# Validation according to ESH International Protocol of Somnotouch NIBP, a device for noninvasive continuous blood pressure monitoring.

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## *Background*

- Conventional 24h ambulatory blood pressure (BP) monitoring has several important limitations including discontinuous nature of BP measurements and poor acceptance by many patients due to discomfort associated with repeated cuff inflations.
- This discomfort may affect nocturnal sleep quality, potentially leading to spurious nocturnal BP alteration.
- Somnotouch NIBP is a novel cuffless continuous BP monitor, based on pulse transit time (PTT) measurement (Fig. 1)

## *Aim*

To assess the validity of Somnotouch NIBP in accordance with ESH International Protocol (IP)[1], 2010 revision.

[1] O'Brien et al. Blood Pressure Monitoring 2010,15:23–38

## *Methods – device and technique principles*

Somnotouch NIBP (Somnomedics, Germany, Figure 1) estimates BP based on the PTT measurement derived from simultaneous recording of ECG and finger photoplethysmogram. Based on the arterial wall stress-strain characteristics a function was derived linking changes in transmural pressure with PTT (BP increase translates into arterial wall stiffening and PTT is consequently reduced) (Figure 2).

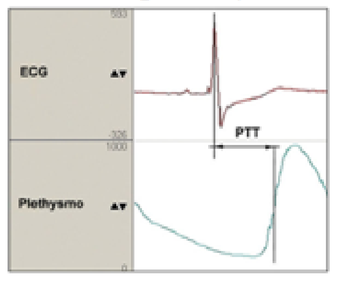
Figure 1. Somnotouch NIBP device

Pulse wave velocity (PWV) can be obtained from height and pulse transit time (PTT):

$$\mathrm{PWV\ (cm/ms)} = \frac{\mathrm{BDC} \times \mathrm{height\ (cm)}}{\mathrm{PTT\ (ms)}}$$

BDC: correction factor

Davies and Struthers J Hypertens 2003




Function deriving current BP from current PWV and from initial calibration BP:

$$\mathrm{BP_{PTT}} = P1 \times \mathrm{PWV} \times e^{(P3 \times \mathrm{PWV})} + P2 \times \mathrm{PWV}^{P4} - (\mathrm{BP_{PTT,cal}} - \mathrm{BP_{cal}})$$

Gesche et al. Eur J Appl Physiol 2011

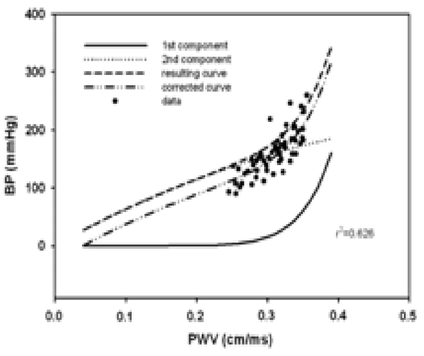



Figure 2. Principles of Somnotouch NIBP technique

## *Methods – study protocol*

Study protocol was based on European Society of Hypertension International Protocol revision 2010 for the validation of blood pressure measuring devices in adults (O'Brien et al. Blood Pressure Monitoring 2010,15:23–38) (Figure 3).

Because the device has several distinct characteristics which make it different from oscillometric devices for which the ESH IP protocol was intended the protocol had to be adapted taking these charcateristics into account:

1) Entry BP measurement was followed by calibration measurement; validation measurements were delayed by 15 minutes to verify short-term calibration stability
2) Both auscultatory device cuff and test device were placed on nondominant arm
3) To ensure the concomitance of calibration of the signal with the actual calibration measurement, the calibration was performed on a device placed on controlateral (dominant) arm
4) Test device remained attached to the subject throughout the validation.
5) Quality of recorded signals was periodically checked
6) In the analysis phase, good quality segments of recording (duration 10-30 sec), at least 10 sec after the end of cuff deflation, were used for BP estimation

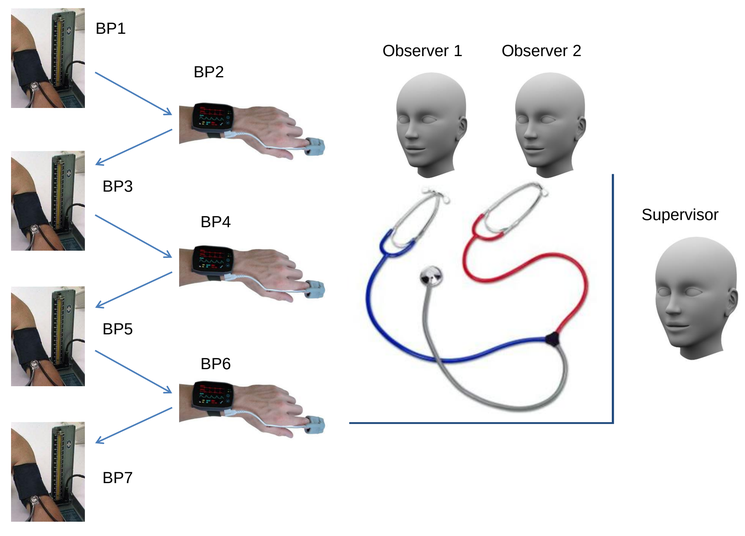



Figure 3. Validation procedure

## *Results*

41 subjects were included of whom 8 of them were excluded (because of arrythmias, poor recording quality, technical issues and consent withdrawal).
Thus data of 33 subjects were analysed (mean age 63.5 (25-78) ; BMI 26.3±16.0 kg/m2; arm circumference 27.6 (20-32) cm; 22 M/11 F; entry BP 143.1/90.5 (range 89-221/64-154) mmHg.
Blood pressure ranges were represented according to ESH IP requirements.

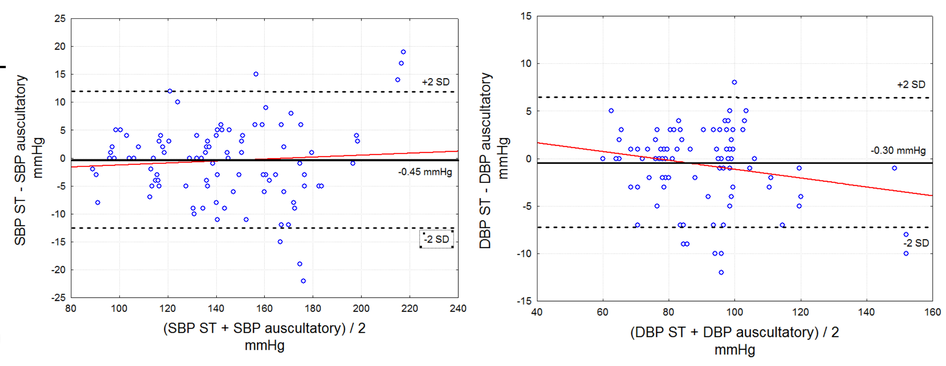
Table 1. Validation outcome. Two out of three criteria (columns A, B, C) must be fulfilled for threshold a; three out of three criteria must be fulfilled for threshold b. Column D: number of subjects in whom two out of three differences were ≤5mmHg; Column E: number of subjects in whom none of the differences was ≤5mmHg

| **Requirement:** | **A** **≤ 5 mmHg** | **B** **≤ 10 mmHg** | **C** **≤ 15 mmHg** | **D** **2/3 ≤5mmHg** | **E** **0/3 ≤5mmHg** | **Result** |
|---|---|---|---|---|---|---|
| *Required* | *73[a] or 65[b] ** | *87[a] or 81[b] ** | *96[a] or 93[b] ** | *≥ 24* | *≤ 3* | |
| SBP – achieved | 76 | 91 | 96 | 28 | 2 | **PASS** |
| DBP – achieved | 90 | 99 | 99 | 31 | 1 | **PASS** |

Table 2. Comparison and correlations between Somnotouch NIBP and auscultatory measurements

| **Variable** | **SBP** | **DBP** |
|---|---|---|
| Mean difference (mmHg) | -0.45±6.1 (range -22 to 19) | -0.30±3.4 (range -10 to 8) |
| Mean abs. difference (mmHg) | 4.37±4.2 (range 0 to 22) | 2.46±2.4 (range 0 to 10) |
| Correlation coeff. (Spearman) | 0.973 | 0.976 |

Figure 4. Bland-Altman plots comparing Somnotouch NIBP and auscultatory measurements of SBP (left) and DBP (right)




## *Conclusions*

Somnotouch NIBP fulfils ESH IP validity requirements and represents a potentially useful option for cuffless 24 h BP monitoring with lesser interference with nocturnal sleep compared with traditional cuff-based BP monitoring methods.

Poster presented during ESH congress 2014, Athens

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