# SecureUltrasound

# Distributed Intelligent Ultrasound Imaging System for Secure in-community Diagnostics

# Final Report

# Contents

# Executive Summary

## 1. Project Overview

The aim of the proposed research was to develop and integrate technology which enables capture and use of clinically valuable ultrasound data for prenatal care without need of real-time ultrasound image based visual feedback. The hypothesis for the research was that "it is possible to conduct prenatal screening with high level of confidence using the advanced freehand 3D ultrasound and augmented reality technologies without the ultrasound image based visual feedback".

### 1a. Project Background

The proposed research set out to develop low cost, secure, point of care ultrasound imaging for prenatal care for India. The availability of skilled technician or doctor that can conduct ultrasound scanning for pregnant mothers in remote areas remains a major challenge in India. Usage of diagnostics ultrasound in India has also been controversial because of its extensive misuse for sex-selective abortions. Indian government introduced legislation back in 1994 to ban the disclosure of foetus gender through the PC-PNDT (Pre-Conception and Prenatal Diagnostic Techniques) Act and continuously tightened regulation to limit such misuse, these efforts have had limited or no effect on the ground. The nature and scale of the problem is indeed unique to India. A secure ultrasound scanning system with guided image capture and a remote diagnostic service, that can work in rural areas in India, is essential to significantly improve the prenatal care, health assessment and wellbeing for the baby and the mother. The Indian challenge is also valid in other Low and Middle Income Countries (LMICs) on the OECD DAC list of ODA recipients, such as African states.

The proposed research builds on state-of-the-art freehand 3D ultrasound technology, care pathway modelling and design, cloud based framework for ultrasound image analysis, servitization of the healthcare provision and augmented reality based digital medical assistant for prenatal scanning. This research will build on the existing research and investigate new technology development to address the 'skills shortage' and 'selective abortion' challenges in India during prenatal care. The research will bring the best universities and research institutes in India to work directly with Cranfield University to solve this social challenge using latest technologies.

This research will build capability and capacity in less-skilled ultrasound scanning for prenatal care with no visual feedback during scanning in India. The research will start with a two week long stakeholder interaction in India and intensive literature review. The interaction will involve direct prenatal care observation in unstructured rural areas, rural healthcare centres, semi-urban municipality areas, urban deprived areas and modern hospitals as per the ethical guidelines of India. A shorter interaction will take place with three surgeries and three hospitals in the UK. Engaging with the end user to better understand their expectations and requirements will be a major focus of this part of the research. The requirements will be the basis for the ultrasound scanning system development, starting with a concept design. The system will have two major components: the ultrasound transmit and receive system with customised ultrasound transducer and the AR based data capture assistant. Working prototypes of the technologies will be built for controlled clinical validations. During the research across the two countries, ethical guidelines and processes will be implemented in a systematic manner in compliance with the requirements from Cranfield University, IISc, SJRI and NIAS. The research will address the cultural and social sensitivities of the participating communities. This will have direct impact on the user interaction, data capture, transmission and storage. New technologies developed will be tested in laboratory conditions first and then in SJRI within a controlled clinical environment. The new ultrasound hardware and software performance will be compared to the best quality ultrasound scanners available in the commercial market. In parallel, the impact of the secure ultrasound scanning service for mothers across different communities will be studied using a combination of quantitative and qualitative methods. The impact of the novel technologies on the Indian society will be studied in detail by NIAS. the research team will engage with the manufacturers and their supply chain to further exploit the results of this research.

## 1b. Project Goals

The objectives for this research:

1. Design, prototype and test an advanced but low cost ultrasound system for 3D ultrasound imaging for prenatal care based on MEMS based sensors.
2. Design, prototype and test an intelligent augmented reality (AR) based ultrasound scanning assistant to automatically judge and correct ultrasound data acquisition parameters
3. Develop a cloud based and intelligent 3D ultrasound image construction (from tracked 2D images) and analysis framework for diagnostics (screening) that protects against the misuse by hiding the identity of mother at the site of analysis.
4. Analyse the effectiveness of the novel imaging capability for its ethical use and its impact on the society.
5. Identify current clinical pathways for prenatal care in Indian context. Design and model future prenatal screening clinical pathways across multiple scenarios and set the performance requirements without ultrasound image based visual feedback

# 2. Key findings

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|---|---|
| **Key Findings?** | Yes |
| **Discoveries** | There have been three major research outcomes this year: - we are now able to analyse the image quality of ultrasound data acquisition and to distribute that data to those in remote locations using the cloud - we are now able to utilise sensors to track the location of the transducer and capture its motion. We can also share that data with other data analysis and visualisation software - we are now able to correlate information about the location transducer, the grade of image acquisition quality, and visual feedback through augmented reality. In the previous year we had developed a novel approach for image-reconstruction when collecting data from ultrasound scanning. We have also integrated that into our system with benefits realised in enhancing the image quality gathered. |
| **Objectives** | Partially |
| **Reasons** | Higher than anticipated risk levels |
| **Expand** | Due to covid, we were not able to conduct patient level analysis using the prototypes that were developed. However, we are aiming to achieve these in the project extension that will last until October 2021. |
| **Further Details** | |

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|---|---|
| **Taken Forward** | The COVID19 pandemic has further increased the gap between the demand for healthcare and the capacity in hospital-centric healthcare systems, which constrained by shortage of physicians and cost of technology. It is of critical importance to develop technology-based solutions that can be used by operators with less skills and in community settings.<br>The general and specific findings of the SU project are therefore very relevant, considering the lack of physicians and sonographers able to perform diagnostic ultrasound, In about 80% of cases, these physicians or sonographers do not find any abnormalities during ultrasound examination. By de-skilling the capturing of ultrasound data, the SU technology has the potential to screen out that 80% so that physicians and sonographers can focus on the 20%, thereby increasing overall capacity and efficiency.<br>The SU projects has developed, to prototype level, two key components (1. Image reconstruction and processing, 2. AR guided image capture) focused on pregnancy as a use-case. During the project other conditions and parts of the human body have been used to validate the technology. Future developments should: (1) validate the technology for pregnancy in specific Indian context and wider application (2) explore other common conditions that could be diagnosed in the community i.e. gall stones, breast lumps.<br>The developed methods can be used for NDT (e.g. thermography) based studies to determine the health of components. |
| **Interest to sectors** | Aerospace, Defence and Marine, Digital/Communication/Information Technologies (including Software), Healthcare, Manufacturing, including Industrial Biotechology |

# 3. Impact

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|---|---|
| **Impacts?** | Yes |
| **Findings** | The project has numerous cultural and ethical implications. Through this project, we have been able to open up conversations about the value and implications of hiding the gender information of babies. Based on engagement with medical experts and patients, we have been able to collate information about how they perceive the information that can be communicated in rural and urban settings. We will conduct further research to understand whether the patients and the medical experts trust the communicated information. We have also found initial results that can aid policy makers in respect to how data can be collected and distributed within the context of ultrasound scanning. |
| **Date Materialised** | 2020 |
| **Type of Impact** | Cultural, Societal, Policy & public services |
| **Sectors used** | Healthcare |

# Project Achievements

## 4. Publications

### 4a. Journal articles

| ID | AUTHOR(S) | TITLE |
|---|---|---|
| 1 | Honarvar Shakibaei Asli B, Zhao Y, Erkoyuncu J | Motion blur invariant for estimating motion parameters of medical ultrasound images |
| 2 | Honarvar Shakibaei Asli B, Flusser J, Zhao Y, Erkoyuncu J, Banerjee Krishnan K, Farrokhi Y, Roy R | Ultrasound Image Filtering and Reconstruction Using DCT/IDCT Filter Structure |
| 3 | Honarvar Shakibaei Asli B, Flusser J, Zhao Y, Erkoyuncu J. | Filter-generating system of Zernike polynomials |
| 4 | | |
| 5 | | |
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| 10 | | |

## 4b. Conference papers

| ID | AUTHOR(S) | TITLE |
|---|---|---|
| **1** | Honarvar Shakibaei Asli B, Flusser J, Zhao Y, Erkoyuncu J, Roy R | DCT/IDCT Filter Design for Ultrasound Image Filtering |
| **2** | Harindranath A, Bharadwaj S, Shah K, Nadiger S, Krishnan K, Arora M | An improved freehand 3D-ultrasound volume reconstruction technique for fast scans with scanline motion correction |
| **3** | | |
| **4** | | |
| **5** | | |
| **6** | | |
| **7** | | |
| **8** | | |
| **9** | | |
| **10** | | |

## 4c. In draft

| ID | AUTHOR(S) | TITLE |
|---|---|---|
| **1** | Satvika Bharadwaj, Komal Nikhil Shah, Yifan Zhao, Aparna Harindranath, Arun George, Kajoli Banerjee Krishnan, Manish Arora | Semi-Blinded Freehand 3D Ultrasound with Novice Users |
| **2** | | |
| **3** | | |
| **4** | | |
| **5** | | |
| **6** | | |
| **7** | | |
| **8** | | |
| **9** | | |
| **10** | | |

## 5. Collaboration and Partnerships

| | |
|---|---|
| **Collaboration Title** | Clinical Feasibility of Secure Ultrasound system |
| **Partners** | |
| **Organisation Name** | IISc |
| **Contributed Financially** | No |
| **In-kind contribution** | No |
| **Organisation Name** | SJRI |
| **Contributed Financially** | No |
| **In-kind contribution** | No |
| **Organisation Name** | NIAS |
| **Contributed Financially** | No |
| **In-kind contribution** | No |
| **Contributions Made** | Preparation of documents at IISc (Device specification, List of Equipment, Instruments and Test protocols) and submission for Institutional Ethics Committee (IEC) and regulatory government body to obtain permission to conduct clinical investigation. |
| **Partner Contributions** | Approval from Institutional Ethics Committee of St John's to conduct clinical investigation. Central Drugs Standard Control Organisation (CDSCO) communicated to National Institute of Advanced Studies (NIAS) that the device for feasibility testing is considered equivalent to an ultrasound equipment and will not be regulated till 01.11.2021. |
| **Year Commenced** | 2019 |
| **Year Ended** | 2020 |
| **URL** | |
| **Resultant Outcomes** | Institutional Ethics Committee approval to conduct clinical investigation with Secure Ultrasound system. |
| **Categorisation of impact** | No impact yet |
| **Formally Governed** | Yes |

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|---|---|
| **Collaboration Title** | Clinical feedback for system development |
| **Partner** | |
| **Organisation Name** | IISc |
| **Contributed Financially** | No |
| **In-kind contribution** | No |
| **Organisation Name** | SJRI |
| **Contributed Financially** | No |
| **In-kind contribution** | No |
| **Contributions Made** | Design and Development of lab prototype for Secure Ultrasound at IISc. |
| **Partner Contributions** | Feedback received from Radiologist to make further improvements based on clinical appropriateness and usability, such as imaging protocol and ergonomic considerations for probe housing. |
| **Year Commenced** | 2018 |
| **Year Ended** | 2021 |
| **URL** | |
| **Resultant Outcomes** | Feedback incorporated into improved design. |
| **Categorisation of impact** | No impact yet |
| **Formally Governed** | Yes |

| | |
|---|---|
| **Collaboration Title** | Clinical insights on measurement methods |
| **Partners** | |
| **Organisation Name** | IISc |
| **Contributed Financially** | No |
| **In-kind contribution** | No |
| **Organisation Name** | SJRI |
| **Contributed Financially** | No |
| **In-kind contribution** | No |
| **Contributions Made** | Acquisition of fetal phantom data, 3d volume reconstruction at IISc and introducing PLUS to Radiologist at SJRI for viewing images to make measurements. |
| **Partner Contributions** | Feedback received from Radiologist on the choice and process of extracting planes from the volumes to make biometric measurements of head circumference, biparietal diameter, abdominal circumference and femur length. |
| **Year Commenced** | 2020 |
| **Year Ended** | 2021 |
| **URL** | |
| **Resultant Outcomes** | User Manual Version 1.0 for Biometry |
| **Categorisation of impact** | No impact yet |
| **Formally Governed** | Yes |

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|---|---|
| **Collaboration Title** | Fetal phantom scans at different speeds |
| **Partner** | |
| **Organisation Name** | IISc |
| **Contributed Financially** | No |
| **In-kind contribution** | No |
| **Organisation Name** | Cranfield University |
| **Department** | Centre for Digital Engineering and Manufacturing |
| **Contributed Financially** | No |
| **In-kind contribution** | No |
| **Contributions Made** | Assisted collaborators to test a signal processing method by providing controlled data acquired in our lab. |
| **Partner Contributions** | The research was published in IEEE Access. |
| **Year Commenced** | 2019 |
| **Year Ended** | 2021 |
| **URL** | https://doi.org/10.1109/ACCESS.2020.3011970 |
| **Resultant Outcomes** | Research paper was published and DOI link has been provided above. |
| **Formally Governed** | Yes |

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|---|---|
| **Collaboration Title** | 72 Volumes Study |
| **Partners** | |
| **Organisation Name** | IISc |
| **Contributed Financially** | No |
| **In-kind contribution** | No |
| **Organisation Name** | SJRI |
| **Contributed Financially** | No |
| **In-kind contribution** | No |
| **Contributions Made** | Designed scanning experiments conducted by novice users at IISc. Data acquisition, reconstruction and biometric measurements by non-experts. Data analysis and documentation. |
| **Partner Contributions** | Biometric measurements by expert. Feedback on 3d image completeness and quality. |
| **Year Commenced** | 2020 |
| **Year Ended** | 2021 |
| **URL** | |
| **Resultant Outcomes** | A paper on the use of the prototype system for scanning a fetal phantom by novice users has been written and submitted for SPIE Medical Imaging 2022 Conference. |
| **Categorisation of impact** | No impact yet |
| **Formally Governed** | Yes |

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| **Collaboration Title** | Long-term academic collaboration development |
| **Contributions Made** | The grant will further develop long-term research collaboration between Cranfield and IISc (the top ranked Indian University), NIAS (a National Centre of Excellence) and SJRI (A major medical research institute in India). This will support capability and capacity building in medical research in India. The development will significantly contribute to wellbeing of people in India. Through the Inclusive Manufacturing Forum, the research will also influence other ODA listed countries, such as Kenya, Nigeria and Bangladesh. |

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|---|---|
| **Partner Contributions** | WP1: Pathway modelling and requirements capture (IISc, Cranfield, HEEE, NIAS and SJRI). Dr. Arora and Dr. Erkoyuncu shall take a lead on this part of the research. They will be supported by Professor Roy and Professor Amaresh Chakrabarti. Deliverables from the research: D11: Successful interactions: two weeks in India and one week in the UK D12: A report on the five To-Be pathways for India and one for the UK D13: A requirements document for the USS WP2: A working prototype of a system for freehand 3D ultrasound imaging for prenatal care based on ultrasound transducer integrated with MEMS based sensors (IISc, SJRI, NIAS and outsourced). Dr. Arora will lead the activity with support from Professor Amaresh Chakrabarti, Professor Baldev Raj and Professor Bhujanga Rao. Production of three prototyped systems will be outsourced to a commercial company in India. D21: Three working prototypes of the ultrasound imaging system D22: A report on the detailed design and manufacturing D23: A report on the lab based testing and initial validation study WP3: A working prototype of an intelligent augmented reality (AR) based ultrasound scanning assistant integrated with the ultrasound transducer (Cranfield, IISc, HEEE, NIAS). Dr. Erkoyuncu and Professor Roy shall lead this WP and will be supported by Dr. Arora. D31: Three working prototypes for the AR based scanning assistant D32: Three working prototype ultrasound systems integrated with AR based scanning assistant D33: A report on the detailed design, manufacturing and integration of the system D34: A report on the lab based hardware and software testing at the development phase D35: A report on integration of AR based scanning assistant with the ultrasound system WP4: A working prototype of the Cloud based secure prenatal diagnostics system without visual feedback to the technician (Cranfield, HEEE, SJRI, IISc). Dr. Zhao and Professor Roy will lead this WP. They will be supported by Dr. Nayar and Dr. Tony Raj for the medical diagnostics knowledge. D41: A working prototype of the secure cloud based system for identity protection D42: A report on the 3D volume creation technique and the test results on completeness D43: A report on the vital health parameter extraction D44: A report on the diagnosis of the baby’s, mothers and placentas’s health D45: A report on the analysis of the data stored in the Cloud to identify any patterns WP5: Comprehensive testing of the prototypes and identifying the technology impact (NIAS, IISc, Cranfield, SJRI and HEEE). Professor Rao will lead this part of the research, supported by |

| | |
|---|---|
| | Professor Chakrabarti, Professor Baldev Raj, Professor Roy and Dr Nayar. D51: A technical test and compliance report for the prototypes D52: An environmental test report for the prototypes D53: A report on the initial validation study user trials D54: A report on the impact of the USS on the society in India and the UK |
| **Year Commenced** | 2018 |
| **Year Ended** | 2021 |
| **URL** | |
| **Resultant Outcomes** | D11: Successful interactions: two weeks in India and one week in the UK D12: A report on the five To-Be pathways for India and one for the UK D13: A requirements document for the USS D21: Three working prototypes of the ultrasound imaging system D22: A report on the detailed design and manufacturing D23: A report on the lab based testing and initial validation study D31: Three working prototypes for the AR based scanning assistant D32: Three working prototype ultrasound systems integrated with AR based scanning assistant D33: A report on the detailed design, manufacturing and integration of the system D34: A report on the lab based hardware and software testing at the development phase D35: A report on integration of AR based scanning assistant with the ultrasound system D41: A working prototype of the secure cloud based system for identity protection D42: A report on the 3D volume creation technique and the test results on completeness D43: A report on the vital health parameter extraction D44: A report on the diagnosis of the baby's, mothers and placentas's health D45: A report on the analysis of the data stored in the Cloud to identify any patterns D51: A technical test and compliance report for the prototypes D52: An environmental test report for the prototypes D53: A report on the initial validation study user trials D54: A report on the impact of the USS on the society in India and the UK |
| **Categorisation of impact** | Cultural, Societal, Policy |
| **Formally Governed** | Yes |

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|---|---|
| **Collaboration Title** | Probe contact algorithm |
| **Partner** | |
| **Organisation Name** | IISc |
| **Contributed Financially** | No |
| **In-kind contribution** | No |
| **Organisation Name** | Cranfield University |
| **Department** | Centre for Digital Engineering and Manufacturing |
| **Contributed Financially** | No |
| **In-kind contribution** | No |
| **Contributions Made** | IISc proposed that an algorithm to detect inadequate coupling between the ultrasound probe and scanning surface due to lack of gel contact could help in providing feedback on quality of volume reconstructed and that the expertise of the collaborator could be utilised in the algorithm design and implementation. IISc also suggested improvements in the algorithm that was designed. |
| **Partner Contributions** | Collaborators at Cranfield designed an algorithm that could detect lack of probe contact and has been integrated with Secure Ultrasound system that has been prototyped in the lab and tested with a fetal phantom. |
| **Year Commenced** | 2019 |
| **Year Ended** | 2021 |
| **URL** | |
| **Resultant Outcomes** | The algorithm is a part of the prototype Secure Ultrasound system. |
| **Categorisation of impact** | No impact yet |
| **Formally Governed** | Yes |

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|---|---|
| **Collaboration Title** | AR guidance system |
| **Partner** | |
| **Organisation Name** | IISc |
| **Contributed Financially** | No |
| **In-kind contribution** | No |
| **Organisation Name** | Cranfield University |
| **Department** | Centre for Digital Engineering and Manufacturing |
| **Contributed Financially** | No |
| **In-kind contribution** | No |
| **Contributions Made** | IISc suggested the use of point cloud data from an external camera to model scanning surface. Introduced PLUS opensource software to track ultrasound probe through OpenIGTLink. |
| **Partner Contributions** | Exploration of these options - work in progress. |
| **Year Commenced** | 2018 |
| **Year Ended** | 2020 |
| **URL** | |
| **Resultant Outcomes** | Work in progress |
| **Categorisation of impact** | No impact yet |
| **Formally Governed** | Yes |

## 6. Further Funding

*What funding, fellowship, studentships have resulted from the work?*

## 7. Next Destination and Skills

| | |
|---|---|
| **Role of the individual member when they and/or their research was supported by this award** | Research Project Leader |
| **Has the individual moved to a role where they are active in research?** | Yes |
| **Do you know the name of the organisation the individual has moved to?** | Yes |
| **Organisation name** | City, University of London |
| **Organisation URL** | http://www.city.ac.uk |

# 8. Engagement Activities

| | |
|---|---|
| **Activity Title** | 2018 Engagement Activities |
| **Activity Type** | Event, workshop or similar |
| **How many people?** | |
| **Geographical Reach** | International |
| **Primary Audience** | Study participants or study members |
| **Other Audience** | Professional Practitioners, Public/other audiences, Supporters, Other audiences, Study participants or study members, Patients, carers and/or patient groups, Third sector organisations |
| **Activity Years** | 2018 |
| **Result Description** | Engagement activities include: Visit to St. Johns Medical College Hospital (SJMCH), Site visit to semi-urban Government Health Centre located at Sarjapur and also to a semi-urban Private Health Centre located at Sarjapur, Site visit to Rural Public Health Centre (Mugalur). Meeting with IISc and SJNAHS experts to discuss on functional requirements. IISc team visited the Department of Radiology with a custom phantom device to learn the techniques used to capture the 3D and 4D ultrasound images. Site visit and discussion with Stake Holders at Department of Radiology, BSM Medical University Dhaka |
| **Most important impact?** | Plans made for future related activity |
| **URL** | |
| **Digital ID** | |
| **Source** | Manual |
| **Publication ID** | 5c828fc4103cb3.36460524 |

| | |
|---|---|
| **Activity Title** | 2019 Engagement Activities |
| **Activity Type** | Event, workshop or similar |
| **How many people?** | 1 - 10 |
| **Geographical Reach** | Local |
| **Primary Audience** | Study participants or study members |
| **Other Audience** | Professional Practitioners, Other audiences, Study participants or study members, Patients, carers and/or patient groups, Third sector organisations |
| **Activity Years** | 2019 |
| **Result Description** | Engagement activities include: Visit to St. Johns Medical College Hospital (SJMCH). Meeting with IISc, NIAS and Cranfield University experts to discuss on functional requirements. IISc, NIAS and Cranfield University team visited the Department of Radiology at St Johns Medical College Hospital to learn the techniques used to capture the 3D and 4D ultrasound images. Site visit included discussions with Stake Holders at the Department of Radiology, and the Department of Obstetrics and Gynecology, St Johns Medical College Hospital. |
| **Most important impact?** | Plans made for future related activity |
| **URL** | |
| **Digital ID** | |
| **Source** | Manual |
| **Publication ID** | 603e3970d5a413.65911801 |

| | |
|---|---|
| **Activity Title** | 2019 Engagement Activities |
| **Activity Type** | Participation in an open day or visit at my research institution/facility |
| **How many people?** | 1 - 10 |
| **Geographical Reach** | Local |
| **Primary Audience** | Professional Practitioners |
| **Other Audience** | Professional Practitioners |
| **Activity Years** | 2019 |
| **Result Description** | IISc team visited the Department of Radiology to learn the method used during the Ultrasound scanning process. 3D Ultrasound data was captured and anonymized data was in DICOM Format was analyzed by the IISc team. Measurements were noted and co-related with 23-week Foetal Phantom's measurements. |
| **Most important impact?** | Plans made for future related activity |
| **URL** | |
| **Digital ID** | |
| **Source** | Manual |
| **Publication ID** | 603e3c5e1abe41.11684014 |

| | |
|---|---|
| **Activity Title** | Visit to City University London |
| **Activity Type** | Event, workshop or similar |
| **How many people?** | 1 - 10 |
| **Geographical Reach** | Local |
| **Primary Audience** | Professional Practitioners |
| **Other Audience** | Professional Practitioners |
| **Activity Years** | 2019 |
| **Result Description** | This event involved presenting an overview of the Secure Ultrasound project to practitioners in ultrasound scanning. The event opened up an opportunity exchange knowledge on current practice and helped to identify challenges in the field. There have been further engagements on collaboration opportunities related to GCRF funding and other means. |
| **Most important impact?** | Requests about (further) participation or involvement |
| **URL** | |
| **Digital ID** | |
| **Source** | Manual |
| **Publication ID** | 5e625b097c0817.99667315 |

## 9. Influence on Policy, Practice, Patients & Public

*What participation / consultation / influence has the work produced*

# 10. Research Tools & Methods

| | |
|---|---|
| **Material Type** | Improvements to research infrastructure |
| **Material Name** | Estimation of Motion Parameters for Ultrasound Images Using Motion Blur Invariants |
| **Description** | The quality of fetal ultrasound images is significantly affected by motion blur while the imaging system requires low motion quality in order to capture accurate data. This can be achieved with a mathematical model of motion blur in time or frequency domain. We propose a new model of linear motion blur in both frequency and moment domain to analyse the invariant features of blur convolution for ultrasound images. Moreover, the model also helps to provide an estimation of motion parameters for blur length and angle. These outcomes might imply great potential of this invariant method in ultrasound imaging application. |
| **Provided to Others** | Yes |
| **Year First Provided** | 2020 |
| **Year First Provided** | |
| **Impact Description** | We have been able to characterise the image acquisition quality. |
| **URL** | https://arxiv.org/abs/2009.11117 |
| **Digital ID** | |
| **Source** | Manual |
| **Publication ID** | 6041f9c5bcfae7.96813391 |

| | |
|---|---|
| **Material Type** | Improvements to research infrastructure |
| **Material Name** | Filter-generating system of Zernike polynomials |
| **Description** | This work proposes a new approach to find the generating function (GF) of the Zernike polynomials in two dimensional form. Combining the methods of GFs and discrete-time systems, we can develop two dimensional digital systems for systematic generation of entire orders of Zernike polynomials. We establish two different formulas for the GF of the radial Zernike polynomials based on both the degree and the azimuthal order of the radial polynomials. In this paper, we use four terms recurrence relation instead of the ordinary three terms recursion to calculate the radial Zernike polynomials and their GFs using unilateral 2D Z-transform. A spatio-temporal implementation scheme is developed for generation of the radial Zernike polynomials. The case study shows a reliable way to evaluate Zernike polynomials with arbitrary degrees and azimuthal orders. |
| **Provided to Others** | Yes |
| **Year First Provided** | 2019 |
| **Year First Provided** | |
| **Impact Description** | This provided a novel mechanism to evaluate images. |
| **URL** | https://dspace.lib.cranfield.ac.uk/handle/1826/144 20 |
| **Digital ID** | |
| **Source** | Manual |
| **Publication ID** | 6041fab2764615.90329299 |

## 11. Research Databases & Models

An image database consisting of 72 reconstructed 3d volumes of a fetal phantom with raw scan and tracker data acquired at different speeds of scan and phantom orientations by novice users in a single sweep without feedback from display on the monitor.

## 12. Intellectual Property & Licensing

*Copyrighted works, patents, and trademarks*

## 13. Medical Products, Interventions & Licensing

*Diagnostic tools, therapeutic interventions, and management*

## 14. Artistic & Creative Products

*Artefacts, exhibitions, performances etc*

## 15. Spin Outs

*What enterprise activities have resulted from the work?*

## 16. Awards & Recognition

*Prizes, fellowships, appointments, honours etc*

### 16a. 2nd prize in the category theoretical publication

This prize has been awarded from The Czech Academy of Sciences (Institute of Information Theory and Automation) for publishing a high impact journal paper in Automatica journal titled 'Filter-generating system of Zernike polynomials'. This paper contributes on designing of an automated system to generate the Zernike polynomials which are playing an important role in image classification, recognition and reconstruction. The first author of this paper – Barmak Honarvar – is an image processing scientist with wide experiences in mathematical analysis and modelling who was awarded by this prize.

The paper awarded for this prize describes a novel and automatic system for generating of Zernike polynomials have found numerous applications in a variety of fields: optics, wavefront sensing, aberration theory, scaled pupils, adaptive optics, high-resolution optical wave-front control system, and image processing. With the derived generating function, the paper proposed a spatio-temporal implementation scheme for producing of the radial Zernike polynomials.

## 17. Use of Facilities & Resources

*What contributed to the work?*

## 18. Other Outputs & Knowledge/Future Steps

*Anything further not covered in previous sections*

# Work Packages

## 19. WP1: Pathway modelling and requirements capture

*Reporting the deliverables for the work*

### 19a. D1.1: Successful interactions: two weeks in India and one week in the UK

Several visits were made during the project between India and UK prior to the pandemic. Further travel restrictions during the pandemic limited the number of subsequent visits.

### 19b. D1.2: A report on the five To-Be pathways for India and one for the UK

The aim of this deliverable was to develop and propose pathway alternatives for discussion with stakeholders of the SU technology in India and the UK to enable them to agree on the optimal patient journey for this new technology. This optimal pathway will be used to guide and support development and validation of the SU device. Furthermore, it will serve in the practical implementation and adoption of the technology.

The objectives for this work:

1. Describe current (AS-IS) pathways for ultrasound investigation during pregnancy in India and the UK
2. Identify pathways elements that can be varied when SU technology is used
3. Select suitable method and technique for drawing pathways
4. Develop 5 alternative (TO-BE) pathways enabled by SU for India and 1 for UK

The diverse pathways all demonstrate that, from the main stakeholders' (patients and clinicians) perspective, using the SU system is a step backwards from established practice. Their current benefits, of immediate and visible results, are lost; patients will have to wait longer for results, clinicians will not feel trusted by patients or authorities. This needs to be investigated in more detail and addressed in the development of the SU system. Policymakers and wider society will gain the intended benefit of promoting gender equality, but the price for that will be paid by patients and clinicians.

A full report of the work is available on request.

### 19c. D1.3: A requirements document for the USS

The project developed a comprehensive set of constraints, functional and non-functional requirements that led to the design and implementation of the prototypes.

Requirements are a need that a particular design, product or process aims to satisfy. Requirements can be distinguished into 'musts' and 'wants': 'musts' are needs that are not-negotiable and the product must satisfy; 'wants' are negotiable - 'it would be good if ... There are at least 10 sources or categories of 'external' requirements:

1. Customer - the people and organisations that buy and use the product
2. Technology e.g. stability; affordability; future-proofing; IPR
3. Political
4. Regulation and legislation
5. Distribution, from manufacturer to user
6. Environmental

7. Economics
8. Socio - cultural
9. Supply chain
10. Competition

Furthermore there are internal sources of requirements too such as 'must match technical capability and facilities' or 'must build platform for future product extensions'.

A full report of the work is available on request.

# 20. WP2: Prototype development of ultrasound transducer

*Reporting the deliverables for the work*

## 20a. D2.1: Three working prototypes of the ultrasound imaging system

## 20b. D2.2: A report on the detailed design and manufacturing

## 20c. D2.3: A report on the lab based testing and initial validation study

Prototype Secure Ultrasound system was developed at IISc by integration of following components : Telemed Micrus – A USB powered pocket sized Ultrasound Imaging device with a probe connector for (2) C5-2R60S-3 convex transducer probe with frequency range 2-5 MHz, 60 mm radius applicable for obstetrics and controlled by a local computer (3) with standard specs such as Intel(R) Core (TM) i3 CPU@2GHz, 4GB RAM, 64-Bit OS that communicates through a cloud based server (4) provided by an appropriate Infrastructure-as-a-Services (IaaS) provider with the following (typical) configuration: large Xeon Platinum 8000, 3.4GHz and 64-bit operating system to transfer 2-D ultrasound images, position and orientation of the tracker(s) (5) Electromagnetic tracker Polhemus - 3SPACE® and FASTRAK ®device that makes use of radio frequency waves to detect position and orientation of a device/object; remote computer (6) with standard specs such as Intel(R) Core (TM) i5 CPU@2.7GHz , 64-Bit OS that generates 3-D ultrasound volumes and displays it on a monitor (7) with a standard display to a Radiologist.

The SU device is supported by software during data collection, transmission, volume reconstruction, visualization and analysis. The components described above are shown in figure 1 and the laboratory set-up of the SU system is seen in figure 2 in Annexure A

For the lab-based testing of the prototype Secure Ultrasound System, data was collected using Telemed Micrus, a USB powered pocket-sized Ultrasound Imaging device with programmable presets for clinically specific obstetric imaging. A C5-2R60S-3 convex transducer probe with frequency range 2-5 MHz, 60-degree field of view and a radius of curvature of 65 mm was utilised for imaging. A local computer acquired 2-D ultrasound images from Micrus and position, orientation from an Electromagnetic Tracker (EMT) Polhemus - 3SPACE® and FASTRAK ®device strapped on the probe. Seventy-two volumes were generated using a reconstruction algorithm from the ultrasound and EMT data from scans performed by three novice users in a single longitudinal sweep across a 23-week fetus phantom in four different configurations for six scan durations ranging from 5-s to 30-s. The acquisition was semi-blinded: the users knew the fetal orientation but scanned without image display and guidance of a conventional scan. Three nonexpert readers and one expert Radiologist extracted the clinically relevant planes and measured four key biometric features from the 3D images. A novel risk metric R designed as part of the project was used to rate the quality of the scan as a function of probe motion and contact and a newly proposed measurability index M was used to quantify the availability of the 2D planes within the volume and visibility of the biometric features. Analysis of results showed that R is the lowest and M the highest for 15-s acquisitions corresponding to an average transducer sweep speed of 2.4-cm/s. The finding was consistent with a reported speed range of 3-4 cm/s recommended for a low cost teleradiology solution for 2D ultrasound. The errors in average biometric measurements compared to the 50th percentile values in the fetal biometry tables for corresponding gestational week were within -3.8 to 5.7%. R, M, accuracy and precision of measurements were shown to be useful indicators of performance of the prototype 3D Ultrasound system. Illustrative graphs and tables are in Annexure A.

## 21. WP3: System integration of the ultrasound and AR

This research contribution builds upon state-of-the-art 3D ultrasound technology and Augmented Reality (AR) based digital assistant for freehand scanning protocols. Position tracking in freehand protocols uses sensors that can acquire position and orientation information using sensor fusion algorithms. This combined with a dynamic AR visualisation that tracks features and guides the scanning protocol creates novel approaches that employ state of the art methods that replace conventional on-screen feedback with operator guidance overlaid on the subject by an AR headset.

This work demonstrates a change from an expert-driven scanning tool to a secure diagnostic tool deskilled for competent professionals. Images collected by the system are not explicitly shown on a public screen, instead restricted to permitted operators for secure diagnosis via a head mounted AR device.

To provide the initial basis for visual overlay, a procedural mesh is generated from set of vertex points, with each mesh triangle defined by these vertices. The original vertex position is cached, then a deforming force is applied at specific location, displacing vertices. For displaced vertices, a return spring force clamps to original vertex position over time.

To test the mesh overlay in context, we have developed a marker-less approach has been developed using PTC Vuforia AR SDK. Digital content is placed on surfaces within environment, with two points defining the basis for a mesh overlay. However significant shortcomings have been found with fast motion panning causing tracking loss/scaling errors.

Software development work has continued with prototyping of the system for adaptive registration on an amorphous structure using the HoloLens device. Although the project desired a solution that could function on a low-cost device, it was agreed that the capabilities offered by the HoloLens would soon be matched in lower-cost devices. In less than a year, new AR API capability has been introduced for depth mapping on mobile devices - monocular method on Android ARCore and LIDAR method with iOS ARKit.

Initial experiments sought to compare earlier results obtained with PTC Vuforia AR SDK with the HoloLens approach. By moving from a rigid coordinate system to the spatial coordinate system offered by the HoloLens the tracking loss/scaling errors for fast motion panning were significantly reduced.

The first hypothesis for adaptive registration on an amorphous structure was to determine characteristics from the observer fixation point and use this to drive a segmentation of the spatial mapping data to dynamically register the amorphous structure. A method was employed similar to that used for integrating ARToolkit with the HoloLens by loading a Dynamic Link Library to marshal methods from the underlying Windows.Media.Capture C++ API to the prototype C# code. This enabled direct access to the RGB camera enabling the sampling of colour pixel data at the observed fixation point.

The next challenge was to manipulate the spatial mapping data for effective segmentation around the fixation point on the amorphous structure. First experiments explored manipulation of the spatial data by rendering quads at each vertex of the mesh. However, this presented significant performance penalties with low frames-per-second (fps) and dropped frames.

To tackle the apparent rendering problem, the Graphics Processing Unit (GPU) was directly targeted in the HoloLens after observing significant under-utilisation whilst debugging. Initial tests demonstrated a 125x performance improvement when sending spatial data from the HoloLens API to the GPU via a ComputeBuffer. However, it was later discovered that there was an apparent synchronisation bug with the spatial data made available via the API and what was actually sent to the GPU.

To solve this apparent mismatch with API and rendered spatial data, a direct method that employed the GPU graphics pipeline with a solution that combined Vertex, Geometry and Fragment shaders to render the entire spatial mapping data set in a single render pass with a negligible performance penalty.

Using the camera pinhole model in reverse, an observed point in space can be mapped to an intersecting point on the focal plane of the HoloLens RGB camera and therefore determine the pixel colour of the observed point. This can then be extended to assign RGB colour data to all vertex points in the spatial map mesh. Subsequent vertex points of the mesh can then be filtered that do not satisfy threshold depth and RGB colour values.

To provide operator guidance, a series of visualisation components were developed to provide the relevant features to achieve a complete ultrasound scanning protocol. A series of protocol waypoints are visualised by display of targets within the operator’s field-of-view. During use, the operator is directed to each target in sequence. To assist with this task, a direction indicator is shown on the leading edge of the ultrasound transducer to navigate across the patient subject. Contact indication is shown as a function of transducer motion and current position. The path taken is overlaid with scan quality coverage according to a traffic-light approach. The guidance correction factor is then determined from motion trajectory calculation from observed movements.

Additional work in the project explored the utility of determining the transducer path by frame-sequence reconstruction. Taking each image slice in sequence, a correspondence is found between match in features in each image pair. The fundamental matrix is calculated using these correspondences to determine the relative transducer position and rectify for alignment. A disparity map is then calculated for the image pairs to compute a depth map. With the combination of the depth map and transducer position, the 3D positions are calculated by back projection to create the 3D position of the transducer across the entire image set.

## 21a. D3.1: Three working prototypes for the AR based scanning assistant

Several software prototypes have been created as part of the ongoing research this project has set out to achieve. Each prototype considers various aspects of the completed system, to fully understand the functionality and performance of the prototype developed.

Table 1. AR based scanning assistant prototypes

| ID | PROTOTYPE | PURPOSE |
|---|---|---|
| **1** | SpatialMappingTest | Explore spatial mapping data for dynamic segmentation via GPU shader |
| **2** | OpenIGTLinkData | Test sytem integration with OpenIGTLink data protocol for interoperation with SLICER and PLUS Tookit |
| **3** | ColourTest | Experimental study of scene object colour properties |
| **4** | FlockingTest | Implementation of boids algorithm for guidance tasks |
| **5** | GuidanceTest | A series of methods for guidance of tasks and associated visualisation |
| **6** | MeshTest | Procedural mesh grid overlay experimentation |
| **7** | RegisterTest | Data model for tracking guidance components |
| **8** | RotateTest | Alignment of visualisation objects to operator guidance |
| **9** | ScreenTest | Screen overlay for message display and user interface components |
| **10** | SensorTest | Experimentation with device sensors to respond to additional user input |
| **11** | ShaderTest | Extensive shader development to explore how to visualise and manipulate spatial datasets |
| **12** | SRPTest | Alternative approach for shader development using the Scriptable Render Pipeline |
| **13** | VertexTest | Visualisation method for understanding shape geometries |

## 21b. D3.2: Three working prototype ultrasound systems integrated with AR based scanning assistant

The system developed uses a modular approach that supports multiple hardware configurations. Implementation is with the open-source Mixed Reality Toolkit and PLUS Toolkit that allow various cross-platform hardware combinations. With the research capability at Cranfield University, prototypes can be produced with the following AR hardware.

| ID | HARDWARE | FEATURES |
|---|---|---|
| **14** | HoloLens 1 | Operating system: Windows Mixed Reality; CPU: Intel 32-bit (1GHz); Memory: 2 GB RAM; 1 GB HPU RAM; Storage: 64 GB (flash memory); Display: 2.3 megapixel widescreen head-mounted display; Sound: Spatial sound technology; Input: ; Inertial measurement unit (Accelerometer, gyroscope, and magnetometer); 4 sensors; 1 120°×120° depth camera; Controller input: Gestural commands via sensors and HPU; Camera: 2.4 MP |
| **15** | HoloLens 2 | Operating system: Windows 10 Holographic; System on a chip: Qualcomm Snapdragon 850 Compute Platform; CPU: Qualcomm Snapdragon 850; Display: See-through holographic lenses 2K 3:2, 1440x936; Graphics: Adreno 630; Input: Eye tracking, spatial tracking, hand tracking.; Camera: 8 MP 1080P30 video; Connectivity: Bluetooth LE 5.0, 802.11 2x2 Wi-Fi; Platform: Universal Windows Platform |

| ID | HARDWARE | FEATURES |
|---|---|---|
| **16** | Magic Leap | CPU: 2 Denver 2.0 64-bit cores + 4 ARM Cortex A57 64-bit cores (2 A57's and 1 Denver accessible to applications); GPU: NVIDIA Pascal™, 256 CUDA cores; Graphic APIs: OpenGL 4.5, Vulkan, OpenGL ES 3.1+AEP; RAM: 8 GB; Storage Capacity: 128 GB (actual available storage capacity 95 GB); Audio Input: Voice (speech to text) + real world audio (ambient); Audio Output: Onboard speakers and 3.5mm jack with audio spatialization processing; Connectivity :Bluetooth 4.2, Wi-Fi 802.11ac/b/g/n, USB-C; Haptics: LRA Haptic Device; Tracking: 6DoF (position and orientation) |

## 21c. D3.3: A report on the detailed design, manufacturing and integration of the system

The system design was commenced with a full requirements analysis that defined key functional, non-functional and constraints of the work. Early-stage prototypes developed explored aspects of design elements before integration into a system architecture. A two-phase approach was adopted for lab-based testing and data connectivity within the system. The architecture was further refined into controller units for device setup, data acquisition control and full data transfer and logging. Devices supported by the system included: Transducer harder; Tracking hardware; AR headsets; Image analysis; Result storage. These components shared common characteristics for operation: system initialisation; control activation; data messaging; connection management. Owing to challenges faced by the project from the Covid-19 pandemic, manufacturing during the project was postponed until later clinical trials have completed.

## 21d. D3.4: A report on the lab based hardware and software testing at the development phase

A comprehensive testing programme was developed for the goal of find and fixing errors within the system. To test the integrated system, a series of higher-order test cases was prepared to inspect the system design, user specification, system objectives and requirements. Each test case developed specified an identifier; author; statement of purpose; preconditions and a series of test inputs and expected outputs. During testing further metrics recorded the date of testing, testing team, version tested and test result.

Validation of the system was proposed with a mixture of novice, expert, and end-user practitioners. Verification was first with simulated data generated for the system, moving to expert validation to evaluate the system prior to use with patients. The final phase concluded with modifications to the system before proceeding to clinical trials.

## 21e. D3.5: A report on integration of AR based scanning assistant with the ultrasound system

System integration is achieved by means of the open-source PLUS Toolkit and relevant data transfer via the OpenIGTLink protocol. Due to the implementation differences of the OpenIGTLink protocol library and the project development environment, a native plugin interface was developed using a C++ Dynamic Link Library (DLL). This is then integrated into the Universal Windows Platform (UWP) environment for deployment on an AR device by means of .NET plugin architecture and System.Runtime.InteropServices to marshal data types between unmanaged and managed memory architectures.

# 22. WP4: Prototype of cloud based secure prenatal diagnostics system

## 22a. D4.1: A working prototype of the secure cloud-based system for identity protection

An MSc individual project has been developed for design and implementation of a secured cloud-based framework for the ultrasound image processing of prenatal scanning. Secure Ultrasound relies on Cloud service for its data storage due to its high security, low cost and scalability. In the proposed framework, Security and Privacy are taken as an utmost important feature as data security is vital for business continuity, reputation, auditing, to comply with government's law and to gain customer's trust to invest. To protect the privacy of the data, it is suggested that cloud should store only name and aadhar card no. of the patient and link it to the Ref_ID. It will ensure that no sensitive information such as date of birth, bank details etc will be disclosed in case of data breach. On top of it, all the data stored in the cloud in any state, will be encrypted by combination of two techniques to strengthen the security. The drawback will be that it might be time consuming to encrypt the huge medical data. The proposed framework can be found below.

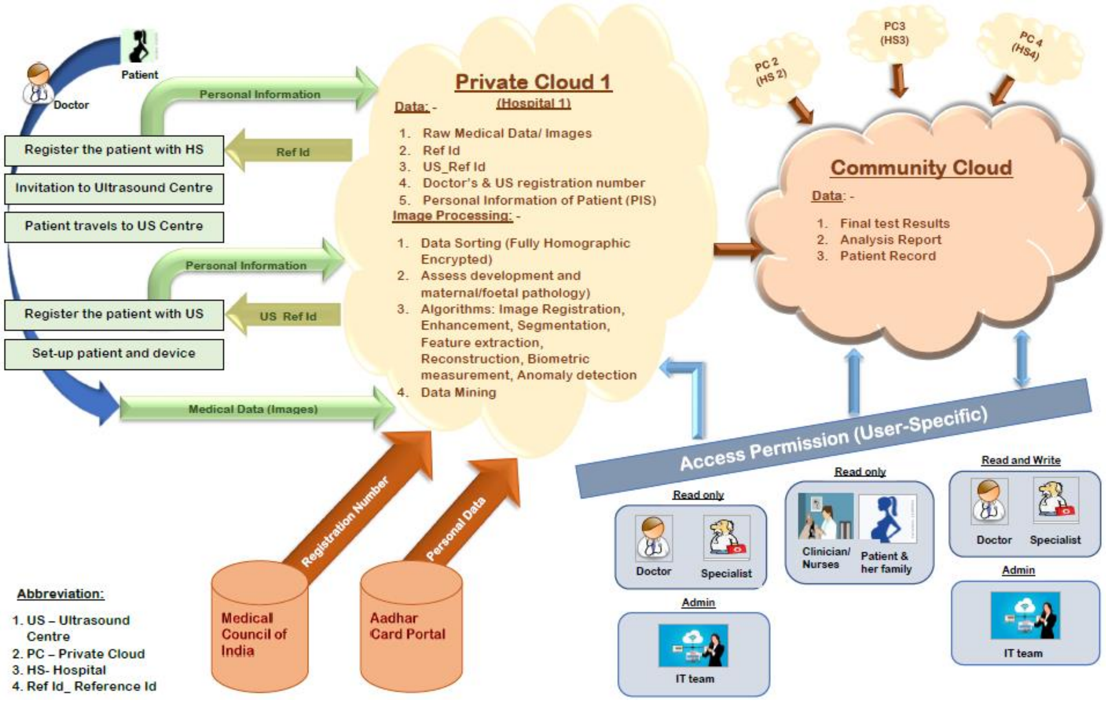


Figure 1. Developed cloud-based framework

## 22b. D4.2: A report on the 3D volume creation technique and the test results on completeness

## 22c. D4.3: A report on the vital health parameter extraction

Three numerical experiments were conducted in order to prove the validity and the efficiency of the proposed methods. The first and the third experiments have been performed using two sets of videos (five slow and five fast scans) without any visual feedback in a trajectory (axially from head to toe or toe to head followed by moving the probe in the opposite direction after placing it in a perpendicular orientation) based on scans of a foetal phantom (SPACEFAN-ST, Kyoto Kagaku) by a convex transducer probe with a Telemed MicrUs Scanner (Telemed Ultrasound Medical Systems, Lithuania). In these experiments, different foetal scans (normal and anomaly), foetal spinal and foetal hydronephrosis scans have been used too. These scans were performed in a trajectory (axially from head to toe or toe to head followed by sagittally in the opposite direction) in a display-less mode. All images were extracted from different sets of videos. Since data are blurry, we have decided to obtain and present such data for the proposed frequency invariants algorithm. Moreover, in the second part of the third experiment, a malignant type of the breast cancer ultrasound image has been used. In the second experiment, we used an 11 weeks' gestation foetal ultrasound image. All examinations were performed in accordance with relevant guidelines and regulations. The local ethical review committee (the Urmia University of Medical Sciences) approved this study with all its experimental protocols. All dataset was obtained from pregnant women in the age range between 27 to 43 years old. Informed consent was obtained from all the participants. There were no subjects under 18 which needed parent/legal guardian.

## 22d. D4.4: A report on the diagnosis of the baby's, mothers and placenta health

We have developed a set of algorithms to determine the quality of capture ultrasound images, including

A. A Matlab-based algorithm to measure the contact quality. We divide the contact quality into four levels: lack of contact, inadequate pressure, adequate contact (normal), and excess contact leading to no anatomical information.
B. A Matlab-based algorithm to measure the image quality using a non-reference approach. The matrices include BIQE, PIQE and BRISQUE.
C. An invariant method to estimating motion blur and reduce the effect of motion blur during the ultrasound image acquisition.
D. An DCT/IDCT based filter to enhance ultrasound image quality.
E. A deep learning-based method Mask-RCNN to segment fetus' head and provide the biometric measurement.

## 22e. D4.5: A report on the analysis of the data stored in the Cloud to identify any patterns

## 23. WP5: Prototype testing and evaluation

*Reporting the deliverables for the work*

## 23a. D5.1: A technical test and compliance report for the prototypes

## 23b. D5.2: An environmental test report for the prototypes

## 23c. D5.3: A report on the initial validation study user trials

## 23d. D5.4: A report on the impact of the USS on the society in India and the UK

# Future plans

*Further research, grant proposals*

# Esteem Factors

*Academic esteem factors for the permanent academic staff involved in the project as Principle or Co-Investigators*

## 24. Principle Investigator:

| CRITERIA | DETAILS |
|---|---|
| **Invited talks** | |
| **Academic awards** | |
| **Fellowships** | |
| **Membership** | |
| **Activities** | |

## 25. Co-Investigator: Manish Arora

| CRITERIA | DETAILS |
|---|---|
| **Invited talks** | Manish Arora gave an invited talk at IEEE SPS Winter School, Bangalore, Nov 2019 on "Freehand 3D Ultrasound : Challenges and Opportunities" |
| **Academic awards** | |
| **Fellowships** | |
| **Membership** | |
| **Activities** | |

# Annex

## A. WP2 D2.1

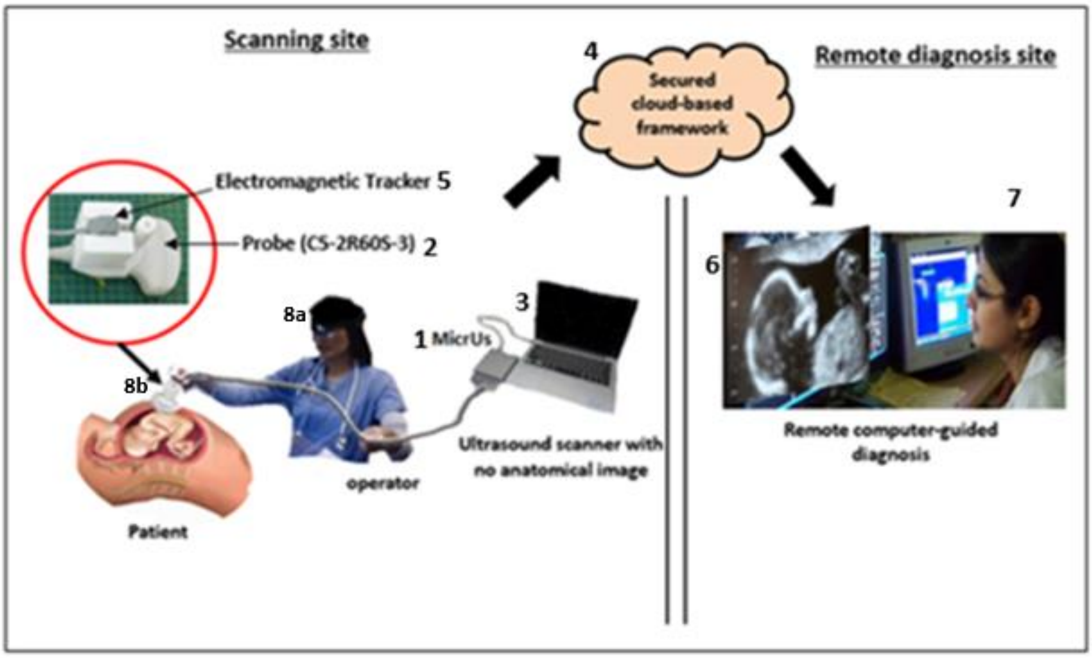


Figure 2. The proposed Secure Ultrasound System diagram

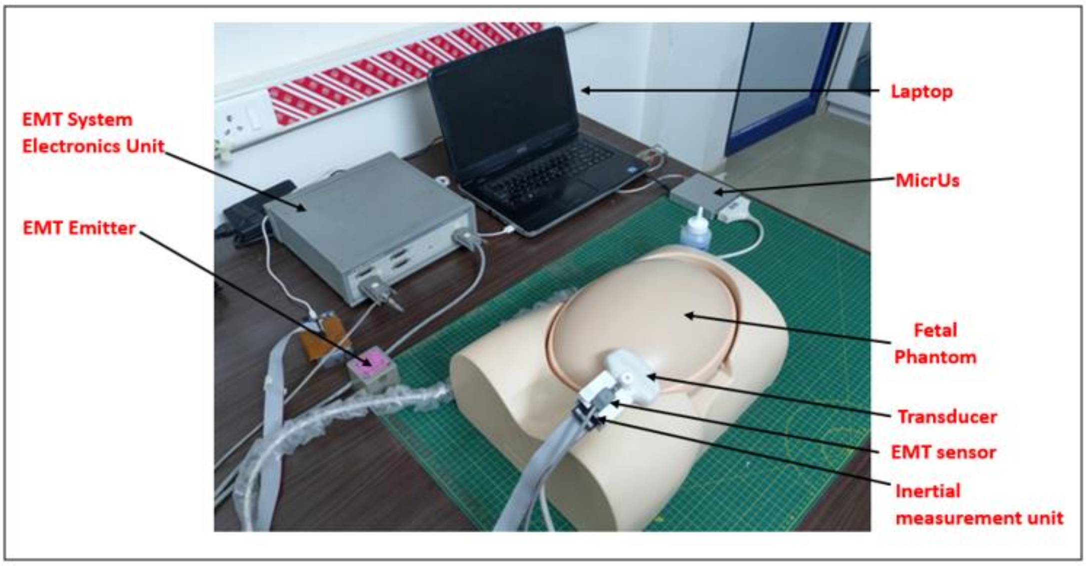


Figure 3. Laboratory set-up of the Prototype Secure Ultrasound system using a 23-week gestation age fetal phantom

# B. WP2 D2.3 Illustrative Output

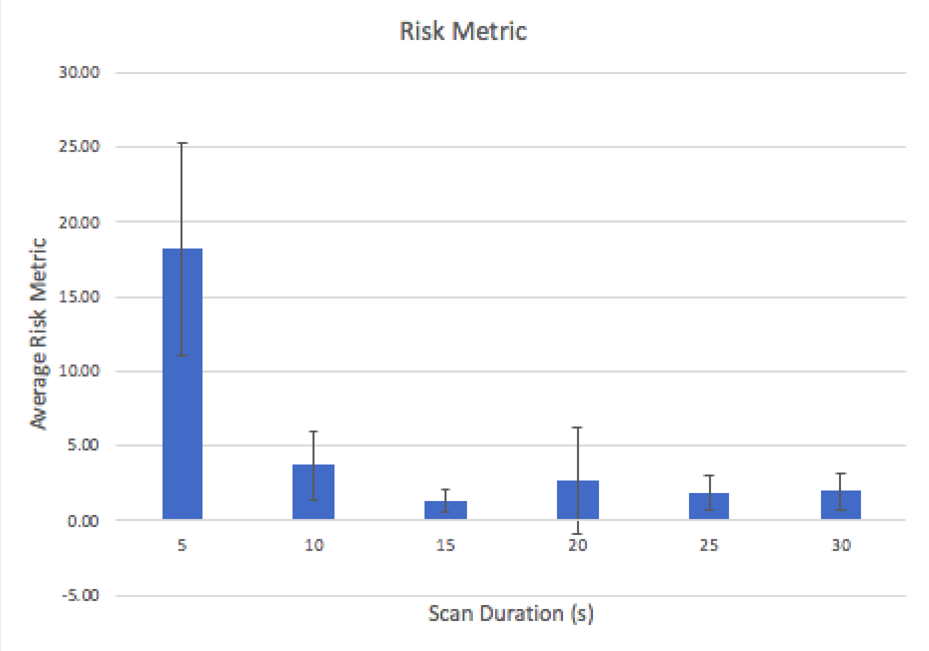


Figure 4. Representative Risk Metric R at each scan duration

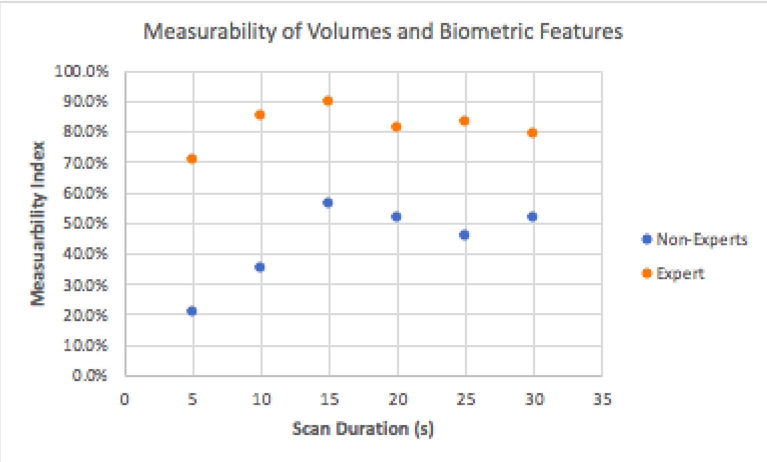


Figure 5. Measurability Index M at each scan duration

Table 2. Summary of measurements of femur length made by the non-experts

| **FL** | **TRIAL - 1** | | | **TRIAL - 2** | | | **TRIAL - 3** | | |
|---|---|---|---|---|---|---|---|---|---|
| | NE-1 | NE-2 | NE-3 | NE-1 | NE-2 | NE-3 | NE-1 | NE-2 | NE-3 |
| **Measurable** | 63 | 58 | 56 | 60 | 57 | 55 | 62 | 55 | 56 |
| **Average (mm)** | 43.3 | 40.7 | 39.5 | 42.2 | 40.3 | 39.5 | 41.8 | 39.7 | 39.45 |
| **SD (mm)** | 1.6 | 1.1 | 1.9 | 1.3 | 1.4 | 1.4 | 1.1 | 1.0 | 1.11 |

Table 3. Summary of measurements of femur length made by the non-experts

| BIOMETRY FEATURE | MEASURABLE (OUT OF 72) | AVERAGE (MM) | SD (MM) |
|---|---|---|---|
| **BPD** | 49 | 59.10 | 2.61 |
| **HC** | 49 | 214.51 | 7.13 |
| **AC** | 70 | 179.54 | 6.06 |
| **FL** | 67 | 39.84 | 3.43 |