Abstract #2733

Machine-Learning Estimation of Pulmonary Capillary Wedge and Right Atrial Pressures With a Non-invasive Multisensor Device

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Disclosures

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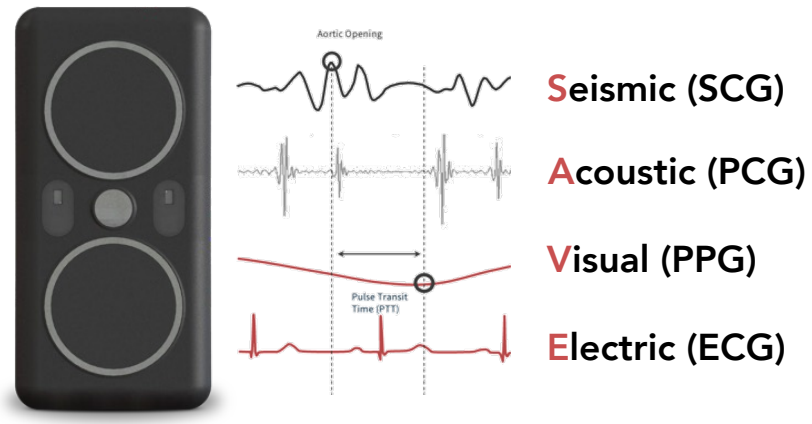
- Stock ownership in ISHI and Pulsli

CAPTURE-HF: Study Design & Methods

Summary: A multi-site observational clinical investigation to collect non-invasive sensor data during a right heart catheterization (RHC), to train machine learning models to estimate intracardiac hemodynamic parameters and test them in a prospective patient cohort

Data acquisition: 5-minute recordings within minutes of RHC using multi-sensor platform



Acorai 1st generation device & the SAVE Sensor System

Design: Prospective two-phase observational study; N=1,568 adults undergoing RHC across 20 hospitals (core-lab adjudicated RHC data)

Enrollment and ML-model development
(October 2023 to July 2025)

ML-model test
(July 2025)

Phase-1 (14 sites, n = 1,240) in US/EU/UK) → **Prospective Phase-2 (6 new sites, n = 328 in US/CA)** → **ML model test on pre-specified out-of-sample dataset**

Adults scheduled for RHC → *5-min device recording* → *Core-lab adjudication of RHCs* → *ML-models train and test*

Phase 1 ML-model training: *Ensemble-based modelling approach, using cross-validation, locked in Phase 1.*
Phase 2 testing: *Pre-specified patient cohort for prospective validation of ML-models defined in Phase 1.*

Results:

Endpoints: AUC, sensitivity, specificity for **PCWP >15 mmHg and RAP >10 mmHg**
Topline results: **High sensitivity (≥86%) with negative predicted values of 90–97%**

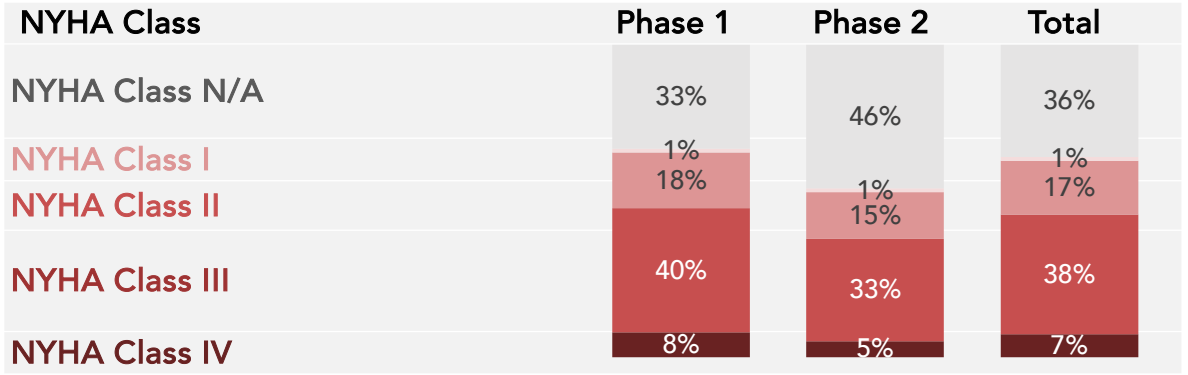
CAPTURE-HF Full Patient Cohort Overview

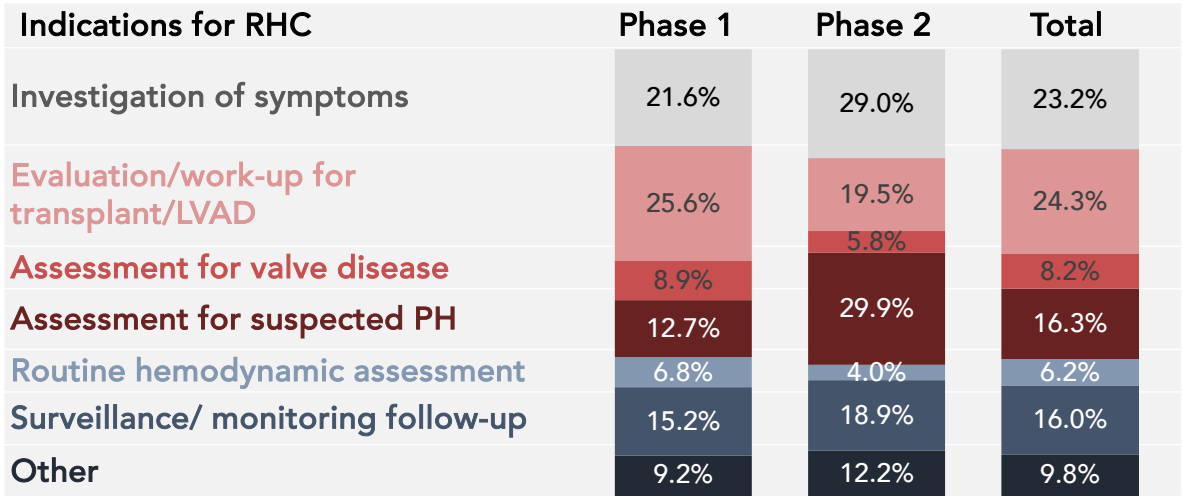
Diverse patient cohort and broad inclusion criteria; ejection fraction agnostic

Overview	Phase 1	Phase 2	Total
Enrollment	1240	328	1568
US patients %	50.7%	71.6%	52.9%
Mean age (SD)	63.27 (14.41)	60.95 (13.77)	62.78 (14.31)
Male%	63.2%	61.3%	62.8%
White%	80.9%	61.3%	76.8%

Prevalence	Phase 1	Phase 2	Total
RAP > 10	29.8%	16.8%	27.1%
PCWP > 15	42%	33.2%	40.2%

Discordance	Phase 1	Phase 2	Total
PCWP > 15 vs. RAP > 10 classes different	299 (24.1%)	77 (23.5%)	376 (24.0%)





Results: PCWP and RAP with 86-87% Sensitivity and 90-97% NPV to Rule Out Hemodynamic Congestion in a Prospective Patient Cohort

Prospective Phase 2 patient flow

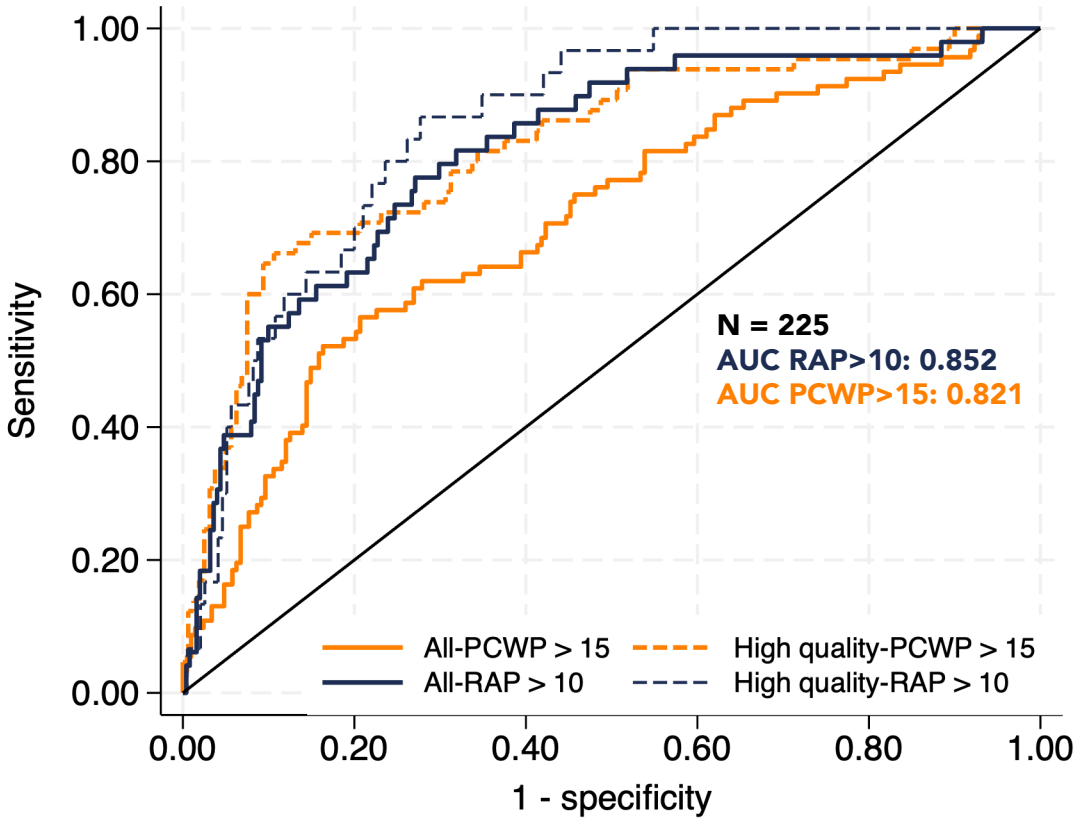
328 enrolled → *2* incomplete RHC data → *26* data transmission failures → *76* removed due to low-quality flagging → *225* patients included in final test

Endpoint (Phase-2 locked)	N	AUC	Sensitivity	Specificity	NPV
PCWP >15 mmHg	225	**0.821**	86%	53%	90%
RAP >10 mmHg	225	**0.852**	87%	70%	97%

Low-quality flagging (e.g. patient movements/sound) has been mitigated in subsequent analysis

Subgroup analysis for PCWP > 15 mmHg	N	AUC	Sensitivity	Specificity
Overweight (BMI 25-30)	82	**0.85**	0.90	0.48
Non-white	84	**0.896**	0.92	0.53
Female	92	**0.754**	0.63	0.67

ROC Curves for PCWP > 15 and RAP >10



AUCAll PCWP = 0.708; High quality PCWP = 0.821; All RAP = 0.814; High quality RAP = 0.852

Conclusion

Background: Prospective, two-phase, multi-site study collecting 5-minute signals from a non-invasive multimodal sensor device during right-heart catheterization to train & test ML models classifying right atrial pressure and pulmonary capillary wedge pressures.

Cohort & Design: N=1,568 across 20 hospitals;

- Phase-1 train/validate n=1,240 (14 sites, US/EU/UK);
- Phase-2 locked test n=328 (6 new sites, US/CA); RHC core-lab adjudicated.

Endpoints: Classify elevated **PCWP >15 mmHg** and **RAP >10 mmHg** (AUC, sensitivity, specificity).

Primary Results (Phase-2):

- PCWP>15—AUC **0.821**, **86%** sensitivity, **53%** specificity, **90%** NPV;
- RAP>10—AUC **0.852**, **87%** sensitivity, **70%** specificity, **97%** NPV.

Clinical Takeaway: High sensitivity and NPV support efficient **rule-out of hemodynamic congestion** at point of care, across a broad range of HF-phenotypes

Next Steps:

- Implement **real-time data-quality/device positioning checks** to control signal acquisition quality
- Expand machine learning models (incl. Hemodynamic Congestion Index to **enable decongestion trending**)
- Pivotal **CAPTURE-HF 2** for Gen-2 device ahead of **2026 FDA submission**; HEOR studies to validate clinical utility

Questions