reviewers with any conflicts did not participate in the review.

In the advisory group meeting that took place 27-29 April 2010 in Copenhagen, the experts were divided into four groups, two for each category. The four expert groups reviewed the original selection as well as identified outliers. Outliers here refer to technologies that had been graded very differently by different evaluators. Each member of the group read the information provided on the application. Subsequently the groups discussed the submissions

with regard to the six selection criteria. All groups provided their recommendation for or against selection including reasoning and general comments. After reviewing all submissions, the two teams for each category presented their results to each other and engaged in further discussions. The final recommendation to the WHO Secretariat was provided in a plenary session.

Reviewers considered the following criteria when evaluating the submitted technologies:

- level of safety for the user, patient and the environment;
- effectiveness in addressing the health concern in question;
- level of adaptation to local infrastructures in resource-limited settings;
- ease of use and maintenance;
- total cost of ownership, cost-effectiveness and affordability; and
- level of cultural and social acceptability.

The major limitation identified by the experts was the difficulty to apply a single set of criteria in a consistent fashion to applications pertaining to a vast array of medical devices addressing numerous diseases and at very different levels of development.

The final selection of the 15 technologies discussed in this report was made by WHO based on the recommendations from the AGIT.

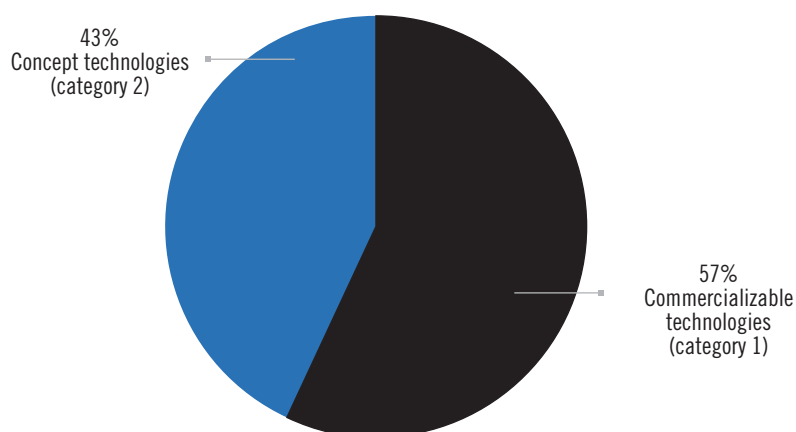
Evaluations were based solely on the information provided in the submitted documents. Therefore, further independent evaluation will be needed to ensure the successful implementation of the submitted technological innovations.

### 3.3 The Response

#### 3.3.1 Submissions by category

Of the 68 submissions that passed initial screening more than 50% were commercialized or able to be commercialized (Figure 3).

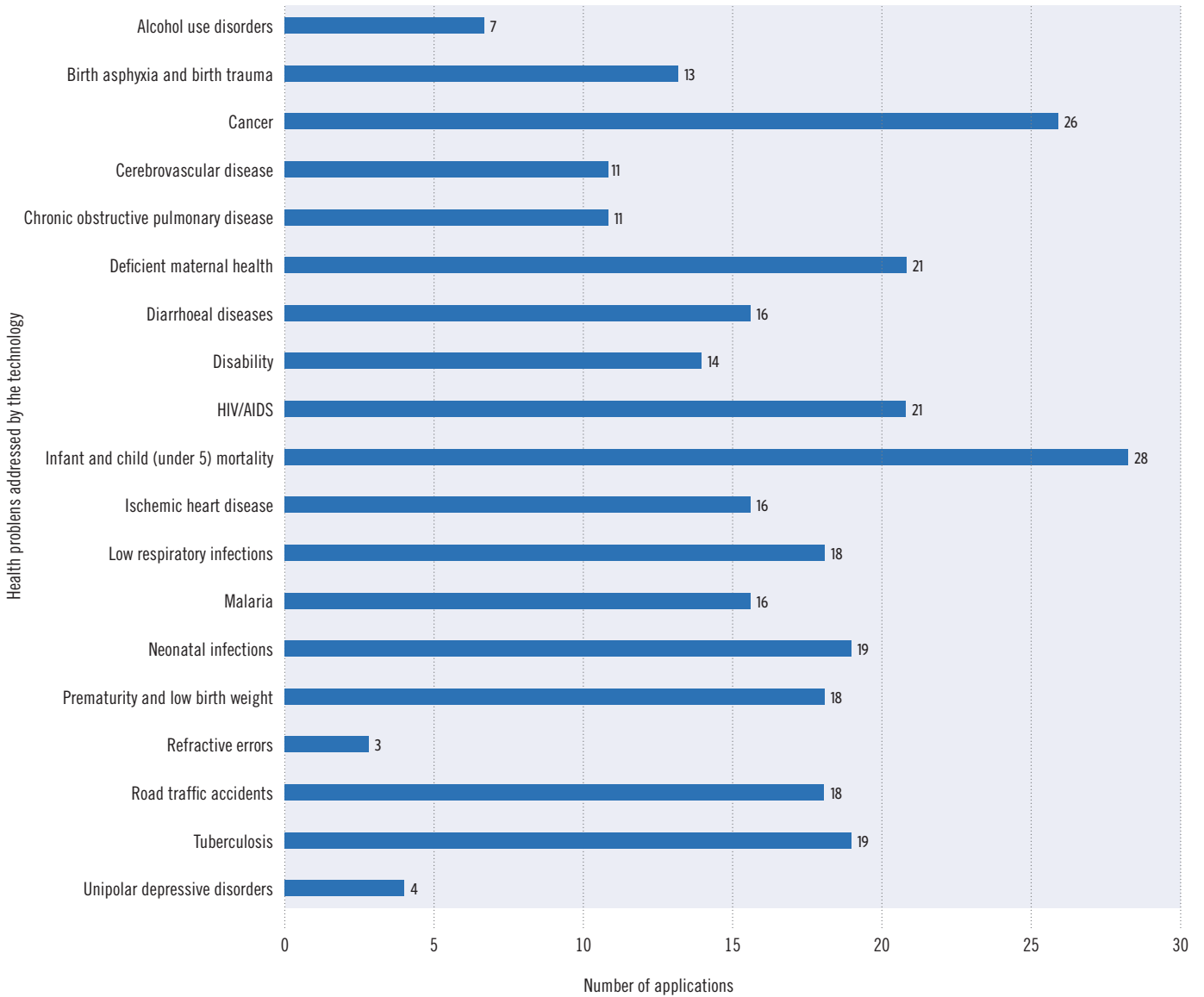
**Figure 3. Submissions by category: commercializable and concept technologies**



### 3.3.2 Global health concerns addressed

Each applicant claimed that the submitted technology addressed one or more of the 19 global health concerns indicated in the scope of the call. Each applicant could select more than one health concern and a number of the products do in fact serve multiple needs within the medical sector (Figure 4).

**Figure 4. Global health concerns addressed by the technology (by number of applications)**

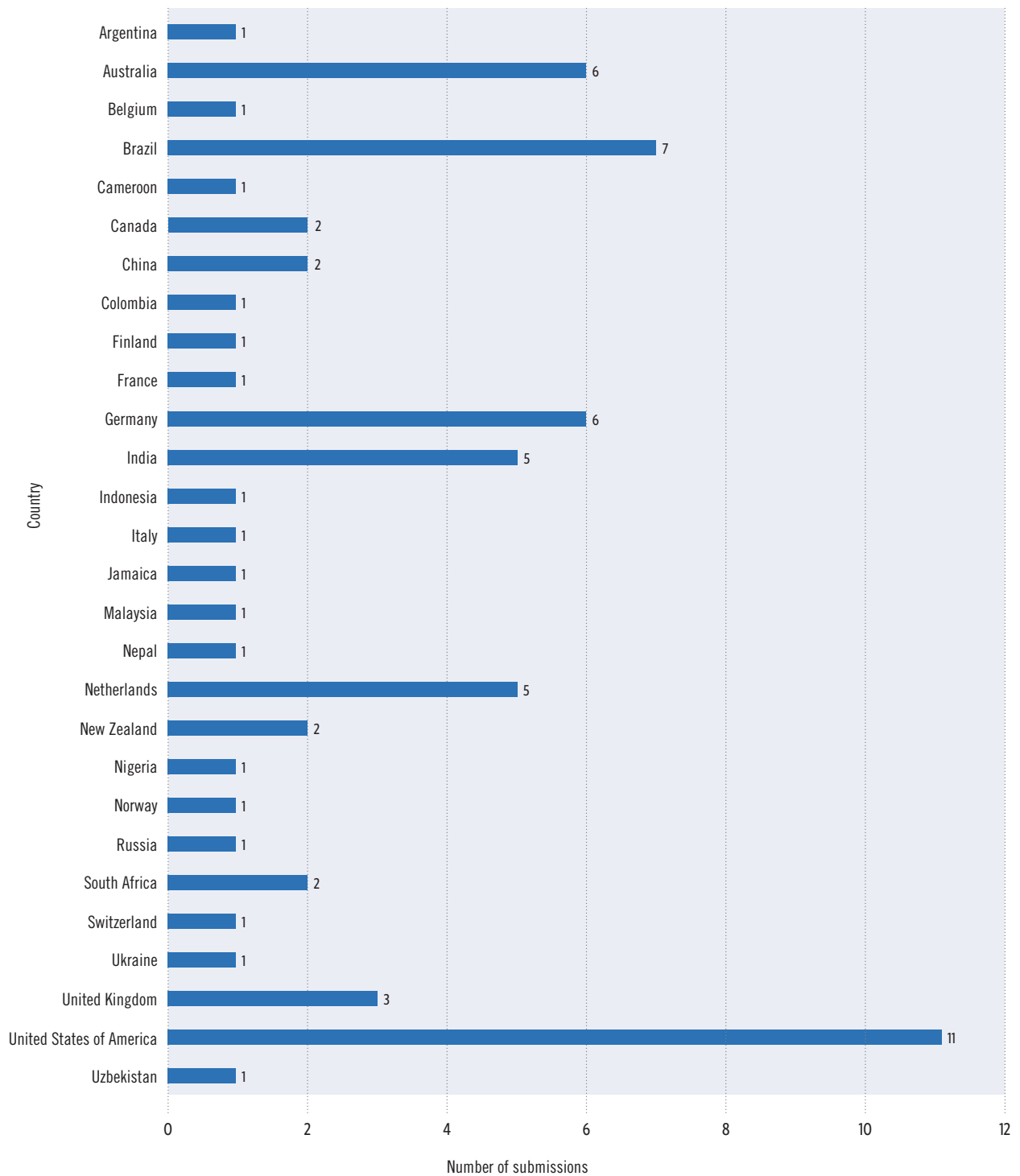




### 3.3.3 Country submissions

Figure 5 shows the 28 countries from which technologies were submitted. Participation came from countries with diverse income levels.

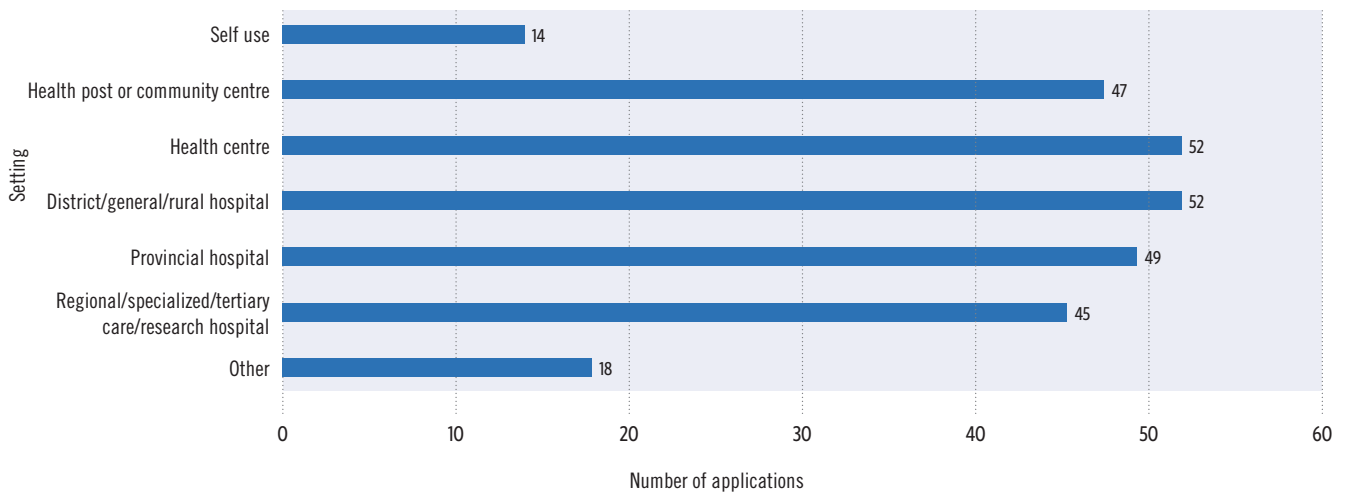
**Figure 5. The number of technology submissions received, by country**



### 3.3.4 Intended users of submitted technologies

Most submissions are intended for use by health-care professionals but 14 are intended for self-use. Each applicant could select more than one intended user and it seems that most innovations can be used in multiple health care settings (Figure 6).

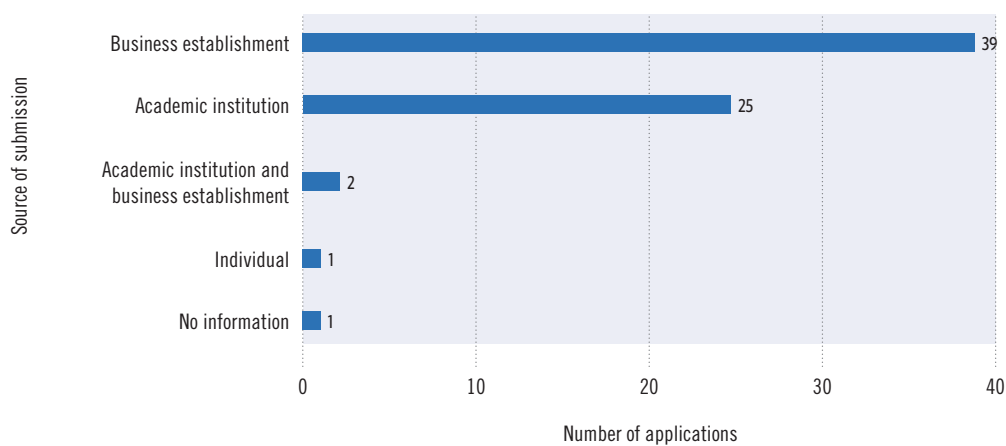
**Figure 6. Settings for intended use of proposed technologies**



### 3.3.5 Source of submissions

The vast majority of proposals were submitted by academia and industry; a few were also contributed by individuals and organizations specialized in innovative technologies for resource-scarce settings (see Figure 7).

**Figure 7. Submissions received, by type of institution**



## 3.4 Submissions

### 3.4.1 Submitted technologies

Tables 1 and 2 show the 84 submitted technologies, and reflect the variety of technologies and diversity of intended use.

**Table 1. Submitted commercialized technologies or those ready to be commercialized (category 1)**

Cervical cancer screening based on detection of cell membrane cancer markers in cervical smears
Clinical decision support software
Clinical patient data software
Congenital disease screening system
Diabetic foot detection system based on temperature measurement
Diagnostic/Screening test for bladder cancer
Digital X-ray system
Electric stimulation neurotherapy
Electronic health record patient interface
Exercise kit
External fixator
Face masks
Fluorescence visualization of abnormalities in oral cavity
Fuel efficient wood stove
Gravity-based blood separation system
Isothermal nucleic acid amplification system for tuberculosis diagnosis
Laryngoscope
LED phototherapy unit
Magnetic coils for destruction of pathogens
Mobile laboratory for diagnosis (cardiac, cancer, respiratory)
Mobile phone system for sending microscope images
Multi parametric patient monitor
Nano filters for water treatment
Newborn simulator
Patient data information system
Patient management system software
Portable haemoglobin meter
Portable telemedicine system
Portable ultrasound imaging system
Portable ventilator for chronic obstructive pulmonary disease
Radiation treatment system for health care waste
Reusable neonatal suction system

Rotational field quantum nuclear magnetic resonance
Single use male circumcision device
Short message service (SMS) for smoking cessation
Stool sample collection and preparation kit
System for on-site production of wound irrigation solution
Telehealth system
Transcutaneous bilirubin measurement system
Ultrasound transducer disinfection system
Vapour sterilization system
Water dispenser for hand wash
Web-based ECG cardiac diagnosis system
Wheelchair based on standard components
X-ray imaging system

**Table 2. Submitted technologies in a non-commercialized stage of development (category 2)<sup>1</sup>**

Accuracy tester for electronic fetal heart rate monitor
Ambient gas plasma system for antisepsis
Anti thrombotic coronary artery bypass graft
Bio potential and impedance measurement-based monitoring for cardiovascular diseases
Birth simulator
Decision support system for paediatric HIV
Drug authentication system
Drug packaging with extended shelf life
External fixator
Isolator system for minimally invasive surgery
Laboratory in a backpack
Micro-endoscope for cancer screening
Mobile phone-based pregnancy risk assessment system
Mobile phone-based pulse oximeter
Mosquito repellent skin lotion
Multi fever diagnosis system
Paediatric stretcher
Patient data information system
Portable infant warmer
Portable infusion system
Portable on-site cell sorter and counter for HIV and malaria diagnosis

<sup>1</sup> Two submitted applications were incomplete and one was a repeat application and are therefore not presented in the list.

Portable telemedicine system
Remote fetal heart rate and activity monitoring
Remote palliative radiotherapy system for terminal cancer
Safety seat for children (road transport)
Semi-automated system for mycobacteria detection
Simplified anaesthesia unit
Single use assistive vaginal delivery system
Single use male circumcision device
Solar reading light
Solar-powered autoclave
Sub-dermal implant for drug delivery
System for biological screening to be used in current hygiene products
Telemedicine resource for emergency care
Transcutaneous anaemia monitoring system
Wireless system for transmission of vital signs in neonatal intensive care units

### 3.5 The selected technologies

Fifteen innovative medical devices were selected from the submissions: eight from category 1 and seven from category 2. In this section, each selected medical device is briefly introduced. Each applicant provided a poster that describes the submitted technology. Applicants' contact information is also provided to facilitate communication between the innovator and any interested parties.

The innovative technologies that were selected by the AGIT, external evaluators, and the WHO Secretariat, show potential to help reduce the global burden of disease.

Bearing in mind that the evaluation by the team of experts is solely based on the assessment of data and information submitted in the applicants' dossiers, inclusion in the Lists of Selected Innovative Technologies does not constitute a warranty of the fitness of any selected technology for a particular purpose. Besides, the responsibility for the quality, safety and efficacy of each selected technology remains with the manufacturer. The decision to list a particular technology is subject to change on the basis of new information that may become available to WHO. If there is evidence of serious safety and/or quality issues in relation to a listed technology, WHO may withdraw the technology concerned from the list until results of further investigations become available and are assessed by WHO.

WHO will not be held to endorse nor to recommend any listed technology. The Lists of Selected Innovative Technologies solely aim at drawing stakeholders' attention to innovative medical devices, either existing or under development, with a view to fostering the development and availability of, and/or access to, innovative health technologies which are likely to be accessible, appropriate and affordable for use in low- and middle-income countries.

Inclusion in the Lists of Selected Innovative Technologies does not furthermore warrant or represent that:

1. the list is complete or error free; and/or that
2. the technologies which have been found to meet the selection criteria will continue to do so; and/or that
3. the use of the selected technologies listed is, or will be, in accordance with the national laws and regulations of any country, including but not limited to patent laws; and/or that
4. any medical device or product that may be developed from selected applications will be successfully commercialized in target countries or that WHO will finance or otherwise support the development or commercialization of any such medical device or product.

WHO disclaims any and all liability and responsibility whatsoever for any injury, death, loss, damage or other prejudice of any kind whatsoever that may arise as a result of, or in connection with the procurement, distribution and/or use of any listed technology or resulting medical device or product and any future development thereof.

# COMMERCIALIZABLE TECHNOLOGIES (CATEGORY 1)

## 3.5.1 Stool sample collection and preparation kit

The purpose of the kit is to simplify faecal examination by reducing the number of consumables and steps required for the procedure. The kit could therefore facilitate the diagnosis of parasitological diseases. Additionally, the kit does not appear to require water or electricity and is claimed to prevent contamination of the environment.

### Technological Innovation in the Diagnosis of Enteroparasitosis

Lapenna, José Carlos - Brazil

**Introduction**

Intestinal parasites are still responsible for the onset of neglected diseases in billions of people, mostly children, in both developing and developed countries<sup>1</sup>. Parasitism may compromise physical and cognitive development of its carrier<sup>2</sup>. The practice of deworming in children has been common without proper diagnosis of the causative agent of infection, which may contribute to perpetuating the parasite species in poor communities with poor socioeconomic conditions<sup>3</sup>. Additionally, it may mask the actual conditions of sanitation in these regions, especially the final allocation of human waste and water treatment for human consumption. Therefore, the improvement of parasitological methods in order to make them more efficient, safe and fully accessible to low-income countries is a social need as well as a priority for global public health.

- Eliminates bad odors
- No refrigeration needed
- Preserves stool sample for over 30 days
- No Ethyl acetate necessary
- Reduces drastically the Diagnostics time and costs



**Method of Collection Parasitological Examination**

**Collecting**



Open the plastic bag, remove the container, hold it firmly and open the screw cap.



Fill coned portion of premeasurement spoon with stool specimen. Only two full premeasured spoon is required\*  
\*In case of diarrhea use three premeasured spoon portions.



Scratch stool specimen against the extractor inside the container to release the stool into formula. Discard premeasured spoon; securely fasten cap and label container; place container back in original packaging and return it to your medical provider.

**Laboratory Direction**



Remove cap before shaking the flask. It will release any gases generated inside the vial.



Shake the vial until you get a homogenous moisture; then open it up again, in order to release any gases.



With the flask still open, over a paper towel, turn the vial up side down, without pression, just to remove any excess and put in the tray for at least 15 minutes.



Remove the vial, squeeze gently and place two drops of homogenized sample onto a glass microscope plate.



**The future is in our hands.**

**A Proposal for Technological Innovation in the Coprological Diagnosis**

As a proposal for technological innovation, a kit was developed in Brazil, whose principle is based on the spontaneous concentration of parasite forms. This kit involves filtration in a closed system that ensures environmental and handlers' biosecurity and contains a liquid for preserving the parasite forms. Easy and inexpensive, the kit is the only innovation in recent years that may contribute to the prevention and control of intestinal parasites, particularly in low-income countries.

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### 3.5.2 LED phototherapy unit

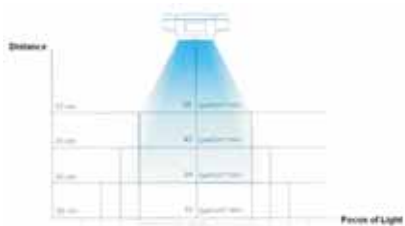
The purpose of the unit is to treat hyperbilirubinaemia in newborn infants by phototherapy. The unit could increase the safety of the procedure by using a radiation source that produces blue light and minimizes exposure to harmful ultraviolet radiation. Further potential advantages are that the unit measures the actual output of light at useful wavelengths and is claimed to have lower energy consumption than previous designs.

## Jaundice: Innovative LED phototherapy

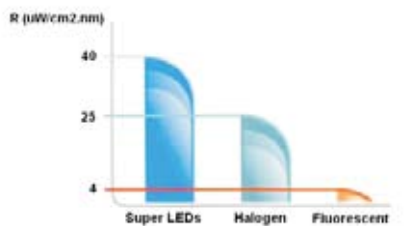
### Need of Phototherapy

Phototherapy is used for treatment for jaundice, a common condition in newborn infants caused by high levels of seric bilirubin, which may cause chronic bilirubin encephalopathy (kernicterus). Jaundice newborns have yellowing of the skin and the whites of the eyes. This condition is common in more than 70% of the newborns. Phototherapy treatments decrease the bilirubin levels in the blood by changing the trans-bilirubin into cis-bilirubin isomer, which is water-soluble.

### Data and Testing Methodology



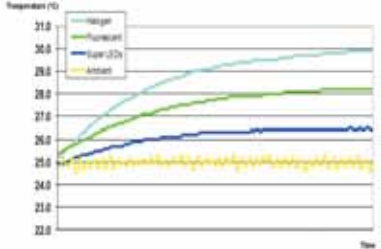
*Estimated Radiance at different Distances*



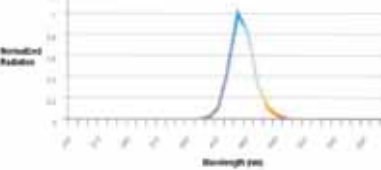
*Radiance Measured by different light sources*

### Technology by Super LEDs

Phototherapy is the most effective treatment when the light used is around 450nm of the light spectrum wavelength, which corresponds to the blue color. Super LEDs provide light precisely at this wavelength and have an abrupt attenuation of the irradiance from the infra-red and ultra-violet wavelength ranges, reducing undesired effects to the infant's skin. The radiance levels are higher, which decreases treatment time considerably. Also, the power consumption and the heating caused by the Super LEDs are very low when compared with other sources of light.




*Temperature measured at laboratory tests placed at the same distance for treatment by using different light sources*




*Super LEDs Radiation Spectral Curve Range*

### Product Features


- Reduced Size (23.5cm x 11.5cm)
- Great radiation in both the middle and the borders of the irradiation area
- Low energy consumption
- Advanced blue spectrum irradiation technology
- Infra-red and ultra-violet rays attenuator
- Soft touch buttons and microprocessor of various functions
- Wide adjustment of radiation intensity according to basic necessities
- Watch/Calendar
- Lamp time counter
- Treatment time counter
- Memory of radiation, manual or automatic measurements, to print in report.
- RS-232 output for printers or computers
- Easy Access to the supply module, for cleaning and maintenance
- Radiometer with Optical Probe can be integrated



*Super LEDs Phototherapy with Integrated Radiometer*



### Versatility



*Infant can be treated in cradles, incubators and infant warmers*

**References:**  
 1. 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):253-256.  
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### 3.5.3 System for on-site production of wound irrigation solution

The purpose of the system is to produce aqueous solutions for the topical treatment of wounds and infections using a power source, dematerialized water, and salt. Solutions produced by the system could be used to treat a host of conditions including traumatic injuries, post-natal infections, and neglected tropical diseases that cause ulcerations and infections.

Martina Janßen  
Hermann Kranzl  
Immanuel Jacobs

## System for On-Site Production of Wound Irrigation Solution

#### MEDICAL ISSUE

##### On-site Production of Wound Irrigation Solutions

The Technology and the specifically designed equipment allow for need-based and cost effective on-site manufacturing of high quality wound irrigation solutions for decontamination, control of infections and stimulation of wound healing in accordance with modern standards for moist wound treatment.

##### Wound Irrigation Solutions for Modern Treatment Standards

The Technology provides means for topical treatment of wounds and infections meeting modern standards of wound management, such as wound irrigation, moistening and moisture of wounds. Users are provided with the possibility to manufacture their own solution for wound irrigation and wound moisture in a basic and cost effective way. Due to the specific properties of the solutions moist wound treatment conditions can be implemented in combination with simple and cost-effective wound dressing materials (e.g. cotton swabs and cotton compresses).

Wounds

Burns

**Health Issues Addressed**

Skin Diseases

Mucous membranes Infections

Neonatal / Postnatal Infections

##### Features of the Technology

- Covers a wide range of applications in a neglected sector of primary health care;
- Can prevent enormous secondary health complications with basic means;
- Shows immediate positive effects on the health situation;
- Requires no programs in preparation;
- Facilitates autonomy in supplies;
- Can be applied by using existing structures;
- Is safe and environmentally compatible.

##### CE-Certification

The Technology is a quality assured advancement and optimization of existing diaphragm-electrolysis for application in the medical field. The wound irrigation solutions are meeting all requirements for medical application and all relevant EU standards with regard to safety and efficiency of medical devices.

#### IMPLEMENTATION

##### Equipment

The production devices are designed for decentralized and on-demand manufacture of the solutions from basic source materials (dematerialized water and sodium chloride) using advanced diaphragm-electrolysis-technology.

Water  
H<sub>2</sub>O

Salt  
NaCl

**Operational requirements:**

- **Water**  
dematerialized (or distilled, if available)
- **Salt**  
max. 2,0 g per liter
- **Electric power**  
power supply: 100-240 V AC or 24 V DC;  
max. 300 W.

**Device Specifications:**

Total weight: 18 kg  
Dimensions: 41,5 x 33,0 x 51,5 cm  
Automatic controls

The production device is a compact, portable desktop device for on-site production of Anode and Anode Neutral solutions. For production a source solution of dematerialized water and sodium chloride (max. 2,0 g of salt per liter) is prepared and filled into the respective feed container of the device. When the production process is started, the source solution flows through the membrane-electrolytic cell and is electro-chemically activated. When finished the device stops automatically.

Production of 1 liter Anode or Anode Neutral solutions (concentrate) takes 12 minutes. Diluted with water to a maximum concentration of 30% this provides for 3,3 liters of ready for use irrigation solution.

##### Production Technology

The basic technical process of the Technology is based on diaphragm-electrolysis (a special form of electrolysis). The technical procedure is called electro-chemical activation.

In the diaphragm-electrolysis process, a source solution - dematerialized water and a small quantity of highly pure salt - is conducted through the electrolysis cell and exposed to the effect of electric current.

Thereby different processes of chemical and electro-chemical nature are running parallel and generate products, which in comparison to the source solutions show modified physical and chemical properties (electrical conductivity, pH value, ORP, structural composition). Besides different chlorine compounds the solutions contain a high number of ROS (reactive oxygen species) such as oxygen ions, ozone, hydroxide ions and hypochlorous acid and have a high oxidation-reduction-potential.

Due to the specific production process the shelf-life is limited.

#### HEALTH IMPACT

##### Cleansing and Decontamination of Wounds

The interaction of different, highly reactive oxidants in the fluids leaves no chance for microorganisms. Tests have confirmed that the solutions are effective in decontamination against a wide spectrum of microorganisms.

**Decontamination Properties of Anode solution / Anode Neutral Solution**

**Staphylococcus aureus**  
**Multiresistant Staphylococcus aureus (MRSA)**  
**Escherichia coli**  
**Pseudomonas aeruginosa**  
**Legionella pneumophila**  
**Candida albicans**

##### Stimulation of Wound Healing / Bioelectrical Effects

Electrical processes are playing a central part in and on wounds („wound electricity“). Intact, vital skin has endogenous bioelectrical properties. Deeper skin layers are positively, the skin surface is negatively charged. The charge balancing (short circuit), that occurs in injuries, generates a measurable wound current. Defensive cells, fibroblasts and epithelial cells (Galvano-/Electrotaxis) are attracted and activated. The physiological processes of wound healing - provision and release of mediators and stimulation of blood circulation - in the wound perimeter can be favourably affected and stabilized. However the electrical potential is exhausted in complicated resp. large wounds or extended healing processes. In chronic wounds the wound current ceases almost entirely.

The Anode and Anode Neutral Solutions contain a high density of negative charges. Irrigation, moist swabs or moist dressings contribute to the stabilization resp. renewal of the electrical potential in the wound area, re-activation of the wound current, and optimization wound healing.

Irrigation and moistening of a wound with Anode / Anode Neutral solution

##### Case Study Wound Healing

Patient, 76 years old, Diabetic Foot Syndrome, severe wound healing disorder following amputation of big toe. Treatment with moist swabs and moist dressings using Anode Solution 30% concentration.

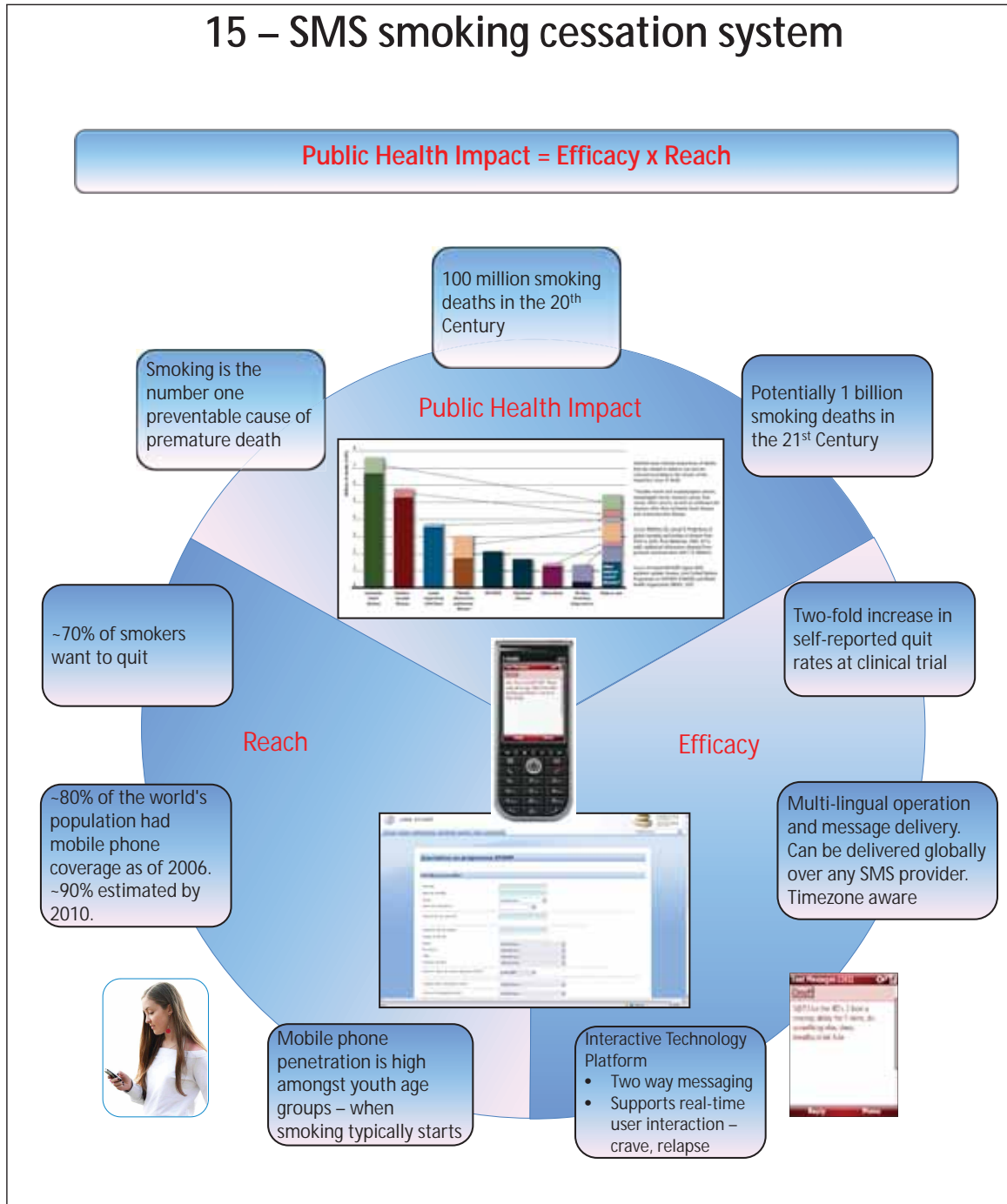
Condition at the beginning of treatment with Anode Solution

Condition after 5 months of treatment with Anode Solution

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### 3.5.4 Short messaging service (SMS) smoking cessation system

The purpose of the system is to provide tailored SMS-based smoking cessation support to its users. According to preliminary research the system facilitates self-management of smoking cessation and increases the likelihood of user adherence to smoking cessation programmes. The interactive system is claimed to be capable of answering messages about cravings to support the user.



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### 3.5.5 Reusable neonatal suction system

The purpose of this system is to remove obstructive mucus from the air passages of newborn infants, to reduce the risk of asphyxia, and support neonatal resuscitation. The device is claimed to be made of silicone and therefore reusable (capable of being boiled between uses). The device also requires no electricity.

## Reusable neonatal suction system

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#### BACKGROUND

**Actual need**  
WHO estimates that nearly 1 million newborns in low and middle income countries die from birth asphyxia each year. A similar number are disabled due to inadequate breathing at birth.<sup>1</sup> To stimulate spontaneous breathing, or perform bag-mask ventilation effectively, an open airway is mandatory. Often this requires clearing the mouth and nose of mucous and meconium using vacuum.<sup>2,3</sup>

**Current situation**  
Whereas available neonatal suction devices available cannot be cleaned for reuse, budgets generally prevent single patient use.<sup>4</sup>

**Meeting a challenge**  
UN's Millennium Development Goal No 4 (MDG 4) aims at reducing the mortality of children, including newborns, by 2/3 by 2015. To help reach the MDG 4 we have developed a new neonatal suction device which is clinically effective, easy and safe to use, available at a low price and can be reused for multiple patients over a very long period of time. This device is also suitable for large scale training of birth attendants.

#### PRODUCT QUALITIES



**Design**

- Ergonomic shape allows convenient one hand operation
- Inviting non-clinical look as represented by a friendly penguin
- Easy opening and closure in connection with emptying and cleaning
- One-part design requires no disassembly/reassembly

**Material**

- Transparent silicone rubber permits immediate visual inspection of any suctioned matter
- Can be cleaned in high temperatures by methods including boiling and autoclaving
- Soft beak shaped nozzle will not hurt baby's mouth and nostrils
- Withstands aging and discoloring during storage over extended periods of time

**Cleaning**



- Penguin head can easily be flipped to the side to allow easy emptying of suctioned matter during use, and can as easily and quickly be flipped back for continued suction
- After mechanical removal of debris boiling in water for 10 min. has been documented to provide effective decontamination to be safely ready for reuse<sup>5</sup>


**Effectiveness**

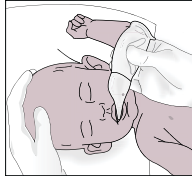
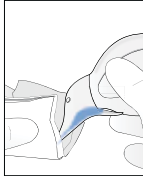
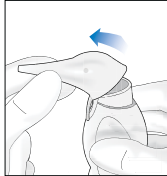
- Meets recommendations of providing vacuum of up to 100 mm HG (136 cm H<sub>2</sub>O)

**Affordability**

- Low purchase price and use for large numbers of patients over years make this suction device most suitable for general use in low income countries.
- Also ideal for large scale sponsor facilitated distribution on a not-for-profit basis.



*To suction*

*To empty during suction*

*To prepare for cleaning after use*

**References:**

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Technical specifications	
<b>Nozzle dimensions at tip:</b>	Inner diameter (ID): 3.0 mm Outer diameter (OD): 4.5 mm
<b>Suction strength (typical):</b>	100 mm Hg (136 cm H <sub>2</sub> O)
<b>Operating temperature:</b>	0 °C (32 °F) to 50 °C (122 °F)
<b>Storage temperature:</b>	-20 °C (-4 °F) to 60 °C (160 °F)
<b>Material:</b>	Transparent silicone rubber

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### 3.5.6 Fluorescence visualization of abnormalities in oral cavity

The purpose of the system is to use the natural fluorescence of mucosal tissues when excited by a violet/blue light to inform clinicians about the presence of abnormalities in the mucosa in the oral cavity. This system could aid in the early detection of oral/oropharyngeal cancers and thereby reduce morbidity and mortality associated with these diseases.

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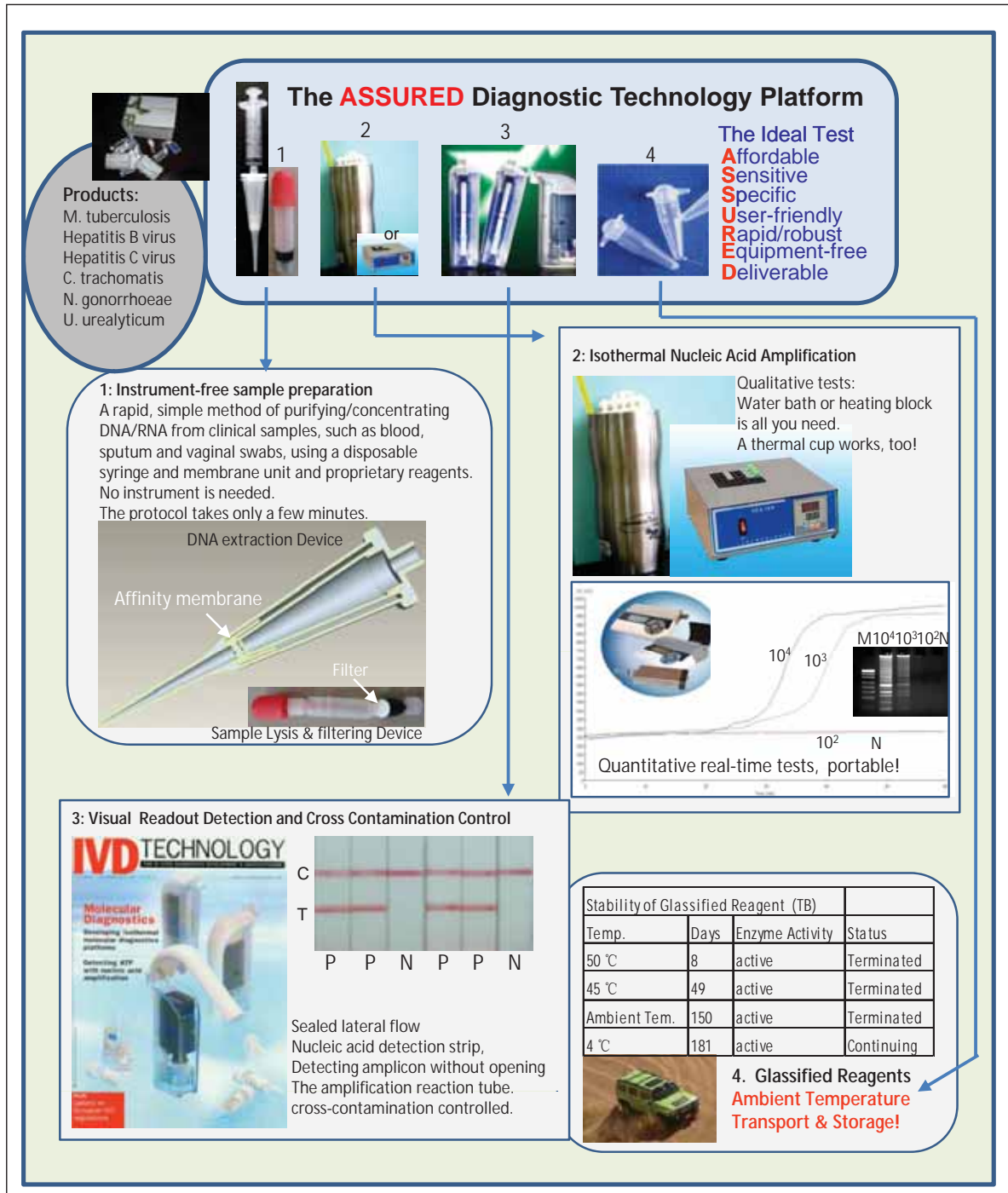
### 3.5.7 Transcutaneous bilirubin measurement system

The purpose of the system is to provide an alternative to blood sample analysis for the diagnosis of hyperbilirubinaemia in newborn infants. The system uses spectral analysis of light reflected from the patient's vascular bed to determine levels of blood bilirubin. The device is claimed to be non-invasive and to provide a rapid read-out.

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### 3.5.8 Isothermal nucleic acid amplification system for tuberculosis diagnosis

The purpose of the system is to offer a point-of-care alternative to sputum smear microscopy. The technology is claimed to require no additional equipment and to yield a rapid visual read-out of the diagnostic result..



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## CONCEPT TECHNOLOGIES (CATEGORY 2)

### 3.5.9 Simplified anaesthesia unit

The purpose of the unit is to function as an anaesthesia machine for surgical use in low-resource settings. The device features an innovative valve system with reduced technical complexity compared to traditional devices. The device is claimed to function with oxygen from different sources, including ambient air, and therefore would not require compressed oxygen.

# Making Anesthesia

## RELIABLE.....

Designed to work-anywhere, be affordable and look good



The novel breathing system that allows the UAM concept was developed during 10 years 1999-2008 by Dr. Paul Fenton, DTM&H, FRCA, Professor of Anesthesia, with more than 30 years clinical and teaching experience in the UK, Africa, Asia and the Pacific and is manufactured by a UK based manufacturer of anesthesia equipment and accessories headed by Richard Fiedorowicz the Managing Director who has over 20 years experience in the medical engineering market.

The company now consists of a highly skilled workforce dedicated to the manufacture of high quality medical products. The company is certified to CE and ISO standards and is audited semi annually by one of the largest UK independent testing, inspection & certification companies.

As a complete anesthesia system, the UAM couples the safety and simplicity of older systems with a mainstream modern patient breathing circuit acceptable to all users. So it can be used in any hospital in the world, but without the need for the usual compressed gases.

This system utilizes the useful features of continuous flow (and will include recycling) while retaining the safety and adaptability of old fashioned draw-over. It allows for access to any oxygen source at any pressure and defaults to room air, if both electricity and oxygen are not available.

The Details:  
 The UAM is a full size electric plug-in-and-go anesthesia machine, which needs no oxygen cylinders, only a volatile agent. Using a work station layout, the system employs a 10 liter/min O<sub>2</sub> concentrator, a bellows assembly to control gas flow with conventional patient connections using a Y-piece or coaxial tubing, a large capacity vaporizer (halothane or isoflurane), a reservoir bag, oxygen rotameter and integral fuel cell oxygen monitor. A second rotameter is included for either air or nitrous oxide.

Other features include a failsafe alternative oxygen inlet, oxygen/nitrous oxide cylinder yokes and air inlet and failure detectors with alarms including an apnea alarm. The patient breathing system allows conventional scavenging and bacterial filters as there is no breathing valve at the patient's airway. The inclusion of a mechanical ventilator and circle option with soda lime absorber is being considered for a second-generation version.

## Affordable....

The aim in pricing the UAM is to ensure that it is affordable and available to non-profit, low-resource health care facilities while ensuring long term sustainability, high-quality manufacture and spares support with local training of BMET service engineers.





## .....Available Worldwide

The UAM is a CE/ISO marked device with certificates to all current standards and has been evaluated in Poole NHS Hospital, UK by 5 independent NHS Consultant Anesthetists since April 2010. The UAM is currently installed in Nepal at four sites. Other placement sites are contemplated for 2011 in Africa and Asia.

For more information please contact us:  
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### 3.5.10 Single use assistive vaginal delivery system

The purpose of the system is to assist fetal extraction, in cases of prolonged second stages labour, without having to use forceps, a vacuum extractor, or to resort to caesarean sectioning. The lack of rigid instruments in the system is claimed to reduce the risk of injury to both mother and child.

## SINGLE USE ASSISTIVE VAGINAL DELIVERY SYSTEM

**Background**

World-wide, 10- 20% of deliveries require some form of intervention, and this intervention is frequently a caesarean section.(1) Instrumental vaginal deliveries (forceps and vacuum extraction) account for 2-23% of deliveries.(2-3) Obstetric history of assisted vaginal delivery started with the invention of instruments designed 400 years ago. However, it is only in the last 20 years of different intervening methods that scientific evaluation of risks and benefits have been discussed (4). Operative vaginal delivery rates in Latin American countries are low compared with those in most developed countries. Data from hospital deliveries in 18 countries show that rates do not exceed 6% and are below 2% for half of them (Latin American Center for Perinatology, 1985 - 1995). It is a region with low operative vaginal delivery rates and high caesarean section rates (5). The forceps is the standard instrument used in our countries. This profile makes particularly relevant the introduction of a new device which would prioritize maternal fetal safety, would be easy to use, disposable and would not require a highly skilled attendant. In this sense, people from all over the world could have access to it and the most vulnerable populations would benefit to a higher extent. The new device provides an extractive mechanism as well as a mechanism to facilitate the physiological expulsion of the cephalic pole, and neither instruments nor devices for the extraction of the fetal head have been developed over the last 160 years. It also provides a physical mechanism of action different from the forceps or the vacuum extractor, or Thierry spatulas.

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**Device physical mechanism of action**

This instrument has been designed on the basis of a double physical phenomenon consisting of a conveyor belt and an air clamp. The device consists of a polyethylene sleeve with a cuff-like fold on the fetal insertion edge, which fits the fetal head diameter. This sleeve is introduced using two flexible plastic spatulas 3-mm thick. One of them is straight and is used to crown the fetal head, and the other one follows the fetal cephalic curvature and allows placing the device in the adequate final position. After applying the device, a small amount of air may, or not, be insufflated at zero pressure. The atmospheric air entering during the device application with the spatulas is generally enough to produce the air clamp around the fetal head. However, the air clamp effect may be enhanced by insufflating a small amount of air at zero pressure through an insufflation cannula, which runs along the device until reaching a chamber in the distal edge of the fold. Thus, an air clamp is obtained, which holds the fetal head at 360°. This adds to the conveyor belt or sliding effect occurring between the inner parts of the fold upon force exertion. Such force may be either external, i.e., through traction from outside the device, or internal, i.e., arising from the natural forces that bring about uterine contractions and maternal pushing. The optional traction handle would allow maintaining the polyethylene sleeve diameter, thus facilitating maternal soft tissues distension during the extraction of the cephalic pole. In order to test the physical phenomenon, a real size pregnant uterus was designed. This was a 1-inch glass uterus at full cervical dilation (10 cm). Through its transparent walls can be seen both physical phenomena: the air clamp (figure 1) and the belt conveyor phenomenon (figure 2).

**Figure 1:** The air clamp is achieved when a minimal amount of air is insufflated. This results in a sealing effect between the cephalic pole and the maternal uterus.



**Figure 2:** The belt conveyor phenomenon is observed by the displacement of the lines printed in the device.



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**Simulation Laboratory**

To perform a preclinical study, an obstetric simulator was considered. Superior primates (chimpanzee, gorilla, and orangutan) would be the best choice for testing the device. However, this option is not feasible, since any experimental maneuver would require general anesthesia and would interfere in the physiological mechanisms of labor. Previous studies have demonstrated the effectiveness of childbirth simulator for the teaching of forceps placement, and the extraction manipulation.(6-8). According to the above mentioned, the research was performed in a childbirth simulator (simulator S 575 – “Noelle”) at the Obstetric Simulation Laboratory in Des Moines University (DMU), Iowa, USA, October 21-23, 2008. Multiple trials were successful. Action physical mechanisms (A- the air clamp and B- conveyor belt) generated upon device placement were objectively proved in the simulator obtaining the expulsion of the cephalic pole.

We believe that the use of the device in humans will be technically easier because of the elasticity of tissues and the biological fluids lubrication compared with the rigidity and lack of lubrication of the simulators. On the other hand, uterine contractions and the strength of maternal pushes represent another advantage compared with the simulators.

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**Potential comparative advantages over other devices: forceps or vacuum**

**Medical advantages:**

- It could decrease the risk of fetal-maternal injury
- It could help to the physiologic development of the second stage of labor
- It could help to contraction forces and maternal pushing efforts
- It could reduce prolonged second stage
- It could reduce postpartum hemorrhage (uterine atony) through a reduction in the second stage of labor
- It would decrease operative delivery
- It would reduce perineal damage (low incidence of episiotomy)
- It would result in less malpractice claims
- It would decrease perinatal infections acquired through the birth canal (HIV and Streptococcus B haemoliticus)

**Technical advantages:**

- It does not require expertise and individual training
- Easy-to-learn technique
- Easy, rapid and smooth insertion
- Very low production cost
- Disposable

**FEASIBILITY AND SAFETY STUDY OF THE DEVICE FOR ASSISTED VAGINAL DELIVERY**

**Main Objective:** The main objective is to evaluate the safety and feasibility, in terms of ease of application and successful delivery, of the new device in assisted vaginal delivery in singleton term pregnancies during the second stage of labor. Safety will be assessed by examining potential short and long-term maternal and infant outcomes. Feasibility will be evaluated by observing successful expulsion of the fetal head after one-time application of the device under standardized conditions (full cervical dilation, anterior presentation, +2 station, normal fetal heart rate) in singleton non-complicated pregnancies.

**Study design and Population:** A prospective study enrolling 100 pregnant women at the Centro de Educación Médica e Investigaciones Clínicas “Norberto Quirno” (CEMIC) University Hospital in Buenos Aires, Argentina over a period of 12 months. Only women with singleton uncomplicated pregnancies will be enrolled in the study.

**Ethical Considerations:** This project has been approved by CEMIC and the World Health Organization Ethics Committees.

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### 3.5.11 Portable on-site cell sorter and counter for HIV and malaria diagnosis

This is a lab-on-a-chip device to monitor AIDS in HIV-infected people as well as blood cell alterations indicating malaria. The device appears to be small and portable and it is claimed to allow for rapid automated screening of a blood sample for indicators of AIDS and/or malaria.

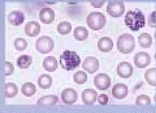
## Portable on site cell sorter and counter for HIV and malaria diagnosis

**GLOBAL HEALTH CONCERN**

Developing countries are suffering most for the two global diseases **HIV/AIDS and Malaria**. A great bottleneck is the lack of a dedicated, mobile, robust, easy-to-use and low-cost diagnostic equipment for CD4+ T cell enumeration and for the counting of parasitized erythrocytes in the blood, respectively. A simple and portable cell counting device would be of great benefit for diagnostic purposes in resource-limited settings.




*The binding of HIV to a T helper cell which possesses the CD4 receptor*



*A blood smear showing Plasmodium infected red blood cells*

**PROPOSED SOLUTION: THE CONCEPT**

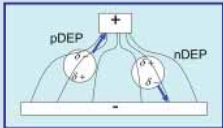
An integrated **lab-on-chip solution** for cell counting is proposed to bring innovative techniques directly to where they are needed most.



*A microfluidic disposable cartridge, pre-charged with the biological reagents needed, is filled with a drop of blood from the patient and the diagnosis is performed by a portable, handheld, battery powered and no life-time limited device. Integrated electronics elaborates and shows the results. The technology is operable also by untrained personnel.*

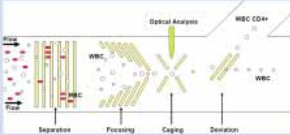
**THE PHYSICAL PRINCIPLE**

**Dielectrophoresis (DEP)** is a method for cell handling without physical contact: cells with different sizes and/or dielectric properties can be separated using optimized-shaped microelectrodes generating high-gradient electric fields and patterned on the silicon substrates of microfluidic channels.

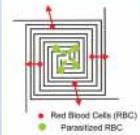


Depending on dielectric properties of cells and frequency of the electric field, cells can be attracted at the electrodes by positive (pDEP) force or ejected away by negative (nDEP) force, allowing a separation between different cell populations.

**OBJECTIVES**



*Schematic top view of the designed layout for the CD4+ sorter biochip: a combination of the developed DEP microelectrodes can perform a first separation between red blood cells (RBC) and white blood cells (WBC), followed by the sorting and counting of CD4+ T-lymphocytes subpopulation for AIDS diagnosis.*

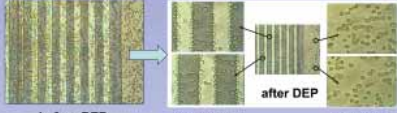


*Schematic top view of the designed layout for the malaria-biochip: a spiral microelectrodes array perform the separation between intact and infected red blood cells (RBC), while parasitized RBC are concentrated at the center for counting and malaria infection assessing.*

Numerical modelling has been performed to describe dielectric cell properties, to simulate the electric field distribution and to quantify the consequent pico-Newton DEP forces acting at the cell microscale.

**STAGE OF DEVELOPMENT**

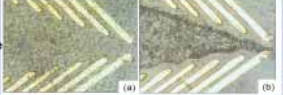
The proposed solution is now at a proof-of-concept research study. It could be ready to be commercialized after the system level integration of its components and the required certifications assessing its diagnostic function. Several microelectrodes manipulation stages have been designed, prototyped and tested as functional units with available demonstrative experimental cell types.



*before DEP*      *after DEP*

yeast cells      SRB cells

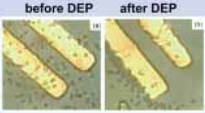
*The multi-bar array filter traps Saccharomyces Cerevisiae yeast cells at the electrode edges, while Sheep Red Blood (SRB) cells are levitated and driven away by the DEP electric field. Images at 10x - 50x magnification.*



*before DEP*      *after DEP*

(A)      (B)

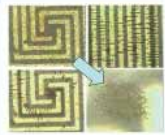
*The fishbone-like focusing module allows the alignment of a cell population along the axis of the microfluidic channel. The image shows the focusing of yeast cells at 10x.*



*before DEP*      *after DEP*


(A)      (B)

*The deviation module is activated to move yeast cells cells in a dedicated microfluidic outlet. Images at 10x magnification.*




*The spiral array module acts as a cell concentrator. The figures show a progressive yeast cells concentration at the centre of the configuration by DEP force. Images at 10x - 50x.*

Silicon dies have been embedded in prototyped plastic support stages, with the requested properties of biocompatibility and optical transparency.

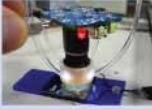


20 mm  
30 mm



25 mm  
75 mm

An opto-electronic image sensor for detecting the collected cells has been included in the same lab-on-chip package, together with the embedded image processing software.



The necessary driving and control electronics can be assembled in a compact and battery powered solution, adaptable to a handheld, automatic and low-cost instrument, operable by untrained personnel.

**COST EFFECTIVENESS AND AFFORDABILITY**

The electronic equipment is an integration of already available low-cost products for mass market, cheaper than existing diagnostic technologies at high production volumes. The proposed solution for a portable on site cell sorter and counter for HIV and malaria diagnosis paves the way for an integrated mobile diagnostic lab-on-chip instrument, with low cost and great benefit, especially in rural areas of developing countries.

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### 3.5.12 Decision support system for paediatric HIV


The purpose of this system is to move away from paper-based medical records while ensuring easy and reliable access to patient-centred information. This electronic health records system is targeted at paediatric HIV cases and is intended to aid clinical decision-making processes such as weight-based dosing support for antiretroviral drugs.

## Decision Support System for Pediatric HIV

#### Context

**A Smart Mobile Electronic Health Record System Designed to Improve the Quality of Care Delivered to Children with HIV in India**


A lack of patient centered point of care information is a major barrier to the provision of quality health care especially for chronic diseases in resource limited settings. Electronic Health Records (EHRs) can organize clinical information systems and provide point of care clinical decision support two key domains required for the provision of quality care for chronic conditions.



Pediatric HIV is a chronic disease and requires the collection, preservation, evaluation and synthesis of a large amount of data over time. This information has to be available at the point of care. Using pediatric HIV as a model we developed a smart web-based EHR, with a mobile interface and embedded clinical decision support designed to improve the quality of health care delivered.

#### Innovation 1 Pediatric HIV Knowledge base:


#### Innovation 2 Real-time clinical decision support for Medication Prescribing:



Automated Weight Based Dosing of:


- Antiretrovirals
- Antitubercular Agents
- Cotrimoxazole


#### Innovation 3 Secure Web Based Access through Desktop or Mobile Device:



Linux Based Open Source Platform

<Capacity for Offline Storing >StoreForward Technology






Storage / Retrieval of Multimedia Data

Marking / Zooming on Images

Available on Desktop and Mobile Device




SMS Message Management


#### Innovation 4 Deployment and Population studies:

**Current Deployment**

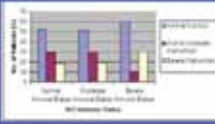
- Installed at Pediatric ART Centre of Medical College & Hospital, Kuvempu
- Implementation began in July 2008
- To Date 272 patients are registered in the system



*Subsidiary Network in West Bengal*



District wise patient distribution



Population based data showing Relationship between Malnutrition and Immune Status:

This system is designed to help improve the quality of health care delivered. It captures and makes available patient centered information at the point of care. It helps clinicians with varying expertise integrate vital pieces of clinical information to make decisions. It addresses the safety issues in pediatric medicine, by providing weight based pediatric dosing. Modules are set up so that information is shared by various practitioners such as counselors and physicians to provide for more effective management. Mobile devices have become ubiquitous. It allows for the access of this information over a mobile device, and facilitates communication between clinical providers, not only through a desktop but also using a mobile platform. All this is done in a data safe environment.

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### 3.5.13 Transcutaneous anaemia monitoring system

The purpose of this system is to screen populations for insufficient levels of haemoglobin in the blood and to carry out diagnosis of severe anaemia. The system is claimed to be based on spectrophotometric analysis. The device appears to be portable, non-invasive and is claimed to provide a read-out in less than a minute.



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### 3.5.14 Solar-powered autoclave

This device is intended to sterilize medical instruments and is claimed to run solely on solar power. This technology could allow sterilization of medical instruments in remote areas with no access to electricity and hence reduce the risk of infections associated with performing medical interventions with unhygienic equipment.

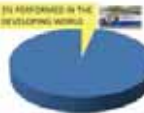
## Distributed surgical instrument sterilization using

# SOLAR POWERED AUTOCLAVES


in low resource settings

### THE NEED FOR SURGICAL CARE




**GLOBAL SURGERIES**



**GLOBAL DISEASE BURDEN**



As the world's burden of surgical diseases increases, so does the gap between access to life saving and disability preventing surgical care, both between and within countries. As seen in Figure 1, less than 5% of the world's surgical procedures are performed in countries ranked in the lowest third of per capita health expenditure. Barriers to the delivery of safe and timely surgery include deficiencies in capacity and quality. <sup>1</sup> Surgery is often the only solution to prevent disabilities and death from conditions resulting from road traffic accidents, falls, burns, disasters, domestic violence, pregnancy related complications, infections and congenital defects. The WHO estimates that 500,000 women die annually from complications in pregnancy that can be easily solved with simple surgical intervention at the primary health clinic point of care. <sup>2</sup> Pregnancy complications and other surgical diseases seen in Figure 2 account for 11% of the Global Disease Burden.

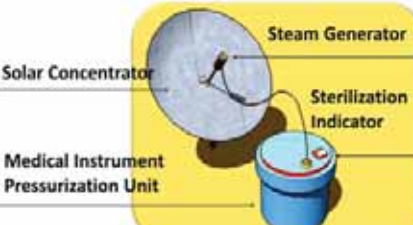
1 in 5 wound sufferers in developing countries suffers from infection.

The surgical care gap between developing and developed countries could be substantially reduced through integrated strategies including appropriate medical equipment design for surgical procedures in low-infrastructure areas.

The WHO states that most of the surgical care required to reduce the global disease burden can be given at the primary level of health care, which for most of the world, is provided by rural clinics. <sup>4</sup> Rural clinics in developing countries provide primary care for 3 billion people worldwide, but more than half of them do not have access to electricity. Additionally, although they lack the proper equipment, nurses at these clinics are faced with the decision to compromise patient safety by attempting to provide care. When minor wound injuries are left untreated or are inappropriately treated by the primary care clinics, infections can rapidly spread. Every year there are 50-60 million people in the developing world suffering from wound injuries. Even in areas where surgeries are already performed, one fifth of the patients suffer from post-operation infection, due to, among other causes, the use of improperly sterilized equipment used in the procedure (Gomez-Marquez, 2010).

### AN APPROPRIATE AND AFFORDABLE SOLUTION

**SOLARCLAVE SYSTEM DESIGN**



We describe a new method for medical instrument sterilization using solar energy instead of conventional fuels, the Solarclave. The technology allows for the safe and reliable steam sterilization of surgical instruments in clinics without electricity, such as those often found in the developing world. An autoclave is defined as a vessel capable of holding high pressure steam at 15psi and insulation to maintain the internal temperature at 121°C. <sup>3</sup> Our solar autoclave uses a parabolic solar concentrator and a small boiler to collect solar energy to generate steam that is transferred to an insulated pressure vessel and an electronic sterilization indicator (Figure 3). Proof of concept experimentation was done to ensure that the 250ML boiler and parabolic concentrator generated the appropriate amount of steam for a 5L insulated pressure vessel. Early testing showed the system will need two concentrators for this amount of steam. A sterilization indicator measures temperature and activates an LED when the appropriate measures for sterilization are reached. Advantages of this solar autoclave design include: (1) decoupled solar concentrator and pressure vessel to reduce volatility in solar collection (2) ability to scale the system size with additional solar concentrators (3) modular electronics to measure temperature, pressure, sunlight and external energy (4) design for manufacturing and flat pack shipping.

**ADVANTAGES OF SOLAR STERILIZATION**




Figure 4 compares current options for sterilization against the cost and effectiveness of those efforts. Moving from the left side of the compass, **boiling water** to clean instruments is not endorsed by the WHO as a reliable method of sterilization. It does not kill 100% of the microbes present on surgical devices. **Chemical sterilants** are another option for instrument sterilization. However, this process is complex and which create a high probability for user error to result in improperly sterilized equipment. Rural health clinics without access to electricity typically use sterilization equipment at central hospitals, often a day-long bus ride away. At **central hospitals**, high-powered, electric autoclaves are one of the main pieces of equipment which regularly fails and cannot run on a back-up generator in a power outage. Thus, when nurses bring their equipment from the rural clinics to be sterilized, there is a high probability that the autoclave at the hospital will not be available. **Tabletop autoclaves** are another option, but are prohibitively expensive and most require a source of electricity for power. The alternative source of power is a propane stove, however, according to the logistics supervisor of Doctors Without Borders, the supply chain for these items is limited. Our solution: a **solar powered autoclave**. The sterilization cycle for the solar autoclave is the same as a tabletop autoclave, but is powered using renewable energy, a free and abundant resource.

DEVELOPMENT	SOLAR OVEN I	SOLAR OVEN II	SOLARCLAVE
SUBASSEMBLIES	8 PARTS	5 PARTS	8 PARTS
SUPPLY CHAIN COMPLEXITY	100% LOCAL MATERIALS	90% LOCAL MATERIALS	90% LOCAL MATERIALS; 100% LOCAL REPLACEABLE PARTS
ASSEMBLY TIME	1 DAY	1 DAY	3 DAYS
MANUFACTURE TRAINING	7 DAYS	8 DAYS	10 DAYS
USER TRAINING	3 HOURS	3 HOURS	1 DAY
VOLUME	LOW	LOW	HIGH
COST	~\$300	~\$300	~\$400

**REFERENCES**

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<sup>3</sup> Centers for Disease Control, *Guidelines for Disinfection and Sterilization in Healthcare Facilities* 2008.

<sup>4</sup> WHO. *Emergency and Essential Surgery: the backbone of primary health care*. <http://www.who.int/whd/whn/> (accessed on 26 Aug. 2010)

<sup>5</sup> Komb, R., et al. Solar autoclaves for sterilizing medical instruments in remote settings.

**COLLABORATION**

The Solarclave<sub>TM</sub> research team has partnerships with Universities, NGOs, medical professionals and engineers for the device design, testing and implementation. We welcome the opportunity to collaborate with other medical care providers delivering surgical care in resource poor settings and practitioners developing solutions to surgical needs in developing countries.

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### 3.5.15 Portable infant warmer


The purpose of this device is to improve the care of premature and low-birth-weight babies by providing a constant temperature in order to prevent hypothermia. This portable device is claimed to require no electricity and would allow for close mother-to-baby contact. The product is targeted for use in urban and rural health care settings, as well as home settings.

# Portable Infant Warmer


## Background of Problem

Each year, 20 million low-birth-weight (LBW) and premature babies are born around the world; 4 million of them die annually. Delivery of an optimal thermo-neutral environment for low-birth-weight infants at risk for environmental hypothermia is universally accepted as essential. While incubators and heat lamps have traditionally provided this optimal environment, the downside to these existing technologies are their prohibitive cost (\$500-\$20k), complexity, and need for continuous electricity, which poses a problem in developing countries. Skin-to-skin care is widely promoted, but practical and cultural limitations have hampered it from being done continuously.

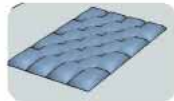
## Technology




The purpose of the portable infant warmer is to improve thermal care for premature and low weight babies by providing heat at a constant temperature in order to prevent hypothermia. The product uses an innovative phase change material (PCM) incorporated in a sleeping bag to regulate a baby's temperature. A clinical version of the product is designed for use in clinics and during transport. A home use version is designed for family members to use at home to complement KMC.



A precision heat source used to melt wax within 30 minutes. Models exist that work with and without electricity.



A sealed pouch containing PCM. Maintains ~37°C for 4+ hours without electricity. Pouch can be reheated repeatedly.



A hypoallergenic sleeping bag which holds the baby and has an isolated compartment to hold the warmed wax.

**PRODUCT FEATURES: Clinical version**

- Stable microclimate for at least 4 hours
- Portable
- Easy to sanitize
- No electricity near infant
- Allows for close mother to child interaction

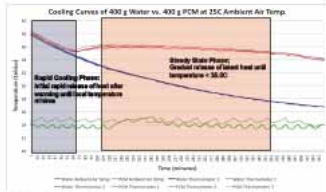
**PRODUCT FEATURES: Home version**

- Complements KMC
- Works without electricity
- Stable microclimate for at least 8 hours
- Easy to sanitize
- Allows for close mother to child interaction

## Data and Testing Methodology

To evaluate the PCM's ability to maintain a steady temperature, as part of *in vitro* testing, we compared temperature cooling curves between 400 grams of PCM and a 400 gram pure water control and among 400 grams of PCM in varying clinically-relevant ambient air temperatures. For each test, we melted the PCM entirely (>38.0C) and placed the pouch into the sleeping bag. Cooling curves were divided into phases: (1) Rapid Cooling and (2) Steady State. Heat loss was calculated in Celsius/minute and averaged across the thermometers in a test. Different tests were compared with ANOVA.

Our bench data confirms that without an internal heat mass the temperatures in the interior of the sleeping bag can remain between 35.0C and 38.0C (as specified by the WHO for comparable warming technologies) for a period of at least 240 minutes.



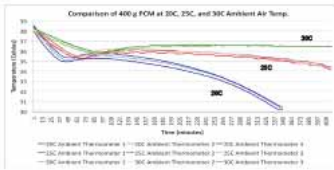
Cooling Curves of 400 g Water vs. 400 g PCM at 25C Ambient Air Temp.

Thermometer Placement	1	2	3
400 g Water	0.0001	0.0001	0.0001
400 g PCM	0.0001	0.0004	0.0001
Significance	p < 0.0001	p < 0.0001	p < 0.0001

Further *in vivo* testing is being conducted with pre-term lambs at the University of Utah, led by Professor Kurt Albertine.

A randomized controlled study (standard of care vs Portable Infant Warmer) is currently being conducted in hospitals in Bangalore, India to determine the ability of the device to support thermo-stability in low birth weight neonates within the range of 36.5 C to 37.5 C during the treatment phase, lasting for 4 hours. Axillary temperature is being measured, along with the maintenance of sterility (as assessed by microbiology testing).

A study conducted at Stanford will test the viability of using phase-change-material as a supplemental warming technology in the nurseries. Stanford researchers will perform randomized controlled trials comparing the ability of the phase-change-material to help warm infants and promote mother-to-child bonding to that of current best practices and technology.



Average Heat Loss (Different Ambient Temperatures)	Rapid Cooling Phase	Steady State Phase	Steady State Phase	Steady State Phase
30C Ambient	0.0011	0.0001	0.0001	0.0001
25C Ambient	0.0011	0.0001	0.0001	0.0001
30C Ambient	0.0011	0.0001	0.0001	0.0001

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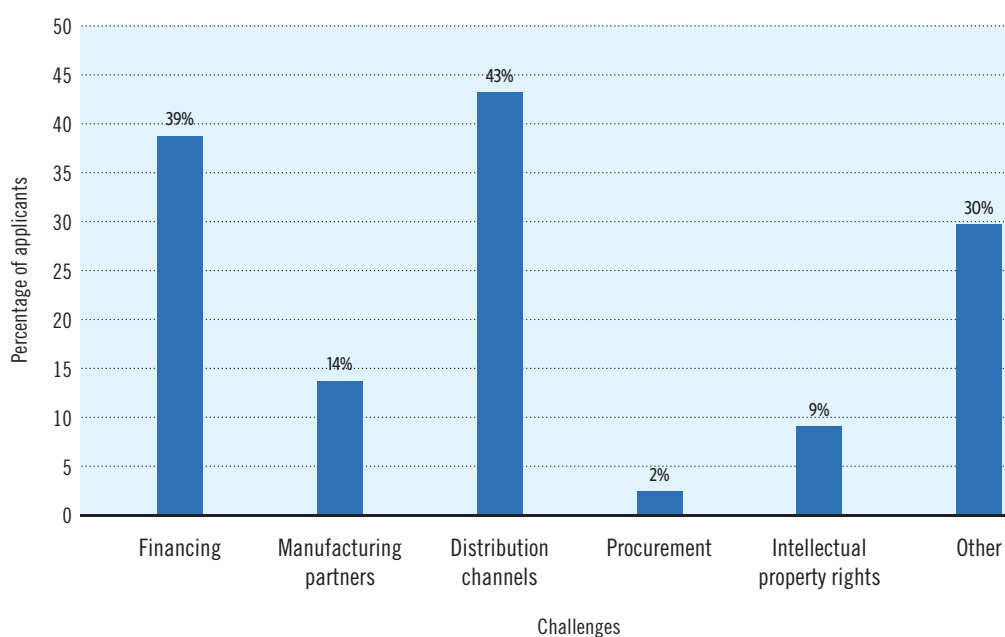
# 4. Challenges to making innovative technologies available

Each applicant was asked to identify any challenges they could foresee with regard to the successful implementation of their technology. Figures 8 and 9 show the challenges cited by applicants of commercialized and non-commercialised technologies respectively. A great challenge foreseen by all applicants was a lack of funding: 39% of category 1 and 83% of category 2 applicants cited this.

Distribution was also identified as a major challenge for innovations in category 1 and 2 (43% and 61% of applicants respectively; Figure 8 and 9). This is the largest concern identified by category 1 technologies, which may be due to the fact that products in this category are either on the market (or soon will be) and therefore require effective distribution channels to ensure their success. Alternatively, applicants of technologies in category 2 noted a greater need for manufacturing partners (50% compared to 14% of category 1 applicants; Figure 9 and 8 respectively), as their products are in the earlier stages of development.

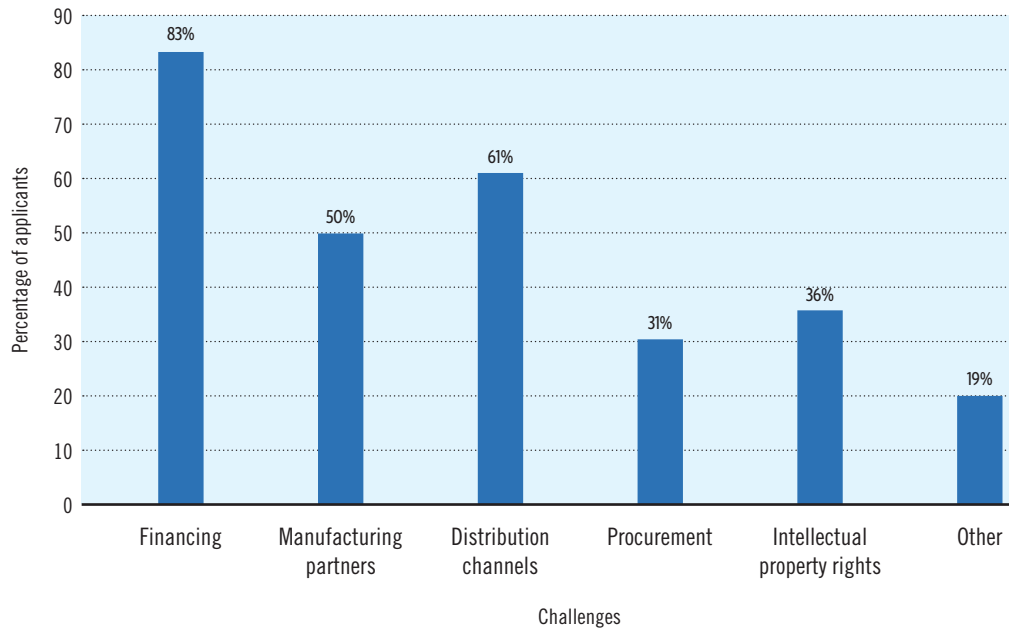
**Figure 8. Expected challenges to the success of innovation as described by applicants to category 1**

### Commercializable technologies (category 1)



**Figure 9. Expected challenges to the success of innovations as described by applicants to category 2**

**Concept technologies (category 2)**



## 5. Conclusion

This report presents a selection of innovative technologies from those submitted in response to the WHO call for innovative technologies. The call is one of the ways that WHO is working to achieve its strategic objective to ensure improved access, quality and use of medical products and technologies (3). Further work is required to ensure that these innovations are accessible to those in need of them in low- and middle-income countries. In particular, further evaluation of the clinical safety and effectiveness of the technologies and assessment of their robustness and affordability is required.

Innovative technologies are necessary to increase the cost-effectiveness of health care and ease the burden of chronic diseases worldwide. However, much work remains to be done to achieve results in this domain. Specifically, stakeholders need to explore novel ways of approaching distribution and financing which are appropriate to local infrastructure.

WHO will continue to interact with industry, funding agencies, academia and international organizations to raise awareness of the need to design, produce and commercialize innovative, accessible and robust technologies which address the needs of health systems particularly in low-resource settings.

Through this first call for innovative technologies, WHO is working towards making innovative and appropriate technologies affordable and accessible in all settings to increase the quality of health care, and most importantly improve the quality of life of all people.

## 6. References

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# Annex 1: Rules of the call for innovative technologies

## 1. Background and Aim of the Call

Medical devices are indispensable in health care delivery as tools for prevention, diagnosis, treatment and rehabilitation. However, despite the exponential growth of scientific and technological development, availability of and access to appropriate and affordable health technologies in low- and middle-income countries are still insufficient.

One of the WHO Department of Essential Health Technologies' goals is to help make available the benefits of core health technologies with a view to addressing global health concerns by developing a framework for health technology programmes and by challenging the scientific and business community to identify and develop innovative technologies.

This call for innovative technologies aims at identifying and evaluating innovative medical devices, including assistive devices, either existing or under development, which address global health concerns and which are likely to be available, appropriate and affordable for use in low- and middle-income countries.

Selected innovative technologies will be highlighted on the WHO Essential Health Technologies website. They will be shared with governments, donors and other stakeholders, with a view to generally fostering the development, availability of and access to innovative health technologies, particularly in low- and middle-income countries.

## 2. Key Dates

<b>11 September 2009</b>	Launch of the call for innovative technologies at the World Congress on Medical Physics and Biomedical Engineering, Munich <sup>1</sup> .
<b>31 January 2010</b>	Deadline for submission of applications.
<b>27–29 April 2010</b>	Selection of applications by the Advisory Group on Innovative Technologies, Copenhagen.
<b>30 June 2010</b>	Posting of the list of selected innovative technologies on the WHO website <sup>2</sup> .

## 3. Eligibility

### 3.1 Who can apply

The call for innovative technologies targets manufacturers, institutions, universities, governments, individuals and non-profit organizations which design, manufacture and/or supply any type of medical device that address the global health concerns mentioned in section 5. One submission per applicant will be accepted.

## 4. The Scope of Innovative Technologies

### 4.1 Medical Devices

Eligible health technologies are limited to medical devices as defined by the Global Harmonization Task Force (GHTF)<sup>3</sup>. They include instruments, medical equipment, implants, disposables, assistive devices and software used mainly for the purpose of prevention, diagnosis, monitoring or treatment of disease, rehabilitation, control of conception and/or measuring, restoring correcting physiological functions.

The call for innovative technologies does not cover clinical procedures, medicinal products, vaccines, biological therapeutic products or tissue engineered medical products.

### 4.2 Innovative Technologies

To qualify for consideration, a technology must be deemed "innovative" by providing the evidence that the solution:

- Has not previously existed;
- Has not previously been made available in low- and middle-income countries;
- Is safer and/or simpler to use than earlier solutions; and/or
- Is more cost effective than previous technologies.

### 4.3 Two Categories

#### Category 1 Commercialized/-sable products

- New products
- Products which have been commercialized for less than five years in high-income countries and which are not (yet) widely used in low- and middle-income countries
- Recent adaptation of existing non-health products for a health purpose
- Recent adaptation of an existing medical device for low- and middle-income country settings

#### Category 2 Products in a non-commercialized/-sable stage

- Products which are under development or otherwise in a conceptual stage

<sup>1</sup> <http://www.wc2009.org/World-Congress-2009/Pages/Home.aspx>

<sup>2</sup> [http://www.who.int/medical\\_devices/en/](http://www.who.int/medical_devices/en/)

<sup>3</sup> <http://www.ghtf.org/documents/sg1/sg1n29r162005.pdf>

## 5. The Health Problems to be Addressed

The health problems addressed by the innovative technologies should be related to the following key global health concerns:

- Lower respiratory infections
- Diarrhoeal diseases
- HIV/AIDS
- Malaria
- Prematurity and low birth weight
- Neonatal infections
- Birth asphyxia and birth trauma
- Unipolar depressive disorders
- Ischemic heart disease
- Cerebrovascular disease
- Tuberculosis
- Road traffic accidents
- Chronic obstructive pulmonary disease
- Alcohol use disorders
- Refractive errors
- Deficient maternal health
- Infant and child (under 5) mortality
- Cancer
- Disability.

## 6. Submission of Applications and Deadline

Interested applicants can download the submission form from: [www.who.int/medical\\_devices](http://www.who.int/medical_devices). The applications should be completed in English, signed, scanned and e-mailed as a PDF document to [medicaldevices@who.int](mailto:medicaldevices@who.int).

Deadline for applications is 31 January 2010. Receipt of applications will be confirmed by e-mail.

## 7. Screening and Selection

**Step 1** — WHO will screen all applications. The ones which are incomplete will, in principle, not be processed further. An identifier code will be assigned to the application and all information about the applicant will be removed to maintain confidentiality.

**Step 2** — Applications without identification data will be sent to selected WHO collaborating institutions for a second screening with respect to conformity to the scope of the call for innovative technologies. Those applications which do not fall within the scope of the call will not be sent to the selection committee, the so-called Advisory Group on Innovative Technologies.

**Step 3** — Proposals are evaluated and selected by the Advisory Group on Innovative Technologies, which is composed of experts in the field of health technologies. A confidentiality agreement will be signed by the members of such Advisory Group. Any expert reviewer with a declared conflict of interest will not be authorized to participate in the review.

## 8. Selection Criteria

The following considerations will be taken into account in the selection of the applications:

- Level of safety for user, patient and the environment;
- How effectively the technology addresses the related health concern;
- How well the technology is adapted to local infrastructures in resource-limited settings;
- Ease of use and maintenance;
- Total cost of ownership, cost-effectiveness and affordability; and
- Cultural and social acceptability of the technology.

## 9. Notification

Each applicant will be notified in writing (by e-mail) in June 2010 whether or not the submission has been selected. A list of the selected innovative technologies will then be posted on the WHO web site.

## 10. Terms, Conditions and Disclaimers

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 there from, 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, either existing or under development, 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 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.

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

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