

CardioFlux

A Breakthrough in Cardiac Imaging

Powered By  Genetesis

 **Current Challenge With Chest Pain Triage in the Emergency Department**

8 million² Americans go to the ED for chest pain every year.

Yet the causes in 75% of these cases are not heart-related.



Testing

The first tests employed in chest pain triage include serial assessment of biochemical markers of necrosis and ECG. If early testing is inconclusive, the patient is subject to stress testing based on ECG, echocardiography and nuclear Imaging techniques, the latter being highly Invasive with Injection of radiopharmaceuticals. Positive test results will lead to coronary angiography.



Length of Stay

Patients that go into the hospital for chest pain may be kept for an 8-23 hour stay.¹ Long hospital stays are currently needed to rule out the possibility of a severe adverse cardiac event.



High Costs

The many diagnostic tests plus long hospital stays make the triage process for chest pain very expensive.² This cost is felt by both hospitals and patients.

1

Hsia RY, Hale Z, Tabas JA. A National Study of the Prevalence of Life-Threatening Diagnoses in Patients With Chest Pain. *JAMA Intern Med.* 2016; 176(7):1029-1032. doi:10.1001/jamainternmed.2016.2498

2

Amsterdam, EA, et al. Testing of Low-Risk Patients Presenting to the Emergency Department With Chest Pain. *Circulation* 2010;122(17): 1756-1776. doi: 10.1161/CIR.0b013e3181ec6t1df

 **The Power of CardioFlux®**

CardioFlux Is a fast, simple, noninvasive and radiation-free cardiac diagnostic technique

leveraging the fifty years of steady progress that magnetocardiography (MCG) has made in the diagnosis of myocardial ischemia and coronary artery disease. Applied very early in the initial triage of patients presenting to the Emergency Department with suspicion of an acute coronary syndrome (ACS), CardioFlux can be used adjunctively with the results of biomarkers to rule in or rule out a patient for ACS.



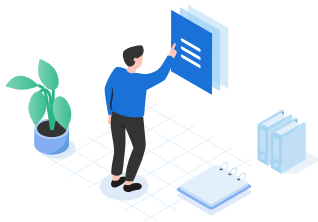
1 Non-Invasive & Radiation-Free

CardioFlux® is effectively non-contact and completely radiation-free, ionizing or non-ionizing. Other than the bed on which the patient lies, nothing contacts the patient before, during or after a scan.



2 90 Seconds

A patient encounter for a CardioFlux® scan is completed in under 5 minutes. The scan itself is over in 90 seconds.



3 Simple and Intuitive Interpretation

Scan interpretation is logical and straightforward. Results are presented as magnetic field maps which the reader can play back in millisecond increments to identify potential abnormalities in cardiac electrical function, a direct indicator of underlying ischemic processes.

CardioFlux® is an FDA cleared biomagnetic imaging system.

How Does CardioFlux Fit into the Standard of Care?

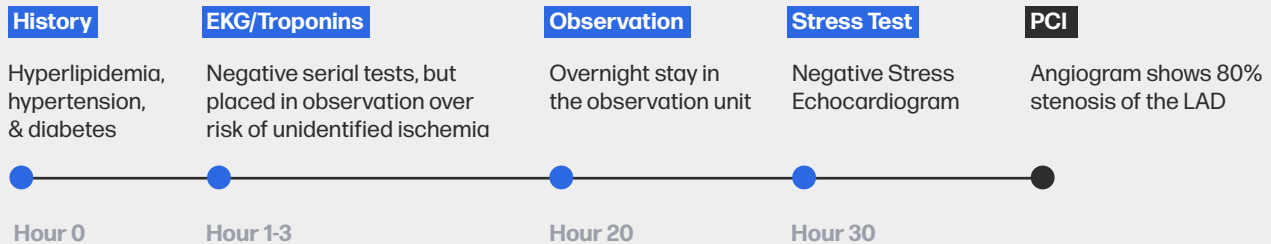
Initial triage of potential ACS patients begins with serial ECG and biomarkers.

The low sensitivity of ECG and strict cut-off criteria of new highly sensitive biomarkers typically result in many patients sent to observation for additional, typically provocative testing. If these tests were less invasive and not deliver high levels of ionizing radiation to the patient, they would be performed early in triage. But they are not. Only Cardioflux®, a technique as benign as ECG, but with demonstrated diagnostic accuracy equivalent to these more invasive tests can be applied early in triage.¹

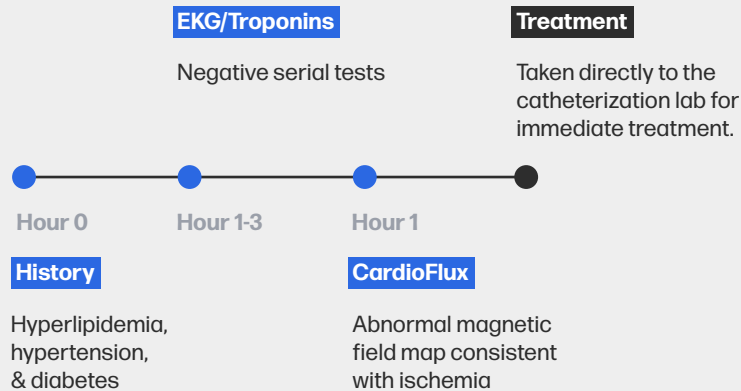
The result: a clinical diagnostic pathway that can rule out ACS patients sooner and rule in ACS patients earlier, the consequence being more efficient utilization of resources, and in the latter case, improved patient outcomes.

Patient Case Study

Standard of Care



CardioFlux® Path



¹ Endpoint of current multicenter clinical trial NCT04044391

Patient Case Study*

James could have had a faster, more accurate and less invasive ER visit with CardioFlux.

*Patient story is based off of a clinical trial case, and the name has been changed to protect patient privacy.

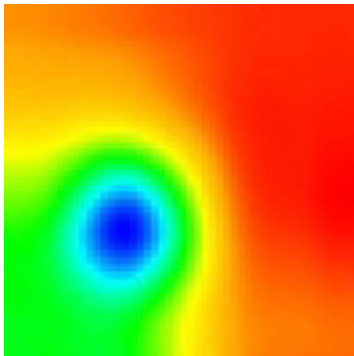


Name: James

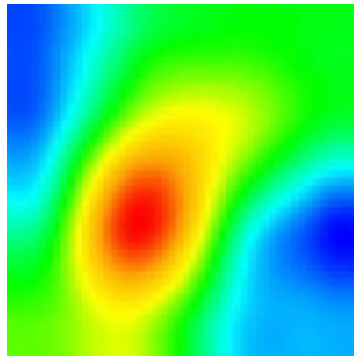
Heart Score: 6 **Age:** 68

Situation:

Presented to the Emergency Room with chest pain and began an over 36-hour long journey of invasive testing and waiting for a diagnosis. James has a family history of hyperlipidemia, hypertension and diabetes.



R-Peak

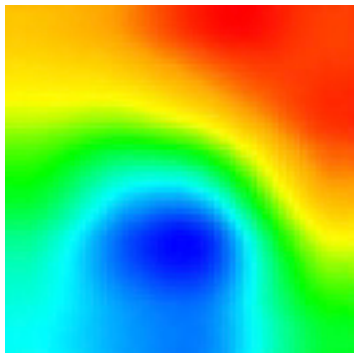


T-Peak

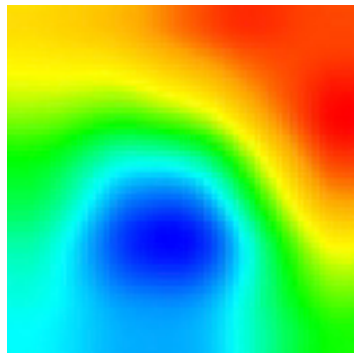


James's Abnormal MCG

The markedly different features of magnetic field maps at R-peak and T-peak are commonly found in individuals with underlying coronary artery disease.



R-Peak



T-Peak

Normal MCG

A nearly identical appearance of magnetic field maps at R-peak and T-peak is commonly found in individuals without coronary artery disease.

 How Does CardioFlux® Work?

CardioFlux® can be used within the first hour of the chest pain triage process in the Emergency Department.

Within minutes after starting a CardioFlux® scan, a personalized, magnetic field map of the patient's functional heart health is generated.



1

Scan Start

Operator starts scan and verifies it was successful. Data is stored and processed in cloud for analysis.



2

Upload

Analysis is uploaded in web-enabled application to allow physician access anywhere.



3

Review

Physician reviews report and provides final diagnosis.

Today, ED physicians do not have the tools they need to accurately rule out or rule in ACS patients.

CardioFlux® will change that.

CardioFlux is safe and FDA cleared.¹ However, CardioFlux may not be appropriate for everyone.

If you have metal implants or implanted devices in your torso (e.g., pacemaker) or large amounts of implanted metal in other parts of your body, these may make your scan unreadable.

There are no risks to you if you enter CardioFlux with metal.

This scenario would simply require a re-scan, if the metal can be removed, or an unusable scan. A small number of patients have reported experiencing claustrophobia while being scanned.

+ **Please inform** your prescribing physician and CardioFlux technician if any of these apply to you.

About Genetesis

Genetesis® is a rapidly growing medical technology company redefining the way patients with a risk of myocardial ischemia and coronary artery disease are clinically diagnosed, monitored and screened.

♥ **Genetesis has built an end-to-end imaging solution,** by combining CardioFlux®, a first-in-class FDA-cleared non-invasive biomagnetic imaging technology with Faraday, the company's proprietary cloud-based image analysis and workflow solution.

♥ **The Company's Mission** is to build a better standard of care by providing clinicians and payors with most patient-centric and cost effective solutions.

To learn more, visit www.genetesis.com

1

Indications for Use: The CardioFlux FAC Magnetocardiograph is intended for use as a tool which non-invasively measures and displays the magnetic signals produced by the electric currents of the heart. Genetesis is currently interacting with FDA to expand intended use to include a diagnostic claim.