

683078

NOTICE OF ENTITLEMENT

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of 7000 Central Avenue, NE, Minneapolis, Minnesota, 55432,
United States of America

the applicant and nominated person in respect of an application for a patent for an invention entitled:
Determining hemodynamic variables from a pressure sensor

filed under Australian Application No. 73159/94 state the following:

PART 1 - Must be completed for all applications.

The person(s) nominated for the grant of the patent

☐ is (are) the actual inventor(s)

~~or~~

☒ has, for the following reasons, gained entitlement from the actual inventor(s)
The nominated person is the assignee of the invention from the said
actual inventor(s)

PART 2 - Must be completed if the application is a Convention application.

The person(s) nominated for the grant of the patent is (are):

☐ the applicant(s) of the basic application(s) listed on the patent request form
or

☐ entitled to rely on the basic application(s) listed on the patent request form by reason of the following:

PART 3 - Must be completed if the application was made under the PCT and claims priority.

The person(s) nominated for the grant of the patent is (are):

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The nominated person is the assignee of the application from the said
actual inventor(s)

Dated this 19th day of February 19 96

Signature Harold R. Patton

Signatory's Name Harold R. Patton, Vice President and Chief Patent Counsel



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DETERMINING HEMODYNAMIC VARIABLES FROM A PRESSURE SENSOR
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- (56) Prior Art Documents
US 4566456
WO 92/03183
US 4986270
- (57) Claim

1. A pressure monitoring system for determining the hemodynamic status of a patient from measurements of right ventricular pressure obtained from a single absolute pressure sensor, comprising:

an absolute pressure sensor which provides an output signal having an amplitude which varies according to said right ventricular pressure, adapted to be implanted in said right ventricle of said patient;

first and second holding means;

means for detecting R-waves and for enabling said first and second holding means to store output signal amplitudes upon detecting an R-wave;

differentiation means for deriving a first derivative value of said output signal;

storage means for storing a first amplitude of said output signal in said first holding means in response to the first time said first derivative value is less than zero following detection of an R-wave, wherein said first stored output signal amplitude is equal to said patient's pulmonary artery systolic pressure;

(11) AU-B-73159/94
(10) 683078

-2-

differentiation means for deriving a second derivative value of said output signal; and

storage means for storing a second amplitude of said output signal in said second holding means in response to the first time said second derivative value is less than zero following detection of an R-wave, wherein said second stored output signal amplitude is equal to said patient's pulmonary artery diastolic pressure.



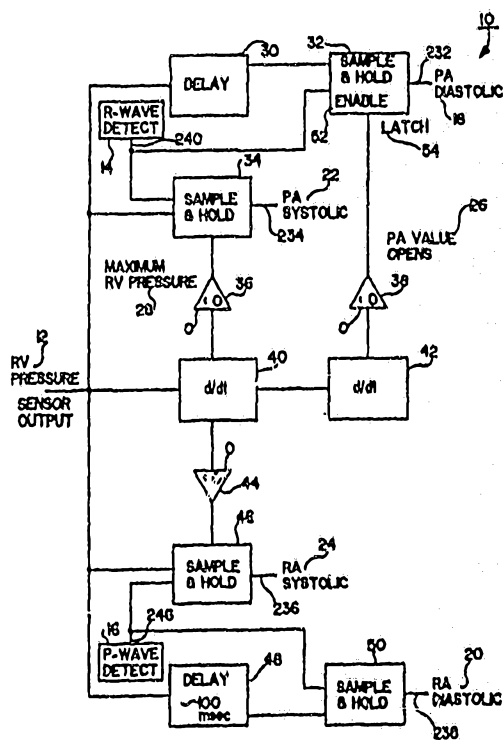
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683078

(54) Title: DETERMINING HEMODYNAMIC VARIABLES FROM A PRESSURE SENSOR

(57) Abstract

A system and method for determining the hemodynamic status of a heart patient detects pulmonary artery systolic and diastolic pressure as well as right atrial systolic and diastolic pressure from pressure measurements obtained from a single absolute pressure sensor implanted in the patient's right ventricle.



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APPARATUS AND METHOD FOR DETERMINING A PLURALITY
OF HEMODYNAMIC VARIABLES FROM A SINGLE,
CHRONICALLY IMPLANTED ABSOLUTE PRESSURE SENSOR

5

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates to implantable medical devices,
and more specifically, relates to chronically implantable
10 devices for determination of a plurality of hemodynamic
variables including but not limited to right atrial
pressure and pulmonary arterial pressure.

2. Description of the Prior Art

Intravascular pressure sensors are known in the art.
15 U.S. Patent No. 4,407,296 issued to Anderson teaches a
chronically implantable pressure transducer suitable for
use in the cardiovascular system. A pressure transducer
with an improved electronic circuit is taught in U.S.
Patent No. 4,432,372, issued to Monroe. A further improved
20 pressure transducer is taught in U.S. Patent No. 4,485,813,
issued to Anderson et al. These pressure sensors have been
directed to the control of artificial cardiac pacers using
algorithms which convert measurements of pressure or change
of pressure into pacing rate.

25 Increases in the complexity of pacemakers and other
implantable medical devices have increased efforts at
producing sensors and transducers to monitor a variety of
physiologic functions. Such transducers allow the
exploitation of the additional capability of such medical
30 devices.

The measurements of pressures (particularly pulmonary
wedge pressure and central venous pressure) inside the
heart are typically used to determine the health of the
patient and provide a proper therapy. A number of
35 restrictions are placed on defining the approach to a
chronically implantable pressure sensor. Three of these
restrictions are:

- (1) it is generally unacceptable to implant any
hardware on the left side of the heart, so



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pressures are normally measured from the right side,

- (2) a chronic wedge pressure measurement is unacceptable due to pulmonary infarction, and
- 5 (3) chronically implanted leads in the pulmonary artery have not yet been proven to be safe.

One system for treating a malfunctioning heart based on hemodynamics i.e., the pressure at a site in a patient's circulatory system is taught in U.S. Patent No. 4,986,270,
10 issued to Cohen.

None of these references teaches the use of a single, chronically implanted absolute pressure sensor in the right ventricle for determining a plurality of hemodynamic variables, i.e., right atrial pressure, right ventricular
15 pressure, and pulmonary arterial pressure in a patient.

SUMMARY OF THE INVENTION

The present invention is a method and apparatus to determine the hemodynamic status of a patient from
20 measurements of pulmonary pressure and right atrial pressure obtained from a single absolute pressure sensor implanted in the right ventricle. Both of these values have been shown to correlate with the degree of cardiac failure of a patient. The inventive technique employs
25 continual monitoring of the right ventricular pressure using an absolute pressure sensor and marking the right ventricular pressure at the moment of specific events.

When the pulmonary valve is open during right ventricular systole, the pressure in the right ventricle is
30 nearly identical to the pulmonary arterial pressure. Therefore, pulmonary artery systolic pressure equals right ventricle systolic pressure. This pressure can be determined using the right ventricular pressure by:
pulmonary artery (PA) systolic pressure = right ventricle
35 (RV) pressure at the time $dp_{RV}/dt = 0$ during ventricular systole.

The pulmonary artery diastolic pressure is similarly determined from the right ventricle. As long as the pulmonary artery pressure is higher than the right



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ventricle pressure, the pulmonary valve is closed. As the ventricle begins to contract during systole, however, the right ventricle pressure surpasses the pulmonary artery pressure and the valve opens. The pressure in the
5 pulmonary artery at the time the valve opens is the lowest pressure seen by the pulmonary artery and, therefore, is the pulmonary artery diastolic pressure. Thus, the pulmonary artery diastolic pressure is the pressure in the right ventricle at the moment the pulmonary artery valve
10 opens. The time at which the valve opens has been shown to be nearly identical to the time of maximum dP_{RV}/dt . Therefore, in one preferred embodiment, the pulmonary artery diastolic pressure can be determined using right ventricular pressure by:

15 PA diastolic pressure = RV pressure at the time $d^2P_{RV}/dt^2 = 0$ at the start of systole.

In another preferred embodiment, the pulmonary artery diastolic pressure can be determined directly using right ventricular pressure at the requisite moment determined
20 with the aid of ultrasound measurements.

In a further preferred embodiment, the pulmonary artery diastolic pressure can be determined with the aid of acoustic signature measurements to determine the precise moment in time that the right ventricular pressure is
25 equivalent to the pulmonary artery diastolic pressure.

In yet another preferred embodiment, the precise moment for determining the validity of the pulmonary artery diastolic pressure can be determined by impedance change
30 measurements performed on the patient.

From the above discussion, it is apparent that numerous ways and methods can be used to determine the precise moment in time when the pulmonary valve opens. Therefore, the present invention, although discussed in
35 terms relating to calculation of derivatives of ventricular pressure measurements, is not so limited.

Right atrial systolic and diastolic pressure can also be determined from an absolute pressure sensor in the right ventricle with the present inventive apparatus and method.



AMENDED SHEET

This is possible because the valve between the right atrium and right ventricle is open at all times except during right ventricular contraction. Therefore, the atrial diastolic pressure is the same as the right ventricular pressure just prior to atrial contraction (atrial pulse or P-wave sense). Atrial systolic pressure can be determined in much the same way as pulmonary artery systolic pressure. In this case however, the inventive apparatus must find $dp/dt = 0$ after the start of atrial systole.

The present invention is applicable anywhere that the measurement of hemodynamic status is important, and includes, but is not limited to the diagnosis of the severity of congestive heart failure, pulmonary artery disease, and pulmonary hypertension or the measurement of hemodynamic variables like vascular resistance, contractility, etc. For example, the maximum dp/dt signal derivation capability of the present invention can also approximate contractility; and the RV diastolic pressure in combination with mean arterial pressure (e.g. measured by a cuff) and a separate measure of cardiac output (measured either invasively or noninvasively) can provide a measure of vascular resistance.

Other features and advantages of the present invention will be set forth in, or become apparent from, the following description and claims and illustrated in the accompanying drawings, which disclose by way of example and not by way of limitation, the principle of the invention and the structural implementation of the inventive concept. For example, the present invention can be used to control devices that provide therapy i.e., cardiac pacemakers, defibrillators or drug pumps.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGURE 1 is a partially block, schematic diagram of a control system, responsive to a right ventricular pressure sensor signal, an ECG R-wave signal and an ECG P-wave signal.



APPENDIX SHEET

FIGURE 2 is a block diagram of an implantable telemetry system which incorporates the control system of Fig. 1.

5 FIGURE 3 is a diagrammatic, generalized illustration of an exemplary, right ventricular, implanted absolute pressure sensor and an associated telemetry device such as that illustrated in Fig. 2.

FIGURE 4 is an illustration of an absolute pressure sensor positioned within a heart.

10 FIGURE 5A illustrates a typical ECG signal.

FIGURE 5B illustrates a typical right ventricular pressure signal.

15 FIGURE 5C illustrates a signal derived from the derivative of the signal depicted in Fig. 5B, and which can be used to determine pulmonary artery systolic pressure as well as right atrial systolic and diastolic pressure.

FIGURE 5D illustrates a signal derived from the derivative of the signal depicted in Fig. 5C, and which can be used to determine pulmonary artery diastolic pressure.

20 FIGURE 6A illustrates an actual patient cardiac waveform of an ECG signal.

FIGURE 6B illustrates actual patient cardiac waveforms of pulmonary artery pressure and right ventricular pressure signals.

25 FIGURE 6C illustrates a waveform resulting from the derivative (dp/dt) of the right ventricular pressure signal depicted in Fig. 6C.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

30 Starting generally with Fig. 1, there is depicted one embodiment of a pressure sensing circuit 10 which forms part of an implantable monitoring device 302 illustrated in Fig. 3 and used for determining the hemodynamic status of a patient. It is to be understood that device 302 is
35 contained within a hermetically-sealed, biologically inert outer shield or "can", in accordance with common practice in the art. The sensing circuit 10 is operable in conjunction with an implantable absolute pressure sensor 402 which is implanted in the patient's right ventricle as



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depicted in Fig. 4. Implantable monitoring device 302 includes pressure sensing circuit 10 as well as additional control, power, memory and transmission circuitry illustrated in Fig. 2 and hereinafter discussed in detail.

5 Operation of the implantable monitoring device 302 will now be discussed in more detail with reference to FIG's 1-6. As stated hereinbefore, the measurements of pressures, particularly pulmonary wedge pressure inside the heart are typically used to determine the health of a patient and provide a proper therapy. One illustrative method for determining pulmonary artery and right arterial diastolic and systolic pressure begins with reference to the simplified block diagram of pressure sensing circuit 10 illustrated in Fig. 1. The basic functional components are 10 differentiators 40,42, comparators 36,38,44, sample-and-holds 32,34,46,50, and delays 30,48. Embodiment 10 also requires the output 14 from an R-wave sense amplifier (not illustrated in Fig. 1) and the output 16 from a P-wave sense amplifier (not illustrated in Fig. 1), but known to 20 those skilled in the art of cardiac pressure monitoring. Operation of the preferred embodiment 10 shown in Fig. 1 begins by twice differentiating the signal 12 from an absolute pressure sensor 402 which is chronically implanted in the right ventricle, to provide dP/dt and d^2P_{RV}/dt^2 . A 25 typical ECG signal is illustrated in Fig. 5A while its associated right ventricular (RV) pressure sensor waveform 12 is shown in Fig. 5B. Differentiator 40 provides an output signal 502 illustrated in Fig. 5C which is the first derivative of waveform 12. Differentiator 42 provides an 30 output signal 504 illustrated in Fig. 5D which is the second derivative of waveform 12.

Looking at the waveforms shown in FIG's 5A - 5D, it can be seen that the maximum RV (and PA) systolic pressure occurs the first time after the R-wave 506 that dP/dt 502 goes negative (passes through zero). It follows (from the 35 discussion above) that the maximum dP/dt (PA diastolic pressure) occurs the first time after the R-wave 506 that d^2P_{RV}/dt^2 504 goes negative.



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Fig. 6A illustrates an actual human cardiac ECG waveform. The ECG P-wave 602 and R-wave 604 are obvious.

Looking now at Fig. 6B, actual cardiac waveforms of a patient's pulmonary artery (PA) pressure and right ventricular (RV) pressure are illustrated. From Fig. 6B it can be seen that the PA diastolic pressure (minimum PA) occurs at nearly the same pressure where the PA pressure and RV pressure signals cross each other.

Fig. 6C is the dP/dt waveform 606 resulting from a first derivative of the patient's RV pressure signal 12. It is important here to note that the peak of dP/dt waveform 606 occurs at the same time that the PA pressure 18 equals the RV pressure 12.

Referring again to Fig. 1, the PA systolic pressure 22 is determined by feeding the RV pressure sensor output 12 into a sample and hold circuit 34. The sample and hold circuit 34 is enabled by the sensing of the R-wave 506 shown in Fig. 5A. The systolic pressure 22 is then latched when dP/dt 502 illustrated in Fig. 5C goes negative as determined by comparator 36 output signal 28. This value of systolic pressure will be held until the next R-wave 506 is sensed, enabling the sample and hold circuit 34 to change values.

Similarly, the PA diastolic pressure is determined by feeding the RV pressure 12 into a sample and hold circuit 32 which is latched by comparator 38 the first time that d^2P_{RV}/dt^2 504 illustrated in Fig. 5D goes negative after a sensed R-wave 506. In this case, a short delay 30 in the pressure signal path balances the electronic delays in the two signal paths, keeping the timing synchronized.

From the above description of the present invention, it is apparent that numerous pressure readings other than those described hereinbefore, can be obtained with the present invention. For example, the present invention can be used to obtain right ventricular systolic and diastolic maximum dP/dt , etc.

Measurement of atrial pressures can also be accomplished similarly as follows. The right atrial (RA) systolic pressure 24, like PA systolic pressure 22, is



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latched by a sample and hold circuit 46. Unlike PA pressure measurements however, latching occurs the first time that dP/dt 502 passes through zero subsequent to detection of a P-wave 508 as depicted in Fig. 5A. RA diastolic pressure 20 is determined in the preferred embodiment shown in Fig. 1 by latching the RV pressure 12 at a time (eg. 100 msec) before the RA systolic pressure 24 measurement of interest. This is accomplished by delaying the RV pressure signal 12 with a delay circuit 48, and then latching the delayed signal with a sample and hold circuit 50 upon detection of a p-wave 508.

The preferred embodiment 10 described hereinbefore and illustrated in Fig. 1 is shown as pressure sensing circuit 10 in Fig. 2. Turning now to Fig. 2, there is illustrated in block diagram form, a complete implantable pressure telemetry system 200 for measurement and transmission of patient pulmonary and venous pressure values to an external communication device.

Although a particular implementation of a pulmonary and venous pressure measurement and telemetry system 200 is disclosed herein, it is to be understood that the present invention may be advantageously practiced in conjunction with many different types of telemetry systems.

Telemetry circuit 202 is schematically shown in Fig. 2 to be electrically coupled via P-wave/R-wave sensor leads 240, 246 and RV pressure sensor leads 404, 406 to a patient's heart 400. Leads 240, 246, 404, 406 can be of either the unipolar or bipolar type as is well known in the art; alternatively, a single, multiple-electrode lead may be used.

Telemetry system 200 contains the analog circuits 202 for interface to the heart 400, an antenna 230, and circuits (not shown, but conventional to those skilled in the art) for the detection of pressure signals from the heart 400.

It will be understood that each of the electrical components represented in Fig. 2 is powered by an appropriate implantable battery power source 206, in accordance with common practice in the art. For the sake



AMENDED SHEET

of clarity, the coupling of battery power to the various components of telemetry circuit 202 has not been shown in the Figures.

5 An antenna 230 is connected to telemetry circuit 202 for purposes of uplink/downlink telemetry through an RF transmitter and receiver unit 224. Unit 224 may correspond to the telemetry and program logic employed in U.S. Patent No. 4,556,063 issued to Thompson et al. on December 3, 1985 and U.S. Patent No. 4,257,423 issued to McDonald et al. on 10 March 24, 1981, both of which are incorporated herein by reference in their entirety. Telemetering analog and/or digital data between antenna 230 and an external device, such as the aforementioned external communication device (not shown in Fig. 2), may be accomplished in the presently 15 disclosed embodiment by means of all data first being digitally encoded and then pulse-position modulated on a damped RF carrier, as substantially described in U.S. Patent No. 5,127,404 issued to Wyborny et al entitled "Improved Telemetry Format", which is assigned to the 20 assignee of the present invention and which is incorporated herein by reference in its entirety.

A crystal oscillator circuit 228, typically a 32,768-Hz crystal-controlled oscillator, provides main timing clock signals to digital controller/timer circuit 216. A 25 V_{REF} and Bias circuit 220 generates stable voltage reference and bias currents for the telemetry system 200 analog circuits. An analog-to-digital converter (ADC) and multiplexer unit 222 digitizes analog signals and voltages to provide "real-time" telemetry communication signals and 30 battery end-of-life (EOL) replacement functions. A power-on-reset (POR) circuit 226 functions as a means to reset circuitry and related functions to a default condition upon detection of a low battery condition, which will occur upon initial device power-up or will transiently occur in the 35 presence of electromagnetic interference, for example.

The timing functions of telemetry system 200 are controlled by event timer 204 in conjunction with digital controller/timer circuit 216 wherein digital timers and counters are employed to establish the overall event timing



AMENDED SHEET

of the telemetry system 200, including timing windows for controlling the operation of the peripheral components within telemetry circuit 202.

5 Event timer 204 monitors the pressure event signals received from heart 400 by pressure sensing circuit 10, and handshakes with digital controller/timer circuit 216 on a bidirectional bus 208 to synchronize measurement of and rf transmission of the desired pressure signal values to an external communication device.

10 Digital controller/timer circuit 216 is coupled to pressure sensing circuit 10. In particular, digital controller/timer circuit 216 receives PA diastolic signal 18 on line 232, PA systolic signal 22 on line 234, RA diastolic signal 20 on line 238 and RA systolic signal 24
15 on line 236. P-wave and R-wave sense amplifiers (not shown) are coupled to leads 240 and 246, in order to receive ECG signals from heart 400. The sense amplifiers correspond, for example, to that disclosed in U.S. Patent No. 4,379,459 issued to Stein on April 12, 1983,
20 incorporated by reference herein in its entirety.

 Sense amplifier sensitivity control (also not shown) is provided to adjust the gain of sense amplifier circuitry in accordance with programmed sensitivity settings, as would be appreciated by those of ordinary skill in the
25 pacing art.

 While a specific embodiment of pressure sensing circuit 10 has been identified herein, this is done for the purposes of illustration only. It is believed by the inventor that the specific embodiment of such a circuit is
30 not critical to the present invention so long as it provides means for temporarily storing PA and RA systolic and diastolic pressures and providing digital controller/timer circuit 216 with signals indicative of PA and RA systolic and diastolic pressures accordingly. It is
35 also believed that those of ordinary skill in the art could choose from among the various well-known implementations of such circuits in practicing the present invention.

 While the invention has been described above in connection with the particular embodiments and examples,



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one skilled in the art will appreciate that the invention is not necessarily so limited. It will thus be understood that numerous other embodiments, examples, uses, modifications of, and departures from the teachings
5 disclosed may be made, without departing from the scope of the present invention as claimed herein.



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WHAT IS CLAIMED IS:

1. A pressure monitoring system for determining the hemodynamic status of a patient from measurements of right ventricular pressure obtained from a single absolute pressure sensor, comprising:

an absolute pressure sensor which provides an output signal having an amplitude which varies according to said right ventricular pressure, adapted to be implanted in said right ventricle of said patient;

first and second holding means;

means for detecting R-waves and for enabling said first and second holding means to store output signal amplitudes upon detecting an R-wave;

differentiation means for deriving a first derivative value of said output signal;

storage means for storing a first amplitude of said output signal in said first holding means in response to the first time said first derivative value is less than zero following detection of an R-wave, wherein said first stored output signal amplitude is equal to said patient's pulmonary artery systolic pressure;

differentiation means for deriving a second derivative value of said output signal; and

storage means for storing a second amplitude of said output signal in said second holding means in response to the first time said second derivative value is less than zero following detection of an R-wave, wherein said second stored output signal amplitude is equal to said patient's pulmonary artery diastolic pressure.

2. A pressure monitoring system according to claim 1, further comprising:

third and fourth holding means;

means for detecting P-waves and for enabling said third and fourth holding means to store signal amplitudes upon detecting a P-wave;

storage means for storing a third output signal amplitude value in said third holding means in response to



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said first derivative value being less than zero for the first time following said detected P-wave, wherein said third stored output signal amplitude is equal to said patient's right atrial systolic pressure;

5 delay means for delaying said output signal to provide a delayed output signal; and

storage means for storing a delayed output signal amplitude value in said fourth holding means in response to detection of a P-wave, wherein said stored delayed output signal amplitude is equal to said patient's right atrial diastolic pressure.

10 3. A pressure monitoring system for determining the hemodynamic status of a patient from measurements of right ventricular pressure obtained from a single absolute pressure sensor, comprising:

first and second holding means;

15 means for detecting P-waves and for enabling said first and second holding means to store signal amplitudes upon detection of a P-wave;

storage means for storing an output signal amplitude value in said first holding means in response to a first derivative value being less than zero for the first time following said detected P-wave, wherein said stored output signal amplitude is equal to said patient's right atrial systolic pressure;

20 delay means for delaying said output signal to provide a delayed output signal; and

storage means for storing a delayed output signal amplitude value in said second holding means in response to detection of a P-wave, wherein said stored delayed output signal amplitude is equal to said patient's right atrial diastolic pressure.

25 4. A pressure monitoring system substantially as described with reference to the accompanying drawings.



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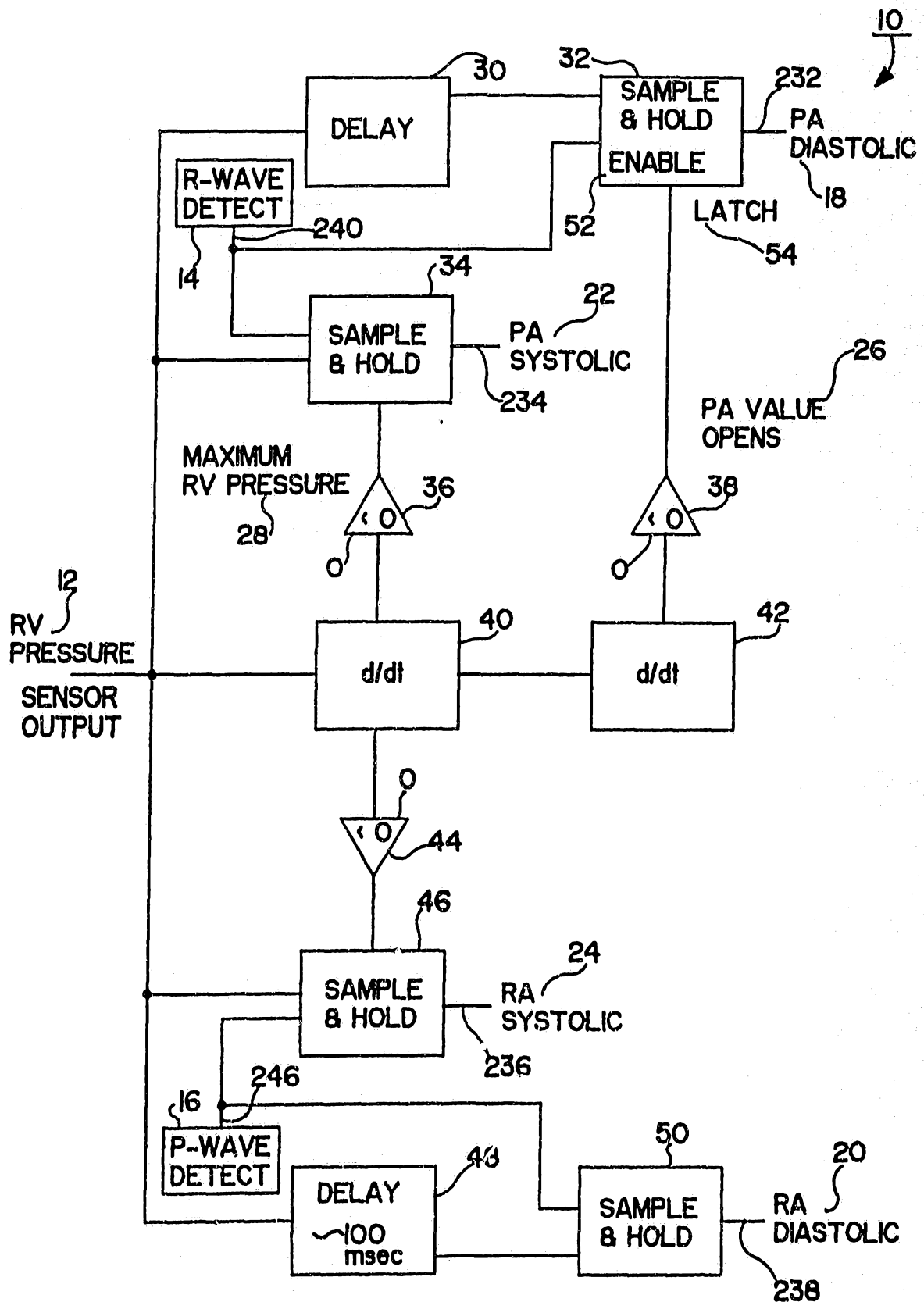
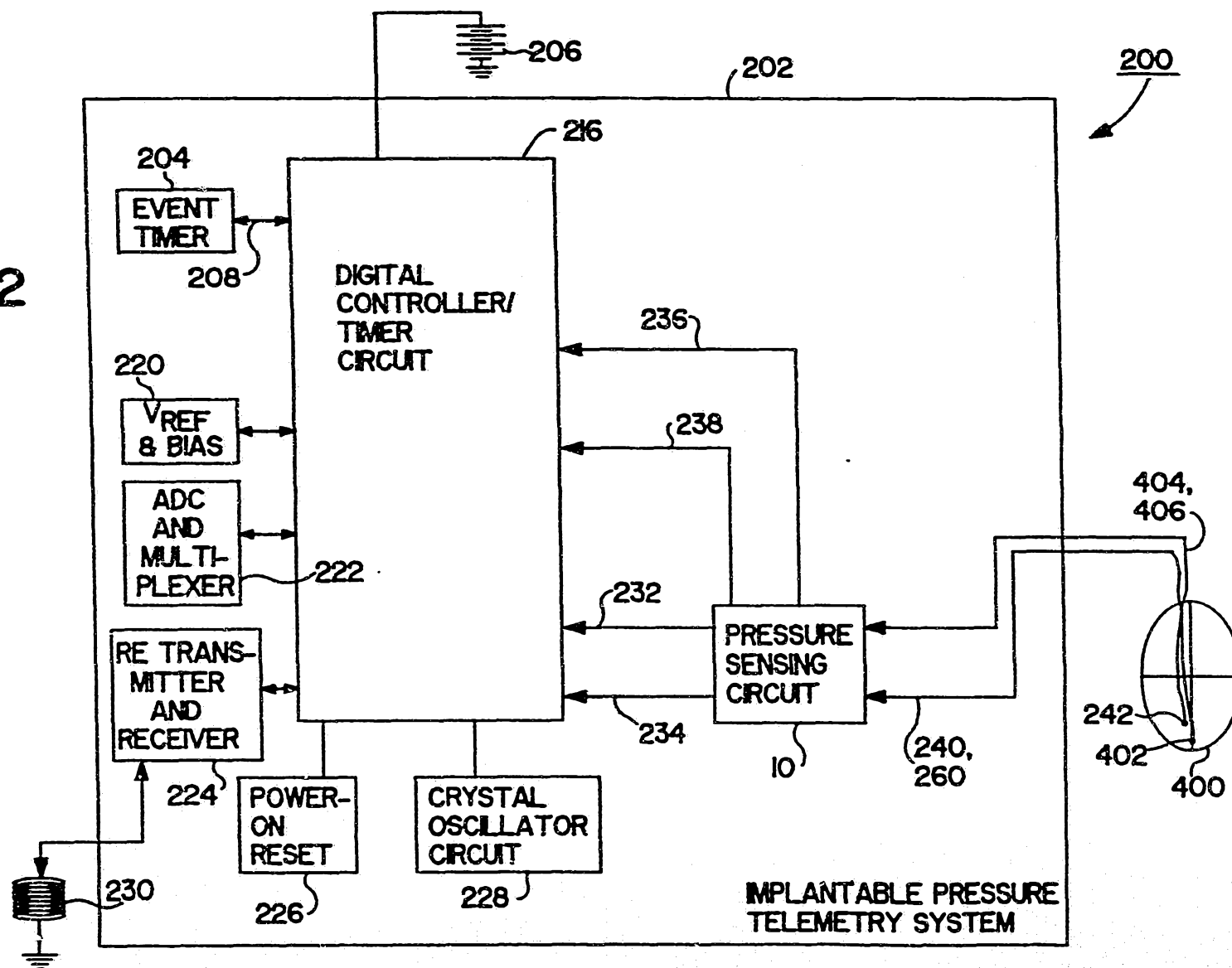


FIG. 1

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FIG. 2

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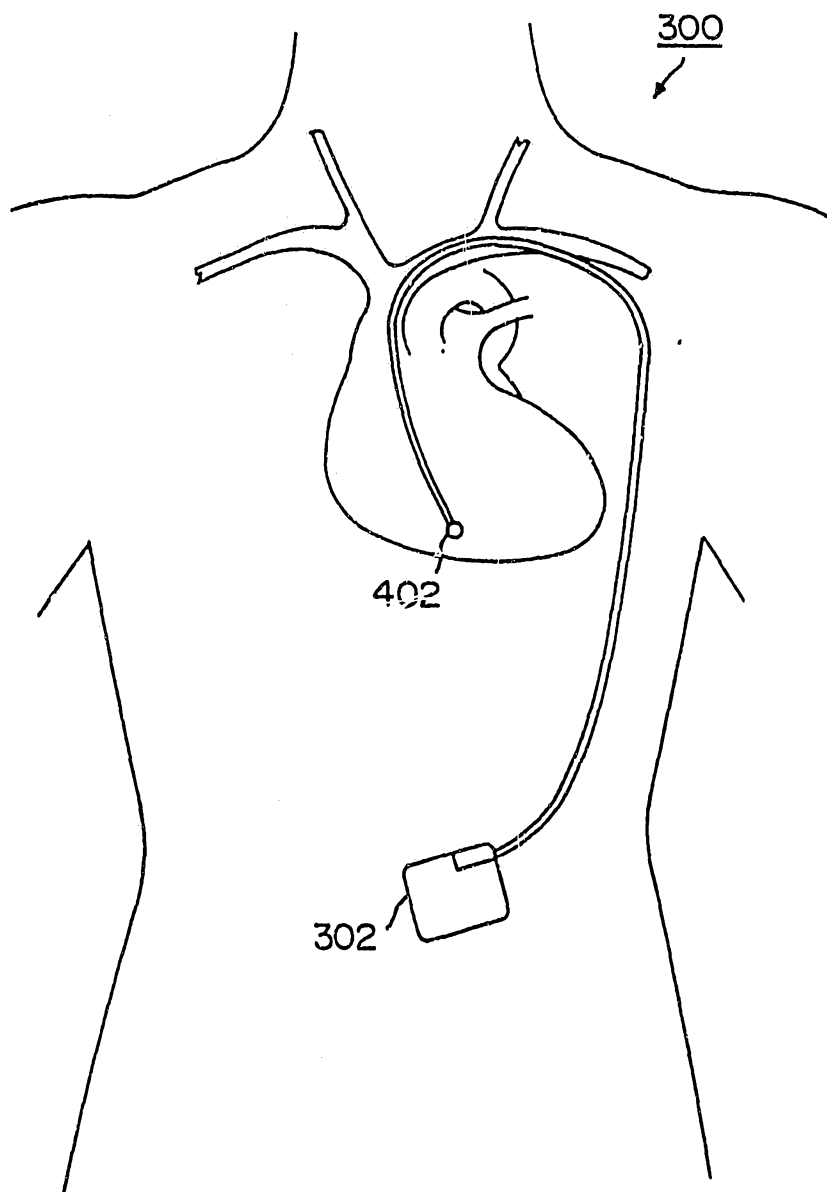


FIG. 3

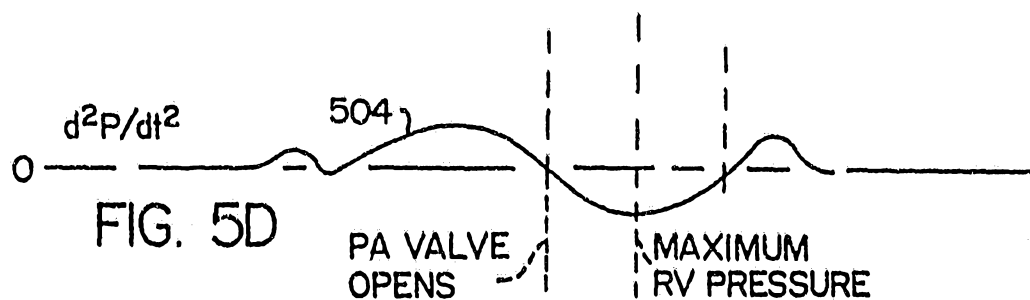
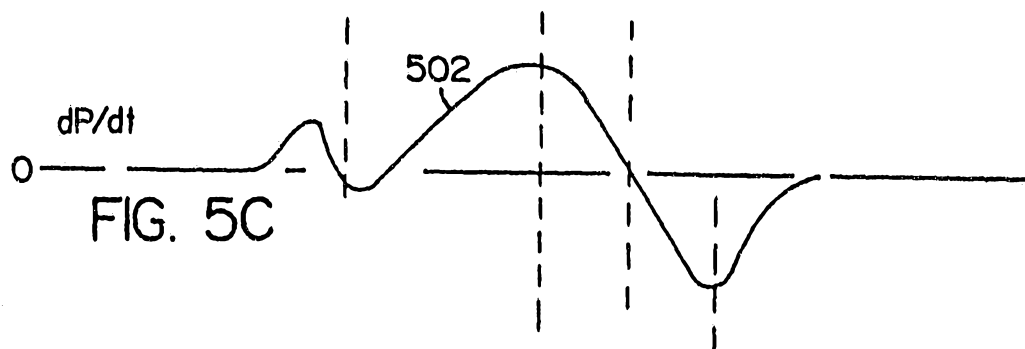
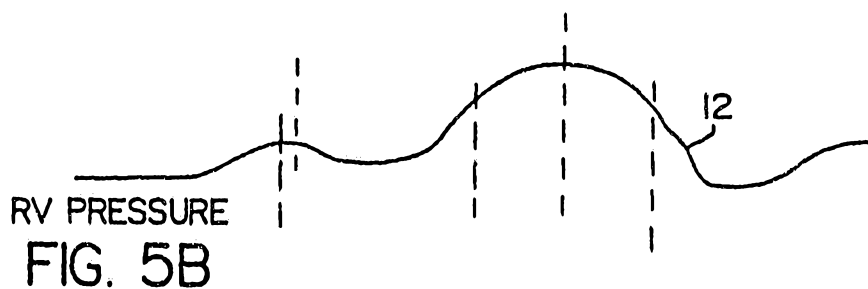
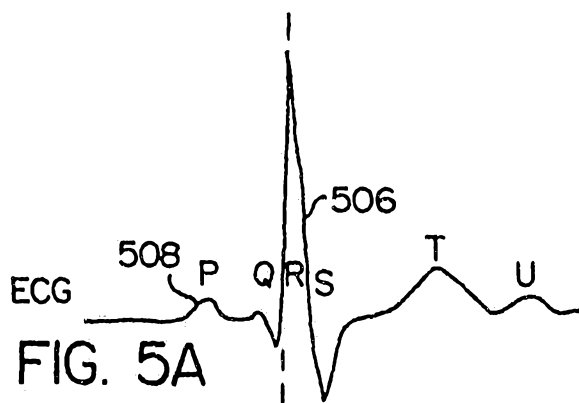


FIG. 6A

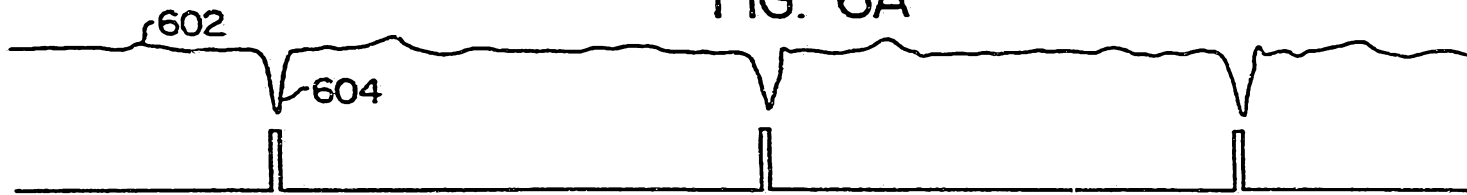


FIG. 6B

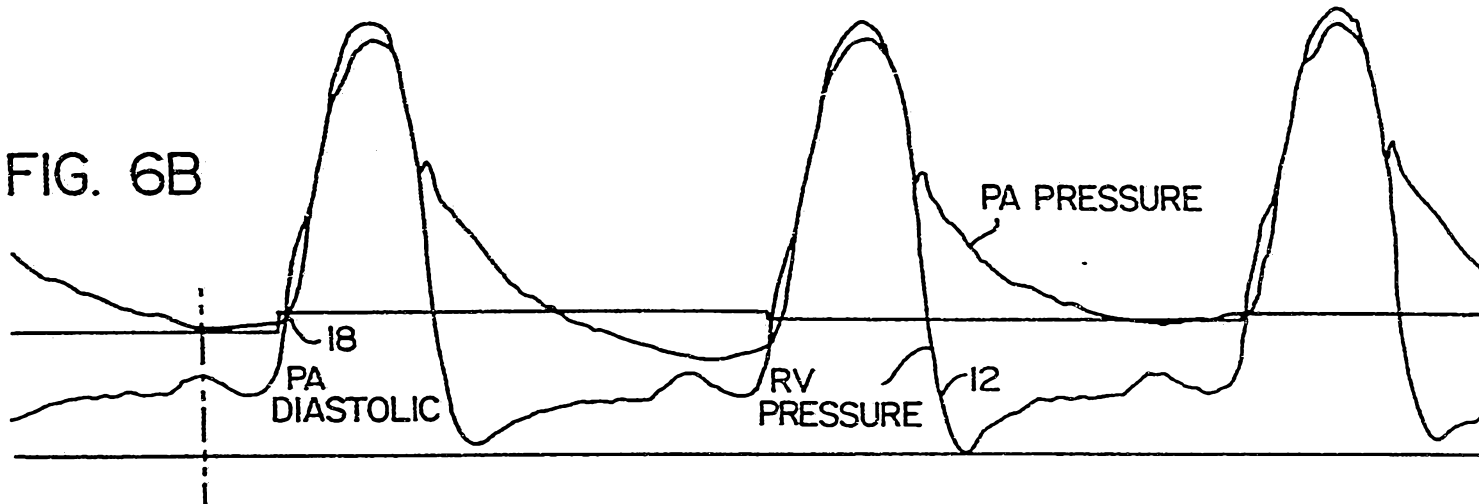
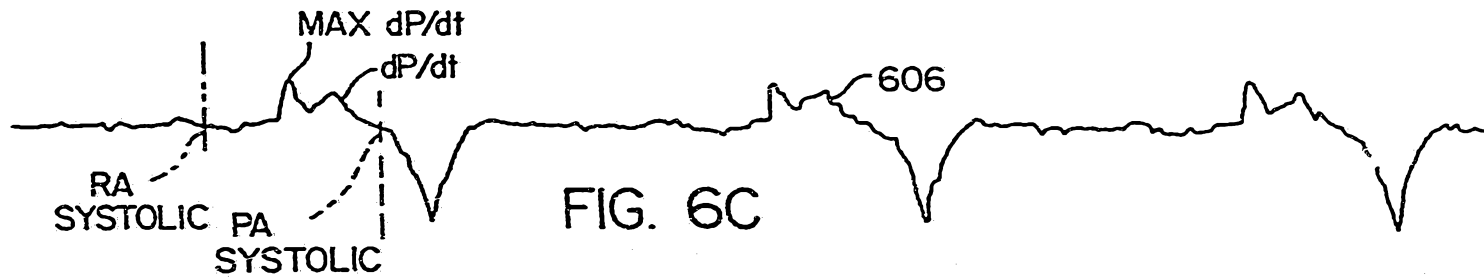


FIG. 6C



INTERNATIONAL SEARCH REPORT

Inter. Appl. Application No

PCT/US 94/07036

A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 A61B5/0215 A61N1/365

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61B A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US,A,4 566 456 (G. KONING ET AL.) 28 January 1986 see column 5, line 2 - column 6, line 21 ---	1-3
A	WO,A,92 03183 (MEDTRONIC, INC.) 5 March 1992 see page 6, line 30 - page 9, line 36 see page 13, line 18 - page 15, line 3 ---	1-3
A	US,A,4 986 270 (T.J. COHEN) 22 January 1991 cited in the application see column 3, line 46 - column 4, line 18 see column 7, line 57 - column 9, line 9 see column 11, line 15 - column 12, line 42 -----	1-3

☐ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

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X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

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Date of the actual completion of the international search

8 November 1994

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16. 11. 94

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

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