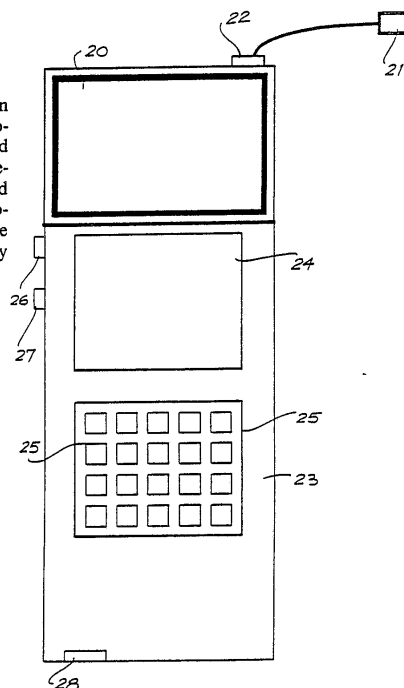




INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(21) International Application Number: PCT/AU88/00225 (22) International Filing Date: 30 June 1988 (30.06.88) (31) Priority Application Number: PI 2804 (32) Priority Date: 30 June 1987 (30.06.87) (33) Priority Country: AU (71) Applicant (for all designated States except US): MIC- ROMEDICAL INDUSTRIES PTY LIMITED [AU/ AU]; 397 Darling Street, Balmain, NSW 2041 (AU). (72) Inventors; and (75) Inventors/Applicants (for US only) : PLATT, Harry, Lo- uis [AU/AU]; 41 Meagher Avenue, Maroubra, NSW 2035 (AU). SATCHWELL, Bruce, Richard [AU/AU]; 126 Victoria Road, West Pennant Hills, NSW 2120 (AU).		(74) Agent: SPRUSON & FERGUSON; G.P.O. Box 3898, Sydney, NSW 2001 (AU). (81) Designated States: AT, AT (European patent), AU, BB, BE (European patent), BG, BJ (OAPI patent), BR, CF (OAPI patent), CG (OAPI patent), CH, CH (Eu- ropean patent), CM (OAPI patent), DE, DE (Euro- pean patent), DK, FI, FR (European patent), GA (OAPI patent), GB, GB (European patent), HU, IT (European patent), JP, KP, KR, LK, LU, LU (Euro- pean patent), MC, MG, ML (OAPI patent), MR (OA- PI patent), MW, NL, NL (European patent), NO, RO, SD, SE, SE (European patent), SN (OAPI pa- tent), SU, TD (OAPI patent), TG (OAPI patent), US. Published <i>With international search report.</i>
(54) Title: MODULAR PHYSIOLOGICAL MONITOR (57) Abstract A modular, hand held physiological monitor comprising a main unit (23) to which can be removably attached a variety of specialist modules (20). The main unit (23) incorporates data entry means (25) and visual display means (24) and is adapted to receive data from the specialist module (20). Each specialist module (20) adapted to be attached to the main unit (23) is specifically adapted to sense particular physiological parameters such as blood pressure, EEG, pH and the like. The device allows convenient, portable, hand held monitoring of a variety of physiological functions either in the hospital or in the field.		



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MODULAR PHYSIOLOGICAL MONITORField of the Invention

The present invention relates to a hand held modular physiological monitor.

The base unit of the modular device is related to and incorporates many of the features and principles of the portable physiological monitor described in copending International Application PCT AU88/00016, the specification and drawings of which are incorporated herein by cross-reference.

10

Background of the Invention

Prior art data acquisition and display systems for monitoring information derived from patients have tended to be large bulky devices which require transport on trolleys or equivalent.

It is an object of the present invention to provide a hand held, non-invasive, modular instrument which can record and display a plurality of vital signs and ancilliary information derived from a patient in real time.

It is a further object of the present invention to provide a modular unit which, by virtue of its modularity, allows for relatively sophisticated data acquisition operations to be carried out in flexible fashion by use of a hand held device.

20

Summary of the Invention

In one broad form there is provided a modular physiological monitor comprising standard input means adapted to receive a plurality of input signals; specialist input means adapted to receive and pre-process signals from specialist sensors; data processing means adapted to receive information from said standard input means and said specialist input means; display means to display selected processed data; storage means for storing selected unprocessed and processed data; said specialist input means being detachably attached to said monitor.

30

Preferably, the monitor is a hand held non-invasive instrument which comprises a base unit which records and displays:-

- Heart Wave Form (ECG)
- Heart Rate
- Respiration Rate
- Oral or Rectal Temperature

together with a detachable specialist unit adapted to receive and pre-process specialist information from a patient.

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The above configuration comprises of the basic unit. By the addition of specialised modules to the basic monitor, the unit can be configured for specialist use.

Speciality modules include:-

- oximeter
- invasive blood pressure
- capnograph
- PO₂/PCO₂
- Phonocardiogram
- 10 - EMG
- EEG
- pH meter
- non-invasive blood pressure (oscillometric method).

Preferably said monitor uses liquid crystal display (LCD) technology, special custom integrated circuits, and surface-mount technology (SMT) in construction.

Preferably the LCD is used to display the electrocardiogram (ECG) waveform in analog form and the other vital signs in numeric form allowing immediate diagnosis and intervention if required.

20 Preferably the monitor has features commonly found (if at all) only on larger non-portable hospital patient monitors. These include:-

- Hold/Freeze display - enabling ECG waveform evaluation
- Record data - the unit will record all inputted data for later manipulation, either hard copy printout or computer download
- Trend data - all information stored can be plotted against time, providing graphic output on the LCD display
- Alarm - these can be set for measured inputs to alert the user of abnormal patient condition
- Error detection - operational errors are detected and warnings
- 30 indicated. These include 'low battery', incorrect cuff inflation and no sensing signal
- Calibration - provides a reference of 1mV at input

Preferably the monitor is battery operated (using four penlight AA cells), thus allowing use of the device in any situation.

In one preferred form said specialist input means incorporates a limited amount of signal conditioning circuitry which pre-processes the raw input signal derived from a patient, said specialist input means then communicating the pre-processed data in analog form to said monitor (main

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unit).

In a further broad form said specialist input means includes digital data processing means adapted to pre-process raw data received from a patient by said specialist input means, said pre-processed data then being communicated in digital form to said monitor (main unit).

Preferably said main unit includes digital data processing means located within said monitor (main unit) to further process said pre-processed data.

Drawings

10 Two embodiments of the present invention will now be described with reference to the drawings in which:

Figure 1 is a block diagram of the functional blocks comprising a first preferred embodiment.

Figure 2 shows an external view of the front casing of a second embodiment,

Figure 3 shows a typical combined wave form and digital data display available from either the first or second embodiments,

Figure 4 shows a block diagram of the interconnection of the specialist module and main unit of the second embodiment,

20 Figure 5 shows a more detailed block diagram of the components comprising the main unit of the second embodiment,

Figure 6 shows a more detailed block diagram of the components comprising the specialist unit of the second embodiment,

Figure 7 shows an electronic diagram of the components of one version of the main unit of the second embodiment,

Figure 8 shows details of the analog pre-processing functions of one version of the main unit of the second embodiment,

Figures 9, 10 and 11 show details of the software in flow chart form for producing the ECG display for the second embodiment, and

30 Figures 12, 13 and 14 show further details of the algorithms for producing the ECG and heart rate display for the second embodiment.

First Embodiment

In a first embodiment of the invention the specialist module 2 incorporates essentially analog signal pre-processing means, the resulting pre-processed data being communicated in analog form to the monitor (main unit) 1. The monitor 1 also receives raw data input signals direct from a patient (ECG, temperature, respiration and the like) and pre-processes this raw data internally. The pre-processed data from the specialist module to

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and the pre-processed data received directly at the main unit 1 are then further processed and either displayed on display 3 and/or stored for subsequent recall by said main unit or stored for subsequent or concurrent external output to external data processing means (computer, printout or the like).

Referring to Figure 1 the device of the first preferred embodiment comprises a portable physiological monitor system comprising a base unit 1 and a specialist module 2. The specialist module is adapted to be detachably received by the base unit 1.

10 The base unit 1 provides functions similar to those provided by the portable physiological monitor described in PCT AU88/00016 (previously referenced herein). This unit can obtain information using the electrode system and sensors as described in PCT AU88/00016. Similarly, its output can be a visual display as shown in PCT AU88/00016.

20 Additionally, the base unit is adapted to receive the specialist module 2 and process and display and store signals received from it. The specialist modules include those listed in the introductory part of this specification. By this means a convenient, hand held, non-invasive monitoring instrument is provided which has a broad range of base functions together with an ability to be adapted for further specialist monitoring in a quick and simple fashion.

Referring to Figure 1 the various functional blocks operate as follows:

Physiological Sensors Block (4, 5)

30 The device acquires various physiological signals from the living body, which are later displayed and analysed. This block describes the sensors which connect to the body to gather these signals. These consist of three multifunctional sensors which are placed at the skin of the chest wall. These sensors combine the function of ECG electrodes to detect the electrical signal of the heart, a microphone to detect heart sounds, a thermal sensor to measure temperature, and an impedance measuring technique to sense respiration.

Signal Conditioning Block (6, 7)

The various electrical signals from the sensors need to be amplified and filtered, in order to be converted into digital information for later measurement and display. This block will also exclude any extraneous signals or noise.

Analog - Digital Conversion Block (8)

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The analog electrical signals are converted to digital information which can then be more readily processed.

Measurement and Calculation Block (9)

The digital information derived from the original physiological signals needs to be processed to display parameters which are useful to the user. The heart rate is calculated by measuring the average period of the ECG. The respiration rate is calculated by measuring the average period of the respiration signals. The temperature must be scaled appropriately so that the temperature in degrees can be displayed.

10 Display Block (3)

The wave forms and calculated values need to be available to the user. The function of this block is to display on a screen, (for instance, a high resolution dot matrix LCD display) the various analog wave forms as traces on a screen, and the calculated values as numerals on the same screen. In addition, the screen can be used to warn the user of faults or problems, and the user of the current mode of operation. Previously stored information can also be recalled to the screen for further analysis by the user.

Storage Block (10)

- 20 Wave forms and calculated values are stored in memory to allow later recall by the user, either to make a hard copy on a printer, which is connected via the external output, or to redisplay them on the screen for further analysis.

Control Block (11)

The integrated operation of the various other blocks is controlled by this block. The user controls the operation of the device via control switches which indicate to the control microprocessor exactly what signals need to be acquired, processed and displayed.

- 30 Some of the base unit functions and specialist unit functions are as follows:

BASE UNIT

Electrocardiogram (ECG)

The ECG can be acquired rapidly and easily even in an emergency, by means of a simple disposable electrode patient connection. The ECG is displayed on the LCD screen along with the actual heart rate which is displayed numerically. The monitor stores the ECG information in memory for later recall. The ECG may then be printed on a separate printer or downloaded to a computer database.

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Respiration

At the same time the ECG is being recorded the respiration rate is also measured and displayed on the LCD screen.

Temperature

Using a temperature probe with disposable sheaths, that attaches to the monitor, oral, rectal or skin temperatures can be measured, displayed and recorded for later recall.

SPECIALIST UNITSPulse Oximetry Module

- 10 The arterial oxygen saturation (SaO_2) as a percentage is measured by the Pulse Oximetry Module. A probe is connected to a suitable location on the body (eg finger, ear lobe or nose) and is attached to the unit by a cable. The standard technique using a measure of the relative absorption of light at different frequencies by the blood is used to measure its percentage oxygen saturation. The signal obtained can also be used to derive the pulse rate. The signal is processed by a microprocessor within the module to derive a value for SaO_2 and pulse rate and obtain a filtered pulse wave form (in digital form). This information is sent to the base unit for display, storage and later recall if required. SaO_2
- 20 and pulse rate are displayed as numeric information whilst the pulse wave form is shown as a trace on the LCD display in the base unit.

Non-Invasive Blood Pressure (NIBP Module)

The non-Invasive blood pressure is measured using the oscillometric method. By using an inflated cuff on the arm, the blood pressure is automatically measured and displayed numerically on an LCD display integral to the module. In addition, the pulse rate is also measured and displayed on the LCD. Error checking functions are inbuilt to detect possible fault situations. All data collected by the module is sent to the base unit for later recall and data manipulation.

- 30 A typical specification for the monitor of the present invention is as follows:

MONITOR SPECIFICATIONECG

ECG input:	3 electrodes, positive, negative and indifferent,
Electrode type:	disposable or finger cuff
ECG vectors:	equivalent of Lead II
Patient input impedance:	> 60 Mohms
Leakage current:	< 1 microamp

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- ECG bandwidth: (-3dB) 0.5 - 100 Hz
 Common mode rejection: > 90db 0 - 100 Hz
 Artifact filter: 18db @ 60hz
 Sweep speed: 12.5 mm/sec
 Sensitivity: 2.5 cm/mV
 Calibration: 1 mV
 Audible monitor R wave activated
 Heart rate: R wave activated
 Range: 0 - 255 b.p.m. $\pm$ 1 b.p.m.
- 10 Thermometer
 Function: C 32.0 - 43.0 $\pm$ 0.1C
 F 90.0 - 110.0 $\pm$ 0.2F
 Temperature sensor: probe type thermistor, with disposable sheath
 Measurement method: predictive
Respiration
 Method: impedance
 Sensitivity: 0.2 ohms
Pulse Oximetry Module
 Measurement: SaO₂ (Percentage Oxygen Saturation)
 20 Resolution: 1%
 Range: 40%-100%
 Accuracy: +/- 2% for readings 80%-100%
 +/- 3% for readings 50%-79%
 Settling Time: 10 seconds typically
 Pulse Rate (beats per minute):
 Range: 30-250 b.p.m.
 Resolution: 1 b.p.m.
 Accuracy: +/- 1%
 Settling Time: 10 seconds typically
 30 Display: Uses Base Unit LCD display
 Numerical Display of SaO₂ and Pulse Rate
 Pulse Waveform Display
 Sensor Probe Types: Finger Clips
 Ear Clips
 Disposable Type (suitable for ear, nose or finger)
- Non-Invasive Blood Pressure (NIBP module)
 Measurement method: oscillometric
 Display method: custom LCD

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Pressure accuracy: $\pm 3\text{mmHg}$ or $\pm 2\%$ whichever is greater
Pulse rate accuracy: $\pm 5\%$
Measurement range: 20 - 250 mmHg
30 - 150/min
Deflation - Rapid: rapid deflation
Measurement: automatic cuff deflation
Inflation method: manual inflation with bulb
Auto power off: non use after 3 mins.

Electrical Characteristics

10 Display: high resolution (120 pixel hor. by 480 pixel ver.)
Display size: 50.8 mm wide by 38.1 mm height
External output: optically isolated digital output
Battery type: 4 AA alkaline cells or equivalent rechargeable
Battery life: > 10 hours continuous use

Physical Characteristics

Dimensions: 230 mm length
75 mm wide
30 mm depth

20 The present invention possesses characteristics which allow it to be used immediately and conveniently to receive information from a patient by utilising a hand held instrument applied directly to the skin surface of a patient together with the connection of suitable probe units. Specialist units can be added in situ to provide additional specialist information as listed in the introductory part of the specification.

Second Embodiment

A second embodiment will now be described with reference to Figures 2 to 14. Figure 2 shows the external appearance of the front of the second embodiment. Referring to Figure 2 there is shown a specialist module 20 having a sensor 21 connected to the specialist module 20 by means of sensor
30 connector 22. The specialist module 20 is removably connected to a main unit 23 having on its front a display 24 and a key pad 25. Also shown in Figure 2 as part of the main unit 23 are the patient cable input 26, the temperature probe input 27 and the infrared data link 28.

Figure 3 shows a typical display output available from the second embodiment (and, indeed, the first embodiment). The display shows an ECG wave form 29 and digital data 30 displayed on the one screen. In this particular case the digital data comprises a heart rate display and a

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temperature display. Other digital data and other wave form data are available depending upon the specialist module 20 specifically connected at any one time to the main unit 23.

Referring to Figure 4 there is shown a block diagram of the interconnection of the main unit 23, the specialist unit 20 and the sensor 21. In this embodiment the specialist module 20 and the main unit 23 are interconnected by a digital data bus (I/O bus) 31. Also shown is a control bus 32 for control commands and a power bus 33 for supplying power from the main unit 23 to the specialist module 20.

10 Figure 5 shows a block diagram in greater detail of the main unit 23. Specifically the main unit 23 comprises a microprocessor 34, a signal conditioning unit 35, ram 36, EE prom 37, display controller 38 and power supply 39 all interconnected as shown in Figure 5. The display controller 38 communicates with the display 34 on the main unit 23. Various sensors 40 communicate directly with the main unit 23 by means of either the patient cable input 26 or the temperature probe input 27. The patient cable input 26 can include connection to devices such as ECG probes and the like..

20 Figure 6 shows further detail of the functional blocks comprising the specialist module 20. The specialist module incorporates a microprocessor 41, signal conditioning means 42, sensor control 43, ram 44 and EE prom 45 all interconnected as shown in Figure 6. A sensor 21 can be any one of the specialist module sensors as described in the introductory portion of the specification. The microprocessor 41 is suitably programmed according to the sensor 21 specifically connected to any given specialist module in order to appropriately pre-process data received from the sensor 21. Pre-processed information is then transferred by means of the data bus 31 to the processor of the main unit 23 for further processing and output.

30 Referring to Figure 7 there is shown the specific interconnection of the electronic units comprising a variant of the second embodiment. In this embodiment there is incorporated an analog circuit 46 for receiving information from ECG probes connected by the patient cable input 26 to the main unit 23.

 Figure 8 shows a block diagram of the analog circuit 46, which circuit with the appropriate electrode connection made via input 26 provides a pre-processed ECG signal 47 and, as appropriate, a pacemaker pulse signal 48 to the microprocessor 34 for subsequent display (as shown in Figure 3) on the display 24.

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Figures 9 to 14 inclusive show software flow diagrams of the display algorithms programmed in the microprocessor 34 of the main unit which allow the processor to operate the display 24 in the manner shown in Figure 3.

The foregoing describes only one embodiment of the present invention and modifications, obvious to those skilled in the art, can be made thereto without departing from the scope and spirit of the present invention.

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MODULAR PHYSIOLOGICAL MONITORCLAIMS

1. A modular physiological monitor comprising:
 - standard input means adapted to receive a plurality of input signals;
 - specialist input means adapted to receive and pre-process signals from specialist sensors;
 - data processing means adapted to receive information from said standard input means and said specialist input means;
 - 10 display means to display selected processed data;
 - storage means for storing selected unprocessed and processed data;
 - said specialist input means being detachably attached to said monitor.
2. The monitor of Claim 1 wherein said monitor is a hand held non-invasive instrument comprising a base unit which records and displays one or more of at least:
 - heart wave form (ECG);
 - pacemaker pulse wave form;
 - 20 heart rate;
 - respiration rate;
 - oral or rectal temperature;
 - together with a detachable specialist unit adapted to receive and pre-process specialist information from a patient.
3. The monitor of Claim 2 wherein said specialist unit comprises one or more of at least:
 - oximeter;
 - invasive blood pressure;
 - capnograph;
 - 30 PO_2/PCO_2 ;
 - phonocardiogram;
 - EMG;
 - EEG;
 - pH meter;
 - non-invasive blood pressure.
4. The monitor of Claim 3 wherein said main unit and said specialist unit communicate by analog means.
5. The monitor of Claim 3 wherein said specialist unit and said main unit communicate by digital means on a digital bus.

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6. The monitor of Claim 5 wherein said specialist unit incorporates on board data processing means to pre-process raw data received from sensors.

7. The monitor of Claim 6 wherein said main unit includes further digital data processing means and on board memory which allows for the further processing and display of data derived by said specialist module together with data derived directly from sensing means connected directly to said main unit.

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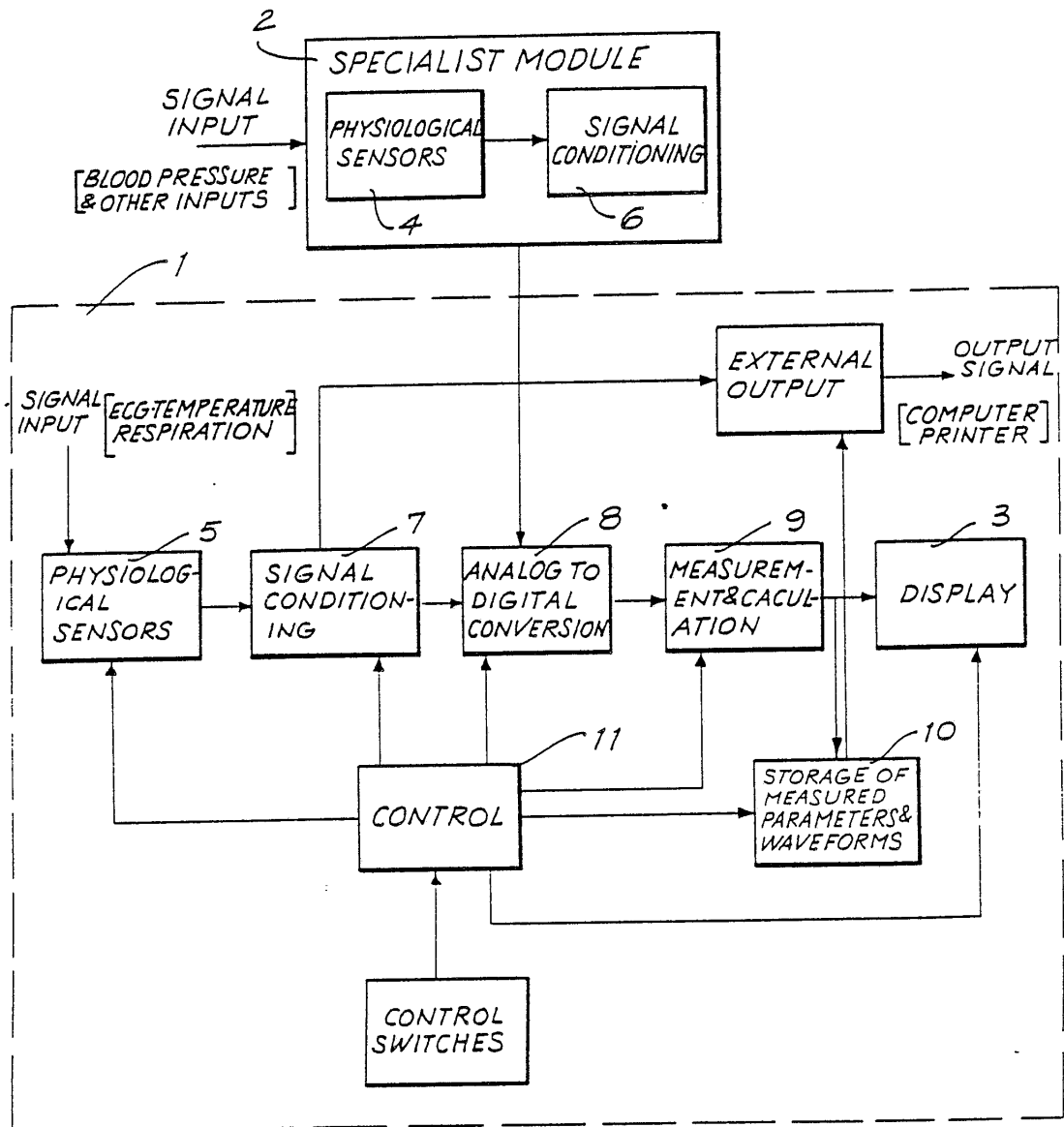


FIG. 1

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14 SHEETS, SHEET 2

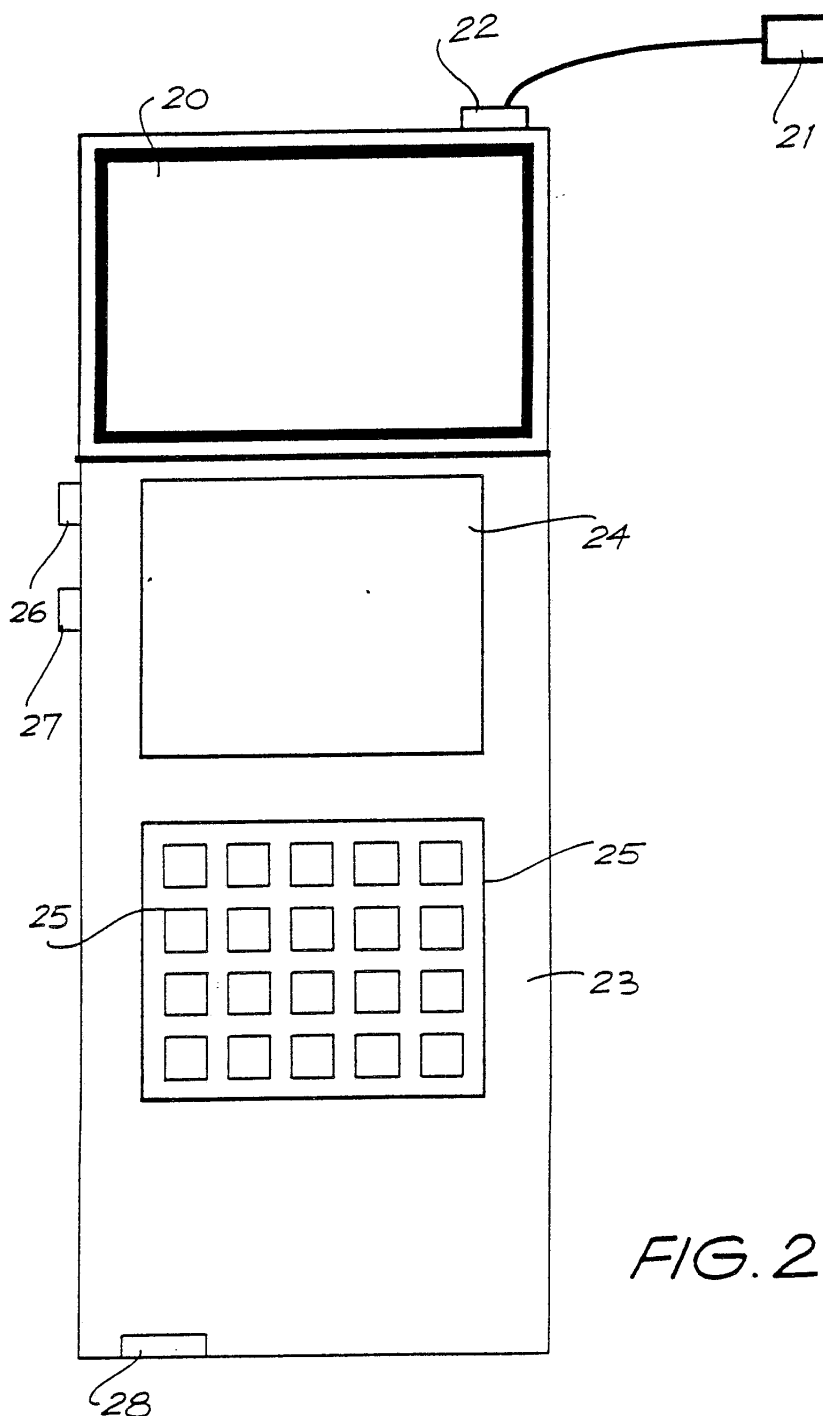


FIG. 2

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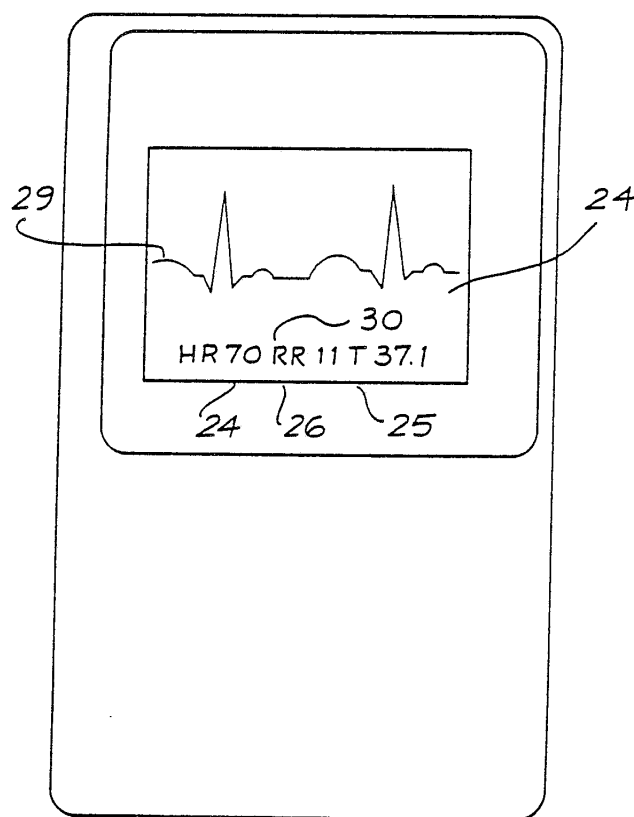


FIG. 3

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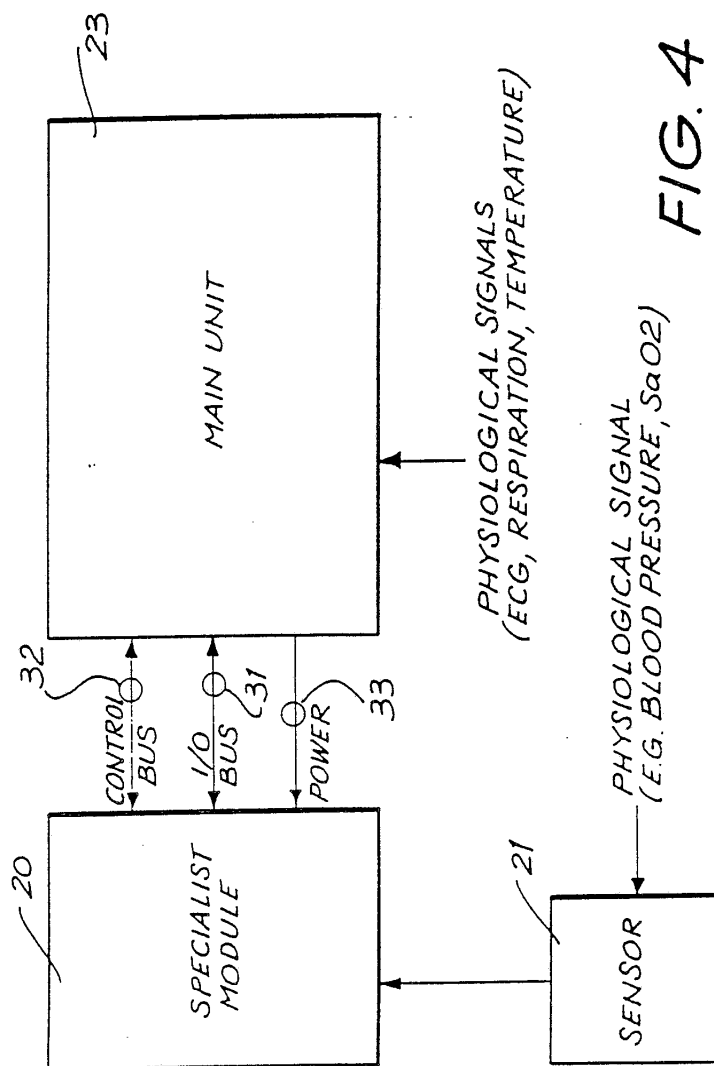
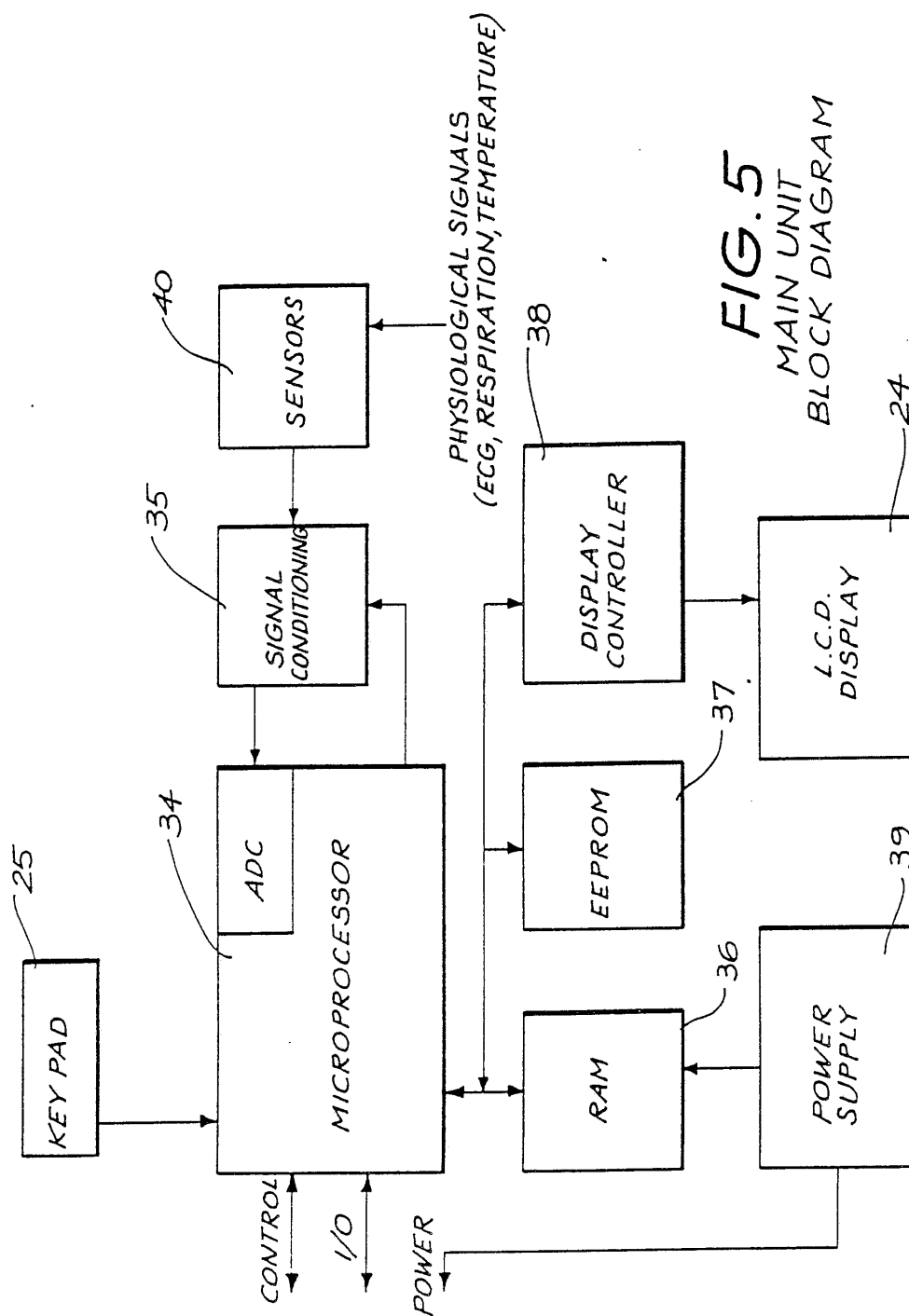


FIG. 4

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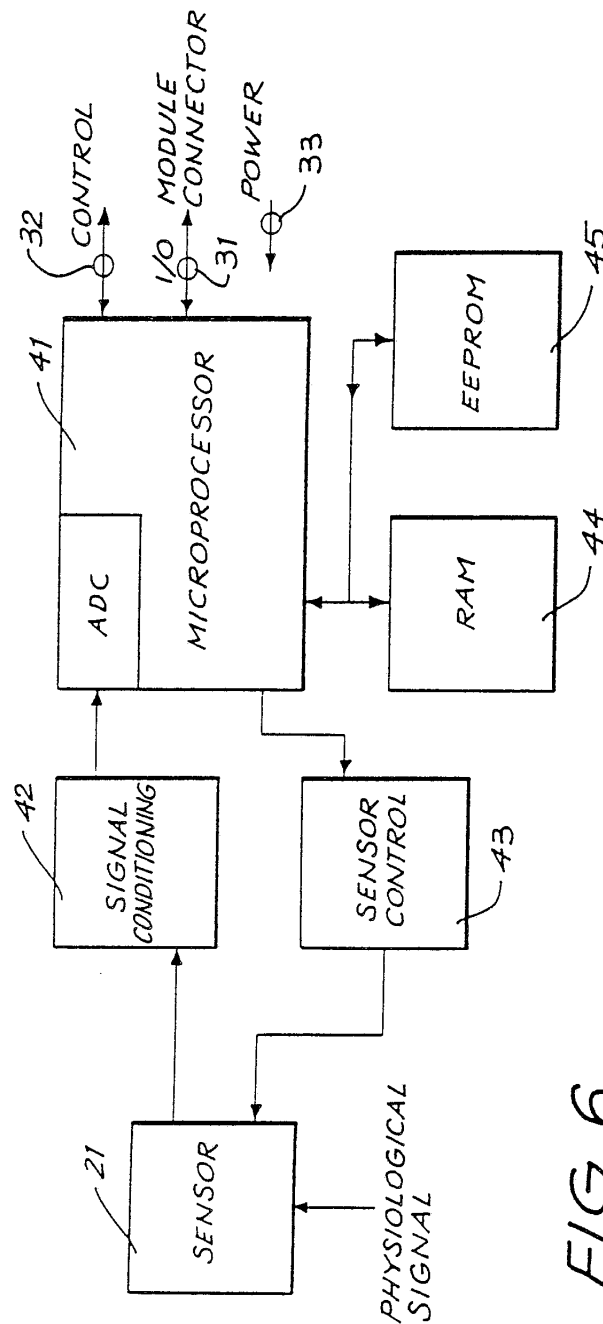
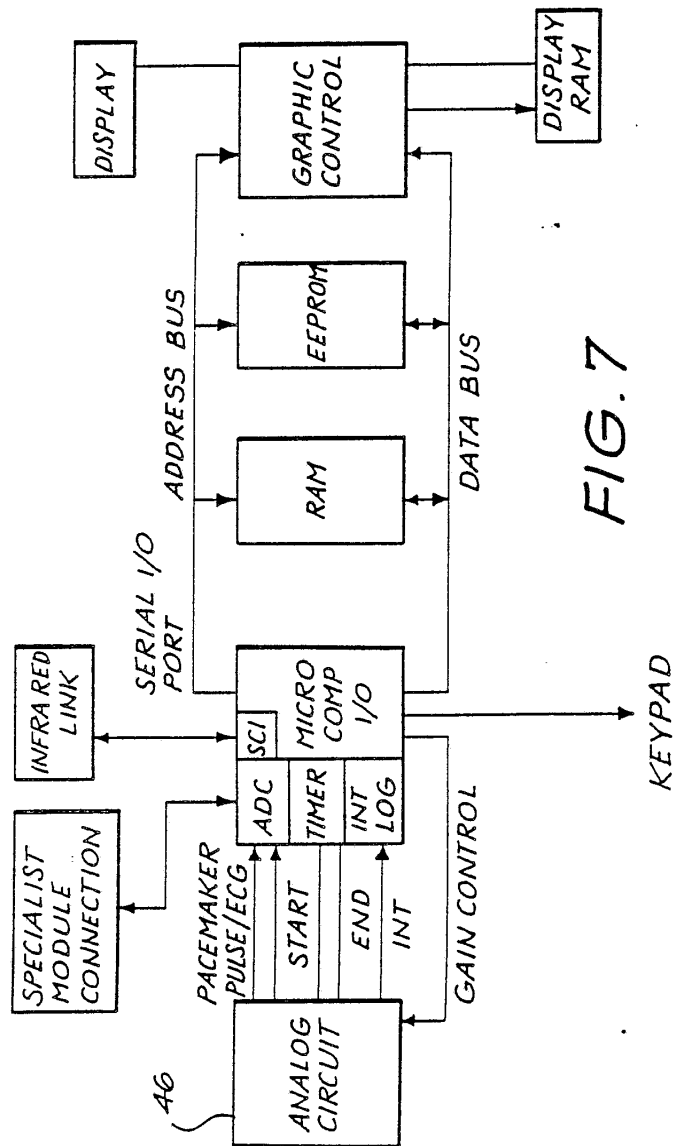


FIG. 6

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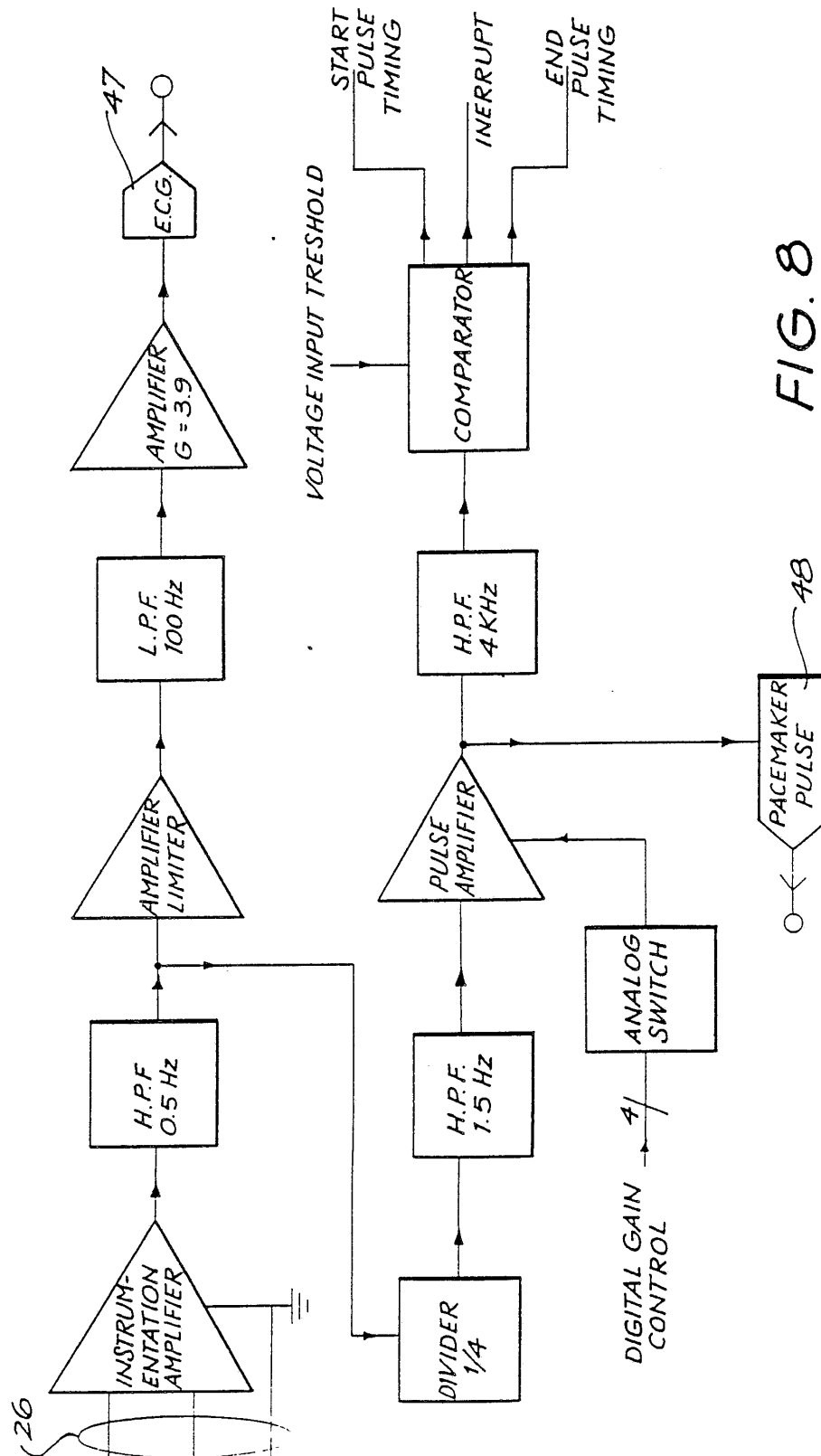
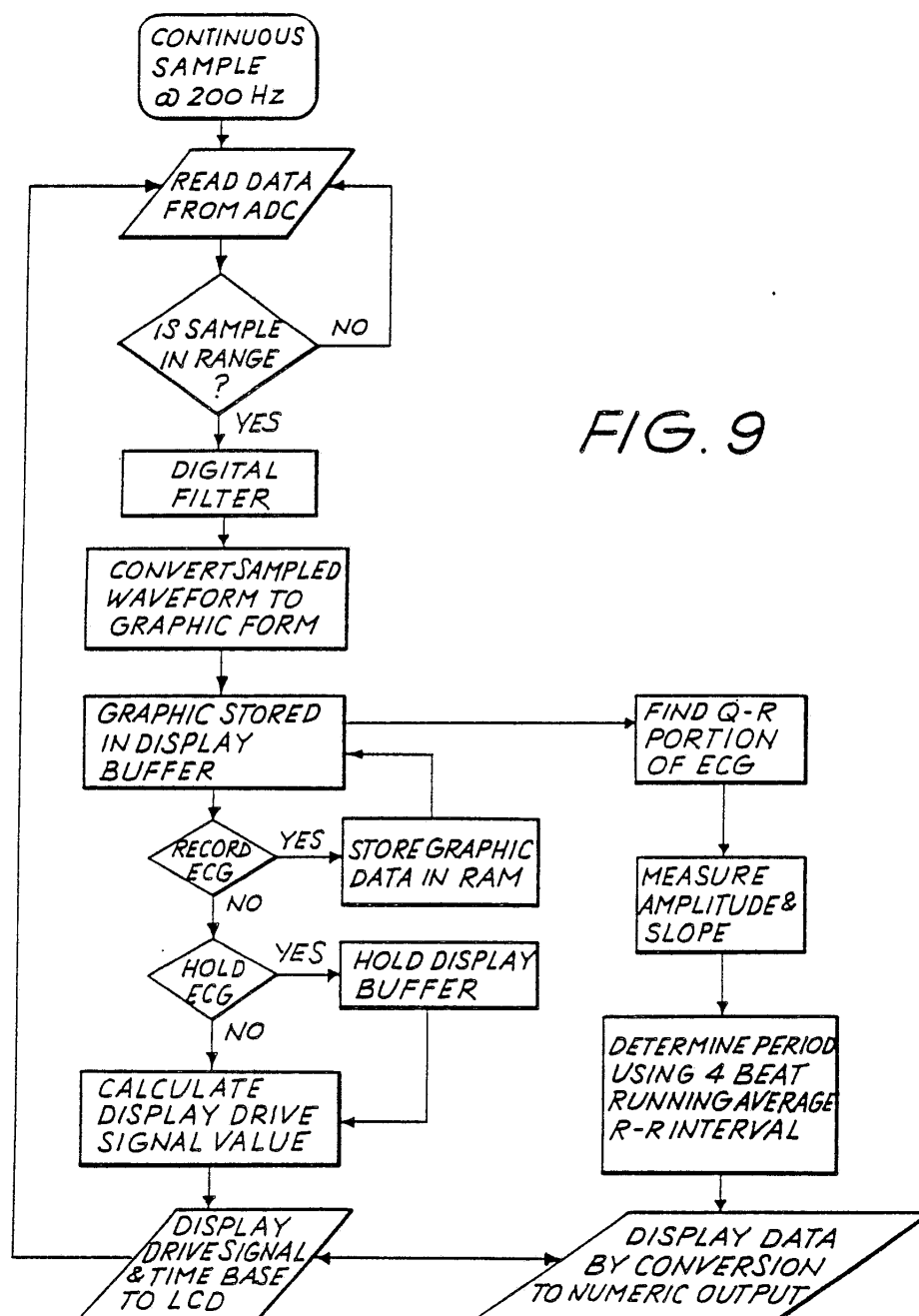


FIG. 8

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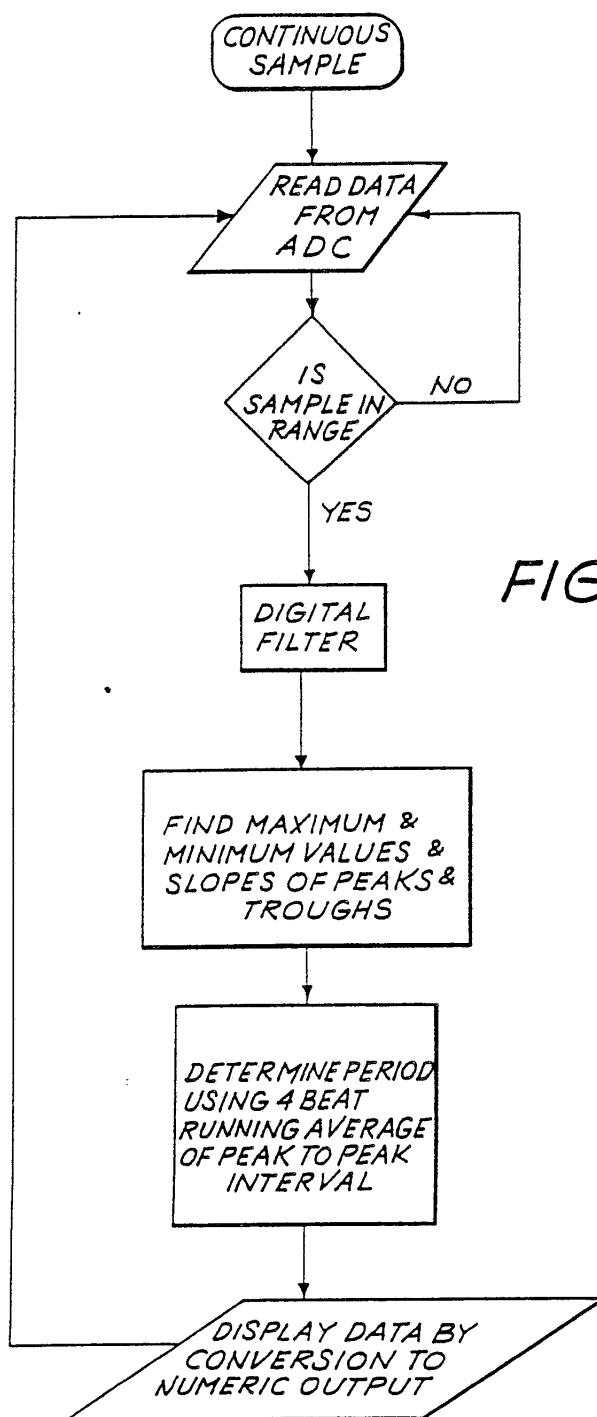
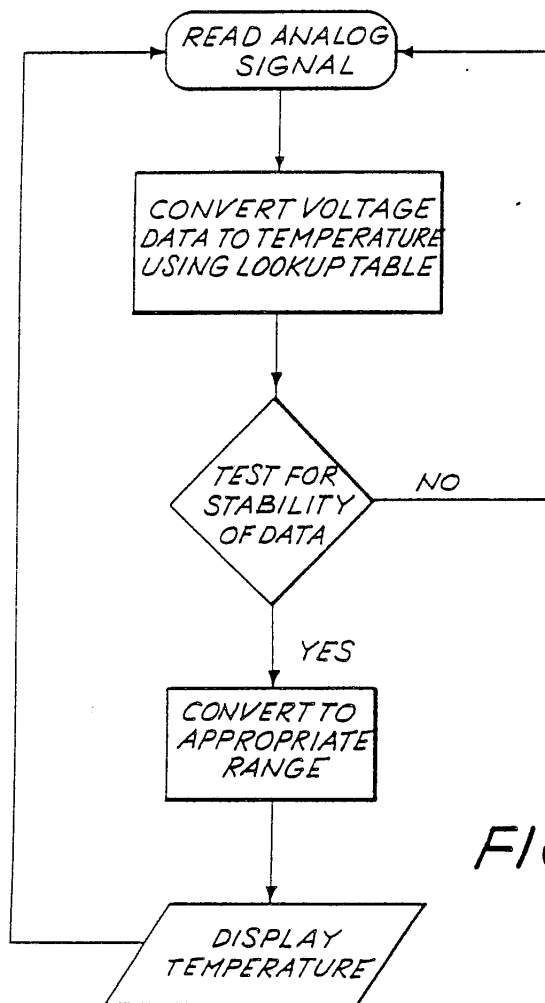


FIG. 10

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*FIG. 11*

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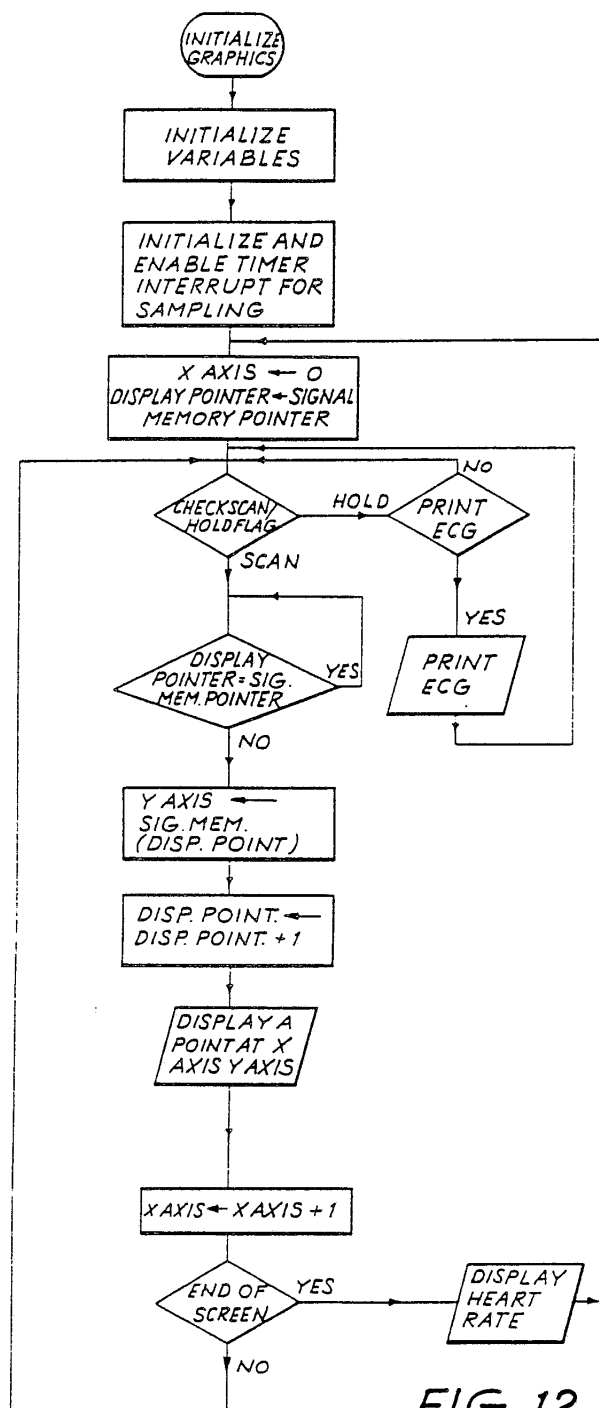


FIG. 12

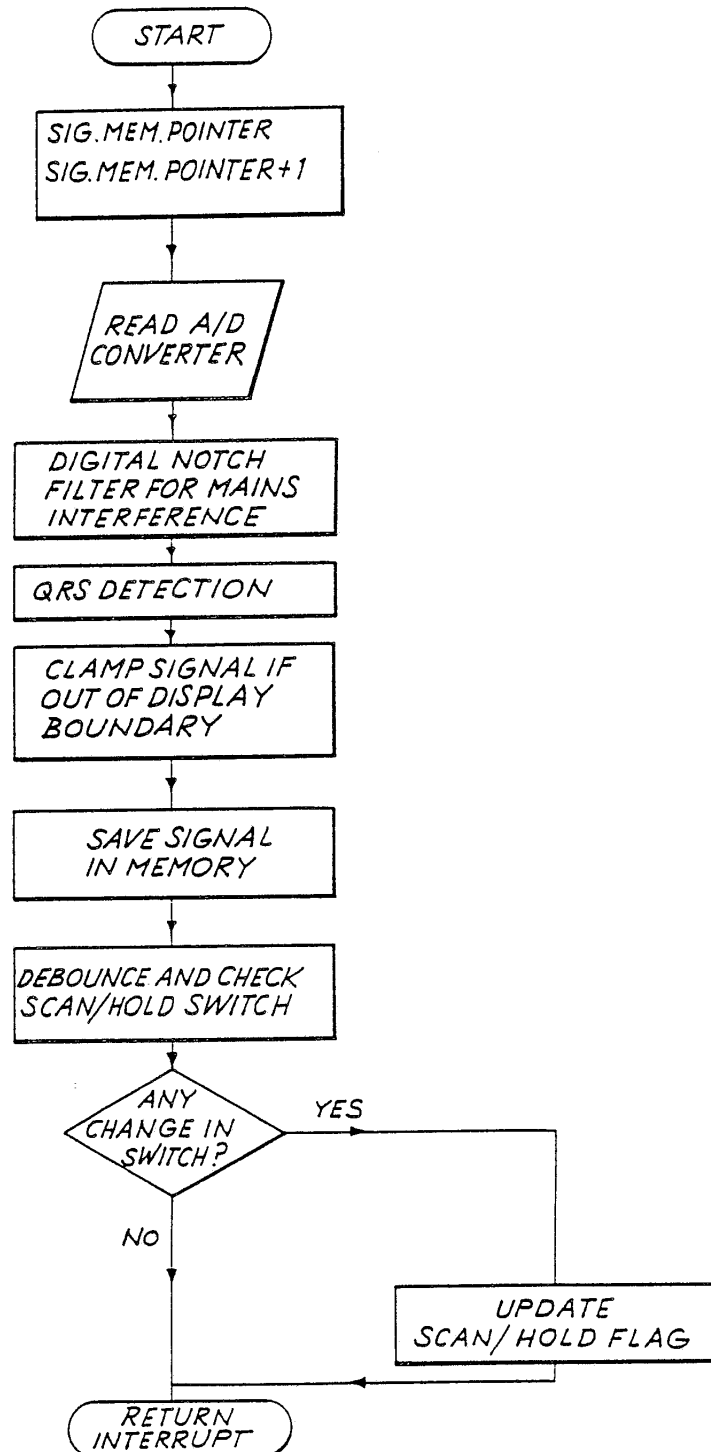
MAIN ROUTINE FOR ECG AND HEART RATE DISPLAY

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**FIG. 13**

TIMER INTERRUPT SERVICE ROUTINE FOR
ECG AND HEART RATE DISPLAY

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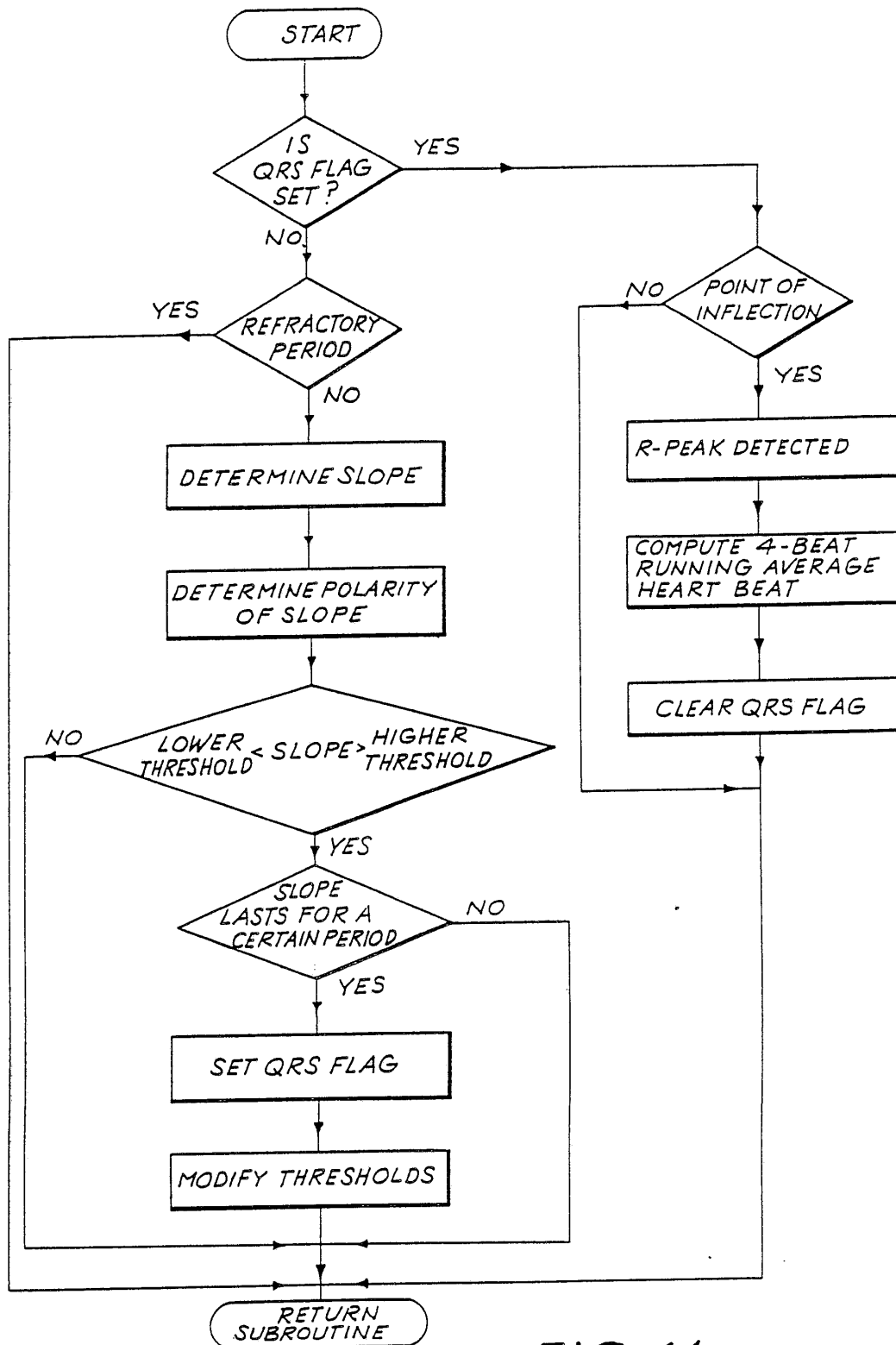


FIG. 14

QRS DETECTION ALGORITHM FOR
ECG AND HEART RATE DISPLAY.

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INTERNATIONAL SEARCH REPORT

International Application No.

PCT/AU 88/00225

I. CLASSIFICATION OF SUBJECT MATTER (If several classification symbols apply, indicate all)		
According to International Patent Classification (IPC) or to both National Classification and IPC		
Int. Cl. ⁴ A61B 5/00		
II. FIELDS SEARCHED		
Minimum Documentation Searched *		
Classification System	Classification Symbols	
I P C	A61B 5/00, 5/02, 5/04	
Documentation Searched other than Minimum Documentation to the extent that such documents are included in the fields searched *		
AU : IPC as above		
III. DOCUMENTS CONSIDERED TO BE RELEVANT *		
Category *	Citation of Document, ** with indication, where appropriate, of the relevant passages **	Relevant to Claim No. **
X,Y	US,A, 4325385 (HOLTE) 20 April 1982 (20.04.82)	(1-4)
X,Y	US,A, 4276888 (SMITH ET AL) 7 July 1981 (07.07.81)	(1-4)
X,Y	FR,A, 2535964 (MESNARD & BAKKAR) 18 May 1984 (18.05.84)	(1-3)
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Y	US,A, 4121574 (LESTER) 24 October 1978 (24.10.78)	(1,2)
Y	FR,A, 2438872 (INSTITUTE NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE) 9 May 1980 (09.05.80)	(1,2)
(CONTINUED OVER)		
* Special categories of cited documents: ** "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 doubt 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. "Z" 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	
13 October 1988 (13.10.88)	18 OCTOBER 1988 (18.10.88)	
International Searching Authority	Signature of Authorized Officer	
AUSTRALIAN PATENT OFFICE	E.N. PERRIS	

Form PCT/ISA/210 (second sheet) (January 1985)

III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)		
Category *	Citation of Document, with indication, where appropriate, of the relevant passages	Relevant to Claim No
y	AU,B, 54818/65(404714) (INTERNATIONAL BUSINESS MACHINES CORP.) 11 August 1966 (11.08.66)	(1)
Y	US,A, 4116228 (HUDSPETH ET AL.) 26 September 1978 (26.09.78)	(2)

Form PCT ISA 210 (extra sheet) (January 1985)

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON
INTERNATIONAL APPLICATION NO. PCT/AU 88/00225

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian 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		Patent Family Members		
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