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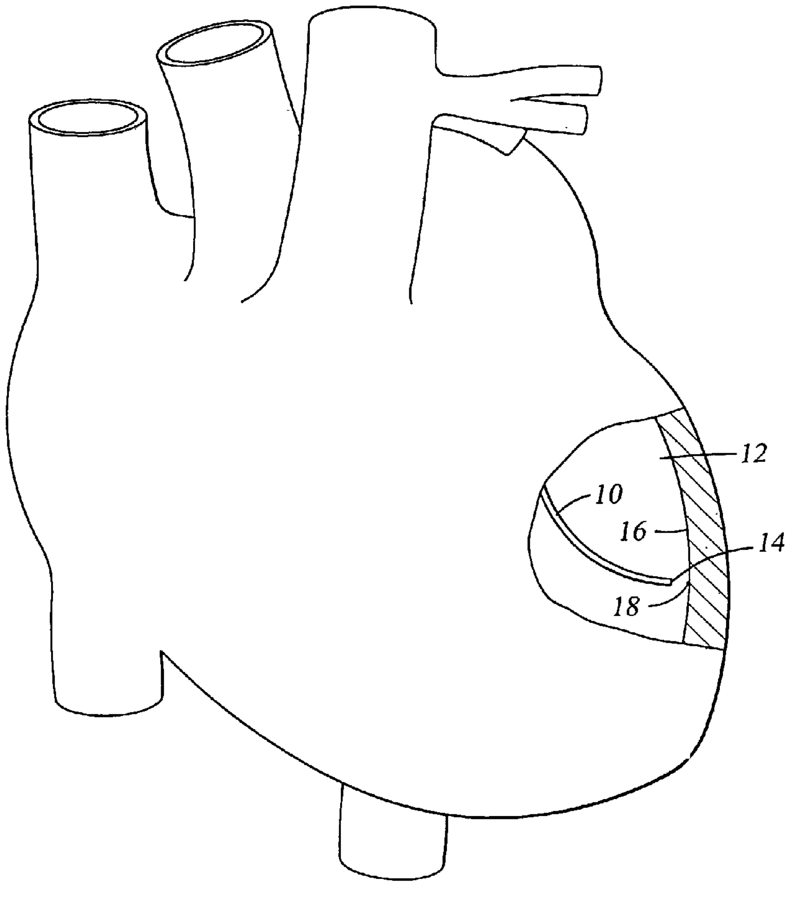
# (54) Title: ULTRASONIC BASED DETECTION OF CATHETER CONTACT AND ALIGNMENT




**(57) Abstract:** A method and apparatus for remotely monitoring the location of an interventional medical device(IMD) using ultrasonic signals. Both the proximity and alignment of the IMD are calculated from ultrasound signals reflected off the tissue surface. The inclusion of an offset between the distal end of the IMD and the ultrasound transducer enables accurate position and alignment monitoring of when the IMD is in contact with, or very close to, the tissue surface. The timing of the reflected signal is used to measure proximity or contact. A comparison of the strength between multiple reflected signals is used to measure the alignment of the IMD in 3D space or perpendicularity to a given surface. The present invention may be used as a location indicator within a wide variety of IMDs, and in a wide variety of medical procedures.

WO 02/22031 A1

# ULTRASONIC BASED DETECTION OF CATHETER CONTACT AND ALIGNMENT

## Field of the Invention

The present invention relates to monitoring interventional medical devices (IMDs). More particularly, the present invention relates to an ultrasonic system of monitoring the proximity and alignment of the IMD relative to a tissue surface.

## Background of the Invention

Interventional medical devices (IMDs), such as catheters and surgical lasers are used for many medical procedures. Laparoscopy, the insertion of a fiber optic instrument into the abdomen, is just one relatively common type of IMD procedure. Minimally invasive surgery (MIS) is a term that, as used in this disclosure, encompasses a broader range of such procedures, and in which an IMD is introduced into the patient through a relatively small incision. A major problem inherent with the use of IMDs in MIS procedures is detecting the current location and orientation of the IMD, and remotely guiding it within a patient. It would be desirable to have an apparatus or method that assisted in precisely determining the location and orientation of a wide range of IMDs. It would be particularly desirable to have an apparatus or method for determining when the distal end of the IMD is in contact with and perpendicular to a tissue surface.

U.S. Patent 5,109,859 issued to Jenkins on May 5, 1992 (the ‘859 patent), discloses an ultrasound guided laser for use in angioplasty. The ‘859 patent is specifically directed at a method of imaging the lateral walls of arteries for laser ablation procedures and can not easily be adapted to function with a wide range of IMDs.

U.S. Patent 5,313,950 issued to Ishikawa, et al. on May 24, 1994 (the '950 patent), discloses an ultrasonic probe for providing images in hollow objects such as blood vessels. The '950 patent, like the '859 patent, creates images at 90° to the longitudinal axis of the IMD. This lateral imaging provides little data for determining IMD alignment and indicating when the distal end of the IMD is in contact with a tissue surface.

U.S. Patent 5,377,682 issued to Ueno, et al. on January 3, 1995 (the '682 patent) also teaches an ultrasonic probe for imaging perpendicular to the longitudinal axis. Again, there is no description which assists in determining alignment of the probe and indicating when the distal end of the IMD is in contact with a tissue surface.

U.S. Patent 5, 893,848 issued to Negus, et al. on April 13, 1999 (the '848 patent), teaches a gauging system for monitoring the depth of an IMD as it penetrates into heart tissue. However, the '848 patent does not provide data on the proximity of the IMD to the tissue surface prior to penetrating the surface, nor does it indicate the angle of the IMD relative to the tissue surface.

U.S. Patent 6,024,703 issued to Zanelli, et al. on February 15, 2000 (the '703 patent), measures the distance between the distal end of the IMD and the tissue surface both prior to contacting the surface and after penetrating the surface. This invention is primarily directed at measuring the distance between a laser IMD that has penetrated the tissue surface and the rear surface of that tissue. It is not as well suited for providing positional data prior to the laser penetrating the tissue, or for indicating when contact has been made between the IMD and the front surface of the tissue. A weakness of the device taught in the '703 patent is the inability to achieve high measurement accuracy when the IMD is very close to, or in contact with, the tissue surface. It would be desirable to accurately determine the IMD proximity to the tissue surface when it is close to the tissue surface, as well as accurately indicating contact with the tissue surface.

## Summary of the Invention

A method and apparatus for remotely monitoring the location of an interventional medical device (IMD) using ultrasonic signals. Both the proximity and alignment of the IMD are calculated from ultrasound signals reflected off the tissue surface. The inclusion of an offset between the distal end of the IMD and the ultrasound transducer enables accurate position and alignment monitoring of when the IMD is in contact with, or very close to, the tissue surface. The timing of the reflected signal is used to measure proximity or contact. A comparison of the strength between multiple reflected signals is used to measure the alignment of the IMD in 3D space or perpendicularity to a given surface. The present invention may be used as a location indicator with a wide variety of IMDs, and in a wide variety of medical procedures.

Brief Description of the Drawings

**Figure 1** is a sectional view of a medical device inside a heart.

**Figures 2A** and **2B** are detailed representations of a medical device approaching a tissue surface.

**Figures 3A** and **3B** are detailed representations of a medical device being aligned perpendicular to a tissue surface.

**Figures 4A** and **4B** show the prior art and a transducer offset in accordance with an embodiment of the present invention.

**Figure 5** is a representative plot of an ultrasound echo signal strength versus time or distance.

**Figures 6A** through **6D** show various transducer configurations in accordance with embodiments of the present invention.

**Figure 7** shows a flow chart for locating an IMD in accordance with an embodiment of the present invention.

**Figure 8** is an illustration of a sample user interface for displaying the measurements made in accordance with an embodiment of the present invention.

**Figure 9A** and **9B** are illustrations of other user interfaces for displaying the measurements made in accordance with an embodiment of the present invention.

Detailed Description

The present invention is directed to an ultrasound system used to remotely determine proximity and perpendicularity of an interventional medical device (IMD) with respect to a tissue surface. Typically, although not exclusively, the IMD is a tool that is used as part of a minimally invasive surgical (MIS) procedure. MIS procedures, such as laparoscopy, are well known in art. The present invention is not, however, intended to be limited to any particularly surgical procedure. Similarly, the types of IMDs that may be used in conjunction with the present invention is intended to be broad, including, but not limited to, catheters, probes, endoscopes, fiber optic devices, cannules, stylets, needles, laparoscopes and surgical lasers. As used in the present disclosure, the location of an IMD is a general term and consists of both proximity and perpendicularity to a tissue surface. The proximity is a distance between the distal end of an IMD and the tissue surface, which may also be expressed as the state "contact" when the distance is zero. Perpendicularity is a measure of whether or not the longitudinal axis of an IMD, at the distal end of the IMD, is at right angles to the plane of the tissue surface at a point where there is contact between the IMD and the tissue surface, or projected contact along the longitudinal axis. As discussed more fully below, the perpendicularity of an IMD is generally defined in three dimensional (3D) space, often using two orthogonal planes passing through the longitudinal axis of the IMD. Degree of perpendicularity is a synonym for perpendicularity and is used in some instances to further emphasize that perpendicularity is a term of measurement.

One application of the present invention is use with a catheter to perform a transmyocardial revascularization (TMR) procedure. This embodiment is chosen because it well illustrates the present invention and is not intended to indicate a limit of the scope of uses for the present invention. The TMR procedure is well known in the art. TMR involves creating channels in the left ventricle, from inside the heart, to increase the blood and oxygen supply to the heart muscle. Surgical lasers and mechanical devices are some of the many means for creating the channels. Regardless of the channel creating device used, medical personnel operate the device remotely. That is, the distal end of the IMD will be inside the heart.

**Figure 1** is a sectional view of an IMD 10 inside a heart ventricle 12 with the distal end 14 of IMD 10 near the tissue surface 16 at location 18. In order to reach the stage depicted in **Figure 1**, medical personnel have had to guide IMD 10 through the patient's blood vessels and into ventricle 12. This global scale guidance of IMD 10 can be accomplished using any of a variety of techniques and is not the objective of the present invention. The present invention is instead directed towards indicating proximity, or contact, between distal end 14 and tissue surface 16 at location 18 and indicating the perpendicularity of distal end 14 with tissue surface 16. In a TMR procedure, prior to beginning the process of creating channels in the heart wall, the physician may like to confirm that distal end 14 is in contact with and perpendicular to, tissue surface 16 at location 18.

As used in this disclosure, the term distal end will be used to describe both the portion of IMD 10 within the patient (*e.g.*, the opposite of the proximal end), and a point at the "tip" of IMD 10, the furthest from the proximal end. Thus, the proximity or distance between distal end 14 and tissue surface 16 corresponds to the distance, measured along a projection of the longitudinal axis of IMD 10, between a point at the extreme end of IMD 10 and tissue surface 16. Although, for clarity, the geometry of the distal end 14 of IMD 10 is shown as a flat surface, perpendicular to the longitudinal axis of IMD 10, the present invention is not intended to be limited to any particular configuration.

**Figures 2A** and **2B** are detailed representations of distal end 14 and tissue surface 16 near location 18. The proximity 20 of distal end 14 to tissue surface 16 decreases from **Figure 2A** to **Figure 2B** as IMD 10 approaches tissue surface 16. The present invention provides a remote indication of the magnitude of proximity 20. Preferably, embodiments of the present invention are configured to clearly indicate when IMD 10 is in contact with tissue surface 16, at location 18, corresponding to a proximity 20 equal to zero.

**Figures 3A** and **3B** are also detailed representations of distal end 14 and tissue surface 16 near location 18, depicting the perpendicularity of IMD 10. Within a single plane, such as that depicted in **Figure 3A**, a number of possible angular measurements may be used to depict the degree of perpendicularity of IMD 10, relative to tissue surface 16. A few of these possible perpendicularity measurements are noted in **Figure 3A** as references 22, 24 and 26. Those of ordinary skill in the art will appreciate that the number of possible perpendicularity measurements is virtually unlimited and the present invention is not intended to be limited to any particular metric. For example, embodiments of the present invention may use direction cosines instead of angular values to indicate perpendicularity. The degree of perpendicularity within a single plane is essentially a measure of how close the orientation of IMD 10 is to that depicted in **Figure 3B**, where angles 22 and 26 are both equal to 90°.

Of course, IMD 10 must be oriented in 3D space, not just in a single plane. To depict the perpendicularity in 3D space, an embodiment of the present invention uses perpendicularity measurements in at least two different planes, with each plane passing through the longitudinal axis 28 of IMD 10. Preferably, although not necessarily, the two perpendicularity measurement planes are orthogonal. In one embodiment of the present invention, the perpendicularity measurement planes are oriented so that they are cooperatively aligned with the axes by which IMD 10 is remotely "steered" or controlled. Such steerability of catheters is known in the art. Using such an embodiment, the user will have perpendicularity information directly corresponding to the IMD 10 orientation controls, resulting a highly ergonomic feedback and control system for maneuvering IMD 10.

The present invention uses ultrasound signals reflected off tissue surface 16 for both proximity 20 and perpendicularity measurements. The timing of the reflected signals is used to measure proximity and the reflected signal strengths are used to measure perpendicularity. Using the timing of reflected or echo signals to measure a distance is not new, and determining distance based on the reflected signal is known to those of ordinary skill in the art. Displaying the echo signal amplitude, or signal strength, as a function of the time interval between pulse and echo is a traditional amplitude mode (A-mode) display known to those of ordinary skill in the art. The present invention, unlike the prior art, uses two properties of the reflected signals, the timing and the amplitude, to measure two aspects of the IMD orientation, proximity and perpendicularity. The present invention is particularly suited to indicate contact between distal end 14 and tissue surface 16. As discussed more fully below, prior art methods of measuring the proximity of distal end 14 to tissue surface 16 with ultrasound signals are not well suited for accurately indicating contact.

The perpendicularity measurement uses multiple transducers arranged around the circumference of IMD 10. When IMD 10 is perpendicular to tissue surface 16, as shown in **Figure 3B**, the reflected ultrasound signals received at each transducer will be at the maximum amplitude and equal. When IMD 10 is not perpendicular to tissue surface 16, as shown in **Figure 3A**, tissue surface 16 causes a portion of the reflected signals to diverge somewhat, resulting in a lower amplitude signal being reflected back to the transducer. Those of ordinary skill in the art, with the benefit of the present disclosure, will recognize that timing of the reflected signals will (intrinsically) differ along with the amplitude when IMD 10 is not perpendicular to tissue surface 16.

The present invention compares the strength of the reflected signals, as measured at multiple transducers, to indicate perpendicularity. Because perpendicularity is measured in 3D space, a minimum of three, and preferably four, transducers are used. Embodiments of the present invention may use four transducers spaced at 90° to allow perpendicularity measurements in two orthogonal planes. Preferably, in such a four transducer embodiment, the transducers are aligned so the axes used to steer IMD 10 correspond to the planes used for perpendicularity measurements.

Referring now to **Figures 4A** and **4B**, depicting distal end 14 of IMD 10 near tissue surface 16, as measured by proximity 20, the prior art is shown in **Figure 4A** and the present invention is shown in **Figure 4B**. A pair of ultrasound transducers 30 are shown mounted on IMD 10. Transducers 30 transmit the ultrasound signal 34 and receive the reflection of that signal off of tissue surface 16.

The time for signals 34 to travel ($t_d$) roundtrip over a distance (d) is given by the formula:

where $v_m$ is the velocity of the ultrasound signal in the particular media. In **Figure 4A**, proximity 20 (and distance d) approaches zero as IMD 10 approaches contact with tissue surface 16, which also causes the travel time $t_d$ of signals 34 to approach zero. On the other hand, in an embodiment of the present invention, as depicted in **Figure 4B**, transducers 30 are mounted on IMD 10 with an offset 36 from distal end 14, so that the travel time $t_d$ of signals 34 will never drop below $\frac{2d}{v_m}$ , where d equals the offset 36 distance, when IMD 10 is in contact with tissue surface 16. This non-zero time period between transmitting and receiving the echo of signal 34 is used to accurately receive and measure the reflection of signal 34 off surface 16 when distal end 14 is close to, or in contact with, tissue surface 16.

Ultrasonic transducers are often reciprocal. That is, the same device may be used to both transmit and receive the acoustic wave signals. However, it is extremely difficult to transmit and receive simultaneously. The phrase "you cannot be listening while you are screaming," applies to electro-mechanical devices such as transducers, as well as humans. This problem may best be addressed by one of two techniques, separating the transmission and detection either spatially (distance) or temporally (time). In the context of MIS procedures generally, and TMR procedures in particular, these choices are limited because the size of IMD 10 is preferably very small (*e.g.*, it must fit inside a blood vessel). With such small devices, it may not be feasible to spatially separate the transmission and detection sufficiently. This physical constraint effectively recommends the temporal separation techniques. In a temporal separation technique, a signal 34 is transmitted, and a finite time later detection of the echo begins.

Referring to **Figure 5**, a representative plot of echo signal 38 amplitude 40, as received at transducer 30, versus time or distance 42, where t = 0 corresponds to the time when the transmission of signal 34 begins. Those of ordinary skill in the art will recognize that time and distance are equivalent values on such a plot, and are directly related through the value of $v_m$. Prior to a time indicated by reference point 44, the "ringing" caused by the bleed of the transmission makes accurate measurement of echo signal 38 difficult. The present invention uses offset 36 so that when distal end 14 is in contact with tissue surface 16, the travel time of signal 34 exceeds that shown at point 44. Amplitude peak 45 indicates the location of tissue surface 16 relative to distal end 14. Note, peak 46 corresponds to the echo of the ultrasound signal off a second tissue surface, such as the outer well of the heart. Proximity 20 to the first tissue surface 16 will always correspond to the first peak 45.

The location of reference point 44 on axis 40 is dependent on the design characteristics of the particular ultrasound transducers 30, the form of signal 45, and the velocity of sound for ultrasound signals ($v_m$) in the particular media. Preferably, embodiments of the present invention modify offset 36 for various transducer designs and the anticipated signal transmission media(s). The present invention is not, however, intended to be limited to any particular transducer design characteristics use in any particular media, or use with a single media. For TMR procedures, a reference point 44 corresponding to a distance on the order of 2mm may be used.

The mounting of transducers 30 on IMD 10 shown in **Figures 4A** and **4B** is only one of many possible configurations that might be used with the present invention. Referring now to **Figures 6A** through **6D**, four configurations are shown for mounting transducers 30 on a catheter-like IMD 10 with offset 36. **Figure 6A** depicts an embodiment with transducers 30 mounted on the external surface of IMD 10. In **Figure 6B**, transducers 30 are mounted within IMD 10 with an ultrasonically transparent channel 48 located along the offset 36 between transducers 30 and distal end 14. **Figure 6C** is similar to **Figure 6B**, but omits channel 48. **Figure 6D** mounts transducers 30 within recesses 50, at a slight angle to the longitudinal axis of IMD 10. Those of ordinary skill in the art will recognize that there are many more transducer mounting configurations for catheter-like devices, as well as other types of IMDs 10 than are illustrated in **Figures 6A** through **6D**, and the present invention is not intended to be limited to any particular transducer mounting configuration.

As shown in **Figure 6C**, embodiments of the present invention may use a transducer ring assembly 52 instead of multiple individual transducers. Often such transducer ring assemblies 52 are less expensive than individual transducers and such rings may only require a single pair of conductors for the entire ring 52, instead of a pair of conductors for each transducer 30.

Those of ordinary skill in the art recognize that ultrasound transducers can be fabricated from a variety of materials, in a variety of shapes, to transmit at a variety of frequencies and amplitudes, and with a variety of signal detection characteristics. The present invention is not intended to be limited to use with any particular transducer design.

**Figure 7** is a flow chart depicting the process followed by an embodiment of the present invention. The process start 54 may be initiated manually, by the system operator, or automatically based on either the passage of time or detecting the location of IMD 10 within a particular area. Multiple transducers transmit an ultrasound signals 56 either simultaneously or in accordance with a predefined firing sequence. Following transmission 56, transceivers 30 attempt to receive the echo signals 58 reflected off tissue surface 16. A signal detector controller 60 receives signal data from the plurality of transducers 30 and controls the re-transmission, if necessary. If a sufficient number of signals are not detected, or are below a minimum signal strength, such as when distal end 14 is too far from tissue surface 16, the transmit step 56 is repeated. Controller 60 passes the received echo signal data to echo timing analyzer 62 and echo strength analyzer 64 for proximity and degree of perpendicularity calculations, respectively, and output reporting 66 and 68. The calculations and reporting are preferably performed in real-time or near real-time, with the entire process repeated continuously. Echo timing analyzer 62 may use the echo signal from either a single or a plurality of transducers 30 to calculate proximity. Those of ordinary skill in the art will recognize that using multiple signals is a technique to increase the accuracy of the proximity measurement process.

Echo strength analyzer 64 requires signals from at least two transducers in order to calculate perpendicularity in a single plane. Embodiments of the present invention may compare two pairs of echo signals from three transducers 30, two or more pairs of echo signals from four transducers 30, or virtually any combination of signals from a ring of transducers 30 to calculate perpendicularity. In one embodiment, perpendicularity is calculated and displayed in the planes corresponding to the steering axes of IMD 10.

There are many ways the proximity and perpendicularity information may be presented to the user, and the present invention is not intended to be limited to any particular user interface. One embodiment of a user interface 70 for use with the present invention is shown in **Figure 8**. Proximity indicator 72 uses a needle gauge with a mark on the face of the gauge indicating contact between IMD 10 and tissue surface 16. Perpendicularity indicators 74 and 76 also use needle gauges to indicate when IMD 10 is perpendicular along a first and second axis respectively. Measurement calibration graduations could be added to any, or all, of the gauges. Other types of indicators such as light emitting diodes (LEDs), rows of lights, digital displays, and audio signals could also be used with the present invention to indicate proximity and perpendicularity measurements to the user.

While a user interface, like interface 70, is used with one embodiment of the present invention, it is expected that a variety of different user interface formats will be used in conjunction with the present invention. Those of ordinary skill in the art will be familiar with designing a user interface to accept output signals 66 and 68 from the present invention as input to the user interface. Preferably, the user interface is highly customized to the particular application in which it will be used. The present invention is not, however, intended to be limited to any particular user interface design and it is recognized that there are many ways to present proximity and perpendicularity information to the user.

In one embodiment of the present invention illustrated in **Figure 9A**, the perpendicularity along two axes are displayed simultaneously. Dual axis perpendicularity indicator 78 uses two movable supports 80 and 82, corresponding to the perpendicularity along two respective axes. The intersection of movable supports 80 and 82 is the current perpendicularity position dot 84, which moves relative to bullseye 86. When IMD 10 is perpendicular to tissue surface 16 along both axes, dot 84 is aligned with bullseye 86.

Another embodiment of the present invention also displays proximity adjacent to dual axis perpendicularity indicator 78. This embodiment may display an A-mode graph, similar to that shown in **Figure 5** and shown here in **Figure 9B**, directly below indicator 78.

While embodiments and applications of this invention have been shown and described, it would be apparent to those skilled in the art, after a review of this disclosure, that many more modifications than mentioned above are possible without departing from the inventive concepts herein. The invention, therefore, is not to be restricted except in the spirit of the appended claims.

What is claimed is:

1. A method of monitoring the position of an interventional medical device (IMD) relative to a tissue surface along the axis of the IMD, comprising:

transmitting a first ultrasound signal toward the tissue surface;

transmitting a second ultrasound signal toward the tissue surface;

receiving a first echo from said first ultrasound signal reflected from the tissue surface;

receiving a second echo from said second ultrasound signal reflected from the tissue surface;

determining a proximity of the IMD to the tissue surface;

comparing said first echo and said second echo to determine a first perpendicularity of the IMD relative to the tissue surface; and

reporting said proximity.

2. A method in accordance with claim 1, further comprising:

reporting said first perpendicularity.

3. A method in accordance with claim 1, wherein:

determining said proximity from said first echo.

4. A method in accordance with claim 3, further comprising:

reporting said first perpendicularity.

5. A method in accordance with claim 1, wherein:

determining said proximity from both said first echo and said second echo.

6. A method in accordance with claim 5, further comprising:

reporting said first perpendicularity.

7. A method in accordance with claim 2, further comprising:

transmitting a third ultrasound signal toward the tissue surface;

receiving a third echo from said third ultrasound signal reflected from the tissue surface;

comparing said first echo and said third echo to determine a second perpendicularity of the IMD relative to the tissue surface; and

reporting said second perpendicularity.

8. A method in accordance with claim 5, wherein:

determining said proximity from said first echo, said second echo and said third echo.

9. A method in accordance with claim 2, further comprising:

transmitting a third ultrasound signal toward the tissue surface;

receiving a third echo from said third ultrasound signal reflected from the tissue surface;

comparing said first echo, said second echo, and said third echo to determine a second perpendicularity of the IMD relative to the tissue surface; and

reporting said second perpendicularity.

10. A method in accordance with claim 2, further comprising:

transmitting a third ultrasound signal toward the tissue surface;

transmitting a fourth ultrasound signal toward the tissue surface;

receiving a third echo from said third ultrasound signal reflected from the tissue surface;

receiving a fourth echo from said fourth ultrasound signal reflected from the tissue surface;

comparing said third echo and said fourth echo to determine a second perpendicularity of the IMD relative to the tissue surface; and

reporting said second perpendicularity.

11. A method in accordance with claim 10, wherein:

determining said first proximity and said second proximity from said first echo, said second echo, said third echo and said fourth echo.

12. A method of monitoring the position of an intervention medical device (IMD) relative to a tissue surface, comprising:

transmitting a plurality of ultrasound signals toward the tissue surface;

detecting a plurality of echo signals reflected off the tissue surface;

analyzing the elapsed time between said transmitting and said detecting to measure proximity; and

comparing said plurality of echo signals to measure perpendicularity.

13. A method in accordance with claim 12, wherein:

measuring perpendicularity is performed along two orthogonal planes.

14. A method in accordance with claim 13, further comprising:

reporting said proximity and perpendicularity.

15. An apparatus to monitor the position of an interventional medical device (IMD) relative to a tissue surface, along the axis of the IMD, comprising:

a first ultrasonic transducer for transmitting a first signal toward the tissue surface and for receiving a first echo, said first ultrasonic transducer mounted on the IMD and located an offset distance from the distal end of the IMD;

a second ultrasonic transducer for transmitting a second signal toward the tissue surface and for receiving a second echo, said second ultrasonic transducer mounted on the IMD and located an offset distance from the distal end of the IMD;

an echo timing analyzer coupled to said first ultrasonic transducer for measuring a proximity; and

an echo strength analyzer coupled to said first ultrasonic transducer and said second ultrasonic transducer for measuring a first perpendicularity.

16. An apparatus in accordance with claim 15, wherein:

said echo timing analyzer is coupled to said second ultrasonic transducer.

17. An apparatus in accordance with claim 15, further comprising: a third ultrasonic transducer for transmitting a third signal toward the tissue surface and for receiving a third echo, said third ultrasonic transducer mounted on the IMD and located an offset distance from the distal end of the IMD, said third ultrasonic transducer coupled to said echo strength analyzer for measuring a second perpendicularity.

18. An apparatus in accordance with claim 17, wherein: said echo timing analyzer is coupled to said third ultrasonic transducer.

19. An apparatus in accordance with claim 17, further comprising: a fourth ultrasonic for transmitting a fourth signal toward the tissue surface and for receiving a fourth echo, said fourth ultrasonic transducer mounted on the IMD and located an offset distance from the distal end of the IMD, said fourth ultrasonic transducer coupled to said echo strength analyzer for measuring said second perpendicularity.

20. An apparatus in accordance with claim 19, wherein: said echo timing analyzer is coupled to said fourth ultrasonic transducer.

21. An apparatus to monitor the position of an interventional medical device (IMD) relative to a tissue surface, comprising:

a transducer ring assembly mounted on the IMD, with an offset distance from the distal end of the IMD, aligned to transmit signals substantially parallel to the axis of the IMD toward the distal end of the IMD and receive echo signals reflected off the tissue surface;

a signal detection controller coupled to said transducer ring for routing the echo signals received by said transducer ring;

an echo timing analyzer coupled to said controller for measuring proximity; and

an echo strength analyzer coupled to said controller for measuring perpendicularity.

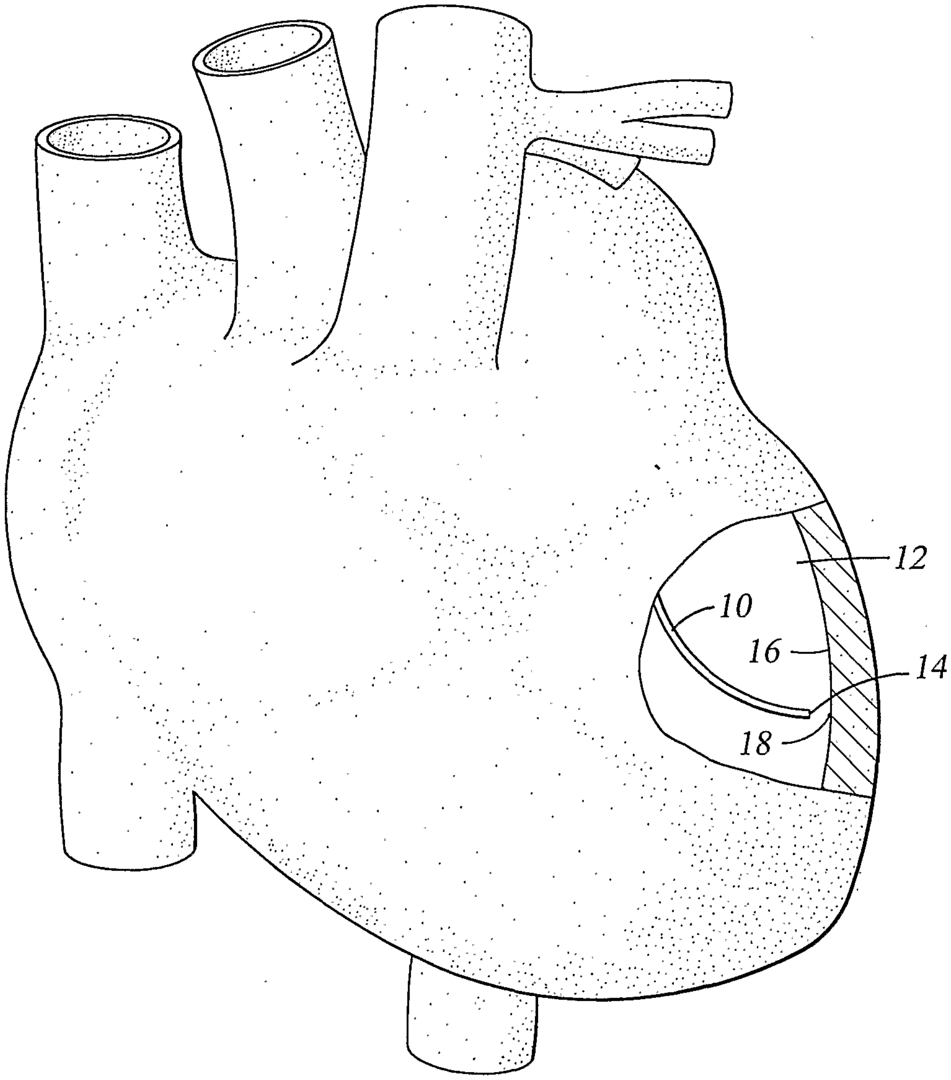



*Fig. 1*

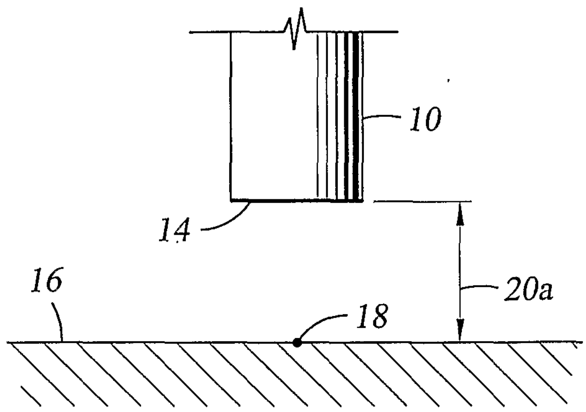



Fig. 2A

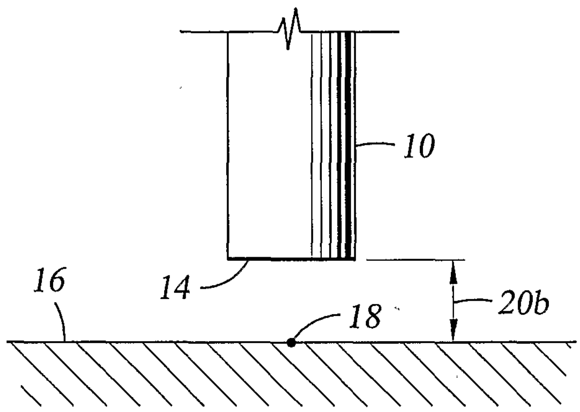



Fig. 2B

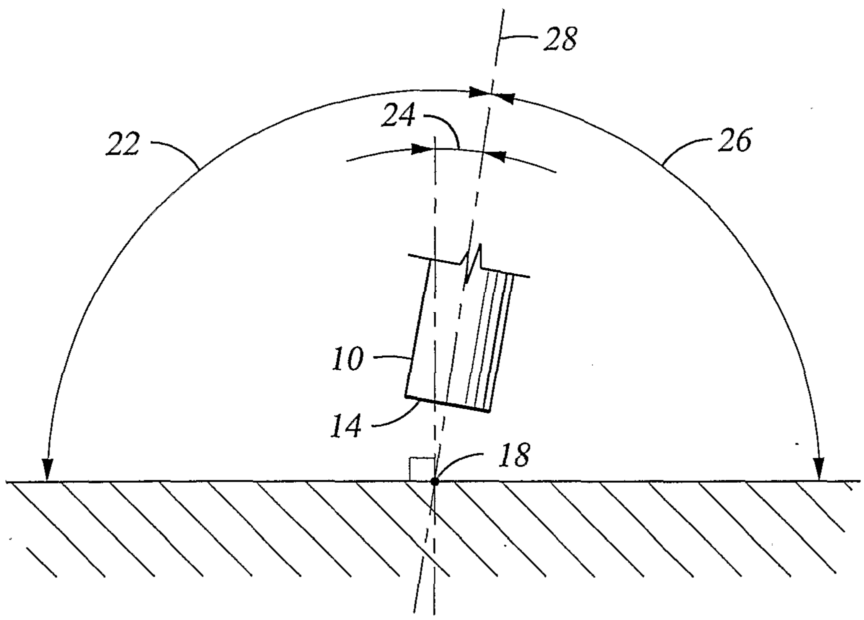



Fig. 3A

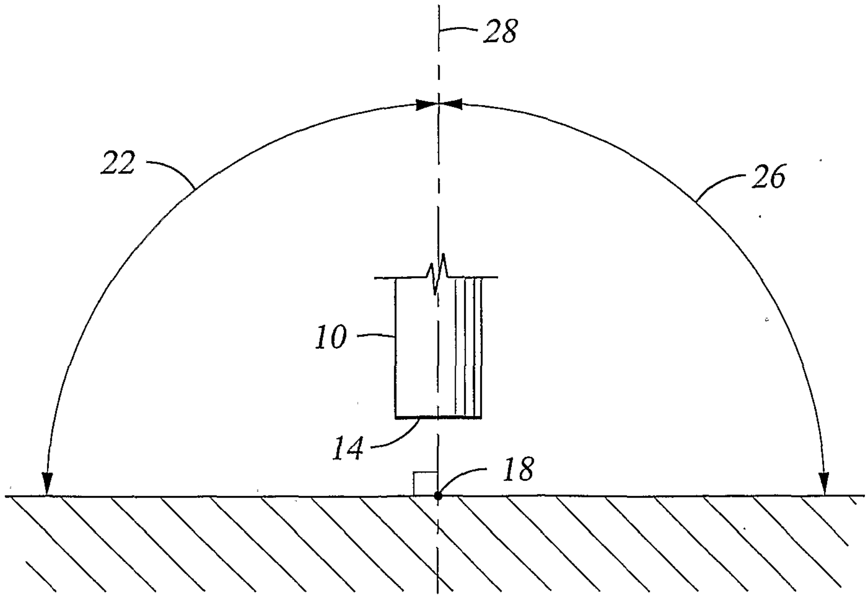



Fig. 3B

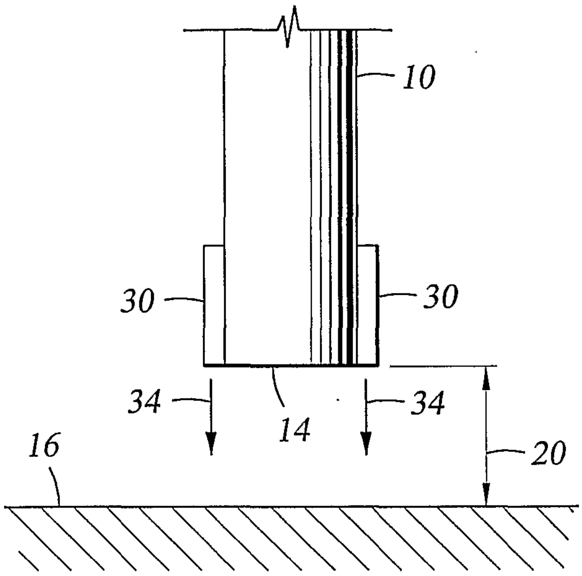



Fig. 4A
(PRIOR ART)

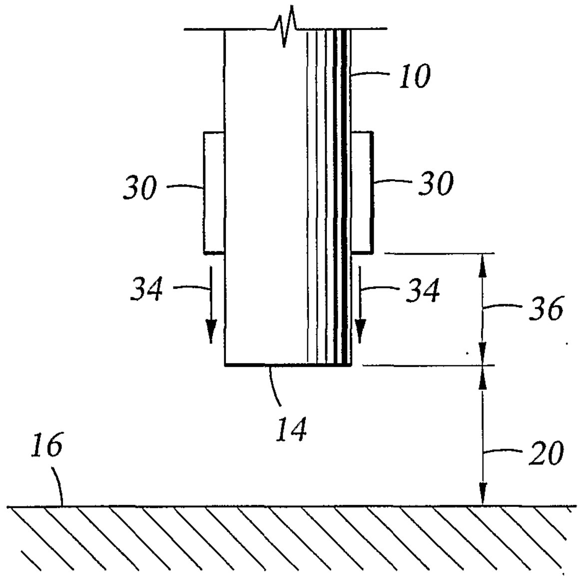



Fig. 4B
(PRIOR ART)

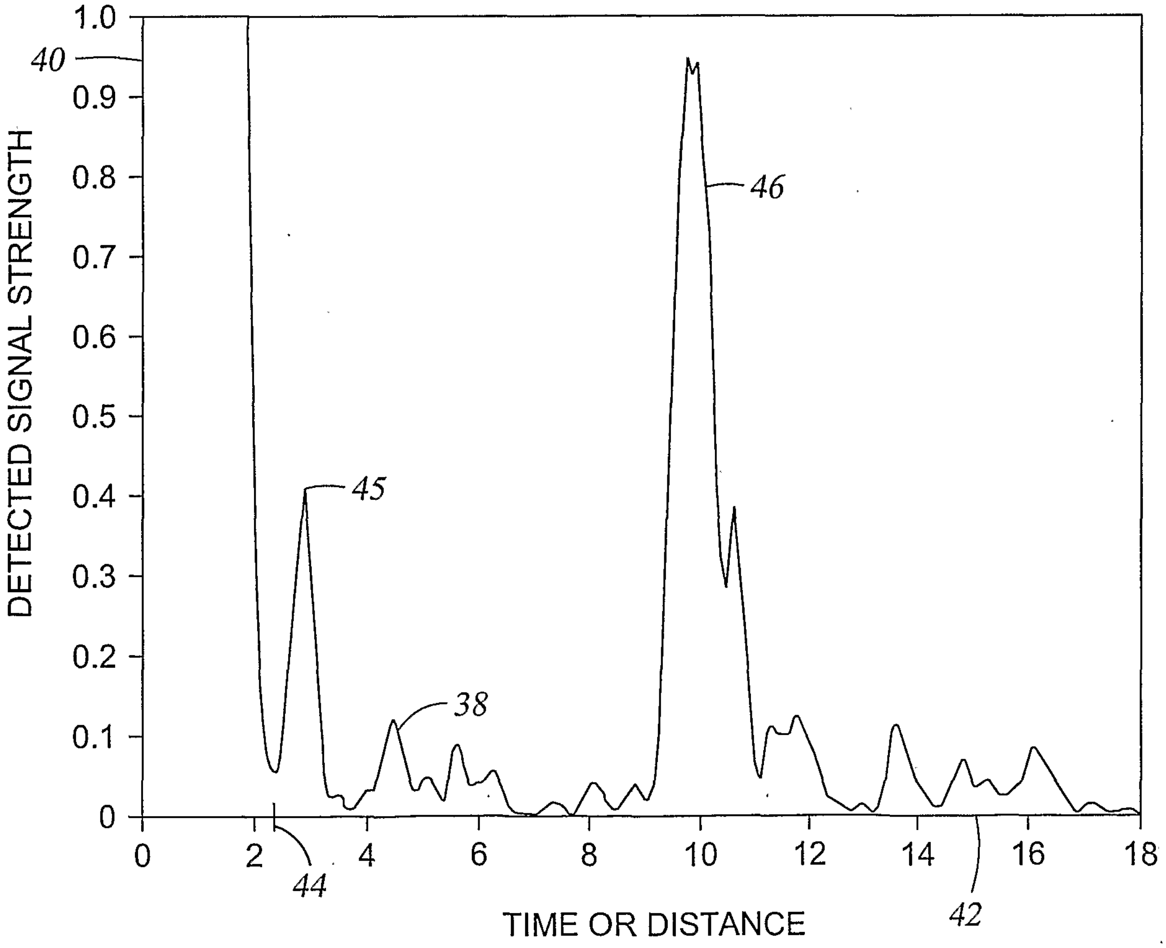



Fig. 5

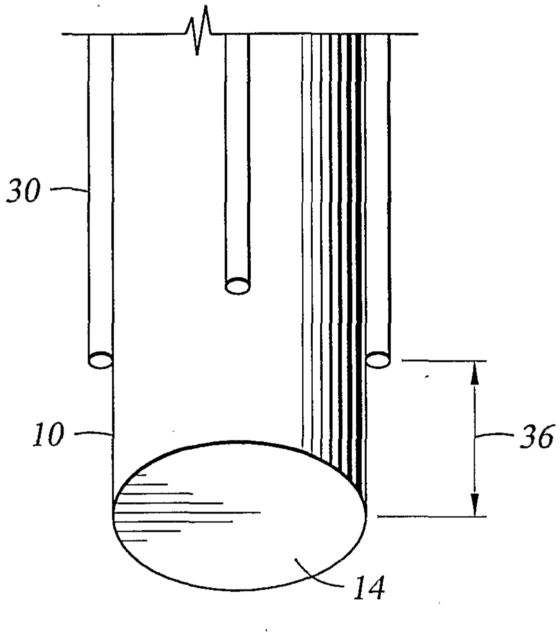



Fig. 6A

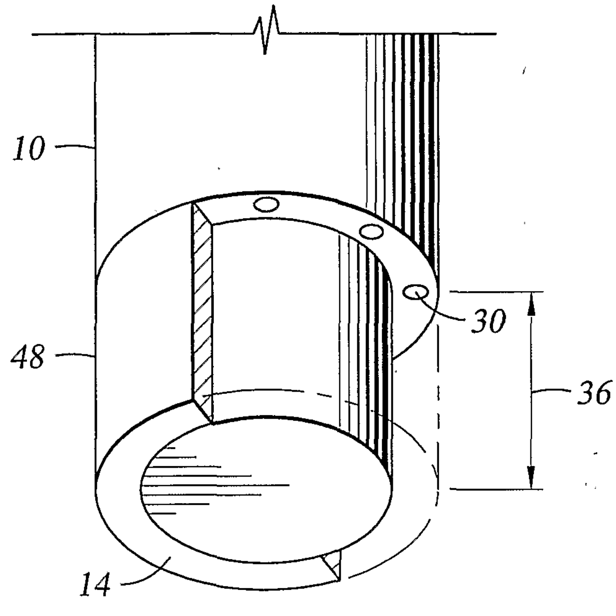



Fig. 6B

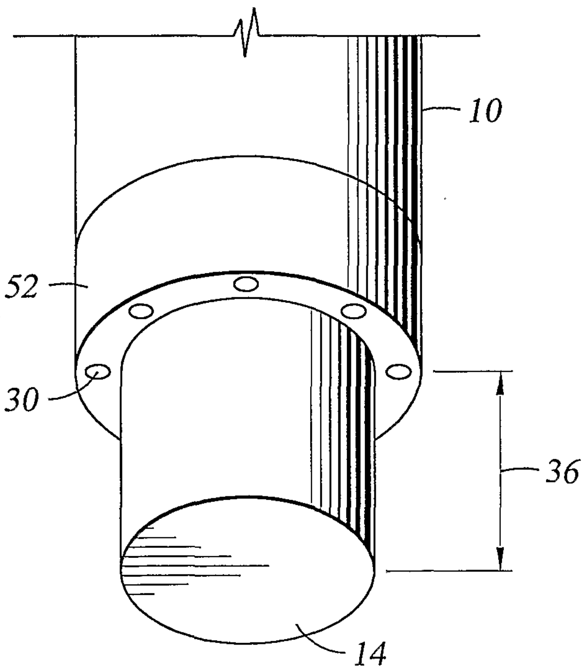



Fig. 6C

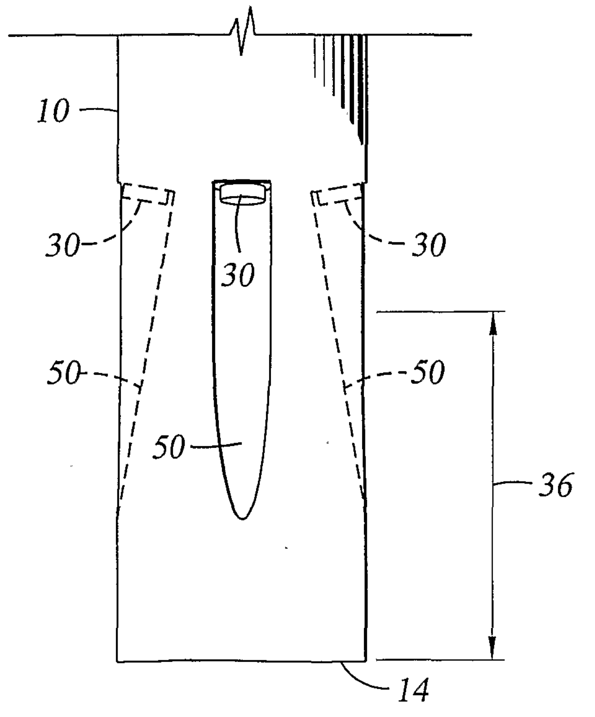



Fig. 6D

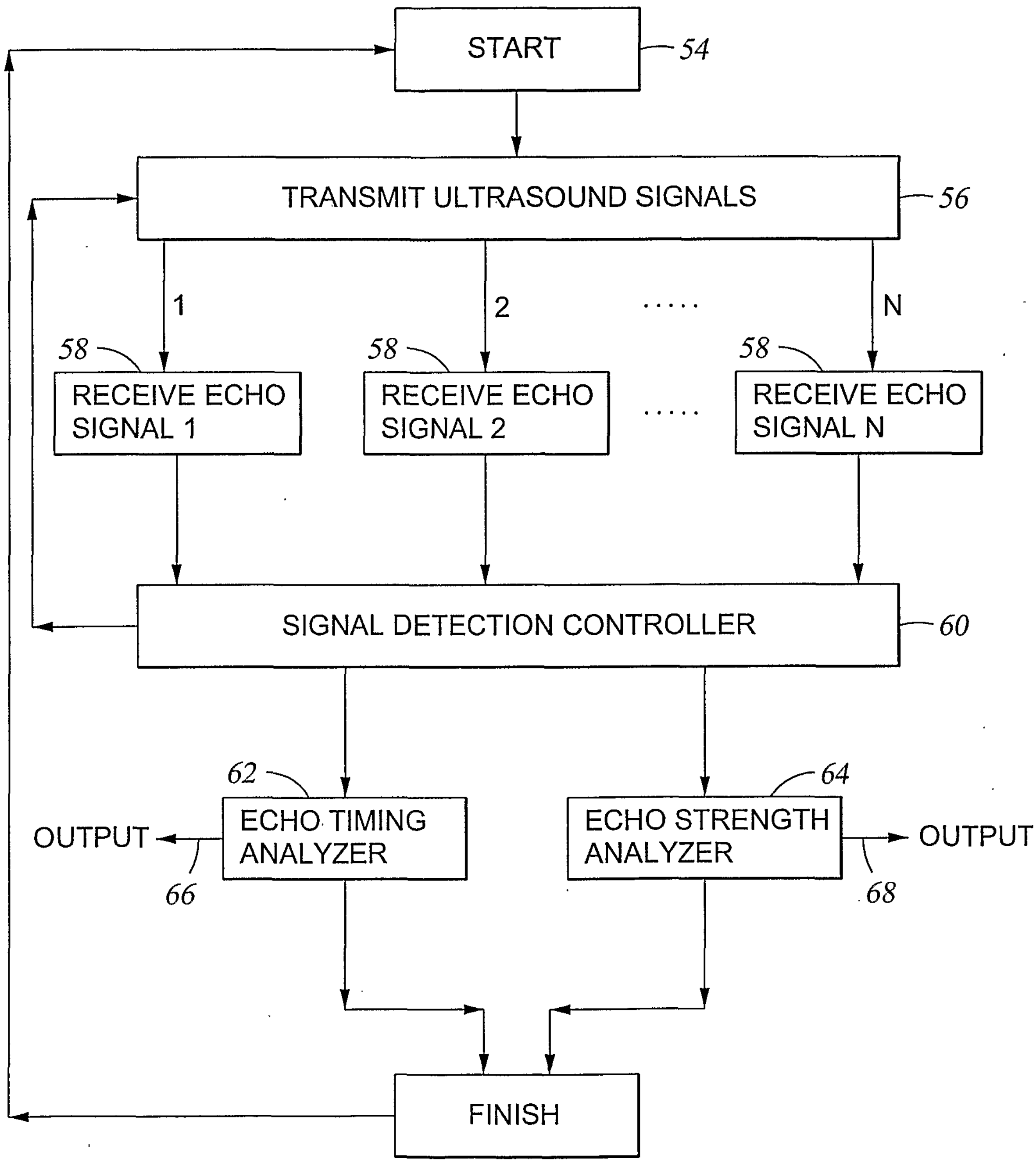

START
54
TRANSMIT ULTRASOUND SIGNALS
56
1
2
.....
N
58
RECEIVE ECHO SIGNAL 1
58
RECEIVE ECHO SIGNAL 2
.....
58
RECEIVE ECHO SIGNAL N
SIGNAL DETECTION CONTROLLER
60
62
ECHO TIMING ANALYZER
OUTPUT
66
64
ECHO STRENGTH ANALYZER
OUTPUT
68
FINISH

*Fig. 7*

70

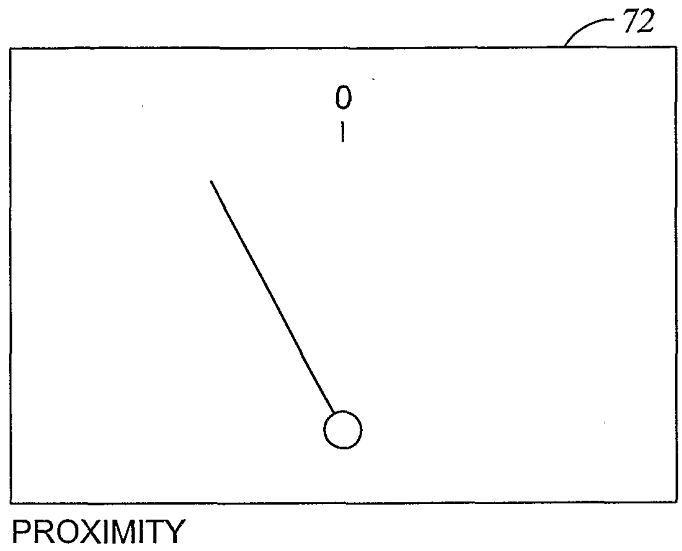



Fig. 8A

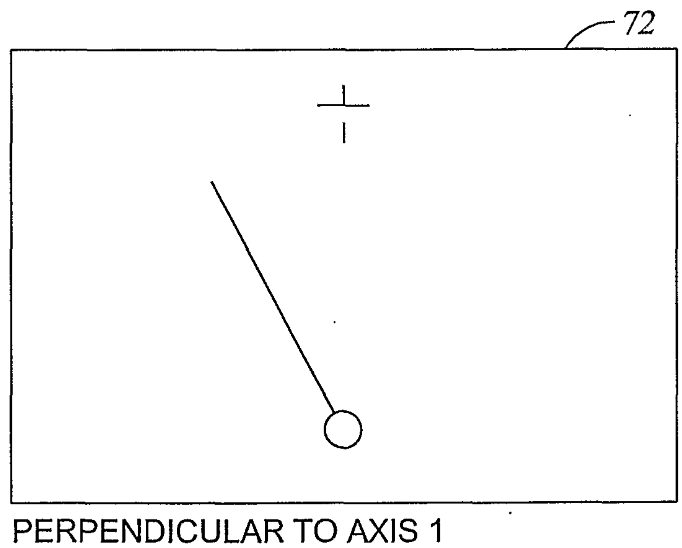



Fig. 8B

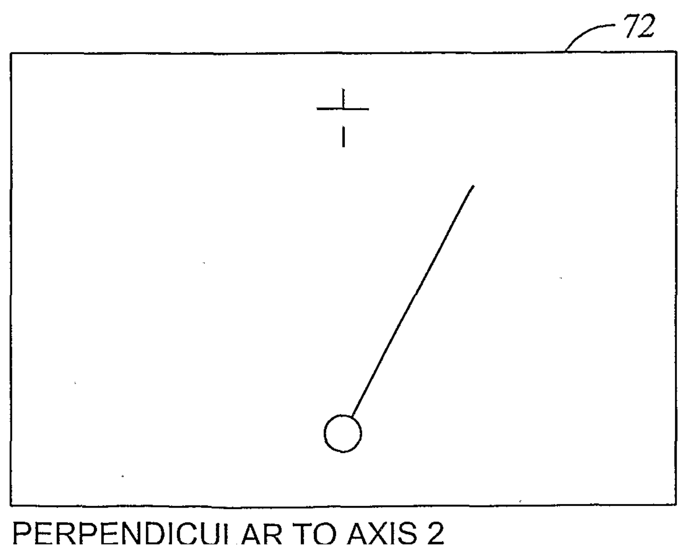



Fig. 8C

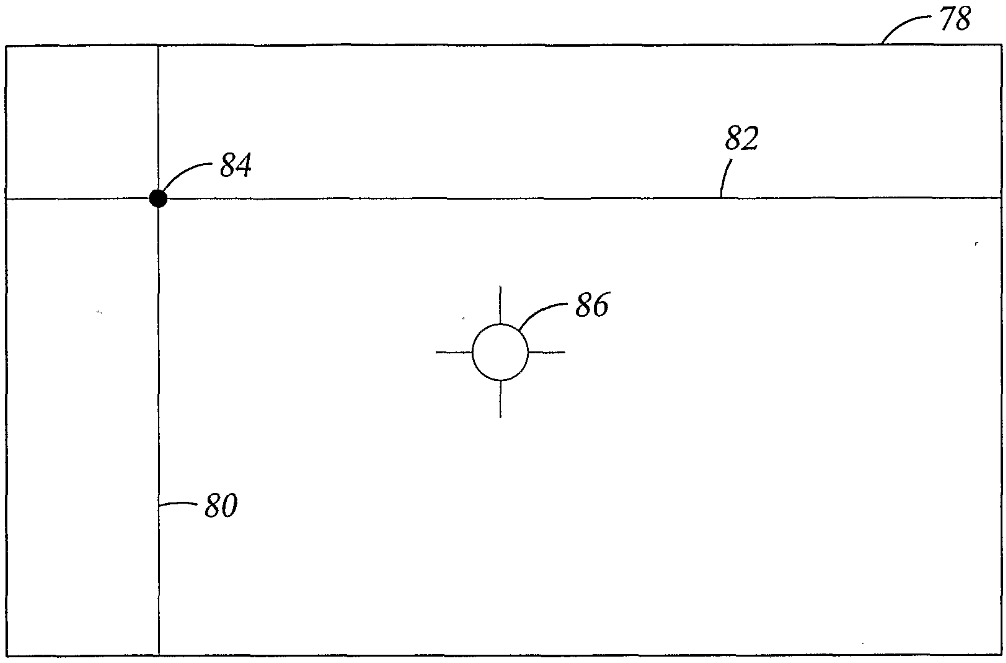



Fig. 9A

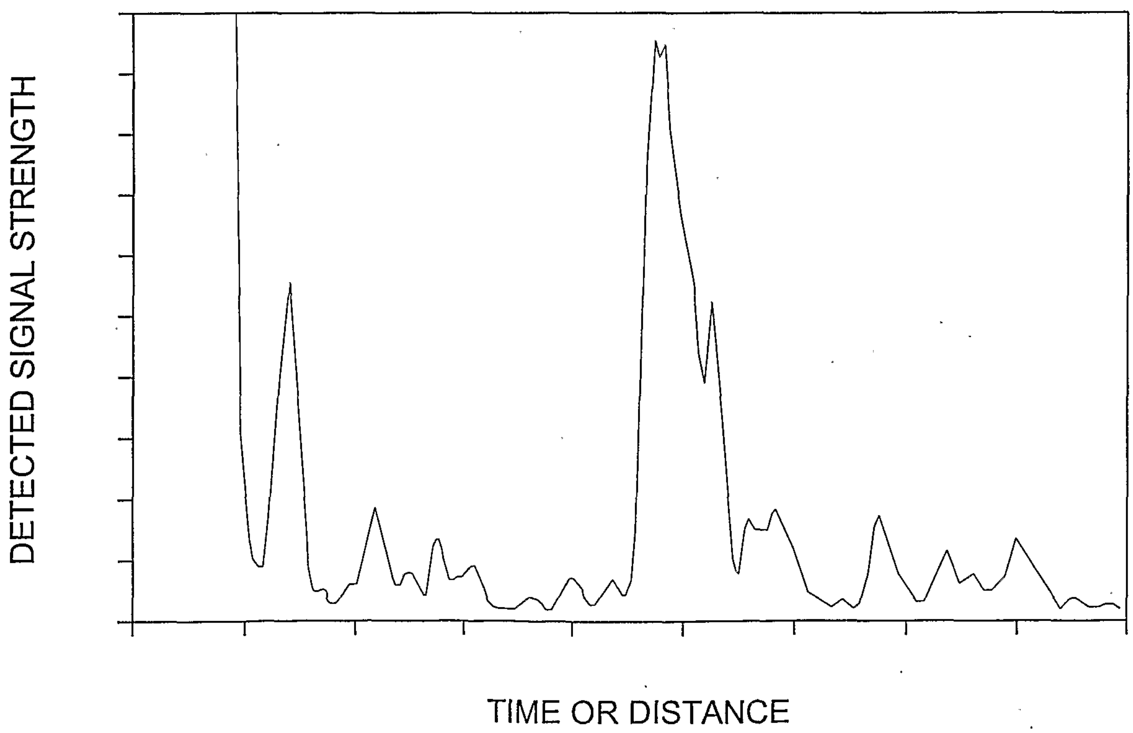



Fig. 9B

# INTERNATIONAL SEARCH REPORT

Inte | Application No
PCT/US 01/28017

**A. CLASSIFICATION OF SUBJECT MATTER**
IPC 7 A61B18/14

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)
IPC 7 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 practical, search terms used)

PAJ, EPO-Internal

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

| Category ° | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| Y | JP 09 038089 A (FUJI PHOTO OPTICAL CO LTD) 10 February 1997 (1997-02-10) paragraphs ‘0027!-‘0029!,‘0035! | 15-21 |
| Y | US 6 086 534 A (KESTEN RANDY J) 11 July 2000 (2000-07-11) column 3, line 66 -column 4, line 32 | 15-21 |

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

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"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

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"&" document member of the same patent family

| Date of the actual completion of the international search | Date of mailing of the international search report |
|---|---|
| 14 February 2002 | 20/02/2002 |

| Name and mailing address of the ISA | Authorized officer |
|---|---|
| European Patent Office, P.B. 5818 Patentlaan 2<br>NL – 2280 HV Rijswijk<br>Tel. (+31–70) 340–2040, Tx. 31 651 epo nl,<br>Fax: (+31–70) 340–3016 | Martelli, L |

# INTERNATIONAL SEARCH REPORT

**Information on patent family members**

| Inte Application No |
|---|
| PCT/US 01/28017 |

| Patent document cited in search report | | Publication date | Patent family member(s) | | Publication date |
|---|---|---|---|---|---|
| JP 09038089 | A | 10-02-1997 | NONE | | |
| US 6086534 | A | 11-07-2000 | AU | 6347998 A | 22-09-1998 |
| | | | EP | 1014860 A1 | 05-07-2000 |
| | | | WO | 9838916 A1 | 11-09-1998 |