The State of AI in Commercial Products

Tico Blumenthal
Vice President of Product, Eko Health

Heartland Workshop on Heart Sounds and AI
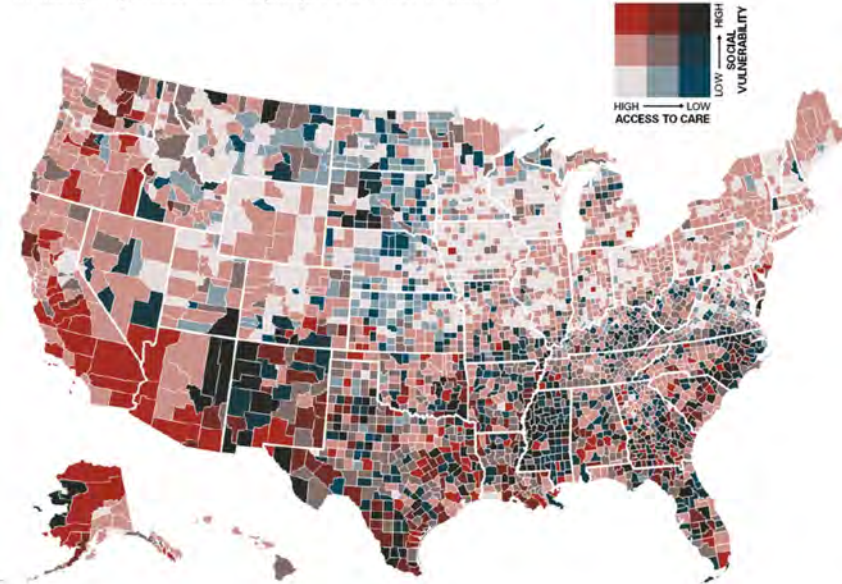June 2023

Access, Cost and Quality are critical objectives

INEQUITABLE ACCESS

This map shows where social vulnerability and poor access to healthcare in the United States intersect. Massive gaps persist in the South and among rural, urban and tribal communities, which illustrate shortcomings of the industry to provide care to people that need it most.
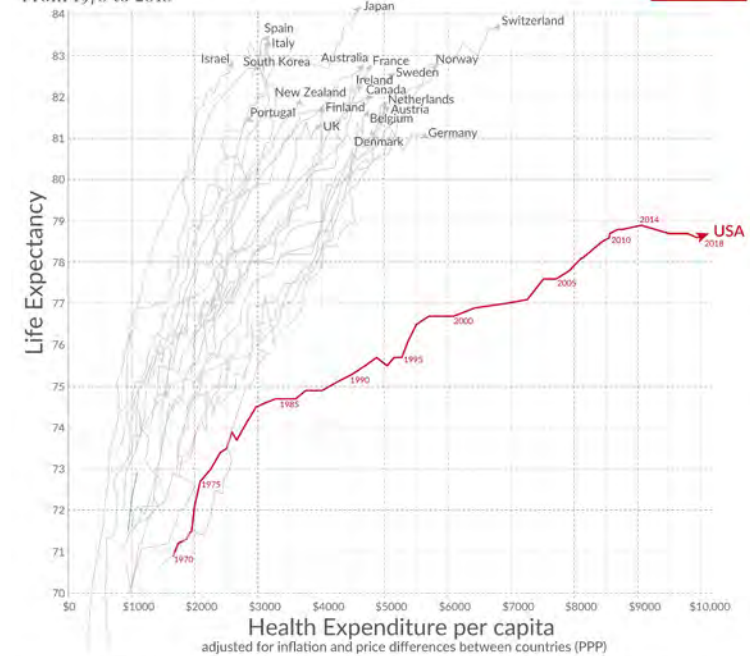
HIGH — LOW
ACCESS TO CARE

LOW — HIGH
SOCIAL VULNERABILITY

Source: Modern Healthcare analysis of Centers for Disease Control and Prevention and the Health Resources and Services Administration data

Life expectancy vs. health expenditure
From 1970 to 2018

Our World in Data

Life Expectancy

Health Expenditure per capita
adjusted for inflation and price differences between countries (PPP)

Data source: OECD — Note: Health spending measures the consumption of health care goods and services, including personal health care (curative care, rehabilitative care, long-term care, ancillary services, and medical goods) and collective services (prevention and public health services as well as health administration), but excluding spending on investments.
Shown is total health expenditure (financed by public and private sources). Licensed under CC-BY by the author Max Roser.

OurWorldinData.org – Research and data to make progress against the world's largest problems.

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Clinically-facing AI offers opportunities, rapid growth [1]

Logos: eko, anumana, enlitic, Ambience, Optellum, DeepMind, Butterfly, aidoc, TEMPUS, IDOVEN, HeartFlow®

Nurses call for pause on healthcare AI

Giles Bruce - Thursday, May 16th, 2024

Nurses around the country continue to raise their concerns about artificial intelligence use in healthcare, with the country's biggest nursing union calling for a pause on the technology.

Hundreds of nurses protested AI April 22 in front of a Kaiser Permanente hospital in San Francisco, while nearly 100 gathered April 27 in Nashville, Tenn., in part to bargain for the "responsible implementation" of AI at Nashville-based HCA Healthcare, the nation's largest health system.

National Nurses United released the results of a survey of over 2,300 registered nurses and union members May 15 that found 80% didn't trust their employers to implement AI with a focus on patient safety.

"The survey and reports from nurses across the country demonstrate that we need an immediate pause on implementing AI in healthcare settings," said Deborah Burger, RN, president of National Nurses United, in a statement. "As patient advocates, it is our duty to assess the evidence in front of us and question the unfounded marketing claims that AI will complement our bedside skills or improve the quality of care for our patients."

Here are more findings from the survey, according to National Nurses United:

— Half of the respondents said their employers analyze EHR data with algorithms to deduce patients' acuity and predict the number of nurse hours needed. Of those nurses, 69% said their assessment doesn't align with the AI, as it doesn't take into account the "educational, psycho-social, or emotional needs" of patients.

Source: Beckers Hospital Review, May 16th, 2024, link

Hospitals report 10-15+ AI companies calling *per week*

38% of physicians report using AI[1], many see success, some barriers

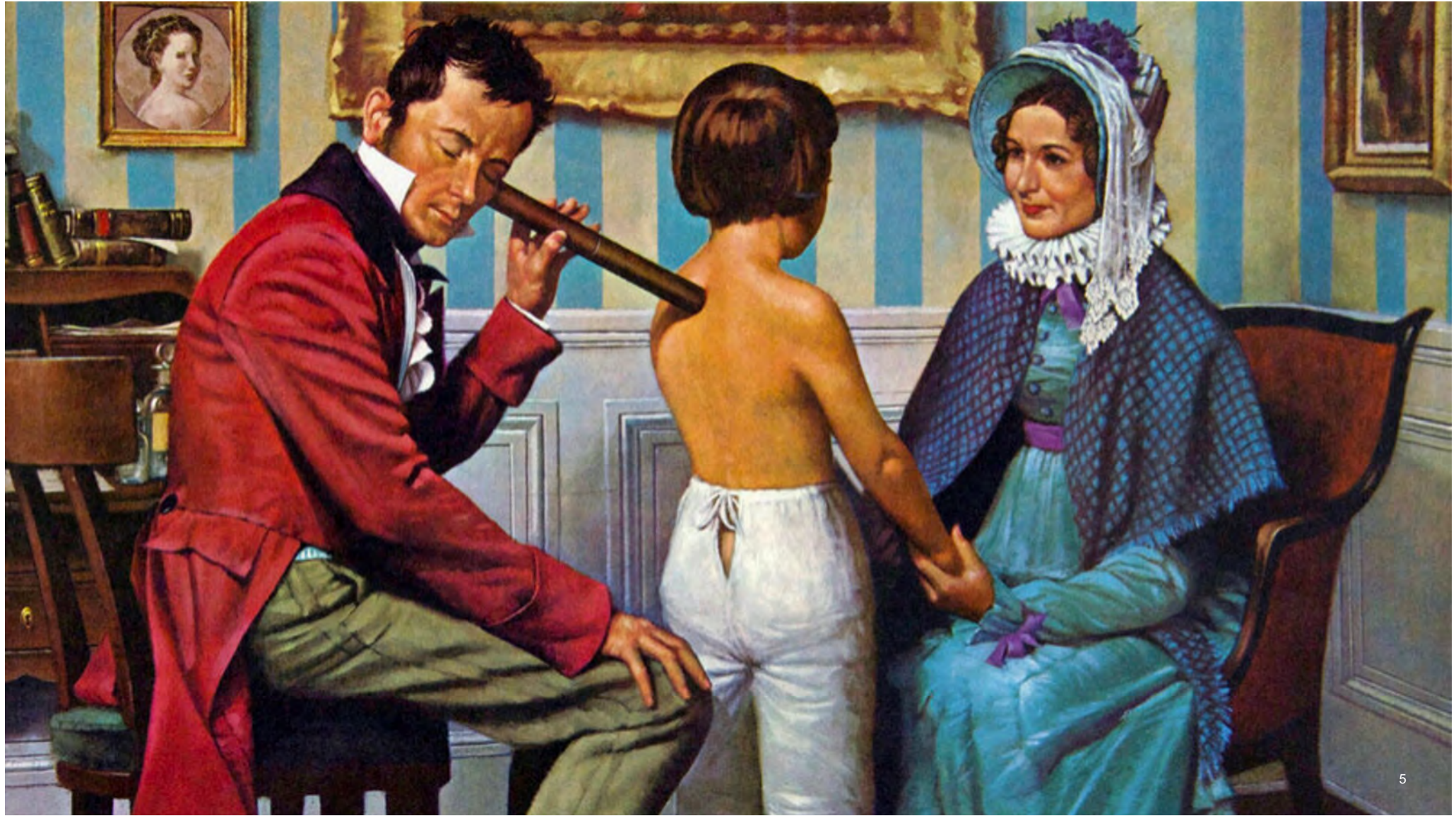*The pace of innovation is accelerating*

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Eko's founding insight

Over 1 billion stethoscope exams per year

Every day, cardiopulmonary disease is going undetected on the front-lines of care.

.. because they're using **outdated tools**.

By helping clinicians hear better, and listen confidently

we earn their trust to help them find disease earlier, when better care is most impactful
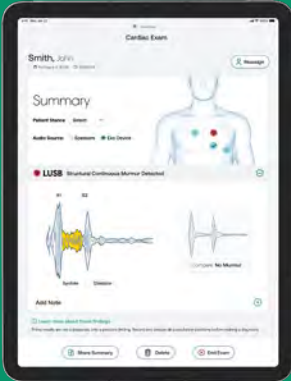
The Eko Health Platform

CORE
Sensors

DIGITAL STETHOSCOPE
AND ECG

SENSORA™
AI / ML

CARDIAC MURMUR AND
ARRHYTHMIA DETECTION

ENTERPRISE
Telehealth

REMOTE PATIENT CARE

*EHR integration/SSO optional

500,000+
Eko devices
in clinician hands

Largest installed base of AI-enabled
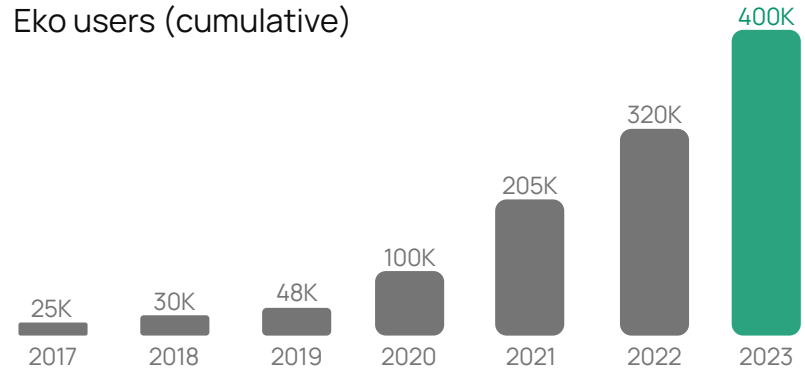point-of-care devices, globally

A growth story

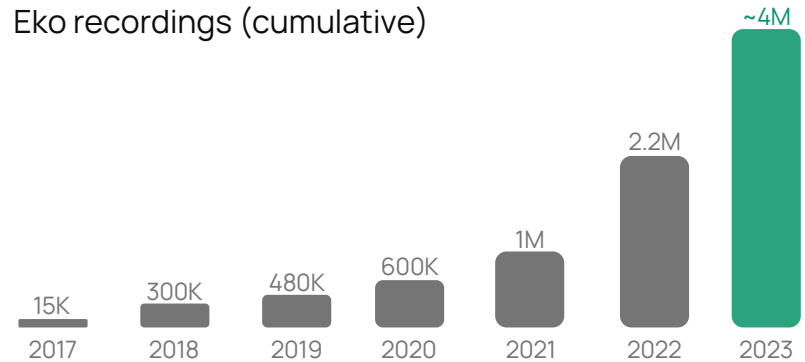Eko collected the largest dataset of heart sounds and lung sounds for AI development.

Better auscultation and more insights have become a reality for millions of patients every week.

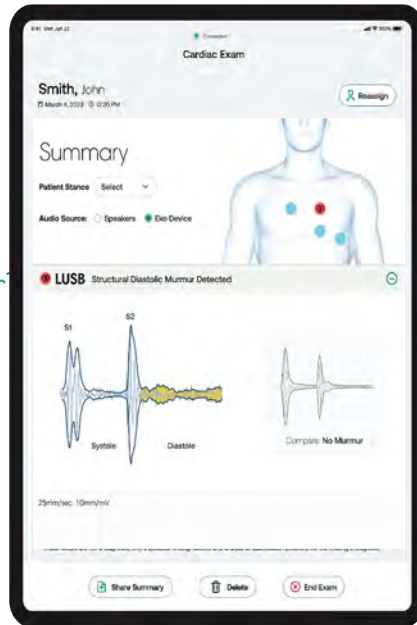Quicker answers, and solutions, for higher quality care.

Eko users (cumulative)

2017	2018	2019	2020	2021	2022	2023
25K	30K	48K	100K	205K	320K	400K

Eko recordings (cumulative)

2017	2018	2019	2020	2021	2022	2023
15K	300K	480K	600K	1M	2.2M	~4M

SENSORA™

Cardiac Disease Detection

Structural Heart Disease Detection
Murmur Analysis Software (FDA K213794)

+

Atrial Fibrillation
Eko Analysis Software (FDA K192004)

+

Heart Failure Detection
Reduced Ejection Fraction (FDA K233409)

+

Adventitious Lung Sounds**

+

COPD**

Results in seconds

**Not FDA approved or cleared. On future roadmap.

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Our Key Markets: HF and VHD

Over 423,000 people die from HF and VHD each year…[1]

15M+

patients in the US have Valvular Heart Disease[2] or Heart Failure[1]

$80 billion

annual US cost for treating HF and VHD patients[1]

1. Martin et Al (2024). 2024 Heart Disease and Stroke Statistics: A Report of US and Global Data From the American Heart Association. JCirculation. 2024;149:e347–e913
2. Otto CM, Bonow RO. Valvular Heart Disease: A Companion to Braunwald's Heart Disease. 4th ed. Philadelphia, PA: Elsevier Saunders; 2014.

…and detection before presentation to the emergency room remains a challenge, leaving many untreated.

every 10 min

someone dies in the US from HF or Valvular Heart Disease[3]

3. Centers for Disease Control and Prevention, National Center for Health Statistics. Underlying Cause of Death 1999-2017 on CDC WONDER Online Database, released December, 2018. Data are from the Multiple Cause of Death Files, 1999-2017, as compiled from data provided by the 57 vital statistics jurisdictions through the Vital Statistics Cooperative Program. Accessed at http://wonder.cdc.gov/ucd-icd10.html on Oct 24, 2019.

Roughly 40% of HF is discovered in acute care [1]

Accurate and timely detection is key to ensuring the best patient care and outcomes

Detection

Auscultate: Murmur identification and characterization

Diagnosis

Diagnose: Confirm with echocardiogram

Treatment

Treat: Medical Management, Intervention

1 d'Arcy JL et al.Large-scale community echocardiographic screening reveals a major burden of undiagnosed valvular heart disease in older people: the OxVALVE Population Cohort Study. Eur Heart J. 2016 Dec 14;37(47):3515-3522. doi: 10.1093/eurheartj/ehw229
2 Eko Murmur Analysis Software User Manual, LBL 295 Rev B. Structural murmur identification in adult patients (>18 years old)).FDA submission data.
3 Gardezi, Syed Khurram Mushtaq, et al. Cardiac auscultation in diagnosing valvular heart disease: a comparison between general practitioners and cardiologists. European Heart Journal, Vol. 38 (2017): 1155

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SENSORA™ Platform
What's included?

Digital Sensor

Digital Stethoscope

(with or without ECG)

Advanced Machine Learning

Cloud-based Algorithm

FDA cleared Structural Murmur Analysis

Customized Analytics

Care Pathway Analytics

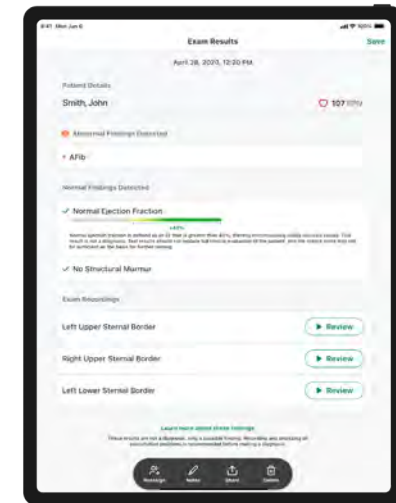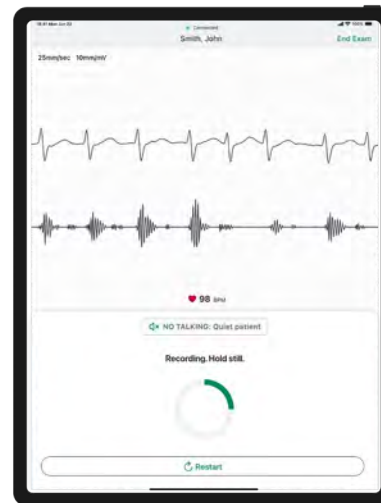Capture and centralize your data

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Sensora AI

Algorithms & Evidence

Arrhythmia Detection

FDA 510k cleared in Nov 2019

Detects:

- Atrial Fibrillation
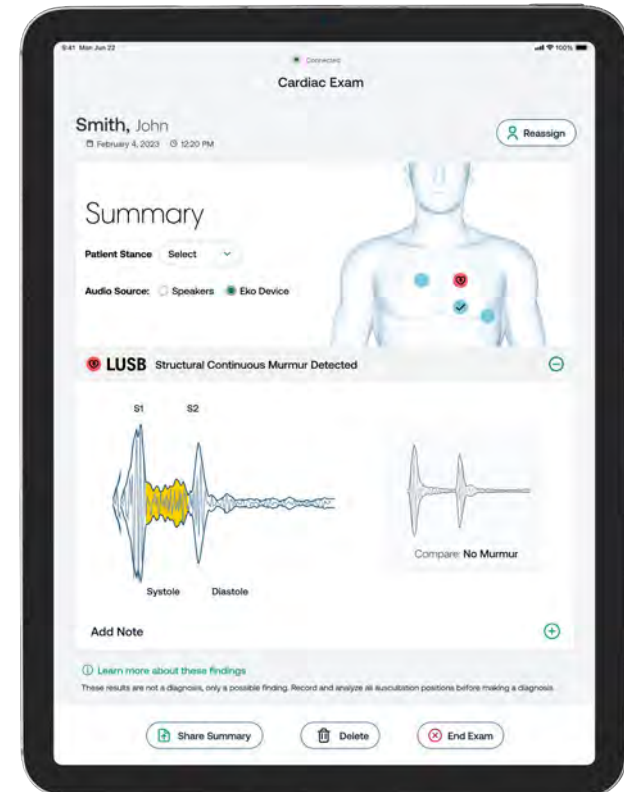- Bradycardia/Tachycardia
- "Other" Arrhythmia
- Normal Sinus Rhythm

15-second Recordings, across 1 or multiple points
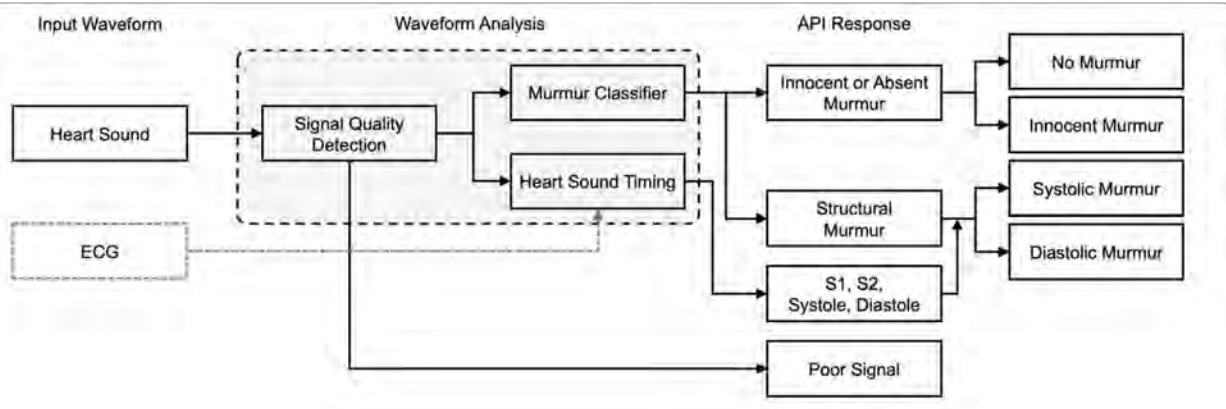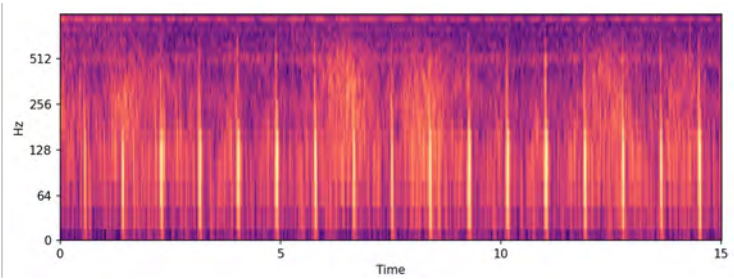
Murmur Characterization

FDA 510k cleared in June 2022

Detects:

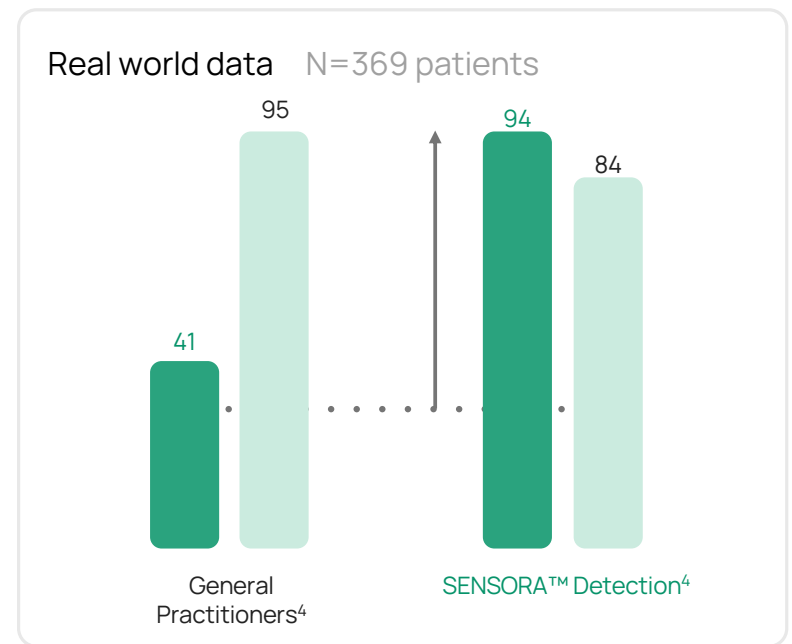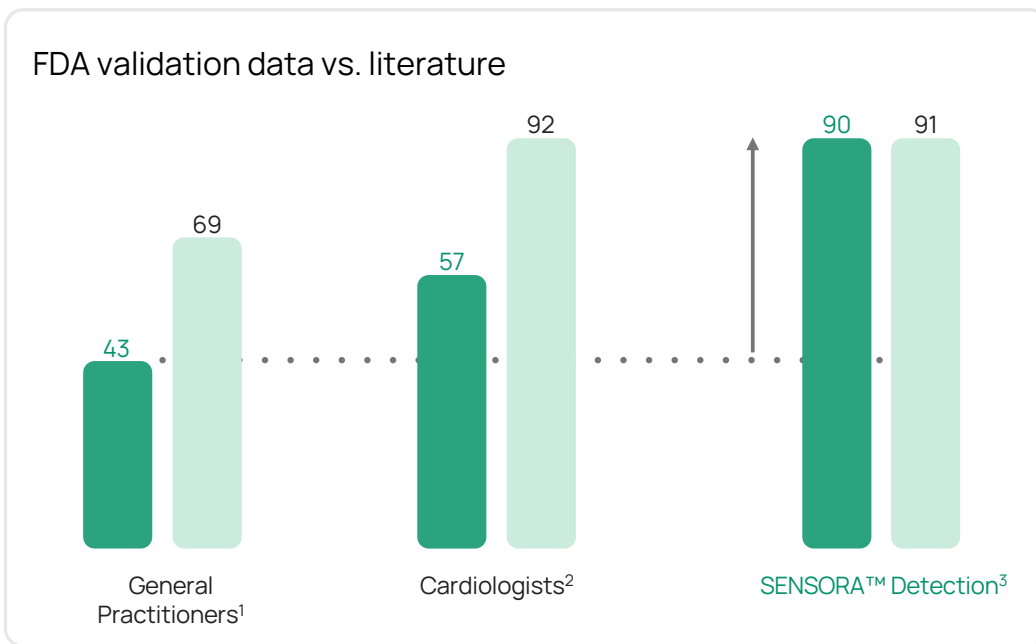- Structural Systolic Murmurs
- Structural Diastolic Murmurs

Murmur Characterization

SENSORA™ AI more than doubles detection accuracy vs. PCPs

■ Sensitivity ■ Specificity

FDA validation data vs. literature

General Practitioners[1]: 43, 69
Cardiologists[2]: 57, 92
SENSORA™ Detection[3]: 90, 91

Real world data   N=369 patients

General Practitioners[4]: 41, 95
SENSORA™ Detection[4]: 94, 84

[1] Gardezi, Syed Khurram Mushtaq, et al. Cardiac auscultation in diagnosing valvular heart disease: a comparison between general practitioners and cardiologists. European Heart Journal, Vol. 38 (2017): 1155

[2] Siliste RN, Siliste C. Physical examination in aortic valve disease: do we still need it in the modern era? European Society of Cardiology, Vol. 18 (2020), N° 12

[3] Eko Murmur Analysis Software User Manual, LBL 295 Rev B. Structural murmur identification in adult patients (>18 years old)).FDA submission data.
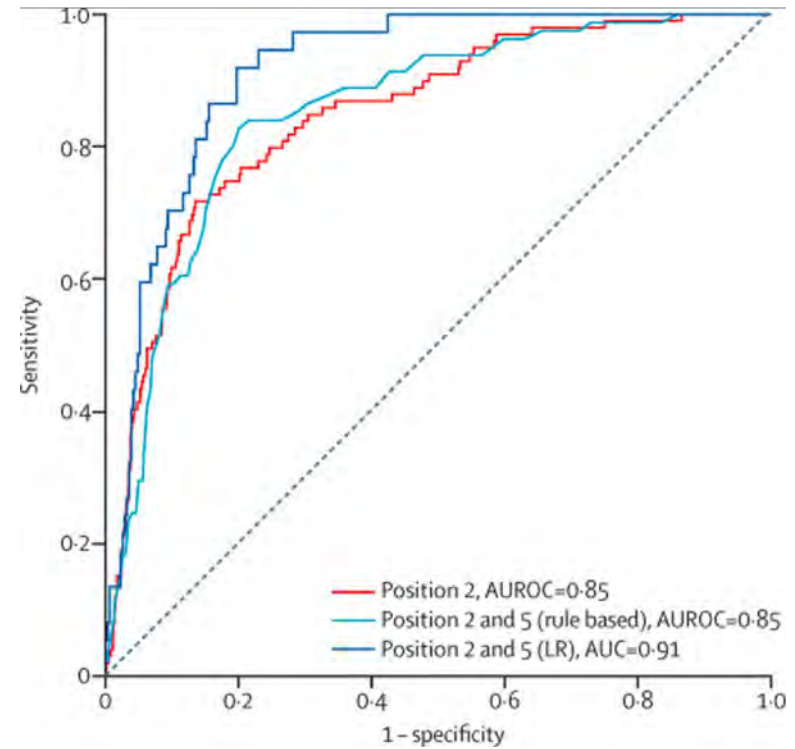
[4] Data on file. Announcing at AHA

Reduced Ejection Fraction

FDA 510k cleared in March 2024

Detects:

- Individuals with Ejection fraction < 40%

Reduced Ejection Fraction

FDA Test Set

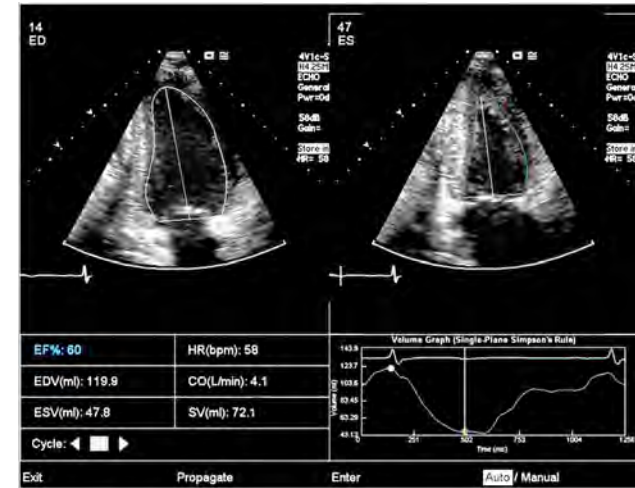Leveraging ECG & Heart Sounds

Prospective study on 3,456 unique individuals

Ground truth confirmed by echocardiogram

10% prevalence of Reduced EF

Sensitivity = 74.7%

Specificity = 77.5%

American Heart Association 2023

A Randomized Controlled Trial of 1,195 women between the ages of 18 and 49 were enrolled in the study and completed necessary baseline tests. About 73% were pregnant at the beginning of the study; and 39% were in their third trimester.

Results

AI-guided screening (digital stethoscope maximum prediction across all locations recorded) doubled cardiomyopathy detection (4.1%) compared to the control arm (1.8%).

AI showed an impressive AUC of 0.98, 100.0% sensitivity, and 79.4% specificity, underscoring its significant potential to assist in the detection and appropriate management of cardiomyopathy in pregnant women.

Community Partnerships
HeartSense

Antoine Keller, MD, FACC, FACS · 1st
Co-founder of HeartSense | Cardiothoracic Surgeon at Ochsner Lafayette ...
1d · 🌐

Being part of our community's events and well-being is imperative in shifting the heart health equity and access paradigm. This weekend HeartSense had the opportunity to participate in the Love Heals Free Clinics event at the Raising Cane's River Center - ASM Global. Using the Eko Health SENSORA™ platform, we detected ten structural murmurs - Of those, six individuals had no prior knowledge of their condition nor access to a cardiologist.

Thank you to our HeartSense volunteers and staff and Cody Hitchcock for training on the SENSORA™ platform to further enhance our heart screening capabilities.

If you want to partner with HeartSense to bring heart screening to your community, please get in touch with info@heart-sense.org.
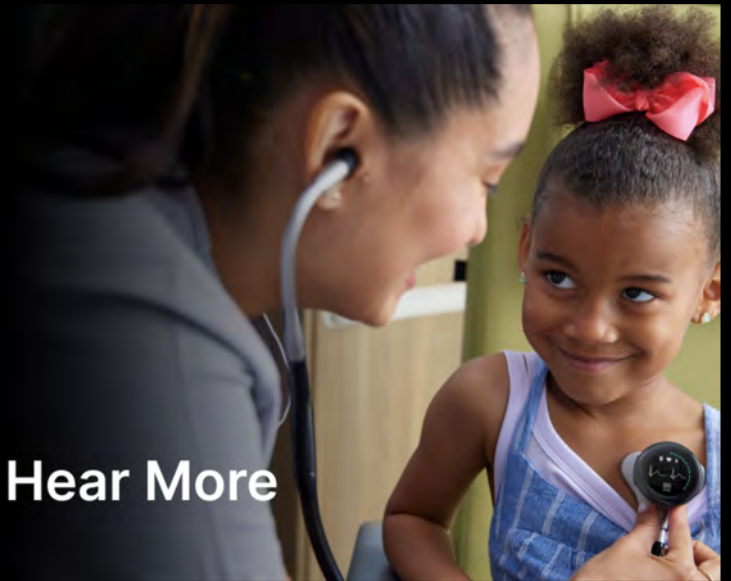
#hearthealth #healthequity #healthcareonlinkedin #ekohealth

The insight and skills of a specialist, in the hands of physicians and patients, to deliver care everywhere.

This is the future of healthcare.

Hear More

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Appendix

Indications for Use

CORE

Indications for Use: The Eko CORE is an electronic stethoscope that enables amplification, filtering, and transmission of auscultation sound data (heart, lungs, bowel, arteries, and veins), whereby a clinician at one location on network can listen to the auscultation sounds of a patient on site or at a different location on the network. Eko CORE is intended for use on pediatric and adult patients. The Eko CORE is intended to be used by professional users in a clinical environment or by lay users in a nonclinical environment. The device is not intended for self-diagnosis.

DUO

Indications for Use: The Eko DUO System is intended to be used by healthcare professionals to electronically amplify, filter, and transfer body sounds and single-channel electrocardiogram (ECG) waveforms. The Eko DUO System also displays ECG waveforms and phonocardiogram waveforms on the accompanying mobile application for storage and sharing (when prescribed or used under the care of a physician). It can be used to record heart sounds and cardiac murmurs, bruits, respiratory sounds, and abdominal sounds during physical examination in normal patients or those with suspected diseases of the cardiac, vascular, pulmonary, or abdominal organ systems. The device can be used on adults and pediatrics.

The data offered by the device is only significant when used in conjunction with physician over read as well as consideration of other relevant patient data.

The device should not be used on infants weighing less than 10kg.

Eko Murmur Analysis Software

The Eko Murmur Analysis Software is intended to provide decision support to clinicians in their evaluation of patients' heart sounds. The software analyzes heart sounds and phonocardiograms (and ECG signals, when available). The software will automatically detect murmurs that may be present, and the murmur timing and character, including S1, S2, innocent heart murmurs, structural heart murmurs, and the absence of a heart murmur.

The Eko Murmur Analysis Software is not intended as a sole means of diagnosis and is for use in environments where healthcare is provided by clinicians. The interpretations of heart sounds offered by the software are meant only to provide decision support to the clinician, who may use the result in conjunction with their own evaluation and clinical judgment. The interpretations are not diagnoses. The Eko Murmur Analysis Software is intended for use on pediatric and adult patients.