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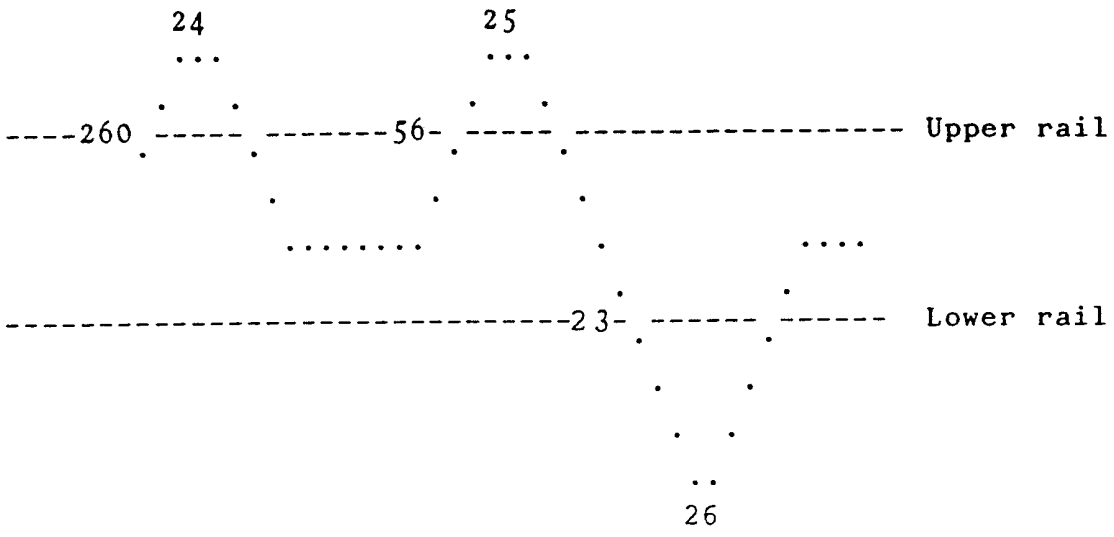
(54) ECG signal monitoring

(57) For monitoring a signal which comprises successive waveforms, such as a signal from an ECG corresponding to a heart beat, the waveform may be represented by time characteristics such as the length of time spent above an upper reference level (upper rail), the length of time spent below a lower reference level (lower rail), or the length of time taken to fall from one reference level (rail) to another. This representation is compared to a corresponding representation of a reference waveform. The waveform may be sampled and digitised in preparation for processing by a microprocessor. The apparatus is suitable for use in an implantable device sch as a heat pacer.

FIGURE 2



The claims were filed later than the filing date within the period prescribed by Rule 25(1) of the Patents Rules 1982.

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FIGURE 1

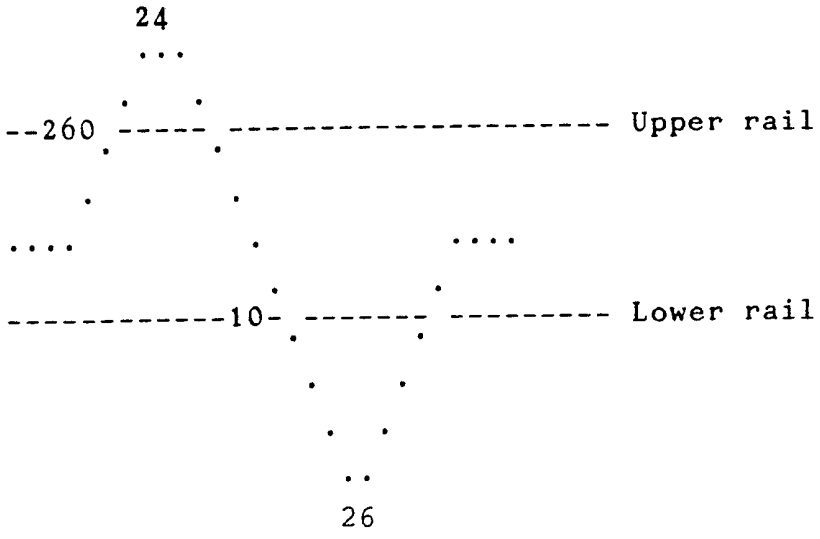
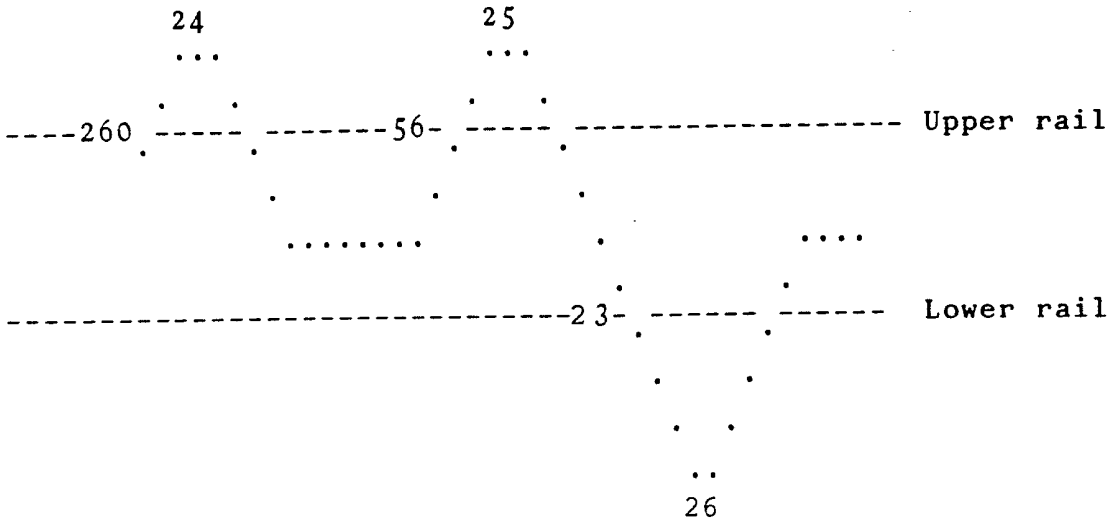


FIGURE 2



Signal Monitoring Apparatus and Method

The present invention relates to apparatus and a method for monitoring a recurring waveform and identifying the occurrence of an abnormal waveform. It is preferred to utilise such a method in a heart stimulation device such as an implantable heart pacer.

Heart pacers and in particular implantable heart pacers are well known. Modern heart pacers are of the so-called demand type i.e. they only supply heart stimulating impulses upon detection of arrhythmia. One difficulty with such pacers is that it is necessary to distinguish a physiological arrhythmia e.g. an increase in heart rate due to exercise, from a pathological arrhythmia which requires treatment. There is a need for an arrangement which will monitor a signal indicative of the heartbeat of a patient and quickly identify a pathological arrhythmia.

Previous proposals have relied upon a diagnosis of a disturbance in the rhythm of heartbeats and have been found to be either too slow or not sufficiently accurate.

The present invention provides a method for monitoring a signal comprising successive waveforms, the method comprising: producing a machine readable representation of each waveform in the signal,

comparing the produced representation with a reference representation and indicating when the produced representation differs therefrom.

Preferably, each waveform is sampled and digitised and the amplitude of the digitised samples compared with one or more reference level signals. Various timing relationships are thus established relative to the reference level or levels, which relationships are characteristic of and constitute a representation of the waveform. The characteristic timing relationships for a sampled waveform are then compared with similar timing relationships for one or more reference waveforms.

This method has been found to be fast and accurate but still simple enough to be implemented in an implantable device. It will signal the onset of pathological heart rhythms and cause initiation of appropriate reversion pacing or defibrillation.

Further features and advantages of the present invention will become apparent from the following description of an embodiment thereof, given by way of example, with reference to the accompanying drawings, in which:-

Figure 1 shows a diagrammatic representation of an ECG complex; and

Figure 2 shows an abnormal ECG complex.

The present method is intended to be implemented by use of a microprocessor whose inputs are supplied from an electrode or electrodes attached to the heart. Signals from the electrodes are then digitised by any suitable conventional technique and the digitised signals are compressed into a form containing timing, amplitude and slope information. A simple pattern is thereby associated to each ECG complex and this is shown in Figure 1 where each dot represents a digitised sample.

According to the invention, the microprocessor compares each of the samples with at least one, and preferably two reference level signals indicated by the upper and lower rails in Figure 1. Excursion of the ECG signal above and below the rails are timed by the microprocessor. Further, the times between excursions are also determined.

For example, the ECG complex of Figure 1 would be characterised as the following timing relationships

Upper rail 260
Upper excursion 24
Lower rail 10
Lower excursion 26.

By the expression "upper rail 260" is meant that 260 millisecond have passed since the previous ECG complex.

By the expression "upper excursion 24" means that the excursion of the complex above the upper rail has lasted 24 milliseconds.

By the expression "lower rail 10" is meant that 10 milliseconds have passed since the lower rail timer was reset. As will be discussed below, this timer is reset at the end of the previous upper excursion. Consequently, 10 milliseconds is the time occupied by the ECG complex in falling from the level of the upper rail to the level of the lower rail.

By the expression "lower excursion 26" is meant that the excursion of the ECG below the lower rail lasted 26 milliseconds.

The microprocessor is arranged to monitor these various timing relationships, to compare them with one or more standard sets of timing relationships to indicate when one or more timing relationships of the

sampled waveform do not correspond to respective timing relationships of one of the standard sets.

It is preferred that the morphology of the compared patterns must substantially match. That is, a sequence of timing relationships identified above must correspond almost identically with one of the sequences of reference timing relationships. Each individual timing relationship need however, only match within a certain predetermined margin of error. This margin is a signal parameter expressed as a percentage: times must be within a predetermined time of the reference time.

In addition as the times between complexes will vary with heart rate, the first of the sequence of times in a pattern may take any value. As one example, the following set of timing relationships constitutes a match.

Complex	Reference	Timing margins (@ 50%)
UR 260	UR 100	Don't care
UE 24	UE 20	[10 - 30]
LR 10	LR 7	[4 - 10]
LE 26	LE 19	[10 - 28]

If the compressed data fails to match any of the reference sets of timing relationships, then either they may have been a glitch, or an unexpected complex may have appeared. In the current implementation, a viable complex must comprise at least four elements; any set of three or less elements between recognisable complexes is considered to be a glitch and is thrown away. Any set of four or more elements occurring between recognisable complexes is considered to be an unexpected complex and may be formed into a new reference either automatically or, preferably, on

instruction by a programmer.

It may be, however, that a stream of unexpected complexes appears undemarcated by recognisable complexes. As a last resort, therefore, before forming a new reference, unexpected streams would be scanned first for recurring four-element (or greater) patterns, and if such exist, it would be the recurring pattern that is formed into the new reference.

The system reports on the number of occurrences of complexes matching each reference set of timing relationships (template) and can attempt to store an instantaneous representation of the ECG complex of a newly formed reference. In this way, the system can report on irregularities that would otherwise be very tedious to detect.

A further feature is that the range of excursion time values of ECG complexes matched is determined, and the median calculated. If desired the templates can be edited (perhaps to use the median values) saved to a file, and read from the file.

In the present implementation, it is preferred that the two threshold rails are set at independently programmable levels above and below the isoelectric line and advantageously at equal levels above and below the isoelectric line. The ECG signal is digitised at a sample rate of 512 Hz. The timers count the number of samples received, each corresponding to a rough 2 millisecond interval.

The topology and timing information is saved in a buffer. When the number of elements in the buffer is at least as great as the number of elements in the first reference set of timing relationships, the two are compared. Upon a match, the matched elements are removed from the buffer. If they do not match, the first reference set of timing relationships is replaced

by the second and so on. If there is no match with any set of reference timing relationships a new template may be started by dumping the first element from the buffer into a new reference timing relationship slot. The process then re-starts. Upon a subsequent match, the newly forming reference set of timing relationships is sealed off; if it contains less than four elements it is considered to be a glitch and discarded. Once the forming set of reference timing relationship comprises at least four elements, it is used as if it were a known reference, although it may continue to grow in size.

The worst case is where a new pattern has started but it is preceded by a glitch so that what is in the forming reference set of timing relationships will not match any subsequent ECG complexes - the glitch must first be discarded. This is handled by searching the newly forming set of reference timing relationships for any consecutive four-element pattern that matches the input buffer.

To eliminate phase differences each new set of reference timing relationships is rotated until the excursion with the longest time period is placed first. This therefore assumes that the longest time interval reference set of timing relationships is that of the inter-complex spacing.

It is to be noted that at the end of outward excursion of the ECG complex, both the rail timers are reset. This accomplishes two things. Firstly, the times between complexes are relatively long and depend on the heart rate, which varies. Resetting both timers minimises redundant information whilst still enabling the obtaining of one timing relationship which reflects the inter-complex spacing. Secondly a direct measure of the slope between opposing outward excursions is built in.

Note, however, there are no problems associated to undefined slopes in situations where successive excursions occur in the same direction without an intervening opposing excursion such as is shown in Figure 2 where there are two excursions above the upper rail before an excursion below the lower rail.

Claims:

1. A method for monitoring a signal comprising successive waveforms, the method comprising:

storing a machine readable representation of a reference waveform;

producing a machine readable representation of each waveform in the signal;

comparing the produced representation with a reference representation; and

indicating when the produced representation differs from a reference representation by a predetermined amount.

2. A method according to claim 1 wherein said step of producing a machine readable representation of each waveform comprises

sampling each waveform;

digitising the samples so produced; and

comparing the amplitude of the digitised samples with one or more reference amplitude levels.

3. A method according to claim 1 or 2, wherein said step of producing a machine readable representation of each waveform comprises

establishing timing relationships of the waveform relative to said one or more reference amplitude levels,

whereby said timing relationships constitute said machine readable representation of a waveform;

and wherein said reference representation is constituted by corresponding timing relationships of a reference waveform.

4. A method according to claim 3 wherein said step of comparing the produced representation with a reference representation comprises

ascertaining whether each one of said produced timing relationships is equal to a corresponding one of said reference timing relationships within a given margin of error.

5. A method according to claim 2, 3 or 4, wherein said reference amplitude levels are independently programmable.

6. An apparatus for monitoring a signal comprising successive wave-forms comprising:

means for storing a machine readable representation of a reference waveform;

means for producing a machine readable representation of each waveform in the signal;

means for comparing the produced representation with a reference representation; and

means for indicating when the produced representation differs from a reference representation by a pre-determined amount.

7. An apparatus according to claim 6, wherein said means for producing a machine readable representation of each waveform comprises

means for sampling each waveform;

means for digitising the samples so produced; and

means for comparing the amplitude of the digitised samples with one or more reference amplitude levels.

8. An apparatus according to claim 6 or 7 wherein said means for producing a machine readable representation of each waveform comprises

means for establishing timing relationships of the waveform relative to said one or more reference amplitude levels,

whereby said timing relationships constitute said machine readable representation of a waveform;

and wherein said reference representation is constituted by corresponding timing relationships of a reference waveform.

9. An apparatus according to claim 8 wherein said means for comparing the produced representation with a reference representation comprises;

means for ascertaining whether each one of said produced timing relationships is equal to a corresponding one of said reference timing relationships within a given margin or error.

10. An apparatus according to claim 7, 8 or 9, wherein said reference amplitude levels are independently programmable.

11. An implantable device comprising the apparatus of any one of claims 6-10.

12. An implantable device according to claim 10, wherein said device is a heat pacer and wherein the signal which is monitored corresponds to a heart beat.

13. A method substantially as hereinbefore described with reference to the accompanying drawings.

14. Apparatus substantially as hereinbefore described.

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