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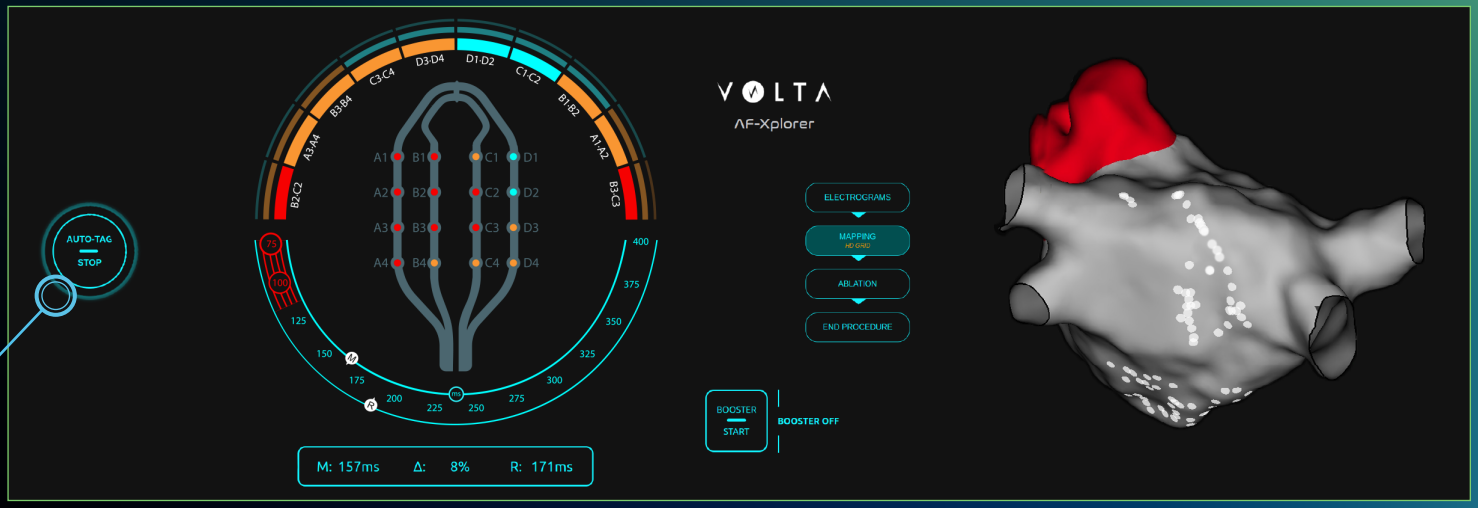
ENSITE™ LIVESYNC MODULE

AN OPEN ECOSYSTEM FOR TODAY AND TOMORROW

AI SOFTWARE-GUIDED ABLATION WITH VOLTA AF-XPLORER‡: **POWERED BY ENSITE™ LIVESYNC MODULE**

VOLTA AF-XPLORER‡ ON ENSITE™ X EP SYSTEM ELEVATES THE STANDARD OF AF CARE WITH AUTOMATIC DISPERSION TAGGING

Automatically tags regions of interest on the mapping system - **ONLY AVAILABLE WITH ENSITE X EP SYSTEM.**



Bi-directional communication with EnSite™ X EP System

Clinical trial results showed that a **tailored cardiac ablation procedure supported by AI** provided better results for persistent and long-standing AF[1]

78% of patients in the tailored arm experienced **acute termination of AF** compared to 10% of patients in the anatomical arm[1]

89% of patients in the tailored arm experienced **12- month freedom from AF** compared to 67% of patients in the anatomical arm[1]

*VOLTA AF-XPLORER‡ is a separate add-on module and not part of the standard EnSite™ X EP System package.
1. Deisenhofer I. Tailored cardiac ablation procedure for persistent atrial fibrillation guided by artificial intelligence: the TAILORED-AF randomized clinical trial. Presented at: HRS 2024. May 18, 2024. Boston, MA.

Rx Only. Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events, and directions for use.

United States: Required Safety Information

Indications: The EnSite™ X EP System is a suggested diagnostic tool in patients for whom electrophysiology studies have been indicated. The EnSite™ X EP System provides information about the electrical activity of the heart and displays catheter location during conventional electrophysiological (EP) procedures. **Warnings:** For patient safety, any connections that directly connect the patient to the EnSite™ X EP System must be routed through the appropriate modules: EnSite™ X EP System SurfaceLink Module, EnSite™ X EP System 20 pin Catheter Input Module, EnSite™ X EP System 80-pin Catheter Input Module and Direct Connect Ports on the EnSite™ X EP System Amplifier. When using the EnSite™ X EP System, full protection against the effects of cardiac defibrillator discharge and other leakage currents is dependent upon the use of appropriate cables. The use of this device in conjunction with radio frequency ablation, as a part of the diagnosis and treatment of cardiac arrhythmias, may pose an increased risk of adverse events such as cardiac perforation, myocardial infarction, air embolism, and hematoma requiring surgical repair and/or blood transfusion. Non-SE catheters cannot collect location data and should not be used for navigation in VoXel Mode because they do not have a magnetic sensor. However, they can be visualized and display intracardiac signals. Only connect items that have been specified as part of the EnSite™ X EP System or compatible with the EnSite™ X EP System to the multiple socket-outlets. The EnSite™ X EP System model display should be used in conjunction with conventional EP techniques to confirm catheter location. The AutoMark feature does not indicate lesion effectiveness. AutoMarks are placed based on user-defined parameters for catheter stability and RF metrics only. Sudden impedance changes of the body or catheter electrodes caused by the connection of other devices (e.g., stimulator, defibrillator, and other devices) may create a location shift. **Precautions:** Ensure that surface electrodes, Patient Reference Sensors, and associated connectors do not contact one another, electrical ground, or metallic objects. EnSite™ X EP System components should be connected to power through an isolation transformer or the multiple socket outlet supplied with the system carts. Connecting equipment directly to a wall outlet may result in excessive leakage current. Do not operate the EnSite™ X EP System Field Frame within 10 m of another operating Field Frame. Do not place the EnSite™ X EP System Field Frame Cable inside the measurement volume or wrap it around the EnSite™ X EP System Field Frame, as it may create a magnetic interference. Metallic equipment used in close proximity to the magnetic field during the procedure, such as a sterile drape holder, may cause metal distortion. Do not place tool cables within 30 mm of the EnSite™ X EP System Field Frame Cable. If placed this close-particularly if the cables are parallel to each other the tool cable may become subject to electromagnetic interference. Do not use the EnSite™ X EP System in the presence of other magnetic fields. Do not drop the EnSite™ X EP System Field Frame or subject it to impact. Physical damage to the EnSite™ X EP System Field Frame may alter the EnSite™ X EP System Field Frame's factory calibration.

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