

## The Effect of Beat-to-beat Arterial Pulse Pressure Variability on the Measurement of Endothelial Function: The Cordex SmartCuff™ Device

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**Background:** The Cordex SmartCuff™ System is a non-invasive, non-operator dependent, non-imaging technology that operates on the platform of an automated blood pressure (BP) cuff. Utilizing a proprietary mathematical algorithm, the SmartCuff System assesses vascular endothelial function through oscillometry, plethysmography and signal processing from the BP cuff. This system is intended to provide key individual information to assess cardiovascular health. The study was designed to examine the relationship between *direct* (via an indwelling radial arterial catheter) and *indirect* (via the SmartCuff) arterial beat-to-beat pulse waveform analysis.

**Objective:** The primary objective of this study was to examine whether or not beat-to-beat fluctuations in arterial pulse pressure cause variability in the Cordex endothelial function measurement (EnDys™ Score), as pulse pressure is a key variable present in the Cordex SmartCuff endothelial function measurement algorithm.

**Method:** The study protocol was approved by the Fundación Cardioinfantil-Instituto de Cardiología (Bogotá, Colombia) Clinical Research Ethics Committee (IRB) and all subjects gave written informed consent. Acquisition of intra-arterial pressure measurements and waveforms for each cardiac cycle were obtained utilizing a system composed of a Phillips MP20 and M1006B invasive pressure system/monitor and a Cardiotek EP-Tracer-2 system/monitor. The pressure waveforms obtained from the invasive pressure monitoring system provided the beat-to-beat waveform analysis framework for each cardiac cycle. Non-invasive measurements by the SmartCuff system were obtained for each cardiac cycle from the non-catheterized upper extremity using a band pass filtered pressure waveform from the pressure transducer, in series with the Cordex System, which provided peak-to-peak delta pressure values during cuff pressure descent. The Cordex SmartCuff signal and the intra-arterial signal were captured on the same time axis. Following time series alignment of arterial pulses from both sources (intra-arterial pressure measurement and SmartCuff System), analysis of each individual pulse pressure and the average value from the series of those pulse pressures was determined for each subject. This measurement is expressed via a magnitude differential in arterial volume measurement when substituting individual pulse pressure for average pulse pressure over the entire arterial transmural pressure range. Data management and analysis was conducted by Cordex Systems, Inc.

**Results:** Twenty-three (23) adult Hispanic subjects, with a clinical indication for cardiac catheterization via a radial artery approach, were enrolled following standard procedure. The mean age of the study population was 61 years (range 44 – 84) and 39% of the subjects were female. 78% of the subjects had a history of cardiovascular disease, including hypertension, prior myocardial infarction, coronary artery disease and congestive heart failure. Two (2) of the subjects also had insulin dependent diabetes mellitus. All test procedures were well tolerated by the subjects without incident.

The average arterial compliance difference between the intra-arterial and SmartCuff measurements for all subjects, pressure pulses, and transmural pressure ranges was  $-0.4\%$  ( $SD = 1.35$ ).

**Conclusion:** Beat-to-beat pulse pressure variation was not a significant contributor to the endothelial function measurement and therefore did not negatively impact the data acquired noninvasively by the Cordex SmartCuff System.