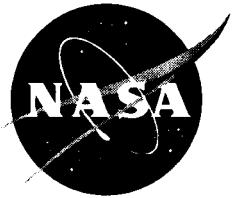NASA/CR-2003-208937

Evaluation of Critical Care Monitor Technology During the U.S. Navy Strong Angel Exercise

John Johannesen
Wyle Laboratories

Jack Rasbury
Wyle Laboratories

August 2003

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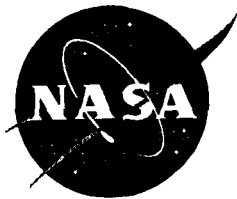
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CONTENTS

Preface

This document is an after action report summarizing all activities completed up to July 31, 2000 on the Strong Angel project. The report also identifies the tasks that remain and must be completed prior to project completion. All data and results in this report are preliminary and require further analysis. Analysis will continue as more data are acquired from the remaining tasks. A final report will be generated and distributed at the conclusion of the Strong Angel project.

Executive Summary

With the construction of the International Space Station and the resulting longer mission durations it has become necessary to expand the on-orbit medical capabilities. The Medical Operations Branch (MOB), at Johnson Space Center (JSC), has taken responsibility for expanding these capabilities under the Clinical Care Capability Development Project (CCCDP). One element of CCCDP is to enhance the critical care monitoring capabilities.

Medical Operations was invited to participate in exercise "Strong Angel", a civilian/military humanitarian relief effort. Strong Angel was a component in the "Rim of the Pacific" (RIMPAC) 2000 exercise that took place in Hawaii June 6, to June 18. Medical Operations used this opportunity to evaluate the ability of commercial portable critical care monitors to provide real-time patient data from a remote environment to a clinician using a satellite communication network (SCN). This communication scenario was analogous to ISS conditions. The objectives of Medical Operations were to:

- Determine state of the art and evaluate critical care monitors
- Develop collaborative relationships and information exchange with medical device vendors
- Identify current trends in critical care monitoring clinical communications standards
- Determine future trends and technologies of critical care monitors
- Define requirements for space mission critical care monitoring capability
- Validate procedures for treating a critically injured astronaut aboard the ISS

Medical Operations performed a market search on commercially available critical care monitors and acquired several monitors for evaluation purposes. Three of the five monitors received satisfied all of the original functionality requirements including the ability to send medical data across a TCP/IP network. These three monitors were then evaluated using a satellite communications simulator to determine their ability to support TCP/IP data transfer of simulated patient data with various satellite latencies and error rates. Critical care monitors able to operate with predetermined latencies and error rates were used in the Strong Angel field trials in Hawaii.

Once in Hawaii the monitors were tested through a real SCN in conjunction with simulated medical scenarios. The simulated medical data used in all the evaluations were generated using calibrated biomedical test instruments. Additional evaluations included evaluating the monitor's user interface, usability of the monitor's remote interface, its clinical functionality in harsh environments, its engineering design with respect to potential use on ISS, and validating the procedures for treating a critically injured astronaut aboard the ISS.

Overall, all monitors and equipment performed well. Notable achievements to date include 1) a demonstration of real time remote diagnostics and treatment using commercial-off-the-shelf critical care monitors. Moreover, this demonstration was implemented using the public Internet; 2) development and implementation of clinical scenarios for hip pocket procedure development; and 3) a detailed survey of the state-of the-art in critical care monitor technology.

This project, even though it is not complete, is proving to be very successful. The evaluations have provided valuable data that will be used in enhancing the on-orbit critical care capabilities. At the time of writing evaluation data are still being acquired. A final report, including a complete set of requirements for ISS critical care monitoring capabilities, will be completed at the conclusion of the this project. This report will be shared with all participating vendors.

Introduction

The NASA critical path road map identifies "trauma and acute medical problems" as a clinical capability risk category (http://criticalpath.jsc.nasa.gov). Specific risks include major trauma, organ laceration or contusion, hemoperitoneum, pulmonary failure, pneumo- and hemothorax, burn, open bone fracture, blunt head trauma, and penetrating injury. Mitigation of these risks includes the capability for critical care monitoring. Currently, the International Space Station (ISS) Crew Health Care System (CHeCS) does not provide such a capability. The Clinical Space Medicine Strategic Planning Forum (4/8/97), sponsored by NASA Medical Operations, identified the development of trauma care capabilities as one of the top priorities for space medicine. The Clinical Care Capability Development Project (CCCDP) subsequently undertook the task to address this need.

In January 2000, Johnson Space Center's (JSC) Medical Operations Branch (MOB) was invited to participate in the RIMPAC 2000/Strong Angel exercise in the Hawaiian Islands. This exercise was conducted on 6-18 June 2000, and involved seven nations and several public health and disaster-response organizations. A key component of this exercise was the establishment of a 300-person mock refugee camp to simulate mass dislocation due to conflict or natural disaster. This refugee camp was located on the big island of Hawaii.
(See Appendix A for a listing of URLs that will provide additional information)

Both a wireless network (Refugee camp to CMOC only) and a satellite system provided by ECU and Medweb connected the refugee camp to the East Carolina University School of Medicine (ECU). The satellite system was the primary method of communication and was configured to support a TCP/IP network. Many organizations used the network to send real-time Internet protocol (IP) video, biosensor data through telemetry, store/forward data from clinical telemedicine sessions, and real-time critical care monitoring data. One of Strong Angel's objectives was to build a nomadic computing network matrix that would link together the seven countries participating in this exercise through the ECU bridge.

Medical Operations personnel used this exercise to evaluate critical care monitors in a real-world telemedicine setting analogous to ISS conditions and to simulate potential ISS medical scenarios. The simulated patient was located in Hawaii, whereas, the medical consultants (NASA flight surgeons) were located in Houston. There were additional experts located in Star City, Russia, Toronto, Canada, and Philadelphia, Pennsylvania. This exercise afforded the CCCDP a unique opportunity to work with commercial vendors and evaluate their leading-edge technology and to evaluate the feasibility of treating an astronaut aboard the ISS using limited medical resources. These opportunities were consistent with the CCCDP critical path towards enhancing long-term Advanced Life Support System (ALS) capabilities.

CCCDP Strong Angel activities were subdivided into four separate phases:

Phase 1	In-House Testing	Houston	1 March, 2000
Phase 2	Remote Monitoring/TDRSS Simulator Testing	Houston	20 April, 2000
Phase 3	**Operational Deployment**	**Hawaii**	**8 June, 2000**
Phase 4	Post-Deployment	Houston	19 June, 2000

At this writing, only Phase 3 has been completed. Phase 1 and 2 activities were limited to configuration and data transmission capability testing to determine which monitors should be deployed during Phase 3. Activities are still ongoing for Phases 1, 2, and 4. This report will describe the accomplishments to date. A final report will be issued when all phases are completed.

Phase 1 – In-House Testing

Phase 1 involved a trade study researching the portable critical care monitor industry, acquiring equipment and becoming familiar with the systems. Phase 1 plans also called for usability and human factor tests on the various systems, but due to time constraints, these tests are planned for the Post Deployment phase.

The trade study consisted of consulting with industry contacts, consulting with the MDB Information Network, reviewing publications written by the Emergency Care Research Institute (ECRI), and contacting the vendors of critical care monitors. After performing a market trade study, eight vendors were identified as having products that might meet the requirements identified in the Strong Angel Project Plan (refer to Appendix B). These vendors were contacted to gauge their interest in supporting the project and, of these, six expressed interest in participating and supplying equipment for testing. These six vendors agreed to loan monitors and their appropriate accessory equipment to Medical Operations/CCCDP for a one year period. However, only five of the vendors were able to deliver equipment within the time frame needed to support testing before actual deployment. At the time of writing one company is still working on delivering equipment to Medical Operations.

Vendors provided detailed technical information regarding their products and several sent engineering staff to support the initial monitor setup and familiarization. After familiarization with the equipment, review of the supplied documentation, and performing initial tests with the monitors, only three met the criteria for deployment to Hawaii. The main factor for determining whether a monitor went to Hawaii was its capability to deliver medical data across a TCP/IP network and the ability to view these data at a remote site. Table 1 summarizes the vendor transactions.

Table 1: Matrix describing vendor transactions

Vendor	Monitor(s)	Responded positively to initial invitation	Provided monitor(s) before deployment to Hawaii	Monitor(s) actually deployed in Hawaii
HP-Agilent	M3	Yes	Yes	No
GE-Marquette	Dash 3000 or Eagle 4000	No	No	No
SpaceLabs	Ultraview 1050	Yes	Yes	Yes
Datex-Ohmeda	CS3	Yes	Yes	Yes
Datascope	Expert or Passport	Yes	Yes	No
Critikon	Dinamap Select	No	No	No
Protocol	Propaq CS or Propaq	Yes	No	No
Siemens	SC7000	Yes	Yes	Yes

Phase 2 – Remote Monitoring/TDRSS Simulator Testing

Phase 2 was comprised of the following tasks:

1. Configuring the critical care monitors for networking across a TCP/IP network
2. Verifying that communications were valid
3. Testing the monitors on a simulated satellite network
4. Developing a physiologic simulator test system for use in Hawaii
5. Developing several medical scenarios for use during the deployment phase.

Three of the five monitors sent to Medical Operations were able to satisfactorily complete the first three tasks. These monitors were tested using a communications link simulator system located in the Building 44 Avionics Laboratory at JSC[1]. However, due to time constraints, only two of the monitors were actually tested with this simulated link.

Equipment

Communications Link Simulator System

The Avionics group at JSC developed the communications link simulator to imitate the communications link (KU-band) between Mission Control Center (MCC) and the Space Shuttle or the International Space Station (ISS). The system consists of two local area networks (LAN) that are connected to each other through the TDRSS satellite simulator or "delay box." These LANs represent the MCC (ground-side) and either the Shuttle or the ISS (flight side). Each LAN has several workstations, a hub, and a router containing an orbital communications adapter (OCA) communications card that interfaces directly to the delay box. The delay box simulates the delay introduced when a communications signal travels through a satellite (i.e., a TDRSS satellite). The delay box has the capability to simulate various signal delays (0 sec., 0.55 sec., 0.80 sec., and infinite) and various data bit error rates (0, 1/100000, 1/1000, and 3/1000 bit errors per data bits).

Critical Care Monitors

Monitors tested during this phase were required to connect to a TCP/IP network. Three monitors satisfied this requirement, the CS/3 (Datex-Ohmeda, Tewksbury, MA); SC7000 (Siemens Medical Systems, Inc., Danvers, MA); and the Ultraview 1050 (Spacelabs Medical, Inc., Redmond, WA). These monitors lacked the ability to connect directly to a TCP/IP network, but used their own proprietary network protocol. Thus, all monitors required the use of a gateway running proprietary software that would translate their protocol into TCP/IP. Two of the monitors used a gateway provided by Wyle Laboratories (Panasonic Toughbook) that was then configured with the appropriate software provided by the vendors. The third monitor used a gateway provided by the vendor.

---

[1] Contacts for this lab are Brett Parrish and Steven Schadelbauer.

Physiologic Simulators

To test each monitor, physiologic simulators were used to create the following signals:
- electrocardiogram – ECG,
- pulse oximetry – SpO_2,
- noninvasive and invasive blood pressures – NIBP and IBP,
- temperature
- respiration

Consultant Workstation

The computer workstation, located at the primary consultant station in Houston, was an Intel Pentium II based computer. It was running the Windows '95 operating system. Internet Explorer 5.0 and Siemens' WinView client software packages were both installed. Internet Explorer was used to view data sent by Datex-Ohmeda's CS/3 and Spacelab's Ultraview 1050. WinView client was used only to view data sent by Siemens' SC7000 monitor.

The secondary workstations were also Intel Pentium II based machines running either Windows '98 or Windows 2000. All used Internet Explorer 5.0 to view the transmitted monitoring data.

Test Setup and Protocol

For each test in the Building 44 Avionics Lab, one monitor was connected to its respective gateway. The gateway was then connected to the flight-side LAN via the flight-side hub. A multipurpose workstation running Windows NT and Internet Explorer 5 was plugged into the ground-side LAN via the ground-side hub. Before testing began, it was ensured that both the multipurpose workstation and the monitor's gateway could 'ping' each other, verifying a good network connection. Once a good connection was verified, Internet Explorer was run on the multipurpose workstation and used to acquire and display the real-time data coming from the monitor being tested. Each monitor tested displayed four waveforms, two ECG, pulse oximeter, and respiration waveforms as well as NIBP, temperature, pulse rate, respiratory rate, and oxygen saturation. On the workstation end, the four waveforms and all numerical data were displayed (Figure 1).

Each monitoring system underwent a series of four tests. The first test was conducted to determine how the monitoring system reacted to a time delay in the communications link. Initially, the delay box was set to no delay and no data bit errors. Once the data displayed on the workstation were stable (the system was allowed to run for approximately 60 sec.), the settings on the delay box were changed. For the first test only, the delay times were changed (they were increased to 0.55 and then to 0.80). Each time they were changed, time was given to allow the systems to stabilize, and then the effect on the system was noted.

The second test was designed to determine how the monitoring system reacted to errors in the data stream. For this test, the delay time was set to a constant 0.55 sec., as this was the same delay that the systems would encounter in Hawaii. The data bit error rate was increased from

0 to 3/1000 incrementally. Each time the rate was increased, time was allowed for the system to stabilize. Notes were taken on how the error rates affected the system.

The third test determined how the monitoring system would react if a loss of signal (LOS) was experienced. This was done by physically disconnecting one of the communication cables from the delay box thereby severing all communications.

The fourth test determined how the monitoring system would react if individual components of the communications signal were lost independently of one another. This was done by bypassing the delay box with a set of "breakout cables." The set consisted of four cables carrying the following signals: TxD (data down), TxD clock, RxD (data up), and RxD clock. Each signal was disconnected and the system's response was noted.

Simulators

Spacelabs System

Also used for Datex system

Toughbook Gateway
3COM IP: 192.168.50.99
Mask:255.255.255.0
Default:192.168.50.10

Spacelabs
IP: 192.168.50.**100**
Mask:255.255.255.0
Default:192.168.50.10

Other Workstations

HUB
(Flight Side)

Datex-Ohmeda Monitor

HUB

Datex-Ohmeda Gateway
IP: 192.168.50.99
Mask:255.255.255.0
Default:192.168.50.10

Flight Router

Datex System

Delay Box

Flight

Ground

HUB
(Ground Side)

Multipurpose Workstation
IP: 192.168.10.**98**
Mask:255.255.255.0
Default:192.168.10.10

Ground Router

Other Workstations

● Figure 1   Diagram of setup for testing equipment with satellite communications simulator.

Phase Two Results

SpaceLabs Ultraview 1050:

The SpaceLabs Ultraview 1050 monitor worked well with delays between 0 and 0.80 seconds. However, the time it took for the web browser to load data increased proportionally to the increase in delay. Moreover, the data being displayed on the workstation increasingly lagged the monitor sending the data, resulting in a phase delay between the simulated patient and the remote patient monitor (workstation). This delay varied from 7 sec. with no delay introduced in the link, to about 15 sec. with 0.8 sec. delay. These were expected results.

When data bit errors were introduced to the system, data were lost. The data became patchy (missed data) when the data bit error rate was set to 1/100000, the lowest setting on the box. This setting is the worst-case specification for the TDRSS satellite system. Although the data were patchy, the system recovered and continued to display data. Occasionally, one waveform was lost. When the rate was increased to 1/1000, the data became even more patchy and occasionally all data were lost. Both waveform and numeric data were effected. Occasionally the web browser recovered from this, but more often than not it required restarting. When the rate was increased to 3/1000, data were displayed for a few seconds before it completely crashed – no data were displayed. The web page was restarted, but it never was able to reconnect to the monitor/gateway and resume operation. A 3/1000 data bit error rate corresponds to a 15 to 20% loss of data.

Overall, when there was data loss, the waveform data were compromised more than the numeric data.

Loss of signal (LOS) was simulated for 45 seconds. During this test, the workstation receiving the data went blank after 7 seconds and the gateway went blank after 12 seconds. The gateway response was not expected. Once the signal was reestablished, the gateway displayed data again, but the workstation never recovered. The web browser, Internet Explorer, needed to be restarted.

Loss of individual signal lines was also simulated for 45 seconds. The results were similar to the LOS test. The one difference was that the gateway did not lose data. The data were being displayed continuously. Data was lost on the gateway only when all four signals were disconnected simultaneously.

Datex-Ohmeda CS3:

The Datex-Ohmeda monitor was initially tested with no delay in the communications link. There were no anomalies in the data being displayed at the workstation. Once a 0.55 second delay was introduced to the system, some data at the workstation were lost. Two of the waveforms, pulse oximeter and respiration, and some of the numeric data were dropped. When the delay was increased to 0.80 seconds, only the two ECG waveforms

appeared on the display and, at times some of their data were lost resulting in patchy waveforms. The numeric data were lost at times too.

When data bit errors were introduced to the system, the data being displayed on the workstation became patchy with more data dropping out, both waveform and numeric. When the data bit error rate was set to 1/100000, one of the waveforms was lost and the others had sections of missing data. A couple of the numerical data points were lost. When the error rate was set to 1/1000, the workstation lost all data. It was intermittent for about 10 seconds, and then went blank. When the 3/1000 rate was dialed in, no data were displayed on the workstation.

Loss of signal (LOS) was simulated for 45 seconds. During this test, the workstation receiving the data went blank after a few seconds. Once the connection was reestablished, the web browser at the workstation never recovered. It was only after it was restarted that it began displaying data again.

When simulating the loss of individual signal lines each loss was done for 45 seconds. When TxD (data down), TxD clock lines were disconnected, the results were similar to the LOS test. However, when the other lines, RxD (data up), and RxD clock, were disconnected there was no noticeable effect. During this testing phase the CS3 monitor did exhibit a few anomalies. The display would flicker occasionally and once went completely blank. It was noticed that when this happened, the alarm on the CS3 did not sound normal but made a sound similar to a metronome (a ticking sound instead of the normal alarm tone). The Datex-Ohmeda representative concluded that the problem was probably a loose connector on the display panel. The CS3 monitor had been used previously on KC-135 flights and the strip-chart recorder assembly had been removed from the unit and a VGA cable installed to provide VGA video output. This may have compromised the integrity of the system.

Siemens CS 7000

The Siemens monitor was not tested in the avionics lab using the above protocol. It was received on 26 May, leaving only 7 days until the shipping deadline for deployment to Hawaii. The system was tested using the CCCDP LAN and remote Internet accesses.

Summary

Overall, all monitors and equipment worked well through the test link. The testing provided good feedback on the expected behavior of the monitors under various communications link conditions. This proved to be useful information for troubleshooting the systems in Hawaii. See Table 2.

Monitors	Delay time			LOS	Bit error rate				Loss of Signal lines			
	0s	0.55s	0.8s	45s	0	1/100000	1/1000	3/1000	TxD	TxD clk	RxD	RxD clk
CS/3	X	M	M	-	X	M	-	-	-	-	X	X
Ultraview 1050	X	X	X	-	X	M	M	-	-	-	-	-
SC7000	Not Tested			Not Tested	Not Tested				Not Tested			

Key:
- X   Good; no data loss
- M   Marginal; some data loss
- -   Transmission completely lost

• Table 2   Summary of monitor performance in satellite communicaitons test

Physiologic Simulator System Development

Physiologic input signals (electrocardiogram - ECG, pulse oximetry - SpO2, non-invasive blood pressure – NIBP, invasive blood pressure – IBP, temperature, and respiration) were generated using an array of medical equipment calibrators that were controlled by a computer. The calibrators were loaned and then subsequently purchased from Bio-Tek, Incorporated and consisted of the following:

- LionHeart 3 – a lightweight, portable patient simulator that provides ECG (3, 5, or 12 lead), invasive blood pressure (static or dynamic), respiration, and temperature outputs. It also provides multiple heart arrhythmias (over 30 types), artifacts, and other simulation functions (such as S-T segments, pacing, etc.). It also provides a variety of signals (sine, square, triangle waves) that can be used to verify the performance of ECG monitors.
- Index 2 – a pulse oximeter tester that provides the ability to simulate the blood oxygen conditions of a patient and presents the signal to a pulse oximeter's finger sensor. It provides oxygen saturation levels from 35 to 100 % and pulse rates from 25 to 250 beats per minute. In addition, abnormal conditions in O2 sat and pulse rate caused by physiologic conditions can be generated through pre-programmed simulations. It also provides the ability to electrically verify pulse oximeter probe diodes, LEDs, and wire continuity. Also, since different R-curves can be programmed into the simulator, it can be used with any pulse oximeter on the market.
- BP-PUMP – a non-invasive blood pressure monitor tester that provides dynamic blood pressure simulations, static calibration, automated leak testing, and high/low pressure release verification. The simulations provided include normal pressures and pulse volumes; those produced by abnormal physical conditions, and motion artifacts. It contains an internal cuff that can be used instead of the original BP monitors cuff to eliminate the variability of cuff volume.

The simulators can be used independently to test and calibrate various medical devices or to train medical personnel in recognition and interpretation of physiologic signals. The calibration of each simulator can be traced directly or indirectly to the U.S. National Institute of Standards and Technology (NIST), and Bio-Tek's calibration program meets the requirements of the U.S. FDA's Good Manufacturing Practices (GMP), ISO 9001, and MIL-STD-45662A. Because of the highly accurate nature of the physiologic signals, the simulators will provide for thorough equipment evaluation, system development and prototype validation, as well as providing a full range of patient pathology simulations.

For the Strong Angel project, the simulator system provided the basis for evaluating and comparing the critical care monitors. Medical scenarios relevant to space operations risk data were designed based on the equipment's ability to simulate the physiologic signals. As the 'patient' progressed through the scenario, the signals changed appropriately. Computer control of the simulators was accomplished using Bio-Tek's OTIS software application loaded onto a PC. The simulators were connected to the computer via an electronic switcher (Smart Switch, model 232XS5 manufactured by B&B Electronics).

The OTIS software contained all of the device commands for each simulator and provided a programming environment to automate sending the commands to each device.

The instruments used for the medical scenarios were primarily designed for the purpose of calibrating medical monitoring devices, not to simulate medical scenarios as in Strong Angel. Therefore, there were limitations to the fidelity of the medical scenarios associated with the off-nominal use of the simulators. Specifically, the following observations from the development period should be noted:

- The interfaces of the different simulators (LionHeart 3, Index 2, BP Pump) operate at different baud rates and require different inter-character delays. This required additional programming and switching time from device to device. Device settings for the simulations were:
  - LionHeart 3 – 9600 baud, 100 msec delay
  - Index 2 – 9600 baud, no delay
  - BP-PUMP – 2400 baud, 1000 msec delay
  - Smart Switch – 9600 baud, no delay
- The heart rate (HR) is not adjustable on second and third degree heart block or pacing simulations. More flexibility in setting HR is desirable.
- Although the ECG and IBP signals coming from the LionHeart 3 are synchronized, the heart rate pulse signal for SpO_2 generated by the Index 2 cannot be synchronized with the LionHeart 3. The ability to synchronize the SpO_2 signal with the ECG/BP signals would enhance the capability to produce high fidelity patient simulations.
- The IBP levels provided by the LionHeart 3 are limited and do not correspond to all the levels available from the BP-PUMP. It is desirable to have the NIBP and IBP values agree during the simulations.
- The Index 2 seemed especially sluggish in accepting commands from the computer. Usually a five-second delay after sending the command was required to allow the unit enough time to accept the command. Changing the baud rate on the Index 2 to lower settings did not appear to make a difference.
- The BP-PUMP settings could not be changed if the monitor was taking an NIBP measurement at the time a command was sent. It is desirable to implement a command memory buffer in BP-PUMP to accept commands while the unit is performing a measurement. For these simulations a user message instructing the operator to check for NIBP measurement. However, this still requires the simulation coordinator be aware of the monitor's NIBP measurement cycle.
- It is desirable to have built-in defibrillation and CPR rhythm simulations in the LionHeart 3. For these simulations, a defibrillation pulse was roughly approximated with a square wave, 0.125 Hz from the LionHeart 3. A CPR rhythm would facilitate the simulation of many medical scenarios that might be encountered on ISS. The OTIS program editing capability is very awkward. The vendor has stated that a newer version will correct some of the weaker aspects of the program noted below:
  - Program lines cannot be selected for cut, paste, or delete anywhere on the line. The cursor must be positioned directly over the check item number. However, it does allow multiple lines to be selected.

- Editing is slower as the program gets longer because it takes more time to paste lines and renumber. For the OTIS simulation program used in Hawaii (which was 328 lines long), the paste operation took 5 to 6 seconds on a 486 PC.
- Cut and paste in OTIS was limited to approximately 10 program lines. If more lines were selected, the lines would not necessarily be pasted contiguously.

Phase III – Operational Deployment

Phase three consisted of deploying all qualified monitors and their support equipment to Hawaii, testing the monitors using detailed patient scenarios, evaluating the monitors, and evaluating the feasibility of treating a critically injured astronaut aboard the ISS. Two Advanced Projects (AP) personnel traveled to Kailua-Kona, Hawaii June 8-18 2000. Approximately 400 lbs. of equipment (three critical care monitors and support equipment) was shipped to the Pohakaloa Training Center, a U.S. Marine facility on the Big Island, via UPS 2-Day air.

Pre-Deployment Check-Out

Prior to set up at the Strong Angel site, the monitors were set-up for a pre-deployment checkout and tested along with the ECU equipment at a facility located 20 miles from the site. During the pre-deployment checkout, CCCDP personnel set up their equipment facing into the sun to evaluate the performance of the monitors in direct sunlight. The only monitor that could be seen (able to view the data displayed on the monitor) was the SpaceLabs' Ultraview 1050. All other monitors, including computers, were impossible or very difficult to view. Other than difficulty viewing the monitors in the sunlight the equipment performed nominally. This opportunity was used to pre-configure and make last minute changes to the equipment and to verify the set-up and placement of equipment before transporting to the work site. This checkout also provided an opportunity to show the equipment to the other organizations that were involved in the Strong Angel exercise (American Red Cross, DARPA, Unicef, U.S. Navy, U.S. Marines, and the United Nations).

Strong Angel Exercise Site

The Strong Angel site was located just outside of Waimea, HI (this was about 30 minutes from AP personnel's hotel). The Command Missions Operations Center (CMOC) was about 0.5 miles from the main road at mile marker two and the refugee camp was located about three miles beyond the CMOC just at the base of Puu Paa, the central landmark in this volcanic ash field. (See figures 2 and 3)
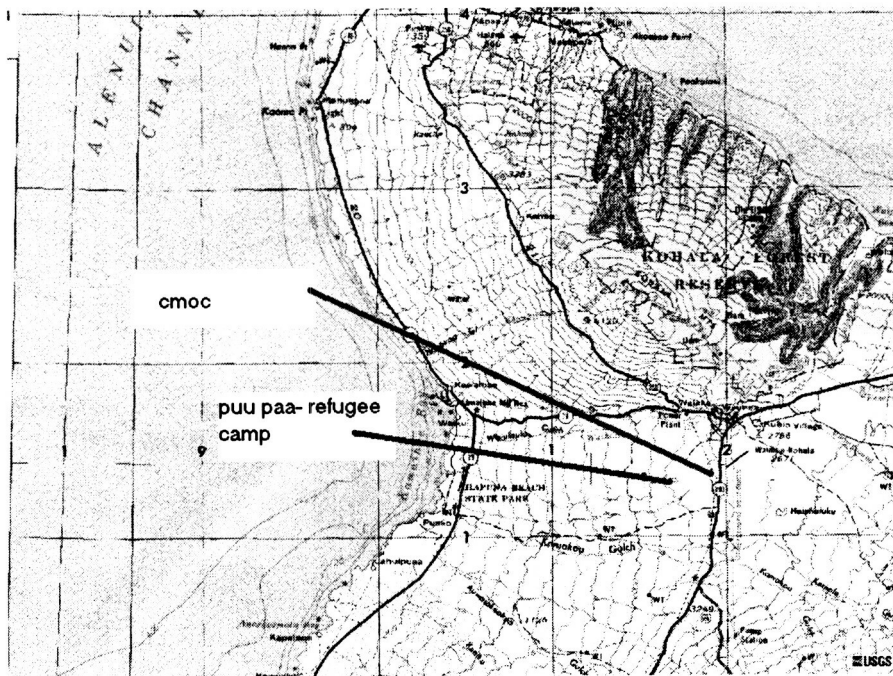
• Figure 2: Northwest Corner of the big island of Hawaii
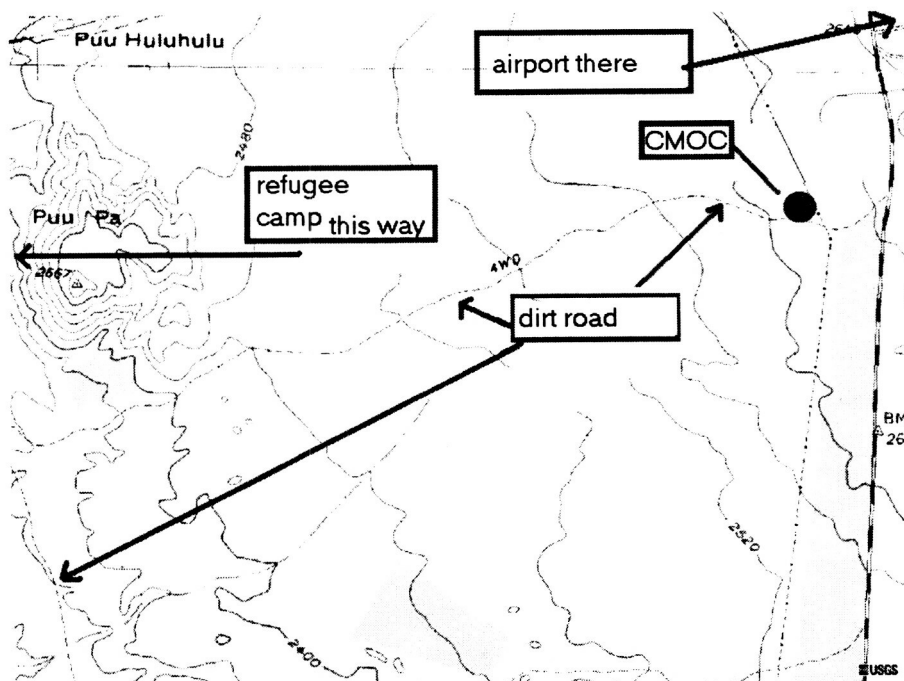
• Figure 3: Detail of CMOC and refugee camp

The CMOC and refugee camp consisted of 78 large green military canvas tents without flooring. Due to road conditions, no civilian vehicles were allowed past the CMOC to go to the refugee camp without prior approval. The only transportation to the refugee camp was by military transport vehicles: the high-mobility multipurpose wheeled vehicle (HMMWV) or 5-ton flatbed trucks. The conditions were very dirty, with an extremely fine dust, and wind. During the operation, gale force winds blew down tents and other facilities including communications equipment. Weather conditions throughout the deployment were cool with low humidity and rain on one occasion. During the day the temperature inside the experiment tent was approximately 90°F with night temperatures in the high 50's. All AP equipment was located in the medical tent somewhat sheltered from the elements – although not completely. Volcanic dust, driven by the strong winds, required that equipment be covered with plastic to prevent dust from getting on/in equipment. When personnel left for breaks all equipment was covered with a large tarp. (See Figures 4 to 6)

• Figure 4 :   Picture taken at CMOC site (note the windy/dusty conditions)
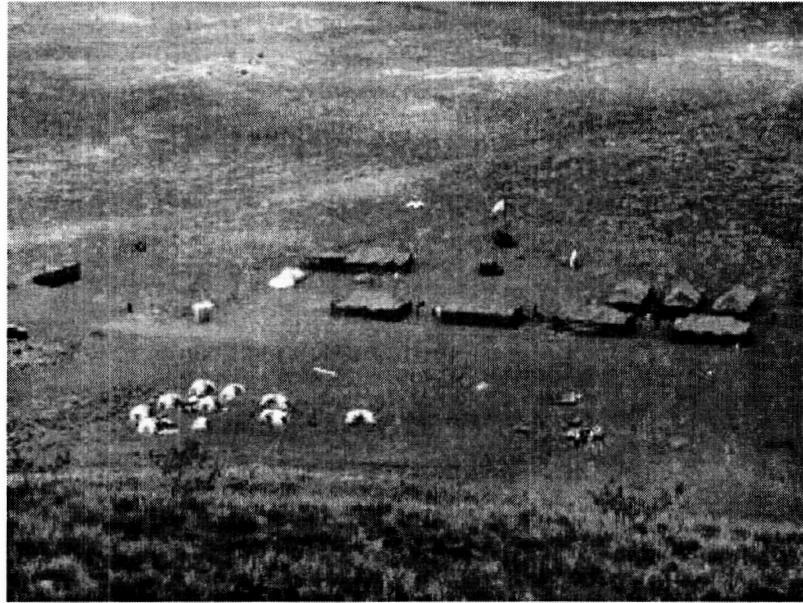
• Figure 5: View of refugee camp from the top of Puu Paa (med. tent is 2nd from left, bottom)
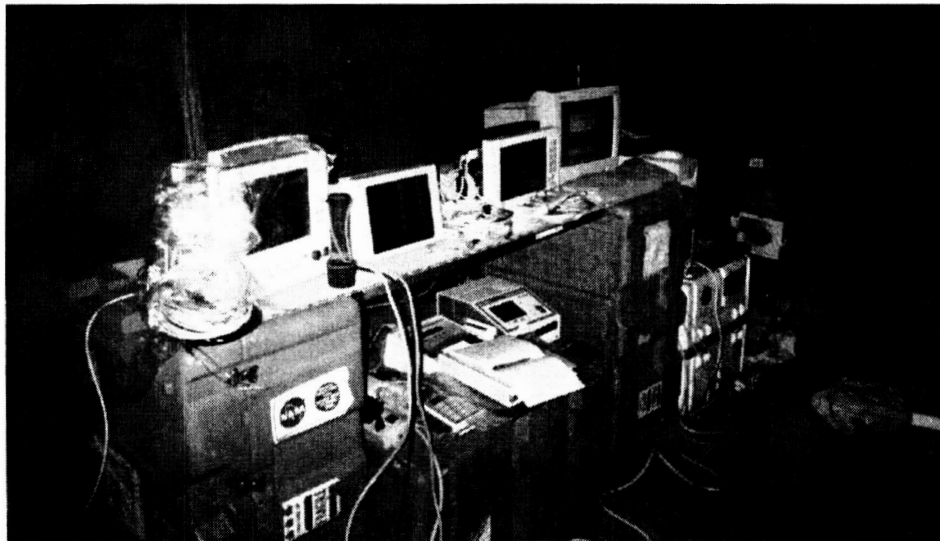
• Figure 6: Medical Operations' equipment in medical tent

Equipment

Medical Equipment

The following is a listing of equipment that was taken to the Strong Angel work site:

- Datex-Ohmeda CS/3 Critical Care Monitor
- Siemens SC7000 Critical Care Monitor
- SpaceLabs Ultraview 1050 Critical Care Monitor
- Compaq Deskpro – Datex-Ohmeda Central Station

  Pentium III 450 MHz, 15in. SVGA monitor
- Panasonic Toughbook Ruggedized Laptop – Siemens and Spacelabs gateway

  Pentium II 300MHz, WinNT, 12.1 SVGA Touchscreen Monitor
- BioTek Physiologic Simulators
- LionHeart 3 – multi-parameter simulator
- Index 2 – pulse oximetry simulator
- BP-PUMP – non-invasive blood pressure simulator
- IBM Thinkpad 740 Laptop – Simulator Control Computer

  Pentium, 100MHz, Win95, 10.1 Flatpanel Monitor

Support Equipment in Hawaii

As part of the preparation for the Strong Angel exercise, additional support equipment items were anticipated and subsequently ordered or manufactured. This included essentials such as hand tools, duct tape, rope, flashlights, and batteries. In addition, some other not-so-obvious, but just as essential, items used for this project are listed below:

- Tarpaulin – used to cover the equipment when not in use. Eliminated need to repack the equipment in crates after each session and kept most of the volcanic dust off the equipment.
- Workbench – a wooden surface of approximately 2 x 6 feet placed on top of two shipping containers (assembly required). A simple but very effective asset.
- Desk lamp – the lighting in the medical tent consisted of two 40-watt incandescent bulbs, hardly adequate for equipment setup and note taking.
- Portable vacuum – an item that seemed unnecessary when packed but was used extensively in the test tent by CCCDP engineers and others.
- Goggles, dust masks, plastic wrap – these items were needed to keep dust off the operators and equipment. These items helped, but the dust was so fine there was no way to completely block it.

Primary Receiving Station

The following describes the workstation/network utilized at the primary receiving station:

Location: Johnson Space Center, Building T585, Houston, TX
Computer Specifications: Pentium II 350 MHz, 21-inch color monitor
Operating System: Windows 95
Network Connection: JSC internal network via a 10baseT connection
Software: Microsoft Internet Explorer 5.0
                                Siemens WinView

Secondary Receiving Stations

The following describes the workstation/network utilized at the secondary receiving stations:

Location: Star City, Russia
Computer Specifications: Pentium II, 300 MHz, Dell Inspiron 7000 laptop
Operating System: Windows 98
Network Connection: T1 connection
Software: Microsoft Internet Explorer 5.0

Location: Toronto, Canada
Computer Specifications: Pentium II, 466 MHz, color monitor
Operating System: Windows 98
Network Connection: Bell High Speed dial-up 50-60 kbs to ISP/public Internet
Software: Microsoft Internet Explorer 5.0

Location: Philadelphia, PA
Computer Specifications: Pentium II, 266 MHz, 17-inch color monitor
Operating System: Windows 2000 Server
Network Connection: 608/128 kbs DSL to ISP/public Internet
Software: Microsoft Internet Explorer 5.0

Session Communications

The nominal network connection to the mainland was provided by a direct satellite link between the refugee camp and ECU. This was supposed to be available by Sunday June 11, but due to technical issues was not available until Tuesday afternoon. The original satellite dish was too small to provide the necessary signal gain for the large distances involved. A larger dish was eventually located and installed at the refugee site. ECU personnel attempted to use the wireless LAN connection to the CMOC until the satellite connection was operational, but weather conditions made this an unreliable link. As a result MOB activities were condensed to three sessions instead of five.
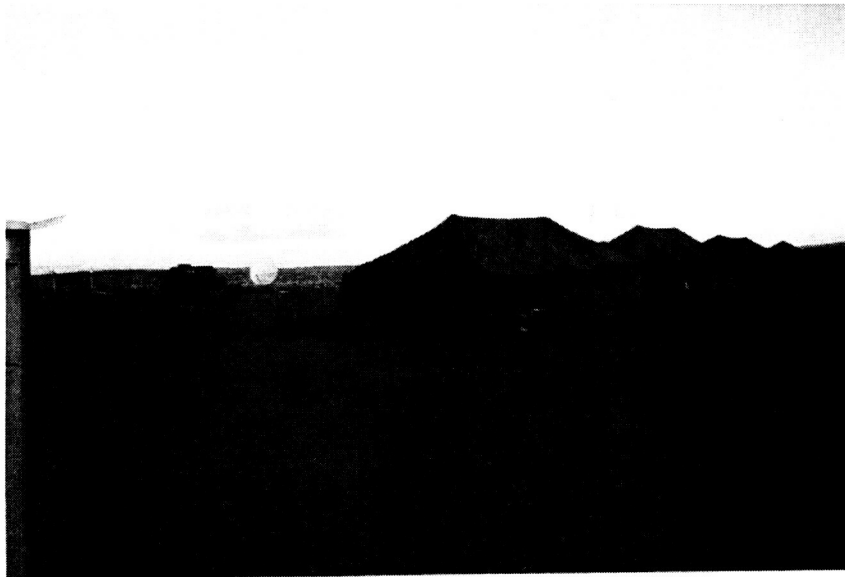
• Figure 7:   Photo of satellite dish at refugee site (dish is facing East)
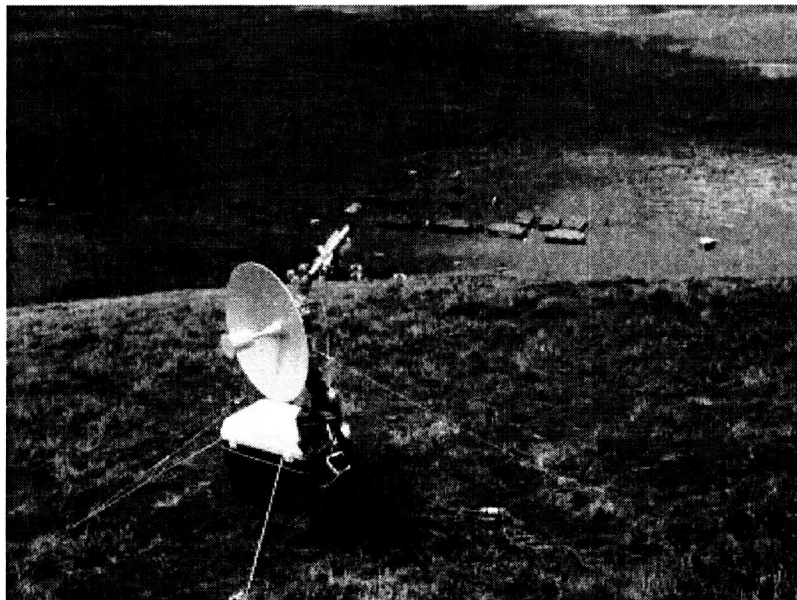
• Figure 8:   Photo of Wireless LAN Repeater on top of Puu Paa (Linked refugee Camp with CMOC)

During the three sessions, Microsoft NetMeeting (providing voice over the Internet) and a cell phone were used to communicate between the operators in Hawaii and the primary receiving station in Houston, Texas. The cell phone connection was used to coordinate session initiation and termination and then on an as needed basis during the session. The phone was not used through the whole session because of the cost of doing so and the limited battery life of the phone. In addition the cell phone connection in Hawaii was unreliable and was dependent on the user's location in the tent and direction the user was facing. This factor also compromised the ability to receive calls with the cell phone.

The NetMeeting audio connection worked reasonably well, but due to multiple people and ambient noise at both ends, using the computer speakers for audio output was not ideal. Headsets would have provided for more effective communication. The NetMeeting audio was used in Hawaii mainly to listen to the medical scenarios described in Houston. Although AP personnel were able to consistently make a NetMeeting connection, the audio connection was intermittent. The most reliable communication tool was the NetMeeting Chat window, which provided real-time text messaging. This was used throughout all three sessions.

Session Logistics

The U.S. Navy provided 120 VAC power to the exercise site. ECU provided the TCP/IP RJ45 network drop for data communications (this consisted of a Telemedicine Cube from Medweb). The data communications network consisted of a bi-directional 1Mb/s TDRSS satellite link between Hawaii and ECU. The satellite connection was then connected to the ECU network and made available to JSC via a standard Internet connection. AP personnel were scheduled for communications during the off hours, midnight to 4AM (Hawaii time) 12-16 June, but the communications system was not fully functional until late Tuesday afternoon (13 June). As a result of the lost communication time, access time was rescheduled for all experiments. CCCDP was rescheduled to three sessions for a total of 13 hours of satellite time. The session times (Hawaii time) were as follows:

Wednesday	14 June	0000-0500
Wednesday	14 June	1500-1900
Thursday	15 June	0100-0500

For each session, the simulators were connected to each monitor and multiple medical scenarios were conducted for each monitor. Flight surgeons, biomedical engineers, and others monitored physiologic signals remotely at the Johnson Space Center (JSC) (Bldg. T-585, Houston, TX), the Canadian Space Agency (Toronto, Canada), and the Gagarin Cosmonaut Training Center (Star City, Russia). Data collection focused primarily on usability and human factors. Data were collected from each remote physician using an evaluation form to rate the interface, quality of the data, ease of use, and overall ability to remotely monitor a patient. A log was kept to catalog problems that arose during deployment and data were collected on videotape for analysis of data integrity. (See Appendix C for Communications Diagram)

Medical Simulations

The three critical care monitors were tested using three simulations: Conduction blocks, Dropping blood oxygen saturation, and Swan-ganz catheterization. To vary the reviewer's experience, three different space medicine case histories/scenarios were created for each simulation giving a total of nine scenarios. These simulations are described in Appendix D.

In order to evaluate the clinical utility of the monitors under evaluation when used in a remote monitoring context, a series of medical case histories/scenarios were developed. Scenarios were designed based on risk data relevant to space operations[2]. Each scenario followed the clinical presentations and time course case presentations drawn from published literature with analogous injury mechanisms and clinical pathology. Flight surgeons were asked to monitor the presenting patient via the remote web browser interface. The simulation moderator stated the clinical presentation and history to the evaluating clinician who also had a copy of the case presentation for reference during the exercise. Following this, the simulation program was initiated in Hawaii and the case progressed as outlined in the flow diagrams below. Evaluating physicians monitored the clinical course of the patient and were instructed to comment when a physiologic parameter changed. Once the evaluator noted a changed, the moderator presented additional clinical data and/or asked for what instructions or information requests should be sent to the crew to manage the given situation. During the scenarios, the moderator in communication with personnel in Hawaii was able to change the flow of the case based on the intervention of the evaluating physician. At the conclusion of each scenario the evaluating physician was asked what recommendation should be made to the flight control team regarding the impact of the medical emergency on the mission.

In addition to their value in the evaluation of the critical care monitors, the scenarios were a first attempt by CCCDP to develop a simulation tool that could be used to test and evaluate space medical care capability. Simulations of this sort provide an opportunity to evaluate and identify deficiencies in the medical care infrastructure, clinical procedures for the crew/flight surgeon/biomedical engineer, equipment testing, and communications. In addition, they provide an effective, low cost training or certification tool that, given the remote access capability demonstrated, can be used anywhere or at any time. The array of simulators selected for this project allow for simulations to be run on the actual equipment operating in a standard configuration provide an opportunity to evaluate and validate both the equipment and user under operational conditions.

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[2] Billica RD, et al. Perception of the medical risk of spaceflight. Aviat Space Environ Med 1996; 67:467-73

Evaluations from Simulation Participants

The simulation participants consisted of flight surgeons, medical trainers, and biomedical engineers. Although the reviewers were not able to compare all three monitors together, some general conclusions can be drawn from the evaluation forms each reviewer was asked to submit. The evaluation form is included as Appendix E.

- 9 of 10 reviewers were confident using this technology to manage a patient. One reviewer did not respond.
- Training is major issue. Several reviewers were not sure that non-medical users would be able to set up all the sensors to receive reliable data. In addition, there were some concerns that a non-medical user might get "information overload" using these types of monitors.
- 8 of 10 reviewers felt that this type of technology should be used for low earth orbit missions. One reviewer was not sure, and one reviewer did not answer.
- Several reviewers commented that the most useful features of the monitors were clear graphical presentation of waveforms. Several recommended enlarging and/or changing the font color of the numerical parameters for better readability.
- Several reviewers commented on the usefulness of the medical simulations in general. The scenarios included the number of crewmembers, types of return vehicles and landing opportunities, all of which greatly affected the flight surgeons' decisions on treatment and patient management. These types of physiologic simulators may be incorporated into future space training simulations.

Because of time constraints, reviewers were unable to fill out the evaluation forms in their entirety; therefore significant aspects of the critical care monitors have not yet been evaluated. This particularly refers to questions concerning the system capabilities (numerical and graphical trending, data storage, etc.). Little or no time was available for reviewers to access these capabilities and to experiment with the monitors themselves. In addition to evaluating critical care monitors, the simulation capabilities were identified as a potential training tool that could be useful in the future. Although the simulators were not designed to simulate medical scenarios, this appears to be a promising application.

Equipment Performance

In the field, all monitors and simulators performed exceptionally well given the extreme conditions and no anomalies were encountered with any of the monitors. Since the tent was not well illuminated, the monitor displays were very easily viewed. Additional observations on deployment and implementation are given below:

- Entanglement of the cables and tubing of the monitors was prevented by using Velcro tie-wraps.
- End tidal carbon dioxide ($EtCO_2$) simulation was provided by the monitor operators in Hawaii. This proved cumbersome for one person to oversee the computer and provide

breaths to match the respiration rate provided by the LionHeart 3 at the same time. It is desirable to develop and fabricate an EtCO2 simulator.

- The ST (referring to a segment of the ECG wave) elevation rhythm did not work in some of the earlier simulations due to a programming error. This was corrected prior to leaving Hawaii.
- The simulation program was written somewhat modularly, with 2-minute pauses at the end of each medical scenario. These pauses should be removed to allow the operator to change rhythms sooner if desired. Several times during the simulations, the instructor (on the JSC end) wanted to convert a rhythm or go to pacing but had to wait for the programmed 2 minutes to pass before proceeding.
- Communication between the instructor (JSC) and operator (Hawaii) is essential. Voice communication over the PC speakers was less than adequate, especially if the instructor was not facing the microphone. Chat over NetMeeting worked well but it required a second person on the JSC end to transmit orders from the instructor. Two-way headsets would probably work best.

Due to time constraints of reviewers and communication links, none of the reviewers were able to evaluate all of the three monitors. In addition, all of the features of the monitors were not tested due to the compressed schedule. However, all of the reviewers seemed satisfied with the information that they received during their simulations and were able to make medical decisions based on this information. Time will be scheduled for a more in-depth evaluation of the monitors and their features.

SpaceLabs Ultraview 1050:

This critical care monitor performed nominally. The only software needed was Internet Explorer 5.0 and the data streams were continuous to the viewer. On occasion, one or all data streams would disappear for a few seconds and then reappear. No user intervention was necessary. Because this was the only monitor that did not require additional software, only this monitor was tested at the secondary locations. The data were successfully accessed from Canada, Russia, and Philadelphia in addition to the primary receiving station in Houston. This demonstrated the capability of accessing data by a flight surgeon at Mission Control, and an International Partner or medical specialist at the same time.

Datex-Ohmeda CS3:

This critical care monitor was not able to use the web browser to view the data. The company logo and background of the monitor application were visible but no data streams were received. The connection was tried on several days with no success. An alternate solution was reached: a NetMeeting connection was established from the gateway computer in Hawaii to the primary receiving station in Houston. Using the NetMeeting Desktop sharing function, the primary receiving station was allowed to view what was on the gateway desktop. This allowed the primary station to receive streaming data; however, the data streams were choppy, most likely due to sampling rate issues. Although the NetMeeting connection was not nominal, the data received were sufficient for the flight surgeons to make medical decisions.

Siemens SC7000:

This critical care monitor performed nominally. Proprietary software was loaded on the receiving station to view the data; therefore, this monitor was only tested at the primary receiving station in Houston. The data streams were continuous to the viewer and there were only a few instances when the data streams were lost.

Conclusion

The deployment phase was a great success with all objectives being met. Three out of the five critical care monitors received were deployed to Hawaii and setup at the refugee campsite. The monitors themselves operated very satisfactorily at the refugee camp despite the horrendous operating conditions. All three monitors were connected to a data network that ultimately linked the refugee camp to Johnson Space Center (JSC) via satellite and the commercial Internet. Consultants at JSC and other sites were able to successfully view the medical data and use it to prescribe treatment during the simulated medical scenarios.

These simulations provided a realistic telemedicine link. There were both hardware and communications problems with data occasionally dropping out and requiring real-time solutions. It was noted that on some occasions, when the Internet was very congested and bandwidth was at a premium, that Internet Explorer would not work in displaying the data at the consultant sites. Instead, Microsoft Netmeeting was used to share the desktop of a computer displaying the data at the refugee camp with the consultant's workstation.

Medical scenarios used in this evaluation provided an effective way to evaluate the critical care monitors as well as the feasibility of treating an astronaut aboard the ISS. These scenarios allowed NASA flight surgeons to test current space medical procedures using only the medical supplies and equipment that are currently scheduled to be on-board the ISS. This highlighted the strengths and weaknesses of the current ISS crew health care system.

Overall, this exercise has been successful and commences the process of enhancing the advanced life support capabilities on the ISS.

Lessons Learned

This exercise has proven to be very beneficial and has provided Medical Operations with much data as well as many lessons learned. The lessons learned have been categorized into three areas, hardware, logistical, and clinical and operational. They are summarized below:

Hardware

- The physiological simulators were not designed for this application, but still performed adequately. Certain design changes could broaden the use of these devices in training medical personnel for ISS and other medical scenarios. This should be explored more thoroughly with the equipment manufacturer.
- A more reliable audio communication method was needed the cell phone used was intermittent and at the refugee site calls could only be made from Hawaii – not received. GTE Wireless was chosen since they had service available (analog) throughout the big island of Hawaii.
- Voice-over-Internet, via Netmeeting, worked after Internet connectivity was established, but it was at times it was difficult to hear over background noise in the tent. It would be better to use headphones fitted with a headset rather than use the speaker that was internal to the computer.
- More time should have been spent on evaluating the critical care monitors remote displays. There may have been sufficient time if things had gone as planned and the number of sessions hadn't been cut from five to three.
- Of the monitors evaluated, the Spacelabs monitor was the best in terms of transmission over TCP/IP.
- Datex-Ohmeda and Spacelabs were the most cooperative vendors in terms of working with us to provide the equipment and support needed.

Logistical

- Acquire as much information as possible on field conditions prior to travel. Because this was a military operation and the information was being filtered through a second party (CRNC and ECU), we were not quite prepared for the dusty conditions. Knowledge of this beforehand would have allowed us to prepare the equipment for these conditions before shipment.
- It would have been better to stay at the refugee camp between sessions instead of traveling back and forth from the hotel to the camp. This would have avoided the hassles of transporting between the refugee camp and CMOC.

Clinical and Operational

- It is important for flight surgeons to be very familiar with CHeCS medications and equipment in order to facilitate a rapid response to medical contingencies.

- Realization that the current emergency evacuation vehicle, the Soyuz, does not support many of the ALS CHeCS components, and due to its small size, make many procedures difficult if not impossible to perform.
- Heavy reliance on critical care monitor data to make diagnostic and treatment decisions necessitates a full understanding of how the monitoring equipment works.
- Patient management via a non-physician crew medical officer (CMO) presents potential difficulties and delays in carrying out routine procedures especially if the CMO is the patient.
- These simulations displayed how challenging patient management is using limited personnel (i.e. 3 member crew – 1 patient, 1 CMO, one pilot).
- There are apparent discrepancies between terrestrial and space medical diagnostic and treatment approaches.
- The flight surgeons, when directing the administration of medications, must have an awareness of the limited quantities and how these quantities are being used. It may be necessary to ration these medications during an emergency to ensure there will be enough to last until the patient is returned to Earth. It would be beneficial to maintain a detailed inventory of used drugs.
- The possible loss of communication between the MCC and ISS during a medical contingency must be planned for and accommodated. There may only be limited windows of opportunity for data exchange. The flight surgeon should always be thinking ahead as to what problems might unfold especially if communication is lost.
- Conducting the medical simulations with the critical care monitors illustrated the fact that there is a number of factors influencing medical decisions, including the severity of a medical problem, the abundance of primary landing site (PLS) and emergency landing site (ELS) opportunities, and critical time of illness.
- Additional simulations should be performed to refine protocols for patient management both during and after a code.
- The real-time critical care monitor data will be invaluable in managing a remote critically injured patient.

Follow-on Activities

- Continue to follow-up with vendors and pursue other vendors for participation in this ongoing evaluation.

- Complete in-depth evaluation of each critical care monitor received. This will include:

  1. Operational testing - power usage, battery life, etc. To be completed August 2000.
  2. Evaluation of human factors - man-machine interface. A usability test will be performed on all monitors beginning July 2000 and continuing through September 2000, depending on availability of monitors. The usability test plan is included as Appendix F.
  3. Evaluation of clinical capabilities. This may take the form of a side-by-side comparison matrix.

- Testing of remote monitoring capabilities for each critical care monitor including operational testing, human factors, and clinical functionality at the remote site.

- Side by side comparison of all critical monitors reviewed by flight surgeons, trainers, and biomedical engineers. Two-day workshop tentatively scheduled for September 2000. Multiple flight surgeons and external reviewers will be invited, as well as vendor representatives.

- Analyze the evaluations done during the simulations in Hawaii and determine a general consensus.

- Define space critical care monitoring needs, define discrepancies between state-of-the-art equipment and NASA's needs, summarize the state-of-the-art in critical care monitors, and develop a white paper to document these results.

- Final recommendation/specifications for space medicine critical care monitoring.

CCCDP Strong Angel Personnel

John Johannesen	Strong Angel Project Lead, Engineer, Wyle Laboratories
Jack Rasbury	Engineer, Wyle Laboratories
Shannon Melton	Engineer, Wyle Laboratories
George Beck	Engineer, Wyle Laboratories
Doug Hamilton	Lead Clinician, Wyle Laboratories
Kelly Halacka	Intern, NASA JSC/ Wyle Laboratories
Bojana Djordjevic	Intern, Wyle Laboratories
Vernon McDonald	CCCDP Lead, Wyle Laboratories

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Byron A. Smith, M.S.Egr. BME, Technical Lead, CMIS Project Epidemiology Section, Medical Operations Division, Wyle Laboratories

COL Paul Stoner, M.D., Flight Medicine Clinic, NASA JSC, U. S. Air Force/NASA Liaison Officer

Cristina Zeppieri, BME, Medical Operations, Mission Support, Wyle Laboratories

Appendix A – List of URLs

The following websites will provide additional information on the exercise:

Strong Angel specific websites
- Strong Angel briefing
  http://www.quasar.org/memes/intellimedcom/RIMPAC2000-Strong-Angel-brief.htm
- Strong Angel website
  http://www.strongangel.org/
- RIMPAC website
  http://www.cpf.navy.mil/rimpac2000/index.htm

Medical equipment vendors websites
- Spacelabs Medical Systems, Inc. website
  http://www.slmd.com
- Datex-Ohmeda website
  http://www.datex-ohmeda.com/products/monitoring_cccm.htm
- Siemens Medical website
  http://www.med.siemens.com/medroot/en/prod/diag/elec/index.html
- Agilent Technologies
  http://www.healthcare.agilent.com/patient_monitoring/cgi-bin/show_product.pl?M3%20and%20M4%20Series%20Patient%20Monitors
- GE/Marquette
  http://www.gemedicalsystems.com/medical/index.html
- Datascope, Corp.
  http://www.datascope.com/
- Critikon, Co.
  http://www.critikon.com/
- Protocol Systems, Inc.
  http://www.protocol.com/
- Biotek Instruments website
  http://www.biotek.com/

Other websites
- Medweb website
  http://www.medweb.net/
- MDB Information Network
  http://www.mdbinfonet.com/

Appendix B – Critical Care Monitor Requirements

1. Power:
   a. The system shall be able to be powered from either 110VAC at 60Hz or 220VAC at 50Hz.
   b. The system shall have a battery back-up capability. This capability shall be integral to the systems' design and should allow the monitor to operate for 30 or more minutes under most monitoring situations.
   c. The battery should recharge by connecting the monitoring system to an external power source and should not require battery removal.

2. Physical:
   a. The system should be portable and able to withstand a field/transport environment.
   b. The system should weigh no more than 30 pounds, and the physical volume should be no greater than 1 cubic foot.

3. Data:
   a. The system should have the capability to connect to a 10-BaseT Ethernet network.
   b. The system should transfer medical data real time via IP.

4. Medical Monitoring:
   a. The system shall be able to acquire a 5-lead electrocardiogram (ECG) at a minimum.
   b. The system should be able to monitor SpO_2.
   c. The system shall be able to monitor non-invasive blood pressure.
   d. The system shall be able to monitor invasive blood pressure.
   e. The system shall be able to monitor body temperature.
   f. The system shall be able to monitor $ETCO_2$.

Medical Operations Data Communications Between Hawaii, ECU, Houston, and Other Consultant Sites
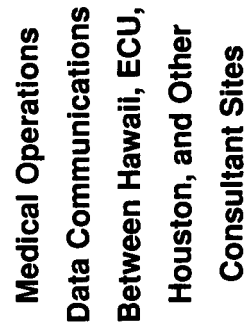
Appendix D – Medical Simulations

A session administrator presented the following scenarios to NASA flight surgeons. After the flight surgeons were presented a case they were shown, on a consultant workstation, real-time data streaming from a critical care monitor in Hawaii. They were then told to manage the patient using only supplies on-board the ISS. The monitor in Hawaii was connected to patient simulators that were programmed to vary the parameters in a manner that was consistent with the patient's condition. There was two way interaction between the flight surgeons and the session administrator. The session administrator was in contact with personnel in Hawaii and directed them when to vary the parameters by initiating certain programs.

Simulation 1 – Cardiac Arrhythmia Conduction blocks

Monitor display sequence

```
                    ┌──────────────┐
                    │     NSR      │
                    └──────┬───────┘
                           │
                           ▼
                    ┌──────────────┐
                    │   Mobitz II  │
                    └──────┬───────┘
                           │
                           ▼
                    ┌──────────────┐
                    │3rd degree block│
                    └──────┬───────┘
                           │
                           ▼
                    ┌──────────────┐
                    │3rd degre block│
                    │with 6 PVCs/min│
                    └──────┬───────┘
                           │
                           ▼
                    ┌──────────────┐
                    │    VTACH     │
                    └──────┬───────┘
                           │
                           ▼
              ◇ defibrilate? ◇──No──▶ [ VFIB ] ──▶ ◇ defibrilate? ◇
                    │                                      │
                    │                ──Yes──               No
                   Yes                  │                   │
                    │                   │                   ▼
                    ▼                   ▼              ( asystole )
              ┌──────────────┐◀─────────
              │3rd degree block│◀──────┐
              └──────┬───────┘         │
                     │                 No
                     ▼                 │
                ◇ pace? ◇──────────────┘
                     │
                    Yes
                     │
                     ▼
              ( paced rhythm
                with occasional
                    sinus )
```
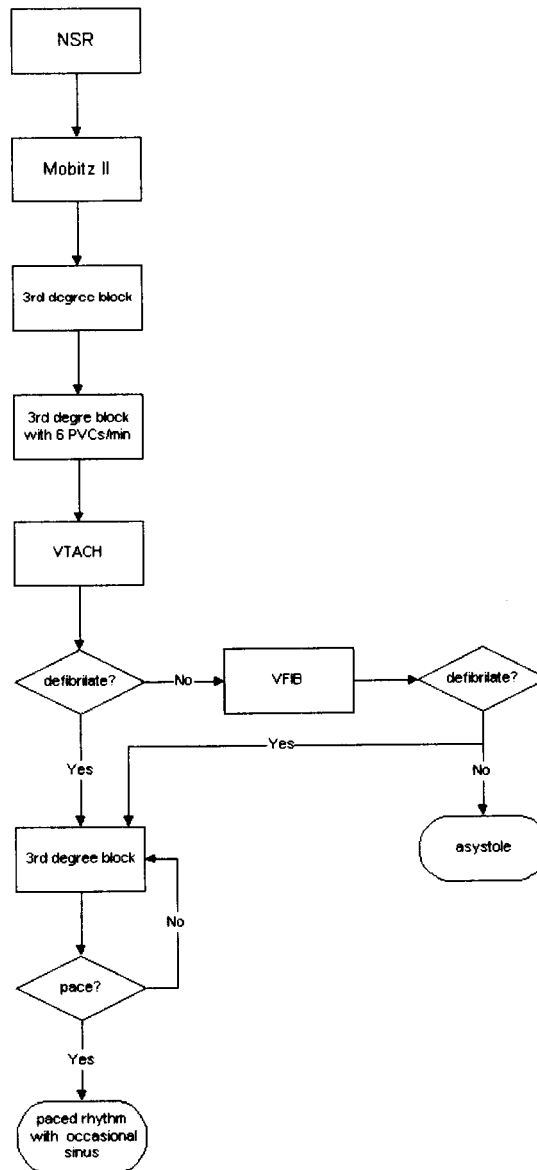
Corresponding Case Histories/scenarios

Case A

50 y/o female pre extra-vehicular activity (EVA). Complains of light-headedness and palpitations after working long hours to repair CO_2 scrubbers. Patient has no history of cardiac problems. Risk factor (RF) positive for family history with father having MI at 60 years and slightly raised LDL cholesterol and reduced HDL cholesterol. Has felt tired over last 7 days. Total time on ISS 60 days. No other medical or psychological issues being worked.

Vitals as per monitor. Patient looking anxious and concerned. Plan?

Case B

45 y/o male astronaut who presents to an unscheduled private medical conference (PMC) with serious concerns about palpitations and chest pressure after exertion on the treadmill 10 minutes ago. The shuttle has been docked to the ISS for 6 days and this is his first mission. He confesses this has happened before and was seen privately by a cardiologist in the booming community of Nowhere, Montana. The astronaut was reassured at that time that the findings on a 24-hour holter monitor were only significant for five runs of 3 to 4 beat wide complex tachycardia. The cardiologist reported it to be supraventricular tachycardia (SVT) with aberrancy. The astronaut did not inform the Flight Medicine Clinic (FMC) of these findings, since he was told it was not serious and that reporting it would ground him. He is very concerned now because the discomfort has not abated after exercise. The patient had a 220-msec first degree block, which was wavered by the Aerospace Medicine Board (AMB) because of the 10-year history of the finding. The patient notices palpitations when he has alcohol or consumed large amounts of caffeine. The patient recalls one episode of syncope where he woke up on the floor of the bathroom early in the morning with a laceration on his chin where he hit the sink, probably during the fall. He never reported the incident. The patient has a history of avoiding yearly exams and has refused to participate in investigations that monitor ECG. Positive family history for MI in mother age 55 and grandmother MI 60, with hypercholesterolemia.

Patient has complaints of chest pain radiating into the left-arm and dyspnea. The pain radiates to the neck. The patient complains of extreme nausea.
Vitals as per monitor. Plan?

Case C

55 y/o male astronaut is on the end of the P6 truss when he becomes giddy, confused and eventually nonresponsive. The patient is dragged back to the airlock, repressed and the helmet is doffed. The following vitals are measured on the patient. (vitals are given by session administrator)

The suit is eventually completely doffed and the patient is transported back to the Lab module. Vitals as per monitor.
Paced rhythm. The next primary landing site (PLS) is three hours away. Plan?

Simulation 2 – Dropping Blood Oxygen Saturation

Monitor display sequence

```
┌─────────────┐
│    NSR      │
│  60bts/min  │
│  SPO2:98%   │
└─────────────┘
       │
       ▼
┌─────────────┐
│    NSR      │
│  80bts/min  │
│  SPO2:90%   │
└─────────────┘
       │
       ▼
┌──────────────────┐
│ NSR with 24PVCs/min │
│    80bts/min     │
│    SPO2:98%      │
└──────────────────┘
       │
       ▼
┌──────────────────┐
│ NSR with +0.5mV ST │
│    60bts/min     │
│    SPO2:88%      │
└──────────────────┘
       │
       ▼
┌─────────────┐
│    VTACH    │
└─────────────┘
       │
       ▼
```

defibrilate and give 02? —No→ VFIB —No→ defibrilate and give 02?

Yes / —Yes— / No

NSR 60bts/min SPO2:98%   asystole
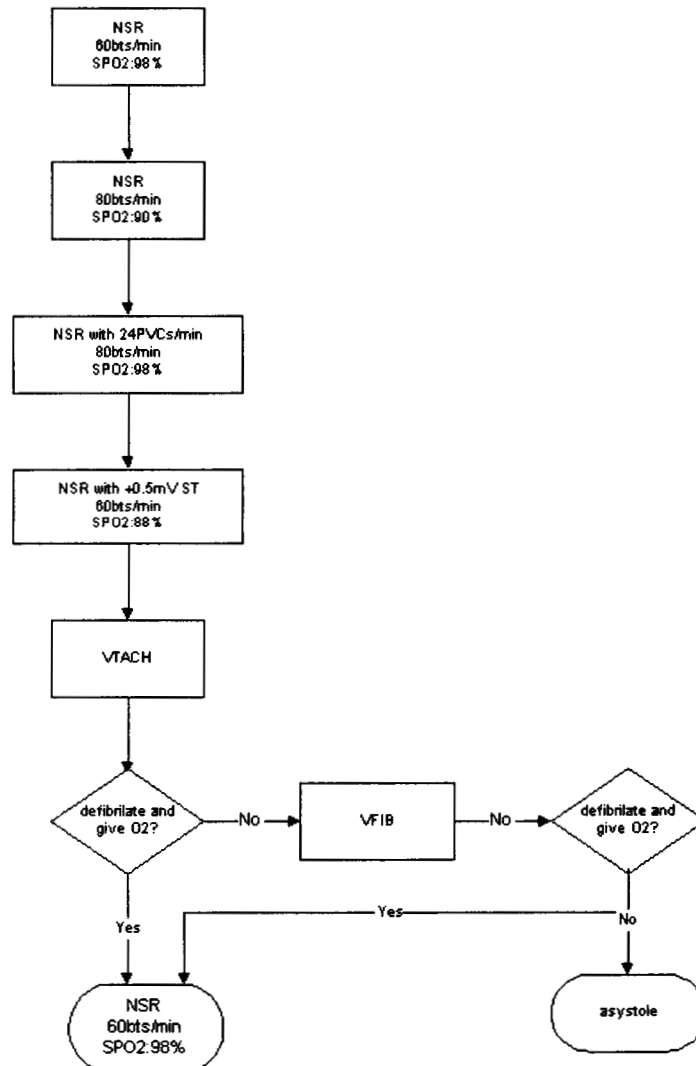
Corresponding Case Histories/scenarios

Case A

55 y/o male astronaut post second EVA in 3 days to repair gyrodynes. In the middle of the sleep period he is awoken with chest discomfort and shortness of breath. Has noticed some pressure in the chest with no radiating pain. Pain is not pleuritic in nature. Has some reflux symptoms when asked specifically and has noticed them on several other flights, but this is different. States he has been having trouble breathing and is obviously shortness of breath (SOB). Patient is working to breathe and finds it

easier to breathe when he grabs the rack and braces his feet... something like a microgravity semi-Fowlers position. Crew medical officer (CMO) can hear breath sounds in both lungs.

What is your differential? Vitals as per monitor.

On O_2 patient begins to become confused and complains of feeling weak. Patient has signs of left-sided hemiparesis with reduced strength as per decompression sickness (DCS) patient. Patient is not oriented to person, place, or time. Breathing effort reduced.

The commander notices the O_2 line on the mask leaking (cabin noise prevents crew from hearing leak). Plan?

Case B

47 y/o veteran astronaut intravehicular activity (IVA) crew member notices an intense irritation of the eyes when the airlock door is opened to help the two extravehicular activity (EVA) crew members who have recently ingressed from a 6-hour EVA. The IVA crew member advises the rest of the crew to don quick-don masks (QDM) and for the EVA crew members to stay on the services and cooling umbilical (SCU). The patient goes on QDM but notices a cough and irritation that prevents him from speaking in complete sentences. The other 3 crew members are now helping the disabled crew member. The EVA crew members return to the airlock and close the hatch. The patient is taken to the lab module and the hatch is closed to the node on the Russian and American side, effectively isolating the airlock. Drager tubes are used by the EVA members and found to be positive for nitrogen tetroxide.

Patient is stable for 20 to 30 minutes but now is complaining of shortness of breath (SOB) and pleuritic chest pain. The communications at this time is poor due to TDRSS communication interruptions. The crew medical officer (CMO) is concerned that we just missed the last primary landing site (PLS) opportunity and the next one is not for 24 hours in Russia. The shuttle is not present. The transport vehicle is the Soyuz. The Assured Crew Return Vehicle (ACRV) has been delayed due to budget and technical problems.

Oxygen, intubate, physical exam, start IV.

Physical exam is visualized more clearly using the Medical Operations virtual private network (VPN) videoconferencing system. The patient has intercostal indrawing, accessory muscle use with tracheal tug and has a visible pulses of 15 to 20 on the monitor. Auscultation using a digital stethoscope reveals diffuse inspiratory and expiratory wheezes with a prolonged expiratory phase. A new X-ray on the ISS shows the following (findings described by the session administrator). The patient has removed the QDM and is now on 5 L/min 100% oxygen by non-rebreather. O_2 sat is 97%, heart rate (HR) is 105. respiratory rate (RR) is 18.

The patient continues to maintain his airway and ventilation rate. The EVA crew members are venting the airlock and the Flight Dynamics (FD) instructs the crew to configure the ISS for autonomous Ops. and to power up both Soyuz spacecrafts. The EVA crew is still on SCU and one crew member is performing air sampling procedures from the Node 1 hatch. FD is preparing to vent the Node so the crew can power up the Soyuz on the Russian side after repress. The CMO only has one assistant since the commander needs to safe the ISS.

The patient is deteriorating and x-ray 12 hours later (10 hours before the next PLS) shows the following (session administrator presents data). O_2 sat is deteriorating and the patient is now on 100% at 10 L/min. The patient is showing signs of reduced level of consciousness (LOC) and the respiratory rate has decreased to 14/min. Patient is very light-headed and confused.

Vitals as per monitor. Intubate? With Soyuz coming up? Plan?

Case C

A 52 y/o astronaut ISS increment candidate has been brought out of the Hydrolab tank at Star City after a 6-hour run in the Orlan spacesuit. The patient starts to complain of chest pain and SOB. The patient further complains of knee pain and the flight surgeon notices a rash over the patient's back. He collapses 30 minutes after doffing his suit. The patient is connected to a patient monitor and the data presented here at MCC-H. The Star City flight surgeon is at the Black Sea supporting crew survival training.

Vitals as per monitor. Plan?

Simulation 3 – Swan-Ganz catheterization

Monitor display sequence

```
        ┌──────────────┐
        │      RA       │
        │  CVP: 15/10   │
        │  PA: 15/10    │
        └──────────────┘
                │
                ▼
        ┌──────────────┐
        │      RV       │
        │  CVP: 15/10   │
        │  PA: 25/0     │
        └──────────────┘
                │
                ▼
        ┌──────────────┐
        │      PA       │◄──┐
        │  CVP: 15/10   │   │
        │  PA: 25/10    │   │  5 cycles
        └──────────────┘   │
                │          │
                ▼          │
        ┌──────────────┐   │
        │    wedge      │───┘
        │  CVP: 15/10   │
        │  PA: 10/2     │
        └──────────────┘
                │
                ▼
        ╭──────────────╮
        │      PA       │
        │  CVP: 15/10   │
        │  PA: 25/10    │
        ╰──────────────╯
```
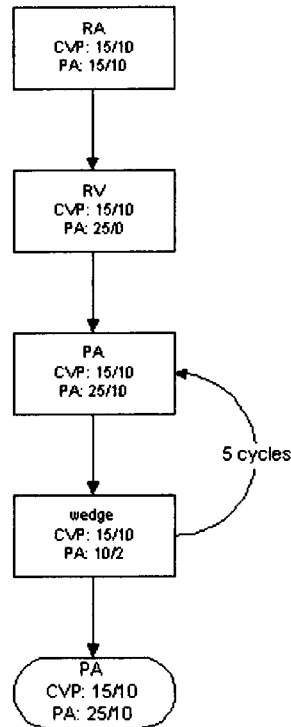
Corresponding Case Histories/scenarios

Case A

45 y/o physician astronaut is intubated and invasively monitored after having a Mars Ford Grand Navigator fall on her, crushing her left leg. Patient suffered pulmonary fat emboli, which put the patient into acute right ventricular failure. Patient was stabilized using advanced trauma and life support (ATLS) procedures and subsequently surgerized by Dr. Mark Campbell Jr., the other Mars mission physician who amputated the crushed limb. Patient is stable on inotropic support of Dopamine.

Patient is in the 1/3 gravity intensive care unit (ICU) on Mars with a 4-minute delay in data feed. Patient is being managed by Dr. Campbell and wishes to have the flight surgeon, Dr. (insert name), on call to follow the insertion of the right pulmonary catheter and help determine the wedge pressure. Dr. (insert name) has requested that you follow this procedure from your computer at home. It is 4 AM in the morning Earth time and you have just been awakened by the phone. You are covering for Dr. Green who is out of town for 2 days.

Is the catheter proceeding correctly? Dr. Campbell has concerns about the transducer zero... are these pressures okay for 1/3 gravity? Should the patient be given more fluids given the cardiac index is __ (value given by session administrator). Dr. Campbell wants to know if the Earth cardiac index normals the same as on 1/3g?

Vitals as per monitor. Please advise.

Case B

A new station is on the moon with 20 crew members. A 35 y/o patient has been admitted to the intensive care unit (ICU) for treatment of an episode of acute pneumonia secondary to aspiration. The patient experienced an episode of nausea and vomiting during an extravehicular activity (EVA) and aspirated in the suit. The patient was brought back to base one hour later and the lunar extravehicular mobility unit (EMU) was doffed. The lunar base is pressurized at 5 psi at 100% oxygen. The patient deteriorated and was intubated and placed on a positive end-expiratory pressure (PEEP) of 20 and rate of 18 with inverse ration SIMV. A central line was placed and a Swan floated. You are asked to help watch the wedge pressure. Is the wedge pressure appropriate for 1/6 g and an atmosphere of 5 psi of 100% O2?

Vitals as per monitor. Plan?

Appendix E– Evaluation Forms

Form 1

Strong Angel Exercise Evaluation

Date: _____ Reviewer: _____

Medical Specialty: _____ Monitor: _____

Background Information:

1. Have you used critical care monitors before?		Yes	No
If yes, when was the last time you used this technology?	Days	Weeks	Years
If yes, how many patients have you assessed?	Many	Some	None
If yes, for what purpose were the monitors used? (i.e. ICU, diagnosis, management)			
2. Have you used *this* monitor (manufacturer/model) before?		Yes	No
3. Have you ever diagnosed or treated patients long-distance?		Yes	No
4. Have you ever supported a space mission as a flight surgeon?		Yes	No

Performance:

1. Please rate the following technological performance qualities of the primary interface screen:

Simple	5	4	3	2	1	Complex
High Tech.	5	4	3	2	1	Low Tech.
Safe	5	4	3	2	1	Unsafe
Accurate	5	4	3	2	1	Inaccurate
Reliable	5	4	3	2	1	Unreliable
Easy to use	5	4	3	2	1	Difficult to use
Durable	5	4	3	2	1	Fragile
Attractive	5	4	3	2	1	Unattractive
High Quality	5	4	3	2	1	Low Quality
I like	5	4	3	2	1	I dislike

2. Please rate the following system capabilities (5-Excellent, 1-Poor):

Numerical Trending	5	4	3	2	1	N/A
Graphical Trending	5	4	3	2	1	N/A
Data Storage	5	4	3	2	1	N/A
Alarms	5	4	3	2	1	N/A
Calculated Parameters	5	4	3	2	1	N/A

3. Were you able to confidently assess the patient using the data on the monitor screen?	Yes	No
4. Were you able to confidently manage the patient using the data on the monitor screen?	Yes	No
5. Was this technology helpful in mitigating the risks of the patient?	Yes	No

Usability:

	Agree			Disagree
1. Overall, I found this monitor easy to use.	4	3	2	1
2. I was able to view the screen comfortably.	4	3	2	1
3. The waveform data were presented effectively on the screen.	4	3	2	1
4. The numerical data on the screen were easy to read.	4	3	2	1
5. I was able to access the system capabilities effectively. (i.e. trending, graphing)	4	3	2	1

Comments:

1. Would you be confident using this technology to manage a remote patient?	Yes	No
Why or why not?		
2. From a clinical, operational, and ethical standpoint, would you recommend using critical care monitors in Low Earth Orbit?	Yes	No
Why or why not?		
3. How did using this technology affect your ability to effectively manage your patient?		
4. What were the most useful features on this monitor?		
5. If you could change any aspect of this monitor, what would it/they be?		

6. I found the following aspects of this monitor particularly difficult to use:

7. a) Do you feel that non-clinical care providers could use this interface?

7. b) What modifications would you recommend be made to support use by non-clinical professionals?

8. Would you feel comfortable changing the monitor configuration at the screen interface?

Form 2

Strong Angel Comparison Evaluation

Date: _____ Reviewer: _____

1. Of the [two or] three critical care monitors (Siemens, Datex-Ohmeda, and SpaceLabs) that you have interfaced with, which did you like the most and why? Please be specific.

2. Of the [two or] three critical care monitors (Siemens, Datex-Ohmeda, and SpaceLabs) that you have interfaced with, which did you not like and why? Please be specific.

(Usability Test Plan for Critical Care Monitors in support of Strong Angel Project)

Purpose

The main purpose of this test is to evaluate and compare subjective usability/human factors of the various monitors used in the Strong Angel project. This test fits into the overall evaluation of the state-of-the-art in critical care monitors as documented in the Strong Angel project plan (April 2000). The test will measure the time it takes to complete various tasks that might be performed on ISS using each of the monitors.

Test Objectives

The specific objectives of the test are:

1. Determine which method of user interface (com. wheel vs. touch screen) is preferable to most participants.
2. Determine which monitor(s) takes the least amount of time for participants to complete a given task.
3. Determine which monitor(s) provides the best viewing angle and readability of data as distance from the monitor increases.
4. Determine which display format (color, font size, etc.) is preferable to most participants.

Methodology

At least 5 participants that fit the expected profile will be used in the test, unless more personnel are available. Prior to the test, each participant will be asked to fill out a short questionnaire to gather background information. Then, the participants will be given a brief orientation period with each monitor (not to exceed three minutes for each). The participants to be selected will have at least a basic understanding of physiological signals and their acquisition so that background information in this area need not be provided.

The first part of the test will consist of performance measurements. The participants will be asked to carry out a series of tasks with each of 7 monitors (depending on availability). During the performance test, the time it takes to complete each task will be recorded and any difficulty encountered during the test (either through participant error or equipment malfunction) will be noted. The monitors will be presented to each participant in a different order. Breaks will be taken between each monitor to allow for equipment setup. The participant and monitor(s) will be videotaped for later analysis and verification of test results. An evaluation the effectiveness of monitor alarms will also be performed during this part of

the test. The participant will be instructed at the beginning of the test that alarm conditions may occur during the course of the test and when an alarm is sounded, to identify the source as quickly as possible. The alarm condition selected will be different for each monitor and will fall at varying times during each test sequence.

In the second part of the test, the participant will be asked to determine the maximum viewing angle and distance from the monitor with which they feel comfortable viewing the data. This will be accomplished using a string attached to the tabletop directly in front of the monitor. The string will be held by the participant and will rotate through angle indicators marked on the tabletop as the participant moves from side to side. Once the participant has indicated when the viewing angle and distance have reached the limit for clear readability, the angle and distance from the monitor will be recorded. Since this test is very dependent on the participant's vision, they will be instructed to wear their glasses or contacts if they normally do so.

Following the test, each participant will be asked to fill out a brief questionnaire that asks questions relating to subjective parameters and preferences (display colors, ease of use, button labeling, user interface, etc.).

Task List

The following tasks are to be performed (in order) for each monitor:

Task #	Task Description	Task Detail
1	Power on & discharge patient	Power on unit and discharge previous patient, erasing data. Time to complete: 2 minutes
2	ECG connections & measurement	Connect ECG cable to monitor and ECG simulator and call out heart rate value. Time to complete: 2 minutes
3	NIBP connections & measurement	Connect NIBP tubing to monitor and patient, initiate NIBP and call out value when displayed. Time to complete: 3.5 minutes
4	SpO_2 connections & measurement	Connect SpO2 cable to monitor and patient and call out SpO2 percentage. Time to complete: 2 minutes
5	Change channel 2 waveform	Configure monitor to display Respiration waveform on Channel 2. Time to complete: 5 minutes
6	View trend graph (HR & SpO2)	Configure monitor to display a graph of heart rate and SpO2 trend data. Time to complete: 4 minutes
7	Return to normal screen	Return monitor to normal monitoring screen. Time to complete: 10 seconds

Test Environment/Equipment

The test environment will be in a typical laboratory, with varying amounts of activity taking place. It will not be a quiet environment since this would not be expected on-orbit in the event that one of these monitors was used.

The test administrator, in addition to recording data and making notes will also serve as the patient for NIBP, SpO2, and ETCO2. The test administrator will offer no guidance in the completion of tasks. However, the user's manuals for each monitor will be available for reference.

The monitors to be tested are listed below. All cables and tubing for each monitor will be available at the start of the test and the participant must select the proper attachments.

Monitor	Manufacturer	Model
A	Datex-Ohmeda	CS3
B	Siemens	SC7000
C	SpaceLabs	Ultraview 1050
D	Datascope	Passport
E	Datascope	Expert
F	Protocol	Propaq CS
G	Protocol	Propaq
H	Hewlett-Packard	M3

Evaluation Measures

The following data will be collected and/or calculated:

1. The average time to complete each task for each monitor.
2. The number of errors encountered during each task and whether the error was due to human error, equipment error, or both.
3. The percentage of participants who finished each task successfully.
4. The percentage of participants who correctly identified all alarm conditions within the allotted time.
5. The average maximum viewing angle for each monitor.
6. The average maximum readability distance from each monitor.
7. Rankings of equipment usability/human factors.

Test Report

The results of this test are part of a larger evaluation of critical care monitors. Therefore, the usability test results will be reported in the final Strong Angel project report. The final report will be completed following Flight Surgeon evaluation.

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13. ABSTRACT *(Maximum 200 words)*
The NASA critical path road map identifies "trauma and acute medical problems" as a clinical capability risk category. Specific risks include major trauma, organ laceration or contusion, hemoperitoneum, pulmonary failure, pneumo- and hemothorax, burn, open bone fracture, blunt head trauma, and penetrating injury. Risk mitigation includes capability for critical care monitoring. Currently, the ISS Crew Health Care System does not provide such capability. The Clinical Space Medicine Strategic Planning Forum (1997) identified developing trauma care capabilities as a top priority for space medicine. The Clinical Care Capability Development Project (CCCDP) subsequently undertook the task to address this need. In January 2000, JSC Medical Operations Branch was invited to participate in the RIMPAC 2000/Strong Angel exercise, which involved seven nations and several public health and disaster-response organizations, establishing a 300-person mock refugee camp to simulate mass dislocation due to conflict or natural disaster. A wireless network and satellite system connected the camp to the East Carolina University School of Medicine. One of Strong Angel's objectives was to build a nomadic computing network matrix to link the 7 countries participating in this exercise through the ECU bridge. Medical Operations personnel used this exercise to evaluate critical care monitors in a real-world telemedicine setting analogous to ISS conditions and to simulate potential ISS medical scenarios. This exercise afforded a unique opportunity to work with commercial vendors and evaluate their leading-edge technology and evaluate the feasibility of treating an astronaut aboard ISS using limited medical resources. These opportunities were consistent with the CCCDP critical path

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