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of first time ICD recipients were candidates for S-ICD.[1]

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Arrhythmia-Specific Settings for Automated High-Density Mapping: A Multicenter Experience

Short Title:

Thresholds for automated electroanatomical mapping

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Abstract:

Background: Advancements in electrophysiology 3D mapping systems facilitate the broadening scope of electrophysiology study and catheter ablation to treat complex arrhythmias. While

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electroanatomical mapping systems have default settings available for a variety of mapping parameters, significant operator customization driven by arrhythmia type and experience can occur. However, multicenter comprehensive reporting of customized mapping settings is lacking.

Methods: In this prospective, multicenter observational registry, subjects with cardiac arrhythmias underwent electrophysiology study and ablation procedure using the EnSite Precision™ electroanatomical mapping system per standard of care, and associated automated mapping thresholds and procedural characteristics were observed.

Results: Cardiac mapping and ablation was performed in 503 patients (64.4% male, 59.6±13.2) for a variety of indications including atrial fibrillation (N=277), atrial flutter (N=67), other supraventricular tachycardias (N=96), and ventricular tachycardia (N=56). Automated electroanatomical mapping was used to generate 88.2% of all maps, and arrhythmia-specific adjustments of mapping thresholds were utilized to collect electrophysiologically relevant data. The most commonly used thresholds for mapping in AF were Distance (average 2.7±3.5mm) and Signal-to-Noise Ratio (5.2±1.1) while mapping in VT commonly used Score (88.5±6.5%) and Distance (0.6±0.5mm). Automated mapping collected and utilized 8.8 times more data than manual mapping without increasing mapping time.

Conclusions: This registry revealed arrhythmia-specific automated mapping settings used to generate electroanatomical maps of multiple cardiac rhythms with higher point density than manual mapping without increasing mapping time. Commonly used mapping threshold settings could serve as an important reference for new automated electroanatomical mapping users or those expanding their usage to new indications and arrhythmias.

Keywords: atrial fibrillation; atrial flutter; electroanatomical mapping; catheter ablation; ventricular tachycardia; Ensite Precision™

Introduction

Cardiac arrhythmias impart a global burden on health and healthcare systems. Patients with atrial tachycardia (AT) and atrial fibrillation (AF) have an increased risk of stroke, dementia, heart failure, and death.[1,2] Atrial fibrillation has become one of the most important public health problems and a significant cause of increasing healthcare costs in Western countries.[1-3] Cardiac ablation is recommended for treatment of drug refractory paroxysmal AF patients.[4-6] While paroxysmal AF is more common, ablation is also used to treat more challenging persistent AF cases. Persistent AF currently accounts for as much as 45% of all AF ablations, and incidence is expected to increase.[7,8]

Ventricular tachycardia, which can deteriorate into fatal ventricular fibrillation, is a leading cause of sudden cardiac death.[9] Sudden cardiac death occurs in as many as 50-100 per 100,000 people in

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North America and Europe.[10,11] Catheter ablation can be used to treat VT alone or in combination with implantable cardiac defibrillators (ICD) or antiarrhythmic medication. Successful catheter ablation of VT depends on mapping strategies to localize and ablate substrate responsible for abnormal electrical conduction.[12]

The growing use of catheter ablation to treat increasingly complex cases amplifies the need for electrophysiology-specific 3-dimensional (3D) mapping systems to navigate such cases. Electroanatomical mapping systems combine anatomical and electrical information to create anatomical representations of intracardiac electrical activation or other electrophysiological parameters and provide detailed functional and structural insight into the initiation and perpetuation of cardiac arrhythmias.[13] Mapping system accuracy is a key requirement to maximize success of challenging procedures. As a result, electroanatomical mapping systems have introduced features such as automatic mapping and workflow flexibility to aid in the success of complex ablation procedures including persistent AF and VT. EnSite Precision™ is a cardiac mapping system which contains novel automated mapping software, AutoMap, to enable rapid acquisition of high-density maps for a number of cardiac arrhythmias.

Automated electroanatomical mapping systems have enabled efficient treatment of increasingly complex arrhythmias, and the automated mapping thresholds are often customized from default settings based on the arrhythmia type and operator preference and experience. However, there is no comprehensive report on how default mapping settings are adjusted. Therefore, this observational registry aimed to identify clinically relevant AutoMap settings and threshold configurations used in ablation procedures for a variety of cardiac arrhythmias in real-world clinical settings.

Methods

Study Design

The EnSite Precision™ 2.0 observational registry (NCT02757430) was a prospective, multicenter, observational registry designed to assess and characterize the clinical use and performance of the

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EnSite Precision™ Cardiac Mapping System and the EnSite Precision™ Software V2.0 (Abbott, St. Paul, MN) in a variety of electrophysiological (EP) procedures and clinical settings in real-world environments. The Ethics Committee or Institutional Review Board at each participating site approved the study protocol, and all patients enrolled in the registry provided written informed consent.

Study Population

Patients with any cardiac arrhythmia indicated for cardiac electrophysiology study and ablation procedure using a 3D mapping system were eligible for participation in the registry. Patients over 18 years of age able to provide informed consent and willing to comply with the protocol were included in this registry. Patients with contraindication to anticoagulation, the presence of thrombus, an implanted mechanical prosthetic heart valve, a recent (<3 months) myocardial infarction or unstable angina or coronary artery by-pass, or were pregnant or nursing were excluded. The patient became a subject once he/she was fully informed about the registry, agreed to participate, and signed and dated the Informed Consent Form.

Mapping and ablation protocol

Patient demographics and clinical history was collected at enrollment and/or baseline visit. Subjects underwent cardiac electrophysiology study and ablation procedure using a 3D electroanatomical mapping system according to the IFUs of all medical devices used during the procedure, and standard of care and physician's discretion for diagnosed arrhythmia. Procedure and data collection guidelines were provided. Types and classification of AF and AT were determined in reference to the 2012 HRS/EHRA/ECAS Expert Consensus Statement on Catheter Ablation of Atrial Fibrillation.[14] The types and classification of ventricular arrhythmias were determined in reference to the 2009 EHRA/HRS Expert Consensus on Catheter Ablation of Ventricular Arrhythmias.[15]

The EnSite™ Cardiac Mapping System was used for electroanatomical mapping, and allowed the use of manual mapping, automated mapping with the EnSite™ AutoMap module (hereafter referred to as

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AutoMap), and retroactive secondary mapping with the EnSite™ TurboMap module (hereafter referred to as TurboMap) by applying AutoMap thresholds to recorded segments.

Automated electroanatomical mapping uses specific detection thresholds that can be customized by the operator. AutoMap detection thresholds include Score Threshold (12-lead surface morphology similarity to template beat), Cycle Length Tolerance (intracardiac cycle length deviation from original template beat), Speed Limit (maximum mapping catheter speed during mapping point collection), Distance Threshold (minimum 3D distance from previously collected mapping point), and Signal-to-Noise Ratio Threshold. Each threshold has a range of optional settings that can be implemented to enable automatic filtration of mapping data to collect information from relevant electrophysiological beats.

Nominal, or default, settings for AutoMap thresholds include Score Threshold morphology matching of 90%, Cycle Length Tolerance of 20ms, Speed Limit of 10mm/s, Distance Threshold of 1mm, and Signal-to-Noise Ratio of 5. Enhanced Noise Rejection is an additional threshold that is enabled by default.

Data was collected during the procedure on mapping activities, including creation of up to 4 maps per patient, procedural characteristics, electroanatomical mapping system and automated mapping software usage and customization of settings, and physician experience. A pre-discharge visit was performed within 1 day post-procedure and included physical examination, 12-lead ECG, review of medication, and assessment of any reportable adverse events or protocol deviations.

End Points

The registry used descriptive endpoints for characterization and evaluation of the electroanatomical mapping system, including the characterization of automated mapping software use and assessment of mapping time associated with mapping one or multiple arrhythmias in a single patient with AutoMap, TurboMap, and manual mapping.

Statistical Methods

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The target sample size of 500 subjects was determined in order to characterize mapping for a minimum of 50 subjects with each arrhythmia (AF, atrial flutter (AFL), other supraventricular tachycardia (SVT), and VT) and expecting VT to occur at the lowest rate, estimated to be 10%.

Statistical analysis, including descriptive summary statistics (mean, median, standard deviation), was performed to summarize use and distribution of AutoMap settings, and to compare mapping efficiency across mapping approaches. Distribution of continuous variables was compared with Student's T-test. Distribution of discreet variables was performed with Fischer's exact test or comparable nonparametric testing. Statistical analysis was performed using SAS version 9.4 (Cary, NC).

Results

Between August 30th 2016 and February 10th 2017, 515 patients were enrolled in the registry. Twelve subjects were withdrawn from the study due to inclusion or exclusion criteria not being met, no mapping or ablation procedure was performed or subject was otherwise terminated due to physician discretion. Cardiac mapping and arrhythmia ablation were performed on the analysis population of 503 patients at 19 centers throughout Europe (Supplemental Table 1).

Patients (64.4% male, 59.6±13.2 years of age) diagnosed with a variety of cardiac arrhythmias were enrolled. Patient characteristics and cardiovascular history stratified by procedural indication are summarized in Table 1. Of the 503 patients with mapping and ablation, 277 (55.1%) were indicated for treatment of AF (72.2% paroxysmal, 26.0% persistent, and 1.8% longstanding AF), 67 (13.3%) for AFL (70.1% typical, 25.4% atypical AFL), 96 (19.1%) for other SVTs, 56 (11.1%) for VT, and 46 (9.1%) for other indications including premature ventricular contractions (PVC). A total of 617 maps were created, with 50.7% of the maps created in sinus rhythm (SR). Other rhythms mapped in this registry included AF (N=61), AFL (N=72), AT (N=58), PVC (N=49), and VT (N=36).

Automated mapping thresholds

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The use of the AutoMap and TurboMap modules, manual mapping, or other mapping methods to create electroanatomical maps for subjects in this registry is summarized in Table 2. AutoMap or TurboMap were used to generate 88.2% of all maps, creating an opportunity to observe trends in how AutoMap thresholds were customized to automate the creation of maps for multiple cardiac arrhythmias in both atrial and ventricular chambers using multiple different catheters. Figures 1 and 2 provide examples of high density electroanatomical maps generated using automated mapping.

The real-world clinical settings observed in this registry, including the frequency of use and the average settings used for each AutoMap threshold, differed for mapped rhythm (Figure 3). This registry also revealed the range and distribution of settings used across all operators for each threshold, which varied to account for characteristics of the different arrhythmias (Figure 4). For instance, when mapping in AF, operators tended to turn off the Cycle-Length Tolerance threshold, and primarily relied on Distance (used in 94.9% of maps with 2.7±3.5mm average setting) and Signal-to-Noise Ratio thresholds (83.1% of maps with 5.2±1.1 average setting). When mapping in VT, operators tended to rely on Score (used in 100% of maps with 88.5±6.5% average setting), Distance (used in 92.6% of maps with 0.6±0.5 average setting), and Speed Limit (used in 88.9% of cases with 11.8±4.6mm/s average setting).

Mapping Characteristics

Mapping characteristics observed in this registry are summarized in Table 3. While mapping times using manual mapping or AutoMap did not significantly differ, during initial map creation and when comparing all mapping instances, Automap collected up to 12.7 times more data points, and used up to 8.8 times more data points than manual mapping (Table 3). Automap thereby allowed for significantly more mapping data to be collected in the same period of time, collecting over 5 times as many used data points per minute ($P<0.001$).

When TurboMap was used to generate secondary maps, mapping time was significantly shorter than manual or AutoMap mapping times ($P=0.0018$, $P=0.0067$ respectively). Additionally, TurboMap

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generated secondary maps including more than 15 times as many data points as the average manual map (Table 3, P<0.001). TurboMap used over 18 times more data points per minute than manual mapping and 3 times more data points per minute than AutoMap maps (Table 3, P<0.001).

To account for variability in the number of mapping electrodes present during mapping, the number of mapping points used per minute per electrode for cases using defined catheter types was also determined to be significantly greater for AutoMap compared to manual mapping, and for TurboMap compared to either AutoMap or manual mapping (Table 3, P<0.001).

Discussion

This observational registry provided insight into the use of automated electroanatomical mapping in different cardiac arrhythmia cases in the real world. The use of comparable automated mapping systems used in preclinical and clinical settings has been described previously.[16-21] The current registry uniquely observed the use of, and settings employed by, multiple operators to create electroanatomical maps for different arrhythmias. The current registry confirmed that automated mapping thresholds, especially Score Threshold and Cycle Length Tolerance, are manipulated by the operator to customize the filtration of electrophysiological data to accommodate characteristics of different cardiac arrhythmias.

Ventricular Rhythms

By enabling and manipulating the morphology Score Threshold, operators can ensure electroanatomical mapping of ventricular arrhythmias is generated from only electrophysiologically relevant cardiac beats. Reflecting the need to capture and save only data that closely matches a selected template beat, in this registry Score threshold was used 100% of the time during the automated mapping of PVC and VT with an average setting near 90% morphology match. A low Cycle Length Tolerance threshold can be used during the mapping of regular rhythms like VT, as seen in the narrow distribution of Cycle Length Tolerance when used in mapping of VT (20-30ms) here. However, the Cycle Length Tolerance threshold was not frequently used during VT mapping

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reflecting the ability of other thresholds, especially Score Threshold, to better filter mapping points for this rhythm. The Cycle Length Tolerance threshold was rarely used to map PVC. This reflects the inconsistent nature of the PVC coupling interval which makes Cycle Length Tolerance an irrelevant metric to discriminate in this rhythm. In such cases, the Score Threshold is sufficient to filter relevant data, as supported by this registry. The lowered Distance Threshold settings used in VT allow for redundant localized data collection important for clearly defining scar tissue. The Signal-to-Noise Ratio Threshold also tended to be reduced from nominal settings and a narrow range of settings was used, most likely to allow mapping of low voltage areas crucial for VT cases. When mapping VT subjects in SR, Cycle Length Tolerance and Distance thresholds were used even less frequently than when mapping in VT, reflecting the need to collect high quantities of data quickly, relying primarily on the Score threshold to exclude data. The use of automated mapping allows for higher density acquisition and display of electrophysiologically relevant data to assist in understanding mechanisms of ventricular arrhythmias, such as the example shown in Figure 1. In this case, automated high density acquisition of SR activation timing facilitated the rapid and enhanced understanding of the dynamics of wave front conduction in left ventricular substrate maps (14.5min of mapping, 17,010 data points collected, 1,451 data points used). The regions of late activation and the corresponding electrograms and voltage map were used to support the mapping and therapeutic analysis of the ischemic VT being mapped. Identifying such regions of late activation in SR quickly and accurately can facilitate mapping and therapy strategies when treating ischemic VT.

Atrial rhythms

In this registry, operators used a wider distribution of Score Threshold settings to allow for the range of electrophysiological data needed to map atrial cases. The P wave morphology in atrial arrhythmias may have low amplitude, resulting in decreased matching scores. In this case, users can and should reduce the Score Threshold to collect mapping data. Decreasing the Score Threshold without turning it off allows the system to capture AutoMap data for atrial arrhythmias with lower P wave amplitude while still rejecting beats where the QRS complex would cause far field artifact to be inappropriately

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saved. For example, mapping 2:1 and 3:1 atrial arrhythmias with exact morphology matching of P-waves is less important than eliminating beats with QRS complexes or other far-field signals. These reasons are likely why the Score Threshold appears bi-nodal or more disperse in atrial rhythms than ventricular arrhythmias in the real world clinical settings observed here (Figure 4). During mapping of regular rhythms like AFL, Cycle Length Tolerance was often used with the nominal 20ms setting. However in arrhythmias with natural cycle length variability, such as focal arrhythmias, the Cycle Length Tolerance was increased or disabled to allow a greater amount of data to be collected. In this registry, the Speed Limit threshold was often increased above the nominal setting of 10mm/s without turning the threshold off. This indicates that users were comfortable in collecting data in this system while moving the catheter to allow for more efficient data collection that remains protected from collection of mechanical artifact. This threshold was turned off occasionally for some rhythms, such as AF, most likely reflecting the need for operators to collect as much data as possible as fast as possible. In such cases, increased speed does not necessarily result in collection of bad data, as data collection can still be automatically filtered using a combination of other thresholds. When mapping AF subjects in SR, the use of Score and Cycle Length Tolerance thresholds are increased relative to mapping in AF. This reflects the ability to create a detailed map with greater data specificity that can be allowed in SR compared to mapping in AF where mappers may be more focused on collecting a high quantity of data without exclusivity. Figure 2 demonstrates how using a conventional circular mapping catheter with AutoMap algorithm thresholds can yield an accurate high resolution atrial map. The propagation of counterclockwise left atrial macroreentrant tachycardia, specifically counterclockwise mitral annular flutter, was revealed using a combination of thresholds which were optimized to accomplish efficient and accurate data collection.

In addition to the flexibility allowed by automated mapping thresholds to accurately capture and filter mapping data and characterize cardiac rhythms, this registry also confirmed that automated mapping significantly increased the efficiency of electroanatomical mapping that has been shown preclinically.[22] Although automated mapping did not significantly reduce mapping time, mapping

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speeds were relatively fast using manual mapping, averaging 14.2 min, such that a reduction in mapping time would offer little clinical benefit. However, in the same amount of time, automated mapping was able to collect and use significantly more electroanatomical data points. The use of automated thresholds removes the need to manually collect and filter every mapping data point collected. Therefore, significantly more data points, and significantly more filtered relevant data points can be collected in the same amount of time, even when standardized for the number of electrodes used for mapping. This results in more detailed electroanatomical maps than manual mapping in a variety of cardiac rhythms using a variety of catheters.

A unique strength of the automated electroanatomical mapping system used here is the ability to rapidly create secondary maps of the same rhythm retroactively using the TurboMap software feature. When used, data collected during original mapping can be replayed at accelerated speeds with revised automated thresholds applied. In this way, physicians are able to learn additional information from mapped points using TurboMap even if the target arrhythmia has terminated. This is because newly defined threshold criteria based on the theory of the rhythm being mapped can be applied retroactively rather than requiring the collection of new data. This allows the physician to understand complex arrhythmias quickly. This allows the physician to understand complex arrhythmias quickly. For example, when there are multiple different PVCs occurring during electroanatomical mapping, AutoMap can be used to collect high density mapping data for one PVC. Subsequently, remapping can be performed with TurboMap to automatically create a secondary PVC map using the same high density mapping data already collected. Similarly, AutoMap could be used to create a ventricular map of local activation time (LAT) while a clinical PVC is occurring. While the ventricular LAT map is created first, TurboMap can be used to automatically map the PVC from the previously recorded segment or vice versa. In the atria, mapping of an atrial flutter that oscillates between two circuits with different cycle lengths in a bigeminal pattern could benefit from TurboMap. While one cycle length can be captured in the original map, the second cycle length can be quickly mapped using TurboMap on the recorded mapping data with adjustments to the automated mapping thresholds. Such

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virtual remapping of arrhythmias was shown to significantly reduce mapping time compared to creating a new manual or second automatic map, while also recording significantly more usable mapping points per minute.

Limitations

This observational registry evaluated electroanatomical mapping with no long-term follow up or randomization. Therefore benefits of mapping technologies to clinical outcomes can only be inferred. The limited variety of catheters used, including multipolar mapping catheters, may limit the extrapolation of these results to other electroanatomical mapping scenarios. To account for catheter variability, efficiency of mapping was also determined per electrode. Additionally, there is likely a learning curve with the use of automated electroanatomical mapping and mapping settings applied for different arrhythmias. Physician preference and performance may evolve with experience and familiarity with the system.

Conclusions

This observational registry demonstrated the arrhythmia-specific customization offered by EnSite Precision™ automated electroanatomical mapping. Application of automated mapping resulted in over 8 times higher mapping point density without increasing mapping time, thereby providing efficient and detailed information regarding electrical activation for the various rhythms mapped here. The current registry has provided valuable insight into real-world usage and settings of automated mapping thresholds, demonstrating how automated mapping thresholds allow for an individualized approach to electroanatomical mapping tailored to specific rhythm characteristics. Commonly used automated mapping thresholds identified in this study may serve as an important reference for users new to the system or those expanding their usage to new indications and arrhythmias.

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Table 1. Patient Characteristics

Parameter	All Patients with procedure (N=503)	Indication for Current Procedure: Atrial Fibrillation 277/503 (55.1%)	Atrial Flutter 67/503 (13.3%)	Other SVT 96/503 (19.1%)	Ventricular Tachycardia 56/503 (11.1%)
Age (Years)	59.6±13.2 (503)	61.9±10.0 (277)	61.3±11.2 (67)	54.7±15.2 (96)	62.7±14.0 (56)
Gender - Male	324/503 (64.4%)	197/277 (71.1%)	43/67 (64.2%)	38/96 (39.6%)	48/56 (85.7%)
Ejection Fraction (%)	54.2±12.0 (285)	56.6±9.6 (147)	56.0±11.0 (36)	57.4±10.9 (49)	44.5±15.0 (45)
Left Atrial Diameter (mm)	43.1±8.3 (113)	45.1±5.7 (74)	42.7±9.4 (18)	36.7±7.6 (22)	51.3±13.8 (6)
Left Atrial Volume (ml)	82.3±42.7 (136)	90.6±44.3 (96)	73.5±26.7 (15)	65.4±47.0 (11)	75.4±35.2 (17)
NYHA Class					
Class I/II	167/501 (33.3%)	87/277 (31.4%)	28/66 (42.4%)	36/95 (37.9%)	19/56 (33.9%)
Class III/IV	17/501 (3.4%)	9/277 (3.2%)	3/66 (4.5%)	1/95 (1.1%)	3/56 (5.4%)
Not Evaluated	317/501 (63.3%)	181/277 (65.3%)	35/66 (53.0%)	58/95 (61.1%)	34/56 (60.7%)
Cardiac Disease History					
No cardiovascular Disease	335/503 (66.6%)	201/277 (72.6%)	45/67 (67.2%)	75/96 (78.1%)	11/56 (19.6%)

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Parameter	All Patients with procedure (N=503)	Indication for Current Procedure			
		Atrial Fibrillation 277/503 (55.1%)	Atrial Flutter 67/503 (13.3%)	Other SVT 96/503 (19.1%)	Ventricular Tachycardia 56/503 (11.1%)
Coronary Artery Disease	48/503 (9.5%)	20/277 (7.2%)	8/67 (11.9%)	10/96 (10.4%)	9/56 (16.1%)
Myocardial Infarction	27/503 (5.4%)	10/277 (3.6%)	3/67 (4.5%)	3/96 (3.1%)	11/56 (19.6%)
Previous CABG	14/503 (2.8%)	4/277 (1.4%)	2/67 (3.0%)	2/96 (2.1%)	4/56 (7.1%)
Percutaneous coronary intervention/stent/atherectomy	39/503 (7.8%)	15/277 (5.4%)	4/67 (6.0%)	7/96 (7.3%)	9/56 (16.1%)
Cardiomyopathy	101/503 (20.1%)	39/277 (14.1%)	11/67 (16.4%)	6/96 (6.3%)	40/56 (71.4%)
Valvular Heart Disease	59/503 (11.7%)	24/277 (8.7%)	11/67 (16.4%)	5/96 (5.2%)	15/56 (26.8%)
Other Cardiovascular Disease	19/503 (3.8%)	12/277 (4.3%)	6/67 (9.0%)	1/96 (1.0%)	1/56 (1.8%)
Arrhythmia History					
Atrial Fibrillation	318/503 (63.2%)	276/277 (99.6%)	46/67 (68.7%)	15/96 (15.6%)	10/56 (17.9%)
Paroxysmal	218/318 (68.6%)	194/276 (70.3%)	33/46 (71.7%)	11/15 (73.3%)	4/10 (40.0%)
Persistent	89/318 (28.0%)	77/276 (27.9%)	11/46 (23.9%)	4/15 (26.7%)	2/10 (20.0%)
Longstanding Persistent	11/318 (3.5%)	5/276 (1.8%)	2/46 (4.3%)	0/15 (0.0%)	4/10 (40.0%)
Atrial Flutter	92/503 (18.3%)	57/277 (20.6%)	57/67 (85.1%)	7/96 (7.3%)	2/56 (3.6%)
Typical	70/90 (77.8%)	42/56 (75.0%)	45/56 (80.4%)	5/7 (71.4%)	1/2 (50.0%)
Atypical	20/90 (22.2%)	14/56 (25.0%)	11/56 (19.6%)	2/7 (28.6%)	1/2 (50.0%)
Atrial Tachycardia	62/503 (12.3%)	7/277 (2.5%)	5/67 (7.5%)	51/96 (53.1%)	2/56 (3.6%)
Ventricular Tachycardia	52/503 (10.3%)	2/277 (0.7%)	0/67 (0.0%)	2/96 (2.1%)	46/56 (82.1%)
Ischemic	22/50 (44.0%)	1/2 (50.0%)		1/2 (50.0%)	19/45 (42.2%)
Non-Ischemic	28/50 (56.0%)	1/2 (50.0%)		1/2 (50.0%)	26/45 (57.8%)
Other Arrhythmia History	101/503 (20.1%)	7/277 (2.5%)	1/67 (1.5%)	41/96 (42.7%)	13/56 (23.2%)

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Parameter	All Patients with procedure (N=503)	Indication for Current Procedure			
		Atrial Fibrillation 277/503 (55.1%)	Atrial Flutter 67/503 (13.3%)	Other SVT 96/503 (19.1%)	Ventricular Tachycardia 56/503 (11.1%)
Previous arrhythmia treatments					
Medication	337/503 (67.0%)	211/277 (76.2%)	48/67 (71.6%)	49/96 (51.0%)	34/56 (60.7%)
Cardioversion	145/503 (28.8%)	101/277 (36.5%)	25/67 (37.3%)	16/96 (16.7%)	17/56 (30.4%)
Ablation	123/503 (24.5%)	69/277 (24.9%)	22/67 (32.8%)	22/96 (22.9%)	15/56 (26.8%)

Table 2. Mapping module used by mapped rhythm.

Category	Manual	AutoMap	TurboMap	Other
All Arrhythmias	11.3% 70/617	85.9% 530/617	2.3% 14/617	0.5% 3/617
Rhythm Mapped				
Sinus Rhythm	2.9% 9/313	95.8% 300/313	1.0% 3/313	0.3% 1/313
Atrial Fibrillation	3.3% 2/61	95.1% 58/61	1.6% 1/61	0.0% 0/61
Atrial Flutter	9.7% 7/72	83.3% 60/72	5.6% 4/72	1.4% 1/72
Atrial Tachycardia	24.1% 14/58	72.4% 42/58	3.4% 2/58	0.0% 0/58
Ventricular Tachycardia	22.2% 8/36	72.2% 26/36	2.8% 1/36	2.8% 1/36
PVC	20.4% 10/49	73.5% 36/49	6.1% 3/49	0.0% 0/49
Other	71.4% 20/28	28.6% 8/28	0.0% 0/28	0.0% 0/28

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Table 3. Mapping Characteristics

						Pairwise P-Values (t-test)		
	Total	Manual	AutoMap	TurboMap	Overall P-value (ANOVA)	Auto vs. Manual	Turbo vs. Manual	Auto vs. Turbo
Mapping time (min)								
All Maps	13.0±12.0 (604)	14.2±13.9 (62)	13.1±11.9 (527)	6.6±5.7 (13)	0.145	0.0782	0.0018	0.0067
1st Map	14.5±12.9 (421)	16.2±14.8 (24)	14.4±12.8 (397)	N=0	0.520	0.2612	.	.
Total points collected								
All Maps	2071±3375 (607)	178±392 (63)	2268±3499 (528)	2827±3221 (14)	<0.001	<0.0001	<0.0001	0.7808
1st Map	2260±3663 (420)	223±398 (23)	2378±3732 (397)	N=0	0.006	<0.0001	.	.
Total points used								
All Maps	781±1062 (607)	97±163 (63)	855±1093 (528)	1064±1156 (14)	<0.001	<0.0001	<0.0001	0.6780
1st Map	872±1151 (420)	132±201 (23)	915±1169 (397)	N=0	0.001	<0.0001	.	.
Points Used/Minute								
All Maps	79.6±101.7 (603)	14.1±33.1 (61)	82.4±86.3 (527)	260.0±352.0 (13)	<0.001	<0.0001	<0.0001	<0.0001
1st Map	73.9±81.9 (420)	13.5±19.8 (23)	77.4±82.8 (397)	N=0	<0.001	<0.0001	.	.
Points Used/Minute/Electrode [†]								
All Maps	9.74±13.49 (509)	1.65±3.72 (42)	10.03±12.99 (458)	36.90±29.28 (8)	<0.001	<0.0001	<0.0001	<0.0001
1st Map	9.23±13.55 (357)	1.34±1.66 (15)	9.57±13.73 (342)	N=0	0.021	<0.0001	.	.

Values reported as mean ± SD (N).

[†]Excludes cases using unknown catheter or number of electrodes.

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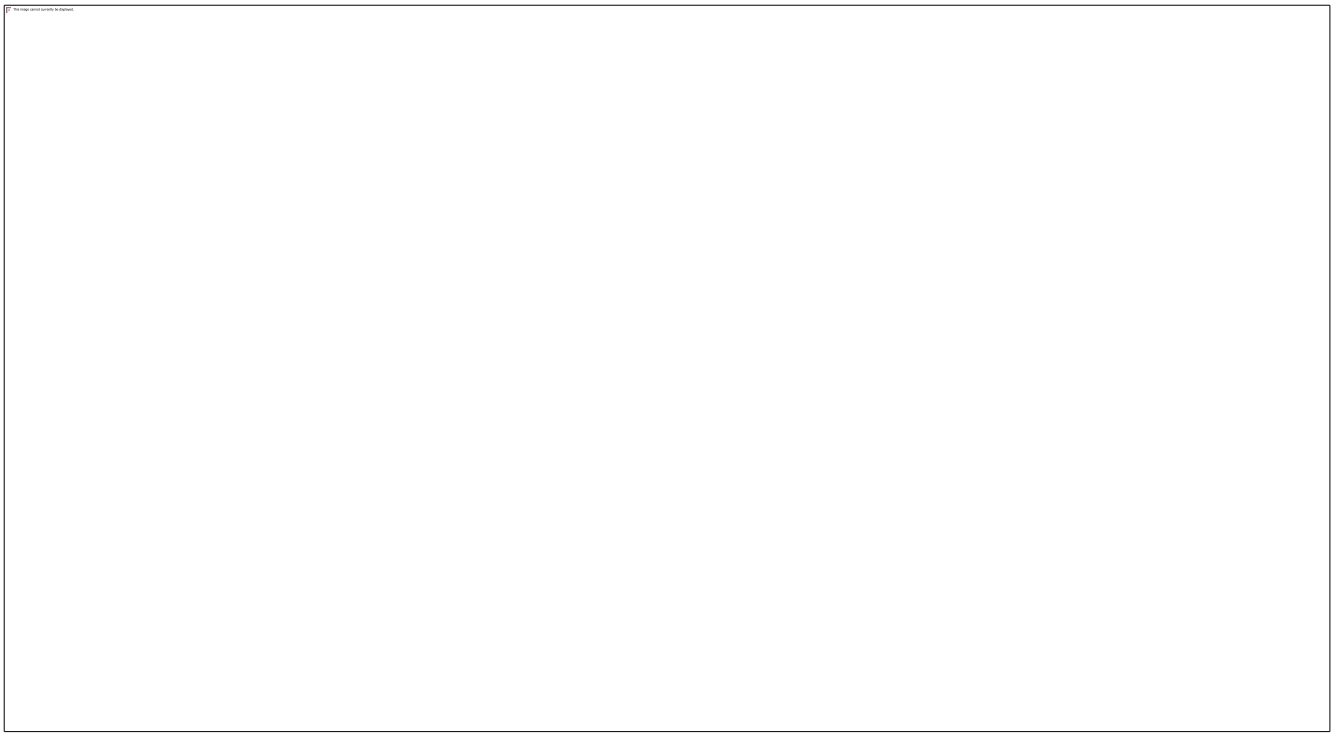

Figure 1. Activation and voltage map of sinus rhythm during ischemic VT procedure performed using automated electroanatomical mapping. Automated electroanatomical map of sinus rhythm during an ischemic VT case demonstrates high density of data collection possible within the region of interest in the left ventricle. High density activation timing map (left) shows a region of late activation that is supported by the adjacent electrograms. Electrodes on the catheter shown within the late activation regions of the map correspond with the compelling electrograms showing late activation within the user-defined template window. The substrate voltage map (right), displayed at scale of 0-1.5mV, highlights the low voltage region corresponding with the late activation region of the activation map. Thresholds applied in this case were Score Threshold 90%, Speed Limit 15mm/s, and Signal-to-Noise ratio threshold of 3:1. Yellow surface points indicate location of every data point collected.

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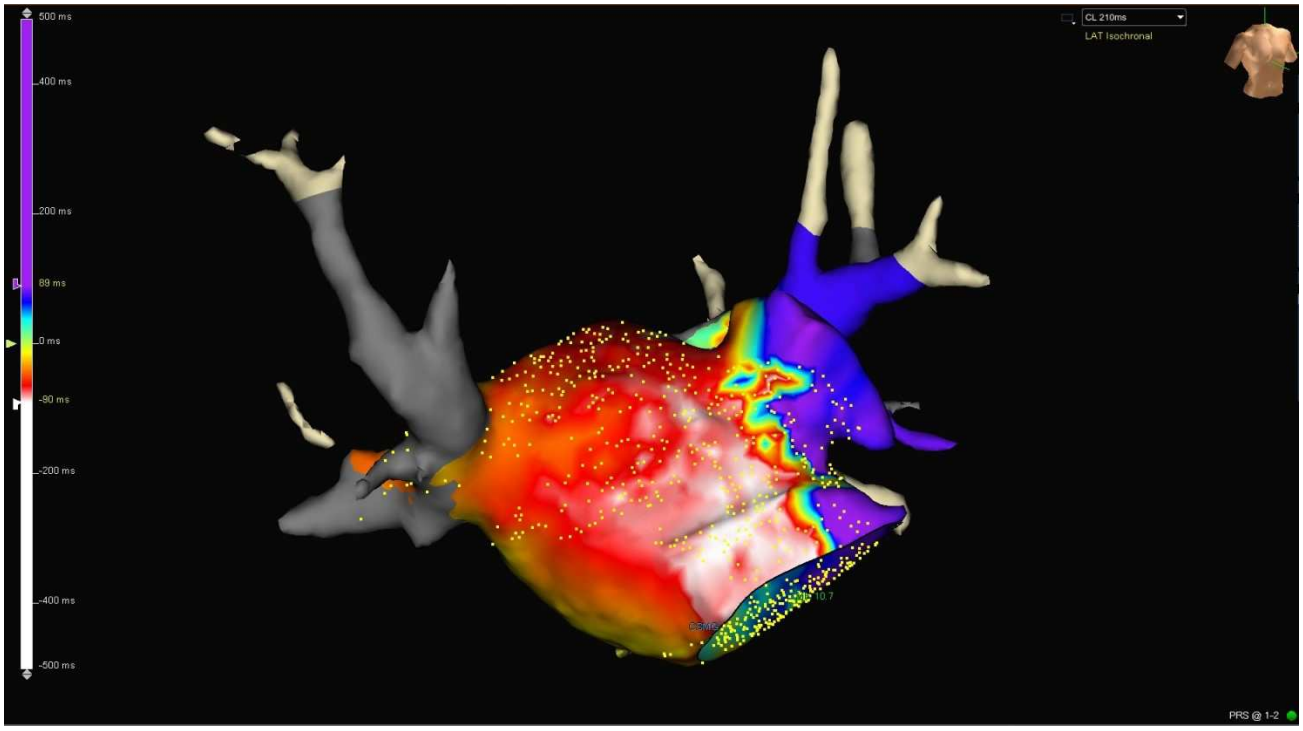

Figure 2. Activation map revealing counter clockwise left atrial mitral annular flutter. Automated electroanatomical map of the left atrium generated using a circular mapping catheter and individualized automated data filtration thresholds. Thresholds applied in this case were Cycle Length Tolerance set to 40ms, Score Threshold set at 90%, and Signal-to-Noise ratio threshold of 5:1. Yellow surface points indicate location of every data point collected.

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Mapping settings	All Arrhythmias (N=544)	Sinus Rhythm: SR with all indications (N=303)	Sinus Rhythm: SR with AF indication (N=178)	Sinus Rhythm: SR with VT indication (N=54)	Atrial Fibrillation (N=59)	Atrial Flutter (N=64)	Atrial Tachycardia (N=44)	PVC (N=39)	Ventricular Tachycardia (N=27)	Other (N=8)
Score (%)										
% Used	73.0%	72.6%	61.8%	100%	33.9%	70.3%	86.4%	100%	100%	100%
n/N	397/544	220/303	110/178	54/54	20/59	45/64	38/44	39/39	27/27	8/8
Mean ± SD	74.6 ± 22.4	78.1 ± 18.4	74.2 ± 21.7	87.0 ± 5.2	70.7 ± 29.8	53.6 ± 26.3	51.3 ± 18.8	91.5 ± 4.2	88.5 ± 6.5	85.1 ± 10.4
Median (Range)	86 (0 - 98)	90 (9 - 98)	82.5 (9-98)	90 (71-95)	85 (0 - 95)	50 (0 - 95)	50 (2 - 90)	90 (80 - 97)	90 (74 - 97)	90 (61 - 90)
Cycle length tolerance (ms)										
% Used	38.1%	30.0%	31.5%	5.6%	8.5%	93.8%	90.9%	5.1%	22.2%	37.5%
n/N	207/544	91/303	56/178	3/54	5/59	60/64	40/44	2/39	6/27	3/8
Mean ± SD	37.8 ± 35.1	53.2 ± 41.9	57.2 ± 42.1	40 ± 34.6	42.0 ± 61.0	27.3 ± 24.4	22.3 ± 10.0	15.0 ± 21.2	23.3 ± 5.2	23.3 ± 5.8
Median (Range)	20 (0 - 150)	44 (0 - 150)	50 (0-150)	20 (20-80)	20 (0 - 150)	20 (10 - 150)	20 (10 - 60)	15 (0 - 30)	20 (20 - 30)	20 (20 - 30)
Speed limit (mm/s)										
% Used	91.0%	93.1%	91.6%	98.1%	66.1%	95.3%	95.5%	100%	88.9%	100%
n/N	495/544	282/303	163/178	53/54	39/59	61/64	42/44	39/39	24/27	8/8
Mean ± SD	12.7 ± 6.1	13.9 ± 6.0	14.2 ± 6.6	14.5 ± 6.2	11.4 ± 10.3	10.0 ± 4.0	11.5 ± 4.8	11.9 ± 3.6	11.8 ± 4.6	12.0 ± 3.5
Median (Range)	10 (0 - 70)	15 (0 - 70)	15 (0.1-70)	15 (6-30)	10 (6 - 70)	10 (6 - 21)	10 (6 - 21)	10 (6 - 21)	10 (6 - 20)	13 (6 - 15)
Distance (mm)										
% Used	84.0%	79.9%	89.9%	46.3%	94.9%	89.1%	97.7%	69.2%	92.6%	87.5%
n/N	457/544	242/303	160/178	25/54	56/59	57/64	43/44	27/39	25/27	7/8
Mean ± SD	1.2 ± 1.8	1.1 ± 1.5	1.0 ± 1.1	0.5 ± 0.4	2.7 ± 3.5	0.9 ± 0.5	1.0 ± 1.5	1.1 ± 1.5	0.6 ± 0.5	0.6 ± 0.4
Median (Range)	1 (0 - 10)	1 (0 - 10)	1 (0.1-10)	0.1 (0.1-1)	1 (0 - 10)	1 (0 - 2)	1 (0 - 10)	1 (0 - 8)	1 (0 - 1)	0.3 (0.1 - 1)
Signal-to-noise ratio										
% Used	79.0%	77.2%	79.8%	79.6%	83.1%	85.9%	65.9%	89.7%	77.8%	87.5%
n/N	430/544	234/303	142/178	43/54	49/59	55/64	29/44	35/39	21/27	7/8
Mean ± SD	5.3 ± 2.2	5.3 ± 2.6	5.8 ± 3.2	4.7 ± 0.8	5.2 ± 1.1	5.7 ± 2.4	4.9 ± 0.7	5.1 ± 1.8	4.7 ± 0.9	5.0 ± 0.0
Median (Range)	5 (2 - 20)	5 (2 - 20)	5 (2-20)	5 (2-5)	5 (3 - 10)	5 (5 - 16)	5 (3 - 7)	5 (3 - 15)	5 (2 - 5)	5 (5 - 5)
Enhanced noise rejection										
% Used	88.4%	90.9%	90.2%	92.6%	71.9%	92.1%	88.4%	89.7%	100.0%	37.5%
n/N	473/535	271/298	156/173	50/54	41/57	58/63	38/43	35/39	27/27	3/8

Figure 3. AutoMap threshold settings by cardiac arrhythmia. Frequency of AutoMap threshold use and average, median, and range of AutoMap thresholds used by investigators in real-world settings to create 544 maps encompassing different atrial and ventricular arrhythmias (N=number of maps generated). SR=Sinus Rhythm; AF=Atrial Fibrillation; PVC=Premature Ventricular Contraction; VT=Ventricular Tachycardia.

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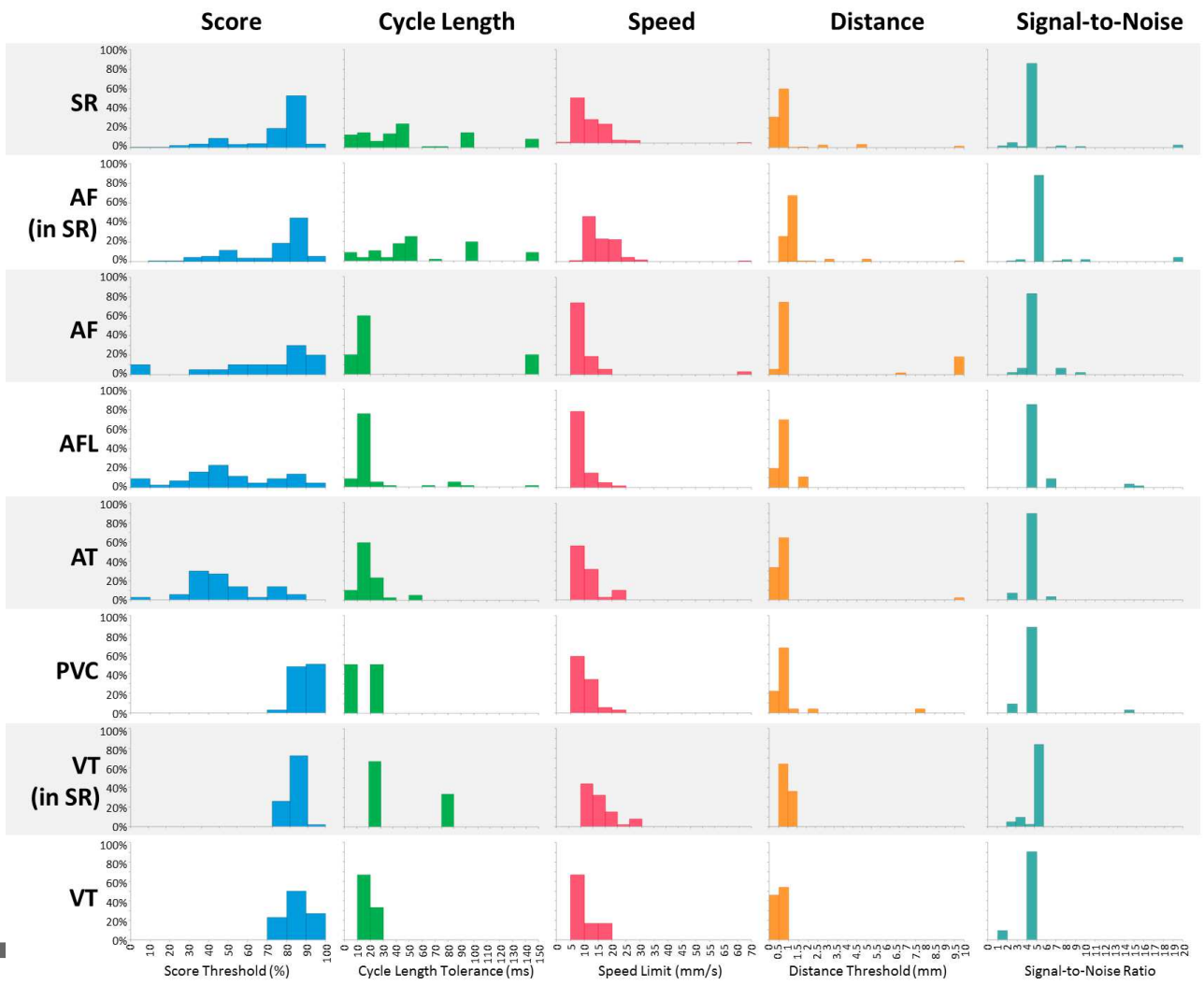

Figure 4. Distribution of AutoMap threshold settings

Histograms showing the distribution of EnSite™ AutoMap threshold settings used by investigators for 544 maps generated with AutoMap and TurboMap stratified by cardiac rhythm mapped. AutoMap thresholds include Score Threshold (% morphology match), Cycle Length Tolerance (ms), catheter Speed Limit (mm/s), Distance Threshold (mm), and Signal-to-Noise Ratio (signal amplitude/baseline noise). SR=Sinus Rhythm; AF=Atrial Fibrillation; AFL=Atrial Flutter; AT=Atrial Tachycardia; PVC=Premature Ventricular Contraction; VT=Ventricular Tachycardia.

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