



(51) International Patent Classification:

A61B 5/06 (2006.01) A61M 25/01 (2006.01)
A61B 5/042 (2006.01) G06T 15/00 (2011.01)
A61B 5/00 (2006.01) A61B 5/0402 (2006.01)
G06F 19/00 (2011.01) A61B 5/0452 (2006.01)

(21) International Application Number:

PCT/IB2016/000929

(22) International Filing Date:

30 June 2016 (30.06.2016)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

00961/15 2 July 2015 (02.07.2015) CH

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(81) Designated States (unless otherwise indicated, for every
kind of national protection available): AE, AG, AL, AM,
AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY,
BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM,

DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT,
HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR,
KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG,
MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM,
PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC,
SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN,
TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every
kind of regional protection available): ARIPO (BW, GH,
GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ,
TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU,
TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE,
DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU,
LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK,
SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ,
GW, KM, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

- as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))
- of inventorship (Rule 4.17(iv))

Published:

- with international search report (Art. 21(3))

(54) Title: SYSTEM AND METHOD FOR PROVIDING A REPRESENTATION OF CARDIAC CELL CHARGE STATE

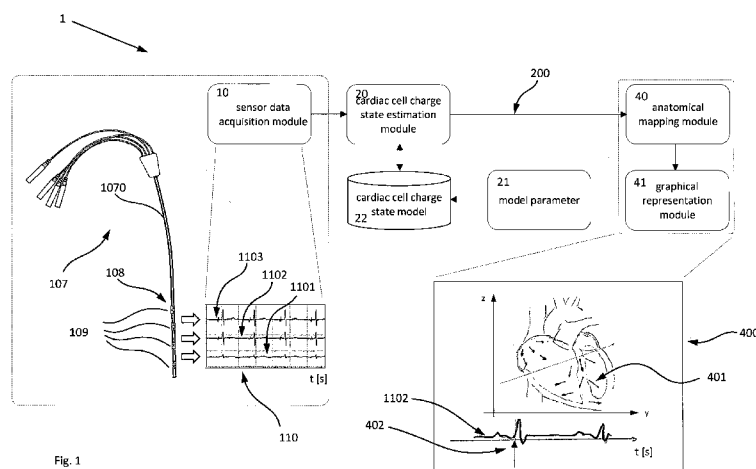


Fig. 1

(57) Abstract: The invention is related to a system (1) for providing a representation of dynamic cardiac cell charge state, comprising a sensor unit (107, 109) for receiving cardiac potential data, further comprising a sensor data acquisition module (10) for acquiring and providing said cardiac potential data to a cardiac cell charge state estimation module (20) of the system (1), wherein said estimation module (20) generates an estimation (200) of the cardiac cell charge state, wherein that the sensor unit (107) is realised as an esophageal ECG catheter.

System and method for providing a representation of cardiac cell charge state.**Field of invention**

This invention relates generally to the field of heart rhythm disorders and more specifically to a system and method thereof for providing a representation of cardiac cell charge state.

Background of the invention

An accurate registration of a cardiac de-/repolarization sequence often does simplify and speed up the diagnostics in human medicine. By visually comparing ECG signals based on a patient's heart electrical activity, correlations can be drawn with cardiac de-/repolarization sequence representing that electrical activity. Having such physiological data from patient, it is a common method to detect known diseases or irregularities of the patients heart.

The standard ECG is a very simple, ubiquitous method and hence a very widely spread system or tool. It gives a good, but very compressed overview of the cardiac depolarization and repolarization sequence. The so called "Gold Standard" is set by the transcutaneous measurement with an intracardiac catheter directly placed on the myocardium of interest, which is a complex, costly and invasive method and is often related to risks, e.g. such as bleeding, thromboembolism, stroke, etc. to name a few.

Different new methods have been developed to conclude from surface ECG measurements, non-invasively taken from electrodes placed on the patients skin to the current de-/repolarization state of the heart. Results giving three dimensional (3D) reconstructions or representations tend to impress. But all these methods need an individually adapted model of the torso and the patients heart, mostly registered by an initial CT or an MRI scan beforehand, or without an individual model, the quality of the result decreases tremendously. Therefore the methods are time-consuming, complex and expensive and hence not yet established in the daily clinical routine.

The document WO 2010151130 discloses a method of inverse imaging of electrical activity of a heart muscle. To provide a representation of the distribution, fluctuation and/or movement of electrical activity through heart tissue it is proposed to obtain an ECG of the heart comprising said tissue, obtaining a model of the heart geometry, obtaining a model of the torso geometry and relating the measurements per electrode or sensor of the ECG to the heart and torso geometry and estimating the distribution, fluctuation and/or movement of electrical activity through heart tissue based upon a fastest route algorithm, shortest path algorithm and/or fast marching algorithm.

As mentioned, it is a common problem, that performing such methods, initial estimates are based on knowledge about the electrophysiology of the heart. Furthermore heart and/or torso geometry is based upon a measurement by MRI, which makes said proposed method not only time-consuming and complex, but also expensive and hence it yet lacks of cost-effectiveness to be interesting in daily clinical routine. A further disadvantage of said method and systems based on is, that an accurate registration of a cardiac re-/depolarization sequences is exclusively performed in locations where said systems are available.

It is therefore the object of the invention to propose an improved system and method thereof to achieve more effectively a representation of cardiac cell charge state with a sufficient spatial and temporal resolution. It is yet another object of the invention, to propose an improved sensor unit for cardiac potential data acquisition.

These objects are achieved according to the present invention through the elements of the independent claims. Further preferred embodiments follow moreover from the dependent claims and from the specification.

According to the present invention these objects are in particular achieved in that a system for providing a representation of dynamic cardiac cell charge state, comprises a sensor unit for receiving cardiac potential data, further comprises a sensor data acquisition module for acquiring and providing said cardiac potential data to a cardiac cell charge state estimation module of the system, wherein said estimation module generates an estimation of the cardiac cell charge state, and wherein that sensor unit is realised as an esophageal ECG catheter.

One of the advantages of that system is, that a simpler way to achieve a representative of the dynamic cardiac charge state, representing the depolarization and repolarization process of the myocardium, has been made available. An esophageal catheter generally is comprising multiple electrodes with a known geometry and alignment. Such a catheter is placed in the esophagus and used to record the electrical cardiac signal potentials observable in the esophagus. Inserting an esophageal catheter is a very minimally invasive and very low risk method, comparable to the insertion of a common feeding tube. With a subsequent model based processing, a representative of the current charge state is gained. This obtained current charge state is then either presented as is or further mapped to anatomical cardiac structures and displayed graphically.

Esophageal electrodes are much closer to the myocardium, and in particular to the atrium, than standard skin electrodes and therefore the influence, attenuation and distortion due to the various tissues and tissue borders (such as lungs, fat and others) is reduced. Thereby the influence of the inter-individual differences in torso and cardiac anatomy and geometry are reduced and the analysis with predefined models is sufficient to already provide useful information about the dynamic cardiac charge state to the physician.

In an embodiment of the system, the estimation module continuously applies estimation data sets from a cardiac cell charge state model.

One of the advantages of said system is, that through various estimation algorithms a correlation can be performed. As a much less personalized, or even non-personalized model is sufficient, no CT or MRI scans are needed. For this reason, this method is applicable as an instant, real-time and cost-efficient bed-side method and thereby also suitable in an emergency setting. This method shall support physicians in gaining and confirming their diagnosis. Said model can be realised as formula or a data set, stored in a digital data storage.

According to the present invention a further object is achieved proposing an esophageal catheter electrode arrangement for an ECG catheter, wherein said catheter has two or more electrodes, wherein at least one electrode is configured as ring electrode and at that the catheter further comprises a set arrangement of electrodes, preferably realised as rings or ring segments, more preferably realised as point- or pinhead-shaped electrodes,

wherein said set arrangement of electrodes is spatial, to receive spatial cardiac potential data.

One of the advantages of the invention is, that the configuration of all electrodes (ring and non-ring electrodes) must be arranged on the catheter in such a way, that the
5 vectors of the cardiac potentials, which are measured between any two electrodes, are covering all three dimensions of the space.

Brief description of the drawings

The above mentioned and other features and objects of the invention will be better
10 understood when considered in the light of the following description of a broad aspect of the invention taken in conjunction with the accompanying drawings, in which:

Fig. 1 shows schematic block diagram of the cardiac cell polarization-state analysing system;

15 Fig. 2 shows a detail of an insertion member of an ECG catheter with a ring-formed electrode and with a triple-segment electrode configuration;

Fig. 3 shows yet another detail of an electrode configuration for an ECG catheter with a set of multiple ring and triple-segment electrodes, and

Fig. 4 showing the placement of surface electrodes for rotation tracking.

20

General description

Figure 1 illustrates a schematic block diagram of the cardiac cell polarization-state analysing system.

To analyse position and time based cardiac cell polarization or charge state of the
25 heart, an electro-catheter 107 of the system 1 is inserted into the esophagus of a patient. Said catheter 107 has one or more electrodes 109 in an electrode arrangement 108. The electrodes can not only be configured as rings, but also as spatial arranged electrode contacts or plates. The electrodes 109 are arranged on an insertion member 1070 of the catheter 107. The placement of the catheter into the esophagus is a well-known procedure
30 and can be performed a low risks. The insertion member 1070 is preferably configured as

thin tube and can be inserted through the mouth or nose without causing bleeding and partly even without anaesthesia (anaesthetic or narcosis). Yet a comfortable and simple handling of the catheter is possible, which is important to ensure a proper positioning of the electrodes.

5 For providing a representation of dynamic cardiac cell charge state, cardiac potential data needs to be obtained by means of a sensor unit 107, 109 of a representation system 1. Said sensor unit 107, 109 preferably is an esophageal electrode ECG catheter 107. For providing a multi-dimensional representation of dynamic cardiac cell charge state, e.g. a triple-segment electrode configuration (reference numeral 1091 in figure 2) is required. Two
10 or three dimensions representation are possible. These electrodes need to be configured in a spatial arranged. Once the esophageal catheter 107 is situated and using connection means of the catheter to connect the electrodes 109 to the sensor data acquisition module 10.

By means of a sensor data acquisition module 10 of the system 1, said probed
15 cardiac potential data will be further processed using a cardiac cell charge state estimation module 20 of the system 1. Said estimation module acts as filter by and walking through a set of cardiac cell charge states and by trying to best-fit them to said cardiac potential data. Apart from a best-fit method, other filtering, mapping or correlation methods are possible. Said estimated or mapped best-fit data will be generated as an estimation data set or
20 estimation of cardiac cell charge state 200. The estimation data set is also understood as estimation of myocardial cell charge state. Reference numeral 21 indicates model parameters.

A cardiac cell charge state model 22 or cardiac cell charge state dataset can be used as knowledge base to perform the estimation using said cardiac cell charge state estimation
25 module 20.

An anatomical mapping module 40 and a graphical representation module 41 will perform a graphical representation recording 400 according to the estimation data set 200. A charge state change indicator (arrow) 401 shows the depolarisation-front, or any surrogate for it, currently represented in the graphical representation recording 400. In

parallel to this representation, a time index indicator or arrow 402 shows the current position in the cardiac potential waveform resp. eECG.

A multichannel esophageal electrocardiogram (eECG) recording, plot or waveform is referenced with numeral 110. A first, second and third cardiac potential waveform are referenced with numerals 1101, 1102 and 1103. These waveforms correspond with the
5 respective cardiac potentials measured using the eECG catheter.

In a further embodiment of the invention, the system consists of a calibration unit to provide a modulated electrical current to external skin electrodes, whereby said current is being measured on the esophageal catheter electrodes and provided to the data acquisition
10 module, wherein said data acquisition module generates an electrode position data set using said measured current, while based on said electrode position data set the position and orientation of the catheter in relation to the torso can be identified. Said calibration unit is an optional configuration.

Figure 2 illustrates a detailed view of an insertion member 1070 of an esophageal
15 ECG catheter with a ring-formed electrode 1090 and with a triple-segment electrode configuration 1091. According to the current invention said novel electrode arrangement allows data acquisition based on which cardiac potential data a three-dimensional reconstruction of representation of dynamic cardiac cell charge state is possible.

Figure 3 illustrates an electrode configuration where electrodes are arranged as
20 single 1090 or grouped ring- or non-ring electrodes 1091 along and around the insertion member of the catheter. Said insertion member is not visualised in figure 3.

Non-ring electrodes only cover a well-defined angle of the circumference of the catheter. The total of all electrodes (ring and non-ring electrodes) must be arranged on the catheter in such a way, that the vectors of the cardiac potentials, which are measured
25 between any two electrodes, are covering all three dimensions of the space.

In general, esophageal catheters enable to retrieve cardiac potentials via the esophageal mucosa. Using multiple and correctly placed electrodes mounted onto an esophageal catheter tube, eECG signals reveal a local view of the cardiac electrical activity and enable to perform a spatial and temporal analysis. Depending on the spatial dimension

to analyse, multiple ring electrodes or non-ring electrodes or both are lined-up onto a catheter tube.

eECG signals reveal an improved resolution, particularly in the atrial signal parts compared to a standard surface ECG. The anatomical proximity of esophagus and myocardium allows to record local myocardial fields and opens the field for analysis of local cardiac activity with a limited number of electrodes.

To take advantage of these anatomical and physical conditions, we propose to use esophageal catheter with multiple either ring or non-ring electrodes or any combination of both. Recording the electrical potential at each electrode simultaneously and with an appropriate sampling frequency and time resolution, temporal and spatial localization of myocardial electrical activity, or any surrogate of it, becomes reachable.

The localization preciseness depends among others on the quantity and arrangement of the electrodes, the recording quality and sampling rate. In contrast to standard ECG signals recorded with surface (skin) electrodes, eECG signals do not or only marginally have to pass (or bypass) lung, fat or other high impedance tissues.

Reference numeral 107 indicates the esophageal electrode catheter or sensor unit. A catheter electrodes or electrode arrangement is numerated with 108. A single catheter electrode is referenced with numeral 109. A group of electrodes is referenced with numeral 108. Typical ring electrodes are referenced with 1090. On the other hand, non-ring electrodes, ring segment, point- or pinhead-shaped electrodes are indicated with reference numeral 1091.

In an embodiment of the invention, the esophageal catheter electrode arrangement for an ECG catheter 107 has two or more electrodes 109, wherein the catheter comprises a set arrangement of electrodes 1091, wherein said set arrangement of electrodes 1091 is spatial, to receive spatial cardiac potential data.

In a further embodiment, said set arrangement of electrodes 1091 is preferably realised as ring segments, more preferably realised as point- or pinhead-shaped electrodes

In yet another embodiment of an ECG catheter 107 at least one electrode is configured as ring electrode 1090.

Figure 4 illustrates the placement of surface electrodes for rotation tracking. The positive electrode centrally on the sternum (+), the negative electrode on thoracic vertebra Th6 (-). The angle coding herein is defined as follows using position and angle: ventral (0°),
5 left (90°), dorsal (180°) and right (270°).

The described system consists of a calibration unit to provide a modulated electrical current to external skin electrodes, whereby said current is being measured on the esophageal catheter electrodes and provided to the data acquisition module, wherein said
10 data acquisition module generates an electrode position data set using said measured current, while based on said electrode position data set the position and orientation of the catheter in relation to the torso T can be identified.

A tracking signal is injected via two surface Ag/AgCl electrodes, the positive electrode – identified with the character “+” – centrally on the sternum, the negative on the
15 spine on vertebra Th6 – identified with the character “-”. Both lines of the electrodes are protected with resistors, limiting the injection current. The signal injected is non-symmetric given by $y(t) = a_0(\sin(\omega_0 t) + \sin(2\omega_0 t))$. A typical tracking signal is configured with $\omega_0 = 180\text{Hz}$.

List of reference numerals

	1	system for providing a representation of cardiac cell charge state
	10	sensor data acquisition module, data acquisition module
5	107	esophageal electrode catheter, sensor unit
	1070	insertion member of catheter
	108	catheter electrodes, electrode arrangement
	109	catheter electrode, electrode
	108	group of electrodes
10	1090	ring electrodes
	1091	non-ring electrodes, ring segment, point- or pinhead-shaped electrodes
	110	multichannel eECG recording, plot or waveform
	1101	cardiac potential waveform
	1102	cardiac potential waveform
15	1103	cardiac potential waveform
	20	cardiac charge state estimation module
	200	estimation of cardiac cell charge state, estimation of myocardial cell charge state
	21	model parameter
	22	cardiac charge state model
20	40	anatomical mapping module
	41	representation module, graphical representation module
	400	graphical representation recording
	401	charge state change indicator (arrow)
	402	time index indicator (arrow) to cardiac potential waveform resp. eECG
25	S	surface electrode
	T	torso

Claims

1. A method for providing a representation of dynamic cardiac cell charge state, said method **comprising:**

5 obtaining cardiac potential data by means of an sensor unit (107, 109) of a representation system (1), wherein said sensor unit is an esophageal electrode ECG catheter,

processing said cardiac potential data by means of a sensor data acquisition module (10) of the system (1) and

10 providing said cardiac potential data to a cardiac cell charge state estimation module (20) of the system (1), and

generating an estimation data set (200) by mapping said cardiac potential data to cardiac cell charge state using a cardiac cell charge state model (22).

- 15 2. Method according to claim 1, **whereby**

the esophageal electrode ECG catheter (107) is used to obtain a multi-dimensional representation of dynamic cardiac cell charge state.

3. A system (1) for providing a representation of dynamic cardiac cell charge state, comprising a sensor unit (107, 109) for receiving cardiac potential data, further comprising a sensor data acquisition module (10) for acquiring and providing said cardiac potential data to a cardiac cell charge state estimation module (20) of the system (1), wherein said estimation module (20) generates an estimation (200) of the cardiac cell charge state, **characterised in**

25 that the sensor unit (107) is realised as an esophageal ECG catheter.

4. A system (1) according to claim 3, **characterised in**

that the estimation module (20) continuously applies estimation data sets from a cardiac cell charge state model (22).

5. A system (1) according to claim 3 or 4, **characterised in**
that the system consists of a calibration unit to provide a modulated electrical current to external skin electrodes, whereby said current is being measured on the esophageal catheter electrodes 109 and provided to the data acquisition module 10,
5 wherein said data acquisition module generates an electrode position data set using said measured current, while based on said electrode position data set the position and orientation of the catheter in relation to the torso can be identified.
6. An esophageal catheter electrode arrangement for an ECG catheter (107), wherein
10 said catheter has two or more electrodes (109), **characterised in**
that the catheter comprises a set arrangement of electrodes (1091), wherein said set arrangement of electrodes (1091) is spatial, to receive spatial cardiac potential data.
- 15 7. An esophageal catheter electrode arrangement for an ECG catheter (107) according to claim 6, **characterised in**
that set arrangement of electrodes (1091) is preferably realised as ring segments, more preferably realised as point- or pinhead-shaped electrodes.
- 20 8. An esophageal catheter electrode arrangement for an ECG catheter (107) according to claim 6 or 7, **characterised in**
that at least one electrode is configured as ring electrode (1090).

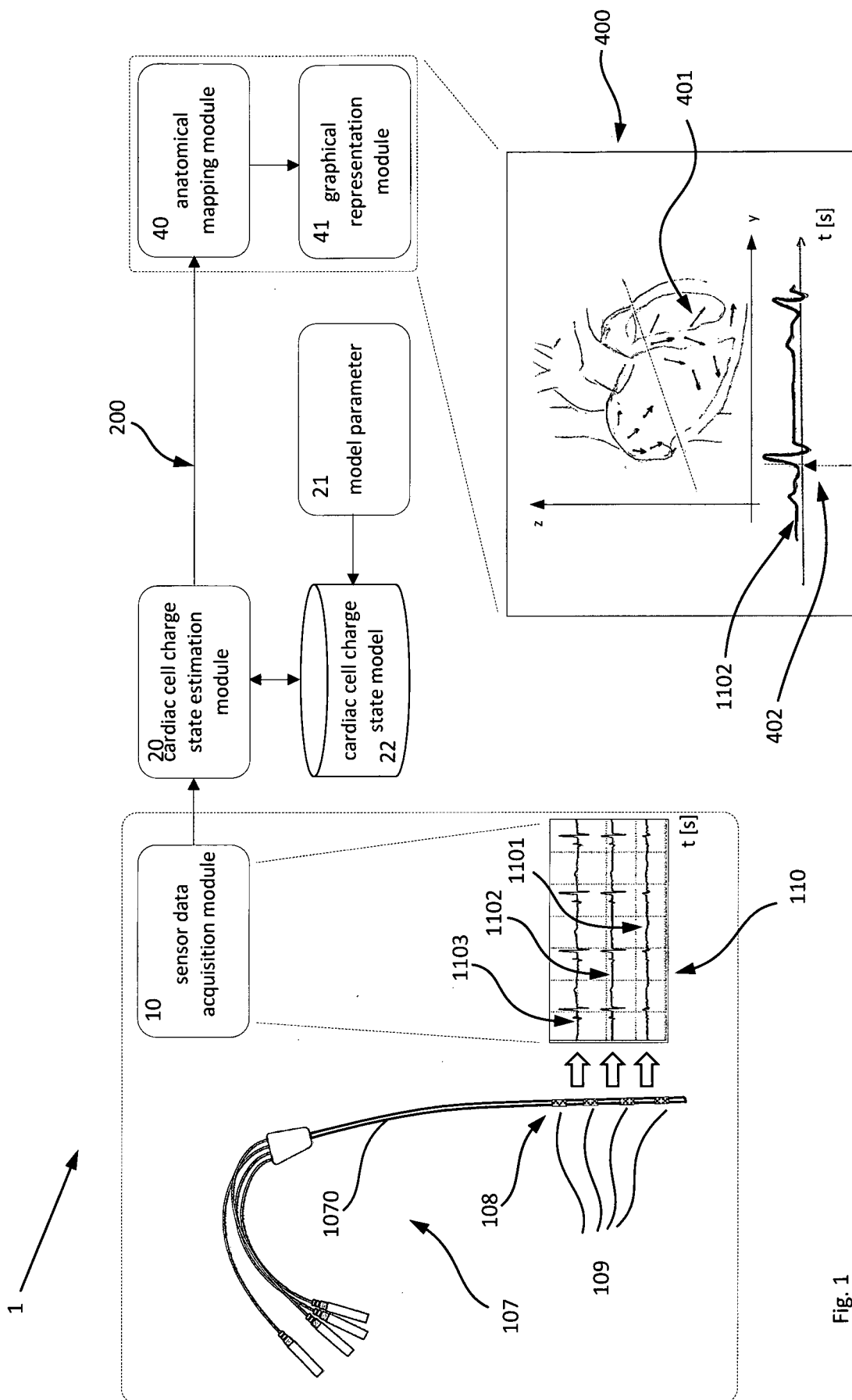


Fig. 1

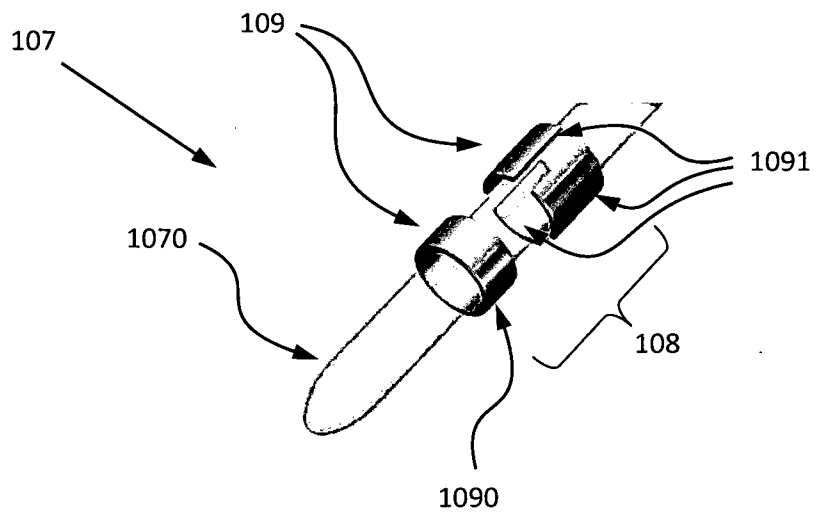


Fig. 2

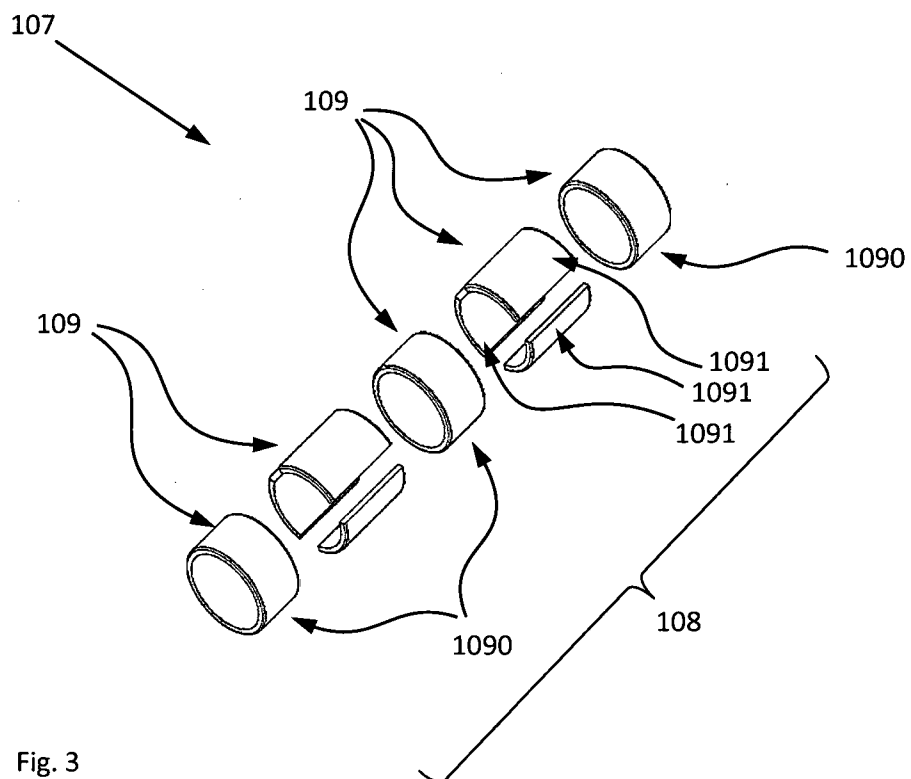


Fig. 3

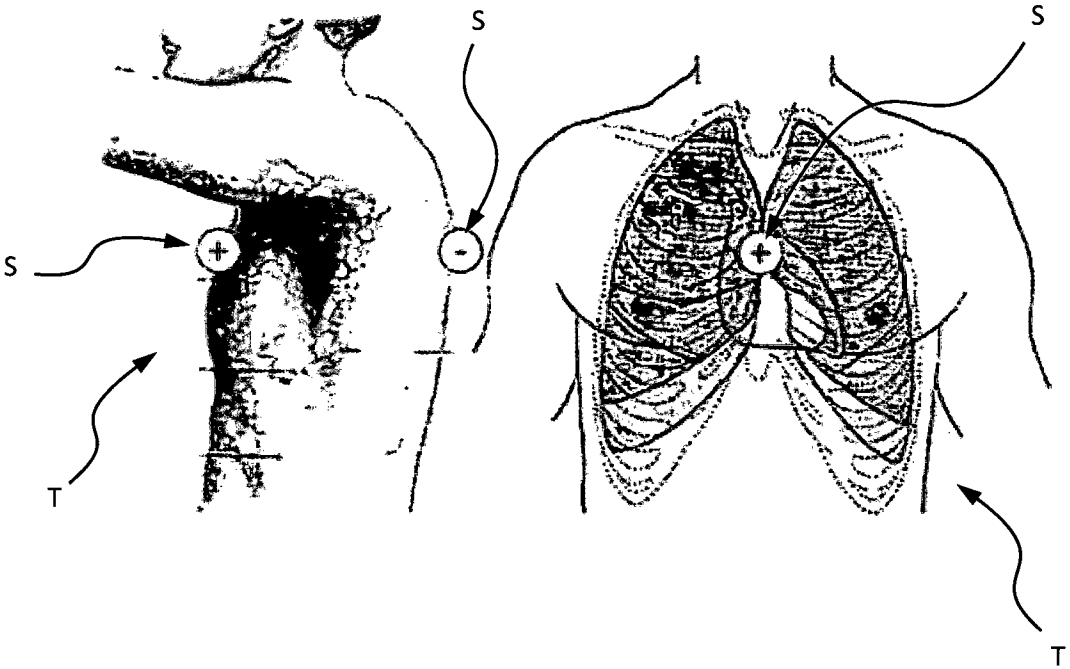


Fig. 4

INTERNATIONAL SEARCH REPORT

International application No

PCT/IB2016/000929

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61B5/06 A61B5/042 A61B5/00 G06F19/00
ADD. A61M25/01 G06T15/00 A61B5/0402 A61B5/0452

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61B G06F G06T

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

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

EP0-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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X	----- US 2002/038093 A1 (POTSE MARK [NL] ET AL) 28 March 2002 (2002-03-28) paragraphs [0034], [0045], [0060], [0085]	1-5
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Further documents are listed in the continuation of Box C.



See patent family annex.

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Date of the actual completion of the international search

22 September 2016

Date of mailing of the international search report

29/09/2016

Name and mailing address of the ISA/

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INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2016/000929

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

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A	US 2004/059237 A1 (NARAYAN SANJIV MATHUR [US] ET AL) 25 March 2004 (2004-03-25) the whole document -----	1-8
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Information on patent family members

International application No

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