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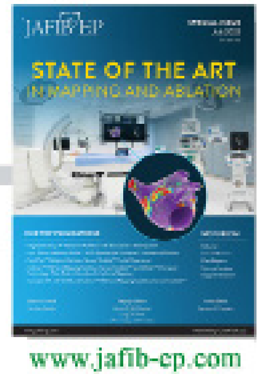

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Evolution of Abbott Mapping Technology from ESI to the EnSite™ X EP System

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Introduction

Practitioners of cardiac electrophysiology (EPs) have routinely adapted technology to manage rhythm disorders, beginning with little more than electrocardiography, fluoroscopy, and pacemakers. Some 30 years ago, 3D electroanatomic mapping was introduced to understand arrhythmia mechanisms, diagnose, and guide arrhythmia therapies. Advances in computing power, graphics, and catheters enabled implementations that offered continuous visualization of 3D cardiac anatomy and catheters without ionizing radiation. The ability for operators to guide catheters back to locations after exploring other positions and provide definitive treatments eventually dispelled the "tool or toy" skepticism that tends to accompany new technologies[1].

This article will describe advances in Abbott's 3D mapping technology, beginning in 1992 with Endocardial Solutions' EnSite 3000 through 2023 with Abbott's EnSite™ X EP System and associated devices (Figure 1). Throughout, the EnSite platform has continued with innovations to improve workflows for practitioners with features like Real Review, optical contact force sensing, AutoMap, and dual navigation modalities. High density mapping began with EnSite™ 3000 as it generated more than 3000 virtual electrograms over the entire endocardial surface. Despite increasingly strict requirements in ablation, EnSite NavX™ Mode, EnSite's impedance primary navigation today remains an open platform, enabling mapping with any diagnostic catheter. Abbott's EnSite™ X EP System has pioneered a technology that is widely accepted in the management of complex arrythmias and anatomies.

Key Words
Biomedical Engineering; Cardiac Arrhythmias; Cardiac Electrophysiology; Electrophysiology Mapping; Mapping; EnSite; Omnipolar Technology

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ESI and Non-Contact Mapping

Endocardial Solutions Inc. (ESI), originally called Endocardial Therapeutics, was founded in 1992 by Graydon Beatty, Jeffrey Budd, Tracy Young, and Jonathan Kagan in St. Paul MN. They envisioned a new endocardial approach to a decades old problem of estimating a cardiac time varying voltage distribution on a surface from a number of electrodes separated from that surface. ESI's approach depended on a stationary endocavitary probe holding an 8x8 array of electrodes made from laser ablated insulated wires – wires woven as a mesh basket on the outside of a balloon insulator (Figure 2). Up to 4 roving electrodes could be continuously located in 3D from 5.68 kHz locator signals – all with respect to the stationary electrode array. From the locations of these electrodes an anatomic model of the endocardial anatomic surface was produced. The cardiac surface together with the electrode array's spatial distribution and electrogram signals enabled a customized BEM (boundary element method) inverse solution for endocardial unipolar voltage signals. Virtual electrogram signals could be constructed at arbitrary locations including thousands of endocardial locations.

Locator signal generators and electrogram amplifiers were housed in a custom Patient Interface Unit or PIU and connected to a powerful (for the time) Silicon Graphics Octane workstation running IRIX, a variant of Unix. Programmed in C++, the EnSite 3000 system could capture long stretches of location and electrogram signals. Signals could be observed in real-time, frozen, or played back and forth slowly to watch depolarization patterns over the entire endocardial chamber. The location of the peak negative potential could be tracked and used to locate focal sources or regions of breakout (Figure 3). Voltages were rendered on the surface using color, creating time varying isopotential maps. Unipolar signals could also be visualized at a series of virtual electrodes at locations drawn by users on the endocardial surface using a mouse and displayed as signals time aligned with the surface ECG and electrodes on the roving catheter. Software engineers brought 3D maps to life with the assistance of graphics hardware to color and shade surface mesh triangles from BEM voltage solutions. Hardware

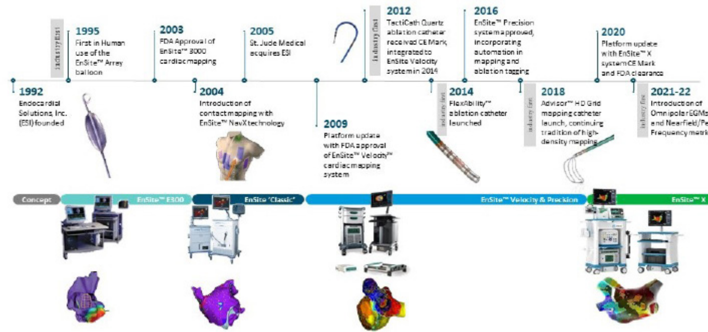

Figure 1: Timeline of EnSite™ major innovations from the formation of Endocardial Solutions in 1992 to Abbott's EnSite™ X EP System in 2023.

and systems engineers verified locational accuracy and proper probe wiring as suggested in Figure 4.

The first human studies with the EnSite™ 3000 occurred in Dr. Wyn Davies' lab in 1995 and results were presented at various meetings in 1996 including NASPE, ESC, and ACC[2]. Publications followed including early applications in the LV[3,4]. This non-contact mapping system was commercially released in 1998, achieving continuous, one-beat global mapping. Even rare single beat ectopy could be mapped over the entire chamber. The technology located focal sources and indicated depolarization patterns in rhythms such as atrial flutter, inappropriate sinus tachycardia, and RVOT PVCs. Formal publications, however, are inadequate to convey the impact on the EnSite™ 3000's developers and investigators. Consider the following vignette from an early clinical use. "The patient presented for AF ablation, and pulmonary vein isolation was achieved but remained in AF. AF was then cardioverted to sinus rhythm but spontaneously reverted to AF. The probe however remained in place and from recorded signals enabled us to locate the site of initiation to the posterior wall of the left atrium. There was a single deflection coincident with Vein of Marshall's location. Ablation there successfully terminated the AF to the delight of all involved."[5]

The path from conception to clinical use involves design, testing, and refinement. The earliest patent on this technology was filed in 1992. Among later more comprehensive patents is US 6,240,307, awarded in 2001 to Beatty, Kagan, and Budd[6]. Engineers and physicians conducted validation tests that included an implanted lead study in 5 canines. They measured the distance between bipolar plunge electrode signal sites and RF lesions guided to these LV sites by EnSite noncontact maps, reporting a mean distance error of 4.0 ± 3.2 mm [7]. The earliest models for cardiac chambers evolved from a simple spheroid, through a convex-hull algorithm that "shrink-wrapped" roving catheter points. In 2001 a new detailed geometry algorithm was released that accommodated more complex shapes. It started from a small sphere, collected geometry points into directional "bins" with distant points representing the endocardium, and fitted a triangle-mesh surface to them. However, it became increasingly clear that sequential contact mapping was important, and this drove the development of impedance localization technology enabling visualization and mapping independent of the balloon array probe.

EnSite NavX™ Mode and Contact Mapping

As 3D mapping grew in significance, additions to capabilities were made to meet clinical expectations and address newly understood needs. Software capabilities, catheter designs, and accessory instrumentation were enhanced as important changes were made to the mapping platform as the company transitioned from Endocardial Solutions to St. Jude Medical in 2005 and then to Abbott Laboratories in 2017.

The first major platform change was the commercial release in 2004 of a platform we refer to today as EnSite™ Classic. EnSite NavX™ Mode impedance localization was (and still is) a straightforward way to locate any electrode, facilitating low fluoro use, by tracking catheters through the abdomen and thorax. By measuring small voltages at 8.14 kHz, a frequency substantially greater than those of electrograms, EnSite NavX™ Mode signals provided patient centered coordinates with +X (left), +Y (posterior), and +Z (superior) at 102 samples/second relative to a fixed reference electrode. Custom hardware generated the cutaneous patch electrode currents necessary to generate EnSite NavX™ Mode signals and demodulated electrode voltages into orthogonal coordinates. This work was described by its inventors in US patent 7,263,397 issued in 2007[8]. As a result, multielectrode catheters could be rapidly moved over cardiac surfaces to generate geometry point clouds. Voth's DxL mapping algorithm [9] together with Olson's EnSite NavX™ Mode field scaling[10] addressed customer needs for increasingly accurate and detailed maps and cardiac surface models.

EnSite™ Classic marked the beginning of several other changes to 3D mapping. Verismo image segmentation software was brought to Classic to process volume scans from CT or MR into endo and epicardial surfaces. The EnSite Fusion™ feature[10,11] was FDA cleared in 2008 and allowed detailed cardiac models segmented using Verismo to be registered within the EnSite NavX™ Mode coordinate system mitigating native model distortions caused by inhomogeneous tissue conductivities.

Hardware and software engineers met physician needs for flexibility, addressing the need for multichambered maps, more input channels, and high-density catheters by creating the next major 3D mapping platform, EnSite™ Velocity™ Cardiac Mapping System. The 128 channel EnSite™ Velocity™ Cardiac Mapping System was FDA cleared in 2009 and implemented on a more powerful commercial workstation with professional graphics cards. It became possible to

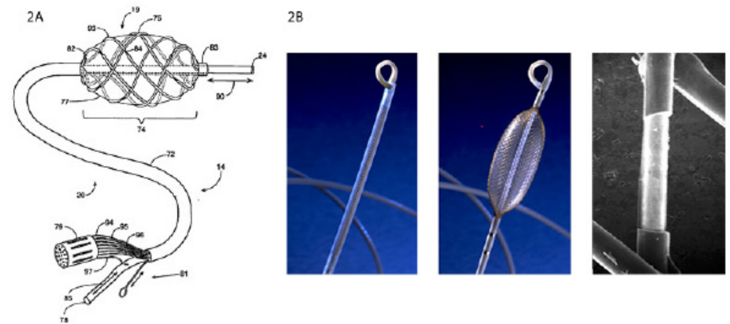

Figure 2: Innovative multielectrode array on a catheter (left) that enabled the EnSite™ 3000 3D mapping system to operate using signals from its laser ablated conductors (right).

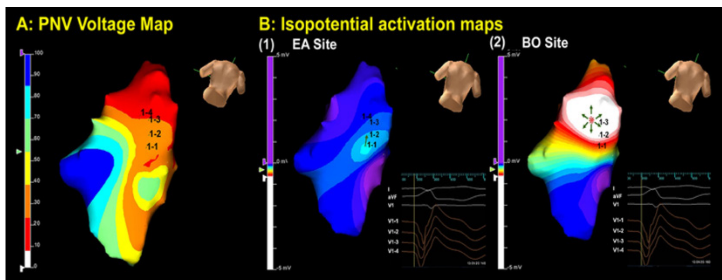

Figure 3: Mapping capabilities of the non-contact mapping EnSite 3000 are demonstrated by a peak negative voltage map (left), early activity site (middle), and breakout site (right).

collect maps of hundreds of thousands of map points from multiple surfaces or chambers, all stored in computer memory and capable of being rendered in high resolution on the 3D display. Software engineers developed 3D maps of voltage and local activation timing (LAT), processing single beat electrograms from a user defined RAI (roving activation interval). Maps were customized by introducing flexibility in how electrogram waveforms could be annotated (e.g., maximal -dV/dt criteria for unipoles and peak detection for bipoles). The system also introduced "duplicate handling", a process that facilitated map interpretation by grouping map points from different beats by proximity and resolving them to single map points.

Many projects came to fruition in 2011 on EnSite™ Velocity™ Cardiac Mapping System. Software developers Thompson and Starks' OneModel algorithm[12] used voxel-based treatments of geometry points with dilation and erosion to represent cardiac anatomy in exceptional detail. With OneModel, physicians and mappers could merge and reassign surfaces and obtain a more uniform triangular mesh at millimeter detail. Afonso and Belhe were awarded a US patent for maps characterizing the level of electrogram fractionation[13]. Abbott's unique Adaptive RespComp completed testing and was released in 2012, allowing EPs to collect map data throughout the respiratory cycle by virtue of synthesizing and subtracting a surrogate for ventilation-associated location artifact from thoracic impedance signals.

Important innovations in EP catheters came from linking expertise in cardiac catheters from SJM's Daig Corporation division and Irvine Biomedical, Inc. (IBI) to Endosense. Endosense's TOCCATA force sensing catheter trial, begun in 2009, showed that by providing force data to clinicians during ablation, 12-month arrhythmia outcomes were improved. SJM acquired this technology in 2013 with the TactiCath™ Quartz Contact Force Ablation Catheter and TactiSys™ Ablation Catheter instrumentation determined by fiber-optic interferometry (Figure 5) into displays of force magnitude and direction. Force sensing technology has improved the safety and efficacy of ablation procedures by giving EPs immediate feedback[14]. Force sensing was followed by introducing a revolutionary laser-cut flexible tip that was fully irrigated, obtaining FDA clearance in 2014 as SJM's Cool Flex catheter (Figure 6). Responding to needs for a more maneuverable ablation catheter, the FlexAbility™ Ablation Catheter, Sensor Enabled™ mounted the flexible tip on a redesigned shaft obtaining FDA clearance in 2015. Combinations of these technologies offer greater tip stability, outstanding irrigation, contact force, and magnetic sensor localization in the TactiFlex™ Ablation Catheter, Sensor Enabled™, approved for use in Europe and Japan in 2022 and under review by the FDA as of 2023.

Technical innovations to improve mapping and ablation workflows were the driving factors behind the introduction of EnSite Precision™ Cardiac Mapping System (FDA cleared in 2016). The Ampere™ RF generator's ablation power, temperature, and impedance were integrated into EnSite Precision™ Cardiac Mapping System. This information permitted the mapping system to automatically generate color coded lesion markers with a feature called EnSite™ AutoMark Module. Animation was further enhanced with SparkleMap in which activation points flash in chronologic order to assist visualization of timing activation maps[15]. OneMap and AutoMap were introduced to improve map efficiency and accuracy. OneMap permitted the simultaneous creation of anatomic models and maps. AutoMap mated criteria necessary for accurate map point acquisition with the ability to obtain map data on every heartbeat. Users could set limits to filter incoming data points if, for example, a beat's electrograms or cycle length were too discrepant from the map's template beat and rhythm. In addition, In-Sheath detection (by sensing a navigational signal reactance change) was introduced to improve map and model accuracy by automatically excluding points when electrodes are in a sheath.

Magnetic navigation grew in significance with the European and US approvals of TactiCath™ Ablation Catheter, Sensor Enabled™ (sensor enabled) in 2017 and 2019 respectively and Abbott's revolutionary Advisor™ HD Grid Mapping Catheter, Sensor Enabled™[16]. The Advisor™ HD Grid Mapping Catheter, Sensor Enabled™ featured a regular 2D arrangement of electrodes, obtaining FDA clearance in 2018. For the first time, a single mapping catheter supplied local bipole signals in orthogonal directions, visualizing important low level

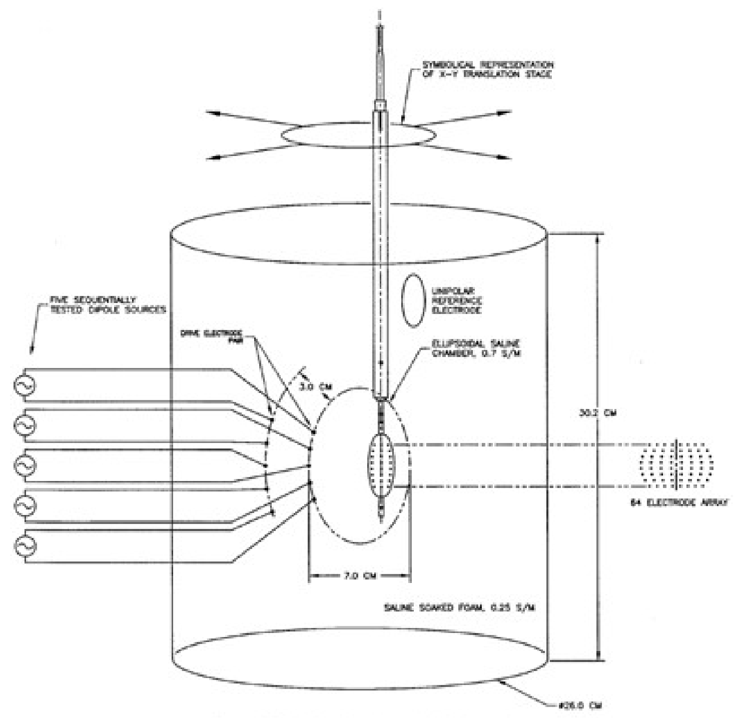

Figure 4: Test engineer's bench apparatus, constructed in this fashion and filled with saline, verifies the 3D location of electrogram signals for the EnSite™ 3000 non-contact mapping system.

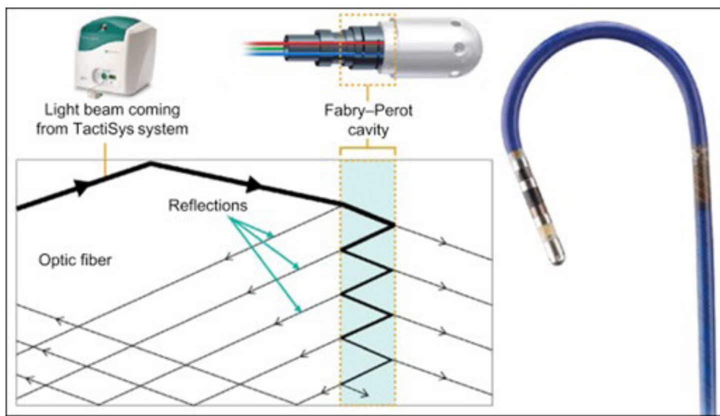

Figure 5: Optical force sensing technology pioneered by Endosense has appeared within the EnSite 3D mapping system on multiple generations of ablation catheters. Changes in interference fringes encode small deflections resulting from force.

deflections while addressing "bipole blindness". A bipolar catheter configuration called the HD Wave Solution™ software used the greatest voltage bipole from orthogonal bipole pairs to map low voltage areas with greater specificity[17].

Clinical studies with recent catheters and EnSite Precision™ Cardiac Mapping System features reported the system performed well. In a 515 patient registry study, over 95% of physicians rated the accuracy of AutoMark lesion markers Good or Excellent[18]. Preclinical and clinical data went into an implementation of LSI™, a lesion associated metric that combined contact force, RF current, impedance, and ablation duration. The LSI Workflow study employed LSI and TactiCath SE to obtain first pass PV isolation results in 76.2% of cases and found that use of LSI ≥ 5 resulted in shorter procedures, less RF and fluoroscopy as well as fewer touchup lesions[19].

EnSite™ X EP System

EnSite™ X EP System platform became available in 2020 and represented a major upgrade in capability as discussed below, but also brought along many features found in its predecessors. Clinicians, investigators, and engineers alike continue to enjoy a flexible, open system to

- capture screen images and make illustrative videos,
- export location and electrogram signals as well as EnSite™ X EP System surface models and maps to CSV and HTML files,
- connect on-site operators to Abbott support personnel sharing screen, keyboard, and mouse capabilities via secure internet connection and chat window with EnSite™ Connect Remote Support,
- support nearly any diagnostic catheter with electrode positions and electrogram signals through CIMs (catheter input modules),
- create a new map from previously recorded segments at 10 times the original speed with TurboMap,
- explore new features in research software branches, and
- store and retrieve EnSite studies, retrieve CT/MR DICOM images, or import pre-segmented 3D models with EnSite Courier PACS.

EnSite™ X EP System introduced new capabilities targeted at improving model and map accuracy and facilitate evolving workflows. Among the most important of these is the addition of a magnetic sensor-based navigation option, EnSite™ VoXel Mode, to the more traditional EnSite NavX™ Mode and EnSite™ NavX™ Navigation and Visualization Technology, Sensor Enabled™ Magnetic and impedance locations are fused into a common magnet-based coordinate frame. EnSite™ VoXel Mode technology avoids collecting map points or geometry where there is insufficient coincident magnetic and impedance localization. This has resulted in improved stability, catheter tracking, and model accuracy as demonstrated in bench and preclinical testing (Figure 7, Figure 8) as well as reported with clinical use.

The EnSite™ X EP System was built around a redesigned amplifier and more powerful DWS workstation. Unipolar electrogram signals, sampled at 2000 Hz, are considerably less noisy, as low as 0.01-0.02 mV peak-peak in fully instrumented preclinical studies. Small but important deflections are now better perceived and processed. All electrode impedances are continuously monitored by a method known as BECI, allowing improvements to In-Sheath detection. Catheter connections to the amplifier and recognition by the system are easier and automatic. The workstation has additional computing, graphics, and networking capabilities which will support features into the future.

Map functionality was also enhanced with the introduction of EnSite™ Omnipolar Technology (OT) which exploited orthogonal bipoles on Advisor™ HD Grid Mapping Catheter, Sensor Enabled™ electrode array[20]. Using vector electrocardiogram principles, it became possible to produce local bipolar electrogram signals at any 360° orientation, not just the along and across spline bipoles, as with HD Wave Solution™ Software. This ability is a key step to more accurately determining local activation direction and wave speed (Figure 9) from the shapes of unipoles and bipoles. EnSite™ OT activation vectors are local to 3-electrode groups and immediately displayed over Advisor™ HD Grid Mapping Catheter, Sensor Enabled™'s 2 cm^2 rendering. EnSite's capacity for immediate EnSite™ LiveView Dynamic Display displays of EnSite™ OT activation direction vectors, responsive to catheter maneuvers, has made possible new and more accurate maps of gaps and focal sources[21]. Since EnSite™ OT activation direction vectors depend on waveshapes and not timing, visualization of breakout and gaps during AF became possible, independent of a stable reference electrogram. And finally, all map polarities (unipole, bipole, and for Advisor™ HD Grid Mapping Catheter, Sensor Enabled™ omnipole)

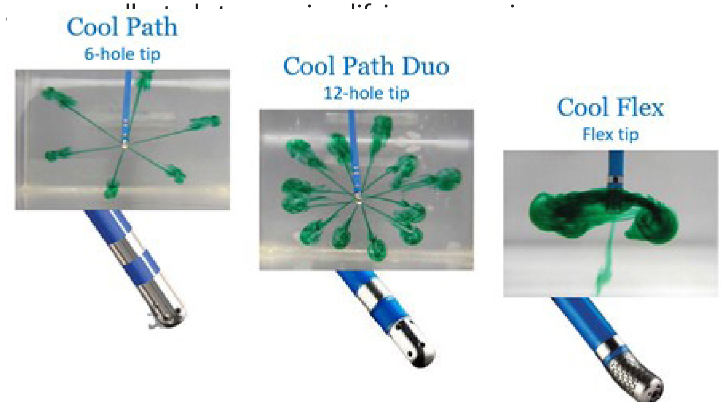

Figure 6: SJM's Cool Flex catheter (right) provides more dense local irrigation than predecessors Cool Path and Cool Path Duo.

Figure 7: Bench testing occurs in saline tanks where both catheter location as well as electrogram mapping can be evaluated in a controlled context. Systems engineers and test personnel conduct rigorous evaluations of accuracy, for example with catheter position and orientation, omnipolar voltage orientation independence, activation direction vectors, and wavefront speed.

Additional improvements and features were added. The option of respiratory gating was added to restrict model acquisition to end-expiration where ventilation associated artifact is minimal. Outlier removal has been added to optionally reduce visual distraction resulting from divergent map point data. Investigators can now rely on Map Statistics to quantify map surface area and compute descriptive statistics of locations where map values are above or below a user set threshold.

But perhaps the most significant enhancements were those associated with EnSite™ OT Near Field (NF) electrogram annotation, peak frequency (PF) maps, and emphasis maps. In a PF map, bipole or omnipole electrogram signals during map acquisition are characterized by the greatest frequency content, regardless of signal amplitude. This may help visualize regions with sharp local electrogram deflections. Near Field maps process electrograms for timing annotations corresponding to the moments of peak frequency content and may better portray local activation in the presence of far field signals. And finally, Emphasis Maps streamline map interpretation by emphasizing

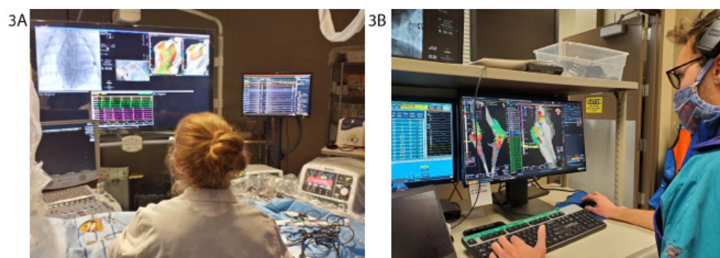

Figure 8: Abbott applied research, human factors, and preclinical engineers conduct pre-release mapping system and catheter evaluation in animal models. Abbott field personnel and EP physician advisors may also assist and recommend refinements.

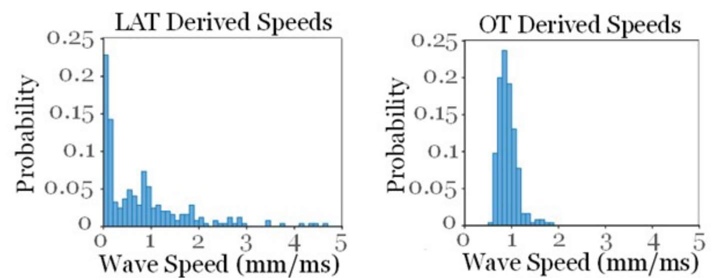

Figure 6: Comparison of wave speeds from the same 245 beat electrograms and locations from 6 EnSite™ X EP System clinical cases. The LAT timing-based approach from small groups or cliques of electrodes produces widely scattered speed estimates (left) whereas OT traveling wave-based methods (right), which are independent of timing, are more tightly gathered around accepted physiologic speeds of 1 mm/ms.

key information from related data sets. As an example, by making high amplitude locations less prominent, gap identification may be improved by emphasizing peak frequency information in low voltage regions.

Future Developments

The evolution of cardiac electrophysiology is intertwined with the tools and technologies applied. Physician scientists will continue to seek to understand arrhythmias and propose therapies based on those mechanisms. Abbott engineers will continue to develop and expand high-definition mapping and ablation with novel catheter designs and energy delivery such as PFA (pulsed field ablation) systems. The EnSite platform's tradition of open support is expected to stream location, electrogram, and geometry data to third party platforms. Anticipated workflow improvements include contact force arrow visualization, enhanced lesion designations, more convenient transitions in low fluoro cases from EnSite NavX™ Mode to EnSite™ VoXel Mode navigation, improved RespComp compensation for ventilatory artifact, and easier to use tools for editing anatomic model geometries. In addition, EnSite™ Connected Care will combine EnSite™ Connect Remote Support mapping support with Medinbox, an integrated audio-visual system allowing remote viewers to converse with physicians and lab staff as it transmits live video of the mapping system, fluoro, recording system, ICE, and video feed of the lab, changing the potential paradigm of procedure support. EnSite™ X EP System is well positioned to both keep pace with and lead in the technology driven domain of cardiac electrophysiology and its promises to deliver to patients sustained improvements and lifetime cures.

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