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14. ABSTRACT

Divers operate in a hostile environment that is physically stressful and mentally demanding. They must also function autonomously as communications are very limited during the dive. Each diver must be responsible for his/her own safety, as well as accomplishment of mission objectives. For some time, dive computers have been used to monitor dive profiles (depth and dive duration) and equipment (tank pressure and gas mixture). However, divers have no tools for monitoring the most critical determinant of their safety and effectiveness—their body.

The goal of this project is development of a Diver Health Monitoring System (DHMS). The DHMS will provide the Navy with a powerful capability for real-time monitoring of the electrocardiogram and other key physiological parameters during diving. The system evolves the concept of the current dive computer into a physiological monitor capable of measuring the diver's critical "vital signs" and ultimately predict impending problems (e.g., hypothermia and excessive fatigue).

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DIVER HEALTH MONITORING SYSTEM

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Creare Inc.

SEPTEMBER 15, 2011
Final Report

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TABLE OF CONTENTS

Section **Page**

LIST OF FIGURES

LIST OF TABLES

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1.0 SUMMARY

Divers operate in a hostile environment that is physically stressful and mentally demanding. They must also function autonomously as communications are very limited during the dive. Each diver must be responsible for his/her own safety, as well as accomplishment of mission objectives. For some time, dive computers have been used to monitor dive profiles (depth and dive duration) and equipment (tank pressure and gas mixture). However, divers have no tools for monitoring the most critical determinant of their safety and effectiveness—their body.

The goal of this Small Business Technology Transfer (STTR) Phase II project is the development of a Diver Health Monitoring System (DHMS). The DHMS will provide the Navy with a powerful capability for real-time monitoring of the electrocardiogram and other key physiological parameters during diving. The system will evolve the concept of the current dive computer into a physiological monitor capable of measuring the diver's critical "vital signs" and ultimately predict impending problems (e.g., hypothermia and excessive fatigue).

In the Base portion of this STTR Phase II project, we developed a complete hardware and software system for monitoring a diver's electrocardiogram (ECG) and demonstrated that the system provides accurate monitoring of heart rate in both dry and wet environments. The core of the system is a wireless ECG sensor that is worn on the diver's chest. This unit records the diver's ECG, processes it to measure instantaneous heart rate, and stores the raw and processed data using nonvolatile memory for later retrieval. In dry conditions, the sensor also wirelessly transmits the raw and processed data, which can be received by a computer for real-time monitoring by a dive master or researcher. The Creare DHMS includes the wireless sensor, a dock for recharging the sensor, and PC software for controlling the sensor, for receiving its data in real time, and for retrieving its data after use.

The Creare DHMS was tested as part of a human subject study at the Center for Research and Education in Special Environments (CRESE) at the State University of New York (SUNY) at Buffalo. We tested the system on five human subjects. Each subject wore the system during rest and exercise (bicycle ergometer) under dry conditions, when submerged in fresh water at ambient pressure, and when submerged and pressurized to 20 feet of sea water (fsw). A comparison of the raw ECG and measured heart rate is compared to a laboratory-grade ECG system. The mean error in heart rate was found to be -0.52 ± 1.19 beats per minute (bpm).

The Creare DHMS was successfully tested in both wet and dry environments at ambient pressure and pressure equivalent to 20 fsw. These tests demonstrated that the DHMS provided accurate heart monitoring when compared to a conventional 12-lead ECG recording system as a "gold standard." During the course of this effort, we also identified candidate enhancements for future versions of the system to be incorporated in future revisions of the system.

2.0 INTRODUCTION

2.1 Document Purpose and Scope

This is the final report for the Base portion of the STTR Phase II on the development of the DHMS. This doeument describes the system that was developed, as well as the human subject testing that was performed to verify its operation.

2.2 Overall Program Goal

Divers operate in a hostile environment that is physieally stressful and mentally demanding. They must also funetion autonomously as eommunieations are very limited during the dive. Eaeh diver must be responsible for his/her own safety, as well as aeeomplishment of mission objeetives. For some time, dive eomputers have been used to monitor dive profiles (depth and dive duration) and equipment (tank pressure and gas mixture). However, divers have no tools for monitoring the most eritieal determinant of their safety and effectiveness—their body.

The goal of this STTR Phase II projeet was the development of a DHMS. The DHMS will provide the Navy with a powerful eapability for real-time monitoring of the ECG and other key physiological parameters during diving. The system will evolve the eoncept of the current dive eomputer into a physiologieal monitor eapable of measuring the diver's eritieal "vital signs" and ultimately predict impending problems (e.g., hypothermia and exeessive fatigue).

2.3 Program Structure

This program began as an STTR Phase I study to demonstrate the feasibility of developing the Creare DHMS such that it would address the needs expressed by the Navy. In particular, we identified the diving researeh team at the NEDU as a possible user of our teehnology. Based on the work in Phase I, we prepared a work seope for Phase II.

Reported in this doeument is the work from the Base portion of the STTR Phase II. In the Base phase, we have developed the diver-worn ECG sensor that can be used underwater and at depth. We have also developed the supported elements (reeharging doek and software for the personal eomputer [PC]) so that the deviee ean be used in a researeh setting. We performed human subjeet testing to validate the operation of the system.

2.4 Teaming

The development of the DHMS is being led by Creare Inc. of Hanover, NH, with Mr. David Kynor as the Prineipal Investigator. CRESE at SUNY at Buffalo is performing the human subjeet testing. Dr. David Pendergast is the lead for this work at CRESE. Custom electrode and adhesive development has also been supported by Vermed Ineorporated (Bellows Falls, VT).

3.0 METHODS, ASSUMPTIONS, AND PROCEDURES

3.1 Purpose of the System

The Creare DHMS is a body-worn sensor system for monitoring a diver's physiologic condition, as well as of his environment. Currently, the DHMS consists of a single body-worn sensor that measures the diver's ECG. The DHMS sensor records the ECG and determines the diver's current heart rate. The device logs the data for later retrieval and it also broadcasts the data in real time over a wireless link to a nearby computer. The use of the DHMS system is aimed at researchers performing experiments on divers. The system can be used wet or dry, and at the surface or at depth.

3.2 Overview of the System

The DHMS is composed of three components: (1) one or more body-worn sensors, (2) a general purpose PC running a custom-written application to control the sensors and to receive the data, and (3) a dock for recharging the body-worn sensors. The system components are shown in Figure 1.

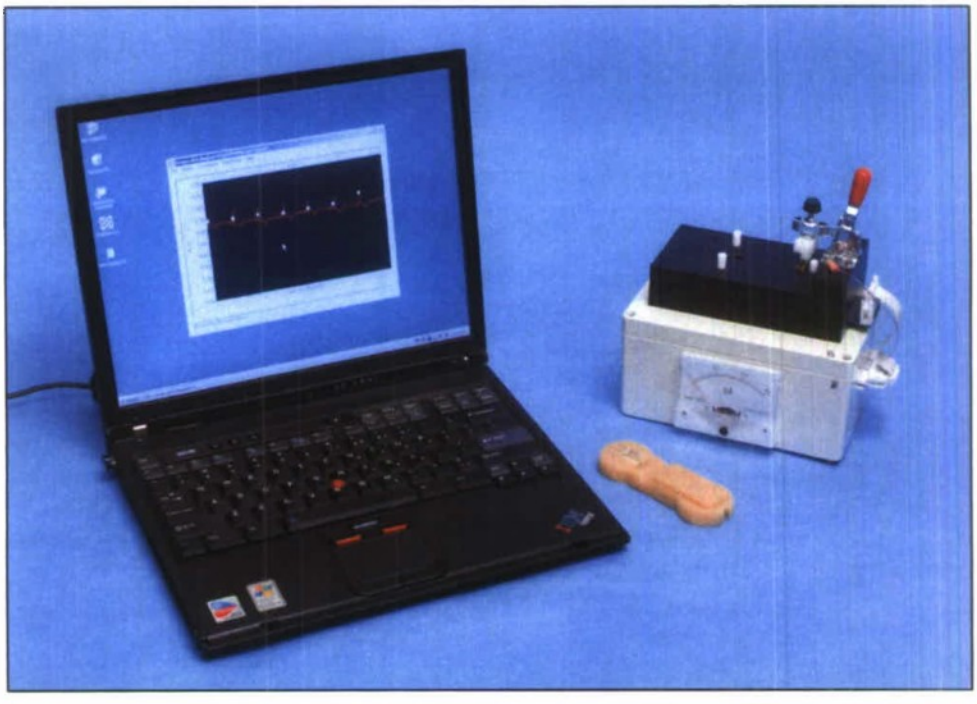


Figure 1. The Creare Diver Health Monitoring System

Currently, only one type of body-worn sensor is available for the DHMS. The DHMS sensor records the subject's ECG and computes the subject's instantaneous heart rate. The sensor stores both the raw ECG waveform and the heart rate values on nonvolatile memory within the device. The stored data can be downloaded from the device for post-test analysis. The sensor also can transmit that data in real time to the PC for immediate monitoring.

The sensor can be worn in dry or wet conditions, and at normal ambient or elevated pressures (up to 300 fsw). The sensor is attached to the body using a consumable adhesive strip, which is supplied by Creare. The built-in battery on the sensor lasts four to eight hours when transmitting in real time, or 18 to 28 hours when not transmitting. The battery is recharged by placing it its dock, which is connected via universal serial bus (USB) to the PC.

The PC is used to control the sensor, to collect the data from the sensor, and to recharge the sensor. The PC can be any general-purpose PC running Microsoft Windows XP or later. It must have two free USB ports: one for a Bluetooth® wireless adapter (supplied by Creare) and one to connect to the dock to recharge the sensor.

3.3 Detailed Description of the DHMS ECG Sensor

The DHMS ECG sensor is a body-worn device for measuring the instantaneous heart rate. The device is attached to the chest with an adhesive strip. It uses two integrated ECG electrodes to record the diver's ECG. The sensor detects the R-waves within the ECG and computes the instantaneous heart rate by measuring the difference between successive R-waves. The device logs the raw ECG signal and the heart rate values in nonvolatile memory. It also transmits the data in real time over a wireless data link to a PC (this initial version of the wireless data link is designed to operate in air, not when the diver is submerged). The DHMS ECG sensor is shown in Figure 2.

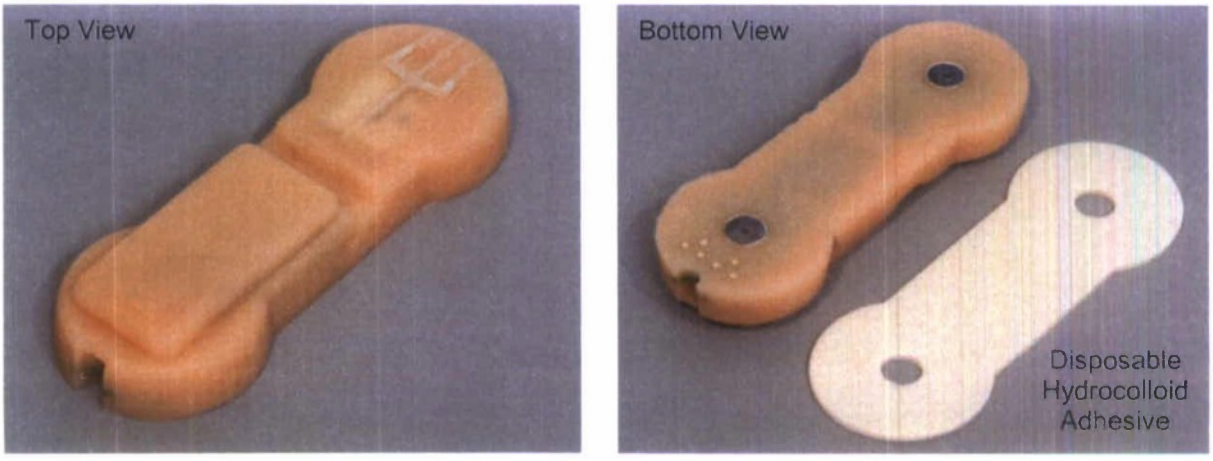


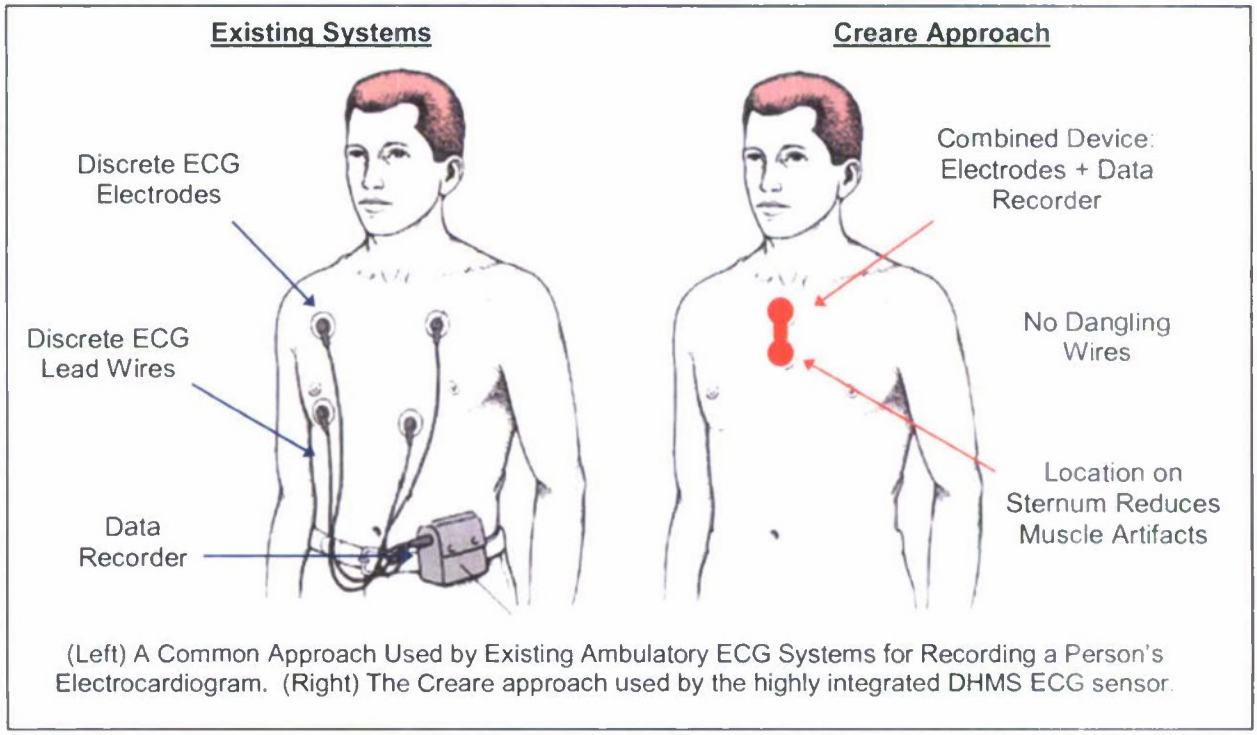
Figure 2. DHMS Electrocardiogram Sensor

3.3.1 Wearing the Sensor

The DHMS ECG sensor is a highly integrated device intended to be worn by physically-active test subjects. As shown in Figure 3, existing ambulatory ECG systems often require the application of a number of discrete electrodes, which are then wired back to a data recording device. These lead wires are prone to failure, frequently generate noise and signal artifacts, and

often encumber the test subject. The Creare DHMS sensor avoids these issues with its integrated design.

Furthermore, ECG signal corruption due to contraction of skeletal muscles is a common problem when using a traditional placement of ECG electrodes. The DHMS sensor is designed to be worn directly on the sternum where skeletal muscles are thinner and less likely to corrupt the signal. This nontraditional placement does affect the apparent morphology of the ECG signal complex, but the individual signal elements are still visible and the timing of the signal elements is preserved.



(Left) A Common Approach Used by Existing Ambulatory ECG Systems for Recording a Person's Electrocardiogram. (Right) The Creare approach used by the highly integrated DHMS ECG sensor.

Figure 3. Differing Approaches for Ambulatory ECG Monitoring

3.3.2 Sensor Construction

The major internal components of the DHMS ECG sensor are shown in Figure 4. As can be seen, the device is built around a MSP430 processor from Texas Instruments. The MSP430 digitizes the ECG signals, processes the signals to measure the heart rate, stores the data in local nonvolatile memory (an embedded secure digital [SD] card), and services the digital wireless link (Bluetooth). The ECG signals themselves are received from the body via two integrated ECG electrodes on the bottom of the device. The low-level ECG signals from the body are conditioned by analog circuitry built into a daughter card mounted above the MSP430. The device is powered by an integrated, rechargeable, lithium polymer battery pack (3.7 V, 280 mA-hrs). The battery is recharged via gold pads that are exposed on the bottom of the

sensor which mate to power pins on the Creare DHMS sensor dock. The whole device is potted in urethane to make it waterproof and pressure tolerant.

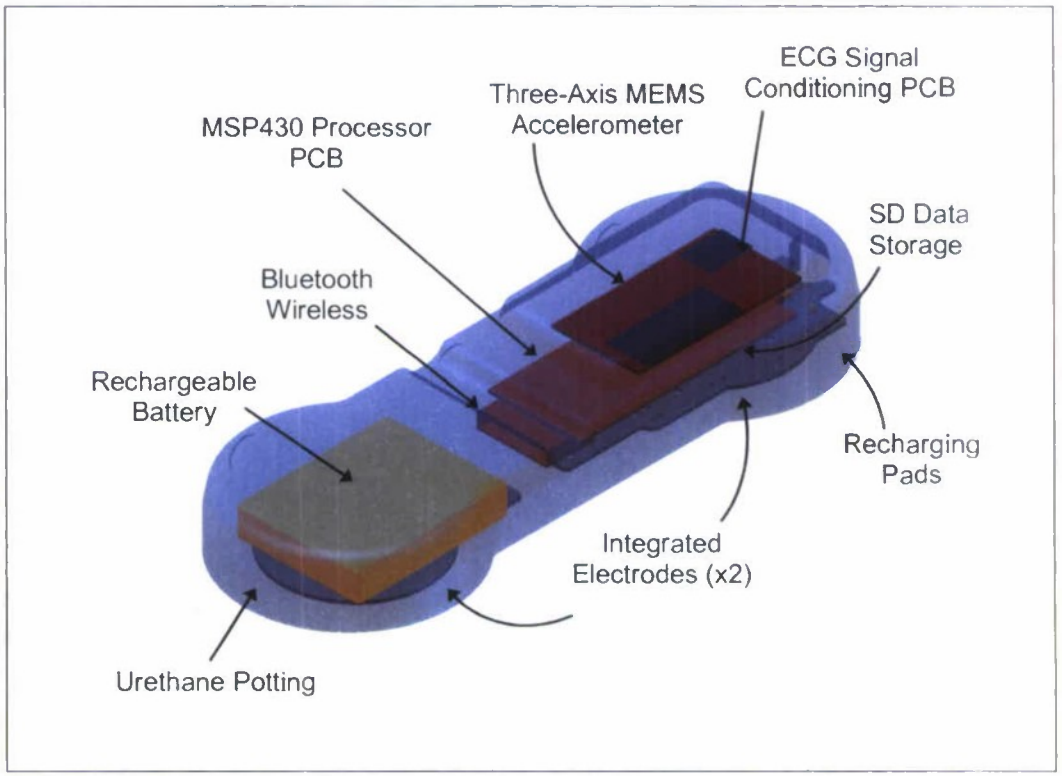


Figure 4. Layout of Components within the DHMS ECG Sensor

3.3.3 Data Processing and Transmission

The DHMS sensor records the subject's ECG using a novel, two-lead differential recording method. It then processes the signal to detect each heart beat and then to compute the instantaneous heart rate. The signal processing routines utilized to detect the heart beats were developed to minimize the impact of any signal artifacts due to muscle activity or sensor motion relative to the skin.

Once the data is acquired, the sensor transmits the raw ECG and the instantaneous heart rate over its wireless link to the PC. This data can be displayed for real-time monitoring of the diver.

3.3.4 Data Storage and Downloading

During each test session, the raw ECG signal and the instantaneous heart rate measurements are also saved to nonvolatile memory on the sensor. This is useful when the test subject is submerged underwater, which blocks the wireless link to the PC. At the conclusion of a test, the diver can exit the water and the stored ECG data can be downloaded from the sensor to a PC

using the software application provided by Creare. Data can be deleted from the nonvolatile memory using the same PC software.

3.3.5 Battery Life

The battery integrated with the DHMS ECG sensor is a rechargeable lithium-polymer battery with built-in protection for over-charge and over-discharge. It has a nominal capacity of 280 mA-hrs and a nominal voltage of 3.7 V. Due to the complexities of the Bluetooth wireless protocol (dynamic power adjustments, dynamic retransmissions to ensure deliver), battery life is highly dependent on the power required to maintain radio communications in the local environment.

While streaming the raw ECG data in real time, our testing has shown operating lifetimes between four to eight hours. In tests where the real-time Bluetooth transmission was stopped, our tests have shown operating lifetimes between 18 to 28 hours. In mixed testing environments (some real-time streaming followed by a loss of streaming due to being underwater), we have seen lifetimes of eight to nine hours.

3.3.6 Sensor Specifications

Table 1. Specifications for the DHMS ECG Sensor

ECG Data	Single differential channel Input protection for electrostatic discharge (ESD), radio frequency (RF)/electromagnetic interference (EMI) filtering, and current limiting Analog gain of 175 (nominal) Analog passband of 0.05 Hz to 159 Hz Digital sampling at 500 Hz with12 bits of resolution
Data Logged	Raw ECG and instantaneous heart rate (~2000 bytes/sec) 2 GB nonvolatile storage (> 100 hrs)
Wireless Telemetry	Standard Bluetooth connection (2.4 GHz, unlicensed) Roving networks RN-46 Class 2 Bluetooth module Real-time raw ECG and heart rate Post-test download of Raw ECG and heart rate
Battery Life	Integrated lithium-polymer battery (280 mA-hr, 3.7 V nominal) 4 to 8 hours while streaming the raw ECG data 18 to 29 hours without wireless streaming
Pressure Tolerance	Potted in urethane Proof tested in air to 300 fsw Tested on divers in fresh water to 20 fsw

3.4 Detailed Description of the DHMS PC Software

In the DHMS, the PC is used to control the DHMS ECG sensor, to collect the data from the sensor, and to recharge the sensor. Software provided by Creare allows the PC to perform these functions. The software runs on any PC running Microsoft Windows XP (or later) and which has a Bluetooth interface (a USB Bluetooth interface is provided by Creare).

3.4.1 Graphical User Interface

The graphical user interface of the Creare DHMS software is shown in Figure 5. As can be seen, there is a menu bar at the top, a large area for displaying the ECG data streamed wirelessly from the sensor, and a text display at the bottom for showing the current heart rate transmitted by the sensor.

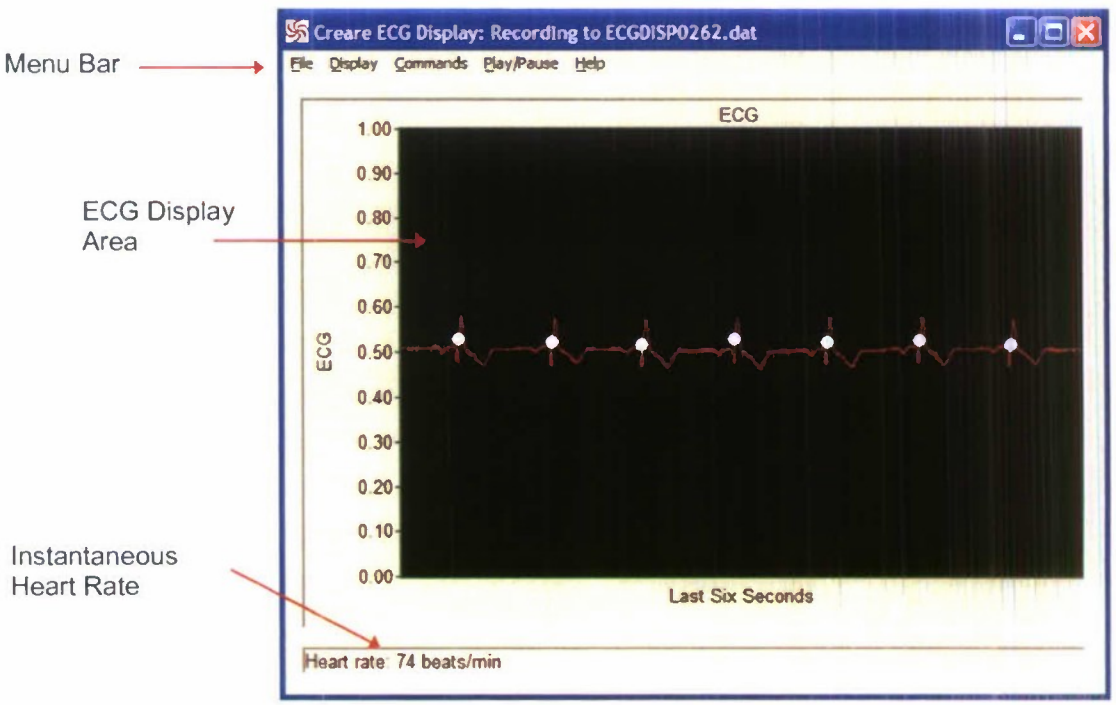


Figure 5. Graphical User Interface for the Creare DHMS PC Software

3.4.2 Controlling the DHMS ECG Sensor

Wireless Interface. All interactions between the DHMS PC software and the DHMS ECG sensor are through the wireless (Bluetooth) interface. Therefore, the sensor must have power (i.e., be charged or be sitting on the dock), it must be within Bluetooth communication range (10 to 20 feet), and it must be "connected" over Bluetooth so that Microsoft Windows assigns a COM port. The DHMS PC software connects to the DHMS sensor using this COM port. For details on configuring the Bluetooth connection, see The DHMS User Manual.

Starting an ECG Recording Session. The DHMS PC software can command the DHMS ECG sensor to start a new ECG recording session. Simply press the Play/Pause entry in the Menu bar. This commands the PC software to connect to the DHMS sensor, to initiate data acquisition and transmission on the sensor, and to begin data reception, display, and logging on the PC.

Monitoring During Testing. As long as the sensor is able to maintain its Bluetooth connection during the testing, the PC application will continue to receive and display the ECG and heart rate data.

Stopping an ECG Recording Session. When the sensor is within Bluetooth range of the PC, the recording session can be stopped by pressing the Play/Pause menu item. This closes all data files.

Downloading Data. After completing a recording session, the PC application can be used to download the data from the sensor. Simply choose the Commands menu item and select File Download.

Activating or Deactivating the Sensor. The DHMS cannot be turned on or off. As long as it has power, it will stay active so that it can respond to commands issued from the PC.

3.4.3 Using the Downloaded Data

The data files downloaded from DHMS ECG sensor are in binary format. The data can be read in any environment that can read binary data (such as MATLAB®). See the DHMS User Manual (Kynor 2011) for the details of the data format and for example code to read the data.

A data format conversion program (for Microsoft Windows) is also provided to convert the binary data into ASCII text. This allows the data to be opened in any software that can read text data (such as Microsoft Excel).

3.5 Detailed Description of the DHMS Sensor Dock

The DHMS dock (Figure 6) is used to recharge the DHMS ECG sensor. Power is supplied to the sensor via its protruding gold pins which mate to gold pads on the bottom side of the ECG sensor. Power is supplied to the dock itself via a USB connection to the PC.

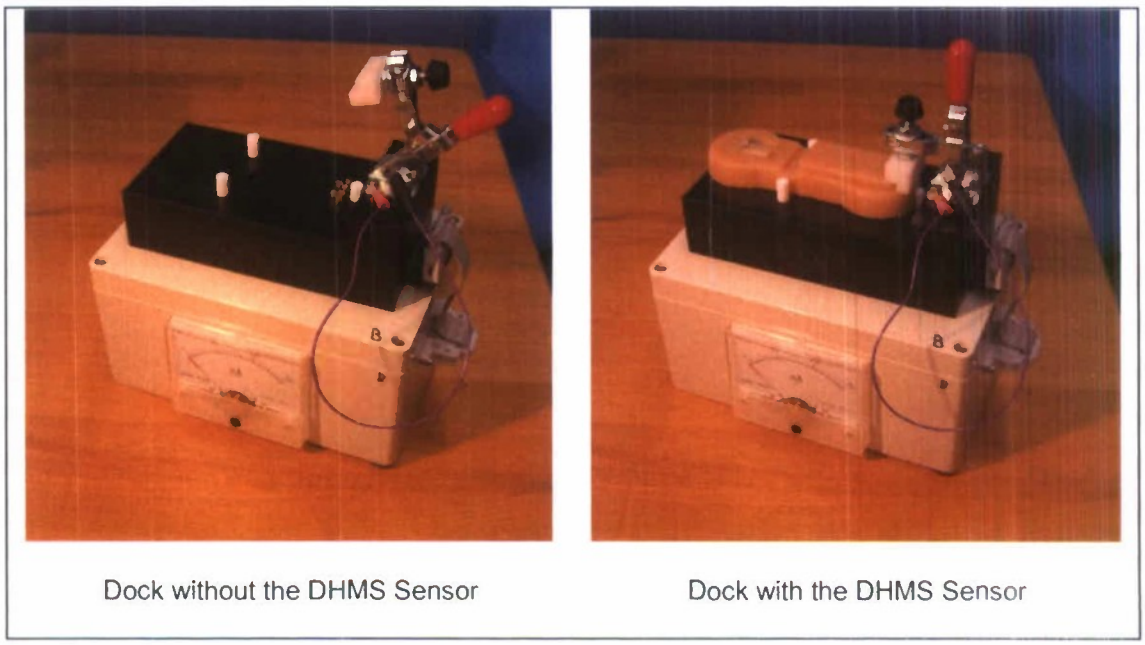


Figure 6. DHMS Sensor Dock

The large analog ammeter displays the amount of electrical current flowing to the ECG sensor. When the current flow is down to below 20 mA, the sensor is charged. If an ECG sensor is completely out of power, placing it on the dock does not always immediately induce current flow. It may take a few minutes for the sensor to accept current and for the ammeter to move. Using the magnet to reset the sensor (via the sensor's built-in magnet-activated reed switch) can speed this initialization process.

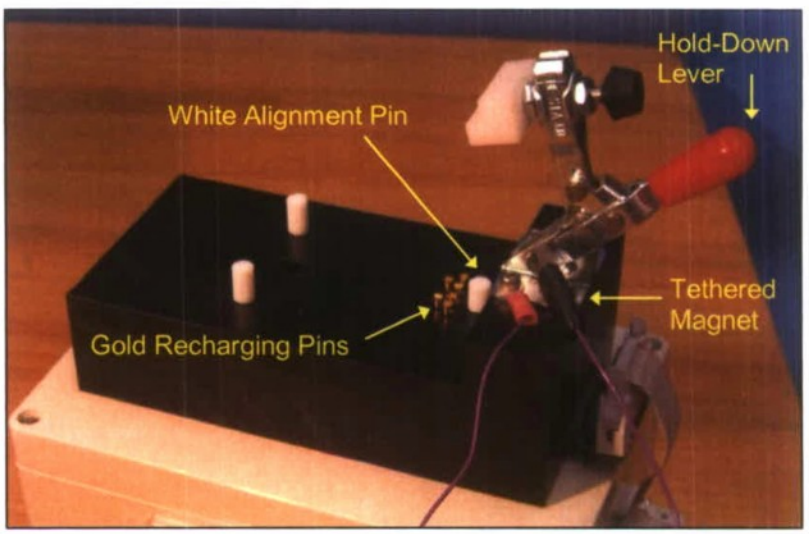


Figure 7. Features of the DHMS Sensor Dock

3.6 Instructions for Use

Detailed instructions on the use and care of the Creare DHMS are available in the Creare's DHMS User Manual.

3.7 System Validation

3.7.1 Approach

To validate the performance of the Creare DHMS, we worked with CRESE to develop a human subject test protocol to test the device. The purpose of the testing would be to confirm proper system operation, confirm the quality of the ECG trace, confirm the detection of heart beats, and to confirm the accuracy of the estimated heart rate. The performance of the DHMS would be compared to a laboratory-grade ECG system, which would be simultaneously recording the subject's ECG. The human subject testing would be performed across a range of heart rates and across a range of environmental conditions, including dry, wet, and wet under pressure. The testing itself would be performed by CRESE at their facility using volunteer subjects that they recruit.

3.7.2 Institutional Review Board

The human subject test protocol and volunteer consent form were reviewed and approved by the Health Sciences Institutional Review Board and Institutional Animal Care and Use Committee at SUNY at Buffalo.

3.7.3 Subject Pool

CRESE recruited six volunteer subjects to participate in this testing. Subject eligibility was limited to certified divers, to people of an age that is similar to most Navy divers, and be a nonsmoker. Table 2 describes the five test subjects who participated in the primary test protocol.

Table 2. Description of Human Test Subjects

Subject	Age (yrs)	Height (cm)	Weight (kg)
1	26	183	97.5
2	25	178	80.0
3	21	180	87.5
4	18	183	79.8
5	47	173	81.7

3.7.4 Test Equipment and Test Facility

The system being tested is the Creare DHMS system, including the body-worn DHMS ECG sensor. The subject will also be wearing three standard ECG electrodes connected via tethers to a laboratory-grade ECG system from Biopac Systems Inc.

The testing was performed at the wet/dry hyperbaric facility at CRESE at SUNY at Buffalo. The wet/dry hyperbaric facility was equipped with a recumbent cycle ergometer. For the wet tests, the facility was filled with heated fresh water.

3.7.5 Subject Preparation

For each human subject, the DHMS device was mounted on the sternum using the procedure described in the DHMS User Manual. This involves cleaning the skin with gauze and alcohol, attaching the sensor with its adhesive strip, and securing the sensor with an overlay of Bioclosive transparent surgical dressing.

The electrodes for the Biopac system were attached to the subject's chest near his right shoulder and left hip. The driven-ground electrode was attached to the left shoulder. The tether from the subject to the data acquisition system was attached once the subject was inside the test facility.

All testing was completed within one day. Unless there was a problem with the DHMS sensor or the Biopac electrodes, the same equipment was used throughout the day's testing without being removed.

3.7.6 Primary Test Protocol

The first five subjects performed the primary test protocol. In this protocol, each subject executed a six-part test within one day. Each segment of the test is described in Table 3. The schedule for the tests were such that segments 1 and 2 were performed in the morning, the test chamber was filled with water and heated through lunch, and then segments 3 through 6 were performed in the afternoon.

Table 3. Test Protocol

Test	Wet/Dry	Pressure	Rest/Exercise	Description
1	Dry	Ambient	Rest	30 minutes rest. Subject seated on recumbent ergometer in test chamber.
2	Dry	Ambient	Exercise	5 minutes at 100 W on cycle ergometer followed by 25 minutes at 60 W.
3	Wet	Ambient	Rest	30 minutes rest. Subject submerged within the test chamber. Subject seated on recumbent ergometer.
4	Wet	Ambient	Exercise	5 minutes at 100 W (accounting for water resistance) followed by 25 minutes at 65 W.
5	Wet	20 fsw	Rest	30 minutes rest. Subject submerged in test vessel which has been pressurized to 20 fsw.
6	Wet	20 fsw	Exercise	5 minutes at 100 W (accounting for water resistance) followed by 25 minutes at 60 W.

For the exercise portions of the test, the first test subject was required to produce 100 W for all three 30-minute periods. This proved to be overly strenuous as we were performing all the testing within one day. Therefore, for Subjects 2 through 5, we utilized the 100 W/65 W protocol shown in Table 3.

The exercise was performed on a recumbent cycle ergometer. The target speed was approximately 60 rotations per minute (rpm). When underwater, the resistance due to the water was assumed to be 25 W. Therefore, for the underwater tests, the ergometer was set to 75 W and 40 W in order to achieve the target loads of 100 W and 65 W.

3.7.7 Test Observers

For the first two test subjects, a Creare engineer was present at the CRESE test facility during the testing. For the other subjects, only CRESE staff were present.

3.7.8 Data Collection

The data produced by this test includes raw ECG traces recorded by the Creare DHMS (at a sample rate of 500 Hz), as well as by the Biopac system (at a sample rate of 1000 Hz). Additionally, the Creare DHMS detects the individual heart beats and estimates the heart rate.

The Creare DHMS data was collected in real time via the wireless interface (when available) and was also downloaded from the DHMS sensor after tests were complete. The Biopac data was recorded to a laboratory computer in real time during testing.

3.7.9 Data Analysis

The purpose of the data analysis is to evaluate the quality of the data produced by the Creare DHMS compared to the laboratory-grade Biopac system. We compare the quality of the raw ECG traces, the heart beat detection performance, and the accuracy of the estimated heart rate. As long as it is of high quality, the Biopac data will be our "truth."

The raw ECG traces are compared qualitatively by anecdotal visual examination of the waveforms.

The heart beat detection and heart rate estimates are compared quantitatively by matching up the data beat-for-beat between the DHMS output and the Biopac output.

Proeessing the DHMS Data

The DHMS sensor performs heart beat detection as each beat occurs. It then differences the time of each of these deteetions to compute the instantaneous heart rate. This (along with the ECG traee) are the raw data provided by the DHMS system.

For the presentation of most of the results in this report, we have applied an additional filter to the data to reject outliers. The outlier algorithm simply rejects any heart beat detection if the instantaneous heart rate changes by too much relative to the mean of the last 12 heart beats.

The outlier-rejection algorithm is currently implemented as a bateh post-processing step during data analysis, but the algorithm is simple and could be integrated onto the DHMS sensor or it eould be integrated into the DHMS real-time PC display. This integration effort is proposed as future work.

Processing the Biopae Data

The key metric used in this study is the beat-by-beat heart rate comparison to the Biopae ECG data. Unfortunately, the Biopae system utilized in this test does not detect the individual heartbeats nor does it compute the heart rate. Therefore, Creare developed a set of algorithms to post-proeess the Biopae ECG signal to deteet the peak of each R-wave. The instantaneous heart rate is then simply the difference between successive detected beats. Finally, the same outlier-rejeetion algorithm as used on the Creare data is applied to the Biopae data.

When there are few signal artifacts in the raw Biopae ECG traces, the Creare algorithm for heartbeat detection can be expected to be highly aeeurate. When the Biopae ECG traces are of lower quality, however, the ability to deteet the heart beats also degrades. As a result, for times when the Biopae data is of poor quality, there will be no "truth" measurement to which the DHMS ean be compared.

Aligning the Heart Beats

To perform a beat-by-beat eomparison, it is neeessary to match up the heart beats detected by the DHMS to the beats deteeted in the Biopae data. Creare developed a set of algorithms to perform this time-alignment and matehing process. Challenges ineluded: (1) drift between the sampling eloek in the Biopae system versus the Creare system, and (2) missing heart beats or extra (false) heart beats in either the DHMS or Biopae data. The Creare algorithms are largely suceessful in addressing both challenges. In some eases, individual heart beats cannot be matched. These unmatched beats are rejeeted when reporting summary results from the beat-by-beat comparison.

3.7.10 Alternate Test Protocol

For test subject #6, we performed an alternate test protocol for the purpose of validating the effectiveness of the DHMS during a free swim. The test and its results are summarized in Appendix A.

4.0 RESULTS AND DISCUSSION

This section describes the results of the human subject testing performed at CRESE to validate the operation of the system.

4.1 Photographs from Testing at CRESE

As described in Section 3.7.5, each subject was prepared by attaching the Creare DHMS sensor and the Biopac ECG electrodes. The preparation of Subject #1 and #2 are shown in Figure 8. Example photographs from the testing itself are shown in Figure 9.

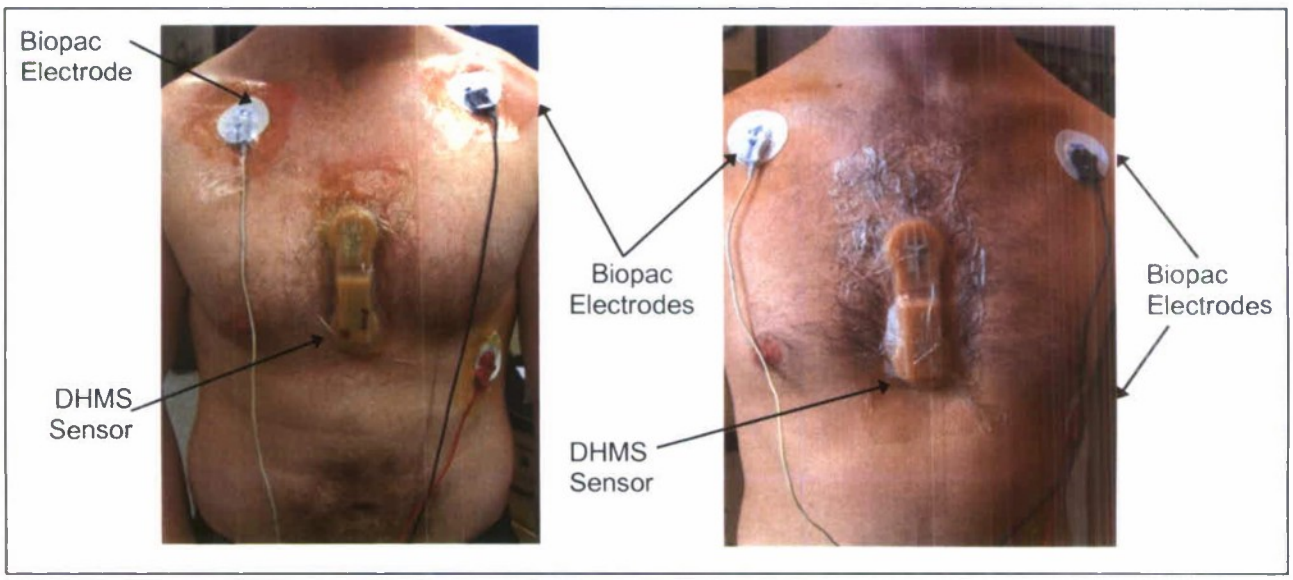
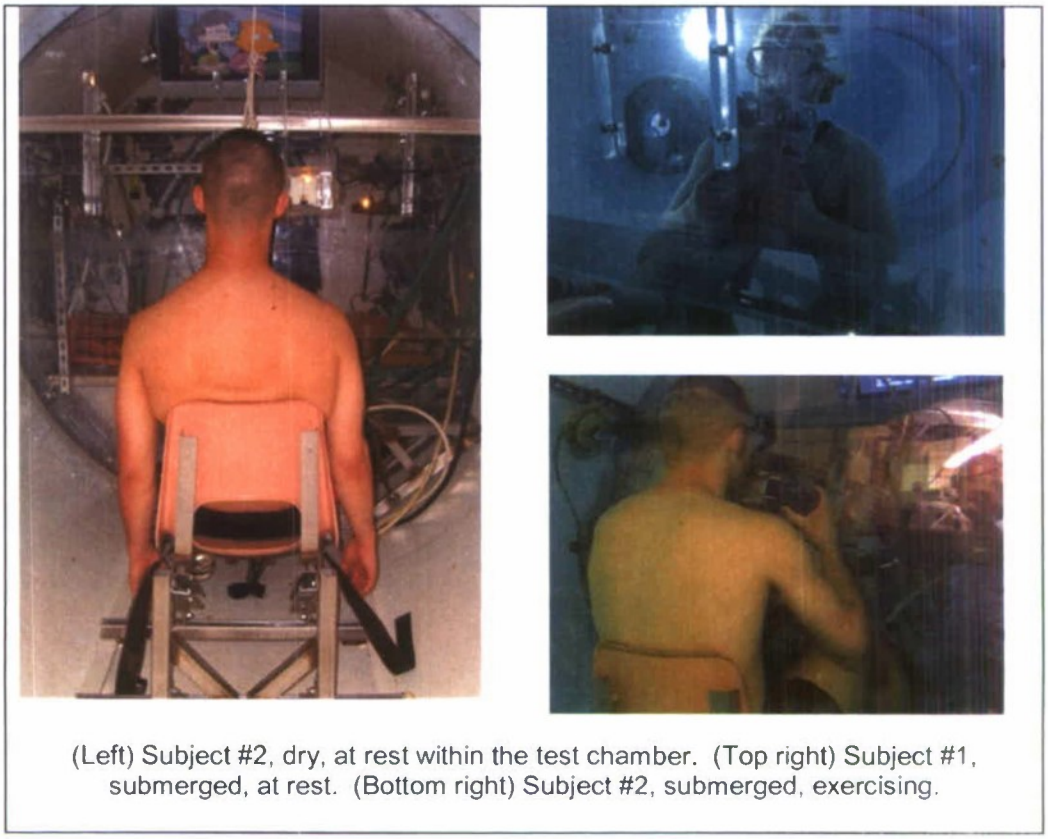


Figure 8. Preparation of Subject #1 (left) and Subject #2 (Right) with Both the Creare DHMS Sensor and the Biopac ECG Electrodes



(Left) Subject #2, dry, at rest within the test chamber. (Top right) Subject #1, submerged, at rest. (Bottom right) Subject #2, submerged, exercising.

Figure 9. Photographs from the Validation Testing at CRESE

4.2 System Operation

During the testing, the goal was to use a single DHMS sensor for all six portions of the day's testing on that subject. Because the DHMS allows for wireless streaming of its data, we were able to confirm system operation throughout the dry testing. For the wet tests, we could use the wireless streaming whenever the subject moved very close to a window, where the wireless signal would not have to penetrate much water. If any of these checks showed a problem, the subject exited the chamber and the sensor was replaced.

Table 4 summaries the operational success of the DHMS. As can be seen, we had two subjects where the first sensor was used successfully throughout all six tests. We had two subjects where we appeared to lose contact with the skin (the streamed ECG trace disappeared or become noisy). Finally, we had one subject where the sensor appeared to work correctly throughout the testing, but the data for Tests 3 through 6 could not be retrieved. We consider this to be the only serious anomaly during testing. The cause for the anomaly has not yet been identified.

Table 4. Summary Operational Success During Testing	
Subjeet 1	Used a single sensor sueeessfully throughout all six tests.
Subject 2	Tests 1 and 2 used one sensor, which then appeared to lose contact with the skin at the very end of Test 2. Another sensor was applied and used successfully for Tests 3 through 6.
Subject 3	Used a single sensor throughout all six tests. System appeared to function eorreetly. Data was obtained for Tests 1 and 2, but not for Tests 3 through 6. The eause of the anomaly has not yet been identified.
Subjeet 4	Tests 1 and 2 used one sensor, which then appeared to lose contaet with the skin as the subjeet erawled into the wet chamber for Test 3. Another sensor was applied and used sueeessfully for Tests 3 through 6.
Subject 5	Used a single sensor suceessfully throughout all six tests.
Subject 6	Tested using alternate protoeol. Used a single sensor successfully throughout the dry and wet tests, at rest and during the free swim.

4.3 Example ECG Traces

One important function of the DHMS is the ability to record (and wirelessly stream) the raw ECG trace. In this section, we show some example ECG traees to eonfirm that the signal clarity is good.

Example ECG waveforms from the testing of Subjeet #2 are shown in Figure 10. Notice that the overall clarity of the waveforms from the Creare system compare well to the (tethered) Biopac system. Notice also that the morphology of the ECG signal is different between the two systems (the T-wave is negative as seen by the DHMS while it is positive as seen by the Biopac system). This reflects that the differenee in eleetrode position for the DHMS compared to the Biopac system.

Looking at the data during exercise, the baseline portion of the ECG (the period between R-waves) as seen by the DHMS has some oseillation that is not seen in the Biopae data. It appears that this oscillation is synchronized to the subjeet's leg motions while on the cycle ergometer. Therefore, it appears that the DHMS is suseeptible to some motion artifact. The motion artifaet seen here, though, is small. The R-waves are still easily detected with high accuracy.

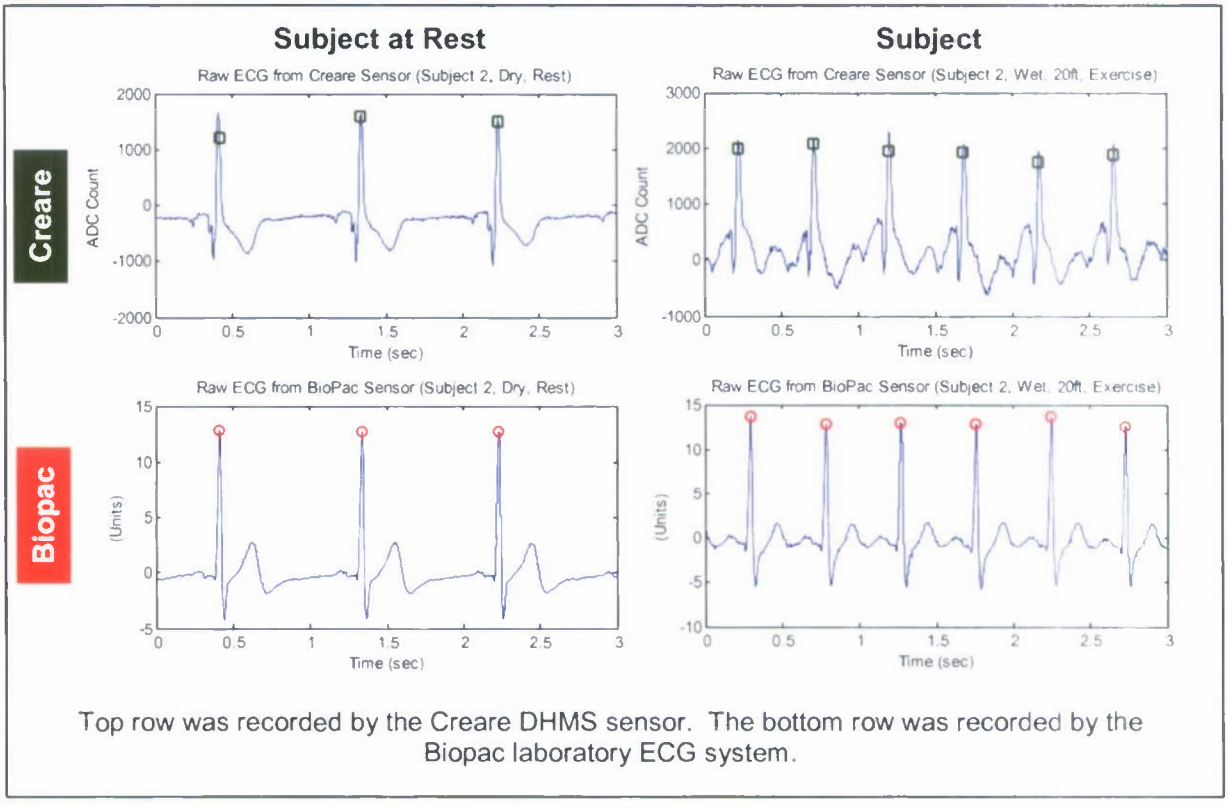


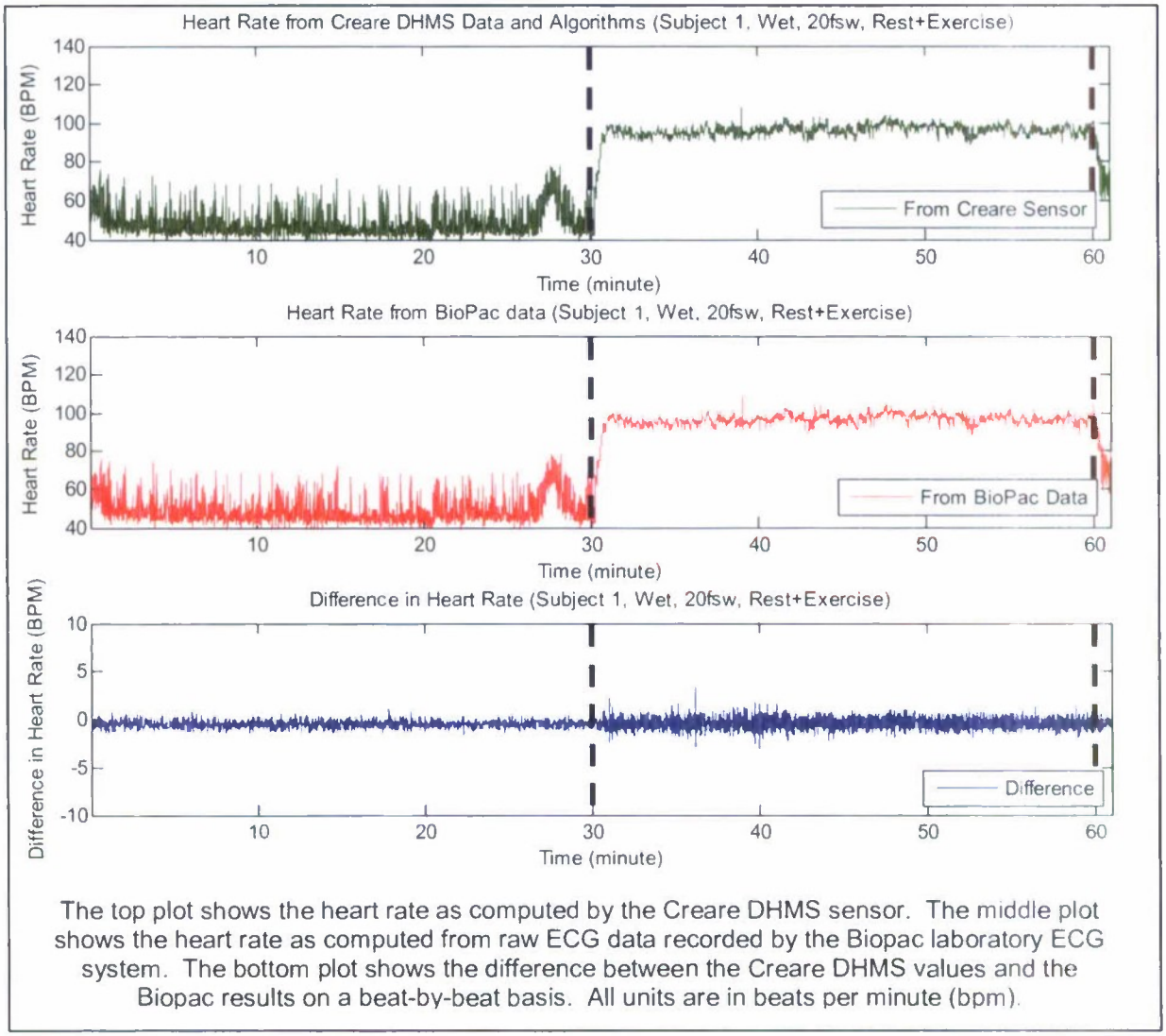
Figure 10. Example ECG Waveforms from Subject #2

4.4 Example Heart Rate Results

Another important function of the DHMS is to estimate the heart rate, which can then be used in real-time monitoring by the dive master, or for analysis by researchers. This section presents some examples for the heart rate results seen during testing.

Figure 11 shows the results for Subject #1 when wet and at a pressure of 20 fsw. The figure shows the heart rate computed by the Creare DHMS sensor compared to the heart rate computed through post-test R-wave processing of the Biopac ECG waveforms. Both traces have had outliers removed to improve the clarity of the plot. As can be seen, the Creare system tracks the changes in heart rate very well. One can see the large difference in heart rate between rest and exercise, as well as the smaller variations in the heart rate during the rest period.

The third plot in Figure 11 shows the beat-by-beat difference in the DHMS output to the Biopac data. The Creare and the Biopac data are in very close agreement. Comparison of the estimates of instantaneous heart rate across all 4,200+ beats reveals that the average heart rate as measured by the Creare DHMS and Biopac system agree with within 0.45 bpm on average. The standard deviation of the difference between the two systems is only 0.54 bpm.



The top plot shows the heart rate as computed by the Creare DHMS sensor. The middle plot shows the heart rate as computed from raw ECG data recorded by the Biopac laboratory ECG system. The bottom plot shows the difference between the Creare DHMS values and the Biopac results on a beat-by-beat basis. All units are in beats per minute (bpm).

Figure 11. Example Heart Rate Data Recorded from Subject #1 During a Wet Test at 20 fsw

4.5 Summary across All Tests

Looking across all tests, we have the beat-to-beat heart rate from the DHMS and we can compute the beat-to-beat heart rate from the Biopac data. A key performance metric for the DHMS is how closely its heart rate measurement agrees with accepted laboratory systems (such as Biopac).

4.5.1 Median Heart Rate

Table 5 shows the heart rate for each test subject as measured by the Creare DHMS and as estimated from the Biopac ECG recording. The table shows the median heart rate seen during each test segment.

Looking at these results, we see the range of sustained heart rate values to which the DHMS was exposed—from a low of 52 bpm in Subject 5, up to a high of 132 bpm in Subject 3. Furthermore, by comparing the difference between the DHMS and Biopac values, we that these median values are in close agreement.

Table 5. Median Heart Rate from the DHMS Compared to Biopac

Test Segment		1	2	3	4	5	6
Condition		Dry	Dry	Wet	Wet	Wet, 20fsw	Wet, 20fsw
Activity		Rest	Exercise	Rest	Exercise	Rest	Exercise
Subject	System	Median Heart Rate (bpm)					
1	DHMS	55.0	108.0	49.0	106.0	46.0	96.0
	Biopac	55.4	108.6	49.0	107.9	46.6	96.8
2	DHMS	72.0	110.0	80.0	122.0	80.0	120.0
	Biopac	72.1	111.1	80.6	123.0	80.6	121.0
3	DHMS	88.0	132.0	*No Data*			
	Biopac	88.2	132.7	*No Data*			
4	DHMS	79.0	124.0	75.0	127.0	81.0	123.0
	Biopac	79.4	125.0	75.4	127.1	81.5	123.0
5	DHMS	96.0	124.0	66.5	111.0	52.0	109.0
	Biopac	96.8	127.1	67.0	111.9	51.9	110.3

4.5.2 Difference in Median Heart Rate

Table 6 shows the median difference in instantaneous (beat-to-beat) heart rate estimates between the DHMS and the Biopac data. As can be seen, the difference between the two systems is approximately 0.5 bpm, which is fairly consistent across most tests.

Table 6. Beat-by-Beat Comparison of Instantaneous Heart Rate from the DHMS compared to Biopac. This is the median difference in the instantaneous heart rate in bmp.

Test Segment	1	2	3	4	5	6
Condition	Dry	Dry	Wet	Wet	Wet, 20fsw	Wet, 20fsw
Activity	Rest	Exercise	Rest	Exercise	Rest	Exercise
Subject	Median Difference in Heart Rate (DHMS minus Biopac, bpm)					
1	-0.49	-0.45	-0.44	-0.57	-0.49	-0.43
2	-0.50	-0.45	-0.47	-0.71	-0.47	-1.22
3	-0.44	-0.43	*No Data*			
4	-0.49	-0.49	-0.47	-0.36	-0.47	-0.45
5	-0.43	-0.89	-0.47	-0.47	-0.43	-0.46

We examined several possible causes of this bias in our heart rate estimate. We believe that the difference is mostly due to the software on the DHMS sensor rounding its heart rate value to the nearest integer bpm. Unfortunately, the software operation used on the DHMS actually truncates the value (rounds down) instead of using the normal rounding rules. Therefore, the DHMS heart rate estimate should be biased downward by about 0.5 bpm. This is very close to the 0.52 bpm value seen when averaging across all of the data.

4.5.3 Standard Deviation in Difference in Heart Rate

If there is a bias in the system's estimate of heart rate, such errors can be corrected or calibrated away in a production system. A more revealing metric for the accuracy of the heart beat and heart rate algorithms is the error that varies from beat-to-beat. If we assume that the heart rate computed from the Biopac data is "truth," than we can compute the standard deviation of the beat-to-beat difference in heart rate from the DHMS versus Biopac. These values are tabulated for all test subjects and for all tests in Table 7.

Table 7. Beat-by-Beat Comparison of Instantaneous Heart Rate from the DHMS Compared to Biopac. This is the standard deviation of the difference in the instantaneous heart rate in bpm.

Test Segment	1	2	3	4	5	6
Condition	Dry	Dry	Wet	Wet	Wet, 20fsw	Wet, 20fsw
Activity	Rest	Exercise	Rest	Exercise	Rest	Exercise
Subject	Standard Deviation of Difference in Heart Rate (bpm)					
1	0.32	0.59	1.15	1.70	0.41	0.59
2	0.86	1.22	1.60	1.00	1.31	3.19
3	0.44	0.72	*No Data*			
4	0.40	0.66	0.50	0.92	0.61	0.72
5	0.58	1.04	0.57	1.74	1.17	1.58

As can be seen, the standard deviation in this error spans 0.32 bpm up to 3.19 bpm. Most values are centered around 1.2 bpm. If the Biopac data is "truth," than this is the magnitude of the error in the DHMS heart rate estimate that cannot be calibrated out.

Looking into the details of the ECG signals where the DHMS instantaneous heart rate diverges from the Biopac heart rate, it appears that the difference is mostly due to the signal processing used by the DHMS to detect the individual heart beats. The DHMS filters the raw ECG signal using a bandpass frequency range matched to the energy content typical of a QRS complex, and then uses an energy detection method to find the moment when a QRS complex has occurred.

By this method, the time when a heartbeat occurs is simply the moment when the signal energy passes some threshold. The true definition of a heartbeat, however, is the time when the R-wave is at its maximum excursion from the baseline. The time resulting from the energy method used by the DHMS does not necessarily correspond to the moment of maximum R-wave. Therefore, the two systems can yield different heart rate estimates depending upon how the morphology of the QRS complex varies from beat-to-beat.

4.5.4 Summary Across All Subjects

Lumping together all subjects, we can evaluate the mean error in heart rate (assuming that the Biopac is truth) for all tests when resting, for all tests during exercise, and for all tests in general. Table 8 shows these values. The values reported are the mean beat-to-beat heart rate difference (which could be calibrated out) plus or minus the standard deviation of the beat-to-beat heart rate difference (which cannot be calibrated out). Therefore, it is this standard deviation portion of the error that is most relevant.

As can be seen, the error during exercise (standard deviation = 1.43 bpm) is higher than when at rest (standard deviation = 0.89 bpm). It is unclear if this additional error is due to the higher heart rate seen during exercise, due to some sort of morphologic variation of the QRS complex during exercise, or due to increased motion artifact during exercise.

Table 8. Difference in Heart Rate Estimate from DHMS compared to Biopac

	Rest (bpm)	Exercise (bpm)	Overall (bpm)
DHMS Mean Heart Rate	70.7	116.3	93.5
Biopac Mean Heart Rate	71.1	117.3	94.2
Beat-to-Beat Difference in Heart Rate Between DHMS and Biopac	-0.47 ± 0.86	-0.57 ± 1.39	-0.52 ± 1.16

Across all tests, however, a standard deviation of 1.16 bpm is small and validates the performance of our system across five different subjects, under three different environments, and two different types of activity.

5.0 CONCLUSIONS

In the Base portion of this STTR Phase II project, we developed a complete hardware and software system for monitoring a diver's ECG in dry and wet environments. Our conclusions from the development effort and from the human validation testing are:

- We successfully designed and built a working DHMS system for recording and monitoring the heart rate of a human subject using a low-profile body-worn device that requires no tether back to a data acquisition system.

- Successful operation of the DHMS was demonstrated on human test subjects both dry and wet, when at the surface and at 20 fsw of pressure, and when resting or during exercise.

- The accuracy of the DHMS ECG sensor is good, showing an overall error in heart rate of -0.52 ± 1.16 bpm.

- While the testing was successful, a number of technical improvements to the system are recommended prior to use by a wider community.

6.0 RECOMMENDATIONS

In testing the system at CRESE, we have identified a number of areas for improving the DHMS in future versions of the system. Specifically, we recommend:

- Improving the battery life through better management of the wireless communications and through an enlarged battery.
- Improving the robustness of the data logging on the onboard nonvolatile memory through additional development of the embedded software or through a hardware redesign of the electronics.
- Improved adhesion when mounting the sensor to the body through the use of alternate adhesives.
- Improved data download speeds.
- Improving the manufacturability of the device to lower system cost and to increase system reliability.
- Improving the accuracy of the heart rate estimate and improving the system's robustness to motion artifact.
- Enabling additional sensing modalities such as use of the existing accelerometer data to determine diver body orientation and/or exertion level.
- Incorporation of additional sensors to measure ambient temperature, diver heat loss, or pressure.
- Examination of systems materials (e.g., battery chemistry) for optimal compatibility with the hyperbaric environment.

7.0 REFERENCES

Kynor, D. B. and Audette, W. E., "Diver Health Monitoring System: User Manual," Creare Inc., Hanover, NH, TM-3192, Aug 2011.

8.0 APPENDIX A: TESTING USING ALTERNATE PROTOCOL

8.1 Summary

The sixth test subjeet was tested using an alternate protocol. The purpose of this alternate test was to evaluate the performanee of the DHMS during a free swim in a pool. During the test, the subject sat at rest in the pool for 30 minutes and then performed a self-paced fin-swim for 30 minutes. The only reeording system on the swimmer was the Creare DHMS, so there is no truth data available. The results from this test indieate that the Creare DHMS reeorded clear ECG signals and that the heart rate values are reasonable. Given that this test was only performed on a single subject, it does suggest that the DHMS should be suitable for use on free swimmers.

8.2 Test Protocol

The protoeol used for this test was to first prepare the subject as deseribed in Seetion 3.7. Then, the subjeet performed Test Segments 1 and 2 (dry rest and dry exereise on the cycle ergometer) as deseribed in Table 3. These two test segments were used to eonfirm that the Creare DHMS was operating eorreetly and was stable on the subject's body. Then, after a lunch break, the Biopae system was removed from the subjeet so that only the Creare DHMS sensor remained on his body. The subject donned swim fins and entered the annular pool at CRESE. The subject rested for 30 minutes in the water. The subjeet then performed a self-paeed free swim in the annular pool for 30 minutes.

8.3 Test Results

8.3.1 Dry Rest and Dry Exercise

During the dry testing, the subjeet was wearing both the Creare DHMS sensor and was tethered to the laboratory-grade Biopae ECG reeording system. Therefore, we ean eompare the results from the DHMS to the Biopae data. The data was proeessed as deseribed in Seetion 3.7.

The median heart rate seen during the dry rest portion was 82 bpm by the DHMS and 82.9 bpm by the Biopae system. On a beat-by-beat basis, the DHMS heart rate differed from the Biopae system by -0.45 ± 0.39 bpm. During the dry exercise portion, the median heart rate was 121 bpm as seen by the DHMS and 122 bpm as seen by the Biopae system. On a beat-by-beat basis, the DHMS heart rate differed from the Biopae system by -0.43 ± 0.57 bpm. These values are consistent with the results reported in the main body of this report.

Overall, the ECG data looked good and the heart rate values from the Creare DHMS were in agreement with the Biopae data. Therefore, the system was operating correctly and seemed to be attached well to the diver.

8.3.2 Wet Rest and Fin Swim

Example ECG waveforms from the rest and swim portion of the test are shown in Figure 12. As can be seen, the ECG clearly shows the QRS complex as well as the T-wave and small indications of the P-wave.

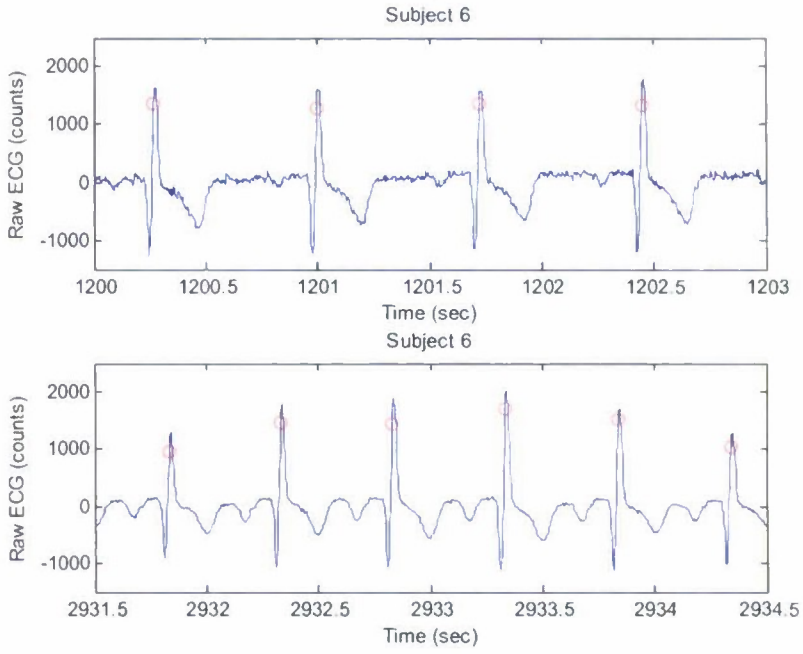


Figure 12. Example ECG Waveforms from the Creare DHMS for Subject #6. The top figure shows the ECG for the subject submerged in the pool but at rest. The bottom figure shows the ECG for the subject executing a self-paced fin swim within the pool.

Looking at additional traces from throughout the test, we see an interesting behavior during the fin swim. Specifically, we see that the amplitude of the QRS complex oscillates between small amplitude and large amplitude. An example is shown in Figure 13. The period of the oscillation is about four seconds. Presumably, the oscillation in QRS amplitude is due to the respiration of the swimmer.

During this oscillation, the amplitude of the QRS changes by about a factor of two. When the QRS is smallest, the DHMS occasionally fails to detect those individual beats (there are no missed beats in the example in Figure 13).

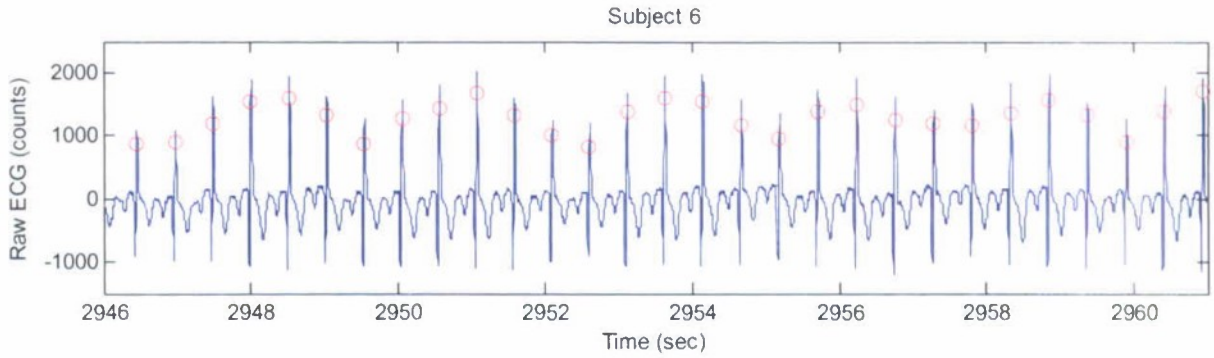


Figure 13. Example ECG Waveform from the Creare DHMS During the Fin Swim Showing an Oscillation in QRS Amplitude

The heart rate measured by the DHMS during the wet tests is shown in Figure 14. The median heart rate measured by the DHMS during the rest portion was 87 bpm. The median heart rate during the fin swim was 114 bpm. The ability of the DHMS to traek the varying heart rate during rest and exercise is elearly seen. Beeause the tethered Biopae system was removed from the diver to enable this free swim, there is no Biopae heart rate results to whieh these values can be eompared. This qualitative examination, however, looks positive.

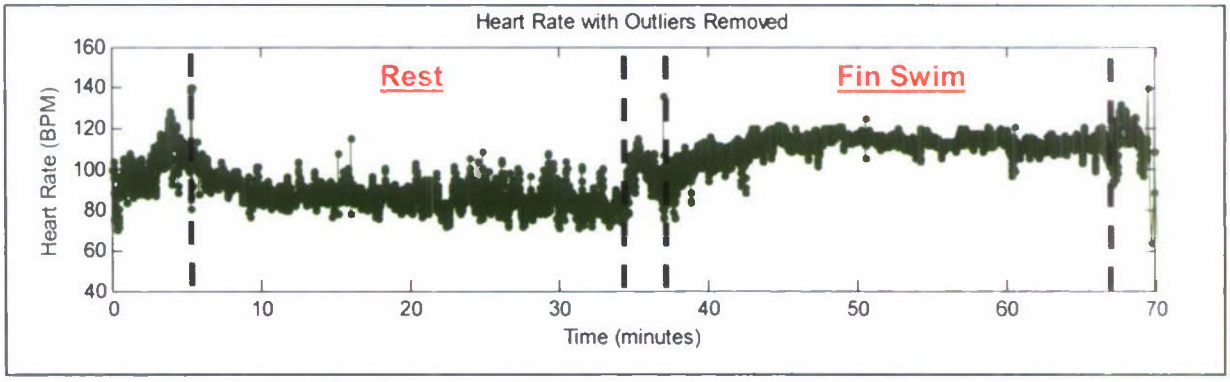


Figure 14. Heart Rate as Computed by the Creare DHMS Sensor in Beats Per Minute (bpm). The data are for a rest period for an untethered fin swim in an annular pool.

8.4 Conclusion

One subject was tested untethered in a pool. During rest and during a fin swim, the Creare DHMS reeorded high quality ECG traees and reasonable heart rate values. This suggests that the DHMS should be suitable for use on free swimmers.

LIST OF ACRONYMS, ABBREVIATIONS, AND SYMBOLS

Acronym	Description
CRESE	Center for Research and Education in Special Environments
DHMS	Diver Health Monitoring System
ECG	electrocardiogram
EMI	electromagnetic interference
ESD	electrostatic discharge
NEDU	Naval Experimental Diving Unit
ONR	Office of Naval Research
PC	personal computer
RF	radio frequency
SD	secure digital
STTR	Small Business Technology Transfer
SUNY	State University of New York
USB	universal serial bus

Abbreviation	Description
bpm	beats per minute
COM	serial communications port
fsw	feet of sea water
GB	gigabyte
GHz	gigahertz
kg	kilogram
hrs	hours
Hz	hertz
mA	milliamp
mA-hr	milliamp-hour
rpm	rotations per minute
sec	second
V	volt

Symbol	Description
~	approximately
=	equals
>	greater than
±	plus or minus
®	registered trade-mark
+	plus
×	times