WORLD INTELLECTUAL PROPERTY ORGANIZATION International Bureau



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6: G10K 11/24, A61B 8/12 **A1**

(11) International Publication Number:

WO 97/34288

(43) International Publication Date: 18 September 1997 (18.09.97)

(21) International Application Number:

PCT/US97/03225

(22) International Filing Date:

28 February 1997 (28.02,97)

(30) Priority Data:

08/614,572

13 March 1996 (13.03.96)

US

(71) Applicant: HEWLETT-PACKARD COMPANY [US/US]; 3000 Hanover Street, Palo Alto, CA 94304 (US).

(72) Inventors: DIAS, J., Fleming; 251 Iris Way, Palo Alto, CA 94303 (US). MELTON, Hewlett, E., Jr.; 1138 Royal Ann Drive, Sunnyvale, CA 94087 (US).

(74) Agent: SCHUYLER, Marc, P.; Hewlett-Packard Company, Legal Dept., 20BN, 3000 Hanover Street, Palo Alto, CA 94303 (US).

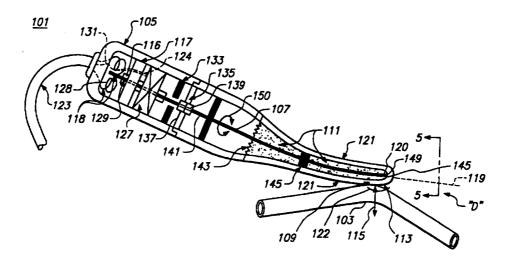
(81) Designated States: CA, JP, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published

With international search report.

Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: DIRECT CONTACT SCANNER AND RELATED METHOD



(57) Abstract

A direct contact scanner (101) uses a fiber acoustic waveguide (107, 141) to convey ultrasound from an ultrasound transducer (117) to a direct contact area (122). The waveguide extends from a main body (105) of the scanner into an oblong nose (109), and terminates in a deflector (149). To minimize thickness of the nose, the waveguide and deflector are rotated about an ultrasound transmission axis (119) of the waveguide, enabling the scanner to be used in a variety of situations where quarters are cramped. A coupling fluid (111) conveys ultrasound between the deflector (149) and a radome (113), which directly contacts the object (103) to be scanned. Using the waveguide, an ultrasound transducer and supporting electronics (118) may be distanced from the direct contact area (122) and separated from the fluid (111), thereby insulating the fluid from possible electronic leakage currents and heat.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

	Armenia	GB	United Kingdom	MW	Malawi
AM		GE	Georgia	MX	Mexico
AT	Austria	GN	Guinea	NE	Niger
ΑU	Australia	GR	Greece	NL	Netherlands
BB	Barbados	HU		NO	Norway
BE	Belgium		Hungary	NZ	New Zealand
BF	Burkina Faso	IE	Ireland	PL	Poland
BG	Bulgaria	IT	Italy	PT	Portugal
BJ	Benin	JP	Japan	RO	Romania
BR	Brazil	KE	Kenya	RU	Russian Federation
BY	Belarus	KG	Kyrgystan	SD	Sudan
CA	Canada	KP	Democratic People's Republic	SE.	Sweden
CF	Central African Republic		of Korea	_	
CG	Congo	KR	Republic of Korea	SG	Singapore
CH	Switzerland	KZ	Kazakhstan	SI	Slovenia
CI	Côte d'Ivoire	LI	Liechtenstein	SK	Slovakia
CM	Cameroon	LK	Sri Lanka	SN	Senegal
CN	China	LR	Liberia	SZ	Swaziland
	Czechoslovakia	LT	Lithuania	TD	Chad
CS	Czech Republic	LU	Luxembourg	TG	Togo
CZ		LV	Latvia	TJ	Tajikistan
DE	Germany	MC	Monaco	TT	Trinidad and Tobago
DK	Denmark	MD	Republic of Moldova	UA	Ukraine
EE	Estonia	MG	Madagascar	UG	Uganda
ES	Spain	ML	Mali	US	United States of America
FI	Finland			UZ	Uzbekistan
FR	France	MN	Mongolia	VN	Viet Nam
GA	Gabon	MR	Mauritania	*	

DIRECT CONTACT SCANNER AND RELATED METHOD

The present invention relates to a direct contact scanner. More particularly, it provides a novel hand-held probe that can be used in a wide variety of imaging applications, including invasive intraoperative surgical applications.

5

10

15

BACKGROUND

Open heart surgery is sometimes used to clear stenosed artery segments which are in close proximity to the heart. It is not uncommon during this procedure for surgeons to literally feel arterial segments with their fingers to locate hard segments (a process known as "palpation"), and in that way establish and localize a stenotic segment of the artery. While well-trained and experienced surgeons are typically adept at this task, the potential for uncertainty and error exists.

Recently, some hospitals have begun to develop direct contact scanners that use ultrasound to image areas of the body. Scanners of this type are typically used for non-invasive procedures, for example, in obstetrics. In operation, these devices direct ultrasound into the body, with various body tissues producing ultrasound echoes which are detected by the scanner and electronically used to construct an image. These scanners have proven very useful in obtaining images of certain internal body tissues, though their resolution of deep or intricate tissues is limited, and they are not readily applied to invasive situations.

20

A typical scanner 11 is seen in FIG. 1. The scanner includes a main scanner body 13, and a radome 15 that directly contacts an object 17 to be scanned (the human body). The radome 15 also houses a coupling fluid 19 which is used to help transmit ultrasound. As used herein, "radome" is a surface that is transparent to the imaging waves used to scan the object 17, such as an acoustically transparent

5

10

15

20

25

window. The coupling fluid 19 is necessary in the case of ultrasound, because it permits scanning movement of an ultrasound transducer 21, as indicated by reference arrow 23, and because high frequency ultrasound does not transmit well in air.

Within the radome 15 and the coupling fluid 19, the scanner 11 includes a transducer assembly 27, consisting substantially of the transducer 21 (a directional ultrasound transducer operating in the range of 2.5 to 10.0 megahertz) and a pivotal support 29 for the transducer. The pivotal support enables the transducer to be pivoted such that the direction of produced ultrasound sweeps through a sector, as indicated by reference arrow 31, causing ultrasound to image a plane or section of object 17 to be scanned. The transducer 21 has insulated electric leads 32 which are connected to processing circuits (not shown) in the main scanner body 13. These processing circuits control the transducer to both produce ultrasound in discrete bursts, and also to detect ultrasound echoes and responsively generate an image. Typically, the leads 32 supply an excitation signal to the transducer which is on the order of 100 volts. An angle encoder 33 in the main scanner body generates a sync signal that informs the main processing unit as to the beginning of a new image frame. The transducer is moved by a reciprocating motor 35, located in the main scanner body, which pulls a belt 37 back-and-forth to pivot the transducer through the sector. The belt wraps around a pulley 39 of the transducer and is, in turn, anchored to the main body by a spring 41 and a fixed support 43.

While generally useful for non-invasive applications, such as obstetrics, cardiology and the like, direct contact scanners of the type just described have a number of shortcomings. In particular, these shortcomings make it impractical to use the scanners in invasive surgical procedures, for example, open heart surgery, or in a wide variety of other applications.

First, the transducer and its electrical leads are typically located within the coupling fluid, in order that ultrasound can be directly coupled to the object to be scanned while the transducer is being pivoted. However, this construction generally

requires the use of electric potentials immediately adjacent to the radome, in close proximity to body tissues, which presents a danger of electrical leakage during surgery. This danger is particular acute if the scanner will be used near highly sensitive tissues, for example, the heart or brain.

5

10

15

20

25

Second, the size of the probe required to house the transducer and pivotal mounting in close proximity to the radome makes a direct contact area of the probe excessively large, rendering it difficult to use the probe in hard-to-access areas within the body cavity during surgery. For example, during brain surgery, it might be desirable to use a direct contact scanner through a bore hole in the skull to image a tumor; the typical scanner just described presents a direct contact area which is generally too large to be usable in these situations. This difficulty renders the scanners unusable for many invasive applications, as well as for most non-medical applications where quarters are cramped.

A third, related problem, is that the frequencies of ultrasound producible by the scanner just described are limited; since frequency of ultrasound produced is inversely proportional to transducer thickness (transducer material generally must be about one-half wavelength thick, given the desired frequency's speed of travel in the transducer material), high frequency transducers are relatively thin and more prone to damage where a moving transducer assembly is utilized. Generally, use of a moving transducer assembly requires use of a thick solid backing for high frequency transducers, which unfortunately imposes undesired weighting and high inertia considerations at the direct contact end of the scanner. This arrangement is undesirable, and it in practice limits the range of ultrasound frequencies that are produced by the scanner. In turn, limitation in the range of ultrasound frequencies places a limitation on the resolution that can be achieved with the scanner. To be able to properly diagnose the nature of a tumor or an occlusion in a blood vessel such as a coronary artery, it would be extremely useful to be able to characterize these tissues or lesions in extreme detail, which is generally achievable using ultrasound frequencies in the range of thirty- to fifty- megahertz, and perhaps higher.

There is a dire need for a method or device for safely imaging body tissues, particularly during surgery, which does not mandate reliance upon a surgeon and which does not expose a patient to leakage currents. Such a method or device should require only a small contact area such that it is usable in remote areas, for example, in body tissue areas such as the brain that are not easily accessed. Preferably, such a method or device should offer a precise, high-resolution imaging procedure, to enable quick diagnosis of maladies with a high degree of accuracy. Also, it would serve the physician well if the operating frequency of a scanner could be changed while the scanning is in progress. Finally, because of the requirement of disposableness due to fear of contagion, the device or method should use inexpensive, easily assembled parts which may replaced as necessary, which would also enable the use of interchangeable parts to adapt the scanner to different applications. The present invention solves these needs and provides further related advantages.

15 <u>SUMMARY</u>

5

10

20

25

The present invention provides a novel hand-held scanner that is safer, and can be used in invasive surgical applications. As a result, it provides an imaging tool that assists a surgeon in real time during a surgical process, and that does not require a surgeon to physically feel by hand internal body tissues. Still further, the present invention provides a direct contact scanner with reduced risk of leakage currents and reduced risk of exposure to contagion. The present invention places imaging equipment away from a direct contact area, and as a result, the scanner of the present invention utilizes a relatively small direct contact area. This facilitates use of the scanner in remote areas, thereby providing a means of safely imaging tumors and other sensitive body tissues during surgery. In addition, the provision of a narrow direct contact area enables the scanner to be adapted to a wide variety of applications outside the field of medicine.

5

10

15

20

25

30

In accordance with the principles of the present invention, the novel scanner includes a transducer that transduces electronic signals and imaging waves; this transducer can be electromagnetic, sonic, or any type of transducer that generates imaging waves in response to an electronic signal, or that detects such waves. The scanner also has a scanner surface that directly contacts an object to be scanned. This scanner surface, or "radome," is made of a material chosen to be transparent to the imaging waves, and it is positioned between the transducer and the object. In between the scanner surface and the transducer is a coupling media having good transmission characteristics for the imaging waves (whether ultrasound, light, microwave, etc.). The coupling media can be air, water, or any other substance with good transmission characteristics for the imaging waves chosen, such that the waves are not attenuated substantially in between the transducer and an imaging target. Finally, the scanner includes a waveguide for the imaging waves which couples the transducer and the coupling media. The waveguide can be of a practical length or shape necessary to assist conveyance of the imaging waves to the radome. In this manner, the transducer can be positioned away from the radome, in a position that minimizes the danger of leakage currents, and permits a small direct contact area with the object, e.g., since the transducer need not be mounted immediately adjacent to the radome, within a coupling media. The waveguide also permits the coupling media to be distanced from heat-generating and electronic elements, such as electronics in the device, thereby providing heightened accuracy in some imaging applications.

In more particular aspects of the invention, the waveguide includes a deflector (which presents either a mirror or refractor to redirect the imaging waves) mounted by the waveguide. The waveguide preferably is a cladded fiber having a cladding layer that is much greater in diameter than a core layer, for example, four times as thick. The waveguide can be rotated about its longitudinal axis, such that the deflector is rotated at a distal end of the scanner, without requiring a large direct contact area with the imaging target. The deflector is positioned at an angle to the waveguide such that, as the waveguide is oscillated around its longitudinal axis, the

5

10

15

imaging waves are distributed radially in a sector through the radome and into the object, with reflections returning along the same path. The waveguide (e.g., a cladded fiber of fused quartz) can be made to be relatively long (as limited by practical loss), and thus, electrical and mechanical parts may be positioned well away from the radome and the direct contact area.

Another form of the invention provides an improvement to ultrasound scanners. This improvement includes the use of a radome to directly contact the object; an ultrasound transmission fluid inside the scanner in direct contact with the radome, the fluid permitting transmission of the ultrasound produced by the transducer toward the radome without substantial attenuation; and, an ultrasound waveguide that couples the transducer to the transmission fluid. As mentioned, this enables a small direct contact area and heightened accuracy in scanning. Moreover, since the ultrasound transducer may be positioned away from the direct contact area, in a hand-held portion of the scanner, a relatively thin (high frequency) transducer may used with a solid backing, as the backing's position in the hand-held portion of the scanner does not undesirably affect weighting or impose difficult inertia considerations. In turn, this construction permits use of relatively high ultrasound frequencies, such as frequencies greater than thirty or fifty megahertz.

Finally, a third form of the invention provides a method of imaging an object using a direct contact scanner, by conveying imaging waves between the coupling media and the imaging mechanism, while isolating the imaging mechanism from direct contact with the coupling media. In invasive surgical procedures, such as open heart surgery, hard-to-access or sensitive tissues may be scanned without exposing those tissues to a surgeon's subjective judgment, and without significant risk of exposure to electric potentials.

The invention may be better understood by referring to the following detailed description, which should be read in conjunction with the accompanying drawings. The detailed description of a particular preferred embodiment, set out

below to enable one to build and use one particular implementation of the invention, is not intended to limit the enumerated claims, but to serve as a particular example thereof.

BRIEF DESCRIPTION OF THE DRAWINGS

- FIG. 1 is a schematic view of a prior art ultrasound scanner, showing a main body and a radome that houses a coupling fluid and a pivotally-mounted transducer.
 - FIG. 2 is a sideways cross-sectional view of a scanner which embodies the principles of the present invention, used to image an artery.
- FIG. 3 is a close-up of a distal end of the scanner of FIG. 2, indicated by the reference arrow "D" of FIG. 2.
 - FIG. 4 is a cross-section of a cladded acoustic fiber used in the scanner of FIGS. 2 and 3, taken across line 4-4 of FIG. 3.
- FIG. 5 is an end view of the scanner of FIG. 2, taken along line 5-5 of FIG. 2.

DETAILED DESCRIPTION

The invention summarized above and defined by the enumerated claims may be better understood by referring to the following detailed description, which should be read in conjunction with the accompanying drawings. This detailed description of a particular preferred embodiment, set out below to enable one to build and use one particular implementation of the invention, is not intended to limit the

20

5

10

15

20

25

enumerated claims, but to serve as a particular example thereof. The particular example set out below is the preferred specific implementation of a direct contact scanner, namely, a hand-held diagnostic probe that uses a fiber acoustic waveguide to provide enhanced ultrasound transmission and a safer probe. The invention, however, may also be applied to other types of systems as well.

As seen in FIG. 2, the preferred embodiment is a hand-held probe 101 that scans an object (namely, a stenosed blood vessel during an open heart surgery) 103 by direct contact. All of the electronics 118 of the probe are housed within a cylindrical main body 105 of the probe, and a cladded fiber acoustic waveguide 107 is used to transmit ultrasound between the cylindrical main body 105 and a detachable, oblong nose 109. As with conventional probes, the present probe 101 uses a moving body, a coupling media 111 and a radome 113 to scan the object 103 by direct contact, and also to provide a direct return of reflected imaging waves. Unlike conventional probes, however, the present probe 101 utilizes oscillatory, rotational motion of an ultrasound transducer 117 about a direction of ultrasound transmission. A section 115 of the object 103 which is to be scanned is drawn as a line in FIG. 2, indicating that the direction of scanning is into and out of FIG. 2, in a sense perpendicular to FIG. 2.

The present probe 101 uses ultrasound as the imaging waves and, thus, employs the ultrasonic transducer 117 to generate ultrasound and to detect reflected ultrasound returning from the object 103. In a conventional manner, the probe electronics 118 generates ultrasound for a relatively small period of time, and most of the time controls the transducer 117 to passively detect reflected ultrasound. Preferably, the transducer 117 generates a single ultrasound wave and then, is used to detect reflected ultrasound for period of time sufficiently large to detect any expected reflections before generation of another ultrasound wave in a slightly different direction.

In contradistinction to conventional wisdom, the transducer 117 of the preferred embodiment is mounted within the cylindrical main body 105, well away from the coupling media 111 (a coupling fluid) and the radome 113. In this manner, the coupling media 111 may be insulated from both electric current leakage and heat generation, which can affect accurate ultrasound measurement. Further, the cladded waveguide 107 can be made as long as practical (in terms of minimizing ultrasonic loss), and thus, the cylindrical main body 105 can be very large as compared to the direct contact area 122 of the probe. In this manner, the transducer 117 and any associated backing material may be made relatively large and bulky without imposing undesired weighting or inertia considerations to the direct contact area 122 of the probe.

5

10

15

20

25

30

In this regard, a very narrow direct contact area 122 is achieved by the preferred probe by reciprocally rotating the fiber acoustic waveguide 107 around a longitudinal axis 119, which is also a transmission axis for ultrasound. That is to say, unlike other probe designs which utilize a pivoting transducer assembly, the preferred probe 101 performs scanning motion using a sweep mechanism (including probe electronics 118 and a reciprocating motor 127) to rotate the fiber acoustic waveguide 107 about the longitudinal axis 119. The fiber acoustic waveguide 107 directly contacts the transducer 117 at a first end 116 and conveys ultrasound between the transducer and a second end 120 of the waveguide, which is adjacent to the radome 113, and which mounts a deflector 149. It is the reciprocal rotation of the deflector 149 about the longitudinal axis 119 that causes imaging waves to be distributed in a scanning motion. Consequently, the oblong nose 109 does not require substantial thickness (as indicated by reference arrows 121), and may be made practically as narrow as desired for the purposes of accessing hard-to-reach locations. Since oscillatory, scanning motion of the cladded waveguide 107 and the transducer 117 occurs as "to-and-fro" rotational motion about the longitudinal axis 119, inertia considerations are also reduced. Finally, since the waveguide 107 and transducer 117 are not continually rotated in one direction, but rather, are oscillated "to-and-fro" in opposite rotational directions, the transducer 117 and probe electronics 118 do not

PCT/US97/03225 WO 97/34288

require a commutator arrangement for electrical connection; rather, the transducer is coupled to the probe electronics by a flexible circuit based on an insulating material.

Since the transducer 117 is mounted within the cylindrical main body 105, the sizing of the body 105 is not critical, and a high frequency transducer may be used with appropriate solid backing to prevent damage to the transducer during its rotation. This construction advantageously permits the production of nearly any desired frequency of ultrasound; optimal production of ultrasound by each transducer having thickness "t" is described by the relation

5

10

15

20

$$f = \frac{v_t}{2t},\tag{1}$$

Ultrasound produced by the probe 101 may be electronically varied within a small range for a given transducer, and multiple, alternate transducers may be included for switching between a wider range of ultrasound frequencies. In the preferred probe

where v_t is the velocity of the ultrasound in the transducer material (PZT).

101, however, the ultrasonic transducer 117 may be selected to produce ultrasound having very high frequencies, generally at about 50-100 megahertz, and multiple transducers may be cascaded at the first end 116 of the waveguide to permit switching between different ultrasound frequencies. Appropriate high frequency transducers for use in the present application are disclosed in U.S. Patent No.

5,291,090, which is hereby incorporated by reference.

With reference to FIG. 2, the construction of the hand-held probe 101 will be described in greater detail. An electronic cable 123 provides transducer electronics 118 with (1) a pulsed ultrasound input signal, which directs production of ultrasound by the transducer 117; (2) a power supply signal 124, for operating the reciprocating motor 127 that rotates the waveguide about its longitudinal axis 119; and (3) a return signal, which carries image information used to generate a visual display of the section 115. The latter signal is configured by the probe electronics to 25

10

5

10

15

20

25

include both a frame sync signal 128 which is generated by an angle encoder 129 of the sweep mechanism, as well as an image output signal 131 which is output by the transducer 117 at times when the transducer 117 is used for ultrasound detection.

The cylindrical main body 103 is made of a hard plastic exterior, and includes a mounting 133 which, in addition to the motor 127, constrains the fiber acoustic waveguide to reciprocally rotate about the longitudinal axis 119. As seen in FIG. 4, the fiber acoustic waveguide 107 is a circular symmetric cladded fiber 138 having a fused quartz 3% germanium doped core layer 125 of diameter "a" (which transmits the ultrasound), and a relatively thick fused quartz cladding layer 126 of diameter "b." A cladded fiber is used to substantially eliminate loss through an outer periphery of the core layer 125, except at the second end 120 of the fiber, where ultrasound is deflected away from the longitudinal axis 119. Importantly, the core layer 125 is expected to be between 250- and 500- microns in thickness, whereas the cladding layer 126 should be made as thick as practical, such that the overall diameter of the fiber "b" is at least four times as great as the diameter "a" of the core. Preferably, the fiber 138 is selected such that the diameter "b" is at least five times as great as the diameter "a" of the core. Notably, although fused quartz is the presently prefered fiber material, other suitable materials can be used, such as a metal or sapphire core. In fact, a suitable sapphire fiber core having a suitable cladding and a medical grade polyester cladding should be obtainable from Saphikon Inc., of Milford, New Hampshire.

Returning again to FIG. 2, the fiber acoustic waveguide 107 extends from the main cylindrical body 105 to an interface 135, where the oblong nose 109 screws on to the main cylindrical body. At this interface 135, the waveguide 107 terminates in a coupling 137, which mates with a coupling 139 of the oblong nose 109. In this manner, various configurations of the main cylindrical body 105 and the oblong nose 109 may be made interchangeable, enabling a variety of different fittings to be used in multiple applications.

5

10

15

20

25

The oblong nose 109 includes a continuation 141 of the fiber acoustic waveguide 107, which conveys ultrasound to a distal end "D" of the probe. The continuation 141 receives ultrasound from the transducer 117 via the couplings 137 and 139, and extends through a gasket 143 into the coupling media 111. A series of supports 145 retains the waveguide in the approximate center of the oblong nose, and the gasket 143 prevents leakage of the coupling media 111 (i.e., coupling fluid) from the distal end "D" of the probe. The coupling fluid permits the fiber acoustic waveguide 107 to be reciprocally rotated (i.e., oscillated, as indicated by arrows 150), yet minimizes the effect of the rotation upon ultrasound propagation through the coupling media 111 and the radome 113. The oblong nose 109 is seen in FIG. 2 to be slightly curved, and the waveguide may be made flexible to accommodate such bending as appropriate for the particular application.

FIG. 3 shows a close-up of the distal end "D" of the probe and of the second end 120 of the fiber acoustic waveguide 107. As seen in FIG. 3, the second end 120 is angled to form the deflector 149, to redirect ultrasound between the section 115 of the object 103 and the waveguide's longitudinal axis 119. The term "deflector" indicates that ultrasound is redirected in the physical sense, meaning that it encompasses refraction of ultrasound, which is actually the physical condition occurring at the second end 120 of the waveguide 107. Not only does the deflector 149 divert ultrasound between the waveguide's longitudinal (transmission) axis and the section 115, but in combination with the reciprocal motion of the fiber acoustic waveguide 107, the reflector is effective to distribute ultrasound in scanning motion, much like the raster of a television set, to facilitate generation of a video or similar format of visual display. A solid material may also be used as a lens 122, to converge or diverge ultrasound traveling between the radome 113 and the deflector 149. In this regard, the deflector 149 may also be made parabolic concave or convex to also converge or diverge ultrasound, the defelctor is seen to be substantially planar, as seen in FIG. 3.

5

10

15

20

25

The scanning motion is seen to sweep a sector 151 in FIG. 5, which shows a cross-section of the probe 101 of FIG. 2, taken across lines 5-5 of FIG. 2. In particular, FIG. 5 shows the cylindrical main body 103 of the probe, as well as the oblong nose 109 and the radome 113. As indicated by FIG. 5, oscillatory motion of the fiber acoustic waveguide 107 (and the deflector 149) causes imaging waves and reflected imaging waves to sweep a sector within the object 103, as indicated by the reference numeral 116. Preferably, the angular width of the sector is made electronically variable via a control knob 153, which modifies the power supply signal 124 (FIG. 2) for increasing or decreasing the magnitude of reciprocal rotation provided by the motor 127. In this manner, the resolution of specific features within the generated image of the section 115 may be enhanced by increasing the signal-to-noise ratio by focussing the sector scan to only image a region of interest.

What has been described is a novel hand-held probe 101 that is useful in a wide range of applications, particularly in invasive medical procedures, such as open heart surgery. Use of an oblong nose, such as the nose 109 seen in the accompanying drawings, facilitates access to remote tissue areas, for example, for use during brain surgery as previously alluded. In addition, the interchangeable nature of the main cylindrical body 105 and the oblong nose 109 facilitates use of replaceable parts, thus minimizing possibility of contagion. Finally, since the main cylindrical body 105 is mounted away from a direct contact area of the probe, different or multiple transducers may be used, thereby enabling production of a wide range of ultrasonic frequencies (when ultrasound is used for the imaging waves). Alternatively, multiple transducers may be used in a single probe, such that ultrasound frequency may be more readily varied during a procedure. As can be seen from the above description, the preferred probe provides a safer scanner that may be used in a wide variety of applications, particularly in intraoperative procedures.

Having thus described an exemplary embodiment of the invention, it will be apparent that further alterations, modifications, and improvements will also occur to those skilled in the art. Further, it will be apparent that the present invention is not

limited to the specific form of an ultrasound device, as described above, nor just to the field of surgery or medical procedures. Rather, the preferred probe, and the invention in general, may be applied to a wide variety of applications. Various alterations, modifications, and improvements, though not expressly described or mentioned above, are nonetheless intended and implied to be within the spirit and scope of the invention. Accordingly, the foregoing discussion is intended to be illustrative only; the invention is limited and defined only by the various following claims and equivalents thereto.

5

CLAIMS

1. In an ultrasound scanner that produces ultrasound and directs it into an object, and that receives ultrasound reflections from the object for imaging a section of the object, the improvement comprising:

5

10

15

a radome (113) of the ultrasound scanner, the radome (113) directly contacting the object (103);

a transducer (117) that both produces ultrasound and receives ultrasound reflections, producing an electronic output signal in response to the latter;

a sweep mechanism (118,127) of the scanner that causes the ultrasound to sweep the section;

an ultrasound transmission fluid (111) inside the scanner in direct contact with the radome (113), the fluid permitting transmission of the ultrasound produced by the transducer (117) toward the radome (113); and

an ultrasound waveguide (107,141) that couples the transducer (117) to the transmission fluid (111);

wherein the transducer (117) is isolated from direct contact with the transmission fluid (111), and ultrasound is conveyed between the transducer (117) and the fluid (111) via the waveguide (107,141).

2. An improvement according to claim 1, the improvement further comprising:

a deflector (149) of the waveguide that redirects ultrasound between a sector (116) defined by sweep of the section (115) and a transmission axis (119) of the waveguide;

wherein

5

the entire waveguide (107,141) and the deflector (141) are rotationally moved about the transmission axis by the sweep mechanism (118,127), and

the sweep mechanism (118,127) and the transducer (117) are both insulated from the transmission fluid (111).

- 3. An improvement according to claim 1, wherein the waveguide is a cladded fiber acoustic waveguide having a core portion (125) and a cladding portion (126).
- 4. An improvement according to claim 1, further comprising an ultrasound transducer (117) that produces ultrasound at frequencies greater than thirty megahertz.
- 5. An improvement according to claim 1, further comprising a sector control mechanism (153) that selectively varies angular width of a sector (116) being imaged within the section.
- 6. A method of imaging an object (103) using a direct contact scanner, the scanner including a imaging mechanism (117), a radome (113) adapted to directly contact the object and permit passage of imaging waves between the scanner and the object, a waveguide (107,141) and a coupling media (111), said method comprising:
- placing the radome (113) in direct contact with the object (103);

transmitting the imaging waves between the object (103) and the coupling media (111) through the radome (113);

using the waveguide (107,141) to convey imaging waves from the coupling media (111) to the imaging mechanism (117) while isolating the imaging mechanism (117) from direct contact with the coupling media (111); and

using the imaging mechanism (111) to generate an electronic image signal (131) from the imaging waves.

7. A method according to claim 6, wherein the scanner further includes a sweep mechanism (127) that is also isolated from the coupling media, and wherein the waveguide (107,141) has a transmission axis (119), extends from a main scanner body (105) into the coupling media (111) and includes a deflector (149) within the coupling media (111), said method further comprising:

5

10

using the deflector (149) to deflect imaging waves from the object (103) into the waveguide (107,141) along the transmission axis (119);

using the sweep mechanism (127) to rotationally move the waveguide and to thereby rotationally move the deflector (149), such that imaging waves directed into the waveguide represent a sweep sector (116); and

isolating electrical signals associated with the sweep mechanism (127) and the imaging mechanism (117) from the coupling media (111).

8. A method according to claim 7, wherein the scanner further includes an angle encoder (129) and wherein using the sweep mechanism to rotationally move the waveguide includes using the angle encoder (129) to generate a synchronization signal (128) for the electronic image signal (131).

9. A method according to claim 7, wherein the scanner further includes a sector control mechanism (153) and wherein using the sweep mechanism to rotationally move the waveguide includes selectively using the sector control mechanism (153) to vary angular width of a sector (116) of the object (103) being imaged.

- 10. A method according to claim 6, wherein the imaging mechanism is an ultrasound transducer (117) and the scanner includes control electronics (118) coupled to the transducer, said method further comprising:
- using the control electronics (118) to cause production of ultrasound by
 the transducer (117) in discrete bursts; and

using the control electronics (118) to control the transducer (117) to detect reflected imaging waves which are returning from the object (103) at times when ultrasound is not being produced by the transducer, and to responsively produce the electronic image signal (131).

11. A scanner that scans an object, comprising:

5

5

10

a transducer (117) that transduces electronic signals and imaging waves;

a scanner surface (113) that directly contacts the object (103), the scanner surface transparent to the imaging waves and positioned between the transducer (117) and the object (103);

a coupling media (111) having good transmission characteristics for the imaging waves, operatively between the transducer (117) and the scanner surface (113); and

a waveguide (107,141) for the imaging waves, the waveguide coupling the transducer (117) and the coupling media (111);

wherein the transducer (117) is isolated from direct contact with the coupling media (111) and imaging waves are coupled therebetween via the waveguide (107,141).

- 12. A scanner according to claim 11, further comprising a sector control mechanism (153) that selectively varies angular width of a sector (116) being imaged.
- 13. A scanner according to claim 11, further comprising a sweep mechanism (127) that causes the transducer (117) to sample imaging waves in a manner representing a sweep of at least part of the object (103).
- 14. A scanner according to claim 13, wherein the sweep mechanism (127) mechanically moves the waveguide (107,141).
 - 15. A scanner according to claim 14, wherein:

5

10

the transducer (117) produces outgoing imaging waves in response to an electronic input signal, the outgoing imaging waves being directed by the waveguide (107,141) toward the coupling media (111);

the waveguide (107,141) includes a transmission axis (119) that extends between two longitudinal ends (116,120) of the waveguide, and a deflector (149) mounted along the transmission axis between the two ends;

a first one (116) of the two ends is proximate to the transducer (117) and receives the imaging waves from the transducer;

a second one (120) of the two ends terminates the waveguide (107,141) in the coupling media (111) and passes the imaging waves into the imaging media (111), toward the scanner surface (113) and the object (103); and

PCT/US97/03225 WO 97/34288

the sweep mechanism (127) at least partly rotates the waveguide about 15 the transmission axis (119), the deflector (149) thereby effective to cause imaging waves to be redirected at the second one (120) of the ends to sweep, as the waveguide (107,141) rotates, through the scanner surface (113) to scan at least part of the object (103).

> A scanner according to claim 15, wherein: 16.

> > said scanner further comprises

5

10

5

electronics (118) that control the transducer (117) to produce outgoing imaging waves in discrete bursts and to detect reflected incoming imaging waves returning from the object (103), and

the transducer (117) produces an output signal (131) in response to detection of reflected incoming imaging waves; and

the sweep mechanism (127) includes an angle encoder (129) that

produces sync information (128) corresponding to the output signal (131).

A scanner according to claim 11, wherein: 17.

the transducer is an ultrasound transducer (117);

the coupling media (111) is selected to be a liquid that transmits ultrasound;

the waveguide (107,141) is a solid material; and

the scanner surface (113) is a radome that is transparent to ultrasound and retains the liquid (111) within the scanner.

18. A scanner according to claim 17, wherein said scanner further comprises:

electronics (118) that control the transducer (117) to produce outgoing imaging waves in discrete bursts, and also to detect reflected incoming imaging waves returning from the object (103) when the transducer is not controlled to produce outgoing imaging waves; and

an image output signal (131) produced in response to the reflected incoming imaging waves.

19. A scanner according to claim 17, wherein:

the waveguide (107,141) has a transmission axis (119) that extends between two longitudinal ends (116,120) of the waveguide, including a first end (116) in contact with the transducer (117) and receiving outgoing ultrasound therefrom, and a second end (120) in contact with the coupling media (111);

the waveguide (107,141) further includes a deflector (149) proximate to the second end (120), the deflector selected from at least one of a reflective surface and a refractive surface and positioned along the transmission axis (119) to redirect outgoing ultrasound away from the transmission axis (119);

the scanner further comprises a sweep mechanism (127) that rotates the waveguide around the transmission axis (119), thereby causing outgoing ultrasound to sweep at least a sector (116) in the coupling media (111) and the object (103), through the scanner surface (113); and

reflected incoming ultrasound returning from the object are redirected onto the transmission axis (119) toward the transducer (117).

5

5

10

15

20. A scanner according to claim 11, wherein the waveguide (107,141) is a cladded fiber acoustic waveguide.

21. A scanner according to claim 20, wherein:

the cladded fiber acoustic waveguide (107,141,138) includes

a core portion (125) having a predetermined diameter ("a"), and

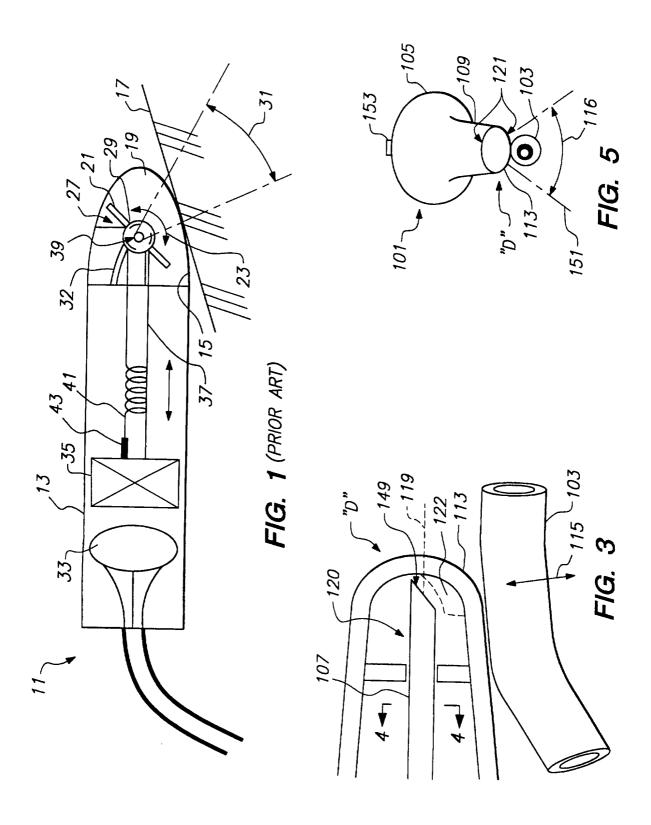
a cladding portion (126) coaxially about the core portion (125);

and

5

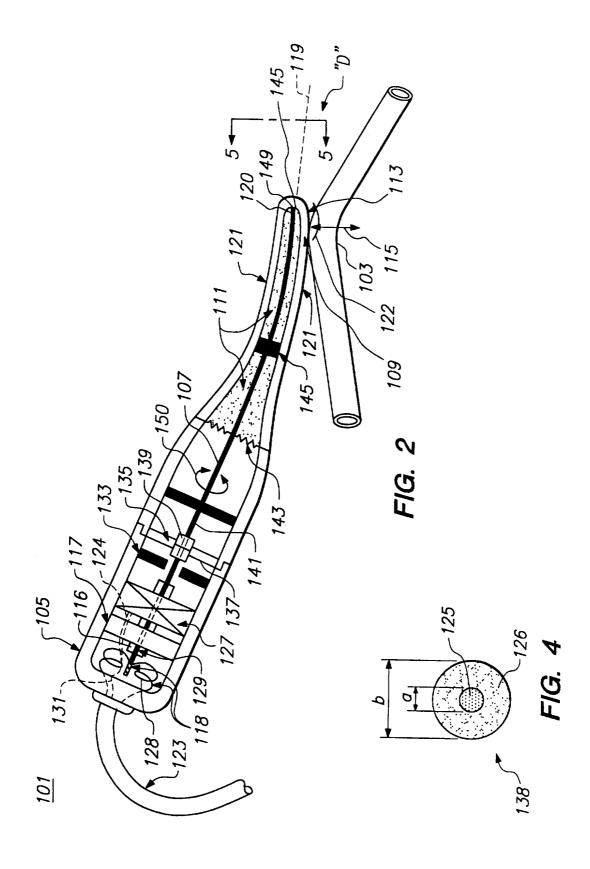
the cladding portion (126) has a thickness such that the cladded fiber acoustic waveguide has a diameter ("b") at least four times the predetermined diameter ("a").

- 22. A scanner according to claim 20, wherein the cladded fiber acoustic waveguide (107,141,138) includes a core portion (125) made of doped fused quartz, and a cladding portion (126) made of fused quartz.
- 23. A scanner according to claim 20, wherein the cladded fiber acoustic waveguide (107,141,138) includes a core portion (125) and a cladding portion (126) which are each made of a silicate material.
- 24. A scanner according to claim 20, wherein the cladded fiber acoustic waveguide (107,141,138) includes a core portion (125) made of a metal material.
- 25. A scanner according to claim 20, wherein the cladded fiber acoustic waveguide (107,141,138) includes a core portion (125) made of a sapphire material.
- 26. A scanner according to claim 11, wherein the transducer (117) produces ultrasound of frequencies greater than about fifty megahertz.



SUBSTITUTE SHEET (RULE 26)

2/2



SUBSTITUTE SHEET (RULE 26)

INTERNATIONAL SEARCH REPORT

Internatic Application No PCT/US 97/03225

		PCT/U	S 97/03225
A. CLASS IPC 6	IFICATION OF SUBJECT MATTER G10K11/24 A61B8/12		
According	to International Patent Classification (IPC) or to both national class	sification and IPC	
	S SEARCHED		
IPC 6	documentation searched (classification system followed by classific G10K A61B	ation symbols)	
Documenta	tion searched other than minimum documentation to the extent tha	t such documents are included in the	fields searched
Electronic o	data base consulted during the international search (name of data b	ase and, where practical, search term	s used)
		, , =	-
C. DOCUM	MENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the	relevant passages	Relevant to claim No.
Х	EP 0 580 304 A (HEWLETT PACKARD January 1994	CO) 26	1-4,6,7, 10,11, 13-15,
A	see column 1, line 5 - line 23; figure 14		17-20,24 5,8,9, 12,16,26
	see column 5, line 30 - column 8 figures 1-4		12,10,20
	see column 10, line 13 - line 23 5A,5B	; figures	
A	US 5 271 402 A (YEUNG KING-WAH W 21 December 1993 see column 7, line 28 - column 8	•	8,16
A	US 4 590 803 A (HARROLD RONALD T) 27 May	22,25
į	see column 2, line 62 - line 66		
		-/	
χ Furt	er documents are listed in the continuation of box C.	X Patent family members are	listed in annex.
'A' docume conside	egories of cited documents: Int defining the general state of the art which is not little to be of particular relevance document but published on or after the international	"T" later document published after or priority date and not in conf cited to understand the principl invention	flict with the application but e or theory underlying the
filing of L' docume which i	ate nt which may throw doubts on priority claim(s) or s cited to establish the publication date of another or other special reason (as specified)	 "X" document of particular relevance cannot be considered novel or involve an inventive step when "Y" document of particular relevance 	cannot be considered to the document is taken alone te: the claimed invention
O" docume other n	nt referring to an oral disclosure, use, exhibition or	cannot be considered to involve document is combined with one ments, such combination being in the art.	e an inventive step when the e or more other such docu- obvious to a person skilled
	actual completion of the international search	'&' document member of the same Date of mailing of the internation	
30) June 1997	- 4. 07.	•
Name and m	ailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk	Authorized officer	
	Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Anderson, A	

Form PCT/ISA/218 (second sheet) (July 1992)

1

INTERNATIONAL SEARCH REPORT

Internal Application No
PCT/US 97/03225

.(Continu	ation) DOCUMENTS CONSIDERED TO BE RELEVANT	
egory °		Relevant to claim No.
	US 4 742 318 A (JEN CHENG-KUEI ET AL) 3 May 1988 see claim 8	22,23
4	US 5 291 090 A (DIAS J FLEMING) 1 March 1994 cited in the application	

INTERNATIONAL SEARCH REPORT

Information on patent family members

Internati Application No
PCT/US 97/03225

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 0580304 A	26-01-94	US 5284148 A US 5400788 A US 5488955 A	08-02-94 28-03-95 06-02-96
US 5271402 A	21-12-93	NONE	
US 4590803 A	27-05-86	CA 1236209 A DE 3522771 A FR 2566910 A GB 2160974 A,B JP 7006903 B JP 61018859 A	03-05-88 09-01-86 03-01-86 02-01-86 30-01-95 27-01-86
US 4742318 A	03-05-88	CA 1288701 A	10-09-91
US 5291090 A	01-03-94	EP 0602949 A JP 6209930 A	22-06-94 02-08-94