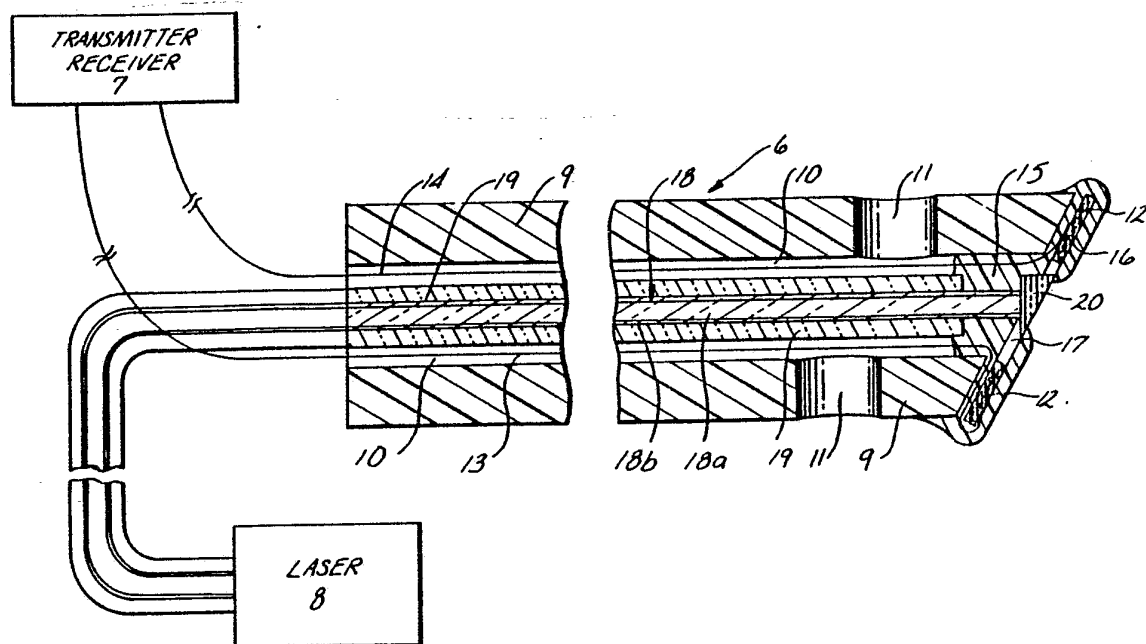




INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ³ : A61B 10/00	A1	(11) International Publication Number: WO 85/ 00510 (43) International Publication Date: 14 February 1985 (14.02.85)
(21) International Application Number: PCT/US84/00474 (22) International Filing Date: 29 March 1984 (29.03.84) (31) Priority Application Number: 518,817 (32) Priority Date: 1 August 1983 (01.08.83) (33) Priority Country: US (71)(72) Applicant and Inventor: WEBSTER, Wilton, W., Jr. [US/US]; 1388 Crest Drive, Altadena, CA 91001 (US). (74) Agent: DILLARD, David, A.; Christie, Parker & Hale, 201 South Lake Avenue, Pasadena, CA 91101 (US). (81) Designated States: AT (European patent), BE (European patent), CH (European patent), DE (European patent), FR (European patent), GB (European patent), JP, LU (European patent), NL (European patent), SE (European patent).		Published <i>With international search report.</i>

(54) Title: CATHETER FOR REMOVING ARTERIOSCLEROTIC PLAQUE



(57) Abstract

An apparatus and method for identifying and removing arteriosclerotic plaque deposits from blood vessels. The apparatus comprises a catheter (6) having an optical fiber (18) for transmitting laser irradiation and an ultrasonic transducer (12) mounted at the tip of the catheter for transmitting and receiving ultrasonic signals. The apparatus further comprises a transmitting unit (7) for generating electrical impulses for activating the ultrasonic transducer, a receiving unit for displaying electrical signals from the ultrasonic transducer and a laser (8). Arteriosclerotic plaque deposits are identified by the ultrasonic echoes which result from transmitted ultrasonic signals and are removed by laser irradiation.

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.

AT	Austria	KR	Republic of Korea
AU	Australia	LI	Liechtenstein
BE	Belgium	LK	Sri Lanka
BG	Bulgaria	LU	Luxembourg
BR	Brazil	MC	Monaco
CF	Central African Republic	MG	Madagascar
CG	Congo	MR	Mauritania
CH	Switzerland	MW	Malawi
CM	Cameroon	NL	Netherlands
DE	Germany, Federal Republic of	NO	Norway
DK	Denmark	RO	Romania
FI	Finland	SD	Sudan
FR	France	SE	Sweden
GA	Gabon	SN	Senegal
GB	United Kingdom	SU	Soviet Union
HU	Hungary	TD	Chad
JP	Japan	TG	Togo
KP	Democratic People's Republic of Korea	US	United States of America

1

5

-1-

10

CATHETER FOR REMOVING ARTERIOSCLEROTIC PLAQUE15 Field of the Invention

This invention relates to catheters and specifically to a catheter for identifying and removing arteriosclerotic plaque deposits in blood vessels.

20 Background of the Invention

Arteriosclerotic plaque deposits which occlude and restrict the blood flow of coronary arteries are a major cause of heart disease. Treatment of such arteriosclerotic plaque has traditionally included open heart surgery or
25 angioplasty.

Presently there is growing interest in the use of laser irradiation to remove arteriosclerotic plaque from occluded blood vessels, particularly coronary arteries. Such laser irradiation is delivered to the occluded
30 vessel by means of a catheter comprising an optical fiber. Laser light is passed through the optical fiber

35



-2-

1 and onto the arteriosclerotic plaque. A laser beam,
thus delivered, has been found to remove arterio-
sclerotic plaque resulting in patency of the blood vessel.

For example, Circulation, Volume 66, Supplement II
5 (October, 1982) at page 368 describes a method wherein
a fiberscope including quartz fiber was inserted via
the left subclavian artery to the aortailiac bifurcation
in dog. The right iliac artery was then successfully
photoirradiated by YAG laser.

10 Circulation, Volume 66, Supplement II (October,
1982) at page 366 describes a method using laser irradiation,
delivered through a silicon fiber to the right
iliac artery of rabbits to remove arteriosclerotic
plaque.

15 The use of laser irradiation to remove arterio-
sclerotic plaque requires means to accurately position
the end of the optical fiber with respect to the plaque
which is to be removed. It also requires means to
determine the thickness and hardness of the arterio-
20 sclerotic plaque deposit so that plaque removal may be
maximized while arterial damage is minimized.

Methods for positioning the end of the optical fiber
include X-ray fluoroscopy and/or viewing through a flexi-
ble fiberoptic scope inserted into the occluded artery.
25 For example, U.S. Patent No. 4,207,874 to Choy describes
a device using X-ray fluoroscopy and viewing through
a fiberoptic scope to locate obstructions in blood
vessels and the like. Laser irradiation is then trans-
mitted through an optical fiber to vaporize the
30 obstruction.

X-ray fluoroscopy methods involve the positioning
of the catheter tip by the injection of a radiopaque
material into the occluded blood vessel and viewing the

35



-3-

1 X-ray shadow images of the artery and the catheter by a
fluoroscope. Such images do not generally give suffi-
2 ent detail of the occluded blood vessel to accurately and
safely position the catheter tip with respect to an
5 arteriosclerotic plaque deposit. Further, X-ray fluoro-
scopy methods also provide little information regarding
thickness and density of the plaque deposits.

Fiberoptic scopes have both illumination and view-
ing capabilities but require blocking of the blood flow
10 through the blood vessel followed by flushing of the
blood vessel with a clear liquid such as saline, until a
clear pathway is achieved. Viewing can then be done
with the eye directly or, for example, with a television
camera and monitoring system.

15 There are several disadvantages associated with the
fiberoptic scope methods, including the fact that view-
ing cannot be done during laser irradiation and that the
blood flow must be stopped during viewing. Further,
viewing by a fiberoptic scope reveals little or no infor-
20 mation with regard to the thickness or density of the
arteriosclerotic plaque deposit. Also, fiberoptic scopes
tend to be very expensive and generally have only a
limited life before costly repairs are required.

25 Summary of the Invention

In accordance with the present invention, there is
provided an apparatus for determining the position and
character of occlusions in blood vessels, such as
arteriosclerotic plaque, and for removing occlusions
30 whose position and character have been determined. The
apparatus comprises a catheter, a transmitting unit, a
receiving unit and a laser.

35



-4-

1 The catheter comprises a catheter tube with an
ultrasonic transducer mounted at the distal tip of the
catheter tube. An optical fiber is disposed within the
catheter tube and extends the length of the catheter
5 tube. The ultrasonic transducer is electrically con-
nected to the transmitting unit and the receiving unit
by a pair of wires which are also disposed in and extend
the length of the catheter tube.

 The catheter is inserted into and positioned within
10 a blood vessel. The ultrasonic transducer is activated
by an electrical impulse generated by the transmitting
unit and delivered through the wires. The ultrasonic
transducer transmits an ultrasonic signal in response
to the electrical impulse. The ultrasonic transducer
15 then receives ultrasonic echoes, i.e., ultrasonic signals
reflected by the tissues surrounding the catheter tip,
and transmits electrical signals to the receiving unit
in response to the received ultrasonic echoes. The
received electrical signals carry information regarding
20 the distance and character of the tissues which reflect
the ultrasonic signals and constitutes a "signature"
of the tissues. The presence of occlusions can be
determined from the signature.

 Occlusions whose position and character have been
25 determined can be removed by laser irradiation which is
directed from the laser through the optical fiber onto
the occlusion.

 In a preferred embodiment of the invention, the
transmitting unit has two modes. The first mode is a
30 pulse-echo mode wherein a short electrical impulse is
generated and delivered to the ultrasonic transducer
which transmits an ultrasonic pulse signal in response.

35



-5-

1 Ultrasonic echoes are then received by the ultrasonic transducer which generates electrical signals which are delivered to the receiving unit. These electrical signals provide a signature of the surrounding tissue.

5 The second mode is a pulsed-doppler mode wherein the transmitting unit generates electrical bursts which are delivered to the ultrasonic transducer which transmits tone bursts in response. Ultrasonic echoes from the tone bursts are received by the ultrasonic transducer
10 which generates electrical signals which are delivered to the receiving unit and are used to determine the blood flow velocity at two selected distances from the catheter tip. The tissue signature and the change in blood flow velocity are used to determine the presence of occlusions.

15 In a particularly preferred embodiment of the invention, the ultrasonic transducer is mounted at an angle from the longitudinal axis of the catheter so that the transmitted ultrasonic signal is generally directed toward the blood vessel wall. The catheter also com-
20 prises coupling optics to direct laser irradiation, transmitted from the distal tip of the optical fiber, in the direction of the transmitted ultrasonic signal.

25

30

35



1 Brief Description of the Drawings

 These and other features and advantages of the
present invention will be better understood by reference
to the following detailed description when considered
5 in conjunction with the accompanying drawings wherein:

 FIG. 1 is a schematic of an apparatus according
to the invention including an enlarged cross-sectional
view of a preferred catheter;

 FIG. 2 is a block diagram of a transmitter-
10 receiver applicable to this invention;

 FIG. 3 is a cross-sectional view of another catheter
according to the invention;

 FIG. 4 is an end view of a catheter having a multi-
element ultrasonic transducer; and

15 FIG. 5 is a cross-sectional view of a catheter
having a second lumen for accommodating a guide wire.

20

25

30

35



1 Detailed Description

 The present invention is particularly applicable to removing arteriosclerotic plaque deposits from blood vessels, especially coronary arteries. With reference to FIG. 1, a preferred apparatus comprises a catheter 6, a transmitter-receiver 7, and a laser 8.

 The catheter 6 comprises an elongated flexible catheter tube 9 constructed out of a suitable biologically non-reactive material, e.g., polyurethane. The catheter tube 9 has a generally circular, transverse cross-section.

 The preferred outer diameter of the catheter tube 9 varies according to the application, i.e., according to the size of the blood vessel within which the catheter is positioned. For example, a catheter having an outer diameter of about 1 millimeter is presently preferred for identifying and removing arteriosclerotic plaque deposits in coronary arteries.

 The lumen of the catheter tube also has a generally circular transverse cross-section. The diameter of the lumen is sufficiently large to enable an optical fiber and a pair of wires to be disposed through the lumen and is preferably sufficiently large to provide a space 10 between the optical fiber and the catheter tube wall. Further, the catheter tube 9 comprises holes 11 at its distal end which extend from the space 10 through the wall of the catheter tube. The space 10 and holes 11 provide a passage for the injection of a radiopaque material through the catheter into the blood vessel which allows the rapid positioning of the distal tip of the catheter in the approximate area of the suspected plaque deposit by X-ray fluoroscopy. The same passage can also be used for the withdrawal of a sample of the blood or fluid in the blood vessel following irradiation of an arteriosclerotic plaque deposit.



-8-

1 An ultrasonic transducer 12 is mounted at the distal
end of the catheter tube 9 and is electrically connected
on opposite sides to a pair of wires 13 and 14, which
extend through the lumen of the catheter tube to the
5 transmitter-receiver 7. Ultrasonic transducers suitable
for use with catheters are known in the art. For
example, see Circulation, Volume 56, No. 1 (July, 1977)
pages 18 to 25; IEEE Transactions on Sonics and Ultra-
sonics, Volume SU-27, No. 6 (November, 1980) pages
10 277 to 286.

 The ultrasonic transducer 12 is generally disc-shaped
and has a substantially flat face 16 and a generally
circular opening 17 through its center. The preferred
outer diameter of the ultrasonic transducer is about the
15 same as the outer diameter of the catheter tube and
likewise varies according to the application in which
the catheter is used. For removing arteriosclerotic
plaque from coronary arteries, a diameter of about 1
millimeter is presently preferred. The diameter of the
20 opening 17 is generally not critical but is sufficiently
large to enable the distal end of an optical fiber 18 to
extend into and through the opening 17.

 The thickness of the ultrasonic transducer is also
not critical. For a disc-shaped ultrasonic transducer
25 having a diameter of about 1 millimeter, a thickness of
about 0.1 to about 0.3 millimeters is suitable.

 The ultrasonic transducer 12 is made of a piezo-
electric material, preferably a piezoelectric ceramic
crystal and generally has a response frequency of from
30 about 10 to about 30 MHz. The presently preferred
piezoelectric material comprises lead zirconate-titanate.

 The ultrasonic transducer 12 is mounted at the dis-
tal end of the catheter tube 9 so that the plane of the



-9-

1 front face of the ultrasonic transducer is at selected
angle to the longitudinal axis of the catheter tube. In
this arrangement, the ultrasonic signals transmitted from
the transducer are directed toward the wall of the blood
5 vessel rather than along the length of the blood vessel.
In other words, the included angle between the plane of
the face of the ultrasonic transducer and the longitudinal
axis of the catheter body is less than 90°.

The ultrasonic transducer 12 may be attached to the
10 distal end of the catheter tube 11 by any suitable means,
such as by epoxy cement 15.

The distal ends of wires 13 and 14 are electrically
connected to opposite sides of the ultrasonic transducer
12, by conventional means such as soldering, ultrasonic
15 bonding, cold welding and the like. Wires 13 and 14 can
be made of any suitable metal, such as copper, stainless
steel, or the like. The wires are preferably clad with
a non-conductive coating, e.g., nylon, to assure that
electrical contact between the wires is prevented.

20 An optical fiber 18 is disposed within the lumen
of the catheter tube 9. The optical fiber has a gener-
ally circular transverse cross-section and comprises a
core 18a made of fused silica or its equivalent sur-
rounded by an optical clad 18b made of a material having
25 a lower refractive index than the core, as is well known
in the art. Surrounding the optical fiber 18 is a protec-
tive buffer 19 which is generally made of a semi-rigid
plastic such as an epoxy resin or the like.

The optical fiber 18 has a diameter sufficiently
30 large to transmit laser irradiation of sufficient strength
to vaporize arteriosclerotic plaque desposits without a
detrimental increase in the temperature of the optical
fiber. The presently preferred diameter is about the
minimum diameter which results in a safe increase in

35



-10-

1 temperature during laser transmission in order to minimize
the overall diameter of the catheter. For removing
arteriosclerotic plaque from coronary arteries, an optical
fiber having a diameter in the range of from about 0.1
5 millimeters to about 0.5 millimeters is preferred.

At the distal end of the optical fiber 18, the pro-
tective sheath is removed or cut back and the distal tip
of the optical fiber 18 is rigidly mounted within the
central opening 17 of the ultrasonic transducer 12.
10 Mounting can be done by any suitable means, such as by
epoxy cement. The diameter of the central opening 17 of
the ultrasonic transducer is sufficiently larger than
the diameter of the optical fiber to allow the distal tip
of the optical fiber to be mounted within the opening 17,
15 and to provide a sufficient gap between the ultrasonic
transducer and the optical fiber to prevent detrimental
heating of the ultrasonic transducer as a result of heat
generated by the optical fiber during laser transmission.

In such an arrangement, wherein the tip of the opti-
20 cal fiber is mounted in the opening of the transducer,
laser irradiation is transmitted from the center of the
ultrasonic transducer. To direct the laser irradiation
in the same general direction as the transmitted ultra-
sonic signal, i.e., toward the wall of the blood vessel,
25 coupling optics are used. A microlens 20 or its equiva-
lent is mounted within the opening 17 in the transducer
adjacent the distal tip of the optical fiber 18 so that
laser irradiation emanating from the tip of the optical
fiber will pass through the microlens 20 which changes
30 the direction of the laser irradiation to about the
center of the transmitted ultrasonic signal. Mounting
of the microlens may be by any suitable means, such as
epoxy cement.

35



-11-

1 The transmitting and receiving units may be of
conventional design. In a preferred embodiment of the
invention, the transmitting unit and receiving unit
are combined in a single transmitter-receiver 7.

5 The transmitter-receiver comprises two modes of
operation and means for switching between the two modes.
The first mode is a pulse-echo mode which activates the
ultrasonic transducer to transmit an ultrasonic pulse
signal and senses the time delay and amplitude content of
10 the ultrasonic echoes resulting from the transmitted
ultrasonic pulse signal for identification of the tissue
character at a selected distance from the catheter tip.

 The second mode is a pulsed-doppler mode which acti-
vates the ultrasonic transducer to transmit a tone burst
15 and senses the phase and frequency of echoes resulting
from the transmitted tone burst for identifying the blood
flow velocity at two selectable distances from the cath-
eter tip. The pulsed-doppler mode is used to determine
the presence of a restriction in the blood vessel and the
20 pulse-echo mode is used to identify the character of the
tissue causing the restriction.

 In the pulse-echo mode, the transmitter-receiver
generates short electrical impulses at selected intervals
which are delivered to the ultrasonic transducer 12
25 through wires 13 and 14. The ultrasonic transducer emits
an ultrasonic signal in response to each electrical
impulse. Ultrasonic echoes, i.e., reflections of the
transmitted ultrasonic signal, are received by the trans-
ducer which then transmits electrical signals, correspond-
30 ing to the received echoes, back to the transmitter-
receiver, again through wires 13 and 14. The time delay
and amplitude content of the ultrasonic echoes are
determined from the received electrical signals and

35



-12-

1 provide a "signature" of the reflecting tissue. Analysis of this signature provides information related to the distance and character, e.g., density, of the reflecting tissue.

5 With reference to FIG. 2, the transmitter-receiver comprises an oscillator 21 which controls the timing of the pulse-echo mode. A synchronous gating logic 22 triggers a pulse generator 23 to produce a single short electrical impulse at selected intervals, e.g., inter-
10 vals in the 50 to 100 KHz range, for activating the ultrasonic transducer. The electrical impulse is short, comprising as little as a single cycle of the oscillator signal.

The short electrical impulse is amplified by a radio
15 frequency power amplifier 24 and is delivered by wires 13 and 14 to the ultrasonic transducer 12. The ultrasonic transducer emits an ultrasonic pulse signal in response to the short electrical impulse. The interval between consecutive electrical impulses is sufficient to allow
20 the ultrasonic transducer to receive reflected ultrasonic echoes resulting from the transmitted ultrasonic pulse signal and to transmit electrical signals to the transmitter-receiver in response to those ultrasonic echoes before transmitting another ultrasonic pulse
25 signal.

Ultrasonic echoes, i.e., reflections of the transmitted ultrasonic signal, occur at every boundary between materials differing in the velocity of the propagation of sound, including boundaries between blood and arterio-
30 sclerotic plaque deposits and between arteriosclerotic plaque deposits and the wall of the blood vessel.

The ultrasonic echoes are received by the ultrasonic transducer which transforms the ultrasonic echoes into

35



-13-

1 electrical signals which are transmitted to the trans-
mitter-receiver through wires 13 and 14. The electrical
signals from the ultrasonic transducer are sensed and
amplified by a radio frequency receiving amplifier 26.
5 The gain of the radio frequency receiving amplifier 26,
i.e., the increase in signal amplitude, is controlled by
a swept gain generator 27 which compensates for the
reduced signal amplitude of echoes returning from greater
distances. The amplified signal is then displayed or
10 monitored by any suitable means, e.g., an oscilloscope
25, and provides a "signature" of the reflecting tissue.

To display the amplified signal on the oscilloscope
25, a transmission gate 28 is used as an oscilloscope
trigger for indicating the onset of the transmitted
15 electrical pulse. Direct observation of the amplified
signal received from the ultrasonic transducer on the
oscilloscope 25 provides information related to the dis-
tance of the reflecting tissue, as determined by the time
on the oscilloscope trace, and the character of the
20 tissue interface as determined by the amplitude of
reflection on the oscilloscope trace.

The amplified signal can also be gated by a receiv-
ing gate 29 to provide a signal which can be used by a
spectrum analyzer for further identification of the
25 character or properties of the reflecting tissue. The
receiving gate 29 removes all portions of the signal
except that portion corresponding to a selected distance
from the catheter tip. To accomplish this, the receiving
gate 29 is controlled by a first delay function 31 which
30 activates the receiving gate 29 to pass a signal of
preset width at a selected time after the transmission
gate 28 has signaled the onset of the transmitted elec-
trical impulse.

35



-14-

1 To determine the presence of arteriosclerotic plaque
deposits in a blood vessel from the tissue signature, a
comparison is made between the signature of the unknown
tissue and previously obtained signatures for which the
5 character of the tissue, i.e., the presence or absence of
arteriosclerotic plaque, was determined by conventional
means. That is, preceding the analysis of an unknown
tissue, tests are performed, for example on laboratory
animals, wherein the catheter is inserted into non-
10 occluded blood vessels, i.e., blood vessels having little
or no arteriosclerotic plaque, as well as blood vessels
occluded to various degrees by arteriosclerotic plaque,
and tissue signatures are obtained from those blood
vessels. The character of the tissues, i.e., the amount
15 of arteriosclerotic plaque, of the "test" blood vessels
is then determined by visual inspection, e.g., surgery,
or other conventional means and a correlation between
the presence and amount of arteriosclerotic plaque and
the tissue signatures is made. Once a correlation is
20 made, the presence and amount of plaque in an unknown
blood vessel can then be determined from the signature of
that tissue.

In the pulsed-doppler mode, the transmitter-receiver
generates electrical bursts, i.e., electrical signals
25 comprising multiple cycles, e.g., ten to twenty cycles,
of the oscillator signal which are delivered to the
ultrasonic transducer and results in the transmission of
a tone burst, i.e., a longer ultrasonic signal having a
duration corresponding to the duration of the electrical
30 burst. Comparison of the phase and frequency of the
ultrasonic echoes resulting from a transmitted tone
burst, at two or more selected times following the trans-
mission, with a signal from the oscillator provides
information which yields the velocity of the blood flow
35 at two distances from the transducer.



-15-

1 Again with reference to FIG. 2, the synchronous
gating logic 22 of the transmitter-receiver sends a
signal to the transmission gate 28 to transmit an elec-
trical signal comprising a select number of cycles of
5 the oscillator signal at selected intervals, e.g., an
interval in the 50-100 KHz range, the electrical signal
is amplified by the radio frequency power amplifier 24
and is then passed to the ultrasonic transducer 12 by
wires 13 and 14. The ultrasonic transducer 12 receives
10 the electrical signal and transmits a corresponding
ultrasonic signal, i.e., a tone burst in response.

The transmitted ultrasonic signal is reflected by
tissue interfaces including moving interfaces in the
blood stream, e.g., corpuscle-plasma interfaces. Echoes
15 are sensed by the ultrasonic transducer which transmits
an electrical signal to the transmitter-receiver in
response to the received echoes. The received electrical
signal contains information regarding the distance and
velocity of tissues in the path of the sound signals.
20 The interval between the transmission of electrical sig-
nals from the transmitter-receiver to the transducer is
selected to allow the transducer to receive the ultra-
sonic echoes resulting from the tone burst and to trans-
mit electrical signals to the transmitter-receiver in
25 response to the received echoes before transmitting
another tone burst.

The electrical signal received from the ultrasonic
transducer is amplified by the radio frequency receiving
amplifier 26 and is mixed by mixer 32 with the signal
30 from the oscillator 21 to yield a signal comprising the
sum and difference of the frequencies of the received
signal and the oscillator signal.

The first delay function 31 and a second delay func-
tion 33 provide delayed gating signals for first and

35



-16-

1 second sample and hold amplifiers 34 and 36 for sensing
the velocity at two distances from the ultrasonic trans-
ducer as selected by first and second distance selectors
37 and 38, which are adjustable receiver gates. First
5 and second band pass filters 39 and 41 eliminate those
portions of the combined signals corresponding to the
carrier signal, the sum of the combined signals and
signals resulting from stationary interfaces, leaving
only the portion of the combined signals resulting from
10 motion of tissue interfaces at the two selected distances.
The outputs of the band pass filters are then used to
drive headphones or speakers 42 and 43 for providing
audible signals. Alternatively, the outputs from the
band pass filters can be used to produce analog voltages
15 proportional to the respective velocities, which can be
monitored and recorded, by using frequency to voltage
converters.

By monitoring signals received from two different
distances from the catheter tip, i.e., a first distance
20 nearer the catheter tip and a second distance farther
from the catheter tip, the blood velocity can be deter-
mined at those distances. These blood velocities are
used to determine the presence and extent of a restric-
tion in the blood vessel. A greater blood velocity, at
25 the second distance as compared with that at the first
distance, indicates a restriction in the blood flow at
that second distance due to a narrowing of the blood
vessel, e.g., due to the formation of tributaries, or
as a result of the occlusion of the blood vessel by
30 arteriosclerotic plaque. Conversely, a lower blood
velocity at the second distance indicates greater patency
of the blood vessel, possibly due to a broadening of the
blood vessel or the absence of or at least a lesser
amount of arteriosclerotic plaque at the second distance
35 as compared with the first.



1 If desired, the direction of the blood flow can also
be monitored. This can be accomplished by providing a
reference frequency to the mixer 32 which is offset in
frequency from oscillator 21. With reference to FIG. 3
5 the reference frequency can be generated, for example, by
reference oscillator 45. In such an arrangement, the
output signal can be monitored, for example, by metering
devices 42 and 43, each having an indicator. The indi-
cator would be displaced in one direction from a zero
10 position for motion toward the transducer and in the
opposite direction for movement away from the transducer.
The amount of displacement would indicate the velocity.

 Alternatively, as shown in FIG. 4, by using dual
channel circuitry from the mixer stage through the output
15 stage, i.e., dual mixer 46, dual sample and hold ampli-
fiers 47 and 48, and dual band pass filters 49 and 50, in
conjunction with a phase shifter 51 and phase quadrature
signal processing stage 47, direction sensing may also be
provided, as is well known in the art.

20 The transmitter-receiver comprises a switch 44 for
rapidly switching between the pulse-echo mode and the
pulsed-doppler mode. Switching is sufficiently rapid
that the received signals from both modes can be dis-
played "simultaneously". For example, the signals
25 received in the pulse-echo mode can be displayed on an
oscilloscope while the signals received in the pulsed-
doppler mode can be used to drive a pair of speakers.
Switching between modes is preferably sufficiently
rapid so that, to an operator, each displayed signal
30 appears continuous.

 The combined information as to the position and
extent of a blood vessel restriction and the character
or properties of the restricting tissue provides an
accurate determination of the presence, position and

-18-

1 amount of restriction caused by arteriosclerotic plaque
deposits and the need for its removal. Such removal can
be effected immediately and with enhanced precision by
vaporizing the plaque with laser irradiation delivered
5 through the optical fiber.

Referring again to FIG. 1, the apparatus also comprises a laser 10 for generating the laser irradiation which is delivered through the optical fiber. Lasers for such applications are well known in the art. Suitable
10 lasers include argon-ion, neodymium-YAG, and carbon dioxide lasers.

This invention provides several unique advantages over similar systems using a fiberoptic scope. For example, the presence of arteriosclerotic plaque deposits
15 in a blood vessel can be determined without the need to stop the flow of blood through the blood vessel. Additionally, monitoring of the plaque deposits need not be interrupted by laser transmission. A catheter according to this invention can also be made sufficiently small
20 to be positioned in coronary arteries and thus presents a new non-surgical treatment for heart disease due to occluded coronary arteries.

While the preceding description has been presented with reference to a presently preferred embodiment of the
25 invention, it is apparent that changes and alterations in the above-described apparatus can be practiced without departing from the scope of the invention. For example, the ultrasonic transducer in the preferred embodiment described above is annular, i.e., disc-shaped and having a
30 central opening. This enables the mounting of the distal tip of the optical fiber in the central opening. Further, the ultrasonic transducer is preferably mounted at a selected angle to the longitudinal axis of the catheter

35



-19-

1 so that the transmitted ultrasonic signals are directed
toward the wall of the blood vessels. However, other
ultrasonic transducer shapes and mounting configurations
are equally suitable as is mounting the distal tip of the
5 optical fiber to one side of the ultrasonic transducer
rather than through an opening in the transducer. Further,
coupling optics are not required if it is desired to
direct the laser irradiation in a direction generally
along the length of the blood vessel rather than toward
10 the blood vessel wall.

As illustrative, FIG. 5 shows rectangular ultra-
sonic transducer 53 mounted to the distal end of a cath-
eter tube 54 with an optical fiber 56 extending through
the catheter tube and mounted so that its distal end is
15 to one side, e.g., below, the ultrasonic transducer.
No coupling optics are used.

In another embodiment of the invention, the ultra-
sonic transducer may be comprised of a plurality of
elements, each element being capable of independently
20 transmitting and receiving ultrasonic signals. A pre-
ferred multiple-element ultrasonic transducer is shown
in FIG. 6. The elements 57 are positioned symmetrically
about the longitudinal axis of the catheter and provide
a central opening 58 at the distal tip of the catheter.
25 Each element 57 has a generally flat face and is mounted
on the distal end of the catheter tube 59 at a select
angle to the longitudinal axis of the catheter tube 59.
Each element is electrically connected by separate pairs
of wires 61 to the transmitter-receiver so that each
30 element can be activated independently. An optical fiber
62 is disposed through the lumen of the catheter tube 59
and its distal tip is mounted in the central opening 58.

35



-20-

1 Multiple-element ultrasonic transducers provide the
advantage that tissue signatures can be obtained in
several radial directions without moving the catheter.
However, for small blood vessels, e.g., coronary arteries,
5 multiple-element ultrasonic transducers do not provide
a significant advantage over single-element ultrasonic
transducers and hence are not presently preferred.

If desired, the catheter tube can be designed to
accommodate a guide wire to assist in the positioning
10 of the catheter within the blood vessel. Such guide
wires and their use are well known in the art. To
accommodate a guide wire, the catheter tube can have a
lumen sufficiently large to accommodate both the optical
fiber and a guide wire and have an opening at the distal
15 tip of the catheter to allow the distal extension of the
guide wire. Alternatively, as shown in FIG. 7, the
catheter tube 63 can comprise a first lumen 64 through
which the optical fiber 66 and wires 67 and 68 are dis-
posed and a second lumen 69 through which a guide wire 71
20 extends and is afforded lengthwise movement. Such a
second lumen can also be used for the injection of a
radiopaque fluid or other material into the blood vessel
or the removal of fluid from the blood vessel.

25

30

35



1

WHAT IS CLAIMED IS:

- 5 1. A catheter having proximal and distal ends
 comprising:
 an elongated optical fiber having proximal and
 distal ends extending the length of the catheter for
 transmitting laser irradiation;
 an ultrasonic transducer mounted at the distal
10 end of the catheter for transmitting and receiving ultra-
 sonic signals; and
 a pair of wires electrically connected to the
 ultrasonic transducer extending the length of the catheter.
- 15 2. A catheter as claimed in claim 1 wherein the
 ultrasonic transducer is a piezoelectric ceramic crystal.
3. A catheter as claimed in claim 1 wherein the
 ultrasonic transducer has a response frequency in the
20 range of from about 10 to about 30 megahertz.
4. A catheter as claimed in claim 1 wherein the
 ultrasonic transducer is generally circular.
- 25 5. A catheter as claimed in claim 4 wherein the
 ultrasonic transducer comprises a circular opening
 through its center and wherein the distal tip of the
 optical fiber is mounted in the opening.
- 30 6. A catheter as claimed in claim 1 wherein the
 ultrasonic transducer is mounted at a selected angle
 to the longitudinal axis of the catheter.

35



1 7. A catheter as claimed in claim 1 further comprising means for directing laser irradiation transmitted from the distal end of the optical fiber at a selected angle to the longitudinal axis of the catheter.

5

8. A catheter as claimed in claim 1 wherein the ultrasonic transducer comprises a plurality of elements, each element being capable of independently transmitting and receiving ultrasonic signals.

10

9. A catheter comprising:

an elongated, flexible catheter tube having proximal and distal ends and a lumen;

15 an elongated optical fiber having proximal and distal ends disposed within the lumen of the catheter tube and extending at least about the length of the catheter tube for transmitting laser irradiation;

20 an ultrasonic transducer having a generally flat face mounted to the distal end of the catheter tube at a selected angle to the longitudinal axis of the catheter tube; and

25 a pair of wires disposed within the lumen of the catheter tube and electrically connected to the transducer, said wires extending at least about the length of the catheter tube.

10. A catheter as claimed in claim 9 wherein the ultrasonic transducer is a piezoelectric ceramic crystal.

30 11. A catheter as claimed in claim 9 wherein the optical fiber is made of fused silica.

35



-23-

1 12. A catheter as claimed in claim 9 further comprising means for directed laser irradiation transmitted from the distal tip of the optical fiber at a selected angle from the longitudinal axis of the optical fiber.

5

 13. A catheter as claimed in claim 12 wherein the means for directing laser irradiation transmitted from the distal end of the optical fiber at a selected angle to the longitudinal axis of the optical fiber comprises
10 coupling optics mounted adjacent the distal end of the optical fiber so that laser irradiation emanating from the optical fiber passes through the coupling optics.

 14. A catheter as claimed in claim 9 wherein the
15 ultrasonic transducer comprises an opening through the ultrasonic transducer and wherein the distal end of the optical fiber is positioned in the opening.

 15. A catheter as claimed in claim 9 wherein the
20 diameter of the ultrasonic transducer is about 1 millimeter.

 16. A catheter as claimed in claim 15 wherein the
diameter of the optical fiber is from about 0.1 to about
25 0.5 millimeters.

 17. A catheter as claimed in claim 9 wherein the lumen of the catheter tube is sufficiently large to provide a space extending the length of the catheter
30 tube between the optical fiber and the wall of the catheter tube and wherein the catheter tube comprises at least one hole through the wall of the catheter tube near the distal end of the catheter tube.

35



-24-

1 18. A catheter as claimed in claim 9 wherein the catheter tube comprises a second lumen which is open at the distal tip of the catheter.

5 19. A catheter as claimed in claim 18 further comprising a guide wire disposed in the second lumen and afforded lengthwise movement through the second lumen.

10 20. An apparatus comprising:
 a catheter comprising:
 an elongated optical fiber having proximal and distal ends for transmitting laser irradiation applied to its proximal end;
 an ultrasonic transducer at the distal tip
15 of the catheter for transmitting and receiving ultrasonic signals;
 a transmitting unit for generating electrical impulses for activating the ultrasonic transducer to transmit ultrasonic signals; and
20 a receiving unit for receiving and displaying electrical signals transmitted by the ultrasonic transducer in response to ultrasonic signals received by the ultrasonic transducer.

25 21. An apparatus as claimed in claim 20 wherein the transmitting unit comprises:
 a pulse-echo mode for generating short electrical impulses for activating the ultrasonic transducer to transmit ultrasonic pulse signals;
30 a pulsed-doppler mode for generating electrical bursts for activating the ultrasonic transducer to transmit ultrasonic tone bursts; and
 means for switching between the pulse-echo mode and the pulsed-doppler mode.

35



-25-

1 22. An apparatus as claimed in claim 20 wherein
the receiver comprises an oscilloscope for displaying
electrical signals received from the ultrasonic trans-
ducer.

5

23. An apparatus as claimed in claim 20 wherein
the receiver comprises speakers for audibly monitoring
electrical signals received from the ultrasonic trans-
ducer.

10

24. An apparatus as claimed in claim 20 further
comprising a laser for applying laser irradiation to
the proximal end of the optical fiber.

15 25. A method for removing occlusions in blood
vessels comprising the steps of:

(a) inserting into a blood vessel a catheter
comprising:

20 (1) an optical fiber for transmitting
laser irradiation;

(2) an ultrasonic transducer at the
distal tip of the catheter for transmitting and receiving
ultrasonic signals;

25 (b) activating the ultrasonic transducer to
transmit short ultrasonic pulse signals at selected
intervals;

(c) receiving ultrasonic echoes resulting from
the transmitted ultrasonic pulse signals;

30 (d) determining the presence and character of
occlusions in the blood vessel based upon the received
ultrasonic echoes; and

35 (e) directing sufficient laser irradiation
through the optical fiber onto occlusions whose presence
and character have been determined to remove at least a
portion of the occlusion.



-26-

- 1 26. A method as claimed in claim 25 further comprising, prior to step (d) of claim 25:
- (a) activating the ultrasonic transducer to transmit tone bursts at selected intervals;
- 5 (b) receiving ultrasonic echoes resulting from the transmitted tone bursts;
- (c) determining the velocity of blood flow at two selected distances from the catheter tip from the received ultrasonic echoes of the tone burst; and
- 10 (d) determining the presence and character of occlusions based upon the ultrasonic echoes received in response to transmitted ultrasonic pulse signals and upon the velocity of blood flow at two selected distances from the catheter tip.
- 15 27. A method as claimed in claim 25 further comprising, prior to step (d), determining the direction of the blood flow at the two selected distances from the catheter tip from the received ultrasonic echoes of the toneburst.

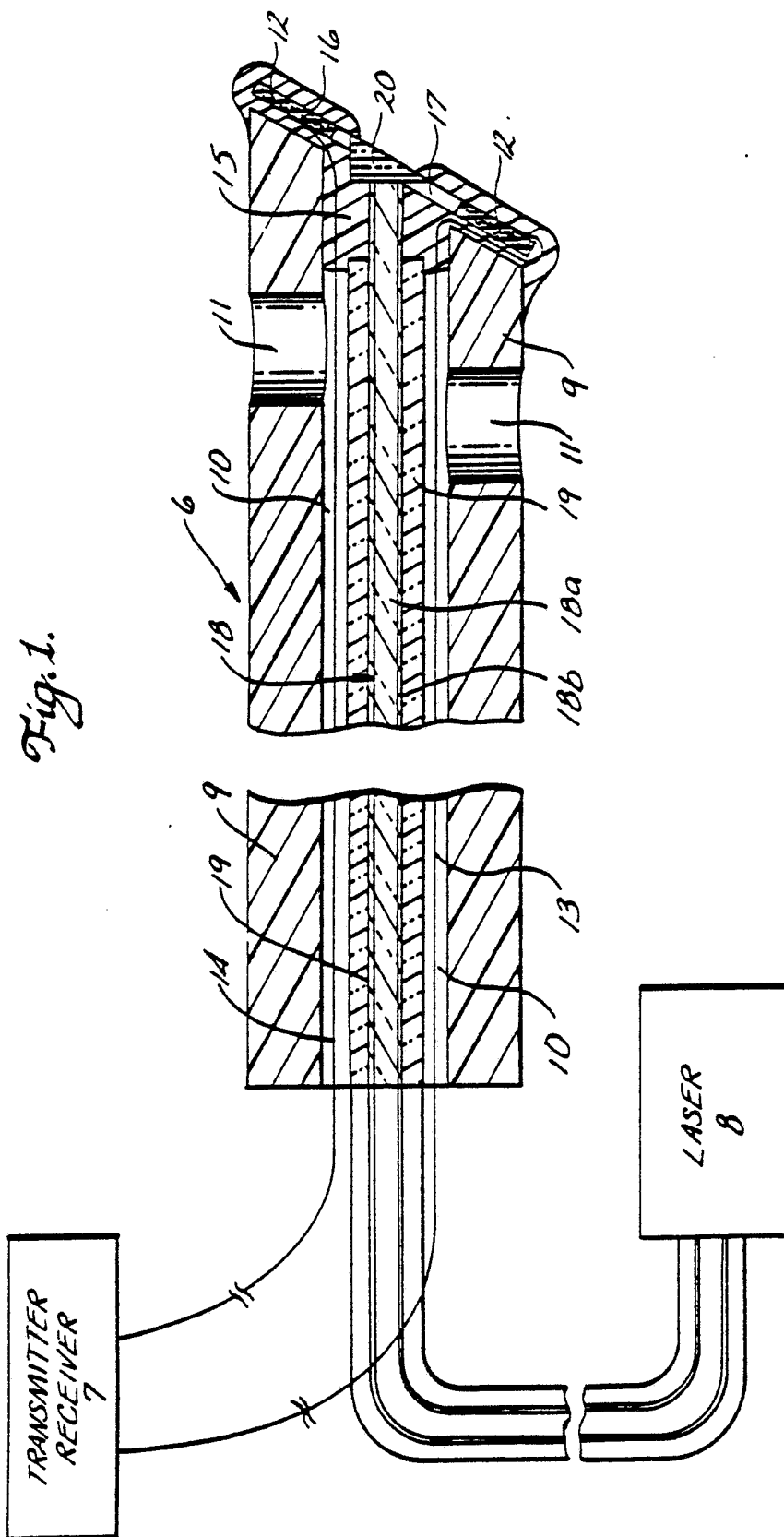
20

25

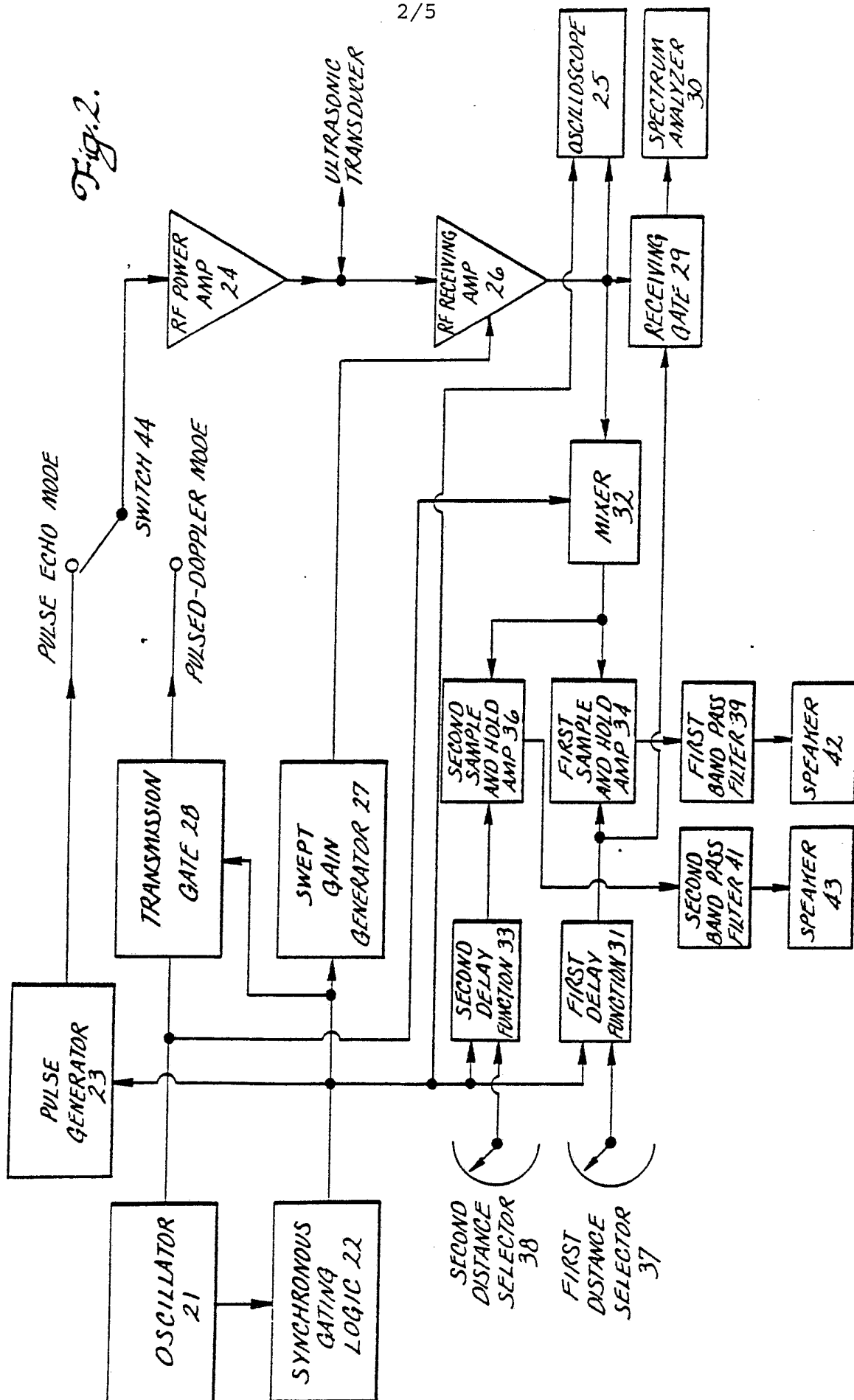
30

35

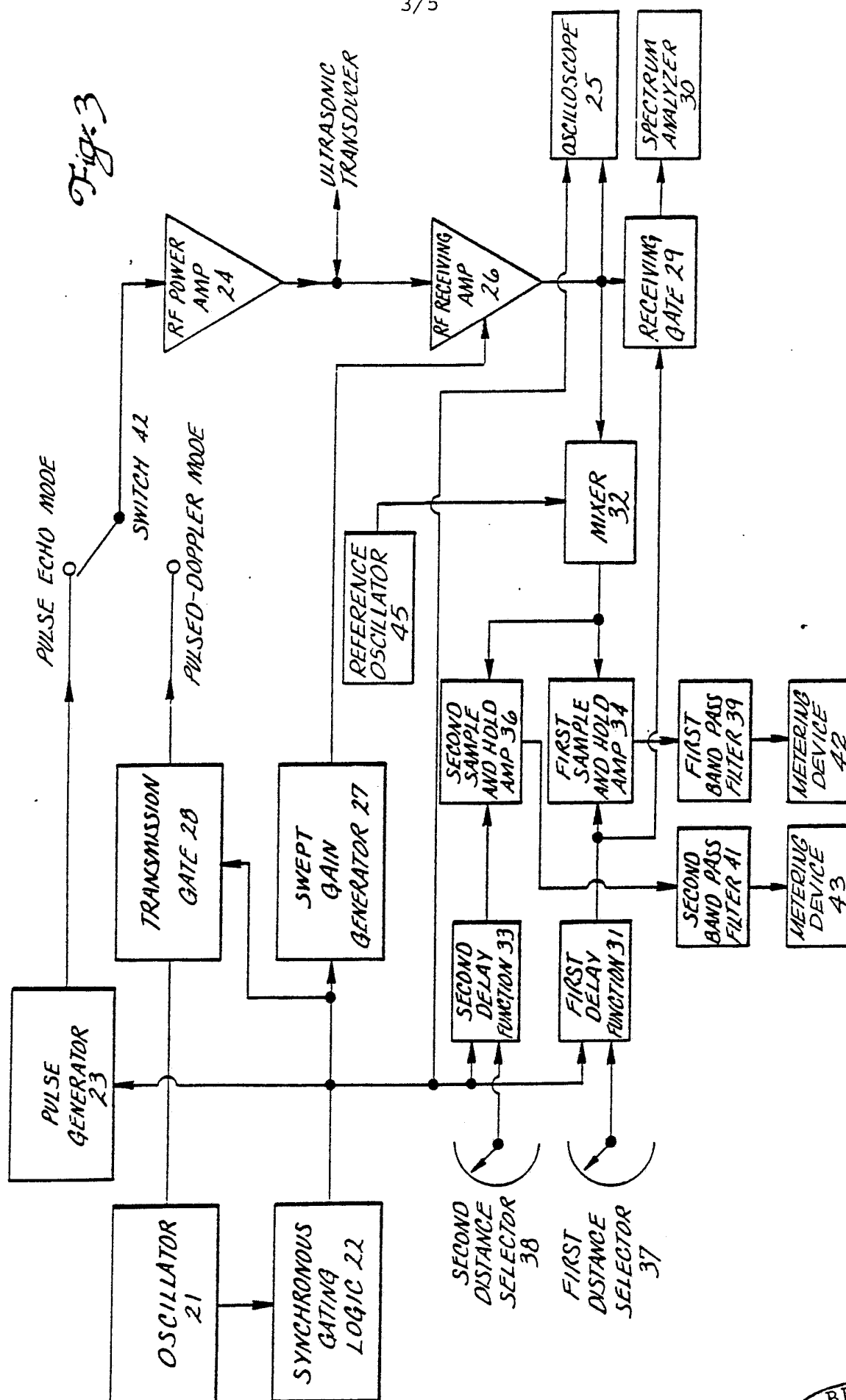




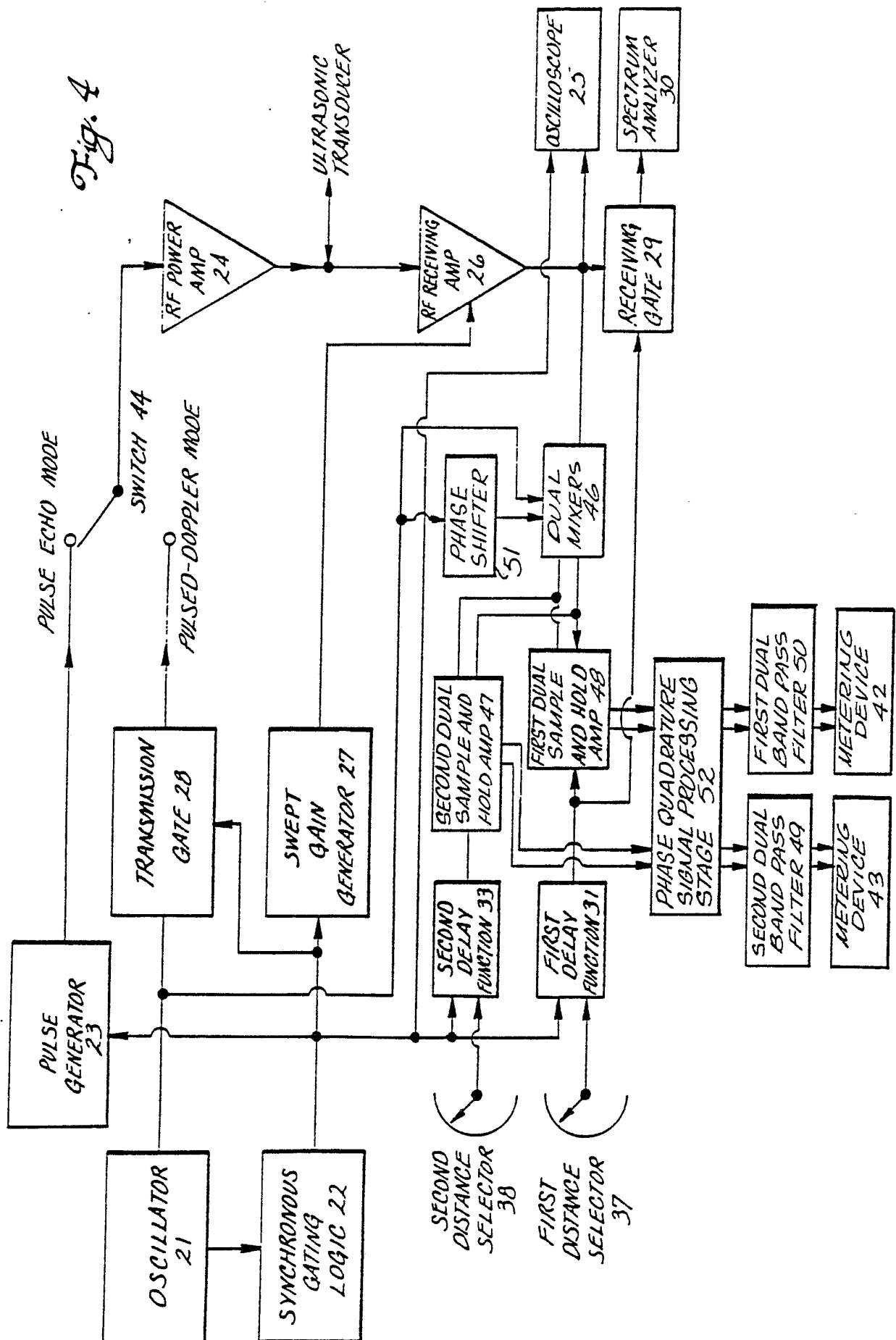
2/5



3/5



4/5



5/5 *Fig. 5*

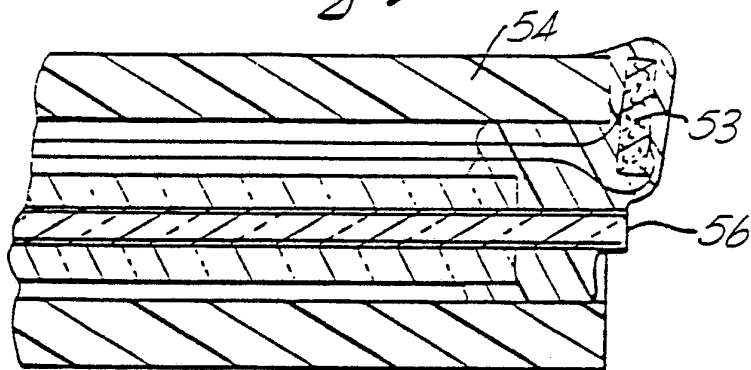


Fig. 6

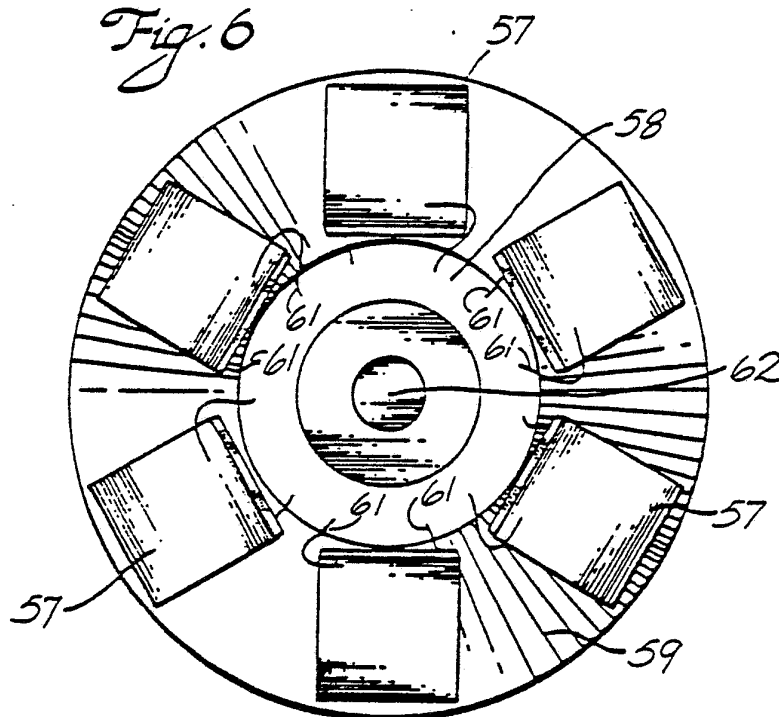
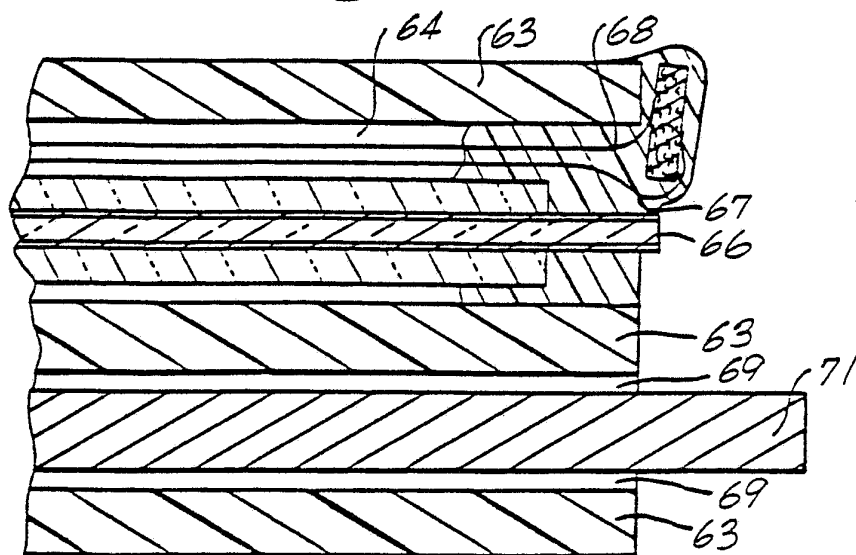
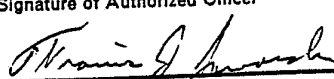


Fig. 7



INTERNATIONAL SEARCH REPORT

International Application No PCT/US84/00474

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) ³		
According to International Patent Classification (IPC) or to both National Classification and IPC		
IPC 9 A61B 10/00		
US 128/660		
II. FIELDS SEARCHED		
Minimum Documentation Searched ⁴		
Classification System	Classification Symbols	
US	128/660, 661, 663, 4-8, 303.1, 375-378	
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched ⁵		
III. DOCUMENTS CONSIDERED TO BE RELEVANT ¹⁴		
Category *	Citation of Document, ¹⁶ with indication, where appropriate, of the relevant passages ¹⁷	Relevant to Claim No. ¹⁸
X	N, IEEE Transactions on Sonics and Ultrasonics, Vol. SU-27, No. 6, published November 1980, R.W. Martin et al, An Ultrasonic Catheter for Intravascular Measurement of Blood Flow: Technical Details, pages 277-286	8, 17
Y	N, DISCOVER Magazine, published December 1982, Denise Grady, The Artery Zapper, pages 36-37, 40	1-7, 9-12, 14-16, 18-20, 23-25
Y	N, Medical Instrumentation, Vol. 8, No. 4, published for July-August 1974, Craig J. Hartley et al, A Single Crystal Ultrasonic Catheter Tip Velocity Probe, pages 241-243	1-7, 9-12, 14-16, 18-20, 23-25
Y	N, British Medical Journal, Vol. 286, published 01 January 1983, M.R. Hetzel et al, Laser Treatment of Carcinoma of the Bronchus, pages 12-16	1-7, 9-12, 14-16, 18-20, 23-25
* Special categories of cited documents: ¹⁵ "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier document but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art. "&" document member of the same patent family		
IV. CERTIFICATION		
Date of the Actual Completion of the International Search ²	Date of Mailing of this International Search Report ³	
26 May 1984	11 JUN 1984	
International Searching Authority ¹	Signature of Authorized Officer ²⁰	
ISA/US		

III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)		
Category *	Citation of Document, ¹⁶ with indication, where appropriate, of the relevant passages ¹⁷	Relevant to Claim No ¹⁸
Y	N, IEEE Transactions on Biomedical Engineering, Vol. BME-21, No. 2, published March 1974, R. Olson et al, A Non-Destructive Ultrasonic Technique to Measure Diameter and Blood Flow in Arteries, pages 168-171	21-22, 26
A	N, Conference: Proceedings of the 26th Annual Conference on Engineering in Medicine and Biology, Leamington Hotel, Minneapolis, Minnesota, 30 September -04 October 1973, C.J. Hartley et al, A Pulsed Doppler Catheter for Measuring Coronary Artery Velocity.	1-7, 9-12, 14-16, 18-20, 23-25
A	US, N, International Application Publication Number WO 83/01893 Published Under The Patent Cooperation Treaty on 09 June 1983, Garrett Lee, A Catheter Assembly	1-26

FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

X	N, Ultrasonics, Conference: Digest of the Third International Conference on Medical Physics, Including Medical Engineering Chalmers University of Technology, Goteborg, Sweden 1972, F.A. Duck et al, An Intravenous Doppler Probe for Arterial Flow Monitoring	6, 9
Y	US, A, 4,146,019 27 March 1979 BASS et al (see Figure 3, elements 24, 25)	13

V. ☐ **OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE** ¹⁰

This international search report has not been established in respect of certain claims under Article 17(2) (a) for the following reasons:

1. ☐ Claim numbers because they relate to subject matter ¹² not required to be searched by this Authority, namely:

2. ☐ Claim numbers _____, because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out ¹³, specifically:

VI. ☐ **OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING** ¹¹

This International Searching Authority found multiple inventions in this international application as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims of the international application.
2. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the international application for which fees were paid, specifically claims:
3. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim numbers:
4. ☐ As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additional fee.

Remark on Protest

- ☐ The additional search fees were accompanied by applicant's protest.
☐ No protest accompanied the payment of additional search fees.