

# CT/MR IMAGING INTEGRATED WITH ELECTROPHYSIOLOGICAL MAPPING: A REVIEW OF TWO PRE-CLINICAL STUDIES

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*In recent years, three-dimensional (3D) mapping systems have become a central part of the electrophysiological (EP) laboratory. New technological developments now enable integration of computed tomography (CT) or magnetic resonance imaging (MRI) with 3D EP maps. However, can image integration provide the accuracy EP physicians require? This paper looks at two pre-clinical studies to answer this question.*

Three-dimensional EP mapping systems (3D mapping systems) provide electroanatomical information about complex arrhythmias. However, successful implementation of an ablation strategy to treat such arrhythmias is dependent upon predefined anatomic targets.<sup>1</sup>

More recently 3D mapping systems have been used to develop ablation strategies based on anatomic considerations. However, these systems cannot provide the detailed morphology available from computed tomography (CT) or magnetic resonance imaging (MRI).

Fluoroscopy has been, and still is, used for certain EP procedures. However, the limited soft-tissue resolution makes it difficult to re-navigate an EP catheter to the same locations. In addition, electrophysiological studies are traditionally lengthy and can result in prolonged exposure to fluoroscopy, a less than optimal situation for both the patients and the physician.

As a result, 3D mapping systems are increasingly being used for conducting EP studies and determining a treatment strategy.<sup>2</sup> A chief advantage of 3D mapping systems is their ability to track and display the real-time position of catheters in relation to the cardiac anatomy. This is a particularly important feature when planning an ablation strategy.

Nevertheless, as stated above, 3D mapping systems have their limitations. Complex arrhythmias are often treated when the ablation strategy is applied to a predefined anatomical target. It is here that 3D mapping systems may be inadequate—they cannot provide the detailed morphological data that is displayed in CTs and MRIs.

## Image Integration with 3D Mapping Systems

The clinical need for accurate morphological data, together with the electroanatomical information provided by 3D mapping systems has led to the development of pre-acquired image integration systems.<sup>1</sup>

Image integration systems combine the 3D map data with that of preacquired CTs or MRIs. The goal is to provide EP physicians

with the accurate anatomical details needed to plan an ablation strategy that can safely treat complex arrhythmias.

One of the most popular 3D mapping systems is the CARTO<sup>®</sup> XP System (Biosense Webster, Inc.). In 2005, a new CARTOMERGE<sup>®</sup> Image Integration Software Module was released. This module was the first to enable true integration of CT/MRI data with that of 3D EP maps.

The CARTOMERGE<sup>®</sup> Module is used to import CT/MRI data for the creation of 3D surface images which are displayed on the CARTO<sup>®</sup> XP System, together with the 3D EP maps. The 3D maps and surface images are registered to each other, enabling the physician to use the pre-acquired CT/MRI data for developing an ablation strategy.

Another 3D mapping system is the NavX EP System (St. Jude Medical). The image integration module, called EnSite Fusion<sup>™</sup>, was released in 2008. Like the CARTO<sup>®</sup> XP System with CARTOMERGE<sup>®</sup> Module, the NavX System enables registration of 3D surface “models” to 3D EP maps via the EnSite Fusion<sup>™</sup> module.

While there have been clinical studies that examine the effectiveness of both systems in humans, this author is aware of only two pre-clinical studies to date that actually investigate the accuracy of image integration with these 3D mapping systems.

## Review of Pre-Clinical Studies

The known pre-clinical studies were performed by two different groups using two different systems: 1. CARTO<sup>®</sup> XP System with CARTOMERGE<sup>®</sup> Module (Johns Hopkins University, Bloomberg School of Public Health, University of Maryland, and Biosense Webster, Inc.)— hereinafter CARTOMERGE<sup>®</sup> Module Study; 2. EnSite NavX System with EnSite Fusion<sup>™</sup> (University of Virginia and St. Jude Medical<sup>3</sup>)—hereinafter Fusion<sup>™</sup> Study.

Both studies were performed in order to determine the accuracy of their respective systems utilizing image integration. The studies, although performed two years apart with different equipment, were similar in methodology (Table 1).

**Table 1. Comparison of Study Methodologies**

Study Methods	CARTO® XP System with CARTOMERGE® Module <sup>1</sup>	NavX System with EnSite Fusion™ <sup>4</sup>
Animal	9 mongrel dogs	At least 6 adult swines
Number of markers	1 or more markers over each cardiac chamber	At least 2 markers over each cardiac chamber
CT Imaging and Segmentation	<ul style="list-style-type: none"> <li>Imaging during end-expiration</li> <li>Segmentation of cardiac structures via CARTOMERGE® Module</li> <li>CT markers included in extracted 3D surface images</li> </ul>	<ul style="list-style-type: none"> <li>Imaging during end-expiration</li> <li>Segmentation of cardiac structures via EnSite Fusion™ Module</li> <li>CT markers included in extracted 3D surface images</li> </ul>
EP Mapping	<ul style="list-style-type: none"> <li>4 chambers</li> <li>30–50 data points per chamber</li> </ul>	<ul style="list-style-type: none"> <li>4 chambers</li> <li>3D surface image displayed during mapping to assure acquisition of same anatomic structures</li> </ul>
Image Registration	<ul style="list-style-type: none"> <li>Step 1: Fluoroscopy to three anatomically defined intracardiac locations and match to 3D maps to perform landmark registration</li> <li>Step 2: “Surface” registration with software algorithm that positions map to 3D surface image based on smallest average distance between the endocardial catheter positions and the corresponding surface images</li> </ul>	<ul style="list-style-type: none"> <li>Manual dynamic registration until map surface matched CT surface geometry</li> </ul>
Ablating Markers	<ul style="list-style-type: none"> <li>Ablation lesions placed targeting radiopaque markers, relying on CT data alone</li> </ul>	<ul style="list-style-type: none"> <li>Ablation lesions placed targeting radiopaque markers, relying on CT data alone</li> </ul>

The differences between the two studies are noteworthy. These differences relate to the number of animals studied and the image registration methodology. While the CARTOMERGE® Module Study was performed on nine canine subjects, the Fusion™ Study was performed on six swine. The CT/MR image registration methodologies are also markedly different.

The CARTOMERGE® Module Study used two independent registration steps. The first step relied on landmarks. Using fluoroscopy, the catheter was navigated to three anatomically defined intracardiac locations in the right atrium; these were matched to corresponding cursor locations on CARTO® System Maps. The second step, “surface registration”, was used to fine tune registration between the maps and surface images. An automatic software algorithm was used, which looked for the smallest average distance between the endocardial catheter positions and the corresponding surface images. The result was a matching of the CARTO® System Map to the surface image.

The Fusion™ Study relied on dynamic manual registration. Registration markers were manually defined on each 3D CT surface model, along with a “registration algorithm”.<sup>1</sup> Markers were added manually until the surface of the EP map matched the CT surface geometry.

**Results Comparison**

In both studies, the animals were sacrificed and measurements made between the epicardial markers and the center of the endocardial lesions. Table 2 summarizes the results.

Table 3 gives a closer look at the error range and maximum possible error for both studies.

Figure 1 graphically combines both study results and presents the mean error and STD per chamber and all chambers.

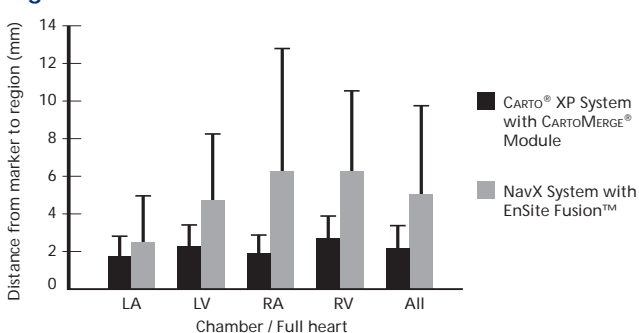
**Table 2. Summary of Results from Both Studies**

Chamber	CARTO® XP System with CARTOMERGE® Module <sup>1</sup>			NavX System with EnSite Fusion™ <sup>4</sup>		
	# Markers	Mean (mm)	Standard Deviation	# Markers	Mean (mm)	Standard Deviation
LA	11	1.8	1.0	12	2.5	2.4
LV	10	2.3	1.1	12	4.7	3.4
RA	11	1.9	0.9	11	6.2	6.5
RV	12	2.7	1.2	10	6.2	4.3
All	44	2.2	1.1	45	5	4.7

**Table 3. Error Range and Maximum Error (Max Error ± Standard Deviation)**

	CARTO® XP System with CARTOMERGE® Module <sup>1</sup>	NavX System with EnSite Fusion™ <sup>4</sup>
Error Range	1.8–2.7 mm	2.5–6.2 mm
Maximum Error (One Chamber)	3.9 mm (Right Ventricle)	12.7 mm (Right Atrium)

**Fig 1. Mean Error and Standard Deviation from Both Studies**



## Important Findings

Both studies indicate that image integration is a modality that will indeed aid physicians in planning and implementing ablation lesions. In particular:

1. Image integration enables accurate placement of ablation lesions based on anatomy in all cardiac chambers, with a maximum error of 3.9 mm (right ventricle) with the CARTO® XP System and CARTOMERGE® Module, and 12.7 mm (right atrium) with the NavX System with EnSite Fusion™ Module. These values were obtained from the maximum error results plus the maximum standard deviation in the same chamber.
2. Image integration systems can be used to successfully implement RF lesions for complex anatomical and electroanatomical procedures.<sup>1</sup>
3. While manual registration, or a combination of manual and automatic (landmark/surface) registration provide acceptable results, the combined methodology provides better accuracy.<sup>1</sup>

## Limitations

This review has certain limitations due to the published differences between the two studies. The resolution of the CARTO® System Maps is known, while the resolution of the NavX EnSite maps is not known. Differences in map resolution could be a factor in considering the results.

The Fusion™ Study discussed fewer subjects. Here again, the results might have been different if a larger study population had been used.

Both studies are pre-clinical evaluations. The results are not necessarily applicable to clinical use.

Both studies utilized CT images that had to be acquired before the studies were performed. As a result, interval changes may not have been accurately represented. Nevertheless, both studies attempted to compensate for this issue by performing mapping at the same phase in the cardiac cycle, and by registering images using anatomic points acquired during the procedures.

## Conclusion

The CARTOMERGE® Module and Fusion™ Studies successfully demonstrated that image integration provides a long-needed solution for EP studies that require the accurate morphology previously available only from CTs or MRIs. The ability to combine EP maps with 3D CT/MR surface images brings the promise of increased success rates when faced with complex treatment strategies.<sup>1</sup>

Available systems offer different techniques and vary from each other in functionality, and accuracy. Clearly, EP systems with image integration are here to stay. The EP physician's task is to wisely evaluate all that each system offers.

## References

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