19TH European Meeting on Hypertension
MILAN
JUNE 12 - 16, 2009
ESH

Can We Trust Ambulatory Blood Pressure Monitors? Approved Monitor Underestimates Diastolic Pressure & Misclassifies Patients

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BACKGROUND

1. Health-care providers & clinicians urged to consider advantages of using 24-hr ABPM.
2. ABPMs theoretically appealing – up to 200 values ≤ 24 hr
   a. refine classification of suspected hypertensives,
   b. establish diurnal impact of treatments &
   c. tailor specific plans for optimizing BP.
3. Each step is entirely contingent upon obtaining data that is both accurate & reliable.
4. International (ESH, BHS) & US national (AAMI) approval protocols require testing only for subjects who are seated, yet ABPMs that achieve a passing grade are deemed accurate & reliable over 24-hr when patients assume multiple postures.

U.S. National Library of Medicine Database January 1, 1988 – December 1, 2008 www.ncbi.nlm.nih.gov

- 4579 articles with key words *ambulatory blood pressure*
- 91 (~ 2%) contained key word *validation*
- 17 (~ 0.4%) classified as true validation studies
- 3 studies measured all postures for all subjects
- 12 of 19 ABPMs currently available are recommended for use, yet only 2 have been tested for a variety of postures
- 1 ABPM is approved for multiple body positions

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KEY QUESTIONS

1.

If ABPM accuracy & reliability differ based on posture, could this lead to errors in classifying patients & in comparing data?

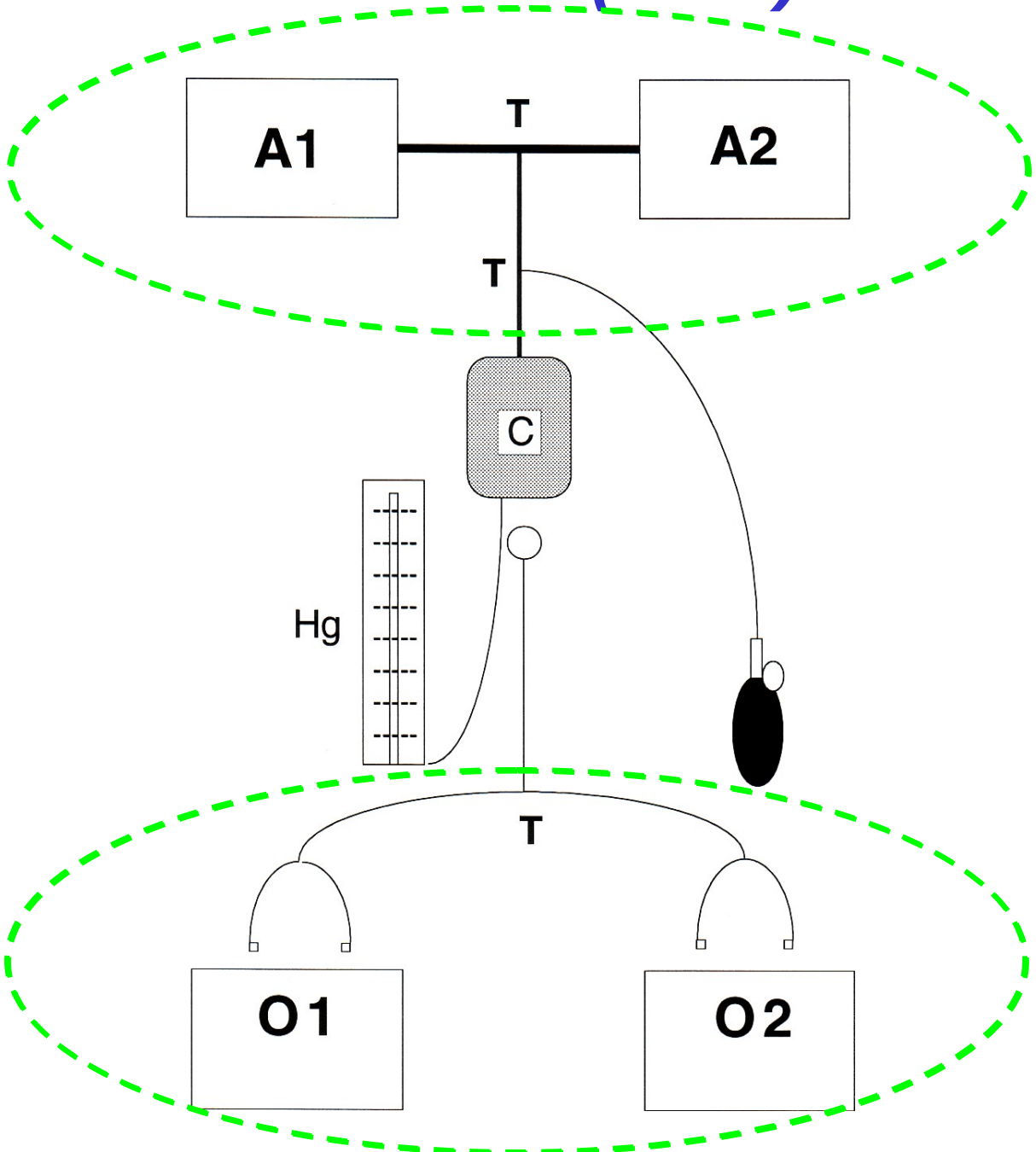
2.

How do two approved, identical ABPMs differ in assessing same arm BPs simultaneously in the lab & in the field?

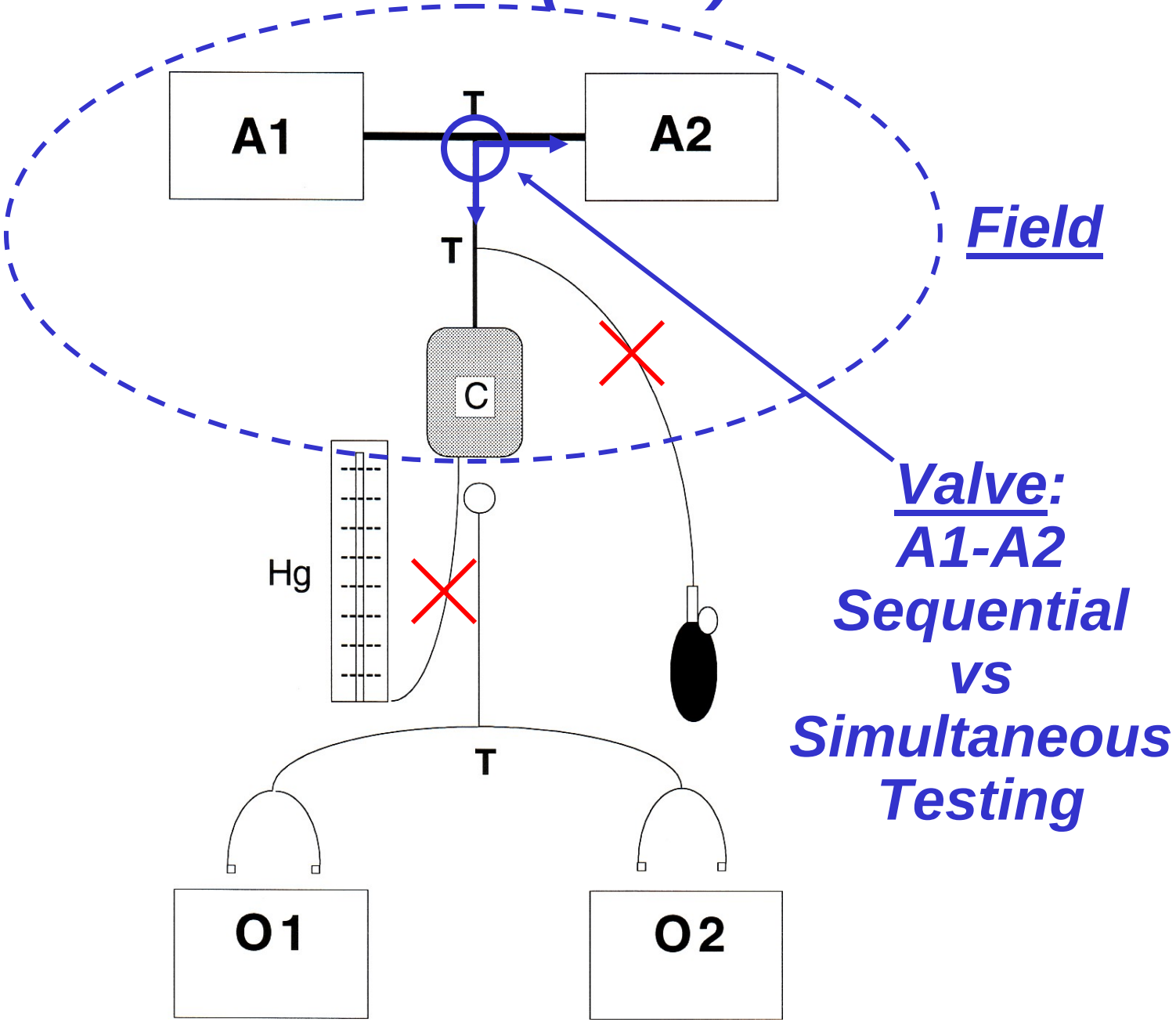
3.

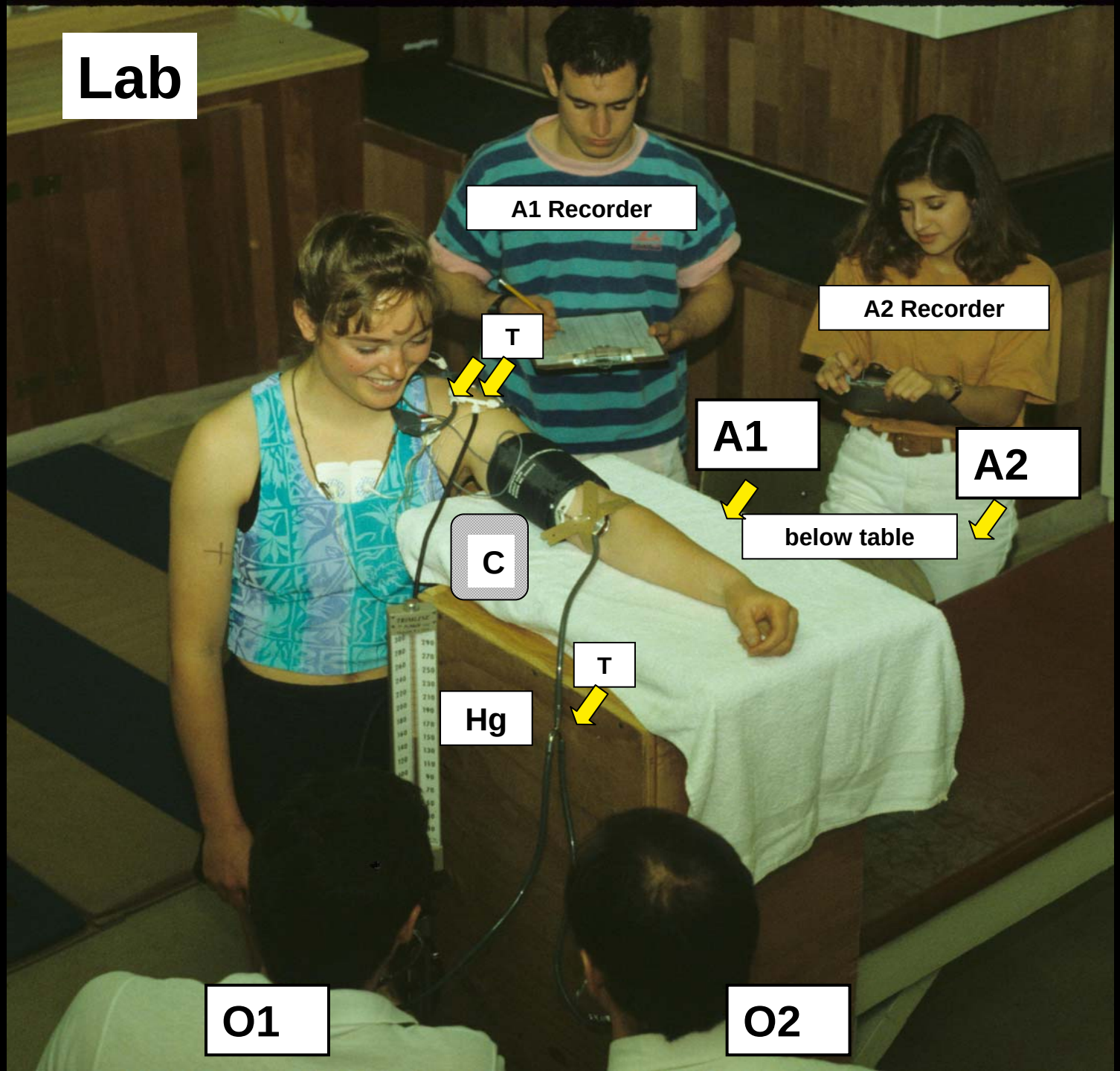
How do ABPMs differ from clinicians using a Hg column when assessing subjects who assume multiple postures?

Dual Monitor Protocol (DMP): Lab + Field



Dual Monitor Protocol (DMP): Lab + Field




Lab
A1 Recorder
A2 Recorder
T
A1
A2
below table
C
T
Hg
O1
O2

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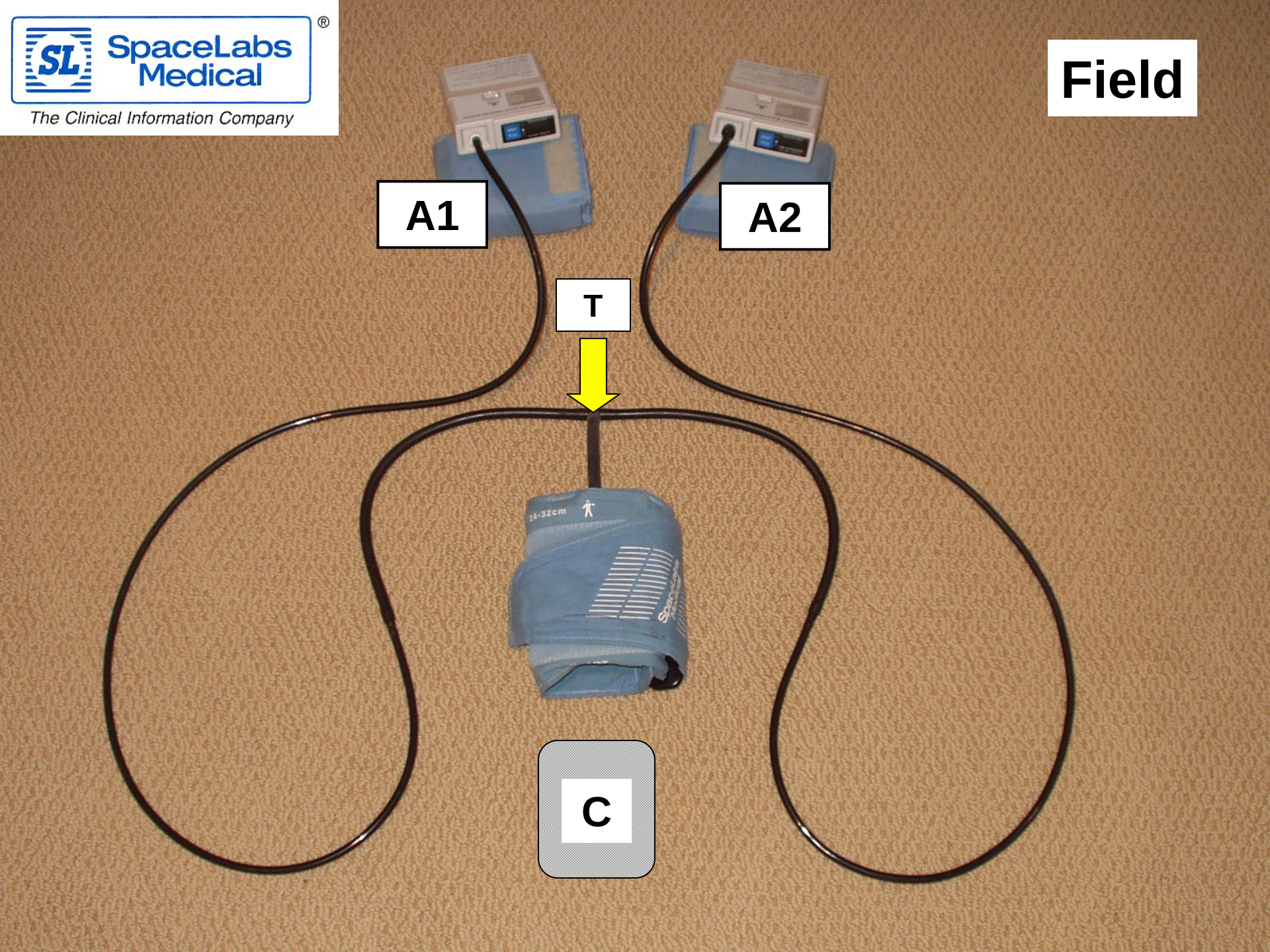
Field



Results Presented Today

Subjects	*Gender*	*Age*
1. 1 Labile HTN	♂	35 yr
2. 15 Normotensives	8 ♀ 7 ♂	24 ± 5 yr
3. 14 Hypertensives	8 ♀ 6 ♂	50 ± 14 yr
4. 11 1^0 ETOH	2 ♀ 9 ♂	38 ± 9 yr

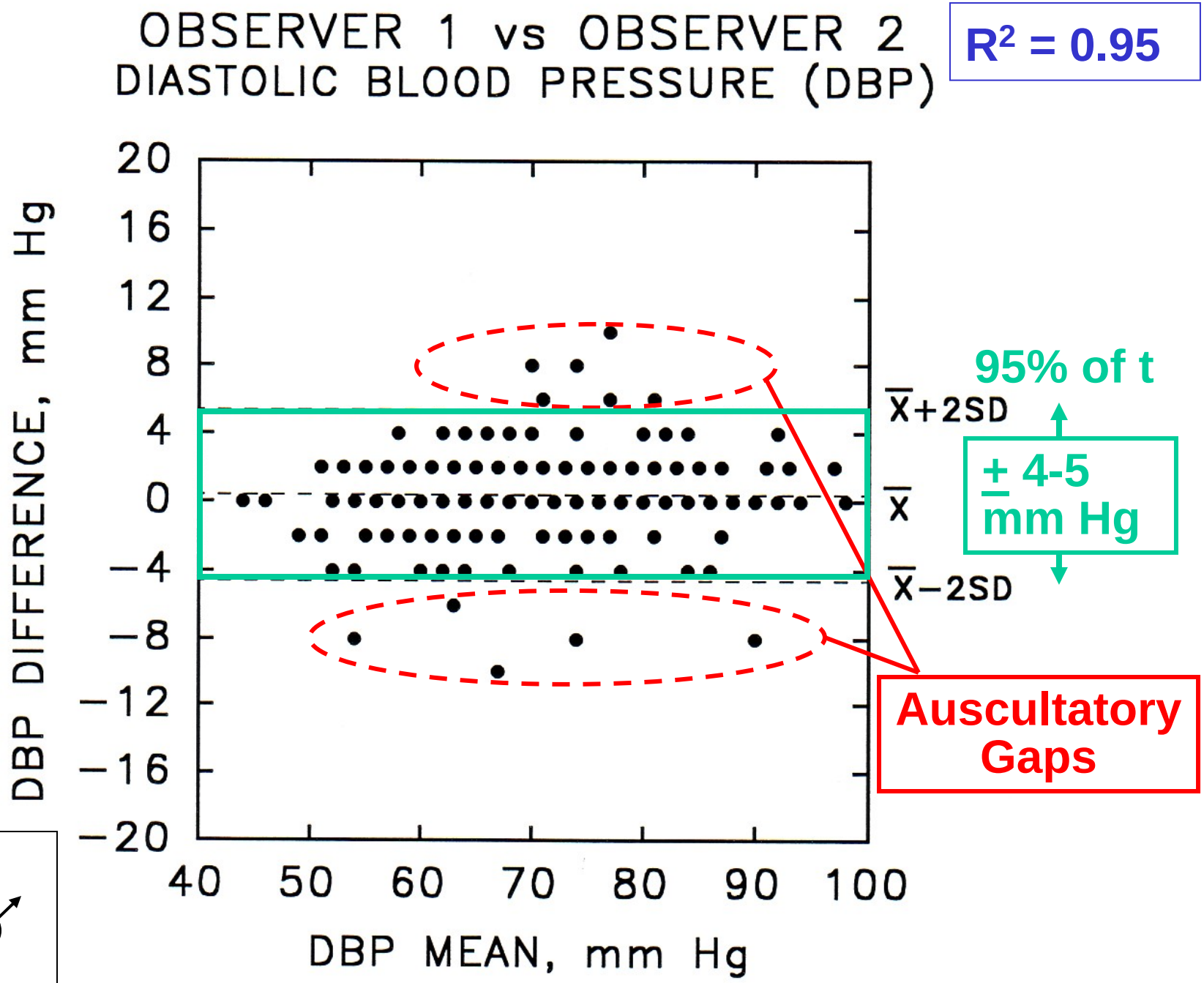
Original Dual Monitor Field Protocol,10 hr Case Study, Labile Hypertensive, 35 yr ♂ 151 Simultaneous, Same Arm BPs

	SBP*** (mm Hg)	△	DBP** (mm Hg)	△	HR** (bpm)	△
A1	134.3 ± 10.8		86.9 ± 8.8		69.2 ± 7.2	✓
		2.7 ± 4.3		1.7 ± 6.6		-0.6 ± 2.7
A2	131.6 ± 11.1		85.2 ± 8.8		69.8 ± 7.3	

**P < 0.01, ***P < 0.001

NB: A1 & A2 accounted for 85% of SBP variance (R = 0.92) but only 52% of DBP variance (R = 0.72)

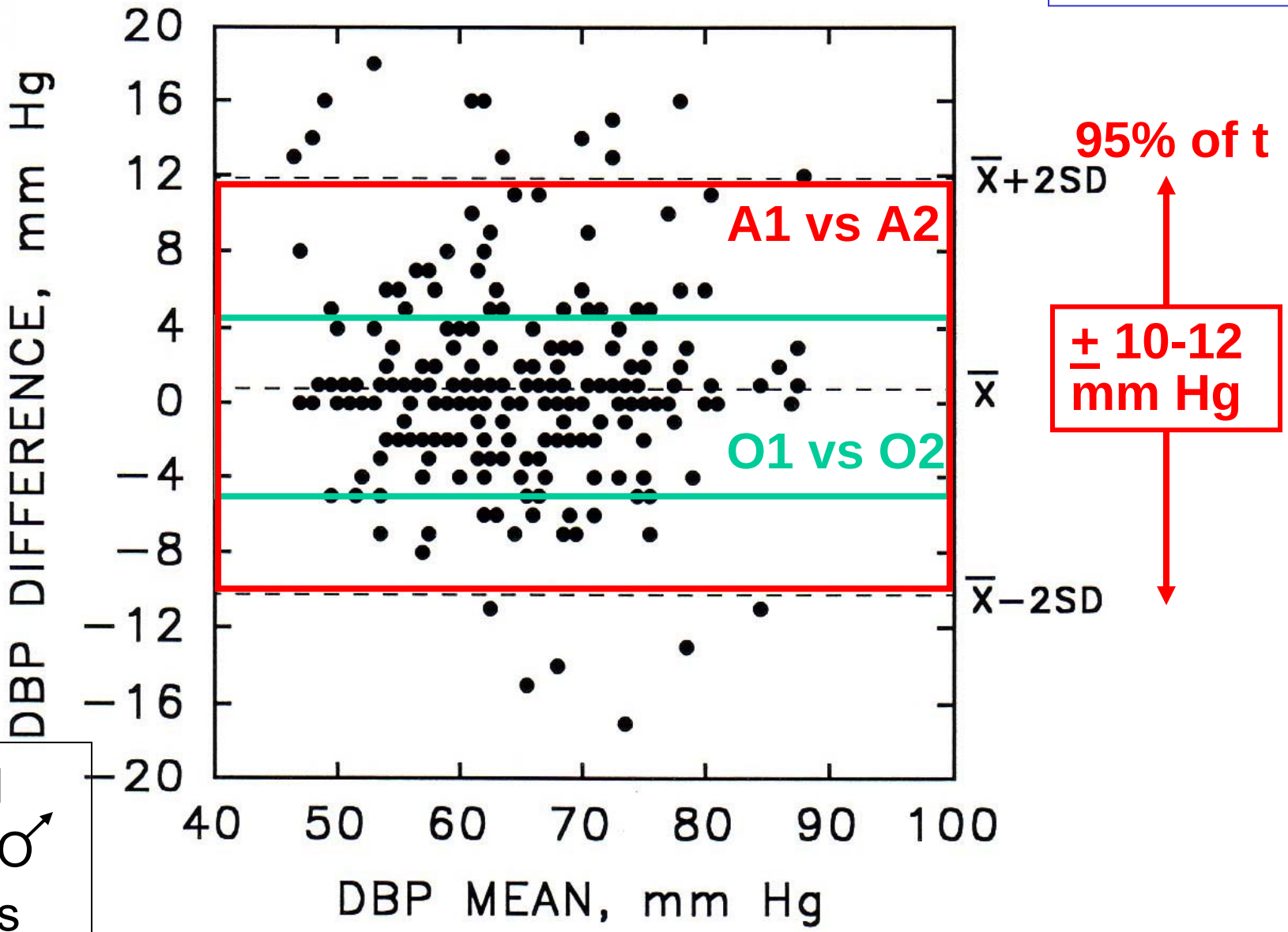
Lab



15 NTN
8 ♀ , 7 ♂
243 BPs

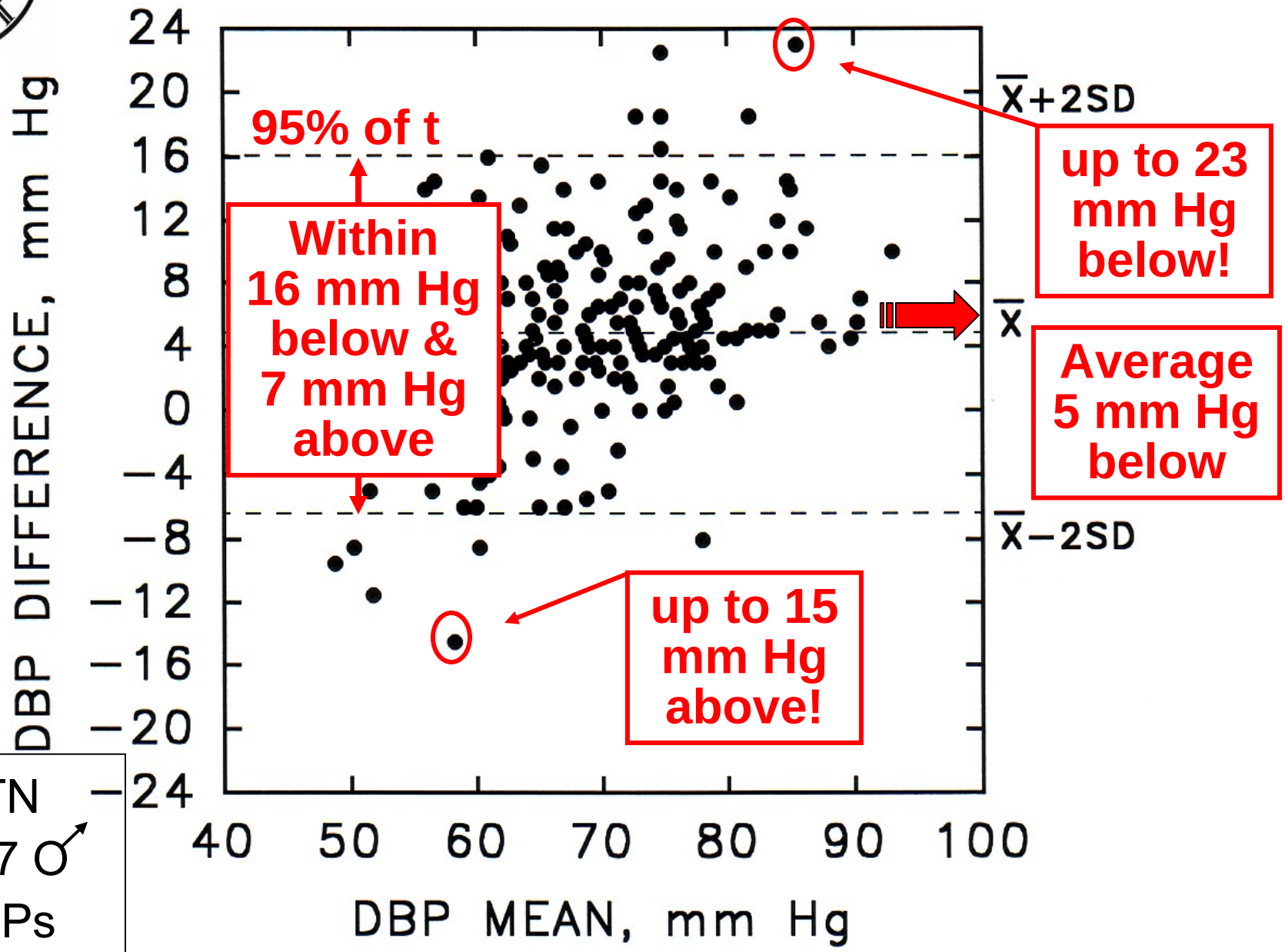
ACCUTRACKER 1 vs ACCUTRACKER 2
DIASTOLIC BLOOD PRESSURE (DBP)

$R^2 = 0.69$



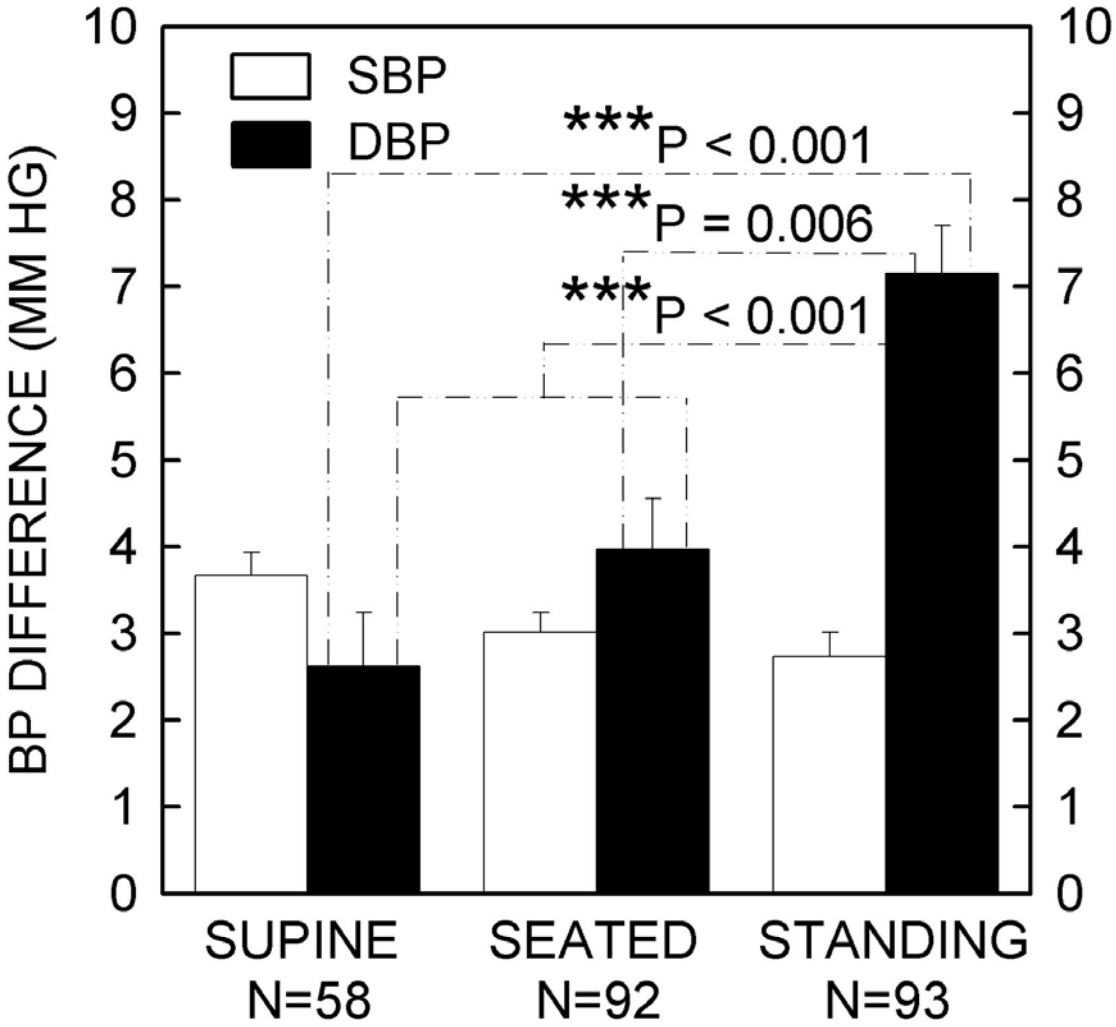
15 NTN
8 ♀ , 7 ♂
243 BPs

OBSERVERS vs ACCUTRACKERS
DIASTOLIC BLOOD PRESSURE (DBP)



15 NTN
8 ♀ , 7 ♂
243 BPs

OBSERVERS vs ABPMs in NORMOTENSIVES
POSTURAL DIFFERENCES

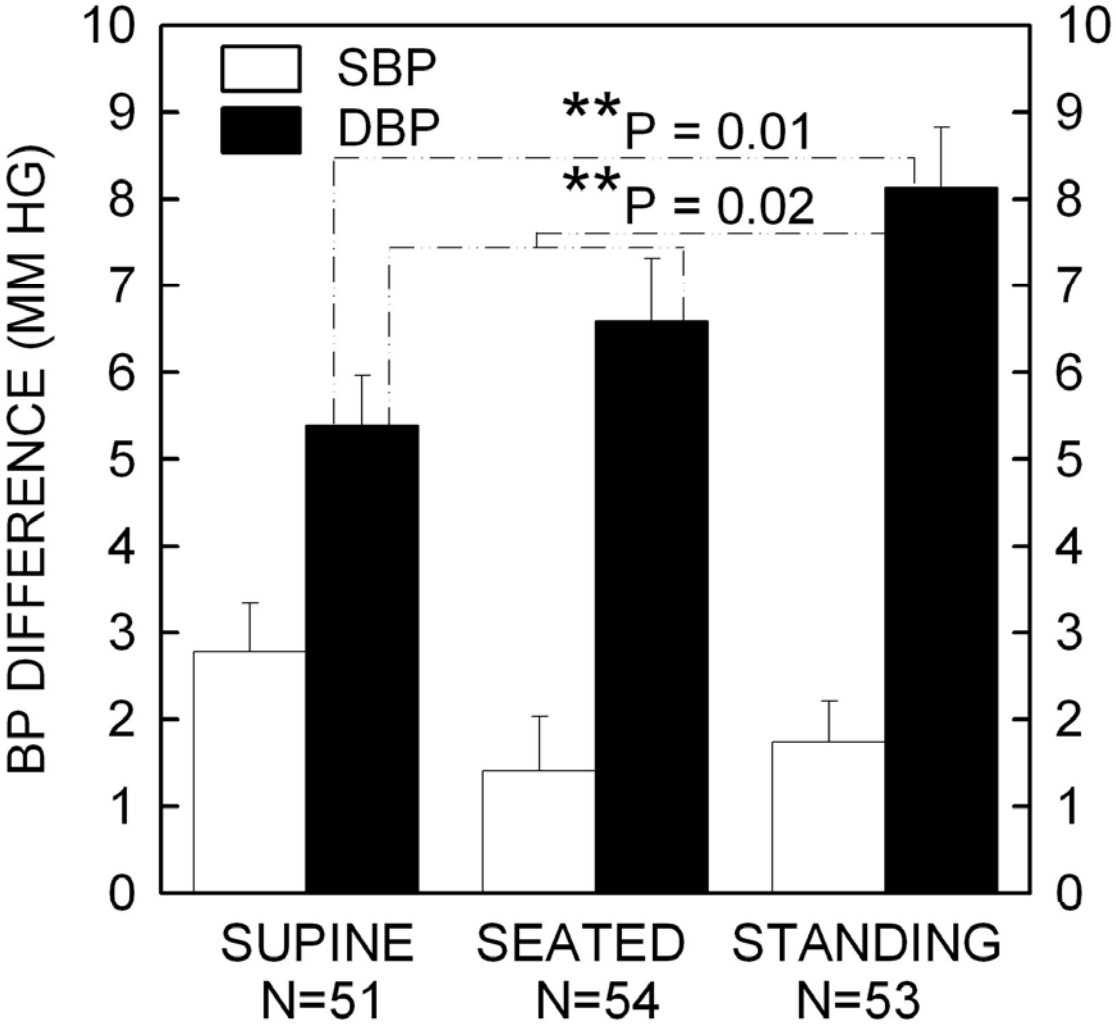


***P < 0.001, DBP Supine vs Standing

***P = 0.006, DBP Seated vs Standing

***P < 0.001, DBP Standing vs Supine & Seated

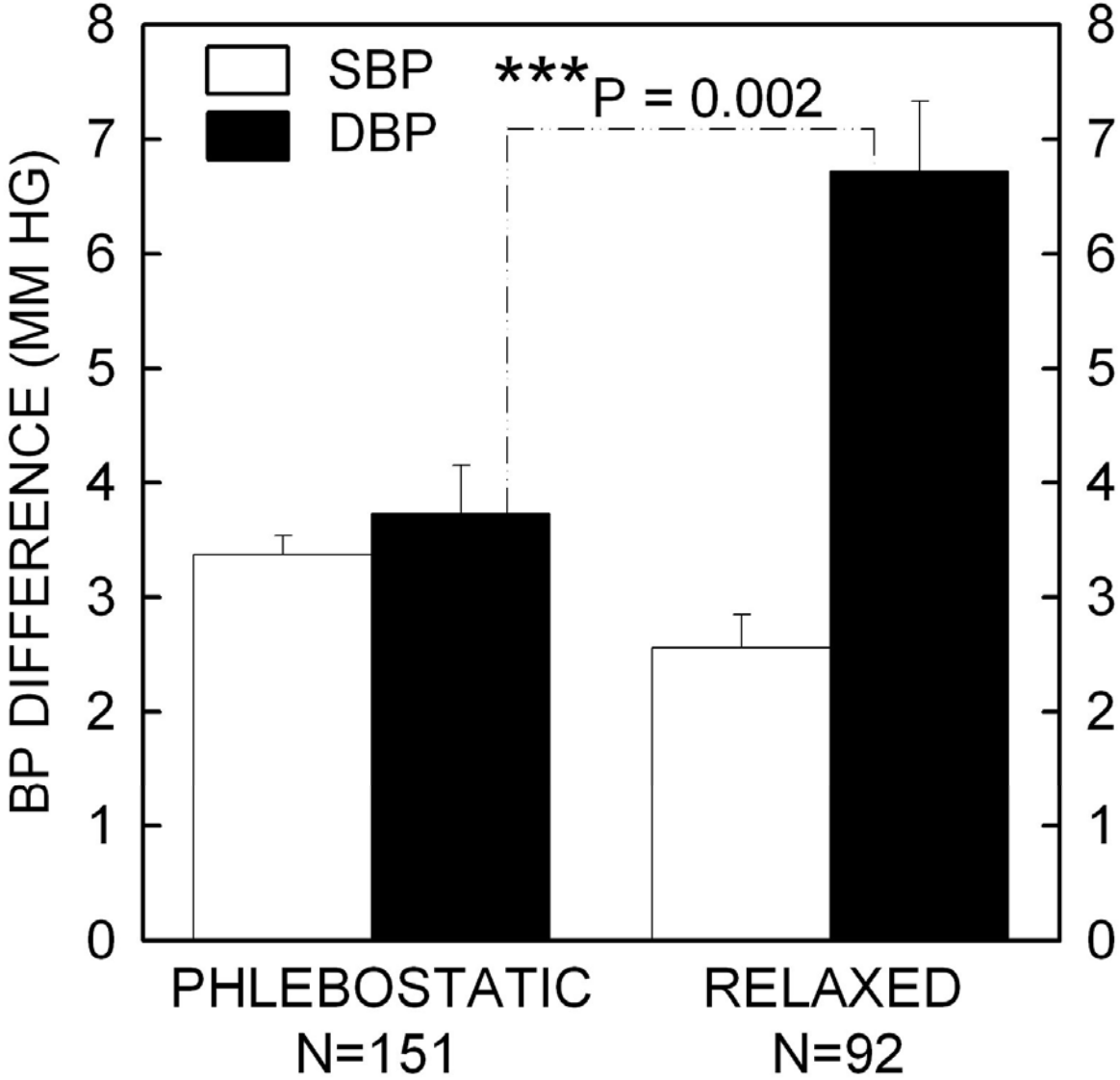
OBSERVERS vs ABPMs in 1^0 ETOH-DEPENDENTS POSTURAL DIFFERENCES



**P = 0.01, DBP Supine vs Standing

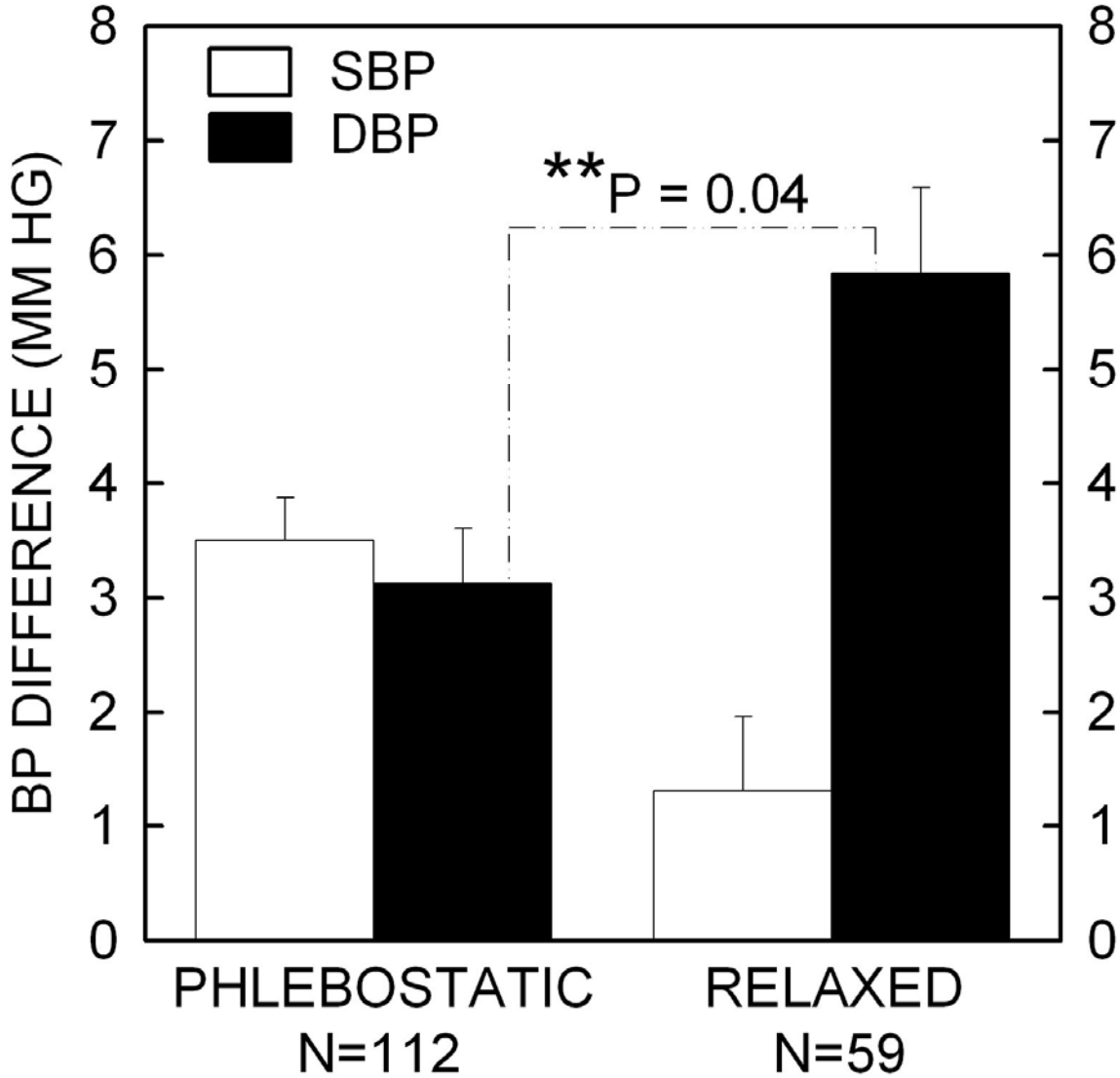
**P = 0.02, DBP Standing vs Supine & Seated

OBSERVERS vs ABPMs IN NORMOTENSIVES
ARM POSITION DIFFERENCES

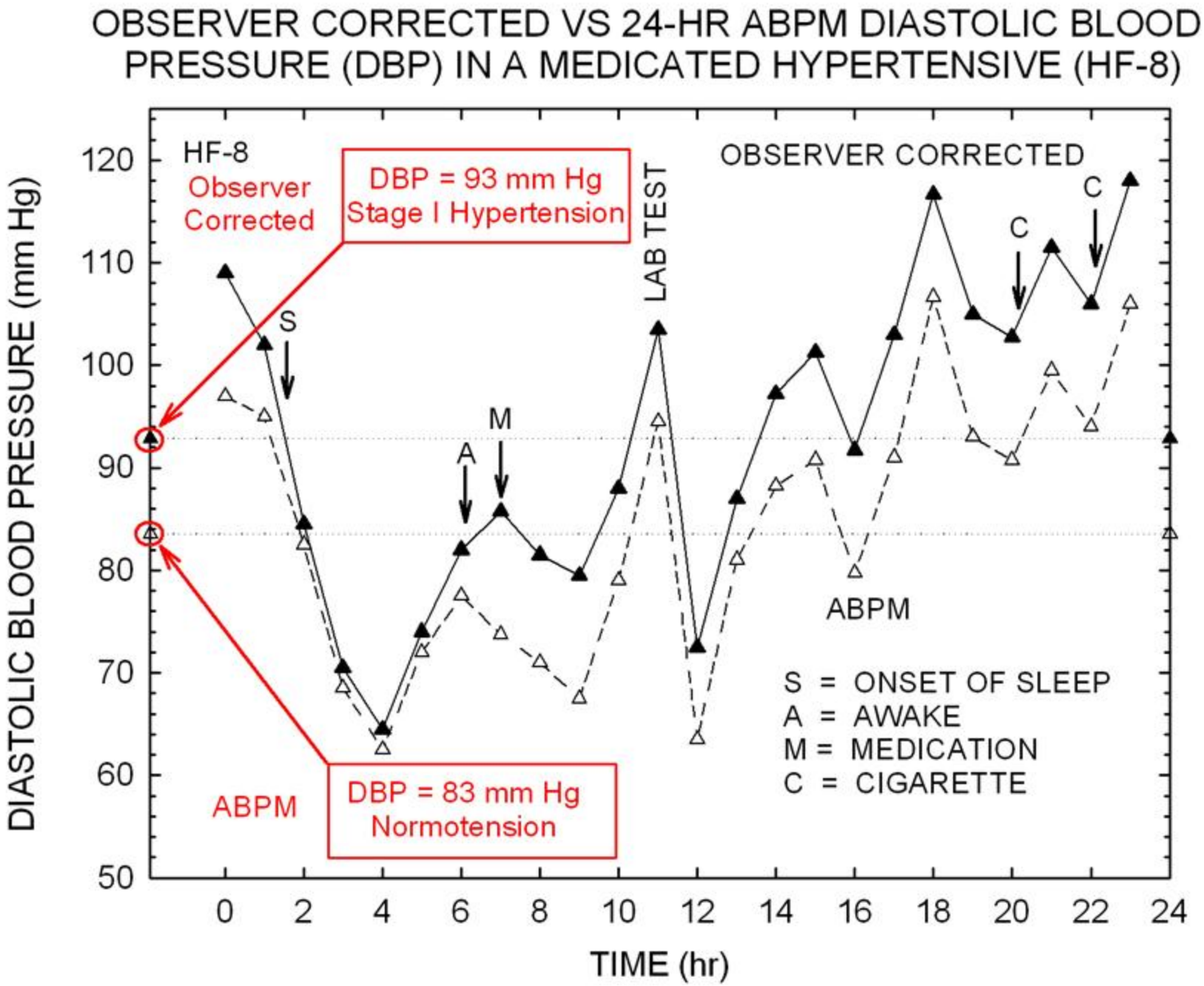


***P = 0.002, DBP Relaxed vs Phlebostatic

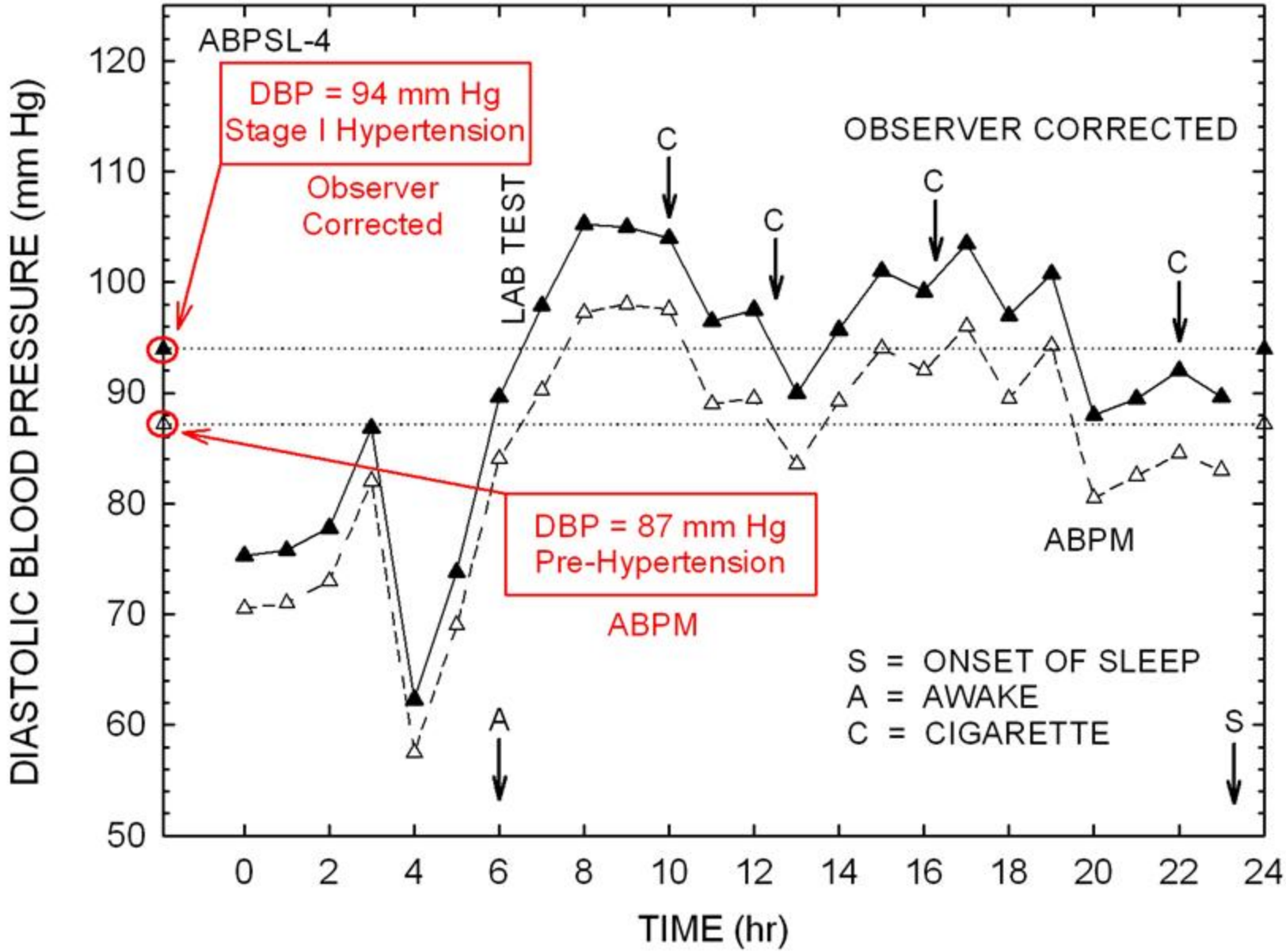
OBSERVERS vs ABPMs IN HYPERTENSIVES
ARM POSITION DIFFERENCES



**P = 0.04, DBP Relaxed vs Phlebostatic


OBSERVER CORRECTED VS 24-HR ABPM DIASTOLIC BLOOD PRESSURE (DBP) IN A MEDICATED HYPERTENSIVE (HF-8)
HF-8
Observer Corrected
DBP = 93 mm Hg
Stage I Hypertension
LAB TEST
OBSERVER CORRECTED
S
A
M
C
C
ABPM
ABPM
DBP = 83 mm Hg
Normotension
S = ONSET OF SLEEP
A = AWAKE
M = MEDICATION
C = CIGARETTE
DIASTOLIC BLOOD PRESSURE (mm Hg)
120
110
100
90
80
70
60
50
0
2
4
6
8
10
12
14
16
18
20
22
24
TIME (hr)

OBSERVER CORRECTED VS 24-HR ABPM DIASTOLIC BLOOD PRESSURE (DBP) IN A PRIMARY ALCOHOL DEPENDENT (ABPSL-4)



CLINICALLY SIGNIFICANT DIFFERENCES IN ABPM & OBSERVER-CORRECTED NHLBI (1997, 2003) CLASSIFICATIONS OF 1275 ABPM FIELD SYSTOLIC (SBP) & DIASTOLIC (DBP) PRESSURES IN 11 PRIMARY ALCOHOL-DEPENDENTS

ABPM vs Observer NHLBI Classification	%SBP Values	%DBP Values
+1 ***ABPM 1 Category Above Observers*** (eg ABPM indicates Prehypertension, Observers Normotension)	3%	1%
+0 ***ABPM Identical Category as Observers*** (eg Both ABPM & Observers indicate Normotension)	85%	44%
-1 ***ABPM 1 Category Below Observers*** (eg ABPM indicates Normotension, Observers Prehypertension)	12%	~40%
-2 ***ABPM 2 Categories Below Observers*** (eg ABPM indicates Normotension, Observers STAGE I Hypertension)	0%	15%
-3 ***ABPM 3 Categories Below Observers*** (eg ABPM indicates Normotension, Observers STAGE II Hypertension)	0%	~1%

56%

CLINICALLY SIGNIFICANT DIFFERENCES IN ABPM & OBSERVER-CORRECTED NHLBI (1997, 2003) CLASSIFICATIONS OF LABORATORY SYSTOLIC (SBP) & DIASTOLIC (DBP) PRESSURES IN 11 PRIMARY ALCOHOL-DEPENDENTS

Patient	BP Source	SBP	NHLBI Class		DBP	NHLBI Class	
1 ♂ 37 yr	Observers	129.7	Normal	✔	87.5	Pre HTN	⊘
	ABPM	127.7	Normal		80.8	Normal	
	Δ	2.0			6.7		
2 ♂ 37 yr	Observers	128.4	Normal	✔	89.1	Pre HTN	⊘
	ABPM	124.5	Normal		80.6	Normal	
	Δ	3.9			8.5		
3 ♂ 49 yr	Observers	155.7	Stage I HTN	✔	92.9	Stage I HTN	⊘
	ABPM	151.2	Stage I HTN		88.4	Pre HTN	
	Δ	4.5			4.5		
4 ♂ 32 yr	Observers	121.8	Normal	✔	86.6	Pre HTN	⊘
	ABPM	120.2	Normal		79.9	Opt Normal	
	Δ	1.6			6.7		
5 ♀ 29 yr	Observers	104.5	Optimal BP	✔	80.3	Normal	⊘
	ABPM	103.8	Optimal BP		71.2	Optimal BP	
	Δ	0.7			9.1		

6 ♂ 31 yr	Observers	119.3	Optimal BP	✔	87.6	Pre HTN	⊘
	ABPM	117.9	Optimal BP		79.9	Optimal BP	
	Δ	1.4			7.7		
7 ♂ 39 yr	Observers	138.7	Pre HTN	✔	91.0	Stage I HTN	⊘
	ABPM	138.2	Pre HTN		84.7	Normal	
	Δ	0.5			6.3		
8 ♀ 35 yr	Observers	114.3	Optimal BP	✔	80.4	Normal	⊘
	ABPM	110.0	Optimal BP		68.4	Optimal BP	
	Δ	4.3			12.0		
9 ♂ 30 yr	Observers	112.5	Optimal BP	✔	81.9	Normal	⊘
	ABPM	109.8	Optimal BP		73.5	Optimal BP	
	Δ	2.7			8.4		
10 ♂ 43 yr	Observers	120.8	Normal	✔	92.6	Stage I HTN	⊘
	ABPM	120.4	Normal		86.4	Pre HTN	
	Δ	0.4			6.1		
11 ♂ 59 yr	Observers	165.1	Stage II HTN	✔	98.8	Stage I HTN	✔
	ABPM	165.1	Stage II HTN		97.1	Stage I HTN	
	Δ	0.0			1.7		

SUMMARY & CONCLUSIONS

1. An approved ABPM significantly underestimates DBP. Two identical model ABPMs have a lower level of agreement than two clinicians using a Hg column.

2. The magnitude of ABPM underestimation is statistically & clinically significant & varies according to posture.

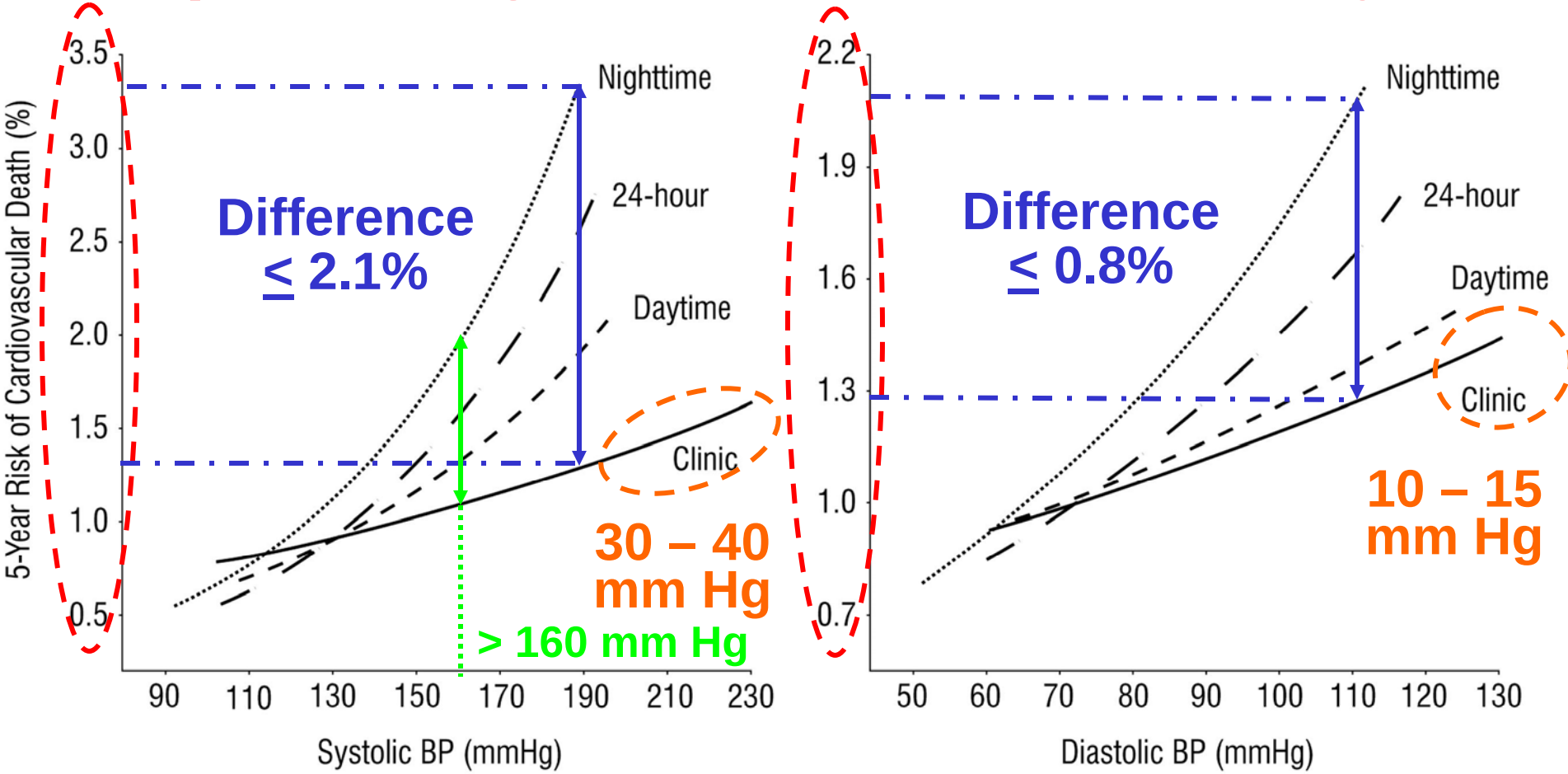
3. Diastolic pressure underestimations are greatest when subjects are awake & standing with the arm relaxed.

4. Variable underestimations may lead to misdiagnosis & mismanagement of patients & to errors in interpreting research results.

5. International (ESH, BHS) & US National (AAMI) approval protocols should be revised to require testing for a variety of postures. Without more comprehensive, postural & activity testing, ABPMs cannot be claimed as approved for truly ambulatory conditions.

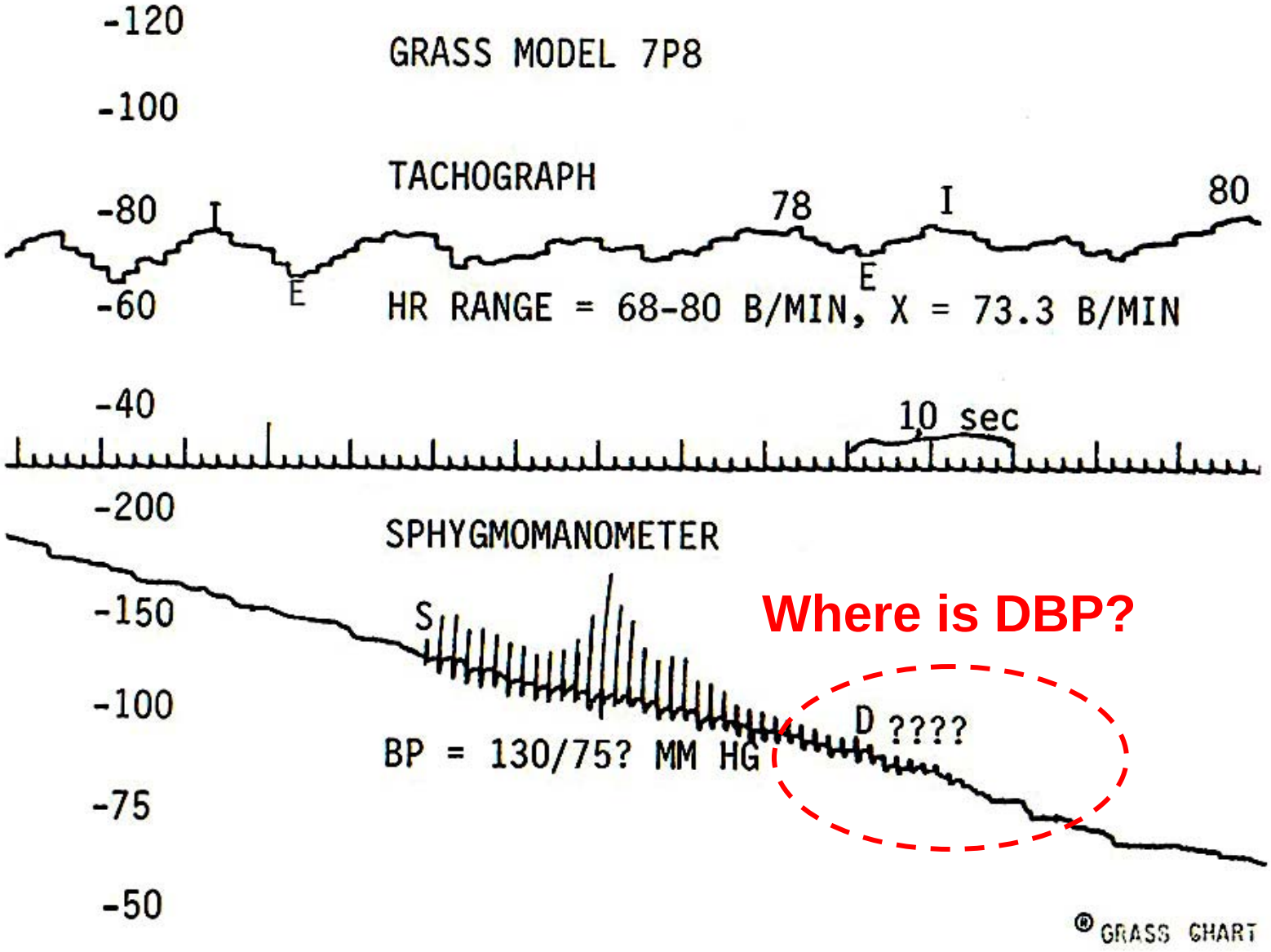
DISCUSSION

Are ABPMs truly superior to Clinic BPs in predicting cardiovascular mortality?

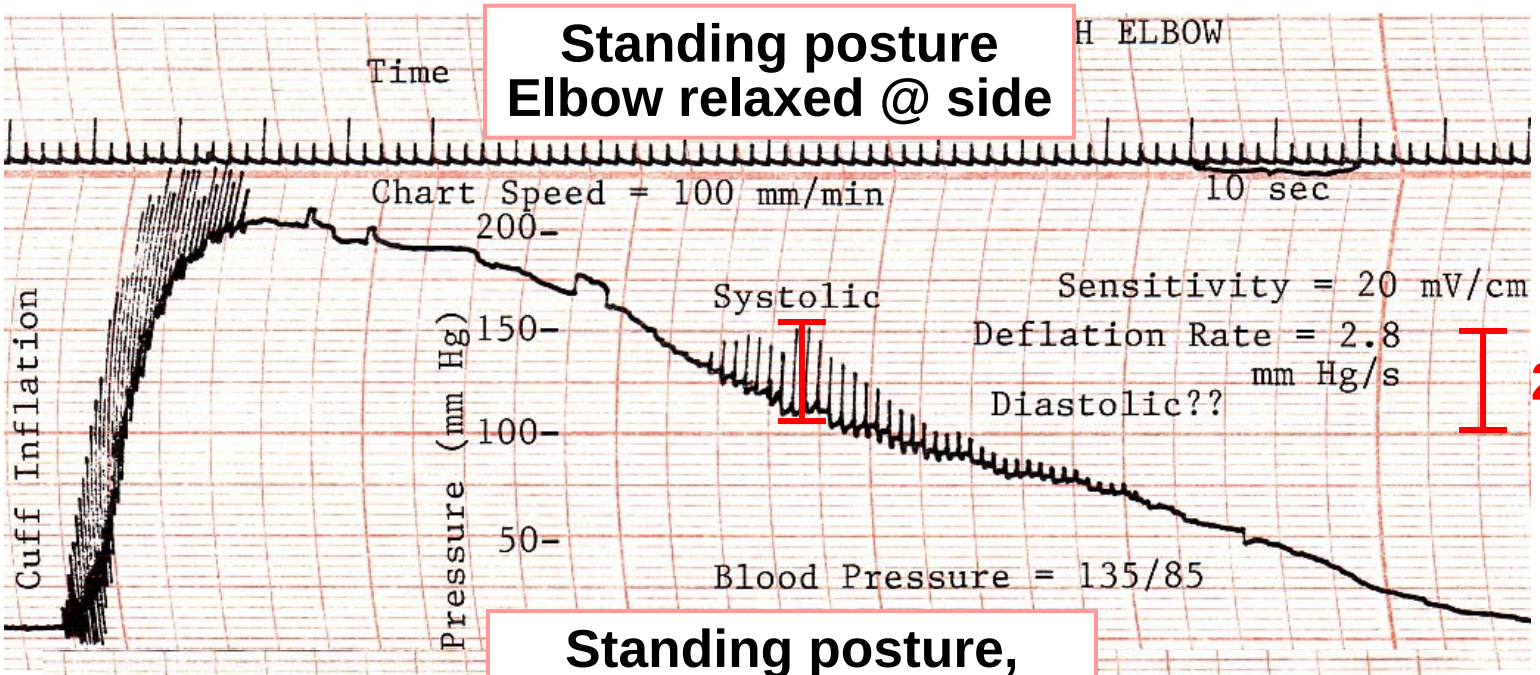


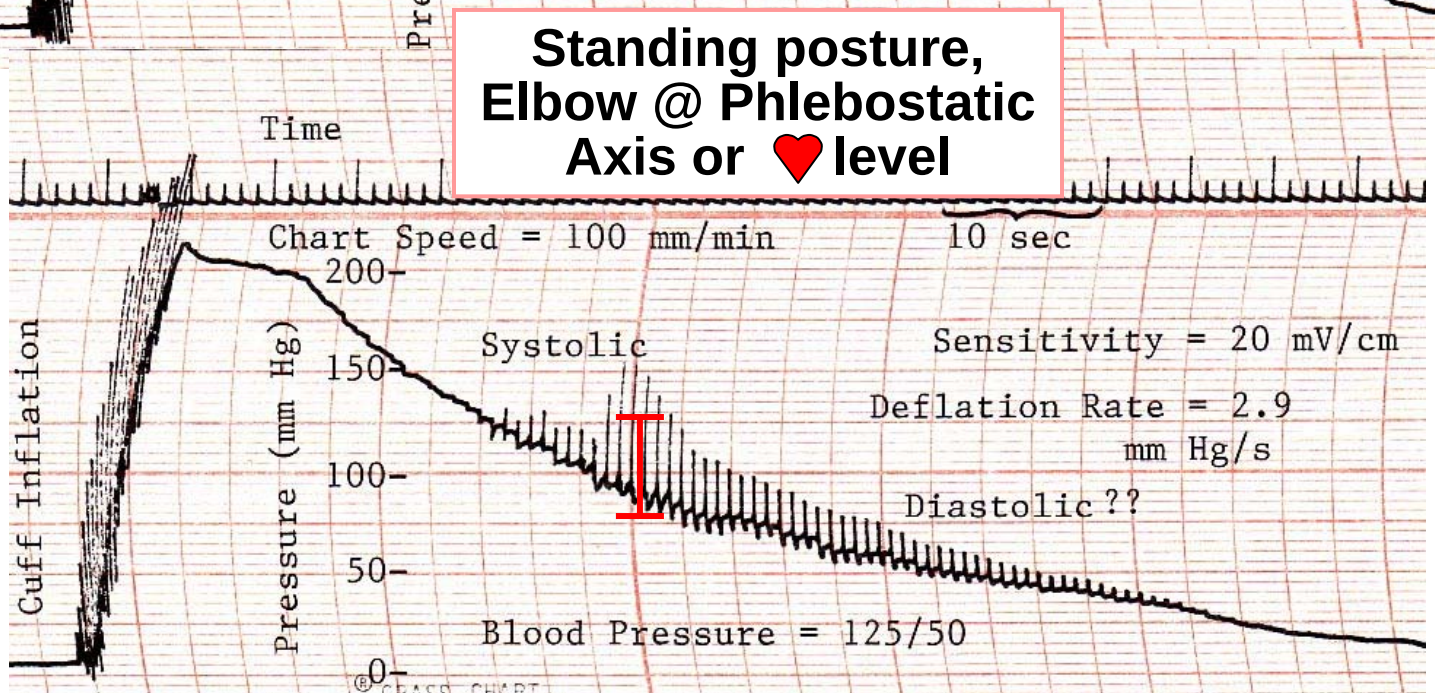
Source: E. Dolan, A. Stanton, L. Thijs, K. Hinedi, N. Atkins, S. McClory, E.D. Hond, P. McCormack, J.A. Staessen, E. O'Brien. *Hypertension*. 2005; 46:156-161.

Difficulty in Determining Diastolic Endpoint

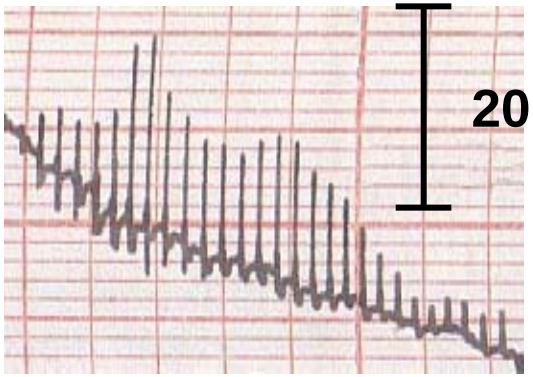


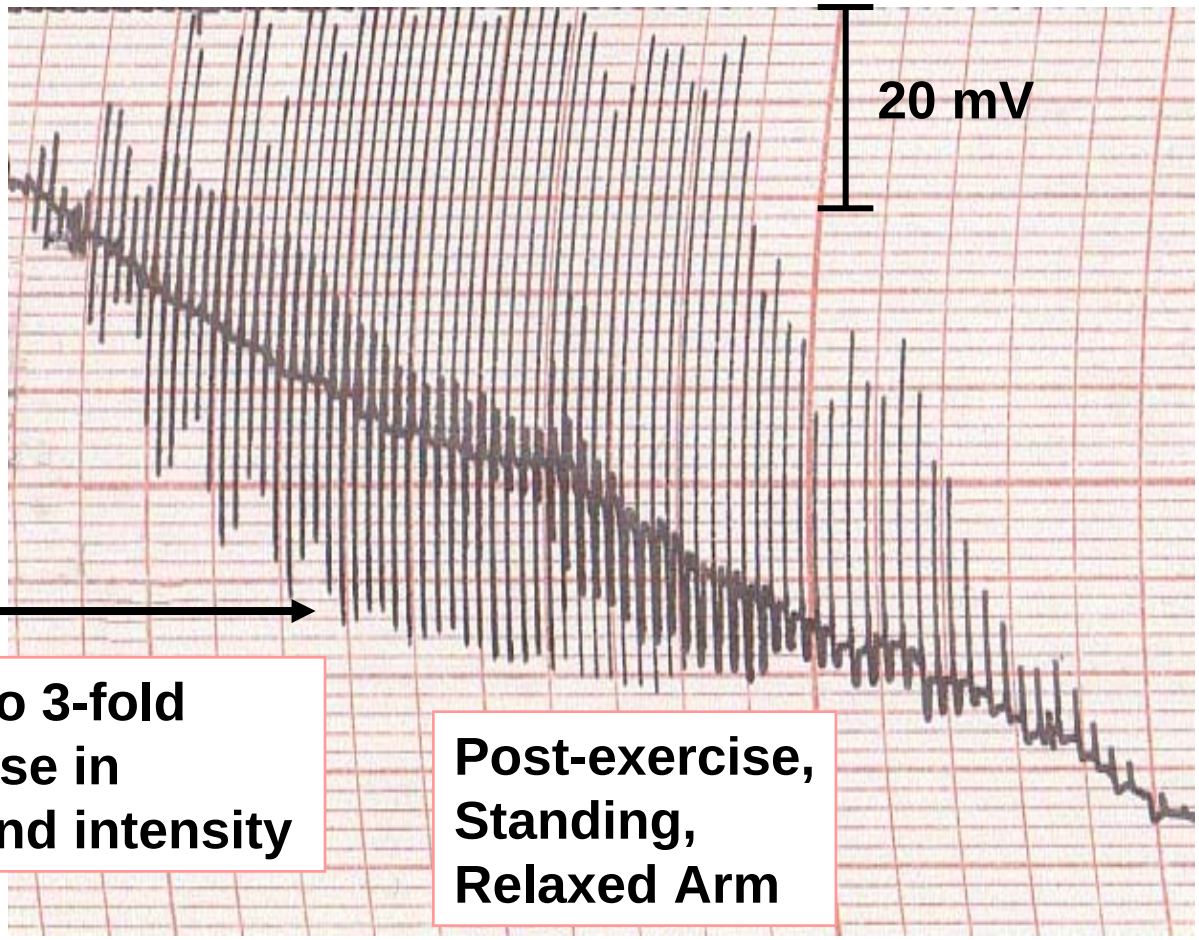
K-Sound Intensity Changes w/Body & Arm Position





K-Sound Intensity Changes with Activity





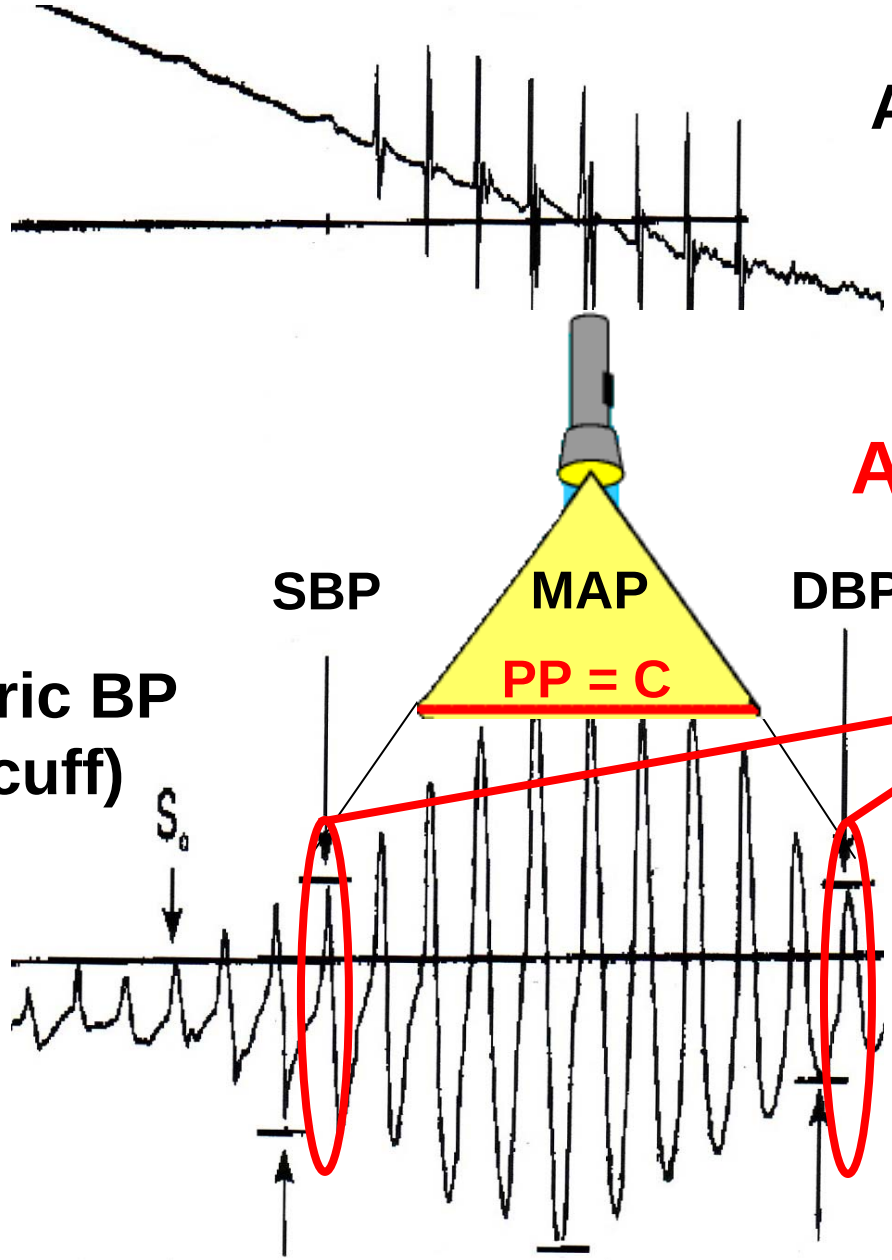
Pre-exercise, Standing, Relaxed Arm

≥ 2.5 to 3-fold increase in K-sound intensity

Post-exercise, Standing, Relaxed Arm

15 squat repetitions

Oscillometry Flashlight-Nomogram Effect



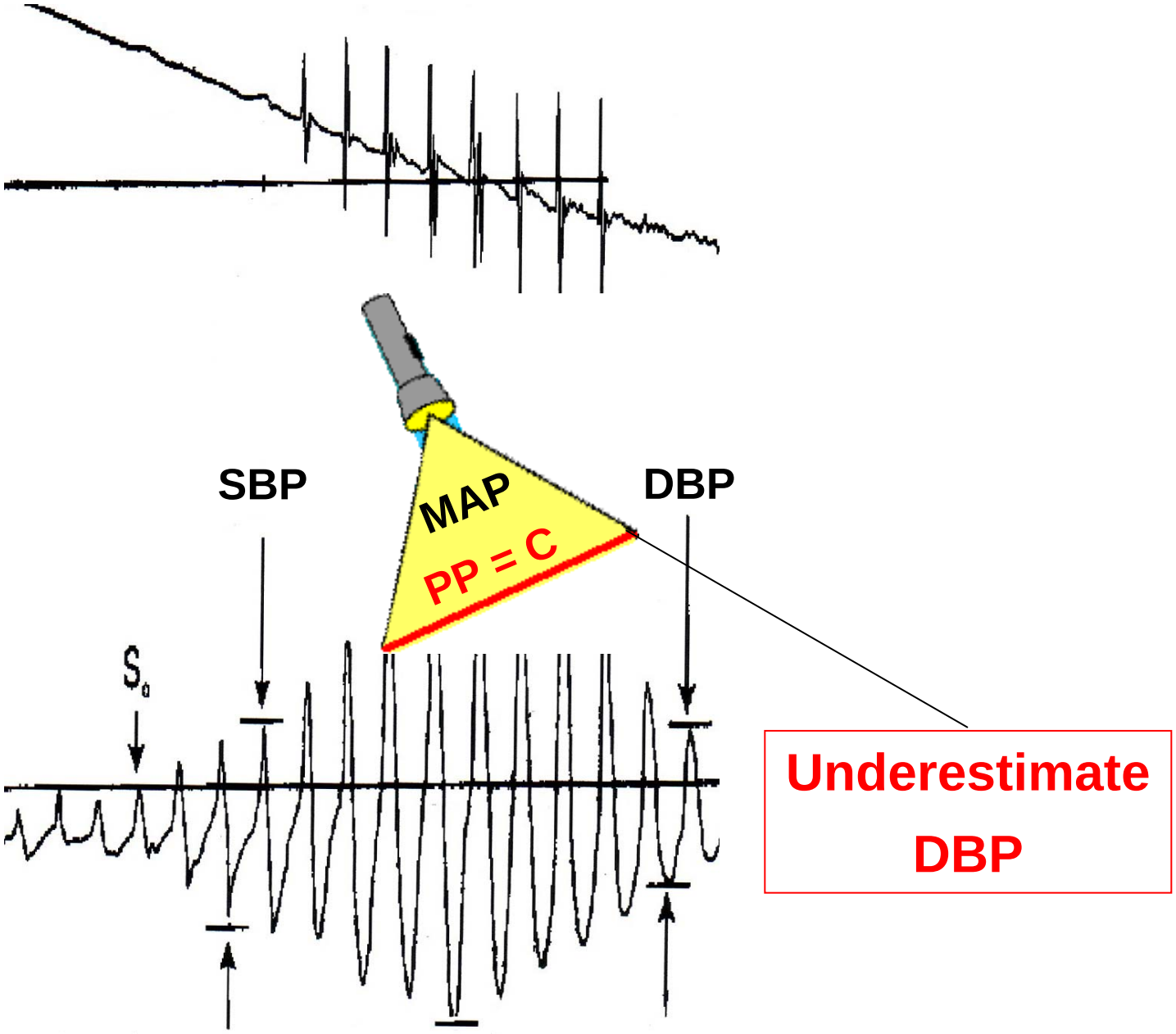
Auscultatory BP (K-sounds)

Assume PP = C

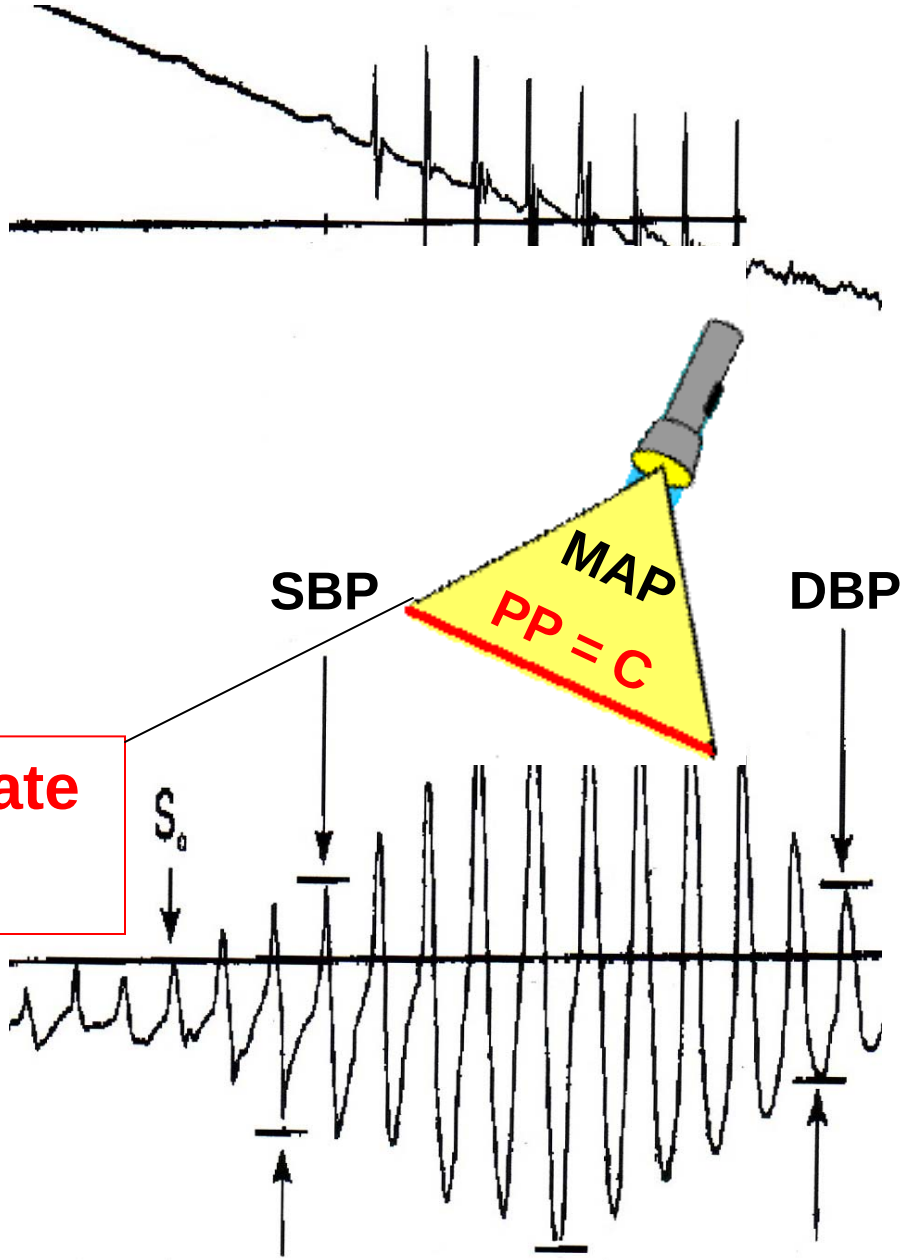
Oscillometric BP (Pulses in cuff)

Difficult to determine cut points, especially Diastolic BP

Oscillometry Flashlight Effect



Oscillometry Flashlight Effect



Overestimate SBP

1. Use Dual Monitor Protocol with postural challenges to verify accuracy & reliability

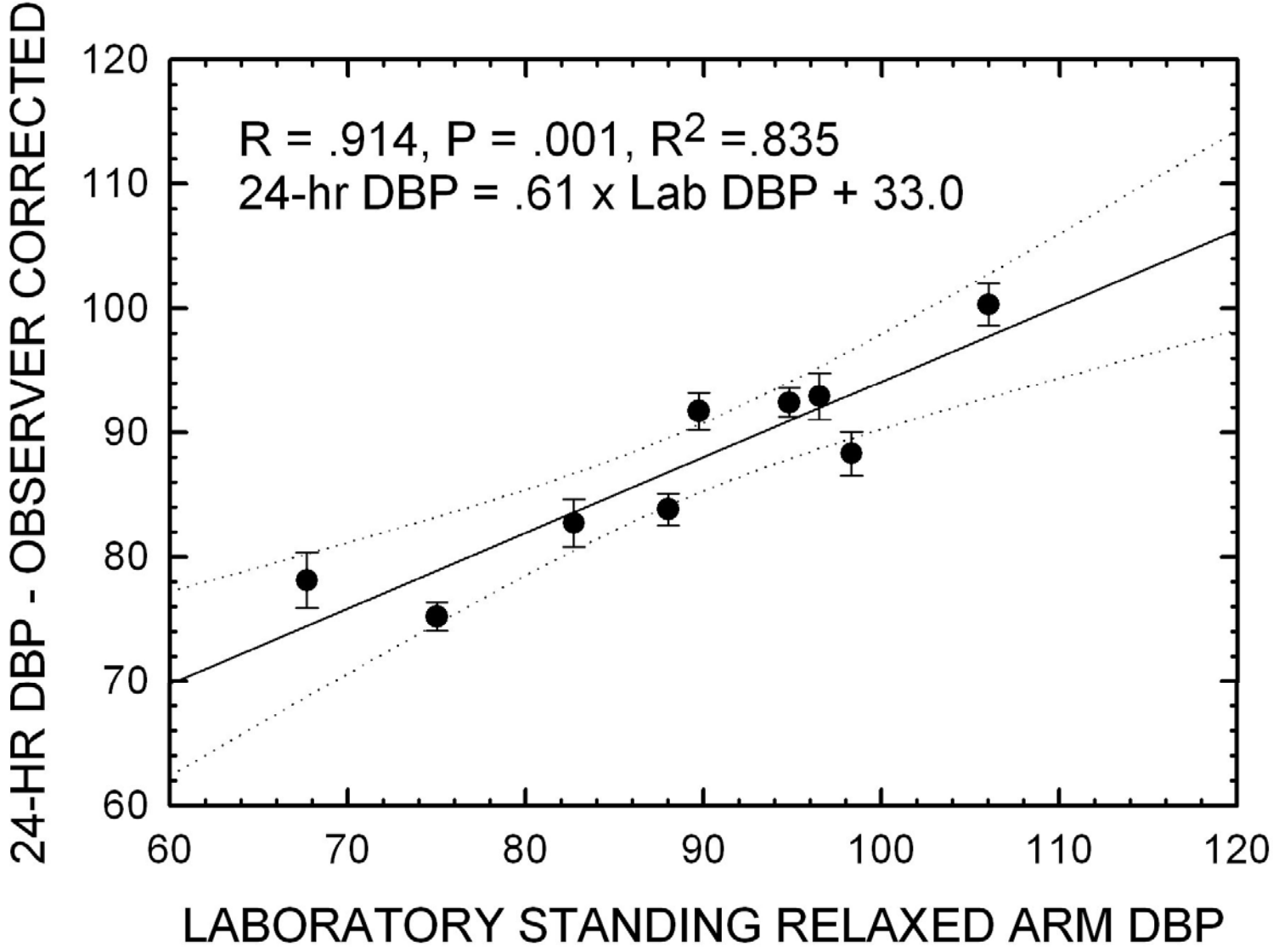
2. Use Correction Factors for 24-hr ABPM values

3. Develop postural & activity adjusting ABPMs

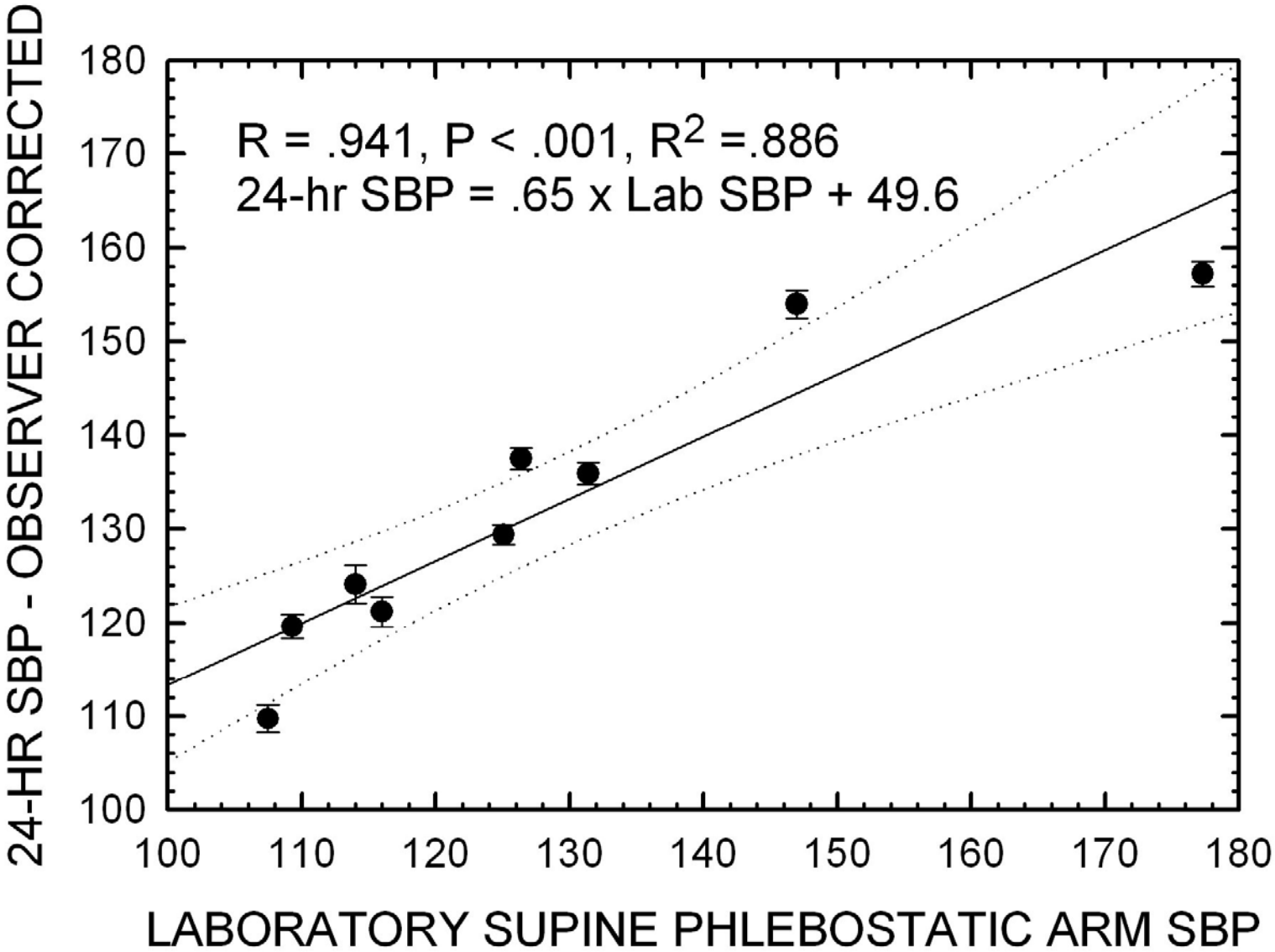
4. Modify AAMI, BHS, & ESH/IP criteria to require postural & activity challenges

5. Reflect back & return to basic physiology

AVERAGE 24-HR DIASTOLIC BLOOD PRESSURE (DBP) vs. LABORATORY STANDING RELAXED ARM DBP IN SUSPECTED HYPERTENSIVES



AVERAGE 24-HR SYSTOLIC BLOOD PRESSURE (SBP) vs. LABORATORY SUPINE PHLEBOSTATIC ARM SBP IN PRIMARY ALCOHOL DEPENDENTS (1^0 ETOH)



Comparing Posture & Arm Position for Lab Measurements with 24-hr, Awake & Sleep Systolic (SBP) and Diastolic (DBP) Blood Pressures Obtained by Ambulatory Blood Pressure Monitoring (ABPM) In Medicated & Non-Medicated Hypertensives

	SBP from ABPM						DBP from ABPM					
	24-hr		Awake		Sleep		24-hr		Awake		Sleep	
Lab Position	R	R^2	R	R^2	R	R^2	R	R^2	R	R^2	R	R^2
Supine Phlebostatic	.671*	.450	.516	.266	.555	.308	.762*	.581	.652	.425	.694*	.481
	P=.048		P=.155 NS		P=.121 NS		P=.017		P=.057 NS		P=.038	
Seated Phlebostatic	.680*	.462	.426	.181	.625	.391	.695*	.483	.542	.294	.681*	.464
	P=.044		P=.253 NS		P=.072 NS		P=.038		P=.132 NS		P=.043	
Seated Relaxed ✓	.752*	.566	.578	.334	.520	.270	.667*	.445	.760*	.578	.403	.162
	P=.019		P=.103 NS		P=.151 NS		P=.050		P=.017		P=.282 NS	
Standing Phlebostatic	.327	.107	.174	.030	.400	.160	.800*	.640	.724*	.524	.734*	.539
	P=.390 NS		P=.655 NS		P=.286 NS		P=.010		P=.027		P=.024	
Standing Relaxed ✓	.489	.239	.257	.066	.582	.339	.914*	.835	.828*	.686	.761*	.579
	P=.181 NS		P=.505 NS		P=.100 NS		P=.001		P=.006		P=.017	
Overall	.581	.338	.584	.341	.418	.175	.866*	.750	.768*	.590	.762*	.581
	P=.101 NS		P=.099 NS		P=.263 NS		P=.003		P=.016		P=.017	

Best Lab/Clinic Postures, Arm Positions & Equations for Predicting ABPM 24-hr, Awake & Sleep Blood Pressures in Primary Alcohol-Dependents (1^0 ETOH) & Hypertensives (HTN)

Group	Pressure	24-hr	Awake	Sleep
1^0 ETOH	SBP	Supine Phlebostatic R=.941, P<.001, R^2=.886 *24-hrBP=.65LabBP+49.6*	Seated Relaxed* R=.921, P<.001, R^2=.848 *AwakeBP=.85LabBP+30.1*	Supine Phlebostatic R=.864, P=.001, R^2=.746 *SleepBP=.79LabBP+12.7*
	DBP	Supine Phlebostatic R=.732, P=.010, R^2=.536 *24-hrBP=.49LabBP+45.5*	Supine Phlebostatic R=.670, P=.024, R^2=.449 *AwakeBP=.39LabBP+57.1*	Supine Phlebostatic R=.672, P=.023, R^2=.452 *SleepBP=.94LabBP-7.5*
HTN	SBP	Seated Relaxed R=.752, P=.019, R^2=.566 *24-hrBP=.47LabBP+73.9*	NS	NS
	DBP	Standing Relaxed R=.914, P=.001, R^2=.835 *24-hrBP=.61LabBP+33.0*	Standing Relaxed R=.828, P=.006, R^2=.686 *AwakeBP=.50LabBP+48.7*	Standing Relaxed R=.761, P=.017, R^2=.579 *SleepBP=.51LabBP+25.3*

*NB: For 1^0ETOH, in predicting ***Awake*** ABPM, Supine Phlebostatic (R=.920, P<.001, R^2=.846; *AwakeBP=.61LabBP+58.3*) was a close second behind the Seated Relaxed position.

SpaceLabs 90207 Problems with Variability Underestimation & Special Populations

In pregnancy

In pregnancy

In pre-eclampsia**

In pre-eclampsia

In children

In elderly, supine over all pressures

During hemodialysis

NB: **SBP Underestimation 10 ± 10 mm Hg
**DBP Underestimation 8 ± 7 mm Hg

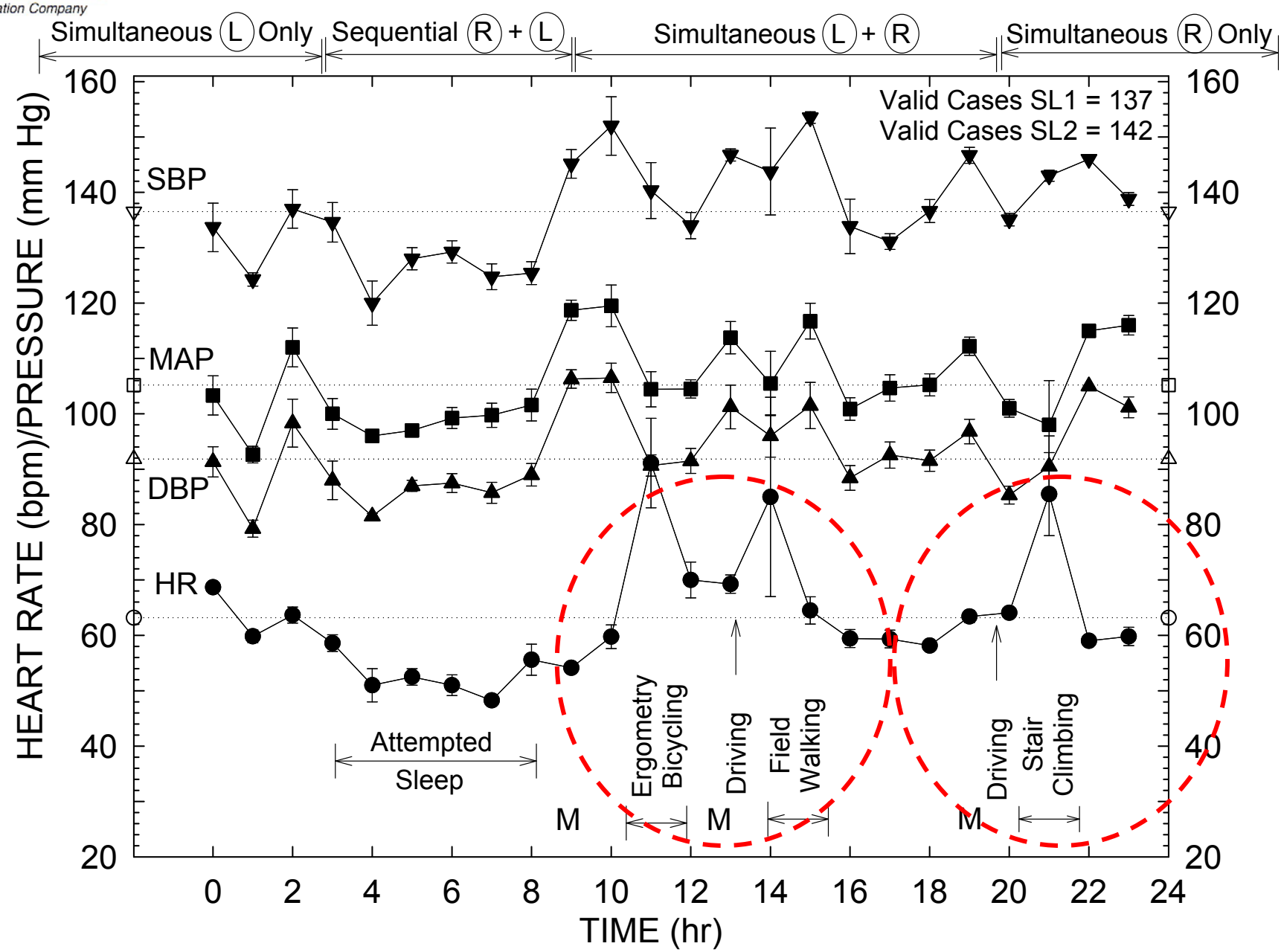
See *www.dableducational.org* for detailed references.

SpaceLabs 90207 BP Success (S), Error (E) & Movement Artifact (M), Dual Monitor Field Protocol

	Overall, Limited Motion		Stair Ascent/Descent Only	
	SL1	SL2	SL1 **	SL2 **
S	81%	81%	12%	29%
E	19%	19%	88%	71%
M	(14%)	(11%)	(13%)	(20%)

**NB: Both SL1 & SL2 exhibited "run-away" inflations on stair ascent, likely incorrectly perceiving motion artifact as inability to exceed SBP. Both devices largely motion & vibration intolerant.

TWO 24-HR ABPM SPACELABS 90207 UNITS
DUAL-MONITOR FIELD PROTOCOL, LABILE HYPERTENSIVE



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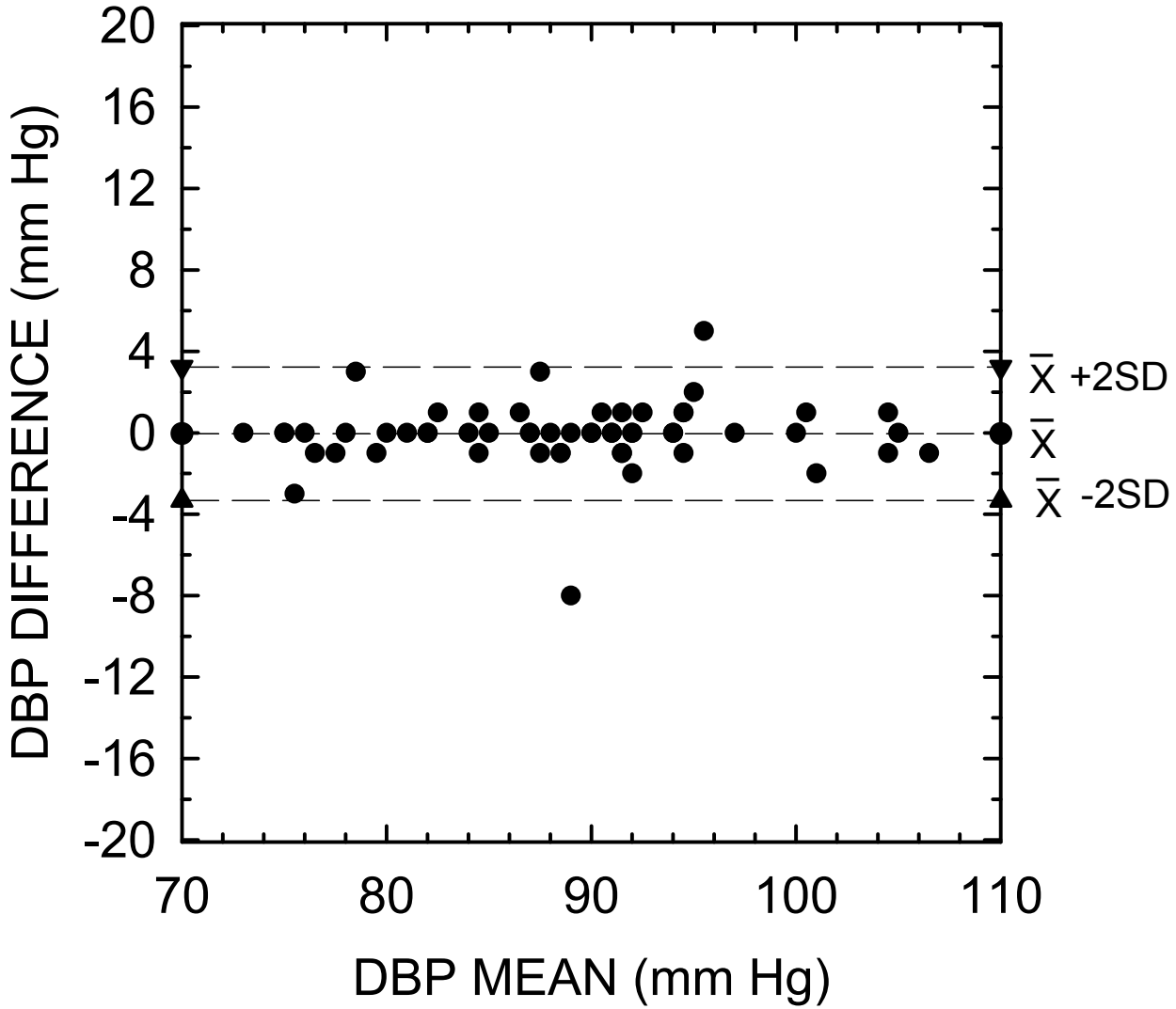
The Clinical Information Company

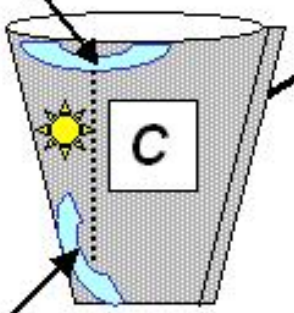
SPACELABS 1 vs SPACELABS 2
DIASTOLIC BLOOD PRESSURE (DBP)
LABILE HYPERTENSIVE (52 yr ♂) FIELD TEST
SIMULTANEOUS, SAME ARM, N = 57 TRIALS



AO-pABPM Prototype Model

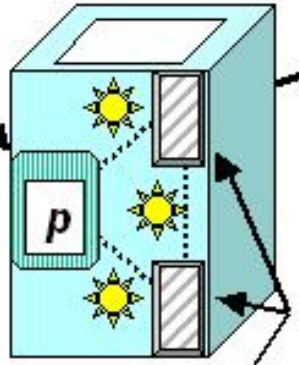
***O* = *Oscillometric Transducer* ***
detects pulse △s in BP cuff

connecting pressure tube



C* = *Cone-shaped, velcro cuff* *
5 sizes: large adult, adult,
small adult, pediatric, neonatal

p = pump



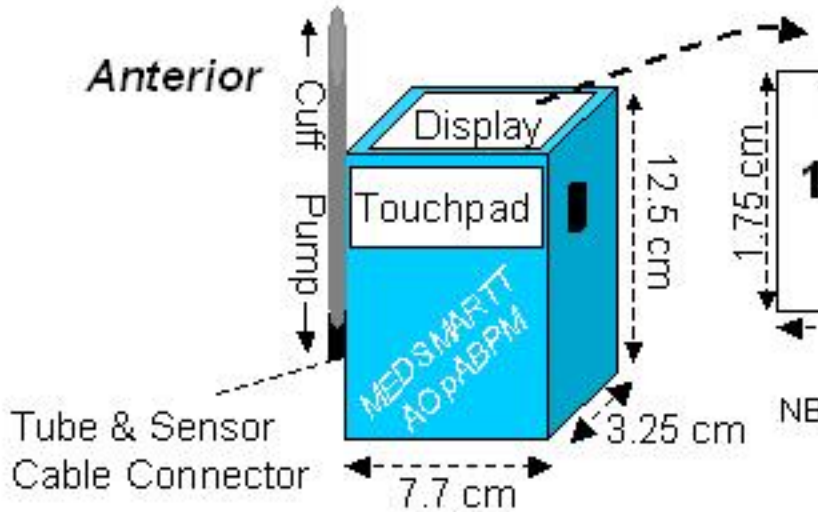
A* = *Ausculatory Transducer* *
piezo-electric *curved* crystal
microphone detects K-sounds

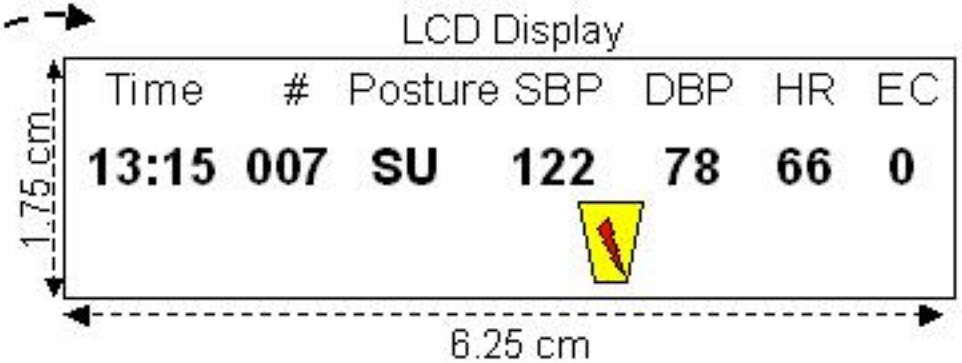
MedSmartt* **
AO-pABPM

d = distance between components
i = interference potential

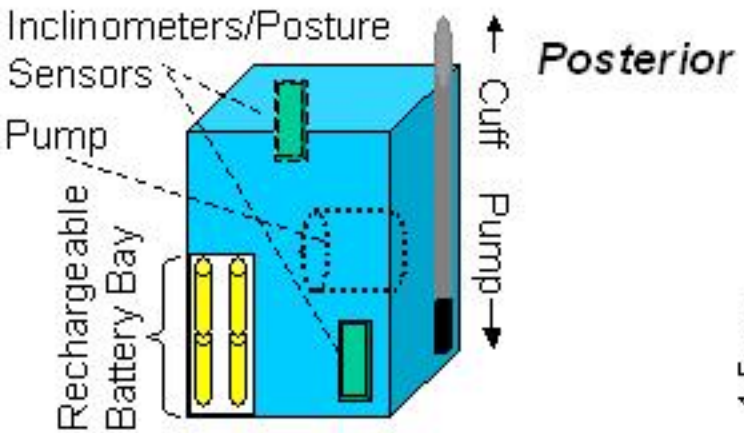
***a_1, a_2* =**
accelerometers 1 & 2
detect static acceleration,
tilt = body position

*1979, **1992, ***2005-2006





NB: Inverted from Anterior view so technical staff can view during baseline calibration and subjects during subsequent testing. The AO pABPM will have an option for blocking column display output, so that subjects may view only Time, Measurement #, Posture, and EC/Error Codes for 1 min after each field test measurement.



NB: Potential pump types: (1) Piezo-electric pump enables silent pumping & consumes little power, but currently has too low of a flow rate, (2) CO2 gas canister which has near-silent pumping but with potential safety issues, & (3) Conventional diaphragm pump which is noisier and has higher power consumption.