# Validation of a Blood Pressure Simulator that Regenerates Oscillometric Cuff Pressure Waveforms

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## Abstract

*Blood pressure (BP) simulators that regenerate oscillometric waveforms provide an alternative for BP device validation. However, their ability to regenerate oscillometric waveforms recorded from unstable conditions has not been fully investigated. This study aimed to provide this information.*

*Manual auscultatory systolic and diastolic blood pressures (SBP and DBP) were measured on 10 healthy subjects under both resting and regular deep breathing conditions. During the manual measurement the oscillometric cuff pressure waveforms were recorded digitally. A specially designed BP simulator was used to regenerate the oscillometric waveforms, which were presented to a clinically validated automatic oscillometric non-invasive BP device to obtain automated BPs from all the 20 waveforms. The SBP and DBP changes induced by deep breathing were finally quantified and compared with the measurement by the automatic device and the manual auscultatory method.*

*Deep breathing decreased both manual and automated SBPs significantly by 5.0 and 6.0 mmHg in comparison with those from the resting condition (both $P<0.01$). The corresponding decreases of manual and automated DBPs were 2.6 and 3.3 mmHg (both $P<0.05$). The automated BP decrease induced by deep breathing was not significantly different from that for manual BP (both $P>0.5$).*

*Our results demonstrated that the BP simulator can regenerate unstable physiological oscillometric waveforms, confirming that it could be an alternative to clinical trials.*

## 1. Introduction

Automatic non-invasive blood pressure (NIBP) measurement devices are widely used in many health care institutions or at home [1]. The most common automatic NIBP devices use the oscillometric technique [2, 3]. Technically, these BP devices analyse the small pressure pulse changes (oscillometric pulses) induced in a pressurized cuff wrapped round the upper arm. Every NIBP device has its own empirical algorithms to determine the systolic and diastolic blood pressures (SBP and DBP). Before these NIBP devices can be sold on the market, it is required by the International Organization for Standardization that they should be validated clinically to confirm their accuracy by comparing with either directly measured invasive pressures or with manual auscultatory measurements [4].

Clinical trials involving human participants are currently the only approved method to validate the NIBP devices. However, clinical trials are very expensive, and several trails are required for the same device to validate its measurement accuracy in different population groups. We have developed a special BP simulator that regenerates physiological oscillometric waveforms pre-recorded from human subjects [5, 6]. This BP simulator could provide an alternative for BP device validation.

However, the ability for the BP simulator to regenerate oscillometric waveforms recorded from unstable conditions has not been fully investigated. This study aimed to provide this information.

## 2. Methods

### 2.1. Subjects

Ten healthy normotensive subjects (aged from 28 to 61 years) were studied. They had no known cardiovascular disease. The subject recruitment received ethical permission from the Newcastle & North Tyneside Research Ethics Committee, and all subjects gave their written informed consent to participate in the study.

### 2.2. Manual auscultatory blood pressure measurement

Manual SBP and DBP measurement were performed

under both resting and regular deep breathing conditions using a clinically validated manual electronic sphygmomanometer (Accoson Greenlight 300 from AC Cossor & Son (Surgical) Ltd) [7]. All BP measurements were performed by a trained observer in a quiet and temperature controlled clinical measurement room while the subjects were seated on a chair. The whole BP measurement procedure followed the guidelines recommended by the American Heart Association and British Hypertension Society [8].

During the manual measurement, the oscillometric cuff pressure was deflated linearly at a recommended rate of 2-3 mmHg/s, and was recorded digitally to a computer. In total, 20 oscillometric cuff pressure waveforms were obtained.

## 2.3. Blood pressure simulator assessment

A BP simulator, designed and constrcusted at the Physikalisch-Technische Bundesanstalt (PTB) and capable of generating previously recorded oscillometric wavefroms [5, 6], was used to regenerate the 20 oscillometric waveforms. Each regenerated oscillometric waveform was then presented to a clinically validated automatic oscillometric NIBP device to obtain auto SBP and DBP. Figure 1 shows the block diagram of the set-up of BP simulator connented to a NIBP device.

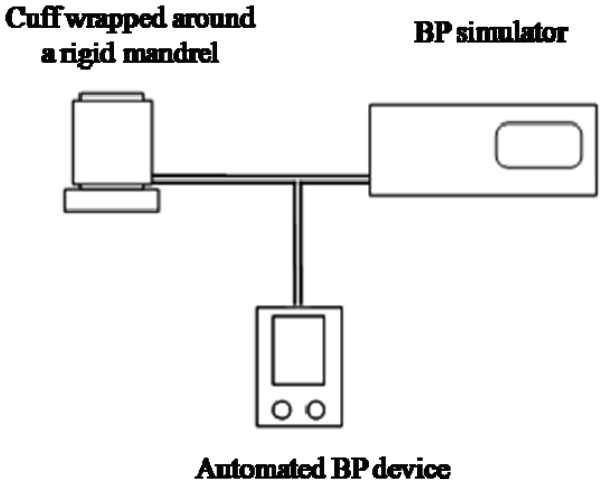


Figure 1. Schematic set-up of BP simulator connected to an automated BP device.

## 2.3. Data and statistical analysis

The mean and standard deviation (SD) of the manual and auto BPs across all subjects were calculated for the two measurement conditions (resting and regular deep breathing).

The SPSS Statistics 19 software package (SPSS Inc, USA) was then employed to investigate the effect of regular deep breathing on both manual and automated SBP and DBP. The SBP and DBP changes induced by deep breathing were finally compared with the measurement by the NIBP device and the manual auscultatory method. A P value below 0.05 was considered statistically significant.

# 3. Results

## 3.1. Effect of deep breathing on manual and automated systolic blood pressures

As shown in Figure 1, deep breathing decreased manual SBP significantly by 5.0 mmHg in comparison with that from the resting condition (mean±SD: 113.4±10.3 mmHg vs 118.4±10.2 mmHg, P<0.01). The corresponding decrease of auto SBP was 6.0 mmHg (mean±SD: 110.2±11.0 mmHg vs 116.2±10.5 mmHg, P<0.01).

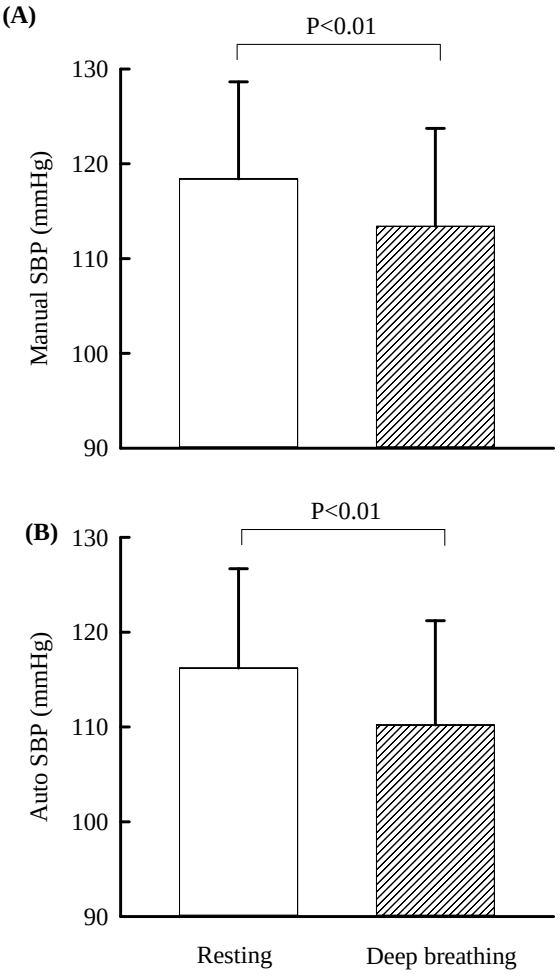


Figure 2. Overall mean±SD of manual (A) and auto (B) SBPs measured from resting and regular deep breathing conditions.

### 3.2. Effect of deep breathing on manual and automated diastolic blood pressures

As shown in Figure 3, deep breathing decreased manual DBP significantly by 2.6 mmHg in comparison with that from the resting condition (mean±SD: 75.0±8.0 mmHg vs 77.6±9.0 mmHg; P<0.01). The corresponding decrease of automated DBP were 3.3 mmHg (mean±SD: 67.0±9.2 mmHg vs 70.3±8.2 mmHg; P<0.01).

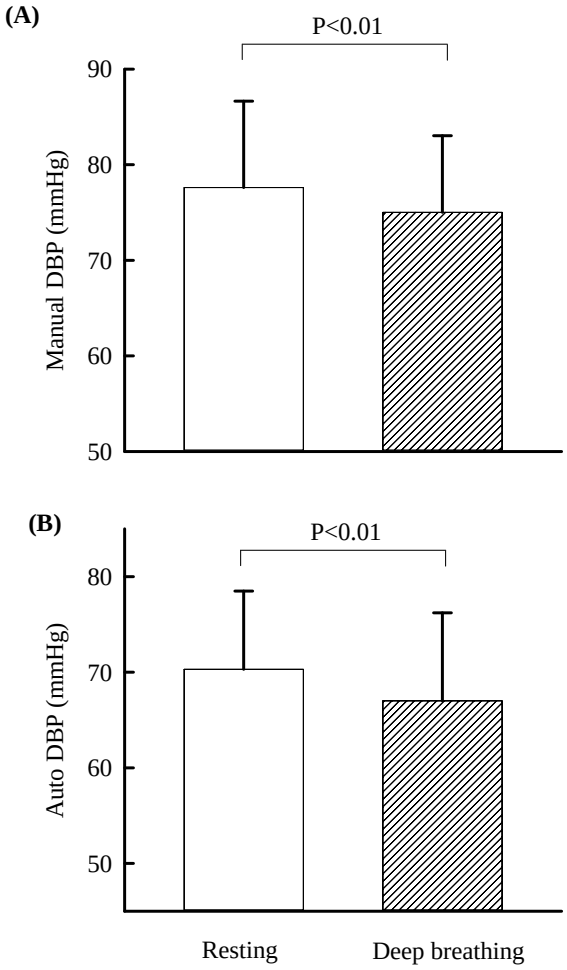


Figure 3. Overall mean±SD of manual (A) and auto (B) DBP measured from resting and regular deep breathing conditions.

### 3.2. Comparison of changes of manual and automated blood pressures induced by regular deep breathing

The auto SBP and DBP decreases induced by deep breathing was not significantly different from that for manual SBP and DBP (both P>0.5), indicating that oscillometric waveforms recorded from non-resting conditions were reliably regenerated by the BP simulator.

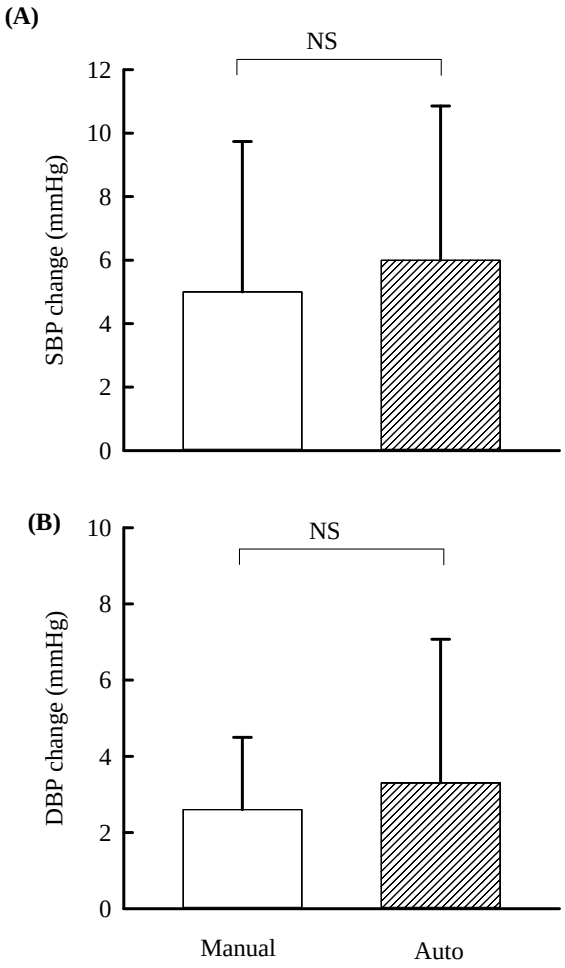


Figure 4. Comparison of SBP (A) and DBP (B) changes induced by regular deep breathing between the measurements by the manual method and the automated BP device.

## 4. Discussion and conclusion

This study represents a preliminary validation of a simulator that generates previously recorded clinical oscillometric waveforms. Our study was conducted to assess the ability of the simulator to regenerate the unstable oscillometric waveforms, rather than to evaluate the NIBP device itself, since the NIBP device used in this study had previously been validated in clinical trials against auscultatory measurements.

Our manual BP changes with deeper breathing agreed with the published clinical study that both SBP and DBP decreased significantly in comparison with the resting condition [9]. This manual BP decrease suggests that the characteristics of oscillometric waveforms are different when they are recorded under resting and regular deep breathing conditions. In this study, the difference in the characteristics of oscillometric waveforms was reliably regenerated by the BP simulator, which was confirmed

from the non-significant automated BP decrease determined by a clinically validate NIBP device in comparison with that from the manual auscultatory method.

Whilst our results together with the published results [5, 6] with the simulator are encouraging, further development is still required for it to fully replace the current clinical trials. The validation of the BP simulator should be done with a sufficient number of oscillometric cuff pressure waveforms and waveforms from patient groups with defined pathologies. Protocols for simulator evaluation should also be submitted to professional and standards organisations for critical assessment and approval.

In summary, our results demonstrated that the BP simulator can regenerate unstable physiological oscillometric waveforms, confirming that it could be an alternative to clinical trials.

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