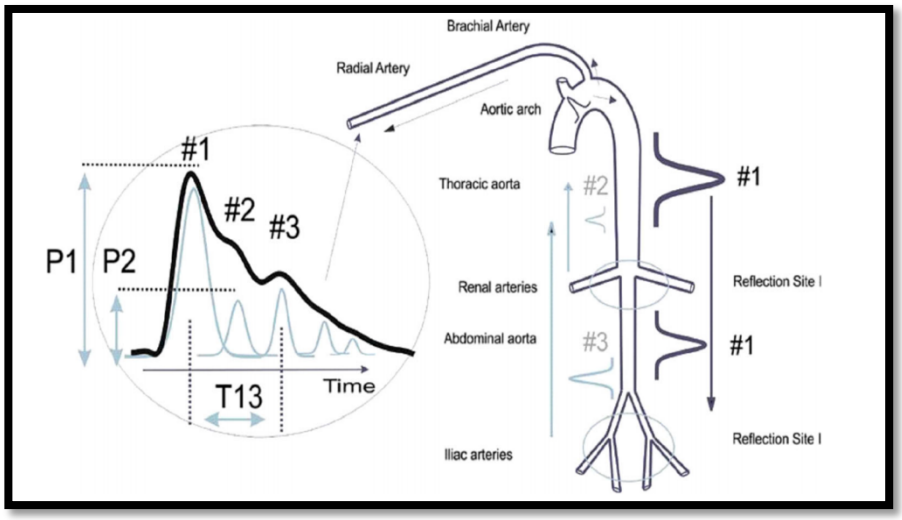
## Pulse Decomposition Analysis (PDA)

VitalStream™ is a highly compact and low weight physiological monitor that is FDA-cleared for the beat-by-beat measurement of blood pressure, hemodynamics, heart rate and respiration. The device communicates physiological data wirelessly to a display device such as an Android tablet or phone.

VitalStream's operational principle is based on the Pulse Decomposition Analysis (PDA) algorithm that analyzes the components of the arterial pressure pulse envelope, which are the left ventricular ejection pulse component and the trailing pulse components.




*Sketch of the aorta/arm complex arterial system and its effect on the arterial pressure pulse line shape that is observed at the radial/digital artery. Two reflection sites, one at the height of the renal arteries, the other one in the vicinity of the iliac bifurcation, give rise to the reflected pulses (gray) that trail the primary left ventricular ejection (black).*

The reflection component pulses are due to two major arterial reflection sites located in the central arteries. The first reflection site is the juncture between thoracic and abdominal aorta, which is marked by a significant decrease in diameter and a significant change in elasticity. The reflection coefficient of this juncture is highly sensitive to blood pressure changes because of the pressure- dependent expansion of the diameter of the thoracic artery relative to that of the abdominal artery. The second site arises from the juncture between abdominal aorta and the common iliac arteries.

The two reflected arterial pressure pulses counter- propagate with respect to the original left ventricular ejection pulse. In the arterial periphery, at the radial or digital arteries, these reflected pulses, the renal reflection pulse (P2), also known as the second systolic pulse) and the iliac reflection pulse (P3, also known of as the diastolic pulse because it arrives during diastole), arrive with distinct time delays.
Physiological parameters, such as blood pressure, are determined by extracting and tracking pulse parameters. Changes in central blood pressure are tracked using the ratio of the amplitude of the renal reflection pulse (P2) to that of the primary systolic pulse (P1). Other pulse parameters have been shown to track arterial stiffness and blood volume and are in the validation stage.

Completed and ongoing clinical studies have validated the PDA model and demonstrated accuracy. [i] [ii] [iii] These efforts are ongoing to further enhance and refine the approach. Further references can be found on the website.

Based on demonstrated compliance with the ANSI/AAMI/ISO 81060-2:2013 standard Caretaker Medical has received four FDA clearances for the non-invasive and continuous monitoring of blood pressure, heart rate and respiration rate, as well as the calibration of the blood pressure readings using either an externally obtained calibration, such as from an upper arm cuff, or through the device's self-calibration mode.

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i Baruch MC, Warburton DE, Bredin SS, Cote A, Gerdt DW, Adkins CM, Pulse Decomposition Analysis of the digital arterial pulse during hemorrhage simulation, Nonlinear Biomed Phys. 2011 Jan 12;5(1):1

ii Baruch MC, Kalantari K, Gerdt DW, Adkins CM. Validation of the pulse decomposition analysis algorithm using central arterial blood pressure. Biomed Eng Online. 2014 Jul 8;13:96

iii Gratz I, Deal E, Spitz F, et al. Continuous Non-invasive finger cuff Caretaker® comparable to invasive intra-arterial pressure in patients undergoing major intra-abdominal surgery. BMC Anesthesiology. 2017;17:48. doi:10.1186/s12871-017-0337-z.