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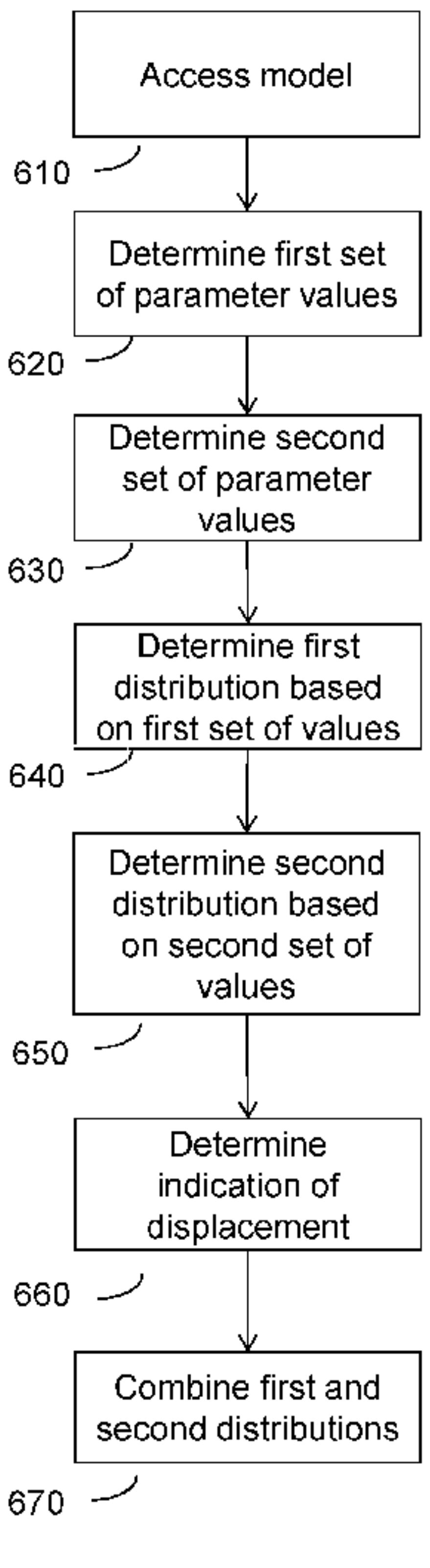

Figure 6

(57) **Abstract:** A method of determining a spatial distribution of one or more dielectric properties in a region of a human or animal body is disclosed. The method comprises accessing a model defined by one or more model parameters representing structural and dielectric properties of a structure, determining a first set of values of parameters of the model and determining a second set of values of parameters of the model. The first set of values is based on measurements from a first set of field sensing electrodes disposed on a tool and at positioned at a respective first set of positions in the region. The second set of values is based on measurements from a second set of field sensing electrodes disposed on the tool and positioned at a respective second set of positions in the region. The method further comprises determining a first distribution of one or more dielectric properties in a first portion of the region based on the first set of values and the model, and determining a second distribution of one or more dielectric properties in a second portion of the region based on the second set of values and the model. An indication of displacement between the first and second set of positions is determined and the first and second spatial distributions are combined using the indication of the displacement.

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SYSTEM, METHOD AND ACCESORIES FOR DIELECTRIC-MAPPING

FIELD AND BACKGROUND OF THE DISCLOSURE

[001] The present disclosure relates to mapping physical properties of a body part or organ, for example in medical imaging and, more specifically, but not exclusively, to systems and methods for dielectric mapping and imaging, e.g., for the construction of maps or images of body tissues and organs. Electrical Impedance Tomography (EIT) systems and methods of medical imaging, as is known in the art, are implemented by deploying electrodes at the body's surface of a subject, injecting electrical excitation to some of the employed electrodes, measuring the electrical signals received at other employed electrodes, calculating, based on the measured signals, 3D image(s) of tissues and organs inside the body and providing a display of the calculated 3D images. EIT techniques are based on the fact that muscle and blood conduct the applied currents better than fat, bone, or lung tissue and are therefore able to resolve different tissue types.

SUMMARY

[002] In overview, the disclosure provides a method of generating a dielectric map of a region of an organ of a human or animal body using intrabody electrodes that were or are disposed inside or adjacent to the region. In some embodiments, the intrabody electrodes are moved through the region and dielectric maps mapping different parts of the region, each part being mapped using the electrodes in a different position or orientation, are combined, for example, stitched together, to generate the dielectric map of the region. Alternatively, a tool carrying a plurality of electrodes is stationary in the region and different sets of the electrodes on the tool are used to generate dielectric maps. The different sets of electrodes are at different respective sets of positions despite the tool being stationary, therefore providing dielectric maps at different positions in the region. The dielectric map of the region or each portion of the region is a spatial distribution of one or

more dielectric properties of tissue in the mapped region. The tissue may be, for example, blood, muscle, bone, nerve, and/or fat tissue. Examples of dielectric properties that may be mapped in the dielectric map includes conductivity, complex conductivity, real or imaginary part of conductivity, magnitude or phase of conductivity, permittivity, complex permittivity, real or imaginary part of permittivity, magnitude or phase of permittivity, impedance, complex impedance, real or imaginary part of impedance, magnitude or phase of impedance etc.

[003] Structural and dielectric properties in the region or each portion of the region are obtained in order to determine a spatial distribution of dielectric properties in the region. In the methods disclosed herein, a parametric model is used to find the structural and dielectric properties in the region.

[004] In general, a structure (for example, the region in the body or portion of the region) can be modelled by a model which is defined by model parameters that represent the structural properties of the structure, and by model parameters that represent the dielectric properties of the structure. Structural properties may include shape, size, configuration, and dielectric properties may include conductivity, impedance, resistivity, or any dielectric properties known to the skilled person.

[005] The model is defined by the model parameters describing structural properties of the structure. The model may be constructed by choosing/defining for each structural property of the structure a corresponding model parameter. Each structural property may describe or be applicable to the whole structure or to a portion of the structure. Different portions of the structure may have different structural and/or dielectric properties, and the collection of properties of portions of the structure describes the properties of the whole structure.

[006] In one illustrative example, the structure may be a blood vessel, and the structural properties may include an inner diameter of the blood vessel, and/or an outer diameter of the blood vessel, whilst dielectric properties may include dielectric properties of the blood inside the blood

vessel, dielectric properties of the tissue outside of the blood vessel, and/or dielectric properties of the tissue forming the blood vessel. Determining structural and dielectric properties of a modelled structure involves determining values of one or more of the model parameters, which may involve determining values of model parameters representing only dielectric properties of the structure, or may involve determining model parameters representing only structural properties of the structure, or may be a combination of both. The determined values minimise or otherwise reduce an error between voltages that are measured in response to electric fields that interact with the structure, and calculated voltages which are calculated based on the model of the structure (i.e. based on the model parameters). The resulting determined parameter values, together with any remaining parameter values that have been set to a constant value rather than being determined based on the measurement, therefore give an indication of the corresponding structural properties and dielectric properties of the actual structure.

[007] As mentioned, one or more of the model parameters may be fixed, such that values of these parameters are not determined based on a comparison of modelled and measured voltages. In these examples, a subset of the model that are not fixed may be determined. For example, model parameters representing dielectric properties of a structure may be fixed values that are assumed to be known and not determined using the disclosed methods, whilst the values of the other model parameters, such as those representing a shape or configuration of the structure, or other dielectric properties of the structure that aren’t assumed to be known, may be determined using the disclosed methods. Additionally or alternatively, model parameters representing the shape and/or size of a model may be fixed values, whilst the values of model parameters representing dielectric properties of the structure may be determined. In some examples, both one or more parameters representing a structural property of the structure and one or more parameters representing a dielectric property of the structure may be fixed at constant values, whilst the values of one or

more remaining structural and/or dielectric parameters are determined using the disclosed methods.

[008] In more detail, one or more model parameters may be fixed based on predetermined values for that parameter. As an example, model parameters representing dielectric properties of a structure may be fixed based on predetermined information, such as data indicative of the dielectric properties of the structure. Additionally or alternatively, other model parameters, such as those representing a size of a structure, may be fixed based on predetermined information regarding the size of the structure. For example, the values of model parameters representing the dimensions of the structure may be fixed based on knowledge or an estimation of the dimensions of the structure. Fixed model parameters may be fixed explicitly in terms of a corresponding constant in the model, or implicitly in terms of numerical values in the model resulting from a combination of constants or in a structure of the model. It would be understood that reference to fixing a model parameter refers to setting that parameter to a constant value. Additionally or alternatively to fixing model parameters, model parameters to be determined may be constrained to a predefined range, which may be defined based on approximate knowledge of the corresponding property of the structure. In such embodiments, methods disclosed herein may be used to determine a value of those constrained model parameters within the respective predefined range.

[009] Reference is made herein to model parameters representing structural properties of a structure, such as shape, size, configuration (such as position and orientation), and reference is also made to model parameters representing dielectric properties of a structure. Model parameters may represent structural properties or dielectric properties of the whole of the structure, or for a portion of the structure, the parameters for the portions of the structure collectively describing the structure. In some examples, a model may comprise one or more model parameters representing

dielectric properties of a portion of a structure, and may further comprise one or more model parameters representing structural properties, such as a size or shape, for that same portion. In this manner, different portions of a structure may have one or more associated model parameters representing structural properties of that portion, and one or more associated model parameters representing dielectric properties of that portion. In other words, the model may comprise two or more parameters representing dielectric properties of respective different portions of the structure, and may further comprise two or more parameters representing structural properties, such as a shape and size, of those respective portions of the structure. The model may further comprise model parameters representing the relative arrangement of different portions of the structure.

[0010] It can be considered that a model as discussed herein may be used to model any structure in general. In the disclosed methods, a model is used to model various portions of a region in a body. Thus where reference is made to a structure in general terms, for example a model of a structure, or properties of a structure, that this discussion may be applied to the disclosed methods in which the structure is a portion of the region in a body.

[0011] In a first aspect, a method of determining a spatial distribution of one or more dielectric properties in a region of a human or animal body is disclosed. The method comprises accessing a model defined by one or more model parameters representing structural and dielectric properties of a structure. A first set of values of parameters of the model is determined. The first set of values is based on measurements from a first set of field sensing electrodes that are disposed on a tool and that are positioned at a respective first set of positions in the region. A second set of values of the parameters of the model is determined. The second set of values is based on measurements from a second set of field sensing electrodes that are disposed on the tool and that are positioned at a respective second set of positions in the region. The method further comprises determining a first distribution of one or more dielectric properties in a first portion of the region based on the first set of values and the model, and determining a second distribution of one or more dielectric properties in a second portion of the region based on the second set of values and the model. The method further comprises determining an indication of displacement between the first and second set of positions and combining the first and second spatial distributions using the indication of the displacement. The first and second portions of the region are at least partially overlapping, such that the first and second distributions have at least one point or sub-portion in common.

[0012] In some embodiments, determining the first and second sets of values may comprise, for each of the sets of values: accessing voltage measurements made using the respective set field sensing electrodes disposed on the tool in response to currents applied to one or more field supplying electrodes, and computing the parameter values by adjusting the parameter values to fit predicted voltage values to the accessed voltage measurements, wherein the predicted voltage values are predicted from the model for the currents applied to the respective field supplying electrodes. Computing the parameter value may comprise: accessing current data indicative of the currents applied at the one or more field supplying electrodes when the voltages were measured; accessing position data indicative of positions of the field supplying and field sensing electrodes at the time the voltages were measured; and computing the values of the one or more model parameters using the accessed voltage measurements, the current data, and the position data. The field supplying electrodes may also be disposed on the same tool as the field sensing electrodes, but may additionally or alternatively be disposed elsewhere such as on a separate tool inside the body or disposed on the surface of the body.

[0013] In more detail, computing the values of the one or more model parameters may comprise accessing starting values for each of the one or more model parameters and setting the one or more model parameter values to the respective starting values. The method may then comprise repeatedly: computing model voltage data (also known as predicted voltage values) modelling the voltages measured at the field sensing electrodes using: the current data, the position data, and the model parameter values; computing an error signal indicative of an error between the model voltage data and the accessed voltage measurements (also known as measured voltage data); and adjusting the one or more model parameter values using the error signal. The steps of computing model voltage data, computing an error signal, and adjusting the one or more model parameter values may be repeated until a stopping criterion is reached. The step of adjusting the one or more model parameter values may comprise adjusting to reduce a magnitude of the error signal. Reducing a magnitude of the error signal may involve updating the model parameter values using an optimisation process to determine new parameter values. The optimisation process may use the previous values and the error signal, as well as other relevant factors depending on the specific optimisation process in order to determine new parameter values. In some embodiments, the optimisation process uses gradient descent. In some embodiments, the optimisation process uses Adam optimisation.

[0014] In some embodiments, one or both first and second sets of field sensing electrodes comprise a single electrode disposed on the tool. Alternatively, the first and/or second set of electrodes comprises a plurality of electrodes disposed on the tool. The first set of electrodes may consist of a first subset of all of the electrodes disposed on the tool, and the second may consist of a second subset of all the electrodes disposed on the tool. The first and second sets may have one or more common electrode and one or more unique electrode. That is, the first set may have at least one electrode that is not in the second set and the second set may have at least one electrode that is not in the first set. In these embodiments, measurements from the first set of field sensing electrodes and the measurements from the second set of field sensing electrodes may have taken when the tool was in the same position in the region. Despite the tool being positioned in the same position in the region, it would be appreciated that the measurements made using the first and second sets of electrodes were made at different sets of positions, since at least one of the electrodes in each set are at different positions to the electrodes in the other set. It is therefore possible to obtain measurements at different positions in the region (for use in modelling different portions of the region) whilst the tool remains stationary within the region, by taking measurements using different sets of electrodes disposed on the tool.

[0015] In some embodiments, the tool itself may be positioned at different locations in the region when the measurements from each of the first and second sets of electrodes were made. For example, the tool may have been positioned at a first location in the region when the measurements from the first set of field sensing electrodes were taken, and the tool may have been positioned at a second location in the region, different from the first location, when the measurements from the second set of field sensing electrodes were taken. In these embodiments, the first and second sets of electrodes may consist of the same set of electrodes disposed on the tool. Therefore, the same set of electrodes may be used to take measurements at different positions in the region, because the tool on which the electrodes are disposed can be moved to different locations in the region. Throughout the present disclosure, the ‘position’ of the tool may refer to position of the tool within a region and may also refer to an orientation of the tool. The location of the tool may be defined by the location of a specific point on the tool, for example a center of mass of the tool, or some other defined point on the tool. The orientation of the tool may be defined as pitch and/or yaw and/or roll angles with respective to a coordinate system. Different positions of the tool as described above may refer to different positions and/or different orientations of the tool.

[0016] The accessed voltage measurements are indicative of voltages sensed by one or more field sensing electrodes in response to electric fields generated by currents applied to one or more field supplying electrodes. The generated electric fields are generated using the field supplying electrodes, by applying currents to the field supplying electrodes, meaning that the field supplying electrodes supply the electric field as a result of the currents applied to the field supplying electrodes. The electric fields are generated in the vicinity of the region, where the field sensing electrodes disposed on the tool are positioned. The electric fields supplied by the field supplying electrodes give rise to voltages which are sensed by the field sensing electrodes. A field sensing electrode may produce an electrical signal based on the sensed voltage, and the signal may be measured to determine the value of the voltage sensed by the electrode. For example, a voltmeter (or other suitable measuring apparatus) may be connected to the field sensing electrode to measure the sensed voltage, thus producing a measured voltage value from the voltage sensed by the electrode. The voltage measurements may be accessed in real-time for use in the disclosed methods, i.e. accessed at the same time as when the voltages are measured by the one or more field sensing electrodes. Alternatively, the voltages may be measured at an earlier time to when the measurements are accessed, such as one hour, one day, or one week before the measured voltage data is accessed for use in the disclosed methods. Specifically, the voltages may be measured during a surgical or other medical procedure, which is then stored and is accessed at a later time separate to the procedure. It would be appreciated that the time difference between measuring and accessing the voltages may be longer than one week, or may be any intermediate time between real-time and one week. The voltage data may be acquired during a surgical or other medical procedure, which is then stored and accessed for use in the disclosed methods at the same or a later time, and subsequent to accessing the voltage data, further voltage data may be acquired as part of the same surgical procedure. This process may be repeated any number of times during the same surgical procedure.

[0017] Where reference is made to generating electric fields and supplying electric fields, it would be understood that electric fields are generated using the field supplying electrodes, for example by applying currents to the field supplying electrodes. The field supplying electrodes themselves therefore supply the electric field as a result of the current applied to those electrodes.

[0018] In some embodiments, at the time the voltages were measured, one or more field supplying electrodes were disposed on the tool in the vicinity of the region such that the field supplying electrodes were disposed to supply an electric field that interacted with material in the region and the field sensing electrodes (disposed on the tool) were disposed to measure a voltage resulting from the electric field interacting with the material in the region. For example, the tool may be positioned inside the region, for example the region may be a heart cavity or a portion of a heart cavity and the tool ia disposed inside the cavity. The tool may be a catheter, optionally a Lasso® catheter, basket catheter, spiral catheter, or pig tail catheter. In some embodiments, field supplying electrodes were alternatively or additionally disposed on a surface of the body at the time the measurement was obtained. Additionally or alternatively, one or more field supplying electrodes may have also been disposed inside the body on a separate tool at the time the measurements were obtained.

[0019] The voltage measurements may be acquired using one or more field supplying electrodes supplying electric fields and one or more field sensing electrodes sensing voltages resulting from the supplied electric fields. Acquiring the voltage can be performed using various arrangements of the field supplying and field sensing electrodes. The following examples are illustrative examples of electrode arrangements that may be used to acquire the voltage measurements.

[0020] In a first example, alternating electric currents are applied to a single field supplying electrode so as to generate an electric field in the region. The field supplying electrode may be disposed on the tool in the region. The applied current may be applied to the field supplying electrode at a given frequency, and amplitude. One or more field sensing electrodes disposed on the tool sense the generated electric field and as a result, the respective voltages on field sensing electrodes change. The respective voltages on the one or more field sensing electrodes are measured, and the measured voltages form a data set. Current data that is indicative of the current applied to the field supplying electrode may also be stored. The current data may be indicative of the identity of the field supplying electrode and of the frequency and magnitude of the applied current. The current data may comprise values of the applied currents known in advance of the application, or the current data may comprise measured values of the actual currents applied to the field supplying electrodes, wherein the actual measured values may be slightly different to the values intended to be applied to the electrodes.

[0021] The first example may be extended to applying currents to a plurality of field supplying electrodes at a given frequency at the same time. In some examples, the phase of the currents applied to each of the field supplying electrodes may be controlled, such that the phases are different. In other words, a plurality of field supplying electrodes simultaneously excite electric fields at the same frequency, with a controlled phase difference between the generated electric fields that are simultaneously excited. Voltages are measured using the field sensing electrodes in response to the electric fields supplied via the plurality of field supplying electrodes at the same frequency. Thus, a plurality of different voltage measurements may be made at the same time using each field sensing electrode, each measurement being a voltage resulting from an electric field generated at a different phase. In these examples, the measured voltage data may include voltages measured at each field sensing electrode at a given time for each of the electric fields generated simultaneously at the same frequency and at different phases. The current data may include the amplitude and the phase of currents applied at each field supplying electrode.

[0022] Furthermore, in some examples a field supplying electrode may supply electric fields and resulting voltages at a field sensing electrode may be measured at a plurality of different times. For example, at each of a plurality of different times, an alternating current of a given frequency may be applied to a different single field supplying electrode, and at each time, a voltage measurement may be made using a different one of a plurality of electrodes. In another example, at each of a plurality of different times, an alternating current of a given frequency may be applied to a different plurality of field supplying electrodes, and at each time, a plurality of voltage measurements may be made using a different plurality of field sensing electrodes. The accessed voltage measurements may therefore comprise voltage measurements made at different times, wherein the voltage measurements made at each time are voltages measured using different ones of the field sensing electrodes resulting from electric fields generated using different ones of the field supplying electrodes. In one specific example, the tool may comprise 10 electrodes and one of which acts as a field supplying electrode whilst the remaining electrodes are field sensing. The field supplying electrode may be different for different voltage measurements made at different times.

[0023] In another example, electric currents are applied to a plurality of field supplying electrodes at the same time (i.e. simultaneous excitation of each of a plurality of field supplying electrodes). The current applied to each field supplying electrode may be of a different frequency, such that each field supplying electrode supplies an electric field at a different respective frequency. In this example, a plurality of electric fields are generated at the same time, each at a different frequency. One or more field sensing electrodes sense the generated electric fields and are used to measure voltages resulting from the respective electric fields. Specifically, each of the one or more field sensing electrodes may be used to simultaneously measure voltages resulting from one or more, and preferably all, of the electric fields at the different frequencies. For example, signal processing can be performed on the received signals at each field sensing electrode (e.g. using a demultiplexer) to determine voltage measurements at each frequency. In this sense, it can be considered that a field sensing electrode is configured to sense voltages in response to electric fields supplied at a plurality of different frequencies by means of being connected to such a signal processor. In other words, the signal processor configures the electrode to be able to sense voltages at a plurality of different frequencies at the same time. Thus, in reality whilst it is the signal processor that is configured to measure voltages at different frequencies which are sensed by electrodes, this is referred to throughout as the electrodes being configured to sense voltages at different frequencies. An example of signal processing that could be used to separate the signals at respective frequency is to analyse the frequency spectrum of the measured signals, for example using a Fourier transform, as is well known to the person skilled in the art. It would be appreciated that this example equates to a plurality of simultaneous and independent instances of the first example discussed above, wherein each instance has electric fields generated and voltages measured at a different respective frequency. The measured voltages form a data set that comprises the voltages measured at each field sensing electrode at each frequency, in response to the excitation of the plurality of field supplying electrodes at each respective frequency. Current data that is indicative of the current applied to each of the field supplying electrodes may also be stored. The current data may be indicative of the magnitude and/or frequency and/or phase of the applied current at each field supplying electrode, and identification of each of the respective field sensing and field supplying electrodes. This example may be extended to applying currents to a plurality of field supplying electrodes at a plurality of different frequencies, wherein for each frequency, there are a plurality of field supplying electrodes supplying electric fields at that frequency. In some examples, the phase of the currents applied to each of the field supplying electrodes for a given frequency may be controlled, such that the phases are different.

[0024] It would be appreciated that an electrode can function as a field supplying electrode at a first frequency, and can simultaneously function as a field sensing electrode at all the frequencies. In some embodiments, a voltage measurement made by an electrode at the same frequency supplied by that electrode is noisy to such an extent that it is preferable not to use such measurements for finding model parameters. Thus in some examples comprising a plurality of electrodes, each of the plurality of electrodes functions as a field supplying electrode at a different respective frequency and simultaneously functions as a field sensing electrode for each of the other frequencies corresponding to the electric fields supplied by the remaining plurality of electrodes.

[0025] In some embodiments, one or more ground electrodes are also provided in conjunction with a corresponding field supplying electrode. Whilst the field supplying electrode functions as a field source, i.e. supplying an electric field, the ground electrode functions as a field sink. A single ground electrode may be used in conjunction with a single corresponding field supplying electrode, or a single ground electrode may be used in conjunction with a plurality of different field supplying electrodes exciting electric fields at the same or different frequencies. Alternatively, there may a respective ground electrode for each different frequency. The ground electrode(s) may be a surface electrode positioned on the surface of the body, such as attached to the skin of a patient, or the ground electrode(s) may be disposed on the tool disposed inside the body. In some specific embodiments, the field supplying electrodes and field sensing electrodes are disposed on a tool comprising 3 or more, preferably 10 or more, electrodes arranged in a circle. That is, the electrodes may be disposed along the circumference of a notional circle defined by the structure of the tool carrying the electrodes. The distance between each pair of adjacent electrodes in the circle may be equal, so that the electrodes are arranged at regular points along the circumference of a circle. A first electrode on the tool may function as the field supplying electrode and an adjacent or opposite electrode may function as the ground electrode, while the remaining electrodes on the tool may function as field sensing electrodes. In other specific embodiments, the each one of the plurality of electrodes supply an electric field at a different respective frequency, and simultaneously measure voltages at the frequencies excited by the other electrodes, whilst a respective ground electrode for each different frequency is disposed on the surface of the body or on a tool inside the body. Voltage measurements made using the field sensing electrodes may be voltages measured between the respective field sensing electrode and a ground electrode.

[0026] In the examples discussed above, it is possible that an electrode transmitting at a given frequency (i.e. functioning as a field supplying electrode at a given frequency) may also simultaneously act as a field sensing electrode for that same frequency. In other words, an electrode transmitting at a frequency can also be used to measure a voltage at the same transmitted frequency at the same time.

[0027] In some embodiments, voltage measurements may be sampled at a specific rate, that is voltage measurements are made a certain number of times in a given period of time. As would be understood by the skilled person, the sampling rate is at least twice as high as the highest frequency at which electric fields are to be measured. In some examples, the sampling rate is between 300kHz and 500kHz, and in some examples the sampling rate can be up to 1MHz or more. A certain number of samples may be recorded at the sample rate, or samples may be recorded for a certain amount of time at the sampling rate. The sampled signals may be multiplexed signals for electric fields generated at different frequencies and/or phases, and the signals may be demultiplexed using signal processing techniques as would be known to the skilled person. An example of signal processing that could be used to separate the signals at respective frequencies and/or phases is to analyse the frequency spectrum of the measured signals, for example using a Fourier transform. Performing the signal processing on the multiplexed signals therefore provides voltage measurements for each field sensing electrode at each respective frequency and/or phase.

[0028] In one specific example, a set of 625 samples is recorded at a sample rate of 500kHz. The samples are multiplexed signals for different frequencies and/or phases, which are demultiplexed using a discrete Fourier transform, for example. The processing provides, for each field sensing electrode, an amplitude of the measured signal at each respective frequency and/or phase of the generated electric fields, thereby providing the measured voltage data for each electrode at each frequency and/or phase. Sets of samples may be repeatedly taken at the sampling rate, which are then demultiplexed using the signal processing at a rate of at least 100Hz (i.e. the demultiplexing process may occur 100 times a second, each time for a different set of 625 samples). The measured voltage data can therefore be updated with new measurements recorded at each field sensing electrode at each frequency and/or phase at the rate of at least 100 times a second.

[0029] In some examples, the demultiplexing rate and the rate at which voltage measurements are updated is 400 times a second. For example, 625 samples are recorded at a sampling rate of 500kHz, which lasts for a duration of 1.25ms. These samples are then demultiplexed and added to the measured voltage data, and then 1.25 ms later (after the 625 samples were recorded), 625 new samples are recorded and demultiplexed. Samples are recorded demultiplexed and resulting measurements added to the measured voltage data every 2.5ms (i.e. at a rate of 400 times per second). Demultiplexing may also be used in the same manner to determine the applied currents at each field supplying electrode at the respective frequency and/or phase, and the applied current data may be updated accordingly at a rate of at least 100 times a second, optionally 400 times a second.

[0030] The accessed voltage measurements may be considered as a data set comprising voltage values sensed at each field sensing electrode and the identification of the respective field sensing electrode. The voltages in the set are sensed in response to electric fields supplied by one or more field supplying electrodes. In the case of excitation of a plurality of electrodes at different frequencies, the data set may comprise the measured voltage values indicative of voltages sensed at the field sensing electrodes at the different frequencies, as well as the respective frequencies and identification of the field sensing electrode at which the voltage was read. Each data set may include voltage measurements that were acquired at different points in time using one or more field sensing electrodes, for example where at each separate point in time, the one or more field supplying electrodes and/or one or more field sensing electrodes are disposed at different locations relative to the structure. Additionally or alternatively, the data set may include voltages that were measured at the same point in time at multiple different frequencies using one or more field sensing electrodes.

[0031] With reference to the specific disclosed methods require measurements from each of a first and second set of field sensing electrodes positioned at respective first and second sets of positions, the above illustrative examples of arrangements of field sensing and field supplying electrodes may be used to obtain these measurements using each of the first and second sets of field sensing electrodes. In some embodiments, the measurements made using the first set of electrodes are taken at a different time to the measurements made using the second set of electrodes. For example, this may be the case if the tool is moved to a new position after the measurements using the first set of electrodes are made, and before measurements using the second set of electrodes are made. This may also be the case if different subsets of electrodes on a stationary tool are used. Measurements using a first subset may be taken, and at a later time measurements using a second subset may be taken.

[0032] In embodiments where different subsets of electrodes on the tool are used for the first and second sets of field sensing electrodes, the measurements taken using the first set of field sensing electrodes and the measurements taken using second set of electrodes may be recorded simultaneously. In these embodiments, the first set of field sensing electrodes and the second set of field sensing electrodes may each sense electric fields generated at different frequencies. That is, the first set of field sensing electrodes senses electric fields at a first frequency, whilst the second set of field sensing electrodes senses electric fields at a second frequency. Thus, the first set of field sensing electrodes may be used to record voltage measurements of the first frequency, whilst the second set of field sensing electrodes are used to simultaneously record voltage measurements of the second frequency.

[0033] The accessed voltage measurements may comprise measured voltages, or may otherwise comprise other quantities indicative of measured voltages which have been derived from the measured voltages, such as electric field measurements, impedance measurement or any other measurement derivable from a voltage sensed at the field sensing of electrodes. The currents are typically time varying currents, for example varying at a given frequency or within a frequency range, for example to generate radio frequency (RF) fields, more specifically within a frequency range of 1 to 1000 kHz, preferably 10 to 400kHz, 1 to 100kHz or more specifically 15 to 65kHz. Frequencies up to 4MHz may also be used.

[0034] With reference to the accessed position data, the position data is indicative of positions of the field supplying and field sensing electrodes at the time the voltages are measured. In particular, the position data for the first set of field sensing electrodes indicates the respective first set of positions, which includes the position of each electrode in the first set of electrodes at the time the voltage measurements were made using the first set of field sensing electrodes. Similarly, the position data for the second set of field sensing electrodes indicates the respective second set of positions, which includes the position of each electrode in the second set of electrodes at the time the voltage measurements were made using the second set of field sensing electrodes. In some embodiments, the first set of positions corresponds to the first portion of the region, and wherein the second set of positions corresponds to the second portion of the region. The position data may be explicit in terms of positions of the electrodes. For example, the position data may include position coordinates for each electrode in a reference frame, the reference frame being fixed to the tool, or the coordinates may be defined relative to an external reference system (outside the body). For example, the reference frame may be defined with respect to a belt, a jacket, or other garment incorporating electrodes that is worn by a subject (i.e. on the body) during data acquisition. Another example is a reference frame defined with respect to a static catheter positioned in the body. The positions of electrodes disposed on the catheter may be defined with respect to a reference frame fixed on the body, and the positions may be determined using medical imaging, such as x-ray, ultrasound, or Electrical Impedance Tomography.

[0035] In some examples the positions of the electrodes may be defined in a coordinate system that is not fixed to any known reference frame, such as a reference frame external to the body, fixed to the body or fixed to a tool. The electrode positions may instead be defined in a coordinate system that is independent of a tool or body and is not defined relative to an external reference outside of the body. A common reference frame may be determined using electrodes that move to different positions and take voltage measurements at different times. A coordinate system is determined in which the positions of all the electrodes at all the different times can be found, thereby providing a common reference frame for all the electrode positions that does not rely on landmarks inside or outside of the body to define the coordinate system.

[0036] One particular example of finding a common reference frame for moving electrodes is using the “V-to-R” or “measurement-to-location” navigation and imaging system as described in WO2019034944A1, in which voltage measurements made using the field sensing electrodes are used to determine a position of those electrodes in a common reference frame. This is done by transforming a cloud of voltage measurements (referred to as the V-cloud) that are acquired at different sets of positions of the electrodes, into positions of the electrodes at which the measurements were taken (referred to as the R-cloud).

[0037] In some examples, one way of finding the common reference frame involves making a plurality of voltage measurements for a plurality of different respective locations of the electrodes, such that enough points exist in the V-cloud (there are enough measurements at different electrode positons) to produce a voltage-to-position transformation of sufficient accuracy. In other words, the electrodes may be repeatedly moved to different positions and voltage measurements made for the electrodes at those positions until enough measurements have been made to generate an R-cloud (by transforming the voltage measurements (the V-cloud)) with a sufficiently large number of points. The transformation to the R-cloud may then be used to find the position of each electrode in a common reference frame for the existing voltage measurements and for future measurements. A reference frame may be defined based on the cloud of positions, for example with an origin at the centre of the R-cloud, and so the positions of the electrodes for each voltage measurement can be determined in this reference frame. Whilst this frame of reference may not be known, for example relative to an external reference, the common frame of reference is the same for all voltage measurements taken at all the different positions of the respective electrodes. The positions of the electrodes when subsequent voltage measurements made (e.g. when a tool carrying the electrodes is moved to a new position) can then be determined in the common reference frame using the transformation.

[0038] Any other suitable coordinate system and reference frame apparent to the skilled person may be used to define the positions of the electrodes, defined relative to a known reference frame or internally defined for the measured positions, for example with an origin fixed on a selected one of the measured positions or a centre of mass of all measured positions.

[0039] In some examples, the position data may be implicit rather than being expressed by a numerical value in the data set, for example, in terms of an identifier of an electrode that links the voltage measurement made at that electrode, or the current applied at that electrode, with a corresponding position of the electrode, The identifier may be implicit, for example, the place of the electrode in a known sequence of electrodes or measurements (i.e. an index value), and/or the identifier of an electrode may be a pointer to data indicative of the position of that electrode, for example at a given time.

[0040] With reference to the accessed current data, the current data is indicative of the currents applied to the one or more field supplying electrodes when the voltage data was measured. In other words, the currents applied to the one or more field supplying electrodes at the time the voltages were measured are stored in a data set and accessed for computing the values of one or more model parameters. The current data may comprise the magnitude and/or frequency (and/or phase if there is more than one field supplying electrode) of the currents applied to each of the one or more field supplying electrodes at the time the voltage data was measured. The current data may include current values for currents applied to multiple field supplying electrodes (at the same or at different frequencies) at the same point in time. Additionally or alternatively, the current data may include values for currents applied to one or more field supplying electrodes (at the same or at different frequencies) at different points in time, for example where at each separate point in time, the one or more field supplying electrodes and/or one or more field sensing electrodes are disposed at different positions relative to the region.

[0041] In some embodiments, the one or more field supplying electrodes may comprise a plurality field supplying electrodes. In these embodiments, when the voltage measurements were taken, the current applied to each field supplying electrode may have been at a different respective frequency such that each field supplying electrode supplied an electric field at the frequency of the respective applied current. In some embodiments, each of the respective set of field sensing electrodes sensed voltages in response to each of the electric fields supplied at the different frequencies.

[0042] With reference to the first and second sets of model parameter values, the first set of model parameter values may describe structural and dielectric properties of the first portion of the region, and the second set of model parameter values may describe structural and dielectric properties of the second portion of the region. The one or more model parameters may comprise model parameters defining one of a shape, a size, a dimension, and an aspect of shape of the portions of the region, and more generally any structure to be modelled. Additionally or alternatively, the one or more model parameters may comprise model parameters defining one or more of a position and an orientation of a structure. The position and/or orientation of a structure may be defined in a reference frame fixed relative to the body. The position and/or orientation of the structure may be defined relative to the tool. Additionally or alternatively, the one or more model parameters may comprise one or more model parameters defining dielectric properties of a structure. The term 'dielectric properties' used herein may refer to one or more of: conductivity, complex conductivity, real or imaginary part of conductivity, permittivity, complex permittivity, real or imaginary part of permittivity, impedance, complex impedance, and real or imaginary part of impedance. It would be understood that the real and imaginary parts of a complex value of a dielectric property can also be used to determine the magnitude and phase of the dielectric property. The dielectric property may therefore equally refer to the magnitude or phase of a dielectric property of the structure, which, as appreciated by the skilled person, can be derived from the real and imaginary parts of the complex value of the dielectric property.

[0043] In some embodiments, the model parameters may include parameters representing a position of the structure relative to a reference frame. The position parameters may be a single 3-dimensional vector (e.g. with Cartesian or polar position coordinates), or may be three separate parameters, each defining one component (e.g. x, y or z, or radial, azimuthal, or inclination) of the position. Additionally or alternatively, the model parameters may include parameters representing an orientation of the structure in a reference frame. The orientation parameters may be represented as a single three-dimensional vector or as three separate parameters, each defining an angle of rotation (e.g. pitch, yaw and roll relative to respective rotation axes). While reference is made to a three-dimensional position, methods of the present disclosure may equally relate to one- or two-dimensional position. For example, the position of the structure may be defined by one, two, or three spatial coordinates. Similarly, the orientation of the structure may be defined .by one, two, or three angles. The position and/or orientation of the structure may be defined with respect to a reference frame fixed to the body or a reference frame that is independent of the body, such as a reference frame fixed to the tool.

[0044] In some embodiments, the model parameters include parameters representing a shape of the structure. There may be a plurality of shape parameters, each shape parameter corresponding to an aspect of the shape of the model. For example, the shape parameters may include a radius of curvature of a curved portion of the structure, an angle subtended between two lines or planes, parameters of a spline defining a curved edge or surface of the structure, or distances or relative coordinates between defined points on the structure. Shape parameters may also include parameters describing a set of polygons which define the surface of a structure, such as 3D coordinates for the corners of each of the set of polygons. The model parameters may include size or other dimension parameters, for example representing a length, width, depth, thickness, diameter of the structure or aspect of the structure. Model parameters may simultaneously be indicative of two or more structural properties. For example, a radius may be indicative of both a shape and a size of a structure or portion of a structure.

[0045] In some embodiments, the method comprises accessing dielectric data indicative of one or more dielectric properties of one or both of the first and second portions of the region, and fixing the values of one or more corresponding model parameters based on the dielectric data. Accessing the dielectric data may involve accessing the predefined values from a database. In these embodiments, the model parameters representing dielectric properties of either or both of the first and second portions of the region may be fixed based on the dielectric data. For example, the dielectric data may be indicative of the value of conductivity (or other suitable dielectric property) of the first and/or second portion, and so the corresponding model parameter may be fixed at this value. In these embodiments, the dielectric parameters are thus kept constant and are not determined based on the accessed voltage, current, and position data. In some embodiments, the dielectric data may indicate a predefined range for a value of conductivity (or other dielectric property) of the structure or a portion thereof, and so a corresponding model parameter may be constrained to be a value within this predefined range, meaning that the parameter is optimised to be a value within that range.

[0046] It would be understood that setting the parameters to the starting values applies only to the model parameters that have not been set at fixed values (i.e. setting the starting values only applies to those parameters to be optimized). For example, if the dielectric model parameters are fixed based on the accessed dielectric data which is indicative of predefined values of dielectric properties of the structure, then these fixed values are not set as other starting values and are not updated based on the model voltage data and the error between the model voltage data and the measured voltage data. In these examples, any fixed parameters may be used to constrain the model voltage data, by using these fixed values as appropriate in the calculation of the model voltage data. As described above, one or more model parameters to be optimised may be constrained to a predefined range, meaning that the presently disclosed methods are used to determine a value of those model parameters within the respective predefined range. In these embodiments, the starting values of the constrained model parameters may be set at values within the respective predefined range, optionally at the centre point of the respective range.

[0047] In some embodiments, the step of accessing a model comprises accessing a plurality of candidate models defined by respective different sets of one or more model parameters. In these embodiments, determining the first and second sets of values of the model parameters may comprise determining the first and second sets of values for each accessed candidate model. This may comprise carrying out the disclosed method for computing model parameter values for each candidate model for each of the first and second sets of values. This may comprise, for each candidate model, computing predicted voltage values, computing an error signal, and adjusting the one or more model parameter values, and repeating until a stopping criterion is reached.

[0048] In some embodiments, one of the candidate models may be selected in order to determine the first and second spatial distributions. In these embodiments, determining the first and second distributions may comprise selecting one of the plurality of candidate models, determining the first distribution based on the first set of values for the selected candidate model, and determining the second distribution based on the second set of values for the selected candidate model.

[0049] The selected candidate model may be selected based on the respective number of repetitions of: computing predicted voltage values; computing an error signal; and adjusting the one or more model parameter values, that are required before a stopping criterion is reached. Optionally, the candidate model that requires the fewest number of repetitions before the stopping criterion is reached is selected.

[0050] In some embodiments, determining the indication of displacement may comprise determining an indication of displacement between the first and second distributions.

[0051] In some embodiments, combining the first and second spatial distributions may comprise using a correspondence between locations in the first spatial distribution and locations in the second spatial distribution. Combining the first and second spatial distributions may comprise combining, for example averaging, values of the one or more dielectric properties at respective locations in the second spatial distribution with values of the one or more dielectric properties at corresponding respective locations in the first spatial distribution. The method may comprise determining the correspondence between locations in the first spatial distribution and locations in the second spatial distribution using the indication of the displacement.

[0052] Determining the indication of displacement may comprise computing a value indicative of the displacement, and then accessing the computed value. Computing the value indicative of the displacement may comprise computing a cross-correlation between the first and second spatial distributions and determining the indication of displacement between the first and second spatial distributions as the displacement at which the cross-correlation exceeds a comparison value, preferably the displacement for which the cross-correlation has a maximum value. Alternatively or additionally, computing the value indicative of the displacement may comprise accessing first voltage values measured using the first set of field sensing electrodes in response to at least three respective mutually non-parallel electric fields that have been generated in the region from outside the body, accessing second voltage values measured at the second set of field sensing electrodes on the tool at the second location in response to the at least three respective mutually non-parallel electric fields, computing an electric field gradient for each mutually non-parallel electric field using the first voltage and computing the indication of the displacement using the first and second voltage values and the computed electric field gradients.

[0053] Alternatively or additionally, the method may comprise computing the value indicative of the displacement using data collected from electrodes placed in a fixed relationship to the body. For example, the data collected from static electrodes may comprise voltages recorded at the static electrodes in response to currents applied to static electrodes. For example, the static electrodes may be disposed on the body and/or on a tool that has been placed in a stationary position inside the body, preferably inside the region or in the vicinity of the region.

[0054] In some embodiments, the method may comprise determining the respective sets of positions of the first and second sets of electrodes in a reference frame fixed relative to the body and determining the indication of the displacement using the determined sets of positions. In embodiments where the first and second sets of electrodes are different subsets of electrodes disposed on the same stationary tool, it is straightforward to determine the indication of the displacement between the first and second sets of positions. The position of each electrode in each set will be known in a reference frame fixed to the tool (i.e. the position of the electrode on the tool is known). Since the tool is stationary, the indication of displacement can be determined from the known positions of the electrodes on the tool. The following examples may be used in embodiments where the tool is moved to different positions in the body, and the position of the tool is required to determine an indication of displacement. In these embodiments, the sets of positions of the first and second sets of electrodes correspond to first and second positions of the tool respectively. Reference to a “stationary” tool will be understood to mean a tool that is stationary for all practical purposes, for example a tool that moves so slowly that its movement during one sample period is less than the resolution with which its position can be measured, for example less than 10 mm/s, or less than 8 mm/s. The tool may be stationary relative to the measurement frame of reference, or the tool may move within the frame together with the region in which measurements are taken, so that it is stationary relative to the region. In other words, the tool may move as the region moves (for example due to body movements such as breathing).

[0055] Determining the first and second positions of the tool may comprise generating a third and fourth (global) spatial distributions of one or more dielectric properties in a body part comprising the region when the tool is respectively at the first and second sets of positions. Each of the global spatial distributions may be generated by a method as described above, but with the electrodes placed in a fixed relationship to the body, for example, fixed to the skin of the patient or worn on a belt or garment, or disposed on a tool that has been placed in a stationary position inside the body, preferably inside the region or in the vicinity of the region.

[0056] Specifically, determining the positions of the tool may comprise analyzing each of the third and fourth spatial distributions to detect one or more electrodes on the tool in each of the third and fourth spatial distribution and determining the respective positions using the positions of the one or more electrodes in the respective spatial distribution. Alternatively or additionally, determining positions of the tool may involve using cross-correlations to determine different positions of the tool . Specifically this may comprise: computing a cross-correlation between the first and third spatial distributions; determining the position of the tool at a first location using the displacement between the first and third spatial distributions at which the cross-correlation exceeds a comparison value, preferably the displacement for which the cross-correlation has a maximum value; computing a cross-correlation between the second and fourth spatial distributions; and determining the position of the tool at a second location using the displacement between the second and fourth spatial distributions at which the cross-correlation exceeds a comparison value, preferably the displacement for which the cross-correlation has a maximum value. In some embodiments, determining the respective positions may comprise: accessing first voltage values measured at the electrodes on the tool at the first location in response to at least three respective mutually non-parallel electric fields that have been generated in the region by a seventh set of electrodes that have been disposed in a fixed relationship with the body; accessing second voltage values measured at the electrodes on the tool at the second location in response to the at least three respective mutually non-parallel electric fields; accessing a voltage to position mapping with the first voltage values to determine a first one of the respective positions; accessing the voltage to position mapping with the second voltage values to determine a second one of the respective positions. The electrodes of the seventh set of electrodes may have been disposed on the body and/or are disposed on a tool that has been placed in a stationary position inside the body, preferably inside the region or in the vicinity of the region.

[0057] In a second aspect, there is provided a method of generating an image, the method comprising generating a spatial distribution of one or more dielectric properties in a region of a body as described above, generating a dielectric map of the one or more dielectric properties based on the spatial distribution, and assigning a tissues type, colour or greyscale value to one or more locations in the dielectric map based on the value of the one or more dielectric properties at the one or more locations.

[0058] In a third aspect, a system from generating a dielectric map is disclosed. The system comprises a processor configured to implement a method as described above and a memory for storing the measurements, the sets of model parameter values and data indicative of the first and second distributions.. Where applicable, the memory may further be configured to store an image as generated using the method described in the second aspect. The system may also comprise a display for displaying the image. In some cases, the system may a plurality of electrodes disposed on one or more tools, an electric field generator configured to apply currents to the electrodes, and an electric field receiver configured to receive voltages measured at the electrodes.

[0059] In a fourth aspect, there is provided a non-transitory computer readable medium carrying instructions that, when executed by one or more processors, cause the processors to carry out any one or more of the disclosed methods.

[0060] The methods described above are specifically independent of how and when the voltage measurements were acquired, In some cases, the step of accessing voltage measurements for each of the first and second sets of field sensing electrodes as described above, may comprise defining the respective set of field sensing electrodes on the tool, defining a set of field supplying electrodes, generating an electric field in the region using the set of field supplying electrodes, and measuring a voltage at the set of field sensing electrodes to generate a plurality of data sets. Accessing the voltage measurements may further comprise accessing the plurality of data sets, each data set comprising measured voltage data indicative of voltages measured at the set of field sensing electrodes. Accessing the voltage measurements may further comprise placing a tool in the region.

[0061] Where reference is made herein to a vicinity, and specifically a vicinity of a region, it would be understood that this refers to a volume of space near to or surrounding the region. As such, a tool placed in the vicinity of a region may be placed near to the region, and may be for example less than 5cm away from the region, optionally less than 2.5cm away from the region, preferably less than 1cm away from the region. Thus, measurements made in the vicinity of a region are made using electrodes positioned near to the region for example less than 5cm away from the region, optionally less than 2.5cm away from the region, preferably less than 1cm away from the region, and optionally inside the region (if the region is or is part of a cavity).

[0062] Unless otherwise defined, all technical and/or scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which the present disclosure pertains. Although methods and materials similar or equivalent to those described herein can be used in the practice or testing of embodiments of the present disclosure, exemplary methods and/or materials are described below. In case of conflict, the patent specification, including definitions, will control. In addition, the materials, methods, and examples are illustrative only and are not intended to be necessarily limiting.

[0063] As will be appreciated by one skilled in the art, aspects of the present disclosure may be embodied as a system, method or computer program product. Accordingly, aspects of the present disclosure may take the form of an entirely hardware embodiment, an entirely software embodiment (including firmware, resident software, microcode, etc.) or an embodiment combining software and hardware aspects that may all generally be referred to herein as a “circuit,” “module” or “system” (e.g., a method may be implemented using “computer circuitry”). Furthermore, some embodiments of the present disclosure may take the form of a computer program product embodied in one or more computer readable medium(s) having computer readable program code embodied thereon. Implementation of the method and/or system of some embodiments of the present disclosure can involve performing and/or completing selected tasks manually, automatically, or a combination thereof. Moreover, according to actual instrumentation and equipment of some embodiments of the method and/or system of the present disclosure, several selected tasks could be implemented by hardware, by software or by firmware and/or by a combination thereof, e.g., using an operating system.

[0064] For example, hardware for performing selected tasks according to some embodiments of the present disclosure could be implemented as a chip or a circuit. As software, selected tasks according to some embodiments of the present disclosure could be implemented as a plurality of software instructions being executed by a computer using any suitable operating system. In some embodiments of the present disclosure, one or more tasks performed in method and/or by system are performed by a data processor (also referred to herein as a “digital processor”, in reference to data processors which operate using groups of digital bits), such as a computing platform for executing a plurality of instructions. Optionally, the data processor includes a volatile memory for storing instructions and/or data and/or a non-volatile storage, for example, a magnetic hard-disk and/or removable media, for storing instructions and/or data. Optionally, a network connection is provided as well. A display and/or a user input device such as a keyboard or mouse are optionally provided as well. Any of these implementations are referred to herein more generally as instances of computer circuitry.

[0065] Any combination of one or more computer readable medium(s) may be utilized for some embodiments of the present disclosure. The computer readable medium may be a computer readable signal medium or a computer readable storage medium. A computer readable storage medium may be, for example, but not limited to, an electronic, magnetic, optical, electromagnetic, infrared, or semiconductor system, apparatus, or device, or any suitable combination of the foregoing. More specific examples (a non-exhaustive list) of the computer readable storage medium would include the following: an electrical connection having one or more wires, a portable computer diskette, a hard disk, a random access memory (RAM), a read-only memory (ROM), an erasable programmable read-only memory (EPROM or Flash memory), an optical fiber, a portable compact disc read-only memory (CD-ROM), an optical storage device, a magnetic storage device, or any suitable combination of the foregoing. In the context of this document, a computer readable storage medium may be any tangible medium that can contain, or store a program for use by or in connection with an instruction execution system, apparatus, or device.

[0066] A computer readable storage medium may also contain or store information for use by such a program, for example, data structured in the way it is recorded by the computer readable storage medium so that a computer program can access it as, for example, one or more tables, lists, arrays, data trees, and/or another data structure. Herein a computer readable storage medium which records data in a form retrievable as groups of digital bits is also referred to as a digital memory. It should be understood that a computer readable storage medium, in some embodiments, is optionally also used as a computer writable storage medium, in the case of a computer readable storage medium which is not read-only in nature, and/or in a read-only state.

[0067] Herein, a data processor is said to be “configured” to perform data processing actions insofar as it is coupled to a computer readable memory to receive instructions and/or data therefrom, process them, and/or store processing results in the same or another computer readable storage memory. The processing performed (optionally on the data) is specified by the instructions. The act of processing may be referred to additionally or alternatively by one or more other terms; for example: comparing, estimating, determining, calculating, identifying, associating, storing, analyzing, selecting, and/or transforming. For example, in some embodiments, a digital processor receives instructions and data from a digital memory, processes the data according to the instructions, and/or stores processing results in the digital memory. In some embodiments, “providing” processing results comprises one or more of transmitting, storing and/or presenting processing results. Presenting optionally comprises showing on a display, indicating by sound, printing on a printout, or otherwise giving results in a form accessible to human sensory capabilities.

[0068] A computer readable signal medium may include a propagated data signal with computer readable program code embodied therein, for example, in baseband or as part of a carrier wave. Such a propagated signal may take any of a variety of forms, including, but not limited to, electro-magnetic, optical, or any suitable combination thereof. A computer readable signal medium may be any computer readable medium that is not a computer readable storage medium and that can communicate, propagate, or transport a program for use by or in connection with an instruction execution system, apparatus, or device.

[0069] Program code embodied on a computer readable medium and/or data used thereby may be transmitted using any appropriate medium, including but not limited to wireless, wireline, optical fiber cable, RF, etc., or any suitable combination of the foregoing.

[0070] Computer program code for carrying out operations for some embodiments of the present disclosure may be written in any combination of one or more programming languages, including an object oriented programming language such as Java, Smalltalk, C++ or the like and conventional procedural programming languages, such as the “C” programming language or similar programming languages. The program code may execute entirely on the user's computer, partly on the user's computer, as a stand-alone software package, partly on the user's computer and partly on a remote computer or entirely on the remote computer or server. In the latter scenario, the remote computer may be connected to the user's computer through any type of network, including a local area network (LAN) or a wide area network (WAN), or the connection may be made to an external computer (for example, through the Internet using an Internet Service Provider).

[0071] Some embodiments of the present disclosure may be described below with reference to flowchart illustrations and/or block diagrams of methods, apparatus (systems) and computer program products according to embodiments of the present disclosure. It will be understood that each block of the flowchart illustrations and/or block diagrams, and combinations of blocks in the flowchart illustrations and/or block diagrams, can be implemented by computer program instructions. These computer program instructions may be provided to a processor of a general purpose computer, special purpose computer, or other programmable data processing apparatus to produce a machine, such that the instructions, which execute via the processor of the computer or other programmable data processing apparatus, create means for implementing the functions/acts specified in the flowchart and/or block diagram block or blocks.

[0072] These computer program instructions may also be stored in a computer readable medium that can direct a computer, other programmable data processing apparatus, or other devices to function in a particular manner, such that the instructions stored in the computer readable medium produce an article of manufacture including instructions which implement the function/act specified in the flowchart and/or block diagram block or blocks.

[0073] The computer program instructions may also be loaded onto a computer, other programmable data processing apparatus, or other devices to cause a series of operational steps to be performed on the computer, other programmable apparatus or other devices to produce a computer implemented process such that the instructions which execute on the computer or other programmable apparatus provide processes for implementing the functions/acts specified in the flowchart and/or block diagram block or blocks.

BRIEF DESCRIPTION OF THE DRAWINGS

[0074] Specific embodiments of the present disclosure are described below by way of example and with reference to the accompanying drawings in which:

[0075] Fig. 1 schematically depicts deployment of a set of electrodes on and in a body;

[0076] Fig. 2A is a schematic illustration of a catheter useful in the present disclosure;

[0077] Fig. 2B is a diagrammatic presentation of a basket catheter for dielectric mapping;

[0078] Fig. 2C and 2D illustrate a Lasso catheter useful in the present disclosure;

[0079] Fig. 3 schematically depicts an electric field generator/measurer;

[0080] Fig. 4 is a schematic block diagram of a system for dielectric mapping and imaging;

[0081] Fig. 5 is a schematic block diagram of a computer system configured to perform methods of the present disclosure

[0082] Fig. 6 is a flow chart for a method of determining a spatial distribution of one or more dielectric properties in a region of a human or animal body;

[0083] Fig. 6A illustrates the stitching together of a plurality of maps, including combining maps in overlapping areas;

[0084] Fig. 7 is a flow chart for a method of determining the values of one or more model parameters for a model modelling a structure in a body;

[0085] Fig. 8 is a flow chart for a method of computing values of one or more model parameters according to some embodiments of the present disclosure

[0086] Fig. 9 is a flow chart for a method of accessing a measured voltage data according to some embodiments of the present disclosure

[0087] Fig. 10 is a flow chart of a process of computing a map displacement and combining maps using the displacement;

[0088] Fig. 11 is a flow chart of a process of applying a displacement to map defined on a non-uniform mesh;

[0089] Fig. 12 is a flow chart of a process of calculating a displacement using externally applied field gradients; and

[0090] Fig. 13 is a flow chart of a process of calculating a displacement using a dielectric map obtained using static electrodes, for example surface electrodes.

[0091] It will be appreciated that for simplicity and clarity of illustration, elements shown in the figures have not necessarily been drawn to scale. For example, the dimensions of some of the elements may be exaggerated relative to other elements for clarity. Further, where considered appropriate, reference numerals may be repeated among the figures to indicate corresponding or analogous elements.

DETAILED DESCRIPTION

General considerations

[0092] The present disclosure relates to conductivity mapping, for example for dielectric mapping or imaging, e.g., for reconstruction of body tissues and organs. For the sake of simplicity, conductivity or conductance is described below as an example of a mapped quantity in a dielectric map, but it will be appreciated that any other dielectric property, for example as set out above, may be mapped instead and any such quantity can be used in place of conductivity where conductivity is recited in the description that follows. A dielectric map will be understood to represent a spatial distribution of a dielectric property of the mapped region.

[0093] In more detail, the present disclosure relates to obtaining a spatial distribution or dielectric map of one or more dielectric properties in a region of a human or animal body. A first spatial distribution of a first portion of a region and a second spatial distribution of a second portion of a region are obtained. The first and second spatial distributions are combined to provide a spatial distribution of one or more dielectric properties in the region.

[0094] The first and second spatial distributions are obtained by determining the values of model parameters of a model representing structural and dielectric properties of a structure. The model can be used to model any structure in general, but in the disclosed methods the model is used to model each of the first and second portions for the region. A first set of values of the parameters of the model are determined, representing the structural and dielectric properties of the first portion. A second set of values of the model parameters are determined, representing the structural and dielectric properties of the second portion of the region. The first and second spatial distributions are determined based on the first and second sets of values of the model parameters respectively. Details of how the values of the model parameters are obtained for each of the first and second portions are provided below.

[0095] As described above, methods of the present disclosure determine values of parameters of a model. The model in general models structural and dielectric properties of a structure, and the parameters of the model are each defined as representing a specific structural property or a specific dielectric property of structure. Where reference is made to modelling a structure, it would be understood that in the specific disclosed method, the model is user to model a region or different portions of a region. That is, the parameters of the model are evaluated and represent structural and dielectric properties of the modelled region or portion of the region.

[0096] Methods of the present disclosure are advantageous in that the number of parameters to be determined to model a region or portion of a region can be reduced compared to finite element analysis methods, preferably to be fewer than the number of voltage measurements required to evaluate the parameter values. Instead of calculating a dielectric map where the value of the dielectric property must be determined for each element of a finite element model, model parameters are evaluated which represent dielectric properties or structural properties for aportions of a region. For example if the region is or includes a portion of a heart chamber, a single parameter may represent a conductivity on the blood inside the heart, a further parameter may represent a conductivity of the heart wall and a further parameter may represent a conductivity of the tissue outside of the heart wall. The heart wall may be modelled as a surface, such as a planar surface, a portion of a spherical surface or a portion of a cylindrical surface. Parameters related to dimensions of the surface can be used to characterize the model of the heart wall. Thus, the parameters representing geometric properties of the heart wall and the parameters representing the dielectric properties of the heart wall can together be used to determine a spatial distribution of dielectric properties of the heart wall. In the presently disclosed methods, different portions of a region such as a heart wall are modelled separately. That is, different portions are modelled with respective different sets of model parameter values. Spatial distributions of each portion are determined based on the respective sets of the model parameter values for each portion. The spatial distributions for each different portion of the region may then be combined to generate a spatial distribution of dielectric properties for the whole region.

[0097] Thus, in contrast to known methods where each parameter to be found describes only a dielectric value of a single voxel in a dielectric map, which by itself does not convey any useful information regarding a modelled structure, the disclosed methods model a structure using parameters that describe structural properties or dielectric properties of the structure as a whole, wherein the structure is a region or portion of a region in a body. Each model parameter is therefore by itself indicative of a structural property or a dielectric property of the structure, and significant information on the structure may be provided by each parameter. This means that fewer parameters need to be evaluated in order to determine spatial distributions of dielectric properties in a region or portion of a region, compared to known finite analysis methods.

[0098] Furthermore, in some embodiments, the field supplying and the field sensing electrodes are on the same tool positioned inside the body and near the region. These embodiments are particularly advantageous because voltage measurements can be taken using field sensing electrodes that are very close to the field supplying electrodes. This means that the resulting measurements are affected less by long-range noise (e.g. noise as a result of a patient's thorax moving, due to breathing) since the electrodes are in close proximity (e.g. less than 5cm away from one another) and, depending on the specific type of catheter used, they may be in a fixed position relative to one another. With all of the electrodes disposed on a single catheter, the measurements made using the field sensing electrodes are 'local', since they are made as a result of an electric field produced by field supplying electrodes that are close to the field sensing electrodes. This means that the measured voltages are a result of the electric field interacting with tissue local to the electrodes. Therefore, distanced tissues and events have less of an impact on the resulting measurements. Additionally, in certain embodiments the catheter carrying all of the electrodes may be positioned very close to the structure of interest (e.g. the particular part of a heart chamber wall that is to be modelled), and possibly contacting the structure (e.g. contacting the wall). This can also improve the accuracy of measurements by reducing the effect of noise.

[0099] Methods of the present disclosure exploit the advantages described above in order to generate a dielectric map (spatial distribution of dielectric properties) of a region in a body. Distributions are generated for different portions of the region, based on respective local measurements taken near each of those portions. The local measurements for each portion can be taken using a tool configured to move to different positions (corresponding to the different portions) in the region. The distributions for each portion are then combined to produce a larger portion for the whole region.

[00100] While reference is made herein to combining first and second spatial distributions for first and second portions of the region, it would be appreciated that the disclosed methods may apply to any number of a plurality of different portions of a region and any number of corresponding spatial distributions that are combined to produce a spatial distribution of dielectric properties in the region.

[00101] In the following description, numerous specific details are set forth in order to provide a thorough understanding of the disclosure. However, it will be understood by those skilled in the art that the present disclosure may be practiced without these specific details. In other instances, well-known methods, procedures, and components have not been described in detail so as not to obscure the present disclosure. The terms ‘injecting signal’, injecting current’, ‘exciting signal’ and ‘exciting current’ will be all used herein after to describe signals provided to electrodes used in the process of imaging as described below.

[00102] It will be understood that the present disclosure may be embodied in a system, a method, and/or a computer program product. The computer program product may include a computer readable storage medium (or media) having computer readable program instructions thereon for causing a processor to carry out aspects of the present disclosure.

[00103] The flowchart and block diagrams in the Figures illustrate the architecture, functionality, and operation of possible implementations of systems, methods, and computer program products according to the disclosure. In this regard, each block in the flowchart or block diagrams may represent a module, segment, or portion of instructions, which comprises one or more executable instructions for implementing the specified logical function(s). In some alternative implementations, the functions noted in the block may occur out of the order noted in

the figures. For example, two blocks shown in succession may, in fact, be executed substantially concurrently, or the blocks may sometimes be executed in the reverse order, depending upon the functionality involved. It will also be noted that each block of the block diagrams and/or flowchart illustration, and combinations of blocks in the block diagrams and/or flowchart illustration, can be implemented by special purpose hardware-based systems that perform the specified functions or acts or carry out combinations of special purpose hardware and computer instructions.

[00104] In the following detailed description, the terms catheter may refer to any physical carrier of one or more electrodes for insertion of the one or more electrodes into a living body – for example: endoscope, colonoscope, enteral feeding tube, stent, graft, etc. More generally, a tool for insertion into a body may be read in place of “catheter” in what follows. The electrodes on such a catheter or tool may be referred to as intra-body electrodes or in-body electrodes. A catheter or tool may include or may be, for example: a guidewire with electrodes, a micro catheter with electrodes, a sheath with electrodes, a suture thread with electrodes, a spiral catheter with electrodes, a basket catheter with electrodes or a pig tail catheter with electrodes.

[00105] The terms ‘injecting signal’, ‘injecting current’, ‘exciting signal’ and ‘exciting current’ will be all used herein after to describe signals provided to electrodes used in systems and methods described below. Moreover, the term “field supplying electrodes” used herein refers to electrodes at which current is applied or ‘injected’ in order to generate an electric field or fields which interact with the modelled structure. It is therefore considered that the field supplying electrode supplies an electric field. The term “field sensing electrodes” used herein refers to electrodes at which voltages are sensed, the voltages resulting from the electric fields supplied by the field supplying electrodes. It will be appreciated that any given electrode may be a field sensing electrode at one time and a field supplying electrode at another time.

[00106] The following detailed description is made with reference to voltage measurements. However, it should be noted that embodiments of the present disclosure are not limited to voltage measurements and may deploy other measurements, such as current and/or impedance measurements. Impedance measurements may be obtained from voltage and current measurements on the one or more electrodes. Voltage and current measurements may be real-valued or fully complex.

[00107] Reference is now made to Fig. 1, which schematically depicts deployment of a set of electrodes 100 on and in a body. In this example, three pairs of surface electrodes (or surface pads) are shown: 102A/102B, 104A/104B and 106A/106B. The pairs of surface electrodes may be disposed on the body substantially at antipode locations. In some embodiments, a smaller or larger number of surface electrodes may be used, and their number may be even or odd. Additionally, set of electrodes 100 comprises intra-body electrodes 103. In the depicted embodiment, the intra-body electrodes (for example the field sensing electrodes) are disposed on catheter 108. Catheter 108 may be insertable into a patient's body. In some embodiments, the intra-body electrodes may be carried by more than one catheter, for examples, two electrode-carrying catheters may be inserted into the patient's body, and used for generating an image as described below. In some embodiments, surface electrodes may be replaced with stationary intra-body electrodes or omitted altogether. In some embodiments particularly useful for imaging the heart, specifically the left or right atrium, stationary intra-body electrodes may be placed in the coronary sinus, for example on a catheter that is stationary during imaging.

[00108] Surface electrodes 102A/102B, 104A/104B and 106A/106B may be connected to signal source(s) that is/are adapted to inject (or excite) electrical signals in desired strength, frequency and phase.

[00109] Voltages developing on the intra-body electrodes during the excitation may be measured when the intra-body electrodes are actively moved (e.g., by a physician during a medical procedure) around a region of interest (or inside it or along it, etc.) – e.g., around or inside a tissue to be imaged. In some cases, there may be several regions of interest, and the intra-body electrodes may be “dragged” from one to another, back and forth. For example, inside a left atrium there are many structural features that may be of interest, e.g., the openings of the pulmonary veins (which are of high interest for treating atrial fibrillation), the left atrial appendage, the mitral valve, etc. The catheter may be guided to visit all of them (and especially those relevant to an ongoing treatment), and so the image quality at these regions and their vicinity may be improved, as described below.

[00110] Reference is now made also to Fig. 2A, which is a schematic illustration of catheter 208. Catheter 208 may be, in some embodiments, identical or substantially identical to catheter 108 of Fig. 1. Catheter 208 may comprise one or more electrodes (also referred to herein as intra-body electrodes or in-body electrodes), and in the drawn example four electrodes 210, 212, 214, 216. Each of the electrodes may have connection wire 220, 226, 224, 222, respectively, to enable connecting to electrical excitation unit, such as electric field generator/measurer, e.g. as described with respect to Fig. 3 hereinafter. Electrodes 210, 212, 214, 216 may be disposed spaced from each other along the longitudinal axis of catheter 208 by longitudinal distances 211, 213, 215. The longitudinal distances may be, for example, in the range of lower than 1 millimeter or few millimeters and up to 1-2 cm or up to 4-6 cm between the farthest intra-body electrodes. In some embodiments, the electrodes may be arranged in pairs spaced about 2-3 mm apart, with about 8mm between pairs. The electrodes may have a length of 1-2.5mm. In some embodiments, the electrodes may be annular in shape and may be disposed across the catheter with their outer surface substantially flush with the catheter. In some embodiments, these annular electrodes may be dimensioned and spaced as described above. In some embodiments it may be beneficial to

have the electrodes spaced apart by a distance that is in the magnitude of order of the size of the scanned organ, or less.

[00111] Fig. 2B is a diagrammatic presentation of a basket catheter 100C. Basket catheter 100C may have a pigtail catheter portion 120C, with a plurality of electrodes 122C, optionally arranged in pairs, e.g., 3 or 4 electrode pairs. Basket catheter 100C further includes a basket portion 124C. The basket portion may comprise a plurality of strands 126C, for example, 8 strands or more, usually 12 strands or less, e.g., between 8 to 12 strands. Each strand 126C may include a plurality of electrodes 128C, optionally arranged in pairs.

[00112] Basket catheter 100C may further include a proximal catheter portion 130C. In some embodiments, proximal catheter portion is blind, i.e., with no electrodes. In some embodiments, proximal catheter portion 130C may include one or more electrodes, for example, 3 electrodes.

[00113] Basket catheter electrode 100C may, in some arrangements, include a chip 132C. In other arrangements, the electrodes are electrically connected to apparatus outside the body by conductive leads. The chip may receive conductive wires (not shown here) connecting the chip to each electrode of the basket catheter electrode 100C, including the electrodes at the proximal catheter portion, and the catheter portion (128C) and at the pigtail catheter portion (122C).

[00114] Chip 132C may include a D2A device, transforming digital data to analog signals. The D2A may be used to receive digital data through communication line 134C, and transferring them to analog signals, and transmit the analog signals to the electrodes. In some embodiments, the digital data includes a different set of instructions for each of the electrodes (or for different electrode groups), multiplexed so that each channel carries data with instructions to one of the electrodes. The chip may also include a demux, for demultiplexing the multiplexed signals received, and sending each set of instructions only to the electrode to which the instructions are addressed.

[00115] Chip 132C may include an A2D device, transforming analog signals to digital data. For example, to receive measurement results from the electrodes, and digitizing them, to send digitized measurement results through the communication line, for example, to a controller configured to receive the measurement results and analyze them (e.g., control unit 402 and/or controller 404). In some embodiments, some or all of the analysis is done at the chip, and the analysis results are sent via the communication line. Chip 132C may also include a multiplexer, for multiplexing digitized measurement results for sending via a single communication line 134C.

[00116] It should be noted that although chip 132C is disclosed in connection to Fig. 2B, it may be included in any catheter or medical device described herein or otherwise.

[00117] In some specific examples, the tool carrying the field sensing electrodes and the field supplying electrodes may comprise a lasso ® catheter, for example as depicted in figures 2C and 2D. Figure 2C depicts a top-view of a lasso® catheter whilst figure 2D depicts a side view of a lasso® catheter. As can be seen from these drawings, the catheter 150 comprises electrode pairs 152 each comprising two electrodes, wherein the pairs are disposed on a loop portion 154. The electrodes disposed on the loop portion may lie substantially flat in a plane defined by the loop. In other words, in some embodiments the loop portion 154 is considered as a ring of electrodes that lie in a plane. This plane in which the electrodes lie and as defined by the loop is referred to herein as the lasso plane. It will be appreciated that other geometries that define a catheter plane can be used in place of the lasso catheter in these specific examples. A tip electrode 156 is also provided which is disposed at the end of the loop portion as illustrated. In the example depicted in figure 2C, the catheter comprises 8 pairs of electrodes and a tip electrode, and in the example depicted of figure 2D, the catheter comprises 10 pairs of electrodes and a tip electrode. In other examples (not depicted), the catheter may comprise 5 pairs of electrodes (i.e. 10 electrodes and a tip electrode), or any number of pairs up to 10 pairs plus a tip electrode. In examples, the diameter

of the loop may be between 10 and 40 mm, and more specifically may be 12mm, 15mm, 20mm, 25mm, or 35mm. In examples, the spacing between each pair 152 of electrodes is between 4mm and 11mm, and more specifically may be 4mm, 4.5mm, 6mm, 8mm or 11mm. The catheter may comprise a stem portion to which an end of the loop portion (the opposite end to which the tip electrode is disposed) is attached.

[00118] Knowledge of the relative distances between electrodes may be used as part of the methods of the present disclosure. These relative distances may be derived from the position data, indicative of the positions of the electrodes at the time the voltages were measured. Specifically, as would be appreciated by the skilled person, the distance between a field sensing electrode and a field supplying electrode can be used to determine the expected electric field at the field sensing electrode as a result of a current applied at the field supplying electrode. Specifically, the skilled person would understand how to apply the laws of electromagnetics to determine the expected electric field at a given location (the field sensing electrode) relative to an electric field source (the field supplying electrode), based on a current applied to the field supplying electrode. Moreover, the skilled person would understand how to apply the spatial distribution of dielectric properties of the material(s), defined by the model parameters, in between and surrounding the field supplying and field sensing electrodes in order to determine the expected electric field at the field sensing electrode location as a result of the currents applied to the field supplying electrodes.

[00119] Schemes of electrical excitations of field supplying surface or intra-body electrodes (also referred herein as excitation scheme or scheme of excitation) yield voltages measurable on one or more field sensing surface or intra-body field sensing electrodes. The voltage readings (voltages sensed by the field sensing electrodes) may be used to reconstruct a spatial distribution of the electrical conductivity or other dielectric property of tissues/materials through which the electrical signals pass. Schemes of excitation may comprise one or more of: selection of the field

supplying electrode(s) and field sensing electrodes, selection of the frequency of the transmitted signals, selection of the amplitude of each of the transmitted signals, selected duration of the transmission, selection phase differences (or de-phasing) between signals transmitted concurrently from two or more field supplying electrodes at a same frequency, and the like. A particular excitation scheme may involve a plurality of electrodes each supplying an electric field at a respective frequency at the same time. Considering the specific example of the electrode arrangement on the catheter in figure 1, excitation schemes may be used to invoke transmission from, for example, at least one electrode (110) acting as a field supplying electrode and the resulting voltages developing on at least the remaining electrodes (112, 114, 116) may be recorded, thereby providing an indication of the conductivity of the material surrounding the catheter along three respective signal paths. In this specific example, a ground electrode may be positioned on the surface of the body to function as a field sink for the generated electric fields. Alternatively one of the electrodes on the probe (112, 114, 116), other than the field supplying electrode, may function as the ground electrode. Each of the electrodes may have different roles for different frequencies. For example, each electrode (110, 112, 114, 116) may simultaneously function as a field supplying electrode at a different frequency, and the each electrode may function as a field sensing electrode for the frequencies other than the frequency that electrode is transmitting at. In other words, four different frequencies may be transmitted and sensed at the same time using the four electrodes in this specific example. In other words, each of the electrodes supplying a field at a respective frequency may simultaneously function as a field sensing electrode that senses voltages resulting from the electric fields supplied by the remaining electrodes at the other respective frequencies. In some examples, each electrode transmitting at a given frequency may also simultaneously act as a field sensing electrode for that same frequency. In other words, an electrode transmitting at a frequency can also be used to measure a voltage at the same transmitted frequency.

[00120] It would therefore be appreciated that reference to field supplying electrodes and field sensing electrodes refers to the function of an electrode. Thus a reference to a field supplying electrode and a field sensing electrode may actually refer to the same electrode which is functioning as a field supplying electrode at one frequency and is simultaneously also functioning as a field sensing electrode at other frequencies, and optionally at the same frequency. Furthermore, reference to a field supplying electrode and a field sensing electrode may actually refer to the same electrode which is functioning as a field supplying electrode at one point in time and is functioning as a field sensing electrode at another point in time, optionally at the same or at a different frequency. It will be appreciated that excitation schemes may vary in terms of the placement and identity of electrodes used. In some embodiments, both surface and intra-body electrodes are used. In some embodiments, the intra-body electrodes are disposed on a moveable catheter or tool, which is moved from one position to the next to acquire respective sets of data.

[00121] Transmitted signals may be transmitted from one or more of the field supplying electrodes, and voltages developing on one or more of the field sensing electrodes during the excitation may be received and recorded for further processing, e.g., for determining model parameters. The further processing may occur on-line, i.e. in real time as the voltages are recorded, or may occur off-line, i.e. at a later time (not in real time, e.g., when the electrodes are no longer in the body). The voltages may be indicative of the conductivity or other dielectric property of the material (e.g. body tissue or surgical implement that is a separate implement to a tool or tools carrying the electrodes) through which the electrical signals have passed. Since the conductivity along any electrical path of a signal is indicative of the nature of the material along that path, the more different signal paths are sampled (i.e. between different combinations of field supplying and field sensing electrodes), the richer the data is regarding the nature of the material through which the different electrical signals have passed. In other words, sampling a number of signal paths between different ones of the field supplying and field sensing electrodes at different

locations results in voltage data indicative of the spatial distribution of the conductivity (or other dielectric property) of the material through which the electrical signals travel. If the values of conductivity of the material is already known, it is possible to use these values to fix the values of corresponding model parameters that represent dielectric properties of the structure, which can be used as a constraint to obtain information on the spatial distribution of the known dielectric property of the material through which the electrical signals have travelled and thus build a physical picture of the material, by comparing the measured voltages to modelled voltages, wherein the model voltages are calculated based on the structural and dielectric parameters, including those that are fixed . Otherwise, if the values of conductivity of the material are not known, it is possible to determine the values of the parameters representing dielectric properties of the structure together with solving for the other model parameters to obtain information on the spatial distribution of the dielectric property of the material through which the electrical signals have travelled. Specifically, solving for the parameters of the model involves adjusting the values of those parameters in order to reduce a difference between measured voltages and modelled voltages, wherein the modelled voltages are voltages predicted to be measured based on the model or the structure (based on the values of the parameters). In some embodiments, values of one or more of the parameters, such as dielectric properties or dimensions of the structure are not known, but are expected to be within a known range. The calculations can be constrained to find values of the parameters within these ranges that minimize the difference between calculated and measured voltages. In other words, the optimisation process may have constraints imposed on it such that the values of these parameters are found within the respective predefined range.

[00122] While reference is made herein to a ‘known’ conductivity, impedance, or other dielectric property of the structure, it would be appreciated that the ‘known’ values may not reflect the exact value of the dielectric property of the structure, but may be a value that has been otherwise predetermined, for example as an estimation or approximation, or an assumption of the

real value. The ‘known’ values of the dielectric properties of the structure that may be used to fix the values of corresponding model parameters therefore refer to predefined values that are not necessarily the exact real values for the structure but may instead be assumed values based on an estimation or knowledge of the material of the structure. Furthermore, instead of accessing ‘known’ predefined dielectric data for the structure, the values of the dielectric properties of the structure may be model parameters to be solved using the disclosed methods in addition or as an alternative to the structural properties of the structure. It would be appreciated that solving for the values of the dielectric properties involves analogous steps to those discussed in relation to solving for the values of the structural properties of the structure.

[00123] The paths along which transmitted signals pass are not known, as the signals do not travel in straight lines, but mainly along paths of minimal resistivity. However, obtaining a number of voltage measurements using different field sensing electrodes as a result of electric fields supplied by different field supplying electrodes provides data indicative of the spatial distribution of dielectric properties of the material in the region of the electrodes. Thus for a structure in the region of the electrodes, it is possible to determine values of model parameters characterising the structural properties and/or the dielectric properties of the whole structure, or of portions of the structure using voltages calculated based on the known currents supplied and starting values for the parameters. The parameter values can then be iteratively updated by comparing the calculated voltages with the measured voltages in order to increase the accuracy of the parameter values to more closely resemble the corresponding real structural and dielectric properties of the structure.

[00124] The methods referred to herein involve computing model parameters of a model of a structure, the parameters defining structural properties and dielectric properties of a structure in a body. In other words, the methods refer to determining the structural and dielectric properties of a structure given the positions of field sources (resulting from injected currents) and the positions

of field (voltage) measurements. An approach to determining the structural and dielectric properties of the structure involves a form of optimization to find parameters for the model that give rise to calculated voltages consistent with measured voltages. For example, a model of the structure may be initialized with parameter starting values that may be based on a starting guess and then optimized to be consistent with measured voltage data.

Exemplary methods for computing and combining spatial distributions

[00125] With reference to Figure 6, a method of determining a spatial distribution of one or more dielectric properties in a region of a human or animal body comprises a step 610 of accessing a model. As described above, the accessed model is defined by model parameters that represent structural and/or dielectric properties of a structure that is modelled by the model. For example, the model may be defined by one or more model parameters representing structural properties, such as a shape, a size, an aspect of a shape or a dimension of the modelled structure. The model may be defined by one or more model parameters representing dielectric properties of the modelled structure. As discussed with reference to steps 620 and 630 below, in this particular method, the model is used to model different portions of a region in a human or animal body. That is, the values of the model parameters are evaluated for different portions of a region of the body.

[00126] The type of model accessed at step 610 may depend on the particular region of the body for which the spatial distribution is to be determined. For example, the region of the body may be an internal wall, such as a wall of a heart chamber, for which different portions of the wall are modelled using the accessed model. In some examples, the model may be a model of a surface, such as a planar surface, a portion of a spherical surface, or a portion of a cylindrical surface. The model may comprise model parameters representing structural properties of the surface (such as a radius in the case of a spherical or cylindrical surface). In other examples, the region of the body

may be a blood vessel, for which different portions of the blood vessel (e.g., different sections along the vessel, or different angular sections about a center line through (or center point in) the vessel) are modelled. Different sections along the blood vessel may be modelled by moving the tool to different positions along the blood vessel and generating local spatial distributions for each of those positions, and then combining the distributions to produce a single spatial distribution for the whole length of the blood vessel. Modelling different angular sections of a blood vessel are described in more detail below with reference to the basket catheter of figure 2B. In these examples, an appropriate model to model the blood vessel may be cylindrical or conical and may include a radius parameter, a parameter representing a dielectric property inside the blood vessel (the dielectric property of the blood) and a parameter representing a dielectric property outside the blood vessel (the tissue outside of the blood vessel). In some embodiments, dielectric properties of the tissue forming the blood vessel may also be modelled. Different portions of the blood vessel are modelled separately (the different portions have different respective sets of model parameters) in order to evaluate the properties of those different portions. For example, a first portion modelled as a cylinder may have a different radius to a second portion. As discussed further below, accessing the model at step 610 may comprise accessing a plurality of candidate models and ultimately selecting one of the models to be used for determining the spatial distribution. The selected model may be the model that produces the most accurate results and provides a best fit to the portion of the region being modelled. Additionally or alternatively, the selected model may be the model that leads to more (or most) quickly-converging results, as described in more detail below.

[00127] The method further comprises a step 620 of determining a first set of values of the parameters of the accessed model. The first set of values is determined based on a first set of voltage measurements taken using a first set of field sensing electrodes positioned at a respective first set of positions in the region of the body. Details of how the parameter values are derived

from the voltage measurements are provided below with reference to Figures 8 and 9. The first set of field sensing electrodes are disposed on a tool, such as a catheter depicted in any of figures 2A – 2D which is positioned in the vicinity of the region. For example, if the region is a heart chamber wall, the tool may be positioned inside the heart chamber. The first set of field sensing electrodes may be a subset of all the electrodes disposed on the tool, which may be predefined. The first set of positions is the set containing the position of each field sensing electrode in the first set of field sensing electrodes at the time the voltage measurements were taken. The positions may be recorded as position data which may be accessed for determining the parameter values as described with reference to Figure 7.

[00128] The method further comprises a step 630 of determining a second set of values of the parameters of the accessed model. The second set of values is determined based on a second set of voltage measurements taken using a second set of field sensing electrodes positioned at a respective second set of positions in the region of the body. The second set of positions is different to the first set of positions and therefore corresponds to a different portion of the region.

[00129] In some embodiments, the first and second sets of positions be may defined by the position of the tool in the region. For example, the tool may be a moving tool that moves to different positions in the region and takes voltage measurements (using the field sensing electrodes on the tool) at the different positions. The different voltage measurements are then used to determine respective different sets of the model parameters. The different sets of model parameters correspond to the respective different portions of the region at which the corresponding measurements were made, and are used to determine spatial distributions of dielectric properties for those portions. In these examples, the first set of positions may correspond to a first position of the tool in the region (positioned in the vicinity of a first portion of the region) and the second set of positions may correspond to a second position of the tool in the region (positioned in the

vicinity of a second portion of the region). The first and second set of field sensing electrodes may be the same set of electrodes disposed on the tool (which may be all of the electrodes or the same subset of electrodes on the tool). Thus, the first and second sets of positions of the field sensing electrodes represent the first and second overall position of the tool.

[00130] Alternatively, in other embodiments, the first and second sets of positions may be defined by the specific subset of electrodes used in the first and second sets of field sensing electrodes. In particular, the first and second sets of electrodes may be different subsets of the electrodes on the tool (but may have one or more common electrodes). In these embodiments, the tool may also move to different positions in the region to determine the different voltage measurements for the different sets of model parameter values as described above. However, alternatively, the tool may instead be stationary in the region when the first and second sets of electrodes each take the respective measurements. For example, a first subset of electrodes on the stationary tool is used to take measurements that are used to determine a first set of model parameter values (as in step 620), and a second subset of electrodes on the stationary tool is used to take measurements that are used to determine a second set of model parameter values (as in step 630). In some examples, the first subset of electrodes may be positioned near a first end of the tool. For example, with reference to the catheter in Figure 2A, the first set of electrodes may consist of electrodes 216, 214 and 212. Thus, the first set of model parameter values represent properties of a first portion of a region near that first end of the catheter (a region in the vicinity of the first set of electrodes). The second subset of electrodes may be positioned near a second end of the tool. For example, the second set of electrodes may consist of electrodes 210, 212 and 214. Thus, the second set of model parameter values represent model parameter values represent properties of a second portion of a region near that second end of the catheter (in the vicinity of the second set of electrodes).

[00131] In other examples, with reference to the catheter in Figure 2B, the first set of electrodes may be the electrodes on a first and second on the plurality of strands 126C, whilst a second set of electrodes may be the electrodes disposed on a second and third of the plurality of strands. In this way, the first and second sets have at least one common electrode (the one or more electrodes disposed on the second strand) and also have at least one unique electrode (i.e. at least one electrode not comprised within the other subset). In embodiments where the region of the body is a heart chamber, the basket portion 124C may be expanded within the heart chamber such that the strands press against the walls of the chamber. The first and second sets of the electrodes can then be used to take measurements for modelling different portions of the heart chamber wall. It would be appreciated that the different portions overlap where the second stand (common to both the first and second set of electrodes) is. It is noted that the pigtail portion 120C may be omitted from the catheter in these embodiments.

[00132] In embodiments where the region of the body is a blood vessel, different angular sections of the blood vessel may be modelled as mentioned above. In more detail, this may involve a basket catheter positioned inside the blood vessel that is expanded such that the strands 126C press against the internal walls of the blood vessel. Different sets of electrodes on different strands (for example, in a similar configuration to that described above) can be used to model different angular sections within the blood vessel. More than two different sets of electrodes (e.g. employing all the strands on the basket portion) can be used to model different angular sections around the whole circumference of the blood vessel. Again, pigtail portion 120C may be omitted from the catheter in these embodiments.

[00133] Once the first set of model parameter values has been determined, a first spatial distribution of one or more dielectric properties is determined at step 640 based on the first set of values. It is noted that step 640 does not rely on step 630 and thus may be performed before, at

the same time, or after step 630. A spatial distribution is constructed from the values of the model parameters and based on knowledge of the structural or dielectric property that each parameter represents. In other words, the spatial distribution is constructed based on the accessed model (i.e. the type of model used and the parameters that define the model) and the values of those parameters that define the model. In particular, evaluated parameters representing structural properties may be combined with evaluated parameters representing dielectric properties in order to determine a spatial distribution. At step 640, the first spatial distribution determined based on the first set of parameter values is a spatial distribution of dielectric properties in the first portion of the region, since the first set of values were based on measurements taken using a first set of electrodes in positions corresponding to the first portion of the region. As described above, the tool may have been positioned in the vicinity of the first portion when the measurements were taken, or the first set of field sensing electrodes comprises a subset of electrodes positioned near the first portion.

[00134] Similar to step 640, step 650 involves determining a second spatial distribution based on the second set of model parameter values determined at step 630. Since step 650 does not rely on step 640, this step may be performed before, at the same time, or after step 640. The second spatial distribution determined based on the second set of parameter values is a spatial distribution of dielectric properties in the second portion of the region, since the second set of values were based on measurements taken using a second set of electrodes in positions corresponding to the second portion of the region. As described above, the tool may have been positioned in the vicinity of the second portion when the measurements were taken, or the second set of field sensing electrodes comprises a subset of electrodes positioned near the second portion.

[00135] At step 660, an indication of displacement between the first and second sets of positions of the electrodes is determined. This may involve determining the displacement between the

position of the tool at the first and second positions corresponding to the first and second regions (in the case of a moving tool). In other words, the displacement may be the displacement between first and second positions of the tool in the region. Additionally or alternatively, determining the indication of displacement may involve determining the displacement between the electrodes of the first set and electrodes of the second set (in the case that different subsets of electrodes on a single tool are used). In the case of a stationary tool in which different subsets of electrodes are used to take measurements for modelling different portions of the region, the indication of displacement may be related only to the electrodes and may be independent of the tool position. The indication of displacement may therefore be determined directly from the positions of the electrodes, which in some embodiments may be known directly from the structure of the tool. In other examples, the tool may be flexible (such as the basket catheter depicted in figure 2B) and the structure of the tool may depend on where the tool is positioned within the body (for example squeezed inside a narrow lumen, or positioned inside a large cavity in which it is free to expand). In these examples, the indication of displacement may depend on the location of the tool since this dictates the structure of the tool and thus the relative positions between different electrodes on the tool.

[00136] Additionally or alternatively, a displacement between the first and second spatial distributions may be determined, which is indicative of a displacement between the first and second sets of positions of the electrodes. The displacement may be computed as a linear translation between the two spatial distributions, for example a displacement vector (or equivalently a diagonal displacement matrix corresponding to the displacement vector), or by a translation and rotation, for example encoded in a displacement matrix with appropriate off-diagonal entries.

[00137] At step 670, the first and second spatial distributions are combined. In more detail, the first spatial distribution of dielectric properties in the first portion of a region is combined with the second spatial distribution of dielectric properties in the second portion of the region, to produce a larger spatial distribution encompassing both the first and second portions of the region. The distributions are combined using the indication of displacement, to ensure that the final combined distribution is continuous and smooth. Combining the first and second distributions may, for example, involve averaging the two distributions together in the region of overlap (optionally rotated as appropriate) between the two distributions, as determined by the computed displacement. Other ways of combining are of course equally possible, for example, picking the values of one distribution in any region of overlap. It will be appreciated that in these examples the order of the steps is not important, as long as the two distributions and the displacement are available for combining at step 670.

[00138] Subsequent to step 670, further distributions, as well as further corresponding displacements may be computed using the methods described above and combined. In some embodiments, a larger number of individual distributions are calculated, as well as corresponding mutual displacements and these are then used to produce combined distributions. The process is thus not limited to merely combining two adjacent distributions (distributions captured at adjacent locations of the catheter) but a number of overlapping distributions can be combined to compute a single distribution. It is worth noting that adjacent distributions that are combined may be overlapping but in examples where more than two distributions are combined, non-adjacent distributions do not necessarily need to overlap. Irrespective of how the combined distributions are derived, the combined distribution may be computed for the respective regions of overlap only or may also include non-overlapping regions. The individual combined distributions may then be stitched together to provide a distribution that covers the structure near more than one tool position and may cover the structure near some or all of the track of the tool through the organ, as illustrated

in Figure 6A. In this particular example, the shaded region indicates a region of increased resolution along the track of the tool, where the combined distribution benefitted from the overlapping data from two or more individual distributions. Similar advantages can be achieved using different subsets of electrodes on a stationary tool. For example, two different subsets of electrodes, each at opposing ends of an elongated catheter may be used to obtain voltage measurements. Distributions corresponding to regions at each end of the catheter are generated using measurements from the subsets, which can be combined to produce a distribution corresponding to a region surrounding the whole catheter. Numerous techniques for combining maps are available to the person skilled in the art, for example from the field of image processing, adapting techniques for the combining and/stitching together of images, for example super resolution techniques, for use with the 3D spatial distributions or maps of the present disclosure.

[00139] Figure 7 depicts a general method of determining the values of one or more model parameters of a model that models a structure. Whilst Figure 7 refers to a structure in general, this method may be applied for determining the first and second sets of model parameter according to steps 620 or 630 of Figure 6 respectively. The method depicted in Figure 7 may be applied for each set of model parameter values determined in steps 620 and 630, with regards to each set of field sensing electrodes at each set of positions respectively. Where reference is made to a structure in general, this may be considered as the first and second portions of the region. The method comprises a step 710 of accessing measured voltage data, wherein the measured voltage data comprises voltage values that, at the time of the measurement, are measured using one or more field sensing electrodes in response to electric fields generated by currents injected at one or more field supplying electrodes. The measured voltage data accessed at step 710 may also be referred to as voltage measurements, for example the voltage measurements that are referred to in the discussion of steps 620 and 630 above. At the time of measurement, the field sensing electrodes (e.g. the first or second sets of field sensing electrodes) (and optionally field supplying electrodes)

are disposed on one or more tools positioned inside the body. The measured voltage data comprises an indication of the specific field sensing electrode at which each of the voltage readings is sensed. For example, the indication may be an index value for the electrode, or may be indicative of the position of the electrode. The measured voltage data may be comprised within a data set that also comprises values indicative of currents applied to the corresponding field supplying electrodes (for example current values, electrode charge values, electric field values at the electrode in question). In other words, data for currents applied at field supplying electrodes and data for resulting voltages measured using field sensing electrodes may be stored in a single data set. Alternatively, the current data may be stored in a separate data set.

[00140] Details of how the measured voltages are obtained are provided below with reference to Figure 9. It will be appreciated that methods of the present disclosure may include a precursor to step 710 of placing surface electrodes on a patient (e.g. field supplying electrodes) and/or inserting the intrabody electrodes into the patient (e.g. field sensing and optionally field supplying electrodes). However, in some embodiments, the method excludes any surgical steps and is limited to receiving or accessing data sets of values indicative of voltage measured using the field sensing electrodes (for example voltage values, impedance values, electric field values) and performing the disclosed data processing on the received data sets to determine parameter values for the model of the structure. For example, the measured voltage and current data may have already been recorded at a previous time and stored in data storage, and the step 710 may involve accessing the data from data storage. In other examples, accessing the data may happen in real time as the voltage measurements are made. In other words, the step of accessing the voltage data may involve receiving the measurements directly from the field sensing electrodes. Alternatively, the electrodes at which the voltages are sensed may send signals to a processor to which the electrodes are connected. The processor may then record a voltage measurement based on the

signal, and the step of accessing the voltage data may involve receiving the measured voltages from the processor.

[00141] As discussed above, the voltages measured using the field sensing electrodes are indicative of the electric field at the position of those electrodes. The electric field at the positions of the field sensing electrodes results from the electric field supplied by the field supplying electrodes that travels through or interacts with dielectric material in the region of the electrodes. It would be understood by the skilled person that the electric field strength at the field sensing electrodes depends on factors such as the distance from the electric field source (the field supplying electrodes) and the dielectric properties of the material that an electric signal passes through. Thus the voltages sensed by the field sensing electrodes depend on the dielectric properties of the material in the region of the electrodes.

[00142] At the time the voltage measurements are taken, the field supplying electrodes are disposed relative to a structure (for example the first or second portion of the region) such that the electric field supplied by the electrodes interacts with the structure. The field sensing electrodes are disposed relative to the structure such that the field sensing electrodes can sense a voltage resulting from the generated electric field interacting with the structure. In other words, the electrodes are positioned near the structure such that the electric field supplied by the field supplying electrodes interacts with the structure which gives rise to the resultant measured voltages. It would be understood that reference to the electrodes being near the structure may depend on the structure in question, and the types of electrodes used. Where reference is made herein to an electric field interacting with a structure. The skilled person with a knowledge of electromagnetism will understand how a structure with given dielectric properties interacts with an electric field to which the structure is subjected. For example, it would be understood that the

conductivity of a structure affects the current that can pass through the structure, and thus affect the resultant voltage that can be sensed by field supplying electrodes.

[00143] The method further comprises a step 720 at which current data is accessed. The current data is indicative of the currents applied to the corresponding field supplying electrodes at the time the voltage data was measured at the field sensing electrodes.

[00144] The method further comprises a step 730 at which position data for the electrodes is accessed. Specifically, the position data indicates the positions of the field supplying and field sensing electrodes at the time the voltage data accessed at step 710 was obtained. For example, if the method of Figure 7 is applied at step 620 of Figure 6, the position data will comprise the first set of positions of the first set of field sensing electrodes. Similarly, if the method of Figure 7 is applied at step 630, the position data will comprise the second set of positions of the second set of field sensing electrodes. In some embodiments, the position data indicates the position of the electrodes relative to a reference frame fixed relative to the body. For example, some of the electrodes may be surface electrodes placed on the body, and their position is defined in a reference frame relative to the body. In some embodiments, some or all of the electrodes are disposed on one or more tools, and the position of each electrode is known relative to the respective tool on which it is disposed. The positions of the one or more tools may be defined with respect to a common reference frame, optionally, fixed relative to the body. In other embodiments, the positions of the electrodes may be defined relative to a reference frame fixed to one of the tools, and the reference frame may be independent of the body. In other embodiments, the positions of the electrodes are defined in a common reference frame that is independent of the tools or the body.

[00145] The method further comprises an optional step 735 at which dielectric data for the structure is accessed (for example dielectric data for either or both of the first or second portions

of the region). Accessing the dielectric data may involve retrieving the data from a database. It is noted that step 735 is depicted in the figure as a dashed box to indicate that this step is optional and by no means essential to the disclosed methods. Specifically, this step may be carried out if dielectric properties of the structure are known or if the dielectric properties can be estimated. Based on the dielectric data, model parameters representing corresponding dielectric properties of the structure may be fixed, that is, set at fixed values. Alternatively, the model parameters representing the dielectric properties of the structure may be determined in addition to the model parameters representing structural properties of the structure. It would be appreciated that accessing dielectric data for certain portions of the structure and fixing parameters representing the dielectric properties of those portions may be performed in addition to determining values of parameters representing dielectric properties for certain other portions of the structure.

[00146] In embodiments where dielectric data is accessed (i.e. step 735 is carried out) the dielectric data indicates values of one or more dielectric properties of the structure, such as conductivity, impedance, resistivity, permittivity or any other dielectric property known to the skilled person, and may include real, imaginary or complex values of that property. The dielectric data may provide dielectric information for different portions of the structure, or may be indicative of a distribution of dielectric properties of the structure. For example, the dielectric data may contain a first value or first set of values corresponding to a first portion of the region, and a second value or second set of values corresponding to the second portion of the region.

[00147] The values of the dielectric properties contained in the dielectric data may be based on knowledge of the material of the structure. If the structure is a portion of the body, such as a blood vessel, the values of the dielectric properties of the material inside (e.g. blood) and outside (e.g. body tissue) may also be known, at least approximately. Optionally, the values of the dielectric

properties contained in the dielectric data may be estimated based on knowledge of the material of the structure.

[00148] In addition to or instead of accessing predefined dielectric data at step 735, other model parameters may be fixed based on predefined knowledge. For example, a shape or size of a structure or portion of a structure may be known (or estimated to sufficient accuracy), and corresponding parameters in the model may be fixed based on this knowledge.

[00149] The method further comprises a step 740 of determining parameter values for the parameters of the model. In more detail, step 740 comprises computing the values of the model parameters for the model of the structure, based on the voltage data accessed at step 710, the current data accessed at step 720, the position data accessed at step 730 and optionally the dielectric data accessed at step 735. The model of the structure is characterised by one or more parameters that define structural properties and dielectric properties of the model, which correspond to structural properties and dielectric properties of the modelled structure. The parameter values determined at step 740 therefore provide information on the structural properties of the actual structure in the body, such as one or more of: the position, orientation, shape, and dimension of the structure in the body, as well as dielectric properties of the structure. With reference to Figure 6, the parameter values determined at step 740 may be the first or second sets of values referred to in steps 620 and 630 respectively. Further details of how the values of the model parameters are determined is provided below with reference to Figure 8.

[00150] With reference to Figure 8, a flowchart of a method of computing the values of the model parameters according to some embodiments is depicted. The method of claim 8 may be applied at steps 620 or 630 for determining the first or second sets of model parameter values. Reference to a structure as used below may also refer to the first or second portions or the region. The method uses accessed voltage data, position data, and current data as described above, and

optionally also uses accessed dielectric data to fix the values of model parameters representing corresponding dielectric properties of the structure. The method comprises a step 810 of setting the model parameter values to starting values. The starting values may be accessed from memory on a computing system or may be inputted by a user. The starting values may be randomly initialized, based on a starting guess or may be based on knowledge of the structure. For example, in some embodiments the structure is a blood vessel and the diameter of the blood vessel is modelled by a model parameter. In these embodiments, the starting value for the diameter parameter may therefore be based on knowledge of a typical diameter size. In some embodiments, position coordinates of the structure may be modelled, either in a reference frame or relative to other position coordinates of the model determined for a different set of voltage measurements (e.g. taken when the one or more tools are in different positions). In these embodiments, the starting values for the position parameters may be set to zero. Alternatively, the position parameter values may be initialized to a set of coordinates based on an approximate location of the structure.

[00151] The starting values for the model parameters representing dielectric properties of the structure (if not fixed using predefined dielectric data) may be based on knowledge of the structure. For example, in some embodiments the structure is a blood vessel and the starting values may be based on knowledge of dielectric properties of blood.

[00152] At step 820, the model voltage data is calculated for each field sensing electrode based on the parameter values determined at step 810. The model voltage data (also referred to as predicted voltage values) represents the voltages expected to be sensed by the field sensing electrodes based on the currents applied at the field supplying electrodes, the position data for the electrodes, and the values of the model parameters. The model voltage values for each field sensing electrode is calculated using physics knowledge apparent to the skilled person, such as Maxwell’s equations or Laplace’s equations. The model voltage data for the voltages expected to

be sensed by each field sensing electrode is calculated given the locations of the field sensing electrodes in a reference frame (or given the locations of the electrodes relative to one another), and is based on current data indicative of currents applied to the field supplying electrodes at known positions. The model voltage data is further based on the model of the structure, specifically the parameters representing the structural and dielectric properties of the structure. In practice, the electric field supplied by the field supplying electrodes will interact with the structure and thus the structural and dielectric properties of the structure may affect the voltages sensed at the field sensing electrodes, and the resulting measured voltages based on the sensed voltages. The effect that the structure has on the measured voltages is therefore reflected in the model voltage data simulating the voltages sensed by the field sensing electrodes, since the model voltage data is calculated based on the structural and dielectric properties of the model.

[00153] At step 830, the error between the model voltage data and the measured voltage data is determined for each field sensing electrode. The error signal is computed as a function of the magnitude of the difference between measured and modelled voltage values. The function may be simple, for example the absolute or squared difference, or may include further terms to guide optimization as is well known in the art of function optimization. Once the error has been calculated, a stopping criterion is checked at step 840. The stopping criterion may be that the error has fallen below a threshold value, or the error is changing by less than a threshold amount compared to previous iterations. The stopping criterion may also be based on a number of iterations of the method, or may be any other suitable stopping criterion apparent to the skilled person.

[00154] If the stopping criterion has not been met, the method proceeds to step 850 at which the parameter values are updated. If there exist two or more parameters, one, some or all of the parameter values may be updated. Any parameters that may have been fixed already, for example

using predefined data, are not be updated. In some embodiments, updating the parameter values involves using an optimisation process to determine new parameter values. The error signal is used to update the model parameter values using gradient descent on a gradient of the error or other well-known optimization techniques (treating the model parameters as the optimization parameters, that is, as parameters with values that are changed to reach the stopping criterion). Specifically, in some examples, the optimization technique may be an Adam optimization technique, otherwise known as an adaptive moment estimation optimization technique. Reference is made to Kingma, D.P. & Ba, J. (2014), 'Adam: A Method for Stochastic Optimization', available at https://arxiv.org/abs/1412.6980, which outlines the method of Adam optimisation. Alternatively, any appropriate optimization technique apparent to the skilled person may be used to determine new parameter values.

[00155] Once the parameter values have been updated, the method circles back to step 820 at which new model voltage data is calculated based on the updated parameter values. The method proceeds to step 830 at which the new error is calculated between the measured voltage data and the new model voltage data, and the stopping criterion is again checked at step 340. This process is repeated and the parameter values are iteratively updated until the stopping criterion has been reached.

[00156] Once the stopping criterion has been met, the method proceeds to step 860 at which the current parameter values (the parameter values set in the last iteration of the process, or the parameter values set at step 820 if there are no iterations) are outputted. If model parameters have been fixed, for example based on predefined dielectric data or other knowledge of the structure, these parameters may not be output since they are already known. Outputting the parameter values may involve storing the values in memory in a computing system, and/or may involve printing the values, for example to a display of a computing system. With reference to the parameter values,

the outputted parameter values represent estimates of the corresponding structural and dielectric properties of the modelled structure and are indicative of that structural or dielectric property. For example, if the diameter of a blood vessel is modelled and the diameter is represented by a parameter, the outputted value of that parameter is an estimate of the actual blood vessel diameter. The error in that estimate may be given by the calculation made at step 830.

[00157] With reference to Figure 6, the outputted parameter values at step 860 of Figure 8 may be the first or second sets of values referred to in steps 620 and 630.

[00158] With reference to any dielectric parameter values, the outputted values represent estimates of the corresponding dielectric properties of the modelled structure. For example, if a blood vessel is modelled and the dielectric properties of the material inside and outside of the blood vessel are modelled, the outputted parameter values are estimates of the respective dielectric properties inside and outside of the blood vessel, with an error given by the calculation made at step 330.

[00159] Reference is now made to Figure 9, which depicts a flowchart describing a method comprising steps for measuring voltages sensed by a set of field sensing electrodes disposed on a tool positioned at a respective set of positions in the region, in response to electric fields supplied by field supplying electrodes. The steps depicted in this flowchart may be performed as a precursor to step 710 of Figure 7 in order to generate the measured voltage data accessed at step 710. The steps may alternatively occur at a separate point in time to obtain the measured voltage data which is then stored, for example in a computer system memory. The measured voltage data may then be accessed at a later time when the method of Figure 7 is carried out.

[00160] The method of Figure 9 comprises defining one or more field supplying and field sensing electrodes at step 910. Specifically, step 910 comprises defining a set of field sensing electrodes disposed on a tool inside a body, and further defining a set of field supplying electrodes.

The set of field supplying electrodes may comprise electrodes inside the body, optionally on the same tool as the set of field sensing electrodes, and/or may comprise electrodes disposed on a surface of the body. This step may optionally also may involve inserting the tool or tools into the relevant portion of the body (where the region to be modelled is), for example into a heart chamber. The step 910 may also involve placing the surface pads on the body, optionally at predetermined locations on the body (if the set of field supplying electrodes includes surface electrodes). For example, surface pads may be placed in specific locations on the body, such as having one electrode placed on the chest just above the heart, one on the back, and two at the two sides of the patient. In some embodiments, a wearable garment with electrodes is worn on the body.

[00161] The positions of each field sensing electrode with respect to the tool on which it is disposed, or with respect to a reference frame may be known. In some embodiments, the reference frame is fixed relative to the tool on which the electrodes are disposed, or may be fixed relative to the body. It should be noted that the reference frame need not be fixed relative to any known entity such as a tool or the body, but may be any reference frame that is common for all of the electrodes. In particular, if measurements are acquired as electrodes are moved to different positions, a common reference frame for all of the electrodes at each respective position can be determined, and the positions of the electrodes are defined in this reference frame. Thus, the positions of each electrode may be known relative to one another. Defining the one or more field supplying and field sensing electrodes comprises assigning each of the electrodes as a field supplying or field sensing electrode. Each electrode is therefore assigned as a field supplying electrode at which currents are injected, or a field sensing electrode at which voltages are sensed. In some embodiments, one or more electrodes may instead be assigned as a ground electrode. The assignment may be based on a specific excitation scheme which defines the magnitude, duration and frequency of current applied at the field supplying electrodes, and further defines which

electrodes are to function as field supplying electrodes and which electrodes are to function as field sensing electrodes (and optionally, which electrodes are to function as ground electrodes). Some or all of the electrodes disposed on the tools may be assigned. It would be appreciated that any given electrode may be assigned as a field supplying electrode for a first frequency and a field sensing electrode for one or more other frequencies, optionally, different from the first. In other words, an electrode may function as both a field supplying and field sensing electrode simultaneously, transmitting (i.e. supplying an electric field) at a first frequency and simultaneously receiving (i.e. sensing an electric field) at all other frequencies, and optionally also at the first frequency. Thus, in a system with multiple electrodes, each electrode may transmit at a unique frequency, which may be sensed by all the other electrodes in the system.

[00162] In a system of multiple electrodes according to some embodiments, a series of different frequencies may be used, each electrode supplying an electric field at one of those frequencies in the series. In some examples, the difference between adjacent frequencies in the series is 800Hz. It would be appreciated that the different between adjacent frequencies must be sufficiently large to avoid cross-talk between the electric fields generated at different frequencies. At the same time, the difference between adjacent frequencies may need to be sufficiently small in order to provide a sufficient number of frequencies in a given frequency band.

[00163] The method further comprises injecting currents and measuring voltages, respectively at steps 420 and 430. Specifically, at step 420, electric fields are generated in the region (where the field sensing electrodes are positioned) by injecting/applying currents to the assigned field supplying electrodes in accordance with the excitation scheme, for example at a given magnitude, frequency, and relative phase. At step 930, the assigned field sensing electrodes sensed voltages resulting from the electric fields excited by the filed supplying electrodes. The voltages sensed by the field sensing electrodes is then recorded as measured voltage data, which, along with the

applied current data are then stored (step 940), for example in a memory of a computing system, for use in the methods described with reference to Figures 6, 7, and 8.

[00164] The steps 920 and 930 may be repeated after one or more of the field sensing electrodes are moved to a new position in the body. For example, the measured voltage data may comprise voltages measured using a one or more field sensing electrodes each at a plurality of different positions at different points in time. Alternatively, instead of moving electrodes within the body, a new set of field sensing electrodes may be defined on the tool inside the body. For example, steps 920 and 930 may be repeated for different subsets of field sensing electrodes on the tool. Each subset of electrodes may be used to record respective voltage measurements which are then used to model different portions of a region in the body (using the methods of Figures 7 and 8, for example). The different portions of the region may be modelled for the purposes of determining spatial distributions of dielectric properties in those portions, as described with reference to Figure 6.

Candidate models

[00165] Reference is made again to step 610 of Figure 6. As described above, a model is accessed, wherein the model is defined by model parameters that represent structural and dielectric properties of a structure that is modelled by the model.

[00166] In some embodiments, step 610 may comprise accessing a plurality of candidate models, each candidate model defined by respective different sets of model parameters. Each candidate model may correspond to a candidate structure, each different candidate structure having different geometric properties. For example, a first candidate model models a structure as a planar surface, a second candidate model models a structure as a cylindrical surface, a third candidate model may model a structure as a spherical surface. Other candidate models may model a structure as different geometric shapes, such as a cylinder, a cone, a truncated cone, and so on.

Therefore, if the general geometric properties of a structure are unknown (what general shape the structure is), then different candidate models such as these can be used to model the structure as different shapes. As discussed below, one of these models may later be selected based on the respective model voltages, which is the most suitable model for modelling the structure.

[00167] In general, for each of the candidate models, computed voltages based on those models can be ‘fit’ to measured voltages (e.g., comparison with measured voltages to determine an error, update the model parameters using an optimization process and repeating). A comparison between the fit of the different models to the measured voltages can give an indication of the suitability of that model for modelling the structure, and hence can give an indication of the geometric properties (i.e. the general shape) and even type of structure being modelled. For example, the magnitude of the error between computed and measured voltages, or the time/number of iterations required to converge on model parameter values that give rise to an error below a threshold, may indicate how suitable any given model is for modelling the structure. Thus, the most suitable model from a plurality of candidate models can be found for accurately modelling the structure, and based on which model is the most suitable model, the type of structure being modelled can be classified.

[00168] More specifically and in reference to the method of Figure 6, determining the first and second sets of values as described with reference to steps 620 and 630 may be carried out for each of the plurality of accessed candidate models. This means that the measurements obtained using the first set of field sensing electrodes are used to determine a first set of values for the sets of parameters of each candidate model. That is, the same measurements are used to evaluate parameters for each candidate. Similarly, the measurements obtained using the second set of field sensing electrodes are used to determine a second set of values for the sets of parameters of each candidate model.

[00169] Based on the first and second sets of values for each candidate model, one of the candidate models may be selected for determining the first and second distributions at steps 640 and step 650. The first and second distributions are then determined based on the first and second sets of values of the selected candidate model respectively.

[00170] As described above, the selected candidate model may be the model that produces the most accurate results (causes the closest fit between measured and model voltages). The selected model may also be the model the causes model voltages to converge on the measured voltages the quickest. That is the candidate model that requires the fewest number of repetitions of steps 820 – 850 before a stopping criterion is reached.

[00171] The use of candidate models is useful in classifying a shape of a structure. For example, a shape of a blood vessel can classified (i.e. whether the blood vessel more closely resembles a cylinder or a truncate cone) by modelling the blood vessel as both a cylinder and a truncated cone and determining which model fits the measured voltages best. Each of the cylinder model and truncated cone models are different types of model defined different respective model parameters. The error signal computed for each model, or the number of iterations required to converge on parameter values which give rise to error signals below a threshold value, may serve as an indication of the suitability of the model for modelling the blood vessel. It may also be the case that one or more types of model do not converge at all, in which case it would be understood that such models are not suitable for modelling the structure. By determining the best fit or by eliminating one or more candidate models if parameter values do not converge, it is possible to determine the most suitable type of model (among the candidates) for modelling the blood vessel, and thus infer the general shape of the blood vessel from that model. In other words, based on which model is most suited to modelling the structure, the type of structure can be classified from

the candidate model structure (in this example whether the blood vessel is cylindrical or frustoconical).

[00172] In another illustrative example, a heart chamber wall may be modelled by a plurality of candidate models, a first being a flat surface, a second being a portion of a cylindrical surface and a third being a portion of a spherical surface. In addition, different candidate models may comprise different features, such as the presence or absence of an opening (i.e. a hole) in the wall. Thus, the disclosed methods can be used to determine whether the wall should be modelled as a flat, cylindrical or spherical surface, and whether there exists an opening in the heart chamber wall. In other words, the wall can be classified as a flat, cylindrical or spherical surface, and can be classified as comprising an opening or not. A practical application of the latter is to determine whether the portion of the heart chamber wall being modelled has such an opening, such as a pulmonary vein ostium.

[00173] Thus, for any given structure in a body, a plurality of different candidate models may be ‘tested’ to see whether those models can be fit to the measured voltages. This allows one to find the most suitable model out of the plurality of candidate models that may lead to the most accurate results for the values of the model parameters. In turn, the structure being modelled can be classified as the candidate model structure of the most suitable model (e.g. blood vessel structure classified as a cylinder or cone, heart wall classified as flat, spherical or cylindrical).

Computing the indication of displacement

[00174] Various techniques for computing a displacement (with or without rotation) between the first and second maps in the above processes are now described. Were the term ‘map’ or ‘dielectric map’ is used throughout, it would be appreciated that this term may equally refer to a spatial distribution of one or more dielectric properties, since a dielectric map represents a spatial

distribution of dielectric properties. It will be understood that these techniques may be useful in their own right to compute displacements between catheter or electrode positions for reasons other than to determine the overlap between maps, in the context of combining maps or otherwise.

[00175] While the methods discussed below refer to different locations of a tool or a catheter, for example first and second locations, it would be appreciated that the methods may equally apply to different sets of electrodes positioned at different respective sets of positions on a stationary tool. The different sets of electrodes are each a subset of all the electrodes on the tool. In other words, in some embodiments the tool itself on which the electrodes disposed does not change position, but the electrodes on the tool are effectively moved, since different sets of electrodes at different positions are used to obtain different spatial distributions corresponding to different portions of a region.

[00176] With reference to Figure 10, a process for computing a displacement matrix (or vector) D comprises computing 1002 the multidimensional cross-correlation between the respective maps (spatial distributions) M1, M2 corresponding to the first and second locations. In the case of a pure displacement or translation, the cross-correlation function would be three-dimensional (one for each direction in Cartesian space, for example), whereas a displacement matrix allowing for some or full rotation to be captured would have up to 9 dimensions to capture the corresponding affine transformation. Subsequently, an indication of displacement between the maps, being the displacement at which the cross-correlation exceeds a comparison value (for example the displacement for which the cross-correlation has a maximum value) can be found. Specifically, a displacement vector or matrix Dmax at which the cross-correlation is at a maximum is found 1004 and Dmax is applied to M1 to displace M1 into alignment with M2 and the result is combined 1006 with M2. Combining M1 and M2 may comprise averaging M1 and M2, or M1 may be used as a starting point for a re-calculation of M2. A bootstrap procedure may be used by which M1 is

used as a starting point for re-calculating M2, then M2 is used as a starting point for M1 and so forth until M1 and M2 converge to a respective value. Using one map as a starting point for calculating another map has been described above. Whilst in this example the displacement vector or matrix Dmax is the displacement at which the cross-correlation is at a maximum value, the displacement vector/matrix may be the displacement at which the cross-correlation exceeds any other threshold, otherwise referred to as a comparison value.

[00177] The above description of combining a displaced version of a first map with a second map in the region of overlap between the first and second maps is applicable in a straight forward manner if the first and second maps are defined on a uniform, common, mesh so that the displacement calculated for the first map is meaningful in terms of the mesh of the second map. However, a non-uniform mesh may also be used. In such cases, or other cases in which the meshes of the two maps differ from each other, the displacement between the first and second positions of the catheter cannot be directly applied to the first map. With reference to Figure 11, a process to deal with this, which may for example be incorporated with steps 670 and 1006, comprises projecting 1102 the first map onto a regular mesh, for example a Cartesian mesh, applying 1104 the displacement to the projected map and projecting 1106 the result to the mesh in which the second map is defined. Alternatively, both maps may be projected onto a common, regular mesh for the purpose of combination.

[00178] Computing correlations as described above, requires the maps to have sufficient structure and/or contrast in their values so that the correlation peak is sufficiently sharp to enable a desired level of confidence in the computed displacement. An alternative method uses three or more pairs of surface electrodes (or other static electrodes such as may be provided on a stationary catheter) to generate electric fields, the gradients of which are used to calculate local displacements as discussed below. The electric fields generated by the pairs of electrodes are mutually non-

parallel, for example mutually orthogonal, to set up a corresponding coordinate system. Equally, the fields (or currents generating them) are separate either in time or in frequency, so that separate field gradient can be calculated for each field and corresponding gradient direction.

[00179] With reference to Figure 12, in some such embodiments, a number of voltage measurements $V_{k,l}$ are taken 1202 using a number of respective spaced apart electrodes on the catheter at respective locations. For these measurements pairs of voltages $V_{k,l}$ and V'_{kl} measured at a corresponding pair of electrodes can be defined. It will be appreciated that in methods that are not carried out online, this step may be replaced with a step of accessing previously measured values in a database. For example, the electrodes may be spaced along a direction of travel of the catheter, as illustrated in Figure 2A, or define a subset of electrodes that are spaced along a direction of travel of the catheter, for example in an arrangement as in Figure 2B. The electrodes (and hence their position along the catheter) are indexed by $l$and the gradient electric field (and hence the corresponding direction) is indexed by k.

[00180] A local voltage gradient g_k is calculated 1204 for each gradient field based on the configuration of (distance between) the l electrodes. Based on the difference between corresponding voltages $V_{k,l}$ and $V'_{k,l}$ recorded at respective catheter positions and the calculated gradients g_k, corresponding local displacements are calculated 1206 in a linear approximation as $d_{k,l} = \frac{V'_{k,l} - V_{k,l}}{g_k}$. A displacement D is then calculated 1208. Depending on the calculation and the placement of the electrodes used, D may be calculated as a diagonal matrix or displacement vector by averaging $d_{k,l}$over l and using the resulting values (or a linear combination thereof) as entries in the diagonal matrix or vector. Alternatively, a full displacement matrix accounting for changes in orientation may be constructed using knowledge of the configuration of the l indexed electrodes and the respective $d_{k,l}$ displacements between them.

[00181] Other alternative techniques for combining local maps generated based on voltage measurements at various positions of a moving catheter, or various sets of electrodes on a stationary catheter, involve locating each respective position of the catheter in a frame of reference fixed with respect to the body and then either to combine the respective maps in that frame of reference or use that frame of reference to calculate displacements between maps, possibly with suitable mesh transformations, as described above. Such alternative techniques may involve computing electrical impedance tomography images or other dielectric maps using time varying electric fields generated by surface or other static electrodes, for example disposed statically inside the body, and locating the catheter in these images, for example by detecting dielectrically salient features or landmarks on the catheter, such as the electrodes disposed on the catheter. Another alternative example is to set up at least three non-parallel electric fields separated in time or in frequency and using a pre-computed mapping from local voltages measured on the catheter to catheter positions to find the required catheter positions.

[00182] Yet a further example that employs surface electrodes, or other electrodes disposed in a fixed relationship with the body, for example disposed on a static catheter disposed in the vicinity of the moving catheter, computes the required displacements between maps using cross-correlations with a static conductance map calculated using fields generated by static electrodes. For example, the static catheter may be disposed in the coronary sinus for imaging the left or right atrium. With reference to Figure 13, a first displacement D1 between the first map M1 and the static map Mstat is computed 1302 using a cross-correlation as described above for cross-correlation between local maps. Likewise, an analogous displacement D2 is calculated 1304 between the second map M2 and the static map Mstat. D1 and D2 are then used to combine 1306 M1 and M2, for example by computing a displacement D between M1 and M2 in the M2 frame of reference or even in the frame of reference of Mstat, fixed relative to the body.

Exemplary systems and devices

[00183] With reference to Figure 3, a signal generator/measurer 300 is depicted that enables two electrodes or two groups of one or more electrodes to be configured to transmit each at a different frequency, and receive (and measure) at both frequencies. Specifically, the signal measurer/generator is connected to the electrodes and is configured to measure and transmit voltages at different frequencies via the electrodes. In this sense, it can be considered that the electrodes are configured to transmit and/or sense voltages at different frequencies at the same time by means of the signal generator/measurer to which the electrodes are connected. In more detail, the signal generator/measurer comprises a signal source 310 configured to provide a first frequency f1. This signal is fed to one or more electrodes 210, such as electrodes disposed on a catheter or on surface pads, via terminal point 350. The signal at frequency f1 reaches another one or more electrodes 212 and is received by it. Similarly, signal source 320 provides signal in frequency f2. This signal is fed to one or more electrodes 212 via terminal point 360 and the signal reaches electrode 210 and is received by it. As a result, junction points 301 and 302 experience a multiplexed signal comprised of frequencies f1 and f2. D is a demultiplexer that is configured to receive, in the current example, multiplexed signal (comprising signals in frequencies f1 and f2) and enable only signal in one of the frequencies to pass through – signal in frequency f1 passes via D 332 and D 344 and signal in frequency f2 passes via D 334 and D 342. Accordingly, voltmeter 312 measures the amplitude of the signal in frequency f1, as originated from signal source 310 and received by electrode 210, and voltmeter 214 measures the amplitude of signal in frequency f2 as originated from signal source 320 and received by electrode 210. The demultiplexing of the signals at section 300B of electric field generator/measurer 300 is done in the same manner. It will be apparent that for exciting more electrodes the sections 300A, 300B of the electric field generator/measurer 300 may be repeated. In some embodiments, other signal demultiplexers may be used, as is known in the art.

[00184] Figure 4 illustrates a schematic of an electric field generating/measuring system 400, such as electric field generating/measuring system depicted at 510 in Figure 5. In some embodiments, the system 400 is part of system 510 and is configured to carry out some of the steps of the methods disclosed herein. For example, the system 400 may be used to carry out the surgical steps of applying currents at the field supplying electrodes and measuring voltages using the field sensing electrodes disposed on one or more tools in or near the modelled structure.

[00185] The system 400 may comprise a main control unit 402 in active communication with a surface electrodes unit 410 (where present) and an intra-body electrodes unit 420 via communication channels 410A and 420A| respectively. The main control unit 402 may comprise a processor 404 and a signal generator/measurer 406, such as the arrangement described below with reference to Figure 10, connectable via an electrodes I/O interface unit 408. The control unit 402 may include a processor that may be, for example, a central processing unit processor (CPU), a chip or any suitable computing or computational device, equipped with an operating system, a memory, an executable code, and a storage (not shown in order to not obscure the drawing). The main control unit 402 may be configured to carry out methods described herein, and/or to execute or act as the various modules, units, etc. More than one computing device may be included in the system, and one or more computing devices may act as the various components of the system.

[00186] The signal generator/measurer 406 is configured to apply currents to surface electrodes 410 or intra-body electrodes 420 acting as field supplying electrodes in accordance with an excitation scheme. The processor 404 may be configured to control the signal generator/measurer 406 to apply a certain current to one or more field supplying electrodes defined by the excitation scheme. The current may be applied at a certain strength and at a certain frequency according to the excitation scheme. The signal generator is further configured to record voltage data for the voltages sensed by the electrodes acting as field sensing electrodes, and the one or more field

sensing electrodes may be defined in accordance with the excitation scheme. The signal generator/measurer 406 may further be configured to cause two electrodes to transmit signals each at a different frequency, and receive (and measure) at this frequency, and at the frequency transmitted by the other electrode. In other words, a first signal may be transmitted by a first electrode, and a second signal transmitted by a second electrode. The first electrode may receive (and measure) the signal transmitted by the second electrode at the second frequency and the second electrode may receive and measure the signal transmitted by the first electrode at the first frequency. A voltage can be measured as the amplitude of each signal received at each electrode. In this manner, each electrode can act as a field supplying electrode at a first frequency and a field sensing electrode at a second frequency.

[00187] Data including the currents applied at the field supplying electrodes and the voltages measured at the field sensing electrodes can then be stored by the processor 404, or sent to a computing device such as the system 500 depicted in Figure 5 for storing in memory 504. The data provided by the electric field generator/measurer 400 can then be used in the methods described below with reference to Figures 6 to 8.

[00188] With reference to Figure 5, a system 500 for carrying out any one or more of the disclosed methods may be a computing device within which are a set of instructions, for causing the computing device to perform any one or more of the methodologies discussed herein. The computing device may be a personal computer (PC), a tablet computer, a cellular telephone, a web appliance, a server, or any machine capable of executing a set of instructions (sequential or otherwise) that specify actions to be taken by that machine. Further, while only a single computing device is illustrated, the term “computing device” shall also be taken to include any collection of machines (e.g., computers) that individually or jointly execute a set (or multiple sets) of

instructions to perform any one or more of the methodologies discussed herein. For example, the apparatus may be configured to carry out any or all of the methods discussed herein.

[00189] The system 500 comprises at least a processor configured to carry out a method according to the present disclosure, for example the method described above with reference to Figures 6 to 8. The system further comprises a memory 504 configured to store information for use in the methods of the present disclosure. For example, the memory 504 is configured to store measured voltages, current data for the currents applied at the field supplying electrodes, as well as position data for the electrodes and optionally dielectric data comprising values of dielectric properties for one or more portions of the modelled structure. Memory 804 is also configured to store values of the model parameters defining the structural properties of the structure and/or values of model parameters defining dielectric properties of the structure. The memory may also be configured to store data indicative of the first and second spatial distributions.

[00190] The system 500 may optionally further comprise a display 506 for displaying the outputted values of the model parameters or for displaying an image of the first and/or second spatial distributions or the combined spatial distribution. The system 500 may also optionally comprise an interface 508 for interfacing with an electric field generating/measuring system 510, such as a system described above with reference to Figure 4. The electric field generating/measuring system 510 is optionally also part of system 500. The system may further comprise a plurality of electrodes disposed on one or more tools (not shown in this figure). The components of the system 500 are able to communicate with one another via a bus 501.

Other considerations

[00191] It is expected that during the life of a patent maturing from this application many relevant intra-body probes will be developed; the scope of the term intra-body probe is intended to include all such new technologies a priori.

[00192] As used herein with reference to quantity or value, the term “about” means “within ±10% of”.

[00193] The terms “comprises”, “comprising”, “includes”, “including”, “having” and their conjugates mean: “including but not limited to”.

[00194] The term “consisting of” means: “including and limited to”.

[00195] The term “consisting essentially of” means that the composition, method or structure may include additional ingredients, steps and/or parts, but only if the additional ingredients, steps and/or parts do not materially alter the basic and novel characteristics of the claimed composition, method or structure.

[00196] As used herein, the singular form “a”, “an” and “the” include plural references unless the context clearly dictates otherwise. For example, the term “a compound” or “at least one compound” may include a plurality of compounds, including mixtures thereof.

[00197] The words “example” and “exemplary” are used herein to mean “serving as an example, instance or illustration”. Any embodiment described as an “example” or “exemplary” is not necessarily to be construed as preferred or advantageous over other embodiments and/or to exclude the incorporation of features from other embodiments.

[00198] The word “optionally” is used herein to mean “is provided in some embodiments and not provided in other embodiments”. Any particular embodiment of the present disclosure may include a plurality of “optional” features except insofar as such features conflict.

[00199] As used herein the term “method” refers to manners, means, techniques and procedures for accomplishing a given task including, but not limited to, those manners, means, techniques and procedures either known to, or readily developed from known manners, means, techniques and procedures by practitioners of the chemical, pharmacological, biological, biochemical and medical arts.

[00200] As used herein, the term “treating” includes abrogating, substantially inhibiting, slowing or reversing the progression of a condition, substantially ameliorating clinical or aesthetical symptoms of a condition or substantially preventing the appearance of clinical or aesthetical symptoms of a condition.

[00201] Throughout this application, embodiments may be presented with reference to a range format. It should be understood that the description in range format is merely for convenience and brevity and should not be construed as an inflexible limitation on the scope of descriptions of the present disclosure. Accordingly, the description of a range should be considered to have specifically disclosed all the possible subranges as well as individual numerical values within that range. For example, description of a range such as “from 1 to 6” should be considered to have specifically disclosed subranges such as “from 1 to 3”, “from 1 to 4”, “from 1 to 5”, “from 2 to 4”, “from 2 to 6”, “from 3 to 6”, etc.; as well as individual numbers within that range, for example, 1, 2, 3, 4, 5, and 6. This applies regardless of the breadth of the range.

[00202] Whenever a numerical range is indicated herein (for example “10–15”, “10 to 15”, or any pair of numbers linked by these another such range indication), it is meant to include any number (fractional or integral) within the indicated range limits, including the range limits, unless the context clearly dictates otherwise. The phrases “range/ranging/ranges between” a first indicate number and a second indicate number and “range/ranging/ranges from” a first indicate number “to”, “up to”, “until” or “through” (or another such range-indicating term) a second indicate number are used herein interchangeably and are meant to include the first and second indicated numbers and all the fractional and integral numbers therebetween.

[00203] Although descriptions of the present disclosure are provided in conjunction with specific embodiments, it is evident that many alternatives, modifications and variations will be apparent to those skilled in the art. Accordingly, it is intended to embrace all such alternatives, modifications and variations that fall within the spirit and broad scope of the appended claims.

[00204] It is appreciated that certain features which are, for clarity, described in the present disclosure in the context of separate embodiments, may also be provided in combination in a single embodiment. Conversely, various features, which are, for brevity, described in the context of a single embodiment, may also be provided separately or in any suitable subcombination or as suitable in any other described embodiment of the present disclosure. Certain features described in the context of various embodiments are not to be considered essential features of those embodiments, unless the embodiment is inoperative without those elements.

Claims

1. A method of determining a spatial distribution of one or more dielectric properties in a region of a human or animal body, the method comprising:

accessing a model defined by one or more model parameters representing structural and dielectric properties of a structure;

determining a first set of values of parameters of the model, wherein the determination of the first set of values is based on a first set of measurements, measured from a first set of field sensing electrodes disposed on a tool and positioned at a respective first set of positions in the region;

determining a second set of values of the parameters of the model, wherein the determination of the second set of values is based on a second set of measurements, measured from a second set of field sensing electrodes disposed on the tool and positioned at a respective second set of positions in the region;

determining a first distribution of one or more dielectric properties in a first portion of the region based on the first set of values and the model;

determining a second distribution of one or more dielectric properties in a second portion of the region based on the second set of values and the model;

determining an indication of displacement between the first and second set of positions; and

combining the first and second spatial distributions using the indication of the displacement.

2. The method of claim 1, wherein determining the first and second sets of values comprises, for each of the sets of values:

accessing voltage measurements made using the respective set of field sensing electrodes disposed on the tool in response to currents applied to one or more field supplying electrodes;

and

computing the parameter values by adjusting the parameter values to fit predicted voltage values to the accessed voltage measurements, wherein the predicted voltage values are predicted from the model for the currents applied to the respective field supplying electrodes.

3. The method of claim 2, wherein the one or more field supplying electrodes are disposed on the tool.

4. The method of claim 2 or 3, wherein computing the parameter values comprises:

accessing current data indicative of the currents applied at the one or more field supplying electrodes when the voltages were measured;

accessing position data indicative of positions of the field supplying and field sensing electrodes at the time the voltages were measured; and

computing the values of the one or more model parameters using the accessed voltage measurements, the current data, and the position data.

5. The method of any preceding claim, wherein the first set of model parameter values describe structural and dielectric properties of the first portion of the region, and wherein the second set of model parameter values describe structural and dielectric properties of the second portion of the region.

6. The method of any preceding claim, wherein the first set of positions of the field sensing electrodes corresponds to the first portion of the region, and wherein the second set of positions corresponds to the second portion of the region.

7. The method of any preceding claim, wherein the one or more model parameters comprise model parameters defining one of: a position, an orientation, a shape, a size, a dimension, and an aspect of shape of the structure.

8. The method of any preceding claim, wherein the first and second sets of values comprise values for one or more model parameters defining dielectric properties of a structure.

9. The method of any preceding claim wherein the one or more dielectric properties are one or more of: conductivity, complex conductivity, real or imaginary part of conductivity, magnitude or phase of conductivity, permittivity, complex permittivity, real or imaginary part of permittivity, magnitude or phase of permittivity, impedance, complex impedance, real or imaginary part of impedance, and amplitude or phase of impedance.

10. The method of claim 4, wherein computing the values of the one or more model parameters comprises accessing starting values for each of the one or more model parameters, setting the one or more model parameter values to the respective starting values and repeatedly:

computing model voltage data modelling the voltages measured at the field sensing electrodes using: the current data, the position data, and the model parameter values;

computing an error signal indicative of an error between the model voltage data and the accessed voltage measurements; and

adjusting the one or more model parameter values using the error signal.

11. The method of claim 10, wherein computing model voltage data, computing an error signal, and adjusting the one or more model parameter values are repeated until a stopping criterion is reached.

12. The method of any preceding claim, wherein the number of parameters for which values are computed is fewer than the number of voltage measurements comprised within the accessed voltage measurements.

13. The method of any preceding claim, further comprising:

accessing dielectric data indicative of one or more dielectric properties of at least one of the first and second portions of the region; and

fixing the values of one or more corresponding model parameters based on the dielectric data.

14. The method of any preceding claim, further comprising:

accessing structural data indicative of one or more structural properties of at least one of the first and second portions of the region; and

fixing the values of one or more corresponding model parameters based on the structural data.

15. The method of claim 2, wherein the one or more field supplying electrodes comprise a plurality field supplying electrodes, and wherein, when the voltage measurements were taken, the current applied to each field supplying electrode was at a different respective frequency such that each field supplying electrode supplied an electric field at the frequency of the respective applied current.

16. The method of claim 15, wherein, when the voltage measurements were taken, each of the respective set of field sensing electrodes sensed voltages in response to each of the electric fields supplied at the different frequencies.

17. Th method of any preceding claim wherein the tool is a catheter, and the catheter was disposed inside the body when the measurements from the first and second sets of field sensing electrodes were taken.

18. The method of any preceding claim, wherein, when the measurements from the first and second sets of field sensing electrodes were taken, the measurements were sampled at a sampling rate of between 300kHz and 500kHz.

19. The method of claim 16, further comprising performing signal processing on the measurements and updating data indicative of the measurements at a rate of at least 100 times a second.

20. The method of claim 2, wherein when the measurements from the first and second sets of field sensing electrodes were taken, applied current measurements indicative of the currents applied to the one or more field supplying electrodes were sampled at a sampling rate of between 300kHz and 500kHz.

21. The method of claim 20, further comprising performing signal processing on the current measurements and updating data indicative of the applied currents at a rate of at least 100 times a second.

22. The method of any preceding claim, wherein the first set of field sensing electrodes consists of a first subset of the electrodes disposed on the tool, and wherein the second set

consists of a second subset of the electrodes disposed on the tool, wherein the first and second subsets each comprise at least one electrode not comprised within the other subset.

23. The method of claim 22, wherein the first and second subsets comprise at least one common electrode.

24. The method of claim 22 or 23, wherein the measurements from the first set of field sensing electrodes and the measurements from the second set of field sensing electrodes were taken when the tool was in the same position in the region.

25. The method of any one or claims 1 to 21, wherein the first set of field sensing electrodes and the second set of field sensing electrodes consist of the same set of electrodes disposed on the tool.

26. The method of any of claims 1 to 23 or claim 25, wherein the measurements from the first set of field sensing electrodes were taken when the tool was positioned at a first location in the region, and wherein the measurements from the second set of field sensing electrodes were taken when the tool positioned at a second location in the region.

27. The method of any preceding claim wherein one or more of the model parameters corresponds to an orientation or a position of a structure in a reference frame fixed relative to the body.

28. The method of any preceding claim wherein one of the one or more model parameters corresponds to an orientation or a position of a structure relative to the tool.

29. The method of any preceding claim, wherein determining the indication of displacement comprises determining an indication of displacement between the first and second distributions.

30. The method of any preceding claim, wherein combining the first and second spatial distributions comprises using correspondence between locations in the first spatial distribution and locations in the second spatial distribution.

31. The method of claim 30, wherein combining the first and second spatial distributions comprises combining values of the one or more dielectric properties at respective locations in the second spatial distribution with values of the one or more dielectric properties at corresponding respective locations in the first spatial distribution.

32. The method of claim 30 or 31, comprising determining the correspondence between locations in the first spatial distribution and locations in the second spatial distribution using the indication of the displacement.

33. The method of any preceding claim, wherein determining an indication of displacement comprises computing a cross-correlation between the first and second spatial distributions and determining the indication of displacement as the displacement at which the cross-correlation exceeds a comparison value, preferably the displacement for which the cross-correlation has a maximum value.

34. The method of any one of claims 1 to 32, wherein determining an indication of displacement is based on measured gradients of electric fields in the region measured using the field sensing electrodes.

35. A method according to any one of claims 1 to 32 comprising determining the indication of the displacement using data collected from electrodes placed in a fixed relationship to the body.

36. The method of claim 35, wherein the data collected from the electrodes placed in a fixed relationship to the body comprise voltages recorded at the electrodes placed in a fixed relationship to the body in response to currents applied to electrodes placed in a fixed relationship to the body.

37. The method of claim 35 or 36, where in the electrodes placed in a fixed relationship to the body are disposed on the body and/or on a second tool that has been placed in a stationary position inside the body, preferably inside the region.

38. The method of any preceding claim, further comprising:

determining the first and second sets of positions of the field sensing electrodes in a reference frame; and

determining the indication of the displacement using the determined sets of positions.

39. The method of claim 38 when dependent on claim 26, wherein determining the first set of positions comprises determining a first position of the tool corresponding to the first location, and wherein determining the second set of positions comprises determining a second position of the tool corresponding to the second location.

40. The method of claim 39, wherein determining the respective positions of the tool comprises:

computing respective global spatial distributions of one or more dielectric properties in a portion of the body including the region when the tool is positioned in the first and second position, wherein the global spatial distributions are defined in a frame of reference fixed to the portion of the body; and

determining the respective sets of positions using the global spatial distributions.

41. The method of claim 40 wherein determining the respective positions of the tool comprises:

analyzing each of the global spatial distributions to detect one or more electrodes on the tool in each of the global spatial distribution and determining the respective sets of positions using the positions of the one or more electrodes in the respective global spatial distribution.

42. The method of claim 40 or 41, wherein determining the respective positions of the tool comprises:

computing cross-correlations between each of the first and second spatial distributions and the respective global spatial distribution;

determining the position of the tool at the respective location using the displacement between the respective one of the first and second spatial distributions and the global spatial distributions at which the cross-correlation exceeds a comparison value, preferably the displacement for which the cross-correlation has a maximum value.

43. The method of any one of claims 39 to 42 wherein determining the respective positions comprises:

accessing voltage values measured at the field sensing electrodes on the tool at the respective sets of positions;

accessing a voltage to position mapping and applying the voltage to position mapping to the respective voltage values to determine the respective positions of the tool.

44. The method of claim 9, wherein adjusting the one or more model parameter values comprises adjusting to reduce a magnitude of the error signal.

45. The method of claim 44 wherein adjusting the one or more model parameter values to reduce a magnitude of the error signal comprises determining new values for the one or more model parameters using an optimisation process and the error signal, and setting the one or more parameter values to the respective new values.

46. The method of claim 45, further comprising computing new model voltage data using the respective new values of the one or more parameter values.

47. The method of claim 45 or 46 wherein the optimisation process is gradient descent process.

48. The method of claim 45 or 46 wherein the optimisation process is an Adam optimisation process.

49. The method of any preceding claim, wherein accessing a model comprises:

accessing a plurality of candidate models defined by respective different sets of one or more model parameters.

50. The method of claim 49, wherein determining the first and second sets of values comprises:

determining the first and second sets of values for each candidate model.

51. The method of claim 50, wherein determining the first and second distributions comprises:

selecting one of the plurality of candidate models;

determining the first distribution based on the first set of values for the selected candidate model; and

determining the second distribution based on the second set of values for the selected candidate model.

52. The method of claim 51 when dependent on claim 10, wherein selecting one of the plurality of candidate models is based on the respective number of repetitions of: computing model voltage data; computing an error signal; and adjusting the one or more model parameter values, according to claim 10, required before the stopping criterion is reached.

53. A method accordingly to claim 52, wherein selecting one of the plurality of candidate models comprises:

selecting the candidate model that requires the fewest number of repetitions before the stopping criterion is reached.

54. A method of generating an image, the method comprising:

determining a spatial distribution of one or more dielectric properties in a region according to any preceding claim and further comprising:

generating a dielectric map of the one or more dielectric properties based on the spatial distribution; and

assigning a tissues type, colour or greyscale value to one or more locations in the dielectric map based on the value of the one or more dielectric properties at the one or more locations.

55. A system for generating a dielectric map, the system comprising:

a processor configured to implement the method of any one of claims 1 to 54; and

a memory for storing the measurements, the sets of model parameter values and data indicative of the first and second distributions.

56. A system for generating an image of a region of an organ of a human or animal body, the system comprising:

a processor configured to implement the method of claim 54;

a memory for storing the measurements, the sets of model parameter values, the first and second distributions, and the image; and

a display for displaying the image.

57. The system of claim 55 or 56, further comprising:

a plurality of electrodes disposed on one or more tools;

an electric field generator configured to apply currents to the electrodes, and

an electric field receiver configured to receive voltages sensed at the electrodes.

58. A non-transitory computer readable medium carrying instructions that, when executed by one or more processors, cause the processors to carry out the method of any one of claims 1 to 53.

59. The method of claim 2, wherein accessing the voltage measurements made using each set of field sensing electrodes comprises:

(a1) defining the set of field sensing electrodes on the tool, defining a set of field supplying electrodes, generating an electric field in the region using the set of field supplying electrodes, and measuring a voltage at the set of field sensing electrodes to generate a plurality of data sets; and

(a2) accessing the plurality of data sets, each data set comprising measured voltage data indicative of voltages measured at the set of field sensing electrodes.

60. The method according to claim 59 further comprising placing the tool inside in the region inside the body.

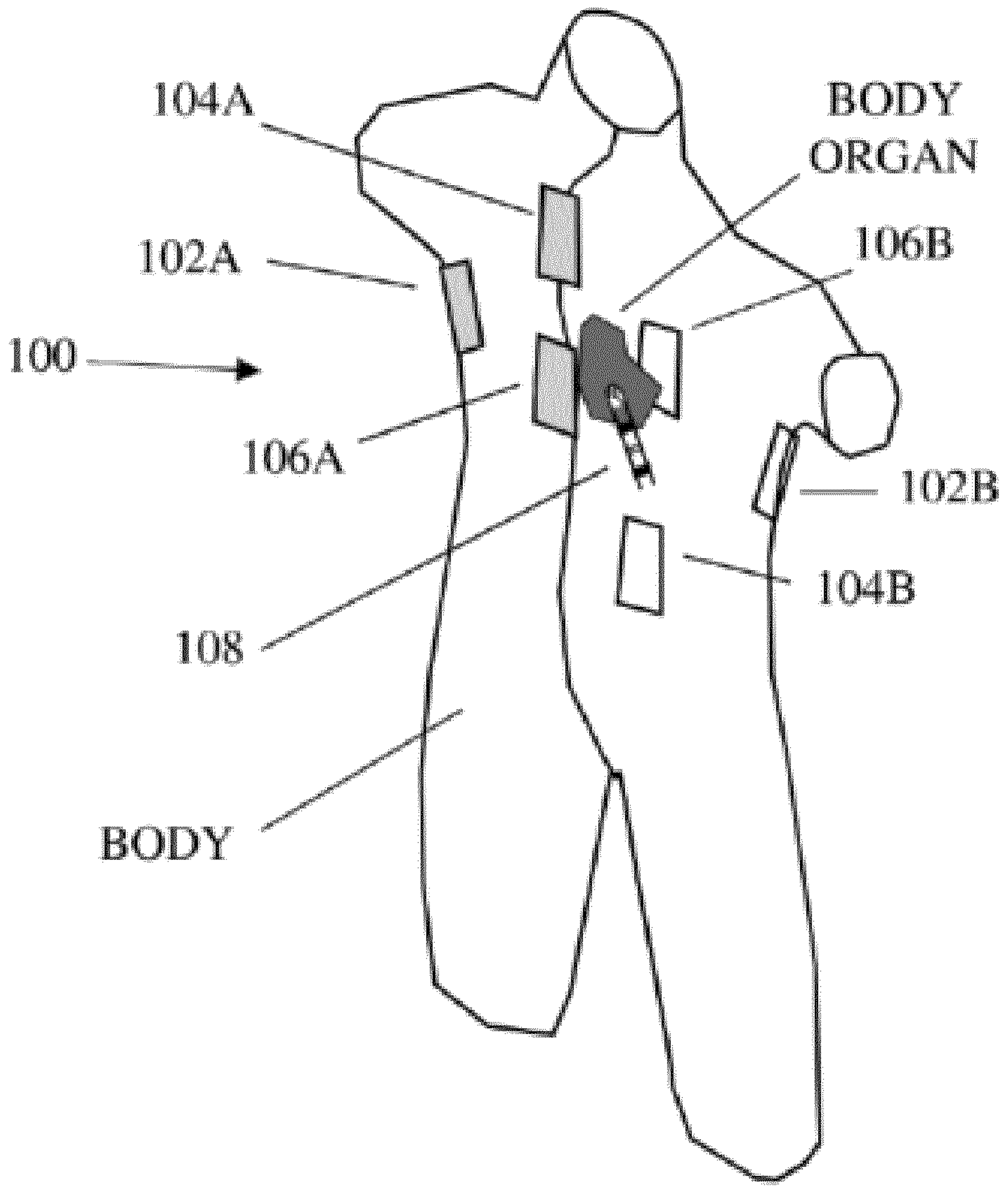

Fig. 1

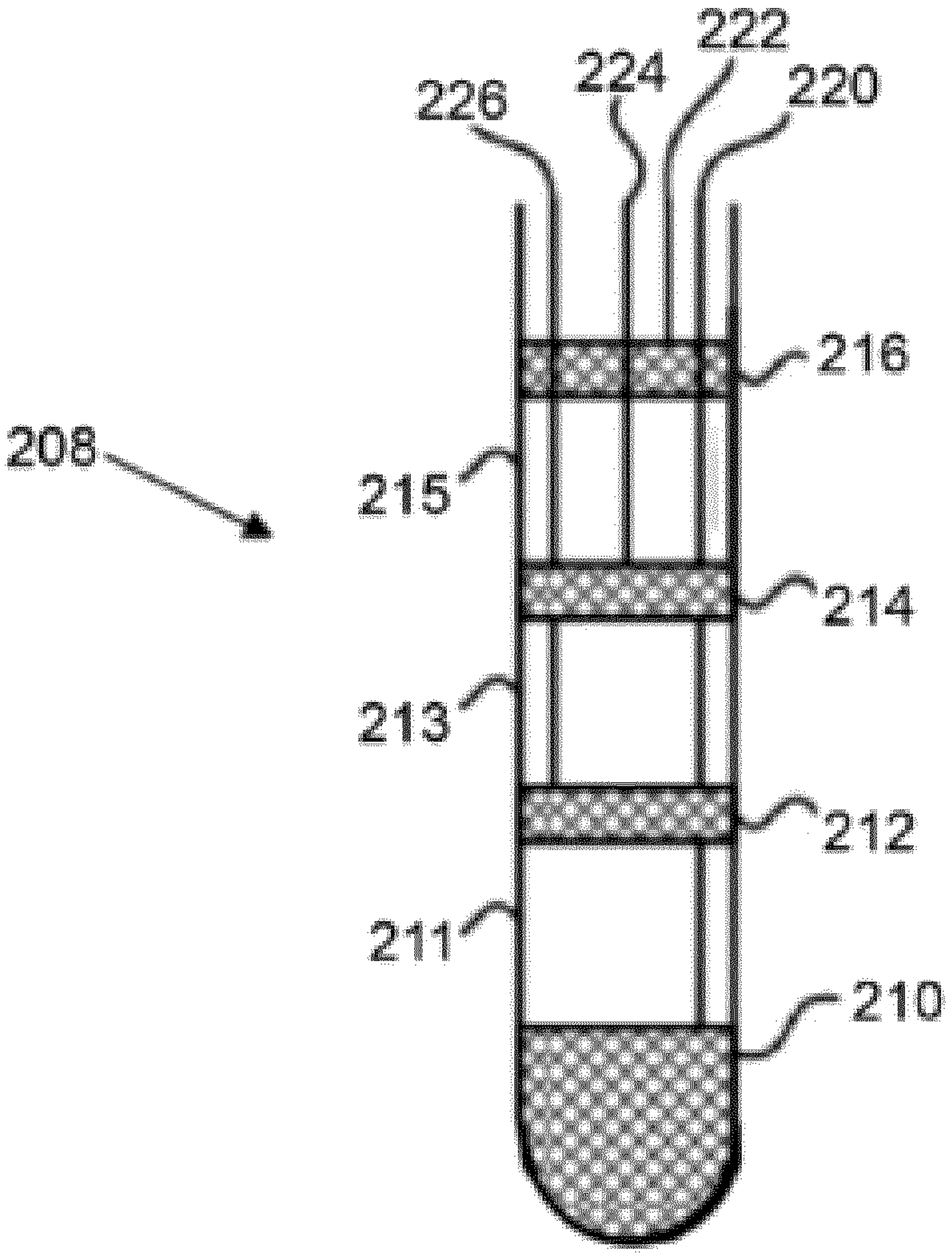

Fig. 2A

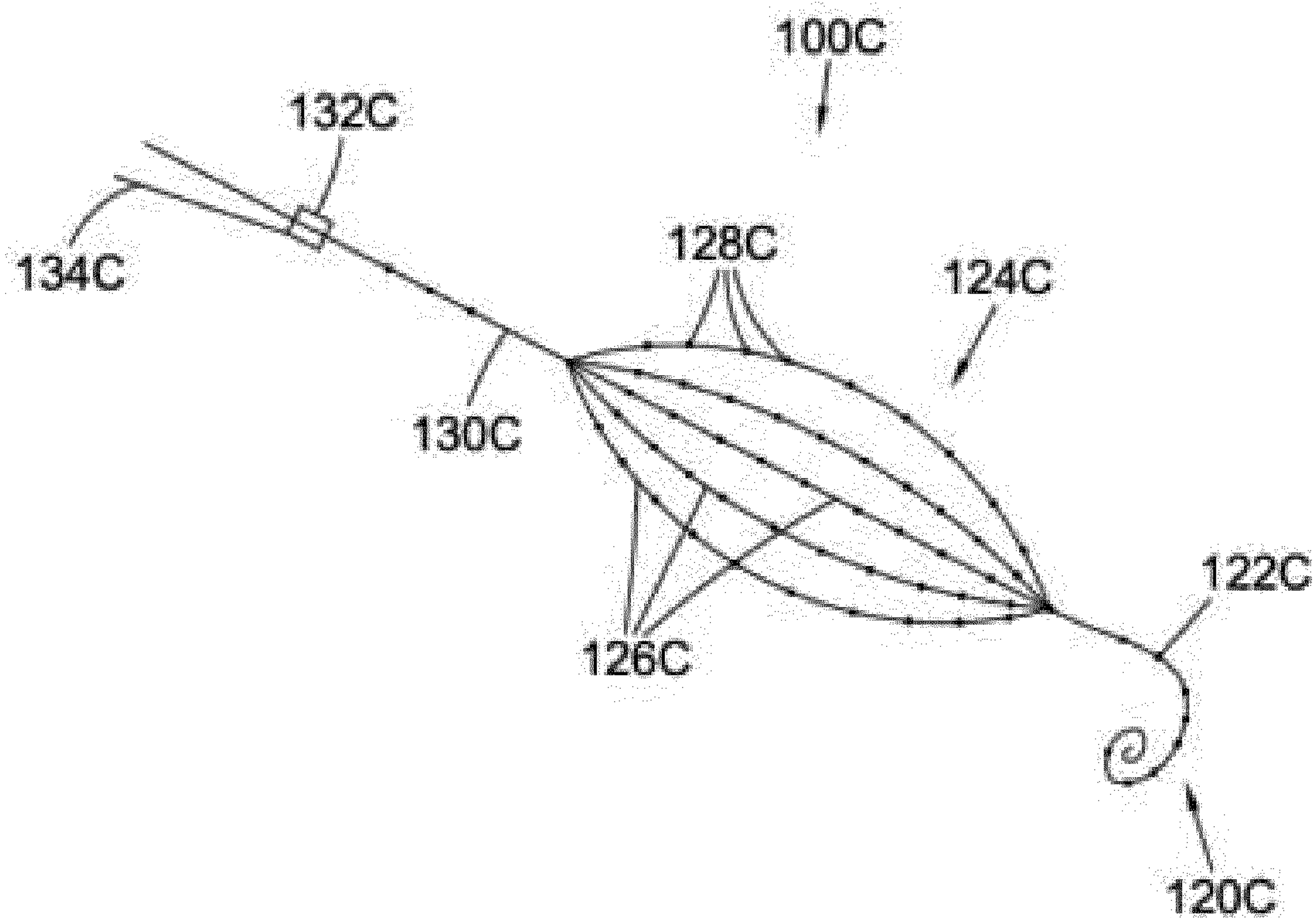

Fig. 2B

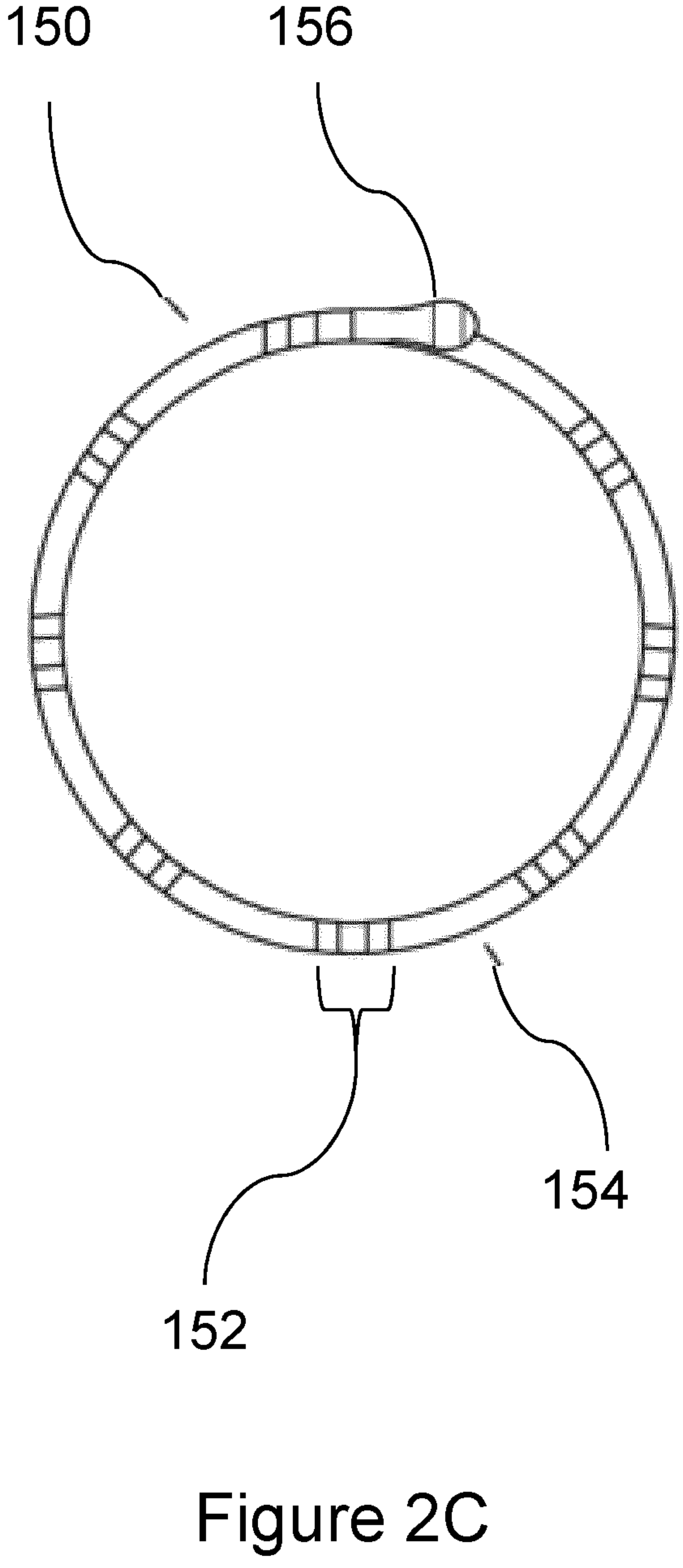

Figure 2C

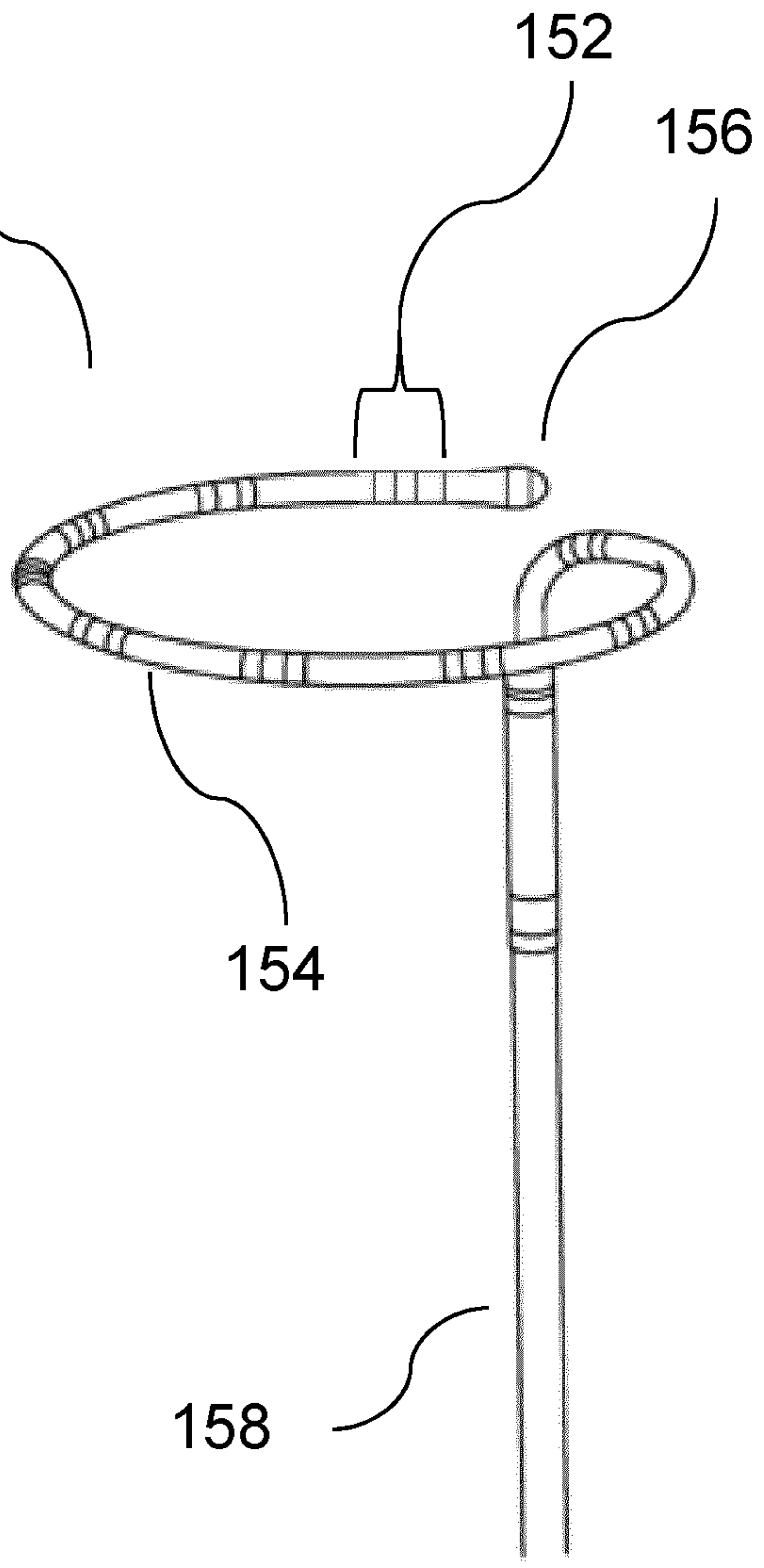

Figure 2D

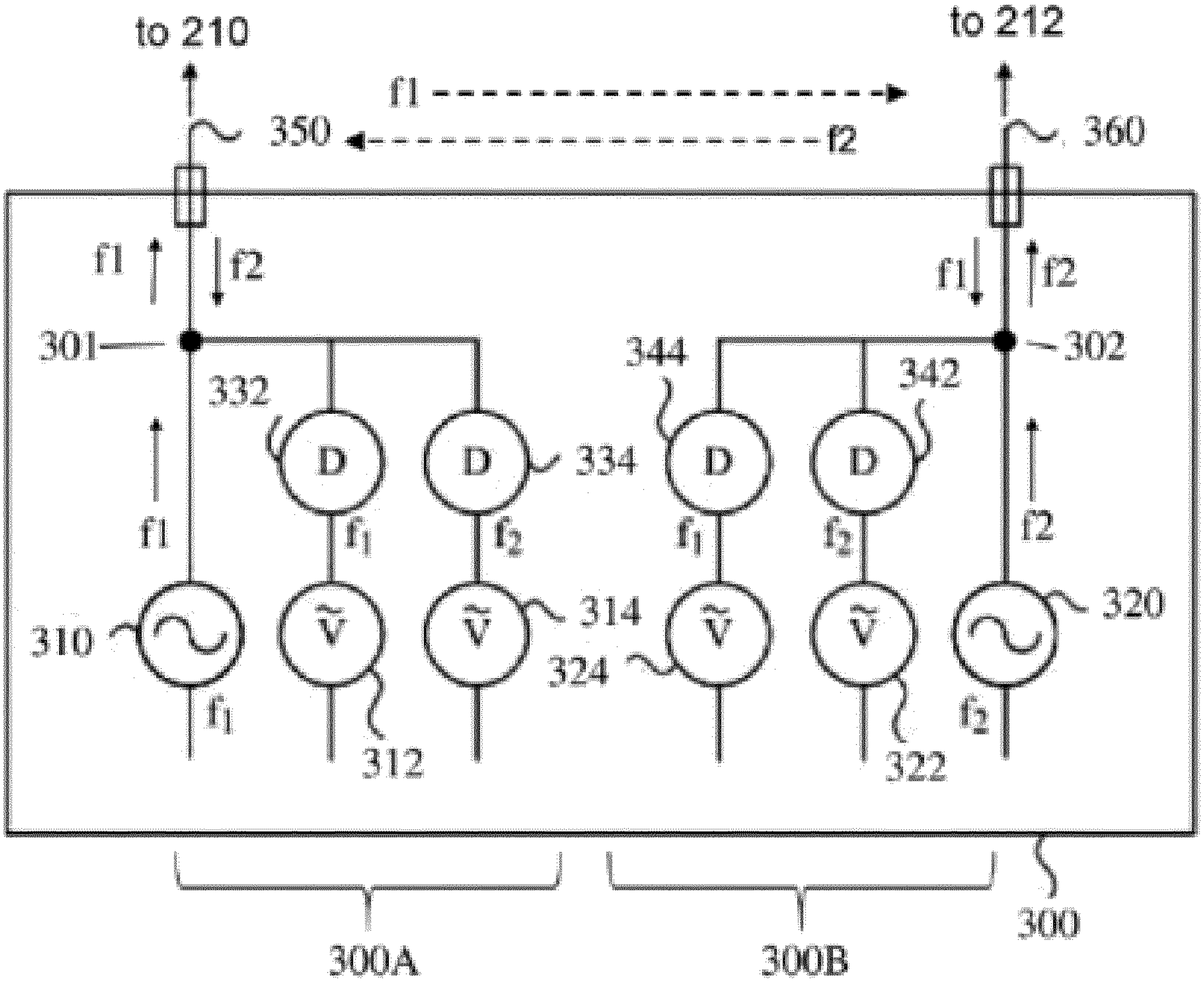
to 210
to 212
f1
f2
350
360
f1
f2
f1
f2
301
302
332
334
344
342
D
D
D
D
f1
f1
f2
f1
f2
f2
310
314
324
320
f1
312
322
f2
300
300A
300B

Fig. 3

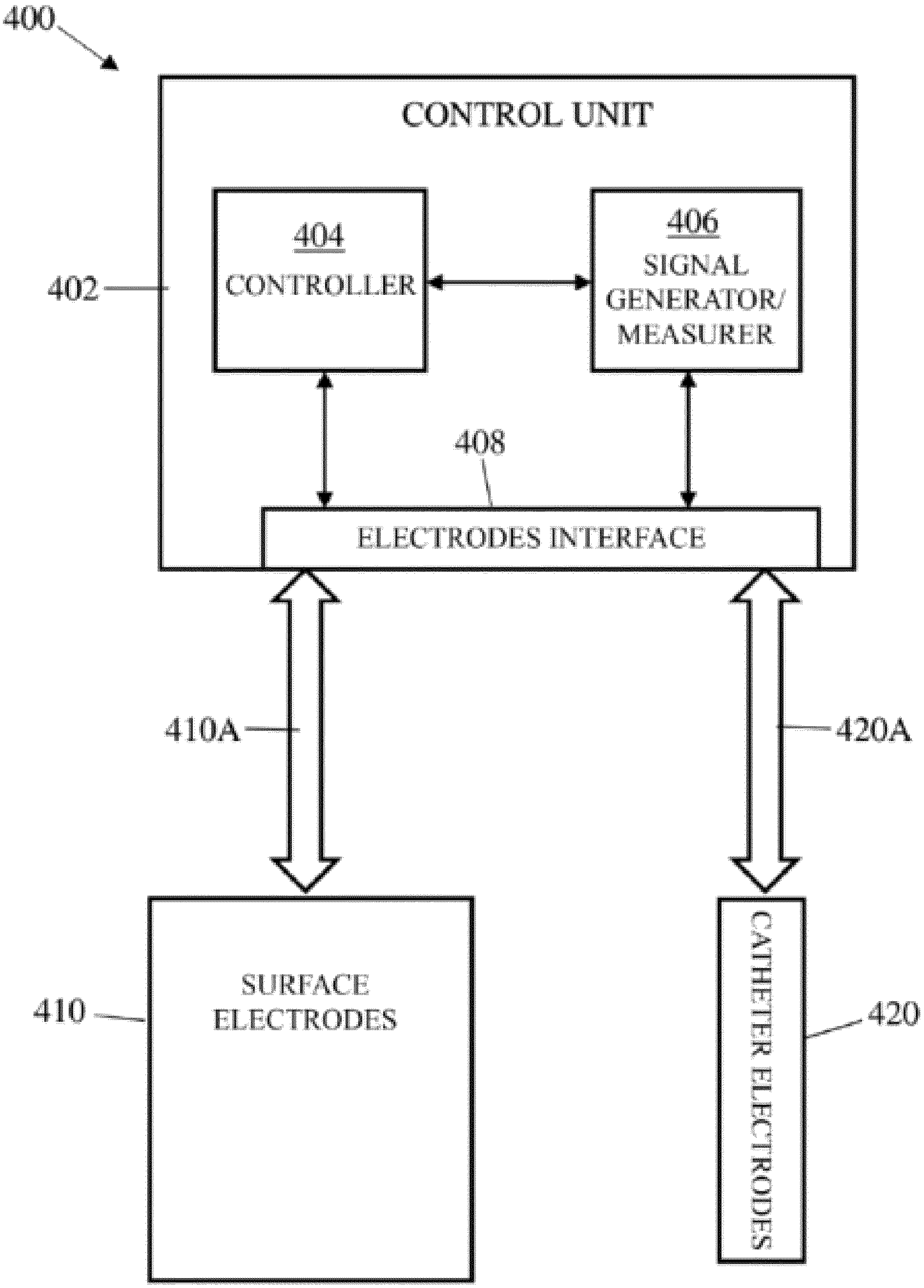
400
CONTROL UNIT
402
404
CONTROLLER
406
SIGNAL GENERATOR/ MEASURER
408
ELECTRODES INTERFACE
410A
420A
410
SURFACE ELECTRODES
420
CATHETER ELECTRODES

Fig. 4

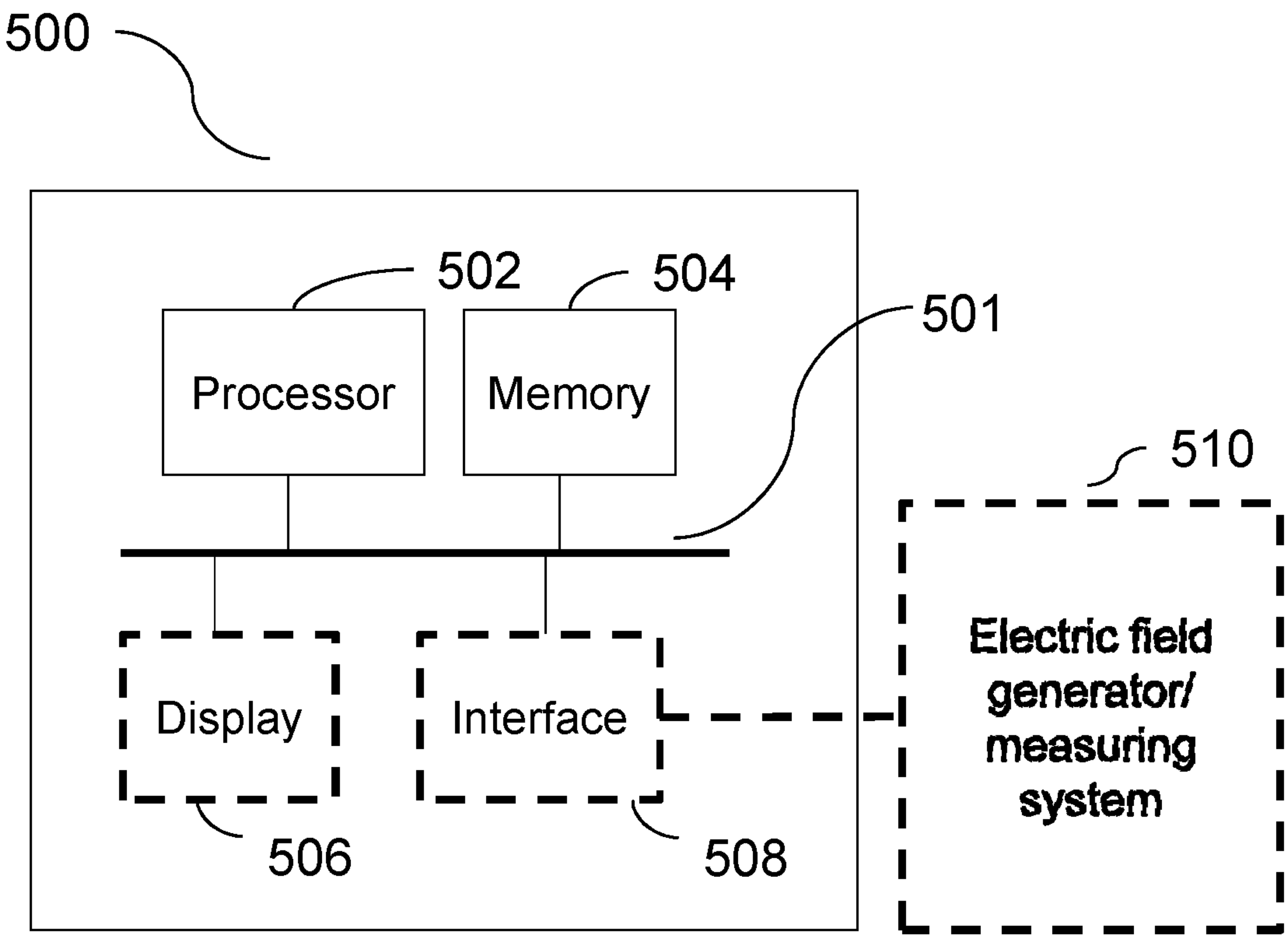
500
502
504
501
Processor
Memory
510
Display
Interface
Electric field generator/ measuring system
506
508

Figure 5

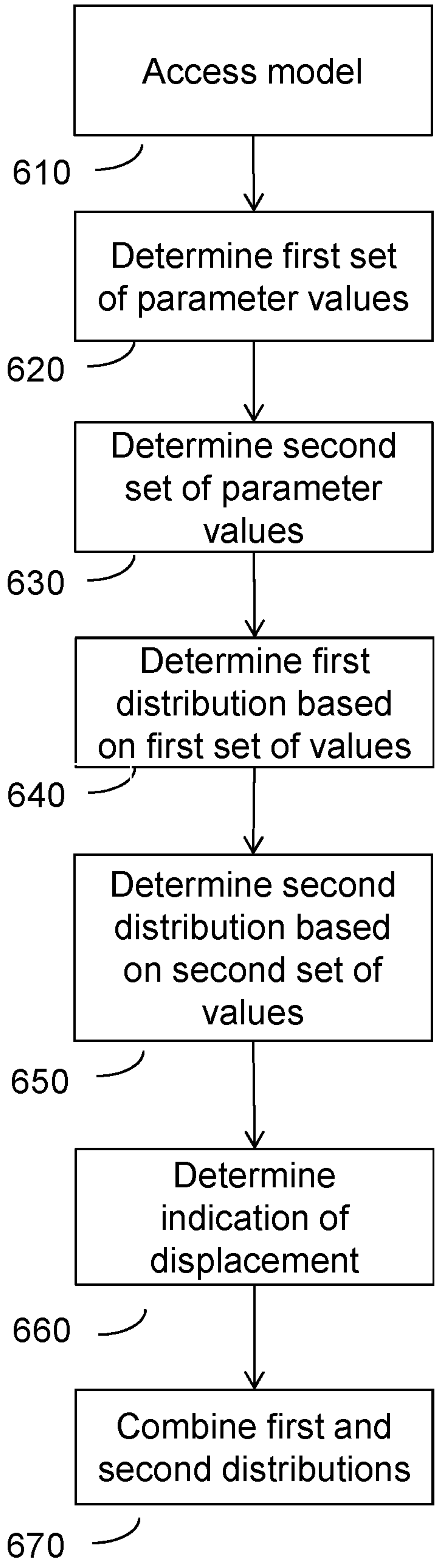
Access model
610
Determine first set of parameter values
620
Determine second set of parameter values
630
Determine first distribution based on first set of values
640
Determine second distribution based on second set of values
650
Determine indication of displacement
660
Combine first and second distributions
670

Figure 6

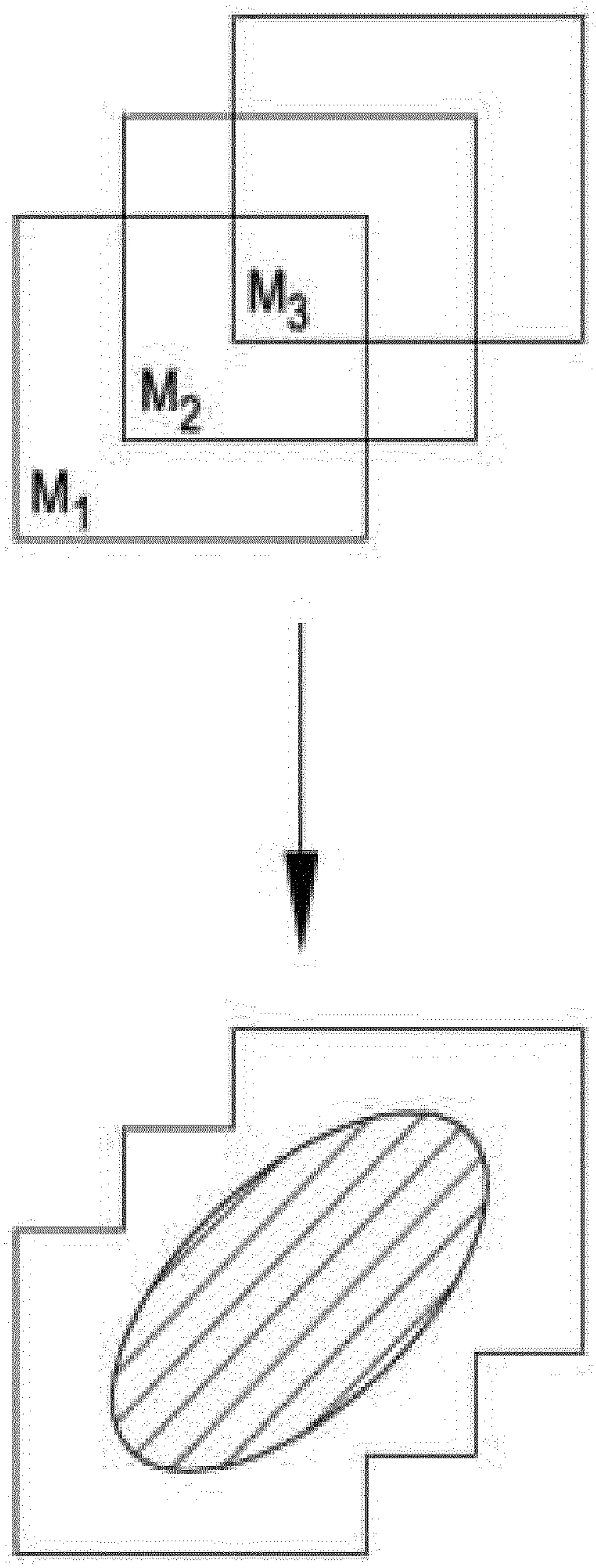

Figure 6A

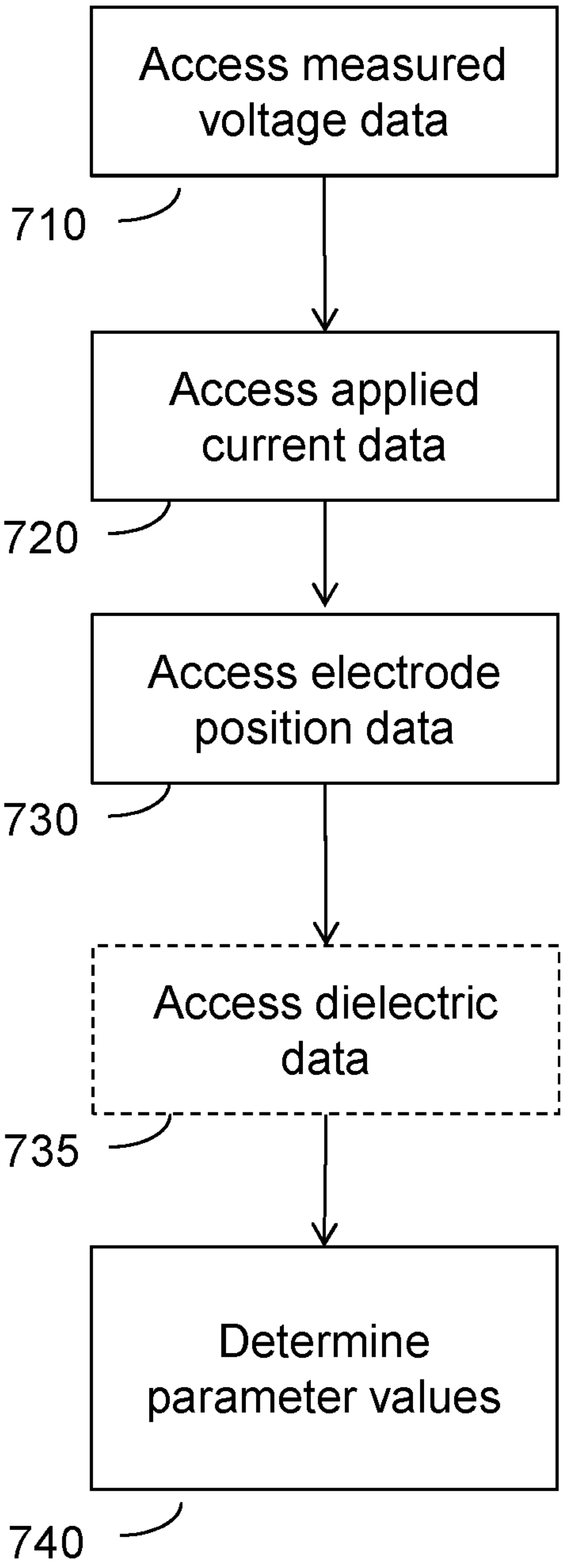
Access measured voltage data
710
Access applied current data
720
Access electrode position data
730
Access dielectric data
735
Determine parameter values
740

Figure 7

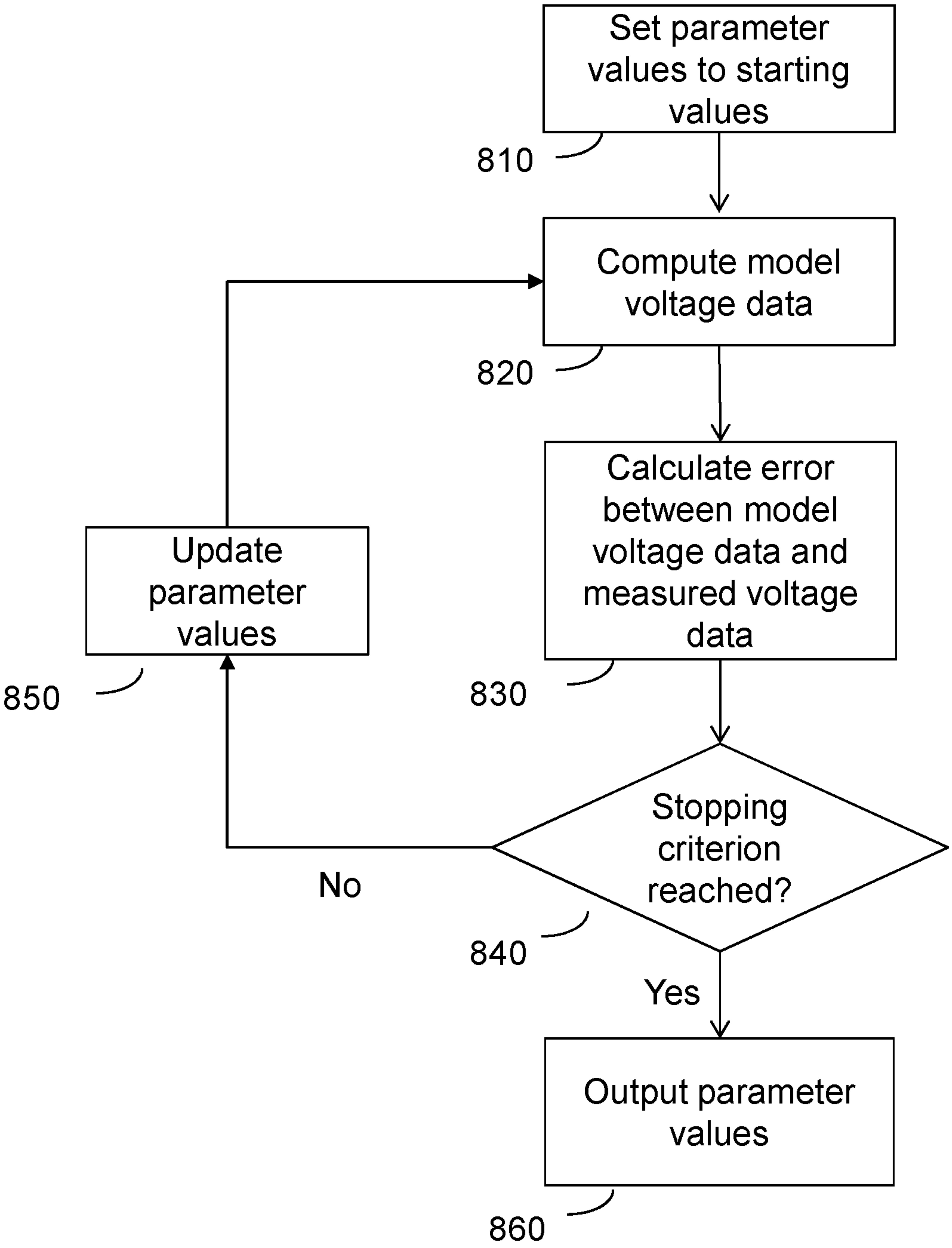
Set parameter values to starting values
810
Compute model voltage data
820
Calculate error between model voltage data and measured voltage data
830
Stopping criterion reached?
840
No
Update parameter values
850
Yes
Output parameter values
860

Figure 8

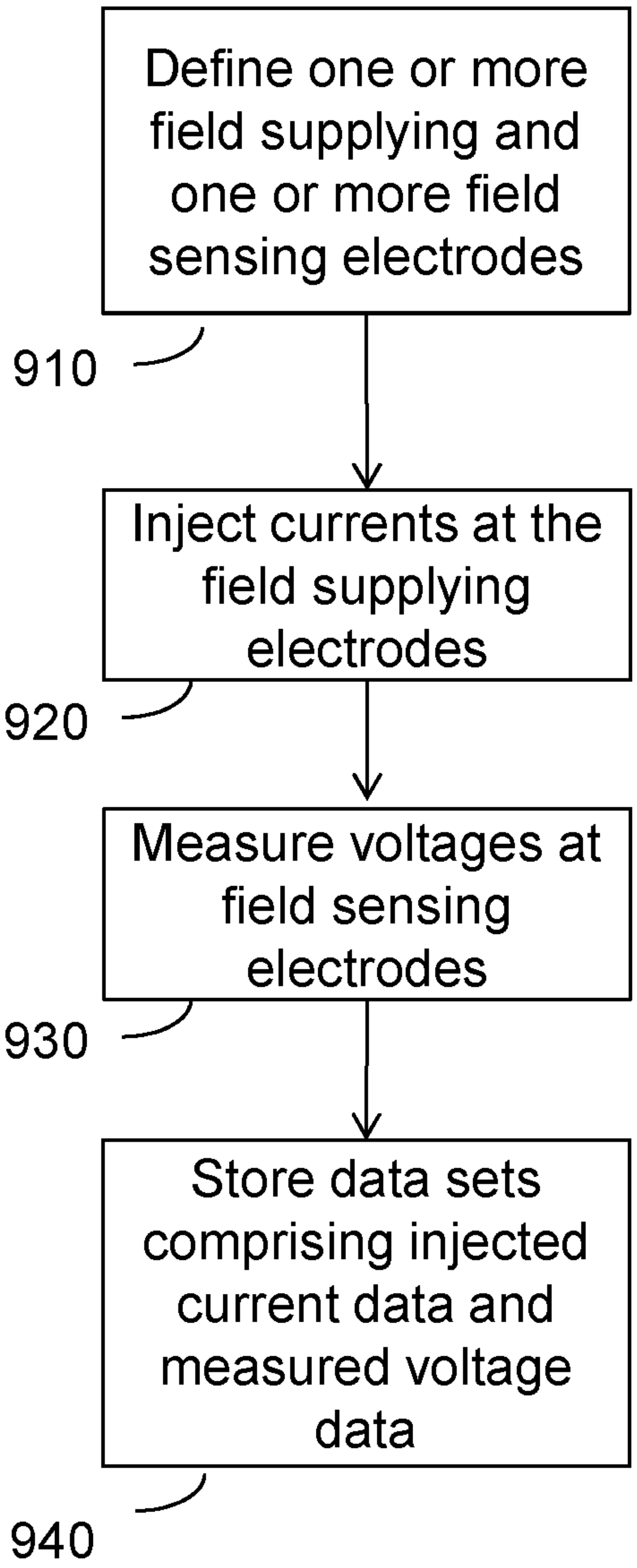
Define one or more field supplying and one or more field sensing electrodes
910
Inject currents at the field supplying electrodes
920
Measure voltages at field sensing electrodes
930
Store data sets comprising injected current data and measured voltage data
940

Figure 9

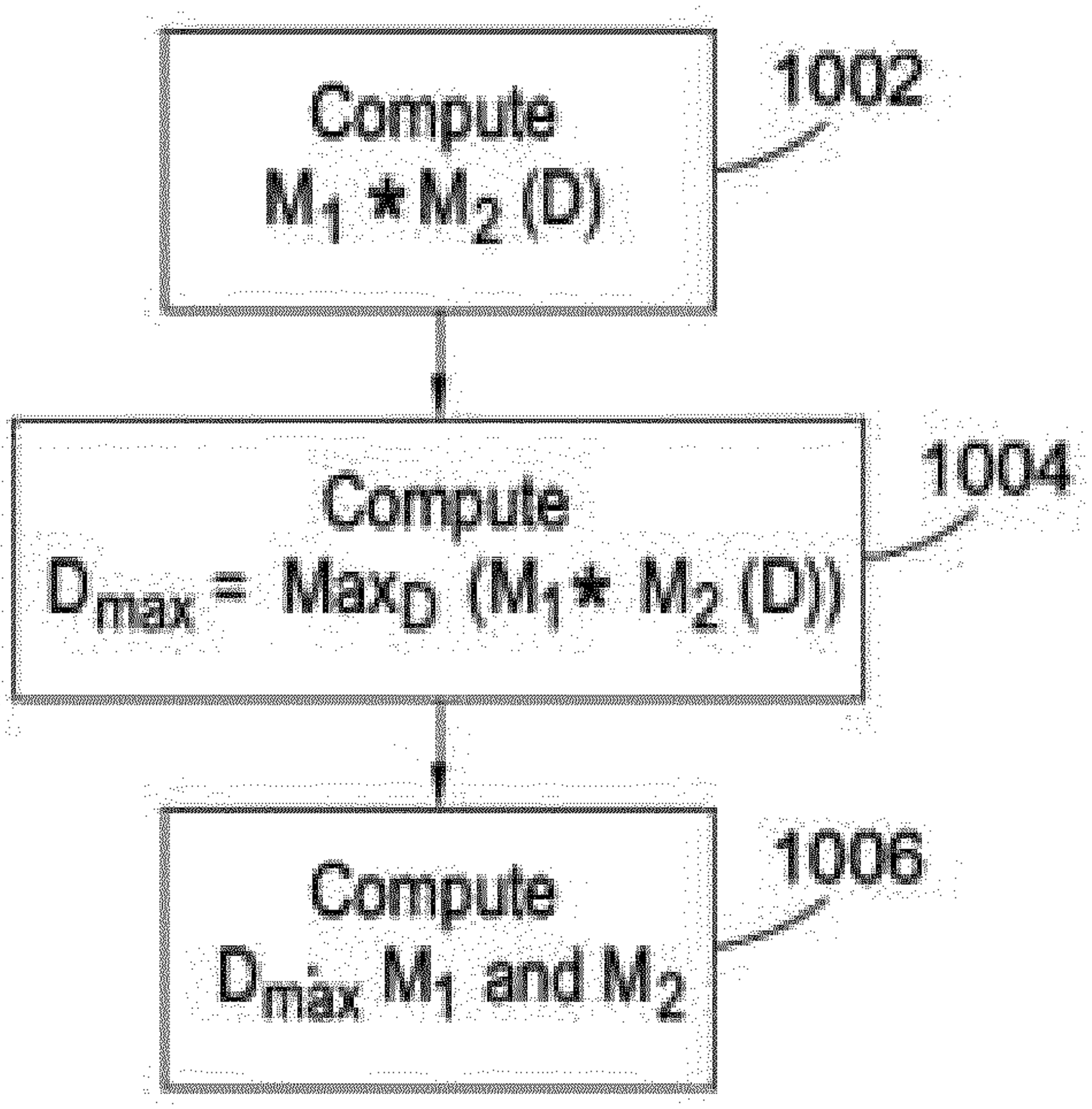
Compute
$M_1 * M_2 (D)$
1002
Compute
$D_{max} = Max_D (M_1 * M_2 (D))$
1004
Compute
D_{max} M_1 and M_2
1006

Fig. 10

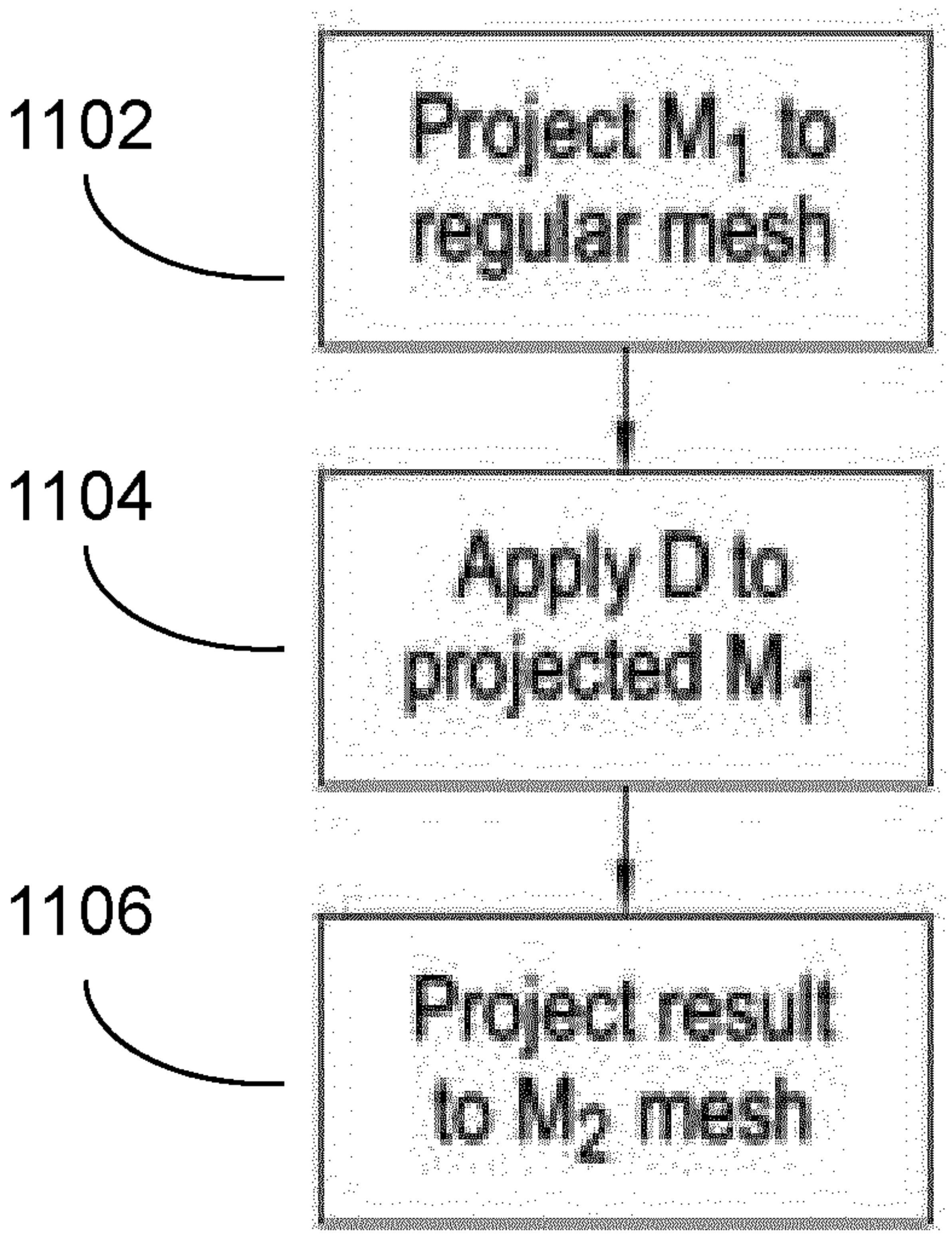
1102
Project M_1 to regular mesh
1104
Apply D to projected M_1
1106
Project result to M_2 mesh

Fig. 11

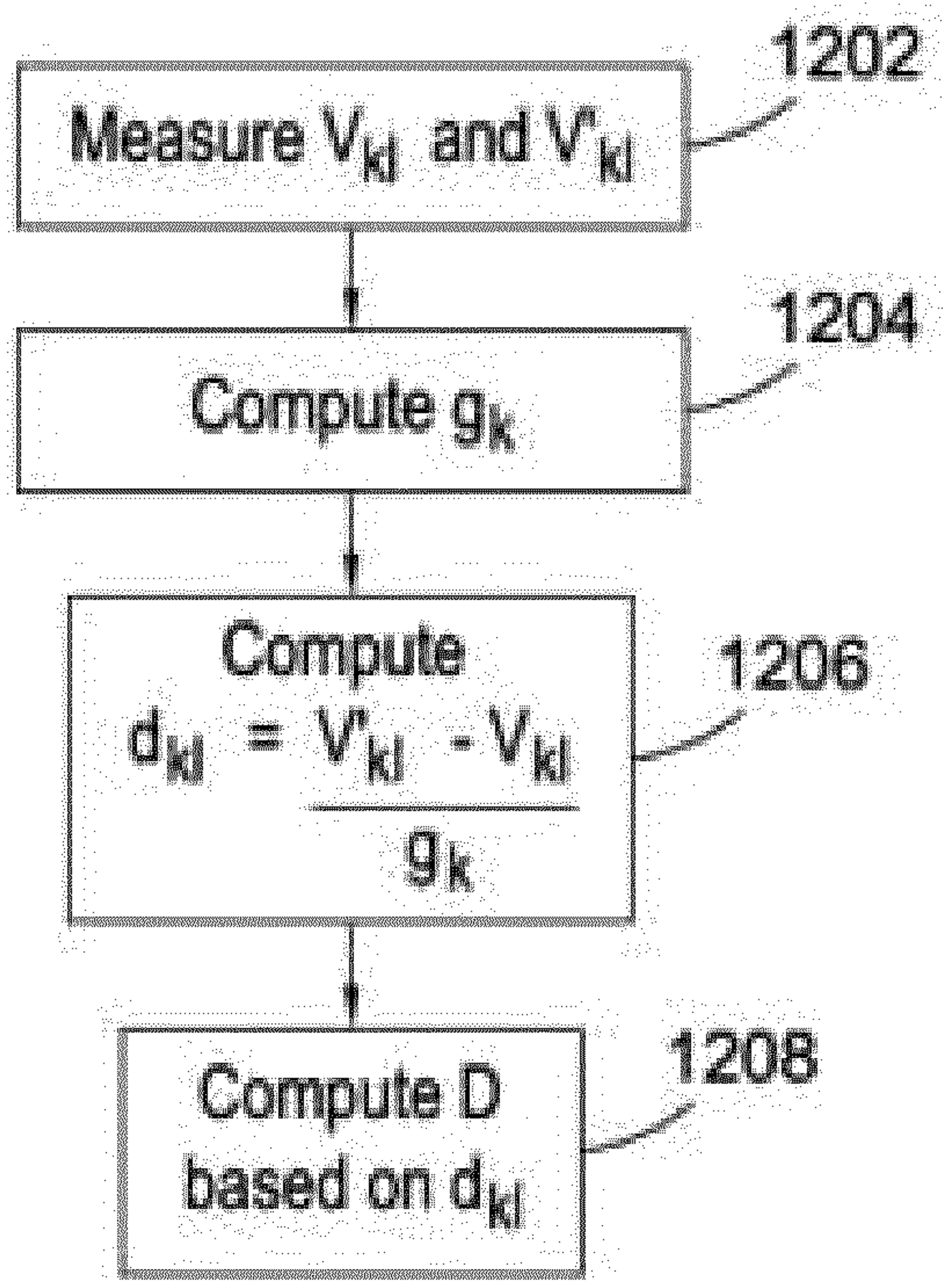
Measure V_{kl} and V'_{kl}
1202
Compute g_k
1204
Compute $d_{kl} = \frac{V'_{kl} - V_{kl}}{g_k}$
1206
Compute D based on d_{kl}
1208

Fig. 12

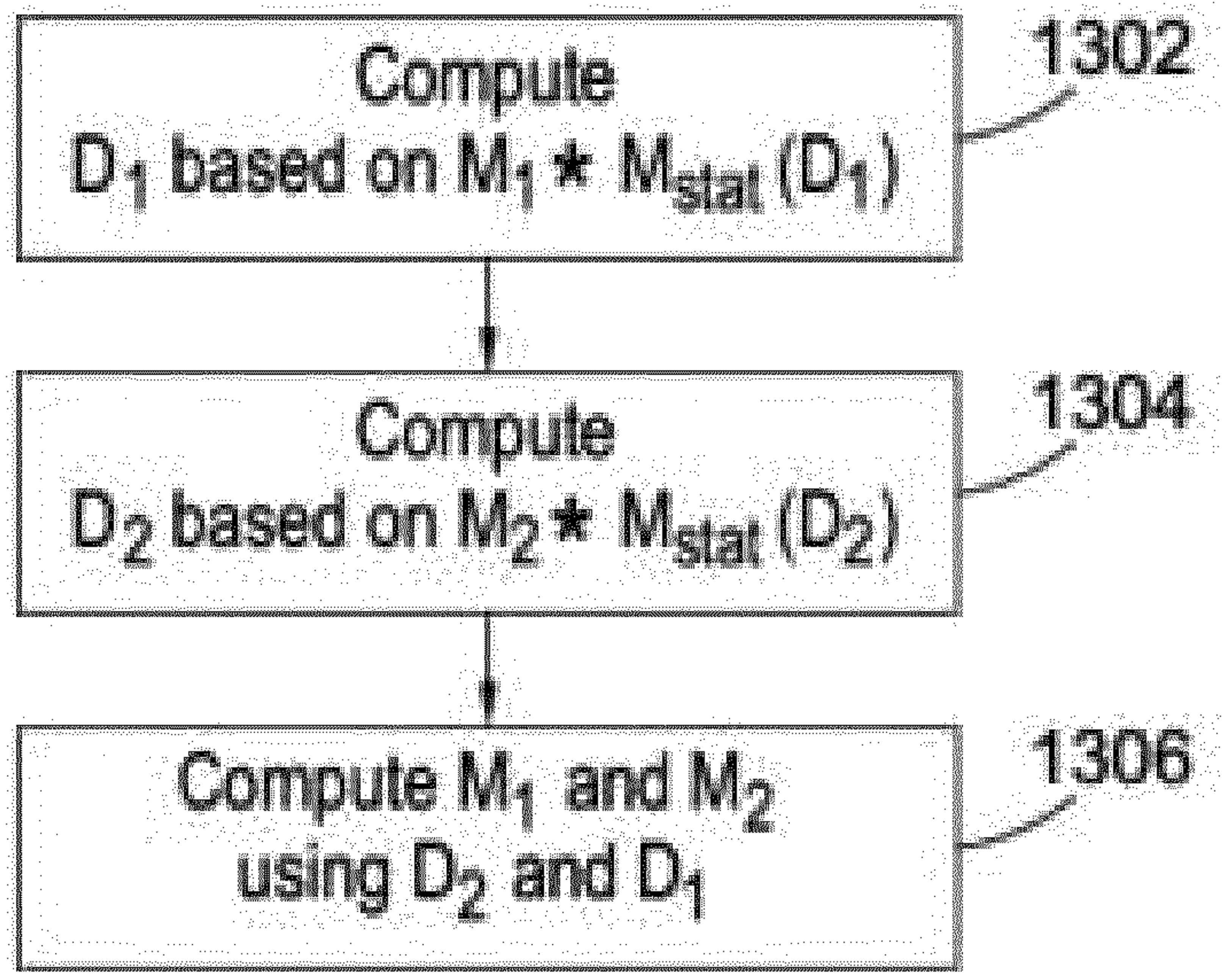
Compute D_1 based on $M_1 * M_{stat}(D_1)$
1302
Compute D_2 based on $M_2 * M_{stat}(D_2)$
1304
Compute M_1 and M_2 using D_2 and D_1
1306

Fig. 13

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2020/078932

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B5/053 A61B5/00
ADD.

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2014/107508 A1 (HARLEV DORON [US] ET AL) 17 April 2014 (2014-04-17) abstract; figure 1 paragraphs [0156] - [0157] paragraphs [0005], [0007], [0010], [0032] - [0033] the whole document -----	1-59
X	WO 2018/092070 A1 (NAVIX INTERNATIONAL LTD; SCHWARTZ YITZHACK [IL] ET AL.) 24 May 2018 (2018-05-24) abstract; figures 1A, 4A pages 2, l. 10 the whole document ----- -/--	1-59

☒ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search 21 December 2020	Date of mailing of the international search report 15/01/2021
Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Authorized officer Furlan, Stéphane

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INTERNATIONAL SEARCH REPORT

International application No

PCT/EP2020/078932

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2019/035023 A1 (NAVIX INTERNATIONAL LTD) 21 February 2019 (2019-02-21) abstract; figures 12-13 page 21, lines 13-26 the whole document -----	1-59

1

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2020/078932

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 60
because they relate to subject matter not required to be searched by this Authority, namely:
see FURTHER INFORMATION sheet PCT/ISA/210

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 60

Claim 60 defines a surgical method practised on the human or animal body in the meaning of Rule 39.1(iv) PCT. Therefore, according to Article 17(2)(a)(i) PCT no written opinion regarding novelty, inventive step or industrial applicability is given for this claim. Claim 60 explicitly claims placing the tool " inside in the region inside the body", which encompasses substantial health risk even when carried out by trained practitioners.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP2020/078932

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2014107508 A1	17-04-2014	AU 2011253403 A1	22-11-2012
		AU 2011253404 A1	22-11-2012
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		JP 2013526334 A	24-06-2013
		JP 2013528433 A	11-07-2013
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		WO 2011142932 A1	17-11-2011
WO 2018092070 A1	24-05-2018	CN 110072449 A	30-07-2019
		US 2020163569 A1	28-05-2020
		WO 2018092070 A1	24-05-2018
WO 2019035023 A1	21-02-2019	CN 111050641 A	21-04-2020
		WO 2019035023 A1	21-02-2019