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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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Zip Code:	94035	**Congressional District:**	18
Comments:			
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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:	NOTE: Original PI was Fritz Moore. Sean Winther took over the project in early 2014.		
COI Name (Institution):			
Grant/Contract No.:	Directed Research		
Performance Goal No.:			
Performance Goal Text:			

Task Description:	NOTE: Original PI was Fritz Moore. Sean Winther took over the project in early 2014. The current ISS 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 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.
	Dry Electrode Evaluation and Recommendation: The Exploration Medical Capability (ExMC) Element of the Human Research Program has a need to develop requirements for a suite of medical capabilities for Exploration Missions. The Intravehicular Physiological Monitoring System (IPMS) project addresses the ExMC Gap 4.19: Limited Biomedical Sensing Capabilities for Intravehicular Activities (such as Performing Periodic Clinical Status Evaluations and Contingency Medical Monitoring). The IPMS project focuses on the assessment of commercial off the shelf (COTS) products and identifies emerging technologies that augment current physiological monitoring and diagnostic capabilities to meet Exploration Mission needs. The use of dry electrode technology with Electrocardiogram (ECG) measurements has the potential to minimize both consumables and crew time and address problematic issues related to skin preparation and irritation currently experienced with traditional wet gel based ECG electrodes. Based on the testing and evaluation described in this recommendation report, the Cognionics dry electrode is recommended for advancement to Exploration Medical System Demonstration (EMSD) ground system testing in 2014 and potential use in a flight demonstration in 2016. We have produced a Recommendation Report for the EMSD Dry Electrodes that provides a summary of the performance of several dry electrode brands. A description of the test methods, test data, and decision matrix scores with weights for candidate dry electrodes are included. Evaluation of physical characteristics and electrical performance testing were used to rank the electrodes and recommend the most promising candidate. A decision is required to select and advance the Cognionics dry electrodes to EMSD system level testing. Exploration mission architecture limits the medical equipment, consumables, and procedures that will be available to treat medical conditions during human exploration missions. These missions will require hardware with long operational life, as there will be few resupply and refurbishment opportunities. The ExMC Operational Concept Document (JSC-6021) identifies the desire to minimize skin preparation and reduce discomfort by avoiding wet gel electrodes for the IPMS. The operational concept for the IPMS addresses ExMC Gap 4.19 with the following targeted closure goals: reusability and long operational life, reduced consumables (absence of gels, solvents, or adhesives), reduced potential for irritation or discomfort, and reduced crew time. Derived goals include a format that allows the use of an easy to don harness that correctly orients the electrodes on the body. Conventional wet gel electrodes are single use items that have limited shelf life and use adhesive and gel materials which can cause discomfort and skin irritations. Dry electrodes used with ECG have the potential to minimize consumables because they are reusable and do not require as much skin preparation which also reduces crew time for application. In addition, dry electrodes offer the additional advantage of reducing skin irritation associated with skin preparation, adhesives, and electrolyte gels. Although dry electrode technology has been around for a number of years, inferior electrical performance has previously limited their use in clinical applications (Chi) 2010. Recent market surveys suggest that current dry electrode performance may now be adequate for use in critical monitoring and diagnostic use. Still, there is limited market presence and availability and the market viability for dry electrodes is not well known. Objective performance metrics have not been available. The IPMS market survey identified an initial set of candidate dry electrodes for possible evaluation. Candidates to undergo further testing were identified based on their commercial availability, development in SBIR funding grants, and

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recommendation by subject matter experts. All three electrodes considered in this report (Nanosonics, Orbital, and Cognionics) were developed through NASA, SBIR funding opportunities.

The Cognionics dry contact electrode is recommended as the primary candidate for system testing and evaluation. Because all of the candidates have limited market presence and unknown market viability and availability it is also recommended that the Orbital dry electrode is advanced to system testing as an alternate candidate. The decision matrix rankings and final cumulative scores indicate that the Cognionics electrode is the overall higher performing electrode with respect to electrical performance. Not only did it have a higher cumulative score but it also was ranked the highest in each of the electrical performance tests that were scored. Considering that the EMSD is a one-time use demonstration, the appropriate storing conditions can be met. Based on observations in the lab, we expect that the Cognionics electrode is a good choice to demonstrate the potential use of dry electrodes. The Orbital ranked second in each of the electrical performance tests but was the overall higher performing electrode in physical attributes and characteristics because of its decreased dependency on environmental storage conditions.

Electrocardiograph Device Evaluation and Recommendation:

The Recommendation Report for the EMSD ECG that we produced provides a summary of the performance of two wireless PC based ECG units as well as a cable connected (USB) PC based ECG (Imed, CARDIAX Model-USB only). This unit has been on the market for several years and used extensively by Todd Schlegel, MD, a subject matter expert at JSC. A description of the test methods, test data, and decision matrix scores with weights for candidate ECG units are provided. Evaluation of physical characteristics and electrical performance testing were used to rank the ECG units and recommend the most promising candidate. A decision is required to select and advance the Imed CARDIAX PC Based Electrocardiograph Model WiFi/USB to EMSD system level testing.

Exploration mission architecture limits the medical equipment, consumables, and procedures that will be available to treat medical conditions during human exploration missions. These missions will require hardware with long operational life, and improved interoperability and resource sharing with onboard systems. Additionally the operational concept for the IPMS addresses ExMC Gap 4.19 with the following targeted ECG electrode closure goals: reusability and long operational life, reduced consumables (absence of gels, solvents or adhesives), reduced potential for irritation or discomfort, and reduced crew time. Recent dry electrode technology developments have the potential to meet these needs. However, dry ECG electrodes have inherently higher skin contact impedance than conventional wet-gel ECG electrodes therefore it is important to verify their performance with prospective host ECG devices. Selection of a candidate ECG device is necessary so that system testing with the candidate dry electrode can proceed.

The IPMS market survey and conversations with subject matter experts identified an initial set of candidate ECG devices for possible evaluation. Candidates to undergo further testing were identified based on their commercial availability, wireless connectivity, and potential for interconnectivity with electronic medical systems.

Imed’s CARDIAX PC Based Electrocardiograph Model WiFi/USB is recommended as the exclusive candidate for system testing and evaluation. Not only did the CARDIAX unit outscore the Corescience, BT-12 in every test and in cumulative ranking but also it has several key features that will help assure its success in eventual ground or flight demonstrations as well as in use with dry reusable electrodes. The presence of a redundant connection on the CARDIAX unit, which is hard wired, greatly reduces risk from unforeseen wireless interference. Additionally the absence of a non-defeatable “lead-off” detector makes it a much better candidate for dry reusable electrodes.

Combined System testing of Dry Electrodes and ECG device:

EMSD ECG combined system testing was conducted following ECG electrode and ECG device component selection to check compatibility between Imed’s Cardiax ECG device and Cognionic’s dry contact ECG electrodes. The testing was undertaken to screen for interactive effects which could compromise system performance and to provide baseline data for evaluation of dry electrode harnesses. The system testing was not designed to produce definitive performance metrics but rather as a spot check to identify any large performance discrepancies that result from component interactions before additional resources are used to develop a harness for this system.

The results suggest that there is a great deal of similarity in ECG traces obtained with the Cardiax/Dry and Cardiax/Wet ECG systems when subject motion is carefully controlled.

1. Visual form is well conserved with regards to amplitude and phase and was considered comparable in subjective visual comparisons.

2. Results indicate R wave detection was also adequate with all target R peaks being identified by both the Cardiax/Wet and Cardiax/Dry systems. R-R interval calculations also agreed well between systems and when compared to an algorithm optimized for the stationary studies.

3. Results indicate baseline wander amplitude was greater in the Cardiax/Dry system, a problem we have observed previously in the laboratory and with dry electrodes in general. We believe the baseline wander is largely the result of motion which results from breathing and low level tremor or postural motion. A primary goal of harness development is the minimization of motion related ECG noise which presumably results from impedance variations at the less compliant dry electrode-skin junction.

4. Results indicate a decrease in high frequency noise amplitude when using the Cardiax/Dry system and was an unexpected finding. The wavelet extraction method employed for noise estimates gives us reasonable confidence that there was an actual decrease in noise rather than a subtraction of content because it normalizes the noise estimates against an estimate of the QRST wave form and therefore compares signal content outside that needed to describe the basic wave.

5. Additionally, results indicate that the majority of the high frequency noise occurs in the upper regions of the ECG frequency spectrum and is of very low amplitude. This portion of the spectrum is infrequently studied and noise here is unlikely to obscure the visual interpretation of clinical ECG but could be of interest to researchers doing high frequency ECG studies. However, the low amplitude of this noise suggests that the lower noise floor of the Cardiax/Dry is most likely of little practical value or consequence.

Based on these findings we conclude that at this time there are no observable interactive effects between Imed’s Cardiax ECG device and Cognionics Dry Pad Contact ECG Electrode that compromise system performance and therefore a harness development effort could benefit the dry electrode ECG system performance.

ECG Dry Electrode Harness Evaluation and Recommendation:

The Recommendation Report for the Exploration Medical System Demonstration (EMSD) Electrocardiogram (ECG) Dry Electrode Harness that we produced provides a summary of the performance of two independently designed harnesses, one from Cognionics and one from Nimbleheart. The report includes descriptions of the test methods, test data, and decision matrix scores. Harnesses were evaluated and ranked on several criteria: operational and physical characteristics, measured electrical performance, and harness requirements. Both harnesses provided an effective, comfortable solution to holding dry electrodes in place. However, Nimbleheart achieved a higher score overall and there were some concerns regarding the design and durability of the Cognionics harness. It is recommended to award Nimbleheart the opportunity to work on designing a 12-lead harness for the flight demonstration.

One of the greatest challenges in using dry electrodes is maintaining firm and stable contact ensuring the electrodes sustain an adequate conduction path across the skin-electrode junction. Only then can accurate cardiac biopotentials be conducted to the ECG system. With an effective ECG harness, the dry electrodes are held in place by providing sufficient down pressure against the skin, while minimizing the effects of skin distortions.

Based on the data, both vendors supplied harnesses with satisfactory performance. The differences in operational and performance data were so minimal that a recommendation could not be made solely on them. Based on durability and requirements, it is recommended that NASA pursue a contract with Nimbleheart to design a 12 lead harness using their 4-lead ambulatory harness design as a foundation for the flight demonstration.

References

Chi YM, Jung TP, Cauwenberghs G. Dry-contact and noncontact biopotential electrodes: methodological review. http://www.ncbi.nlm.nih.gov/ IEEE Rev Biomed Eng. 2010;3:106-19.

JSC-6021. Exploration Medical Capability Operational Concept Document, content baselined per System Requirements Review Board Meeting, Content baselined per SRR2 September 2012.

Bibliography Type: Description: (Last Updated:)