Fiscal Year:	FY 2014	**Task Last Updated:**	FY 07/23/2014
PI Name:	Levinson, Mitchell M.S.		
Project Title:	Preventing Secondary Brain Injury by Early Detection of Cerebral Bleeding and Edema		
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) **HHC**:Human Health Countermeasures		
Human Research Program Risks:	(1) **SANS**:Risk of Spaceflight Associated Neuro-ocular Syndrome (SANS)		
Space Biology Element:	None		
Space Biology Cross-Element Discipline:	None		
Space Biology Special Category:	None		
PI Email:	mlevinson@cerebrotechmedical.com	**Fax:**	FY
PI Organization Type:	INDUSTRY	**Phone:**	925-399-5392
Organization Name:	Cerebrotech Medical Systems, Inc.		
PI Address 1:	1249 Quarry Lane Suite 120		
PI Address 2:			
PI Web Page:			
City:	Pleasanton	**State:**	CA
Zip Code:	94566	**Congressional District:**	15
Comments:			
Project Type:	Ground	**Solicitation / Funding Source:**	NSBRI-RFA-SMARTCAP
Start Date:	04/01/2013	**End Date:**	03/31/2014
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:**	NSBRI
Contact Monitor:		**Contact Phone:**	
Contact Email:			
Flight Program:			
Flight Assignment:			
Key Personnel Changes/Previous PI:			
COI Name (Institution):			
Grant/Contract No.:	NCC 9-58-SMST03301		
Performance Goal No.:			
Performance Goal Text:			

Task Description:	The goal of this project was to 1) improve the Cerebrotech Intracranial Fluid Monitor clinical prototype device design and 2) establish human feasibility through clinical trials. Both objectives have been achieved. The prototype was improved by 1) redesigning the mechanical patient interface, 2) improving the electronics to maximize signal-to-noise ratio, and 3) developing algorithms to correlate the intracranial fluid (ICF) volume measurements to intracranial pressure (ICP) measurements on patients in the ICU (Intensive Care Unit) with severe brain injuries. The study results demonstrate that ICF measurements correlate linearly with ICP in patients exhibiting good intracranial compliance. And, conversely, patients with poor intracranial compliance display a poor correlation of ICF to ICP. These results confirm our original hypothesis based on established neuroscience, and demonstrate the feasibility of non-invasive ICF monitoring using Volumetric Integral Phase-shift Spectroscopy (VIPS) technology. We believe our study was the first to demonstrate the relationship of intracranial fluid volume and pressure using real-time, continuous ICP and ICF measurements in human patients with brain injury. Continued clinical research and validation is warranted. A proposed research plan for the coming year has been detailed in the March 24, 2014 proposal entitled, "Noninvasive Self-Contained Helmet Intracranial Fluid Monitor." Device iteration and development of a prototype helmet will demonstrate feasibility of a device configuration compatible with use in the International Space Station (ISS). Earth-based clinical validation of the prototype will be performed in association with the Baylor College of Medicine.
Rationale for HRP Directed Research:	
Research Impact/Earth Benefits:	There is a glaring gap in diagnosing and monitoring patients for brain edema and bleeding. At most, CT (computed tomography) and MRI (magnetic resonance imaging) only provide daily snapshots, and other probes like intracranial pressure (ICP) monitors are extremely invasive and are only used in the most serious cases. Most patients are left largely unmonitored in their hospital beds, except for periodic subjective clinical neurological exams, leaving them exposed to a risk of undetected brain edema or bleeding, until it causes a significant and detectable neurological deficit—and by then it is too late. Cerebrotech will offer a completely noninvasive device for monitoring small changes in brain edema and bleeding, which will provide a continuous and objective measure of brain fluids and ischemia at the patient's bedside. Patients include over 3 million admitted each year worldwide for stroke, traumatic brain injury, brain surgery, and other disorders that place them at high risk for clinical degradation. Early detection of adverse changes in patient condition is the key to improving outcomes and reducing cost for hospitals and payers.
Task Progress:	The goal of this project was to 1) improve the Cerebrotech Intracranial Fluid Monitor clinical prototype device design and 2) establish human feasibility through clinical trials. Both objectives have been achieved. The prototype was improved by 1) redesigning the mechanical patient interface, 2) improving the electronics to maximize signal-to-noise ratio, and 3) developing algorithms to correlate the intracranial fluid volume (ICF) measurements to intracranial pressure (ICP) measurements on patients in the ICU with severe brain injuries. The study results demonstrate that ICF measurements correlate linearly with ICP in patients exhibiting good intracranial compliance. And, conversely, patients with poor intracranial compliance display a poor correlation of ICF to ICP. These results confirm our original hypothesis based on established neuroscience, and demonstrate the feasibility of non-invasive ICF monitoring using VIPS technology. We believe our study was the first to demonstrate the relationship of intracranial fluid volume and pressure using real-time, continuous ICP and ICF measurements in human patients with brain injury. Continued clinical research and validation is warranted.
Bibliography Type:	Description: (Last Updated:)