Test and Evaluation of the Protocol Systems Propaq 106EL Physiologic Patient Monitor

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October 1996
NOTICES

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The Propaq 106EL is a portable patient monitor capable of monitoring, non-invasive blood pressure, invasive blood pressure, patient temperature, pulse oximetry, and respiratory rate. A Protocol Universal Power Adapter, Part Number 503-0054-00 100 - 120VAC 50/60 Hz line voltage to low voltage DC 16 - 24 VDC. This operates the 106EL and charges the internal battery. The Propaq 106EL can receive 28 VDC input power via the Protocol DC power cord. The internal battery lasts approximately 4 - 8 hours with a recharge time between 6 - 12 hours.
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ACKNOWLEDGMENTS

I would like to thank all those who helped and advised during the evaluation of the Protocol Systems Propaq 106EL. I would especially like to thank Lt Col Jacqueline D. Hale, MSgt Victor Elizondo, TSgt Butch Blake, TSgt Allen Jones, TSgt Mary Thomas, Mr. Edward Hade, Mr. Douglas Townsend, personnel from ASC/ENAI Wright Patterson AFB, AL Laboratory of Aerospace Cardiovascular Research, personnel from the 332nd at Randolph AFB, and Ms. Grace Day, Director of Marketing for Protocol Systems.
TESTING AND EVALUATION OF THE PROTOCOL SYSTEMS
PROPAAQ 106EL PHYSIOLOGIC PATIENT MONITOR

BACKGROUND

Air Training Command Surgeon General and the Department of Surgery, Wilford Hall USAF Medical Center briefed HQ AMC/SG (Brig Gen Roadman) on the feasibility of a Critical Care Aeromedical Transport Team (CCATT). During this meeting a request for evaluation of a patient monitor for air worthiness was presented. The Director, Aeromedical Evacuation and Medical Plans & Requirements requested the Human Systems Center at Brooks AFB have Armstrong Laboratory evaluate the Propaq 106EL compatibility with aeromedical aircraft systems and the airborne environment.

DESCRIPTION

The Propaq 106EL, SN: AE00127 with modules: BD00128, MD00153, and CI00128 (component printer, pulse oximeter, and carbon dioxide monitor unit), will hereby be referred to as the 106EL (figure 1). This unit is a light weight portable patient monitor capable of monitoring the following: ECG (1 channel: 3-lead); NIBP, noninvasive blood pressure, (1 channel: cuff); IBP, invasive blood pressure, (2 channels); temperature (1 channel: YSI); pulse oximetry (1 channel: SpO2); CO2 (1 channel); and respiratory rate (figure 2). This unit has a printer and HP Connector-Compatible Side Panel. The display in the 106EL is electroluminescent (EL). With printer/SpO2/CO2, the dimensions of the unit are: height, 9.8 in (24.9 cm); Width, 8.3 in (21.1 cm); depth, 7.3 in (18.5 cm); weight, 12.3 lbs (5.6 Kg). DC input power required: 12 - 28 Volts, 25 Watts. The 106EL is powered from an internal, 8 V/6 Amp Hr, sealed lead acid battery or suitable external power source. Battery life is rated at 4-8 hours depending on product configuration with a recharge time at 6 to 12 hours.

The Protocol Universal Power Adapter, Part Number 503-0054-00 converts 100-120VAC, 500 mA, 50/60 Hz line voltage to low voltage DC, 16 - 24 VDC, 25 watts. It operates the 106EL and charges the internal battery. The 106EL can also receive the required input power from Protocol DC power cord, Part Number 008-0290-00. In order to use DC power on USAF aircraft, a Hubbell Twist - Lock® plug, Catalog Number 7545C or equivalent is required to be installed. For a detailed description of 106EL options reference the Propaq User’s Guide.
Fig. 1 Protocol Systems Propaq 106EL Monitor and Expansion Module.

Fig. 2 Protocol Systems Propaq 106EL and its connections.
METHODS

Aeromedical Research personnel derived test methods, procedures and performance criteria from various military standards (1-4), nationally recognized performance guidelines (5-6), Aeromedical Research Procedure's Guide(9), electrical safety standards (4), and the Propaq User's Guide and Service Manual (10). A test setup and performance check were developed to evaluate the 106EL's performance throughout testing.

BASELINE PERFORMANCE

The baseline performance assessment involved an initial inspection, electrical safety analysis, and following development of a specific test procedure for the device, a baseline performance check.

Initial Inspection

The 106EL was inspected for quality of workmanship, production techniques and potential damage incurred during shipment.

Electrical Safety

Biomedical equipment technicians and aeromedical research engineers performed this evaluation on the 106EL to ensure the safety of both the equipment operator and the patient. This assessment involved measuring the equipment's leakage current and ground to chassis resistance, in addition to a general inspection of the device. The required limits are established in National Fire Protection Agency (NFPA) 99 Health Care Facilities Code (6), and Equipment Management in Hospitals AFI 41-201 (7), Electrical Shock Hazards AFI 41-203 (8).

Test Setup and Performance Check

A test setup and performance check were developed to evaluate the 106EL's operation in accordance with manufacturer/customer specifications throughout the various testing conditions.

a. Test Setup. Plug the 3-lead ECG cable into the ECG port on the 106EL. Attach the 3 ECG leads to the corresponding color coded receptacles on the BIO-TEK Lionheart multiparameter simulator (Lionheart). Plug the YSI temperature cable into the temperature port on the 106EL. Attach the tri-axil end of the temperature probe into the 300 series temperature output of the Lionheart. Configure the Lionheart with the following settings: temperature, 30°C; lead select, I/II; ECG amplitude, 1.0; and ECG BPM, 60. Secure the non-invasive blood pressure (NIBP) tubing line to the NIBP port. Use a T connector to place the Dynatech Nevada Cufflink NIBP Analyzer (Cufflink) cuff connect port in line between the BP cuff and the 106EL. Wrap the BP cuff tightly around the appropriate adult cuff mandrel. For an adult cuff use 2 end and 2 spacer blocks. After zeroing the transducer and allowing the Cufflink to warm up for 15-20 minutes, configure the Cufflink with the following settings: ADAMS Adult, 120/80
(90). Ensure the Cufflink is disconnected from any tubing while zeroing the transducer. Plug the SpO2 cord into its corresponding port on the SpO2 port on the 106EL. Attach the free end of the SpO2 line to the Nellcor pocket tester. Plug the CO2 sensor cord into its corresponding port on the 106EL's CO2 module. Attach an airway adapter and sensor to the CO2 line. Plug the invasive pressure sensor line into its corresponding P1 port on the 106EL. Zero P1 through the sensor options menu and configure the 106EL to monitor ECG lead II and display temperature in °C. The 106EL will continuously monitor temperature, P1, SpO2 and CO2. The NIBP operation can be initiated manually or programmed at set intervals. Set the 106EL so that it will not print Apnea tickets, and, when using the printer, limit paper usage by rewinding paper after individual tests.

b. Performance Check. The Performance Check as outlined in the approved test plan was used to validate the function of the 106EL in each of the test conditions. Measurements were taken during initial operation at standard ambient conditions and served as a baseline for later comparison. The performance check consisted of recording the values for each monitored physiologic parameter three times and activating the printer to ensure its function. In many cases the 106EL was continuously monitored through the duration of the test, with the performance checks occurring at defined intervals throughout the test.

**ELECTROMAGNETIC COMPATIBILITY**

Electromagnetic compatibility testing is a primary concern for equipment to be used on USAF aeromedical evacuation aircraft. This is mainly for the safety of everyone on board the aircraft and the effects of excessive electromagnetic emissions may have on aircraft navigation and communication equipment. Additionally, medical devices may be susceptible to fields generated by the aircraft equipment or other medical devices, and may malfunction in their presence.

The 106EL was evaluated for compliance with MIL-STD-461D (1) -susceptibility field strength levels were less than the D standard requires (refer to RS 103 below). WL/AAWA-2, Wright-Patterson AFB, personnel performed the evaluation in their electromagnetic compatibility facility, with Aeromedical Research personnel present. ASC/ENAI personnel evaluated the electromagnetic compatibility data and determined the airworthiness of the medical device. Specific tests conducted were as follows:

a. Radiated Emissions (RE-102): "Radiated Emissions, Electric Field, 10 kHz to 18 GHz." For Air Force aircraft applications, radiated emissions were tested in a range of frequencies from 2 MHz to 1 GHz. This test determined the amount of EMI emitted by the equipment during its operation. This test was performed to ensure that the device did not affect other pieces of equipment that may be susceptible to electromagnetic emissions (i.e., aircraft navigation and communication equipment).

b. Conducted Emissions (CE-102): "Conducted Emissions, Power Leads, 10 kHz to 10 MHz." For Air Force aircraft applications, conducted emissions were tested throughout the band of 10 kHz to 10 MHz. This test measured emissions
generated by the medical device along its power supply lines. This test was performed to ensure that operating the device using line power did not affect other items connected to the same power source, particularly aircraft systems.

c. Radiated Susceptibility (RS-103): "Radiated Susceptibility, Electric Field, 10 kHz to 40 GHz." For Air Force aircraft applications, radiated susceptibility was tested in a frequency range from 30 MHz to 12.4 GHz at the following field strength levels: 20 V/M below 1 GHz and 60 V/M above 1 GHz (field strength values from Table IV, category Aircraft Internal, of 461D). Because the 106EL was a device tested as the laboratory was switching from 461C to 461D, the field strength levels were as depicted in figure 3 below. This test determined whether or not the device would withstand pre-defined levels of EMI generated by antennas both internal and external to the aircraft.

<table>
<thead>
<tr>
<th>POWER SOURCE</th>
<th>FREQUENCY (MHz)</th>
<th>FIELD STRENGTH (V/M)</th>
<th>461D FIELD STRENGTH (V/M)</th>
</tr>
</thead>
<tbody>
<tr>
<td>115VAC/60Hz</td>
<td>30-950</td>
<td>10</td>
<td>20</td>
</tr>
<tr>
<td></td>
<td>990-1,000</td>
<td>20</td>
<td>20</td>
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<tr>
<td></td>
<td>1,000-3,000</td>
<td>20</td>
<td>60</td>
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<tr>
<td></td>
<td>3,000-8,000</td>
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</tr>
<tr>
<td></td>
<td>8,000-12,000</td>
<td>60</td>
<td>60</td>
</tr>
<tr>
<td>BATTERY</td>
<td>30-200</td>
<td>20</td>
<td>20</td>
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<tr>
<td></td>
<td>200-400</td>
<td>10</td>
<td>20</td>
</tr>
<tr>
<td></td>
<td>400-1,000</td>
<td>20</td>
<td>20</td>
</tr>
<tr>
<td></td>
<td>1,000-12,000</td>
<td>60</td>
<td>60</td>
</tr>
<tr>
<td>28VDC</td>
<td>30-200</td>
<td>20</td>
<td>20</td>
</tr>
<tr>
<td></td>
<td>200-400</td>
<td>10</td>
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<td>400-1,000</td>
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<tr>
<td></td>
<td>1,000-12,000</td>
<td>60</td>
<td>60</td>
</tr>
</tbody>
</table>

Fig. 3 Field Strength Levels for Propaq 106EL RS103 Testing.

d. Conducted Susceptibility (CS-101): "Conducted Susceptibility, Power Leads, 30 Hz to 50 kHz." For Air Force aeromedical aircraft applications, conducted susceptibility was tested throughout the entire frequency band, from 30 Hz to 50 kHz. This test determined whether the components "withstood ripple voltages associated with allowable distortion of power source voltage wave forms."(1)

e. Conducted Susceptibility (CS-114): "Conducted Susceptibility, Bulk Cable Injection, 10 kHz to 400 MHz." For Air Force aeromedical aircraft applications conducted susceptibility was tested throughout the frequency band, from 10 kHz to
200 MHz. This test was performed to determine whether "simulated currents which were developed on platform cabling from electromagnetic fields generated by antenna transmission affected the equipment under test." (1)

f. Conducted Susceptibility (CS-115): "Conducted Susceptibility, Bulk Cable Injection, Impulse Excitation." This test was performed to ensure the 106EL could withstand the "fast rise and fall time that may be present due to platform switching operations and external transient environments such as lightning and electromagnetic pulse." (1)

During emissions testing, all options were operated for the duration of the test to create the "worst case" emissions scenario. Throughout the testing, the recorder (printer) ran continuously, and the apnea alarm continuously sounded at maximum volume. The 106EL was in turbo-cuff mode, such that the NIBP option was continuously activated. For susceptibility testing, the unit was operated as discussed earlier in the equipment set-up and performance check sections. For both emissions and susceptibility testing, the 106EL was tested for operation on 115 VAC/60 Hz, 28 VDC, and internal batteries.

**VIBRATION**

Vibration testing is critical to determine "the resistance of equipment to vibrational stresses expected in its shipment and application environments" (3). Vibration testing was conducted at Aeromedical Research's vibration facility. This testing involved a set of operational tests performed along each of the three axes of the 106EL, X, Y, and Z, with the 106EL mounted on the simulated litter on the shaker head as it would most likely be found in the aircraft. It was subjected to vibration curves with slightly modified levels and lengths from those derived from MIL-STD-810E, Category 10, figures 514.4-16 and 514.4-17 (Fig. 4).
Fig. 4  MIL-STD-810E, Category 10, figures 514.4-16 and 514.4-17
ALTITUDE/RAPID DECOMPRESSION

Testing was conducted in the Armstrong Laboratory research chambers which were operated and monitored by chamber operations personnel assigned to the Systems Research Branch (CFTS) of the Crew Technology Division at Armstrong Laboratory, Brooks AFB, TX.

a. Hypobaric Chamber Testing: Altitude testing is critical for aeromedical evacuation equipment due to the potential effects of barometric pressure changes on the equipment. A majority of the aircraft that are characterized as opportune aircraft available for use in aero medical evacuation pressurize their cabin to barometric pressures equivalent to 8,000-10,000 feet above sea level. However, the differences in pressures can be critical to the effective operation of some medical equipment. Altitude testing consisted of operating the 106EL while ascending from ground level to 10,000 feet (maintaining altitude for one hour) and then descending back to ground, at rates of 5000 ft/min, while stopping at 2000 ft increments to allow for performance checks.

b. Rapid Decompression Testing: Rapid decompression is caused by the loss of aircraft cabin pressurization and subsequent pressure equalization with ambient atmospheric pressures. It is important to determine how medical equipment will function during and after such a decompression and ensure that it will not endanger a patient, the aircraft personnel, or the aircraft itself. The 106EL operated inside the rapid decompression test chamber as the chamber was pressurized to an equivalent of 8,000 ft (2,438 meters) altitude. Then, the pressure in the chamber altitude was taken to the equivalent of 40,000 ft (12,192 meters) over a period of 60 seconds, held at 40,000 ft for a few minutes, and then brought back down to ground level pressure at a rate of 10,000-12,000 ft/min. The test was repeated twice with the decompressions occurring over seven and one seconds, respectively. The 106EL was monitored throughout the series of decompressions, including performance checks each time the unit returned to ground level. The simulator equipment remained outside the chamber. Cables joining the Lionheart, Cufflink, and Nellocor to the 106EL were run through putty-sealed access ports in the chamber walls.

THERMAL/HUMIDITY

Extreme temperature and humidity testing is critical to determine if aeromedical equipment can be stored and operated under severe environmental conditions "without experiencing physical damage or deterioration in performance." Extreme environmental conditions can have numerous detrimental effects on medical equipment including, but not limited to, changes in material characteristics and material dimensions, possible overheating, changes in lubricant viscosity, changes in electronic components, and electronic or mechanical failures due to rapid water or frost formation.

Testing was conducted in the Armstrong Laboratory environmental research chambers which were operated and monitored by chamber operations personnel
assigned to the Systems Research Branch (CFTS) of the Crew Technology Division at Armstrong Laboratory, Brooks AFB, TX. The 106EL was placed in the center of the environmental chamber. All input and output cables and wires were routed through a port in the chamber wall, which was subsequently sealed with a precut sponge plug. The other components of the test setup were outside the chamber. For operational tests, the 106EL was monitored continuously, and a performance check was conducted every fifteen minutes. For storage tests, the 106EL was placed in the chamber and remained nonoperational throughout the storage portion of the test. The following describe the conditions of the environmental tests performed:

a. Humidity: 94 +/- 4% Rh, 85°F +/- 3.6°F (29.5°C +/- 2°C) for 4 hrs

b. Hot Temp. Operation: 120°F +/- 3.6°F (49°C +/- 2°C) for 2 hrs

c. Cold Temp. Operation: 32°F +/- 7.2°F (0°C +/- 4°C) for 2 hrs

d. Hot Temp. Storage: 140°F +/- 3.6°F (60°C +/- 2°C) for 6 hrs

e. Cold Temp. Storage: -40°F +/- 3.6°F (-40°C +/- 2°C) for 6 hrs

AIRBORNE FEASIBILITY

Airborne feasibility evaluations are an invaluable means of validating a piece of equipment for clinical and operational suitability under actual operating conditions. By carefully evaluating medical equipment items in their actual environment, Aeromedical Research ensures that all pertinent casualty care issues are adequately addressed by the test protocols. Ensuring safe and effective clinical operation of medical equipment is the primary goal of the inflight evaluation and forms the basis for subsequent recommendations to the users.

This phase of inflight testing was conducted by a Biomedical Research engineer and an aircraft-qualified Aeromedical Research technician on board a C-9 aeromedical evacuation mission. Throughout the flight, the 106EL was secured to either equipment brackets on a NATO litter or Waters bracket secured to a stanchion pole. Human factors characteristics, securing methods, and equipment setup times and locations were also evaluated.
RESULTS

Aeromedical Research evaluated the non-invasive blood pressure (NIBP) option on the 106EL throughout all stages of testing. However, Protocol's NIBP algorithm utilizes a relationship between the blood pressure and the electrocardiogram when determining NIBP, particularly to avoid accepting environmental artifact as pulses. Without this synchronization between our simulators during testing, the NIBP values were within 10% of the simulator, an accuracy recommended by ECRI, as it is comparable to those "obtained by an experienced nurse using a stethoscope and an occluding cuff." However, through several portions of testing, the 106EL was intermittently unable to determine the blood pressure. The 106EL would flash errors such as "measurement time out" or "no valid blood pressure found." Protocol's NIBP algorithm experts and Aeromedical Research engineers have pinpointed these errors as results of the non-synchronized simulators. However, without using synchronized simulators it is impossible to verify the Propaq's ability to consistently take a NIBP.

BASELINE PERFORMANCE

Initial inspection results revealed no manufacturing defects. The 106EL leakage current and ground resistance characteristics remained within allowable limits for battery, 28VDC and 115VAC/60Hz operation.

ELECTROMAGNETIC COMPATIBILITY

The 106EL passed all phases of electromagnetic compatibility testing in both the monitoring and printing mode with one exception. The 106EL temperature option exhibited susceptibility during CS114. ASC/ENAI experts determined that these susceptibility events would be brief (seconds), but that the temperature readings "should not be relied on in critical situations." Aeromedical Research discussed this issue with HQ AMC/SGXR who concluded this situation was not critical, as the crew would have alternate methods of temperature determination. As a result, Aeromedical Research recommends that the user be aware of the potential for temporarily, inaccurate temperature readings. After initial electromagnetic interference evaluations, ASC/ENAI, Wright Patterson AFB, approved the 106EL for use on large-bodied USAF aircraft only. They also recommended that the 106EL be individually evaluated for each small aircraft platform. Aeromedical Research and ASC/ENAI did evaluate and certify the 106EL for use inflight on the C-21. The 106EL will require additional evaluations to fly on other small aircraft. Additionally, ASC/ENAI recommends that "the 106EL not be operated during takeoff and landing when used on smaller air vehicles."

VIBRATION

The 106EL operated within manufacturer's specifications throughout the vibration testing.
ALTITUDE/RAPID DECOMPRESSION

a. Altitude: The 106EL operated within manufacturer's specifications during altitude testing.

b. Rapid Decompression: The 106EL operated within manufacturer's specifications following each rapid decompression and did not present a safety hazard throughout the decompression. However, during rapid decompression testing, the 106EL experienced the following: (1) internal "altimeter failure, rate" which renders the carbon dioxide and breath rate sensors inoperative, and (2), cuff "overpressure condition, cycle power" which renders the cuff inoperative. To recover the carbon dioxide and breath rate sensor, simply disconnect and reconnect the sensor from the 106EL. In a cuff overpressure condition, the unit will continue to operate; however, to recover the cuff channel, simply cycle the power by turning the unit off and then on. Aeromedical Research recommends that personnel be aware of the following potential occurrences during a rapid decompression and be knowledgeable on how to recover the unit.

THERMAL/HUMIDITY

The 106EL experienced problems during both operational and storage temperature evaluations. The carbon dioxide and breath rate sensor ceased operation during the laboratory's hot operation test because it is only designed to operate within a limited ambient temperature range (50°F to 104°F). The sensor recovers when the temperature returns within the acceptable range; however, this is not automatic. The operator must unplug the CO2 connector and then plug it back in to reactivate the sensor. Aeromedical Research recommends restricting operational use in extreme hot/cold environments if the carbon dioxide and breath rate sensor is a critical portion of patient monitoring. Additionally, Aeromedical Research recommends that the unit only be stored in environmentally controlled areas because of unit failures during cold storage testing and subsequent conversations with Protocol's engineers concerning temperature sensitive components not designed to meet Aeromedical Research's extreme storage temperature specifications.

AIRBORNE FEASIBILITY

The inflight evaluation of the 106EL was successfully completed with the following comments: (1) the audible alarms are difficult to hear in the noisy aircraft environment, and (2), the alarm indications are difficult to view from the side of the unit. For these reasons, Aeromedical Research recommends that the 106EL be mounted such that a crew member is consistently monitoring the display from a front view. The securing capabilities with the 106EL are adequate, utilizing litter equipment brackets with litter straps or the Waters bracket. However, patient connectors and the display limit positioning of the cargo straps and may result in the user needing a more adequate mounting system for the 106EL. Analysis of flight data indicated this unit was easy to enplane and deplane and was compatible with aircraft electrical systems.
CONCLUSIONS

The test and evaluation of Protocol System's Propaq 106EL, SN: AE00127, and expansion modules, SN: BD00128, MD00153 and CI00128, is complete. Aeromedical Research found this unit conditionally acceptable for use during all phases of flight on large-bodied USAF aircraft and inflight on the C-21 only while operating on battery, 115 VAC/60 Hz, and 28 VDC in the aeromedical evacuation environment with the following comments and recommendations:

a. Aeromedical Research recommends that the unit only be stored in environmentally controlled areas because of unit failures during cold storage testing and subsequent conversations with Protocol's engineers concerning temperature sensitive components not designed to meet military extreme storage temperature specifications.

b. Because the carbon dioxide and breath rate sensor is designed to operate within a limited ambient temperature range (50°F to 104°F) and ceased operation during the laboratory's hot operation test (120°F), Aeromedical Research recommends restricting operational use in extreme hot/cold environments if the carbon dioxide and breath rate sensors are a critical portion of patient monitoring. The sensor recovers when the temperature returns within the acceptable range; however, this is not automatic. The operator must unplug the CO2 connector and then plug it back in to reactivate the sensor.

c. Aeromedical Research recommends that personnel be aware of the following potential occurrences during a rapid decompression and be knowledgeable on how to recover the unit. During the laboratory rapid decompression, the 106EL experienced the following: (1) internal "altimeter failure, rate" which renders the carbon dioxide and breath rate sensors inoperative, and (2), cuff "overpressure condition, cycle power" which renders the cuff inoperative. However, neither of these conditions present a safety hazard, and both are correctable when the aircraft returns to cruising altitude or ground. To recover the carbon dioxide and breath rate sensors, simply disconnect and reconnect the sensors from the 106EL. In a cuff overpressure condition, the unit will continue to operate; however, to recover the cuff channel, simply cycle the power by turning the unit off and then on.

d. Aeromedical Research evaluated the non-invasive blood pressure (NIBP) option on the 106EL. Protocol's NIBP algorithm utilizes a relationship between the blood pressure and the electrocardiogram when determining NIBP, particularly to avoid accepting environmental artifact as pulses. Without this synchronization between our simulators during testing, the NIBP values were within 10% of the simulator, an accuracy recommended by ECRI as it is comparable to those "obtained by an experienced nurse using a stethoscope and an occluding cuff." However, through several portions of testing, the 106EL was intermittently unable to determine blood pressure. The 106EL would flash errors such as "measurement time out" or "no valid blood pressure found." Protocol's NIBP algorithm experts and Aeromedical Research engineers have determined these errors were a result of using non-
synchronized simulators. However, without using synchronized simulators it is difficult to verify the Propaq's ability to consistently take a NIBP.

e. The 106EL temperature option exhibited susceptibility during electromagnetic interference testing. ASC/ENAI experts determined that these susceptibility events would be brief (seconds), but that the temperature readings "should not be relied on in critical situations." Aeromedical Research discussed this issue with HQ AMC/SGXR who concluded this situation was not critical as the crew would have alternate methods of temperature determination. As a result, Aeromedical Research recommends that the user be aware of the potential for temporarily, inaccurate temperature readings.

f. Aeromedical Research recommends that the 106EL be mounted such that a crew member is consistently monitoring the display from a front view as the audible alarms are difficult to hear in the noisy aircraft environment and the alarm indications are difficult to view from the side of the unit. The securing capabilities with the 106EL are adequate, utilizing litter equipment brackets with litter straps or the Waters bracket. However, patient connectors and the display limit positioning of the cargo straps and may result in the user needing a more adequate mounting system for the 106EL.

g. The 106EL has many additional features/options to include: HP connectors, multiple power adapters, and defibrillator synchronization. The 106EL is certified for use with the UPA/Style B 503-0054-00 Power Adapter and the Abbott Critical Care invasive pressure sensor, the Transpac IV Single Pressure Kit, part # 4285-05. It is not certified for use with defibrillator synchronization, other power adapters, or HP connectors.

h. After initial electromagnetic interference evaluations, ASC/ENAI, Wright Patterson AFB, approved the 106EL for use on large-bodied USAF aircraft only and recommended that the 106EL be individually evaluated for each small aircraft platform. Aeromedical Research and ASC/ENAI did evaluate and certify the 106EL for use inflight on the C-21. The 106EL will require additional evaluations to fly on other small aircraft. ASC/ENAI recommends that "the Propaq not be operated during takeoff and landing when used on smaller air vehicles."
REFERENCES

1. MIL-STD-461D, Electromagnetic Emission and Susceptibility Requirements for the Control of Electromagnetic Interference, Category A1e.


7. AFI 41-201, Equipment Management in Hospitals.

8. AFI 41-203, Electrical Shock Hazards.


## APPENDIX

**SPECIFICATIONS OF THE PROTOCOL SYSTEMS PROPAQ 106EL PHYSIOLOGIC PATIENT MONITOR**

### ECG SPECIFICATIONS

<table>
<thead>
<tr>
<th>Specification</th>
<th>Details</th>
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<tbody>
<tr>
<td><strong>CONNECTOR</strong></td>
<td>AAMI 6 pin or Hewlett-Packard compatible 12-pin style connector (optional).</td>
</tr>
<tr>
<td><strong>SELECTABLE LEADS</strong></td>
<td>I, II, III</td>
</tr>
<tr>
<td><strong>LEAD FAULT INDICATOR</strong></td>
<td>LA, LL, RA, MULTIPLE</td>
</tr>
<tr>
<td><strong>ECG SIZE IN mV/cm</strong></td>
<td>4, 2, 1, 1.5, 2</td>
</tr>
<tr>
<td><strong>DISPLAY SWEEP SPEEDS</strong></td>
<td>12.5, 25, and 50 mm/sec</td>
</tr>
<tr>
<td><strong>QRS TONE VOLUME</strong></td>
<td>High, Low, Medium, Off</td>
</tr>
<tr>
<td><strong>QRS TONE FREQUENCY</strong></td>
<td>2625Hz; variable pitch with SpO2 option and SpO2 being monitored</td>
</tr>
<tr>
<td><strong>FREEZE BUFFER</strong></td>
<td>4.25 secs at 25 mm/sec</td>
</tr>
<tr>
<td><strong>BANDWIDTH</strong></td>
<td>.5 to 40 Hz</td>
</tr>
<tr>
<td><strong>INPUT PROTECTION</strong></td>
<td>Electro surgery and defibrillator protected. All models also include electro surgery interference suppression</td>
</tr>
<tr>
<td><strong>LEAD FAIL SENSE CURRENT</strong></td>
<td>25nA dc for active leads</td>
</tr>
<tr>
<td><strong>TALL T-WAVE REJECTION</strong></td>
<td>50nA dc for driven leads</td>
</tr>
<tr>
<td><strong>COMMON MODE REJECTION</strong></td>
<td>Meets and exceeds AAMI (USA) EC-1983, section 3.1.2.1, part 3, for 1.2 mV T-wave and 1mV QRS using AAMI test waveform</td>
</tr>
<tr>
<td><strong>&lt;1mV p-p RTI for 10Vrms, 50/60Hz input, input unbalanced, FILTER function OFF</strong></td>
<td></td>
</tr>
<tr>
<td><strong>INPUT IMPEDANCE</strong></td>
<td>&lt;.1mV p-p RTI for 10Vrms, 50/60Hz input, input unbalanced, FILTER function ON</td>
</tr>
<tr>
<td><strong>INPUT RANGE (ac)</strong></td>
<td>&gt;2.5 MΩ differential at 60Hz</td>
</tr>
<tr>
<td><strong>INPUT RANGE (dc)</strong></td>
<td>+/- 5mV</td>
</tr>
<tr>
<td><strong>QRS DETECTOR</strong></td>
<td>up to +/- 300mV</td>
</tr>
<tr>
<td><strong>HEART RATE COUNTER RANGE</strong></td>
<td>Width range: 25-120 ms amplitude</td>
</tr>
<tr>
<td><strong>HEART RATE METER RESPONSE TIME</strong></td>
<td>Range: .3 to 5mV (RTI)</td>
</tr>
<tr>
<td><strong>HEART RATE ACCURACY</strong></td>
<td>25-250 bpm</td>
</tr>
<tr>
<td><strong>HEART RATE AVERAGING METHOD</strong></td>
<td>Responds to change in heart rate within 5-9 seconds depending on physiological waveform. (Including AAMI 3.1.2.1 parts 6 and 7 waveforms.) Includes 1 second readout update interval.</td>
</tr>
<tr>
<td><strong>DRIFT TOLERANCE</strong></td>
<td>+/- 3 bpm or 3%, whichever is greater</td>
</tr>
<tr>
<td><strong>PACER DISPLAY</strong></td>
<td>see User's Guide</td>
</tr>
<tr>
<td><strong>PACER PULSE REJECTION</strong></td>
<td>80 bpm indicated for 80 bpm ECG plus drift waveform</td>
</tr>
<tr>
<td><strong>RESPONSES TO IRREGULAR RHYTHM</strong></td>
<td>Pacer indicator shown on screen if PACER function turned on; pacer spike always shown if of sufficient amplitude. see User's Guide</td>
</tr>
<tr>
<td>Ventricular Bigeminy (VB)</td>
<td>77-82 bpm</td>
</tr>
<tr>
<td>Slowing Alternating VB</td>
<td>63-81 bpm</td>
</tr>
<tr>
<td>Rapid Alternating VB</td>
<td>115-123 bpm</td>
</tr>
<tr>
<td>Bidirectional Systole</td>
<td>87-93 bpm</td>
</tr>
</tbody>
</table>
## INVASIVE PRESSURE SPECIFICATIONS

<table>
<thead>
<tr>
<th>Specification</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>TRANSDUCER TYPE</td>
<td>Strain-gauge resistive bridge</td>
</tr>
<tr>
<td>TRANSDUCER EXCITATION IMPEDANCE</td>
<td>200 - 2000 Ω</td>
</tr>
<tr>
<td>RANGE</td>
<td>5 micro V/V/mmHg</td>
</tr>
<tr>
<td>TRANSDUCER SENSITIVITY</td>
<td>5 V pulsed dc @ 181 Hz</td>
</tr>
<tr>
<td>EXCITATION VOLTAGE</td>
<td>ITT-Cannon plug MS3106F-14S-6P Std.</td>
</tr>
<tr>
<td>CONNECTOR</td>
<td>Hewlett-Packard compatible 12 inch connector</td>
</tr>
<tr>
<td>BANDWIDTH</td>
<td>digital filtered, dc to 25 Hz</td>
</tr>
<tr>
<td>ZERO DRIFT</td>
<td>+/- 1mmHg without transducer drift</td>
</tr>
<tr>
<td>ZERO ADJUSTMENT</td>
<td>+/- 200 mmHg including transducer offset</td>
</tr>
<tr>
<td>NUMERIC ACCURACY</td>
<td>+/- 2mmHg or 2% of reading, whichever is</td>
</tr>
<tr>
<td>PRESSURE RANGE</td>
<td>greater, plus the transducer error</td>
</tr>
<tr>
<td>PULSE RANGE</td>
<td>-30 to 300 mmHg</td>
</tr>
<tr>
<td>LEAKAGE CURRENT</td>
<td>25-250 bpm</td>
</tr>
<tr>
<td>ELECTROSURGERY SUPPRESSION</td>
<td>Meets ANSI/AAMI risk requirements</td>
</tr>
<tr>
<td></td>
<td>Included in all EL display monitors</td>
</tr>
</tbody>
</table>

## CUFF SPECIFICATIONS

<table>
<thead>
<tr>
<th>Specification</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>METHOD</td>
<td>Oscillometric</td>
</tr>
<tr>
<td>CONTROL</td>
<td>Automatic and manual measurement control</td>
</tr>
<tr>
<td>AUTO INTERVALS</td>
<td>1, 2, 3, 5, 10, 15, 30, and 60 minutes</td>
</tr>
<tr>
<td>TURBOCUFF</td>
<td>Maximum measurements allowable in a 5 minute</td>
</tr>
<tr>
<td></td>
<td>period</td>
</tr>
<tr>
<td>DISPLAYED PRESSURES</td>
<td>Systolic, Diastolic, and Mean plus on-screen</td>
</tr>
<tr>
<td>CUFF SIZES:</td>
<td>monitor</td>
</tr>
<tr>
<td>Adult</td>
<td>25-35 cm</td>
</tr>
<tr>
<td>Large Adult</td>
<td>33-47 cm</td>
</tr>
<tr>
<td>Thigh</td>
<td>46-66 cm</td>
</tr>
<tr>
<td>Child</td>
<td>18-26 cm</td>
</tr>
<tr>
<td>LIMB CIRCUMFERENCE</td>
<td>18-66 cm</td>
</tr>
<tr>
<td>HOSE CONNECTION</td>
<td>Quick connect</td>
</tr>
<tr>
<td>SYSTOLIC RANGE</td>
<td>30-250 mmHg</td>
</tr>
<tr>
<td>DIASTOLIC RANGE</td>
<td>20-230 mmHg</td>
</tr>
<tr>
<td>MEAN RANGE</td>
<td>25-240 mmHg</td>
</tr>
<tr>
<td>NUMERIC ACCURACY</td>
<td>+/- 3 mmHg or 2%, whichever is greater</td>
</tr>
<tr>
<td>MINIMUM INFLATION PRESSURE</td>
<td>100 mmHg</td>
</tr>
<tr>
<td>DEFAULT INFLATION PRESSURE</td>
<td>Adult - 140 mmHg, Child - 120 mmHg</td>
</tr>
<tr>
<td>CUFF OVERPRESSURE</td>
<td>260 mmHg</td>
</tr>
<tr>
<td>CUFF OVERPRESSURE BACKUP</td>
<td>280-330 mmHg</td>
</tr>
<tr>
<td>PLUMBING LEAK RATE</td>
<td>&lt; 8 mmHg/min measured at 250 mmHg after 30</td>
</tr>
<tr>
<td></td>
<td>seconds for pressure stabilization</td>
</tr>
<tr>
<td>PULSE RATE RANGE</td>
<td>25-160 bpm (without ECG)</td>
</tr>
<tr>
<td>PULSE RATE ACCURACY</td>
<td>25-200 bpm (with ECG)</td>
</tr>
<tr>
<td>MAXIMUM DETERMINATION TIME</td>
<td>6 bpm or 6%, whichever is greater</td>
</tr>
<tr>
<td>TYPICAL DETERMINATION TIME</td>
<td>3 minutes</td>
</tr>
<tr>
<td>TYPICAL DETERMINATION TIME WITH</td>
<td>15-40 seconds</td>
</tr>
<tr>
<td>ARTIFACT</td>
<td>up to 70 seconds</td>
</tr>
<tr>
<td>MINIMUM TIME BETWEEN MEASUREMENTS</td>
<td>25 seconds</td>
</tr>
<tr>
<td>ELECTROSURGERY SUPPRESSION</td>
<td>Included in all EL display monitors</td>
</tr>
</tbody>
</table>
PULSE OXIMETRY

RANGE
PROBE ACCURACY
(specified at 28-42°C)
PULSE RATE RANGE
PULSE RATE ACCURACY
SENSOR COMPATIBILITY
ELECTROSURGERY SUPPRESSION

0-100%
70-100% +/- 2 digits, 0-70% unspecified
20-250 bpm
+/- 3 bpm
Compatible only with NELLCOR sensors listed in
Chapter 2 of the User's Guide
Included in all units, whether EL or LCD

CO2 OPTION

CO2 SENSOR
Sensor type
Principle of operation
Warm-up time
Response time
Calibration

Mainstream
NDIR single-beam, singlepath/wavelength,
ratiometric
20 sec typical, 3 min maximum
30 ms typical, 60 ms maximum
Verify semi-annually, calibrate only as required

CO2 SENSOR AND CABLE DIMENSIONS AND WEIGHT
Sensor Height
Sensor Width
Sensor Depth
Sensor Weight
Sensor Volume
Cable Length
1.003 in
1.036 in
.78 in
< .39 oz
.81 cubic inches
10 ft nominal

CO2 AIRWAY ADAPTER
Type
Size
Material
Deadspace

Per ISO 3040, single-use
15 mm ID (meets ISO specifications)
clear polycarbonate, with sapphire windows
< 5 cc

CO2 DISPLAY
Screen display
Measurement ranges

CO2 waveform and ETCO2 and INCO2 numerics
ETCO2: 0-99 mmHg, 0-13 kPa, 0-23%
INCO2: 0-25 mmHg, 0-5 kPa, 0-5%
ETCO2 and INCO2 same as measurement range
mmHg, kPa, %; user-selectable
3:13, 6:25, 12.5 mm/sec; user-selectable
FAST: 15 sec sampling time period
NORMAL: 30 sec sampling time period
SLOW: 45 sec sampling period
see User's Guide

Gas compensation
Alarm limit ranges

Resolution
Accuracy

1 mmHg
+/-.3 mmHg (0-30 mmHg CO2)
+/-.10% of reading (31-99 mmHg CO2)
130 ms maximum
+/-.4%/1000 ft

Waveform rise time
Altitude error

BREATH RATE DISPLAY
Screen display
Units
Range
Resolution
Accuracy
numeric
bpm
1-99 bpm
+/-.1 bpm
+/-.1 bpm or 5%, whichever is greater
APNEA ALARMS AND TICKETS
Apnea ticket set to auto print after apnea event and after 1
Apnea alarm accuracy minute continued apnea
Resolution +/- 1 sec
Alarm limits range, adult and pediatric 5 sec
BAROMETRIC PRESSURE
Pressure compensation 15-30 sec delay, 5 sec increments
Operating range automatic
Screen display -2000 ft to 15,000 ft
Units numeric (CO2 status window)
Accuracy mmHg +/- 2.5% of reading (calibrated at sea level)
IN-SERVICE VALUES
ETCO2 initial value: 38, alternate value: 60
INCO2 initial value: 0, alternate value: 8
Breath rate initial value: 12, alternate value: 31

CO2 SENSOR ENVIRONMENTAL SPECIFICATIONS
Sensor housing temperature 42°C nominal
Operating ambient temperature 10°C to 40°C
Storage temperature 0-50°C
Operating altitude -2000 ft to 15000 ft
Storage altitude 30000 ft
Storage humidity 0 to 95%, noncondensing
Shock 100 g for 4 msec
Vibration 5-35 Hz, .015 in p-p
Drop 35-100 Hz, 1 g acceleration
36 inches free fall to floor (tile over concrete, one
drop each face, one drop each edge/corner)

TEMPERATURE
RANGE 17°C to 50°C; 62.6°F to 122°F
DISPLAYS T1
PROBES Compatible with YSI Series 400 and 700 and
Electromedics Series 2100 probes. HP side
panel only compatible with YSI 400 and has HP
connector
UNITS °C or °F, user selectable
ACCURACY +/- .1°C (+/- .2°F) plus probe tolerance
RESOLUTION .1°C or °F
ELECTROSURGERY SUPPRESSION Included in all EL display monitors

ALARMS
INDICATORS ALARM light, ALARM(S) OFF light, Audible tone
Lights continually flash .5 secs on and .5 secs off
if an alarm is suspected
Flashing Numerics. Numeric in violation
alters between normal and reverse video
with 1 second duration each.
TONE FREQUENCY 2625 Hz
Tone is steady for a patient alarm and sounds for
1 second every 4 seconds for an equipment
alert
SELECTABLE TONE VOLUME
LIMITS low, medium, high
CONTROL settable on all parameters
ALARM ON TACHYCARDIAS Automatic preset or manual settings
Most tachycardias will alarm in less than 8
seconds. These include AAMI 3.1.2.1 part 7 waveforms. Certain multifocal tachycardias may initially alarm as "low rate."

15-30 secs delay, 5 sec increments

MODEL 106 PARAMETERS

CUFF, P1, P2, T1, HR (hear rate/pulse rate),
SpO2, End-tidal CO2, Inspired CO2, Breath
Rate

5 hours displayed, 8 hours printed
2 minutes

graphic and tabular

selectable depending on parameter

DISPLAY

GENERAL
Matrix
Active viewing area
Pixel pitch
Character pitch

276X128 pixels
146.2 mmX67.8 mm
.53 mmX.53 mm
Large: 8.2 mm (.3in)
Small: 3.8 mm (.15in)

ELECTROLUMINESCENT DISPLAY
Viewing angle
Contrast ratio
Display window
Display color
Display background color

> 160° Horizontal and vertical
> 100:1 with contrast enhancement filter
contrast enhancement filter
amber
black

MONITOR (Environmental)

OPERATING TEMPERATURE
0° to 50°C

SHIPPING AND STORAGE TEMPERATURE
-20° to 60°C

OPERATING ALTITUDE
-2000 to 15000 ft

SHIPPING AND STORAGE ALTITUDE
-2000 to 40000 ft

OPERATING RELATIVE HUMIDITY
0-97%, noncondensing

SHIPPING AND STORAGE RELATIVE
HUMIDITY
0-97%, noncondensing

50 g

SHOCK

VIBRATION
Random vibration, .02 g^2/Hz from 10 to 300 Hz,
ramping down to .002 g^2/Hz at 500 Hz.
Operating 1 hour per axis, 3 hours per test.
per FDA Standard MDS-201-0004 (emissions
only)

ELECTROMAGNETIC INTERFERENCE

WATER RESISTANCE

IPX1 Drip-proof per IEC Publication 529

MONITOR (Physical)

PROTECTION CLASSIFICATIONS
Type of protection against electric shock

- monitor powered by power adapter
- monitor powered by internal batteries
- monitor powered by external low-voltage
DC source
Degree of protection against electric shock

- Class I (protectively earthed)
- Internally powered equipment
- Class II Equipment
- Type CF equipment, Defibrillator-proof

19
Degree of protection against harmful ingress of water
Method of disinfection
Flammable anesthetics
- IPX1, protected against vertically dripping water
- not suitable for autoclaving
- not suitable for use with flammable anesthetics

MONITOR ONLY
Height 6.6 in
Width 8.3 in
Depth 4.8 in
Weight 5.8 lb

MONITOR WITH EXPANSION MODULE
Height 9.8 in
Width 8.3 in
Depth 7.3 in
Weight 10.4 lb

PRINTER

OPERATION
Operating modes
Auto Print Intervals
Auto trend shifts
Number of waveforms
Grid
Annotation
Continuous, Snapshot, Freeze Print, Auto Interval Print, Auto Interval Trend, Tabular Trend, Alarm Print, Cuff Ticket, Apnea Ticket
15 min, 30 min, 1 hour, 2 hours, 4 hours
once every 8 hours
up to three: ECG, SpO2, P1, P2, CO2
5 mm and 1 mm gradations
Date, Time, Print mode, Speed, Heart rate, Systolic, Diastolic, Mean, SpO2, Breath rate, ETCO2, INCO2, Temperature, Pacer status
6.25, 12.5, 25.0 mm/sec, simulated 6.25

Printing Speeds
PRINTER MECHANISM
Printing method
Dot structure
Printing width
Horizontal dot pitch
Vertical dot pitch
Paper feed method
Paper feed precision
Paper width
Reliability
thermally sensitive dot method
53 mm
.165 mm, 6 dots/mm
.165 mm
friction feed
+/-.2% @ 25°C and 60% relative humidity
60 mm
30 million pulses/dot

ENVIRONMENTAL
Operating temperature
Shipping and storage temperature
Operating relative humidity
Shipping, storage relative humidity
Shipping and operating altitude
Storage altitude
Shock
Vibration
5°C to 40°C
-20°C to 60°C
35% to 85% noncondensing
5% to 90% noncondensing
-2000 to 15000 ft
-2000 to 40000 ft
30 g
Random vibration, .02 g²/Hz from 10 to 300 Hz, ramping down to .002 g²/Hz at 500 Hz. Operating 1 hour per axis, 3 hours per test, per standard MDS-201-0004 (emissions only)

EMI
PAPER
Short-term storage environment (up to 7 days)
Long-term storage environment (up to 5 years)
-20°C to 40°C, 5% to 80% RH noncondensing
25°C (optimal), 65% RH noncondensing
POWER

MODE OF OPERATION
Continuous

BATTERY PACK TYPE
Sealed lead acid

BATTERY PACK CAPACITY
Monitor only - 8 volts, 3 amp-hours
Monitor with expansion modules - 8 volts, 6 amp-hours

BATTERY RECHARGER CIRCUITRY
Internal, powered by external power adapter

DC INPUT POWER REQUIRED
12-28 Volts, 10.5 Watts, w/CO2: 25 Watts

INPUT FUSE RATING
3 A/250 V, Slow-blow, Type 2 AG (.57X.177 in)

OPERATING TIMES ON BATTERY
Range of 4 to 8 hours depending on product configuration

BATTERY RECHARGE TIME WITH 106EL ON
Range of 8 to 12 hours typical, depending on product configuration

BATTERY RECHARGE TIME WITH 106EL OFF
Range of 6 to 8 hours depending on product configuration

POWER ADAPTERS

UNIVERSAL POWER ADAPTER, PART NO.
503-0054-00

Length 5.0 in
Width 3.6 in
Height 3.1 in
Weight 3.1 lb
Rated input 100-120VAC, 500 mA, 50/60 Hz
Rated fuses T800 mA/250V, Time-delay, 5X20 mm
Rated output (continuous) 16-24 VDC, 25 watts
Connector Style B
Additional Features Detachable power cord, pilot light, mains switch