PORTABLE CARDIAC MONITOR/DEFIBRILLATOR SPECIFICATIONS

The following specifications define a portable, lightweight; battery operated portable cardiac monitor/defibrillator to treat patients requiring basic and advanced cardiac life support. The equipment shall be capable of monitoring patients ECG, deliver defibrillation energy, and document critical ECG medication events.

A. Physical Specifications

1. Weight - Complete unit, excluding batteries, shall not exceed 12 pounds.

2. Dimensions - To aid in storage and portability, the general overall dimensions shall not exceed 13" X 12.5" X 5.3"

3. Case Construction - The case shall be constructed to withstand the harsh operating conditions associated with ambulance use. The unit shall be available with an accessory carrying case with handle and shoulder strap.

4. Safety - The unit shall be safe to use both for the operator and the patient. The unit must comply with IEC 601-1 for leakage currents.

5. Service Life - Under normal usage, the unit shall have a service life of not less than five years (excluding routinely replaced items such as a battery, accessories, etc.).

6. Warranty - Parts and labor shall be furnished under warranty for seven full years.

B. Operating Specifications

1. The unit shall operate after exposure shock forces as described in MIL-STD-810E, Method 516.4 (shock); Procedure I (functional).

2. The unit shall operate after exposure to vibration forces as described in MIL-STD-810E, Method 514.4, Category I (Basic transportation).

3. The unit shall operate when exposed to non-condensing humidity of 15-95% at 20 degrees Celsius.

4. The unit shall pass IEC 529, Level 2 (IP2X) for enclosure protection, solid foreign object ingress.

5. The unit shall pass IEC 529 Level 3 (IP3X) (spraying water) for enclosure protection, water ingress.

6. Operating temperature range shall be 0 to 45 C, with storage temperature range -30 C to 70 C.
C. **ECG Monitor**

1. The unit shall have a minimum 6.5" diagonal color active matrix TFT display.

2. The display resolution shall be 640 X 480 pixels.

3. The ECG display shall have six fixed gain settings and an auto-range setting.

4. ECG signal shall be via defibrillator paddles, disposable defibrillation electrodes, 3-lead patient cable or a 5-lead patient cable with AAMI standard connector.

5. The unit shall have a momentary ECG freeze control.

6. The unit shall provide five (5) momentary push buttons for a quick access of frequently used features (i.e., volume adjustment, disabling/enabling alarms, QRS beeper on and off, calibration signal, setting auto heart rate alarm).

7. The unit shall provide 1 volt output for radio telemetry.

8. The unit shall allow for displaying multiple traces. ECG, Plethysmograph and/or respiration waveforms shall be user selectable.

9. The unit shall be capable of displaying a Respiration Waveform and the breath per minute measurement. The operator shall be able to adjust the Respiration waveform size, trace speed and response.

10. Frequency Response - Shall be user selectable. Three settings shall be available, 2 to 20Hz or 0.5 to 40Hz or 0.05 to 150Hz. The chart recorder will automatically be set to the same frequency response.


12. The unit shall have the following lead selections available; Paddles (Pads), I, II, III, aVR, aVL, aVF, V.

13. The unit shall display a heart rate. The heart rate range shall be 20 to 300 BPM from ECG electrodes. If no ECG source is available, the heart rate shall be determined from the SpO₂ measurement. If there is no SpO₂ available the heart rate shall be determined from the NIBP measurements.

14. The unit shall have a heart rate alarm with an auto heart rate setting which automatically sets the upper and lower heart rate alarms at 20% of the heart rate set point or 10 beats - whichever is greater.
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D. Document

1. The strip chart recorder shall utilize thermal array print-head technology.

2. The recorder shall have a single “ON-OFF” operation and not require any operator adjustment.

3. Paper width - 50mm.


5. Frequency Response - Automatically set with the monitor’s frequency response.

6. The recorder shall provide a minimum automatic 6 sec delay, which the operator can turn off or on.

7. The recorder shall document the following:
   8. The time and date the unit was turned on and the results of the self test.
   9. When printing the ECG, the recorder shall also document time date, size, lead selected, heart rate and frequency response setting.
   10. Upon defibrillation, both pre and post defibrillation ECG shall automatically be printed with time, date, joules selected and SYNC if used.
   11. The unit shall provide a minimum of six (6) event buttons through the use of which information can be printed on the chart recorder. The recorder shall document the specific name of the event (i.e., IV, INTUB, EPI, LIDO...) from a pre-programmed menu plus the time and 4 seconds of ECG. The above information shall be automatically stored into the internal memory of the unit, enabling the operator to print out a complete summary at the end of use. The unit shall display the log’s memory capacity with a log icon. The information in the log shall be retained in the internal memory, until it is erased by the user.
   12. The recorder shall also document pace mode (demand or fixed), rate, output current and ECG/pace lead fault.
E. Defibrillator

1. The defibrillator shall produce the trapezoidal waveform per AAMI DF-2 standard.

2. The defibrillator shall incorporate a load compensation circuit to adjust the defibrillation waveform, based upon the patient’s impedance, to precisely deliver the selected energy.

3. The defibrillator must have the following energy selections:
   2,5,7,10,20,30,50,70,100,150,200,300,360 joules.

4. The defibrillator shall charge to 360J in 7 seconds, with charged battery inserted in the unit.

5. The defibrillator shall incorporate a charging bar graph on the display with an intermittent audible tone during charge to signify charging of the defibrillator. Continuous ready tone and solid bar graph shall indicate defibrillator fully charged. The operator shall be able to charge the defibrillator from the front panel or a remote button on the Apex paddle.

6. The defibrillator shall have a synchronized cardioversion capability, with a visual indicator on the front panel and the ECG display. The defibrillator shall deliver the defibrillation pulse within 60 Msec of a sync marker.

7. The defibrillator shall be capable of staying in the SYNC mode after each cardioversion or return to the asynchronous defibrillation mode after each synchronized cardioversion discharge. This feature shall be selectable from a supervisor menu.

8. The defibrillator shall provide quick installation of pediatric paddles, remote defibrillation capability and internal paddles.

9. The internal paddles shall be limited to 50J maximum output for the safety of surgery patients.

10. The unit shall have a dedicated disarm button on the front panel.
F. **Power**

1. Removable battery shall be located conveniently on the side and facilitate easy removal.

2. Battery pack shall have a duplicate set of connectors enabling unit to operate when battery is incorrectly inserted in reverse.

3. Battery system shall utilize nickel metal hydride (NiMH) technology.

4. The unit shall have a battery icon which will indicate the relative charge state of the battery. There shall be a minimum of 6 graduated levels of the battery icon to indicate the relative battery capacity.

5. Each battery shall provide a minimum of 260 minutes of monitoring or 120 - 360 joules discharges at 25°C.

6. The unit shall be capable of operating from mains via the battery charger. When the unit is connected to the auxiliary power and a battery is inserted in the unit, the internal battery will be trickle charged.

G. **Battery Charger**

1. Electrical Characteristics - 90 to 240 VAC, 50-60Hz.

2. Charger shall be capable of charging 3 battery packs simultaneously.

3. Battery charger shall charge a depleted battery in <10 hours to 100%.

4. Charger shall contain 50 ohm defibrillator test load.

5. Charger shall incorporate a simple one-button recondition operation.
H. **External Transcutaneous Pacer**

1. Shall provide both demand and asynchronous pacing capability.
2. Available pacing rate of 30 - 180 BPM ± 5%.
3. Pulse type - rectangular constant current.
4. Output current - 30 to 180MA ± 10% or 5mA (whichever is greater).
5. Pulse duration fixed at 20m ± 1ms.
6. External pacing unit shall provide status indicator for; Pace Output, ECG Lead Fault and Pace Lead Fault. Additionally, a pace marker shall be provided on both the display and chart recorder.
7. Output protection - 360 joules.

I. **Pulse Oximeter**

1. The measurement range shall be 31% to 99%.
2. The accuracy shall be ± 2% between 81% and 99% and ± 3% between 70% and 80%.
3. The unit shall be able to determine the heart rate from the pulse oximeter measurement. The heart rate range shall be 30 to 250 BPM ± 5% or 5 BPM, whichever is less.
4. The unit shall provide messages for: Check Probe, Searching, Signal OK, No Signal, Low Perfusion, Alarm Status (enable or disabled).
5. The unit shall provide an alarm for both upper and lower SpO2 limits.
6. The unit shall allow for displaying the plethysmograph on the display and allow the operator to adjust the size of the pleth waveform.
7. The unit shall provide for a finger probe or a multi-site probe.
J. Blood Pressure and Temperature

1. The unit shall utilize a non-invasive oscillometric method technique.

2. The unit shall provide for both manual and automatic measurement capability. During the automatic mode, the unit shall allow for automatic measurement cycles of 1, 2, 3, 5, 10 and 30 minute intervals.

3. The blood pressure range shall be 30 to 245 mmHg for systolic measurements and 10 to 210 mmHg for diastolic measurements.

4. The blood pressure accuracy shall be ± 5 mmHg mean error and ± 8 mmHg standard deviation.

5. The initial cuff inflation pressure shall be 170 mmHg for adult and child cuffs and 123 mmHg for infant cuffs. The unit shall automatically detect the proper cuff size.

6. The unit shall be able to determine the heart rate from the blood pressure measurement. The heart rate range shall be 30 to 250 BPM ± 10% or 5 BPM.

7. The unit shall provide messages for: Artifact, Check Cuff, Tighten Cuff, Cuff Leak and Motion.

8. The unit shall provide or high and low alarm limits for systolic, diastolic and mean measurements.

9. The temperature range shall be 0 to 50 °C.

10. The temperature accuracy shall be ± 0.2 °C, with a resolution of 0.1 °C.

11. The temperature measurements shall be displayed in either Fahrenheit or Celsius and shall be user configurable.

12. The unit shall provide for a high and low temperature alarm.

13. The temperature probe shall be compatible with the YSI 400 series probes.
K. Twelve Lead Diagnostic Monitoring

1. The unit shall be capable of optional 12 lead diagnostic monitoring via 10 independent leads. The 12 lead option shall have separate modules for fax transmission and interpretive analysis.

2. The operation of the 12 lead functions shall incorporate user-friendly icons. There shall be icons for interpretation results, transmitting a 12 lead FAX, printing a 12 lead report.

3. During acquisition of a 12 lead, the display and chart recorder shall automatically change to diagnostic frequency response of 0.05 to 150 Hz and the display shall display three ECG traces. During the acquisition, the display shall indicate acquiring. The unit shall acquire a 10 second sample.

4. After acquisition is complete, the screen shall display both the stored ECG as well as provide real time ECG. By pressing the LEAD button, the operator shall be able to quickly view all twelve leads of the stored ECG with 4 presses of the LEAD button.

5. The device shall incorporate Telemed™ 12 lead ECG analysis program

6. The device shall provide the option of printing the interpretation on the 12 lead ECG report

7. The device shall print 12 lead ECG and interpretation on 50mm printer paper

8. The device shall provide the option of transmitting 12 lead reports to a fax machine

9. The device shall provide the option of communicating with SmartView™ patient data management software via non-proprietary data card and/or serial communication port.
L. Capnography (EtCO₂ Monitoring)
   1. The device shall incorporate Capnography using mainstream technology
   2. The device shall have a CO₂ sensor external to the device
   3. The device shall be capable of displaying CO₂ value in mmHg
   4. The device shall not use any external water traps
   5. The sensor shall be IPX-7 waterproof
   6. The sensor shall weight <6 oz.
   7. The sensor shall be factory calibrated – requiring no operator calibration.
   8. The rise time of the CO₂ waveform shall be less than or equal to 200msec.
   9. The device shall have a typical warm up time of <5 seconds – requiring no heater
  10. The airway adapter shall be of “anti-fogging” membrane
  11. The device shall be of low power consumption ≤0.04W

J. Semi-Automatic External Defibrillation (SAED)
   1. The device shall be capable of being configured to power on in the SAED mode – allowing BLS user to respond to cardiac emergencies
   2. The device shall offer a system to continuously monitor the patient ECG for a potentially shockable rhythm.
   3. The device shall offer access to the manual defibrillation mode via passcode
   4. The device shall be alert user upon detection of motion or artifact during the analysis process.
   5. The device shall display an “analyze” and CPR timer after each set of three defibrillation attempts or 3 consecutive NO SHOCK analysis results.
H. Biphasic Defibrillation Capability:

1. The device shall utilize Orbital Biphasic waveform technology as the primary energy delivery option

2. The waveform shall be biphasic truncated exponential

3. The biphasic waveform shall compensate for patient impedances by adjusting the duration of the waveform

4. The biphasic energy protocol shall be supervisor configurable to adapt to local and / or changing protocols and protected via supervisor passcode access.

5. The biphasic waveform shall allow for escalating energies up to 360 Joules

6. The biphasic waveform shall employ a terminating current to depolarize the myocardial cells utilizing a BTE waveform tilt that shall not vary significantly for patient impedance from 25Ohms to 100 Ohms.

7. The device shall utilize a 500-microfarad capacitor to facilitate the functions of the BTE waveform

8. Each phase of the waveform shall be truncated exponential

9. The waveform shall exhibit the same general characteristics for impedances above and below 85 ohms.