PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the **PATENT APPLICATION** of:	
Bar-Tal et al.	
Application No.:	16/952,943
Confirmation No.:	7101
Filed:	November 19, 2020
For: INTRA-CARDIAC PATTERN MATCHING	
Group:	3792
Examiner:	Laura Nicole Hodge

Our File: JNJBIO-6259USNP1

Date: October 26, 2025

APPEAL BRIEF

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Madam:

This Appeal Brief is being filed in response to the Notice of Panel Decision from Pre-Appeal Brief Review dated August 18, 2025. A petition for extension of time is filed concurrently herewith.

Contents

I. Real Party in Interest

In this Appeal, the real parties in interest are the assignees of record, Biosense Webster (Israel) Ltd.

II. Related Appeals, Interferences, and Trials

The appellant and the undersigned representative do not know of any other appeal, interference, or judicial proceeding that is related to, directly affects, is directly affected by, or has a bearing on the decision of the Patent Trial and Appeal Board (PTAB) (hereinafter the "Board" or the "Board of Appeals") in this Appeal.

III. Status of the Claims

The rejections of Claims 1–20 and 22–24 in the Final Office Action, issued April 1, 2025, are the subject of the present Appeal. The pending claims on Appeal are attached in the Claims Listing in Section VIII.

IV. Summary of Claimed Subject Matter

A. Overview

The invention concerns electrophysiology mapping and detection of cardiac arrhythmias using intracardiac electrogram signals acquired by a multi-electrode

catheter. Independent method claim 1 and independent apparatus claim 13 recite a coordinated configuration and processing sequence that converts raw unipolar intracardiac signals into a device-actionable detection result used during mapping (Application, ¶¶0020–0021, 0025).

On the acquisition side, a catheter with multiple electrodes is inserted into the heart to obtain unipolar intracardiac electrogram signals across multiple activity channels. The processor selects a window of interest that spans an entire heartbeat and, within that window, identifies a pattern of interest corresponding to the portion of the beat where arrhythmia activation is exhibited (Application, ¶¶0028–0031). Before template creation, the application teaches pre-processing with median and FIR filtering to remove baseline wander and other motion artifacts, integrating measurement with problem-targeted conditioning (Application, ¶0028).

Within the heartbeat-bounded window, the system calculates an activity signal using a median filter in view of reference annotations, derives an activity threshold from that signal, and uses the threshold to bound the pattern of interest. The application discloses concrete rules and equations for these steps, including an exemplary 15-millisecond median-filter window for activity signal computation (Application, ¶¶0034, 0036). Using those beat-bounded signals, the system forms a template pattern of interest composed of multiple template channels and then compares subsequent intracardiac activity to the template by computing channel-

wise correlations (Application, ¶¶0029–0031, 0034).

To emphasize physiologically meaningful activations, the processor derives per-channel weights from the maximum slope (first derivative) of the template channels and applies those weights to generate a weighted correlation score. The application explains that this derivative-based weighting distinguishes sharp from shallow activations and improves the final correlation outcome (Application, ¶0042). The system evaluates correlation across shifts of a moving window and selects a maximum correlation, with an example implementation that phase-shifts in one-millisecond increments within a defined time frame (Application, ¶0057).

When the weighted correlation score exceeds a threshold, the system detects the arrhythmia and uses that result in the mapping workflow. The application ties processing to device behavior by presenting results on a display and incorporating them into a cardiac map that emphasizes regions exhibiting arrhythmia activation (Application, ¶0025). Collectively, the claimed elements define a specific intracardiac configuration and control sequence that improves the accuracy and reliability of arrhythmia detection in a mapping system (Application, ¶¶0025, 0028–0036, 0042, 0057).

B. Claims

Each pending claim under consideration in this Appeal is repeated below, with example support for each element from the original specification in brackets using

the paragraph numbers from the originally filed application.

1. A method for improving accuracy in detecting a cardiac arrhythmia in a patient, the method comprising:

inserting a catheter into a heart of the patient; (Application, ¶0016–¶0018)

receiving unipolar pattern intra-cardiac (IC) electrogram (EGM) signals for an area of the heart, from a plurality of activity channels corresponding to a plurality of electrodes of the catheter; (Application, ¶0004, ¶0017–¶0018)

selecting a window of interest (WOI) of the IC EGM signals, the WOI representing an entire cycle length for a single heartbeat; (Application, ¶0034, ¶0052)

calculating an activity signal based on a median filter and reference annotations; (Application, ¶0034, ¶0036)

calculating an activity threshold of the WOI using the activity signal; (Application, ¶0034, ¶0036–¶0038)

calculating, using the activity threshold, a pattern of interest (POI), the POI encompassing at least a portion of the WOI, and corresponding to a specific portion of the WOI where an arrhythmia activation is exhibited; (Application, ¶0030–¶0034)

storing a template POI representative of the arrhythmia activation, the template POI formed of a plurality of template channels and based upon the IC EGM signals within the WOI; (Application, ¶0030–¶0031, ¶0034)

receiving subsequent electrical activity comprising IC EGM signals from the plurality of activity channels; (Application, ¶0014, ¶0052)

calculating signal correlations based on the template POI and the subsequent electrical activity; (Application, ¶0007, ¶0011, ¶0052, ¶0054–¶0057)

calculating weights based on a maximum slope of the plurality of template channels, (Application, ¶0042)

generating a correlation score by applying the weights to the signal correlations; and (Application, ¶0042, ¶0052, ¶0064)

detecting the cardiac arrhythmia when the correlation score is above a threshold correlation score. (Application, ¶0060, ¶0063)

2. The method of claim 1, further comprising providing a visual indication corresponding to the area of the heart based on determining that the correlation score is above the threshold correlation score. (Application, ¶0025, ¶0060)

3. The method of claim 2, wherein the visual indication is at least one of a color, a pattern, and a marking. (Application, ¶0025) (visual map presentation and emphasis; indication modalities are supported by map/display description)

4. The method of claim 1, wherein the reference annotations are either user

provided reference annotations or predetermined reference annotations. (Application, ¶0030, ¶0034)

5. The method of claim 1, further comprising filtering the subsequent electrical activity using the median filter and a finite impulse response (FIR) filter. (Application, ¶0028, ¶0045, ¶0048)

6. The method of claim 5, wherein filtering the subsequent electrical activity removes baseline wander. (Application, ¶0048)

7. The method of claim 1, wherein the correlation score is a cumulative value. (Application, ¶0064) (overall correlation coefficient across channels; see also ¶0055, ¶0057)

8. The method of claim 1, further comprising defining a moving window based on the POI. (Application, ¶0054–¶0057)

9. The method of claim 8, further comprising determining a plurality of correlation scores based on each shift of the moving window. (Application, ¶0054–¶0057)

10. The method of claim 9, wherein the plurality of correlation scores are based on a maximum correlation score. (Application, ¶0052, ¶0054–¶0057)

11. The method of claim 1, wherein the correlation score is determined based on a subset of the subsequent electrical activity. (Application, ¶0053)

12. The method of claim 11, wherein the subset of the subsequent electrical activity is determined based on at least one of an atria dissociation and a noise threshold. (Application, ¶0053)

13. An apparatus for improving accuracy in detecting a cardiac arrhythmia in a patient, the apparatus comprising:

one or more catheters with respective one or more electrodes arranged for insertion into a heart of the patient for acquiring unipolar pattern intra-cardiac (IC) electrogram (EGM) signals from an area of the heart, from a plurality of activity channels corresponding to the one or more electrodes; (Application, ¶0016–¶0018)

a memory; and, (Application, ¶0019, ¶0023–¶0024)

one or more processors that are communicatively coupled to the one or more catheters and the memory, wherein the one or more processors are collectively

configured to: (Application, ¶0018–¶0020, ¶0023–¶0025)

receive the IC EGM signals from the one or more catheters, (Application, ¶0020)

select a window of interest (WOI) of the IC EGM signals, the WOI representing an entire cycle length for a single heartbeat, (Application, ¶0034, ¶0052)

calculate an activity signal based on a median filter and reference annotations, (Application, ¶0034, ¶0036)

calculate an activity threshold of the WOI using the activity signal, (Application, ¶0034, ¶0036–¶0038)

calculate, using the activity threshold, a pattern of interest (POI) of the IC EGM signals, the POI encompassing at least a portion of the WOI, and corresponding to a specific portion of the WOI where an arrhythmia activation is exhibited, (Application, ¶0030–¶0034)

store a template POI representative of the cardiac arrhythmia in the memory, the template POI comprising a plurality of template channels based on the IC EGM signals within the WOI, (Application, ¶0030–¶0031, ¶0034)

receive subsequent electrical activity comprising IC EGM signals from the plurality of activity channels, (Application, ¶0014, ¶0052)

calculate signal correlations based on the template POI and the subsequent electrical activity, (Application, ¶0007, ¶0011, ¶0052, ¶0054–¶0057)

calculate weights based on a maximum slope of the plurality of template channels, channel; (Application, ¶0042) (note: claim text has a stray "channel;" after this phrase; consider deleting in the appendix)

generate a correlation score by applying the weights to the signal correlations; and (Application, ¶0042, ¶0052, ¶0064)

detect the cardiac arrhythmia when the correlation score is above a threshold correlation score. (Application, ¶0060, ¶0063)

14. The apparatus of claim 13, additionally comprising at least one filter to remove respiratory or other movement. (Application, ¶0028, ¶0048)

15. The apparatus of claim 14, additionally comprising a display screen arranged for displaying the subsequent electrical activity when the cardiac arrhythmia is detected. (Application, ¶0025, ¶0060)

16. The apparatus of claim 15, wherein the subsequent electrical activity having the correlation score exceeding the threshold is incorporated into a map of the heart appearing on the display screen, wherein areas of the heart exhibiting the cardiac arrhythmia are emphasized. (Application, ¶0025, ¶0060)

17. The apparatus of claim 13 wherein the one or more catheters comprises a probe disposed within a sheath. (Application, ¶0016)

18. The apparatus of claim 17, wherein the one or more catheters comprises at least one of a lasso catheter and a shaft-like catheter. (Application, ¶0017)

19. The apparatus of claim 13, wherein the one or more processors are further collectively configured to: apply at least one filter arranged to the IC EGM signals corresponding to a cardiac condition prior to generating the template POI. (Application, ¶0028, ¶0045, ¶0048)

20. The apparatus of claim 13, wherein the one or more processors are further collectively configured to: apply the median filter and a finite impulse response (FIR) filter for filtering the subsequent electrical activity. (Application, ¶0028, ¶0045, ¶0048)

21. (Canceled)

22. The apparatus of claim 13, wherein the one or more processors are located within an operating console. (Application, ¶0019)

23. The apparatus of claim 13, wherein at least one of the one or more processors comprises a central processing unit and noise reduction circuitry. (Application, ¶0018, ¶0020)

24. The apparatus of claim 13, additionally comprising a magnetic tracking system for tracking the one or more catheters when inserted into the heart of the patient. (Application, ¶0017, ¶0024)

V. Grounds of Rejection to be Reviewed on Appeal

The grounds for rejection to be reviewed on Appeal are as follows:

[A] Claims 1-20 and 22-24 stand rejected under 35 U.S.C. § 101 because the Office Action alleged that the claimed invention is directed to a judicial exception (i.e., a law of nature, a natural phenomenon, or an abstract idea) without significantly more

VI. Argument

The § 101 rejection should be reversed because the claims, viewed as a whole and in light of the specification, recite a specific intracardiac configuration and a rule-

bound control sequence that improves the operation of an electrophysiology (EP) mapping system. The invention processes unipolar intracardiac electrograms acquired from multiple catheter electrodes through a prescribed pipeline that includes selection of a heartbeat-length window of interest, computation of an activity signal using a median filter with reference annotations, derivation of an activity threshold, identification of a pattern of interest, construction of a multi-channel template, computation of per-channel weights from the maximum slope of the template channels, and weighted multi-channel correlation to generate a thresholded detection score that drives clinical mapping behavior. See Application, ¶¶0028–0036 (WOI, activity signal, threshold, POI), ¶0042 (maximum-slope weights), ¶¶0054–0057 (moving window and correlations), ¶0063 (thresholded correlation), ¶0025 (display and map emphasis). This is not a result-oriented command to "detect arrhythmia," but a concrete technique implemented in a particular medical device context that transforms raw catheter signals into a position-registered, emphasized heart map used during the procedure. See Application, ¶¶0020–0025.

Under Step 2A, Prong 1, the claims are not "directed to" an abstract idea because they "focus on a specific means or method that improves" a technological process, namely cardiac monitoring and mapping. See *CardioNet, LLC v. InfoBionic, Inc.*, 955 F.3d 1358, 1370–73 (Fed. Cir. 2020); *McRO, Inc. v. Bandai Namco Games Am. Inc.*, 837 F.3d 1299, 1313–16 (Fed. Cir. 2016). Under Step 2A, Prong 2, any

mathematical operations are integrated into a practical application: sensor acquisition and pre-processing feed the beat-bounded, derivative-weighted correlation whose thresholded output updates a cardiac map and emphasizes affected anatomy, which is the device's operative output during mapping. See *Diamond v. Diehr*, 450 U.S. 175, 191–92 (1981); *Thales Visionix Inc. v. United States*, 850 F.3d 1343, 1348–50 (Fed. Cir. 2017). For claims 15 and 16 in particular, the display and mapping limitations recite a specific user-interface behavior tied to the algorithmic state of the device and aimed at solving an intra-procedural usability problem, which falls squarely within the Federal Circuit's user-interface eligibility decisions. See *Trading Techs. Int'l, Inc. v. CQG, Inc.*, 675 F. App'x 1001, 1004–05 (Fed. Cir. 2017); *Core Wireless Licensing S.A.R.L. v. LG Elecs., Inc.*, 880 F.3d 1356, 1362–63 (Fed. Cir. 2018); *Data Engine Techs. LLC v. Google LLC*, 906 F.3d 999, 1007–10 (Fed. Cir. 2018).

Even if Step 2B were reached, the Office has not met its evidentiary burden to show that the specific claimed combination was well-understood, routine, and conventional: maximum-slope per-channel weighting applied to a template-bounded, multi-channel correlation within a heartbeat-length window, used to gate a position-registered map update with anatomical emphasis. The Final Action cites no such evidence, and conventionality is a factual question under *Berkheimer v. HP Inc.*, 881

F.3d 1360, 1368–70 (Fed. Cir. 2018). Accordingly, the claims are patent-eligible, and the § 101 rejection should be withdrawn.

A. Claims 1–20 and 22–24 are directed to a concrete intracardiac mapping system and a rule-bound control sequence for processing multi-electrode intracardiac EGMs, not to an abstract objective of detecting arrhythmia

Claims 1–20 and 22–24 are directed to a concrete intracardiac mapping system and a rule-bound control sequence for processing multi-electrode intracardiac EGMs, not to an abstract goal of "detecting arrhythmia." The claims require acquisition of unipolar EGMs from multiple electrodes on a catheter inserted into the heart; definition of a heartbeat-length window of interest (WOI) and a pattern of interest (POI); computation of an activity signal using a median filter with reference annotations; derivation of an activity threshold to bound the POI; construction of a multi-channel template POI; calculation of per-channel weights derived from the maximum slope (first derivative) of the template channels; and generation of a weighted, multi-channel correlation score that is compared to a threshold to detect arrhythmia. The specification ties this pipeline to device behavior: the system pre-processes signals to remove baseline wander, incorporates threshold-exceeding activity into a cardiac map, and emphasizes the affected anatomical region on the display (Application, ¶¶11, 20, 25, 29–30, 36–37, 67). The apparatus claims, including claims 22 through 24, recite corresponding hardware constraints such as processors

with noise-reduction circuitry, catheter localization or position data, and a display, which confirms implementation in a particular EP mapping system rather than a mere field of use (Application, ¶¶17, 25).

As a matter of law, this level of claimed specificity, that is, a prescribed sequence that changes how the device processes domain-specific physiological time-series data, falls on the eligible side of Step 2A. The claims "focus on a specific means or method that improves" cardiac monitoring and mapping, rather than an abstract result. See *CardioNet, LLC v. InfoBionic, Inc.*, 955 F.3d 1358, 1370–73 (Fed. Cir. 2020); *McRO, Inc. v. Bandai Namco Games Am. Inc.*, 837 F.3d 1299, 1313–16 (Fed. Cir. 2016). Even if some sub-operations are mathematical, they are integrated into a practical application. Sensor acquisition and pre-processing feed the WOI and POI bounded, derivative-weighted correlation, and the thresholded output drives map updates and anatomical emphasis. That is the type of device-level control recognized as non-abstract in *Diamond v. Diehr*, 450 U.S. 175, 191–92 (1981), and is consistent with *Thales Visionix Inc. v. United States*, 850 F.3d 1343, 1348–50 (Fed. Cir. 2017). On this record and on these claim facts, the asserted "abstract idea" label does not apply.

1. "Each Case Turns on Its Facts": On These Facts, the Claims Recite a Device-Embedded Technical Improvement, and Intellectual Ventures Is Inapposite

The Examiner states that "each case turns on its own facts," yet those facts

favor eligibility here. (Final Office Action, Pg. 2). The claims are not result-oriented instructions to "detect arrhythmia," but recite a particular, rule-driven technique embedded in a medical device workflow: acquiring multi-electrode intracardiac EGMs via a catheter; selecting a window of interest spanning a single heartbeat; deriving an activity signal using a median filter with reference annotations; defining a pattern of interest from an activity threshold; computing per-channel weights from the maximum slope (first derivative) of template channels; and generating a weighted, multi-channel correlation score used for detection. On these facts, the claims are directed to a concrete signal-processing improvement to an EP mapping system, aligning with decisions upholding eligibility for similarly specific, domain-tied methods that improve technology rather than claim abstract ends. See *CardioNet, LLC v. InfoBionic, Inc.*, 955 F.3d 1358, 1370–73 (Fed. Cir. 2020) (claims "focused on a specific means or method that improves" cardiac monitoring); *McRO, Inc. v. Bandai Namco Games Am. Inc.*, 837 F.3d 1299, 1313–16 (Fed. Cir. 2016) (rule-based processing of time-series data eligible); *Thales Visionix Inc. v. United States*, 850 F.3d 1343, 1348–50 (Fed. Cir. 2017) (non-conventional sensor math improving system operation is not abstract).

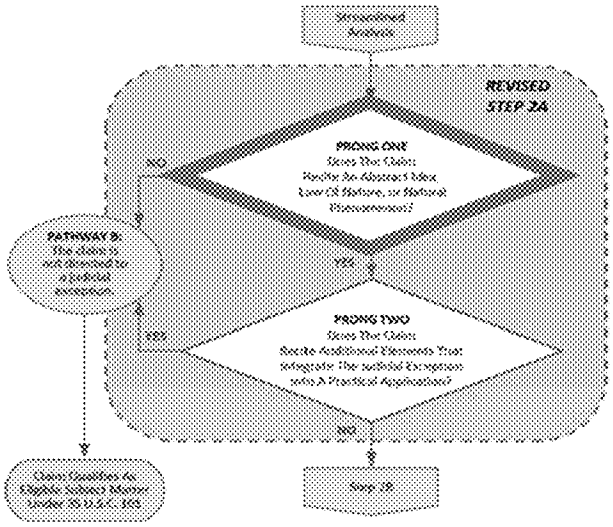
The Examiner's reliance on *Intellectual Ventures I LLC v. Capital One Bank* (USA), 792 F.3d 1363 (Fed. Cir. 2015), is misplaced because that line of cases addresses using generic computers to perform information processing more quickly,

not a new technical method that changes how a medical device processes physiological signals. *Intellectual Ventures* rejected claims that merely computerized an abstract idea without specifying a different way of performing the underlying processing. Id. at 1367–69. By contrast, these claims do not take a preexisting manual method and make it faster; they require a different method—median-filter-derived activity signals, activity-threshold-bounded POIs, and derivative-based per-channel weighting applied to multi-channel correlation—implemented in the specific context of intracardiac EGM acquisition and used to drive device behavior (e.g., thresholded arrhythmia detection and map emphasis in the apparatus/dependents). That is the sort of claimed specificity the Federal Circuit has distinguished from the "do it on a computer faster" paradigm in *Intellectual Ventures* and its progeny. See *CardioNet*, 955 F.3d at 1370–73; McRO, 837 F.3d at 1314–16; *Thales*, 850 F.3d at 1348–50. Even if Step 2B were reached, the Office has identified no evidence that this particular combination—template-bounded correlation with derivative-based channel weighting in intracardiac EGMs—was well-understood, routine, and conventional, which is a factual showing required by *Berkheimer v. HP* Inc., 881 F.3d 1360, 1368–70 (Fed. Cir. 2018). On the actual facts of these claims, Intellectual Ventures does not control.

Therefore, because the Examiner has not shown that the claims merely computerize a preexisting manual method, and because the claims instead recite a

different method in kind that changes how a cardiac device processes physiologic signals, Intellectual Ventures is inapposite. *CardioNet*, *McRO*, and *Thales* control on these claim facts and the §101 rejection should be withdrawn.

2. The Amended Claims Are Focused On A Technological Improvement To Medical Devices And Are Therefore Patent-Eligible Under *Cardionet, LLC V. Infobionic, Inc.*



In *CardioNet, LLC v. InfoBionic, Inc.*, 955 F.3d 1358, 1368 (Fed. Cir. 2020), the United States Court of Appeals for the Federal Circuit dealt with a patent infringement case concerning U.S. Patent No. 7,941,207. This patent, owned by CardioNet, describes a method and device for detecting and reporting certain types of cardiac arrhythmias, including atrial fibrillation and atrial flutter. The district court dismissed CardioNet's complaint, holding that the patent claims were directed to ineligible subject matter under 35 U.S.C. § 101, stating that the claims were

abstract and lacked inventive concept, which led to a failure to state a claim under Federal Rule of Civil Procedure 12(b)(6).

On appeal, the Federal Circuit reversed the district court's decision, concluding that the patent claims were not directed toward an abstract idea but rather to a specific improvement in cardiac monitoring technology. The Court noted that the invention improves upon existing methods by incorporating a device that detects beat-to-beat cardiac activity and distinguishes between atrial fibrillation or flutter and other forms of arrhythmia by accounting for premature ventricular beats. The Court emphasized that the claims focused on a technological improvement, specifically a device capable of real-time monitoring with enhanced accuracy in distinguishing between different arrhythmias.

Specifically, the Court stated, "the language of claim 1 indicates that it is directed to a device that detects beat-to-beat timing of cardiac activity, detects premature ventricular beats, and determines the relevance of the beat-to-beat timing to atrial fibrillation or atrial flutter, taking into account the variability in the beat-to-beat timing caused by premature ventricular beats identified by the device's ventricular beat detector" and accordingly "the claims "focus on a specific means or method that improves cardiac monitoring technology; they are not directed to a result or effect that itself is the abstract idea and merely invoke generic processes and

machinery." *CardioNet, LLC.*, 955 F.3d 1358, 1368 (internal citations and marking omitted)

The similarity between pending claim 13 and the patent-eligible claim 1 in *CardioNet* are explained below.

Eligible Subject Matter in *CardioNet*	**Amended Claim 13**	**Notes**
1. A device, comprising: a beat detector to identify a beat-to-beat timing of cardiac activity;	An apparatus for improving accuracy in detecting a cardiac arrhythmia in a patient, the apparatus comprising: one or more catheters with respective one or more electrodes arranged for insertion into a heart of the patient for acquiring unipolar pattern intra-cardiac (IC) electrogram (EGM) signals from an area of the heart, from a plurality of activity channels corresponding to the one or more electrodes; a memory; and,	Both claims recite a device/apparatus that detects cardiac signals.
a ventricular beat detector to identify ventricular beats in the cardiac activity;	one or more processors that are communicatively coupled to the one or more catheters and the memory, wherein the one or more processors are collectively configured to: receive the IC EGM signals from the one or more catheters,	Both claims recite identification/selection of one or more aspects of the detected cardiac signals.

	select a window of interest (WOI) of the IC EGM signals, the WOI representing an entire cycle length for a single heartbeat,	
relevance determination logic to identify a relevance of the variability in the beat-to-beat timing to at least one of atrial fibrillation and atrial flutter; and	calculate an activity signal based on a median filter and reference annotations, calculate an activity threshold of the WOI using the activity signal, calculate, using the activity threshold, a pattern of interest (POI) of the IC EGM signals, the POI encompassing at least a portion of the WOI, and corresponding to a specific portion of the WOI where an arrhythmia activation is exhibited, store a template POI representative of the cardiac arrhythmia in the memory, the template POI comprising a plurality of template channels based on the IC EGM signals within the WOI, receive subsequent electrical activity comprising IC EGM signals from the plurality of activity channels,	Both claims recite analysis of the detected signals to make a "determination" or render a "score" associated with abnormal cardiac activity.

	calculate signal correlations based on the template POI and the subsequent electrical activity, calculate weights based on a maximum slope of the plurality of template channels, channel; generate a correlation score by applying the weights to the signal correlations;	
an event generator to generate an event when the variability in the beat-to-beat timing is identified as relevant to the at least one of atrial fibrillation and atrial flutter in light of the variability in the beat-to-beat timing caused by ventricular beats identified by the ventricular beat detector.	detect the cardiac arrhythmia when the correlation score is above a threshold correlation score.	Both claims recite "event generation" / detection of abnormal cardiac activity based on the previous "determination" or "score."

Accordingly, like in *Cardionet,* the present claims "do not merely collect electronic information, display information, or embody mental processes" and, therefore, "do not fit into the familiar class of claims that focus on certain independently abstract ideas that use computers as tools and instead "they fit into the class of claims that focus on an improvement in computers [and other technologies] as tools." *CardioNet, LLC*, 955 F.3d 1358, 1371 (Fed. Cir. 2020) (internal

citations and marking omitted). Accordingly, like in *Cardionet,* the present claims are eligible under Alice Step 1.

The Office Action stated that the claims "are directed to a mathematical concept and mental process of performing concepts in a human mind or by a human using a pen and paper" because the claims involve several calculation steps (Final Office Action, Pg. 4). However, in *Caridionet,* the virtually identical argument was rejected by the Federal Circuit *(*"The claims recite the basic steps that any doctor could (and would) perform to make such diagnoses—collecting and analyzing a patient's heartbeat data." *CardioNet, LLC,* 955 F.3d 1358, 1370). In rejecting the "any doctor" argument, the Court held that "[g]eneralizing the asserted claims as being directed to collecting, analyzing, and reporting data is inconsistent with our instruction that courts be careful to avoid oversimplifying the claims' by looking at them generally and failing to account for the specific requirements of the claims." *Id.*, 955 F.3d 1358, 1371.

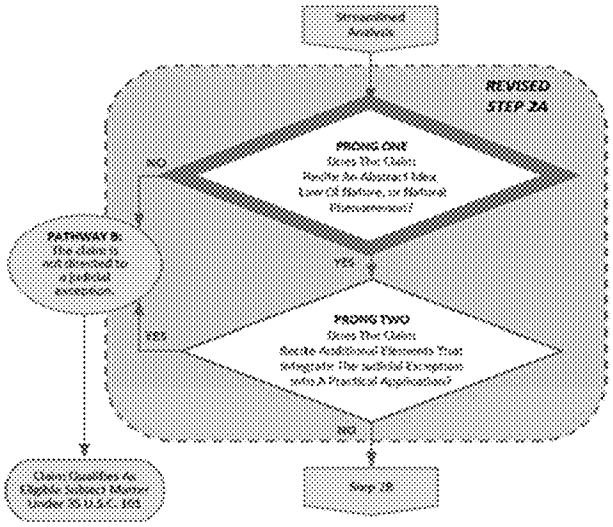
In the present case, the Office Action has contravened the Federal Circuit and improperly generalized the present claims by failing to account for the specific requirements of the claims. Instead, the Office Action has imposed an improper test of whether the claims elements are "more than a medical professional receiving print outs of the intra-cardiac (IC) electrogram (EGM) signals." (Final Office Action Pg. 5). In fact, if the Office Action's erroneous test were applied to claim 1 in *CardioNet*

(reproduced above), every element recited could be performed by a physician manually using a stethoscope and recording what is heard on a piece of paper. Therefore, under the Office Action's test, the claims in *CardioNet* would be ineligible. However, the Court expressly found that the "'207 patent claims are not directed to a patent-ineligible abstract idea." *CardioNet, LLC*, 955 F.3d 1358, 1374. Therefore, like *CardioNet*, the claims recite a specific rule-bound technique that improves cardiac-signal diagnostics: median filtering → activity threshold → POI → weighted multi-channel correlation (with weights from maximum slope) → thresholded detection. The focus is not the result "detect arrhythmia," but the particular technique implemented in a cardiac device context. That is Step 2A-1 eligibility. Accordingly, the Office Action's reliance on an improper test for patent eligibility is inconsistent with the Federal Circuit's findings in *CardioNet*, and the rejection of the present claims under 35 U.S.C. § 101 should be withdrawn.

Therefore, much like in *CardioNet.*, the present claims are not directed to an abstract idea or a process that can be performed manually by a clinician. Instead, the claims improve upon existing technology by providing specific and tangible technological advancements, particularly in real-time monitoring and analysis of cardiac signals. The Federal Circuit's clear rejection of overly broad generalizations in *CardioNet* applies equally here, as the Office Action's argument fails to account for the specific limitations and requirements of the present claims. The claims at issue

focus on a technological improvement and, therefore, meet the standard for patent eligibility under Alice Step 1. Consequently, the rejection under 35 U.S.C. § 101 should be withdrawn.

3. The Amended Claims Are Not Directed To An Abstract Idea And Are Therefore Patent-Eligible Under *Thales Visionix, Inc. V. United States.*



In *Thales Visionix, Inc. v. United States*, claims directed to the helmet-mounted display system used in the F-35 Joint Strike Fighter were held to be patent-eligible. (*Thales Visionix, Inc. v. United States*, 850 F.3d 1343, 1349 (Fed. Cir. 2017)). The Court reasoned that "[j]ust as claims directed to a new and useful technique for defining a database that runs on general-purpose computer equipment are patent eligible [as in *Enfish*] so too are claims directed to a new and useful technique for using sensors to more efficiently track an object on a moving platform." (*Id.*, 850 F.3d

1343, 1349). Therefore, the Court concluded using "sensors in a non-conventional manner to reduce errors in measuring the relative position and orientation of a moving object" is patent-eligible subject matter. (*Id.*, 850 F.3d 1343, 1348-49).

Similar to patent-eligible claims in *Thales,* the amended claims also use sensors (i.e., a first sensor respective one or more electrodes arranged for insertion into a heart of the patient for acquiring unipolar pattern intra-cardiac (IC) electrogram (EGM) signals from an area of the heart) in an unconventional manner to solve a problem that originates from attempting to use data that originates from different sources (i.e. detect the cardiac arrhythmia). The similarity between the patent-eligible claims in *Thales* and the amended claims is shown below:

Eligible Subject Matter in *Thales*	**Amended Claim 13**
A system for tracking the motion of an object relative to a moving reference frame, comprising:	An apparatus for improving accuracy in detecting a cardiac arrhythmia in a patient, the apparatus comprising:
a first inertial sensor mounted on the tracked object; a second inertial sensor mounted on the moving reference frame; and	one or more catheters with respective one or more electrodes arranged for insertion into a heart of the patient for acquiring unipolar pattern intra-cardiac (IC) electrogram (EGM) signals from an area of the heart, from a plurality of activity channels corresponding to the one or more electrodes;;

an element adapted to receive signals from said first and second inertial sensors	receive the IC EGM signals from the one or more catheters, … receive subsequent electrical activity comprising IC EGM signals from the plurality of activity channels,
and configured to determine an orientation of the object relative to the moving reference frame based on the signals received from the first and second inertial sensors.	calculate an activity signal based on a median filter and reference annotations, calculate an activity threshold of the WOI using the activity signal, calculate, using the activity threshold, a pattern of interest (POI) of the IC EGM signals, the POI encompassing at least a portion of the WOI, and corresponding to a specific portion of the WOI where an arrhythmia activation is exhibited, store a template POI representative of the cardiac arrhythmia in the memory, the template POI comprising a plurality of template channels based on the IC EGM signals within the WOI, … calculate signal correlations based on the template POI and the subsequent electrical activity, calculate weights based on a maximum slope of the plurality of template channels, channel; generate a correlation score by applying the weights to the signal correlations; and

	detect the cardiac arrhythmia when the correlation score is above a threshold correlation score.

Like in *Thales*, the amended claims use sensor data in a non-conventional manner, namely, to "detect the cardiac arrhythmia," as recited in the amended claims. As a result, the amended claims are patent-eligible because the claims are directed to an improved usage of sensor data and not an abstract idea, as suggested by the Office Action.

The Office Action alleges that "In the case of the present application, the sensors are not being used in a non-conventional manner, which is the reasoning behind the decision in Thales." (Final Office Action, Pg. 3). The Applicant respectfully disagrees. As shown above, the only requirement that is imposed on the sensors in *Thales*, is that a first inertial sensor and the second inertial sensor be mounted on the "on the tracked object" and "the moving reference frame." The inertial sensors are conventional, and clearly, mounting sensors on an object is conventional. However, the Court ruling was based on how the data was used to solve a technical problem: the orientation of the frames of reference. Just like in *Thales*, the present invention uses the sensor data to solve a technical problem, namely the detection of cardiac arrhythmia. Accordingly, like in *Thales*, the present claims are patent-eligible.

As a result, the answer to decision block 2A of "Subject Matter Eligibility Test for Product and Processes" is "NO". Accordingly, under *Alice* Step 1, the present

claims are patent-eligible. Further, since the present claims are "not directed to ineligible subject matter, we do not reach *Alice* step two." (*McRO, Inc.,* 837 F.3d 1299, 1316). Consequently, under the two-part *Alice* test, the present claims recite patent-eligible subject matter and comply with 35 U.S.C. §101.

4. The Present Claims Are Patent-Eligible Under Ex Parte Fautz and Thales as They Provide a Technological Improvement in Medical Diagnostics

The Office Action's rejection of the present claims under 35 U.S.C. § 101 is legally flawed and inconsistent with the reasoning articulated by the Patent Trial and Appeals Board (PTAB) in *Ex Parte Fautz* (Appeal No. 2019-000106) (PTAB May 15, 2019) (informative)[1], which applied the Federal Circuit's holding in *Thales*. The PTAB in *Ex Parte Fautz* found claims were not direct to abstract ideas but practical applications that enhanced the functionality of a medical device. Similarly, the present claims utilize mathematical analysis of biometric data to improve cardiac mapping accuracy during electrophysiology procedures, addressing the real-world issue of erroneous heart mapping. The Office Action's attempt to dismiss the claims as abstract because they involve data collection and analysis mirrors the Examiner's flawed reasoning in *Ex Parte Fautz*, which the PTAB explicitly rejected.

In *Ex Parte Fautz,* the PTAB found a "claimed invention [that] uses the recited

[1] Available at https://www.uspto.gov/sites/default/files/documents/Ex%20Parte%20Fautz.pdf

mathematical equations to improve the imaging system" "is "not directed to an abstract idea" and therefore patent eligible under 35 U.S.C. §101. Specifically, the invention at issue *Ex Parte Fautz* was "concerned with solving the technical problem of improving sensitivity correction in MR tomography devices" and is directed to a "solution [that] overcomes the limitations of existing approaches." (*Ex Parte Fautz, Pg. 10*)**.** The Examiner had rejected the claims (representative claim 8 is reproduced below) under 35 U.S.C. §101 and alleged that the claim was "similar to abstract ideas relating to mathematical formulas and "collecting information, analyzing it, and displaying certain results of the collection and analysis." (*Ex Parte Fautz*, Pg. 5). The Examiner also argued that the MR tomography apparatus and its processor were conventional elements in the field and that the data collection and processing steps were insignificant extra-solution activities that failed to confer eligibility.

8. A magnetic resonance (MR) tomography apparatus comprising:

an MR data acquisition unit comprising a radio frequency (RF) transmission system comprising a number n of single RF coils E_i with which reception signals I_i are respectively acquired, with $i = 1, \ldots, n$;

a processor provided with or configured to determine, for each single coil E_i, an individual reception sensitivity profile in the spatial domain r $B1_i^-(r)$:

$$B1_i^-(r) = |a_i(r)| * e^{i\varphi_i(r)}$$

with amplitude $a_i(r)$ and phase $\varphi_i(r)$;

said processor being configured to operate the MR tomography apparatus to scan an examination subject introduced into the MR tomography apparatus to acquire reception signals $I_i(k)$ in the frequency domain with wave number k via the n reception coils E_i;

said processor being configured to determine Fourier-transformed signals $IF_i(r)$ from the reception signals $I_i(k)$, wherein:

$$IF_i(r) = \rho(r) \cdot e^{i\Phi(r)} \cdot B1_i^-(r) + N$$

with N:= noise term, $\rho(r)e^{i\Phi(r)}$:= proton density;

said processor being configured to determine complexly corrected signals $\tilde{I}F_i(r)$ on the basis of the signals $IF_i(r)$ and the individual reception sensitivity profiles $B1_i^-(r)$;

said processor being configured to determine a sum signal MR(r) via complex addition of the corrected signals $\tilde{I}F_i(r)$:

$$MR(r) = \sum_i \tilde{I}F_i(r)\,; \text{and}$$

said processor being configured to reconstruct image data of the examination subject on the basis of the sum signal MR(r), and to make the image data available at an output of the processor as an electronic data file.

The PTAB "disagree[d] with the Examiner that the recited data collection is a field of use or merely adds token components to the mathematical equations." (*Ex Parte Fautz*, Pg. 9). Instead, the PTAB held that "as in Thales, the independent claims solve a technical problem" and are therefore patent eligible under 35 U.S.C. §101 **(***Ex Parte Fautz*, Pg. 9).

In reaching this conclusion, the PTAB applied the Alice/Mayo framework to determine the eligibility of the claims. In the first step of the framework, the Board acknowledged that the claims involved mathematical concepts through the use of formulas for calculating reception sensitivity profiles, Fourier-transformed signals, and sum signals for image reconstruction. These formulas constituted an abstract idea under USPTO guidelines.

However, under the second step—specifically, Step 2A, Prong Two of the eligibility framework—the Board determined that the claims were not directed to an abstract idea because "the claimed invention uses the recited mathematical equations to improve the imaging system." (*Ex Parte Fautz*, Pg. 11). Specifically, the PTAB held that "[t]he independent claims recite a practical application of these results because the claimed method, device, and medium improve the output by reconstructing "image data of the examination subject on the basis of the sum signal." (*Ex Parte Fautz*, Pg. 11).

Specifically, the PTAB looked to *Thales* and explained that "the Federal Circuit

found claims eligible when they were directed to a particular configuration of inertial sensors and a particular method of using the raw data from the sensors, which improved the accuracy of calculating an object's position and orientation." (*Ex Parte Fautz*, Pg. 8). The PTAB further highlighted that simply because "a mathematical equation is required to complete the claimed method and system does not doom the claims to abstraction." (*Ex Parte Fautz*, Pg. 11).

Accordingly, when applying *Thales* in *Ex Parte Fautz*, the PTAB found the claims were patent eligible because"[t]he mathematical calculations recited in the independent claims are "a consequence of the arrangement of" the device's coils and how they receive signals during the scan and "the reception coil's physical properties--i.e., the reception-sensitivity profiles --are used in the analysis" that "results in an improved reconstructed image." (*Ex Parte Fautz*, Pg. 11). Thus, the PTAB concluded that the claims in *Ex Parte Fautz* were patent-eligible under 35 U.S.C. §101 because the mathematical calculations were not merely abstract ideas but were fundamentally integrated into the technological operation of a medical device, resulting in a concrete improvement in patient diagnostics.

In the present case, like the Examiner in *Ex Parte Fautz*, the Office Action in the present case is attempting to reject the claims as ineligible under 35 U.S.C. §101 because they are allegedly similar to abstract ideas relating to mathematical formulas and collecting information, analyzing it, and displaying certain results of

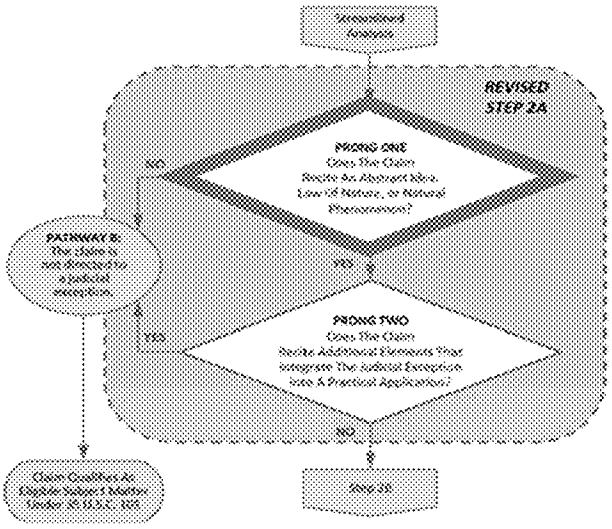
the collection and analysis. (see Final Office Action, Pg. 4-5 "mathematical calculations of calculating an activity signal (see Equation 2 in ¶36 of Applicant's specification), calculating an activity threshold (see Equation 3 in ¶37 of Applicant's specification), calculating a pattern of interest (POI) (see Equation 4 in ¶38 of Applicant's specification), calculating a signal correlation (see Equation 5 in ¶41 of Applicant's specification), calculating weights (see Equation 6 in ¶42 of Applicant's specification), and calculating a score based on the previously calculated correlations (¶53 of Applicant's specification) in order to detect a cardiac arrhythmia in a patient..")

However, the PTAB in *Ex Parte Fautz* clearly held that this oversimplification of an invention contravenes the Federal Circuit's holding in *Thales*. Accordingly, *Thales* supports claims that use sensors in a non-conventional manner to improve how a system determines a physical condition (there, pose; here, arrhythmia activation across electrode positions). *Ex parte Fautz* (informative) confirms that mathematical operations embedded in, and improving, a medical device's operation are not abstract under Step 2A, Prong 2. Here, the derivative-based weighting of template channels and POI-bounded correlation improve sensitivity/specificity of real-time mapping, i.e., operation of the EP system itself.

As a result, the Office Action's rejection of the present claims under 35 U.S.C. § 101 is legally erroneous and directly contradicts the reasoning set forth in *Ex Parte*

Fautz and the Federal Circuit's holding in *Thales*. Just as the PTAB in *Fautz* recognized that mathematical equations integrated into a technological process to improve medical imaging were not abstract but a practical application of technology, the present claims similarly employ mathematical analysis of biometric data to enhance cardiac electrograms accuracy during electrophysiology procedures. The Office Action's oversimplification of the claims as mere data collection and analysis ignores the clear precedent established in *Fautz*, where the PTAB held that solving a concrete technical problem through the application of mathematical concepts within a medical device context constitutes patent-eligible subject matter. Therefore, consistent with *Ex Parte Fautz* and *Thales*, the present claims are directed to a concrete technological improvement and should be deemed patent-eligible under 35 U.S.C. § 101, warranting withdrawal of the rejection.

5. Like The Hypothetical Patent-Eligible Example In The MPEP, The Present Claims Measure Physiological Parameters And Are, Therefore, Similarly Patent-Eligible Under 35 U.S.C. §101

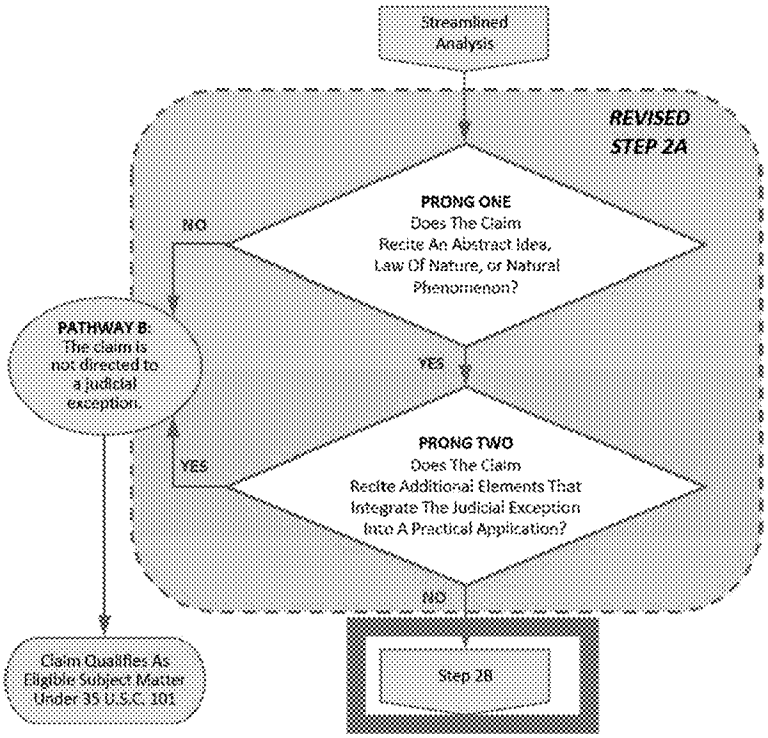


The MPEP provides a list of "hypothetical examples of claims that do not recite (set forth or describe) an abstract idea." One such example claims "an earring comprising a sensor for taking periodic blood glucose measurements and a memory for storing measurement data from the sensor." Like that hypothetical example, the present claims are also directed to a method of measuring physiological parameters. For purposes of §101, there is no material difference between a system that takes glucose measurements and a system that identifies "detect the cardiac arrhythmia when the correlation score is above a threshold correlation score", as claimed. Accordingly, like in the hypothetical example recited in the MPEP, the present claims are patent eligible under 35 U.S.C. 101.

The record also forecloses the "pre-solution measuring" label. The application teaches that EGM acquisition is functionally coupled to pre-processing (median/FIR and analog front-end to remove baseline wander), WOI/POI definition within a

heartbeat, rule-based activity thresholds, derivative-based per-channel weights, channel-wise and weighted correlations, and a thresholded decision that controls device behavior by incorporating the result into a cardiac map with emphasized regions. (Application ¶¶11, 20, 25, 29–30, 36–37, 67.) That is *Diehr*-type integration of measurements into a control workflow, not insignificant data gathering; and, under *Berkheimer*, the Examiner cites no evidence that this particular combination was well-understood, routine, and conventional.

6. Like Example 4 In The 2019 Patent Eligibility Guidance, When Viewed In Combination, The Claims Amount To Significantly More Than The Judicial Exception (Step 2B)



Example 4 of the Subject Matter Eligibility Examples: Abstract Ideas

(Examples 1–36), Example 4 (GPS/SiRF)[2] provides hypothetical claims modeled after *SiRF Technology Inc. v. International Trade Commission* pertaining to U.S. Patent No. 6,417,801, involving improvements in Global Positioning System (GPS) technology. The patent in that case describes a system and method where a server, wirelessly connected to a mobile GPS receiver, utilizes mathematical models to determine the receiver's position without needing satellite positioning data or absolute time information directly from the satellite. This innovation enhances the GPS receiver's accuracy and sensitivity, especially in low-signal environments. The mobile device includes components such as a GPS receiver, microprocessor, display, and communication transceiver to receive pseudo-random noise (PN) codes from satellites, calculate pseudo-ranges, and transmit them to the server. The server then estimates the GPS receiver's position using stored location data and time data, calculates the absolute time of signal reception, and creates a mathematical model to determine the receiver's absolute position, which is sent back to the mobile device for display. These technological improvements amount to significantly more than just abstract mathematical operations, rendering them patent-eligible.

Specifically, patent-eligible claim 1 from Example 4 recites:

> 1. A system for calculating an absolute position of a GPS receiver and an absolute time of reception of satellite signals comprising:
>
> a mobile device comprising a GPS receiver, a display, a

[2] Available at https://www.uspto.gov/sites/default/files/documents/101_examples_1to36.pdf

> microprocessor and a wireless communication transceiver coupled to the GPS receiver, the mobile device programmed to receive PN codes sent by a plurality of GPS satellites, calculate pseudo-ranges to the plurality of GPS satellites by averaging the received PN codes, and transmit the pseudo-ranges, and
>
> a server comprising a central processing unit, a memory, a clock, and a server communication transceiver that receives pseudo-ranges from the wireless communication transceiver of the mobile device, the memory having location data stored therein for a plurality of wireless towers, and the central processing unit programmed to:
>
> estimate a position of the GPS receiver based on location data for a wireless tower from the memory and time data from the clock,
>
> calculate absolute time that the signals were sent from the GPS satellites using the pseudo-ranges from the mobile device and the position estimate,
>
> create a mathematical model to calculate absolute position of the GPS receiver based on the pseudo-ranges and calculated absolute time,
>
> calculate the absolute position of the GPS receiver using the mathematical model, and
>
> transmit the absolute position of the GPS receiver to the mobile device, via the server communication transceiver, for visual representation on the display.

The PEG explains that the claim is patent-eligible under 35 U.S.C. §101 because it involves a system comprising a mobile device and a server, satisfying the requirements of a machine. Despite reciting abstract mathematical operations, the claim is patent-eligible as it includes specific components and interactions that

improve GPS technology by enhancing signal acquisition and accuracy in weak-signal environments, thus providing significantly more than the abstract idea alone.

Similarly, the present claims include specific components (i.e., "one or more catheters with respective one or more electrodes arranged for insertion into a heart of the patient for acquiring unipolar pattern intra-cardiac (IC) electrogram (EGM) signals from an area of the heart, from a plurality of activity channels corresponding to the one or more electrodes"") and interactions (i.e., receive the IC EGM signals from the one or more catheters, select a window of interest (WOI) of the IC EGM signals, the WOI representing an entire cycle length for a single heartbeat, calculate an activity signal based on a median filter and reference annotations, calculate an activity threshold of the WOI using the activity signal, calculate, using the activity threshold, a pattern of interest (POI) of the IC EGM signals, the POI encompassing at least a portion of the WOI, and corresponding to a specific portion of the WOI where an arrhythmia activation is exhibited, store a template POI representative of the cardiac arrhythmia in the memory, the template POI comprising a plurality of template channels based on the IC EGM signals within the WOI, receive subsequent electrical activity comprising IC EGM signals from the plurality of activity channels, calculate signal correlations based on the template POI and the subsequent electrical activity, calculate weights based on a maximum slope of the plurality of template channels, channel; generate a correlation score by applying the weights to the signal

correlations;,") that improve the accuracy of the detection of cardiac arrhythmias.

As a result, like in Example 4, "taking all the additional claim elements individually, and in combination, the claim as a whole amounts to significantly more than the mathematical operations by themselves." (PEG, Pg. 13). Consequently, the answer to decision block 2B of the Subject Matter Eligibility Test for Products and Processes" (reproduced above) is "YES" and the amended claims contain patent-eligible subject matter.

7. The Claims Do Not Merely "Measure" as Pre-Solution Data Gathering; They Integrate Physiological Acquisition with a Specific Processing Pipeline That Controls Device Behavior

The Examiner's assertion that the claims are directed only to "measuring" and thus amount to pre-solution data gathering omits the claimed—and disclosed—processing chain that transforms raw intracardiac signals into a device-actionable output that changes how the EP system operates.(Final Office Action, Pg. 3). The application teaches that intracardiac EGMs from multiple catheter electrodes are first acquired and then pre-processed with median/FIR filtering and analog front-end conditioning expressly to remove baseline wander and other artifacts before any template is created—integrating measurement with problem-targeted conditioning rather than treating measurement as antecedent data gathering (Application, ¶20). The claims then require defining a window of interest (WOI) spanning an entire heartbeat and, within it, a pattern of interest (POI) corresponding to arrhythmia

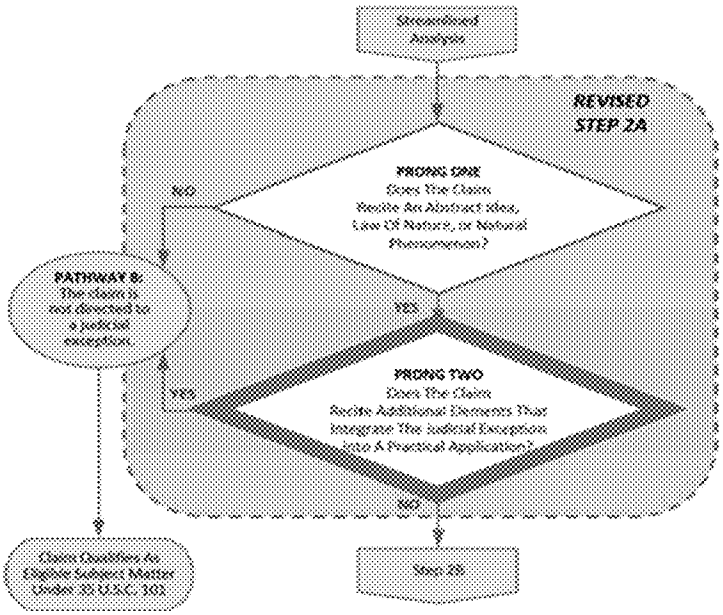
activation—again tying the data to a medically significant temporal structure, not merely "collecting" it (Application, ¶¶29–30). From there, the application discloses concrete rules and equations: an activity signal computed with a median filter within an activity segment (e.g., 15 ms window); an activity threshold derived from that signal; POI boundaries set by threshold intersections; and per-channel weights computed from the maximum slope (first derivative) of template channels to emphasize sharp activations—followed by channel-wise correlation and a final weighted correlation over all channels (Application, ¶¶36–37). This is not mere "measuring"; it is a rule-bound pipeline that changes the state of the system by converting signals into a thresholded correlation score used to make the detection decision and to select the best alignment by phase-shifting a moving template window (e.g., within ±40 ms in 1 ms increments)—operations a clinician cannot practically perform mentally or on paper (Application, ¶67).

Critically, the application ties this processing to device behavior: when correlation exceeds threshold, the system presents the results and incorporates them into a cardiac map displayed to the user—so the claimed processing is used to guide mapping, not to report raw measurements (Application, ¶25). The disclosure also explains that the system receives subsequent electrical activity across multiple channels and assigns a weighted correlation score in the multichannel unipolar context to determine whether the activity correlates to the template—again reflecting

an integrated detection workflow rather than isolated data capture (Application, ¶11; ¶20). In short, acquisition is functionally coupled to filtering, thresholding, template formation, derivative-based weighting, correlation, thresholded decision, and map update—an integrated practical application, not pre-solution data gathering (Application, ¶¶11, 20, 25, 29–30, 36–37, 67).

This is the *Diehr* paradigm—sensor measurement feeding an industrial (here, medical-device) control process—rather than a case of attaching generic sensors to an abstract idea. See *Diamond v. Diehr*, 450 U.S. 175, 191–92 (1981). And even if Step 2B were reached, the Office identifies no evidence that derivative-based per-channel weighting applied to a template-bounded, multi-channel intracardiac correlation—tied to a beat-length WOI and used to drive a cardiac map emphasis—was "well-understood, routine, and conventional," which is a factual showing required by *Berkheimer v. HP Inc.*, 881 F.3d 1360, 1368–70 (Fed. Cir. 2018). On this record, the "pre-solution data gathering" label does not apply, and the §101 rejection should be withdrawn.

8. The present claims improve the operation of a cardiac sensor and are therefore eligible under Step 2A Prong 2.



In connection with the Step 2 A Prong 2 analysis, the Office Action stated, "In the case of the present application, the sensors are not being used in a non-conventional manner, which is the reasoning behind the decision in Thales." (Final Office Action, Pg. 3).

However, under Step 2A, Prong Two, the MPEP instructs Examiners to determine whether any additional elements in the claim integrate the abstract idea into a practical application, such as improving the functionality of a computer. Specifically, the MPEP explains that the "improvements" analysis in Step 2A determines whether the claim pertains to an improvement to the functioning of a computer or to another technology **without reference to what is well-understood, routine, conventional activity.** That is, the claimed invention may integrate the judicial exception into a practical application by demonstrating that it

improves the relevant existing technology **although it may not be an improvement over well-understood, routine, conventional activity."** (2106.04(d)(1))(emphasis added). Accordingly, a claim that improves the functioning of a technical system is patent-eligible regardless of whether the improvement is obtained through well-understood, routine, conventional activity.

In the present case, the Examiner bears the initial burden to provide evidence that the specific sequence recited—(a) median-filter "activity signal," (b) activity-threshold-defined POI spanning a heartbeat's WOI, and (c) derivative-based channel weighting applied to multi-channel correlation to detect arrhythmia with a thresholded score driving a map update—was well-understood, routine, and conventional in EP mapping systems at the relevant time. The Final Action cites general catheters/electrodes but no evidence that derivative-based per-channel weighting for template-matching intracardiac EGMs—in the claimed real-time, multi-electrode context—was conventional. Under Berkheimer and Aatrix, this is a dispositive factual question; in the absence of particularized evidence, Step 2B cannot sustain the rejection.

Therefore, under Step 2A, Prong Two, the present claims are patent-eligible because the elements are integrated into the practical application and solve a specific technical computer problem with a specific technical solution.

9. The Office Action Has Failed To Meet Its Burden Of

Establishing That The Claims Are Ineligible Under 35 U.S.C. §101

The Office bears the initial burden to establish a prima facie case of ineligibility. That burden requires more than labeling the claims "abstract." It requires (i) identifying, under Step 2A, the particular judicial exception to which the claims are "directed," and, if any is identified, explaining why the claims are not integrated into a practical application; and (ii) under Step 2B, supporting with evidence any assertion that the specific, claimed combination is "well-understood, routine, and conventional" (WURC). See *Alice Corp. v. CLS Bank Int'l*, 573 U.S. 208, 217–18 (2014); *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 77–80 (2012); *Berkheimer v. HP Inc.*, 881 F.3d 1360, 1368–70 (Fed. Cir. 2018); *Aatrix Software, Inc. v. Green Shades Software, Inc.*, 882 F.3d 1121, 1128 (Fed. Cir. 2018). The Final Action does not carry that burden.

First, the claims are not directed to an abstract idea under Step 2A, prong one. They do not merely announce a result ("detect arrhythmia") or claim unconstrained data analysis. Rather, they recite a specific, rule-bound signal-processing technique embedded in a cardiac mapping system: acquisition of multi-electrode intracardiac EGMs via a catheter; selection of a window of interest spanning a heartbeat; computation of an activity signal using a median filter with reference annotations; derivation of an activity threshold to define a pattern of interest (POI); formation of a multi-channel template POI; computation of signal correlations to subsequent

EGMs; computation of per-channel weights from the maximum slope (first derivative) of template channels; and generation of a weighted multi-channel correlation score compared to a threshold correlation score to detect the arrhythmia. (Application, ¶¶11, 20, 25, 29–30, 36–37.) Claims with this level of algorithmic specificity that improve how a technological system processes domain-specific time-series data are eligible. See *CardioNet, LLC v. InfoBionic, Inc.*, 955 F.3d 1358, 1370–73 (Fed. Cir. 2020) (claims "focused on a specific means or method that improves" cardiac monitoring); *McRO, Inc. v. Bandai Namco Games Am. Inc.*, 837 F.3d 1299, 1313–16 (Fed. Cir. 2016) (rule-based processing of time-series data eligible); *Thales Visionix Inc. v. United States*, 850 F.3d 1343, 1348–50 (Fed. Cir. 2017) (non-conventional sensor math improving system operation not abstract).

Second, even assuming arguendo that some sub-steps could be characterized as mathematical, the claims are integrated into a practical application (Step 2A, prong two). The specification ties the processing chain to an electrophysiology (EP) system workflow: the EGMs are pre-processed (median/FIR and analog front-end) to remove baseline wander and artifacts before template formation; the WOI/POI are defined with clinically meaningful boundaries; and, crucially, when the weighted correlation exceeds threshold, the system incorporates the beat into a cardiac map and emphasizes anatomical regions exhibiting arrhythmia activation—device behavior used to guide mapping, not mere reporting of measurements. (Application,

¶¶20, 25, 29–30, 36–37, 67.) This is the *Diehr* paradigm, where sensor measurement feeds and controls the operation of a machine, not "insignificant extra-solution activity." *Diamond v. Diehr*, 450 U.S. 175, 191–92 (1981).

Third, the Final Action provides no evidence under Step 2B that the claimed combination—including derivative-based (maximum-slope) per-channel weighting applied to a template-bounded, multi-channel intracardiac correlation within a heartbeat-length WOI, used to produce a thresholded detection score and to update a cardiac map—was WURC in EP systems at the relevant time. General references to catheters, electrodes, or correlation do not establish conventionality of this particular sequence of operations. Berkheimer makes clear that conventionality is a factual question that must be supported by evidence; attorney argument is insufficient. 881 F.3d at 1368–70; *Aatrix*, 882 F.3d at 1128. The record here is silent on conventional use of maximum-slope-derived channel weights in the claimed template-matching pipeline (and on the disclosed thresholding and moving-window alignment granularity). (Application, ¶¶36–37, 67.) Absent such evidence, Step 2B cannot sustain ineligibility.

Fourth, the Examiner's reliance on the "speed/efficiency" maxim from Intellectual Ventures I LLC v. Capital One Bank (USA), 792 F.3d 1363, 1367–69 (Fed. Cir. 2015), is misplaced. Those cases involved generic information handling made faster by computerization. These claims, by contrast, recite a different method in

kind—median-filtered activity signals, activity-threshold-bounded POIs, and maximum-slope per-channel weighting—that changes how the device processes physiological signals to yield a thresholded, device-actionable correlation score and map update. (Application, ¶¶11, 20, 25, 29–30, 36–37, 67.) That distinction is precisely why *CardioNet*, *McRO*, and *Thales* govern, *not Intellectual Ventures*.

Because the Final Action neither demonstrates that the claims are "directed to" a judicial exception in light of their claimed specificity and practical integration, nor adduces the evidence required by *Berkheimer* to show that the specific claimed combination was WURC, the Office has not made a prima facie case of ineligibility. The § 101 rejection should be reversed.

B. Claims 15 and 16 Are Patent-Eligible Under § 101 and Align With Federal Circuit UI Precedent

In addition to the reasons discussed above, claims 15 and 16 are additionally patentable. Claims 15 and 16 recite a specific medical-device user interface and mapping workflow that is integrated with, and conditioned on, the output of the claimed intracardiac signal-processing pipeline. Claim 15 requires a "display screen arranged for displaying the subsequent electrical activity when the cardiac arrhythmia is detected," and claim 16 further requires that only the subsequent electrical activity with a correlation score exceeding the threshold is "incorporated into a map of the heart" with areas exhibiting arrhythmia "emphasized." These

limitations are not generic presentation of information. They specify when, how, and what is displayed, and they tie the display behavior to the operation of the device's detection algorithm that uses a heartbeat-bounded WOI, an activity signal computed by a median filter with reference annotations, an activity-threshold-defined POI, derivative-based (maximum-slope) per-channel weights, and weighted multi-channel correlation to produce a thresholded detection result. See Application, ¶¶0028–0036 (WOI, activity signal, threshold, POI), ¶0042 (maximum-slope weights), ¶¶0054–0057 (moving window and correlations), ¶0063 (thresholded correlation), and ¶¶0025, 0060 (display and map emphasis behavior).

Under Step 2A, Prong 1, the claims are not directed to an abstract idea because they recite a specific way of improving how an EP mapping system conveys procedurally relevant information at the moment of detection. The mapping and emphasis limitations are functionally and structurally constrained by the detection pipeline and are triggered only upon satisfaction of the correlation threshold. This is a device-embedded improvement to a technological process, not a results-oriented instruction to "display data." See *CardioNet, LLC v. InfoBionic, Inc.*, 955 F.3d 1358, 1370–73 (Fed. Cir. 2020) (claims focused on a specific means that improves cardiac monitoring); *McRO, Inc. v. Bandai Namco Games Am. Inc.*, 837 F.3d 1299, 1313–16 (Fed. Cir. 2016) (rule-based processing of time-series data eligible). Under Step 2A, Prong 2, the claims are integrated into a practical application because the

thresholded outcome controls device behavior: the system incorporates qualified activity into a position-registered cardiac map and emphasizes anatomical regions that exhibit arrhythmia activation, which is the work product used during the clinical procedure. Application, ¶¶0025, 0060. This is analogous to the integration of sensor measurements into machine control recognized in *Diamond v. Diehr*, 450 U.S. 175, 191–92 (1981).

The Office Action's treatment of the display and map features as mere post-solution presentation also conflicts with Federal Circuit decisions holding that user interfaces are patent-eligible when they implement specific functionalities that resolve identified technological problems. In *Trading Technologies International, Inc. v. CQG, Inc.*, the court upheld claims because they were "not merely directed to displaying information on a graphical user interface," but instead required "a specific, structured graphical user interface paired with a prescribed functionality directly related to the graphical user interface's structure that is addressed to and resolves a specifically identified problem in the prior state of the art." 675 F. App'x 1001, 1004–05 (Fed. Cir. 2017). In *Core Wireless Licensing S.A.R.L. v. LG Electronics,* Inc., the court held claims eligible where the interface "improved the efficiency of using the electronic device," emphasizing that the claims recited "a particular manner of summarizing and presenting information in electronic devices" to solve a navigation problem. 880 F.3d 1356, 1362–63 (Fed. Cir. 2018). Applying these principles, *Data*

Engine Techs. LLC v. Google LLC held claims eligible that "differ[ed] from prior art navigation methods and provide[d] for rapidly accessing and processing information," because the claims specified the way the interface organized and presented content to overcome known usability limits. 906 F.3d 999, 1007–10 (Fed. Cir. 2018).

Claims 15 and 16 fit comfortably within this line of cases. The specification identifies the clinical problem that physicians confront during intracardiac procedures: dense, multi-channel EGMs must be interpreted in real time while the physician's ability to manipulate interfaces is constrained. Application, ¶¶0003, 0017, 0025. The claims do not simply display raw signals. They require a particular interface behavior that is tied to the algorithmic state of the device: only when the weighted correlation score exceeds the threshold does the system display the "subsequent electrical activity" and incorporate it into a position-registered heart map with emphasized regions. Application, ¶¶0025, 0060. That prescribed interface functionality corresponds to, and solves, the identified problem by surfacing only clinically significant activity and by visually emphasizing the affected anatomy at the moment it is detected, thereby reducing cognitive load and improving intra-procedural decision making. As in Trading Technologies, the claimed UI behavior is "paired with a prescribed functionality" directly related to its structure and operation; as in Core Wireless and Data Engine, it provides a specific manner of organizing and

presenting information that enhances the user's ability to access and process critical information in a constrained environment.

Even if Step 2B were reached, the record contains no evidence that this particular combination was well-understood, routine, and conventional in EP mapping systems: computing maximum-slope per-channel weights for a heartbeat-bounded, template-based multi-channel correlation and then automatically incorporating only threshold-exceeding results into a position-registered cardiac map with emphasized regions. Application, ¶¶0042, 0054–0057, 0060. Under *Berkheimer v. HP Inc.*, 881 F.3d 1360, 1368–70 (Fed. Cir. 2018), conventionality is a factual question that must be supported by evidence, not by general references to displays or mapping.

Accordingly, consistent with *Trading Technologies, Core Wireless,* and *Data Engine,* and given the claim-specific ties to the device's detection pipeline and mapping workflow, claims 15 and 16 are not directed to an abstract idea and are patent-eligible under 35 U.S.C. § 101. The rejection should be withdrawn.

VII. Conclusion

For the reasons set forth above, the § 101 rejection should be reversed. The appealed claims are not directed to an abstract idea under Step 2A, Prong 1 because they recite a specific intracardiac configuration and a rule-bound control sequence that improves the operation of an electrophysiology mapping system. They are, in any

event, integrated into a practical application under Step 2A, Prong 2. The claimed processing pipeline, including a heartbeat-bounded WOI, an activity signal computed with a median filter and reference annotations, an activity-threshold-defined POI, maximum-slope per-channel weighting, and weighted multi-channel correlation, produces a thresholded detection result that controls device behavior by updating a position-registered cardiac map and emphasizing affected anatomy. The Examiner's reliance on "speed or efficiency" cases such as Intellectual Ventures is misplaced; the claims recite a different method in kind, not the same idea performed faster. The "pre-solution data gathering" label is likewise inconsistent with Diehr and with the specification, which discloses measurement steps that are functionally coupled to control of the medical device. Claims 15 and 16 provide an additional, independent basis for eligibility because they recite a specific user-interface and mapping behavior tied to the algorithmic state of the device, which aligns with Trading Technologies, Core Wireless, and Data Engine. Finally, under Step 2B, the Office has not met its evidentiary burden under Berkheimer to show that the specific claimed combination, including maximum-slope per-channel weighting applied to a template-bounded, multi-channel correlation within a heartbeat-length WOI and used to gate a position-registered map update with anatomical emphasis, was well understood, routine, and conventional at the relevant time.

Accordingly, Appellant respectfully requests that the Board reverse the § 101

rejection of the appealed claims and order withdrawal of the rejection. In the alternative, if the Board identifies any new rationale or factual deficiency in the record, Appellant requests that the Board vacate and remand for further prosecution consistent with the Board's opinion.

Respectfully submitted,

Biosense Webster (Israel) Ltd.

By /Brandon R. Theiss/
Brandon R. Theiss
Registration No. 70,507

Volpe Koenig
30 South 17th Street
Philadelphia, PA 19103-4009
Telephone: (215) 568-6400
Facsimile: (215) 568-6499

BRT/pf
Enclosure

VIII. Claims Appendix

1. (Previously Presented) A method for improving accuracy in detecting a cardiac arrhythmia in a patient, the method comprising:

inserting a catheter into a heart of the patient;

receiving unipolar pattern intra-cardiac (IC) electrogram (EGM) signals for an area of the heart, from a plurality of activity channels corresponding to a plurality of electrodes of the catheter;

selecting a window of interest (WOI) of the IC EGM signals, the WOI representing an entire cycle length for a single heartbeat;

calculating an activity signal based on a median filter and reference annotations;

calculating an activity threshold of the WOI using the activity signal;

calculating, using the activity threshold, a pattern of interest (POI), the POI encompassing at least a portion of the WOI, and corresponding to a specific portion of the WOI where an arrhythmia activation is exhibited;

storing a template POI representative of the arrhythmia activation, the template POI formed of a plurality of template channels and based upon the IC EGM signals within the WOI;

receiving subsequent electrical activity comprising IC EGM signals from the plurality of activity channels;

calculating signal correlations based on the template POI and the subsequent electrical activity;

calculating weights based on a maximum slope of the plurality of template channels,

generating a correlation score by applying the weights to the signal correlations; and

detecting the cardiac arrhythmia when the correlation score is above a threshold correlation score.

2. (Original) The method of claim 1, further comprising providing a visual indication corresponding to the area of the heart based on determining that the correlation score is above the threshold correlation score.

3. (Original) The method of claim 2, wherein the visual indication is at least one of a color, a pattern, and a marking.

4. (Previously Presented) The method of claim 1, wherein the reference annotations are either user provided reference annotations or predetermined reference annotations.

5. (Previously Presented) The method of claim 1, further comprising filtering the subsequent electrical activity using the median filter and a finite impulse response (FIR) filter.

6. (Original) The method of claim 5, wherein filtering the subsequent electrical activity removes baseline wander.

7. (Previously Presented) The method of claim 1, wherein the correlation score is a cumulative value.

8. (Original) The method of claim 1, further comprising defining a moving window based on the POI.

9. (Original) The method of claim 8, further comprising determining a plurality of correlation scores based on each shift of the moving window.

10. (Previously Presented) The method of claim 9, wherein the plurality of correlation scores are based on a maximum correlation score.

11. (Previously Presented) The method of claim 1, wherein the

correlation score is determined based on a subset of the subsequent electrical activity.

12. (Original) The method of claim 11, wherein the subset of the subsequent electrical activity is determined based on at least one of an atria dissociation and a noise threshold.

13. (Previously Presented) An apparatus for improving accuracy in detecting a cardiac arrhythmia in a patient, the apparatus comprising:

one or more catheters with respective one or more electrodes arranged for insertion into a heart of the patient for acquiring unipolar pattern intra-cardiac (IC) electrogram (EGM) signals from an area of the heart, from a plurality of activity channels corresponding to the one or more electrodes;

a memory; and,

one or more processors that are communicatively coupled to the one or more catheters and the memory, wherein the one or more processors are collectively configured to:

receive the IC EGM signals from the one or more catheters,

select a window of interest (WOI) of the IC EGM signals, the WOI representing an entire cycle length for a single heartbeat,

calculate an activity signal based on a median filter and reference annotations,

calculate an activity threshold of the WOI using the activity signal,

calculate, using the activity threshold, a pattern of interest (POI) of the IC EGM signals, the POI encompassing at least a portion of the WOI, and corresponding to a specific portion of the WOI where an arrhythmia activation is exhibited,

store a template POI representative of the cardiac arrhythmia in the memory, the template POI comprising a plurality of template channels based on the IC EGM signals within the WOI,

receive subsequent electrical activity comprising IC EGM signals from the plurality of activity channels,

calculate signal correlations based on the template POI and the subsequent electrical activity,

calculate weights based on a maximum slope of the plurality of template channels, channel;

generate a correlation score by applying the weights to the signal correlations; and

detect the cardiac arrhythmia when the correlation score is above a threshold correlation score.

14. (Original) The apparatus of claim 13, additionally comprising at least one filter to remove respiratory or other movement.

15. (Previously Presented) The apparatus of claim 14, additionally comprising a display screen arranged for displaying the subsequent electrical activity when the cardiac arrhythmia is detected.

16. (Previously Presented) The apparatus of claim 15, wherein the subsequent electrical activity having the correlation score exceeding the threshold is incorporated into a map of the heart appearing on the display screen, wherein areas of the heart exhibiting the cardiac arrhythmia are emphasized.

17. (Previously Presented) The apparatus of claim 13 wherein the one or more catheters comprises a probe disposed within a sheath.

18. (Previously Presented) The apparatus of claim 17, wherein the one or more catheters comprises at least one of a lasso catheter and a shaft-like catheter.

19. (Previously Presented) The apparatus of claim 13, wherein the one or more processors are further collectively configured to:

apply at least one filter arranged to the IC EGM signals corresponding to a cardiac condition prior to generating the template POI.

20. (Previously Presented) The apparatus of claim 13, wherein the one or more processors are further collectively configured to: apply the median filter and a finite impulse response (FIR) filter for filtering the subsequent electrical activity.

21. (Canceled)

22. (Previously Presented) The apparatus of claim 13, wherein the one or more processors are located within an operating console.

23. (Previously Presented) The apparatus of claim 13, wherein at least one of the one or more processors comprises a central processing unit and noise reduction circuitry.

24. (Previously Presented) The apparatus of claim 13, additionally comprising a magnetic tracking system for tracking the one or more catheters when inserted into the heart of the patient.