Supplemental material

Invasive validation of the Antares algorithm for determining central blood pressure based on upper arm oscillometric pulse waves in individuals with type 2 diabetes

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Table S1. *Summary of validation protocol components and requirements of the 2017 ARTERY Society Task Force consensus statement and ANSI/AAMI/ISO 81060-2:2019.*

Protocol section	Protocol item ARTERY 2017	Protocol requirement ARTERY 2017	Protocol item ANSI/AAMI/ISO 81060-2:2019 and requirement	Protocol item undertaken (Yes / No / Comment)
Study setting	Isolated room without disturbing influences	Should	Not specified	Yes
Non-invasive (central) BP device measurement standards	List manufacturer, model, software version, operating principles, signal processing step/s, calibration process	Must	Not specified	Yes
	Time for BP measures; time points of brachial BP and central BP; cuff deflation speed	Should	Must	Yes, full description published in Dörr et al. [19]
	Define and use appropriate cuff size	Must	Must	Yes, full description published in Dörr et al. [19]
	Dimensions of inflatable bladder for all cuff sizes available; process to determine cuff size	Should	Must	Yes
	Separate validation studies for additional or optional features or functions	Must	Not specified	Yes, here focus on central BP
	Process/s of quality control; process used to delineate acceptable quality; number of unacceptable readings; reason/s for exclusion	Must	Not specified	Yes
Invasive (intra-arterial) central BP reference standard	Micromanometer-tipped catheter used if minor inflection points to be identified	Should	Not specified	Not applicable because no invasive waveform features are topic of this validation
	Full description of catheter; frequency response and handling procedures	Must	Not specified	Yes, full description published in Dörr et al. [19]

Table S1. (continued)

Protocol section	Protocol item ARTERY 2017	Protocol requirement ARTERY 2017	Protocol item ANSI/AAMI/ISO 81060-2:2019 and requirement	Protocol item undertaken (Yes / No / Comment)
	Performance comparison of fluid-filled catheter with micromanometer-tipped catheter	May	Not specified	No
Data acquisition at rest	Period of undisturbed rest; medications used	Should	Not specified	Yes
	No talking. Free from acute hemodynamic interventions	Must	Not specified	Yes
	Test device compared with reference over time-period matching the test device deflation cycle; recorded under stable conditions	Must	Must	Yes
	Complete description of protocol; time interval between test device and reference measures	Must	Not specified	Yes
Data acquisition at BP intervention	Hemodynamic change from resting state	May	Must, in case of an intended use of automated non-invasive BP device in physical exercise testing	Not applicable because no intervention done
	Description of the intervention procedure	Must	Not specified	
Sample characteristics	Sample size of at least 85 adults	Should	Sample size of at least 15 patients with not more than 10 valid BP measurements per patient. At least 150 valid BP measurements	ARTERY 2017 requirements were fulfilled but ANSI/AAMI/ISO 81060-2:2019 requirements were not
	Sex distribution of at least 30% male and female	Should	Must	No, study population consisted of 76% males and 24% females

Table S1. (continued)

Protocol section	Protocol item ARTERY 2017	Protocol requirement ARTERY 2017	Protocol item ANSI/AAMI/ISO 81060-2:2019 and requirement	Protocol item undertaken (Yes / No / Comment)
	Participants should have sinus rhythm unless the device is being tested for accuracy during arrhythmias	Should	Not specified	Yes
	Devices should be tested over a range of BP	Should	Must	Yes, but not testable for all proposed indicative ranges, see Table S2
	Device accuracy should be tested across a range of heart rates (i.e., 60-100/min)	Should	Not specified	Yes
Statistical requirements	Description of subjects	Must	Not specified	Yes
	Comparison between non-invasive and reference BP's must report mean difference, SD of the mean difference, and limits of agreement, illustrated by modified Bland-Altman plots	Must	Comparison between non-invasive and reference BP's must report mean difference and SD of the mean difference	Yes, mean difference between the estimated and invasively measured central BP was calculated according to ANSI/AAMI/ISO 81060-2:2019
	Scatter plots of the measures obtained with the non-invasive device (on Y axis) the reference method (on X axis), with the line of equality	May	Not specified	Yes
	Absolute BP differences from the reference should be presented as a clinical meaningful illustration of the results but without a pass/fail criteria	Should	Not specified	No

BP, blood pressure; SD, standard deviation

Table S2. *Invasive central (aortic) blood pressure (cBP) and data distribution of individuals with type 2 diabetes (n=119).*

cBP Distribution	**N (%)**
cSBP≤100 mmHg	8 (7)
cSBP>100<140 mmHg	56 (47)
cSBP≥140<160 mmHg	35 (29)
cSBP≥160 mmHg	20 (17)
cDBP≤60 mmHg	28 (24)
cDBP>60<85 mmHg	86 (72)
cDBP>85<100 mmHg	5 (4)
cDBP≥100 mmHg	0 (0)

cSBP, central systolic blood pressure; cDBP, central diastolic blood pressure

Table S3. *Beat-to-beat variations in invasive central (aortic) blood pressure (cBP) in individuals with type 2 diabetes (n=119) presented as standard deviation (SD).*

SD of invasive cBP	
cSBP [mmHg]	4.5 ± 1.8 (1.3-9.6)
cDBP [mmHg]	2.4 ± 1.1 (0.3-5.7)
cMAP [mmHg]	3.1 ± 1.4 (0.8-7.8)

Values are presented as mean ± standard deviation (min-max); cSBP, central systolic blood pressure; cDBP, central diastolic blood pressure; cMAP, central mean arterial pressure