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# An Arrhythmia–Anomalous Beat Monitoring System

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*Abstract*—**An electronic monitoring system has been developed to detect the four conditions that usually lead to fibrillation in the infarcted heart. Artifact-free *QRS* detection is accomplished by passing the preamplified *QRS* through a bandpass filter, an automatic gain-control (AGC) circuit, a full-wave rectifier, a nonlinear amplifier, and positive and negative slope detectors. High-threshold logic circuitry then applies the timing criteria necessary for positive identification of a *QRS* complex. A printout of the ECG is made if 1) the number of premature beats in the last minute exceeds a physician-set number (0 through 10), 2) the number of successive anomalous beats (i.e., area increase, *QRS* increase, or polarity reversal) exceeds a physician-set number (0 through 5), 3) an "early" premature beat occurs (i.e., $R\text{-}R' \leq QT$), or 4) a multiformal beat is detected (i.e., its morphology differs from that of the previous anomalous beat).**

**An ECG printout is also initiated if more than one *R-R* interval elapses from the last *QRS*. In all instances, the use of an electronic delay to the paper recorder allows printout of the ECG complexes that caused the alarm. The unit's performance, using special patient tapes, was ≥ 98-percent freedom from false positives and ≥ 99-percent freedom from false negatives.**

## I. Introduction

ALTHOUGH the needs of a coronary-care unit (CCU) or an intensive-care unit (ICU) are very basic physiologically, the realization of these needs can require some very complex monitoring systems and/or therapeutic devices [1]-[8]. The essential function of these very specialized hospital units consists of monitoring those vital physiological functions that would act as early indicators of an impending life-threatening crisis or, failing that, would act as an alarm in such a crisis.

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### *General Medical Requirements*

In operation, such a monitoring system must cause a minimum number of false-positive alarms and, at the same time, cause virtually no false-negative alarms. Intimately involved in the reliable determination of alarm conditions is the problem of patient-induced artifact. The system must either be inherently insensitive to patient movement artifacts or contain a mechanism to evaluate the input signal-to-noise ratio and disable the alarm circuitry when this ratio falls below that threshold which most satisfactorily corresponds to the presence of artifact. The patient interface must be such that it causes minimum discomfort and no danger to the patient. Minimizing patient discomfort will aid in reducing artifact by removal of one possible cause for patient movement.

Since we are monitoring a dynamic system in a transient mode, that is, a living biological system in a condition of stress due to injury and hopefully in the process of self repair, the monitoring system must be of sufficient dynamic range to accommodate all the expected combinations and levels of the various criteria under its scrutiny. Changes in the medical criteria for alarm will occur repeatedly in the course of a patient's surveillance and must therefore be easily programmed into the monitoring system. It should be pointed out that such monitoring systems will have dual roles.

First, in the initial critical stages just after a patient's admission (and presumably just after his attack), the system must function in parallel with trained medical personnel who will most certainly be observing the patient. In this mode, the utility lies in the system's ability to detect important changes in the patient's condition that are too subtle for even the trained observer and to do so tirelessly with no attention lapses similar

to those which must be expected from even the most dedicated of the human monitors who will be present.

The second role for such a monitoring system lies in that stage after the crises are past, and the patient's condition no longer justifies the undivided human attention provided at first. The patient is now presumably well on the road to recovery, but is still in some danger of a setback. In this second stage, the major advantage of such a monitoring system is its constant surveillance ability that frees medical personnel for the more critically ill patients, since the staff can now rely on the system to make them aware of any situation demanding their attention and/or action.

The need for the type of sophisticated monitoring systems described above comes as a result of the maturity of the original concepts of ICU's and CCU's. These units were originally designated as special areas where a critically ill patient could be surrounded with the best in life-saving and monitoring equipment, as well as highly trained medical personnel who would be in a state of constant readiness to intervene in life-threatening syndromes and save the patient. While it is still necessary, this function is no longer the primary one served by a CCU or an ICU. The primary responsibility of today's units is to intercept the preconditions for life-threatening sequences long before an emergency situation develops, and, in so doing, accomplish the dual results of both a more speedy and a more probable recovery. Both the trauma involved in emergency resuscitation procedures and the deterioration that must precede such an emergency condition can only diminish the patient's chances for eventual recovery.

### *Specific Medical Requirements*

The physiological indicator that was the subject of this investigation is the electrocardiographic (ECG) representation of the cardiac depolarization potential, the *QRS* complex [9]-[14]. It is obtained by monitoring the differential potentials appearing between two chest electrodes with respect to a third, or neutral, electrode. Specifically, what is needed is some criteria that could be derived from the ECG signal and could serve as an early warning of an impending life-threatening episode.

Clinical experience has related the following events as significant preconditions to ventricular fibrillation in the infarcted heart: 1) frequent premature ventricular contractions (PVC's), 2) runs of successive anomalous beats (AB's), 3) occurrence of a PVC in the vulnerable period, and 4) occurrence of multifocal PVC's (MFPVC's). In addition to the above, the following conditions must also be detected: sinus arrest or pause in rhythm, premature atrial contractions (PAC's), and patient movement.

The output of a monitoring system that detects these clinically important events should be in the form of a permanent record of that ECG complex that actually caused the alarm condition. This requirement establishes the need for some form of a signal storage facility (or delay) so that, after analysis, a signal may be retrieved and printed out for evaluation by the attendant medical staff whose responsibility it is to make a final judgment based on the patient's condition, history, and therapy. Thus the final diagnosis resides with the medical personnel, while the monitoring system functions as a highly efficient and tireless sentinel ready to provide automatically the data necessary to aid in making that diagnosis.

Despite the sophistication that will be required to accomplish the type of analysis described, the system-staff interface should be one of the utmost simplicity. It must be easily operated by nurses since it is the nursing staff of a CCU who are its backbone.

The final requirement to be met is that of minimum "down time." The on-line monitoring system must be amenable to rapid corrective action on the part of the hospital staff in the event of system malfunction. Such malfunctions must be very rare and should be "local" in nature (that is, a malfunction should only affect one bed, not a whole unit of five to ten beds). The system should be designed for easy recognition of faulty operation so that immediate substitutions can be accomplished by the hospital staff, using back-up system units stored at the hospital, and the defective units then serviced by an off-site service facility.

## II. Design Philosophy

To meet the needs discussed above, the monitoring system required must operate in "real-time" and be as simple and reliable as possible, consistent with the functions it must perform. This is best accomplished by means of a compact hybrid computer that would be at the bedside or nurses' central station. It should be of modular design for easy unit substitution by the hospital staff and consist of reliable high-threshold logic (HTL) chips and integrated circuits (IC) mounted on printed-circuit boards, which are easily replaced. This will provide high reliability and easy maintenance at low cost per bed. With small independent hybrid systems for each bed, there is no danger of the whole CCU being out of operation because "the computer went down," as occurs when a large-scale digital computer is used on a time-shared basis. In the monitoring of critically ill patients, the "computer-is-down" situation is intolerable and not permissible.

Arguments concerning cost per bed in the maxi-computer versus mini-computers argument usually fail to take into account one very important consideration: even if the cost per bed were shown to be lower with the large digital computer (which is still subject to debate), the fact that most hospitals cannot afford the huge dollar outlay for the installation and maintenance of such a system makes this argument irrelevant. The attractive feature of the bedside computer concept is that the units could be installed with a minimum of installation procedure and cost as they are needed by a hospital or as the money becomes available. Small units have a flexibility of placement and interconnections to central stations due to their portability, which also is an advantage.

The final consideration that supports the hybrid mini-computer philosophy involves the actual implementation of the monitoring system's most important function: positive identification of a *QRS* complex. While there are many programs in existence to accomplish this task on a digital computer, none have successfully transformed this basically analog procedure into the digital domain with enough reliability to be clinically acceptable. The problem is so difficult because the extremely variable nature of the input signal makes exact specification of the parameters for recognition a very difficult, if

not impossible, task. What is required is not a static set of individual parameters but a continuously variable set of relative parameters, and this is more conducive to analog procedures. To digitize it involves unnecessary additional complexity that results in reduced reliability and increased cost.

What this means, in terms of implementation, is that the "front end" of the maxi-computer system necessarily would consist of an analog signal conditioner for each bed that would then feed into the central digital computer. Since this requires analog hardware for each bed, one of the main arguments for time-shared central computation (i.e., no duplication of equipment) loses its strength. This, coupled with the threat of the central processor "going down" and knocking out all the beds, reinforces the choice of a bedside, hybrid mini-computer.

*Functional Requirements*

To accomplish its most important function, that of positive *QRS* identification, the input signal must be subjected to a unique combination of analog manipulations in the frequency, amplitude, and time domains that will enhance the *QRS* and deemphasize the *P* and *T* waves [15], [16]. The criteria involved in these functional transformations must be relative criteria with the input signal providing the reference. The system must automatically adjust to the 40:1 dynamic amplitude range and 10:1 dynamic frequency range that may be expected from the broad spectrum of ECG inputs possible. The method chosen to accomplish this task involves the following functions in the order listed: 1) narrow-band filtering, 2) automatic gain control (AGC), 3) dead-zone of amplitude, 4) full-wave rectification (FWR), 5) nonlinear saturation amplification or squaring (SQR), 6) differentiation or slope detection (SD), and 7) timing criteria applied to the series of SD pulses. It is only by the application of such a set of functions and timing criteria that we have been able to obtain positive *QRS* identifications with percentages of correct identification ranging from 98 to 100 percent over the wide spectrum of patient inputs that are encountered in a CCU.

Once a positive *QRS* identification has been made, HTL circuitry then accomplishes most of the desired analysis and provides the system with the flexibility necessary to meet the variable alarm criteria required for the many clinical conditions found in any given population of patients. To accomplish the diagnoses necessary to provide alarms for any of the four clinical conditions listed above, decisions are required in two general areas: rhythm and morphology. The use of the terms rhythm and morphology, instead of such terms as pulse repetition rate and waveform, is mediated by the need to convey meaningful concepts to those in the medical community who must use such a device. From the rhythm of the *QRS* complexes we can detect arrhythmias, and from the morphology or waveform of a *QRS* complex we can detect anomalous beats. Within these broad categories are subcategories that serve to define further the criteria necessary to detect those changes in rhythm and morphology which correspond to clinically significant arrhythmias and anomalous beats. All comparisons are made on a beat-to-beat basis with both fixed and variable references derived from the patient's own prevailing rhythm and waveform. These references do not usually correspond to any standard values given in medical textbooks for "normal" ECG's. In the CCU, one is faced with the abnormal ECG's of patients in a transient condition (either deterioration or recovery) due to a myocardial infarction. What is important to detect is any worsening of the patient's condition that presents itself as a change in his ECG. It is his present condition that is the reference to which comparisons should be made in order to detect the subtle changes that may lead to fatal arrhythmias.

In the monitoring of rhythm, therefore, the *R-R* interval of the ECG is compared, on a beat-to-beat basis, to the average *R-R* interval that this particular patient exhibited. This average time *T* is constantly (but slowly) updated and provides the reference against which the determination of whether or not a particular beat is premature is made. If the latest *R-R* interval is less than $0.8T$, the beat is classified as premature. The number of such premature beats per minute is calculated by circuitry that keeps a running record of the past minute. If the number of premature beats detected exceeds the value set in by the attending physician (or nurse), an alarm in the form of an ECG printout is given.

Also in the category of rhythm monitoring is the detection of a premature beat in or near the vulnerable period of the complex. Now, the vulnerable period of a *QRS* complex is usually defined in medical textbooks as a 40-ms period occurring near the peak of the *T* wave; more of this 40-ms window precedes than follows the actual peak. Since the realities of nature do not conform to any magic period with sharp boundaries to define just when a premature beat will cause ventricular tachycardia and when it will not, and since the position of such a window (if it could be so sharply defined) would vary in any given population, and also since it seems likely that any patient whose tissue has been made irritable by an infarct would exhibit a larger-than-normal window, our criterion for a vulnerable-period premature beat is broader than the specified 40-ms window at the peak of the *T* wave. In fact, any beat occurring before the end of the whole *QT* interval is classified as an early premature beat (EPB) and will cause an alarm printout of that beat on an ECG record. This is done by generating another reference that is a function of *T* and tracks the patient's *QT* interval as his heart rate varies.

In monitoring the morphology of each *QRS* complex, there are three criteria that are evaluated to determine whether a particular complex will be classified and counted as an anomalous beat: *QS* width, polarity reversal, and area of the full-wave rectified complex. The *QS* width criterion is determined by comparing the *QS* width of each *QRS* complex with a preset value that was derived from the patient's *QS* width when the monitoring began or when this reference was last updated by the hospital staff. This reference value is not allowed to change automatically because drug therapy often causes a slow increase in *QS* width that would go undetected if the reference value was allowed to tract this slow increase. When the *QS* width of a complex is 1.4 times as great as the reference value, the beat is classified and counted as anomalous. Polarity reversal is detected by comparison of the polarity of each *QRS* complex with that set in at the start of monitoring. If a beat is inverted from those the patient normally has, it is classified and counted as anomalous. The third criterion for anomaly is *QRS* area. Here, the area under each full-wave rectified *QRS* complex is compared with an automatically up-

TABLE I
MEDICAL AND SYSTEM CRITERIA

| MEDICAL | SYSTEM |
|---|---|
| 1. Number of Premature Beats/min. exceeds physician-set value. | 1.a) P.B. $\triangleq$ R-R' $\leq$ .8T where T = average R-R interval<br>b) # P.B. occurring in past 60 sec. > preset value |
| 2. Occurrance of Premature Beats in, or near, Vulnerable Period. | 2. EPB $\triangleq$ R-R' $\leq$ QT* where QT* = average QT = f(T) |
| 3. Number of Successive Anomalous Beats exceeds Physician-set value. | 3.a) AB $\triangleq$ QS $\geq$ 1.4 QS* where QS* = preset QS value and/or Polarity Reversal from "normal" polarity and/or $\text{Area}_{QRS} \geq 2\ A^*_{QRS}$ where $A^*_{QRS}$ = running average of area of QRS.<br>b) # Successive AB $\geq$ preset value |
| 4. Multiformal PVC's occurring. | 4. MFPVC $\triangleq$ $f(QS,PR,A)_{AB\#2} \neq f(QS,PR,A)_{AB\#1}$ |

TABLE II
ADDITIONAL CRITERIA

| MEDICAL | SYSTEM |
|---|---|
| 1. Sinus Arrest (Pause) | 1. R-R' $\geq$ 1.5T $\geq$ 2.5T (Following a P.B.) |
| 2. Patient having PAC's which we do not wish to count. | 2. Engage "PAC Reject."* To be counted as a P.B. a beat must now either a) be both premature and anomalous or b) be premature and have a compensatory pause $\geq$ 1.95T |
| 3. Patient Movement | 3. An Artifact Rejection circuit disables all alarms in the presence of muscle and movement noise. |

*This mode allows counting of PVC's (with or without abnormal morphology), PAC's with aberrant conduction, and interpolated PVC's with abnormal morphology and will not allow counting of PAC's with normal morphology, nodal premature beats with normal morphology, or interpolated PVC's with no morphological abnormalities (very rare).

dated average of past areas, and if it exceeds the reference by a factor of two, the beat is classified and counted as anomalous. Thus any or all three of the morphological criteria can cause a beat to be considered anomalous, and if the number of successive anomalous beats counted by the anomalous beat counter exceeds the value entered by the hospital staff, the system prints out the complexes. Any morphologically normal beat serves to reset this counter.

The diagnosis of multiformal premature ventricular contractions is accomplished by means of a memory circuit that compares the particular combination of morphological alarms that cause a beat to be classified as anomalous with the stored combination that caused the last anomalous beat classification. This is done regardless of the time between the two occurrences. The memory then updates by dumping the old combination that caused the last anomalous beat classification. comparison reveals a change in combination of morphological criteria, the beat is classified as an MFPVC and is printed out. The class of multiformal includes within it the subclass of multifocal. Multifocal infers different foci of origin of cardiac depolarizations while multiformal infers either different foci of origin or different condution pathways, or both. Table I summarizes the system criteria used to fulfill the four basic medical requirements.

In addition to the four important clinical diagnoses cited above, the monitoring system also performs additional tasks. The condition of sinus arrest (pause) is detected by the rhythm circuitry when $1.5T$ has elapsed since the last detected *QRS* complex. This criterion is automatically changed to $2.5T$ after a premature beat is detected to allow for the occurrence of a compensatory pause. If this time elapses between beats, the ECG record is printed out. If a patient is having premature atrial contractions and the staff decides that they no longer wish them to cause printouts, the PAC reject mode allows more stringent criteria to determine what will be classified and averaged as premature beats. In this mode, a beat must either be both premature and anomalous or be premature and have a full compensatory pause ($\geq 1.95T$) to be classified as premature. While tightening the criteria allows the system to ignore most PAC's, there are also some other types of beats that will go undetected in this mode. The staff must make this decision based on the patient's condition and prognosis. Where the patient exhibits constantly changing morphology, it is possible to eliminate from consideration those criteria that are not constant. The final task, the detection of patient movement, is accomplished by a special artifact detection circuit that disables all alarms in the presence of such artifact. The system criteria used to satisfy the additional medical requirements are summarized in Table II.

## III. System Configuration

Given the infinite variety of input waveforms possible, the reliable identification of the *QRS* complex presents a formidable problem in signal analysis. In order to accomplish this task, all avenues of analog enhancement of the *QRS* complex and diminution of the *P* and *T* waves (most importantly the *T* wave, since the *P* wave is usually of a low amplitude) are employed. This involves working in the frequency, amplitude, and time domains to distort systematically the original ECG waveform is such a way that identification of the *QRS* portion can be accomplished in a reliable manner.

### *Signal Preconditioning*

The appearance of the normal ECG waveform immediately suggests the possibility of separation of *QRS* and *T* portions solely by frequency domain methods [17]-[20]. While this approach will not suffice when applied to the many abnormal ECG waveshapes, it is an important and necessary first step in the required multistep treatment that will result in a reliable analog preconditioning for *QRS* identification. An analysis of the frequency spectra of the *QRS* and *T* waves for the ranges of *QRS* widths and *T*-wave widths that can be expected from patients in a CCU resulted in the specification of a narrow bandpass filter centered about 16 Hz with 3-dB points at 10 and 22 Hz. Such a filter will remove 98 percent of the energy of most *T* waves and essentially all pacemaker pulse energy while passing much of the energy of the *QRS* complexes.

With the narrow bandpass filter as its front end, a system of consecutive analog functions is used to enhance further the *QRS* complex and eliminate most *T* waves completely. Immediately following filtering, an AGC circuit serves to standardize the peak-to-peak amplitude of the *QRS* complexes over the expected 40:1 input amplitude range and 10:1 input frequency range (25 beats/min to 250 beats/min). This function is necessary so that subsequent operations may be specified and performed on a signal with one nonvarying parameter. To accomplish AGC on a biological signal with its characteris-

tic long period and extremely low duty cycle, an optically coupled feedback circuit with additional positive rate-feedback and an active pinch-off circuit was designed. It provides a constant output amplitude signal and automatically increases its gain in response to a 6-s absence of a positive *QRS* identification.

The final step in analog preconditioning is the sensing and digitizing of the *QRS* complex, which is accomplished by the positive and negative slope detection (SD) circuitry (+SD and -SD). The outputs $+\overline{SD}$ and -SD are sharp short-duration pulses that are then processed by the *QRS* identification logic.

### *QRS Identification Criteria*

Having performed analog operations in the frequency and amplitude domains and having digitized the resulting representation of the *QRS* complex, what remains is the application of time-domain criteria before making a positive identification of the complex. This is accomplished by the *QRS* identification circuitry that employs high-threshold logic and unijunction transistor (UJT) timing circuits to impose stringent timing criteria on the $+\overline{SD}$ and -SD pulses before generating the pulse $\overline{TRIG}$, which signifies the positive identification of a *QRS* complex. In this circuitry, additional high-frequency noise protection and baseline shift protection are provided.

The methodology involved in the application of the timing criteria to the input slope detector pulses is best understood with the aid of Fig. 1. The first pulse to arrive must always be a positive-slope detection, regardless of the polarity of the input, due to the analog functions employed in preconditioning. Assuming that the last *QRS* identification occurred more than 20 ms previously, this input will reset the 200-ms false detection (FD) timer, the 40-ms $\tau_0$ timer, and, since it is the first positive-slope detection, will allow the negative slope input to act on all following negative-slope detection pulses. The first negative-slope input pulse will now serve to ready the 60-ms $\tau_0'$ timer for the second positive pulse that will start its timing cycle. For the present, we will ignore the functions of the 5-ms inhibit line and 5-ms delay circuits and concentrate on the major functions of this circuitry. The first negative pulse also starts the 200-ms FD timer, which will time out in 200 ms and reset all circuits unless a second positive-slope detection pulse arrives before that time. This FD timer protects against rapid baseline shifts being identified as a *QRS* complex. The second positive-slope detection pulse will now reset the FD timer, the $\tau_0$ timer, and start the $\tau_0'$ timer. If the $\tau_0'$ timer times out, a positive *QRS* identification is made, a 20-ms refractory period initiated, and all circuits reset. If a second negative pulse occurs before $\tau_0'$ times out, it will reset the $\tau_0'$ timer and start the $\tau_0$ timer. If the $\tau_0$ times out, a positive *QRS* identification is made as before. If a third positive-slope detection pulse arrives before the $\tau_0$ timer cycles, it will reset the $\tau_0$ timer and again start the $\tau_0'$ timer. In this manner, from the second positive-slope detection pulse onward, there is, at all times, a timer in operation that will cause a positive *QRS* identification when it cycles. Returning to the function of the 5-ms timers, they serve to insure that the time between the last negative-slope detection pulse and the next positive-slope detection pulse is greater than 5 ms. This is accomplished by generating a 5-ms inhibit period after each negative-slope detection pulse during which any positive-slope detection pulse will be delayed by the 5-ms delay timer. This protects the input flip-flops of the $\tau_0$ and $\tau_0'$ timers against conflicting commands arriving too closely in time.

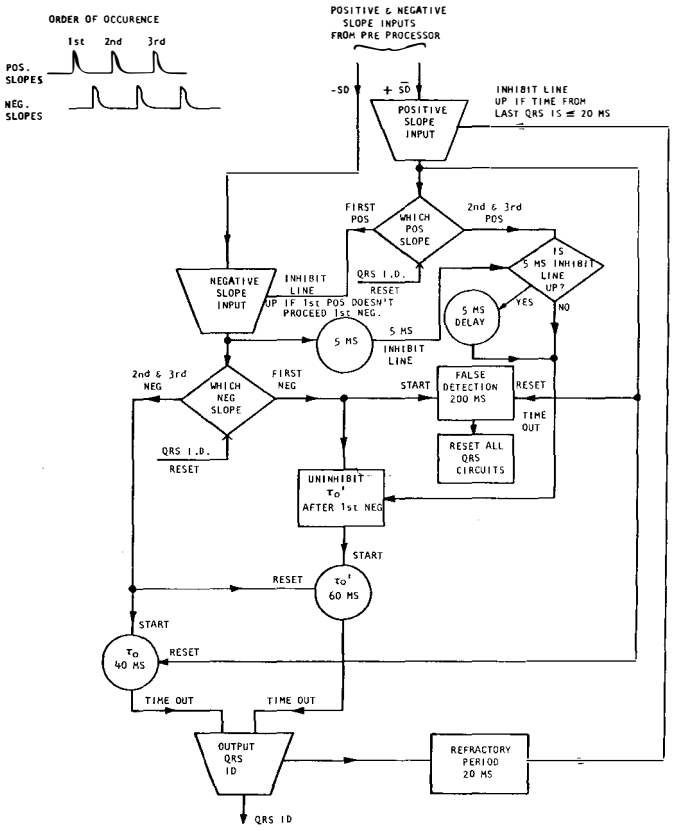


Fig. 1. Slope detector timing methodology.

The analog preconditioning together with the *QRS* identification circuitry forms the all-important subsystem that is responsible for the reliability of the complete monitoring system and is the determining factor as to whether the unit will be acceptable to the medical community or not.

### *System Block Diagram*

The various building blocks and their interconnections that serve to make up the complete arrhythmia-anomalous beat-monitoring system are shown in Fig. 2. All that lies within the dashed lines constitutes the monitoring system, and outside the dashed lines are the various modules that work with such a system to provide initial amplification and patient isolation, signal delay and display, ECG printout, and rate-meter display and alarm settings. Along the top of the diagram are the six blocks that constitute the analog signal preconditioning and *QRS* identification, which are described in the preceding sections of this paper. The remaining functions are carried out using HTL, IC, and UJT timing circuitry.

Rhythm monitoring is carried out by the blocks labeled "*R-R*," "rate ref," "early premature beat," and "premature beat avg." The rate-reference circuitry provides the reference signals against which a premature beat is detected by the *R-R* circuit, an early premature beat is detected by the early premature beat circuit, a PAC is detected by part of the alarm circuitry, and the AGC circuit sets its output criteria. The

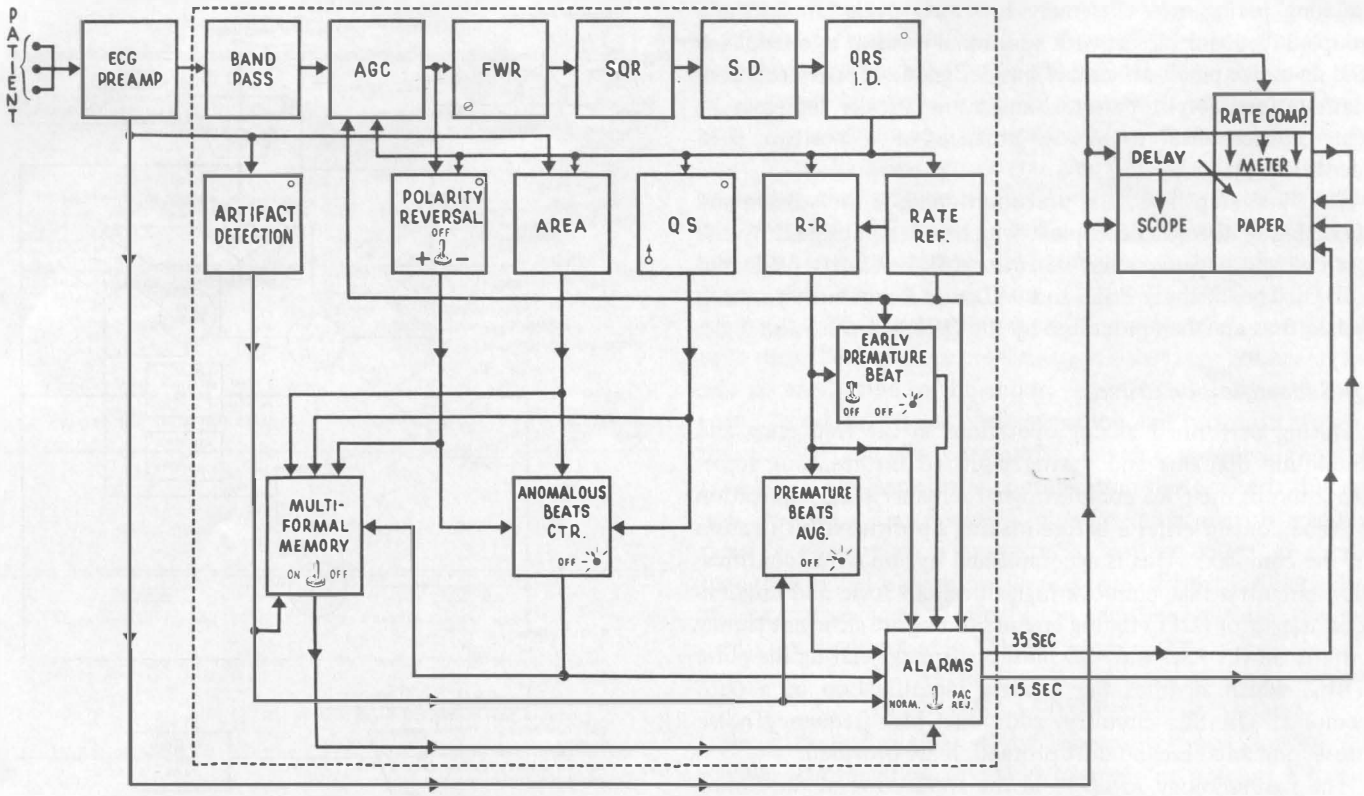


Fig. 2. Arrhythmia–anomalous beat monitoring system.

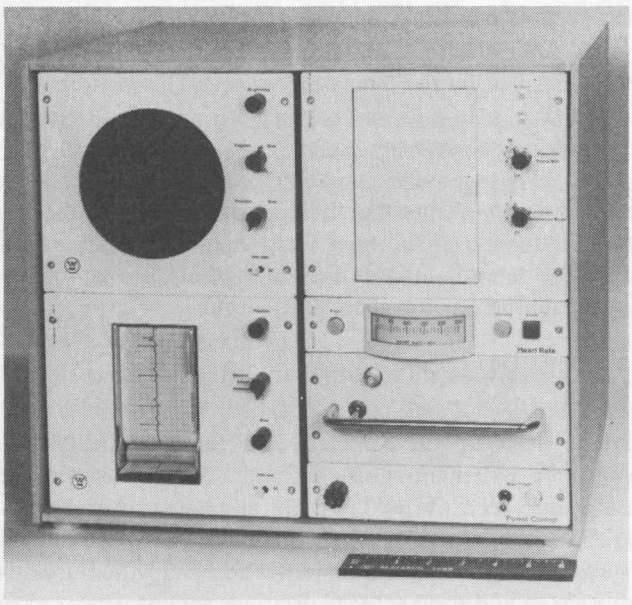

Fig. 3. Clinical prototype.

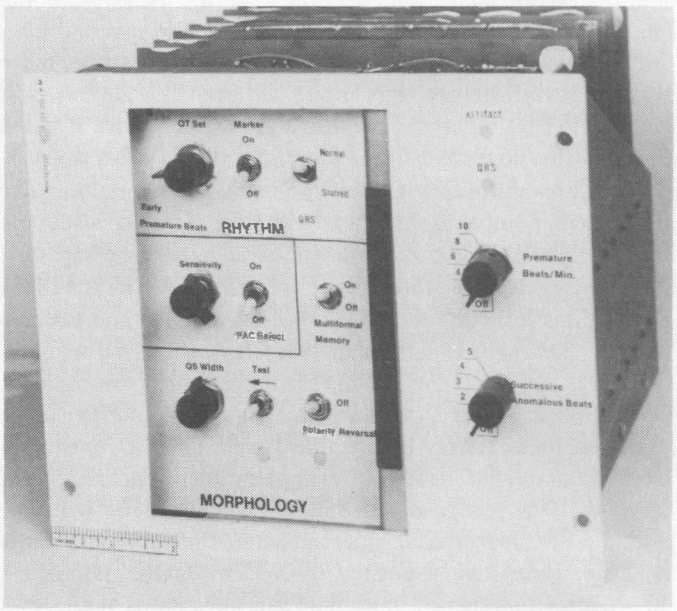


Fig. 4. Front panel.

timing criteria for these circuits are applied by UJT timers specially designed to have a linear charging rate such that, by using the rate-reference signals, they always time-out in a fixed percentage of $T$. This insures constant timing criteria regardless of changing heart rate ($1/T$). The $R$–$R$ circuit sends its output to the premature beat averaging circuit, which then determines when an alarm condition is present. The early premature beat circuit outputs directly to the alarm circuitry.

Morphological monitoring is carried out by the blocks labeled "$QS$," "area," "polarity reversal," "anomalous beats ctr," and "multiformal memory." Using the timing of the first-positive slope detection (FP) and the positive identifica-

tion of a *QRS* complex, the *QS* circuit determines when a wide beat has occurred by comparison with the set-in reference for the patient being monitored. It outputs to the AB counter and multiformal (MF) memory. The area circuit determines when the area of the undistorted full-wave rectified input exceeds the patient's average area by a factor of two and it also outputs to the AB counter and MF memory. The polarity reversal circuit, using the constant-amplitude AGC signal as its input, determines when a complex has undergone a polarity reversal from that which has been set in for the patient being monitored. It outputs to the AB counter and MF memory. The AB counter counts the number of successive anomalous beats and outputs to the alarm circuit when the count exceeds the set-in value for the patient being monitored. It also outputs to the MF memory to initiate the compare-and-store sequence of that circuitry. The MF memory circuit compares the outputs of the *QS*, area, and polarity reversal circuitry, which are causing an AB count with those that caused the last AB count. If they differ, it outputs to the alarm circuitry, dumps the old combination, and stores this new combination in its memory.

The final two blocks, those labeled "artifact detection" and "alarm," operate in conjunction with those involved in both rhythm monitoring and morphology monitoring. The artifact detection circuitry disables the MF memory, the premature beats averager, and the alarm circuits when artifact is detected in the input ECG. It operates by looking for the high-frequency "grass" associated with muscle potentials and patient movement. When the amount of such artifact exceeds a preset value, a 6-s artifact period is initiated during which various functions are reset and no alarm conditions acted upon.

The alarm circuitry contains the logic necessary to integrate the various alarm conditions impinging upon it into the proper commands to pass on to the paper drive circuitry, which then drives the recorder and furnishes the permanent ECG record for the CCU staff to evaluate before making their decisions regarding treatment.

Two clinical prototypes were constructed using plug-in printed-circuit cards that mated with a "mother board" and formed a module that fitted into existing monitoring equipment (see Figs. 3 and 4). The choice of functions is made with toggle switches on the front panel. Those few adjustments necessary are also easily made by the inclusion of indicator lights on the front panel, which signal proper adjustment of *QS* width and polarity. Similarly, a marker appearing on the scope display of the ECG makes the setting of the *QT* interval an extremely simple task. The arrhythmia-anomalous beat monitor itself was contained in a pull-out module measuring roughly 7 by 7 by 9 in. The two prototypes were used in clinical evaluations using tapes as well as patients.

## IV. Clinical Evaluation

The process by which the arrhythmia-anomalous beat monitoring system evolved was one of constant interfacing of medical requirements, hospital observations, bench-tested circuit realizations, and hospital-tested subsystem operation.

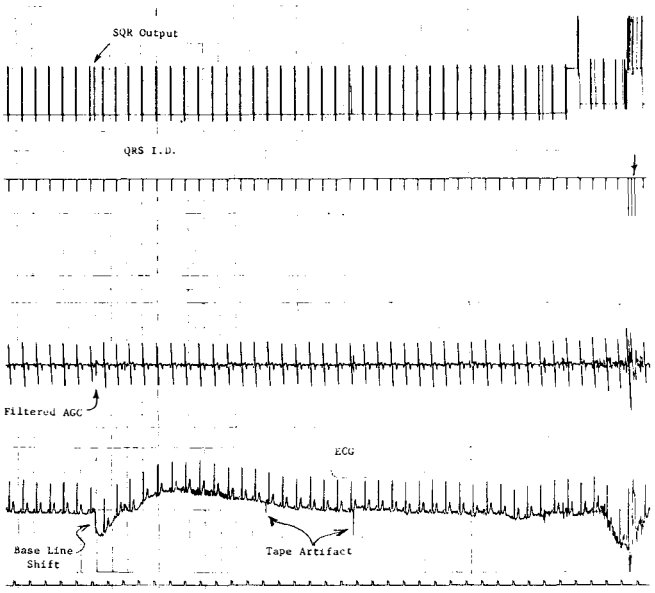


Fig. 5. Regular sinus rhythm with 60-Hz interference and a baseline shift.

For this reason, there is no clear-cut point at which one could say that engineering testing ceased and clinical testing began. Rather, both were conducted simultaneously by repeated trials in the hospital interspaced with periods of redesign and bench-testing conducted at the research laboratory.

In addition to on-line testing in the CCU, special patient tapes, which were chosen for their bizarre rhythms and waveforms, were used to evaluate the system. In the hospital, signals were used from a variety of both disposable and reusable commercially available electrodes. The nurses placed these electrodes in many configurations on the chest due to specific patient conditions (skin rashes, sutures, etc.). We have no knowledge of the electrode types or configurations that were used in recording the patient tapes. When possible, electrodes should be placed to minimize motion artifact. This usually means location away from muscle masses, such as over the manubrium and xiphoid process of the sternum. The accuracy of the *QRS* identification circuitry can be seen from Figs. 5-7, which are small portions of 3 of 12 patient tapes (each of which was 10 min long) used to evaluate the instrument.

The record shown in Fig. 5 contains some interesting artifacts along with 60-Hz interference superimposed on a regular sinus rhythm. A baseline shift is identified on the record and successfully processed by the system and rejected. The *QRS* output shows only a single pulse for the baseline shift, as opposed to the double pulses produced by the *QRS* complexes (the double pulses appear as darker, thicker lines on this slow time recording), and no *QRS* identification pulse appears for the shift since the false detection circuitry has successfully eliminated the baseline shift from consideration. Further on in the record tape, artifact spikes appear and they too are discarded by the identification circuitry. Baseline wander and 60-Hz interference are eliminated by the filter and AGC circuitry, as shown in the AGC tracing. The system's response to this

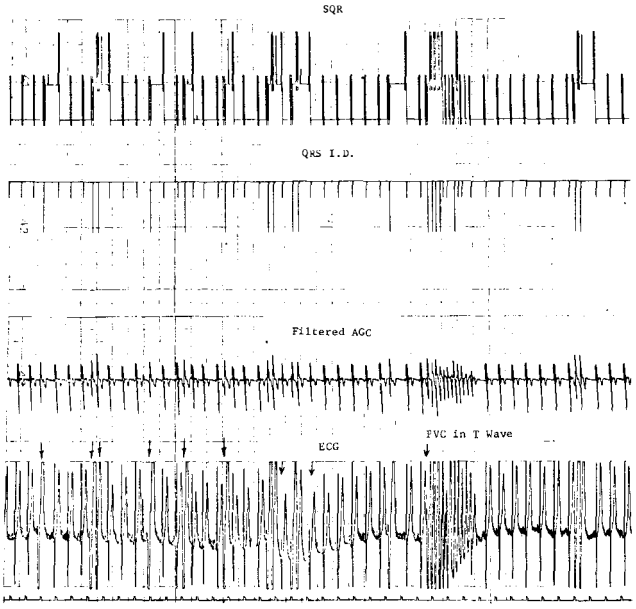


Fig. 6. High spiked $T$ waves, MFPVC's, and an EPB, which triggers ventricular tachycardia.

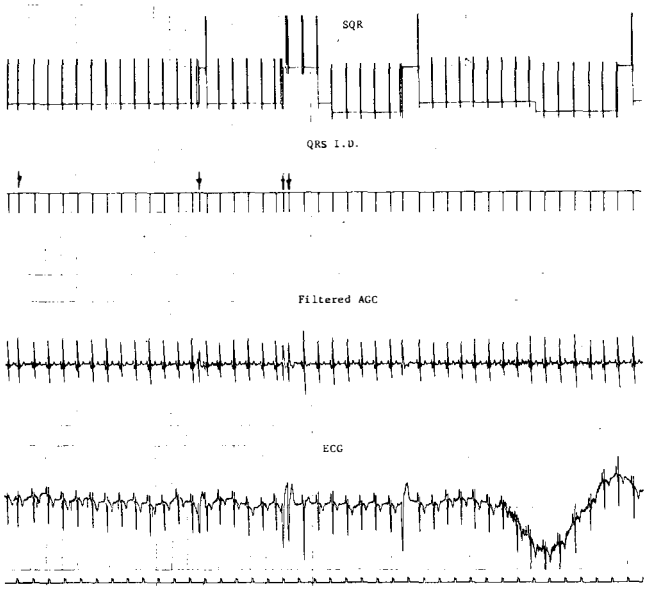


Fig. 7. MFPVC's and baseline wander.

10-min record was 98 percent free from false-positive and completely free from false-negative detections.

The record of Fig. 6 contains the most difficult type of *QRS* complex to identify reliably: the complex with a high spiked $T$ wave. Also on this record are MFPVC's and an EPB that triggers ventricular tachycardia. Several of the ECG complexes are marked to show the low-amplitude *QRS* relative to the high-amplitude $T$ wave associated with it. The system performance for this exceptionally difficult 10-min record was almost perfect, with 99.98 percent freedom from false positives and 99.21 percent freedom from false negatives.

Fig. 7 shows a patient record containing MFPVC's and baseline wander. The system performance was 99.99 percent free of false positives and completely free of false negatives. Additional tests, both bench and clinical, are still under way, and system modifications that may be required are under study.

## V. Summary

An overview of the medical requirements, design philosophy, system synthesis, and clinical evaluations associated with the development of an on-line real-time arrhythmia-anomalous beat monitoring system that meets the four basic requirements of cardiac monitoring, while performing several valuable additional monitoring functions, has been presented.

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