ALL YOU NEED IS THE ONE SYSTEM SOLUTION

FOR ALL ARRHYTHMIAS AND ABLATIONS

Clinical trials show a significant and detrimental impact of fluoroscopy on the health of physicians and patients during AFib procedures[1]. Clinical data also shows the value of using 3D mapping systems to reduce radiation exposure in both RF and PFA procedures[2,4] - as well as to increase procedural success rates for all AF types when mapping beyond PVI[3].

The right system for your procedures is the one that allows you to treat AFib your way for **optimal outcomes, safety and efficiency.**

Abbott gives you more opportunities to choose the course of treatment and workflow that's right for your patients. EnSite™ X EP System - THE INDUSTRY'S ONLY OPEN ARCHITECTURE DESIGN - is the only system to offer a comprehensive solution for **RF and PFA procedures** – from mapping to outcomes.

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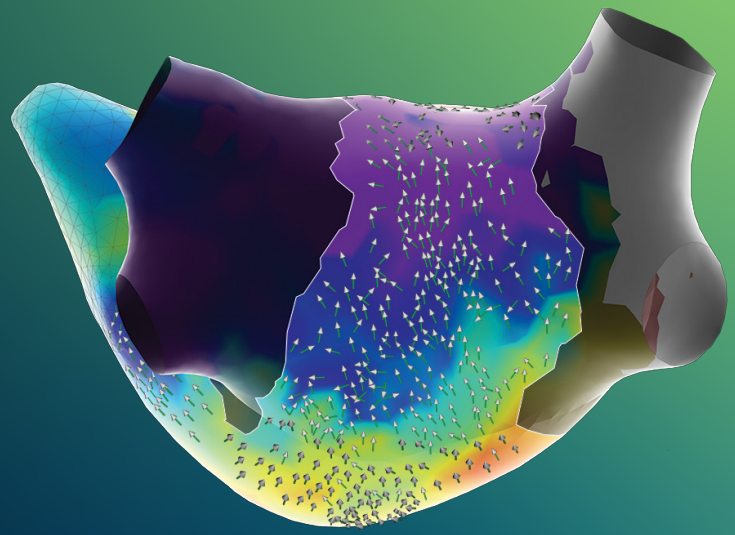
#MAPPINGMATTERS: MAP TO REDUCE RADIATION AND ELEVATE SAFETY.

Every patient deserves 3D mapping to increase navigation accuracy, reduce radiation risk, optimize workflow, and potentially improve outcomes in mapping PVI and beyond.



RADIATION RISK DURING EP PROCEDURES

2-3x higher rate of radiation exposure than radiologists

=

~250 chest x-rays per year (5 mSV)[1]

Leading to an increased risk of cognitive impairment and brain malignancy[1]

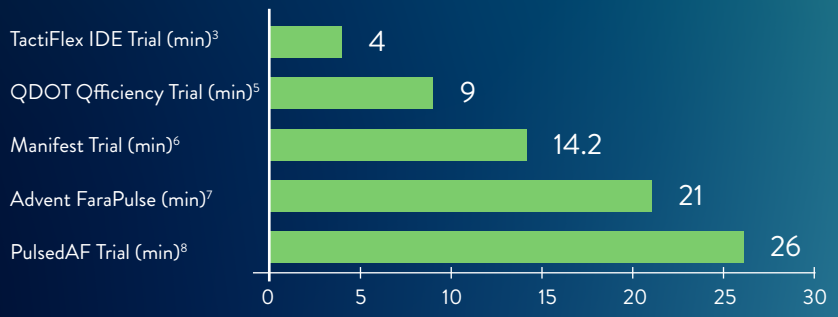
A 35-YEAR-OLD PATIENT UNDERGOING:

	Conventional Procedure	Fluoroless Procedure
Time of life lost	1 WEEK	5 HOURS
Time of life affected[1]	2 WEEKS	12 HOURS

> Low or zero fluoroscopy AF RFA has been instrumental in increasing safety profile for patients, operators, and EP lab staff[4]
>
> Dr. Jose Osario et al.

NEARLY ZERO RADIATION WITH ENSITE™ X EP SYSTEM

EnSite™ X EP System stands alone as the only open architecture mapping system capable of **driving fluoroscopy exposure to nearly zero**[1] with its combination of 3D mapping, PFA visualization and lowest radiation exposure ablation times[3].

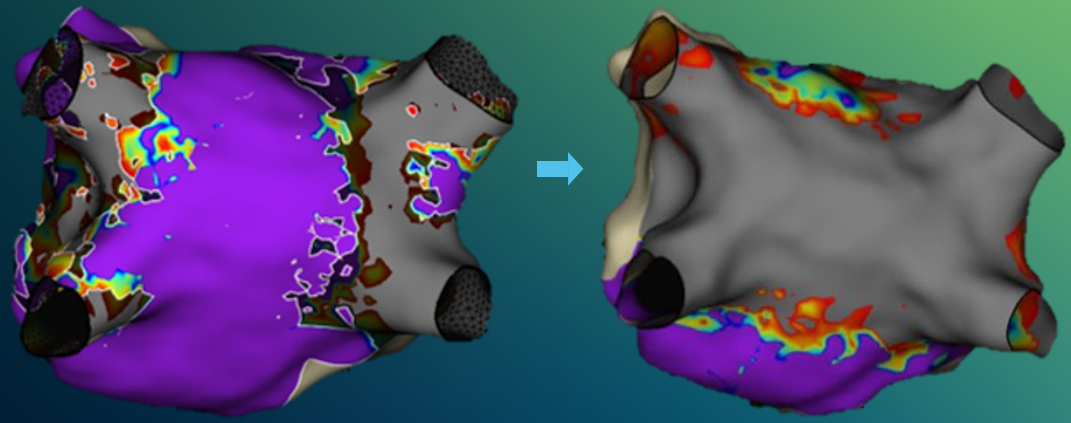


PFA visualization with EnSite™ X EP System may reduce fluoroscopy times during PFA procedures.

EnSite™ X EP System with TactiFlex™ Ablation Catheter, Sensor Enabled™ has the **lowest radiation**[3] exposure time compared to other technologies in the market, proven by the TactiFlex IDE trial. Ablate with the lowest exposure time possible.

IMPROVE PROCEDURAL SUCCESS RATES FOR ALL AF TYPES. MAP BEYOND PVI.

EnSite™ X EP System provides the mapping flexibility, detail and real-time technology vital for low-voltage area ablation procedures. Map beyond PVI to identify, target and ablate cardiac tissue with specificity for acute and long-term outcomes. Patients undergoing 3D mapping-guided low-voltage area are experiencing greater freedom from paroxysmal and persistent AF.



SIGNIFICANTLY REDUCE ATRIAL TACHYARRHYTHMIA RECURRENCE WITH 3D MAPPING-GUIDED LOW-VOLTAGE AREA THERAPY[9]

Adjunct 3D mapping-guided low-voltage area ablation is proven **effective** and **safe** for patients undergoing AF ablation.

- Fewer atrial tachyarrhythmia recurrences[9]
- Lower number of redo ablation procedures[9]
- Similar results for all AF types – paroxysmal, persistent and long-standing persistent AF[9]

REDUCE ATRIAL ARRHYTHMIA RECURRENCE RATES AND AVOID OVERABLATION[10]

15% lower rate of recurrence for patients with persistent AF undergoing PVI with substrate modification vs PVI only (35% vs. 50%)[10]

Specifically targeting ablation to truly diseased myocardium using voltage maps helps to create dedicated lesions that spare healthy tissue[10]

IMPROVE LONG-TERM OUTCOMES IN OLDER PATIENTS WITH PAROXYSMAL AF[3]

39% decrease in atrial tachyarrhythmia recurrence risk with mapping-guided low-voltage area ablation beyond circumferential PVI (CPVI) vs. CPVI alone[3]

2-3 year improved outcomes; differentiation in patient populations noted at 1 year[3]

TAILOR ABLATION STRATEGIES TO PROMOTE BETTER ACUTE AND LONG-TERM CLINICAL OUTCOMES FOR PERSISTENT AF[11]

PATIENTS UNDERGOING CIRCUMFERENTIAL PV ABLATION[11]:

	with 3D mapping	without mapping
Acute atrial termination	61%	30%
1-year freedom from atrial arrhythmia	73.2%	50%

50% Improved acute intraprocedural arrhythmia termination[11]

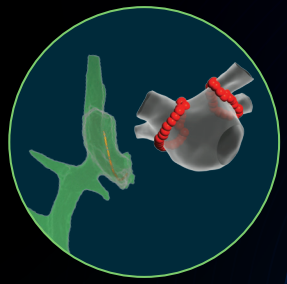
13% Higher procedural success rates[11]

CREATE EFFICIENCIES. MAP TO OPTIMIZE WORKFLOW.

Our One System Solution delivers diverse, advanced and innovative technology with **the industry's only open architecture design.**

1. CREATE GEOMETRY FROM ANY CATHETER YOU CHOOSE

Seamlessly transition between impedance and magnetic based mapping throughout your case on our 2-in-1 system with **EnSite™ VoXel Flex Mode.**



ONE SYSTEM SOLUTION:
the only open architecture design that gives you full flexibility to treat AFib your way.

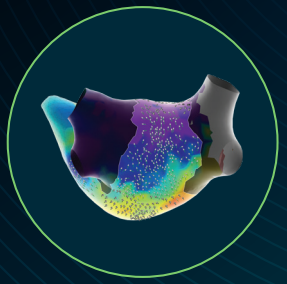
2. NAVIGATE AND ABLATE IN ALL MODALITIES

Perform high-power RF ablation with safety, stability and efficiency with the **TactiFlex™ Ablation Catheter, Sensor Enabled™** – the first and only contact force catheter with a flexible tip.

Visualize catheter position with outstanding image quality using ICE-guided ablation during PFA ablation with **ViewFlex™ Xtra ICE Catheter and ViewMate™ Multi Ultrasound System.**

3. MAP COMPLEX ARRHYTHMIAS WITH UNIQUE SOFTWARE SOLUTIONS

Simply, objectively and automatically assess near field signals by isolating true, localized signals with the automated point annotation of **EnSite™ OT Near Field** software.



Increase workflow efficiency and tailor treatment to individual cases through 3rd party system integration with **EnSite™ LiveSync Module.**

RHYTHM AI
VOLTA
STEREOTAXIS

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3. Chen, H. et al. (2023). Circumferential pulmonary vein isolation with vs without additional low-voltage-area ablation in older patients with paroxysmal atrial fibrillation. JAMA Cardiology, 8(8), 765. https://doi.org/10.1001/jamacardio.2023.1749.
4. Jose Osorio, Gustavo Morales, Michael Raiman (2023) High Efficiency Workflow During Atrial Fibrillation Ablation: Protocol and Experience with EnSite X Mapping System, July 2023, Vol.16 Issue 5.
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9. Rivera, A. et al. (2024). Adjunctive Low-voltage area ablation for patients with atrial fibrillation: An updated meta-analysis of Randomized Controlled Trials. Journal of Cardiovascular Electrophysiology. https://doi.org/10.1111/jce.16290.
10. Huo, Y. et al. (2022). Low-voltage myocardium-guided ablation trial of persistent atrial fibrillation. NEJM Evidence, 1(11). https://doi.org/10.1056/evidoa2200141.
11. Pappone, C. et al. (2018). Clinical outcome of electrophysiologically guided ablation for nonparoxysmal atrial fibrillation using a novel real-time 3-dimensional mapping technique. Circulation: Arrhythmia and Electrophysiology, 11(3). https://doi.org/10.1161/circep.117.005904.

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.

Indications: The TactiFlex™ Ablation Catheter, Sensor Enabled™ is indicated for use in cardiac electrophysiological mapping and for the treatment of drug refractory recurrent symptomatic paroxysmal atrial fibrillation and concomitant atrial flutter, when used in conjunction with a compatible RF generator and three-dimensional mapping system. **Contraindications:** Do not use for any of the following conditions: recent ventriculotomy or atriotomy heart surgery; prosthetic valves; active systemic infection; use in coronary vasculature; myxoma or intracardiac thrombus, transseptal approach with an interatrial baffle or patch; retrograde trans-aortic approach in patients with aortic valve replacement; patients unable to receive heparin or an acceptable alternative to achieve adequate anticoagulation. **Warnings:** The temperature data transmitted by the sensor in this catheter is representative of the irrigated electrode only and does not provide tissue temperature data. Application of RF energy on the left atrial posterior wall exceeding 40 W in power, or use of contact force ≥15g, increases the risk of esophageal perforating complications including atrio-esophageal fistula and death. Application of RF energy outside of the power and duration recommendations may increase the likelihood of steam pop occurrence. Patients undergoing septal accessory pathway ablation are at risk for complete AV block which requires the implantation of a permanent pacemaker. Implantable pacemakers and implantable cardioverter/defibrillator (ICDs) may be adversely affected by RF current. The combination of intracoronary placement of the ablation catheter and RF energy application has been associated with myocardial infarction and death. Inspect tubing, connections, and saline irrigation for air bubbles prior to and throughout its use in the procedure. Air or bubbles in the saline irrigation may cause emboli, potential injury, or fatality. Increased contact force may increase the risk for perforation during manipulation of the catheter. Contact force in excess of 20 g may not significantly change the characteristics of lesion formation. Contact force accuracy above 50 g has not been established. Caution should be taken when placing lesions in the proximity of the specialized conduction system. To avoid thromboemboli, intravenous heparin should be used when entering the left heart during ablation. Always maintain a constant saline irrigation flow to prevent coagulation within the lumen of the catheter. When using the catheter with conventional EP lab system (using fluoroscopy to determine catheter tip location) or with a 3D navigational system, careful catheter manipulation must be performed, especially when used in combination with a long sheath, in order to avoid cardiac damage, perforation, or tamponade. **Precautions:** Always straighten the catheter tip before insertion or withdrawal. If irrigation flow is interrupted, immediately inspect and re flush the catheter outside of the patient. Re-establish irrigation flow prior to placing catheter in the body. Irrigated ablation systems have been shown to create larger lesions than standard radiofrequency ablation catheters. Be careful when ablating near electrically vulnerable, thin walled, or other arterial structures. **Potential Adverse Events:** Potential adverse events include, but are not limited to, cardiovascular related complications, including hematoma, pericardial effusion and infection. More serious complications are rare, which can include damage to the heart or blood vessels; blood clots (which may lead to stroke); tamponade; severe pulmonary vein stenosis; heart block; myocardial infarction; esophageal fistula, or death.

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One St. Jude Medical Dr., St. Paul, MN 55117 USA, Tel: 1 651 756 2000
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