Fiscal Year:	FY 2010	**Task Last Updated:**	FY 08/06/2010
PI Name:	Crum, Lawrence A. Ph.D.		
Project Title:	Smart Therapeutic Ultrasound Device for Mission-Critical Medical Care		
Division Name:	Human Research		
Program/Discipline:	NSBRI		
Program/Discipline--Element/Subdiscipline:	NSBRI--Smart Medical Systems and Technology Team		
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:	98105-6606	**Congressional District:**	7
Comments:			
Project Type:	GROUND	**Solicitation / Funding Source:**	2007 Crew Health NNJ07ZSA002N
Start Date:	08/01/2008	**End Date:**	07/31/2012
No. of Post Docs:	4	**No. of PhD Degrees:**	1
No. of PhD Candidates:	3	**No. of Master' Degrees:**	0
No. of Master's Candidates:	0	**No. of Bachelor's Degrees:**	0
No. of Bachelor's Candidates:	1	**Monitoring Center:**	NSBRI
Contact Monitor:		**Contact Phone:**	
Contact Email:			
Flight Program:			
Flight Assignment:			
Key Personnel Changes/Previous PI:			
COI Name (Institution):	Bailey, Michael (University of Washington) Carter, Stephen (University of Washington) Sapozhnikov, Oleg (University of Washington)		
Grant/Contract No.:	NCC 9-58-SMST01601		
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Task Description:

The major goal of this effort is to utilize existing ultrasound platforms and the concept of image-guided therapy to control traumatic bleeding, ablate benign and malignant tumors, and to diagnose and reposition kidney stones. Our methods and devices are countermeasures to specific risks described in the Human Research Program Integrated Research Plan, viz.,
(1) Lack of advanced therapeutic capability,

(2) lack of capability to treat renal stones, and

(3) lack of non-invasive diagnostic imaging capabilities.

The original specific aims are:

Specific Aim 1: Support ongoing leveraged efforts in Acoustic Hemostasis (AH) and HIFU Tumor Ablation (TA) by addressing fundamental scientific issues as well as to ensure NSBRI relevance.

Specific Aim 2: Develop methods and technologies that would enable detection of renal stones with ultrasound.

Specific Aim 3: Develop technology and perform in vitro studies of stone comminution.

Specific Aim 4: Utilizing technology and protocols developed in SAs 2 and 3, perform in vivo studies in a porcine model.

The key findings and associated research productivity for year 1 are:

• Successfully completed a collaboration with Siemens of a DARPA-funded Phase II project to develop an automated system to detect and control bleeding on the battlefield. Phase III funding is pending. Leveraged this effort to build automated bleeding detection and ultrasound-based treatment monitoring with NSBRI funding. Paper published, presentation made, and Record of Invention submitted.

• Conducted in vitro and animal tests toward transcutaneous tumor ablation treatment with HIFU. Completing initial investigation of HIFU-induced, tumor-specific immune response in collaboration with Fred Hutchinson Cancer Research Institute and initiated a second animal study on Philips clinical HIFU system with Seattle Cancer Care Alliance. Characterized the acoustic output and optimized exposure parameters of the Philips machine. Efforts are underway for commercially sponsored clinical trials for pancreatic cancer. Utilized NSBRI funding to develop modeling and characterization tools, test ultrasound guidance, replicate acoustic output with smaller instrumentation, and initiate additional research. Papers published and others are pending approval by commercial collaborators.

• Developed new method to emulsify tissue with transcutaneous ultrasound. Our method has several potential advantages over the technique used in competitor's $11 million start-up. Our method also has promise as a potential surgical tool. Submitted provisional patent and published papers.

• Developed second prototype to detect and reposition kidney stones with ultrasound. This is a proposed new treatment for stones in microgravity for early detection as well as to reposition them near the exit of the kidney for natural clearance. It also has significant earthbound clinical and commercialization potential. Human studies of the detection algorithm have begun and approval in principle for treatment in human subjects has been granted pending final acoustic output measurements. Safety and efficacy has been demonstrated in pigs. An intellectual-property package has been prepared by UW for potential licensing. A business/commercialization plan has been developed. A commercial partner has been identified and initial investigation into the regulatory and reimbursement pathways has taken place. This information was shared during NASA's meetings to identify the next ultrasound system for ISS as our capabilities to address gaps could be integrated directly into certain existing ultrasound systems.

• A miniaturized device to size stone fragments for safe extraction has been tested in a porcine kidney: Submitted U.S. utility patent application and published paper. This topic has been the subject of licensing negotiations between the University of Washington and a potential commercial sponsor.

Ultrasound for treating bleeding, benign and malignant tumors, and stone disease are revolutionary therapies; as such, our approach is to leverage funding to demonstrate that they are clinically safe and efficacious. In particular, we utilized NSBRI funding to understand the acoustic exposures needed to develop light-weight instrumentation for potential use in microgravity. NSBRI has also embraced the commercialization of our system to detect and reposition stones, and great progress has been made this year. The earthbound, as well as the space application is to enable the passage of stones and residual fragments and thus prevent complications from impacted stones. We licensed revolutionary diagnostic ultrasound hardware from an Original Equipment Manufacturer and added a few changes of our own. With NSBRI's help, we made the case that if similar hardware were selected as the ultrasound system on ISS, our capability to detect and treat stones could be immediately deployed (TRL/CRL level 9) for emergency treatment of urolithiasis.

To summarize, in our acoustic hemostasis effort, we have results ready to publish, expect to continue our substantial DARPA-funded effort working toward human subjects testing, and will utilize our NSBRI-developed systems in animal studies. On our HIFU ablation studies, animal experiments should soon be completed and published this year, and all pieces should be in place for and IDE/IRB to initiate human studies. On stone disease, our device is expected to be tested on human subjects; a new transducer will be developed; acoustic output characterization for regulatory approval will begin, and it is planned to transfer some of this technology to a new start-up.

Rationale for HRP Directed Research:

We have been encouraged by our interactions with the urology, ultrasound, and business communities that our technology to detect and reposition stones could significantly alter the way kidney stones are treated on Earth. We have won awards in the four poster or business plan competitions we have entered. Most stones are small enough to pass naturally and thus patients are encouraged, through hydration and a drug Flomax, to try to pass the stone without intervention. This natural process might take 6-8 weeks and result in considerable discomfort to the patient over this interval. With our technology, the stone could potentially be cleared in the first office visit. Many stones do not clear with hydration, and thus more aggressive approaches are required. More invasive procedures are often necessary if the stone is in the lower pole because even if fragmented the pieces are unlikely to pass from this location. Our technology might keep the least invasive option open for these patients. In most existing procedures, there is a significant chance

Research Impact/Earth Benefits:	stone pieces will remain behind as seeds for future stones and further surgery. Our technology could help these pieces pass. In addition, stones are often recurrent; recurring-stone patients are often monitored, so that new stones can be detected early - this monitoring could be done in astronauts with our precise stone imaging approach. Our technology could also move these stones to the kidney exit before they are symptomatic. This technology reduces risk of surgery, complications of surgery for the patient, and the cost of surgery to the insurance companies; furthermore, the technology does not preclude any surgical options. Lastly, the algorithms to detect kidney stones alone stand to spare many patients the ionizing radiation of a CT scan or provide options to pregnant women or children with stones who are unlikely to receive CT. NSBRI quickly recognized the value of this technology and help us initiate our commercialization effort that now has the full support of the UW, the Washington Research Foundation, and a commercial hardware provider as well as the interest of several venture capitalists and ultrasound companies. The applications of our technology to the control of bleeding and for tumor ablation are at least as profound. Specifically, this year we have worked with the latest clinical HIFU machine - one developed by Philips Medical. This machine is intended for many clinical applications. We have used some of our effort to characterize the output of the machine and assess its potential bio-effects. Our work provides the clinicians, who intend to use this machine, the ability to select a thermal dose. At UW alone, it helps train the clinicians and establish the specificity of what size targets are treated. With our contribution, the clinicians are then likely to pursue their own clinical studies and with Philips backing regulatory approval for various tumor treatments. Before our involvement, the machine sat dormant for a year. We are also exploring the effect of HIFU on the immune system and have proposed clinical trials to combine HIFU with chemotherapy agents. We believe that our efforts to carefully describe outputs and bio-effects will help the US catch up with the rest of the world where over 400,000 patients have been treated by HIFU. In addition, our intimate knowledge of these details enable us to consider ways in which a similar, much reduced-in-size system could be developed for NASA to reduce some major risks to astronauts. The control of bleeding with ultrasound has great potential to save lives from both civilian and battlefield trauma. Our most directed work leverages DARPA funding and is in partnership with a commercial entity. This ambitious project seeks to develop a fully autonomous system that would both detect bleeding and induce hemostasis without major user involvement.
Task Progress:	Task 1A. Perform studies of bleeding detection in a flow-phantom model. Successfully detected and treated sites in a phantom developed with DARPA and FDA in a blind test with an automated system. Task 1B. Perform studies to determine pressure and temperature in ex vivo tissue exposed to HIFU. Paper M.S. Canney, et al., "Millisecond boiling produced by high intensity focused ultrasound," Ultrasound Med. Biol., 2009 and others led to invitation to join IEC working group on HIFU standards and to measure acoustic output of Philips clinical HIFU machine. Also, discovered method to emulsify tissue with ultrasound. Task 2A. Develop new stone detection techniques based on radiation force and reverberation responsible for twinkling artifact and vibroacoustography. As part of our graduate student's dissertation, efforts continue to understand the origins of the twinkling artifact and to further refine the algorithms we have developed, implemented, tested, and submitted to UW for patent submission. Task 2B. Test stone sizing technology in tissue. Published paper M.D. Sorensen, et al., "A Proof of Principle of a Prototype Ultrasound Technology to Size Stone Fragments During Ureteroscopy," J. Endourology 2010; filed U.S. and international utility patent applications, and are negotiating licensing. Task 3A. Utilize the YUANDE HIFU tumor ablation device as a platform for determining the acoustic protocols necessary for ultrasound-based stone comminution. This project is ongoing. Task 3B. Engineer and optimize an image-guided, two-frequency HIFU system for renal stone comminution. We have focused on moving small stones within the kidney with ultrasound to facilitate natural stone clearance. A system to detect and reposition stones based on an OEM diagnostic ultrasound platform has been built and demonstrated to be safe and effective in a porcine model. Commercialization effort has begun. Results were reported at the American Urology and Laparoendoscopy Society meetings. Efforts to generate shorter higher amplitude pulses such as those used in shock wave lithotripsy (SWL) to break stones have begun, both to add a useful capability as well as to pursue a SWL regulatory pathway. Task 4A. Perform in vivo tests of the imaging protocols developed in Task 2. Paper in preparation comparing twinkling to standard B-mode for stone detection in patients. New algorithm for stone detection implemented on clinical machine and tests of the algorithm initiated on human subjects. Task 4B. Perform studies to determine the potential for HIFU-induced stone comminution as well as any associated tissue injury. In vivo studies of our stone clearance system have been shown to be safe and effective. A new assay and ultrasound imaging technology are being tested by a graduate student to quantify tissue injury. Stone clearance and injury measurements will begin on human subjects.
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