EMBLEM™/ EMBLEM™ MRI S-ICD System
Advanced Physician Training

Detection Algorithms
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Brief Summary: EMBLEM™ MRI S-ICD
After completing this module, you should be able to:

- Describe the process used by the EMBLEM™ S-ICD System to filter non-cardiac S-ECG signals.
- Explain how the EMBLEM S-ICD System transitions between detection profiles as the heart rate changes.
- Describe how the EMBLEM S-ICD System certifies the accuracy of heart rate calculations.
- Describe the arrhythmia analysis strategies used by the EMBLEM S-ICD System to classify arrhythmia detections.
- Describe the therapy decision strategy used by the EMBLEM S-ICD System to confirm the need for shock therapy.
- Describe how the SMART Pass filter reduces T-wave oversensing.
- Explain how the AF Monitor helps detect silent or new onset AF and AF progression.
Detection algorithms are designed to accurately detect cardiac signals, ensure the detection is cardiac in nature, and decide if therapy is warranted.

- During the detection phase, the system filters (removes) non-cardiac signals and uses rate detection profiles to sense likely cardiac activations.
- During the certification phase, the system confirms the cardiac nature of sensed activations and uses several algorithms to identify and correct oversensing, thereby ensuring the accuracy of heart rate calculations.
- During the decision phase, the system analyzes the certified heart rate and classifies detections to determine if there is a shockable arrhythmia. *Detecting within the Conditional Shock Zone (dual zone programming) are analyzed via the three rhythm discrimination algorithms.*

The amplitude of a subcutaneous signal (S-ECG) is smaller than that of a transvenous signal (TV-ECG) and the frequency content differs significantly. The extra step of certification prevents counting of non-cardiac signals.
**Signal Filters**

- **Band Pass** and **Notch filters** permit cardiac signals to pass through for analysis.
  - The **Band Pass filter** accepts S-ECG signals within the cardiac frequency range and rejects signals outside that range.
  - The **Notch filter** removes power line frequencies. This filter is automatically configured during initial programming upon selection of the **Time Zone** (geographic region). In North America the setting is 60 Hz; in Europe it is 50 Hz. See Figure B.

**KEY CONCEPT**

Signal filters reject S-ECG signals outside the cardiac frequency range.

**NOTES**

The programmer prompts the user to reset the Time Zone after a battery charge.
The EMBLEM™ S-ICD System transitions between detection profiles as the heart rate changes. Dual zone programming reduces the chance of inappropriate shock (IDE Study).

- The faster the detected heart rate, the more aggressive the detection profile.
- Detection sensitivity can be adjusted by programming higher or lower rates for the Shock Zone (170-250 bpm) and Conditional Shock Zone (170 to 240 bpm).
The Waveform Appraisal algorithm ensures noise detections are not included in heart rate calculations.

- During Waveform Appraisal, the EMBLEM S-ICD System analyzes the characteristics of the detected signal. If noise is suspected, the S-ECG is marked with an N (noise) and the intervals before and after the N are not used to calculate the heart rate. See Figure A.

- Example: In Figure B, the yellow dots represent noise superimposed on the NSR. The green dots represent the certified rate. The black dots show that noise detections do not alter the certified rate. Essentially, the system cannot detect and treat arrhythmias when noise is present.

At the one month follow-up, consider asking the patient to perform isometric exercises (palm press, chair raise) to assess myopotential sensing. If the S-ECG shows noise markers (N), evaluate other sense vectors.
Rate Certification algorithms ensure double detections are not included in heart rate calculations.

- **Algorithm 1: Static Template Analysis** identifies and corrects T-wave double detection (alternating morphology pattern). It compares the morphology of the stored NSR template to that of the last three intervals and looks for a match-nonmatch-match pattern.

- **Algorithm 2: Wide Complex Analysis** identifies and corrects double detection of wide morphology complexes, which may occur with bundle branch block. It looks for a repeating pattern of closely coupled detections and applies various criteria.

- **Algorithm 3: Interval Analysis** identifies double detections (wide complex or T-wave) by looking for a pattern of alternating interval durations (e.g., long-short, long-short).

- **Algorithm 4: Alternating Morphology Analysis** identifies an alternating morphology pattern in a group of three successive complexes (match-nonmatch-match pattern). It uses the stored template for width.

Overcounted detections are marked with a dot and discarded. Valid intervals are combined into one certified interval.

**KEY CONCEPT**

Static Template Analysis identifies and corrects T-wave double detection based on the stored NSR template.

Wide Complex Analysis identifies and corrects double detection of wide morphology complexes.

Interval Analysis corrects oversensing by identifying alternating interval durations.

Alternating Morphology Analysis identifies an alternating morphology pattern in a group of three successive complexes.

**NOTES**

The EMBLEM™ S-ICD System manages oversensing via pre-implant patient screening, post-implant template formation, and rate certification algorithms.
Upon certification, the EMBLEM™ S-ICD System decides if the detection falls into a non-shockable zone (NSR Mode) or therapy zone (Tachy Mode).

- The system transitions from **NSR Mode** to **Tachy Mode** when the certified heart rate reaches the lowest programmed therapy zone.

- The system transitions from **Tachy Mode** to **NSR Mode** when the heart rate remains below the Hysteresis Zone (40 ms) for 24 consecutive intervals. *This prevents a premature return to NSR Mode in the event of underdetection.*

**KEY CONCEPT**

Tachy Mode starts when the heart rate reaches the lowest programmed therapy zone and ends when the rate is maintained below the Hysteresis Zone for 24 intervals.

**NOTES**
The **Arrhythmia Classification** diagram shows how the EMBLEM™ S-ICD System decides if the certified detection is a normal sensed beat (S) or ventricular tachycardia (T) requiring shock therapy.

- All certified detections within the programmed Shock Zone are considered shockable.
- All certified detections within the Conditional Shock Zone are analyzed via the rhythm discrimination algorithms as follows:
  - **Static Morphology** compares the degree of morphology similarity between the current detection and the stored NSR template.
  - **Dynamic Morphology** compares the degree of morphology similarity between two consecutive detections.
  - **QRS Width** compares the QRS width of the current detection with the stored NSR template. A monomorphic arrhythmia with a wide QRS is considered shockable (T). One with a narrow QRS is considered normal (S).

**KEY CONCEPT**

Arrhythmia Classification is used to identify VT/VF episodes that require shock therapy.

**NOTES**

It is important to store an NSR template to ensure optimal application of algorithms.
After identifying shockable VT/VF episodes, the EMBLEM™ S-ICD System performs several therapy decision steps to confirm the patient’s need for shock therapy.

- **The system evaluates X/Y criteria** to ensure the VT/VF episode is sustained. X/Y is a counter that compares detections and compensates for double detections and noise.

- **SMART Charge** ensures the VT/VF episode (X/Y count) is sustained for a sufficient duration before charging. The nominal duration before charging is two additional intervals after x/y criteria are met (e.g. 18/24). The system automatically extends the duration in the presence of a non-sustained VT/VF (up to five extensions and fifteen intervals).

- **Charge Confirmation** ensures the two most recent detections remain shockable before initiating the capacitor charge.

- **Shock Confirmation** ensures the VT/VF episode is still present after capacitor charging is complete. This strategy prevents unnecessary therapy for short VT runs after spontaneous VT/VF termination.

Upon shock confirmation, the EMBLEM S-ICD System delivers a shock synchronized to the next detection.
SMART Pass is a third generation software update that reduces the incidence of cardiac oversensing by applying an additional High Pass filter.

- SMART Pass reduces the amplitude of low frequency signals such as T-waves. It allows high frequency signals such as R-waves, VT, and VF to pass through. Figure A.

- When SMART Pass is On, the EMBLEM S-ICD uses the Rate Certification algorithms to calculate the heart rate as usual. Certified detections are analyzed via the rhythm discrimination algorithms as usual.

- Figure B compares sensing with SMART Pass OFF and On. When programmed On, low amplitude T-wave signals are filtered out.

EFFORTLESS study results at three years showed that S-ICD software updates reduced the incidence of inappropriate shock from 8.1% to 3.8%. Figure C.

**KEY CONCEPT**

SMART Pass reduces the amplitude of low frequency signals (T-waves) to reduce cardiac oversensing and inappropriate shock.

**NOTES**

Use Manual Setup to update the EMBLEM S-ICD software (See IFU). Store an exercise test template to ensure optimal application of SMART Pass.
The **AF Monitor** notifies clinicians when at least six minutes of AF have accumulated in 24 hours. It is a tool to help in diagnosing silent or new onset AF and its progression.

- The AF Monitor uses a 192 beat window to analyze and classify the detected rhythm (NSR or AF). To be classified AF, at least 60% of the beats in the window must be AF. The S-ICD adds the durations of all windows that meet AF criteria to determine how many minutes of AF accumulated in 24 hours.

- All windows are analyzed via two algorithms. The **Ventricular Scatter** algorithm calculates beat-to-beat rate differences to determine if the rate is stable (NSR), unstable (AF), or random (PVC, double detection). It classifies the rhythm based on the ratio of events in each rate bin.* See Figure A.

- The **Heart Rate Density Index (HRDI)** places each of the 192 beats in a histogram depicting the heart rate distribution. It then determines the HRDI and Heart Rate mode and classifies the rhythm as NSR (narrow distribution, slower rate) or AF (wider distribution, faster rate). See Figure A.

Collected AF Monitor data (number of days; number of minutes per day) can be accessed from the programmer for 90 days and from Latitude NXT for 100 days.

**KEY CONCEPT**

The AF Monitor uses a 192 beat window and two algorithms to determine how many minutes of AF accumulated in 24 hours.

**NOTES**

- The duration of a 192 beat window is about three minutes at 60 bpm.

- When programmed On, the AF Monitor operates even when tachy therapy is programmed Off.

- Bench testing showed that the AF Monitor has a sensitivity ≥ 87% and a positive predictive value ≥ 90%.²

*A stable rhythm varies less than 5 bpm from beat to beat. An unstable rhythm varies more than 5 bpm.
**NSR to shockable polymorphic VT**

- Static morphology (red): decreased correlation to NSR template
- Dynamic morphology (green): beat-to-beat dissimilarity
- QRS width (pink): wider than NSR

**KEY CONCEPT**

NSR to shockable polymorphic VT

**NOTES**

- Detection Algorithms

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NSR to monomorphic VT

- Static morphology (red): decreased correlation to NSR template
- Dynamic morphology (green): beat-to-beat similarity
- QRS width (not shown): If QRS widens compared to NSR, shock therapy is required

KEY CONCEPT

NSR to monomorphic VT

NOTES
**NSR to shockable VT**

- Static morphology (red): drops during VT
- Dynamic morphology (green): remains high during beat-to-beat
- QRS width (pink): is narrow during NSR and wide during VT
Summary of arrhythmia evaluation:

- **Detection Phase** The EMBLEM™ S-ICD System filters (removes) non-cardiac signals and uses rate-dependent detection profiles to sense likely cardiac activations.

- **Certification Phase** The EMBLEM S-ICD System certifies detections via Waveform Appraisal; then certifies the heart rate via oversensing algorithms.

- **Decision Phase** The EMBLEM S-ICD System analyzes the rate to identify possible tachyarrhythmias; then analyzes subsequent detections using discrimination algorithms and X/Y criteria to decide if therapy is necessary.

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**KEY CONCEPT**

Phases of arrhythmia detection
1. Detect cardiac signals
2. Certify detections
3. Decide if therapy is needed

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**NOTES**

The discrimination algorithms apply only to the Conditional Shock Zone (dual zone programming).
References


**Indications for Use**
The S-ICD System is intended to provide defibrillation therapy for the treatment of life-threatening ventricular tachyarrhythmias in patients who do not have symptomatic bradycardia, incessant ventricular tachycardia, or spontaneous, frequently recurring ventricular tachycardia that is reliably terminated with anti-tachycardia pacing.

**Contraindications**
Unipolar pacing and impedance-based features are contraindicated for use with the S-ICD System.

**Warnings**
Read the manual thoroughly before using the S-ICD System to avoid damage to the pulse generator and/or subcutaneous electrode. Such damage can result in patient injury or death. For single patient use only. Do not reuse, reprocess, or resterilize. All Boston Scientific S-ICD implantable components are designed for use with the Boston Scientific S-ICD System only. Connection of any S-ICD System components to a non-compatible component will result in failure to deliver life-saving defibrillation therapy. Always have external defibrillation equipment and medical personnel skilled in CPR available during implant and follow-up testing. Using multiple pulse generators could cause pulse generator interaction resulting in patient injury or a lack of therapy delivery. Test each system individually and in combination to help prevent undesirable interactions. Concomitant use of the S-ICD System and implanted electromechanical devices (for example a ventricular assist device, VAD; or implantable insulin pump or drug pump) can result in interactions that could compromise the function of the S-ICD, the co-implanted device, or both. Electromagnetic (EMI) or therapy delivery from the co-implanted device can interfere with S-ICD sensing and/or rate assessment, resulting in inappropriate therapy or failure to deliver therapy when needed. In addition, a shock from the S-ICD pulse generator could damage the co-implanted device and compromise its functionality. To help prevent undesirable interactions, test the S-ICD system when used in combination with the co-implanted device, and consider the potential effect of a shock on the co-implanted device. Handle the components of the S-ICD System with care at all times and maintain proper sterile technique. Do not modify, cut, kink, crush, stretch or otherwise damage any component of the S-ICD System. Use caution handling the subcutaneous electrode connector. Do not directly contact the connector with any surgical instruments such as forceps, hemostats, or clamps. Use appropriate anchoring techniques as described in the implant procedure to prevent S-ICD System dislodgement and/or migration. Do not implant in MRI site Zone III. Use caution when placing a magnet over the S-ICD pulse generator because it suspends arrhythmia detection and therapy response. In patients with a deep implant placement (greater distance between the magnet and the pulse generator) magnet application may fail to elicit the magnet response. Do not expose a patient with an implanted S-ICD System to diathermy. EMBLEM S-ICD devices are considered MR Conditional. Unless all MRI Conditions of Use are met, MRI scanning of the patient does not meet MR Conditional requirements for the implanted system. The Programmer is MR Unsafe and must remain outside the MRI site Zone III. During MRI Protection Mode the Tachycardia therapy is suspended. MRI scanning after ERI status has been reach may lead to premature battery depletion, a shortened device replacement window, or sudden loss of therapy. The Beeper may no longer be usable following an MRI scan. It is strongly recommended that patients are followed on LATITUDE NXT after an MRI scan if they are not already. Advise patients to seek medical guidance before entering environments that could adversely affect the operation of the active implantable medical device, including areas protected by a warning notice that prevents entry by patients who have a pulse generator. The pulse generator may be more susceptible to low frequency electromagnetic interference at induced signals greater than 80 uV. The S-ICD System has not been evaluated for pediatric use.
Precautions
For specific information on precautions, refer to the following sections of the product labeling: clinical considerations, sterilization and storage, implantation, device programming, environmental and medical therapy hazards, hospital and medical environments, home and occupational environments, follow-up testing, explant and disposal and supplemental precautionary information.

Advise patients to avoid sources of EMI because EMI may cause the pulse generator to deliver inappropriate therapy or inhibit appropriate therapy.

Potential Adverse Events
Potential adverse events related to implantation of the S-ICD System may include, but are not limited to, the following: Acceleration/induction of atrial or ventricular arrhythmia, adverse reaction to induction testing, allergic/adverse reaction to system or medication, bleeding, conductor fracture, cyst formation, death, delayed therapy delivery, discomfort or prolonged healing of incision, electrode deformation and/or breakage, electrode insulation failure, erosion/extrusion, failure to deliver therapy, fever, hematoma-seroma, hemothorax, improper electrode connection to the device, inability to communicate with the device, inability to defibrillate or pace, inappropriate post shock pacing, inappropriate shock delivery, infection, keloid formation, migration or dislodgement, muscle/nerve stimulation, nerve damage, pneumothorax, post-shock/post-pace discomfort, premature battery depletion, random component failures, stroke, subcutaneous emphysema, surgical revision or replacement of the system, syncope, tissue redness, irritation, numbness or necrosis.

Patients who receive an S-ICD System may develop psychological disorders that include, but are not limited to, the following: depression/anxiety, fear of device malfunction, fear of shocks, phantom shocks.

For a list of all potential adverse events associated with MRI scanning, refer to the MRI Technical Guide.

Refer to the product labeling for specific indications, contraindications, warnings/precautions and adverse events. Rx only. (Rev A)