ACORAI

EXECUTIVE SUMMARY

Non-invasive Cardiac and Pulmonary Pressure Sensing in Hospitalized Heart Failure Patients

DRAFT VERSION

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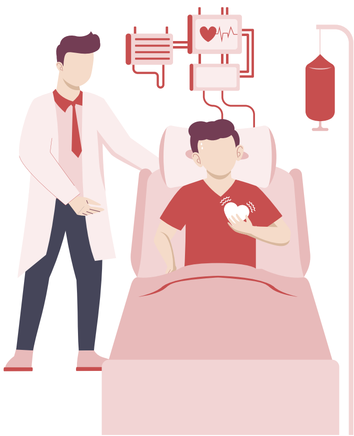
Background: hemodynamic challenges in HF care



Heart failure (HF) is one of the leading causes of unplanned hospitalization and readmission worldwide. Hospitalizations account for the largest share of direct HF-related costs, and a substantial proportion of patients are rehospitalized within 30–90 days of discharge. Even in well-resourced systems, HF care is characterized by recurrent congestion, high bed utilization, and persistent outcome gaps despite guideline-directed therapy.

Across this pathway, teams repeatedly face the same hemodynamic challenges:

→ In the emergency department (ED), clinicians must decide who truly requires admission versus who might be safely managed in observation or hospital-at-home models, often without reliable insight into filling pressures.

→ On the inpatient ward, they must judge when a patient is genuinely decongested and ready for discharge, despite the well-described problem of residual congestion at discharge.

→ In the early post-discharge period, they are tasked with rapidly initiating and up-titrating guideline-directed medical therapy (GDMT) while lacking repeatable information on how close a patient is to hemodynamic decompensation.

Direct hemodynamic data from right heart catheterization (RHC) are highly actionable but invasive, costly, and operationally impractical for serial monitoring. As a result, most day-to-day decisions rely on indirect surrogates such as symptoms, weight, natriuretic peptides and imaging, rather than repeatable measures of right atrial pressure (RAP), pulmonary capillary wedge pressure (PCWP), and pulmonary artery pressures.

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Burden of HF hospitalization and residual congestion

HF affects tens of millions of individuals globally and is among the most common causes of hospitalization in adults. A recent systematic review from the United States reported mean HF-specific inpatient costs of roughly $10,700–$17,800 per admission, with HF hospitalizations accounting for about half or more of direct HF-related medical costs.

Congestion, or elevated cardiac filling pressures and fluid accumulation, is the primary reason for admission for acute decompensated heart failure (ADHF). Observational cohorts show that:

- → Residual congestion at discharge is common. Many patients still exhibit signs of congestion days after admission, even when symptoms and weight have improved.
- → Residual congestion is prognostically important. It is consistently associated with higher risks of rehospitalization and death.

These patterns highlight that the burden of HF extends beyond the index admission. Patients move from the ED to the ward and then into a high-risk early post-discharge phase, often carrying forward unresolved hemodynamic congestion that drives recurrent events.

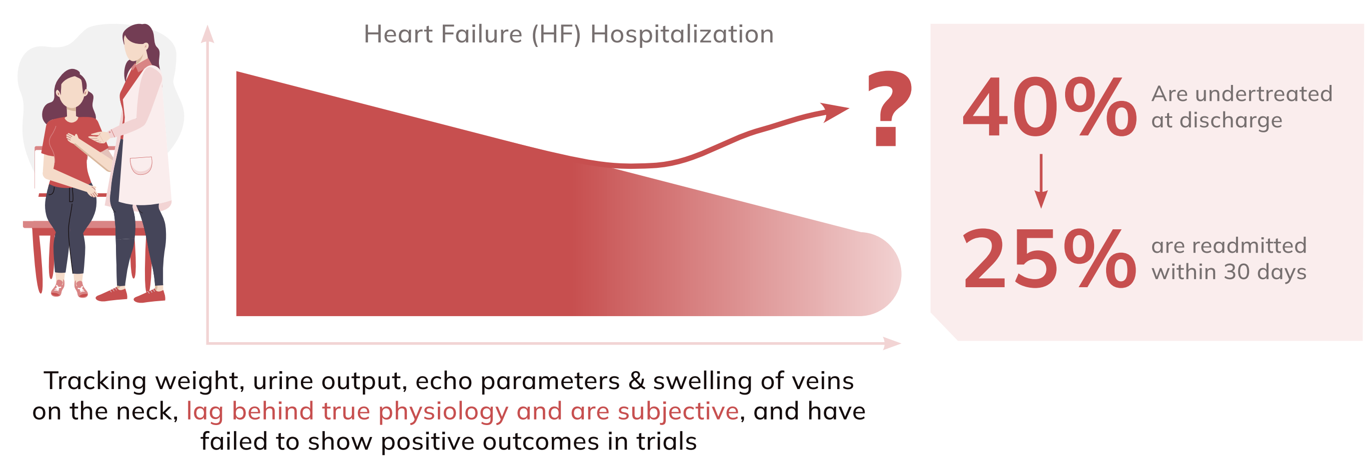

Figure 1. Residual congestion in the hospitalized heart failure patient workflow is an important contributor to readmission rates

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Current tools: invasive and non-invasive hemodynamic monitoring

3.1 Invasive hemodynamics

RHC remains the gold standard for measuring RAP, PCWP, and pulmonary artery pressures, and for defining hemodynamic profiles. However, because RHC requires invasive vascular access, specialized staff, and catheterization-lab resources, it is generally used only at a few critical decision points, not as a routine, serial monitoring tool across ED, ward, and post-discharge care.

3.2 Current non-invasive surrogates

Outside the cath lab, clinicians rely on several conventional surrogates: symptoms and physical exam (edema, rales, jugular venous distension); natriuretic peptides (BNP/NT-proBNP); chest radiography and lung ultrasound; echocardiographic indices (E/e', TR velocity, left atrial size, etc.); and body weight and urine output.

These tools are valuable and widely available, but they are indirect, subject to important confounders, and often track poorly with true intracardiac pressures over time.

3.3 Existing advanced monitoring technologies

Several advanced tools are already in use. Implantable pulmonary artery (PA) pressure sensors provide daily or frequent hemodynamic data in selected high-risk ambulatory HF populations, and randomized trials show that PA pressure-guided management can significantly reduce HF hospitalizations compared with symptom-based care. Non-invasive lung-fluid monitoring, such as remote dielectric sensing, quantifies lung fluid percentage in seconds and has shown that adding an objective congestion metric to discharge decisions and early follow-up can reduce short-term adverse events in recently hospitalized patients.

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Guidelines and the case for hemodynamic-guided GDMT

Contemporary HF guidelines emphasize early achievement of euvolemia during hospitalization, rapid initiation and up-titration of GDMT during the index stay and early post-discharge period, and close follow-up with careful monitoring of symptoms, blood pressure, renal function, and congestion markers.

Yet, implementing such strategies in real-world practice is challenging. Clinicians are often unsure how much hemodynamic reserve patients have, especially when clinical and laboratory markers send mixed signals. A patient who appears euvolemic but has elevated PCWP and RAP may be at higher risk of hypotension or renal dysfunction if vasodilators or neurohormonal antagonists are up-titrated aggressively. A patient with mild residual symptoms but normalized filling pressures might safely tolerate more intensive GDMT, and further diuretic escalation could be unnecessary or harmful.

More precise, non-invasive hemodynamic assessment could therefore support both decongestion and therapy optimization, aligning care more closely with the hemodynamic principles embedded in the guidelines.

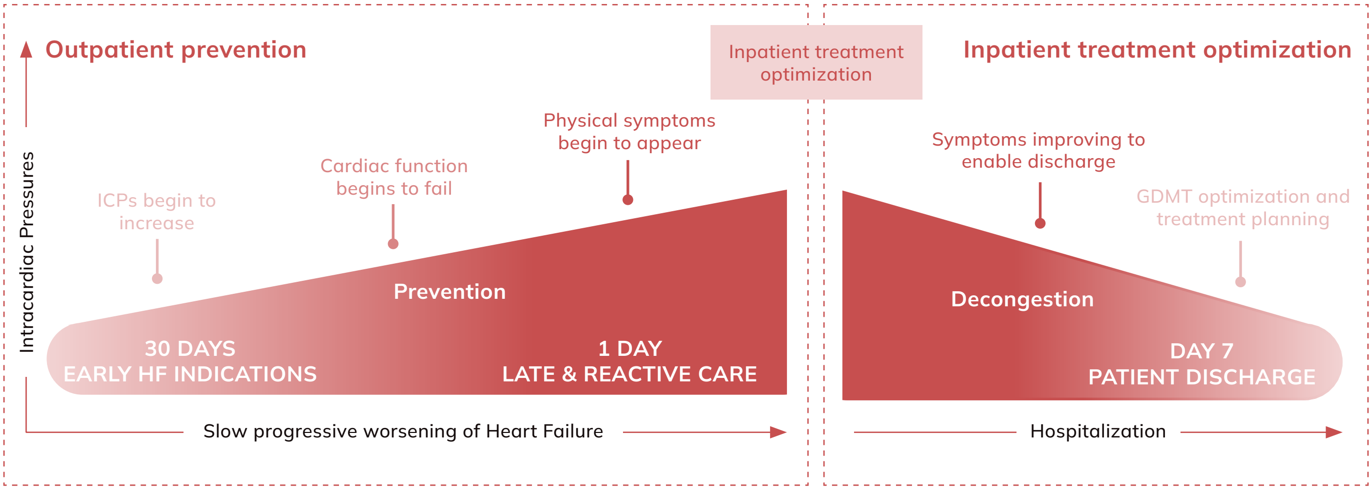

Figure 2. Successful heart failure patient management requires an end-to-end approach, enabling early detection & preventive care in the outpatient setting, coupled with improved inpatient decongestion and treatment optimization

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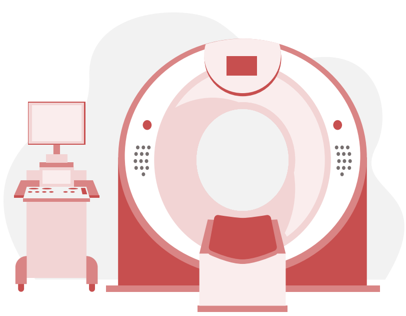
ED triaging and potentially avoidable admissions

ED triaging decisions are a major driver of HF bed-days. More than 80% of patients presenting to the ED with acute HF are admitted, even though only a minority have life-threatening conditions such as cardiogenic shock, ongoing ischemia, or respiratory failure. Contemporary analyses suggest that up to half of current AHF admissions may be potentially avoidable if low-risk patients can be reliably identified and managed in alternative pathways.

Many HF patients present with isolated congestion, are hemodynamically stable, and do not require invasive procedures or prolonged monitoring. Randomized trials and meta-analyses of hospital-at-home and virtual ward models show that, in carefully selected HF patients, home- or virtual-ward care can achieve outcomes comparable to inpatient treatment while reducing bed utilization.



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Next-generation non-invasive cardiac and pulmonary pressure sensing

Against this clinical backdrop, there is growing interest in technologies capable of estimating intracardiac and pulmonary pressures non-invasively, repeatedly, and at the bedside.

Early-phase studies of multi-sensor chest devices suggest that non-invasive estimation of right- and left-sided filling pressures may be feasible. The CAPTURE-HF study, for example, was a large, prospective, multicentre evaluation of a multi-sensor non-invasive cardiac and pulmonary pressure estimation system in patients undergoing RHC, designed to compare non-invasive estimates with invasive gold-standard measurements and characterize performance across a wide range of HF phenotypes.

These systems remain investigational. Large-scale validation, subgroup performance analyses, and prospective outcome trials are needed before routine adoption. Nonetheless, they point toward a future in which RAP and PCWP may become bedside-accessible metrics, not just invasive endpoints.

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Design principles and real-world workflow integration

For non-invasive pressure sensing to move from research into standard care, several design principles emerge:

1. Repeatability and ease of use: bedside measurements should be obtainable in minutes by nurses or allied professionals, and systems must be robust across body habitus, arrhythmias, and respiratory variability.
2. Accuracy at clinically relevant thresholds: performance should be judged by ability to discriminate thresholds such as PCWP ≥15 mmHg or RAP ≥10 mmHg, with high sensitivity and negative predictive value for ruling out dangerous congestion and adequate specificity for guiding therapy.
3. Actionable, interpretable outputs: outputs must translate into decisions—congestion indices, probability bands, and trends rather than opaque scores.
4. Applicability across HF phenotypes: validation must encompass HFrEF, HFmrEF, HFpEF, pulmonary hypertension, RV failure, and significant valve disease.
5. Broad hemodynamic insight (RAP and PCWP): right- and left-sided pressures are frequently discordant; systems focusing on a single surrogate risk misclassification. Ideally, platforms provide indices that reflect both right- and left-sided congestion.
6. Minimal workflow friction and scalable economics

In practice, a non-invasive system could be used as a nurse-led, 2–3 minute bedside scan incorporated into routine vitals, with pressure levels and congestion values assessed during multidisciplinary rounds to guide diuretics, discharge readiness, and GDMT titration.

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Economic and workflow implications

From a health-system lens, improved hemodynamic assessment offers three main levers of value.

First, length of stay (LOS) reduction: more precise assessment of decongestion and discharge readiness can shorten hospital stays for a subset of patients. Early-supported discharge and HF virtual wards have already shown LOS reductions while maintaining outcomes, suggesting that better hemodynamic classification could further enhance these models.

Second, readmission reduction and admission avoidance: residual congestion at discharge is a major driver of early readmissions; strategies that reliably reduce residual congestion and support structured follow-up are likely to have outsized impact on both outcomes and margins.

Third, workforce and protocolization benefits: non-invasive pressure data can be embedded into nurse-driven protocols and standardized order sets, reducing practice variability and cognitive load.

Beyond LOS and readmissions, better hemodynamic characterization can also improve alignment with downstream device-based and structural interventions, by systematically identifying patients with persistently elevated RAP and PCWP who may benefit from advanced HF therapies, CRT, or valvular interventions and prompting earlier referral to multidisciplinary teams.

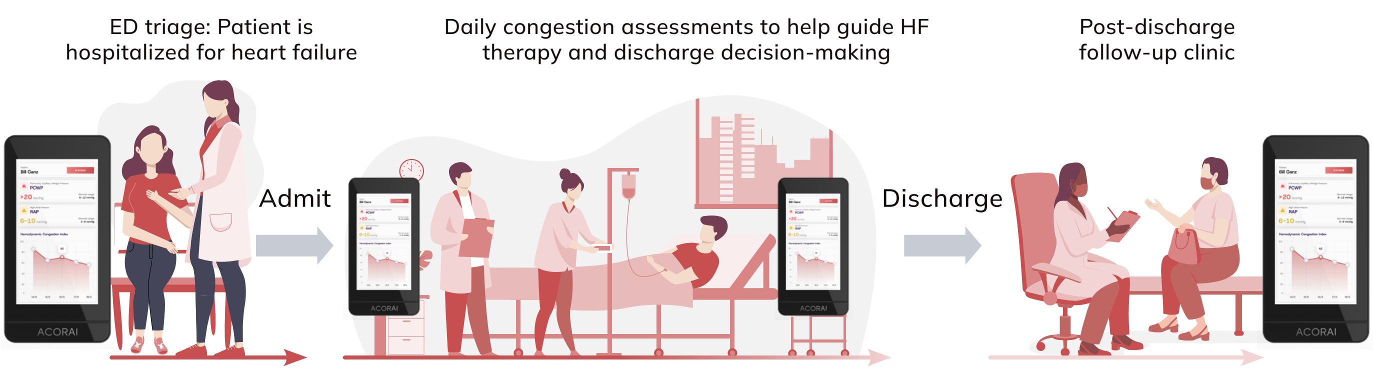

Figure 3. Heart failure care journey with potential touchpoints for non-invasive pressure assessment from ED triage through inpatient decongestion and early post-discharge monitoring.

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Outlook

Figure 3. Illustrative user interface of a cardiac and pulmonary pressure sensing device in development by Acorai and an overview of Acorai's multi-modal SAVE Sensor System hardware

The convergence of rising HF burden, persistent residual congestion, hospital capacity pressures, and value-based care incentives creates a strong rationale for real-time, scalable hemodynamic insight.

Implantable PA pressure monitoring, lung-fluid technologies and guidelines collectively point in the same direction: when HF care is aligned more closely with underlying hemodynamics, rather than relying solely on symptoms and conventional surrogates, patients experience fewer decompensations and better outcomes.

Next-generation non-invasive cardiac and pulmonary pressure sensing aims to bridge this gap by transforming intracardiac pressures from rarely measured invasive endpoints into safe, repeatable bedside and home metrics. These technologies remain investigational, and robust multicenter validation and outcome trials are essential for clinical adoption. But their potential to support more precise decongestion, enable safer and faster GDMT optimization, improve ED triaging and improve discharge and therapy planning, is clear.

For cardiologists and HF teams, near-term opportunities include deepening familiarity with hemodynamic-guided care pathways, participating in clinical trials of emerging non-invasive technologies, and advocating for multidisciplinary models that integrate congestion assessment, GDMT optimization, and structured patient follow-up.

For health-system leaders and industry partners, non-invasive cardiac and pulmonary pressure sensing sits at the intersection of cardiovascular medicine, next-generation multi-modal sensing technology, and artificial intelligence, and is directly aligned with priorities for a value-based care system. This class of technology addresses a large, durable unmet need while offering a clear path for evidence-based adoption across ED, inpatient, and post-discharge heart failure patient care.