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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This report has been reviewed and is approved for publication.


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Testing and Evaluation of the Protocol Systems, Inc. PROPAQ 206 EL Enclore Vital Signs Patient Monitor

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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 (SpO2), and Capnography (CO2) 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: SpO2); CO2 (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/SpO2/CO2, 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.
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 SpO2 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% SpO2 and a pulse rate of 60 bpm.

f. Plug the CO2 sensor cord into its corresponding port on the Encore. Attach the sensor to the CO2 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, SpO2, and CO2. The NIBP operation can be initiated manually or programmed at set intervals.

![Propaq Encore 206EL Diagram]

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 opportunistic 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


5. *Emergency Care Research Institute* (ECRI)


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).
I, II, III, aVR, aVL, aVF, V
LA, LL, RA, MULTIPLE
4, 2, 1, .5, .2
12.5, 25, and 50 mm/sec
High, Low, Medium, Off
900 Hz; variable pitch with SpO2 option and
SpO2 being monitored
3.9 sec at 25 mm/sec
0.5 to 40 Hz
Electrosurgery and defibrillator protected. All
models also include electrosurgery interference
suppression
50 nA dc for active leads
100-200 nA dc for driven leads
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
<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
>.25 M differential at 60Hz
+/- 5 mV
up to +/-300mV
Width range: 25-120 ms amplitude
Range: .3 to 5mV (RTI)
25-250 bpm
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.
+/- 3 bpm or 3%, whichever is greater
see User's Guide
80 bpm indicated for 80 bpm ECG plus drift
waveform
Pacer indicator shown on screen if PACER
function turned on; pacer spike always shown if
of sufficient amplitude.

INPUT IMPEDANCE
INPUT RANGE (ac)
INPUT RANGE (dc)
QRS DETECTOR
HEART RATE COUNTER RANGE
HEART RATE METER RESPONSE TIME

HEART RATE ACCURACY
HEART RATE AVERAGING METHOD
DRIFT TOLERANCE
PACER DISPLAY
PACER PULSE REJECTION
RESPONSES TO IRREGULAR RHYTHM
Ventricular Bigeminy (VB)
Slowing Alternating VB
Rapid Alternating VB
Bidirectional Systole

see User's Guide
77-82 bpm
63-81 bpm
115-123 bpm
87-93 bpm

INVASIVE PRESSURE SPECIFICATIONS

TRANSDUCER TYPE
TRANSDUCER EXCITATION IMPEDANCE
RANGE
TRANSDUCER SENSITIVITY
EXCITATION VOLTAGE
CONNECTOR

Strain-gauge resistive bridge
200 - 2000
5 micro V/V/mmHg
4.85-V pulsed dc @ 181 Hz
ITT-Cannon plug MS3106F-14S-6P Std.
Hewlett-Packard compatible 12 in. connector
digital filtered, dc to 25 Hz
+/- 1 mmHg without transducer drift
+/- 200 mmHg including transducer offset
+/- 2mmHg or 2% of reading, whichever is
greater, plus the transducer error
-30 to 300 mmHg
25-250 bpm
Meets ANSI/AAMI risk requirements
Included in all EL display monitors

PULSE RANGE
LEAKAGE CURRENT
ELECTROSURGERY SUPPRESSION

NIBP SPECIFICATIONS

METHOD
CONTROL
AUTO INTERVALS
TURBOCUFF

Oscillometric
Automatic and manual measurement control
1, 2, 3, 5, 10, 15, 30, and 60 min
Maximum measurements allowable in a 5 min
period
Systolic, Diastolic, and Mean plus on-screen
monitor
30-260 mmHg
20-235 mmHg
25-255 mmHg
+/- 3 mmHg
100 mmHg
Adult - 160 mmHg, Child - 120 mmHg
280 mmHg
30-220 bpm (without ECG)
25-200 bpm (with ECG)
3 min
30-45 sec
up to 70 sec
30 sec
Included in all EL display monitors

DISPLAYED PRESSURES

SYSTOLIC RANGE
DIASTOLIC RANGE
MEAN RANGE
NUMERIC ACCURACY
MINIMUM INFLATION PRESSURE
DEFAULT INFLATION PRESSURE
CUFF OVERPRESSURE
PULSE RATE RANGE

MAXIMUM DETERMINATION TIME
TYPICAL DETERMINATION TIME
TYPICAL DETERMINATION TIME WITH
ARTIFACT
MINIMUM TIME BETWEEN MEASUREMENTS
ELECTROSURGERY SUPPRESSION

15
**PULSE OXIMETRY**

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

**CO₂ OPTION**

<table>
<thead>
<tr>
<th>CO₂ SENSOR</th>
<th>Mainstream</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensor type</td>
<td>NDIR single-beam, single path/wavelength,</td>
</tr>
<tr>
<td>Principle of operation</td>
<td>ratiometric</td>
</tr>
<tr>
<td><strong>Warm-up time</strong></td>
<td>45 sec typical, 3 min maximum</td>
</tr>
<tr>
<td><strong>Response time</strong></td>
<td>30 ms typical, 60 ms maximum</td>
</tr>
<tr>
<td><strong>Calibration</strong></td>
<td>Verify semi-annually, calibrate only as required</td>
</tr>
</tbody>
</table>

**CO₂ SENSOR AND CABLE DIMENSIONS AND WEIGHT**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensor Height</td>
<td>1.003 in</td>
</tr>
<tr>
<td>Sensor Width</td>
<td>1.036 in</td>
</tr>
<tr>
<td>Sensor Depth</td>
<td>.78 in</td>
</tr>
<tr>
<td>Sensor Weight</td>
<td>&lt; .39 oz</td>
</tr>
<tr>
<td>Sensor Volume</td>
<td>0.81 in³</td>
</tr>
<tr>
<td>Cable Length</td>
<td>10 ft nominal</td>
</tr>
</tbody>
</table>

**CO₂ AIRWAY ADAPTER**

<table>
<thead>
<tr>
<th>Type</th>
<th>Per ISO 3040, single-use</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Size</strong></td>
<td>15 mm ID (meets ISO specifications)</td>
</tr>
<tr>
<td><strong>Material</strong></td>
<td>clear polycarbonate, with sapphire windows</td>
</tr>
<tr>
<td><strong>Deadspace</strong></td>
<td>&lt; 6 cc</td>
</tr>
</tbody>
</table>

**CO₂ DISPLAY**

| Screen display                | CO₂ waveform and ETCO₂ and INCO₂ numerics         |
| Measurement ranges            |                                                   |
| **Display ranges**            | ETCO₂: 0-99 mmHg, 0-13 kPa, 0-23%                  |
| Units                         | INCO₂: 0-25 mmHg, 0-5 kPa, 0-5%                    |
| **Sweep speed**               | ETCO₂ and INCO₂ same as measurement range         |
| **Response modes**            | mmHg, kPa, %; user-selectable                      |
| **Gas compensation**          | 3.13, 6.25, 12.5 mm/sec; user-selectable           |
| **Alarm limit ranges**        | FAST: 15 sec sampling time period                  |
| **Resolution**                | NORMAL: 30 sec sampling time period                |
|                               | SLOW: 45 sec sampling period                       |
|                               | see User's Guide                                   |
|                               | ETCO₂: 0-99 mmHg, 0-14 kPa, 0-14%                  |
|                               | INCO₂: 2-25 mmHg                                    |
Accuracy
+/- 3 mmHg (0-30 mmHg CO2)
+/- 10% of reading (31-99 mmHg CO2)
120 ms maximum
+/- .4%/1000 ft

Waveform rise time
Altitude error

BREATHE RATE DISPLAY
Screen display
umERIC
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 to 15,000 ft
Screen display
numeric (CO2 status window)
Units
mmHg or kPa
Accuracy
+/- 3 mmHg

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

TEMPERATURE
RANGE
17°C to 50°C; 62.6°F to 122°F
DISPLAYS
TI
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 LIMITS
CONTROL
ALARM ON TACHYCARDIAS

DISPLAY

GENERAL
Matrix
Active viewing area

ELECTROLUMINESCENT DISPLAY
Viewing angle
Display window
Display color
Display background color

552 X 256 pixels
145.75 mm X 67.56 mm

> 160° Horizontal and vertical contrast enhancement filter
amber
black

MONITOR (Environmental)

OPERATING TEMPERATURE
SHIPPING AND STORAGE TEMPERATURE
OPERATING ALTITUDE
SHIPPING AND STORAGE ALTITUDE
OPERATING RELATIVE HUMIDITY
SHIPPING AND STORAGE RELATIVE HUMIDITY
SHOCK
VIBRATION

0-40°C
-20-60°C
-2000-15000 ft
-2000-40000 ft
15-95%, noncondensing
15-95%, noncondensing
50 g
Random vibration, .02 g²/Hz from 10 - 500 Hz, ramping down to .002 g²/Hz at 2000 Hz.
Operating 1 hr per axis, 3 hr per test.
Per IEC 601-1-2

ELECTROMAGNETIC INTERFERENCE

MONITOR (Physical)

PROTECTION CLASSIFICATIONS
Type of protection against electric shock
- monitor powered by power adapter
Degree of protection against electric shock
Method of disinfection
Flammable anesthetics

- Class I (protectively earthed)
- Type CF equipment, Defibrillator-proof
- not suitable for autoclaving
- not suitable for use with flammable anesthetics

MONITOR ONLY
Height
Width
Depth
Weight

6.65 in
8.25 in
5.10 in
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, SpO2, P1, P2, CO2
Grid 5 mm and 1 mm gradations
Annotation Date, Time, Print mode, Speed, Heart rate,
Systolic, Diastolic, Mean, SpO2, Breath rate,
ETCO2, INCO2, 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.
per standard IEC 601-1-2

EMI

PAPER

Short-term storage environment -20-40°C, 5% to 80% noncondensing
(up to 7 days)
Long-term storage environment 25°C (optimal), 65% noncondensing
(up to 5 years)
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/CO2: 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
Detach able power cord, pilot light, mains switch