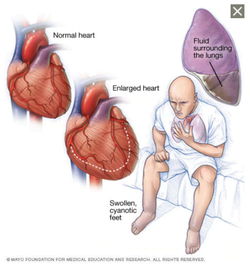
Non-Invasive Monitoring of Hemodynamics through Breaths: Respirix Cardiospire

Congestive Heart Failure: A Pandemic

- **6 million patients in the U.S.**
- **26 million patients worldwide**
- **$32 billion annual costs in U.S.**
- **> $100 billion cost / yr worldwide**

	Annual HF Costs ($ millions)
Europe	$ 34,000
USA	$ 31,000
Japan	$ 11,420
China	$ 5,400
Canada	$ 4,000
Middle East	$ 2,600

Congestive Heart Failure (CHF) is a condition where the heart cannot pump enough blood effectively through the body, caused by the weakened left and / or right ventricles. While many CHF patients generally feel fine during their daily lives, they often end up in a hemodynamic imbalance called "decompensation" which can be exacerbated by ingesting too much sodium or fluid. These patients often end up at emergency departments worldwide with shortness of breath, severe edema, and fatigue, sometimes with fluid in their lungs. In addition to the human burden, these hospitalizations cost the U.S. over $30 billion a year in direct and indirect expenses.

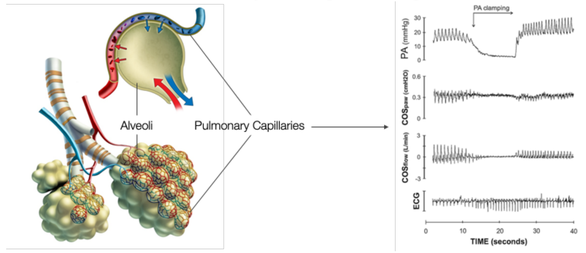


Cardiospire: Non-Invasive + Actionable Technology

Respirix has developed the Cardiospire, a handheld device that incorporates low-cost commodity sensors to reliably acquire patient data streams at home non-invasively. The Cardiospire readings are transmitted to the cloud, where Respirix algorithms determine if a patient is approaching deterioration due to a cardiopulmonary illness like CHF, alerting their care provider to guide medication changes to interdict a traumatic and costly hospitalization.

We believe that the Cardiospire platform can change remote monitoring and management of CHF patients by offering a device and software that is very affordable and effective, providing a solution that will lower costs, improve clinical outcomes, and increase access to care for millions of patients in need worldwide. Ultimately, we expect that the Cardiospire will be able to address unmet clinical needs in CHF, COPD and pneumonia.

A Novel Physiological Signal

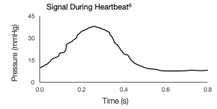


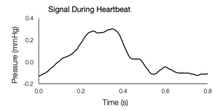
The Cardiospire acquires and analyzes a pressure wave from breaths called a cardiogenic oscillation; this signal is caused by right ventricular function, specifically blood flowing into the pulmonary vasculature.

Little research has been performed on interrogating this waveform for information about patient health. Studies published demonstrate the causation of this waveform, but no medical technology exists to date built around the unique features of the cardiogenic oscillation—until now.

CardioMEMS

Respirix





510(k) Regulatory Pathway

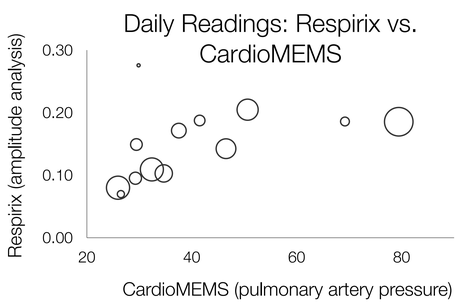
FDA CMS CENTERS for MEDICARE & MEDICAID SERVICES

The Respirix Cardiospire can be registered with the FDA as a Class II 510(k) device; all our sensors in the current generation Cardiospire are off the shelf commodity hardware (EKG, PPG, airway pressure) and we anticipate leveraging several additional readily available sensors in our next generation device, maintaining 510(k) eligibility while bolstering our data steams and diagnostic capabilities.

CMS reimbursement for the CHF indication will require a multi-hundred patient longitudinal, outcomes-based study demonstrating that diuretic, vasodilator etc. therapy guided by our algorithm can reduce CHF related hospitals. This outcome will pave the way for coding and pricing of the Respirix device and software as a service to manage this patient population.

Respirix has filed 21 patents in three international PCT families covering the acquisition and analysis of our waveform for managing patient health. We have also developed trade secrets related to our computational approach to mining our data streams, and actively file additional patents as we proceed with development.

Clinical Results Correlate to Gold Standard

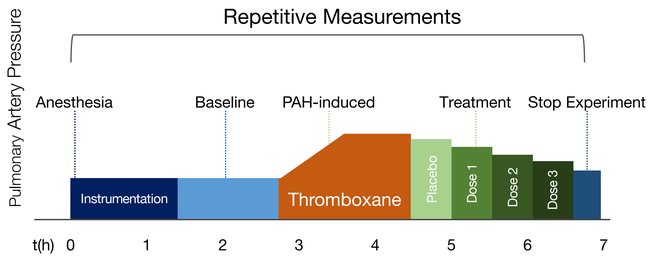


Respirix conducted a longitudinal study with daily breaths obtained from our Cardiospire device in conjunction with measurements from the CardioMEMS implant, with 14 patients enrolled across 4 sites and an average enrollment of ~ 1 year. In this pilot study we obtained a highly statistically significant inter-patient correlation between our signal and the CardioMEMS readings.

We are currently working on improved correlation using machine learning (ML) techniques informed by our research sponsored by Bayer in a preclinical model. Respirix is also complementing this approach with new research on decompensated CHF patients at UCSF and KUMC, sponsored in part by Umass CAPCaT through a POCT grant. This data should support new ways of using our method to detect CHF decompensation in advance.

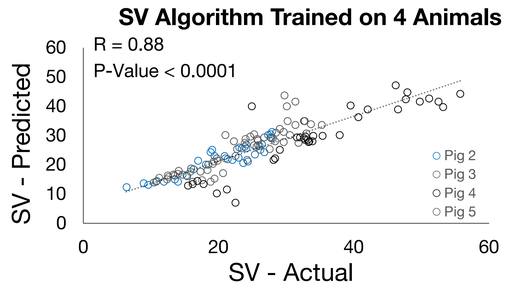
Hemodynamics through Breaths: Machine Learning

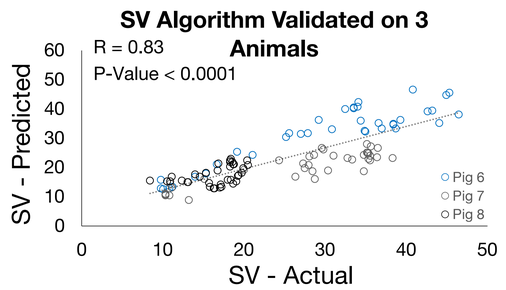
Study Sponsored by: BAYER



Animals were intubated and anesthetized with right-heart catheter placed at start of protocol. The Respirix Cardiospire device was connected to the ventilator tubing near the airway of the animal. After several hours of baseline, Thromboxane was administered to raise pulmonary artery pressures. A placebo was administered, followed by a compound to modulate pulmonary pressures.

Measurements from the right-heart catheter were obtained every 30 seconds. Respirix measurements obtained through ventilator pauses every ~ 10 mins.





Clinical Collaborators

PennState Health · Bryan HEART · JOHN MUIR HEALTH · UCSF Medical Center

Investors and Supporters

StartX Stanford-StartX Fund · SIGNATURES CAPITAL · 205 CAPITAL · SYNERGY · SBIR·STTR America's Seed Fund · NVIDIA INCEPTION PROGRAM · MEDTECH INNOVATOR · UMASS LOWELL M2D2 Advancing Med Device & Biotech Innovations · Johnson & Johnson INNOVATION | JLABS

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