About 6.5 million adults in the United States have heart failure

Heart failure was the contributing cause of 1 in 8 deaths in 2020

Total expenditure for heart failure in the United States is expected to increase by 127% between 2012 and 2030

Annual economic burden is $31B and is expected to reach $70B by 2030

Up to 50% of hospitalized patients will be readmitted within 4-6 months and nearly half of all HF readmissions are preventable

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GAP IN CURRENT HEART FAILURE MONITORING

Swan-Ganz: Gold Standard, but invasive, inpatient only, limited to OR and ICU, requires skilled clinician

Pulmonary Artery Pressure (PAP) Monitoring: Latest Technology, but requires surgical implantation, expensive and limited in patient scope

The only effective remote monitoring solution to date

Less than 2% HF Patients have PAP Monitoring

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UNMET NEED

Heart failure (HF) is the leading cause of US hospital admissions and incidence continues to rise, posing distinct challenges to the healthcare system.

- About 6.5 million adults in the United States have heart failure
- Heart failure was the contributing cause of 1 in 8 deaths in 2020
- Total expenditure for heart failure in the United States is expected to increase by 127% between 2012 and 2030
- Annual economic burden is $31B and is expected to reach $70B by 2030
- Up to 50% of hospitalized patients will be readmitted within 4-6 months and nearly half of all HF readmissions are preventable

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TEAM

Kyle Hocking, PhD, CEO
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Colleen Brophy, MD, CMO
Bret Alvis, MD, CSO
Katharine Miller, Director Product Quality
Rene Harder, PhD, Senior Engineer
Jon Sharp, MS, Senior Engineer
Jon Whitfield, ME, Senior Engineer
Reid Sutton, Engineer

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CLINICAL VALIDATION AND REGULATORY

- Multicenter observational study to compare NIVA\_HF with PCWP during right heart catheterization
- Filed pre-submission with FDA
- Held in person and virtual pre-submission meetings with FDA
- NIVA\_HF received Breakthrough Device Designation from FDA
- De Novo pathway

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NIVA\_HF is intended to estimate pulmonary capillary wedge pressure in hospitals, hospital-type facilities and home environment Non-Invasively

Preliminary correlation between NIVA Score and PCWP

A. $r=0.92, n=106$
B. $r=0.24, n=81$
C. $r=0.64, n=84$

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>90% of patient monitoring

Clinical symptoms
Input/output charting
Arterial waveform analysis
Chest x-ray
Bioimpedance/bioreactance

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VoluMetrix

The next wave in vital monitoring