

ST. JUDE MEDICAL: ST MONITORING

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by
Anna Marie Kinney
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COMMITTEE MEMBERSHIP

TITLE: St. Jude Medical: ST Monitoring

AUTHOR: Anna Kinney

DATE SUBMITTED: March 2010

COMMITTEE CHAIR: Lily Laiho, BMED

COMMITTEE MEMBER: Kristen O'Halloran Cardinal, BMED

COMMITTEE MEMBER: Robert Crockett, BMED

ABSTRACT
St. Jude Medical: ST Monitoring
Anna Marie Kinney

Myocardial infarction is the leading cause of death in the western world. Time is critical when treating patients with myocardial infarction. The major problem is that many patients who are symptomatic wait too long before seeking medical attention, and some patients have no symptoms at all. In order to improve patient outcome there needs to be a better way to diagnose myocardial infarction. One solution is the continuous monitoring of the ST-Segment of the intrinsic ventricular beat morphology, called the QRS complex. There have been many studies that show that there are detectable shifts of the ST-Segment during coronary occlusion. These shifts can be detected by implanted cardiac leads, like those used with implantable cardioverter defibrillators (ICD). The St. Jude Medical algorithm called ST Monitoring was designed to continuously monitor the ST-Segments and detect when there has been a significant shift. This thesis describes the implementation of the St. Jude Medical ST Monitoring algorithm on the St. Jude Medical Unity ICD platform. The process involved working on the requirements, design, implementation, and tests in order to verify the algorithm. The project was successfully completed and received FDA approval for an IDE study in the US and CE Marking in Europe. The data collected from the patients in the IDE will give confidence that the algorithm can successfully identify ST-Segment shifts that lead to myocardial infarction. If this is shown then the ST Monitoring algorithm can be used to reliably notify patients that they are having a significant cardiac event and need to seek medical attention immediately.

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I. BACKGROUND AND CLINICAL IMPORTANCE

Myocardial infarction, commonly known as a heart attack, is one of the leading causes of mortality in the western world. Myocardial infarction occurs when the blood supply to part of the myocardium is interrupted causing some of the cardiomyocytes to die. The coronary arteries supply the myocardium with the oxygenated blood that the heart needs to function [1]. When the coronary artery flow is restricted (see Figure 1) then the cardiomyocytes will not get the oxygen they need to function, and could die. As the cardiomyocytes die, the ability of the heart to pump blood throughout the body is impaired.

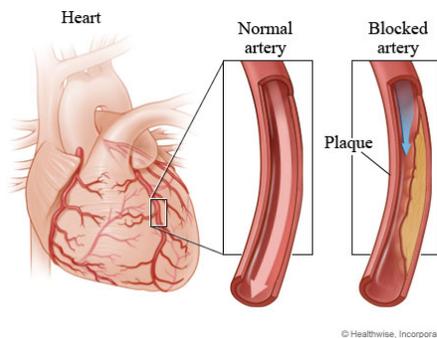


Figure 1: Coronary Artery System ^[1]

Early detection and prompt intervention of an acute myocardial infarction significantly improves the clinical outcome. The mean time from myocardial infarction symptom onset to arrival at a hospital for treatment is about 2.5 to 3 hours [2,3]. Surveys and focus groups of heart patients, family members, and the public report that they thought the presenting symptoms were less dramatic than expected. Many patients take a “wait and see” approach until they are more certain of the symptoms significance [4]. A large proportion of irreversible myocardial injury and fatal ventricular arrhythmias occur in the first several hours after closure of a coronary artery [2,3]. The longer the time between closure of the artery and the treatment lead to further myocardial necrosis and

worse clinical outcomes [3]. Treatment could include a defibrillation shock if the patient has an irregular heart arrhythmia, medication to help dissolve blood clots and open a blocked coronary artery, or a stent placement to open the blocked coronary artery. In order to improve upon the treatment of myocardial infarction there needs to be an easy and reliable way to diagnose the acute myocardial infarction.

Myocardial infarction is an acute form of myocardial ischemia. Myocardial ischemia is a disorder caused by a critical coronary artery obstruction termed atherosclerotic coronary artery disease (CAD). Atherosclerosis occurs when fatty material and plaque build up on the walls of the artery. The buildup narrows the artery and the blood flow is decreased potentially leading to myocardial infarction. Myocardial ischemia may be temporary and reversible, or permanent and irreversible leading to myocardial infarction [5]. Myocardial ischemia can be temporary when there is brief periods of coronary occlusions followed by reperfusion, possibly in situations when the coronary blockage is not significant enough during normal conditions but as demand increases, for example with exercise, the blockage could become significant until the demand returns to normal. This has been termed myocardial stunning [5]. Reversible myocardial ischemia depends mostly on the amount of time the myocardial cells have been restricted of oxygen, the shorter the amount of time the better, from seconds to minutes. The damage becomes permanent and irreversible when the blockage is severe or the flow has been compromised for longer, from minutes to hours (see Figure 2).

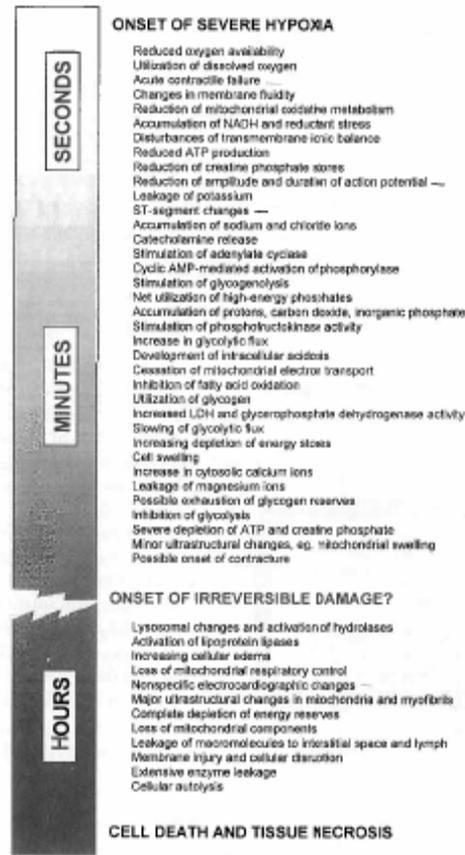


Figure 2: General timeline of changes at onset of ischemia [5]

Diagnosis of myocardial ischemia prior to a heart attack is important for optimal disease management. This year approximately 1.5 million Americans will have a heart attack resulting from myocardial ischemia, and 500,000 of those will be fatal. In one third of those patients, CAD is not diagnosed until after a heart attack occurs [6]. Treating known CAD is beneficial. Coronary artery revascularization, such as angioplasty, coronary artery bypass graft (CABG), or stent placement, and other medical therapies, such as medication, significantly reduce the morbidity and mortality rates of this disease. Therefore, early detection and diagnosis of CAD is critical.

The diagnosis of CAD is difficult because in many cases the disease is not diagnosed until after the patient has had a heart attack. Some patients with CAD

experience symptoms such as unstable angina while others have no symptoms at all. This disease occurs in a range of patients, both the young and old, women and men, and in patients with and without co-morbidities [6]. There currently is not a uniformly accepted screening method for CAD but the most common forms of testing are treadmill, or stress testing, and for patients with moderate-to-high risk for CAD a cardiac imaging study. These tests, explained later, are looking for changes in the cardiac signal.

Myocardial ischemia results in electrophysiological changes that are detectable. Within seconds of the onset of myocardial ischemia there are ventricular morphology changes, including ST segment changes, called an ST shift, which can be seen on a surface electrocardiography (EKG) [5,6,7] (See Figure 3). The ST segment is the portion of an electrocardiogram between the QRS complex (ventricular depolarization or R wave) and the beginning of the T wave (ventricular re-polarization) as seen in Figure 4.



Figure 3: Surface EKG (ECG) of morphology changes due to occlusion [7]

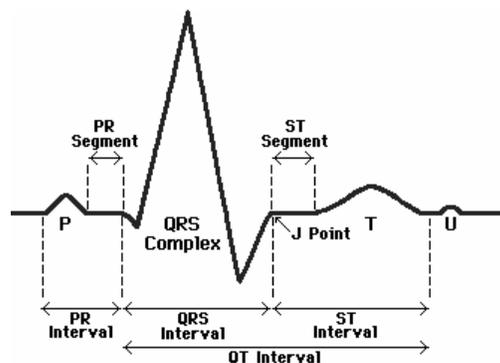


Figure 4: QRS Complex [6]

Myocardial ischemia impairs ventricular contraction and relaxation, therefore altering the ST segment. In general, the underlying cause of the ST shift is an altered ion transport across the myocardial cell membrane [5]. Measuring the ST segment deviation on the surface EKG, usually using a caliper-based technique or automated system, is the most common clinical technique for diagnosis of myocardial ischemia [7].

Treadmill tests are used on patients with symptoms or signs of CAD and patients with significant risk of CAD. Surface EKG monitoring is used during treadmill tests to see if there are any morphology changes in the beat complex, such as ST changes, during exercise when the heart requires more oxygen. This type of test will indicate if the patient, who may have no symptoms at rest, has symptoms, such as pain in the chest or other areas in the upper body or changes seen the heart monitor, when the heart is stressed.

Another method for detecting myocardial ischemia is with long-term electrocardiography recording using a Holter EKG monitor. A patient will wear the Holter EKG monitor (see Figure 5) with 3-4 electrodes placed on the body for approximately 24 hours to allow for long-term monitoring for ST segment changes. The leads are typically placed below the right and left clavicle and one on the lower chest. The placement may also depend on which coronary artery is involved. The continuous electrical signals are stored onto the device to be retrieved and analyzed by the physician later. Many holter devices now have accompanying software to help analyze the data.



Figure 5: Holter EKG Monitor from Cardio Labs ^[12]

Holter EKG monitoring can help in detecting both symptomatic and asymptomatic, or silent, myocardial ischemia and is fundamental for characterizing episodes in patients with suspected or documented CAD [6,7]. Long-term monitoring is beneficial since studies have shown that some patients, particularly with angina, experience short myocardial episodes at night or in the morning. Therefore these patients' treadmill tests are usually negative [8]. Holter EKG monitoring may reveal ischemia in about 10% of those with a negative treadmill test [9]. Holter EKG monitoring has also shown that episodes of subendocardial (occurring under the endocardial, the inner most layer of tissue, of the wall of the heart) ischemia have a typical circadian distribution with a first peak in the morning hours and a second peak in the afternoon [10]. Many studies have indicated that ischemia, even transient ischemia, on Holter EKG monitoring are among the major predictors of cardiac events in patients [6].

Practical application of long-term monitoring for ST segment deviations have been limited, due in part to the inconvenience of Holter EKG monitoring and the prevalence of false-positive ST segment deviations as a result of noise, postural changes, and artifacts [7]. Chronic ischemia monitoring would be very beneficial in documenting the reproducibility of the ischemic pattern since day-to-day episodes can be variable [6]. Also, early and reliable detection of myocardial ischemia would be clinically valuable if the result is an improvement of the time to treatment for patients [2,3,7].

Another approach to chronic monitoring of the ST segment deviations is to use intracardiac electrograms (IEGM) that are recorded by permanently implanted electrodes which are used for pacemakers and implantable cardioverter defibrillator (ICD) devices. IEGM avoid the insulating effects of the lungs and thorax due to the distance between the electrodes, giving a 5 to 10 times larger signal amplitude than a surface EKG. Noise and signal artifacts are also greatly reduced due to the lack of electrode-skin interfaces [7]. The location of the implanted electrodes is convenient, consistent, permanent, and capable of continuously monitoring of the ST segment using the IEGM. Indication for an ICD implant generally revolves around patients having or being at risk for ventricular arrhythmias and about 50% of ICD patients either have documented CAD or are at risk of developing CAD [6,7]. Several studies have shown that cardiac ischemia can be detected from IEGM of an ICD and that the sensitivity of IEGM for detection of ischemia may be superior to that of surface EKG (see Figure 6) [2,3,7]. Another advantage of using implanted cardiac rhythm management devices is the ability to correlate ST segment changes with other cardiac events, such as ventricular arrhythmias.

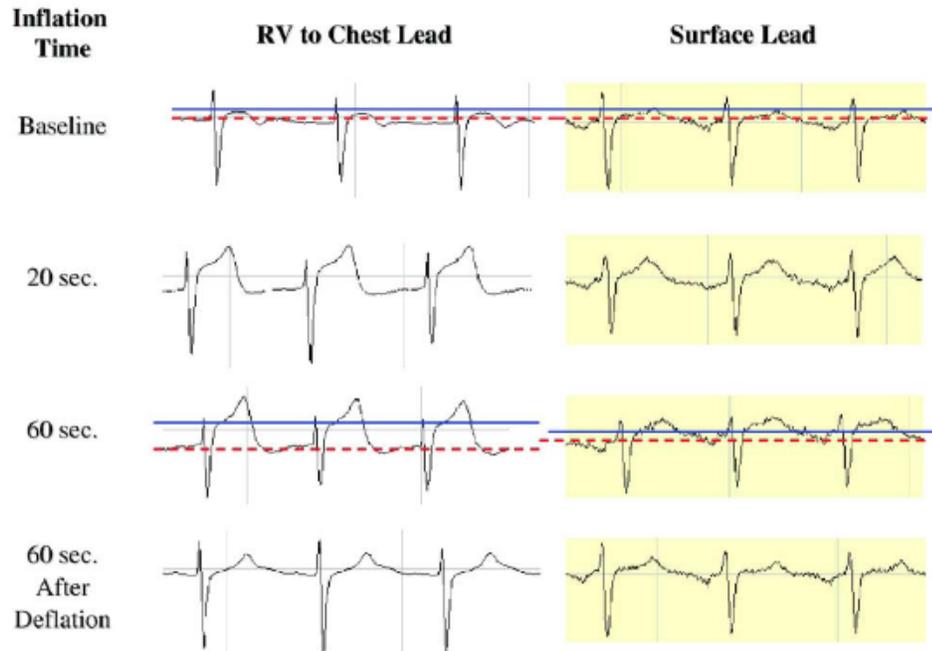


Figure 6: Comparison of IEGM and Surface EKG ^[2]

The immediate benefit of chronic ST segment monitoring is the early confirmation of an acute coronary event or acute myocardial infarction in patients who have an implanted device. A second benefit is the potential to notify patients upon detection of a significant coronary event [3,6]. This could greatly decrease the amount of time between ischemia onset and treatment. Additionally, the monitoring of the ST segment provides the possibility of early intervention that could positively affect clinical outcomes in CAD patients who have changes in their ischemia profile over the course of their disease [6].

It is for these reasons that St. Jude Medical developed the ST Monitoring algorithm on the ICD platform. The ICD platform was chosen because approximately 50% of patients with an ICD have some form of CAD [6]. St. Jude Medical collaborated with Angel Medical Systems, Inc. on the initial algorithm for ST-segment analysis for

non-paced beats. Currently, no commercial device exists that is capable of chronically monitoring cardiac signals for the recording and detection of myocardial ischemia.

An initial ST Monitoring algorithm was developed on the St. Jude Medical Epic 2 ICD platform for research and evaluation purposes only in 2006. However the Epic 2 platform, the hardware and software platform used for previous St. Jude Medical devices, is not in active production anymore. During preliminary algorithm evaluation research personnel at St. Jude Medical performed testing to characterize ST-segment changes associated with acute ischemia using data from canine tests [6]. The testing included the evaluation and recording of ST-segment changes during occlusion of various coronary locations within the heart. The canine study was designed to assess the algorithm behavior and to evaluate feature diagnostics.

A chronic pig study was also performed to evaluate the chronic performance of the detection algorithm and diagnostics. In summary, six pigs were implanted with an ICD, one week following implant two copper stents per animal were placed in various coronary vessels. At the time of the stent implant, a balloon catheter was inflated in the coronary vessels to provoke ischemic changes on the IEGM. At the termination of the study, it was determined that the study design was not optimal for this project. The pigs were too small and the ICD lead implants caused significant trauma to the heart resulting in numerous ST-T wave abnormalities [6].

Clinical studies were also performed on the initial ST Monitoring algorithm to investigate various aspects of the cardiac signal related to chronic IEGM analysis of the ST-segment changes. One study evaluated the stability of the ST-segment during daily life activities and/or ST-changes during exercise. The results from this study showed that

there is a reasonable daily range of the ST shift allowing a threshold to be set to avoid false positives. It also showed that the proposed algorithm was only appropriate for intrinsic complexes. In another study, simultaneous recordings of IEGM and surface EKG were taken during a balloon angioplasty to compare changes during balloon occlusion and subsequent re-opening of coronary vessels. The results from this study showed poor correlation between the IEGM and surface EKG most likely due to the poor contact of the lead with the myocardium. Angel Medical Systems performed a similar study which resulted in very good correlation. In this study the lead was screwed well inside the myocardium which may account for the difference [6].

With the results of the studies conducted by St. Jude Medical, the studies conducted by others, and the apparent need for such an algorithm available on a marketed device St. Jude Medical decided to implement the ST Monitoring algorithm onto the next generation devices, called the Unity platform, that are now available as the AnalyST Accel™ family of ICDs which is the focus of this thesis.

II. PROJECT OBJECTIVE

The objective of this thesis is to implement the algorithm as described by the St. Jude Medical research department in collaboration with Angel Medical Systems and described here.

The St. Jude Medical ST Monitoring algorithm is a diagnostic algorithm implemented on the ICD platform that continuously monitors the IEGM for ST shifts. The ST Monitoring algorithm is implemented on the Unity device platform which has a dedicated IEGM filtered channel in the hardware of the device with a [REDACTED] filter with sampling at [REDACTED] for use by ST Monitoring. The filter characteristics determine the amount of data from the analog signal that is retained in the digital signal where a smaller frequency retains more data and the sampling frequency digitizes more of the data. If these characteristics are not optimized the signal will not be sufficient for detecting changes in the ST portion, as shown in preliminary testing with a [REDACTED] filter [6]. The [REDACTED] filter characteristic was determined to be sufficient to analyze and detect ST shifts on the IEGM.

The vector analyzed is from the tip of the lead in the right ventricular chamber to the can of the device, RV tip-to-Can (see Figure 7). The vector is the anode and cathode of the signal that is used to obtain the IEGM signal. This vector is used because it captures most of the ventricle. Changes in the IEGM signal will be detectable no matter where the ischemic injury may be or the direction of the signal shift (see Figure 8). Transmural injury occurs on the outside of the myocardium and sub-endocardial injury occurs on the inside cavity of the myocardium.

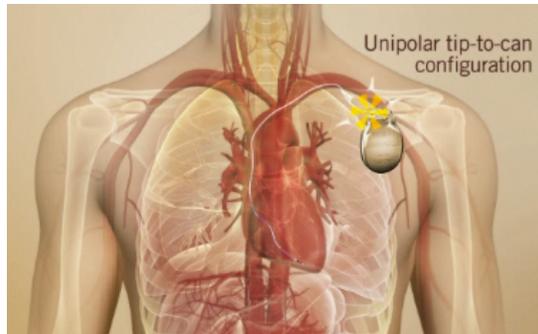


Figure 7: RV tip-to-Can Lead Configuration ^[11]

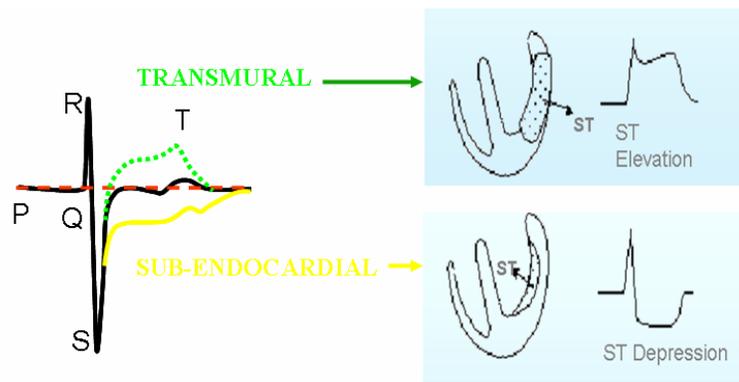


Figure 8: RV tip-to-Can IEGM vector ^[6]

Analysis of the ST-segment is done every 30 or 90 seconds by comparing the relative amplitude of the ST-segment portion to a reference window measured immediately prior to the R wave of the intracardiac signal. This relative ST-segment amplitude change is further normalized to the R peak in order to accommodate non-physiological changes in amplitude of the intracardiac signal. Such changes might occur if the sensing lead is not stable within the ventricle or if the sensing vector changes due to variations of the patient's body position.

An intrinsic ventricular cardiac signal is monitored every 30 or 90 seconds for changes in the ST-segment. A set of cardiac beats consists of no more than 15 ventricular complexes. A ventricular complex is a ventricular event, either a ventricular paced beat

or a ventricular intrinsic beat, called QRS complex or R wave. The criteria of 6 out of 8 beats are used to determine if a ST-shift occurs within the set being analyzed. For example, if 6 beats are measure as “shifted” before three “non-shifted” beats are analyzed the set is classified as “shifted”. The algorithm will wait until the next 30 or 90 second interval and re-evaluate the ventricular complexes. If three consecutive “shifted” sets are detected, the algorithm will consider this a ST episode. When sets are classified as “non-shifted” the algorithm waits 90 seconds between analyzing sets. Once a set is classified as “shifted” the algorithm will analyze a set every 30 seconds.

There are two levels of ST episodes that can be detected, minor ST episodes and major ST episodes, based on the degree of ST-shift. The distinction is made based on the ST-segment shift threshold which can be set independently as either a positive or negative shift. The threshold is a predefined value that the ST-shift value needs to exceed to be considered either a minor shift or a major shift. This will be explained in more detail later. There is also another type of minor ST episode called a persistent minor ST episode. If a minor ST episode is ongoing, meaning the ST-shift is greater then the minor threshold, for a period of time that exceeds a predefined “persistence time” the detection of a persistent minor ST episode will be triggered. An ST episode is terminated when two consecutive “non-shifted” sets occur.

ST-Shifts can be determined because the current ST-segment being evaluated is compared to a baseline, non-shifted ST-segment. The algorithm performs baseline extraction once every six hours, called a time segment. A baseline set is a qualified reference of the patient’s normal, non-shifted rhythm. This qualified reference is used to determine how the patient’s current ST-Shift deviates from the non-shifted rhythm.

Baseline sets are averaged over the last three days and then are used to classify intervals in the same time segment, 24 hours later. If the signal shows a ST-shift when a baseline is attempted then the baseline can not be extracted at this time and the algorithm will need to wait until there is no ST-shift.

As part of the ST Monitoring algorithm there are numerous diagnostics stored that will be expanded on in the next section. These diagnostics have been deemed important by the voice of customer interviews. The ST Monitoring algorithm stores other diagnostics that are being used internally by the Clinical and Systems Engineering department to evaluate the performance of the algorithm that will also be described on in the next section.

The objective is to take the initial ST Monitoring algorithm that was for evaluation purposes that was described above and implement it on commercially available St. Jude Medical device.

III. DESIGN AND IMPLEMENTATION

As part of the St. Jude Medical firmware development team my role for the ST Monitoring algorithm was to provide my knowledge on the Unity device platform for implementation. The process of design and development included requirements, design, implementation, and verification testing.

The ST Monitoring, or STM feature was broken up into sub-features. ST Monitoring Controller (STMC) initializes the algorithm and controls when analysis will be performed. ST Monitoring Analysis (STMA) does the complex analysis and determines when a set is complete. ST Monitoring Baseline Extraction (STMB) extracts the non-shifted baseline set. ST Episode Detection (STME) determines the entry/exit criteria for a ST episode. ST Monitoring Stored IEGM (STMS) collects the IEGM signal for diagnostics. There are also diagnostic for ST-Segment data, Baseline data, and ST Episode data.

The work in this thesis focuses on the design and implementation of the ST Monitoring feature as well as the process in order to implement the feature successfully. As a development engineer my portion of the project was to implement one of the ST Monitoring sub features, specifically ST Monitoring Controller, as well as participating in all other aspects of the feature implementation, as described here. Working on this feature required helping with requirements and verification testing. The requirements are used to fully specify how the software works. It was important that all engineers that work on a feature have the same understanding of the requirements. An initial part of developing a feature was to work with the requirements engineer to ensure the state of the requirements was satisfactory. The requirements specify all parameters and algorithm

behavior. An example of a requirement that specifies a parameter is for the ST Monitoring Mode. An example of a behavioral requirement is the definition of what a Good Interval is for ST Monitoring (see Figure 9).

43054	STM	ST Monitoring Mode Range: ON or OFF Resolution: N/A Sync Mode: non-Cardiosynchronous
43915	STM	On an STM Ventricular Tachy Event, when <ul style="list-style-type: none"> • ST Monitoring Status \neq OFF, and • current Ventricular Tachy Interval \leq Heart Rate Zone 1 Lower Bound, and • current Ventricular Tachy interval \geq Heart Rate Zone 4 Upper Bound, and • current Ventricular Tachy Interval \geq 80% of the Pre-Set Interval Average the device software shall consider the Good Interval Criteria as met for the current interval.

Figure 9: Requirement Example

Once the requirements were complete then the firmware development engineer analyzed the requirements and designed how the feature works. The firmware development engineer decided how the implementation would flow and negotiated the interfaces between their feature and other features in the system. Once the design was complete the firmware development engineer implemented the design in C code. Firmware development engineers also test their code in two ways. Unit testing is a code base test that ensures the feature code executes as expected, and bench testing ensures the feature code runs correctly with the rest of the system on the hardware target. The amount of bench testing was determined by the firmware development engineering and can be simple manual test or tests developed on a framework that allows for automation. For the STM feature code the framework that allowed for automation testing was used. These test cases interfaced with the device and other test tools, such as a heart simulator, to generate known scenarios so that the device response could be determined to be correct.

Another part of working on a feature was to help the verification engineer write test scenarios. The verification engineer also had to fully understand the requirements in order to test the feature to make sure the implementation meets the requirements. It was important for the firmware development engineer to work with the verification engineer throughout the verification process. The verification engineer would find bugs, or errors, during testing which would need to be analyzed so having knowledge of how a test case was designed was helpful to the firmware development engineer when trying to determine what caused the error. The firmware development engineer also supports the code through all future projects.

All firmware development engineers were key reviewers for the other sub-features which required knowledge of how the sub-feature worked in order to provide feedback and ensure it was implemented correctly. During the development process there were many reviews that were performed. Firmware development engineers were involved in these reviews for other features. Such reviews include requirements, design, implementation, and verification reviews. It was also important to have knowledge of other features so that if the original firmware development engineer was not available, there are others that know how the feature works. This was particularly true for the ST Monitoring project because the original development engineers for the ST Monitoring Baseline Extraction, ST Episode Detection, and ST Monitoring Stored IEGM sub-features left the company before the project was completed.

In the next sections the design for each sub-feature is described. These designs were then implemented in software. The software matches the design exactly.

III.1 ST MONITORING CONTROLLER

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III.2 ST MONITORING ANALYSIS

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III.3 ST MONITORING BASELINE EXTRACTION

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III.4 ST MONITORING EPISODE DETECTION

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III.5 ST MONITORING STORED INTRACARDIAC ELECTROGRAMS

ST Monitoring Stored IEGM (STMS) is a sub-feature of ST Monitoring. It provides IEGM data, markers and timestamps to be retrieved and displayed on the external instrument so that the clinician can examine the ST Segment variations. STMS stores IEGM data for baseline sets and specific sets when an ST Episode occurs. The four most recent successful baseline sets and the four most recent unsuccessful baseline sets are stored. When an ST Episode is detected the IEGM data of the baseline set that was referenced by STMA to determine the ST Shift is saved as well as the entry set and the set that contains the maximum ST Shift during the ST Episode.

III.6 ST MONITORING STORED DIAGNOSTICS

The IEGM data is part of the diagnostics that is gathered by the ST Monitoring algorithm. There are many diagnostics the ST Monitoring algorithm collects. These diagnostics are intended to help the physician make informed decisions as a patient's disease progresses. The ST Monitoring algorithm collects data on the ST Deviations that are analyzed. Every single ST Deviation the algorithm calculates is stored into a daily histogram which consists of bins with a specified ST Deviation range for each heart rate zone for each day. After the ST Deviation is determined for a good beat the histogram bin that corresponds to the day, heart rate zone, and ST Deviation value for this beat is incremented by one. ST Deviation from the most recent seven days is also stored (see Figure 10).

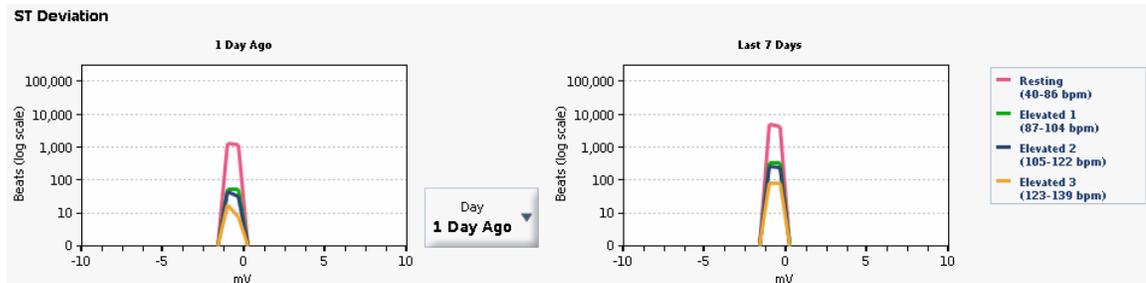


Figure 10: ST Deviation Histograms

At the end of each 24 hour period, or day, the ST Deviation Daily Trend is updated. The daily trend holds the minimum, maximum, and mode (most frequent) ST Deviation from the current day for each heart rate zone. Again, there are seven days of trend data stored. Similarly there is a ST Deviation Weekly Trend that holds the minimum, maximum, and mode ST Deviations for each heart rate zone for the week. The weekly trend holds up to six months of data (see Figure 11).

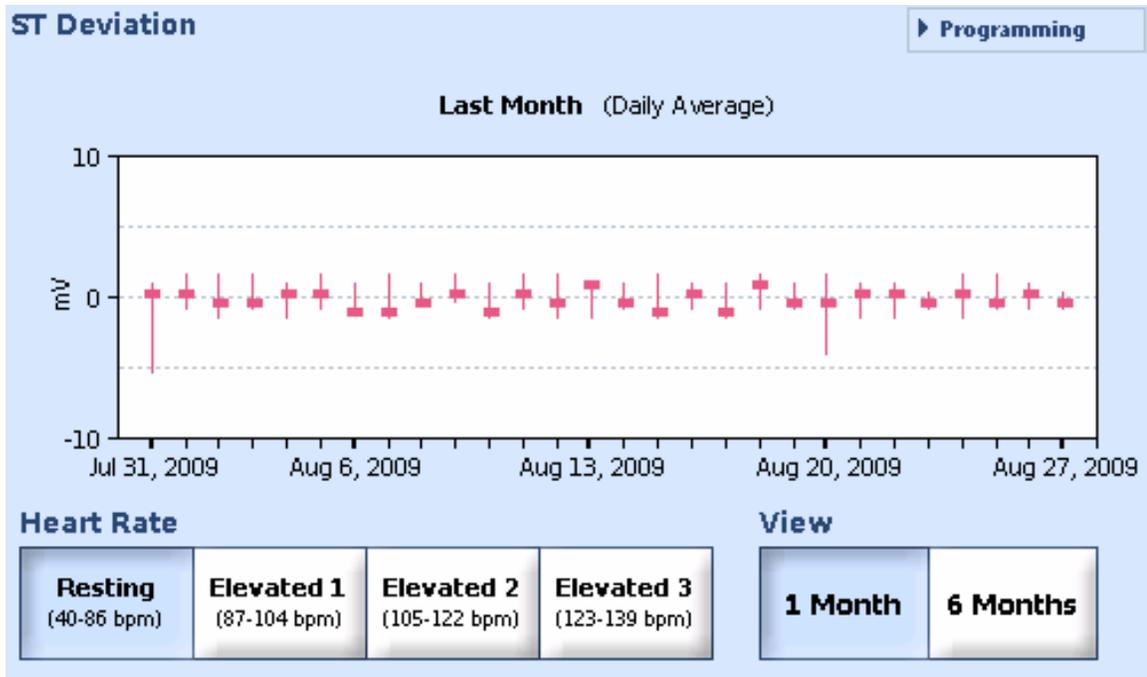


Figure 11: ST Deviation Weekly Trend

The ST Monitoring algorithm also stored diagnostics associated with the baseline sets that are extracted. Some of these diagnostics are for the clinician to see and some are for research purposes only and are not displayed to the clinician. The baseline diagnostics that are available on the display are associated with the four baselines, one for each six hour time segment, which include the IEGM data as well as the average ST Deviation and average R peak for the baseline set (see Figure 12). The research diagnostics that are collected by the device are the four most recent unsuccessful baseline diagnostic, the unsuccessful baseline failure reason counters, the raw baseline log, the Quick-Initialization counter, and the paced set diagnostics. The unsuccessful baseline diagnostic includes the IEGM data and failure reason for the most recent four unsuccessful baseline extractions. The reasons for failure listed in the unsuccessful baseline diagnostic also have counters. The device keeps track of how many times a baseline fails for one of four

reasons, excess shift, high heart rate zone, saturated R waves, and non-classified beats. Baseline extraction could fail due to the ST Shift being too high or the heart rate of the set is too high. Also, if the R wave amplitude value is too high or too low the baseline extraction will fail. The last reason occurs when there are too many bad beats in a set, due to PVC beats or paced beats.

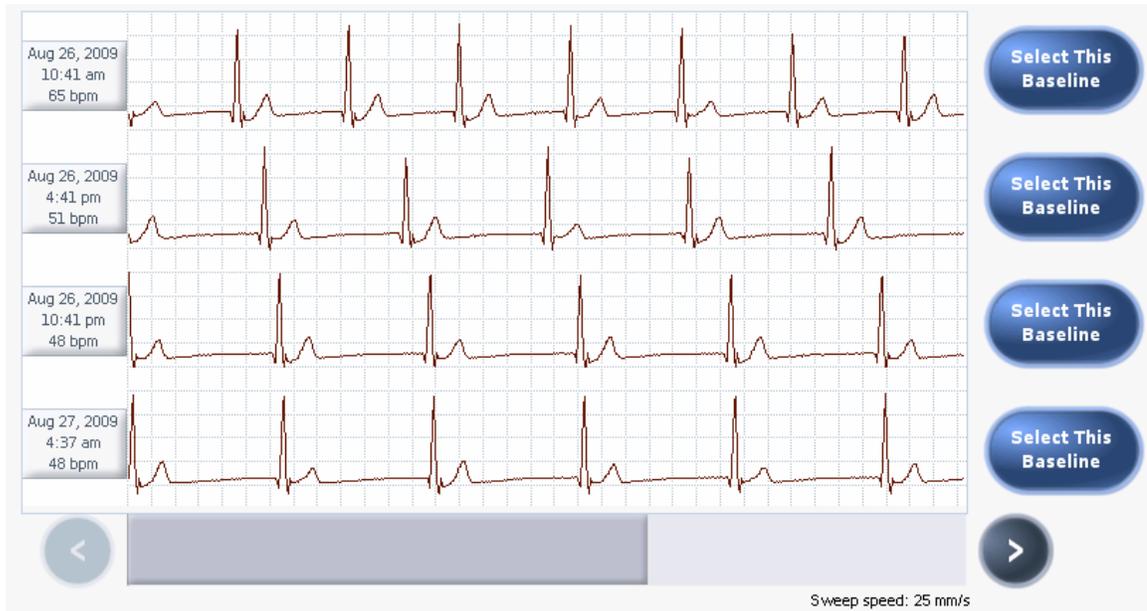


Figure 12: ST Baseline IEGM data

Another diagnostic associated with baselines is the raw baseline log. The result of baseline extraction for each time segment for the last 100 days is stored. When a baseline set is extracted for a segment the timestamp, ST Deviation, and R peak of the successful baseline is stored. If baseline extraction is unsuccessful for a segment the timestamp, ST Deviation, and R peak are stored for the set that was the first attempt of the segment. If baseline extraction was not allowed for a segment, possibly due to an interaction or ST Episode ongoing, then the log is updated with a timestamp and values that indicate there was no baseline extraction attempted.

The last of the research diagnostics are the Quick-Initialization counter and the paced set diagnostics. The Quick-Initialization counter is updated every time Quick-Initialization occurs. The paced set diagnostics is a 100 day log. Each entry represents a day and holds the total number of sets analyzed and the number of those sets that included at least one paced event.

The ST Monitoring algorithm also stores diagnostics associated with ST Episodes. There are three ST Episode logs, Major Episode, Persistent Minor Episode, and Minor Episode. Each log holds the same type of information (see Figure 13). There is a counter for the total number of ST Episodes for that type. There is a timestamp for when the ST Episode was entered and exited, which is used to calculate the duration of the ST Episode. The interval average of the rhythm prior to the entry set and the average ST Shift of the entry set are recorded. The average R peak of the reference baseline set that was used to determine the ST Shift is recorded. The interval average of the rhythm prior to the set with the max ST Shift and the average ST Shift of the set with the max ST Shift are recorded. Lastly the reason for the episode to exit is recorded, including non-detect sets detected, non-classified sets detected, critical interaction terminated, episode exceeded three days, or Minor/Persistent Minor exited due to Major ST Episode detected. As mentioned before, each ST Episode has three sets of IEGM data associated with it, the reference baseline data, the entry set data, and the max ST Shift set data (see Figure 14).

EGM	Date	Time	Heart Rate at Onset bpm	Max ST Shift % (HR bpm)	Duration M:S
	Aug 18, 2009	5:47 am	70	-32 (70)	37:56
	Aug 10, 2009	4:27 pm	70	-23 (70)	44:32
	Jul 17, 2009	10:20 am	70	-41 (70)	36:02
	Jul 15, 2009	9:35 pm	70	-25 (70)	31:02
	Jun 28, 2009	8:37 am	98	-84 (114)	30:50

11 Total

EGMs appear for the 4 most recent episodes and the first episode collected since last cleared.

Figure 13: ST Episode Log

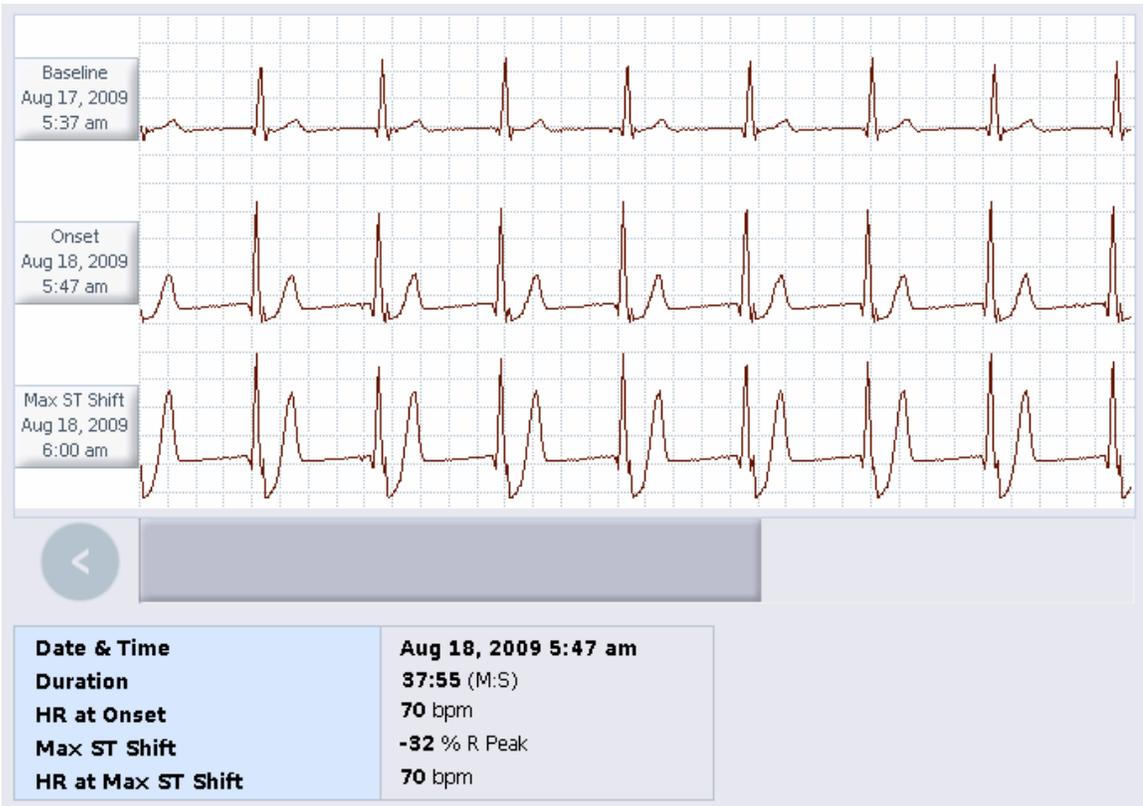


Figure 14: ST Episode Detection

IV. RESULTS

During feature implementation each development engineer, including myself, was responsible for testing their feature. This included input/output unit testing run in the development environment and bench testing run on the hardware target. Running these tests gives the development team a chance to find and fix problems before formal verification tests are done by the Verification test engineers. All unit testing and bench tests must have passing results before the feature can be considered complete. The ST Monitoring algorithm successfully passed all unit and bench testing. The unit test concept is to execute every single line of code with known inputs to ensure that the output from the code is correct. The granularity of the code tested can vary from one single function to a flow of functions. The purpose is to ensure that the code executed as development engineer expected. Examples of unit tests for the STM feature are checking that when the program parameter for ST Monitoring Mode (as seen in Figure 9) is set to ON and the programming function is called, that the correct state is entered, see

APPENDIX B for this example. The feature is required to have every single line of code covered by at least one unit tests, i.e. have 100% code coverage, and all unit tests need to pass (see

APPENDIX C for examples of the output). The other, less formal form of testing was bench testing. The amount of bench testing done was up to the development engineer, as well as the method of testing. For STMA, STMB, and STMC automated tests were developed which allowed the same tests to be run at any time. These bench tests have a similar concept to unit tests where the tests start with a known input then the feature is ran with a known scenario and the output is tested. Most of the bench tests revolve around a known cardiac event sequence, for example (see

APPENDIX D) the R wave amplitude value that is known is ran through the gain algorithm to test that the correct gain setting is selected. Another example would be the R wave with a known ST-shift is the input to the episode detection algorithm to test that the ST episode is entered correctly.

Once the firmware development team had confidence that the algorithm was working correctly the other teams executed their own tests on the algorithm. The ST Monitoring algorithm was verified against the requirement specification to prove that the algorithm ran as specified by the Verification team. Another level of testing was done by the Clinical and System team. The clinical and system engineers ran tests on the whole system, the device plus the external instrument, to ensure that all diagnostics collected by the device were displayed correctly to the clinician. The system engineers also do animal testing to see how the algorithm handles real data. The testing done by the other teams are beyond the scope of this thesis, but the ST Monitoring algorithm needed to pass all levels of testing, unit, bench, verification, and clinical and system testing to be considered complete. All levels of testing resulted in passing marks for the algorithm and the device was sent to the Food and Drug Administration (FDA) and European Union for approval for human use. The ST Monitoring algorithm is available on St. Jude Medical devices called AnalyST. The AnalyST device has been approved by the FDA for an Investigational Device Exemption (IDE) study, which is still being developed by the System and Clinical team, and has been given the CE marking for use in Europe.

V. DISCUSSION

Since the device has received approval for human use St. Jude Medical is collecting all the diagnostic data the device is storing to support the concept that the ST Monitoring algorithm can successfully identify when an ischemic event is occurring. There has been extensive research done to show that ST-Segment deviations can be detected by an ICD type device. The AnalyST device will be the first ICD device in use that will attempt to characterize ST-Segment deviations and determine when a patient is having an ischemic episode. Also, since the AnalyST device is an ICD the diagnostics collected by the ST Monitoring algorithm as well as other algorithms will be able to correlate ST Episodes with other cardiac events, such as Ventricular Tachyarrhythmia episodes.

The AnalyST device has a patient notification system that can alert the patient when critical events in the device occur. These alerts inform the patient to seek medical attention immediately by vibrating the device. The ST Monitoring algorithm has a similar alert for when a Major ST Episode is detected. This feature is currently 'locked out' and is not available. It was implemented so that as clinical confidence grows that the algorithm is capable of detecting ST-Segment deviations that are critical cardiac events, then the patient notification for these events can be 'turned on'. This will then allow patients an opportunity to seek medical attention prior to an ischemic myocardial infarction.

VI. CONCLUSION AND FUTURE WORK

The ST Monitoring algorithm available on the AnalyST device is the first ICD device available in the market place that does continuous ST-Segment monitoring. The ST Monitoring algorithm was successfully implemented on the Unity device platform. It received FDA approval for an IDE study and the CE Marking for use in Europe. The diagnostics stored by the devices in use will be collected and analyzed by the Clinical and System Engineering department to determine the accuracy and effectiveness of the algorithm.

The ST Monitoring algorithm was originally developed for ICD devices. There is work being done by St. Jude Medical that will also include the ST Monitoring algorithm on pacemaker devices. This will allow more data to be collected to support the IDE study. Although pacemaker patients may not have as high a risk for myocardial infarction, they can have or can develop CAD. Having the ST Monitoring algorithm available for these patients will help their physicians manage their disease progression.

As more data becomes available the current high level algorithm design will be evaluated to see what is working and what may not be working. In the future the algorithm may be optimized.

The ST Monitoring algorithm should be a great asset to the features available on St. Jude Medical devices. Such innovative technologies provide St. Jude Medical with the opportunity to present itself as a market leader for patient care. Algorithms like ST Monitoring also vastly improve individual patient care by providing an early warning system that something is wrong. This would allow patients to seek medical treatment early so intervention will likely be more successful and less costly.

VII. REFERENCES

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VIII. APPENDIX A: Gain Selection

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IX. APPENDIX B: Unit Test

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X. APPENDIX C: Code Coverage Report

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XI. APPENDIX D: Bench Test

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