

- [54] **PATIENT MONITORING SYSTEMS**
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128/2.05 R, 2.05 T, 2.06 A, 2.06 F, 2.06 R,
2.1 B, 2.1 R

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[57] **ABSTRACT**

A patient monitoring system is provided in which signals are obtained from transducers to represent parameters of the patient's condition and these signals are integrated with a time-loading and then compared with reference levels to provide digital signals indicating whether the integrated signals exceed the reference levels or not. Predetermined combinations of the digital signals denote patient conditions requiring attention and such combinations are recognised by logic to generate warning or alarm signals. Any one transducer can be associated with both relatively short and long time constant integration with the short and long term integrated signals being separately compared with respective references. Furthermore, such short and long term integrated signals can be differenced and compared with a further reference. It may also be appropriate to compare the transducer signals directly with yet further references. All such comparison can provide digital signals relevant to indicating patient's condition, and all such comparisons can be made with both high and low level references.

7 Claims, 6 Drawing Figures

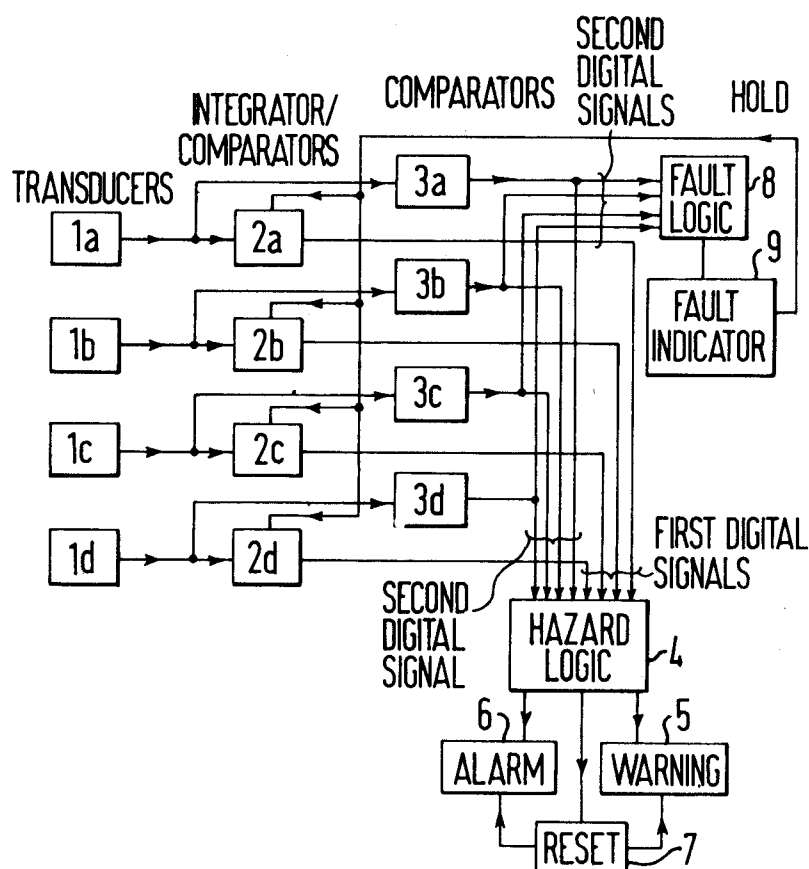
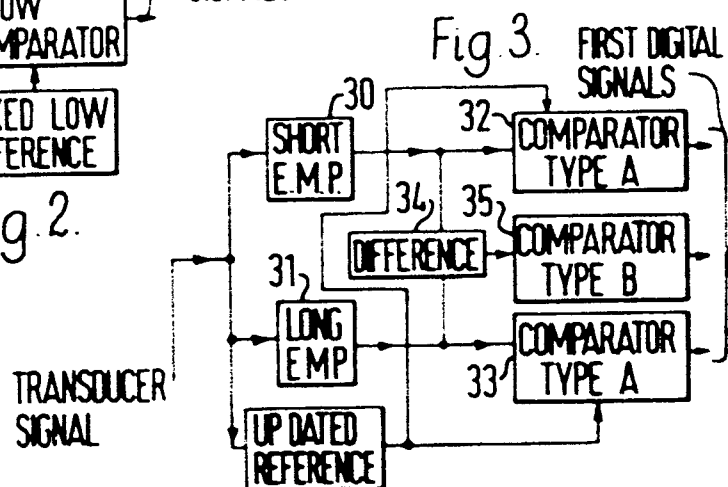
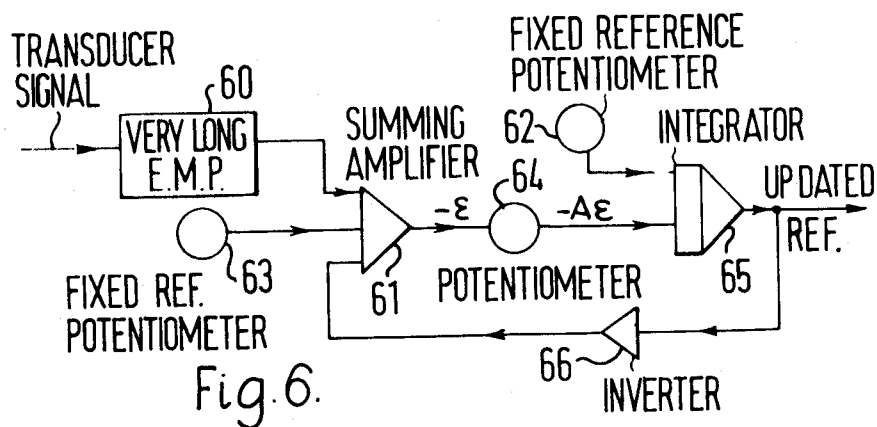
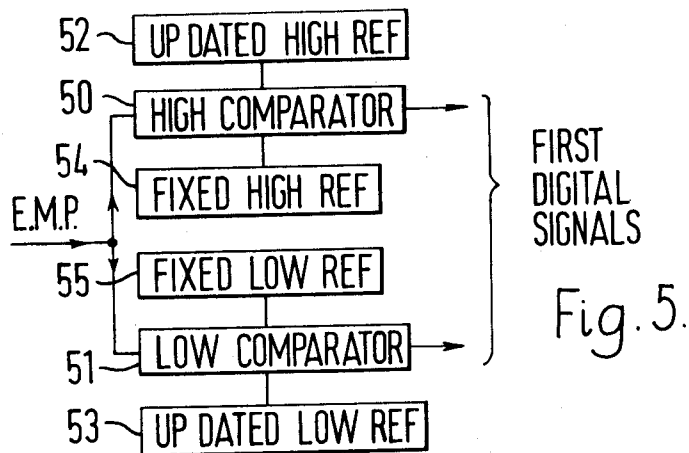
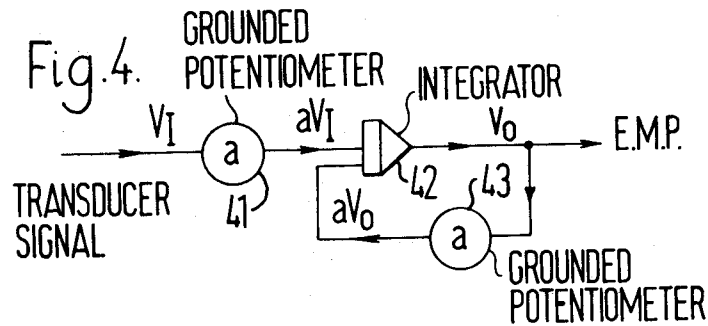


Fig. 2.





PATIENT MONITORING SYSTEMS

Various systems have been proposed for automatically and continuously monitoring the condition of a patient, typically in an intensive care ward, for example, with a view to triggering an alarm when the patient's condition is such as to require further attention. However, generally speaking, these proposals have proved unsatisfactory for one reason or another.

Many of the proposed systems can only monitor instantaneous values of parameters such as blood pressure, respiration rate, pulse rate, etc., with an alarm being triggered if the monitoring parameter passes a predetermined level which is clinically significant. Such systems are prone to produce a high incidence of false alarms since the parameters concerned can pass transiently through the relevant levels without necessarily denoting a specific cause for concern. The obvious expedient of so setting the relevant levels to reduce the incidence of false alarms is equally clearly hazardous and undesirable.

More recent proposals seeking to remedy this situation suggest the simultaneous monitoring of several parameters and triggering an alarm in response to predetermined patterns of parameter values. Again, though, it is proposed that reference be made only to instantaneous values, the likelihood of false alarms must still exist as a significant factor.

The present invention distinguishes from the above systems in a more general sense by taking account of the trend of parameter values representing a patient's condition. This reflects the fact that the trends of individual parameters and the trend pattern of a group of parameters are, traditionally, significant factors considered by the physician in diagnosis and prognosis. Indeed, attempts have been made to take account of these factors in a patient alarm system by use of a digital computer facility. However, this last approach is clearly very expensive in terms of equipment, and few hospitals would be able to provide the necessary on-line facility.

The present invention, on the other hand, seeks to afford a similarly useful result by way of special-purpose, simplified equipment which will normally be of hybrid analogue-digital form.

The invention has been developed following retrospective analysis of monitored parameter outputs from many patients in an intensive care ward. Such an analysis shows that the waveform of the commonly monitored parameters is a compounded series of phasic oscillations having cycle times ranging from a short term of 3 - 6 seconds for first order sinusarrhythmia to about 20 minutes for a fourth order oscillation. Moreover, it is found that the various orders of oscillation have no regular mathematical relationship with each other. Accordingly, assessment of such signals can be made by use of random noise analysis techniques.

More particularly, it is proposed that, since the variation in an observed parameter signal can be of similar order to clinically significant variation without necessarily being significant, each parameter signal should be assessed on the basis of a mean representation thereof. At the same time, assessment of a trend in a signal should take account of time so that distant values have a consistently reduced significance relative to more recent values. Both of these requirements can be

met by providing a time-loaded, integrated or accumulated representation of each parameter signal.

In any event, a more general form of the invention provides a patient monitoring system comprising at least two integrating means for providing respective time-loaded integrated signals in response to transducer signals representing respective parameters of a patient's condition, respective comparison means for comparing each of said integrated signals with reference level signals to provide digital signals indicating whether said integrated signals are higher or lower than the associated reference level signals, and logic means for operating a warning or alarm indicator in response to at least one predetermined combination of said digital signals.

The time factor to each integrating means will be chosen in relation to the parameter involved and the potentially hazardous patient condition or conditions against which monitoring is to be effected. The time factor will normally be relatively long term, but an individual transducer signal may be subjected to two integrating functions with differing time factors for use in relation to different conditions. More particularly, it is useful to generate both relatively long and short term functions for some parameters since the sense and magnitude of the difference or 'error' between these is itself a useful indicator of trend. Indeed a more accurate determination of change and trend can be obtained by integration of such an error signal, but this is not normally necessary for practical purposes.

Short term functions and also the instantaneous transducer signals themselves are, in any case, useful in their own right in order that potentially acute emergencies, such as cardiac arrest, can be detected.

Also, it is to be noted that it will normally be appropriate to compare at least some of the integrated signals with both high and low reference level signals.

Regarding the form of integrating functions to be used in practical application of the invention: one function suitable for this purpose, and used as a basis for initial development of the present invention, is the exponentially mapped past function, hereinafter denoted as EMP (Otterman, 1960) defined mathematically as:-

$$f(T) = a \int_{-\infty}^T f(t) \cdot e^{-a(T-t)} \cdot dt$$

In this function, a can be regarded as the time factor since it determines the term during which the significance of the integrated function $f(t)$ reduces to a low level. For example, the significance is reduced to 5 percent in a time of $3/a$ seconds.

For a fuller understanding of the present invention, the same will now be described by way of example with reference to the accompanying drawings, in which:-

FIG. 1 schematically illustrates one embodiment of a system according to the invention,

FIG. 2 illustrates part of the embodiment of FIG. 1 in more detail,

FIG. 3 similarly illustrates another part of FIG. 1, and

FIGS. 4 to 6 illustrate respective parts of FIG. 3 in yet more detail.

FIG. 1 schematically illustrates a patient alarm system according to the invention in which four basic parameters relevant to the patient's condition are taken

into account. These parameters are mean arterial blood pressure, pulse rate, mean central venous blood pressure, and temperature, the last-mentioned being in the form of body core temperature, skin temperature, or the difference between such temperatures. Electrical signals representing the current values of these parameters are readily obtained by the use of any suitable forms of transducers and such transducers are denoted at 1a - 1d in FIG. 1.

The transducer output signals are applied to respective integrator/comparator arrangements of similar form denoted at 2a - 2d. These arrangements serve to provide various time-loaded, integrated signals in response to the transducer signals, compare the integrated signals with appropriate reference signals, and provide first digital signals indicating whether or not the integrated signals exceed the corresponding reference signals or not.

The transducer output signals are also applied to respective comparators 3a - 3d for direct comparison with further reference signals and generation of second digital signals having a similar function to the first digital signals.

All of the first and second digital signals are applied to hazard indicator logic denoted at 4 which may be of any appropriate arrangement of AND and OR gates to provide active output signals in response to predetermined combinations of digital signal inputs. Such a combination will be chosen to represent a patient's condition which is hazardous, or at least potentially so. If a given combination of digital signals represents a potentially hazardous condition then the relevant active output is applied to a warning indicator 5, while if the condition is currently hazardous the active output is applied to an alarm 6.

A reset facility 7 is provided for the warning indicator and alarm, and this facility must be activated through a manual switch to signify acknowledgement of the patient's condition after a warning or alarm is generated, whereafter the facility automatically resets the warning indicator and alarm in the absence of an active output from the hazard logic, that is to say, when the patient returns to a non-hazardous condition.

The second digital signals are additionally applied to fault indicator logic denoted at 8 which, as the terminology suggests, indicates when a fault has occurred. This logic is responsive to non-integrated transducer signals since such signals will show up faults most rapidly and the most common fault will be in transducer operation. The logic 8 comprises an arrangement of OR gates of any suitable form to produce an active output in the event of a fault and so energise a fault indicator 9. Any such active output is also applied to all of the integrator/comparators to hold the integrated signals at their current values when the fault occurs and until the fault is cleared.

The comparators 3a - 3d are of similar form and it is convenient to describe only one of these in more detail with reference to FIG. 2. FIG. 2 in fact serves to show that the relevant transducer signal is not compared with a single reference signal but is compared in a first or high comparator 20 with a fixed high level electrical reference signal from a source 21, and in a second or low comparator 22 with a low level electrical reference signal from a source 23. The high and low comparators can be of any appropriate form to compare the relevant parameter and reference signals, suitably in analogue

form, and generate the second digital signals denoting whether the parameter signals exceed the reference signals or not.

It is to be noted that the only effective difference which will normally occur between the comparators 3a - 3d arises from the fact that different reference level values will be appropriate to different parameters.

The integrator/comparators 2a - 2d are also of similar form with the only effective differences arising from the use of different reference levels, and possibly different integration time constants, for different parameters, and it is again convenient to describe only one arrangement in more detail.

The relevant integrator/comparator is shown in more detail in FIG. 3 with further detail of parts thereof in FIG. 4.

FIG. 3 shows application of the relevant parameter signal to first and second integrators 30 and 31 which are of similar form but differ in respect of time constants such that they can be regarded as respectively providing relatively short and long term integral signals. More particularly, the integrating function in question is the EMP referred to above and so integrators 30 and 31 can be denoted as short and long EMP's. These integral signals are applied to respective comparators 32 and 33 of similar overall kind denoted as 'type A' to provide first digital signals.

The two integral signals are also applied to a difference amplifier 34 to provide a difference signal. This last signal is applied, in turn, to a comparator 35 of a kind denoted as 'type B' and similar to that of FIG. 2 except that different values of fixed high and low reference signals will normally be appropriate, even for type B comparators associated with the same parameter.

Lastly in FIG. 3, the transducer signal is applied to an up-dated reference signal generator 36 the output of which is applied to the two type A comparators 32 and 33.

The more particular form of the integrators 30 and 31 is shown by FIG. 4, these two integrators being essentially the same except for different time constant factors in integration. In FIG. 4 the relevant transducer signal is applied as input voltage V_i through a grounded potentiometer 41 to produce an output voltage $a.V_i$. This output voltage is then applied as input to an integrator 42 to produce a further output voltage V_o which is fed back to the integrator input through a second grounded potentiometer 43 so that the feedback voltage is $a.V_o$. The output voltage V_o then represents the EMP function for the parameter denoted by the input V_i , with the time factor of the function being determined by the time constant of the integrator.

The more particular form of the type A comparators 32 and 33 is shown by FIG. 5, these two comparators being essentially the same except for the provision of different reference level signals for different parameters. As with the comparator of FIG. 2 in that the input signal for comparison, in this case the relevant EMP output voltage, is applied to both a high comparator 50 and a low comparator 51, these comparators serve to compare the EMP signal with respective high and low level reference signals from sources 52 and 53, and with respective further high and low level reference signals from sources 54 and 55. The difference between these reference signals is that the first two are not fixed, but are of a variable up-dated form as will be explained hereinafter, while the second two reference signals are

of fixed form, different from, but having a similar function to those of the type B comparator in indicating a hazardous level for the relevant parameter. The comparators 50 and 51 produce the previously mentioned first digital signals to indicate when any of the high reference levels are exceeded, or the low reference levels passed in a downward sense, by the EMP.

The remaining FIG. 6 illustrates the manner in which the up-dated reference level signals are provided for the type A comparators, that is to say, it shows further detail of the up-dating reference signal generator 36 of FIG. 3. This involves application of the transducer signal to a further EMP integrator 60 of similar form to that of FIG. 4 but which will be of yet longer time constant than the long EMP integrator 31 of FIG. 3. The EMP signal is applied to a summing amplifier 61 together with the desired reference level signal which, initially, will be of first fixed value from a source 62, and with a third input which is a second fixed value signal from a source 63 representing the difference between the initial EMP signal (the transducer signal) and the first fixed value signal. The output of the amplifier 61, denoted as $-\epsilon$, is applied to a potentiometer 64 to produce a signal $-\Delta\epsilon$ which is a small fraction of the potentiometer input, and this fraction signal is applied in turn to an integrator 65 together with the first fixed signal from source 62. The integrator output is the desired variable reference level and this is fed back to the summing amplifier through an inverter 66.

It will be appreciated that the up-dated reference signal represents a common factor and is applied to both of the high and low reference sources 52 and 53 of the type A comparator of FIG. 5, while other individually different factors in both of these sources make appropriate adjustment of the in-coming signal for the purposes of the respective reference levels.

It remains to discuss some more general points relevant to the above embodiment. Reference has been made to short and long term EMP functions and the introduction of the specification indicates pertinent orders of time constants for such functions. In practice, it is presently considered desirable to use increased terms for at least some of the parameters and the short term EMP function can have a time constant of up to above 5 minutes, and the long term EMP function up to about 40 minutes. The other EMP function of interest is that relevant to the up-dated reference signals, and this can have a time constant of up to about 4 hours.

It is also useful to mention some combinations of the digital signals which are effective in indicating a patient's condition which requires attention. For example: a warning state is denoted by the combination of a trend to a low level over a long term for mean arterial blood pressure with a trend to high level over a long term for pulse rate; while an alarm state is denoted by a combination of a trend to a high level, negative long term/short term difference signal for mean arterial blood pressure with a trend to a high long term/short term difference signal, whether positive or negative, for pulse rate.

I claim:

1. A patient monitoring system comprising: a plurality of transducers providing analogue transducer signals representing respectively different parameters of a patient's condition;

respective integrating means each connected with an associated one of said transducers to provide analogue time-loaded integrated signals in response to said transducer signals;

respective reference sources providing first and second reference level signals;

respective first comparison means connected to each of said integrating means and the respective one of said reference sources to provide a first digital signal in response to said integrated and first reference level signals, indicating the relative levels of the latter signals;

respective second comparison means connected to each of said transducers and the respective one of said reference sources to provide a second digital signal in response to said transducer and second reference level signals, indicating the relative level of the latter signals;

logic means connected to each of said comparison means to provide an indicator signal in response to each of a plurality of predetermined combinations of said first and second digital signals; and

a patient hazard indicator connected to said logic means, which indicator is operable in response to said indicator signal.

2. A system according to claim 1 wherein at least one of said integrating means comprises first and second integrators having respectively short and long time constants, each responsive to said transducer signals to provide respectively short term and long term integrated signals; and wherein the respective one of said first comparison means is in two parts, both connected with the respective one of said reference sources, and respectively connected with said first and second integrators, to individually provide said first digital signals.

3. A system according to claim 2 comprising differencing means connected to said first and second integrators to provide a difference signal in response to said short and long term integrated signals; and wherein said first comparison means comprises a third part connected to said differencing means and the respective one of said reference source to individually provide, in response to said difference and second reference level signals, said first digital signals.

4. A system according to claim 1 wherein at least one of said reference sources provides fixed value second reference level signals, and comprises third integrating means connected to the respective one of said transducers to provide up-dated first reference level signals in response to said transducer signals.

5. A system according to claim 1 wherein at least one of said integrating means provides its integrated signal output to represent the exponentially mapped past function of the respective transducer signal.

6. A patient monitoring system comprising: at least two transducers for providing transducer signals representing respectively different parameters of a patient's condition; respective integrating means connected with each of said transducers to provide time-loaded integrated signals in response to said transducer signals; a plurality of reference sources for providing individual high reference level signals and individual low reference level signals for each of said integrated signals; respective comparison means connected with each of said integrating means and with said reference sources to compare each of said integrated signals with asso-

ciated ones of said reference level signals and to provide first digital signals indicating whether said integrated signals are higher or lower than said reference level signals; a plurality of further reference sources for providing further individual high reference level signals and further individual low reference level signals for each of said transducer signals; respective further comparison means connected with each of said transducers and with said further reference sources to compare said transducer signals with associated ones of said further reference signals and to provide second digital signals indicating whether said transducer signals are higher or lower than said further reference level signals; hazard logic means connected to each of said comparison means and said further comparison means to provide a warning signal in response to at least one predeter-

mined combination of said first and second digital signals, and an alarm signal in response to at least one other predetermined combination of said first and second digital signals; fault logic means connected to each of said further comparison means to provide a fault signal in response to at least one predetermined combination of said second digital signals, and respective indicator means connected to said hazard and fault logic means for operation in response to said alarm and fault signals.

7. A system according to claim 6 wherein each of said integrating means comprises both relatively short and long time constant integrating means connected with the respective one of said transducers to provide individual integrated signals.

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