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2.1 R, 419 D

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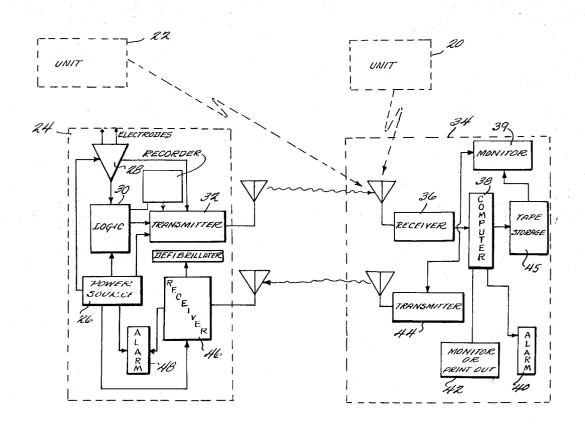
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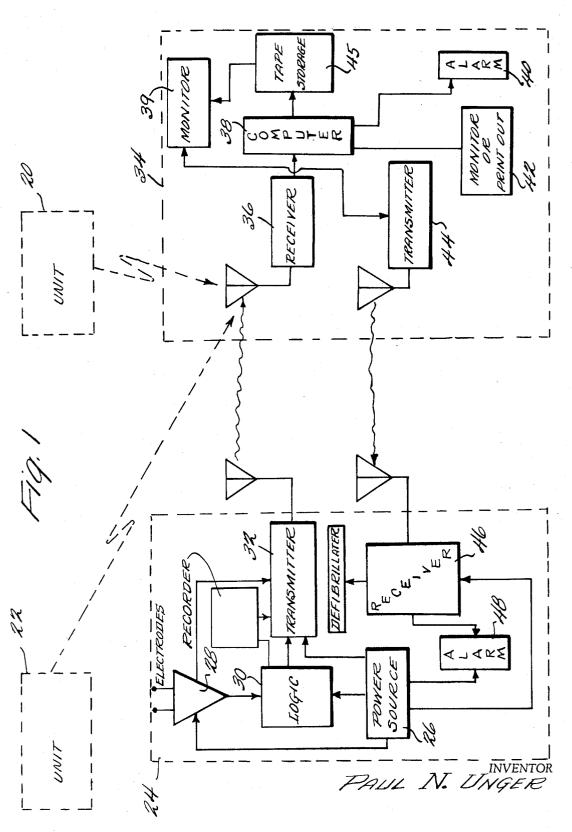
[57] ABSTRACT

A method and apparatus for detecting and responding to herald signs in the cardiac waveform, such as a fast heartbeat rate, a low rate or a skipped heartbeat. In one embodiment the detection of a herald sign causes the ECG waveform to be transmitted to a remote location where it is analyzed and a signal retransmitted to the patient triggering an alarm or causing other appropriate action. In another embodiment, the detection of a herald sign causes the ECG to be recorded on a loop of magnetic tape or a modular solid state memory device in the unit so that the tape can be replayed and acoustically coupled to the telephone line after the patient calls the central facility. In yet another embodiment, the detection of different herald signs causes different alarm signals, e.g., colored lights, different alarm signals identifying the abnormality, to be operated to indicate to the patient what medication he should administer to himself or whatever other action he should take in the event that communication with central facility cannot be immediately achieved.

10 Claims, 4 Drawing Figures

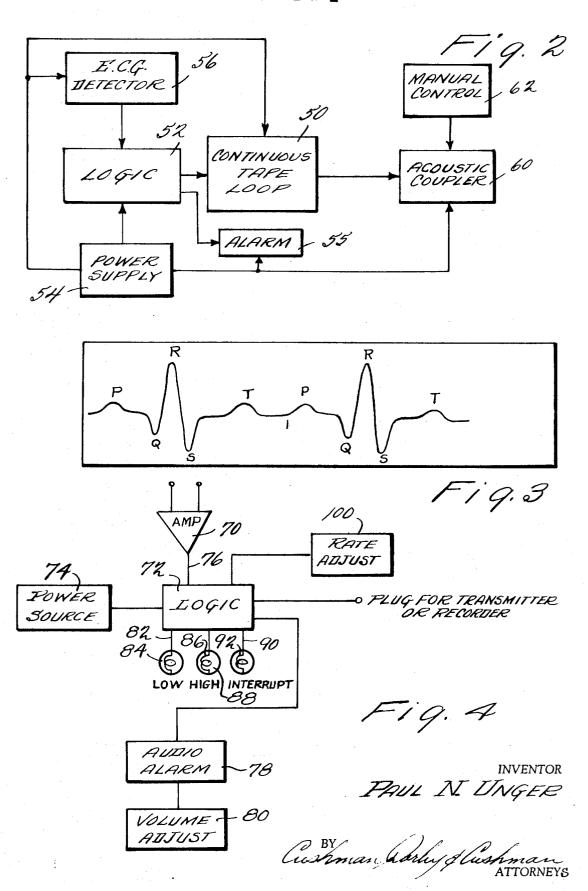


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CARDIAC WARNING DEVICE

BRIEF DESCRIPTION OF THE PRIOR ART AND SUMMARY OF THE INVENTION

This invention is described in Document Disclosure 5 Number 001756 filed Apr. 11, 1970.

The invention relates to a method and apparatus for detecting premonitory signs of cardiac attacks and transmitting the detecting signs to a central location.

Almost all, if not all serious or potentially serious cardiac attacks are prefaced by warning or patient unrecognizable herald signs in the ECG wave which occur in many patients long before recognizable symptoms become manifest. A number of such signs have been discovered and these include reduction in the heart rate below a low selected rate limit, e.g., 54 and an increase above a high selected limited rate, e.g., 120–130, premature heart beats, failure to discharge an impulse, failure of an electrical impulse to be conducted from the upper to the lower chambers, widening of the QRS complex, base line shift depression or elevation, and abrupt ST deviation.

While all of these signs do not always indicate a cardiac attack is imminent, their occurrence, particularly in individuals with previous cardiac difficulties or established potential cardiacs, is serious enough to warrant careful study by an expert and, following recognition, institution of precautionary measures, such as indicated treatment with drugs. For some signs, for example, when the rate slows below about 50, action should be taken immediately. However, inasmuch as many of the signs do not normally cause distress or perceptible physical symptoms, they may pass unnoticed or even if noticed their import may not be fully appreciated or 35 may be rationalized away.

The present invention relates to a novel method and apparatus whereby a number of individuals known to be cardiacs or potential cardiacs are each equipped with a portable unit which they carry on or with their 40 person and which constantly monitors the ECG wave for herald signs.

In one embodiment of this invention, the detection of a herald sign by the unit causes the ECG to be transmitted to a central facility where it triggers a pro- 45 grammed signal in a central computer in addition to that generated in the unit. The ECG wave received at the central facility is then analyzed, preferably by a digital, single purpose computer which then generates an output based on a programmed input which a 50 human expert can then study, preferably after transmission by magnetic tape via dataphone or similar device onto a receiving screen or other ECG display. If the expert considers that the detected signs warrant precautionary measures, he after identifying by coded number 55 the patient and physician, directs the activation of a transmitter which sends a signal to the unit transmitting the ECG waves, triggering an audio signal to the patient. He simultaneously communicates with the patient's physician, advising him of the event of the 60 identified patient. This maintains the patient-personal physician relationship without interposing the interpreter as a patient identifiable consultant, but retaining his identity as a physician consultant.

This alarm within the patient unit indicates to the individual that he should contact his own physician immediately for instructions, or, if that proves impossible, 2

the central facility. At the same time that the expert directed activation of the alarm transmitter, he also alerted the personal physician to the situation. He can also transmit to the personal physician, via a telephone transmitter or similar device, the actual ECG which the computer has processed and presented to him. The alarm signal may also indicate to the patient what self medication should be administered, e.g., by the color of a light lit by the signal as a fail safe device in the event of any breakdown in communication such as inability to reach computer monitor facility and/or his physician. The detection of a herald sign by the unit may also cause the alarm to be activated if desired.

One of the advantages of this arrangement is that the logic in each personal unit need not make sophisticated decisions as to whether a detected sign warrants precautions; those decisions are made by the computer and ultimately evaluated by a human expert. Accordingly, the logic in each unit can be made fairly simple, responding only to a few simple conditions which always occur when a herald sign exists. This permits the unit to be made relatively inexpensively and small enough to be easily carried by the patient. Another advantage is that the patient is not bothered by periodic false alarms which breed anxiety and cause loss of sleep. The patient's alarm operates only when a potentially serious consideration exists which warrants further study and which he has been taught is an early warning signal which may warrant preventive protective actions.

In another embodiment of the invention each unit includes an endless loop of magnetic tape or a solid state memory device on which the ECG wave can be continuously recorded and when the logic network in the unit determines that a herald sign is occurring permits playback and prevents erasure. Alternately the ECG waveform is recorded on the tape where it is used only after the event has occurred. Alternately, a solid state memory device permits continuous recording with modularity in choice of playback time with 10 seconds deemed adequate to meet the overwhelming majority of events and 30 seconds virtually all events. It has been found that the waveform after the event almost always indicates the herald sign which caused the alarm to be given.

The logic also triggers an audio alarm in the unit which indicates to the individual that he should go to the nearest telephone and call the central facility. One or more visual signals can be also given by different colored signals to inform the individual as to which medicine should be self-administered where particular hazard exists and communication cannot be immediately established. When the telephone connection has been made, the magnetic tape or solid state memory device is played back while linked to the telephone by a conventional or miniaturized acoustic coupler and the recorded ECG thus transmitted to the central facility. The received signals are then processed by a single purpose properly programmed computer simultaneously displayed on a screen and continuously recorded on tape and transmitted to a human expert who then studies the output and determines what actions should be taken. Instructions can then be immediately given to the individual's physician or in his absence, to the individual, over the telephone.

In a third embodiment of the invention, the detection of a herald sign causes one of a plurality of colored lights or similar indicators to light, thus indicating to the patient what self-medication he should administer to himself or whatever other steps he should take in the inability to immediately communicate with the center and his physician, or whenever immediate danger exists. Particularly, the detection of a heartbeat rate below a given value, detection of a heartbeat rate above a given value or detection of a skipped heartbeat are three herald signs which can cause different lights to be lit, in addition to the operation of an audio alarm.

Many other objects and purposes of the invention will become clear from the following detailed description of the drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 shows a first embodiment of this invention, whereby the ECG waveform of an individual wearing 20 the unit is transmitted to a central facility continuously, etc. when the unit detects a herald sign.

FIG. 2 shows a second embodiment of this invention.

FIG. 3 shows a normal ECG waveform.

FIG. 4 shows a third embodiment of this invention.

DETAILED DESCRIPTION OF THE DRAWINGS

Reference is now made to FIG. 1 which shows a first embodiment of this invention. In this embodiment, a number of individuals with established cardiac difficulties or who are cardiac prone are each equipped with a portable, self contained and powered unit which monitors their ECG waveforms continuously and responds to conditions which appear to be herald signs. In FIG. 1, three such units 20, 22 and 24 are diagrammatically illustrated.

As shown, unit 24, which is intended to be identical to units 20 and 22, includes a power source 26 which may be a small nickel-cadmium or other battery and which supplies the energy requirements of unit 24. If desired, provision may be made for visually or audibly indicating to the wearer when the battery is marginally depleted or the electrical system is malfunctioning.

A conventional amplifier 28 of which many types are 45 known detects the minute electrical signals produced by the electrodes connected to the body and amplifies them to produce the conventional ECG waveform. A normal ECG wave is shown in FIG. 3. The ECG waveform signal produced by amplifier 28 is passed to 50 logic network 30 which then determines, by built-in programming, if a condition exists which might be a herald sign. For example, logic 30 may include a timing circuit which checks the temporal separation between each R wave peak and the last R wave peak and 55 produces an alarm signal if the separation is less than a first given time or greater than a second given time, thus detecting high and slow heartbeat rates as well as skipped beats. As discussed below, unit 24 preferably includes a recorder 31.

Whenever logic 30 detects a herald sign, it produces a trigger signal which is passed to transmitter 32 which causes transmitter 32 to transmit, at an assigned frequency, the ECG waveform signal being produced by amplifier 28. The ECG information may be modulated onto the transmission frequency or otherwise sent. While microwave or low RF signals may be

satisfactory in regions where there are few large steel structures VHF signals are believed to be more satisfactory under all conditions based on present technology. Each of the units in the system will preferably be assigned a different frequency so that the source of received signals can be quickly and reliably ascertained. The use of six digits to each multihertz cycle with multiplexing permits the simultaneous transmission of large numbers of ECG signals from different individuals only at such times when a herald sign is detected.

The central facility 34 receives the signals transmitted by unit 24 and, more particularly, a receiver 36 detects the transmitted signals and converts them to a frequency or form, such as AC current, suitable for use by the digital computer 38 which is properly programmed to analyze the ECG waveform and provide information as an output, including the ECG waveform, useful to the expert, who is continuously on alert when signalled.

Computer 38 analyzes the information received and, when warranted, triggers an output alarm 40 and provides an output on monitor or print-out 42 for the human expert to study. The monitor may be an oscilloscopic monitor and/or print-out and the information provided preferably includes the ECG waveforms received, the patient's identification and the identification of the patient's personal physician.

The computer 38 also preferably permanently records the received ECG waveform on tape storage 45 which may be destroyed from time to time. If desired, computer 38 may at the same time transmit the ECG to another remote monitor 39 such as the office or bed35 side of the personal physician and/or cardiac consultant of the person transmitting the ECG waveforms.

The human expert studies the ECG on monitor 42 and/or monitor 39 and if he considers that the situation warrants precautions, he directs manual activation of transmitter 44 after it is automatically set to the frequency of the unit to be contacted by computer 38. The signals transmitted for example by transmitter 44 are received by receiver 46 which includes a filter tuned to the frequency assigned to unit 24. If the signal as produced or passed by receiver 46 is at the assigned frequency, a signal is produced or passed by receiver 46 which triggers alarm 48 which includes an audio alarm and which tells the person wearing unit 24 that he should contact his personal physician or, if he is unavailable, center 34 immediately. The transmitted signal received by receiver 46 can also be used to trigger other devices in unit 24. For example, in FIG. 1 a defibrillator is provided which can be triggered by facility 34 upon detection of ventricular fibrillation. Different colored lights indicating varying causes and hence different courses of action can also be lit as discussed below. The human expert preferably alerts the personal physician before or just after transmitter 44 is activated.

One of the drawbacks of the above discussed embodiment is the difficulty in transmitting through all environments in which the wearer may find himself including large buildings of steel and concrete. Even at VHF frequencies transmission may be impaired or distorted with possible failure of the center to detect or receive herald signs, but at frequencies between roughly 2-50 MHz this problem is believed minimized.

In a second embodiment of the invention shown in FIG. 2 this problem is eliminated by providing a continuous tape loop 50 or a solid state memory device in the portable unit which is triggered by logic 52 when the logic determines that a condition which is a herald 5 sign exists. As in the embodiment of FIG. 1, a conventional power supply 54 and ECG detector 56 are provided.

When triggered, an erasable tape loop 50 or solid state memory device or other recorder, records the 10 ECG waveform for some given time, e.g., until the entire loop has been filled. If desired, tape loop 50 can record continuously and stop erasing only when a herald sign is detected. However, it has been determined that the ECG signal after the event occurs al- 15 most always indicates the nature of the problem and the event. Accordingly, the greater simplicity in design and less power consumption of this approach suggests that recording will usually be desirable only upon detection of a herald sign. Logic 52 also responds to the 20detection of a condition which might be a herald sign by operating an audio alarm 55 which alerts the patient, who has been instructed to go immediately to a telephone and call the central facility which as in FIG. 1 is equipped with a computer and accessibility to a 25 human expert for analyzing the recorded ECG waveform. Alarm 55 can also include lights or other indicators which further tell the patient what actions should be taken. If desired, the patient can be continuously coupled to the phone and his ECG continuously 30 monitored by the computer.

When the center has been reached, the tape is played and the information passed to the center via acoustic coupler 60 which is operated by manual control 62 and the telephone lines. The computer at the central facility then receives the information and produces an output as in FIG. 1 for the human expert to study. After the ECG has been completely transmitted, the unit wearer receives detailed instructions from the human expert as to what he should do.

Reference is now made to FIG. 4 which shows a further embodiment of the invention of this application. In this embodiment, the ECG waveform is detected by properly placed electrodes and an amplified signal from amplifier 70 is applied to logic 72 which, like the other logic devices described above, detects one or more herald signs. In particular, logic 72 is designed to detect when the heartbeat rate is less than a given value, for example, about 54 beats per minute, greater than a second value, for example, 120-130 beats per minute, or when a heartbeat has been skipped. Many simple logic arrangements for detecting these conditions should be apparent and these include arrangements for determining the time between adjacent R-wave peaks and for triggering appropriate signals on different outputs when that spacing is greater than, or less than, preset values. A conventional power supply 74, which may also be of the type described above, supplies the power to logic 72 as well as the 60 other elements of the device.

Whenever a herald condition is detected an appropriate signal is produced on line 76 which triggers an audio alarm 78 which the patient can hear. A manual volume adjustment 80 is provided so that the volume can be increased during sleep, or when the patient is under conditions where the audio alarm 78 might not otherwise be heard.

Further, logic 72 is provided with three or more additional outputs each of which are connected to a separate indicator which is in this embodiment a colored light. Thus when a low heartbeat rate is detected, a signal is produced on line 82 which causes line 84 to become illuminated and remain illuminated. Similarly, the detection of a high heartbeat rate causes an appropriate signal to be produced on line 86 to cause illumination of colored light 88. Further, the detection of a skipped heartbeat produces a signal on line 90 which causes light 92 to be lit. Each of the lights 84, 88 and 92 are preferably of different colors, for example, red, yellow and green.

Thus, the patient is not only warned that a herald sign has occurred, he is specifically informed as to the condition which caused the audio alarm 78 to operate. This is important since there are many circumstances under which it is necessary for the patient to respond to the detected condition. A low heart rate is particularly critical since competing lower and mechanically inadequate rhythmic centers may escape with resultant cardiac arrest and/or shock. The detection of a skipped beat may also be important enough to justify some immediate action. High heartbeat rates except ventricular tachycardia do not normally require immediate action unles ventricular fibrillation results, in which case the patient will be unable to respond to the warning himself.

Accordingly, it is contemplated that with this embodiment, the patient will be provided with appropriate drugs to use when the associated light goes on, when immediate communication with the physician is impossible. The drugs may be taken in any form. While the critical point for the low rate is fairly constant, the point at which logic 72 should trigger a warning for a high heartbeat rate may vary from individual to individual and according to the activities of that individual. Accordingly, it is desirable to be able to adjust 40 the rate value which triggers logic 72 and a suitable mechanism 100 for accomplishing that purpose is shown in FIG. 4. Normally, this adjustment will be unavailable to the patient but will be made by the physician at the time that the individual is given the 45 unit or subsequently when indicated.

While the patient can administer medicine to himself in response to the various alarm signals, it is contemplated that he will be instructed to contact his physician or someone else whenever he receives an alarm. Further, it is contemplated that this type of unit can be used in combination with the transmitter unit or the recording device shown in FIGS. 1 and 2, and that logic 72 will be designed so as to be compatible with such other devices. The unit shown in FIG. 4 may then be used initially with those patients who are not thought to be extremely serious. If later the patient's condition warrants it, the appropriate recording mechanism and acoustical coupler or transmitter can be added.

Many changes and modifications in the above embodiment of the invention can, of course, be made without departing from the scope of the invention and that scope is intended to be limited only by the scope of the appended claims.

What is claimed is:

1. An apparatus for detecting potentially dangerous herald signs in a cardiac waveform of an individual comprising:

means for detecting the cardiac waveform and producing a signal representing that waveform.

means for receiving said representing signal, producing a first output signal when the heartbeat rate is less than a first given rate and producing a second 5 output signal when the heartbeat rate is greater than a second given rate,

means for receiving said first output signal and producing a light of a first color to the individual that the rate has been determined to be less than 10

means for receiving said second output signal and producing a light of a second color different from said first warning signal and indicating to the individual that the rate has been determined to be 15 greater than said second rate,

means for receiving said representing signal, said first output signal and said second output signal and for recording said representing waveform for a given time after receipt of either said first output or 20 second output signal,

means for transmitting the recorded signal, to a remote facility after said herald sign is detected. and

means for receiving said first output signal and said 25 second output signal and producing an audible noise whenever either said first color light or said second color light is produced.

2. An apparatus as in claim 1 including means for manually adjusting the volume of said third warning 30 signal.

3. An apparatus as in claim 1 wherein said transmitting means includes means for detachably coupling said transmitting means to a telephone line.

- 4. An apparatus as in claim 1 wherein said receiving 35 and first and second output signal means includes means for producing a third output signal when a heartbeat is skipped and including means for receiving said third output signal and producing a third warning signal indicating to the individual that the heartbeat has been 40
- 5. An apparatus as in claim 1 including a housing containing all of said means and adapted to be carried by said individual.
- herald signs in the cardiac waveform of an individual comprising:

means for detecting the cardiac waveform and producing a signal representing that waveform,

means for receiving and recording said representing 50 signal, and

means for receiving said representing signal for detecting herald signs and for controlling said receiving and recording means so that said receiving and recording means preserves a portion of said 55 representing signal whenever a herald sign is detected, including

means for translating said recorded representing signal into a radio signal and transmitting said radio signal to a remote facility,

means for receiving a radio signal from said remote facility and producing an alarm signal which is manifest to said individual.

- 7. An apparatus as in claim 6 wherein said receiving and producing means includes defibrillating means operable in response to a given signal from said remote receiver.
- 8. A system for detecting and responding to herald signs in the cardiac waveforms of individuals comprising:
 - a central monitoring facility including computer means for receiving and analyzing a received signal, means for displaying the output of said computer means, memory means for storing the output of the computer and means for transmitting the output of the computer to a remote location,

a plurality of individual units each adapted to be carried with an individual and each including,

means for detecting the cardiac waveform and producing a signal representing that waveform,

means for detecting a herald sign,

means for receiving and recording said representing signal for a given time after a herald sign is detected, and

means for transmitting said recording to said central facility.

9. A method of detecting and responding to herald signs in the cardiac waveforms of individuals in a system with a central monitoring facility and a plurality of individual units each adapted to be carried with an individual comprising the steps of:

detecting the cardiac waveform in each individual unit and producing a signal representing that waveform,

detecting a herald sign in each unit,

recording and retaining said representing signal in a unit for a given time after a herald sign is detected in that unit, and

transmitting said recording to said central facility after a herald sign is detected, analyzing said transmitted recording in said central facility and transmitting information with respect to future actions to be taken from said central facility back to the individual having a unit which has transmitted said recording after detecting a herald sign.

10. A method of detecting and responding to herald 6. An apparatus for detecting and responding to 45 signs in the cardiac waveforms of individuals in a system with a central monitoring facility and a plurality of individual units each adapted to be carried with an individual comprising the steps of:

> detecting the cardiac waveform in each individual unit and producing a signal representing that waveform.

detecting a herald sign in each unit,

recording and retaining said representing signal in a unit for a given time after a herald sign is detected in that unit, and

transmitting said recording to said central facility after a herald sign is detected, receiving and analyzing the transmitted signal in computer means at said central facility, displaying the output of said computer means, storing the computer output and transmitting the computer output to a remote location.