Fiscal Year:	FY 2015	**Task Last Updated:**	FY 04/29/2015
PI Name:	Winther, Sean B.S.		
Project Title:	Biosensors for Exploration Medical 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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Organization Name:	CSS-Dynamac/NASA Ames Research Center		
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City:	Moffett Field	**State:**	CA
Zip Code:	94035	**Congressional District:**	18
Comments:			
Project Type:	FLIGHT,GROUND	**Solicitation / Funding Source:**	Directed Research
Start Date:	07/01/2011	**End Date:**	06/30/2016
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:	ISS		
Flight Assignment:	NOTE: Project completed and transferred to Medical Operations; closeout as of 6/30/2016 (original end date was 9/30/2018) (Ed., 4/4/18)		
Key Personnel Changes/Previous PI:			
COI Name (Institution):	Toscano, William (NASA Ames Research Center)		
Grant/Contract No.:	Directed Research		
Performance Goal No.:			
Performance Goal Text:			

Task Description:	The current International Space Station (ISS) electrocardiogram (ECG) system for donning the biomedical sensors is time consuming and inconvenient, requiring shaving, application of electrodes, and signal checks. A more efficient ECG system will save crew time and reduce the overhead of stowing additional supplies. Additionally, the current ECG hardware requires dedicated ISS power and significant volume, but advances in microelectronics has significantly reduced the volume and power required for ECG applications. The Biosensors-EMSD (Exploration Medical System Demonstration) will demonstrate the integration of small, battery powered, easy to use biomedical sensors and data acquisition devices that will have the ability to measure, store, and transmit physiologic parameters during operational and ambulatory scenarios. Specific Aims: 1. Demonstrate that commercial off the shelf (COTS) and emerging technologies satisfy exploration physiological monitoring requirements and operational requirements 2. Reduce the time required of an on-orbit crew and ground personnel to store, access, transfer, and process physiological data 3. Provide a mechanism for interfacing biomedical sensor technology with a common data management framework and architecture to enable the EMSD objectives. The functionality of the ECG system will be verified through a ground demonstration and an ISS flight demonstration, both as part of the Exploration Medical System Demonstration. The project will begin with a market survey of available COTS ECG systems that meet physiological monitoring requirements followed by a direct COTS procurement. The ECG system will then be tested and verified for proper capabilities by CMO analogs. Ground testing will require CMO analogs to don the ECG system and execute a series of predetermined tasks while a variety of ECG data and video is collected. ECG data and video will be examined to ensure data quality, appropriate data routing, and to demonstrate system efficiency. Flight testing will be similar to ground testing, but may not be as comprehensive given in-flight resource limitations. The availability of more varied medical condition simulations, more extensive supply of power, fewer time and space limitations, and enhanced system characterization capabilities will allow the ground demonstration to expand the on-orbit objectives by assessing system effectiveness and performance.
Rationale for HRP Directed Research:	The study team is uniquely positioned to perform this function because the physiological monitoring requirements and operational requirements needed for this task require specialized information that is unique to NASA. The study team will also help ensure that the ECG component of the overall Exploration Medical System Demonstration (EMSD) is well integrated with other components of the system.
Research Impact/Earth Benefits:	Our purpose is to better equip crew member medical monitoring for future exploration missions.
Task Progress:	Biosensors for Exploration Medical System Demonstration Electrocardiograph (EMSD ECG) Performance Goal: For an exploration mission, NASA needs a health monitoring system composed of hardware that is compact, fully interoperable with an integrated data management system, and requires minimal consumables. This system will be achieved through the integration of small, easy to use biomedical sensors that will have the ability to measure, store, and transmit physiologic parameters during operational and ambulatory scenarios. Among the parameters of interest are key physiological signals that indicate crewmembers' work load and other physiologic parameters, including electrocardiogram (ECG). Task Description: To address limitations of the current ECG system on the International Space Station (ISS) and specifically Human Research Program (HRP) Exploration Medical Capability (ExMC) Risk #95 "risk of unacceptable health and mission outcomes due to limitations of in-flight medical capabilities" the EMSD ECG project team at Ames Research Center (ARC) has developed a 12 lead ECG dry electrode harness system that meets requirements for both 12-lead diagnostic and reduced lead personal fitness evaluations. A flight technology demonstration is planned in fiscal year (FY)16 to evaluate the EMSD ECG system with ISS crew and obtain high fidelity data that will support decisions for transitioning the system to operational use. Additionally, evaluation on board the ISS is necessary to demonstrate operational feasibility including wireless operations in the ISS environment, and the crew's ability to successfully don the ECG harness assembly and operate the ECG device with only procedural guidance. This evaluation is required to validate the system in a relevant environment and to elevate the system to a technology readiness level (TRL) 7. The Flight demonstration contributes to closing ExMC Gap 4.19: We do not have the capability to monitor physiological parameters in a minimally invasive manner during exploration missions. Task Progress: ECG Harness Development: The Exploration Medical Capabilities (ExMC) Element at Ames Research Center entered into a contract with NimbleHeart on October 2014 to design and develop a prototype 12-lead dry electrode harness for the Exploration Medical System Demonstration (EMSD) Electrocardiogram (ECG) system. The goals of the project were to deliver a harness designed for both ambulatory and diagnostic use scenarios, while also being compatible with dry electrodes and the IMED Cardiax ECG device. The research and development phase was completed on December 1, 2014 when the vendor finalized their physical design and materials selection. The initial prototype was completed and demonstrated on January 26, 2015. Following the prototype demonstration, additional evaluations were performed in the Biosensors Lab at Ames Research Center to address fit and signal quality. The vendor will be providing small, medium, and large harnesses based on gender in an attempt to encompass the size range of the astronaut corps. Delivery for both male and female medium harnesses was April 28, 2016, with additional sizes to be delivered at a later date. Procedure Development and Demonstration: Functional tests procedures were developed for both the ECG device and dry electrode harness. Procedures were written for each test to fully satisfy qualification and acceptance for flight. Ground demonstrations procedures were developed and tested as a foundation for flight procedures. Flight procedures will be completed upon final delivery of harnesses from vendor. In preparation of the EMSD Ground demonstration, the ARC ExMC team traveled to Johnson Space Center (JSC) in September, 2014 and provided ECG hardware and software

	training and support to the JSC team. An end-to-end validation of the ground demonstration procedures was also provided. Flight Certification: The flight safety data package 0/I/II was completed and submitted for review. An RF (radio frequency) agreement has been approved and is in place for use of on-station wireless frequency. EMI (electromagnetic interference) testing was only required for the ECG device. EMI testing was completed for emission and susceptibility, and the ECG device passed without any concerns. Flight Protocol Approval: Notification of Approval was received from JSC's IRB (Institutional Review Board) on March 10, 2015. Protocol Number: Pro1569; NASA MPA Number: NASA 7116301606HR; FWA Number: 00019876. Upcoming: 5/19-21/15 ARC ExMC site visit to JSC; The ARC ExMC team will conduct a demonstration of the EMSD ECG and 12-Lead dry electrode harness at JSC on May 19, 2015. The team will meet with the Exercise Physiology Lab, medical operational physicians, engineers, and other technical staff representing the Health Maintenance System (HMS) and Countermeasures System (CMS) as part of an assessment of potential use of the system after the ExMC EMSD ECG in-flight demonstration scheduled for FY16. In addition, the EMSD ECG team will participate in flight certification activities including the Payload Safety Review Panel Review also on 5/19 and discussions with representatives from the Human Factors Implementation Team (HFIT) and ISS Payload Label Team (IPLAT) in support of completing ISS flight certification activities.
Bibliography Type:	Description: (Last Updated:)