



(51) International Patent Classification:

G16H 40/63 (2018.01) *G16H 50/30* (2018.01)
A61B 5/04 (2006.01) *G16H 50/20* (2018.01)
A61B 5/0452 (2006.01) *A61B 5/00* (2006.01)

(21) International Application Number:

PCT/NL2018/050228

(22) International Filing Date:

12 April 2018 (12.04.2018)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

PCT/NL2017/050225

12 April 2017 (12.04.2017) NL

(71) Applicants: **PEACS B.V.** [NL/NL]; Peacs B.V., Herkenboschstraat 42, 6845 HN Arnhem (NL). **PEACS INVESTMENTS B.V.** [NL/NL]; Weij land 38, 2415 BC Nieuwerbrug Aan Den Rijn (NL).

(72) Inventors: **VAN DAM, Eelco Mattias**; Herkenboschstraat 42, 6845 HN Arnhem (NL). **VAN DAM, Peter Michael**; Herkenboschstraat 42, 6845 HN Arnhem (NL).

(74) Agent: **HOEBEN, Ferdinand Egon**; Postbus 1551, 1200 BN Hilversum (NL).

(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, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JO, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME,

(54) Title: HEART CONDITION DETERMINATION METHOD AND SYSTEM

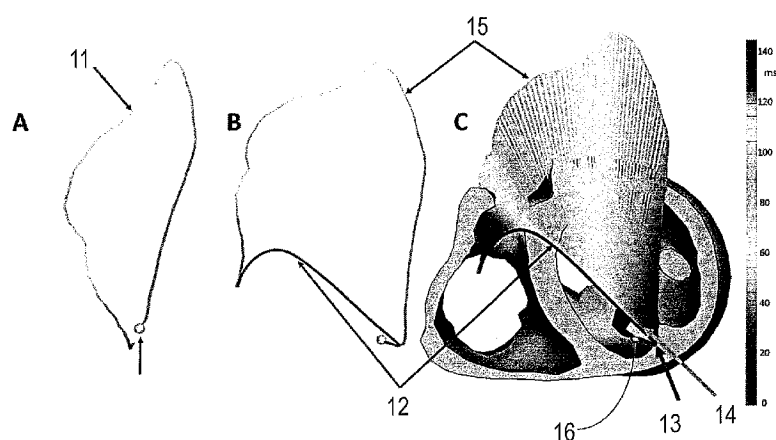


Fig. 2

(57) Abstract: The present invention relates to a method to provide a mean temporal spatial isochrone (TSI) path relating to an ECG feature (wave form) of interest, such as the activation of the heart from a single point (QRS), relative to the heart in a torso while using an ECG measurement from an ECG recording device, the method comprising steps of: - receiving ECG measuring data from the ECG recording device, - determining vector cardiogram (VCG) data, - receiving a model of the heart, preferably with torso, as an input, preferably based on a request comprising request parameters, - determining mean TSI data values representing the TSI path relating to an electrophysiological phase representing the ECG feature, the mean TSI providing a location within the heart representing the mean location of the ECG feature at the corresponding time, - positioning the mean TSI path and preferably the vector cardiogram data points in the model of the heart and/or torso at an initial position, - rendering the model of the heart, preferably with torso, with the mean

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).

Published:

- with international search report (Art. 21(3))
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))

HEART CONDITION DETERMINATION METHOD AND SYSTEM

The present invention relates to a method to provide a mean temporal spatial isochrone (TSI) path relating to an ECG feature (wave form) of interest, such as the activation of the heart from a single point (QRS), relative to the heart in a torso while using an ECG measurement from an ECG recording device. Furthermore, the present invention relates to a system performing a method to that effect.

A vector cardiogram (VCG) signal is a signal with x,y,z coordinates per time sample. Such a VCG represents the direction of activation in the heart and can be viewed as a single dipole model. This model is thus a simplification of the complex electrical activity (activation and recovery) of the myocardial tissue. There are several existing methods to obtain a VCG signal from ECG signals, such as a frontal mean QRS axis from only the aVr, aVl, aVf, and lead I, II, and III, a Gabor Nelson system, a Frank lead system, or a statistical based transformation matrix, e.g. Dower or Kors transform.

To a doctor, such a vector cardiogram can provide an idea of the development of an activation of the myocardium. However, it requires a lot of experience to use it on the real body as there is only a representation in the form of the ECG loop relative to a starting point at which or from which it is graphically represented, the starting point not providing a relation to the physics of a patient.

In order to improve upon the prior art, the present invention provides a method

to provide a mean temporal spatial isochrone (TSI) path relating to an ECG feature (wave form) of interest, such as the activation of the heart from a single point

(QRS), relative to the heart in a torso while using an ECG measurement from an ECG recording device, the method comprising steps of:

- 5 - receiving ECG measuring data from the ECG recording device,
- determining vector cardiogram (VCG) data,
- receiving a model of the heart, preferably with torso, as an input, preferably based on a request comprising request parameters,
- 10 - obtaining the location information relating to a number of ECG electrodes relative to the torso model and or hearts model of the subject,
- based on the location information in the torso model and/or heart model, positioning of the number of ECG
- 15 electrodes,
- determining mean TSI data values representing the TSI path relating to an electrophysiological phase representing the ECG feature, the mean TSI providing a location within the heart representing the mean location of the ECG
- 20 feature at the corresponding time,
- positioning the mean TSI path and preferably the vector cardiogram data points in the model of the heart and/or torso at an initial position,
- rendering the model of the heart, preferably with
- 25 torso, with the mean TSI path, preferably with VCG data related to the TSI, for displaying on a display screen for interpretation of the displayed rendering.

An advantage of applying a method according to the present invention is that it is directly related to the

30 actual physical location of the heart as the mean TSI path is related to the vector cardiogram data, which is related to the model of the heart by means of the known locations of the electrodes of the ECG recorder.

According to a first preferred embodiment, the steps of positioning the mean TSI path comprise steps for using a predetermined position, such as the center of mass of the heart, for positioning the first data value of the TSI path. By performing the steps, and initial match between the mean TSI path and the heart as it is in the body is created. The better this initial position is chosen, the better the actual mean TSI path fits with the reality within the heart.

10 According to a further preferred embodiment, the steps of positioning the mean TSI path comprise steps of determining at least one initial position in which the first data point of mean TSI path is to be positioned, preferably such that this position is located in the myocardium.

Both the beginning and the end of the mean TSI path are preferably located within the myocardium. As such, the steps of finding positions in which the 1st data point of the mean TSI path is located in the myocardium provide a basis for further processing of the method.

Further preferably, the steps of positioning the mean TSI path comprise steps of determining at least one final position in which the last data point of the TSI path is to be positioned, preferably such that this position is located in the myocardium. If these both steps are fulfilled, a set of possible positions of beginning and ending both fulfilling the said requirement will lead to a subset thereof in which all certain requirements of the next preferred embodiment is fulfilled.

30 As such, a further preferred embodiment provides that the steps of positioning the mean TSI path comprise steps of determining that the mean TSI path is fully located within the heart, preferably of a blood cavity of

the heart and/or the wall thereof, such as the ventricles or the chambers.

It is most preferred that the positioning of the mean TSI path in the model of the heart fulfills these 3 preferred requirements. Based on fulfilling these 3 requirements, a very small set of possible solutions will be obtained, after which the method preferably determines the preferred solution of the set of possible solution is to be graphically rendered for display.

According to a further preferred embodiment, the method comprises steps of determining which of the TSI data values represents the last data point of the TSI path. As the end of an electrophysiological phase representing the ECG feature of interest is not a priori known, such endpoints needs to be determined in order to be able to both fit the 1st and last point of the mean TSI path in the myocardium.

To this end, the method further preferably comprises steps to make a determination that a change of direction of the TSI path in the ending phase of the electrophysiological phase representing the ECG feature of interest represents the end of the electrophysiological phase. It is presently believed that for examples at the end of the QRS phase, when most of the myocardium has been depolarized, leading to providing a direction to the mean TSI path, the repolarization of the bulk of the myocardium that follows on the depolarization, provides a change of direction in the mean TSI path, shown as a final curve thereof. This happens e.g. somewhere between 80 and 180 ms after the onset of the QRS, preferably between 90 and 150 ms, more preferably between hundred and 40 ms. This mean TSI path curve is represented in the drawings relating to described embodiments below.

According to a further preferred embodiment the mean TSI value provides a position to be rendered within the boundaries of the heart representing a point per ECG measurement, such as per millisecond, and in which over the
5 measurement of the ECG feature, such as the QRS, the combined points represent a line indicating the progress of the average position of successive isochrones of the development of the ECG feature, such as the activation front in case of a QRS. As such, the mean TSI path may be deter-
10 mined and plotted based on distinct measurements from the ECG recorder for example with an interval of a millisecond.

Further preferably, a propagation velocity of the ECG feature is a factor in calculating the mean TSI value.

15 Further preferably, the mean TSI is related to the vector cardiogram data.

Further preferably, a mean TSI is computed at successive predetermined time points during a cycle of the heart, such as per value in a range of 0.1 ms-5 ms, preferably 0.5 ms -3 ms further preferably 0.5 ms-2 ms, fur-
20 ther preferably about 1 ms.

further preferably, the mean TSI is calculated while applying following formula:

- $mean\ TSI(x, y, z; t + 1) = mean\ TSI(x, y, z; t) + v \cdot VCG(x, y, z; t)$
25 - in which t represents a time point of a number of time points, such as per millisecond,
- VCG represents a VCG data point of the ECG data,
- v is velocity of the ECG feature or the electrophysiological phase activity.

30 Further preferably, the method comprises steps of determining one or more areas of probability in which a first data value of the TSI path is located.

This preferred embodiment provides advantageously that for instance a location ventricular arrhythmia (VA) may be determined by correct positioning of the mean TSI path. The mean TSI path, when correctly placed in the heart model directly pinpoints the ventricular arrhythmia, such as a PVC when the initial point is location of the onset of the QRS, such as the activation thereof.

Further preferably, the method comprises steps of comparing the angle of the ECG feature axis, such as the QRS axis, with the TSI direction at or close to the respective area of probability, preferably comprising the steps of determining the area of probability of choice for positioning the beginning of the TSI path. If an above-described valid positioning of the mean TSI path, which is fully in the heart, beginning and ending in the myocardium, provides a direction of the mean TSI path that is closest to the direction of a QRS axis, then this is the most likely position of the mean TSI path in the heart, and therefore the most likely position of the ventricular arrhythmia is in the area of the beginning of the mean TSI path.

In order to provide a further graphical representation, such as in figure 2, according to a further preferred embodiment the VCG data is preferably subsequently added to the progressing mean TSI position. A preferred effect of such a way of correcting the VCG signal with the estimated mean TSI signal is that small signals are shown as a relative large change in signal. The initial ECG (first 40 ms) of a PVC is very low in amplitude, but actually does indicate a direction, difficult to be detected by signals analysis. This low amplitude signal gets amplified in a physiological way because it represents the progressing of initial activation through the myocardium.

A further aspect according to the present invention relates to a system for under application of a method according to one or more of the preceding claims provide a mean temporal spatial isochrone (TSI) path relating to an ECG feature (wave form) of interest, such as the activation of the heart from a single point (QRS), relative to the heart in a torso while using an ECG measurement from an ECG recording device, comprising:

- a processing unit,
- 10 - a memory coupled with the processing unit,
- receiving means for receiving location information relating to a number of ECG electrodes,
- receiving means for receiving electro data of the respective ECG electrodes,
- 15 - outputting means for outputting of result data and/or results comprising image data. Such a system provides advantages such as described in relation to the above described aspect of the method.

According to a further preferred embodiment, the system comprises a recording device, such as an optical recording device for determining of a position of respective ECG electrodes relative to a torso.

Further preferably, the system comprises a display screen and inputting means for inputting of instructions.

25 For the purpose of providing a user-friendly system, the processing unit, the memory and the recording device are integrated in one physical housing, comprising in memory program coding means for performing of the method according to the present invention and preferred embodiments as indicated in the above.

30 Further advantages, features and details of the present invention will be described in the following in greater detail relating to one or preferred embodiments in

the reference to the drawings. Similar yet not necessarily identical parts of different preferred embodiments may be indicated with the same reference numerals.

Fig. 1 is a block diagram of a preferred embodiment
5 of a system according to the present invention.

Fig. 2 is a graphical representation of path information and vector information in relation to a heart.

Fig. 3 is a flow diagram of a preferred embodiment according to the present invention.

10 Fig. 4 is a graphical representation of a mean QRS axis of the ECG in a heart.

Fig. 5 is a graphical representation of path information and vector information relation to a heart.

15 Fig. 6 is a torso plane representation of a preferred embodiment according to the present invention.

Fig. 7 is a projection representation of a preferred embodiment according to the present invention.

Fig. 8 is a flow diagram of a preferred embodiment according to the present invention.

20 Fig. 9 is a projection representation of a preferred embodiment according to the present invention.

Fig. 10 is a projection representation of a preferred embodiment according to the present invention.

25 Fig. 11 is a projection representation of a preferred embodiment according to the present invention.

Fig. 12 is a flow diagram of a preferred embodiment according to the present invention.

Fig. 13 is a graphical representation of a preferred embodiment according to the present invention.

30 Fig. 14 is a graphical representation of vector information in relation to a heart.

A system according to the present invention, such as shown in figure 1, a preferred embodiment is shown of a

system 1 for performing the method. A three-dimensional camera 2, for detecting ECG electrodes arranged at a torso T, is arranged above the torso T (schematically shown) of a person. The camera is suitable for moving thereof relative to the torso such that from several sides the torso can be recorded for detecting of the ECG electrodes in place. Data from the camera are transferred to a computer 5. The computer is connected to a monitor 7, keyboard 8 and mouse 9 for receiving input data from these peripherals from a user and for outputting of image data to the user. The computer is furthermore coupled with an ECG amplifier 6 that in its turn is coupled to ECG electrodes 3 on the torso T. A practical number of electrodes that is supplied is between 4 and 16, preferably substantially 12. A larger number for achieving a higher resolution is envisaged and use thereof dependent on the surroundings in which the installation is applied also usable. The skilled person would be able to determine the number of electrodes as a correct choice based on available equipment.

For example, for a P-wave or QRS complex, a VCG represents the activation direction at a certain time relative to an arbitrary reference point. This reference point represents the mean temporal-Spatial Isochrone (TSI) 12. Consequently the position of the mean TSI progresses within the heart space, approximately the myocardium and the blood cavities. As a result of this, the traditional VCG loop 11 can become a vector path or trajectory.

This invention describes a method to derive e.g. the mean TSI from the ECG, taking the mean TSI into account to correct for the VCG direction, relating the mean TSI and VCG to a standard heart geometry, or an estimated heart geometry or an patient specific heart geometry derived from medical images (MRI or CT).

The invention is explained using the activation of the heart from a single point, Fig. 2, or a premature ventricular contraction (PVC). The invention is preferably also be applied to the P wave of the ECG.

5 The VCG signal gives the mean direction of activation. Assuming an propagating activation in case of the PVC, the position progresses in this direction. Assuming a default propagation velocity in the heart of $v = 0.8 \frac{m}{s}$ the position over time ($position(t)$) will be:

10

$$mean\ TSI(x, y, z: t + 1) = mean\ TSI(x, y, z: t) + v \cdot VCG(x, y, z: t)$$

for every ms (ECG sample).

15 The VCG signal is subsequently added to the progressing mean TSI position (see figure 2b and 2c).

20 An effect of this way of correcting the VCG signal with the estimated mean TSI signal is that small signals are shown as a relative large change in signal. The initial ECG 13-14 (first 40 ms) of a PVC is very low in amplitude, but already shows a direction, difficult to be detected by signals analysis. This low amplitude signal is amplified in a physiological way because it represents the progressing of initial activation through the myocardium.

25 Steps according to Fig. 3 comprise the following. In step 200, patient information 201 is obtained and based thereon, a heart torso model based on available patient data is selected. Step 120 comprises recording an ECG, preferably by applying a standard 12 lead ECG. Step 130 comprises recording of the VCG directly, for instance using the frank lead system VCG, for which an ECG is required. The measuring of the ECG (120) and measuring of the VCG (130) is performed with ECG recording equipment. This can be ECG, e.g standard 12 lead, that is known per

30

se or any Body surface map system with any number of ECG leads.

Step 140 comprises taking a 3D image of the respective thorax with ECG electrodes applied on the chest. The result is a 3D recording indicating the positions of the ECG electrodes on the chest for using in selecting a heart torso model. In step 140 a 3D image is recorded with the 3D camera to localize the ECG electrodes relative to the thorax. The objective is to localize the 3D position of the ECG electrodes on the thorax. So both a hull of a part of the thorax is obtained as well as the electrodes on them. The camera enables the measurement of electrode positions for every individual ECG measurement. Both a single movable camera and a plurality of stationary cameras are envisaged to cover the relevant surface parts of the thorax for a sufficient 3D recording.

In step 150, the location of the ECG electrodes is determined in the 3D recording and model. In step 160 the information relating to the ECG, electrodes and the selected heart torso model is converted into a VCG representation.

In step 170, a standard matrix ECG to VCG conversion is performed. In step 180, the mean TSI is computed and the position of the origin of the vector signals is corrected. In step 190, an orthogonal view of the respective cardiac anatomy is created and the signals are projected in the three views of the heart and the results are displayed in these views.

Three ways to obtain an vector signal are described. The first preferred method comprises measuring of an ECG (120) and converting it patient specifically by means of steps as 140 and 150 to a VCG signal. Such method takes aspects of the anatomy into account, such as a) the body

build, b) heart shape and position, and c) the electrode position. As such, this is the preferred route, because patient specific data are used in performing the determinations.

5 A second method comprises steps of Measuring an ECG (120) and converting the same using a transformation matrix (170) into a VCG signal. Applying such transformation matrices comprises the use of a statistical approach. Such transformation matrix approach converts the standard 12
10 lead ECG into three x,y,z signals of the VCG. The matrix coefficients preferably represent an average patient conversion, i.e. the mean body build lead locations etc.

 A third method comprises measuring of an VCG directly (130). The VCG can be measured directly using a
15 specific lead system, e.g. the frank lead system, or a body surface map from which a Gabor-Nelson VCG can be constructed. The frank lead system has been designed using a homogeneous volume conductor model. This model is used to compute the x,y,z signals of the VCG from the measured ECG
20 signals at predefined electrode positions. The Gabor-Nelson integrates the potentials on the body surface.

 In step 150, the electrodes need to be detected from the 3D photographic image in the 3D space. Automatic detection is preferably performed based on visible features
25 of the electrode as present on the thorax, such as the color of the electrode or the shape of the electrode.

 In step 160, the objective is to compute the x, y, z signals of the VCG as a weighted sum of the ECG signals and a normalized vector between the heart and the ECG
30 electrode, for which reference is made to WO 2017/099582 incorporated herein with reference. The weight (α_n) per ECG signal is preferably set equal or is preferably derived from a volume conductor matrix, representing the

contribution of the heart surface potentials to the potentials measured at the ECG electrode location.

In step 200, a torso model or heart torso model is retrieved from the patient either from a database or from MRI or other 3D imaging methods or systems. The objective is to determine and/or estimate a relationship between the heart and said ECG electrodes. The more patient specific the torso model and or the heart torso model is, the more accurate this relation can be determined.

$$VCG = \sum_{n=1}^{leads} \alpha_n \cdot \frac{(p_{heart} - p_{ECG\ electrode})}{\|p_{heart} - p_{ECG\ electrode}\|} \cdot ECG_n$$

An advantage of this VCG computation system is that the electrode position, heart position and/or orientation of the heart is the basis of this relationship. The value of α_n can be derived from the standard deviation of the row of the volume conductor transfer matrix or it can be dependent on the time of the measurement, such as when using the depolarization direction derived from the mean QRS axis.

In step 165, the mean QRS axis is computed, which represents the major direction of activation. For PVC's and VT's the major mean QRS direction originates from the region from where the PVC/VT originates. A summation of the VCG signal from 160 over time results in the mean QRS axis direction, which is preferably positioned at the center of mass of the viable ventricular myocardium.

$$mean\ QRSvector = \int_{t=QRS\ onset}^{QRS\ end} VCG(t)dt$$

The mean QRS axis of the ECG is shown in Fig. 4 with reference numeral 41. The center of the ventricular mass

is shown with reference numeral 42. The center of mass is used to take into account the shape of the ventricular anatomy. Hypertrophic parts of the heart (thicker wall) are thus for example accounted for, some for dilated hearts.

In step 180, the VCG indicates the direction in which the activation is progressing at each time of the ECG, it however does not provide an indication as to where the activation is located. The mean TSI (temporal spatial isochrone) is an estimation of a, preferably spatial, position of an isochrone in the myocardium at a certain point in time (temporal) of the ECG.

Where the VCG represents the direction of activation and as such provides a limited indication as to the cardiac anatomy, the mean TSI represents the mean activation wave front and consequently preferably is located within the heart, either the blood cavity or the myocardium. This position thus provides an indication from which region the electrical ECG signal is originating. For an activation from LVOT, the mean TSI 51 starts at the origin of activation of the heart and ends in the area activated last. The mean TSI can be computed in several ways.

Firstly, the VCG provides an indication of the direction of activation and consequently of the direction of progress of the mean TSI. Assuming a uniform propagation velocity, the mean TSI is preferably displaced every ms in the direction of the VCG with that constant speed.

Secondly, the simulated activation sequence for an activation sequence in an area close to the mean QRS axis is applied as a basis to compute the mean TSI for every time instant.

A major advantage of the mean TSI is that it provides an indication of the latest activated region of the heart, as it progresses into the region activated last.

For instance, in a patient with a left bundle branch
5 block (LBBB) the activation starts on the right and ends
in the left. In such instance, the mean TSI progresses
from an area activated first at the right side of the
heart to the area activated last on the left side of the
heart. Once the mean TSI has been established the VCG sig-
10 nal is recomputed using the progressing position of the
vector representing the VCG signal.

In step 190 The visualization of the VCG and mean
TSI can be represented in color as shown in fig 2 in grey
shades which enables a physician to interpret, in a user
15 friendly manner, the visual relation between direction,
position and the cardiac anatomy.

The more the model of the heart corresponds with the
anatomy of the patient, the stricter the rules on the mean
TSI and VCG construction can be maintained. For a patient
20 specific heart model the mean TSI preferably remains in-
side the myocardial heart space. This provides support to
obtain a respectively accurate reconstruction of mean TSI
and VCG.

With the above description the first mean TSI posi-
25 tion is not determined. Without availability of a respec-
tive cardiac anatomy, an arbitrary reference point is
preferably used. A relation to the cardiac anatomy pro-
vides support relating to a diagnosis. Traditionally the
VCG signal is shown in the orthogonal planes of the torso.

30 The representations of the mean TSI and VCG signal
have a direct relation with the cardiac anatomy from which
the ECG signals are originating. Further preferably, the
heart orientation is used as a basis for projecting the

signals on the cardiac anatomy. A LAO (from base to apex), ROA (from right to left chamber), and the 4-chamber projection view (anterior to posterior) are preferably used.

The cardiac anatomy is preferably obtained from an MRI scan or CT scan performed on the patient, selected from a model database, or a general model is used. In case more than one model is available, such as models that are not directly based on the anatomy of the respective person, the selection of the best fitting model is preferably, at least in part, based patient data, like age, height, chest circumference, further preferably estimated from a 3D photo, or from an echo image. To project the torso oriented VCG onto the heart oriented VCG, the long axis and the left-right axis need to be known. The long axis is determined by the line between the point representing the mean of the aorta and/or mitral valve and the apex of the left chamber. The left-right axis is perpendicular to the long axis and is determined by the line between the point representing the mean of the mitral valve and the mean of the tricuspid valve. These axes are preferably determined from the MRI or CT images or optionally determined by means of indicative manual input by means of e.g. the keyboard and/or mouse. In case no patient specific heart model is available the respective long and left-right axis is preferably estimated from general descriptions of the patient or the 3D image, such as the weight, height, chest circumference, etc.. However, although decreases in exactness would affect embodiments according to the invention, such embodiments also function if such types of data are only partly.

In step 200, a hear model or heart torso model of the patient is obtained or selected from a plurality of obtainable models. When imaging data, such a obtained by

means of MRI or CT imaging, is available a patient specific model can be created (240). This is the most accurate method, but always requires the imaging, which for a standard 12 lead ECG only is not be available. For those
5 situations, an estimation of the patient model can be created based on known characteristics of the patient in steps 220, optionally with step 230. If also such patient characteristics are unavailable, a general model can be used in step 250. This later situation is for instance applicable when only an ECG is available and the ECG is converted into a VCG through a matrix transform, such as in
10 step 170.

In step 210, it is determined what info is available to select the model, such as patient specific information, with or without 3D imaging, general information, or model
15 information from a model database.

In step 240, A patient specific model of the heart and torso is assembled based on such imaging data, such as disclosed in WO 2017/099582 optionally, In step 250, use is
20 made of a general model. This model uses a standard model of the heart and torso and thus also 12 lead ECG electrode positions.

In step 220, the most appropriate model from the model database is selected. The model database preferably
25 contains several models of different patient types, such as a) a normal heart for different age groups; or b) genetically influenced morphological hearts. An example thereof is ARVC patients, for which the right base is generally somewhat lower and they often have an enlarged
30 right chamber. A further example comprises tetralogy of Fallot patients, which have very specific cardiac anatomy changing over time. A still further example comprises patients with hypertrophic heart diseases. Within such

scope, many other types of hearts are envisaged to be included in such data base.

Several selection criteria can be used to select the right model are Age, Height, Weight, Chest circumference, Thorax height and/or Genetical profile.

Preferably a 3D photo is available from which the chest circumference and/or the length of the thorax can be obtained. This chest circumference and height is preferably used in selecting the right model. For genetically diseased patients the information is preferably added separately.

In step 230, the heart orientation of the selected model is corrected for the heart orientation of the patient as observed or derived based on patient parameters as indicated in the above. An example thereof is that the chest circumference, as is preferably derived from the 3D photo, has a relation with the heart orientation. A larger chest circumference indicates for instance that the patient has a bigger belly area, thus pushing the heart in a more horizontal position.

The orientation of the heart is preferably expressed by two rotations. A first rotation is a rotation to align the long axis of the heart with the estimated long axis direction. A second rotation is a rotation over the long axis such that the axis between mitral valve and tricuspid valve aligns with the estimated direction.

In step 260 the corrected long axis of the heart is determined to enable a LAO projection view of the heart. This way the VCG can be visualized in this plane which relates the VCG and mean TSI directly to the cardiac anatomy. Such feature provides a diagnostic value of the ECG/VCG/mean TSI has such graphical representation is readily interpretable.

In step 270, the corrected axis between mitral valve (LV) and tricuspid valve (RV) is determined to enable a RAO projection view of the heart. This LV-RV axis is preferably orthogonal to the long axis of the heart. This way
5 the VCG is preferably visualized in this plane which relates the VCG and mean TSI directly to the cardiac anatomy. Such feature provides a diagnostic value of the ECG/VCG/mean TSI

in step 280, based on the two axes, a third axis is
10 defined as the one orthogonal to these two orthogonal axes. Each of the axis are preferably used to create a 2D projection of the heart, such as the LAO, ROA, and/or four chamber view.

In Fig. 9, an example of the VCG from PVC (single
15 focus activation) signal as computed with the embodiment described projected on the 3 heart planes. It can be readily observed that the PVC originates from the RVOR region and progresses from the RVOT to the left apical posterior wall.

20 The center of mass, i.e. either ventricles or atria, is preferably used as the reference point for the mean TSI and VCG signals. Further preferably, the position of the VCG and mean TSI signals is shifted over the cardiac anatomy to match the heart space, i.e. the mean TSI preferably
25 remains inside the atrial or ventricular heart space. The ventricular heart space is used for ECG phenomena originating from the ventricular electrical activity, the atrial space for activity originating from the atria.

For ectopic activations, the center of mass is not
30 the most appropriate place to let the mean TSI and consequently the VCG start as it starts from one point. To determine the origin of the PVC the mean QRS axis is deter-

mined, for instance by taking the integral of the VCG signal directly derived from the ECG, as in step 140 or by measurement, as in step 130, according to the following formula.

$$5 \quad \text{mean QRS axis} = \int_{t=\text{QRS begin}}^{\text{QRS end}} VCG(x,y,z:t)dt$$

As the mean activation follows this mean QRS axis by approximation, the origin is preferably close to a point along this mean QRS axis extending through the center of mass. For the largest part of the heart the origin of the
 10 PVC is found close to the point where the mean QRS axis leaves the ventricular heart space, i.e. leaves the ventricular myocardium or ventricular blood cavity (see Fig. 10).

For septal or papillary muscles an exception is
 15 preferably made. Further analysis of the VCG signal and mean TSI is required to localize it appropriately. To distinguish the ventricular septum from the right free wall the initial part of the VCG signal is analyzed. If the initial activity initially progresses in an opposite direction than the mean QRS axis the activity originates from
 20 the septum. For PVC's originating from papillary muscles the VCG signal shows a less uniform direction of activation as the activation follows a more complex path. This complexity can be used to localize the origin to the appropriate anatomical structure.
 25

A similar procedure is preferably followed for atrial ectopic activity, such as by analyzing the P wave and using the atrial geometry. For Normal His-Purkinje activation the center of the ventricular mass is a good initial estimate, as well as for the T-wave.
 30

For complex anatomical hearts an adapted center of mass is preferably applied, for instance in Tetralogy of Fallot patients.

In step 310, the ECG contains both the activation
 5 and recovery of the atria and ventricles. Each part is preferably approached differently for analysis. A selection regarding which feature of the ECG is going to be analyzed is made, such as P-wave or QRS complex.

In step 320, a computation of the center of mass of
 10 the atria and ventricle is performed. This point is preferably used as an anchor point for the VCG and mean TSI signals. For heavily deformed hearts the center mass is preferably adapted.

In steps 330, 340, 350 the mean axis per feature is
 15 determined. Here the example will be shown for the QRS, but it also applies for the P wave.

$$\text{mean QRSvector} = \int_{t=\text{QRS onset}}^{\text{QRS end}} \text{VCG}(t)dt$$

Where the mean QRS vector runs through the center of
 20 the heart mass.

In step 380, the deviation angle and distance of the VCG direction and the mean QRS is computed, preferably one value over the whole activation cycle, preferably related to the anatomy. The purpose is to be able to improve the
 25 classification of the ECG feature and to correct the origin of the VCG and mean TSI.

The distance is a measure of the variation in vector direction and can also be expressed as the first and second eigen value of the VCG, representing the first and
 30 second order axis in which the VCG is drawn.

For a PVC for instance originating from a single point, the dominant region will be in one direction, consequently the length of axis 2 will be much smaller than

axis 1. This can also be expressed in the distance of the VCG to the mean axis line. The larger the mean of this deviation distance is, the larger the second axis. The advantage of using the deviation angle or the deviation distance is that it enables the analysis of parts of the VCG or mean TSI. For instance, if the deviation angle of the initial part of the VCG/mean TSI has an opposite direction to the mean QRS axis this is indicative of about the distinction in endo versus epi direction, or the distinction between septal RVOT versus anterior RVOT.

The x,y,z signals of the VCG and mean TSI can be represented in color, i.e. every time sample the line will change color so it is easy to understand where the signals start and where they end.

A further aspect according to the present invention comprises a method to estimate a mean temporal spatial isochrone (TSI) path through the heart from a vector signal derived from the ECG or directly measured (vector cardiogram using the Frank lead system), electrode positions, and heart position, preferably in which a position of the vector changes every time sample in a direction indicated by the vector signal. Further preferably, vector position changes are limited to the heart space, such as that the VCG vector position remains within the epicardial boundaries (blood cavities or myocardium). It is preferred that the speed of vector position change per time sample is set as a variable over time or set at a fixed value.

Further preferably, the VCG direction and position is be visualized in an orthogonal heart system, LOA view (apex to base), ROA view, anterior to posterior, and the 4 chamber view (inferior to superior). Electrode and heart positions are preferably obtainable or obtained from a

model database. Electrode positions are obtainable or obtained from a 3D imaging recording.

Further preferably, thorax dimensions, optionally derived for a 3D image, are used to select the most appropriate heart model. Such model selection is preferably adapted by the use of a further user input, such as genetic defects, weight, known morphological aberrations in the heart morphology, etc.

7) Vector signals (VCG) can be computed in the way described in the vector patent, but also by a transformation matrix such as the Dower transform. This matrix converts a 12 lead ECG into XYZ signals for the VCG.

8) The orthogonal heart system is obtained by determining the long axis of the heart (from MRI, model or echo) and the axis between the mid mitral valve and the mid tricuspid valve. The third axis is perpendicular to these two axis.

The present invention has been described in the foregoing on the basis of several preferred embodiments. Different aspects of different embodiments are deemed described in combination with each other, wherein all combinations which can be considered by a skilled person in the field as falling within the scope of the invention on the basis of reading of this document are included. These preferred embodiments are not limitative for the scope of protection of this document. The rights sought are defined in the appended claims.

CLAIMS

1. Method to provide a mean temporal spatial isochrone (TSI) path relating to an ECG feature (wave form) of interest, such as the activation of the heart from a single point (QRS), relative to the heart in a torso while using an ECG measurement from an ECG recording device, the method comprising steps of:
- receiving ECG measuring data from the ECG recording device,
 - 10 - determining vector cardiogram (VCG) data,
 - receiving a model of the heart, preferably with torso, as an input, preferably based on a request comprising request parameters,
 - obtaining the location information relating to a number of ECG electrodes relative to the torso model and or hearts model of the subject,
 - 15 - based on the location information in the torso model and/or heart model, positioning of the number of ECG electrodes,
 - 20 - determining mean TSI data values representing the TSI path relating to an electrophysiological phase representing the ECG feature, the mean TSI providing a location within the heart representing the mean location of the ECG feature at the corresponding time,
 - 25 - positioning the mean TSI path and preferably the vector cardiogram data points in the model of the heart and/or torso at an initial position,
 - rendering the model of the heart, preferably with torso, with the mean TSI path, preferably with VCG data related to the TSI, for displaying on a display screen for interpretation of the displayed rendering.
 - 30

2. Method according to claim 1 in which the steps of positioning the mean TSI path comprise steps for using a predetermined position, such as the center of mass of the heart, for positioning the first data value of the TSI
5 path.

3. Method according to claim 1 in which the steps of positioning the mean TSI path comprise steps of determining at least one initial position in which the first data
10 point of TSI path is to be positioned, preferably such that this position is located in the myocardium.

4. Method according to claim 2 or 3 in which the steps of positioning the mean TSI path comprise steps of
15 determining at least one final position in which the last data point of the TSI path is to be positioned, preferably such that this position is located in the myocardium.

5. Method according to one or more of the preceding
20 claims in which the steps of positioning the mean TSI path comprise steps of determining that the mean TSI path is fully located within the heart, preferably of a blood cavity of the heart and/or the wall thereof, such as the ventricles or the chambers.

25

6. Method according to one or more of the preceding claims comprising steps of determining which of the TSI data values represents the last data point of the TSI
path.

30

7. Method according to claim 6, comprising steps to make a determination that a change of direction of the TSI path in the ending phase of the electrophysiological phase

representing the ECG feature of interest represents the end of the electrophysiological phase.

8. Method according to one or more of the preceding
5 claims, in which the mean TSI value provides a position to be rendered within the boundaries of the heart representing a point per ECG measurement, such as per millisecond, and in which over the measurement of the ECG feature, such as the QRS, the combined points represent a line indicat-
10 ing the progressing of the average position of successive isochrones of the development of the ECG feature, such as the activation front in case of a QRS.

9. Method according to one or more of the preceding
15 claims in which a propagation velocity of the ECG feature is a factor in calculating the mean TSI value.

10. Method according to one or more of the preceding
claims in which the mean TSI is related to the vector car-
20 diogram data.

11. Method according to one or more of the preceding
claims in which a mean TSI is computed at successive pre-
determined time points during a cycle of the heart, such
25 as per value in a range of 0.1 ms-5 ms, preferably 0.5 ms-3 ms further preferably 0.5 ms-2 ms, further preferably about 1 ms.

12. Method according to one or more of the preceding
30 claims in which the mean TSI is calculated while applying following formula:

$$- \text{mean TSI}(x, y, z; t + 1) = \text{mean TSI}(x, y, z; t) + v \cdot \text{VCG}(x, y, z; t)$$

- in which t represents a time point of a number of time points, such as per millisecond,
- VCG represents a VCG data point of the ECG data,
- v is velocity of the ECG feature or the electro-physiological phase activity.

13. Method according to one or more of the preceding claims comprising steps of determining one or more areas of probability in which a first data value of the TSI path is located.

14. Method according to claim 13 comprising steps of comparing the angle of the ECG feature axis, such as the QRS axis, with the TSI direction at or close to the respective area of probability, preferably comprising the steps of determining the area of probability of choice for positioning the beginning of the TSI path.

15. Method according to one or more of the preceding claims in which the VCG data is preferably subsequently added to the progressing mean TSI position.

16. System for under application of a method according to one or more of the preceding claims provide a mean temporal spatial isochrone (TSI) path relating to an ECG feature (wave form) of interest, such as the activation of the heart from a single point (QRS), relative to the heart in a torso while using an ECG measurement from an ECG recording device, comprising:

- a processing unit,
- a memory coupled with the processing unit,
- receiving means for receiving location information relating to a number of ECG electrodes,

- receiving means for receiving electro data of the respective ECG electrodes,

- outputting means for outputting of result data and/or results comprising image data.

5

17. System according to claim 16 comprising a recording device, such as an optical recording device for determining of a position of respective ECG electrodes relative to a person.

10

18. System according to claim 16 or 17 comprising a display screen and inputting means for inputting of instructions.

15

19. System according to claim 16, 17 or 18 in which the processing unit, the memory and the recording device are integrated in one physical housing, comprising in memory program coding means for performing of the method according to one or more of the claims 1-15.

20

1 / 12

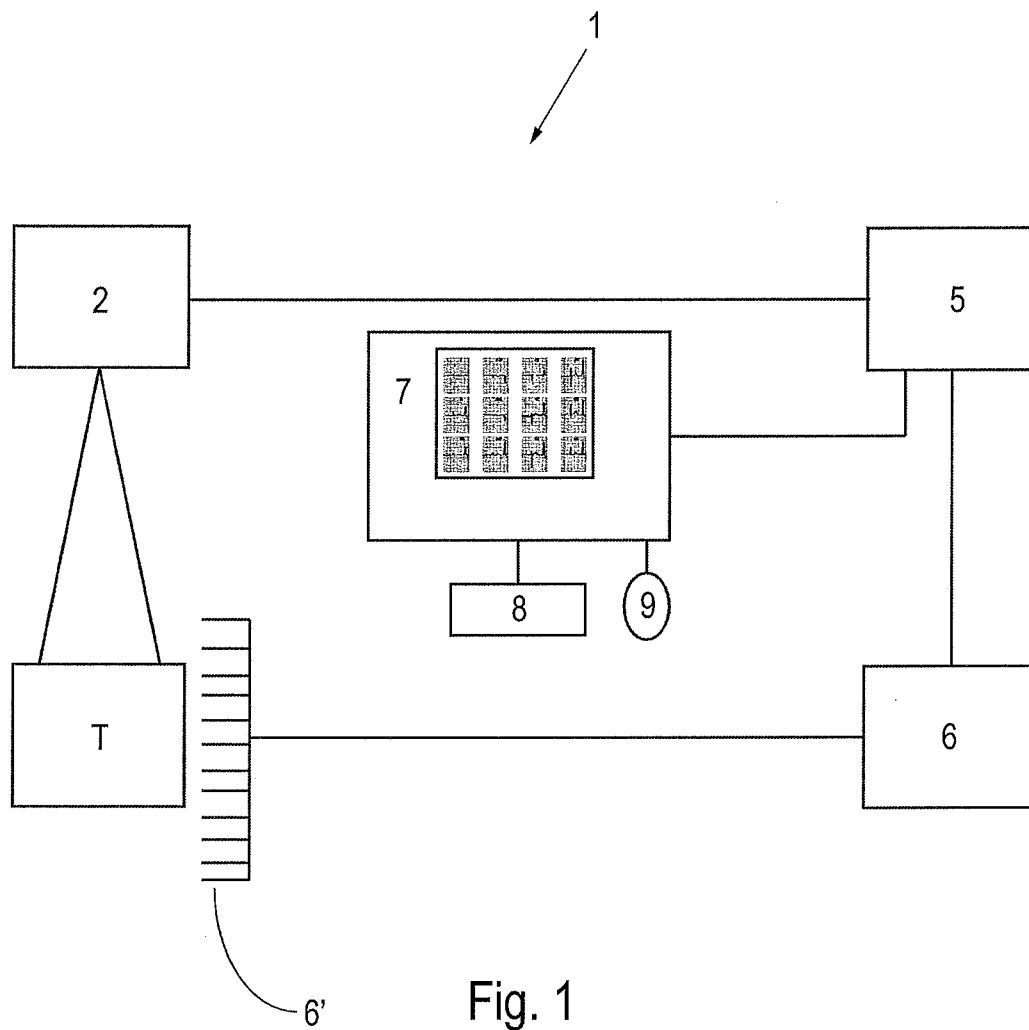


Fig. 1

2 / 12

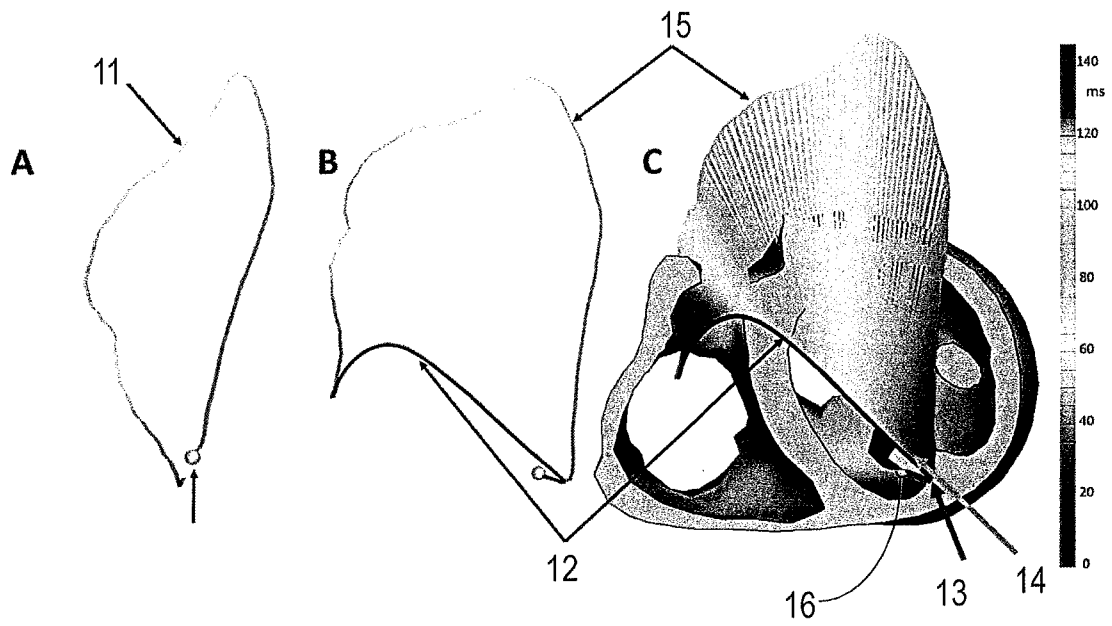


Fig. 2

3 / 12

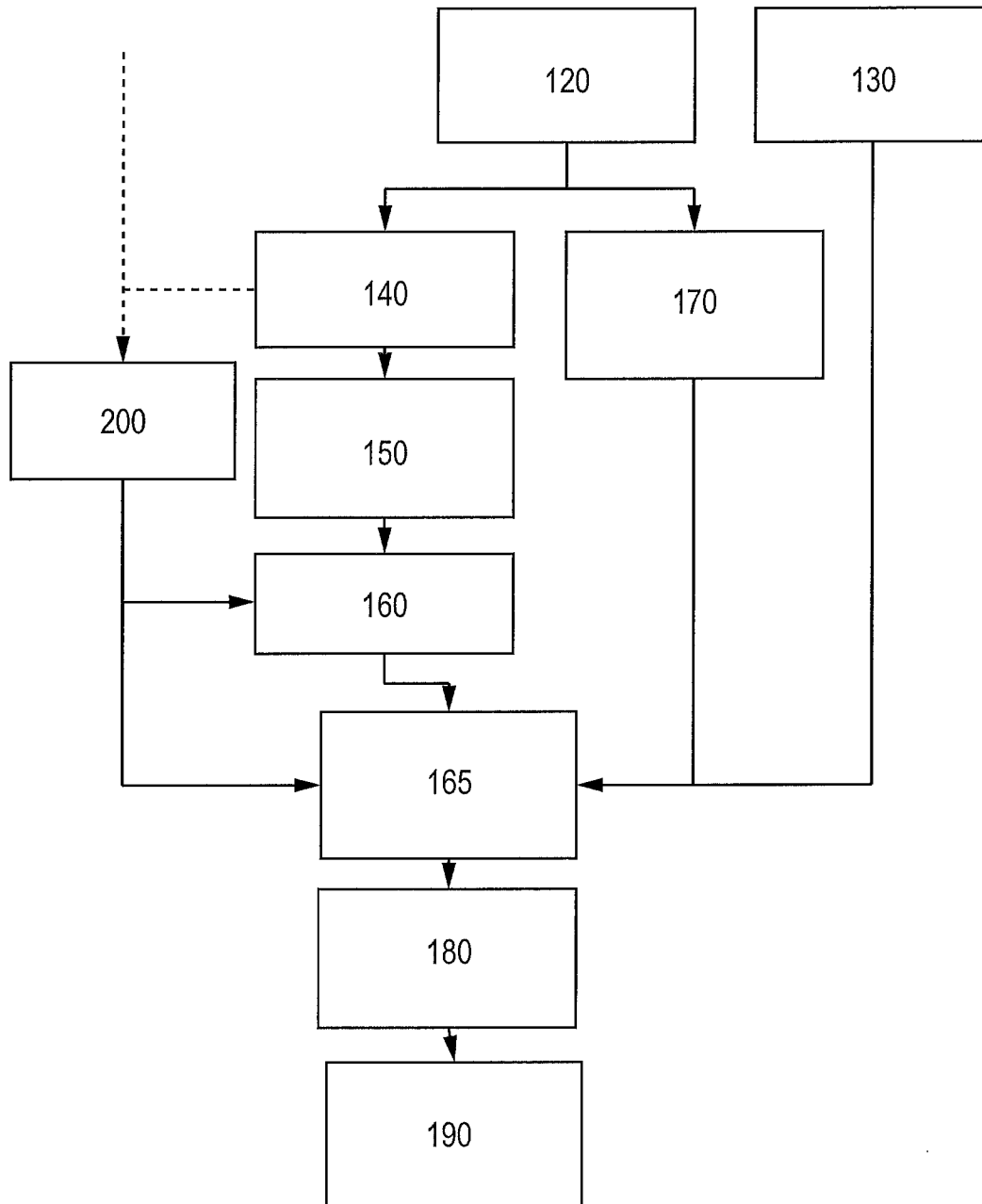


Fig. 3

4 / 12

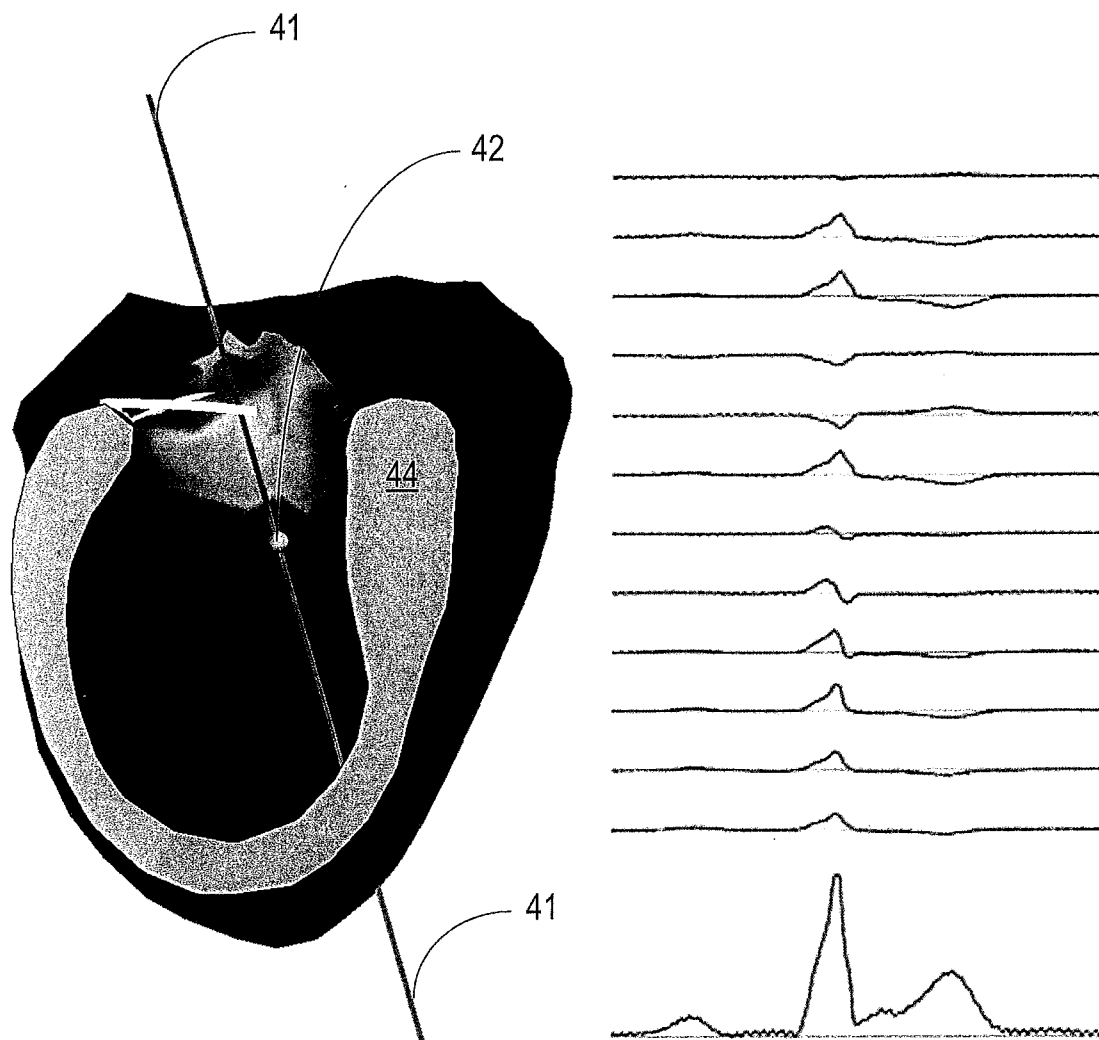


Fig. 4

5 / 12

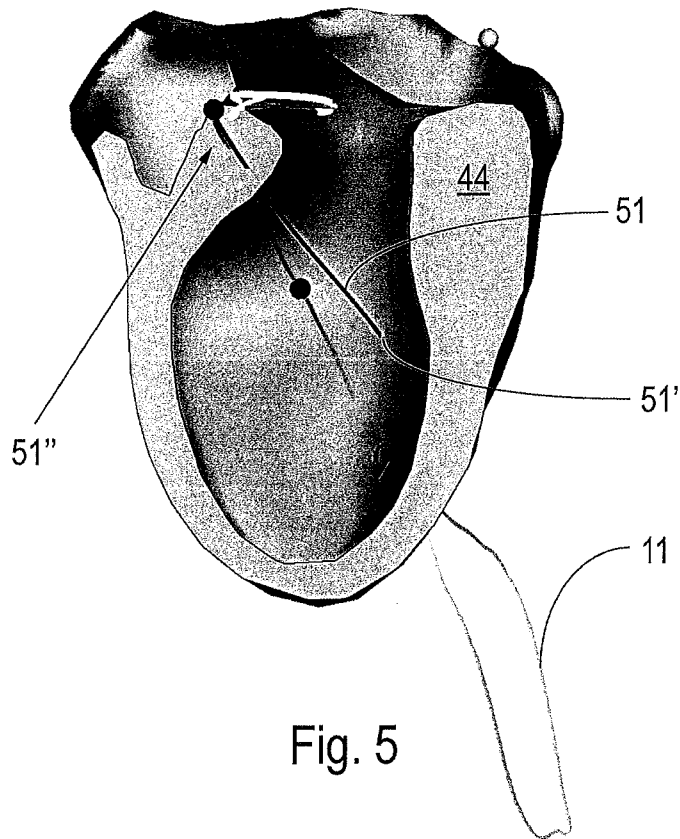


Fig. 5

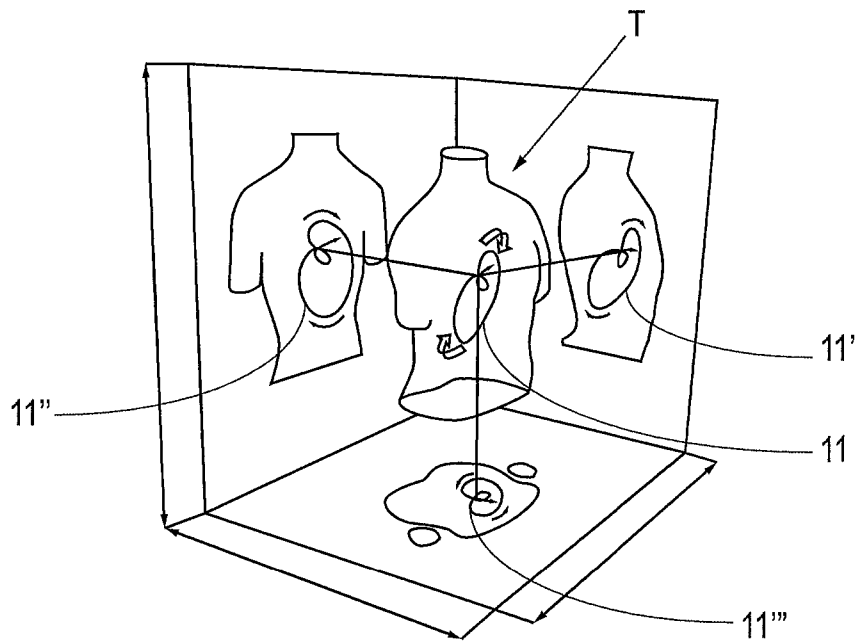


Fig. 6

6 / 12

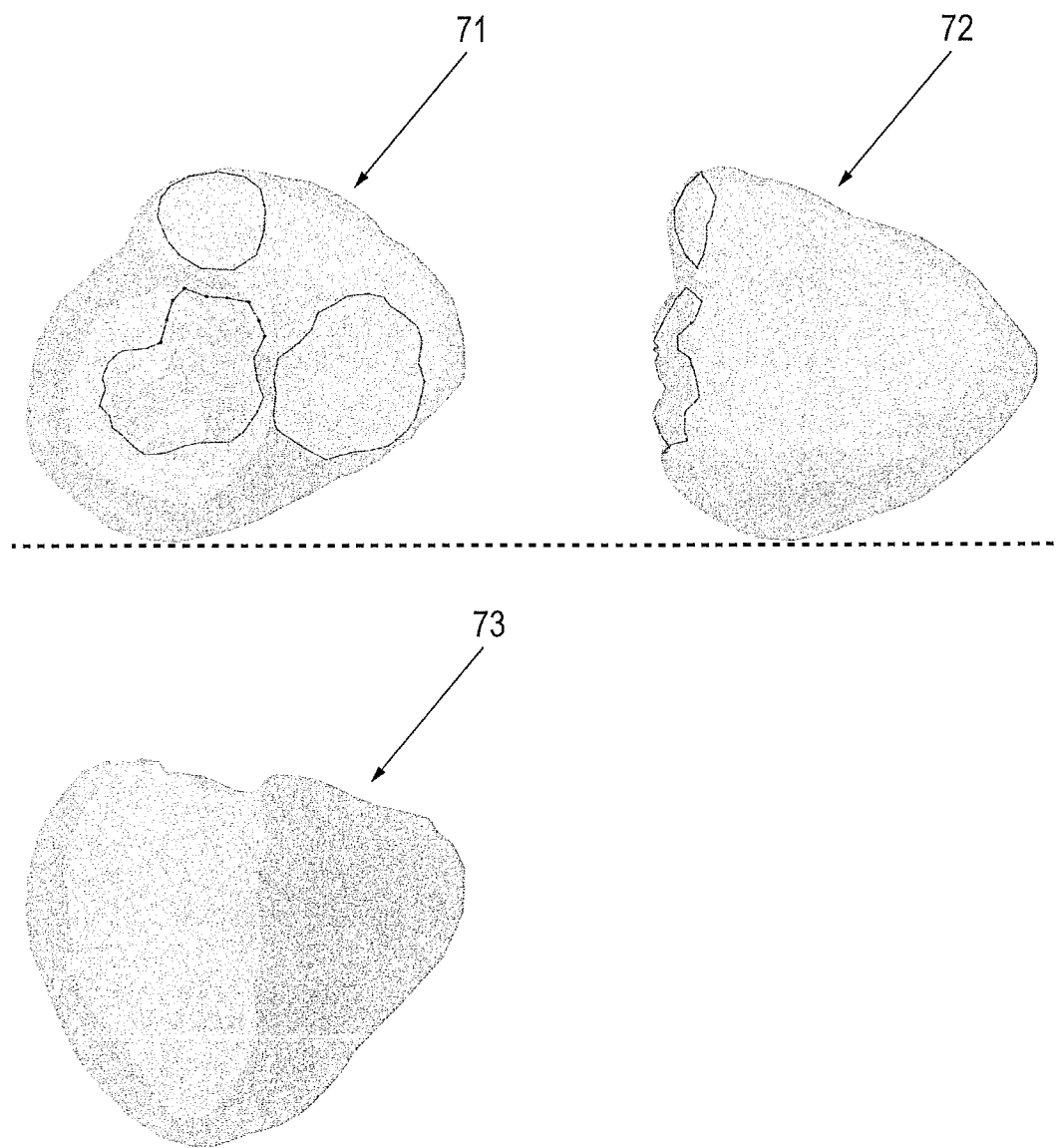


Fig. 7

7 / 12

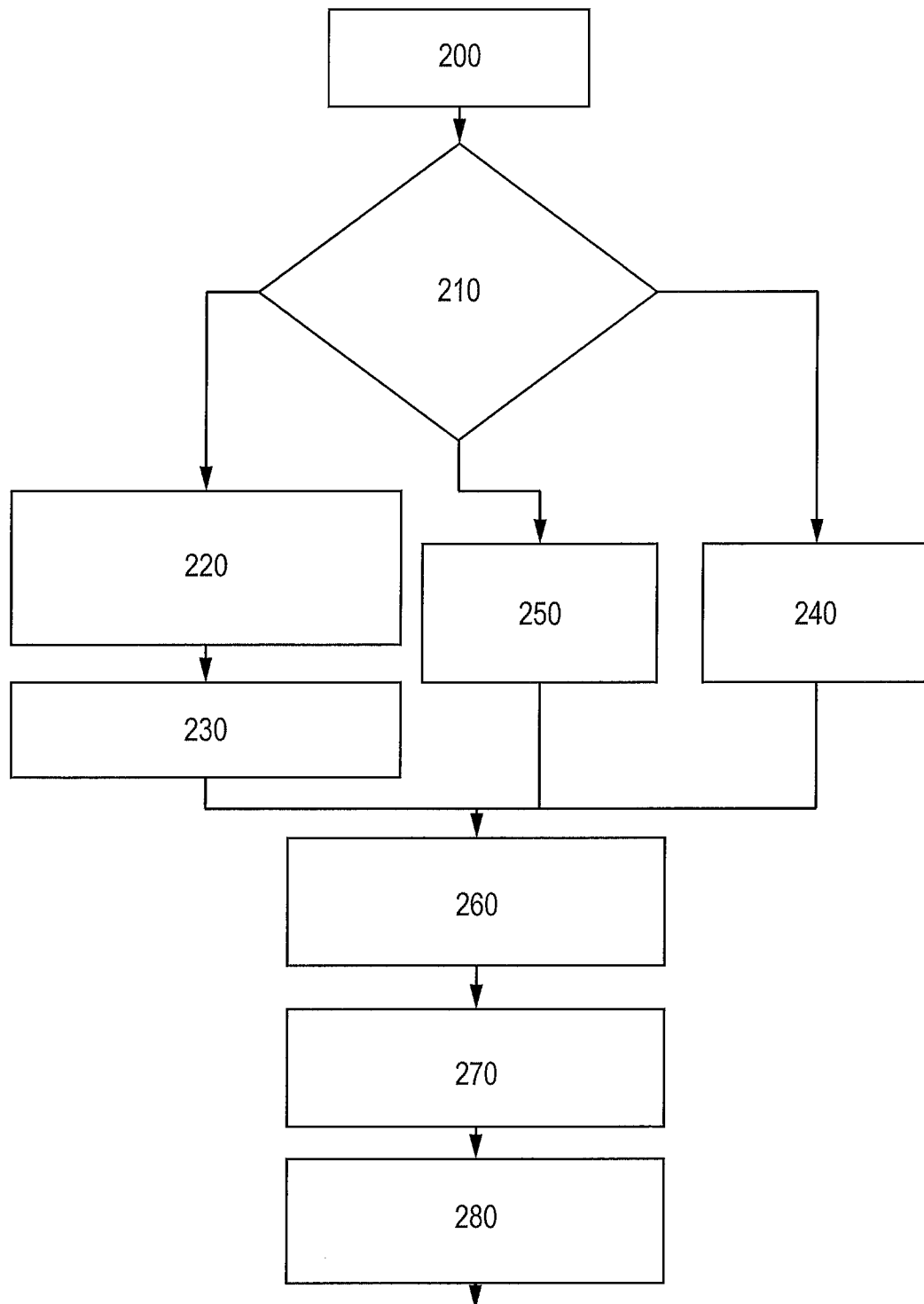


Fig. 8

8 / 12

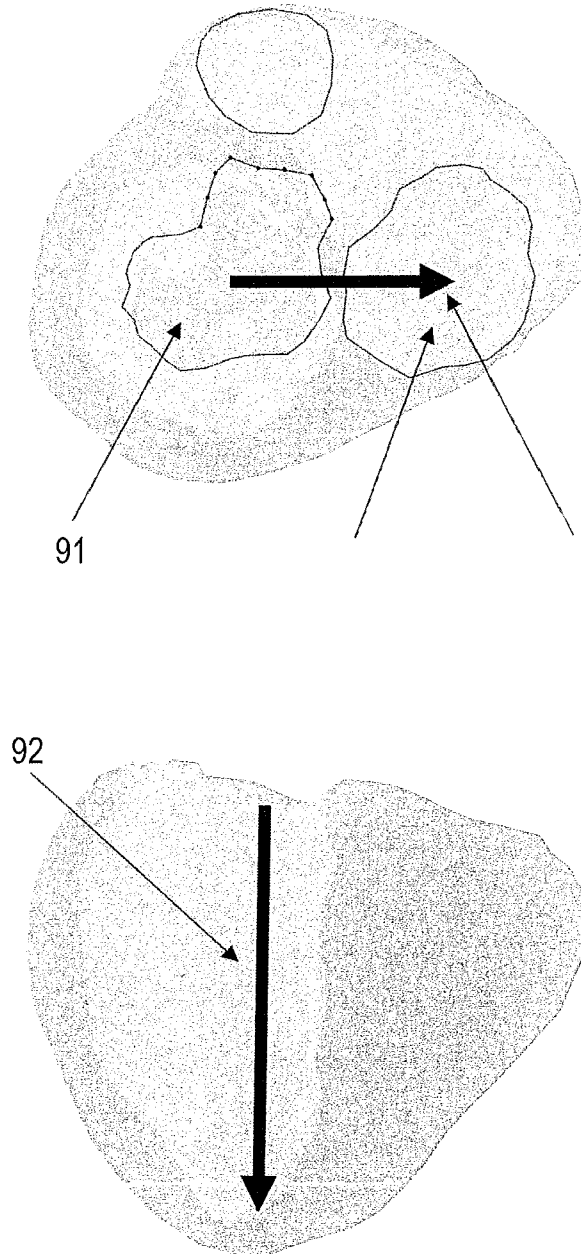


Fig. 9

9 / 12

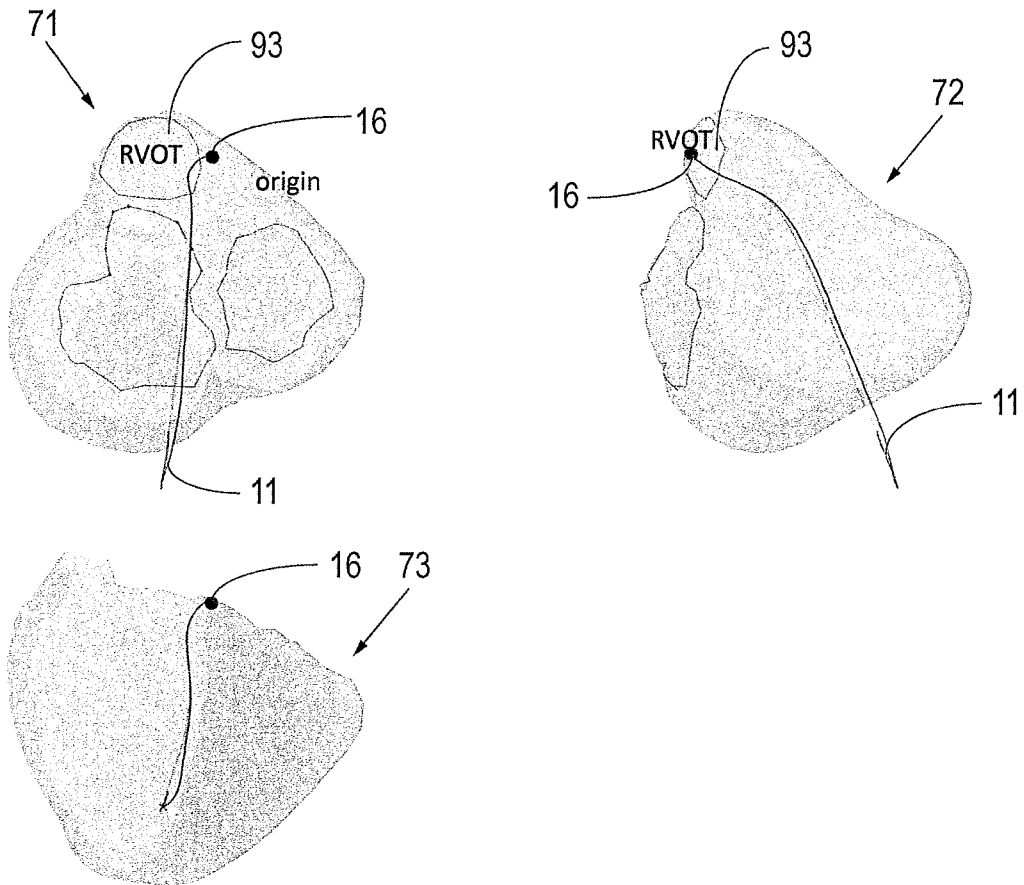


Fig. 10

10 / 12

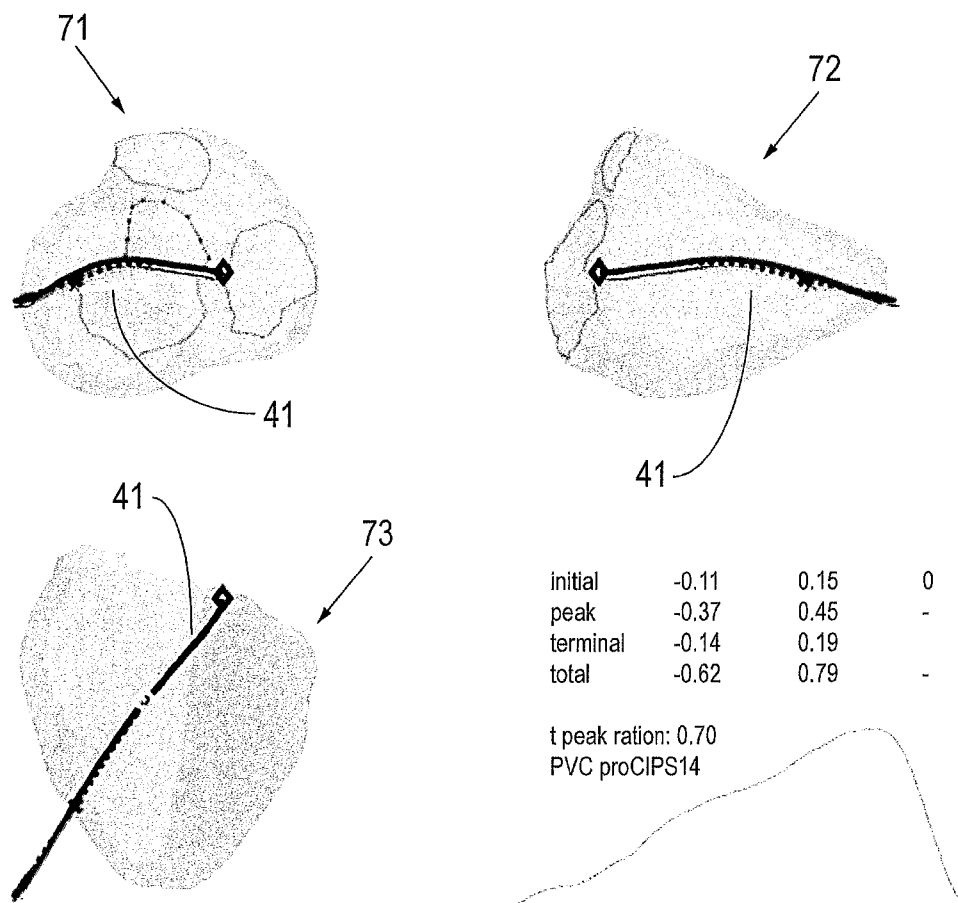


Fig. 11

11 / 12

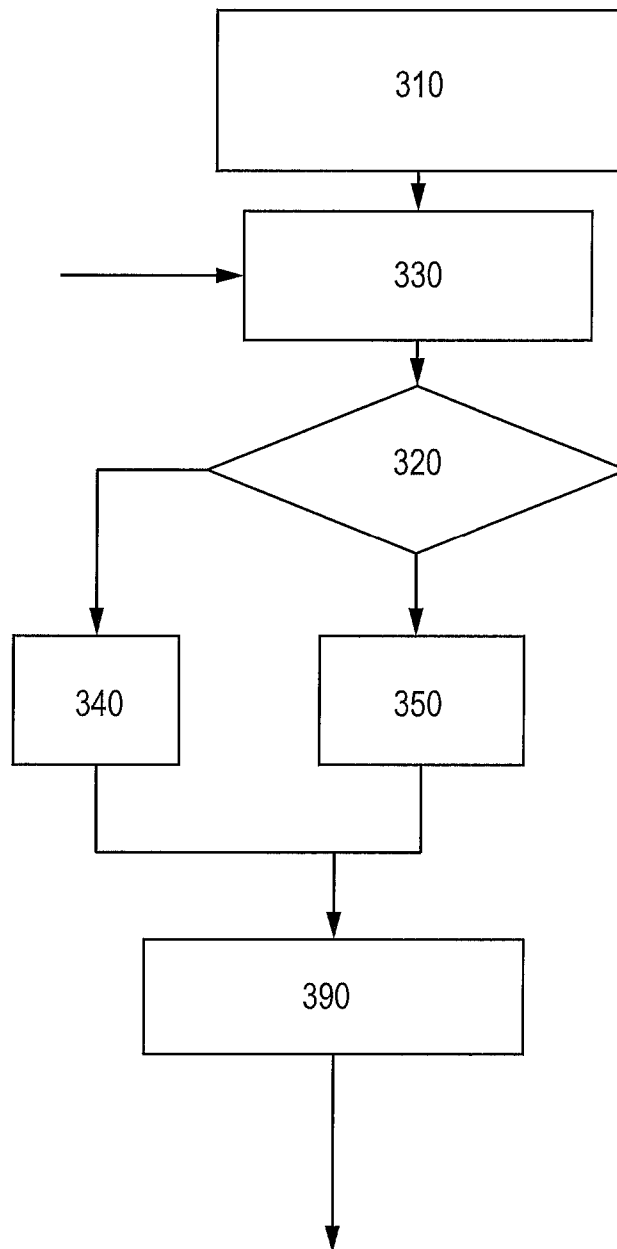


Fig. 12

12 / 12

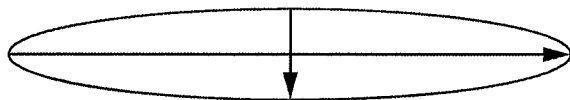


Fig. 13

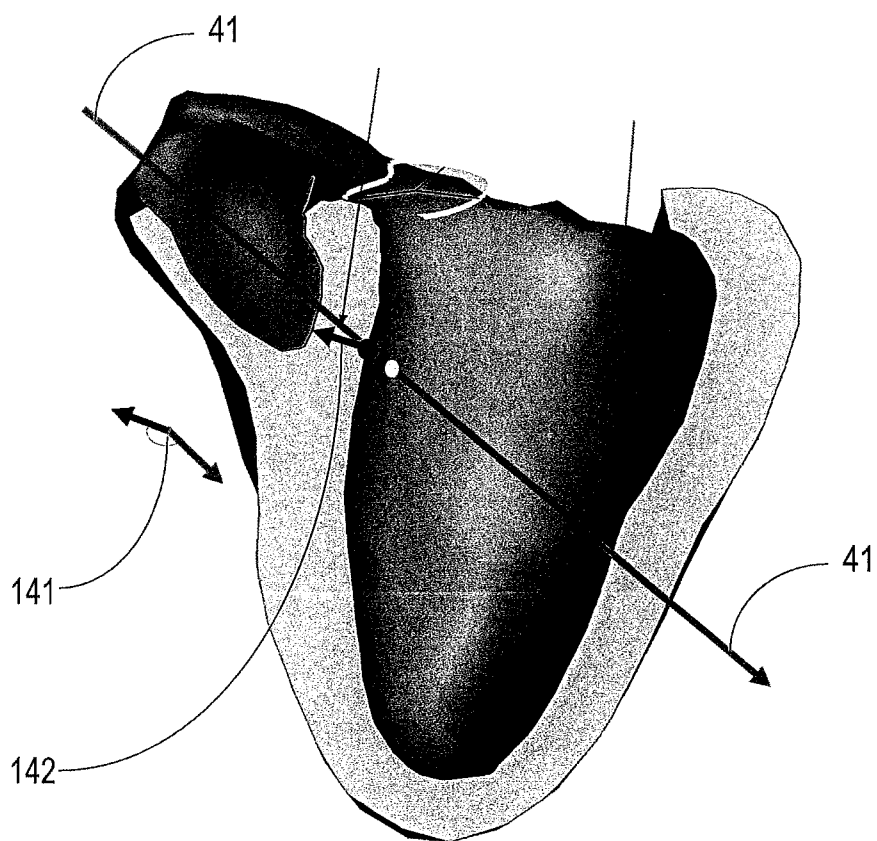


Fig. 14

INTERNATIONAL SEARCH REPORT

International application No
PCT/NL2018/050228

A. CLASSIFICATION OF SUBJECT MATTER INV. G16H40/63 A61B5/04 A61B5/0452 G16H50/30 G16H50/20 A61B5/00 ADD. According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) G16H A61B Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) EPO-Internal, WPI Data		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2017/071492 A1 (VAN DAM PETER MICHAEL [NL] ET AL) 16 March 2017 (2017-03-16) paragraph [0002] paragraphs [0009] - [0010] paragraph [0024] figure 1 -----	1-19
☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.		
* Special categories of cited documents : "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier application or patent but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family		
Date of the actual completion of the international search 6 September 2018		Date of mailing of the international search report 18/09/2018
Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016		Authorized officer Reinbold, Bernhard

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/NL2018/050228

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2017071492	A1	16-03-2017	NONE

专利名称(译)	确定心脏的方法和系统		
公开(公告)号	EP3610482A1	公开(公告)日	2020-02-19
申请号	EP2018749582	申请日	2018-04-12
[标]申请(专利权)人(译)	PEACS		
申请(专利权)人(译)	PEACS B.V.		
当前申请(专利权)人(译)	PEACS B.V.		
[标]发明人	VAN DAM EELCO MATTIAS VAN DAM PETER MICHAEL		
发明人	VAN DAM, EELCO MATTIAS VAN DAM, PETER MICHAEL		
IPC分类号	G16H40/63 A61B5/04 A61B5/0452 G16H50/30 G16H50/20 A61B5/00		
CPC分类号	A61B5/0013 A61B5/04011 A61B5/0452 G16H40/63 G16H50/20 G16H50/30 A61B5/0402 A61B5/04085 A61B5/044 A61B5/0472 G06F17/18 G06T15/00 G06T19/20 G06T2210/41 G06T2219/2004 G16H50/50		
优先权	PCT/NL2017/050225 2017-04-12 WO		
外部链接	Espacenet		

摘要(译)

本发明涉及一种提供与感兴趣的ECG特征(波形)有关的平均时间空间等时(TSI)路径的方法,例如相对于心脏中的单个点(QRS)激活心脏。使用来自ECG记录设备的ECG测量时,躯干处于躯干状态。该方法包括:从心电图记录设备接收心电图测量数据;以及确定向量心电图(VCG)数据;优选地基于包括请求参数的请求来接收心脏模型,优选地以躯干为输入;确定表示与表示ECG特征的电生理阶段有关的TSI路径的平均TSI数据值,该平均TSI在心脏内提供表示在相应时间的ECG特征的平均位置的位置;将平均TSI路径以及矢量心电图数据点定位在心脏和/或躯干模型中的初始位置;并优选地用躯干,平均TSI路径,优选地使用与TSI相关的VCG数据来渲染心脏模型,以在显示屏上显示以解释所显示的渲染。