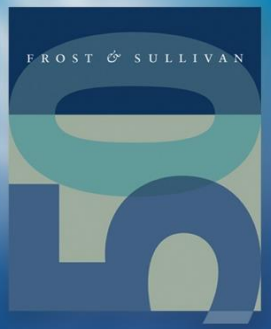
Frugal Innovations in Medical Device Industry – Medical Device TechVision Opportunity Engine (TOE)

Identifying Low-cost Medical Device Innovations Transforming Patient Care



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Contents

Frugal Innovations in Medical Device Industry

Cost-effective Phototherapy Device for Treatment of Neonatal Jaundice

Little Sparrows Technologies, Boston, MA, US

Problem Statement

One of the most common medical conditions in new born babies is neonatal jaundice. Around 60% of newborns over the world develop jaundice in the first week of their lives.
Timely diagnosis and treatment (usually with phototherapy) is extremely crucial for recovery.

However, more than 40% of the world's infants (6 million new born), especially those in economically weak nations, do not have access to proper treatment. This is due to high equipment costs. Currently, neonatal jaundice is responsible for 30% of newborn mortality in underdeveloped areas.

Other than high cost, there is also another challenge of continuously powering the phototherapy device which is a problem in areas with power outages and voltage fluctuations.

Innovation Attributes

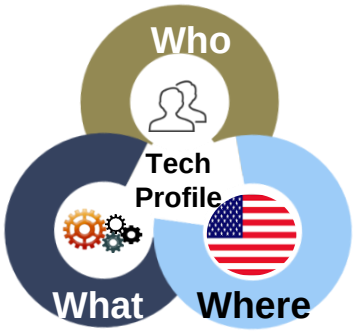
Miniaturization: Unlike commercial phototherapy devices that are large, and heavy, Bili-Hut is a small, light weight, and portable device.

Design: The light array is arranged in a radial pattern on a reflective surface. This increases light delivery and exposure to the skin.

Energy Efficient: It doesn't require a continuous power line. It is battery operated and uses low-energy consuming LED (light-emitting diode) lights.

Clinically Effective: The device complies with recommendations of the American Academy of Pediatrics for delivering high-intensity phototherapy, treatment

Tech Profile



- Understanding the industry's needs, Little Sparrows Technologies (LST) has developed an affordable, battery-operated neonatal phototherapy device called the Bili-Hut.
- This device will be of utmost importance in economically weak nations with low resources.

Future Scope

- Bili Hut costs a fraction of commercial phototherapy devices, making it highly accessible to poor regions, where it is difficult to afford phototherapy for neonatal jaundice.
- Currently, a Bili Hut prototype is being evaluated for use in remote communities in India. With ongoing research and feedback, the device is continuously being improved.

Heparin-based Microfilter for Blood Transfusion

ExThera Medical, US

Market Trends and Demands

Bacteremia is one among the top seven causes of death, with an annual incidence of an estimated 677,000 cases in North America and over 1.2 million cases in Europe.

Staphylococcus aureus and Enterobacteriaceae are among the common bacterial strains responsible for causing bacteremia or other nosocomial infections, the severity of which depends on bacterial load and duration.

In terms of high risk groups, patients undergoing dialysis are under increasing risk of developing bloodstream infections and Staphylococcus aureus is found to be the leading cause of bloodstream infections.

Innovation Attributes

Design: Microbind Affinity Blood Filter is designed as a single-use cartridge that is filled with proprietary microsphere coated with a molecular receptor, heparin.

Functionality: The microspheres mimic the body's natural receptors within human cells, which are used by pathogens to invade the human body.

Filtration: The microspheres within the filter bed attract the pathogens, which then bind to the surface of the filter, thereby removing them from attaching to the bloodstream.

Technology Profile

Who: A California-based company, ExThera Medical has designed a device that can be used to treat patients with existing infections within their bloodstreams and purify the banked blood, thus preventing disease transmission during the process of transfusion.

Advantages

Seraph is designed to offer the highest treatment efficiency, as it operates at blood flow rates of up to 300 mL/minute.

Seraph's blood-contacting surface is both anti-thrombogenic and anti-inflammatory, making it ideal for use along with existing medical devices and implants.

The device uses immobilized heparin, which is ideal for use in blood transfusion, as it prevents the risk of heparin-induced thrombocytopenia and hemorrhage.

Future Developments

Clinical impact of the patented Seraph device to remove virus, bacteria, toxins and other parasites from whole blood are being investigated by ExThera Medical.

Low-cost HIV and Syphilis Screening
Columbia University, NY, US

Industry Needs

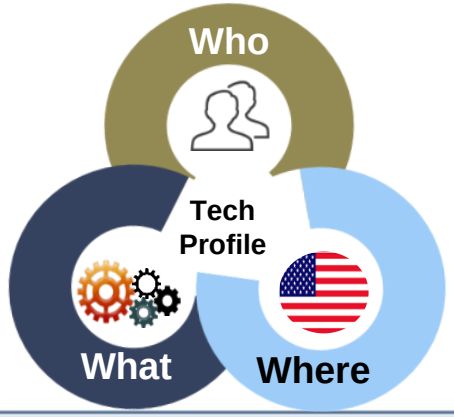
According to the World Health Organization (WHO)'s 2014 statistics, 36.9 million people are living with HIV/AIDS worldwide. In 2014 alone, 1.2 million people died of AIDS-related illnesses. The WHO also estimates that there are 10.6 million cases of syphilis around the world.

Due to a weak surveillance system and low awareness, specially in emerging economies, the prevalence and incidence of these sexually transmitted diseases continues to rise.

Cheap and rapid diagnostics, specially in developing nations, can help control the disease burden to some extent.

Tech Profile

COLUMBIA | ENGINEERING
The Fu Foundation School of Engineering and Applied Science



Researchers from the Columbia University have developed a low-cost, rapid diagnostic device, which when attached to a smart phone can screen for fatal infectious diseases, HIV, and syphilis. This can help reduce the infection and the transmission rate.

Innovation Attributes

Faster: The test can give results in just 15 minutes, which is 10 times quicker than normal laboratory tests.

Cost-Effective: The diagnostic device is priced at $34, while lab-based diagnostic equipment costs around $15,000

Miniaturized: Laboratory-scale tests for HIV and syphilis have been packed into a device of the size of a dongle.

Accessible
It is a point-of-care diagnostics for infectious diseases and is extremely helpful in remote areas where visiting a doctor or pathological labs may not be feasible. A smartphone is used as power source and its screen is used for result display. The device performs Enzyme-linked Immunosorbent Assay (ELISA) without requiring any stored energy.

Clinical Efficacy

- In a pilot study in Rwanda, the device when tested for HIV and syphilis, correctly identified HIV and syphilis infections with an accuracy of 92% to 100% and specificity of 79% to 100%.
- This test is highly acceptable due to its user-friendliness and fast turn-around time.
- This diagnostic device may be helpful for scaling up HIV testing at the community level and stop disease transmissions.

Freeze-dried Paper-based Test for Zika Virus

University of Toronto, Canada

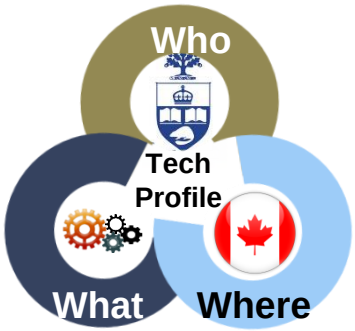
Problem Statement

The widespread epidemic of viral fever due to Zika virus is ongoing in both the Americas and the Pacific as of mid-2016, the outbreak of which began in Brazil and other parts of South America as early as 2015.

Spread by the bite of an infected Aedes mosquito, Zika fever is characterized by symptoms such as fever, rash, joint pain, and conjunctivitis.

Scientific studies indicate the incidence of microcephaly and other birth defects during pregnancy, thus creating a demand for rapid diagnosis of the Zika virus.

Tech Profile



A team of researchers from the University of Toronto in Canada has employed the use of toehold switch RNA sensors and isothermal RNA amplification to create diagnostic sensors on a freeze-dried piece of paper, which is designed to be the size of a stamp.

Innovation Attributes

The detection device is portable, reliable, and inexpensive and is poised to achieve a scale that would reduce test cost to as low as US$1.

The new technique does not require any specific expertise or training for detection of the Zika virus and is designed to provide results in less than an hour.

The deployment of a free-dried biomolecular platform helps address some of the practical limitations of using molecular diagnostics.

The diagnostic sensor is designed to discriminate among viral strains with a single-base resolution, especially when coupled with a novel CRISPR/Cas9-based module. The test area turns purple when the sample contains the RNA of the Zika virus.

The sample activates the diagnostic sensors to measure concentrations of Zika virus sequences, demonstrating specificity against closely related sequences of the Dengue virus.

Future Scope

- A proof-of-concept was published in the journal 'Cell'.
- The team is seeking to partner with commercial organizations for product development and to scale up manufacturing and distribution of its rapid portable diagnostic tests.

Affordable and Effective Infant Warmer

GE Healthcare, Little Chalfont, UK

Problem Statements

- New born babies and infants are often kept in a warm and comforting environment, helping them adjust to room temperature.
- In emerging economies, not only the cost of the device but other factors such as power outages, voltage fluctuations, and high levels of dust and pollution leading to intensive equipment use can make the usage of a baby warmer extremely costly and difficult.

Technology Profile

GE Healthcare

Understanding the needs of emerging economies, GE healthcare has developed the Lullaby baby warmer which caters to clinical and economic demands of emerging nations.

Economic Benefits

The Lullaby warmer by GE is affordable and less costly than its counterparts. It helps in cost savings of up to one lakh Indian rupees ($1,500).

On start-up, the lullaby warmer uses 60% less power. Also, 20% less power is consumed when it runs for over 24 hours.

The Calrod heater used in the warmer has lifetime warranty, thereby, eliminating any replacement costs. Its lower wattage consumption and rugged probes are associated with lower failure rates.

Innovation Attributes

Innovative: It uses the microprocessor technology and has built-in monitors to observe the baby's pulse and weight. The novel guard probe is prevented from getting detached from the baby, avoiding the risk of baby not being monitored.

Ease of Use: Color-coded, easy to read, safety alarms and control panel are well placed for easy usage

Safety: The lullaby baby warmer is enabled with a "check baby" alarm. The alarm rings if the baby's skin temperature deviates by 1 degree C from the set point. This automatically controls the temperature of the warmer.

Efficacy: Lullaby baby warms 69% faster, spreads heat uniformly, and no heat escapes from above the walls of the warmer, increasing its efficiency, and keeping the temperature stable.

Smartphone-enabled Urine Dipstick Test
Stanford University, US

Problem Statements

Using a simple color-changing paper test for analyzing urine samples consumes more time, is expensive, and often creates backlogs for clinics and primary care physicians.

Do-It-Yourself (DIY) dipstick studies often necessitate proper control of sample volume, timing, and interpretation of results.

Technology Profile

Who: A team of researchers from the Department of Electrical Engineering at the Stanford University (US).

What: The researchers have created new low-cost, portable device for accurate analysis of urine samples in a home environment. The dipstick study, carried out through the use of a customized software, enables high precision in analysis.

Innovation Attributes

Precision: Each layer fills up appropriate channels and leads.

Multi-layered Analysis: It is a multi-layered system into which urine is loaded with the help of a dropper. The urine sample is placed using a dropper on the first layer.

Reusability: Reusable all-acrylic slipping manifold is reliable and inexpensive, with a simple timing mechanism for appropriate read out of results.

Custom Analysis: Videos of the sample are captured through a mobile phone placed on top of the black box, focusing on the dipstick inside the box. The sample is analyzed using a customized software, with a precise timing control and analysis of color change.

Future Developments

Designing a customized app to perform analysis on the phone with the results mailed directly to the doctor's office for assessment in real-time.

Working with Stanford Office of Technology Licensing to commercialize their idea to a dipstick home test or as a baseline medical instrument in areas of restricted access to well-stocked clinics

Key Value Proposition

Use of the device enables faster disease diagnosis at the convenience of the patient's home, complementing resources lacking appropriate facilities to do these tests.

Smartphone based Ultrasound Imaging System

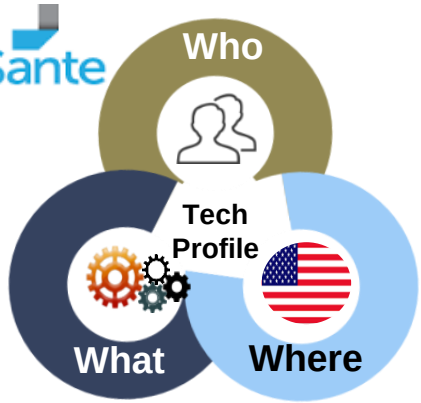
Mobisante, Inc., Redmond, WA, US

Industry Trend

Medical ultrasound, is a safe and efficient diagnostic imaging technique. However, due to its high cost and bulky design and shape, a major part of the patient population does not have access to an ultrasound system. In fact, 60% of the world still does not have access to this highly versatile imaging system.

Tech Profile

- Mobisante Inc., a mobile health company has developed a point-of-care diagnostic imaging solution.
- It has developed a smartphone-based ultrasound imaging system called the MobiUS™.



Innovation Attributes

Application Diversity: Used in fetal/OB, abdominal, cardiac, pelvic, pediatric, mucoskeletal, and peripheral vessel imaging.

Small and Portable System: This pocket-sized MobiUS SP1 System is light and can be carried anywhere.

Affordable: Unlike a large, bulky, and costly system, MobiUS is an affordable system and can reach any resource constrained area or medical center, offering complete care.

Connected Health: The images can be stored in its 8 GB memory capacity. Through Mobisante's unique cloud-based image management system, physicians can securely store, review, edit, and share ultrasound images acquired through a MobiUS

Commercialization Success

- This compact smartphone-enabled ultrasound imaging system can be used by physicians in remote areas and this basic care can be available at the point of service.
- The unnecessary delays by referring to diagnostic centers after the physician check up all are avoided and diagnosis is made at the same time
- The integrated image management solution with MobiUS, reduces the expense and complexity of a dedicated PACS (picture archiving and communication system) for ultrasound image management.
- MobiUS™ SP1 system was the first smartphone-based ultrasound-imaging device to be cleared by the US FDA for clinical use in the United States.

Low-cost Device for Sepsis Diagnosis

Indian Institute of Technology, India

Industry Trend

An overwhelming response of the immune system to an infection often results in sepsis. It is estimated that about 200,000 cases of deaths occur due to sepsis in the US alone (Source: paper published in journal Analytical Chemistry, October 2015)

Currently available methods for diagnosis of sepsis are either expensive or time consuming, creating a huge demand for an inexpensive and precise diagnosis method.

Innovation Attributes

Placement of serum on the membrane of the device filters out rest of the blood constituents, except endotoxins. The severity is analyzed by the membrane surface turning red.

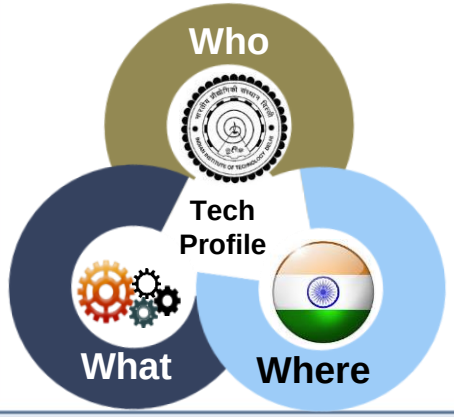
The test involves detection of endotoxin levels in the human serum sample using a colorimetric rapid card test.

The drug-conjugated nanoparticles that get bound to endotoxins appear red in color, which deepens based on the degree of infection.

When the device is used, a combination of colistin and gold nanoparticles binds to the endotoxins in serum samples.

The detection probe is designed by combining gold nanoparticles with colistin, an antibiotic to detect the endotoxins.

Tech Profile



A team of researchers from Indian Institute of Technology (IIT) Delhi, and the Global Medical Education and Research Foundation in Hyderabad have developed a low-cost, disposable, and bedside Point-of-Care (PoC) diagnostic device for the diagnosis of sepsis.

Competitive Advantage

- The new invention is very helpful in resource-constrained facilities, especially at primary care centers in rural areas where there is limited access to advanced diagnostic facilities.

Future Developments

- The research team had conducted validation of 80 sepsis samples and will soon begin validation on blind samples. It is looking to commercialize the device by the end 2016.

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