



# Establishing Correction Factors for the Oscar 2 & Spacelabs 90207 Ambulatory Blood Pressure Monitors

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## INTRODUCTION

Ambulatory blood pressure monitors (ABPMs) are validated by protocols developed by the Association for the Advancement of Medical Instrumentation (AAMI, 2013, 2003, 1996, 1993, 1987), the European Society of Hypertension (ESH, 2010, 2002), and the British Hypertension Society (BHS, 1993, 1990). Despite multiple revisions, protocols do not require testing of patients for a variety of postures and activities they engage in during a typical 24-hr monitoring period.

We developed a Dual Monitor Protocol (DMP) with postural challenges (1) to determine the accuracy of ABPMs compared to clinicians using a mercury (Hg) column in the lab. The DMP can be modified for two ABPMs in the field. We calculate the difference between ABPMs and observers' Hg measurements for each posture and each subject in the lab to develop correction factors we apply to 24-hr data points for a more accurate representation of blood pressure. We established in 15 normotensives, 14 medicated and non-medicated hypertensives and 11 primary alcohol-dependents, that an auscultatory ABPM, the Accutracker II, had a poor level of agreement with clinicians' Hg column measurements. Though systolic blood pressure (SBP) appeared less troublesome, the ABPM's diastolic blood pressure (DBP) misclassified 7 of 10 hypertensives and 10 of 11 alcohol-dependents. Accutracker II manufacturing was discontinued by SunTech Medical in 2010.

## PURPOSE

Though we have tested auscultatory monitors, our goal was to apply our DMP to two of the most popular oscillometric monitors, the Oscar 2 ABPM (SunTech Medical, Morrisville, NC) and the Spacelabs 90207 ABPM (Spacelabs Health, Snoqualamie, WA).

## HYPOTHESES

We predicted that since oscillometric ABPMs were developed using auscultation, that like the Accutracker II, the Oscar and Spacelabs monitors would have a high degree of variability and potentially misclassify patients. Oscillometric APBMs, rely upon the peak pressure in the cuff as an estimate of mean arterial pressure (MAP) and what we term the *Flashlight-Nomogram Effect* to estimate SBP and DBP from MAP (2). Thus, we predicted errors at either end of the BP continuum, because algorithms cannot adjust for variations in MAP amplitude and pulse pressure (PP = SBP - DBP).

## METHODS

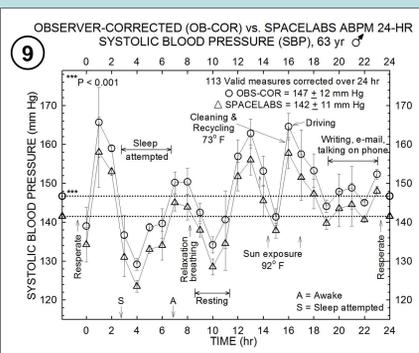
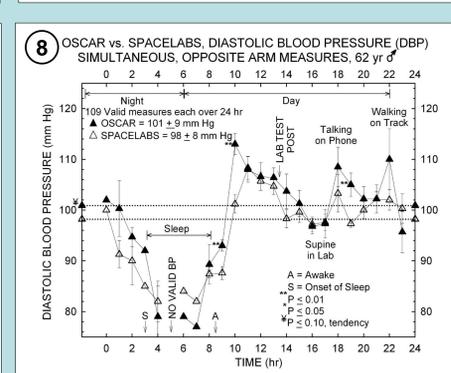
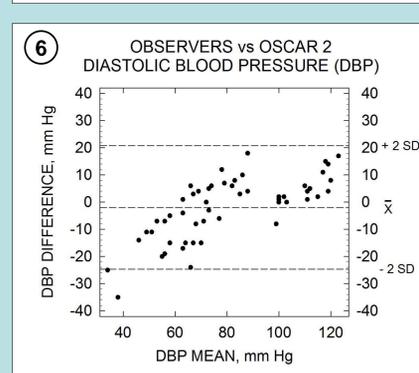
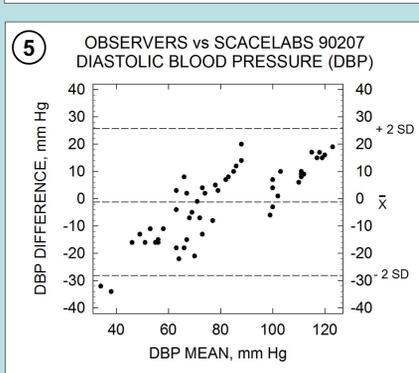
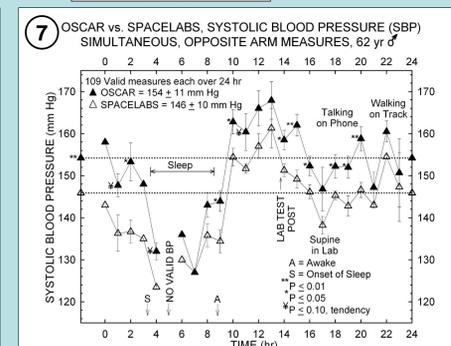
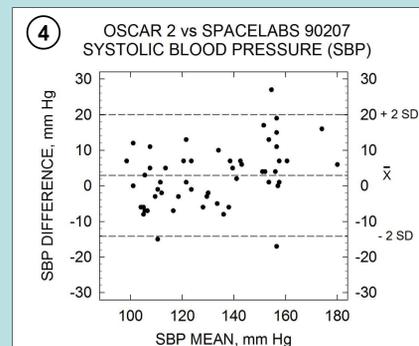
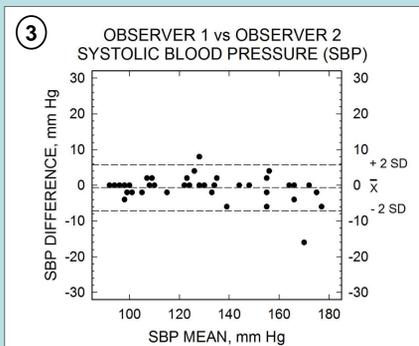
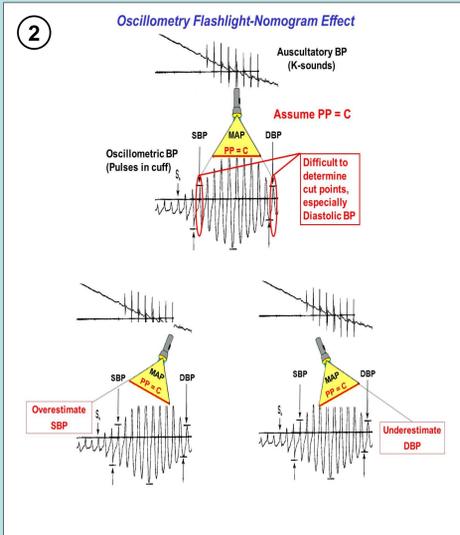
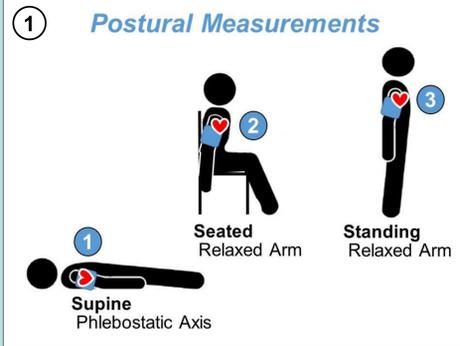
**Baseline.** Simultaneous, same arm BPs were measured in the lab in 5 subjects (3 males, 2 females) by 2 observers using a Hg column and a Thinklabs digital stethoscope with high-resolution auscultation and 2<sup>nd</sup>-generation ambient noise reduction. Simultaneous, opposite arm BPs were assessed by the Oscar and the Spacelabs ABPMs because standard cuff size specifications differed. Arms used by APBMs were switched to minimize any inter-arm differences. Thus, BPs were performed on both arms in triplicate with all 4 techniques (2 observers w/Hg column, Oscar, Spacelabs) while the subjects were seated with the arm elevated to the phlebostatic axis.

**Postural.** Simultaneous, same arm BPs measured by the observers with Hg column were interspersed with sequential Oscar 2 and Spacelabs measurements on the same arm used for 24-hr ABPM. For each posture – supine, seated and standing – each technique assessed BPs in triplicate, first, second and third relative to other techniques, to minimize any order effect biases.

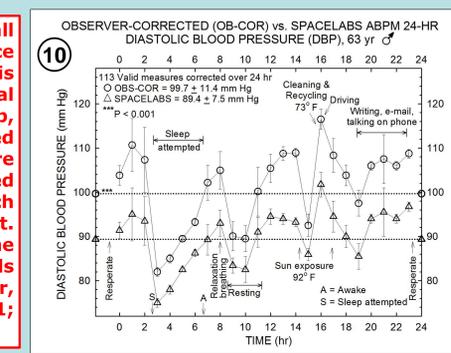
**24-hr ABPM.** Monitors assessed BPs every 15 min from 6 am to 10 pm & every 30 min from 10 pm to 6 am. When a single monitor was worn, it was done so on the non-dominant arm. When two monitors were used, the cuff sides were switched every 2-3 hr except during sleep. After each measurement when awake, subjects recorded the time, postures & activities using a matrix-type log book. Each data point was corrected based on differences found in the lab.



AHA Council on Hypertension  
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American Society of Hypertension  
Joint Scientific Sessions 2018, September 6-9, 2018  
Hyatt Regency, Chicago, IL USA 60601



An accurate device is fundamental to all blood pressure measurement; if the device used to measure blood pressure is inaccurate, attention to methodological detail is of little relevance. (Beavers, Lip, O'Brien, *BMJ* 2001). It is acknowledged that the accuracy of blood pressure measuring devices should not be based solely on claims from manufacturers, which can at times be somewhat extravagant. Instead, independent validation, with the results published in peer-reviewed journals should be demanded (O'Brien, Waerber, Parati, Staessen & O'Brien, *BMJ* 2001; O'Brien & coworkers, *J Hypertens* 2003).



## SUMMARY & CONCLUSIONS

Ocillometric like auscultatory ABPMs, have a high degree of variability compared to observers' Hg column BPs. (3) (4) (5) (6)

Depending upon the ABPM chosen, the outcome may be different. (7) (8)

Like the auscultatory Accutracker II ABPM, two leading oscillometric monitors, the Oscar 2 and Spacelabs 90207 can misclassify patients, particularly those who are suspected hypertensives. (9) (10)

Though in a small number of subjects, our results seem to confirm our predictions of a *Flashlight-Nomogram Effect*, the inability of oscillometric ABPMs to adjust for variations in mean arterial pressure (MAP) & pulse pressure (PP) & thus underestimating or overestimating at either end of the blood pressure continuum.

All protocols (ESH, AAMI, BHS) should insist upon postural testing in evaluating ABPMs.

Manufacturers should be required to reveal specific patient characteristics from whom equations & algorithms were derived. Otherwise, clinicians will not know which of their patients match the specific group tested & which monitor might be more appropriate.

While ABPMs may provide a rough snapshot for comparison in large population studies, their high degree of variability & susceptibility to errors make us question their use for the accurate diagnosis & treatment of hypertension. We also think it makes ABPM results questionable in the evaluation of white-coat syndrome and non-dipping status.

We welcome suggestions & look forward to improving upon our Dual Monitor Protocol & postural challenge techniques to ensure that someday, a more accurate measurement of blood pressure over 24 hr is possible.

We are especially grateful to the American Foundation for Hypertension Research & Education for giving us a travel award & to Ashley Clark & the American Heart Association staff for their continued help & dedication to conference participants.

Special thanks to Katie Foster and Richard Padgett, MD, of Oregon Heart & Vascular Institute and John Halliwill, PhD, of U of O Human Physiology for their help with ambulatory monitors.

For further information about protocols & results, please contact V. Pat Lombardi at lombardi@uoregon.edu