

INSTRUCTIONS FOR USE

EMBLEM™ S-ICD
Automated Screening Tool (AST)

REF **3889**
REFERENCE
NUMBER

CAUTION: Federal law (USA)
restricts this device to sale by or on
the order of a physician trained or
experienced in device implant and
follow-up procedures.

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Description

The Model 3889 EMBLEM S-ICD Automated Screening Tool (AST) is software used on the Model 3300 LATITUDE Programming System to screen patients to assess them for implant of the EMBLEM Subcutaneous Implantable Cardioverter Defibrillation (S-ICD) system. These instructions describe how to use the AST.

Intended Use

The AST application is solely intended to screen patients for S-ICD implant and is not intended to be used for any cardiac diagnostic purpose. The AST is an alternative to the Model 4744 Patient Screening Tool. The two screening tools serve the same purpose and may be used independently or together, except for the printed filtered report, which cannot be used with the manual screening tool.

Intended Audience

This literature is intended for use by professionals trained or experienced in device implant and/or follow-up procedures.

Indications for Use / Contraindications / Warnings and Precautions

There are no indications, contraindications, warnings or precautions specific to the Model 3889 EMBLEM S-ICD Automated Screening Tool (AST). Refer to the appropriate S-ICD System Pulse Generator (PG) and Programmer User's Manuals for a list of indications for use, allowed concomitant device settings, contraindications, and warnings and precautions for the S-ICD system.

Equipment Needed

- Model 3300 Programmer with AST software application
- External ECG cables compatible with the Model 3300 Programmer and associated accessories (e.g. electrodes and skin prep material)
- Measuring tool for measuring 14 cm (Model 4744 Patient Screening Tool may be used)

NOTE: The Instructions tab contains a 14 cm line for reference.

- External printer or pen drive connected to the Model 3300 Programmer

Collecting Surface ECG

In order to perform the patient screening process, a surface equivalent of the subcutaneous sensing vectors used by the implanted S-ICD system must be obtained. The Model 3300 Programmer is used to collect the surface ECG and the AST software application evaluates the QRS complexes for each patient posture tested.

Navigating to the AST Application

1. Power on the Model 3300 Programmer.
2. Click **S-ICD Application** to go to the **S-ICD Applications** screen.
3. Click **EMBLEM S-ICD Automated Screening Tool** from the **S-ICD Applications** screen.

Establishing the ECG Connection

Preparing Skin Prior to Placing Surface Electrodes

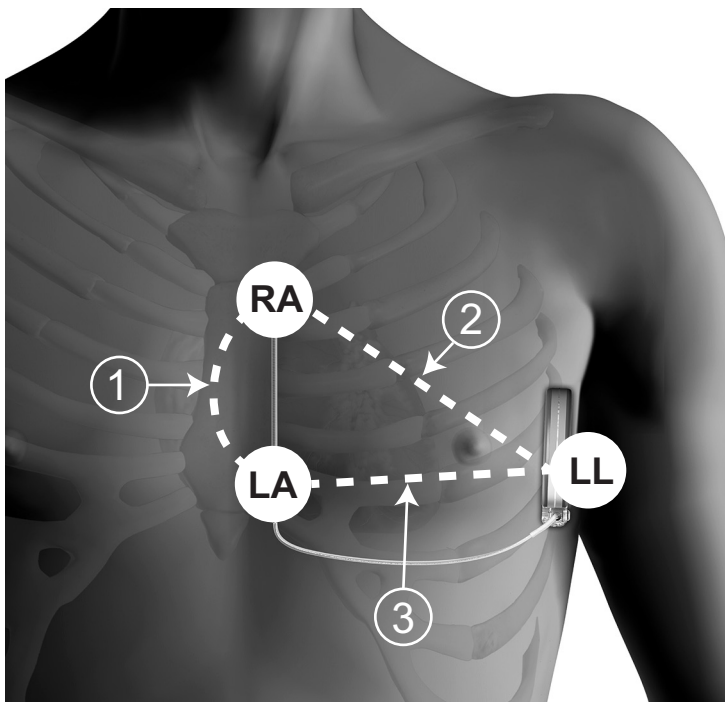
1. Remove hair.
2. Clean skin using a non-alcohol wipe and/or skin prep gel.

Positioning the Surface ECG Electrodes

It is important to collect the surface ECG in the location that represents the intended position of the implanted S-ICD System. When placing the S-ICD System in the typical implant location, the surface ECG electrodes should be positioned as follows (**Figure 1 Typical Placement of Surface ECG Electrodes for Patient Screening**). If a non-standard S-ICD System subcutaneous electrode or pulse generator placement is desired, the surface ECG electrode locations should be modified accordingly.

For typical implantation:

- **ECG Electrode LL** should be placed in a lateral location, at the 5th intercostal space along the midaxillary line to represent the intended location of the implanted pulse generator.
- **ECG Electrode LA** should be placed 1 cm left lateral of the xiphoid midline to represent the intended location of the proximal sensing electrode of the implanted subcutaneous electrode.
- **ECG Electrode RA** should be placed 14 cm superior to the ECG Electrode LA, to represent the intended position of the distal sensing tip of the implanted subcutaneous electrode.
 - Measure 14 cm using Model 4744 Patient Screening Tool or other measuring tool.
- **ECG Electrode RL** is recommended at the desired location to serve as the patient reference electrode.



1 - Alternate (LEAD I); 2 - Secondary (LEAD II); 3 - Primary (LEAD III)
RA - Right Arm; LA - Left Arm; LL - Left Leg


Figure 1 - Typical Placement of Surface ECG Electrodes for Patient Screening

The following best practices are recommended to obtain an ECG with a stable baseline, free of noise and motion artifacts:

- Ensure surface electrodes are new. Avoid using electrodes from packaging that was previously opened. Electrodes dry out quickly after the package is opened.
- Ensure enough electrode gel is on the electrode contact point.

Verifying a Clean ECG

Observing the ECG on the Screen

1. Observe the ECG signal on the Model 3300 Programmer screen. Each ECG signal should have a **stable baseline** and be **free of noise** and **motion artifacts**.
2. Enter the full screen view to zoom in on the signal by clicking the magnifying glass  button in the upper right-hand corner. Gain may be adjusted to enhance view. Manual gain adjustments will not affect AST results or printed reports.

Consider the following troubleshooting tips if noise or a wandering baseline is observed:

- Replace ECG cables used to collect surface ECGs.
- In particularly difficult cases, re-prepare the skin with some light abrasion at the electrode sites (using a gauze pad, for example).
- Ask patient to inhale then exhale and hold for 10 seconds to manage respiratory artifact.

Using the AST Application

The AST application is arranged in tabs. Complete each tab to run the screening tests.

Information Tab

Complete the patient information (**Patient Name or ID** and **Date of Birth** are required fields).

NOTE: This information can be edited at any point in the screening process.

Screening Tab

EMBLEM™ S-ICD Automated Screening Tool

Primary: _____ Secondary: _____ Alternate: _____ Surface Rate: <30

Information | **Screening** | About | Instructions

- Place Leads.
 - Run tests with the patient both supine and standing/sitting.
 - Consider also testing at elevated heart rate for active patients.
 - Minimum screening criteria: One lead must be OK in all tested postures.

Sternal Lead Position: **Left Sternal Margin**

[Run] Supine [Run] Standing/Sitting [Choose] Optional Posture [Choose] Optional Posture [Choose] Optional Posture [Choose] Optional Posture

Primary						
Secondary						
Alternate						
Notes						

[Save Report] [Print Report] [Add Filtered Electrograms to Report] [End Screening Session]

Utilities | About | Select PG | RealTime Log


Figure 2 - Screening Tab of the S-ICD Automated Screening Tool


Run the ECG screening tests on the **Screening** tab.

1. Select the **Sternal Lead Position** by clicking the pull-down menu (defaults to the most common placement – **Left Sternal Margin**; other options are **Right Sternal Margin** and **Medial**). The **Sternal Lead Position** represents the planned location of the vertical portion of the S-ICD implanted electrode.

NOTE: Data can be collected for multiple lead positions within a single AST session.

2. Run **Supine** posture (required) - Put the patient into a supine posture and click the corresponding Run button to run the ECG screening test. Results are displayed when the test is complete.
3. Run **Standing/Sitting** posture (required) - Have the patient assume either a standing or sitting posture and click the corresponding Run button to run the ECG screening test.

4. If desired, choose optional postures or conditions - Click the **Choose** button associated with an **Optional Posture** column to add patient-specific postures or conditions, as needed. Click the drop-down to select from a list of commonly used optional postures or type in the text field to add posture or condition descriptions.
5. Click the magnifying glass  button below each column to access the **Snapshot** screen and review the details of each test. Each ECG signal should have a **stable baseline** and be **free of noise** and **motion artifacts**.

*NOTE: It is possible to repeat a test. A clinician might want to repeat a test if the test result is **FAIL** but a review of the ECGs reveals a disruption in the signal from a noise source, patient movement, or intermittent issue with the connection to the surface leads. To repeat a test, simply click the Run  button for the desired posture again, then observe the results.*

NOTE: If testing more than 6 postures or conditions per sternal lead position, save the report and start a new session. The user interface provides only 6 columns for postures or conditions for a single sternal lead position.

*NOTE: The **Advanced View** option on the **Snapshot** screen adds the filtered surface ECG data used by the AST. Your local Boston Scientific representative or Technical Services may assist in using this view to further understand the AST results.*

Using the Screening Report to Determine an Acceptable Sense Vector

Report Description

The EMBLEM S-ICD Automated Screening Report PDF summarizes screening results and instructs users to check QRS complex morphology across postures to identify acceptable leads. The ECG data used by the AST is provided for each lead/posture combination tested.

NOTE: The gain of the ECG signal for each vector is automatically adjusted prior to printing. This allows the printed report ECGs (excluding advanced view ECGs) to be assessed with the Model 4744 Patient Screening Tool, if desired. Always

ensure that printed ECGs are scaled correctly by confirming that the distance between major gridlines is 1 cm.

Saving, Printing and Exporting the Report

1. To save the report, click the **Save Report** button on the lower left-hand corner of the **Screening** tab - a PDF of the report is saved to the Model 3300 Programmer hard drive.

NOTE: It may take a couple of minutes to generate the PDF report, depending on the number of postures or conditions run.

NOTE: The Programmer limits patient data stored on the hard drive by automatically deleting the data after 90 days.

NOTE: Clinicians have the option to include filtered signals in the printed or saved report. Do not assess filtered signals with the Model 4744 Patient Screening Tool.

2. To print the report, click the **Print Report** button to send the report to a connected external printer.
3. To export the data to a pen drive:
 - Click **End Screening Session** to return to the programmer home screen.
 - Insert pen drive into the USB port of the Model 3300 programmer.
 - Click **Patient Data Management**, then select the **Export Screening Data** tab.
 - Select the reports to export.
 - Click **Save** or **Save with Password Protect** and follow the prompts (all selected reports are exported).

Note: In the AST application, the USB pen drive used to store exported patient data can contain both encrypted and non-encrypted patient data.

Determining an Acceptable Sense Vector

The physician must review the report and determine whether the patient is suitable for implant of the S-ICD System. Confirm that the following conditions are met:

- At least one common ECG lead must be deemed acceptable for all tested postures. At a minimum, **Supine** and **Standing/Sitting** postures must be tested.

Reasons for failure include:

- **R waves too small**
The average amplitude of the R wave peaks was too small
- **Score too low due to large R waves**
The average amplitude of the R-wave peaks was too large
- **Score too low due to low R/T ratio**
The ratio of the average R wave amplitude to the average post-R wave amplitude was too low
- **Score too low**
A combination of factors caused a low score
- The morphology of the intrinsic/paced QRS complex is stable across postures (similar positive/negative peak amplitudes and QRS widths). No significant change to the QRS complex is noted as a result of postural changes. For notched signals, ensure that the location of the larger peak is consistent in relation to the smaller peak.

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 and/or inappropriate shock is increased.

Maintenance, Troubleshooting, Handling, Standards, and Specifications

Refer to the LATITUDE Programming System Operator's Manual, Model 3300 for maintenance, troubleshooting, handling (including symbols on devices and packaging), standards, and specifications information for the Model 3300 Programmer device.

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