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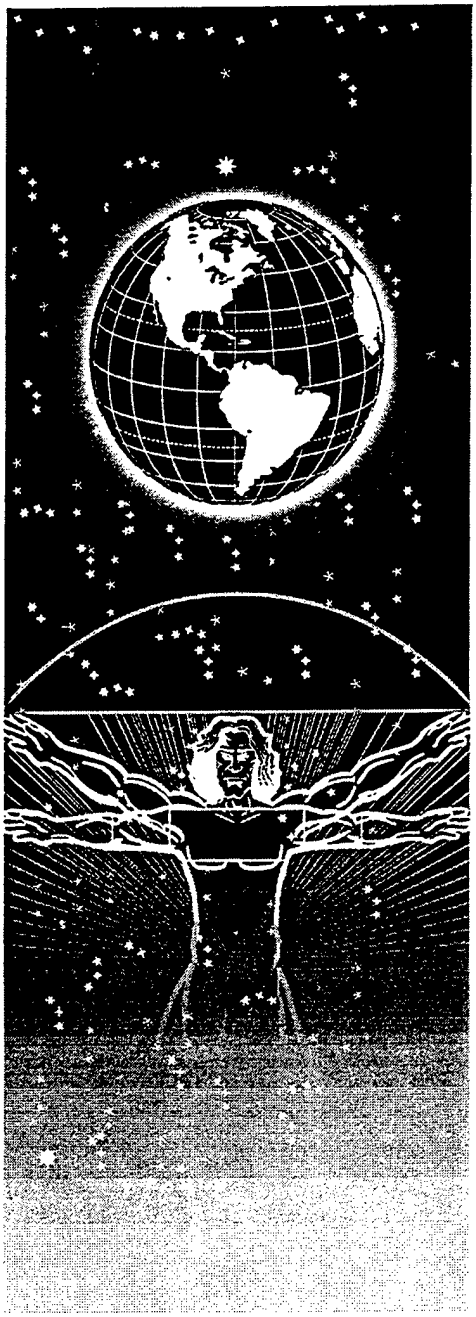

UNITED STATES AIR FORCE RESEARCH LABORATORY

TESTING AND EVALUATION OF THE PROTOCOL SYSTEMS, INC., PROPAQ 206 EL ENCORE VITAL SIGNS PATIENT MONITOR

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July 1998

NOTICES

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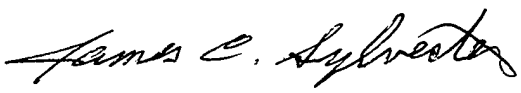

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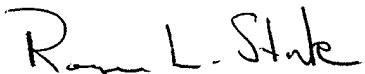

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The Protocol Systems Inc., 206 EL Monitor is a portable, self-contained, general purpose monitor capable of continuous reception and display of multiple patient physiological parameters. The unit operates on 115 VAC/60-400 Hz,external 12 VDC, and an internal battery pack. The unit weighs approximately 12.68 lbs and its dimensions with the expansion module are 9.65 in.H X 8.25 in. W X 7.56 in. D. It has a separate UPA/Style B 503-0054-00 power adapter as an available attachment.

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Mr. Douglas Townsend

TESTING AND EVALUATION OF THE PROTOCOL SYSTEMS, INC. PROPAQ 206 EL ENCORE VITAL SIGNS PATIENT MONITOR

BACKGROUND

Representatives of Protocol Systems, Inc. requested an Aeromedical Research evaluation of their Propaq 206 EL Encore vital signs monitor for use on board USAF aeromedical evacuation aircraft.

DESCRIPTION

The unit tested was the Protocol Propaq Encore model 206 EL, SN: DA006428 with expansion module SN: DC003733. The Propaq Encore expansion module attaches to the monitor and houses additional capabilities. This expansion module was fitted with Printer, Pulse Oximetry (SpO_2), and Capnography (CO_2) options. The unit tested will hereby be referred to as the 206 EL, or Encore (figure 1). This unit is a light-weight portable patient monitor capable of monitoring: ECG (1 channel: 3-lead*); NIBP, noninvasive blood pressure, (1 channel: cuff); IBP, invasive blood pressure, (2 channels); temperature (2 channels: YSI-400 and 700 series-compatible connectors); pulse oximetry (1 channel: SpO_2); CO_2 (1 channel); and respiratory rate. This unit has a printer and Hewlett Packard Connector-Compatible Side Panel. The display in the 206 EL is Electroluminescent (EL). With printer/SpO_2/CO_2, the dimensions of the unit are as follows: height, 9.65 in. (24.5 cm); width, 8.25 in (20.9 cm); depth, 7.56 in (19.2 cm); weight, 12.68 lb (5.8 Kg). The 206 EL has an internal, 8 V/6 amp-hr, sealed gel-type lead-acid battery. Battery life is rated at 3.5-4.5 hours depending on product configuration with a recharge time of 8-12 hours with the instrument on, or 6 to 8 hours with the instrument off. The unit has an adapter, which converts 100-120 VAC/60Hz to 16-24 VDC/25 VA: part number 503-0054-00. The unit can also be powered by an external 12-28 VDC source.

*Note: This device also offers the option of a 5 lead ECG monitoring system. This 5 lead option was not evaluated as part of airworthiness testing.

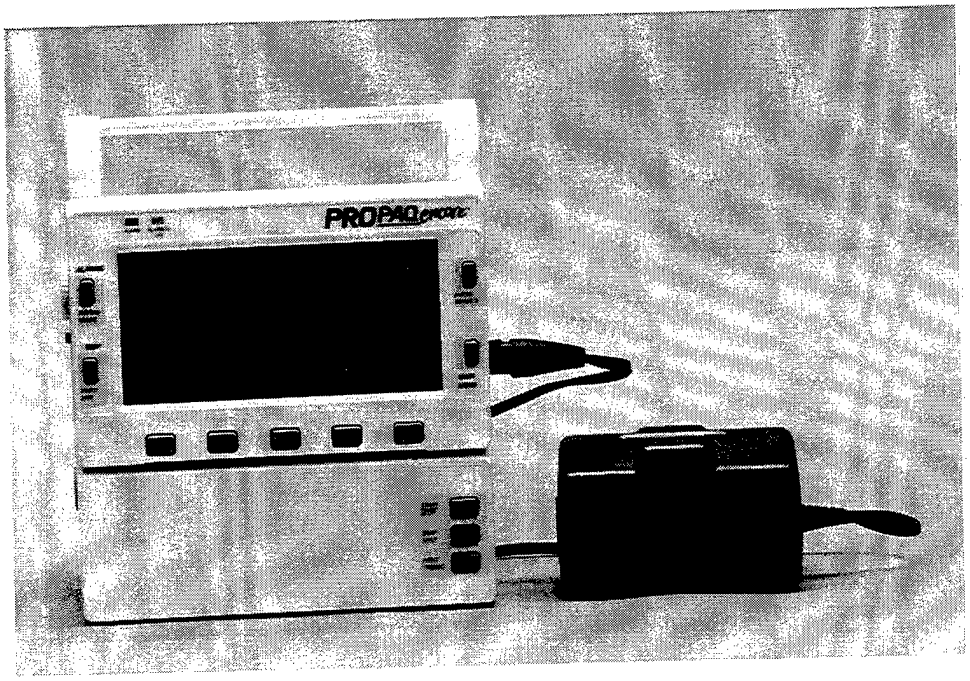

Figure 1. The Protocol Systems, Inc., Propaq 206 EL Encore.

PROCEDURES

Test methods and performance criteria were derived from various military standards (Reference List 1-4), nationally recognized performance guidelines (5), and manufacturer's literature (6). The Aeromedical Research Procedures Guide describes additional safety and human interface issues to be considered during equipment testing (7). A test setup and performance check were developed specific to this product to verify proper functioning of the equipment when subjected to various tests representing the airborne environment and stresses of flight.

The device was subjected to the following laboratory and inflight tests to observe and evaluate its performance under anticipated operational conditions.

1. Initial Inspection

2. Vibration

3. Electromagnetic Compatibility (EMC)

4. Thermal/ Humidity Environmental Conditions, encompassing:

   a. Hot Operation

   b. Cold Operation

   c. Humidity

   d. Hot Temperature Storage

   e. Cold Temperature Storage

5. Hypobaric Conditions

   a. Cabin Pressure/Altitude

   b. Rapid Decompression to Ambient pressure

6. Airborne Feasibility

INITIAL INSPECTION AND TEST PREPARATION

a. The Propaq 206 EL Encore was inspected for quality of workmanship, production techniques and possible damage that might have occurred during shipment.

b. The Propaq 206 EL Encore was checked to ensure it met safety requirements and operating characteristics established in National Fire Protection Agency (NFPA) 99, Standards for Health Care Facilities (7), Electrical Shock Hazards, AFI 41-203 (8), and Equipment Management in Hospitals, AFI 41-201 (9). Ground resistance and leakage current measurements were made at 115 VAC/60 Hz.

c. The Propaq 206 EL Encore was examined to verify it met basic requirements for acceptable human factors design as outlined in MIL-STD 1472 (3).

d. A test setup and performance check were developed to evaluate the Propaq 206 EL Encore's operation in accordance with manufacturer/customer specifications throughout the various testing conditions.

TEST SETUP

a. Connect the three ECG leads from the Encore to the corresponding (color coded) receptacles on the Lionheart.

b. Plug the YSI temperature cable (1/4 inch phone jack side) into the Encore's "T1" port. Plug the opposite end of the cable (tri-axil side) into the Lionhearts' 700 series temperature output connector.

c. Configure the Lionheart with the following settings:

- Temperature: 30°C
- Lead Select: III
- ECG Amplitude: 1.0 mV

d. Secure the non-invasive tubing line to the NIBP port on the Encore. Using a T connector, attach the Cufflink inline between the BP cuff and the non-invasive tubing attached to the NIBP port. Wrap the BP cuff tightly around the appropriate adult cuff mandrel. For an adult cuff, use two end and two spacer blocks. After zeroing the transducer, the Cufflink is configured to: ADAMS Adult-120/80 (90).

e. Plug the SpO_2 cable into its corresponding port on the Encore (9 pin connector) and the other end into the Nellcor Pulse Oximeter Simulator. Set the Nellcor Pulse Oximeter Simulator to 98% SpO_2 and a pulse rate of 60 bpm.

f. Plug the CO_2 sensor cord into its corresponding port on the Encore. Attach the sensor to the CO_2 line. Secure it to one end of a section of corrugated ventilator tubing. At the other end, place a moisture trap filter.

g. To limit paper usage during evaluation, loop a four inch piece of printer paper through the printer and secure the ends with tape.

The Encore will continually monitor temperature, SpO_2, and CO_2. The NIBP operation can be initiated manually or programmed at set intervals.

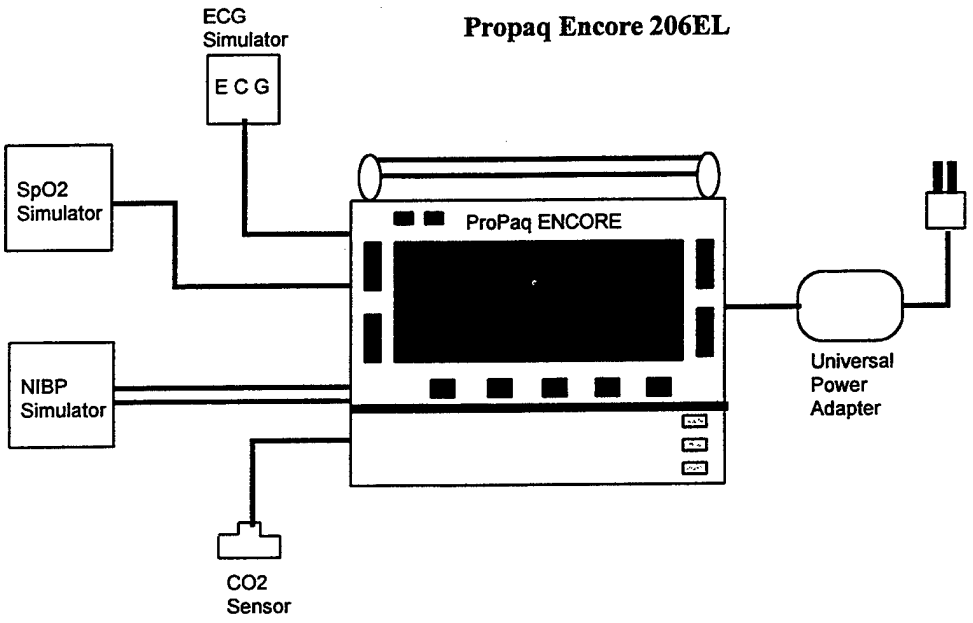

Figure 2. Test Setup

PERFORMANCE CHECK

The Performance Check, as outlined in the approved test plan, was used to validate the function of the 206 EL 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 206 EL was continuously monitored through the duration of the test. Performance checks occurred at defined intervals throughout the test.

VIBRATION

Vibration testing is critical to determine "the resistance of equipment to vibrational stresses expected in its shipment and application environments" (2). Vibration testing was conducted at Aeromedical Research's vibration facility. This testing involved a set of operational tests performed along each of the Encore's three axes - X, Y, and Z; the Encore's components were mounted on the NATO litter segment on the vibration table as they would be in the aircraft (Figure 3). They were subjected to vibration curves with levels and lengths derived from MIL-STD-810E, Category 10, Figures 514.4-16 and 514.4-17 (Figure 4).

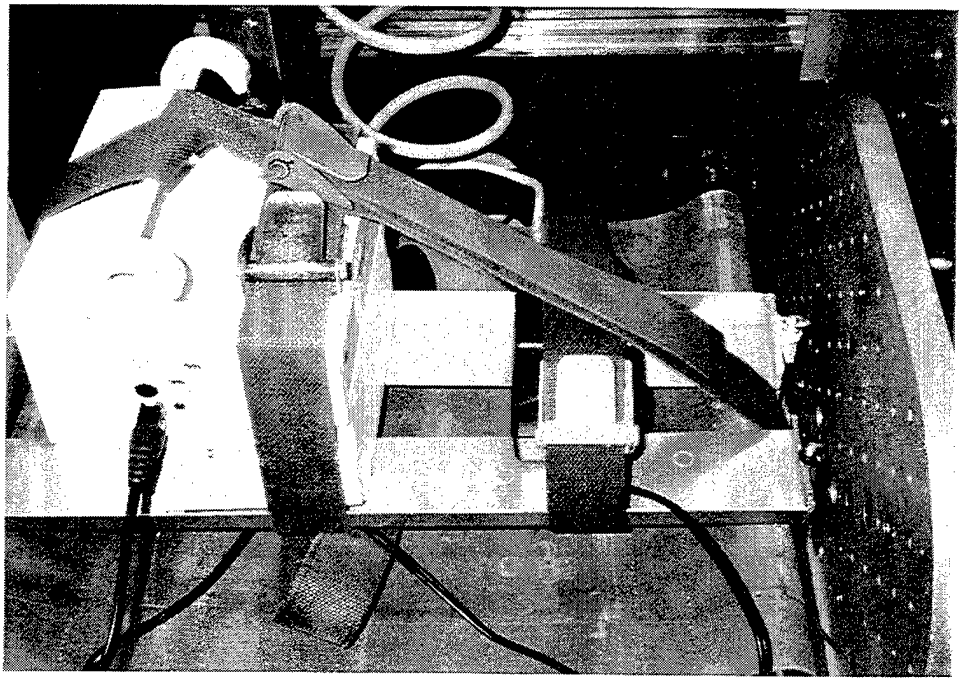

Figure 3. Vibration Table Mounting

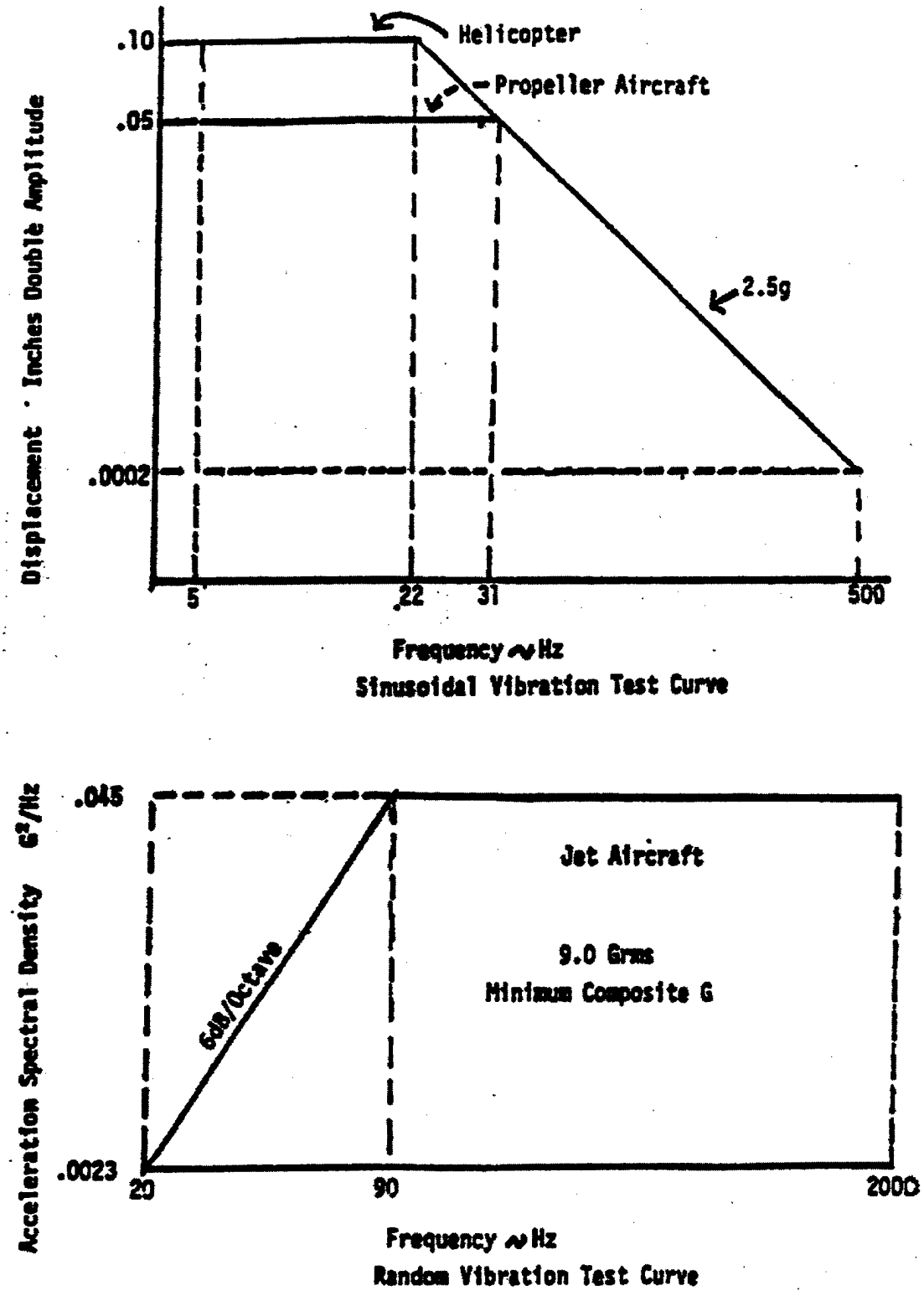

Figure 4. MIL-STD-810E, Category 10, figures 514.4-16 and 514.4-17

ELECTROMAGNETIC COMPATIBILITY

Electromagnetic compatibility testing is a primary concern on USAF aeromedical evacuation aircraft. Ensuring the safety of everyone on board is the driving factor to assessing the effects of excessive electromagnetic emissions and their influence on aircraft navigation and communication equipment. Medical devices may also be susceptible to fields generated by the aircraft equipment or other medical devices and malfunction in their presence.

The Encore was evaluated for compliance with MIL-STD-461D (1) and 462D (2). ASC/ENAI, Wright-Patterson AFB performed all of the EMI evaluation in their electromagnetic compatibility facility 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 narrower range of frequencies from 2 MHz - 1 GHz. This test measured the amount of EMI emitted by the equipment during its operation. It was performed to verify that the device does 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 entire band of 10 kHz - 10 MHz. This test which measured emissions generated by the medical device along its power supply lines, was performed to verify that operating the device using line power does 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 narrower frequency range from 30 MHz - 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). 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.

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 would "withstand ripple voltages associated with allowable distortion of power source voltage wave forms."

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 a narrower portion of the frequency band, from 10 kHz to 200 MHz. This test determined whether "simulated currents that will be developed on platform cabling from electromagnetic fields generated by antenna transmission would affect the equipment under test."

f. Conducted Susceptibility (CS-115), "Conducted Susceptibility, Bulk Cable Injection, Impulse Excitation": This test was performed to verify that the Encore 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."

g. Conducted Susceptibility (CS-116), "Conducted Susceptibility, Damped Sinusoidal Transients, Cables and Power leads, 10 kHz to 100 MHz," respectively. The "basic concept of this test is to simulate electrical current and voltage waveforms occurring in platforms from excitation of natural resonances."

During emissions testing, all options were operating 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 206 EL was in turbo-cuff mode, such that the NIBP option was continuously activated. For susceptibility testing, the unit was operated as described earlier in the equipment set-up and performance check sections. For both emissions and susceptibility testing, the 206 EL was tested for operation on 115 VAC/60 Hz, and internal batteries.

THERMAL/HUMIDITY ENVIRONMENTAL CONDITIONS

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" (3). 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's, Thermotron Industries, Model SM-32C environmental chamber operated and monitored by aeromedical research personnel assigned to the Systems Research Branch (CFTS) of the Crew Technology Division at Armstrong Laboratory, Brooks AFB, TX. The 206 EL 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 206 EL was monitored continuously and a performance check was conducted every fifteen minutes. For storage tests, the 206 EL was placed in the chamber and remained nonoperational throughout the storage portion of the test. Upon completion of this test the chamber and device was brought to standard ambient conditions for 30 minutes. Aeromedical Research personnel then conducted a performance test and monitored the unit for one hour to verify successful operation. 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 hr

b. Hot Temp Operation: 120°F ± 3.6°F (49°C ± 2°C) for 2 hr

c. Cold Temp Operation: 32°F ± 7.2°F (0°C ± 4°C) for 2 hr

d. Hot Temp Storage: 140°F ± 3.6°F (60°C ± 2°C) for 6 hr

e. Cold Temp Storage: -40°F ± 3.6°F (-40°C ± 2°C) for 6 hr

HYPOBARIC CONDITIONS

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 aeromedical 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 206 EL 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 decompressions are 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 verify that it will not endanger a patient, the aircraft personnel, or the aircraft itself. The 206 EL operated inside the rapid decompression test chamber as the chamber was depressurized to an equivalent of 8,000 ft altitude. Then, the chamber altitude was brought to 45,000 ft over a period of 60 seconds, held at 45,000 ft for a few minutes, and then brought back down to ground 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 206 EL 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 Nellcor to the 206 EL were run through putty-sealed access ports in the chamber walls.

AIRBORNE PERFORMANCE

Airborne performance evaluations are a cost-effective and invaluable means of validating equipment clinical and operational performance during actual operating conditions. By carefully evaluating medical equipment items in their actual environment, Aeromedical Research ensures that all pertinent patient care issues are adequately addressed by the test protocols. Safe and reliable operation of this medical device is the primary goal of the inflight evaluation and forms the basis for subsequent recommendations to the users.

This phase of testing was conducted by an aircraft-qualified aeromedical flight nurse and aeromedical research technicians on board both a C-9 and C-130 aeromedical evacuation mission. The 206 EL was secured to the litter and evaluated throughout the flights by Aeromedical Research technicians as well as by the other members of the aeromedical evacuation crew. Human factors characteristics, securing methods, and equipment setup times and locations were also evaluated.

EVALUATION RESULTS

INITIAL INSPECTION

Initial inspection revealed no manufacturing defects. The unit performed to the manufacturer's specification. Electrical safety test results showed that all parameters were within referenced guideline limits.

VIBRATION

The Propaq Encore operated within manufacturer's specifications throughout vibration testing.

ELECTROMAGNETIC COMPATIBILITY

While at the Wright-Patterson AFB EMI testing facilities, the Propaq Encore experienced EMI failures. After initial electromagnetic interference evaluations, ASC/ENAE, Wright Patterson AFB, approved the Propaq Encore model 206 EL for use on large-bodied USAF aircraft only. The Wright-Patterson EMI certification letter stated that the 206 EL would not interfere with communication or navigation systems on large bodied aircraft, and it would be unlikely that the normal aircraft RF transmitting systems would cause interference to the 206 EL with the following exceptions: "heart rate" and "ECG" may be affected and should not be solely relied upon for clinical judgements in critical situations. Protocol Systems, working with Wright-Patterson AFB, WL/AASW, and Aeromedical Research, Brooks AFB developed new circuitry within the 206 EL (Printer and CO2) in order to overcome these EMI difficulties.

WL/AASW tested and ASC/ENAE certified the newly modified 206 EL in June 1997 for operation during all phases of flight on all USAF aircraft.

THERMAL/HUMIDITY ENVIRONMENTAL CONDITIONS

The Propaq Encore model 206 EL operated satisfactorily during all five phases of testing. Testing was conducted in the Armstrong Laboratory's Thermotron Environmental Chamber operated and monitored by Aeromedical Research personnel assigned to the Systems Research Branch (CFTS) of the Crew Technology Division at Armstrong Laboratory, Brooks AFB, TX.

HYPOBARIC CONDITIONS

1. Cabin Pressure/Altitude: The Propaq Encore model 206 EL performed in accordance with manufacturer's specifications throughout testing.

2. Rapid Decompression: The 206 EL operated within manufacturer's specifications following each rapid decompression and did not present a safety hazard throughout the decompression.

AIRBORNE PERFORMANCE

The inflight evaluation of the Propaq Encore model 206 EL was performed on a C-9 aeromedical evacuation mission and C-130 aeromedical readiness mission. The inflight evaluations of the 206 EL were 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 206 EL be mounted such that a crew member is monitoring the display from a front view. The securing capabilities with the 206 EL 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. Analysis of flight data indicated that this unit was easy to enplane and deplane and was compatible with aircraft electrical systems.

SUMMARY

The test and evaluation of Protocol System's Propaq 206 EL, SN: DA006428, and expansion module, SN: DC003733 is complete. Aeromedical Research found this unit, and all 206 ELs with serial numbers higher than EA000225*, acceptable for use during all phases of flight on all USAF aircraft (including small and large body, fixed and rotary wing) while operating on battery, 115 VAC/60 Hz, and 28 VDC in the aeromedical evacuation environment with the following comments and recommendations:

a. Because the carbon dioxide and breath rate sensor ceased operation during the laboratory's hot operation test (120°F), Aeromedical Research recommends restricting operational use in extreme hot environments if the carbon dioxide and breath rate is a critical portion of patient monitoring.

b. Aeromedical Research recommends that the 206 EL be mounted such that a crew member is consistently able to monitor the display from a front view because the audible alarms are difficult to hear in the noisy aircraft environment and the visual alarm indicators are difficult to view from the side of the unit. The securing capabilities with the 206 EL proved adequate, utilizing litter equipment brackets with litter straps or the Waters bracket. However, patient connectors and the display limit positioning of the cargo straps may indicate the need for a more versatile mounting system for the 206 EL.

c. The 206 EL has many additional features/options to include: HP connectors, multiple power adapters, and defibrillator synchronization. The HP connector-compatible option makes the Propaq Encore compatible with many Hewlett-Packard sensors and accessories used with the Hewlett-Packard Component Monitoring System. This option was not tested and therefore not approved for use. As the Defibrillator Synchronization feature is designed to operate only with the Physio-Control LifePak 5 and LifePak 6 defibrillators, it was not tested and likewise not aeromedical airworthiness certified. The Propaq Encore is approved for use only with the UPA/Style B 503-0054-00 Power Adapter.

d. Based on the prior analysis of Protocol Systems comparison of the Propaq 206 EL with the 202 EL and 204 EL, Aeromedical Research has concluded that these physiologic patient monitors (with serial numbers higher than EA000225*) will not require additional testing and can also be considered approved for use on all USAF aircraft.

e. Protocol Systems agreed to place a label on each Propaq Encore stating "Serial No. EA000225 and greater are approved for use during all phases of flight aboard U.S. Air Force aircraft." Label will be antique gold with black lettering. The label will be 3.69" W X 1.25" H X 0.25" Radius.

* NOTE: Units with serial numbers lower than EA000225 were certified for operation during all phases of flight only on cargo (large body) USAF aircraft.

REFERENCES

1. Department of Defense: *Requirements for the Control of Electromagnetic Interference Emissions and Susceptibility.* MIL-STD 461D, Washington DC: January 1993.

2. Department of Defense: *Measurement of EMI Characteristics.* MIL-STD 462D, Washington DC: February 1996

3. Department of Defense: *Environmental Test Methods and Engineering Guidelines.* MIL-STD 810E, Washington DC: 1989

4. Department of Defense: *Human Engineering Design Criteria for Military Systems, Equipment, and Facilities.* MIL-STD-1472D, Washington DC: March 1989

5. *Emergency Care Research Institute* (ECRI)

6. Protocol Systems, Inc., Propaq Encore 206 EL, Operator's Manuals.

7. *Aeromedical Research Procedures Guide,* Internal Operating Instruction, Systems Research Branch, Armstrong Laboratory.

8. National Fire Protection Agency (NFPA) 99, *Health Care Facilities Code*

9. AFI 41-203, *Electrical Shock Hazards*

10. AFI 41-201, *Equipment Management in Hospitals*

APPENDIX

MANUFACTURERS SPECIFICATIONS OF THE PROTOCOL SYSTEMS, INC. PROPAQ ENCORE 206 EL PHYSIOLOGIC PATIENT MONITOR

ECG SPECIFICATIONS

CONNECTOR	AAMI 6 pin or Hewlett-Packard compatible 12-pin style connector (optional).
SELECTABLE LEADS	I, II, III, aVR, aVL, aVF, V
LEAD FAULT INDICATOR	LA, LL, RA, MULTIPLE
ECG SIZE IN mV/cm	4, 2, 1, .5, .2
DISPLAY SWEEP SPEEDS	12.5, 25, and 50 mm/sec
QRS TONE VOLUME	High, Low, Medium, Off
QRS TONE FREQUENCY	900 Hz; variable pitch with SpO_2 option and SpO_2 being monitored
FREEZE BUFFER	3.9 sec at 25 mm/sec
BANDWIDTH	0.5 to 40 Hz
INPUT PROTECTION	Electrosurgery and defibrillator protected. All models also include electrosurgery interference suppression
LEAD FAIL SENSE CURRENT	50 nA dc for active leads 100-200 nA dc for driven leads
TALL T-WAVE REJECTION	Meets and exceeds AAMI (USA) EC-1983, section 3.1.2.1, part 3, for 1.2 mV T-wave and 1 mV QRS using AAMI test waveform
COMMON MODE REJECTION	<1 mV p-p RTI for 10Vrms, 50/60 Hz input, input unbalanced, FILTER function OFF <.1 mV p-p RTI for 10 Vrms, 50/60 Hz input, input unbalanced, FILTER function ON
INPUT IMPEDANCE	>2.5 M differential at 60Hz
INPUT RANGE (ac)	+/- 5 mV
INPUT RANGE (dc)	up to +/-300mV
QRS DETECTOR	Width range: 25-120 ms amplitude Range: .3 to 5mV (RTI)
HEART RATE COUNTER RANGE	25-250 bpm
HEART RATE METER RESPONSE TIME	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-sec readout update interval.
HEART RATE ACCURACY	+/- 3 bpm or 3%, whichever is greater
HEART RATE AVERAGING METHOD	see User's Guide
DRIFT TOLERANCE	80 bpm indicated for 80 bpm ECG plus drift waveform
PACER DISPLAY	Pacer indicator shown on screen if PACER function turned on; pacer spike always shown if of sufficient amplitude.

PACER PULSE REJECTION	see User's Guide
RESPONSES TO IRREGULAR RHYTHM	
Ventricular Bigeminy (VB)	77-82 bpm
Slowing Alternating VB	63-81 bpm
Rapid Alternating VB	115-123 bpm
Bidirectional Systole	87-93 bpm

INVASIVE PRESSURE SPECIFICATIONS

TRANSDUCER TYPE	Strain-gauge resistive bridge
TRANSDUCER EXCITATION IMPEDANCE RANGE	200 - 2000
TRANSDUCER SENSITIVITY	5 micro V/V/mmHg
EXCITATION VOLTAGE	4.85-V pulsed dc @ 181 Hz
CONNECTOR	ITT-Cannon plug MS3106F-14S-6P Std. Hewlett-Packard compatible 12 in. connector
BANDWIDTH	digital filtered, dc to 25 Hz
ZERO DRIFT	+/- 1 mmHg without transducer drift
ZERO ADJUSTMENT	+/- 200 mmHg including transducer offset
NUMERIC ACCURACY	+/- 2mmHg or 2% of reading, whichever is greater, plus the transducer error
PRESSURE RANGE	-30 to 300 mmHg
PULSE RANGE	25-250 bpm
LEAKAGE CURRENT	Meets ANSI/AAMI risk requirements
ELECTROSURGERY SUPPRESSION	Included in all EL display monitors

NIBP SPECIFICATIONS

METHOD	Oscillometric
CONTROL	Automatic and manual measurement control
AUTO INTERVALS	1, 2, 3, 5, 10, 15, 30, and 60 min
TURBOCUFF	Maximum measurements allowable in a 5 min period
DISPLAYED PRESSURES	Systolic, Diastolic, and Mean plus on-screen monitor
SYSTOLIC RANGE	30-260 mmHg
DIASTOLIC RANGE	20-235 mmHg
MEAN RANGE	25-255 mmHg
NUMERIC ACCURACY	+/- 3 mmHg
MINIMUM INFLATION PRESSURE	100 mmHg
DEFAULT INFLATION PRESSURE	Adult - 160 mmHg, Child - 120 mmHg
CUFF OVERPRESSURE	280 mmHg
PULSE RATE RANGE	30-220 bpm (without ECG) 25-200 bpm (with ECG)
MAXIMUM DETERMINATION TIME	3 min
TYPICAL DETERMINATION TIME	30-45 sec
TYPICAL DETERMINATION TIME WITH ARTIFACT	up to 70 sec
MINIMUM TIME BETWEEN MEASUREMENTS	30 sec
ELECTROSURGERY SUPPRESSION	Included in all EL display monitors

PULSE OXIMETRY

RANGE	0-100%
PROBE ACCURACY	
(specified at 28-42°C)	70-100% +/- 2 digits, 0-70% unspecified
PULSE RATE RANGE	20-250 bpm
PULSE RATE ACCURACY	+/- 3 bpm
SENSOR COMPATIBILITY	Compatible only with NELLCOR sensors listed in Chapter 2 of the User's Guide
ELECTROSURGERY SUPPRESSION	Included in all models 202 EL, 204 EL, 206 EL

CO_2 OPTION

CO_2 SENSOR	
Sensor type	Mainstream
Principle of operation	NDIR single-beam, single path/wavelength, ratiometric
Warm-up time	45 sec typical, 3 min maximum
Response time	30 ms typical, 60 ms maximum
Calibration	Verify semi-annually, calibrate only as required
CO_2 SENSOR AND CABLE DIMENSIONS AND WEIGHT	
Sensor Height	1.003 in
Sensor Width	1.036 in
Sensor Depth	.78 in
Sensor Weight	< .39 oz
Sensor Volume	0.81 in^3
Cable Length	10 ft nominal
CO_2 AIRWAY ADAPTER	
Type	Per ISO 3040, single-use
Size	15 mm ID (meets ISO specifications)
Material	clear polycarbonate, with sapphire windows
Deadspace	< 6 cc
CO_2 DISPLAY	
Screen display	CO_2 waveform and $ETCO_2$ and $INCO_2$ numerics
Measurement ranges	$ETCO_2$: 0-99 mmHg, 0-13 kPa, 0-23% $INCO_2$: 0-25 mmHg, 0-5 kPa, 0-5%
Display ranges	$ETCO_2$ and $INCO_2$ same as measurement range
Units	mmHg, kPa, %; user-selectable
Sweep speed	3.13, 6.25, 12.5 mm/sec; user-selectable
Response modes	FAST: 15 sec sampling time period NORMAL: 30 sec sampling time period SLOW: 45 sec sampling period
Gas compensation	see User's Guide
Alarm limit ranges	$ETCO_2$: 0-99 mmHg, 0-14 kPa, 0-14% $INCO_2$: 2-25 mmHg
Resolution	1 mmHg

Accuracy	+/- 3 mmHg (0-30 mmHg CO_2) +/- 10% of reading (31-99 mmHg CO_2)
Waveform rise time	120 ms maximum
Altitude error	+/- .4%/1000 ft

BREATH RATE DISPLAY

Screen display	numeric
Units	bpm
Range	2-150 bpm

APNEA ALARMS AND TICKETS

Apnea ticket	set to auto print after apnea event and after 1 minute continued apnea
Apnea alarm accuracy	+/- 1 sec
Resolution	5 sec
Alarm limits range, adult and pediatric	15-30 sec delay, 5 sec increments

BAROMETRIC PRESSURE

Pressure compensation	automatic
Operating range	-2000 ft to15,000 ft
Screen display	numeric (CO_2 status window)
Units	mmHg or kPa
Accuracy	+/- 3mmHg

IN-SERVICE VALUES

$ETCO_2$	initial value: 38, alternate value: 60
$INCO_2$	initial value: 0, alternate value: 8
Breath rate	initial value: 12, alternate value: 31

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 0.5 sec on and 0.5 sec off if an alarm is suspected
TONE FREQUENCY	900 Hz Tone is steady for a patient alarm and sounds for 1- sec every 4 sec for an equipment alert

SELECTABLE TONE VOLUME	low, medium, high
LIMITS	settable on all parameters
CONTROL	Automatic preset or manual settings
ALARM ON TACHYCARDIAS	Most tachycardias will alarm in less than 8 sec.

DISPLAY

GENERAL	
Matrix	552 X 256 pixels
Active viewing area	145.75 mm X 67.56 mm
ELECTROLUMINESCENT DISPLAY	
Viewing angle	> 160° Horizontal and vertical
Display window	contrast enhancement filter
Display color	amber
Display background color	black

MONITOR (Environmental)

OPERATING TEMPERATURE	0-40°C
SHIPPING AND STORAGE TEMPERATURE	-20-60°C
OPERATING ALTITUDE	-2000-15000 ft
SHIPPING AND STORAGE ALTITUDE	-2000-40000 ft
OPERATING RELATIVE HUMIDITY	15-95%, noncondensing
SHIPPING AND STORAGE RELATIVE HUMIDITY	15-95%, noncondensing
SHOCK	50 g
VIBRATION	Random vibration, .02 g^2/Hz from 10 - 500 Hz, ramping down to .002 g^2/Hz at 2000 Hz. Operating 1 hr per axis, 3 hr per test.
ELECTROMAGNETIC INTERFERENCE	Per IEC 601-1-2

MONITOR (Physical)

PROTECTION CLASSIFICATIONS	
Type of protection against electric shock	
- monitor powered by power adapter	- Class I (protectively earthed)
Degree of protection against electric shock	- Type CF equipment, Defibrillator-proof
Method of disinfection	- not suitable for autoclaving
Flammable anesthetics	- not suitable for use with flammable anesthetics
MONITOR ONLY	
Height	6.65 in
Width	8.25 in
Depth	5.10 in
Weight	6.25 lb

MONITOR WITH EXPANSION MODULE

Height	9.65 in
Width	8.25 in
Depth	7.50 in
Weight	12.68 lb

PRINTER

OPERATION

Operating modes	Continuous, Snapshot, Freeze Print, Auto Interval Print, Auto Interval Trend, Tabular Trend, Alarm Print, Cuff Ticket, Apnea Ticket
Auto Print Intervals	15 min, 30 min, 1 hr, 2 hr, 4 hr
Auto trend shifts	once every 4 hr
Number of waveforms	up to three: ECG, SpO_2, P1, P2, CO_2
Grid	5 mm and 1 mm gradations
Annotation	Date, Time, Print mode, Speed, Heart rate, Systolic, Diastolic, Mean, SpO_2, Breath rate, $ETCO_2$, $INCO_2$, Temperature, Pacer status
Printing Speeds	6.25, 12.5, 25.0 mm/sec, simulated 6.25

PRINTER MECHANISM

Printing method	thermally sensitive dot method
Dot structure	320 dots per line
Printing width	53 mm
Horizontal dot pitch	0.165 mm, 6 dots/mm
Vertical dot pitch	0.165 mm
Paper feed method	friction feed
Paper feed precision	+/- 2% @ 25°C and 60% RH
Paper width	60 mm
Reliability	30 million pulses/dot

ENVIRONMENTAL

Operating temperature	5-40°C
Shipping and storage temperature	-20-60°C
Operating relative humidity	35% to 85% noncondensing
Shipping, storage relative humidity	15% to 90% noncondensing
Shipping and operating altitude	-2000 to 15000 ft
Storage altitude	-2000 to 40000 ft
Shock	30 g
Vibration	Random vibration, .02 g^2/Hz from 10 to 500 Hz, ramping down to .002 g^2/Hz at 2000 Hz. Operating 1 hour per axis, 3 hours per test.
EMI	per standard IEC 601-1-2

PAPER

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

POWER

MODE OF OPERATION	Continuous
BATTERY PACK TYPE	Sealed gel-type 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/CO_2: 25 Watts
INPUT FUSE RATING	3 A/250V, Slow-blow, Type 2AG (.57 X .177 in.)
OPERATING TIMES ON BATTERY	Range of 3.5 to 4.5 hr depending on product configuration
BATTERY RECHARGE TIME WITH 206 EL ON	Range of 8 to 12 hr typical, depending on product configuration
BATTERY RECHARGE TIME WITH 206 EL OFF	Range of 6 to 8 hr 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 V-120 VAC, 500 mA, 50/60 Hz
Rated fuses	T800 mA/250 V, Time-delay, 5 X 20mm
Rated output (continuous)	16-24 VDC, 25 VA
Additional Features	Detachable power cord, pilot light, mains switch