

Streamline Automation, LLC

Non-Invasive Cardiac Output Measurement Based on Pulse Oximetry

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Value Proposition

- Non-invasive measurement with minimal risk
- Extracts information contained in the pulse oximeter output signal to measure cardiac stroke volume and cardiac output
- Leverages a well known base technology with good market penetration
- The technology will enable the reliable use of cardiac stroke volume information for:
 - Supporting patient assessment and diagnosis
 - Determination of fluid responsiveness
 - Detection of traumatic blood loss



Market

- Cardiac output measurements are currently performed with invasive procedures
 - Swan-Ganz catheterization
 - Transesophageal echocardiography
- There are about 2.7 million Swan-Ganz procedures performed annually at a cost of about \$5B
- Pulse oximetry market is about \$1B annually



Motivation

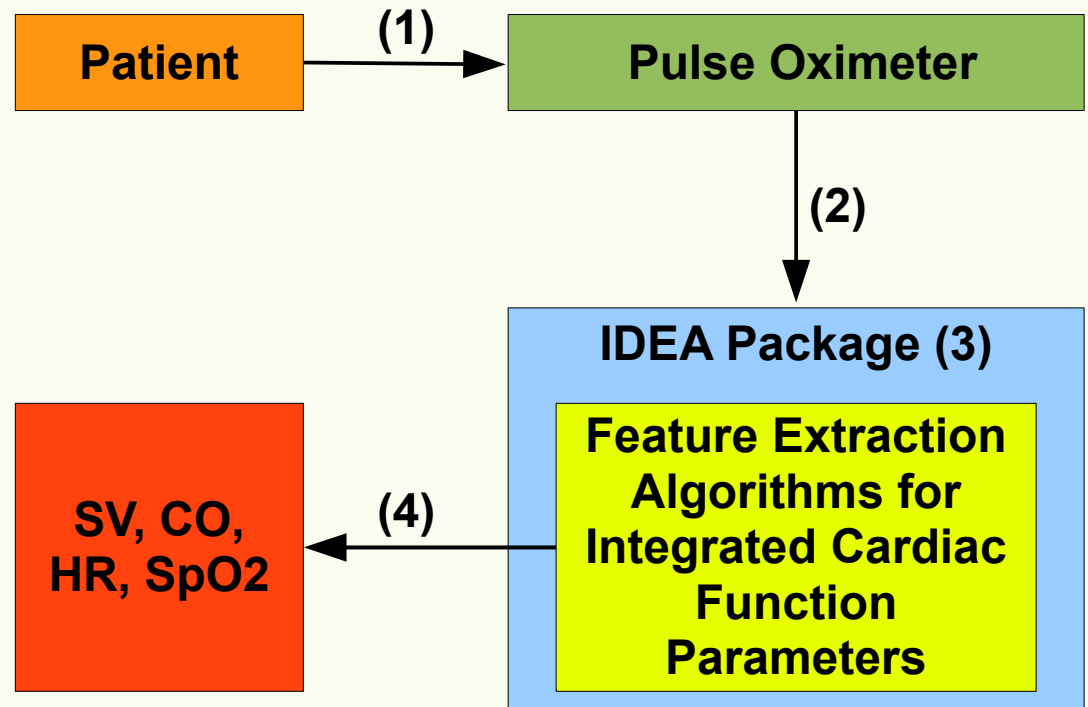
“This would be great data to adjust treatment for a patient in heart failure. This would allow the physician to treat any hemodynamic event. This technology would minimize the time in the hospital and discomfort for the patient.” — Dr. Alex Vasquez, Cardiologist at the Heart Center

“With the workload that nurses have, asking them to use a new piece of equipment is often difficult; whereas using a conventional pulse oximeter to detect cardiac stroke volume would be easy for a nurse since we use a pulse oximeter as a matter of routine.” — Lisa Walker, Nurse at Huntsville Hospital



Cardiac Output Measurement

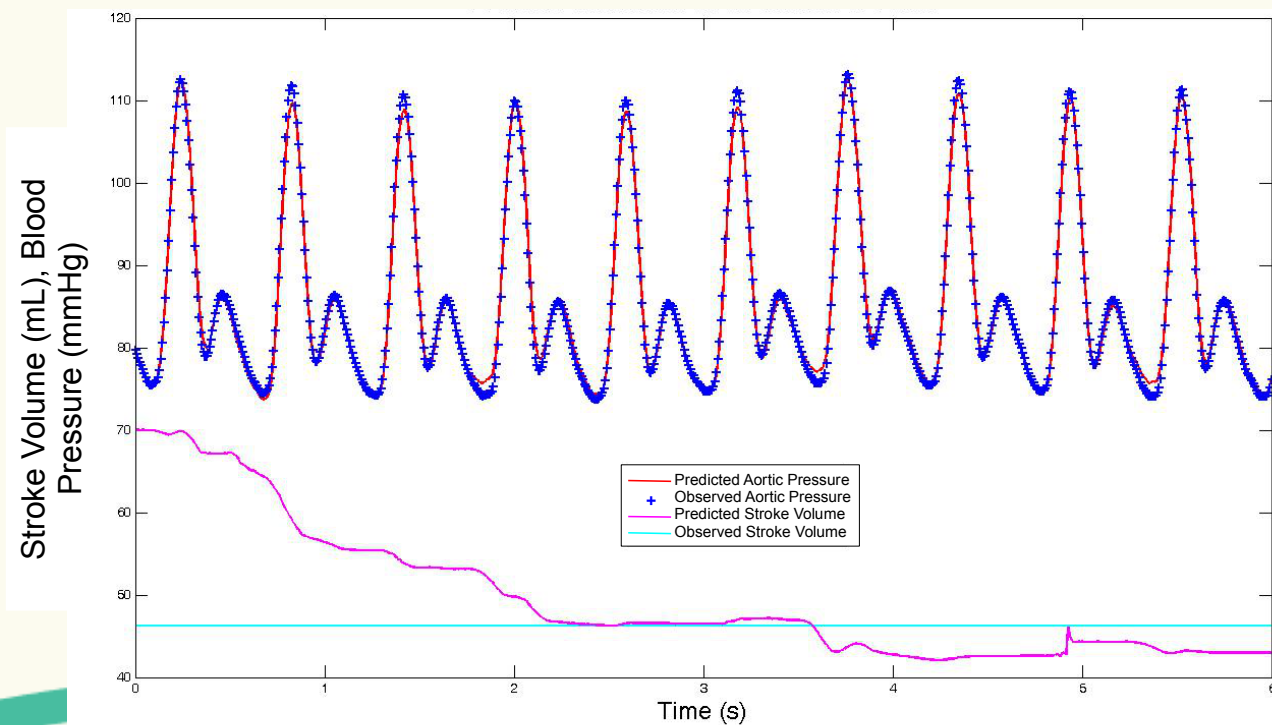
- (1) Patient Output: Blood Volume and Oxygen Time-Varying Signals
- (2) Pulse Oximeter Output: Pulse Rate and Percutaneous Oxygen Saturation Signals
- (3) Streamline Automation's IDEA Probabilistic Inference Package
- (4) Output of Time-Averaged Circulatory Parameters: Stroke Volume, Cardiac Output, and Percutaneous Oxygen Saturation



Initial Validation – MIMIC Data

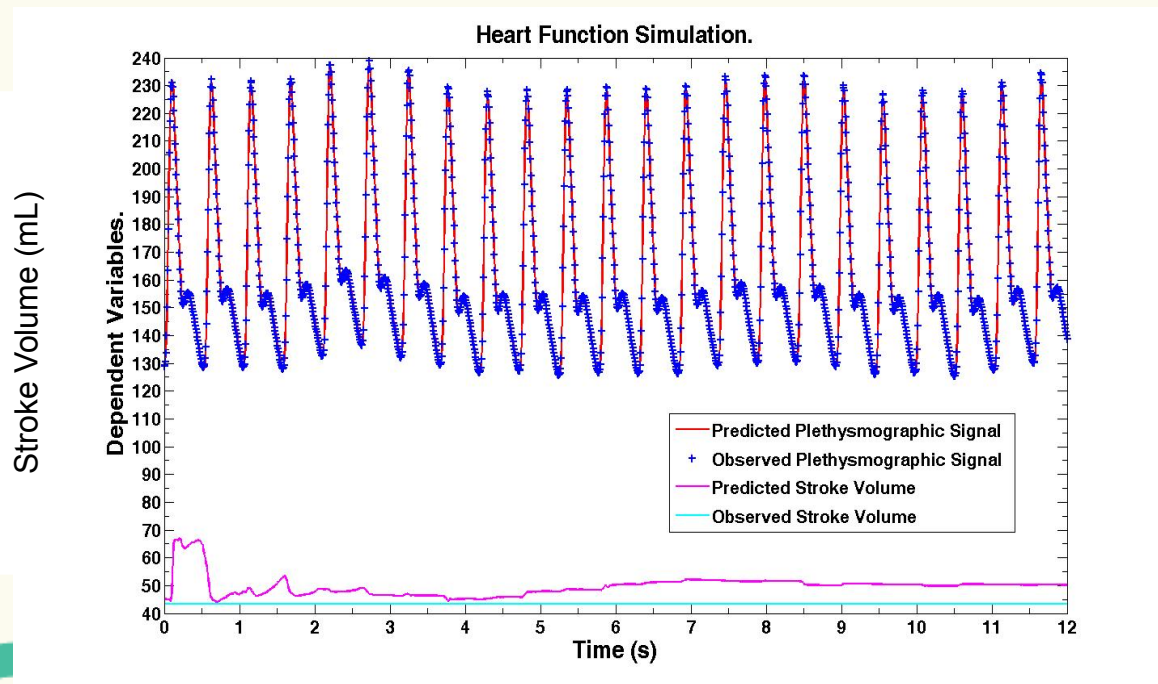
- Data set from the MIMIC database (a database of anonymous patient data) that contains the PLETH waveform and measured cardiac output
- Data is processed to compute the stroke volume

38 year old male - Respiratory failure



Heart Center Validation

- Collected PPG waveform data from patients at the Heart Center in Huntsville, AL
- Swan-Ganz invasive measurements were performed on these patients to provide a baseline for comparison



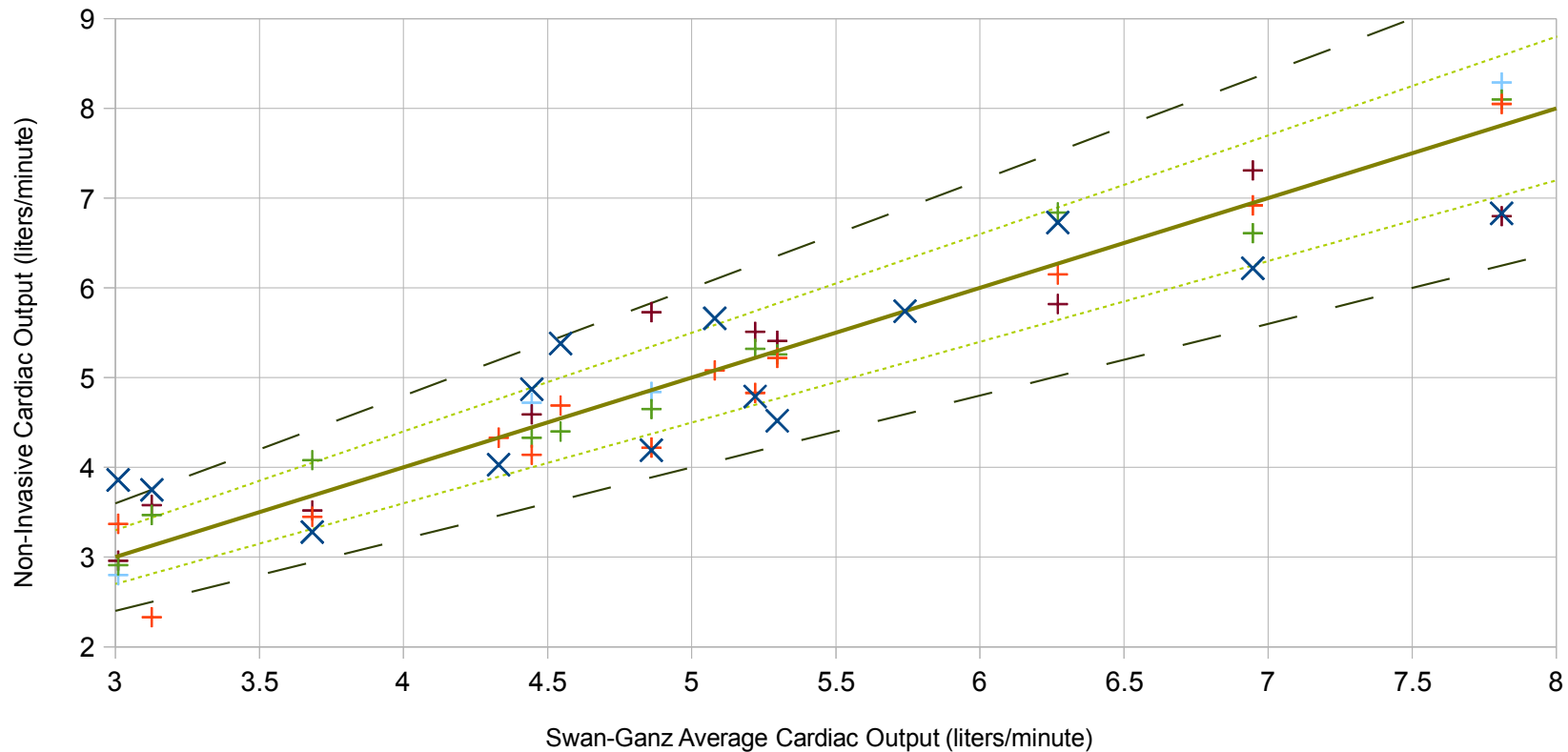
Comparison With Swan-Ganz

- The invasive Swan-Ganz cardiac output measurement generally involves 3 or 4 “raw” measurements that are averaged to get the final measurement
- The plot compares our non-invasive measurement (**X**) with the final, average Swan-Ganz measurement
- The raw Swan-Ganz measurements (+ + + +) are shown for comparison
- The lines on the plot:
 - Solid: Exact correlation
 - Dotted: $\pm 10\%$ from Swan-Ganz
 - Dashed: $\pm 20\%$ from Swan-Ganz



Comparison With Swan-Ganz

Comparison of Non-Invasive Cardiac Output Measurements
with Swan-Ganz Measurements

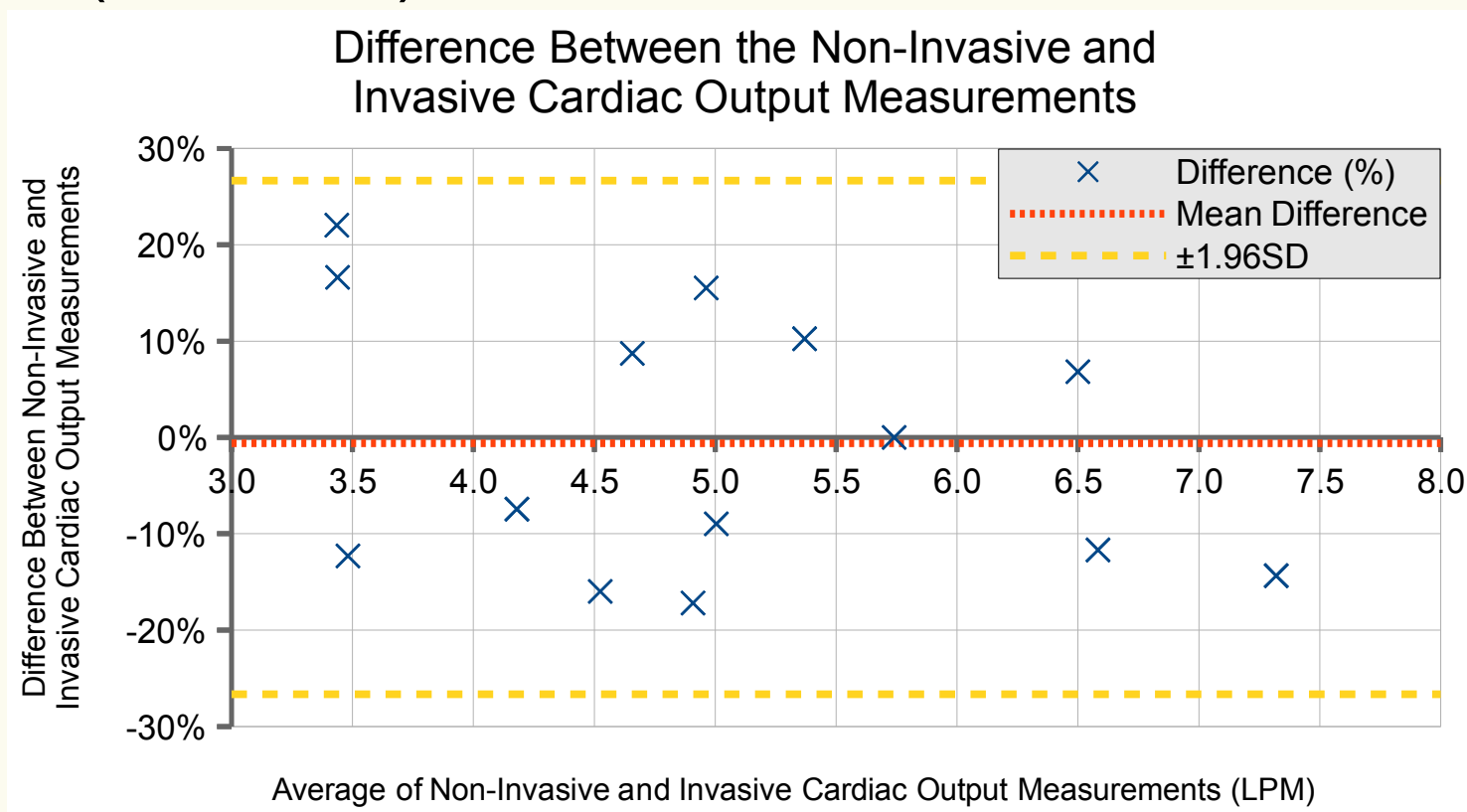


- Non-invasive measurement compares favorably with the invasive Swan-Ganz measurements



Bland-Altman Plot

- Evaluates agreement between measurement methods
- Mean difference and 95% confidence interval ($\pm 1.96SD$) are shown



Current Status

- Commitment for private investment funding has been received from several investors
- Seeking additional investment funding from individuals and corporate partners
- Currently 1 patent allowed on the technology
 - 6 additional US patents pending
 - European (EPO) patent pending
 - Additional patent applications are likely



Summary

- Received National Science Foundation SBIR Phase II award in 2010 to develop and test a prototype of the algorithm and software to enhance pulse oximetry
- Testing indicates that our non-invasive measurement compares favorably with the invasive Swan-Ganz measurements with significantly less risk to the patient
- First patent on the technology has been allowed

