## Medical devices and eHealth solutions

Compendium of innovative health technologies for low-resource settings

2011-2012





WHO Library Cataloguing-in-Publication Data

Medical devices and eHealth solutions: compendium of innovative health technologies for low-resource settings 2011-2012.

1.Biomedical technology. 2.Inventions. 3.Innovation. 3.Medical informatics. 4.Equipment and supplies. 5.Data collection. I.World Health Organization.

ISBN 978 92 4 150591 8

(NLM classification: W 82)

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Printed by the WHO Document Production Services, Geneva, Switzerland

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## Acknowledgements

The coordination and organization of the Compendium project and the evaluation of the medical device submissions were managed by the Diagnostic Imaging and Medical Devices unit of the Essential Medicines and Health Products department of the World Health Organization under the direction of Adriana Velazquez-Berumen, team coordinator, and Heike Hufnagel, technical officer.

The coordination and evaluation of the eHealth solution submissions were managed by the eHealth Unit of the Knowledge Management and Sharing department of the World Health Organization under the direction of Diana Zandi, Health Academy Project Manager, and Misha Kay, Manager, Global Observatory for eHealth.

The contribution of the following persons and institutions has been invaluable:

For the evaluation of submitted medical devices we thank Euroscan represented by Sue Simpson and Brendon Kearney and the following Euroscan members:

- Rosimary Terezinha de Almeida, Angaja Phalguni, and Beth Boddice from the National Horizon Scanning Centre (NSCH), University of Birmingham, United Kingdom;
- Alexandre Barna, Emmanuel Charpentier, Bjorn Fahlgren, and Marc Vanicatte from the Committee for Evaluation and Diffusion of Innovative Technologies (CEDIT), Paris, France;
- Setefilla Luengo, Iñaki Imaz-Iglesia, and Jesús González Enríquez from the Agencia de Evaluacion de Tecnologias Sanitarias (AETS) -ISCIII, Madrid, Spain;
- Aurora Llanos from Agencia de Evaluación de Technologías Sanitarias de Andalucía (AETSA), Seville, Spain;
- Antonio Migliore and Maria Rosaria Perrini from the Agenzia Nazionale per i servizi sanitari regionali (Agenas), Rome, Italy;
- Orna Tal from the Division of Medical Technology Policy (DMTP), Ministry of Health, Jerusalem, Israel;
- Sirpa-Liisa Hovi and Marjukka Mäkelä from the Finnish Office for Health Technology Assessment (FinOHTA), Helsinki/Tampere, Finland;
- Kees Groeneveld and Cees A. Postema from the Health Council of the Netherlands (GR), The Hague, The Netherlands:
- Inger Natvig Norderhaug, Helene Arentz-Hansen, and Tove Ringerike from the Norwegian Knowledge Centre for the Health Services (NOKC), Oslo, Norway;
- Paul Fennessy, Linda Mundy, Kaye Hewson, and Brendon Kearney from the Health Policy Advisory Committee on Technology (HealthPACT), Queensland, Australia;
- Nora Ibargoyen-Roteta, Gaizka Benguria-Arrate, and Iñaki Gutiérrez-Ibarluzea from the Basque Office for Health Technology Assessment (Osteba), Vitoria-Gasteiz, Spain.

We also thank DIMDI (German Institute of Medical Documentation and Information) represented by Hans-Peter Dauben for their support concerning the organization of the evaluation phase as well as Ahmet Metin Gulmezoglu and Helena Ardura-Garcia from WHO for their input..

For the evaluation of submitted eHealth solutions we are grateful to:

- Antoine Geissbuhler, University Hospital Geneva, Switzerland
- Kendall Ho, University of British Columbia, Canada
- Pradeep Ray, University of New South Wales, Australia
- Tove Sorensen, Norwegian Centre for Telemedicine, Norway

For their collaboration we thank the Centre for Global Health at the University of Michigan represented by Kathleen Sienko and directed by Sofia Merajver; we especially thank Amir Sabet Sarvestani and Eva Shiu for their assistance with identifying potential technologies and contacting the respective developers for the Compendium.

For her design of the Call announcement as well as her contribution to the successful launch of the Call we thank Lisa Stroux. For their valuable input on the submission template we thank Tony Easty from the University of Toronto, Mladen Poluta from the University of Cape Town, Lisa Stroux from the University of Oxford, and Santiago Ocejo from ProMujer, Mexico City.

We would like to thank the following WHO interns: Yen Low for her support in producing the Call announcement, Bryan Ranger for his support in producing the Compendium, and Rahul Rekhi, Shreesh Naik, Alicia De Hoyos Reyes, and John Akrofi for their support in different phases of the project.

All illustrations were provided by the developers who submitted the technologies.

For their financial support in the 2012 edition we thank the Ministry of Health, Labour and Welfare, Government of Japan, as well as The Netherlands Ministry of Health, Welfare and Sport. For their financial support in the 2011 edition, we profoundly thank the Bill and Melinda Gates Foundation.

Graphic design and layout - Jillian Reichenbach Ott (Genève Design).

## Table of contents

F	Acknowledgements									d
I	ntroduction									iii
[	Disclaimer									iv
Me	edical devices 2012									
A	Auto stop electrochlorinator .									2
A	Automated solar-powered blood pr	essu	re mo	nito	r					3
Е	Birthing simulator for training .									4
1	nterventional cardiovascular lab									5
I	ntramedullary nail and interlocking	scre	w sys	tem						6
L	_ow smoke stove									7
1	Mobile ECG with web-based teleme	edicir	ne pla	tforr	n					8
1	Multi-parameter remote diagnostic	kit								9
1	Neonatal sleeping bag warmer .									10
1	Non-invasive hypothermia indicator	r for r	newb	orns						11
1	Non-invasive vascular age risk pred	ictior	٦.							12
1	Non-surgical male circumcision dev	vice								13
(	Oral syringe dosing clip									14
F	Point of care diagnostic device for t	total	WBC							15
F	Portable anaesthesia machine .									16
9	Solar charger for hearing aid .									17
9	Sputum mobilization device .									18
Į	Jrine albumin test									19
eF	Health solutions 2012									
	Biometric technology in healthcare									2
(	Case-based smartphone messaging	g plat	form							2:
(	Cervical cancer screening informati	on sy	/stem	١.						2
(	Computer-aided detection for Tube	erculo	sis							24
ŀ	Health workforce information system	ms								2
I	ntegrated smartreader & cloud serv	vices								20
1	Maternal health Tanzania									2
1	Medical cloud									28
r	mHealth platform for community he	ealth	work	ers						2
1	New media to train health workers									30
F	Primary health care continuous qua	ality ir	mpro	veme	ent (	CQI)	tools	5.		31

	Rapid SMS providing availability of essential r	medi	cines				32
	Real-time measurement of meteorological events on public health						33
	Registre electronique de consultation (REC)						34
	Smart phones for supportive supervision for	ТВ					35
	Telemedicine for HIV/AIDS care						36
	Telemedicine network						37
	Tele-ophthalmology software application.						38
	Teletrauma						39
<u>\</u>	ledical devices 2011						
	Fetal heart rate monitor						41
	Isothermal nucleic acid amplification system	for P	OC c	liagn	osis		42
	Manual wheelchairs and mobility devices .						43
	Newborn simulator for resuscitation training						44
	Non-pneumatic anti-shock garment						45
	Oxytocin in prefilled auto-disable injection sy	stem					46
	Parasitological test system						47
	Phototherapy for neonatal jaundice treatmen	t					48
	Point-of-use water disinfection system .						49
	Portable haemoglobin meter						50
	Portable ventilator						51
	Prefilled auto-disable injection system .						52
	Reusable neonatal suction device						53
	Self-powered pulse oximeter						54
	Transcutaneous bilirubin measurement syster	n for	infaı	nts			55
	Ventilator using continuous positive airway p	ressu	ire				56
	Water filter						57
el	Health solutions 2011						
	Medical data communication system						59
	Mobile technology to connect patients to ren	note	doct	ors			60
	Treatment response software application.						61
Δ	ppendix						
_							67
	2012	•					63 65
	71 III						

## Introduction

Medical devices and eHealth solutions have the potential to save lives. However, too many worldwide suffer because they don't have access to appropriate health care technology.

The compendium series of innovative medical devices and eHealth solutions has been created as a neutral platform for technologies which are likely to be suitable for use in low-resource settings. It presents a snapshot of several health technologies which might have the potential to improve health outcomes or to offer a solution to an unmet medical need in low-resource settings. The compendium specifically focuses on showcasing innovative technologies that are not yet widely available in developing countries. It is released to encourage the dialogue between ministries of health, procurement officers, donors, technology developers, manufacturers, clinicians, academics and the general public. In doing so, WHO aims at raising awareness of the pressing need for appropriate and affordable design solutions and for further development and technology dissemination.

All submissions to the Call for innovative health technologies for low-resource settings underwent an evaluation process; technologies were assessed by an expert panel based on the material and evidence provided by the applicant as well as publicly available information.

Note that for a selected technology, the inclusion in the compendium does not constitute a warranty for fitness of the technology for a particular purpose.

Technologies in the compendium are presented in one page summarizing the health problem addressed, the proposed solution and product specifications, based on data and information provided by the developers of the technologies concerned.

### Disclaimer

Eligibility for inclusion in the compendium has been evaluated by EuroScan member agencies, WHO Collaborating Centres, and WHO. However, the evaluation by EuroScan member agencies, WHO Collaborating Centres, and WHO has been solely based on a limited assessment of data and information submitted in the developers' applications and, where available, of additional sources of evidence, such as literature search results or other publicly available information. There has been no rigorous review for safety, efficacy, quality, applicability, nor cost acceptability of any of the technologies. Therefore, inclusion in the compendium does not constitute a warranty of the fitness of any technology for a particular purpose. Besides, the responsibility for the quality, safety and efficacy of each technology remains with the developer and/or manufacturer. The decision to include a particular technology in the compendium is subject to change on the basis of new information that may subsequently become available to WHO.

WHO will not be held to endorse nor to recommend any technology included in the compendium. Inclusion in the compendium solely aims at drawing stakeholders' attention to innovative health technologies, either existing or under development, with a view to fostering the development and availability of, and/or access to, new and emerging technologies which are likely to be accessible, appropriate and affordable for use in low- and middle-income countries.

WHO does not furthermore warrant or represent that:

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- 2. the technologies which are included in the compendium will be embodied in future editions of the compendium; and/or that
- 3. the use of the technologies listed is, or will be, in accordance with the national laws and regulations of any country, including but not limited to patent laws; and/or that
- 4. any product that may be developed from the listed technologies will be successfully commercialized in target countries or that WHO will finance or otherwise support the development or commercialization of any such product.

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# Medical devices

2012

## Auto stop electrochlorinator

Country of origin United States of America

### Health problem addressed \_

Over 1 billion people worldwide do not have access to safe water. Furthermore, 1.8 million children under the age of 5 years die annually from diarrheal disease caused by unsafe water in places with poor sanitation. The auto stop chlorinator produces chlorine, which is a highly effective disinfectant for drinking water. Treating drinking water with chlorine has been shown to reduce rates of diarrhea in children by up to 29%.

### Product description \_

The electrochlorinator consists of a salt brine bottle where the salt and water is poured. It also consists of power leads to connect to a battery source as well as a control panel at the base of the brine bottle to start and stop the chlorination process.



### Product functionality.

The auto stop electrochlorinator localizes chlorine production, eliminating shelf life and inventory management issues experienced with liquid chlorine and water filters while requiring little maintenance. The intended kiosk model centralizes water treatment to trained operators and can treat water for 200 people per day.

### Developer's claims of product benefits

Drinking water can be treated by many methods, including boiling, chemical disinfection, filtration, and UV light. All methods have their advantages and drawbacks, mostly related to cost, ease of use, and appropriateness for the source water conditions. This device is innovative because of its low capital and recurring costs, income generation potential, and its relative ease of use. The chlorinator is durable, has no moving parts, and very minimal maintenance requirements. Disinfection of clothing, hard surfaces and medical equipment is greatly simplified. With a low wholesale price and high chlorine generation rate, it is an excellent candidate for microloan-supported entrepreneurial programs. The kiosk model also provides financial incentives to operators.

### Operating steps \_

Add salt and water to the indicated lines in the salt brine bottle. Shake until all salt is dissolved. Attach the power leads to a 12 V battery. Fill the device with 50 mL of salt brine and press start. Wait about 5 minutes until the device beeps and the light flashes. Dose chlorine into drinking water storage containers.

### Development stage \_

The device has been proven for its simplicity and has undergone many field trials without incident. In field trials, random checks of participating households showed a 2-3 log E. coli reduction against controls. Lab testing found greater than 4 log reduction of virus and 6 log reduction of bacteria. Device conforms to US EPA guide standard and protocol for microbiological water purifiers, as tested in-house.

### Future work and challenges -

Challenges include cost, distribution, and appropriate support. Efficient manufacturing process that reduces costs and ensures high quality is required to reach target sale price. Partnerships with local and international NGOs implementing water and health programs is required to develop implementation support materials to ensure successful, sustainable use of technology in different scenarios.

### User and environment.

User: Self-use/patient, physician, technician, nurse, midwife, shop owner

Training: Training can be conducted programmatically in under 30 minutes with instruction manual and device.

Maintenance: None

### Environment of use \_

Settings: Rural settings, Urban settings, primary (health post, health center), secondary (general hospital), tertiary (specialists hospital)

Requirements: This product requires a minimally trained operator and a charged 12V battery. It also requires a power supply for recharging.

### Product specifications \_

Dimensions (mm):  $100 \times 77 \times 122$ 

Weight (kg): 0.2

Consumables: Salt, Water, Battery Power

Life time: 20 years Shelf life: 10 years List price (USD): 100 List price of consumables (USD): 0.05/1000 liters of

water treated

Other features: Software use, Installed stationary, Reusable

Year of commercialization: 2012 Currently sold in: Worldwide

Contact details Tim Oriard | Email emergingmarkets2@gmail.com | Telephone + | 206 694 1511 | Fax + | 206 694 1559

## Automated solar-powered blood pressure monitor

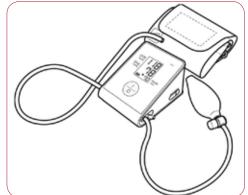
Country of origin | Japan

### Health problem addressed \_

There is a progressive increase in the prevalence of cardiovascular diseases resulting in approximately 8 million deaths annually worldwide which can be attributed to high blood pressure. Low- and middle-income countries shoulder 80% of the cardiovascular disease burden, more than half of which occurs in people of working age and pregnant women.

### Product description \_

This electronic automated blood pressure monitor operates with solar power alone, as well as AC adapter and regular dry battery. It is also equipped with ultraviolet-tolerant plastic parts and dust-preventive structure to bare direct sunlight exposure for battery charge.



### Product functionality \_

Functions as a standard blood pressure monitoring system.

### Developer's claims of product benefits \_

With progressive integrated circuit technology, the electronic circuit of the device consists of an ultimately small number of components resulting in very low energy consumption which can be supplied with a solar panel. The chassis of the device is made of ultraviolet-tolerant plastic which bare direct sunlight. To the best of the submitters' knowledge, this is the world's first product according to WHO's specifications, including solar power and accuracy.

### Operating steps \_

Charge battery by exposing the device to strong light, such as direct sunlight. Attach blood pressure cuff to upper arm. Inflate the cuff by pumping bulb up to estimated systolic blood pressure, then the device starts measurement. Remove the pressure entirely by pressing release button when the device displays the results.

### Development stage

The product underwent field tests in Uganda and Zambia. In the evaluation, healthcare providers used the product in 700 patients and in comparison with conventional method (auscultation), 95% of the providers preferred the product with the reasons of easiness, solar power, and automated measurement. The product is approved as medical equipment in Japan, Europe and the US based on respective regulatory systems.

### Future work and challenges \_

Currently, the price of the product is set relatively high level because of little manufacturing quantity. When the product sells more, the unit price aims to be much lower.

### User and environment \_

User: Self-use/patient, physician, technician, nurse, midwife, family member, care person

Training: None Maintenance: None

### Environment of use \_

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

Requirements: None

### Product specifications \_

**Dimensions (mm):** 90 x 75 x 125 Other features: Portable (hand-held), reusable

Weight (kg): 0.2 Life time: 5 years Retail Price (USD): 100 List price (USD): 100

Year of commercialization: 2009 Currently sold in: Japan, EU Nations

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## Birthing simulator for training

Country of origin | Norway

### Health problem addressed\_

Appropriately skilled birth attendants could save the majority of the annual 350,000 maternal deaths, 99% of which occur in low-resource settings. In order to reduce the high number of unnecessary maternal and newborn deaths on the day of birth, there is an urgent need to train birth attendants and other "Frontline Health Workers" in Basic Emergency Obstetric and Newborn Care (BEmOC).

### Product description \_

The birthing simulator supports training in BEmOC in developing countries. It enables the instructor to create very compelling simulations of normal to more complex birthing scenarios, and is particularly suitable for training control of post-partum hemorrhage, the leading cause of maternal deaths.



### Product functionality \_

Behind the birthing suit, the instructor can manually control: cervical dilation, position of the baby, delivery of the baby, delivery of placenta, bleeding (amount and nature), uterus condition, and fetal heart sounds.

### Developer's claims of product benefits \_

The simulator is distinctively different from other birthing simulators available on the market. It aims to respond to the needs of a supportive device that can improve quality of BEmOC as presented in "International Journal of Gynecology & Obstetrics" by being highly realistic where essential (particularly in simulating post-partum hemorrhage and uterus contraction), and culturally adapted. It facilitates effective communication training and integrated training with newborn routine care and resuscitation. It is flat packed for easy transport and storage, highly affordable, durable, and easy to use.

### Operating steps \_

The simulator is strapped onto the instructor, who acts as the mother, and creates and controls the various scenarios and situations directly with his/hers hands.

### Development stage \_

It is offered on a not-for-profit price to the 68 countries that have been identified by UN as focus countries relative to MDG 4 and 5. It has been field tested in several countries including USA, Norway, Tanzania, and Ethiopia.

### Future work and challenges \_

Financing: Although the product is available on a not-for-profit basis, healthcare facilities and educational institutions in low and middle income countries often have limited financial resources.

Distribution channels: bureaucracy and often prohibitive customs rates in importing such material to the countries where the need for these products is greatest.

### User and environment \_

User: Family member, midwife, nurse, physician

Training: None required

Maintenance: Instructor in courses

### Environment of use \_

Settings: Rural, urban, health post, health center, general hospital, specialists hospital

Requirements: No specific infrastructure requirements. Access to 3-4 liters of water would be desirable to create simulated blood and to fill the newborn simulator with water.

### Product specifications \_

**Dimensions (mm):** 500 x 350 x 200 Retail Price (USD): 100

Weight (kg): 4.5 (filled with simulated blood), List price (USD): 100

3.5 (empty)

Consumables: None

Life time: 3 years Shelf life: 3 years

Other features: Portable and reusable

Year of commercialization: 2011

Currently sold in: 68 countries that have been identified by UN as focus countries relative to MDG 4 and 5.

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## Interventional cardiovascular lab

Country of origin India

### Health problem addressed \_

Cardiovascular diseases (CVDs) are the number one cause of death globally. An estimated 17.3 million people died from CVDs in 2008. Out of that, more than 80% of CVD deaths take place in low and middle-income countries due to lack of access to affordable equipment for diagnosis and treatment.

### Product description \_

The catheterization lab has a high power 80 KW generator digital X-ray system, a patient table, and a gantry stand with varying degrees of movements, and different X-ray modes.

### Product functionality \_

The X-ray system provides real time images which help to visualize and identify blocks in blood vessels and makes it possible to treat them by means

of stenting, coiling, etc. The patient table and gantry stand allows imaging that makes it possible to view blood vessels in different parts of body in real time. Different X-ray modes facilitate the imaging.



The economy catheterization lab is tailored for the economy section as it has the flexibility to perform a wide variety of procedures. Infrastructure requirements are also lesser as the system has a small footprint which makes it possible to fit it in even small hospitals emerging economies. Low cost of ownership/maintenance makes the product ideal for low and middle-income sections. The lab requires less training to operate as it has an intuitive user interface and simple workflow. User manual and localized software interface helps ensure the product is well-suited for different countries. Overall, it is a robust product and withstands high workload demand, which is typical for resource-constrained countries. Configurable options and mobile table allow a variety of procedures in cardiac and vascular areas.

### Operating steps \_

The principle of operation is that of a general x-ray system. For specifics, the user manual reference needed.

### Development stage .

Internal verification and validation testing completed. External evaluations done at hospitals globally. CE marked product. Compliance to European Medical Devices Directive MDD/93/42EEC. Manufacturing facility is ISO13485 certified. The catheterization lab has been commercially released and is in use in various markets like India, Nepal, Egypt, Turkey, Latin America and Eastern Europe.

### Future work and challenges

Availability of trained interventional cardiologist and radiologist is one of the major challenges and targeting this would be the next step.

### User and environment \_

User: Interventional cardiologist and interventional radiologist

Training: Required Maintenance: Annually

### Environment of use \_\_

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

Requirements: Stable 120 kVA power supply and good earthing. Procedure room should be semi-sterile. Lead shielding on doors and windows should be present to protect from scattered radiation. Technician operating the system needs to be trained. Temperature range is 15-35°C and humidity range is 30-75%.

### Product specifications \_

**Dimensions (mm):** 2000 x 1000 x 2000

Weight (kg): 300

Retail Price (USD): 180000 - 250000 List price (USD): 180000 - 250000

Other features: Software use, installed stationary,

reusable

Year of commercialization: 2010

Currently sold in: India, Nepal, Egypt, Turkey, Chile,

Columbia, Peru, Poland



## Intramedullary nail and interlocking screw system

Country of origin | United States of America

### Health problem addressed \_

According to WHO statistics, road traffic accidents (RTAs) cause about 25.4 million severe injuries per year. RTAs are projected to become the third leading cause of DALYs lost worldwide by 2020. Developing countries lack the surgical tools to treat severe fracture injuries effectively. Those who live in poverty cannot afford the cost of surgical implant they need in order to quickly recover and provide for their dependents.

### Product description.

The intermedullar (IM) nail and interlocking screw system is designed to be used without electricity or x-ray imaging in the operating room. The system consists of stainless steel nails which are placed down the middle of the bones with screws that are placed through the bone and nail to stabilize the fracture.



### Product functionality \_

This method allows patients to walk using crutches the day after surgery and be discharged usually three days after surgery. The same instruments and implants of different sizes are used to treat fractures of the femur, tibia, and humerus. Results are recorded on an online database to ensure the proper technique is being followed and to learn more about fracture healing.

### Developer's claims of product benefits.

The IM nail and interlocking screw system's cost effectiveness is reflected in less disability after the fracture, ability to return sooner to work, and more efficient utilization of hospital beds. The IM nail interlocking screw technique is globally recognized as the preferred treatment for long bone fractures. This system makes it possible for surgeons to use this treatment on patients who couldn't afford it otherwise. Total cost is less than other systems of equivalent quality.

### Operating steps \_

During surgery, the fracture is reduced and the stainless steel IM nail is placed through the canal of the bone. A target arm and special instruments are used to place screws through the slots in the nail and through the bone to stabilize the tibia, femur, or humerus fracture. No electricity or x-ray imaging is necessary for the surgery.

### Development stage .

FDA cleared for use in the USA. The stainless steel alloy composition is approved for implantation in humans. The associated online database has over 50,000 entries and is the largest database of treatment of long bone fractures in the world. This has been reviewed by surgeons and reported in peer reviewed medical journals. Biomechanical tests have been obtained as noted in listed articles.

### Future work and challenges.

Though the product is comparatively low-cost and available on a not-for-profit basis, it is a challenge to keep up with the increasing number of requests for the IM nail and interlocking screw system as financing is limited. Continual updating of technique is also a challenge due to the increasing number of hospitals which have this system.

### User and environment

User: Physician, orthopaedic surgeon

Training: Yes; training and tools are given by surgeons familiar with the technique (over 10+ surgeries)

Maintenance: Yes; periodic replenishments (by nurse, technician, manufacturer, physician)

### Environment of use \_

Settings: Rural, urban, secondary (general hospital), tertiary (specialists hospital)

Requirements: Operating room with sterile conditions, anesthesia personnel and machines, well trained nurses, and sterilizing personnel are all required

### Product specifications \_

**Dimensions (mm):** 8-12 x 8-12 x 280-420

Weight (kg): 0.118-0.389

**Consumables:** Surgical supplies

Retail Price (USD): Varies

List price (USD): Varies

Year of commercialization: 2002

Other features: Portable

Currently sold in: United States, Vietnam, Iran,

Guatemala, & Indonesia. Donated to 48 other countries

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### Low smoke stove

Country of origin | India

### Health problem addressed \_

Total world deaths from indoor air pollution due to burning solid fuels are estimated at 1,619,000 each year. India accounts for 25% of such deaths.

### Product description \_

The stove has a bypass duct for efficient draft, soot collector and chimney connector.

### Product functionality \_\_\_\_

The stove can be easy to use and maintain, and can be used with indigenous biomass as fuel. Cooking time is reduced by 1.5 hours per day and fuel consumption (wood and cow dung) is reduced by 60-70%.



### Developer's claims of product benefits \_

Most people in the targeted areas don't use a stove, but have a 'three-stone' cooking setup without any form of ventilation. Traditional stoves sold in these regions (e.g. India) are monolithic (in one piece), which makes them more difficult to transport and expensive to replace. The developers therefore added a chimney and designed a modular solution. It has been designed with respect to Indian cooking needs and in order to accommodate different culinary habits. The design of the stove allows the chimney to take exhaust fumes out of the kitchen area. As the stove is locally produced and distributed, it is relatively cheap and easily available. Stove production uses local materials and processes, and also allows for easy installation.

### Operating steps \_

Operates like a traditional stove.

### Development stage \_

This product has been used successfully, mostly in India, but also in countries like Kenya and Laos. It's technical performance has been assessed and certified by the College of Engineering, Pune and Approvecho, Pondicherry, India.

### Future work and challenges \_

To take the next step in empowering local entrepreneurship and enabling NGOs to implement the solution, the company has set up a webpage. The corresponding online platform aims to support the dissemination of the stove by free distribution of the design specifications. It also enables networking with other involved stakeholders and facilitates transfer of knowledge.

### User and environment \_\_\_\_\_

**User:** Self-use/patient

Training: Training can be conducted by local entrepreneurs who produce and install the stove and explain about use

Maintenance: Chimney and soot collector cleaning once per month.

### Environment of use \_

Settings: Rural settings

Requirements: Low tech manufacturing using only cement and clay.

### Product specifications \_

**Dimensions (mm):** 800 x 450 x 270

Weight (kg): 90

Consumables: Biomass fuel (wood or cow dung)

Retail Price (USD): Approximately 20 including product,

transportation and installation.

List price (USD): Approximately 20 including product,

transportation and installation.

Other features: Installed stationary, reusable

Year of commercialization: 2008

Currently sold in: India, Kenya, Laos, Guatemala, Peru

7

## Mobile ECG with web-based telemedicine platform

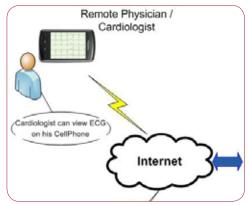
Country of origin | India

### Health problem addressed.

Coronary heart disease is one of the leading causes of death across the globe. Every second in some part of the world a person suffers from chest pain or has a heart attack with lack of early warning systems. The problem gets compounded by the fact that the ratio of doctors attending patients is far less in lower and middle income regions.

### Product description.

The system has been designed to provide a telecardiology platform for remote ECG analysis and real time reporting from the doctor for the attending paramedic or the general practitioner. The portable system gives specialists the possibility to interpret ECG's from their mobiles, thus bridging the gap between the patient and the specialist. Also the system



gives an auditable trail of all the reports right from acquisition to reporting of the patient ECG.

### Product functionality.

Patient details are entered in the device along with taking their ECG. 20 ECG's can be stored in the device. Each patient details can be transmitted to the doctor in real time.

### Developer's claims of product benefits.

Prevalent solutions use facsimile and dual-tone multi-frequency solutions to implement transmission of ECG's to the remote doctors. These are one way communications without proper platform for digital reporting of diagnosis from the doctor. This has been overcome with comprehensive auditable online storage. This device has been so designed keeping in view the ease of use, adaptability and scalability. The device can be used not only as an emergency single point of care, but with its local and cloud printing capabilities, it also means that the same device can replace a conventional ECG machine.

### Operating steps \_

1. Connect the patient cable to the ECG connector at the bottom of the device. 2. Clean the skin surface before/after applying electrodes. 3. Connect the electrodes to the patient. 4. Attach the patient cable leads to the electrodes placed on the patient's skin surface 5. Switch on. 6. Follow the process on device as mentioned in section 7.2 in manual.

### Development stage .

The unit was tested and deployed at a renowned 800 bedded multi-specialty hospital and a cardiac critical care center in Mumbai. Further in the first 12 months the devices has been used in cardiac screening camps at multiple remote rural locations within India with more than 10000 ECGs being taken and reported in this period. Certified for CE - 1293.

### Future work and challenges

- 1) Availability of: reliable communication networks, electrical power for device charging in remote rural locations, doctors to report the ECGs on timely basis.
- 2) Seamless integration of various emergency response teams to take follow actions.
- 3) Developing and managing software clients for various different smartphones.
- 4) Slow adoption by medical professional / local administration agencies.

### User and environment \_

User: Patient, physician, technician, nurse

Training: 3 hrs; delivered by company technician Maintenance: Preventative; once per year

### Environment of use \_

Settings: Urban, rural, ambulatory, at home, primary (health post, health center), secondary (general hospital), tertiary (specialists hospital)

Requirements: Access to cellphone network, power supply for recharging

### Product specifications \_

Dimensions (mm):  $140 \times 97 \times 43$ Retail Price (USD): 1000-1200

List price (USD): 1400 Weight (kg): 0.65

Consumables: ECG gel, reporting paper Other features: Portable, reusable, uses software

Year of commercialization: 2010 Life time: 7 years Currently sold in: India, Mauritius Shelf life: 5 years

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## Multi-parameter remote diagnostic kit

Country of origin | India

### Health problem addressed.

70% of the rural population in India has very poor access to health care. 76% of the medical facilities are concentrated in the urban areas, and there is an overall shortage of medical personnel.

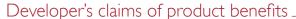
### Product description \_

The technology comprises of a USB powered multiparameter diagnostic device which captures ECG, temperature, heart & lung sounds, SPO2 and BP, and communicates with the remote doctor through a low bandwidth audio/video/data conferencing.

### Product functionality.

The technology enables rural patients to reach urban doctors through a telemedicine solution that integrates the whole healthcare delivery

ecosystem to provide meaningful services. The solution also captures the workflow of delivery processes, and enables resource optimization by capturing and analysing operational data in service delivery.



Infrastructure (bandwidth) and skillset limits the reach of technological solutions. This solution works at extremely low bandwidths (32 kilobits/s onwards) for real-time audio/video/data tele-consultation, thereby reaching places where other existing solutions can't reach. It is very easy to use by a village operator and is extremely power efficient (works on USB power). Further, it is a comprehensive solution linking multiple providers (doctors/pharmacies/labs/hospitals), and addresses 75% of healthcare needs at the point-of-care at sub USD 1.0 fees.

### Operating steps \_

A rural operator carries out remote consultation for the patient at the village with a doctor sitting anywhere with an internet connection. The doctor remotely controls the device to obtain medical parameters, and to provide prescription to the patient, while medical records are stored. The solution also supports supply-chain, lab reports, and referrals.

### Development stage

More than 850 devices have been operational in the rural areas of India with low bandwidths (mostly over 64 kilobits/s bandwidth) and semi-skilled village operators, and more than 100,000 tele-consultations have been carried out successfully. IEC60601-1 compliance and ISO13485 manufacturing process compliance have been completed. CE marking process is underway.

### Future work and challenges \_

Implement large scale projects with healthcare service delivery partners and e-governance players. Enhance technology with further diagnostics and better ground level delivery processes. Develop mobile Bluetooth based solution for places lacking 32 kilobits/s bandwidth. Build relations with partners having complementary solutions. Modify business model to include software-as-a-service.

### User and environment \_

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

Training: On-site individual/group training, videoconferencing/teamviewer based e-training, 2-4 hrs

Maintenance: Annual, Preventive. To be conducted by Manufacturer.

### Environment of use

Settings: Rural settings, urban settings, at home, primary (health post, health center), secondary (general hospital) Requirements: USB 1.0 connection to a desktop or laptop computer. Windows XP/Vista operating system on the desktop or laptop. Minimum 32 kilobits/s internet speed for real-time audio / video / data tele-consultation. Fixed static IPs at both ends for professional edition, and at server for enterprise edition.

### Product specifications \_

**Dimensions (mm):** 225 x 165 x 40

Weight (kg): 0.61 Consumables: ECG Gel

Life time: 5 years Shelf life: 2 years

Retail Price (USD): 1800

List price (USD): 1800

Other features: Software use, installed stationary,

Year of commercialization: 2008

Currently sold in: Primarily in India, some countries in

Africa and South East Asia

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## Neonatal sleeping bag warmer

Country of origin | United States of America

### Health problem addressed \_

Over 20 million low birthweight infants are born around the world every year, and more than 95% of these are in developing countries. 4 million of these babies die every year, and those babies who survive often develop chronic health conditions, including early onset of diabetes, heart disease, and low IQ. Other issues include lack of access to healthcare facilities (travel time and costs) and intermittent electricity in the developing world.

### Product description.

The infant warmer consists of three parts - a sleeping bag to place the baby, a pouch of phase change material and an electric heater. The pouch is heated for 30 mins in the heater and then placed in the sleeping bag. It maintains the WHO recommended temperature of 37 deg C for 4-6 hours, after which it can be reheated.



### Product functionality \_

This infant warmer is an innovative device that works without a constant supply of electricity. It has no moving parts and is portable, which enables newborns to be kept warm during transport.

### Developer's claims of product benefits.

In low resource areas in developing countries, common infant warming methods include blankets, hot water bottles and light bulbs. All these methods are ineffective and unsafe, often causing burns on babies. This infant warmer can be used to support care of hypothermia in neonates, it is easy to use and has very low operating costs.

### Operating steps.

Sanitize sleeping bag, pouch of phase change material, and electric heater. Insert pouch into heater, and heat for 25 minutes until the alarm rings and green light turns on. Remove pouch only when needed. Check if indicator on pouch says OK and place in sleeping bag. Wrap newborn and tighten straps and monitor its temperature hourly for 4-6 hours. When indicator says TOO COLD, remove newborn. Remove pouch and reheat.

### Development stage \_

The product has undergone a series of clinical studies and trials with 100% positive results. One RCT that was conducted over 160 babies across 3 facilities showed that the device is non-inferior to the SOC (including radiant warmers). Internal processes are ISO13485 certified. CE certification is being filed in June 2012. The device is available in 4 Indian states and is helping babies in India, China, and Somalia.

### User and environment \_

User: Physician, nurse

Training: No intensive training required. Basic instructions included with device in pictorial form.

Maintenance: None

### Environment of use \_

Settings: Rural settings, primary (health post, health center), secondary (general hospital), tertiary (specialists hospital) Requirements: Intermittent supply of electricity for recharging.

### Product specifications.

**Dimensions (mm):** 440 x 290 x 70 Other features: Portable (hand-held), reusable

Weight (kg): 4.1 Life time: 1 year

Retail Price (USD): 220 List price (USD): 220

Year of commercialization: 2011

Currently sold in: India

## Non-invasive hypothermia indicator for newborns

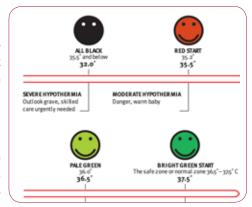
Country of origin | United Kingdom/United States of America

### Health problem addressed.

The problem of detecting hypothermia exists throughout the "disadvantaged world" where up to 4 million newborns die within their first 28 days of life from either disease, malnutrition or a combination of both. Preterm, sick and low birth weight babies are especially at risk. The effect for a newborn that has suffered from hypothermia and survived is poorly researched and is in need of urgent attention.

### Product description \_

The hypothermia indicator is a 12mm diameter disc with a black 'face' with two small white "dots" on one side, the other side has a self-adhesive facility. This device comes in a strip of 5 units. Liquid crystal technology provides function for it to perform reliably and accurately within an operating tolerance of +/- 0.5 degree Celsius.



### Product functionality \_

When in situ on a healthy newborn (temperature 36.5 -37.5° C), the device shows a 'bright green' background with a smiling 'face' clearly visible which is the 'safe-zone' for the average 'normal' temperature. Should the temperature drop below 36.5° C, the color fades to a 'pale green' before a 'red/brown' color is displayed. At 35.5° C the 'black' color shows.

### Developer's claims of product benefits

A naked newborn exposed to an environmental temperature of 23° C suffers the same heat loss as a naked adult at 0° C. This heat loss is even greater for preterm, sick and low birth weight babies, especially if left wet and uncovered at birth. Hypothermia in the newborn can occur in all climates due to a lack of knowledge and/or procedure. The availability of a very simple, low cost device placed either in an axilla, above the liver or the great vessels of the neck would empower to maintain "the warm chain" immediately following birth. The device has been designed so that also illiterate mothers can understand and safely use it.

### Operating steps \_

1. Choose site under an arm or on the right side of the abdomen. 2. Clean site with an alcohol. 3. Press device firmly into site, white "dots" upright. 4. Provided the body temperature is within the "safe-zone", a smiling face will appear on a bright-green background. Observe every two hours. 5. Mothers should seek advice if the "smiling face" begins to fade or reverts to "black". 6. The device remains attached for up to a week and can be reused.

### Development stage \_

Published, tested, clinical trials conducted. Commercially available. CE No: 0434.

### Future work and challenges \_

Currently, the device is difficult to read in poor light and in the dark. Getting the device widely established has been unexpectedly slow.

### User and environment \_

User: Physician, nurse, midwife, family member

Training: None Maintenance: None

### Environment of use \_

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

Requirements: Storage in cool, dark location (out of direct sunlight)

Product specifications \_

**Dimensions (mm):** 80 x 20 x 0.001

Weight (kg): 0.002

Consumables: Disposable alcohol wipes, transparent

medical tape

Life time: 5 years Shelf life: 2+ years List price (USD): 0.40

Other features: Portable, reusable Year of commercialization: 2010

Currently sold in: India, Russia, USA, UK, Haiti. Australia, Canada, Cyprus, Egypt, Kenya, Netherlands, Papua New

Guinea, Peru, Tanzania, Zimbabwe

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## Non-invasive vascular age risk prediction

Country of origin | Malaysia

### Health problem addressed\_

According to WHO 17.3 million people died from cardiovascular diseases (CVD) in 2008 and over 80% of CVD deaths are in low and middle income countries. Over the past 10 years, the trend of hospitalizations and death due to cardiovascular and circulatory diseases has increased from 13% in 2008 to 16% in 2009 as reported by Malaysian Ministry of health.

### Product description \_

Photoplethysmography (PPG) is a non-invasive technique to detect blood volume changes. Analysis of the PPG signal can provide sufficient information on the cardio-vascular related performance. The proposed simple, user friendly and operator independent vascular risk prediction method is a noninvasive quantification of hemodynamic vascular properties.



### Product functionality \_

The system utilizes PPG to assess cardiovascular health in a non-invasive, inexpensive manner.

The advancement of the Information Technology enables the medical personnel access the clinical data irrespective to the geographical location and reduces the number of visits to hospital as well as consultation costs. The portability and server-based processing features allow its use in low-resources settings.

### Developer's claims of product benefits

The conventional technique to assess the cardiovascular health is to measure the thickness of the carotid artery wall (CIMT). The CIMT technique is ultrasound-based, costly and requires expertise in measurements. PPG is a non-invasive and low-cost optical technique to detect blood volume changes in the micro vascular bed of tissue. The system can be a part of standard health screenings in public and private medical sectors for general vascular risk assessment and as a cost effective and efficient alternative to current methods of screening. The system is applicable in rural and mobile clinics due to its convenience and portability.

### Operating steps.

a. Upon arrival, verify patients fasting status. b. The patients need to rest for 10 minutes before data recording. c. PPG signal will be recorded for a duration of 90 seconds at a room temperature of 24-25° C. Recording is done at a sampling rate of 50 Hz and saved in ASCII format. d. Subject to be in supine position with arms rested on pillows during the data recording session. PPG to be obtained from tip of the left index finger.

### Development stage \_

In 2010, the clinical trials and community health screening program have been conducted in several places including universiti kebangsaan Malaysia medical center (UKMMC), Taman Melewar Gombak (urban) and Felda Sungai Tengi Kuala Kubu Baru (sub-urban). Approximately 370 subjects participated. The study was granted the Ethical Committee approval from the UKMMC Research Ethical Committee.

### Future work and challenges.

Vascular age is a newly develops concept and technology which have a great potential to improve the health care services especially in CVD screening. The main challenge is the acceptance among the medical personals. The vascular age model is the ethnic and population dependent. Therefore, data acquisition across the nations would help to establish and improve the existing model.

### User and environment \_

**User:** Patient Training: None Maintenance: None

### Environment of use \_

Settings: Urban, rural, at home, primary (health post, health center)

Requirements: Laptop, access to Internet

### Product specifications \_

Dimensions (mm):  $80 \times 110 \times 40$ 

Weight (kg): 0.3

Consumables: None

Life time: 3 years Shelf life: 3 years

Retail Price (USD): 2000 List price (USD): 2000

Other features: Mobile, reusable, uses software

Year of commercialization: 2010

Currently sold in: Malaysia

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http://www.who.int/medical\_devices

## Non-surgical male circumcision device

Country of origin | Israel

### Health problem addressed.

Three randomized controlled clinical trials in Africa showed that male circumcision can reduce risk of HIV transmission among heterosexual men by as much as 60%. Public health leaders aim to circumcise 20 million men by 2015 in 14 nations in Sub-Saharan Africa; Africa has reached less than 5% of its goal with existing surgical methods.

### Product description \_

The device consists of an Inner Ring, Elastic Ring and Applicator. The device applies controlled radial elastic pressure to compress the foreskin and cut off circulation. The distal foreskin becomes necrotic and is removed after 5-7 days. The procedure takes less than 5 minutes, is bloodless, requires no injected anesthesia, no sutures, no sterile settings and can be conducted by low cadre nurses, as validated scientifically by the Government of Rwanda.



### Product functionality \_

This simple and scalable device was specifically developed to provide voluntary circumcision to men, ages 15 to 49, living in 14 priority nations in Sub-Saharan Africa where there are high rates of HIV transmission and limited healthcare infrastructure.

### Developer's claims of product benefits.

Currently, the only WHO recommended method for circumcision is surgery, which entails skills and infrastructure that are hard to attain in resource-scare settings. Other devices that were not specifically designed for resourcepoor settings entail blood (albeit less than surgery), require injected anesthesia, cutting of live tissue and a sterile setting. Compared to surgery, this device is safer, simpler (no sutures, 3 vs 10 days of training, and with low cadre, non-surgically trained nurses, significantly reducing burden to health system), and more scalable (done in less than 5 minutes vs. over 20). It is the only non-surgical device in market --bloodless, no injected anesthesia, no sterile settings--offering a viable solution for resource poor settings.

### Operating steps \_

Clients are measured to select ring size. The circumcision line is marked based on WHO guidelines. The inner ring is inserted. An elastic ring is aligned with the inner ring to compress the foreskin and stop blood flow. Verification thread is then cut. Ischemic necrosis is initiated. Device remains in situ for 5-7 days, and is then removed.

### Development stage \_

The device is FDA cleared (K103695) and certified CE Mark Class IIa and is manufactured using USP Class VI biocompatible elastomeric materials compliant to ISO 13485 Medical Devices (Quality Management systems) and FDA, 21 CFR177. 2600. The device is currently undergoing clinical trials by the government of Zimbabwe and Rwanda. To date the device was studied in 3 independent clinical trials in Rwanda on over 880 subjects.

### Future work and challenges.

The challenges are scalability, uptake and government commitment. If governments have a viable and sustainable solution with minimal burden to the health system, they are more likely to commit resources, enable task shifting policies, and achieve the national and regional HIV prevention goals.

### User and environment \_

User: Nurse, community health workers

Training: Yes; will be provided by Rwandan Centers of Excellence

Maintenance: None

### Environment of use

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

Requirements: Clean (though nonsterile) setting, trained healthcare provider, bed, biologics disposal box

### Product specifications.

Dimensions (mm):  $22 \times 60 \times 60$ Life time: 5 years Weight (kg): 0.011 Shelf life: 2 years Consumables: Gauze pads, scissors, spatula, forceps, List price (USD): 15-20

dressing, betadine, anesthetic cream Other features: Portable

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## Oral syringe dosing clip

Country of origin | United States of America

### Health problem addressed \_

Studies show that 40-60% of parents make errors when giving children liquid medication. Misdosing medication can have serious consequences. For example, with liquid Anti-Retroviral Medications (ARVs) for HIV-positive infants and children, inaccurate doses can lead to drug resistance, which can be fatal.

### Product description \_

The oral syringe dosing clip is a small, plastic clip that fits into the barrel of an oral syringe and acts as a stopping mechanism for the plunger, ensuring that the correct dose of medication is drawn into the syringe. The clips are color-coded by dose and can be pre-set by a physician, do not come into contact with the medication and can be reused.



### Product functionality \_

The oral syringe dosing clip enables caregivers and patients to deliver accurate doses of liquid medication when using an oral syringe.

### Developer's claims of product benefits \_

It was found in laboratory and community settings that inserting the clip into the syringe enables a greater proportion of users to deliver an accurate dosage of liquid medication when compared to a syringe without a clip and a teaspoon. The clips are inexpensive and can be used by caregivers to improve dosing of liquid medication, regardless of literacy and numeracy skills, manual dexterity, and visual acuity. The clip may therefore be particularly beneficial in low-resource settings.

### Operating steps \_

Pull back plunger. Insert clip into syringe barrel. Push plunger into barrel. Twist and lock clip into place. Draw liquid medication into the syringe until the clip stops the plunger, preventing further intake of liquid. Dispense dose of medication with syringe as normal.

### Development stage \_

The dosing clips are being used by the Swaziland Ministry of Health in its national Prevention of Mother to Child Transmission of HIV/AIDS (PMTCT) program. More than 213,000 clips have been distributed to mothers participating in the program to ensure that infants receive the proper dose of liquid anti-retroviral medication.

### Future work and challenges

The clip has been licensed and is available globally for purchase. A preferred pricing structure for Global Alliance for Vaccines and Immunisation (GAVI) countries has been established. Challenges ahead include identifying new nongovernmental, governmental, and corporate partners to scale up dissemination of the clip.

### User and environment \_

User: Self-use/patient, family member

Training: Healthcare provider can demonstrate clips and syringe to user in less than 2 minutes.

Maintenance: None

### Environment of use \_

Settings: Rural, urban, ambulatory, at home

Requirements: None

### Product specifications.

Dimensions (mm):  $53 \times 14 \times 3$ **Retail Price (USD): 0.10-0.25** Weight (kg): 0.001 List price (USD): 0.10-0.25

Consumables: None Other features: Portable and reusable Year of commercialization: 2011 Life time: 1 year Shelf life: 2 years Currently sold in: Swaziland

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14

## Point of care diagnostic device for total WBC

Country of origin | Sweden

### Health problem addressed.

Measuring white blood cells (WBC) can provide information which may aid in the diagnosis of infection, inflammatory diseases or leukemia and aid in judicious prescription of antibiotics. A WBC POC will be beneficial in rural settings to increase access of a vital test. The system is designed as a portable device to be used in rural settings or where near patient testing for WBC is of benefit. As only a small blood volume is needed it is useful also for small children and anemic patients.

### Product description.

The system consists of an analyzer and single use cuvettes. One drop (10µL) of capillary or venous blood is drawn into the cuvette by capillary action. The portable analyzer consists of a microscope and a camera and the cells are counted by image analysis.

### Product functionality \_

The microcuvette serves as pipette, mixing and reaction chamber and the correct specimen volume is obtained by capillary action.

### Developer's claims of product benefits.

No similar system exists which can be used by the intended user/environment. Automated cell counters or manual microscopy technologies are available at laboratories but requires laboratory educated staff and requires specimen to be transported. The suggested solution is performed as near patient testing. The WBC system will provide rural areas with increased availability to one of the most frequently used lab parameters. Instant results of the white blood cell count will facilitate more well informed decisions in several clinical situations and facilitate monitoring of diseases and treatment (for example in infections, HIV, inflammatory diseases etc.). Making the WBC more rapidly accessible to rural settings will improve healthcare as well as save costs and transportation time.

### Operating steps \_

1. Fill the cuvette. 2. Place it in the analyzer. 3. Result is available < 3 min.

### Development stage \_

The device is CE-marked and FDA 510(k) cleared. Besides internal evaluations, the accuracy of the device has been validated in 2 published studies: a study by Osei-Bimpong et al (Osei-Bimpong; Int Journal of Laboratory Hematology; 2008) and a study by Casey et al (Casey et al; Clinical Pediatrics, 2009).

### Future work and challenges.

The company will use its well established distribution network to make the system available to the intended user. Through an extensive network the hemoglobin systems have been made widely available in developing regions, and has proved experience in bringing POC tests to rural settings including set up and local training. The main challenge lies in introducing and getting local acceptance of a new test and challenges regarding local decision making policies.

### User and environment \_

User: Physician, technician, nurse, midwife

Training: Required; provided by device distributors

Maintenance: Minimal; cleaning

### Environment of use \_

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

(specialists hospital)

Requirements: Power supply

### Product specifications .

**Dimensions (mm):** 120 x 135 x 183 List price (USD): 624.50

Other features: Portable, single use consumables and Weight (kg): 0.6

reusable device Consumables: Yes

Year of commercialization: 2008 Life time: >7 years Currently sold in: US, Europe Shelf life: >7 years

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## Portable anaesthesia machine

Country of origin United Kingdom

### Health problem addressed \_

In remote locations, anaesthesia may be non-existent or unreliable which can prevent emergency surgery. For instance, millions of mothers and babies die from birth complications; many of which could be saved by C-sections if safe anaesthesia were available. Anaesthesia is also vital for treatment of traumas, hernias, animal bites, burns, infections, and congenital deformities.

### Product description \_

This device is a complete inhalational anaesthesia system that is suitable for a variety of settings. It includes a valve with a circuit removing the valve, a reservoir unit for pre-oxygenation, a vaporiser for consistency over a wide temperature range, and is calibrated for Halothane/Isoflurane or Sevoflurane to overcome possible supply problems.



### Product functionality \_\_\_

The device is used for spontaneous breathing or assisted ventilation, and drawover or continuous flow inhalational anaesthetics.

### Developer's claims of product benefits \_\_

Most anaesthetic machines are designed to function in high-resource environments by specialized operators and require skilled technical support and maintenance. Current solutions require compressed gases and stable electricity supplies, which are not suitable for rapid response in austere environments. This device is robust, affordable, lightweight and easily transportable. It is easy to operate and virtually maintenance free, making it suitable for use by local personnel. It is extremely cost-effective and economic to use as there is no requirement for expensive consumables. Supremely safe, it can be used where supply of electricity and medical gases are unreliable or non-existent.

### Operating steps \_

Following the rapid assembly of the three principal components: vaporiser, reservoir, and breathing system, the product is ready for use. The product is intended for use by medical personnel trained in delivery of draw-over anaesthesia (e.g. anaesthesia physician, nurse or officer). It is designed to be easy to operate and require little maintenance.

### Development stage \_

The product was developed at the request of and with feedback from those operating in the field. The product is in use in 15 low-income countries and feedback from operators confirms its ease of use.

### Future work and challenges

This product will be promoted at existing training courses for anaesthetists in North America, UK, Africa and Australia. It will be demonstrated at exhibitions worldwide, and published in international peer-reviewed journals.

### User and environment \_

User: Anaesthesia physician, nurse, officer

Training: None Maintenance: None

### Environment of use \_\_\_

Settings: Rural settings, ambulatory, primary (health post, health center), secondary (general hospital), tertiary

(specialists hospital) Requirements: None

### Product specifications \_

**Dimensions (mm):** 470 x 330 x 170

Weight (kg): 9.5

Consumables: Inhalational anaesthetic agent

Life time: >10 years Shelf life: >10 years Retail Price (USD): 4589 List price (USD): 4589

Other features: Portable and reusable Year of commercialization: 2010

Currently sold in: Sold from UK for use in Australia, Bangladesh, Burma, Canada, Democratic Republic of Congo, Fiji, Gabon, Guatemala, Haiti, Honduras, India, Kenya, Mexico, Nepal, New Zealand, Rwanda, Sudan, Togo, Uganda, Zambia.

http://www.who.int/medical\_devices

## Solar charger for hearing aid

Country of origin | Botswana & Brazil

### Health problem addressed \_

7% of the world's population is hearing impaired. That is a total of 312 million people, of whom two-thirds are living in developing countries. The extent of hearing loss leads to unnecessary poverty and hardship in the families and communities affected, and by extension, to the larger society. It also costs governments up to 3% of their GNP.

### Product description \_\_

Rechargeable hearing aid, solar charger and rechargeable hearing aid

### Product functionality \_

This device has a rechargeable hearing aid battery which costs \$1 and lasts 2-3 years. To charge the battery, a novel, but not patented, solar powered

battery recharger was developed, which can be recharged via the sun, household light or plug in using a Nokia cell phone electrical recharger.

### Developer's claims of product benefits \_\_\_

This device is the only low-cost rechargeable analogue and digital hearing aid on the market.

### Operating steps \_

During the day a solar panel charges 2 AA rechargeable batteries. Once or twice a week, one takes out the rechargeable hearing aid battery and puts them in the charger. The next morning these batteries are ready to use again. One can also charge the batteries using a household light or plug-in. The batteries fit into 85% of all hearing aids.

### Development stage \_

Countries that receive these rechargeable hearing aids, solar charger and rechargeable batteries to do not require FDA or CE approval, but all of these component suppliers have FDA, CE and are ISO approved.

### Future work and challenges \_

The technology is offered for free to like-minded non-profit organizations. In addition, the company helps write the business plans, raise money, and set up manufacturing operations for others for free.

### User and environment \_

**User:** Self-use/patient Training: None

Maintenance: Yes, 3-5 years change batteries

### Environment of use

Settings: Rural, urban, at home Requirements: Sunlight

### Product specifications \_

Dimensions (mm):  $40 \times 20 \times 15$ 

Weight (kg): 0.3

Consumables: Rechargeable AA and rechargeable

hearing aid battery Life time: 10 years

Shelf life: 5 years

Retail Price (USD): 48 List price (USD): 24

Other features: Portable, reusable Year of commercialization: 2002

Currently sold in: 39 developing countries

ess of any technology for a particular purpose. All the information provided by the developers. WHO will not be held to endorse to recommend any technology in the developers.

## Sputum mobilization device

Country of origin | United States of America

### Health problem addressed \_

Obtaining a proper deep lung specimen is a critical step in the diagnosis and management of respiratory tuberculosis; both for the adult community and pediatric community. Neither spontaneous samples, which result in many false negatives, nor sputum induction using hypertonic saline are practical or optimal.

### Product description \_

A low frequency acoustic wave is generated at the mouth, travels retrograde into the lower airways and increases mucociliary clearance. This device, which is FDA approved, produces such a wave with vigorous exhalation to aid in secretion clearance.



### Product functionality.

The patient simply needs to blow repeatedly into the device with the same effort as blowing out a candle. The secretions mobilizes within 5-15 minutes after the therapy session ends. Its simple design and operation result in high compliance.

### Developer's claims of product benefits \_

Existing technology is a spontaneous sputum sample. This does not produce the deep lung secretion required. The preferred method is hypertonic saline sputum induction. This method, though effective, is not widely used in the field because of complications and discomfort to the patient. Reducing the number of inadequate sputum samples and thus the frequency of false negatives. The device presented here is highly effective at producing a deep lung secretion sample, which saves times, and is very easy to use with no counter indications.

### Operating steps

The patient sits upright, leaning forward slightly. The devices works in 2 blow repetitions: blow out with enough force to activate the reed, and repeat steps to complete 2 repetitions. After two blow repetitions, the patient removes the mouthpiece, inhales normally, and repeats the above steps to perform up to 20 cycles. After 5-10 minutes, the patient coughs and collects sputum.

### Development stage \_

As published in a 2009 study, use of this device enabled rapid diagnosis of TB in 47% of confirmed TB patients, who had produced no sputum prior to using the device. The device was user-friendly as assessed by a questionnaire completed by the patients.

### Future work and challenges \_

This device could be manufactured at considerably lower cost with locally available materials, technologies and labor.

### User and environment

**User:** Self-use/patient

Training: Healthcare professional delivers training, written instructions are provided, training takes 3-5 min

Maintenance: None

### Environment of use \_

Settings: Rural, urban, primary (health post, health center)

Requirements: None

### Product specifications \_

Dimensions (mm):  $350 \times 60 \times 30$ 

Weight (kg): 0.25 Consumables: None

Year of commercialization: 2006

Currently sold in: Australia, Austria, Canada, Germany, Greece, India, Italy, Japan, Lebanon, Malaysia, Philippines, Singapore, South Korea, Switzerland, Turkey, United

States

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## Urine albumin test

Country of origin Sweden

### Health problem addressed \_

Chronic kidney disease (CKD) is common and harmful yet can be easily treated if detected early through a simple urine test and the measurement of low levels of albumin in the urine. If not detected, it may escalate to end stage renal disease (ESRD) which requires expensive treatment and risk of poverty due to inability to work.

### Product description \_

This devices uses a quantitative rapid turbidimetric immunoassay of albumin in human urine using a specially-designed analyzer.

### Product functionality \_

The system can be used for the quantitative determination of low levels of albumin in human urine for the purpose of screening, diagnosing, monitoring and to supplement the clinical evidence in the treatment of microalbuminuria.

### Developer's claims of product benefits \_

Current devices are semiquantitative dipsticks, some with visual reading only. In comparison, this new system provides lab equivalent results in 90 seconds, and is easy to use by anyone. It requires minimal maintenance since it is factory calibrated, does not require any further recalibration, and results can be compared between sites. The system makes it possible to perform large screening programs in rural settings as long as power supply is available.

### Operating steps \_

The microcuvette serves as pipette, mixing and reaction chamber and the correct specimen volume is obtained by capillary action. First, the cuvette is filled, then it is placed in the analyzer. The result can then be read.

### Development stage \_

The system has not been part of any clinical studies, but has been evaluated. The system has been used during a World Kidney Day screening event in Kenya, in hospitals in Kenya, in a large screening program in Morocco and Mexico, in the Nordic Countries, in the US, and in Europe.

### Future work and challenges \_

The scope of the problem and the need is huge, but the awareness of it and the priority on health care are limited. The subjects who are not detected early may face a devastating future as the treatment in the later stages, such as dialysis and transplantation, is not available or very expensive. However, through early detection and cost-effective treatment, a near normal life can be lived.

### User and environment \_

User: Physician, technician, nurse, midwife, anyone also without laboratory education

Training: Easy to follow documentation is provided with the analyzer. Distributors can support training.

Maintenance: Minimal maintenance - cleaning.

### Environment of use \_

Settings: Rural, urban, ambulatory, primary (health post, health center), secondary (general hospital)

**Requirements:** Continuous power supply

### Product specifications \_

Dimensions (mm):  $170 \times 115 \times 66$ 

Weight (kg): 0.350

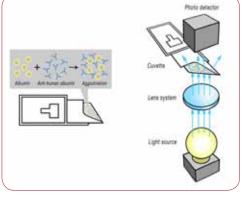
**Consumables:** Urine Albumin Microcuvettes

Life time: >7 years Shelf life: >7 years Retail Price (USD): N/A List price (USD): 600 (device) 2.99-3.99 (consumables)

Other features: portable, single-use Year of commercialization: 2006

Currently sold in: US, Europe, Mexico, Kenya, South

Africa, Russia



# eHealth solutions

2012

## Biometric technology in healthcare

Country of origin | India

### Health problem addressed \_

Tuberculosis (TB) is one of the biggest public health problems in India. The country holds one-fifth of the global TB burden with nearly 2 million new cases and 330,000 TB-caused deaths every year. Patients who do not complete the entire course of treatment often develop drug resistance.

### Solution description .

The system utilizes a simple interface with minimal text and color coding for ease of use in low-literacy areas. The system synchronizes up-to-date reports with a central Electronic Medical Record (EMR) database located at the office headquarters. The application uses .NET Framework and runs locally on any Windows machine. Primarily an offline application, it sends daily attendance reports through SMS to an online server, through the USB modem. When the patient registers onto the system they provide a fingerprint, which is used throughout their course of treatment to track their treatment schedule. If a patient misses a dose, an SMS is sent to their counselor by the end of the day.

### Functionality -

Patients registered at the terminal log their visit to a TB center on a fingerprint reader. At the end of each day, the attendance record is compressed into a text message and sent to an online server. If a patient misses a dose, the counselor receives a text message and must follow up with the patient within 48 hours to take their medication.

### Developer's claims of solution benefits

The eCompliance initiative is the first to apply biometric attendance monitoring to tuberculosis treatment. No other TB control system can provide verifiable evidence to back up their TB statistics. The innovation's transparency and accountability are two of its strongest aspects. While other TB programs have digitized their systems, these programs rarely cater to impoverished areas, relying on the Internet or 3G networks to relay information.

### Future work and challenges \_

Funding is needed for operations of the system and the ever-changing field of technology.

### User and environment

User: technician, counselors.

Training: training on the system takes 3-4 hours and is given by one of the biometric team members.

Settings: rural, urban, home, ambulatory, primary, secondary, and tertiary.

### Solution specifications \_

**Solution is used to support:** Electronic Health Record/ Electronic Medical Record; mHealth.

**Software/Hardware requirements:** Netbooks for use in the treatment centers and access to SMS network to work with the netbook. The software is open-source and can be downloaded from the website for free.

Country used in: India

**Evaluation:** There has been one pilot study at the treatment centers, and a follow up of a qualitative study in 25 centers in two states. Over 2,300 patients have been registered. The qualitative study interviewed 8 health workers, 4 center owners and 23 patients. Findings suggest that the terminal helps draw patients to the center by incentivizing health workers and convincing patients to come.

## Case-based smartphone messaging platform

Country of origin United States of America

### Health problem addressed \_

This technology is focused on addressing the diagnostic/treatment support and information resource needs of healthcare providers in Botswana, a country with the 2nd highest prevalence of HIV and 4th highest prevalence of TB. There are about 40 physicians per 100,000 people and access to physician care outside of city centers remains challenging.

### Solution description \_

A mobile medical platform that 1) connects resident physicians to their peers & faculty for timely team-based case consultations related to patient care; 2) provides access to a global network of physicians (via Swinfen Charitable Trust's Telemedicine programme) for external referrals; and 3) enables easy, centralized access to important medical resources relevant to Botswana.

### Users can:

- · Complete case forms, including images & videos, and send to colleagues for consultation
- · Send messages to the entire team or individuals
- Search message history
- Share geographic location
- Search and share references such as local treatment guidelines and PubMed.

### Functionality\_

Users sign-on and set their status as "on call" or "online" and indicate their location. They can see others' status and location. Users complete a case consult form, attach media such as photos or videos, and share with team members for comments. Users are notified of news messages & replies via notifications on their device and in the app.

### Developer's claims of solution benefits \_

The application provides an integrated platform for physicians to communicate efficiently about patient care and to access and share reference information through a single app on a mobile device. Users benefit from telemedicine consults & searchable message threads (thereby learning through a shared case-based model) and have access to country-specific guidelines & journal abstracts. The product captures usage data allowing for analysis and is designed for low-resource/marginal-connectivity settings.

### Future work and challenges \_

The challenges - and the opportunities for solutions - are spread across a number of categories: namely, Software -> Hardware -> Personnel -> Programs. Given that each of these category silos have their own unique set of issues (e.g., design & development of information architectures optimized for low-bandwidth settings; procurement at a cost-effective price of smart devices for Sub-Saharan Africa; recruitment, training, & engagement of field pilot professionals; and administrative management of multiple groups through protocols, feedback & study design) it is essential to operate across categories in an integrated and iterative manner.

### User and environment \_\_\_\_

User: physician

Training: an initial two-hour training session, including demonstrations and cases.

Settings: rural, urban, home, ambulatory, primary, secondary, and tertiary.

### Solution specifications \_

**Solution is used to support:** Telemedicine; eLearning/mLearning; mHealth; Geographic Information System

Software/Hardware requirements: Use of this product requires an Android mobile device and access to mobile Internet or WiFi connection for full-access to all the features of the system. However, users without a data connection can still prepare and save case information using an "offline mode" for later uploading. Software is proprietary developed specifically for deployment by the Botswana-UPenn Partnership and its physician teams.

The product is still in Field Pilot / R&D phase and has not yet been commercialized.

**Standards:** It adheres to HIPAA security & privacy rules for PHI data.

Currently used in: Botswana

**Evaluation:** No studies have been conducted on the technology yet, but the team is in the process of designing a study to evaluate the technology with local partners.

## Cervical cancer screening information system

Country of origin | Argentina

### Health problem addressed

In Argentina, cervical cancer is the second most common cause of death by tumours, in women from 35 to 64 years old, there is a death rate of 7.1 / 100,000 and an incidence of 23.2 / 100,000. Each year, in Argentina, 1,800 women die and a further 3,000 new cases are diagnosed. Women of low socioeconomic status are more vulnerable due to lack of access to screening.

### Solution description \_

The national information online system of screening allows for the monitoring and appropriate treatment of affected women by providing nominalized lists of women included in the national prevention programme. The national information system identifies women with pathological paps

for their diagnosis and treatment. It also provides indicators to monitor and evaluate the prevention programme.



### Functionality\_

The national online information system allows for coordination of health services that are involved with uterine cervical cancer prevention, serving as a support of the monitoring of health services. It is used at the primary care level, cytology laboratories, gynaecology services and central level.

### Developer's claims of solution benefits.

It is an online information system that links services and users so that the information related to screening, diagnosis and treatment supports the management of the service network. It allows for the flow of information among different health services and country areas, allowing the monitoring of women in all stages of prevention, even those living in remote areas. It has an alert system that allows for faster detection of problems with women in need of diagnosis and treatment.

### Future work and challenges \_

Incorporation of modules on breast and colon cancer screening, diagnosis and treatment.

### User and environment \_

User: physician, technician, nurse, midwife, administrative staff.

Training: none

Settings: rural, urban, ambulatory, primary, tertiary.

### Reviewer's comments

This system is deployed nationally for cervical cancer screening, treatment and capturing of data. It is also being developed and used locally and requires very low resources. A formal evaluation of this program would be helpful to contribute evidence, and this would form a basis upon which other countries might want to consider adopting it.

### Solution specifications \_

**Solution is used to support:** Decision Support Systems; Electronic Health Record/Electronic Medical Record

Software/Hardware requirements: Access to a computer connected to the Internet. It uses the database engine SQL- Server, ASP programming language. The ministry of health has licenses for using them, so it was decided to develop the described tool on this platform. The software development is an open source and it belongs to the ministry of health.

Standards: ICD-10; Bethesda

Currently used in: Argentina

**Evaluation:** Arrossi, S; Paolino, M: Proyecto para el mejoramiento del Programa Nacional de Prevención de Cáncer de Cuello Uterino en Argentina - Informe Final: Diagnóstico de situación del Programa Nacional y Programas Provinciales. Buenos Aires. Organizacion panamaericana de la Salud; 2007, page 33.

## Computer-aided detection for Tuberculosis

Country of origin | The Netherlands

### Health problem addressed \_\_

Tuberculosis is the second deadliest infectious disease in the world. With early detection and proper treatment, most people with tuberculosis can fully recover. Combined efforts and investment in Tuberculosis detection can help to save millions of lives worldwide.

### Solution description \_

Digital X-rays can efficiently make large numbers of chest radiographs at low cost. Computer Aided Detection software (CAD) can immediately analyse these digital images. The CAD software gives a probability percentage normal vs. abnormal consistent with TB.

CAD follows the processing steps:

- · Lung shape analysis
- · Clavicle detection
- Texture analysis.

Texture within the lung fields and the shape of the extracted lung fields are compared with a training database obtained from thousands of training images. Based on this analysis a grade for the image is computed. Based on the grade and the expected prevalence in the population, the probability that the image contains signs of TB is calculated.

### **Functionality**

The software can be configured to run automatically after a digital X-ray has been made: the image is sent automatically to a separate computer on which the CAD software is installed, the program performs the quality check and the image analysis steps and the result is stored on disk.

### Developer's claims of solution benefits \_\_

Present technologies are time consuming and quality/temperature sensitive or costly for hundreds of tests. With a portable digital X-ray even remote groups can be screened at low cost as the incremental costs of digital X-ray and CAD are very low. Studies done by universities and Zambart show that the sensitivity and specificity of the software to diagnose culture positive TB from chest radiograph is the same as done by clinical officers and CRRS certified human observers (no significant difference in performance).

### Future work and challenges \_\_

Challenges ahead:

- 1. Creating a computerized decision support by combining X-ray signs with clinical symptoms.
- 2. Evaluate CAD with GeneXpert (cartridge-based, automated diagnostic test ) as an efficiency "filter" in TB screening to determine who gets GeneXpert.
- 3. Regulatory approval.

### User and environment \_

Users: physician, technician

Training: a 3-hours training is provided on a laptop or PC.

Settings: rural, urban, ambulatory, primary, and secondary.

### Solution specifications \_

**Solution is used to support:** Telemedicine; Electronic Health Record/Electronic Medical Record; mHealth; Health Research.

**Software/Hardware requirements:** Laptop or computer with MS Windows, Intel Pentium preferably i7, 8 GB RAM 120 GB HDD, Calculation time depends on amount of RAM and type of processor. CAD4TB is proprietary software that runs on any laptop or PC that meets the above specifications.

Currently used in: Zambia, South Africa, The Gambia

**Evaluation:** The CAD software is currently used prospectively in clinical trial to make a selection with TB suspects should undergo other more expensive and time-consuming further testing.

The partners CIDRZ and Zambart in Zambia are using the CAD software as a "filter" in TB screening to determine who gets GeneXpert.

Standards: DICOM, HL7

## Health workforce information systems

Country of origin United States of America

### Health problem addressed \_

The 2006 World Health Report identified 57 countries with human resources for health crises that have less than 2.3 health workers per 1000 population. It is estimated that more than a billion people do not have access to a health worker. Associated challenges include health workforce planning, policy, training, deployment, management and retention.

### Solution description \_

The software is an open source LAMP-architecture solution (Linux, Apache, MySQL, PHP) that, once established, may be accessed via a web browser on the same computer the software is deployed, or via a LAN, or from anywhere on the World Wide Web. The software supports easy configuration of key variables (such as job titles, cadres, competencies and job structures). Information is then collected on the health workforce, either through a centralized national architecture, or a decentralized subnational architecture that can then be aggregated for national analysis. The software supports easily customized reports and charts, or the exporting of data in many common formats.

### Functionality \_

Typical steps for setting up and using the software include:

- Adding Geographical Areas
- Configure database 'drop-downs'
- · Create a job structure
- · Create positions
- Enter employee information including identifying information, contact information, dependents, position, qualifications, trainings, employment and education history
- Create and run reports as needed.

### Developer's claims of solution benefits \_\_\_\_\_

A free and open source solution is designed to support full country adoption and ownership. The software is cost effective, easy to configure and is supported with strong documentation, eLearning, and other resources. This solution also support countries to avoid vendor lock-in. All data can be exported in a variety of formats at any time for migration to a new solution if desired.

### Future work and challenges

The biggest challenge remains whether the users have enough access to the Internet to learn about and access the technology and associated resources. As infrastructure continues to strengthen and this situation improves, a cloud-based version can be offered to minimize initial configuration and set-up challenges. It is also part of the future plan to move from an HR 'Information' System to an HR 'Management' System, which is less about collecting and reporting on workforce data, and more on taking consistent and high-quality management actions.

### User and environment \_

**User:** health managers, supervisors, workforce planners and regulators.

Training: administrator training is currently available online, and user training is under development.

Settings: rural, urban, secondary, tertiary, district management offices, Ministry of Health.

### Solution specifications \_

**Solution is used to support:** Decision Support Systems; mHealth; eLearning/mLearning; Health Research.

Software/Hardware requirements: At minimum, a computer running Linux with Apache, MySQL and PHP installed is required. The solution offers a preconfigured 'appliance' that has everything ready to plug into a LAN. It can also be run from a flash drive, or freely downloaded and configured as a Linux install package. LAN, WAN or Internet access is needed for remote data entry or reports.

Standards: SDMX-HD

**Currently used in:** Botswana, Ghana, India, Kenya, Lesotho, Mali, Nigeria, Rwanda, Sierra Leone, Tanzania, Togo, Uganda.

**Evaluation:** An extensive independent evaluation has not been done.

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## Integrated smartreader & cloud services

Country of origin | Canada

### Health problem addressed \_

Two of the biggest problems in infectious diseases are inadequate diagnosis and case management at point of care (POC) by health workers and inadequate resource allocation and monitoring by health managers and funders.

### Solution description \_

The smartreader is a rugged, companion device for use by health workers at POC that captures and transmits a broad range of data to the cloud via local cell networks. The reader currently interprets commercially-available malaria rapid diagnostic tests (RDTs). Additional infectious disease targets are to follow in rapid succession, e.g. HIV, dengue, hepatitis.



Via standard web browsers, the portal provides health managers and funders with a host of cloud information services, including data management and reporting, mapping and surveillance, based on data captured by smartreaders. Managers can connect with workers in the field to implement quality control measures, and disseminate clinical and operational guidelines.

### Functionality .

Smartreader software guides the user through RDT processing steps and data entry, interprets test results, and automatically transmits patient and worker activity data, GPS, image of RDT over cell networks to the cloud. Managers log into the portal to view/create reports, query real-time data, disseminate messages and content to readers.

### Developer's claims of solution benefits \_

This solution transforms infectious disease healthcare delivery and healthcare management by enabling:

- · high-quality healthcare delivery by minimally trained health workers at point of care
- · real-time monitoring and analysis of point-of-care data for resource management and timely response to outbreaks
- evidence-based resource allocation and investment decisions by healthcare funders and industry.

### Future work and challenges \_

Distribution via franchises with local entrepreneurs, thus not only contributing to local economies and skill development, but also accelerating sales.

### User and environment

User: physician, nurse, midwife, technician, community health worker.

**Training:** optional training will be provided by qualified local distributors.

Settings: rural, urban, ambulatory, primary, and secondary.

### Reviewer's comments \_

The innovation of the project is mostly related to the hardware (smart reader for rapid diagnostic tests). However, its information components are very well integrated into a coherent set of tools, which represents the state-of-the-art.

### Solution specifications \_

**Solution is used to support:** Decision Support Systems; mHealth; Geographic Information System; Health Research.

**Software/Hardware requirements:** Smartreader at POC: minimally trained health worker. Data transmission from POC to cloud: any local cell network. Cloud information services: health program manager with standard web browser on any computer. Smartreader functions for 4 days on internal battery rechargeable by electric outlet, solar panel, handcrank.

The software is proprietary and is charged on a pay per use basis. The system hosts third-party mHealth applications.

**Standards:** Upcoming releases will support HL7 and HIPAA.

**Currently used in:** Colombia, Ecuador, Kenya, Tanzania, Ghana.

**Evaluation:** Performance was validated for 7000 patients by 50 health workers at 30 sites in four countries. Diagnostic accuracy studies fully blinded and expected to be submitted for publication in peer-reviewed journals in 2012.

## Maternal health Tanzania

Country of origin | Tanzania

### Health problem addressed -

Maternal and neonatal healthcare in Africa faces well-documented challenges, including: 1) Limited qualified health staff, 2) Ineffective referral systems for triage to urban/higher facilities, 3) Inadequate diagnostics at point of care, 4) Limited community-level data and connectivity, 5) Uninformed patients, 6) Limited Public Private Partnership (PPP) financial models.

### Solution description \_

The platform is accessed through the Internet by a netbook computer, smartphone, or other modern web device. Users submit patient data, which is validated before being sent via encrypted connection to a central database. The platform features sending / receiving SMS to patients and clinicians, portable ultrasound integration, dynamic filter-based patient cohorts for targeted follow-up, scheduling of return visits or patient referrals in a central calendar, and recording of orders and payments made during a clinic visit. An additional continuing medical education module allows online creation and publication of multimedia courses and informal clinician accreditation.

### Functionality \_

1) User registers mother at clinic. 2) User submits outcome of clinical examination and schedules follow-up visit. 3) Specialist conducts portable ultrasound examination and saves image to the mother's record. 4) Upon referral, user at another facility accesses mother's full record. 5) Mother receives targeted educational and reminder SMS.

### Developer's claims of solution benefits \_

Validate data instantly and track user performance to identify areas of weakness for retraining.

Enable community-based care outside of clinic setting using networked computers.

Retain a full record of mother's information in health system.

Generate system-wide clinical and operational reports without tedious data collection/aggregation.

Enable portable obstetric-ultrasound screenings: better diagnosis, early intervention.

Browser-based platform overcomes limitations of phone-based platforms.

### Future work and challenges \_

A large portion of active deployment costs come from the Internet usage and SMS costs for follow-up with patients. Deployment on a large scale would be greatly facilitated by partnership with mobile operators (e.g. corporate social responsibility initiative or volume-based pricing).

Emphasis on the importance of record-keeping and the power of data will help highlight the advantages of the platform's various modules working together and motivate adoption (e.g. targeted SMS follow-up based on early identification of high-risk mothers, accreditation of health workers through online training to assess quality of human resources, detailed reports to assist management in budget allocation).

### User and environment \_

User: physician, nurse, midwife, technician, facility or health system administrator.

Training: one week hands-on training.

Settings: rural, urban, ambulatory, primary, secondary and tertiary.

### Solution specifications \_

**Solution is used to support:** Telemedicine; Electronic Health Record/Electronic Medical Record; eLearning/ mLearning; mHealth; Reporting, portable diagnostics, facility management.

Software/Hardware requirements: The server-side component of the platform requires specific software running on a secure Internet-connected data centre. The software is being made available on an international free-for-use license. Customization of data forms for use outside Tanzania may require modest technical development investment.

**Standards:** Format of structured data adheres to the Tanzania Ministry of Health maternal health card.

Currently used in: Tanzania

### Medical cloud

Country of origin | United States of America

### Health problem addressed \_

Picture Archiving and Communication Systems (PACS) represent the integration of medical diagnostic images and records playing a critical role in patient diagnosis and outcome. Traditionally only medical centres in developed countries have been benefactors leaving a significant disconnect globally for resource-poor locations to also benefit.

### Solution description .

Patient information regardless of the imaging modality (ultrasound, x-ray and beyond) and/or digital medical records are scanned and uploaded by an authorized medical professional. Automatically the information is sent through a secure Digital Imaging and Communications in Medicine (DICOM) process over a standard web browser from a digital device the



user is accustomed to using such as any smart phone or mobile computer. Physicians, teams of specialists and qualified medical professionals across the globe have on-the-go access through a log in user name and password with access to review patient medical information providing accurate diagnosis and second opinion reports.

### Functionality\_

The DICOM sender module offers a zero foot print viewer system that allows for images to be viewed on the web. This cloud based approach requires no additional hardware or software to be purchased. Native studies are sent directly to fully functioning PACS systems or viewed through a log in user name and password over any personal digital device.

### Developer's claims of solution benefits \_

Physicians will have access to images and reports allowing them to take their services to patients who could not be reached previously. Informed patient care decisions allow for a faster accurate diagnosis from anywhere in the world that has access to the Internet. Statistics show there are 2.2 billion mobile phones in the developing world while some parts have a patient-doctor ratio of one in 20,000. A mobile cloud service enables better care to be provided to more patients at a lower cost. The fundamental financial and operational model has a primary focus on the healthcare industry, one known to be cautious with technology.

### Future work and challenges \_\_

Confusion hinders adoption and there is some confusion about what Cloud computing can do.

### User and environment

User: physician, nurse, technician, authorized medical professionals and health care providers.

Training: remote training is provided. The service team is accessible online through a live chat feature.

Settings: rural, urban, home, ambulatory, primary, secondary, tertiary.

### Reviewer's comments \_

This proposed iCloud Web PACS, having been tried by several countries, can conceivably be built up over time to facilitate more exchanges. The affordability of this technology in underserved communities depends largely on the company's case use fees. This is an important consideration for prospective countries when considering this system.

Crossing jurisdictional governance between countries could hamper some privacy and confidentiality issues.

### Solution specifications \_

**Solution is used to support:** Telemedicine; Electronic Health Record/Electronic Medical Record; RIS (Radiology Information Systems).

**Software/Hardware requirements:** Access to the Internet is required with a recommended minimum bandwidth of 512K. Medical images are uploaded and viewed over personal PC or PDA's. Medical images need to be in the DICOM format.

**Standards:** HL7, DICOM, HIPAA (The Health Insurance Portability and Accountability Act).

**Currently used in:** Technology is used globally. The service has been originated in the USA. The current focus is throughout the Caribbean, and Central/South American markets.

## mHealth platform for community health workers

Country of origin United States of America

#### Health problem addressed \_

High infant and maternal mortality in developing countries are a major public health concern. Community health programmes have been effective in reducing mortality but their effectiveness is limited due to lack of sufficient training, absence of performance evaluation and feedback, absence of standardized protocols and ineffective care coordination.

#### Solution description .

The platform has a mobile app and a Health Insurance Portability and Accountability Act (HIPAA) compliant cloud-based platform with web interface. Community health workers(CHW) use mobile phones in the field to capture data, educate patients and provide case management. The web interface is used for monitoring the program and generating reports. In the



field, patient data can be stored on the phone or sent to the server. The platform supports audio, images, video data and also uses GPS and bar code data. The platform can also send reminder SMS messages, emails or generate other alerts required in the workflow. Through active monitoring of data, timely, interpretable reports and targeted follow up actions can be created for CHWs and the supervisors.

#### Functionality \_

The CHW logs into CommCare using a username and password. The CHW selects the module (e.g. Pregnant Women) and the form (e.g. Pre-Natal) for this type of visit. The form guides the CHW through a series of questions and education prompts to provide patient specific referrals and counseling. The form is submitted to the web interface for monitoring.

#### Developer's claims of solution benefits \_

This technology improves care across four areas: access to care through client lists on the CHWs' phones and SMS reminders when visits are due; client engagement through audio and video clips and improved credibility of the CHW; quality of care through checklists, decision support, and delivery of sensitive information through recorded voices; and data-driven management through real-time monitoring of the CHWs activities.

#### Future work and challenges \_

The success of this platform is contingent on availability of funding for community health worker programmes, using this platform has demonstrated return on investment. A dollar-for-dollar effectiveness ratio of 3.48 is anticipated. This will be confirmed through randomized controlled evaluations.

#### User and environment \_

User: physician, nurse, midwife, community health worker.

Training: our team of field engineers deliver training using field-tested methodologies over a two day period.

Settings: rural, urban, home.

#### Solution specifications \_

Solution is used to support: mHealth

Software/Hardware requirements: The mobile component of the software runs on either simple Nokia phones or Android Smartphones. Cellular data plan is required to transmit data from the field. The cloud-based platform can be accessed through a web browser via any internet connected computer.

The software platform is open source and is available to anyone at no cost. Organizations with less than 20 users are offered hosting, implementation and support for free. After 20 users, the charge is \$0.75 per user / month. In case the clients want customized project design, deployment and support they pay standard software development rates.

Standards: HL7

Currently used in: India, Tanzania, Zambia, Malawi, Bangladesh, Mexico, South Africa, Afghanistan, USA, Mozambique, Nicaragua, Benin, Guatemala.

Evaluation: A recent randomized controlled trial in Tanzania showed that a reminder system incorporated into the system with eventual escalation to supervisor notification generated significant results, with 85% more timely visits for the groups that received SMS reminders. Also, a preliminary controlled trial in Tanzania found increased adherence to protocols by over 20% compared to traditional methods.

## New media to train health workers

Country of origin | United States of America

#### Health problem addressed \_

Frontline health workers need more and better training. Current methods—lectures and written materials—are not effective, and often fail to consider the reality of resource-poor settings. Health worker shortages make it difficult and costly for them to spend time in workshops. Current approaches are not able to reach the large numbers who need training.

#### Solution description \_

The new media consists of videos that combine live footage with animated segments, and are designed and created for playback on portable devices. The films are brief vignettes that "bring alive" international clinical guidelines. They cover topics in a simple and concise way with "need-to-know" information. They are carefully scripted to provide step-by-



step instruction that is easy to understand and put into action. They are voiced over to enable narration in different languages, and shot and formatted for the small screen of mobile devices.

#### Functionality\_

Operation consists of standard procedures for video viewing. Varies based on available technology: 1) offline on video-capable phones using memory cards or computers (where the Internet connectivity or electricity is limited); 2) on basic video equipment (portable players or TVs) using DVDs; 3) on smartphones or computers with live streaming.

#### Developer's claims of solution benefits.

New media can deliver step-by-step instruction on clinical skills and procedures in an effective and efficient way. With expansion of the Internet access and the proliferation of mobile devices, this solution can reach far more people with better health care information than was conceivable only a few years ago. New media for medical training is still in its infancy in resource-poor countries, but it is readily scalable and can help better train providers at much lower cost than traditional methods.

#### Future work and challenges \_\_\_\_

The intention is to make this new media accessible to any and all frontline health workers who need better training; thus, the plan is for an open-access model that makes the videos freely available to users. The challenge is to obtain funding that will make this goal feasible. Other challenges related to its adoption include: 1) environmental and hardware constraints: access to viewing devices, power supply, and the Internet; 2) modification of the videos for use across many regions: accurate translation of languages and effective voice over.

#### User and environment \_\_\_

User: self-use/patient, physician, nurse, midwife, family member, technician, community health worker.

Settings: rural, urban, home. ambulatory, primary, secondary, schools and training programmes.

#### Solution specifications \_

**Solution is used to support:** eLearning/mLearning; mHealth.

**Software/Hardware requirements:** A basic viewing device is required, for example a battery-powered DVD player. As access to more sophisticated devices, the Internet, and stable power supply increases, more options for viewing the videos become available.

Currently used in: India, South Africa.

**Evaluation:** Videos have been shown to be effective instructional tools and are commonly used to teach medical practices and skills in high-income countries; however, they remain vastly underutilized and unavailable in the developing world. The content is based on best practice standards and is subjected to rigorous review by global content experts. Content is field tested for effectiveness in teaching, and for comprehension and relevance.

## Primary health care continuous quality improvement (CQI) tools

Country of origin | Australia

#### Health problem addressed \_

Lack of data on care processes and outcomes in primary care is an on-going problem for applying evidence-based practice. CQI approaches have potential to address this challenge. The approach presented provides a flexible and tailored solution, facilitating use of local level data and targeted CQI appropriate to the burden of disease.

#### Solution description \_

A CQI process developed to assist primary health care services to improve their clinical services and client outcomes by collecting data using specially developed audit tools and protocols. The tools are based on best practice standards and recommended scheduled services for a range of clinical services i.e. child and maternal care. Audit data are entered onto a web-based database which provides automated real-time analysis and generation of a quality improvement report for use at the local health centre level. In addition to the audit data, qualitative data are collected from the primary health care team through a facilitated discussion using a system's assessment tool for action planning.

#### Functionality.

Training in applied continuous quality improvement and clinical auditing. Data collected through clinical audits. The primary health care team participates in a system's assessment to collect quantitative data. All data are entered into a web-based database and reports are generated. The team sets goals and action plans for the next 12 months.

#### Developer's claims of solution benefits \_

This approach comprehensively addresses the development of capacity to apply CQI in a health service context starting at the stage where the health service is at. It embeds ownership of the process by the health service staff. It uses systems currently in place to collect health data. It provides tools to measure health service practice against accepted best practice. It encourages the process of quality improvement in steps to address areas identified as priorities by the health service.

#### Future work and challenges \_

The existing technology is modelled on Australian terminology and best practice for disease which is not necessarily suitable for other settings. Recommended changes include: tools abbreviated to include key disease outcomes, and corresponding modification to electronic database interface including capacity for local users to edit specific field options (e.g. drug doses, ethnicity) and download/upload capacity to support off-line use. Coordinators should be trained and supported to maintain the technology locally.

#### User and environment \_

User: physician, nurse, midwife, technician, health workers, indigenous/other health workers.

Training: training is required and is given initially by an Australian team who can build more sustainable capacity among local trainers.

Settings: rural, urban, primary, secondary, and tertiary.

#### Reviewer's comments \_

The continuous quality improvement (CQI) system is an innovative approach developed to support high-quality primary health care for Aboriginal and Torres Strait Islanders. CQI can be adapted and used with limited IT equipment.

#### Solution specifications \_

http://www.who.int/goe

Solution is used to support: Decision Support Systems; Continuous Quality Improvement(CQI).

**Software/Hardware requirements:** In the Australian context, it uses customised software to support webbased clinical audit tools for the collection of data to allow reporting of key performance indicators against best practice guidelines. The technology is not dependent on this specific software solution.

Microsoft SQL, Microsoft ASP. Net, Menzies proprietary

Standards: Clinical Guideline Standards for Chronic Disease, Maternal, Preventive, Child Health, and Mental Health.

Currently used in: Australia

Evaluation: Rumbold A et al. Delivery of maternal health care in Indigenous primary care services: baseline data for an on-going quality improvement initiative. BMC Pregnancy and Childbirth 2011, 11:16 doi:10.1186.

Gardner KL, Dowden M, Togni S, Bailie R. Understanding uptake of continuous quality improvement in Indigenous primary health care: lessons from a multi-site case study of the Audit and Best Practice for Chronic Disease project. Implement Sci. 2010;5:21

## Rapid SMS providing availability of essential medicines

Country of origin United States of America, Tanzania, Malawi

#### Health problem addressed \_

Many public health supply chains in Africa suffer chronic shortages and stock out of essential medicines, contributing to high morbidity and mortality rates. Decision makers have little access to stock levels, rendering them unable to monitor stock availability and address stock outs.

#### Solution description \_

At pre-scheduled time intervals, facility/community users send text messages with key data to a toll-free short code using their personal mobile phones. Data is used to calculate resupply quantities, which are sent via SMS to resupply facilities to enable prepacking of orders. Reported data items, such as stock on hand, as well as monthly email summary reports and supply management reports are displayed on an interactive web-based interface, with varying access levels, to enable decision making. The solution also alerts higher level staff via SMS if stock levels are limited or depleted.

#### Functionality.

Refer to solution description.

#### Developer's claims of solution benefits \_

In Tanzania, evaluation results indicated that 88% of facilities improved on-time stock report submission rates, and 93% improved stock counting exercises because of receiving routine mobile alerts; 45% of facilities reported improved product availability. In Malawi, community health worker(CHW) logistics reporting rates grew to 97% from 43%; and lead times were reduced. The group messaging feature enables managers to reinforce skills and procedures.

#### Future work and challenges

Some challenges include maintaining the system and solving software problems when they occur. Timely resolution of problems is key to maintaining user confidence in the system. Common human resources challenges also can occur such as turnover of trained staff. Additionally, transitioning the system to full Ministry of Health ownership can be a challenge if they are not engaged from the outset in the technology development. Future challenges include how to continue to ensure increased product availability, use of data for decision making and determining to what extent it can supersede the existing paper-based system rather than be a supplement.

#### User and environment \_

User: community health worker, health facility staff, district health staff, and national health staff.

Training: training is conduct by trained trainers using phones and training manuals for one or two days.

Settings: rural, urban, primary, secondary, tertiary and national level.

#### Reviewer's comments \_

Very good use of SMS, a well-used feature by cell phone users, to trace medication stock, and also analyse their use and distribution. The pilot of this tool has shown promising results, with high comfort of use and also good results not only on replenishing medications but also tracking usage and reminders to restock.

#### Solution specifications \_

Solution is used to support: Decision Support Systems; mHealth; Supply Chain Data.

Software/Hardware requirements: Requirements include simple mobile phones for health workers and access to network coverage, and electricity to recharge phones. Health centre and district staff reviewing the data dashboard online need regular access to a computer with the Internet access.

The software is open-source and built on the rapid SMS platform. The source code is available for any user that would like to adopt and adapt the system for their use.

Standards: HL7

Currently used in: Tanzania, Malawi.

Evaluation: In Tanzania, of the 5 district users and 17 facility users surveyed, 100% indicated that they preferred SMS based reporting, and 88% of the facility users further said that the stock reporting system has also helped improve their reporting rates and adherence to reporting groups. At the facility level, the stock reporting system has increased the attention of health workers on their reproductive health commodities and as a result, improved the timeliness of ordering and stock management.

## Real-time measurement of meteorological events on public health

Country of origin | Canada

#### Health problem addressed

A changing climate leads to changes in the frequency and intensity of extreme weather events. Deaths, injuries, diseases, and mental health problems related to extreme weather events result from the exposure and vulnerability of human systems. The average number of people killed by natural disasters for 1972-1996 was about 123,000/year worldwide.

#### Solution description \_

The objective of this integrated web application system is to provide in real-time a complete meteorological picture (actual conditions, forecasts and alerts) and population's health status on relevant indicators. Other environmental and spatial information is also provided for preventive purposes and for supporting emergency preparedness. The system



comprises four functions: F1 - Data acquisition and integration, F2 - Risk analysis and alerts, F3 - Cartographic application, and F4 - Climate change and health information.

#### Functionality.

The system is available through a secure web information portal and provides access to weather forecasts, historic and real-time health and weather indicators, alerts, and various cartographic data for conducting prevention and emergency measures. Currently the heat wave function is fully developed, and the floods function will be completed in 2012.

#### Developer's claims of solution benefits \_

No other system is known to offer a dynamic cartographic application showing the urban heat islands and having tools for identifying vulnerable areas using a combination of numerous user-selected and user-controlled indicators. Furthermore, all the cartographic layers are available as Web Map Services (WMS), ensuring better access to the data since they can be reused within other OGC-compliant systems without any development effort.

#### Future work and challenges \_

As this is not a commercial product, the strategy to make the product accessible has been through publications and presentations, notably through webinars organized by the Pan American Health Organization, the Public Health Agency of Canada, etc. The implementation of the system in two less developed countries will also serve as a case study in using such a system in countries where the basic data may be less widely available than in Canada. Indeed, availability of data probably represents the main challenge for such a system. Currently, the system allows for any type of georeferenced data to be published as a layer of information. Other data are also used for automatic charts and reports.

#### User and environment \_\_\_

User: physician, nurse, technician, public health or municipal officers.

Training: training by developer through the Internet and simple means such as Beam my Screen; duration 1-4 hours. Settings: rural, urban, home, ambulatory, primary, secondary, tertiary, municipalities, and civil protection.

#### Reviewer's comments.

This innovative approach, especially if and when coupled with disease surveillance systems like www.healthmap.org, can start to uncover known and unknown correlations of disease outbreaks as they relate to weather. The requirement of technologies is not onerous and easy to learn which makes the use and sustainabiltiy of the system very achievable.

#### Solution specifications \_

Solution is used to support: Decision Support Systems; Geographic Information System; Health Research; Health Surveillance.

or laptop or network and access to the Internet. The Système intégré des données de vigie et surveillance des application can be installed on a single computer, no aléas hydrométéorologiques et géologiques: Évaluation need for a network. It can also be installed on a server de l'utilisation du volet chaleur au cours de l'été 2010. and accessed over a Local Area Network, the Internet or a cellular/mobile network.

Standards: Open Geospatial Consortium (OGC) standards.

Currently used in: Canada.

Software/Hardware requirements: personal computer Evaluation: Bustinza R, Toutant S, Bélanger D, Gosselin P.

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## Registre electronique de consultation (REC)

Country of origin | Burkina Faso

#### Health problem addressed \_

In Burkina Faso, 1 in 6 children die before the age of 5. The Integrated Management of Childhood Illness (IMCI) protocol was developed by WHO to reduce child mortality but its implementation is difficult due to an insufficient number of trained health workers and because arduous working conditions increase the lack of rigor and motivation.

#### Solution description .

The registre electronique de consultation (REC) is an offline web application that guides the health professionals throughout the consult to help them strictly apply the IMCI. A step-by-step approach allows for determining in real-time the illnesses of the patients as the health worker identifies the symptoms. Once the diagnostic is established, the REC identifies the



appropriate treatment and the medicines to be prescribed with their dosages. The diagnostic and treatment data are centralized and restored via a secured synchronization procedure via USB drives. The REC allows agents to easily create a personal file for each patient with the history of diagnostics and treatments administered.

#### Functionality\_

Users launch the REC or synchronization process through a single main menu.

The diagnosis is in 3 simple steps:

- 1. Search if the patient already has a file in the system
- 2. Evaluate each question of the IMCI protocol is answered sequentially
- 3. Treat follow the identified treatment and medicines.

#### Developer's claims of solution benefits \_

The REC addresses key problems of the implementation of the IMCI protocol. The guided step-by-step approach ensures that the protocol is correctly applied. It avoids diagnostic errors as long as symptoms are correctly identified. Since little computer training is required to use the application, even health workers without IMCI training can safely apply the protocol. The user interface also allows for a quick data entry, reducing the time of consult per patient.

#### Future work and challenges \_

The global user experience could be improved by porting the REC to tactile devices. It would ease the learning curve and limit the number of devices to one for easier maintenance. With the improvement of the telecommunication networks a wireless data synchronization would make data centralization seamless and ease the integration of the REC to national health systems.

#### User and environment \_

User: nurse, physician, midwife.

Training: a 2-day session to learn the use of the computer and the REC.

Settings: rural, urban, ambulatory, primary.

#### Reviewer's comments \_

IMCI is known to be difficult to implement in primary care settings and this tool provides guidance and learning opportunities for healthcare professionals, and improves continuity of care thanks to a basic electronic medical record module.

#### Solution specifications \_

Electronic Health Record/Electronic Medical Record; locally. eLearning/mLearning.

Software/Hardware requirements: Netbook, The REC operates in rural areas with a solar panel. Electricity is required for at least a couple of hours per day in order to recharge the batteries of the netbook.

The REC was developed exclusively with open source software. The operating system is a customized Linux

Solution is used to support: Decision Support Systems; providing the environment necessary to run a web server

Currently used in: Burkina Faso

Evaluation: The pilot implementation period Oct 2010 -Oct. 2011 was documented by the University of Geneva. A baseline study is currently in progress with the London School of Hygiene and Tropical Medicine in order to monitor the extension to 75 health centres in 2012.

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## Smart phones for supportive supervision for TB

Country of origin United States of America

#### Health problem addressed \_\_

Nigeria ranks 4th among the 22 high TB burden countries in the world. The TB burden is further compounded by the high HIV/AIDS prevalence. The HIV prevalence for Nigeria is 4.4% (2005 National sentinel survey). There is low capacity to provide high-quality TB-DOTS and TB-HIV services in public and private sector facilities.

#### Solution description .

Introduced Smartphones for data collection and analysis. Built a real-time feedback mechanism on Android Smartphones platform coded on Pendragon Forms and EpiSurveyor. Created an excel-based tool that allows transfer of forms from one mHealth tool to another: Created forms and connected the forms to the users: Distributed the forms wirelessly via Wi-Fi or SIM cards; Uploaded to centralized web database; Built and deployed database that: Provides online data aggregation for analysing and disseminating data in real-time; Provided quality control system for data including online government approvals of data; Enabled access to the data along with operational and quality of care indicators.

#### Developer's claims of solution benefits \_

Supervisors have indicated that the system is enabling them to monitor and assess performance of the TB health delivery system, identify problems and opportunities, and in many cases take immediate action for improvements. For example, the rate of drug stock-outs has significantly decreased, and external quality control is easily obtained for quality service with far less delay.

#### Future work and challenges

Scale up of initial training to Lagos and Abia States to nationwide implementation requires careful needs analysis and planning.

#### User and environment \_

User: technician, clinic supervisor,

Training: some level of training is required and will be provided by Ministry of Health officials.

Settings: rural, urban, primary.

#### Solution specifications \_

Solution is used to support: Decision Support Systems; mHealth.

Software/Hardware requirements: Access to a cellular network; access to the Internet to link to the online database. Android OS coded with Pendragon (proprietary - 1 license) with open source EpiSurveyor software.

Currently used in: Ethiopia, Nigeria.

http://www.who.int/ehealth

## Telemedicine for HIV/AIDS care

Country of origin | Belgium

#### Health problem addressed.

The policy of scaling-up antiretroviral therapy for HIV patients coupled with the increasing availability of generic HIV drugs have been effective in achieving the target of four million HIV patients under treatment in developing countries. However one of the main obstacles to that has been the workforce shortage and lack of training and continuing professional development (CPD).

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#### Solution description \_

The HIV/AIDS telemedicine referrals are managed through a web site discussion forum (http://telemedicine.itg.be) based on a free, open-source package, which allows registered users to follow and contribute to discussion of referrals, both online and by email.

#### Functionality \_

The patient's history, physical examination, non-identifying pictures, laboratory findings and questions to be answered are posted on the http://telemedicine.itg.be discussion forum, using an electronic format available on the telemedicine website.

#### Developer's claims of solution benefits \_

ITM Telemedicine is one of the very few long-running telemedicine networks delivering humanitarian services to physicians working in resource-limited settings. Telemedicine is a possible way to offer support, mentorship and supervision to physicians working in developing countries. A web-based approach helps to learn from others' experiences, submitting cases and questions and to be aware of other ways to manage patients.

#### Future work and challenges

Telemedicine is a powerful educational method. A follow up users' survey showed that telemedicine advice was valuable in the management of specific cases, and significantly influenced the way that clinicians managed other similar cases subsequently. Despite this success, a trend of decline in use of service has been recognised. Sustaining the interest of users remains a key challenge and further information is required about users' satisfaction and network performance. In addition, anchoring the service to partner institutions or regional partnerships needs to be explored. Collaboration with larger groups to address these challenges has begun.

#### User and environment \_

User: physician (Alumni of the Institute of Tropical Medicine in Antwerp).

Settings: rural, urban, home, primary, secondary, tertiary.

#### Solution specifications \_

Solution is used to support: Telemedicine

Software/Hardware requirements: Personal computers

with access to the Internet.

Standards: DICOM

Currently used in: 42 countries

**Evaluation:** Telemedicine in HIV/AIDS care: a users' satisfaction survey: Proceedings\_Med\_e\_tel\_2011.

## Telemedicine network

Country of origin | Switzerland

#### Health problem addressed \_

Continuing education of healthcare professionals and access to specialized advice are keys to improve the quality, efficiency and accessibility of health systems. In developing countries, these activities are usually limited to capitals, and remote professionals do not have access to such opportunities.

#### Solution description \_

A suite of software tools specifically designed to work in low-bandwidth, low-infrastructure settings, to provide distance education ("Dudal" module) and tele-expertise consultations ("Bogou" module). These software modules are developed in Java, and deployed using Java Web Start technology.

#### Functionality \_

For distance education, slide presentations are converted using open-source office automation software (OpenOffice) into a webcastable format. The webcasting environment includes an instant messaging tool for interactivity.

The tele-expertise environment uses a PKI infrastructure to secure information exchange, and a forum interaction paradigm.

#### Developer's claims of solution benefits \_

Most existing tools are not designed and optimized to work in low-infrastructure environments. They lack the ability to connect to medical information sources (e.g., DICOM) and have insufficient security for exchanging sensitive medical information.

#### Future work and challenges \_\_\_\_

The main limiting factor for mainstreaming is the availability of the Internet connectivity in remote settings. The situation is rapidly evolving with the deployment of mobile networks and related GPRS/3G/4G connections, in particular in East Africa. In West Africa, satellite connections are still needed, and remain expensive thus limiting the economic sustainability of these tools to larger hospitals.

Other challenges include the necessity to anchor these services in the institutional framework of each country, which is facilitated if countries have a eHealth strategy and related policies and coordination structures.

#### User and environment \_

User: physician, nurse, midwife, technician.

**Training:** training is required and is provided by online documentation and through the support of national coordination teams.

Settings: rural, urban, secondary and tertiary.

#### Solution specifications \_\_\_\_

**Solution is used to support:** Telemedicine; eLearning/mLearning.

**Software/Hardware requirements:** The software tools require low-bandwidth Internet access, which can be provided by DSL, 3G or satellite links. Uplink bandwidth of 20 kbps and downlink bandwidth of 40 kbps are sufficient to run all services.

Dudal and Bogou modules are Java applications based on open-source libraries, freely available with no license fee.

Standards: DICOM

http://www.who.int/goe

**Currently used in:** Mali, Mauritania, Senegal, Burkina Faso, Niger, Ivory Coast, Chad, Cameroon, Congo, DRC,Guinea, Madagascar, Liberia, Ghana, Tanzania, Egypt, Tunisia, Morocco, Bolivia, Laos.

**Evaluation:** Bagayoko CO et al. Deploying portable ultrasonography with remote assistance for isolated physicians in Africa: lessons from a pilot study in Mali. Stud Health Technol Inform. 2010;160:554-8.

Bagayoko CO et al. Can ICTs Contribute to the Efficiency and Provide Equitable Access to the Health Care System? Year Med Inform. 2011;6(1):33-8.

## Tele-ophthalmology software application

Country of origin | Canada

#### Health problem addressed \_\_

Diabetic retinopathy (DR) is a leading cause of blindness and visual disability in the world. Diabetes affects 8 to 10% of the population in the developed countries. Approximately 2% of people become blind after 15 years of diabetes.

#### Solution description \_

The online screening management application collects captured fundus images, patients personal data, clinical data, and transfers the data for reading and reporting medical follow-ups. This online screening application also provides yearly management recall and scheduling, quality control and inter-professional consultation. It maintains complete trackability, security, confidentiality and easy access to data (with/without immediate access to the Internet).



#### Functionality\_

New patient file: nominal and clinical data, visual acuity are added.

Patient's eyes are imaged, the images added to the file and uploaded to the server.

A doctor accesses and reads the file.

Medical report are generated.

Patient is given follow-up or put on recall list.

Overview of process with alerts.

Quality control.

Data organized at will.

#### Developer's claims of solution benefits \_

This solution integrates all aspects of the screening process, from the initial appointment, uploading of data and fundus images to reading, reporting, follow-up and automated recall scheduling. Access to full history. It further sets itself apart by the comprehensiveness of its flow management, health result analysis and reading tools, and its automated medical quality control. It allows e-consultation. Can be used in situations with/without immediate access to the Internet.

#### Future work and challenges \_

Ways to promote global adoption and integration and to motivate people to increase the use of teleophthalmology for DR need to be found as it is a proven strategy to improve the quality of health care and collaboration among professionals worldwide. The biggest obstacle is not that of attitude or that of access to the equipment, but that of the will and of carrying out its organization to provide systematic screening for diabetic retinopathy to all diabetics.

#### User and environment \_

User: physician, nurse, technician.

Training: intuitive solution with instructions for every step are provided; no training needed.

Settings: rural, urban, primary, secondary, and tertiary.

#### Reviewer's comments \_

Well-organized, integrated system for managing tele-consultations for ophthalmology, mostly for the screening of diabetic retinopathy, which is also becoming a significant issue in developing countries.

The innovation lies mostly in the comprehensive integration of the whole process, and includes quality control. The solution has been validated in rural settings in Canada but not in developing countries.

#### Solution specifications \_

**Solution is used to support:** Telemedicine; Electronic Health Record/Electronic Medical Record; Health Research.

**Software/Hardware requirements:** Any facility with access to a fundus imaging camera and a computer. Solution is a web-based software application; it is proprietary and subject to a license fee.

Standards: HL7, DICOM

Currently used in: Canada

Evaluation: Can J Ophthalmol 2008:43:658-68.

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## **Teletrauma**

Country of origin | Ukraine

#### Health problem addressed \_

Trauma is the main cause of death for people younger than 40 years old worldwide. There are 2 million injured persons per year in Ukraine (4% of population). Polytrauma due to industrial disasters and motor vehicle accidents (MVAs) are a critical problem for Donetsk's large industrial region, because 70% are lethal or result in extremely high level of disabilities.

#### Solution description \_

Web-platform: open source iPath secure server. Server allows to upload and download clinical data and images, perform discussions, upload additional information as evidence-base for recommendations, send/receive e-mail alerts.

Scheme "E-mail+SMS": referral doctor prepares anonymous clinical data, sends it via e-mail to the expert hospital and sends SMS as alert about urgent request. Doctor on duty after receiving SMS opens e-mail and reads the case; sends answer immediately via e-mail.

Perform discussion, upload additional information as evidence base for recommendations, send/receive e-mail alerts.

#### Functionality\_

Telemedicine service is provided by both synchronous and asynchronous telemedicine methods. Patient confidentiality and security achieved by: patient's consent, secure server, VPN-lines, anonymity, sending data in DICOM or SCP-ECG.

#### Developer's claims of solution benefits \_

Cost effective and available, based on existing IT infrastructure, easy to introduce and use, clinically effective, do not need technicians or long preparation.

#### Future work and challenges \_\_

Integration of digital signature tools. Development of tele-assistance based on low-cost devices for transmission of video from arthroscopy and ultrasound devices. Randomised trials for evaluation.

#### User and environment \_\_\_\_\_

User: physician, nurse.

**Training:** training is required on basic computer skills, medical data preparation skills, security skills - 3-6 academic hours.

Settings: rural, urban, primary and secondary.

#### Reviewer's comments \_\_\_

The organizational aspects for using ICT meaningfully to address the management of trauma patients are good, and have demonstrated convincing results.

#### Solution specifications \_\_\_

**Solution is used to support:** Telemedicine; eLearning; mHealth.

**Software/Hardware requirements:** standardized equipment (PC, digital camera, printer, web-camera) and IP data transfer protocol (based on principles of low-resource telemedicine); iPath.

Standards: DICOM

Currently used in: Ukraine, Russia

**Evaluation:** Vladzymyrskyy A.V., Klymovytskyy V.G., Kalinovsky D.K. et al. Clinical Efficiency of Telemedicine in Trauma and Orthopaedics / Med-e-Tel 2008.-Luxembourg,2008.-P.87-88.

## Medical devices

2011

### Fetal heart rate monitor

Country of origin United Kingdom

#### Health problem addressed

Every year, 1 million babies die during childbirth. Complications during childbirth kill half a million mothers, and a further 1 million babies within a month of birth. Over 99% of these deaths occur in the developing world and many are preventable with timely detection of complications.

#### Product description \_

Using advanced Doppler ultrasound technology, the monitor detects and measures the fetal heart rate. This vital indicator of fetal stress allows rural healthcare workers to make life-saving decisions during childbirth. Destined for use in low resource settings, its design focuses on simplicity of use, durability and electrical power independence.



#### Product functionality.

The fetal heart rate monitor is designed for ruggedness and simplicity of use, but its most distinguishing element is the human-powered electricity solution. By using the self-powered technology, simply winding a handle will charge the batteries. Each minute of winding provides about 10 minutes of monitoring time.

#### Developer's claims of product benefits \_

Fetal monitoring methods in low income countries are limited to Pinard fetal stethoscopes. Current availability of monitoring in the majority of primary and district care facilities in middle and especially low income countries being limited makes this monitoring unreliable. The accuracy of the Pinard is without much evidence indicating improved outcomes in situations of fetal distress. Doppler ultrasound fetal heart rate monitors are recommended but only 1% of these devices worldwide are available in low income countries. This device aims at a reduction in perinatal mortality and neonatal encephalopathy. The majority of the midwives who used the monitor preferred it to the Pinard as the device was easy to charge; it was very easy to obtain a reading and quick to identify the fetal heart rate within 30 seconds.

#### Operating steps \_

The powerful narrow beam Doppler head is placed on a pregnant woman's abdomen. The fetal heart rate is delivered as an audio signal and displayed as a number in beats per minute.

#### Development stage \_

This fetal heart rate monitor won the Index Global Design Award in 2009 and has the potential to dramatically improve health outcomes especially for babies. Pilot field testing was carried out in 9 South African primary care maternity facilities run only by midwives (without doctors).

#### Future work and challenges \_

The fetal heart rate monitor is currently available and in production.

#### User and environment \_

User: Nurse, midwife, physician

Training: None

Maintenance: Technician

#### Environment of use

Setting: Rural, primary (health post, health center), secondary (general hospital)

Requirements: None

#### Product specifications \_

**Dimensions (mm):** 170 x 85 x 75

Weight (kg): 0.7 Consumables: None Life time: 5 years Shelf life: 3 years List price (USD): 350 Other features: Portable and reusable. Runs on batteries. Uses software.

Year of commercialization: 2010

Currently sold in: United Kingdom, South Africa and

other African countries.

## Isothermal nucleic acid amplification system for POC diagnosis

Country of origin | China

#### Health problem addressed\_

One major limitation of effective tuberculosis control is the lack of a suitable diagnostic technology. Current technologies, such as sputum smear microscopy, are insensitive; immuno tests are indirect, and the available molecular tests are complex and expensive. It is the responsibility of scientific and business communities to provide rapid, simple, accurate and affordable technologies and products.

#### Product description -

This TB diagnostic is based on 5 core technologies: 1. Glass transition of reagents for ambient temperature transport/ storage; 2. Instrument free sample preparation; 3. Isothermal Nucleic-acid amplification; 4. Visual read-out: a DNA lateral-flow device (LFD); 5. Cross-contamination control device. The TB DNA test with these integrated technologies can be delivered and performed at almost any location.

#### Product functionality \_

Sample preparation: using syringe and a membrane unit, no centrifugation; Amplification: proprietary Cross Priming Amplification (CPA) technology, water bath is the only instrument needed; Lateral-flow strip detection: visual readout in an enclosed device, cross contamination proof; Glass transition of reagents: the entire kit can be transported/stored at ambient temperature.

#### Developer's claims of product benefits \_

The amplification method (CPA) and cross-contamination proof detection device are the primary inventions. The glass transition method and sample preparation device are improvements on existing technology: Cost effectiveness: No setup cost, almost no instrument cost; Ease of use and Maintenance: Single test package, simple operation; Reduced training Requirements: No highly trained personnel required; Labour and time saving: Sample to result in 2 hours; Reduced resource Requirements: The only equipment needed is a water bath maintaining a temperature around 63°C; Technical superiority: Detected 10 or less pathogens with high specificity; Better accessibility: Shipped and stored at ambient temperatures; Cross-contamination control: Sealed cartridge ensuring amplicon is never exposed.

#### Operating steps

Step 1: Sample preparation - Use our instrument-free nucleic acid extraction device. The process takes 15 minutes after sputum specimen liquefied and boiled; Step 2: Amplification - Amplification can be accomplished with any incubator that keeps a constant temperature. CPA takes 60 minutes at 63°C. Step 3: Detection and read-out - Place the CPA reaction tube into the cartridge and lock. Read result in 10 minutes.

#### Development stage.

The Isothermal Amplification Diagnostic Kit was approved by TUV for CE marking. Our manufacturing facilities are EN ISO 9001:2000 and EN ISO 13485+AC:2007 approved. One example of product trials conducted was at Taipei Medical University, Municipal Wan Fang hospital - sensitivity: 99%, specificity: 94%, PPV: 97%, and NPV: 97%.

#### Future work and challenges.

Market education: The technologies are new and little known. It requires significant effort to educate users, promote products and gain acceptance. Regulatory approval: The CE mark has been obtained for the TB tests. Entry approval from individual governments is still needed requiring time and resources. Network: A network for distribution and demonstration, covering health centers in developing countries, needs to be established.

#### User and environment

User: Nurse, physician, technician

Training: Product brochure, instruction for use, actual testing kits. Training takes about 3 hours.

Maintenance: Nurse, physician

#### Environment of use

Setting: Rural and urban health care facilities.

Requirements: The assays can be used at community health centers with minimal or no lab infrastructure, and can be performed by personnel with minimal training; water and method to boil for bacteria decontamination, water-bath to maintain temperature between 58 to 65°C, and temporary electricity (battery/solar) are required. Long-term storage at larger clinics would need to transport the devices to hard-to-reach areas.

#### Product specifications \_

Weight: 500g/20 tests Shelf time: 1 year

**Consumables:** Pipette tips

amplification and detection)

Other features: The diagnostic test is portable and singleuse.

Year of commercialization: 2009

Retail Price (USD): \$6 (including sample preparation, Currently sold in: China, Thailand, Singapore, Taiwan,

Canada and USA (research only)

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42

## Manual wheelchairs and mobility devices

Country of origin | United Kingdom

#### Health problem addressed.

An estimated 20 million people in need of a wheelchair in low-income countries do not have one. Many donated wheelchairs are unsuitable for the local terrain, do not fit properly and do not provide adequate comfort or postural support. These factors can restrict a person's mobility, hinder their health and well-being and even cause life threatening secondary complications such as pressure sores.

#### Product description \_

The technology encompasses a range of 3-wheel and 4-wheel wheelchairs, sports wheelchairs, supportive seating and tricycles specifically designed for use in less resourced settings. The products are available in a range of sizes and have many adjustable features. Each product is flat-packed, requires local assembly and must be distributed through a wheelchair service.



#### Product functionality.

Products in the range require assembly by trained local staff. Basic hand tools are required and pictorial assembly instructions for each product are provided. Once assembled to the client's prescription, the client is fitted comfortably and given instructions on how to use the product safely and carry out basic maintenance. The products are manual and easy to maneuver by the client or an attendant.

#### Developer's claims of product benefits.

The complete product range can be uniquely shipped in any volume to service centres around the world and provides a mean to facilitate and expedite the provision of appropriate manual wheelchairs in low-income countries. Providing a range promotes choice for people with disabilities and ensures they receive a product that is most suited to their need and aids their rehabilitation. The products are affordable, high in quality and durable and use locally available components. The adjustable features optimize comfort. The majority of products are supplied with a pressure relieving cushion, a life saving device that is often not provided with other donated wheelchairs. Training is provided to local staff to ensure they have the skills to assemble, fit and adjust the products correctly and competently.

#### Operating steps \_

The products are assembled according to the assembly instructions. Once set up the client is fitted with the wheelchair or mobility device. If necessary, adjustments can be made to maximize comfort, for example the footrest, backrest height or seat depth can be altered. Once the client is happy, he or she is then able to self-propel manually or can be assisted by an attendant.

#### Development stage

The first product commercialized is the wheelchair for rough terrain, on the market since 2005. However, design reviews and upgrades are carried out periodically. Studies were carried out in South Africa to measure the impact the product has had on the quality of life of users. Two international NGOs have performed their own successful trials in Angola and the Philippines over a six and two months period respectively. The product is distributed to over 20 countries. The range includes other commercialized mobility devices and accessories. The product has regulatory approval.

#### Future work and challenges \_

Challenges include: Provision of products to the end user (client) is heavily dependent on donated funds; competition from other products on the market that are donated to organizations and end users free of charge; capital to maintain stock of products to enable quicker dispatch from factory.

#### User and environment.

User: Patient, family member, clinician, technician

Training: Training is required to assess the client and assemble the product. Training for the full product range is a minimum of three days. Basic workshop hand tools and clinical equipment such as a therapy bed and foot blocks are required. Maintenance: Patient, technician

#### Environment of use \_

Requirements: The product must be distributed through a service centre where local staff has been trained to assess wheelchair and the service centre where local staff has been trained to assess wheelchair and the service centre where local staff has been trained to assess wheelchair and the service centre where local staff has been trained to assess wheelchair and the service centre where local staff has been trained to assess wheelchair and the service centre where local staff has been trained to assess wheelchair and the service centre where local staff has been trained to assess wheelchair and the service centre where local staff has been trained to assess wheelchair and the service centre where local staff has been trained to assess wheelchair and the service centre where local staff has been trained to assess wheelchair and the service centre where local staff has been trained to assess the service centre where local staff has been trained to assess the service centre where local staff has been trained to assess the service centre where local staff has been trained to assess the service centre where the service centre where local staff has been trained to be a service centre where the service cusers and assemble and fit the products. A workshop and clinical assessment are required. The centre will act as a point for clients to return to for follow up and product maintenance or repairs. The products are manual and do not have any special operational requirements. The ease of use of the product can depend on the local infrastructure i.e. often buildings are inaccessible so may prevent the user from independently accessing the building.

#### Product specifications .

Dimensions (mm): approx. 1212 x 740 x 865

Weight (kg): 22 Life time: 5 years Retail Price (USD): 171

Year of commercialization: 2005

Currently sold in: Argentina, Australia, East Timor, Ethiopia, Ghana, India, Kiribati, Lebanon, Lesotho, Liberia, Malawi, Nepal, Pakistan, Papua New Guinea, Serbia, Sierra Leone, Solomon Islands, South Africa, Sri Lanka, Sudan, Thailand, Uganda, Zimbabwe

## Newborn simulator for resuscitation training

Country of origin | Norway

#### Health problem addressed \_

UN Millennium Development Goal (MDG) 4 aims at reducing child mortality by 2/3 from 1990-2015. To date, the improvement is far from sufficient, particularly for neonatal mortality. To reach MDG 4, there is an urgent need to train large numbers of birth attendants in developing countries in neonatal routine care and resuscitation.

#### Product description \_

The proposed solution is a highly realistic and affordable newborn simulator. The baby's status can be simulated as desired to facilitate role playing in relevant scenarios covering basic newborn care as well as standard resuscitation measures. The simulator is available with therapeutic tools.



#### Product functionality \_

By squeezing the bulbs connected to the simulator, an instructor can simulate three vital signs: Crying; spontaneous breathing; and palpable umbilical pulse. Depending on how the learner assesses the situation and acts, the instructor can easily provide feedback to the learner by changing the vital signs.

#### Developer's claims of product benefits —

The simulator facilitates effective and affordable simulation training in low-resource settings that can improve quality of neonatal resuscitation as it is: Very low cost (available at USD 50); Allows assessment of key competencies (e.g. ability of trainee to ventilate adequately); Durable, easy to take apart/reassemble/transport; Culturally sensitive (available in dark or light complexion).

The simulator is also highly realistic. It has the size and appearance of a newborn baby, and natural weight, feel and touch when filled with water. As it comes deflated in a compact container and can be emptied between uses, distribution and transport of the simulator is convenient.

#### Operating steps \_

The simulator is easily prepared for use by filling the body with 2 liters of water (alternatively by air). An instructor can simulate vital signs by squeezing the simulation bulbs. The simulator facilitates practice in effective bag-maskventilation as the chest only will rise with correct technique.

#### Development stage \_

The product was introduced in 2009. It is available on a not-for-profit basis for projects in the 68 developing countries identified by UN as focus countries for MDG4. The use of the Simulator was validated in pilot tests in Kenya, Tanzania, Pakistan and India and is today a fundamental part of several courses in developing countries in basic newborn resuscitation.

#### Future work and challenges \_

Financing: Although the product is available on not-for-profit basis, individual health care facilities and educational institutions in low-and middle income countries often have limited financial resources and may need to obtain funding from governments or international aid organizations.

Distribution channels: Bureaucracy and often prohibitive customs rates render import to countries where the need is greatest difficult.

#### User and environment \_

User: Nurse, midwife, physician, course instructors, students, all other health care personnel needing refresher training Maintenance: Any user

#### Environment of use \_\_

Setting and Requirements: The product can be used in any setting, there are no specific requirements to the infrastructure.

#### Product specifications \_\_\_\_\_

Dimensions during transport (mm):  $300 \times 200 \times 70$ (simulator deflated in a kit with accessories)

Dimensions in use (mm3):  $480 \times 230 \times 120$ 

Weight during transport (kg): 0.8

Life time: 3 years

Weight filled (kg): 2.2

Retail Price (USD): 50

Other features: The simulator is portable und reusable.

Year of commercialization: 2009

Currently available in: 68 countries identified by UN as focus countries relative to UN Millennium Development Goal 4.

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## Non-pneumatic anti-shock garment

Country of origin | United States of America

#### Health problem addressed.

Postpartum hemorrhage (PPH) in developing countries continues to be the single most common cause of maternal morbidity and mortality, accounting for approximately 25 percent of maternal deaths globally. Over 90 percent of these deaths occur in developing countries.

#### Product description \_

For women suffering from uncontrollable PPH, a method to control the bleeding, reverse the shock, and stabilize the patient for safe transport to a comprehensive obstetric care facility could be lifesaving. One method to manage PPH is the use of a non-pneumatic anti-shock garment (NASG).



#### Product functionality \_

The NASG is a lightweight neoprene garment that is made up of five segments

that close tightly with Velcro. The NASG applies pressure to the lower body and abdomen, thereby stabilizing vital signs and resolving hypovolemic shock. When fitted correctly, the reusable NASG forces blood to the essential organs - heart, lungs, and brain.

#### Developer's claims of product benefits \_

This garment provides an improvement over existing products in that is a validated, low-cost, high-quality garment. This is achieved by providing direct access to qualified manufacturers who can supply the garment at the price of US\$54 (purchaser is responsible for freight forward from China and import regulations, minimum order is 1,000 units).

#### Operating steps \_

1. Place NASG under woman; 2. close segments 1 tightly around the ankles; 3. close segments 2 tightly around each calf; 3. close segments 3 tightly around each thigh, leave knees free; 4. close segment 4 around pelvis; close segment 5 with pressure ball over the umbilicus; 6. Finish closing the NASG using segment 6. Segments 1, 2, 3 can be applied by two persons simultaneously, segments 4, 5, 6 should only be applied by one.

#### Development stage .

Clinical trials led by Suellen Miller at the University of California, San Francisco are on-going. Currently, the large-size device is cleared by the US Food and Drug Administration and has been tested in low-income settings. The device is ready for manufacturing and sale in China.

#### Future work and challenges \_

NASG Sizes: The NASG is not a one-size-fits-all PPH tool. Three sizes (small, medium, and large) of NASG have been developed to accommodate the significant population-dependent anthropomorphic variations around the world. In our interviews in Nigeria, it was also clear that an extra-large-size NASG was desired to accommodate larger women in that region. Only the large-size NASG has been qualified with manufacturers.

Cleaning of the NASG: Cleaning is another challenge. There is no established method of accurately tracking the number of uses and cleanings, thus it is difficult to identify when sufficient degradation has occurred to retire the NASG and replace it with a new one.

#### User and environment \_

User: Family member, nurse, midwife, physician, technician

Training: Pathfinder International has developed course curriculum and training materials which vary in length depending on target audience, and whether the intended user is applying or removing the garment.

Maintenance: Hospital orderlies are generally responsible for cleaning.

#### Environment of use \_

**Setting:** At home and in health care facilities in rural or urban settings.

Requirements: Water and bleach for cleaning.

#### Product specifications \_

Life time: Approx. 40 uses Other features: Portable and reusable List price (USD): 53.76 Currently sold in: United States of America

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## Oxytocin in prefilled auto-disable injection system

Country of origin | United States of America

#### Health problem addressed \_

Postpartum hemorrhage (PPH) is the leading cause of maternal death worldwide. Women delivering outside of health facilities or in facilities with constrained resources may not receive the WHO-recommended dose of 10 IU of oxytocin for the prevention of PPH. There is a need for an easy-touse delivery system for oxytocin that increases access.

#### Product description \_

A compact, prefilled, auto-disable injection system is used to deliver Oxytocin. A time-temperature indicator on each package indicates heat exposure. Oxytocin in this device can enable minimally trained health workers to provide the PPH prevention dose in low-resource facilities, emergency situations, or remote locations.



#### Product functionality \_

As a prefilled system the easy-to-use device allows caregivers to safely inject drugs or vaccines with minimal training. The system prefilled with Oxytocin ensures that an accurate dose is delivered to a patient with minimal preparation, minimum waste, and a guarantee that the syringe and needle will not be used again.

#### Developer's claims of product benefits.

Current practice is to use a syringe and two 5-IU ampoules or one 10-IU ampoule of Oxytocin. Oxytocin in described injection system is prefilled with 10 IU and ensures an accurate dose by minimally skilled health workers. It is individually packaged and sterile in an injection-ready format, optimal for low-resource settings. It is compact and prefilled so generates minimal waste.

#### Operating steps \_

1. Check the time-temperature indicator; 2. Open the foil pouch; 3. Activate the device; 4. Remove the needle shield; 5. Continue to hold the injection device by the port and insert the needle into the patient; 6. Squeeze the reservoir to inject the oxytocin; 7. Do not re-cap; 8. Dispose according to medical waste procedures.

#### Development stage \_

Oxytocin in conjunction with described injection device is currently being produced in Argentina and India. Oxytocin in Uniject is commercially registered in Argentina, Guatemala, Honduras, Paraguay, and India. Additional registrations in Latin America and Africa are being pursued.

#### Future work and challenges

The value of oxytocin in conjunction with described injection system has been demonstrated in the field. More and more countries are recognizing the need to reduce maternal mortality, and the easy and safe delivery of oxytocin has been identified as an important tool, but more must be done to raise awareness. The next phase of work will include efforts to raise awareness, increase demand, and ensure a sustainable supply.

#### User and environment -

User: Nurse, midwife, physician, technician

Training: User instructions are included in the box and on the primary packaging. Training requires no more than 1 day.

#### Environment of use \_

Setting: At home and in health care facilities in rural and urban settings.

Requirements: Cold chain is ideal, but the time-temperature indicator on the package allows for brief excursions outside the cold chain, like to low-resource health posts or to a woman's home.

#### Product specifications \_

**Dimensions (mm):** (foil pouched product) 148 x 56 x 10

(reservoir height)

Weight (kg): 0.0025 (filled, excluding pouch)

Shelf life: 24 months

Retail Price (USD): Varies by country

Other features: Portable and single-use.

Year of commercialization: 2009

Currently sold in: Argentina, Guatemala, India

## Parasitological test system

Country of origin | Brazil

#### Health problem addressed \_

Intestinal parasites - types of helminthiasis and protozooses - are endemic and afflict more than 1 billion people all over the world, particularly affecting the mental and physical development of our children. Affected children are unable to develop their abilities which consequently compromises the Human Development Index of the respective country.

#### Product description \_

This solution allows the user to easily detect the extent of parasite infestations. The product allows for economic analysis integration into national health plans in communities of low and medium incomes. The product is a prefilled container used for filtering, concentrating and recovering parasites from fixed/preserved body waste.



#### Product functionality \_

In a vial with preservative solution, a stool sample is collected by the patient. At the laboratory, the technician places the vial upside down in a tray and waits for 15 minutes, allowing the preserved sample to pass through the filter system. Subsequently, the sample can be directly analysed under the microscope.

#### Developer's claims of product benefits.

This product, unlike other methodologies, does not need any equipment or reagents to perform the parasitological examination of feces. The system includes a special filter inside, made of polyester with 266 micra, which renders the sample much cleaner and makes it easier to find the parasites. In just one step the sample is ready to be analysed under the microscope. Another important difference is the new preservative liquid that does not use formalin or any other toxic and aggressive reagent, an exclusive development to preserve the environment and the people that work directly with this kind of process.

#### Operating steps \_

By the patient: Open the vial, and with the help of a spoon (provided) collect a portion of feces and put it inside the vial, directly into the preservative liquid. Close the vial and bring it to the laboratory.

By the Technician: Homogenize the sample by shaking the vial, turn over the vial and put it in the tray (provided) for 15 minutes. Place two drops directly on glass microscope plate.

#### Development stage \_

The product is on the market since 2007, and it number of laboratories that choose this method is growing.

Conformity assessment: ISO 9001-2008 / ISO 13485-2003 / CE Mark / FDA.

#### Future work and challenges \_

The technology is ready to be used in any country. It is accessible, affordable, available and applicable. The company needs to find funding to move to the next stage (supply worldwide).

#### User and environment \_

User: Patient, technician

Training: None Maintenance: None

#### Environment of use \_\_\_

Requirements: Product should be stored at room temperature (15°C to 30°C).

#### Product specifications.

**Dimensions (mm):** 35 x 35 x 70

Weight (kg): 0.02

Consumables: None Shelf time: 3 years.

Retail Price (USD): 1.5

Other features: Portable. Single use.

Year of commercialization: 2007

Currently sold in: Brazil, Saudi Arabia, United Arab

**Emirates** 

## Phototherapy for neonatal jaundice treatment

Country of origin | Brazil

#### Health problem addressed \_

Neonatal Jaundice (Hyperbilirubinemia) is a frequent issue in newborns. Approximately 60% of newborns become clinically jaundiced. It is a clinical condition generally benign and reversible if properly treated, but its exacerbated intensification may generate serious sequelae into the central nervous system, which may lead patient to death.

#### Product description \_

Phototherapy is an efficient mean to treat Hyperbilirubinemia. By emitting blue light over the patient's skin, it converts toxic bilirubin molecules in the blood into less toxic isomeric forms, by photo-oxidation and photoisomerization. The device uses high power LEDs for treatment and negligible emission of UV / IR radiation.



#### Product functionality \_

The phototherapy uses a set of 5 high power LEDs, positioned 30 cm above the patient. The treatment uses high radiation emitted at the blue range of the spectrum, from 400 to 550 nm (the most recommended for Jaundice treatment). The device also provides extra functions, such as integrated radiometer and treatment time counter.

#### Developer's claims of product benefits.

Traditional devices use fluorescent or halogen lamps, or many conventional LEDs. Lamps may require filters to attenuate UV / IR rays and have a low life expectancy (around 2.000h). Conventional LEDs are low power devices. To work effectively, hundreds of LEDs must be used, making the phototherapy complex and prone to failure. The proposed technology uses only 5 high power LEDs, which is equivalent to more than 250 conventional LEDs. The result is a compact, highly efficient, long life time (20.000 h) and low cost phototherapy. It provides new resources: output radiation level adjustment, embedded radiometer and irradiance measurement reports. In addition, it is compact, saving space in the intensive care unit.

#### Operating steps \_

Place the device over the newborn, 30 cm away. Turn it on and press 'Menu' to go to the irradiance level screen. Set the irradiance using the 'up'/'down' keys and press 'Enter' to confirm. Be sure the newborn is exposed to the light at the chest and abdomen area. Protect the newborn's eyes.

#### Development stage .

The product is being manufactured and commercialized. It has been fully validated and clinically tested. Studies verify that the blue high power LEDs are more efficient for Jaundice treatment. The market confirms those studies. It has the Brazilian ANVISA regulatory approval, the CE marking and it is currently obtaining the UL recognition approval.

#### Future work and challenges.

Promoting the technology's ease-of-use, efficient treatment system and affordable cost in low and middle income countries is the greatest challenge. Assistance herein is required, e.g. through workshops by professionals to explain the importance and advantages and to make users familiar with new functions that improve the treatment quality, like the embedded radiometer and the timer.

#### User and environment \_

User: Nurse, physician

Training: Concept presentation (2 hours training).

Maintenance: Technician

#### Environment of use \_

Setting: Secondary (general hospital), tertiary (specialists hospital)

Requirements: Power supply (100 to 240 Vac), 50 or 60Hz; ambient temperature between 18°C and 28°C; air humidity between 10% and 95%; eye protection for the patient.

#### Product specifications \_

Dimensions (mm):  $230 \times 116 \times 50$ 

Weight (kg): 1

**Consumables:** Eye protector

http://www.who.int/medical\_devices

Other features: Portable and reusable. It utilizes software.

Year of commercialization: 2005

Currently sold in: Algeria, Australia, Bolivia, Brazil, Colombia, Costa Rica, Ecuador, Spain, Finland, France, Indonesia, Iran, Iraq, Jamaica, Lithuania, Malaysia, Mexico, Nicaragua, Paraguay, Peru, Poland, Portugal, Russia, Syria, Sudan, Sweden, Uruguay, Venezuela, Vietnam, Yemen.

## Point-of-use water disinfection system

Country of origin United States of America

#### Health problem addressed

Worldwide, gastrointestinal illness (GI) is estimated to cause over 1.5 million deaths annually. In addition, an estimated 4 billion cases every year make GI the third highest cause of morbidity globally. Unsafe drinking water is recognized as one of the major pathways responsible for the transmission of GI causing pathogens.

#### Product description \_

The UV tube is easy to operate and maintain point-of-use water disinfection system that uses ultraviolet light to inactivate pathogens at a fast flow rate of 5 liters per minute, without producing unpleasant or harmful disinfection by-products. The UV Tube is appropriate for households, schools, clinics, and small communities.



#### Product functionality \_

The UV tube uses a 15 watt germicidal lamp to deliver a UV-C (254nm) dose of 900 J/m<sup>2</sup> to inactivate virus, protozoa, and bacteria suspended in water.

#### Developer's claims of product benefits \_

The UV tube was developed by an interdisciplinary team of students and professors, who recognize that a wide array of safe water options are urgently needed in order to address the severe and widespread health problems caused by drinking water contaminated with pathogens. Through rigorous laboratory and extensive field testing, the UV Tube was designed to be an effective, easy to use, low-cost, and adaptable point-of-use safe water solution. The dose is more than twice the minimum recommended by the US NSF/ANSI Standard 55, providing a safety factor that guarantees its effectiveness even in certain non-ideal conditions.

#### Operating steps.

To disinfect water, a user has to: (1) turn on the switch; (2) confirm that the lamp is on; (3) open the water valve; (4) wait for the safe storage container to fill up, 1 minute for each 5 liters; (5) close the water valve; (6) drain the system; (7) turn off the switch. No consumables required, but every 1-3 years some components need replacement.

#### Development stage \_

The product was validated in the laboratory and a prototype tested in 24 households in Mexico in 2005. Positive water quality and user acceptance results led to piloting the technology in 150 households, 3 schools and 13 communities between 2007 and 2008. Successful results motivated the development of a scalable model in 2009. In 2010, 450 household systems were installed in Mexico as part of a stepped-wedge cluster randomized trial. In 2011 the UV tube will be installed in at least 8 schools and 38 community systems serving approx. 10,000 people.

#### Future work and challenges.

As most water treatment technologies seeking to make real improvements, the device must be implemented as part of a program that allows for needs assessment; adaptation to local conditions; hygiene education; operation and maintenance training. For this reason, we see the UV tube being scaled up through partnerships with institutions, organizations, and/or companies that have local presence and are committed to improving the health of the populations they serve.

#### User and environment \_

User: Self-user, family member, nurse, technician

Training: Although the system is easy to use and most people can learn how to operate it from a manual, it is recommended that they participate in a basic (20-30 minute) training session

Maintenance: Trained nurse / community member, technician

#### Environment of use \_

Requirements: Access to electricity. The product consumes 20 watts. To disinfect 1,000 liters it only uses 0.1 kilo watt hours of electricity. The source can be direct current (e.g. 12-24 volts from a solar powered battery) or alternate current (e.g. 110-220 volts from the grid). If water is turbid or contaminated, pre-disinfection filtration is required.

#### Product specifications

**Dimensions (mm):** 600 x 150 x 150

Weight (kg): 3

Life time: 3-5 years Retail Price (USD): 45 Other features: Reusable, can run on batteries.

Year of commercialization: 2009

Currently sold in: Mexico, but projects can be established

in new countries.

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http://www.who.int/medical devices

## Portable haemoglobin meter

Country of origin | Brazil

#### Health problem addressed \_

Anemia is one of the most common blood disorders globally. Iron deficiency anemia is the most prevalent nutritional disorder in the world. Anemia diagnosis is frequently not performed or the test results are delayed, causing aggravations or even sequels in the most vulnerable population, children and pregnant women.

#### Product description \_

Portable hemoglobin meters that are user-friendly can be a great aid to change the global anemia scenario. Avoiding the displacement of patients and shortening the diagnostic process, this solution can spread this clinical test to people with low access to health services.



#### Product functionality \_

The portable hemoglobin meter is a micro processed photometer. In a disposable vial, containing Drabkin's reagent, 10 uL of blood sample are dropped. Reaction follows inside the vial, also used as the lecture cuvette. Hemoglobin content is read and calculated by a microprocessor and proprietary software. Results are presented in a LCD display.

#### Developer's claims of product benefits \_

The reagents are stable for a long periods and extreme environmental conditions. The use of the injection vial, containing the reagent, as a cuvette, reduces the number of operations, reduces costs, speeds lecture and allows portability. The equipment is battery (rechargeable) driven allowing the use in any environment.

#### Operating steps \_

After cleaning the skin, a puncture is done and a 10 uL blood sample is collected with a micropipette and transferred to the reagent vial. After 30 seconds of mixing, the vial is inserted in the equipment and a button is pressed. The sample hemoglobin content is exhibited in the display in g/dL.

#### Development stage .

The device is fully developed and extensively tested (over 20,000 patients). In Brazil validation was performed by PP-SUS program, a governmental trial of innovative technologies for public health care. PAHO and IPTI are performing tests (process n° BR/LOA/1000065.001). Researchers from S<sub>1</sub>0 Paulo University and FIOCRUZ Foundation are performing tests in anemia trials.

#### Future work and challenges \_

For the moment, it is commercialized only in Brazil, in compliance with the standards from Brazilian national regulatory legal demands (ANVISA). International certifications need to be performed. Additionally, there exists a need for investors and/or commercial partners interested in business improvement.

#### User and environment.

User: Nurse, physician, technician

Training: One to two days, blood collection practice by puncture and pipette

Maintenance: Manufacturer

#### Environment of use \_\_

Requirements: Powered by batteries and designed for a global environment use, there are no special requirements. The tests are disposable and previously sterilized.

#### Product specifications \_

Dimensions (mm):  $167 \times 108 \times 37$ 

Weight (kg): 0.358

Consumables: Hemoglobin meter reagent vial, tips

Life time: several years Retail Price (USD): 1500

List price (USD): 1500

List price of consumables (USD): 1.0/vial

Other features: Portable and reusable. Runs on batteries,

uses software.

Year of commercialization: 2010

**Currently sold in: Brazil** 

Fax +55 | | 4792 4326 http://www.who.int/medical\_devices

## Portable ventilator

Country of origin | United States of America

#### Health problem addressed.

Patient groups most likely to benefit include those with COPD, Cardiogenic Pulmonary Edema, Immunocompromised patients (e.g. HIV), and COPD patients weaning from mechanical ventilation. COPD is one of the fastest growing causes for death today worldwide. Over the next 20-30 years, it is poised to become the 3rd or even 2nd leading causes of death.

#### Product description \_

The device is a small size, portable, versatility and can run on batteries.

#### Product functionality \_

The device's primary innovation is owed to its use of micro-blower technology and unique gas control algorithms. In combination the device is able to meet the needs of a wide variety of ventilatory demands, including

high leaks seen in noninvasive ventilation while still maintaining patient-ventilator synchrony.



By costing a third of other ICU ventilators and offering both invasive and noninvasive capabilities, the device is ideally suited for patients in respiratory distress, no matter what their location or severity.

#### Operating steps \_

The device employs a micro-blower to generate airflow and connects directly to oxygen supplies to provide between 21-100% oxygen enriched, pressurized gas. Pressure and flow sensors provide signals to a very sophisticated controls algorithm to precisely meter pressure, flow and volume even in leak prone, noninvasive applications.

#### Development stage

The device was market released July 2010 and is sold worldwide. Several investigators have compared the device's performance to other ventilators, in various patient populations, and under different clinical conditions such as leakprone noninvasive applications. The results of such studies show the relative superiority of the device's design elements and precise gas delivery. One bench study demonstrates the unique ability of the device to maintain accurate volume control mode delivery even while using cheap and simple intentional leak breathing circuits.

#### Future work and challenges \_\_\_

None

#### User and environment \_

User: Nurse, physician, technician

Training: Interactive CD-ROM (self paced), User's Manual (reference material), various slide presentations.

Maintenance: Technician, engineer, manufacturer

#### Environment of use \_

Settings: Ambulatory, secondary, and tertiary health care facilities.

Requirements: Basic electrical power 100 - 240 VAC, 50/60 Hz, 2.1 A, 5-40C temperature range and high pressure oxygen source (40-87 psi) via compressed gas tanks or wall outlets. Optional: available equipment to disinfect breathing circuits if reusable circuits are preferred.

#### Product specifications \_

**Dimensions (mm):** 21.3 x 28.5 x 23.5 Weight (kg): 5.6 (including batteries)

Consumables: Breathing circuit and patient interface

(artificial airway or facemask)

Life time: Several years Retail Price (USD): 11,500 List price (USD): 11,500

List price of consumables (USD): 80 (Std. Adult reusable circuit), 14 (disposable circuit)

Other features: Portable and reusable. Runs on batteries, uses software and is compatible with telemedicine systems.

Year of commercialization: 2010

Currently sold in: US, Eastern and Western Europe, all Scandinavia, most countries in Asia/Pacific, India, Africa, Japan, Latin America and Middle East.

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## Prefilled auto-disable injection system

Country of origin | United States of America

#### Health problem addressed\_

Solutions are needed in low-resource settings to increase access to drug and vaccine delivery. It is also necessary to prevent reuse of syringes, helping to prevent transmission of bloodborne disease and to minimize waste in these settings.

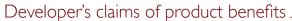
#### Product description \_

The device developed to address this health problem is a compact, sterile, prefilled, nonreusable injection system for delivery of vaccines or drugs.

#### Product functionality \_

The prefilled, sterile injection system may allow minimally trained health workers to accurately inject drugs or vaccines that they would not otherwise be allowed to deliver. The auto-disable feature prevents reuse, helping

prevent transmission of bloodborne disease between patients. The compact, prefill device also minimizes waste.



Compared with standard syringes and ampoules (depending on the drug delivered), the developed injection system is prefilled ensuring an accurate dose by minimally skilled health workers. It is individually packaged and sterile in an injection-ready format, optimal for low-resource settings. It is compact and prefilled so generates minimal waste.

#### Operating steps.

1. Open the foil pouch; 2. Push the needle shield into the port; 3. Push until you close the gap between needle shield and port; 4. Remove the needle shield; 5. Hold the device by the port and insert needle into patient; 6. Squeeze reservoir firmly to inject; Discard according to medical waste procedures.

#### Development stage.

The injection system was developed around 15 years ago, and as a viable container for drugs is fully developed. The availability of important drugs in the injection device for use in low-resource settings is established in some areas and developing in others. Oxytocin, hepatitis B vaccine, and tetanus Toxoid vaccine are available in some countries; other drugs and vaccines are in early stage development. Injectable contraceptives are in their final stage of regulatory approval. Betamethasone and gentamicin are still in research stages.

The unfilled device is available for purchase by pharmaceutical manufacturers worldwide.

#### Future work and challenges \_

The injection system itself is designed to be portable and requires minimal resources for preparation. Depending on the drug or vaccine applied, cold chain may be needed. Some applications can include a time-temperature indicator which allows brief excursions out of the cold chain, like to low-resource health posts or for rural/home delivery.

#### User and environment \_

User: Patient, family member, nurse, midwife, physician

Training: User instructions are included in the box and on the primary packaging.

#### Environment of use \_

Setting: At home and in health care facilities in rural and urban settings.

Requirements: The device itself is designed to be portable and requires minimal resources for preparation. Depending on the drug or vaccine applied, cold chain may be needed.

#### Product specifications \_

Dimensions (mm): max.100 (excl. pouch) x 23 x 10 (reservoir height)

Weight (kg): 0.002 - 0.0025 (filled, excluding pouch)

Shelf life: 5 years

Retail Price (USD): Varies by drug/vaccine and country

Other features: Portable and single-use.

Year of commercialization: 1998

Currently sold in: Indonesia, India, Argentina, Belgium

## Reusable neonatal suction device

Country of origin | Norway

#### Health problem addressed.

Nearly 1 million newborns in developing countries die from birth asphyxia each year. A similar number are disabled due to compromised breathing at birth. To stimulate spontaneous breathing, or bag-mask ventilate effectively, an open airway is mandatory. Often this requires clearing the mouth and nose of mucous and meconium using vacuum.

#### Product description \_

The proposed solution is a bulb suction device that is particularly suitable for use in developing countries. It is easy to use and reusable when disinfected in accordance with instructions, over the product's lifespan.

#### Product functionality \_

The product benefits newborns suffering from birth asphyxia and in need of clearing the upper airways. Squeezing the bulb generates vacuum so that the birth attendant can extract mucus and meconium from the baby's mouth and nostrils.

#### Developer's claims of product benefits \_

This product is clinically effective, easy and safe to use. It is an improvement over the neonatal suction devices typically used in low-resource settings (i.e., mouth suction or hand bulb suctions, available in non-cleanable versions and mainly intended for single patient use) as it can be easily opened, cleaned and boiled for disinfection after use, it is made of very durable silicone and withstands several hundred times of reuse. The transparent material makes it easy for the user to see whether it has been cleaned since last use situation; the price (available on a not-for-profit basis) combined with number of use situations dramatically reduces the cost per use compared to existing products.

#### Operating steps \_

Ensure that the device is clean before use on patient. Squeeze bulb to generate vacuum, and place the nozzle tip into the newborn's oral or nasal cavity. Slowly release bulb squeeze to extract the mucus, discharge contents into a water container, towel or similar. For repetitive suctioning, keep the body squeezed until suctioning again.

#### Development stage \_

The product has been available on a not-for-profit basis for newborn resuscitation projects in developing countries since April 2010. It has been FDA device listed, and is developed to applicable standards and regulation required for CE-marking. Self-declaration for CE-marking is imminent within March 2011.

#### Future work and challenges

Financing: Although the products is highly affordable and available on not-for-profit basis, individual health care facilities and educational institutions in low-and middle income countries often have limited financial resources and may need to obtain funding from governments or international aid organizations.

#### User and environment \_

User: Family member, midwife, nurse, physician

Training: None

Maintenance: Any person responsible for disinfection.

#### Environment of use \_

Requirements: The only requirement is that it must be possible to clean and disinfect the device (before first use and between patient uses). Cleaning can be performed by boiling the one-piece device in water, or by more advanced methods.

#### Product specifications \_

Dimensions (mm):  $40 \times 40 \times 130$ 

Weight (kg): 0.06 Consumables: None Life time: 5 years Retail Price (USD): 3 List price (USD): 3

Other features: Portable and reusable. Year of commercialization: 2010

Currently available in: 68 countries identified by UN as

focus countries relative to UN Millennium.

## Self-powered pulse oximeter

Country of origin | United Kingdom

#### Health problem addressed \_

10.8 million children die every year. 99% of these deaths are in developing countries and 2.7 million are due to congestive diseases that result in hypoxemia. Early detection of hypoxemia is essential in reducing mortality and morbidity. SPO2 monitoring facilitates this. SPO2 monitoring is also essential during anesthesia. It is called the 5th vital sign.

#### Product description \_

This pulse oximeter is a portable, easy to use monitor that measures blood oxygen saturation levels and the pulse rate. It is designed for use in low resource settings, is rugged and has its own on board human powered energy source.



#### Product functionality \_

The oximeter offers the highest quality pulse oximetry on the market. It analyses the entire plethysmographic wave form, locating the onset of a pulse and resulting in extreme pulse detection. It has excellent low perfusion and motioncompensating performance, warning the user and preventing inaccurate readings.

#### Developer's claims of product benefits \_

This is a monitor specifically designed for use in low resource settings or where electricity supply is a problem. The SPO2 monitor is rugged and reliable and has its own on-board power generator. Human energy is converted into electricity and saved in rechargeable batteries. The monitor gives 10-15 minutes of monitoring per minute of winding. The monitor may also be recharged using grid power when available. The pulse oximeter is designed to be compatible with a wide range of probes to take advantage of generic offerings when available. Unlike monitors designed for mainstream medical markets, it is very simple to use at low cost.

#### Operating steps \_

The SPO2 monitor is a solution to the problem of measuring blood oxygen saturation in developing world health environments. By turning the crank human energy is efficiently converted into electricity and stored in rechargeable batteries. Generic probes ranging from pediatric to adult provide accurate pulse and saturation levels.

#### Development stage \_

The pulse oximeter is currently available and in production. It is manufactured in India. Pilot field testing was carried out in South African secondary hospitals and its performance was congruent with "gold standard" high-end pulse oximeters.

Regulatory approval is completed.

#### Future work and challenges \_\_\_\_\_

Product is commercialized.

#### User and environment \_

User: Nurse, midwife, physician.

Training: None

Maintenance: Nurse, physician, technician

#### Environment of use \_

Setting: Rural. Ambulatory, primary (health post, health center), secondary (general hospital)

Requirements: none

#### Product specifications .

**Dimensions (mm):** 170 x 85 x 75

Weight (kg): 0.7 Consumables: None

Life time: 5 years Shelf life: 3 years List price (USD): 600

Other features: Portable and reusable. Runs on batteries.

Uses software.

Year of commercialization: 2011 Currently sold in: South Africa

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## Transcutaneous bilirubin measurement system for infants

Country of origin | United States of America

#### Health problem addressed \_

Hyperbilirubinaemia is a common condition in many newborns, affecting nearly 1 in 10 newborns and nearly 90% of premature infants in the first week of life. If undetected and untreated the levels of bilirubin may rise high enough to pass through the blood brain barrier and is deposited in the brain causing kernicterus and brain damage.

#### Product description \_

The device provides a numerical measurement of predicted bilirubin count in mg/dL or µmol/L within a clinically beneficial range that has been correlated with total serum bilirubin concentration measured by High Pressure Liquid Chromatography (HPLC).



#### Product functionality \_

The device works by directing white light into the skin of the newborn and measuring the intensity of the specific wavelengths that are returned. By knowing the spectral properties of the components within the skin, one can subtract out the interfering components and determine the concentration of bilirubin.

#### Developer's claims of product benefits \_

The technology of the device evaluates melanin, collagen, hemoglobin and bilirubin in a patient's subcutaneous tissues through a proprietary algorithm and optics system. Existing technologies measure the yellowness of the skin as it relates to jaundice.

#### Operating steps \_

Simple button push for calibration, place on infants head or sternum and press the measurement button 5 times in succession and the results appears on the screen. Test taken in minutes.

#### Development stage \_

This product has been sold globally since 2002. To date over 5000 units have been delivered to hospitals, clinics, physicians and community health workers.

Technical evaluation and health technology assessment review: FDA 510K # k010052.

Regulatory approval complete. Conformity assessment has been carried out (USA).

#### Future work and challenges \_

The product is not registered as a medical device in all countries. Depending on the country of use, the product may need to be registered before it is used.

#### User and environment \_

User: Nurse, midwife, physician

Training: Technique education on how to properly take a measurement.

Maintenance: Manufacturer

#### Environment of use \_\_\_\_\_

**Setting:** Rural and urban health care facilities.

Requirements: Power supply to charge the battery, disposal of calibration tip and cleansing products for pre-patient use.

#### Product specifications \_

**Dimensions (mm):** 2045 x 50.23 x 59.4

Weight (kg): 0.346

Consumables: Disposable calibration tip (per test)

Life time: 5 years Shelf life: 20 months Retail Price (USD): 3500 List price (USD): 4295

List price of consumables (USD): approx. 360 (bag of 50)

Other features: Portable and reusable. Runs on batteries and uses software.

**Year of commercialization:** 2009 (first version in 1996) Currently sold in: Most of Europe, as well as in Australia and several African, Asian, North- and South-American countries (65 countries)

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## Ventilator using continuous positive airway pressure

Country of origin | Vietnam

#### Health problem addressed

Every year hundreds of thousands babies die because of respiratory failure. Infant mortality could be reduced by application of CPAP — relatively simple therapy addressing 90% of cases. Diseases treated: pneumonia, apnea, hypoxia, and respiratory failure - main cause of infant mortality worldwide.

#### Product description .

CPAP is one of the methods used to support infants with respiratory distress and assist them in maintaining continuous positive airway pressure while breathing on their own. This solution is customized for the use in hospitals with basic infrastructure and limited resources. It is simple in use with only short training required.



#### Product functionality \_

CPAP provides mixed gas flows down the inspiratory limb to nasal cannula while expired gas returns via the expiratory limb to the pressure bottle. The medical staff is able to control appropriate mix of gases as well as desired temperature, humidity and flow.

#### Developer's claims of product benefits \_

The Complete CPAP system is designed to be used in the low resources settings. The only requirement is power supply and oxygen. The system provides its own air compressor, humidifier, oxygen and air blender, air heater. All the functions can be controlled by the user through simple interface requiring minimum training. The system is fully reusable and washable limiting the need for consumable parts to nasal connectors. It allows the user to keep running expenses at very low level keeping the treatment costs at less than a few dollars per patient.

#### Operating steps \_

Connect the system to oxygen and power source; Connect the tube circuit to the patient; Turn the system on, Set the desired oxygen concentration and flow rate; set the temperature and humidity.

#### Development stage .

The device is based on the concept of the CPAP technology developed by Colin Sullivan at Royal Prince Alfred Hospital, Australia, 1981. To this, the adaptation element to low resource settings was added. The system has been proven by extensive use in countries such as Vietnam, Laos, Cambodia and East Timor following initial studies at National Hospital of Pediatrics in Hanoi in 2006/2007. By now it is a national standard in countries mentioned above being used in over 200 public hospitals treating thousands of patients every year.

#### Future work and challenges

Due to a lack of funds in public healthcare barring commercial ventures, the strategy is to introduce the technology using charity money and leverage from such demonstration in the future. The biggest challenge is to convince local authorities to start spending public funds on such solutions which could make the whole system sustainable.

#### User and environment \_

User: Nurse, physician Training: CPAP set, 3 days

Maintenance: Nurse, physician, technician

#### Environment of use \_

Settings: Rural as well as urban secondary and tertiary health care facilities Requirements: Stable power supply, oxygen supply (wall, cylinder, concentrator)

#### Product specifications \_

**Dimensions (mm):** 330 x 330 x 1400 List price (USD): 2,300

Weight (kg): 15 Other features: Reusable. Uses software.

Consumables: None Year of commercialization: 2006

Life time: 5 years Currently sold in: Vietnam, Laos, Cambodia, East Timor

Retail Price (USD): 2,500

#### Water filter

Country of origin United States of America

#### Health problem addressed -

"Infectious diseases caused by pathogenic bacteria, viruses, protozoa and helminthes are the most common and widespread health risk associated with drinking water." (WHO, 2004). In Ghana where the ceramic pot filter is made, 50% of people lack access to improved water supply. Ghana has the 4th lowest worldwide rate of sanitation coverage.

#### Product description \_

The filter unit consists of a fired clay pot filter element, a plastic bucket storage unit, a "ring lid" to support the ceramic pot, a tap and a cover lid. These filters are made from red clay and wood saw-dust or rice-husk which gets mixed, pressed in mold and fired in a kiln.



#### Product functionality \_

Particles, bacteria, guinea worm cyclops and protozoa are removed by physical straining, and also by the mechanisms of sedimentation, adsorption, diffusion, inertia, and turbulence. The filter element is treated with colloidal silver which may act as a bactericide and viricide.

#### Developer's claims of product benefits \_\_

The ceramic pot filter, made of terracotta clay, can be produced in most countries around the world because of the simple component parts and the universality of clay and combustible material inputs. Moreover, there is the potential to create local, self-sustaining businesses from this endeavor.

#### Operating steps \_

1. Settle turbid water in a storage vessel before filling the ceramic pot; 2. Keep the ceramic pot filled to the top. This will improve filtration rate; 3. Clean filter with brush provided when flow rate becomes too slow; 4. Clean storage unit with soap and filtered water if necessary. Disinfect with chlorine bleach, iodine or boiling water.

#### Development stage

The product is being manufactured in >20 countries. In Ghana, in 2007, it has been approved by UNICEF and the government for emergency distribution during a flood emergency. In 2008, it was approved for emergency distribution during a guinea worm outbreak. The product is being locally manufactured and sold in the region with the highest rates of diarrhea in Ghana. The technology has become known through efforts of several international aid organizations and the work of several renowned academic institutions.

#### Future work and challenges

In Ghana, the current challenge is to build a self-sustaining enterprise. This effort has taken 6 years, and there are still struggles to reach those who lack improved water at an affordable price. Willingness to pay ranges from \$2 - \$15, but the product price is \$25. Moreover, emergency distribution of the product is free, which distorts the market further, even while making the product familiar to a wider customer base. There is a need for a reliable stream of buyers, support for technical training, human resources and financial management and support for further R&D to improve the product.

#### User and environment \_

User: Self-user, family member

Training: Each filter comes with an educational sticker. Hands-on demonstration training takes 1 hour in groups.

Maintenance: Self-user

#### Environment of use \_

Requirements: This filter removes microbes from unclean water. It does not require any power supply, internet, cell phone, etc. . There is no specialized personnel needed to operate the filter.

#### Product specifications \_

Dimensions (mm): 500 x 42 (diameter)

Weight (kg): 7

**Consumables:** The ceramic pot filter element needs

replacement after 2-3 years.

Life time: 3 years Retail Price (USD): 25 List price of consumables (USD): 8 (to replace the pot element after three years)

Other features: Portable and reusable.

Currently sold in: The filter is commercialized in certain countries (Guatemala, Cambodia, and largely promoted

by NGOs in other countries)

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# eHealth solutions

2011

## Medical data communication system

Country of origin | United States of America

#### Health problem addressed \_

Access to medical opinion by cardiovascular specialists can be difficult to obtain in rural or poor areas. As a result, medical data obtained at the point of care such as EKG's, medical images, lab results or any other type of information cannot be adequately reviewed by the required clinicians and appropriate treatment cannot be prescribed.

#### Product description \_

The medical communication system is a technology that allows any type of medical data to be transmitted from the point of care to the desired specialist(s). The data is transmitted securely and rapidly for delivery to mobile devices or computers so that physician's can review the data and provide opinions.



#### Product functionality \_\_\_

The system is a proprietary push delivery and review platform allowing remote review using the internet and cell phone network of EKG's/medical images. Medical data is recorded at the point of care and then uploaded to the system's server from which it is then delivered to a physician's smartphone or PC. The transaction is fully traceable and secure.

#### Developer's claims of product benefits.

Current practice includes mailing video tapes, DVD's or faxing data to desired physician. These methods suffer from systematic insufficiencies and are slow and non-traceable. Instead, this system offers a technically sound and more accessible solution. Given the prevalence of cell phone networks and the internet it is easily reachable.

#### Operating steps \_

Data is acquired at the point of care and uploaded to a secure server. Physician reviews data and has the option to respond back to the point of care or forward to a colleague. Physician can review data on their smartphone or PC as convenient.

#### Development stage \_

Has been in technically evaluated. Has been in production for over two years. System is classified as a hospital IT product. System conforms to DICOM standards.

#### Future work and challenges \_\_\_

Product is commercialized.

#### User and environment \_

User: Nurse, physician, technician.

Training: Web based and/or self training CD. Maintenance: Technician, engineer, manufacturer.

#### Environment of use \_

Requirements: Sending side: EKG and/or imaging systems and connectivity to internet/ phone line, connection to a

Receiving side: access to cell phone network on a smartphone and/or access to internet and PC.

#### Product specifications \_\_\_\_\_

Dimensions (mm): N/A

Weight (kg): N/A

Consumables: none.

Retail Price (USD): Base \$50,000 (depends on

configuration) + customization and other charges may

apply.

Other features: Portable and reusable. Uses software.

Telemedicine system.

Year of commercialization: 2009

**Currently sold in: USA** 

## Mobile technology to connect patients to remote doctors

Country of origin United States of America

#### Health problem addressed \_

The bottom of the pyramid population in the developing world continues to face fundamental challenges in healthcare, due to lack of access, low affordability, low quality and exploitative care, and a reactive, emergency-driven system. Existing solutions lack financial and human resources and show sub-optimal use of limited resources.

#### Product description.

This product is an Integrated Mobile Health Technology Platform that enables frontline health providers (community health workers, rural nurses and doctors) to connect patients to remote doctors in order to obtain timely medical diagnosis and administer effective treatment for underserved patients. Selected awards: Winner at the 2008 MIT 100K Entrepreneurship Competition and Best Telemedicine Innovation at the 2009 World Health Care Congress.

#### Product functionality.

Frontline health providers use the mobile application to perform health risk screening and medical triage to identify health concerns. The diagnostics application on the phone instructs health providers with immediate actions to care for the patient, or transmits the case to remote doctors for further diagnosis and treatment advice.

#### Developer's claims of product benefits.

This solution is cost-effective as it requires no additional equipment or infrastructure by using available mobile phones, mobile connectivity and local health providers. Training for local health providers takes less than an hour because all users are already familiar with the use of mobile phones. Maintenance is minimal as local phone stores are capable of maintaining the mobile devices. The service reduces travel costs, minimizes time to obtain treatment (from weeks to minutes), and is accessible locally to underserved patients via health workers or close-by rural clinics.

#### Operating steps.

Frontline health providers use mobile phones to access the diagnostics application. They enter patient symptoms information by going through a series of decision-tree based medical algorithm. For cases requiring remote doctor consultation, the phone transmits the patient symptoms information via mobile broadband or SMS/MMS to the remote doctor.

#### Development stage.

The product was technically evaluated and tested for clinical effectiveness via concordance rates between in-person and mobile-transmitted remote diagnosis in Egypt, Ghana, Botswana, the US. We pursue various partnerships. Partners include mHealth Alliance, BRAC, Sajida Foundation, Mobinil Egypt, Orange Botswana, University of Pennsylvania Medical School, Harvard, MIT, American Academy of Dermatology.

#### Future work and challenges

These applications and corresponding business models were tested through pilots in over 10 countries. The basic technology proposition was proven and patient acceptability demonstrated. Commercial scalability is now ready to be tested by 1) improving the technology platform to support large scale usage from current ~500,000 beneficiaries to >1 million, 2) expanding distribution channels, 3) refining service models to suit our markets.

#### User and environment \_

User: Patient, family member, nurse, midwife, physician Training: 30-60 min walk-through of the mobile application

Maintenance: Technician, engineer, manufacturer

#### Environment of use

Requirements: Mobile connectivity, access to a power source to charge mobile phones.

#### Product specifications.

**Dimensions (mm):** 110 x 47 x 14 (approx.) Retail Price (USD): Varies

Weight (kg): 0.008 Year of commercialization: 2009

Life time: Varies by phone model Currently sold in: US, Botswana, Bangladesh

## Treatment response software application

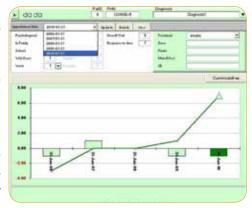
Country of origin | Canada

#### Health problem addressed\_

Tracking patient response to specific treatments other than measurable physiological changes (laboratory test results), survival or death remain a matter of clinical judgment. Diagnostic validity and reliability is an ongoing problem in applying evidence-based practice. The system application presented here provides a gold RCT standard to this problem.

#### Product description \_

This application may be used to track and graphically represent individual patient responses to treatments over time. Additionally, patients may be assigned to up to four specific treatment groups (RCT) to compare treatments. Students can compare the diagnostic accuracy of their assessments and interventions with experts.



#### Product functionality \_

Download and open - this is an Excel/VBA based application. It may be used to track and represent individual patient responses to treatments over time. Additionally, patients may be assigned to specific treatment groups. User defined variables representing treatment and response parameters may be defined across clinically relevant domains.

#### Developer's claims of product benefits.

The application is intended to support physicians or nurses in tracking patients responses to treatment. It will permit outcome measurement for any treatment for any disease or health concern. The application and manual are available free of charge.

#### Operating steps \_

This is a Microsoft Excel software program that is user completed.

#### Development stage \_

The current program is complete and self-contained.

Regulatory approval status of the product is completed. Conformity assessment has been carried out in Canada.

#### Future work and challenges \_

Since posted on the web approximately 1000 individuals have either visited or downloaded the application. Future versions will have more robust operability (e.g. automated amalgamation of data from individual cases).

#### User and environment \_

User: Nurse, midwife, physician

**Training:** Manual – 1 hour **Maintenance:** None

#### Environment of use .

**Requirements:** A compatible computer is required. Visual Basic for Applications, Microsoft Excel 11.0 Object Library, OLE Automation, Microsoft Office 11.0 Object Library, Microsoft Forms 2.0 Object Library, Microsoft Calendar Control 11.0.

#### Product specifications \_

Consumables: None Year of commercialization: 2010

Retail Price (USD): 0 Currently sold in: Available for all

List price (USD): 0

# Appendix

## **Appendix**

All submissions to the call for innovative health technologies for low-resource settings underwent an evaluation process. The technologies were reviewed by WHO, WHO collaborating centres, members of EUROSCAN and other relevant stakeholders. However, no in-depth assessments of the technologies were performed, and no prequalification process was done. The evaluation relied solely on the material and evidence provided by the applicant as well as publicly available information that served to analyze the potential of the technology to improve health outcome in low-resource regions.

eading about technologies and respective health problems; refer to references provided in the submission documents.

For to	For further reading about technologies and respective health problems: refer to references provided in the submission documents				
Pg	Name	Regulatory	References		
2	Auto stop elecrochlorina- tor	Conforms to US EPA guide standard and protocol for microbiological water purifiers, as tested in- house.	<ul> <li>Arnold BF, Colford JM Jr. Treating water with chlorine at point-of-use to improve water quality and reduce child diarrhea in developing countries: a systematic review and meta-analysis. Am J Trop Med Hyg February 2007 vol. 76 no. 2 354-364</li> </ul>		
3	Automated solar-powered blood pressure monitor	The product is approved as medical equipment in Japan, Europe and the US based on respective regulatory system	Gianfranco Parati, Eoin O'Brien, et al. A New Solar-Powered Blood Pressure Measuring Device for Low-Resource Settings. Hypertension Nov. 8, 2010		
4	Birthing simulator for training		<ul> <li>Hofmeyr GJ, Haws RA, Bergström S, Lee ACC, Okong P, Darmstadt GL, Mullany LC, Oo EKS, Lawn JE. Obstetric care in low-resource settings: What, who, and how to overcome challenges to scale up? IJGO 2009;107:s21-s45.</li> <li>The portable Glostavent: a new anaesthetic machine for use in difficult situations. R Tully, R Eltringham, IA Walker, AJ Bartlett. Anaesthesia and Intensive Care, 2010, 38(6): 1085-9</li> <li>The Diamedica Draw-Over Vaporizer: a comparison of a new vaporizer with the Oxford Minature Vaporizer. WA English, R Tully, GD Muller &amp; RJJ Eltringham. Anaesthesia 2009, 64: 84-92.</li> <li>Modification of a draw over vaporizer for use with sevoflurane. T Payne, R. Neighbour &amp; R.Eltringham. British Journal of Anaesthesia 2012, 108(5):763-72012</li> <li>http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(10)60518-1/abstract</li> </ul>		
5	Interventional cardiovascular lab	CE marked product. Compliance to European Medical Directive Directive MDD/93/42 EEC. Manufacturing facility is ISO 13485 certified.	http://www.who.int/mediacentre/factsheets/fs317/en/		
6	Intramedullary nail and interlocking screw system	FDA cleared for use in the USA, Regulation Number 888.3020.	<ul> <li>WHO Global Status Report on Road Safety, 2009,</li> <li>WHO Global Burden of Disease Study, 2004.</li> <li>Ikem IC, Ogunlusi JD, Ine HR. Achieving interlocking nails without using an image intensifier. SICOT 2007 31:487-490.</li> <li>Calafi LA, Antkowiak T, Curtiss S, et al. A biomechanical comparison of the Surgical Implant Generation Network (SIGN) tibial nail with the standard hollow nail. Injury 41 (2010) 753-757.</li> <li>Young S, Lie SA, Hallan G, Zirkle LG, et al. Low infection rates after 34,361 intramedullary nail operations in 55 low-and middle-income countries. Acta Orthopaedica 2011; 82(6) 727-743.</li> <li>Sekimpi P, Okike K, Zirkle L, Jawa A. Femoral fracture fixation in developing countries: an evaluation of the Surgical Implant Generation Network (SIGN) intramedullary nail. J Bone Joint Surg Am. 2011 Oct; 93(19):1811-8.</li> </ul>		
8	Mobile ECG with web-basd telemedicine platform	Certified for CE - 1293			
9	Multi-parameter remote diagnostic kit	IEC60601-1 compliance completed, ISO13485 manufacturing process compliance. CE marking process underway.			
10	Neonatal warm sleeping bag	Our internal processes are ISO 13485 certified and we are on track to file for CE certification in June 2012	http://www.unicef.org/publications/index_24840.html		

Pg	Name	Regulatory	References		
11	Non-invasive hypothermia indicator for newborns	CE No: 0434	<ul> <li>Green.D.A, Kumar.A,Khanna.R. Neonatal hypothermia detection by ThermoSpot in Indian urban slum dwellings. Arch Dis Child Fetal Neonatal Ed 2006;91:f96-F9 doi;10.1136/adc.2005.078410</li> <li>http://www.who.int/reproductivehealth/publications/maternal_perinatal_health/MSM_97_2/en/index.html ("Thermal protection of a newborn")</li> </ul>		
12	Non-invasive vascular age risk prediction		<ul> <li>Yusuf, S, Reddy, S, Ounpuu, S &amp; Anand, S. 2001. Global burden of cardiovascular diseases: Part 1: General considerations, the epidemiologic transition, risk factors and impact of urbanization. Circulation, 104(22):2746-53.</li> <li>Vintro, IB. 2004. Control and prevention of cardiovascular disease around the world (Editorials). Rev Esp Cardiol, 57(6):487-94.</li> <li>Yusuf, S, Hawken, S, Ôunpuu, S, et al. 2004. Effect of potentially modifiable risk factors associated with myocardial infarction in 52 countries (the INTERHEART Study): Case-control study. Lancet, 364(9438):937-52.</li> <li>Allen, J. &amp; Murray, A. 2000a. Similarity in bilateral photoplethysmographic peripheral pulse wave characteristics at the ears, thumbs and toes. Physiological Measurement 21:369-377.</li> <li>Bots ML., Carotid intima-media thickness as a surrogate marker for cardiovascular disease in intervention studies. Curr Med Res Opin. 2006 Nov;22(11):2181-90.</li> <li>Bots ML, Dijk JM, Oren A, Grobbee DE.Carotid intima-media thickness, arterial stiffness and risk of cardiovascular disease: current evidence. J Hypertens. 2002 Dec;20(12):2317-25.</li> <li>Allen, J., Photoplethysmography and its application in clinical physiological measurement. Physiol. Meas. 2007, 28 R1</li> <li>Zahedi E., Chellappan K., Mohd Ali M.A. &amp; Singh H. Analysis of the Effect of Ageing on Rising Edge Characteristics of the Photoplethysmogram using a Modified Windkessel Model. Cardiovascular Engineering. 2007. 7(4):172-181.</li> </ul>		
13	Non-surgical male circumcision device	FDA cleared (K103695) Certified CE Mark Class IIa Compliant to ISO 13485 Medical Devices (Quality Management systems) and FDA, 21 CFR177. 2600.	<ul> <li>Auvert B, Taljaard D, Lagarde E, Sobngwi- Tambekou J, Sitta R, Puren A. — Randomized, controlled intervention trial of male circumcision for reduction of HIV infection, risk: the ANRS 1265 Trial. PLoS Med. 2005 Nov;2(11):e298. Erratum in: PLoS Med. 2006 May;3(5):e298.</li> <li>Bailey RC, Moses S, Parker CB, et al. —Male circumcision for HIV prevention in young men in Kisumu, Kenya: a randomised controlled trial. Lancet. 2007 Feb 24;369(9562):643-56.</li> <li>Gray RH, Kigozi G, Serwadda D, et al. —Male circumcision for HIV prevention in men in Rakai, Uganda: a randomised trial.  Lancet. 2007 Feb 24;369(9562):657-66.</li> <li>World Health Organization. —Progress in scale-up of male circumcision for HIV prevention in Eastern and Southern Africa: Focus on service delivery.   2011. Accessed online 2/3/2012: http://whqlibdoc.who.int/publications/2011/9789241502511_eng.pdf</li> <li>Bitega, Jean. —Safety and Efficacy of the PrePex Device for Rapid Scale-Up of Male Circumcision for HIV Prevention in Resource-Limited Settings.   JAIDS Journal of Acquired Immune Deficiency Syndromes: 15 December 2011 - Volume 58 - Issue 5 - p e127-e134. Accessed online 2/4/2012: http://journals.lww.com/jaids/Fulltext/2011/12150/Safety_and_Efficacy_of_the_PrePex_Device_for_Rapid.16.aspx</li> </ul>		
14	Oral syringe dosing clip		<ul> <li>Yin HS, Dreyer BP, Van Schaick L, Foltin GL, Dinglas C, Mendelsohn AL. Randomized controlled trial of a pictogram-based intervention to reduce liquid medication dosing errors and improve adherence among caregivers of young children. Arch Pediatr Adolesc Med. 2008; 162(9):814–822.</li> <li>Yin HS, Wolf MS, Dreyer BP, Sanders LM, Parker RM. Evaluation of consistency in dosing directions and measuring devices for pediatric nonprescription liquid medications. JAMA. 2010;304(23)(doi:10.1001/jama/2012.1797)</li> </ul>		
15	Point of care diagnostic device for total WBC	Medical products Agency, FDA 510(k) Clearance Ref 7 Certificate of Registration (LV) Ref 8 k 053253	<ul> <li>Point-of care method for total white blood count; An evaluation fo the Hemocue WBC device A Osei Bimpong, C Jury R McLean, S.M Lewis Int Jnl. Lab.Hem 2009 31 657-664</li> <li>A Comparison of 2 White Blood Cell Count Devices to Aid Judicious Antibiotic Prescribing, Janet R. Casey and Michael E. Pichichero Clin Pediatr (Phila) 2009; 48; 29</li> </ul>		
17	Solar charger for hearing aid		World Health Organization, 2001, Guidelines for Hearing Aids and Services		
18	Sputum mobilization device	USFDA 501(k): K091557, K060439; Class I CE mark	Novel method for sputum induction using the Lung Flute in patients with suspected pulmonary tuberculosis Fujita et al, Respirology, 2009		
19	Urine albumin test	CLIA waiver certificate Ref 7 k530253 -A002 Medical products Agency, FDA 510(k) Clearance Ref 9 Certificate of Registration (LV) Ref 10 k 053253	<ul> <li>Sarafidis PA, Riehle J, Bogojevic Z, Basta E, Chugh A, Bakris GL. A comparative evaluation of various methods for microalbuminuria screening. Am J Nephrol. 2008;28(2):324-9. Epub 2007 Nov 29.</li> </ul>		

For further reading about technologies and respective health problems: refer to references provided in the submission documents.

Pg	Name	Regulatory	References	
42	Isothermal nucleic acid amplification system for POPC diagnosis	CE Mark Our current manufacturing facility (capable of 1 million tests per year) has been approved by TUV for ISO 9001 and ISO 13485, and our TB tests are CE qualified	<ul> <li>Neglected diagnostics", Nature Methods - 4, 877 - 878 (2007).</li> <li>Reference(s): Fang, R., Li, X., Hu, L., You, Q., Li, J., Wu, J., Xu, P., Zhong, H., Luo, Y., Mei, J. et al. (2009) Cross-priming amplification for rapid detection of Mycobacterium tuberculosis in sputum specimens. J Clin Microbiol, 47, 845-847.</li> </ul>	
43	Manual wheelchairs and mobility devices	ISO standard 7176, including fire retardant foam and fabric and is ISO 9001 (2008- 2013) and ISO 13845 (2008- 2013) certified	WHO Guidelines on the provision of Manual Wheelchairs in less resourced settings.	
44	Newborn simulator for resuscitation training		<ul> <li>Lawn, J.E, Lee, A.C, Kinney, M., Sibley, L., Carlo, W.A., Paul, V.K., Pattinson, R., Darmstadt, G.L. Two million intrapartum-related stillbirths and neonatal deaths: Where, why, and what can be done? IJGO 2009; 107: s5-19.</li> <li>Stephen N. Wall, Anne CC Lee, Susan Niermeyer, Mike English, William J. Keenan, Wally Carlo, Zulfiqar A. Bhutta, Abhay Bang, Indira Narayanan, Iwan Ariawan, Joy E. Lawn. (2009). Neonatal resuscitation in low-resource settings: What, who, and how to overcome challenges to scale up? IJGO 2009; 107: s47-64.</li> </ul>	
45	Non-pneumatic anti-shock garment		<ul> <li>World Health Organization (WHO) Department of Reproductive Health and Research. Maternal Mortality in 2000: Estimates Developed by WHO, UNICEF, and UNFPA. Geneva: WHO; 2004.</li> <li>Hensleigh PA. Antishock garment provides resuscitation and haemostasis for obstetric haemorrhage. BJOG. December 2002;109:1377-1384.</li> <li>Miller S, Ojengbede A, Turan J, Ojengbede O, Butrick E, Hensleigh P. Antishock garments for obstetric hemorrhage. Current Women's Health Reviews, 2007; 3:3-11.</li> <li>Miller S, Martin HB, Morris JL. Antishock garment in postpartum haemorrhage. Best Practice &amp; Research Clinical Obstetrics and Gynaecology. 2008; 22(6):1057-1074.</li> </ul>	
46	Oxytocin in prefilled auto-disable injection system		Tsu VD, Sutanto A, Vaidya K, Coffey P, Widjaya A. Oxytocin in prefilled Uniject injection devices for managing third-stage labor in Indonesia. International Journal of Gynaecology and Obstetrics. 2003;83(1):103-111.	
47	Parasitological test system	ISO 9001-2008 / ISO 13485-2003 CE mark / FDA		
48	Phototherapy for neonatal jaundice treatment	CE mark	<ul> <li>Martins BM, de Carvalho M, Moreira ME, Lopes JM. Efficacy of new microproces phototherapy system with five high intensity light emitting diodes (Super LED) Pediatr (Rio J). 2007;83(3):253-258.</li> </ul>	
49	Point-of- Use water disinfection system	A cluster randomized control trial was carried out by UC Berkeley in 2009-2010 in 450 households using the UV Tube. The results are expected to be published in 2011 or 2012	<ul> <li>WHO. Diarrhoeal disease. Programmes and projects. Media center. Fact sheets. Vo 2010, 2009.</li> <li>Brownell, Sarah A., Alicia R. Chakrabarti, Forest M. Kaser, Fermin Reygadas, Micah J. Lang, Lloyd G. Connelly, Rachel L. Peletz, Daniel M. Kammen, and Kara L. Nelsor 2008. Assessment of a low-cost, point-of-use, ultraviolet water disinfection technology. Journal of Water and Health 6, no. 1 (3): 53.</li> </ul>	
50	Portable haemoglobin meter	BPF ANVISA / Brazil registration number: 80431950001 (http:// www.anvisa.gov.br/ datavisa/Consulta_ Produto_correlato/ rconsulta_produto_ detalhe.asp)	<ul> <li>Stoltzfus R.J. J. Defining Iron-Deficiency Anemia in Public Health Terms: A Time for Reflection. J. Nutr. 131: 565S-567S, 2001.</li> <li>Juliana, C.T et al. Prevalence of anemia among preschoolers and response to iron supplementation. Jornal de Pediatria, vol 87(1), 2011.</li> </ul>	

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51	Portable ventilator	IEC 60601-1 Medical electrical equipment,Part 1: General requirements for safety IEC 60601-1-2 General requirements for safety - collateral standard Electromagnetic compatibility- requirements and tests IEC 60601-2-12 Medical electrical equipment Part 2-12: Particular requirements for the safety of lung ventilators -Critical Care ventilator	
52	Prefilled auto-disable injection system		<ul> <li>Tsu VD, Sutanto A, Vaidya K, et al. Oxytocin in prefilled Uniject injection devices for managing third-stage labor in Indonesia. International Journal of Gynaecology and Obstetrics. 2003;83(1):103-111.</li> <li>Bahamondes L, Marchi NM, Nakagave HM, et al. Self-administration with Uniject of the once-a-month injectable contraceptive Cyclofem. Contraception. 1997;56:310-304.</li> <li>Otto B, Suarnawa IM, Stewart T, et al. At-birth immunisation against hepatitis B using a novel pre-filled immunisation device stored outside the cold chain. Vaccine. 2000;18:498-502.</li> <li>Sutanto A, Suarnawa IM, Nelson CM, et al. Home delivery of heat-stable vaccines in Indonesia: outreach immunization with a prefilled, single-use injection device. Bulletin of the World Health Organization. 1999;77(2):119-126.</li> </ul>
53	Reusable neonatal suction device	The Product is FDA device listed and CE-marked. The product has been developed in accordance with ISO 9001 and ISO 13485	<ul> <li>Lawn, J.E, Lee, A.C, Kinney, M., Sibley, L., Carlo, W.A., Paul, V.K., Pattinson, R., Darmstadt, G.L. Two million intrapartum-related stillbirths and neonatal deaths: Where, why, and what can be done? IJGO 2009; 107: s5-19.</li> <li>WHO, Managing Newborn Problems: A guide for doctors, nurses, and midwives. WHO, Geneva, 2003.</li> <li>Stephen N. Wall , Anne CC Lee, Susan Niermeyer, Mike English , William J. Keenan , Wally Carlo, Zulfiqar A. Bhutta , Abhay Bang , Indira Narayanan, Iwan Ariawan, Joy E. Lawn. (2009). Neonatal resuscitation in low-resource settings: What, who, and how to overcome challenges to scale up? IJGO 2009; 107: s47-64.</li> </ul>
55	Transcutaneous bilirubin measurement system for infants	FDA 510K # k010052	
56	Water filter		<ul> <li>WHO, Guidelines for Drinking Water Quality, 3rd Ed. 2004. http://www.who.int/water_sanitation_health/dwq/GDWQ2004web.pdf</li> </ul>



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2011-2012

ISBN 978 92 4 150591 8

