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<th>Symbol</th>
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Software Upgrade Kit

Software Upgrade Kit
Introduction

Module description

The EnSite™ AutoMap Module is a software entitlement feature within the EnSite™ Cardiac Mapping System. The AutoMap Module automates the point collection process, based on the user-defined settings. As the catheter is moved, points are collected when the user-defined settings are met.

NOTE: Refer to the EnSite™ Cardiac Mapping System Instructions for Use for complete operating instructions and Regulatory considerations.

Indications for use

Refer to the EnSite™ Cardiac Mapping System Instructions for Use for Indications for Use.

Important Safety Information

WARNING: A Warning indicates that there is a risk of injury to the patient or user.

CAUTION: A Caution refers to a condition that may lead to damage or malfunction of the equipment.

NOTE: A Note provides additional information.

Operator Requirements

The EnSite™ AutoMap Module must be operated by, or under the supervision of, an electrophysiologist trained in the operation of the EnSite™ Cardiac Mapping System with the EnSite™ AutoMap Module and supported by other qualified personnel trained in the field of cardiac electrophysiology (EP). It must be used in conjunction with other equipment required for electrophysiology studies such as suggested by the Heart Rhythm Society.


Developed in partnership with the European Heart Rhythm Association (EHRA); European Cardiac Arrhythmia Society (ECAS); American College of Cardiology (ACC); American Heart Association (AHA); Society of Thoracic Surgeons (STS), and the Heart Rhythm Society.


EnSite™ AutoMap Module Overview

Continuous Mapping Features

![Mapping Screen](image)

**Figure 1. Mapping Screen**

<table>
<thead>
<tr>
<th>Item</th>
<th>Feature</th>
<th>Description</th>
</tr>
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</table>
| 1    | ![AutoMap start/stop buttons](image) | **Start AutoMap/Stop AutoMap button:** Click to begin automatic mapping point collection — click again to stop automatic mapping point collection.  
**Stop All button:** Stops automatic mapping point collection AND stops anatomic model point collection. This is relevant when AutoMap is being used with the OneMap™ feature.  
- The AutoMap control is only available in the Mapping Workflow.  
- The user can also start/stop the AutoMap feature by using shift+F11 key. |
| 2    | ![AutoMap threshold settings](image) | The software allows users to Display/Hide the AutoMap Settings by clicking on the gear button.  
- The software allows users to Pin/Unpin the AutoMap Settings menu by clicking the pin button. |
### AutoMap Settings

AutoMap Settings define the minimum criteria that must be met for a mapping point to be automatically collected. Select the box next to each criteria you want to use for automatic point collection.

**Score Threshold:** Full or any combination of the 12 Surface Leads. Only collect mapping points if the 12-Lead Surface Morphology is XX% similar or higher compared to the original template beat 12-Lead Surface Morphology. The user has the ability to set the Score Threshold from 0 to 100%.

- By default the Score Threshold is enabled and is set to 90%.

**Cycle Length Tolerance:** Only collect mapping points if the intracardiac measured (CS, HIS, other) Cycle Length is within +/- XX ms of original template beat Cycle Length. User has the ability to set the Cycle Length Tolerance from +/- 0 to 150 ms.

- Default the Cycle Length Tolerance is enabled and is set to +/- 20 ms.

**Speed Limit:** Only collect mapping points if the mapping catheter is moving less than XX.X mms/s. User has the ability to set the Speed Limit from 0.1 to 75 mm/s.

- Default the Speed Limit is enabled and is set to 10.0 mm/s.

**Distance Threshold:** Only collect mapping points if the 3D position of the roving catheter electrode is X.X mm or more from the previously collected mapping point from that electrode. User has the ability to set the Distance Threshold from 0.1 to 10 mm.

- Default Distance Threshold is enabled but the default value is set to 1.0 mm.

**SNR Threshold:** Only collect mapping points if the Signal-To-Noise Ratio on the roving catheter signal is X.X or higher. User has the ability to set the SNR Threshold from 1 to 50.

- Default the SNR Threshold is enabled and is set at 5.0.

**Force (Contact Force Range):** This criteria can only be used if the EnSite™ Contact Force Module is installed and the physician is mapping with a TactiCath™ catheter. Only collect mapping points if the Average Contact Force (as measured by a TactiCath™ Contact Force Catheter) is at least X grams and less than Y grams. User has the ability to set the Lower Threshold from 0 to 150 grams. User has the ability to set the Upper Threshold from 0 grams to 150 grams.

- Default the Contact Force Threshold is not enabled but the default lower threshold is 10 grams and the default upper threshold is 50 grams.

**Enhanced Noise Rejection:** Only collect mapping points if the roving catheter signal does not have certain types of noise (Signals with saturations, electrode-to-electrode contact, open electrode noise, signals with degraded conditions such as no location or dropped data). Only uncheck for pace mapping. User has the ability to set the Enhanced Noise Reduction on or off.

- Default the Enhanced Noise Reduction is enabled.
<table>
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</table>
| 4    | ![Diagram](image1.png) | When mapping points are collected a flash occurs at the active roving catheter, mapping electrodes that met all of the point collection criteria.  
- The flash at electrodes indicators may be disabled by unchecking the Flash New Points box. |
| 5    | ![Diagram](image2.png) | Click the Meter icon on the Tool Pallet to access the Meter Displays menu.  
The Point Collection Status defaults to disabled. It can be turned on by checking the box within the Meter Displays menu.  
Once the Point Collection Status is enabled, it can be disabled within the Meter Displays menu or by right clicking the mouse on top of the point collection status box and clearing the checkmark. |
6  Point Collection Status

<table>
<thead>
<tr>
<th>Feature</th>
<th>Description</th>
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<tbody>
<tr>
<td>Score Icon</td>
<td>The individual point collection status icons flash red when the respective user-defined settings are not met. When one or more of these icons is red, mapping points will not be collected.</td>
</tr>
<tr>
<td>Cycle Length Icon</td>
<td>In the example to the left, mapping points would not be collected because the current beat Cycle Length is outside the Cycle Length of interest, thus the Cycle Length icon is red.</td>
</tr>
<tr>
<td>Speed Limit Icon</td>
<td>The entire mapping Point Collection Status box flashes white when a point is collected.</td>
</tr>
<tr>
<td>Distance Threshold Icon</td>
<td>When a particular point collection criteria is not enabled, the point collection status icon for that criteria will be displayed gray.</td>
</tr>
<tr>
<td>Noise Icon</td>
<td><strong>NOTE:</strong> The Noise Icon includes SNR and Enhanced Noise Rejection if both are enabled.</td>
</tr>
<tr>
<td>Contact Force Icon</td>
<td><strong>NOTE:</strong> For Speed Limit, Distance Threshold, and Noise criteria; the particular criteria must be unmet for all roving electrodes being collected in order for the icon to turn red. As an example, the SNR would have to be beneath the threshold for every roving electrode being collected in order for the icon to turn red.</td>
</tr>
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</table>

7  Selected Point Data Box

<table>
<thead>
<tr>
<th>Feature</th>
<th>Description</th>
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<tbody>
<tr>
<td>Score</td>
<td>Displays the Score, Cycle Length, Contact Force (if the EnSite™ Contact Force Module is installed and if the physician is using a TactiCath™ Catheter to map), and LAT for the current beat or the selected mapping point.</td>
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<tr>
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<tr>
<td>Force 1 g</td>
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<td>LAT -22 ms</td>
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<td>Item</td>
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</table>
| 8    | Independent Scoring Interval | The Independent Scoring Interval defines the portion of the template mapping point’s 12-lead surface morphology that is used to compare with the current beat’s 12-lead surface morphology to determine the Score of correlation between the two.  

If the independent scoring interval is not enabled (the checkbox is not selected), then the 12-lead surface morphology match score will be determined using the entire portion of the roving activation interval.  

Select the checkbox for Show Scoring Interval Lines so that the two, red Independent Scoring Interval lines are displayed and can be adjusted to contain the relevant portion of the signal. |
|      | ![Image](image1) | ![Image](image2)                                                                                                                                |
| 9    | TurboMap         | Use the **TurboMap** speed to play back through a recording at 10x’s real-time speed. This may be useful for creating a secondary map from the original mapping dataset. |
The EnSite™ AutoMap Module Workflow

1. Set up Mapping settings as usual (refer to the EnSite™ Cardiac Mapping System Instructions for Use for information).
2. Manually Freeze/Save the first point.
3. Set up the AutoMap Settings point collection criteria as described above.
4. Click the Start AutoMap button and start collecting mapping points.
5. Click the Stop AutoMap button to stop collecting mapping points.

Score Map

A Score Map is a map type that plots the surface lead morphology match score associated with each mapping point collected compared to the originally collected template beat surface lead morphology. The physician may want to use this feature during pace mapping where it may be useful to plot the 90%-100% morphology match scores in the area of interest.

The user may also sort the points list by score from highest score surface lead morphology match compared to the template beat to lowest score surface lead morphology match compared to the template beat. When the user clicks on the mapping point, they will be able to view the current mapping point surface lead morphology on top of the template beat surface lead morphology trace. This may be useful to determine which surface lead(s) are different from the template beat.

It is possible to adjust the map scale to only display the 90-100% matches on the map.

The Score Map can also be used during automated mapping to allow users to automatically collect only those points with morphology match scores that are XX% similar or higher compared to the template beat and automatically reject those points that are not XX% similar or higher compared to the original template beat.
**Automatic Recorded Segments when the EnSite™ AutoMap Feature is Activated**

When Start AutoMap is activated, the software automatically records the data from 10 seconds before the EnSite™ AutoMap feature was activated and continues recording as long as the EnSite™ AutoMap feature is active.

**TurboMap**

Once original mapping has occurred, the user may change mapping criteria and play back through the original dataset at TurboMap speed to generate a new map at 10x’s real-time speed. This is called the TurboMap feature. As an example, if the original mapping time was 10 minutes, the user can generate a second map in only 1 additional minute. This same concept could be employed for map3, map4, etc. This may be useful if the physician is mapping Sinus Rhythm and intermittent, multiple PVC or VT morphology beats are occurring. This may also be useful if the physician is trying to map multiple, distinct Cycle Length atrial tachycardias.

**Number of Mapping Points per Map and number of Maps per Study**

There is no limit to the number of mapping points that may be collected per map. The number of mapping points in the map is listed on the screen.

There is no limit to the number of maps that may be collected per study.

**Catheters for Use with Automated Mapping with the EnSite™ AutoMap Module**

Automated mapping with the EnSite™ AutoMap Module does not require a specific or special EP catheter. Physicians may take advantage of automated mapping with the EnSite™ AutoMap Module with conventional EP catheters with any number of electrodes. Physicians may take advantage of automatically including/excluding mapping points based on average contact force when the EnSite™ Contact Force Module is installed and when the physician is using a TactiCath™ Contact Force Catheter to map.
Example 1 (atrial mapping with multiple distinct cycle length atrial tachycardias)

In the atrial chambers, physicians may want to automatically collect mapping points as long as the intracardiac (CS, HIS, etc) measured Cycle Length is within +/- XX ms of the original template beat (first point saved into the map). In the example below the physician simultaneously and automatically built the right atrial anatomy and atrial tachycardia LAT timing and voltage maps in the right atrium by:

1. Collecting anatomic modeling points with the OneMap™ feature (this allows mapping points and anatomic modeling points to be collected simultaneously).
2. Saving the first atrial tachycardia (Cycle Length 1) beat into the map, ensuring that the Roving Activation Interval does not include a ventricular complex.
3. Checking the "Cycle Length Tolerance" box and setting it to +/- 20 ms.
4. Checking the "Score Threshold" box and setting it to 50 (this may eliminate roving catheter points polluted with far field ventricular activity).
5. Clicking "Start AutoMap".

6. If a secondary atrial tachycardia (Cycle Length 2) was intermittently occurring during original mapping, the user can save one of those points into a new map, pulling up the primary AutoMap mapping segment, setting the AutoMap Settings for the secondary map, and clicking TurboMap speed to generate this new map with the TurboMap feature.
Example 2 (ventricular mapping with multiple distinct surface lead morphologies)

In the ventricular chambers physicians may want to automatically collect mapping points as long as the surface lead morphology is XX% similar to the template beat (first point saved into the map). For example the physician can simultaneously and automatically build the left ventricle anatomy and Sinus Rhythm voltage/timing maps in the left ventricle by:

1. Collecting anatomic modeling points with the OneMap™ feature (this allows mapping points and anatomic modeling points to be collected simultaneously).
2. Saving the first Sinus Rhythm beat into the map.
3. Checking the "Score Threshold" box and setting it to 90.
4. Clicking "Start AutoMap".

NOTE: When the surface lead morphology is not 90% similar to the template Sinus Rhythm 12-lead Surface Morphology, the red box turns red indicating that mapping points were not collected because the Surface Lead Morphology Match Score was outside the morphology of interest. This feature can be used to automatically reject ectopy as the ectopy would not be 90% similar to the template beat.

In some instances secondary arrhythmias may intermittently occur during primary map collection. If this occurs, the physician could use the TurboMap feature to create a map with points only associated with that secondary intermittent arrhythmia by:

1. Record a segment when the secondary arrhythmia occurred during primary map collection.
2. Saving a mapping point of the secondary arrhythmia into a new map.
3. Pulling up the AutoMap Mapping Segment of the original map
4. Clicking Start AutoMap
5. Selecting TurboMap speed to play back through the original dataset at 10x’s real-time speed
6. Selecting Play on the segment

NOTE: When the surface lead morphology is not 90% similar to the secondary arrhythmia template beat morphology, the red box turns red indicating that mapping points were not collected because the Surface Lead Morphology Match Score was outside the morphology of interest.

This same concept could be applied to other secondary arrhythmias that occurred during the original map creation.
Example 3 (pace mapping using Score Map)

In a Pace map, it is possible to automatically collect mapping points at any surface lead morphology as long as the pacing impulse has been captured.

1. Collecting anatomic modeling points with the OneMap™ feature allows mapping points and anatomic modeling points to be collected simultaneously.

2. Mapping detection settings (Figure 2).

![Detection Settings](image1)

**Figure 2. AutoMap Detection Settings for Pace Mapping**

a. Ref – Multiple ECG (Use full 12-lead for scoring and timing)

b. Roving – Pacing catheter (pacing pair only). Example, D-2 if pacing from D-2.

3. AutoMap Threshold settings (Figure 3).

![AutoMap Threshold](image2)

**Figure 3. AutoMap Threshold Settings for Pace Mapping Using Score Map**

a. Default map setting for Speed (10 mm/sec) and Signal to Noise (5.0).

b. Score Threshold set to 0.

c. CL Tolerance threshold OFF.

d. Distance threshold OFF.

e. Enhanced Noise Rejection OFF.

4. Freeze a beat of interest.

5. Set the Reference Offset to the onset of the QRS.

6. Set the Independent Scoring Interval to the QRS duration (onset to terminal).
7. Set the Roving Activation Interval (RAI) so the pacing spike is included and the RAI is less than or equal to pacing cycle length (approximately 80%-90% or -20ms to -30ms).

8. Save the beat of interest.

9. Click “Start AutoMap.”

10. Once points are collected, click the Stop AutoMap button. Review the mapping points and sort by LAT. Make sure that the Points filter (that hides unused points) is not selected. Delete any points with LAT values that are greater than 0ms. These points are non-capture pacing beats (Figure 4).

11. Sort the mapping points by Score.

12. Set the mapping color bar so the color range is 90-100 (%)

NOTE: Do not change the reference offset after saving the first beat when using Score Map. Changing of the reference offset after the first beat may lead to an incorrect mapping display.

Figure 4. Points filter off, sort by LAT, delete all points with a positive LAT
Automatic Non-Cardiac Triggered Maps

AutoMap can be used for creating non-cardiac triggered maps as well. AutoMap is started the same way as cardiac-triggered maps.

**NOTE:** AutoMap Score Threshold and CL Tolerance are unavailable for Non-Cardiac Triggered maps.

1. Start a new map.
2. Change to non-cardiac triggered map and set up mapping parameters, including AutoMap settings.
3. Save the first point manually by clicking freeze and save.
4. Click the Start AutoMap button to start acquiring points.
5. Click Stop AutoMap when done acquiring points.

**Stable Distance Indicator**

When the Point Collection Status is shown, the speed limit indicator is replaced with the Stable Distance indicator. The Stable Distance indicator shows the stability of the catheter in the form of a pie graph. The longer the catheter is stable, the more slices of the pie are colored green. The pie graph is full when all the mapping electrodes haven't moved more than the Stable Distance millimeters for the time period specified by the Segment Length control. When the AutoMap Stable Distance Threshold is enabled, the system will not acquire a point until the pie is all green. This prevents the system from acquiring a point when the catheter has moved part-way through the acquisition period.

**NOTE:** The Stable Distance indicator is only applicable to non-cardiac triggered maps.