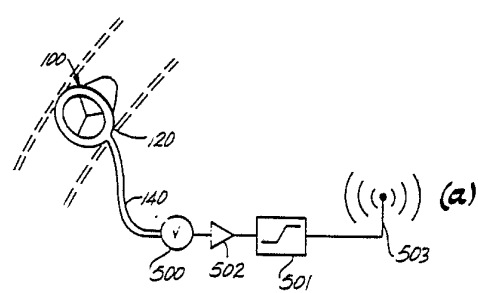
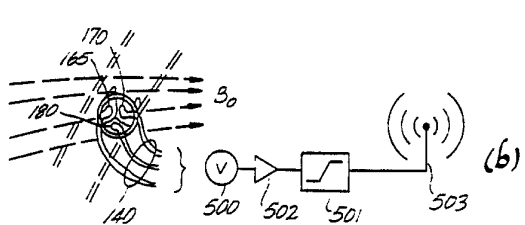
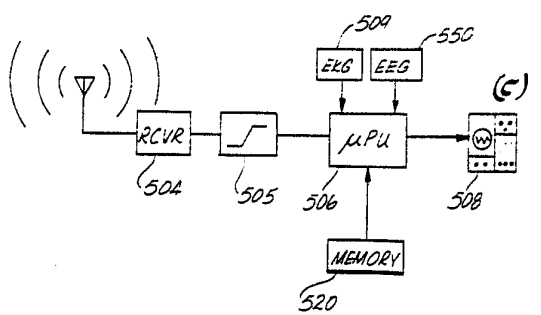




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(54) Title: PROSTHETIC VALVE AND MONITORING SYSTEM AND METHOD (57) Abstract A prosthetic heart valve which can be externally monitored. In a first embodiment, the leaflets (130) of the valve are magnetized, and the voltage induced in a coil (140) juxtaposed thereto may be monitored. In a second embodiment, conductors (165, 170, 180) are integrated with the leaflets (130). When the valve is then placed in a magnetic field, a voltage is induced in the conductors. The voltages induced in both valve configurations may be analyzed to indicate valve operation and conditions.   		

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PROSTHETIC VALVE AND MONITORING
SYSTEM AND METHOD

Field of The Invention

This invention relates generally to an improved prosthetic heart valve and to an instrument and method for measuring the velocity of heart leaflets moving in a heart valve, in order to monitor valve condition and performance. More particularly, the instrument measures quantitatively a voltage induced by the motion of the heart leaflet in the heart valve.

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For several years, both porcine and non-porcine artificial heart valves have been used for replacement of degenerating heart valves. Monitoring the condition of these prosthetic heart valves is important. Particularly in the case of porcine artificial heart valves, "early calcification and tearing is a life threatening complication that must be recognized promptly and treated by emergency valve replacement." B.F. Lewis, Early Calcification and Obstruction of a Microporcine Bioprosthesis, Annals of Thoracic Surgery, 30(6): 592-4 (Dec. 1980). Several studies indicated that a very large percentage of the recipients of porcine artificial heart valves are susceptible to heart failure due to the tearing and/or calcification of the valve leaflets. J.L. Bosch, Late Tears in Leaflets of Porcine Bioprosthesis in Adults, Annals of Thoracic Surgery, 37(1):78-93 (Jan. 1984). In addition, both porcine and

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1 non-porcine artificial heart valves are subject to
malfunctions in operation due to degeneration, thrombosis,
endocarditis, bacterial infection, etc.

5 In general, malfunctions of artificial heart valves
occur suddenly and without warning. Therefore, recipients
of artificial heart valves are subject to a continual
possibility of unexpected valve malfunction and deleterious
heart failure. To some extent the possibility of malfunction
can be evaluated by periodic testing. At present, the
10 most common method of evaluating artificial heart valve
operation is by way of an echocardiogram. This test is
very expensive and requires a time delay prior to diagnosis
of the echocardiogram test results. In addition, this
test can only be performed at established health facilities
15 which have suitable echocardiogram equipment and staff
personnel trained and qualified for performing the test
and interpreting the test results.

Therefore, it is the object of the present invention
to provide an improved method of monitoring the operation
20 of an artificial heart valve, which in particular will
enable monitoring of the subtle changes in the leaflet
structure of the valve in an inexpensive, non-invasive,
substantially real-time manner, on a continual or periodic
basis.

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Summary of The Invention

The present invention replaces the need for an
echocardiogram by allowing the recipient to monitor his
own valve continuously at home, or periodically in a doctor's
30 office or in a medical clinic, or other health care facility,
etc.

According to the invention, an artificial heart
valve is provided with means for generating a detectable
electrical current upon motion of the valve leaflets
35 responsive to blood flow therethrough. The current signal

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1 can then be analyzed to determine the leaflet's condition.

Generally, the apparatus of the invention operates on the principle of electromagnetic induction. Specifically, the invention operates according to Faraday's Law:

5

$$V = \oint \vec{E} \cdot d\vec{l} = - \frac{d\Phi}{dt}$$

and the electromotive force law for static magnetic fields:

10

$$V = \int (\vec{U} \times \vec{B}) \cdot d\vec{l}$$

For a more detailed description of the principles of electromagnetic induction, reference is made to Cheng, Field and Wave Electromagnetics, Addison-Wesley Publishing Company, 272-283 (1983).

In the preferred embodiment of the invention, the leaflets of an artificial heart valve are impregnated with magnetizing ions prior to implantation of the valve into the heart. Thereafter, blood flow through the heart valve opens the ion-impregnated heart leaflets. The motion of the leaflets induces a voltage in a solenoid coil juxtaposed to the valve. The voltage varies in accordance with the velocity at which the valve leaflets open, following Faraday's Law for time varying magnetic fields:

25

$$V = \oint \vec{E} \cdot d\vec{l} = - \int \frac{d}{dt} \vec{B}(t) \cdot d\vec{s} = - \frac{d\Phi}{dt}$$

In these equations,

V = electromotive force induced;

30

$\vec{E}$ = induced electric field;

Φ = magnetic flux;

35

$\frac{d\vec{B}}{dt}$ = Time-varying magnetic field generated by the movement of the magnetized leaflet; and

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1 ds = surface encircled by the solenoid coil.

 The signal voltage induced in the solenoid coil can then be determined by a sensitive potentiometer and amplified
 5 for analysis. For example, diagnosis analysis can be performed by a microprocessor-controlled system or presented on an oscilloscope for analysis by a physician.

 In a second embodiment of the invention, the leaflets of the artificial heart valve are impregnated with
 10 conductors, which may be actual wires or may be formed by ion-impregnation in the shape of a conductive coil prior to implantation of the valve into the heart. Thereafter, motion of blood flow through the heart valve opens the conductor-impregnated leaflets. If a constant magnetic
 15 field is juxtaposed to the valve, the motion of the leaflets induces a voltage in the conductors. The voltage varies in accordance with the velocity with which the valve leaflets open. In this embodiment of the invention, the following electromotive force law equation for static magnetic fields
 20 provides the measure of the induced voltage:

$$V = \int (\vec{U} \times \vec{B}) \cdot d\vec{l}; \quad \vec{U} = \frac{d\vec{y}}{dt}$$

 In this equation:

25 V = electromotive force induced;

$\vec{B}$ = uniform applied magnetic field;

 L = length of the conductor; and

30 $\frac{d\vec{y}}{dt}$ = velocity of the moving valve leaflets.

 In the case when the conductor is a loop, the voltage

35

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1 induced therein will follow Faraday's Law:

$$V = \frac{d\vec{B}}{dt} \circ \int ds = \frac{-d\Phi}{dt} = \frac{-d}{dt} \int \vec{B}(t) d\vec{s}$$

5 In these equations:

V = electromotive force induced;

$\vec{B}$ = uniform applied magnetic field;

10 $\frac{ds}{dt}$ = rate at which the surface of the valve moves in relation
to the magnetic field; and

Φ = flux of the magnetic field.

15 Faraday's Law also applies when the conductor is
impregnated over an area on the surface of the leaflets.

The signal voltage induced in the conductors can
then be detected by a sensitive potentiometer and amplified
for analysis, as above.

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1 Brief Description of The Drawings

 The invention will be better understood if reference is made to the accompanying drawings, in which:

 FIG. 1A is a magnetized-leaflet (MIL) porcine mitral
5 heart valve prosthesis, shown in atrial view, having had its leaflets impregnated with magnetizing ions and showing the signal wires wrapped concentrically around the base of the MIL porcine heart valve;

 FIG. 1B is an MIL porcine mitral heart valve
10 prosthesis shown in ventricular view, with its leaflets impregnated with magnetizing ions and showing signal wires wrapped concentrically around the base of the MIL porcine heart valve;

 FIG. 1C is an MIL porcine mitral heart valve
15 prosthesis shown in side view, with its leaflets impregnated with magnetizing ions and showing signal wires wrapped concentrically around the base of the MIL porcine heart valve;

 FIG. 1a' is a coil-integrated leaflet (CIL) porcine
20 mitral heart valve prosthesis, shown in atrial view, having had its leaflets impregnated with conductors;

 FIG. 1b' is a CIL porcine mitral heart valve
 prosthesis shown in ventricular view, with its leaflets impregnated with conductors;

25 FIG. 1c' is a CIL porcine mitral heart valve prosthesis shown in side view, with its leaflets impregnated with conductors.

 FIG. 2 shows the steps in the process of insertion
30 of either a CIL or MIL porcine mitral heart valve prosthesis into the heart, and includes the following sub-figures:

 FIG. 2A shows the preferred incision,

 FIG. 2B shows the cannulae introduced into the heart,

 FIG. 2C shows the mitral valve,

35 FIG. 2D shows the mitral valve and papillary

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1 muscles excised,
FIG. 2E shows the prosthesis valve inserted,
FIG. 2F shows a catheter placed across the
valve, and
5 FIG. 2G shows the incision to the heart
being closed.

FIG. 3 shows the steps in the insertion of either a
CIL or MIL aortic valve prosthesis into the heart, and
includes the following sub-figures:

10 FIG. 3A shows the preferred incision,
FIG. 3B shows the aortic valve exposed
after incision,
FIG. 3C shows the porcine valve,
FIG. 3D shows the porcine valve sutured
15 into place,
FIG. 3E shows the porcine valve positioned
within the aorta, and
FIG. 3F shows the incision closed.

FIG. 4A shows a block diagram of the signal detection
20 and conditioning electronics of the MIL system;

FIG. 4B shows a block diagram of the signal detection
and conditioning electronics of the CIL valve monitoring
system;

FIG. 4C shows the analysis system in block diagram
25 form.

FIG. 5 shows a flowchart of the processing steps of
the invention.

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1 Detailed Description of The Preferred Embodiment

In the past, electromagnetic induction principles have been used in the application of blood flow probes. The probes quantitatively measure the volumetric rate of blood flow through blood vessels. See U.S. Patents 5 3,487,826; 3,696,674; 3,529,591, and 3,516,399. The operation of the devices described in these patents is based upon the induction of a voltage through a conductor (blood) moving through a uniform applied magnetic field. 10 The magnitude of the induced voltage, in such cases, is determined by the velocity of the blood, the strength of the field, and the length of the conductor. This device can be modeled by the electromotive force law for static magnetic fields as described in the following equation:

15

$$V = \int (\vec{U} \times \vec{B}) \cdot d\vec{l}; \vec{U} = \frac{d\vec{y}}{dt}$$

where V is the electromotive force induced;

20

$\vec{B}$ is the uniform magnetic field;

L is the length of the conductor, that is, the width of the blood vessel; and

25

$\frac{d\vec{y}}{dt}$ is equal to the velocity of the moving conductor, that is, to the blood flow rate.

30

As mentioned, the conductor in these systems is actually the blood flowing past reference points defined by the positions of the probe electrodes. In order to sense the flow, these electrodes must make direct contact with the blood or outer surface of the vessel wall.

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The prosthesis valve of the invention, in both magnetized leaflet and coil-integrated leaflet form, operates on entirely different principles than do the electromagnetic blood flow meters described in the patents listed above.

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1 In the prior art blood flow meters, the magnetic field is
uniform and the flowing blood is the conductor in which an
electromotive force is induced. In the magnetized embodiment
of the present invention, the motion of the leaflet produces
5 a varying magnetic field. A voltage is then induced in a
juxtaposed coil or wire, in contrast to the blood flow
meters discussed above, which use an applied field to
induce a voltage in the blood. No current or voltage need
be supplied to the artificial valve of the invention for
10 signal generation. In the coil-integrated embodiment of
the invention, motion of the conductor integrated within
the leaflet in an applied uniform magnetic field induces a
voltage therein which can be directly measured.

More specifically, the measurement technique of the
15 invention permits a direct indication of the motion of the
leaflet, which is a direct indication of its condition.
By comparison, the blood flow meters discussed above measure
only the velocity of the blood. This is a very important
clinical distinction. Observing the motion of the leaflets
20 is a much more accurate indicator of the condition of the
leaflets. Observing only the velocity of the blood through
the valve will not provide an indication of degradation of
the leaflets in all cases. For example, blood flow meters
may not allow detection of a calcified, stenotic heart
25 valve. The leaflets of a stenotic heart valve do not
move, although blood may still flow through the valve at
its normal rate. By comparison, the method of the invention
provides a direct indication of the movement of the leaflets.
Thus, stationary leaflets will be detectable using the
30 system of the invention.

In FIG. 1, an MIL valve prosthesis is shown having
been equipped with a solenoid coil. Typically such
prosthesis are manufactured together with supporting
structure (such as the woven material shown in FIG. 1) of
35 plastic, metal or combination thereof. According to the

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1 invention, a solenoid coil of concentrically wrapped wires
120 is tightly packed within the base 110 of the valve
100. The solenoid coil 120 is encased by a nontoxic
substance which is accepted by the surrounding tissue.
5 Two leads 140 connect the coil to the analysis equipment
(not shown). In this embodiment of the invention, each of
the heart leaflets 130 is implanted with magnetizing ions
or is surgically impregnated with magnetizing iron oxide
covered by a non-toxic substance which is acceptable to
10 the surrounding tissue. Motion of the magnetized prosthesis
leaflets then induces a current in the coil 120. The
current can be monitored for analysis of valve condition
and performance.

FIG. 1A provides an atrial view of the MIL valve,
15 while the ventricular view is provided in FIG. 1B. In
this case the valve is porcine, but other types of prosthetic
valves are within the scope of the invention. In both
figures, it will be noted that the solenoid coil 120 is
concentrically wrapped about the base 110 of the heart
20 valve 100, and that the heart leaflets 130 are indicated
as having been implanted or impregnated with magnetizing
ions at 150. FIG. 1C shows a side view of the MIL valve,
and indicates the location of the solenoid coil 120 within
the base 110 of MIL valve 100. Stationary leaflet supports
25 160 extend vertically downward from the base 110 of the
porcine heart valve 100 and contact the leaflets 130 as
they open.

Prior to the insertion of a MIL mitral valve
prosthesis into a heart, the necessary elements of the MIL
30 valve must be incorporated, and the valve leaflets must be
magnetized. In the case of porcine valve, the solenoid
coil is incorporated into the base 110 of the artificial
heart valve. The solenoid coil is treated with a non-
toxic substance so that the surrounding body tissue does
35 not reject it.

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1 In FIG. 1', a CIL valve prosthesis is shown equipped
with conductors. Again, the prosthetic valve can be porcine
or otherwise, and is manufactured together with supporting
structure (such as the woven material shown in FIG. 1') of
5 plastic, metal or both. According to the invention,
conductors 165, 170 and 180 are impregnated in the leaflets
130 of the porcine valve 100. The conductors 165, 170 and
180 are encased by a non-toxic substance which is accepted
by the surrounding tissue. Two leads 190 are connected to
10 each conductor 165, 170 and 180 and to the analysis equipment
(not shown). The conductors may be formed by ion
implantation in a suitable circuit pattern or by surgical
impregnation with actual wire conductors.

FIG. 1A' provides an atrial view of the CIL valve,
15 which the ventricular view is provided in FIG. 1B. In
both figures, it will be noted that the conductors 165,
170 and 180 are implanted or impregnated into the leaflets.
FIG. 1C' shows a side view of the CIL valve, including
leads 190 extending from conductors 165, 170 and 180.
20 Leaflet supports 160 extend vertically downward from the
base 110 of the porcine heart valve 100 and contact the
leaflets 130 as they open.

Prior to the insertion of a CIL porcine or non-
porcine mitral valve prosthesis into a heart, the valve
25 leaflets are impregnated with the conductors 160, 170 and
180. The conductors are treated with a non-toxic substance
so that the surrounding body tissue does not reject it.
Thereafter, if the patient is placed in a magnetic field,
a current will be induced in the coil upon motion of the
30 leaflets. The current can be detected for analysis of
valve performance.

The magnetization of the leaflets of the MIL valve
of the invention may be accomplished by surgical
implantation of magnetic material, for example, iron oxide
35 or samarium cobalt pellets. The coil of the CIL embodiment

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1 of the invention may be similarly surgically implanted.
Either embodiment of the invention may be implemented by
following the procedure set forth generally in Picraux and
Pearcy, Ion Implantation of Surfaces, Scientific American,
5 (March 1985) pp. 102-112, which is incorporated by reference
herein. According to that technique, a beam of magnetizing
ions is electrostatically accelerated into the surface of
a material. In this way, a controllable quantity of almost
any element can be mingled with a host material. In this
10 case an artificial heart valve leaflet, made either of
porcine or non-porcine substances, can be implanted with
foreign ions, either magnetizing or conductive ions, to
form a thin layer of substantially any desired configuration
at any predetermined depth.

15 More specifically, ions of the material to be
implanted, originate at one end of an accelerator in a
chamber in which electrons boil from a heated filament.
The ions are accelerated by electric fields. Another
electric field draws the ions from the chamber. The beam
20 of ions is focused and accelerated to high energies,
typically between 10 and 500 kiloelectron volts. Just
before the ions strike the target, varying electric fields
created by charged plates deflect the beam to eliminate
neutral particles and to sweep the beam across the target
25 for a uniform surface treatment. It is possible to
anticipate, and therefore to control, not only the depth
and distribution of the implanted atoms, but also the
change in composition (i.e. magnetic and conductive
composition) which they produce in the host material.

30 In this manner, magnetizing and/or conductive ions
can be ion-implanted in any desired configuration of lines,
defining circles or areas on the heart leaflets, whether
porcine or non-porcine, to create a valve which can be
conveniently monitored. In the MIL embodiment, the leaflets
35 would simply have a portion of their surfaces implanted

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1 with magnetic material. In the CIL embodiments, a circuit
of conductive material would be created.

After surgical insertion of the valves as described
below, motion of the leaflets can be detected. The MIL valve
5 involves induction of a current in a coil due to the motion
of magnetized material juxtaposed thereto, and follows
Faraday's Law:

$$10 \quad V = \oint \vec{E} \cdot d\vec{l} = - \frac{d}{dt} \int \vec{B} (t) \cdot d\vec{s} = - \frac{d\Phi}{dt}$$

where V = electromotive force (emf) induced;

$\vec{E}$ = induced electric field;

15 $\frac{d\vec{B}}{dt}$ = Time-varying magnetic field due to motion of the
magnetized leaflets;

$d\vec{s}$ = d (surface enclosed by the coil); and

20 Φ = flux.

In the CIL embodiment, conductors embedded in the
25 leaflets move in a steady magnetic field, and a current is
induced therein, obeying the following:

$$V = \int (\vec{U} \times \vec{B}) \cdot d\vec{l}; \quad \vec{U} = \frac{d\vec{y}}{dt}$$

V = emf induced;

30 $\vec{B}$ = uniform magnetic field;

$\frac{d\vec{y}}{dt}$ = velocity of the leaflet; and

35 l = length of the conductor.

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1 The remaining steps in the method of the invention
involve the insertion of an artificial porcine or non-
porcine valve for replacement of any malfunctioning heart
valve (i.e., the pulmonary, tricuspid, mitral or aortic
5 valves.) The replacement of the mitral and aortic valves
is discussed below. The surgical procedure described in
Schwartz, Principles of Surgery, 4th ed., pp. 826-841 (1985),
incorporated by reference herein, for removal and replacement
of heart valves, is followed.

10 FIG. 2 depicts the sequence of steps for the
replacement of the mitral valve following the method referred
to in the Principle of Surgery. FIG. 2a shows the making
of a median sternotomy incision 210 into the chest. As
shown in FIG. 2b, cannulae 220 and 222 are introduced
15 through the arterial wall 224 into the vena cava 226.
These cannulae connect the patient to an external pump for
performing the heart function during surgery. As shown in
FIG. 2c, the mitral valve 230 is exposed with an incision
in the left atrium 232 anterior to the point of entry of
20 the right pulmonary veins. As shown in FIG. 2d, the mitral
valve with the papillary muscles is completely excised
leaving a small annulus 240. As this point, the cavity of
the left ventricle is carefully inspected and a MIL or
CIL, porcine or non-porcine mitral valve is selected.
25 FIG. 2e, shows insertion of the prosthesis 250, which is
secured with 12-15 mattress sutures 252 of O-Dacron.
These mattress sutures may be buttressed with Teflon pledgets
on the ventricular surface. FIG. 2f shows a catheter 260
which is placed across the valve to keep the valve
30 incompetent, that is, open, to avoid air embolism. Referring
to FIG. 2g, the leads 140 connected to the coil in the
MIL-valve and to the conductors in the CIL-valve are drawn
through the atrial wall to the epicardium. Lastly, FIG.
2g shows the closing of the atriotomy incisions 274 around
35 the catheter 260, after which the heart is allowed to fill

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1 with blood and displace air. At that time, the catheter
260 is removed, which permits the left ventricle 272 to
contract normally, and the heart function is resumed.

5 The process of preparation and insertion of a MIL/CIL
porcine/non-porcine aortic valve prosthesis into the heart
is generally similar to that outlined above with respect
to the mitral valve. The valve preparation steps, implanting
the solenoid coil and magnetizing the artificial heart
10 leaflets, of the MIL valve forming coils on the leaflets
of the CIL valve, are as described above. The replacement
procedure described in Schwartz, Principle of Surgery, 4th
ed., pp. 838-839 (1985), incorporated by reference herein,
is preferred. As shown in FIG. 3a, a cardiopulmonary
15 bypass is instituted following cannulation of the right
atrium 314 with a single large cannula 312. The aorta is
opened with a oblique incision 310, initially begun about
a centimeter above the base of the right coronary artery
311. The aortic valve 320 is then excised as indicated at
FIG. 3b. As shown in FIGS. 3c and 3d, the aortic valve
20 prosthesis 330 in either MIL or CIL configurations is
sutured into a position as shown at 340. In FIG. 3e, the
valve 330 is sewn into the aortic cavity. The leads 140
connected to the coil of the MIL valve and to the conductors
of the CIL valve are drawn through the aorta to the
25 epicardium. Lastly, the aorta is closed with a synthetic
suture 360 as shown in FIG. 3f.

After the MIL or CIL porcine or non-porcine valve
has been secured into position, and the heart is operating,
the operation of the valve can be monitored. As discussed
30 above in connection with FIGS. 1 and 1', motion of the
blood through the heart valve 100 opens the leaflets 130
of the valve. The motion of the heart leaflets 130 induces
a voltage in the coil 120 of the MIL-valve, which may be
monitored. If a patient having had a CIL-valve replacement
35 installed as discussed above is then disposed in a magnetic

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1 field, a voltage is induced in the conductor formed on the
leaflets. In either case, the voltage is proportional to
the rate at which the leaflets on the MIL/CIL-valve open,
as described by Faraday's Law, discussed above. If the
5 leaflets on the MIL/CIL-valve are damaged, or become stiff,
or if blood diffuses around the valve base 110, the leaflets
do not open as rapidly, reducing the induced voltage. The
voltage signal is thus directly indicative of valve function.

FIGS. 4a and 4b, show both MIL and CIL embodiments
10 in schematic form. In the MIL system (FIG. 4a), the coil
120, which is concentric with the prosthetic valve 100, is
connected by leads 140 to a sensitive potentiometer 500
which is surgically implanted in the epicardium, in an
adjacent body cavity or on the body surface. Similarly,
15 in the CIL system (FIG. 4b), conductors 165, 170 and 180
which are implanted within the leaflets 130 of the prosthetic
valve 100, are connected by leads 140 to a sensitive
potentiometer 500 which is surgically implanted in either
the epicardium, in an adjacent body cavity or on the body
20 surface. The patient is exposed to a magnetic field B_0 ,
which passes through the CIL-valve. The field can be
generated either externally or internally to the patient's
body. In the internal configuration, one or more solenoid
coils are juxtaposed to the heart valve so that constant
25 lines of magnetic flux are directed through the CIL-valve.
In the external configuration, magnets direct lines of
flux through the body cavity and through the CIL-valve.

Electronic signal detection, amplification, and pro-
cessing apparatus is essentially similar in both embodiments
30 of the invention. For example, potentiometer 500 detects
the voltage signals generated from the valve. The potent-
iometer 500 is connected to a microamplifier 502, a filter
501 and suitable transmitter circuitry 503. The voltage
signals induced by either the MIL or CIL valve are filtered
35 at 501 for removal of noise generated by pacemakers, tran-

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1 sistor radios, etc. The signal can then be provided to an
analysis system (FIG. 4c). The connection can be by wire,
or by wireless transmission as shown. The signal is
transmitted at 503 to a receiver 504 external to the body.
5 The voltage signals are filtered a second time at 505 and
are then supplied to a microprocessor controlled diagnostic
system 506 for analysis. The voltage signals can be made
available for presentation on an external oscilloscope 508
for analysis by a physician, or can be analyzed by
10 microprocessor 506 for indication of dangerous valve
conditions. Such analysis can include comparison to prior
signals stored at 520, and correlation to data from other
instruments as indicated at 509, 550.

FIG. 5, shows flowchart form exemplary operations of
15 the diagnostic system 506. The diagnostic system 506
receives as input signals the MIL/CIL valve output signals.
These output signals can be conveniently displayed on an
oscilloscope 508 for monitoring of the valve function by a
physician. The diagnostic system 506 may also be provided
20 with data stored at 520 relating to normal operating
parameters, indicative of healthy valve signal amplitude
and morphology. The signals can be compared to the MIL/CIL
valve signal data at 530. If there is a detectable
deviation, the diagnostic system 506 will offer a series
25 of suggested reasons for the valve malfunction. When the
deviation is significant, the diagnostic system will activate
an alarm 535.

The data stored in the memory device 520 may included
data collected during prior examination of the particular
30 patient or from a large selection of patients. In the
preferred embodiment, the data stored will typically comprise
voltage signals produced by the particular MIL/CIL valve.
In addition to the MIL/CIL valve signals, other diagnostic
signals (i.e. EKG-output, blood pressure, respiratory rate,
35 temperature, etc. signals) may be jointly analyzed as

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1 indicated at 550 in order to better evaluate valve function.
For example, as indicated at 540, the phase of the EKG and
MIL/CIL signals may be compared.

5 It will be appreciated that there has been described
a new method of monitoring valve conditions and operations
by sensing a voltage induced in a coil by moving magnetized
leaflets or sensing the changes in voltage induced in
conductors carried by leaflets moved in a magnetic field.

10 The above description of the invention relates to
the use of the MIL and CIL valves and the method of the
invention in the operating theater and post-operative,
convalescent environments. The invention is also expected
to be useful in long-term monitoring of valve replacement
patients.

15 The invention has been described in an exemplary
and preferred embodiment, but is not to be limited thereto.
Those skilled in the art will recognize that a number of
additional modifications and improvements can be made to
the invention without departure from its essential spirit
20 and scope. Therefore, the invention is not to be limited
by the above disclosure, but only by the following claims.

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1 WHAT IS CLAIMED IS:

5 1. Method of replacement of a heart valve of a patient with a prosthetic valve and of monitoring operation of the prosthetic valve, comprising the steps of:

magnetizing one or more leaflets of a prosthetic valve;

10 surgically replacing a dysfunctional heart valve or dysfunctional prosthetic valve with said prosthetic valve, said step of surgical replacing including the step of juxtaposing a coil of wire to the prosthetic valve; and
monitoring the voltage induced in the coil of wire as a result of movement of the magnetized leaflets of the prosthetic valve.

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2. The method of claim 1, where said coil is formed integrally with said valve.

20 3. The method of claim 2, where said coil is formed integrally with a base portion of said valve to which said one or more leaflets are pivotally attached.

25 4. The method of claim 1, wherein said valve is sutured to a vessel at its base portion.

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5. The method of claim 1, wherein said leaflets are magnetized by ion implantation.

30 6. The method of claim 1, where said leaflets are magnetized by implantation of magnetized ion oxide pellets into one or more said leaflets.

35 7. The method of claim 1, where said step of surgically replacing a dysfunctional heart valve includes the step of implanting signal conditioning and/or processing

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1 circuitry in the patient.

8. The method of claim 1, wherein said step of
monitoring includes comparison of voltage signals derived
5 from said coil with stored data.

9. The method of claim 8, wherein said stored data
is data stored with respect to said patient.

10 10. As an article of manufacture, a prosthetic
heart valve comprising one or more magnetized leaflets.

11. The article of claim 10 further comprising a
coil of wire located in predetermined relation to said
15 leaflets.

12. The article of claim 11 wherein said coil of
wire is disposed in a base portion of said valve to which
said one or more magnetized leaflets are pivotally mounted.

20 13. The article of claim 12 wherein said base
portion is adapted to be sutured to a vessel.

14. In combination:
25 a prosthetic heart valve having one or
more magnetized leaflets;
a coil of wire juxtaposed to said valve in
order to have a voltage induced therein as a result of
movement of said magnetized leaflets; and
30 a diagnostic device adapted to be connected
to said coil and to analyze the voltages induced therein.

15. The combination of claim 14 wherein said coil
of wire is formed integrally with said valve.

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1 16. The combination of claim 15 where said coil of
wire is formed within a base portion of said valve to
which said leaflets are pivotally attached.

5 17. The combination of claim 16 wherein said base
portion of said valve is adapted to be sutured to a vessel.

10 18. The combination of claim 14 further comprising
signal processing means adapted to be implanted in the
body of a patient.

15 19. The combination of claim 14 wherein said
diagnostic device comprises means for comparing voltages
induced in said coil with stored comparison data.

20 20 The combination of claim 19 further comprising
additional physiological monitoring devices and wherein
said diagnostic device comprises means for comparing voltages
induced in said coil with data produced by said additional
physiological monitoring devices and with stored comparison
data.

25 21. The combination of either claim 19 ~~and~~ 20 wherein
said stored comparison data is derived from a particular
patient for subsequent comparison.

30 22. The combination of claim 14, further comprising
oscilloscope means for providing a visible display responsive
to the voltage induced in said coil.

35 23. The combination of claim 14 further comprising
means responsive to said diagnostic device for providing
an assessment of valve condition.

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1 24. Method of replacement of a heart valve of a patient with a prosthetic valve and of monitoring operation of the prosthetic valve, comprising the steps of:

 attaching one or more conductors to one or
5 more leaflets of a prosthetic valve;

 surgically replacing a dysfunctional heart valve or dysfunctional prosthetic valve with said prosthetic valve;

 directing a magnetic field through the
10 prosthetic valve; and

 monitoring the voltage induced in said one or more conductors as a result of movement of said one or more leaflets of the prosthetic valve.

15 25. The method of claim 24 wherein said magnetic field is produced by a magnetic field generated within the body of the patient.

 26. The method of claim 24 wherein said magnetic
20 field is produced by means outside the body of the patient.

 27. The method of claim 24 wherein said valve comprises a base portion adapted to be sutured to a vessel.

25 28. The method of claim 24 wherein said conductors are formed on said leaflets by implantation thereof with conductive ions.

 29. The method of claim 24 wherein said conductors
30 are discrete wires.

 30. The method of claim 24 wherein said step of surgically replacing a dysfunctional heart valve includes the step of implanting signal conditioning and processing
35 circuitry in the patient.

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1 31. The method of claim 24 wherein said step of
monitoring includes comparison of signals derived from
said one or more conductors with stored data.

5 32. The method of claim 31 wherein said stored
data is data stored with respect to said patient.

10 33. As an article of manufacture, a prosthetic
heart valve comprising one or more leaflets each having
one or more electrical conductors formed thereon.

 34. The article of claim 33 wherein said conductors
are formed on said leaflets by ion implantation.

15 35. The article of claim 34 wherein said leaflets
pivot on a base portion adapted to be sutured to a vessel.

 36. In combination:

20 a prosthetic heart valve comprising one or
more leaflets each having one or more conductors integrated
therewith;

 means for generating a magnetic field
passing through said valve; and

25 a diagnostic device adapted to be connected
to said conductors and to analyze the voltages induced
therein.

30 37. The combination of claim 36 wherein said magnetic
field is produced by coils within the confines of the body
of a patient and juxtaposed to the valve.

 38. The combination of claim 36 wherein said magnetic
field is produced by coils outside of the confines of the
body of the patient.

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1 39. The combination of claim 38 wherein said valve
comprises a base portion adapted to be sutured to a vessel.

5 40. The combination of claim 36 wherein said
conductors are formed by implantation of conductive ions
on said leaflets.

10 41. The combination of claim 36 wherein said
conductors are discrete wires which are integrated into
said leaflets.

15 42. The combination of claim 36 further comprising
signal processing means adapted to be implanted in the
body of a patient.

 43. The combination of claim 36 wherein said
diagnostic device comprises means for comparing voltages
induced in said conductors with stored comparison data.

20 44. The combination of claim 43 wherein said stored
comparison data is derived from a particular patient for
subsequent comparison.

25 45. The combination of claim 43 wherein said
diagnostic device further comprises additional physiological
monitoring devices and comprises means for analyzing voltages
induced in said coil using signals produced by said
additional devices.

30 46. The combination of claim 36 further comprising
oscilloscope means for providing a visible display responsive
to the voltage induced in said conductors.

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1 47. The combination of claim 46 further comprising
means responsive to said diagnostic device for generating
an assessment of valve condition.

5 48. A prosthetic heart valve, comprising one or
more leaflets adapted to move responsive to passage of
blood through said valve; and
 signal generation means for generating a
detectable signal responsive to motion of said one or more
10 leaflets.

 49. The valve of claim 48, wherein said leaflets
are magnetized and said signal generation means is a
conductor juxtaposed to said leaflets.

15 50 The valve of claim 49, wherein said conductor
is a coil.

 51. The valve of claim 50, wherein said leaflets
20 are pivotally mounted to a generally circular base portion
of said valve adapted to be sutured to a vein and said
coil is disposed around said base portion of said valve.

 52. The valve of claim 48, wherein said one or
25 more leaflets comprise conductors, and said signal generation
means comprise means for applying a magnetic field to said
valve in operation.

 53. The valve of claim 52, wherein said conductors
30 are formed by implantation of conductive ions in the surface
of the one or more leaflets.

 54. The valve of claim 52, wherein said conductors
comprise wires surgically integrated with said leaflets.

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1 55. The valve of any of claim 52-54 in combination
with surgically implantable means for applying a magnetic
field to said valve in operation.

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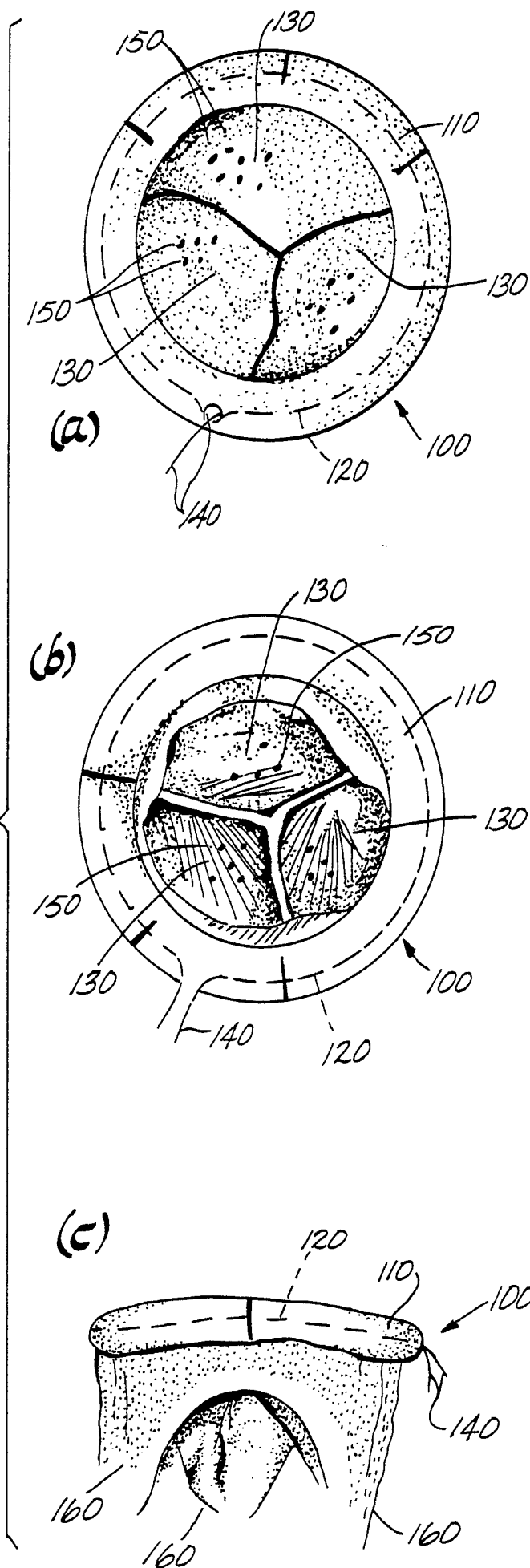
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Fig.
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Fig. 1'

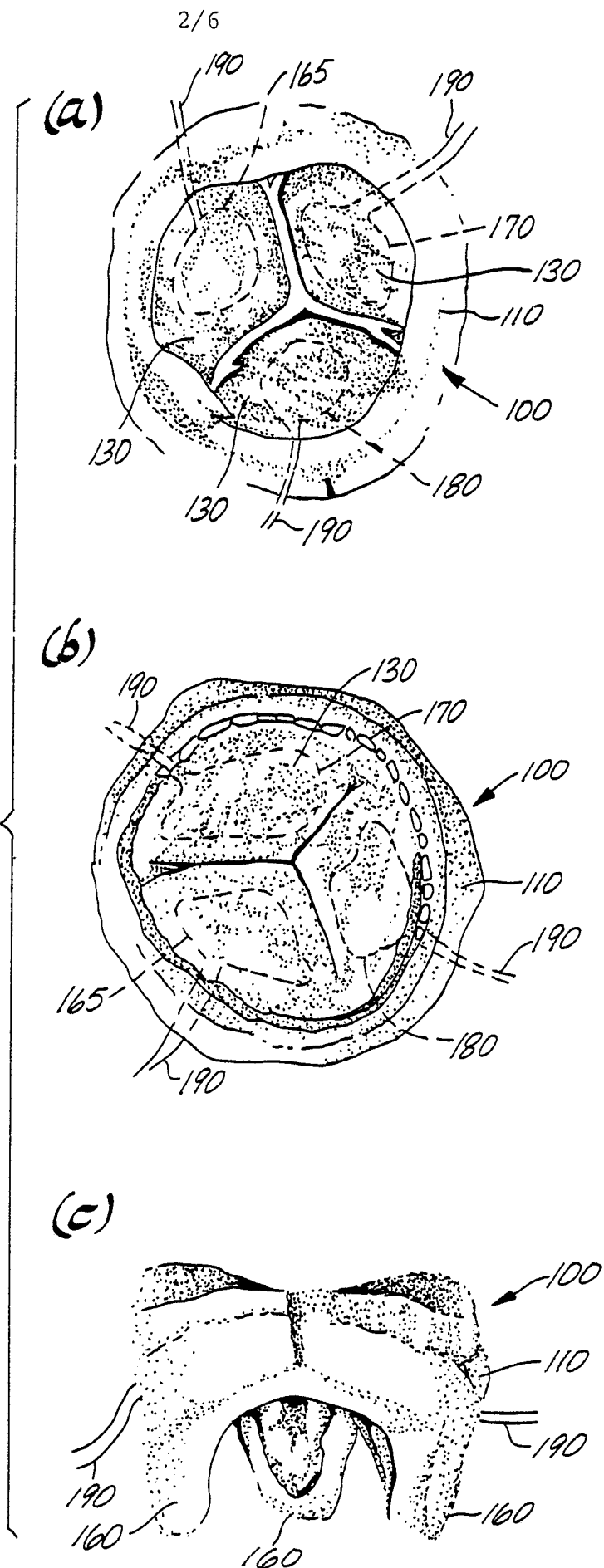


Fig. 2

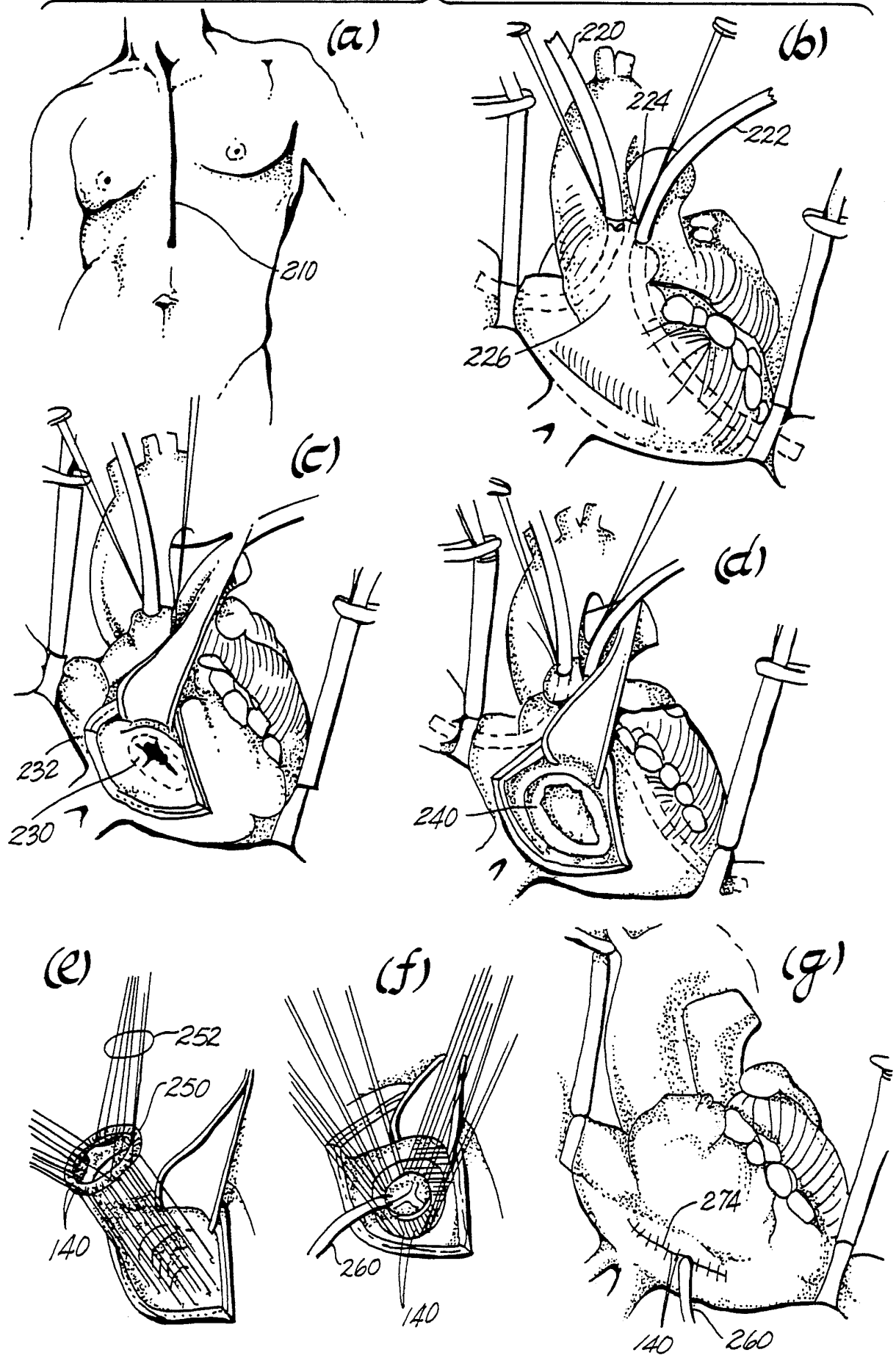
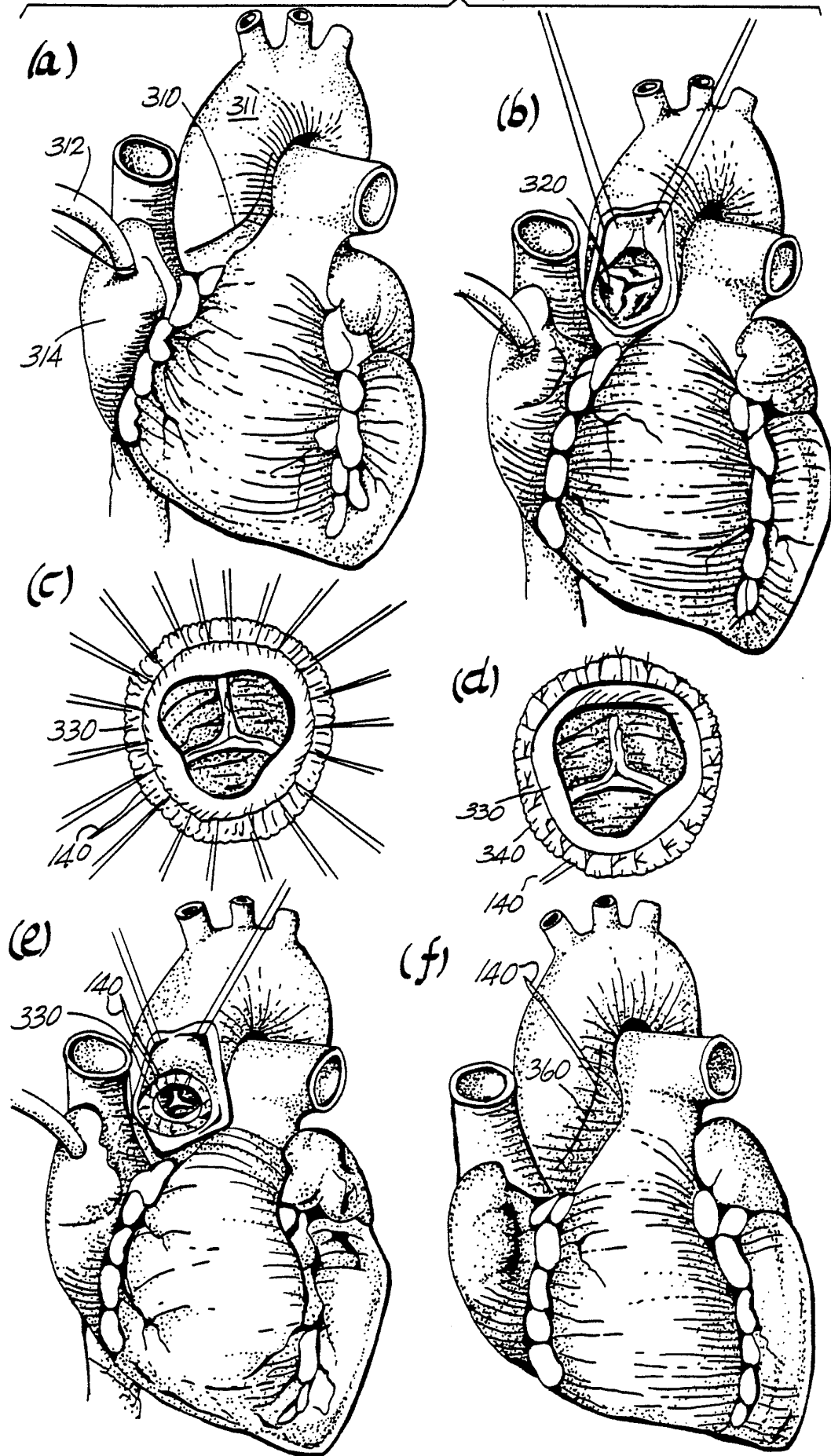
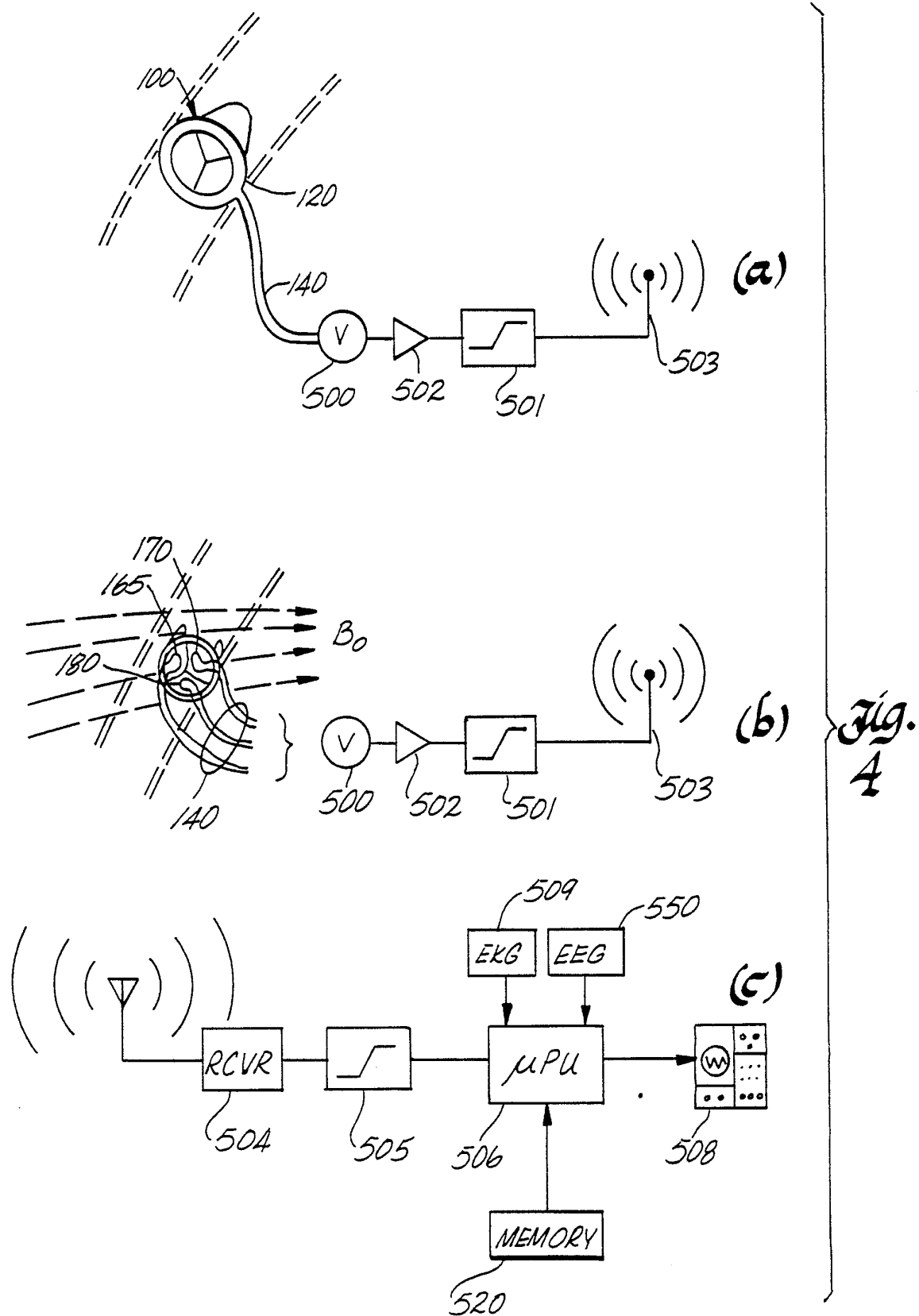


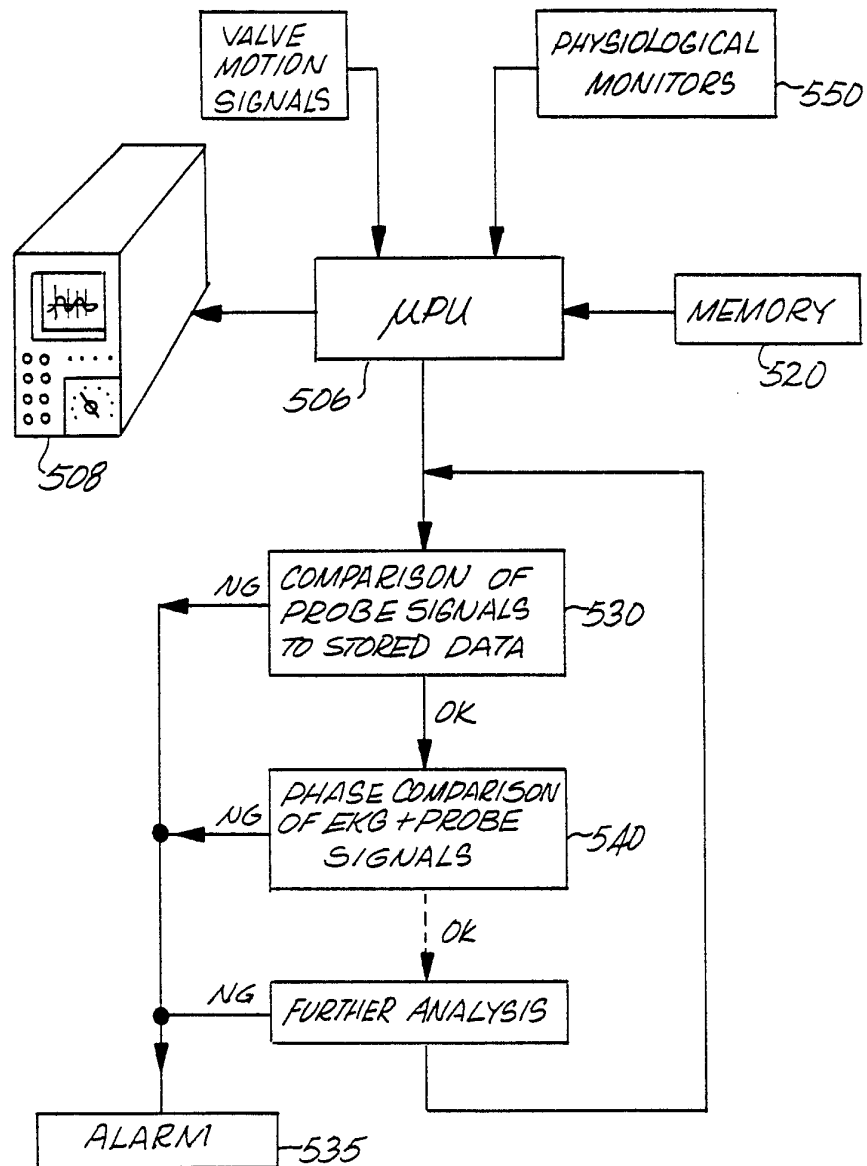
Fig. 3





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Fig. 5



INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 87/00494

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) ⁶ According to International Patent Classification (IPC) or to both National Classification and IPC IPC ⁴ : A 61 F 2/24; A 61 B 5/10		
II. FIELDS SEARCHED		
Minimum Documentation Searched ⁷		
Classification System	Classification Symbols	
IPC ⁴	A 61 F; A 61 B	
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched ⁸		
III. DOCUMENTS CONSIDERED TO BE RELEVANT ⁹		
Category ⁹	Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³
X	US, A, 4417360 (MOASSER) 29 November 1983 see abstract; figures 1,3,10	10
Y	--	11-14,33, 34
Y	US, A, 4342086 (F. ADIB) 27 July 1982 see figures 1-3	11-14
A	US, A, 4378022 (SUOBANK et al.) 29 March 1983 see abstract; figures 5,6,9-12	19,21-23, 43-47,49
Y	US, A, 3803571 (H.G. LUZ) 9 April 1974 see figures 1-3	33,34
X	US, A, 4349498 (ELLIS et al.) 14 September 1982 see abstract; column 6, lines 56-63	48

[*] Special categories of cited documents: ¹⁰ "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	Date of Mailing of this International Search Report	
16th June 1987	12 JUL 1987	
International Searching Authority	Signature of Authorized Officer	
EUROPEAN PATENT OFFICE	M. VAN NOL	

FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

V. ☒ OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE ¹

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 ~~XX~~, because they relate to subject matter not required to be searched by this Authority, namely:

~~XX~~ Claims 1-9, 24-32

See PCT Rule 39.1(iv)

Methods for treatment of the human or animal body by means of surgery or therapy, as well as diagnostic methods.

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, specifically:

3. ☐ Claim numbers, because they are dependent claims and are not drafted in accordance with the second and third sentences of PCT Rule 6.4(a).

VI. ☐ OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING ²

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.

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON
-----INTERNATIONAL APPLICATION NO. PCT/US 87/00494 (SA 16543)

This Annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on 03/07/87

The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US-A- 4417360	29/11/83	None	
US-A- 4342086	27/07/82	None	
US-A- 4378022	29/03/83	None	
US-A- 3803571	09/04/74	FR-A- 2157300	01/06/73
		DE-A,B,C 2152406	26/04/73
		GB-A- 1350848	24/04/74
		SE-B- 379275	06/10/75
US-A- 4349498	14/09/82	None	

For more details about this annex :
see Official Journal of the European Patent Office, No. 12/82