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(54) **METHOD AND APPARATUS FOR ELECTROMAGNETIC NAVIGATION OF A SURGICAL PROBE NEAR A METAL OBJECT**

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(57) **ABSTRACT**

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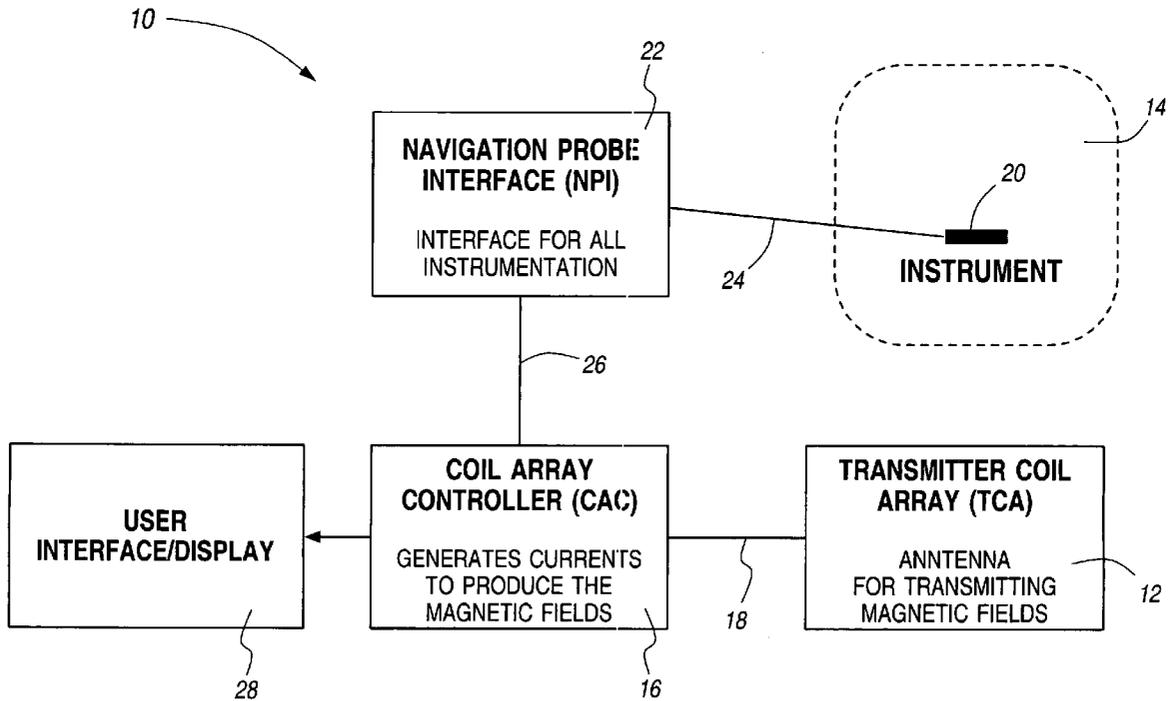
A method and apparatus for electromagnetic navigation of a surgical probe near a metal object. The electromagnetic navigation system includes a transmitter coil array and a shield. The transmitter coil array has a plurality of transmitter coils and is operable to generate the electromagnetic field to navigate the probe. The shield is positioned adjacent the metal object and is operable to shield the metal object from the electromagnetic field generated by the transmitter coil array, such that the shield substantially reduces distortion of the electromagnetic field by the metal object.

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Related U.S. Application Data

(63) **Continuation of application No. 09/873,604, filed on Jun. 4, 2001, now Pat. No. 6,636,757.**



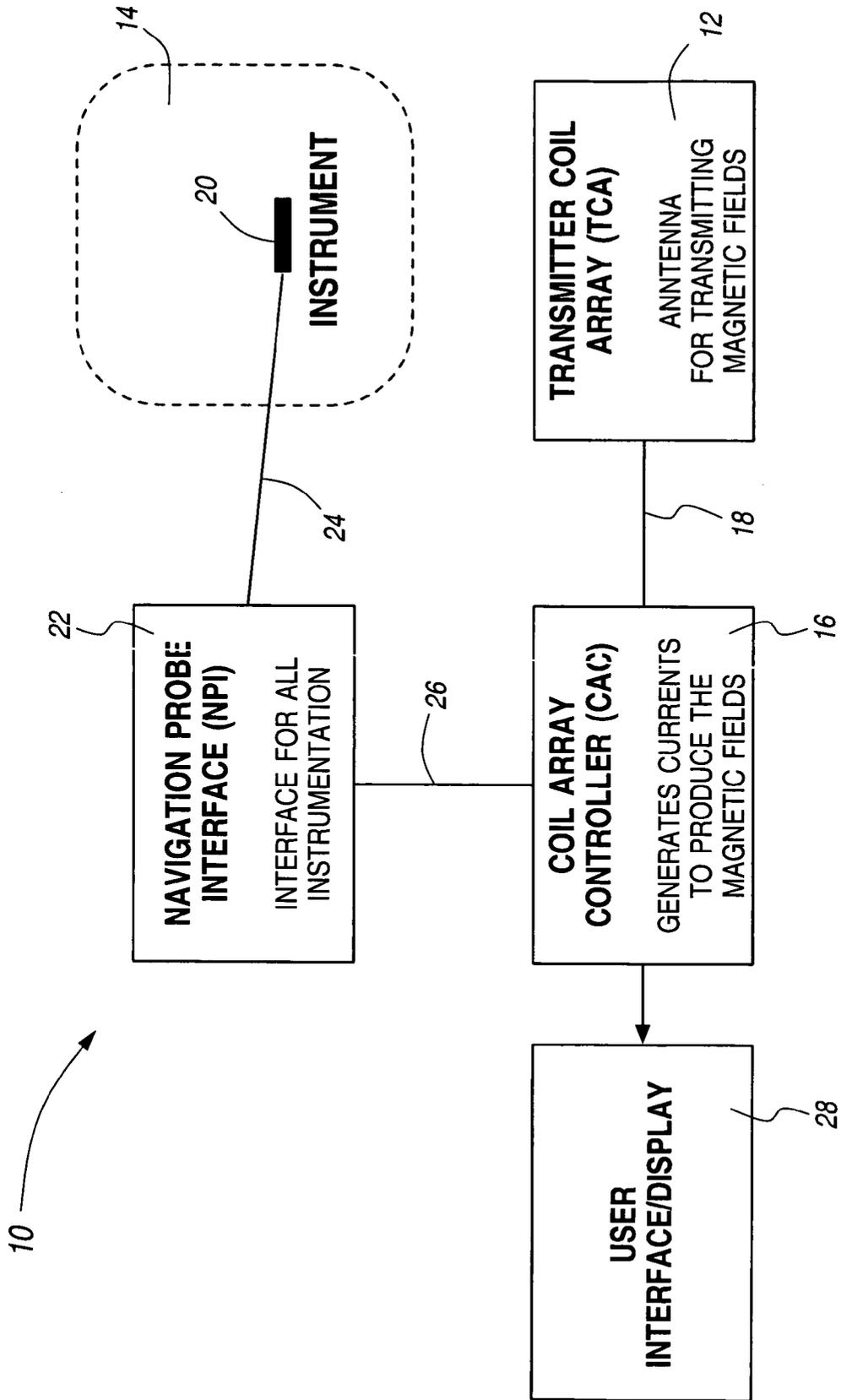


FIG.- 1

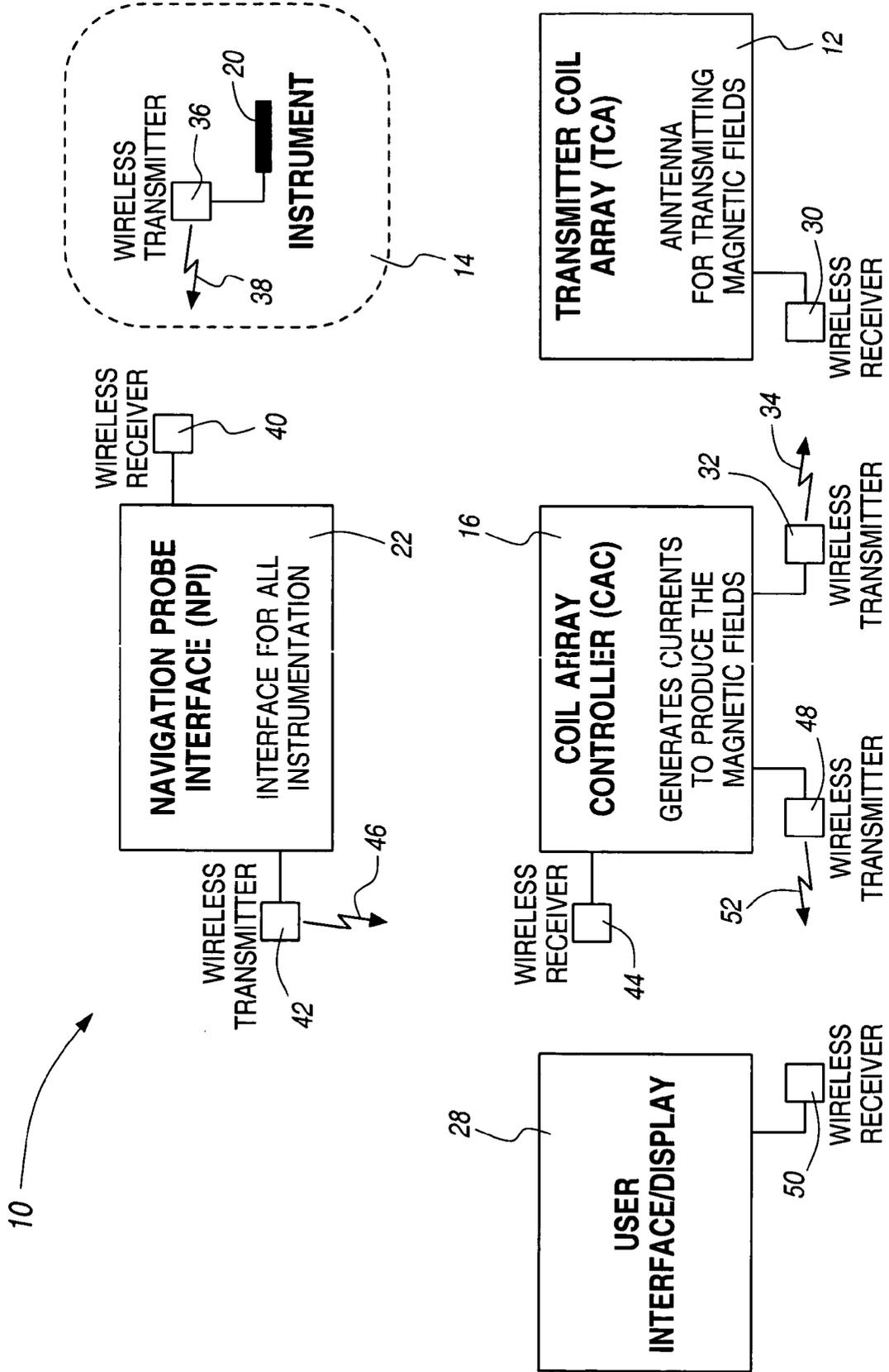


FIG.- 2

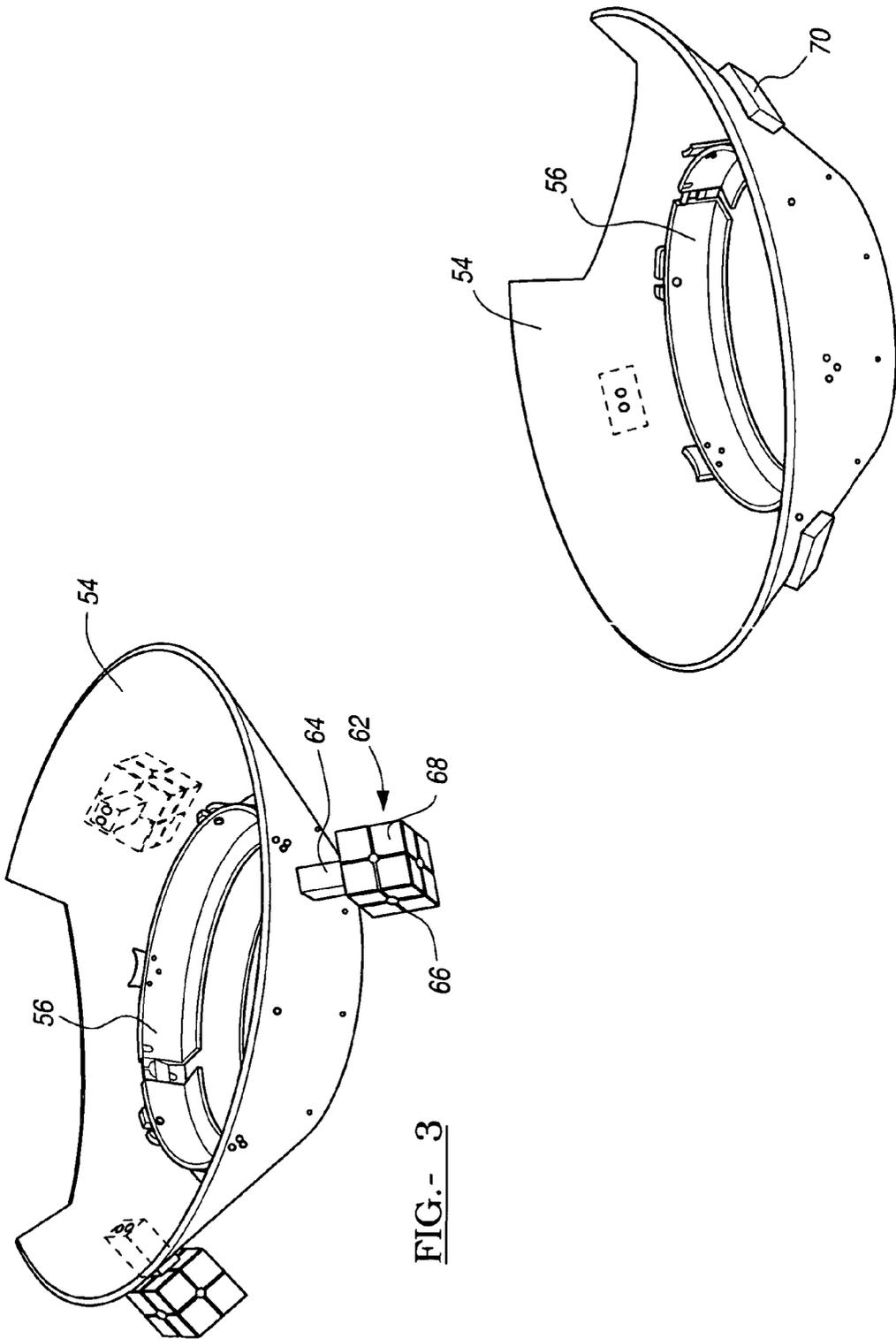


FIG.- 3

FIG.- 4

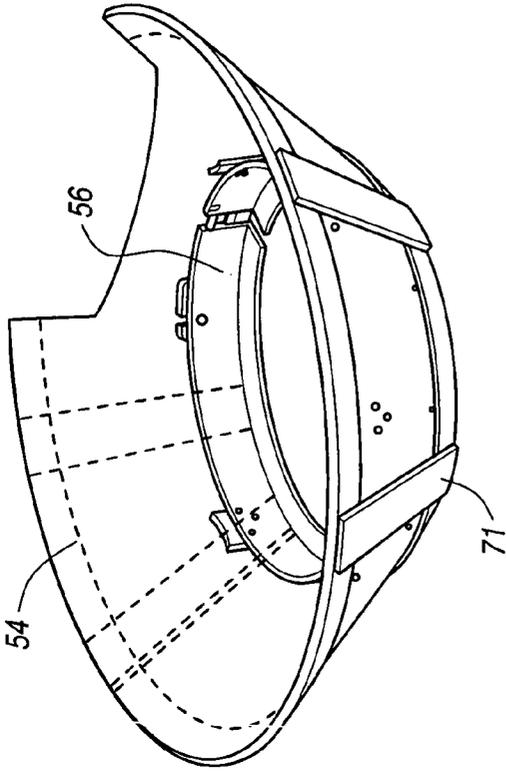


FIG.- 5

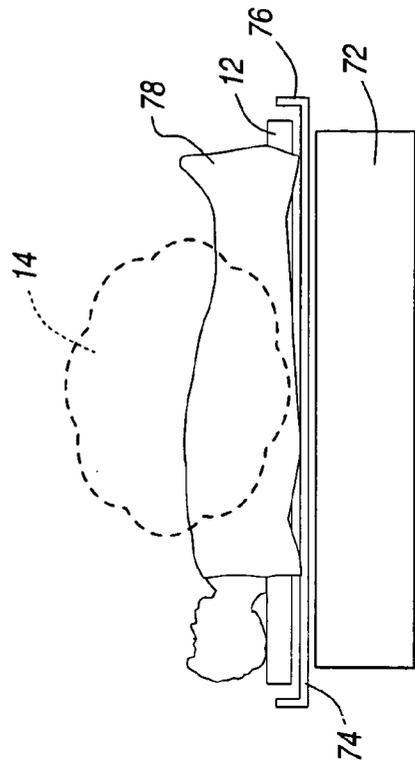


FIG.- 7

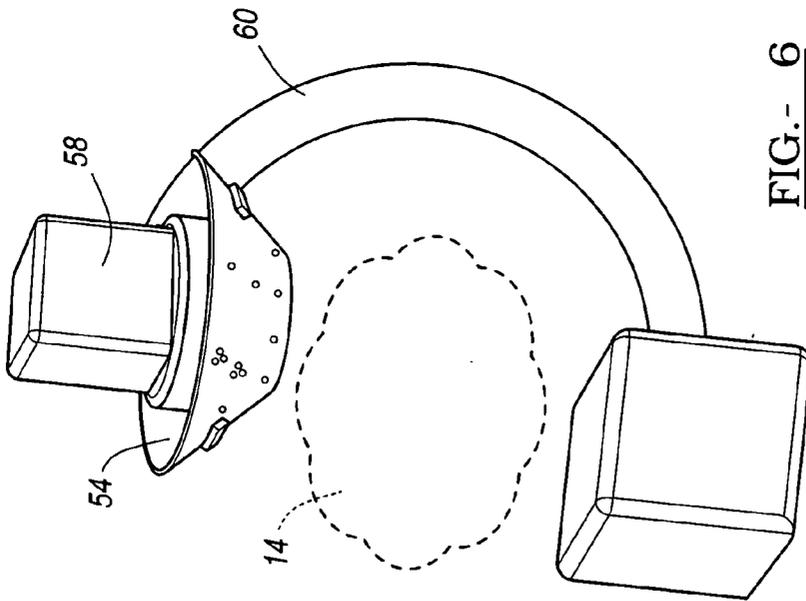


FIG.- 6

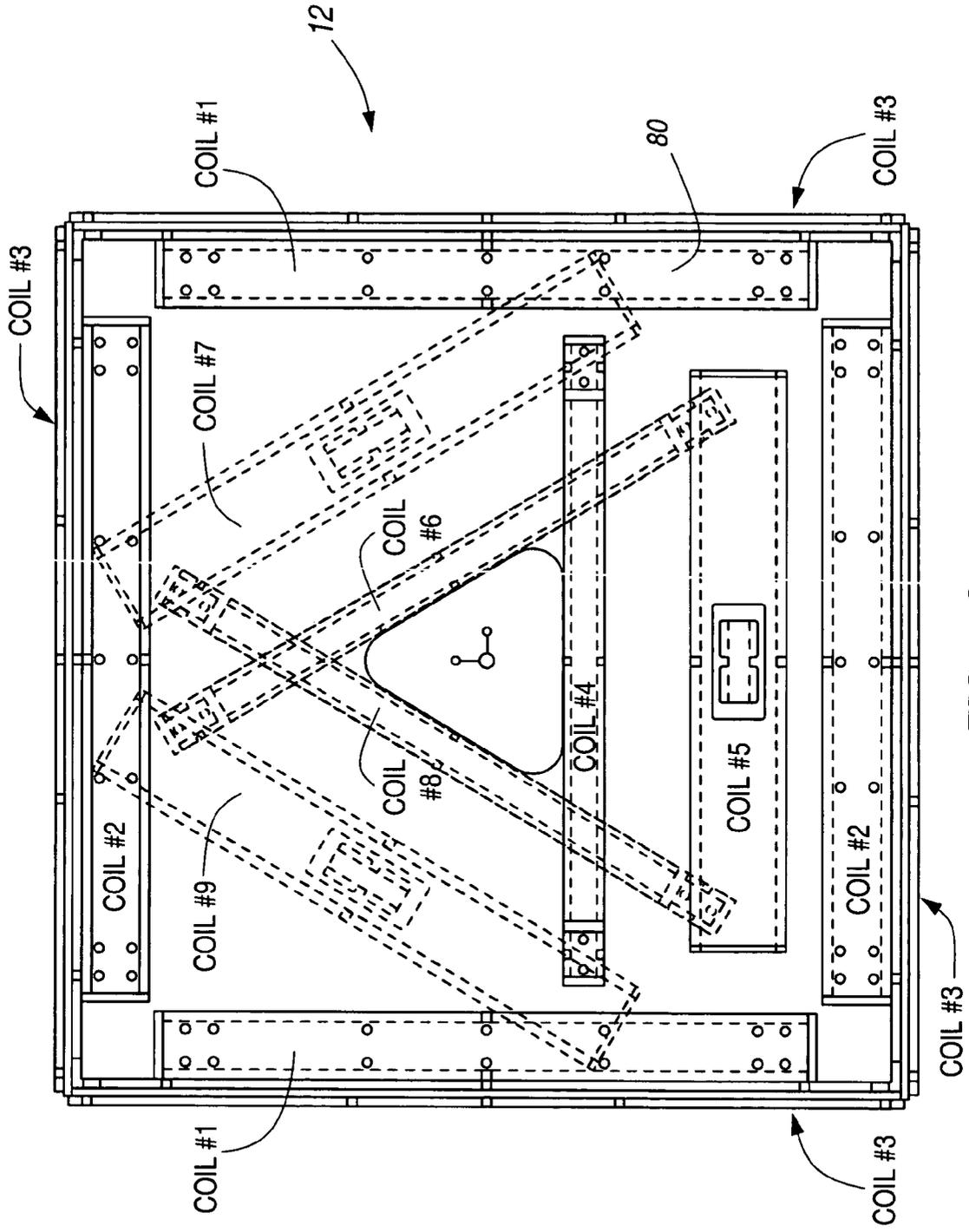


FIG.- 8

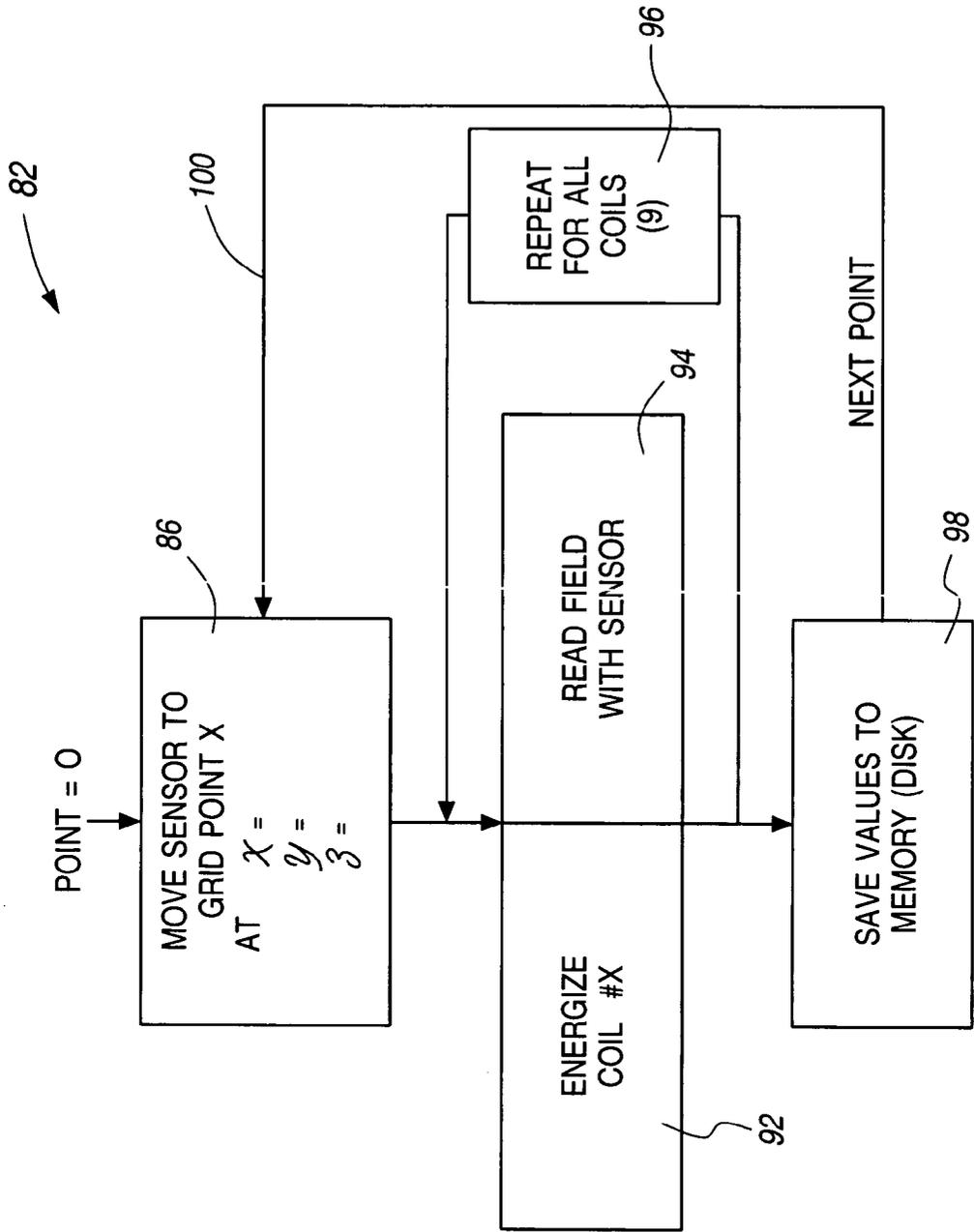


FIG.- 9

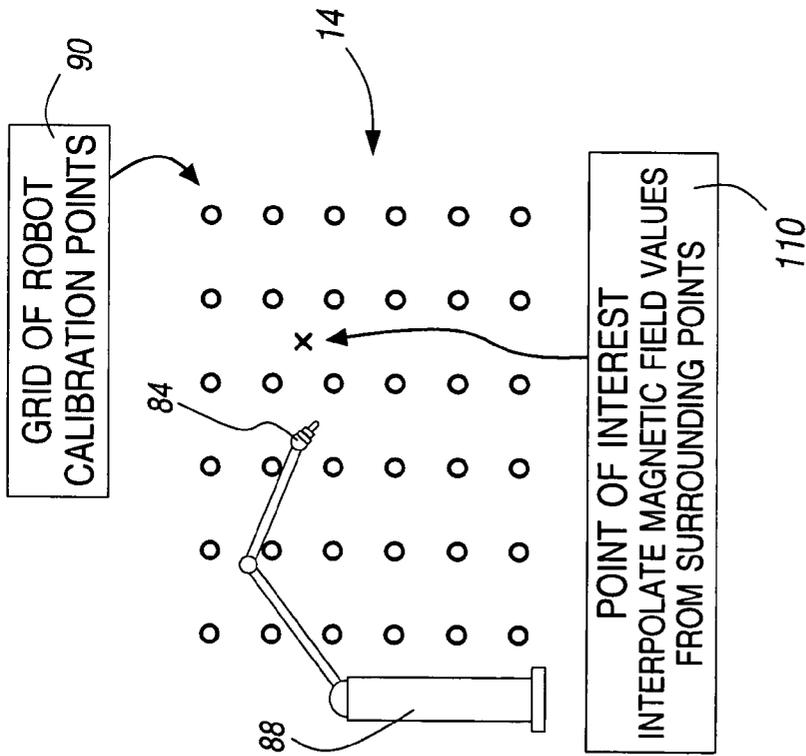


FIG.- 10

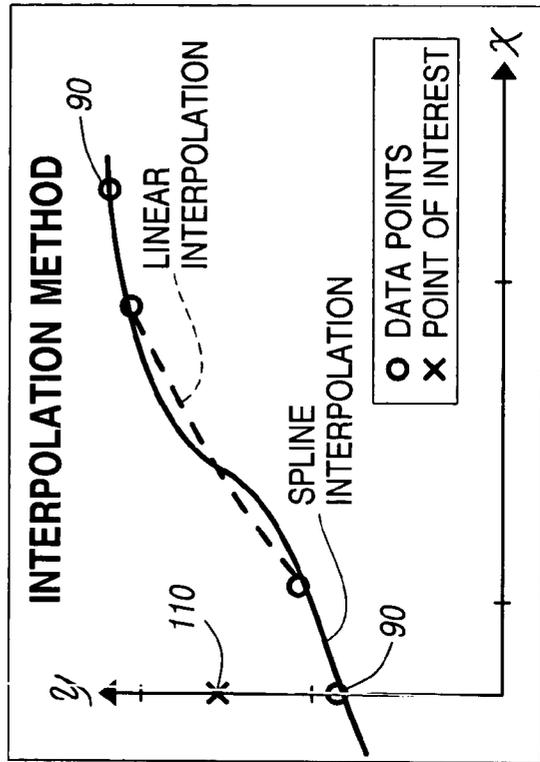


FIG.- 12

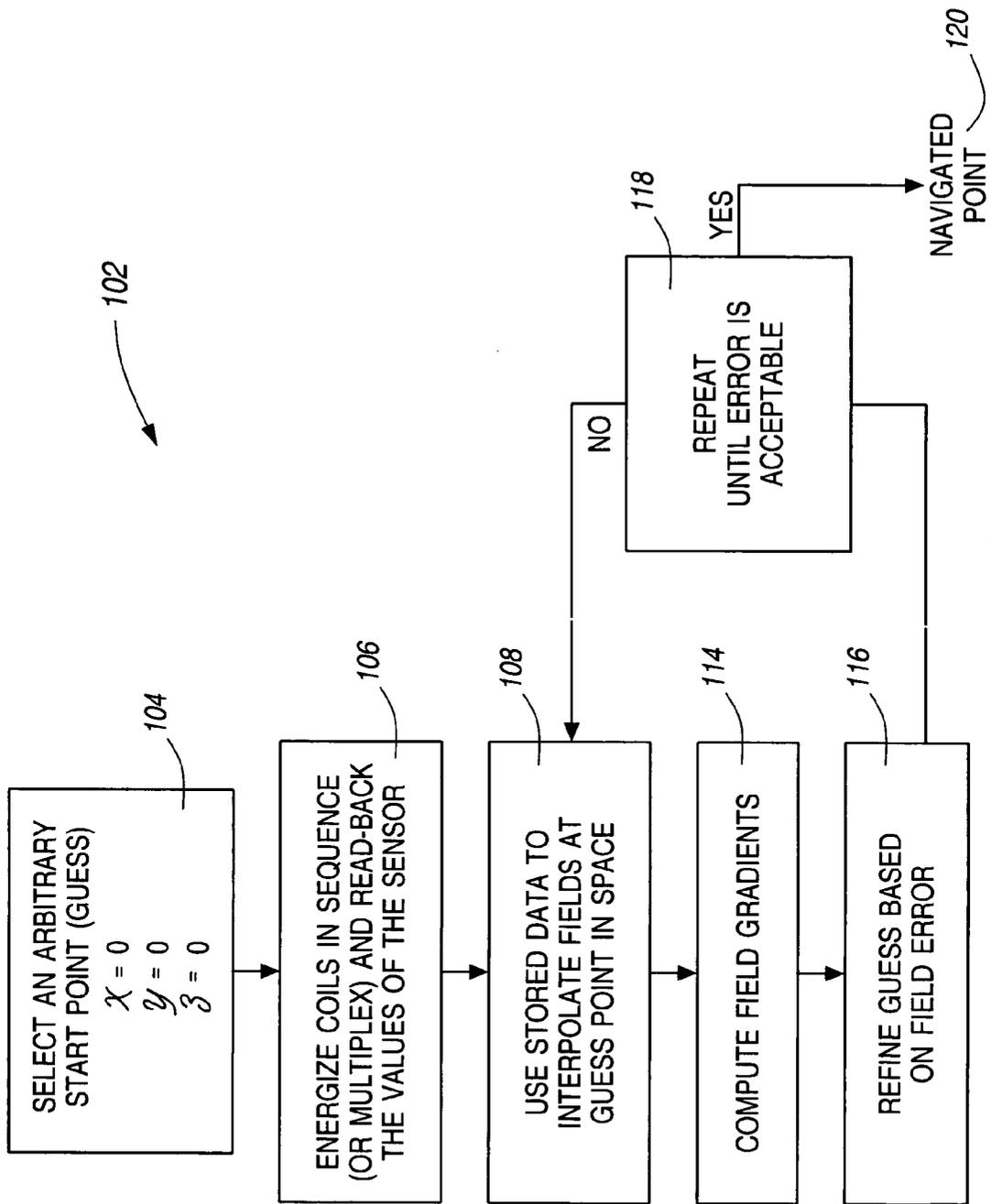


FIG.- 11

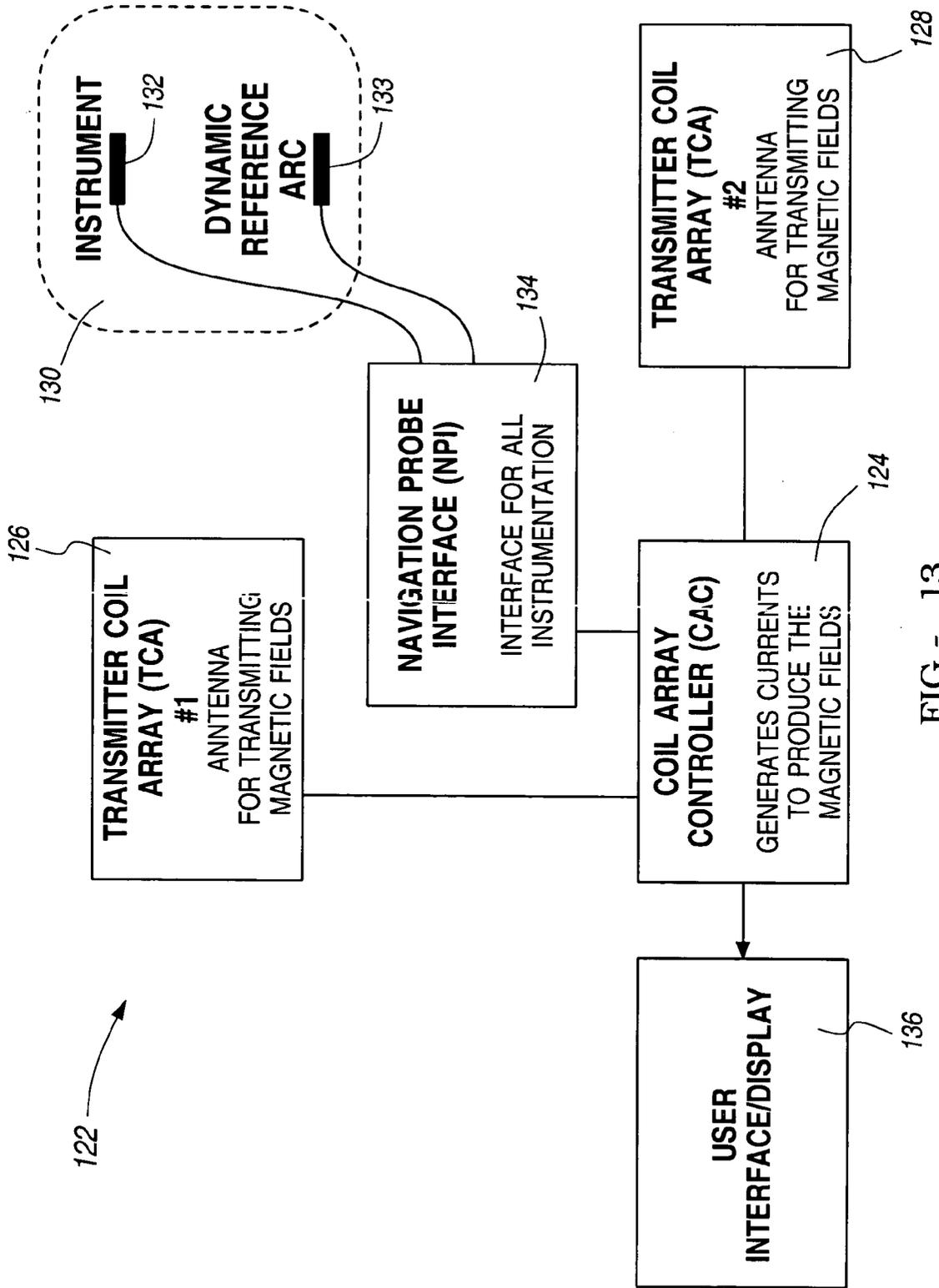


FIG.- 13

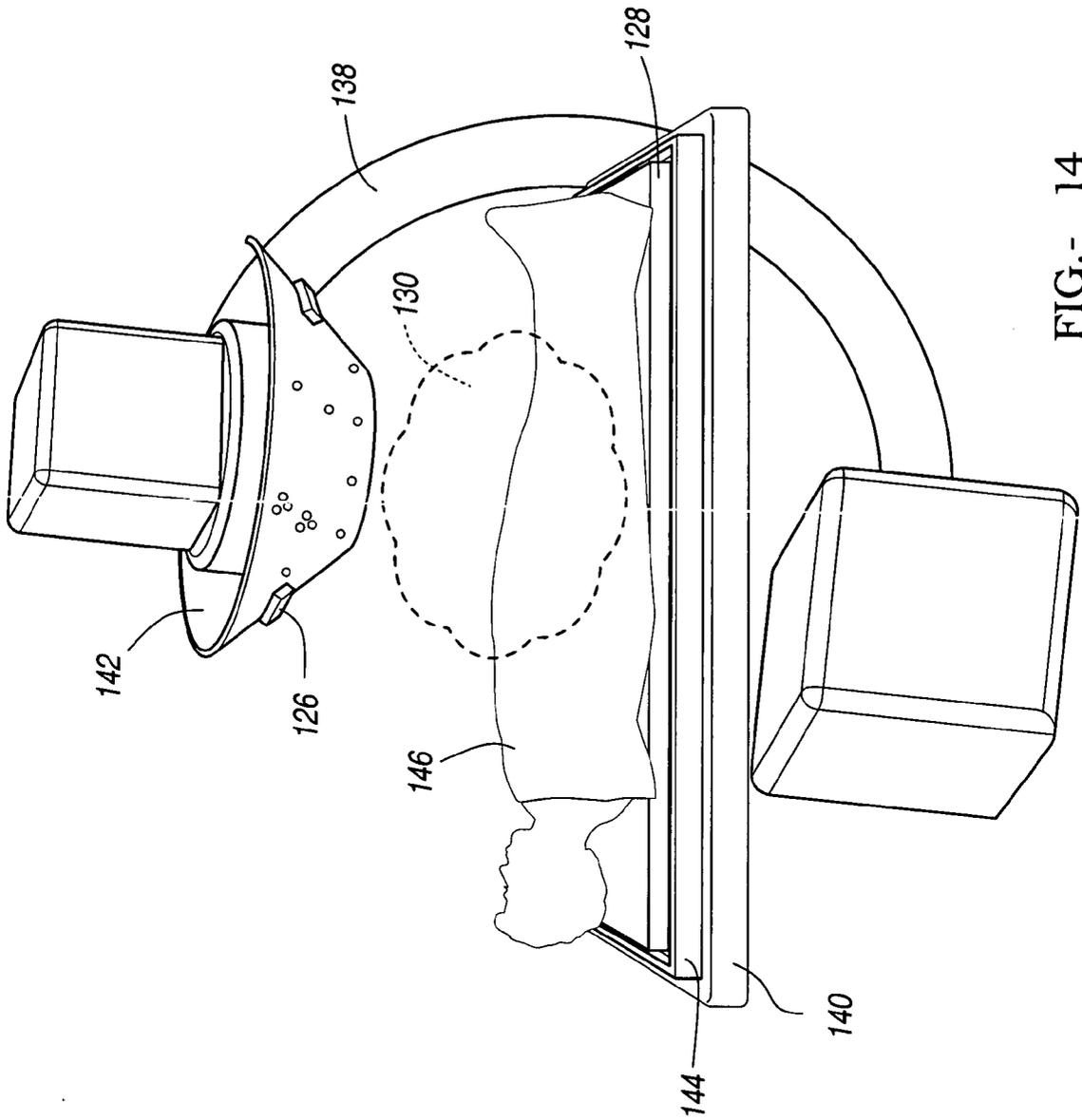


FIG.- 14

METHOD AND APPARATUS FOR ELECTROMAGNETIC NAVIGATION OF A SURGICAL PROBE NEAR A METAL OBJECT

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation of U.S. patent application Ser. No. 09/873,604 filed on Jun. 4, 2001, entitled "Method and Apparatus for Electromagnetic Navigation of a Surgical Probe Near a Metal Object". The disclosure of the above application is incorporated herein by reference.

FIELD OF THE INVENTION

[0002] This invention relates generally to navigation of a probe and, more particularly, to a method and apparatus for electromagnetic navigation of a surgical probe near a metal object.

BACKGROUND OF THE INVENTION

[0003] Various systems currently exist, which assist in guiding and navigating a surgical probe through a patient undergoing a surgical procedure. These systems include, for example, fluoroscopic, ultrasonic, conductive, optical and electromagnetic type navigation systems.

[0004] Various electromagnetic type navigation systems have already been proposed, such as that disclosed in U.S. Pat. No. 4,821,731 to Martinelli, et al., U.S. Pat. No. 5,592,939 to Martinelli and U.S. Pat. No. 5,913,820 to Bladen, et al., which are each hereby incorporated by reference. Advantages of such electromagnetic tracking navigation systems are significant over existing navigation systems. For example, low-frequency electromagnetic waves are not attenuated by the body and therefore, there are no "line-of-sight" issues as with existing optical systems. The transmitter coil array may also be placed underneath or above the patient and the navigated surgical instrument or probe may be used above or below the transmitter coil array. The receiver coils utilized in the surgical instrument or probe are also generally much smaller than existing type navigation systems, which may enable surgical procedures that were previously impossible due to instrument size. The small size of the receiver coils also enable the receiver coils to be placed near the tip of the instrument providing further accuracy and the ability to navigate non-rigid instruments.

[0005] However, electromagnetic type navigation systems do have the disadvantage that the electromagnetic field may be distorted by metal objects, sometimes referred to as metallic distortions. In this regard, metal objects that are generally large in size cause the magnetic field to bend, thereby possibly causing inaccuracy in the reported probe position. The other effect of positioning a metal object near the electromagnetic field being navigated is conduction effects. For example, a metal object positioned near or in the electromagnetic field, such as a fluoroscope (C-arm) or an OR table, may create a virtual coil along the metal surface that creates an interference back into the magnetic field. Again, this may create an inaccuracy in the reported probe position because the exact field strengths in the previously known electromagnetic fields have been altered due to the metal object.

[0006] In order to reduce or eliminate the effects of distortion due to metal objects, known mathematical models of the electromagnetic fields produced by the transmitter coil array may be utilized. If these mathematical models are accurate, they can be used to represent a set of "known" fields used during the navigation process. However, the disadvantage with using mathematical models for the transmitted fields is that there are inherent inaccuracies in the manufacturing process of the transmitting coils in the transmitting coil array, which can lead to incorrect field values, which are mathematically modeled. These incorrect field values may lead to inaccuracy in the overall navigation process. The mathematical models are also generally very mathematically complex and may, therefore, take an unreasonable amount of time for a computer to calculate and process.

[0007] What is needed then is a method and apparatus for electromagnetic navigation of a surgical probe near a metal object, which does not suffer from the above-mentioned disadvantages. This will, in turn, provide electromagnetic navigation of a surgical probe near a metal object that has greater accuracy, provide a shield to reduce or eliminate the effects of the metal object, provide a universal connection to connect the shield to the metal object, provide a calibration process that takes into effect either the shield or the metal object, provide a set of transmitting coils, which may be attached to the shield, integrated into the shield or integrated into the metal object itself, and provide wireless communications in the electromagnetic navigation system for ease of assembly into existing hardware. It is, therefore, an object of the present invention to provide such a method and apparatus for electromagnetic navigation of a surgical probe near a metal object.

SUMMARY OF THE INVENTION

[0008] In accordance with the teachings of the present invention, a method and apparatus for electromagnetic navigation of a surgical probe near a metal object is provided.

[0009] In one embodiment, an electromagnetic navigation system for use in navigating a probe through an electromagnetic field positioned near a metal object includes a transmitter coil array and a shield. The transmitter coil array has a plurality of transmitter coils and is operable to generate the electromagnetic field to navigate the probe. The shield is positioned adjacent the metal object and is operable to shield the metal object from the electromagnetic field generated by the transmitter coil array, wherein the shield substantially reduces distortion of the electromagnetic field by the metal object.

[0010] In another embodiment, an electromagnetic navigation system for use in navigating a probe through an electromagnetic field during a surgical procedure includes a metal instrument and a transmitter coil array. The metal instrument is used during a surgical procedure and is formed at least in part by metallic material. The transmitter coil array has a plurality of transmit coils and is operable to generate the electromagnetic field used to navigate the probe. The transmitter coil array is integrated into the metal instrument, wherein the effects of metallic distortion on the electromagnetic field by the metal instrument is characterized during a calibration process to provide substantially accurate navigation of the probe during the surgical procedure.

[0011] In another embodiment, a method for calibrating an electromagnetic navigation system having a transmitter coil array that generates an electromagnetic field is provided. This method includes positioning the electromagnetic navigation system in a working environment to account for metallic distortion caused by a metallic object adjacent to the electromagnetic field, positioning a calibration sensor at a first calibration point, energizing a first coil in the transmitter coil array to generate a first field, sensing the first field strength in the first field with the calibration sensor, and repeating the positioning, energizing and sensing at a second calibration point, wherein effects of metallic distortion caused by the metallic object is taken into account during the calibration process.

[0012] Use of the present invention provides a method and apparatus for electromagnetic navigation of a probe through an electromagnetic field near a metal object. As a result, the aforementioned disadvantages associated with the currently available techniques have been substantially reduced or eliminated. Further areas of applicability of the present invention will become apparent from the detailed description provided hereinafter. It should be understood that the detailed description and specific examples, while indicating the preferred embodiment of the invention, are intended for purposes of illustration only and are not intended to limit the scope of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

[0013] Still other advantages of the present invention will become apparent to those skilled in the art after reading the following specification and by reference to the drawings in which:

[0014] FIG. 1 is an electromagnetic navigation system block diagram according to the teachings of one embodiment of the present invention;

[0015] FIG. 2 is an electromagnetic navigation system block diagram according to the teachings of another embodiment of the present invention;

[0016] FIG. 3 is a perspective view of a shield having extended transmitter coils according to the teachings of one embodiment of the present invention;

[0017] FIG. 4 is a perspective view of a shield having integrated transmitter coils according to the teachings of another embodiment of the present invention;

[0018] FIG. 5 is a perspective view of a shield having integrated transmitter coils according to the teachings of another embodiment of the present invention;

[0019] FIG. 6 is a perspective view of a fluoroscope (C-arm) employing the shield of FIG. 4 according to the teachings of the present invention;

[0020] FIG. 7 is a side view of an operating room (OR) table having a transmitter coil array (TCA) positioned atop the OR table with a shield positioned between the OR table and transmitter coil array (TCA) according to the teachings of another embodiment of the present invention;

[0021] FIG. 8 is a diagram illustrating the transmitter coil array configuration of FIG. 7 in further detail;

[0022] FIG. 9 is an illustration of a calibration process according to the teachings of the present invention;

[0023] FIG. 10 is a two dimensional grid of robotically measured calibration points used in the calibration process according to the teachings of the present invention;

[0024] FIG. 11 is an illustration of a navigation process according to the teachings of the present invention;

[0025] FIG. 12 is a graph illustrating two interpolation methods utilized in the navigation process according to the teachings of the present invention;

[0026] FIG. 13 is an electromagnetic navigation system block diagram according to the teachings of another embodiment of the present invention; and

[0027] FIG. 14 illustrates the electromagnetic navigation system of FIG. 13 associated with a fluoroscope (C-arm) and an OR table.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0028] The following description of the preferred embodiments concerning a method and apparatus for electromagnetic navigation of a surgical probe near a metal object is merely exemplary in nature and is not intended to limit the invention or its application or uses. Moreover, while the present invention is described in detail in association with a fluoroscope (C-arm) or an operating room (OR) table, those skilled in the art will readily understand that the present invention may be employed in many other environments having metal objects.

[0029] Referring to FIG. 1, an electromagnetic navigation system 10 according to the teachings of one embodiment of the present invention is shown. The electromagnetic navigation system 10 is implemented utilizing a transmitter coil array (TCA) 12, which emits low energy, low frequency AC signals to generate an electromagnetic field or region 14 adjacent to the transmitter coil array 12. The transmitter coil array 12 includes a plurality of coils, further discussed herein, which are driven by a coil array controller (CAC) 16. The coil array controller 16 sources AC current to drive each coil housed within the transmitter coil array 12, via transmission lines 18. The coil array controller 16 may drive the coils housed within the transmitter coil array 12 either sequentially, via time division, or simultaneously, via frequency division, or a combination of both. The electromagnetic field 14 generated by the transmitter coil array 12 provides very accurate known magnetic field strengths over the field of view (FOV) of the electromagnetic navigation system 10. Because the low-frequency electromagnetic waves generated by the transmitter coil array 12 are not attenuated by the body of a patient, there are no line-of-sight issues as with currently available optical systems.

[0030] An instrument 20, such as, but not limited to, a surgical probe, catheter, steerable catheter, endoscope, shunt, drill guide, awl/tap, orthopedic implant instrument, etc. located or positioned within the electromagnetic field 14 is able to detect the electromagnetic signal and measure the magnetic field strength by way of small loops of wire or receive coils attached to the instrument 20. The receive coils may be any diameter but are generally made small, for example, about one millimeter to about two millimeters in diameter, which provides for a much smaller instrument 20 than other existing instruments used in navigation systems, such as optically navigated systems. Because of the reduced

size of the receiver coils, this enables the receiver coils to be placed near the distal tip of the instrument **20**, thereby further reducing accuracy concerns that exist when the receiver coils are positioned more proximally in the instrument **20**, since the instrument **20** may bend during navigation. The instrument **20** may include a single receiver coil consisting of multiple loops of wire or a single loop of wire and may also include multiple receiver coils to provide further positional information regarding the instrument **20**, as is known in the art and further discussed herein.

[0031] The magnetic field strengths sensed by the instrument **20** are received by a navigation probe interface (NPI) **22**, via a transmission line **24**. The navigation probe interface **22** gathers the magnetic field strengths received by the instrument **20** and processes this information in order to identify the magnetic field strength generated by each coil in the transmitter coil array **12**. The navigation probe interface **22** is able to track up to any number of coils, located in the transmitter coil array **12** based on the number of input ports provided, at a sampling rate of about thirty frames per second. The navigation probe interface **22** also directs or triggers the coil array controller **16** to drive each coil located in the transmitter coil array **12** either in a time multiplexed manner, frequency multiplexed manner or a combination of both. The navigation probe interface **22** is generally configured as a digital signal processor (DSP), but may also be configured as discrete logic circuits or any other type of electrical processor. The navigation probe interface **22** is also capable of supporting multiple instruments **20** in a multiplexed manner should this be desirable for the particular surgical procedure.

[0032] Once the magnetic field strengths of all the transmitting coils in the transmitter coil array **12** are measured and processed by the navigation probe interface **22**, this field strength information is forwarded to the coil array controller **16**, via transmission line **26**. A general purpose computer or PC incorporated into the coil array controller **16** is then applied to "look-up" the single point in space where the field strengths detected by the receiver coil in the instrument **20** is equivalent to the known field strengths transmitted by the transmitter coil array **12**. In this regard, the magnetic field strengths measured by the instrument **20** identify a unique position and orientation in space to determine the X, Y, Z point and the angle and azimuth of the receiver coil located in the instrument **20**. Should rotation about the axis of the receiver coil positioned in the instrument **20** be desired, a second receiver coil may be required in the instrument **20**. The process used by the coil array controller **16** employs known minimization techniques, such as Newton's method, further discussed herein.

[0033] Thus, the electromagnetic navigation system **10** is able to support electromagnetic navigation of the instrument **20** by generating electromagnetic fields from the transmitter coil array **12** throughout the region **14**. Instrument **20** measures the magnetic field strengths by way of an electromagnetic sensor or receiver coil. Through design of these electromagnetic fields generated by each coil in the transmitter coil array **12**, every position and orientation of each field generated has a unique set of electromagnetic field strengths that is known in the art. These electromagnetic levels or magnetic field strengths generate a system of

equations that can be solved mathematically to determine the position and orientation of the instrument **20**, as is known in the art.

[0034] The localized information which is determined in the coil array controller **16** is then forwarded to an application specific user interface/display **28**. The user interface/display **28** may consist of a general purpose computer and a video display to provide image guidance to a surgeon with real time visual feedback of the surgery or navigation being performed. The user interface/display **28** may be configured to provide application specific interfaces for various surgical procedures, such as, but not limited to, cranial, 3-D spine, virtual fluoroscopy, cranial biopsies, tumor resections, craniotomies/craniectomies, thalamotomies/pallidotomies, spinal implant procedures, such as pedicle screw placement, sinus procedures, such as maxillary antrastomies, ethmoidectomies, sphenoidotomies/sphenoid explorations, turbinate resections, and frontal sinusotomies, cardiac mapping procedures, cardiac lead placements, orthopedic, interventional radiology, etc.

[0035] Turning to FIG. 2, the electromagnetic navigation system **10** according to the teachings of another embodiment of the present invention is shown. In this regard, like reference numerals will be used to identify like elements, as set forth in FIG. 1. The electromagnetic navigation system **10** includes the transmitter coil array **12**, which is driven by the coil array controller **16** to generate an electromagnetic field or region **14**. This electromagnetic field **14** is sensed by the instrument **20** and the navigation probe interface **22** processes the magnetic field strengths sensed by the instrument **20**. Again, the navigation probe interface **22** forwards this information to the coil array controller **16**, which then determines the position of the instrument **20** in the field or region **14**. The location of the instrument **20** is again forwarded to the user interface/display **28** for use by the surgeon during the surgical procedure being performed to provide real time visual feedback of the instrument **20** during the surgical procedure.

[0036] The electromagnetic navigation system **10**, as shown in FIG. 2, is substantially the same as the electromagnetic navigation system **10**, shown in FIG. 1, except that this system employs wireless communications between each element. In this regard, the transmitter coil array **12** includes a wireless receiver **30**, which receives control information, via a wireless transmitter **32** coupled to the coil array controller **16**. In this configuration, the transmitter coil array **12** will include the amplifiers that are normally positioned in the coil array controller **16** to drive the coils and the coil array controller **16** will simply control the operation of the transmitter coil array **12**, via the wireless communication channel **34**. Likewise, the instrument **20** includes a wireless transmitter **36** that transmits information over a wireless channel **38** to a wireless receiver **40** in the navigation probe interface **22**. The navigation probe interface **22** also includes a wireless transmitter **42**, which transmits information to the coil array controller **16**, via a wireless receiver **44** over communication channel **46**. Finally, the coil array controller **16** forwards navigation information to the user interface/display **28**, via a wireless transmitter **48**, wireless receiver **50** and wireless channel **52**.

[0037] The wireless communication or transmission may be accomplished through many types of wireless mediums,

such as analog or digital methods. The analog transmission methods may include amplitude modulation (AM), frequency modulation (FM) or phase modulation (PM). Various digital communication standards may also be used such as Ethernet, Blue Tooth or any other type of appropriate digital communication protocol. For example, the wireless communications system, as set forth in Surgical Communications in Power Systems, filed Oct. 28, 1999, U.S. Ser. No. 09/428,722, may be used as one form of wireless communications, which is hereby incorporated by reference. By providing this type of wireless communication of the electromagnetic navigation system 10, as shown in FIG. 2, the transmission lines, as shown in FIG. 1 are substantially eliminated, thereby reducing the amount of cabling required in an operating room environment. This also enables the electromagnetic navigation system 10 to be retrofitted to existing hardware structures without requiring significant modifications to the existing structures. It should further be noted that the electromagnetic navigation system 10 may selectively use both transmission lines and wireless communication.

[0038] The electromagnetic navigation system 10 provides significant advantages over existing navigation systems, as discussed above, however, the electromagnetic navigation system 10 must account for electromagnetic navigation near metal objects that may distort the electromagnetic field. This environment typically exists in the operating room and other surgical environments because the metal structure causes or creates distortions in the magnetic field needed for the navigation process. These metal objects, devices or instruments may include, but are not limited to operating room (OR) tables, fluoroscope (C-arms), microscope, ultrasound hand-piece, high-intensity focused ultrasound systems, computer topography imaging (CT), interoperative CT, magnetic resonance imaging (MR), interoperative MR, surgical robot imaging, etc. In order to take into account the distortions caused by such metal objects, the current electromagnetic navigation system 10 may either utilize a shield positioned adjacent to the transmitter coil array 12 to shield the effect of the metal object or the transmitter coil array 12 may be incorporated directly into the metal object and the distortion effect characterized during the calibration process itself since the distortions will generally remain static, further discussed herein.

[0039] An exemplary shield 54, shown in FIG. 3, may be used to shield metal objects, such as a fluoroscope (C-arm) (see FIG. 5). The shield 54 is designed to be removably coupled to the C-arm or any other metal object or device requiring shielding by way of a universal band clamp 56. The mounting mechanism or band clamp 56 is able to be adjustably engaged around an intensifier tube 58 of a conventional C-arm 60, which usually has a diameter of about 9 to about 12 inches (see FIG. 5). The shield 54 is substantially conically shaped to substantially reduce or eliminate the effects of the C-arm 60, along with its associated components, such as the intensifier 58. The shield 54 can also be configured in any other shape to create a virtual surface or infinite plane to reflect or shield any type of metal object desired. Reflecting or shielding of these fields prevents field distortion, and thus prevents disturbances by objects on the opposite side of the shield 54.

[0040] The shield 54 is formed from a conductive or semi-conductive material, such that the shield's effect on the

magnetic field should dominate the effect of the item, such as the C-arm 60 being shielded. The shield 54 may be constructed from materials, such as sheet metal, aluminum, copper, titanium, mu-metal, conductive mylar, etc. The shield 54 may also be formed as a solid shield, a mesh or be modified with holes or slots to reduce the overall weight of the shield 54. Since electromagnetic navigation is generally performed at relatively low frequencies (less than about one megahertz), these frequencies represent long wavelengths that do not pass through the openings, such that the shield 54 essentially acts as a solid shield to these low frequency signals. Therefore, by adding holes or a mesh, the performance of the shield 54 will not be degraded.

[0041] Positioned adjacent to or about the periphery of the conically shaped shield 54 is the transmitter coil array 12 which is formed by three sets of transmitting coils 62, which are displaced from the shield 54 by an extension member 64. Each set of transmitting coils 62 consists of three sets of coils 66, each positioned orthogonal to one another and consisting of about fifty wire loops positioned about a cube 68. Offsetting the set of transmitting coils 62 from the shield 54 creates less interference or canceling of the electromagnetic field because of the shield 54 to provide enhanced performance.

[0042] Another embodiment of the shield 54 is shown in FIG. 4, where the shield 54 includes three sets of integrally formed transmitting coils 70, also positioned about the perimeter of the shield 54. The transmitting coils 70 are formed substantially adjacent to, or integral with, the shield 54, as opposed to being somewhat displaced from the shield 54, as shown in FIG. 3. While this may create some canceling of the electromagnetic field, this also provides a smaller package should clearance concerns exist in particular applications. The transmitting coils 70 each may include multiple coils configured substantially similar to the set of transmitting coils 62, shown in FIG. 3 or in any other type of configuration. It should further be noted that while the shield 54 shown in FIGS. 3 and 4 include three sets of three orthogonal coils providing for a total of nine coils for navigation purposes, any number of coils or coil configurations may be used. In this regard, generally a minimum of five coils is required to identify the six degrees of freedom (X, Y, Z, angle, azimuth). These coils may be configured with either five transmit coils or more and one receiver coil, or three transmit coils and three receiver coils or any other type of combination. Moreover, should only three degrees of freedom (i.e., X, Y, Z) be desired, only three coils would be required, as is known in the art.

[0043] An additional embodiment of the shield 54 is shown in FIG. 5, where the shield includes several integrally formed transmitting coils 71, located about the shield 54. In this regard, the transmitting coils 71 are wrapped and formed integral with the shield 54 with multiple coils extending about the top and bottom perimeter of the shield 54, as well as transmitting coils 71 extending radially from the shield 54. Here again, the coil configuration may be arranged in any manner, as long as each coil has a unique orientation relative to the other coils.

[0044] Turning briefly to FIG. 6, the C-arm 60 is shown, which incorporates the shield 54 of the electromagnetic navigation system 10 to generate the electromagnetic field or region 14 for navigating the instrument 20. By using the

shield **54**, which may be formed integral with the C-arm **60**, the distortion created by the C-arm **60** is substantially reduced or attenuated so that accurate navigation of the instrument **20** within the region **14** may be achieved. It should further be noted that either the three sets of transmitting coils **62** or the three sets of transmission coils **70** may be incorporated directly into the C-arm **60**. With the three sets of transmitting coils **62** and **70** being an integral part of the C-arm **60**, the calibration process may be completed with the entire assembly. If the calibration process is completed in this manner, a separate shield is not required. In this embodiment, the effect of distortion caused by the C-arm **60** or any other metal object on the transmitted fields, would be taken into account and characterized during the calibration process and since these distortions are generally static, accurate navigation is achieved.

[0045] Referring to FIGS. 7 and 8, another embodiment of the transmitter coil array **12** is shown incorporated over an operating room (OR) table **72**. Positioned between the transmitter coil array **12** and the operating room table **72** is a planar shield **74** having an upturned peripheral lip **76**. The shield **74** again acts as an infinite plane to reflect and shield the electromagnetic field or region **14** generated by the transmitter coil array **12** from the metal operating room table **72**. The upturned lip **76** also directs the electromagnetic field or region **14** in the vicinity of the patient **78**. The OR table **72**, shield **74** and transmitter coil array **12** may be separate components or attached to one another.

[0046] The configuration of the transmitter coil array **12** used with the OR table is shown in further detail in FIG. 8. The transmitter coil array **12** includes nine discrete coils **80** positioned about the transmitter coil array **12**. Each coil **80** is located or positioned at a different orientation relative to the remaining coils **80**, such that each coil **80** generates its own unique electromagnetic field. Three sets of coils **80** are generally driven at a time so that there are three sets of three coils **80** driven sequentially with each coil **80** in each set of three driven at its own unique frequency to identify that particular field. Here again, other types of coil arrangements and numbers of coils may be utilized in the electromagnetic navigation system **10**. Moreover, as shown herein, the transmitter coil array **12** may be configured in any number of ways to accommodate for its particular application and the use in association with the C-arm **60** and the OR table **72** are merely exemplary in nature.

[0047] Turning now to FIGS. 9 and 10, the calibration process **82** according to the teachings of the present invention is disclosed in further detail. The calibration process **82** is conducted at the factory and is implemented by simulating the environment in which the electromagnetic navigation system **10** will be employed. In this regard, should a shield **56** or **74** be used, as is shown in FIGS. 6 and 7, that particular configuration with the C-arm **60** or the OR table **72** will be calibrated at the factory prior to shipment of the electromagnetic navigation system **10** to characterize the effects of the particular metal object or surgical device being used. Likewise, should the transmitter coil array **12** be integrally formed or incorporated directly into the surgical device having metallic portions rather than retrofitting the surgical device with the shield, the surgical device with the incorporated electromagnetic navigation system **10** will also

be calibrated prior to shipment or delivery. This calibration process **82** assumes that the distortion from the metal object or device will remain static.

[0048] The calibration process **82** starts by moving a calibration sensor **84** to a point in the electromagnetic field or region **14** at step **86**. Preferably, the starting point will be identified as the origin (i.e., equals zero) and all other measured points will be referenced back to this origin. In this regard, a robotic calibration arm or unit **88** having the calibration sensor **84** (see FIG. 10) is employed to measure the magnetic field strength of each energized coil, along a pre-determined grid of calibration points **90**. As shown in FIG. 10, a two-dimensional grid is illustrated having a plurality of calibration grid points **90** disposed equally throughout the two-dimensional grid. For example, each grid point **90** may be separated every 15 millimeters. During the calibration process **82**, a three-dimensional grid will be employed to measure the magnetic field strength of each calibration point **90** throughout the region **14** for each coil in the transmitter coil array **12**. For example, a one meter cubed (m^3) region **14** may be separated into several calibration grid points **90**, such as eight thousand grid points **90**, which are sensed by the calibration sensor **84** on the robotic unit **88** as the calibration sensor **84** is positioned at each one of these discrete grid points **90**.

[0049] Referring back to FIG. 9, with the calibration sensor **84** positioned at the first grid point **90** or origin at step **86**, one of the coils in the transmitter coil array **12** is energized at step **92** and the magnetic field strength generated is sensed or read at this grid point **90** with the calibration sensor **84** at step **94**. Again, the navigation probe interface **22** instructs the coil array controller **16** to drive a particular coil in the transmitter coil array **12**. With the magnetic field sensed by the calibration sensor **84**, the magnetic field strength is determined for that particular calibration point **90** by the navigation probe interface **22**. Each coil in the transmitter coil array **12** is then driven by the coil array controller **16** at that particular calibration point **90**, via step **96**. With the magnetic field strength values known for each coil in the transmitter coil array **12**, these magnetic field strengths are then stored to memory at step **98**. In this regard, these magnetic field strengths are forwarded from the navigation probe interface **22** through the general purpose computer in the control array controller **16** and stored on a flash ROM or any other type of memory housed within the transmitter coil array **12**. In this way, the transmitter coil array **12** may be operated by any coil array controller **16**, since the calibration values are stored with the transmitter coil array **12**.

[0050] The calibration process **82** continues by moving to a next calibration point **90** at step **100** to again determine the magnetic field strengths from each coil. With the navigation probe interface **22** synchronizing the coil array controller **16** to drive each coil in the transmitter coil array **12** and with the robotic unit **88** positioning the calibration sensor **84** at each calibration point **90** within the three-dimensional calibration grid, the calibration process **82** continues until all of the field strengths for all of the coils at each calibration point **90** in the calibration grid is stored. Accordingly, the calibration process **82** stores actual measurements of the magnetic field strength generated by the transmitter coil array **12**, while taking into account or characterizing the distortion effects of either the particular shield, coupled to the surgical device or

the transmitter coil array 12 incorporated directly into the surgical device. In this way, any metallic distortions caused by the metal object or device, such as the C-arm 60 or the OR table 74 is taken into account by performing the real time measurements with these objects in place. Therefore, any distortions caused by utilizing the electromagnetic navigation system 10 in its environment are already accounted for during the factory calibration process to provide accurate navigation of the instrument.

[0051] Referring now to FIGS. 10-12, the navigation process 102 will be described in further detail. The navigation process 102 is a minimization process, as is known in the art, such as Newton's method, which begins at step 104. At step 104, an arbitrary starting point is selected, which is generally the center of volume of the region 14 (i.e., 0, 0, 0). Once the arbitrary start point or guess point 110 is selected at step 104, the navigation process 102 continues to step 106 where the coils in the transmitter coil array 12 are energized, either sequentially or by frequency multiplexing and the magnetic field strength values are received by the sensor located in the instrument 20. Once these values are determined at step 106, the navigation process continues to step 108 where the previously stored calibration data or field strengths for the calibration points 90 in the calibration grid are used to interpolate the fields at the guess point 110 in space. In this regard, should the guess point 110 not be one of the known calibration grid points 90, the guess point 110 is interpolated using known interpolation techniques. These techniques, for example, may include linear interpolation or spline interpolation as shown in FIG. 12. The location of the guess point 110 may be determined from the known calibration grid points 90 using these known interpolation methods to determine the magnetic field strengths between the known calibration grid points 90. Additionally, any other type of interpolation method may also be used such as polynomial curve fitting, etc.

[0052] Once the field strengths are determined for the guess point 110 at step 108, the navigation process 102 continues to step 114 where computation of the field gradients or the difference in field strengths between the guess point 110 and the measured fields at the instrument location are determined. These field gradients or errors are then used at step 116 to refine the guess point 110 during the minimization process to select a new guess point 110 which is closer to the actual sensor location. Once the refined guess point 110 is determined, this process is continued without requiring additional measurements from the instrument 20 until the error between the guess point 110 and the actual instrument location is minimized to an acceptable value at step 118. If the error value is not acceptable, the navigation process 102 again continues with a new guess point 110 selected which is closer to the actual instrument location and the error again computed, via the steps in blocks 108, 114 and 116. Should the error be acceptable, as determined in step 118, the navigation process 102 ends with the guess point 110 now representing the actual instrument location or navigated point 120. In this way, navigation of the instrument 20 is performed very accurately without having metal objects effect the overall navigation since the calibration process has already taken into effect the metal object during creation of the look-up table for the calibration grid points 90, which is used during the navigation process 102.

[0053] Finally, referring to FIGS. 13 and 14, an electromagnetic navigation system 122 according to the teachings of another embodiment of the present invention is shown. The electromagnetic navigation system 122 is substantially similar to the electromagnetic navigation systems 10, shown in FIGS. 1 and 2, except that the electromagnetic navigation system 122 includes an additional transmitter coil array and a dynamic reference arc. In this regard, the electromagnetic navigation system 122 includes a coil array controller 124 which drives a first transmitter coil array 126, as well as a second transmitter coil array 128. Both transmitter coil arrays 126 and 128 generate an electromagnetic field or region 130 where the instrument 132 is navigated and a dynamic reference arc 133 is positioned. Here again, instrument 132 provides the received magnetic field strengths to navigation probe interface 134 for processing and forwarding to the coil array controller 124 and the dynamic reference arc 133 is used for a reference by the instrument 132, further discussed herein. The coil array controller 124 again forwards the navigation information to a user interface/display 136 for use during the surgical procedure being performed.

[0054] The electromagnetic navigation system 122 is shown configured in FIG. 14 in association with a C-arm 138 and an OR table 140. Here again, the transmitter coil array 126 may be configured within shield 142 of the C-arm 138 or incorporated directly into the C-arm 138. The transmitter coil array 128 is shown positioned above the OR table 140 with a shield 144 positioned therebetween.

[0055] By providing both the transmitter coil array 126 and the transmitter coil array 128 to generate the electromagnetic field or region 130 about the patient 146, each transmitter coil array 126 and 128 may be driven simultaneously, sequentially or independent from one another. In this regard, the coil array controller 124 is capable of driving the transmitter coil arrays 126 and 128 simultaneously at different frequencies so that the particular fields may be identified. Alternatively, the transmitter coil arrays 126 and 128 may be time multiplexed or driven sequentially, via the coil array controller 124. In other situations, it may be desirable to initially drive the transmitter coil array 126 located on the C-arm 138 during the surgical procedure while the C-arm 38 generates a fluoroscopic image. However, the C-arm 138 may be in the way for certain portions of the surgical procedure. If so, the C-arm 138 may be rotated or moved out of the way after the image is captured to provide for further surgical clearance while still conducting navigation, via the second transmitter coil array 128 associated with the OR table 140.

[0056] In this way, navigation handoff can be performed between both transmitter coil arrays 126 and 128 without requiring the surgeon to have to stop during the overall surgical procedure should one of the particular metal or surgical instruments be in the way. The dynamic reference arc 133 is substantially similar to the instrument 132 in that it includes receive coils capable of providing six degrees of freedom information. However, the dynamic reference arc 133 is used as a reference and is fixed relative to the patient being navigated to provide a reference point for the instrument 132. In other words, the instrument 132 may be referenced back to either transmitter coil array 126 or 128 and the dynamic reference arc 133 may be also referenced back to the transmitter coil arrays 126 and 128 to determine

the relative positions of each. By having this information, the instrument **132** may then be simply referenced back to the dynamic reference arc **133** by simple subtraction of the fields, as is known in the art, which removes the transmitter coil arrays **126** and **128** out of the calculation process, thereby enabling unobstructed hand-offs between the transmitter coil array **126** and the transmitter coil array **128**. Use of the dynamic reference arc **133** may also be employed with the navigation system **10**, shown in **FIGS. 1 and 2** should this be desired. An example of such hand off technology is set forth in System For Translation of Electromagnetic and Optical Localization Systems, filed Oct. 28, 1999, U.S. Ser. No. 09/429,568, which is hereby incorporated by reference. Moreover, it should be further noted that the calibration process **82** will be performed with both the C-arm **138** and the OR table **140** in proximity to one another, as shown in **FIG. 14** to take into effect the entire surgical environment, thereby providing further accuracy and surgical versatility.

[0057] The electromagnetic navigation systems **10** and **122**, therefore, provide for very accurate surgical navigation of the instruments **20** and **132** during the surgical procedure because the calibration process **82** takes into account and characterizes the distortion effect of the surgical device used during the surgical procedure. This accuracy is achieved by using the information determined during the calibration process **82** in the navigation process **102**. In this way, accurate navigation of the instruments **20** and **132** are achieved in an efficient, cost effective and versatile manner that also takes into effect the tolerance of the transmitter coil array and the surrounding environment.

[0058] The description of the invention is merely exemplary in nature and, thus, variations that do not depart from the gist of the invention are intended to be within the scope of the invention. Such variations are not to be regarded as a departure from the spirit and scope of the invention.

What is claimed is:

1. A method for calibrating an electromagnetic navigation system having a transmitter coil array that generates an electromagnetic field, said method comprising:

- (a) positioning the electromagnetic navigation system in a working environment to account for metallic distortion caused by a metallic object adjacent to the electromagnetic field;
- (b) positioning a calibration sensor at a first calibration point;
- (c) energizing a first coil in the transmitter coil array to generate a first field;
- (d) sensing a first field strength of the first field with the calibration sensor; and
- (e) repeating steps (b), (c) and (d) at a second calibration point, wherein effects of metallic distortion caused by the metallic object is taken into account during the calibration process and wherein the metallic object is a medical device.

2. The method as defined in claim 1 further comprising energizing a plurality of coils sequentially in the transmitter coil array to generate a plurality of fields and sensing field strengths of each of the plurality of fields with the calibration sensor.

3. The method as defined in claim 1 further comprising repeating step (e) to generate about eight thousand calibration points.

4. The method as defined in claim 1 wherein positioning the calibration sensor at a first calibration point further comprises utilizing a robotic unit to position the calibration sensor at the first calibration point.

5. The method as defined in claim 1 wherein the medical device is selected from a group consisting of operating room table, fluoroscope, microscope, ultrasound hand piece, high-intensity focused ultrasound systems, computer topography imaging (CT), interoperative computer topography, magnetic resonance imaging (MR), interoperative magnetic resonance and surgical robot.

6. The method as defined in claim 5 wherein at least one of function and movement of the medical device is simulated during the calibration process.

7. The method as defined in claim 1 further comprising navigating a probe through the electromagnetic field by using the stored field strengths sensed by the calibration sensor.

8. The method as defined in claim 7 further comprising comparing the stored field strengths sensed by the calibration sensor with field strengths measured by the probe.

9. The method as defined in claim 8 further comprising using the stored field strengths sensed by the calibration sensor to interpolate fields at a guess point in space.

10. The method as defined in claim 9 further comprising computing the difference in field strengths between the guess point with the field strength measured by the probe.

11. The method as defined in claim 10 further comprising using the measured difference to refine the guess point during a minimization process to select a new guess point that is closer to the probe location.

12. The method as defined in claim 11 further comprising minimizing the error between the guess point and the actual location of the probe to an acceptable value.

13. The method as defined in claim 1 further comprising creating a look-up table for a plurality of calibration points which is operable to be used during navigation process, where the look-up table stores field strengths for the plurality of calibration points that take into account the metallic distortion caused by the metallic object adjacent to the electromagnetic field.

14. The method as defined in claim 1 further comprising energizing the plurality of coils in the transmitter coil array in at least one of a time division multiplex manner, frequency division multiplex manner, or a combination of both.

15. The method as defined in claim 7 wherein navigating the probe includes navigating a probe selected from at least one of a surgical probe, catheter, steerable catheter, endoscope, shunt, drill guide, awl/tap, orthopedic instrument and a combination thereof.

16. The method as defined in claim 7 further comprising providing a dynamic reference arc that is affixed relative to a patient and used as a reference point for the probe.

17. A method for navigating an instrument in an electromagnetic navigation system having a transmitter coil array that generates an electromagnetic field, said method comprising:

- (a) referencing a look-up table of calibration field strengths that account for metallic distortion caused by a metallic object adjacent to the electromagnetic field;

- (b) selecting a guess point where the instrument is located;
- (c) energizing the transmitter coil array to generate the electromagnetic field adjacent to the metallic object;
- (d) sensing the electromagnetic field with the instrument;
- (e) interpolating the field strength at the guess point using the look-up table;
- (f) calculating the difference in field strengths between the guess point and the field sensed by the instrument; and
- (e) refining the guess point.

18. The method as defined in claim 17 wherein selecting the guess point includes selecting an arbitrary start guess point.

19. The method as defined in claim 17 further comprising energizing the plurality of coils in the transmitter coil array in at least one of a time division multiplex manner, frequency division multiplex manner, or a combination of both.

20. The method as defined in claim 17 wherein interpolating the field at the guess point includes using at least one interpolation method selected from linear interpolation, spline interpolation, and polynomial curve fitting.

21. The method as defined in claim 17 wherein refining the guess point includes performing a minimization process to select a new guess point that is closer to the actual instrument location.

22. The method as defined in claim 21 further comprising minimizing the error between the guess point and the actual instrument location to an acceptable value.

23. The method as defined in claim 17, wherein the metallic object is selected from a group consisting of operating room table, fluoroscope, microscope, ultrasound hand piece, high-intensity focused ultrasound systems, computer topography imaging (CT), interoperative computer topography, magnetic resonance imaging (MR), interoperative magnetic resonance and surgical robot.

24. The method as defined in claim 17 wherein navigating the probe includes navigating a probe selected from at least one of a surgical probe, catheter, strobe catheter, endoscope, shunt, drill guide, awl/tap, orthopedic instrument and a combination thereof.

25. The method as defined in claim 17 wherein the transmitter coil array is controlled via a wireless channel.

26. The method as defined in claim 17 wherein the instrument senses the electromagnetic field and operates via a wireless channel.

27. An electromagnetic navigation system for use in navigating an instrument through an electromagnetic field positioned near a metal object, said electromagnetic navigation system comprising:

- (a) a transmitter coil array having a plurality of transmitter coils, said transmitter coil array operable to generate the electromagnetic field to navigate the instrument; and
- (b) a shield positioned adjacent the metal object, said shield operable to substantially shield the metal object from the electromagnetic field generated by said transmitter coil array, said transmitter coil array being attached to said shield, wherein shield substantially reduces distortion of the electromagnetic field by the metal object, thereby enabling accurate navigation of the instrument in the electromagnetic field.

28. The electromagnetic navigation system as defined in claim 27 wherein said transmitter coil array is integrally formed transmitting coils positioned about a perimeter of said shield.

29. The electromagnetic navigation system as defined in claim 27 wherein said transmitter coil array is displaced from said shield.

30. The electromagnetic navigation system as defined in claim 29, wherein said transmitter coil array includes at least three sets of transmitter coils which are displaced from said shield.

31. The electromagnetic navigation system as defined in claim 30 wherein said three sets of transmitter coils are displaced from said shield by an extension member.

32. The electromagnetic navigation system as defined in claim 30, wherein each set of transmitter coils includes three sets of coils positioned orthogonal to one another.

33. The electromagnetic navigation system as defined in claim 27 wherein said transmitter coil array is driven in at least one of a time division multiplexed manner, a frequency division multiplexed manner or a combination of both.

34. The electromagnetic navigation system as defined in claim 27 wherein the metal object is a fluoroscope.

35. The electromagnetic navigation system as defined in claim 34 wherein said fluoroscope is a C-arm fluoroscope.

36. The electromagnetic navigation system as defined in claim 27 wherein at least one of said shield and transmitter coil array is removably attached to said metal object.

37. The electromagnetic navigation system as defined in claim 34 wherein said shield is integral with said fluoroscope.

38. The electromagnetic navigation system as defined in claim 27 wherein said instrument includes at least one electromagnetic sensor attached at a distal end of said instrument.

39. The electromagnetic navigation system as defined in claim 38 wherein the instrument is non-rigid and may bend during navigation and the instrument includes a plurality of electromagnetic sensors to provide further location information regarding the instrument.

40. The electromagnetic navigation system as defined in claim 27 wherein said transmitter coil array is controlled over a wireless channel.

41. The electromagnetic navigation system as defined in claim 27 wherein said instrument operates over a wireless channel.

42. The electromagnetic navigation system as defined in claim 27 wherein the field strength of each coil in the transmitter coil array is stored on a memory medium where each field strengths takes into account interference from the metal object.

43. The electromagnetic navigation system as defined in claim 42 wherein the memory medium is a flash ROM.

44. An electromagnetic navigation system for use in navigating an instrument through an electromagnetic field positioned near a fluoroscope, said electromagnetic navigation system comprising:

- (a) a transmitter coil array having a plurality of transmitter coils, said transmitter coils array operable to generate the electromagnetic field to navigate the instrument; and

(b) a shield attached to the fluoroscope, said shield operable to substantially shield the fluoroscope from the electromagnetic field generated by said transmitter coil array, wherein said shield substantially reduces distortion of the electromagnetic field by the fluoroscope, thereby enabling accurate navigation of the instrument in the electromagnetic field.

45. The electromagnetic navigation system as defined in claim 44 wherein at least one of said transmitter coil array is integrally formed transmitting coils positioned about a perimeter of said shield.

46. The electromagnetic navigation system as defined in claim 44 wherein said transmitter coil array is displaced from said shield.

47. The electromagnetic navigation system as defined in claim 46 wherein said transmitter coil array includes at least

three sets of transmitter coils which are displaced from said shield.

48. The electromagnetic navigation system as defined in claim 47 wherein said three sets of transmitter coils are displaced from said shield by an extension member.

49. The electromagnetic navigation system as defined in claim 44 wherein each set of transmitter coils includes three sets of coils positioned orthogonal to one another.

50. The electromagnetic navigation system as defined in claim 44 wherein said transmitter coil array is driven in at least one of a time division multiplexed manner, frequency division multiplexed manner or a combination of both.

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