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PORTABLE MEDICAL STATUS
AND TREATMENT SYSTEM
CONTRACT NAS 9-15821

Submitted to
NASA
Lyndon B. Johnson Space Center
Houston, Texas

By
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PORTABLE MEDICAL STATUS AND TREATMENT SYSTEM

FINAL REPORT

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1.1 TECHNICAL DETAILS

1.1.1 ECG SUBSYSTEM

- **ECG PREAMPLIFIER**
  The basic preamplifier is the DRI hybrid Circuit.

- **DEFIBRILLATION PROTECTION**
  Defibrillation protection circuitry placed around the preamplifier protects it from the discharge of the defibrillator into its input leads.

- **RFI PROTECTION**
  Radio-frequency interference is inhibited on the ECG input leads by the placement of RF filters.

- **PATIENT ISOLATION**
  Patient isolation to the generally accepted risk current limits is provided by optical path coupling.

- **BANDWIDTH**
  The overall bandwidth of the displayed ECG is from 0.05 to 40 Hz on the scope and from .05 to 40 Hz on the chart recorder.

- **PATIENT CABLE**
  The patient cable is a shielded three lead cable with removable lead adapters.

- **CALIBRATION**
  A one - millivolt calibration signal is sent through the system whenever the "1 mV" switch is pressed.

- **LEAD SELECTOR**
  Lead Selection is accomplished by digitally switching the input to the preamplifier. The following leads can be selected:

  "STD" - All Leads Shorted
  "Lead I"
  "Lead II"
  "Lead III"
  "Paddles" (PDLs) - Defibrillator Paddle Input
• **SCOPE DISPLAY**

The ECG scope display is described as a moving-trace type of memory display with electronic Freeze/Thaw capabilities. The entire width of the Cathode Ray Tube is used at an apparent trace speed of 25mm/sec.

• **SIZE CONTROLS**

The "size" of the scope and chart recorder displays are simultaneously adjusted with the size controls. One of three fixed settings of ¼, 1 and 2 cm/mV can be selected by pressing the appropriate switch.

• **CHART RECORDER**

A heated-stylus type chart recorder is used to record the ECG at 25mm/sec (fixed). The ECG is always recorded from memory, i.e., from the left-hand side of the scope. If the Freeze switch is pressed, the chart recorder will record a straight line until the display is "thawed". The flow of the display from the scope to the chart recorder is designed to appear as a continuous motion. In the "Auto" mode, the chart recorder will start running automatically when either a heart rate alarm or a respiration rate alarm occurs.

• **HEART RATE DISPLAY**

The QRS pulses from the ECG preamplifier are tracked in real time by a complex phase-locked-loop type detector. This circuit calculates heart rate with a second order response having a rise time of approximately 3 seconds. The heart rate in beats per minute appears in 3 digits on the left side of the scope display over the ECG trace. The range of this display is 20 to 255 beats per minute.

1.1.2 **RESPIRATION SUBSYSTEM**

• **IMPEDANCE PNEUMOGRAPH**

The discrete-device impedance pneumograph is used to detect and process respiration.

• **RESPIRATION RATE DISPLAY**

Each breath is detected in real time by a phase-locked-loop detector. The rise time of the computation circuitry is approximately 15 seconds. The respiration rate in breaths per minute appears in 2 digits next to the heart rate display over the ECG trace. The range of the display is 4 to 64 breaths/minute. Under true apnea conditions, the display will be "zero".
1.1.3 TEMPERATURE SUBSYSTEM

- **PROBE**

  A linearized thermistor probe with disposable, plastic sheaths is used. Both rectal and oral probes are available. The disposable sheaths are designed for rapid heat transfer.

- **PREPROCESSING**

  Analog pre-processing is performed by circuitry designed to operate over the probe temperature range of 60°F to 110°F. This is a wider range than that for which the hybrid module was designed.

- **CALIBRATION**

  Calibration is in degrees Fahrenheit.

- **OUTPUT LINEARITY**

  Within 1 percent of a straight line.

- **PRECISION**

  The precision of the measurement is ±0.2°F.

- **MEASUREMENT**

  The measurement will be the instantaneous temperature at the tip of the probe, where the response of the probe is approximately 10 seconds.

- **ISOLATION**

  The tip of the probe is electrically insulated from the patient.

1.1.4 INDIRECT BLOOD PRESSURE SUBSYSTEM

- **CUFF**

  A standard adult blood pressure cuff is used with a manually-operated inflation bulb. Cuff pressure is sensed inside the VSM by a gage-type pressure transducer.
• MICROPHONE

A contact microphone is mounted in the distal one-third of the cuff width. The face of the microphone must be placed over the palpated brachial artery. The microphone contains a ruggedized piezo-ceramic element and is designed such that static loads on the face of the microphone do not affect its sensitivity.

• SYSTOLIC FILTERS

Filters are used to optimize detection of the "systolic sound", which is generally lower in frequency than subsequent sounds.

• DIASTOLIC FILTERS

The diastolic filters are optimized for diastolic decisions and the bandpasses are located at higher frequencies than those of the systolic filters.

• "SOUNDS" AUDIO

The "sounds" are displayed aurally as a frequency-modulated tone. A piezo-ceramic element is driven by an audio amplifier.

• SYSTOLIC AND DIASTOLIC DISPLAYS

The systolic and diastolic pressures in millimeters of mercury are each displayed in 3 digits over the ECG trace on the right hand side of the scope display.

1.1.5 ALARM SUBSYSTEM

• HEART RATE ALARM

The heart rate alarm has an upper and lower limit each of which is set independently from the front panel. The heart rate alarm sounds and "HR ALRM" appears on the display when the heart rate crosses the set limit. It is locked in the alarm condition on the display until the limits are reset. The audio alarm is not locked. If the chart recorder is in the "Auto" mode, it will start automatically. The upper limit can be set between 0 and 255 beats per minute and the lower limit can also be set between 0 and 255 beats per minute.

• RESPIRATION RATE ALARM

The respiration rate alarm has an upper and lower limit each of which is set independently from the front panel switches. The respiration rate alarm sounds and "RR ALRM" appears on the display when the respiration rate crosses the set limit. It is locked in the alarm condition until the limits are reset, except that the audio position of the alarm is not locked.
. **BATTERY LOW WARNING**

The condition of the battery is continuously monitored; and, when the battery voltage under load conditions drops below 1.15 Volts per cell, the "battery low" warning occurs.

1.1.6 **POWER SUBSYSTEM**

. **NI CAD BATTERY PACK**

Ten D-sized cells are used in a replaceable pack configuration. These Ni Cad cells have a rated capacity of 4.0 amp-hours. This battery pack will supply all the power needs of the VSM, defibrillator and radio. The VSM will operate 5.0 hours from the battery pack. The chart recorder and radio module will each reduce the monitor operation time by 40 minutes for each hour of operation. The defibrillator will reduce the monitor operation time by 2 1/2 minutes for each 400 Joule discharge and 6 minutes for each hour of standby operation.

. **UNIVERSAL CHARGER**

The battery charger consists of a C/10 (trickle) charger for the batteries and a reserve power supply which automatically augments the charging current to allow system operation during battery recharge.

1.2 **SUBSYSTEM OPERATION**

1.2.1 **ECG SUBSYSTEM**

- Apply electrodes to patient using proper technique. Electrochemically-reversible electrodes such as those made of silver/silver chloride are recommended. All three electrodes are required for proper system operation.

- Attach patient cable.

- Select the lead of ECG to be displayed ("Lead I", "Lead II" or "Lead III"). Alternately, if there is not sufficient time for electrode application, select "PDLS" position for transduction of the ECG directly from the defibrillator paddles. The lead selected will appear at the bottom of the scope display, such that a glance at the display will convey information on the ECG and its lead.

- Select the size of the ECG that is desired by pressing "1/2", "1", or "2". These designation apply to the size of the display on both the scope and the chart recorder in centimeters per millivolt of ECG input.
• Press the "CAL" (1 mV) switch to check the calibration of the chart recorder and scope. Each time this switch is pressed, one millivolt is superimposed on the signal. Calibration often is best accomplished with the "STD" lead selected where a flat baseline is assured.

NOTE: "STD" means that all electrode leads are shorted together, and no ECG input is allowed.

• The ECG will move across the screen from the right toward the left. When the "FREEZE" switch is pressed, the display will stop, and new data will not be presented. The "FREEZE" switch must be pressed again in order to "thaw" the display and make it active once again.

• Turn the chart recorder "on" by pressing the "RUN" switch. The recorder will record the ECG as it moves off the left side of the scope. Thus, if the scope display is frozen, the chart recorder will record a straight line until the display is "thawed". Then the chart recorder will record the ECG that had been stored on the scope and will continue to record the new data impressed on the scope following the "thaw" operation.

• Place the chart recorder in the automatic start mode by pressing the "AUTO" switch. In this mode, the chart recorder will start and run automatically whenever the upper or lower heart rate or respiration rate limits are exceeded.

• The heart rate display on the scope should track the ECG input and stabilize within 15 seconds after all controls are set for the desired presentation.

1.2.2 RESPIRATION SUBSYSTEM

• The respiration signal is derived from the ECG electrodes by impedance pneumography. Thus, all three electrodes must be in place for the respiration subsystem to operate.

• There are no controls on the respiration subsystem. Each breath is automatically detected by the respiration circuitry.

• The respiration rate display on the scope should track the respiration of the patient and stabilize within 60 seconds after application.

1.2.3 TEMPERATURE SUBSYSTEM

• Select either an oral or a rectal probe.

• Place disposable sheath on probe - sheath made of a plastic material.
• Display will read 60°F or actual temperature whichever is higher. When probe is not connected to Vital Signs Monitor, the display will be 60°F.

• Upon insertion of the probe, the display is updated every second. The temperature displayed is that measured at the tip of the probe.

1.2.4 BLOOD PRESSURE SUBSYSTEM

• Press "ON" - this turns on the Blood Pressure circuit and sets the filters to Systolic position. Systolic display reads the cuff pressure. Diastolic display is blank.

• Pump up cuff - systolic display continues to track cuff pressure. Diastolic display is blank.

• Press "SYS" switch when first warble is heard. Systolic display locks at that cuff pressure and the diastolic display is turned "ON". Diastolic display tracks cuff pressure. Filters are switched to diastolic position.

• Press "DIAS" switch with each sound, or depress and hold, or depress when last warble is heard. With DIAS switch depressed, the diastolic display tracks cuff pressure. When DIAS switch is released, the cuff pressure is latched and displayed. A 3-second timer is reset each time DIAS switch is released. When the timer "times out", the Blood Pressure circuits are disabled. Both diastolic and systolic displays remain frozen until the next time that the "ON" switch is pressed.

1.2.5 ALARM SUBSYSTEM

• Press the "HEART RATE" switch. "HR ALRM" will appear in the lower right corner of the scope.

• Set the upper limit on the Heart Rate by pressing and holding the "UPPER LIMIT" switch while simultaneously pressing and holding either "ADJA" or "ADJ↓". Whenever "UPPER LIMIT" is pressed, the heart rate display will present the upper limit on the heart rate alarm, and "UL" will appear in the lower right corner of the scope. Then, when this limit is adjusted, the increments or decrements will appear on the scope.

• Set the lower limit on the Heart Rate by pressing and holding the "LOWER LIMIT" switch while simultaneously pressing the holding either "ADJA" or "ADJ↓". The scope display reads the lower heart rate limit during this process, and "LL" appears in the lower right corner.

• Press the "HEART RATE" switch to clear the "HR ALRM" from the display.
• Press the "RESP RATE" switch. "RR ALRM" will appear in the lower right corner of the scope.

• Set the upper limit on respiration rate by pressing and holding the "UPPER LIMIT" switch while simultaneously pressing and holding either "ADJ A" or ADJ T. Whenever "UPPER LIMIT" is pressed, the respiration rate display will present the upper limit on the respiration rate alarm, and "UL" will appear in the lower right corner of the scope. Then, when this limit is adjusted, the increments or decrements will appear on the scope.

• Set the lower limit on respiration rate by pressing and holding the "LOWER LIMIT" switch while simultaneously pressing and holding either "ADJ A" or "ADJ T". The scope display reads the lower respiration rate limit during this process, and "LL" appears in the lower right corner.

• Press the "RESP RATE" switch to clear the "RR ALRM" from the display.

• When the patient's heart rate crosses either the upper limit or the lower limit, an alarm tone sounds and the letters "HR ALRM" appear on the scope. If the heart rate then returns within the set limits, the tone disappears but the "HR ALRM" signal remains displayed on the scope until it is reset by depressing the "HEART RATE" switch.

• When the patient's respiration rate crosses either the upper limit or the lower limit an alarm tone sounds and the letters "RR ALRM" appear on the scope. If the respiration rate then returns within the set limits, the tone disappears but the "RR ALRM" signal remains displayed on the scope until it is reset by depressing the "RESP RATE" switch.

• If the chart recorder is in the "AUTO" mode, activation of either the heart rate alarm or the respiration rate alarm will cause the recorder to start and to record the ECG until it is reset.

• As the battery pack nears depletion of charge, the alarm circuits will be triggered to display "BATTERY LOW". This alerts the operator that the unit should be plugged into the battery charger immediately for continued operation.

1.2.6 POWER SUBSYSTEM

• Plug the charger into the back of the Vital Signs Monitor. It will charge the battery pack to full capacity within 16 hours. No damage to the system will occur if the charger is left connected for longer periods of time. The system will operate from the charger with a completely depleted battery.

The VSM can also be operated directly from vehicle power with a source of 13.8 Volts ± 2 Volts.
1.2.7 SUBSYSTEM INITIALIZATION

Press and release the power "ON" switch. The ECG trace will appear, and the ECG Lead II will be displayed. The heart rate, respiration rate, and temperature will appear sequentially. The blood pressure display will remain blank. The heart rate and respiration rate alarm limits will be set to the appropriate full scale values in order to prevent alarm turn on.
Figure 1  Vital Signs Monitor Subsystems Diagram
Figure 2—Contents of PMSTS
The DC defibrillator provides the means to deliver a controlled monophasic defibrillating pulse to the patient's heart. The paddles provided with the unit may be used either to monitor the patient's ECG signal, when used in conjunction with the cardioscope/recorder, or to deliver the defibrillating pulse. Operation of the DC defibrillator module is accomplished entirely through controls mounted on the paddles. This provides the user with a greater flexibility, helping to eliminate the dependency on other personnel.

### LIFEPAK 5 GENERAL SPECIFICATIONS

<table>
<thead>
<tr>
<th>CHARACTERISTIC</th>
<th>QUANTITY OR SPECIFICATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>DC DEFIBRILLATOR MODULE:</td>
<td></td>
</tr>
<tr>
<td>SIZE (envelope)</td>
<td>3.8x9.2x13.3 inches (9.7x23.4x33.8 cm)</td>
</tr>
<tr>
<td>WEIGHT (including battery/pak)</td>
<td>10.6 pounds (4.8 kg)</td>
</tr>
<tr>
<td>WAVEFORM</td>
<td>Monophasic Pulse, 5 milliseconds (Ede, r.)</td>
</tr>
<tr>
<td>OUTPUT ENERGIES (delivered)</td>
<td>40, 80, 120, 160, 240, 320 joules ± 10%</td>
</tr>
<tr>
<td>CHARGE TIME TO 300 JOUTES (CHARGE TIME TO 400 JOUTES)</td>
<td>(Optional 20, 50, 100, 200, 300, 400 joules ± 10 seconds)</td>
</tr>
<tr>
<td>ENERGY BLEED DOWN AFTER 30 SECONDS</td>
<td>12.5 seconds</td>
</tr>
<tr>
<td>BATTERY TEST INDICATOR (flashes when down to)</td>
<td>15+ maximum</td>
</tr>
<tr>
<td>OUTPUT PADDLES:</td>
<td></td>
</tr>
<tr>
<td>Size</td>
<td>Terminal voltage of 10.2 nominally @ 25°C</td>
</tr>
<tr>
<td>Coil cord length</td>
<td>82 cm²</td>
</tr>
<tr>
<td>POWER SOURCE (Battery/Pak)</td>
<td>7.5 feet (2.3 m)</td>
</tr>
<tr>
<td>Capability (see below also)</td>
<td>Nickel Cadmium Battery, 12 VDC, 1 AH</td>
</tr>
<tr>
<td>DEFIBRILLATOR SYNCHRONIZER (option)</td>
<td>12 300 joule discharges minimum at -10°C. 32 400 joule discharges minimum at +25°C.</td>
</tr>
<tr>
<td>Synchronized defibrillating pulse for elective cardioversion timed to occur on the down slope of the first patient-generated R-wave which follows defibrillate command.</td>
<td></td>
</tr>
<tr>
<td>Sync Indicator</td>
<td>Intensification marker on CRT trace identifies sync trigger point.</td>
</tr>
<tr>
<td>Sensitivity Control</td>
<td>ECG size control acts as threshold control.</td>
</tr>
<tr>
<td>Sync-Defib Mode Control</td>
<td>Pushbutton switch can be depressed to change mode instantly from Sync to Defib or Defib to Sync.</td>
</tr>
</tbody>
</table>
ENVIRONMENTAL CONDITIONS (excluding battery/pak charger):

Unless otherwise stated the performance requirements of LIFEPAK 5 shall be met under the following storage and operating conditions.

- TEMPERATURE RANGE .................... -10°C to +55°C (operating)
  -35°C to +65°C (storage)

- ATMOSPHERIC PRESSURE ................... 525 mm Hg to 800 mm Hg

- RELATIVE HUMIDITY ...................... 0 to 95%

- VIBRATION (capable of meeting after vibration) ...................... MIL-STD-810C Method 514.2 curve V

- SHOCK (capable of meeting after shock) ............................ MIL-STD-810C Method 516.2 Procedure 1, figure 516.2-2

- SPLASH TEST (capable of meeting after splash, excluding paper recorder) MIL-STD-108E, paragraph 4.9

- DROP (without resulting in operator or patient hazard during drop) .... 1.5 foot (45.7 cm) drop on a concrete floor on each axis (6 drops)

- ECG telemetry equipment (operating at 450 MHz up to 15 watts) shall not be located closer than 6 inches (15.3 cm)
2.3 MISCELLANEOUS SUPPLIES

Appropriate space is included in the system package for the following items:

- ECG Electrodes
- ECG Cable and Adapters
- Voice Recorder (Olympus E420)
- Blood Pressure Cuff/Bulb
- Defibrillator Electrode Gel
- Temperature Probe and Disposable Covers
3.0 PACKAGING

• Enclosure

The system enclosure is an orange, waterproof, polyethylene plastic, suitcase style carrying case from Gemini, Inc.

• Size

The overall dimensions for the system enclosure are 14" (35.56 cm) x 20" (50.8 cm) x 8" (20.32 cm).

• Weight

The total system weight is 40.0 pounds (18.1 kg). The following list is a breakdown of the weight for each module.

<table>
<thead>
<tr>
<th>Item</th>
<th>Weight (Pounds)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vital Signs Monitor</td>
<td>12.9</td>
</tr>
<tr>
<td>Defibrillator</td>
<td>9.6</td>
</tr>
<tr>
<td>Radio</td>
<td>7.8</td>
</tr>
<tr>
<td>Voice Recorder</td>
<td>0.6</td>
</tr>
<tr>
<td>Miscellaneous Supplies</td>
<td>1.6</td>
</tr>
<tr>
<td>Enclosure</td>
<td>7.5</td>
</tr>
</tbody>
</table>

40.0 Pounds Total
4.0 TEST RESULTS

4.1 VITAL SIGNS MONITOR

4.1.1 ECG SUBSYSTEM

• DEFIBRILLATION PROTECTION

ECG inputs were tested according to the AAMI (draft) Standard for Cardiac Monitors. A high energy pulse was applied between each lead and the remaining two leads tied together and between all of the leads tied together and chassis. No damage, or performance degradation to the VSM was observed after performing this test.

• PATIENT ISOLATION

The unit was tested according to the ANSI Standard, Safe Current Limits for Electromedical Devices, with the charger connected. An acceptable maximum chassis leakage current of 12.3uA was measured with chassis ground wire unconnected. The maximum patient lead leakage was measured to be 5.4uA source current and 23.5uA sink current.

• BANDWIDTH

The overall bandwidth of the ECG on the scope and chart recorder was measured to be 0.1 to 43 Hz.

• COMMON-MODE REJECTION

The common-mode rejection (CMR) was measured as a function of frequency at 10 Hz, 40 Hz, and 60 Hz, the CMR was measured to be 67 dB, 56 dB, and 51 dB, respectively. A 60 Hz notch-filter with a 35 dB notch was used to reduce 60 Hz interference, resulting in a 86dB or greater CMR at 60 Hz.

• HEART RATE DISPLAY

The digital heart rate display was calibrated at 60 and 180 BPM. Over the 40 to 220 BPM range, the maximum error was measured to be + 1 BPM.

4.1.2 RESPIRATION SUBSYSTEM

• RESPIRATION RATE DISPLAY

The digital respiration rate display was calibrated at 12 and 36 BPM. Over the range of 6 to 60 BPM, the maximum error was measured to be + 1 BPM.

4.1.3 TEMPERATURE SUBSYSTEM

The maximum digital temperature reading error over 95 to 105 F was measured to be ± 0.2 F with the probe in a water bath. The probe time constant in a non-stirred water bath was determined to be 8 seconds with the disposable plastic sheath installed.
4.1.4 BLOOD PRESSURE SUBSYSTEM

- SYSTOLIC AND DIASTOLIC DISPLAYS
  
  The digital display was calibrated at zero and 100 mmHg. Over the range 0 to 255 mmHg the maximum error was measured to be ± 2 mmHg with a ± 1 mmHg random noise.

- SYSTOLIC FILTER
  
  The bandwidth of the systolic filter was measured to be 13 to 30 Hz with a center frequency of 21 Hz.

- DIASTOLIC FILTER
  
  The bandwidth of the diastolic filter was measured to be 52 to 112 Hz with a center frequency of 79 Hz.

4.1.5 POWER SUBSYSTEM

- NI-CAD BATTERY PACK
  
  VSM operating time of 6.3 hours was determined by starting with a fully-charged battery and allowing the VSM to run (with the chart recorder off) until the low battery indicator was activated. The VSM operation time after the battery low indicator activated was measured to be approximately 30 minutes.

- BATTERY CHARGER
  
  The battery charger output was measured to be 0.39A for the (1/10C) charge current. In the augmented power mode, the charger was capable of delivering an additional 0.730 A to allow monitor operation during battery recharge. A (13.0 Volt) voltage clamp circuit with sufficient capacity to run the defibrillator and radio was also found to be operating properly.

4.2 DEFIBRILLATOR MODULE

  The defibrillator delivered energy at switch settings of 20, 50, 100, 200, 300 and 400 Joules was measured to be 18.9, 44, 95, 195, 289, and 380 Joules, respectively, and the accuracy of these readings meet the requirements of the AAMI Standard for Cardiac Defibrillator Devices.
4.3 RADIO MODULE

The radio transceiver was tested to meet FCC regulations with 1.0 watt transmit power over the following transmit/receive frequencies.

<table>
<thead>
<tr>
<th>RF CHANNEL</th>
<th>TRANSMIT</th>
<th>RECEIVE</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>468.000 (MHZ)</td>
<td>463.000 (MHZ)</td>
</tr>
<tr>
<td>2</td>
<td>468.025</td>
<td>463.025</td>
</tr>
<tr>
<td>3</td>
<td>468.050</td>
<td>463.050</td>
</tr>
<tr>
<td>4</td>
<td>468.075</td>
<td>463.075</td>
</tr>
<tr>
<td>5</td>
<td>468.100</td>
<td>463.100</td>
</tr>
<tr>
<td>6</td>
<td>468.125</td>
<td>463.125</td>
</tr>
<tr>
<td>7</td>
<td>468.150</td>
<td>463.150</td>
</tr>
<tr>
<td>8</td>
<td>468.175</td>
<td>463.175</td>
</tr>
<tr>
<td>9</td>
<td>467.950</td>
<td>462.950</td>
</tr>
<tr>
<td>10</td>
<td>467.975</td>
<td>462.975</td>
</tr>
</tbody>
</table>

The transmit and receive frequencies were tuned to within ± 200 Hz of center frequency. The receiver sensitivity was measured to be 0.4 microvolts for 12 dB SINAD. The receiver desense due to the transmitter was measured to be ± 2 dB or less. In the receive only mode, the unit consumed 1.2 watts, and with the transmitter turned on, the power consumption was measured to be 8 watts.
6.0 EVALUATION AND RECOMMENDATIONS

Three prototypes were delivered to NASA-JSC for evaluation purposes. Two of these units were sent to the Department of Transportation (DOT) for field testing. This report is based on limited feedback from the DOT evaluation, on repair and maintenance experience with the units, and on comments received during demonstration of the units.

6.1 VITAL SIGNS MONITOR

6.1.1 ECG SUBSYSTEM

No repairs were required for the ECG subsystem. It was noted that the RFI protection performed very well in comparison to other Narco Telecare units. The switching transients which occurred at ECG Lead changes were considered to be distracting but acceptable. It was noted that the capture time of the heart rate after initial application of the ECG electrodes appeared to be excessive. The problem was traced to the AGC circuit in the DRI ECG amplifier hybrid, however, the problem was not considered to be severe enough to warrant any redesign.

6.1.2 RESPIRATION SUBSYSTEM

No repairs were required for the respiration subsystem. The impedance pneumograph sensing technique was found to be susceptible to motion artifact. Consequently, the respiration sensing was limited to use on stationary patients. No design changes were considered necessary.

6.1.3 TEMPERATURE SUBSYSTEM

One of the temperature probes was damaged and was replaced. The probe was damaged when the unit arrived for repair, and no damage report was included. It was assumed that the damage occurred during shipment. No significant operational problems were noted for the temperature subsystem.

6.1.4 INDIRECT BLOOD PRESSURE SUBSYSTEM

No repairs were required for the blood pressure subsystem. In field use, it was noted that the audible tone was not loud enough for proper detection of the systolic and diastolic blood pressures. From previous experience with this sensing technique, it was felt that lack of proper operator training was the source of the problems. Additionally, the audible tone was routed to the radio headset for use in areas with high ambient noise levels.
6.1.5 ALARM SUBSYSTEM

No repairs were required for the alarm subsystem. The technique for setting the alarm limits via the front panel switches was considered to be somewhat cumbersome but usable. The requirement for pressing two switches simultaneously for adjusting the limits was found to be the problem. In the production units now under development, the alarm limit adjustment procedure has been modified to require activation of only one switch at a time.

6.1.6 POWER SUBSYSTEM

Repairs were required for the power subsystem in all three of the evaluation prototypes. The problem was traced to the scope blanking circuit where the reverse breakdown voltage of the LED in the optical coupler (Z4) was being exceeded. The problem was solved by adding a diode from pin 3 of Z4 to the +75V supply to limit the voltage across the LED. The noise from the fan in the battery charger was also noted as a potential problem, however, it was intended that the charger be located at a central site for overnight recharging while the PMSTS units would be transported to remote sites. For this reason, the noise problem was not considered to be serious.

6.1.7 FRONT PANEL AND CONTROLS

No repairs were required for the front panel and controls. The operation of the membrane switch type controls was found to be satisfactory with the visual feedback from the scope. However, it was felt that audible or tactile feedback for switch activation would enhance the operational efficacy of the unit. For the production units under development, a membrane switch with a distinct tactile actuation feedback and inherent audible feedback was selected. The technique for audible feedback via an electronically generated tone was rejected because it might be confused with alarms or other tone indicators.

6.2 DC DEFIBRILLATOR MODULE

No repairs were required for the DC defibrillator module. Some operational difficulty was reported in removing the paddles for use, however, the means for paddle removal was considered to be adequate.

6.3 RADIO MODULE

The velcro-type strip for securing the hold-down flap for the headset and phone coupler was reglued in all three units. A broken wire was repaired in one of the headsets. Additionally, the radio headset was found to be difficult to use because it required assembly for operation and disassembly for storage. The headset was also considered to be somewhat fragile for field operation. At the time of selection, the headset was considered to be the best lightweight, small-sized model available.
6.4 PACKAGING

No repairs were required for the enclosures in the unit. The weight (40 lbs) was found to reduce the ease of hand-transport of the unit. The weight of the unit was found to be about the same as other units with similar features. For the evaluation prototypes, a modularized packaging concept was adopted to allow usage of existing commercial products. It was recognized that the weight of the unit would be substantial where modules in self-contained enclosures are installed in a system enclosure. A more expensive custom-designed enclosure has been utilized in the production units under development.