



Detection of Silent MI In an Ambulatory Patient with Complex Coronary Artery Disease by The Guardian[®] System

This case is a common example of **Technology-Enabled** early detection of a silent heart attack. It underscores the importance of continuous cardiac monitoring in high-risk patients with complex coronary artery disease (CAD) and prior revascularizations.

The Guardian[®] System captures, digitizes, and analyzes a 10-second electrogram every 30 to 90 seconds. The analysis is personalized and looks for a statistically significant change from what is “normal” for each patient. “Normal” is defined by the **Guardian System’s** machine learning algorithms which incorporate the continuous analysis of thousands of the patient’s recent heartbeats. The system detects acute change that is independent of everyday ischemia that may normally exist due to how severe the patient’s CAD is.

Patient Overview

The patient is a 75-year-old male with a history of CAD. He was implanted in June of 2021 with the **Guardian System**, the only FDA-approved implantable cardiac device designed to detect the onset of acute coronary syndrome events such as heart attacks.

Guideline Directed Medical Monitoring and Management Upon ER Arrival

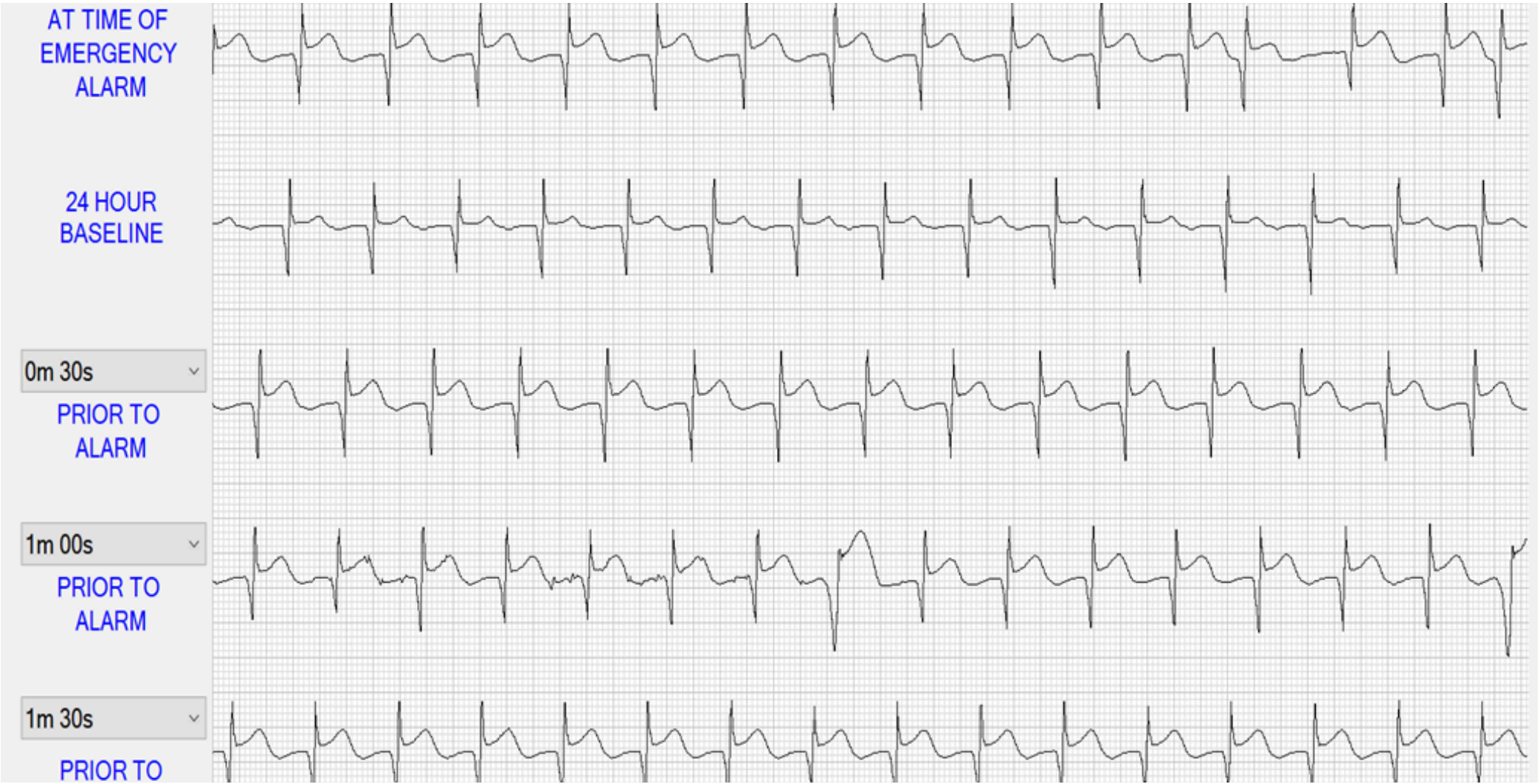
On January 30, 2025, the **Guardian System** triggered a **Positive ST Shift at Normal Heart Rate** Emergency Alarm, even though the patient was not experiencing any symptoms. This led to the following:

- The patient arrived at the ER within 1 hour of the alarm.
- At initial ER triage, the patient reported no symptoms.
- A 12-lead ECG was negative for STEMI.
- The ER staff performed a high sensitivity Troponin blood test as per the standard of care. The result **was extremely elevated**, confirmation of a myocardial infarction (MI).
- The patient was monitored and medically managed with a 48-hour heparin infusion.

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- The patient was admitted to the hospital and underwent a cardiac catheterization procedure with an echocardiogram.
 - The patient was referred to specialists for the best course of treatment given the complexity of the patient's coronary anatomy and CAD status. Options discussed included a redo of CABG, atherectomy, additional PCI, or a combination of options.

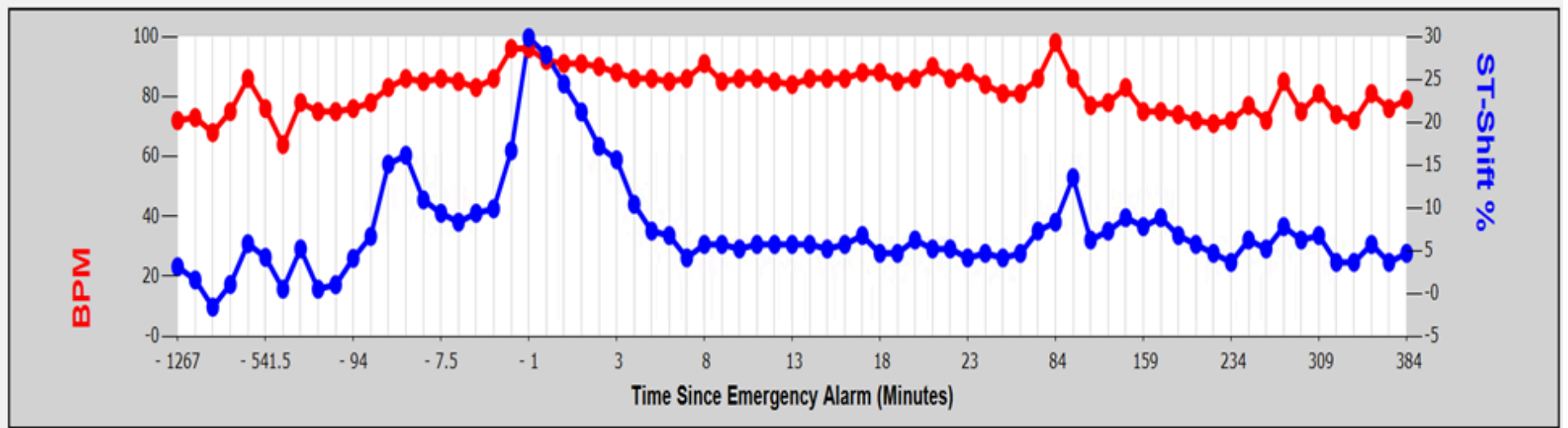
Detection

The 10-second electrograms below led to the Emergency Alarm from the **Guardian System**.



For this patient, a comparison of the four electrograms leading up to the Emergency Alarm illustrates the ST segment elevation detected by the **Guardian System** when compared to the **24-hour Baseline** electrogram. The Guardian System assesses this acute change in the ST segment to make sure it persists for the required amount of time, is **not** a demand induced response (such as may occur at an elevated heart rate due to exercising), and that the **magnitude** of the acute change in the ST segment exceeds this patient's unique alarm detection threshold. All these requirements were met for this patient, and the patient was then alerted to call 911 for transport to the ER. The alarm was robustly provided by the multi-modal internal (vibration) and external (auditory and visual) alerting capabilities built into the Guardian System.

The patient promptly arrived at the ER for diagnosis and treatment using the standard of care protocols. The local hospital was aware of the Guardian System and responded to the Emergency Alarm presentation using the same guideline directed medical monitoring and management that would be used for a patient presenting with potential heart attack symptoms – the Guardian System alarm will cause patients to get to the ER and be assessed even when symptoms are absent. Below is a summary of average heart rate and proprietary measure termed “ST Shift% “ for the ~21 hours leading up to the alarm and the ~ 6 hours after the alarm. The alarm-threshold for this patient was set at 19.4% positive ST shift. Note that the Heart Rate mostly remains un-elevated (i.e., below 90 beats per minute) during the hour before and after the alarm occurs.



Cardiac Catheterization Findings

- **100% occlusion in:**
 - Ostium to mid-LAD with side branch involvement
 - Distal LAD
 - Distal Circumflex
 - Proximal RCA
 - Origin to proximal graft
- **99% stenosis in:**
 - Mid LAD to distal LAD
 - Distal Circumflex
- **70% stenosis in:**
 - Mid LAD
- **50% stenosis in:**
 - Proximal graft to mid graft

Conclusions from Angiography:

- Native coronary arteries are **chronically occluded**.
- **Patent LIMA–LAD with occlusion proximal and distal to anastomosis.**
- **Patent SVG–PDA and SVG–OM with stents.**
- **SVG–Diagonal is chronically occluded.**

Clinical Interpretation:

The patient has **severe triple vessel coronary artery disease** (CAD) with:

- Multiple critical occlusions and **chronic total occlusions (CTOs)**
- **Recurrent ischemia**, despite prior interventions (CABG and stenting)

The massively elevated troponin test result is indicative of myocardial injury and is the result of a new onset (or recurrent) coronary occlusion in what is already a complex coronary anatomy state.

- Led to timely ER visit and confirmed (via Troponin testing) myocardial infarction

Significance and Technology Highlight

The Guardian System detected ischemic changes indicative of the onset of a coronary occlusion in the absence of patient symptoms.

The Guardian System identified progressive ST segment elevation at normal heart rates:

- Positive ST Shift%: 0.0% → 3.1% → 12.5% → 20.4% (1 minute prior)
- Alarm triggered at 19.4% positive ST shift.