

Executive Summary



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1. Title of the Project: Large Scale Validation/Field Trial of an Indigenous Non-Invasive Non-Contact Robust Portable Hand-held Device for Accurate Measurement of Bilirubin Level, Hemoglobin Concentration and Oxygen Saturation in Neonatal Subject

2. Date of Start of the Project: 01.08.2018

3. Aims and Objectives:

- Objective 1: To clinically validate at large scale a simple, inexpensive and non-invasive hand-held device that can measure bilirubin level, hemoglobin concentration and oxygen saturation in neonates very quickly, without the need of painful blood test.
- Objective 2: Few non-invasive devices are available commercially but they are expensive. Our proposed device will reduce cost to 50% of the current costs of measurement of oxygen saturation in critical patients.

4. Significant Achievements (not more than 500 words to include List of patents, publications, prototype, deployment etc)

- Non-contact, non-invasive device for detection of neonatal bilirubin level from nail bed is developed (hospital trial grade prototype).
- The device is tested on 1,968 neonates at neonatal intensive care unit (NICU), NRS Medical College & Hospital, Kolkata. The subjects included risk factors like G6-PD deficiency, Rh-incompatibility, congenital heart disease. The commercially available

transcutaneous bilirubinometers are unable to measure bilirubin level in such disease conditions.

- Before clinical trial, all necessary ethical clearances were taken from competent authority.
- The device provided accurate bilirubin levels as analyzed using various statistical methods including simple linear regression analysis, Bland & Altman method of comparison, positive predictive (PPV), the negative predictive (NPV), and receiver operative characteristic (ROC).
- The trial of the developed non-invasive device in measurement of haemoglobin level and oxygen saturation in neonates is underway.
- 32 research articles have been published in various International Journals during this period.
- 14 patents has been granted during this period.
- 6 technology have been transferred to various companies.
- The inventor received the prestigious Nina Saxena Excellence in Technology Award 2019 from Indian Institute of Technology (IIT), Kharagpur.
- The National Academy of Sciences, India (NASI)- Reliance Industries Platinum Jubilee Awardees (2020) for Application Oriented Innovations.
- Prof. Samir K. Pal has been elected as the Fellow of the Indian National Academy of Engineering (INAE) effective from November 1, 2020.

5. Concluding Remarks:

For developing countries like us, the under-five mortality rate (U5MR) is a major challenge for the health sector. A decrease in U5MR is possible if one can rapidly diagnose jaundice, anemia and oxygen deficiency because these 3 diseases are responsible for a huge proportion of U5MR. This device can perform the diagnosis of the mentioned diseases within a few seconds without any requirement of blood. Not only the cost per test is much lower compared to the available one and data can be transferred to miles away just in few minutes, which provide a platform of e-diagnosis. So this device will help to improve our health care system and also to reduce the high U5MR in India.

The technology is beneficial for all the developing countries who have been battling against a high U5MR.

The direct beneficiaries of the technology are the inhabitants of the low income group particularly the residents of the lower middle class. In addition, the rural areas and the sub urban sector, particularly in regions without a proper primary healthcare sector, diagnosis of the aforementioned diseases can be challenging accompanied by proper treatment due to lack of adequate expertise. This device can perform the diagnosis of 3 disease parameters within a few seconds in a cost effective manner and transfer the data to miles away, providing immediate assistance and thereby reducing the mortality rate of the children with age group under 5.

Technology Demonstration and Transfer (Ongoing activities):



Figure 1: Demonstration of the device at Neonatal Intensive Care Unit (NICU) of NRS Medical College & Hospital (Kolkata) in the presence of Binu S. Pillai, Director of ZYNA MEDTECH Private Limited and Dr. H. Purushotham, Chairman & Managing Director of National Research Development Corporation (NRDC), Govt. of India.



Figure 2: A Discussion about technology transfer for the device to measure neonatal bilirubin level was held between the Samit Kumar Ray(Director) and Samir Kumar Pal(Inventor, Senior Professor) of SN Bose National Centre for Basic Sciences and Maninder Singh Lal, Director of Zyna Medtech Private Limited, Andhra Pradesh, India (left Panel) in the presence of Dr. H. Purushotham, Chairman & Managing Director of National Research Development Corporation (NRDC) Govt. of India (right panel) at SN Bose National Centre for Basic Sciences.



Figure 3: Discussion about possible international technology transfer of AJO Neo device between FANEM LTDA, Sao Paulo, Brazil, at NRS Medical College and Hospital, Kolkata.



Figure 4: Developed prototype device being demonstrated in front of Saleh A. Ahmed Professor, Department of Chemistry, Faculty of Applied Sciences, Umm Al-Qura University,(Upper Left panel), and other distinguished guests.



Figure 5: Developed prototype device being demonstrated at ICONSTAT 2020, BBCC, Kolkata. (Left Panel: From left Prof. Samir Kumar Pal, Senior Professor SNBNCBS, Prof. Dipankar Das Sharma, Professor IISc, Professor Samit Kr. Ray, Director SNBNCBS, Prof. Ajay Kr. Sood, Honorary Professor, IISc.)



Figure 6: Developed prototype device being demonstrated at IISF 2020 at Science City, Kolkata.



Figure 7: Launching event of 'Bosetizer' and 'Boseshield'. From left Prof. Samit Kumar Ray, Director SNBNCBS, Ms. Chandrima Bhattacharya, Minister of State for Health and Family Welfare, Dr. Subhash Singh, Director NIH, Kolkata, Dr. Debasish Pal. Principal. Uluberia College, Dr. Asim Kumar Mallick, Prof and incharge Neonatal unit NRS Medical college and hospital (Upper Panel). Prof Samir Kumar Pal shared his thoughts about the Bosetizer and BoseShield.

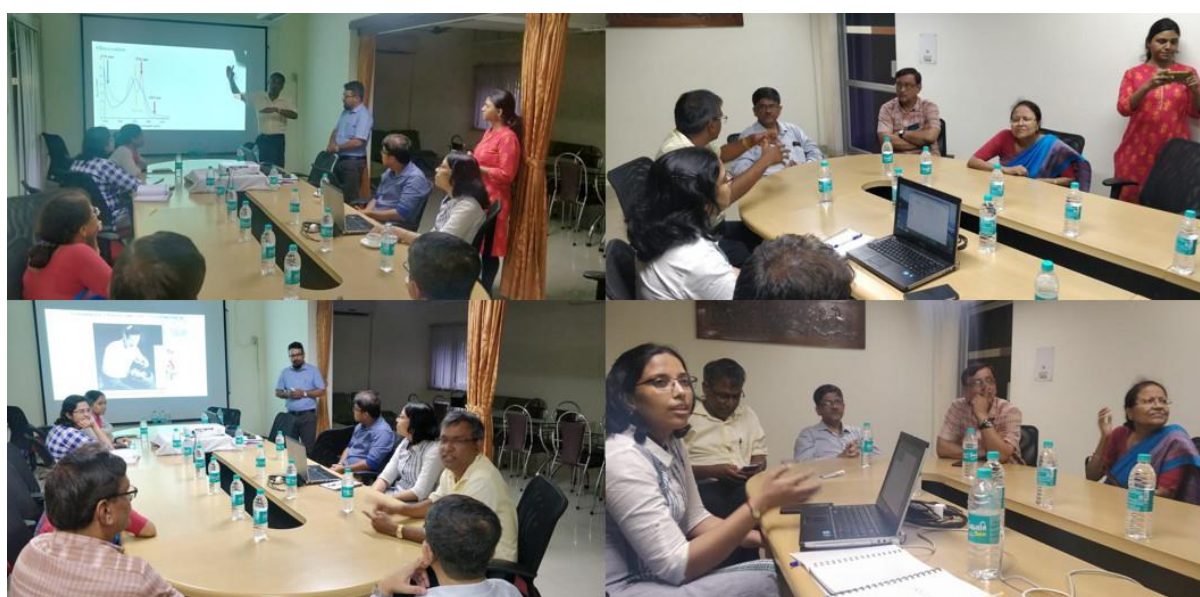


Figure 8: Discussion about the progress of the clinical

