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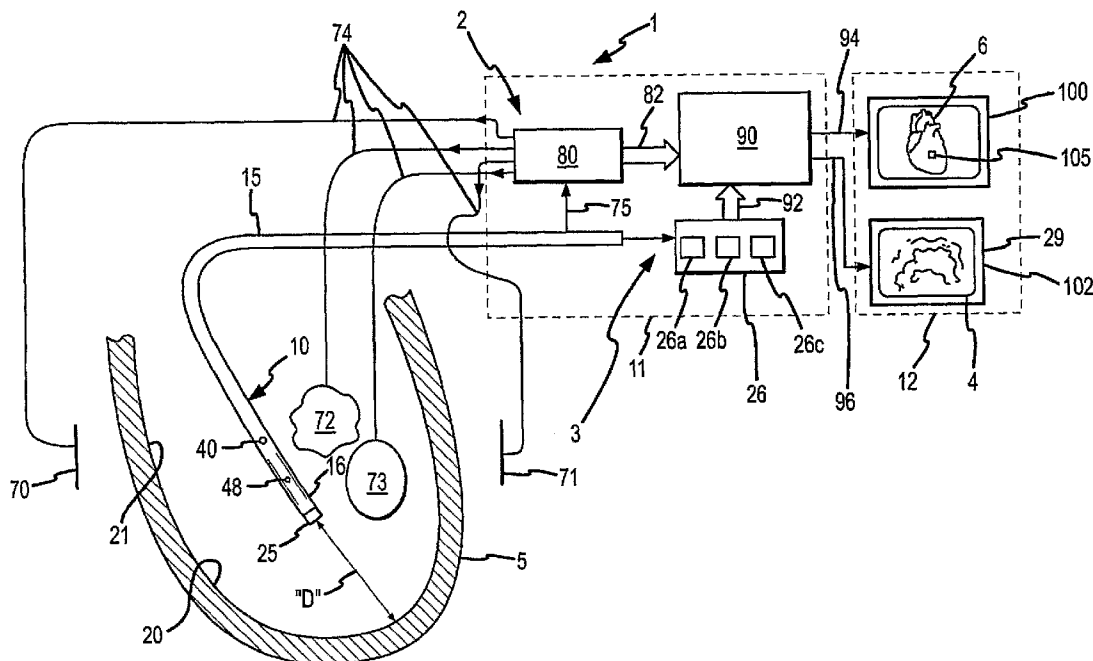
- as to the identity of the inventor (Rule 4.17(i))
- as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))
- as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))

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(54) Title: SYSTEM AND METHOD FOR NAVIGATING AN ULTRASOUND CATHETER TO IMAGE A BEATING HEART



(57) Abstract: Catheter navigation is coupled with ultrasound imaging to yield a context map (6) showing the location on a heart (5) of the ultrasonically imaged frame (4).

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## System and method for navigating an ultrasound catheter to image a beating heart

### CROSS-REFERENCE TO RELATED APPLICATIONS

**[0001]** This present application claims priority to U.S. provisional patent application, 60/539,540, filed January 27, 2004. The present application is a continuation-in-part of U.S. patent application 10/819,027, filed April 6, 2004, which in turn claims priority to U.S. provisional patent application 60/461,004, filed April 7, 2003, which is a continuation-in-part of U.S. patent application 09/107,371, filed June 30, 1998. Each application referenced in this paragraph is incorporated herein by reference in its entirety.

### BACKGROUND OF THE INVENTION

#### a. Field of the Invention

**[0002]** The present invention relates generally to a system and method for navigating an ultrasound catheter to image a beating heart. More particularly, the present invention relates to the coordination of catheter position data with ultrasound imaging data imaging a heart via ultrasound.

#### b. Background Art

**[0003]** Using ultrasound to image the interior of a beating heart is a known technique. A series of patents (U.S. 5,345,940, issued Sept. 13, 1994; U.S. 6,544,187, issued April 8, 2003; U.S. 5,713,363, issued Feb. 3, 1998) to Seward et al. describes the intra-cardiac ultrasound echo (ICE) technique and are incorporated herein, in their entirety, by reference. According to this technique, an ultrasonic transducer is situated at a distal end of a catheter that is positioned in a heart chamber. The transducer vibrates in response to a control signal to generate an ultrasonic wave. The transducer senses the reflected wave and transmits the corresponding signal to transceiver circuitry that analyzes the incoming signal and generates an image signal that is shown on a display. In this manner, a user can see, on a monitor, a real-time image of a small portion of the interior surface of the heart. Repositioning or reorienting the catheter, such that the transducer's wave bounces off a different portion of the surface, will yield a new image.

**[0004]** The ICE technique has lacked the ability to link the ultrasound information with other clinical information such as cardiac electrographic data anatomic orientation of the ultrasound data or images.

[0005] Further, Wittkampff, in a series of patents (U.S. 5,983,126, issued Nov. 9, 1999; U.S. 5,697,377, issued Dec. 16, 1997), describes the application of orthogonal current pulses to an electrode arrangement on a catheter to yield three-dimensional position data to assist a user in navigating the catheter. More specifically, in the Wittkampff system, current pulses are applied to orthogonally placed patch electrodes placed on the surface of the patient. These patches are used to create specific electric fields inside the patient. The Wittkampff patents teach the delivery of small-amplitude low-current pulses supplied continuously at three different frequencies, one on each axis. Any measurement electrode placed in these electric fields experience a voltage that depends on its location between the various patches or surface electrodes on each axis. The voltage on the measurement electrode in the field when referred to a stable positional reference electrode indicates the position of the measurement electrode with respect to that reference. The three voltages give rise to a location of the measurement electrode in "three space."

[0006] Co-pending application 10/819,027 describes the application of the Wittkampff technique, with improvements, to locate a catheter positioned in the interior of the heart and to image a catheter in real time. Further, application 10/819,027 describes how to sequentially use locations of an electrode in contact with the heart wall to sequentially build a model of a heart chamber.

[0007] Devices and techniques are known for determining the location in space and the orientation of the tip of a catheter. A series of patents to Desai (U.S. 5,215,103, issued June 1, 1993; U.S. 5,231,995, issued Aug. 3, 1993; U.S. 5,397,339, issued March 14, 1995; U.S. 4,940,064, issued July 10, 1990; and U.S. 5,500,011, issued March 19, 1996), incorporated herein by referenced in their entirety, describes an electrode array arrangement located on a catheter that can be used to determine the location of the catheter tip using Wittkampff's technique.

[0008] What has been needed is a device and method for producing images of the interior of a heart via ultrasound coupled with a navigational system for allowing the user to see what portion of the heart is appearing on the ultrasound image. Further, what has been needed is a method for building a geometry of the heart by successively imaging portions of the heart surface, with successive images being framed based on the location of the frames previously taken and by corresponding manipulation of the imaging device to select a new frame.

## BRIEF SUMMARY OF THE INVENTION

[0009] An object of the present invention is to provide a convenient, easy-to-use system and method for ultrasonically imaging a desired portion of a beating heart.

[0010] Another object of the present invention is to provide a system for identifying, on a context map, the location of an image obtained of an interior surface of a beating heart via ultrasound.

[0011] Yet another object of the present invention is to build a model of a heart chamber through sequential ultrasound imaging with collection and calculation of position and orientation data.

[0012] Still another object of the present invention is to allow easy updating or elucidation of important heart structure after a working model of the heart is constructed.

[0013] Another object of the invention is to build a geometry of a beating heart without touching the endocardial wall with a probe.

[0014] Yet another object of the present invention is to provide a system to provide lower cost transseptal puncture procedures using a smaller catheter than is typically used for ICE.

## BRIEF DESCRIPTION OF THE DRAWINGS

[0015] An exemplary version of a system for navigating an ultrasound transducer is shown in the figures wherein like reference numerals refer to equivalent structure throughout, and wherein:

[0016] Fig. 1 is a schematic representation of a system for navigating an ultrasound transducer;

[0017] Fig. 2 is a partial view of the system of Fig. 1, with an electrode array in a deployed configuration and with ultrasound waves and echoes depicted;

[0018] Figs. 3A, 3B, and 3C are prior art depictions of an electrode array that is employed in the system of Figs. 1 and 2;

[0019] Fig. 4a is a schematic illustration of an image of heart geometry and an ultrasonic image generated by the system of Fig. 1 taken at a first frame;

[0020] Fig. 4b is a schematic illustration of an image of heart geometry and an ultrasonic image generated by the system of Fig. 1 taken at a second frame; and

[0021] Fig. 5 is a flow chart depicting a method of using the system of Fig. 1 to generate a geometry of the heart.

## DETAILED DESCRIPTION OF THE INVENTION

**[0022]** Fig. 1 shows a cardiac imaging and navigation system 1 that coordinates an ultrasonic data acquisition and imaging system 2 with a catheter navigation system 3. The system 1 produces an ultrasonic image 4 of the heart 5 and displays a context or reference map 6 of the heart indicating the portion of the heart 5 that appears in the ultrasonic image frame 4. In a preferred use, the system 1 observes a beating heart 5. The navigation system 1 includes a catheter system 10 electronically linked to a signal processing system 11 that in turn is electronically linked to an image display system 12. In one embodiment, these electronic linkages are made via wire connections. In other embodiments, wireless links may be used for data transfer.

**[0023]** A preferred catheter system 10 is illustrated in Figs. 1 and 2. The catheter system 10 includes a guide tube 15 that is somewhat flexible so that in use it can easily pass through a patient's cardiovascular structures. In use, the catheter's distal end or tip 16 can be positioned within a heart chamber 20 defined by a chamber wall 21, as shown in Figs. 1 and 2.

**[0024]** Proximate the distal end 16 of the catheter system 10, is an ultrasonic transducer 25 that includes a crystal or array of crystals for sending and sensing ultrasonic waves. The transducer 25 is electronically linked to a dedicated ultrasound processor 26 having or linked to transceiver circuitry 26a, control circuitry 26b and imaging circuitry 26c. Via the transceiver 26a, the ultrasound processor 26 triggers a vibration in the ultrasonic transducer 25 that in turn imparts a sound wave 27 (Fig. 2) to the surrounding blood in the heart chamber 20. The wave 27 propagates through the blood in a direction determined or calculable from the known position and orientation of the crystals in the transducer 25. The wave 27 "bounces" against the chamber wall 20. A portion 28 of the wave 27 is reflected by the chamber wall 20 and returns to the transducer 25. The transducer 25 senses the returned wave 28 and sends a signal to the ultrasound processor 26. The ultrasound processor 26 has data storage and processing functions that calculate the distance "D" between the transducer and the heart wall 21, using the time of travel (t) of the wave 27 through the blood pool that has a known density. In addition, the reflected wave 28 signal is used by the imaging circuitry 26c to generate an image 4 that is displayed on a screen or monitor 29. This frame of the image 4 is typically relatively small (on the order of a few millimeters by a few millimeters) due to the size of the ultrasonic

transducer 25 (i.e., the diameter and arrangement of the crystals in the transducer 25), which must be of a small scale to be used in intracardiac applications.

**[0025]** To aid the user in interpreting the ultrasound image 4, the present system 1 employs a catheter navigation system 3 as illustrated in Figs. 1 and 2. This navigation system 3 determines the location in space and the orientation of the catheter distal end 16 and is thereby able to highlight or indicate on a context map 6 what portion of the heart wall 21 is displayed in the ultrasound image 4. Read together, the ultrasound image 4 and the highlighted context map 6 give the user information to position the catheter in a desired location to view pertinent areas of the hearts. In addition, the coordination of the image 4 and the highlighted context map 6 allow the user to manipulate the catheter to sequentially capture a number of image frames to generate a geometry of a larger portion of the heart or of the whole heart.

**[0026]** In greater detail, the catheter navigation system 3 includes a sensor electrode array 35 proximate the distal end 16 of the catheter tube 15. The electrode array 35 preferably includes a small collection of spaced sensor electrodes 40, 42, 44, 46, 48, that are deployed such that they are spaced from one another sufficiently to yield accurate position and orientation data when exposed to orthogonal currents as taught by Wittkamp. An example of an electrode array 35 configuration that achieves this objective is that disclosed by Desai in the patents discussed above, and incorporated herein by reference, in the Background section. The Desai configuration is illustrated in Figs. 3A-3C and is characterized by a plurality of side sensor electrodes 42, 44, 46, 48 equally spaced around the distal end 16 of the tubular catheter 15. A further, central electrode 40 is fixed to the distal end 16 on the catheter axis 50. The four side electrodes 42, 44, 46, 48 lie in the same plane 52 (Fig. 2) and are equally spaced from adjacent electrodes. The side electrodes 42, 44, 46, 48 are at the apexes of a square pattern with the central electrode 40 in the center of the square. The electrodes may be made of highly electrically conductive material. A plurality of longitudinally-directed slits, as exemplified by slits 55 and 56, are cut through the tube 15 from a point adjacent to the terminating end 60 to a distance away from the terminating end 60. The slits 55, 56 define and form intermediate limbs 62, 63, 64, 65. The electrodes 42, 44, 46, 48 are positioned with one electrode to a limb 62, 63, 64, or 65. By applying a compressive force to the end 60, the limbs 62-65 buckle, thereby spreading the side electrodes 42, 44, 46, 48 apart, as illustrated in Fig. 3C.

[0027] Alternative electrode arrangements are contemplated. An arrangement with at least two electrodes can provide position and orientation data, though increasing the number and spacing of electrodes yields a higher degree of accuracy.

[0028] Fig. 1 illustrates additional elements of the navigation system 3. External patch electrodes 70, 71, 72, 73 are placed on the patient, directed substantially near the heart. The electrodes 70-73 are electrically connected to navigation circuitry 80 (as depicted by arrows 74) which imparts controlled current in a desired fashion to the electrodes 70-73. The navigation circuitry is also electronically connected to the sensor electrodes 40, 42, 44, 46, 48 (as depicted by arrow 75) and receives and processes signals from the sensing electrodes 40, 42, 44, 46, 48.

[0029] According to the techniques described by Wittkamp in the patents noted above in the Background section and incorporated herein by reference, the navigation circuitry 80 imparts orthogonal current signals through the patient. Each of the signals has a respective characteristic that renders it distinguishable from the other orthogonal signals. In response to the field generated by this current, the sensing electrodes 40, 42, 44, 46, 48 send voltage signals to the navigation circuitry 80. The navigation circuitry 80 processes this signal information in the manner described in pending U.S. patent application 10/819,027 to determine the location of the catheter distal end 16, as well as the orientation of the catheter tube 15 as defined by the vector "R" (Fig. 2) extending axially from the end 16 of the catheter tube 15.

[0030] In a preferred embodiment the navigation circuitry 80 is linked for data transfer (as depicted by arrow 82) to a computer system 90 having a user interface to allow control of the navigation circuitry. In addition, in a preferred embodiment, the ultrasound processor 26 is linked for data transfer (as depicted by arrow 92) to a computer system having a user interface to allow control of the ultrasound processor. Most preferably, the navigation circuitry 80 and the ultrasound processor 26 are linked to a single computer 90 that coordinates the operation of the imaging being done by the ultrasound system 2 with the navigation system 3.

[0031] The navigation circuitry 80 is linked for data transfer (as depicted by arrow 94) to a display screen or monitor 100. Similarly, the ultrasound processor 26 is linked for data transfer (as depicted by arrow 96) to a screen or monitor 102. The navigation circuitry 80 generates a context map 6 of the whole heart 5 or of a relatively large section

of the heart 5 with an indication thereon of the location of the catheter distal end 16. More specifically, the computer system 90, with processing capabilities, coordinates the position and orientation data from the navigation system 3 with the distance-to-wall data received from the ultrasound system 2 to compute and illustrate, on monitor 100, the location on the heart of the frame 4 that is simultaneously displayed on an ultrasound image display screen or monitor 102. In this manner, the highlighted or animated region 105 of the context map 6 depicts the portion or frame of the heart wall at which the ultrasound is "pointed." In one embodiment, monitors 100 and 102 are separate screens; in alternate embodiments, both images (the context map 6 and the ultrasound image 4) are depicted on one monitor. The process of capturing ultrasound data and making the locating calculations occurs fast enough that the distance data can be used to computer motion data if desired.

[0032] Fig. 4a further illustrates the relationship between the context map 6 and the ultrasound image frame 4. The highlighted region 105 of the context map 6 indicates the location in the heart of the ultrasound image frame 4. The context map 6 presents a wider field of view than is shown by the ultrasound image frame 4, and the context map 6 includes the frame 4 shown by the ultrasound image. This relationship between the relatively small field of view shown by the ultrasound frame 4 and the relatively larger field of view (including the frame 4) shown by the context map 6 is suggested by projection lines 110, 111.

[0033] The system 1 can be used to generate a geometry of the heart through iterative ultrasound imaging made feasible through the manipulation of the catheter system 10 using the navigation system 3 for guidance. Fig. 5 is a flow chart depicting the steps in the iterative process 200. The user positions (205) the catheter system 10 in the chamber of the heart 5. As depicted in step 210, electric potentials are applied to electrodes 70-73 and this potential is sensed by electrodes 40, 42, 44, 46, 48. Using Wittkamp's method, the 3D positions of each sense electrode 40, 42, 44, 46, 48 are determined and displayed. In addition, an orientation vector R is determined. Because the ultrasound crystal is in the known fixed location in relation to the catheter head 60, the location (Lxtal) of the ultrasound crystal is determined.

[0034] At essentially the same time, the ultrasound system 2 emits and senses a sound wave. The distance D to the heart wall 21 is calculated as  $D = V_b * t$ , where  $V_b$  is the apriori known velocity of the ultrasound signal in blood and t is the time measured from



issuing the pulse to sensing the returned echo 28. This ultrasound process is indicated by block 215.

[0035] Applying the position data from step 210 and the ultrasound data from step 215, the location of a frame or patch 4 of the wall is calculated (220). The ultrasound data is stored in association with the location and orientation data. The location  $L_w$  of the center of the patch or frame 4 is calculated as follows:  $L_w = L_{xstal} + D * R$ . This location is located in relation to the catheter ( $L_w$ ); in addition, the x, y, z coordinates of the wall patch in space can be calculated and stored, since the 3D position and orientation of the transducer 25 is known, along with the distance  $D$  to the wall.

[0036] A graphic rendering 105 of the patch or frame 4 is created (225) on a screen or monitor 100.

[0037] As indicated by decision block 230, if the view of the single frame 4 is sufficient for the user's purposes (235), the process may end here (240). However, if the user has not viewed the site of interest in full (242), the user may, based upon the graphic image in the context map 6, "build" a geometry of a larger portion of the heart, or of the whole heart, by iteratively or sequentially imaging different frames (which may or may not overlap) of the heart, with the system 1 collecting and storing position and orientation data in association with the ultrasound data for each such frame. To move from frame to frame, the user manipulates the catheter system 10 to change the orientation  $R$  of the catheter system 10 or to move the catheter system 10 to a new position within the heart 5, such that the ultrasound system "points at" and displays a different frame or patch 4'. This repositioning step is indicated at reference number 245. Thereafter, the position determining step 210, the ultrasound step 215, the calculation step 220 and the graphic rendering step 225 and the decision step 230 are repeated until the resulting geometry of the heart is sufficient (235) for the user's purposes. The completed geometry is displayed (250). Positioning and orientation of the catheter system 10 may be accomplished manually. Alternatively, the catheter system is coupled to a robotic mechanism controlled, for example, by the computer 90, to position and orient the catheter.

[0038] Fig. 4b shows the how the context map 6' appears with the ultrasound system 2 trained on a second patch or frame 105'. The first frame 105 is indicated for reference with broken lines in the drawing of Fig. 4b; it may or may not be indicated in some manner on the context map 6' shown on the monitor 100. Fig. 4b also shows the relationship

between the frame 105' on the context map 6' to the ultrasound frame 4' shown on the ultrasound image monitor 102.

**[0039]** The system 1 of the present invention offers advantages over traditional ICE, where a large number of crystals in the transducer are necessary to achieve the desired image quality, because the present invention allows for a smaller number of crystals to achieve a comparable level of performance, because it has the ability to signal average the acquired data. This is possible because the ultrasound data is acquired from a known location. Combining this knowledge with cardiac gating, multiple acquisitions from a site may be averaged.

**[0040]** Another advantage of the present invention with a smaller number of crystals over traditional ICE is that the head of the catheter may be forward-looking, i.e. the wave 27 **[propogated]** propagated by the transducer 25 travels in a direction R that is generally parallel to the axis 50 of the catheter 10. Traditional ICE catheters, like those shown by Seward, "look" off to the side of the catheter and therefore are somewhat more difficult to operate.

**[0041]** Yet another advantage is that the catheter system 10, having a customary size and flexibility and being equipped with electrodes, may be used as a standard cardiac electrophysiology mapping catheter.

**[0042]** Although an illustrative version of the device is shown, it should be clear that many modifications to the device may be made without departing from the scope of the invention.

## CLAIMS

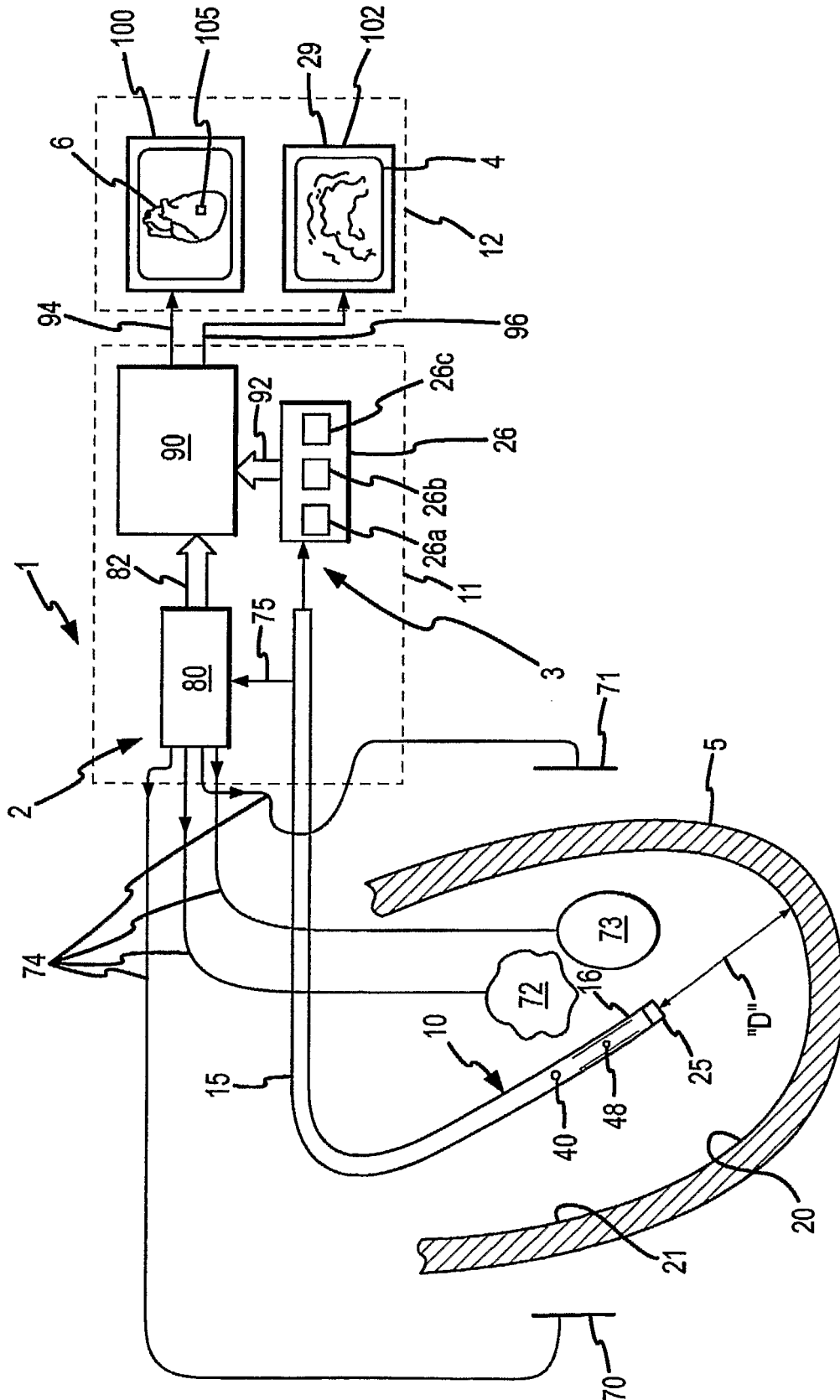
What is claimed is:

1. A system for navigating an ultrasound catheter to image a beating heart, comprising:
  - a) a catheter system carrying sensor electrodes and an ultrasonic transducer;
  - b) an ultrasound system operatively coupled to said transducer to generate a sound wave and to sense an echo wave to yield and capture ultrasound data for a frame of the interior surface of the heart;
  - c) a navigation system operatively coupled to said electrodes for determining the location, in the context of a larger portion of the heart than is captured in the ultrasound frame, of the frame.
2. A system according to claim 1, further comprising:
  - d) an imaging system for displaying a context map of the heart with an indication of the location of the frame on the heart.
3. A system according to claim 2, further comprising:
  - e) an imaging system for displaying an ultrasound image of said frame.
4. A system according to claim 1, wherein said system further comprises:
  - d) data processing and storage for storing ultrasound data in association with location data.
5. A system according to claim 1 wherein said navigation system further determines the orientation of the catheter system as said ultrasound data is captured.
6. A system according to claim 5, wherein said system further comprises:
  - d) data storage for storing ultrasound data in association with location and orientation data.
7. A system according to claim 1 wherein said catheter system carries five electrodes, one of said electrodes lying on the axis of the catheter and the four other electrodes being spaced approximately equally from one another and equally spaced radially from said axis.
8. A system to generate images of the interior of a beating heart comprising:
  - a) a catheter carrying multiple electrodes, said electrodes being spaced from one another sufficiently to generate location and orientation data;

- b) an ultrasonic transducer attached to said catheter's distal end, for generating an image of a first portion of a surface within the heart;
  - c) signal processing system electrically coupled to said electrodes for receiving location and orientation data from said electrodes and coupled to said transducer for receiving image data from said transducer;
  - d) imaging system coupled to said signal processing system for displaying an image transmitted by the transducer and for simultaneously displaying a context map showing the location of said first surface portion within an image of a second heart portion that is larger than and contains said first surface portion, whereby the imaged portion of the surface of the heart is displayed and simultaneously the location in the heart of that displayed surface portion is displayed.
9. An image-generating system according to claim 8, wherein the imaging system displays the ultrasound image in real time.
10. An image-generating system according to claim 8, wherein said catheter carries a central electrode and four side electrodes proximate its distal end.
11. An image-generating system according to claim 10, wherein said central electrode lies on the longitudinal axis of the catheter and is spaced longitudinally from said side electrodes.
12. A method of imaging the interior of a beating heart, comprising the steps of:
- a) positioning a catheter in the interior of a heart chamber, said catheter carrying multiple electrodes spaced from one another sufficiently to generate location and orientation data and said catheter having an ultrasonic transducer coupled to its distal end;
  - b) applying orthogonal current across the heart to generate voltage signals from the electrodes to yield position and orientation data;
  - c) with the ultrasonic transducer, generating a wave and sensing its echo to generate an image of a surface of the interior of the heart;
  - d) displaying the ultrasonic image and simultaneously indicating on a context map of the heart the frame of the heart surface that is displayed in the ultrasonic image.

13. A method of generating an image of the interior of a beating heart according to claim 10, further comprising the step of:
  - e) repositioning the catheter such that the catheter yields an ultrasonic image of another surface portion of the interior of the heart, said repositioning being accomplished by observing the context map.
14. A method of generating an image of the interior of a beating heart according to claim 13, further comprising the step of:
  - f) storing each surface portion image in association with location and orientation data; and
  - g) repeating steps a) through f) until a complete image of the heart chamber is completed.

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**FIG. 1**

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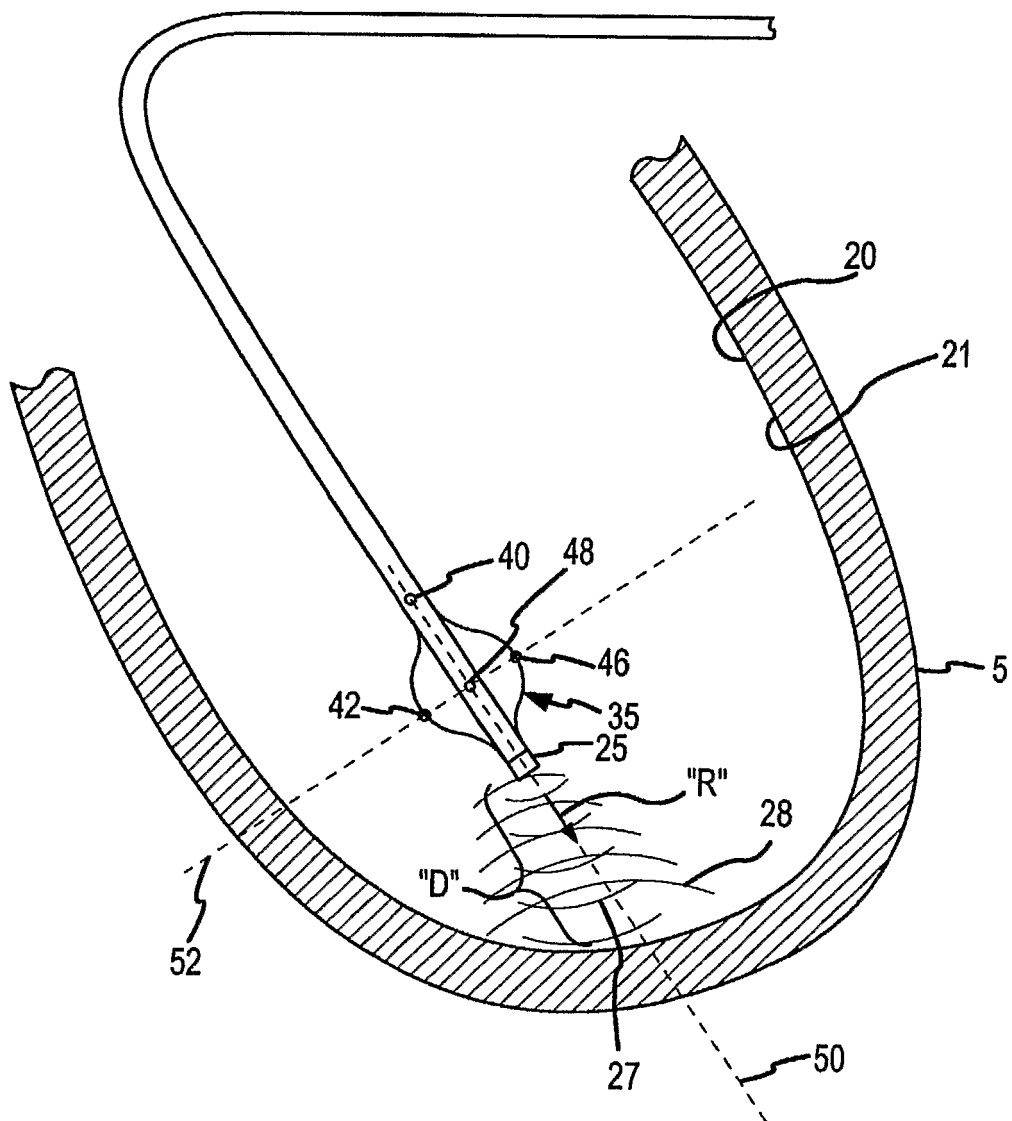


FIG.2

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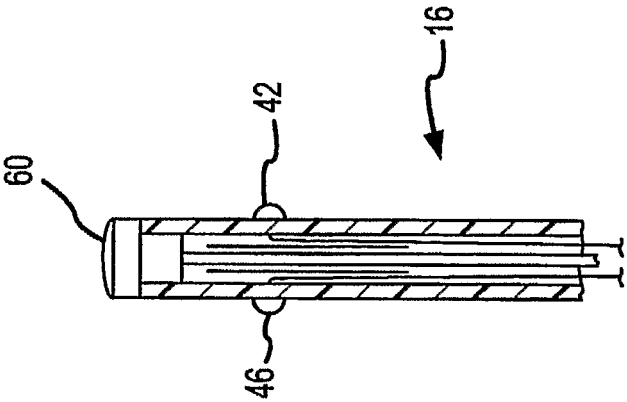


FIG. 3C  
PRIOR ART

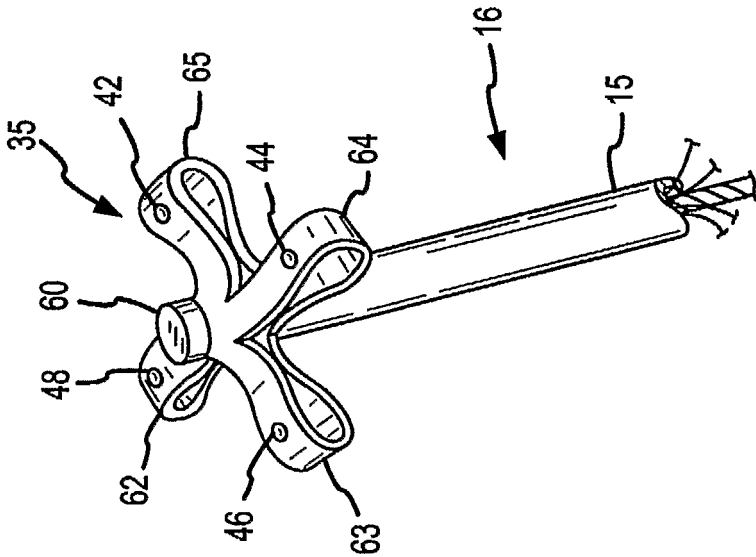


FIG. 3B  
PRIOR ART

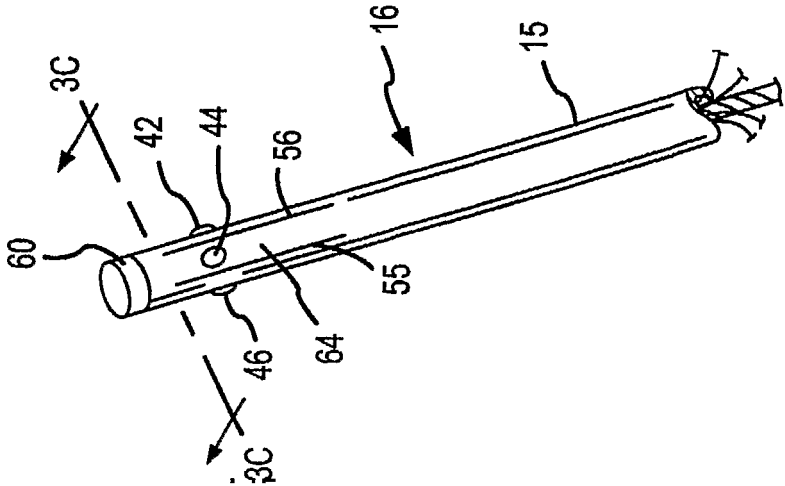


FIG. 3A  
PRIOR ART



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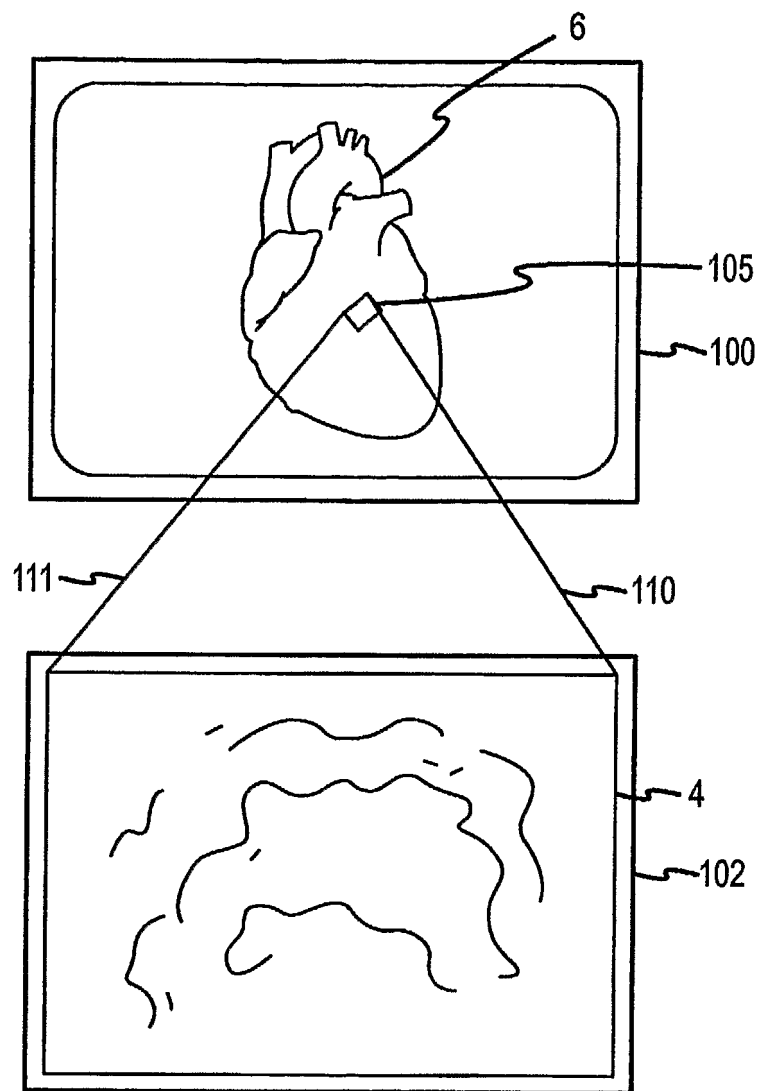


FIG. 4a

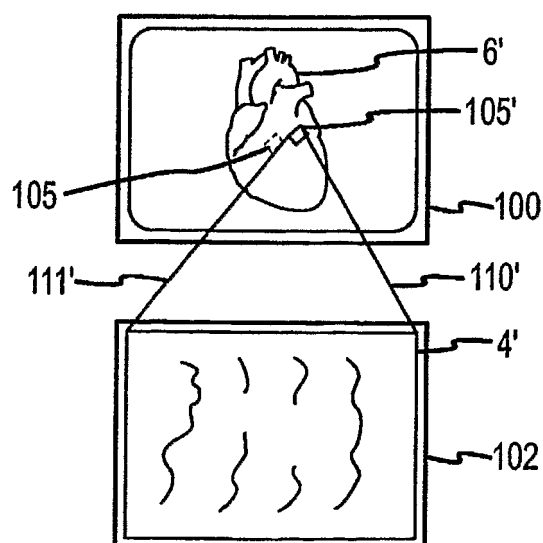


FIG 4b

5/5

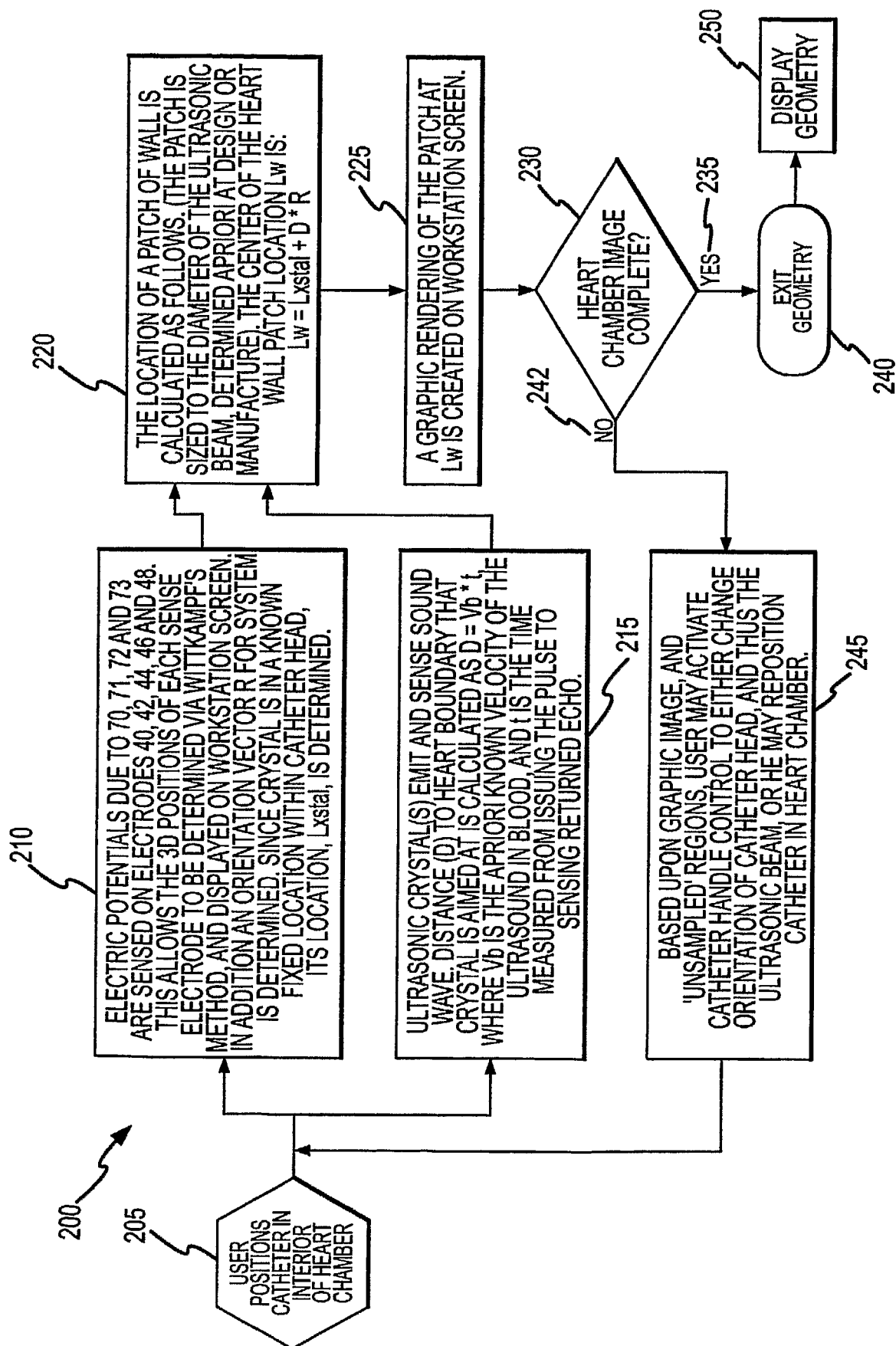


FIG. 5

专利名称(译)	用于导航超声导管以对跳动的心脏成像的系统和方法		
公开(公告)号	<a href="#">EP1845855A2</a>	公开(公告)日	2007-10-24
申请号	EP2006719666	申请日	2006-01-27
[标]申请(专利权)人(译)	圣犹达医疗用品电生理部门有限公司		
申请(专利权)人(译)	ST.犹达医疗用品，房颤DIVISION，INC.		
当前申请(专利权)人(译)	ST.犹达医疗用品，房颤DIVISION，INC.		
[标]发明人	HAUCK JOHN		
发明人	HAUCK, JOHN		
IPC分类号	A61B8/00 A61N1/18 A61B8/14 A61B5/042 A61B5/05 A61B5/107 A61B19/00 A61N1/05 A61N1/08 A61N1/362 A61N1/37		
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代理机构(译)	KRAMER - HARSH - 施密特陈		
优先权	11/044344 2005-01-27 US		
其他公开文献	EP1845855B1 EP1845855A4		
外部链接	<a href="#">Espacenet</a>		

#### 摘要(译)

导管导航与超声成像耦合以产生上下文图 ( 6 )，其示出超声成像帧 ( 4 ) 的心脏 ( 5 ) 上的位置。