Department of Homeland Security
Science and Technology Directorate
First Responders Group
National Urban Security Technology Laboratory
New York, N.Y.

Test Report

Wireless Patient Vital Signs Monitoring Device Operational Field Assessment

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Executive Summary

On Dec. 3, 2013, the Department of Homeland Security (DHS) Science and Technology Directorate (S&T), Sotera Wireless® Inc., First Responders Group, and first receiver subject matter experts (SMEs) from around the nation convened at the American Medical Response facility in San Diego, Calif., to evaluate and assess the ViSi Mobile®. Sotera Wireless Inc., developed ViSi Mobile to meet the capability needs of the Wireless Patient Vital Signs Monitoring Device Operational Requirements Document, developed by DHS S&T with the assistance of emergency medical field SMEs. Participants offered varied years of experience and training and included two physicians, a trauma nurse, two firefighter/paramedics, and two paramedics from across the country.

All participants responded positively to the operational capability of ViSi Mobile and provided suggestions for improvements. This included methods of improving the flow of patient information between medics and creating a seamless process for moving vital sign information with the patient without transferring the mobile viewing device (laptop) between medics.

Another topic of discussion focused on the physical configuration of the device. The medics with Special Weapons and Tactics (SWAT) training and experience expressed a desire to remove certain components. All first responders expressed an interest in making the switch between a 3, 5, and 12-lead electrocardiogram easier, and potentially redesigning the chest connection method to further reduce the amount of wires involved.

Additional suggestions for improvement varied, but all sought to extend the functionality of the system. Ideas included adding Global Positioning System, capnography (monitoring of carbon dioxide in respiratory gases), and integrating the system with a defibrillator.

In summary, the assessment demonstrated ViSi Mobile's value in improving basic life support medical care. ViSi Mobile achieves its goal of reducing entanglement and eliminating the need to constantly connect and disconnect to different vital signs monitoring systems. It also possesses the potential to continue to grow and improve to incorporate additional future capabilities such as defibrillation.

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1 Introduction

The current instruments used by emergency medical services (EMS) personnel to monitor a patient's vital signs are cumbersome and must be tethered to the patient with numerous wires. Although the information received from these instruments can be displayed on one screen, the number of wires that must be connected to and disconnected from the patient can be overwhelming and confusing. Further, the equipment takes up valuable space in confined ambulatory environments (i.e., the back of an ambulance or an aircraft). Additionally, moving patients up and down stairs, from beds to stretchers, and in or out of vehicles is difficult when those patients are connected to heavy, bulky instruments and numerous wires.

To address this gap, the Department of Homeland Security (DHS) Science and Technology Directorate (S&T) worked with emergency medical subject matter experts (SMEs) in June 2011 to develop an Operational Requirements Document (ORD) for a Wireless Patient Vital Signs Monitoring Device. DHS S&T awarded a contract to develop such a device to Sotera Wireless® Inc. (Sotera) in December 2012. In December 2013, DHS S&T conducted an operational field assessment (OFA) of the developed prototype in San Diego, Calif. This report summarizes and analyzes the findings from the OFA.

1.1 Purpose

The OFA sought to gauge the suitability of Sotera's "ViSi Mobile®" system in its current state.

1.2 Objectives

The OFA used trained first responders utilizing the ViSi Mobile in realistic operational scenarios to assess and evaluate the system's suitability for first responder operations.

1.3 Requirements

The ORD defined operational performance requirements which the prototype has to fulfill to satisfy responder needs. Table 1 lists these requirements.

Table 1 – Requirements matrix

Performance Parameter	Threshold	Objective
Single Location Monitoring	N/A	The system shall function in a single monitor location that will provide patient vital statistics information from multiple other sources.
Wireless Ability	N/A	The system shall operate wirelessly and receive signals from other equipment wirelessly.
Interoperability and Compatibility	N/A	The system shall be interoperable and compatible with existing vital statistics monitoring equipment currently in use by EMS agencies, as well as current data exchange standards, such as the common alerting protocol and the National Emergency Medical Services Information System.
Size	N/A	The system shall be compact enough to fit in the back of an ambulance and other ambulatory situations without taking up critical space.

1.4 System Description

The ViSi Mobile Monitoring System is a patient-worn, portable, battery-operated, physiological monitoring device for monitoring of electrocardiography (ECG) (3/5/12 lead-wire), heart rate, pulse rate, respiration, non-invasive blood pressure, pulse oximetry, and skin temperature.

The system consists of a monitor, thumb sensor, chest sensor cable (3/5/12 lead-wire), cuff module, charger, and patient tile (Figure 1).

Powered by a rechargeable battery that lasts at least 12 hours, the monitor is lightweight (approximately 125 grams) and features a high-resolution, full-color touchscreen display with visual and audible alarms and alerts. Figure 1 shows the name of each component and how the device is attached to a patient. A full overview of the system and its components is in the Operation and Maintenance Manual (available from the vendor).

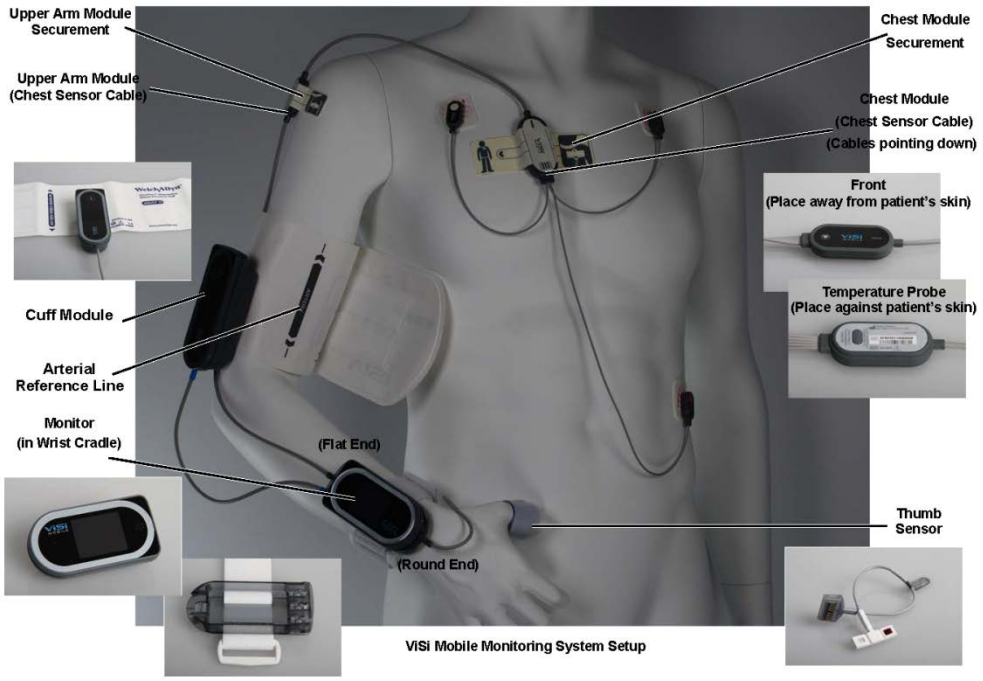

Figure 1- Overview of ViSi Mobile

Patient vital signs can be viewed on the monitor (Figure 2) or the ViSi Remote Viewer (Figure 3).

Figure 2 - Vital sign display from cuff module monitor

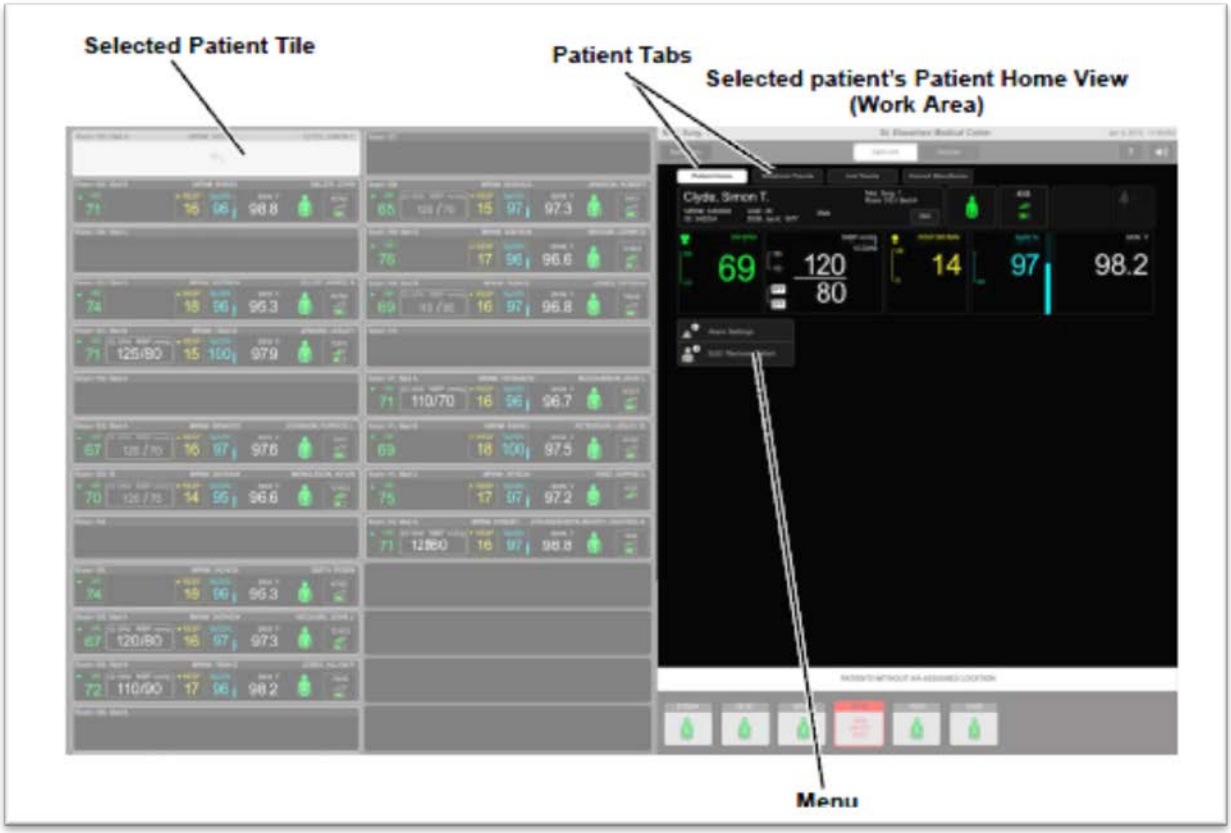

Figure 3 - Vital sign display from ViSi Remote Viewer

2 Operational Field Assessment Design

For a full set of procedures and further details, please request the *Operational Field Assessment Plan for the Wireless Patient Vital Signs Monitoring Device* from Bhargav Patel at Bhargav.patel@hq.dhs.gov.

DHS S&T, with support of paramedics from the San Diego area, designed four operational scenarios to test the ViSi Mobile. The four scenarios included an ambulatory drive, the use of a stair chair, the transport of a spinal injury patient, and the extraction and treatment of a car accident victim.

2.1 Deviations from Operational Field Assessment Plan

On the day of testing, first responder participants determined the stair chair scenario would offer minimal useful information about the ViSi Mobile. As an alternative, they suggested a Kendrick Extrication Device® (KED) with a cervical collar be used during the car accident scenario. This provided insight into how the ViSi Mobile might interact with other commonly used equipment in tight spaces, particularly equipment used to secure the body in rigid positions. The car accident scenario was modified to incorporate a spinal board.

2.2 Summary of Events

On Dec. 3, 2013, DHS S&T, Sotera, and first responders from around the nation convened at the American Medical Response (AMR) facility at 8808 Balboa Avenue, Suite 150, San Diego, Calif., 92123, to evaluate and assess the ViSi Mobile®. Participants represented a wide range of emergency medical experience and training, and included two physicians, a trauma nurse, two firefighter/paramedics, and two paramedics. (See Appendix 7 for a full list of participants). Sotera representatives provided a brief history of the product and training on the system. A follow-on discussion produced several suggestions for improvement and proposed methods of implementation of the system.

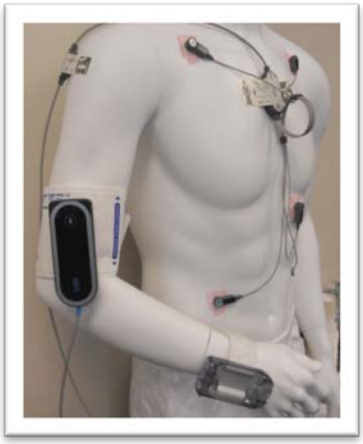

Figure 4 - ViSi Mobile emplaced on a mannequin

Figure 5 - Close up of wrist monitor

After training on the ViSi Mobile, participants gathered outside to begin the operational scenarios.

The first scenario involved applying the ViSi Mobile to a patient on a stretcher in a stationary setting. Trauma nurse Jackie Kennedy and firefighter Torie Wood placed the device on the volunteer "patient." Although they had some initial difficulty placing the cuff module and properly connecting the wrist module to the thumb sensor, due to the connection design, they quickly overcame these issues.

They then discovered that the SpO^2 sensor was not providing data. To remedy this situation, test administrators replaced the SpO^2 sensor with another, which functioned properly. Participants reported no issues of interoperability with the spinal board. Once in the ambulance, however, the responders were unable to obtain accurate readings of respiration while the vehicle was in motion.

Figure 6 - ViSi Mobile worn while patient is on a stretcher

The next scenario involved placing the ViSi Mobile onto a patient while in a moving ambulance. Dr. Natasha Powell and paramedics Anne-Marie Jensen and Michael Marsh conducted this scenario and decided to use a prototype 12-lead ECG. They reported issues viewing all 12 wave forms simultaneously on the laptop display due to dropped data packets. This issue resolved itself after a system reset.

The first responders in the ambulance succeeded in wirelessly transmitting a static shot of the 12-lead ECG wave forms to the laptop in the AMR conference room for review by the other first responders. Dr. Thomas Burnett affirmed the fidelity of the received ECG image was of sufficient quality to be used to make patient health assessments. Burnett suggested subsequent models of the system include the ability to zoom in on any single waveform.

Figure 7 - ViSi Mobile on a patient in the back of an ambulance

Burnett and firefighter Rob McLafferty entered the ambulance next. They also applied the 12-lead ECG attachment to the patient while the ambulance was in motion. During this scenario, the battery on the laptop died, and both responders expressed the need for a forward storage capability (the ability to store data off site, in real-time) to retain patient data.

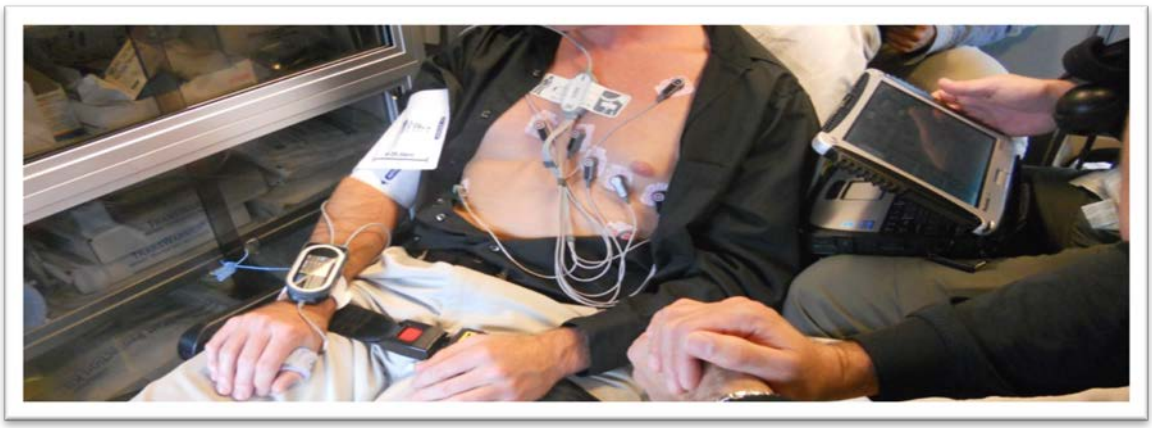

Figure 8 - 12 Lead ECG connected to a patient

The final scenario simulated responding to a car accident with a KED. Jensen, Marsh, and Wood applied the ViSi Mobile to the patient from the driver-side window and passenger-side door. They reported no immediate issues resulting from using the ViSi Mobile in conjunction with the KED and a cervical collar. The first responders did comment, however, that medics will tend to pre-configure the ViSi Mobile much as possible before going into the field. They also recommended that all stickers and adhesives be labeled for identification, and that ViSi Mobile components be brightly colored (orange or yellow) to alert first responders of their presence.

To conclude the scenario, the responders transferred the patient onto the spinal board and placed him into the ambulance via a stretcher

Figure 9 - ViSi Mobile being applied to a victim in a KED

A short onsite debrief followed the operational scenarios. Test administrators conducted a final recap and debrief on Dec. 4, 2013 at Sotera's offices. A phone conference with Cantor followed. Cantor described the results of his brief piloting of the ViSi Mobile at a local area hospital. The feedback from the debrief sessions and the conversation with Cantor are in Section 4.

3 Data Analysis

This section describes data collection methods, forms, and methods of analysis. Participants completed and submitted the questionnaires below; the data collector and test director compiled additional notes.

3.1 Operational Scenario Survey

After each scenario, participants completed the short survey in Table 2. Participants did not answer question six, because the stair chair was not used.

Table 2 - Operational Scenario Survey

No.	*Questions/Response*	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
1	I had a thorough understanding of the ViSi Mobile and Monitor.					
2	The training associated with this device was accurate and helpful.					
3	Operating the user interface of the ViSi Mobile was easy and intuitive.					
4	Operating the user interface of the ViSi Monitor was easy and intuitive.					
5	I had no trouble applying the ViSi Mobile to a patient during the Ambulatory Scenario.					
6	I had no trouble applying the ViSi Mobile to a patient during the Stair Chair Scenario.					
7	I had no trouble applying the ViSi Mobile® to a patient during the Spinal Board Scenario.					
8	I had no trouble applying the ViSi Mobile to a patient during the Car Accident Scenario.					
9	The ViSi Mobile does not interfere with my ability to complete tasks in a timely manner.					
10	The visual and audible indicators are sufficient enough to alert me of changes and alarm levels.					

No.	*Questions/Response*	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
11	The ancillary equipment is minimal and easy to use.					
12	Storing the ViSi equipment and its accessories for later use was difficult.					
13	I am confident in the ViSi Mobile's ability to operate in different environments.					
14	It was easy to remove the ViSi Mobile device from a patient.					
15	The ViSi enhanced my ability to monitor vital signs under varying circumstances.					

3.1.1 Data Analysis of Operational Scenario Survey

The Operational Scenario Survey is presented in the form of a Likert Scale. The responses were assigned a value from one (strongly disagree) to five (strongly agree). All questions are written in the affirmative, except for question 12, so that a higher score corresponds to a more positive experience with the prototype. In the case of question 12, the scale used was reversed because the statement has a negative connotation.

We used the following scale:

1 = Strongly Disagree
2 = Disagree
3 = Neutral
4 = Agree
5 = Strongly Agree

3.2 Phase 2 – Operational Scenario Debrief

Participants were debriefed after completing each operational scenario. The test director led a conversation to obtain participants' views on the suitability of the ViSi Mobile, deficiencies, efficiencies, and possible improvements. Section 4 summarizes the recorded feedback.

4 Results

This section contains results of the operational scenario survey and first responder comments and feedback. The results of this section are not an endorsement or rejection of the product or vendor. The goal is to provide an understanding of how the participating responders interacted with the prototype system and document their concerns, comments, and recommendations.

4.1 Operational Scenario Survey Results

Table 13 illustrates the results of the Operational Scenario Survey in a color-coded format. The final column (Average Score) shows the average score based on the scale system discussed in section 3.1.1. Based on the wording of the question, a score of five can be associated with a highly positive response to the prototype and a score of one a very negative response, except for question 12 where the scale is reversed.

Table 3 - Results of Operational Scenario Survey

No.	*Questions/Response*	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree	Average Score
1	I had a thorough understanding of the ViSi Mobile and Monitor	5	1				4.83
2	The training associated with this device was accurate and helpful	6					5.00
3	Operating the user interface of the ViSi Mobile was easy and intuitive	2	4				4.33
4	Operating the user interface of the ViSi Monitor was easy and intuitive	2	4				4.33
5	I had no trouble applying the ViSi Mobile to a patient during the Ambulatory Scenario	3	3				4.50
6	I had no trouble applying the ViSi Mobile to a patient during the Stair Chair Scenario						
7	I had no trouble applying the ViSi Mobile to a patient during the Spinal Board Scenario	4	1		1		4.33
8	I had no trouble applying the ViSi Mobile to a patient during the Car Accident Scenario	4	1		1		4.33
9	The ViSi Mobile does not interfere with my ability to complete tasks in a timely manner	3	1	1	1		4.00
10	The visual and audible indicators are sufficient enough to alert of me changes and alarm levels	1	2	3			3.67
11	The ancillary equipment is minimal and easy to use	1	4	1			4.00
12	Storing the ViSi equipment and its accessories for later use was difficult			2	3	1	3.83

No.	*Questions/Response*	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree	Average Score
13	I am confident in the ViSi Mobile's ability to operate in different environments	2	3		1		4.00
14	It was easy to remove the ViSi Mobile device from a patient	1	4	1			4.00
15	The ViSi enhanced my ability to monitor vital signs under varying circumstances	2	4				4.33
	Overall Average Score:						4.25

Table 3 is color-coded like a traffic signal to better represent the results. In the left portion of the chart, a green box represents a strong consensus among the responders, while a red box indicates little or no consensus. In the "Average Score" column, a green box indicates a very positive response to the prototype, and a red box represents a negative response to the prototype. Using the **scale of one to five,** the ViSi Mobile received an overall average score of **4.25** from the six first responders who participated in this assessment.

4.2 Operational Suitability Debrief and Feedback

Table 4 provides a categorized list of first responder recommendations.

Table 4 - First responder recommendations

Graphical User Interface	The Graphical User Interface (GUI) should be designed to alert first responders of a patient's proximity and can gain access to that patient's information.
	A full screen mode should be included to view all 12 wave forms when the 12-lead ECG is connected.
	When viewing ECG wave forms, first responders want to be able to zoom in on a single wave form and annotate it if necessary.
	The ViSi Mobile should offer the capability to pause ECG waveforms and take a static image or screen shot.
	The GUI should be altered to make it easier to send Portable Document Format files of ECG readings to hospitals.
Patient Information	First responders desire the capability to transmit or rebroadcast a patient's connection and information from one mobile device to another, allowing for a more continuous flow of patients from one first responder to the next. This is particularly important during a mass casualty type of event.
	First responders desire the capability to review patient data history while in the field and not be limited to a real-time stream of vital sign data.
	The device should offer a means to identify a patient to a device (i.e., barcode system), facilitating the assignment of a patient to an available medic.
	The device should offer a means of terminating the association of a patient to certain ViSi Mobile device, allowing the device to be reused on another patient.
	Medical personnel should be able to access data in additional file formats, such as comma separated file (.csv).
Physical	The blank spaces on the devices should be utilized to provide information on how to connect to and download patient information.
	The thumb module should be disposable. Potential issues of contamination and liability exist. All first responders concurred that the thumb modules will easily be lost or accidently thrown away, given their similarity in appearance to disposable equipment.
	A new sweat proof adhesive is needed for attaching sensors and other components to the body. First responders suggested using an adhesive similar to what athletes currently use for muscle support and injury relief.
	The process for changing between a 3,5, and 12-lead ECG chest mount should be revaluated and streamlined, allowing it to be changed quickly in the field or in a moving vehicle. Participants suggested a "snap on" chest mount concept.
	All adhesives need to be boldly labeled and include instructions for use.
	The components of the ViSi Mobile should be brightly colored as a secondary means of alerting any new first responders on the scene that the patient is wearing a monitoring device that should not be tampered with.
Other	First responders expressed that Global Positioning System capability may further enhance logistics and organization in mass casualty events.
	First responders should be able to initiate the system to check blood pressure from a mobile device instead of manually interfacing with the cuff module.
	All participants agreed that capnography (monitoring of carbon dioxide in respiratory gases) should be added as a means of monitoring respiration.
	A forward storage capability for data retention would make the system more robust and reduce the possibility of lost patient information due to hardware issues.

	If this prototype could be integrated with a fully-certified defibrillator, it could be used more frequently.

Table 5 lists the participants' general comments and concerns that did not relate directly to specific features or capabilities in the ORD.

Table 5 - General comments and concerns of first responders

Comments
Participants suggested that during (SWAT) scenarios, a light version of the ViSi Mobile system would be greatly beneficial. This version would not require the upper arm and cuff module.
The device would be useful during mass casualty events, such as Hurricane Katrina.
This device could be distributed to aid in disaster relief incidents similar to the Haiti earthquake or Typhoon Haiyan.
The device could be used by Federal Emergency Management Agency.
Participants debated as to whether interpretive algorithms should be used to diagnose incidents of ST segment elevation myocardial infarction, a type of heart attack.
Some first responders would use this as an adjunct to normal tool set.
Some first responders envision this tool being used for home care support.
In active shooter scenarios, communications are purposefully limited, and this device may help tactical EMS communicate vital information.
Concerns
Participants experienced issues viewing the LCD screen in ambient-light and outdoors.
Participants expressed concerns of defibrillator interoperability with the ViSi Mobile.
Mobile first responders found the respiration readings to be unreliable.
The upper arm module does not readily connect to a patient wearing clothes. Another method of securing it to the patient should be explored.
Slight artifacts (transient shifts or disturbances) appear in the ECG waveforms when a patient is moved (i.e., from vehicle to stretcher) and while in a moving ambulance.
Data packets were dropped between the ViSi Mobile and laptop while using the prototype 12-lead ECG connections.
Participants noted concern over implementation, expressing difficulty envisioning the relationship between EMS and hospital personnel in managing the equipment.

The first responders agreed that this technology serves as a valuable tool for improving basic life support medical care. Some of the discussion revolved around ways of improving the flow of patient information between medics, reducing the connections and wires on the system, and integrating additional capabilities, such as a defibrillator.

4.3 Requirements Compliance Matrix

Table 6 contains the requirements compliance matrix. Note that there are no threshold requirements; the system meets or partially meets all objective performance parameters.

Table 6 - Requirements compliance matrix

Performance Parameter	Threshold	Objective	Result
Single Location Monitoring	N/A	The system shall function in a single monitor location that will provide patient vital statistics information from multiple other sources.	**Meets Objective Performance Parameter.** The system as designed is capable of monitoring multiple patients from a single laptop.
Wireless Ability	N/A	The system shall operate wirelessly and receive signals from other equipment wirelessly.	**Meets Objective Performance Parameter.** The system uses both Wi-Fi and cellular frequencies to transmit and receive data.
Interoperability and Compatibility	N/A	The system shall be interoperable and compatible with existing vital statistics monitoring equipment currently in use by EMS agencies, as well as current data exchange standards, such as the common alerting protocol and the National Emergency Medical Services Information System.	**Partially Meets Objective Performance Parameter.** The equipment displayed no interoperability issues during the assessment (i.e., stretcher, KED, Cervical Collar, etc.). Other devices were not tested (i.e., defibrillator), however. Sotera did state they can potentially output the system's data into multiple formats (such as XML which is required by the National Emergency Medical Services Information System), but the prototype system did not currently support the exporting of data in that file format.
Size	N/A	The system shall be compact enough to fit in the back of an ambulance and other ambulatory situations without taking up critical space.	**Meets Objective Performance Parameter.** The system is compact enough to fit in the back of an ambulance without taking up critical space.

5 References:

1. Ambulatory Hands Free Patient Monitoring Operational Requirements Document (June 2011)
2. CCAT Prototype Development, Statement of Work, Sotera Wireless Inc. (Sotera) (Dec 2012)
3. Operational Field Assessment Plan for the Wireless Patient Vital Signs Monitoring Device (Dec 2013)

Please contact Bhargav.patel@hq.dhs.gov or King.waters@hq.dhs.gov for access to these documents.

6 Definitions List

CSV	-	Comma Separated Value
DHS	-	Department of Homeland Security
ECG	-	Electrocardiogram/Electrocardiography
EMS	-	Emergency Medical Services
FEMA	-	Federal Emergency Management Agency
GUI	-	Graphical User Interface
GPS	-	Global Positioning System
HR	-	Heart Rate
KED	-	Kendrick Extrication Device
NIBP	-	Non-invasive Blood Pressure
NUSTL	-	National Urban Security Technology Laboratory
LCD	-	Liquid Crystal Display
ORD	-	Operational Requirements Document
PDF	-	Portable Document Format
PR	-	Pulse Rate
RESP	-	Respiration
SpO^2	-	Pulse Oximetry
S&T	-	Science and Technology Directorate
SWAT	-	Special Weapons and Tactics
TEMP	-	Skin Temperature

7 Appendix A

List of Participants

Physician	Dr. Thom Burnett
Physician	Dr. Natasha Powell
Firefighter/EMT	Torie Wood
Firefighter/EMT	Robert McLafferty
Paramedic	Michael Marsh
Paramedic	Anne-Marie Jensen
Trauma Nurse	Jackie Kennedy
Sotera Product Manager	Sarah Sandwell
Sotera Vice President	Jim Welch
DHS S&T Project Manager	King Phil Waters
DHS S&T Test Director	Bhargav Patel