Validation of ARTSENS Plus in Comparison to SphygmoCor XCEL for Assessing Arterial Stiffness During Pregnancy: A Cross-Sectional Study

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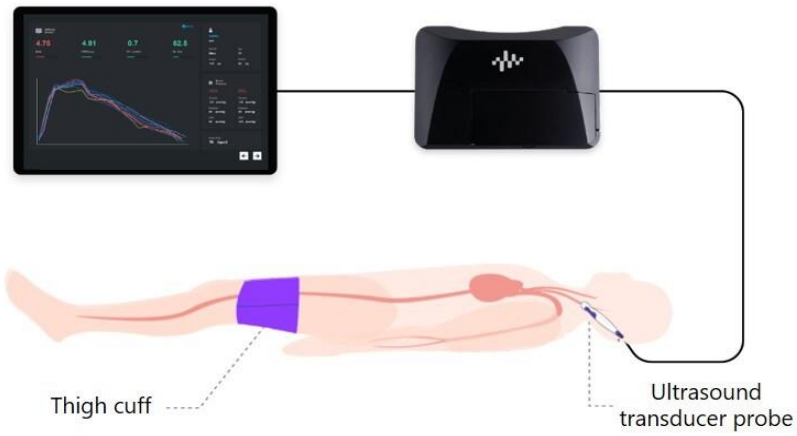
SUPPLEMENTAL MATERIAL

ARTSENS Plus Device Description:



Supplemental Figure 2. Overall Device schematic of ARTSENS Plus.

ARTSENS Plus device measures Pulse Wave Velocity (PWV), through the analysis of synchronously and non-invasively captured pulse wave information from carotid and femoral artery sites [1]. The device is a compact and portable, composed of an ultrasound transducer probe (with single element piezo-crystal),

and bladder-type thigh cuff (Supplemental Figure 2). The ultrasound transducer probe is utilized on the neck to non-invasively capture the carotid artery pulse wave. Simultaneously, the femoral artery pulse wave is captured using an inflatable cuff wrapped around the thigh, the pressure of which is tapped via a pressure sensor. The device uses an OEM Pressure module to control the inflation and deflation of the thigh cuff. The aortic PWV is calculated by dividing the PWV-distance by Pulse Transit Time (PTT). PWV-distance from the carotid to femoral is measured through the 'subtraction method' as per international guidelines [2, 3]. Likewise, the 'intersecting tangent algorithm' yields the required carotid-to-femoral PTT from the captured pulse wave pair. The device is connected to a host computer, via USB, on which a dedicated software is installed for data analysis, display and storage.

The ARTSENS Series device has been put through thorough validations and testing to ensure that the safety and effectiveness requirements are met well [1]. A study was carried out among 90 asymptomatic individuals to verify the device's performance and functionality as per the Artery Society guidelines [3]. The device's accuracy of stiffness measures was validated against the reference measures. The study demonstrated ARTSENS Plus's ability to perform an effortless and reliable evaluation of the local and regional vascular stiffness and central BP with an accuracy that meets clinical standards, and yielded as "excellent grade" accuracy as per Artery Society guidelines [1].

[1]. Nabeel PM, Raj Kiran V, Joseph J. Image-free ultrasound for local and regional vascular stiffness assessment: The ARTSENS® Plus. *J Hypertens* 2022; 40:1537–1544.

[2]. Spronck B, Terentes-Printzios D, Avolio AP, Boutouyrie P, Guala A, Jerončić A, et al. 2024 recommendations for validation of noninvasive arterial pulse wave velocity measurement devices. *Hypertension* 2024; 81:183–192.

[3]. Wilkinson IB, McEniery CM, Schillaci G, Boutouyrie P, Segers P, Donald A, et al. ARTERY Society guidelines for validation of non-invasive haemodynamic measurement devices: Part 1, arterial pulse wave velocity. *Artery Res* 2010; 4:34–40.

Supplemental Table. Reporting checklist for device validation study as per '2024 Recommendations for Validation of Noninvasive Arterial Pulse Wave Velocity Measurement Devices [1]'.

Item	**Check**	**Section**
Identification of two measurement sites used to measure the pressure pulse	✓	Measurement Protocol
Method to obtain transit distance	✓	Measurement Protocol
Does a reference standard device exist?	✓	Introduction & Discussion
If "no" to previous item: mention that this is a "preliminary validation study"	-	Not Applicable
Which device is used as a reference?	✓	Introduction & Discussion
Does the device cause any relevant physiological alteration (e.g., occlusion of vessel, baroreceptor activation due to carotid artery applanation, etc.)? If so, please specify.	No	-
Type of signal (velocity, pressure, flow, other)	✓	Measurement Protocol
Sampling rate (temporal resolution) of acquired and processed signals	✓	Measurement Protocol
Method for detection of fiducial point	✓	Measurement Protocol
Additional input information that is used by the device/algorithm for calculating PWV	-	Not Applicable
Are anthropometric data used in the estimation process?	No	-
Are blood pressure data used in the estimation process?	No	-
Are the algorithms used trained using datasets? If yes, are datasets disclosed?	No	-
If training data is used: Is the training dataset completely independent of the validation dataset?	-	Not Applicable
Have all version numbers of hardware and software used in the validation study been reported, both for the reference device and for the device under test?	✓	Measurement Protocol

Have raw PWV data been recorded in a precision of at least tenths of meters per second (i.e., one decimal when values are recorded in m/s)?	✓	Results
Statement that the device was validated using the 2024 version of the validation recommendations for PWV devices.	✓	Introduction & Discussion
Have all funding and conflicts of interest been declared?	✓	Funding Statement
Has data been uploaded to a publicly accessible repository?	No	Data Availability statement
Has a study population characteristics table (number of individuals, age/sex/blood pressure distribution) been included?	✓	Results (Table 1)
Have Bland-Altman and scatter plots been included comparing the device under test to a reference device?	✓	Results (Figure 2)

[1] Spronck B, Terentes-Printzios D, Avolio AP, Boutouyrie P, Guala A, Jerončić A, et al. 2024 recommendations for validation of noninvasive arterial pulse wave velocity measurement devices. *Hypertension* 2024; 81:183–192.