SMT White Paper

Validity of Vicorder Determined Aortic Pulse Wave Velocity (PWV_a) Pulse Wave Analysis (PWA) Central Pressures

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1 Pulse Wave Velocity (PWV)

1.1 Specifications

Pump rate, large cuff (10 cm):	500 cc to 150 mmHg, less than 10 seconds
Pump rate, neck cuff (1.9 cm):	100mmHg, less than 6 seconds
Deflation time:	500cc, 150mmHg to 10mmHg, typically 3 seconds
Pressure resolution:	7.15E-5 mmHg
Time resolution:	1.798 ms
Target pressure default:	65 mmHg
Pressure setting steps:	5 mmHg
Sweep speed:	3.5 s

1.2 PWV Parameters Definition and Accuracy

During the PWV test parameters are derived from the plethysmographic wave forms in both pressure channels.

$$PWV = L / TT \quad [m/s]$$

where *L* (Length) in m is the distance between the two pulse waves displayed on the Vicorder screen and *TT* (Transit Time) in s is the time delay between the two waves. For purpose of better resolution and understanding TT is displayed in milliseconds (ms).

L needs to be entered into the data window by the operator in centimetres with one decimal resolution, e.g. 52.5 [cm]. A definition and thorough description of the anatomical distance that leads to length is given in the SMT White Paper "*Distance Measurement in Pulse Wave Velocity Testing by Vicorder*".

TT represents the essential parameter determined in PWV testing. While Vicorder can be used to determine PWV between any two accessible locations along the arterial tree, the most relevant is the aortic PWV (PWVa), best approximated by measuring the PWV between carotid and femoral arteries (PWVcf). PWVcf represents an internationally recognized gold standard in arterial stiffness testing [1, 27].

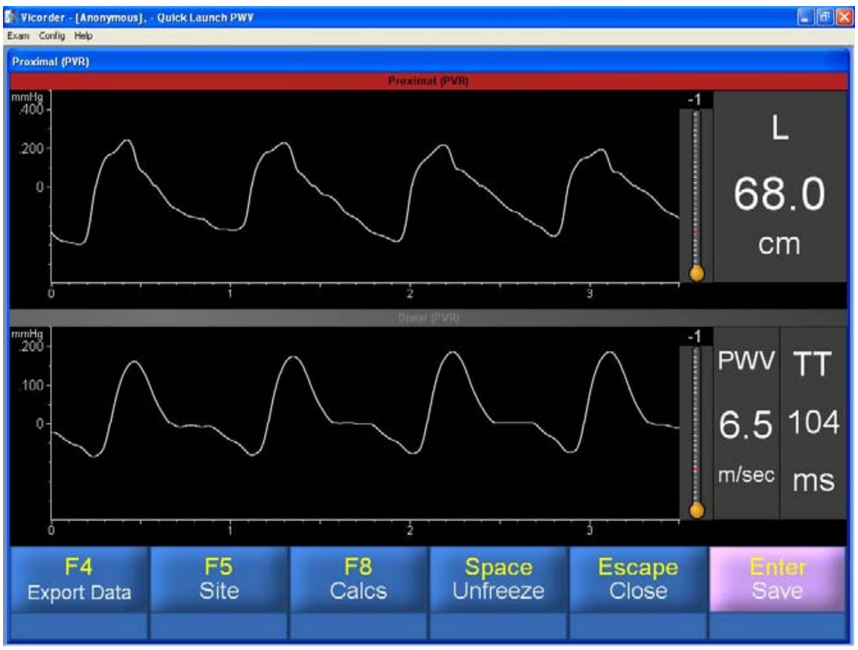

Fig. 1.2: Vicorder PWV test screen

Preparing the PWVcf test, a special neck band with a small pad cuff is placed at the lateral right side of the neck over the common carotid artery region and a standard 10 cm cuff is placed at the upper thigh. Traces of pulse waves in the carotid and femoral arteries are displayed online, as can be seen in above figure 1.

PWV between brachial and femoral arteries (PWVbf) have been proposed as an alternative approximation of PWVa [2]. Potentially the test could be more convenient – not requiring the placement of a neck pad - and probably faster. Different distance definitions have been proposed as congruence with existing published norms should be sought. This test is especially fast, reliable, and operator independent. It can also easily be combined with Ankle-Brachial-Index (ABI) testing which is included in any Vicorder model.

For determination of TT from displayed pulse waves, a proprietary algorithm selects the rapidly rising lower portions of all systolic sections from both, the proximal and distal waves. The other wave parts, i.e. the upper systolic and the diastolic parts, are not considered for evaluation. The selected portions of the waves are processed by cross correlation to yield TT. Erratic waves not meeting certain quality criteria will be discarded and not considered by the TT algorithm. This algorithm offers crucial methodological and practical advantages over the algorithm used by tonometry based devices as the Sphygmocor.
Additional more detailed explanations about the algorithm determining TT which can be found in the SMT White Paper 'Vicorder Methods Research'.

Further PWV indicators are:

Heart Rate (HR) derived by analysing the lower channel wave form, given in beats per minute (bpm)

Beats: Number of heart cycles that are available for evaluation.

Pulse Pressure Index (PPI) reflects the pressure amplification of the pressure wave along the arterial tree

$$PPI = PP_p / PP_d$$

where PP_p is the mean proximal pulse pressure and PP_d the mean distal pulse pressure; i.e. PPI represents the ratio of mean pulse pressure in the proximal channel over the mean pulse pressure in the distal channel indicating the increase in pulsatility.

1.3 PWV Validation

Extensive validation of the PWV test has been taking place at the University of Cambridge, UK, Vascular Research Institute (Head: Prof. I.B. Wilkinson), University of Perugia, Italy, (Dr. G. Pucci), University of Heidelberg, Germany (Pediatric Nephrology, Prof. F. Schaefer, Assistant Prof. Dr. A. Wuehl), Hannover Medical School, University of Hannover, Germany (Pediatric Nephrology, Prof. A. Melk, Adult Nephrology Ass. Prof. B. Schmidt), Great Ormond Street Hospital, London (Dr. R. Schroff), University of Budapest (Department of Pediatrics, Dr. Kis) and other renowned institutions. Results from several studies have been published [2, 3, 4, 5, 8, 15, 16, 21, 22, 23], are pending publication or still ongoing. These studies compared PWV test results obtained in the Vicorder with those obtained by the Sphygmocor Vx model, prior to 2012 (SCor), a device manufactured by Atcor Medical in Australia, and other devices. As the SCor has been in use in various countries for several years, it serves as a reference standard for other devices [24]. Because SCor implements tonometry for pulse wave recording, tests can be carried out only in one vessel site, e.g. femoral, at one time, and requires ECG synchronisation to estimate transit time (TT) between sites. Users describe the operation of SCor as "technically challenging and demanding and operator dependent" [2]. To ensure low variability in tonometry based, ECG gated instruments tests need to be discarded in case blood pressure and heart rate changes between carotid and femoral recording [23]. Vicorder uses plethysmographic oscillometry which has the advantage of synchronous recording and direct determination of TT. While Vicorder implements more user friendly technology and offers much better pressure and time resolution, its methodology keeps close to that of the SCor device allowing direct comparison of results.

The documented advantage of Vicorder lies in its speedy, operator independent test results which have been repeatedly confirmed by researchers. In 122 adults (58±18 years of age) the mean difference between PWVcf in Vicorder and SCor was 0.31 m/s [3]. Vicorder measured PWVcf had an intra-subject variability of only 2.8% and a paired mean difference of only 0.01 m/s.

In 131 healthy school children (aged 6-18 years) Vicorder measured PWVcf was 4.6±0.6 m/s versus 4.9±0.6 in SCor [4]. In a more recent publication [5] "intra- and inter-observer repeatability of the Vicorder results were excellent, with coefficients of variation of 5.6% and 5.8% and intraclass correlation coefficients of 0.8 and 1.0."

In a pediatric and adolescent population (n=98, 6-27 years) Vicorder acquired PWVcf was compared to SCor and PulsePen (PP), the latter being a tonometer made in Italy, similar in technology and methodology to Scor. When using the suprasternal notch to mid of thigh cuff distance that we recommend in our manuals Kis et al. [23] found that "PWV measured by the three devices showed highly significant correlations" and "all instruments tested were in excellent concordance using the ARTERY Society guidelines" [24]. While the mean PWVcf difference between SCor and PP was 0.12 m/s, the differences between Vicorder and Scor and PP were -0.17 and -0.03 m/s respectively. The variability in the differences was lower for the Vicorder (0.74 and 0.72 vs SCor and PP) than between the other two instruments (0.77 m/s). Also the intraobserver variability was the lowest for the Vicorder at 5.1% (PP 5.7%, SCor 7.2%) in line with the findings of Kracht et al. [5] and others. In [23] the authors make some controversial statements about the distance measurement and claim that the Vicorder manual recommends the use of SSN to *top of thigh cuff* distance which is incorrect. The manual leaves the distance determination to the user but recommends the SSN-mid of the cuff distance. Already before the publication of [23] the subject of distance measurement was covered by both Kracht [5] and Hickson [3] and the measurement to mid of cuff clearly marked as the method of choice.
Although one of the authors in [23] is financially related to the makers of the PP system, as mentioned in the conflict of interest statement, they, in concordance with other researchers, document the excellent accuracy and lower variability of Vicorder as compared to other devices.

In conclusion, a review of current scientific literature confirms, Vicorder offers similar or better accuracy and reliability in Pulse Wave Velocity testing as compared to other validated and internationally acknowledged instruments but Vicorder impresses with better repeatability, faster test times, lower operator dependence.

1.4 PWV Diagnostic Information and Interpretation

In a "Scientific Statement from the American Heart Association" [6] the importance of PWV as a clinical surrogate of arterial stiffness and an early indicator of atherosclerosis is described as follows: "PWV increases with increasing arterial stiffness and vascular damage. In adults, aortic PWV is strongly associated with the presence and extent of atherosclerosis and is increased in the presence of various cardiovascular risk factors, including diabetes, hypertension, end-stage renal disease, hyperlipidemia, increasing age, and sedentary lifestyle. PWV is an important, perhaps even the strongest, independent predictor of cardiovascular events." Other publications emphasize the extraordinary significance of PWV

in evaluating cardio-vascular complications in different diseases, such as chronic kidney disease, diabetes, and hypertension.
With a mounting prevalence of hypertension The European Societies of Cardiology and Hypertension issued recommendations for hypertension management, postulating PWV testing in clinical practice [7].

In a large multi-center study led by the University of Heidelberg the complex interrelation between chronic kidney disease and heart failure in children and adolescents will be investigated www.4c-study.org. In this international study funded by the European Union and conducted in more than 50 clinical centres in 14 European countries Vicorder instruments are widely used to measure arterial stiffness parameters in children 6-17 years old. As most of the children undergoing dialysis may succumb in the early part of their life – usually not from the underlying kidney disease but most likely from the complications of cardiac events – this study has a high profile among pediatric nephrologists around the world. The first papers concerning PWV in nephrotic children have already been published [4, 8], with more to follow soon.
As many diseases in which arterial stiffness and endorgan damage occur are (Western) lifestyle related, epidemiology is particularly interested in PWV, PWA, and ABI. Currently Vicorder is used in several epidemiological studies, e.g. in the Leipzig Life Study www.uni-leipzig-life.de conducted at the University of Leipzig. This study funded by the European Union and the German Federal State of Saxonia will follow the health of about 30000 inhabitants of the city of Leipzig by clinical testing over a period of more than 10 years. In this study, Vicorder is used for testing of both adults and children.
Vicorder has also been used in other epidemiological and clinical studies in Germany, Italy, Spain, The Netherlands, UK, Qatar, Malaysia, Hongkong, New Zealand and others. The instrument has been chosen not only for its fast, operator independence, but for its reliable testing in obese and indigent subjects.

Recently normative data for PWV have been published by the European Society of Hypertension [9]. Although this paper documents normal reference data related to various degrees of blood pressure, the evaluation of PWV in a mid age range and at fairly normal blood pressure range can be categorized simply into:

Normal	PWV $<$ 10 m/s
Borderline	10 $\leq$ PWV $<$ 12 m/s
Pathological	PWV $\geq$ 12 m/s

Also the German Society of Arterial Stiffness ‘DeGaG’ takes a similar simplistic approach [10, 11]. Already in 2005 the dependence of PWV on age was described [12] showing an increase of PWV from 5 m/s in youth to values above 12 m/s in elderly persons aged 90+, independently of gender.

As early as 1983, Aviolo et al. [13] investigated the arterial (vessel wall) compliance by measuring aortic Pulse Wave Velocity in a Chinese population. This publication represents one of the first and possibly the most important epidemiological aortic PWV study to date. Despite the congruence with more current studies of PWV in large populations we should consider the enormous progress PWV testing has taken, both in simplicity and speed of application, availability, and cost.

2 Pulse Wave Analysis (PWA) and Central Pressures

2.1 PWA Specifications

Pump rate, large cuff:	500 cc to 150 mmHg, less than 10 seconds
Deflation time:	500cc, 150mmHg to 10mmHg, typically 3 seconds
Pressure resolution:	7.15E-5 mmHg
Time resolution:	1.798 ms
Target pressure set to:	65 mmHg
Pressure setting steps:	5 mmHg
Sweep speeds:	3.5 s

2.2 PWA Indicator Definition and Accuracy

Pulse Wave Analysis (PWA) is a rather general description for the analysis of arterial pressure waves at different vessel sites. The Vicorder based PWA relates to the recording of plethysmographic pressure waves at the upper arm, i.e. the analysis of the brachial pulse wave. The aim of this analysis consists in the assessment of aortic central pressure waves and different parameters of arterial pulse wave reflection. The application requires the placement of a cuff on the upper arm which will be inflated to (approximately) diastolic pressure. If diastolic pressure is unknown, a target pressure of 65 mmHg is sufficient. Brachial waves will be displayed and averaged, while the averaged brachial wave will be displayed additionally. In real time, the aortic central pressure wave will be calculated from a ‘global transfer function’. The global transfer function determines the relation between brachial and central pressure and is based on studies using invasive data from catheterisation of brachial and central arteries. This relation is applicable to all ages, as well as healthy and diseased persons, therefore it is called “global” transfer function. The transfer function used in the Vicorder PWA test was found by Prof. M. O’Rourke, a legend in vascular research, and published as early as 1970 [14].

The prime parameters of PWA are the systolic and diastolic central pressure, the augmentation pressure and augmentation index as indicators of arterial wave reflection properties (also refer to section 2.4 below).

A typical Vicorder PWA result screen is given below:

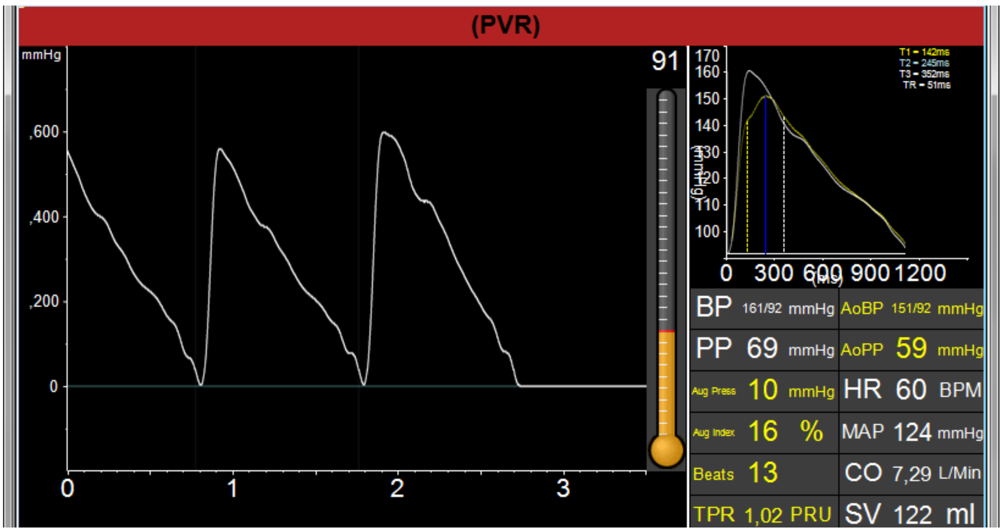

Fig. 2.2: Vicorder PWA test screen

On the left side real time brachial pressure waves are displayed. The right part of the panel shows the mean brachial wave (white colour trace) averaged from previously recorded brachial pressure waves. While pressure waves on the left reflect the plethysmographic cuff reading, represented by a fairly low pressure of only some tenth of mmHg, the mean brachial wave in the right panel is scaled to systolic and diastolic pressure. The yellow trace in the right upper panel indicates the central aortic pressure wave derived from the brachial wave by applying the global transfer function. A yellow vertical cursor (dashed yellow line) is placed at the “shoulder notch”, where the incident wave originating from the heart is superimposed by the reflected wave. The blue line indicates peak systolic pressure of the central wave while the white cursor is set at the end-systolic point, separating systolic and diastolic wave sections. On the upper right side of this panel, the times T1 through T3 are given corresponding to the time related location of yellow, blue, and white cursors. TR gives the estimated Reflection Time.

Based on the 24 bit A/D conversion of the Vicorder which yields a pressure resolution of 0.0000715 mmHg per bit, the brachial pressure wave with a peak of about 0.5 mmHg contains a resolution of more than 6600 dots. Compared to the Sphygmocor (Scor) device which is accepted as an international standard (refer also to section 1.3 above) this resolution is by a factor of about 1000 higher. As SCor reads absolute pressure, its pressure resolution of 12 bit or 0.073 mmHg per bit would only lead to an equivalent curve consisting of less than 1000 dots.

In the lower part of the right panel the following indices are given:

Brachial blood pressure (BP) in mmHg, reflecting the brachial systolic and diastolic pressures.

Aortic blood pressure (AoBP) in mmHg, reflecting the aortic central systolic and diastolic pressures, calculated from the global transfer function.

Pulse pressure (PP) reflecting the brachial pulse pressure, the difference between systolic and diastolic pressure.

Aortic pulse pressure (AoPP) in mmHg reflecting the central aortic pulse pressure, the difference between systolic and diastolic central aortic pressure.

Peripheral augmentation pressure (pAI) in mmHg reflecting the peripheral augmentation pressure derived from the brachial pressure wave, for explanation see below.

Augmentation pressure (Aug Press) in mmHg reflecting the central aortic augmentation pressure derived from the central pressure wave, for explanation see below.

Augmentation index (Aug Index) in % reflecting the central aortic augmentation index, the percentage ratio of central aortic pulse pressure over central aortic augmentation pressure, both derived from the central pressure wave, for explanation see below.

Mean Pressure (MAP) in mmHg referring to mean arterial pressure, derived as the arithmetic mean over the brachial pressure wave, where the mean pressure is supposed to be equal throughout the arterial tree.

Heart rate (HR) in beats per minute (BPM) reflecting the mean heart rate derived from the timing of the brachial waves.

Number of heart beats (Beats) referring to the number of recorded heart cycles that were evaluated.

Total peripheral resistance (TPR) in Peripheral Resistance Units (PRU) referring to the estimation of total peripheral resistance derived from the post systolic and diastolic portion of the central pressure wave.

Cardiac output (CO) in L/min relates to the non-invasive cardiac output that is calculated by Ohm's law:

$$CO = MAP / TPR$$

where MAP and TPR are the above given parameters

SV stroke volume in ml refers to the cardiac stroke volume that is derived from CO by

$$SV = CO / HR$$

where CO and HR are the above given parameters

2.3 PWA Validation

Extensive validation of the PWA test has been taking place at the University of Cambridge, UK, Vascular Research Institute, Head: Prof. I.B. Wilkinson), University of Perugia, Italy, (Dr. G. Pucci), the University Paris Decartes (Dr. A. Redheuil), and other renowned institutions. Results from several studies have been published [15, 16, 21, 22, 26], are pending publication or still ongoing. Basically, these studies compared central pressures obtained in the Vicorder with those obtained by invasive measurements using catheterization and/or by the Sphygmocor (SCor), a device manufactured by Atcor Medical in Australia. As the SCor has been in use in various countries for several years, it serves as a reference standard for other devices. SCor implements tonometry for pressure wave recording at the radial, brachial, or carotid arteries. Users describe the operation of SCor as "technically challenging and demanding and operator dependent" [2]. In contrast, Vicorder uses plethysmographic oscillometry which has the advantage of employing a cuff placed on the upper arm. While Vicorder implements more user friendly technology and offers much better pressure and time resolution, its methodology keeps very close to that of the SCor device allowing direct comparison of results.

In 30 patients undergoing elective diagnostic cardiac angiography, central systolic (SBP) and diastolic (DBP) blood pressures were determined by a fluid-filled catheter inserted into the femoral artery and advanced into the aortic root [15]. Obtained invasive pressures were compared to Vicorder as well as to SCor estimated central pressures. While both instruments apply a global transfer function for deriving central pressure, Vicorder records brachial pressure waves while SCor records radial pressure waves. Mean invasive central SBP was 136 mmHg, Vicorder derived SBP was 135, and SCor SBP was 129 mmHg. Vicorder SBP was highly correlated with invasive SBP (R=0.946). While deviation from invasive SBP was -0.7 in Vicorder, Scor deviated by -6.6 mmHg. The variation of Vicorder pressures was lower at 5.7 than SCor at 6.8 mmHg respectively. Only when SCor was calibrated to mean brachial pressure, not to systolic and diastolic pressures as usually done in clinical setting, SCor delivered similar accuracy as the Vicorder. Also in the assessment of central DBP Vicorder was closer to invasive pressures than SCor. Only when calibrated to mean pressure SCor was able to attain a similar accuracy in pulse pressure reading as Vicorder. A peer-reviewed paper has been published recently [26] in which results of a larger study conducted at the University of Cambridge, Vascular Research Institute (Head: Prof. I.B. Wilkinson) were documented, extending and basically confirming the above findings.
Redheuil [16] compared the Vicorder assessed non-invasive central SBP in 49 subjects without overt cardiac disease during a Magnetic Resonance Imaging (MRI) procedure with those obtained from tonometry based carotid SBP determined by SCor. Although central

SBP was assessed by Vicorder during MRI and carotid SBP by SCor right after the procedure – outside the coil of the MRI device - there was a high agreement between results. Average SBP was 106±14 mmHg in the Vicorder and 105±13 mmHg in the SCor. Vicorder assessed the central SBP through measurement of the brachial pressure and application of a global transfer function entirely operator independent while the subjects were in the coil of the magnet. To our knowledge Vicorder is the only commercial instrument that can readily be used for the assessment of central SBP during MRI and other procedures where remote testing of blood pressures may be desirable. SCor determined the carotid SBP after the subjects were removed from the coil, needing additional test labour by operators performing the test. The authors also compared aortic distensibility using the Vicorder and found a higher correlation to Augmentation Index and carotid femoral PWV than in values derived from the carotid SCor measurement.

In conclusion Vicorder is able to non-invasively determine central pressures accurately, when compared to invasive catheter based readings or when compared to similar non-invasive instruments, but is less operator dependent and can even be used in difficult situations and circumstances such as MRI.

2.4 PWA Diagnostic Information and Interpretation

When considering the clinical relevance of PWA testing there are two aspects of importance. First and foremost, PWA allows non-invasive assessment of central aortic pressure, logically and undisputed the closest link to left ventricular load. Secondly, in PWA testing Augmentation pressure or Augmentation Index (AIx), the ratio of Augmentation pressure to central pulse pressure, is evaluated, in order to assess the reflecting properties of the arterial tree, linking central and brachial pressures. For over a century brachial pressure has been used as a gold standard in attaining a gauge of cardiac load. In every day practice it has become the standard of care. The international societies, such as the European Society of Cardiology issued recommendations in treating hypertension [7]. Besides maintaining (brachial) blood pressure in tight boundaries, the societies also recognized the urgent need for more relevant descriptors, such as central pressure and AIx. A very thorough outline of PWA testing and interpretation is given in [17]. Although the testing modality described in the latter paper consists in operator dependent applanation tonometry it can be readily replaced by less cumbersome plethysmographic oscillometry as executed by Vicorder.
There is a good chance that central pressure will soon replace brachial pressure in the mind of the clinician. The technology for attaining this goal is available: Central pressure can be derived from Global transfer function by Fast Fourier Transform and built into any digital sphygmomanomter.
While AIx and its clinical value have been extensively described in the scientific literature over the past years [18], no reliable normative data have been published. From the few studies that are available it is clear, that AIx may be a good bio-marker in youth and middle aged subjects as AIx rises steadily with age, but less suitable for an elderly population as AI remains fairly constant over the upper decades.
The reflecting properties of the arterial tree are well described by AIx, but not necessarily arterial stiffness. There is common ground between AIx and PWV, but crucial differences exist [19]. In disease, at least in nephrotic patients, PWV is a more powerful parameter, allowing better recognition and differentiation of arterial stiffness than Aix [25].

In conclusion, Vicorder based PWA is a scientifically and clinically viable, operator independent tool in the non-invasive assessment of central pressures and augmentation.

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Vicorder is a product of Skidmore Medical Ltd., Upton Cheyney, Bristol, UK

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