Johnson&Johnson MedTech

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Biosense Webster Launches New Version of CARTO™ 3 Electro-Anatomical Mapping System

New CARTO™ 3 System Version 8 software introduces machine learning capabilities

Increases efficiency, reproducibility, and accuracy[i] in the electro-anatomical maps electrophysiologists use in catheter ablation procedures

Irvine, CA – May 8, 2024 – Biosense Webster, Inc., a global leader in cardiac arrhythmia treatment and part of Johnson & Johnson MedTech, announces the launch of CARTO™ 3 System Version 8, the latest version of the company's leading three-dimension (3D) heart mapping system used in cardiac ablation procedures. The software features new modules including the CARTO ELEVATE™ Module and CARTOSOUND™ FAM Module, designed for efficiency, reproducibility, and accuracy for electrophysiologists performing catheter ablation procedures to treat patients with atrial fibrillation (AFib) and other arrhythmias.

"We are pleased to announce this new version of our CARTO™ 3 System, which reflects our continued focus on harnessing the latest science and technology to advance tools for electrophysiologists to treat cardiac arrhythmias," said Jasmina Brooks, President, Biosense Webster, Inc. "The CARTO™ 3 System has been the cornerstone of catheter ablation procedures for more than a decade, helping electrophysiologists make treatment decisions. This new version advances the CARTO™ 3 mapping and ablation experience through enhanced signal analysis, improved substrate characterization, and utilization of ultrasound technology."

New optional CARTO™ 3 System Version 8 modules include:

CARTOSOUND™ FAM: the first use of an artificial intelligence algorithm, cleared by the FDA in intracardiac ultrasound for Biosense Webster. The algorithm enables automatic generation of the left atrial anatomy before inserting the catheter to the left atrium, saving time while also providing a highly accurate map.

CARTO ELEVATE™: incorporates several new features designed to meet electrophysiologists' needs:

- ***Multipolar with the OPTRELL™ Mapping Catheter*** for localized unipolar signals to significantly reduce far field potentials and provide a more accurate activation map;[ii]
- ***Complex signals identification*** for efficient and reproducible identification of critical areas of interest when diagnosing the arrhythmia;[i]
- ***Pattern acquisition*** to automatically track arrhythmia burden pre- and post-ablation, enabling a more informed decision of the relevant premature activation map; and
- ***Enhanced CONFIDENSE™ Module*** to create optimized maps with higher overall Smart Index scores, ensuring maps are continuously improved.[iii]

"CARTO™ 3 System Version 8 incorporates a novel component, the CARTOSOUND™ FAM Module, which, for the first time, utilizes artificial intelligence to reconstruct the left atrial anatomy, streamlining the process for electrophysiologists,"[1,2, iv] said Luigi Di Biase, M.D.[v], PhD, FACC, FHRS, FESC, System Director Electrophysiology at Montefiore-Einstein Health System

[i] 91% of cases (n=27) the new algorithm identified critical isthmuses that may have result in successful ablation of all inducible atrial arrhythmias.

[ii] Compared to previous version of CARTO™ 3 System software. The preclinical validation was conducted using retrospective analysis of 4 atrial flutter maps with or without pacing (2xRA and 2xLA) and 12 ventricular maps (3xVTs and 9x ischemic OPTRELL™ (part number D-1409) Catheter on CARTO™ 3 System.

[iii] When using Smart Index mapping. Optimized maps are referred to as overall higher Smart Index score indicating the quality of the map. 25 out of 25 cases used to evaluate the performance the Enhanced ConfiDENSE algorithm passed the acceptance criteria.

[iv] CARTOSOUND™ FAM Module uses Deep Learning, which is a subset of AI

[v] Dr. Luigi Di Biase is compensated by and presenting on behalf of BWI and must present information in accordance with applicable regulatory requirements.

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and Professor of Medicine (Cardiology), Albert Einstein College of Medicine. “By eliminating the need for manual contouring, the new system represents a new approach to anatomy creation, improving the efficiency of the procedure workflow.”

“Accuracy and precision in mapping the heart when treating cardiac arrhythmias are critical for electrophysiologists, and therefore, our patients,” continued Dr. Di Biase. “The CARTO ELEVATE™ Module raises the bar for electro-anatomical mapping systems used in catheter ablation procedures. Capabilities such as Multipolar mapping make a difference for electrophysiologists in the electrophysiology lab, facilitating a reduction in far-field signal and increased focus on the electrical signals in the patient's heart that contribute to arrhythmias.”[vi]

AFib is the most common type of cardiac arrhythmia and affects more than 8 million people in the United States and nearly 50 million people worldwide.[vii] Catheter ablation is a safe and effective procedure when drugs don’t work to help restore the heart’s incorrect electrical signals, which cause an abnormal heart rhythm.[viii]

About CARTO™ 3 System Version 8
The CARTO™ 3 System is a three-dimensional mapping system that uses electromagnetic technology to generate real-time maps of a patient’s cardiac structures. First launched in 2009, the system is designed to help electrophysiologists navigate the heart by generating 3D maps and pinpoint the exact location and orientation of catheters in the heart during diagnosis and therapeutic procedures for patients with cardiac arrhythmias. CARTO™ 3 System Version 8 includes the CARTO ELEVATE™ Module which features OPTRELL™ Mapping Catheter with MULTIPOLAR to improve signal quality and localized annotation, independent of the catheter orientation. The system also includes the CARTOSOUND™ FAM module to deliver automated 3D shell creation using deep-learning technology.

About Biosense Webster
Biosense Webster, part of Johnson & Johnson MedTech, leads in cardiac arrhythmia diagnosis and treatment worldwide. We are dedicated to advancing electrophysiology and interventional cardiology tools and solutions for improved patient care. Learn more at biosensewebster.com and connect on LinkedIn and X, formerly Twitter.

About Johnson & Johnson MedTech[ix]
At Johnson & Johnson MedTech, we unleash diverse healthcare expertise, purposeful technology, and a passion for people to transform the future of medical intervention and empower everyone to live their best life possible. For more than a century, we have driven breakthrough scientific innovation to address unmet needs and reimagine health. In surgery, orthopaedics, vision, and interventional solutions, we continue to help save lives and create a future where healthcare solutions are smarter, less invasive, and more personalized. For more information, visit thenext.jnjmedtech.com.

Cautions Concerning Forward-Looking Statements
This press release contains “forward-looking statements” as defined in the Private Securities Litigation Reform Act of 1995 regarding the CARTO™ 3 System Version 8 Platform. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or known or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Biosense Webster, Inc. and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: uncertainty of regulatory approvals; uncertainty of commercial success; challenges to patents; competition, including technological advances, new products and patents attained by competitors; product efficacy or safety concerns resulting in product recalls or regulatory action; changes to applicable laws and regulations, including global health care reforms; changes in behavior and spending patterns of purchasers of healthcare products and services; and trends toward healthcare cost containment. A further list and descriptions of these risks, uncertainties and other factors can be found in Johnson & Johnson’s Annual Report on Form 10-K for the fiscal year ended December 31, 2023, including in the sections captioned “Cautionary Note Regarding Forward-Looking Statements” and “Item

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[vi] The preclinical validation was conducted using retrospective analysis of 4 atrial flutter maps and 12 ventricular maps collected from clinical cases. All maps were created with the OPTRELL™ Catheter on CARTO™ 3 System.

[vii] Mensah, G, Fuster, V, Murray, C. et al. Global Burden of Cardiovascular Diseases and Risks, 1990-2022. J Am Coll Cardiol. 2023 Dec, 82 (25) 2350–2473.

[viii] Calkins, et al. 2017 HRS_EHRA_ECAS_APHRS_SOLAECE expert consensus statement on catheter and surgical ablation of atrial fibrillation. Heart Rhythm. 2017 October ; 14(10): e275–e444. doi:10.1016_j.hrthm.2017.05.012

[ix] Johnson & Johnson MedTech comprises the surgery, orthopedics, vision, and interventional solutions businesses within Johnson & Johnson’s MedTech segment.

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1A. Risk Factors," and in Johnson & Johnson's subsequent Quarterly Reports on Form 10-Q and other filings with the Securities and Exchange Commission. Copies of these filings are available online at sec.gov, jnj.com or on request from Johnson & Johnson. Neither of Biosense Webster, Inc. nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

[1] Di Biase L, Zou F, Lin AN, et al. Feasibility of Three-Dimensional Artificial Intelligence Algorithm Integration with Intracardiac Echocardiography for Left Atrial Imaging During Atrial Fibrillation Catheter Ablation. Europace. 2023 Aug 2;25(9):euad211.
[2] CARTOSOUND™ FAM Module Instructions for Use. UG_5462-00A. February 2024