

Heart Failure Is Often Silent Until It's Severe

The Vivio® System helps clinicians identify heart failure earlier by bringing non-invasive LVEDP measurement into the outpatient setting.



1 THE SCALE OF THE PROBLEM

6.7M

U.S. adults have heart failure.¹

1 IN 4

People face a lifetime risk of developing heart failure.²

≥50%

of heart failure is HFpEF—a form that can be particularly hard to diagnose.³

HFpEF

Leading cause of hospitalization + highest readmission rate among Medicare patients with HF.

65%

of Medicare patients are first diagnosed in the ER or inpatient setting.^{4,5}

2 THE DIAGNOSTIC GAP AND THE HIDDEN DISEASE BURDEN

Stage B is heart failure. Period.

Patients can have structural abnormalities or abnormal cardiac function—including evidence of increased filling pressures—**before heart failure becomes symptomatic**. And because Stage B heart failure is pre-symptomatic, it's hard to spot in the primary care setting.

Standard tools consistently miss the mark—especially for HFpEF. A normal NT-proBNP and a normal resting echo do not rule out early HFpEF in many patients, especially those with risk factors consistent with Cardiovascular-Kidney-Metabolic syndrome (CKM).



BP/NT-proBNP

With a specificity barely above 50%, results are distorted by the main conditions that cause HFpEF. Obesity and diabetes push NT-proBNP down, producing false negatives.⁶



Echocardiography

More than 60% of catheter-confirmed HFpEF cases show normal or only mildly abnormal echo findings despite elevated filling pressure.⁷

③ VIVIO MAKES THE INVISIBLE VISIBLE



The only FDA-cleared class II medical device that enables clinicians to non-invasively measure left ventricular end-diastolic pressure (LVEDP) in any outpatient setting in under 5 minutes.

- CalTech developed physics-based cardiovascular model—no AI or machine learning.
- FDA-cleared Class II medical device with over 55,000 real-world patients screened.
- 3-minute non-invasive test right in the exam room.
- Accurately identifies elevated LVEDP—clinical hallmark of heart failure.
- Supports compliant diagnosis of heart failure in the primary care setting.

④ FROM HIGH RISK TO DEFINITIVE DIAGNOSIS

With Vivio and the embedded Kansas City Cardiomyopathy Questionnaire:

>40% of patients who entered the office merely at high-risk for heart failure left with a definitive diagnosis of either Stage B or Stage C heart failure.⁸

>10% had heart failure at NYHA Class II-III.⁹

⑤ EARLIER DIAGNOSIS LEADS TO EARLIER ACTION

GDMT works but utilization lags.

While GDMT has been proven to reduce admissions, readmissions and mortality, its use continues to lag due to low prescribing rates, incorrect dosing and poor patient adherence.

The good news...primary care clinicians can confidently start treatment immediately.

Thanks to Vivio®, patients with elevated LVEDP are identified earlier, helping guide initiation of GDMT, including SGLT2 inhibitors, and making a meaningful difference in patient care.

Vivio gives primary care clinicians an opportunity to identify and treat heart failure earlier, helping to improve clinical outcomes and total cost of care.

Discover more about the Vivio System at
ventrichealth.com/vivio-system.



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¹ Bozkurt, Biykem. "HF stats 2024: Heart Failure Epidemiology and Outcomes Statistics an updated 2024 report from the Heart Failure Society of America." *Journal of Cardiac Failure*, vol. 31, no. 1, Jan. 2025, pp. 66-116, <https://doi.org/10.1016/j.cardfail.2024.07.001>.

² Vasan, Ramachandran S, et al. "Lifetime Risk of Heart Failure Among Participants in the Framingham Study." *Journal of the American College of Cardiology*, vol. 79, no. 3, 2022, pp. 250-263. DOI: 10.1016/j.jacc.2021.10.043. ³ Hajjoui, Said. "Heart Failure With Preserved Ejection Fraction (HFpEF)." *StatPearls*, StatPearls Publishing, 2024. NCB Bookshelf, www.ncbi.nlm.nih.gov/books/NBK599960/. ⁴ Cuthbertson CC, Heiss G, Wright JD, et al. Socioeconomic status and access to care and the incidence of a heart failure diagnosis in the inpatient and outpatient settings. *Annals of Epidemiology*. 2018;28(6):350-355. doi:<https://doi.org/10.1016/j.annepidem.2018.04.003>. ⁵ Hayhoe B, Kim D, Aylin PP, Majeed FA, Cowie MR, Bottle A. Adherence to guidelines in management of symptoms suggestive of heart failure in primary care. *Heart*. 2018;105(9):678-685. doi:<https://doi.org/10.1136/heartjnl-2018-313971>. ⁶ Verbrugge, Frederik H, et al. "Heart Failure with Preserved Ejection Fraction in Patients with Normal Natriuretic Peptide Levels Is Associated with Increased Morbidity and Mortality." *European Heart Journal*, vol. 43, no. 20, 2022, pp. 1941-51. DOI: 10.1093/eurheartj/ehab911. ⁷ Borlaug, Barry A, et al. "Exercise Hemodynamics Enhance Diagnosis of Early Heart Failure with Preserved Ejection Fraction." *Circulation: Heart Failure*, vol. 3, no. 5, 2010, pp. 588-95. DOI: 10.1161/CIRCHEARTFAILURE.109.930701. ⁸ Ventric Health internal data. ⁹ Amlani, Faisal, Thomas Cheek, and Rashid Alavi. "Noninvasive left ventricular end-diastolic pressure assessment using a novel workflow and device in primary care settings to enhance heart failure diagnosis." *Physiological Measurement*, vol. 47, no. 5, May 2026, p. 055007, <https://doi.org/10.1088/1361-6579/ae64a8>.