# Description

# Title

# AI Substrate-Planner and LBBAP Depth Guide System

## Technical Field

The present invention relates to the field of cardiac electrophysiology and interventional cardiology, and more particularly to computer-assisted systems for planning catheter ablation procedures and guiding pacemaker lead implantation. The system lies at the intersection of medical imaging, electroanatomic mapping, and artificial intelligence (AI) decision support. It is designed as a software-based medical device to improve the accuracy of cardiac ablation lesion placement and left bundle branch area pacing lead deployment depth.

## Background

Catheter-based cardiac ablation is a common therapy for cardiac arrhythmias such as atrial fibrillation (AF) and ventricular tachycardia (VT). In these procedures, clinicians create lesions (tissue scars) with an ablation catheter to interrupt arrhythmogenic circuits. Effective ablation requires careful planning of lesion lines and points based on the patient's unique cardiac substrate (scar tissue, fibrosis, conduction pathways). Traditional electroanatomic mapping (EAM) systems like CARTO™ or EnSite™ allow operators to construct 3D maps of the heart and visualize electrical signals, sometimes overlaying pre-acquired imaging data (e.g., MRI late gadolinium enhancement for scar) . These systems can display scar regions and help tag ablation points, and they provide metrics such as Ablation Index (AI) or Lesion Index (LSI) that combine factors like contact force, time, and power to indicate lesion quality . However, current mapping systems largely rely on physician experience to determine where to ablate, and they offer limited predictive guidance. Indeed, despite technological advances in mapping, major systems have not yet convincingly improved long-term ablation outcomes for complex arrhythmias . There remains a need for smarter, patient-specific planning tools to address variability in arrhythmia substrates and guide lesion delivery more effectively .

Concurrently, physiological pacing techniques have emerged to improve cardiac resynchronization and avoid dyssynchrony associated with traditional right ventricular pacing. One such technique is left bundle branch area pacing (LBBAP), in which a pacing lead is implanted into the interventricular septum to directly capture the left bundle branch conduction fibers . LBBAP offers more natural ventricular activation than conventional pacing and has gained rapid adoption. To achieve LBBAP, the lead's helix is actively screwed deep into the ventricular septum—typically reaching the subendocardial region of the left ventricle where the left bundle branch fibers run . Proper depth is critical: a shallow lead may fail to capture the conduction system, whereas an overly deep lead risks perforation or entry into the left ventricle. Currently, implanting an LBBAP lead can be technically challenging. Operators rely on indirect cues and trial-and-error, often requiring multiple lead repositioning attempts under fluoroscopic guidance . Standard practice involves observing changes in electrograms and impedance during lead insertion. For example, as the lead is driven deeper, the QRS morphology on surface ECG (lead V1) transitions from a "W" pattern to a narrower complex with an r-wave (indicating proximal left bundle capture), and fixation beats or discrete left bundle potentials may appear on the lead electrogram . Physicians also monitor pacing thresholds and impedance: a sudden rise in unipolar impedance can signal that the lead helix has retracted or reached non-conductive tissue . In many cases, contrast injections via the delivery sheath are used to verify septal wall depth to avoid perforation . These manual techniques demand significant skill. Even with intracardiac echocardiography (ICE) imaging to visualize the septum and lead tip, optimization of lead placement depth is largely subjective. Recent studies have suggested that certain lead measurements (e.g. ring electrode impedance and thresholds) correlate with lead depth and angle , hinting that algorithmic guidance could assist in determining when a lead has reached the desired target zone without needing fluoroscopic contrast each time . To date, no integrated tool exists that automatically synthesizes imaging and electrical data to guide LBBAP lead deployment depth in real time.

There is thus a clear unmet need for advanced decision-support tools in the EP lab: tools that can analyze multimodal data and provide real-time guidance to improve procedural precision. In the context of ablation, such a tool would suggest optimal lesion locations or lines (accounting for scar distribution, wall thickness, and electrophysiological markers of arrhythmia), increasing the likelihood of durable arrhythmia termination. For pacing lead implantation, a guidance system could recommend the optimal lead insertion depth and location based on the patient's septal anatomy and conduction system position, reducing guesswork and fluoroscopy time. The present invention addresses these needs by combining advanced imaging, mapping, and AI modeling in a unified platform for AI-guided substrate planning and lead depth optimization.

# Summary of the Invention

The invention provides a multi-modal AI guidance system—referred to as the "AI Substrate-Planner and LBBAP Depth Guide"—that assists clinicians in planning cardiac ablation lesions and in determining optimal implantation depth for left bundle branch area pacing leads. The system integrates several components and novel techniques, summarized as follows:

- Multi-Modal Data Ingestion: The system receives and synchronizes data from multiple cardiac modalities. This includes preoperative or intraoperative imaging (such as cardiac MRI for scar/fibrosis visualization and wall thickness measurement, and real-time intracardiac echocardiography for anatomical guidance), electroanatomic mapping data (catheter location coordinates and local electrograms from mapping systems), surface ECG and intra-cardiac electrograms, and optionally tissue characterization inputs like shear-wave ultrasound elastography (to gauge myocardial stiffness changes during ablation) or lesion biomarkers from ablation catheters (e.g. local impedance drop, contact force metrics, temperature). By fusing these data, the system creates a comprehensive representation of the patient's cardiac substrate and procedural context.

- AI-Powered Lesion Planning: An AI-driven Substrate Planner module analyzes the fused data to propose optimal ablation lesion sets. In one aspect, the module uses trained machine learning models (e.g. deep neural networks or probabilistic models) to identify regions of arrhythmogenic substrate (such as fibrotic scar tissue or areas of abnormal electrogram voltage) and suggest lesion lines or clusters that would isolate or modify these regions. For example, in atrial fibrillation, the system might recommend linear lesions encircling the pulmonary vein ostia and additional lines (e.g., roof line, mitral isthmus line) based on patient-specific atrial fibrosis distribution. In ventricular tachycardia, the system could highlight conducting channels within a scar and suggest lesion points to block those channels or to connect scar to anatomical barriers. The suggestions are displayed as virtual ablation tags or lines on a 3D map (FIG. 2A, 2B), which the operator can review and adjust. The AI's recommendations may include optimal endpoints for each line (e.g., terminating at anatomical boundaries like valves or thick scar to ensure bidirectional block). This planning considers the thickness of tissue (to ensure transmural lesions) and proximity to critical structures (to minimize collateral damage). The novelty lies in the AI's ability to cross-reference imaging-derived scar maps with live electrical data to predict which lesion pattern will most likely achieve conduction block or arrhythmia termination. By leveraging a large dataset of prior ablation cases and outcomes in its training, the system can suggest lesion strategies that have a high probability of success, thus standardizing care and potentially improving outcomes.

- AI-Guided LBBAP Depth Prediction: The invention also includes a specialized Depth Guide module for left bundle branch area pacing lead implantation. This module uses patient-specific inputs—such as septal wall thickness (obtained from pre-op imaging or intra-procedural ICE), fibrosis in the septum (from MRI LGE indicating any scarring that might affect electrical capture), and real-time signals and metrics during lead insertion (EGM features, lead impedance, pacing threshold responses)—to estimate the optimal depth for the screw-in lead. A trained AI model correlates these inputs with known successful LBBAP implant depths. For example, if pre-procedure imaging shows an interventricular septum thickness of 10 mm at the target site, the model might predict that the pacing lead should be advanced to ~8 mm depth to capture the left bundle fibers on the left side of the septum while maintaining a safety margin. As the physician begins

inserting the lead, the system can provide real-time feedback: FIG. 4A illustrates an example cross-section of the septum with various depth levels, and FIG. 4B shows an ICE image with the lead tip approaching the target depth. The system might display a dynamic indicator of depth (e.g., a percentage of septal thickness reached) and a recommendation such as “advance 2 more turns” or “optimal depth reached” based on the AI’s interpretation of the live data. It could also warn if the lead is at risk of perforation (e.g., if the lead appears to breach the far septal side or if impedance changes suddenly indicate the helix is no longer in myocardium). By integrating ICE imaging (seeing the actual lead position) with electrical cues (QRS changes, the presence of a discrete left bundle potential, and lead impedance measurements), the Depth Guide provides a level of decision support not available in conventional practice. This improves the accuracy of hittting the conduction system target on the first attempt and reduces dependency on fluoroscopic contrast injections or purely empirical rules. In essence, the module serves as a digital “depth coach” during LBBAP implantation, translating subtle data patterns into actionable guidance for the operator.

- System Architecture and Deployment: The AI Substrate-Planner and Depth Guide system is implemented as a flexible software architecture that can run either on cloud infrastructure or on local hardware in the lab. In one embodiment, the system is a cloud-based platform: procedural data (imaging, signals) are streamed securely to a cloud server where heavy AI computations are performed, and guidance results are sent back to the catheterization laboratory in real time. This leverages powerful cloud GPUs for complex model inference and facilitates continuous learning across many procedures. In an alternate embodiment, the system is deployed as an edge device located in the hospital (or even integrated into the mapping system workstation), ensuring that data stays on-site and minimizing latency. Both deployment modes interface with standard EP lab equipment via open APIs or industry-standard data formats. For example, the system can ingest mapping data from a CARTO™ or EnSite™ system (through their export interfaces) and imaging data from DICOM sources or ICE console video. It outputs guidance through a user interface that could be standalone or integrated: e.g., an overlay on the 3D map showing suggested ablation lesions, or a pop-up on the pacing system console indicating lead depth information. FIG. 1 schematically depicts the overall system architecture, including connections to external systems, the core AI engine, and user interface components.

- Clinical Workflow Integration: The invention is designed to fit seamlessly into existing workflows as a clinical decision support (CDS) tool. Prior to a procedure, the clinician can load pre-acquired images (MRI/CT) into the system and identify or mark key structures (e.g., scar regions or the His bundle location on an MRI, if visible). During the procedure, the system continuously updates its recommendations as new data come in (e.g., as mapping points are acquired or as the lead is advanced). The operator remains in control, reviewing AI suggestions and accepting or adjusting them. For ablation, the physician may follow the suggested lesion plan, and the system can track delivered lesions in real time, updating the plan if needed (for instance, if lesion delivery deviates,

or if unexpected signals appear, the AI could suggest additional touch-up ablation points). For LBBAP, as soon as the delivery sheath and lead are positioned at the septum, the Depth Guide will indicate the target depth; as the lead is screwed in, each rotation can be counted (via integration with the lead introducer that measures rotations) and correlated with the depth model. The system could provide immediate feedback if, say, the lead encounters scar tissue (requiring slightly deeper penetration or a different site). By providing this augmented intelligence in the workflow, the system aims to increase first-pass success rates: achieving durable pulmonary vein isolation or VT circuit block with minimal re-ablation, and achieving LBBAP with optimal pacing thresholds and minimal complications in one attempt.

- Safety and Regulatory Aspects: The AI Substrate-Planner and LBBAP Depth Guide can be offered as a software-only solution that is FDA Class II (moderate risk) as a Software as a Medical Device (SaMD), since it provides recommendations but the final action is taken by the clinician. It is intended as an adjunct to physician decision-making, not an autonomous controller of therapy (though in the future it could be integrated for semi-automated ablation, its current scope is advisory). The system prioritizes patient safety: for example, any suggestions that involve areas near sensitive structures (AV node, coronary arteries, esophagus) are flagged with warnings. The models are trained and validated to minimize false recommendations, and the user interface always allows the physician to override or ignore suggestions. The system logs all recommendations and clinician actions, creating an audit trail that can be reviewed. Importantly, the platform supports continuous learning: with appropriate regulatory controls, data from each case (lesion set delivered, whether arrhythmia recurred, pacing lead parameters over time, etc.) can be collected to refine the AI models for future improvements.

In summary, the present invention marries advanced AI analytics with multimodal cardiac data to provide a first-of-its-kind integrated guidance system for electrophysiology procedures. By tackling two critical challenges—ablation planning and LBBAP lead placement—the system significantly enhances the precision of interventions. The integration of imaging, electrical mapping, and AI predictive modeling in one platform is novel and represents a substantial improvement over existing siloed tools. Clinicians are equipped with actionable insights (e.g., “create this lesion line to isolate scar X” or “advance lead 2 mm more for optimal left bundle capture”) derived from data-driven patterns that would be impossible to discern manually. This leads to more consistent outcomes, reduced procedure times, and ultimately improved patient care in cardiac rhythm management.

# Brief Description of the Drawings

FIG. 1 is a block diagram of the overall system architecture of the AI Substrate-Planner and LBBAP Depth Guide. It illustrates data inputs from various sources (MRI imaging, ICE catheter, mapping system, pacing lead interface, etc.), the core AI processing engine, and outputs to the

user interface. Key functional modules including the lesion planning AI and the lead depth prediction AI are shown, along with their interactions with input data streams.

FIG. 2A depicts an example output of the Substrate Planner module for an atrial fibrillation case. The left atrium is shown in posterior-anterior view with pulmonary vein openings visible. Suggested ablation lines (highlighted by dashed lines or shaded regions) encircle the left and right pulmonary veins and extend as a roof line connecting the top of the veins. FIG. 2B shows a different scenario (or a continuation of FIG. 2A) where the system has identified a region of fibrosis (shaded area) in the left atrial appendage ridge and suggests additional lesion clusters there. The figures illustrate how the system marks lesion endpoints (e.g., solid dots) and lines on the 3D cardiac model for the operator's reference.

FIG. 3 is a flowchart showing an example workflow of the AI guidance process during a procedure. The flowchart includes steps such as data acquisition, multimodal synchronization, AI inference to generate recommendations, user review/confirmation, and adaptive updating of guidance based on new data or lesion delivery. This diagram highlights decision points, such as a step where the AI verifies if ablation lesions achieved the intended electrical isolation (using post-ablation signals) and if not, loops to suggest further action.

FIG. 4A illustrates a cross-sectional schematic of the interventricular septum during an LBBAP lead implantation. The diagram shows the right ventricle (RV) side where the lead is inserted and the left ventricle (LV) side where the left bundle branch (LBB) fibers are located. Several depth positions are marked: a shallow position (not reaching LBB), an optimal mid-septal position (engaging the LBB area), and an overly deep position (breaching into LV endocardium). The AI's target zone for the lead tip is indicated (e.g., hatched region near the LBB fibers). FIG. 4B shows an actual intracardiac echocardiography (ICE) image or simulated imaging view corresponding to FIG. 4A. In this ICE view (taken from the RV side), the pacing lead is seen entering the septum, and a graphical overlay (arrow or color band) indicates the AI-predicted target depth. As the lead advances, the system updates this overlay to show the current depth relative to the target. This figure exemplifies how the Depth Guide provides real-time visual feedback to the implanter.

(Note: The drawings are illustrative and not to scale. They are intended to demonstrate the concepts of the invention, such as system layout and guidance outputs, rather than depict actual patient data.)

# Detailed Description of Preferred Embodiments

## System Architecture Overview (FIG. 1)

Referring to FIG. 1, the AI Substrate-Planner and LBBAP Depth Guide system (100) comprises several interconnected modules and interfaces. At the highest level, the system includes: (a) Data Input Interfaces (101) for multimodal data ingestion, (b) a Data Fusion and Preprocessing layer (110), (c) an AI Inference Engine (120) containing specialized models for lesion planning

and lead guidance, (d) an Output Interface and Visualization module (130) for delivering recommendations to the user, and (e) an optional Remote/Local Server Infrastructure (140) which can be cloud-based or on-premises.

Data Input Interfaces (101): These interfaces connect the system to external sources of data commonly available during EP procedures:

- Imaging Input 101a: This interface acquires images such as cardiac MRI or CT scans, as well as real-time imaging like intracardiac echocardiography (ICE) or transesophageal echo. Pre-procedure MRI images may include 3D anatomical models and scar maps of the chambers. During the procedure, an ICE catheter can provide live ultrasound views of cardiac structures (e.g., a view of the septum and the lead position). Optionally, a shear-wave elastography ultrasound system can supply maps of tissue stiffness, which correlate with ablation lesion formation (stiffer tissue implying effective lesion). The imaging input interface may use DICOM standards for static images and streaming protocols for real-time ultrasound.

- Electroanatomic Mapping Input 101b: This interface connects to the electroanatomic mapping (EAM) system used in the lab (for example, CARTO™ 3, EnSite Precision™, or Boston Rhythmia™). It receives the geometry of the cardiac chamber (point cloud or mesh), catheter locations, and electrogram recordings from mapping catheters. It also can receive markers such as existing ablation tags or points of interest that the operator has entered. If the mapping system supports it, the interface may also retrieve any derived maps (voltage maps, activation maps, etc.) that indicate regions of low voltage or late activation which are useful for substrate identification.

- Electrogram and ECG Input 101c: In addition to the mapping system's data, the invention can directly ingest raw or processed electrogram signals from catheters and surface ECG signals. For instance, a coronary sinus catheter's recordings or body-surface ECG (12-lead) can be analyzed by the AI for certain arrhythmia patterns or QRS morphology changes. High-fidelity electrograms can also reveal signals like fractionation or late potentials that the AI uses to pinpoint abnormal substrate.

- Pacing Lead and Device Input 101d: This specialized interface is active during LBBAP lead implantation. It connects to the pacing lead delivery system (or the pacemaker programmer) to get information such as lead impedance, pacing thresholds, and rotation count of the screw-in lead. Many modern pacing leads and introducers have sensors or can be interfaced via the pacing system analyzer; the system leverages that to know, for example, how many clockwise turns have been applied or the current measured impedance of the lead tip and ring. Additionally, if a pressure or force sensor is integrated in the lead or guide sheath (less common but possible), those readings can be taken into account to infer tissue contact quality.

- Auxiliary Sensors/Biomarkers Input 101e: In some embodiments, the system can receive inputs from other sensors like contact force data from the ablation catheter, local

impedance drop measurements (e.g., Boston Scientific's DirectSense™ provides a local impedance metric correlated with lesion formation ), temperature from the ablation catheter, or even blood biomarkers if available (for instance, some advanced research tools measure biomarkers of myocardial injury during ablation, though this is not standard). These inputs, while not essential, can further inform the AI about lesion adequacy (e.g., a significant impedance drop suggests a successful lesion at that location).

Data Fusion and Preprocessing (110): Once the raw data streams are acquired, module 110 aligns and preprocesses them into a coherent internal representation. Spatial registration is a key task here: MRI or CT images are registered to the electroanatomic map coordinate system so that any scar seen on MRI corresponds to the correct location on the map. Techniques like surface mesh registration or fiducial markers (e.g., using the locations of pulmonary vein ostia or other landmarks visible in both MRI and mapping data) are employed. Similarly, the position of the ICE probe is known relative to the heart, and ICE images can be registered to the anatomy (some systems can reconstruct ICE into 3D volumes). The fused dataset might be a 3D grid or mesh of the chamber with multiple layers of information: voltage values, scar density, thickness at each point, etc. Preprocessing also involves noise filtering (e.g., smoothing noisy voltage maps), feature extraction (identifying things like areas of contiguous low voltage as candidate scar, detecting LBB potential spikes in EGM), and time-synchronization (aligning any time-dependent data so that the analysis considers the correct moment in the cardiac cycle or procedure timeline). By the end of this stage, the system has a comprehensive model of the patient's heart and ongoing procedure, onto which advanced analyses can be performed.

AI Inference Engine (120): This is the core "brain" of the system, comprising two primary sub-modules: the Lesion Planning AI (121) and the Lead Depth AI (122), along with shared support from a Decision Logic/Expert Rules component (123).

- Lesion Planning AI (121): Utilizing the fused data, this module applies one or more trained machine learning models to identify optimal ablation targets. In some embodiments, a deep learning model (for example, a 3D convolutional neural network or a graph neural network that operates on the heart mesh) has been trained on thousands of prior ablation cases. The training data includes inputs (scar maps, voltage maps, arrhythmia type, etc.) and outputs (lesion sets that led to successful outcome or those recommended by experts). The model therefore learns patterns such as: "if there is an isthmus of viable tissue between scars A and B in VT, ablate across it to block reentry" or "if the left atrium posterior wall is fibrotic, additional linear lesions may be beneficial". During operation, the model might output a probability map across the chamber indicating "importance" of ablation at each location. The system then post-processes this into discrete suggestions, e.g., drawing a line through a high-importance zone. Alternatively, the AI might directly output a set of points or segments for lesions, possibly in a ranked order of priority. The Decision Logic (123) works with the AI output to enforce any safety rules or known best practices: for example, it might ensure that an AI-suggested line actually connects two anatomical boundaries (if not, it may extend it or

snap the endpoints to nearest boundary). It also checks for redundancy (merging very close suggestions) and avoids suggesting something prohibited (like ablating too close to the AV node for certain tachycardias, unless absolutely necessary). The result is a refined lesion plan proposal that is both data-driven and consistent with clinical constraints.

- Lead Depth AI (122): This sub-module is a specialized predictor for the pacing lead scenario. It can employ a different type of model, perhaps a regression model or classifier that outputs the likelihood of successful left bundle capture versus depth. One approach is a model that, given features (septal thickness, current lead depth estimate from rotations or ICE, impedance readings, ECG morphology indicators), predicts the distance remaining to optimal target. For example, the model may output: "the lead needs ~5 mm further advancement" or conversely "the lead is likely at target, further advancement increases perforation risk". The AI here may use a combination of analytical geometry and learned patterns. A simplified geometric analysis might compute depth as (number of rotations * lead helix advance per rotation) and compare to an ideal depth fraction of septal thickness (e.g., ~70–85% through the septum from the right side). The learned part comes in adjusting that ideal based on tissue characteristics: if MRI shows mid-septal fibrosis, the model might recommend going slightly deeper to engage healthy tissue on the left side. The model is also continuously updated with real-time feedback: as soon as the lead captures the left bundle (which can be inferred by a sudden narrowing of QRS and appearance of a terminal r-wave in V1 or detection of a left bundle potential on EGM ), the system notes the depth at which this occurred. If the operator has not stopped, it may then advise to stop at that point (to avoid going further than needed). Conversely, if the lead has gone as deep as geometry suggests but the QRS hasn't narrowed, the AI could suggest repositioning slightly (maybe the lead missed the target laterally). The Decision Logic (123) for this module includes safety checks like ensuring the lead has not crossed the septum (the system might integrate ICE visual confirmation or a drop of impedance to near-infinite if the lead tip pops out into LV cavity). It can automatically suggest a bail-out if needed, e.g. "withdraw lead 2 mm, possible perforation risk".

- Training Data and Continuous Learning: (Further detailed under the Training section below.) Both AI models (121 and 122) are trained on extensive datasets. The lesion planning model is trained with historical cases where lesion sets and outcomes (success or recurrence) are known, possibly including simulation data as augmentation. The lead depth model is trained with data from LBBAP implants where final lead positions (confirmed by imaging or post-procedure metrics) are known. The system architecture supports feeding data back to model training (with proper validation and regulatory oversight) so that as more cases are performed with the system, the recommendations become even more accurate. This adaptive learning aspect ensures the AI stays up-to-date with evolving techniques and varied patient anatomies.

Output Interface and Visualization (130): Once the AI generates guidance, it must be communicated effectively to the physician. The output module (130) handles this via multiple modes:

- Graphical Overlay on Mapping System (131): For ablation guidance, the preferred mode is to overlay the suggested lesions on the 3D map of the heart that the operator is already viewing. Many mapping systems allow custom annotations or have API hooks for third-party overlays. The system can draw lines, points, or regions in distinctive colors (e.g., yellow lines for "suggested ablation line") on the map. The overlay is synchronized with the map's coordinate system, so if the physician rotates the 3D map or zooms, the suggested lesions move appropriately. The output can also include text labels or tooltips (for instance, "Line A: suggested to isolate scar in septum" or "Ablate here – high likelihood VT circuit"). If integration into the mapping system's display is not possible, the system can provide its own 3D visualization on a separate monitor, showing the cardiac geometry with suggestions.

- Imaging Guidance Display (132): For the LBBAP depth guidance, the system may present a dedicated view, possibly on the ICE imaging screen or a separate GUI panel. This can include a live ICE image with graphical indicators (as mentioned with FIG. 4B). Additionally, a simple textual or graphical meter might be shown: e.g., a bar filling as the lead goes deeper, with a green zone indicating the target depth range. The interface can also emit audible cues – for example, a sound or spoken alert ("target depth reached") so the implanting physician (who may be looking at fluoroscopy rather than at a screen) gets the cue without diverting attention.

- Recommendation Console (133): The system can also provide a summary console listing the recommendations in text form for clarity and record-keeping. For instance, it might list: "Lesion Set Proposal: (1) PVI encirclement lines; (2) Roof line; (3) Mitral isthmus line – optional if fractionated potentials persist. Lead Depth Recommendation: target 18 mm from RV endocardium (~85% septal thickness)." The operator can interact with this console using a touchscreen or mouse to accept/modify each recommendation. If the user modifies a suggestion (e.g., decides to move a lesion line slightly), the system can update its internal model (a form of human-in-the-loop adjustment) and maybe recalc if needed.

- Integration with Robotic Systems (optional): In some advanced labs, robotic catheter navigation systems or remotely controlled sheaths are used. The output module could in theory interface with such systems to automatically move a catheter to the recommended target (upon user confirmation). For example, if a robotic system is present, once the user accepts a suggested ablation point, the system could command the robot to position the ablation catheter there, reducing manual navigation. This is an optional embodiment illustrating how the guidance can translate into action, though in the typical scenario, the human operates the catheter.

Server and Deployment (140): This part of FIG. 1 indicates that the system's computation can occur either on a local server (e.g., a high-performance computer next to the lab equipment) or via a secure internet connection to a cloud service. In a cloud deployment, module 140 represents the cloud environment that hosts the AI inference engine 120. Data from the hospital is encrypted and sent to the cloud, processed, and results returned. This requires reliable network connectivity and addresses patient data security (de-identification or use of hospital VPNs, etc.). In an on-premises deployment, 140 could be a dedicated PC or a specialized hardware box provided with the software. In both cases, the software architecture is the same, but the scalability and maintenance differ. Cloud has the advantage of seamless updates and aggregation of data from multiple sites for learning, whereas edge has advantages in latency and data control. The invention encompasses both models, as different healthcare settings may prefer one or the other.

## AI Lesion Planning Module in Operation (FIG. 2A–2B and FIG. 3)

To illustrate the lesion planning in a concrete scenario, consider an example of an atrial fibrillation ablation in the left atrium. FIG. 2A and FIG. 2B correspond to outputs in this scenario. The patient's pre-procedure MRI shows patchy fibrosis on the posterior wall of the left atrium and around the pulmonary veins. The electrophysiologist has acquired a voltage map of the left atrium: it shows areas of low voltage (<0.5 mV) near the left pulmonary veins indicating scar, and higher voltage elsewhere. The AI's lesion planning module (121) takes this as input.

Using its learned model, the AI identifies that isolating the pulmonary veins is mandatory (standard for AF) and additionally that the fibrosis on the posterior wall might act as a substrate for AF maintenance. The model thus proposes two encircling lesion sets around the left and right pulmonary vein pairs (these appear as continuous loops around the vein ostia in FIG. 2A). It also proposes a connecting roof line (joining the superior aspects of the two encircles) to ensure the posterior wall between veins is isolated – this is a known strategy to prevent macro-reentry across the posterior wall. Furthermore, noticing fibrosis at the left atrial appendage ridge region, the AI suggests a small set of lesions there (FIG. 2B, perhaps denoted by a cluster of points) because it predicts that area might harbor rotational drivers.

The system presents these suggestions. The clinician reviews them on the 3D map. Suppose the clinician agrees with the vein encirclement and roof line but is unsure about the appendage ridge ablation. They can query the system for reasoning: the interface might highlight that area's features (e.g., "fibrosis >60% with complex fractionated EGMs observed during AF, similar to patterns seen in cases where ridge ablation stopped AF"). This adds transparency to the AI's output. The clinician decides to proceed with the encircling lesions first. They perform the pulmonary vein isolation (PVI) lesions as usual, tagging each completed ablation on the mapping system. The system monitors in real-time – it sees the ablation tags and might update color coding to indicate those lesions done. After PVI, the patient is checked for AF termination or inducibility. If AF persists, the physician looks at the posterior wall potentials – the AI meanwhile notes that the roof line wasn't done yet and the posterior wall is still electrically active. It reiterates its suggestion to complete the roof line. The clinician ablates along the roof line as suggested. Now the posterior wall is isolated (no signals inside encirclement).

At this point, suppose AF is terminated. The clinician might choose not to ablate the ridge further. The system's suggestions are not obligatory – they are guidance. If the outcome is already achieved, the extra lesions can be skipped to minimize ablation. The system in this case might learn that those ridge lesions ended up not being needed for this patient; such data can feed back (especially if this patient does well long-term, the model might adjust the weighting of such suggestions in similar future cases).

In a ventricular tachycardia case, the process is analogous but with differences in data. For example, MRI may show a transmural scar in the left ventricle. The voltage map pinpoints a border-zone channel (moderate voltage area) through the scar. The AI identifies that channel as a likely VT isthmus and suggests two or three lesion lines: one to cut across the channel, possibly another connecting the scar to the mitral annulus (to make sure the circuit has no way around), and maybe lesions at the exit site of VT (where the activation meets healthy tissue). These appear on the map as recommended lines or points in the ventricle. The user can follow them, and the system will track that the lines have been completed. If an area was suggested but not fully ablated (e.g., a gap because the operator could not reach a certain part due to catheter stability), the system could flag "potential gap remaining in lesion line X".

Another innovation in lesion planning is the use of lesion biomarkers and feedback to adapt the plan. For instance, if shear-wave ultrasound imaging is available, after each RF application the system can assess whether the tissue's stiffness increased in the targeted area. If not (implying lesion didn't form as expected), it might prompt a repeat ablation there or an alternative approach (higher power or longer duration). Similarly, if a planned lesion line is not achieving electrical block (detected by persistence of conduction or by mapping a breakthrough), the AI could suggest extending the line or adding an intersecting lesion.

The system architecture allows for these adaptive changes; FIG. 3's flowchart shows a loop where after initial guidance and action, the system re-evaluates the result and provides updated guidance. This closed-loop assistance ensures that the end goal (successful isolation or termination criteria) is met, rather than just blindly executing a pre-plan.

## LBBAP Depth Guidance in Operation (FIG. 4A–4B)

Now consider a typical use of the LBBAP Depth Guide. A patient with an indication for pacemaker (e.g., bradycardia or heart failure needing cardiac resynchronization) is undergoing implantation of a left bundle branch pacing lead. The operator has decided to target a location about 1.5 cm apical to the His bundle position on the septum (this is a common starting point for LBBAP). The system has been pre-loaded with the patient's echocardiographic septal thickness measurement, say 11 mm at that segment of the septum (from a pre-procedure echo or the real-time ICE measurement). The operator positions the delivery sheath at the desired site under fluoroscopy and confirms orientation perpendicular to the septum (perhaps using an RAO view as is standard).

At this point, the Depth Guide AI (122) kicks in. Based on the 11 mm thickness, it sets a target depth for the lead tip. Perhaps through prior data it knows that the LBB is usually about 1–2 mm

from the left endocardium; thus, an optimal lead tip depth might be ~9–10 mm from the right side (leaving ~1–2 mm myocardium beyond the tip). It conveys to the operator: “Target lead insertion ~85–90% of septal thickness (~9–10 mm in this patient). This likely corresponds to ~4–5 turns of the helix past initial engagement.” The operator begins screwing in the lead. The system counts rotations, either by an integrated sensor or simply by the user inputting or speaking the count (speech recognition could even be a modality: the implanting doctor often counts out loud the turns, e.g., “1 turn, 2 turns…” and the system could pick that up).

After 3 turns, the system checks data: perhaps the lead’s ring impedance has started to rise significantly – a sign that the ring electrode is entering myocardium deeply . The QRS on the monitor shows some narrowing but still has a W shape. The system displays “Current depth ~7 mm (~65% of wall), continue advancing”. After the 5th turn, a notable change occurs: the surface QRS now shows an rSr’ pattern in V1 (which is the incomplete RBBB pattern indicating left bundle capture) . The local EGM from the lead might show a discrete spike preceding QRS, suggestive of a left bundle potential. The system immediately recognizes these cues (as it continuously monitors the ECG and EGM): it concludes the LBB has been engaged. The Depth Guide now alerts: “Left bundle capture achieved at ~9.5 mm depth (~5 turns). Recommend stop – optimal depth reached.” It might also display the current measurements: e.g., lead tip impedance is stable, ring impedance plateaued, unipolar pacing threshold is say 0.8 V at 0.5 ms which is good (these could be automatically measured by a pacing threshold test at that moment).

The physician stops turning based on this advice. They test pacing at that depth, confirming wide capture range and appropriate threshold. The system might provide a final confirmation: “Pacing morphology and thresholds consistent with LBB capture. No further advancement needed.” This prevents unnecessary additional turns that could risk perforation. If, on the other hand, after 5 turns the desired ECG change had not occurred and the impedance had leveled off below expected, the system might suspect the lead is not yet at LBB or perhaps deflected. It could suggest: “If no LBB capture at 5 turns, consider advancing up to 1 more turn carefully, or reposition”. This kind of conditional guidance is based on what it has learned from cases that required more rotations (maybe some patients with thicker septum need 6–7 turns).

ICE imaging (FIG. 4B) further supplements this. The system can analyze the ICE image and possibly actually see the tip as a bright echo within the septum. Using image processing, it might measure the distance of the tip from the RV side vs LV side on the ICE view. That provides a direct depth measure. So in a variant, the Depth Guide could directly say “Lead tip is ~2 mm from left septal endocardium” if the ICE resolution and angle permit. This visual confirmation is extremely valuable and can be used by the AI to cross-check its model-based estimate. If ICE shows the tip already nearly through while the model predicted it wasn’t, the AI can update and immediately warn.

The integration of multiple modalities (impedance, EGM, ICE) is a standout innovation. In current practice, some operators use just fluoroscopy and EGM; others add ICE for visual, others use contrast injection. Our system could reduce the need for contrast by using

impedance and AI models , and reduce fluoro by giving confidence when to stop. It essentially standardizes the endpoint of LBBAP lead placement.

After deployment, the system might also suggest checking certain things: for instance, rotate the lead a bit to ensure it's fixed, or perform a few pacing threshold measurements at different outputs to ensure selective vs nonselective capture. While these steps are typically done, the system can include them as reminders in its workflow (FIG. 3 flowchart could branch into a pacing test step after depth reached).

## Training and Calibration of AI Models

Developing the AI models for this system requires robust training frameworks, which are part of the invention's disclosure. The lesion planning model is trained on a combination of retrospective patient data and expert planning knowledge. One source of training data is historical ablation cases: for each case, input data (imaging, maps, etc.) can be paired with the lesions that were delivered and the outcome (success or recurrence). By labeling which lesions were likely critical to success (if known) or using outcome as a weak label, the model can be trained with supervised or reinforcement learning techniques to suggest lesion sets that lead to success. In addition, expert electrophysiologists can provide annotations on difficult cases, essentially creating a knowledge base of "if you see this pattern, do X". This expert system knowledge can be used to guide the architecture of the AI (e.g., combining rule-based features with machine learning). The training process involves cross-validation and testing on separate datasets to ensure the model does not overtly bias to training distributions. Because arrhythmia mechanisms vary, the model might be segmented by arrhythmia type (one sub-model for AF, one for VT, etc.), or the arrhythmia type is given as an input parameter to the model.

The lead depth model is trained on data from pacemaker implants. Many centers have records of each lead's final position (some verify with post-implant ECG or imaging) and how many turns were used, what threshold achieved, etc. These can be aggregated. The model can learn, for example, that in 90% of cases with septal thickness ~10 mm, 4–5 turns yielded successful capture. Or it might learn thresholds: if at 4 turns the threshold is still high and no LBB potential, likely not deep enough. It may also incorporate negative examples: cases where perforation occurred indicate too many turns, which the model should learn to avoid (classify as beyond optimal depth). The model could initially be a simple decision tree or regression and become more sophisticated as more data comes in.

To account for patient variability, the system includes a calibration step for the AI. For example, prior to using the lesion planner on a new patient, the system might run a "virtual test" where it compares its predictions to known safe ranges. It might ensure that any recommended line has at least X mm of healthy tissue away from esophagus (if in LA posterior wall), or consult known guidelines (like the line should not be too close to AV node in septal VT unless necessary). These calibrations can be coded from clinical guidelines and ensure the AI doesn't propose something a human expert would immediately flag as unsafe. Essentially, the training includes not just matching data but encoding clinical constraints (this can be done via constrained optimization in training loss or post-processing rules).

Moreover, the system is designed to handle variations and uncertainties. If the input data is incomplete (say MRI not available), the lesion planning AI can fall back on electrogram-based substrate detection alone. The training covers such scenarios by including cases with limited modality input (so the AI knows how to function with whatever is available). In use, the system might display a confidence level for each suggestion, influenced by how much data supports it. For instance, "High-confidence suggestion: roof line, based on clear scar gap" versus "Lower confidence: mitral line, as extrapolated from limited data".

From a regulatory standpoint, the training and validation of these models are documented and controlled, since if this is to be a medical device, the learning procedure must be well-governed. In one embodiment, the system's AI is locked (not self-learning on the fly) when shipped, and updates are provided periodically after re-training on aggregated data at the company level. In another embodiment, a continual learning approach is used but under clinician supervision (the system might suggest a new pattern it learned, but mark it as "newly learned suggestion" until it gains acceptance).

## Variations and Alternative Embodiments

While the preferred embodiments have been described above, the invention is not limited to those specific implementations. Numerous variations, modifications, and alternative embodiments are envisioned:

- Cloud vs. Edge Deployment: As noted, one embodiment runs the AI on a remote cloud server, aggregating data from multiple hospitals to continuously improve the model. An alternative embodiment runs entirely on an edge device in the catheter lab for sites that require offline capability or have strict data policies. A hybrid approach is also possible, where initial heavy computations (like processing pre-op MRI) are done in the cloud, but intra-procedure real-time guidance (which needs low latency) is done on a local machine. The claims of this invention cover all such deployment models, as the core functionality remains the same.

- Imaging Modalities Flexibility: The system can function with various combinations of imaging. In an ICE-only model, even if no pre-op MRI or CT is available, the system uses live echo and mapping data to infer tissue properties (for example, it may use voltage mapping to guess scar if MRI is absent). Conversely, in a high-imaging scenario, MRI, CT, or even live MRI (in labs that do MRI-guided EP) could be used – the system could integrate real-time MRI thermal imaging to see lesion formation. The invention covers models specifically tuned for MRI+EGM input versus those tuned for echo-only input. The AI might switch model weights depending on input availability.

- Lesion Sensor Integration: In one variation, the system is tightly integrated with specific ablation catheter technologies that provide lesion feedback. For example, if using the Abbott EnSite system with Lesion Index (LSI), the system can use the live LSI value to gauge lesion effectiveness . If LSI doesn't reach a threshold, the AI might recommend additional RF time at that spot. If using Boston Scientific's impedance-based

DirectSense, the system could incorporate the local impedance drop as a real-time feature to decide if the lesion is complete . The system is modular to plug in these sensor data. As new lesion assessment tech emerges (e.g., electrical impedance tomography or fiber-optic temperature sensors in the myocardium), those can be added to the data inputs to enrich the AI's decision criteria.

- Alternate Pacing Lead Guidance Modes: While the primary focus is LBBAP (left bundle area in the septum), the architecture can be adapted to guide other types of conduction system pacing. For instance, His bundle pacing (HBP) – capturing the His bundle near the AV junction – is another technique. The Depth Guide could be adapted to help position a lead at the His bundle (which is even trickier due to high thresholds and proximity to AV node). The input would then include where the His signal is found and how to fix the lead optimally there (this might involve less depth and more precise location). Another mode could assist in traditional cardiac resynchronization therapy (CRT) lead placement in coronary veins by analyzing CS venograms and suggesting which vein branch to target (though this is outside current scope, it shows versatility). The claims intend to cover any "lead-specific guidance mode" that uses imaging and AI to optimize lead placement (whether LBB area, His bundle, or even lead extraction guidance for removal procedures).

- Different Clinical Workflows: The system could be used in different points of care. The described use is in the EP lab during procedures. An alternative embodiment could be used pre-procedurally for planning: a doctor in clinic could load a patient's MRI and have the system propose an ablation strategy, which they then use to strategize the procedure (like a "virtual EP study"). The interface for that might be on a laptop or web portal rather than integrated with mapping equipment. Another alternative use is post-procedure analysis: the system can evaluate lesion sets that were delivered and predict risk of gaps or recurrence, prompting earlier re-intervention if needed. These are variations in how the tool aids clinical workflow beyond the immediate moment of ablation or implant.

- Hardware Integration: The invention is primarily software, but it could be bundled in a dedicated hardware unit. For example, a specialized cart or "black box" that connects to the relevant equipment and has all necessary regulatory certifications for safety in the OR environment (electrical isolation, etc.). Alternatively, the software could be integrated into existing mapping systems as a module or into a pacemaker programmer. The claims cover the system as a standalone or as an integrated component of a larger system.

- User Customization and Training Mode: In one embodiment, the system allows users to input their own strategies or adjust the AI suggestions. For instance, an expert user might draw a potential lesion line and ask the AI to evaluate its efficacy (the AI could simulate whether that line would likely block conduction, given the data). This interactive mode turns the system into a training simulator for new electrophysiologists as well, where they can see the AI's reasoning and outcomes for different lesion sets. Also, different operators might have different preferences (some prefer linear lesions, others

substrate homogenization). The system could be tuned to individual users over time ("learning" an operator's style and presenting suggestions in that context). While core algorithms remain, this configurability is a useful variant.

- Regulatory Classification Variants: The system can function purely as Decision Support (CDS) where the physician must confirm all actions (likely Class II, 510(k) path in the US). In another variant, parts of it might be classified as active control (if it were to directly control a catheter or a robotic system, that might elevate risk classification). We note the invention encompasses primarily the CDS use. However, as automation in EP advances, one can foresee an embodiment where, for example, the lesion planning AI directly interfaces with an RF generator to titrate energy delivery for lesion quality optimization (a semi-autonomous ablation system). Our claims broadly cover the AI method and system; specific regulatory class mention is to clarify intended use, but not to limit the scope of potential use under different regulatory permissions in various jurisdictions (US, EU, JP, etc.).

Each of the above variations can be mixed and matched. For example, an institution might use the cloud version with MRI integration but without shear-wave data, or an edge version with only ICE. The invention's claims aim to "ring-fence" the core novel concept—integrating multi-modal imaging/mapping with AI for guiding cardiac therapy—while a "picket-fence" of dependent claims covers these specific embodiments and refinements.

In conclusion of the detailed description, the AI Substrate-Planner and LBBAP Depth Guide system provides an innovative solution addressing key challenges in interventional cardiac electrophysiology. By leveraging the synergy of multi-modal data and artificial intelligence, it enables more informed, patient-tailored decisions in both ablation therapy and physiological pacing lead placement. The foregoing description of embodiments and variations is intended to illustrate the breadth of the invention, not to limit it. Those skilled in the art will appreciate that various modifications can be made without departing from the scope of the invention as defined in the appended claims.