PulsePen[®] The Arterial Tonometer



Pulse Wave Velocity Central Blood Pressure Pulse Wave Analysis

Wireless System

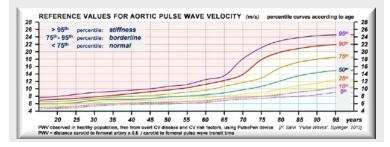
PulsePen is available in two configurations: WPP001-ETT: 2 Tonometers + ECG + USB wireless receiver WPP001-ET: 1 Tonometer + ECG + USB wireless receiver

PulsePen is a class IIa, medical device, CE marked (n. 119/MDR) and certified for all phases ranging from design to production, final inspection and testing. Designed and manufactured in Italy, for both clinical practice and applied research. The quality management system of DiaTecne is ISO 13485 certified (0857.2023).

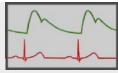
Pulse Wave Velocity

WPP001-ETT and WPP001-ET:

- · Measurement of Pulse Wave Velocity using an arterial tonometer is the non-invasive gold standard method to assess arterial stiffness.
- PulsePen system records pulse waves employing only high-fidelity tonometers, without cuffs.

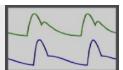


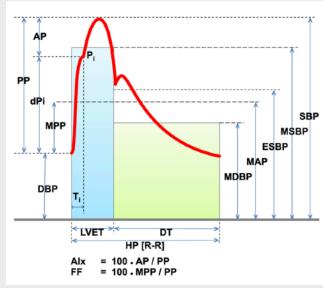
Pulse Wave Velocity is obtained by determining the pulse wave transit time in a certain arterial segment.



WPP001-ET and WPP001-ETT measure the Pulse Wave Velocity in two stages, using the R wave of the gRs complex of the ECG as reference

The two tonometers of the WPP001-ETT allow measurement of the PWV by simultaneously recording pulse waves in two arterial sites.



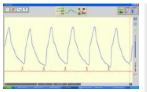


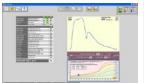
Pulse Wave Analysis

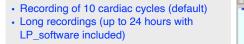
Central Systolic Blood Pressure (cSBP) **Central Pulse Pressure (cPP)** Mean Arterial Pressure (MAP) **Amplification Phenomenon** Form Factor (FF) Augmentation Index (AIx) **Global Reflection Coefficient (GRC) Pulse Wave Separation Analysis** Early Systolic Pulse Wave Slope **Pulse Pressure Variability Heart Rate Variability** End Systolic Blood Pressure (ESBP) Mean Systolic Blood Pressure (MSBP) Mean Diastolic Blood Pressure (MDBP) Isometric Contraction Time (ICT) **Pre-Ejection Period (PEP)** Left Ventricular Ejection Time (LVET) **Diastolic Time (DT) Real SubEndocardial Viability Ratio (SEVR)**

PulsePen® The Arterial Tonometer

Complete Software Suite







• Real time display of the signal quality index



- · Patient database management
- · Import / Export of exams

Separation Analysis

- · Raw data export of curves as text file
- · Automatic export of all parameters to

Central Forward / Backward Pulse Wave

spreadsheet





Automatic Report generation

parameters 3D representation

· Pulse Wave Velocity

Pulse Wave Analysis

Vascular Age

Central Blood Pressure

Integrated Help and Tutorial



- Advanced SEVR estimation (O2 supply / demand ratio at subendocardial level)
- SEVR x CaO₂ assessment
- SEVR x CaO₂ projection
- Ejection Fraction estimation

Technical Specifications

Capture: 16 bit Sampling rate: 1000 S/sec Wireless: ISM @ 2.4 GHz Batteries: AAA - Alkaline 1.5V - IEC LR03 (≥ 50 hours / ≥ 600 exams) Ambient Temperature: +5°C → +40°C Transport and storage Temperature: $^{-}25^{\circ}C \rightarrow ^{+}70^{\circ}C$ Atmospheric Pressure: 860 --- 1060 hPA

Tonometric Unit

Resolution: 0.004 mmHg Differential Range: ≥ 220 mmHg Max Shock: ≤ 150 g Max Vibration: \leq 20 g @ 10 Hz \rightarrow 2 KHz sinusoidal Dimensions [mm]: 114 (L) x 25 (W) x 20 (H) Weight: 25 g (without battery)

ECG Unit

Resolution: 0.15 µV Range: ≥ ± 5 mV Max Vibration: \leq 20 g @ 10 Hz \rightarrow 2 KHz sinusoidal Dimensions [mm]: 49 (L) x 75 (W) x 21 (H) Weight: 36 g (without battery)

USB Wireless Signal Receiver Dimensions [mm]: 67 (L) x 25 (W) x 11 (H) Weight: 12 g

PC (provided by the user) Clock Frequency ≥ 2GHz Ram Memory ≥ 2 GB Free Hard Disk space ≥ 4.5 GB SW + DataBase Graphic Resolution ≥ 1280 x 800, 24 bit color Operating System: Windows® XP SP2/3, Vista, 7, 8, 10 -32/64 bit USB port: USB 1.0 / 2.0 - type A

Browser: HTML5 compatible

Why choose PulsePen:

- · In the assessment of PWV and pulse waveform analysis, PulsePen employs only pressure sensors (tonometers), without cuffs, based on the international recommendations for arterial stiffness estimation.
- Easy recording of the aortic PWV with average running time less than 3 minutes.
 - Validated assessment of central hemodynamic parameters directly based on carotid (central) recording of the pressure waves, without using any "transfer function".
- The PulsePen captures the pressure and electrocardiographic signals at high definition (16 bit) and high sampling rate (1000 Hz).
- Starting from the first model of 2004, PulsePen has been used in numerous clinical and epidemiological studies involving more than 30 thousand patients all over the world.
- More than 180 scientific publications on prestigious international journals (indexed by Scopus and Web of Science) refer to studies in which PulsePen was used
- · The reference values of aortic PWV in the pediatric age have been defined using the PulsePen system.
- · PulsePen allows the estimation of the real balance between subendiocardial oxygen supply and demand (SEVR), taking into account parameters ignored by other systems (such as isovolumic contraction, isovolumic relaxation and diastolic ventricular pressure).
- · The original wireless system allows maximum freedom of movement for the operator.
- · Best performance in terms of signal quality and stability with the lowest variability among similar devices.
- · Designed and certified for use in the daily clinical practice (speed of execution, qualitative evaluation of the signal, automatic reporting) and in the clinical applied research (advanced morphologic analysis of pressure wave, export of parameters to spreadsheet and much more...).
- · Pocket size dimensions. Total system weight less than 100 g.
- · No fees for consumables or periodic updates. Free software upgrades.
- · Competitive price compared with other tonometer instruments on the market.
- PC where to install the PulsePen software, sphygmomanometer for calibration, disposable ECG electrodes and batteries must be provided by the user.





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