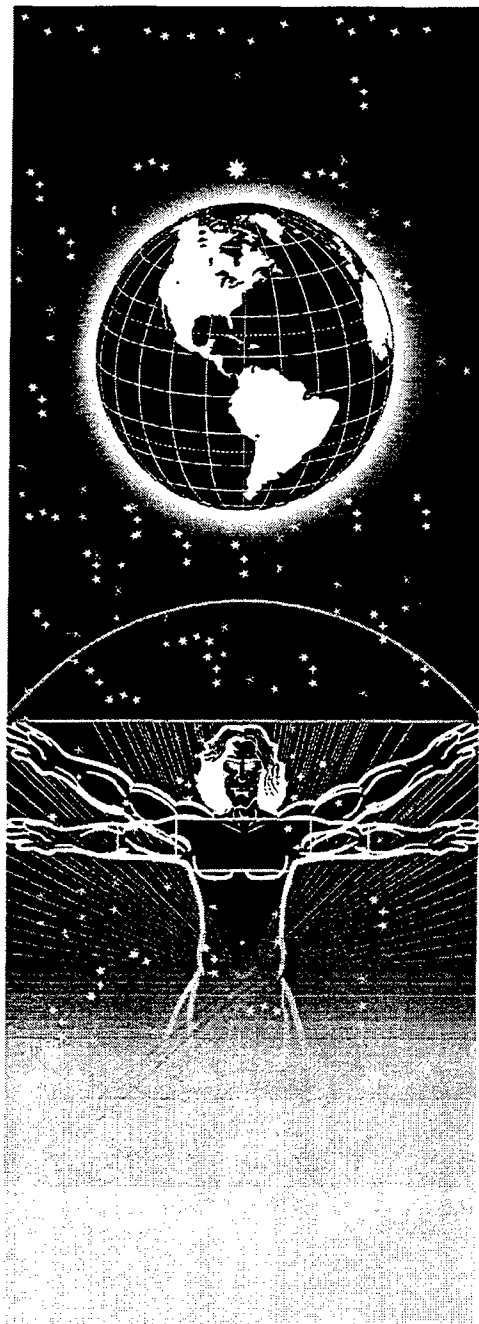




**UNITED STATES AIR FORCE
ARMSTRONG LABORATORY**

**Test and Evaluation of the Hewlett-
Packard CodeMaster 100 Cardiac
Monitor/Pacemaker/Defibrillator
System**

Edward W. Hade

Krug Life Sciences

Jacqueline D. Hale, Lieutenant Colonel, USAF

DTIC QUALITY INSPECTED 2

September 1997

19980227 095

*Approved for public release;
distribution is unlimited.*

**Crew Systems Directorate
Crew Technology Division
2504 Gillingham Dr. STE 25
Brooks AFB, TX 78235-5104**

NOTICES

This final technical report was submitted by personnel of the Systems Research Branch, Crew Technology Division, Armstrong Laboratory, AFMC, Brooks Air Force Base, Texas, under job order 7184-56-01.

This report was prepared as an account of work sponsored by an agency of the United States Government. Neither the United States Government nor any agency thereof, nor any of their employees, nor any of their contractors, subcontractors, or their employees, makes any warranty, expressed or implied, or assumes any legal liability or responsibility for the accuracy, completeness, or usefulness of any information, apparatus, product, or process disclosed, or represents that its use would not infringe privately owned rights. Reference herein to any specific commercial product, process, or service by trade name, trademark, manufacturer, or otherwise, does not necessarily constitute or imply its endorsement, recommendation, or favoring by the United States Government or any agency, contractor, or subcontractor thereof. The views and opinions of the authors expressed herein do not necessarily state or reflect those of the United States Government or any agency, contractor, or subcontractor thereof.

When Government drawings, specifications, or other data are used for any purpose other than in connection with a definitely Government-related procurement, the United States Government incurs no responsibility or any obligation whatsoever. The fact that the Government may have formulated or in any way supplied the said drawings, specifications, or other data, is not to be regarded by implication, or otherwise in any manner construed, as licensing the holder or any other person or corporation; or as conveying any rights or permission to manufacture, use or sell any patented invention that may in any way be related thereto.

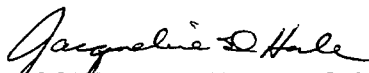
The Office of Public Affairs has reviewed this report, and it is releasable to the National Technical Information Service, where it will be available to the general public, including foreign nationals.

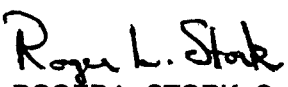
This report has been reviewed and is approved for publication.

Government agencies and their contractors registered with Defense Technical Information Center (DTIC) should direct requests for copies to: Defense Technical Information Center, 8725 John J. Kingman Rd., STE 0944, Ft. Belvoir, VA 22060-6218.

Non-Government agencies may purchase copies of this report from: National Technical Information Services (NTIS), 5285 Port Royal Road, Springfield, VA 22161-2103.


ALLEN E. JONES, TSgt, USAF
Aeromedical Research Technician


JACQUELINE D. HALE, Lt Col, USAF, NC
Chief, Aeromedical Research


ROGER L. STORK, Colonel, USAF, BSC
Chief, Crew Technology Division

REPORT DOCUMENTATION PAGE			Form Approved OMB No. 0704-0188	
Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Washington Headquarters Services, Directorate for Information Operations and Reports, 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302, and to the Office of Management and Budget, Paperwork Reduction Project (0704-0188), Washington, DC 20503.				
1. AGENCY USE ONLY (Leave blank)	2. REPORT DATE September 1997	3. REPORT TYPE AND DATES COVERED Final, December 1996		
4. TITLE AND SUBTITLE Test and Evaluation of the Hewlett-Packard CodeMaster 100 Cardiac Monitor/Pacemaker/Defibrillator System		5. FUNDING NUMBERS PE: 62202F PR: 7184 TA: 56 WU: 01		
6. AUTHOR(S) EDWARD W. HADE, (CIV) JACQUELINE D. HALE, LtCol				
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Systems Research Branch 2504 Gillingham Dr. STE 25 Brooks AFB TX 78235-5104		8. PERFORMING ORGANIZATION REPORT NUMBER		
9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES) Armstrong Laboratory (AFMC) Crew Systems Directorate Crew Technology Division 2504 Gillingham Dr. STE 25 Brooks AFB TX 78235-5104		10. SPONSORING/MONITORING AGENCY REPORT NUMBER AL/CF-TR-1997-0085		
11. SUPPLEMENTARY NOTES				
12a. DISTRIBUTION AVAILABILITY STATEMENT Approved for public release; distribution unlimited.		12b. DISTRIBUTION CODE		
13. ABSTRACT (Maximum 200 words) The CodeMaster 100 is a portable cardiac monitor, defibrillator and pacemaker that offers synchronized defibrillation, electrocardiogram monitoring, noninvasive temporary pacing and pulse oximetry (SpO2) capabilities. The Codemaster receives power via a rechargeable 12 Volt Ni-Cad battery. The unit s pacer can perform external transcutaneous pacing and can monitor oxygen saturation levels.				
14. SUBJECT TERMS Hewlett-Packard medical equipment Pacer airworthy aircraft Defibrillator Cardiac Monitor Conditionally approved Codemaster 100			15. NUMBER OF PAGES 26	
			16. PRICE CODE	
17. SECURITY CLASSIFICATION OF REPORT UNCLASSIFIED	18. SECURITY CLASSIFICATION OF THIS PAGE UNCLASSIFIED	19. SECURITY CLASSIFICATION OF ABSTRACT UNCLASSIFIED	20. LIMITATION OF ABSTRACT UL	

TABLE OF CONTENTS

Background.....	1
Description.....	1
Procedures.....	3
Initial inspection and test preparation.....	3
Test setup.....	4
Performance check.....	4
Vibration	5
Electromagnetic compatibility.....	7
Thermal/humidity environmental conditions.....	8
Hypobaric conditions	9
Airborne feasibility	10
Evaluation results	10
Initial inspection	10
Vibration	10
Electromagnetic compatibility.....	11
Thermal/humidity environmental conditions.....	11
Hypobaric conditions	11
Airborne feasibility	11
Summary.....	12
References.....	14
Appendix	15

LIST OF FIGURES

Figure 1. H/P CODEMASTER 100 System.....	2
Figure 2. Test Setup.....	4
Figure 3. Vibration Table Mounting.....	5
Figure 4. MIL-STD-810E, Category 10, Figures 514.4-16 and 514.4-17.....	6

ACKNOWLEDGMENTS

We would like to thank those who helped and provided advice during the evaluation of the CodeMaster 100 System. We would particularly like to thank:

Mr Douglas Townsend
TSgt Butch Blake
TSgt Allen Jones

TESTING AND EVALUATION OF THE HEWLETT-PACKARD, CODEMASTER 100 CARDIAC MONITOR/ PACEMAKER/DEFIBRILLATOR SYSTEM

BACKGROUND

Representatives of the Hewlett-Packard Company requested an Aeromedical Research evaluation and certification of their CodeMaster 100 System for use on board USAF aeromedical evacuation aircraft. Components of the CodeMaster 100 System included the CodeMaster 100 Cardiac Monitor/Pacemaker/Defibrillator, and the H/P M2480B Battery Support System. All components of the CodeMaster 100 System were tested for airworthiness. Throughout this report the term CodeMaster 100 refers to the CodeMaster 100 Cardiac Monitor /Pacemaker/Defibrillator, while the term CodeMaster 100 System refers to the CodeMaster 100 Cardiac Monitor/Pacemaker/ Defibrillator, and the M2480 Battery Support System.

DESCRIPTION

The CodeMaster 100 is a portable cardiac monitor, defibrillator and pacemaker that offers synchronized defibrillation, electrocardiogram monitoring, noninvasive temporary pacing and Pulse Oximetry (SpO₂) capabilities (Fig. 1). The CodeMaster 100 receives power via a rechargeable 12 volt, 2.5 or 4.0 amp hour Ni-Cad battery pack. The duration of individual battery life varies as a function of the CodeMaster 100 operating mode as well as the level and frequency of defibrillations. The specification for the battery life defines a range of 2.5 to 4.0 hours.

The defibrillator is capable of delivering up to 360 joules of energy. It may be used in synchronized mode for performance of synchronized cardioversion by using the R-wave of the patient's ECG as a timing reference. The CodeMaster 100 uses adult/pediatric, anterior/anterior external paddles, anterior/posterior paddles, external adhesive pads, or internal paddles.

The CodeMaster 100 contains a non-fade monitor for observation of the patient's cardiac rhythm. The monitor displays the ECG in moving trace mode at 25 mm/sec.

A strip chart recorder is provided to document events. The strip recorder operates in either the (A) auto mode (as described in Table 7-2 on page 7-11, one can enable or disable any of the following recordings: Record on Mark, Charge, Shock, or Alarms) or the (B) On mode (the chart recorder will run continuously, printing ECG waveform and annotating status).

The CodeMaster 100 will defibrillate, cardiovert and monitor using the Hewlett-Packard (HP) External defibrillation paddles. HP has labeled one of these Apex and one Sternum. The Apex defibrillator paddle is positioned near the cardiac apex for "paddle pickup" of ECG signal to be displayed on the monitor, while the sternum

defibrillator paddle is positioned on the sternum. There is a remote charge button located on the Apex paddle. Each paddle has a discharge control (orange fire button) which must operate in conjunction with each other in order to discharge; depressing only one control will not cause the paddles to discharge. If the paddles are charged and not actively discharged within 60 seconds, the energy will automatically discharge internally.

The CodeMaster 100 with the pacer can perform external transcutaneous pacing. The pacer provides demand (synchronous) and fixed (asynchronous) pacing modes. The patient is connected to the pacer by external adhesive pads. The patient can be paced and defibrillated through the same set of pads. Current pulse amplitude is from 10-200 mA with pulse rates from 40-180 ppm.

The CodeMaster 100 in the SpO₂ monitoring mode gives information on both cardiac and respiratory systems, and details of oxygen transportation in the body. The SpO₂ system uses three types of sensors (Disposable, Semi-disposable, and Reusable) available from a variety of manufacturers.

The following information defines the general specifications of the CodeMaster 100 defibrillator. Size: 15.9 (H) X 34.9 (W) X 38.4 (D) cm (6.25 (H) X 13.75 (W) X 15.125 (D) in). Weight: 9.76 Kg (21.5 lb). Heart Rate Range: 15-300 BPM. Pacing Rate Range: 40-180 BPM. Pacing Current Range: 10-200 mA. Available Energy Range: 0-360 joules in 14 energy levels. Lead Selection: paddles, I, II, III. Additional leads (aVR, aVF, aVL, V leads) and pads are available. Monitor and recorder indicate selected source. Printer speed: 25 mm/sec.



Figure 1. HP CodeMaster 100 System

PROCEDURES

Test methods and performance criteria were derived from various military standards (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 under various testing conditions.

The device was subjected to various 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
6. Airborne Feasibility

INITIAL INSPECTION AND TEST PREPARATION

- a. The CodeMaster 100 System was inspected for quality of workmanship, production techniques and possible damage that may have occurred during shipment.
- b. The CodeMaster 100 System was checked to verify that it met safety requirements and operating characteristics established in National Fire Protection Agency (NFPA) 99, Standards for Health Care Facilities (8), Electrical Shock Hazards,

AFI 41-203 (9), and Equipment Management in Hospitals, AFI 41-201 (10). Ground resistance and leakage current measurements were made at 115 VAC/60 Hz.

c. The CodeMaster 100 System was examined to verify that it met basic requirements for good human factors design as outlined in MIL-STD 1472 (4).

d. A test setup and performance check was developed to evaluate the CodeMaster 100 System's operation in accordance with manufacturer/customer specifications throughout the various testing conditions.

TEST SETUP

One, of the following two analyzers, was connected to the ECG port on the monitor and provided the ECG waveform for the CodeMaster 100 during the monitor portion of testing: the Lionheart Multiparameter Simulator or the Impulse 4000 Analyzer. The three ECG leads were attached to the corresponding color-coded receptacles on the analyzer. The Lionheart settings were: Lead Select, I/II; ECG amplitude, 1.0; and ECG BPM, beats per minute, 60. The Impulse selections were the following: ECG mode, Normal Sinus Group (NORM), and 60 beats per minute. The Impulse 4000 also analyzed the defibrillator portion of the CodeMaster 100 when it operated in the DEFIB mode. One Ni-Cad battery pack provided power to the CodeMaster 100. The CodeMaster 100 was configured as follows: Lead Select, II; ECG size that allowed for the largest view of the waveform; pacer settings on 100 mA and 100 BPM when pacer was activated; SYNC mode selected (where applicable); when in SYNC mode, ECG size control was adjusted such that the SYNC marker was positioned on the upper portion of the QRS complex.

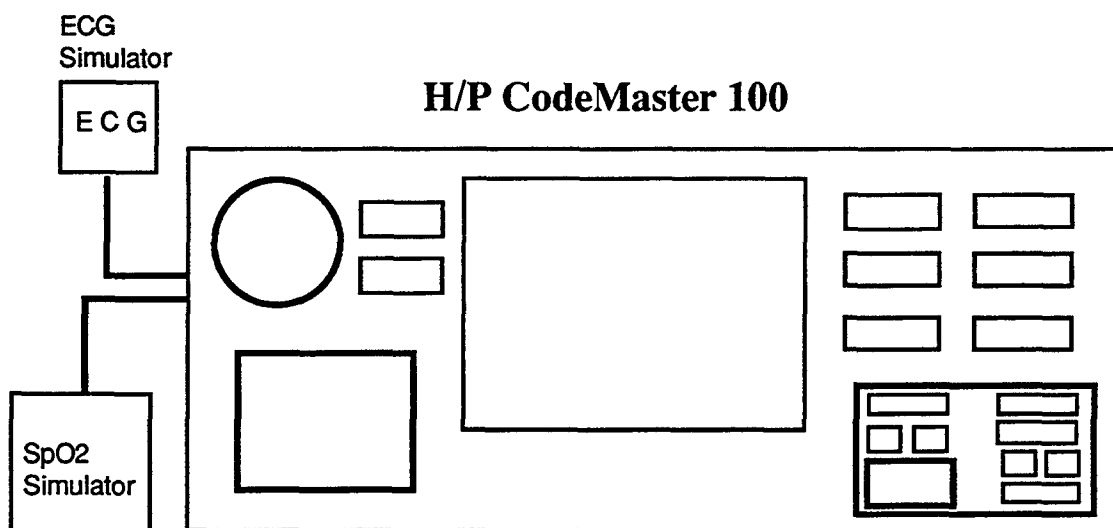


Figure 2. Test Setup

PERFORMANCE CHECK

As the CodeMaster 100 monitored the ECG waveform, defibrillator energy

levels were selected and the paddles subsequently discharged into the energy measuring device. The performance check included discharging the paddles a number of times at both a high-energy level, 360 joules, and a low-energy level, 10 joules. The baseline performance check also included testing synchronized defibrillation at an energy level of 50 joules. The ECG trace was used to visually confirm whether or not the defibrillator fired at the appropriate location on the waveform. The performance check concluded with the verification of the pacer output and recorder function. The Impulse 4000 monitored the pacer, ensuring the accuracy of the pacing frequency and amplitude.

VIBRATION

Vibration testing is critical to determine "the resistance of equipment to vibrational stresses expected in its shipment and application environments" (3). This testing involved a set of operational tests performed along each of the CodeMaster 100 System's three axes - X, Y, and Z; the CodeMaster 100 System'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 similar levels and lengths as those derived from MIL-STD-810E, Category 10, Figures 514.4-16 and 514.4-17 (Figure 4).

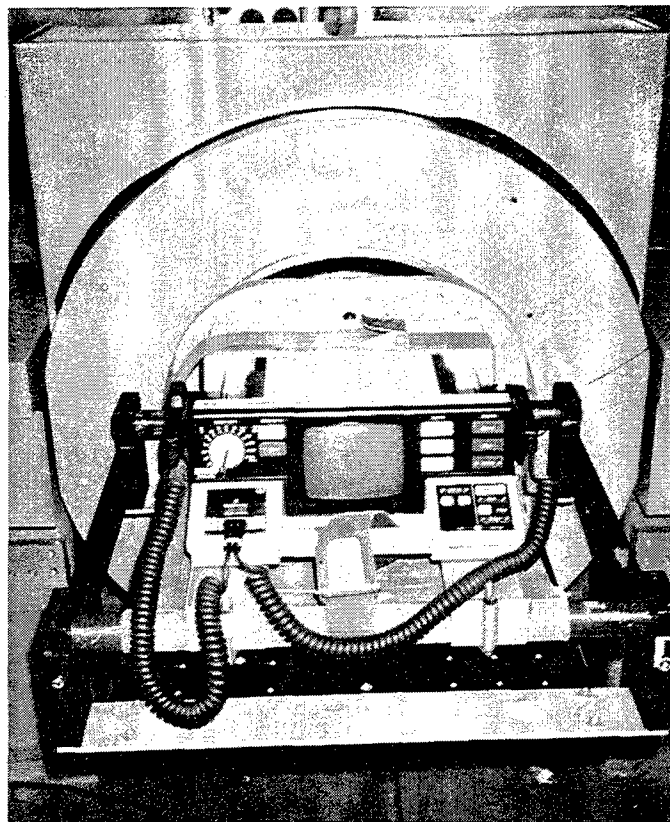


Figure 3. Vibration Table Mounting

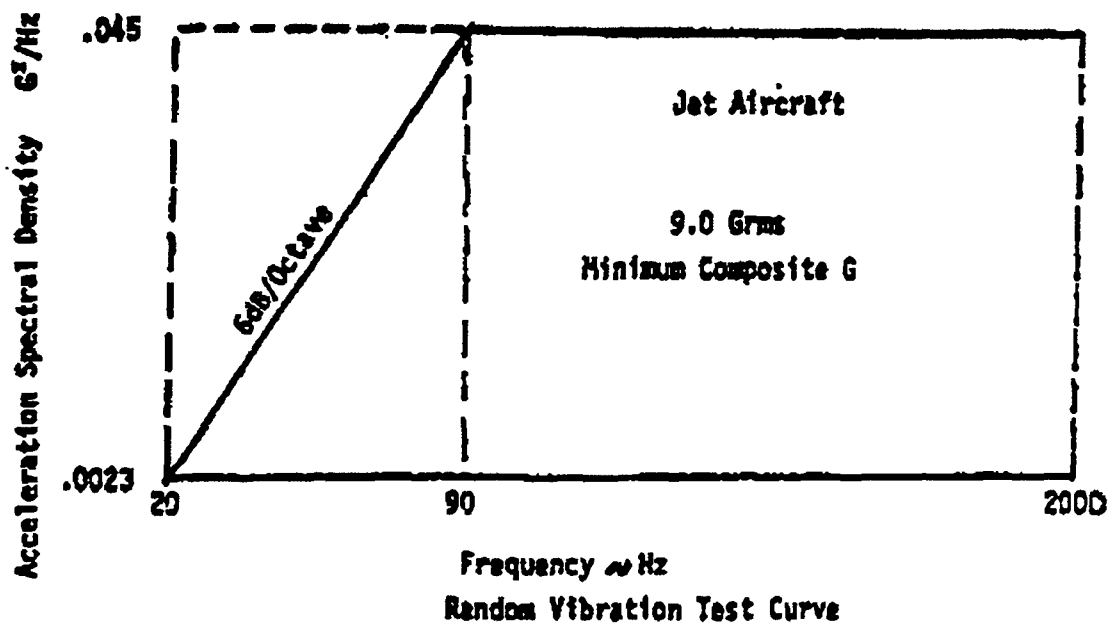
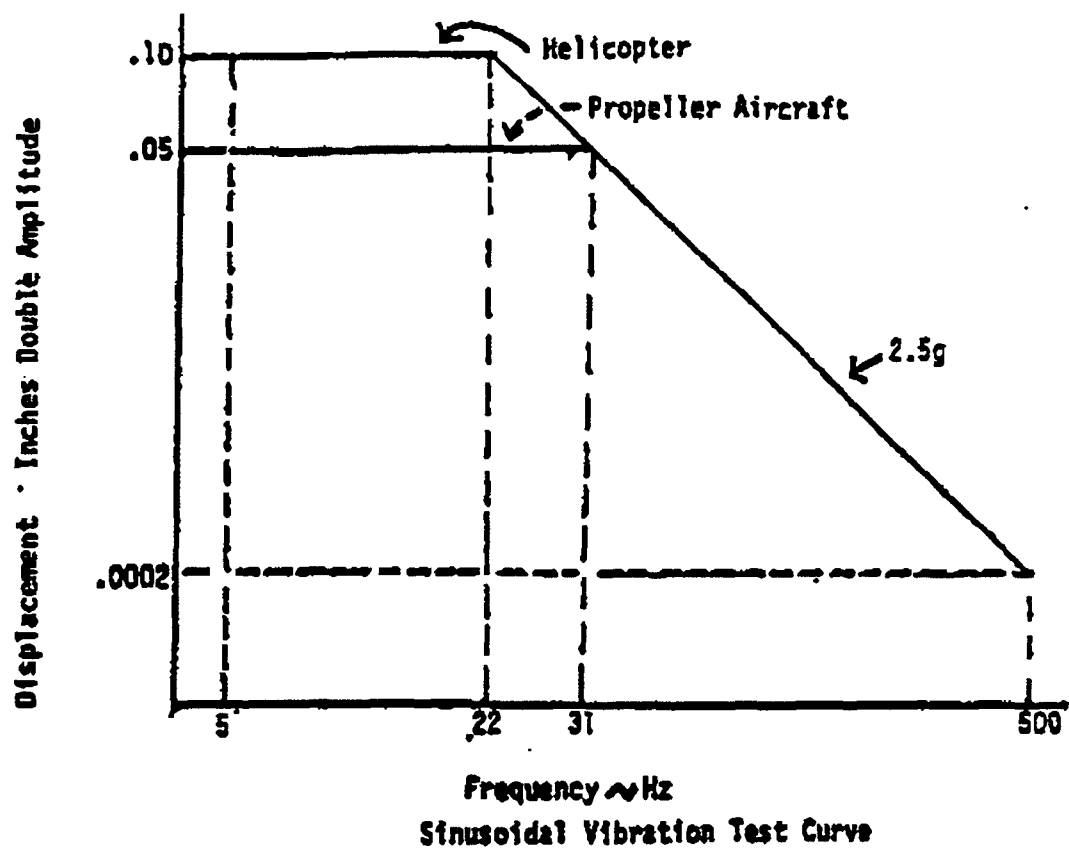


Figure 4. MIL-STD-810E, Category 10, figures 514.4-16 and 514.4-17

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 be susceptible to fields generated by the aircraft equipment or other medical devices and malfunction in their presence.

The CodeMaster 100 System 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 determined the amount of EMI emitted by the equipment during its operation. This test was performed to ensure that the device does not affect other pieces of equipment that may be susceptible to electromagnetic emissions (i.e., aircraft navigation and communication equipment). CodeMaster 100 System.

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 measured emissions generated by the medical device along its power supply lines. This test 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. Battery Support System only.

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. CodeMaster 100 System.

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." Battery Support System only.

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 was performed to determine whether "simulated currents that will be developed on platform cabling from electromagnetic fields generated by antenna transmission would affect the equipment under test." Battery Support System only.

f. Conducted Susceptibility (CS-115), "Conducted Susceptibility, Bulk Cable Injection, Impulse Excitation": This test was performed to verify that the CodeMaster 100 System 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." Battery Support System only.

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." Battery Support System only.

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 QRS beep sounded at maximum volume. For susceptibility testing, the CodeMaster 100 System was operated in the monitoring mode. The paddles were charged and discharged at intervals for two reasons. First, it allowed researchers to crudely determine if EMI would cause the equipment to defibrillate at times other than when the operator depressed the discharge buttons; and second, energy defibrillation levels and monitor function could be confirmed. Aeromedical Research personnel were unable to test the SYNC function because it would have required them to be subjected to dangerous levels of electromagnetic radiation. For both emissions and susceptibility testing, the Defibrillator was tested for operation on internal battery pack while the Battery Support System was tested for operation on 115 VAC/ 60 Hz.

THERMAL/HUMIDITY ENVIRONMENTAL CONDITIONS

Testing at extreme temperatures and humidities is critical to determine if aeromedical equipment can be stored and operated during severe environmental conditions "without experiencing physical damage or deterioration in performance" (3). Extreme environmental conditions can have numerous incapacitating effects on medical equipment including, but not limited to, the following: 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 CodeMaster 100 System 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 CodeMaster 100 System was monitored continuously, and a performance check was conducted every fifteen minutes. For storage tests, the CodeMaster 100 System was placed in the chamber and remained nonoperational throughout the storage portion of the test. Upon completion of this test the chamber was brought to standard ambient conditions. Aeromedical Research personnel then conducted a performance test and monitored the unit for one hour to verify successful operation. The following describes the conditions of the environmental tests performed:

- a. Humidity: $94 \pm 4\%$ RH, $85^{\circ}\text{F} \pm 3.6^{\circ}\text{F}$ ($29.5^{\circ}\text{C} \pm 2^{\circ}\text{C}$) for 4 hr
- b. Hot Temp Operation: $120^{\circ}\text{F} \pm 3.6^{\circ}\text{F}$ ($49^{\circ}\text{C} \pm 2^{\circ}\text{C}$) for 2 hr
- c. Cold Temp Operation: $32^{\circ}\text{F} \pm 7.2^{\circ}\text{F}$ ($0^{\circ}\text{C} \pm 4^{\circ}\text{C}$) for 2 hr
- d. Hot Temp Storage: $140^{\circ}\text{F} \pm 3.6^{\circ}\text{F}$ ($60^{\circ}\text{C} \pm 2^{\circ}\text{C}$) for 6 hr
- e. Cold Temp Storage: $-40^{\circ}\text{F} \pm 3.6^{\circ}\text{F}$ ($-40^{\circ}\text{C} \pm 2^{\circ}\text{C}$) for 6 hr

HYPOBARIC CONDITIONS

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

a. Cabin Pressure/Altitude: 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, which are characterized as opportune aircraft available for use in aeromedical evacuation, pressurize their cabin atmosphere to barometric pressures equivalent to 8,000-10,000 feet above sea level. The differences in pressures can be critical to the effective operation of some medical equipment. Altitude testing consisted of operating the CodeMaster 100 System while ascending from ground level to 10,000 ft (maintaining altitude for one hour) and then descending back to ground, at rates of 5000 ft/min, while stopping at 2000 ft increments 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 to ensure that it will not endanger a patient, the aircraft personnel, or the aircraft itself. The CodeMaster 100 System operated inside the rapid decompression test chamber as the chamber was

pressurized 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 while the equipment response was observed, and then returned 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 CodeMaster 100 System was monitored throughout the series of decompressions, including performance checks each time the unit returned to ground. The simulator equipment remained outside the chamber. Connectors joining the Impulse 4000 analyzer and the CodeMaster 100 and the power connector to the Battery Support System were run through putty-sealed access ports in the chamber walls.

AIRBORNE FEASIBILITY

Airborne feasibility evaluations are a cost-effective and invaluable means of validating a piece of equipment's clinical and operational suitability 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. Ensuring safe and reliable operation of this medical equipment support 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-141 aeromedical evacuation mission. The CodeMaster 100 System 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 all parameters to be within referenced guideline limits.

VIBRATION

The CodeMaster 100 Defibrillator and Battery Support System operated within manufacturer's specifications throughout the vibration testing.

ELECTROMAGNETIC COMPATIBILITY

WL/AAWA-2 tested the H-P CodeMaster 100 Model M2475B for emissions and susceptibility to the limits of MIL-STD-461D and in accordance with MIL-STD-462D test methods. The CodeMaster 100 Defibrillator is certified per AFI 11-206 for operation on large body aircraft only. During aircraft taxi, takeoff, and landing (below 10,000 ft.) the H-P CodeMaster 100 Defibrillator should not be operated on smaller (C-21 type aircraft) and rotary wing aircraft. The CodeMaster 100 Defibrillator has radiated emissions in excess of MIL-STD-461D limits (in the HF, VHF/FM, and VHF/AM frequency bands). Between 137-154 MHz (Vertical Antenna Polarity), the SpO₂ signal display was lost at 15V/M average. Between 109-120 MHz and 145-170 MHz (Horizontal Antenna Polarity), the SpO₂ signal display was lost at 15V/M average. The emissions should not cause any degradation to flight safety, and mission capability when operated as stated above. The pilot and crew should be made aware that the defibrillator system is being operated.

THERMAL/HUMIDITY ENVIRONMENTAL CONDITIONS

The CodeMaster 100 System operated satisfactorily during all five phases of testing. Testing was conducted in the Armstrong Laboratory 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

1. Cabin Pressure/Altitude: The CodeMaster 100 System performed in accordance with manufacturer specifications throughout testing.
2. Rapid Decompression: The CodeMaster 100 System operated satisfactorily following each decompression.

AIRBORNE FEASIBILITY

The inflight evaluation of the CodeMaster 100 System was performed on a C-9 aeromedical evacuation mission and C-141 aeromedical readiness mission. Evaluation confirmed that the unit would operate successfully during all phases of flight. Analysis of flight data indicated this unit was easy to enplane and deplane and was compatible with the C-9 aircraft electrical systems. Several significant human factors recommendations were noted during the airborne feasibility portion of airworthiness testing and are listed below:

1. The CodeMaster 100 System passed our environmental testing; however, Aeromedical Research questions its ability to survive in a harsh "physical" setting. For example the paddle connection in front of the defibrillator makes an excellent rain/

snow "trap". This could become a real safety issue if the defibrillator had to be operated and the connector was filled with water.

2. The CodeMaster 100 carrying case should be modified; e.g., replace the plastic connectors which attach to both sides with metal rings. These rings should have an opening large enough to accept a standard NATO litter strap. This modification would allow a more secure mounting of the CodeMaster 100 to the patient litter.

3. The Battery Support System M2480B case should be modified to allow tie down in any configuration. A real concern here is that when one ties down the unit vertically (Z-axis) the test buttons can be accidentally energized.

4. The CodeMaster 100 needs additional power sources. It would be nice if the unit could be powered with 115 VAC/60 Hz.

5. The consensus of Aeromedical Research technicians was that the upper right portion of the monitor (CRT) was too cluttered with information and tends to obscure the QRS waveform. A better design would be to place the SpO₂ information in the lower left portion of the screen.

SUMMARY

Aeromedical Research found the CodeMaster 100 System to be acceptable for use on large U.S. Air Force aeromedical evacuation aircraft only while operating on 115 VAC/60 Hz (Battery Support System) or battery power with the recommendations and restrictions listed below. The CodeMaster 100 System operated within expected parameters when subjected to environmental extremes and simulated cabin altitudes, and did not produce a hazard to patient or crew during rapid decompression. The pacer portion of the CodeMaster 100 Pacemaker/Defibrillator is not approved for use in the aeromedical evacuation aircraft; however, the inactive pacer portion will survive the flight environment and be an available option for "off the aircraft" use. The following recommendations and operational restrictions accompany the airworthiness approval of the CodeMaster 100 System:

a. Add the following warning to the Operating Instructions and Service Manual:

WARNING: Restrictions for use on USAF aircraft: The pacing option is not to be operational at any time during flight. The M2480B Battery Support System can only be used on 115 VAC/60 Hz.

b. Attach a warning label near the pacer control panel that reads, "Do not operate pacer in flight."

c. Attach a warning label on the M2480B Battery Support System that reads, "Do not operate on 115 VAC/400 Hz."

d. Inform Aircraft Commander that a cardiac monitor will be in use on board, and that they will be notified before the defibrillator is operated because of the possibility of electromagnetic interference with aircraft navigation and communication equipment.

e. Aeromedical Research recommends that Hewlett-Packard Company attaches a plate or label on the CodeMaster 100 M2475B stating that this unit be flown on large bodied USAF aircraft only.

f. The CodeMaster 100 SpO₂ option exhibited susceptibility during electromagnetic interference testing. ASC/ENAI experts determined that these susceptibility events would be brief (seconds), but that the SpO₂ readings **"should not be relied on in critical situations."** Aeromedical Research recommends that the user be alert to the potential for temporary, inaccurate SpO₂ readings.

g. After initial electromagnetic interference evaluations, ASC/ENAI, Wright Patterson AFB, approved the CodeMaster 100 M2475B for use on large-bodied USAF aircraft only. ASC/ENAI also recommends that **"the CodeMaster 100 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.
2. MIL-STD 462D, Measurement of EMI Characteristics.
3. MIL-STD 810E, Environmental Test Methods and Engineering Guidelines.
4. MIL-STD 1472, Human Engineering Design Criteria for Military Systems, Equipment, and Facilities.
5. Emergency Care Research Institute (ECRI)
6. Hewlett-Packard Company CodeMaster 100 System, 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

MANUFACTURER'S SPECIFICATIONS OF THE HEWLETT-PACKARD COMPANY CODEMASTER 100 SYSTEM

SPECIFICATIONS

General

Size	15.9 cm high x 34.9 cm wide x 38.4 cm long (6.25 in. x 13.75 in. x 15.125 in.).
Weight	9.76 kg. (21.5 lb.)
Power	Ni-Cd; 2.5 Ah, 12 V Nominal Ni-Cd: 4.0 Ah, 12 V Nominal
Patient Safety	All patient connections are electrically isolated.
Environmental	Temperature: 0°C to 55°C (operating). -20°C to 70°C (storage and shipping). Humidity: 0% to 95% relative humidity for 24 hours at 40°C.
Atmospheric Pressure	15,000 ft.

Pacemaker

Type	Asynchronous or Demand
Pulse Width	20 msec
Pulse Amplitude	10 mA to 200 mA.
Pacing Rate	Variable from 40 to 180 bpm.

Defibrillator

Waveform	Damped sinusoidal (Lown)
----------	--------------------------

Output (delivered)	Selectable at 2, 3, 5, 7, 10, 20, 30, 50, 70, 100, 150, 200, 300, 360 joules.
Energy Selection	Control on unit front panel.
Charge Time	Less than 5 seconds to 360 joules. Depleted batteries will result in a longer defibrillator charge time.
Synchronized Mode	Synchronized defibrillator pulse to patient's R-wave.
Charge Controls	Control on apex paddle and on front panel.
Electrode Area	83 cm ² (Adult), 21 cm ² (pediatric)

Monitor and Displays

Patient Connection	Via 3-lead ECG cable, paddles or electrodes. Selectable by front panel switch.
Input Protection	Fully defibrillator protected.
Electrical Isolation and Shielding	Input protected against high-voltage defibrillator pulses and radio frequency interference.
Display Format	Non-fade, fixed trace.
Screen Size	5 in. diagonally (12.7 cm), viewing area.
Frequency Response	0.5 to 40 Hz
Sweep Speed	25 mm/sec
Common Mode	> 90 dB

Recorder

Paper	50 mm by 30 mm (100 ft)
Speed	25 mm/sec.

Event Summary	Stores and prints 3 seconds pre- and 8 seconds post-critical event data for up to 28 events. Data remains after unit is turned off.
---------------	---

Battery Packs

Type	Ni-Cd
Voltage	2.5 Ah, 12 V 4.0 Ah, 12 V.
Recharge Time	2-3 hours for full recharge in M2480B Battery Support System
Operating Time	Minimum 2.5 hours of monitoring or fifty (50) 360 joule discharges or 1.75 hr of pacing and ECG monitoring.

Charger	Use Battery Support System M2480B for recharging battery packs.
----------------	---

Charging Capacity	Two Batteries
Capacity Test Time	Approximately 24 hr
Charge Time	2-3 hr
Recommended Chrg Temperature	10 to 30°C