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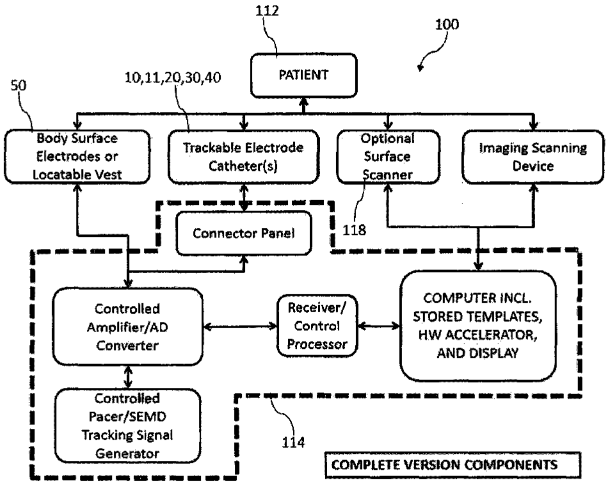

FIG. 2

(57) Abstract: The present invention relates to a computerized system based on non-expandable catheters and electropotential guidance for fast cardiac mapping and ablation. The core components that together make up the architecture of the system are: 1) a catheter or a set of catheters that are multi-polar and non-expandable, at least one of them is steerable and suitable for catheter ablation, all of them allow contact and/or non-contact sensing of potentials from the heart muscle, 2) a multi-channel amplifier and a signal processor, 3) a computer with software and storage and optional hardware accelerator(s), 4) a pacing/driving/tracking generator, and 5) body surface electrodes. Generally speaking, these components are structured such that the catheters are placed within heart chambers or vessels, and body surface electrodes are placed on the body surface in order to pick up synchronously cardiac signals that are collected by the amplifier coupled to the catheters and body surface electrodes, catheters are located and tracked within cardiac chambers in relation to the anatomy of the heart, and the signal processor and computer storage provide data for the software. This architecture allows the system to promptly provide electrical maps on all relevant cardiac surfaces at a time (TH), including and preferably endocardial and preferably from a single beat or limited number of beats of the heart. It should be further noted that the system is based on electropotential measurements and methods of inverse solution suitable for navigation, targeting and guidance during all catheter-based electrophysiology procedures and compatible with all strategies of cardiac catheter ablation.

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Computerized system and method for fast cardiac mapping and ablation

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates generally to a computerized system and method for fast cardiac mapping and relates particularly, but not exclusively, to a method, system and catheter for mapping and ablation of cardiac tissue using non-expandable catheters and inverse solution algorithms.

2. Background

Currently there are a number of techniques used for cardiac mapping, that is collecting information useful for diagnostics, navigation and guidance for physician performing an invasive cardiac electrophysiology procedure using catheters [1,2]. All current routinely performed electrophysiology procedures that lead to curative cardiac ablations (targeted tissue destruction) require at least two multipolar catheters used for mapping, pacing manoeuvres, and delivery of ablative energy, most commonly radiofrequency energy. This type of mapping studies and ablations are especially meant for patients with cardiac rhythm problems known as arrhythmias. Most of these solutions perform mapping directly through touching the surfaces of the heart (contact mapping), but these solutions fail to meet the needs of the industry because they are slow and more invasive then necessary due to time consumption.

An example of this is so-called electroanatomical mapping using point-to-point contact mapping. This type of mapping assembles the map by roving a catheter from site to site during desired cardiac rhythm, localizing and tracking at least the tip of the catheter. This approach poses demand on timing and duration of the mapped cardiac rhythm and manual skill of the human operator. Apart from X-ray based imaging and localization of catheters that has been used for many decades, there are two major types of catheter localization and tracking and geometry formation including maps of cardiac electrical activity necessary to this said electroanatomical mapping based either on external electromagnetic field imposed on the operating field through non-contact antennas or by external current from a generator injected through rather large contact location pads attached to the patient chest (US patents 5443489, 5546951, 5697377, 5983126, 6690963, 7263397, 5662108, 7670297, 8038625). Recently, also MRI-based tracking of special catheters has been introduced into a clinical experiment that could explicitly allow for cardiac electrophysiology mapping (US patents 7505808, 7848788, 8099151). Another recent alternative is an X-ray registered electromagnetic localization termed MPS (or gMPS) allowing mounting sub-millimetre sensors onto various medical instrumentation (US patent 6233476 and successive documents), or purely fluoroscopic (X-ray based) computerized reconstruction of localization (international patent WO/2012/092016). Advantage of the point-to-point mapping is that it usually allows using the same catheter for mapping and ablation. Other catheters that are in use simultaneously have supportive role for either partial mapping of remote areas, measuring of specific intervals and for delivering pacing manoeuvres. This type of procedures still constitute majority of performed cardiac mappings and ablations, allow reliable albeit slow mapping and subsequent ablation using non-expandable catheters [2].

Other solutions attempt to speed up the procedure, but these solutions are similarly unable to meet the needs of the industry because they are even more invasive, structurally complex and more difficult to operate. Example of these are expandable basket, spiral or balloon catheters that either touch the inner heart muscle surfaces (various expandable basket and contact catheters and systems including their tracking methods, US patents 4522212, 4699147, 5237996, 5279299, RE35880, 5546940, 5577509, 5662108, 6014579, 6188924, 6216027, 6241665, 6256540, 6542773, 6658279, 6805131, 6895267, 7189208, 7255695, US pre-grant publications 20080234564) or even provide non-contact mapping (expandable balloon catheters, including methods of locating and orientation of the catheters, US patents 5662108, 6640119, 6647617, 6728562, 6826420, 6826421, 6895267, 6939309, 6947785, 6978168, 7289843, 6990370, 7189208, US pre-grant publications 20080234564) but these catheters often do not provide means for performing catheter ablation, and are either not steerable or in rather a limited way, require larger bore vascular access, and are obtrusive for the physician, who provides catheter ablation with a necessary additional ablation catheter. Also, balloon or basket catheters are capable of simultaneous mapping only in a single heart chamber at a time. Though partial mapping with the said balloon catheter is faster and more effective than the aforementioned contact point-to-point mapping [3,4,5,6], the physical introduction of these catheters into the vascular system of the patient is slower, and requires special medical regime and attention during and after the procedure [bleeding and blood clot formation are more likely with their use, 3].

One of the said expandable balloon catheters is enabled for use through impedance-based location and tracking of the position of the measurement multi-electrode array, and use of inverse solution method based upon boundary element method and solving a set of Laplacian partial differential equations (US patents 6728562, 6826420, 6939309, 6978168, 6990370, 7289843). However, this method has the problem that the electrical source representation is incomplete, limited to one single cardiac chamber at a time, and requires a model of virtual surface to be a closed envelope and contiguous and as such suffers in performance. This is the very reason, why such catheter measurement system has to use expandable balloon in order to stay relatively close to the cardiac chamber wall in all directions in space. Failing proximity to the wall (which frequently happens in cases of dilated heart chambers that need ablation treatment), the system may provide inaccurate results despite using a mechanically and structurally complex expandable catheter [3,5,6]. This system is used in clinical practice for selected minority of cases of ventricular and atrial arrhythmias [3].

Still further recent catheter-based mapping system addresses these issues and uses steerable spatially expandable catheter based on printed circuit board splines that allows manipulating and deploying the catheter in a somewhat less obtrusive way. The used mapping catheter is smaller than the so far used expandable catheters, works in both contact a non-contact way, it is probably less traumatic or invasive (claimed to have 8Fr (2.7mm) bore in collapsed state, which is usual for non-expandable catheters in practical use), and requires a roving motion around the cardiac chamber of interest while being expanded in order to acquire the electrical cardiac maps on the multi-beat integration basis. The mapping catheter probably can deliver ablation after collapsing its splines, or, the system relies on the use of additional ablation catheter. The system provides for all necessary locating and tracking capabilities and geometry constructions (US patents 7505810, 7515954, 7729752, 7930018, 7937136, 7953475, 7957791, 7957792, 8103327, 8103338, US pre-grant publications 20090253976, 20100106154, 20110160574, 20110190625, 20110275949, 20110282186). Such roving manoeuvres, even though they compensate through individual transformations for the above mentioned deterioration of the incomplete information arising from the increased distance from the cardiac wall, however, have to be done during the running arrhythmia.

The reconstruction of maps is again limited to a single cardiac chamber at a time [7]. The system is yet to prove its utility.

One other prior industrial system solution (US patents 6400981, 6584345, 6892091, 6957101) used multi-polar trackable and non-expandable catheter, with miniature electrodes along the circumference and along the shaft of the catheter used for both contact and non-contact sensing. However, again, this system necessitated unusual manipulation on the side of the human operator, requiring roving and rotating movements of the catheter throughout the heart chamber cavity during running arrhythmia and was limited to mapping a single cardiac chamber at a time. The system relies on use of a single mapping catheter. Also, the catheter electrodes again have to stay close to the cardiac chamber wall (preferably up to 8mm) and close to the expected arrhythmia site in order to reconstruct electrical maps as the system does not provide for complete inverse solution accounting for the mutual position of the electrodes and cardiac chamber wall but estimates the signals in the near vicinity of the physical sensing electrodes.

Still other system solutions seek to use single non-expandable multi-polar catheter with miniature electrodes along the circumference and along the shaft of the catheter, but these solutions also fail to meet industry needs because, they are structurally complex (one is steerable spiral or J-shape, another is a barrel thickened shape with complicated inserts), and they do not provide for ablation - the ultimate goal of invasive cardiac mapping (US patents 7187964, 6839588, international patent WO 99/06112, US pre-grant publication 20110190649). They also do not provide simultaneous mapping on multiple surfaces at a time, since they are all invented to map a single cardiac chamber at a time, again with a model construction of an enclosed enveloped endocardial surface of the said chamber. Such said simultaneous mapping is necessary in the cases of cardiac activations related to structures like inter-ventricular and inter-atrial septum, and/or activations that are of unstable and abruptly changing nature, e.g. moving from one chamber or structure to the other (so called flutters, fibrillations and torsade-des-pointes types of rhythm disorders).

Still further recent solutions seek use of primarily non-invasive body-surface electrode measurements in order to map the surface of the heart by means of inverse electrocardiography or so called electrocardiographic imaging (US patents 6772004, 6975900, 7016719, 7471973, 7983743, US pre-grant publications 20100191131, 20110275921, 20120035459). However, body surface mapping (body surface electrode measurements) are known to yield only reconstructions of potentials (mapping) on the exterior (so called epicardial or pericardial) surface of the heart and no interior (endocardial) mapping. Therefore, this method performs well in the case of thin walled structures where endocardium and epicardium are close to each other. In thicker-walled structures like ventricles, and hidden inner structures like inter-ventricular septum, this system and method fails to provide useful cardiac interior (endocardial) maps. The published and marketed systems require strict anatomical framework of the human torso including cardiac muscle anatomy to be acquired via cardiac imaging, either computer tomography (CT) or magnetic resonance imaging (MRI) with an electrode vest or electrodes fastened on the patient body during the obligatory pre-procedure imaging study in order to obtain exact geometry of the torso surface, and to determine the position of the body surface electrodes contained in the vest toward the outer cardiac surface (epicardium or pericardium). One system is currently being introduced into clinical practice as an aid to cardiac procedures and diagnostics dealing with atrial arrhythmias, epicardially located ventricular arrhythmias, and cardiac resynchronization therapy [8,9,10,11,12,13]. It is unknown if the system can be used during cardiac ablation procedure in an unobtrusive way, especially due to a special vest covering the patient's chest that might hamper important manipulations on the patient chest during such procedures (e.g. attachment of defibrillation electrodes, insertion of intrapericardial instruments or chest compressions during cardiac massage); however, one recent system already was invented to do on-site measurements (i.e. inside the operating room) in combination with a catheter in order to allow for endocardial measurement (US pre-grant publication 20110190649), nevertheless, relying on unusually shaped catheter design that does not explicitly allow for ablation through this catheter.

Some published experimental model data [14,15,16] suggested simultaneous use of body surface ECG recording together with stationary non-expandable electrode catheters inside epicardial vessels. Nevertheless, while the probabilistic computational algorithms may be useful also for the present invention, the preferred embodiment uses potential-based deterministic (Tikhonov, isotropy, or transmural regularization) or activation-based inverse solutions for the sake of speed of computational tasks (see further [17,18]). Also, the present invention allows for dynamic catheter manipulations and various catheter locations inside cardiac chambers and vessels necessary for successful fast cardiac mapping and ablation.

Some patented body surface mapping systems allow simultaneous use of the invasive catheters, allowing simultaneous multiple cardiac chamber mapping at a time from limited number of heart beats, let alone a single beat map. These systems rely on the simultaneous use of body surface electrodes for mapping cardiac signals together with expandable or non-expandable catheter(s) in order to perform faster cardiac mapping including endocardial surface (US patent 7957784, and US pre-grant publications 20110213259, 20080058657, European patent application EP1897490A2), and they require additional sensing of spatial information on the body surface electrodes locations (torso shape). One of these systems requires special technology using piezoelectric wires together with a special belt and a patch in order to acquire signals and geometry information that determine the torso surface shape and the positions of the body surface electrodes (US patent 7957784), the other requires electromagnetic sensors. None of these systems are capable of building a common dynamic forward lead-field matrix related to all relevant cardiac chambers presented in this present invention. None of these systems solve the lead-field matrix with respect to the realistic, spatially distributed boundary condition of the manifold cardiac surface comprising both epicardium and endocardium (see further text and Figures 12, 13), they rather resort to simplified envelope surfaces representing a single heart chamber at a time.

None of these systems incorporate invasive measurements (contact and non-contact simultaneously) and body surface measurements into a single formulation of the forward transfer (lead-field) matrix computation. The latter system is also dependent on injecting currents for determining patient-specific trans-thoracic and trans-cardiac impedance for reconstructing the forward matrix of transfer coefficients (US pre-grant publication 20080058657, European patent application EP1897490A2). The cited system tries to reduce a complex relationship between endocardial and epicardial maps into a direct linear correlation (through registration of anatomic or electrical morphological features into a common Cartesian space, and calculating a mathematical transform or even just simple visual projection) between these maps and measured body surface potentials maps. This translation is problematic (despite having correct and measured, though limited impedance readings) due to presence of anisotropic and bi-domain source in between the endocardium and epicardium. Also, such transform will be problematic in geometrically complex regions like interventricular septum and cardiac apex, where epicardium projects onto both ventricular endocardial surfaces, let alone in a complex atrial anatomy. Such correlation may also change in time in a single individual (due to pathophysiology of ischemia, scarring or similar processes) which makes further problematic repeat follow-up measurements suggested by the cited system patent. The cited system reduces the bi-domain source volume represented by myocardial syncytium tissue into a passive conductive fibromuscular tissue exerting just passive conductance tensor that needs to be measured/mapped by injecting external current. Furthermore, injecting currents that are not generated inside the cardiac tissue (electrophysiological signal from within cardiac cells or cardiac syncytium) does not warrant adequate transfer coefficients because of the focal dipolar character of the injected source, which is different in shape and size due to the very existence of cardiac wave front source and due to different boundary conditions as documented in numerous publications. Consequently, this cited system patent does not provide solution how to instantaneously map adequately sources within the inter-ventricular septum and counter-lateral ventricle. Also, this cited invention does not allow for simultaneous instantaneous mapping on all relevant cardiac surfaces at a time and thus fast enough solution and guidance for ablation in sudden complex ventricular and atrial activations. All these shortcomings are solved by the method of construction the lead-field matrix by the present invention that respects spatially and anatomically realistic and complex manifold cardiac surface and resulting spatially distributed boundary conditions (see further text and Figures 12 and 13).

One further solution attempts to use simultaneous tracking potentials and heart potentials in order to quickly ablate unstable ventricular tachycardia using an unspecified ablation catheter and body surface electrodes or a vest (US patents 6308093, 6370412, 7792563, US pre-grant publication 20070219452). However, the system and method relies on reducing the electrophysiology (or arrhythmia) cardiac signal to a single equivalent moving dipole model (SEMD). It is well known that arrhythmias and cardiac signals do not follow this simple equivalent source representation because of the distributed nature of signal sources that reside in numerous cardiac cells (cardiac syncytium) and are variously coordinated according to the healthy or diseased state of the heart, throughout the cardiac cycle, and due to complex boundary conditions related to the shape of the cardiac muscle as is obvious from theory, animal experiments, and recent practical studies of electrocardiographic imaging [11,19,20]. While SEMD model is obviously suitable for catheter tracking (since the catheter electrodes can be constructed so that the resulting source induced by pacing or injected current is very close to a point dipole through a defined electrode pair) [21,22,23], it is not suitable for critical arrhythmia site localization because of its aforementioned distributed nature and complex boundary conditions that are critical in solving inverse solutions in cardiac electrophysiology. Such said invented system and method are not in practical use in the medical practice.

It is desirable to have a system, which is least invasive to the patient, comfortable for the human operators, and safer than the current mapping-related procedures that are cumbersome, time consuming, and in a number of cases pose excess risk. Furthermore, it is also desirable to have a system that uses non-expandable catheters that are less invasive, less obtrusive for the operator, less expensive, and safer for the patient than expandable ones. Still further, it is desirable to have a system that provides mapping on all relevant cardiac surfaces (ΓH), including and preferably endocardial (inner surfaces of the cardiac chambers,) simultaneously and instantaneously, which information is less ambiguous than partial mapping by the current technologies. Therefore, there currently exists a need in the industry for a system that provides fast cardiac mapping preferably from a single heart beat or limited number of beats using non-expandable catheters.

Preferred embodiments of the present invention seek to overcome the above described disadvantages of the prior art and to fulfil the needs set out above.

SUMMARY OF THE INVENTION

According to an aspect of the present invention there is provided an apparatus for mapping the electrical activity of a heart, the apparatus comprising:-

at least one processor for receiving and processing data received from a plurality of electrodes;

at least one non-expandable catheter, for insertion into a heart, the catheter having at least one catheter electrode for measuring electrical signals, at least one said catheter electrode producing catheter electrode data signals for passing to said processor;

at least one catheter locator for determining the locations of the or each catheter electrode within the heart; and

a plurality of body electrodes for placement on a living body containing the heart and for measuring electrical signals, said electrodes placed in known locations relative to each other on the living body and producing body electrode data signals for passing to said processor,

wherein said processor combines said catheter electrode data signals and their locations and said body electrode data signals and their locations to produce electrical activity mapping data relating to the heart.

By using a non-expandable catheter to gather catheter data and body electrodes to gather body electrode data and combining these data to produce an electrical activity map of the heart, the advantage is provided that very rapid and accurate mapping of the electrical activity of a heart can be produced. This is particularly important since the electrical activity that is being mapped is almost always an arrhythmia which may not occur with every beat of the heart. As a result, it may have been necessary in the prior art to maintain a catheter in place within a heart for a significant period of time which is particularly unsatisfactory where an expandable catheter is being used in a chamber of the heart. Furthermore, where the catheter is being used also for ablation of the heart wall the rapid data gathering, which may be for as little as a single arrhythmic beat, allows for the effectiveness of the ablation to be quickly measured, thereby allowing an operator to undertake further ablation if necessary.

In a preferred embodiment, the processor combines said data on the basis of at least one inverse solution matrix.

By using an inverse solution matrix, the advantage is provided that the large volumes of data that is produced from the typically many electrodes formed in the apparatus the present invention can be rapidly processed whilst providing an accurate representation of the electrical activity of the heart.

According to another aspect of the present invention there is provided an apparatus for mapping the electrical activity of a heart, the apparatus comprising:-

at least one processor for receiving and processing data received from a plurality of electrodes;

at least one catheter, for insertion into a heart, the catheter having at least one catheter electrode for measuring electrical signals, at least one said catheter electrode producing catheter electrode data signals for passing to said processor;

at least one catheter locator for determining the locations of the or each catheter electrode within the heart; and a plurality of body electrodes for placement on a living body containing the heart and for measuring electrical signals, said electrodes placed in known locations relative to each other on the living body and producing body electrode data signals for passing to said processor,

wherein said processor combines, on the basis of at least one inverse solution matrix, said catheter electrode data signals and their locations and said body electrode data signals and their locations to produce electrical activity mapping data relating to the heart.

By using a non-expandable catheter to gather catheter data and body electrodes to gather body electrode data and combining these data to produce an electrical activity map of the heart, the advantage is provided that very rapid and accurate mapping of the electrical activity of a heart can be produced. This is particularly important since the electrical activity that is being mapped is almost always an arrhythmia which may not occur with every beat of the heart. By using an inverse solution matrix, the advantage is provided that the large volumes of data that is produced from the typically many electrodes formed in the apparatus the present invention can be rapidly processed whilst providing an accurate representation of the electrical activity of the heart.

In a preferred embodiment the catheter comprises a non-expandable catheter.

In another preferred embodiment the catheter comprises a catheter body in the form of an elongate member, the catheter body adapted to be manoeuvred within blood vessels of said living body so as to extend at least partially into a heart in said living body and a plurality of said electrodes arranged along the length of said catheter body.

In a further preferred embodiment the plurality of catheter electrodes comprise:-

at least one first catheter electrode extending circumferentially around said catheter body; and

at least one plurality of second catheter electrodes arranged circumferentially around said catheter body.

The catheter may comprises ablation means for causing ablation of tissue adjacent said catheter.

At least one of the catheter electrodes may comprise a tracking electrode for providing a tracking current.

The apparatus may further comprise a sheet of a flexible material containing said body electrodes.

By forming the body electrodes into a sheet of flexible material, the advantage is provided that the relative position of one body electrodes to the next can be fixed thereby reducing the need for mapping the location of each body electrode on the patient's body.

The apparatus may further comprise a garment formed from said flexible material.

In a preferred embodiment of the processor produces a voltage map of the heart.

In another preferred embodiment the matrixes are combined using a dynamic lead-field matrix formulation.

In a further preferred embodiment the matrixes are combined using the following formula

$$\begin{bmatrix} A\ noninv\ 11 & A\ noninv\ 12 & \dots & A\ noninv\ 1k \\ A\ noninv\ 21 & A\ noninv\ 22 & \dots & A\ noninv\ 2k \\ \vdots & \vdots & \dots & \vdots \\ A\ noninv\ m1 & A\ noninv\ m2 & \dots & A\ noninv\ mk \\ A\ inv\ 11 & A\ inv\ 12 & \dots & A\ inv\ 1k \\ A\ inv\ 21 & A\ inv\ 22 & \dots & A\ inv\ 2k \\ \vdots & \vdots & \dots & \vdots \\ A\ inv\ n1 & A\ inv\ n2 & \dots & A\ inv\ nk \end{bmatrix} \times \begin{bmatrix} x1 \\ x2 \\ \vdots \\ xk \end{bmatrix} = \begin{bmatrix} b\ noninv\ 1 \\ b\ noninv\ 2 \\ \vdots \\ b\ noninv\ m \\ b\ inv\ 1 \\ b\ inv\ 2 \\ \vdots \\ b\ inv\ n \end{bmatrix}$$

where A denotes lead-field transfer matrix

x denotes unknown source values (sought values)

b denotes measured known values

m denotes the number of body electrodes at known locations,

n denotes the cumulative number of catheter electrodes at known acquired locations (see multi-beat integration, catheter tracking),

k denotes number of source points on the manifold surface of the heart ventricles or atria that are both on endocardium (inner chamber surface) and epicardium (outer heart surface).

In a preferred embodiment the processor further processes said electrical activity mapping data to display a map of electrical activity of the heart on a display device.

According to another aspect of the present invention there is provided a method of mapping the electrical activity of a heart, comprising the steps of:-

creating a data connection between a plurality of electrodes and at least one processor, the processor for receiving and processing data received from said plurality of electrodes;

inserting at least one non-expandable catheter into a heart, the catheter having at least one catheter electrode for measuring electrical signals, at least one said catheter electrode producing catheter electrode data signals for passing to said processor;

determining the locations of the or each catheter electrode within the heart; and placing, in known locations relative to each other on the living body containing the heart, a plurality of body electrodes for measuring electrical signals and producing body electrode data signals for passing to said processor,

combining said catheter electrode data signals and their locations and said body electrode data signals and their locations to produce electrical activity mapping data relating to the heart.

The data may be combined on the basis of at least one inverse solution matrix.

According to a further aspect of the present invention there is provided a method of mapping the electrical activity of a heart, comprising the steps of:-

creating a data connection between a plurality of electrodes and at least one processor, the processor for receiving and processing data received from said plurality of electrodes;

inserting at least one non-expandable catheter into a heart, the catheter having at least one catheter electrode for measuring electrical signals, at least one said catheter electrode producing catheter electrode data signals for passing to said processor;

determining the locations of the or each catheter electrode within the heart; and

placing, in known locations relative to each other on the living body containing the heart, a plurality of body electrodes for measuring electrical signals and producing body electrode data signals for passing to said processor,

combining, on the basis of at least one inverse solution matrix, said catheter electrode data signals and their locations and said body electrode data signals and their locations to produce electrical activity mapping data relating to the heart.

The catheter may comprise a non-expandable catheter.

The method may further comprise ablating portions of the heart wall in response to the mapped data.

The method may also further comprise applying a tracking current to at least one catheter electrode and gathering and processing data from said body electrodes to determine the location of said catheter electrode.

In a preferred embodiment the processor produces a voltage map of the heart.

In another preferred embodiment the matrixes are combined using a dynamic lead-field matrix formulation.

In a further preferred embodiment the matrixes are combined using the following formula

$$\begin{bmatrix} A\ noninv\ 11 & A\ noninv\ 12 & \ldots & A\ noninv\ 1k \\ A\ noninv\ 21 & A\ noninv\ 22 & \ldots & A\ noninv\ 2k \\ \vdots & \vdots & \ldots & \vdots \\ A\ noninv\ m1 & A\ noninv\ m2 & \ldots & A\ noninv\ mk \\ A\ inv\ 11 & A\ inv\ 12 & \ldots & A\ inv\ 1k \\ A\ inv\ 21 & A\ inv\ 22 & \ldots & A\ inv\ 2k \\ \vdots & \vdots & \ldots & \vdots \\ A\ inv\ n1 & A\ inv\ n2 & \ldots & A\ inv\ nk \end{bmatrix} \times \begin{bmatrix} x1 \\ x2 \\ \vdots \\ xk \end{bmatrix} = \begin{bmatrix} b\ noninv\ 1 \\ b\ noninv\ 2 \\ \vdots \\ b\ noninv\ m \\ b\ inv\ 1 \\ b\ inv\ 2 \\ \vdots \\ b\ inv\ n \end{bmatrix}$$

where A denotes lead-field transfer matrix

x denotes unknown source values (sought values)

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m denotes the number of body electrodes at known locations,

n denotes the cumulative number of catheter electrodes at known acquired locations (see multi-beat integration, catheter tracking),

k denotes number of source points on the manifold surface of the heart ventricles or atria that are both on endocardium (inner chamber surface) and epicardium (outer heart surface).

The processor may further process said electrical activity mapping data to display a map of electrical activity of the heart on a display device.

According to an aspect of the present invention there is provided a catheter for use in an apparatus for mapping the electrical activity of a heart, the catheter comprising:-

a catheter body in the form of an elongate member, the catheter body adapted to be manoeuvred within blood vessels of a living body so as to extend at least partially into a heart in said living body,

at least one first electrode extending circumferentially around said catheter body the or each first electrode for detecting electrical signals and relaying said signals to a signal processor; and

at least one plurality of second electrodes arranged circumferentially around said catheter body each second electrode for detecting electrical signals and relaying said signals to a signal processor and/or for delivering tracking current.

The present invention advantageously fills the aforementioned deficiencies by providing computerized system and method for fast cardiac mapping and ablation using non-expandable catheters and inverse solution algorithms which provides newly formulated forward leadfield matrix, necessary geometries, and newly organized data flow and processes in order to better (faster and with greater success) accomplish cardiac mapping and ablations.

The present invention is a system together with an associated computer process and method. The basic system configuration (FIG. 1) is made up of the following components: 1) non-expandable, trackable, multi-polar and steerable electrode catheter(s), capable of sensing and delivering both contact and non-contact potentials generated by heart muscle and/or by pacing/driving/tracking generator, 2) an amplifier and signal processor, 3) a computer equipped with storage, geometry templates (55) and specialized software, 4) a pacing/driving/tracking generator, 5) a limited set of body surface electrodes (20–120 electrodes). These components are connected as follows: Electrode catheters and body surface electrodes pick up simultaneously multiple signals, amplifier and signal processor processes the signals, generator sends signals to catheters and/or body surface electrodes for tracking and pacing, and the computer software processes all the information necessary including desired geometry of the heart and torso and creates the maps. Data for geometry is taken either from stored sized templates (55), external imaging device, or is assembled by a roving catheter(s) via contact mapping, or is constructed by combining the above approaches.

The present invention may also have one or more of the following components: 1) a high-density body surface electrode set (hundreds of contact skin electrodes) for body surface potential mapping or en electrode vest, which are optionally locatable, 2) a cardiac imaging component (ultrasound or similar) 3) a torso surface shape detector (camera, laser scanner, infrared, wireless electromagnetic sensors, antenna transmitters, piezoelectric wires or similar sensors mounted on the body or onto the body surface electrodes), 4) a hardware accelerator used for enhancing and speeding up extensive computations.

It is the combination of non-expandable catheters placed around or along cardiac walls (inside chambers, vessels like coronary sinus, pulmonary or epicardial vessels, or specifically punctured across inter-atrial septum via acknowledged trans-septal puncture), the limited set of body surface electrodes, and the particular model and method of forward and inverse solution that make this system uniquely innovative, fast, safe, and less invasive than the current solutions mentioned above that need expandable, specially-shaped, or large bore catheters and cannot reconstruct the maps on all relevant surface simultaneously at a time. The other innovative and unique aspect of the present invention is the data flow and a stepwise process of spatial, spatiotemporal, potential-based, optionally also activation-based and trans-membrane potential calculating inverse solutions securing correct resolution of endocardial and epicardial sources (typically in ventricles). Lack of this epi-endocardial synchronicity is a known drawback of the prior art systems.

The placement of multiple, relatively thin, and non-expandable catheters inside the cardiac chambers and/or vessels is in any case same as an every-day practice during electrophysiology procedures (see prior art), especially if one contemplates not only to diagnose, but also to cure with catheter ablation and/or to perform cardiac pacing. Also, the placement of the limited set of the body surface electrodes can be accomplished at any desired time including during already initiated catheterization procedure on-site, without a need to place a vest and to scan the electrode positions in the CT or MRI machine and without creating an obstacle for another tools and measures necessary to safely accomplish the procedure (defibrillation patches, intrapericardial instrumentation/puncture, chest compressions for the purpose of cardiac massage etc.). As such, the present invention does not pose any more burden or risk or labour to the patient or physician and conversely poses less burden and risk than the solutions of prior art. At the same time, the fine structure of multi-polar catheters, including a circumferential arrangement of the miniature electrode sensors allow instantaneous mapping of the regions that are geometrically complex such as apical parts of the ventricles, papillary muscles and inter-ventricular septum, where high-density conventional point-to-point mapping is often necessary and thus lengthy and can also fail completely due to lack or short runs of arrhythmia that is pursued. Also, sole body surface measurements and electrocardiographic imaging (prior art) are not capable of delivering such information on these structures.

The present invention is unique in that the overall architecture of the system is different from other known systems. The system structure is mechanically simpler than the prior solutions of fast cardiac mapping especially in avoiding the need for complex mechanics of expandable or specially shaped catheters that in turn require direct contact or close proximity to the cardiac walls in all directions in space or special handling (like sweeping movements during mapping, blood clot prevention in balloon catheters, obtrusive presence of expandable catheters). A new structural complexity is added on the side of miniaturization of the said electrodes on the catheters used for non-contact sensing, their construction and larger number of electrical connections than it is usual in prior art products, including multitude of materials necessary for conducting wires, cables and connectors. Another new structural complexity is added on the side of sophistication and multitude of the computer algorithms including optional hardware accelerator(s) in the form of additional computer components (typically additional circuit boards or modules) involved in inverse and forward solution computations, in order to secure the speed of computations. The computerized workspace also comprises software for generation and storage of template geometries (55) necessary for inverse solutions (see block diagrams in FIG. 1, 2 and 3).

The present invention now will be described more fully hereinafter with reference to the accompanying drawings, which are intended to be read in conjunction with both this summary, the detailed description and any preferred and/or particular embodiments specifically discussed or otherwise disclosed. This invention may, however, be embodied in many different forms and should not be construed as limited to the embodiments set forth herein; rather, these embodiments are provided by way of illustration only and so that this disclosure will be thorough, complete and will fully convey the full scope of the invention to those skilled in the art.

BRIEF DESCRPTION OF THE DRAWINGS

Preferred embodiments of the present invention will now be described, by way of example only, and not in any limitative sense with reference to the accompanying drawings which are as follows.

FIG. 1 is a block diagram showing basic version/embodiment components that secure operation of typical configurations of catheters and limited set of body surface electrodes, while using geometries from internal stored templates (55).

FIG. 2 is a block diagram showing complete version components that secure operation of configuration of catheters and locatable body surface electrodes or a vest, while using geometries from imaging or scanning device and/or optional surface scanner (torso shape detector). Computer may be equipped with hardware accelerator.

FIG. 3 is a block diagram showing computer and software integrator components. Hardware accelerator may be an optional component of the processor.

FIG. 4 shows distal mapping parts of existing standard non-expandable electrophysiology electrode catheters (10) suitable for use with the invented system. All variants are suitable for contact and non-contact sensing and distal tip electrodes are suitable for contact/non-contact sensing. Distal tip electrodes of the 4-pole catheters (11) are suitable for ablation and/or contact/non-contact sensing. Multipolar catheters with ablation tips (20) and standard mapping electrodes both for contact and non-contact sensing are also suitable for the invented system. Catheters may have various thickness ranging from 3-8Fr (1-2.7mm).

FIG. 5 shows distal mapping parts of existing standard (10) and novel (20) non-expandable EP catheters with electrodes variously spaced to form dipoles that are useful for contact and non-contact sensing, SEMD location and tracking, and distal tips are suitable for ablation (20) and/or contact/non-contact sensing. Novel non-expandable catheters with miniature electrodes spaced in 2 longitudinal lines (30) are suitable for non-contact and remote sensing and their distal tips are suitable for ablation and/or contact/non-contact sensing. Catheters may have various thickness ranging from 3-8Fr (1-2.7mm).

FIG. 6 shows distal mapping parts of existing standard non-expandable EP catheters (10) and novel catheters (20) with electrodes variously spaced to form dipoles that are useful for contact and non-contact sensing, SEMD location and tracking, and distal tips are suitable for ablation and/or contact/non-contact sensing. Novel non-expandable catheters with miniature electrodes spaced in 3 longitudinal lines and around the circumference (40) are suitable for non-contact and remote sensing and their distal tips are suitable for ablation and/or contact/non-contact sensing. Catheters may have various thickness ranging from 3-8Fr (1-2.7mm).

FIG. 7 shows examples of distal mapping parts of the previously described catheters (10, 20, and 40) that are bent through a standard steering mechanism to form a defined curve. Such curve facilitates not only manoeuvring as is usual for steerable catheters but also location and computer representation. Catheters may have various thickness ranging from 3-8Fr (1-2.7mm). This is only illustrative example; there is a whole variety of curves possible, including multiple steering directions (bidirectional catheters and similar).

FIG. 8 shows typical configuration for endocardial fast mapping of the heart ventricles using exclusively the standard catheters as in FIG. 4. Standard mapping catheters (10) straddle the interventricular septum and ablation catheter (11) is placed inside the left ventricle along the lateral free wall. All catheter electrodes excluding the distal tips sense non-contact far-field potentials and the distal tips sense the contact potentials. All these potentials are used as input recordings for the inverse solution computation.

FIG. 9 shows typical configuration for endocardial fast mapping of the ventricles using combination of a standard catheter (10) from FIG. 5 and novel ablation catheter with miniature sensing electrodes (40) and distal tip suitable for sensing and ablation from FIG 7. The catheters straddle the interventricular septum and ablation catheter (40) is placed inside the left ventricle. All catheter electrodes excluding the distal tips sense non-contact far-field potentials and the distal tips sense the contact potentials. All these potentials are used as input recordings for the inverse solution computation.

FIG. 10 shows cardiac maps on appropriately sized ventricular template geometry (high resolution (55) – panel A, decimated/downsampled (60) – panel B). The template geometry is built as a triangular surface mesh. Panel A demonstrates simulated activation arising from endocardial surface of the left ventricle (dark patch in between the papillary muscles). Electrode catheters are inserted into both left and right ventricles, straddling interventricular septum. Panel B demonstrates inverse solution (fast cardiac map) as provided by spatial Tikhonov regularization (using surface Laplacian as a regularization constraint matrix) on the ventricular surface as provided by a computer algorithm of the present invention. The algorithm uses input signals sensed by the displayed catheters and by body surface electrodes during a single time instant of a single simulated heartbeat. The localization of the dark area together with the initial potential minimum (white central dot) corresponds to the localization of the activated tissue patch on panel A. The darker shades of grey are low potential values, the lighter shades are high potential values and the mapping scale is relativistic. There is notable smoothing of the inverse map is inherent to spatial Tikhonov regularization.

FIG. 11 shows typical configuration for endocardial fast mapping of the atria using combination of a standard catheter (10) from FIG. 5 inserted into the coronary sinus (a large vein circumventing the left atrium) and the novel catheter (40) with miniature sensing electrodes and distal tip suitable for sensing and ablation from FIG. 7 inserted into both right (RA) and left atrium (LA) through a standard trans-septal puncture. The catheters straddle part of the atrial walls and are in fact placed inside both atria. All catheter electrodes sense non-contact far-field potentials and some (especially the distal tip of the ablation catheter) sense the contact potentials. All these potentials are used as input recordings for the inverse solution computation. The catheters could also be inserted into the pulmonary veins (PV) at the back of the left atrium (LA).

FIG. 12 shows typical configuration for endocardial fast mapping of the atria using combination of a novel catheter (20) from FIG. 4 inserted into the both right and left atrium through the standard trans-septal puncture, and body surface electrodes. All catheter electrodes sense non-contact far-field potentials and some can sense the contact potentials. In addition to the catheter electrodes, there are limited set of body surface electrodes (50) that sense far-field non-invasive electrocardiographic signal. All these potentials are used as input recordings for the inverse solution computation simultaneously. Arrows are used only selectively to illustrate transfer of potentials arising from the cardiac atrial surface (Γ_H), in reality; potentials (measured voltages) are transferred to the measurement electrodes in all directions. The forward model (Laplacian equation solved by finite element solver) assumes passive volume conductor (Ω) same way for conductive blood inside ventricle chambers as inside the surrounding torso volume with corresponding conductivities (σ). Laplacian equation is included in the FIG. 13.

FIG. 13 shows configuration of the endocardial catheter electrodes (20) and limited set of body surface electrodes (50) for fast epicardial and endocardial ventricular mapping. The method utilizes novel and unique formulation of the forward matrix for fast computation of ventricular maps using non-expandable catheter and body surface measurements. Arrows are used only selectively to illustrate transfer of potentials arising from the cardiac ventricular surface (Γ_H), in reality; potentials (measured voltages) are transferred to the measurement electrodes in all directions. The forward model (Laplacian equation solved by finite element solver) assumes passive volume conductor (Ω) same way for conductive blood inside ventricle chambers as inside the surrounding torso volume with corresponding conductivities (σ). Only ventricular surfaces (Γ_H) are considered to be the electrical source. This catheter and model configuration is typically suitable for activations arising from the endocardial regions, interventricular septum, and geometrically complex apical region. The resulting forward matrix and inverse solution (FIG. 10) can be used for initialization of the activation-based inverse solution or as a necessary part of other types of spatiotemporal solutions including trans-membrane potential calculations.

FIG. 14 shows data flow diagram and processes necessary for the present system invention in order to perform fast cardiac mapping that is faster than point-to-point mapping and to speed up the entire procedure leading to ablation or other treatment. From the input data, there is parallel flow of data coming from the conventional EP analysis and electroanatomical point-to-point mapping together with the instantaneous potential mapping and corresponding inverse solutions. Activation-based inverse solutions undergo initialization from potential-based inverse solutions and share the forward lead-field matrix, and trans-membrane potential calculation share the same forward lead-field matrix with potential-based inverse solutions. Inverse solutions continuously update during the EP procedure and help the human operator (optionally assisted by a robotic system) who steers the mapping and ablation catheter on the basis of conventional data analysis together with the inverse solutions. Epicardial versus endocardial resolution is critical for successful treatment of the ventricular activations.

FIG. 15 Panel A demonstrates spatial registration of a high resolution cardiac surface ventricular geometry created from segmented CT image stack (70). The geometry is anchored (registered) in the working Cartesian space, which is readily achieved through routinely acquiring selected points in space (coronary sinus (CS) catheterization – points 0,1,2 represented by distal, mid and proximal CS electrodes, His bundle electrogram site numbered 3, and steered RV catheter to the floor of the right ventricle, point 4). All numbered points are thus used for registration and also transformation of the surface (dotted surface - original, solid transparent surface – registered and transformed). Each new contact point acquired by any of the moving catheters can be used for re-calculating a standard geometric 4x4 transform matrix. Also note that during the procedure, the roving RV catheter acquired multitude of sensor locations (small black dots with connector lines) useful for eventual forward matrix construction and inverse solution. **Panel B** demonstrates further transformation and contact/non-contact mapping with a roving LV catheter of a diseased left ventricle within the same geometry. Further contact points are selectively acquired (0-6) and collected together with the non-contact sensor locations (small dots connected by lines tracking the catheter movement). Transform matrix is successively re-computed (dotted surface – original, solid transparent surface – transformed) and forward lead-field matrix updated with new invasive rows (see text) provided the roving motion was accomplished during desired target rhythm (including baseline rhythm for the purpose of voltage maps). Not all acquired points are necessarily included in the lead-field matrix computations and selection can be made of the points that are in the closest vicinity to the cardiac walls (source) and thus being more important than other points and also because smaller number of points means faster computations.

DETAILED DESCRIPTION OF THE INVENTION

Referring to figures 1 and 2, an apparatus 100 for mapping the electrical activity of a heart 110 of patient 112 includes a processor, generally indicated at 114. The processor 114 contains a number of functional and physical components which will be described in more detail below. The processor 114 may be a standard computer device adapted by the addition of further components or may be a specially constructed computer device.

The apparatus 100 also includes at least one catheter, this catheter being any of the examples shown as labelled 10, 11, 20, 30 or 40. These examples are all non-expandable catheters, which are the preferred form of catheters for use in the present invention. However, expandable catheters would also work in the context of the present invention although they have certain disadvantages compared to non-expandable catheters. The catheters 10, 11, 20, 30 and 40 include at least one, preferably a plurality and generally multiple electrodes, in the form of catheter electrodes, generally indicated at 116. These catheter electrodes may provide more than one function but at least one electrode is capable of measuring electrical signals and producing catheter electrode data signals which are passed to processor 114. Electrodes on the catheters preferably serve other functions and it may be that these functions are served by the same electrode as measures electrical signals or are served by other electrodes on the catheter.

The apparatus 100 further includes a plurality of body electrodes 50. These body electrodes are placed on the body of the patient 112 and measure electrical signals thereby producing body electrode data signals that are passed to processor 114.

The processor 114 is used to combine the catheter electrode data signals and that the body electrode data signals to produce electrical activity mapping data relating to the heart 110. To do this the location of the data gathering electrodes relative to each other must be known. Since the body electrodes are located on the surface of the patient determining and recording the location of these electrodes is a straightforward exercise. This can be achieved by using a surface scanner 118 which typically uses images of the patient's body to determine the location of each of the body electrodes 50. In addition, or as an alternative, the body surface electrodes can be formed into a sheet of material which is placed onto the patient's body surface. Once the location of one electrode is known, the location of all of the other electrodes can be inferred.

Determining the location of the electrodes on the catheter is less straightforward. Various techniques are suitable for determining the location of catheter and its electrodes including ultrasound scanning, contrast X-ray and rotational angiography, fluoroscopic computerized 3D localization, X-ray registered MPS/gMPS, electromagnetic, impedance based, CT imaging, MRI or by any other suitable technique for locating an object with the patient's body. Furthermore, the catheter and body electrodes can themselves be used to act as the catheter locator. In this example, electrical signals are input into the electrodes of the catheter and these signals are detected by the body surface electrodes. The data gathered by the body surface electrodes can be used to calculate the position of the catheter electrodes that produced the signal (details of this process are set out below).

Referring to figures 4 to 7, the catheters 10, 11, 20, 30 and 40 are described in more detail. The catheters are, in their basic make up, of a type used in existing cardiac mapping and ablation systems. That is, the catheter as a catheter body 120, in the form of an elongate member that is adapted to be manoeuvred within blood vessels of the patient's body 112 so that at least part of the catheter extends into the heart on 110. Each catheter has at least one, and preferably many catheter electrodes. The electrodes perform one of three functions and the electrodes can either be of a type that performs a single function or performs two or all three of the functions. The primary function of the catheter is to collect electrical activity mapping data and therefore at least one and preferably several of the electrodes are electrical activity measuring electrodes. If the catheter is to be used for ablation of the heart muscle then and ablation electrode is required which is generally located at the tip 122 or end of the catheter. Finally, if the catheter is being used to produce electrical signals that are detected by the body electrodes to determine the location of the catheter relative to the body electrodes then the electrodes produce a tracking signal.

The measuring and tracking electrodes (which as stated above can be the same electrode providing both of these functions) can be of two types being either directional or non-directional. Examples of directional measuring catheters are indicated at 124. In the example shown in figure 5, these catheters are located on opposing sides of the catheter body and will therefore detect different signals which can be used to determine the direction from which the electrical signal originated. In the example shown in figures 6 and 7 the catheters labelled 40 have for electrodes evenly distributed around the circumference of the catheter body in a ring. This additional data provides even more directional information.

Likewise the tracking electrodes can be directional. Typically, tracking electrodes operate as a pair of electrodes 126. A current is applied across the pair of electrodes at a predetermined frequency (such that it does not interfere with the beating of the heart) and this frequency is detected by the body surface electrodes. As an alternative, the electrode pair can be created on opposing sides of the catheter body 120 by using a pair of partially annular electrodes 128. By applying the current across a pair of electrodes that are arranged tangentially to the axis of the catheter (as opposed to electrodes 126 that are arranged axially along the catheter) these different currents can be distinguished. It should be noted that the electrodes 124 and 128 could be used for either or both of the measuring and tracking functions. However, for measuring it is preferable to have a small electrode and a large gap between electrodes whereas for tracking it is preferable to have large electrodes and small gaps between them.

Operation of the apparatus set out above will now be described. A catheter is inserted through the vascular system of the patient so that the end portion containing electrodes extends into the patient's heart. Once in position the location of each catheter electrode is determined using one of the method set out above. Likewise the location of each of the body electrodes is also determined.

Once all the electrode location has been undertaken, the apparatus can be used for mapping the electrical activity of the heart. As the heart beats the body and catheter electrodes gather electrical activity data which is passed to the processor and stored. This data is then gathered and formed into a matrix allowing the combination of the data on the basis of at least one inverse solution matrix. This data is then combined with the internal stored templates 55 that represent the structure of the heart in order to produce a visual map of the electrical activity of the heart.

The invention will now be described in further detail.

The present invention is directed to computerized system and method for fast cardiac mapping and ablation using non-expandable catheters and inverse solution algorithms.

In its most complete embodiment, the system of the present invention is made up of the following components (FIG. 2):

1) a set of non-expandable, multi-polar catheters capable of sensing and delivering both contact and/or non-contact potentials generated by heart muscle and by pacing/driving/tracking generator
2) an amplifier and signal processor
3) a pacing/driving/tracking generator
4) a limited set of locatable body surface electrodes or high-density set or electrode vest with detectable positions of the electrodes
5) a cardiac imaging component
6) an optional torso surface shape detector (surface scanner)
7) a computer equipped with specialized software and a hardware accelerator for speeding up extensive repetitive computations. (FIG. 3)

These components are combined together to create an architecture for the system that has capability to create promptly synchronous, instantaneous, and also series of cardiac potential and activation maps and electrograms [1] through processing the signals from the multi-polar, non-expandable catheters, capable of sensing non-contact and contact electrical potentials generated from the heart muscle, localization and tracking the positions of all catheters in relation to cardiac chambers, to each other and to the body surface electrodes, processing the image and location information to create the geometry of the heart (tessellated surfaces and volumes), to optionally localize body surface electrodes and/or reproduce the surface of the torso in relation to the anatomy of the heart, and to integrate all previous information by the computer software in order to produce the cardiac maps and allow for ablation.

The preferred system variant does not need to use the complete high density set of body surface electrodes (up to hundreds of electrodes) for body surface potential mapping (or electrode vest like in US patent 6772004) or torso surface shape detector (e.g. laser scanner) or cardiac imaging component (e.g. ultrasound), which usages are at the discretion of the human operator. Also, the majority of catheter cardiac mapping procedures and ablations are performed and are successful on the interior (endocardial) surfaces of the heart muscle both ventricular [3] and atrial [24,25], where this present invention system performs superiorly to the traditional contact mapping-based electroanatomical techniques or the basket or balloon or other types of non-contact and/or contact catheters or body surface measurements (see prior art).

It should further be noted that the catheters use miniature components, where at least one of the catheters is steerable, capable of delivering catheter ablation including the cooled radiofrequency type ablation, temperature sensing, impedance monitoring, and/or contact force sensing, and all the catheters in use are suitable for any required manoeuvres (pacing, manipulations). Preferably, all the signals necessary to create the maps (mapping, localization, and tracking signals) are based on multitude of electrical potentials (measured voltages) either coming from the heart muscle or induced through injected electrical currents for the catheter localization and tracking; nevertheless localization can also be obtained through electromagnetic tracking with wireless electromagnetic sensors, X-ray, or magnetic resonance imaging (MRI)-based cardiac imaging. Computer software integrates anatomical and electrical information by using multitude of available algorithms of image segmentation, surface and volume reconstruction together with mathematical algorithms of inverse solution (forward matrix construction and computation, regularization of the inverse solution, both spatial and spatio-temporal based information, and dipole localization by "brute force" and/or optimization techniques, see further in more detail). A multitude of these algorithms are available through public access and supported by multitude of developments [e.g. http://www.sci.utah.edu/software.html, 17]. Cardiac electrical information is based upon measurements of contact and also far-field (non-contact) potentials from within the heart chambers or vessels [1]. If mapping and/or catheter ablation procedure is desired on the exterior surface of the heart, body surface mapping component in the form of more dense electrode array and epicardially placed catheters (inside epicardial vessels or through pericardial access) are useful and optionally can use algorithms of inverse electrocardiography (called electrocardiographic imaging) in order to reconstruct electroanatomical maps of the said exterior surface [3,26].

Specific detailed aspects of functionality improvement follow:

Fast cardiac mapping using non-expandable catheter(s)

The present invention system is unique when compared with other known systems and solutions in that it provides simultaneous and instantaneous cardiac mapping on multiple relevant cardiac chamber surfaces (either atria or ventricles, epicardial and endocardial) from a single or a very limited number of heart beats using non-expandable catheters in concert with body surface electrodes. Once the desired cardiac geometry is constructed and available, either from a pre-stored and appropriately sized template (55), or from external imaging device, or from an on-site imaging device, or from limited point-to –point mapping by the operator, and registered into a common Cartesian space together with the measurement electrodes, the maps are computed in matter of seconds or minutes, according to the computing power available and algorithms used. This is achieved through a system of preferably a pair (or even a single catheter) or larger set of multi-polar electrode catheters that are non-expandable, at least one of them steerable and capable of delivering cardiac ablation, including cooled type ablation and force-feedback sensing [27], and all of them having usual bore access requirement to the patient's vessels (measured in French units, usually 3-8 Fr (1-2.7mm), see FIG. 4-7). The second or further catheter is a counter-laterally (typically straddling the inter-ventricular septum, see FIG. 8-10), around, along, or across-cardiac or vessel -wall placed catheter (see FIG. 11 and 12) thus sensing cardiac or tracking signals that secure broad enough coverage of cardiac signals in order to map multiple cardiac chambers and surfaces at a time simultaneously despite of an immediate distance of the sensing electrodes from the facing cardiac wall. (FIG. 10) This is achieved through placing the system of 1) body surface electrodes (in the preferred embodiment a limited set of 20-120 body surface electrodes is sufficient to pick up cardiac electricity and tracking signals, however according to some experimental data, even as small number as 9 electrodes may be useful, which is equivalent of a combination of 12-leads of the most common clinical ECG setting) and 2) catheter electrodes capable of sensing in all directions in space of both non-contact (far-field) and/or contact potentials inside the heart chambers or vessels and connecting them to the multichannel amplifier and the signal processor that process the electropotential signals (generated both by the heart and by the pacing/driving/tracking generator including aforementioned SEMD, or electromagnetic, impedance, fluoroscopic, or MRI-based tracking method), and pass the signals to the specialized computer software providing geometry reconstructions, forward transfer matrix, and inverse solution computations.

Novel forward (lead-field) matrix formulation

The described fast cardiac mapping is based upon regularized inversion of a newly and uniquely formulated lead-field matrix that includes non-invasive and invasive potential measurements. (FIG. 12 and 13) These measurements are realized through the aforementioned non-expandable catheters and body surface electrodes simultaneously. Formulations of the forward matrix and corresponding solutions follow:

$$A\vec{x}=\vec{b} \qquad (1)$$

Where *A* denotes forward matrix (lead-field matrix) of transfer coefficients, *x* denotes unknown source (i.e. sought solution in terms of potentials/voltage), *b* denotes measured voltage. In more detailed formulation of the forward matrix:

$$\begin{bmatrix} A\ noninv\ 11 & A\ noninv\ 12 & \dots & A\ noninv\ 1k \\ A\ noninv\ 21 & A\ noninv\ 22 & \dots & A\ noninv\ 2k \\ \vdots & \vdots & \dots & \vdots \\ A\ noninv\ m1 & A\ noninv\ m2 & \dots & A\ noninv\ mk \\ A\ inv\ 11 & A\ inv\ 12 & \dots & A\ inv\ 1k \\ A\ inv\ 21 & A\ inv\ 22 & \dots & A\ inv\ 2k \\ \vdots & \vdots & \dots & \vdots \\ A\ inv\ n1 & A\ inv\ n2 & \dots & A\ inv\ nk \end{bmatrix} \times \begin{bmatrix} x1 \\ x2 \\ \vdots \\ xk \end{bmatrix} = \begin{bmatrix} b\ noninv\ 1 \\ b\ noninv\ 2 \\ \vdots \\ b\ noninv\ m \\ b\ inv\ 1 \\ b\ inv\ 2 \\ \vdots \\ b\ inv\ n \end{bmatrix}$$

(2)

Where *m* denotes number of non-invasive measurement sites (body surface electrodes), *n* denotes cumulative number of invasive measurements sites (realized through catheter sensors), and *k* denotes number of source point (subset of points on the discretized – usually decimated/simplified cardiac surfaces). FIG. 13 shows the partial differential equations (Laplace equation) used by finite element solver in order to calculate the forward transfer coefficients.

Note that *n* (invasive rows) can cumulatively increase when more catheter sensor locations are taken into the mapping solution i.e. if the human operator chooses to move the catheter during measurement to new locations. (FIG. 15) Therefore, the ensuing inverse solution is possibly based upon a single beat or multiple beats of the target cardiac rhythm (be it arrhythmia or a baseline rhythm in the case of so called voltage mapping). In other words, by adding further intracardiac measurements $b_{inv\ nk}$ by moving the mapping catheter, new rows $A_{inv\ nk}$ are added to the forward lead-field matrix and inverse solution can be dynamically recomputed and improved. Eventually and optionally, there may be enough integrated intracardiac invasive non-contact and contact measurements available in order to disconnect mathematically the forward matrix (by matrix row deletion) from the body surface measurements and calculate inverse solutions that utilize small potentials, which do not reach sufficiently the body surface (like certain organized types of atrial fibrillation or flutter). Due to limiting boundary conditions, however, such inverse solution may be limited to only a single cardiac chamber according to where the roving catheter is placed (analogously to US patent 7505810, see prior art). Also note that inverse solution is possible that takes only invasive measurements as input from multiple catheters (like in the configuration on FIG. 11) provided there is broad enough coverage by accumulated sensor locations to allow for meaningful solution.

Inverse solution

With all above information in place, the system software performs mathematical construction of the maps using multiple algorithms of inverse solution including most notably deterministic methods like Tikhonov regularization [28], mathematical "brute-force" methods [21], regularization methods both spatial and spatiotemporal, linear and non-linear [17,29,30,31], including most recent and promising trans-membrane potential calculation methods [32,33] and optionally by purely non-invasive inverse electrocardiography (electrocardiographic imaging) based only on body surface measurements [26].

Inverse solution is well established scientifically and used industrially in practice for the above mentioned non-invasive electrocardiographic imaging [26,10,11,12,13] and in the case of expandable balloon or spline basket catheter systems [3,4,5,6]. In the case of the present invention, which uses non-expandable catheters, the inverse solution is achieved by constructing a different and innovative forward model (see FIG. 13 and above equation (2) (here exemplified for ventricular solution, which is of critical importance for the method) the technological core of the present invention. In this formulation, the non-expandable catheter electrodes and body surface electrodes represent measurement sites, and cardiac points that are subset of the respective surfaces (Γ_H) represent the electrical source for the cardiac mapping. In this model, the measurement electrodes sense either through contact or non-contact setting the electrical potential (measured voltage) generated by this subset of points. This helps estimating in a practically helpful way the shape and location of the activated region on the surface, which is a target for catheter ablation (FIG. 10). The electrical source for the forward solution is represented only by a subset of points on the target surfaces of the heart (typically counted in hundreds up to thousands of points) and does not even need to be spatially contiguous (FIG. 11 and 12), due to a discretization by finite element method involved in the construction of the model. This method allows for individual points of the physical model to be calculated independently (floating points, [17]). Such reconstructed (estimated) potential-based inverse solution can be used as initial step (initialization technique) for more complex spatiotemporal or activation-based inverse solutions or giving way for computation of activation times or direct computation of the cardiac trans-membrane potentials that utilize the same forward transfer matrix. These solutions then provide not only for cardiac activation maps but could also allow means for construction of so called voltage maps useful especially for scar and transmural mapping [34].

It is necessary to initiate some of these methods with an initial estimate of activation (or to supply the forward transfer lead-field matrix), therefore, for a complete cardiac (ventricular or atrial) activation map, the process has to be computed in successive steps, however, these are easily and quickly achieved through the computational framework of the present invention (see FIG. 14) in a matter of seconds up to minutes after recording the single beat or limited run of beats of the targeted cardiac rhythm and assembling the forward lead-field matrix (equation 2). Also, since the system allows for both non-contact and contact sensing/mapping, the computed inverse fast maps can be immediately improved/corrected through contact acquired electrical data. Such augmentation of inverse solution has been described in literature. [14,15,16]

Body surface potential mapping and interpolation (preferably by Laplacian interpolation) is a very useful part of this invention for its capability to faithfully reconstruct standard 12-lead ECG - a necessary part of every cardiac EP assessment – at any moment of the procedure. [35]

Localization and tracking of measuring electrodes

For the software to create correct maps, it is necessary to localize and track the catheters (optionally also to localize body surface electrodes) in relation to the heart and optionally also to each other. That is achieved preferably through electrical measurements like the SEMD-derived electrical potential on the body surface and by the catheters (voltage induced by injected tracking currents). These potentials induced through safely injected optionally modulated currents (in order of hundreds of hertz up to hundreds of kilohertz) into the body are measured by the same electrodes on the body surface or sensor electrodes on the catheters. The SEMD technology is well documented in literature (see prior art) and allows for better accuracy than impedance techniques that inject the current through the body surface location pads. This is due to the larger number of measurement sites represented by body surface electrodes. There is also important advantage against electromagnetic localization and tracking (CARTO, see prior art) in that the catheter electrodes get localized in relation to the electrodes that are attached to the body surface, therefore, the localization does not suffer from inadvertent movements of the patient body in relation the external electromagnetic locator.

Localization of the body surface electrodes is a specific issue. Body surface electrodes can be localized, in basic embodiment of this present invention, on the basis of appropriately sized model torso geometry (a template) and known anatomical landmarks in relation to the electrode positions. [36] In the most complete (and perhaps most accurate) version, this can be achieved by location sensors (wireless electromagnetic – like Nav sensors (US patent application 2004/0068178), or MPS/gMPS sensors or infrared) mounted on the electrodes (or electrode strips or electrode vest) or by imaging the electrode positions by surface scanner (shape detector) or medical imaging scanner or by other specific method (US patent 7190826 or similar). Another specific applicable solution is a geodesic net of electrodes described in the US patent 5291888 and subsequent related work.

Generally, catheter and electrode localization and tracking is also achievable by contrast X-ray rotational angiography, fluoroscopic computerized 3D localization (WO/2012/092016), X-ray registered MPS/gMPS (see prior art), CT imaging or by MRI (in MRI case, only if catheters are MRI-safe and supplied with specialized coils, see prior art).

Meshing and geometry construction, spatial registration and transformation, finite element model

The method of forward and inverse solution requires acquiring geometry information about the heart muscle and optionally about the torso surface and/or further internal organs of the human torso. The present invention allows for acquiring the critical geometries from the computer storage that are constructed as a part of the preferred embodiment of the present invention, or optionally from direct measurements taken either before or during the cardiac procedure (FIG. 1,2,3,10,14). Acquiring from the computer template poses less demand on the resources of the medical provider and less demand on the human patient undergoing further imaging procedures both before and during the cardiac procedure. Basic geometry templates including heart (55) and torso surfaces can be sized and transformed according to the individual patient parameters that are easily acquired by simple routine anthropometric measurements and other routine techniques (e.g. routine non-invasive cardiac ultrasound). Data published by the present inventor on purely non-invasive electrocardiographic imaging, collected geometries from unrelated individuals and reached surprisingly good result in locating activation focal source of arrhythmia from a thin walled structure of the outflow trunk of the right ventricle after a simple registration procedure. [36]. If cardiovascular imaging, however, is needed on the side of the human operator (physician), the invented system allows for doing so.

The cardiac template geometries (e.g. like the one on the FIG. 10) can be parameterized by chamber sizes (diastolic diameters, volumes, and wall thickness). The geometry needs to be anchored in the working Cartesian space, which is readily achieved through routinely acquiring selected points in space (e.g. His bundle electrogram site, coronary sinus catheterization, and pulmonary vein catheterization) and point or surface collocation/registration. (FIG. 15) Such algorithms are widely available and can use segmented imaging output from cardiovascular ultrasound (including intracardiac invasive echocardiography, magnetic resonance imaging –MRI, computed tomography – CT, or X-ray contrast/rotational angiography. Such spatial registration is performed either by the human operator (physician) who acquires routinely familiar points in space defined typically through acquiring specific signals like His bundle electrogram, atrio-ventricular ring signals, coronary sinus signals, pulmonary veins signals [1] and locations and points acquired during conventional electroanatomical mapping, or during image fusion when the operator acquires external images or templates from the computer storage. The geometries can be optionally represented by deformable meshes that can be adapted during the process of cardiac mapping and registration procedure if needed by operator esp. through contact mapping.

This way, the human operator is presented with the cardiac surface (patient-specific or appropriately sized template) from the beginning of the procedure as opposed to the prior art systems. This way, registration and transformation of the heart surface by SEMD (or by other method) located catheter is performed in order to register the geometry in Cartesian space (by above collocating familiar endocardial or vascular sites) and to account for changes of size and shape of the cardiac geometry due to specific clinical condition (e.g. ectopic arrhythmia that can dilate or slightly shift the heart in space away from the location acquired during off-site cardiac imaging like CT or MRI). A standard geometric transform 4x4 matrix can be re-computed instantaneously for each new contact site. At least 3-4 such contact points (preferably far apart) are necessary to calculate a valid standard transform matrix. Each new catheter position and mesh transformation also serves for eventual re-computing of the inverse solution and acquiring contact and non-contact unipolar and bipolar ECG from the catheter sensors if needed. (FIG. 15)

Once the cardiac geometry is in place properly registered and transformed (preferably a high resolution realistic surface, or realistic template (55) surface) the inverse solution can be computed preferably on the subset points of a decimated low resolution surface (FIG. 10) or even isolated floating points. The choice is dependent on the optional inverse solution algorithm (see above) esp. with regard to the optional regularization matrix or other regularization term used.

On the note of torso surface and internal structure/geometry, if no complete torso imaging is available (MRI, CT), then simple model-based template torso registration and transformation (scaling) procedure can be performed on the basis of known anatomical landmarks [36]. If such imaging is available, a complete finite element model can be built including conductivity inhomogeneities. Examples of such models are widely available in the literature including the appropriate stiffness matrix formulations [17]. It is to be emphasized that finite element model is not the only possible method of obtaining the forward matrix transfer coefficients, for it is possible to calculate them by boundary element or finite difference methods.

In conclusion on the functional improvement, this invention allows assistance and improvement (speeding up, decreased invasiveness) to all currently performed types of catheter arrhythmia mapping and ablation. This invention poses no additional demand on human operator (physician) dexterity and endurance than current technologies or more risk on the patient or operator. On the contrary, when compared to the previous basket or balloon expandable catheters, the manoeuvrability of the present invention components - multipolar and steerable catheters - is superior and also directly capable of delivering ablation energy (typically radiofrequency). This invention does not prevent the human operator from using important traditional techniques at any time without compromising the procedure through distracting his/her attention from important information provided by such techniques (like contact bipolar electroanatomical mapping, pacing techniques and manoeuvres, measurement of cardiac intervals and amplitudes, FIG. 14) and still providing new valuable information (fast cardiac maps, realistic geometries) on timely basis. On the other hand, the present invention constitutes an ideal platform for navigation and guidance for emerging remote and robotic technologies in the field of cardiac electrophysiology [37,38].

Present invention system structure is unique due to the presence of:

Electrode catheters, their use and construction

1. Non-expandable, steerable, multi-polar electrode catheters that are suitable for ablation, mapping, and working in concert with another multi-polar electrode catheter through the amplifier, signal processor and software integrator providing inverse solutions dependent primarily on limited body surface recordings (20 – 120 electrodes), using simultaneous input from all these electrodes.
2. The catheter electrodes that are placed within the heart and vessels the way that they embrace or straddle at least one structure containing the heart muscle (septum or other cardiac muscle wall) leading to specific mapping configurations (see FIG. 8, 9,11,12, and 13) that in turn do not differ from what are the human operators (physicians) are used to.
3. The construction of multi-polar electrode catheters that utilizes combination of standard catheter electrodes (see FIG. 4 and 5), electrodes that combine the standard design with electrodes that form spatially diverse dipoles (see FIG. 5 and 6) and multitude of miniature electrodes placed in spatially defined 3 or 2 lines (see FIG. 5, 6 and 7) along the circumference and along the shaft of the catheters to provide unipolar [1] sensing of far-field non-contact potentials , together with common standard catheter electrodes arranged both for commonly used contact both unipolar and bipolar [1] sensing of cardiac potentials, and used also for far-field non-contact sensing
4. Selected pairs of catheter electrodes that form dipoles for injecting pacing and locating current into the volume conductor of the cardiac chambers and torso, and that also form standard electrodes on each of the distal catheter tips used for contact sensing and delivering ablation energy into the cardiac muscle. (see FIG. 6 and 7) The said dipoles are arranged such that the SEMD signal allow for tracking most of the possible movements by the operator (human or robotic) be it advancement, withdrawal, rotation and steering (bending) the catheter shaft.

5. Combination of standard manufactured multi-polar electrode catheter(s) allowing both contact and far-field non-contact sensing together with body surface electrodes, and together with pairs of selected catheter electrodes forming dipoles for injecting pacing and locating current into the volume conductor of the cardiac chambers and torso, and also forming standard electrode on the catheter tip used for contact sensing and delivering ablation energy into the cardiac muscle.
6. Electrode catheters that do not pose any particularly new unusual handling of these instruments
7. Electrode catheters that, besides above described, can accommodate for construction of designs that has already proved its usefulness like soft tip catheters used for magnetic steering and navigation (Stereotaxis), specially shaped catheters (Lasso and similar), and catheters equipped with liquid cooling, contact force sensing, and temperature sensing. [27]
8. Electrode catheters that, besides above described, can be localized and tracked by a system using location pads (impedance techniques in the prior art) and currents injected through these location pads, or by a system using externally imposed electromagnetic field generator through embedded navigation sensors into the said catheters (see prior art, Nav sensors, MPS/gMPS sensors), or by computerized 3D fluoroscopic localization (see prior art) or by combination of all said localization and tracking methods including SEMD method.

It is to be emphasized that the above electrode catheter structures and designs are not exclusive but only preferred. The structures can optionally include expandable catheters including contact basket catheters if deemed necessary in specific situations (atrial fibrillation mapping [39]). As was previously mentioned, the fast cardiac mapping algorithm (FIG. 14) takes into account both contact and non-contact measurements.

Body surface electrodes

Body surface electrodes may not differ from standard ECG electrodes, particularly stressing usual need for radiolucent (i.e. carbon based) design, in order not to obscure optional X-ray imaging during EP procedures and non-metallic or MRI-safe materials for the case of MRI compatibility. Standalone individual electrodes have an advantage of being the least obtrusive to the additional necessary elements of the EP procedures placed onto the body surface like defibrillation patches, current injecting location pads, other instrumentation requiring space for access like pericardial puncture, subclavian puncture or similar. The main advantage of optional strip-mounted electrodes is a defined (preferably vertical) spacing esp. with regard to the preferred embodiment of the system without specific technology for localization of the electrodes. Also, electrode strips allow for optional locating elements/sensors (infrared or wireless/electromagnetic) to be mounted on the strips.

Notable advantage of the preferred SEMD catheter tracking technology is that there is no need for additional location pads on the body surface since the location signals are picked up by the body surface ECG electrodes. Such location pads are rather large and space-occupying without capability of effectively map the ECG signal. The integral body surface electrode array is conversely completely sufficient for reconstruction of the 12-lead ECG as an integral part of the system and therefore no additional chest electrodes are necessary. [35] Optionally, the system can accommodate a locatable body surface vest with high density electrode array (up to hundreds of electrodes, see prior art). Optionally, the body surface electrodes can be located by a combination of above mentioned methods/technologies.

A plurality of body electrodes are required to undertake the cardiac mapping of the present invention. The number of body electrodes is not critical but can range from as few as 9 electrodes to several hundred. The choice of the number of electrodes used balances producing too little data from a small number of electrodes with too much data, making the data processing difficult, from a large number of electrodes. The number of electrodes is preferably between 20 and 120 and most preferably between 40 and 60.

Pacing/locating/tracking generator

The generator is an integral part of the system. Pacing generator is a necessary component of any EP equipment. The innovative part and function is the SEMD compatible circuitry for generating modulated sinusoid signal (in order of hundreds of hertz up to hundreds of kilohertz) or pulses or similar patient-safe signal suitable for locating and tracking catheter electrodes and optionally also body surface electrodes. Since the purpose of the signal is to locate and track not only the tip dipole electrodes but also catheter shaft position, rotation and steering/bending movement, the signal has to be distributed among the other location poles (dipoles) in sufficient frequency by multiplexed sequences.

Optionally, the system is not limited only to an SEMD locator and can accommodate standard impedance/current based location apparatus necessitating placing the location pads on the body surface or electromagnetic wireless locator using exterior (extracorporeal) antenna transmitters and catheter/electrodes-mounted navigation sensors with miniature coils (see prior art) or a combined locator.

Optionally, additional instruments can be adapted for use with SEMD generator, (trans-septal needle or similar) by making small adaptations of their design by mounting miniature dipole-like electrode elements for localization and tracking.

System scalability

The system structure is uniquely scalable, according to the functionality needs on the side of operator (physician, technologist). In the most basic setting, the system resembles typical contemporary mapping and navigation system with the substantial qualitative improvement of the prompt availability of cardiac maps merged onto template (60) or pre-acquired geometries preferably on the basis of a single beat of the targeted arrhythmia or voltage maps acquired during any cardiac rhythm. In at least two stepwise structurally more complex settings, the system allows to additionally construct fast cardiac maps either on the pre-acquired or on-site generated anatomical geometries (e.g. echo-warped surfaces) through available imaging and scanning devices. [40]

While the present invention has been described above in terms of specific embodiments, it is to be understood that the invention is not limited to these disclosed embodiments. Upon reading the teachings of this disclosure many modifications and other embodiments of the invention will come to mind of those skilled in the art to which this invention pertains, and which are intended to be and are covered by both this disclosure and the appended claims. It is indeed intended that the scope of the invention should be determined by proper interpretation and construction of the appended claims and their legal equivalents, as understood by those of skill in the art relying upon the disclosure in this specification and the attached drawings.

ADDITIONAL INFORMATION

Respiration compensation can be considered important component of the system. Several approaches were published and also proprietary solutions are in place (also system components of the prior art cited).

Forward transfer matrix of the preferred embodiments is time-invariant with regard to the cardiac cycle, the proposed system solves only depolarization when the heart is not moving and the model is therefore quasi static. Nevertheless, the presented solution can be extended toward cardiac repolarization by introducing time-variant forward matrix.

The present invention allows for measurement of individual conductivities, especially to establish relative conductivity of blood mass in relation to extracardiac torso conductivity.

The present invention is preferably used in cardiac arrhythmia ablation procedures that utilize removable catheters; however, various instalments can be constructed e.g. toward cardiac pacemakers and defibrillators, including cardiac resynchronization therapy. Generally speaking, any industrial electronic system capable of connecting intra-cardiac multi-polar leads with computer software and with body surface leads can be constructed with the present invention components including the above presented combined invasive/non-invasive forward matrix and inverse solution algorithms. Catheter location and tracking can be accomplished various ways in relation to the body surface electrodes or even mutually without using body surface electrodes like in the Siemens US patent 7792564 about mutual catheter location determination using electricity.

The system may also serve training and demonstration purposes as a mock up, or a model for training of EP specialists.

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Claims

1. An apparatus for mapping the electrical activity of a heart, the apparatus comprising:-

at least one processor for receiving and processing data received from a plurality of electrodes;

at least one catheter, for insertion into a heart, the catheter having at least one catheter electrode for measuring electrical signals, at least one said catheter electrode producing catheter electrode data signals for passing to said processor;

at least one catheter locator for determining the locations of the or each catheter electrode within the heart; and

a plurality of body electrodes for placement on a living body containing the heart and for measuring electrical signals, said electrodes placed in known locations relative to each other on the living body and producing body electrode data signals for passing to said processor,

wherein said processor combines, on the basis of at least one inverse solution matrix, said catheter electrode data signals and their locations and said body electrode data signals and their locations to produce electrical activity mapping data relating to the heart.

2. An apparatus according to claim 1, wherein said catheter comprises a non-expandable catheter.

3. An apparatus for mapping the electrical activity of a heart, the apparatus comprising:-

at least one processor for receiving and processing data received from a plurality of electrodes;

at least one non-expandable catheter, for insertion into a heart, the catheter having at least one catheter electrode for measuring electrical signals, at least one said catheter electrode producing catheter electrode data signals for passing to said processor;

at least one catheter locator for determining the locations of the or each catheter electrode within the heart; and

a plurality of body electrodes for placement on a living body containing the heart and for measuring electrical signals, said electrodes placed in known locations relative to each other on the living body and producing body electrode data signals for passing to said processor,

wherein said processor combines said catheter electrode data signals and their locations and said body electrode data signals and their locations to produce electrical activity mapping data relating to the heart.

4. An apparatus according to claim 3, wherein said processor combines said data on the basis of at least one inverse solution matrix.

5. An apparatus according to any of the preceding claims, wherein said catheter comprises a catheter body in the form of an elongate member, the catheter body adapted to be manoeuvred within blood vessels of said living body so as to extend at least partially into a heart in said living body and a plurality of said electrodes arranged along the length of said catheter body.

6. An apparatus according to claim 5, wherein said plurality of catheter electrodes comprise:-

at least one first catheter electrode extending circumferentially around said catheter body; and

at least one plurality of second catheter electrodes arranged circumferentially around said catheter body.

7. An apparatus according to any of the preceding claims, wherein at least one said catheter comprises ablation means for causing ablation of tissue adjacent said catheter.

8. An apparatus according to any of the preceding claims, wherein at least one said catheter electrode comprises a tracking electrode for providing a tracking current.

9. An apparatus according to any of the preceding claims, further comprising a sheet of a flexible material containing said body electrodes.

10. An apparatus according to claim 10, further comprising a garment formed from said flexible material.

11. An apparatus according to any of the preceding claims, wherein said processor produces a voltage map of the heart.

12. An apparatus according to any of claims 2 to 11, wherein said matrixes are combined using a dynamic lead-field matrix formulation.

13. An apparatus according to any of claims 2 to 12, wherein said matrixes are combined using the following formula

$$\begin{bmatrix} A\ noninv\ 11 & A\ noninv\ 12 & \dots & A\ noninv\ 1k \\ A\ noninv\ 21 & A\ noninv\ 22 & \dots & A\ noninv\ 2k \\ \vdots & \vdots & \dots & \vdots \\ A\ noninv\ m1 & A\ noninv\ m2 & \dots & A\ noninv\ mk \\ A\ inv\ 11 & A\ inv\ 12 & \dots & A\ inv\ 1k \\ A\ inv\ 21 & A\ inv\ 22 & \dots & A\ inv\ 2k \\ \vdots & \vdots & \dots & \vdots \\ A\ inv\ n1 & A\ inv\ n2 & \dots & A\ inv\ nk \end{bmatrix} \times \begin{bmatrix} x1 \\ x2 \\ \vdots \\ xk \end{bmatrix} = \begin{bmatrix} b\ noninv\ 1 \\ b\ noninv\ 2 \\ \vdots \\ b\ noninv\ m \\ b\ inv\ 1 \\ b\ inv\ 2 \\ \vdots \\ b\ inv\ n \end{bmatrix}$$

where *A* denotes lead-field transfer matrix

x denotes unknown source values (sought values)

b denotes measured known values

m denotes the number of body electrodes at known locations,

n denotes the cumulative number of catheter electrodes at known acquired locations (see multi-beat integration, catheter tracking),

k denotes number of source points on the manifold surface of the heart ventricles or atria that are both on endocardium (inner chamber surface) and epicardium (outer heart surface).

14. An apparatus according to any of the preceding claims, wherein said processor further processes said electrical activity mapping data to display a map of electrical activity of the heart on a display device.

15. A method of mapping the electrical activity of a heart, comprising the steps of:-

creating a data connection between a plurality of electrodes and at least one processor, the processor for receiving and processing data received from said plurality of electrodes;

inserting at least one non-expandable catheter into a heart, the catheter having at least one catheter electrode for measuring electrical signals, at least one said catheter electrode producing catheter electrode data signals for passing to said processor;

determining the locations of the or each catheter electrode within the heart; and

placing, in known locations relative to each other on the living body containing the heart, a plurality of body electrodes for measuring electrical signals and producing body electrode data signals for passing to said processor,

combining said catheter electrode data signals and their locations and said body electrode data signals and their locations to produce electrical activity mapping data relating to the heart.

16. A method according to claim 15, wherein said data is combined on the basis of at least one inverse solution matrix.

17. A method of mapping the electrical activity of a heart, comprising the steps of:-

creating a data connection between a plurality of electrodes and at least one processor, the processor for receiving and processing data received from said plurality of electrodes;

inserting at least one non-expandable catheter into a heart, the catheter having at least one catheter electrode for measuring electrical signals, at least one said catheter electrode producing catheter electrode data signals for passing to said processor;

determining the locations of the or each catheter electrode within the heart; and

placing, in known locations relative to each other on the living body containing the heart, a plurality of body electrodes for measuring electrical signals and producing body electrode data signals for passing to said processor,

combining, on the basis of at least one inverse solution matrix, said catheter electrode data signals and their locations and said body electrode data signals and their locations to produce electrical activity mapping data relating to the heart.

18. A method according to claim 17, wherein said catheter comprises a non-expandable catheter.

19. A method according to any of claims 15 to 18, further comprising ablating portions of the heart wall in response to the mapped data.

20. A method according to any of claims 15 to 19, further comprising applying a tracking current to at least one catheter electrode and gathering and processing data from said body electrodes to determine the location of said catheter electrode.

21. A method according to any of claims 15 to 20, wherein said processor produces a voltage map of the heart.

22. A method according to any of claims 16 to 21, wherein said matrixes are combined using a dynamic lead-field matrix formulation.

23. A method according to any of claims 16 to 22, wherein said matrixes are combined using the following formula

$$\begin{bmatrix} A\,noninv\,11 & A\,noninv\,12 & \dots & A\,noninv\,1k \\ A\,noninv\,21 & A\,noninv\,22 & \dots & A\,noninv\,2k \\ \vdots & \vdots & \dots & \vdots \\ A\,noninv\,m1 & A\,noninv\,m2 & \dots & A\,noninv\,mk \\ A\,inv\,11 & A\,inv\,12 & \dots & A\,inv\,1k \\ A\,inv\,21 & A\,inv\,22 & \dots & A\,inv\,2k \\ \vdots & \vdots & \dots & \vdots \\ A\,inv\,n1 & A\,inv\,n2 & \dots & A\,inv\,nk \end{bmatrix} \times \begin{bmatrix} x1 \\ x2 \\ \vdots \\ xk \end{bmatrix} = \begin{bmatrix} b\,noninv\,1 \\ b\,noninv\,2 \\ \vdots \\ b\,noninv\,m \\ b\,inv\,1 \\ b\,inv\,2 \\ \vdots \\ b\,inv\,n \end{bmatrix}$$

where *A* denotes lead-field transfer matrix

x denotes unknown source values (sought values)

b denotes measured known values

m denotes the number of body electrodes at known locations,

n denotes the cumulative number of catheter electrodes at known acquired locations (see multi-beat integration, catheter tracking),

k denotes number of source points on the manifold surface of the heart ventricles or atria that are both on endocardium (inner chamber surface) and epicardium (outer heart surface).

24. A method according to any of claims 15 to 23, wherein said processor further processes said electrical activity mapping data to display a map of electrical activity of the heart on a display device.

25. A catheter for use in an apparatus for mapping the electrical activity of a heart, the catheter comprising:-

a catheter body in the form of an elongate member, the catheter body adapted to be manoeuvred within blood vessels of a living body so as to extend at least partially into a heart in said living body,

at least one first electrode extending circumferentially around said catheter body the or each first electrode for detecting electrical signals and relaying said signals to a signal processor; and at least one plurality of second electrodes arranged circumferentially around said catheter body each second electrode for detecting electrical signals and relaying said signals to a signal processor and/or for delivering tracking current.

26. An apparatus for mapping the electrical activity of a heart substantially as hereinbefore described with reference to the accompanying drawings.

27. A method of mapping the electrical activity of a heart substantially as hereinbefore described with reference to the accompanying drawings.

28. A catheter for use in an apparatus for mapping the electrical activity of a heart substantially as hereinbefore described with reference to the accompanying drawings.

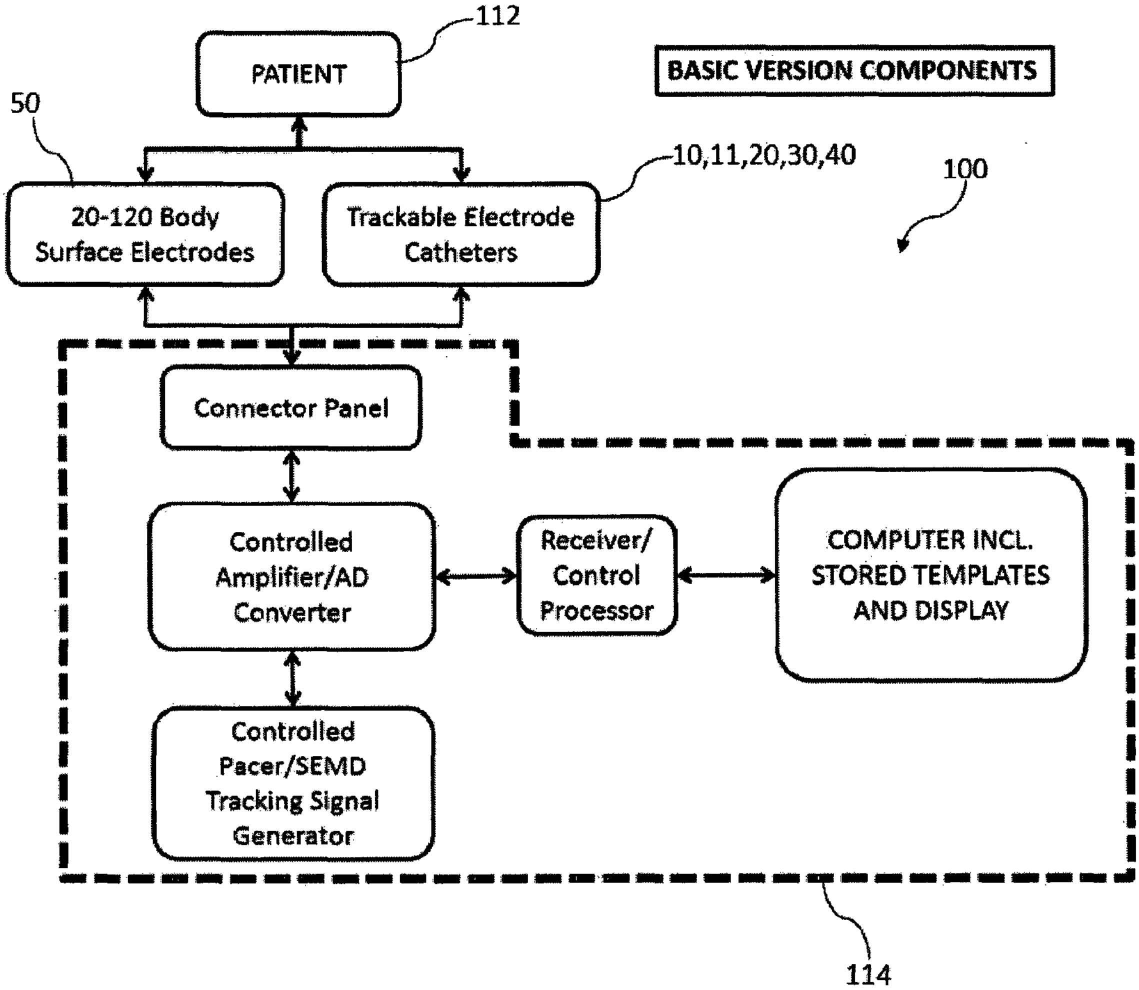

112
PATIENT
BASIC VERSION COMPONENTS
50
10,11,20,30,40
100
20-120 Body Surface Electrodes
Trackable Electrode Catheters
Connector Panel
Controlled Amplifier/AD Converter
Receiver/ Control Processor
COMPUTER INCL. STORED TEMPLATES AND DISPLAY
Controlled Pacer/SEMD Tracking Signal Generator
114

FIG. 1

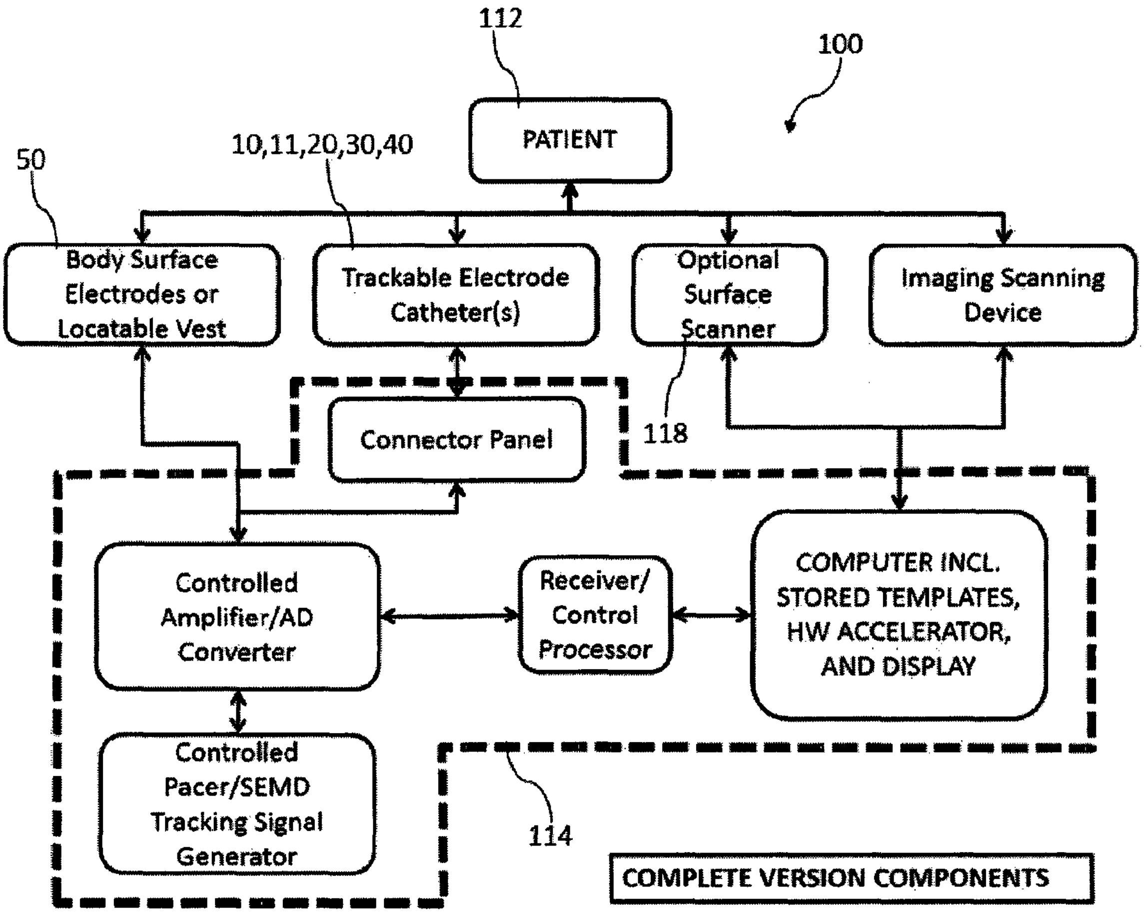

112
100
PATIENT
50
10,11,20,30,40
Body Surface Electrodes or Locatable Vest
Trackable Electrode Catheter(s)
Optional Surface Scanner
Imaging Scanning Device
Connector Panel
118
Controlled Amplifier/AD Converter
Receiver/ Control Processor
COMPUTER INCL. STORED TEMPLATES, HW ACCELERATOR, AND DISPLAY
Controlled Pacer/SEMD Tracking Signal Generator
114
COMPLETE VERSION COMPONENTS

FIG. 2

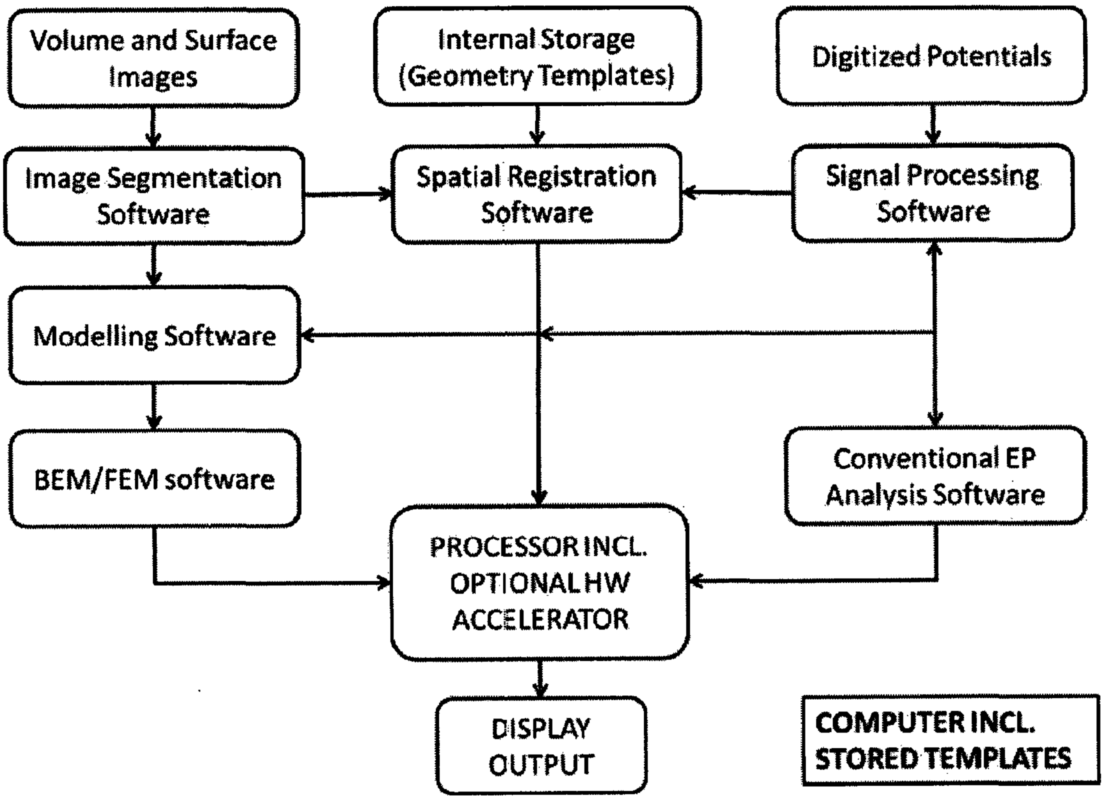

Volume and Surface Images
Internal Storage (Geometry Templates)
Digitized Potentials
Image Segmentation Software
Spatial Registration Software
Signal Processing Software
Modelling Software
BEM/FEM software
Conventional EP Analysis Software
PROCESSOR INCL. OPTIONAL HW ACCELERATOR
DISPLAY OUTPUT
COMPUTER INCL. STORED TEMPLATES

FIG. 3

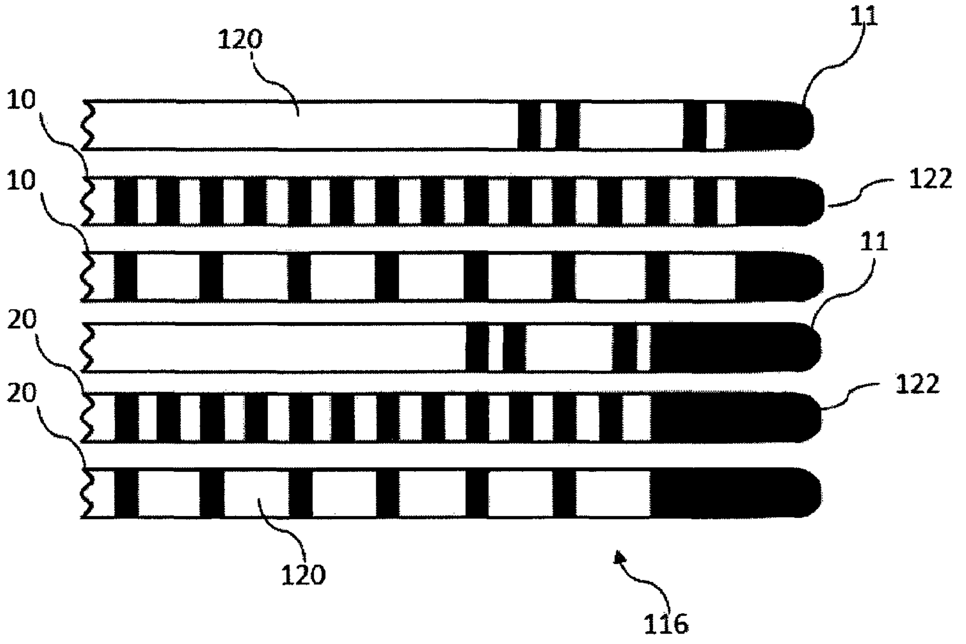

11
120
10
10
122
11
20
122
20
120
116

FIG. 4

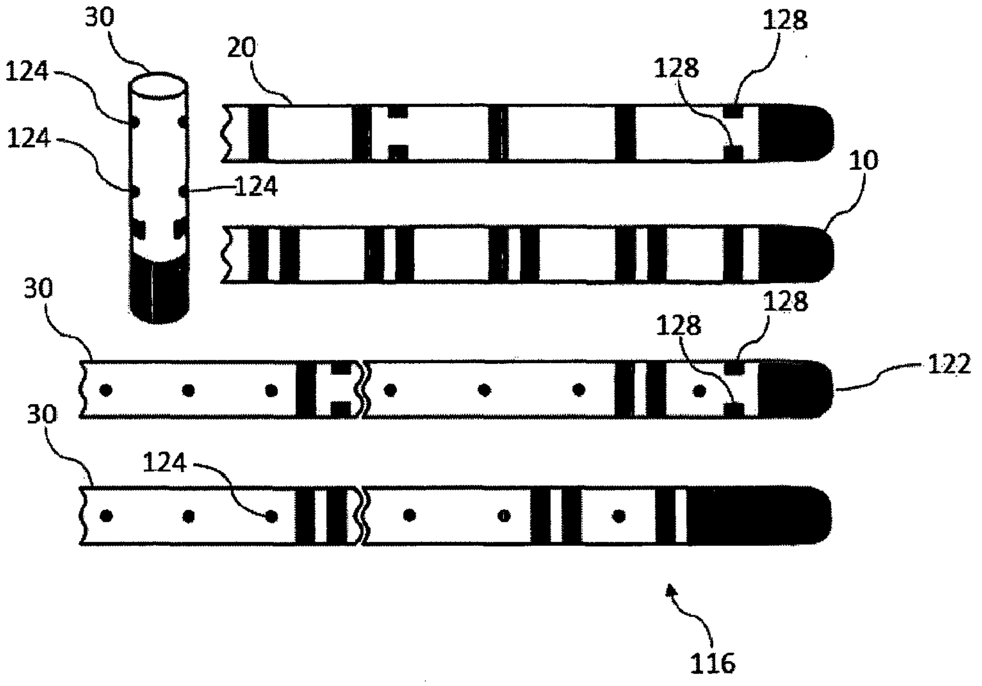

30
124
124
20
128
128
10
124
30
128
128
122
30
124
116

FIG. 5

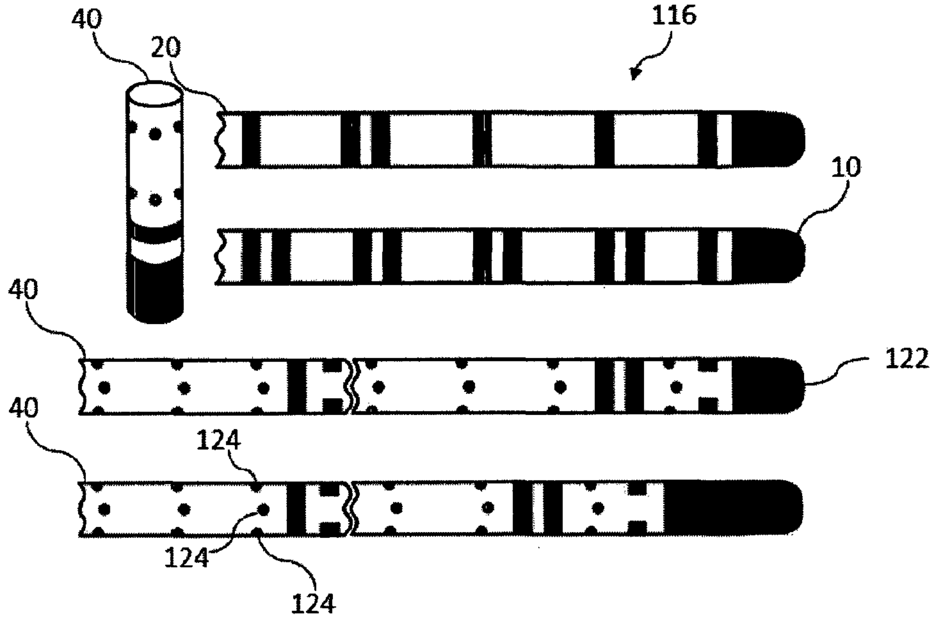

40
20
116
10
40
122
40
124
124
124

FIG. 6

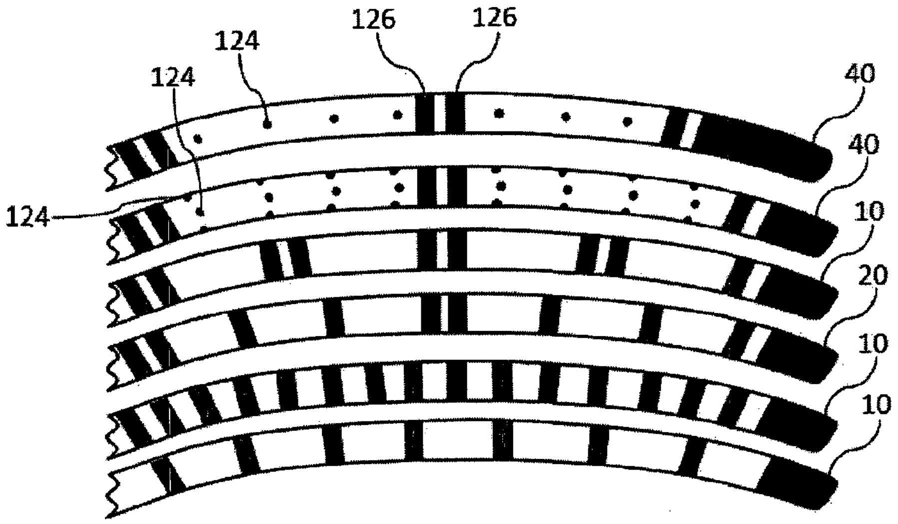

124
124
126
126
40
40
124
10
20
10
10

FIG. 7

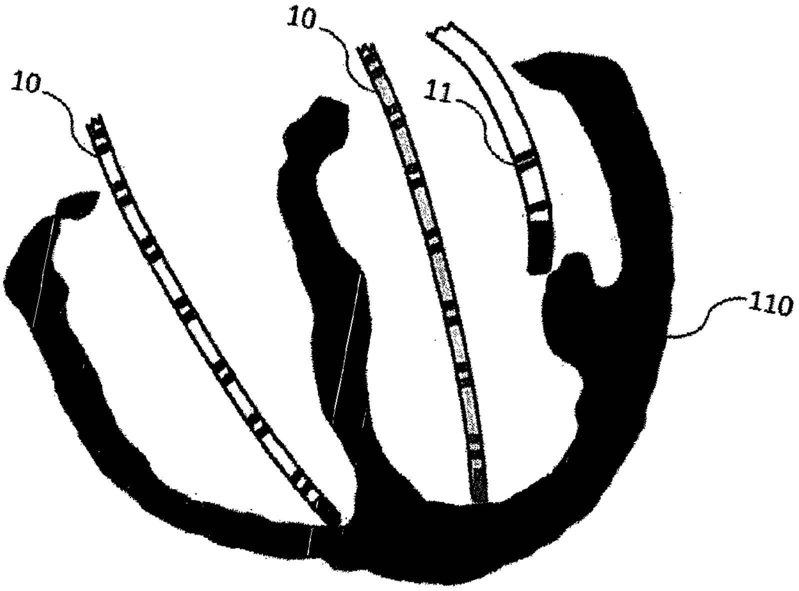


FIG. 8

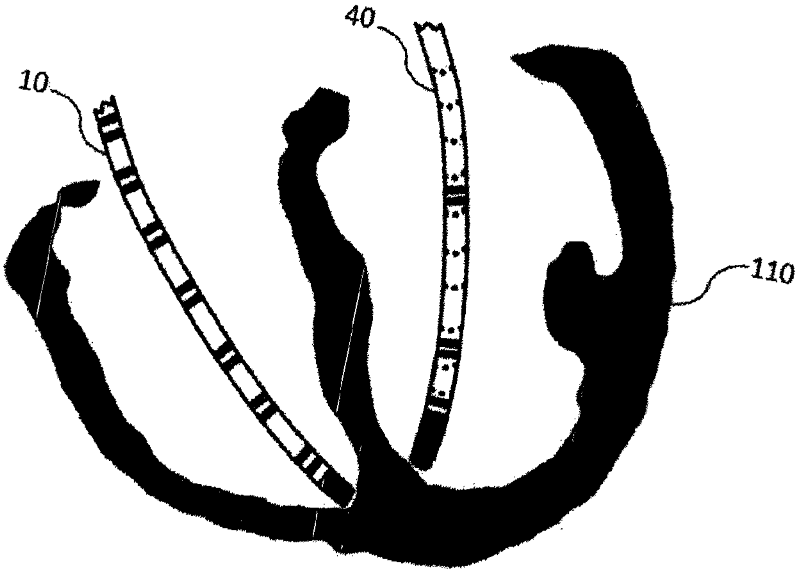


FIG. 9

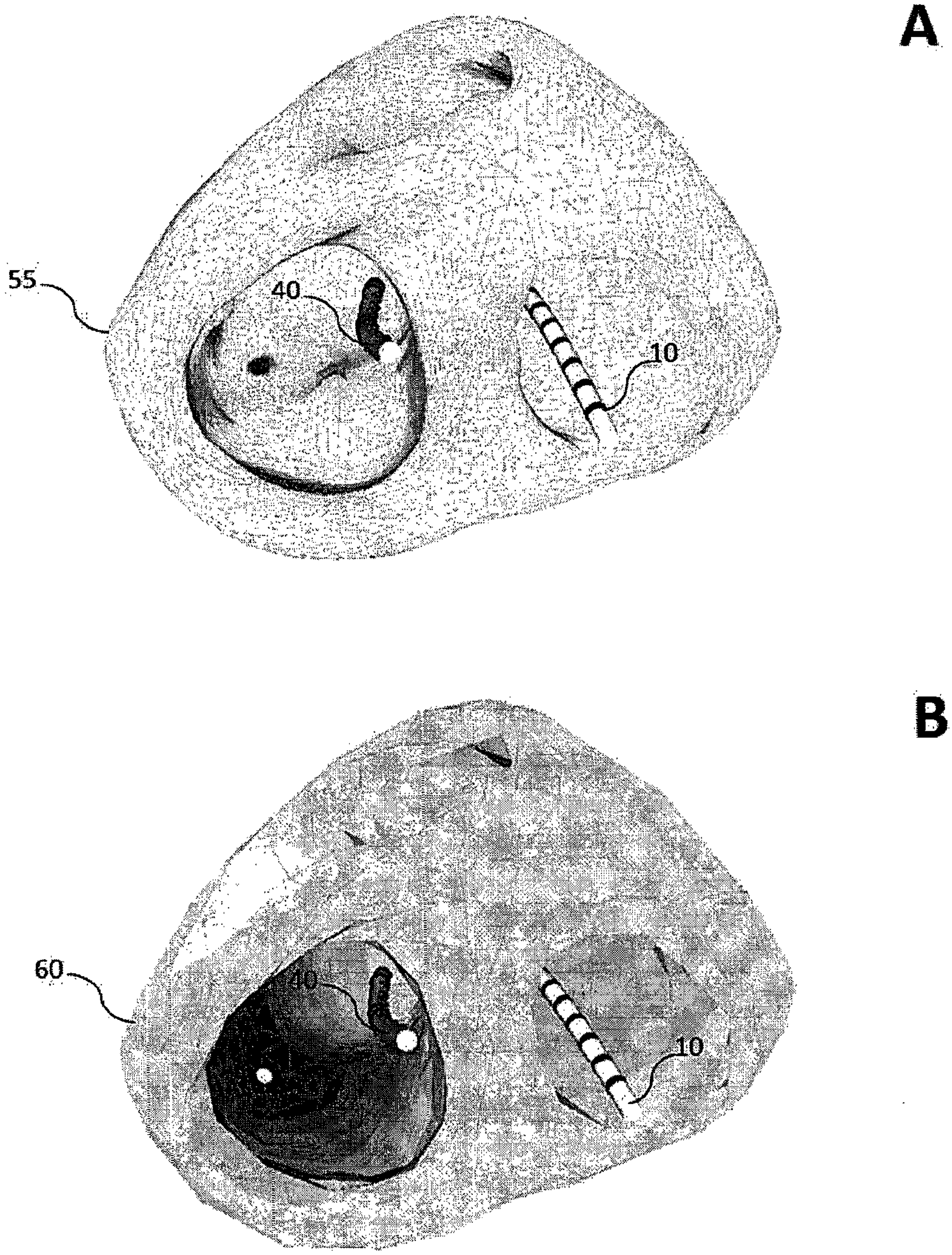


FIG.10

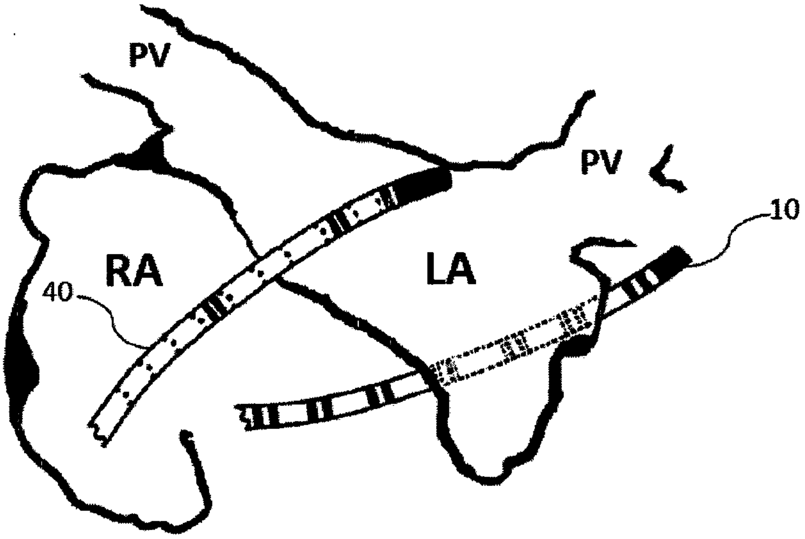


FIG. 11

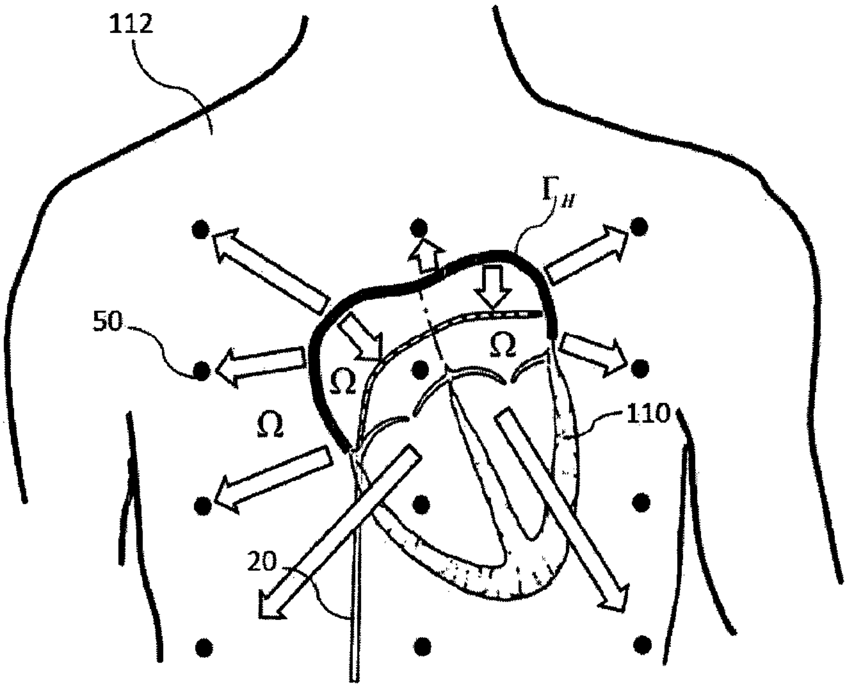
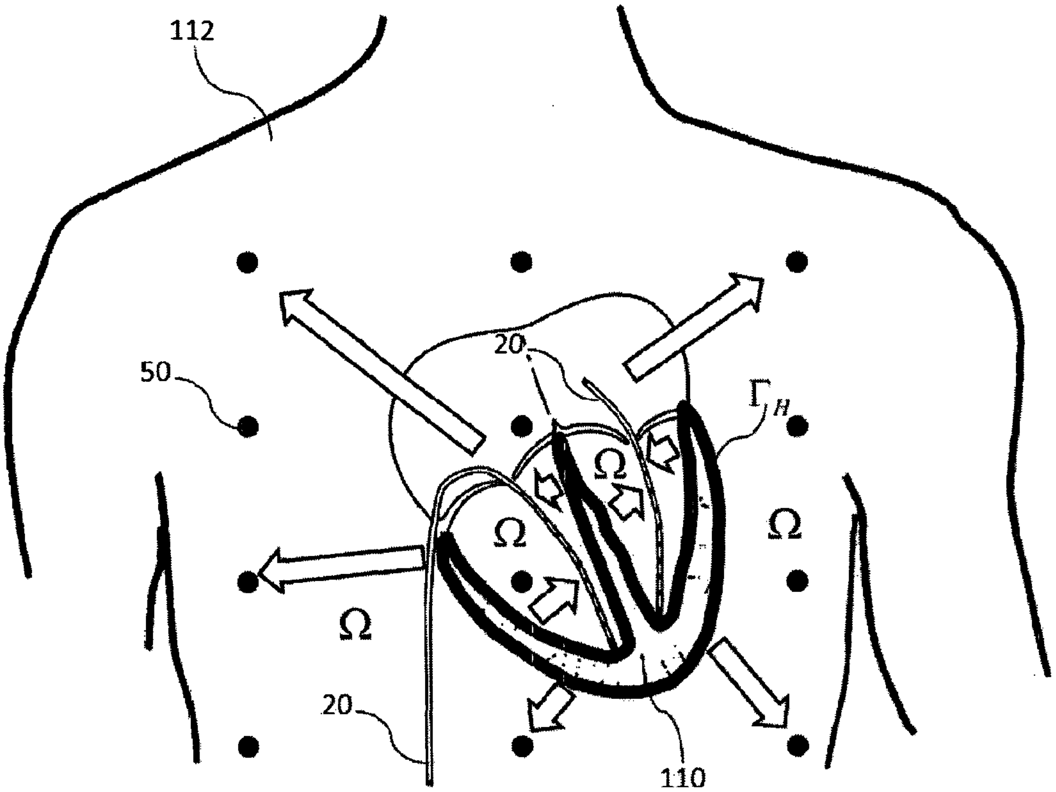


FIG. 12



$$\boxed{\nabla \cdot (\sigma(x) \nabla u(x)) = 0, \quad x \in \Omega}$$

$$\boxed{u(x) = u_H, \quad x \in \Gamma_H}$$

FIG. 13

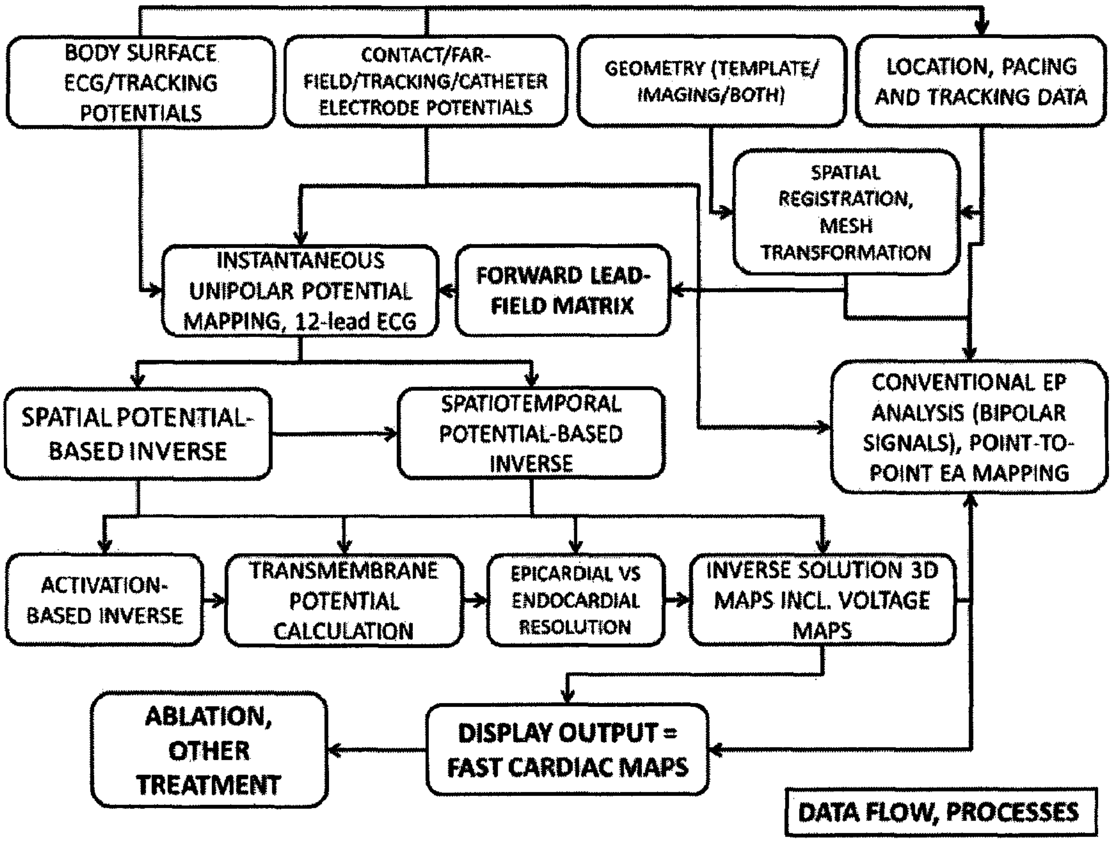

BODY SURFACE ECG/TRACKING POTENTIALS
CONTACT/FAR-FIELD/TRACKING/CATHETER ELECTRODE POTENTIALS
GEOMETRY (TEMPLATE/ IMAGING/BOTH)
LOCATION, PACING AND TRACKING DATA
SPATIAL REGISTRATION, MESH TRANSFORMATION
INSTANTANEOUS UNIPOLAR POTENTIAL MAPPING, 12-lead ECG
FORWARD LEAD-FIELD MATRIX
SPATIAL POTENTIAL-BASED INVERSE
SPATIOTEMPORAL POTENTIAL-BASED INVERSE
CONVENTIONAL EP ANALYSIS (BIPOLAR SIGNALS), POINT-TO-POINT EA MAPPING
ACTIVATION-BASED INVERSE
TRANSMEMBRANE POTENTIAL CALCULATION
EPICARDIAL VS ENDOCARDIAL RESOLUTION
INVERSE SOLUTION 3D MAPS INCL. VOLTAGE MAPS
ABLATION, OTHER TREATMENT
DISPLAY OUTPUT = FAST CARDIAC MAPS
DATA FLOW, PROCESSES

FIG. 14

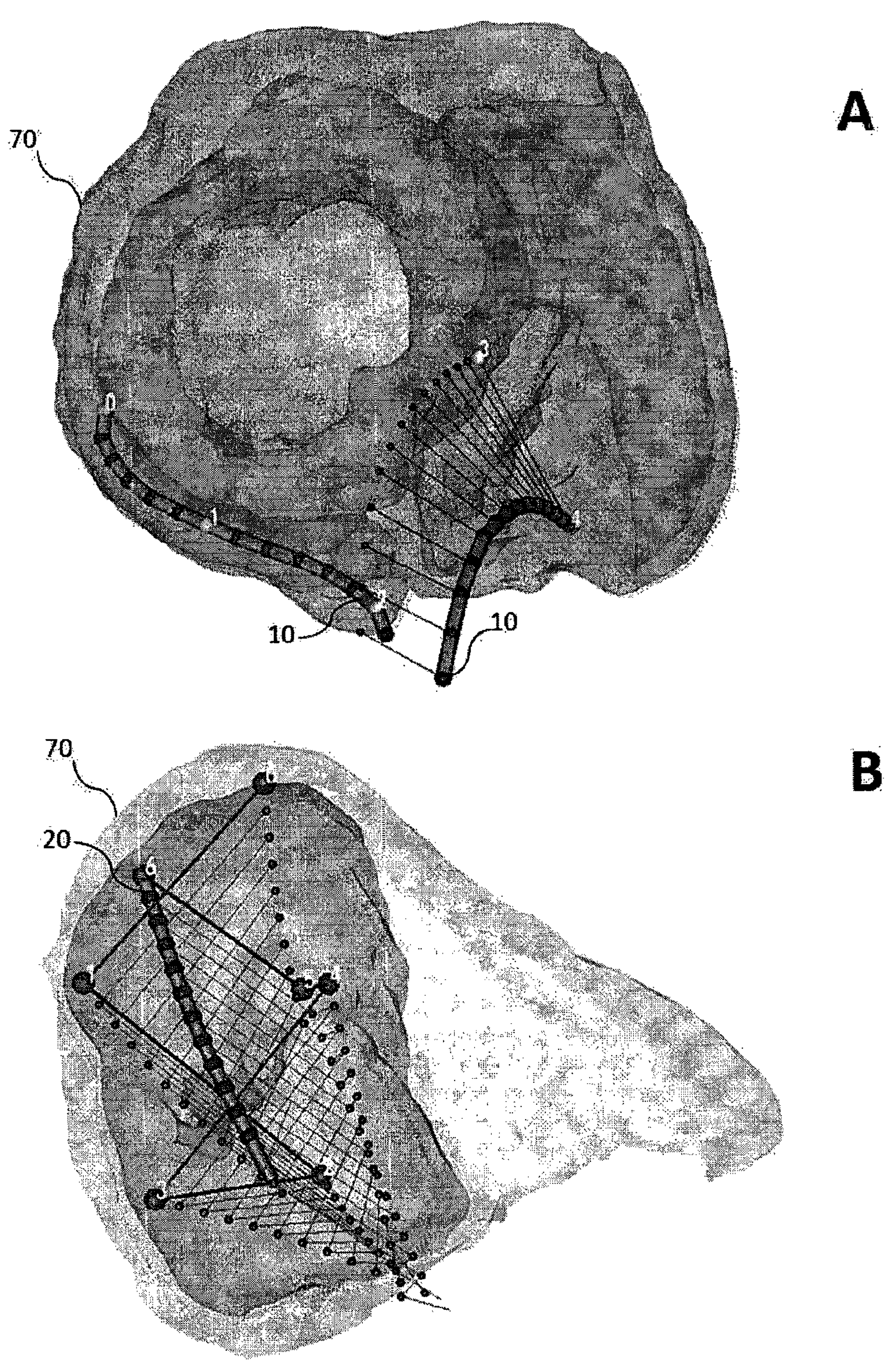


FIG. 15