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(54) **MEDICAL DEVICE POSITION LOCATION SYSTEMS, DEVICES AND METHODS**

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A61B 5/044 (2006.01)
A61B 5/00 (2006.01)

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CPC **G01D 5/2006** (2013.01); **A61B 5/042** (2013.01); **A61B 5/062** (2013.01); **A61B 5/065** (2013.01); **G01D 5/2066** (2013.01); **A61B 5/044** (2013.01); **A61B 5/6851** (2013.01); **A61B 5/6852** (2013.01)

(58) **Field of Classification Search**

None
See application file for complete search history.

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Primary Examiner — Katherine L Fernandez

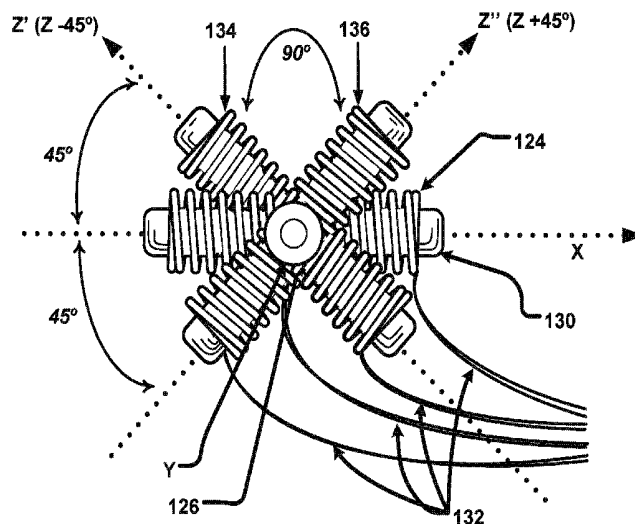
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(57) **ABSTRACT**

Methods, devices and systems for three-dimensional location of the disposition of a sensor coil in a subject including are disclosed. The systems include an array of three or more quadruplet drive coil sets, where each quadruplet drive coil set include at least four discrete drive coils, at least one moveable sensor coil configured to provide one or more sensor coil response signals, a first system component providing AC drive signals to energize the discrete drive coils, a second system component for receiving the one or more sensor coil response signals from the at least one moveable sensor coil, and a processor configured to determine a sensor coil disposition of the at least one moveable sensor coil in the subject relative to the quadruplet drive coil sets based on the one or more sensor coil response signals.

17 Claims, 31 Drawing Sheets



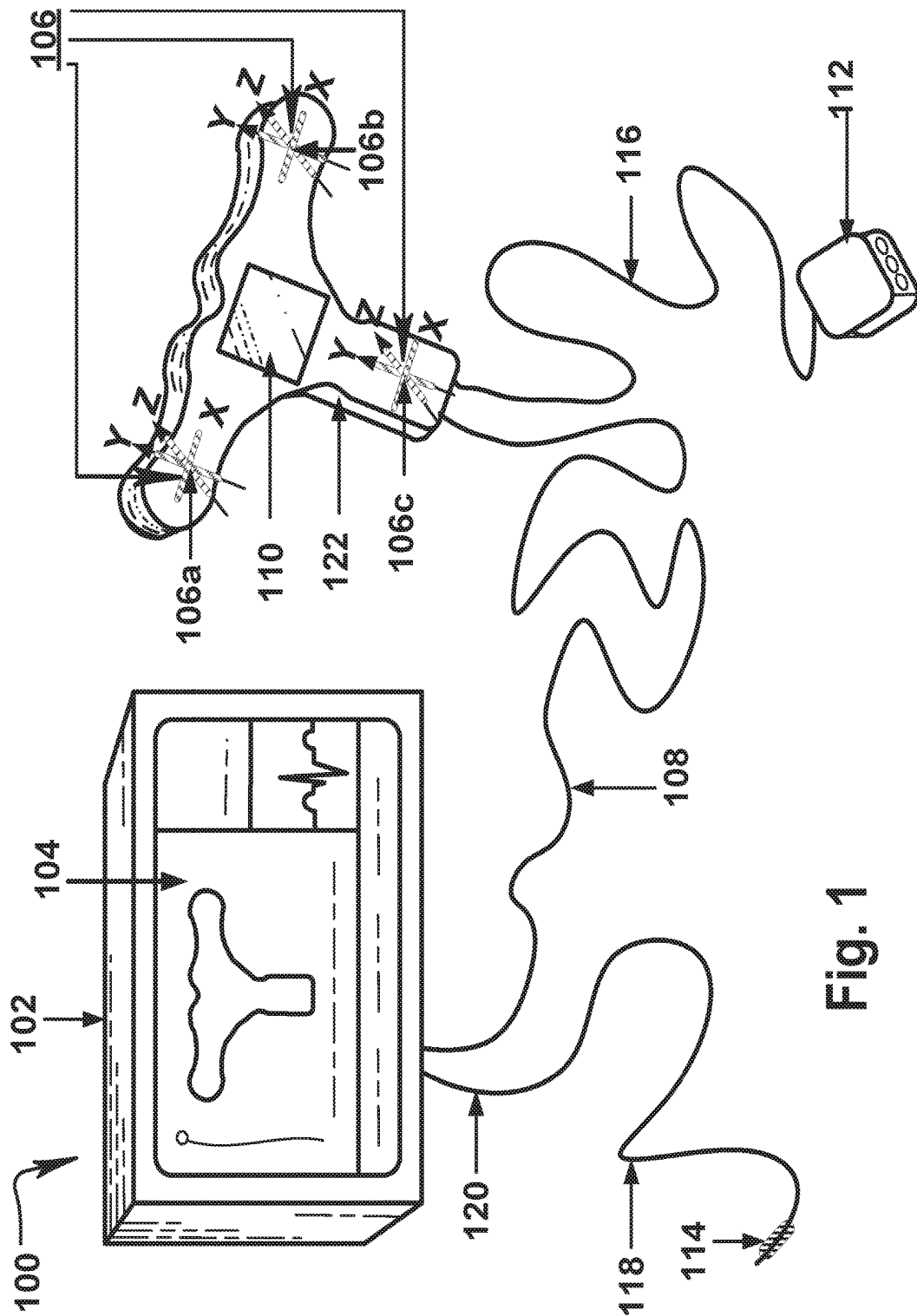
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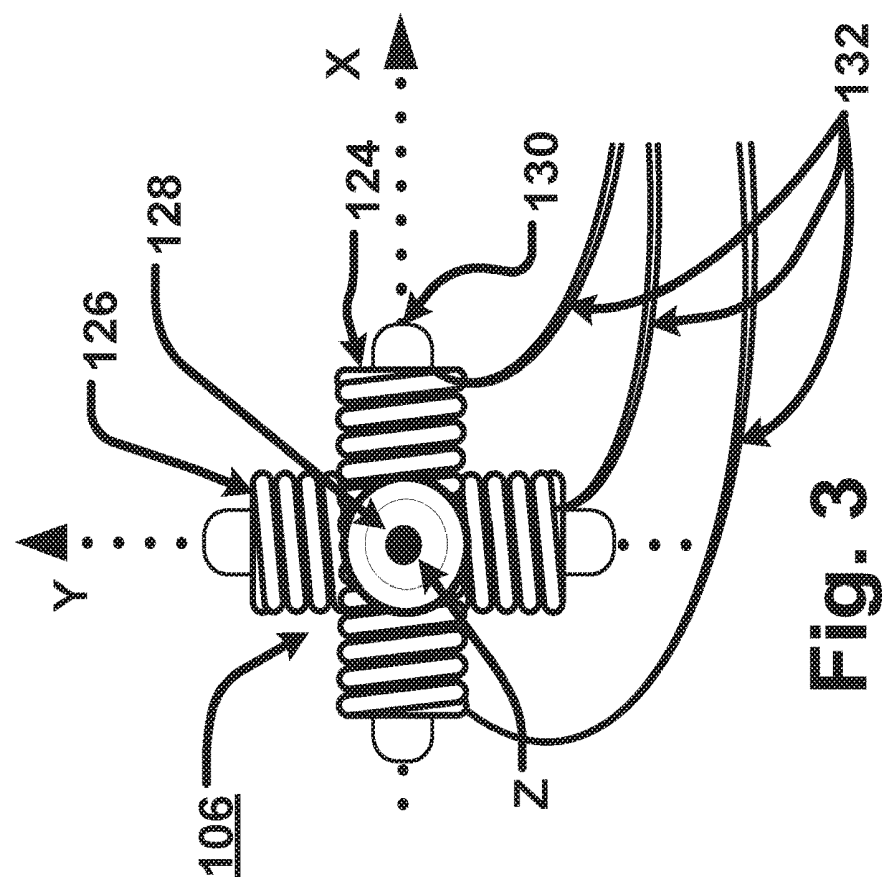


Fig. 2

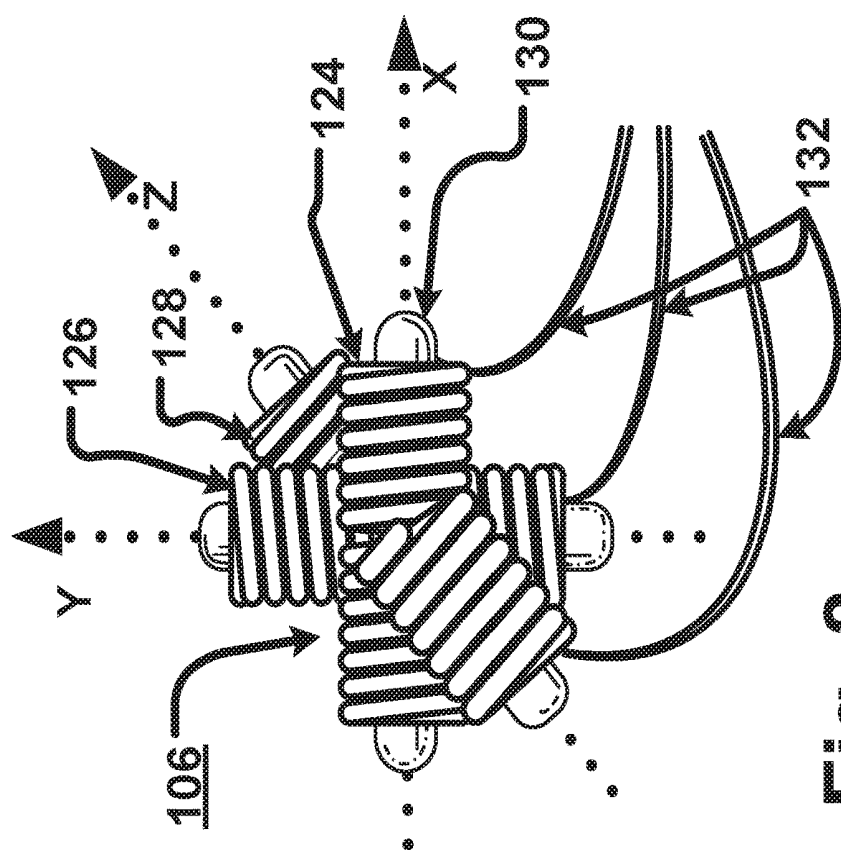
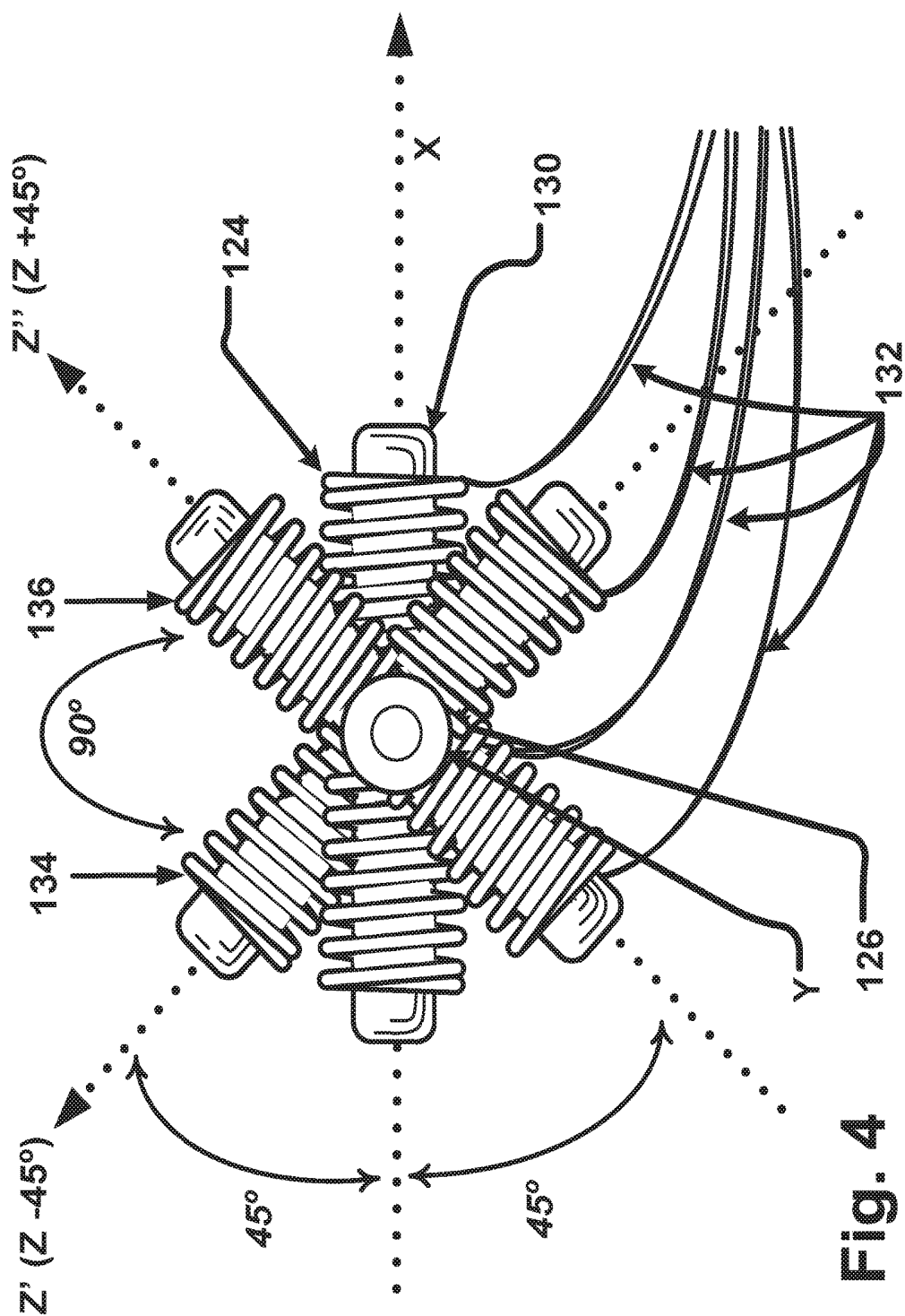
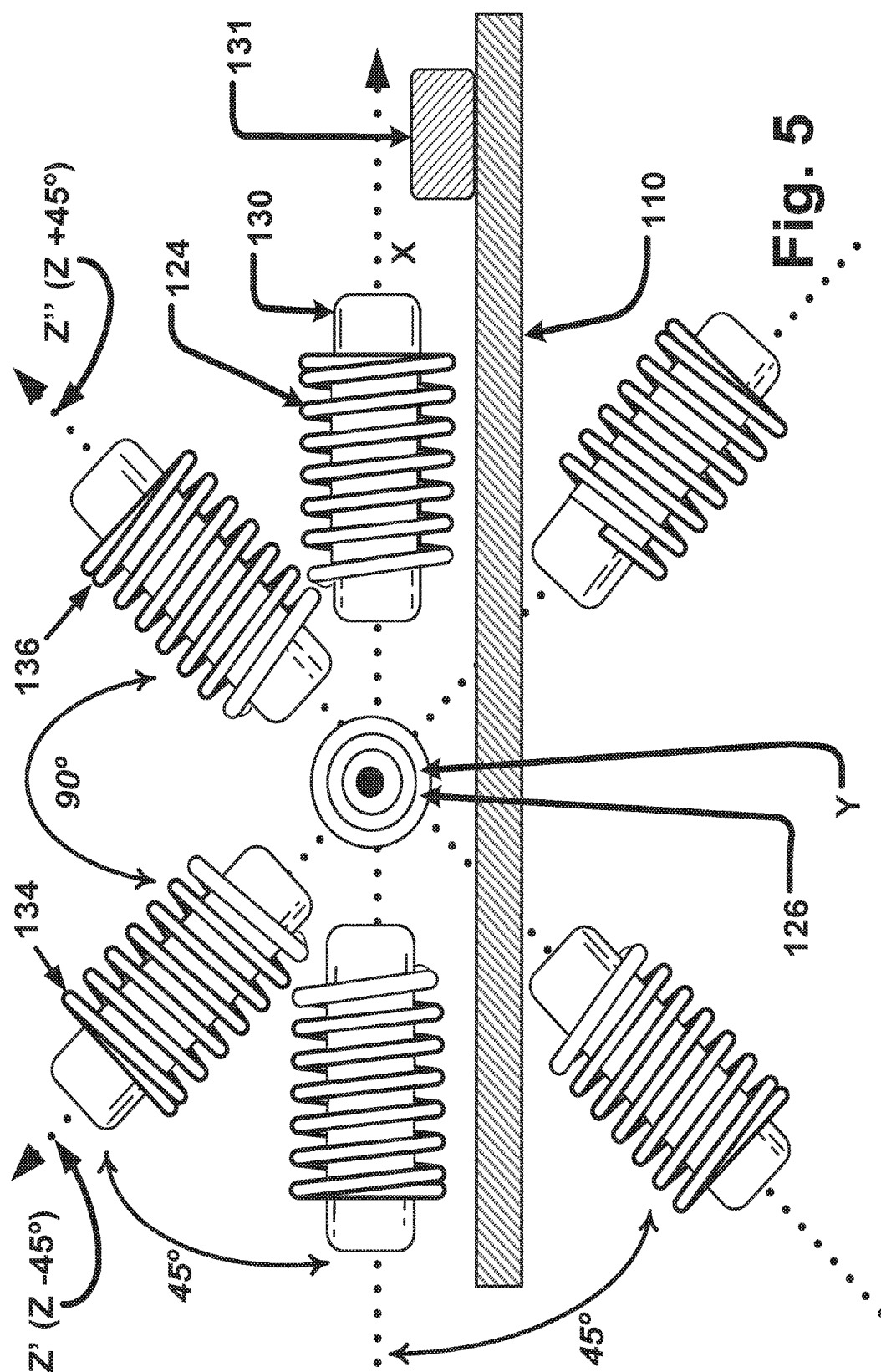
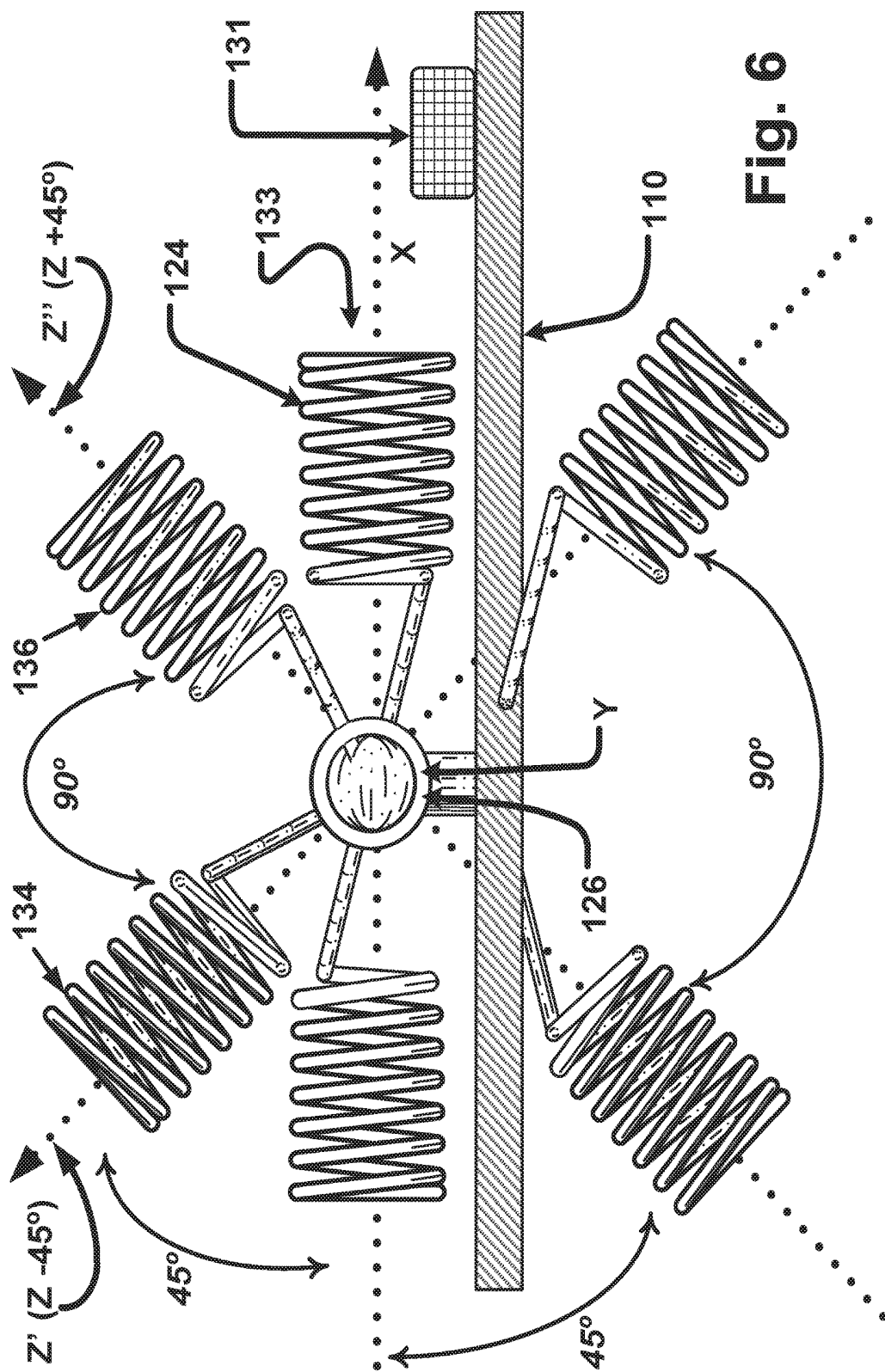


Fig. 3







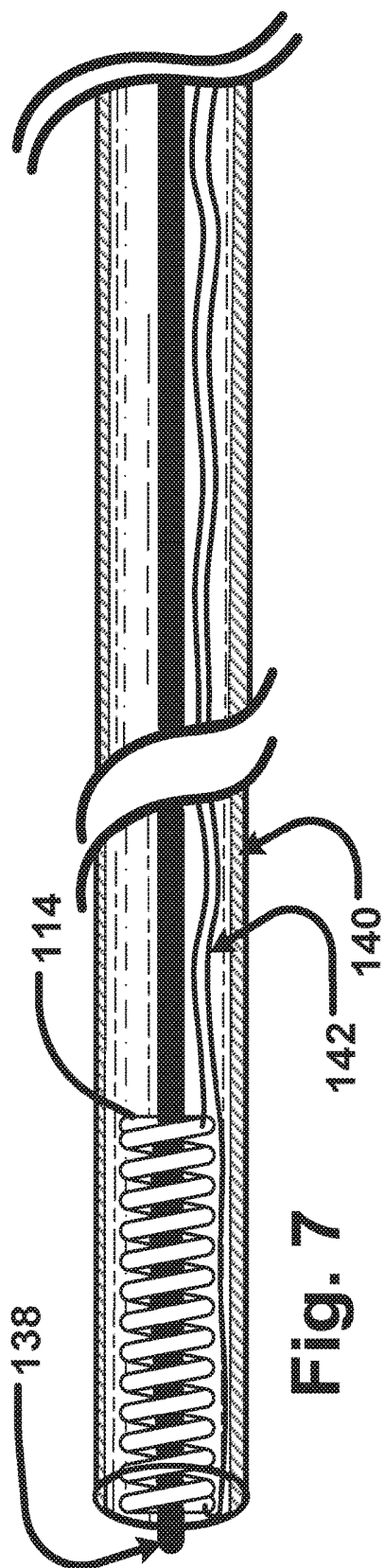


Fig. 7

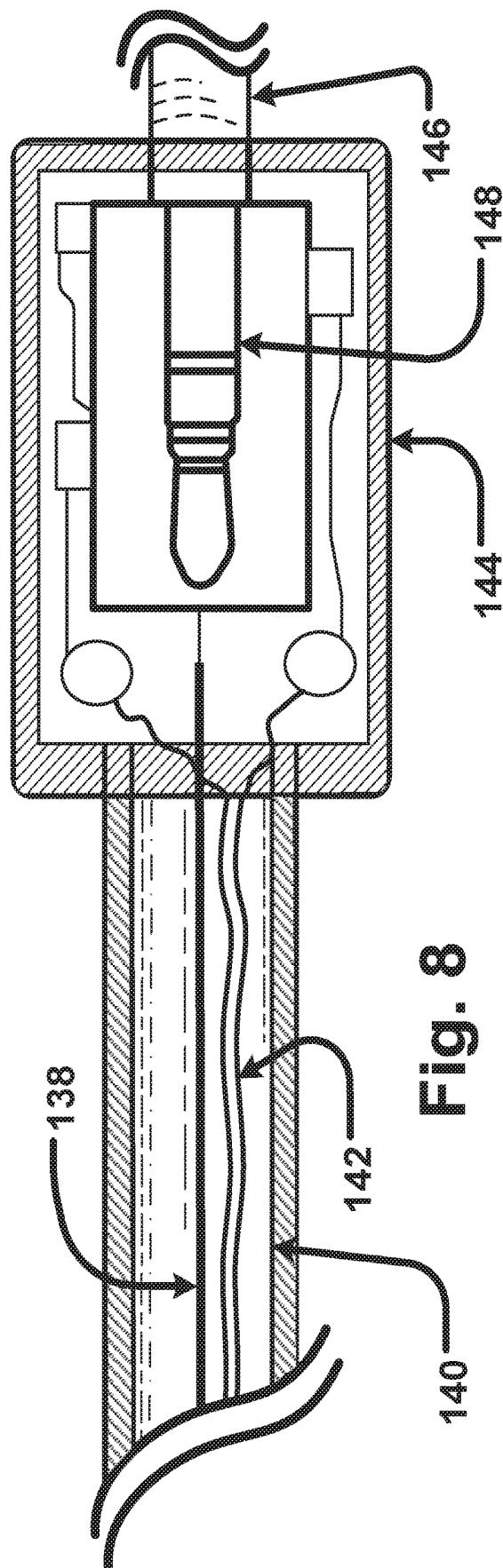


Fig. 8

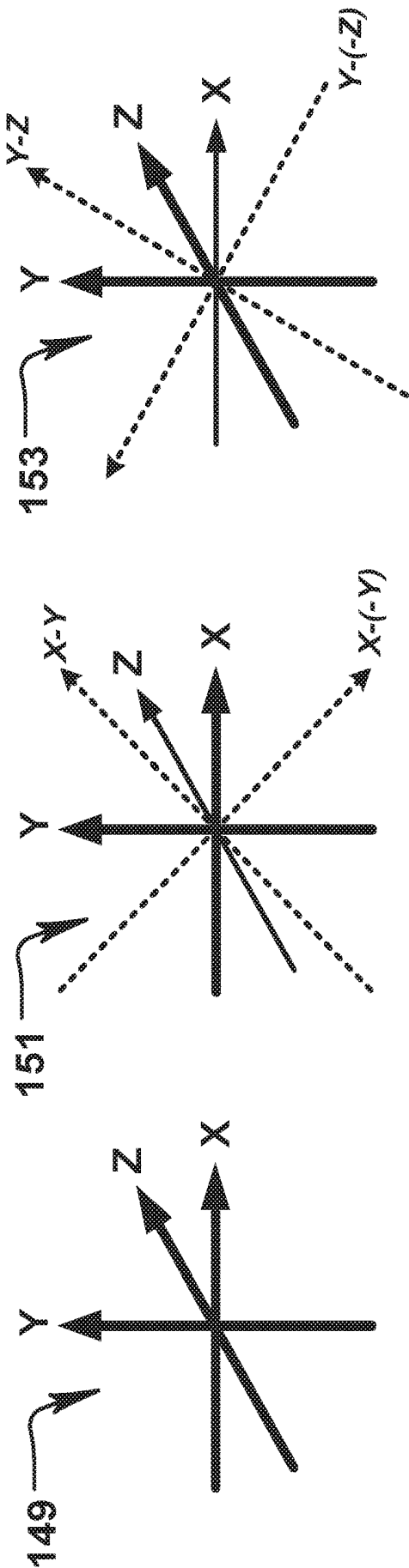


Fig. 9

Fig. 10

Fig. 11

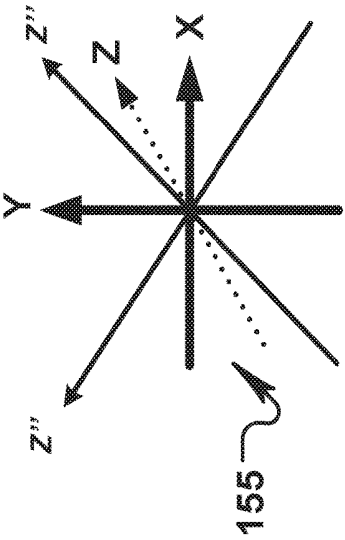


Fig. 13

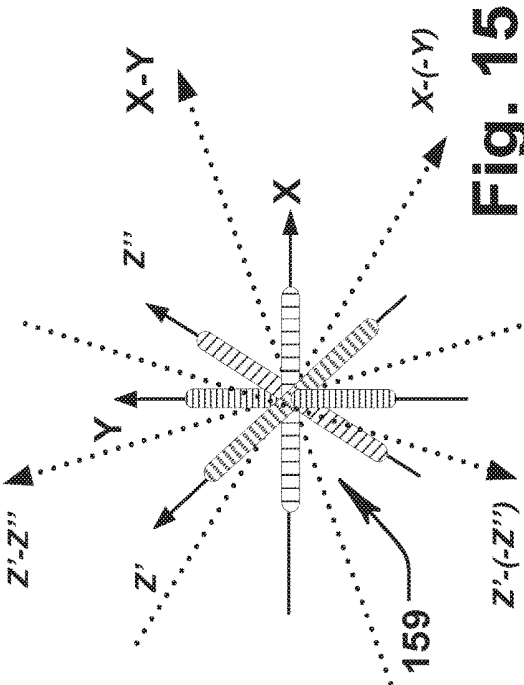


Fig. 15

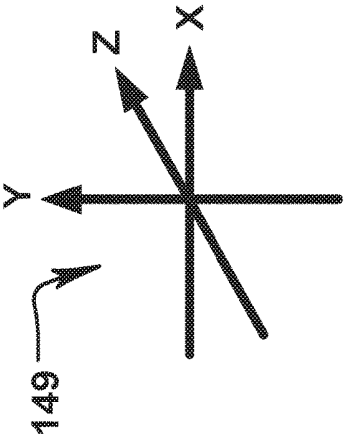


Fig. 12

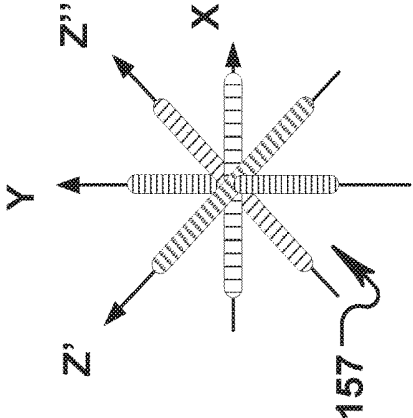
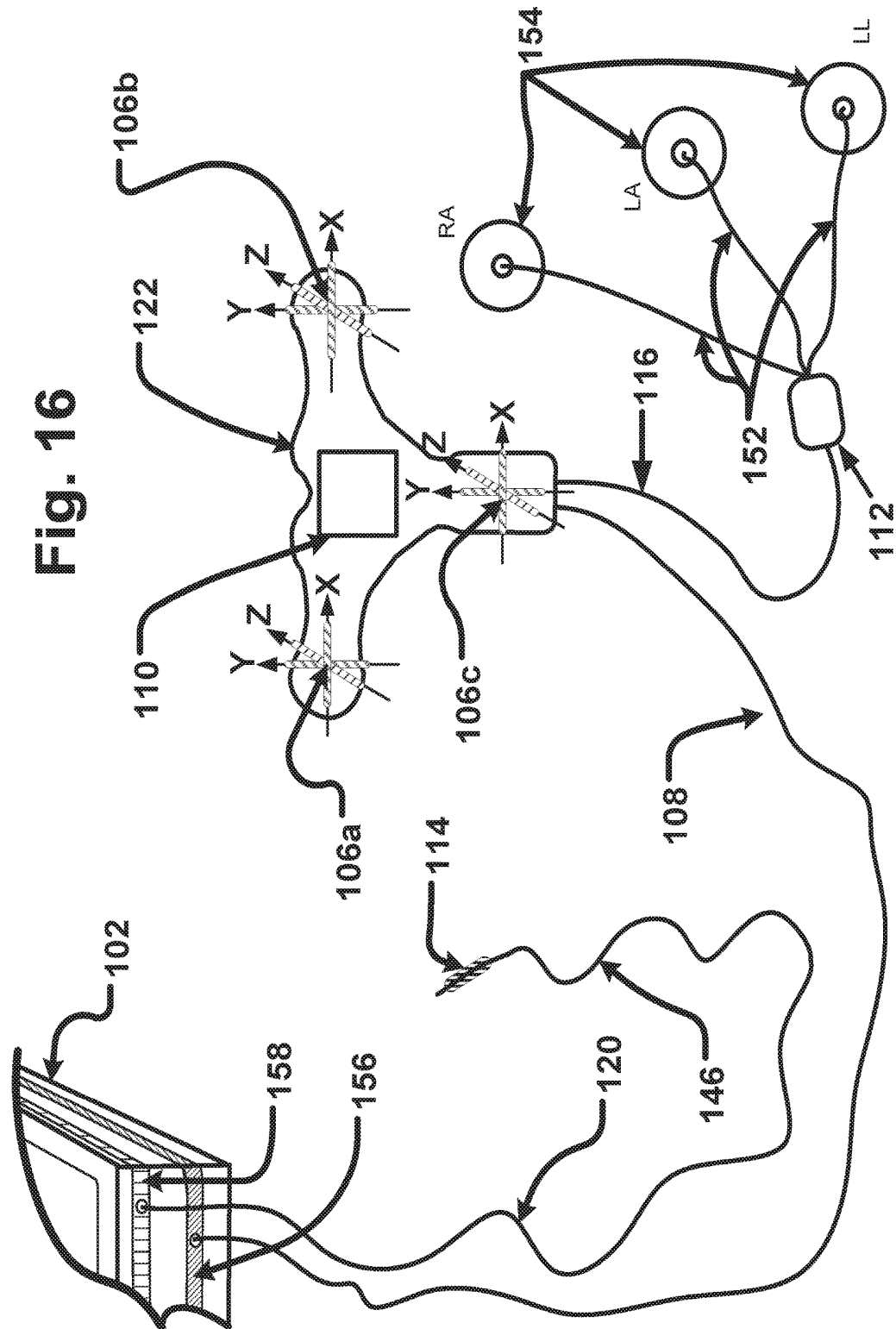


Fig. 14



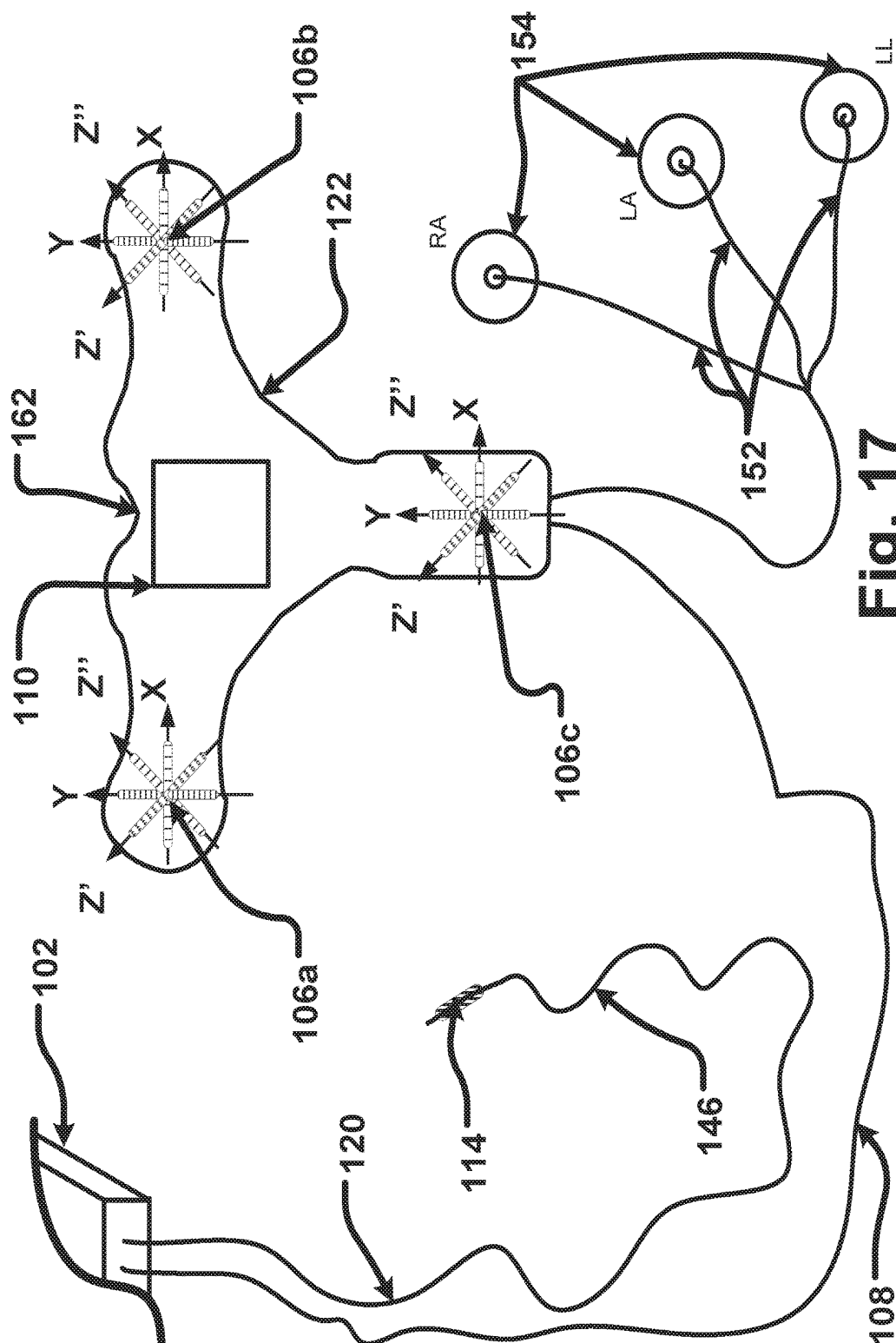
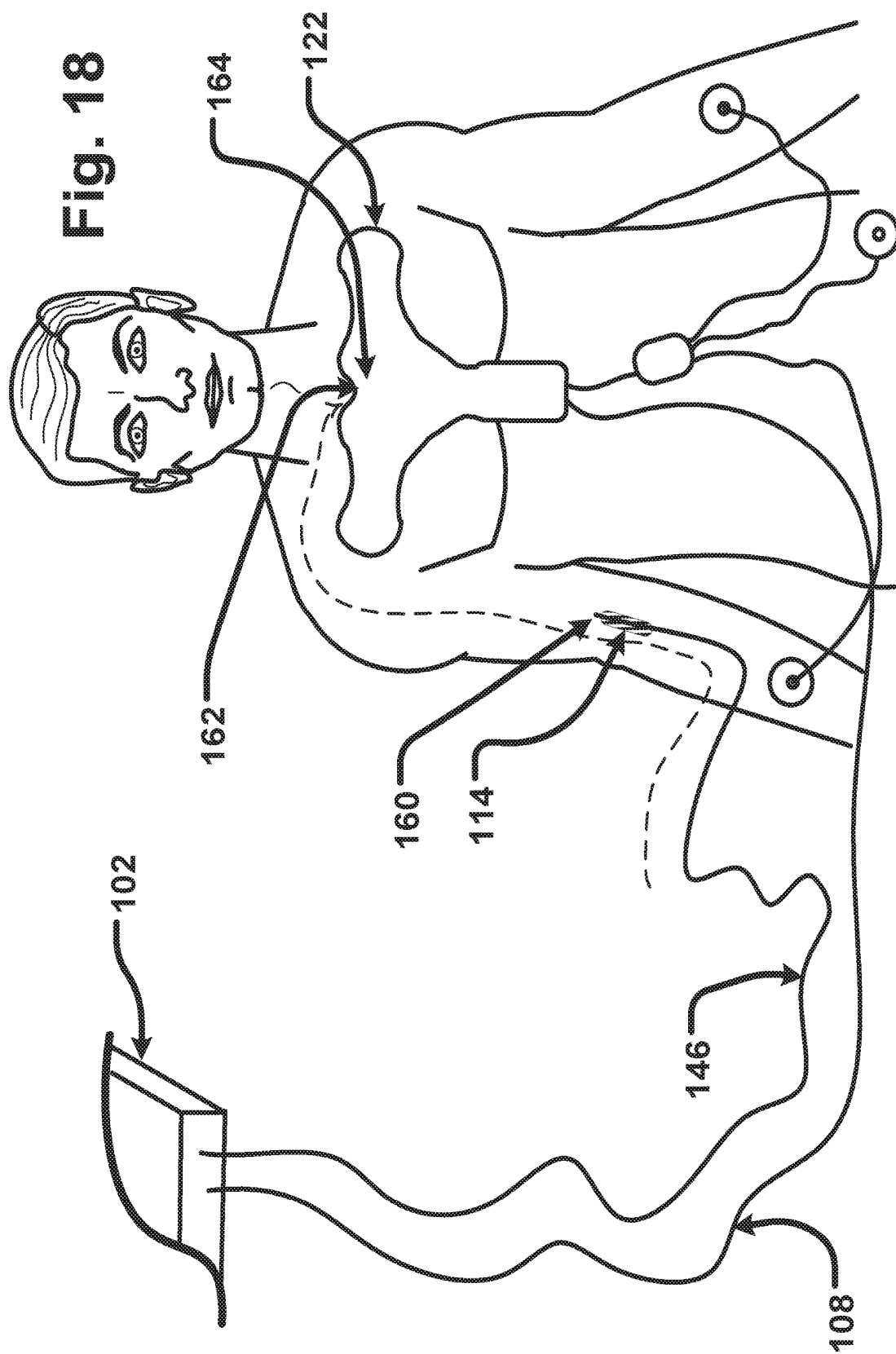


Fig. 17



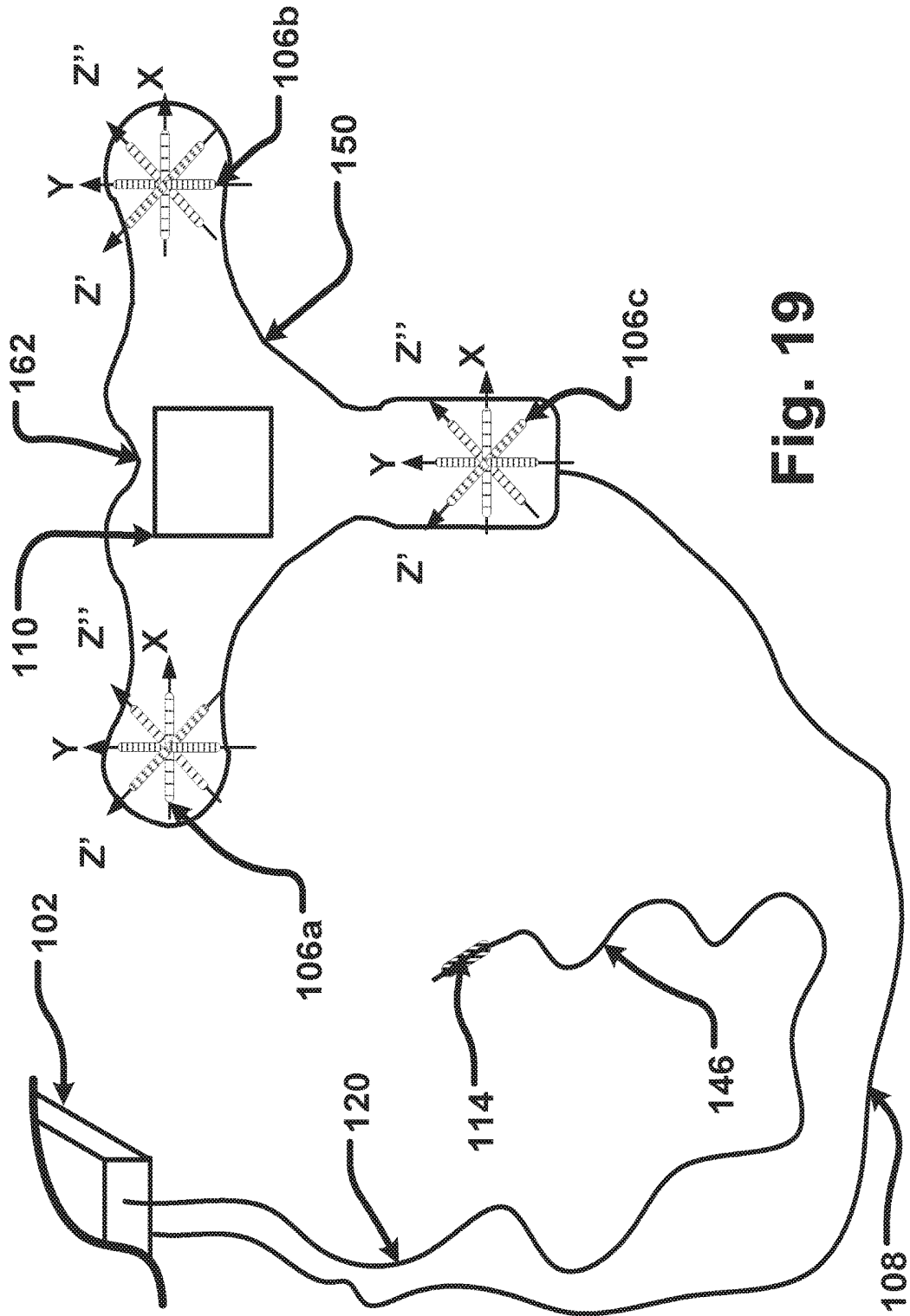


Fig. 19

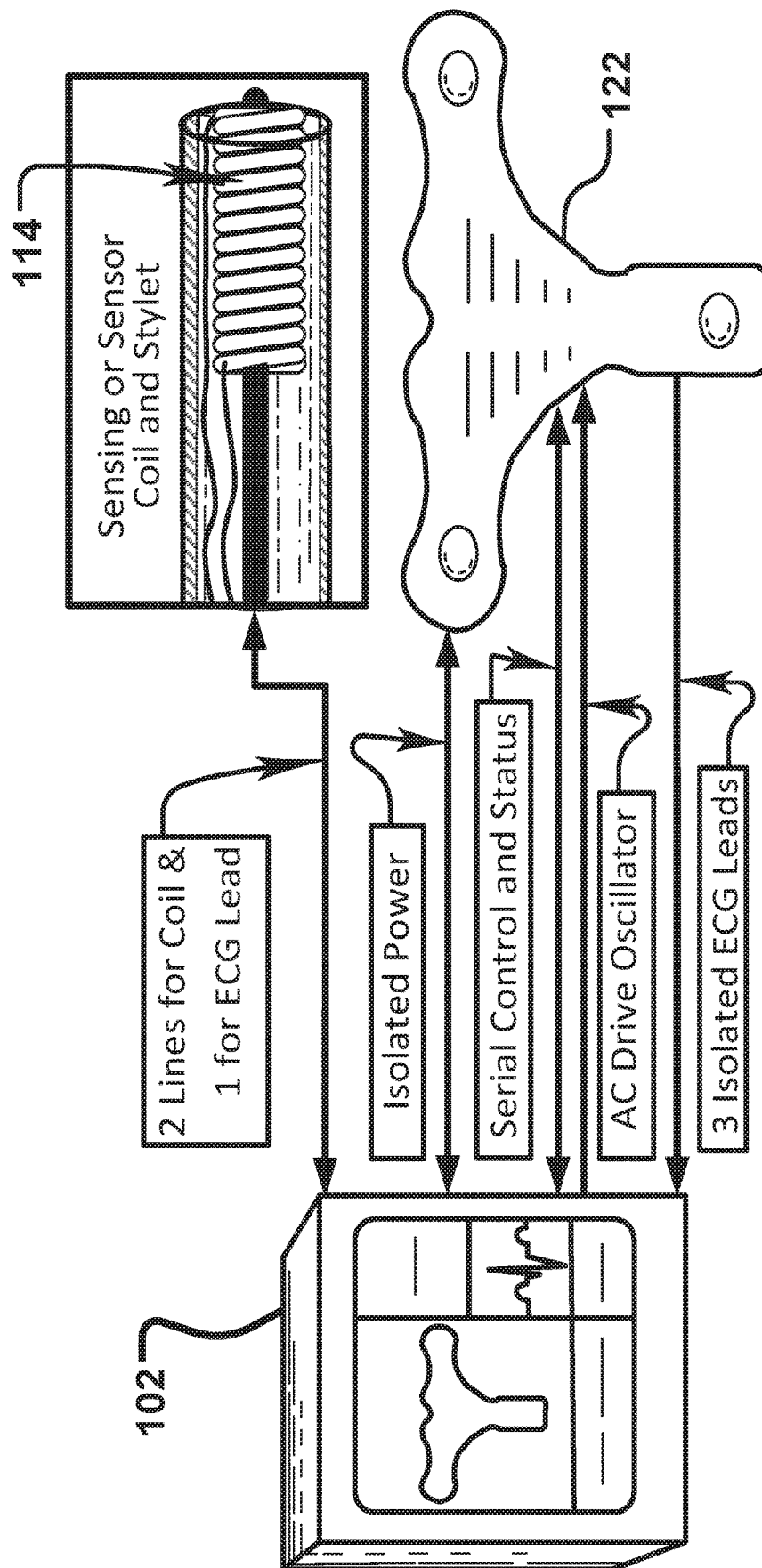
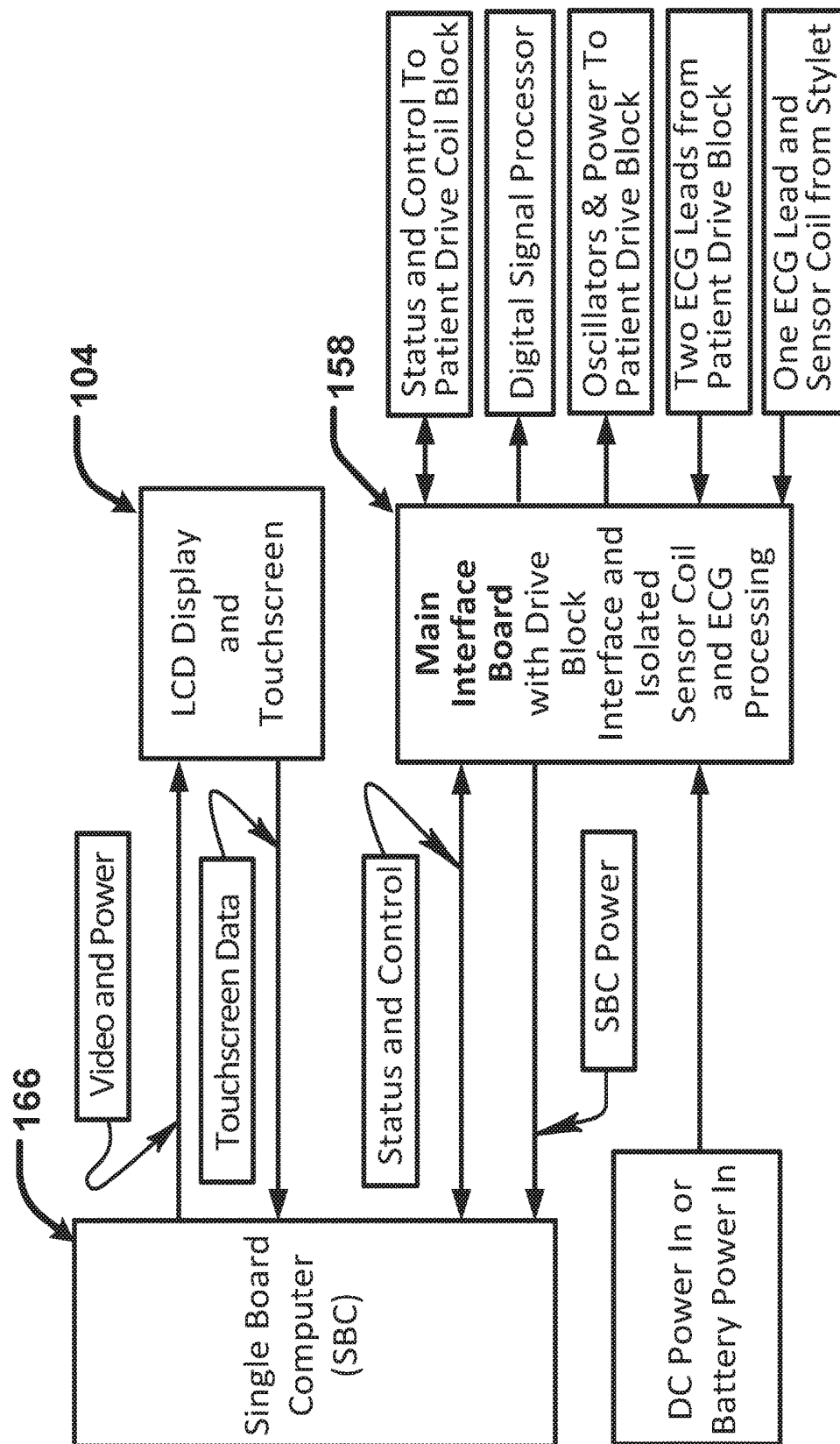


Fig. 20

**Fig. 21**

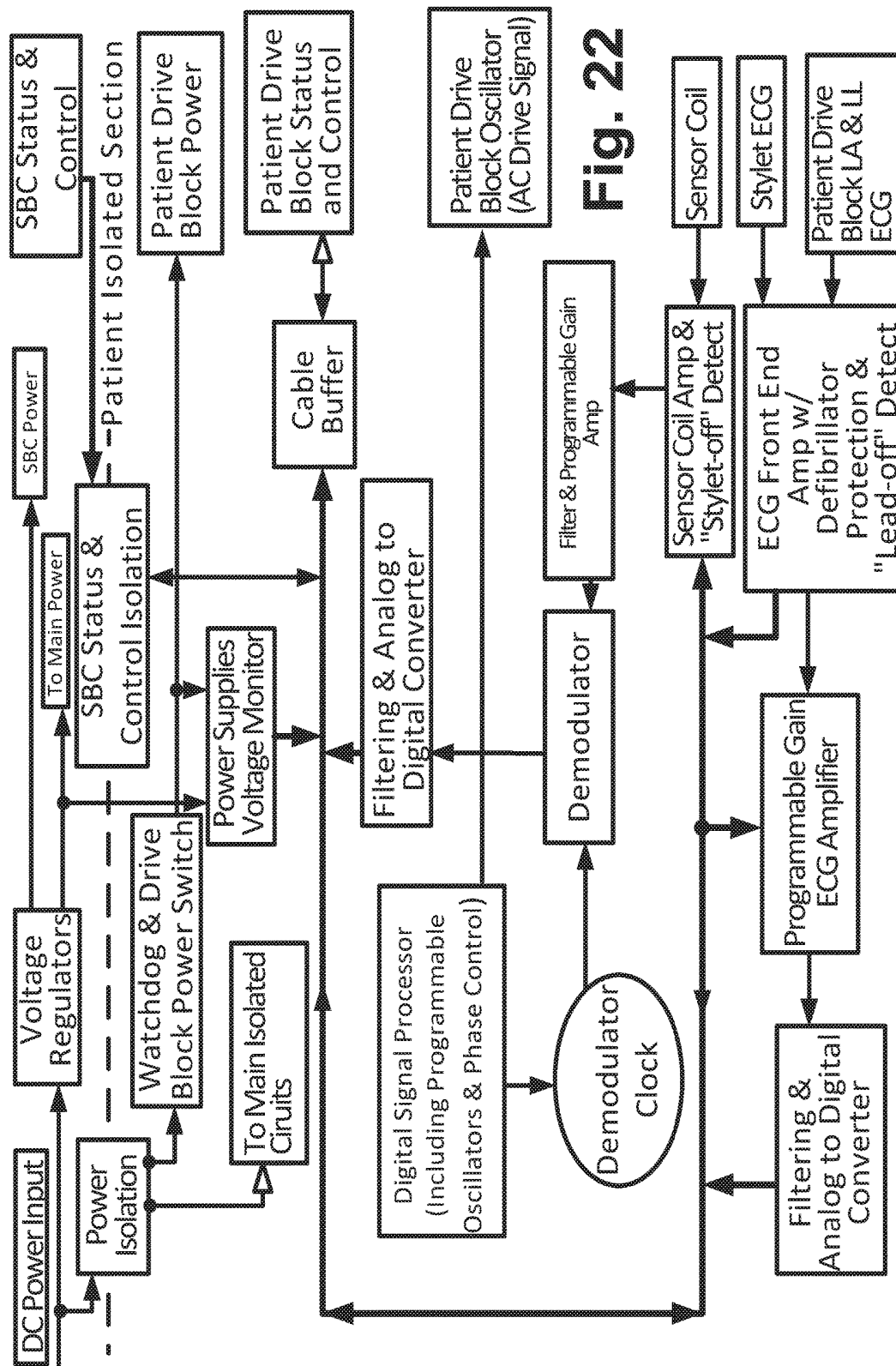
**Fig. 22**

Fig. 23

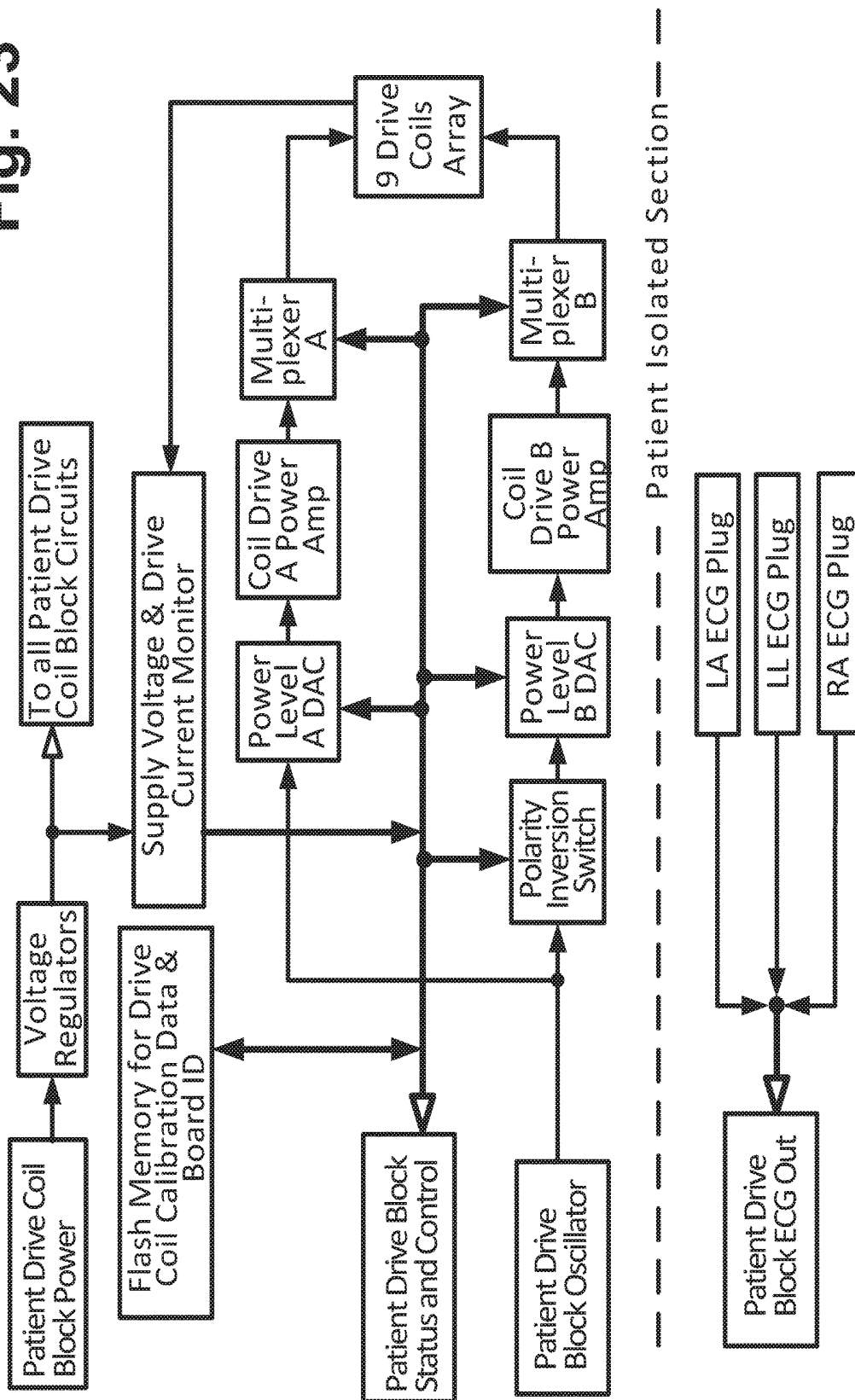
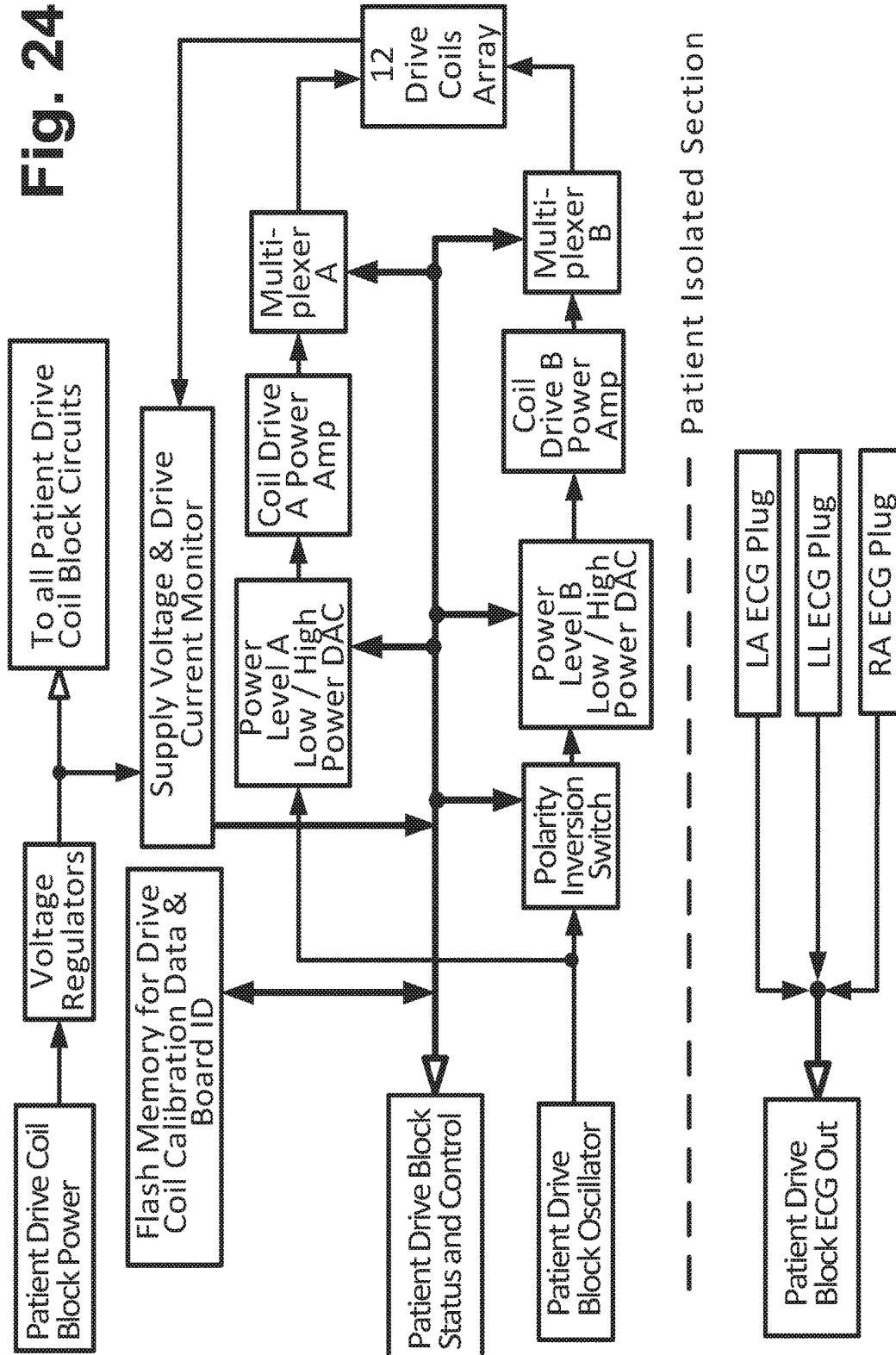
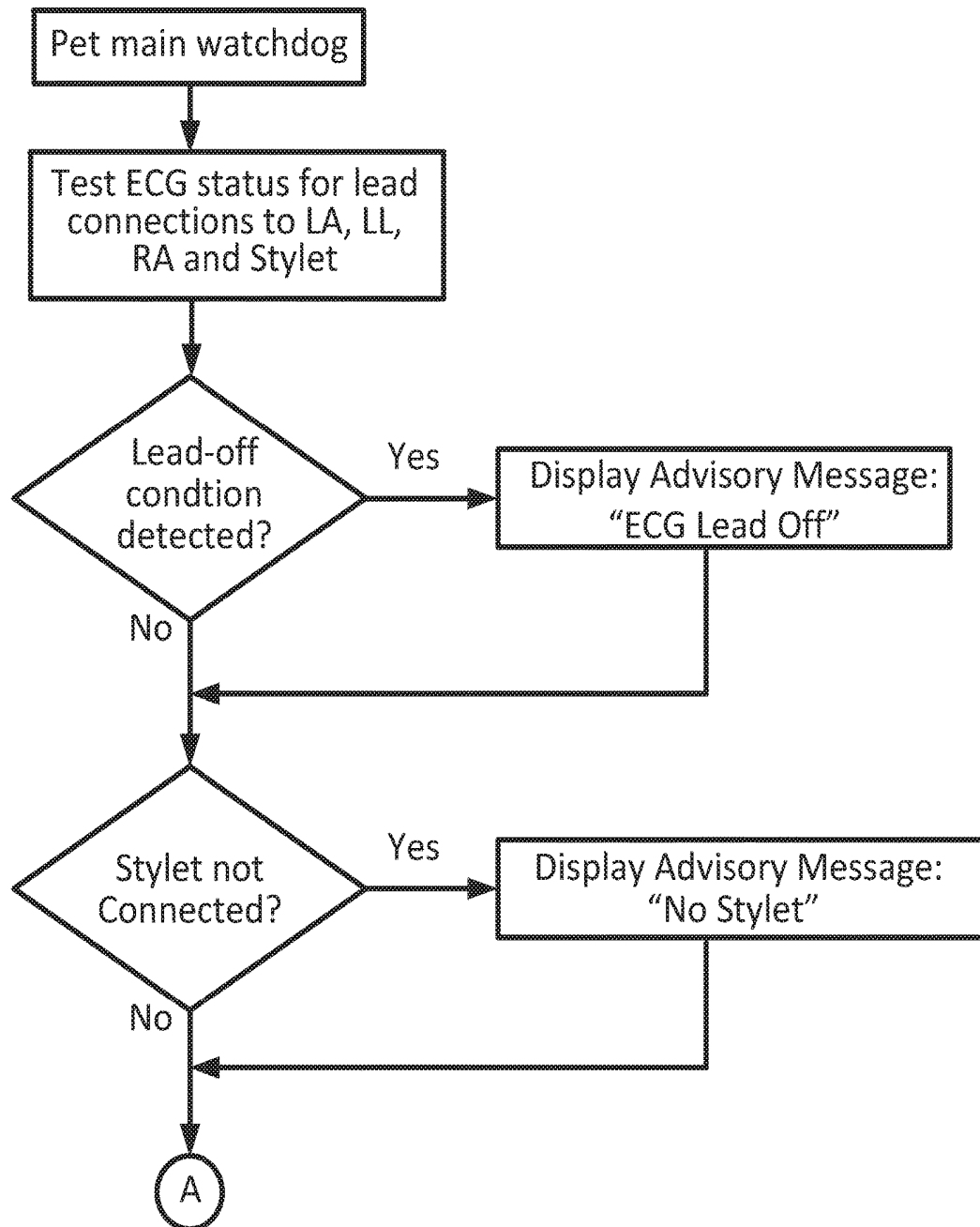


Fig. 24



**Fig. 25a**

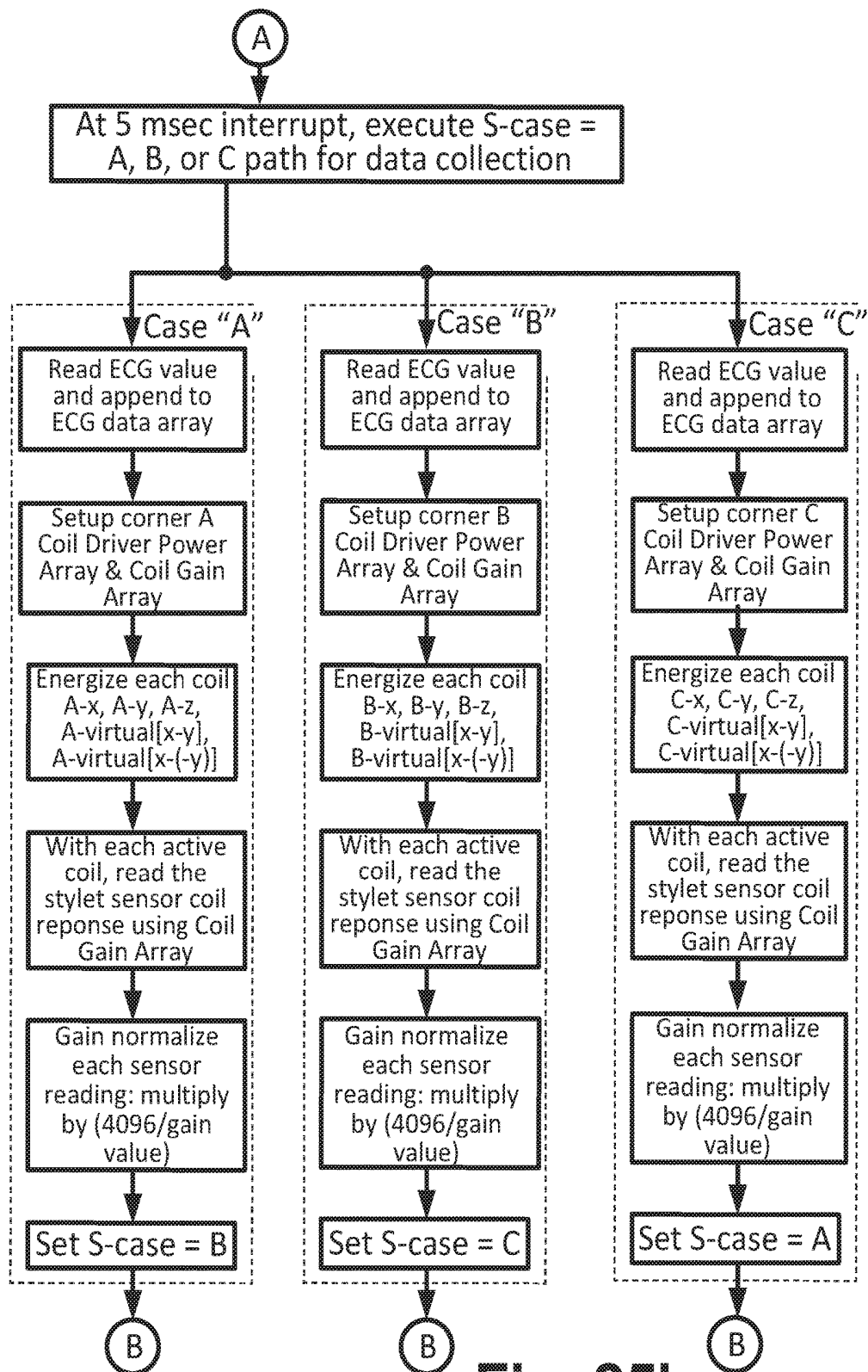


Fig. 25b

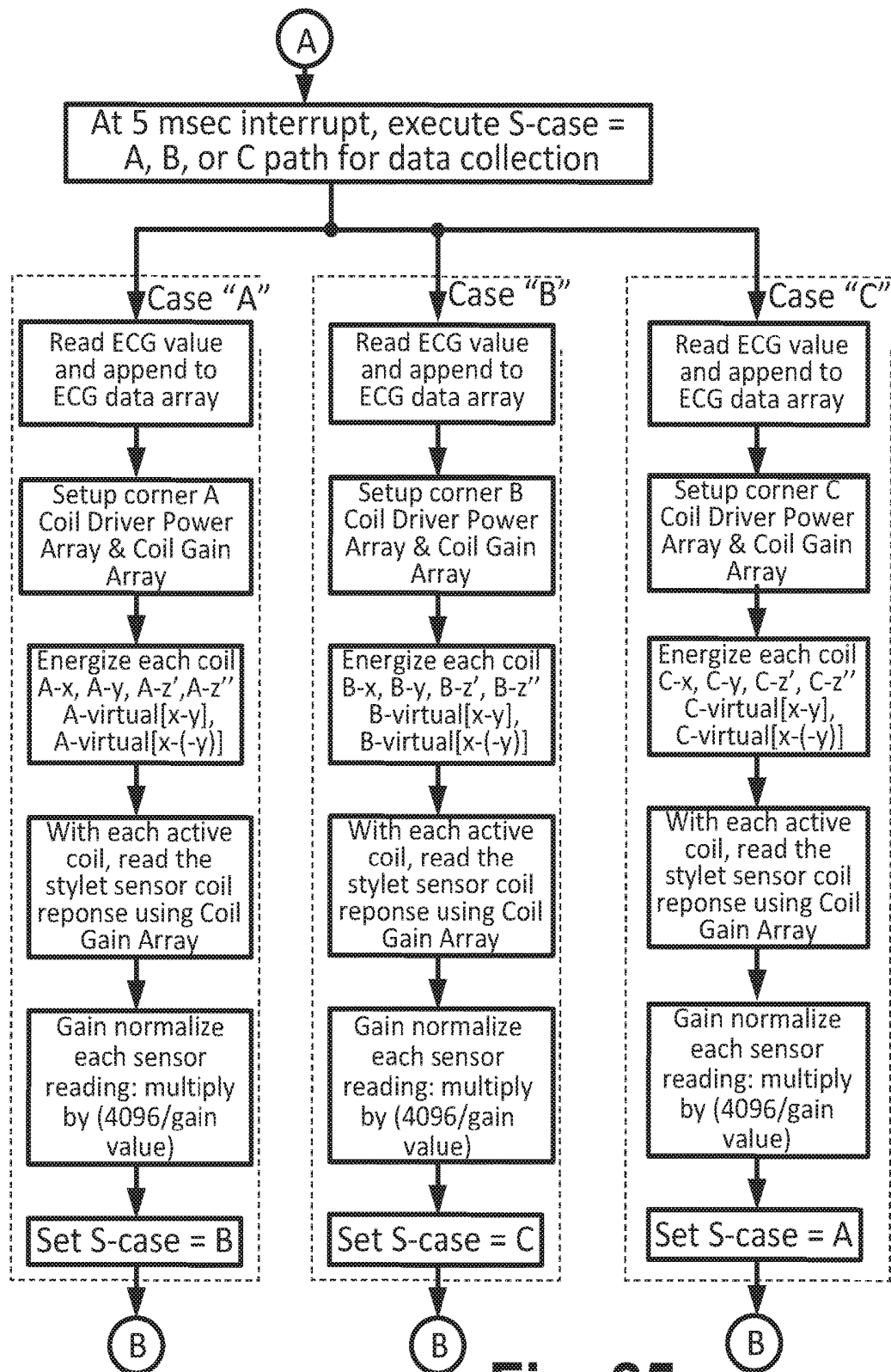
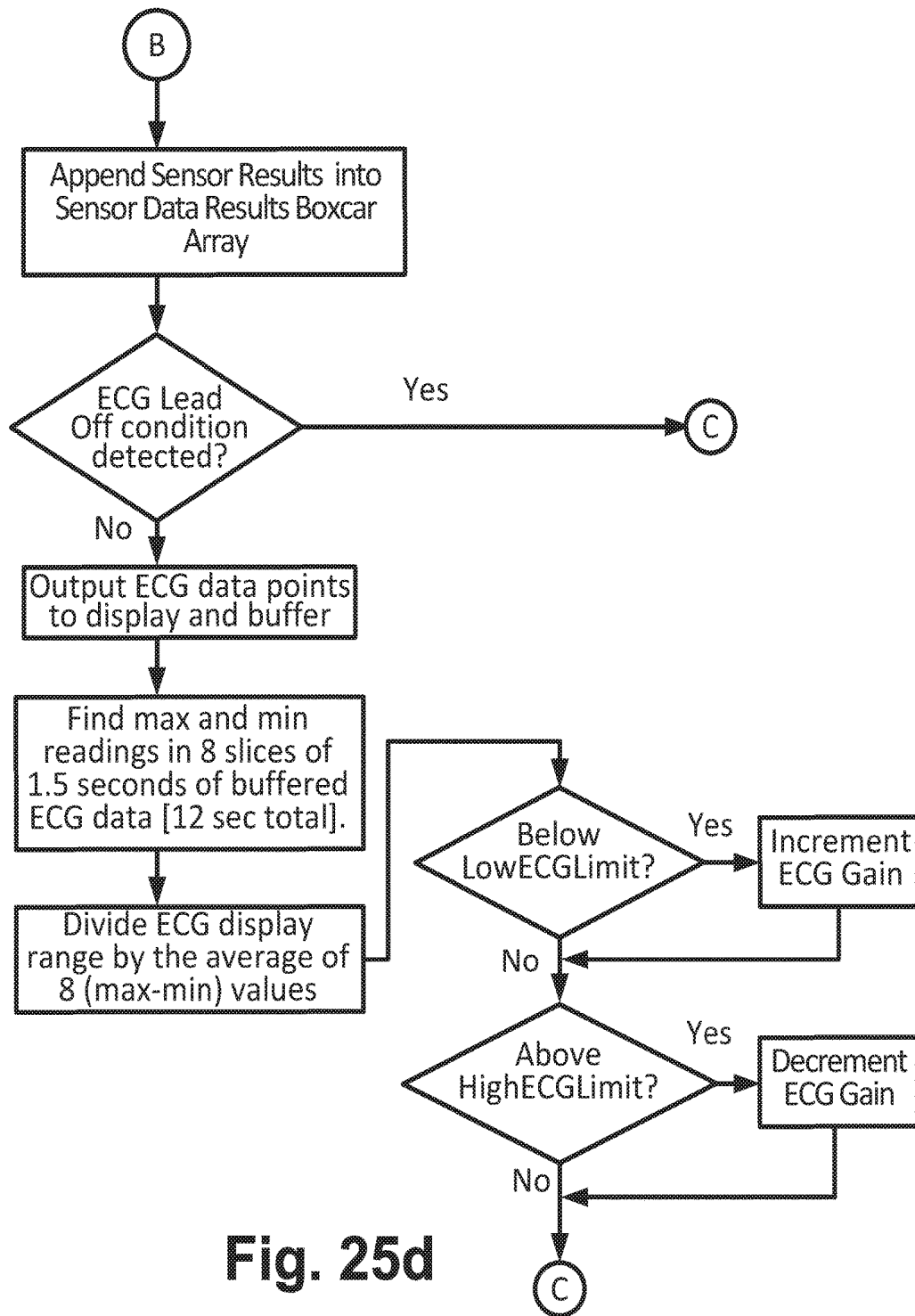
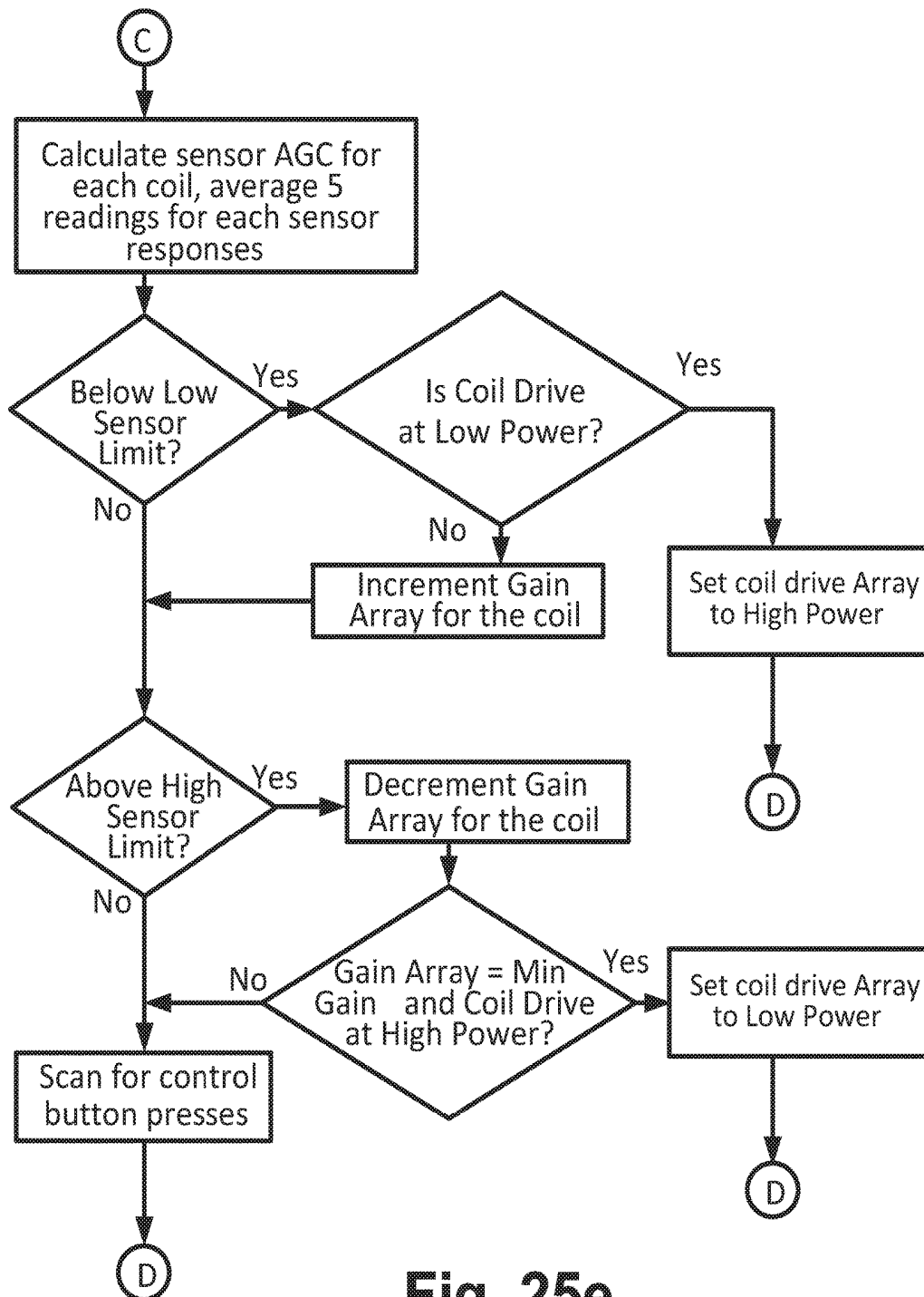
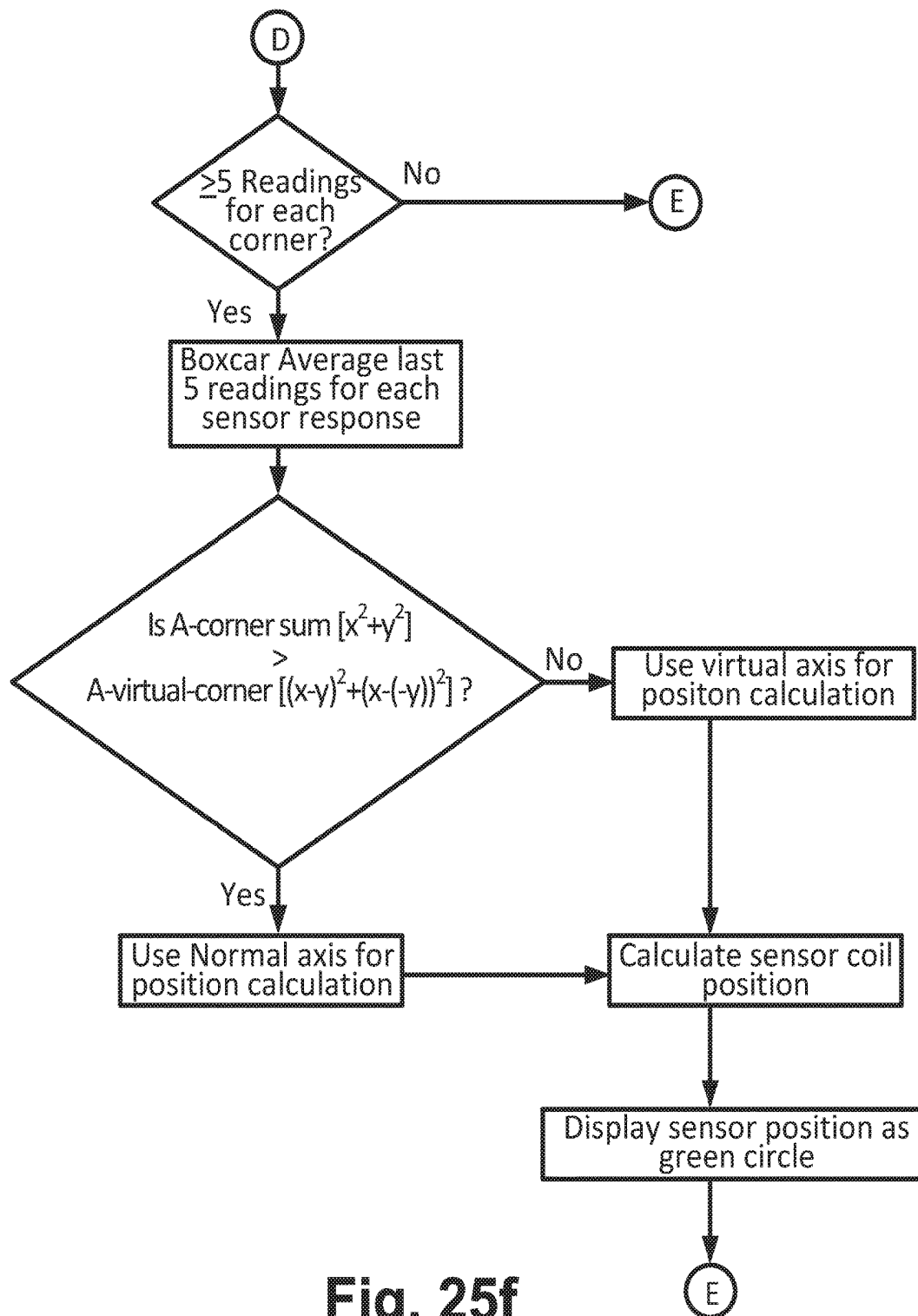
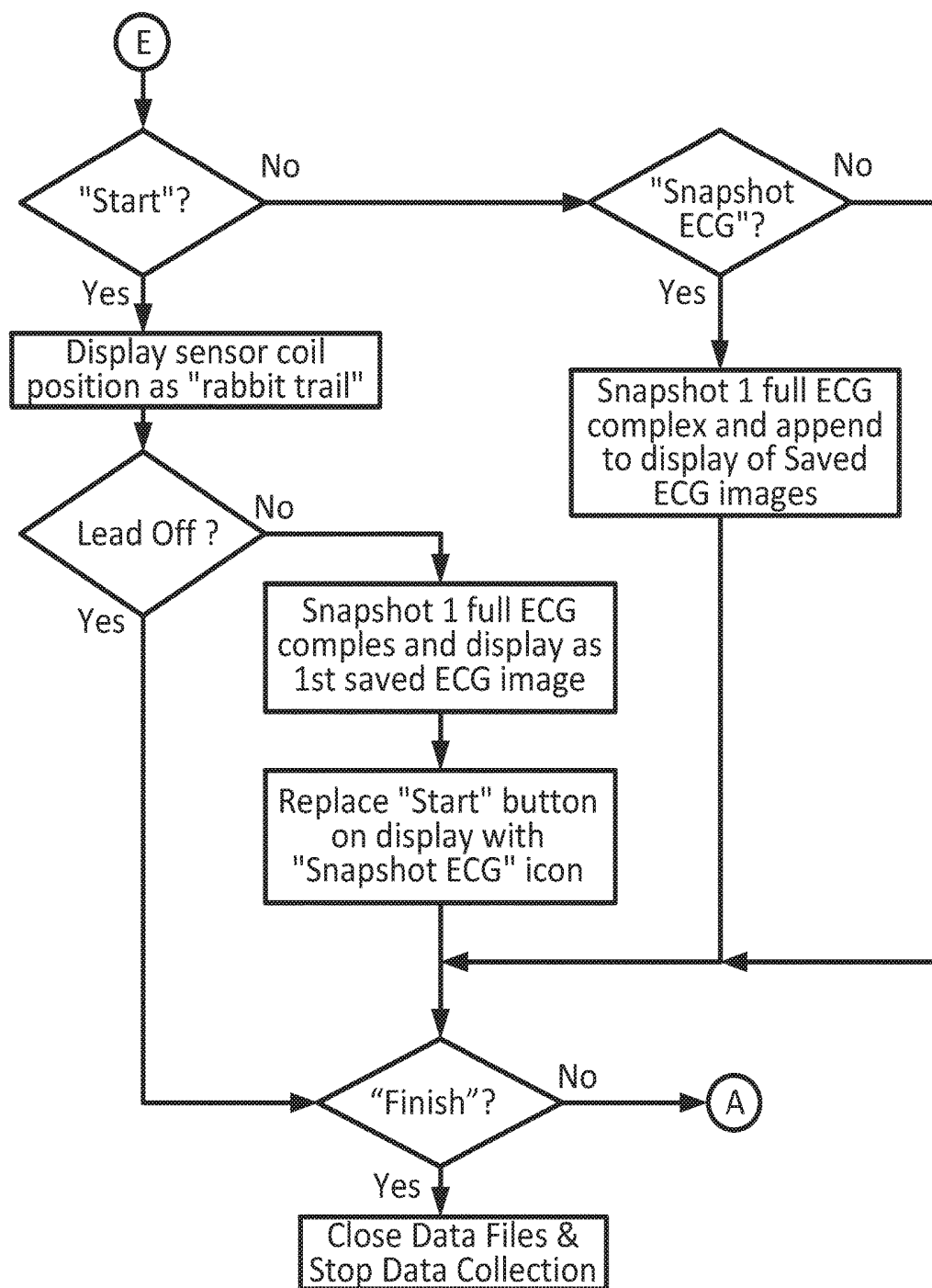


Fig. 25c

**Fig. 25d**

**Fig. 25e**

**Fig. 25f**

**Fig. 25g**

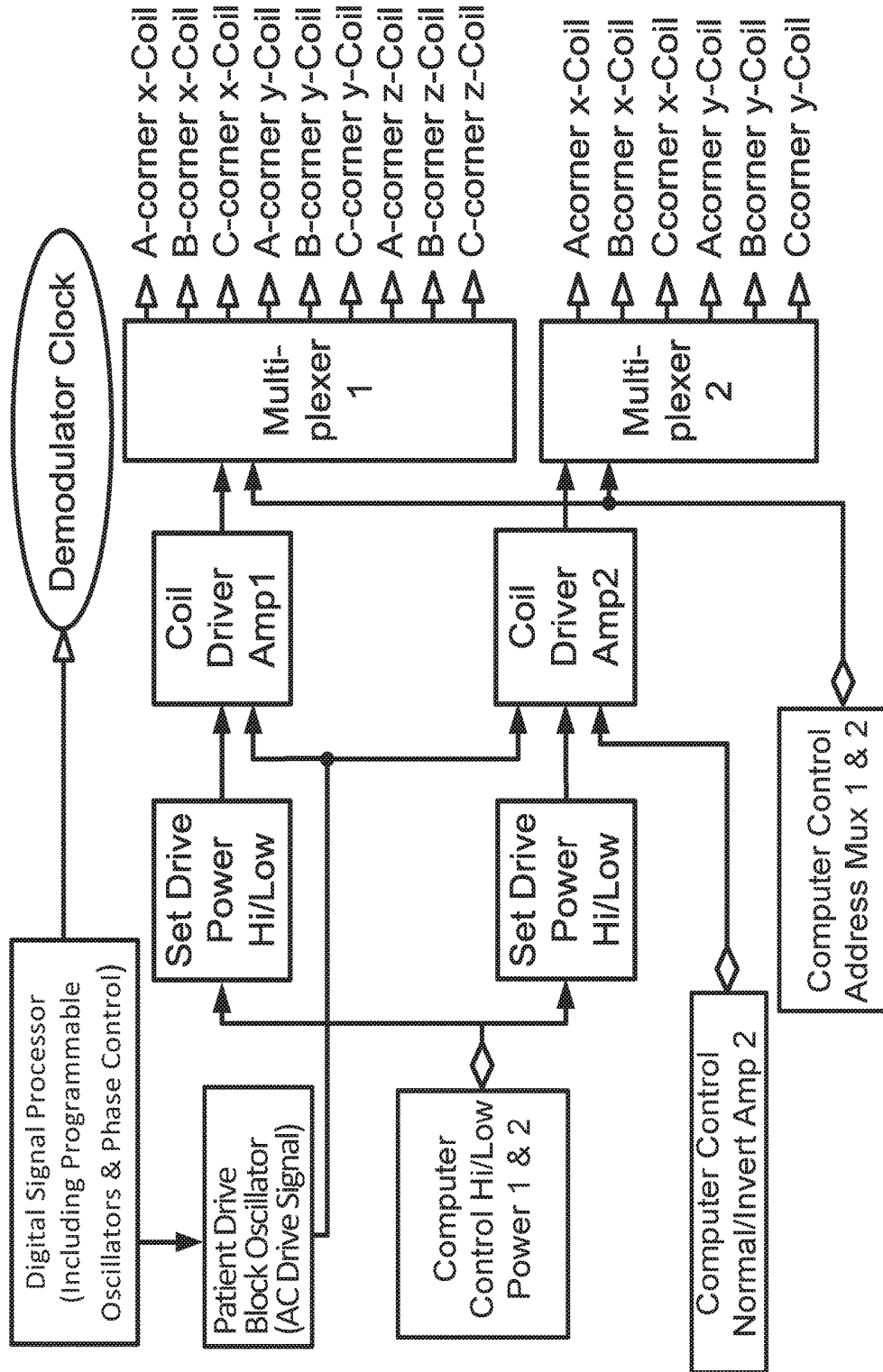


Fig. 26

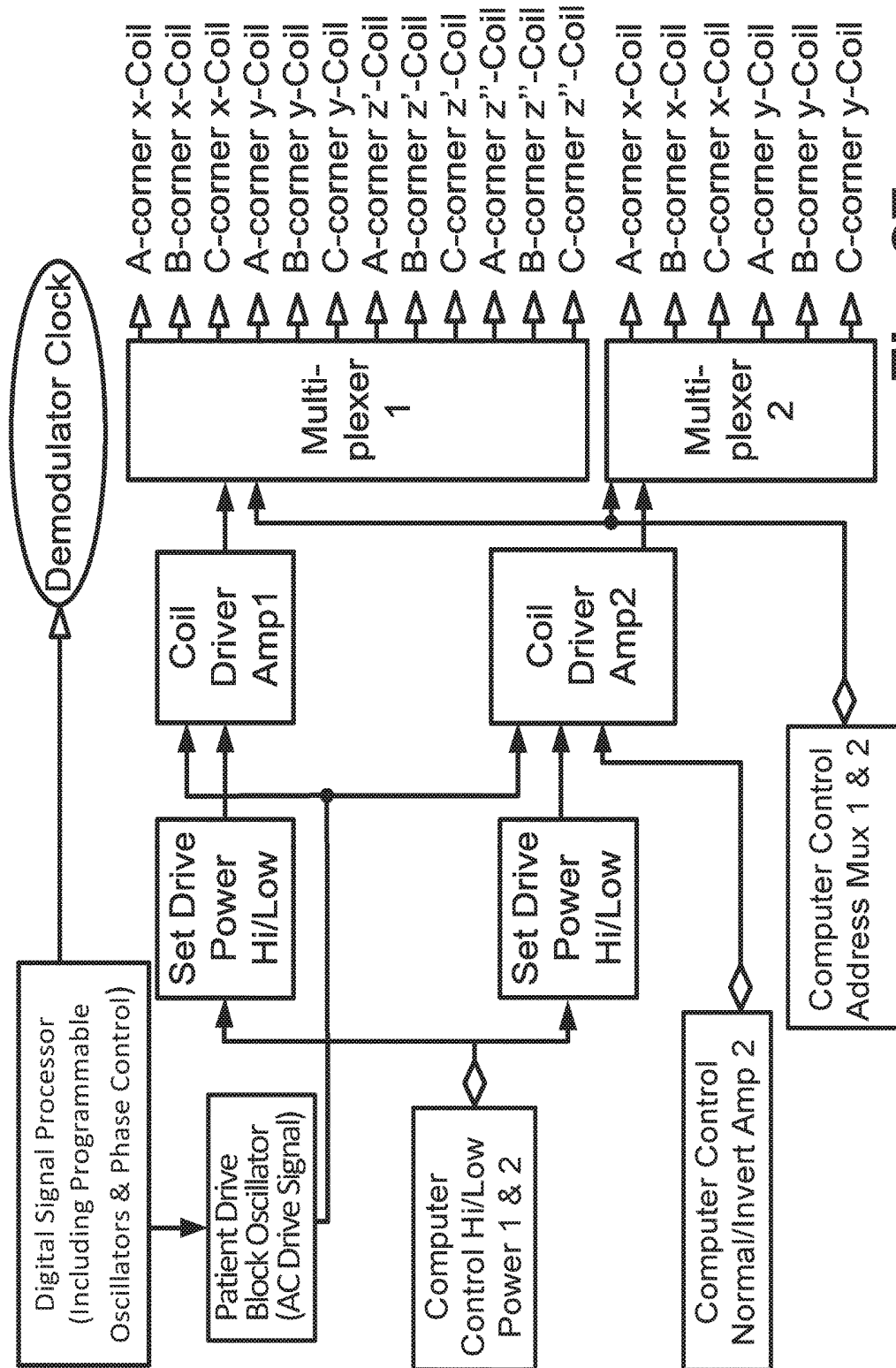
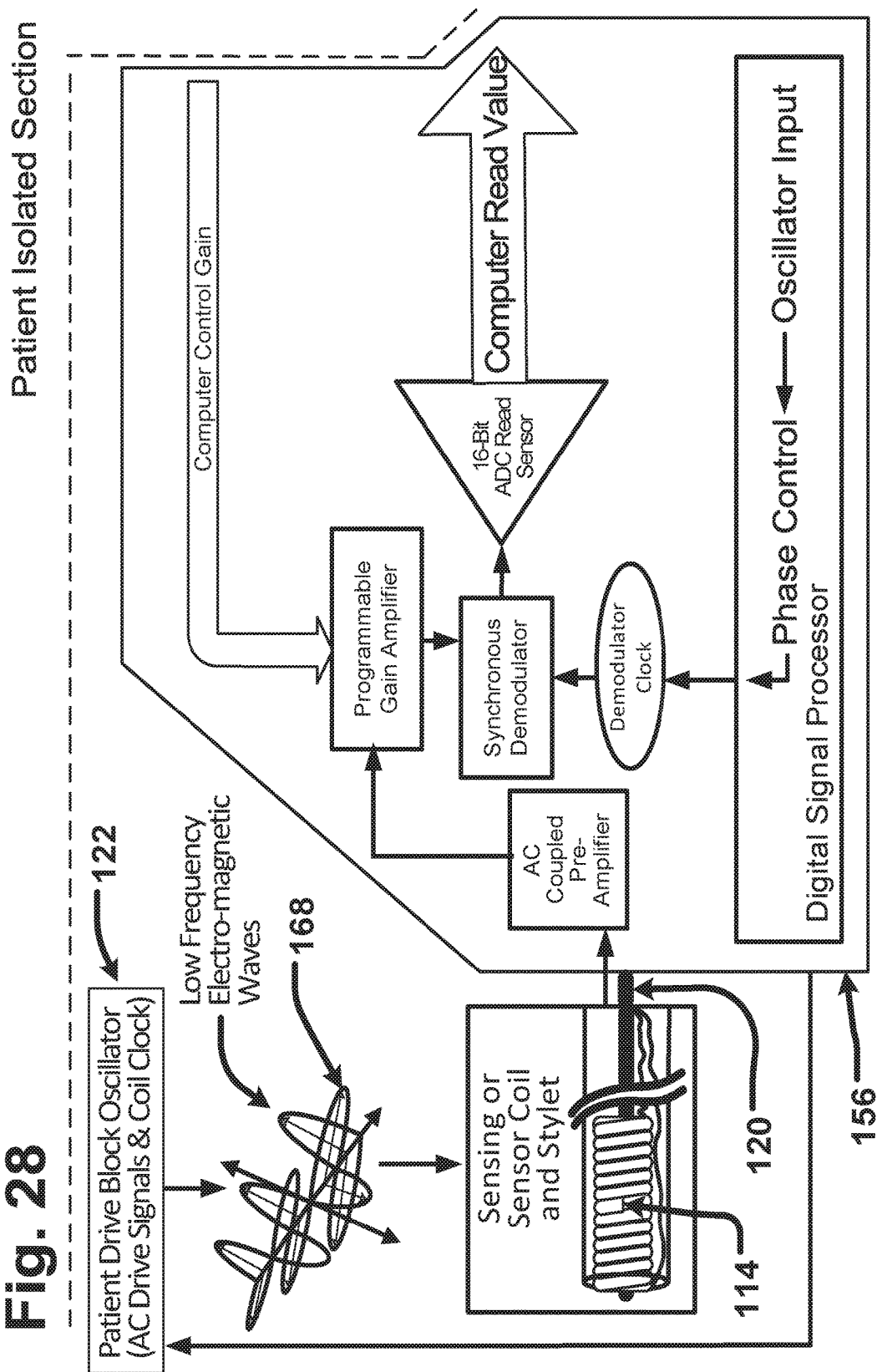
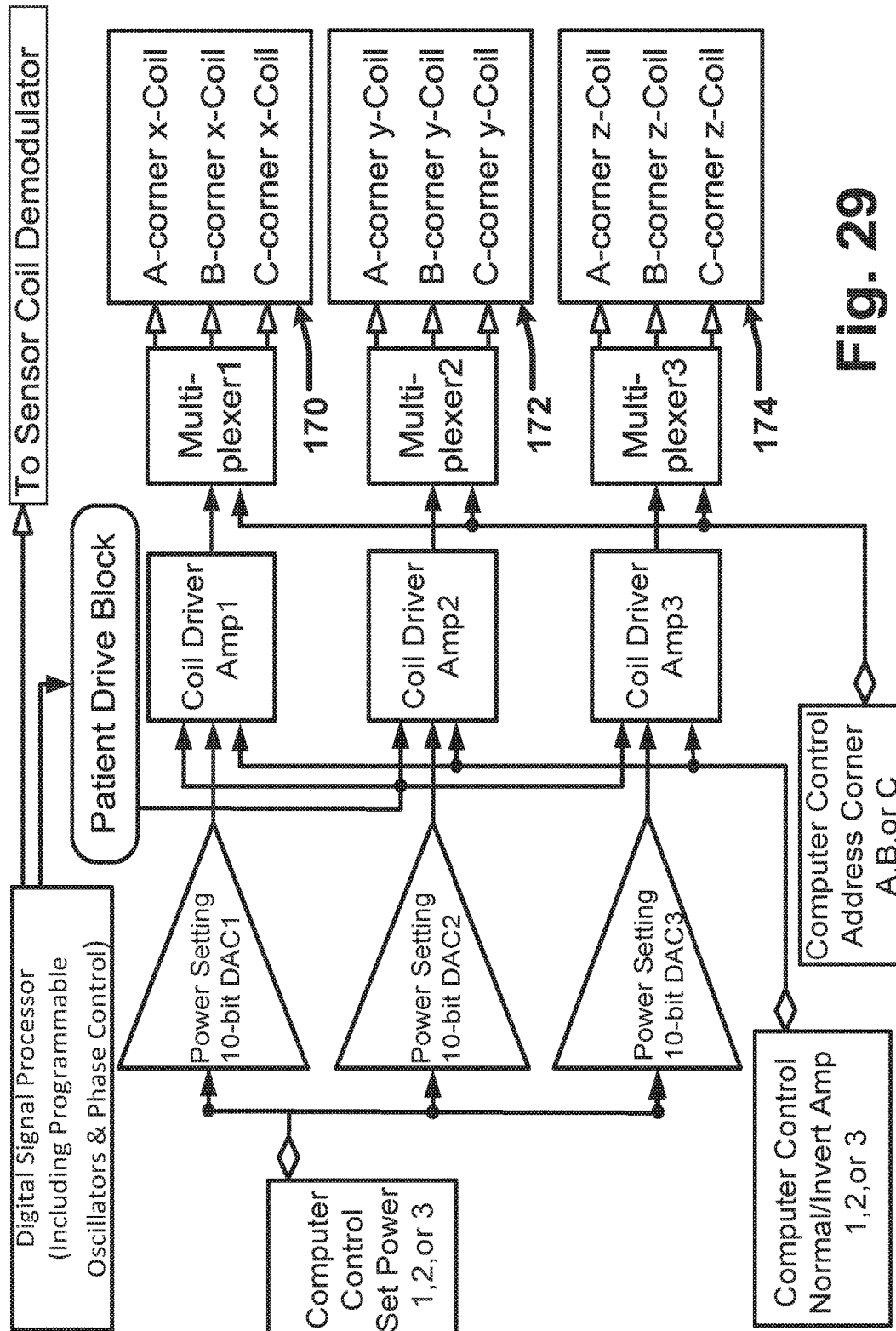


Fig. 27

Fig. 28



**Fig. 29**

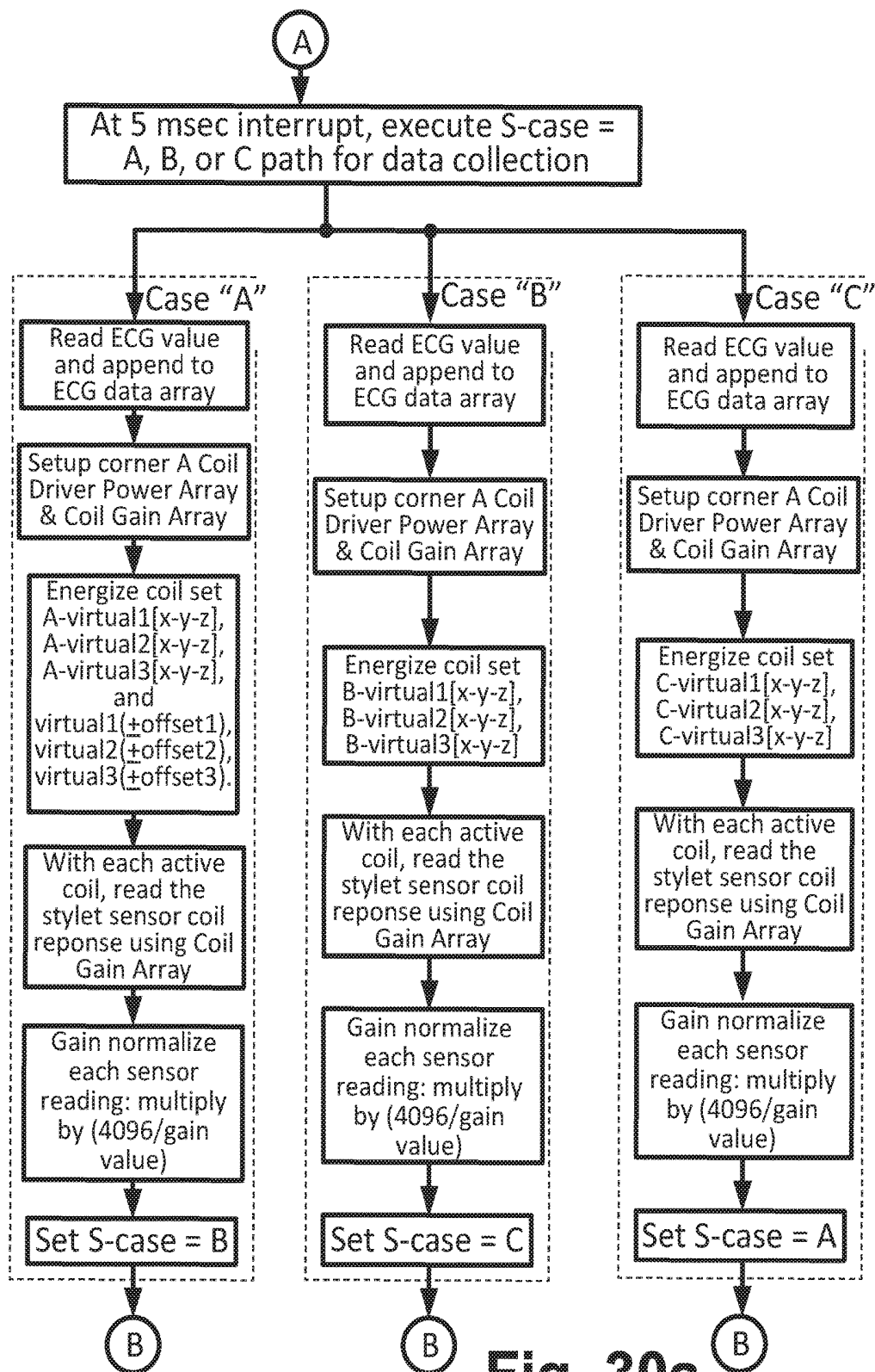
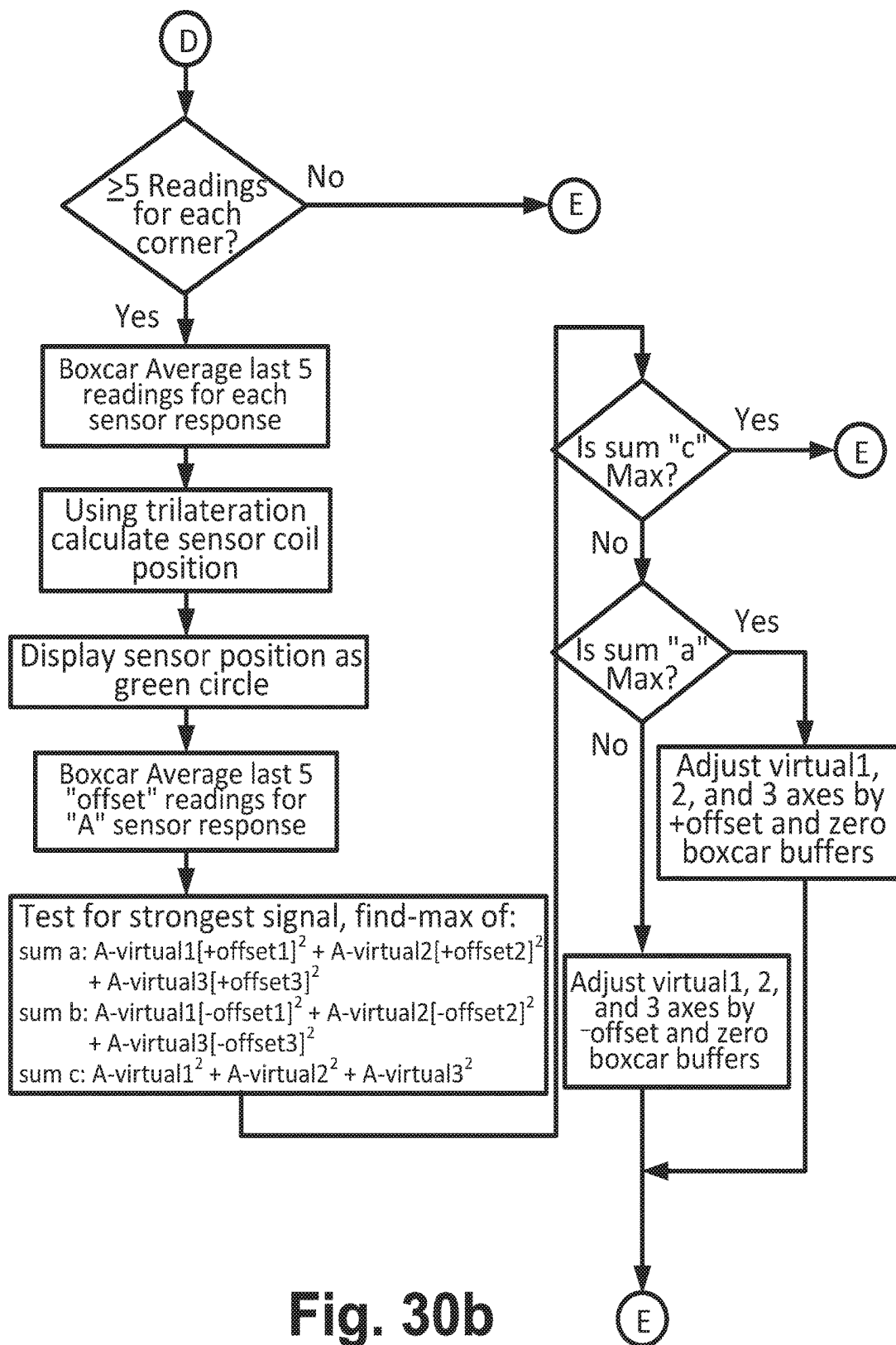
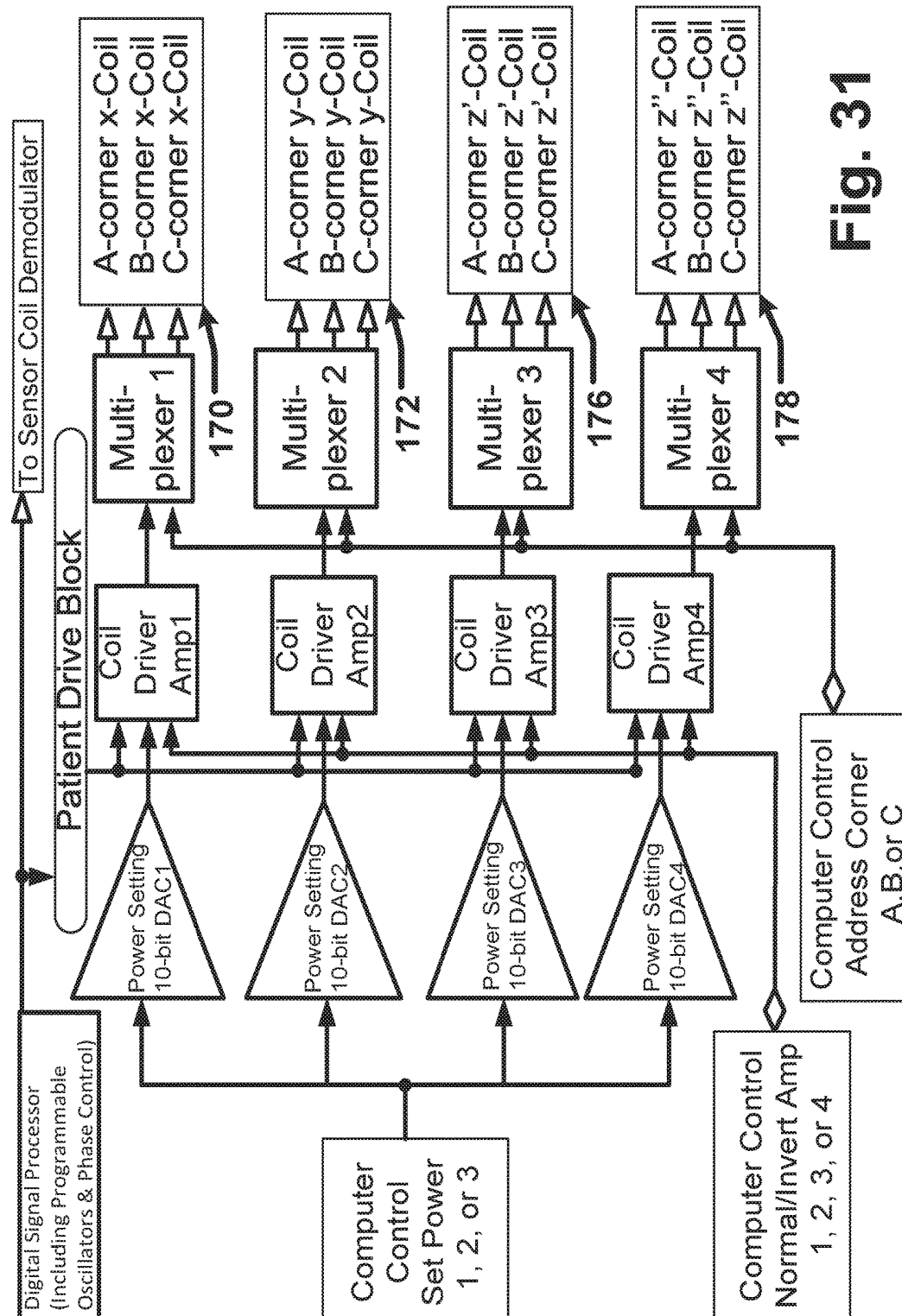


Fig. 30a

**Fig. 30b**



MEDICAL DEVICE POSITION LOCATION SYSTEMS, DEVICES AND METHODS

CROSS REFERENCE TO RELATED APPLICATION

This application claims priority to U.S. Provisional Patent Application No. 62/119,092, filed on Feb. 20, 2015, the entire disclosure of which is incorporated herein by reference.

TECHNICAL FIELD

This disclosure generally relates to locating the position of a medical device within a patient, and more particularly relates to locating the position of a medical device within a patient using electromagnetic field and electrocardiograph responses.

BACKGROUND

In medical care, the correct placement of a medical device such as a catheter or a guide wire in a patient has become increasingly important for a number of reasons. In the case of an infusion catheter, for one example, medications may need to be targeted to or for specific organs or areas of the body. In some instances, it may be important to place a catheter sufficiently near the heart where a particular blood flow rate ensures adequate dilution and mixing of infused fluids. Alternatively, a catheter or other internally-positioned medical device may simply need to be disposed in the right place to function; as for example, an enteral feeding tube within the stomach. Use of a medical device position location and/or guidance system may thus provide for skilled and less skilled practitioners to more simply and/or accurately and reliably position a medical device such as a catheter and in some instances without the use of an x-ray or additional ancillary procedures to confirm the location of the catheter or device. Additionally, the use of a medical device position location system additionally may provide for maintenance of the sterile field, a critical aspect in placing catheters or other internally positioned medical devices.

Accordingly, a variety of systems have been developed to attempt to indicate location or position of catheters or other medical devices disposed within the body of a patient. Relatively reliable location devices have made use of x-ray or fluoroscopy; however, these devices may expose the patient and/or caregiver to undesirable amounts of radiation. As a consequence, a variety of different systems have been attempted to more continuously and accurately indicate location of a catheter or other medical device with a goal of reducing and/or replacing the use of x-rays and as an alternative to fluoroscopy. However, such systems thus far developed still suffer from various drawbacks.

Electromagnetic catheter position location devices have been the subject of research and development. Some such locating systems have used an AC driven coil in the catheter tip with external sensor coils. A disadvantage of such a conventional catheter tip driven system has been the need for heavy or thick wires running into the catheter to carry necessary drive current to generate a sufficient electromagnetic signal for external sensors. This has precluded the use of such a system with smaller diameter catheters or other such smaller medical devices. Other position location systems have used a fixed magnet (or DC) on a catheter tip with external sensor coils. A significant disadvantage to such a fixed magnet location system has been that the magnet

would necessarily be very small, and as such would generate a very small signal from the tip of the catheter. Additionally, DC magnet systems put an additional charge into the patient and as a consequence, other magnetic fields in the vicinity may create significant interference problems for such a system. Furthermore, the field of such a magnet drops off extremely quickly over distance and thus cannot be sensed more than a few inches deep into the patient's tissue. This results in some concern about the depth of the placement in the subject.

Some locating systems have made use of AC driven external coils and a sensor coil in the catheter tip. One such AC drive system has been described including driving two coils simultaneously; however, those respective coils were specified as having been driven at two different frequencies so that the coil drives are not additive and the sensor demodulates the two different frequencies as two independent values. Yet another AC drive system has been described driving two coils simultaneously in quadrature which simulates a single spinning coil; however, this system may only indicate the orientation of the sensor in the x-y plane and its relative position in that plane.

This statement of background is for information purposes only and is not intended to be a complete or exhaustive explication of all potentially relevant background art.

SUMMARY

Briefly summarized, devices, methods and systems of the presently-disclosed subject matter are directed to devices and/or methods configured for accurately determining position and/or location of a sensor coil within a subject by using a moveable sensor coil. This sensor coil communicatively operates with, or responds to an array of drive coil sets of drive coils placed relative to a subject's body to allow detection and/or determining of positioning of the medical device in the subject's body. Each of the drive coil sets and the sensor coil may also be communicatively connected to or cooperative with one or more components which may include an external control and/or display whether in one or more boxes, the one or more components providing for one or more of respective selective driving of the drive coils of the sets of drive coils and/or for receiving response signals from the sensor coil. A determining component may also or alternatively also be included to determine medical device position using the response signals.

Methods, devices and systems may be provided for one or both of two- or three-dimensional location of the disposition of a sensor coil in a subject including: an array of electromagnetic drive coil sets, each set having two or three dimensionally oriented drive coils; a sensor coil being electromagnetically communicative with the array of electromagnetic drive coil sets; and, typically, a system controller or one or more like components communicative with and adapted to energize one or more of the electromagnetic coils in the array of electromagnetic drive coil sets, the energizing of the one or more of the electromagnetic coils including one or more of energizing the coils singly, or in pairs of x-y, and y-z, or x-z coils while measuring the response of the sensor coil; whereby a system hereof may then use the measurements of the responses of the sensor coil to calculate one or both of the location and orientation of the sensor coil relative to said drive coil sets.

The improved methods and systems for electro-magnetic tip location of patient catheters or other internally disposed medical devices described herein may be particularly useful for determining a more accurate z-axis location. The deter-

mination of the z-axis location allows for one or both more accuracy and certainty regarding the final placement of the catheter or medical device. An alternative embodiment incorporating a digital signal processor and alternative methodology, in some instances implemented in software architecture, may be used to determine that a determined and specified axis signal is approaching a null measured value. The sensor coil provides this response to the determining component of the system. The signal may then be estimated using information from the measured axes. For example, if the z-axis is approaching a sensed null value, the methodology is configured to use x-axis signal (x vector sum) and the measured y-axis signal (y vector sum) to calculate and substitute a position vector for the z-axis signal. The methodology may be operable to make the calculation and substitution when the measured response from the z-axis falls below a selected threshold. In turn, this provides a novel approach to using a triplet and/or quadruplet structure to determine the position in three dimensions of the sensor coil.

These and still further aspects and advantages of the present subject matter are illustrative of those which may be achieved by these developments and are not intended to be exhaustive or limiting of the possible advantages which may be realized. Thus, these and other aspects and advantages of these present developments will be apparent from the description herein or may be learned from practicing the disclosure hereof, both as embodied herein and/or as modified in view of any variations that may be apparent to those skilled in the art. Thus, in addition to the exemplary aspects and embodiments described herein, further aspects and embodiments will become apparent by reference to and by study of the following description, including as will be readily discerned from the following detailed description of exemplary implementations hereof especially when read in conjunction with the accompanying drawings in which like parts bear like numerals throughout the several views.

BRIEF DESCRIPTION OF THE DRAWINGS

In the drawings:

FIG. 1 is a schematic overview of an exemplar of some present developments hereof.

FIG. 2 is a detailed view of one three-axis drive coil set.

FIG. 3 is a plan view of one three-axis drive coil set.

FIG. 4 is a detailed view of one four-axis drive coil set.

FIG. 5 is an exploded view of one embodiment of a four-axis drive coil set, including the patient drive coil block.

FIG. 6 is a view of one embodiment of a four-axis drive coil set, including the patient drive coil block.

FIG. 7 is a detailed view of a sensor coil.

FIG. 8 is a detailed view of one embodiment of connection for the sensor coil to the determining component.

FIG. 9 is an illustration of magnetic vectors generated by a normal triplet coil drive.

FIG. 10 is an illustration of orthogonal magnetic vectors generated by an x-y virtual drive.

FIG. 11 is an illustration of orthogonal magnetic vectors generated by a y-z virtual drive.

FIG. 12 is an illustration of magnetic vectors generated by a normal triplet coil drive.

FIG. 13 is an illustration of magnetic vectors generated by a quadruplet drive coil.

FIG. 14 is an illustration of magnetic vectors generated by a quadruplet drive coil.

FIG. 15 is an illustration of orthogonal magnetic vectors generated by a quadruplet drive coil arrangement.

FIG. 16 is a schematic overview of a present development hereof.

FIG. 17 is a schematic overview of another present development hereof.

FIG. 18 is a schematic overview of yet another present development hereof in which the present development is placed on a subject.

FIG. 19 is a schematic block diagram of a present development hereof.

FIG. 20 is a schematic block diagram of a present development hereof.

FIG. 21 is a further schematic block diagram of an exemplar display/interface and user control box as may be used herein.

FIG. 22 is still a further schematic block diagram of a main interface board in a user control box as may be used herein.

FIG. 23 is yet one further schematic block diagram of a patient drive coil block as may be used herein.

FIG. 24 is still yet one further schematic block diagram of a patient drive coil block connected to a 12 drive coil array as may be used herein.

FIG. 25a-25g are methodologies for controlling an acquisition of sensor coil position.

FIG. 26 is a schematic block diagram of a coil drive with virtual x-y capability.

FIG. 27 is a schematic block diagram of a coil drive with virtual x-y capability.

FIG. 28 is a schematic block diagram of sensor coil signal processing.

FIG. 29 is a schematic block diagram of a coil drive with full virtual x-y-z capability.

FIG. 30a-30b are methodology alternatives for controlling one or both the acquisition and display of sensor coil position in virtual x-y-z system.

FIG. 31 is a schematic block diagram of a coil drive with full virtual x-y-z' capability.

DETAILED DESCRIPTION

FIG. 1 provides an overview of an implementation of a medical device position location system 100 hereof. Shown in FIG. 1 are schematic representations of some alternative possible parts including a user control box 102 (which may be or include one or more components for operation of the other parts), and a patient drive coil block 122 with drive coil set 106, representative of any sets 106a, 106b, 106c, a guide wire or stylet with a sensor coil 114 and cable 118 (or other communication medium), and optional ECG connections 112, 116. A user control box 102 may be included though it might more appropriately be defined by the components thereof, a component for driving coils and a second component for receiving response signals, and/or optionally a determining component for determining position from the response signals. These components may be in or define an otherwise "black" box 102, or may otherwise be disparately disposed and merely operatively connected to each other by hard wires or wirelessly, or may alternatively be substantially physically indiscriminate one or more from each other though nevertheless operatively configured to achieve one or more of the driving, receiving and/or determining elements.

Schematically shown in FIG. 1, these components may be in and/or define the schematic box 102. Furthermore, a control box 102 whether of a black box nature or physically disposed may include other operative parts, and according to

this implementation shown in FIG. 1, may contain a display such as a touch screen display 104, a single-board computer (SBC) (not separately shown in FIG. 1) for control and data processing, and/or a main interface board (also not separately shown in FIG. 1) which may connect to a drive block cable 108 and a medical device cable or member 118 (also sometimes referred to as a catheter, or guide wire or stylet cable 118). A patient drive coil block 122 may be connected via drive block cable 108 to the control box 102 (the drive coil block also sometimes being referred to as an emitter block, a patient block or merely a drive block). Coil drive electronics 110 and three drive coil sets 106a, 106b, 106c (also sometimes referred to as emitter coils, or x-y-z drive coils, or x-y-z', and z'') are mounted in the drive block 122. The coil drive electronics 110 allow the SBC to selectively energize any drive coil axis 126, 128, 124 of a set 106 (see FIG. 2) or group of drive coil axes. A sensor coil 114 is, in this implementation, built on or within the tip of a medical device such as a small diameter biocompatible guide wire or stylet cable 118. The guide wire may then be placed in the patient and the catheter then threaded over this wire; or, alternatively, the stylet cable may then be inserted up to the distal end of a catheter before the catheter is placed in the patient. A two-conductor cable 120 may be used to connect the sensor coil of guide wire or stylet back to the user control box. In this embodiment, an ECG main cable 116 connects the ECG signal input receiver 112 to the circuitry associated with the drive block 122 or the coil drive electronics 110.

FIG. 2 shows a detailed drawing of a drive coil set 106 (representative of any of sets 106a, 106b, 106c). Here, the x-coil 124, the y-coil 126 and z-coil 128 each have a ferrite or ferrous core 130 to enhance the magnetic field generation. In an alternative embodiment, the coils, 124, 126, 128 each have an air core or no core material. This figure is only schematically representative of the construction of a drive coil; in actuality, each drive coil may have many windings (e.g. 100 turns) on the ferrite core and may be constructed as three (3) coil pairs to facilitate the intersection of the x, y, and z axes. Each coil here has a set of lead wires 132 to connect back to the multiplexers of the coil drive electronics 110.

FIG. 3 shows a plan view of a triplet drive coil set 106. In this representation the x-coil 124 and the y-coil 126 and the z-coil 128 are disposed relative to each other in an orthogonal arrangement. Each coil here has a set of lead wires 132 to connect back to the multiplexers of the coil drive electronics 110.

FIG. 4 shows a detailed drawing of an alternative quadruplet drive coil set 106 (representative of any sets 106a, 106b, 106c). Here, the x-coil 124, the y-coil 126, and the z'-coil 134, and z''-coil 136 (these latter two also referred to as the "z-coils") each have a ferrite or ferrous core 130 to enhance the magnetic field generation. Additionally, to further enhance the magnetic field generation z'-coil 134 and z''-coil 136 are arranged orthogonally in relation to each other, but non-orthogonally in relation to the x-coil 124 or y-coil 126. In this representation, the z'-coil 134 and the z''-coil 136 are oriented forty-five degrees off the standard arrangement of a z-axis, in a standard x-y-z coil array, also referred to as "off-axis". Alternatively described, the respective z-coils may be arranged in perpendicular to each other and geometrically oriented off axis at both a negative 45 degree angle and positive 45 degree angle away from the respective x, y axis. In such an arrangement, wherein the x-coil and y-coil are arranged orthogonally relative to each other and at least two other z-coils are arranged orthogonally relative to each other but the z-coils are "off-axis" or

non-orthogonal relative to the x-coil and y-coil, the system is referenced as pseudo-orthogonal or in some instances as dually orthogonal. Where four drive coils are contained in one set the set is referred to as a quadruplet.

FIG. 5 shows an exploded two-dimensional schematic drawing of a quadruplet drive coil set. Here, the x-coil 124, the y-coil 126, and the z'-coil 134, and z''-coil 136 each may have a ferrite or ferrous core 130 to enhance the magnetic field generation. Additionally, to further enhance the magnetic field generation z'-coil 134 and z''-coil 136 are arranged orthogonally in relation to each other, but non-orthogonally in relation to the x-coil 124 or y-coil 126. In this representation, the z'-coil 134 and the z''-coil 136 are oriented forty-five degrees off the standard arrangement of a z-axis, in a standard x-y-z coil array. In some embodiments, the drive coil electronics 110 (circuit board) separates the z'-coil 134 and z''-coil 136 in to two distinct segments both above and below the imaginary plane created by the x-coil and y-coil arrangement. Optionally an additional aspect of this embodiment includes, at least one capacitor 131 operably associated with the drive coil to create an LC circuit.

FIG. 6 shows a three-dimensional schematic drawing of a quadruplet drive coil set. Here, the x-coil 124, the y-coil 126, and the z'-coil 134, and z''-coil 136 each may have an air core 133 to enhance the magnetic field generation. Additionally, to further enhance the magnetic field generation z'-coil 134 and z''-coil 136 are arranged orthogonally in relation to each other, but non-orthogonally in relation to the x-coil 124 or y-coil 126. In this representation, the z'-coil 134 and the z''-coil 136 are oriented forty-five degrees off the standard arrangement of a z-axis, in a standard x-y-z coil array. In some embodiments, the drive coil electronics 110 (circuit board) separates the z'-coil 134 and z''-coil 136 in to two distinct segments both above and below the imaginary plane created by the x-coil and y-coil arrangement. Optionally, at least one capacitor 131 is operably associated with the drive coil to create an LC circuit for the inductance, energizing, or driving of the electromagnetic coils.

FIG. 7 shows a detailed view of an exemplar medical device; e.g., a guide wire or stylet sensor coil. The sensor coil 114 may be any suitable gauge (e.g., but not limited to, a very fine gauge (e.g. 0.001" diameter)) wire wound around a ferrous core wire 138. In some instances, the sensor coil 114 and sensor coil lead wires may be insulated. In some embodiments the core wire 138 is composed of an alloy that affects a number of functional characteristics of the sensor coil (e.g. flexibility, semi-permeable magnetic properties, and conductivity). This figure is schematically illustrative only of the sensor coil; here, the sensor coil is approximately 400 turns in single layer, but may be any suitable turns per length, e.g., 50-1000, or any range or value therein, e.g., 100, 200, 300, 350, 400, 450, 500, 550, 600, 650, 700, and the like. The sensor coil lead wires 142 connect back through a cable to the patient isolated portion of the main interface board. An electrical insulator 140 may be used to provide a protective sleeve and/or coating for the assembly. An alternative construction may optionally include two or more sensor coils wrapped around the ferrous core wire 138. An additional sensor coil would likely need additional lead wires to connect back to the patient isolated portion of the main interface board. In an optional ECG version of a catheter location system, the tip of the ferrous, conductive core wire 138 may be polished smooth and may remain uncoated and/or unsheathed and may provide an electrical signal as an ECG lead from within the catheter.

In an alternative representation, the ECG version of the sensor coil location system (e.g., FIG. 8) the conductive core

wire **138** is operably connected to an electrical connector or jack **144** (in this alternative embodiment the connection component may be a 3.5 mm female stereo plug **148**, in one example) which may provide the output and signal to the patient isolated portion of the main interface board. In such a version, the guide wire or stylet sensor connection may be accomplished with three wires, two (2) for the coil sensor and one (1) for the ECG, through a cable **146** to the patient isolated portion of the main interface board in the user control box **102** (not separately shown in FIG. 8).

FIGS. 9, 10 and 11 illustrate an optional version of the operation of a triplet normal-drive and virtual-drive drive coil set. FIG. 9 shows magnetic vectors x, y, and z generated by normal coil **149** driving of the x-axis coil **124**, the y-axis coil **126** and z-axis coil **128** (as shown in FIG. 2). FIG. 10 shows the virtual magnetic vector x-y **151** generated by simultaneously driving the x-axis coil **124** and the y-axis coil **126** (as shown in FIG. 2) and when both are driven at the same power, the vector is forty-five degrees between the x and y axes. The virtual magnetic vector x-(-y) generated by simultaneously driving the x-axis coil **124** and the phase-inverted, y-axis coil **126** (as shown in FIG. 2) and when both are driven at the same power, the vector is minus forty-five degrees between the x and -y axes. If a digital to analog converter (DAC) is added to control power to the x-axis drive and another DAC added to control power of y-axis drive, then it is possible to point the virtual axis to any angle from 0 to 360 degrees between x and y. For example, if x-axis power DAC is maximum and y-axis power DAC is $\frac{1}{4}^{th}$ (one quarter) of maximum then the vector sum of x-y drive yields a virtual axis of approximately fourteen degrees between the x and y axes. FIG. 11 shows a virtual magnetic vector y-z **153** generated by simultaneously driving the z-axis coil **124** and the y-axis coil **126** (as shown in FIG. 2); and a virtual magnetic vector z-(-y) generated by simultaneously driving the z-axis coil **124** and a phase-inverted, y-axis coil **126** (as shown in FIG. 2). These figures illustrate the simplest and one optional form of virtual drive (e.g., see FIG. 25), it is possible to point a virtual magnet vector to any polar coordinate by simultaneously driving x, y, and z coils at independent power levels (e.g., see FIG. 29).

FIGS. 12, 13, 14, and 15 illustrate an optional version of the operation of a quadruplet normal-drive and virtual-drive drive coil set. FIG. 12 shows magnetic vectors x, y, and z generated by normal coil **149** driving of the x-axis coil **124**, the y-axis coil **126** and z-axis coil **128** (as shown in FIG. 2; FIG. 12 provides a reference for the orientation of the pseudo-orthogonal orientation of z'-axis and z''-axis). FIG. 13 shows the x, y, z' and z'' magnetic vectors **155** and shows what would be the virtual z vector formed from the z' and z'' magnetic vectors. It is noted that relative powering of the z'-coil and z''-coil may be used to generate a virtual z vector as depicted in FIG. 13, but also other virtual magnetic vectors from the x, y, z', and z'' normal-drive coils. FIG. 14 shows the discrete x, y, z' and z'' magnetic vectors **157** super-imposed on the quadruplet coil set such as those shown in FIGS. 4, 5, and 6. FIG. 15 shows the four virtual magnetic vectors of x-y and z'-z'' **159** generated by simultaneously driving the x-axis coil **124** and the y-axis coil **126** (as shown in FIG. 2) and by simultaneously driving the z' and z'' axis coils. In this alternative and when both x-axis and y-axis are driven at the same power, the vector is forty-five degrees between the x and y axes. The virtual magnetic vector x-(-y) generated by simultaneously driving the x-axis coil **124** and the phase-inverted, y-axis coil **126** (as shown in FIG. 2) and when both are driven at the same power, the vector is minus forty-five degrees between the x

and -y axes. If a digital to analog converter (DAC) is added to control power to the x-axis drive and another DAC added to control power of y-axis drive, then it is possible to point the virtual axis to any angle from 0 to 360 degrees between x and y. For example, if x-axis power DAC is maximum and y-axis power DAC is $\frac{1}{4}^{th}$ (one quarter) of maximum then the vector sum of x-y drive yields a virtual axis of approximately fourteen degrees between the x and y axes. FIG. 15 further shows a virtual magnetic vector z'-z'' generated by simultaneously driving the z'-axis coil **134** and the z''-axis coil **136** (as shown in FIG. 4); and a virtual magnetic vector z'-(-z'') generated by simultaneously driving the z'-axis coil **134** and a phase-inverted, z''-axis coil **136** (as shown in FIG. 2). These figures illustrate the simplest and one optional form of virtual drive (e.g., see FIG. 26), it is possible to point a virtual magnet vector to any polar coordinate by simultaneously driving x, y, and z coils or in some cases z'-coil and z''-coil at independent power levels (e.g., see FIG. 31).

Furthermore, FIG. 16 provides a schematic diagram of a medical device position location system with an optional electrocardiograph (ECG) measurement. This is similar to the FIG. 1 implementation with the addition of three ECG leads. The user control box **102** connects through a main interface board **158** to the drive block cable **108** and guide wire or stylet cable **146**. The patient drive block **122** may be connected via drive block cable **108**. Three isolated ECG leads **152** communicate signals to the control box **102**. The coil drive electronics **110** and three x-y-z drive coil sets **106a**, **106b**, **106c** may be mounted in the drive block **122**. The coil drive electronics **110** allow the single board controller **166** (SBC) to selectively energize any drive coil axis **126**, **128**, **124** (FIG. 2) or group of drive coil axes. In this embodiment, three ECG pads **154** may be placed on the patient and connected by ECG lead wires **152** to an ECG signal input receiver **112** that connects an ECG main cable **116** to the drive block **122**. These two, three, or more ECG inputs together with the one ECG from the catheter may provide at least a three-lead ECG measurement system (e.g., see FIGS. 23 and 24). The guide wire or stylet sensor **114** here is built onto a small diameter biocompatible conductive-tip guide wire or stylet cable **146** which is inserted into a catheter before (stylet) or after (guide wire) the catheter is placed in the patient. A drive block cable **108** connects the patient drive coil block **122** to the user control box **102**. In alternative embodiments, the user control box houses the main interface board **158**, the single board controller **166**, and in some instances isolates the power supply connections. In some embodiments (not shown in the figures), the ECG signal input receiver **112** may be operably housed, contained, and/or connected to either the drive block **122** or the user control box **102**. Moreover, in alternative embodiments, the ECG pads **154** may connect wirelessly to at least one or more selected from the group of: the ECG signal input receiver **112**, the driver block **122**, or the user control box **102**. In these embodiments, the ECG measurement may be displayed on the user control box **102** and a touch screen **104** may be used in association with a graphical user interface adapted to display the location of the sensor coil **114** in relation to the patient drive block **122** over time. In some embodiments, the ECG measurement may be displayed solely on the touch screen display **104**. In alternative non-limiting embodiments, the ECG measurement may be displayed simultaneously with the location of the sensor coil **114**. In yet another non-limiting embodiment, the sensor coil location and orientation may be displayed on the display **104**, without additional information related to the ECG measurement data.

FIG. 17 provides a schematic diagram of a medical device position location system with an optional electrocardiograph (ECG) measurement wherein the drive coil array contains 12 drive coils arranged and oriented as depicted in FIGS. 13, 14 and 15. The user control box 102 connects through a main interface board to the drive block cable 108 and guide wire or stylet cable 146. The patient drive block 122 may be connected via drive block cable 108. Three isolated ECG leads 152 communicate signals to the control box 102. The coil drive electronics 110 and three x-y-z drive coil sets 106a, 106b, 106c may be mounted in the drive block 122. The coil drive electronics 110 allow the single board controller (SBC) to selectively energize any drive coil axis 126, 124, 134, 136 (FIG. 4) or group of drive coil axes. Two, or three or more ECG pads 154 may be placed on the patient and connected by ECG lead wires 152 to the drive block 122. The guide wire or sensor coil 114 here is built onto a small diameter biocompatible conductive-tip guide wire or stylet cable 146 which is inserted into a catheter before (stylet) or after (guide wire) the catheter is placed in the patient. A drive block cable 108 connects the guide wire or stylet sensor coil and optionally one ECG lead back to the user control box 102. FIG. 17 shows the patient drive coil block 122 may have two or more ECG pads added which connect through a cable 152 to the patient isolated portion of the main interface board. These two, three, or more ECG inputs may together with the one ECG from the catheter provide at least a three-lead ECG measurement system.

FIG. 18 is an overall schematic diagram of a medical device position location system in use relative to a subject or patient. This figure illustrates connections between a user control box 102 and a sensing guide wire or stylet 114 and a patient drive block 122. The control box 102 may include an integrated, separated, or remote user display and/or interface. Each of these components may include cables or connectors or wireless communications for one or more of a coil interface, a power supply, a serial interface, a control interface, a status interface, an ECG interface or lead, an oscillator interface, a processor interface, a computer interface, a data interface, a network interface (cable or wireless), an internet interface, a video interface, a touch-screen interface, an SBC control or power interface, a board interface, a sensor interface, an isolator interface, and/or the like as described herein or as known in the art. One or more of these cables or connectors may attach to the patient drive block 122 or any component thereof. This figure further demonstrates one possible insertion point 160 into the subject. Optionally, in this instance the device may be inserted in a peripheral vasculature of the subject, specifically the right arm of the patient. Optionally, the system may be configured for use at other insertion sites on the patient's body as may be determined by either medical staff and/or the desired application and use of the system. Additionally, FIG. 18 shows placement of this embodiment of the patient drive block where the designated drive block notch 162 is aligned with or near the sternal notch of the subject 164. In alternative embodiments, the system could optionally be implemented for use among a number of different entry or insertion points (e.g. peripheral insertion (cephalic vein), midline insertion (basilic vein), central venous insertion (interjugular vein), chest insertion (subclavian vein or axillary vein) or groin (femoral vein)). Moreover, in yet another implementation, the system could be used for placement at insertion sites for nephrostomy or kidney dialysis. The patient drive block 122 may be adapted to different shapes, configurations, or arrangements that may align with anatomical features of the subject. In alternative non-limiting

embodiments, the designated drive block notch may be adapted to be one or more of a notch, an extrusion, a marked portion, or an alignment hole. These embodiments may assist in the medical personnel placing the patient drive block on the subject aligned with anatomical features of the subject.

FIG. 19 provides a schematic diagram of a medical device position location system wherein the drive coil array contains 12 drive coils. In this embodiment, optional ECG measurement components may be disconnected from the system entirely or not included in the patient drive block 150. In this non-limiting approach the coils are arranged and oriented as depicted in FIGS. 13, 14 and 15. The user control box 102 connects through a main interface board to the drive block cable 108 and guide wire or stylet cable 146. The patient drive block 150 may be connected via drive block cable 108. The coil drive electronics 110 and three x-y-z drive coil sets 106a, 106b, 106c may be mounted in the drive block 150. In this embodiment, the patient drive block 150 may not include two or more ECG leads with patient isolation. The coil drive electronics 110 allow the single board controller (SBC) to selectively energize any drive coil axis 126, 124, 134, 136 (FIG. 4) or group of drive coil axes. The guide wire or sensor coil 114 here is built onto a small diameter biocompatible conductive-tip guide wire or stylet cable 146 which is inserted into a catheter before (stylet) or after (guide wire) the catheter is placed in the patient. A drive block cable 108 connects the guide wire or stylet sensor coil to the user control box 102. It should be noted that, FIG. 16 shows an alternative embodiment wherein the patient drive coil block 122 may have two or more ECG pads added which connect through a cable 152 to the patient isolated portion of the main interface board. FIG. 19, is provided to show that the system 100 may be adapted to use a patient drive block 122 or a patient drive block 150, the patient drive block 150 being a non-limiting aspect not adapted to provide ECG measurements.

FIG. 20 is another schematic diagram of a medical device position location system. This figure illustrates connections between a user control box 102 (again, box 102 may be merely a schematic "black" box or may be physically disposed, the one or more components thereof including one or more of a first component for driving the coils, a second component for receiving signals and a determining component for determining location; noting also that the one or more components may be physically disparate from each other and merely operatively connected, or may alternatively be substantially physically indiscriminate one or more from each other though nevertheless operatively configured to achieve one or more of the driving, receiving, measuring, and/or determining elements) and a sensing guide wire or stylet 114 and a patient drive block 122, 150. The control box 102 may include an integrated, separated, or remote user display and/or interface. Each of these components may include cables or connectors or wireless for one or more of a coil interface, a power supply, a serial interface, a control interface, a status interface, an optional ECG interface or lead, an oscillator interface, a processor interface, a computer interface, a data interface, a network interface (cable or wireless), an internet interface, a video interface, a touch-screen interface, an SBC control or power interface, a board interface, a sensor interface, an isolator interface, and/or the like as described herein or as known in the art. One or more of these cables or connectors or wireless may operatively attach to the patient drive block 122 or any component thereof. In this embodiment the power connection is isolated as further depicted in FIG. 22. Note, the power, serial control

and status and ECG may be optional; i.e., these may be part hereof or discrete functionalities; whereas components, whether in or disparate from a box **102** (black box or otherwise) for driving coil operation, receiving sensor coil signals, and/or determining location would be preferred, though again, these may be together physically, perhaps indiscriminately, or may be disparate physically and merely operatively connected as needed or desired.

FIG. **21** is a block diagram of an exemplar user control box **102** which in this implementation may include a computer **166**, which in a number of examples may include a digital signal processor (aka DSP), a display **104**, optionally either or both LCD with or without touch-screen capabilities, and a main interface board **158**. Each of these components may include cables or connectors or wireless for one or more of a coil interface, a power supply, a serial interface, a control interface, a status interface, an optional ECG interface or lead, an oscillator interface, a processor interface, a computer interface, a data interface, a network interface (cable or wireless), an internet interface, a video interface, a touch-screen interface, a computer control or power interface, a board interface, a sensor interface, an isolator interface, a digital signal processor, a zero insertion force (ZIF) socket, and/or the like as described herein or as known in the art.

FIG. **22** provides a block diagram of a main interface board **158** (FIG. **20**), associated circuitry, and shows a patient isolated section which connects to a guide wire or stylet cable **120** and optional ECG leads from a patient drive block **122**. The remainder of the circuitry controls power/interface to a patient drive block **122** and power to a single board computer **156**, which may include one or more of a voltage regulator, a watchdog switch, a drive switch, a power isolator, a voltage monitor, a cable buffer, a filter, an analog to digital converter, a digital signal processor, a demodulator clock, a phase adjuster, a demodulator, a signal filter, a programmable gain amplifier, a coil isolator, a coil sensor coil amplifier, a detector, memory, flash memory, a multiplexor, a polarity inversion switch, and/or the like. Each of these components may include cables or connectors or wireless for one or more of a coil interface, a power supply, a serial interface, a control interface, a status interface, an optional ECG interface or lead, an oscillator interface, a processor interface, a computer interface, a data interface, a network interface (cable or wireless), an internet interface, a video interface, a touch-screen interface, an SBC control or power interface, a board interface, a sensor interface, and/or the like as described herein or as known in the art. One or more of these cables or connectors or wireless may attach to a patient drive block **122** or any component thereof. In this representation, the circuitry is operably configured to have a power isolation circuit and a single board computer status and control isolation circuit which span the patient isolation line. Additionally, this representation demonstrates the integration of a programmable digital signal processor, which among other functions, may be configured to furnish the appropriate AC drive signal to the patient drive block and control the phase of the signal provided to a demodulator clock.

FIG. **23** is a block diagram of a patient drive block **122** (FIGS. **1**, **16**, **17**, **18**, **19**, **20**). An alternative version/option of a patient drive block **122** has two or more ECG leads connected. The drive coil drive system in this diagram illustrates a two-coil virtual drive capability allowing the first component for driving coil operation (which may include or be configured with methodologies whether in computer software or otherwise) to simultaneously drive

two or more coils at select power levels. Such a system may include one or more of a voltage regulator, a watchdog switch, a drive switch, a power isolator, a voltage monitor, a cable buffer, a filter, an analog to digital converter, a phase adjuster, a demodulator, a signal filter, a programmable gain amplifier, a coil isolator, a coil sensor coil amplifier, a detector, memory, flash memory, a multiplexor, a polarity inversion switch, and/or the like. Each of these components may include cables or connectors or wireless for one or more of a coil interface, a power supply, a serial interface, a control interface, a status interface, an optional ECG interface or lead, an oscillator interface, a processor interface, a computer interface, a data interface, a network interface (cable or wireless), an internet interface, a video interface, a touchscreen interface, an SBC control or power interface, a board interface, a sensor interface, and/or the like as described herein or as known in the art.

FIG. **24** provides a block diagram of the patient drive block circuitry as in FIG. **21**; however, shows the optional connection to a 12 drive coil array (FIG. **16**, inter alia). In alternative embodiments, the drive coil array may have numerous drive coils capable of functioning for the intended purpose (e.g. some embodiments possess 15, 18, 21, 24 or more drive coil arrays). The drive coil arrays are disposed as optionally set out in FIGS. **13**, **14**, **15** and **17**, inter alia, and additional arrangements and configurations are contemplated by the addition of additional drive coil arrays. In alternatives (not depicted in the Figures), the drive coil arrays may be arranged orthogonally or pseudo-orthogonally as described in FIGS. **13-15**, but not limited to those implementations.

FIGS. **25a-g** provide an overview by flow charts of methodology functionality options for a medical device position location system hereof. FIG. **25a** provides an initial check sub-process. FIGS. **25b** and **25c** provide alternatives for operation, including energizing coils and reading of coil responses; FIG. **25b** for a 9-coil array (x, y, z), and FIG. **25c** for a 12-coil array (x, y, z', z''). FIG. **25d** provides subsequent steps including particularly optional ECG data acquisition and evaluation. FIG. **25e** and FIG. **25f** provide some alternative subsequent steps for a determining component to use sensor coil response signals to determine sensor coil position and/or location. FIG. **25g** provides some optional display steps and a finish or loop back to the start.

FIG. **26** is a simplified real and virtual coil drive system located on a patient drive block **122**, **150**. A coil driver hereof may have only two coil drives and only high/low power selection instead of a power control DAC. In this drive system it is possible to generate x-y and x-(-y) virtual coil drive (see FIG. **10**) and also y-z and y-(-z) drive (see FIG. **11**). One additional feature of this drive is a low power setting which allows drive power reduction if the sensor coil is too close to the drive coil (see methodology flow chart FIG. **25e**). It also is possible to have two additional virtual vectors in this drive system by driving x-high-power together with y-low-power or driving x-low-power with y-high-power. Here, driving x-low-power together with y-low-power yields the same virtual axis—forty-five degrees from x and y axes—as driving both at high power. Optionally, this system may be extended to use for and with the x-z and y-z virtual drives and/or virtual drive implementations of z' and z'' coils.

FIG. **27** is a simplified real and virtual coil drive system located on a patient drive coil block **122** wherein the coil array includes a 12 drive coil array inclusive of the z'-coil and the z''-coil.

FIG. 28 is a schematic view of what may be a determining component in a broad sense, and in this implementation is a sensor coil processing system of the main interface board 156 as it uses the electromagnetic signal 168 received by the sensor coil 114. The sensor coil 114 on the guide wire or stylet may be connected through a cable 120, 146 or wirelessly to the main interface board 156. The first system component which may include a programmable digital signal processor (DSP) providing the drive signals to the coils on the patient drive block and/or controlling the oscillation of the drive coils (the electromagnetic emissions) and the coil clock. The first system component with or without a DSP controls and in some implementations selects a preferred low frequency electromagnetic wavelength at which the drive coil array 106 will be driven to oscillate. This sensor coil 114 receives the electromagnetic waves as input which is communicated to/received by the second system component. These are sensor coil response signals. These response signals may be pre-amplified and filtered then optionally passed through a patient isolation transformer to a gain amplifier which may be a software-controlled programmable gain amplifier. This amplified signal is then demodulated using the low frequency (e.g. 16 kHz) drive oscillator. Concurrently, the DSP may be used to provide oscillator input signals and phase control signals to a demodulator clock. The demodulator clock signals may pass to a synchronous demodulator. The synchronous demodulator and associated software then reads the sensor coil value with a high resolution (e.g. 16 bit or higher resolution) analog to digital converter (ADC). This read value is for each drive coil activation and this value is proportional to the magnetic field measured by the sensor coil during that drive coil activation.

FIG. 29 is a schematic view of an optional more complex virtual drive system. This drive system allows the x-axis coil set 170, the y-axis coil set 172 and z-axis coil set 174 to all be driven simultaneously at independent power levels set by computer control through individual digital to analog converters (DAC). In this drive system, the virtual magnetic vector is the vector sum of x-axis drive plus y-axis drive plus z-axis drive. This virtual drive permits the virtual vector to point to any polar coordinate in space, and thus use polar coordinates as an option; however, it may often still be preferable to use a set of three orthogonal "virtual" axes to calculate the sensor coil 114 position. This alternative further demonstrates a possible integration of the digital signal with a complex drive system.

FIGS. 30a-b provide a methodology flow chart showing optional changes for drive and sensor coil response processing for a fully independent x-y-z virtual drive system (see FIG. 29). This methodology may add a positive offset test and a negative offset test to the virtual axes for the A-corner set of coils. If the sensor coil response is stronger for an offset axis (FIG. 30b) than the current virtual axes, the system shifts to use the offset axes.

FIG. 31 is a detailed view of yet another non-limiting embodiment of a more complex virtual drive system. This drive system allows the x-axis coil set 170, the y-axis coil set 172, z'-axis coil set 176, and z''-axis coil set 178 to all be driven simultaneously at independent power levels set by a controller (which may include or involve a computer control) through individual digital to analog converters (DAC). In this drive system, the virtual magnetic vector is the vector sum of x-axis drive plus y-axis drive plus z-axis drive. In this instance, the z-axis drive may be obtained using measured values from the z'-axis drive and the z''-axis drive. This virtual drive permits the virtual vector to point to any polar

coordinate in space, and thus use polar coordinates as an option; however, it may often still be preferable to use a set of three orthogonal "virtual" axes to calculate the sensor coil 114 position. This alternative further demonstrates an integration of the digital signal with a complex drive system.

A feature of the present developments may include providing an accurate system to generate a three-dimensional indication of one or more of location, position, orientation, and/or travel of a medical device such as a guide wire, catheter, or stylet placed within a patient. A system hereof may include a sensor coil which is disposed in or on the tip of a guide wire or stylet cable, this sensor coil being communicatively operative and cooperative with one or more components for driving coils, receiving responses and/or determining position; these components being in or defining in some implementations an external control and/or display box which may also be communicatively connected with an array of three-axis, four-axis, or a multiple array of axes drive coils. This, may in some implementations, include a display of the location and/or travel of the device. The array of drive coils are placed in some implementations in a triangular block on the patient's chest. This is also sometimes referred to as a drive block, an emitter block, or patient drive block. In some embodiments, the location and travel may be displayed in two locations; both on the display of the control box and/or on a display or indicator contained in the patient drive block component. The block may alternatively include or contain the coil-drive controller that facilitates driving single coils, pairs of coils, triplets of coils, quadruplets of coils, or sets of five or more coils together. In one implementation of a triplet of coils, in which a pair of coils are driven, the paired driving allows x-y, x-z, or y-z coils in a corner, i.e., in any particular set 106 of coils, to be energized at the same frequency and same power creating a virtual drive axis at a 45-degree angle between the axis pairs. The coil-drive may also have an additional control to invert the drive waveform (shift the phase 180 degrees). This inversion of one coil in the pair may create a virtual drive axis at -45 degrees, thus creating an orthogonal pair of virtual axes within a plane. For example, the virtual x-y and x-(-y) are in the same plane as the x and y axes but rotated 45 degrees within the plane. This paired drive scheme may assist in improving the measurement accuracy of the system, especially when the sensor coil inside the catheter tip is substantially or exactly perpendicular to a normal coil drive axis. The system controller may sequentially drive/energize each coil, then each pair of coils while measuring the sensor coil response. When the sensor coil is nearly perpendicular to a drive axis there is significantly diminished response; thus, the virtual axis measurement will provide more accurate data for the position algorithm. Algorithms within the controller may be used to select the best data sets—regular x-y-z axis or virtual x-y-z axis, or a combination thereof—to calculate the sensor/medical device (e.g., catheter tip) location, position and/or orientation. A display may be used to show the catheter tip location as a position track of x-y location plotted over time plus an indicator for the z-axis, depth of the catheter. In other embodiments, a display may be used to show the catheter tip location as a position of x-y location plotted over time plus an indicator for lateral view or "depth" view as a position of y-z location plotted over time. Depth could also be indicated by a variety of methods, as for example by thickening the position line segment in the plot as z decreases and thinning the position line segment as z increases. Moreover, the display may be operably programmed to automatically scale or zoom as the sensor coil approaches a designated target placement location chosen on

the display by a default computer setting or a user inputted x-y-z location. In other alternatives, the external control box or the drive block may provide an audible response or command concerning the location, position, or orientation of the sensor coil.

The z-axis (depth) may have particular importance in or for determining the implanted depth and therefore be important for proper placement of the medical device, as for example a catheter. Issues have existed in determining accurate location of the z-axis. Particularly, calculations of the z-axis have been difficult because null sensor coil response values appear in sensing the magnetic field when the sensor coil is approaching a perpendicular orientation to the z-axis drive coils. One alternative implementation of a system includes a quadruplet of coils in each corner of the patient drive block (i.e., a quadruplet in each set 106 of coils, each set also defining or being in a "corner" of the triangle, or trilateration disposition established by the patient drive block) wherein two axes are orthogonally arranged in the z-dimension, referred to as z'-axis and z''-axis. In this system a pair of coils are driven, the paired driving allows x-y, x-z', x'-z'', y-z', y-z'', and z'-z'' coils in a corner (or respective set 24) to be energized at the same frequency and same power creating a virtual drive axis at an angle between the axis pairs.

It is possible to extend this system further using programmable current control to the coil-driver circuit. Here, a virtual axis could be created at any angle between a drive coil pair in a corner (or respective set 106) by energizing two electromagnetic coils at the same frequency but with different current drive (power levels to yield a vector-sum virtual axis at any angle between 0 and 90 degrees and inverting one coil in this drive scheme to yield a vector-sum virtual axis at any angle between 0 and -90 degrees). However, an orthogonal set of axes would typically still be selected to accurately locate the sensor coil. A further extension to this system could include energizing all three electromagnetic coils, x-y-z, together in a corner using the programmable current controls and inversion controls. The result here would be a vector sum from x-drive, y-drive, and z-drive coils that creates a virtual drive at any vector within three-dimensional space. Alternatively, the system could include energizing all four coils, x-y-z'-z'', together in a corner using the programmable current controls and inversion controls. In alternatives that include four coils in a corner (or set 106), the result would be a vector sum from the x-drive, y-drive, z'-drive, and z'' drive coils that creates a virtual drive at any vector within three-dimensional space from these coils.

It is also possible to enhance this system with the inclusion of electrocardiogram (ECG) measurement and display with the location system. Here two, or more reference electrodes may be plugged into or otherwise connected to the display unit or patient block with the additional electrode connected to the stylet or guide wire or catheter. An ECG may then be displayed for the user, so that P-wave changes, or other waveform changes may be shown to indicate proximity of the stylet or guide wire or catheter to the heart.

An aspect of the present developments is an electromagnetic medical device locating system for locating a medical device or the end or the tip thereof in a subject, including one or more of:

- three or more triplet drive coil sets, each drive coil set including at least three orthogonally arranged discrete drive coils, each of the discrete drive coils being electromagnetic (EM) coils;
- at least one moveable sensor coil;

one or more system components that one or both provide drive signals energizing said discrete drive coils and measure resulting sensor coil response signals; wherein the provision of drive signals includes one or both:

- (i) sequentially driving one or pairs of said discrete drive coils within a triplet drive coil set; and
- (ii) selectively providing phase inversion of the drive signal to any one or pairs of said discrete drive coils within a triplet drive coil set;

a computing component for calculating sensor coil position in the subject relative to said triplet drive coil sets from one or more measured resulting sensor coil response signals.

Another aspect of the present developments may be inclusion of a digital signal processor operably configured to modify said AC drive frequency to one or both maximize and optimize the output from the discrete drive coils. Additionally, the system may include a demodulator for selectively measuring said sensor coil response signal. The demodulator further processes the sensor coil signal and controls a demodulator clock that operates at the same frequency as the coil AC drive signal with a phase offset. The digital signal processor controls the demodulator clock to one or both maximize and optimize the drive coils thus one or both maximizing and optimizing the sensor coil response signal. Further, the digital signal processor may be connected to non-volatile memory capable of storing: data necessary for controlling the coil clock frequency data for input to the array of drive coils and data for controlling the frequency and phase data for the demodulator clock.

Another aspect may include: (a) three or more virtual or actual x-y-z axis electromagnetic (EM) triplet drive coils, each including at least three virtual or actual EM drive coils arranged in perpendicular axis to each other along an x-y-z axis, the virtual or actual EM triplet drive coils placed in a two- or three-dimensional geometric array; (b) at least one medical device sensor coil in physical association with at least one medical device tip and connected to at least one demodulator circuit; (c) at least one AC drive controller that (i) drives sequentially one or more of the virtual or actual EM drive coils; and (ii) provides a phase shifted signal to the demodulator; (d) at least one demodulator circuit including at least one demodulator for measuring the sensor coil output signal using frequency correlation with at least one AC coil driver signal from the AC drive controller to provide a synchronously demodulated sensor coil signal; (e) at least one automatic gain control circuit that maximizes the demodulated sensor coil signal; (f) a computing component for normalizing the resultant demodulated sensor coil signal data by dividing or multiplying the determined programmable gain value from the measurement of the demodulated sensor coil signals; (g) a computing component for selecting and calculating the optimized demodulated sensor coil signal data set generated from demodulated sensor coil signals, which optimized coil signal data set is calculated based on the sum of measured squared terms that have relatively higher or highest values; (h) a calculator for calculating the distance of the moveable sensor coil and medical device tip from three or more virtual or actual EM triplet drive coil locations using the optimized demodulated sensor coil data set calculated using intersection of the spheres to provide the location of the sensor coil and corresponding medical device tip in space relative to the location of two or more of the virtual or actual EM triple drive coils provided in the two- or three-dimensional geometric array corresponding to the location of the medical device tip in the subject; and in some implementations, (i) a display. The result is the actual

location of the medical device tip in the subject indicating height, width, and depth of the medical device tip in the subject calculated relative to the position of the drive coil geometric array.

It is possible to extend this system to include one or more of (i) the virtual or actual EM drive coils or the virtual or actual EM triplet drive coils are arranged outside at least one of a two dimensional plane defined by at least three of the virtual or actual EM triplet drive coils; and/or (ii) at least four of the virtual or actual EM triplet drive coils form a tetrahedron as part of the three-dimensional geometric array.

It is possible to enhance such a system to include one or more of wherein (i) the display shows the relative location of the sensor coil or the medical device tip as a tracking of the sensor coil or medical device tip location over time; (ii) the display displays the sensor tip angle graphically for the user of the system, wherein the medical device tip angle is the angle of maximum response of the sensor coil as measured from sweeping the virtual drive axis through x-y plane (e.g. 0 to 360 degrees) then using this x-y maximum response angle as a vector added to the sweep through the virtual z axis; and/or (iii) the display displays the sensor tip angle graphically for the user of the system, wherein the medical device tip angle is the angle perpendicular to the angle of minimum response of the sensor coil as measured from sweeping the virtual drive axis through x-y plane (e.g. 0 to 360 degrees) then using this x-y minimum response angle as a vector added to sweep through the virtual z axis.

It is possible to extend such a system to further include wherein the intensity or power of current running through one or more adjacent EM drive coils in at least one of the EM triplet drive coils is programmable or adjustable using a control box including a programmable computer.

An aspect of the present developments is to provide a system wherein one or more of the EM drive coils are provided as the virtual EM drive coils, and wherein: (a) one or more controllers that select pairs or triplets of drive current values of the EM drive coils at regular time intervals to provide one or more paired magnetic drive coil vector values at angles from 0 to 90 degrees and phase inversion of at least one of the corresponding EM drive coils in at least one pair of the paired or tripled magnetic drive coil vectors to further provide one or more magnetic drive coil vector values at angles from -90 to 0 degrees; (b) one or more controllers that: (i) determine the angle values of maximum and minimum sensor coil responses within a plane using paired coil programmable current drive sweeping a range from 0 to 90 degrees; and (ii) that then determine the angle values of maximum and minimum sensor coil responses within a plane using paired coil programmable current drive sweeping using inverted phases of at least one coil and sweeping a range from -90 to 0 degrees; and/or (c) a calculator that: (i) computes at least one set of optimal virtual drive x and y axes for at least two of the EM triplet drive coils as values corresponding to plus and minus 45 degrees from the maximum and minimum sensor coil responses; and (ii) computes an optimal virtual drive z axis orthogonal to the plane of the optimal virtual drive x and y axes to provide at least one optimal virtual EM triplet drive axes and at least one of the virtual EM triplet drive coils. This aspect can be further extended to systems that utilize a quadruplet of drive coils.

Such a system may be extended wherein the system includes a programmable coil drive current for each of x, y, and z drive coils driven; and wherein (a) the triplets of drive current values selected at regular time intervals are provided as (i) paired magnetic drive coil vector values at angles from

0 to 90 degrees in an x-y plane together with 0 to 90 degrees from the x-y plane to the corresponding z-axis; and (ii) as phase inversion of one or two paired magnetic drive coil vector values at angles from -90 to 0 degrees in an x-y plane together with from -90 to 0 degrees from the x-y plane to the corresponding z-axis; (b) the angle values of maximum sensor coil responses within a plane for both 0 to 90 and -90 to 0 degrees are fixed and used for at least two x and y virtual axes in a virtual plane and the values of maximum sensor coil response are determined for the corresponding virtual z axis to provide at least one maximum virtual x-y-z vector for at least one of the corresponding virtual EM triplet drive coils; (c) the angle values of minimum sensor coil responses within a plane for both 0 to 90 and -90 to 0 degrees are fixed and used for at least two x and y virtual axes in a virtual plane and the values of maximum sensor coil response are determined for the corresponding virtual z axis to provide at least one minimum virtual x-y-z vector for at least one of the corresponding virtual EM triplet drive coils; (d) the at least one optimal virtual EM triplet drive vector and at least one of the virtual EM triplet drive coils are generated using intermediate virtual drive x and y axes as plus and minus 45 degrees from the minimum virtual x-y-z vector and intermediate virtual drive z axis as orthogonal to the intermediate virtual drive x and y axis; the optimal virtual x, y, and z axis are then generated by pivoting the intermediate x, y, and z axes by moving the intermediate z axis 45 degrees about the maximum virtual x-y-z vector. This aspect can be further extended to systems that utilize a quadruplet of drive coils.

Such a system may be enhanced wherein the display further displays P-wave or other cardiac waveform changes over time in combination with the location of the medical device such as a guide wire or stylet tip in relationship to the subject's heart.

Such a system may be extended by further including (i) an x-axis tilt meter and y-axis tilt meter which uses gravity to measure the x-axis and y-axis tilt from true vertical; and (2) a computer to calculate and display the location of the medical device tip as height, width, and depth of the sensor coil corrected for the tilt the geometric array. Such a system may be enhanced wherein the geometric array and sensor coil connected to the display via a wireless interface.

Such system may be extended by further including an electrocardiogram (ECG) operably associated with the geometric array with a display to show the subject's ECG signal over time; or by further including an electroencephalogram (EEG) operably associated with the geometric array with a display to show the subject's EEG signal over time. The system could be further extended wherein the two or more of the ECH leads are operably connected to the system via a wireless connection.

An aspect of the present developments may include a method for locating a medical device in a subject, including: (a) providing a system as presented herein; (b) inserting and positioning the medical device tip associated with a functional and sterile medical device into the subject; and (c) recording or monitoring the output of the display to locate the medical device tip in the subject. Such a method may be extended wherein the method further includes the use of at least one selected an electrocardiogram (ECG), an electroencephalogram (EEG), an x-ray machine, an computer assisted tomography (CAT) machine, a positron emission tomography (PET) machine, an endoscope, or an ultrasound imaging device or composition.

An aspect of the present development may include a system operably connected to a ultrasound imaging device. The ultrasound imaging device is operably connected to the

control box providing a display of the vasculature of the subject. The ultrasound imaging device may be further connected to guidewires, stylets, or catheters that include biocompatible radiopaque markings at distances, lengths, or measurements, that span the circumference or a portion thereof of the guidewire, stylet, or catheter (e.g. inserted component), from the proximal to distal end of the inserted component.

An aspect of the present developments may include methods, computer systems and software, provided as programming code or instructions on computer readable media or hardware or networks or computer systems, for generating virtual electromagnetic (EM) triplet drive coils for generating data corresponding to the location coordinates for a sensor coil, including:

- (a) electronically providing triplets of drive current values generated from at least three EM drive coils of the EM triplet drive coils in detectable proximity to the EM sensor at regular time intervals to provide one or more paired magnetic drive coil vector values generated at angles from 0 to 90 degrees without and from -90 to 0 degrees with phase inversion;
- (b) electronically providing angle values of maximum or minimum EM sensor coil responses generated from the EM triplet drive coils within the x-y plane using paired x-y coils' programmable current drive sweeping a range from 0 to 90 degrees without and from -90 to 0 degrees with phase inversion;
- (c) electronically computing at least one set of optimal virtual drive x and y axes as values corresponding to plus and minus 45 degrees from the maximum or the minimum sensor coil response;
- (d) electronically computing an optimal virtual drive z axis orthogonal to the plane of the optimal virtual drive x and y axes to provide at least one optimal set of virtual EM triplet drive axes for at least one of the EM triplet drive coils.

Such a method may be extended wherein (a) the triplets of drive current values selected at regular time intervals are provided as (i) paired magnetic drive coil vector values at angles from 0 to 90 degrees in an x-y plane added together with coil vectors of the z-axis from 0 to 90 degrees from the x-y plane; and (ii) as phase inversion of one or more paired magnetic drive coil vector values at angles from -90 to 0 degrees in an x-y plane added together with coil vectors of the z-axis from -90 to 0 degrees from the x-y plane; (b) the angle value of maximum sensor coil response within the x-y plane for both 0 to 90 and -90 to 0 degrees is determined as the intermediate virtual maximum x-y axis and this intermediate virtual maximum x-y axis added to the z-axis swept from 0 to 90 and -90 to 0 degrees to determine at least one maximum virtual x-y-z vector for at least one of the corresponding EM triplet drive coils; (c) the angle value of minimum sensor coil response within the x-y plane for both 0 to 90 and -90 to 0 degrees is determined as the intermediate virtual minimum x-y axis, and this intermediate virtual minimum x-y axis is added to the z-axis swept from 0 to 90 and -90 to 0 degrees to determine at least one minimum virtual x-y-z vector for at least one of the corresponding EM triplet drive coils; and (d) the at least one optimal virtual EM triplet drive axes for at least one of the EM triplet drive coils are calculated using the plane defined by the maximum virtual x-y-z vector and minimum x-y-z vector wherein the optimal virtual drive x and y axes are plus and minus 45 degrees from the minimum virtual x-y-z vector and the optimal virtual drive z axis as orthogonal to the optimal virtual drive x and y axes.

FIG. 1 is an overview schematic diagram of an implementation of the present developments. A control box 102 contains a touch screen display 104 with a computer control and data processing. The triangular patient drive block 122 is connected via power and communications cable 108 to the control box 102. The drive and sensor electronics 110 may be located in the block 122 and provide drive coil control and sensor coil demodulation/amplification. In the three corners of the block 122 are mounted each triplet drive coil set 106 (106a, 106b, 106c). Alternatively, each coil set 106 could be mounted as feet protruding from the bottom of the block 122. The sensor coil 114 is built onto a small diameter biocompatible cable 118 which may be inserted into a medical device such as a catheter to be placed in the patient. The sensor signal is connected back to the control box 102 with a two-wire cable 120. FIG. 7 provides a detailed view of a sensor coil 114. Sensor coil performance may be improved by winding the coil about a ferromagnetic wire in the tip of the cable 138. The ferromagnetic material should be used for the length of the sensor coil 114 and may be followed by non-ferrous material. Two fine wires 142 from the sensor coil 114 are attached or associated (e.g., glued, wrapped, insulated, and or sheathed) and sealed 140 down the length of the ferrous core wire 138.

As presented, e.g., in FIG. 18, an aspect of this device may include continuous display at the position of the sensor coil 114 placed in the tip of a medical device as the medical device moves through the patient's tissue. The patient drive block 122 is placed over the patient's body where the medical device will be targeted (e.g., over the chest preferably aligned with the sternal notch if the medical device will be placed in the area of the heart).

As presented, e.g., in FIGS. 1, 16, 17, and 18, respectively, the sensor coil cable 120 and patient drive block cable 108 are connected to a user control box 102. The user control box 102 contains a computer 156 (FIG. 10) which sequentially drives each driver coil 126, 128, 124 (FIG. 2) on each axis in every corner 106a, 106b, 106c of the patient drive block 122, 150. The coil driver creates magnetic drive vectors as shown in FIG. 9, 10, or 11—where FIG. 9 represents normal drive and FIGS. 10 and 11 represent virtual drive. The single board computer 166 (FIG. 21) measures the demodulated output signal from the sensor coil 114 for each sequentially driven coil set 106 (FIG. 1). The single board computer 156 (FIGS. 16 and 21) continuously adjusts the gain of each output signal using a programmable gain stage in the demodulator electronics and scales all the sensor data to be gain normalized (see FIG. 25b, 25c, inter alia). Here, gain normalized means that if a measured response is value "a" collected at a programmable gain of "4.00" times, then the normalized resultant value is "a" divided by 4.00. A non-limiting example of an alternative gain normalizing method is to multiply each value "a" by 4096/gain, e.g. "a"×4096/4.00. The programmable gains that may be used as a non-limiting example are 1.00, 2.00, 4.00, 8.00, 16.00 and 32.00 plus there may be a final gain stage that is selectable for 1.00 or 1.41 (equivalent to 1N2). Examples of a resultant set of programmable gains are 1.00, 1.41, 2.00, 2.82, 4.00, 5.64, 8.00, 11.28, 16.00, 22.56 and 32.00.

From the normalized response data, the single board computer 156 (FIG. 21) compares the sum of the squares of the sensor's normal response to the sum of the squares of the sensor's virtual response. Whichever sum is greater or has the stronger response may be used by the computer 156 to calculate the sensor coil 114 location using trilateration which is the calculation of the intersection of three spheres

where each sphere is defined as the radial distance of the sensor coil **114** from each x-y-z driver coil set **106a**, **106b**, **106c** (FIG. 1).

From each corner, the radial distance can be defined as a constant divided by the 6th root of the sum of the squares of the x, y, and z measured normalized response. Here the constant, k, is a calibration constant reflecting the strength of each drive coil **124**, **126**, **128** (FIG. 2) and the sensitivity of the sensor coil **114** (FIG. 1). In one possible aspect, a calibration constant could be generated during manufacturing for each of the drive coils and then stored as calibration constants for each coil in non-volatile memory of the patient drive block. By trilateration, the radial distance equation for each corner is:

$$r = k \sqrt[6]{((x^2 + y^2 + z^2))}$$

The sensor coil location is then calculated from three equations for the three corners of plate **122**:

$$r_1^2 = k^2 \sqrt[6]{((x_1^2 + y_1^2 + z_1^2))}$$

$$r_2^2 = k^2 \sqrt[6]{((x_2 - d)^2 + y_2^2 + z_2^2)}$$

$$r_3^2 = k^2 \sqrt[6]{((x_3^2 + (y_3 - d)^2 + z_3^2)}$$

Here d is the distance of each coil from the other and k is the calibration constant which scales the result into meaningful units of distance, e.g. centimeters or inches. In this non-limiting example, the coils on the patient drive plate or block **122** (FIGS. 1, 16, 17 inter alia) are arranged in a right triangle, with two sides of equal length, d, as reflected in the 2nd and 3rd equations above, just on different axis, x or y. The solution to these equations yielding the sensor coil location is:

$$x_s = (r_1^2 - r_2^2 + d^2) / 2d$$

$$y_s = (r_1^2 - r_3^2 + d^2) / 2d$$

$$z_s = \pm \sqrt{r_1^2 - x_s^2 - y_s^2}$$

Here the solution for z (vertical axis) is assumed to be negative as the sensor coil **114** cannot be above the plane of the patient drive block **122** (FIGS. 1, 16, 17, 18, 19 inter alia) unless it is outside the patient.

While the above reflects one non-limiting approach to locating the sensor coil **114** (FIG. 1), it is not the only solution for coil location. Specifically when the sensor coil **114** is nearly perpendicular to a driver coil axis the sensor coil response approaches zero; therefore a “virtual axis” drive system, in some instances, provides for the optimal sensor coil response. In this approach the coil driver circuit is designed to selectively drive, within a triplet set, pairs of coils, e.g. **124** and **126** (FIG. 2), together at the same frequency and amplitude with an additional driver control to selectively invert the phase of one coil in the pair. This paired coil drive of x-y coils creates the 1st virtual axis at forty-five degrees from the original x and y axes. The paired coil drive is then operated with x-(-y) which drives the x-coil together with inverted-phase y-coil and this creates the 2nd virtual axis at minus forty-five degrees from the original x and y axes. The result is two orthogonal virtual magnetic vectors as shown by the dashed lines in FIG. 9 for x-y paired coil drive or in FIG. 10 for y-z paired coil drive. For paired drive, the single board computer **156** (FIG. 16) sequentially drives the x-y pair, x-(-y) pair, and z axis for each x-y-z coil set **106a**, **106b**, **106c** (FIGS. 1 and 7). Here, “(-y)” means inverted phase on y axis drive. The measured sensor coil response for paired-coil drive must be scaled down by $\sqrt{2}$ or 1.4142 because of vector summing of the two

coils driven together. Alternatively, the coil-driver power could be scaled down by $1/\sqrt{2}$ or 0.7071 in hardware when driving pairs so that the vector sum of two coils equals the magnetic vector of a single coil drive. The single board computer **156** measures the sensor coil response for each corner in normal drive and paired drive, and then selects the strongest signal from each corner comparing the sum of x^2 , y^2 , and z^2 normal coil drive response to the sum of $(x-y)^2$, $(x-(-y))^2$, and z^2 paired coil drive response. The strongest signal from each corner is used to calculate the location of the sensor coil **114** using the trilateration method described in the above equations. This example illustrates paired x-y coil drive; and by logical extension this may also apply to x-z, or y-z paired drive. An objective in some implementations of these developments may include improving the accuracy of horizontal (x-y) location; therefore the paired x-y drive can be preferred over x-z or y-z.

In an alternative embodiment and/or method, the single board computer **156** (FIG. 21) uses the normalized response data to compare the sum of the squares of the sensor’s normal response to the sum of the squares of the sensor’s virtual response. Whichever sum is greater or has the stronger response may be used by the computer **156** to calculate the sensor coil **114** location using trilateration which is the calculation of the intersection of three spheres where each sphere is defined as the radial distance of the sensor coil **114** from each x-y-z driver coil set **106a**, **106b**, **106c** (FIG. 1).

In this alternative embodiment, from each corner, the radial distance may be defined as a constant divided by the 6th root of the sum of the squares of the x, y, and z measured normalized response. Here the constant, k, is a calibration constant reflecting the strength of each drive coil **124**, **126**, **128** (FIG. 2) and the sensitivity of the sensor coil **114** (FIG. 1). In one possible approach, a calibration constant could be generated during manufacturing for each of the drive coils and then stored as calibration constants for each coil in non-volatile memory of the patient drive block. By trilateration, the radial distance equation for each corner is:

$$r = k \sqrt[6]{((x^2 + y^2 + z^2))}$$

In this approach for calculation of the EM tip location, by trilateration, the sense coil location [x, y, z] distance equation for each corner is:

$$xs = (r_1^2 - r_2^2 + d^2) / (2d)$$

$$ys = [(r_1^2 - r_3^2 + i^2 + j^2) / (2j)] - [(i/j)xs]$$

$$zs = \pm \sqrt{r_1^2 - xs^2 - ys^2}$$

In this alternative, the coordinates of the sphere used for trilateration may be as follows: sphere 1=[0,0], sphere 2=[0,d], and sphere 3=[i,j]. One should note that there are two solutions to the zs answer, in this instance, the “+” and the “-” solution. The computer component is operably programmed to select the solution for the negative answer as the assumption is made that the sensor coil **114** cannot be above the plane of the patient drive block unless it is outside the patient. In this alternative, by trilateration, the radial distance equation for each corner is:

$$r_1^2 = k^6 \sqrt[6]{((mx_1^2 + my_1^2 + mz_1^2))}$$

$$r_2^2 = k^6 \sqrt[6]{((mx_2^2 + my_2^2 + mz_2^2))}$$

$$r_3^2 = k^6 \sqrt[6]{((mx_3^2 + my_3^2 + mz_3^2))}$$

In this alternative, mx_1 , my_1 , and mz_1 are measured sense coil responses from corner 1 **124**; mx_2 , my_2 , and mz_2 are

measured sense coil responses from corner 2 **126**; and mx_3 , my_3 , and mz_3 are measured sense coil responses from corner 3 **128**. Furthermore, a non-limiting approach may be implemented when the sensed or measured z-signal is approaching a null or alternatively when the measuring or determining component determines that a null signal was received. Here, the z-signal is estimated using the following:

$$mz^2 = ((mx^2 + my^2) \times (1/\sqrt{2}));$$

or,

$$mz^2 = ((mx^2 + my^2) \times (0.7071))$$

In this alternative, the location of the sense coil is calculated using the vector sums of x and y to estimate the z vector; thus, preventing the return of a null signal. In this alternative, due to the drive coil fields and due to location and spacing of the drive coils, the nulls of one corner do not overlap the nulls of another corner.

The sensor coil location is then calculated from three equations for the three corners of plate **122**, in this instance substituting the above estimated z-signal in the place of the z vector, to:

$$r_1^2 = k^6 \sqrt{((mx_1^2 + my_1^2 + (mz_1^2 \times (1/\sqrt{2})))$$

$$r_2^2 = k^6 \sqrt{((mx_2^2 + my_2^2 + (mz_2^2 \times (1/\sqrt{2})))$$

$$r_3^2 = k^6 \sqrt{((mx_3^2 + my_3^2 + (mz_3^2 \times (1/\sqrt{2})))$$

The solution to these equations yielding the sensor coil location is:

$$x_s = (r_1^2 - r_2^2 + d^2) / 2d$$

$$y_s = (r_1^2 - r_3^2 + d^2) / 2d$$

$$z_s = \pm \sqrt{r_1^2 - x_s^2 - y_s^2}$$

Here the solution for z (vertical axis) is assumed to be negative as the sensor coil **114** cannot be above the plane of the patient drive block **122**, **150** (FIGS. **1**, **16**, **17**, **18** inter alia) unless it is outside the patient.

While the above reflects one non-limiting approach to locating the sensor coil **114** (FIG. **1**), it is not the only solution for coil location. Specifically when the sensor coil **114** is nearly perpendicular to a driver coil axis the sensor coil response approaches zero; therefore a “virtual axis” drive system provides for an additional sensor coil response. In this approach the coil driver circuit is designed to selectively drive, within a triplet set, pairs of coils, e.g. **126** and **124** (FIG. **2**), together at the same frequency and amplitude with an additional driver control to selectively invert the phase of one coil in the pair. This paired coil drive of x-y coils creates the 1st virtual axis at forty-five degrees from the original x and y axes. The paired coil drive is then operated with x-(-y) which drives the x-coil together with inverted-phase y-coil and this creates the second virtual axis at minus forty-five degrees from the original x and y axes. The result is two orthogonal virtual magnetic vectors as shown by the dashed lines in FIG. **9** for x-y paired coil drive or in FIG. **10** for y-z paired coil drive. For paired drive, the single board computer **156** (FIG. **21**) sequentially drives the x-y pair, x-(-y) pair, and z axis for each x-y-z coil set **106a**, **106b**, **106c** (FIGS. **1** and **15**). Here, “(-y)” means inverted phase on y axis drive. The measured sensor coil response for paired-coil drive must be scaled down by 1.4142 because of vector summing of the two coils driven together. Alternatively, the coil-driver power could be scaled down by 0.7071 in hardware when driving pairs so that the vector sum of two

coils equals the magnetic vector of a single coil drive. The single board computer **156** measures the sensor coil response for each corner in normal drive and paired drive, and then selects the strongest signal from each corner comparing the sum of x^2 , y^2 , and z^2 normal coil drive response to the sum of $(x-y)^2$, $(x-(-y))^2$, and z^2 paired coil drive response. The strongest signal from each corner is used to calculate the location of the sensor coil **114** using the trilateration method described in the above equations, using the improved method. This example illustrates paired x-y coil drive; and by logical extension this may also apply to x-z, or y-z paired drive, or in alternative structures orthogonal pairs of drive coils.

In a non-limiting approach, the z-axis coil is replaced by a pair of orthogonal coils, z' and z'' (FIGS. **4**, **5**, **6**, **12**, **13**, and **14** inter alia). These z' and z'' coils are arranged in pseudo-orthogonal or dual orthogonal placement. In this approach, the z-coil responses or measured z-coil values are calculated as the vector sum of the sense coils response to z' and z'' . By trilateration, the radial distance equation for each corner is:

$$r = k^6 \sqrt{(z'^2 + z''^2 + a^2)}$$

where “a” is calculated using the x-y sense coil measurement information, then here, the location of the sense coil [z' , z'' , a] would be:

$$r_1^2 = k^6 \sqrt{((mz_1'^2 + mz_1''^2 + ma_1^2))$$

$$r_2^2 = k^6 \sqrt{((mz_2'^2 + mz_2''^2 + ma_2^2))$$

$$r_3^2 = k^6 \sqrt{((mz_3'^2 + mz_3''^2 + ma_3^2))$$

In this alternative, mz_1' , mz_1'' , and ma_1 are measured sense coil responses from corner 1 **124**; mz_2' , mz_2'' , and ma_2 are measured sense coil responses from corner 2 **126**; and mz_3' , mz_3'' , and ma_3 are measured sense coil responses from corner 3 **128**. In this alternative, ma_1^2 , ma_2^2 , and ma_3^2 are measured vectors using the x drive coil and y drive coil to obtain the vector sum for each corner. In this alternative method for calculation of the EM tip location the, by trilateration, the sense coil location [z' , z'' , and a] distance equation for each corner is:

$$z' = (r_1^2 - r_2^2 + u^2) / (2u)$$

$$z'' = [(r_1^2 - r_3^2 + v^2 + w^2) / (2 \times w)] - [(v/w) \times a]$$

$$a = \pm \sqrt{[r_1^2 - z'^2 - z''^2]}$$

In this alternative, the coordinates of the sphere used for trilateration may be as follows: sphere 1=[0,0], sphere 2=[0,u], and sphere 3=[v,w]. This or alternative sets or combinations of the above non-limiting approaches may be utilized within the system.

An improvement of the paired-coil drive may be to add programmable (DAC) power control to the coil drivers on the drive coil drive electronics board **110** (FIGS. **22**, **23**, **28**, and **31**). Here, the single board computer **156** (FIG. **16**, **21**) has the capability to select pairs of drive current power settings which steer the virtual axis of the paired coils from 0 to 90 degrees. Inversion of one of the coil drivers in the pair provides the capability for virtual axis from -90 to 0 degrees. In this design, the single board computer **156** selects pairs of power settings output to the x-y paired coil driver to sweep the virtual drive axis from 0 to 90 degrees while recording the sensor coil response and this process is repeated with the y-coil driver phase inverted to sweep from -90 to 0 degrees. The angle of the virtual axis when the sensor coil response data is maximum indicates the sensor

coil **114** (FIG. 1) is parallel to the virtual axis and the angle of the virtual axis when the sensor coil response data is minimum indicates the sensor coil **114** is perpendicular to the virtual axis. Here the maximum angle and minimum angle are orthogonal (perpendicular). The single board computer **156** (FIG. 16, 21) calculates the optimum virtual x axis at forty-five degrees from the measured angle for maximum (or minimum) response and calculates the optimum virtual y axis as an angle orthogonal to the virtual x axis. As all x-y-z coil sets **106a**, **106b**, **106c**, (or x-y-z'-z'') are mechanically aligned the solution for best virtual axes in one corner applies to all corners in the patient drive block **122**, **150** (FIGS. 1, 16, 17 and 18). The single board computer **156** (FIG. 16, 21) measures the sensor coil response for all corners using these optimum virtual x axis, optimum virtual y axis plus normal z axis. The sum of (virtual x)², (virtual y)², and z² sensor coil responses for each corner is used to calculate the position of the sensor coil **114** (FIG. 1) using the trilateration method described in the above equations. This example illustrates paired x-y coil drive; and by logical extension this also applies to x-z, or y-z paired drive; however, the preference in this development is to improve accuracy of horizontal location and thus use paired x-y drive. Furthermore, in arrangements that utilize a quadruplet embodiment of drive coils, the single board computer **156** (FIG. 16) may calculate the sensor coil location for all corners using an optimized choice of the measured x, virtual x, measured y, virtual y, virtual x-y, measured z', virtual z', measured z'', virtual z'', and virtual z'-z''.

An alternative, non-limiting, method for finding the optimum virtual x and virtual y axis in the programmable pair-coil drive above is to use successive approximation instead of sweeping 0 to 90 degrees. In this approach, the single board computer **156** (FIG. 16) has the capability to select pairs of drive current power settings which steer the virtual axis from -90 to +90 degrees. The single board computer first tests the sensor coil response to the paired coils at virtual axes +45 and -45 degrees and selects the virtual axis with the stronger response. Using the stronger axis, the computer then tests the sensor coil response to paired coils at +22.5 and -22.5 degrees from the current virtual axis and selects the virtual axis with the stronger response. This process continues for +/-11.25 degrees, +/-5.625 degrees, until the limits of drive power resolution are reached. The resulting virtual axis is the axis of maximum response. The single board computer **156** calculates the optimum virtual x axis at forty-five degrees from the measured angle for maximum response and calculates the optimum virtual y axis as an angle orthogonal to the virtual x axis. This approach may in some embodiments be extended to the z' and z'' drive coils.

A selection of the best set of virtual axes in a triplet-coil drive scheme may be accomplished with programmable power control to the coil drivers for each axis, and with the driver control to selectively invert the phase of any coil in the triplet x-y-z coil sets **106a**, **106b**, **106c** (see FIG. 16). Here, the single board computer **156** (FIG. 16) has the capability to select pairs of drive current power settings which steer the x-y virtual axis of the paired coils from 0 to 90 degrees. Inversion of one of the coil drivers in the pair provides the capability for x-(-y) virtual axis from -90 to 0 degrees. With the addition of the third coil drive and inversion the single board computer **156** may sweep the virtual axis 0 to 90 and -90 to 0 degrees in z range. The microcomputer (in alternative embodiments multiple microcomputers) may select the pairs of current settings output to the x-y paired coil driver to sweep the virtual drive axis from

0 to 90 degrees while recording the sensor coil response and this process is repeated with the y coil driver phase inverted to sweep from -90 to 0 degrees. The angle of the x-y virtual axis when the sensor coil response data is maximum indicates the sensor coil **114** (FIG. 1, 16) is parallel for the x-y plane. The single board computer **156** then sets this x-y axis and sweeps the z axis drive from -90 to 0 and 0 to 90 degrees while recording the sensor coil response. The polar angle of the x-y-z virtual axis when the sensor coil response data is at maximum indicates the sensor coil **114** is parallel to this virtual x-y-z axis. The single board computer **156** then repeats this process to find the minimum sensor coil response sweeping x, y, and z axes. The polar angle of the x-y-z virtual axis when the sensor coil response data is minimum indicates the sensor coil **114** is perpendicular to this virtual x-y-z axis. These two vectors, virtual minimum and virtual maximum, define a plane intersecting the sensor coil **114**. For optimum response, the single board computer **156** calculates a virtual x axis 45 degrees between the maximum and minimum vectors, then calculates the virtual y axis as 90 degrees from the virtual x in the plane defined previously. Here, virtual z axis is defined as orthogonal to the plane of virtual minimum and virtual maximum vectors. The single board computer **156** then tilts the virtual z axis and the plane of virtual x axis and virtual y axis 45 degrees toward the virtual minimum vector, and the result is the optimal virtual axis set which maximizes the sensor coil response. As all x-y-z coil sets **106a**, **106b**, **106c** are mechanically aligned the solution for best virtual axes in one corner applies to all corners in the driver array. The single board computer **156** measures the sensor coil response for all corners using these optimum virtual x, y, and z axes. The sum of (virtual x)², (virtual y)², and (virtual z)² sensor coil responses for each corner may be used to calculate the sensor coil **114** location and orientation using the trilateration method described in the above equations. One method to maintain the optimum x-y-z axis over time is to continuously test the sensor coil response to small deviations (offset angle) from the optimum axis (see FIG. 29b). Here, the single board computer **156** compares the sum of (virtual x)², (virtual y)², and (virtual z)² sensor coil responses for the current virtual axis to the sum for virtual axis plus offset angle and the sum for virtual axis minus offset angle. The computer **156** then selects the axis with the largest summed response—this becomes the new optimum x-y-z axis and the process continues to iterate testing small deviations over time. This approach may in some embodiments be further extended for use in quadruplet drive coil sets.

The single board computer **156** may then graphically display the sensor coil position on the display **104** of the control box **102**. The position is continuously updated adding onto the previous graphical data to create a track or path of the sensor coil **114** over time. Furthermore, as the track or path of the sensor coil **114** is displayed, the display also shows the orientation of the sensor coil in at least the x-y coordinate plane. The user interface of the single board computer **156** allows the user to clear the recorded track or to save the recorded track to non-volatile memory. Touchscreens have been described; however keyboard or other data input, or user interface options may be used.

The construction details above for the control box **102** (FIGS. 1, 21) may provide for a tethered device with the display/control separate from the patient block **122**, **150** (FIGS. 1, and 21). However, an alternative construction would be to build a device or system in which the patient block **122**, **150** is battery-powered and connected wirelessly to the control box **102**. In another variation, the control box

102 could be integrated into or as part of the patient block and placed on the patient chest or other locations to track medical device position. Wireless and/or wired connections are thus optionally available for the connections of the drive coil sets to the control or system components for the driving thereof; as well as for the connections of the sensor coil to the control or system components for measuring or receiving the response signals of the sensor coil.

An alternative construction would be to use four or more drive coils 106 oriented as a square, rectangle, pentagon, circle, oval, geometric, or any other suitable shape, in or as the patient drive block 122, 150 (FIGS. 1, 18, 19 and 20). In this non-limiting approach, the location, disposition, and orientation may be determined using multilateration.

An alternative construction would be to use a capacitor 131 (FIG. 6) in operable association with each of the discrete drive coils 106 or each axis of each discrete drive coil 124, 126, and 128. This alternative embodiment may create an LC circuit that has unique benefits for optimizing the energizing of the drive coils, the re-energizing of the drive coils, the sequential energizing of the drive coils, the synchronous energizing of the drive coils, and the de-energizing of the drive coils.

An alternative construction (FIGS. 1, 16, 17, and/or 18) is to optionally incorporate electrocardiograph (ECG) monitoring into the medical device location system to facilitate placement of the medical device with sensor coil 114 in close proximity to the heart. Here the patient drive block 150 may be modified with one or more ECG pads 154 and ECG lead wires 152 which attach to the patient's chest and the third ECG lead is provided by a conductive wire 146 added in or otherwise made part of the core of the guide wire or stylet sensor coil 114.

An ECG amplifier may be added to the main interface board 158 (FIG. 22), and the single board computer 156 may then present the ECG on the display 104 as the medical device such as a catheter is advanced within the patient's or subject's body. The user may observe changes in the P-wave or other wave elements of the ECG as the medical device/catheter reaches the heart. Ideally, the single board computer 156 could use a waveform analysis to assist the user in recognizing changes occurring to the P-wave or other waveforms.

A component to this design may include connecting the signals from the sensor coil 114 and ECG 146 to the user control box 102. This is complicated in practice by covering the entire patient and patient block 150 with sterile drapes for insertion of the patient's medical device/catheter. In this design, a miniature stereo phone plug or similar could be used to pierce a plastic bag and connect to cable 120, 146 a pigtail from the user control box 102.

Methods, devices and systems may thus be provided for one or both of two- or three-dimensional location of the disposition of a sensor coil in a subject including: an array of electromagnetic drive coil sets, each set having two or three dimensionally oriented drive coils; a sensor coil being electromagnetically communicative with the array of electromagnetic drive coil sets; and, a system controller communicative with and adapted to energize one or more of the electromagnetic coils in the array of electromagnetic drive coil sets, the energizing of the one or more of the electromagnetic coils including one or more of energizing the coils singly, or in pairs of x-y and y-z or x-z coils or x-y and y-z' and/or y-z" or x-z' and/or x-z" and/or z'-z" coils while measuring the response of the sensor coil; whereby the system uses the measurements of the responses of the sensor

coil to calculate the location and orientation of the sensor coil relative to said drive coil sets.

This may include two- and/or three-dimensional location of a catheter in tissue using an array of x-y or x-y-z or x-y-z'-z" oriented electromagnetic coils, where a sensor coil may be associated with one or more catheter tips, and where the system controller may energize one or more external coils, such as but not limited to, pairs of x-y and y-z or x-z coils or x-y and y-z' and/or y-z" or x-z' and/or x-z" and/or z'-z" coils while measuring the response of the sensor coil; the system may use these sensor coil measurements to calculate the position and orientation of the catheter tip, and in some implementations, the system controller may graphically display the catheter tip position, depth and/or orientation, e.g., but not limited to, over time.

From the foregoing, it is readily apparent that new and useful implementations of the present systems, apparatuses and/or methods have been herein described and illustrated which fulfill numerous desiderata in remarkably unexpected fashions. It is, of course, understood that such modifications, alterations and adaptations as may readily occur to the artisan confronted with this disclosure are intended within the spirit of this disclosure, which is limited only by the scope of the claims appended hereto.

What is claimed is:

1. A medical device locating system for determining a disposition of a sensor in a subject, the system comprising: an array of three or more quadruplet drive coil sets, each of the quadruplet drive coil sets including at least four discrete drive coils, wherein

at least two of the discrete drive coils in each of the quadruplet drive coil sets are arranged perpendicularly relative to each other in one or more of an x-y, x-z, or y-z array, and at least two of the discrete drive coils in the same quadruplet drive coil set are arranged perpendicularly relative to each other and geometrically oriented off axis respectively at a negative 45 degree angle and a positive 45 degree angle away from the respective x, y, or z axis, each of the discrete drive coils being electromagnetic coils;

at least one moveable sensor coil configured to provide one or more sensor coil response signals;

a driving circuit configured to provide alternating current (AC) drive signals to energize the discrete drive coils, wherein

the driving circuit is configured to provide the AC drive signals by:

sequentially driving one or more of the discrete drive coils within each quadruplet drive coil set; or selectively providing phase inversion of the drive signal to any one or more of the discrete drive coils within each quadruplet drive coil set;

a receiving circuit configured to receive the one or more sensor coil response signals from the at least one moveable sensor coil; and

a processor configured to determine a sensor coil disposition of the at least one moveable sensor coil in the subject relative to the quadruplet drive coil sets based on the one or more sensor coil response signals.

2. The system of claim 1, wherein the processor is configured to determine the sensor coil disposition of the at least one moveable sensor coil in the subject using an intersection of spheres, wherein the one or more sensor coil response signals from coil pairs oriented plus and minus 45 degrees off axis are vector summed to yield one axis of data.

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3. The system of claim 1, further comprising a display configured to display the disposition of the at least one moveable sensor coil in the subject relative to the quadruplet drive coil sets.

4. The system of claim 3, wherein the display is configured to display the disposition of the at least one moveable sensor coil in the subject by displaying one or more of a height, width or depth of the at least one moveable sensor coil in the subject relative to the quadruplet drive coil sets.

5. The system of claim 3, wherein the display is configured to display the disposition of the at least one moveable sensor coil in the subject by displaying an angular orientation of the at least one moveable sensor coil relative to the quadruplet drive coil sets.

6. The system of claim 1, wherein the processor is configured to determine the sensor coil disposition of the at least one moveable sensor coil in the subject by:

calculating sensor coil signal data sets generated from the one or more sensor coil response signals;

selecting optimum sensor coil signal data sets from the calculated sensor coil signal data sets based on the magnitude of the sensor coil signal data sets; and

calculating an intersection of spheres using the optimum sensor coil signal data sets to determine the sensor coil disposition of the at least one moveable sensor coil in the subject relative to the quadruplet drive coil sets.

7. The system of claim 1, further comprising one or more electrocardiogram reference leads placed on the subject and an electrocardiogram lead provided by a conductive core wire supporting the sensor coil.

8. The system of claim 7, further comprising a display configured to display the electrocardiogram signal of the subject over time.

9. The system of claim 8, wherein the display is further configured to display the P-wave of the subject over time in combination with the disposition of the at least one moveable sensor coil in the subject relative to the quadruplet drive coil sets.

10. The system of claim 1, further comprising one or more of a catheter, a guide wire or a stylet with the at least one moveable sensor coil being disposed in a distal portion therewith, and further comprising an integrated electrocardiogram lead associated with the sensor coil, the electrocardiogram lead providing an electrical electrocardiogram signal.

11. The system of claim 1, wherein the driving circuit or the receiving circuit comprises an automatic gain control circuit, the automatic gain control circuit being configured to maximize the one or more sensor coil response signals before the one or more sensor coil response signals are received by the second system component.

12. The system of claim 1, further comprising a user control box, wherein the array of the three or more quadruplet drive coil sets and the at least one moveable sensor coil are connected to the user control box.

13. The system of claim 1, wherein the driving circuit is further configured to continually adjust or program the intensity or power of current through one or more of the discrete drive coils in at least one or more of the quadruplet drive coil sets.

14. The system of claim 1, further comprising an x-axis tilt meter and y-axis tilt meter configured to measure the x-axis and y-axis tilt from a true vertical, wherein the processor is further configured to calculate the disposition of the at least one moveable sensor coil as a height, width, and depth of the sensor coil corrected for the tilt of the array of the three or more quadruplet drive coil sets.

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15. A medical device locating system for determining a disposition of a sensor coil in a subject, the system comprising:

an array of three or more quadruplet drive coil sets, each of the quadruplet drive coil sets including at least four discrete drive coils, wherein

at least two of the discrete drive coils in each of the quadruplet drive coil sets are arranged perpendicularly relative to each other in one or more of an x-y, x-z, or y-z array, and at least two of the discrete drive coils in the same quadruplet drive coil set are arranged perpendicularly relative to each other and geometrically oriented off axis respectively at a negative 45 degree angle and a positive 45 degree angle away from the respective x, y, or z axis, each of the discrete drive coils being electromagnetic coils;

at least one moveable sensor coil configured to provide one or more sensor coil response signals;

a driving circuit configured to provide alternating current (AC) drive signals to energize the discrete drive coils, wherein

the driving circuit is configured to provide the AC drive signals by:

simultaneously driving two or more of the discrete drive coils at two or more different current intensity or power levels within each quadruplet drive coil set to generate an electromagnetic field defining a virtual axis, or simultaneously driving two or more of the discrete drive coils within each quadruplet drive coil set with two or more drive signals with inversed phase;

a receiving circuit configured to receive the one or more sensor coil response signals from the at least one moveable sensor coil; and

a processor configured to determine a sensor coil disposition of the at least one moveable sensor coil in the subject relative to the quadruplet drive coil sets based on the one or more sensor coil response signals.

16. The system of claim 15, further comprising a display configured to display the disposition of the at least one moveable sensor coil in the subject relative to the quadruplet drive coil sets.

17. A medical device locating system for determining a disposition of a sensor coil in a subject, the system comprising:

an array of three or more quadruplet drive coil sets, each of the quadruplet drive coil sets including at least four discrete drive coils, wherein

at least two of the discrete drive coils in each of the quadruplet drive coil sets are arranged perpendicularly relative to each other in one or more of an x-y, x-z, or y-z array, and at least two of the discrete drive coils in the same quadruplet drive coil set are arranged perpendicularly relative to each other and geometrically oriented off axis respectively at a negative 45 degree angle and a positive 45 degree angle away from the respective x, y, or z axis, each of the discrete drive coils being electromagnetic coils;

at least one moveable sensor coil configured to provide one or more sensor coil response signals;

a catheter, a guide wire or a stylet with the at least one moveable sensor coil being disposed in a distal portion therewith;

a driving circuit configured to provide alternating current (AC) drive signals to energize the discrete drive coils, wherein the driving circuit is configured to provide the AC drive signals by: 5
simultaneously driving two or more of the discrete drive coils at two or more different current intensity or power levels within each quadruplet drive coil set to generate an electromagnetic field defining a virtual axis, or simultaneously driving two or 10
more of the discrete drive coils within each quadruplet drive coil set with two or more drive signals with inversed phase;
a receiving circuit configured to receive the one or more sensor coil response signals from the at least one 15
moveable sensor coil; and
a processor configured to determine a sensor coil disposition of the at least one moveable sensor coil in the subject relative to the quadruplet drive coil sets based on the one or more sensor coil response signals. 20

* * * * *

专利名称(译)	医疗器械定位系统，装置和方法		
公开(公告)号	US10480959	公开(公告)日	2019-11-19
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[标]申请(专利权)人(译)	NOSTIX		
申请(专利权)人(译)	NOSTIX , LLC		
[标]发明人	NELSON PETER E ZELLERS ROBERT D HENRY CHARLES W		
发明人	NELSON, PETER E. ZELLERS, ROBERT D. HENRY, CHARLES W.		
IPC分类号	G01D5/20 A61B5/06 A61B5/042 A61B5/00 A61B5/044		
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助理审查员(译)	杨 , yi-shan		
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外部链接	Espacenet		

摘要(译)

公开了用于在对象中对传感器线圈的布置进行三维定位的方法，设备和系统。该系统包括三个或更多四联驱动线圈组的阵列，其中每个四联驱动线圈组包括至少四个离散驱动线圈，至少一个可移动传感器线圈配置为提供一个或多个传感器线圈响应信号，第一系统组件提供交流驱动信号，用于为分立的驱动线圈供电；第二系统组件，用于从至少一个可移动传感器线圈接收一个或多个传感器线圈响应信号；处理器，其配置为确定至少一个可移动传感器的传感器线圈布置相对于一个或多个传感器线圈响应信号，相对于四联体驱动线圈组的受试对象中的线圈。

