United States Patent

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[33] **Great Britain**
[31] **38,245/68**

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[54] **DIAGNOSTIC PATIENT MONITOR**
9 Claims, 3 Drawing Figs.

[52] **U.S. Cl.** ..... **128/2.05 R,** 128/2.06 R, 128/2.1 R
[51] **Int. Cl.** **A61b 5/02**
[50] **Field of Search** ..... 128/2.06, 2.1, 2.05 T, 2.05 P, 2.05 S, 2

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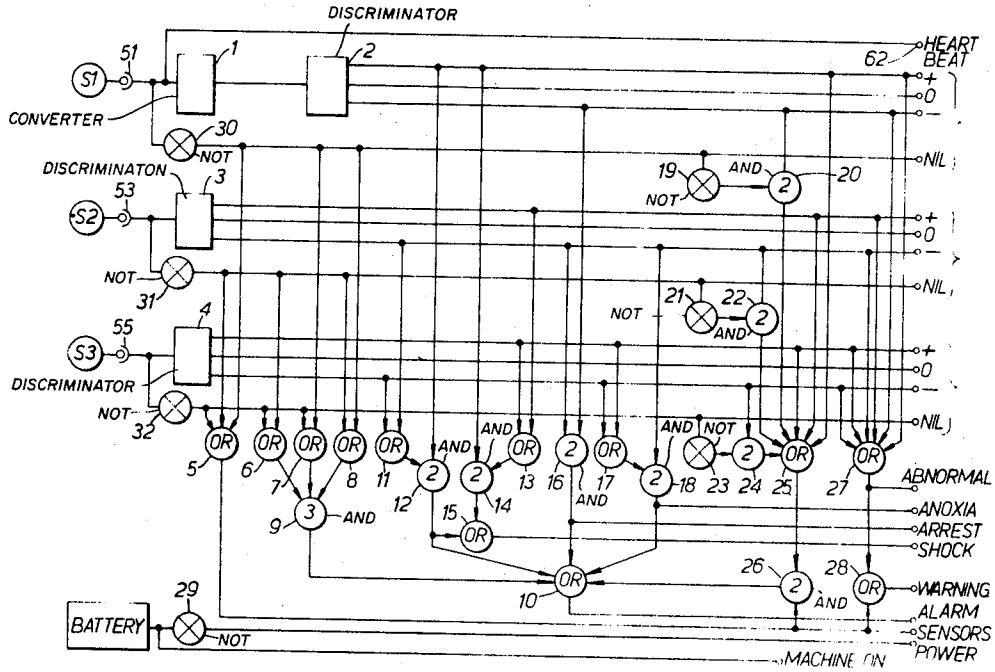
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ABSTRACT: A diagnostic patient monitor is provided which monitors the condition of a patient by means of a sensor system to provide output signals, not less than six in number, indicative of normal, above normal or below normal sensed conditions from at least two sensors. The signals are used to directly indicate each condition and are combined so that specific combinations of abnormal signals provide an indication of the condition of the patient resulting in the abnormal signals. Two abnormal signals occurring simultaneously result in the activation of an alarm.



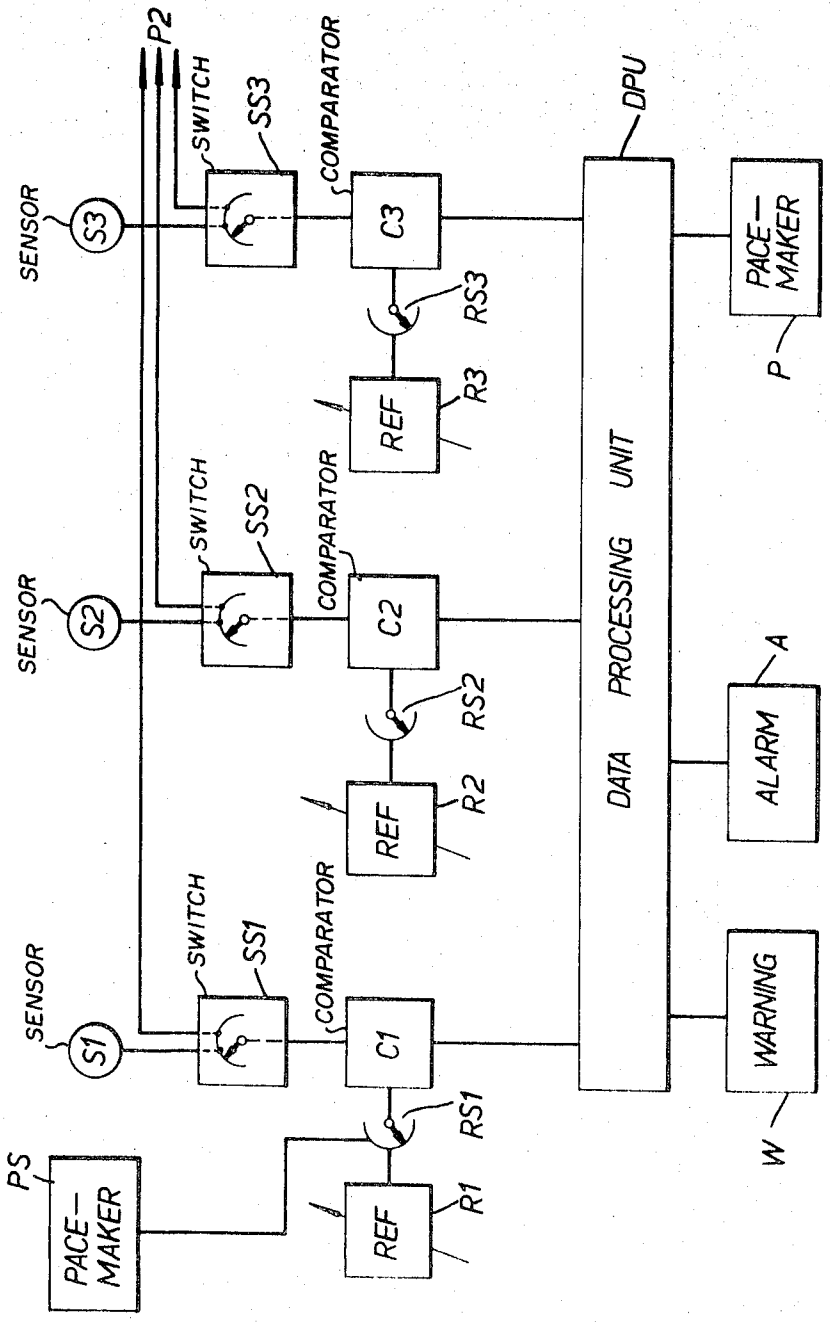


FIG. 1.

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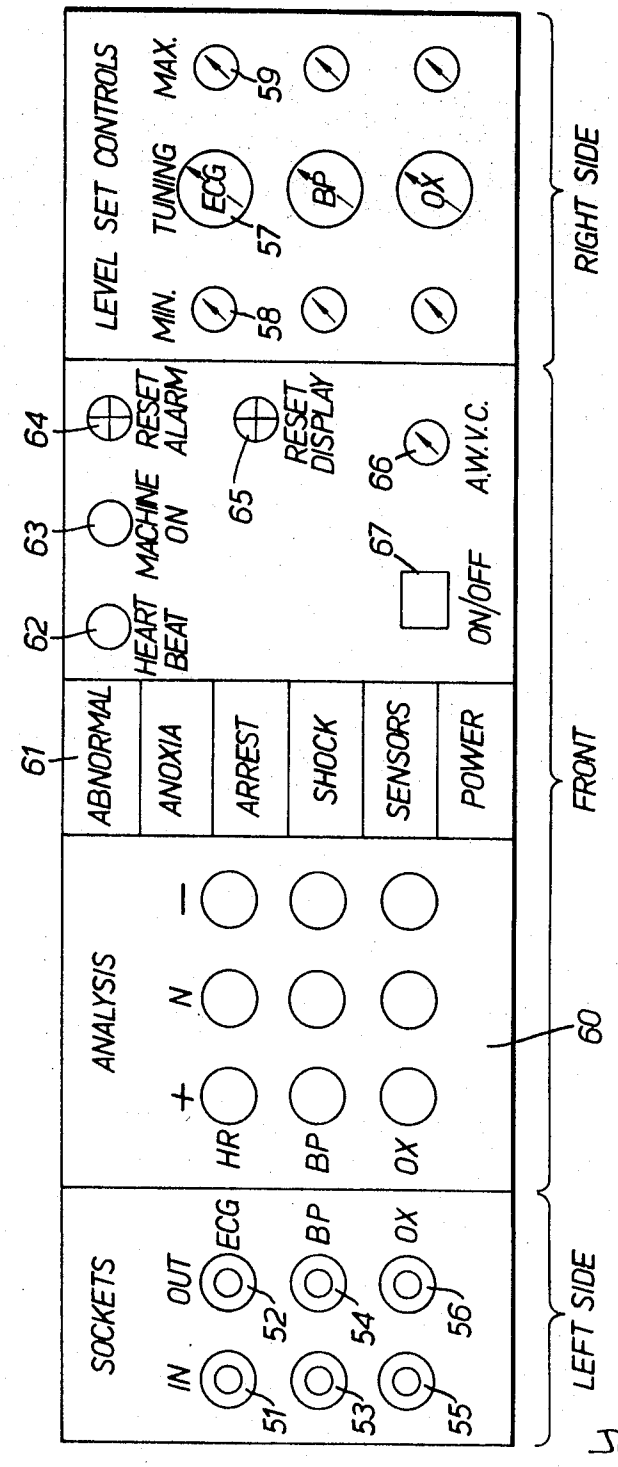


FIG. 2.

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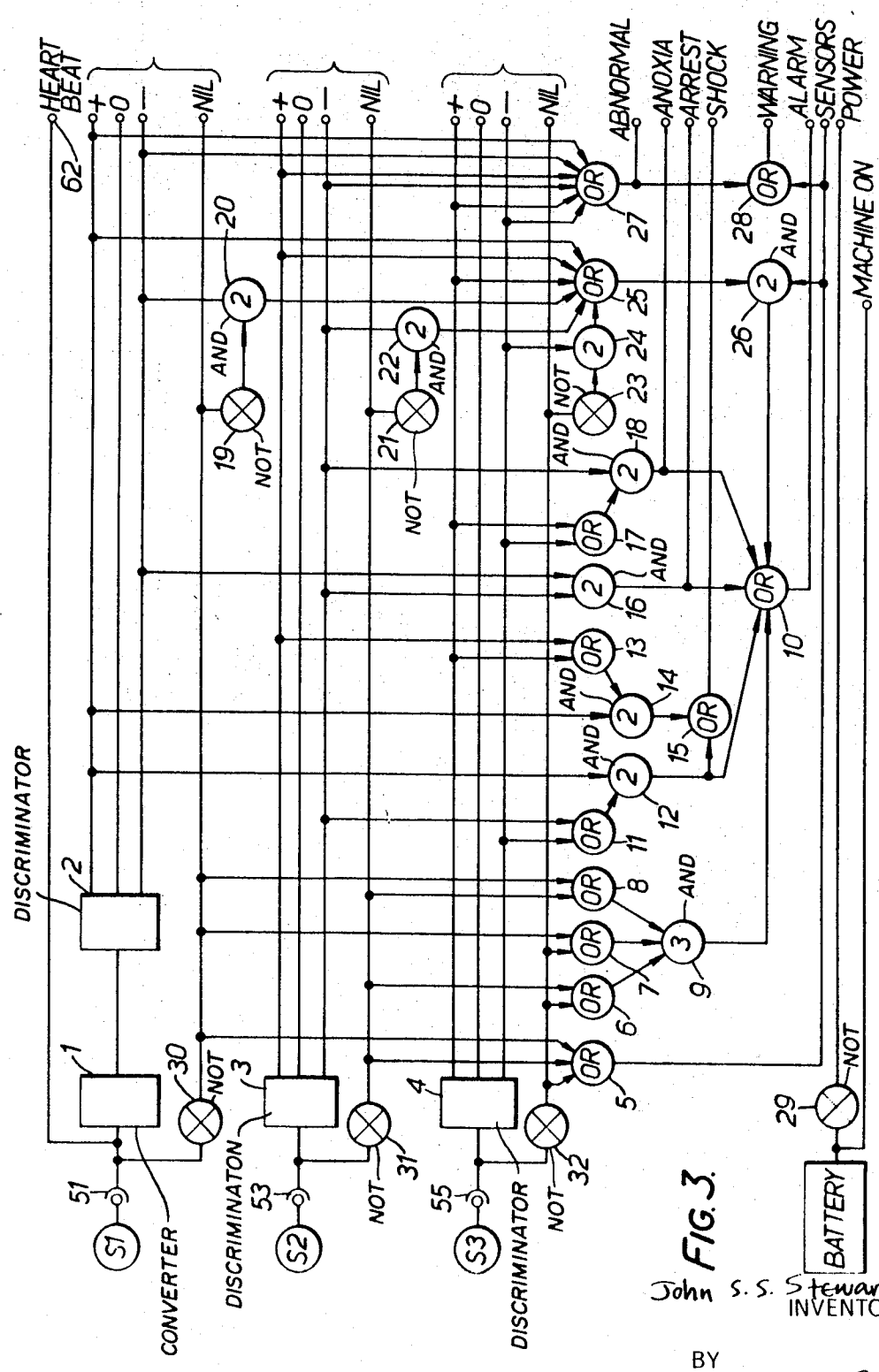


FIG. 3.

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DIAGNOSTIC PATIENT MONITOR

This invention relates to apparatus for supervising the condition of a patient.

In existing apparatus a measurement is derived from a patient by way of a sensor. This measurement or another derived from it and called a parameter is obtained continuously. The clinician sets the upper and lower limits of the range which is acceptable as normal in the patient. Departures from this range are denoted by alarm signals. Several parameters may be similarly and simultaneously derived with their respective alarm signals. The multiplicity of alarms, many of which are trivial or false, distresses the patient and destroys the confidence of the nursing and medical staff in the accuracy and reliability of the apparatus.

The improved apparatus described herein processes the signals from at least three parameters. Preferably the three parameters are heart action, blood circulation and respiration gas exchange. A diagnosis is made of the condition and of its urgency of need for treatment. The diagnosis is in respect of clinical condition, sensor performances and power reserves. This information is communicated in a simple ambiguous way by visual displays and auditory signals. All the important clinical emergencies which are associated with acute circulatory failure: cardiac arrest, hypoxia and shock, are diagnosed and indicated with accuracy and reliability. The features of which each diagnosis is compounded are also indicated.

Many of the alarm systems proposed in the past have suffered from the disadvantage of providing frequent false alarms. Monitoring systems are more reliable if multiple parameters are processed and alarms are restricted to simultaneous transgression of limits in respect to two parameters or if sensors are duplicated. This is because the weakest link in the system is the patient sensor interface. It is the purpose of the invention to provide an improved monitoring system which represents an optimal solution of the problem from the point of view of comprehensiveness and economy.

According to the invention there is provided an apparatus for monitoring the condition of a patient including at least three input terminals to which can be applied signals indicating the condition of a patient with respect to at least three parameters respectively, a circuit arrangement for deriving signals denotive of the departure of the applied signals from inside a predetermined range and means for providing indications when predetermined combinations of derived signals occur.

Features and advantages of the invention will appear from the following description taken in conjunction with the accompanying drawings in which:

FIG. 1 is a block diagram showing an embodiment of the invention;

FIG. 2 illustrates the control panels of an apparatus according to the invention; and

FIG. 3 is a logic diagram illustrating the operation of the apparatus shown in FIG. 2.

Acute circulatory failure may be due to cardiac insufficiency, peripheral vasodilatation or decreased circulating blood volume, commonly due to cardiac arrest, hypoxia and shock. The three preferred parameters, derived in the example from sensors S1, S2, S3 relate respectively to heart action, rate, force, volume or efficiency; to blood circulation, pressure, flow, velocity or efficiency and to respiration, in lungs or tissues, rate, force, volume or efficiency. Thus a type S1 sensor measures, for example, heart rate, stroke volume or ventricular force, etc. Heart rate, for example, may be derived from electrocardiogram, phonocardiogram, peripheral pulses or from the wave form of blood pressure, blood flow, blood velocity, etc. A type S2 sensor measures, for example, blood pressure, blood flow, blood velocity or circulation time. These may be derived from finger pulse or intra-arterial catheter using strain gauge, pressure transducer, electromagnetic flow meter or ultrasonic velocity meter, etc. A type S3 sensor measures, for example, respiration rate, oxygen tension, carbon dioxide partial pressure or acidosis. Respiration rate may be derived from respiration sounds, impedance plethysmography, strain gauge, nasal temperature, etc. Gas levels in blood or tissues may be derived from oximeter, electrode, electroencephalogram, etc.

The responses of the parameters can be in various forms, but it is convenient if the responses are translated to digital or analogue equivalents in a common quantity. Electrical variations of voltage or current are especially suitable but other quantities, such as hydraulic or pneumatic pressure, mechanical force or displacement can be used also but in general electrical equivalents can be obtained easily, if not produced directly by the appropriate sensor and once obtained can be readily processed. In the arrangement described more fully herein the sensors S1, S2 and S3 derive respectively the electrocardiogram heat rate, the blood pressure and the oximeter oxygen tension. Thus the input of the analyzer, or data processing unit, consists of electrical equivalents of heart action, blood circulation and respiration.

Reliability is obtained by a process of comparison and logic analysis performed in the analyzer. The sensor output is examined before or after derivation of the desired parameter to determine if it is characteristic or meaningful. Detachment of a measuring device may be detected in this way. Each parameter is examined in respect of nature, duration and rapidity of response in addition to simple departure from range. Some false signals, for example those due to motion artifact or some true signals of trivial importance, for example tachycardia due to physical exertion, are thus prevented from giving alarms. The same parameters, derived by duplication of sensors or otherwise, from different sources are examined. Disparity indicates false signals due, for example, to artifact or detachment of a sensor.

Accuracy of diagnosis is achieved by a process of logic analysis performed in the analyzer or data processing unit. Data presented to the analyzer can be expressed quantitatively as high (+), normal (0), or low (−). If a quantitative estimate is made successively for heart rate, blood pressure and oximetry, a simple three symbol code expresses the situation. Thus the normal is (0 0 0) and a patient with oligaemic shock who has tachycardia, hypotension and as yet normal oxygen tension, would be represented as (+ − 0). The clinician would be alarmed by (− − −) or (− − 0) which would be found in ventricular fibrillation and would wish to know about warning signs such as tachycardia (+ 0 0), hypertension (0 + 0) and cyanoisis(0 0 +). He would also wish to know about (+ 0 0) which would indicate that the electrocardiogram has been disconnected.

The permutation of three settings (+ 0 −) with three signals, heart rate, blood pressure, oximetry, are 3^3 or 27. The clinical meaning which is assigned to each of the permutations is given in the following table.

TABLE

Heart rate	Blood pressure	Oximeter	Warning	Alarm
0	0	0		
0	0	+	X	
0	0	−	C	
0	+	0	H	
0	+	+	HX	
0	+	−	HC	
0	−	0	L	
0	−	+	LX	A
0	−	−	LC	A(S)
+	0	0	T	
+	0	+	TXS	
+	0	−	TC	S
+	+	0	THS	
+	+	+	THXS	
+	+	−	THC	S
+	−	0	TL	S
+	−	+	TLX	(S)A
+	−	−	TLC	(S)A
−	0	0	B	
−	0	+	BX	
−	0	−	BC	

-Continued TABLE

Heart rate	Blood pressure	Oximeter	Warning	Alarm
-	+	0	BH	
-	+	+	BHX	
-	+	-	BHC	
-	-	0	BL	V
-	-	+	BLX	V(A)
-	-	-	BLC	V(A)

NOTE: X=Oximeter; B=Bradycardia; V=Ventricular fibrillation or asystole; C=Cyanosis; A=Anoxia; T=Tachycardia; S=Surgical shock; H=High B.P.; L=Low B.P.; 0=Normal; -=Low reading; +=High reading.

It is a main purpose of the machine to communicate with those tending the patient if the condition of the patient and the machine is not entirely satisfactory. The output indicates firstly the abnormal state, clinical or machine, secondly the component clinical signs or machine faults which make up the abnormal state, and thirdly the degree of urgency of the indicated condition. The output may be visual with continuous or flashing lights or illuminated panels indicating the condition or it may be auditory with continuous or intermittent warning or alarm sounds. Provision can be made for connection to a pacemaker in which case a panel light PACER can be illuminated when this is in action. A light comes on when the power is switched on and there is also a series of on/off switches.

In practice, one central unit can be used with numerous patients. Each patient is then provided with appropriate sensors and the sensors of each patient in turn can be connected to the data processing part of the apparatus.

Additional optional equipment includes the pacemaker already mentioned, an oscilloscope for display of the electrocardiogram, blood pressure or oximeter reading and a recorder for producing permanent records. It should be noted that it is not necessary to provide digital display, dials or meters showing the numerical values of the measurements. If these are within the permitted limits no record is necessary; if not, a warning is given and the absence of a dial encourages the nurse to look at the patient, where her attention should be directed, not at the machine. In the event of an arrest display and recording equipment might be helpful but such equipment is portable and can be brought: it need not be incorporated for it is not an essential part of every monitor.

The form of one embodiment of the apparatus is shown diagrammatically in FIG. 1. Sensors S1, S2 and S3 are applied to a patient; for reasons mentioned above, the sensors may be duplicated or supplemented. Similar sensors are applied to other patients, the responses being derived over leads P2, etc. The sensor outputs are selected in sequence by selector switches SS1, SS2, SS3 and applied to comparator stages C1, C2, C3, and the outputs compared against settable standard responses from sources R1, R2, R3. If desired, the reference responses may be set for the sensor for each patient, as by reference switches RS1, RS2, RS3, moving with the selector switches.

The derived error or deviation signals are fed to the data processing unit DPU and caused, on the logic of the Table, to operate visual and auditory warning and alarm indicators W, A respectively. The pacemaker PS sensor controls, through the processing unit DPU, the pacemaker indicator P.

In the embodiment described here (FIG. 2) the display consists of illuminated diagnosis panels 61 which give the diagnosis or machine fault and an analysis panel 60 showing the sensor state in a panel of nine indicator lights which give the component features of clinical and sensor conditions. In the diagnosis panel 61 ABNORMAL is illuminated if there is any clinical or sensor abnormality. Diagnosis of ARREST, ANOXIA and SHOCK are illuminated when appropriate according to the logic of the Table. The panels SENSOR and POWER are illuminated in the event of sensor fault or power failure.

The anaylsis panel 60 indicates the state of each sensor of type S1, S2 and S3, whether "normal," "high" or "low" due to clinical condition as in the table or sensor fault. Adjacent to each "high" or "low" indicator light of the analysis panel 60 may be given if desired the appropriate clinical sign or feature, for example, tachycardia, bradycardia, hypertension, hypotension, cyanosis. As noted later, this is dependent to some extent on the type of sensor used.

The type of auditory output, WARNING or ALARM, is also shown in the table. Controls for the auditory warning 66 permit regulation in respect of volume and of time interval between visual display and auditory warning. Usually the person tending the patient will note an abnormality (one parameter abnormal; see Table and correct this early warning before the auditory warning sounds and without disturbing the patient. It is noted (see table) that early shock is a warning condition but severe shock is an alarm condition.

Level set controls are provided for each sensor. For the type S1 sensor, here the electrocardiogram, the central control 57 is used to set the machine "normal" to the patient's heart rate. The adjacent maximum 59 and minimum 58 controls set the upper and lower permitted limits. Similar sets of controls for type S2 and type S3 sensors are provided.

The type S1 sensor input is by a socket 51 and adjacent is an output socket 52 for display, if desired. Similar sockets are provided by the type S2 sensor 53, 54 and the type S3 sensor 55, 56.

Also shown are a "machine on" indicator light 63, auditory warning volume and time delay control 66, switches to reset alarm 64 and display 65 and an on/off switch 67. The alarm reset switch 64 is used to suppress temporarily the auditory alarm when setting up the machine or attending to a patient after an alarm. It returns automatically to the "alert" position after an interval. This display caused by any abnormal condition is held until reset to "normal" by the reset display button 65.

The logic circuit of the apparatus is shown in greater detail in FIG. 3. The sensors are indicated as S1, S2 and S3 at the left-hand side of the drawing, and as stated above they produce signals generally in analogue form related to heart action, circulation and respiration respectively. In the embodiment described herein they are an E.C.G., blood pressure meter and oximeter respectively. The signal from the E.C.G. is applied to the apparatus at the input terminal and transformed by a circuit indicated by the block 1 to an analogue signal the value of which depends on pulse rate, and applied to a discriminator 2 which has three outputs. Signals appear on an appropriate output conductor dependent on whether the rate is normal, too high or too low respectively, these conductors being designated 0, + and - respectively as shown.

In a similar manner signals from a blood pressure meter and oximeter are applied to circuits 3 and 4 respectively which, like the circuit 2, each have three outputs, a signal appearing on the appropriate one of the three in dependence on whether the value is normal, too high or too low.

Associated with each sensor S1, S2 and S3 there is provided a circuit, 30, 31 and 32 respectively, which provides an output signal when no meaningful signal is being received from the appropriate sensor. This can happen for example if the sensor goes faulty or drops off the patient. These output lines are designated NIL.

The three NIL conductors are connected to the OR gate 5 which is connected to the SENSOR indicator so that the SENSOR indicator and warning are operated if any of the sensors fail. Similarly, the NIL conductors are connected in pairs to the three OR gates 6, 7 and 8, which are in turn connected to a 3-gate (three input and gate) 9. The output from the 3-gate 9 is connected to an OR gate 10 the output of which is connected to the ALARM indicator so that the ALARM is operated whenever two or more of the sensors fail to operate.

The − outputs from S2 and S3 are connected to an OR gate 11 the output of which is connected to a 2- gate (two input and gate) 12 the other input of which is a connection from the + output of S1. The output from gate 12 is connected to said OR gate 10 and to an OR gate 15 the output of which is connected to the SHOCK indicator. Thus, both the ALARM and SHOCK indications are given if either low oxygen or low blood pressure are associated with increased rate of heart beat. Similarly, the + outputs from S2 and S3 and the + output from S1 are connected to OR gate 13 and 2-gate (two input and gate) 14 to provide an indication when either increased oxygen or increased blood pressure are associated with increased rate of heart beat. The output from 2-gate 14 is applied to said OR gate 15 so that in these conditions the SHOCK indication is given.

The − outputs from S2 and S1 are connected to a 2-gate (two input and gate) 16 the output of which is connected to said OR gate 10. The output of said 2-gate 16 is also connected to the ARREST indicator. Thus, both ALARM and ARREST are indicated when low blood pressure is associated with reduced rate of heat beat.

The + and − lines from S3 are connected to an OR gate 17 the output of which is connected to a 2-gate (two input AND gate) 18 the other input of which is the − output from S2. Thus, gate 18 provides an output when reduced blood pressure is associated with either increased or reduced oxygen content of the blood. An oximeter is peculiar in that a high reading may be due to disconnection of the sensor from the patient. In such a situation an abnormal condition must be assumed. Alternatively, if the original setting is made during cyanosis, a relatively high reading represents return to normality. With other type S3 sensors a high reading is abnormal if the original setting was normal. The output of 18 is connected to said gate 10 to produce an ALARM indication in these circumstances and also to an indicator ANOXIA.

The NIL conductors from each of the sensors are connected to reversing stages 19, 21 and 23 respectively so as to provide inputs to respective 2-gates (two input and gates) 20, 22 and 24 when signals are being obtained from the sensors S1, S2 and S3. The other inputs of the gates 20, 22 and 24 are the respective − outputs from said sensors S1, S2 and S3. The outputs from said 2-gates 20, 22 and 24 are applied as inputs to an OR gate 25, to which are also applied signals from the respective + lines from the three sensors. The output from OR gate 25 is applied to a gate 26 the other input of which is a signal obtained from the sensor line. The output from said gate 26 is applied to said OR gate 10 so that an alarm is indicated when there is a failure of one sensor in conjunction with an ABNORMAL indication from one or more of the remaining sensors. The purpose of circuits 19, 20 in the S1 complex is to inhibit the − output in the event of a sensor failure which would otherwise give an alarm through circuit 5 and 25. The circuits 21, 22 and 23, 24 perform the same functions in the S2 and S3 complexes.

An OR gate 27 has as its inputs connections from each of the + and − outputs from the three sensors so that there is an output whenever any of the sensors indicate an ABNORMAL condition. This is used to indicate ABNORMAL and also applied to an OR gate 28 the other input of which is a signal from the SENSOR indication. If either is present, a WARNING is indicated.

The battery is connected via a circuit 29 which provides an output when no signal is present to an indicator which indicates when there is a power failure. The battery is connected directly to another indicator which indicates when the machine is on.

The +, 0 and − outputs from the three sensors are connected to the control panel to indicate in the section designated 60 the nature of the outputs from each of the three sensors. It will be seen also that in the section of the front panel designated 61 are the indications for the conditions ABNORMAL, ANOXIA, ARREST, SHOCK, SENSORS and POWER the operation of which has been described in connection with FIG. 3. An output from the heart beat sensor S1 is applied to the panel to provide a flashing indication of the heart beats of the patient as shown at 62.

It will be appreciated that the nature of the condition which gives rise to a WARNING is dependent to some extent on the nature of the sensor which is used. For example, an ear oximeter measures color and diagnoses cyanosis, but a respiration rate monitor diagnoses high or low rates, that is, tachypnoea or apnoea and so on. However, providing the three sensors are of the types S1, S2 and S3 as defined above, then the same logic circuits can be used and all the important ALARM conditions of ANOXIA, ARREST and SHOCK are correctly diagnosed. Moreover, warning of early shock is given and also early warning is given if any one parameter is ABNORMAL.

It will be apparent to those skilled in the art that many changes may be made to the apparatus described above in accordance with the invention thus, whilst FIG. 3 illustrates a preferred logical arrangement, it can be modified by, for example the use of NAND/NOR electronics, fluid logic, reed or other relays and other types of logic switches.

The analyzer will function correctly with a wide variety of sensors provided that one parameter for each group S1, S2, S3, is derived directly or indirectly. It will be apparent to those skilled in the art that there is a multiplicity of ways for deriving parameters from a multitude of sensors.

These or other sensors may be used to derive other parameters which may be used to give additional warnings. For example, venous blood pressure may be used as an index of shock or transfusion requirements; body temperature may be used as an index of sepsis or increased intracranial pressure.

What is claimed is:

1. An apparatus for monitoring the condition of a patient and making a diagnosis which includes at least three sensing means for continuously sensing different physical conditions of said patient, each such sensing means operating in response to sensed deviation from a normal condition to provide one of two abnormal signals, one such abnormal signal being indicative of an above normal condition and the remaining abnormal signal being indicative of a below normal condition, a plurality of condition indicating means, each such indicating means being operative to indicate a physical condition resulting in a specific combination of said abnormal signals, diagnostic logic circuit means connected to receive abnormal signals from said sensing means, said diagnostic logic circuit means operating upon the simultaneous occurrence of a combination of abnormal signals from at least two of said sensing means to provide an activating signal to a specific condition indicating means for indicating the physical condition giving rise to such combination of abnormal signals.

2. The apparatus of claim 1 which includes alarm logic means connected to receive said abnormal signals, said alarm logic means operating upon receipt of at least two simultaneously occurring abnormal signals to provide an output alarm signal.

3. The apparatus of claim 1 wherein said sensing means operates to provide a normal signal in response to a sensed normal condition, and sensor monitoring means connected to each such sensing means, said sensor monitoring means operating to provide a monitor output signal in the absence of a normal or abnormal signal from an associated sensing means, monitor logic means connected to receive monitor output signals from said sensor monitoring means, said monitor logic means operating to provide a monitor alarm signal in response to the simultaneous occurrence of two monitor output signals.

4. The apparatus of claim 3 which includes warning logic means connected to receive said abnormal signals from said sensing means and said monitor output signals from said sensor monitoring means, said warning logic means operating to provide a warning alarm signal upon the simultaneous occurrence of an abnormal signal and monitor output signal.

5. The apparatus of claim 4 which includes alarm means connected to operate upon receipt thereby of either said monitor alarm signal or said warning alarm signal.

6. The apparatus of claim 5 which includes alarm logic means connected to receive said abnormal signals, said alarm logic means operating upon receipt of at least two simultaneously occurring abnormal signals to provide an output alarm signal to operate said alarm means.

7. The apparatus of claim 4 wherein said warning logic means operates to provide a warning signal upon the occurrence of either an abnormal signal or a monitor output signal and warning indicator means connected to to provide a warning indication upon receipt thereby of said warning signal.

8. The apparatus of claim 1 wherein said sensing means are individually responsive to heart action, circulation and respiration.

9. The apparatus of claim 3 which includes a normal indicator means for each of said sensing means connected to provide an indication upon receipt thereby of a normal signal from an associated sensing means, an above normal indicator means for each of said sensing means connected to provide an indication upon receipt thereby of an above normal signal from an associated sensing means and a below normal indicating means for each of said sensing means connected to provide an indication upon receipt thereby of a below normal signal from an associated sensing means.

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