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(54) Title: CONGESTIVE HEART FAILURE PACING OPTIMIZATION METHOD AND DEVICE

(57) Abstract: Conduction volumetry of a heart chamber 32 is measured by a catheter 40 having multiple electrode sites 46 and is used to determine the hemodynamic performance of the heart under various pacing protocols to optimize cardiac output as a function of the pacing protocol.

CONGESTIVE HEART FAILURE PACING OPTIMIZATION
METHOD AND DEVICE

5   <u>Cross reference to Related Cases</u>

The present application is a continuation in part of US Patent
Applications 09/107,371 filed 6/30/98; 09/589,387 filed 6/7/00;
09/589,322 filed 6/7/00 and 09/09/588,930 filed 6/7/00 each of which
is incorporated by reference in its entirety herein.

10   <u>Field of the Invention</u>

The present invention relates generally to cardiac pacing therapy
and more particularly to biventricular pacing for the treatment of
congestive heart failure.

<u>Background of the Invention</u>

15   Congestive heart failure (CHF) is a disease state characterized by
an enlargement of the heart with a concomitant reduction in pumping
efficiency. Treatment regimes for CHF have included drugs, specifically
diuretics, as well surgical interventions to remodel the heart. More
recently it has been shown that pacing both ventricular chambers of the

20   heart in close temporal sequence can improve the cardiac performance
for CHF patients. It is believed that conduction disturbances contribute
to CHF and replicating a "normal" activation sequence will improve
heart function reducing or relieving symptoms.

The primary variables in biventricular pacing are the A-V delay

25   and the V-V right and left ventricular pacing delay. In general the pacer
synchronizes with the atrium and paces both ventricular chambers in
sequence (V-V) after an appropriate A-V delay.

<u>Summary of the Invention</u>

The purpose of the applicant's invention is to provide the

30   physician with a tool to allow him to optimize the biventricular pacing
therapy. The applicant proposes pacing the heart at a variety of sites in
the cardiac chambers using a conventional pacing lead to survey
potential sites for permanent implantation of pacing leads. During the
survey the physician would have access to electrophysiological (EP)

data taken on a beat-by-beat basis along with a calculated index of hemodynamic performance. In general the physician will try to maximize the hemodynamic performance based on the index of performance and then confirm that the pacing stimulus is creating an

5   appropriate pattern of conduction with reference to the observed EP data.

The method of the invention begins with pacing the heart. This is done for several sites selected in the ventricles. This process is carried out with a pacing catheter that can be easily moved between the sites.

10   At each site or candidate location, electrophysiologic data is collected. This data may be displayed to the physician as an activation map to show the interaction of the heart tissue with the pacing stimulus. The most typical display of data will be false color activation maps showing the propagation of the depolarization wave front over the heart as a

15   function of time.

At each candidate pacing site, conduction volumetry is carried out with an indwelling multiple electrode array catheter such as the commercially available "ENSITE catheter" to compute volumetric changes associated with the pacing stimuli. Typically, the best cardiac

20   performance is correlated with the most homogenous activation of the basal region of the heart chamber.

This coherence of action can be seen from the single beat activation map created with the ENSITE system. A hemodynamically based indication of coherence can be computed and expressed as a

25   figure of merit corresponding to the homogeneity in the volume change in the chamber as the heart contracts as well. It is proposed to define and use this hemodynamic index of performance alone or together with electrical conduction measures to allow pacing optimization.

The index is based in part of the "homogeneity" or coherence of

30   the contraction which is believed to correlate with the "vigor" of the contraction. It is preferred to compute the index on a beat-by-beat basis and to display the index of performance along with the

electrophysiology data taken during the same beat. Thus the displayed data sets are from the same pacing event.

Brief Description of the Drawings

Throughout the figures identical reference numerals refer to identical structure wherein:

Fig. 1 is a schematic diagram of the EP system;

Fig. 2 is a schematic diagram of a portion of the system;

Fig. 3 is an equivalent circuit of a measurement made by the system;

Fig. 4 is a diagram of an output display from the EP system;

Fig. 5 is a diagram of a measurement made by the system;

Fig. 6 is a display representing the "coherence" measure and the index of hemodynamic performance.

Detailed Description

Theory

The disclosure is based on the collection of new data, and a new use of data presently collected within the ENSITE system as sold by Endocardial Solutions (ESI) of St Paul MN. In this specification reference is made to patents held by ESI, each patent is incorporated by reference herein. The use of the trade marked term ENSITE is intended to refer to commercially available structures.

It has been widely known that one may pace the heart through an EP catheter or through a separate pacing catheter to explore the electrical behavior of the heart during a diagnostic or ablation procedure. More recently it has been determined that pacing in both the left and right ventricle or bi-ventricular pacing is a useful therapy for the treatment of congestive heart failure. By closely coordinating the contraction of both ventricular chambers, an improved cardiac output can be achieved which tends over time to reduce the overt symptoms of congestive heart failure. It is recently, but not widely, recognized that the timing intervals and pacing sites of biventricular pacing must be carefully selected to generate the benefits of biventricular pacing.

It is becoming well understood that the precise placement of ventricular pacing leads in the heart is critical to achieving success with biventricular pacing or other pacing therapies directed to patients with CHF. It is believed that if the lead system is located in tissue that is

5   refractory, ischemic or scarred, the propagation of activation is delayed and the resulting contraction is disorganized and less effective than normal.

The coherence of electrical activation is a non standard but useful way of expressing the requirement that the electrical activation of the

10   heart be propagated over the diseased tissue in a way to result in an effective contraction. From a hemodynamic viewpoint a coherent contraction arises from a homogenous volumetric contraction, in which all portion of the observable heart chamber contract progressively and in "unison".

15   The coherence of electrical activation can be directly observed by the ENSITE system in the EP data while the homogeneity or hydralic coherence measure is a hemodynamic index computed beat to beat by a modified ENSITE system.

Users of the ENSITE system become skilled at interrupting the

20   propagation of such waveforms and can readily determine the location of infarcted regions in the myocardium based upon their electrical behavior. It is generally wise to avoid attempting to pace these regions of the heart.

Implementation

25   Fig. 1 shows a commercially available ENSITE electrophysiology mapping system sold by Endocardial Solutions of St. Paul, Minnesota. Although the ENSITE system in its current commercial embodiments presents electrophysiologic data on a static geometry of the heart, it should be recognized that certain heart information (EP activation) is

30   available on a single beat basis this attribute is important in understanding the use of the system in this application.

In this system a patient 10 is undergoing a diagnostic procedure through a minimally invasive procedure involving the introduction of

an ENSITE catheter coupled to the breakout box 12. A conventional electrophysiology catheter 16 is also introduced into the patient while a variety of surface electrodes 11 are used to monitor cardiac activity during the procedure. The breakout box 12 permits the ECG cables and

5   EP system to be coupled to additional hardware, which is not shown in this figure. The patient interface unit 18 couples the ENSITE catheter to the workstation computer and its related peripherals. 20. The workstation operates under the control of a software program, which provides a substantial amount of information to the attending

10 physician.

In use the physician will see an activation map image similar to that shown in Fig. 3 on the monitor 23. The computed index 51 will also been shown to the physician as indicated by index value ".93" seen on the monitor 23. In general, the physician is able to visualize the

15 intracardiac cavity 32 containing the ENSITE catheter 14 as seen in Fig. 3 on a color monitor 23. Color is used to reduce the clutter in the image. Expressed or displayed on this wire frame geometry image 50 are activation maps and other electrophysiology information derived from the ENSITE catheter in conjunction with the EP catheter. In this

20 particular instance, the patient is also provided with one or more pacing catheters 24 which are coupled to a temporary pacer 26 through the breakout box 12.The temporary pacer 26 allows the physician to make measurements while varying the A-V delay and the V-V delay time. Pacing rate may be varied to ensure capture.

25 Turning to Fig. 2 the heart 30 is shown schematically with a right ventricle 32 containing the ENSITE catheter 14 and a conventional EP catheter 16 as well as the pacemaker lead 24. In brief, software running on the workstation 20 in Fig. 2 can create an electrophysiological map of the heart during a single heartbeat as follows. In operation current

30 sourced from a pair of electrodes (electrode 40 and 42) and injected into the heart chamber 32. chamber. A roving catheter, shown as EP catheter 16, is located on the endocardial surface 31 toward the exterior of the heart this catheter may be moved widely and may be placed on the

interior heart surface along the septum is shown by reference numeral 33. The injected current is detected through the electrode 44 on the EP catheter 16. This location is determined and as the catheter is moved about the chamber, complete chamber geometry can be built up by

5   noting the sequential positions of the electrode 44. Incorporated references describe this process in more detail but for purposes of this disclosure a convex hull modeling technique is used to build a statically displayed interior geometry of the heart chamber by selecting certain locations developed from the electrode motion. The convex hull model

10   of the interior chamber of the heart can be smoothed and a representative wire grid displayed to the physician. Such a wire grid is shown in Fig. 3 as element 50.

The ENSITE catheter also carries an array of passive electrode sites typified by electrode site 46. These electrodes are arrayed around

15   the geometric access of the ENSITE balloon 47. At any given instant some of these electrode sites are pointed toward the exterior surface wall 31 and the septal wall 33. By computing the inverse solution, the electrophysiologic potentials passing along these surfaces can be measured within one beat. Reference may be had to U.S. Patents

20   5,291,549; 5,311,866; 6,240,307 and 5,553,611 for further discussion of the inverse solution and the creation of the electrophysiologic map. Each of these references is incorporated in its entirety in the present application.

In the commercially available ENSITE system the depolarization wavefront is displayed on a representative geometric surface such as

25   the grid surface 50 of Fig. 3. The workstation 20 animates this electrophysiology data and the propagation of the electrical way front along the interior surfaces of the heart can be monitored. Wavefronts 80 82 and 83 are sequence movements of the stimulus from pacing site 84 seen in Fig. 3.

30   Fig. 4 shows an equivalent circuit implementation to facilitate a description of conduction volumetry measurements made from an ENSITE catheter. Returning to the geometry of the array on the ENSITE catheter 14 the interior of the balloon 47 is non-conductive which

provides a limited field of view for each of the electrode sites on the surface of the balloon. In essence each electrode responds only to electrical activity bounded by the heart wall, which is directly opposite the electrode site. For example, an electrode such as electrode 46 sees

5   electrical activity and conductance data bounded by the wall 31 and is blind to electrical activity on wall 33. In a similar fashion, an electrode such as electrode 50 sees only electrical activity occurring on wall surface 33. By monitoring the voltages on the array electrodes during the pulse, or more particularly measuring the resistance between

10   adjacent columnar pairs of electrodes as indicated by exemplary difference amplifier 86 it is possible to compute the volume of a partial slice 88 of the chamber volume best seen in Fig. 5. It is important to note that the volume measurement is segmented into several local volumes typified by volume 88.

15   Fig. 5 shows a slice of chamber volume computed by measuring the difference in resistance between electrodes adjacent along the axis 21. This view shows that the volume segments are non-overlapping and extend along the axis 21. The conductance term R is the resistance measured at electrodes in the passive array. This value is directly

20   available to the software in the program, and Rho is the conductance of the blood in ohms-centimeters. D represents the distance between adjacent electrode sites in the passive array along the axis 21. This value is known from the geometry of the ENSITE catheter. The preferred conduction volumetry algorithms can be computed very fast and the

25   volume changes throughout a single beat of the heart may be tracked. The measurement of chamber volume is most accurate at the mid volume level indicated in Fig. 4 at reference 90. It is preferred but not required to sum or stack the independent volume measurements to create "columnar values" centered on the axis 21. This is achieved by

30   adding volumes 92 through 96 to create a column volume 90 located near the septum. A similar process is repeated to create a column volume near the wall 31 as shown as a slice 88 in Fig. 5 as well as elsewhere around the chamber.

It is believed that the most effective heartbeat will involve the
simultaneous and progressive activation of all of the muscle tissue,
which should result in a self similar reduction in the measured volume
among all of the volume segments measured.

5   Fig. 6 is a display of four representative volume segments of the
heart chamber displayed as a function of time. It is expected that eight
volumes will be used most effectively. Segment 88 may correspond to
the antero-lateral volume while the other traces represent other
volumes such as the Septal; antero-septal; anterior; antero-lateral;

10   lateral or other volumes defined around axis 21. The preferred way to
compare the self-similarity of the volume waveforms is to cross
correlate them statistically. By cross correlation of the values of the
segment volumes over time one can compute a number that represents
the similarity relationship of the various waveforms to each other. That

15   is if the all the volumes contract identically then they should share the
same waveform morphology and be completely self similar. In this
instance the index value is unity. Real measurements taken have shown
that a CHF patient in normal sinus rhythm has an index value of about
.8. and that by manipulating the A-V delay time, location of stimulus

20   and V-V delay interval this index can by increased to about .9 this is a
very significant improvement in the heart contraction. In Fig. 6 a
computed value of .93 is delayed showing improved contraction
behavior based on the selected pacing parameters. It is important to
note that it is not intended to make a display like Fig. 6 available to the

25   physician because it is difficult to "compute" self-similarity
qualitatively. The figure is designed to show how the performance
index is calculated. index

       In operation the physician will have the index saved for each
pacing location and set of pacing variables. The physician will look for

30   an improved contraction that is reflected by a high index value and a
"normal" activation sequence.

       For example a relatively invariant collection of volumes on one
side of the heart or the other is some indication that wall is not

contracting vigorously and that a better pacing site should be selected. This coherence of contraction index can be displayed as a simple number of percent of a total (unity). It is expected that simple figures of merit will be displayed for the physician to allow him to optimize the

5   location of the pacing lead. It is expected that a measure of hemodynamic performance based upon conduction volumetry will be given independently of a coherence of contraction index.

It must be recognized that such measures are largely arbitrary and they may be combined in a variety of ways to improve the

10   relationship between the hemodynamic performance index and the clinical outcome for the patient based upon pacing site.

What is claimed is:

1.) A method of optimizing a pacing site for a heart chamber of a
5   congestive heart failure patient comprising:
          pacing the heart a plurality of sites;
          measuring a number of partial chamber volumes of the heart
     chamber over time through out one heartbeat generating a
     volume/time data set;
10   constructing a measure that compares the self-similarity of
     volume/time data set;
          selecting the pacing conditions corresponding to the most self-
     similar volume time data.

15   2. A device for carrying out conduction volumetry on the heart
     comprising:
          a catheter having a blood exclusion volume;
          an array of electrodes on said blood exclusion volume;
     means for measuring the resitance between pairs of electrodes;
20   means for computing the partial chamber volume associated
     with at least some of said electrodes over time generating a
     volume/time data set;
          means for computing the similarity between differing members
     of the volume/time data set to create a performance index.
25
     3. A method for selecting a pacing site comprising:
          pacing at a first site;
          monitoring a hemodynamic variable while pacing at said first
     site;
30   pacing at a second site spaced apart from said first site;
          monitoring said hemodynamic variable while pacing at said
     second site:

comparing the value of said hemodynamic variable at said first
and second site:

selecting between said first and second site based upon the
comparison of said hemodynamic variable.

5

4. A method of treating congestive heart failure comprising:

pacing at a first site in the right ventricle;

monitoring a hemodynamic variable while pacing at said first
site;

10   pacing at a second site in said right ventricle spaced apart from
said first site;

monitoring said hemodynamic variable while pacing at said
second site:

comparing the value of said hemodynamic variable at said first
15   and second site:

selecting between said first and second site based upon the
comparison of said hemodynamic variable for selecting a site in said
right ventricle.

20   5. A method of treating congestive heart failure comprising:

pacing at a first site in the right ventricle;

monitoring a hemodynamic variable while pacing at said first
site;

pacing at a second site in said right ventricle spaced apart from
25   said first site;

monitoring said hemodynamic variable while pacing at said
second site:

comparing the value of said hemodynamic variable at said first
and second site:

30   selecting between said first and second site based upon the
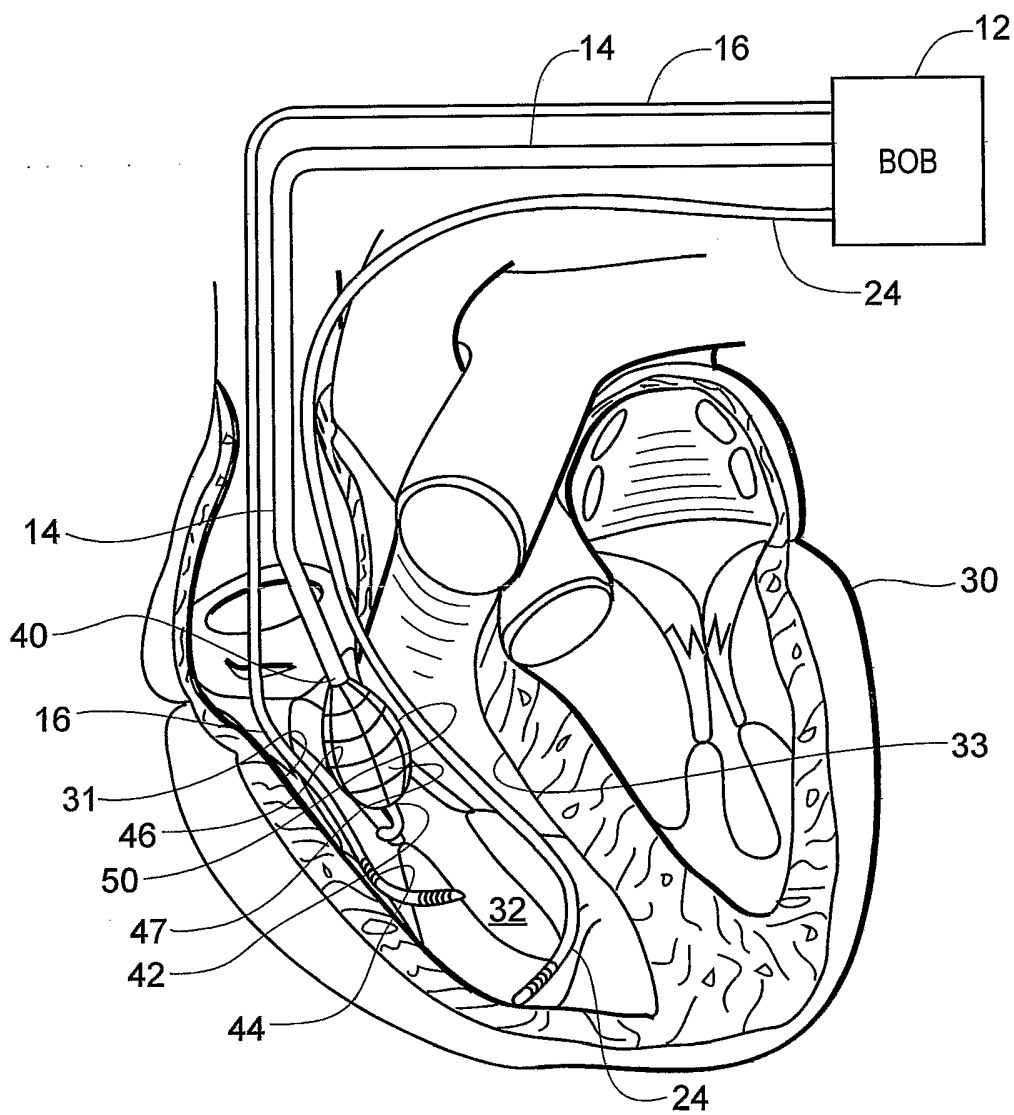comparison of said hemodynamic variable for selecting a site in said
right ventricle;

pacing at a third site in the left ventricle;

monitoring a hemodynamic variable while pacing at said first
site;

pacing at a fourth site in said left ventricle spaced apart from
said first site;

5   monitoring said hemodynamic variable while pacing at said
fourth site:

comparing the value of said hemodynamic variable at said third
and fourth site:

selecting between said third and fourth site based upon the
10   comparison of said hemodynamic variable for selecting a site in said
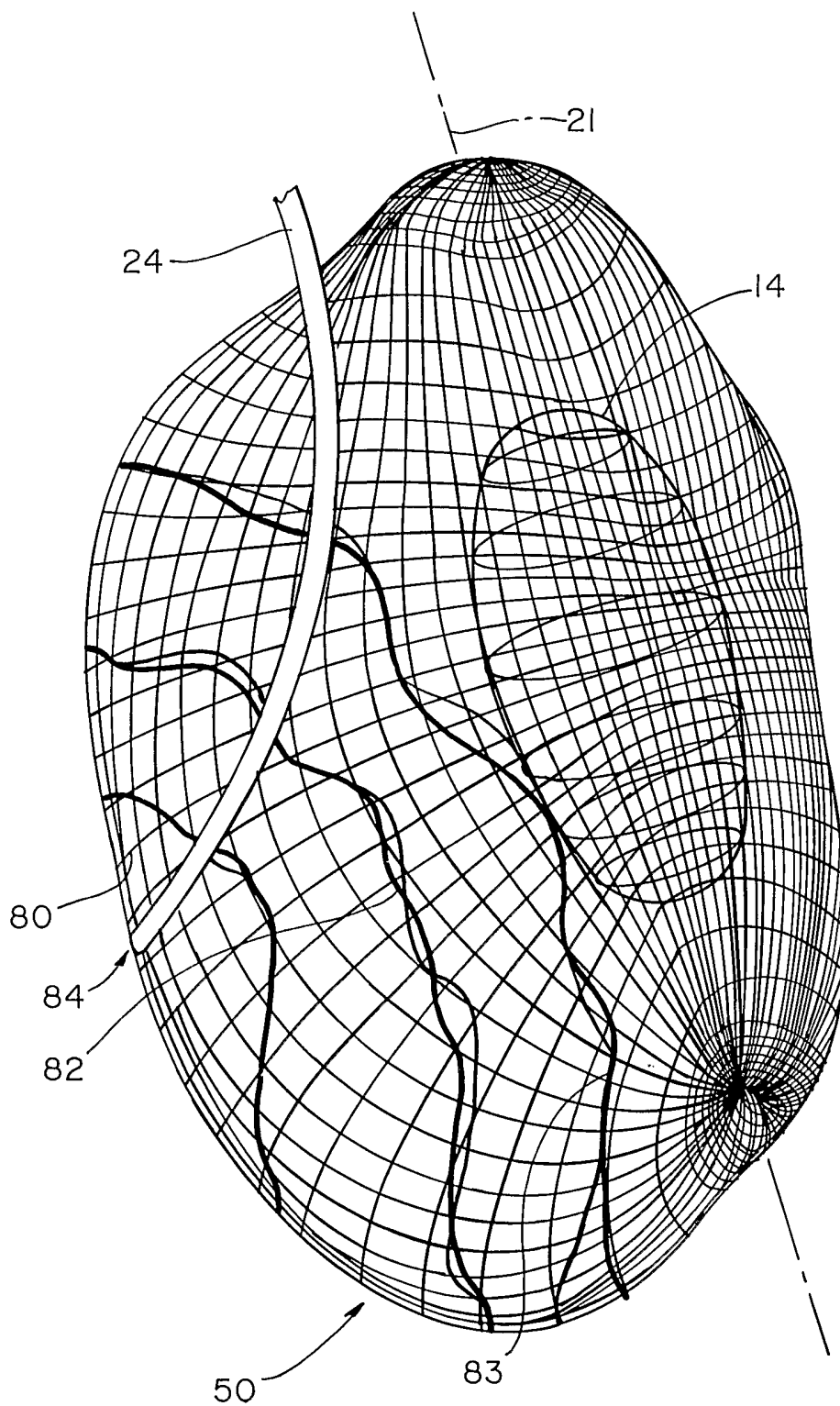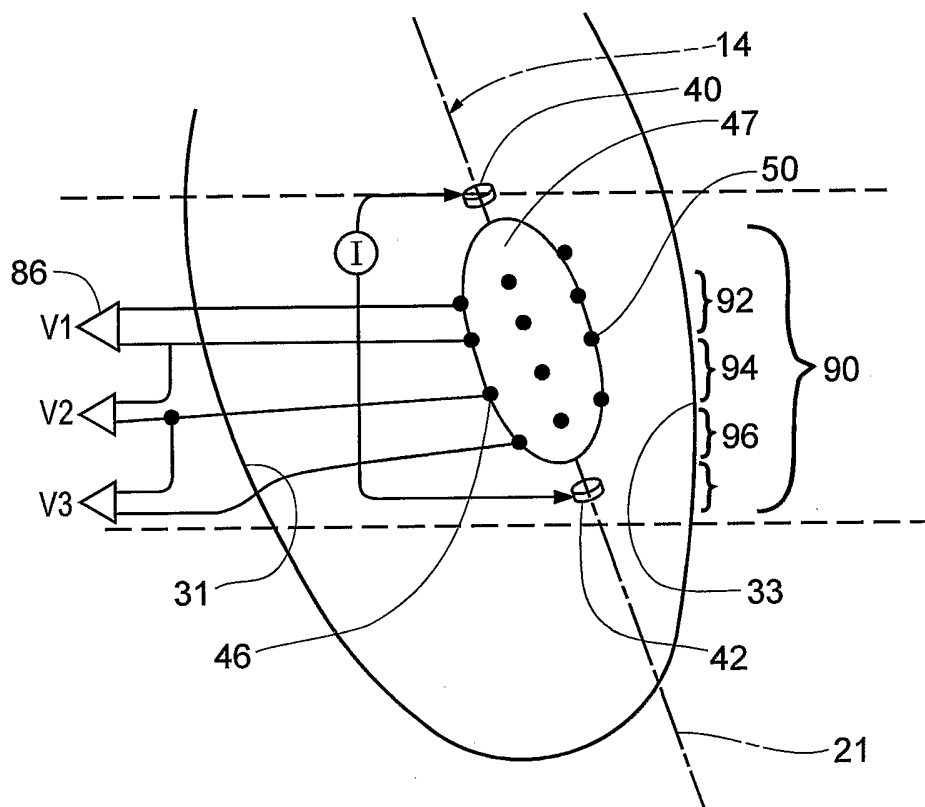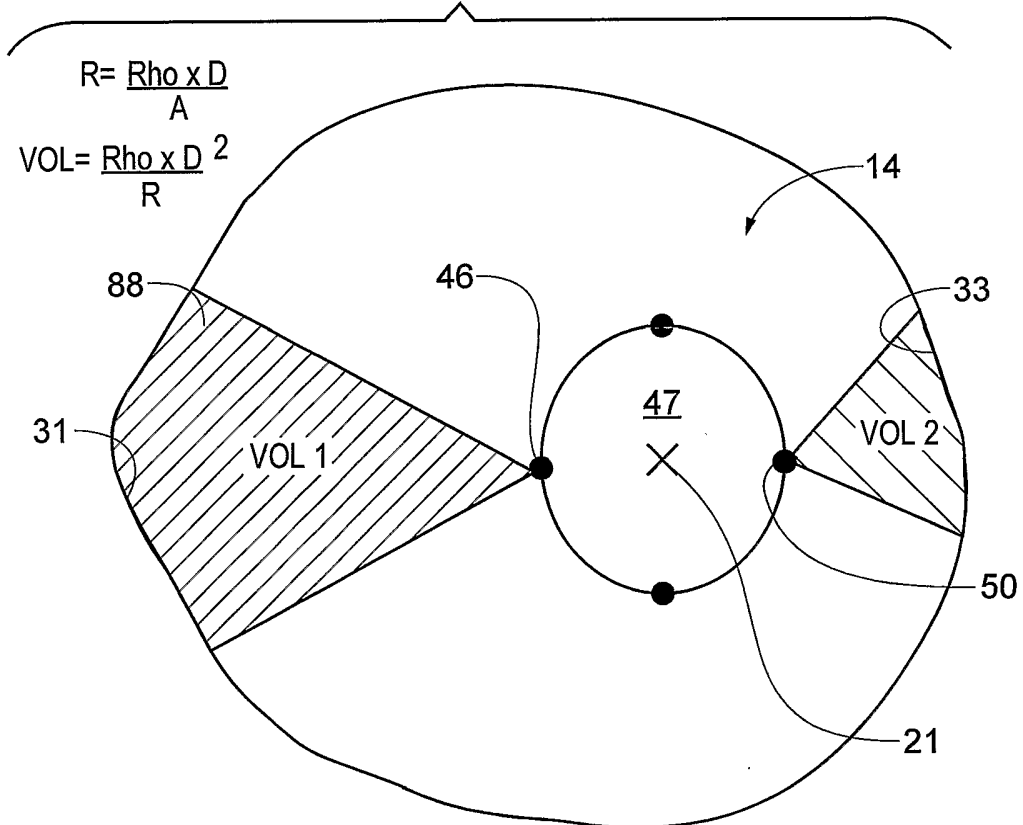left ventricle.

Fig. 1

Fig. 2

Fig. 3

Fig. 4

Fig. 5

$$R = \frac{Rho \times D}{A}$$

$$VOL = \frac{Rho \times D}{R}^2$$

Fig. 6