Fiscal Year:	FY 2012	Task Last Updated:	FY 01/11/2013
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:	NSBRISmart Medical Systems and	Technology Team	
Joint Agency Name:		TechPort:	Yes
Human Research Program Elements:	(1) ExMC:Exploration Medical Capa	bilities	
Human Research Program Risks:		erse Health Outcomes and Decrements in g Term Health Outcomes Due to Mission I	
Space Biology Element:	None		
Space Biology Cross-Element Discipline:	None		
Space Biology Special Category:	None		
PI Email:	lac@apl.washington.edu	Fax:	FY 206-543-3702
PI Organization Type:	UNIVERSITY	Phone:	206-685-8622
Organization Name:	University of Washington		
PI Address 1:	Applied Physics Laboratory		
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City:	Seattle	State:	WA
Zip Code:	98105-6606	<b>Congressional District:</b>	7
Comments:			
Project Type:	GROUND	Solicitation / Funding Source:	2007 Crew Health NNJ07ZSA002N
Start Date:	08/01/2008	End Date:	09/30/2012
No. of Post Docs:	3	No. of PhD Degrees:	1
No. of PhD Candidates:	1	No. of Master' Degrees:	0
No. of Master's Candidates:	1	No. of Bachelor's Degrees:	0
No. of Bachelor's Candidates:	3	Monitoring Center:	NSBRI
Contact Monitor:		Contact Phone:	
Contact Email:			
Flight Program:			
Flight Assignment:	NOTE: End date should be 9/30/2012	(previously 7/31/2012) per NSBRI (Ed.,	5/22/2012)
Key Personnel Changes/Previous PI:			
COI Name (Institution):	Bailey, Michael (University of Was Carter, Stephen (University of Wasl Sapozhnikov, Oleg (University of W	nington)	
Grant/Contract No.:	NCC 9-58-SMST01601		
Performance Goal No.:			
Performance Goal Text:			

Task Description:	The major goal of this effort is to utilize existing ultrasound platforms and the concept of image-guided theory to address (1) Lack of advanced therapeutic capability, (2) lack of capability to treat renal stones, and (3) lack of non-invasive diagnostic imaging capabilitiss. The original specific aims (SA)s are 1) Support ongoing leveraged efforts in Acoustic Hemostasis and High-intensity Focused Ultrasound (HIEU) Tumor Ablation by addressing fundamental scientific issues as well as to ensure National Space Biomedical Research Institute (SNBR) relevance. 2) Develop methods and technologies that would enable detection of renal stones with ultrasound. 3) Develop technology and perform in vito studies of stone comminution. 4) Ultilizing technology and perfoso developed in NaSA 2 and 3. perform in vito studies in a porcine model. The main findings and associated research productivity for year 4 are: - We have cominued to advance ultrasound technology to detect and reposition kindney stones. The imaging technology provides an alternative to imaging technology to detect user and stones before they require sargery. The technology is also used to move a large obstructing stone to a non-obstructing location to delay the need for sargery. The tote-mology is also used to move a large obstructing stone to a non-obstructing location to delay the need for sargery. The tote-mology is also used to move a large obstructing stone to a non-obstructing location to delay the need for sargery. The tote-mology is also used to move a large obstructing stone to an on-obstructing location to delay the need for sargery. The tote-mology is also used to move a large obstructing stone and main the delay the provision and the stones in the uterk: - • Oveothepda to the solicitation for a Flexible Ultrasound System (FUS), both as leaders in the platform and inventors of a needot of an device to characterize the acoustic output of high intensity focused ultrasound (HIFU) devices. The University of Washington (UW) Center for Com
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## **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 in clinical medicine. We have won awards in the six poster or business plan competitions we have entered. Most stones are small enough to pass naturally and thus patients are encouraged, through hydration, 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 innovative technology, a 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 technological approach would keep the least invasive option open for these patients. In most existing procedures, there is a significant chance 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

Research Impact/Earth Benefits:	stones can be detected early—this monitoring could be done 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 to provide options to pregnant women or children with stones who are unlikely to receive CT. NSBRI quickly recognized the value of this technology and helped 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 treatment dose. At UW alone, it helps train the clinicians and establish the specificity of what size targets are treated. With our ontribution, the clinicians are then likely to pursue their own clinical studies, and regulatory approval for various tumor treatments. Before our involvement, the machine sat dormant for a year. We are also exploring the effects of HIFU on the immune system and have proposed clinical trials to combine HIFU with chemical therapeutic agents. We believe that our efforts to carefully describe outputs and bio-effects will help the U.S. catch up with the rest of the world where over 400,000 patients have been treated by HI
	<ul> <li>Task 1A. Perform studies of bleeding detection in a flow-phantom model: Successfully detected and treated sites in a phantom developed with Defense Advanced Research Projects Agency (DARPA) and FDA in a blind test with an automated system.</li> <li>Task 1B. Perform studies to determine pressure and temperature in ex vivo tissue exposed to HIFU: Published several papers, which led to invitation to join IEC (International Electrotechnical Commission) working group on HIFU standards and the AIUM (American Institute of Ultrasound in Medicine) sub-committee on Transiently Increased Outputs, and to measure acoustic output of Philips clinical HIFU machine. Also, discovered and submitted patent application for a method to emulsify tissue with ultrasound.</li> </ul>
	Task 2A. Develop new stone detection techniques based on radiation force and reverberation responsible for twinkling artifact: As part of our graduate student's dissertation, discovered that bubbles are responsible for the twinkling artifact. We have developed, implemented, tested, and patented new software to better detect stones.
	Task 2B. Test stone sizing technology in tissue: Published paper, filed U.S. and international utility patent applications, and are negotiating licensing. We have initiated human clinical studies to test ultrasound stone sizing versus CT.
	Task 3A. We utilized the YUANDE HIFU tumor ablation device as a test platform: Performed a number of studies.
Task Progress:	Task 3B. Engineer and optimize an image-guided, two-frequency HIFU system for renal stone comminution: We will work with Exploration Medical Capabilities (ExMC) Human Research Program Element to implement on the FUS system capability to detect, reposition, and comminute stones. All are implemented in a prototype for which we are pursuing an investigational device exemption (IDE) with the FDA. We have developed a concept of expelling small stones from a kidney before they require comminution or surgery. 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 studies in a porcine model. Commercialization efforts are well underway. Our technology was called a "game changer" in the plenary session of the American Urological Association (AUA) Annual meeting in May 2012.
	Task 4A. Perform in vivo tests of the imaging protocols developed in Task 2: our paper is in press 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. Data from 15 subjects has been collected.
	Task 4B. Performed studies to determine the potential for HIFU-induced stone comminution as well as any associated tissue injury. We used our stone repositioning system to fragment stones in an excised porcine kidney in which they were grown. In vivo tests scheduled for Oct 22, 2012. In vivo studies of our stone clearance system have been shown to be safe and effective. Several studies of safety in pigs have been complete and are in press. These data have been presented to the FDA as part of our application for investigational device exemption for a human feasibility study.
Bibliography Type:	Description: (Last Updated: 03/22/2019)
Abstracts for Journals and Proceedings	Dunmire B, Sorensen MD, Hsi R, Kucewicz, J, Bailey M, Cunitz B, Harper J. "Overestimation of Kidney Stone Size Increases with Depth and Gain Ultrasound-Induced Renal Injury Threshold." 88th Annual Meeting, Western Section of the American Urological Association, Waikoloa, Hawaii, October 7-12, 2012. 88th Annual Meeting, Western Section of the American Urological Association, Waikoloa, Hawaii, October 7-12, 2012. , Oct-2012
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Abstracts for Journals and Proceedings	<ul> <li>Harper JD, Sorensen MD, Hsi R, Cunitz B, Simon J, Wang YN, Paun M, Starr F, Lu W, Evan A, Bailey M. "Preclinical testing of ultrasonic propulsion of kidney stones." 2012 IEEE International Ultrasonics Symposium (IUS), Dresden Germany, October 7-10, 2012.</li> <li>2012 IEEE International Ultrasonics Symposium (IUS), Dresden Germany, October 7-10, 2012. , Oct-2012</li> </ul>

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Abstracts for Journals and Proceedings	Khokhlova VA, Yuldashev PV, Kreider W, Bailey MR, Sapozhnikov OA, Crum LA. "Combined modeling and measurement methods to calibrate nonlinear acoustic fields of HIFU transducers," 12th International Symposium on Therapeutic Ultrasound, Heidelberg, Germany, June 10-13, 2012. 12th International Symposium on Therapeutic Ultrasound, Heidelberg, Germany, June 10-13, 2012. Abstract A-211., Jun-2012
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Articles in Peer-reviewed Journals	Simon JC, Sapozhnikov OA, Wang YN, Khokhlova VA, Crum LA, Bailey MR. "Investigation into the mechanisms of tissue atomization by high-intensity focused ultrasound." Ultrasound Med Biol. 2015 May;41(5):1372-85. http://dx.doi.org/10.1016/j.ultrasmedbio.2014.12.022 ; PubMed PMID: 25662182; PubMed Central PMCID: PMC4398613 , May-2015
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Awards	Simon J. "Runner-up, UW Student Entrepreneurial and Business Association business plan competition, September 2011." Sep-2011
Awards	Simon J. "University of Washington College of Engineering Dean's Fellowship, August 2012." Aug-2012
Awards	Simon J. "UW (University of Washington) Invents Graduate Student Award, February 2012." Feb-2012
Awards	Crum L. "Awarded the Acoustical Society of America's Gold Medal, June 2013." Jun-2013
Awards	Crum L, Bailey M, Simon J. "Best Poster, Society for Engineering and Urology, Annual meeting, May 2012." May-2012
Awards	Bailey M. "Appointed to Membership Committee of the Acoustical Society of America, October 2012." Oct-2012
Awards	Bailey M. "Awarded UW Applied Physics Laboratory Science and Technology Award, December 2011." Dec-2011
Awards	Bailey M. "Member of Transiently Increased Output (TIO) subcommittee of the American Institute of Ultrasound in Medicine, April 2012." Apr-2012
Awards	Khokhlova V. "Elected to Acoustical Society of America Executive Council, May 2012." May-2012
Awards	Khokhlova V. "Elected to Board of the International Society for Therapeutic Ultrasound, April 2012." Apr-2012
Awards	Lu W. "UW Invents Graduate Student Award. UW decided to give 2 awards instead of the usual 1 award; the other award was to student Julianna Simon. February 2012." Feb-2012
Awards	Sorensen MD, Harper JD, Hsi R, Cunitz B, Simon J, Wang YN, Paun M, Starr F, Lu W, Evan A, Bailey M. "2012 Best Poster and Invited Talk for 'Preclinical Efficacy and Safety of Ultrasonic Propulsion of Kidney Stones,' Society of Engineering and Urology, 27th Annual meeting, Atlanta, GA, May 19, 2012." May-2012
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