

Technical Memo – S-ICD System Algorithm Overview

DN-12345

Revision: D

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# Cameron Health S-ICD System

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## Algorithm Overview

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## 1.0 System Description

The Model 1010 SQ-RX pulse generator is a subcutaneous implantable defibrillator that provides life-sustaining therapy to patients experiencing ventricular arrhythmias. The SQ-RX senses and delivers therapy via the implanted Model 3010 Q-TRAK subcutaneous electrode.

### 1.1 The Cameron Health Sensing System

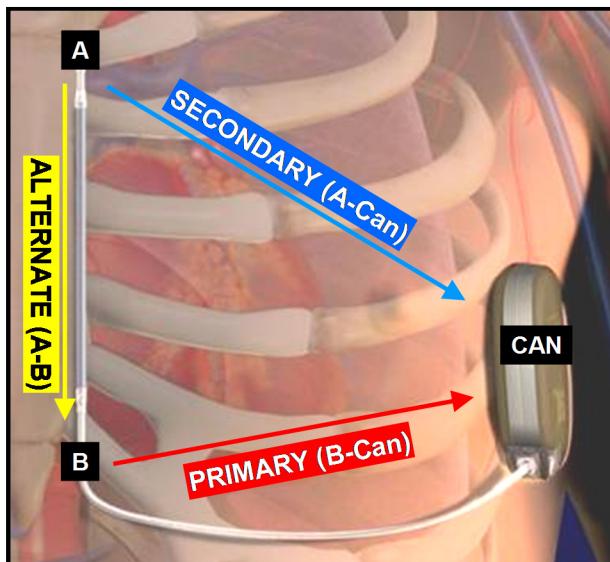


Figure 1: S-ICD System Sense Vectors

The SQ-RX system incorporates three possible sensing vectors: (1) A-Can, (2) B-Can, and (3) A-B (Figure 1: S-ICD System Sense Vectors).

The three vectors are identified as follows from the S-ICD Programmer:

- Primary: B-Can
- Secondary: A-Can
- Alternate: A-B

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## 2.0 Screening Tool

Once a physician identifies a patient for ICD therapy, a Cameron Health provided Screening Tool allows him/her to determine if that patient is a candidate for the S-ICD system. The Screening Tool is easy to use and clearly identifies patients with acceptable sensing characteristics.

Instructions included with the Screening Tool direct the clinician to collect surface ECG signals representing the three subcutaneous S-ICD vectors. These vectors are then analyzed with the Screening Tool to determine if at least one sensing vector is acceptable for subcutaneous sensing. If so, the patient is considered a valid candidate for implantation of the S-ICD System.

The Screening Tool provides a series of profiles (Figure 2: Cameron Health Screening Tool) that are used to test the patient's subcutaneous equivalent signal.

Instructions are provided to determine the correct Screening Tool profile to be used for the analysis.

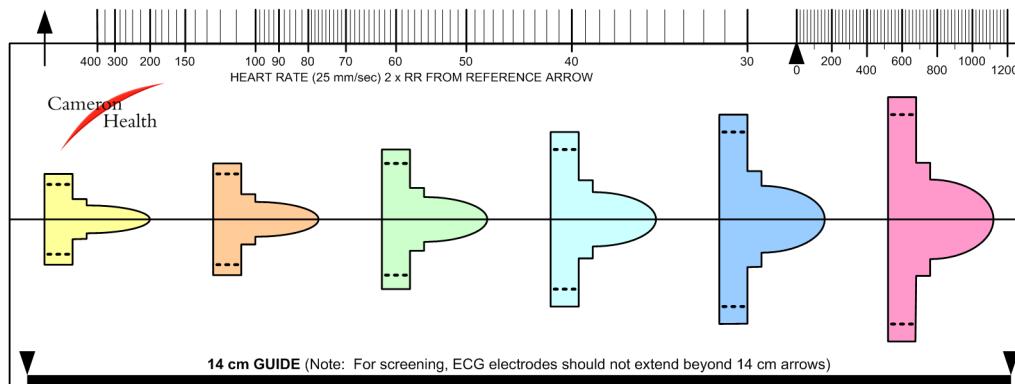


Figure 2: Cameron Health Screening Tool

The Screening Tool emulates some of the detection profile characteristics of the S-ICD System and provides a method to determine the acceptability of a patient's ECG for S-ICD sensing. The Screening Tool can be superimposed upon a single QRS complex to determine if that complex is acceptable for sensing:

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**PASS:** If the QRS complex and trailing T-wave are completely contained within the boundaries of the Screening Tool profile, the QRS complex is deemed acceptable.

**FAIL:** If any portion of the QRS complex or trailing T-wave fall outside of the Screening Tool profile, the QRS complex is deemed unacceptable.

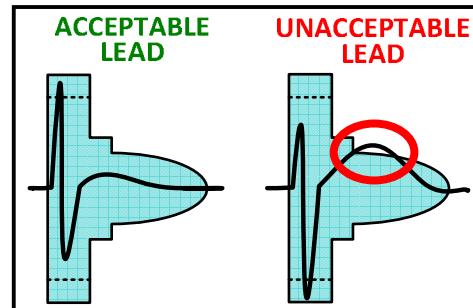


Figure 3: Screening Tool QRS evaluation

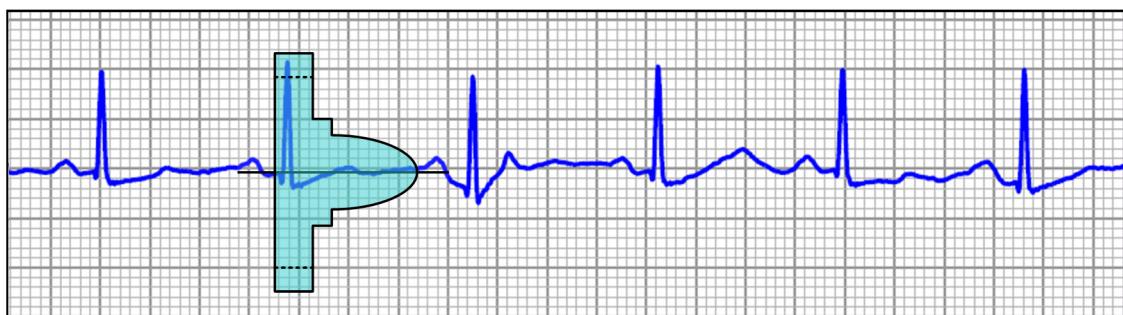


Figure 4: Screening Tool evaluation of sense vector

A surface ECG lead (sense vector) should be deemed acceptable only if all of the following conditions are met:

- All tested QRS complexes and morphologies from the surface ECG lead (sense vector) must pass the QRS evaluation.
- The morphology of the intrinsic/paced QRS complex is stable across postures. No significant change to the QRS complex is noted as a result of postural changes.
- The surface ECG lead (sense vector) must be deemed acceptable in all tested postures.

A patient is considered suitable for implant of the S-ICD System if at least one surface ECG lead (sense vector) is acceptable for all tested postures.

**Note:** Special circumstances may present in which the physician elects to proceed with the implantation of the S-ICD System despite failing the screening process. In this case, careful attention should be applied to the device setup process of the S-ICD System as the risk of poor sensing is increased.

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## 3.0 Sensing Setup

Prior to the commencement of sensing and detection of normal sinus rhythm (NSR) and/or arrhythmic events, sensing setup must be performed. Once implanted, the Automatic Setup process is used to select one of the available sensing vector configurations. In addition, the Automatic Setup process initiates the Reference ECG process in order to store the unique morphology of the patient's NSR. This Reference ECG is used by the algorithm during both the Certification process as well as the arrhythmia Classification process.

In some cases, the Automatic Setup process cannot be used for sensing setup. In these cases, the Manual Setup process can be used to select a sensing configuration.

### 3.1 Automatic Setup

The Automatic Setup process is designed to automatically select the best sensing vector for the system. The process invokes the Vector Selection algorithm which measures critical components of the S-ECG signal and determines the best vector through analysis of signals recorded through these components. The algorithm is intended to balance QRS amplitude, QRS:NOISE ratio and QT interval in order to select the desired sensing vector and gain while minimizing the likelihood of double detection (DD).

#### **QRS amplitude**

The QRS amplitude refers to the measured peak amplitude of the QRS signal in mV. The amplitude of the QRS is registered but not reported. This amplitude is required in order to determine the QRS:NOISE ratio. The QRS amplitude is also used to select the correct sensing gain ( $x_1$ ,  $x_2$ ).

#### **QRS: NOISE ratio**

The QRS:NOISE ratio is calculated by dividing the QRS amplitude by the NOISE amplitude. NOISE will most often refer to the amplitude of the T-wave, but may represent other subcutaneous ECG (S-ECG) artifact. Two or more sense vectors may exhibit similar QRS amplitudes; however, they may demonstrate very different QRS:NOISE ratios (Figure 5: QRS:NOISE ratio examples). The Vector Selection algorithm therefore favors a more desirable QRS:NOISE ratio when selecting a vector.

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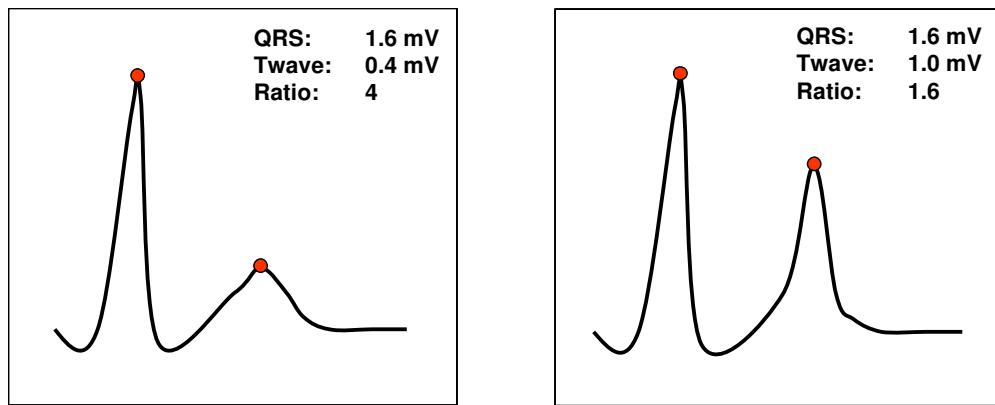


Figure 5: QRS:NOISE ratio examples

### QT Interval

Vector Selection also measures the interval between QRS and T-wave detections. In order to reduce the likelihood of double detecting a cardiac cycle, it is desired to “hide” the T-wave within the portion of the detection profile following a QRS detection; therefore, the Vector Selection algorithm favors vectors with T-waves peaks measured to be within the desired interval range (Figure 6: QT interval preference).

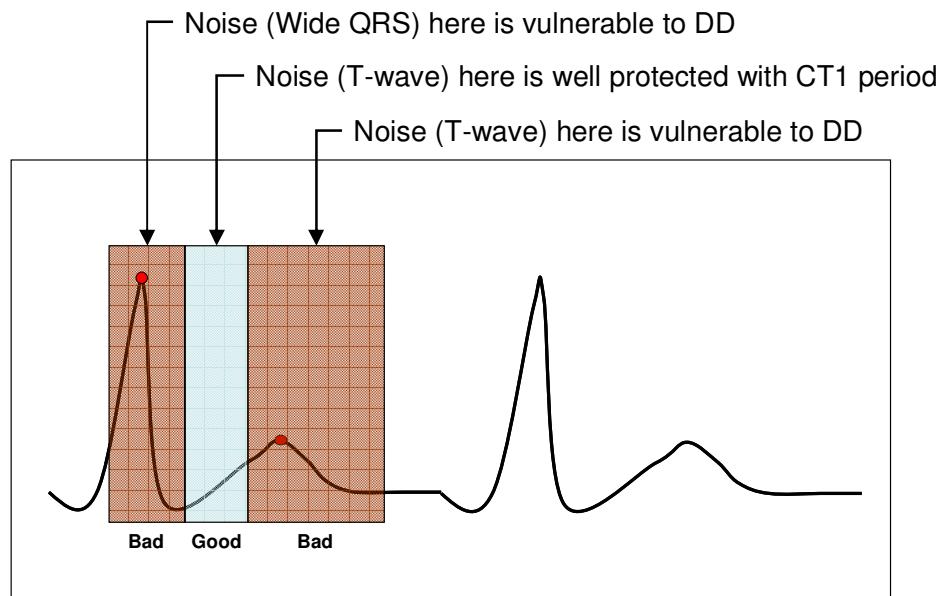


Figure 6: QT interval preference to avoid double detection (DD)

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**3.1.1 Vector Selection operation**

During Vector Selection, each vector is analyzed in order to identify the preferred vector for sensing. A maximum total data collection and analysis timeout of 90 seconds per vector is used. If a timeout is reached, the next vector is selected and analysis continues. Vector Selection is designed to analyze the patient's S-ECG signal while in one posture (supine).

**Heart Rate:**

During the Automatic Setup process, the heart rate must be confirmed to be lower than 130 bpm.

Via the Programmer, the user is prompted with the following screen prior to initializing Vector Selection during the Automatic Setup process (Figure 7: Vector Selection confirmation screening during Auto Setup):

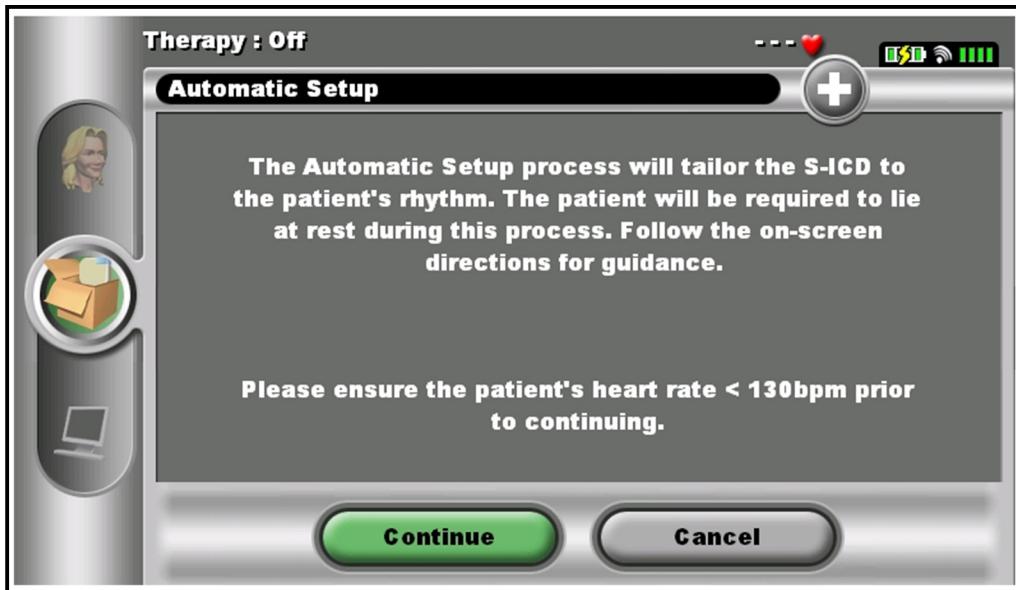


Figure 7: Vector Selection confirmation screening during Auto Setup

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### 3.2 Sense Vector Optimization

The Sense Vector Optimization algorithm is part of the Automatic Setup process and is designed to incorporate the effect of posture into the Vector Selection algorithm.

Vector Selection is designed to evaluate all three sense vectors collected with the patient in a supine posture. Sense Vector Optimization is designed to incorporate a second posture (sitting or standing) into the Automatic Setup process.

Following the Vector Selection operation in the supine posture, the programmer prompts the user to move the patient into a seated or standing posture (Figure 8: Sense Vector Optimization). During the implant procedure, it is expected that the second posture is unattainable; therefore the user may opt to “skip” the PASS assessment.

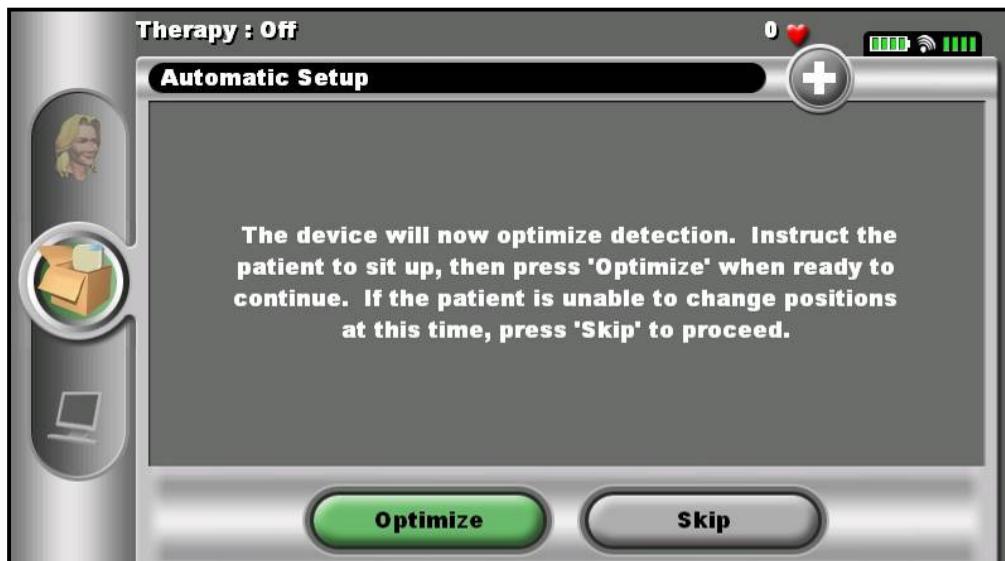


Figure 8: Sense Vector Optimization

When the user confirms the posture movement is complete, the Vector Selection algorithm again assesses the three sense vectors, this time collecting new data from the current posture.

The Sense Vector Optimization algorithm is designed to compare the Vector Selection results from both postures. Sense Vector Optimization prefers vectors with similar sensing qualities across postures. If one vector demonstrates largely different sensing qualities between postures, a vector that demonstrates less desirable single-posture results coupled with similar results across both postures may be selected.

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### 3.3 Reference ECG Acquisition (Template Formation)

Reference ECG acquisition occurs at the end the Automatic Setup and Manual Setup procedures. The Reference ECG process stores the morphology of the patient's NSR for the vector identified during the Vector Selection process.

The Reference ECG Acquisition algorithm analyzes the rhythm to determine if a stable NSR morphology exists. If so, a Reference ECG is created and stored for future use.

In order to form a Reference ECG, the algorithm first determines the dominant polarity of the noted signal. If a dominant polarity is not noted, a polarity is automatically selected. This polarity is used for alignment purposes as NSR beats are compared with each other.

Once an alignment polarity is determined and the QRS width is measured, subsequent beats are analyzed to ensure a stable rhythm is noted with little beat-to-beat morphology change. If a stable morphology is noted, the Reference ECG is created and stored.

The Reference ECG Acquisition process usually completes within 10 detections; however, if a stable rhythm cannot be found within one minute, the user is informed and asked to repeat the process when a stable rhythm can be achieved.

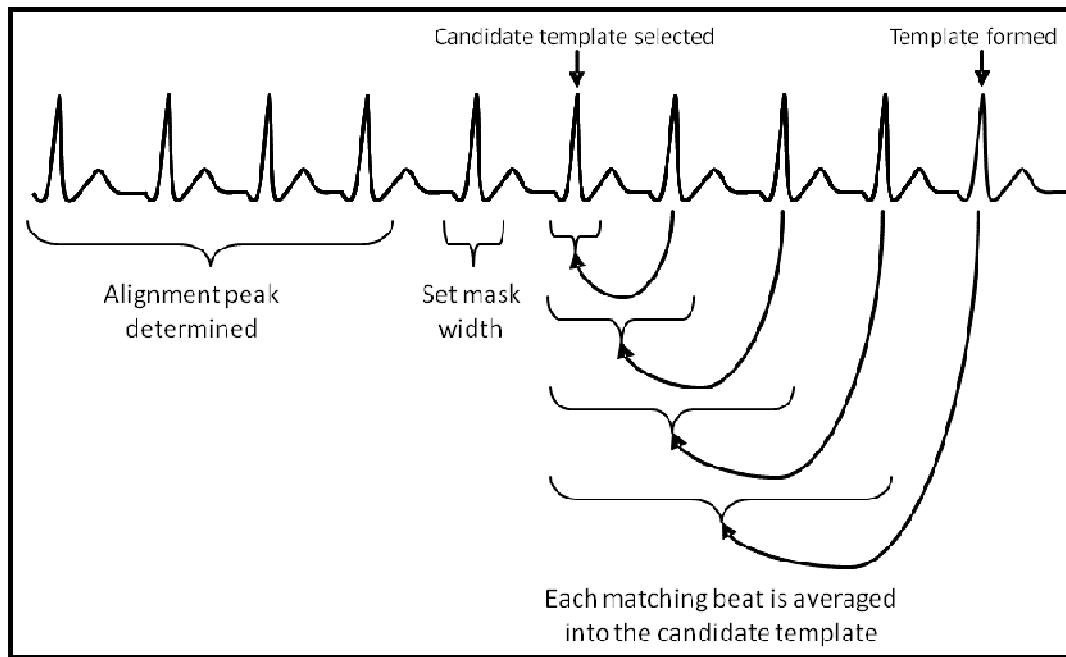


Figure 9: Template formation

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### 3.4 Manual Setup

If the Automatic Setup process is unable to complete or a manual change of the sense vector is required, the Manual Setup process can be used. The Manual Setup process is designed to allow the user to view attributes of the different sensing configurations by temporarily activating different sensing vectors and gains.

The Manual Setup process starts by completing an impedance measurement of the Shock vector. An actual impedance value is not reported to the user; however, the result is reported as “in range” or “out of range.” The user can repeat the impedance measurement multiple times if desired.

Once the impedance test is complete and the CONTINUE button is selected, the Manual Setup Vector Selection screen (Figure 10: Manual Setup Screen) is displayed. This screen allows the user to temporarily select any sense vector and sense gain combination in order to evaluate sensing qualities. The permanently programmed configuration is also highlighted.

The sense vector/gain combination that yields the best sensing qualities should be selected by evaluating the QRS amplitude and QRS:T-wave ratio. The x1 gain should generally be selected unless the x2 gain can be selected without the chance of clipping.

After a sense configuration is selected, the QRS Reference ECG acquisition process is presented to the user in order to store a new QRS template.

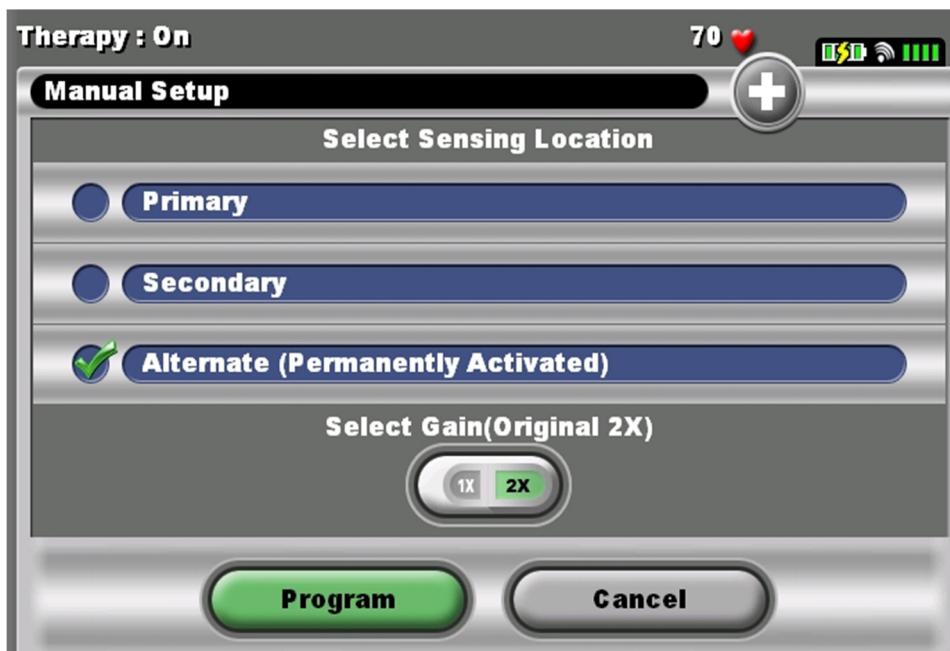


Figure 10: Manual Setup Screen

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## 4.0 Algorithm Architecture

The design of the S-ICD System detection algorithm is sequentially divided into three phases (Figure 11: Algorithm Architecture). The phases include the Detection Phase, the Certification Phase and the Decision Phase.

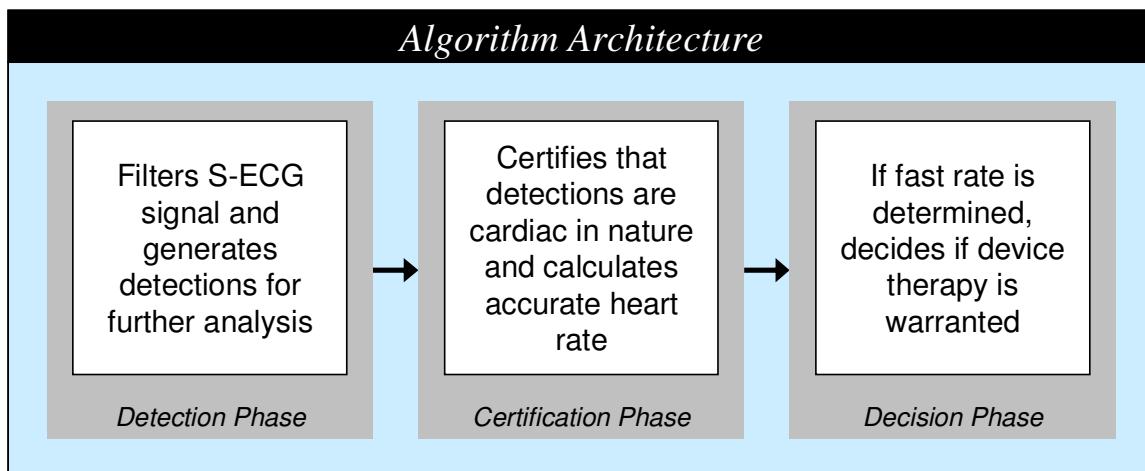


Figure 11: Algorithm Architecture

The three phases can be further broken into elements as shown below. These elements will be covered in more detail within this document.

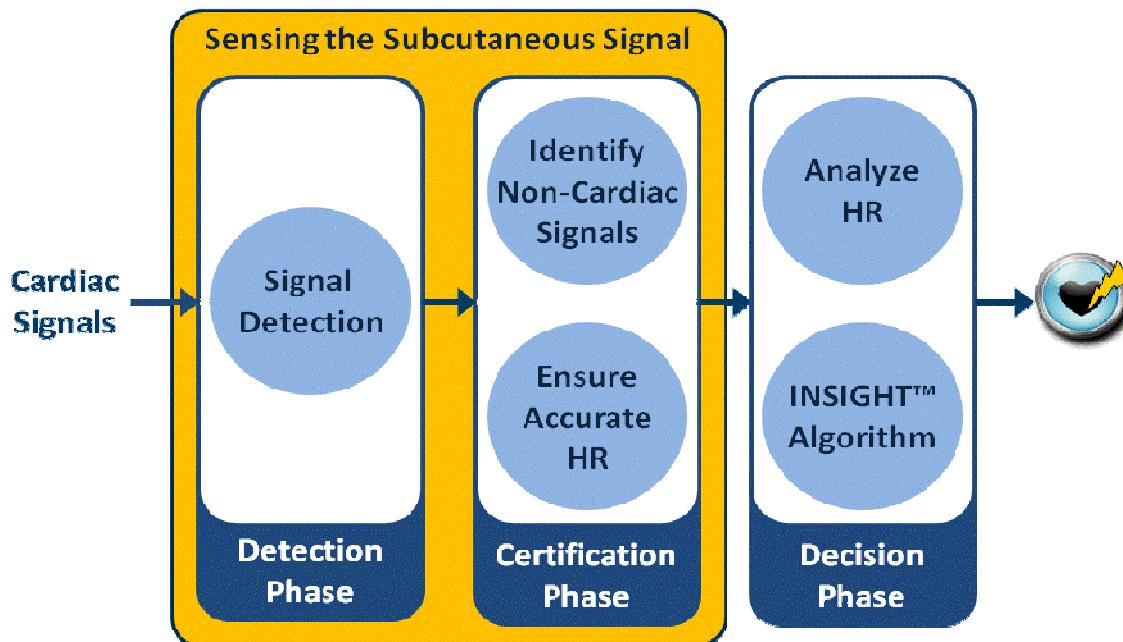


Figure 12: Algorithm Architecture Elements

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## 4.1 Detection Phase

During the Detection Phase, the pulse generator detects all signal events and makes dynamic adjustments to sensitivity settings on a beat-to-beat basis. These settings allow for appropriate sensing of normal sinus rhythm while providing increased sensitivity for ventricular fibrillation. It also prevents inappropriate sensing of noise or artifact which could be misinterpreted as VF.

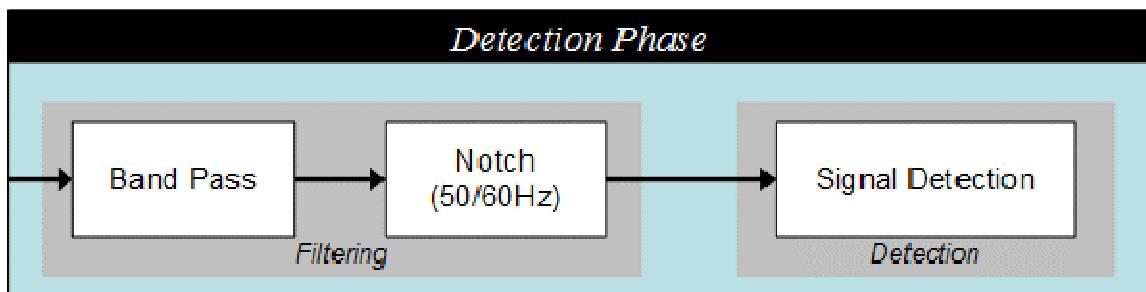


Figure 13: Detection Phase

### 4.1.1 Band Pass Filter

The Band Pass Filter is used to filter away frequencies which are non-cardiac in origin. The filter is designed to allow signals with frequencies between 3 – 40 Hz to pass on for signal detection purposes.

### 4.1.2 Notch Filter

A digital Notch Filter processes the raw S-ECG signal and removes line interference. The Notch Filter is programmed based upon the time zone selected on the programmer. The programmer will automatically configure the power line noise filter for each device upon connection.

### 4.1.3 Signal Detection

Signal detections are created using a detection profile. This detection profile is compared to the S-ECG signal in order to determine detection events. As the rate increases, the detection profile is automatically adjusted in order to allow fast rate analysis of the S-ECG signal. The detection profile is also dynamically adjusted by the size and beat-to-beat similarity of the occurring detections.

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#### 4.1.3.1 Detection Rate Parameters

The device employs three different detection profiles: (1) Slow Rate Parameters (2) Mid Rate Parameters and (3) Fast Rate Parameters. Slow Rate parameters are in use until the average heart rate (4RR) is > 168 bpm. The Mid Rate 1 profile is used between 168 BPM and the programmed Conditional Shock Zone rate. Once the measured heart rate reaches the Conditional Shock Zone, a more aggressive Mid Rate 2 profile is used. Fast Rate Parameters are utilized within the Shock zone. Fast Rate Parameters remain in use until the 4RR falls into the Conditional Shock zone. Mid Rate Parameters remain in use until the 4RR falls below 148 bpm.

**Note:** The switch between Slow Rate and Mid Rate 1 parameters is not dependent upon the programmed therapy rate detection zones. Only 4RR is used as a trigger to transition between Slow and Mid Rate 1 parameters.

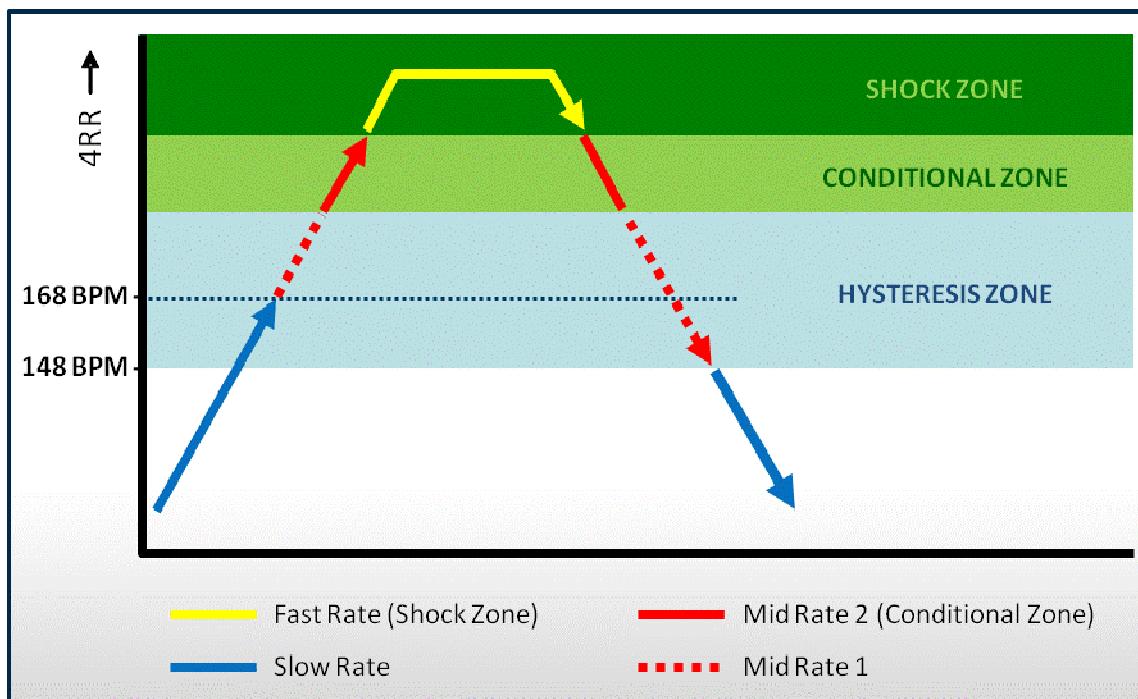


Figure 14: Slow/Mid/Fast Rate parameters transitions

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The Slow Rate Parameter profiles (Figure 17, Figure 18) are designed for accurate sensing during NSR. Longer refractory periods are used with a less aggressive decay profile in order to help prevent over-detection of T-waves. The profiles automatically adapt if dissimilar peak history is noted as T-wave over-detection is suspected. When similar peak history is noted, the detection profiles automatically adjusts accordingly.

The Mid Rate Parameter profiles (Figure 19, Figure 20) are best suited for detection of medium rate rhythms with wider morphologies (e.g. MVT, BBB). The Mid Rate profiles share attributes with the Slow and Fast Rate profiles.

The Fast Rate Parameter profile (Figure 21) is designed to allow for aggressive detection of fast and/or low amplitude arrhythmias. The detection profile utilizes shorter refractory periods and more aggressively decays to the sensing floor.

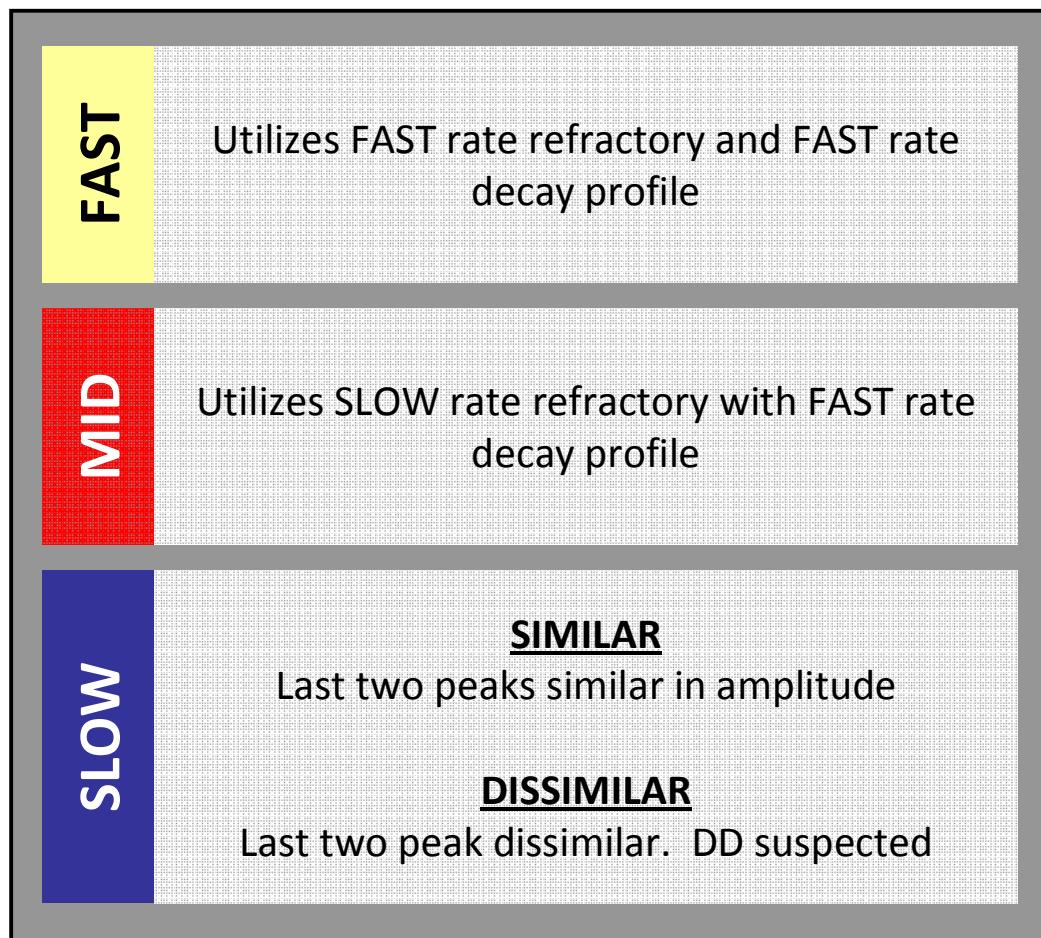


Figure 15: Slow, Mid and Fast Rate detection comparison

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#### 4.1.3.2 Detection Profiles

The device uses a detection profile that is comprised of a Refractory period, two Constant Threshold (CT) periods, and a decay profile to the sensing floor (EDFloor).

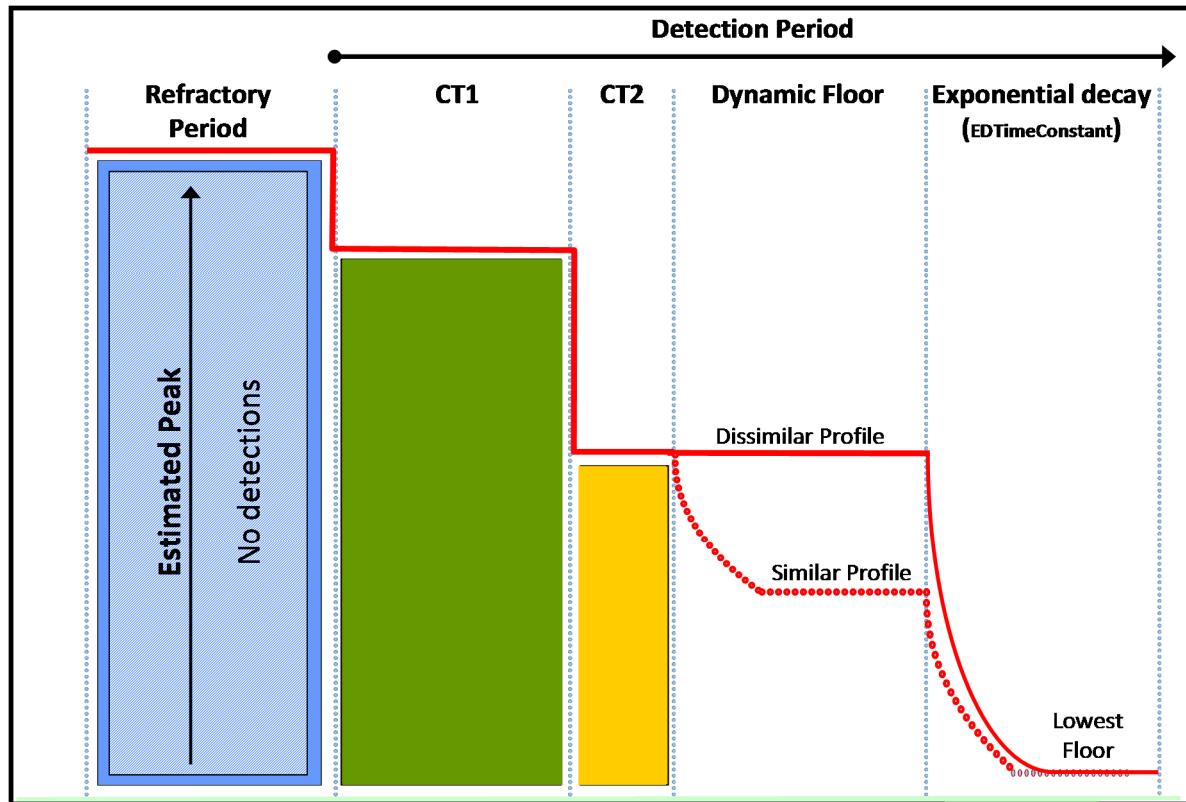


Figure 16: Detection profile

##### 4.1.3.2.1 Estimated Peak

The device calculates Estimated Peak based upon the average of the last two detection's peak values. This allows the detection profile to automatically scale to match the changing S-ECG signal. By averaging across two detections, a single PVC will not dominate a detection profile shift; however, a significant drop in amplitude at the onset of an arrhythmia may cause a slight delay in detection while the Estimated Peak value is averaged.

##### 4.1.3.2.2 Peak Similarity

The detection profile dynamically adjusts to become less aggressive if T-wave detections are suspected. Peak Similarity is used to determine if consecutive peaks are similar in amplitude (suggests QRS-to-QRS detection) or dissimilar (suggests QRS-to-Twave detection).

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When peaks are deemed similar, the detection profile adjusts to be slightly more aggressive. On the other hand, if peaks are deemed to be dissimilar, the detection profile suspects T-wave over-detection is taking place and the detection profile becomes less aggressive to avoid subsequent over-detections.

**4.1.3.2.3 Refractory Period**

Following each detection, a refractory period is initiated in which further detections cannot take place. The device performs morphology analysis within the refractory period and QRS width calculations are performed.

**4.1.3.2.4 CT1 Period**

Following the refractory period, a Constant Threshold Period 1 (CT1) is initiated. Detections can take place during CT1. The CT1 threshold is calculated based upon a percentage of the Estimated Peak.

During Slow Rate parameters, CT1 is dynamically adjusted (threshold and duration) based upon Peak Similarity. Conversely, during Mid Rate and Fast Rate parameters, the CT1 period is fixed.

The detection profile is a horizontal, non-decaying value during CT1.

**4.1.3.2.5 CT2 Period**

Following the end of CT1, a Constant Threshold Period 2 (CT2) is initiated. CT2 is used as a step function for the beginning of the exponential decay to follow; therefore, the CT2 duration is fixed at the shortest duration of 4ms.

The CT2 threshold is calculated as a percentage of the Estimated Peak.

**4.1.3.2.6 EDTimeConstant**

Following CT2, an exponential decay profile is created to decay the detection profile to the desired sensing floor. The EDTimeConstant value refers to the duration of time required for the detection profile to drop to a value equal to 1/3 of the CT2 Threshold value; the shorter the EDTimeConstant value, the more aggressively the detection profile will decay.

**4.1.3.2.7 Dynamic Floor**

The Dynamic Floor algorithm calculates the desired value at which to end the exponential decaying detection profile. Dynamic Floor is designed to aid in the avoidance of T-waves while maintaining the ability to sense low amplitudes when required.

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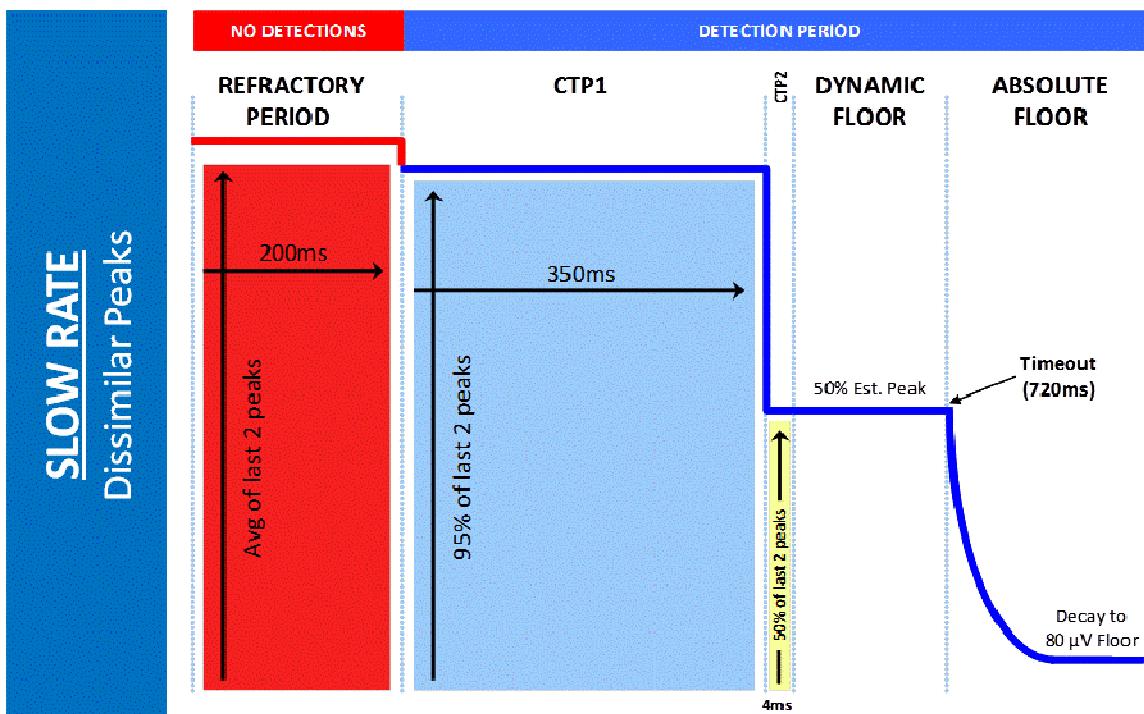


Figure 17: Detection Profile - Slow Rate with dissimilar peak history

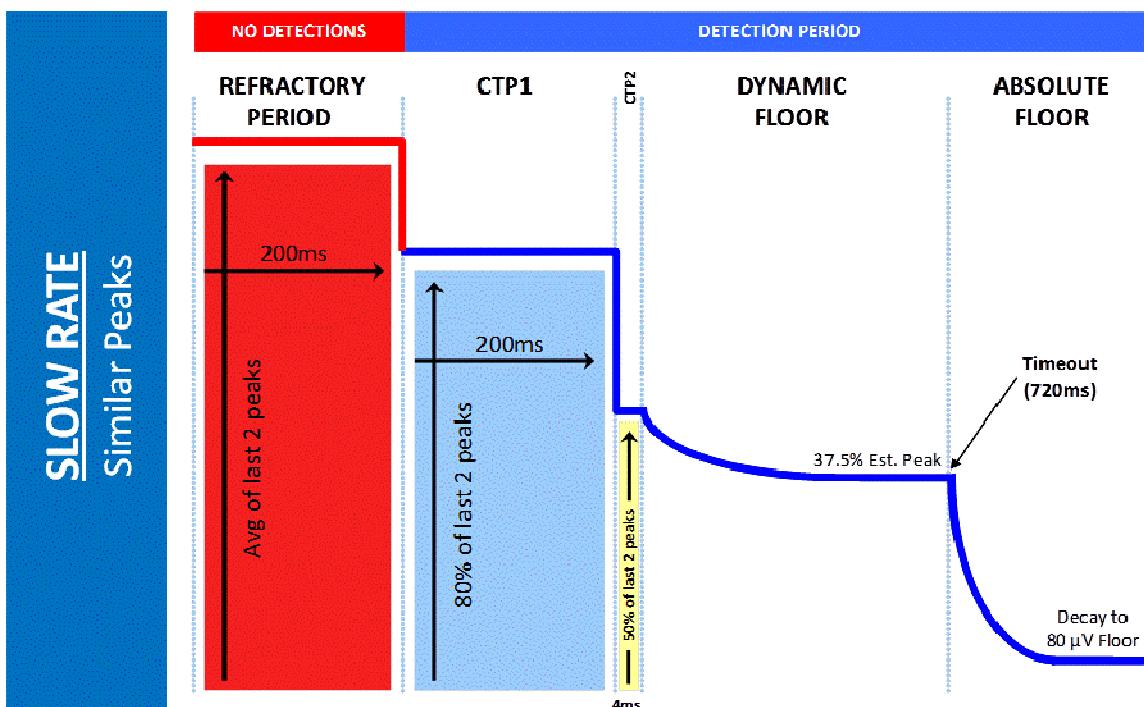


Figure 18: Detection Profile - Slow Rate with similar peak history

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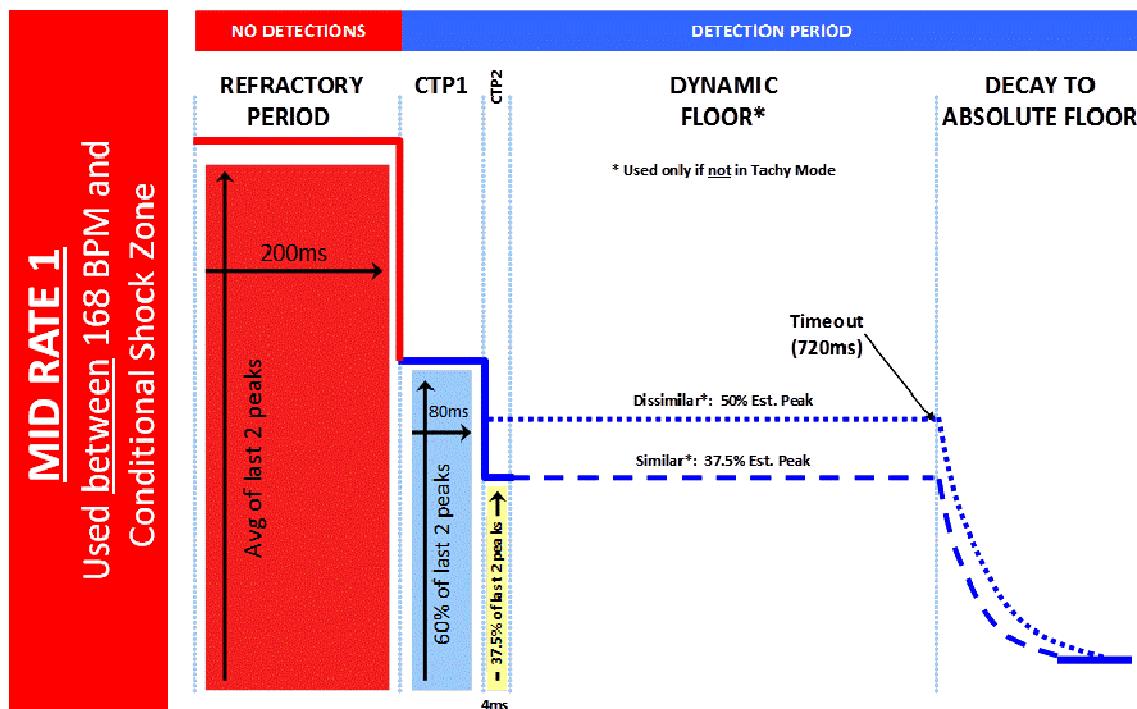


Figure 19: Detection Profile - Mid Rate 1

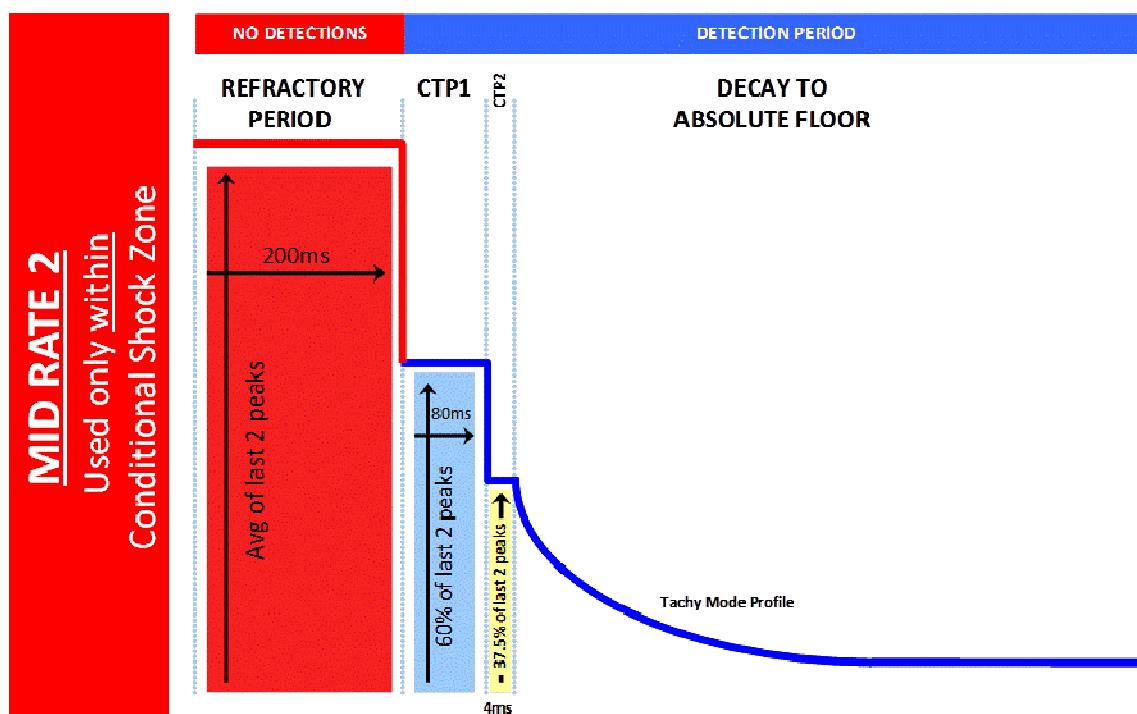


Figure 20: Detection Profile - Mid Rate 2

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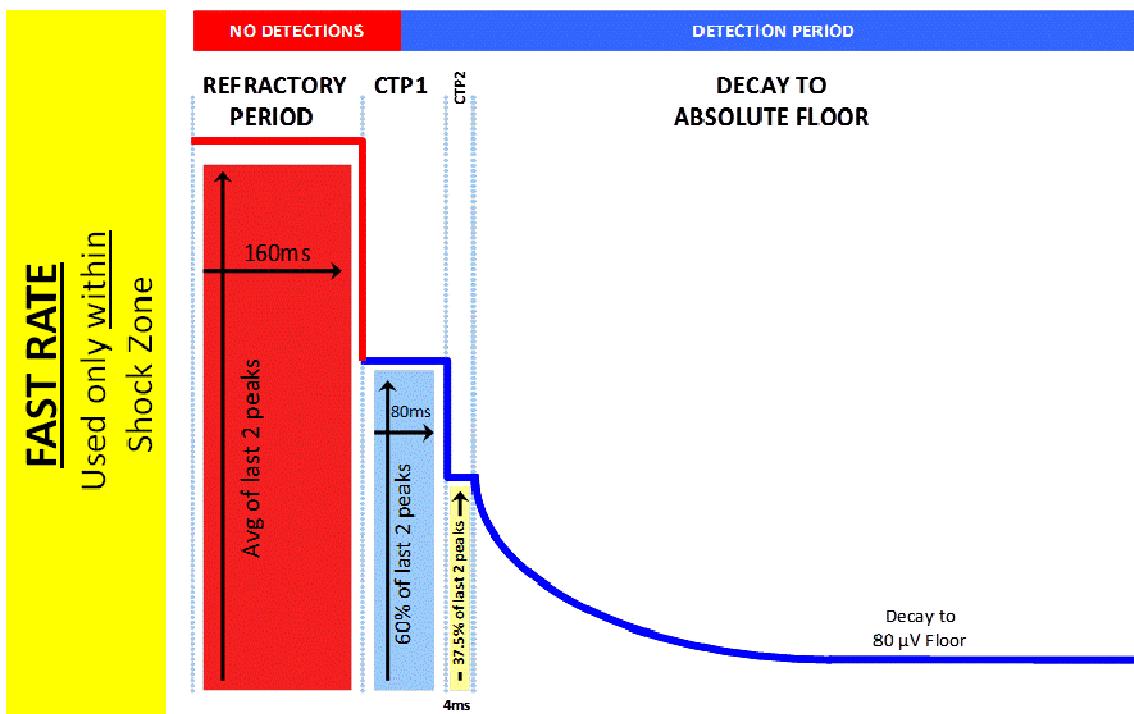


Figure 21: Detection Profile - Fast Rate

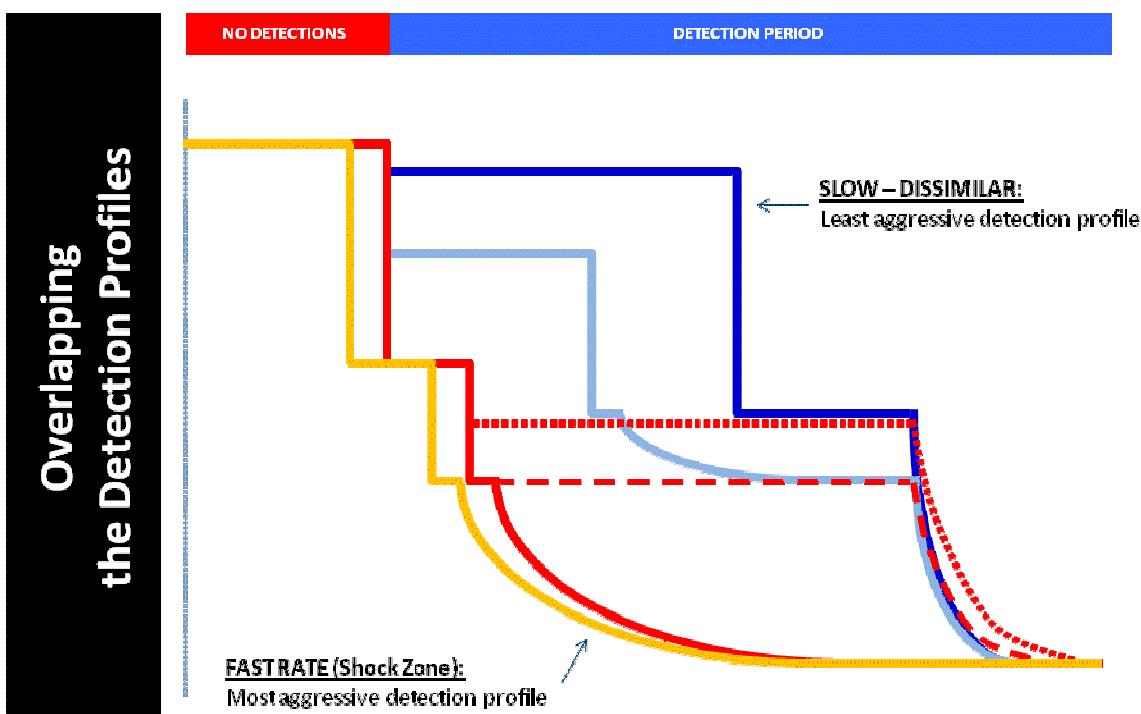


Figure 22: Overlaid detection profiles show the change in detection sensitivity with increased rate

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## 4.2 Certification Phase

Following the Detection Phase the detected signal is sent through the Certification phase. This phase has two components: Detection Certification and Rate Certification. The Double Detection component incorporates three different double detection algorithms: (1) CWADD, (2) WCDD and (3) AIDD.

Unique to the S-ICD System, the Certification Phase is designed to ensure that only detections of cardiac events are passed on for further arrhythmia analysis. Detections that are deemed non-cardiac in origin are discarded. Additionally, within the Certification Phase, several algorithms identify and correct for various forms of over-detection to ensure that an accurate heart rate is passed on to the arrhythmia analysis stage.

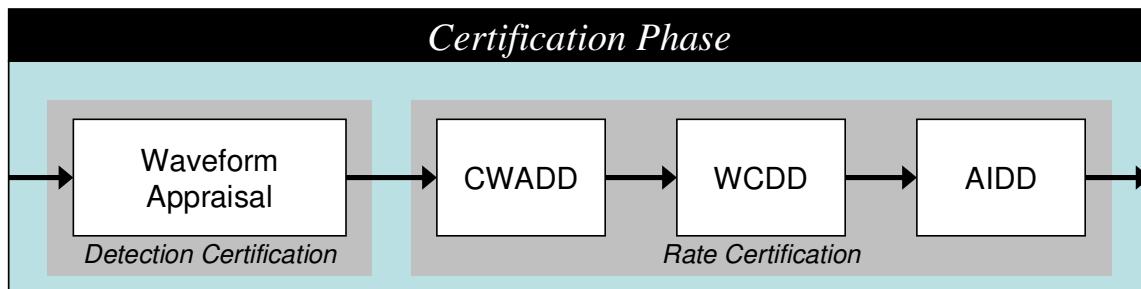


Figure 23: Certification Phase

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**4.2.1 Waveform Appraisal**

Waveform Appraisal is the first algorithm to analyze incoming signals from the detection phase. Waveform Appraisal acts as a filter and determines whether the signal is a certified beat (cardiac in origin) or suspect (non-cardiac in origin). This algorithm is specifically designed to identify noise superimposed upon the S-ECG signal. If noise is suspected and the Waveform Appraisal algorithm rules are met, the detection is labeled with an “N” marker and the 4RR heart rate is not adjusted, ensuring that the noise detections do not raise the measured heart rate.

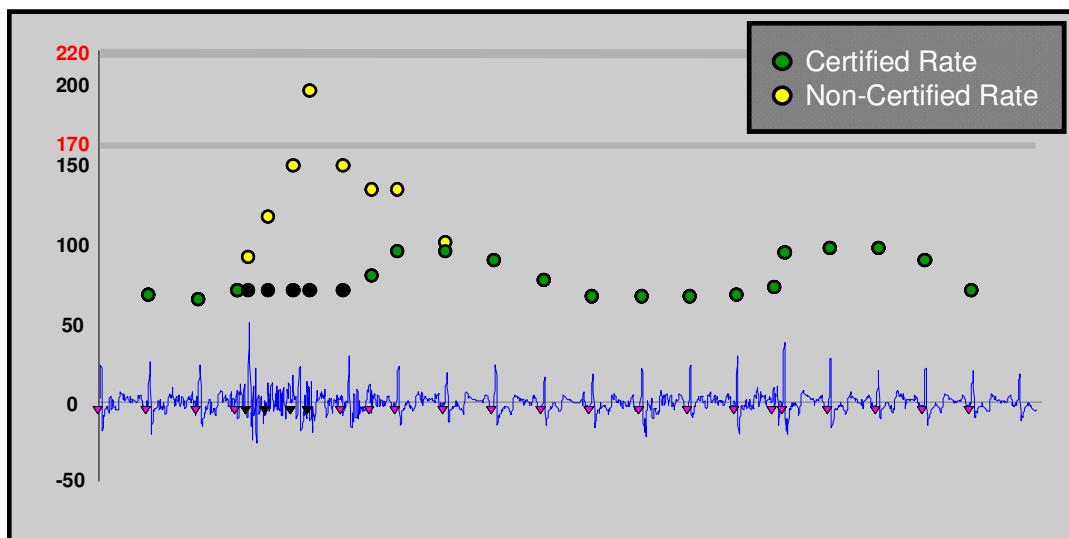


Figure 24: Waveform Appraisal example

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**4.2.2 Correlation Waveform Appraisal Double Detection (CWADD)**

CWADD is used to identify and correct for T-wave over-detection. The algorithm uses the stored template to identify alternating morphology patterns of the three most recent detections. If consistent match → non-match → match patterns are found, double detection is suspected. A template must be formed to utilize CWADD. If a CWADD detection is recognized, the 4RR rate average is adjusted to use the entire interval between the two matching beats, creating one certified interval. The non-match beat is labeled with a “dot” marker.

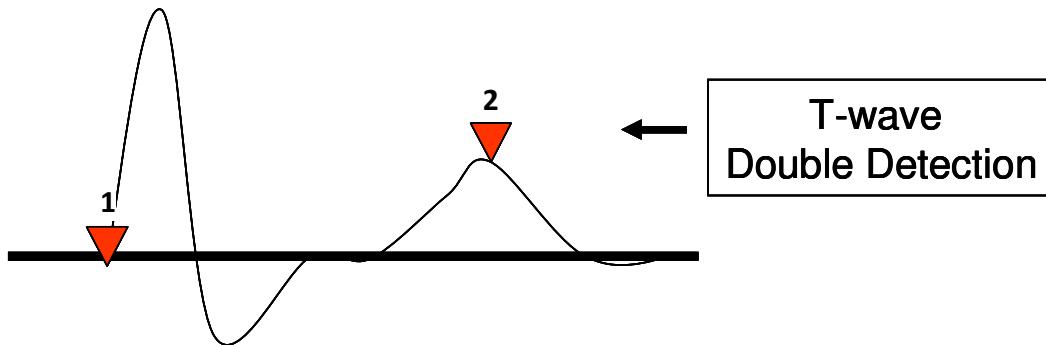


Figure 25: CWADD uses template information to recognize T-wave over-detection

**4.2.3 Wide Complex Double Detection (WCDD)**

WCDD is used to identify and correct for over-detection of wide morphology complexes. The algorithm identifies unique patterns of closely coupled detections using both interval separation and morphology characteristics. A template is not required for WCDD operation. If a WCDD detection is recognized, the 4RR rate average is adjusted to use the sum of both contributing intervals, creating one certified interval. The over-counted detection is labeled with a “dot” marker.

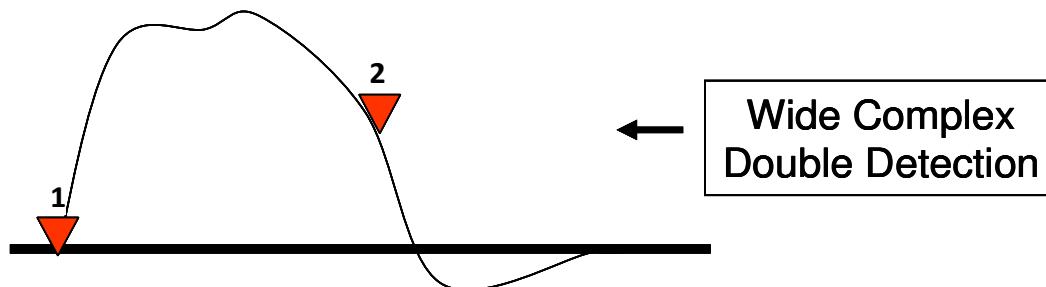


Figure 26: WCDD recognizes over-detection of a wide QRS

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#### 4.2.4 Alternating Interval Double Detection (AIDD)

As double detection occurs (either T-wave or wide complex), an alternating pattern of interval durations is often observed. The AIDD algorithm recognizes and corrects for this repeating alternating pattern in order to establish an accurate R-R interval. If an AIDD detection is recognized, the 4RR rate average is adjusted to use the sum of both contributing intervals, creating one certified interval. The over-counted detection is labeled with a “dot” marker.

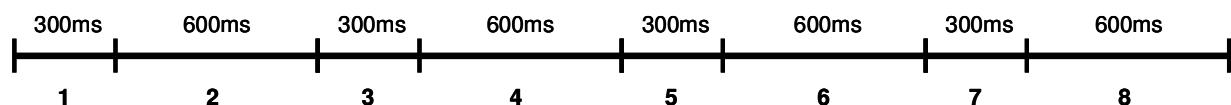


Figure 27: AIDD recognizes consistently alternating intervals without the need for a template

#### 4.2.5 Heart Rate

Following the Rate Certification process, the device calculates heart rate based upon the average of the last 4 certified intervals (4RR). In order to ensure that an accurate heart rate is passed onto the Decision Phase, the heart rate is calculated after the Double Detection algorithms identify and correct for over-detections.

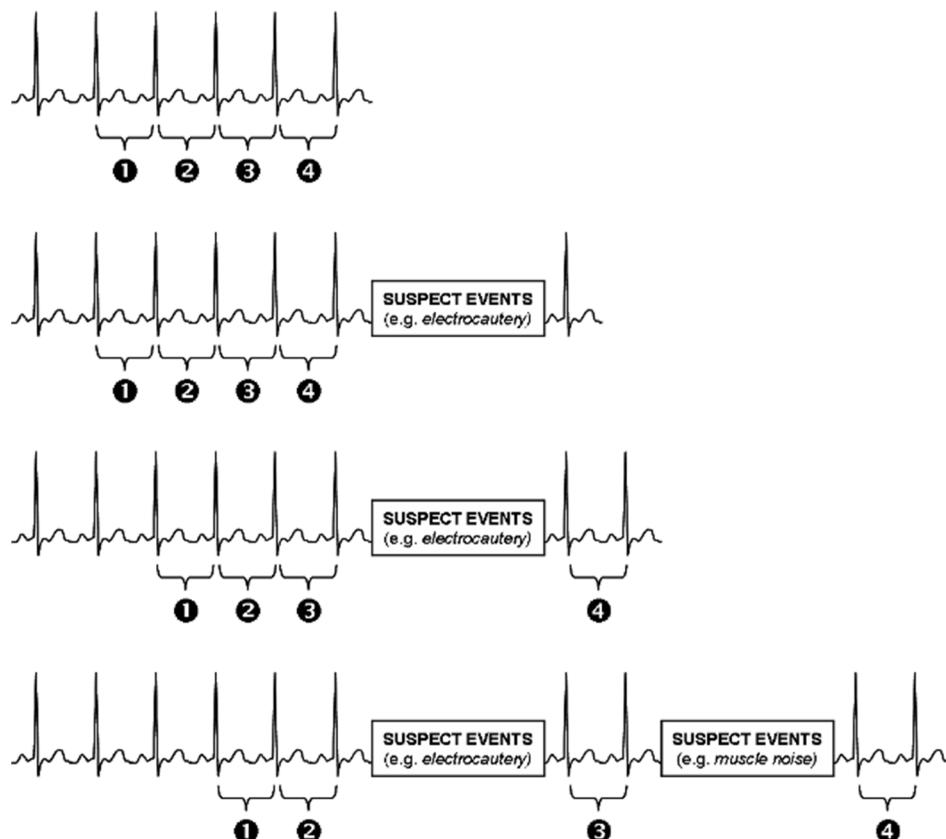


Figure 28: 4RR calculation in the presence of suspect events

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### 4.3 Decision Phase

Following the Certification Phase, the Decision Phase analysis is performed.

The Decision Phase is broken into two components: (1) Arrhythmia Analysis and (2) Therapy Decision.

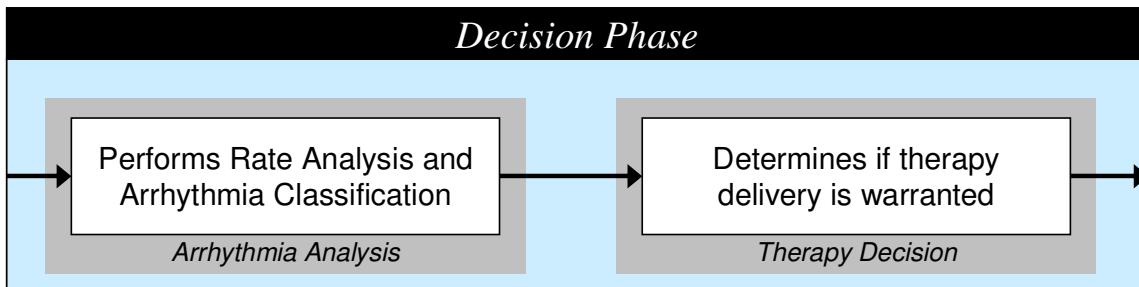


Figure 29: Decision Phase

#### 4.3.1 Arrhythmia Analysis

Arrhythmia Analysis first analyzes the heart rate to determine if a Tachy state should be declared. Upon entering the Tachy state, analysis is performed to determine if therapy is required.

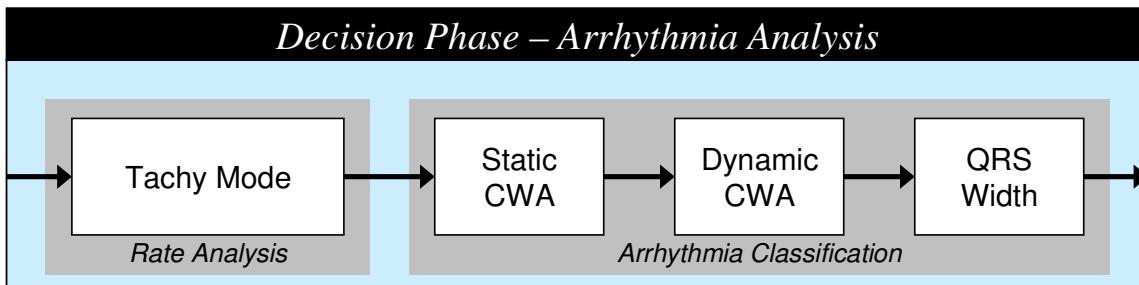


Figure 30: Decision Phase – Arrhythmia Analysis

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#### 4.3.1.1 Tachy Mode

Tachy Mode analysis is performed to determine if the patient is in a Tachy state. Tachy state is declared once the rate crosses the lowest programmed therapy zone. Tachy state ends when the rate falls below the lowest programmed therapy zone + a 40ms Hysteresis zone for 24 contiguous intervals.

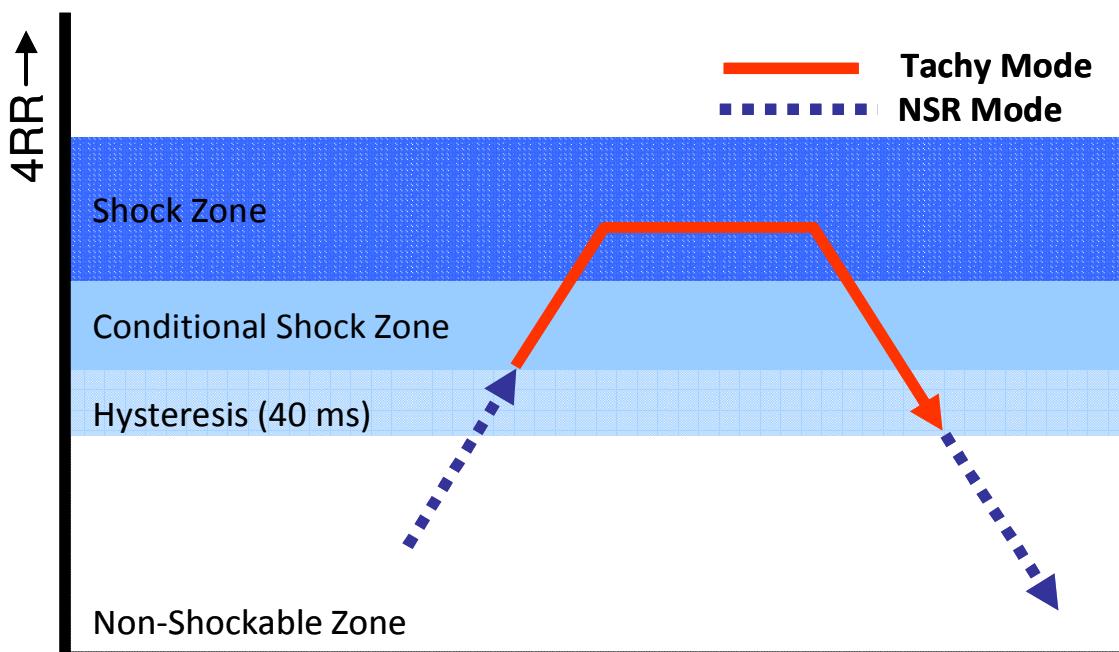


Figure 31: Tachy Mode transitions

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**4.3.1.2 Static CWA**

Static Correlation Waveform Analysis (Static CWA) measures the degree of similarity of the current beat morphology and width with that of the stored NSR Template. If the morphology and width are deemed similar, the beat is labeled as a Sensed (S), non-shockable beat. Further analysis is performed if the current beat morphology and width do not match that of the stored NSR Template.

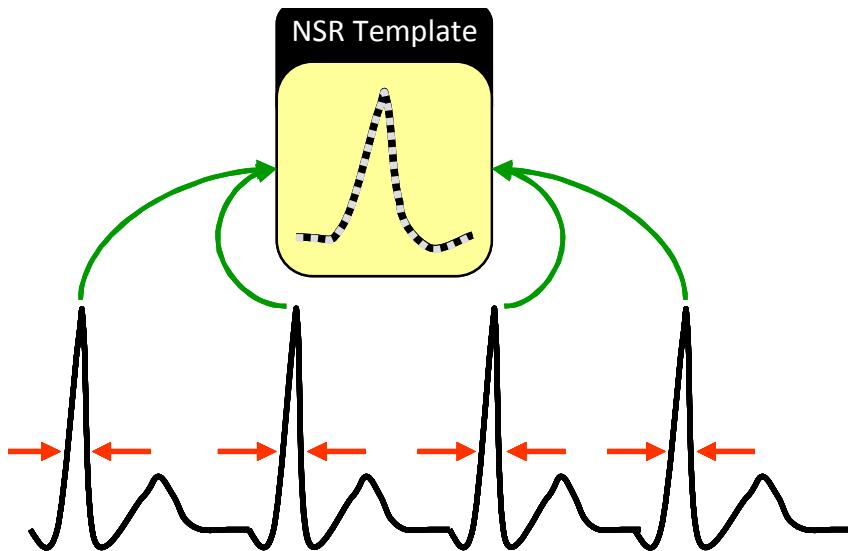


Figure 32: Static CWA

**4.3.1.3 Dynamic CWA**

Dynamic Correlation Waveform Analysis (Dynamic CWA) measures the degree of similarity between the current beat and the previous beat. This beat-to-beat analysis allows the device to quickly identify polymorphic rhythms. Consecutive beats that demonstrate polymorphic relationships are labeled with a "T" as shockable beats. If a monomorphic relationship is noted, further analysis is performed in order to label the current beat.

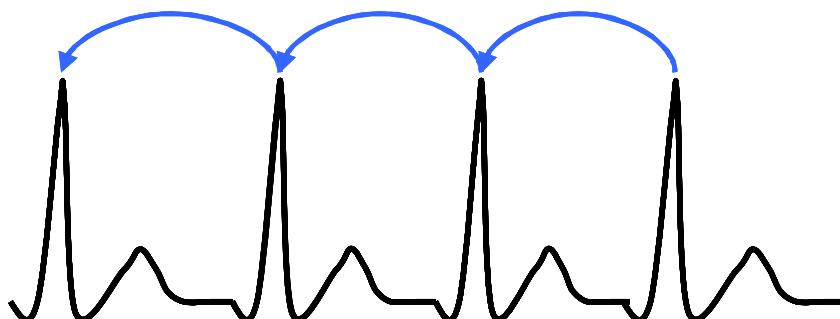


Figure 33: Dynamic CWA

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**4.3.1.4 QRS Width**

If Dynamic CWA deems the last two detections as monomorphic in nature, QRS Width is analyzed. Beats with QRS Width measurements wider than that of the stored NSR Template are deemed shockable and are labeled with a “T” marker, while beats with QRS Width measurements that are narrower than the stored NSR Template are deemed non-shockable and labeled with an “S” marker.

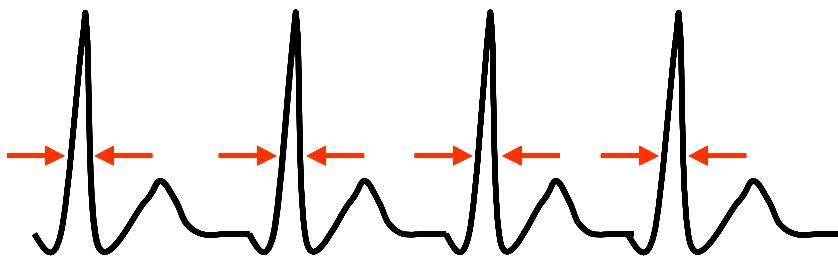


Figure 34: QRS Width

**4.3.1.5 Combining Arrhythmia Analysis Algorithms**

All of the detection algorithms work together to identify and classify the S-ECG signal. All Arrhythmia Analysis algorithms are automatically activated if a Conditional Shock Zone is programmed.

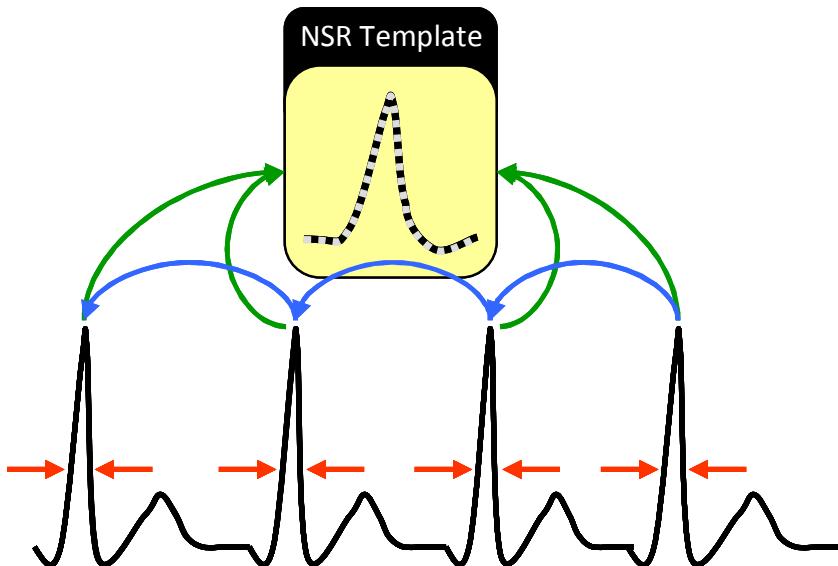


Figure 35: Arrhythmia Analysis algorithms

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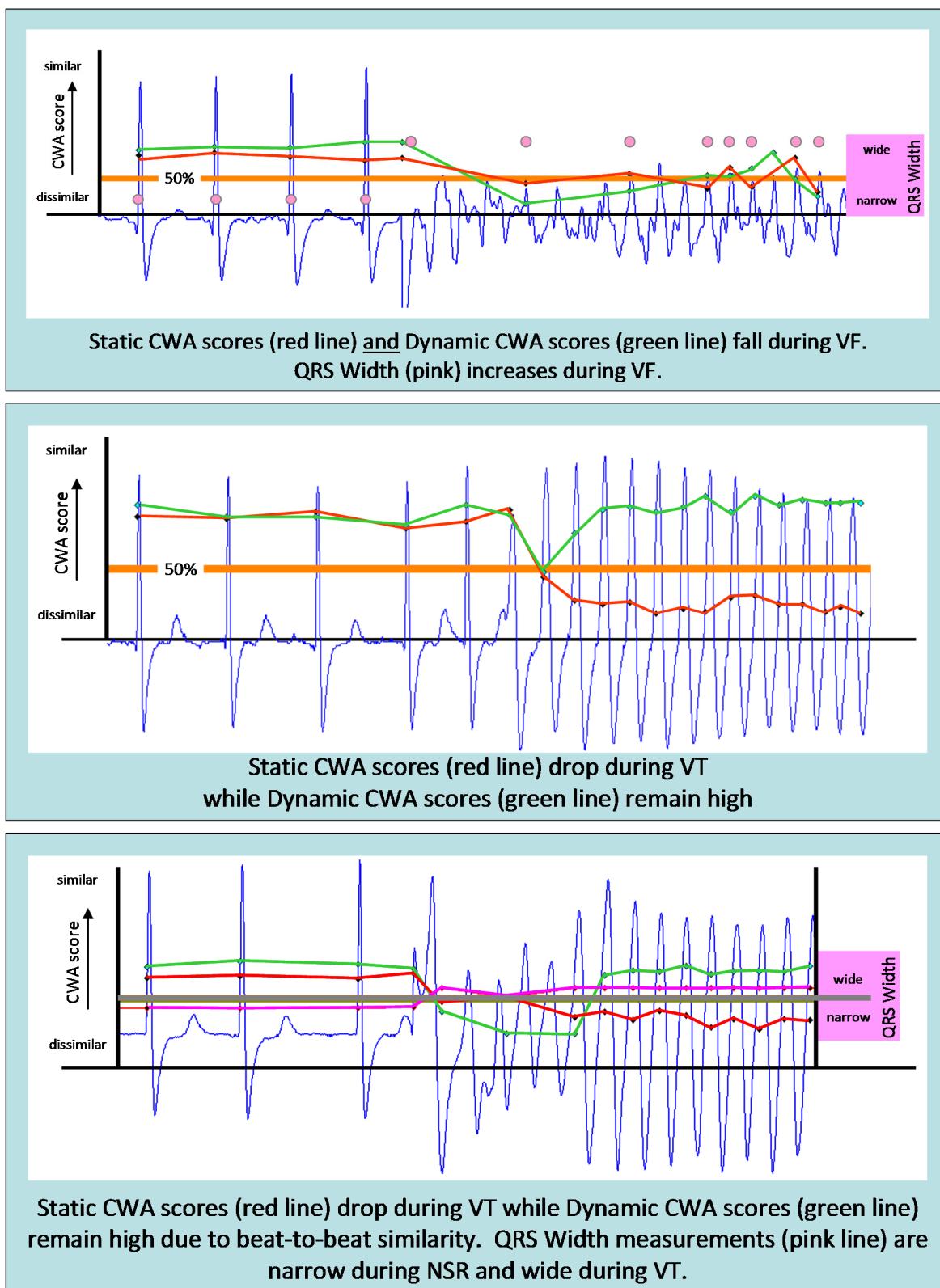


Figure 36: Arrhythmia analysis examples

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**4.3.1.6 Algorithm Decision Tree**

The hierarchy of Arrhythmia Analysis execution is shown below. All detections (following Certification correction) within the Shock Zone are considered shockable Tachy ("T") beats. Within the Conditional Shock Zone, further analysis is applied.

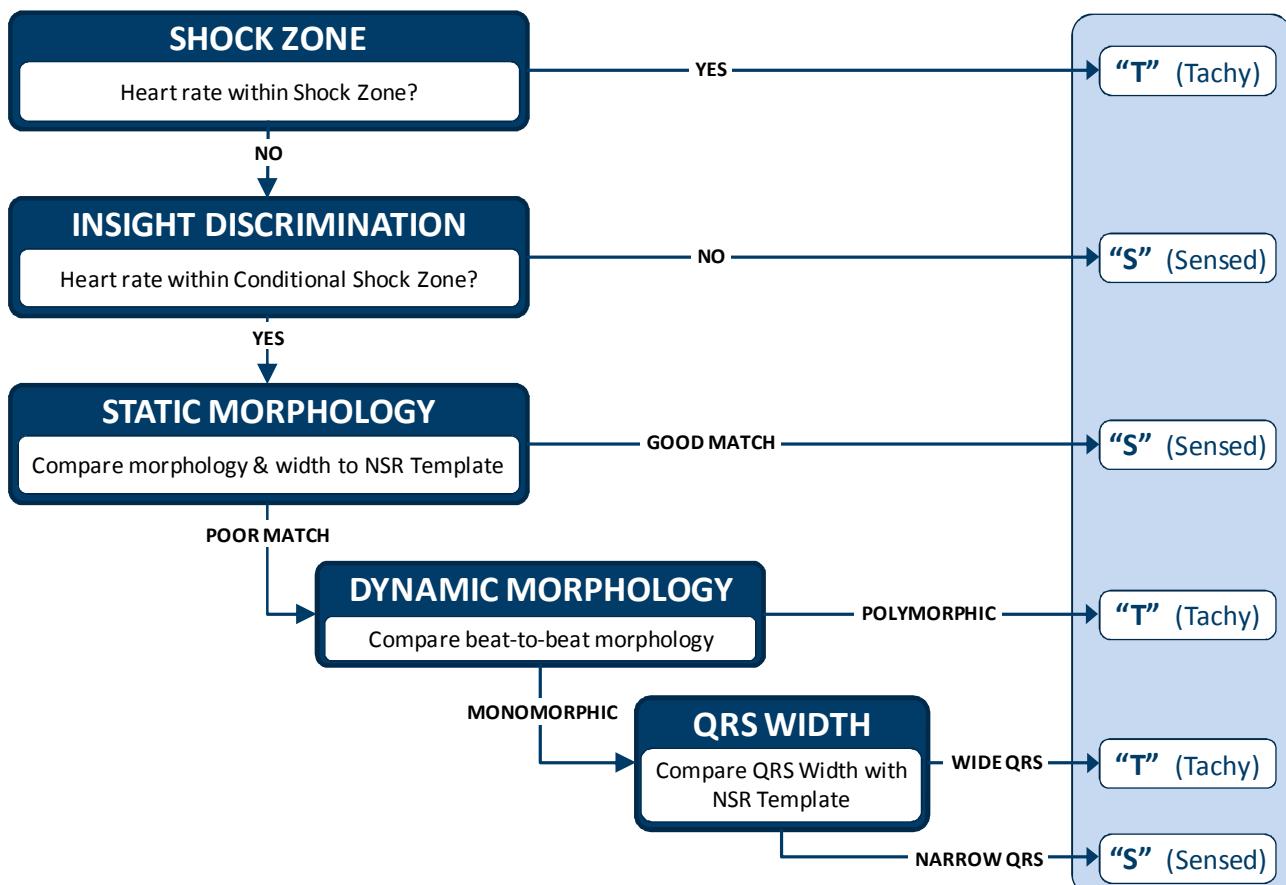


Figure 37: Decision Phase arrhythmia analysis

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### 4.3.2 Therapy Decision

During the Therapy Decision stage, steps are performed to determine if therapy is required for the arrhythmia.

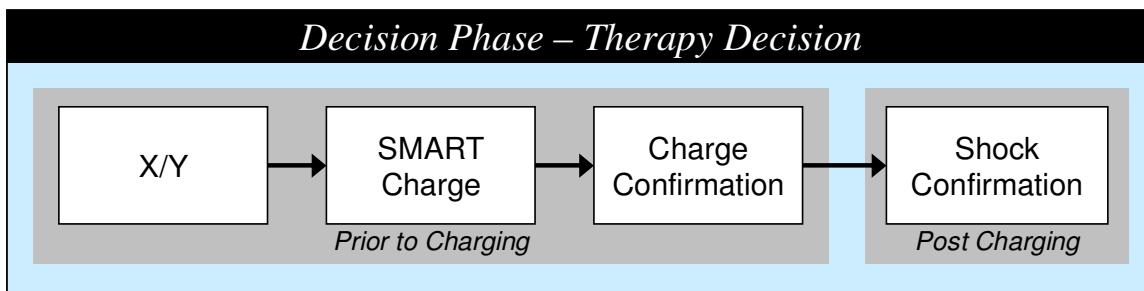


Figure 38: Decision Phase – Therapy Decision

#### 4.3.2.1 X/Y

X/Y criteria is used to initially determine if a rhythm warrants therapy. The X/Y is used to ensure that a sufficient quantity of detections have been labeled as Tachy ("T") beats. Initially, the system utilizes an X/Y criteria of 18/24; however, the X/Y is automatically adjusted for double detection and noise beats. Following the first shock of an episode, the X/Y criteria is adjusted to 14/24 for all remaining shocks of that episode.

The X/Y counter does not act as an up/down counter, nor does it simply count the number of T's in the 24 marker window. Rather, the system compares the most recent detection entering the window, with the oldest detection falling out of the window. The relationship between these two detections is used to adjust the X/Y counter.

#### 4.3.2.2 SMART Charge (Persistence)

Once X/Y criteria have been met, Persistence is used to ensure that the rhythm is sustained for sufficient duration prior to confirming charging for therapy. The nominal value for persistence is two (2) intervals.

SMART Charge automatically increases the persistence value in the presence of non-sustained arrhythmias. If an arrhythmia sustains to the point at which charging is commenced; however, spontaneous termination is noted prior to shock delivery, the system responds with a SMART Charge extension. This extension adds three (3) intervals to the current persistence value in order to delay charging for future events for rhythms that are likely to spontaneously terminate. The system can add up to five (5) extensions, or 15 intervals to the persistence value. SMART Charge can be reset to zero (0) extensions using the programmer.

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**4.3.2.3 Charge Confirmation**

The Charge Confirmation algorithm is the last analysis performed prior to charging the capacitors. The Charge Confirmation algorithm confirms that sufficient X/Y criteria has been maintained, that a high incidence of double counting has not been noted, and that the two most recent detections remain shockable.

The Charge Confirmation algorithm confirms:

- >15 “T” markers are contained within the 24 beat window
- Two most recent detections remain shockable

**4.3.2.4 Shock Confirmation**

Following charging of the capacitors, Shock Confirmation confirms that the arrhythmia has sustained and is sufficiently fast to warrant shock delivery. If a sustained tachyarrhythmia is noted throughout the charging period, three (3) fast intervals with a therapy zone are required for Shock Confirmation.

If spontaneous termination of the ventricular arrhythmia is noted during charging, the Shock Confirmation requirement is automatically extended for each normal “S” beat that is noted, up to a maximum of 24 intervals. This technique allows the system to avoid therapy delivery for a short run of VT following spontaneous termination of an arrhythmia.

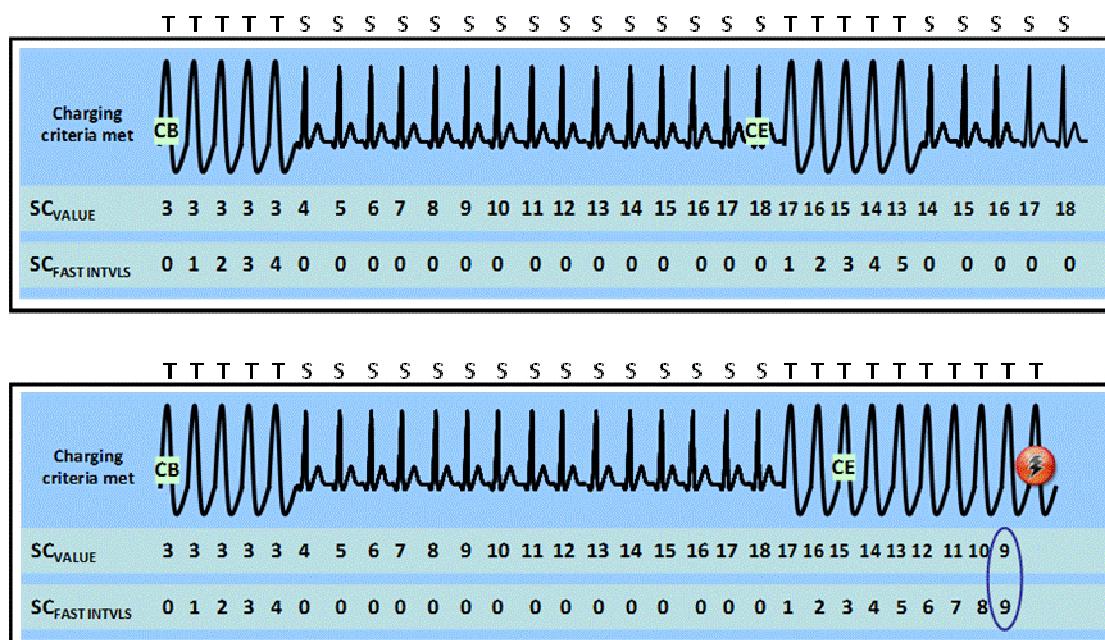


Figure 39: Examples of Shock Confirmation. CB: charge begin; CE: charge end; SC Value: required quantity of consecutive fast intervals for shock delivery; SC Fast Intvl: actual number of consecutive fast intervals for the example rhythms

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## 4.4 Post-Therapy Sensing

In order to ensure appropriate sensing following therapy deliver (induction, shock and pace), the system automatically forces a set of detection profile settings.

### 4.4.1 Post-Induction (PI) Sensing

Following induction delivery, the algorithm is tuned to aggressively look for low amplitude signals. Following a 2000ms post-induction non-sensing period, the detection parameters are seeded to ensure appropriate sensing of low amplitude VF. Post-Induction sensing occurs with the actively programmed sense vector.

### 4.4.2 Post-Shock (PS) Sensing

Following shock delivery, the algorithm is tuned to better sense NSR. Prior research has shown that a full energy 80J shock is likely to successfully return a ventricular arrhythmia to NSR; therefore, the Post-Shock sensing architecture is designed to anticipate a return to NSR rather than a continuation of VF. Following a 2000ms post-shock non-sensing period, sensing parameters are initialized accordingly to prevent over-detection of the post-shock rhythm. Post-Shock sensing occurs with the actively programmed sense vector.

### 4.4.3 Post-Pace (PP) Sensing

In order to sense during Post-Shock Pacing, the system switches to the Alternate (AB) sense vector. During pacing, the Can electrode is acting as a therapy delivery node (pace pulses are delivered between Coil and Can); therefore, sensing with a vector that utilizes the Can (Primary or Secondary) is not possible.

The sense vector is switched to the Alternate (AB) vector only if Post-Shock Pacing is required. If pacing is not required, Post-Shock sensing occurs with the actively programmed sense vector. When Post-Shock Pacing terminates, the sense vector is automatically returned to the permanently programmed vector.

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## 5.0 Therapy Delivery

### 5.1 Delivering Shocks

Once a shock is deemed necessary by the Shock Confirmation algorithm, capacitor top-off is performed and a synchronous shock is delivered. The polarity of the shock is controlled via the Adaptive Shock Polarity algorithm.

#### 5.1.1 Shocks per Episode

The system delivers up to a maximum of five (5) maximum energy 80J shocks per episode.

#### 5.1.2 Shock Synchronization

The device attempts to deliver all shocks (manual and automatic) in a synchronous manner. Following capacitor top-off, a synchronization window is initiated. The following detection (certified or suspect) will trigger shock delivery.

If a 1000 ms Shock Sync Timeout window expires without a detected event, the shock will be delivered in an asynchronous manner.

#### 5.1.3 Adaptive Shock Polarity (Dynamic Shock Polarity)

Adaptive Shock Polarity (ASP) is an algorithm that automatically selects a preferential shock polarity for the first shock of an episode. ASP “remembers” the polarity of the last successful shock and ensures that the next episode utilizes this polarity for the first delivered shock. ASP automatically alternates shock polarity for all subsequent shocks (as needed) within an episode. If a shock successfully reverts the arrhythmia and NSR is declared, ASP retains the shock polarity for future use.

ASP is initialized to Standard Polarity when the device is taken out of Shelf Mode.

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## **5.2 Delivering Post-Shock Pacing**

When pacing is deemed necessary, the sense vector is switched to Alternate and pacing is commenced. Once commenced, Post-Shock Pacing will continue at a rate of 50 ppm (1200ms) as needed, for a maximum duration of 30 seconds.

Post-Shock Pacing operates as a demand based therapy using 200mA constant current biphasic pace pulses. Sensed events will restart the 1200ms pace interval, however four (4) contiguous Waveform Appraisal Certified detections will terminate Post-Shock Pacing therapy

Upon Post-Shock Pacing termination, the sense vector reverts to the permanently programmed vector.

## **5.3 Delivering Induction**

Induction is commanded via the Programmer. The device issues 200mA, 50Hz AC induction pulses in 1-sec increments between the Coil and Can. If the Induction button is held for over 1-sec, the device will automatically extend the induction pulse by one second. This process continues until the button is released.

The programmer limits the induction pulse to a duration of 10 seconds. A subsequent induction pulse can be delivered by releasing the Induction button and reselecting once available.

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## 5.4 Therapy Waveforms

### 5.4.1 Shock Waveform

The SQ-RX delivers a truncated exponential, 50% tilt, biphasic shock between the Coil and Can using 95  $\mu\text{F}$  capacitors. The pulse width is impedance compensated up to a maximum of 15 ms per phase, ensuring 80 J of delivered energy up to 200 $\Omega$ .

Automatic Therapy shocks are all maximum energy 80J shocks.

Manual Shocks can be delivered from 10 – 80J, in increments of 5J.

The first shock in response to an induced rhythm via the programmer can be selected from 10 – 80J in 5J increments.

#### 5.4.1.1 Shock Polarity

The system delivers Standard and Reversed polarity shocks between the Coil and Can. The Shock Polarity can be commanded via the programmer for Manual Shocks as well as the first shock delivered in response to an induced arrhythmia.

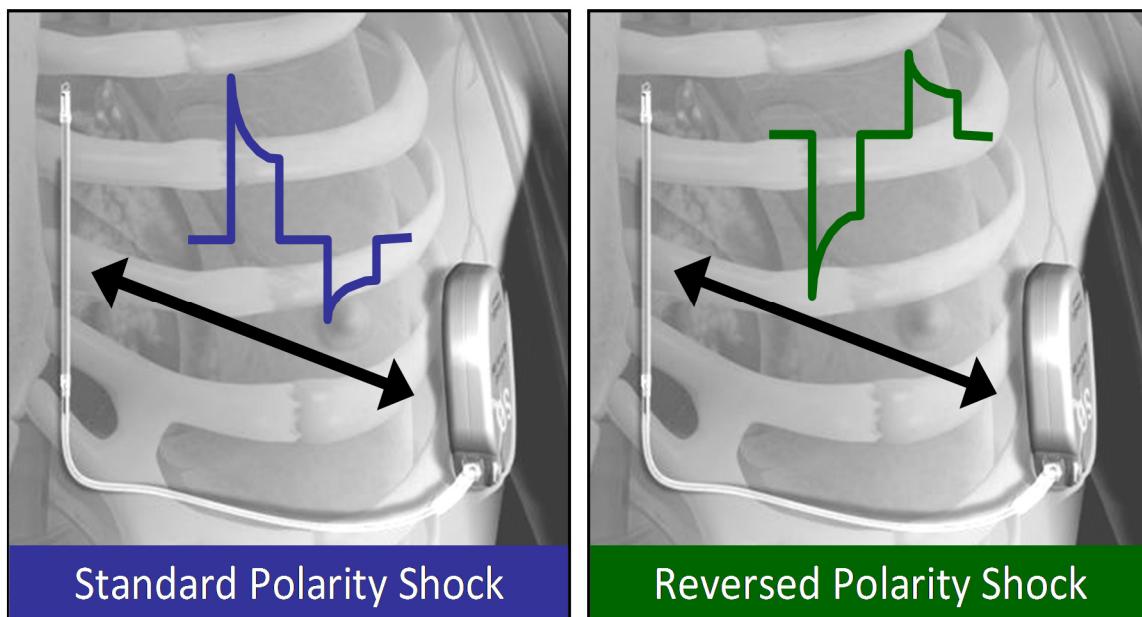


Figure 40: Shock Polarity

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**5.4.2 Pace Pulse Waveform**

The system delivers constant current, 200mA, biphasic pacing pulses with a pulse width of 7.5ms (per phase) at a rate of 50 ppm (1200ms).

All pace pulses are delivered using standard polarity, regardless of the Adaptive Shock Polarity setting for the polarity of the delivered shock.

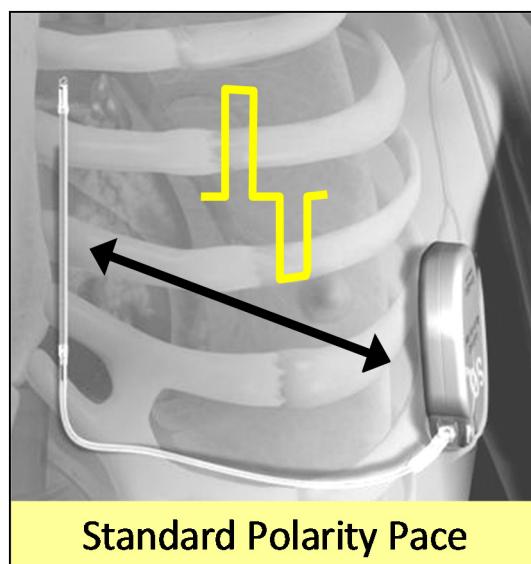


Figure 41: Pace Polarity

**5.4.3 Induction Waveform**

The system delivers constant current, 200mA, 50Hz, AC induction pulses between the Coil and the Can.

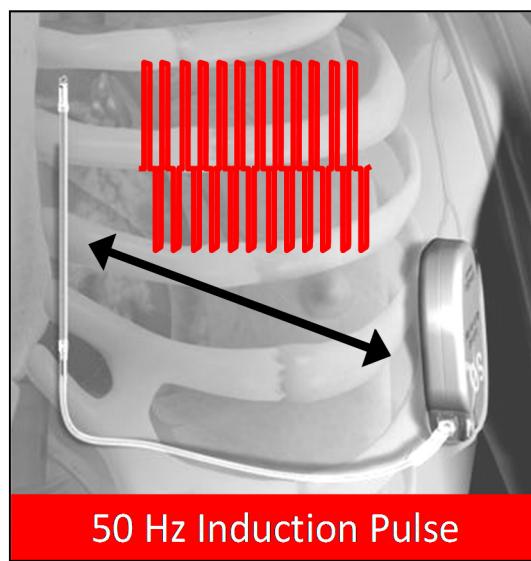


Figure 42: 50Hz Induction Pulse

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## 5.5 Episode History

The device stores Treated and Untreated episodes for retrieval with the programmer. The programmer displays the number of episodes, both Treated and Untreated, as well as the number of delivered shocks since the last follow-up. This data is automatically cleared when the programmer session is ended.

**Note:** Episodes that occur during an active telemetry session are NOT stored in the device memory (i.e. induction testing).

**Note:** An episode that is interrupted by the initiation of a programmer session will be discarded from device memory. Therapy will continue as necessary until therapy has been exhausted, however, stored S-ECG and marker information will be unavailable.

**Note:** An episode that is interrupted by the application of a magnet will be discarded from device memory; regardless if shocks have already been delivered within the episode. Episodes that have previously stored will not be erased.

Arrhythmias that terminate prior to the satisfaction of Charge Confirmation are not retained. An Episode Begin is declared only once Charge Confirmation has been met and capacitor charging has begun.

An Episode End is declared when the Tachy to NSR transition occurs following 24 contiguous intervals below the lowest programmer therapy zone (+ 40ms Hysteresis).

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**5.5.1 Treated Episodes**

An episode is considered Treated when at least one shock has been delivered.

The device stores up to 25 Treated episodes. Episodes are stored in a first-in-first-out format; however, the first stored Treated episode is never overwritten. When additional space is required, episodes are erased four (4) at a time.

Once 25 Treated episodes have been stored and additional memory is required for a subsequent episode, the four (4) oldest episodes (with the exception of Episode 1) are erased. Episode storage continues again until the memory is filled, at which time, if a subsequent episode occurs, four (4) more episodes are erased to make room. This process continues as needed, ensuring that the maximum of 25 Treated episodes is not exceeded. All episodes within a device are labeled with a unique Episode number that will not be repeated. This episode number will be displayed on the episode pick-list and the printed report.

**NOTE:** Induced episodes are NOT stored.

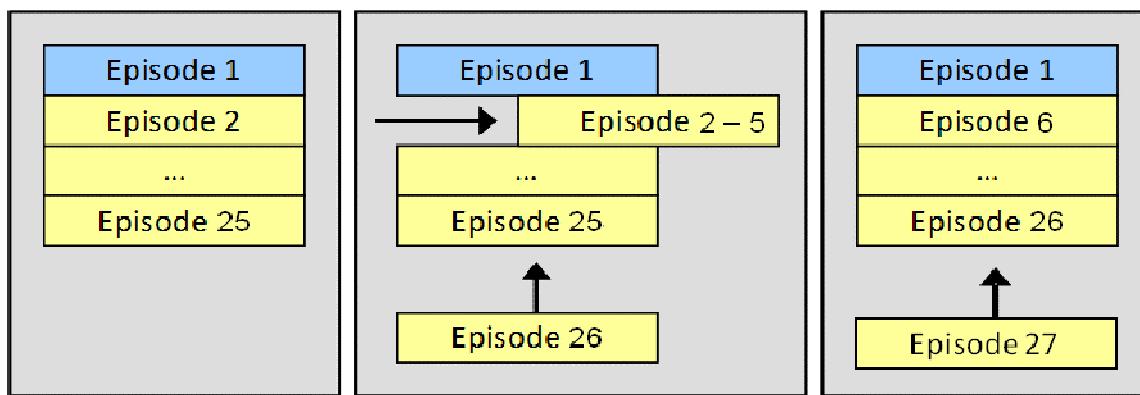


Figure 43: Treated Episode storage priority

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The following example (Figure 44: Treated Episode example) highlights a Treated episode stored from an implanted S-ICD System. Polymorphic ventricular tachyarrhythmia is recognized and capacitor charging is commenced. Following confirmation of the sustained arrhythmia, the shock is delivered.

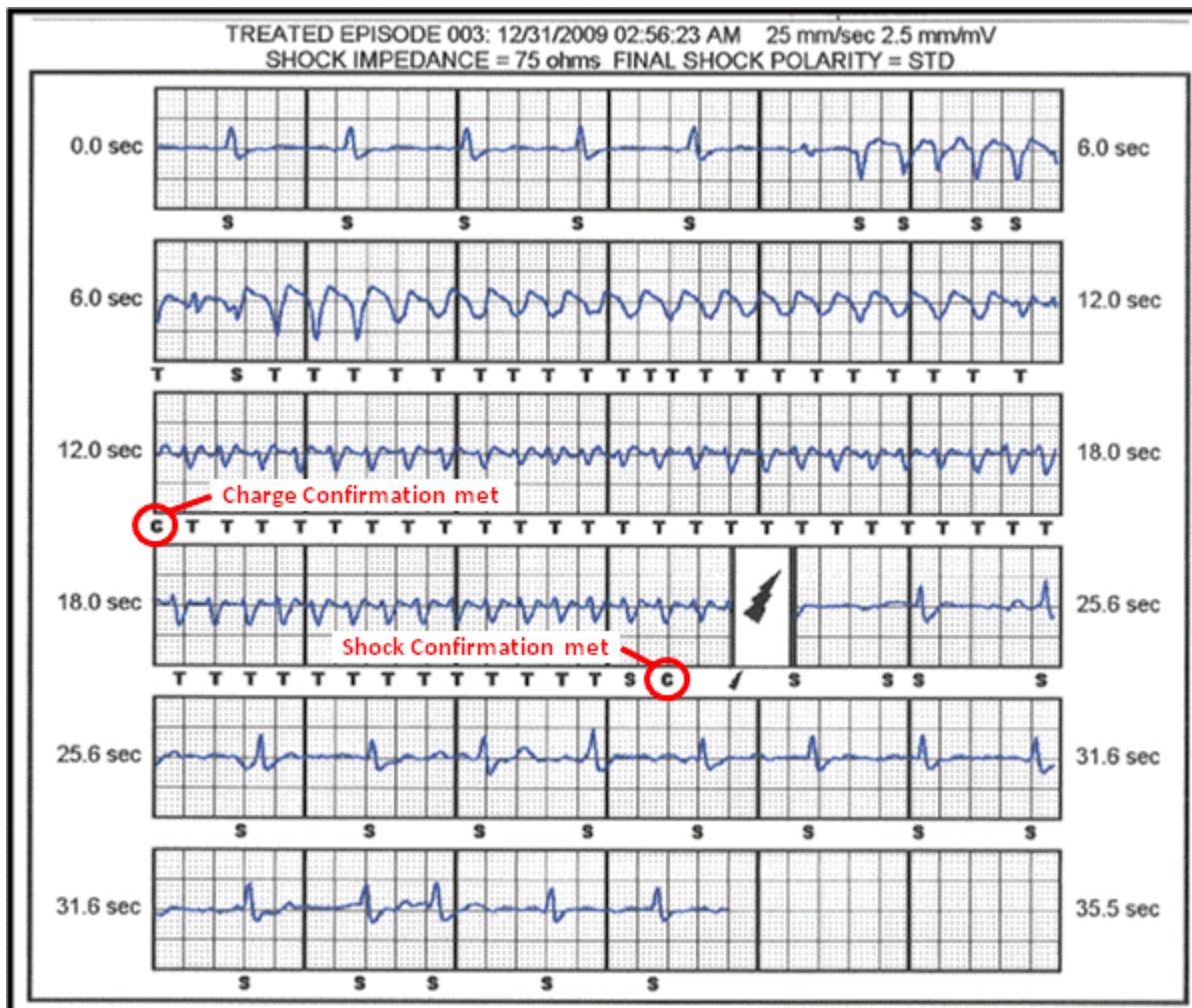


Figure 44: Treated Episode example

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### 5.5.2 Untreated Episodes

An episode is considered Untreated if capacitor charging occurs without the need to deliver any shocks.

The device stores up to 20 Untreated episodes. Episodes are stored in a first-in-first-out format. All episodes are treated with equal priority; however, if additional memory space is required, episodes are erased four (4) at a time. This process is similar to that of Treated episodes; however, the first Untreated episode is NOT retained once the 21<sup>st</sup> Untreated episode occurs. All episodes within a device are labeled with a unique Episode number that will not be repeated. This episode number will be displayed on the episode pick-list and the printed report.

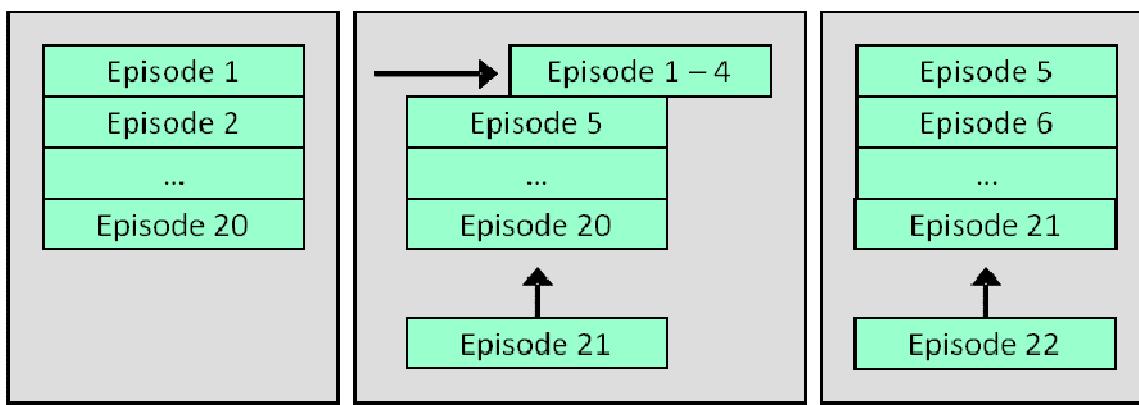


Figure 45: Untreated Episode storage priority

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The following example (Figure 46: Untreated Episode example) highlights an Untreated episode stored from an implanted S-ICD System. Polymorphic ventricular tachyarrhythmia is recognized and capacitor charging is commenced; however, spontaneous termination is recognized and therapy is appropriately withheld.

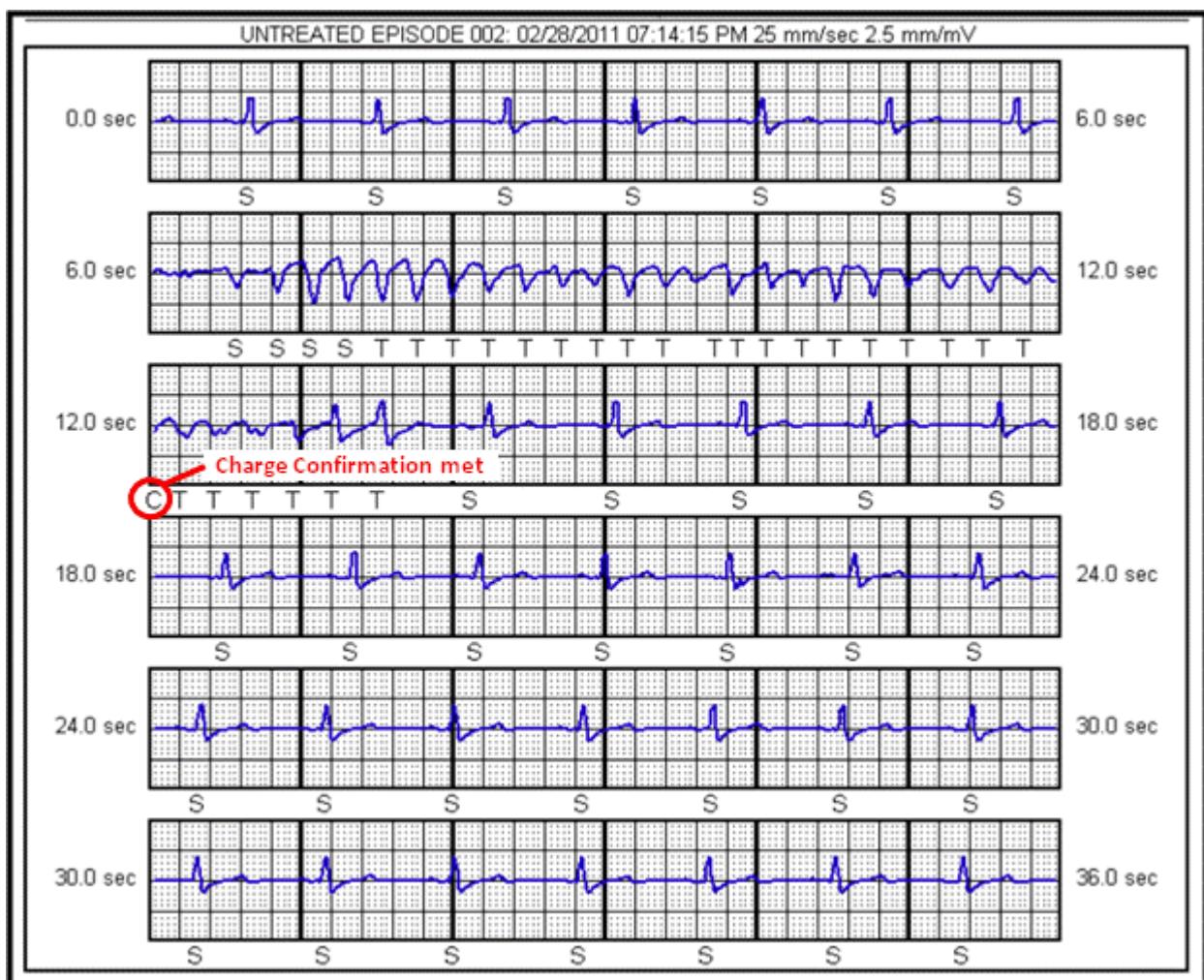


Figure 46: Untreated Episode example

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### 5.5.3 Markers

The markers listed below are displayed on the streaming S-ECG as well as the printed report:

Description	Marker
Sensed Beat (Certified Detection)	S
Noisy Beat (Suspect Detection)	N
Paced Beat	P
Tachy Detection (Shockable beat)	T
Charge Start	C
CWADD, WCDD and AIDD	•
Shock	
Return to NSR	

Table 1: Marker legend

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## 6.0 Programmable Parameters

### 6.1 Main Programming Screen

This section describes the programmable parameters available from the Main Programming Screen of the Programmer.

#### 6.1.1 Therapy ON/OFF

Automatic Therapy is programmable with the Therapy ON/OFF switch.

Therapy ON allows the device to invoke the detection algorithm and automatically treat ventricular arrhythmias. When Therapy is programmed OFF, manual shocks (including Rescue Shock) are available.

When the device is first taken out of Shelf mode, Therapy OFF is programmed.

#### 6.1.2 Post-Shock Pacing ON/OFF

Post-Shock Pacing is programmable with the Post-Shock Pacing ON/OFF switch.

When programmed ON, the device automatically delivers Post-Shock Pacing as required following shock delivery, including Manual and Rescue Shocks.

When programmed OFF, the device will not deliver Post-Shock Pacing for any delivered shocks, including Manual and Rescue Shocks.

#### 6.1.3 Therapy Zones

Two therapy zones are available for programming: Shock Zone and Conditional Shock Zone (optional).

**Nominal settings:**    Shock Zone @ 200bpm.  
                            Conditional Shock Zone OFF

The Shock Zone is programmable from 170 – 250bpm in increments of 10bpm. The optional Conditional Shock Zone, programmable from 170 – 240bpm, must be at least 10bpm below the Shock Zone.

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## **6.2 Other Programming Parameters**

This section describes programmable parameters that are available from other programming screens.

### **6.2.1 SMART Charge**

The current SMART Charge extension value is available from the programmer. The programmer allows the user to reset the extension value to 0 extensions.

### **6.2.2 Sense Vector/Gain**

The Automatic Setup process automatically selects the most robust sense vector and gain; however, these parameters can be manually programmed via the Manual Setup process.

The following Sense Vectors are available:

- Primary (B-Can)
- Secondary (A-Can)
- Alternate (AB)

The following Sense Gains are available:

- x1 (4mV range)
- x2 (2mV range)

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## 7.0 Additional Features

### 7.1 Capacitor Reformation

The SQ-Rx pulse generator automatically performs a full-energy (80 joules) capacitor reformation every four months. The energy output and reformation time interval are non-programmable.

Any full energy charge will reset the 4-month capacitor reformation schedule, thereby preventing unnecessary capacitor reformations when therapy has recently been delivered.

### 7.2 Magnet Behavior

#### 7.2.1 Magnet response

Magnet application over the SQ-Rx pulse generator suspends arrhythmia detection, thereby inhibiting therapy delivery, aborts HV capacitor charging and terminates post-shock pacing. Induction is prohibited during magnet application. If a magnet is applied during an episode, that episode will be discarded and not retained in memory. When the magnet is removed, arrhythmia detection and therapy response will resume; however, a new episode event will be started if therapy is warranted.

A manual or rescue shock may be delivered while a magnet is in contact with the pulse generator.

Magnet application does not affect communication between the pulse generator and the programmer.

Beeper tones are audible with each detected QRS complex for the first 60 seconds while the magnet is continuously applied. Magnet response does not change after 60 seconds; however, beeping tones will no longer be heard.

Parameter	Value
Shelf Mode	No magnet response
Manual Mode	Beeper tones are heard with each detected QRS complex for 60 seconds or until magnet is removed.
Automatic Mode	Arrhythmia detection and response is suspended. Beeper tones are heard with each detected QRS complex for 60 seconds or until magnet is removed.

Table 2: Pulse generator response to magnet application

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### 7.3 Internal Safety Checks: Beeper Control

The S-ICD System has an internal warning system or “Patient Alert” that is activated when the device is taken out of Shelf Mode. The Patient Alert emits an audible beeping tone to alert the patient to conditions within the SQ-Rx pulse generator that requires prompt consultation with the physician.

Once triggered, the Patient Alert beeps for 16 seconds, every nine (9) hours, until the trigger condition has been addressed and resolved.

If a condition triggers the Patient Alert, the beeper can be reset using the Beeper Control window on the programmer. If the condition that initially triggered the Patient Alert is not resolved, the alarm will again be raised and audible tones will alert the patient to consult the physician.

Patient Alerts can only be totally disabled only after the ERI and/or EOL condition has been triggered.

**NOTE:** If the device is taken out of Shelf Mode but not implanted, the device will fail the next Electrode Integrity Check (impedance test) due to a lack of connected electrode and the Patient Alert will be triggered. This alert should be cleared prior to implanting the device; however, normal operation will resume once an electrode is connected.

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## **8.0 Document Change History & Training**

### **8.1 Rev A**

DN-12345, Rev A was released to pair with the original system design and implementation used for the CE Study, Firmware version 89 and Programmer Software version 1.52.0.

### **8.2 Rev B**

DN-12345, Rev B was released to pair with the system design and implementation following the SMR update. This document pairs with Firmware version 2.1.135 and Programmer Software version 1.59.0.

### **8.3 Rev C**

DN-12345, Rev C was released to pair with the system design and implementation following the SMR4 update. This document pairs with Firmware version 2.3.308 and Programmer Software version 1.85.0.

### **8.4 Rev D**

DN-12345, Rev D was released to pair with the system design and implementation following the SMR5 update. This document pairs with Firmware version 2.3.308 and both Programmer Software versions 1.85.0 and 1.90.0.

### **8.5 Training**

<b>TRAINING REQUIREMENT LOG</b>		
<b>Revision</b>	<b>Training Required</b>	<b>No Training Required</b>
<b>A</b>		X
<b>B</b>		X
<b>C</b>		X
<b>D</b>		X

Table 3: Training requirement log