

**NAVAL AEROSPACE MEDICAL RESEARCH LABORATORY
51 HOVEY ROAD, PENSACOLA, FL 32508-1046**

NAMRL Technical Memorandum 95- 3

**DURABILITY TEST OF THE DOLCH® 486DX33 COMPUTER AND BIO-
LOGIC® BRAIN-MAPPING DATA ACQUISITION SYSTEM**

J. P. Dal Santo¹, J. R. Bucci¹, M. D. Hayden, and J. B. Clark

**¹MCJ Corporation
5301 East State Street, Suite 116
Rockford, IL 61108**

ABSTRACT

The purpose of this project was to test a commercially available portable computer and electrophysiologic data acquisition system under a variety of simulated environmental conditions. This durability test would establish the feasibility of this computer to collect human electrophysiologic data in military subjects operating under extreme or adverse environmental conditions. A Dolch® 486DX33 MHz 240 MB portable computer, a Bio-Logic® Systems Corporation brain-mapping card, an electrode attachment box, and a waveform generator to simulate data acquisition and analysis were subjected to various environmental and physical conditions to establish operational limitations. Brain-mapping software was operating during all phases of testing. Norton Utilities® Version 6.0, PC Tools® Version 6.0, and Microsoft® Version 6.21 Scandisk® and Checkdisk® Utilities were used to test the integrity and functionality of the hard drive. The computer's ability to operate and acquire synthetic biological data under various simulated field (temperature and relative humidity (RH)) conditions was assessed in an environmental chamber. The computer system operated for 1 h under each of three conditions: arctic (15 °F/15% RH), desert (120 °F/15% RH), jungle (105 °F/85% RH). The computer was subjected to two simulated flight profiles: high-altitude flight and rapid decompression (cabin pressure loss). The high-altitude profile was 15,000, 20,000, 25,000, 30,000, and 35,000 ft x 10 min each. In the rapid decompression profile, the computer operating at 8000 ft, was rapidly depressurized to 22,000 ft in 2.07 s, then returned to sea level at 36,000 ft per min. The computer was subjected to various acceleration profiles typical of aircraft flight (4.62 - 6.5 G forces), on a 20-ft centrifuge arm. The computer system functioned and acquired data at all altitude/pressure differentials, temperature/humidity, and acceleration/deceleration profiles tested, exceeding all component manufacturers' specifications. Several problems were identified. The computer power ON/OFF switch would stick at high temperatures. Data displayed on the liquid crystal display (LCD) migrated during altitude and environmental chamber tests. This distortion was transient at altitudes above 25,000 ft, affected only the top four lines of the LCD screen, and did not significantly disrupt computer operations.

INTRODUCTION

Military forces routinely operate in harsh conditions of humidity, temperature, altitude, and gravity. The Naval Aerospace Medical Research Laboratory is tasked with studying aircrew operating under these extremes. These studies routinely monitor physiologic parameters during these conditions to determine if the environment adversely affects aircrew performance, which may compromise safety or mission effectiveness. We evaluated a computer system in various environmental scenarios to determine its feasibility of use to study human electrophysiologic activity in military subjects in adverse field operating conditions. A Dolch® portable computer with a 486DX33 MHz microprocessor and 240-MB hard drive, a Food and Drug Administration (FDA) approved Bio-Logic® Systems Corporation brain-mapping system card, a "Brain Box" (electrode attachment box), and a waveform generator to simulate data acquisition and analysis were subjected to three environmental conditions. Brain-mapping software was operating during all phases of testing. The device was configured as a mobile unit requiring 115 V ac external power source.

Norton Utilities® Version 6.0, PC Tools® Version 6.0 and Microsoft® Version 6.21 Scandisk® and Checkdisk® Utilities were used to test for hard drive integrity and functionality. The software and computer system were provided by MCJ Corporation (Rockford, Illinois) with the cooperation of Bio-Logic® Systems Corporation (See attachments 1-3). The product name for the brain-mapping device is the "Sleepscan Express." Environmental and component specifications are provided in attachments 4-6.

MATERIALS AND METHODS

ENVIRONMENTAL CHAMBER

The purpose of this phase was to subject the data acquisition system to various simulated environmental field conditions in the Naval Aerospace Medical Research Laboratory Environmental Chamber. The computer system, while powered and operating, was exposed to simulated arctic, jungle and desert environments.

TEMPERATURE/HUMIDITY PROFILES

Each condition was set for 1 h of test time, with a minimum exposure time of 5 min (Table 1). If more than 1 h was required to reach the required condition, the test time was run for an additional 5 min.

Table 1. Temperature/Humidity Profiles			
Condition	Temp (°F)/Humidity(%)	T-T-C (min)*	Time _T (min)
Arctic	15/15	58.5	63.5
Desert	119.5/5	70.0	75.0
Jungle	106/85	50.0	60.0

T-T-C* is time to reach condition

Time_T is total testing time

ALTITUDE CHAMBER

The purpose of this phase was to subject the computer system to simulated altitude conditions in the Naval Aerospace and Operational Medical Institute low-pressure chamber (LPC). Two profiles were used: high-altitude flight (Table 2), and rapid decompression (cabin pressure loss) (Table 3).

Table 2. High-altitude Flight (Profile A)		
Altitude (ft)	Pressure (psi) ^a	Duration (min)
15,000	8.29	10
20,000	6.75	10
25,000	5.45	10
30,000	4.36	10
35,000	3.46	10

^a psi +/- 0.5

Vertical velocity: 5000 ft per min.

Table 3. Rapid Decompression (Cabin Pressure Loss) (Profile B)		
Level	Altitude (ft)/Pressure ^a (psi)	Time _T (min) ^a
1	15,000/8.29	10
2	20,000/6.75	10
3	25,000/5.45	10
4	30,000/4.36	10
5	35,000/3.46	10

^aTime_T is total testing time

Rapid decompression (cabin pressure loss). The computer system was maintained at 8000 ft and 10.91 psi altitude, then the LPC was rapidly depressurized to an altitude of 22,000 ft (6.21 psi) over 2.07 s, simulating a sudden loss of cabin pressure. The LPC pressure was then rapidly returned to sea level (increased to 14.70 psi) at 36,000 ft/m, as if in a rapid descent to recover from the cabin pressure loss.

CORIOLIS ACCELERATION PLATFORM

The purpose of this phase was to subject the computer system to varying acceleration profiles typical of aircraft flight using the Naval Aerospace Medical Research Laboratory centrifuge arm on the Coriolis Acceleration Platform (CAP).

Profile A: The computer system, while powered and operating with the LCD vertical at the end of a 20-ft centrifuge arm, accelerated from 0 to 25 rpm (0-4.26 G forces), accelerating and decelerating at a constant rate of 15 deg/s².

Profile B: The computer system, while powered and operating with the LCD horizontal, at the end of a 20-ft centrifuge arm, accelerated from 0 to 25 rpm (0-4.26 G forces) at a constant acceleration rate (5 deg/s²), then decelerated at the maximum attainable rate (15 deg/s²) by applying the platform brake.

RESULTS

ENVIRONMENTAL CHAMBER

The brain-mapping system's ability to operate and acquire synthetic biological data under various simulated field (arctic, desert and jungle) conditions was assessed in the Naval Aerospace Medical Research Laboratory's environmental chamber. The waveform signal did not show any abnormality during this phase of the test, and the computer system continued to function properly throughout the environmental exposures. The data on the hard disk were checked after the test, and there was no data distortion. Two problems were noted. During the desert phase test, at 107.96 °F, the top two data display lines on the liquid crystal display (LCD) screen began migrating up and off towards the top of the screen. The ON/OFF switch felt transiently gritty and would stick when cycled on and off, as if contact corrosion had taken place. There was no power loss or discontinuity during switch function. On further inquiry, Dolch ® Computer Company acknowledged that this problem can occur in the normal course of operation. We recommend that the company replace the switch with a heavy-duty switch.

ALTITUDE CHAMBER

The goal of this phase of the system durability test was to assess the system's ability to operate and acquire synthetic biological data during altitude/pressure changes similar to conditions encountered during flight. The intent was to establish maximum operational altitude and pressure differential specifications.

PROFILE A: HIGH-ALTITUDE FLIGHT

Each altitude/pressure (A/P) level was reached over a period of 10 min. The ascent/ descent rate was established at 5,000 ft/min.

The initial level (15,000 ft) was reached in 3 min and sustained for 7 min without visible performance variations during the ascent or sustained period. Level 2 (20,000 ft) was reached in 1 min and sustained for 9 min with no visible variations during the ascent or sustained period. This altitude (20,000 ft) exceeded twice the computer and data acquisition board manufacturers' altitude specification. Level 3 (25,000 ft) was reached in 1 min and sustained for 9 min. A variation in the LCD screen display was noted during the ascent and sustained period. A shifting (migration) of four of the data display lines occurred throughout the period at 25,000 ft. The effect of pressure differential on the LCD screen may have distorted the screen output, and was discussed with the manufacturer. Level 4 (30,000 ft) was reached in 1 min. and sustained for 9 min. The LCD data line shifting was more apparent at 30,000 ft. The software program continued to collect data. At the 30,000 ft, the brain-mapping data acquisition board and computer specifications had exceeded three times the manufacturer's operational altitude specifications. Level 5 (35,000 ft) was reached in 1 min and sustained for 9 min. The data line shift persisted but stabilized. One possibility is that the lines could not shift any further due to the display boundaries established by the software. Only the top four waveform display lines on the LCD screen were affected, and display returned to normal on descent below 25,000 ft. The software program continued to operate and acquire data.

PROFILE B: RAPID DECOMPRESSION (CABIN PRESSURE LOSS)

The computer system was placed in the outer lock in the chamber adjacent to the main cabin of the LPC and brought to 800 ft. The main cabin of the LPC was taken to 25,000 ft when the equalization dump valve was opened to allow pressurization as quickly as possible. The computer system in the lock in chamber ascended to 22,000 ft (6.21 psi) in 2.07 s. The LPC cabins returned to sea level (0 ft altitude or 14.70 psi) in 7 min. The profile was designed to simulate a cabin pressure loss (rapid decompression) from 8,000 ft to 22,000 ft, followed by a rapid descent to sea level. There was no visible damage during ascent or descent other than the LCD shifting noted in Profile A. The target altitude (pressure) 22,000 ft (6.21 psi) was reached in 4.4 min. The computer system operated throughout the test. Computer system integrity checks performed after the test indicated that data were acquired throughout the entire test cycle were intact and readable.

CORIOLIS ACCELERATION PLATFORM

The goal of this phase was to assess the computer's ability to successfully acquire synthetic biological data during acceleration and deceleration. The LCD screen was monitored in real time during the centrifuge run by onboard video cameras and recorded on video tape for later analysis. A read/write program was written to assess the hard drive's ability to accept readable data during changing g forces. Data were written to the computer hard drive at a rate of three writings per second to evaluate the effect of high-speed deceleration.

PROFILE A

The computer system was secured in a upright position, with the long axis of the computer aligned with the acceleration vector, in a metal container 20 ft out on the centrifuge arm of the Coriolis Acceleration Platform. The position was chosen to simulate the normal upright operating position. From a stationary position, the platform was accelerated at 5 deg/s^2 in 0.5 G-force increments up to the normal operating condition of 4.26 G forces.

PROFILE B

The computer was secured on its back (screen facing upward) in the metal container, 20 ft out on the centrifuge arm of the CAP to test read/write capabilities in an alternate position. From a stationary position the platform accelerated at 5 deg/s^2 in 0.5 G force increments to a maximum operating speed of 6.5 G. When the maximum acceleration was reached, the platform brake was applied, rapidly decelerating the computer to a complete stop.

RESULTS: ACCELERATION/DECELERATION

The computer system was removed from the CAP, and diagnostic tests were performed. The computer system withstood all acceleration profiles and continued to acquire data. Review of the video tape of the LCD screen during the profile revealed no distortions.

APPRAISAL

The brain-mapping system withstood physical and environmental stressors far above the manufacturers' specifications. Norton Utilities® Version 6.0, PC Tools® Version 6.0, and Microsoft® Version 6.21 Scandisk® and Checkdisk® Utilities were used to test for hard drive integrity and functionality. A word processing program was loaded onto the hard drive following the durability test, and several paragraphs were drafted and printed and the program functioned without any noticeable problems. The computer power ON/OFF switch should be replaced with a more durable heavy-duty switch.

The display line migration on the LCD could affect interpretation of data being analyzed in realtime under certain conditions. This distortion was transient at altitudes above 25,000 ft, affected only the top four lines of the LCD screen and did not interfere with computer operations, and returned to normal on descent below 25,000 ft. The display line shifts seem to be attributed to the LCD display screen structure, which is not as rugged as a CRT. Data acquisition during LCD display migration was not affected and was intact for later analysis.

CONCLUSION

The Dolch® 486Dx 33MHz computer, Bio-logic® Brain-mapping Data Acquisition hardware, and Bio-logic® Sleepscan Express software systems functioned and acquired data at all altitude/ pressure differentials, temperature/humidity, and acceleration/deceleration profiles tested. Specifications established by the various component manufacturers were exceeded in all test series.

ATTACHMENTS

1. Federal Drug Administration Letter
2. Bio-Logic® Systems Corporation Letter
3. Bio-Logic® Systems Corporation Fax
4. Environmental Specifications
5. Environmental Chamber Circular Data Chart
6. Component Specifications
7. Altitude Chamber Video (available on request)

COPY

Department of Health & Human Services

Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

Ms. Cathy Buhner
Bio-Logic Systems Corporation
One Bio-Logic Plaza
Mundelein, Illinois 60060-3700

Re: EMG Navigator and EMG Traveler
Dated: October 5, 1993
Received: October 18, 1993

Dear Ms. Buhner:

We have reviewed the information dated October 5, 1993, regarding the 510(K) notification (K893130) previously submitted for the device referenced above. Based solely on the information that you have provided, it does not appear that you have significantly changed or modified the design, components, method of manufacture, or intended use of the device referenced above (see 21 CFR 807.81(a)(3)). It is, however, your responsibility to determine if the change or modification to the device or its labeling could significantly affect the device's safety or effectiveness and thus require submission of a new 510(K). The information you have supplied will be added to the file.

If you have any questions regarding the contents of this letter, please contact Marie A. Schroader, M.S., P.T. at (301) 594-2036.

Sincerely yours,

/s/

Paul R. Beninger, M.D.
Director of General and Restorative Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Attachment 2.

COPY

Bio-Logic
One Bio-Logic Plaza
Mundelein, Illinois 60060-3700
(800) 323-8326 Fax: (708) 949-8615

October 5, 1993

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, MD 20850

Ref: K893139 - EMG Navigator and EMG Traveler
K844992A - Navigator and Traveler Evoked Potential Products
K930328 - Navigator and Traveler Evoked Potential Products

Document Control,

We received a finding of SE for our 510K submission ref.#K930328 in July of this year. That submission detailed a modification to current EP and EMG products (ref.# K893130 and K844992A). This letter is to inform you that we are adding new proprietary names for these products. These new names are listed below. In no way are the design, function, or intended use affected. This letter is for information purposes only. Please add it to your files for the above referenced submissions.

EXPLORER (Desktop version)
EXPLORER Express (Portable version)

These products may have EMG-only capabilities, EP-only capabilities, or a combination of both.

If additional information or clarification is necessary, do not hesitate to contact me at (708) 949-5200, ext. 281 or at the above address.

Respectfully,
/s/
Cathy Buhner
FDA Liaison

COPY

Bio-Logic Systems Corp
One Bio-Logic Plaza
Mundelein, Illinois 60060-3700
Tel (708) 949-5200
Fax: (708) 949-8615

FACSIMILE MESSAGE

ATTN: JOHN BUCCI
COMPANY: C/O NAMRL, PENSACOLA, FL
FAX: 1 904 452 9290

DATE: 29 SEP 94

FROM: BOB TARASEWICZ
EXT: 249
RE: CEEGRAPH HARDWARE SPECIFICATIONS

COPIES:

TOTAL NUMBER OF PAGES (INCLUDING THIS ONE): ONE

I HOPE THAT THE FOLLOWING INFORMATION WILL ANSWER SOME OF YOUR QUESTIONS REGARDING HARDWARE RELATED TO THE CEEGRAPH "E" SYSTEM. THIS DOES NOT INCLUDE THE Dolch® PORTABLE COMPUTER, WHICH YOU MENTIONED WOULD NOT BE USED IN YOUR EXPERIMENTS.

OPERATING SPECIFICATIONS

TEMPERATURE	+5 TO +35 C
HUMIDITY	15% TO 95% NON-CONDENSING
ALTITUDE	UP TO 15,000 FT
VIBRATION	2.0 G @ 5-500 Hz
SHOCK	30 G (NO POWER APPLIED)
STORAGE	-40 TO +70 C

I WILL CALL YOU WITH MORE INFORMATION REGARDING YOUR OTHER QUESTIONS. I HOPE THAT THE ABOVE SPECIFICATIONS HELP YOU IN YOUR PREPARATION.

SINCERELY,
/s/
BOB TARASEWICZ
ENGINEERING

COPY

ENVIRONMENTAL SPECIFICATIONS - P.A.C. PORTABLE ADD-IN COMPUTER LINE

APPLICABLE FOR ALL P.A.C. MODELS

OPERATING CONDITIONS:

TEMPERATURE RANGE:	41 DEG. TO 95 DEG. F (5 DEG. TO 35 DEG C)
HUMIDITY RANGE:	20% TO 80%
ALTITUDE:	-200 TO 10,000 FT
OPERATING SHOCK	3 Gs
OPERATING VIBRATION	0.5 Gs PEAK

STORAGE CONDITIONS:

NON-OPERATING SHOCK	30 Gs
NON-OPERATING VIBRATION	3 Gs PEAK

TEMPERATURE RANGE:	-4 DEG. TO 122 DEG. F (-20 DEG. TO 60 DEG. C)
HUMIDITY RANGE:	10% TO 90%
ALTITUDE:	40,000

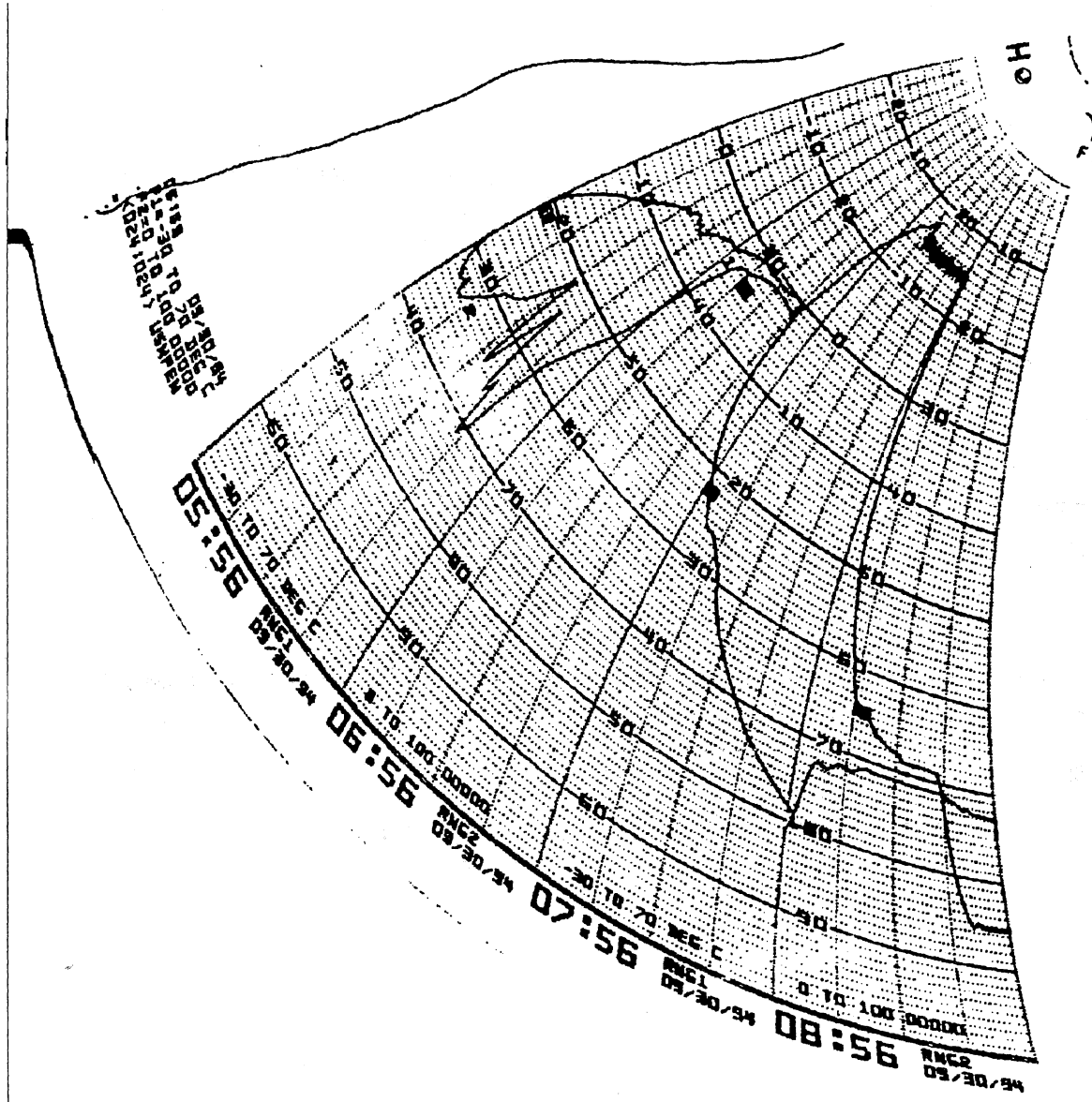
MAGNETIC FIELD:

THE EXTERNALLY INDUCED MAGNETIC FLUX DENSITY MAY NOT EXCEED 6 GAUSS AS MEASURED AT THE UNIT SURFACE.

MTFB: 20,000 HR

(SPECIFICATIONS ARE SUBJECT TO CHANGE WITHOUT NOTICE)

COPY



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ProDrive LPS 120AT/240AT

LOGICAL CONFIGURATION	<u>120AT</u>	<u>240AT</u>
Data Cylinders	901	723
Read/Write Heads	5	13
Sectors/Track	53	51

PERFORMANCE SPECIFICATIONS

Data Transfer Rates

Buffer to AT Bus	5.0MB/s	5.0MB/S
Disk to Buffer	3.75MB/s	3.75mb/s
Cache Size	256KB	256kb

SEEK/MISCELLANEOUS TIMES

	Typical Nominal Worst Case <u>Condition</u>	Maximum Nominal <u>Condition</u>
Average seek time (msec)	16 19	17
Track-to-track (msec)	N/A 4	N/A
Third-stroke seek (msec)	17 20	18
Full-stroke seek (msec)	30 35	32
Average rotational latency (msec)	6.97 6.97	6.97
Sequential head switch (msec)	2.0 TBD	2.0
Power-on to drive ready (sec)	N/A 16	N/A
Power-on to interface ready (sec)	10 10	N/A
Stand-by to drive ready (sec)	N/A 16	N/A

PHYSICAL SPECIFICATIONS

Environment Specification	<u>Operating</u>	<u>Nonoperating</u>
Temperature	5° to 55°C 41°F to 141°F	-40°C to 70°C -40°F to 158°F
Temperature gradient	20°C/hr	48°C/hr
Humidity (no condensation)	8-% to 80%	5% to 95%

Maximum wet bulb	26°C	46°C
Altitude (relative to sea level)	0 m to 2048 m	12.192 m
	0 ft to 10,000 ft	40,000 ft

Power Requirements

Average power consumption (Startup)	11.92 watts
Average power consumption (idle)	<5.1 watts
Average power consumption (Random R/W)	<6.3 watts

Voltage	+12V DC +10%/-5%	+5V DC ±5%
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Power Reset Limits	<u>DC Voltage</u>	<u>Threshold</u>
	+5V	4.5 to 4.6V
	+12V	9.6 to 10.2V

Power Sequencing

You may apply power in any order or manner, or short or open either the power or power return line with no loss of data or damage to the disk drive. However, data maybe lost in the sector being written at the time of power loss. The drive can withstand transient voltages of +10% to -100% from nominal while powering up or down.

Shock and Vibration Specifications	<u>Operating</u>	<u>Nonoperating</u>
Vibration		
5-5000 Hz Sine Wave (peak-to-peak)	0 G	2.0 G
1 Oct/Min Sine Sweep		
Shock	6.0 G (no soft errors)	
½ Sine Wave of		70.0 G
11 msec Duration	10.0 G (one soft error/block)	
(10 hits maximum)		
Acoustics	Measured Noise	Distance
Idle Mode	45 dba (mean)	12 in
45 dba (maximum)	12 in	
Seek Random	50 dba (mean)	12 in
	53 dba (maximum)	12 in

RELIABILITY SPECIFICATIONS

MTBF	70,000 (power on hr) typical usage
(mean time between failure)	250,000 hr (field ORT)
PM (preventative maintenance)	None
MTTR (mean time to repair)	30 min
Start/Stop	10,000 cycles (minimum)

PHYSICAL CONFIGURATION

Physical Specification	<u>LPS120AT</u>	<u>LPS240AT</u>
Formatted Capacity (MByte)	122	245
Read/Write Heads	2	4

Attachment 7.

ALTITUDE CHAMBER VIDEO

Available on request from the senior author:

John Dal Santo
MCJ Corporation
5301 East State Street, Suite 116
Rockford, IL 61108
(815) 399-5097

Reviewed and approved

12.6.95



J. C. PATEE, CAPT, MSC, USN
Commanding Officer



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