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(71) Applicant (for all designated States except US): **SCIMED
LIFE SYSTEMS, INC.** [US/US]; One SciMed Place,
Maple Grove, Minnesota 55311-1566 (US).

(72) Inventor; and

(75) Inventor/Applicant (for US only): **WILLIS, N, Parker**
[US/US]; 98 Reservoir Road, Atherton, California 94027
(US).

(74) Agent: **BURSE, David, T**; Three Embarcadero Center,
Suite 1800, San Francisco, CA 94111-4067 (US).

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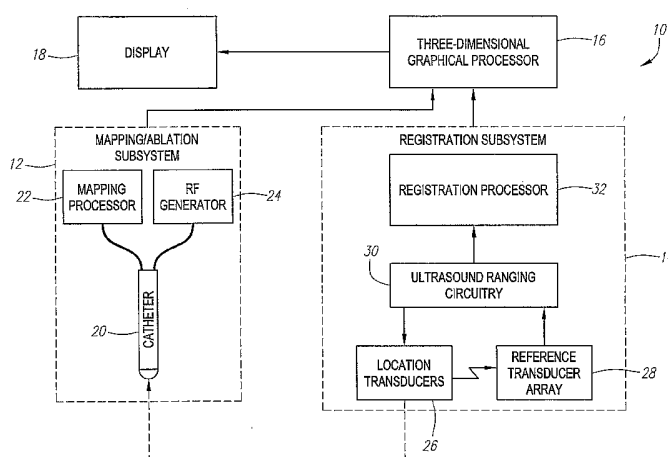
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ance Notes on Codes and Abbreviations" appearing at the begin-
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(54) Title: SYSTEM FOR DETERMINING THE LOCATION OF A MEDICAL PROBE USING A REFERENCE TRANSDUCER
ARRAY



(57) Abstract: Systems for determining the coordinates of a location element mounted on a medical probe. First and second signals are transmitted between the location element and a first and second reference transducers, which may be arranged in a reference array that can be attached to a patient's skin. A transit time difference between the first and second signals is determined, e.g., using a thresholding or correlation technique. A distance difference between a first distance extending from the location element to the first reference element and a second distance extending from the location element to the second reference element is then determined based on the transit time difference. An angle between the reference array and the location element can then be determined based on the determined distance difference and a known distance between the first and second reference transducers.

SYSTEM FOR DETERMINING THE LOCATION OF A MEDICAL PROBE USING A
REFERENCE TRANSDUCER ARRAY

FIELD OF THE INVENTION

5 This invention generally relates to systems for determining the location of a medical probe.

BACKGROUND OF THE INVENTION

It is often necessary or desirable to determine the location of a medical probe when performing a diagnostic and/or therapeutic procedure on a patient. As one example,
10 catheters, whether intravascular or extravascular, must typically be navigated through a patient's body in order to locate the operative portion of the catheter adjacent a target tissue region. Traditionally, this has been accomplished using fluoroscopy. In this case, radiopaque elements are located on the distal end of the catheter and fluoroscopically imaged as the catheter is routed through the body. As a result, a two-dimensional image of the catheter, as
15 represented by the illuminated radiopaque elements, , thereby allowing the physician to roughly determine the location of the catheter. In many procedures, such as cardiac electrophysiology therapy, however, identification of the target tissue region and/or catheter navigation must be made with reference to such features, e.g., the ostium of a pulmonary vein. In this case, fluoroscopy is only used to introduce the catheter within the organ
20 containing the target tissue, e.g., within the heart, and the catheter must be navigated within the heart using other means.

In a more advanced navigation system, commercially available as the Realtime Position ManagementTM (RPM) tracking system from Boston Scientific Corporation, a graphical representation of a catheter is displayed in a three-dimensional computer-generated
25 representation of a body tissue, e.g., heart chamber. The three-dimensional representation of

the body tissue is produced by mapping the geometry of the inner surface of the body tissue in a three-dimensional coordinate system by placing plurality of acoustic location transducers on an ablation/mapping catheter, and moving the catheter to multiple points on the body tissue while tracking the positions of the catheter within the coordinate system using the location transducers. A graphical anatomical shell is then deformed to conform to the transducer positions as they are acquired. The positions of other catheters to be guided within the body, e.g., a mapping/ablation catheter, is determined by placing acoustic transducers on these catheters and tracking the positions of the catheters within the three-dimensional coordinate system. The three-dimensional coordinate system is internally established in the RPM system by placing two reference catheters within known locations of the heart, such as the coronary sinus or right ventricular apex, and transmitting between acoustic transducers located on the reference catheters. The location of the ablation/mapping electrode can then be determined by triangulating each of the location transducers relative to the reference transducers.

U.S. Patent 5,868,673 discloses another means for navigating an ablation probe with tissue in order to facilitate treatment of tumors. In this system, reference acoustic transducers are affixed to the exterior of the patient in order to establish an external three-dimensional coordinate system for locating a location transducer located on the ablation probe as it is moved within the tissue. In order to provide a less invasive and time-consuming electrophysiological procedure, it may be desirable use a system similar to that described in U.S. Patent No. 5,868,673, in order to establish an external three-dimensional coordinate system. For example, acoustic reference transducers can be affixed to regions of the patient's body in a manner that allows communication between these reference transducers and location transducers on an ablation/mapping catheter. In this manner, no reference catheters

need be introduced into the patient's body, thereby lessening the time of the electrophysiological procedure and any discomfort experienced by the patient.

Unfortunately, the availability of acoustic windows through the patient's chest needed to provide communication channels between the spaced-apart reference transducers and the location transducers located within the heart are somewhat limited. Specifically, anatomical regions, such as the ribs and lungs, have vastly different acoustic characteristics than the surrounding tissue. Thus, as the acoustic energy passes through the patient's body, a majority of the energy will reflect backwards at the interface between the surrounding tissue and the ribs and lungs. Even if a transducer does receive a portion of the acoustic signal that passes through the interface, the velocity of the acoustic signal through the ribs and lungs will be different from the velocity of the acoustic signal through the surrounding tissue. As a result, errors will be injected into the navigation algorithm, which assumes a constant acoustic velocity through soft tissue--about the same acoustic velocity as through water.

SUMMARY OF THE INVENTION

A medical system comprises a medical probe, a location element mounted on the medical probe, and first and second reference elements. In one embodiment, the first and second reference elements are mounted on a rigid structure, e.g., a patch that can be applied to the patient's skin. For example, the medical probe may be a catheter, e.g., an ablation and/or electrophysiology catheter. The location element and first and second reference elements may be acoustic transducers, although other types of transducers are contemplated by the invention. The medical system further comprises a registration subsystem that is configured for performing the previously described steps in order to determine the positional coordinates of the medical probe within a coordinate system. Optionally, a third reference element can be provided, so that the registration subsystem can determine the positional coordinates of the medical probe within a three-dimensional coordinate system.

Other objects and features of the invention will become apparent from consideration of the following description taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

The drawings illustrate the design and utility of embodiments of the invention, in which similar elements are referred to by common reference numerals, and in which:

Fig. 1 is a functional block diagram of one embodiment of a medical treatment system constructed in accordance with the invention;

Fig. 2 is a plan view of a mapping/ablation catheter used in the medical treatment system of **Fig. 1**;

Fig. 3 is a plan view of a reference array used in the medical treatment system of **Fig. 1**;

Fig. 4 is a functional block diagram of one implementation of acoustic ranging circuitry used in the medical treatment system of **Fig. 1**;

Fig. 5 is a plot of an exemplary electrical signal used to generate an acoustic signal and three resulting electrical signals derived from the receipt of the acoustic signal by three reference transducers used in the reference array of **Fig. 3**;

Fig. 6 is a perspective view of three receive transducers that can be used in the reference array of **Fig. 3**, particularly showing the dimensional arrangement between the transducers;

Fig. 7 is a side view of the receive transducers and transmit transducer of **Fig. 6**;

Fig. 8 is another side view of the receive transducers and transmit transducer of **Fig. 6**;

Fig. 9 is an alternative embodiment of a registration subsystem that can be used in the medical treatment system of **Fig. 1**;

Fig. 10 is a functional block diagram of an alternative embodiment of acoustic ranging circuitry that can be used in the registration subsystem of **Fig. 9**;

Fig. 11 is a plot of two experimental electrical signals output from a reference transducer array in response to receiving an acoustic signal transmitted from a location transducer;

Fig. 12 is a plot of the cross-correlation energy of the electrical signals of **Fig. 11** as a function of time shift;

Fig. 13 is a plot of a transit time difference of the electrical signal of **Fig. 11** as a function of the angle between the transducer array and the location transducer; and

Fig. 14 is a plot of the calculated angle between the transducer array and the location transducer as a function of the actual angle between the transducer array and the location transducer.

DETAILED DESCRIPTION OF THE ILLUSTRATED EMBODIMENTS

Referring to **Fig. 1**, an exemplary medical treatment system 10 constructed in accordance with the invention is shown. The treatment system 10 is particularly suited for mapping and treating the heart. Nevertheless, it should be appreciated that it can be used for treating other internal anatomical structures, e.g., the prostate, brain, gall bladder, uterus, esophagus and other regions in the body. The treatment system 10 generally comprises (1) a mapping/ablation subsystem 12 for mapping and ablating tissue within the heart; (2) a registration subsystem 14 for registering mapping data and the movement of a probe within a three-dimensional graphical environment; (3) a three-dimensional graphical processor 16 for generating three-dimensional graphical data of the environment in which the mapping data is obtained; and (4) a display 18 for displaying the graphical image. It should be noted that the elements illustrated in **Fig. 1** are functional in nature, and are not meant to limit the structure that performs these functions in any manner. For example, several of the functional blocks

can be embodied in a single device, or one of the functional blocks can be embodied in multiple devices. Also, the functions can be performed in hardware, software, or firmware.

I. MAPPING/ABLATION SUBSYSTEM

5 The mapping/ablation subsystem 12 is utilized to identify and treat a target tissue site or sites, e.g., aberrant conductive pathways. To this end, the mapping/ablation subsystem 12 comprises a mapping/ablation catheter 20, a mapping processor 22, and a radio frequency (RF) generator 24. As further illustrated in Fig. 2, the mapping/ablation catheter 20 comprises an elongate catheter member 34, a plurality of electrodes 36 (in this case, four)
10 carried at the distal end of the catheter member 34, and a handle 38 carried at the proximal end of the elongate member 34. All four electrodes 36 on the catheter member 34 are configured to detect electrical signals in the myocardial tissue for subsequent identification of target sites. The electrode 36 at the distal tip of the catheter member 34 is also configured to be used as an ablation electrode to provide ablation energy to the targeted sites when placed
15 adjacent thereto and operated. The handle 38 includes an electrical connector (not shown) for electrical coupling to the mapping processor 22 and RF generator 24.

Referring back to Fig. 1, the mapping processor 22 is configured to derive activation times and voltage distribution from the electrical signals obtained from the electrodes 36 to determine irregular electrical signals within the heart, which can then be graphically
20 displayed as a map. Mapping of tissue within the heart is well known in the art, and thus for purposes of brevity, the mapping processor 22 will not be described in further detail. Further details regarding electrophysiology mapping are provided in U.S. Patent Nos. 5,485,849, 5,494,042, 5,833,621, and 6,101,409.

The RF generator 24 is configured to deliver ablation energy to the ablation electrode
25 (i.e., the distal most electrode 36) in a controlled manner in order to ablate sites identified by

the mapping processor 22. Alternatively, other types of ablative sources besides the RF generator 24 can be used, e.g., a microwave generator, an acoustic generator, a cryoablation generator, and a laser or other optical generator. Ablation of tissue within the heart is well known in the art, and thus for purposes of brevity, the RF generator 24 will not be described in further detail. Further details regarding RF generators are provided in U.S. Patent No. 5,383,874.

It should be noted that other types of mapping/ablation catheters can be used in the treatment system 10. For example, a catheter having a basket structure of resilient splines, each of which carries a plurality of dedicated mapping electrodes can be used. This catheter may be placed in a heart chamber, so that the resilient splines conform to the endocardial surface of the heart, thereby placing and distributing the mapping electrodes along the entire endocardial surface of the cavity for efficient mapping. The catheter may also have a roving ablation electrode that can be steered in contact with the ablation sites identified by the mapping electrodes. Or a separate ablation catheter with a dedicated ablation electrode or electrodes can be used.

II. REGISTRATION SUBSYSTEM USING THRESHOLDING OF SIGNALS

Referring back to Fig. 1, the registration subsystem 14 generally comprises (1) a plurality of acoustic transducers, and specifically, acoustic location transducers 26 and an acoustic reference transducer array 28; (2) acoustic ranging circuitry 30 configured for determining the transit times (i.e., the "times-of-flight") for acoustic pulses transmitted between each location transducer 26 and the transducers within the reference transducer array 28; and (3) a registration processor 32 configured for registering the location transducers 26 within a three-dimensional coordinate system based on the transit times provided by the acoustic ranging circuitry 30.

A. RANGING TRANSDUCERS

As illustrated in **Fig. 3**, the reference array 28 comprises three acoustic reference transducers 40 and a patch 42 on which the reference transducers 40 are suitably mounted, e.g., using a bonding adhesive. Preferably, the patch 42 is composed of a rigid material, such as stainless steel, so that the respective distances between the reference transducers 40 are fixed and known. Although the reference transducers 40 are arranged in an equilateral triangular configuration, as illustrated in **Fig. 3**, the reference transducers 40 can be arranged in any configuration as long as the transducers 40 are not arranged in a line, so that a three-dimensional coordinate system can be established. Preferably, the reference array 28 is large enough so that any errors in distance measurements are minimized (e.g., there should be at least a wavelength spacing between the reference transducers 40), as will be described in further detail below, but small enough so that the reference array 28 can be placed in a location on the patient's body that allows all of the reference transducers 40 and location transducers 26 to communicate with each other through a single acoustic window, i.e., without interference from the bones and lungs of the patient. Preferably, the reference transducers 40 are spaced from each other a distance less than 10 mm. As illustrated in **Fig. 3**, the reference transducers 40 are arranged in a planar configuration in order to simplify calculation of the positional coordinates of the position transducers 26, as will be described in further detail below. It should be noted, however, that the reference transducers 40 can be arranged in a non-planar configuration without straying from the principles taught by the invention—although such an arrangement would require more complex calculations.

The patch 42 may be secured to the patient's skin, such that the transducer array 28 faces the skin. A material, such as a layer of adhesive (not shown), can be substantially permanently affixed or otherwise provided on a surface of the patch 42 to facilitate adhesion of the patch 42 to the skin. The adhesive may be hydrogel, silicon, polyurethane,

polyethylene, polypropylene, fluorocarbon polymer, and the like. Alternatively, a separate adhesive may be applied to the patch 42 and/or to the patient's skin before applying the patch 42 in order to secure the transducer array 28 to the patient's skin. Such an adhesive may enhance acoustic coupling of the reference transducers 40 to the patient's skin, and consequently to the location transducers 26. Optionally, additional wetting material, including water, silicone oil, silicone gel, hydrogel, and the like, and/or other acoustically conductive material may be provided between the patch 42 and the patient's skin, e.g., to provide substantial continuity and minimize reflection or other losses and/or to secure the patch 42 to the patient.

10 The location transducers 26 are mounted at the distal end of a mapping/ablation catheter 20 (shown in Fig. 2), one of which is mounted at the distal tip just proximal to the tip electrode 32, and the remaining two of which are mounted proximally thereto on the distal end. The location transducers 26 facilitate the mapping of electrophysiological information within the heart chamber and the subsequent ablation thereof. As will be described in further detail below, the location transducers 26 also facilitate structural mapping of the endocardial surface of the heart chamber as the mapping/ablation catheter 20 is moved around within the chamber. Optionally, or alternatively, a location transducer 26 can be mounted on the distal tip of a separate marking catheter (not shown) to provide a dedicated means for structurally mapping the heart. Further details on the use of acoustic transducers within the heart for these purposes are described in U.S. Patent No. 6,490,474 and U.S. Patent Application Ser. No. 09/128,304.

As will be described in further detail below, the reference transducers 40 are operated as receive transducers RX_1 , RX_2 , and RX_3 (shown in Fig. 4), and the positioning transducers 26 are operated as transmit transducers TX (one shown in Fig. 4). It should be noted, however, that, in an alternative embodiment, the reference transducers 40 may be operated as

transmit transducers and the location transducers 26 can be operated as receive transducers.

The significance is that an acoustic signal is transmitted between a location transducer 26 (whether transmitting or receiving) and a reference transducer 40 (whether receiving or transmitting) to determine the distance therebetween.

5 It should also be noted that, for purposes of simplicity, each positioning transducer 26 is described as transmitting an acoustic signal that is received by the three reference transducers 40. For the purposes of the invention, however, an acoustic signal is defined as acoustic energy that follows a single path from a transmitting transducer to a receiving transducer. Thus, if an acoustic pulse is transmitted by a single acoustic transducer and
10 received by three different transducers, three acoustic signals have been transmitted. Similarly, if three different transducers transmit acoustic pulses that are received by a single transducer, three acoustic signals have been transmitted.

B. RANGING CIRCUITRY

 The acoustic ranging circuitry 30 is configured for conditioning the location
15 transducers 26 as transmitters, i.e., to transmit acoustic signals, and for conditioning the reference transducers 40 as receivers, i.e., to receive acoustic signals. As can be appreciated, acoustic transducers can be operated as transmitters by stimulating them with electrical signals, which in turn causes the transducers to vibrate and transmit acoustic signals. Acoustic transducers can be operated as receivers by receiving electrical signals that are
20 induced by the receipt of acoustic signals and subsequent vibration of the transducers. The acoustic ranging circuitry 30 is configured for determining the distances between each location transducer 26 and the reference transducers 40 by conditioning each location transducer 26 to transmit an acoustic signal, and conditioning the reference transducers 40 to receive that acoustic signal. The acoustic ranging circuitry then measures the transit time for
25 each acoustic pulse. As will be described in further detail below, the registration processor

32 will calculate distances from this time information, which are then used to determine the positional coordinates (x, y, z) of the location transducers 26, and thus any structure or tissue adjacent the location transducers 26, within the three-dimensional coordinate system established by the reference array 28.

5 Turning now to **Fig. 4**, the components of the ranging circuitry 30 will now be described in further detail. For purposes of simplicity, the components of the ranging circuitry 30 are described in the context of determining distances between three receive transducers RX_1 , RX_2 , and RX_3 (e.g., the reference transducers 40) and a single transmit transducer TX, (e.g., one of the location transducers 26). The ranging circuitry 30 includes a
10 pulse generator 44 coupled to the transducer TX, a threshold detector 46 coupled to the transducers RX_1 , RX_2 , and RX_3 , distance circuitry 48 coupled to the threshold detector 46, control and timing circuitry 50 coupled to the pulse generator 44, and a distance counter 52 coupled to the control and timing circuitry 50. With further reference to **Fig. 5**, the pulse generator 44 is configured for generating an electrical pulse 54 that is transmitted to the
15 transducer TX, which converts the electrical pulse 54 into an acoustic signal that is received by the transducers RX_1 , RX_2 , and RX_3 .

The control and timing circuitry 50 operates the pulse generator 44, such that a series of pulses 54 are generated at the desired frequency and spacing. In the illustrated embodiment, the electrical pulses are single cycle 500 KHz pulses that are transmitted at a
20 rate of one pulse per millisecond. In the practical case where multiple transmitters TX are used, the control and timing circuitry 50 will also control the multiplexing between the pulse generator 44 and the multiple transducers TX, such that the transducers TX are stimulated by the electrical pulses 54 in a sequential fashion. Thus, the control and timing circuitry 50 will cause a first transducer TX to transmit an acoustic pulse 56, then a second transducer TX, and

so on until the last transducer TX transmits an acoustic pulse 56. The control and timing circuitry 50 will then cycle through the multiple transmitting transducers TX again.

Coincident with the transmission of each electrical pulse 54, the control and timing circuitry 50 is configured for triggering the distance counter 52 to begin counting from zero.

5 The running count value of the distance counter 52 provides a measure of the transit time of the resulting acoustic signal, i.e., the elapsed time from the transmission of the acoustic signal 56 to the receipt of the acoustic signal. This distance counter 52 is reset to zero upon the transmission of the next electrical pulse 54.

After the acoustic signal has been transmitted, the transducers RX_1 , RX_2 , and RX_3
10 receive and convert the acoustic signal into electrical signals 56. The threshold detector 46 is configured for detecting the portion of an electrical signal that is above a threshold level, e.g., a voltage level. The distance circuitry 48 listens for the received electrical signal 56 within a time window, e.g., 100 μ sec. The time window may begin immediately or shortly after the electrical pulse 54 has been transmitted. In determining the detection time of the acoustic
15 signal received by a transducer RX, the distance circuitry 48 interprets the first electrical signal that the threshold detector 46 detects within the time window as the received acoustic signal. Upon receipt of each detected electrical signal 56 from the threshold detector 46, the distance circuitry 48 reads the current count from the distance counter 52, which provides a distance measurement between the transducer RX that received the acoustic signal and the
20 transducer TX in the form a transit time.

Thus, it can be appreciated that the ranging circuitry 30 will output a time in the form of a count value for each combination of a transmitting transducer TX and a receive transducer RX. For instance, if there are three transmitting transducers TX and three receive transducers RX, nine count values will be output, each of which represent transit time of an
25 acoustic signal transmitted between the selected pair of transducers TX and RX. It should be

noted that only one threshold detector 46, distance circuitry 48, and distance counter 52 are shown for purposes of brevity in illustration. In a practical arrangement, there will be a threshold detector 46 and distance circuitry 48 for each receive transducer RX, since the ranging circuitry 50 must be capable of independently receiving and processing the acoustic signals received by the respective transducers RX₁, RX₂, and RX₃. In this arrangement, a single distance counter 52 can be used, in which case, a latch can be associated with each receive transducer RX in order to capture and hold the counter value when the signal detection occurs.

C. REGISTRATION PROCESSOR

Referring back to **Fig. 1**, the registration processor 32 is configured for registering the location transducers 26 within the three-dimensional coordinate system. In performing its registration function, the registration processor 32 first determines the distances between each location transducer 26 and the reference transducers 40 based on the transit times output from the ranging circuitry 30 and a simple distance equation. Once the distances from each location transducer 26 to the three reference transducers 40 are known, the registration processor 32 determines the coordinates of the location transducers 26 within the three-dimensional coordinate system established by the transducer array 28. Specifically, the registration processor 32 determines the coordinates of each location transducer 26 based on a first distance difference between a selected pair of reference transducers 40 and the location transducer 26, and a second distance difference between another selected pair of reference transducers 40 and the location transducer 26.

This procedure will now be described in further detail with reference to **Figs. 6-8**. As best shown in **Fig. 6**, a transmitting transducer TX (e.g., one of the location transducers 26) and three receive transducers RX₁, RX₂, and RX₃ (e.g., the three reference transducers 40) are shown. The receiving transducers RX₁, RX₂, and RX₃ are disposed in a plane of a rigid

structure to form a transducer array. The transducer RX_1 is separated from the transducer RX_2 by a distance d_{12} , the transducer RX_2 is separated from the transducer RX_3 by a distance d_{23} , and the transducer RX_3 is separated from the transducer RX_1 by a distance d_{31} . In the illustrated embodiment the distances d_{12} , d_{23} , and d_{31} are equal. These distances may be different, however, as long as the distances are known by the registration processor 32.

The transducer TX is separated from the respective transducers RX_1 , RX_2 , and RX_3 by distances r_1 , r_2 , and r_3 . To measure the distances r_1 , r_2 , and r_3 , the equations $r_1 = v\tau_1$, $r_2 = v\tau_2$, and $r_3 = v\tau_3$ can be used, where v is the velocity of acoustic pulses transmitted by the transmitting transducer TX through the medium to the receiving transducers RX_1 , RX_2 , and RX_3 , and τ_1 , τ_2 , and τ_3 are the transit times for the acoustic signals, i.e., the time that it takes for the acoustic signal to travel between the transducer TX and the respective transducers RX_1 , RX_2 , and RX_3 . To simplify the distance computation, the velocity of the acoustic signals may be assumed to be constant. This assumption typically only produces a small error, since the velocity of acoustic signals (estimated to be 1540 m/s) varies little in soft tissue and blood, assuming that the acoustic signal are transmitted through an acoustic window through soft tissue, i.e., the acoustic signal does not impinge upon bones or air.

Referring now to **Figs. 7 and 8**, the angles of arrival (θ , φ) of the acoustic signal at two points p_{12} and p_{23} located in the plane of the array are then determined based on distances r_{12} and r_{23} between the transducer TX and the respective points p_{12} and p_{23} . The point p_{12} bisects an imaginary line (having a length d_{12}) extending between the transducers RX_1 and RX_2 , and the point p_{12} bisects an imaginary line (having a length d_{23}) extending between the transducers RX_2 and RX_3 . As illustrated in **Fig. 7**, the angle θ is defined between an imaginary line 58, which is perpendicular to the imaginary line d_{12} , and an imaginary line (having a length r_{12}) extending between the transducer TX and point p_{12} . As illustrated in **Fig. 8**, the angle φ is likewise defined between an imaginary line 60, which is perpendicular

to the imaginary line d_{23} , and an imaginary line (having a length r_{23}) extending between the transducer TX and point p_{23} .

Assuming that $r_{12} \gg d_{12}$ and $r_{23} \gg d_{23}$, then $r_{12} \sim (r_1 + r_2)/2$ and $r_{23} \sim (r_2 + r_3)/2$.

Based on basic geometric principles, the difference between the distances r_1 and r_2 is defined

5 by the equation $dr_{12} = r_1 - r_2 = d_{12}\sin(\theta)$. Thus, the arrival angle θ can be determined by the

equation: $\theta = \sin^{-1}(dr_{12}/d_{12})$. Defining a transit time difference $\Delta\tau_{12} = \tau_1 - \tau_2$, then $\theta = \sin^{-1}(\Delta\tau_{12}v/d_{12})$.

Likewise, the difference between the distances r_2 and r_3 is defined by the

equation $dr_{23} = r_2 - r_3 = d_{23}\sin(\phi)$. Thus, the arrival angle ϕ can be determined by the

equation: $\phi = \sin^{-1}(dr_{23}/d_{23})$. Defining a transit time difference $\Delta\tau_{23} = \tau_2 - \tau_3$, then $\phi = \sin^{-1}(\Delta\tau_{23}v/d_{23})$.

10

It should be noted that although the distance difference dr_{12} is used to calculate the arrival angle θ , and the distance difference dr_{23} is used to calculate the arrival angle ϕ , the distance difference dr_{31} can alternatively be used to calculate either of the arrival angles θ and ϕ . The significance is that two different combinations of the distances r_1 , r_2 , and r_3 are used

15 to calculate the respective angles θ and ϕ .

Given the arrival angles θ and ϕ and the distances r_{12} and r_{23} , the x-y-z positional coordinates of the transducer TX can be calculated as follows, given $r = r_{12} \cong r_{23} \cong r_{31}$, and assuming the receiving transducers RX_1 , RX_2 , and RX_3 form an equilateral triangle configuration:

20

$$\begin{aligned} x &= r \sin \theta \\ y &= r \sqrt{1 - \cos^2 \phi - \frac{1}{4} \sin^2 \theta} \\ z &= r \sqrt{\cos^2 \phi - \frac{3}{4} \sin^2 \theta} \end{aligned}$$

The positional coordinates of the remaining location transducers are calculated in the same manner as just described above with respect to the transducer TX.

It should be noted that the orientation of the imaginary lines 58/60 with respect to the imaginary lines between the respective reference transducer pairs are somewhat arbitrary and will not significantly change the manner in which the positional coordinates of the transducer TX is calculated. For example, if the imaginary lines 58/60 are defined as being parallel to the imaginary lines between the respective reference transducer pairs, rather than orthogonal to it, the x-y-z positional coordinates of the transducer TX can, instead, be calculated by the equations:

$$\begin{aligned} x &= r \cos \theta \\ y &= r \sqrt{1 - \sin^2 \phi - \frac{1}{4} \cos^2 \theta}, \\ z &= r \sqrt{\sin^2 \phi - \frac{3}{4} \cos^2 \theta} \end{aligned}$$

where $\theta = \cos^{-1}(\Delta\tau_{12}v/d_{12})$ and $\phi = \cos^{-1}(\Delta\tau_{23}v/d_{23})$.

III. REGISTRATION SUBSYSTEM USING CORRELATION

Referring to **Fig. 9**, an alternative embodiment of a registration subsystem 114 will now be described. The registration subsystem 114 functionally differs in that it determines the transit time difference $\Delta\tau$ between the received acoustic signals by correlating, rather than thresholding, the signals. By analyzing the entire content of the received signals, errors in calculating the distances between the location transducers 26 and the reference array 28 may be reduced.

Specifically, while the threshold detection method is simple to implement in hardware, it may incur distance errors. This is because the signal is actually detected sometime after it is received, i.e., when the amplitude of the received signal passes a threshold. Thus, there is no guarantee that the detection point will be in the first half cycle of the received signal. It can easily be in the second, or in some circumstances, the third half cycle of the received signal. As a result, the detection point in a first signal received by a first

transducer may be in the first half cycle of the signal, whereas the detection point in a second signal received by a second transducer may be in the second half cycle of the signal. At a frequency of 500 KHz, each half cycle represents a distance of 1.5 mm, so skipping a half cycle creates a significant error. Even when the detection point is consistently within the first half-cycle of the received signal, there can be significant variations in the detected distance as the amplitude of the signal is varied. Consider in Fig. 7, for example, an arrival angle θ of 90°, a predetermined distance d_{12} between two transducers RX₁ and RX₂ of 10 mm, and a distance r_{12} between the transducer TX and array of 100 mm. A relatively small error of 1.5 mm in the signal measurement will be “amplified” into an error equal to $\sin^{-1}(1.5/10) \times 100 = 15$ mm.

The registration subsystem 114 illustrated in Fig. 9 eliminates, or at least, reduces these distance measurement errors. Specifically, the registration subsystem 114 comprises acoustic ranging circuitry 130, which is similar to the previously described ranging circuitry 30 in that it comprises the pulse generator 44 and control and timing circuitry 50, as illustrated in Fig. 10. Unlike the previously described ranging circuitry 30, the ranging circuitry 130 does not output digital counts representing transit times of signals received by the RX₁, RX₂, and RX₃, but rather outputs the analog signals received by the reference transducers RX₁, RX₂, and RX₃. To this end, the ranging circuitry 130 comprises a receiver 146 that filters and amplifies the signals received from the reference transducers RX₁, RX₂, and RX₃, and then outputs three analog signals $s_1(t)$, $s_2(t)$, and $s_3(t)$ for the respective reference transducers RX₁, RX₂, and RX₃.

The registration subsystem 114 further comprises a registration processor 132 that cross-correlates the analog signals received from the ranging circuitry 130 to obtain the transit time differences $\Delta\tau$ between the signals received by the reference transducers RX₁, RX₂, and RX₃. For example, the registration processor 132 may cross-correlate the analog

signals received from transducers RX_1 and RX_2 to obtain the transit time difference $\Delta\tau_{12}$, and thus the distance difference dr_{12} . The registration processor 132 may also cross-correlate the analog signals received from transducers RX_2 and RX_3 to obtain the transit time difference $\Delta\tau_{23}$, and thus the distance difference dr_{23} . The registration processor 132 can then calculate the x-y-z coordinates of the transducer TX using the coordinate transformation equations discussed above.

In the illustrated embodiment, the registration processor 132 determines a transit time difference $\Delta\tau$ by cross-correlating the selected pair of signals and then determining the peak of the cross-correlation as the difference in the time of arrival of the two signals.

Specifically, the signals are cross-correlated by iteratively time-shifting the signals relative to each other, multiplying the time-shifted signals, and then integrating the products to obtain the time-shift that results in the maximum cross-correlated energy. The cross-correlation can be calculated as: $R(\tau) = \int s_1(t)s_2(t-\tau)dt$, where $s_1(t)$ is the first received signal as a function of time t , $s_2(t)$ is the second received signal as a function of time t . The transit time difference is the maximum of the cross-correlation.

This correlation procedure is significantly more accurate than the previously described thresholding procedure, since it the entire signal, rather than the detection times, of the signals that are analyzed. In addition, higher frequency modes of the transducers can be used to achieve higher temporal resolution. In fact, it is desirable to operate the registration subsystem 114 with as wide of a frequency band as possible.

Referring now to **Fig. 11-14**, the results of an experimental correlation procedure used to determine the transit time difference $\Delta\tau$ between signals $s_1(t)$ and $s_2(t)$ are shown. In performing the experiment, a single acoustic transducer was used to transmit an acoustic signal to a sensor array. The sensor array contained two acoustic transducers, which were connected to an analog receiver that output the resulting signals $s_1(t)$ and $s_2(t)$. A National

Instruments 9112 digital oscilloscope card having a sampling rate of 100 MHz was used to record the signals $s_1(t)$ and $s_2(t)$, which are illustrated in **Fig. 11**. As can be seen, the amplitude of the first signal $s_1(t)$ is generally greater than the amplitude of the second signal $s_2(t)$. This is due to the different characteristics between transducers. Such variance in amplitude between the signals, however, does not adversely affect the results, since it is the cross-correlation of the signals $s_1(t)$ and $s_2(t)$ that dictates the results.

A labview program was used to perform a cross-correlation of the signals $s_1(t)$ and $s_2(t)$, while physically changing the angle of the sensor array relative to the transmitting transducer. **Fig. 12** illustrates the cross-correlation. As can be seen, the peak occurs around 3.5 msec. Thus, in this case, the transit time difference $\Delta\tau$ of the acoustic signals received by the two receive transducers is approximately 3.5 msec. **Fig. 13** illustrates the transit time difference $\Delta\tau$ as a function of the angle of the sensor array relative to the transmitting transducer. As predicted, there is a sinusoidal shape to the transit time difference $\Delta\tau$. Notably, the artifact near -90 degrees is caused by the acoustic shadowing of the fixture that holds the transmitting transducer. Thus, in a practical environment, no such artifact will appear in the measurement. **Fig. 14** illustrates the calculated estimated angle of the sensor array relative to the transmitting transducer versus the actual angle of the sensor array. As can be seen, the estimated angle tracks the actual angle fairly closely in the range of -50 to 50 degrees, and tapers off somewhat outside of this range. Much of the angle error outside of the -50 to 50 degree range can be attributed to the fact that the distance between the reference transducers was measured by hand. In a practical scenario, the distances between reference transducers can be more tightly controlled in order to minimize measurement errors. Again, the artifact near -90 degrees is caused by the acoustic shadowing of the fixture that holds the transmitting transducer.

IV. THREE-DIMENSIONAL RENDERING PROCESSOR

The three-dimensional graphical processor 16 is configured for generating a global representation of an internal anatomical structure in the form of a computer-generated representation (i.e., a reconstruction) of the heart chamber within the global coordinate system. The three-dimensional graphical processor 16 accomplishes this by acquiring the positions of the location transducers 26 within the global coordinate system as the mapping/ablation catheter 20 is moved around within the cavity of the internal anatomical structure, and then deforming an anatomical shell to the acquiring positions. The three-dimensional graphical processor 16 is also configured to construct a graphical representation of the mapping/ablation catheter 20 within the graphical representation of the internal anatomical structure based on the calculated positional coordinates of the location transducers 26 located at the distal end of the catheter 20 and the known positional relationship between the location transducers.

The three-dimensional graphical processor 16 is also configured for superimposing an electrical activity map over the graphical representation of the internal anatomical structure based on the electrical activity information acquired from the mapping/ablation subsystem 12 and the positions of the mapping electrodes 36 geometrically derived from the positions of the location transducers 26 obtained from the registration subsystem 16. This electrical activity map illustrates sites of interest, e.g., electrophysiology recording and ablation sites, for providing subsequent ablative treatment. Additional details on this graphical reconstruction technique can be found in U.S. Patent No. 6,490,474 and U.S. Patent Application Ser. No. 09/128,304.

Instead of, or in addition to, graphically reconstructing the body tissue, any one of a number of imaging techniques to generate a three-dimensional image of the body tissue. For example, a Magnetic Resonance Imaging (MRI) imager, or a Computed Tomography (CT)

imager can be used to generate a three-dimensional image of the internal anatomical structure. To accomplish this, the imager may be moved laterally and/or rotationally to obtain multiple cross-sectional or sector images of the body tissue at different positions within the body tissue. The multiple cross-sectional images may then be aggregated (i.e.,
5 pieced together) to reconstruct a three-dimensional image of the internal anatomical structure. The three-dimensional image of the internal anatomical structure may be registered within the global coordinate system by tracking the position of the imager, and therefore the cross-sectional or sector images taken by the imager, for example, by attaching acoustic location transducers to the imager. Alternatively, the position of anatomic landmarks within the body
10 tissue may be determined in the global coordinate system, e.g., using the mapping/ablation catheter 20. The three-dimensional image of the internal anatomical structure may then be registered with the global coordinate system by correlating the positions of the anatomic landmarks in the three-dimensional image of the internal anatomical structure with the determined positions of the anatomic landmarks in the global coordinate system.

15

CLAIMS

1. A medical system, comprising:
a medical probe;
5 a location element mounted on the medical probe;
first and second reference elements; and
a registration subsystem configured for wirelessly transmitting first and second
signals between the location element and the first and second reference elements, determining
a transit time difference of the first and second signals between the location element and the
10 respective first and second reference elements, determining a distance difference between a
first distance extending from the location element to the first reference element and a second
distance extending from the location element to the second reference element, based on the
transit time difference; and determining coordinates of the location element within a
coordinate system based on the distance difference.
- 15 2. The system of claim 1, wherein the location element and first and second
reference elements comprise acoustic transducers.
3. The system of claims 1 or 2, wherein the registration subsystem is
configured for simultaneously transmitting the first and second signals.
4. The system of claims 1 or 2, wherein the registration subsystem is
20 configured for receiving the first and second signals, and determining times that the
amplitudes of the received first and second signals cross an amplitude threshold, wherein the
transit time difference is a function of the threshold crossing times.
5. The system of claim 4, wherein the registration subsystem is configured for
simultaneously transmitting the first and second signals, and the function is a difference
25 function.

6. The system of claims 1 or 2, wherein the registration subsystem is configured for receiving the first and second signals, and cross-correlating the received first and second signals to obtain a time shift between the received first and second signals, wherein the transit time difference is a function of the time shift.
- 5 7. The system of claim 6, wherein the registration subsystem is configured for simultaneously transmitting the first and second signals, and the function is an identity function.
8. The system of any of claims 1 - 7, further comprising a rigid structure on which the first and second reference element are arranged in an array, wherein the registration
10 subsystem is configured for determining an angle between an imaginary line intersecting the location element and the array and a first imaginary plane intersecting the imaginary line, wherein the angle determination is based on the distance difference and a predetermined distance between the first and second reference elements, and the coordinate determination is based on the angle.
- 15 9. The system of claim 8, wherein the coordinate determination is further based on the length of the imaginary line.
10. The system of claim 8, wherein the imaginary plane is perpendicular to another imaginary line extending between the first and second reference elements.
11. The system of claim 8, wherein the imaginary line bisects another imaginary
20 line extending between the first and second reference elements.
12. The system of any of claims 1 - 11, wherein the coordinate system is a two-dimensional coordinate system.
13. The system of any of claims 1 - 12, wherein the rigid structure is a patch configured to be located on the skin of a patient.

14. The system of claim 1, further comprising a third reference element, wherein the registration subsystem is further configured for wirelessly transmitting a third signal between the location element and the third reference element, determining another transit time difference of the first and third signals between the location element and the respective first and third reference elements, determining another distance difference between the first distance and a third distance extending from the location element to the third reference element based on the other transit time difference, and determining coordinates of the location element within a coordinate system based further on the other distance difference.

15. The system of claim 14, wherein the coordinate system is a three-dimensional coordinate system.

16. A medical system, comprising:

a medical probe;

a location element mounted on the medical probe;

a reference array having a rigid structure and first and second reference elements

mounted on the rigid structure; and

a registration subsystem configured for wirelessly transmitting first and second signals between the location element and the first and second reference elements, determining a transit time difference between the first and second signals, determining a distance difference between a first distance extending from the location element to the first reference element and a second distance extending from the location element to the second reference element, based on the transit time difference, determining an angle formed by the location element and the reference array based on the distance difference and a distance between the first and second reference elements, and determining coordinates of the location element within a coordinate system based on the angle.

17. The system of claim 16, wherein the location element and first and second reference elements comprise acoustic transducers.
18. The system of claims 16 or 17, wherein the registration subsystem is configured for simultaneously transmitting the first and second signals.
- 5 19. The system of any of claims 16 - 18, wherein the coordinate system is a two-dimensional coordinate system.
20. The system of any of claims 16 - 19, wherein the rigid structure is a patch configured to be located on the skin of a patient..
21. The system any of claims 16 - 20, wherein the registration subsystem is
10 configured to determine the coordinates of the location element based further on a distance between the location element and the reference array.
22. The system of claim 16, wherein the reference array has a third reference element mounted on the rigid structure, and wherein the registration subsystem is further configured for wirelessly transmitting a third signal between the location element and the
15 third reference element, determining another transit time difference between the first and third signals, determining another distance difference between the first distance and a third distance extending from the location element to the third reference element based on the other transit time difference, determining another angle formed by the location element and the reference array based on the distance difference and a distance between the first and third
20 reference elements, and determining coordinates of the location element within the coordinate system further based on the other angle.
23. The system of claim 22, wherein the coordinate system is a three-dimensional coordinate system.
24. A medical system, comprising:
25 a medical probe;

a location element mounted on the medical probe;
first and second reference elements; and
processing circuitry configured for wirelessly transmitting first and second signals
between the location element and the respective first and second reference elements,
5 receiving the first and second signals, cross-correlating the received first and second signals
to obtain a signal time shift between the received first and second signals, and determining a
transit time difference between the first and second signals as a function of the signal time
shift.

25. The system of claim 24, wherein the location element and first and second
10 reference elements comprise acoustic transducers.

26. The system of claims 24 or 25, wherein the registration subsystem is
configured for simultaneously transmitting the first and second signals.

27. The system of any of claims 24 - 26, wherein the function is an identity
function.

15 28. The system of any of claims 24 - 27, wherein the processing circuitry cross-
correlates the first and second signals by:

incrementally time shifting the first and second signals relative to each other;
multiplying the first and second signals for each time shift;
generating a plurality of values as a function of the signal multiplications over time;
20 identifying a maximum value from the plurality of values, wherein the signal time
shift is the time shift corresponding to the maximum value.

29. The system of claim 28, wherein the function is an integration function.

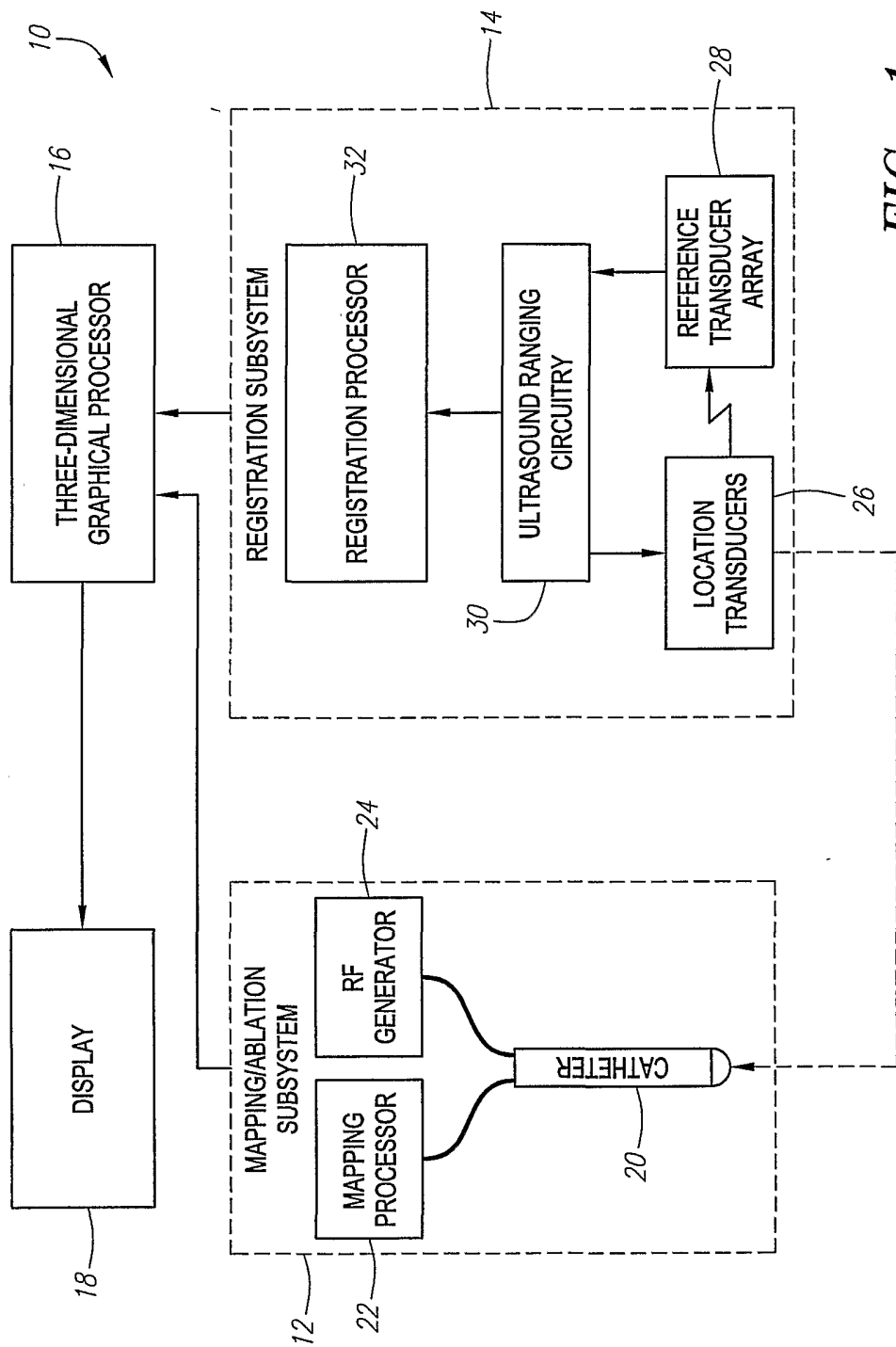
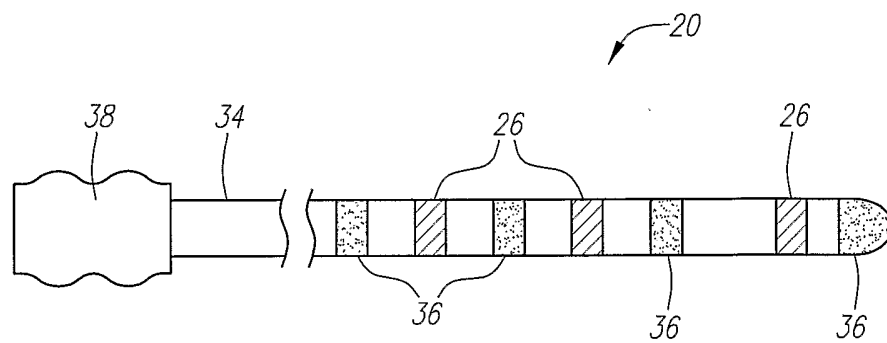
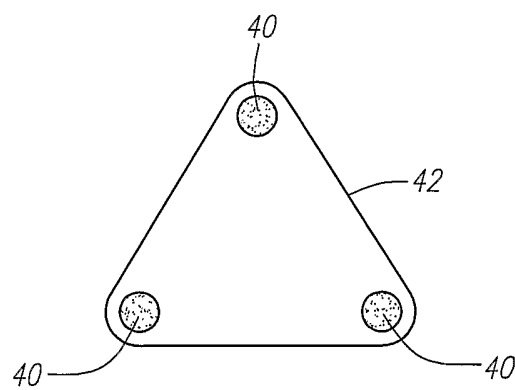


FIG. 1

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*FIG. 2**FIG. 3*

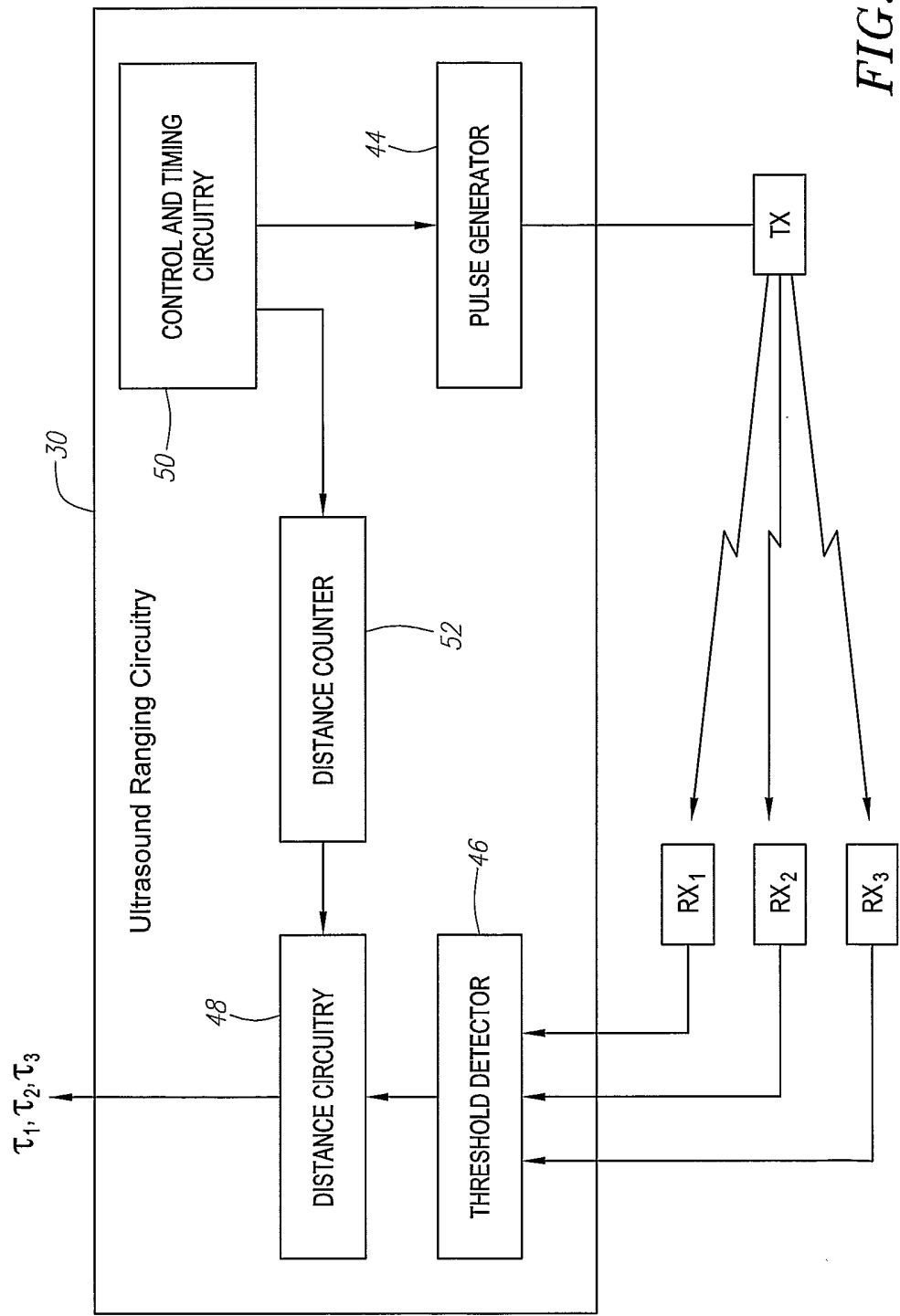
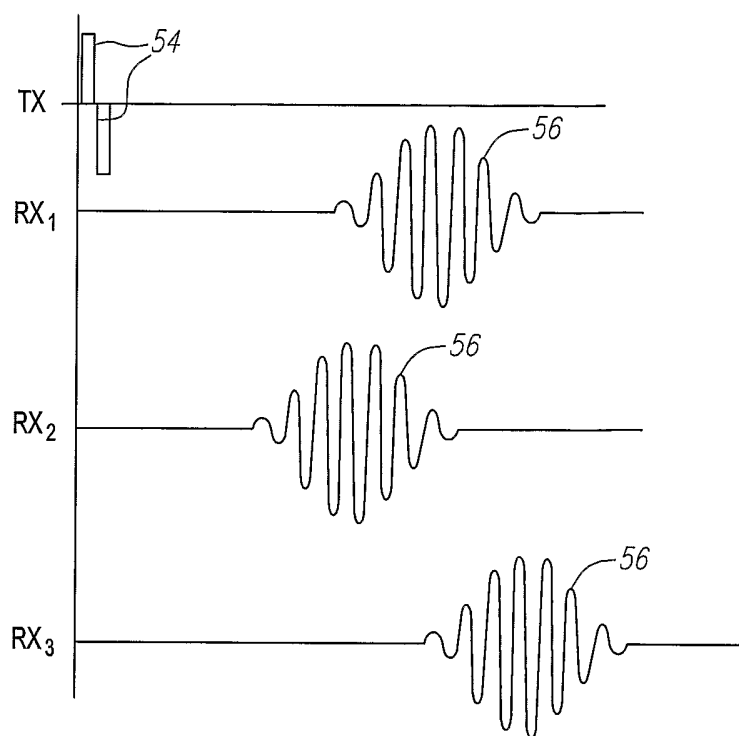
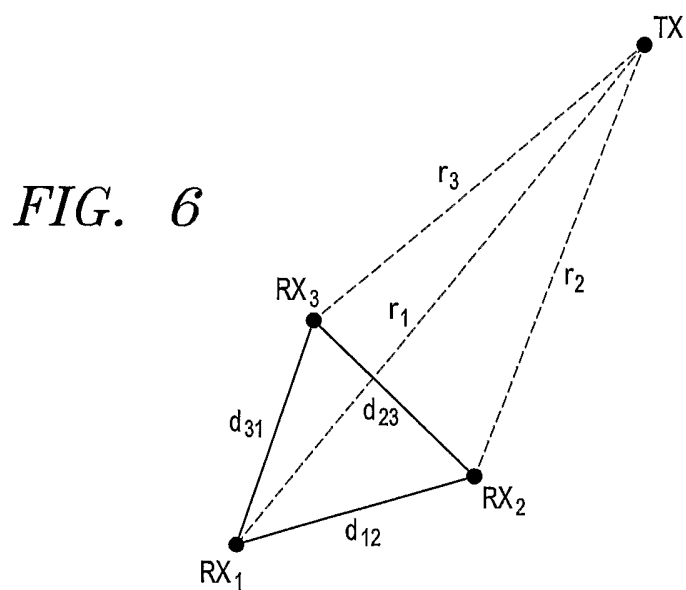


FIG. 4

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*FIG. 5**FIG. 6*

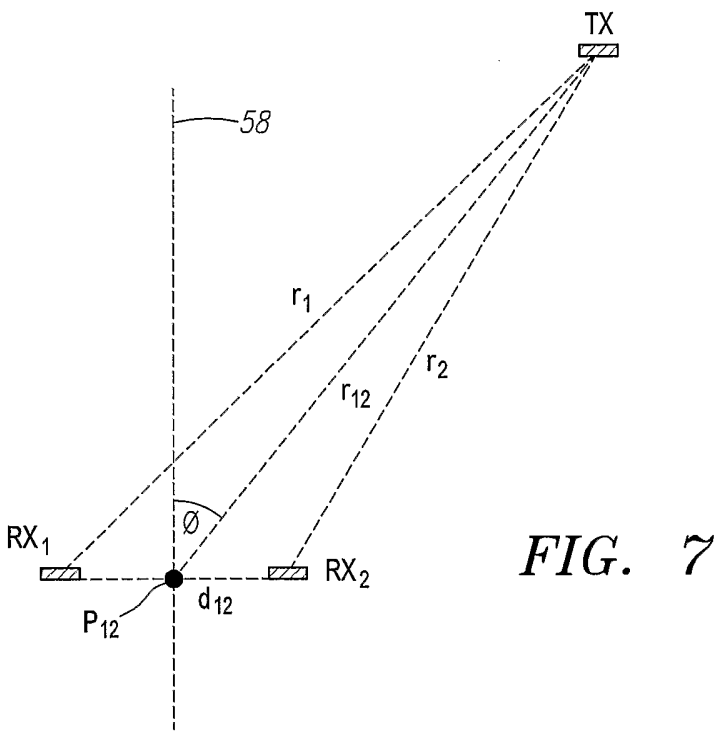


FIG. 7

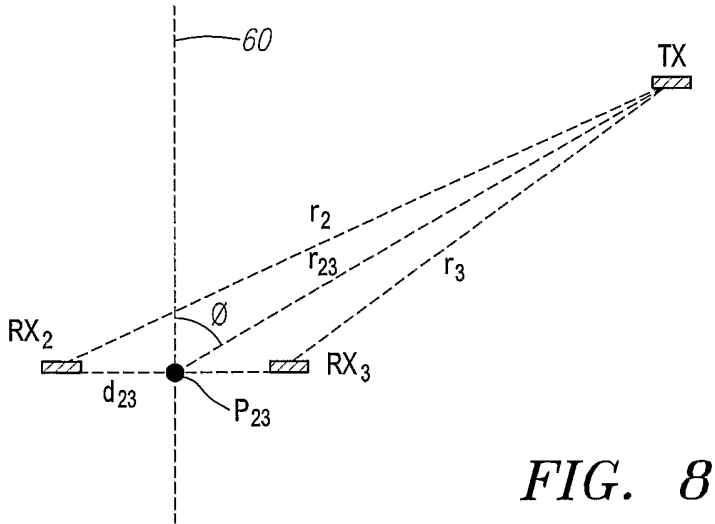
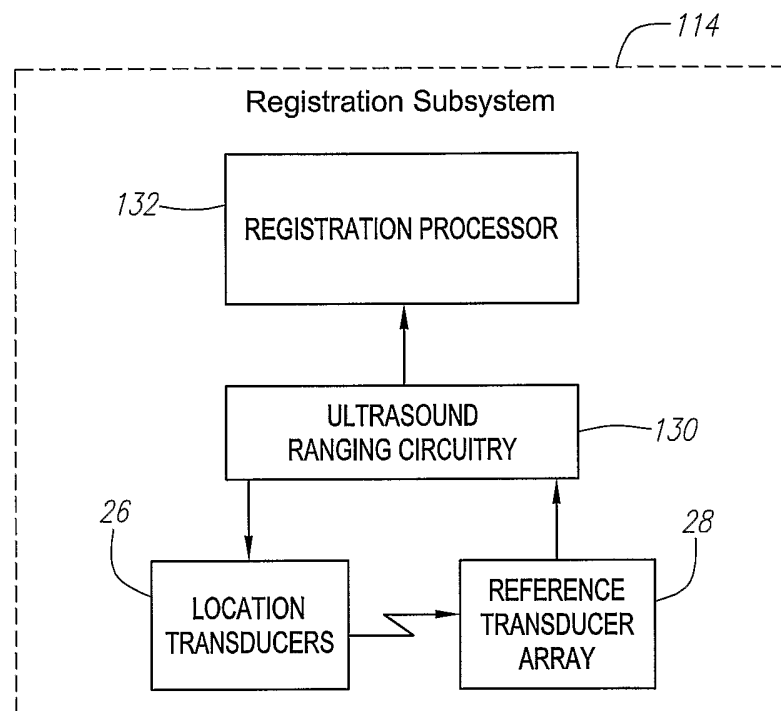


FIG. 8

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*FIG. 9*

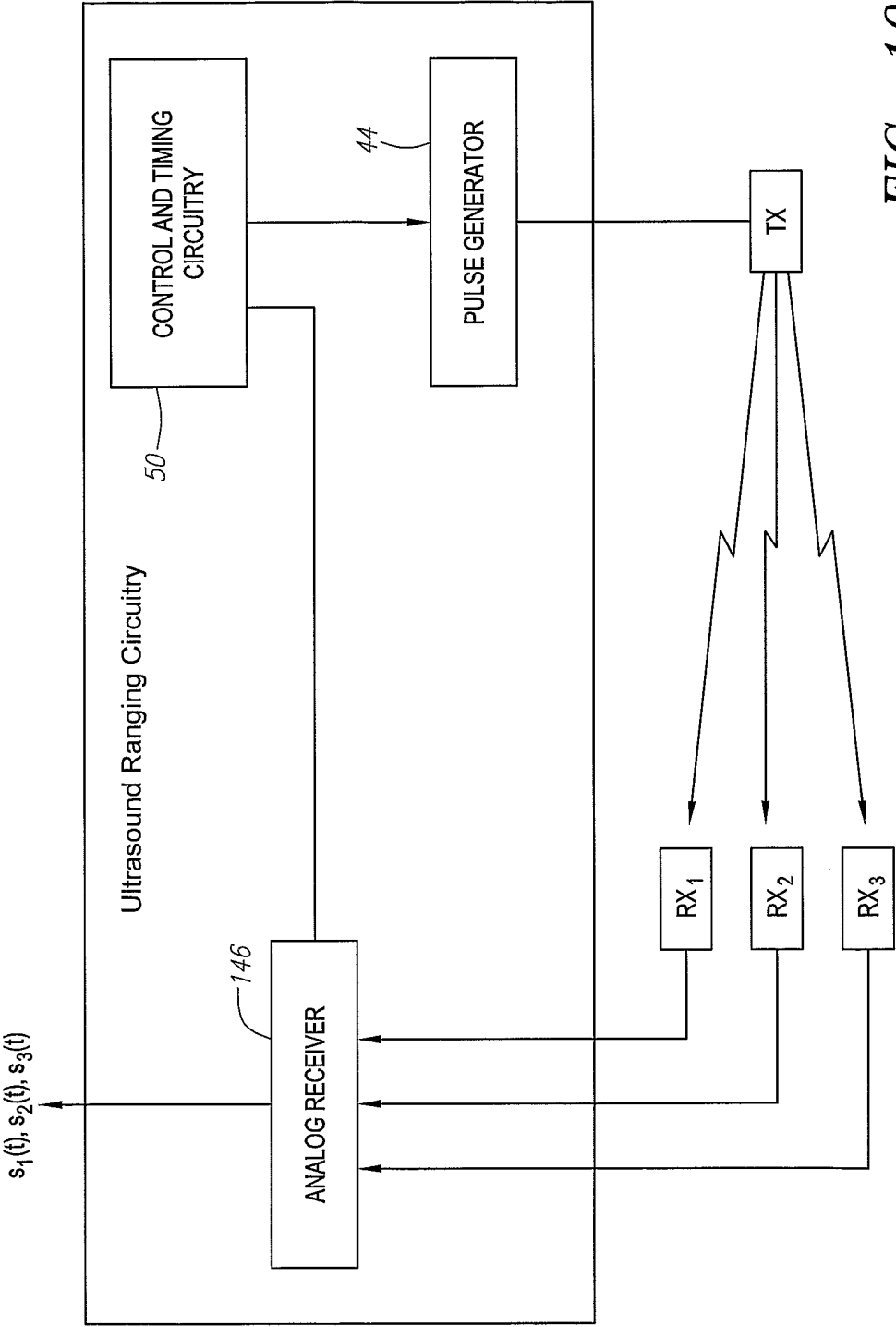
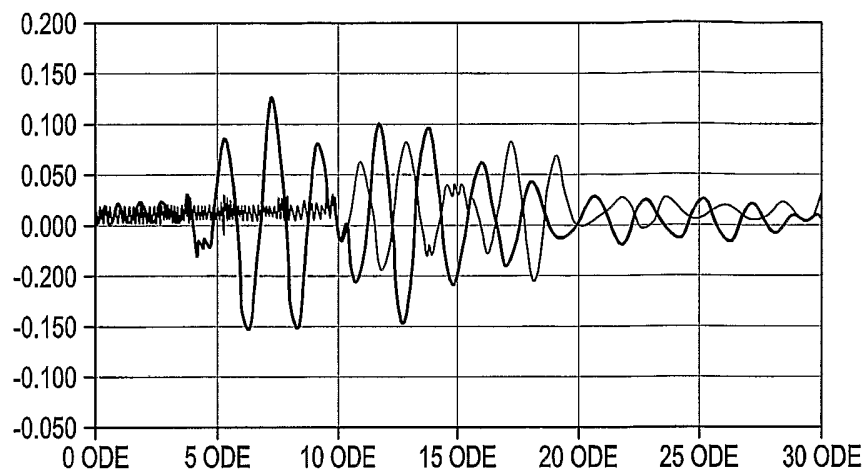
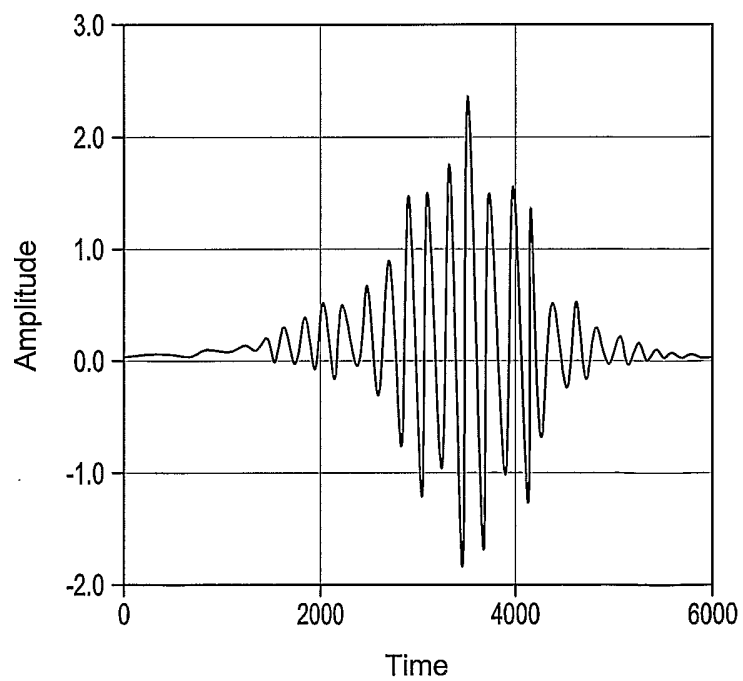
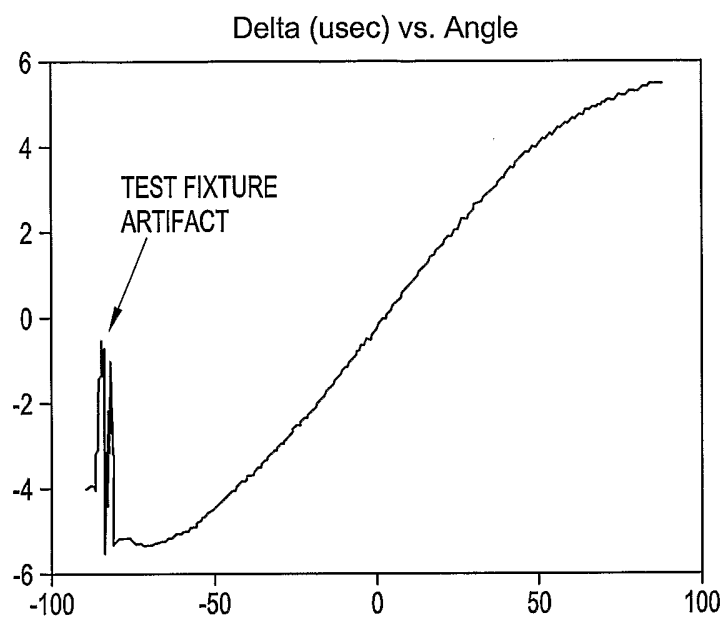
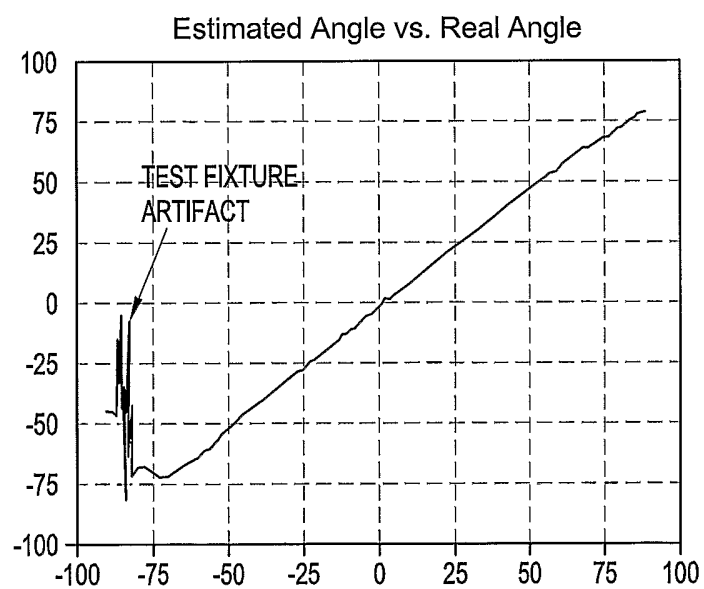


FIG. 10

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*FIG. 11**FIG. 12*

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*FIG. 13**FIG. 14*

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US2004/031476

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 G01S5/22 A61B18/14 A61N1/05

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 G01S A61B A61N

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)

EPO-Internal, WPI Data, PAJ, INSPEC

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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A	page 8 - page 9 page 48, line 21 - page 53, line 15 page 58, line 1 - line 28; figures 15-21	24-29
X	US 6 298 261 B1 (REX JAMES ALEXANDER) 2 October 2001 (2001-10-02) column 2, line 20 - column 6, line 29; figures	24-29
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A		
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☒ Further documents are listed in the continuation of box C.

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Date of the actual completion of the international search

21 January 2005

Date of mailing of the international search report

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Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

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Devine, J

INTERNATIONAL SEARCH REPORT

International Application No
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