

SUMMARY OF A BLOOD PRESSURE STUDY AT SOUTHWEST MEDICAL SCHOOL, DALLAS, TEXAS
February 8-14, 1981

MEDICAL GOAL - To obtain 24-hour blood pressure records of 11 hypertensive male juveniles, 17-19 years old, and a matched cohort, all intensively studied for up to 5 years by Dr. Fixler, Chairman, Pediatric Cardiology.

TECHNICAL GOAL - To compare P-III's with increased gain to those with older gain settings.

EQUIPMENT -

P-III's:

S/N's:	212	}	Supplied by Del Mar Avionics with original gain settings designated LO.
	214		
	236	}	UTMB, modified to increase gain, designated HI
	241		
	256	}	Units on loan to scanning service, latest production, designated HI
	?		
	?		

1979's 2 each

TRS 80 UTMB

PERSONNEL - Thornton, Wallace, W's technician, F's technician, and Terry Hart (scanning service)

FACILITIES - Large lab with excellent support—very well-arranged schedule, totally supported.

PROCEDURES - Either Thornton or Wallace installed and calibrated all BPR's and confirmed operation with 1979 playback. Checked, by phone, all subjects at least once and went to homes in event of suspected malfunction.

Two teams with complete equipment including 1979's went to two schools with two subjects/school typical. Immediate replay with 1979 and then analysis by TRS-80.

SOUTHWEST STUDY RESULTS, continued, Page 2

MEDICAL RESULTS - Twenty-one partial or complete records out of 23 final attempts (two repeats). Records now in analysis.

TECHNICAL RESULTS -

GENERAL - numerous failures, many old friends, some new.

Pressures were highly variable in this population with good to excellent systolic sounds and good to poorly defined diastolic sounds, i.e., extended transition from phase IV to V with high systolic and low DBP, many large muscular arms.

Failures - summary

Straps - 5 metal strap to BPR studs swivels failed
1 strap stud (S/N 214)

Batteries -

Failed after 135 cycles	}	Large cuff, used, fully charged 12+ hours
Failed after 180 cycles		
Failed after 85 cycles		Standard cuff, new, 3+ hours charged

Memories -

S/N 256 - stored only one line, operated and calibrated (on and off) normally. N.B. Would not load data with fresh battery, but functioned normally after sitting in Standby for 24 hours.

S/N 212 - refused to accept data in memory with fresh battery after a normal run—left with battery for 24 hours and then functioned normally.

S/N's ____ and ____ - (shipped from St. Louis) both refused to calibrate properly and to store data when first tried with freshly charged battery—functioned normally after 24 hours with battery in and on Standby.

Failures, continued

Transducers - minimum of 6 failures on installation—either refusal to record any value or only record a narrow (10-20 mm) pulse pressure in mid-range. All recorded normally after a minimum rest period of 24 hours.

Sleep Drop-out Failures - This was complicated by necessity of setting LO units to high sensitivity twice (treated as HI units) and HI units to low sensitivity three times (treated as LO units) and HI unit to high sensitivity once (treated as HI unit).

Sleep Failures, Summary

Attempts (Final)

<u>High Gain</u>	<u>Low Gain</u>	<u>S/N</u>
	5	212
2	4	214
2	2	236
5	1	241
<u>1</u>	—	256
10	12	

NOTE: See previous note on gain designation and setting.

Failures, continued

Sleep Records Lost

<u>Rate</u>	<u>BPR</u>	<u>Transducer</u>	<u>Comment</u>	<u>Sens.</u>	<u>Cuff</u>
12	214	1463	Approx. 50% lost	H	Std.
14	214	?	Approx. 80% lost	N	Std.
10	212	1568	Approx. 50% lost	N	Std.
10	241	1624	Approx. 1-½ hrs. lost	H	Large
12	241	?	Approx. 50% lost	N	Large
14	256	1082	100% lost	N	Large

Failures - LO - 2 HI - 4
 % Fail - LO - 16 HI - 40

Calibration Error

It was necessary to increase gain to HI on 2 of 10 attempts with LO gain units and to decrease gain to LO on 3 of 11 with HI gain units. N.B. It was necessary to increase gain on 2 of 11 attempts to record with HI gain units and this still lost a portion of the sleep record.

Results from the above modified gains are not included in the following data.

Calibration HI vs LO (continued)

Comparison on same subject with excellent sounds and sharp end points—4 trials each unit. Auscultatory readings taken as standard, same transducer and observer.

S/N		Mean Error/Standard Deviation mmHg	
		<u>SBP</u>	<u>DBP</u>
LO	214	0/2.9	-2.5/5.
	212	<u>+2/1.3</u>	<u>-0.8/3.1</u>
Mean		1/2.1	-1.7/4.1
HI	236	+0.3/0.6	+1.3/2.1
	246	<u>-0.3/5.9</u>	<u>+0.8/3.6</u>
		0/3.3	1.3/2.9

difference probably

not significant

		Apply		Remove		Mean
S/N		Mean error (mmHg) of 3 positions (9 trials)				S/D
10	214	-1.8/	+3.3/	-0.5/	+7.11	
8	214	-1.8/	-2.3/	-2.0/	-1.3/	
9	214	<u>-4.0/</u>	<u>-2.3/</u>	<u>-9.2/</u>	<u>+4. /</u>	
	Mean	-2.5	-0.4	-3.9	+4.1	
8	212	0/	-5. /	0.7/	+4.3/	
11	212	+0.4/	-0.1/	-3.1/	+6.9/	
12	212	+1.9/	-3. /	+0.9/	-2.8/	
13	212	<u>+2.8/</u>	<u>-3.7/</u>	<u>—</u> *	<u>—</u> *	
	Mean	+1.7	-3.9	-0.5	+2.8	
Total Mean						
of LO Units		-.8/	-2.0/			

*Unit failed.

Calibration HI vs LO, continued

Date	S/N	<u>Apply</u>		<u>Remove</u>	
		SBP	DBP	SBP	DBP
10	241	-0.4/	-0.4/	— *	— *
11	241	<u>0/</u>	<u>3.7/</u>	<u>-5.7/</u>	<u>+3.1/</u>
	Mean	-0.2	+1.7/	-5.7	+3.1
9	236	-2.2/	-4.4/	-1.7/	0/
11	236	-6. /	+2.4/	-5.7/	-1.3
12	236	<u>-4.3/</u>	<u>-3.5/</u>	<u>+0.9/</u>	<u>+2.3</u>
	Mean	-4.	-1.8	-2.3	+0.3
Tot. Mean of HI Units		-2.5	-0.4	-3.1	+1.3

CONCLUSIONS: First, see DMA memo ENG-72-81 which describes what I found on trying to reconcile above data with supposed changes in gain. I concur entirely with his wondering why the error was not detected by functional tests which I also found to be inconsistent. In short, the intent of the technical test was aborted by errors which resulted in no difference between HI and LO units.

The primary and more important result of the test is a demonstration of the problems we encountered and which were discussed with you.

The system is not ready for general use for the following reasons:

1. It is still unreliable—see the problems noted. (N.B. We did not list the numbers of initial trials, i.e., BPR's, etc., were frequently changed.)
2. Several small additions prevent this from being a usable system for any but the researcher using P-III's and the 1981.
3. With the exception of approximately 6 people, no one knows how to interpret the results.
4. The scanning services don't have any idea how to use the equipment and labor under a load of sales misinformation.

CONCLUSIONS, continued

Attempt to interpret results of units in terms of actual gain; noted as H (high), N (normal) and L (low).

Number of records

<u>S/N</u>	<u>H</u>	<u>N</u>	<u>L</u>
212		5	
214	2	4	
236		2	2
241	2	2	2
256		1	
	4	14	4

Number of Sleep Failures

2	3	0
---	---	---

% of Sleep Failures

50%	21%	0%	Samples are too small to be truly significant.
-----	-----	----	--

It is obvious that increasing gain does not insure against loss of sleep records. Further, it is hoped that this will point up the need to know what total effect changes will have before instituting them, i.e., the gain change should not be done before testing more rigorous than Mac or Engineering can perform.

N.B. Comparison of installation and removal calibrations offer still more evidence for fatigue effects in the transducers. Note that the cumulative means show the DBP calibrations to have risen a mean of +3.75 mmHg and SBP to have fallen -.76 mmHg for a total pulse press. cal. error of -4.5 mm. Although this may seem a small change, it is highly significant under the circumstance.

Individual transducer drifts show much larger drifts. For example, on the ninth, BPR 214 had a Δ SBP calibration of -5.2 and Δ DBP of +6.4, and on the eleventh S/N 212 had a Δ SP of -3.5 and Δ DBP of +7.0. Again, this is a characteristic of the fatigue we see.