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- 1 VALIDATION ACCORDING TO THE ESH-IP 2010 PROTOCOL**
  - 2 AGAINST CUFF-BASED METHOD DURING ERGOMETRY**
  - 3 AGAINST CUFF-BASED METHOD OVER 24 HOURS**
  - 4 AGAINST CUFF-BASED METHOD DURING CPAP THERAPY**
  - 5 AGAINST THE PENAZ METHOD**
  - 6 AGAINST INTRA-ARTERIAL BP MEASUREMENT**

SOMNOtouch™ NIBP is listed on the Dable Educational Trust website as a recommended device  
[http://www.dableeducational.org/sphygmomanometers/devices\\_1\\_clinical.html#ClinTable](http://www.dableeducational.org/sphygmomanometers/devices_1_clinical.html#ClinTable)



## We have validated our patented\* PTT technique against other current methods as described below:

1

### Validation of the Somnotouch-NIBP noninvasive continuous blood pressure monitor according to the European Society of Hypertension International Protocol revision 2010.

Bilo, G., et al. (2015), Blood Press Monit, 20(5): p. 291-4.



- ◆ 33 patients from low, medium and high BP strata as required by the ESH-IP
- ◆ All validation requirements of the ESH-IP were fulfilled:

Requirement	≤ 5 mmHg	≤ 10 mmHg	≤ 15 mmHg	2/3 ≤ 5 mmHg**	0/3 ≤ 5 mmHg***	Result
required	73 or 65*	87 or 81*	96 or 93*	≥ 24	≤ 3	
SBP - achieved	75	90	96	28	2	PASS
DBP - achieved	90	99	99	31	1	PASS

Table 1 Validation results

\* two out of three required for the first threshold; three out of three required for the second threshold

\*\* number of subjects with two out of three differences ≤ 5mmHg

\*\*\* number of subjects with none of the differences ≤ 5mmHg

- ◆ SBP: strong correlation of 0.973, device-observer disagreement of 0.44 +/- 6.1 mmHg
- ◆ DBP: strong correlation of 0.976, device-observer disagreement of 0.33 +/- 3.4 mmHg
- ◆ The SOMNOtouch™ NIBP fulfills all the ESH-IP 2010 validity requirements and passed all validation grades for both SBP and DBP levels. The SOMNOtouch NIBP represents a potentially useful option for cuffless BP monitoring with lesser influence on nocturnal sleep compared with traditional cuff-based BP monitoring methods.

2

### Continuous blood pressure measurement by using the pulse transit time: comparison to a cuff-based method.

Gesche, H., et al. (2011), Eur J Appl Physiol, 112(1): p. 309-15.

- ◆ 50 healthy subjects, PTT against cuff-based method, ergometry with stepwise increased load to induce BP rises
- ◆ Both methods significantly correlated:  $r=0.82$  ( $n=267$ ); limits of agreement in the Bland-Altman plot were +/- 19.8 mmHg

### Validation of an ambulatory blood pressure recorder using pulse transit time and a one point calibration to determine non-invasive systolic and diastolic blood pressure.

Dick, R., et al. unpublished

- ◆ 21 subjects, PTT against cuff-based method, standard exercise test
- ◆ Both methods highly correlated: SBP:  $r=0.94$ ,  $4\pm 8$  mmHg; DBP:  $r=0.74$ ,  $-3\pm 8$  mmHg

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### Continuous and non-invasive blood pressure measurement based on pulse transit time: Comparison to oscillometric 24 h ambulatory blood pressure measurement.

Haberl, R., et al., Poster presented at the ESH 2016

- ◆ 30 adults, PTT against cuff-based method, 24 hours
- ◆ Additionally recorded: 3-channel ECG, motoric activity, finger plethysmogram, oxygen saturation and cuff pressure
- ◆ 29% of all measurements were affected by following cuff related artefacts: motoric activity (18%), arrhythmia (5%) and arousal reactions during sleep (6%, corresponding to 18% of all nocturnal BP measurements)
- ◆ After exclusion of values affected by artefacts:
  - SBP:  $r=0.89$ ; DBP:  $r=0.7$  ( $n=921$ )
  - SBP: 1.4 mmHg,  $+18/-15$  mmHg; DBP: 0.3 mmHg,  $+14/-13$  mmHg
- ◆ This study demonstrates that the PTT method is a reliable and favorable method for BP measurement over 24 hours.



### Cuff-less blood pressure measurement using the pulse transit time - a comparison to cuff-based oscillometric 24 hour blood pressure measurement in children.

Hulpke-Wette, M. et al., preliminary data presented at the ESH 2018 congress

- ◆ 100 children planned (5-18 years), PTT against cuff-based method, 24 hours
- ◆ Additionally recorded: 3-channel ECG, motoric activity, finger plethysmogram, oxygen saturation and cuff pressure
- ◆ Preliminary results of 27 children (after exclusion of cuff related artefacts):
  - SBP:  $r=0.8$ ; DBP:  $r=0.7$  ( $n=228$ )
  - SBP: 2.2 mmHg,  $+22/-17$  mmHg; DBP: 4.9 mmHg,  $+22/-12$  mmHg
- ◆ PTT and cuff-based method closely correlated in children during a 24-hour measurement
- ◆ Despite high activity of children, the PTT method provides considerably more BP values than the cuff-based method
- ◆ **Currently recruiting patients**

### Comparison of the continuous non-invasive blood pressure measurement based on pulse transit time with standard 24-hour ambulatory blood pressure monitoring with oscillometric method (COPTAMBO). International multicenter study led by Prof. G. Parati

- ◆ 500 patients planned ( $\geq 18$  years), PTT against cuff-based method, 24 hours
- ◆ Additionally recorded: 3-channel ECG, motoric activity, finger plethysmogram, oxygen saturation and cuff pressure
- ◆ **Currently recruiting patients**

### Pulse transit time: validation of blood pressure measurement under positive airway pressure ventilation. Schmalgemeier, H., et al. (2011), Sleep Breath, 16(4): p. 1105-12.

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- ◆ 64 patients, PTT against cuff-based method, PAP: 0 (baseline), 4, 8, and 12 cmH<sub>2</sub>O for 10 minutes
- ◆ 0 cm H<sub>2</sub>O: SBP:  $r=0.94$ ,  $4.1 \pm 3.2$  mmHg; DBP:  $r=0.95$ ,  $2.3 \pm 2.2$  mmHg
- ◆ 12 cm H<sub>2</sub>O: SBP:  $r=0.839$ ,  $6.6 \pm 4.9$  mmHg; DBP:  $r=0.855$ ,  $4.4 \pm 3.5$  mmHg

### Measurement of apnea related blood pressure changes using pulse transit time and Penaz principle. (Translated from German) Hennig, A., et al. (2012), Atemwegs- und Lungenerkrankungen, 38(11): p. 447-454.

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- ◆ 11 sleep apnea patients were polysomnographically investigated, PTT against Portapres System
- ◆ Both techniques similarly identified respiratory related (apnea and hypopnea) BP changes.
- ◆ Mean values of apnea-induced BP increases: 28.2 mmHg for Portapres and 28.7 mmHg for PTT
- ◆ It could be shown that apnea/hypopnea goes along with transient elevations of BP, which could be reliably detected by the PTT method.

### Continuous blood pressure measurement using the pulse transit time: Comparison to intra-arterial measurement.

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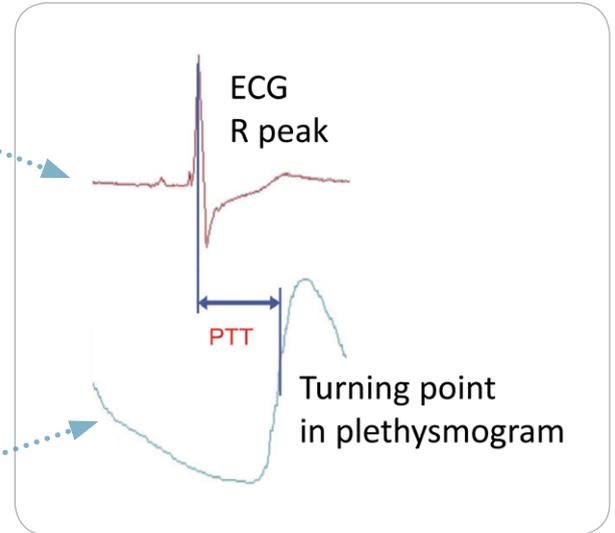
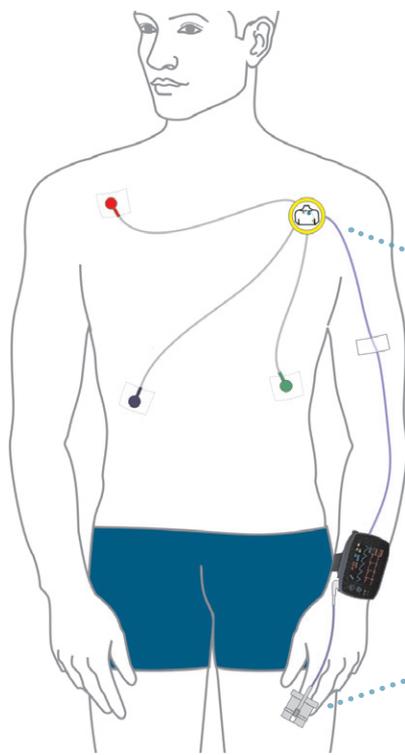
Patzak, A., et al. (2015), Blood Press, 24(4): p. 217-21.

- ◆ 12 healthy subjects, PTT against intra-arterial measurement, dobutamine to create high BP ranges
- ◆ Highly significant correlation: SBP  $r=0.947$ ,  $0.78 \pm 18.9$  mmHg ( $n=107$ )

### Validation of continuous blood pressure measurements by pulse transit time: a comparison with invasive measurements in a cardiac intensive care unit. (Translated from German)

Bartsch, S., et al. (2010), Dtsch Med Wochenschr, 135(48): p. 2406-12.

- ◆ 40 patients on a cardiologic intensive care unit, PTT against intra-arterial measurement
- ◆ Group 1: patients without hypotension and without arrhythmia ( $n=10$ ); Group 2: hypotensive patients ( $n=8$ ); Group 3: Patients with arrhythmia absoluta (by atrial fibrillation and/or complete bundle block;  $n=22$ ).
- ◆ There were no significant differences between recorded SBP and DBP values in subpopulations and the total population.
- ◆ The PTT method can provide reliable values over a period of at least one hour in cardiology patients in whom the R-peak in the ECG and sufficient blood ejection from the heart can be detected.



SOMNOmedics uses an innovative patented algorithm to measure blood pressure via the Pulse Transit Time (PTT). The PTT is the time required for the pulse wave to propagate along the vessel wall between two defined points. In the case of the SOMNOtouch NIBP – from the left ventricle of the heart (defined by the 'R' peak of the ECG) – to the fingertip (detected by the plethysmograph).

Taking a one point calibration at the beginning of the measurement allows us to `set` the software's algorithm – and measure blood pressure continuously throughout the day and night. Because every single pulse wave is detected, a continuous "Beat-to-Beat"-recording and analysis is possible. Reduce artefacts and increase the number of reliable data points – all in a continuous, non-invasive and non-reactive way.



SOMNOtouch™ NIBP

The SOMNOtouch™ NIBP (Non-Invasive Blood Pressure) is a new era in CUFFLESS ambulatory blood pressure monitoring (ABPM).

SOMNOmedics designs, manufactures & distributes diagnostic devices that streamline your workflow by providing innovative, clever, mobile and easy to use solutions that give a deeper insight into your patients health.

Coming from the sleep medicine field we see ourselves as specialists for polysomnography and polygraphy screenings. Additional to that, our experience from the last 25 years also allowed us to tap into cardiology and neurology. Today we provide sophisticated solutions for long-term diagnostic EEGs, long-term ECG and continuous, ambulatory blood pressure measurement. At the same time, we strive to keep our solutions easy to apply, reliable in their results and durable during your daily routine.