



In the ever-evolving landscape of cardiac care, technological advancements are reshaping how clinicians identify and manage life-threatening conditions. Among these innovations, continuous heart monitoring devices have emerged as a critical tool in early detection, enabling a proactive approach that goes beyond traditional symptom-based interventions. By leveraging sophisticated algorithms and patient-specific data, such systems are capable of sensing subtle changes in cardiac function—often before the patient themselves are aware of any discomfort or warning signs. One of the most compelling demonstrations of this technology's transformative potential can be seen in the following case, which involves **The Guardian[®] System** from Avertix Medical Inc.

Early Identification of a 92% LAD Occlusion Utilizing The Guardian® System by Avertix Medical

The Guardian System is designed to continuously acquire, digitize, and analyze 10-second electrograms at intervals between 30 and 90 seconds. The system detects the onset of an acute change from what is normal for each specific patient. This real-time evaluation relies upon statistics which are defined using machine learning algorithms that continuously assess thousands of heartbeats of each patient. This approach enables determination of what is "normal" for each patient, irrespective of the severity of those patients' coronary artery disease. Once "normal" has been determined in this manner, statistically significant deviations from "normal" can be easily detected.

Patient History

The subject is a 77-year-old female with a three-decade long history of Type 2 diabetes. She has had five prior stent placements and suffers from multi-vessel coronary artery disease. In March 2022, she was implanted with **the Guardian System** in a simple procedure lasting about 1 hour. **The Guardian System** is the sole implantable cardiac device that is FDA-approved for the detection of, and patient alerting to, the onset of coronary occlusions that lead to recurrent, acute coronary syndrome (ACS) events.

About three years after being implanted, in July 2025, the **Guardian System** activated an Emergency Alarm after detecting a **Negative ST Shift at Non-Elevated Heart Rate** event; the patient was asymptomatic at the time. She arrived at the emergency department (ED) of her local hospital within 75 minutes following the alarm. Clinical trial data has demonstrated that the Guardian significantly reduces patient arrival times by up to eightfold compared to symptom-based approaches (Holmes et al. 2019[1]) and is a more accurate detector of real ACS events than symptoms alone (Gibson et al. 2019[2]). Such improvements in speed and precision may contribute to reduced myocardial injury and better patient prognoses.

At the ED, the patient remained asymptomatic. A standard 12-lead ECG yielded no evidence of STEMI, and troponin levels were not elevated.

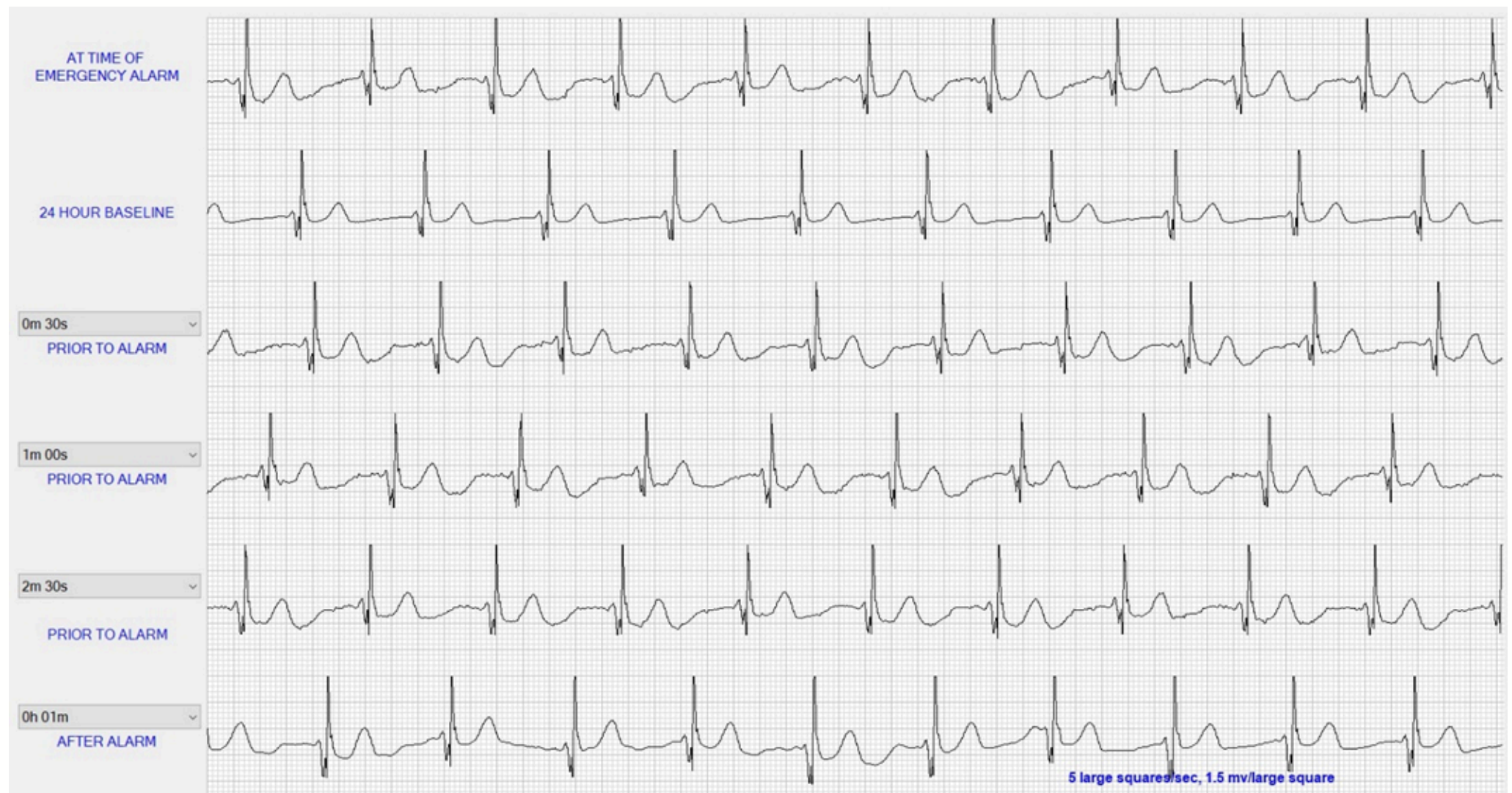
Normally, a negative ECG and troponin test with no symptoms would lead to discharge. However, due to the patient's cardiovascular history, the **Guardian System** data, and the patient's cardiologist being experienced with the capabilities of the **Guardian System**, a left heart catheterization was recommended. That procedure found a 92% LAD lesion, prompting hospital admission and the staging of a successful triple bypass procedure.

[1] Holmes DR Jr, Krucoff MW, Mullin C, et al. Implanted Monitor Alerting to Reduce Treatment Delay in Patients with Acute Coronary Syndrome Events. *J Am Coll Cardiol.* 2019;74(16):2047-2055. doi:10.1016/j.jacc.2019.07.084

[1] Gibson CM, Holmes D, Mikdadi G, et al. Implantable Cardiac Alert System for Early Recognition of ST-Segment Elevation Myocardial Infarction. *J Am Coll Cardiol.* 2019;73(15):1919-1927. doi:10.1016/j.jacc.2019.01.014

Guardian System Electrograms

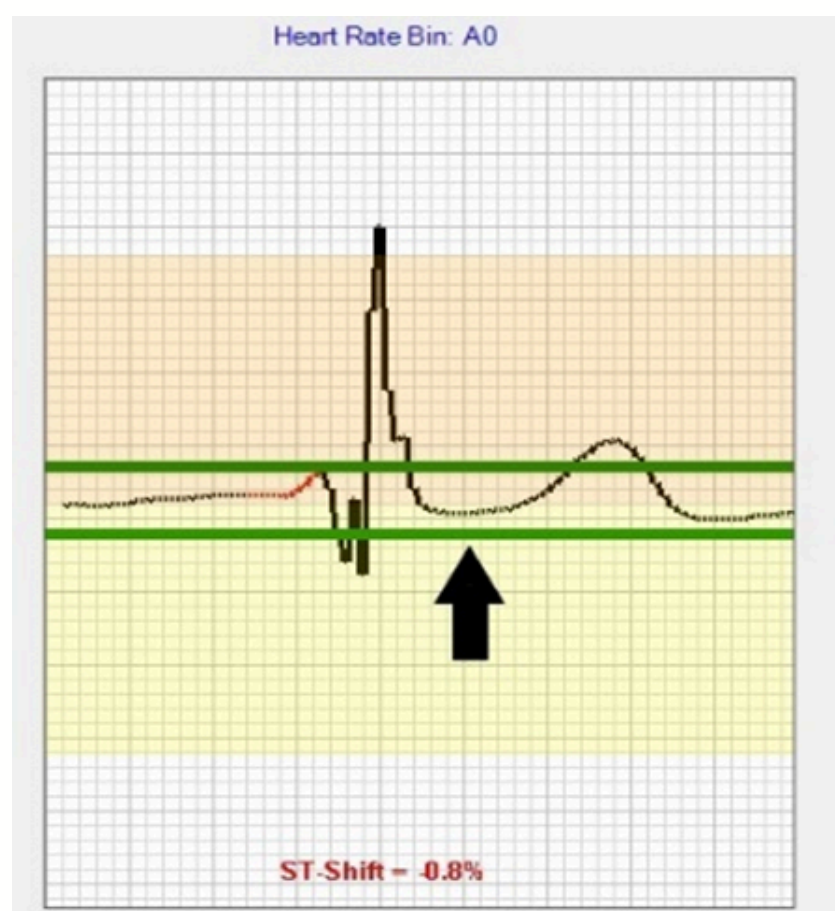
These are the actual 10-second electrograms from the **Guardian System** that triggered the Emergency Alarm. The clean, noiseless electrograms are typical of the **Guardian System**.



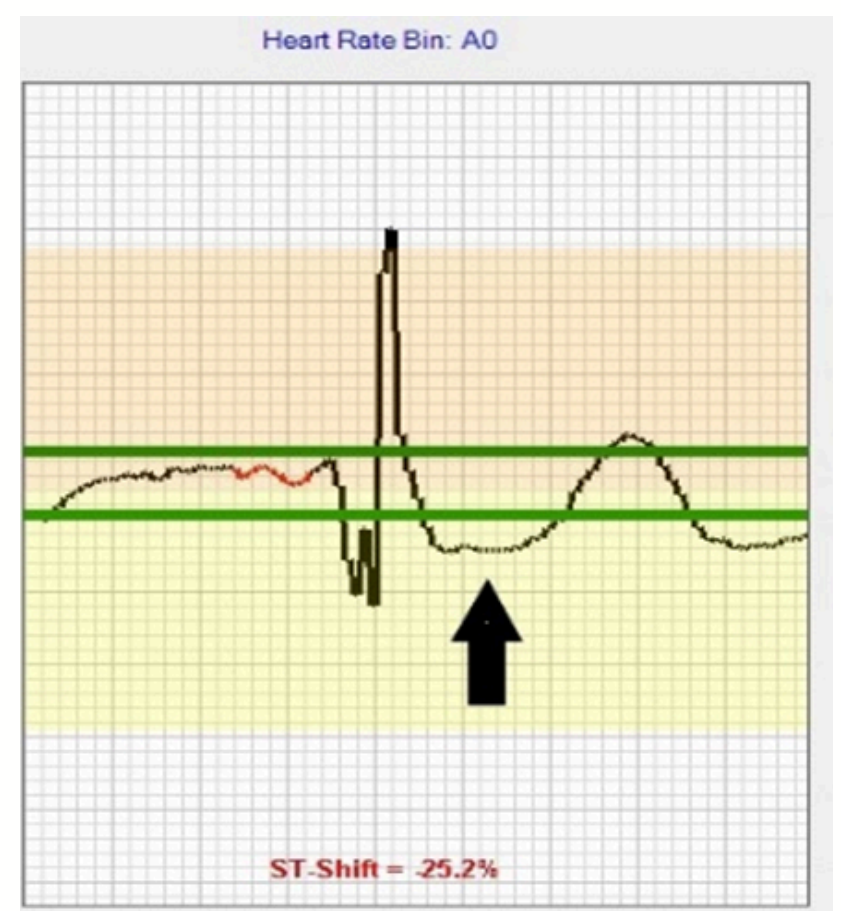
A review of the four electrograms before the Emergency Alarm shows the ST segment depression identified by the **Guardian System**, compared to a normal **24-hour Baseline**. Before declaring an alarm, the system confirms that the ST segment depression:

- **persists** for at least a minimum duration;
- is not immediately preceded by a period of elevated heart rate;
- occurs at a **non-elevated heart rate** and is **not** triggered by activity like exercise; and,
- its **magnitude** exceeds the machine learning-derived alarm threshold for that patient.

After meeting these criteria, the patient received an alarm notification via the **Guardian System's** internal and external notification features. As the example below shows, the ST segment change (black arrows) is especially clear when comparing one baseline heartbeat with one classified as abnormal; in this case, the negative alarm threshold (shown by the lower green line) was exceeded.



Normal Heartbeat



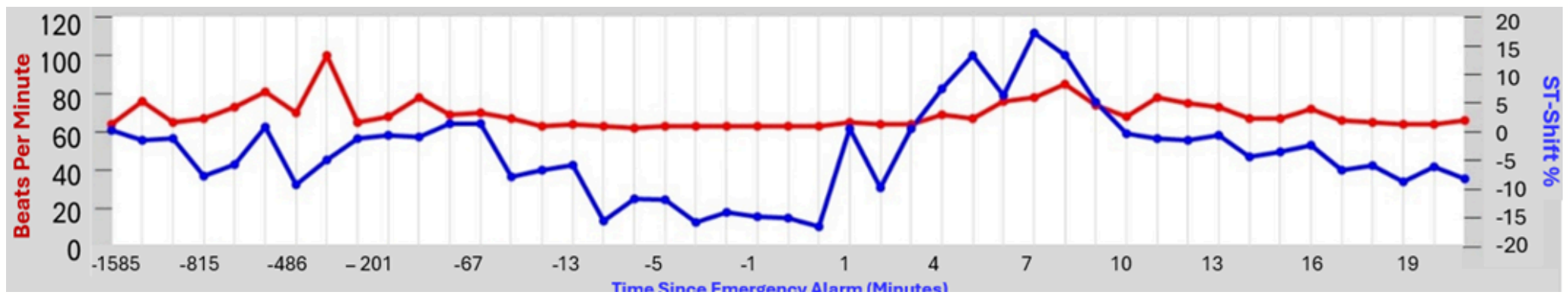
**Negative ST Shifted
Heartbeat**

Whenever an Emergency Alarm is declared, the **Guardian System** records and stores multiple 10-second electrograms for review by ED staff and the patient's cardiologist. Average heart rate and average “percent ST shift” (a proprietary measure) are calculated for each electrogram and are plotted by the **Guardian System** for efficient evaluation.

In this case, the heart rate is shown to have remained relatively constant throughout the period before and after the detected event.

The **average** negative ST shift of all the beats in the three segments (15%) exceeded the detection threshold of 11%.

This was followed by a reversal and a positive ST shift measured five to ten minutes after the alarm was triggered, which is an atypical occurrence.



Cardiac Catheterization Findings

Coronary Artery Bypass Grafts were performed on the following arteries:

1. A saphenous vein graft (SVG) from the left anterior descending coronary (LAD) artery to the left internal mammary artery (LIMA);
2. A SVG from the LAD to the left circumflex artery (LCx);
and,
3. A SVG from the left main (LM) coronary artery to the ramus intermedius coronary artery.

Significance and Technology Highlight

The **Guardian System** detected progressive ST segment depression at normal heart rates in a patient with multi-vessel CAD in the **absence of symptoms**. The **Guardian System** alerted the patient, resulting in a rapid time to door to the ED of 75 minutes. The patient was evaluated at the ED and underwent a cardiac catheterization which identified a potentially life threatening 92% occlusion of the LAD. The patient was then staged and received a successful triple bypass procedure.

Once again, the **power of intracardiac continuous ST segment monitoring** in a patient with complex CAD is evident, particularly when conventional symptoms fail to signal an active ischemic event associated with a coronary occlusion.