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환자경고 및 지능부정맥 시스템

PATIENT WORN, INTELLIGENT ARRHYTHMIA SYSTEMS

o MyoungHo Lee — Dept. of Electrical Engineering, Yonsei University, Seoul, Korea

Willis J.Tompkins — Dept. of Electrical & Computer Eng., University of Wisconsin-Madison, Madison,WI 53706 U.S.A.

ABSTRACT

The device that we are developing is a microprocessor-based,portable arrhythmia monitor that ultimately will need processing algorithm similar to those found now in monitoring systems in the cardiac care unit of today's hospital. Our initial goal is to replace the functions of the Holter tape recorder, the current device of choice for determining if an ambulatory patient has potential heart disease.

1. Introduction

There is a great deal of interest these days in homr monitoring of patients particularly due to cost considerations. If the same diagnostic information can be obtained from an ambulatory patient as can be found in the hospital, it is clearly more cost effective to do the monitoring in the home. Technological evolution has led to a high-performance computing capacity that is manifested in such devices as compact,lab-sized versions of the personal computer. Such battery-powered systems provide us with the ability to do computational tasks in the home or elsewhere that were previously possible only with larger,nonportable, line-powered computers.

This increase in computing capability with its concurrent decrease in size and power consumption has led to the possibility of designing "intelligent" biomedical instrumentation that is small and light enough to be worn by an ambulatory patient. Such instrumentation potentially will perform monitoring functions previously done only in the confines of the hospital. Portable biomedical instrumentation can now be designed that was not contemplated previously because microcomputer technology had not yet evolved far enough to support such applications.

Fig.1 shows that the Holter approach is to record on magnetic tape the ECG of a patient for a full day. This recording and its subsequent return to a laboratory environment for playback and analysis restricts the timely reporting of suspected arrhythmias to the physician. The results of a Holter recording session are typically not known by the physician for several days. It is incorrectly called Holter monitoring. It is not monitoring in the normal context of the word, since monitoring typically provides continuous information about the state of the patient, as in intensive care monitoring.

2. Hardware Design

The hardware design of a portable arrhythmia monitor is quite straightforward, dependent only upon the battery-operable, large-scale-integrated circuit componets available in the marketplace at design time. The primary semiconductor technology available for battery-operated design is CMOS. The hardware generations,however, evolve rapidly with the progressive improvements in semiconductor technology.

Fig.2 shoes a block diagram of our current monitor design. In addition to the microprocessor, a portable arrhythmia monitor requires analog and digital support electronics. Analog amplifiers do the front-end ECG amplification and signal conditioning. An analog-to-digital converter integrated circuit changes the analog ECG to the digital signal representation needed by themicroprocessor. ROM memory holds the program that directs the performance of all the functions of the instrument, and RAM memory stores the captured ECG signal. I/O ports interface audible and visual displays and switch interactions in the device. A modem circuit provides for communication with a remote computer so that captured ECG sig-

nals can be transmitted back to a central site.

All these technologies are changing rapidly, so we must constantly contemplate improving the hardware design. Newer designs permit doing our task with (1) less components, (2) greater computational power(thereby permitting more complex signal processing and interpretive algorithms).

Thus there is a technological force driving us to continuously improve the hardware design. In industry, an engineering compromise must come into play at some point, and the design must be frozen to produce a viable product. however, we are in a university environment, so we can afford to continuously iterate the design.

3. Software Design

Unfortunately the frequent hardware changes lead to continuous software redesign as well. The software for an instrument is very hardware dependent. Each new microprocessor has its own unique machine language. Thus we end up rewriting the same programs for different processors and thereby waste considerable programming time. This software problem has led us to explore higer-level languages that are transportable from one kind of microprocessor to another. We have now developed on the C language conceived at Bell laboratories as the most nearly ideal language in the marketplace for this type of real-time instrumentation application. Its primary advantages are (1) a programming level low enough to achieve the requisite machine control and (2) transportability from one type of microprocessor to another.

Providing that we follow a few software design rules, a program written in the C language for one type of microprocessor can be easily reconfigured to run on a different one. Althoguh imperfact, the language considerably reduces the reprogramming time necessary for rewriting the software when changing microprocessors and lets use our programming time to concentrate instead on improving the algorithms.

For a portable arrhythmia monitor,the two major software design tasks are (1) QRS detection and (2) arrhythmia analysis. The QRS tedection must be nearly perfact, otherwise the arrhythmia analysis algorithms will be fooled too often by false reports of beats that are not really there(fasle positive) or lack of reporting of beats that are missed(fasle negatives).

4. The QRS detection algorithm

Fig.3 shows that the various techniques used to implement a QRS detector are linear digital filters,nonlinear transformations, decision processors, and template matching. Typically two or more of these are combined together in a detector algorithm.

The most common approach in contemporary commercial ECG instrumentation is based on template matching. A model of the normal QRS complexcalled a template is extracted from the ECG during a leaning period on a particular patient. This template is compared with the subsquent incoming real time ECGas it is acquired to look for a possible match using some sort of mathematical criterion of goodness of fit.

Fig.4 shows the elements of our current QRS detection algorithm. We have designed a bandpass filter from a special class of digital filters that require only integer coefficients. This permits the microprocessor to do the signal processing using only integer arthmetic, thereby permitting real-time processing speeds that would be difficult to achieve with floating-point processing.

Fig.5 shows the performance of the algorithm on the 24-hour annotated MIT/BIH database that is composed of recordings of ECGs of 48 ambulatory patients. As shown, our total error in analyzing about 116,000 beats is 0.68%,corresponding to an average error rate of 33 beats per hour. In fact, a great deal of the error comes from particular half-hour tape segments.

Fig.6 shows the results of excluding the four most problematic half-hour tapes from the overall results. Notice that the false-positive errors decrease much more extensively than the false negatives. This indicates that this algorithm is more likely to misclassify noise as a QRS complex than it is to miss a real event. Elimination of these four tapes reduces the error rate below 10 beats per hour.

5. Arrhythmia Analysis

Fig.7 is a conceptual drawing of an arrhythmia analysis algorithm based upon the two parameters, R-R interval and QRS duration. In this two parameter mapping, we establish a region called "normal" by permitting the algorithm to first on a set of eight QRS complexes defined by a clinician as having"normal"

rhythm and morphology for the specific patient. This learning process establishes the initial center of the "normal" region in the two-dimensional mapping space.

Boundaries of all the other regions in the map except for region "0" are computed as percentages of the location of the center of the "normal" region. Region "0" has fixed boundaries based upon physiological limits. Any point mapped into region "0" is considered to be noise because it falls outside what we normally expect to be the physiological limits of the smallest possible R-R interval or QRS duration.

An abnormality such as tachycardia causes clusters of beats to fall in region "1" which represents very short R-R intervals. Bradycardia beats fall in region "6". Typically abnormalities must be classified by considering sequences of beats. For example, a premature ventricular contraction with a full compensatory pause would be characterized by a short R-R interval coupled with a long QRS duration followed by a long R-R interval coupled with a normal QRS duration. This would be manifested as a sequence of two points on the map, the first in region "3" followed by the second in region "5". Thus arrhythmia analysis consists of analyzing the ways in which the beats fall onto the mapping space.

The center of the "normal" region is continuously updated based upon the average R-R interval of the eight most-recent beats classified as normal. This approach permits the normal region to move in the two-dimensional space with normal changes in heart rate that occur with excercise and other physiological changes. The boundaries of other regions are modified beat-by-beat since they are based upon the location of the "normal" region. Thus this algorithm adapts to normal changes in heart rate.

6. Discussion

One reason that is difficult to displace the old Holter technology with a modern high-technology approach is that it is a full-disclosure technique that is inherently resistant to change. That is, even though the typical physician looks only at the final report and almost never looks at all the complete 24-hour ECG signal recorded, it is implicit that a skilled technician has analyzed the ECG. Also the physician has the ultimate security blanket in that the date is there should it ever be necessary to go back through it again.

A second reason that the semiconductor-based, real-time approach has not impacted the Holter market as yet is imperfection of the diagnostic algorithms. It is necessary for a portable monitor to do many of the tasksthat are now being done in the coronary intensive care environment. It must be able to reliably detect QRS complexes, perhaps better than hospital-based systems,since false judgments will cause unnecessary data to be stored in its limited memory space. If problems occur, the portable device must do self diagnosis and make suggestions to the patient as to how to cure problems since there is no technician in the ambulatory environment to correct problems when things go wrong.

There is no doubt that Holter recording will be displaced at some point by microprocessor-based portable monitor. When that time comes, it will lead to lower diagnostic costs, greater device reliability, better clinical research capabilities, and continuously evolving performance. The utility of these devices will evolve with the technology just as the early four-function calculator has evolved into the lap-sized, high-performance portable computer of today.

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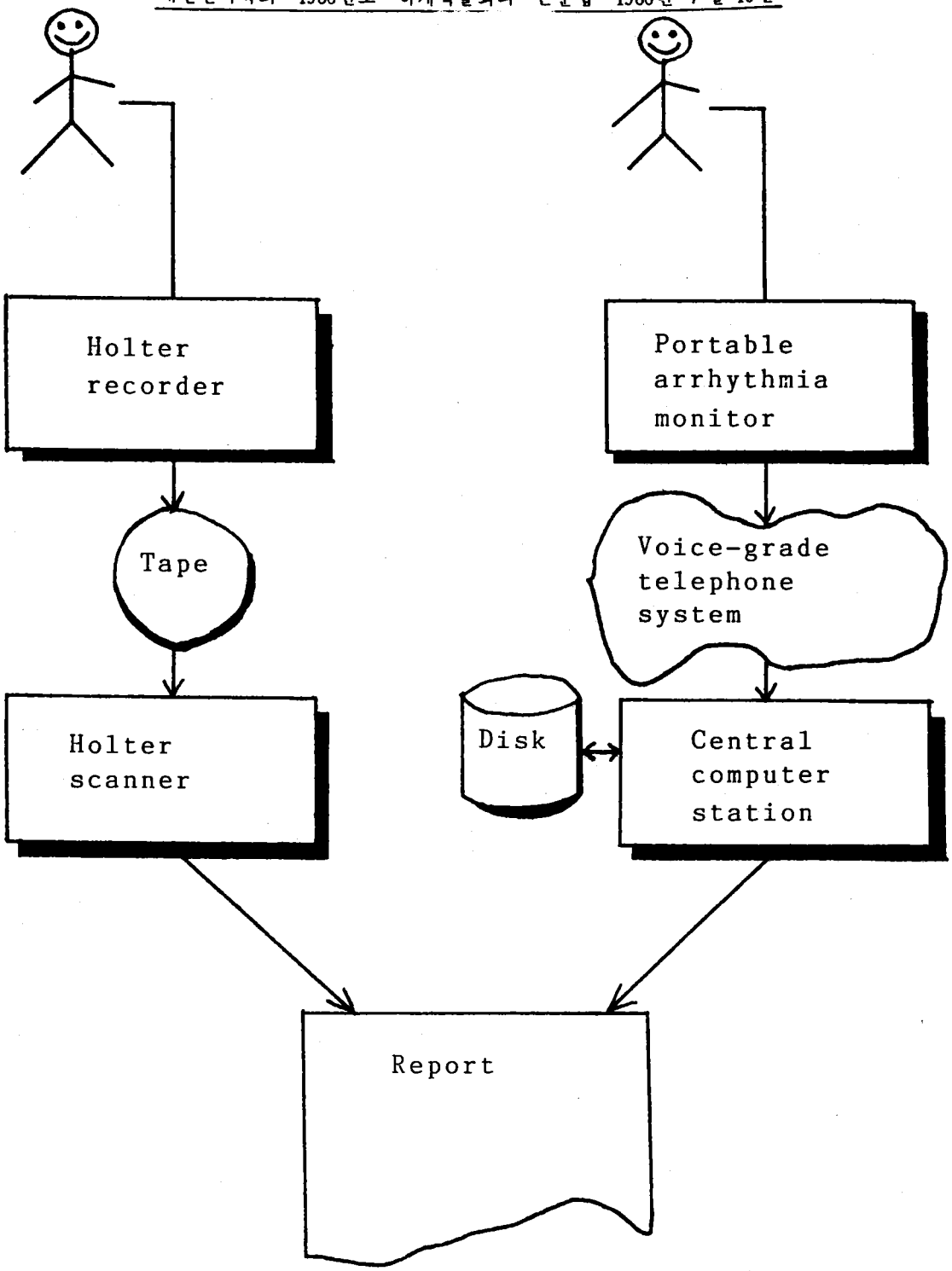

Fig. 1 Arrhythmia capture on ambulatory patients.

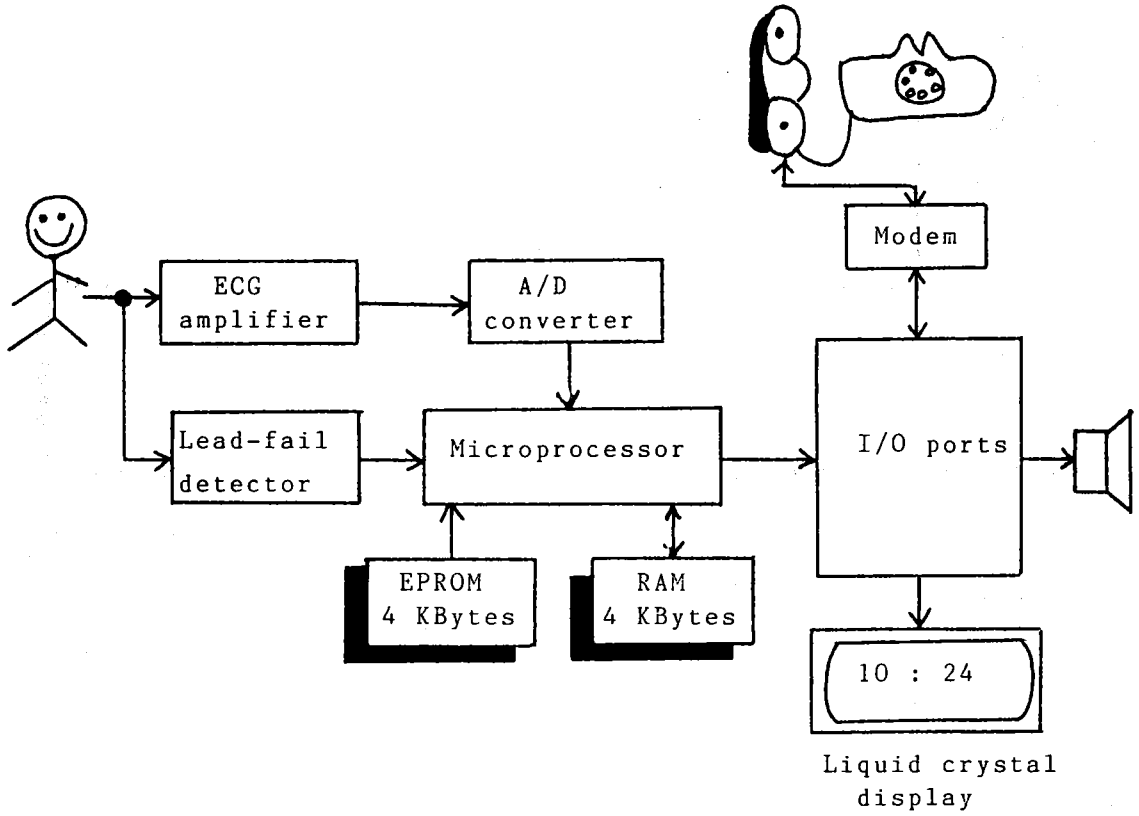

Fig. 2 Block diagram of the portable arrhythmia monitor.

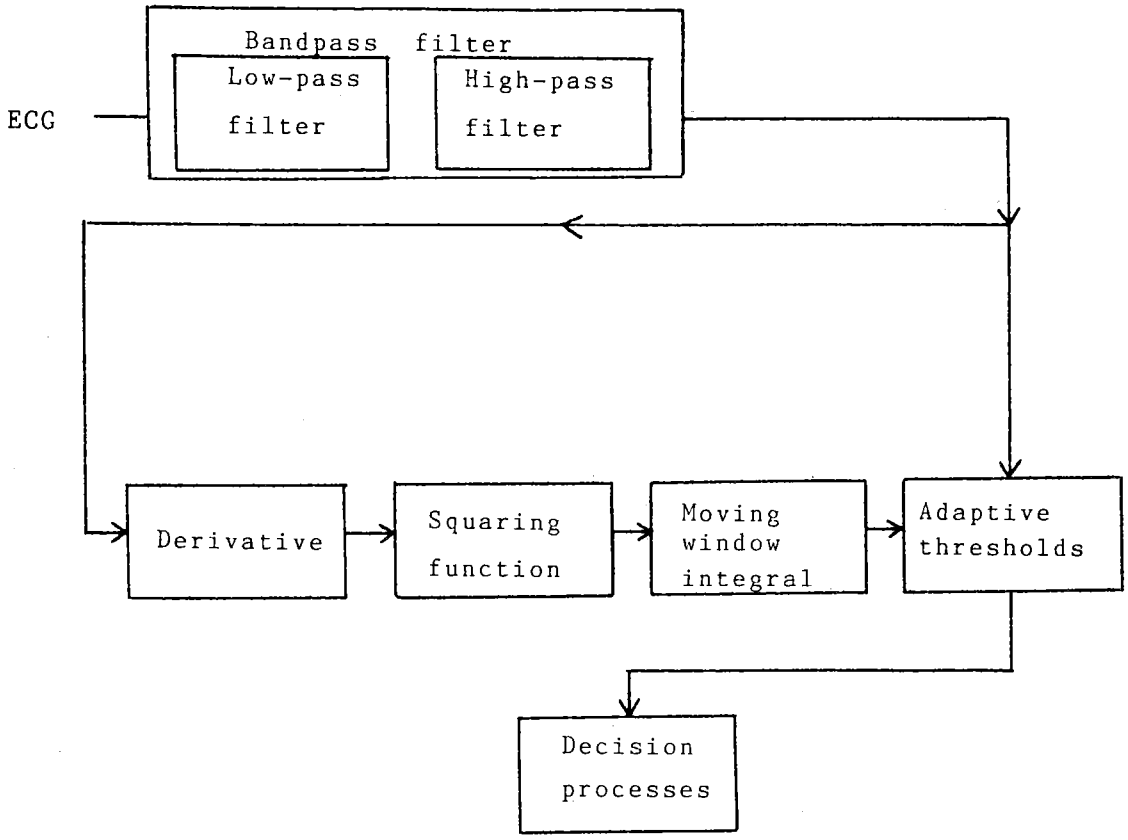

Fig. 4 Block diagram of the QRS detection algorithm.