



VentricHealth

CLINICIAN ONBOARDING GUIDE



Early Heart Detection with the Vivio® System

Implementing rapid, non-invasive LVEDP
measurement at the point of care.

The Clinical Challenge: Late-Stage Diagnosis

Heart failure affects 6.7 million Americans with 1 out of 4 developing heart failure in their lifetime.¹ Yet most patients are first diagnosed in the emergency room or in-hospital, after the disease has already progressed significantly.^{2,3}

Left ventricular end-diastolic pressure (LVEDP), the clinical hallmark of heart failure, has historically only been measurable through invasive cardiac catheterization.

A New Standard in Early Detection

The Vivio® System is the first and only non-invasive solution that definitively identifies elevated LVEDP bringing hospital grade diagnostic insight into the primary care setting.

Diagnostic Limitations of Traditional Modalities in HFpEF

Heart failure is a hemodynamic disease that often develops before structural changes are visible or a patient feels symptoms.

With HFpEF the ejection fraction looks normal, but the heart muscle is stiff and doesn't relax between heartbeats. The pressure builds when the heart can't relax normally. Once chronically elevated, filling pressure will result in symptoms and structural changes to the heart that are only then visible on echocardiogram.



≥50% of HF cases are HFpEF – the subtype hardest to detect.⁴



Echocardiography

Misses HFpEF in roughly one-third of confirmed cases. Scans can appear normal at rest despite active disease.⁵



BNP / NT-proBNP

Ambulatory thresholds miss a substantial portion of HFpEF patients, creating false reassurance.⁶



Comorbidities

Diabetes and CKD increase HF risk while masking early symptoms. The highest-risk patients are also the hardest to identify.⁷



The Result?

Diagnostic delays of up to 30 months — during which guideline-directed therapy could have been initiated and hospitalizations prevented.³

Vivio Key Advantages

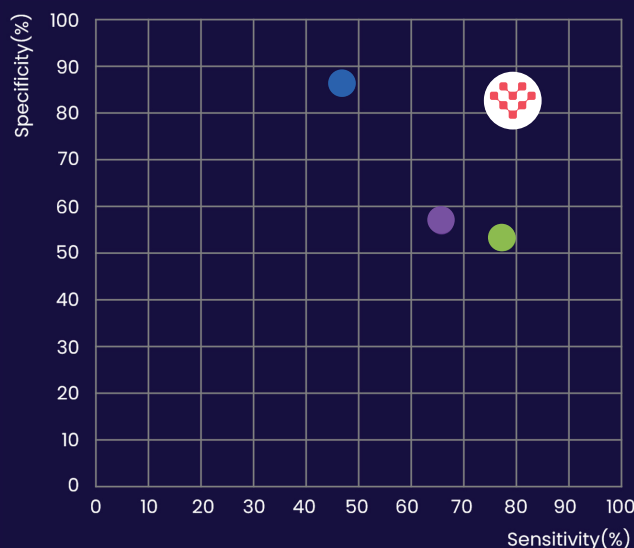
- CalTech developed physics-based cardiovascular model — no AI or machine learning.
- FDA-cleared Class II medical device with over 30,000 real-world patients screened.
- 3-minute non-invasive test right in the exam room.
- Accurately identifies elevated LVEDP — clinical hallmark of heart failure.
- Supports compliant diagnosis of heart failure in the primary care setting.



Beyond Traditional Tools

Traditional methods, such as natriuretic peptides, echocardiography and clinical scoring systems, lack sensitivity to early-stage heart failure and may not detect elevated filling pressures in early disease.

With its higher sensitivity, Vivio will identify patients with elevated filling pressures that an echo may not detect, which enables earlier and more widespread GDMT utilization. While the Vivio can be used as a standalone to diagnose heart failure, the echo may be helpful for characterizing functional issues in segments of the population, for example, to determine if the type of heart failure is HFpEF or HFrEF.



Echocardiogram
 $E/e' > 13$
(estimated filling
pressure ratio)

NTproBNP > 125 pg/mL
(blood biomarker
released when the
heart is under stress)

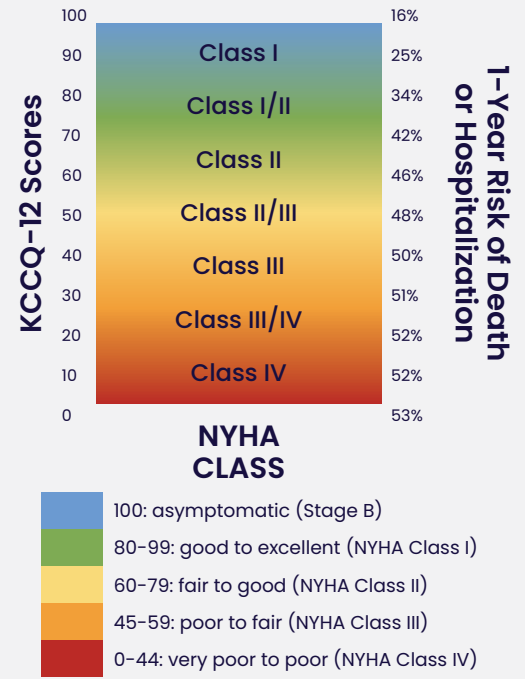
Echocardiogram
GLS $< 16\%$
(measure of the
heart's overall
squeeze efficiency)



Vivio LVEDP

Pairing Vivio With Patient-Reported Outcomes (KCCQ)

- Vivio incorporates the Kansas City Cardiomyopathy Questionnaire (KCCQ) – the most widely used tool for evaluating health status in heart failure patients – directly into clinical workflows.
- The KCCQ provides a standardized, validated history and assessment for all newly diagnosed heart failure patients, supporting consistent care across the system.⁸
- Together, Vivio test results and the KCCQ allow clinicians to assess current and longitudinal patient health status and help determine when specialty referral may be appropriate.



Definitive Heart Failure Diagnosis Means Earlier Treatment and Better Outcomes

Vivio's ability to accurately identify elevated LV filling pressure enables earlier diagnosis of both Stage B and C heart failure. Earlier identification empowers earlier treatment with frontline medications like SGLT-2 inhibitors.

- Early initiation and optimization of guideline-directed medical therapy (GDMT) and prudent clinical referrals can:
 - Slow disease progression and increase patient's overall quality of life.^{2,9}
 - Decrease 30-day and one-year mortality as well as decrease one-year, all-cause hospitalization rates.^{2,9}
 - Reduce total-cost-of-care.³
- Increase PCP ability to categorically diagnose and compliantly code heart failure.

References:

- ¹Bozkurt, Biyikem. "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>.
- ²Cuthbertson 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>.
- ³Hayhoe B, Kim D, Aylin PP, Majeed FA, Cowie MR, Böttle 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>.
- ⁴Barber, K. "Developing core indicators for identifying people at risk of delayed heart failure diagnosis." *BMC Primary Care*, vol. 26, no. 1, 16 Oct. 2025, <https://doi.org/10.1186/s12875-025-03024-4>.
- ⁵Borlaug, 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.
- ⁶Verbrugge, 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.
- ⁷Rosano, Giuseppe M.C., et al. "Heart Failure in Patients with Diabetes and Chronic Kidney Disease: Challenges and Opportunities." *Cardiorenal Medicine*, vol. 12, no. 1, 2022, pp. 1–11. DOI: 10.1159/000520909.
- ⁸Spertus, John A., and Philip G. Jones. "Development and Validation of a Short Version of the Kansas City Cardiomyopathy Questionnaire." *Circulation: Cardiovascular Quality and Outcomes*, vol. 8, no. 5, Sept. 2015, pp. 469–476, <https://doi.org/10.1161/CIRCOUTCOMES.115.001958>.
- ⁹Curtis LH. Incidence and Prevalence of Heart Failure in Elderly Persons, 1994–2003. *Archives of Internal Medicine*. 2008;168(4):418. doi:<https://doi.org/10.1001/archinternmed.2007.80>.

Explore Clinical Resources & Guidelines

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