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(54) Title: A DEVICE AND METHOD FOR ACCURATELY NAVIGATING A CATHETER DURING VASCULAR ACCESS

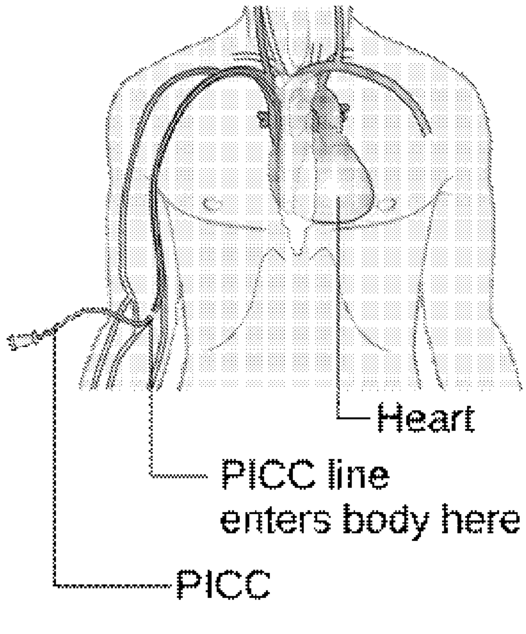

FIGURE 4

(57) Abstract: A device for accurately navigating at least a catheter and locating the tip of said catheter during vascular access, said device comprising: a sensor; a signal capturing mechanism to be communicably coupled with an ECG machine and said sensor in order to capture heart electrical activity in terms of sensed signals; extraction mechanisms configured to extract several information items from parameters from said sensed signal; a first computation mechanism to provide a first computed set of values; and at least a guidance mechanism to provide a set of guidance signals. The first information item is the amplitude of the P-wave and the second information item is the amplitude of the R-wave, and said first computed set of values comprises a ratio of P-wave and R-wave amplitudes. Preferably, the third information item is the change of voltage or slope of the P-wave, whereas the fourth information item is the energy of the P-wave.

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A DEVICE AND METHOD FOR ACCURATELY NAVIGATING A CATHETER DURING VASCULAR ACCESS

FIELD OF THE INVENTION:

This invention relates to the field of medical engineering, electronics engineering, and signal processing.

Particularly, this invention relates to a device and method for accurately navigating at least a catheter and locating the tip of said catheter during vascular access.

BACKGROUND OF THE INVENTION:

The heart is a muscular organ in humans and other animals, which pumps blood through the blood vessels of the circulatory system. In humans, other mammals, and birds, the heart is divided into four chambers: upper left and right atria; and lower left and right ventricles.

A normal rhythmical heart beat, called sinus rhythm, is established by a sinoatrial node, the heart's pacemaker. Here, an electrical signal is created that travels through the heart, causing the heart muscle to contract. Each electrical signal begins in a group of cells called the sinus node or sino-atrial (SA) node. The SA node is located in the right atrium, which is the upper right chamber of the heart.

In a healthy adult heart at rest, the SA node sends an electrical signal to begin a new heartbeat 60 to 100 times a minute.

Electrocardiography (ECG or EKG) is the process of recording the electrical activity of a heart over a period of time using electrodes placed on a patient's body. These electrodes detect tiny electrical changes on the skin that arise from the heart muscle depolarizing during each heartbeat.

Figure 1 shows a patient's heart activity being recorded using electrocardiogram.

A cardiac cycle refers to a complete heartbeat from its generation to the beginning of the next beat, and so includes the diastole, the systole, and the intervening pause. The frequency of the cardiac cycle is described by the heart rate, which is typically expressed as beats per minute.

From the SA node, the signal travels through the right and left atria. This causes the atria to contract, which helps move blood into the heart's lower chambers, i.e. the ventricles. The electrical signal moving through the atria is recorded as P wave on the electrocardiogram (ECG, also known as EKG), as shown in **Figure 2** below.

A typical ECG tracing is a repeating cycle of three electrical entities: a **P wave** (atrial depolarization), a **QRS complex** (ventricular depolarization) and a **T wave** (ventricular repolarization). The ECG is traditionally interpreted methodically in order to not miss any important findings.

The electrical signal passes between the atria and ventricles through a group of cells called the atrio-ventricular (AV) node. The signal slows down as it passes through the AV node. This slowing allows the ventricles enough time to finish filling with blood. On the ECG, this part of the process is the flat line between the end of the P wave and the beginning of the Q wave. The electrical signal then leaves the AV node and travels along a pathway called the bundle of His. From there, the signal travels into the right and left bundle branches. The signal spreads quickly across the heart's ventricles, causing them to contract and pump blood to the lungs and the rest of the body. This process is recorded as the QRS waves on the ECG. The ventricles then recover their normal electrical state (shown as the T wave on the ECG). The muscle stops contracting to allow the heart to refill with blood. This entire process continues over and over with each new heartbeat. The entire ECG ensemble is shown in **Figure 3**.

In an ECG, the **P-wave** represents depolarization of the atria. Atrial depolarization spreads from the SA node towards the AV node, and from the right atrium to the left atrium. The P-wave is typically upright in most leads except for a VR; an unusual P wave axis (inverted in other leads) can indicate an ectopic atrial pacemaker. If the P-wave is of unusually long duration, it may represent atrial enlargement. Typically, a large right atrium gives a tall, peaked p-wave while a large left atrium gives a two-humped bifid P-wave. Its duration is less than 80ms.

In an ECG, the **PR interval** is measured from the beginning of the P-wave to the beginning of the QRS complex. This interval reflects the time the electrical impulse takes to travel from the sinus node through the AV node. A PR interval shorter than 120 ms suggests that the electrical impulse is bypassing the AV node, as in Wolf-Parkinson-White syndrome. A PR interval consistently longer than 200 ms diagnoses first degree atrioventricular block. The PR segment (the portion of the tracing after the P-wave and before the QRS complex) is typically completely flat, but may be depressed in pericarditis. Its interval is 120 to 200 ms.

In an ECG, the **QRS complex** represents the rapid depolarization of the right and left ventricles. The ventricles have a large muscle mass compared to the atria, so the QRS complex usually has a much larger amplitude than the P-wave. If the QRS complex is wide (longer than 120 ms) it suggests disruption of the heart's conduction system, such as in LBBB, RBBB, or ventricular rhythms such as ventricular tachycardia. Metabolic issues such as severe hyperkalemia, or TCA overdose can also widen the QRS complex. An unusually tall QRS complex may represent left ventricular hypertrophy while a very low-amplitude QRS complex may represent a pericardial effusion or infiltrative myocardial disease. Its interval is 80 to 100 ms.

In an ECG, the **J-point** is the point at which the QRS complex finishes and the ST segment begins. The J point may be elevated as a normal variant. The appearance of a separate J wave or Osborn wave at the J point is pathognomonic of hypothermia or hypercalcemia. The J point may be elevated as a normal variant. The appearance of a separate J wave or Osborn wave at the J point is pathognomonic of hypothermia or hypercalcemia.

In an ECG, the **ST segment** connects the QRS complex and the T wave; it represents the period when the ventricles are depolarized. It is usually isoelectric, but may be depressed or elevated with myocardial infarction or ischemia. ST depression can also be caused by LVH or digoxin. ST elevation can also be caused by pericarditis, Brugada syndrome, or can be a normal variant (J-point elevation). It is usually isoelectric, but may be depressed or elevated with myocardial infarction or ischemia. ST depression can also be caused by LVH or digoxin. ST elevation can also be caused by pericarditis, Brugada syndrome, or can be a normal variant (J-point elevation). Its interval is 160 ms.

In an ECG, the **T wave** represents the repolarization of the ventricles. It is generally upright in all leads except aVR and lead V1. Inverted T waves can be a sign of myocardial ischemia, LVH, high intracranial pressure, or metabolic abnormalities. Peaked T waves can be a sign of hyperkalemia or very early myocardial infarction.

In an ECG, the **QT interval** is measured from the beginning of the QRS complex to the end of the T wave. Acceptable ranges vary with heart rate, so it must be corrected to the QTc by dividing by the square root of the RR interval. A prolonged QTc interval is a risk factor for ventricular tachyarrhythmias and sudden death. Long QT can arise as a genetic syndrome, or as a side effect of certain medications. An unusually short QTc can be seen in severe hypercalcemia. Its interval is less than 440 ms.

In an ECG, the **U wave** is hypothesized to be caused by the repolarization of the interventricular septum. It normally has a low amplitude, and even more often is completely absent. If the U wave is very prominent, suspect hypokalemia, hypercalcemia or hyperthyroidism.

Navigation of the catheter and final position of the tip of the catheter during central venous access has remained a major challenge. Several techniques have been proposed and some of these techniques are currently being used. Among non-invasive procedures, X-ray and ultrasound are the most commonly deployed techniques. Invasive procedures include fluoroscopy as well as use of electrocardiography (ECG).

There is a need for a device and method which is superior to prior art devices and methods, wherein the catheter device uses critical pieces of information from the ECG signal in order to accurately guide the catheter and to accurately identify its location for placement.

OBJECTS OF THE INVENTION:

An object of the invention is to provide a device and method, which device is catheter and which method is for determination of location of the tip of catheter based on attributes derived from the ECG waveform.

Another object of the invention is to provide a device and method, which device is catheter and which method is for determination of location of the tip of catheter based on information derived from at least a P-wave of an ECG signal.

Yet another object of the invention is to provide a device and method, which device is catheter and which method is for determination of location of the tip of catheter based on information derived from at least an R-wave of an ECG signal.

Still another object of the invention is to provide a device and method, which device is catheter and which method is for determination of location of the tip of catheter based on information derived from at least energy of an ECG signal.

An additional object of the invention is to provide a device and method, which device is catheter and which method is for determination of location of the tip of catheter based on information derived from at least a rate of change of a component of an ECG signal.

SUMMARY OF THE INVENTION:

According to this invention, there is provided **a device and method for accurately navigating at least a catheter and locating the tip of said catheter during vascular access**, said device comprising:

- a sensor positioned at the operative distal tip of said catheter;
- a signal capturing mechanism configured to be communicably coupled with an ECG machine and said sensor in order to capture heart electrical activity in terms of sensed signals;
- a first extraction mechanism configured to extract a first information item from a first parameter from said sensed signal, said first parameter being a locus of points which forms a P-wave in an ECG signal, said first information item being pre-defined information item related to said first parameter;
- a second extraction mechanism configured to extract a second information item from a second parameter from said sensed signal, said second parameter being a locus of points which forms an R-wave in an ECG signal, said second information item being pre-defined information item related to said second parameter;
- a third extraction mechanism configured to extract a third information item from said first parameter from said sensed signal;
- a fourth extraction mechanism configured to extract a fourth information item from said first parameter from said sensed signal;
- a first computation mechanism configured to compute ratio of said first information item and said second information item in order to provide a first computed set of values; and
- at least a guidance mechanism configured to provide a set of guidance signals in relation to pre-configured threshold values relating to each of said first set of computed values, said third information item, and said fourth information item, characterised in that, said guidance signals comprising at least a first guidance

signal if any combination comprising said first set of computed values, said third information item, and said fourth information item is within said pre-configured threshold values and said guidance signals comprising at least a second guidance signal if any combination comprising said first set of computed values, said third information item, and said fourth information item is outside said pre-configured threshold values.

Typically, said first pre-defined information item amplitude of the P-wave.

Typically, said second pre-defined information item being amplitude of the R-wave.

Typically, said third information item being rate of change of voltage.

Typically, said third information item being slope of P-wave.

Typically, said fourth information item being energy of P wave.

Typically, said first set of computed values comprising ratio of P-wave and R-wave amplitudes.

In at least one embodiment, said guidance mechanism is a visual guide configured to provide at least a visual guidance signal for navigating said catheter device.

In at least one embodiment, said guidance mechanism is an audio guide configured to provide at least an audio guidance signal for navigating said catheter device.

Typically, said pre-configured thresholds comprise at least an amplitude threshold value for said first parameter, characterized in that, said first parameter being a defined P-wave of said sensed signal.

Typically, said pre-configured thresholds comprise at least an amplitude threshold value for said second parameter, characterized in that, said second parameter being a defined R-wave of said sensed signal.

Typically, said pre-configured thresholds comprise at least a slope threshold value for said first parameter, characterized in that, said first parameter being a defined P-wave of said sensed signal.

Typically, said pre-configured thresholds comprise at least an energy threshold value for said first parameter, characterized in that, said first parameter being a defined P-wave of said sensed signal.

Typically, said guidance mechanism configured to provide a first guidance signal upon breach of said pre-configured thresholds comprise at least an energy threshold value for said first parameter, characterized in that, said first parameter being a defined P-wave of said sensed signal.

In at least one embodiment, said catheter is a peripherally inserted central catheter.

In at least one embodiment, said catheter is a central venous catheter.

Typically, said guidance mechanism configured to provide a first guidance signal indicating that said catheter position is moving closer to heart upon sensing that value of said fourth information item is increasing.

Typically, said guidance mechanism configured to provide a second guidance signal indicating that said catheter position is closest to heart upon sensing that value of said fourth information item has relatively dropped.

Typically, said guidance mechanism configured to provide a first guidance signal indicating that said catheter position is moving closer to heart upon sensing that value of said third information item is in a pre-defined Cartesian direction.

Typically, said guidance mechanism configured to provide a second guidance signal indicating that said catheter position is closest to heart upon sensing that value of said third information item is in a direction opposite to a pre-defined Cartesian direction.

Typically, said guidance mechanism configured to provide a first guidance signal indicating that said catheter position is moving closer to heart upon sensing that value of said first set of computed values is increasing.

Typically, said guidance mechanism configured to provide a second guidance signal indicating that said catheter position is closest to heart upon sensing that value of said first set of computed values has relatively dropped.

BRIEF DESCRIPTION OF THE ACCOMPANYING DRAWINGS:

Figure 1 illustrates a patient connected to electrocardiogram (ECG);

Figure 2 illustrates a sino-atrial (SA) node and ECG P-wave; and

Figure 3 illustrates ECG waveform and heart activity.

The invention will now be described in relation to the accompanying drawings, in which:

Figure 4 illustrates peripherally inserted central catheter (PICC); and

Figure 5 illustrates Visual display of E and S.

DETAILED DESCRIPTION OF THE ACCOMPANYING DRAWINGS:

According to this invention, there is provided **a device and method for accurately navigating at least a catheter and locating the tip of said catheter during vascular access**. Typically, the catheter is a peripherally inserted central catheter (PICC) or central venous catheter (CVC).

SA node is the epicenter of heart electrical activity. In simple words, it is a generator of electrical energy. During a cardiovascular examination of a patient, surface ECG electrodes are connected to the various locations in the body. Electrical energy from the SA node is attenuated significantly when it reaches the surface electrodes.

In accordance with an embodiment of this invention, there is provided a **sensor** positioned at the operative distal tip of a catheter. Typically, this catheter is a PICC or a CVC. When a PICC or CVC is inserted in the body, as shown in **Figure 4** of the accompanying drawings, the tip of the catheter also captures the heart electrical activity. The sensor provides an output of a sensed signal with various components.

This sensed signal is used by this device and method wherein its various components are extracted and used collaboratively to accurately navigate and place the catheter.

In accordance with another embodiment of this invention, there is provided a **signal capturing mechanism** in order to be communicably coupled with an ECG machine. This ECG signal can be seen if the external end of the catheter is connected to an ECG machine. ECG signal generated at heart is significantly attenuated by the body resistance when ECG is captured using a surface electrode. A catheter provides a low resistance path to capture the ECG signal because the distal tip of the catheter is approaching close to heart as the catheter is inserted in the body

Energy transmitted from the SA node is attenuated through the body and reaches the tip of catheter. In order to determine if the catheter is progressing towards the SA node, three parameters are most important: 1) energy captured at the tip of the catheter; 2) rate of change of voltage of P wave; and 3) ratio of P wave peak and R wave peak.

In accordance with yet another embodiment of this invention, a **first extraction mechanism** is configured to extract a first parameter from the sensed signal. Typically, this first parameter is a locus of points which represents or forms a P-wave in an ECG signal. Information relating to this P-wave is extracted and stored for use by this device and method. One set of information items relates to amplitude of the P-wave.

In accordance with still another embodiment of this invention, a **second extraction mechanism** is configured to extract a second parameter from the sensed signal. Typically, this second parameter is a locus of points which represents or forms an R-wave in an ECG signal. Information relating to this R-wave is extracted and stored for use by this device and method. One set of information items relates to amplitude of the R-wave.

In accordance with an additional embodiment of this invention, a **third extraction mechanism** is configured to extract a third parameter from the sensed signal. Typically, this third parameter is rate of change of voltage. Information relating to this voltage is extracted and stored for use by this device and method. Typically, this range of change of voltage refers to slope of P-wave.

In accordance with yet an additional embodiment of this invention, a **fourth extraction mechanism** is configured to extract a fourth parameter from the sensed signal. Typically, this fourth parameter is energy. Information relating to this energy is extracted and stored for use by this device and method.

In accordance with still an additional embodiment of this invention, a **first computation mechanism** is configured to compute ratio of amplitudes of P-wave and R-wave. This provides a first computed set of values relating to ratio of P-wave and R-wave amplitudes, fourth extracted set of values relating to energy of P-wave over a pre-defined time period, and third extracted set of values relating to slope of P-wave.

Thus, three components are used in accurately navigation and locating the catheter device of this invention, the three components being:

- Energy (E): average energy of the P wave over several seconds
- Slope (S): rate of change of voltage of the P wave
- Ratio (R): Ratio of P wave amplitude and R wave

In accordance with another additional embodiment of this invention, a **second computation mechanism** is configured to convert the first computed set of values, the fourth extracted set of values, and the third extracted set of values in to at least a visual guide for navigating the catheter device.

In accordance with another additional embodiment of this invention, a **third computation mechanism** is configured to convert the first computed set of values, the fourth extracted set of values, and the third extracted set of values in to at least an audible guide for navigating the catheter device. Typically, the audible guide comprises an audio guidance beep.

The computed values of E, S, and R are used and converted to provide visual and audible guidance or other guidance in terms of guide signals to doctors using the device and catheter of this invention as shown in **Figure 5** of the accompanying drawings.

The visual aid provides average energy level of each sample (taken over several seconds). In this figure, each bar represents the energy for one sample. The time scale is from left to right. As the catheter approaches the SA node, the energy captured at the catheter increases. If the catheter deviates and moves in a different direction away from SA node, the energy captured goes down and the resultant bar size decreases.

When the catheter tip is far from SA node, the audio guidance beep is low frequency and amplitude and is repeated at a lower rate. As the tip of the catheter progresses towards the SA node, both the frequency and amplitude of the audio guidance beep increases and rate of the beep also increases. When the tip of the catheter has reached the destination point, audio guidance beep stays on continuously. Energy of the P wave is always positive and increases, as the catheter gets closer to the SA node. Initially, the slope of P wave is positive when catheter is moving closer to the SA node. When the catheter goes past the SA node, the slope changes from positive to negative. Ratio of P and R wave amplitude is initially very small when catheter is inserted and then it starts to increase as catheter moves closer to SA node. Finally, the ratio become very close to 1 and may even exceed 1. The method of this invention combines these extracted parameters and computed values to provide navigational aid and location determination.

The object of the device of this invention is to provide precise indication that the catheter communicably coupled to it has reached close to the heart. In accordance with the above explanation, one way of determination is based on change in slope of P-wave from positive to negative and / or change in energy level of P-wave. As the catheter moves closer to heart, energy level of the P-wave continues to increase and once the tip of the catheter has reached a point closest to the heart, there is a sudden drop in energy level of P-wave and / or slope of the P-wave changes from positive to negative. Slope change is relative, i.e. if it is assumed that the original slope is positive, then at the point closest to the heart, the direction of slope changes and vice versa. P-wave to R-wave amplitude ratio also exhibits similar behavior, as well. Initially, it continuously increases in value and then suddenly declines. Using these 3 parameters, cumulatively gives a very accurate indication that tip of the catheter has reached a point closest to the heart; in other words, the catheter is accurately placed.

From the time, a catheter is inserted in to a patient, the P-wave to R-wave amplitude ratio is a monotonically increasing function. This behaviour stops when the catheter has reached the closest point to the heart. At this point, the P-wave to R-wave amplitude ratio falls suddenly.

This sudden change is seen in the slope of P-wave as well. Initially, the slope is monotonically increasing, as the catheter is moving towards the heart, and then when the catheter is located closest to the heart, there is sudden change from positive slope to negative slope.

The same behaviour is repeated with the energy function as well. Initially, as the catheter is moving towards the heart, P-wave energy is a monotonically increasing function and once the catheter has reached the point closest to the heart, there is a sudden drop in energy level of P-wave.

The **TECHNICAL ADVANCEMENT** of this invention lies in providing a catheter and a method which uses multiple parameters of an ECG signal for its accurate navigation and positioning. In this invention, the use of energy and rate of change of voltage of ECG signal is presented as a superior means of navigation and location of the tip of a catheter, typically of a peripherally inserted central catheter (PICC) or of a central venous catheter (CVC) during central venous access. The use of two parameters for navigation and location of the catheter has not been performed in the prior art. This method is significantly simpler than X-ray, ultrasound or fluoroscopy. The ECG method proposed herein is a cost-effective alternative to the standard radiological control of the location of the tip of any central venous access device (VAD). This method has the potential to become the de-facto standard for navigation and for providing optimum location of the tip position during PICC or CVC insertion.

While this detailed description has disclosed certain specific embodiments for illustrative purposes, various modifications will be apparent to those skilled in the art which do not constitute departures from the spirit and scope of the invention as defined in the following claims, and it is to be distinctly understood that the foregoing descriptive matter is to be interpreted merely as illustrative of the invention and not as a limitation.

CLAIMS,

1. A device for accurately navigating at least a catheter and locating the tip of said catheter during vascular access, said device comprising:
   - a sensor positioned at the operative distal tip of said catheter;
   - a signal capturing mechanism configured to be communicably coupled with an ECG machine and said sensor in order to capture heart electrical activity in terms of sensed signals;
   - a first extraction mechanism configured to extract a first information item from a first parameter from said sensed signal, said first parameter being a locus of points which forms a P-wave in an ECG signal, said first information item being pre-defined information item related to said first parameter;
   - a second extraction mechanism configured to extract a second information item from a second parameter from said sensed signal, said second parameter being a locus of points which forms an R-wave in an ECG signal, said second information item being pre-defined information item related to said second parameter;
   - a third extraction mechanism configured to extract a third information item from said first parameter from said sensed signal;
   - - a fourth extraction mechanism configured to extract a fourth information item from said first parameter from said sensed signal;
   - a first computation mechanism configured to compute ratio of said first information item and said second information item in order to provide a first computed set of values; and
   - at least a guidance mechanism configured to provide a set of guidance signals in relation to pre-configured threshold values relating to each of said first set of computed values, said third information item, and said fourth information item,

characterised in that, said guidance signals comprising at least a first guidance signal if any combination comprising said first set of computed values, said third information item, and said fourth information item is within said pre-configured threshold values and said guidance signals comprising at least a second guidance signal if any combination comprising said first set of computed values, said third information item, and said fourth information item is outside said pre-configured threshold values.

2. A device as claimed in claim 1 wherein, said first pre-defined information item amplitude of the P-wave.

3. A device as claimed in claim 1 wherein, said second pre-defined information item being amplitude of the R-wave.

4. A device as claimed in claim 1 wherein, said third information item being rate of change of voltage.

5. A device as claimed in claim 1 wherein, said third information item being slope of P-wave.

6. A device as claimed in claim 1 wherein, said fourth information item being energy of P wave.

7. A device as claimed in claim 1 wherein, said first set of computed values comprising ratio of P-wave and R-wave amplitudes.

8. A device as claimed in claim 1 wherein, said guidance mechanism is a visual

guide configured to provide at least a visual guidance signal for navigating said catheter device.

9. A device as claimed in claim 1 wherein, said guidance mechanism is an audio guide configured to provide at least an audio guidance signal for navigating said catheter device.

10. A device as claimed in claim 1 wherein, said pre-configured thresholds comprise at least an amplitude threshold value for said first parameter, characterized in that, said first parameter being a defined P-wave of said sensed signal.

11. A device as claimed in claim 1 wherein, said pre-configured thresholds comprise at least an amplitude threshold value for said second parameter, characterized in that, said second parameter being a defined R-wave of said sensed signal.

12. A device as claimed in claim 1 wherein, said pre-configured thresholds comprise at least a slope threshold value for said first parameter, characterized in that, said first parameter being a defined P-wave of said sensed signal.

13. A device as claimed in claim 1 wherein, said pre-configured thresholds comprise at least an energy threshold value for said first parameter, characterized in that, said first parameter being a defined P-wave of said sensed signal.

14. A device as claimed in claim 1 wherein, said guidance mechanism configured to provide a first guidance signal upon breach of said pre-configured thresholds comprise at least an energy threshold value for said first parameter, characterized in that, said first parameter being a defined P-wave of said sensed signal.

15. A device as claimed in claim 1 wherein, said catheter is a peripherally inserted central catheter.

16. A device as claimed in claim 1 wherein, said catheter is a central venous catheter.

17. A device as claimed in claim 1 wherein, said guidance mechanism configured to provide a first guidance signal indicating that said catheter position is moving closer to heart upon sensing that value of said fourth information item is increasing.

18. A device as claimed in claim 1 wherein, said guidance mechanism configured to provide a second guidance signal indicating that said catheter position is closest to heart upon sensing that value of said fourth information item has relatively dropped.

19. A device as claimed in claim 1 wherein, said guidance mechanism configured to provide a first guidance signal indicating that said catheter position is moving closer to heart upon sensing that value of said third information item is in a pre-defined Cartesian direction.

20. A device as claimed in claim 1 wherein, said guidance mechanism configured to provide a second guidance signal indicating that said catheter position is closest to heart upon sensing that value of said third information item is in a direction opposite to a pre-defined Cartesian direction.

21. A device as claimed in claim 1 wherein, said guidance mechanism configured to

provide a first guidance signal indicating that said catheter position is moving closer to heart upon sensing that value of said first set of computed values is increasing.

22. A device as claimed in claim 1 wherein, said guidance mechanism configured to provide a second guidance signal indicating that said catheter position is closest to heart upon sensing that value of said first set of computed values has relatively dropped.

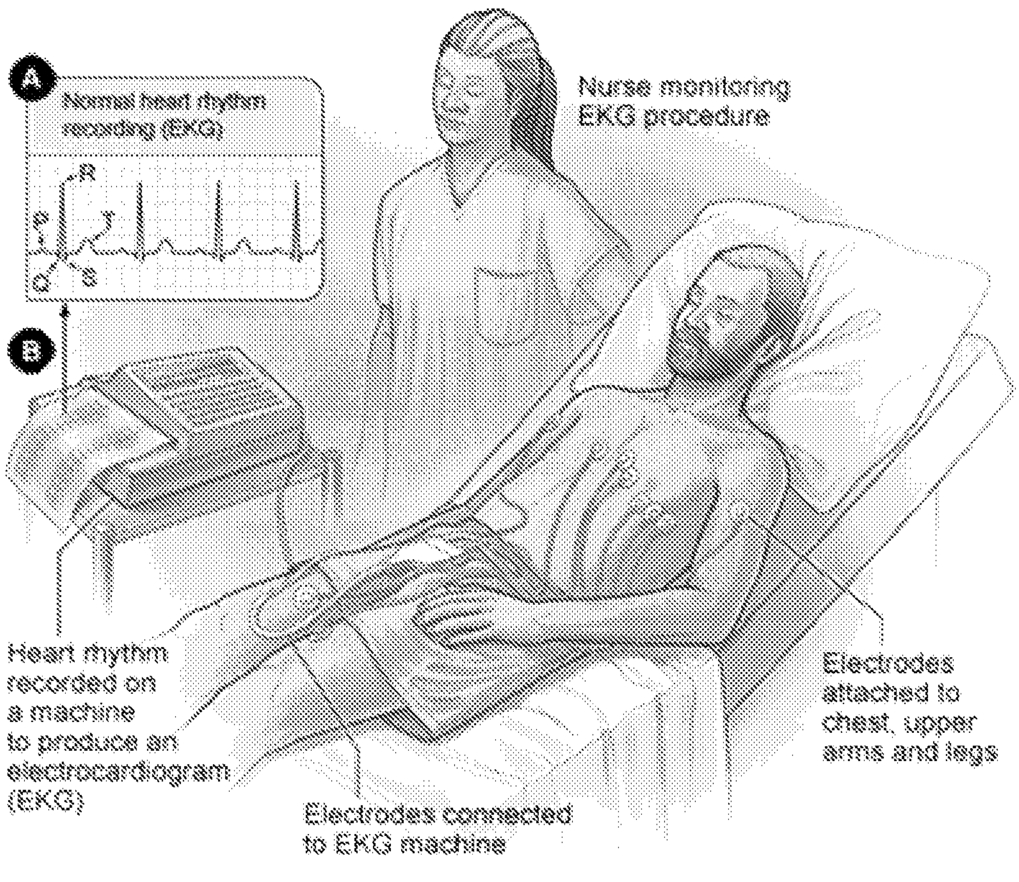
A
Normal heart rhythm recording (EKG)
R
P
T
Q
S
B
Nurse monitoring EKG procedure
Heart rhythm recorded on a machine to produce an electrocardiogram (EKG)
Electrodes connected to EKG machine
Electrodes attached to chest, upper arms and legs

FIGURE 1

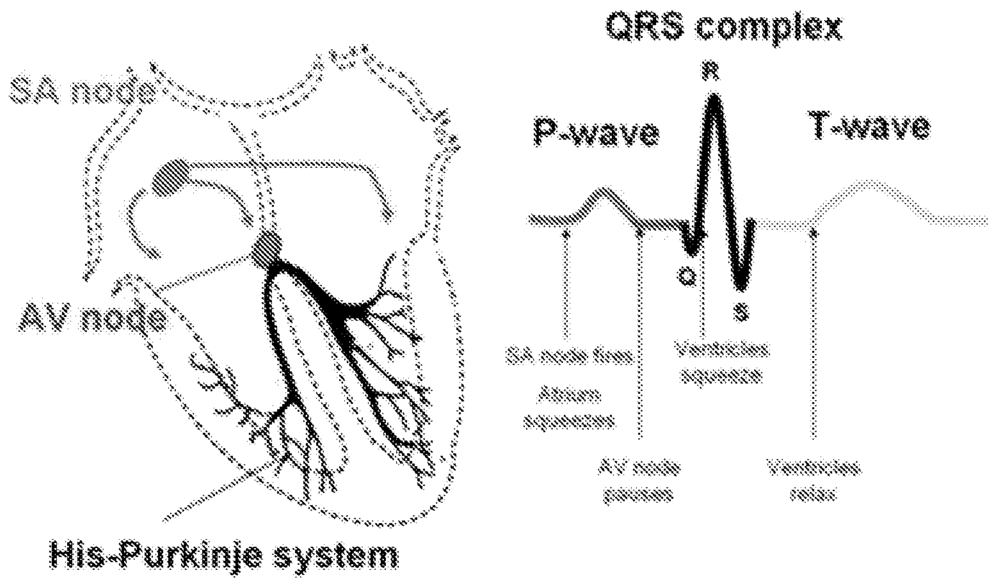
SA node
AV node
His-Purkinje system
QRS complex
R
P-wave
T-wave
Q
S

FIGURE 2

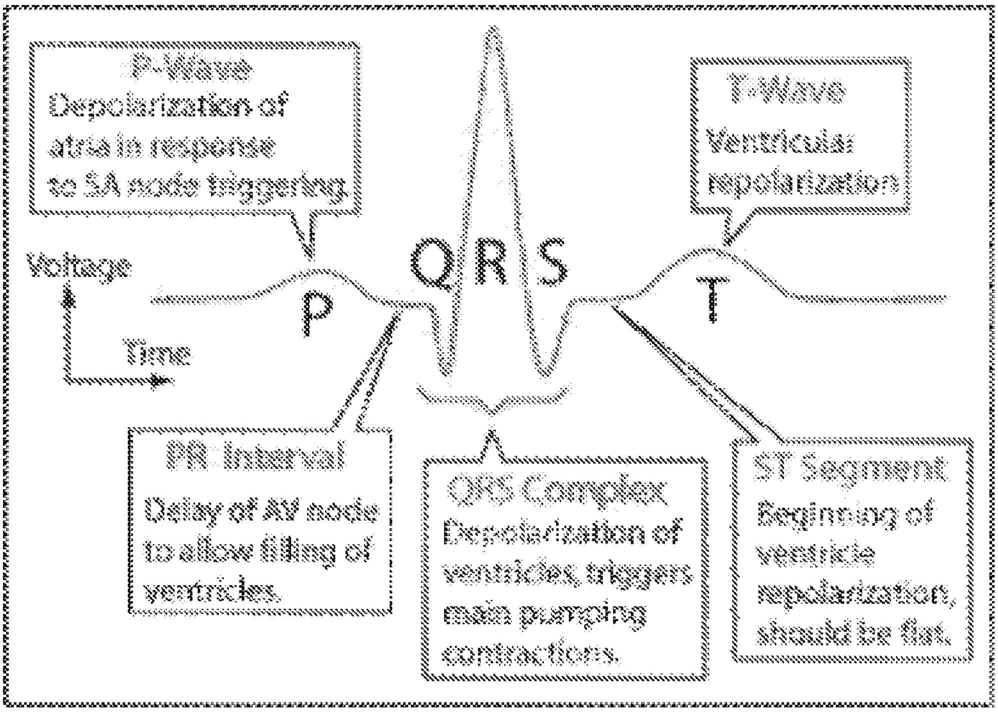
P-Wave
Depolarization of atria in response to SA node triggering.
T-Wave
Ventricular repolarization
Voltage
Time
P
Q
R
S
T
PR Interval
Delay of AV node to allow filling of ventricles.
QRS Complex
Depolarization of ventricles, triggers main pumping contractions.
ST Segment
Beginning of ventricle repolarization, should be flat.

FIGURE 3

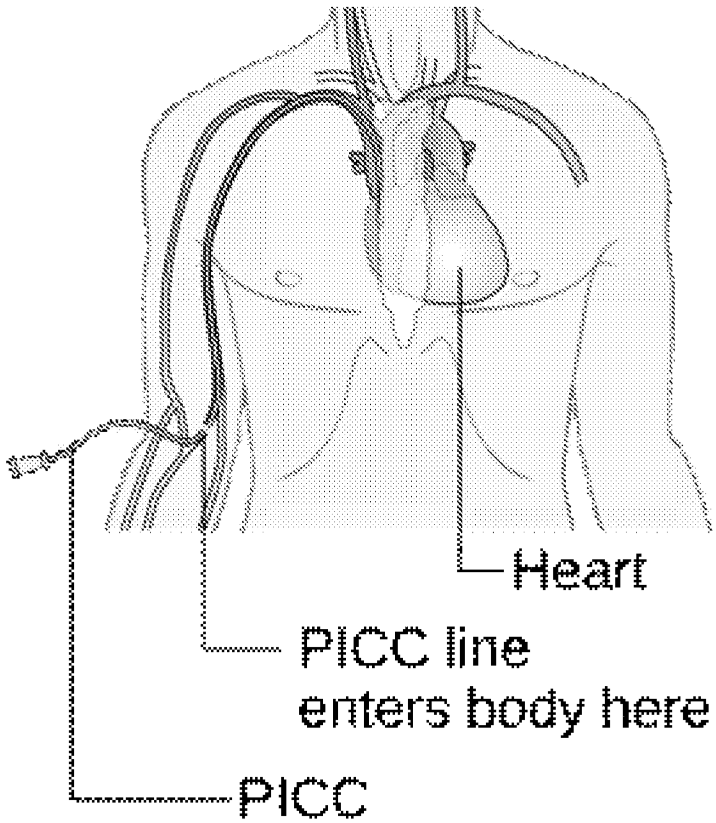

FIGURE 4

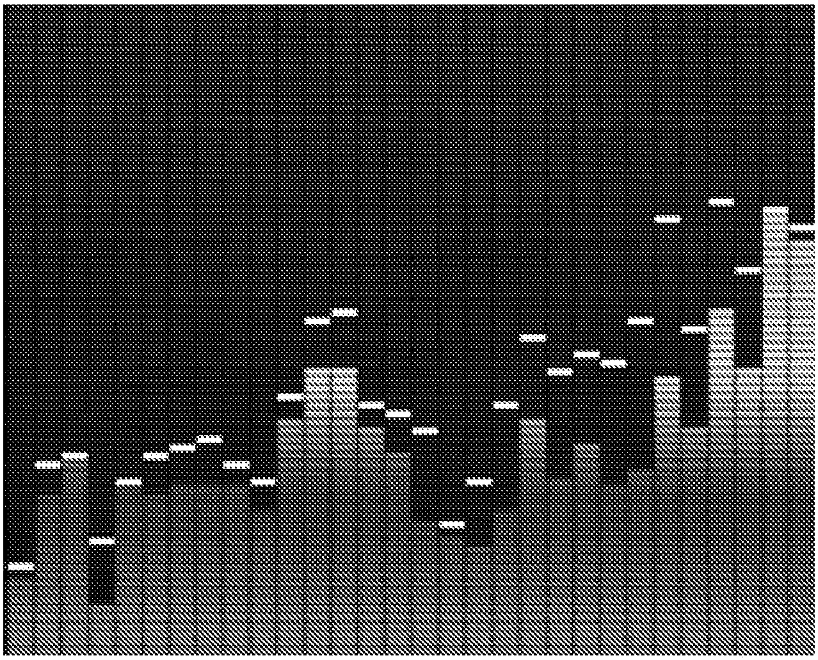

FIGURE 5

INTERNATIONAL SEARCH REPORT

International application No.

PCT/IB2017/050100

A. CLASSIFICATION OF SUBJECT MATTER

A61M 25/095 (2006.01) A61B 5/0452 (2006.01) A61B 5/02 (2006.01)

According to International Patent Classification (IPC)

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61M A61B

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)

FAMPAT/BIOSIS/EMBASE/MEDLINE: Catheter, PICC, CVC, Sensor, Tip, P-wave, R-Wave, ratio, electrocardiography and related terms

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2011/097312 A1 (C.R. BARD, INC.) 11 August 2011 Para 00014, 00061, 00069 – 00072, 00080, 00095, 000100 – 000102, 000113 – 000115, 000130 – 000140 & Fig 11 and 12	1 – 22
X	US 2012/0059270 A1 (GRUNWALD S.) 8 March 2012 Para 0016, 0074, 0080, 0094, 0114, 0129, 0191, 0210, 0238 & Fig 12, 25 – 27	1 – 22
X	WO 2012/064769 A2 (VASONOVA, INC.) 18 May 2012 Entire document, particularly Para 00021, 00027, 00034, 000133, 000146, 000166 – 000172, 000233 – 000236 & 000334	1 – 22
X	WO 2015/120256 A2 (C.R. BARD, INC.) 13 August 2015 Entire document, particularly Para 0002 – 0006, 00035, 00041 – 00062 & Fig 1 – 11	1 – 22
X	US 2015/0289781 A1 (GRUNWALD S. & HUREZAN, I.B.) 15 October 2015 Entire document, particularly Para 0010, 0058, 0079, 0082, 0085 and Fig 1 – 5	1 – 22

☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

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"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

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
18/05/2017 *(day/month/year)*	24/05/2017 *(day/month/year)*

Name and mailing address of the ISA/SG	Authorized officer
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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/IB2017/050100

Note: This Annex lists known patent family members relating to the patent documents cited in this International Search Report. This Authority is in no way liable for these particulars which are merely given for the purpose of information.

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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		EP 3073910 A2	05/10/2016
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