STATEMENT OF WORK FOR THE DESIGN AND DEVELOPMENT OF A DRY ELECTRODE HARNESS FOR USE IN DIAGNOSTIC ELECTROCARDIOGRAM (ECG) MEASUREMENTS

1. BACKGROUND

The Ames Research Center (ARC) Spaceflight Implementation Branch (SCF) plans to purchase a harness to hold dry electrocardiograph (ECG) electrodes for use on the International Space Station (ISS) to measure and record ECG as a part of the Exploration Medical Capability (ExMC) Element Exploration Medical System Demonstration (EMSD). ExMC 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 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. 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. A harness is required to hold the dry electrodes in place by providing sufficient down pressure against the skin, while minimizing the effects of skin distortions. As a part of the EMSD, ARC SCF has the need to certify a single ECG system that can perform both 12 lead diagnostic and reduced lead monitoring measurements utilizing dry electrodes. The EMSD ground system testing will be conducted in 2014 and flight demonstration in 2016. The dry electrode harness will be subjected to a series of tests for space flight certification prior to the flight demonstration.

2. OBJECTIVE

The contractor will develop a design for a dry electrode harness. The dry electrode harness shall provide the functionality to be used for both 12 lead diagnostic ECG (10 electrode in Lund configuration) and a reduced lead ECG recording (4 electrode configuration.) The harness must be compatible with CARDIAX PC Based Electrocardiograph WiFi/USB (ECG) device that will be used in the EMSD. Two dry electrode harnesses will be delivered for testing in March 2015 (period of performance through April 2015 for completion of validation testing at ARC.) Earlier delivery of a prototype is highly desired.

3. APPLICABLE DOCUMENTS/BACKGROUND

N/A

4. DESCRIPTION OF TASKS/TECHNICAL REQUIREMENTS

4.1 The contractor shall design a harness for use with dry electrodes.

4.1.1 The dry electrode harness shall hold 10 dry ECG electrodes in place on the body of a subject in the configuration showed below in Figure 1.

4.1.2 The dry electrode harness shall allow for 12 lead diagnostic ECG (10 electrode in Lund configuration.)

4.1.3 The dry electrode harness shall allow for reduced lead ECG recording (4 electrode configuration.)

4.1.4 The dry electrode harness shall connect to the dry electrodes through snaps (standard ECG electrode snaps.)

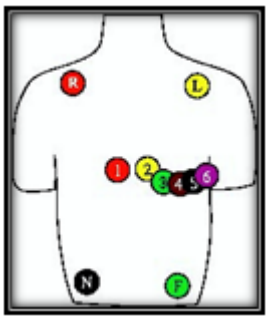

Figure 1 Dry electrode harness locations

4.2 The contractor shall design a harness for use with the CARDIAX PC Based Electrocardiograph WiFi/USB ECG device (CARDIAX ECG.)

4.2.1 The dry electrode harness (not including the electrode) shall have less than 50 kOhms resistance per lead wire.

4.2.2 The dry electrode harness shall provide electrical shielding of the lead wires.

4.2.3 The dry electrode harness shall provide a way for the CARDIAX ECG device to be attached to the harness while being worn by subject.

4.2.4 The harness shall allow dismounting of the CARDIAX ECG device to support remote mounting or tethering while in use and worn by the subject.

4.2.5 The dry electrode harness shall have a DB-15 (female) connector conforming to CARDIAX ECG pin configuration shown in Figure 2.

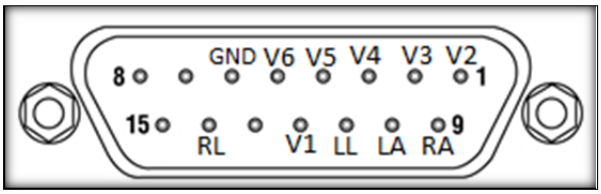

Figure 2 DB-15 Connector pinout

4.3 The dry electrode harness design must be compatible with the use on the International Space Station.

4.3.1 The dry electrode harness design **materials** must have the following characteristics:

4.3.1.1 Non-flammable or self-extinguishing;

4.3.1.2 Contain no volatile off-gassed products.

4.3.2 The contractor will provide dry electrode harnesses designed in the following **sizes:**

4.3.2.1 Female 50th percentile crew member stature: 162.7 cm (64.0 in)

4.3.2.2 Male 50th percentile crew member stature: 176.8 cm (64.9 in)

4.4 The contractor shall participate in the following meetings

MEETING	FREQUENCY/DATE	DURATION	LOCATION
Project Status Meetings	Monthly	1 Hour	Via Telecon
Technical Interchange Meetings	Bi-Monthly	1/2 Day	NASA ARC

5. DELIVERABLES

5.1 The contractor shall provide in the following reporting

MEETING	FREQUENCY/DATE
Project Status Report	Monthly

5.2 The contractor shall provide in the following deliverables

Item No.	DESCRIPTION	Qty.	DUE
1	One dry electrode harness for a 50th percentile US male	2 ea	DATE
2	One dry electrode harness for a 50th percentile US female	2 ea	DATE
3	Complete list of materials used in the harness and its construction	1 ea	DATE
4	As-built drawings and specifications for the harness	1 ea	DATE
5	Certificate of compliance that the dry electrode harness meets the technical requirements defined in Section 4	1 ea	DATE

5.3 The contractor shall provide in the following a quote for the following deliverables to be priced out as options.

Item No.	DESCRIPTION	DUE
1	One additional dry electrode harness for a 50th percentile US crewmember male	DATE
2	One additional dry electrode harness for a 50th percentile US crewmember female	DATE
3	One additional dry electrode harness for a “Small” US crewmember male	DATE
4	One additional dry electrode harness for a “Small” US crewmember female	DATE
5	One additional dry electrode harness for a “Large” US crewmember male	DATE
6	One additional dry electrode harness for a “Large” US crewmember female	DATE