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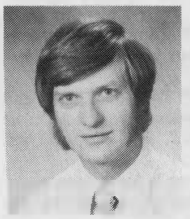

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From Holter Monitors to Automatic Defibrillators: Developments in Ambulatory Arrhythmia Monitoring

NITISH V. THAKOR, MEMBER, IEEE

***Abstract*—In 1961, Holter reported a design of a tape recorder that acquired and stored electrocardiographic (ECG) signals from ambulatory patients. This made long-term monitoring of patients in their day-to-day environments possible. The next generation of devices employ microcomputer circuits for automatic interpretation of cardiac arrhythmias. Implantable pacemakers also show some arrhythmia interpretation capability. A special case is the automatic implantable defibrillator which recognizes the ventricular fibrillation signal. We present here the details of the original Holter recorder, the microcomputer-based arrhythmia monitor, and the automatic implantable defibrillator. In conjunction with the historic account of these developments, we present the current techniques of ambulatory ECG signal acquisition, processing, arrhythmia detection, and performance evaluation of automated arrhythmia detectors.**

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I. Introduction

THE origins of electrocardiography (ECG) can be traced to the design of a string galvanometer in 1893 by Einthoven. Subsequent developments in electronics led to the use of electronic amplifiers, oscilloscopes, and chart recorders for ECG recording. However, the ECG recording technology of the day did not permit long-term continuous recording from active subjects. Holter [1] went beyond traditional ECG techniques "to solve the scientific problem of adequate sampling and the medical problem of obtaining electrocardiograms in situations other than the highly artificial and unrealistic situation of resting quietly on a comfortable pad after a good sleep, with no breakfast, and with calm confidence in one's physician." This led to the development of what is now known as the "Holter recorder," suitable for long-term ECG recording from ambulatory subjects.

Holter first reported the design of an ECG tape recorder in 1961 [1]. This device made the long-term monitoring of patients in their day-to-day environment possible. In about 1974 microprocessors became available for automatic analysis of ECG's. This provided impetus to the development of a microprocessor-based ambulatory ECG monitor that we first reported in 1978 [2]–[4]. The pacemaker is an alternate type of arrhythmia detector for monitoring ECG from inside the heart. Over the last ten years sophisticated pacemakers that sense cardiac arrhythmias have evolved. While a pacemaker delivers a low energy pacer pulse in the event of abnormal conduction, the automatic implantable defibrillator delivers a high energy shock to defibrillate the heart. It must specifically recognize the life-threatening ventricular fibrillation signal. The automatic implantable defibrillator was first successfully implanted in man in 1981 [5]. We review here the basic concepts of ambulatory ECG monitoring and then trace the technical development of three devices: the original Holter monitor, the microcomputer-based ambulatory arrhythmia monitor, and the automatic implantable defibrillator.

II. Ambulatory ECG Monitoring Concepts

Electrodes

Modern ECG recording electrode designs generally use a silver–silver chloride (Ag–AgCl) recording element that makes electrical contact with the skin via an electrolytic gel [Fig. 1(a)] [6]. Usually the gel consists of electrolytes such as NaCl or KCl in isotonic concentrations (on the order of 0.1 M). The electrode body is most often made from porous foam or fabric that does not impede perspiration. The electrode adhesive material should resist perspiration and wetting, but at the same time should not cause irritation.

We studied some commercial electrodes, especially to assess their usefulness in long-term ambulatory ECG monitoring [7]. Table I summarizes the duration of usefulness of some electrodes. The reasons for failure were poor adhesion or excessive skin irritation caused by the gel. This restricts the use of presently available electrodes to a period of about 48 h. The electrode placement on the thorax affects the amplitude of the ECG signal and the artifact levels. We measured artifact level at 15 selected recording sites during an exercise protocol of bending, lifting weights, and jogging. We identified two pairs of electrode locations that produce the highest signal-to-noise ratios [7]: 1) manubrium–left midclavicular/7th rib, and 2) midsternum–left axillary/9th rib [Fig. 1(b)].

ECG Signal and Noise

ECG signal amplitude ranges between 1 and 5 mV. As described above the signal amplitude and the artifact levels greatly depend on electrode placement. The motion artifact manifests itself in the form of: baseline drift or wandering, artifact induced by respiration, displacement of the electrode away from the skin, and muscle noise [8]. Fig. 2(a) shows some examples

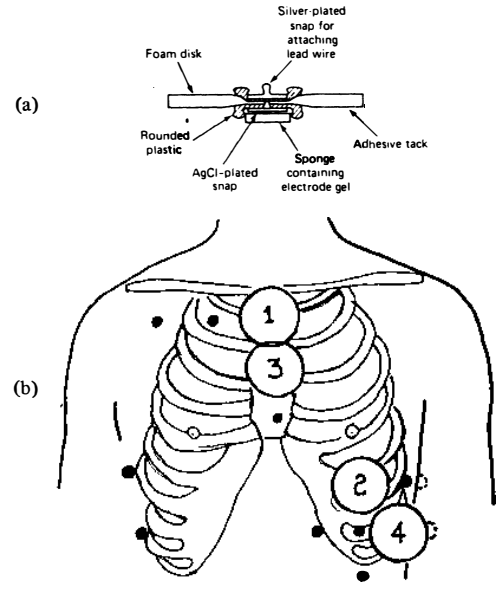

Fig. 1. (a) Schematic of a disposable ECG electrode (reproduced with permission from [6]). (b) Results of ECG and artifact recordings from 15 thoracic locations (0). Two best pairs for ECG recording are identified. (Average artifact levels–1:0.40, 2:0.46, 3:0.40, 4:0.45 mV; average *QRS* amplitudes–pairs 1–2:3.10, pairs 3–4:2.95 mV; average SNR–pairs 1–2:3.61, pairs 3–4:3.52.)

TABLE I
Data on Useful Life time (in hours) of Commercial ECG Electrodes

Subject	NDM 3510	HP 14240	3M 2256	SENTRY 1001	Mean
1	54 A	66 A	54 I	42 I	54
2	54 I	6 A	66 A	42 A	42
3	72 N	54 A	72 N	72 N	67.5
4	18 A	72 N	72 N	72 N	58.5
5	72 N	72 N	72 N	72 N	72
6	42 I	42 A	72 N	54 I	52.5
7	6 A	18 A	30 A	66 A	30
8	72 N	30 A	72 N	72 N	61.5
Average use	49	45	64	61.5	55
time to irrit.	62.5	72	69	64	67
Adhesion failure	49	45	65	66	56

NOTE:
I - irritation, A - Adhesion, N - no failure but end of test
Average use = hours of use for all subjects/number of subjects
Onset of irritation = (all I + all N)/number of cases
Failure of adhesion = (all A + all N)/number of cases

of motion artifact seen in ECG recordings [9]. Usually the motion artifact is reduced by proper electrode connection and skin preparation. For example, providing a stress loop of the electrode lead reduces the pull at the recording element, resulting in reduced artifact. Skin preparations temporarily reduce artifacts by removing the epidermal barrier layer, which is presumed to be the source of artifacts [10]. Abrasion with sandpaper [10], puncturing the epidermis [11], and alcohol rub are commonly used techniques for skin preparation.

Further, environmental electrical interference also affects the ECG signal quality. The major sources of electrical interference are: 60 Hz powerline, radio frequency interference generated by electrical machinery or electrocautery, and electromagnetically induced pickup [8]. The electrical interference is best reduced by proper shielding, twisting the lead wires to lessen induced interference, proper grounding, and electronic filtering. Fig. 2(b) shows the power spectra of the ECG signal and some noise components [12]. A low-pass filter can reduce muscle noise, and a high-pass filter can attenuate the baseline drift. Often ambulatory ECG monitors are designed with

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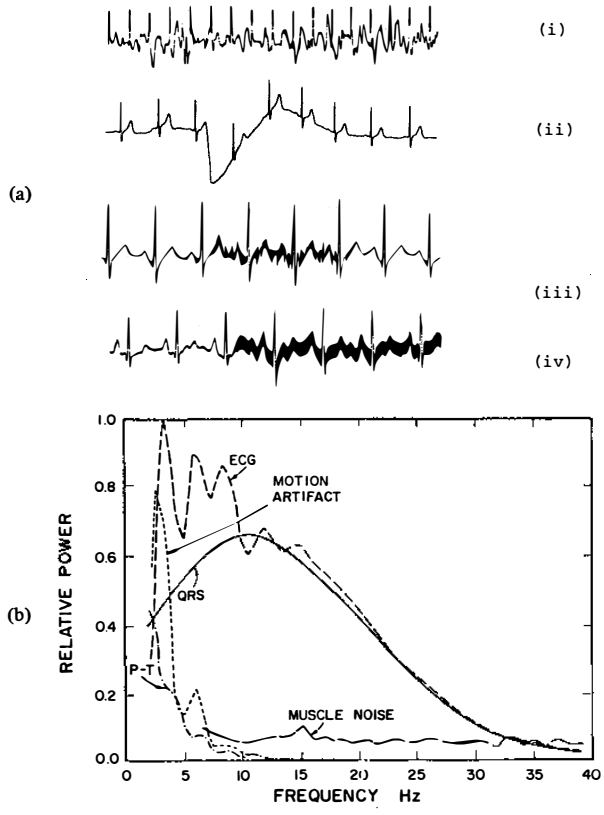

Fig. 2. (a) Some examples of electrical interference in ambulatory ECG: i) motion artifact, ii) baseline drift, iii) muscle noise, and (iv) power-line noise (reproduced with permission from [6] and [9]). (b) Power spectra of ECG, *QRS* complex, and various noise sources (adapted from [12]).

restricted bandwidth of 0.5–40 Hz (as compared to 0.05–100 Hz for diagnostic ECG recording). An analog notch filter or, equivalently, a digital filter can eliminate 60 Hz interference [13].

QRS Detection

Detection of the *QRS* complex is almost always central to the more complex arrhythmia analysis programs. Simple *QRS* detectors take advantage of the difference in power spectra of the *QRS* complex, and of the *P–T* waves and artifacts [Fig. 2(b)], to build filters whose output is the largest when the *QRS* pulse occurs [14]. The output of the *QRS* filter is compared to a detection threshold, and a pulse is produced when the filtered signal exceeds the threshold. False positives (FP's) can occur if some noise spikes exceed the threshold levels. On the other hand, the threshold level may sometimes be kept too high and miss *QRS* complexes with small amplitudes (FN's). Fig. 3(a) illustrates some strategies for determining *QRS* detection thresholds [15]. The most desirable threshold level is the one that produces as few FP's and FN's as possible.

More sophisticated *QRS* detectors are implemented with computer software. For example, syntactic ECG analysis is a technique borrowed from the field of pattern recognition [16]. Various contours and features on the ECG waveform are assigned characteristic alphabetical symbols [Fig. 3(b)]; and ECG waveform now may have a characteristic "signature" that the computer is programmed to recognize. An adaptation of this technique assigns tokens to various features of the *QRS* complex [17]; an occurrence of a given token causes transition of states in a finite state machine. If a correct sequence of states does occur, a *QRS* complex is identified.

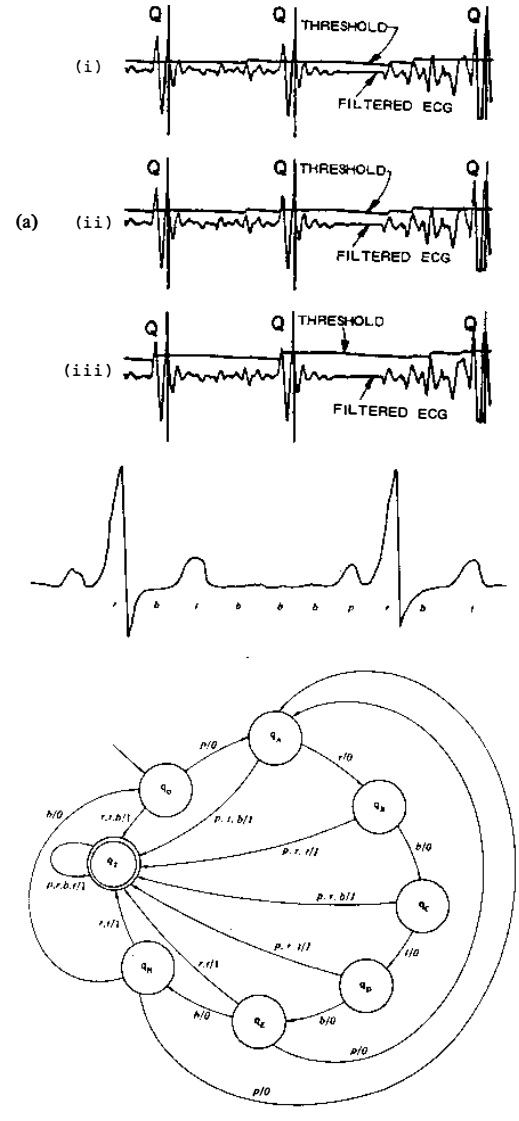

Fig. 3. (a) Filtered ECG signal and various detection threshold schemes to achieve desired FP/FN ratios: (i) FP/PN = 1, (ii) FP/FN = 2, and (iii) FP/FN = 0.5 (reproduced with permission from [15]). (b) Syntacic analysis of ECG waveform, where various features are given alphabetical symbols. A state-transition diagram signals transition from one symbol to next. "0" indicates normal and "1" indicates abnormal transition (reproduced with permission from [16]).

Arrhythmia Analysis

Reliable detection of the *QRS* complex facilitates arrhythmia analysis. Quite elaborate arrhythmia interpretation programs have been developed for the computer analysis of Holter tapes [18], [19]. Cox *et al.* [20], Oliver *et al.* [21], and Thomas *et al.* [22] summarize many of the modern arrhythmia analysis techniques.

The simplest arrhythmia detectors utilize basic decision rules. For example, Fancott and Wong [23] identify a ventricular ectopic beat using the simple rule: either 1) the *QRS* width is greater than 110 ms, or 2) two or more of the following are true: a) the *QRS* width is greater than 90 ms, b) there is a compensatory pause, or c) the slopes of the *RS* segments of the premature beat differ by more than 50 percent from the preceding beat. For the microcomputer-based ambulatory arrhythmia monitor, Abenstein [24] and Mueller [25] also

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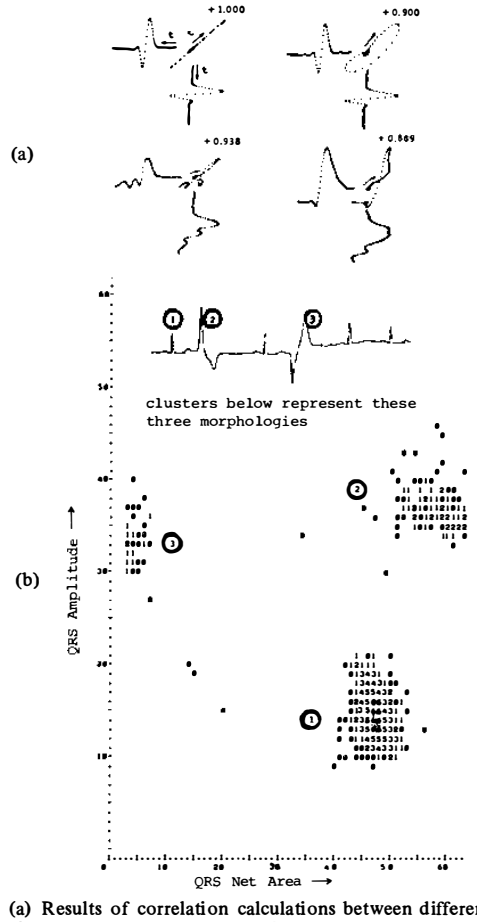

Fig. 4. (a) Results of correlation calculations between different types of ECG patterns. Correlation coefficient varies from 1.0 when the signal is correlated with itself, to lower values when there is a mismatch (reproduced with permission from [20]). (b) An example of feature extraction, where *QRS* amplitude is plotted against net area. Three clusters represent three morphologies (reproduced with permission from [19]).

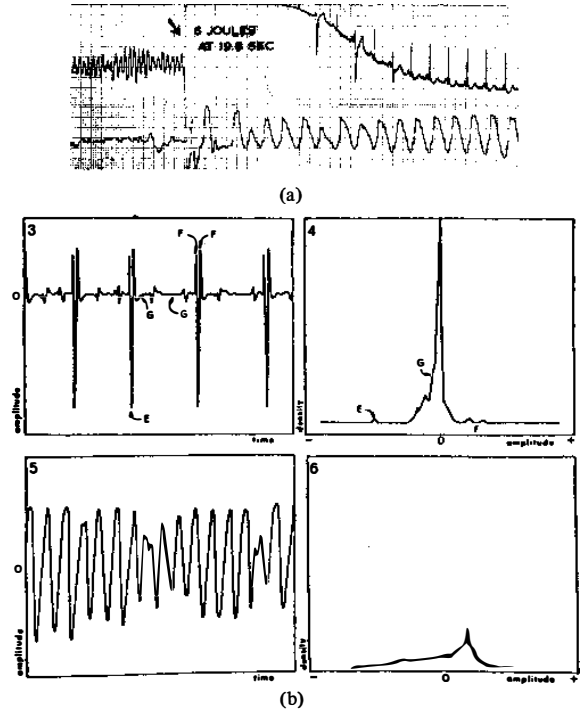

Fig. 5. (a) An example of ventricular fibrillation signal. Also, note that after a shock the normal sinus rhythm is established. The lower trace is that of ventricular pressure. (b) Examples of how the probability density function (traces on the right side) distinguishes between the normal sinus rhythm (top) and the VFIB signal (bottom) (reproduced with permission from [28]).

used such simple rules. With more powerful computer systems, such as those using multiprocessor configurations [26] or minicomputers, more elaborate arrhythmia interpretation algorithms may be employed. Two of the most popular approaches are 1) correlation, and 2) feature extraction. The first technique calculates the cross correlation between the beat under consideration and stored prototypes [Fig. 4(a)] [20]. When the correlation function is reasonably high, the ectopic beat is identified. The feature extraction techniques measure the parameters such as the width, height, and area of each beat and form multidimensional clusters in the feature space [Fig. 4(b)] [19]. The normal and the abnormal rhythms usually form distinct clusters, from which the arrhythmias can be classified. Recently, new techniques have been reported that utilize concepts developed in the field of artificial intelligence. Examples of these are syntactic analysis [16], automata theory [17], and production rule systems [27].

Detection of Ventricular Fibrillation: Detection of ventricular fibrillation (VFIB) is particularly important to the design of automatic defibrillators. The morphology of the VFIB waveform is quite distinct from that of the normal ECG as well as the ECG in other arrhythmias [Fig. 5(a)]. The VFIB recognition technique, developed by Langer *et al.* [28], recognizes that the normal ECG waveform is centered near the baseline most of the time, while the VFIB signal is approximately evenly distributed on either side of the baseline. Consequently, a probability density function is defined that produces histograms of the number of samples around the baseline. As seen from Fig. 5(b), the probability density functions of the normal ECG and the VFIB signal appear to be quite different. Another approach to VFIB recognition looks for the undulating waveform with successive peaks and valleys [29]. Although there are differences between the frequency spectra of the normal ECG and VFIB [30], the interpretation algorithms based on spectral analysis may not be suitable for real-time implementation on implantable or ambulatory arrhythmia detectors.

Performance Evaluation

The automatic arrhythmia detectors must *reliably* detect occurrences of the normal and abnormal *QRS* complexes, as well as correctly interpret arrhythmias. Usually, the performance of the arrhythmia monitors is assessed by expert cardiologists on a beat-by-beat basis. This is an expensive and time-consuming process. In view of this, the American Heart Association has sponsored the development of a database of digitized ECG's on digital tapes that can be used for automatic evaluation of arrhythmia monitors [31]. These include several digital tapes with two channels of Holter ECG data, and an additional channel of beat and rhythm annotations. The data are collected from a number of patients and a large variety of arrhythmia categories are represented [Fig. 6(a)]. A similar database has also been prepared jointly by M.I.T. and Beth Israel Hospital in Boston [32].

The interpretations of the automatic arrhythmia detector can be compared to the annotations on the database and can be cross classified by means of a contingency table. The contingency table summarizes false positives (FP's), false negatives (FN's), true positives (TP's), and true negatives (TN's). From these numbers a variety of performance statistics can be generated [33]. Table II lists these performance statistics and their

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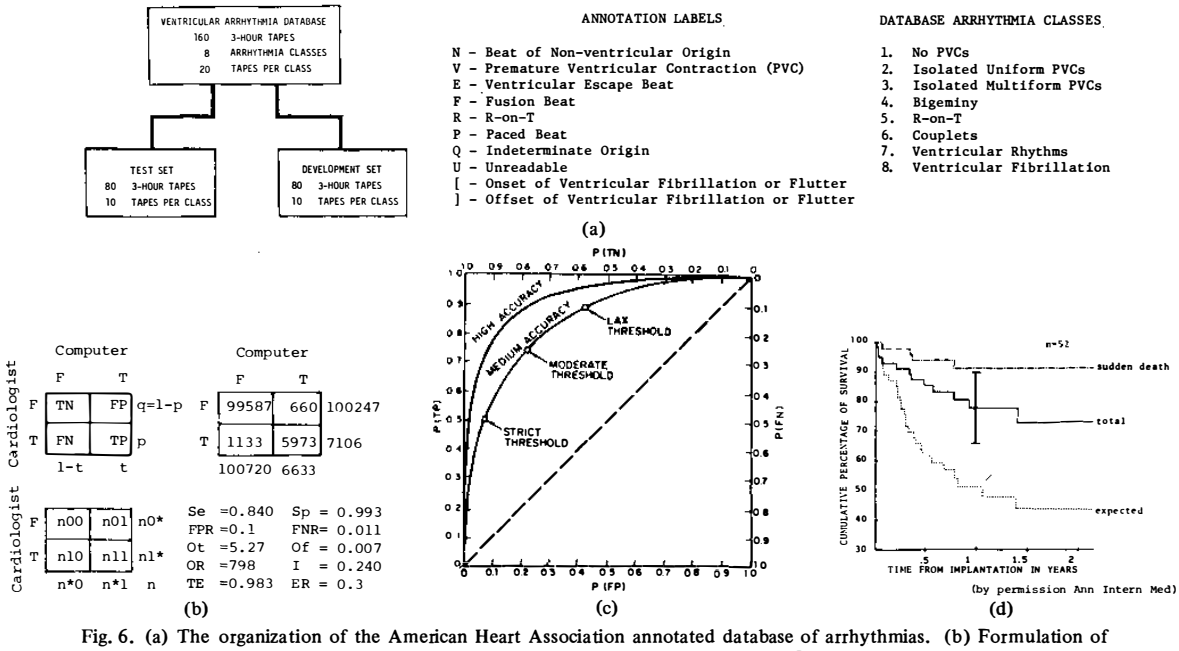

Fig. 6. (a) The organization of the American Heart Association annotated database of arrhythmias. (b) Formulation of the contingency tables (left) and calculations of some performance statistics. (c) Detection curve or receiver operating characteristics used for performance evaluation (adapted from [19]). (d) Survival rates with and without the automatic implantable defibrillator (reproduced with permission from [34]).

TABLE II
SOME PERFORMANCE MEASURES AND FORMULAS TO CALCULATE THEM

SENSITIVITY	FALSE POSITIVE RATE
$Se = \frac{TP}{TP + FN} = \frac{n11}{n1*}$	$FPR = \frac{FP}{FP+TP} = \frac{n01}{n*1} = 1/[1+\frac{pSe}{q(1-Sp)}]$
SPECIFICITY	FALSE NEGATIVE RATE
$Sp = \frac{TN}{TN + FP} = \frac{n00}{n0*}$	$FNR = \frac{FN}{FN+TN} = \frac{n10}{n*0} = 1/[1+\frac{qSp}{p(1-Se)}]$
ODDS OF TRUE EVENT	TEST EFFICIENCY
$Ot = \frac{TP}{FN} = \frac{n11}{n10} = \frac{Se}{1-Se}$	$TE = \frac{n00}{n} + \frac{n11}{n} = pSe + qSp$
ODDS OF FALSE EVENT	ERROR RATIO
$Of = \frac{FP}{TN} = \frac{n01}{n00} = \frac{1-Sp}{Sp}$	$ER = \frac{n01 + n10}{n11} = \frac{1 - TE}{pSe}$
ODDS RATIO	INFORMATION CONTENT
$OR = \frac{Ot}{Of} = \frac{Se\ Sp}{(1-Se)(1-Sp)}$	$I = pI(Sp) + qI(Se) - I(t)$ where $t = n*1/n$ and $I(x)=1+\log(x)+\log(1-x)$

derived formulas. Fig. 6(b) also presents the data for one arrhythmia detector and the calculated performance statistics. An alternate method for presenting and analyzing the performance of the arrhythmia detectors is to plot the FP's versus the TN's to produce the so-called detection curves, or receiver operating characteristics [Fig. 6(c)] [15], [19]. Each curve represents a different database, and each point on a curve represents a distinct detection criterion. Ideally, the operating point selected on the detection curve should result in the fewest FP's and FN's. For example, too low a *QRS* detection threshold would result in more FP's, while too high a threshold would result in more FN's [Fig. 3(a)]. The tolerable combination of FP's versus FN's, determined by the detection threshold, could involve subjective factors. For example, too many FP's caused by noisy data may prove to be annoying; therefore, the threshold should be raised. In the event of a life-threatening arrhythmia, too many FN's could prove to be disastrous in which case a lower threshold may be selected (at the cost of more FP's). The automatic implantable defibrillator has also been evaluated to determine if it indeed is more effective in saving lives as compared to conventional treatments. Fig. 6(d) shows the actuarial display of the mortality data, and the estimates of the survival rates with and without the automatic implantable defibrillator [34].

III. Technological Developments

We now present the details of technical design of three ambulatory ECG monitoring instruments: the original Holter monitor, the microcomputer-based ambulatory arrhythmia monitor, and the automatic implantable defibrillator.

The Holter Recorder

Holter recognized the need to monitor patients in their natural ambulatory environments, where their hearts would commonly be stressed. Because this would entail examination of up to 100 000 beats over a period of one day, Holter and his colleagues developed a system that used: 1) a tape recorder to record the ECG continuously for a period of up to 10 h on a magnetic tape medium, and 2) a recorder-analyzer to play back at high speeds the recorded data and analyze them by means of audio-visual presentation [Fig. 7(a)].

The tape recorder (or the "electrocardiocorder" as Holter called it) was a unit measuring 19.5 X 9.8 cm. and weighing 1 kg. The batteries supplied power for 100 h, although the tape continuously recorded data for 10 h only. The block diagram in Fig. 7(b) shows an ECG amplifier, a power amplifier, and an oscillator that fed a modulated signal via a mixer to the tape recording head. Additional circuits included a temperature compensator, motor drive and control circuits, power source, and motor.

The analyzer (or, as Holter called it, the "AVSEP: audio visual superimposed electrocardiogram presentation" unit) played back the recorded ECG at 60 times the recording speed. A superimposed display of several ECG cycles was produced on an oscilloscope screen. Two mechanically displaced heads were used on the playback unit, one to derive the *R*-wave trigger, and the other to derive the pretrigger signal beginning

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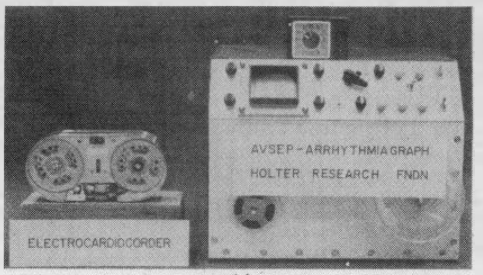
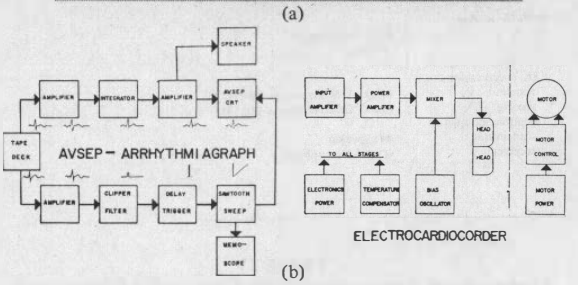


(a)



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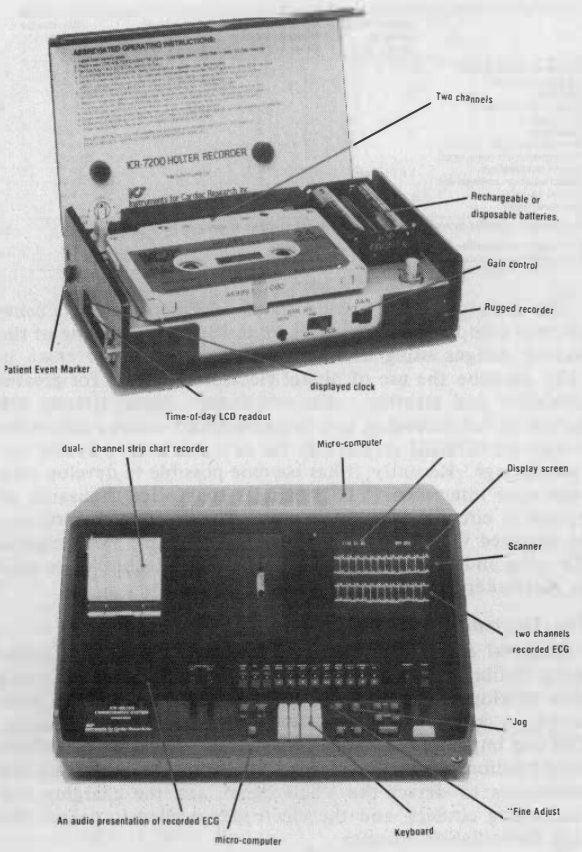
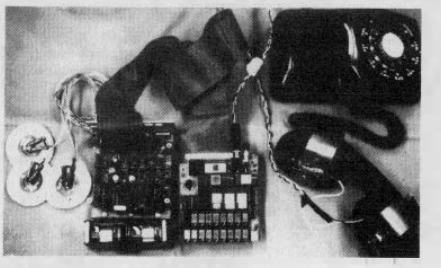


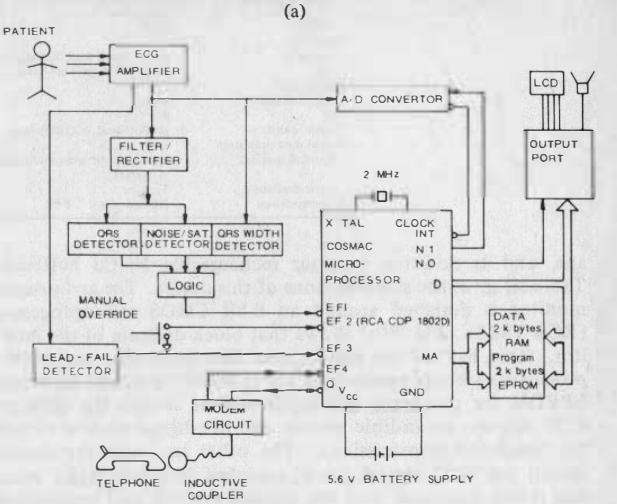
(c)

Fig. 7. (a) Photograph of the original Holter tape recorder (Electrocardiocorder) and playback system (arrhythmiagraph). (b) Block diagram of the two units (reproduced with permission from [1]). (c) Photograph of a modern commercial Holter recorder and playback system (reproduced with permission from ICR, Inc.).

with the P-wave. Guided by the visual display and an audible tone (signaling the occurrence of each beat), the observer could note a significant change in the rhythm. Finally, the analyzer produced a graph of the R–R interval that highlighted



(a)



(b)

Fig. 8. (a) Photograph of the portable arrhythmia monitor prototype, displaying the monitor, electrodes, modem coil, and telephone. (b) Schematic of the arrhythmia monitor (reproduced with permission from [4]).

the pulse intervals and also any rhythm abnormalities such as premature beats.

The modern Holter tape recorders have evolved into sophisticated instruments. The principle improvements are in size (smaller and more compact designs), battery power (longer lasting and smaller sized), recording mechanism (cassette as well as reel-to-reel tape), data recording (two channels, often accompanied by annotations for the time of the day or for some arrhythmic events), length or duration of recording and playback (up to 48 h of recording and up to 360 times real-time playback), sophistication of the playback unit (arrhythmia interpretation capability, and full-disclosure printout), etc. Fig. 7(c) shows a photograph of a modern Holter recording system. Surprisingly, the basic concepts developed by Holter—recording on a magnetic medium, and high-speed playback—have not changed.

The Ambulatory Arrhythmia Monitor

The design of the ambulatory arrhythmia monitor really became possible only after the invention of the microprocessor. Previously, large mainframe computers were used [19]. Microprocessor technology permitted the design of a compact, even portable, device that analyzed the ECG signal in real time. Walters [35] and Schluter [36] developed a microprocessor-based bedside monitor. Our group at the University of Wisconsin first presented the development of a microprocessor-based ambulatory arrhythmia monitor [2]–[4], [24]–[25]. Thakor *et al.* [4] presented the detailed design, implementation, and evaluation. Now, there are commercial arrhythmia monitors available that automatically process ECG's from ambulatory subjects.

Fig. 8(a) shows a picture of the arrhythmia monitor prototype [4]. The entire device fits into a camera case-sized pack-

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TABLE III
SPECIFICATIONS OF THE AMBULATORY ARRHYTHMIA MONITOR PROTOTYPE

General arrhythmia monitor	
Weight	1 kg (excluding batteries)
Size	19 × 14 × 9 cm
Average power consumption	150 mW
Normal operating life (until battery change)	15 days
Power source	lithium or mercury batteries (5·6 V)
Operating temperature	0 to 70 C
Analogue circuits	
ECG amplifier:	
gain	nominal 400. AGC controlled
bandwidth	0·5-40 Hz
input impedance	2 MΩ. common-mode and differential
CMRR	60 dB
Electrodes:	
number	two or three. lead II configuration
type	pregelled. disposable. foam type
QRS detector:	
centre frequency	17 Hz
Q	4
pulse width	proportional to QRS width
Invalid data indication:	
lead-fail detector	impedance between electrodes > 100 kΩ
noise detector	3 s pulse
A D conversion	200 samples s^{-1}. 8-bit
Microprocessor	
CPU clock	2 MHz
Average instruction time	8 μs
Memory:	
Program	2 kbytes
data	2 kbytes
I O:	
visual	liquid crystal
audio	beeper
Serial	300 baud telephonic
Flags	QRS. lead-fail. manual override. serial I O
Interrupts	5 ms
Portable modem	
Mode	FSK. half duplex
Data rate	300 baud
Transmission time	45 s
FSK specifications:	
transmit	mark- 1180 Hz. space- 980 Hz
receive	mark- 2225 Hz. space- 2025 Hz
Telephone coupler:	
transmitter	8Ω speaker
receiver	crystal microphone

age, and is powered by four rechargeable Ni–Cd batteries. Table III gives the specifications of this device. The arrhythmia monitor is designed around an 8-bit CMOS microprocessor (RCA 1802). Fig. 8(b) shows that block diagram of the monitor. One half of the system uses digital circuits: the microprocessor, 4 kbyte memory (2 kbyte RAM for data and 2 kbyte EPROM for program), and input–output circuits (to drive an LCD display, an audible beeper, and the digital modem circuit for telephone transmission). The other half uses the analog circuit for ECG amplification, lead–fail detection, *QRS* pulse and width detection, and the modem receiver and transmitter circuits. The arrhythmia detection algorithm is implemented in software, and principally utilizes the *R–R* interval and *QRS* width information [24]. The arrhythmia monitor acquires and analyzes ECG in real time and detects episodes of PVC's, runs of bigeminy or couplets, bradycardia, tachycardia, asystole, and ventricular fibrillation.

When an arrhythmic episode is detected, 16 s of arrhythmic data are automatically captured and stored in the microprocessor memory. The microprocessor also activates the audible (beeper) and visible (LCD) alarms. In case the patient observes symptoms, for example, those accompanying an attack of angina, he can activate a manual override to store a 16 s ECG strip of that episode. The captured arrhythmic episode may also be transmitted over telephone lines to a remote computer, presumably located in a hospital. Once the telephone link is established, the on-board modem transmits the patient identification, the time of the event, a code for the alarm, and the 16 s long ECG record. These data are received by a remote LSI-11 minicomputer over its modem and are displayed on a graphic terminal for viewing by a cardiologist. The cardiologist may then suggest a possible course of treatment.

The Implantable Arrhythmia Monitors

In a sense, the pacemaker can be considered an arrhythmia detector, because it detects the *QRS* complexes and the conduction defects. Modern pacemakers do indeed have some arrhythmia sensing capabilities. One example is that of pacemakers that detect and convert ventricular tachycardia [37]. Automatic defibrillators detect and convert VFIB [28].

Escher [38] traces the history of pacemaker development and finds its roots in the 18th century. Only in the 20th century—subsequent to the work of Hyman in 1932 with an impulse generator, Zoll's clinical use of an external pacemaker, and the development of an implantable pacemaker by Chardack *et al.*—did an implantable pacemaker as we know it today evolve [38]. Development of the transistor, and subsequently, the integrated circuit (IC) have made implantable and programmable pacemakers possible.

TABLE IV
COMPARISON OF VARIOUS INTEGRATED CIRCUIT (IC) TECHNOLOGIES

	Custom Micro-computer (Single I.C.)	Commercial Microprocessor + Other I.C.'s	Custom Hard-wired I.C. (Non-Microprocessor)	Commercial I.C.
Complexity/"Real Estate"	★★★★ 1	★★	★★★★	★
Development Time	★	★★★★ 2	★★	★★★
Reliability	★★★★ 1	★★★ 2	★★★★	★
System Current Drain	★★★★ 1	★★	★★★★	★★★
Total Size	★★★★ 1	★★ 2	★★★★	★
Availability		★★★★ 2		★★★★
Development Cost		★★★★		★★★
Test System Dev. (time, cost)		★★		★
Ease of Modification	★★★ 1	★★★★ 2	★	★★
Vendor's Design Involvement		★★★ 2		★★★★
Second Sourcing	★	★★★	★	★★★★
Risk (time, cost)	★★	★★★	★★	★★★

Desirability is indicated by number of stars on a scale of 0 to 4 stars, with 4 stars being most desirable.

1 = Custom chip priorities (more complex product)
2 = Commercial microcomputer priorities (less complex product)

The early pacemakers were simple electronic circuits using discrete components. Chardack *et al.* [39] describe one of the earliest designs using transistorized circuits. Keller *et al.* in [38] describe the use of digital electronic circuits for greater reliability and stability. State-of-the-art digital circuits use hybrid circuit packaging, and complementary-metal-oxide-semiconductor (CMOS) technology for low power in a hybrid circuit package. Recently, it has become possible to develop very large-scale integrated (VLSI) circuits that place thousands of transistor circuits on a single chip. Modern pacemakers may be designed with VLSI technology [40]. Table IV compares the costs and the benefits of various modern technologies used in pacemaker designs [41].

The Automatic Implantable Defibrillator

Mirowski *et al.* [42] tested a laboratory model of an automatic defibrillator on dogs in 1970. Over the next ten years they developed and clinically evaluated more modern defibrillators. A commercially available defibrillator (made by Intec, PA) was implanted in man in 1981 [5]. The most important considerations in the development of the defibrillator were the techniques to detect the VFIB signal, and the charging and discharging circuits, and the electrodes needed to deliver the high defibrillation energies.

The first prototype relied on a pressure transducer for sensing the pulsatile right ventricular pressure. The pressure transducer was integrated into a catheter. Subsequently, as it was found to be fragile, the pressure transducer was replaced by a contraction-sensing element that used a conductive elastomer [42]. The electrical activity was monitored simultaneously. The absence of both the *R*-wave and the contraction signal triggered the defibrillator discharge. For the later models, Langer *et al.* [28] developed a more advanced method (described earlier) that only relied on the recognition of the VFIB electrical signal.

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(a)

(b)

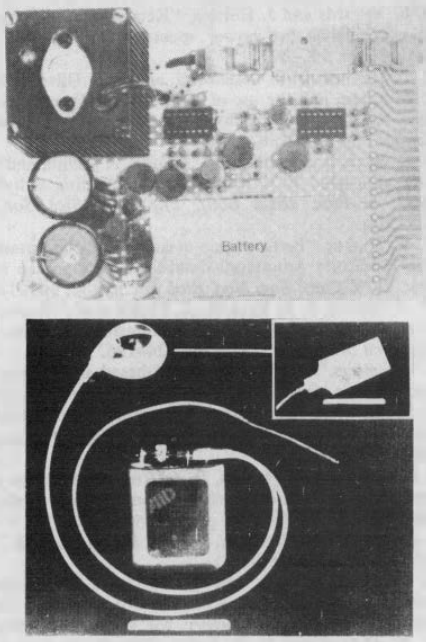

Fig. 9. Photographs of two generations of automatic defibrillators. (a) An early prototype, and (b) a recent commercial model (reproduced with permission from [42], [44]).

The defibrillation discharge itself was delivered by an electrode lead pair comprised of a catheter located in the right ventricular apex and a subcutaneous plate. A later model used a catheter with the electrode pair located so that the distal end was wedged in the right ventricular apex and the proximal end located in the caval system. Work is going on to determine the optimal placement of the defibrillator electrodes [43]. In a recent version of the defibrillator [44], one electrode is a catheter located in the superior vena cava near the right atrial junction, and the other electrode is a cup or a patch placed extrapericardially over the apex of the heart. The electrodes are made from titanium and silicon rubber.

Fig. 9(a) shows the prototype used by Mirowski *et al.* in the 1970's [42], and Fig. 9(b) shows the commercially available automatic implantable defibrillator currently being implanted [34]. It is encased in titanium and hermetically sealed with a laser weld; it weighs 250 g and occupies 145 cm^3 volume. The device is powered by lithium batteries and has an estimated life of 3 years or a capability of delivering 100 shocks. Further developments planned for this device are: the ability to deliver programmed and variable shock levels, different electrode configurations, battery designs with greater discharge capacity, and the incorporation of *QRS* detection and pacemaker functions.

IV. Discussion

The Holter recorder now finds a variety of clinical applications: long-term monitoring of prospective heart patients, clinical studies of antiarrhythmic drugs, stress testing, pacemaker function evaluation, and monitoring athletes or people engaged in strenuous exercises [45], [46]. Yarnall [47] summarizes the current status and the anticipated future developments in Holter monitoring. Indeed, it is a tribute to Holter that his invention has survived, substantially unchanged, for more than 20 years.

One limitation of Holter recorders is that up to 24 h of ECG data are stored on tape producing an overload of data collection and analysis. Typically, the recordings are of normal ECG's with limited clinical significance. In the rapid & weak processes, few events of significance such as occasional ectopic beats or arrhythmic episodes may easily be overlooked. The other major limitation is that the arrhythmic episodes can only be identified retrospectively, usually 24 or more hours later when the tapes are scanned. This is especially futile if an arrhythmic event results in irreversible damage to the heart or even sudden death. The microcomputer-based ambulatory arrhythmia monitor has the potential to alleviate these problems.

This arrhythmia monitoring concept differs from the Holter monitor in that the data analysis is carried out in real time, thus bypassing the need for expensive and time-consuming review. More importantly, the monitor identifies arrhythmias when they occur, hence, immediate treatment can be made available. At the same time, this concept is limited in several ways. Only short episodes are registered by the arrhythmia monitor and may not contain enough information for accurate interpretation by the cardiologist. Further, some cardiologists prefer to review the full record, which the arrhythmia monitor does not preserve. The arrhythmia monitor is prone to false detection as well: false positives could cause unnecessary annoyance or concern; false negatives could mean that treatment would not be available to the patient. Certainly the monitor does not directly attempt to alleviate the arrhythmic episode. This is especially crucial in the case of VFIB. The patient cannot be expected to transmit the ECG data over telephone, and there is very little time within which the patient must be defibrillated. Arrhythmia sensing pacemakers and defibrillators have the potential to go beyond this limitation.

The modern implantable pacemakers have evolved from the early fixed-rate pacemaker designs into sophisticated arrhythmia detectors. The demand pacemakers have always required the capability to detect the atrial and the ventricular excitation signals (the *P*- and the *QRS*-waves). From these signals they derive the rhythm information and appropriately pace the chambers of the heart. Modern pacemakers go farther. For example, the tachycardia converting pacemakers attempt to terminate ventricular tachycardia by rapidly pacing the heart. Even more specific is the action of the automatic implantable defibrillator, which specifically detects VFIB. Through a high energy discharge that converts VFIB into normal sinus rhythm, it can potentially alleviate this life-threatening situation. The latter two devices are still undergoing clinical evaluation; therefore, they presently find selective use. Concern often arises over cost, reliability, and proper clinical use; for example, the effect of a false positive discharge of the defibrillator is not clearly known. Implantation of the pacemakers and defibrillators require surgery, and associated high costs and risks. Therefore, in some cases implantation may not be the best solution. Antiarrhythmic drug treatment accompanied by conventional Holter monitoring or treadmill testing may be preferable.

V. Conclusions

Ambulatory arrhythmia detection technology has made considerable progress since its invention by Holter. The Holter recorder passively records long-term ECG data on magnetic tape for later analysis. The modern microprocessor-based arrhythmia detector analyzes ECG's in real time, and if an arrhythmic episode is identified, captures a record of the event and produces an alarm. Even more significant is the development of the antiarrhythmic pacemaker and the implantable defibrillator with the capability of sensing arrhythmias, and converting them with programmed electrical discharge.

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