VoluMetrix

The next wave in vital monitoring

LOWELL • WORCESTER UMASS M2D2 Advancing Med Device & Biotech Innovations

CAPCaT Center for Advancing Point of Care Technologies

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[1]
- Heart failure was the contributing cause of 1 in 8 deaths in 2020[2]
- Total expenditure for heart failure in the United States is expected to increase by 127% between 2012 and 2030[3]
- Annual economic burden is $31B and is expected to reach $70B by 2030[4]
- Up to 50% of hospitalized patients will be readmitted within 4-6 months[5,6] and nearly half of all HF readmissions are preventable[7]

GAP IN CURRENT HEART FAILURE MONITORING

Swan-Ganz:

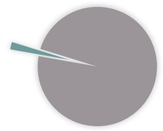
Gold Standard, but invasive, inpatient only, limited to OR and ICU, requires skilled clinician[8]

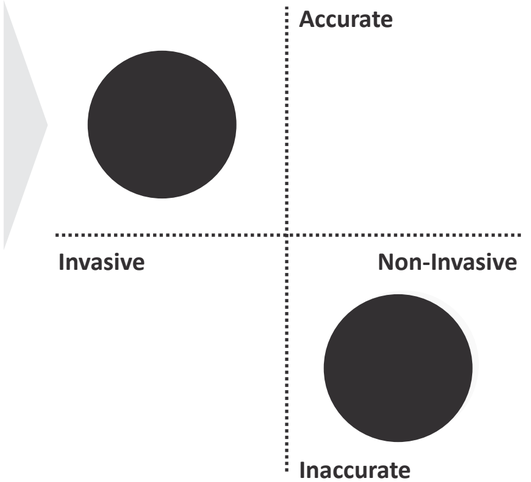
Pulmonary Artery Pressure (PAP) Monitoring:

Latest Technology, but requires surgical implantation, expensive and limited in patient scope [9,10]

The only effective remote monitoring solution to date

Less than 2% HF Patients have PAP Monitoring





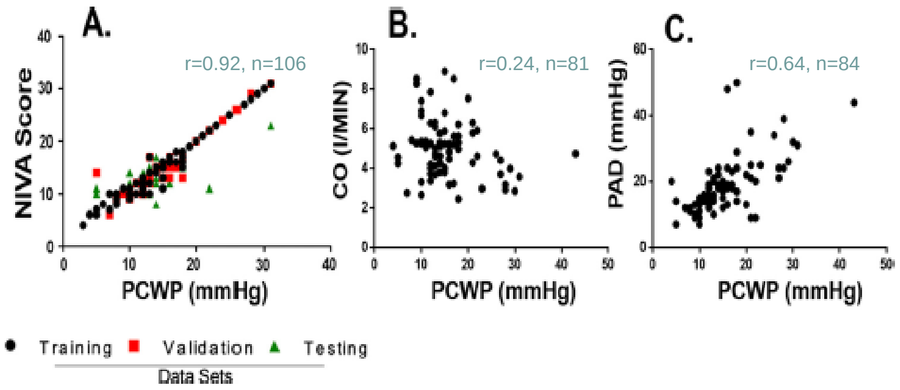
>90%
of patient monitoring[8,9,10]
Clinical symptoms
Daily weight

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

$NIVA_{HF}$

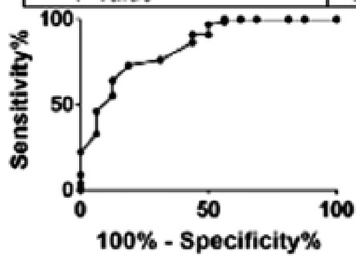
$NIVA_{HF}$ is intended to estimate pulmonary capillary wedge pressure in hospitals, hospital-type facilities and home environment *Non-Invasively*

Preliminary correlation between NIVA Score and PCWP



NIVA 30-day admission prediction

Area under the ROC curve	
Area	0.8424
Std. Error	0.05608
95% confidence interval	0.7324 to 0.9523
P value	<0.0001



TEAM

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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

1. Benjamin EJ, Muntner P, Alonso A, et al. Heart Disease and Stroke Statistics-2019 Update: A Report From the American Heart Association. Circulation. 2019;139(10):e56–528. 2. Centers for Disease Control and Prevention, National Center for Health Statistics. Underlying Cause of Death, 1999–2020. 3. Mozaffarian D, Benjamin EJ, et al. Heart Disease and Stroke Statistics-2016 Update: A report from the American Heart Association. Circulation. 2016;133:e38–e360. 4. Adamson PB, Abraham WT, Stevenson LW, et al. Pulmonary Artery Pressure-Guided Heart Failure Management Reduces 30-Day Readmissions. Circulation Heart failure 2016;9. 5. Chun S, Tu JV, Wijeysundera HC, et al. Lifetime analysis of hospitalizations and survival of patients newly admitted with heart failure. Circulation Heart failure 2012;5:414-21. 6. Joynt KE, Jha AK. Who has higher readmission rates for heart failure, and why? Implications for efforts to improve care using financial incentives. Circulation Cardiovascular quality and outcomes 2011;4:53-9. 7. Vinson JM, Rich MW, Sperry JC, Shah AS, McNamara T. Early readmission of elderly patients with congestive heart failure. Journal of the American Geriatrics Society 1990;38:1290-5 8. ESCAPE Trial: [N=433] Hemodynamic monitoring offers improvements in exercise and quality-of-life endpoints with PAC-guided* therapy. 9. CHAMPION TRIAL: [N=550] Hemodynamic monitoring correlates to a reduction in HF-related hospitalizations in patients with persistent NYHA Class III HF 10. COMPASS-HF TRIAL: [N=274] Hemodynamic monitoring shows a direct relationship between elevated cardiac pressures and hospitalization risk; therefore, use of hemodynamic-guided HF management leads to improved outcomes