

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(54) Title: DIAGNOSTIC APPARATUS			
(57) Abstract			
Diagnostic apparatus for detecting ventricular fibrillation in a patient uses a pair of electrodes (1, 2) to be put in contact with a patient connected to a circuit (16) for distinguishing the signal received characteristic of fibrillation and an indicator (17) which is actuated on receipt of such a signal. A fibrillation signal may be distinguished either by observing its energy content after automatic gain amplification or by processing it to detect the peaks present in signals representing other heart conditions.			

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Title: Diagnostic Apparatus

This invention relates to diagnosis of heart conditions which may require defibrillation.

Ventricular fibrillation very often occurs during a coronary/heart attack and is commonly fatal unless treatment
5 is applied very rapidly. Ventricular fibrillation is a condition in which the heart has ceased to pump or has spasmodically irregular contractions, accompanied by chaotic electrical activity.

This condition can be treated by defibrillation, i.e.
10 by applying a controlled electric shock to the patient, normally through electrodes applied to the chest. This may be achieved using a defibrillator of the type described in our British Patents 1,435,709 and 1,481,469. Before
15 defibrillating a patient it is first necessary to diagnose his condition and a reliable diagnosis normally requires the use of an electrocardiograph, in which the electrical activity of the heart is monitored through electrodes attached to the body and the electric pulses displayed on a cathode ray tube or equivalent device.

20 Accurate interpretation of the signals obtained with an electrocardiograph requires considerable medical training. However in the event of a heart attack it is not always possible to summon a doctor before defibrillation treatment has to be applied. Diagnosis and treatment of the patient's
25 condition then has to be carried out by paramedical or other personnel who may not be fully qualified medically.

The present invention is intended to provide diagnostic apparatus which is capable of detecting fibrillation in a patient automatically without the need for an operator to
30 interpret the data received by the apparatus.

The present invention is intended to provide apparatus for detecting ventricular fibrillation, comprising a pair of electrodes capable of being put in electrical contact with the body of a patient (normally the patient's chest),
'35 a circuit capable of distinguishing a signal received from



the electrodes characteristic of ventricular fibrillation from signals characteristic of other heart conditions, and indicating means to indicate to an operator when said signal is characteristic of ventricular fibrillation.

5 The electric signal received from the heart during normal operation by electrodes positioned on the chest is shown in the accompanying Figure 1, in which the voltage is plotted on the *y*-axis and time on the *x*-axis. This condition is known as the Sinus Rhythm. Ventricular
10 fibrillation is characterised by a disordered trace of the kind shown in Figure 2, plotted in the same manner as in Figure 1.

In one embodiment of the invention, advantage is taken of the different energy contained in the signals of Figures
15 1 and 2 when they are amplified to the same amplitude.

Simple amplification of these signals will normally produce waveforms having different amplitudes. However if they are amplified using an automatic gain control unit set so that the amplitude obtained is the same regardless of the
20 patient's condition, the automatic gain control unit being selective to the frequencies concerned, the amplified signal obtained on fibrillation gives much greater energy on integration than that obtained when the heart is functioning normally. This integrated value may then be
25 measured by a comparator to distinguish the fibrillation condition from normal heart operation.

However simple integration of the amplified signal can give an ambiguous result because of a possible condition known as ventricular tachycardia. This condition is
30 characterised by a signal of the kind shown in Figure 3.

This trace is similar to that obtained from fibrillation in that a similar overall energy is involved when the signal is amplified to the same level but it represents a condition which does not require defibrillation.

35 This problem may be overcome by clipping the amplified signals obtained from the electrodes to remove their positive and negative peaks. The signals obtained on clipping are shown below in Figures 1a, 2a and 3a corresponding to the

unclipped signals shown in Figures 1, 2 and 3.

It will be seen that the energy obtained in Figures 2a and 3a is again greater than that obtained from Figure 1a. However signals 2a and 3a differ in that the energy obtained from the positive component of the wave of Figure 3a is much greater than that of the negative component whereas the positive and negative components of the wave of Figure 2a have similar energies. Signals 2a and 3a may thus be distinguished. This may be achieved by providing clipping units to remove the peaks of the positive and negative components of the amplified signal, integrating units to integrate the positive and negative signals received from the clipping units separately and feeding both results to a dual comparator set to operate indicating means when the magnitudes of the integrated signals show fibrillation.

In another embodiment of the invention, advantage is taken of the fact that the signal generated by ventricular fibrillation is essentially continuous and free from regular peaks (as shown in Figure 2) whereas an ordinary Sinus Rhythm shows regular peaks (Figure 1). This allows use of an analogue switch to actuate the indicating means and circuit means connected to the analogue switch to allow it to operate only when a continuous signal substantially free from peaks characteristic of ventricular fibrillation is fed to the analogue switch.

In one arrangement the positive and negative components of the signal from the electrodes are summed, i.e. the polarity of one of these components is reversed and its magnitude is added to the other. The summed signal is then passed to an automatic gain chip where it may be amplified and successively through a buffer amplifier and peak detector to the analogue switch.

Additionally, the summed signal may be split and the split signals passed respectively to a buffer and to a peak signal capacitor decay circuit and buffer. The outputs from these units are passed to a comparator which is connected to an automatic gain control unit provided with a direct-current pump with decay to the automatic gain control chip. The comparator is such that it emits a substantially

continuous output when the signals it receives represent ventricular fibrillation but emits a pulsed output when the signals it receives show the peaks obtained from Sinus Rhythm. This pulsed output fed to the automatic gain

5 control will prevent the automatic gain chip passing an amplified signal to the peak detector and hence the analogue switch: thus no amplified signal is passed when the comparator detects the presence of peaks in the original signal.

10 The outputs from the peak signal capacitor decay circuit and the buffer may also be fed to an event comparator provided with a direct current pump with decay connected to the analogue switch through an OR gate. The event comparator is arranged such that if a significant number of
15 pulses representing peaks in the original signal is received it generates no output and the analogue switch is closed. Thus the event comparator emits an output allowing the summed signal to pass the analogue switch only when the original signal represents ventricular fibrillation.

20 Provision may also be made to eliminate the effect short bursts of noise or other extraneous signals which may affect the circuit. This may be done by connecting a reset unit, emitting a reset signal at short intervals such as 3 seconds, to a direct current pump and buffer through which
25 the output from the analogue switch is passed.

In all the above embodiments provision should be made for only the relevant frequencies in the signal from the patient to be processed. This may be achieved by passing the signal from the electrodes through a band pass filter
30 passing only frequencies from 2 to 17 Hz: these are the frequencies generated by the normal Sinus Rhythm and by ventricular fibrillation. Finally noise from the mains can be removed by passing the signal from the electrodes through a filter removing the A.C. mains frequency
35 (generally 50 Hz).

The diagnostic unit may be self-contained, battery operated and by use of microcircuits wherever possible it may be made small and highly portable. It may be

incorporated in the same unit as a defibrillator and may use the same electrodes as the defibrillator, with a relay or other device to isolate the diagnosis unit from the electrodes when a defibrillation shock is administered. With this

5 arrangement the operation of a patient's heart may be diagnosed and if defibrillation is required it can be administered immediately through the same electrodes.

The indicating device may comprise any visual or acoustic indicating device to inform the operator that
10 defibrillation is required. This device may be much smaller and simpler than the display system, generally a cathode ray tube, which is required by conventional electrocardiographs.

Apparatus according to different embodiments of the invention will be described by way of example with reference
15 to the accompanying drawings in which:

Figure 1 shows an oscilloscope trace showing the normal Sinus Rhythm from a patient's heart,

Figure 1a shows the same trace after automatic gain amplification and clipping,

20 Figure 2 shows a similar trace of a signal received on ventricular fibrillation,

Figure 2a shows the trace of Figure 2 after automatic gain amplification and clipping,

25 Figure 3 shows a trace of a signal received on ventricular tachycardia,

Figure 3a shows the trace of Figure 3 after automatic gain amplification and clipping,

Figure 4 is a schematic circuit diagram of diagnostic apparatus according to one embodiment of the invention, and

30 Figure 5 is a schematic circuit diagram of diagnostic apparatus according to another embodiment of the invention.

The various block components may be standard components known in the electronics and computer arts and so will not be described in detail.

35 The defibrillator part of the apparatus comprises electrodes 1 and 2 arranged to be placed in electrical contact with the body of a patient and connected in series with a choke 3 and capacitor 4 by relay-operated switches



5 and 6. Capacitor 4 may be charged to a high voltage by means of a high voltage source 7 powered by an oscillator 8. The operation of this part of the apparatus is controlled by circuitry assembled as a hybrid package 9.

5 The defibrillator part may be functionally the same as those described in British Patents 1,481,469 and 1,435,709.

The arrangement is such that switches 5 and 6 are normally open, the capacitor being connected to the electrodes only when a defibrillation shock is being delivered to the patient.

10 Electrodes 1 and 2 are also connected to leads 10 and 11 connected to the diagnostic part of the apparatus. This comprises an amplifier 12 in which the electric signals received by the electrodes from the patient are amplified to about 1 volt. The amplified signals are then sent to an
15 automatic gain control unit 13 which is set to produce an output between the same positive and negative set levels regardless of whether the signals received represent Sinus Rhythm or ventricular fibrillation: the automatic gain control unit is tuned so that the automatic gain is selective
20 for the frequencies obtained from Sinus Rhythm and from defibrillation.

The output from the automatic gain control is then fed to positive and negative clipping circuits 14 which remove the positive and negative peaks of the output from the
25 automatic gain control. The clipped outputs are fed to respective integrator and reset circuits 15 which integrate the outputs for about 3 seconds at a time. The outputs from the integrators are then fed to a dual comparator unit in which they are compared and their magnitudes measured. The
30 comparator unit is provided with a system of AND gates such that a signal is emitted if the absolute magnitudes of the integrated signals, and the relationship between these magnitudes, indicate fibrillation. This signal actuates a visual indicating device 17 which indicates to the operator
35 that defibrillation is required. A defibrillation shock can then be administered to the patient immediately through electrodes 1 and 2 which remain in contact with the patient.

Apparatus according to another embodiment of the invention will be described with reference to Figure 5. In this embodiment the electrodes to be in contact with the patient are connected to a notch filter 1 in order to remove any interfering signal derived from the electric mains: this filter will remove 50 Hz components in countries where this frequency is used for the public electricity supply. The signals passing filter 21 and then passed through the band pass filter 22 which passes only frequencies from 2 to 17 Hz: these are the main frequency components obtained from the ventricular fibrillation condition and the central frequencies obtained with a normal Sinus Rhythm from the heart.

The output from filter 22 is then fed to a unit which carries out negative summing of both the positive and negative components of the signal. This unit comprises a buffer amplifier 23 and an inverting buffer 24, connected as shown with diodes 25 to give a negative summed signal at point 26. If the original signal represents the QRS complex obtained from normal heart operation the summed signal contains pronounced peaks corresponding to the peaks of the complex: if the signal received represents ventricular fibrillation the summed signal is much more uniform and does not contain such pronounced peaks.

The summed signal is passed to automatic gain control chip 27. Chip 27 is controlled by further circuitry described below. The signal may then be passed to buffer amplifier 28, peak detector 29 and analogue switch 30. Analogue switch 30 is arranged to actuate a visible or acoustic indicating means to indicate to an observer the existence of ventricular fibrillation in the patient. This indicating means may be of a conventional type and so will not be described.

The summed signal from point 26 is also fed by signal splitting device 31 to a buffer 32 and a peak signal capacitor decay circuit and buffer 33 to a comparator 34, which is itself connected to an automatic gain control unit 35 having a direct-current pump with decay associated with the automatic gain control chip 27.

Comparator 34 is arranged so as to generate a substantially continuous output when the summed signal received represents ventricular fibrillation but produces pulses corresponding to the Sinus Rhythm peaks when a normal Sinus Rhythm signal is received. The Sinus Rhythm pulses are fed to the control unit 35, which is arranged such that it prevents the signal received by chip 27 from point 26 being passed through the automatic gain when a summed signal displaying peaks is received.

10 Additionally, the outputs from units 32 and 33 are fed to an event comparator with a direct current pump with decay 36 and thence to an OR gate 37 which is itself connected to analogue switch 30. The event comparator is arranged to give an output to the OR gate only when the signal received represents ventricular fibrillation. The analogue switch 30 is opened on receipt of the output through the OR gate allowing the signal from peak detector 29 to pass through.

The analogue switch 30 is provided with an additional direct-current pump and buffer 38 connected to a reset device 39 and a unit 40 generating a 3-second interval reset signal. The purpose of this arrangement is to eliminate the effect of "short" bursts of noise or other signal not derived from the patient which may find its way through the circuit to this point.

25 With this arrangement, when a pair of paddles is applied to a patient's chest and the electric signals from the heart are fed into the device through filter 21, if the heart is in a state of fibrillation a "scrambled" signal of small amplitude with recognisable peaks is received: if the heart is not fibrillating a signal with more or less regular peaks (such as a Sinus Rhythm) is received. When such a peaked signal is received the negatively summed signal at point 26 actuates the comparator 34 to give a pulsed output: these pulses operate the pumping function of unit 35 and, if the pulses are received at a sufficient rate, unit 35 prevents the original summed signal from passing through automatic gain at 27: thus the signal does not reach the peak detector. On the other hand, when the original signal has no or only a

small number of peaks, corresponding to a substantially continuous low-amplitude signal, the automatic gain can operate and an amplified signal is transmitted.

5 The analogue switch 30 is controlled by the event comparator 36. When the number of pulses in the signal received reaches a certain number the pumping action of unit 36 is sufficient to operate the analogue switch to prevent any signal from peak detector 29 being passed.

10 Finally the reset arrangement 39 and 40 resets the pump and buffer 38 at 3-second intervals, thus preventing any stray signals received by the circuit affecting the output for more than a very short period.

15 The effect of this arrangement is to block signals received from the heart which do not show the characteristics of fibrillation while allowing a fibrillation signal to operate a fibrillation indicator.

The apparatus shown in Figure 5 may be incorporated in self-contained apparatus including a defibrillator, as in the embodiment of Figure 4.



CLAIMS:

1. Apparatus for detecting ventricular fibrillation, comprising a pair of electrodes capable of being put in electrical contact with the body of a patient, a circuit capable of distinguishing a signal received from the electrodes characteristic of ventricular fibrillation from signals characteristic of other heart conditions, and indicating means to indicate to an operator when said signal is characteristic of ventricular fibrillation.
2. Apparatus according to Claim 1, in which said circuit comprises an amplifier and automatic gain control unit to amplify the signals received from the electrodes to a uniform maximum amplitude, an integrating unit to integrate the amplified signal, and a comparator to measure the energy of the integrated signal.
3. Apparatus according to Claim 2, in which the circuit comprises clipping means for clipping the positive and negative peaks from the signal received from the automatic gain control unit, integrating units to integrate separately the positive and negative clipped signals and a dual comparator arranged to operate the indicating means when the magnitudes of the integrated positive and negative signals are characteristic of ventricular fibrillation.
4. Apparatus according to Claim 1, in which the circuit comprises an analogue switch operable to actuate said indicating means and circuit means connected to the analogue switch to allow it to operate only when a continuous signal substantially free from peaks characteristic of ventricular fibrillation is fed to the analogue switch.
5. Apparatus according to Claim 4, in which the circuit comprises summing means for summing the positive and negative components of the signal received from the electrodes, an automatic gain control unit to amplify the summed signal,

a peak detector to receive the amplified signal, and an analogue switch operable by the signal from the peak detector to operate the indicating means.

6. Apparatus according to Claim 5, in which the circuit
5 includes means for splitting the summed signal, a buffer amplifier to receive one component of the split signal and a peak signal capacitor decay circuit and buffer to receive the other component, said buffer amplifier and said buffer being connected to a comparator which is itself connected to the
10 automatic gain control, the arrangement being such that the comparator emits a substantially continuous output to the automatic gain control when the signals received are characteristic of ventricular defibrillation and emits a pulsed output when the signals are characteristic of Sinus
15 Rhythm and the automatic gain control cannot pass an amplified signal to the peak detector when the comparator emits a pulsed signal.

7. Apparatus according to Claim 5 or 6, in which the circuit includes means for splitting the summed signal, a
20 buffer amplifier to receive one component of the split signal and a peak signal capacitor delay circuit and buffer to receive the other component, said buffer amplifier and said buffer being connected to an event comparator with a direct current pump with decay unit and an OR gate connected
25 to the analogue switch, the arrangement being such that the OR gate emits an output only when the signal received by the event comparator is characteristic of ventricular defibrillation and the analogue switch is operable to actuate the indicating means on receipt of this output.

30 8. Apparatus according to Claim 5, 6 or 7, in which the circuit comprises a direct current pump and buffer connected to the analogue switch to transmit the signal received therefrom to the indicating means, and a reset device and means for generating a reset signal at intervals connected
35 to the pump and buffer to effect resetting at intervals.

BUREAU

9. Apparatus according to any preceding claim, in which the circuit contains a band pass filter capable of passing frequencies from 2 to 17 Hz from the signals received from the electrodes.

5 10. Apparatus according to any preceding claim, in which the circuit contains a filter to remove from the signals received from the electrodes components having a frequency corresponding to that of the alternating-current mains supply.

10 11. Apparatus according to any preceding claim, provided with a defibrillator circuit arranged to be discharged through said electrodes to administer a shock to the patient.

15 12. Apparatus according to any preceding claim, in which said circuit, indicating means and electrodes are mounted in or on a housing, or housings connected together, to form a portable unit.

13. Apparatus for detecting ventricular fibrillation, substantially as hereinbefore described with reference to Figure 4 or Figure 5 of the accompanying drawings.

FIG. 1

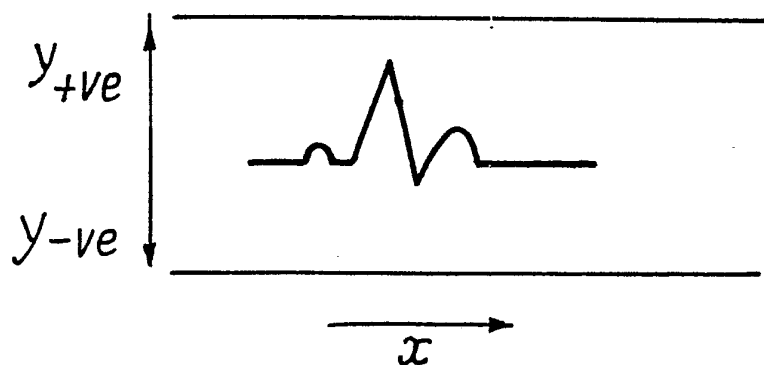


FIG. 2

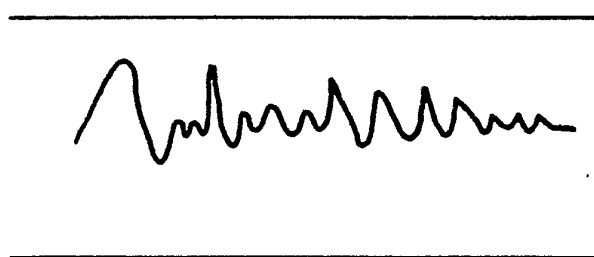


FIG. 3

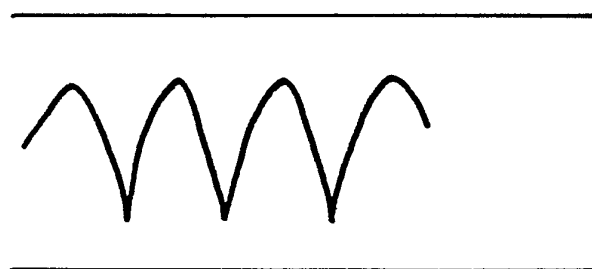


FIG. 1a

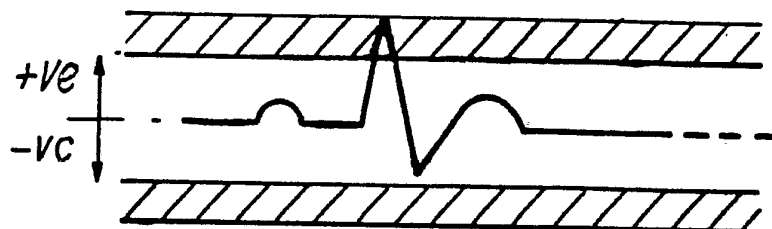


FIG. 2a

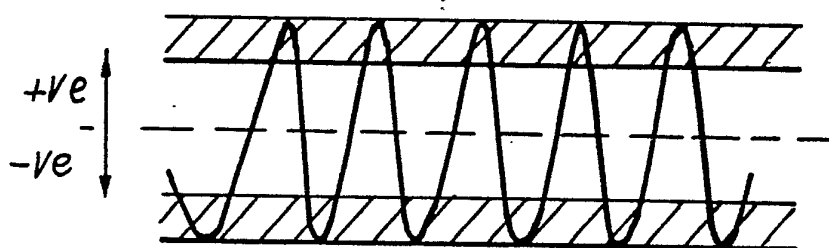
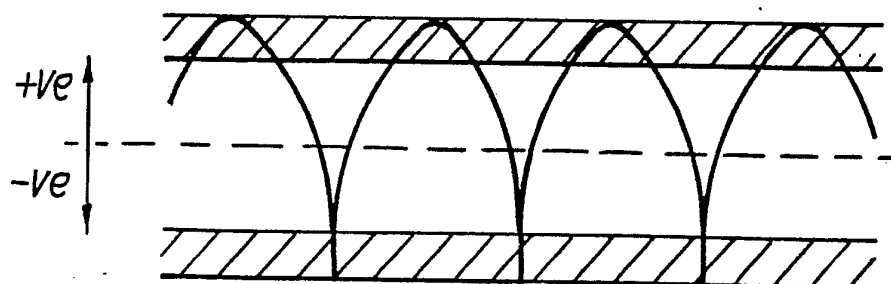


FIG. 3a



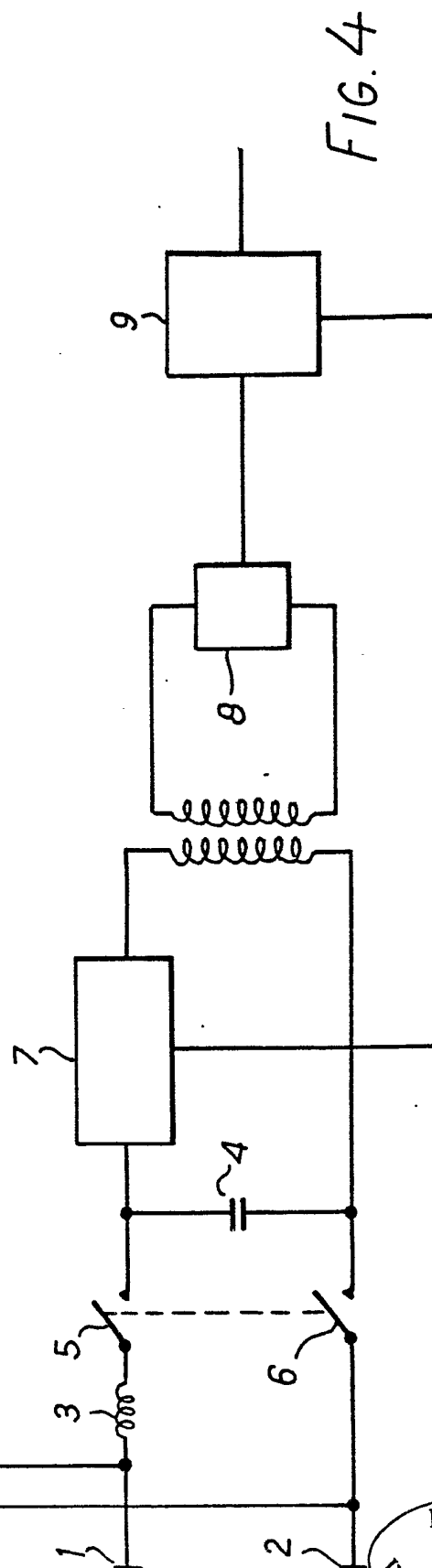
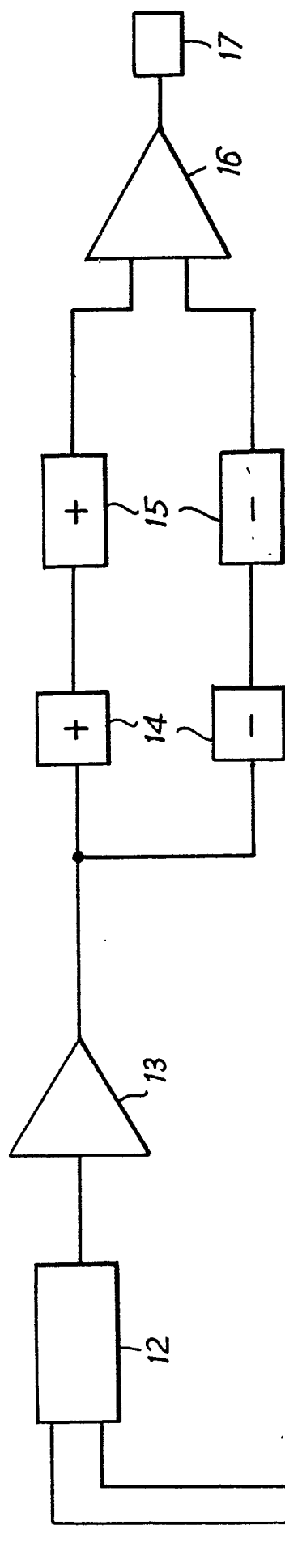
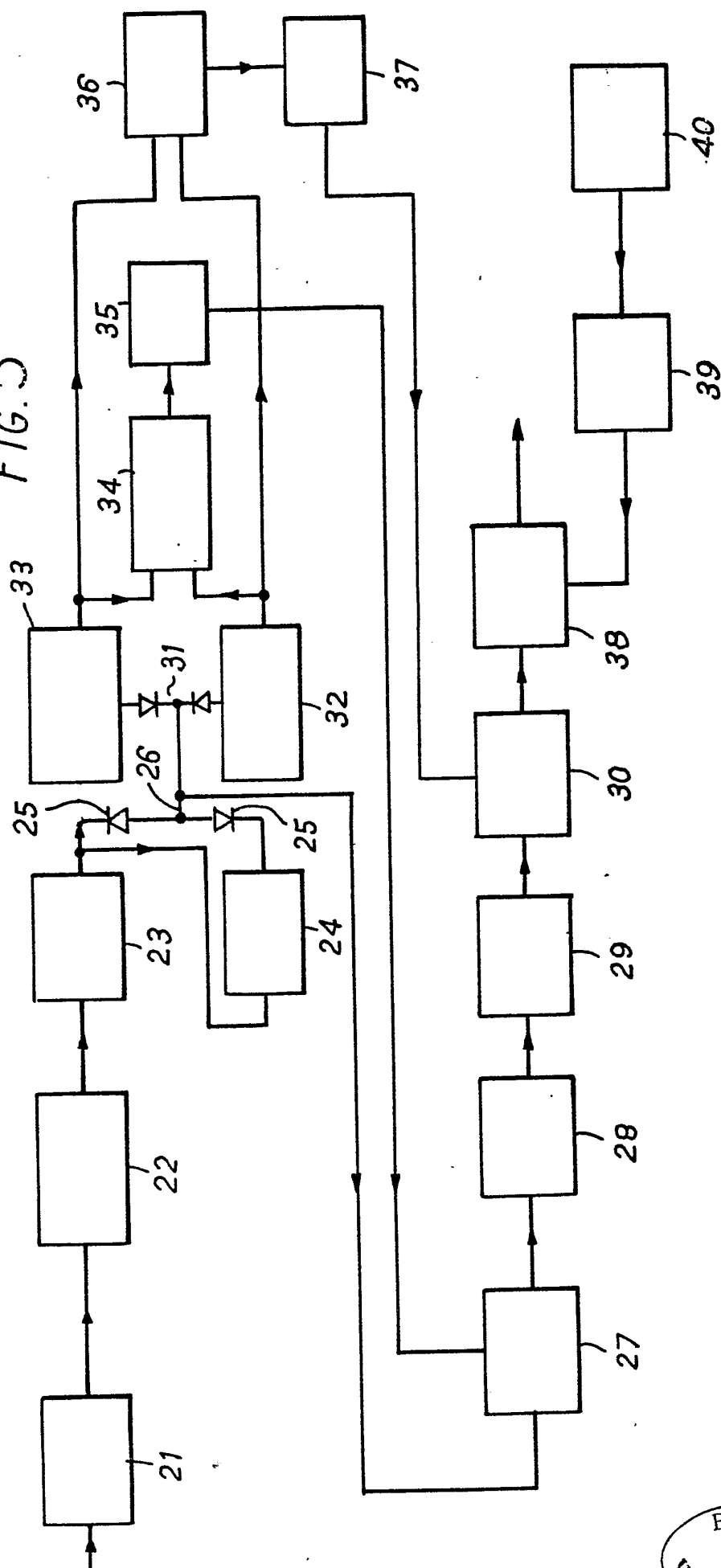


FIG. 4



FIG. 5



INTERNATIONAL SEARCH REPORT

International Application No PCT/GB 79/00094

I. CLASSIFICATION OF SUBJECT MATTER (If several classification symbols apply, indicate all) ¹ According to International Patent Classification (IPC) or to both National Classification and IPC A 61 B 5/04																										
II. FIELDS SEARCHED Minimum Documentation Searched ⁴ <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 5px;"> <tr> <th style="width: 20%;">Classification System</th> <th style="width: 80%;">Classification Symbols</th> </tr> <tr> <td style="padding: 5px;">Int.Cl. ²</td> <td style="padding: 5px;">A 61 B 5/04</td> </tr> </table> Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched ⁵			Classification System	Classification Symbols	Int.Cl. ²	A 61 B 5/04																				
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III. DOCUMENTS CONSIDERED TO BE RELEVANT ¹⁴ <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 5px;"> <tr> <th style="width: 10%;">Category ⁶</th> <th style="width: 60%;">Citation of Document, ¹⁶ with indication, where appropriate, of the relevant passages ¹⁷</th> <th style="width: 30%;">Relevant to Claim No. ¹³</th> </tr> <tr> <td style="text-align: center; vertical-align: top; padding: 5px;">X</td> <td style="padding: 5px;">DE, 2643907, published April 7, 1977, see page 8, line 1 - page 10, line 8; page 15, line 30 - page 18, line 20; figures 4-6e, M. Mirowski</td> <td style="text-align: center; vertical-align: top; padding: 5px;">1-3, 9, 11</td> </tr> <tr> <td style="text-align: center; vertical-align: top; padding: 5px;">P</td> <td style="padding: 5px;">corresponding to GB, A, 1538522</td> <td></td> </tr> <tr> <td style="text-align: center; vertical-align: top; padding: 5px;">X</td> <td style="padding: 5px;">US, A, 3950694, published April 13, 1976, see abstract; column 2, line 55 - column 6, line 61 and the figure, M. Maas/Siemens A.G.</td> <td style="text-align: center; vertical-align: top; padding: 5px;">1, 2, 4-6, 9-11</td> </tr> <tr> <td style="text-align: center; vertical-align: top; padding: 5px;">X</td> <td style="padding: 5px;">corresponding to DE, A, 2362039 and FR, A, 2254791</td> <td></td> </tr> <tr> <td style="text-align: center; vertical-align: top; padding: 5px;"></td> <td style="padding: 5px;">US, A, 3968430, published July 6, 1976, see abstract; column 3, line 40 - column 7, line 46 and the figure, M. Maas/Siemens A.G.</td> <td style="text-align: center; vertical-align: top; padding: 5px;">1, 2, 4-6, 9-11</td> </tr> <tr> <td style="text-align: center; vertical-align: top; padding: 5px;">X</td> <td style="padding: 5px;">corresponding to DE, A, 2362063 and FR, A, 2254790</td> <td></td> </tr> <tr> <td style="text-align: center; vertical-align: top; padding: 5px;">X</td> <td style="padding: 5px;">DE, A, 2362070, published June 19, 1975, see page 4, line 5 - page 11, line 13 and the figure, Siemens A.G.</td> <td style="text-align: center; vertical-align: top; padding: 5px;">1, 2, 4-6, 9-11</td> </tr> </table>			Category ⁶	Citation of Document, ¹⁶ with indication, where appropriate, of the relevant passages ¹⁷	Relevant to Claim No. ¹³	X	DE, 2643907, published April 7, 1977, see page 8, line 1 - page 10, line 8; page 15, line 30 - page 18, line 20; figures 4-6e, M. Mirowski	1-3, 9, 11	P	corresponding to GB, A, 1538522		X	US, A, 3950694, published April 13, 1976, see abstract; column 2, line 55 - column 6, line 61 and the figure, M. Maas/Siemens A.G.	1, 2, 4-6, 9-11	X	corresponding to DE, A, 2362039 and FR, A, 2254791			US, A, 3968430, published July 6, 1976, see abstract; column 3, line 40 - column 7, line 46 and the figure, M. Maas/Siemens A.G.	1, 2, 4-6, 9-11	X	corresponding to DE, A, 2362063 and FR, A, 2254790		X	DE, A, 2362070, published June 19, 1975, see page 4, line 5 - page 11, line 13 and the figure, Siemens A.G.	1, 2, 4-6, 9-11
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¹⁵ Special categories of cited documents: "A" document defining the general state of the art "E" earlier document but published on or after the international filing date "L" document cited for special reason other than those referred to in the other categories "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but on or after the priority date claimed "T" later document published on or 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																										
IV. CERTIFICATION <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 5px;"> <tr> <td style="width: 50%; padding: 5px;"> Date of the Actual Completion of the International Search ¹ 21st August 1979 </td> <td style="width: 50%; padding: 5px;"> Date of Mailing of this International Search Report ² 28th August 1979 </td> </tr> <tr> <td style="padding: 5px;"> International Searching Authority ¹ European Patent Office </td> <td style="padding: 5px;"> Signature of Authorized Officer ²⁰ G.L.M. Kruidenberg </td> </tr> </table>			Date of the Actual Completion of the International Search ¹ 21st August 1979	Date of Mailing of this International Search Report ² 28th August 1979	International Searching Authority ¹ European Patent Office	Signature of Authorized Officer ²⁰ G.L.M. Kruidenberg																				
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