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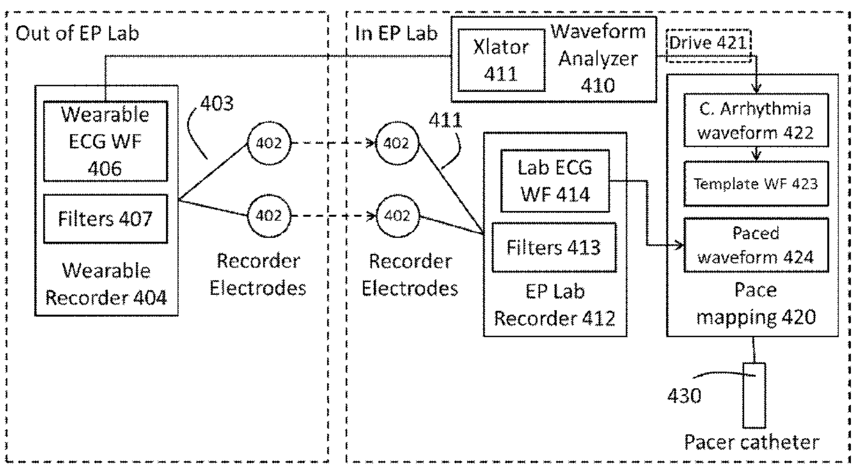
Fig 4A



(57) Abstract: A method for diagnosing arrhythmia focus in the heart of a patient comprising: affixing electrodes to a patient; providing a wearable monitor and connecting the electrodes to a wearable monitor; monitoring the patient by the wearable monitor for a monitoring period to produce a wearable ECG waveform; disconnecting the wearable monitor from the electrodes while leaving the electrodes affixed to the patient or marking the positions of these electrodes; providing a waveform analyzer running on a computer; importing the wearable ECG waveform into the waveform analyzer; defining a composite arrhythmia waveform from the wearable ECG waveform; providing an EP lab ECG and connecting the electrode stickers to the EP lab ECG or connecting new stickers to the marked positions; pacing the heart of the patient using a pacing catheter; and comparing the paced ECG waveform provided by the EP lab ECG with the composite arrhythmia waveform to diagnose the arrhythmia focus.

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SYSTEM AND METHOD FOR ARRHYTHMIA DIAGNOSIS

FIELD OF THE INVENTION

The present invention is of a system and method for arrhythmia diagnosis and in particular, such a system and method that significantly improves the arrhythmia focus diagnostic process.

BACKGROUND OF THE INVENTION

Pace mapping is frequently used in clinical practice as a means for diagnosing ventricular arrhythmia focus. The method of diagnosis generally includes the following steps: A patient is diagnosed with arrhythmia from an electrocardiogram (ECG) recorded using a recorder in a clinic, or from a wearable heart monitor/recorder worn for a specified period of time.

The patient is then invited to an electrophysiology lab (EP lab) or clinic where they are connected to a lab ECG. The output ECG is monitored till the previously diagnosed arrhythmia takes place again. If it does, then the ECG waveform observed during arrhythmia is used as a template and is mapped against an ECG waveform recorded while performing pace mapping using a pacer catheter to pace different areas of the heart. Pacer catheter may also be referred to as a roving or EP catheter. Current computerized comparison systems include, for example, the PaSo module in the CARTO mapping system manufactured by Biosense Webster® or other similar systems from different manufacturers. The pace mapping continues until the focus is diagnosed when the paced and template waveforms overlap to a high percentage (90-95%).

If the diagnosed arrhythmia does not occur spontaneously, attempts will be made to induce the arrhythmia using drugs such as catecholamine and/or cardiac stimulation. However, even with these measures, in as many as 20% of cases the diagnosed arrhythmia will not occur in the EP lab. There are several possible reasons why arrhythmia does not occur in the EP lab including: the intermittent nature of the arrhythmia; the limited time available for the procedure per patient; arrhythmia occurrence is only with particular triggers such as exercise, meals, smoking etc.; sedation of the patient during the procedure prevents arrhythmia; and difficulty with recognition of the “dominant” or "clinically relevant" arrhythmia type with small amounts of arrhythmia, multiple waveforms, and "artificial " arrhythmia caused by catheter movement within the heart. When arrhythmia does not occur or cannot be reproducibly induced, the procedure is abandoned.

The procedure as used today is now described in more detail. Reference is made to figures 1A and 1B which are respectively a schematic system diagram and a flow diagram showing a prior art system and method for diagnosis of the arrhythmia focus. As in figure 1B, in stage 1 electrode stickers102 are affixed to a patient. These are then connected to electrode cables 103 of a wearable recorder 104. Electrode cables may also be referred to as leads or wires. The wearable recorder 104 may also be referred to as a Holter, Holter monitor, Loop recorder, Event recorder or ambulatory electrocardiography device. Wearable recorders 104 currently used in the art typically have one to three cables 103.

Additionally, in stage 1, the recorder 104 records heart activity as an electrocardiograph (ECG) waveform 106 for an extended period of time typically varying between 24 hours and 4 weeks. Recorder 104 comprises filters 107 for filtering out noise and enhancing the output WF 106. The recording may either be constant or may be intermittent. Intermittent recording is generally patient-initiated wherein the patient usually presses a button or otherwise interacts with the recorder to indicate that a cardiac event is occurring and to start a recording period.

While wearing the recorder 104, the patient is outside the electrophysiology (EP) lab and goes about daily activities. EP Lab as used herein may refer to any clinic or hospital facilities where invasive arrhythmia diagnosis and therapy is performed. The output of recorder is herein referred to as wearable ECG waveform (WF) 106. ECG WF 106 is stored in recorder 104 on a recording medium, typically flash memory.

Once sufficient data has been gathered or after a defined period of analysis, electrodes 103 and electrode stickers 102 are removed from the patient and the recorder 104 is returned to the clinic for analysis. The ECG waveform 106 is then analyzed, optionally using ECG analysis software to detect arrhythmia patterns. In stage 2, following such analysis, the identified arrhythmia patterns are reviewed and a clinical diagnosis of arrhythmia is made. In some cases it will be determined that the arrhythmia requires further invasive diagnosis and potentially ablation in the EP lab.

Having made a clinical diagnosis of arrhythmia requiring invasive diagnosis, the patient will now return to the EP lab for diagnosis of the arrhythmia focus within the heart, with an intention to perform curative therapy by ablation (cauterization). In stage 3, electrode stickers 110 are affixed to the patient and electrode cables 111 of EP lab recorder 112 are attached to stickers 110. EP lab recorders 112 as used in the art typically use twelve stickers 110 and ten cables 111. EP lab recorder 112 produces EP lab electrocardiogram (ECG) waveform 114. Lab recorder 112 comprises filters 113 for filtering out noise and enhancing the output WF 114. Filters 113 are different to filters 107 and are configured differently. ECG waveform 114 is provided to pace mapping system 120. System 120 comprises a visual display (not shown) for viewing the lab ECG waveform 114 of recorder 112.

In stage 4, ECG waveform 114 is analyzed within system 120 for detection of an arrhythmia event as observed in the analysis of wearable ECG WF 106. As above, this event may not occur spontaneously and, at stage 5, if arrhythmia is not detected, attempts will be made at stage 6 to induce arrhythmia. These attempts will continue and stages 4, 5, and 6 will be repeated until arrhythmia as previously detected is observed. If the arrhythmia is not observed after significant efforts or if no further time is available, as in stage 6A the procedure will be abandoned.

In stage 7, if arrhythmia as previously detected in ECG WF 106 is observed in EP lab ECG waveform 114 on mapping system 120, the observed arrhythmia waveform is defined as a template waveform 122 for mapping. In stage 8, pace mapping is now performed by probing areas of the heart with pacer catheter 130. ECG waveform 114 is now used by system 120 to provide paced waveform 124 which changes as pacer catheter 130 is moved to different positions. Paced waveform 124 is compared to arrhythmia template waveform 122 until the arrhythmia focus is determined at stage 9. Curative therapy by ablation may then be performed.

As shown, the current method requires repeated arrhythmia diagnosis (first of the wearable WF 106 and then again with lab WF 114), is unduly complicated and unpredictable, particularly in stages 3-6, and more importantly, may result in a failure to diagnose the arrhythmia focus (stage 6A) resulting in medical danger to the patient as well as frustration of clinical staff. Current methods and systems also do not enable use of the wearable waveform 106 in the pace mapping system 120 as it is based on fewer leads, is not accurate enough, and relies on different filters. Further there is no method for importing waveform 106 into system 120.

Thus, there is an urgent need for a solution that streamlines the arrhythmia focus diagnostic process and that significantly increases the probability of diagnosing the arrhythmia focus.

SUMMARY OF THE INVENTION

The present invention overcomes the deficiencies of the background art by providing a system and method for improving the arrhythmia focus diagnostic process. The present invention aims to prevent the situation as described above with the prior art where arrhythmia that is diagnosed outside of the EP cannot be replicated inside the EP lab.

This is achieved by using the ECG waveform from a specially adapted wearable monitor and providing an analyzer computer or software module that can import this waveform, for use in defining an arrhythmia template for the patient based on an arrhythmia event or events that have occurred outside the EP lab while wearing the wearable monitor.

Further, once the arrhythmia template is defined it can be imported into the pace mapping system. Either the analyzer is adapted to export the template in a format that the pace mapping system can utilize (when the analyzer is a separate computer), or the analyzer is a software module that is part of the pace mapping system and this software module can provide the template to the mapping module of the pace mapping system.

To ensure that the ECG waveform from the wearable monitor and the waveform from the EP lab ECG monitor are compatible, the electrode sticker position must be the same. Therefore, either the electrode stickers are left in positon affixed to the patient or their position is marked so that stickers in the EP lab can be affixed to the same positions. Additionally, the same filters and settings used in producing the wearable ECG waveform must be used to produce the EP lab ECG waveform.

Once the template is imported, pace mapping can be performed using a catheter to probe points in the heart of the patient until a match with the template is found (based on the output of the output of the EP lab ECG monitor) and the arrhythmia focus is thus determined. Curative ablation or other therapy may then be performed.

Therefore by providing a system and method for importing the ECG with the arrhythmia detected outside the EP lab, the situation as described in the introduction, where the arrhythmia cannot be duplicated in the EP lab, is remedied. Further, the process is simplified as shown further below.

According to some embodiments of the present invention, a method for diagnosing arrhythmia focus in the heart of a patient comprises: affixing a plurality of electrode stickers to a patient; providing a wearable monitor and connecting the stickers to a wearable monitor; monitoring the patient by the wearable monitor for a monitoring period to produce a wearable ECG waveform; disconnecting the wearable monitor from the stickers while leaving the stickers affixed to the patient; providing a waveform analyzer running on a computer; defining an arrhythmia template waveform by the waveform analyzer from the wearable ECG waveform; providing an EP lab ECG recorder and connecting the stickers to the EP lab ECG recorder; pacing the heart of the patient using a pacing electrode; and comparing the paced ECG waveform provided by the EP lab ECG recorder with the template waveform to diagnose the arrhythmia focus.

Preferably the plurality of electrode stickers comprises up to ten stickers. Preferably the wearable monitor comprises a plurality of electrode cables and the cables are used for the connecting the stickers to the wearable monitor. Preferably the plurality of electrode cables comprises up to 12 electrode cables for recording up to a 12 channel ECG. Preferably the wearable ECG waveform is stored on the wearable monitor. Optionally the wearable ECG waveform is stored in a format selected from the group consisting of SCP-ECG, DICOM-ECG, and HL7 aECG.

Preferably the ECG waveform comprises up to twelve channels. Preferably the wearable monitor filters the signal received from the electrode stickers using filters. Optionally, the filters are selected from the group consisting of low pass, high pass, band pass, notch filters and a combination of the above and the filters have settings that can be configured. Optionally the monitoring period is at least 72 hours.

Preferably the method further comprises importing the wearable ECG waveform into the analyzer and wherein the importing comprises connection of one of the recorder or recorder media to the analyzer by at least one of wireless or wired connection. Preferably the analyzer is adapted to process the wearable ECG waveform. Preferably, the recorder stores the wearable ECG WF in a storage format that can be processed by the analyzer. Optionally the analyzer comprises a translation module and translates the wearable ECG waveform into a format that it can process using the translation module. Preferably the comparing of the paced ECG waveform with the template waveform is performed by a pace mapping system running on a computer. Optionally the pace mapping system and the analyzer run on the same computer. Preferably the method further comprises importing the template waveform into the pace mapping system and wherein the method of the importing the template waveform is selected from the group consisting of: adapting the template waveform to a file format that can be used by the pace mapping system and importing the file into the pace mapping system; connecting the analyzer to the pace mapping system via the ECG input port of the pace mapping system and mimicking by the analyzer the signal that an ECG device would provide to the port; adapting the template waveform to an image file format that can be used by the pace mapping system and importing the file into the pace mapping system; and a combination of the above.

Preferably the template waveform is stored in the internal storage of the pace mapping system. preferably the EP lab recorder comprises a plurality of electrode cables and the cables are used for the connecting the stickers to the EP lab recorder. Preferably the EP lab recorder comprises EP lab recorder filters and wherein the EP lab recorder filters are the same as the filters and are configured with the same filter settings. Preferably the EP lab recorder records up to 12 channels. Preferably the defining an arrhythmia template waveform by the waveform analyzer requires interaction with the analyzer by an operator.

According to some embodiments of the present invention, a system for diagnosing arrhythmia focus in the heart of a patient comprises: electrode stickers for affixing to a patient; a wearable ECG monitor with cables for connecting to the stickers and adapted to record a wearable ECG waveform; a waveform analyzer running on a computer adapted for defining an arrhythmia template waveform from the wearable ECG waveform; an EP lab ECG recorder with cables for connecting to the stickers and adapted to record a pacing ECG waveform; and a pace mapping system running on a computer comprising a pacing electrode for pacing the heart of the patient; wherein the pacing ECG waveform is compared with the template waveform to diagnose the arrhythmia focus.

Preferably the wearable monitor comprises recording media and wearable ECG waveform is stored on the recording media. Optionally the wearable ECG waveform is stored in a format selected from the group consisting of SCP-ECG, DICOM-ECG, and HL7 aECG. Preferably the wearable ECG waveform comprises up to twelve channels. Preferably the wearable monitor comprises filters for filtering the signal received from the electrode stickers. Optionally the filters are selected from the group consisting of low pass, high pass, band pass, notch filters and a combination of the above and have setting that can be configured.

Preferably the analyzer comprises at least one of a wireless or wired connection for connecting the wearable recorder or recorder media to the analyzer. Optionally the analyzer comprises a translation module for translating the wearable ECG waveform into a format that it can process. Optionally the pace mapping system and the analyzer run on the same computer. Preferably the EP lab recorder comprises EP lab recorder filters and wherein the EP lab recorder filters are the same as the filters and are configured with the same filter settings. Preferably the EP lab recorder records up to 12 channels.

According to some further embodiments of the present invention, a method for diagnosing arrhythmia focus in the heart of a patient comprises: affixing a plurality of electrode stickers to a patient; providing a wearable monitor and connecting the stickers to a wearable monitor; monitoring the patient by the wearable monitor for a monitoring period to produce a wearable ECG waveform; disconnecting the wearable monitor from the stickers and marking the positions of before removing the stickers from the patient; providing a waveform analyzer running on a computer; importing the wearable ECG waveform into the waveform analyzer; defining an arrhythmia template waveform from the wearable ECG waveform; affixing a plurality of electrode stickers to a patient in the positions previously marked on the patient; providing an EP lab ECG and connecting the stickers to the EP lab ECG; pacing the heart of the patient using a pacing electrode; and comparing the paced ECG waveform provided by the EP lab ECG with the template waveform to diagnose the arrhythmia focus.

According to further embodiments of the present invention, a system for diagnosing arrhythmia focus in the heart of a patient comprises: affixing a plurality of electrode stickers to a patient; providing a wearable monitor and connecting the stickers to a wearable monitor; monitoring the patient by the wearable monitor for a monitoring period to produce a wearable ECG waveform; providing a waveform analyzer running on a computer; importing the wearable ECG waveform into the waveform analyzer; defining an arrhythmia template waveform from the wearable ECG waveform; pacing the heart of the patient using a pacing electrode; and comparing the paced ECG waveform provided by the wearable monitor with the template waveform to diagnose the arrhythmia focus.

According to further embodiments of the present invention a method for diagnosing arrhythmia focus in the heart of a patient comprises: affixing a plurality of electrode stickers to a patient; providing a wearable monitor and connecting said stickers to a wearable monitor; monitoring the patient by said wearable monitor for a monitoring period to produce a wearable ECG waveform; disconnecting said wearable monitor from said stickers while performing at least one of: leaving said stickers affixed to the patient; or marking the positions of said stickers before removing said stickers; defining a composite arrhythmia waveform from said wearable ECG waveform; providing an EP lab ECG recorder and performing at least one of: connecting said stickers to said EP lab ECG recorder; or connecting a second set of stickers to said EP lab ECG recorder wherein said second set of stickers are positioned on the marked positions; pacing the heart of the patient using a pacing electrode; and comparing the paced ECG waveform provided by said EP lab ECG recorder with said composite arrhythmia waveform to diagnose the arrhythmia focus.

Preferably the method further comprises providing a waveform analyzer and wherein said composite arrhythmia waveform is defined using said analyzer. Preferably said composite arrhythmia waveform comprises at least one arrhythmia waveform detected in wearable ECG waveform. Preferably detecting said at least one arrhythmia waveform comprises at least one of: said analyzer automatically detecting said at least one arrhythmia WF; an operator of said analyzer detecting said at least one arrhythmia WF; or a combination of the above.

Preferably said plurality of electrode stickers comprises up to ten stickers. Preferably said plurality of electrode stickers comprise a die for marking the positons of said stickers on a patient. Preferably the wearable monitor comprises a plurality of electrode cables and said cables are used for said connecting said stickers to said wearable monitor. Preferably said plurality of electrode cables comprises 12 electrode cables. Preferably said wearable ECG waveform is stored on said wearable monitor. Preferably said wearable ECG waveform is stored in a format selected from the group consisting of SCP-ECG, DICOM-ECG, and HL7 aECG. Preferably said wearable ECG waveform comprises up to twelve channels. Preferably said wearable monitor filters the signal received from said electrode stickers using filters.

Preferably said filters are selected from the group consisting of low pass, high pass, band pass, notch filters and a combination of the above. Preferably the monitoring period is at least 72 hours. Preferably said importing said wearable ECG waveform into said analyzer comprises connection of one of said recorder or recorder media to said analyzer by at least one of wireless or wired connection. Preferably said analyzer is adapted to process said wearable ECG waveform. Preferably said recorder stores said wearable ECG WF in a storage format that can be processed by said analyzer. Preferably said analyzer comprises a translation module and translates said wearable ECG waveform into a format that it can process using said translation module.

Preferably said comparing of said paced ECG waveform with said composite waveform is performed by a pace mapping system running on a computer. Preferably said pace mapping system and said analyzer run on the same computer. Preferably the method further comprises: importing said composite waveform into said pace mapping system. Preferably said composite waveform is transferred to a storage device and said storage device is connected to said pace mapping system for importing said composite waveform from said storage device into said pace mapping system. Preferably the method of said importing said composite waveform is selected from the group consisting of: adapting said composite waveform to a file format that can be used by said pace mapping system and importing said file into said pace mapping system; connecting said analyzer to said pace mapping system via the ECG input port of said pace mapping system and mimicking by said analyzer the signal that an ECG device would provide to said port; adapting said composite waveform to an image file format that can be used by said pace mapping system and importing said file into said pace mapping system; and a combination of the above.

Preferably said composite waveform is stored in the internal storage of said pace mapping system. Preferably the EP lab recorder comprises a plurality of electrode cables and said cables are used for said connecting said stickers to said EP lab recorder. Preferably said EP lab recorder comprises EP lab recorder filters and wherein said EP lab recorder filters are the same as said filters and are configured with the same filter settings. Preferably said EP lab recorder records up to 12 channels. Preferably said defining a composite arrhythmia waveform by said waveform analyzer requires interaction with said analyzer by an operator.

Unless otherwise defined, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this invention belongs. The materials, methods, and examples provided herein are illustrative only and not intended to be limiting.

Implementation of the method and system of the present invention involves performing or completing certain selected tasks or steps manually, automatically, or a combination thereof. Moreover, according to actual instrumentation and equipment of preferred embodiments of the method and system of the present invention, several selected steps could be implemented by hardware or by software on any operating system of any firmware or a combination thereof. For example, as hardware, selected steps of the invention could be implemented as a chip or a circuit. As software, selected steps of the invention could be implemented as a plurality of software instructions being executed by a computer using any suitable operating system. In any case, selected steps of the method and system of the invention could be described as being performed by a data processor, such as a computing platform for executing a plurality of instructions.

Although the present invention is described with regard to a “computing device”, a "computer", or “device”, or “mobile device” on a "computer network" or simply “network”, it should be noted that optionally any device featuring a data processor and the ability to execute one or more instructions may be described as a computer or one of the interchangeable terms listed above, including but not limited to any type of personal computer (PC), a server, a cellular telephone, an IP telephone, a smartphone, or a PDA (personal digital assistant). Any two or more of such devices in communication with each other may optionally comprise a "network".

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will now be described in connection with certain preferred embodiments with reference to the following illustrative figures so that it may be more fully understood. With specific reference now to the figures in detail, it is stressed that the particulars shown are by way of example and for purposes of illustrative discussion of the preferred embodiments of the present invention only and are presented in the cause of providing what is believed to be the most useful and readily understood description of the principles and conceptual aspects of the invention. In this regard, no attempt is made to show structural details of the invention in more detail than is necessary for a fundamental understanding of the invention, the description taken with the drawings making apparent to those skilled in the art how the several forms of the invention may be embodied in practice.

In the drawings:

FIGS. 1A and 1B are respectively a schematic system diagram and a flow diagram showing a prior art system and method for diagnosis of the arrhythmia focus;

FIGS. 2A-2C, are schematic system diagrams and a flow diagram showing system and method for diagnosis of arrhythmia focus according to some embodiments of the present invention; and

FIGS. 3A-3C which are exemplary ECG waveforms according to some embodiments of the present invention.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

In the detailed description, numerous specific details are set forth in order to provide a thorough understanding of the invention. However, it will be understood by those skilled in the art that these are specific embodiments and that the present invention may be practiced also in different ways that embody the characterizing features of the invention as described and claimed herein.

The present invention will be more fully understood from the following detailed description of the preferred embodiments thereof, taken together with the drawings. Reference is now made to Figures 2A-2C, which are schematic system diagrams and a flow diagram showing a system and method for diagnosis of arrhythmia focus according to some embodiments of the present invention.

As in figure 2C, in stage 1 electrode stickers 202 are affixed to a patient. Most preferably ten stickers 202 are affixed to the patient. The sticker placement is as known in the art for 12-lead ECG recording. In stage 2, twelve electrode cables 203 are connected to the stickers 202. Electrode cables 203 are connected to a wearable recorder 204 worn by the patient. . Wearable recorder 204 is adapted for 12-lead

ECG recording. Recorder 204 then records heart activity as an ECG waveform 206 for an extended period of time typically varying between 24 hours and 72 hours. During this time the patient is outside the EP lab and goes about daily activities.

The output of recorder 204 is herein referred to as wearable ECG waveform (WF) 206. ECG WF 206 preferably comprises 12 channels. Optionally, any number of channels may be recorded that provides sufficient data for arrhythmia diagnosis as described herein. ECG WF 206 is stored in recorder 204 on a recording medium. A non-limiting example of a recording medium is flash memory, but other forms of storage may be used. Non-limiting examples of ECG storage formats include SCP-ECG, DICOM-ECG, and HL7 aECG, but other formats may be used. Recorder 204 uses filters 207 to enhance the signal received from electrode stickers 202 and cables 203. Non limiting examples of filters 207 include low pass, high pass, band pass, and notch filters or a combination of these. Filters 207 are configurable and comprise settings that can be duplicated in the same filters used in other ECG recorders.

In stage 3, once sufficient ECG waveform data has been gathered or after completion of the monitoring period, electrode stickers 202 remain affixed to the patient and electrode cables 203 are disconnected from stickers 202 and the recorder 204 is returned to the EP lab for analysis. Analysis may be optionally be performed in a clinic or lab associated with EP lab. Alternatively, stickers 202 are removed and their exact positioning on the patient is marked, such as with a non-limiting example of a marker pen. Alternatively and preferably stickers 202 are provided with a dye or ink which marks the skin of the patient such that a mark indicating the position of sticker 202 is left on the patient from the dye after sticker 202 is removed.

In stage 4, ECG waveform 206 is imported from recorder 204 into waveform analyzer 210. The importing of ECG WF 206 is performed by wired or wireless connection of recorder 204 to analyzer 210 followed by interaction by an operator with analyzer 210 to initiate the importing. Alternatively the storage media is extracted from recorder 204 and inserted into a storage media reader connected wired or wirelessly to analyzer 210. Alternatively, the importing comprises exporting from the recorder 204 by interaction with the recorder 204. Analyzer 210 is adapted to process the ECG WF 206 in the ECG storage format used by recorder 204. Alternatively, recorder 204 stores ECG WF 206 in an ECG storage format that can be processed by analyzer 210. Alternatively, analyzer 210 translates the ECG WF 206

ECG format provided by recorder 204 into a format that it can process using a translation module 211 (shown in figure 2A as xlator 211). Processing includes manipulation and analysis as described below.

In the embodiment of figure 2A, waveform analyzer 210 runs on a standalone computer. Alternatively, in the embodiment of figure 2B, analyzer 210 is a software module running on the same computational hardware as pace mapping system 220 described below.

Analyzer 210 preferably comprises a screen (not shown) and interaction means such as a keyboard and mouse (not shown) for viewing and manipulating wearable ECG waveform 206.

ECG waveform 206 is then analyzed optionally using ECG analysis software to detect arrhythmia waveform patterns. The operator/practitioner now interacts with analyzer 210 to define at least one of the identified waveforms as an arrhythmia template waveform 222 for later use during pace mapping of arrhythmia focus. Figure 3A provides an illustration of an identified arrhythmia template waveform ready to be exported from analyzer 210.

In stage 5, for the embodiment of figure 2A, the arrhythmia template waveform 222 is exported from analyzer 210 using wired or wireless means into pace mapping system 220. The export format is preferably adapted to suit the mapping system 220 used. Optionally, analyzer 210 connects to system 220 via the ECG input port (not shown) of system 220 and mimics the signal that an ECG device would provide such that system 220 displays the received template waveform 222 which can then be saved in system 220 as the template waveform 222. Alternatively, template waveform 222 may be saved and exported by analyzer 210 as any standard image file type not limited to jpeg, BMP, PNG, or similar for use by system 220.

Alternatively, as in the embodiment of figure 2B where analyzer 210 is a software module of system 220, the template 222 is stored in the internal storage of system 220 for use during the pace mapping. Alternatively, the template is stored in a separate file store (not shown).

The patient will now return to the EP lab for diagnosis (mapping) of the arrhythmia focus within the heart. Electrode stickers 202 are still affixed to the patient from stage 1. Alternatively, new stickers 202 are affixed at exactly the previously marked positions. In stage 6 electrode stickers 202 are connected to electrode cables 211 of EP lab recorder 212. EP Lab recorder 212 refers to an ECG recorder preferably for 12 channel recording. EP lab recorder 212 comprises filters 213 which are the same as filters 207 and are configured with the same filter settings that were used by filters 207 on wearable recorder 204 for recording wearable ECG WF 206. Optionally, translation module 211 also comprises a filter adaptor module (not shown) for adjusting the ECG WF 206 to match lab ECG WF 214 based on the filters 213 used in EP lab recorder 212. Optionally, wearable recorder 204 is used as EP lab recorder 212, and electrodes 202 optionally remain connected to recorder 204 or are reconnected in the EP lab.

EP lab recorder 212 produces EP lab ECG waveform 214. ECG waveform 214 is provided to pace mapping system 220. System 220 comprises a visual display (not shown) for viewing the lab ECG waveform 214 of recorder 212. The use of the same sticker positions, number of leads, channels and filters ensures that wearable ECG WF 206 and lab ECG WF 214 are compatible and that template waveform 222 can be used as a basis for comparison with paced waveform 224 as described below.

In stage 7, pacing is now performed by probing areas of the heart with pacer catheter 230. ECG waveform 214 is now used by system 220 to provide and display paced waveform 224 which changes as pacer catheter 230 is moved to different positions in the heart. Paced waveform 224 is compared to arrhythmia template waveform 222, defined in stage 4 and exported in stage 5, until the waveforms sufficiently match and arrhythmia focus is diagnosed at stage 8. Preferably, the comparison is performed by system 220 which provides a numeric percentage match indication on a screen (not shown), such that the medical practitioner can determine the arrhythmia focus based on a high percentage match indication, preferably above 95%. Preferably comparison comprises display of the template and paced waveforms overlapped on the screen (not shown) as illustrated in figures 3B and 3C. Following diagnosis, curative therapy by ablation or other means known in the art may then be performed.

Reference is now made to figures 3A-3C which are exemplary ECG waveforms according to some embodiments of the present invention. Figure 3A shows a twelve lead ECG waveform with 12 channels. As shown, an arrhythmia event is defined by definition lines 312. The arrhythmia event as defined by lines 312 is used as an arrhythmia template waveform such as waveform 222 described above.

Figure 3B shows visual comparison of the template waveform of figure 3A with a paced ECG waveform such as waveform 224 described above. Comparison is performed by superimposing template channels 310 on top of paced waveform channels 330. As in figure 3A, the arrhythmia event area is defined by lines 312. In the exemplary comparison of figure 3B, the template and paced waveforms do not match to a sufficient percentage since the pacer catheter is not close enough to the arrhythmia focus in the heart.

In the exemplary comparison of figure 3C the template and paced waveforms match well to a high percentage since the pacer catheter is close to the arrhythmia focus in the heart and a successful diagnosis of the arrhythmia focus is accomplished.

Reference is now made to Figures 4A-4C, which are schematic system diagrams and a flow diagram showing a system and method for diagnosis of arrhythmia focus according to some embodiments of the present invention.

As in figure 4C, in stage 1 electrode stickers 402 are affixed to a patient. Most preferably ten stickers 402 are affixed to the patient. The sticker placement is as known in the art for 12-lead ECG recording. In stage 2, twelve electrode cables 403 are connected to the stickers 402. Electrode cables 403 are connected to a wearable recorder 404 worn by the patient. . Wearable recorder 404 is adapted for 12-lead ECG recording. Recorder 404 then records heart activity as an ECG waveform 406 for an extended period of time typically varying between 24 hours and 72 hours as known in the art. During this time the patient is outside the EP lab and goes about daily activities.

The output of recorder 404 is herein referred to as wearable ECG waveform (WF) 406. ECG WF 406 preferably comprises 12 channels. Optionally, any number of channels may be recorded that provides sufficient data for arrhythmia diagnosis as described herein. ECG WF 406 is stored in recorder 404 on a recording medium. A non-limiting example of a recording medium is flash memory, but other forms of storage may be used. Non-limiting examples of ECG storage formats include SCP-ECG, DICOM-ECG, and HL7 aECG, but other formats may be used. Recorder 404 uses filters 407 to enhance the signal received from electrode stickers 402 and cables 403. Non limiting examples of filters 407 include low pass, high pass, band pass, and notch filters or a combination of these. Filters 407 are configurable and comprise settings that can be duplicated in the same filters used in other ECG recorders.

In stage 3, once sufficient ECG waveform data has been gathered or after completion of the monitoring period, electrode stickers 402 remain affixed to the patient and electrode cables 403 are disconnected from stickers 402 and the recorder 404 is returned to the EP lab for analysis. Analysis may be optionally be performed in a clinic or lab associated with EP lab. Alternatively, stickers 402 are removed and their exact positioning on the patient is marked, such as with a non-limiting example of a marker pen. Alternatively and preferably stickers 402 are provided with a dye or ink which marks the skin of the patient when sticker 402 is applied or removed such that a mark indicating the position of sticker 402 is left on the patient from the dye after sticker 402 is removed.

In stage 4, ECG waveform 406 is imported from recorder 404 into waveform analyzer 410. The importing of ECG WF 406 is performed by wired or wireless connection of recorder 404 to analyzer 410 followed by interaction by an operator with analyzer 410 to initiate the importing. Alternatively the storage media is extracted from recorder 404 and inserted into a storage media reader connected wired or wirelessly to analyzer 410. Alternatively, the importing comprises exporting from the recorder 404 by interaction with the recorder 404. Analyzer 410 is adapted to process the ECG WF 406 in the ECG storage format used by recorder 404. Alternatively, recorder 404 stores ECG WF 406 in an ECG storage format that can be processed by analyzer 410. Alternatively, analyzer 410 translates the ECG WF 406 ECG format provided by recorder 404 into a format that it can process using a translation module 411 (shown in figure 4A as xlator 411). Processing includes manipulation and analysis as described below.

In the embodiment of figure 4A, waveform analyzer 410 runs on a standalone computer. Alternatively, in the embodiment of figure 4B, analyzer 410 is a software module running on the same computational hardware as pace mapping system 420 described below.

Analyzer 410 preferably comprises a screen (not shown) and interaction means such as a keyboard and mouse (not shown) for viewing and manipulating wearable ECG waveform 406.

ECG waveform 406 is then analyzed to detect arrhythmia waveform patterns. The operator/practitioner now interacts with analyzer 410 to identify waveforms indicating arrhythmia. The arrhythmia waveform portions (such as 422-A and 422-B) are preferably automatically identified by arrhythmia waveform detection software. Alternatively arrhythmia waveform portions are identified by waveform detection software and the identified waveform portions are confirmed by the operator of analyzer 410. Alternatively the operator of analyzer 410 identifies arrhythmia waveform portions. Preferably arrhythmia waveform portions are identified using a combination of the above. Preferably the patient has indicated arrhythmia episodes while wearing Wearable Recorder 404 and operator or software use these indications to locate arrhythmia waveform portions using analyzer 410.

Arrhythmia waveform portions are indicated by operator or software on analyzer 410 based on the start and stop times of the waveform of interest on the recorded timeline. Figure 4D shows a non-limiting exemplary wearable WF 406 as viewed in analyzer 410. Arrhythmia waveforms 422-A and 422-B have been indicated by operator or software in analyzer 410. Although two portions (422-A and 422-B) are described herein, this is for the sake of simplicity and preferably any number of arrhythmia waveform portions may be indicated and extracted from waveform 406. Therefore at the end of stage 4, arrhythmia waveform portions will have been identified.

In stage 5, for the embodiment of figure 4A, the arrhythmia waveforms 422 are exported from analyzer 410. The waveforms portions, as indicated by the timestamp data from stage 4, are each extracted and then preferably concatenated together to form a composite arrhythmia waveform 422. Figure 4E shows an exemplary, non-limiting composite arrhythmia waveform 422 comprising indicated waveforms 422-A and 422-B which were extracted from ECG WF 406.

Composite arrhythmia waveform 422 is now exported from analyzer 410 and imported using wired or wireless means into pace mapping system 420. Preferably waveform 422 is exported from analyzer 410 onto removable storage media 421 such as but not limited to a USB storage drive. Preferably drive 421 is adapted for one-time usage to prevent mixing up of patient arrhythmia waveforms 422. Preferably drive 421 comprises encryption mechanisms to prevent patient data stored on drive 421 from being read by systems aside from analyzer 410 and pace mapping system 420. Drive 421 is then connected to mapping system 420 for importing of arrhythmia WF 422 into system 420.

Optionally wearable ECG 406 is in a digital format. Optionally wearable ECG 406 is in an analog format. Optionally composite arrhythmia waveforms 422 are in analog format. Optionally composite arrhythmia waveforms 422 are in digital format. Where wearable WF 406 and composite WF 422 are in different formats (analog or digital), analyzer 410 converts between these formats.

The format of arrhythmia WF 422 is preferably adapted to suit the mapping system 420 used. Optionally, analyzer 410 connects to system 420 via the ECG input port (not shown) of system 420 and mimics the signal that an ECG device would provide to "play back" WF 422 such that system 420 imports, stores and displays constructed arrhythmia waveform 422. Optionally drive 421 is plugged into ECG input port (not shown) of system 420 and mimics the signal that an ECG device would provide to "play back" WF 422 such that system 420 imports, stores and displays constructed arrhythmia waveform 422. Alternatively drive 421 or analyzer 410 are plugged into a data input port (not shown) of system 420 such that system 420 imports, stores and displays constructed arrhythmia waveform 422.

Alternatively, waveform 422 may be saved and exported by analyzer 410 as any standard image file type not limited to jpeg, BMP, PNG, or similar for use by system 420.

Alternatively, as in the embodiment of figure 4B where analyzer 410 is a software module of system 420, the arrhythmia waveform 422 is stored in the internal storage of system 420 for use during the pace mapping. Alternatively, arrhythmia WF 422 is stored in a separate file store (not shown).

In the final part of stage 5, arrhythmia WF 422 is analyzed using pace mapping system 420 to create a template waveform 423 for comparison to Lab ECG WF 414.

In stage 6 the patient will return to the EP lab for diagnosis (mapping) of the arrhythmia focus within the heart. Electrode stickers 402 are still affixed to the patient from stage 1. Alternatively, new stickers 402 are affixed at exactly the previously marked positions. In stage 6 electrode stickers 402 are connected to electrode cables 411 of EP lab recorder 412. EP Lab recorder 412 refers to an ECG recorder preferably for 12 channel recording. EP lab recorder 412 comprises filters 413 which are the same as filters 407 and are configured with the same filter settings that were used by filters 407 on wearable recorder 404 for recording wearable ECG

WF 406. Optionally, translation module 411 also comprises a filter adaptor module (not shown) for adjusting the ECG WF 406 to match lab ECG WF 414 based on the filters 413 used in EP lab recorder 412. Optionally, wearable recorder 404 is used as EP lab recorder 412, and electrodes 402 optionally remain connected to recorder 404 or are reconnected in the EP lab.

EP lab recorder 412 produces EP lab ECG waveform 414. ECG waveform 414 is provided to pace mapping system 420. System 420 comprises a visual display (not shown) for viewing the lab ECG waveform 414 of recorder 412. The use of the same sticker positions, number of leads, channels and filters ensures that wearable ECG WF 406 and lab ECG WF 414 are compatible and that template waveform 423 extracted from arrhythmia WF 422 can be used as a basis for comparison with paced waveform 424 as described below.

In stage 7, pacing is now performed by probing areas of the heart with pacer catheter 430. ECG waveform 414 is now used by system 420 to provide and display paced waveform 424 which changes as pacer catheter 430 is moved to different positions in the heart. Paced waveform 424 is compared to the template WF 423 derived from arrhythmia waveform 422 until the waveforms sufficiently match and arrhythmia focus is diagnosed at stage 8. Preferably, the comparison is performed by system 420 which provides a numeric percentage match indication on a screen (not shown), such that the medical practitioner can determine the arrhythmia focus based on a high percentage match indication, preferably above 95%. Preferably comparison comprises display of the template and paced waveforms overlapped on the screen (not shown) as illustrated in figures 3B and 3C. Following diagnosis, curative therapy by ablation or other means known in the art may then be performed.

It is to be understood that the invention is not limited in its application to the details set forth in the description contained herein or illustrated in the drawings. The invention is capable of other embodiments and of being practiced and carried out in various ways. Those skilled in the art will readily appreciate that various modifications and changes can be applied to the embodiments of the invention as hereinbefore described without departing from its scope, defined in and by the appended claims.

CLAIMS:

1. A method for diagnosing arrhythmia focus in the heart of a patient comprising:
    a. affixing a plurality of electrode stickers to a patient;
    b. providing a wearable monitor and connecting said stickers to a wearable monitor;
    c. monitoring the patient by said wearable monitor for a monitoring period to produce a wearable ECG waveform;
    d. disconnecting said wearable monitor from said stickers while leaving said stickers affixed to the patient;
    e. providing a waveform analyzer running on a computer;
    f. defining an arrhythmia template waveform by said waveform analyzer from said wearable ECG waveform;
    g. providing an EP lab ECG recorder and connecting said stickers to said EP lab ECG recorder;
    h. pacing the heart of the patient using a pacing electrode; and
    i. comparing the paced ECG waveform provided by said EP lab ECG recorder with said template waveform to diagnose the arrhythmia focus.
2. The method of claim 1 wherein said plurality of electrode stickers comprises up to ten stickers.
3. The method of claim 1 wherein wearable monitor comprises a plurality of electrode cables and said cables are used for said connecting said stickers to said wearable monitor.
4. The method of claim 3 wherein said plurality of electrode cables comprises 12 electrode cables.
5. The method of claim 1 wherein said wearable ECG waveform is stored on said wearable monitor.
6. The method of claim 1 wherein said wearable ECG waveform is stored in a format selected from the group consisting of SCP-ECG, DICOM-ECG, and HL7 aECG.
7. The method of claim 1 wherein said wearable ECG waveform comprises

up to twelve channels.

8. The method of claim 1 wherein said wearable monitor filters the signal received from said electrode stickers using filters.
9. The method of claim 8 wherein said filters are selected from the group consisting of low pass, high pass, band pass, notch filters and a combination of the above.
10. The method of claim 1 wherein the monitoring period is at least 72 hours.
11. The method of claim 1 further comprising importing said wearable ECG waveform into said analyzer and wherein said importing comprises connection of one of said recorder or recorder media to said analyzer by at least one of wireless or wired connection.
12. The method of claim 1 wherein said analyzer is adapted to process said wearable ECG waveform.
13. The method of claim 1 wherein said recorder stores said wearable ECG WF in a storage format that can be processed by said analyzer.
14. The method of claim 1 wherein said analyzer comprises a translation module and translates said wearable ECG waveform into a format that it can process using said translation module.
15. The method of claim 1 wherein said comparing of said paced ECG waveform with said template waveform is performed by a pace mapping system running on a computer.
16. The method of claim 15 wherein said pace mapping system and said analyzer run on the same computer.
17. The method of claim 15 further comprising: importing said template waveform into said pace mapping system.
18. The method of claim 17 wherein the method of said importing said template waveform is selected from the group consisting of:
    a. adapting said template waveform to a file format that can be used by said pace mapping system and importing said file into said pace mapping system;
    b. connecting said analyzer to said pace mapping system via the ECG input port of said pace mapping system and mimicking by said analyzer the signal that an ECG device would provide to said port;

c. adapting said template waveform to an image file format that can be used by said pace mapping system and importing said file into said pace mapping system; and

d. a combination of the above.

19. The method of claim 16 wherein said template waveform is stored in the internal storage of said pace mapping system.

20. The method of claim 1 wherein EP lab recorder comprises a plurality of electrode cables and said cables are used for said connecting said stickers to said EP lab recorder.

21. The method of claim 1 wherein said EP lab recorder comprises EP lab recorder filters and wherein said EP lab recorder filters are the same as said filters and are configured with the same filter settings.

22. The method of claim 1 wherein said EP lab recorder records up to 12 channels.

23. The method of claim 1 wherein said defining an arrhythmia template waveform by said waveform analyzer requires interaction with said analyzer by an operator.

24. A system for diagnosing arrhythmia focus in the heart of a patient comprising:

a. electrode stickers for affixing to a patient;

b. a wearable ECG monitor with cables for connecting to said stickers and adapted to record a wearable ECG waveform;

c. a waveform analyzer running on a computer adapted for defining an arrhythmia template waveform from said wearable ECG waveform;

d. an EP lab ECG recorder with cables for connecting to said stickers and adapted to record a pacing ECG waveform; and

e. a pace mapping system running on a computer comprising a pacing electrode for pacing the heart of the patient;

wherein said pacing ECG waveform is compared with said template waveform to diagnose the arrhythmia focus.

25. The system of claim 24 wherein said wearable monitor comprises recording media and wearable ECG waveform is stored on said recording

media.

26. The system of claim 25 wherein said wearable ECG waveform is stored in a format selected from the group consisting of SCP-ECG, DICOM-ECG, and HL7 aECG.
27. The system of claim 24 wherein said wearable ECG waveform comprises up to twelve channels.
28. The system of claim 24 wherein said wearable monitor comprises filters for filtering the signal received from said electrode stickers.
29. The system of claim 28 wherein said filters are selected from the group consisting of low pass, high pass, band pass, notch filters and a combination of the above.
30. The system of claim 25 wherein said analyzer comprises at least one of a wireless or wired connection for connecting said wearable recorder or recorder media to said analyzer.
31. The system of claim 24 wherein said analyzer comprises a translation module for translating said wearable ECG waveform into a format that it can process.
32. The system of claim 24 wherein said pace mapping system and said analyzer run on the same computer.
33. The system of claim 29 wherein said EP lab recorder comprises EP lab recorder filters and wherein said EP lab recorder filters are the same as said filters and are configured with the same filter settings.
34. The system of claim 24 wherein said EP lab recorder records up to 12 channels.
35. A method for diagnosing arrhythmia focus in the heart of a patient comprising:
    a. affixing a plurality of electrode stickers to a patient;
    b. providing a wearable monitor and connecting said stickers to a wearable monitor;
    c. monitoring the patient by said wearable monitor for a monitoring period to produce a wearable ECG waveform;
    d. disconnecting said wearable monitor from said stickers and marking the positions of said stickers before removing said stickers

from the patient;

e. providing a waveform analyzer running on a computer;

f. importing said wearable ECG waveform into said waveform analyzer;

g. defining a composite arrhythmia waveform from said wearable ECG waveform;

h. affixing a plurality of electrode stickers to a patient in the positions previously marked on the patient;

i. providing an EP lab ECG and connecting said stickers to said EP lab ECG;

j. pacing the heart of the patient using a pacing electrode; and

k. comparing the paced ECG waveform provided by said EP lab ECG with said composite arrhythmia waveform to diagnose the arrhythmia focus.

36. The method of claim 35 wherein said electrode stickers comprise a die for marking the positions of said stickers on the patient.

37. A method for diagnosing arrhythmia focus in the heart of a patient comprising:

a. affixing a plurality of electrode stickers to a patient;

b. providing a wearable monitor and connecting said stickers to a wearable monitor;

c. monitoring the patient by said wearable monitor for a monitoring period to produce a wearable ECG waveform;

d. providing a waveform analyzer running on a computer;

e. importing said wearable ECG waveform into said waveform analyzer;

f. defining an arrhythmia template waveform from said wearable ECG waveform;

g. pacing the heart of the patient using a pacing electrode; and

h. comparing the paced ECG waveform provided by said wearable monitor with said template waveform to diagnose the arrhythmia focus.

38. A method for diagnosing arrhythmia focus in the heart of a patient comprising:
    a. affixing a plurality of electrode stickers to a patient;
    b. providing a wearable monitor and connecting said stickers to a wearable monitor;
    c. monitoring the patient by said wearable monitor for a monitoring period to produce a wearable ECG waveform;
    d. disconnecting said wearable monitor from said stickers while performing at least one of:
        i. leaving said stickers affixed to the patient; or
        ii. marking the positions of said stickers before removing said stickers;
    e. defining a composite arrhythmia waveform from said wearable ECG waveform;
    f. providing an EP lab ECG recorder and performing at least one of:
        i. connecting said stickers to said EP lab ECG recorder; or
        ii. connecting a second set of stickers to said EP lab ECG recorder wherein said second set of stickers are positioned on the marked positions;
    g. pacing the heart of the patient using a pacing electrode; and
    h. comparing the paced ECG waveform provided by said EP lab ECG recorder with an arrhythmia template waveform derived from said composite arrhythmia waveform to diagnose the arrhythmia focus.
39. The method of claim 38 further comprising providing a waveform analyzer and wherein said composite arrhythmia waveform is defined using said analyzer.
40. The method of claim 39 wherein said composite arrhythmia waveform comprises at least one arrhythmia waveform detected in wearable ECG waveform.
41. The method of claim 40 wherein detecting said at least one arrhythmia waveform comprises at least one of: said analyzer automatically detecting said at least one arrhythmia WF; an operator of said analyzer detecting said at least one arrhythmia WF; or a combination of the above.

42. The method of claim 41 wherein said plurality of electrode stickers comprises up to ten stickers.
43. The method of claim 41 wherein wearable monitor comprises a plurality of electrode cables and said cables are used for said connecting said stickers to said wearable monitor.
44. The method of claim 43 wherein said plurality of electrode cables comprises 12 electrode cables.
45. The method of claim 44 wherein said wearable ECG waveform is stored on said wearable monitor.
46. The method of claim 45 wherein said wearable ECG waveform is stored in a format selected from the group consisting of SCP-ECG, DICOM-ECG, and HL7 aECG.
47. The method of claim 46 wherein said wearable ECG waveform comprises up to twelve channels.
48. The method of claim 47 wherein said wearable monitor filters the signal received from said electrode stickers using filters.
49. The method of claim 48 wherein said filters are selected from the group consisting of low pass, high pass, band pass, notch filters and a combination of the above.
50. The method of claim 38 wherein the monitoring period is at least 72 hours.
51. The method of claim 49 wherein said importing said wearable ECG waveform into said analyzer comprises connection of one of said recorder or recorder media to said analyzer by at least one of wireless or wired connection.
52. The method of claim 51 wherein said analyzer is adapted to process said wearable ECG waveform.
53. The method of claim 52 wherein said recorder stores said wearable ECG WF in a storage format that can be processed by said analyzer.
54. The method of claim 53 wherein said analyzer comprises a translation module and translates said wearable ECG waveform into a format that it can process using said translation module.
55. The method of claim 54 wherein said comparing of said paced ECG waveform with said composite waveform is performed by a pace mapping

system running on a computer.

56. The method of claim 55 wherein said pace mapping system and said analyzer run on the same computer.

57. The method of claim 56 further comprising: importing said composite waveform into said pace mapping system.

58. The method of claim 56 wherein said composite waveform is transferred to a storage device and said storage device is connected to said pace mapping system for importing said composite waveform from said storage device into said pace mapping system.

59. The method of claim 57 wherein the method of said importing said composite waveform is selected from the group consisting of:
   a. adapting said composite waveform to a file format that can be used by said pace mapping system and importing said file into said pace mapping system;
   b. connecting said analyzer to said pace mapping system via the ECG input port of said pace mapping system and mimicking by said analyzer the signal that an ECG device would provide to said port;
   c. adapting said composite waveform to an image file format that can be used by said pace mapping system and importing said file into said pace mapping system; and
   d. a combination of the above.

60. The method of claim 58 wherein said composite waveform is stored in the internal storage of said pace mapping system.

61. The method of claim 59 wherein EP lab recorder comprises a plurality of electrode cables and said cables are used for said connecting said stickers to said EP lab recorder.

62. The method of claim 60 wherein said EP lab recorder comprises EP lab recorder filters and wherein said EP lab recorder filters are the same as said filters and are configured with the same filter settings.

63. The method of claim 61 wherein said EP lab recorder records up to 12 channels.

64. The method of claim 62 wherein said defining a composite arrhythmia waveform by said waveform analyzer requires interaction with said

analyzer by an operator.

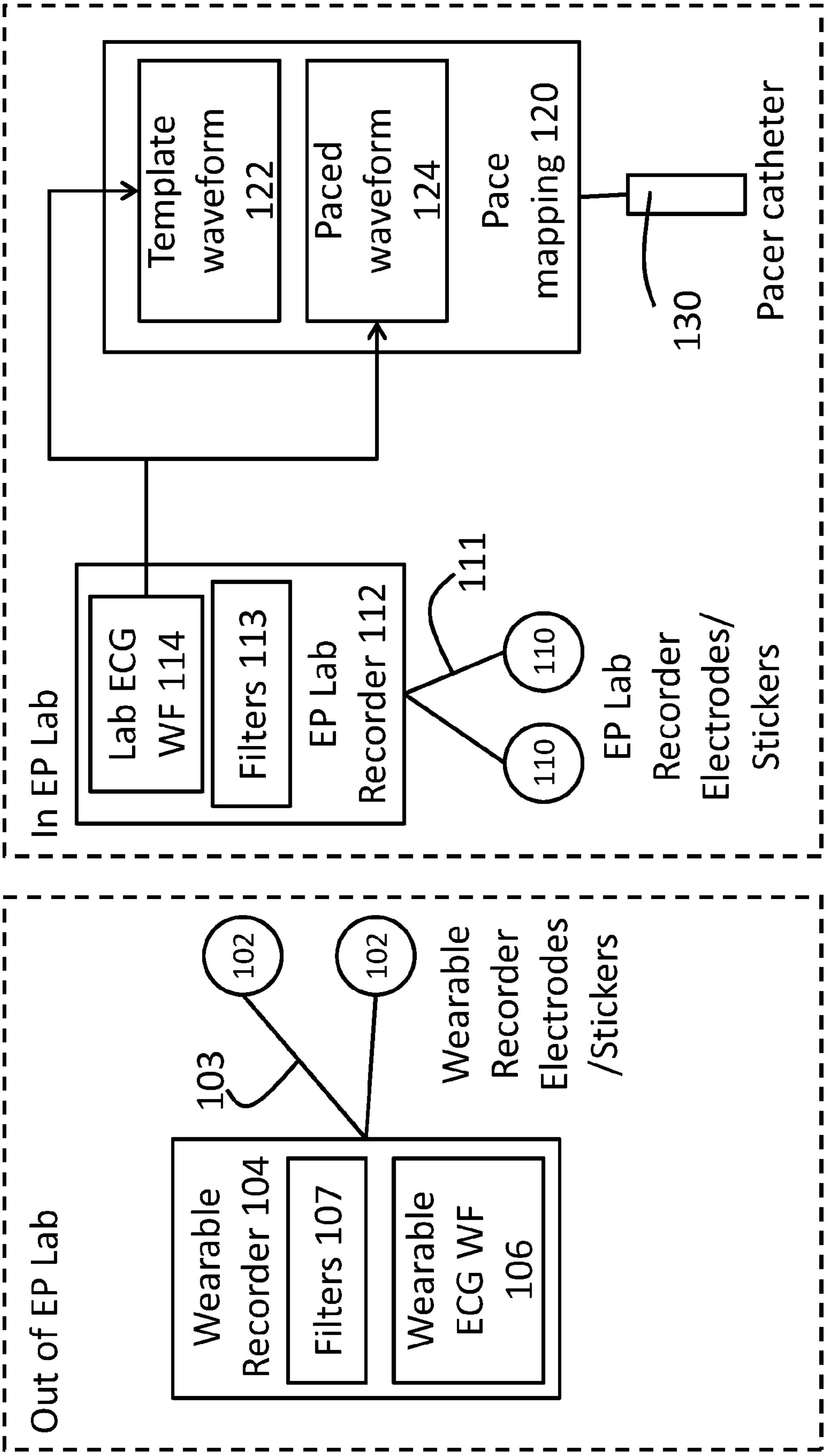


Fig 1A
Prior Art

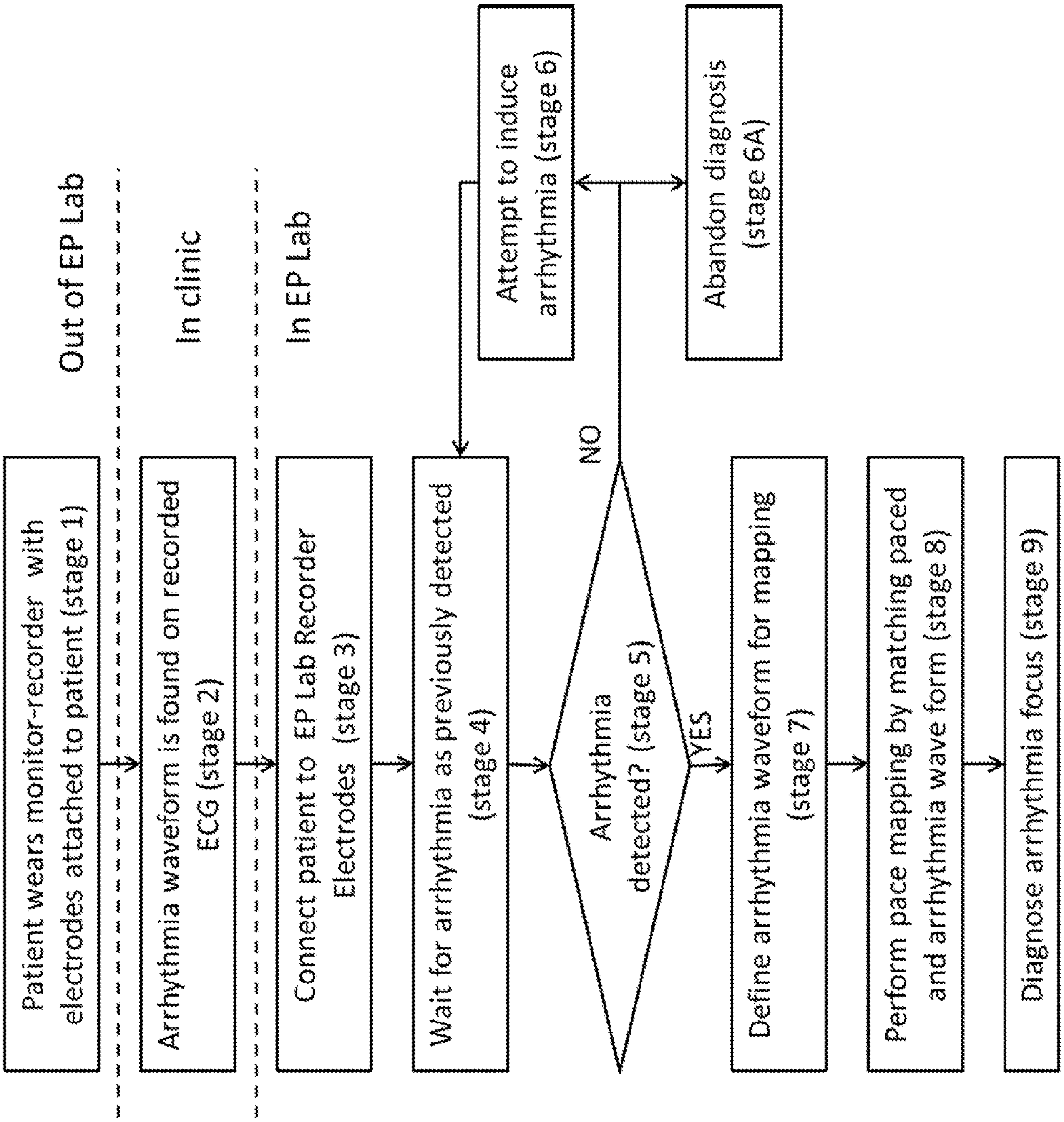
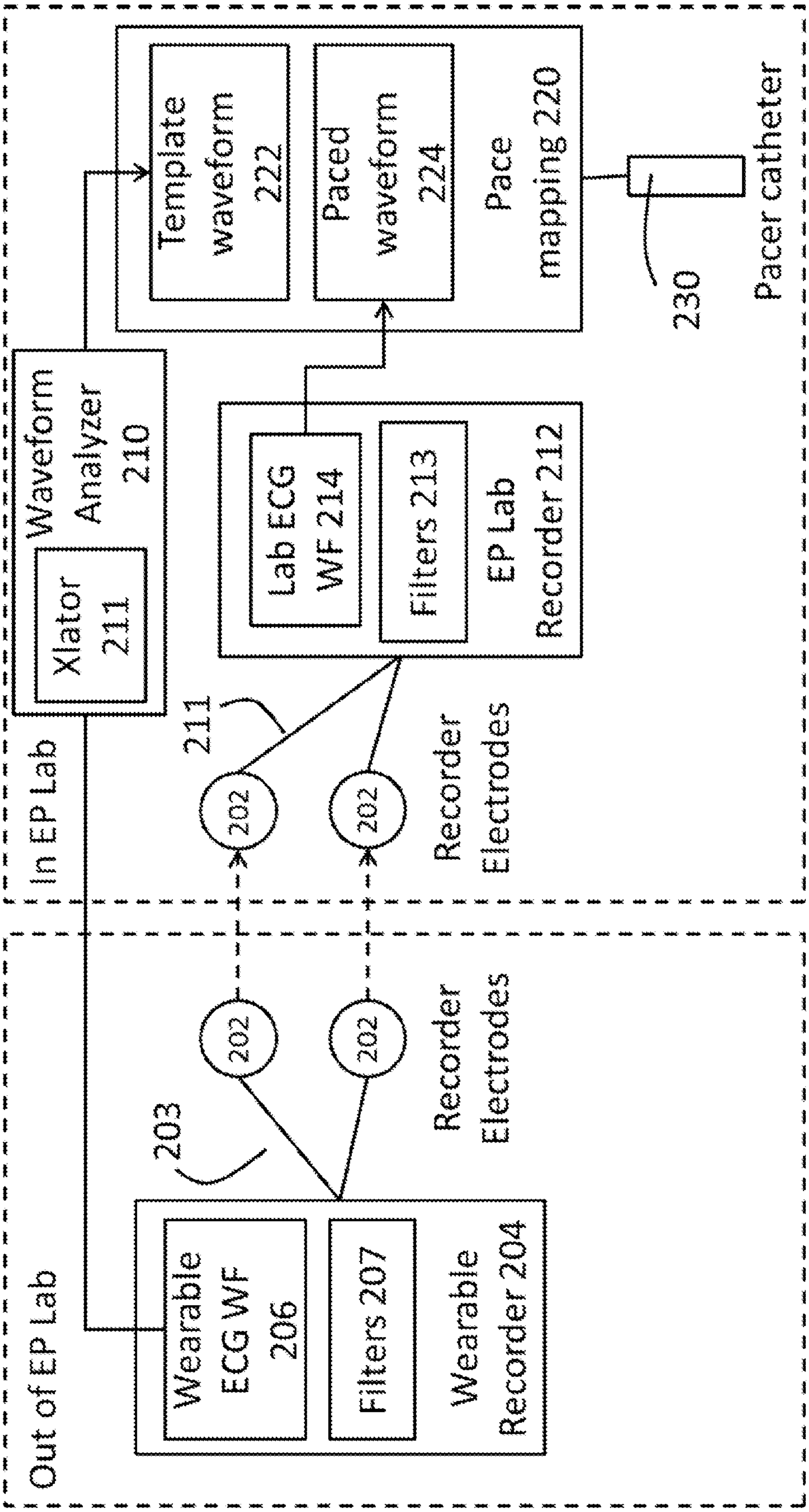


FIG. 1B
Prior Art

Fig 2A


Out of EP Lab
Wearable ECG WF 206
Filters 207
Wearable Recorder 204
203
202
202
Recorder Electrodes
In EP Lab
202
202
Recorder Electrodes
211
Xlator 211
Waveform Analyzer 210
Lab ECG WF 214
Filters 213
EP Lab Recorder 212
Template waveform 222
Paced waveform 224
Pace mapping 220
230
Pacer catheter

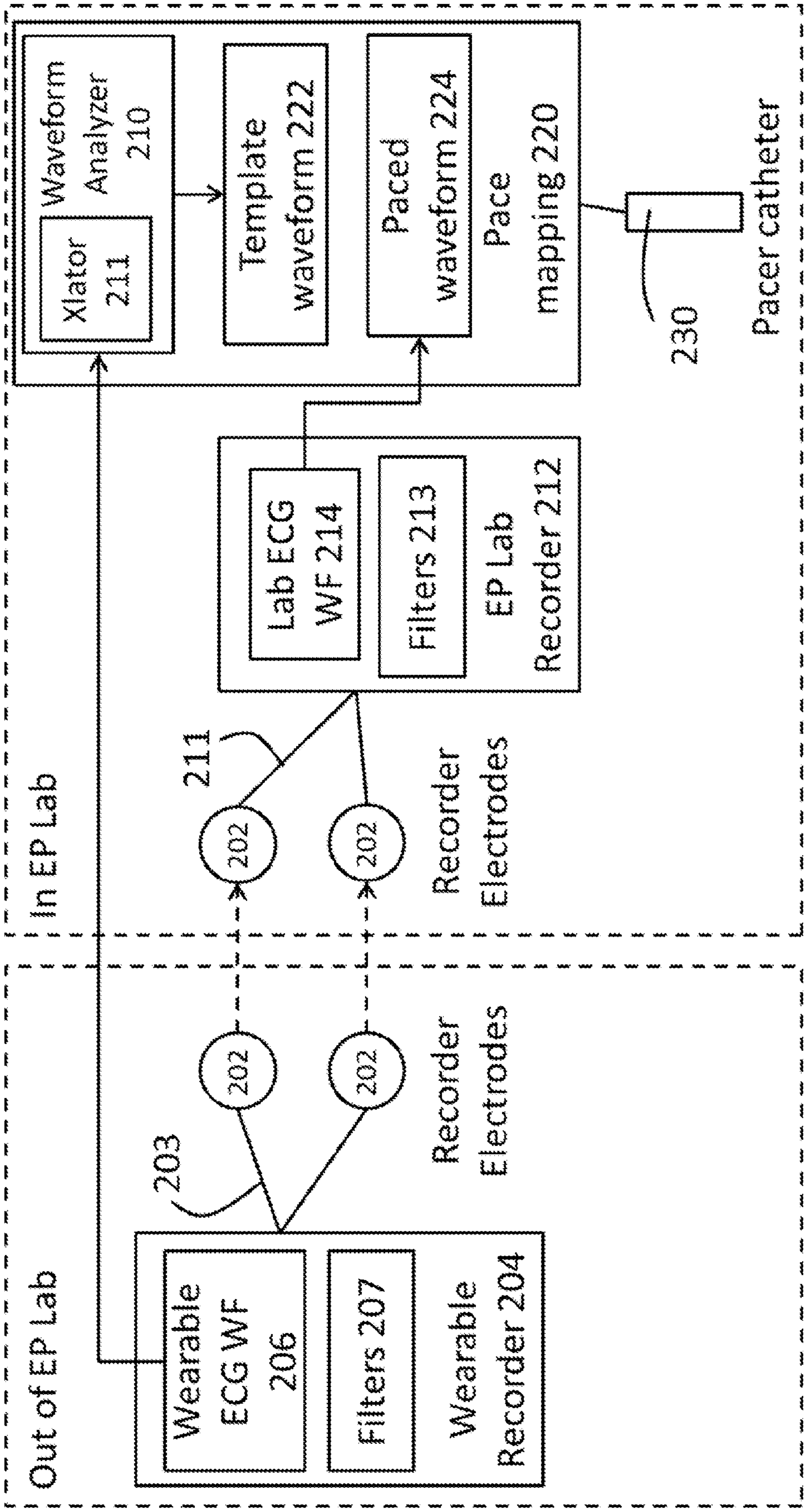

Out of EP Lab
Wearable ECG WF 206
Filters 207
Wearable Recorder 204
203
202
202
Recorder Electrodes
In EP Lab
202
202
211
Recorder Electrodes
Lab ECG WF 214
Filters 213
EP Lab Recorder 212
Waveform Analyzer 210
Xlator 211
Template waveform 222
Paced waveform 224
Pace mapping 220
230
Pacer catheter

Fig 2B

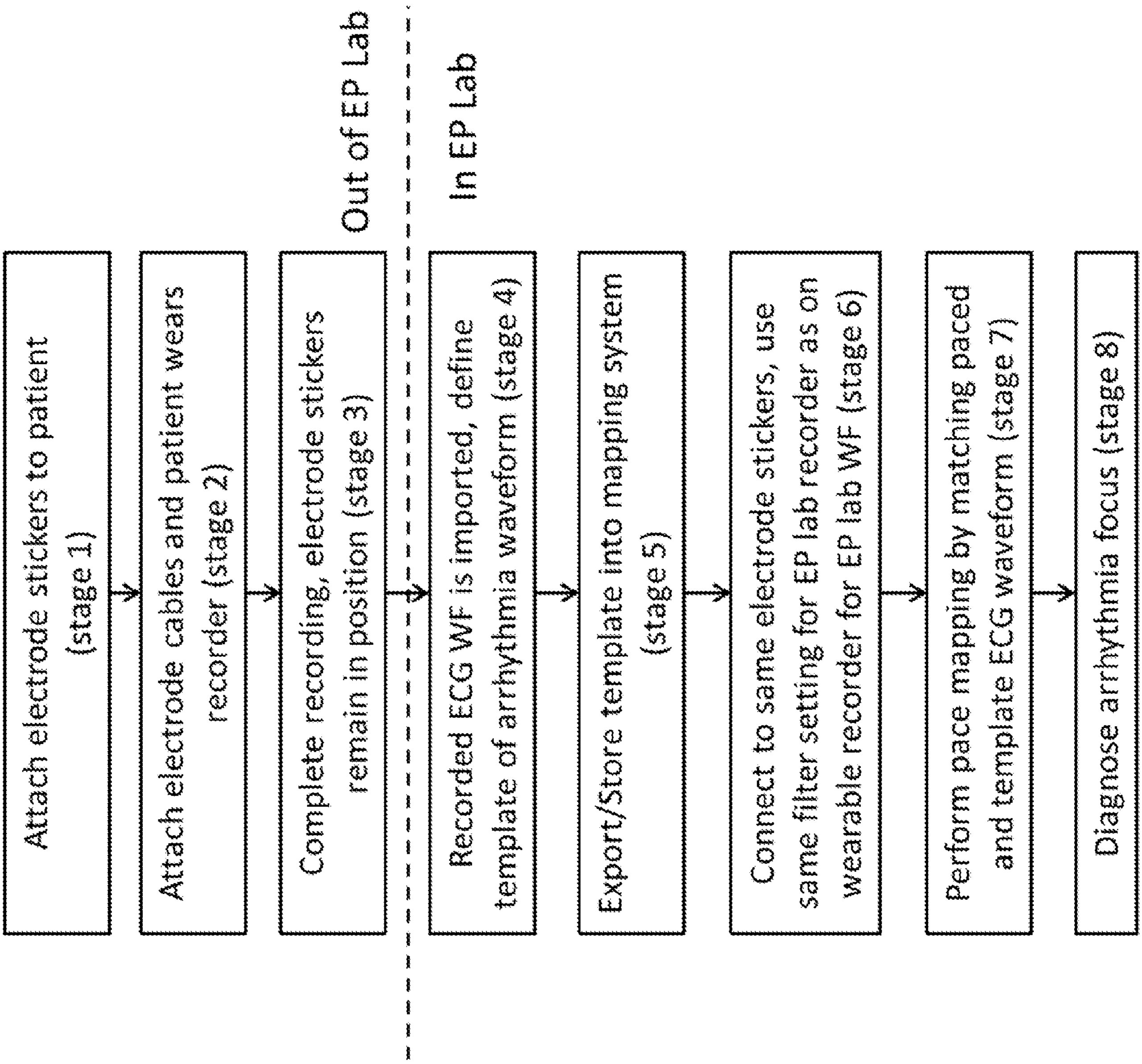

Out of EP Lab
In EP Lab
Attach electrode stickers to patient (stage 1)
Attach electrode cables and patient wears recorder (stage 2)
Complete recording, electrode stickers remain in position (stage 3)
Recorded ECG WF is imported, define template of arrhythmia waveform (stage 4)
Export/Store template into mapping system (stage 5)
Connect to same electrode stickers, use same filter setting for EP lab recorder as on wearable recorder for EP lab WF (stage 6)
Perform pace mapping by matching paced and template ECG waveform (stage 7)
Diagnose arrhythmia focus (stage 8)

FIG. 2C

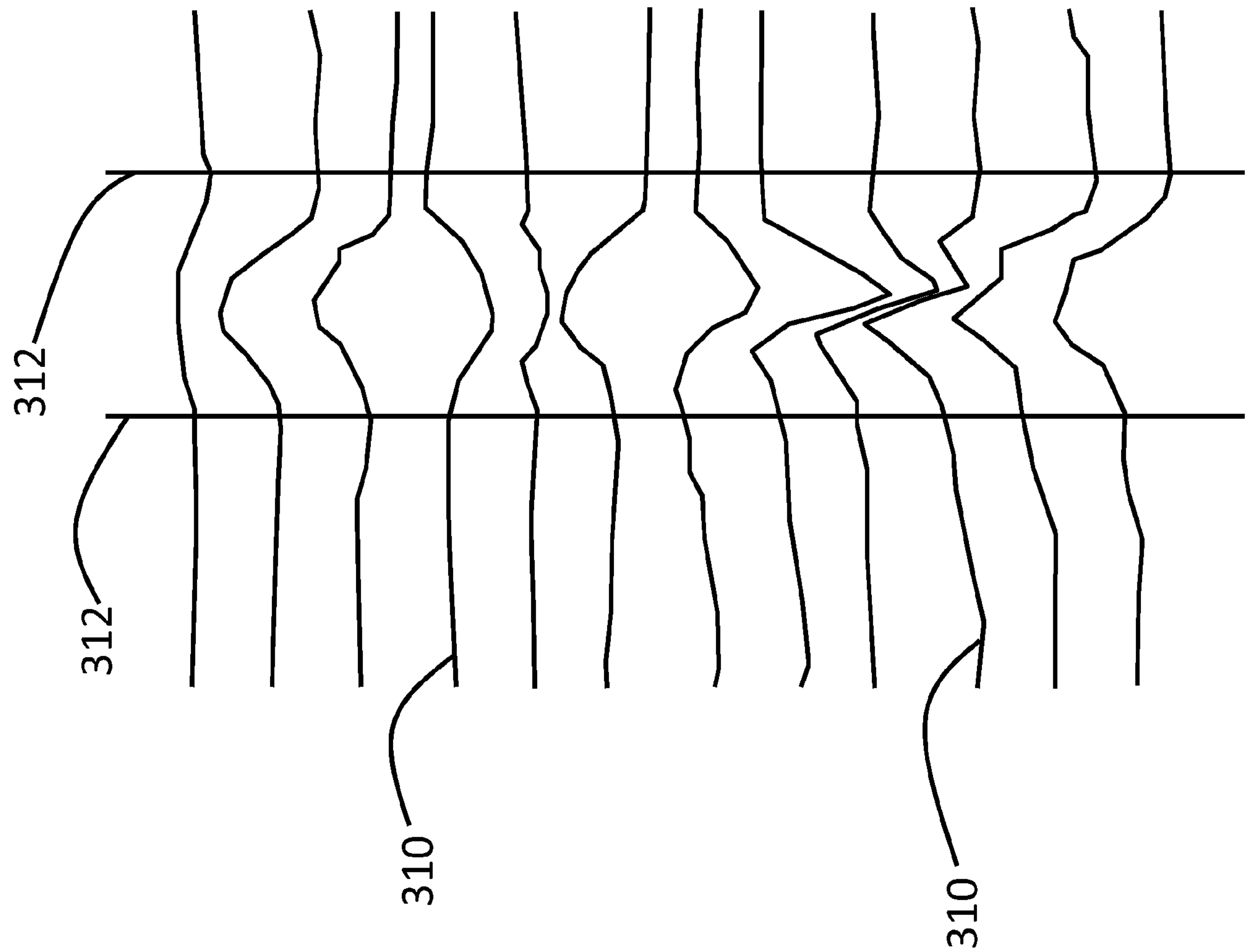


Fig 3A

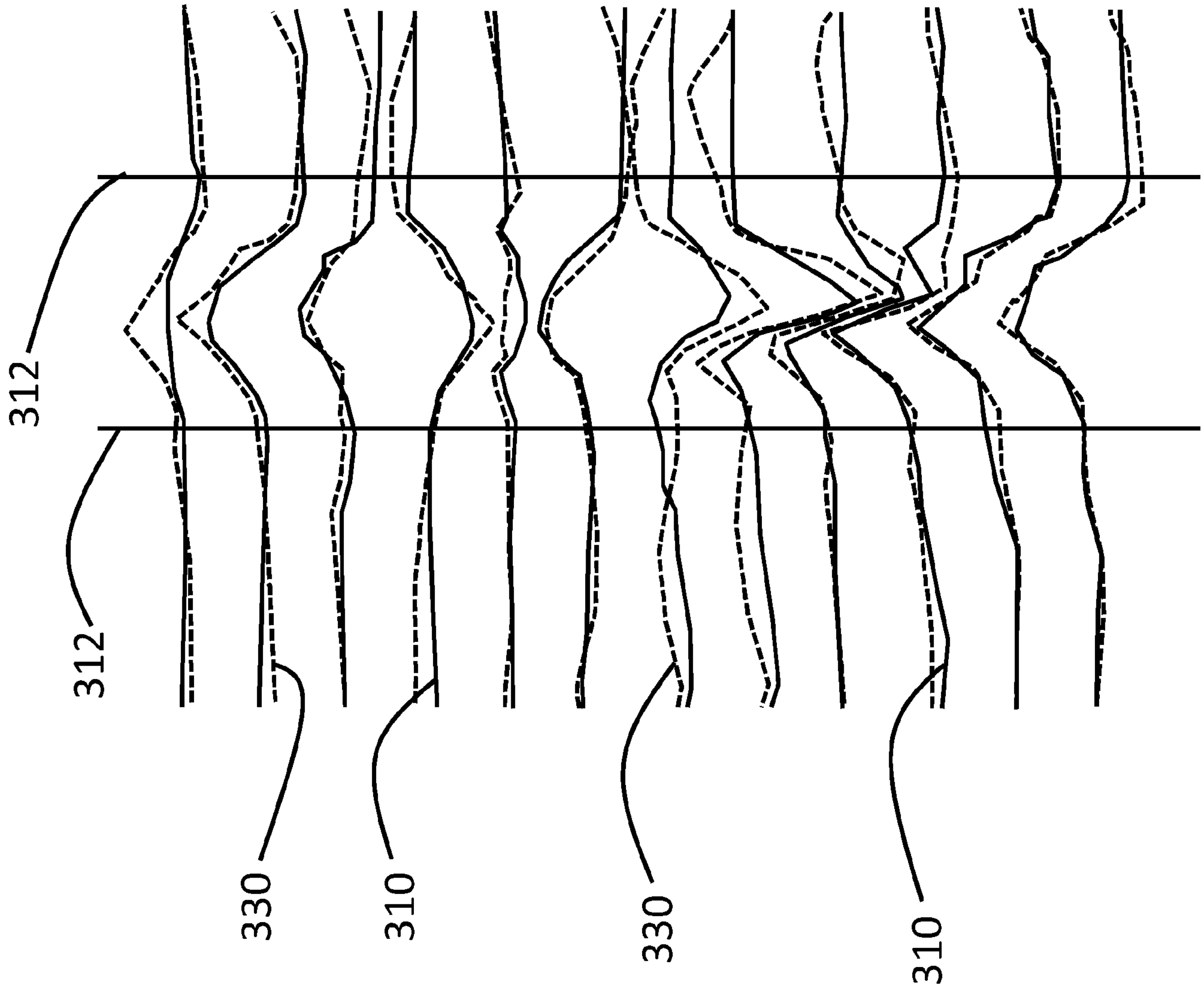


Fig 3B

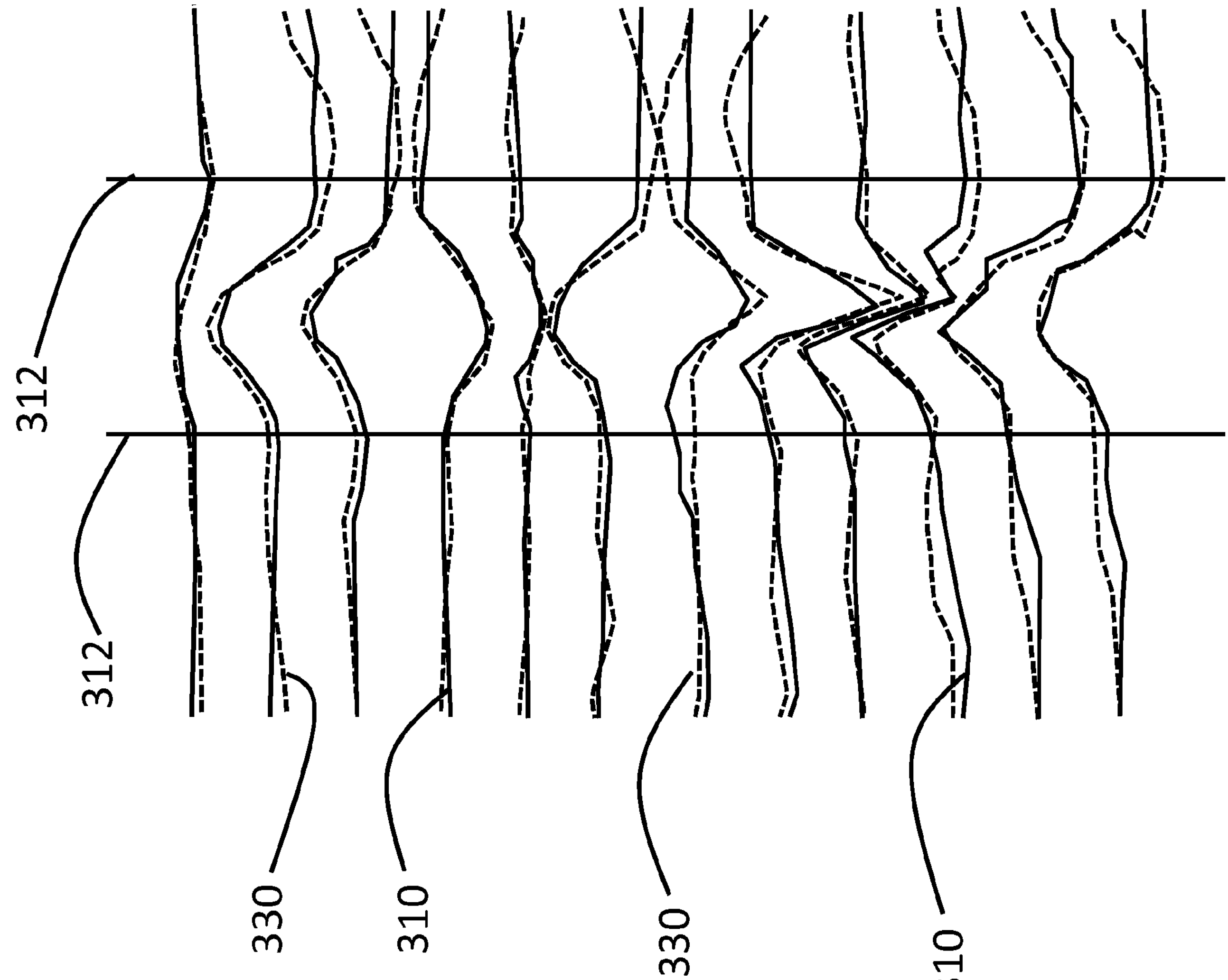


Fig 3C

Fig 4A

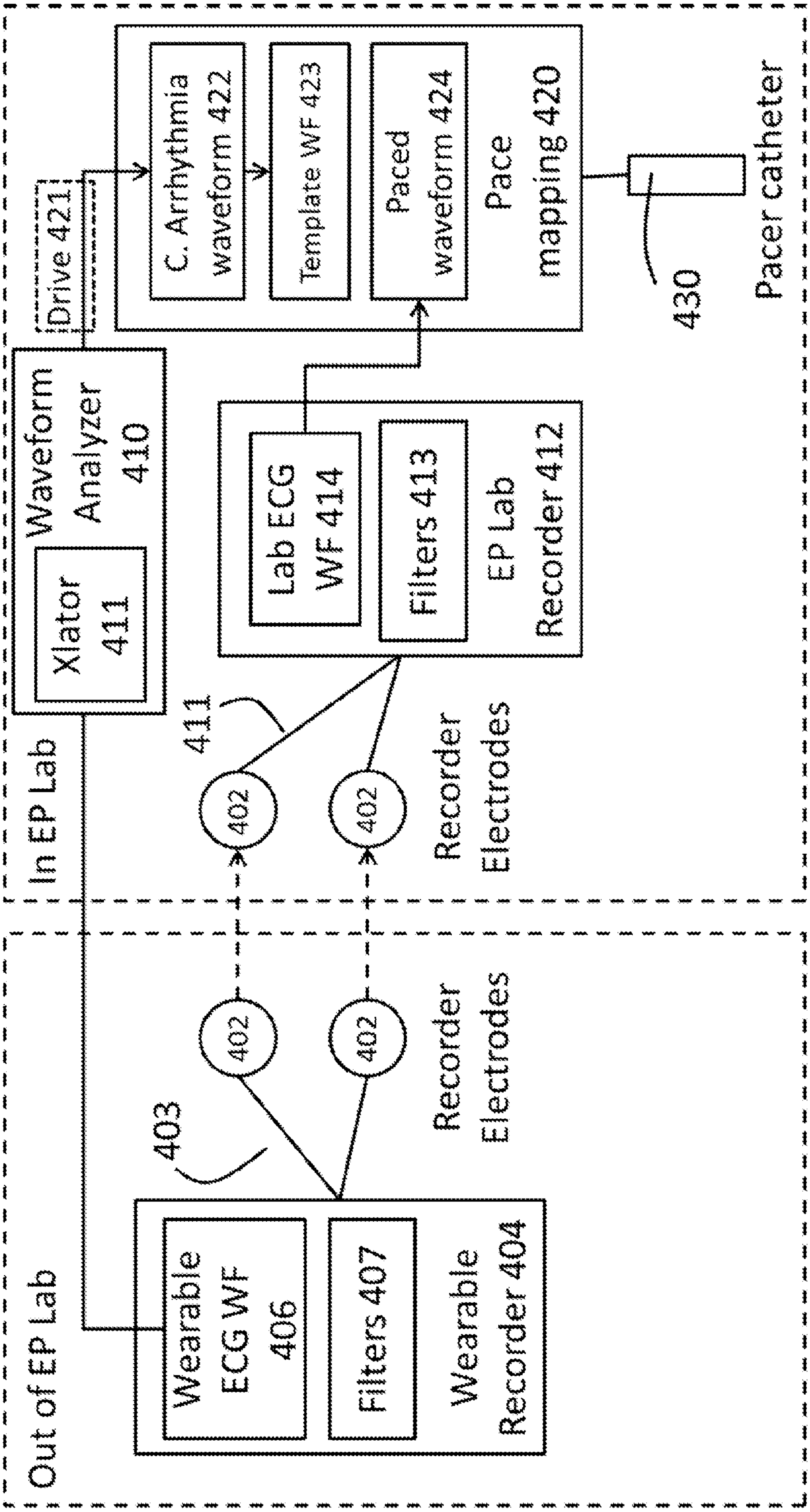

In EP Lab
Out of EP Lab
Waveform Analyzer 410
Xlator 411
Drive 421
C. Arrhythmia waveform 422
Template WF 423
Paced waveform 424
Pace mapping 420
430
Pacer catheter
Lab ECG WF 414
Filters 413
EP Lab Recorder 412
411
402
402
Recorder Electrodes
402
402
403
Recorder Electrodes
Wearable ECG WF 406
Filters 407
Wearable Recorder 404

Fig 4B

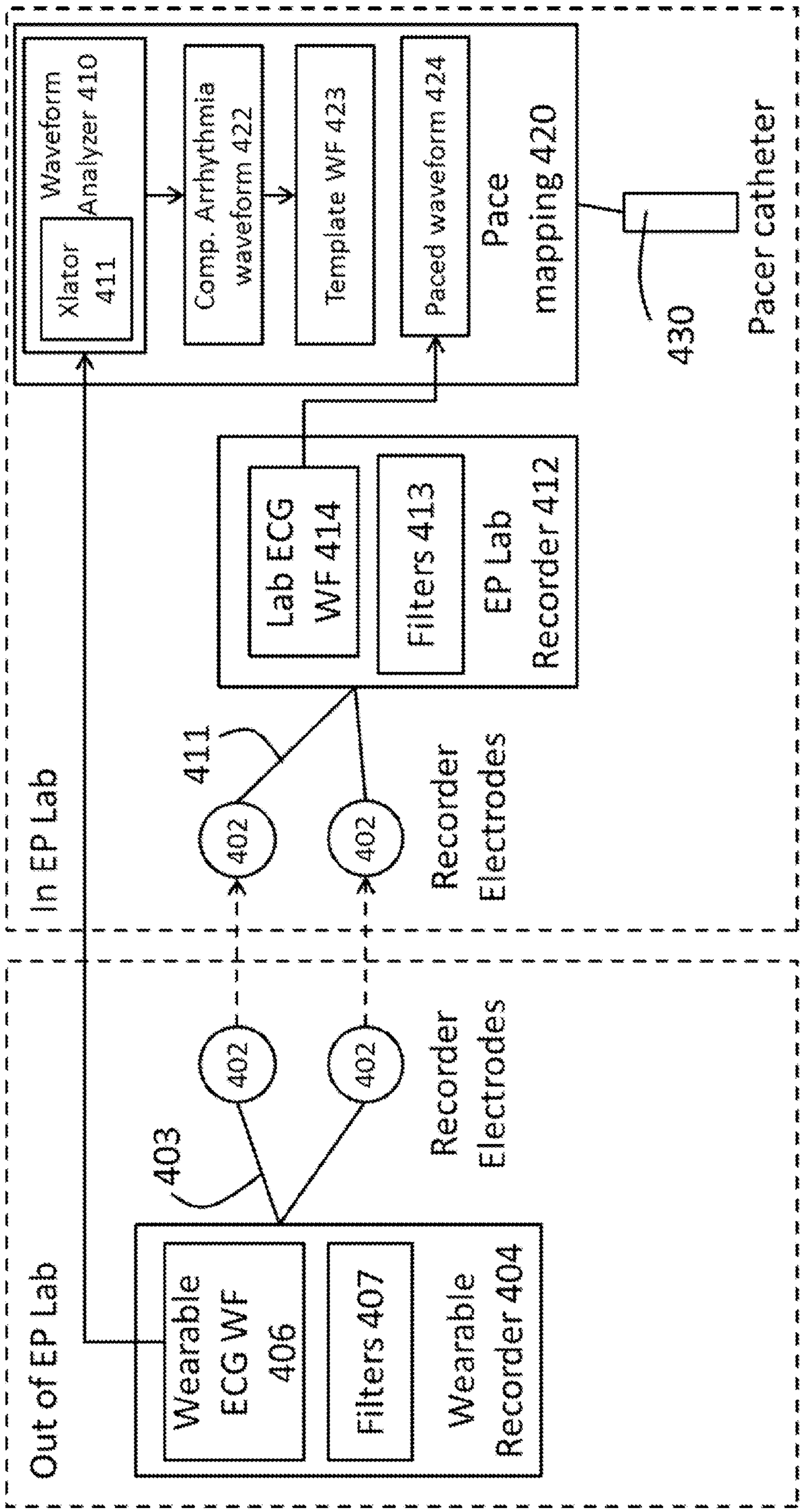
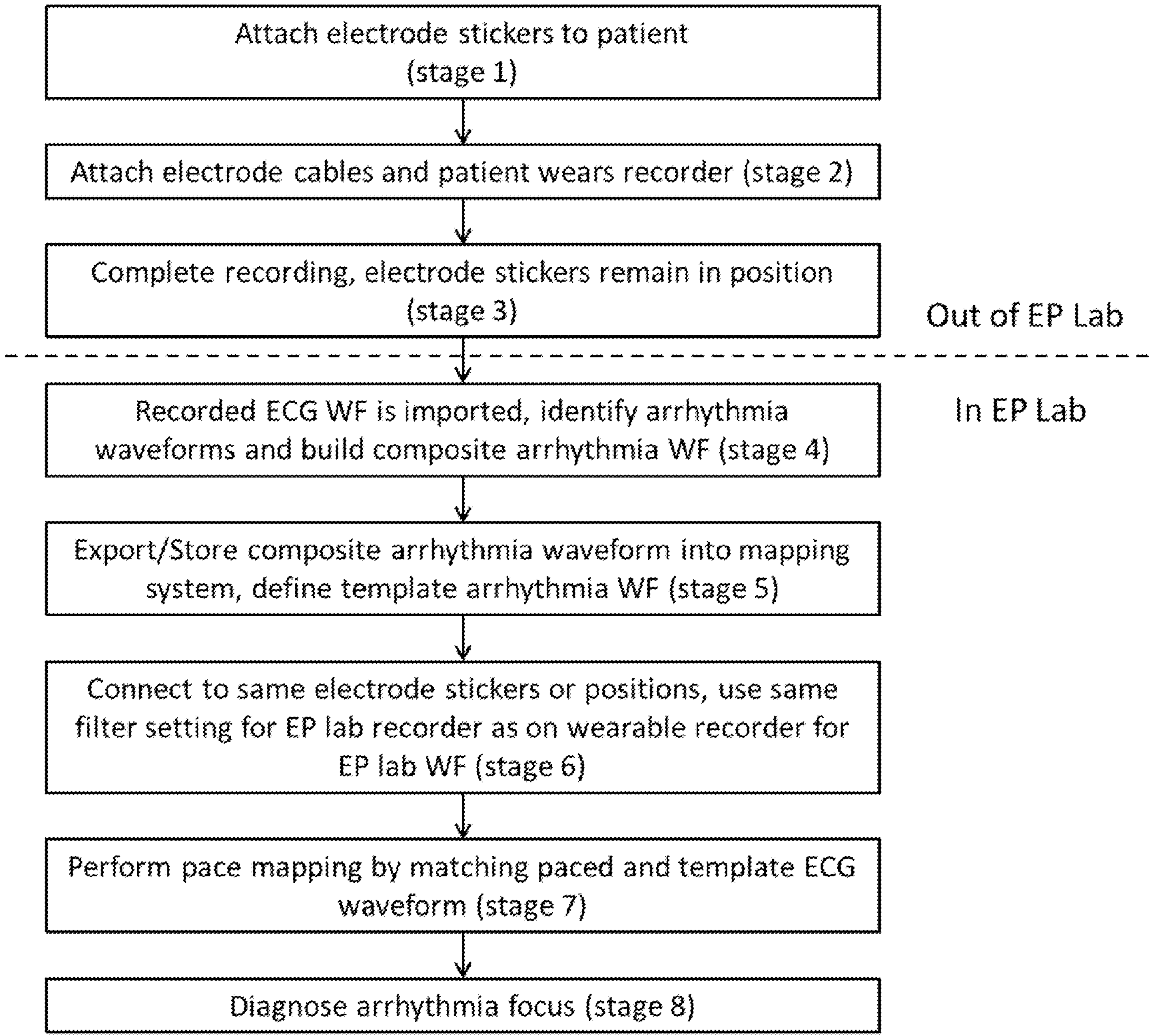

Out of EP Lab
In EP Lab
Wearable ECG WF 406
Filters 407
Wearable Recorder 404
403
402
402
Recorder Electrodes
402
402
411
Recorder Electrodes
Lab ECG WF 414
Filters 413
EP Lab Recorder 412
Xlator 411
Waveform Analyzer 410
Comp. Arrhythmia waveform 422
Template WF 423
Paced waveform 424
Pace mapping 420
430
Pacer catheter

FIG. 4C


Attach electrode stickers to patient (stage 1)
Attach electrode cables and patient wears recorder (stage 2)
Complete recording, electrode stickers remain in position (stage 3)
Out of EP Lab
In EP Lab
Recorded ECG WF is imported, identify arrhythmia waveforms and build composite arrhythmia WF (stage 4)
Export/Store composite arrhythmia waveform into mapping system, define template arrhythmia WF (stage 5)
Connect to same electrode stickers or positions, use same filter setting for EP lab recorder as on wearable recorder for EP lab WF (stage 6)
Perform pace mapping by matching paced and template ECG waveform (stage 7)
Diagnose arrhythmia focus (stage 8)

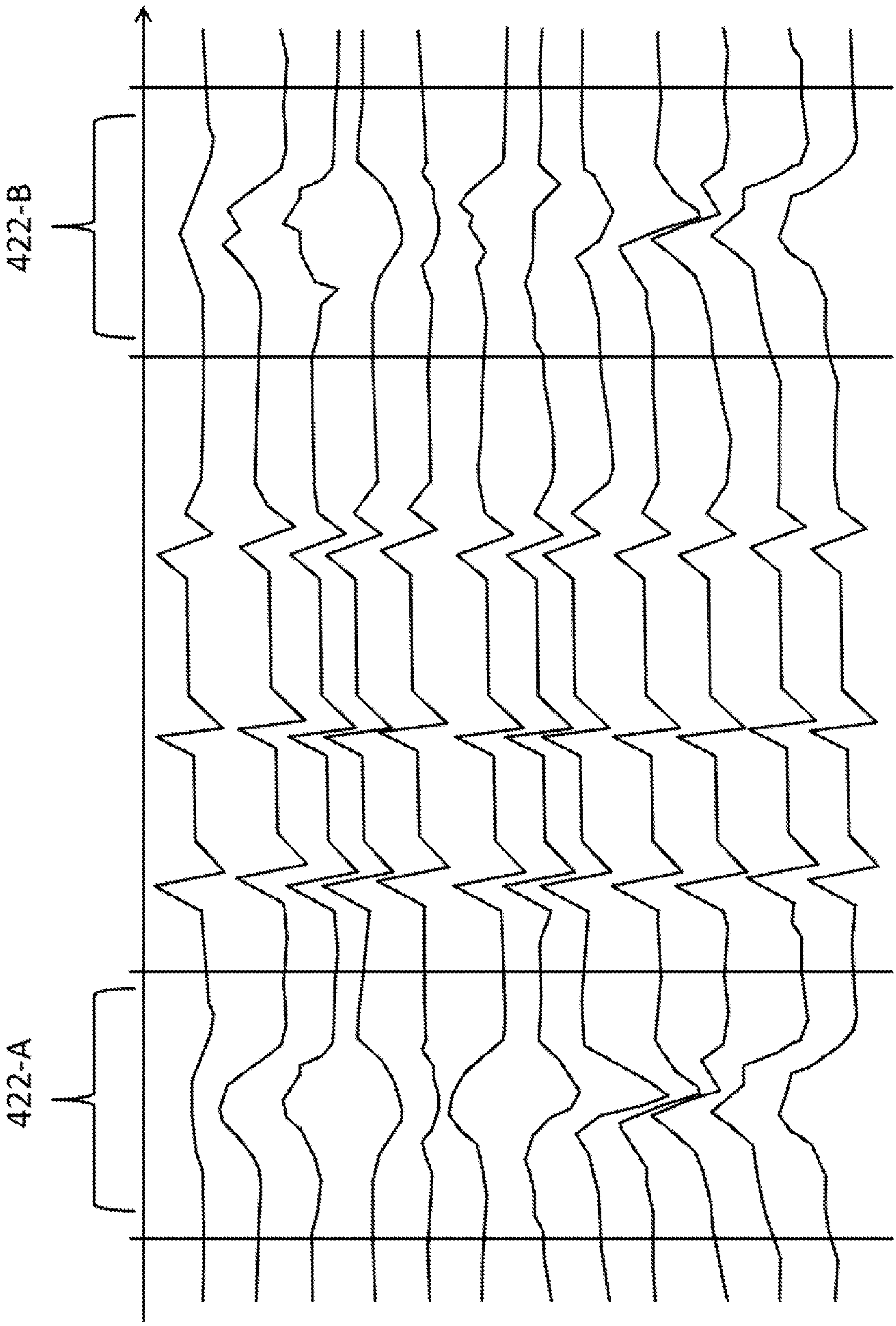


Fig 4D

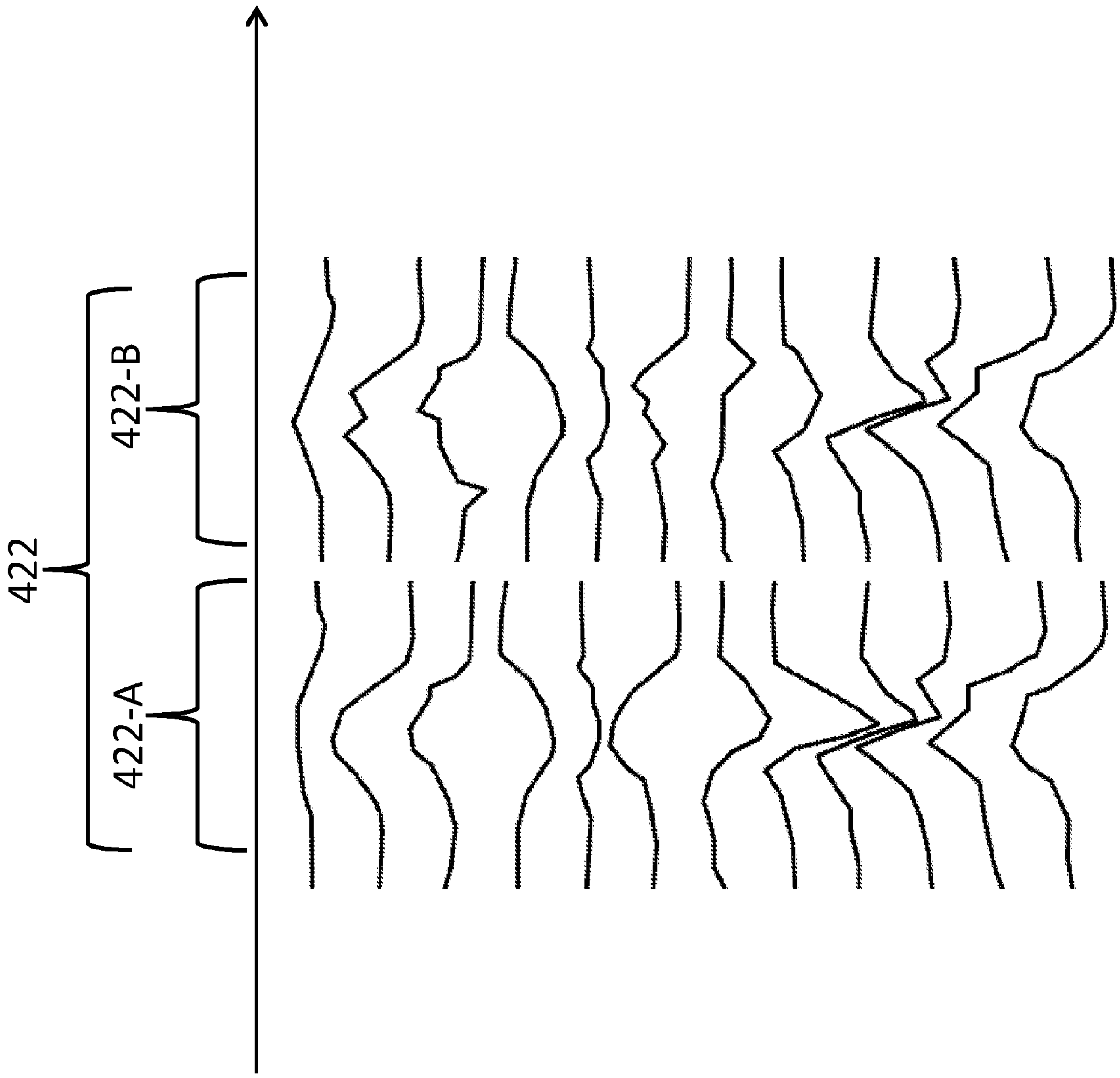


Fig 4E

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IL2018/050173

A. CLASSIFICATION OF SUBJECT MATTER

IPC (2018.01) A61B 5/00, A61B 5/04, A61B 5/024, A61B 5/024500, A61B 5/040200, A61B 5/045200

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC (2018.01) A61B 5/00, A61B 5/04, A61B 5/024, A61B 5/024500, A61B 5/040200, A61B 5/045200

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
Databases consulted: Google Patents, Orbit
Search terms used: Indamed, ShtakeI asher, Schneider chanan,Schnaps yehuda, Manevich vadim, a61b5/04525, a61b5/0432, wear

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2006025697 A1 Raymond C. Kurzweil ET AL. 02 Feb 2006 (2006/02/02) fig 1, para. 84	1,24,35,37,38
Y	para. 22, para. 84, para. 87, fig. 1, fig. 2,	2-14,19-21,23,25-31, 33,36,39-43,45,46, 48-54,58,60-64
Y	US 6944495 B2 C.R. Bard, Inc. 13 Sep 2005 (2005/09/13) col. 3 lines 5-9, col. 6 lines 14-16, col. 7. lines 48-57,	1,24,35,37,38
Y	col. 6 lines 14-42, col. 10, lines 38-50, fig. 4, fig. 5 , fig. 6, fig. 8	5,6,10,12-23,25,26, 31-34,36,39-47,50-64
A	US 9386935 B2 Nihon Kohden Corp. 12 Jul 2016 (2016/07/12) whole doc.	1-64

[X] Further documents are listed in the continuation of Box C. [X] See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
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"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
16 May 2018	17 May 2018

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C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2016166165 A1 Biosence webster (Israel) LTD 12 Jun 2016 (2016/06/12) whole doc.	1-64

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/IL2018/050173

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US 2006025697 A1	02 Feb 2006	US 2006025697 A1	02 Feb 2006
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Information on patent family members

International application No.
PCT/IL2018/050173

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patsnap

专利名称(译)	诊断心律失常的系统和方法		
公开(公告)号	EP3606411A1	公开(公告)日	2020-02-12
申请号	EP2018754165	申请日	2018-02-14
[标]发明人	SHTEKEL ASHER SCHNEIDER CHANAN SCHNAPS YEHUDA MANEVICH VADIM		
发明人	SHTEKEL, ASHER SCHNEIDER, CHANAN SCHNAPS, YEHUDA MANEVICH, VADIM		
IPC分类号	A61B5/00 A61B5/04 A61B5/024 A61B5/0245 A61B5/0402 A61B5/0452		
CPC分类号	A61B5/04012 A61B5/04023 A61B5/0452		
优先权	250610 2017-02-14 IL		
外部链接	Espacenet		

摘要(译)

一种诊断患者心脏心律不齐的方法，包括：将电极固定在患者身上； 提供可穿戴式监视器，并将电极连接到可穿戴式监视器； 通过可穿戴式监视器监视患者一段监视时间，以产生可穿戴式ECG波形； 将可穿戴式监护仪与电极断开连接，同时将电极固定在患者身上或标记这些电极的位置； 提供在计算机上运行的波形分析仪； 将可穿戴式心电图波形导入波形分析仪； 根据可穿戴式ECG波形定义复合性心律失常波形； 提供一个EP实验室心电图，并将电极贴纸连接到EP实验室心电图或将新的贴纸连接到标记的位置； 使用起搏导管对患者的心脏起搏； 并将EP实验室ECG提供的起搏ECG波形与复合性心律不齐波形进行比较，以诊断心律不齐的焦点。