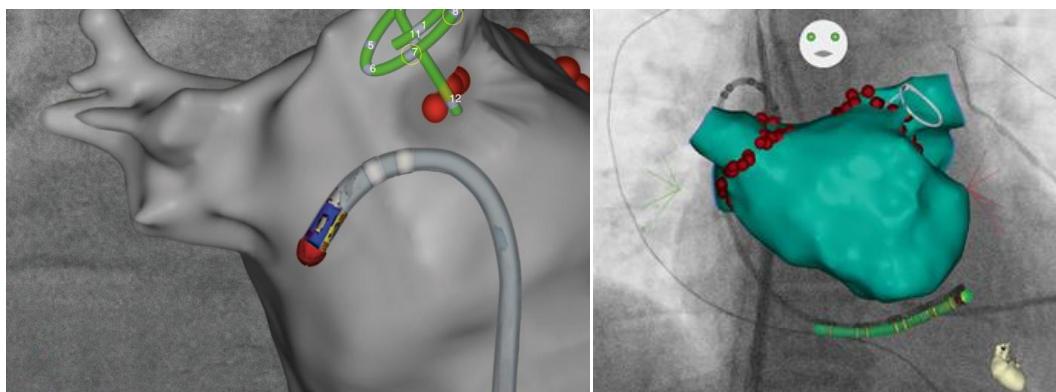


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CARTO® 3 System Fact Sheet

The CARTO® 3 System is an advanced imaging technology that utilizes electromagnetic technology to create real-time three-dimensional (3D) maps of a patient's cardiac structures. The system is designed to help electrophysiologists navigate the heart by generating an accurate 3D map, as well as pinpointing the exact location and orientation of catheters in the heart during diagnostic and therapeutic procedures for patients suffering from heart rhythm conditions (cardiac arrhythmias). The CARTO® 3 System acts very much like an advanced navigation system in a car that guides the driver with visual and audio cues to ensure safe parking and operation of the vehicle.

During a therapeutic catheter ablation procedure, doctors insert a catheter through a small incision in the groin where it is then weaved up to the heart through a blood vessel in the leg. Once it reaches the heart, radiofrequency energy is delivered to specific areas of the heart wall to produce a small lesion, or scar, to block faulty electrical impulses that can cause heart rhythm disorders. The 3D image that's generated by the system helps doctors steer the catheter to areas in the heart where RF energy needs to be administered.



Three-dimensional maps generated by the CARTO® 3 System shows the location and orientation of catheters in the heart

CARTO® 3 System Features

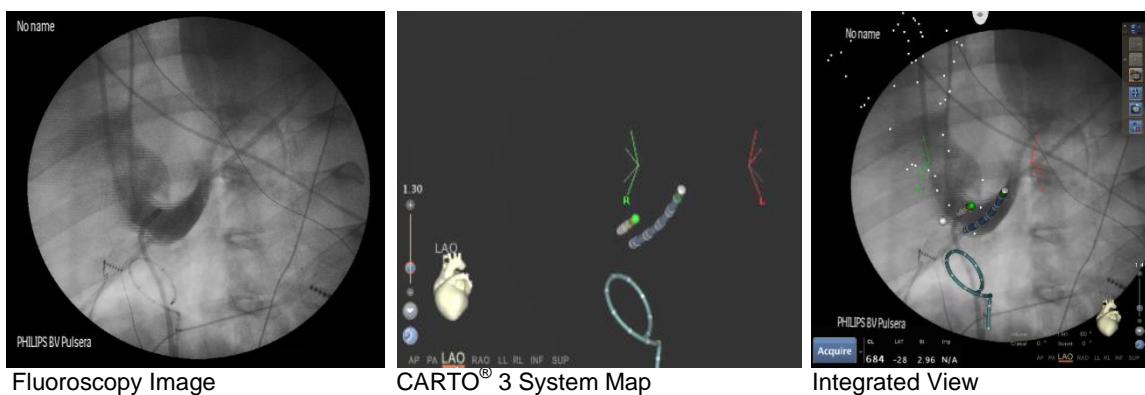


- The CARTO® 3 System enables accurate visualization of multiple catheters in a patient's heart and pinpoints the exact location and orientation of a catheter
- Fast anatomical mapping (FAM) technology allows clinicians to rapidly create a map of the heart with CT like resolution, which minimizes the need for fluoroscopy radiation during catheter ablation procedures¹
- Advanced technology compensates for patient and cardiac motion to ensure accurate, real-time visualization of the cardiac structures
- The computer-like system is capable of running software modules that introduce additional advanced features and continued innovations in the field of electrophysiology

CARTO® 3 System Modules

Biosense Webster manufactures software modules for the CARTO® 3 System that enable advanced cardiac visualization, diagnostic capabilities to enhance clinicians' ability to diagnose and treat heart rhythm disorders. These modules allow the company to continue introducing new innovations that provide electrophysiologists unprecedented access to visual information including the ability to tag, or label, lesions to keep track of treatment strategies for individual patients. For a list of modules for the CARTO® 3 System, please visit www.biosensewebster.com.

- **CARTO® SMARTTOUCH® 3D Module:** This module is the first technology introduced into the electrophysiology field that enables physicians to tag, or label, lesion with customized parameters including the duration or level of radiofrequency (RF) energy applied to each lesion to help achieve stable application of RF energy during the procedure. Physicians are also able to more precisely measure and track the amount of contact force applied against the heart wall during the procedure, eliminating the need to use other indirect measures such as electrogram parameters and impedance, which have been shown to be poor predictors of contact force.¹ These tags are saved in the CARTO® 3 System and can be used to visually evaluate their customized ablation strategy both during and after the procedure to determine whether the lesions they have created meet their defined parameters.
- **CARTOUNIVU™ Module:** This module is the only technology available on the market today that enables clinicians to seamlessly merge a static fluoroscopy image with real-time cardiac maps generated by the CARTO® 3 System into a single, accurate 3D view. It helps to reduce fluoroscopy levels – consistent with the ALARA principle of reducing exposure for physicians, staff and patients to as low as reasonably achievable. Physicians typically generate multiple fluoroscopic images during a catheter ablation procedure as they rely on this traditional imaging modality to give them a current view of the cardiac structures in which they are performing the procedure. By enabling an integrated view, physicians are able to reference multiple sources of visual information using different imaging modalities to help them navigate the patient's cardiac structures - providing greater confidence and reducing the need to generate repetitive fluoroscopic images.²



- **CARTOSOUND® Module:** This 3D ultrasound technology enables physicians to visualize and navigate patients' cardiac anatomy with greater precision by complementing the CARTO® 3 System's mapping capabilities with real-time soft tissue visualization. The ability to visualize soft tissue through ultrasound technology allows an enhanced real-time view of catheter tip-to-tissue contact and helps physicians monitor for potential complications that can occur during the procedure such as blood clots and abnormal accumulation of fluid in the heart.³ The module's advanced catheter location feature also helps physicians navigate around critical structures like the esophagus during the procedure.

References

1. Nakagawa H, Kautzner J, Natale A, et al. Locations of high contact force during left atrial mapping in atrial fibrillation patients: electrogram amplitude and impedance are poor predictors of electrode-tissue contact force for ablation of atrial fibrillation. *Circ Arrhythm Electrophysiol* 2013;6:746-53.
2. Sporton S, Earley M, Nathan A, and Schilling R, Electroanatomic versus fluoroscopic mapping for catheter ablation procedures: A prospective randomized study. *Journal of Cardiovascular Electrophysiology* 2004;15,3:310-315.
3. Data on file.

Always verify catheter tip location using fluoroscopy or IC signals and consult the CARTO® System User Guide regarding recommendations for fluoroscopy use

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