

Computer-aided Detection of Heart Failure in Echocardiography

March 7, 2023

ICD-10 Coordination and Maintenance Committee Meeting

Overview of EchoGo Heart Failure 1.0

Precision heart failure detection from echocardiogram with advanced AI

Developed in collaboration with Mayo Clinic and University of Oxford

Designated a Breakthrough Device by the FDA

FDA-cleared for clinical use in November 2022



Proven

Globally validated outcomes data



Trusted

10 years of outcomes



Cloud-based

No hardware or software needed



Accurate



Seamless

Simple, secure integration



Heart Failure is the greatest unmet need

\$40bn cost of care per year from HF hospitalizations¹

\$70bn per year by 2030¹

50% of people >45 years of age have stage B HF²

5X increase in mortality from stage B to C²

#1 cause of 30-day readmissions in patients >65⁴

65% of patients hospitalized for HF are HFpEF³

75% of patients with HFpEF are being missed⁵⁻¹³



1. Urbich M, et al. *Pharmacoeconomics* 2020;38:1219–1236

2. Khawaja AA, *Circulation*. 2007;115:1563-1570

3. Shah SJ, et al. *Circulation*. 2020;141:1001–1026

4. Zohrabian A, Kapp JM, Simoes EJ. *Ann Transl Med*. 2018 Aug;6(15):298.

6. Cardoso R, et al. *EClinicalMedicine*. 2021 Jun 5;36:100933
5-13.



HFpEF is a diagnostic challenge today

Pretest assessment

Symptoms and signs,
comorbidities/risk factors, ECG,
natriuretic peptides, stress testing.

Diastolic workup

Comprehensive echocardiography.

Advanced workup

Functional test incase of uncertainty

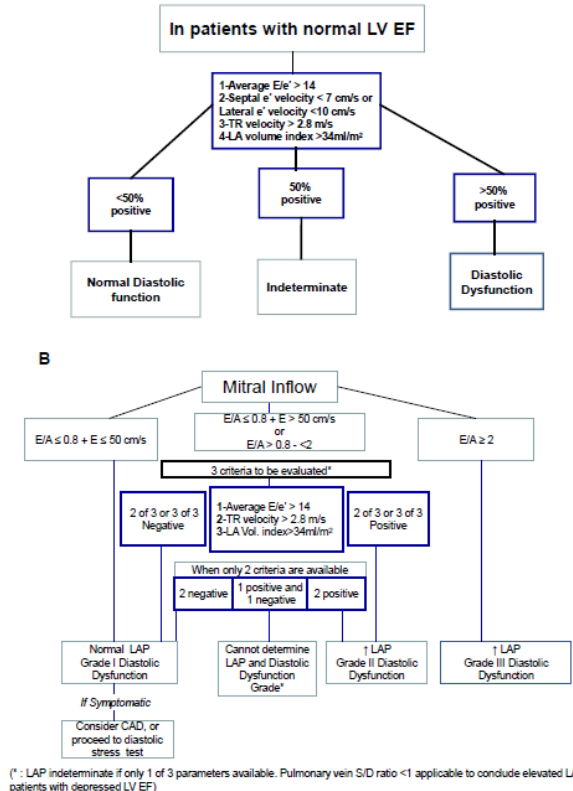
Exercise stress echo, invasive
hemodynamic measurements.

Etiological workup

cMRI, biopsies, CT/PET, genetic
testing, lab tests.



Further and more
invasive testing when
uncertain



Diastolic Function

Excluded groups

Multiple measurements

Correct alignment of Doppler beam

Accurate sample volume positioning

Correct gain settings

Missing data

Missed in 3 of 4 Cases



Diagnosing HFpEF today

**Patient with risk,
signs, symptoms
of HF**

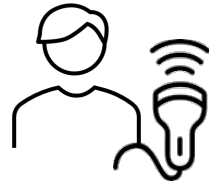


Inpatient



Outpatient

**Order & perform
routine echo**



Subjectivity

Variability

Bias

Time

Skill

**Interpret and
report on echo**

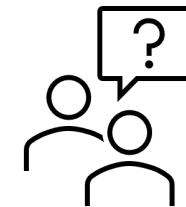


Normal

Abnormal

Pseudo-Normal

**Crisis of
indeterminates**

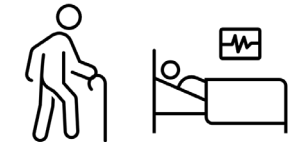
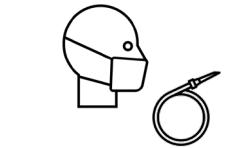


Dx of Exclusion

**Schedule next
test**

**Treat and
monitor Response**

**More Invasive
diagnostic tests**



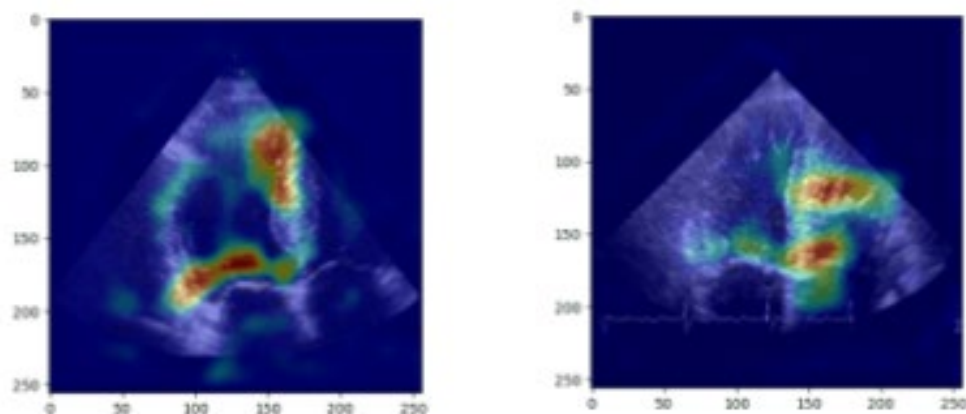
**Patient gives up
or is
misdiagnosed
and disease
progresses**



Diagnose HFpEF with

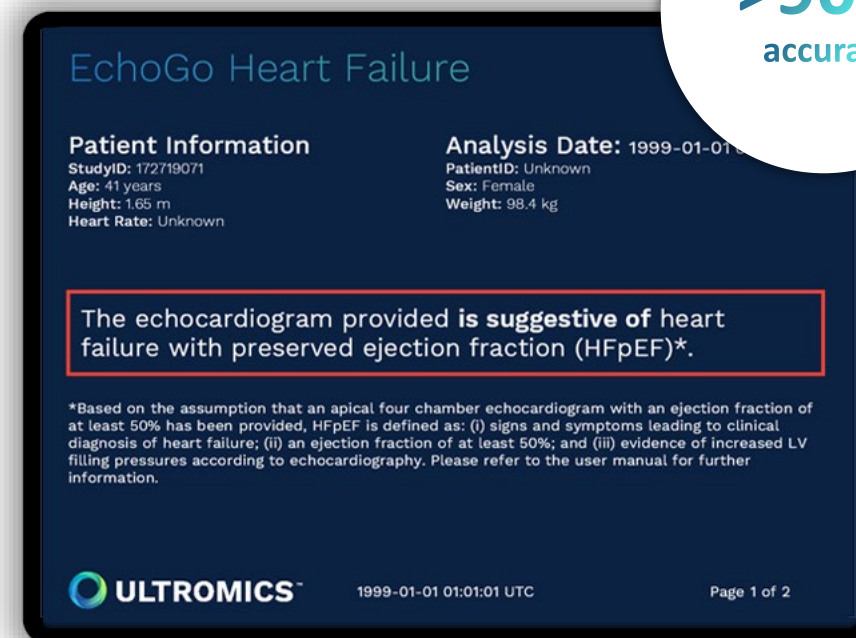


EchoGo Heart Failure detects HFpEF with **>90% accuracy** from a single Apical 4-chamber view, using AI.

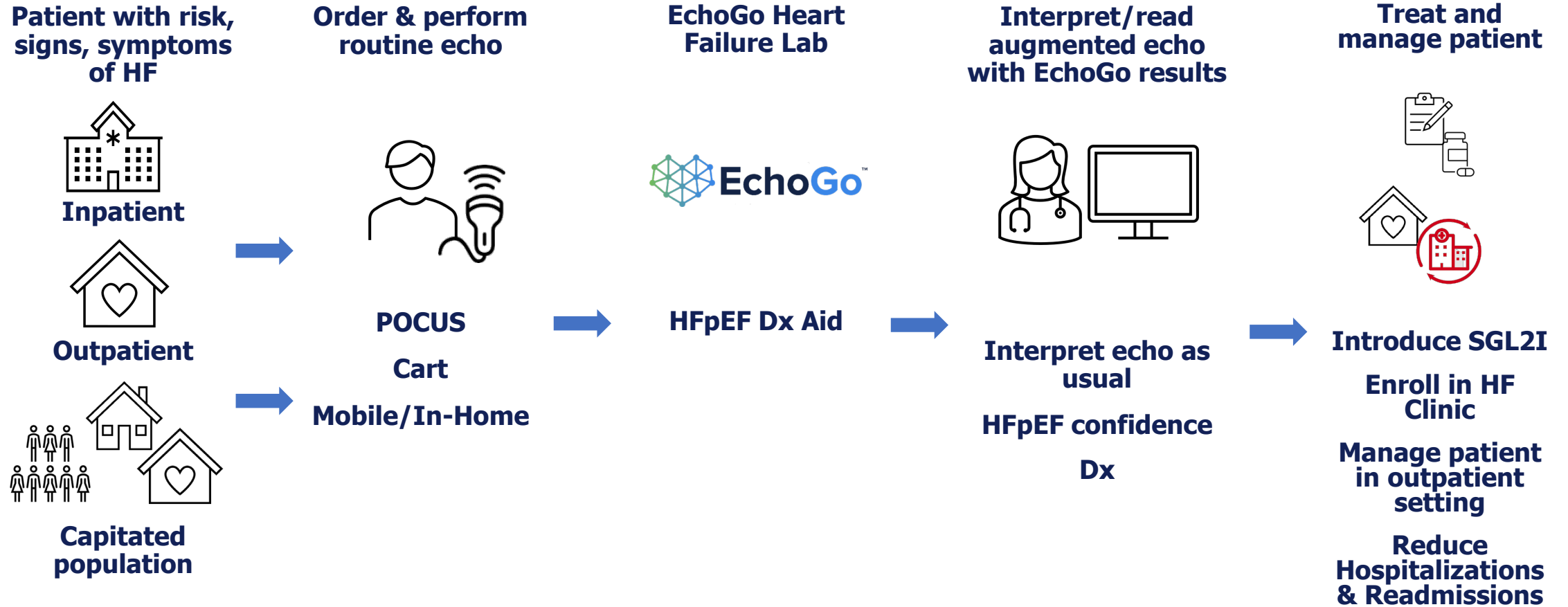


- **Improves HFpEF detection by 68%** vs current clinical risk scores
- **Reduce risk of hospitalizations by 29%** with SGLT2i's.

>90%
accuracy



Diagnosing with EchoGo HF



Patients diagnosed with HFpEF now have impactful therapies



Emporcer-Preserved showed relative risk reduction in HF hospitalization by 29%.



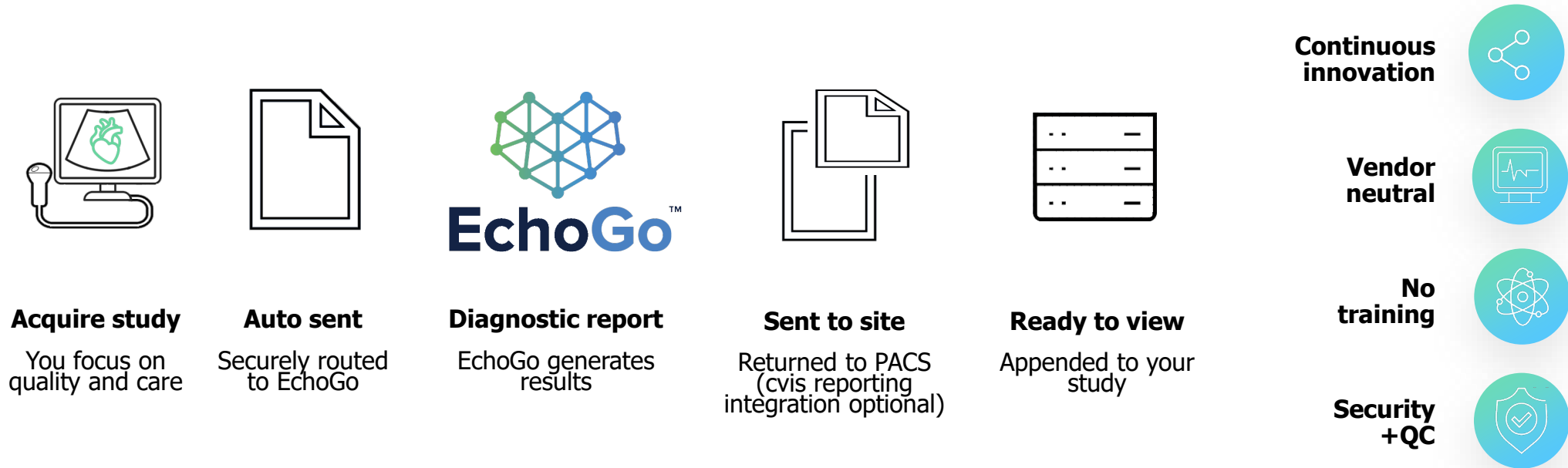
Deliver showed relative risk reduction of 24% for re-hospitalization.



282,879 events could be prevented across US HFpEF population if SGLT2is were implemented effectively.



Clinical Workflow with EchoGo HF



- The approach for documenting the procedure in the medical record will vary by provider
- Documentation Example:
 - Internal procedure code established by the provider
 - Notes AI analysis of echo (EchoGo) in the order set in the medical record



Summary

EchoGo Heart Failure is a breakthrough designated device that received FDA clearance in November 2022.

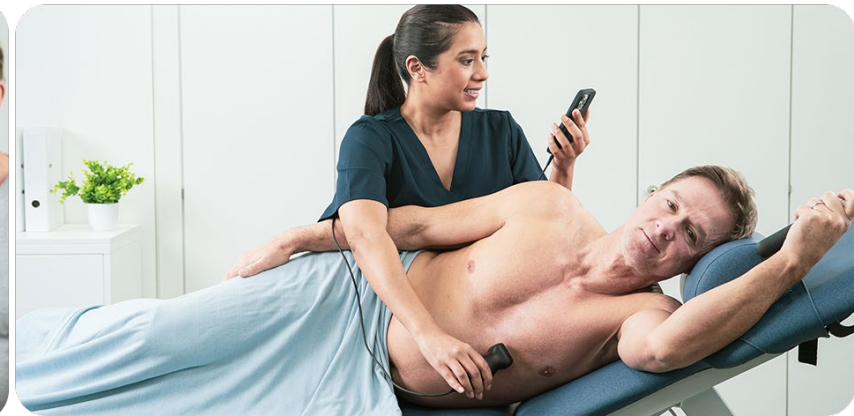
- Ultromics has applied for NTAP for EchoGo Heart Failure as part of the FY 2024 cycle.

The technology is indicated as a diagnostic aid for patients undergoing routine functional cardiovascular assessment using echocardiography. When utilized by an interpreting clinician, this device provides information that may be useful in detecting HFpEF.

While facilities can report the underlying echocardiography with an existing ICD-10-PCS code, there is no existing code that uniquely describes the AI-guided modeling for the detection of HFpEF.



Thank You



ultromics.com

