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| **Fiscal Year:** | FY 2017 | **Task Last Updated:** | FY 03/20/2018 |
| **PI Name:** | Thompson, William M.S. | | |
| **Project Title:** | Flexible Ultrasound System | | |
| **Division Name:** | Human Research | | |
| **Program/Discipline:** | | | |
| **Program/Discipline--Element/Subdiscipline:** | | | |
| **Joint Agency Name:** | | **TechPort:** | Yes |
| **Human Research Program Elements:** | (1) **ExMC**:Exploration Medical Capabilities | | |
| **Human Research Program Risks:** | (1) **Medical Conditions**:Risk of Adverse Health Outcomes and Decrements in Performance Due to Medical Conditions that occur in Mission, as well as Long Term Health Outcomes Due to Mission Exposures | | |
| **Space Biology Element:** | None | | |
| **Space Biology Cross-Element Discipline:** | None | | |
| **Space Biology Special Category:** | None | | |
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| **Zip Code:** | 44135 | **Congressional District:** | 16 |
| **Comments:** | | | |
| **Project Type:** | GROUND | **Solicitation / Funding Source:** | Directed Research |
| **Start Date:** | 06/17/2014 | **End Date:** | 06/30/2017 |
| **No. of Post Docs:** | 0 | **No. of PhD Degrees:** | 0 |
| **No. of PhD Candidates:** | 0 | **No. of Master' Degrees:** | 0 |
| **No. of Master's Candidates:** | 0 | **No. of Bachelor's Degrees:** | 0 |
| **No. of Bachelor's Candidates:** | 0 | **Monitoring Center:** | NASA JSC |
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| **Flight Program:** | | | |
| **Flight Assignment:** | NOTE: Changed end date to 6/30/2017 (originally 8/31/2016) per discussion with PI in Jan 2017 (Ed., 3/20/17) | | |
| **Key Personnel Changes/Previous PI:** | | | |
| **COI Name (Institution):** | Zoldak, John ( Zin Technologies, Inc. ) | | |
| **Grant/Contract No.:** | Directed Research | | |
| **Performance Goal No.:** | | | |
| **Performance Goal Text:** | | | |

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| **Task Description:** | The Flexible Ultrasound System (FUS) is a technology development project that addresses NASA's gap in non-invasive diagnostic capability for imaging of internal body parts on future Exploration missions. Ultrasound will be the "workhorse" internal imaging modality on such missions due to its portability, low power consumption, and avoidance of the use of ionizing radiation. State of the art clinical ultrasound units offer excellent and ever-expanding diagnostic capabilities, but they are difficult to adapt toward accommodating novel custom scans and therapeutic algorithms developed by NASA and its research partners. The FUS-GDU (ground demonstration unit) is an effort to address this gap by introducing advanced research level system access into a clinical diagnostic scanner, while simultaneously expanding the system's functionality with additional hardware capabilities.<br>Aims:<br><br>1. To develop an open architecture ultrasound device that would provide ultrasound imaging and therapies simultaneously with a single integrated system.<br><br>2. To provide a higher degree of control over the scanning parameters and greater access to the raw ultrasound data, thereby facilitating advanced algorithm development.<br><br>3. To identify a path to qualifying medical ultrasound systems for deep space exploration missions by functioning more readily with radiation-tolerant processes.<br><br>Methods: The FUS is based on a clinical scanner, the GE Vivid-E95 with modifications to allow researchers to develop advanced algorithms. There are two separately partitioned hard drives and interfaces with which an FUS user can perform ultrasound scans.<br><br>The clinical user can scan with the FUS in the same manner as a regular Vivid-e95 machine, with all of its FDA (Food & Drug Administration) clearances intact. Research users must boot the machine into a special research mode with a dongle to invoke the applications programming interface (API) for communicating between investigator-developed software and the lower level hardware. Software development kits (SDK) provide both Matlab and C++ programming capability for investigators using FUS. Specially developed external hardware for the FUS permits the accommodation of novel ultrasound probes, higher power output level than traditional clinical scanning, and the use of a dual probe transmit/receive configuration. |
| **Rationale for HRP Directed Research:** | This research is directed because it contains highly constrained research, which requires focused and constrained data gathering and analysis that is more appropriately obtained through a non-competitive proposal |
| **Research Impact/Earth Benefits:** | The Flexible Ultrasound System (FUS) is an enabling technology for developing advanced imaging and therapeutic modalities using ultrasound. By combining a state-of-art clinical scanner with a novel research interface the FUS becomes a powerful tool and development platform for expanding the medical usefulness of ultrasound in diagnosing and treating a host of medical conditions both in space and here on Earth. The FUS's software-based beam forming, software development kit (SDK), communications pipeline, and application-specific peripheral hardware have made possible a variety of exciting technologies for use in space that will pay large dividends here on Earth, too.<br>Renal stones are a problem that plague millions of people each year. Besides being extremely painful and debilitating, stones can lead to further complications if allowed to grow to large sizes. Using the FUS, researchers have developed a novel diagnostic and therapeutic system for detecting stones while they are small, assessing their size, type, and location, and then determining the best course of action for treatment. The best course might be natural passage, or dislodging and repositioning the stones using the acoustic energy from the ultrasound probe, or a more direct intervention such as breaking the stone (lithotripsy).<br><br>Osteoporosis also affects millions of individuals, especially post-menopausal women. Bone loss can be a serious condition, leaving the individual prone to high-risk fractures and associated morbidity. Using FUS technology, we may be able to monitor bone loss in space and here on Earth with a non-invasive method that does not use ionizing radiation such as x-rays. Quantitative ultrasound (QUS) can monitor changes in bone health such as bone density and microarchitecture to help clinicians diagnose and treat bone degradation here on Earth. FUS combines QUS support with high quality clinical imaging to provide a more effective system for assessing overall bone health. Additionally, FUS can support low intensity pulsed ultrasound (LIPUS), a therapeutic use of ultrasound energy to speed healing of fracture and injury sites in the musculoskeletal system.<br><br>FUS researchers are also developing a non-invasive method for monitoring intra-cranial pressure (ICP) elevation in astronauts by measuring the geometry and shape of the eyeball. Elevated ICP is a common problem in spaceflight that can lead to visual impairment. It is also a problem that can occur on Earth due to injury, infection, or aneurysm. Detailed 3D ultrasound scans of the eye can reveal and quantify elevated ICP so that the condition may be monitored during the course of treatment.<br><br>Because FUS is software-based it can also assist with autonomous operation of clinical ultrasound by minimally trained operators. FUS can provide a number of training tools for astronauts to assist them in acquiring clinical-quality diagnostic scans in the remote environment of deep space. Goggle-based procedural guidance, image catalogs, and probe placement technologies are all ways that FUS can help both crew medical officers or medical technicians on Earth in remote environments skillfully acquire high quality ultrasound images for diagnosing a host of medical conditions.<br>Three objectives may be accomplished with this technology:<br><br>1. Develop and implement a group of vascular diagnostic methods related to health conditions on the Exploration Medicine Condition List (Carotid assessments, deep vein thrombosis-DVT, Cardiogenic shock, sudden cardiac arrest secondary to traumatic injury) and vascular access procedural guidance (central venous or arterial cannulation) utilizing the exposed API for the FUS platform.<br><br>2. Implement an Augmented Reality (AR) user interface for these vascular methods that provides procedural guidance in acquiring and initially diagnosing sonographic data for one or more ultrasound procedures to enhanced degree of procedural competency.<br><br>3. Prototype the integration of Volume Navigation on the FUS platform to allow for 3-dimensional ultrasound procedural guidance through the Head Mounted Display. |

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| **Task Progress:** | EXECUTIVE SUMMARY<br>The Flexible Ultrasound System (FUS) is a ground demonstration of software-based ultrasound technology with the simultaneous aims of providing state-of-art clinical internal imaging with additional capabilities, namely:<br><br>1. To develop an open architecture ultrasound device that would accommodate both ultrasound imaging and therapies simultaneously with a single integrated system<br><br>2. To provide a higher degree of control over the scanning parameters and greater access to the raw ultrasound data, thereby facilitating advanced algorithm development<br><br>3. To identify a path toward qualifying medical ultrasound systems for deep space exploration missions by functioning more readily with radiation-tolerant processes<br><br>4. To eventually enable such a high-capability system to be seamlessly integrated into an overall medical system for deep-space missions.<br><br>The FUS is based on the commercial GE Vivid-E95 clinical scanner. Under contract with ZIN Technologies, GE modified the Vivid-E95 by adding a separate hard drive to accommodate a novel research interface that includes software libraries for the development of novel ultrasound algorithms. FUS functions effectively as an ultrasound development platform with a choice of either a MATLAB or C++ programming interface by the user. FUS also includes novel peripheral hardware, namely a high power module for achieving higher output power and duty cycle than the clinical levels programmed into the Vivid-E95, a dual-probe adapter for performing quantitative ultrasound scans, and a special male-male DLP cable.<br><br>With this advanced capability, investigators are using FUS to detect and manipulate renal stones, assess bone health, enhance healing of musculoskeletal fracture and injury sites, monitor intracranial pressure via 3D scans of the eyeball, and provide training tools that enable minimally-trained astronauts to produce diagnostic quality ultrasound scans autonomously on deep space missions. GE has delivered the FUS hardware and associated peripherals. The three ground demonstration units have been loaned to investigators at University of Washington, Stony Brook University, and KBRWyle. As of 01 NOV 2017, it is planned to transfer custody of the #3 unit to Tietronix, Inc. Investigators are currently developing their algorithms on FUS in support of advanced medicine for NASA's missions to deep space.<br><br>2017 PROGRESS<br><br>The FUS hardware and software were all received from GE Global Research Center by the Imaging Integration team at NASA Glenn. Loan agreements with the three Principal Investigator (PI) sites (University of Washington, SUNY (State University of New York) Stony Brook, and Tietronix, Inc.) have all been set in place and the three FUS units currently reside at these PI sites. The Imaging Integration team at NASA Glenn completed the FUS Final Report, which is currently out for signature. The development of the FUS hardware and software has been completed, and the project has entered a purely operational phase of its life cycle. |
| **Bibliography Type:** | Description: (Last Updated: ) |