

SOMNOtouch™  
NIBP

# A PROVEN CUFFLESS SOLUTION FOR CONTINUOUS BEAT-TO-BEAT BLOOD PRESSURE RECORDING



## CUFFLESS ABPM

WITH HOLTER ECG & SpO<sub>2</sub>

**Caution:** Investigational device. Limited by Federal (or United States) law to investigational use.



The **SOMNOtouch™ NIBP** – our powerful All-in-One product, which simultaneously records blood pressure, Holter ECG, oximetry, actigraphy and PWV – A proven cuffless solution that provides continuous beat-to-beat NIBP and offers a complete vital sign recording, comparison and correlation.



**We have validated<sup>1</sup> our patented<sup>2</sup> (PTT) technique against other current methods as described below:**

1. Validation according to the ESH-IP 2010 protocol<sup>3</sup>
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)

<sup>1</sup> Visit [www.somnomedics.de/enus/somnomedics-diagnostic-devices/research/somnotouch-nibp-2/](http://www.somnomedics.de/enus/somnomedics-diagnostic-devices/research/somnotouch-nibp-2/)



Although it poses serious health risks, high blood pressure typically has no symptoms - so it often goes untreated.



**1 in 3** adults worldwide have high blood pressure



**1 in 4** have prehypertension (a risk factor for high blood pressure)



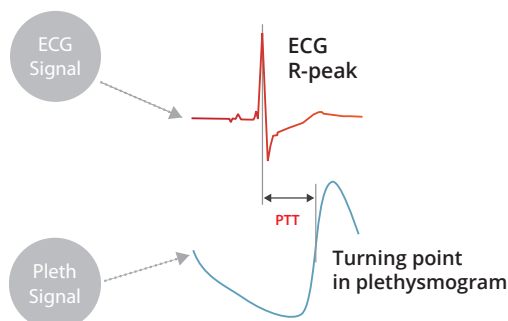
**1 in 5** adults with high blood pressure are **unaware** of it

**7% MORE** Americans will have high blood pressure by 2030, researchers estimate.

Data from [www.who.int](http://www.who.int) and [www.heart.org](http://www.heart.org)



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## How does it work?

SOMNOmedics uses an innovative patented<sup>2</sup> 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, in the case of the SOMNOtouch™ NIBP, from the left ventricle of the heart to the fingertip. Taking a one point calibration at the beginning of the recording allows us to set the software's algorithm – and measure blood pressure continuously throughout the day/night. Because every single pulse wave is detected, a continuous "Beat-to-Beat" recording and analysis is possible.

<sup>2</sup> Patent numbers: DE 102005014048.3-35, EP 20060001181.4-1526, US 11/364174 US 2006/0217616 A1, 7374542

<sup>3</sup> Bilo, G., Parati, G. et al., Validation of the SOMNOtouch™ NIBP non-invasive continuous blood pressure monitor according to the European Society of Hypertension International Protocol revision 2010. Blood Pressure Monitoring. 2015

## SOMNOtouch™ NIBP - 5 measurements from one simple device

### Cuffless blood pressure reading with every heart beat

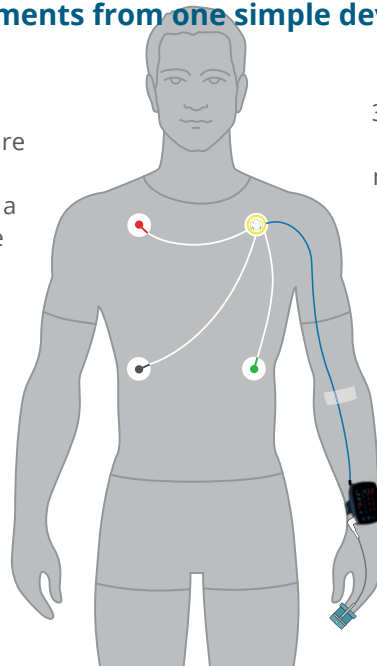
Continuous systolic & diastolic blood pressure (in mmHg) reading that covers all real max. and min. BP values. As we measure without a cuff, our BP values are not influenced by the patients' reaction to cuff inflations. It also minimizes deviations caused by body position changes.

### PWV

Pulse Wave Velocity (PWV) as an indicator for arterial stiffness.

### Actigraphy

Sleep/Wake determination with actigraphy<sup>4</sup>. Correlation of the blood pressure values to physical activity.



### Holter ECG

3 channel ECG. See the max., min. and average heart rate, arrhythmia, bradycardia and tachycardia.

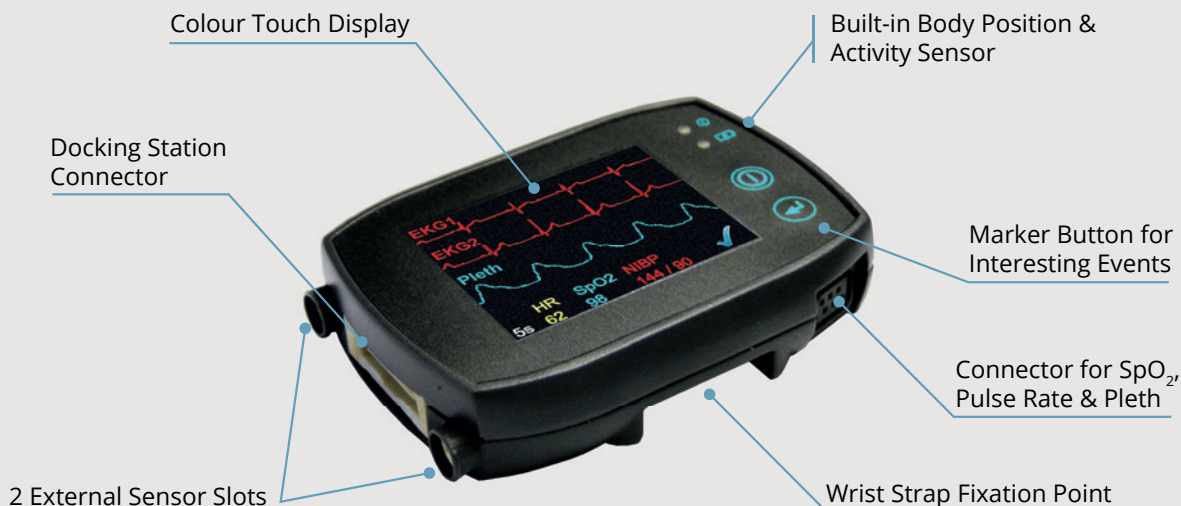
Full Holter ECG analysis with Schiller software plug-in (optional) and a stress report based on HRV.

### Oximetry

Display of the blood oxygen saturation and pulse rate.

Optional respiratory signals can be added for apnea screening and nocturnal correlations.

## Overview



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## Technical Specifications

### Data collection

Data transfer via USB, 12 Bit signal resolution. Individually adjustable sample rate from 1 Hz to 512 Hz

### Data storage

Internal data storage, 512 MB capacity. Charging and data transfer via docking station

### Size and weight

2.9 x 2.2 x 0.7 Inch, 2.05 oz (incl. battery)

22  
Channels

12  
Bit



### Display

High resolution, colour touch display (320 x 240) pixels

### Power supply

Li-Ion battery (rechargeable), up to 24 hours recording duration

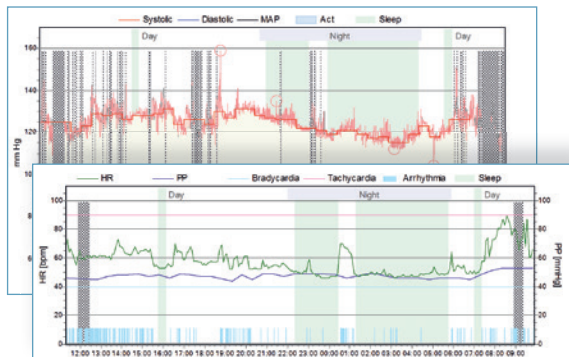
**Analysis software:** DOMINO light

<sup>4</sup> Dick, R., et al., AASM standards of practice compliant validation [...] Physiological measurement, 2010. 31(12): p. 1623-33

<sup>5</sup> Gehring, J., Gesche, H., Drewniok, G. et al. Nocturnal blood pressure fluctuations measured by using pulse transit time in patients with severe obstructive sleep apnea syndrome, Sleep Breath (2018) 22: 337. <https://doi.org/10.1007/s11325-017-1555-9>

## Software Analysis Platform

Imagine being able to see a patient's cardio-health over 24 hours: Where you can see a continuous, reaction-less beat-to-beat data set. That's now possible thanks to the data provided by our patented PTT method.



## Blood Pressure Day/Night

The overview table shows the extremum and mean values of the systolic/diastolic blood pressure, mean arterial pressure (MAP), pulse pressure (PP) and heart rate (HR), for the whole recording, as well as for the day and during time in bed (TIB).

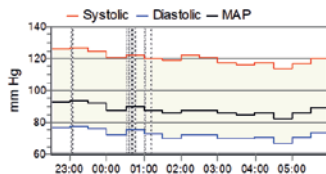
## 24 hour overview

A graphical overview from the entire recording is displayed. The upper part of the figure shows the systolic and diastolic BP, the mean arterial pressure (MAP) and the activity (Act). In the lower part the patients heart rate (HR) and pulse pressure (PP) are presented. Arrhythmias are indicated and the time in bed (TIB) is highlighted as a light green panel behind the graph.

| Blood pressure Day/Night   |         |      |     |      |         |   |  |  |  |
|--|---------|------|-----|------|---------|---|--|--|--|
| Total report   |         |      |     |      |         |   |  |  |  |
|  | Min     | Aver | Max | SD   | > Limit |   |  |  |  |
| Syst. (mmHg)   | 104     | 125  | 159 | 5,7  | 22,1 %  |   |  |  |  |
| Diast. (mmHg)  | 59      | 77   | 92  | 4,5  | 2,4 %   |   |  |  |  |
| HR (bpm)   | 45      | 60   | 120 | 12,1 | 6,1 %   |   |  |  |  |
| MAP (mmHg)   | 75      | 93   | 111 | 4,7  | 12,6 %  |   |  |  |  |
| PP (mmHg)  | 34      | 48   | 73  | 3,2  | 9,3 %   |   |  |  |  |
| No. BP values: 57405 (80% TRT)   |         |      |     |      |         |   |  |  |  |
| Day/Night Dipping  |         |      |     |      |         |   |  |  |  |
| Syst. (mmHg)   | -3,9 %  |      |     |      |         | <input type="radio"/> Reverse Dipper        |  |  |  |
| Diast. (mmHg)  | -6,3 %  |      |     |      |         | <input checked="" type="radio"/> Non-Dipper |  |  |  |
| HR (bpm)   | -17,5 % |      |     |      |         | <input type="radio"/> Dipper                |  |  |  |
| MAP (mmHg)   | -5,3 %  |      |     |      |         | <input type="radio"/> Extreme Dipper        |  |  |  |
| PP (mmHg)  | 0 %     |      |     |      |         |   |  |  |  |
| Classification of BP Levels according to guideline of ESH (WHO)  |         |      |     |      |         |   |  |  |  |
| Optimal <input type="radio"/> normal <input checked="" type="radio"/> High normal <input type="radio"/> Grade 1 HT <input type="radio"/> Grade 2 HT <input type="radio"/> Grade 3 HT |         |      |     |      |         |   |  |  |  |
| Classification according to the mean blood pressure during day   |         |      |     |      |         |   |  |  |  |

## Nocturnal Blood Pressure Fluctuations (NBPF)

|                         | Number (Index) | Time     |
|-------------------------|----------------|----------|
| Inc. (Index)            | 3 (0,5)        |          |
| Maximum Increase (mmHg) | 14             | 02:39:19 |
| Average Increase (mmHg) | 13             |          |
| Max. Systolic (mmHg)    | 135            | 22:50:08 |
| Min. Systolic (mmHg)    | 112            | 04:36:48 |
| Average Systolic (mmHg) | 121            |          |
| Artefact (min)          | 6,4 (1,6%)     |          |



Def. NBPF: Continuous blood pressure increase higher than 12 mmHg within 3 - 30 seconds. Min and Max computed as mean value from 8 values.

## O2 saturation

|                           | Number (Index) | Time     |
|---------------------------|----------------|----------|
| Number of Desaturations   | 33 (5,0)       |          |
| Minimum SpO2 (%)          | 89             | 04:03:35 |
| Baseline O2 Saturation    | 96             |          |
| Average SpO2              | 96             |          |
| Number < 90 %             | 3              | 0,5 %    |
| Number < 80 %             | -              | 0,0 %    |
| Time < 90 %               | 0,0 %          | 00:00:11 |
| Biggest Desaturation (%)  | 8              | 04:02:35 |
| Average Desaturation [%]  | 5,1            | 36,8 s   |
| Longest Desaturation (s)  | 63,0           | 04:25:41 |
| Average Min. Desaturation | 92             |          |

## Nocturnal Blood Pressure Fluctuations

The NBPF™ (Nocturnal Blood Pressure Fluctuations) are shown as an indicator for cardiac stress<sup>5</sup>. NBPF(s)™ are defined as an increase of nocturnal BP of more than 12 mmHg within a timeframe of 3 - 30 seconds. Possible reasons for these short NBPF are periodic limb movement or sleep-related breathing disorders. The majority is caused by apnea, so its recommended that a patient with a high number of NBPF(s)™ should undergo further cardiorespiratory screening.

## Oxygen Saturation

In this report section, users get an overview of the SpO<sub>2</sub> analysis which provides detailed information about the respiratory status of the patient during the night. A table and a graphical overview contain detailed information about the respiratory status of the patient during the night.

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## Conventional BP recording

BP and HR values can be also displayed in the form of a conventional BP report in intervals of 15 (daytime) or 30 (nighttime) minutes. Additionally, the user gets information about the motoric activity (low, median and high activity - thresholds can be user-defined) and desaturations (only during sleep).

This brochure is intended for the USA market only

| Conventional BP recording      |           |            |          |               |        |     |  |  |  |
|--------------------------------|-----------|------------|----------|---------------|--------|-----|--|--|--|
| No. BP values: 57405 (80% TRT) |           |            |          |               |        |     |  |  |  |
| Time                           | BP (mmHg) | HR (bpm)   | HR (bpm) | Activity (mg) | Desat. |     |  |  |  |
| 24.03.2014 11:30:00            | 127/80    | A (W)      | 69       | 80            | 195    | mid |  |  |  |
| 11:45:00                       | 122/76    | 118/74 (W) | 59       | 59            | 113    | mid |  |  |  |
| 12:00:00                       | A         | A (W)      | 62       | 71            | 184    | mid |  |  |  |
| 12:15:00                       | A         | A (W)      | 60       | 56            | 140    | mid |  |  |  |
| 12:30:00                       | 121/74    | 120/74 (W) | 61       | 65            | 108    | mid |  |  |  |
| 12:45:00                       | 119/73    | A (W)      | 61       | 80            | 152    | mid |  |  |  |
| 13:00:00                       | 120/75    | 121/78 (W) | 62       | 63            | 197    | mid |  |  |  |
| 13:15:00                       | 122/76    | A (W)      | 61       | 69            | 153    | mid |  |  |  |
| 13:30:00                       | 122/76    | 124/76 (W) | 61       | 57            | 101    | mid |  |  |  |
| 13:45:00                       | 126/78    | 122/74 (W) | 68       | 67            | 95     | mid |  |  |  |
| 14:00:00                       | 131/82    | 132/81 (W) | 68       | 66            | 75     | mid |  |  |  |