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Envisioning Cardiac Electrophysiology with Artificial Intelligence

Context and Challenge

An estimated 17 million people die of cardiovascular diseases (CVDs) every year worldwide. CVD covers hypertension, sudden cardiac arrest, arrhythmia/rhythm disturbance, stroke, peripheral artery disease, and many more. Arrhythmias constitute a major problem, wherein the heart beats either too quickly or too slowly or with an irregular pattern [1]. This indicates the malfunctioning of the hearth's electrical system. Clinical symptoms including shortness of breath, dizziness, sudden weakness, fluttering in the chest, lightheadedness, and fainting, are indications for malfunctioning of the heart.

An electrophysiology (EP) study is a test to assess a person's cardiac electrical activity. It helps the electrophysiologist to diagnose and determine the precise location and nature of arryhthmias. The test is performed by inserting catheters and wired electrodes to measure electrical activity through blood vessels that enter the heart. The two main goals of a cardiac EP study are (1) to accurately diagnosis the conduction-disturbance mechanism and (2) to determine the best line of treatment for the conduction-disturbances. Treatment following a cardiac EP study could range from ablation therapy to pharmacologic to device to surgical intervention based on the nature of the findings. With healthcare providers looking for a holistic solution, cardiac EP systems have evolved into diagnostic and therapeutic systems with radiofrequency ablation (RFA) to treat the arrhythmia foci.

As technology advances, various industries are adopting technologies such as digital transformation, internet of things (IoT), artificial intelligence (AI), nanotechnology, and so on within their product/service portfolio and the the medical device industry is no exception.

The focus of this paper is to discuss software-based solutions incorporating AI within EP systems that can improve overall system performance, improve the therapeutic outcomes, reduce procedural time, and assist the electrophysiologist during the procedure.

Evolution of EP System

The first EP system that was developed consisted of a recording system as its main component. A recording system records the patient's cardiac electrical activity, leveraging the surface electrocardiogram (ECG) and intracardiac electrograms (EGMs). The recording system has evolved over the years, adding more intracardiac channels with the advent of multi-electrode array catheters (MEAs) to improve accuracy in terms of location and timing references. This is because EGMs provide greater consistency and reliability. For intracardiac catheters, fluoroscopy was used to navigate through the anatomy. This helped electrophysiologists locate where the catheter was residing within the heart.

EP testing and RFA have evolved as curative measures for a variety of arrhythmias, starting with straightforward to more complex ones enabled by technological advancements substantiated by the development of complex three-dimensional (3D) electro-anatomical mapping (EAM) systems. Complex arrhythmias are often associated with significant underlying structural cardiac abnormalities, such as congenital, ischemic, and post-surgical heart diseases. Heart anatomy often poses challenges to the electrophysiologist to accurately localize the site where the abnormalities originate. This requires the extensive clinical experience of the electrophysiologist and is very time-consuming. Also, a conventional fluoroscopic system has limited spatial resolution and may involve prolonged fluoroscopy and high ionizing radiation doses to patients and staff, this is where the development of complex 3D EAM systems integrated with non-fluoroscopic mapping systems bring significant value for the cardiac EP systems.

First Generation **EP Recording (Surface Level)**	• Surface level electrocardiogram(ECG) measures and monitorings like 12 lead ECGs
Second Generation **EP Recording (Intracardiac Level)**	• Intervention catheters to measure intracardiac electrogram under the fluoroscopy
Present Generation **EP Recording (Mapping)**	• 2D/3D map with 4 electrodes with 300+ arrays options for mapping • Electro Anatomical Mapping (EAM) • Fusion of EAM with cardiac anatomy map segmented from CT/MRI
Next Generation **AI Based Clinical Support Systems**	• Prediction of dose and duration of RF energy • Arrythmic area localization • Fusion of EAM with cardiac map automatically • Image stability • Optimized procedure workflow

Mapping techniques have evolved significantly over the past few years, starting with 8 electrodes for 2D mapping to more than 64 electrodes, enabling 300+ points to capture the heart's electrical activity. A large number of electrodes help to map narrow patches and even small scars in the heart's electrical circuit, which eventually helps to improve the ablation procedures. Though investigation and cardiac ablation of straightforward arrhythmias are currently based on optimal knowledge of arrhythmia mechanisms of the cardiac anatomy, Investigation of complex arrhythmias is done using 3D electro-anatomical navigation systems as they can optimally integrate both the anatomical and electrophysiological features of a given arrhythmia for a patient.

EAM fused with the cardiac anatomy data (gathered from computed tomography (CT) or magnetic resonance (MR) scans), makes it possible to accurately determine the location of the origin of the arrhythmia, define cardiac chamber geometry in 3D, delineate areas of anatomic interest, and allow catheter manipulation and positioning without fluoroscopic guidance.

There are few challenges with these techniques that can be of potential consequences for the efficacy of catheter assisted EP procedure such as,

- Registration errors during mapping
- The dependency of accuracy upon the skillset of the technologist
- Conformational changes within cardiac chambers as a result of different loading conditions between the time of imaging and intervention
- Translational changes due to patient movement
- Cardiac and respiratory motion could all lead to discrepancies between structural data and electrical substrate

Newer systems addresses few of these challenges by correction for cardiac motion, respiration compensation, and increasing stability to catheter locations to name a few. This can be substantiated by leveraging machine learning techniques, including recent deep-learning approaches, for gaining new insights from the vast amounts of complex spatio-temporal information generated by various procedures to enable more accurate diagnosis and personalized treatment plans. The high-level procedure flow with the latest technologies incorporated is shown in Figure 1.

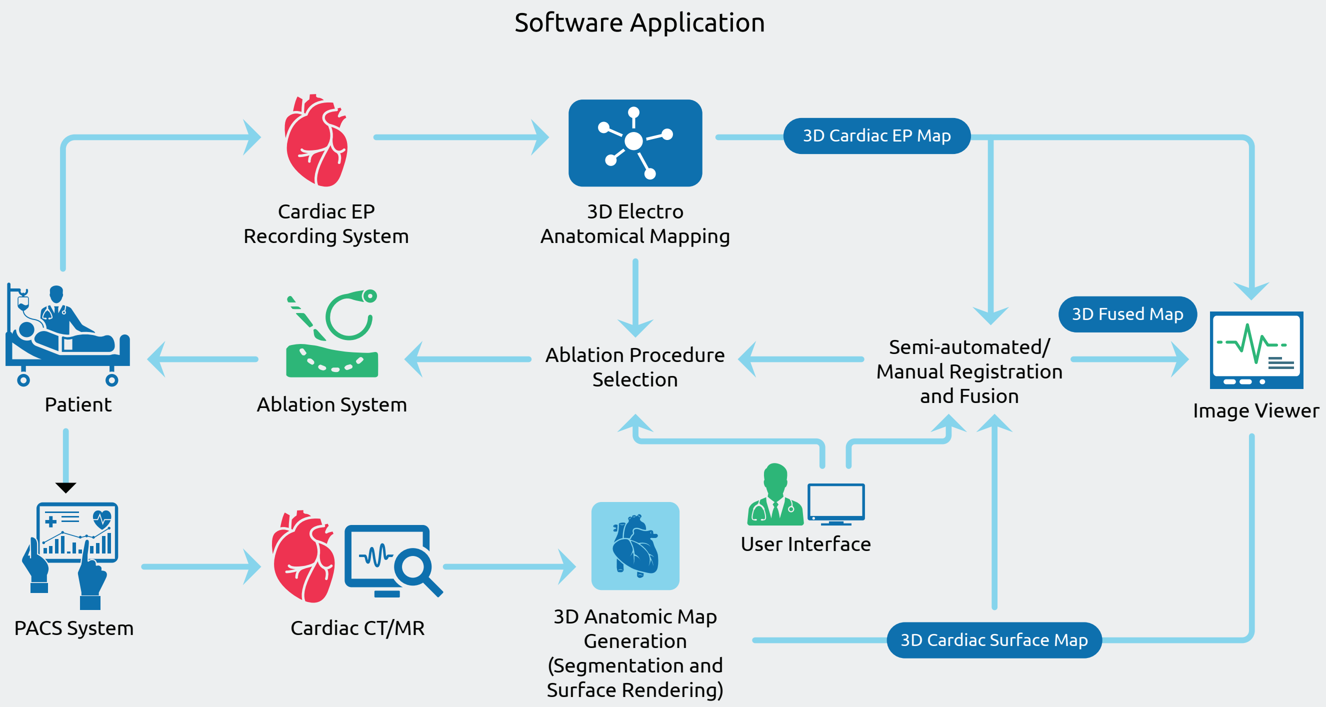

Figure 1: EP procedure flow with latest technology

In summary, the EP procedure system has evolved from 2D recordings to 3D non-fluoroscopic mapping systems with further scope for improvements thanks to technological advancements. New emerging technologies such as artificial intelligence (AI) have promising growth within the healthcare industry, and in the EP domain. The subsequent sections describe the future focus areas of EP systems and AI-powered solution approaches.

Future Focus Areas in EP Systems

The future focus areas within the EP system are emphasized below. We have identified these based on our market research and our domain expertise from over 20 years of building solutions for the medical devices industry. Use cases around these focus areas are detailed out in the subsequent section.

Ablation Targets Localization

Ablation targets localization to precisely localize the site where abnormalities are originating:
Conformational changes within cardiac chambers as well as stability of mapping/diagnostic catheters due to various conditions like cardiac and respiratory artefacts impact computing targets of ablation.

Procedure Workflow Optimization

Optimized procedure workflow to reduce procedural time and improve efficacy:
EP procedures involve recording of high quality electrograms in an environment with significant electromagnetic interference and noise where communication is difficult between team members, that effectively impacts the procedural time and engagement of physicians.

Optimizing RF Ablation

Optimized force, energy, and lesion detection to prevent the perforation of tissues during RF ablation:
RF ablation has its own challenges if not performed adequately with care, such as collateral damage and perforation, ulcer formation and risk of thrombus formation.

Use Cases and AI-powered Solutions

Developing an AI-powered clinical decision support system to achieve accurate intra-procedural guidance will help optimize the workflow of ablation procedures as shown in Figure 2, which has been one of the major challenges faced by the present EP systems. This will be achieved by predicting the diagnostic catheters to use during mapping and recommendations on ablation catheters and ablation parameters.

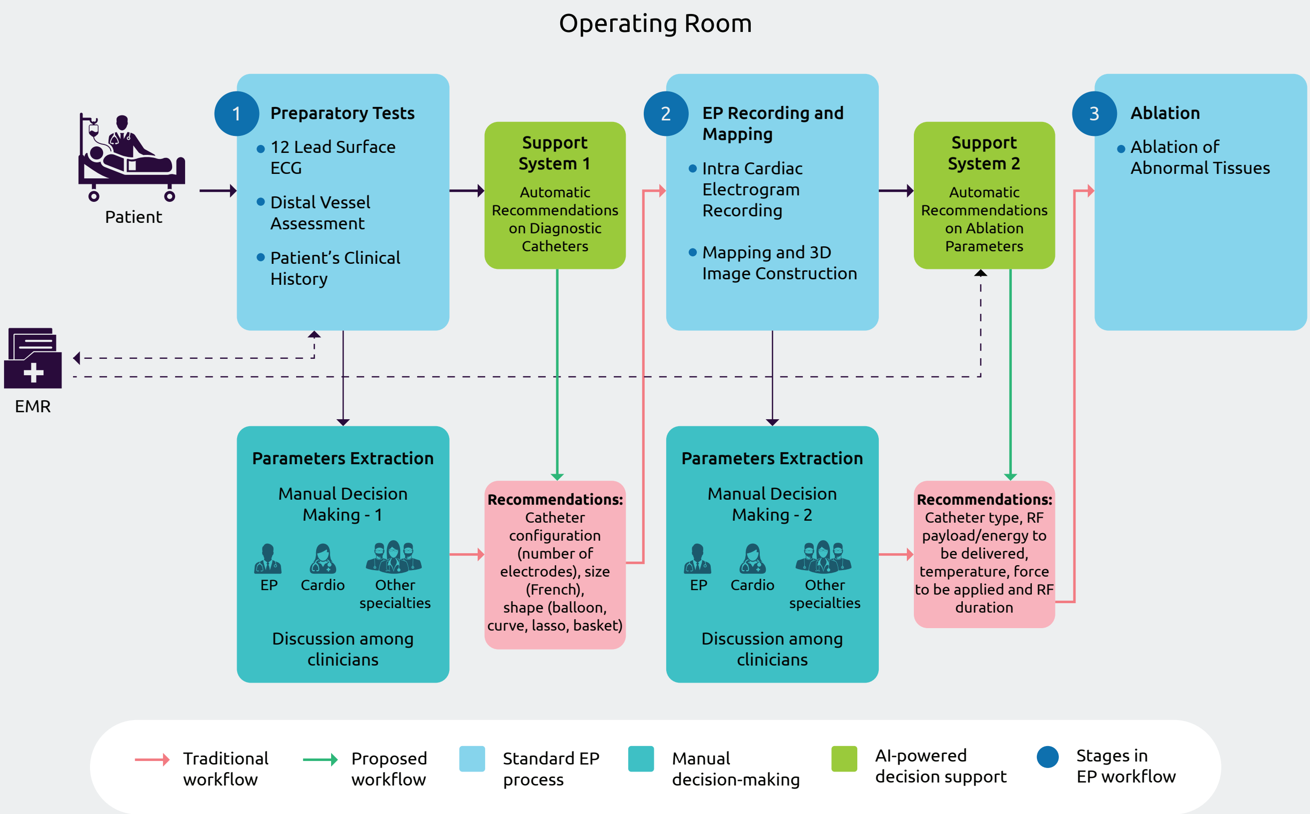

Figure 2: Intra-procedural guidance workflow (Manual vs AI-assisted)

In the proposed clinical decision support system, an AI- based model can be implemented by using appropriate supervised Machine Learning (ML) algorithms. In an abstract context, a model f is shown in equation (1), where, Ø, is one or more parameters, x is input, and y is output.

$$f(x, \emptyset) = y \quad (1)$$

This ML model is prepared by choosing the appropriate combination of classifier and sample splitting methods. The most commonly used classifiers are support vector machine, random forest, and feed-forward neural networks. The sample splitting methods can be but not limited to are 10-fold cross-validation, Monte Carlo cross-validation, and bootstrapping [2]. As an example, we can use the model with a random forest ensemble classifier with a Monte Carlo cross-validation procedure to classify the study samples. After running the model for significant iterations (based on actual available data), the study sample can be divided into training and testing subsets. The objective of training the model is to seek Ø such that for a set of training data {x} with corresponding outcomes {y}, the given loss function is minimized [3]. A simple loss function might be the ε which computes the differences between the predicted outputs and the actual outputs and is given in equation (2).

$$\varepsilon=\sum^{N}_{i=1} f(x_i, \text{Ø})-y_i \quad (2)$$

Recommendation on Diagnostic Catheters

Typical RFA procedure workflow consists of three broad-level activities: i) preparation, ii) recording and mapping, and iii) ablation (Figure 2). Total procedure time is about three to six hours with at least 30 to 45 minutes for procedure preparation [5]. The major step involved in procedure preparation is the selection of mapping and diagnostic catheters to use. Currently, catheter selection is a manual and trial-based process, demanding experience and skill of EP clinicians and communication among clinicians in real-time. Having an AI-assisted clinical decision support system facilitates catheter selection in real time, thus reducing the time from preparation and improving overall procedural time. The detailed architectural flow is presented in Figure 3.

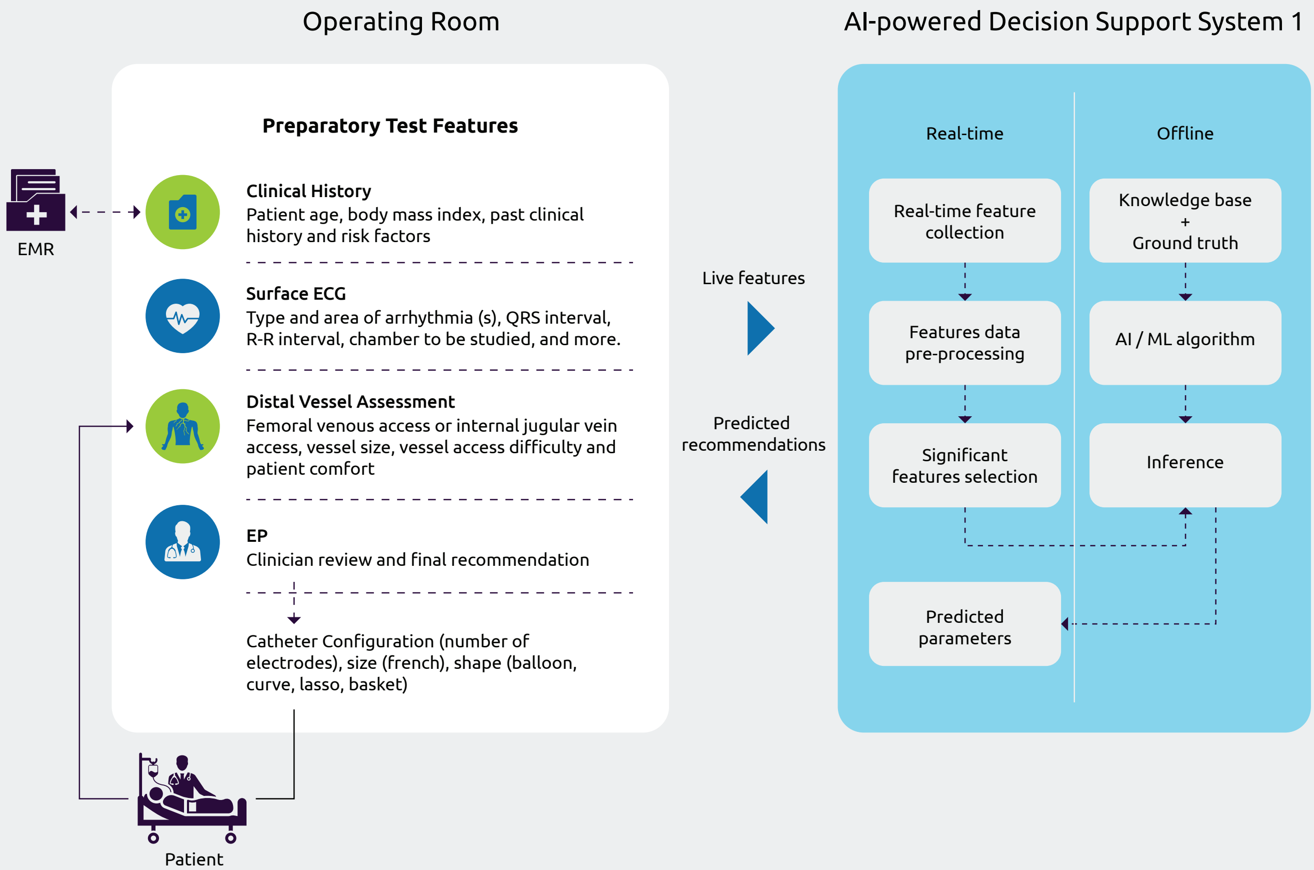

Figure 3: Solution approach of AI-powered decision support for diagnostic catheter selection

Benefits of this solution

Patient
- Improved patient comfort the patient need not undergo multiple catheter trials during mapping
- Reduced healthcare cost and overall procedure time resulting in lower clinician and operating room charges,

Clinicians
- Reduced overall procedure time leads to saving of engagement time for clinicians

Manufacturer
- Increase in market share: Reducing overall procedure time and improved clinical outcomes (for both patients and clinicians) helps to take advantage over competitors and improve overall market share/sales.

Recommendation on ablation

The RFA procedure is associated with many risks, such as perforation, creation of atrial esophageal fistula, or thrombus formation, failure to create durable lesions will result in the recurrence of many complex ablations. Accurate and effective ablation procedures will minimize these associated risks. Having an AI-assisted clinical decision support system helps to accurately select ablation parameters such as the selection of ablation catheter, regions to be ablated, RF payload, temperature, and force to be applied while applying RF energy, thereby improving the efficacy of the ablation process. The detailed architectural flow is presented in Figure 4. In the proposed solution approach for measuring tissue/muscle heat information and microbubble formation in cardiac muscles, intra-cardiac echocardiography (ICE) [4] data are considered.

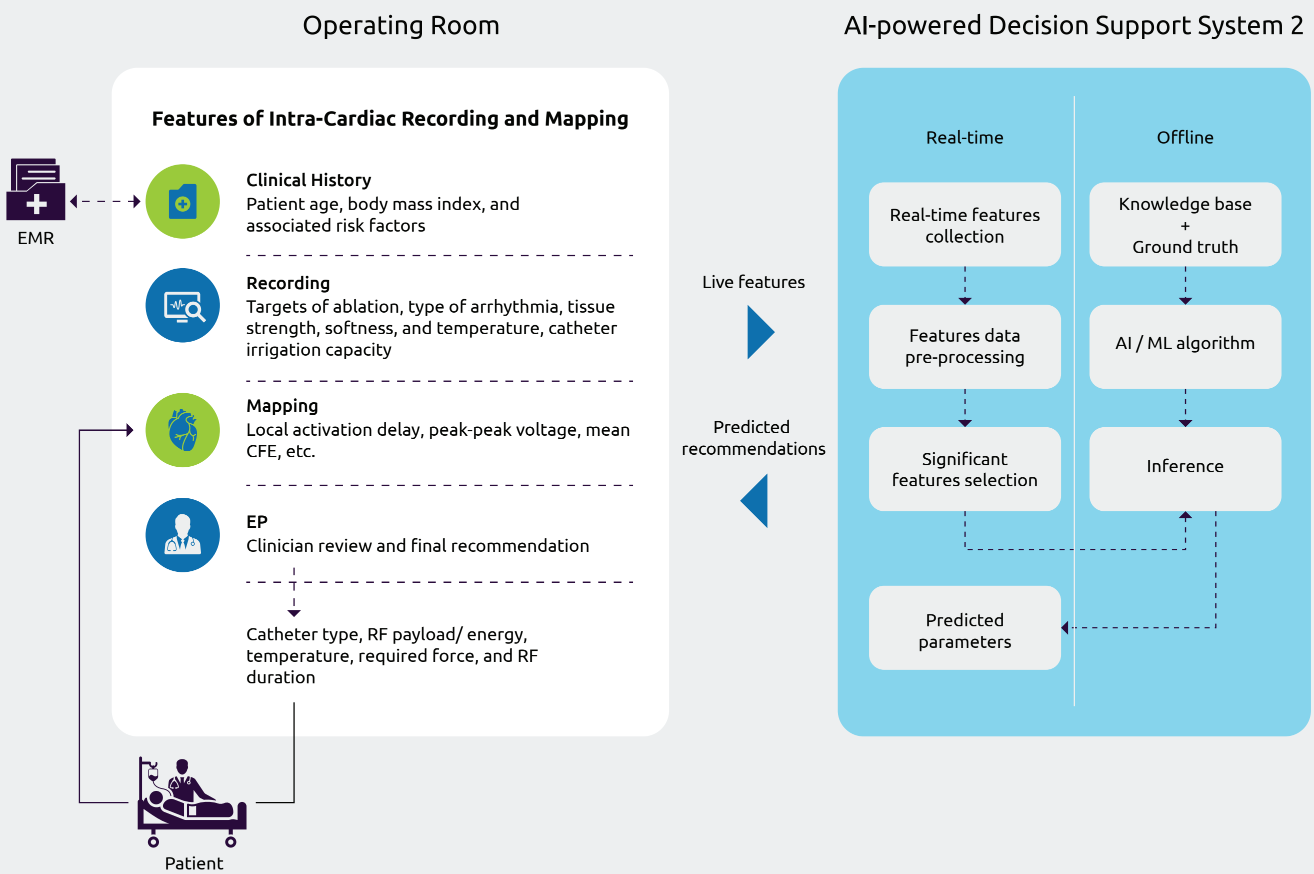

Figure 4: Solution approach of AI-powered decision support for ablation parameters selection

Benefits of this solution

Patient outcome

- With improved efficacy of the ablation procedure, the probability of the patient undergoing the ablation process multiple times is eliminated, thus improving patient comfort and reducing healthcare costs.
- With improved accuracy, clinical side-effects are reduced, thus reducing risks and complications following the ablation procedure.

Clinicians

- Reduced overall procedure time leads to saving of engagement time for clinicians
- Clinicians' reputation and work satisfaction is improved as no/little chances of failure

Manufacturer

- Reduction in overall health care cost with accurate ablation process helps to gain over competitors thus increasing market share/sells.

Conclusion

Cardiac arrhythmias are a major global healthcare problem and there is significant scope for improving their diagnosis and treatment. Improvements are achieved by implementing technology advancements, such as fusion of EP recording systems with mapping systems, fusion of CT/MRI images with electrical mapping systems to create 3D reference models of the heart, and combining mapping systems with ablation systems.

The EP mapping system, combined with an ablation system, has great potential for improvement by using modern machine learning techniques. These intelligent clinical decision support systems with appropriate machine learning techniques, offer a powerful approach towards personalized care by improving effectiveness and accuracy of EP procedures.

References

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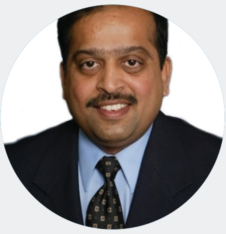

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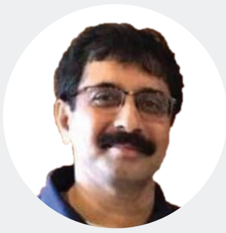

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