Innovation Workshop

Ambulatory Cardiac Monitoring
Problem Statement

Due to the infrequency of some cardiac events and other causes of syncope, it may be difficult to diagnose certain pathologies within the time a patient is in the clinic. Ambulatory cardiac monitoring presents a useful tool to assist the physician for medium and long term monitoring. There are several options to choose from in wearable and implantable ECG recorders using 1-12 leads, each with their own advantages and drawbacks. Because of its low cost and non-invasive nature, a typical first approach would be to use a 24-hr wearable Holter monitor that requires the patient to keep a diary of events and symptoms. However, this may not always work due to the infrequency of the event or due to patient non-compliance (i.e. removing electrodes or not taking notes). If continued monitoring is indicated, the next steps will depend on several factors including the symptoms, suspected causes, patient comfort with minimally invasive procedure and available resources. After prolonged monitoring, many hours of recording has to be analyzed. While automated algorithms are helpful, a trained technician must double check results and compares them with patient logs.

Ultimately the Holter monitor and other recorders of cardiac events can be a burden to the patient if they are large and cumbersome. The ambulatory monitoring can be useful, however due to the burden it places on the patient and hospital, there is still room for improvement to aid in patient compliance, better patient outcomes, and economic use of hospital resources.

Philips DigiTrak XT

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## Holter monitor

<table>
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<td><img src="image" alt="Holter monitor" /></td>
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<td>Inventor</td>
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In medicine, a **Holting monitor** (often simply "Holter" or occasionally **ambulatory electrocardiography device**) is a portable device for continuously monitoring various electrical activity of the cardiovascular system for at least 24 hours (often for two weeks at a time).

The Holter's most common use is for monitoring heart activity (electrocardiography or ECG), but it can also be used for monitoring brain activity (electroencephalography or EEG) or arterial pressure. Its extended recording period is sometimes useful for observing occasional cardiac arrhythmias or epileptic events which would be difficult to identify in a shorter period of time. For patients having more transient symptoms, a cardiac event monitor which can be worn for a month or more can be used.

The Holter monitor is named after physicist Norman J. Holter, who invented telemetric cardiac monitoring in 1949. Clinical use started in the early 1960s.

When used for the heart, (much like standard electrocardiography) the Holter monitor records electrical signals from the heart via a series of electrodes attached to the chest. Electrodes are placed over bones to minimize artifacts from muscular activity. The number and position of electrodes varies by model, but most Holter monitors employ between three and eight. These electrodes are connected to a small piece of equipment that is attached to the patient's belt or hung around the neck, and is responsible for keeping a log of the heart's electrical activity throughout the recording period.

### Data Storage

Older devices used reel to reel tapes or a standard C90 or C120 audio cassette and ran at a 1.7mm or 2mm/second speed to record the data. Once a recording was made, it could be played back and analysed at 60x speed so 24 hours of recording could be analysed in 24 minutes. More modern units record EDF-file onto digital flash memory devices. The data are uploaded into a computer which then automatically analyzes the input, counting ECG complexes, calculating summary statistics such as average heart rate, minimum and maximum heart rate, and finding candidate areas in the recording worthy of further study by the technician.
Components

Each Holter system consists of two basic parts – the hardware (called monitor or recorder) for recording the signal and software for review and analysis of the record. Advanced Holter recorders are able to display the signal, which is very useful for checking the signal quality. Very often there is also a “patient button” located on the front site allowing the patient to press it in specific cases such as sickness, going to bed, taking pills…. A special mark will be then placed into the record so that the doctors or technicians can quickly pinpoint these areas when analyzing the signal.

Recorder

Size of recorder differs depending on manufacturer of the device. The average dimensions of today’s Holter monitors are about 110x70x30 mm but some are only 61x46x20 mm and weight 99 g. Most of the devices operate with two AA batteries. In case the batteries are depleted, some Holters allow their replacement even during monitoring.

Most of the Holters monitor the ECG just in two or three channels. Depending on the model (manufacturer), different count of leads and lead systems are used. Today’s trend is to minimize such number to ensure the patient’s comfort during recording. Although 2/3 channel recording has been used for a long time in the Holter monitoring history, recently 12 channel Holters have appeared. These systems use the classic Mason-Likar lead system, thus producing the signal in the same representation as during the common rest ECG and/or stress test measurement. These Holters then allow to substitute stress test examination in cases the stress test is not possible for the current patient. They are also suitable when analyzing patients after myocardial infarction. Recordings from these 12-lead monitors are of a significantly lower resolution than those from a standard 12-lead ECG and in some cases have been shown to provide misleading ST segment representation, even though some device allow to set the sampling frequency up to 1000 Hz for special purposes exams like the late potential.

Another interesting innovation is the presence of a triaxial movement sensor, which record the patient physical activity, and later show in the software three different status: sleep, stand-up, walking. This helps the cardiologist to better analyze the recorded events belong to the patient activity and diary. Holter monitoring is a very useful part of an ECG.

Some modern devices also have the ability to record a vocal patient diary entry that can be later listened to by the doctor.

Analyzing software

When the recording of ECG signal is finished (usually after 24 or 48 hours), it is up to the physician to perform the signal analysis. Since it would be extremely time demanding to browse through such a long signal, there is an integrated automatic analysis process in each Holter software which automatically determines different sorts of heart beats, rhythms, etc. However the success of the automatic analysis is very closely associated with the signal quality. The quality itself mainly depends on the attachment of the electrodes to the patient body. If these are not properly attached, the electromagnetic disturbance surrounding us will influence the ECG signal resulting thus in a
very noisy record. If the patient moves rapidly, the distortion will be even bigger. Such record is then very difficult to process. Besides the attachment and quality of electrodes, there are other factors affecting the signal quality, such as muscle tremors, sampling rate and resolution of the digitized signal (high quality devices offer higher sampling frequency).

The automatic analysis commonly provides the physician with information about heart beat morphology, beat interval measurement, heart rate variability, rhythm overview and patient diary (moments when the patient pressed the patient button). Advanced systems also perform spectral analysis, ischemic burden evaluation, graph of patient’s activity or PQ segment analysis. Another requirement is the ability of pacemaker detection and analysis. Such ability is useful when one wants to check the correct pacemaker function.

**Procedure**

Although some patients may feel uncomfortable about a Holter examination, there is nothing to worry about. No hazards are involved, and it should have little effect on one's normal daily life.

The recording device can be worn in a case on a belt or on a strap across the chest. The device may be visible under light clothing, and those wearing a Holter monitor may wish to avoid shirts with a low neckline.

Persons being monitored should not limit normal daily activities, since its purpose is to record how a heart works under various actual conditions over an extended period. It is an electrical device, however, and should be kept dry; showering or swimming should probably be avoided. Monitors can be removed for a few minutes without invalidating collected data, but proper reattachment is critical to avoid degradation of its signals. Beyond changing batteries, one should leave its handling to trained personnel.

**Gallery**

A Holter monitor can be worn for many days without causing significant discomfort.

Canine Holter Monitor with DogLeggs Vest

A Holter monitor with a US quarter dollar coin to show scale

Holter monitor can be worn with bra on woman, with no discomfort.

**References**


**External links**

Ambulatory Arrhythmia Monitoring
Choosing the Right Device

Peter Zimetbaum, MD; Alena Goldman, MD

Remote cardiac telemetry was developed to allow home ECG monitoring of patients with suspected cardiac arrhythmias. It was first introduced by the American biophysicist Norman J. Holter (1914–1983) in the 1940s. The original Holter monitor was a 75-lb backpack with a reel-to-reel FM tape recorder, analog patient interface electronics, and large batteries. It could record a single ECG lead for several hours and the ECG signal into an audio signal. The signal is converted back to ECG data at the monitoring station.

**Continuous Monitors (Holters)**

The current state of Holter technology uses smaller recorders (size, 70×95×20 mm; weight, ~190 g) with flashcard technology to record and store data from 2 to 3 ECG leads attached to the patient’s chest and collected continuously over 24 to 48 hours. Once the monitor is returned, the data are analyzed in digital format. To increase the correlation between detected heart rhythm abnormalities and symptoms, patients are asked to keep a diary of their symptoms. The recorders use patient-activated event markers (annotations) specified for the time of day. The major advantages of Holter monitoring are the ability to continuously record ECG data and the lack of need for patient participation in the transmission of data. The short duration of monitoring can be inadequate if symptoms are infrequent. Newer Holter monitors are now available with up to 2 weeks of recording capability. Limitations of Holter monitoring include frequent non-compliance with keeping a log of symptoms and using event markers, which significantly limits the diagnostic value of these devices. The absence of real-time data analysis can also be an important clinical limitation of these devices.

**Intermittent External Patient- or Event-Activated Recorders**

Intermittent patient- or event-activated recorders make up the largest category of devices. They are also referred to as event monitors. Continuous looping monitors are attached to the patient through chest electrodes or a wrist band and record (save) data only when activated by the patient. Some of these devices have automatic triggers that recognize slow, fast, or irregular heart rates. Once activated, data are stored for a programmable fixed amount of time before the activation (looping memory) and a period of time after the activation. These devices are also referred to as external loop recorders (ELRs). Another less sophisticated form of event monitor is the postevent recorder. These devices are not worn continuously (nonlooping) but are worn intermittently and can be worn externally or implanted subcutaneously. Aside from the Holter monitor described above, most of the new devices transmit recordings to a centralized monitoring station via telephone by converting an ECG signal into an audio signal. The signal is converted back to ECG data at the monitoring station.

**Indications for Monitoring**

Traditionally, ambulatory monitoring has been used to determine the cause of palpitations and syncope and, to a lesser degree, to identify ventricular ectopy or nonsustained ventricular tachycardia in patients at potential risk for sudden cardiac death. Atrial fibrillation (AF) has become an increasingly important indication for ambulatory monitoring, predominantly as a tool to monitor the efficacy and safety of pharmacological and nonpharmacological therapies. It is also used to identify asymptomatic AF as a potential source of cryptogenic stroke.

**Ambulatory Monitoring Technologies for the Assessment of Cardiac Rhythm Abnormalities**

Several devices are currently available to remotely assess cardiac rhythm abnormalities in ambulatory patients (Table 1). Devices can record cardiac rhythm continuously or intermittently and can be worn externally or implanted subcutaneously. From the Beth Israel Deaconess Medical Center, Boston, Mass.

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Table 1. Characteristics of Ambulatory Cardiac Monitoring Devices

<table>
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<tr>
<th>Device Type</th>
<th>Usual Duration of Monitoring</th>
<th>Allows Complete Monitoring and Storage of Data (24 h/d)</th>
<th>Remote Monitoring Capability</th>
<th>Physician Cost, $</th>
<th>Technical Cost, $</th>
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<td></td>
<td>Yes</td>
<td>No</td>
<td>31</td>
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<td>Short term</td>
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<td>Yes</td>
<td>No</td>
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<td>Long term</td>
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<td>Yes</td>
<td>No</td>
<td>31</td>
<td>TBD</td>
</tr>
<tr>
<td>Event recorder</td>
<td></td>
<td>No</td>
<td>Yes</td>
<td>30</td>
<td>275</td>
</tr>
<tr>
<td>Continuous loop</td>
<td>Up to 1 mo</td>
<td>No</td>
<td>Yes</td>
<td>30</td>
<td>231</td>
</tr>
<tr>
<td>Postevent (nonlooping)</td>
<td>Up to 1 mo</td>
<td>No</td>
<td>Yes</td>
<td>30</td>
<td>750</td>
</tr>
<tr>
<td>Real-time continuous event recorder</td>
<td>Up to 1 mo</td>
<td>Yes</td>
<td>Yes</td>
<td>30</td>
<td>750</td>
</tr>
<tr>
<td>Insertable loop recorder</td>
<td>Up to 2 y</td>
<td>No</td>
<td>Yes</td>
<td>374</td>
<td>4000</td>
</tr>
</tbody>
</table>

The key features of these devices include continuous real-time ECG monitoring for an extended period of time (up to 30 days) without the requirement of patient activation and transmission of data. The data are transmitted and analyzed immediately by technicians who can contact the patient and/or the physician if an urgent intervention is needed. In a randomized controlled trial with 266 patients comparing real-time telemetry devices with ELRs in patients with a high clinical suspicion for a malignant arrhythmia, history of syncope, presyncope, or severe infrequent palpitations and a nondiagnostic 24-hour Holter, 41.4% of patients in the real-time telemetry group had detection of a clinically significant arrhythmia compared with 14.6% in ELR group.11

Implantable Loop Recorders
Implantable loop recorders (ILRs) are subcutaneously implanted arrhythmia-monitoring devices. These leadless devices record a single-lead ECG signal through 2 electrodes developed to combine the benefits and to overcome the limitations of Holter monitors and standard ELRs. They are worn continuously and are similar in size to the standard ELR. They automatically record and transmit arrhythmic event data from ambulatory patients to an attended monitoring station. Data can also be recorded through patient-triggered activation. This technology is referred to as mobile or real-time cardiac telemetry systems (MCOT). With these devices, cardiac activity is continuously monitored by 3 chest electrodes (some systems use a chest belt with built-in nonadhesive electrodes9,10) that are attached to a pager-sized sensor. The sensor transmits collected data to a portable monitor that has a built-in cell phone and needs to be in proximity to the patient to receive signals. The monitor is equipped with software that analyzes the rhythm data continuously and automatically. If an arrhythmia is detected by an arrhythmia algorithm, the monitor automatically transmits recorded data transtelephonically (by wireless network or land phone line) to a central monitoring station for subsequent analysis. Any patient-activated data also are transmitted. Trained staff members at a monitoring station analyze live incoming patient data and contact the referring physician and patient according to predetermined criteria.10 A built-in cellular phone allows transmission of data from the monitor to the central station when the patient is away from home.

Real-Time Continuous Cardiac Monitoring Systems
Real-time continuous attended cardiac monitoring systems represent the newest form of external ambulatory monitors instead of being applied directly to the chest area once a symptom develops. Therefore, they have no memory to allow recording of the rhythm before the device is activated. Event monitors are generally used for 14- to 30-day monitoring periods. The data are transmitted transtelephonically to a central monitoring station and then uploaded to a personal computer for analysis.

The major advantage of these devices compared with a traditional Holter monitor is that they are small, allow ECG monitoring for longer periods of time, and can provide nearly real-time data analysis when the patient transmits a recording in proximity to the symptomatic event. The limitations of these devices include the following: The patient has to be awake and coherent enough to activate the device unless automatic activation/trigger for cardiac pauses, tachyarrhythmias, and bradyarrhythmias are built into the monitor; in the case of continuously worn devices, a significant percentage of patients are noncompliant with continuous application of the device (mostly because lead irritation/poor skin contact during exercise); and both continuous and postevent recorders require a degree of technological sophistication to transmit the stored data transtelephonically to the central monitoring station. The technical equivalent of this skill is the ability to use an automatic bank teller machine.8 Gula et al8 showed that 84.5% of patients were able to perform a test transmission, but a successful recording and diagnostic transmission was performed by only 58.9% of patients. Patients living alone were much less likely to use an ELR effectively, and factors such as worry about/fear of symptoms and their impact on quality of life were associated with successful use of the device.8 A new form of this device has recently become available that allows automatic transmission of triggered events over the cellular network (no requirement for the patient to transmit the data).

For devices that are not worn continuously (postevent recorders such as wristbands or handheld devices that need to be applied to the chest at the time of symptoms), the initiation of the arrhythmia that may provide a clue to the arrhythmic mechanism is missed, and short arrhythmias that terminate before the device is applied will not be recorded.
within the device. The device can be triggered automatically or by patient activation via placement of an activator over the device. The newest generations of these devices allow remote transmission of data and have a battery life in excess of 24 months.

**Remote Monitoring of Pacemakers and Implantable Cardioverter-Defibrillators**

Pacemakers and implantable cardioverter-defibrillators (ICDs) can also be used as continuous monitoring devices (Table 2). Most dual-chamber pacemakers and ICDs have built-in algorithms to detect supraventricular arrhythmias. Once a supraventricular tachycardia is detected, there is a switch in mode (“mode switch”) from DDD to VVI to avoid rapid tracking of the supraventricular tachycardia. The mode switch continues until the atrial arrhythmia terminates, at which time the device switches back to the dual-chamber tracking mode. Through continuous rhythm monitoring, modern devices provide information about arrhythmia burden with a detailed arrhythmia log that contains the number, duration, and dates of arrhythmia episodes, as well as the maximal atrial and ventricular rates associated with these episodes. Many devices provide histograms with arrhythmia trends, which have the number of hours a day spent in atrial arrhythmia for the prior 6 months. It should be noted that there is no clearly established standard for the minimum atrial rate or duration that constitutes an episode of AF. When programmed appropriately, implanted devices can identify AF with >95% sensitivity and specificity.12

Dual-chamber ICDs have built-in arrhythmia discriminator algorithms to avoid the delivery of inappropriate ICD therapies for supraventricular tachycardia that could otherwise be mistaken for ventricular tachycardia on the basis of the ventricular rate alone. In addition, ICDs store detailed information about ventricular tachyarrhythmia episodes, including time of occurrence, ventricular rate and duration, stored electrograms, and whether device therapy such as antitachycardia pacing or a shock was needed to abort an episode. The electrogram records a few seconds before and after an episode. This allows detailed evaluation of each device therapy to determine its appropriateness and success.

The conventional method of obtaining the stored record of arrhythmia occurrence and treatment requires device interrogation in the physician’s office. Newer technology allows Internet-based remote monitoring of devices to evaluate symptomatic and asymptomatic arrhythmias and delivered therapies.

**How Should These Technologies Be Used?**

With all the available technology, it can be difficult to choose the right device for a particular indication. The newest continuous telemetry devices provide the benefit of real-time, comprehensive data without requiring the patient to participate in the process of data transmission. Compared with Holters, these devices allow immediate transmission of information; compared with looping event recorders, they gather more information and allow remote data transfer while overcoming the technical challenges of data transmission. This large amount of real-time data affords a higher diagnostic yield than standard devices but places a potential burden on the clinician who must be available to review large amounts of information (eg, daily) at any time of the day or night. In addition, standard monitoring devices (including long-term Holters) and loop recorders are inexpensive compared with the newer generation of real-time telemetry devices (Table 1). Insertable loop recorders, which are significantly more expensive than other monitoring devices, are generally reserved for patients with infrequent symptoms.

The choice of a monitoring modality depends on the presenting symptom, symptom frequency, and degree of suspicion of a life-threatening arrhythmia (the Figure). A number of considerations are useful to guide the selection of these devices.

**Is 48 Hours a Sufficient Period of Monitoring?**

The optimal duration of monitoring largely depends on symptom frequency. In the evaluation of palpitations, patients who experience daily symptoms can be evaluated with a Holter monitor. More often, palpitations are sporadic and require slightly longer monitoring. In a study in which patients with palpitations were prescribed an event monitor, the highest diagnostic yield was within the first week, when 80% of patients transmitted at least 1 rhythm strip corresponding to their symptoms. During the next 3 weeks of a standard 1-month monitoring period, only an additional 3.9% of patients received a diagnosis, and no patients received a diagnosis after week 2.13 In studies directly comparing a Holter with 48-hour monitoring and a longer evaluation with a loop recorder, the diagnostic yield of a loop recorder was up to 83% compared with a diagnostic yield of ∼39% for Holter.
monitoring for patients with palpitations\(^3,13–15\) (Table 3). ILRs have been compared with “standard conventional therapy” (24-hour Holter, a 4-week period of an evaluation with a loop recorder, and an electrophysiology study) in patients presenting with infrequent but recurrent unexplained palpitations. In 1 study of patients with infrequent palpitations (\(\leq 1\) episode per month lasting \(\geq 1\) minute), in the absence of severe heart disease, ILRs provided a diagnostic yield of 73% compared with 21% in the group evaluated with standard conventional therapy.\(^16\)

Syncope, in contrast, typically requires a significantly longer monitoring period, and the diagnostic yield of ambulatory monitors of any sort is extremely limited\(^17\) (the Figure and Table 3). The value of arrhythmia monitoring for syncope is both to identify an arrhythmia as a cause for syncope and to document a syncopal event without a corresponding arrhythmia, thus suggesting a nonarrhythmic cause. In 1 study of ambulatory Holter monitoring, symptoms correlated with a documented arrhythmia in 4% of patients and occurred without an arrhythmia on a monitor in 17%\(^{18}\). Increasing the duration of monitoring from 24 to 72 hours does not appear to increase the diagnostic yield for syncope.\(^{18}\)

ELRs have been directly compared with Holter monitors for the diagnosis of syncope or presyncope in several small trials (Table 3). In 1 trial, the overall probability of obtaining a symptom-rhythm correlation was 56% (44 of 78) for loop recorders worn for 1 month versus 22% (12 of 55) for 48-hour Holter monitors.\(^{19}\) In another study of ELRs, the median time for recording a symptom-rhythm correlation was 16 days (mean, 17±13 days) for patients assigned a loop recorder as their first diagnostic strategy. Symptom-rhythm correlation was obtained in 87% of patients by 1 month of monitoring.\(^{18}\) In our experience, identifying a compelling diagnosis for syncope in a 1-month monitoring period is rare. ILRs, which allow a prolonged monitoring period, have been demonstrated to improve the diagnostic yield for syncope, up to 85% in some studies.\(^{20,21}\) One study using ILRs for syncope demonstrated a 75% rate of meaningful change in manage-
ment based on the findings of the device over a monitoring period of 40±10 months. In addition, the use of ILRs in patients with infrequent syncope has been associated with a reduction in recurrent syncopal events and has been shown to be more cost-effective than other conventional approaches.

Circumstances in which a 48-hour monitoring period is preferred include the assessment of rate control in patients with AF and the identification of chronotropic insufficiency in patients with suspected sinus node dysfunction. Ventricular ectopy in patients in whom these arrhythmias may indicate an increased risk for sudden death or left ventricular dysfunction (eg, hypertrophic or dilated cardiomyopathy, post–myocardial infarction patients with left ventricular dysfunction, surgically repaired complex congenital heart diseases with known long-term arrhythmic risk, long-QT syndrome, congenital complete atrioventricular block) also can be identified or quantified by a 48-hour monitoring period, but a prolonged Holter duration may be reasonable for this indication. At present, there are no clear recommendations for the preferred monitor type or duration for the identification of ventricular ectopy in high-risk cohorts.

Is It Necessary to Detect Asymptomatic Arrhythmias?

In the vast majority of circumstances, ambulatory monitors are used to identify a direct correlation between symptoms and the presence or absence of an arrhythmia. As noted above, there are some circumstances in which the identification of asymptomatic arrhythmias such as the frequency and morphology of symptomatic and asymptomatic ventricular premature depolarizations can be of interest. Prolonged asymptomatic pauses can be a clue to the cause of syncope, but caution must be used in the interpretation of the signifi-
cance of these rhythms. For instance, pauses while sleeping are often related to heightened vagal tone and do not constitute an indication for a pacemaker. There are no available data to suggest whether a short (48 hour) monitoring period or a longer monitoring period afforded by a continuous telemetry device or a long-term Holter is advantageous in these cases.

The identification of AF is one of the commonest indications for monitoring in which the documentation of asymptomatic rhythms is desired (the Figure). Clinicians routinely monitor patients on antiarrhythmic drugs or after catheter or surgical AF procedures for arrhythmia recurrence.4,27,28 These recurrences are often asymptomatic, even in previously symptomatic patients, and may not be detected unless an aggressive monitoring strategy is undertaken.4,27,28 In addition, patients with cryptogenic stroke often undergo rhythm monitoring to identify asymptomatic AF as a potential cause.6

AF recurrence in a given individual.31 Specifically, with the availability of short-acting anticoagulants that do not require loading and monitoring, it is conceivable that some patients can use implanted devices to allow the initiation and discontinuation of anticoagulation, depending on the frequency and duration of AF recurrence.

Is It Critical to Have Real-Time Access to the Transmitted Rhythms?

There is an intrinsic appeal to real-time access to potentially serious arrhythmias. This is particularly true for patients who are being monitored for syncope or while starting an antiarhythmic drug with a potential risk of proarrhythmia. In these instances, rapid access to data could result in clinically significant management decisions, and devices with real-time data access are preferred. Conversely, patients being monitored for other indications such as rate control in AF or arrhythmia recurrence after AF ablation may not necessarily require a real-time device and can be monitored with a long-term Holter. Along with continuous availability of data comes the physician’s responsibility to be available to receive and act on the information. This can present a burden and theoretically a potential liability for the treating physician. In practice, the monitoring companies have standard rules for recommending that the patient seek emergency treatment and allow physicians to tailor the criteria for which they wish to be notified for non–life-threatening arrhythmias.

Obstacles to Compliance With Ambulatory Monitoring Devices

Common areas of noncompliance with ambulatory monitoring include the unwillingness to wear a device continuously, intolerance of the electrodes because of rash, failure to activate a monitor in association with symptoms, and inability to transtelphoneclonically download the information. In 1 study, only 53% of patients wore the device and provided recordings 5 days a month during the entire 6-month monitoring period.4 Failure to activate a device in association with symptoms is a significant problem with monitoring with Holter and standard event recorders without automatic triggers.13 In a study mentioned earlier using loop recorders to diagnose syncope, despite patient education and test transmissions, 23% of patients who had recurrence of their syncopal symptoms failed to activate their loop recorder properly.18

Cost and Technical Considerations With Device Selection

A important consideration in our selection of devices is cost. At present, Holter monitors of any duration, postevent recorders, and continuous loop event recorders are relatively inexpensive (Table 1). Real-time continuous cardiac monitors require a greater degree of technical support than standard devices, and the current cost of these devices is approximately twice that of standard ambulatory monitoring devices. Finally, ILRs, which should be reserved for patients with very infrequent events, cost approximately $4000. When used in selected patient populations with infrequent syncope, monitoring with ILRs has been shown to be more cost-effective than conventional methods (ELR, electrophysiological study, and tilt) for the diagnosis of unexplained syncope.32 Remote monitoring of ICDs offers the potential advantage of reduced office visits with a possibility of cost savings approaching $3000 per patient over the lifetime of the device.33,34 Ambulatory monitoring of any type is subject to technical limitations. New devices that use cellular data transmission are subject to the limitation of nonuniform cellular coverage. Signal artifact or dropout is common and can be related to skin preparation at the time of electrode placement for externally worn devices. In the case of subcutaneous devices, the electrogram signal may be inadequate to identify P waves, and T waves may be oversensed and counted as QRS complexes. Signal dropout can also occur with subcutaneous devices, resulting in an artifactual pause. Oversensing of the QRS complex by the atrial lead is also common with pacemakers and ICDs and is an important cause of spurious mode switch episodes (AF detection). As a result, it is important to examine the primary data before clinical decisions are made.
Recommended Approach to Device Selection
In patients with a diagnosis of palpitations, we select a standard continuous loop or postevent recorder because of the low cost and the ability to provide a direct symptom-rhythm correlation. If the patient is unable to manage the technical requirements of a standard loop recorder, we choose a real-time continuous telemetry device. In patients with syncope, we do not routinely use externally applied ambulatory monitoring devices unless symptoms occur relatively frequently. In these cases, we choose a real-time continuous telemetry device as a first choice to allow documentation of asymptomatic rhythms that may provide a clue to the cause of syncope. We choose an ILR for syncopal events that occur infrequently and are suggestive of an arrhythmic cause. In patients with AF being monitored for rate control, we select a standard short-term Holter device. For the identification of AF recurrence or AF as a possible cause of stroke, we favor a device that provides at least 2 weeks of monitoring and captures asymptomatic arrhythmias. At present, this includes real-time continuous telemetry devices, ELRs with AF triggers, and 2-week Holter devices. In most cases, we do not require real-time access to this information, so a 2-week Holter, which is likely to be relatively inexpensive, is an acceptable choice. In patients being monitored for possible antiarrhythmic drug toxicity, immediate access to data is important and a real-time continuous telemetry device is preferred. A standard continuous loop monitor with daily asymptomatic transmissions is a less expensive second choice. It is routine practice to remotely assess tachyarrhythmias resulting in ICD therapy. In addition to ICDs, newer-generation pacemakers will have the capability of remote monitoring, which may allow the adjustment of therapies like antiarrhythmic drugs and possibly anticoagulants based on AF burden.

Disclosures
Dr Zimetbaum is a consultant for Medtronic. Dr Goldman reports no conflicts.

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27. Hanke T, Charitetros E, Stierle U, Karluss A, Kraetz E, Graf B, Hagemann A, Misfeld M, Sievers H. Twenty-four hour Holter monitor follow-up does not provide accurate heart rhythm status after surgical atrial fibrillation therapy: up to 12 months experience with a novel permanently


**Key Words:** monitoring, ambulatory — arrhythmia — atrial fibrillation — diagnosis — stroke — syncope
Ambulatory External Electrocardiographic Monitoring

Focus on Atrial Fibrillation

Suneet Mittal, MD,* Colin Movsowitz, MBC†, Jonathan S. Steinberg, MD*

New York, New York; and Wynnewood, Pennsylvania

There has been progressive development in ambulatory external electrocardiogram (AECG) monitoring technology. AECG monitors initially consisted of 24- to 48-h Holter monitors and patient-activated event and loop recorders. More recently, several ambulatory cardiovascular telemetry monitors and a patch-type 7- to 14-day Holter monitor have been introduced. These monitoring systems are reviewed along with their utility and limitations, with particular emphasis on their role in the diagnosis and evaluation of patients with atrial fibrillation (AF). AECG monitoring is necessary when asymptomatic AF is suspected (as in patients presenting with cryptogenic stroke) or when an ECG diagnosis of unexplained arrhythmic symptoms is warranted. In addition, AECG plays an important role in patients with known AF to guide ventricular rate control and anticoagulation therapy, and assess the efficacy of antiarrhythmic drug therapy and/or ablation procedures. Finally, we outline areas of uncertainty and provide recommendations for use of available AECG monitors in clinical practice. (J Am Coll Cardiol 2011;58:1741–9) © 2011 by the American College of Cardiology Foundation

The 12-lead electrocardiogram (ECG) has served as the “gold standard” for arrhythmia diagnosis for over a hundred years. However, for nearly as long, the limitations inherent to an ECG have also been recognized. Arrhythmias can be paroxysmal and asymptomatic; thus, a baseline resting ECG may be insufficient for diagnosis. Atrial fibrillation (AF) is the prototypical example of an arrhythmia in which a 12-lead ECG is insufficient to guide clinical management. Since the development of the Holter monitor in the 1940s, there has been progressive development in ambulatory external electrocardiogram (AECG) monitoring technology (Fig. 1). This reviews focuses on these new technologies with an emphasis on their role in the diagnosis and management of patients with AF.

Types of Available AECG Monitors

Holter, event, and loop monitors. The 1999 practice guidelines released jointly by the American College of Cardiology and the American Heart Association categorized AECG monitors as either continuous short-term recorders (24 to 48 h) or intermittent longer-term recorders (patient-activated event and loop recorders) (1). During Holter monitoring, a patient is typically connected to 3 to 5 ECG electrodes, which yield 2 ECG vectors and a third derived electrogram. Some systems can also derive a 12-lead ECG recording, which can be useful to evaluate the QRS morphology. The ECG signals are acquired at up to 1,000 samples per second, which yield high-fidelity tracings. The patient maintains a diary to document the time when symptoms are experienced and their description. After the 1- to 2-day recording period is completed, the patient returns the monitor; the data stored within the flashcard memory are digitized and downloaded to a local workstation or transmitted over the Internet to a central workstation. Only then can it be determined whether the ECG tracings were of adequate quality and whether any diagnostic information was obtained. The computer-scanned Holter recording is read by a trained technician who then forwards the report to the physician for final review and official interpretation. Assuming that the recording quality is adequate, Holter monitors can determine the average heart rate and heart rate range, quantify atrial and ventricular ectopy counts, and determine whether AF is present. Information about shortest and longest duration of AF, burden of AF, the heart rate during AF, and pattern of initiation and termination of AF can also be determined.

Patient-activated event and loop recorders can be used for several weeks at a time. Event recorders are small, leadless devices that are carried by the patient. When a patient experiences a symptom, the device is applied to the chest wall. Since electrodes are present on the back of the device, a brief (typically up to 90 s) single-lead ECG recording can be stored. The event recorder can store only a few tracings since they have only about 10 min of storage capacity; thus,
to minimize loss of data, once an event is recorded, it needs to be immediately transmitted transtelephonically (using an acoustic coupler modem) to a central monitoring site for validation and analysis. By design, event recorders do not provide information about asymptomatic episodes.

Loop recorders on the other hand require that ECG leads be attached to the patient. As new ECG data are collected, older ECG data are deleted. When a patient activates the device, it stores a single-lead ECG before (typically about 45 to 60 s) and after (typically about 15 to 90 s) activation. As with event recorders, the devices have limited memory. Thus, to minimize loss of critical data, immediate transtelephonic data transmission following a symptomatic episode is necessary.

By design, loop recorders also do not provide information about asymptomatic episodes. To overcome this limitation, auto-triggered loop recorders were developed. These devices use a proprietary algorithm to trigger ECG storage of arrhythmic episodes such as bradycardia (including prolonged pauses), tachycardia, and atrial fibrillation. The available memory, typically 10 to 20 min in duration, is partitioned for patient-triggered and auto-triggered events. The device alerts (e.g., with a beeping noise) the patient when an auto-triggered event has been detected. The patient must transmit the data transtelephonically to a central monitoring station for review. It has been shown that these auto-triggered devices have higher diagnostic yield than standard 24-h Holter monitors and 30-day loop recorders (2). Auto-triggered loop recorders have evolved capability of transmitting stored ECG data wirelessly to a device that can then send data to a central monitoring station over a landline or cellular telephone network. Although these monitors can detect the onset of an arrhythmia such as AF, their algorithms are not designed to detect the offset of the arrhythmia. Thus, information about the burden of AF cannot be consistently ascertained. As a result, these types of monitors have fallen out of favor in our practice.

Ambulatory telemetry and patch-type monitors. Ambulatory telemetry monitoring was developed to overcome many of the limitations inherent to Holter, event, and loop monitoring, namely the need for long-term monitoring and the ability to capture information about symptomatic and asymptomatic arrhythmias. Currently, several systems are available in the United States (Table 1, Fig. 1B). Typically, patients are connected by 3 or 4 ECG electrodes to a battery-powered sensor for up to 30 days. The sensor can hold anywhere from 6 h to all 30 days of ECG data. In a “sensor-only” system, when the patient is in a location with available cellular coverage, the stored ECG data are transmitted directly to a central monitoring station. More commonly, systems incorporate a second handheld device. In this case, data from the sensor is sent to the handheld device when it is within 10 to 300 feet of the patient. Once the patient is in a location with available cellular coverage, the stored ECG data are transmitted from the handheld device to a central monitoring station. Patients can also use the handheld device to enter information about symptoms. The monitoring center can determine whether the patient is actually wearing the device and ascertain the quality of the contact with the ECG electrodes; by communicating directly with the patient, the compliance with the system and quality of the acquired data may be improved.

Currently available systems handle incoming ECG data differently. Some “push” ECG data to a central monitoring station only when the handheld device confirms that a bradyarrhythmic or tachyarrhythmic event has occurred, based on proprietary algorithms that incorporate (depending on the vendor) information about rate, rhythm, and/or P and QRS morphology. Other systems push all ECG data forward. Since these devices capture information about symptomatic and asymptomatic events, information about AF burden during the recording period can also be ascertained. Not surprisingly, compared with loop monitoring, these systems significantly increase the likelihood of detecting AF (3). In addition to getting a summary report at the end of the recording period (either by fax or online), practices can develop their own emergent, urgent, and routine physician notification criteria.

Several issues with AECG monitoring systems merit comment. First, since the sensor captures beat-by-beat data, complete ECG analysis (like a Holter recording) should be available either intermittently or at the end of the recording period. However, currently only a few vendors offer this analysis, often only upon a specific request from a physician. Thus, physicians typically just assume ECG data has been appropriately recorded, scanned, and analyzed. Second, although touted as “real-time” telemetry, only 2 of these systems actually function in this manner (Table 1). One system sends ECG data from the sensor to a handheld device, which in turn forwards the accrued ECG information every 2 min to a central monitoring station. A physician can access the data over a secure web server. A second system transfers ECG data directly from the sensor to a central monitoring system. In this system, the physician has the ability to access real-time streaming ECG data from their patient on any computer with Internet access. Third, although critical data are made available to physicians on a 24 h/7 days a week basis and routine data on a daily basis, reimbursement to physicians does not take into account the need for daily monitoring for up to a month. Thus, although physicians must assume the responsibility for monitoring daily incoming data, the reimbursement to physicians for ambulatory cardiovascular telemetry is actually lower than that for Holter monitoring (Table 2). The majority of the reimbursement is collected by the independent diagnostic
Figure 1  Types of AECG Monitors Currently Available in Clinical Practice

(A) Holter, event, and loop monitoring; (B) patch-type extended Holter and ambulatory telemetry monitoring. AECG = ambulatory external electrocardiographic; ECG = electrocardiographic. Figure illustration by Craig Skaggs.
testing facility that owns and operates the ECG monitors. On the other hand, there is no mechanism for physicians to be reimbursed daily for their review of incoming ECG data. Since appropriate use guidelines for this type of ECG monitor have not yet been developed, some commercial carriers do not provide coverage or reimbursement at all on the grounds that mobile cardiovascular telemetry monitoring is “investigational.” In addition, the absence of guidelines has to led to uncertainty regarding the potential liability for “missed” critical arrhythmic events. Fortunately, although these monitoring systems detect high-quality, artifact-free ECG recording through the entire recording period. Furthermore, the clinical implications of not having access to ECG information within the recording period need to be determined.

**Indications for AECG Monitoring**

Broadly speaking, the fundamental premise of AECG monitoring is the potential to capture real-time rhythm recordings that can be used to: 1) provide an explanation for an unexplained prior or recurrent symptomatic event; or 2) capture arrhythmic events that aid in assessing prognosis or treatment effect. Table 3 lists the currently accepted indications, based on published evidence demonstrating value in the assorted subcategories. A discussion of the non-AF indications is beyond the scope of this paper and has been the focus of other recent reviews (5); the use of AECG in patients with AF will be reviewed in detail, as this is an area of intense clinical and research interest.

**Diagnosis of AF.** When a patient presents with unexplained symptoms that suggest an arrhythmic mechanism, AF is virtually always among the diagnostic considerations. Symptoms of AF are very varied and include rapid or abnormal heart action, weakness and fatigue, dyspnea, physical limitations, polyuria, and others. Syncope is less common as a direct result of AF, but may be due to post-termination pauses, associated vagal phenomena, slow-conducted ventricular rates, hemodynamic compromise in the presence of severe structural heart disease, or proarrhythmia due to drug therapy. Hence, prolonged AECG recording becomes very valuable to sort out these possibilities, to clarify the need for additional treatment, to help reassure the patient and to project long-term prognosis.

**Diagnosis of AF as the cause of cryptogenic stroke.** Twenty-five percent of ischemic strokes remain unexplained after an initial thorough evaluation including 12-lead ECG and in-hospital telemetry monitoring and are designated cryptogenic stroke. AF is the most common cardioembolic source of ischemic stroke. Because the presence of AF will lead to a specific and effective medical intervention in this setting, that is, chronic oral anticoagulation to prevent recurrent stroke, it is critical to identify the 10% of patients whose index stroke was caused by AF (6). In about 5% of patients, this effort is made simple when AF is present on ECG or telemetry during the index hospitalization (7).

However, prolonged outpatient monitoring will extend the diagnosis of AF to an additional 6% to 8% of patients, with

**Table 1 Commercially Available Ambulatory Telemetry Monitoring Systems**

<table>
<thead>
<tr>
<th>Feature</th>
<th>BioMedical</th>
<th>Cardionet</th>
<th>LifeWatch</th>
<th>Medicomp</th>
<th>MedNet</th>
<th>ScottCare</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name</td>
<td>TruVue</td>
<td>MCOT</td>
<td>ACT III</td>
<td>ACT I</td>
<td>SAVI</td>
<td>ECAT</td>
</tr>
<tr>
<td>Single unit</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Leads</td>
<td>3</td>
<td>3</td>
<td>4</td>
<td>3</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Channels</td>
<td>2</td>
<td>2</td>
<td>3</td>
<td>1</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Sampling rate</td>
<td>256 Hz</td>
<td>250 Hz</td>
<td>250 Hz</td>
<td>250 Hz</td>
<td>250 Hz</td>
<td>205 Hz</td>
</tr>
<tr>
<td>Sensor memory</td>
<td>30 days</td>
<td>30 days</td>
<td>6 h</td>
<td>6 h</td>
<td>4 days</td>
<td>30 days</td>
</tr>
<tr>
<td>Handheld/sensor interaction</td>
<td>100 ft</td>
<td>300 ft</td>
<td>10 ft</td>
<td>10 ft</td>
<td>15 ft</td>
<td>30 ft</td>
</tr>
<tr>
<td>2-way patient communication</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>24-h Holter analysis</td>
<td>Yes</td>
<td>No</td>
<td>Yes*</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Symptom correlation on screen</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Auto/manual transmissions</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>QT/ST-segment analysis</td>
<td>Yes</td>
<td>No</td>
<td>Yes*</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Handheld device data storage capacity</td>
<td>NA†</td>
<td>NA†</td>
<td>28 days</td>
<td>28 days</td>
<td>30 days</td>
<td>NA†</td>
</tr>
<tr>
<td>Ability to visualize real-time ECG data</td>
<td>Yes‡</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Yes§</td>
</tr>
</tbody>
</table>

*Upon request; †information stored on the sensor; ‡up to last 2 min; §streaming real-time.
### Table 2 2011 CPT Codes for AECG Monitoring, Medicare Fee Schedule, and Approved Indications

<table>
<thead>
<tr>
<th>Technology</th>
<th>CPT</th>
<th>Description</th>
<th>Reimbursement</th>
<th>Indications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Holter monitors (up to 48 h; up to twice every 6 months)</td>
<td>93224</td>
<td>External electrocardiographic recording up to 48 h by continuous rhythm recording and storage; includes recording, scanning analysis with report, physician review and interpretation (global)</td>
<td>$118.64</td>
<td>Detection of transient episodes of cardiac dysrhythmias, permitting correlation of these episodes with current cardiovascular symptomology</td>
</tr>
<tr>
<td></td>
<td>93225</td>
<td>Recording (includes connection, recording, and disconnection)</td>
<td>$35.57</td>
<td>Detection of abnormalities of cardiac rhythm or electrocardiographic morphology associated with symptoms of syncope, near-syncope, palpitations, chest pain suggestive of cardiac ischemia, shortness of breath on exertion, and recurrent congestive heart failure where arrhythmia is the suspected cause</td>
</tr>
<tr>
<td></td>
<td>93226</td>
<td>Scanning analysis with report</td>
<td>$52.31</td>
<td>Evaluation of arrhythmias in the patient with documented coronary artery disease, including the assessment of the immediate post-myocardial infarction patient</td>
</tr>
<tr>
<td></td>
<td>93227</td>
<td>Physician review and interpretation</td>
<td>$30.57</td>
<td>Detection of arrhythmias (such as atrial fibrillation) in patients with acute stroke or TIAs</td>
</tr>
</tbody>
</table>

| Mobile cardiovascular telemetry (up to 30 days; once every 6 months) | 92229 | Wearable mobile cardiovascular telemetry with electrocardiographic recording, concurrent computerized real-time data analysis and >24 h of accessible ECG data storage (retrievable with query) with ECG-triggered and patient-selected events transmitted to a remote attended surveillance center for up to 30 days; technical support for connection and patient instructions for use, attended surveillance, analysis and physician-prescribed transmission of daily and emergent data reports | $860.35* | Detection, characterization, and documentation of symptomatic transient arrhythmias, when the frequency of the symptoms is limited and use of a 24-h ambulatory ECG is unlikely to capture and document the arrhythmia |
|                                         | 93228 | Wearable mobile cardiovascular telemetry with electrocardiographic recording, concurrent computerized real-time data analysis and >24 h of accessible ECG data storage (retrievable with query) with ECG-triggered and patient-selected events transmitted to a remote attended surveillance center for up to 30 days; physician review and interpretation with report | $28.95 | Regulation of antiarrhythmic drug dosage, when needed to assess efficacy of treatment |

*Coverage for mobile cardiovascular telemetry monitoring from commercial insurance carriers varies from state to state; several carriers consider the service “investigational” and, thus, provide no reimbursement.

AECG = ambulatory external electrocardiographic; CPT = Current Procedural Terminology; ECG = electrocardiographic; TIA = transient ischemic attack.
longer recordings producing greater yield (8,9), especially when AF is asymptomatic. Because paroxysmal AF is as likely as continuous AF to increase the risk of stroke (10), there is inherent logic in searching for the presence of transient AF over longer periods of surveillance. The appropriate duration of monitoring has not been determined with certainty, but present-day monitors that autocapture AF events accurately over a 21- to 30-day period seem justified. Tayal et al. (11) initiated 21-day mobile cardiac outpatient telemetry after hospitalization in 56 patients with cryptogenic stroke and identified new AF in 23%, although many patients had only AF of uncertain significance, lasting <30 s. The ongoing study CRYSTAL-AF (Study of Continuous Cardiac Monitoring to Assess Atrial Fibrillation After Cryptogenic Stroke) (12) is investigating the value of even longer-term monitoring using an implantable loop recorder, emphasizing the importance of identifying which patients with cryptogenic stroke should be candidates for anticoagulation.

**Monitoring AF.** AF is a chronic condition, and once the diagnosis has been established, periodic monitoring is necessary for a variety of reasons. The management of paroxysmal versus persistent AF may differ. When presented with a patient in AF in the office setting, it may be difficult to confidently determine whether the AF pattern is likely to be continuous or episodic, and thus recording an AECG over the course of 1 or more weeks may be useful. The evolution to persistent AF may be insidious but may suggest the need for more aggressive intervention including cardioversion, antiarrhythmic drug therapy, more intensive rate control regimens, specific ablation techniques (13), or reassessment of prognosis and long-term treatment goals.

The AECG can also be utilized to more accurately ascertain whether excessive ventricular rates are present, for what portions of the day, and to what heights. It is generally believed that exposure to excessive ventricular rates may risk tachycardia-induced cardiomyopathy (14), and the 5-s resting ECG is inadequate to assess this risk and indeed may be misleading. We advocate AECG recording of at least 24 h for rate assessment, prior to and during titration of medical therapy, usually targeting a resting ventricular rate of <80 beats/min and peak activity rates of <110 to 120 beats/min. The RACE II (RAte Control Efficacy in Permanent Atrial Fibrillation) study recently raised doubts about the need to aggressively pursue this objective (15), but particularly in heart failure patients, this treatment goal may still be critical. The AECG will also facilitate simultaneous monitoring of the main risk of aggressive rate control, excessive bradycardia during AF, at termination, or in sinus rhythm. At present, it is unknown whether 24 h is sufficient sampling of ventricular rate or whether longer recording durations would expose much greater day-to-day variability than suspected.

**Assessment of treatment efficacy.** Antiarrhythmic Drug Therapy. Antiarrhythmic drugs are primarily used to reduce AF prevalence in highly symptomatic individuals, but are assumed to be incapable of complete AF eradication in most patients. Patients with stroke risk factors are believed to be at continued risk, and chronic anticoagulation therapy is recommended (16). Thus, it is less important to perform AECG monitoring to confirm AF suppression in antiarrhythmic drug–treated patients.

**Catheter Ablation.** Percutaneous catheter procedures designed to eliminate the likely triggers of AF (usually the pulmonary veins) and sometimes directed to atrial substrate are increasingly used to control AF and its symptoms when medical therapy has been ineffective (13,17,18). AECG recording is often employed after the procedure has been completed and can play several roles: follow AF patterns during the early “blanking period”; clarify the cause of residual symptoms if present; detect asymptomatic AF; and, potentially, confirm the eradication of AF and thus the long-term prognosis and the need for continued medical therapy including anticoagulation.

In the weeks and first few months following ablation of AF, it has been noted that many patients may continue to experience arrhythmias that ultimately or gradually dissipate and do not portend failure to definitively respond to the procedure. In a study designed to comprehensively define the blanking period, Joshi et al. (19) performed continuous
outpatient AECG with a device that utilized autodetection algorithms to capture all AF events greater than 30 s in duration over the first 3 months following ablation in 72 patients. Overall, 65% of patients had at least 1 AF event. The presence of AF during any of the 2-week epochs throughout this early follow-up period did not predict the ultimate response to the procedure (AF suppression in 72% of the cohort, as adjudicated at 6 months), but the absence of AF in the first 2 weeks had a 90% sensitivity for predicting absence of AF in the long-term. This observation would suggest that in the select patients with heavy symptomatic AF burden who undergo ablation, the absence of AF during early AECG monitoring may allow early discontinuation of intense outpatient ECG monitoring. After the blanking period has expired, the focus on post-ablation care is the determination of whether the patient has responded and to what degree. Symptom status will certainly be of value, but studies suggest that as many as one-half of the episodes of AF may be asymptomatic after ablation (20–22) and that ablation itself may increase the proportion of asymptomatic events (23) versus the pre-ablation pattern, perhaps by ablation of cardiac neuronal connections, placebo effect, or concomitant medical therapy. Thus, monitoring is an important tool to assess arrhythmia status post-ablation for capture of asymptomatic and symptomatic AF.

The optimal monitoring strategy has not been defined, although expert consensus documents endorse the importance of periodic AECG (17). There is a continuum of monitoring that can be entertained, ranging from the minimal, 12-lead ECG recording at follow-up outpatient visits, to the ideal that does not yet exist, a permanently implanted and accurate wireless monitoring system (Fig. 2). The latter is only approachable given present-day technology with an implanted pacing device (pacemaker, defibrillator, resynchronization system) inserted for independent implantation and accurate wireless monitoring (ILR) (90%). Recommendations for which AECG monitoring system should be used are also not provided. The optimal monitoring strategy has not been defined, although expert consensus documents endorse the importance of periodic AECG (17). There is a continuum of monitoring that can be entertained, ranging from the minimal, 12-lead ECG recording at follow-up outpatient visits, to the ideal that does not yet exist, a permanently implanted and accurate wireless monitoring system (Fig. 2). The latter is only approachable given present-day technology with an implanted pacing device (pacemaker, defibrillator, resynchronization system) inserted for independent implantation and accurate wireless monitoring (ILR) (90%). Recommendations for which AECG monitoring system should be used are also not provided. There is a continuum of monitoring that can be entertained, ranging from the minimal, 12-lead ECG recording at follow-up outpatient visits, to the ideal that does not yet exist, a permanently implanted and accurate wireless monitoring system (ILR) (90%). Recommendations for which AECG monitoring system should be used are also not provided. There is a continuum of monitoring that can be entertained, ranging from the minimal, 12-lead ECG recording at follow-up outpatient visits, to the ideal that does not yet exist, a permanently implanted and accurate wireless monitoring system (ILR) (90%). Recommendations for which AECG monitoring system should be used are also not provided. There is a continuum of monitoring that can be entertained, ranging from the minimal, 12-lead ECG recording at follow-up outpatient visits, to the ideal that does not yet exist, a permanently implanted and accurate wireless monitoring system (ILR) (90%).

Figure 2 Spectrum of AECG Monitoring Modalities

As one moves from left to right, the duration of monitoring increases, which in turn increases the diagnostic yield. ILR = implantable loop recorder; other abbreviations as in Figure 1.

Areas of Uncertainty

Although ambulatory cardiovascular telemetry monitoring has emerged as a commonly used diagnostic tool in patients with suspected or known AF, some important concerns persist with respect to these systems. First, there are no clinical guidelines that guide practitioners on the use of AECG monitoring in patients with AF. The last American College of Cardiology/American Heart Association clinical competence statement on electrocardiography and ambulatory electrocardiography was published in 1999 (1); at that time, neither auto-triggered loop recorders nor mobile cardiovascular telemetry monitoring were commercially available. In 2007, the Heart Rhythm Society, in conjunction with the European Heart Rhythm Association and European Cardiac Arrhythmia Society, developed a consensus statement to provide recommendations in patients undergoing catheter or surgical ablation of AF (17). Although acknowledging that “the more intensively a patient is monitored and the longer the period of monitoring, the greater the likelihood of detecting both symptomatic and asymptomatic AF,” no specific guidelines were provided regarding the optimal AECG monitoring system. Most recently, the European Society of Cardiology published updated guidelines for AF management (27). They suggest that “the intensity and duration of monitoring should be determined by the clinical need to establish the diagnosis, and should be driven mainly by the clinical impact of AF detection. More intense AF recording is usually necessary in clinical trials than in clinical practice.” However, specific recommendations for which AECG monitoring system should be used are also not provided.
Second, there is a paucity of data regarding the accuracy of these systems for detecting AF. On October 28, 2003, the Food and Drug Administration (FDA) released a statement to guide industry interested in developing an Arrhythmia Detector and Alarm system (28). For AECG monitoring systems, testing needs to be performed according to guidelines stipulated in a 1998 statement from the American National Standard Institute and Association for the Advancement of Medical Instrumentation (29). Any system proposed to provide information on AF must be tested against the Massachusetts Institute of Technology–Beth Israel Hospital Arrhythmia Database (48 records of 30 min each) and the Noise Stress Test Database (12 ECG records of 30 min plus 3 records of noise only). These databases consist of digitized excerpts of 2-channel Holter-type reference recordings, with each beat labeled by expert cardiologist-annotators. Although industry needs to report the sensitivity and specificity of their AF detection algorithms to the FDA, comparative information across vendors is not readily available. Furthermore, with only a single exception (30), the details of the algorithm being used by any given vendor for AF detection are not publically available. Interestingly, although several vendors claim to capture information on every ECG beat acquired during the recording period, none have published the sensitivity and specificity of their autodetect AF algorithm against the “gold standard” of complete ECG data in the same patient.

Third, when ongoing monitoring for AF is required, both ambulatory cardiovascular telemetry and extended Holter-type recordings from a patch are available options. In comparison to the patch, the 2 main advantages of ambulatory telemetry are access to data during the monitoring period and the ability to monitor for up to a month. Assuming that the patch technology could evolve to where it, too, could offer a month of monitoring, there are no compelling data to support the need for real-time access to ECG data as opposed to receiving a singular report at the conclusion of the recording period.

Finally, an emphasis of prolonged ECG monitoring strategies has been the detection of arrhythmias. Even if we assume that these monitors can detect arrhythmias with perfect accuracy, it has yet to be demonstrated in clinical trials that patient outcome is affected. In AF patients, an important goal of monitoring is to use the data to guide decisions regarding anticoagulation. However, before embarking down this road, we need to know what duration or burden of AF is clinically important enough to warrant initiation of anticoagulation and then develop an AECG monitoring device that is capable of reliably accurately detecting AF episodes of this duration or burden.

Conclusions

AECG monitoring often establishes a diagnosis of AF in a given patient. Once established, AF is a chronic disease, and AECG monitoring can be important to its long-term management. Table 4 summarizes our current recommendations for AECG monitoring in clinical practice. Technologic developments are necessary to produce an ECG monitor that can be applied to any AF patient (preferable in the office setting), can capture ECG information accurately and continuously, and can relay critical data to the physician promptly without the need for patient participation. Finally, future studies need to address the impact of data acquired

Table 4  Recommendations for Using AECG Monitoring in AF Patients

<table>
<thead>
<tr>
<th>AECG Monitor</th>
<th>Goal</th>
<th>Role of longer term monitoring unknown</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>24- to 48-h Holter</td>
<td>Assess adequacy of ventricular rate control in patients with persistent or permanent AF</td>
<td>Requires 12-lead Holter monitor</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Assess effective biventricular capture in patients with persistent or permanent AF in patients with a cardiac resynchronization therapy device</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event recorder</td>
<td>Elucidate mechanism of symptomatic arrhythmic episodes not associated with hemodynamic compromise (in patients capable of employing this technology)</td>
<td>If initial 30-day evaluation is nondiagnostic, may need to consider ILR for longer-term ECG monitoring</td>
<td></td>
</tr>
<tr>
<td>30-day ambulatory cardiovascular telemetry monitors</td>
<td>Assess for asymptomatic AF in patients with cryptogenic stroke</td>
<td>Role of 7- to 14-day Holter patch remains unexplored</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Compare average heart rate in sinus rhythm vs. AF; assess pattern of AF initiation and termination; determine whether AF is paroxysmal or persistent</td>
<td>Patients with no AF in the first 2 weeks have excellent long-term outcome; AADs are weaned, and the second 2-week period of monitoring is used to assess the response</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Routinely in the first month post pulmonary vein isolation</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>At 6 and 12 months post-ablation</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Patient-activated loop monitors (with and without automatic detection algorithms) do not offer any distinct advantages for the detection or monitoring of AF. Thus, we routinely use ambulatory cardiovascular telemetry instead in these patients.

AAD = antiarrhythmic drug; AF = atrial fibrillation; ILR = implantable loop recorder; other abbreviations as in Table 2.
through AECG monitoring on short- and long-term patient outcomes.

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REFERENCES


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MINIMALLY INVASIVE IMPLANTABLE DEVICE FOR MONITORING PHYSIOLOGIC EVENTS

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ABSTRACT
A minimally invasive implant, means for insertion, and description of how to most efficiently use it are described in several embodiments. This implant preferably has a segmented loop memory for storing triggered physiologic events. Preferred events for setting autotriggers to record physiologic signals occurring during events include arrhythmias and syncopal events. Preferably the device can function without a microprocessor. An outside device or other patient activated manual trigger is included. Auto triggers and manually set triggers may be of different sizes. The preferred physiologic events are ECG signals. Electrode spacing can be critical. Additional sensors may be provided to the device. Preferred communications with the device is through telemetry such as is used for pacemakers and other implanted devices.

22 Claims, 13 Drawing Sheets
MINIMALLY INVASIVE IMPLANTABLE DEVICE FOR MONITORING PHYSIOLOGIC EVENTS

This application is a CIP of Ser. No. 08/678,219, filed Jul. 11, 1996, now abandoned.

This invention relates to an implantable monitoring device for sensing physiologic events with minimally invasive intrusion into an animal or patient body, and is particularly well suited for long term monitoring of body events like ElectroCardioGrams (ECG's) and in monitoring other body physiologic events related to heart function which may include for example, but not by way of limitation, such parameters as temperature and tissue oxygen levels relevant to normal and abnormal cardiovascular function. By enabling easy monitoring and recording of physiologic events in the patient's body, such events can then be studied at leisure outside the body, providing research, diagnostic and therapeutic opportunities not otherwise available.

BACKGROUND OF THE INVENTION

Syncopal events and arrhythmias of the heart are particularly problematic for diagnostic physicians to observe in living patients. These events, can be of short duration and sudden onset, coming with little or no warning, and may happen very infrequently. Holter monitors are well known for monitoring electrocardiograms periods of time amounting to days or perhaps a week, but these are bulky and are applied externally to the body and interfere with the patient's normal life, making them impractical for long-term use. Further, patient compliance cannot always be guaranteed, and is a common problem in use of the Holter devices. Problems with external monitors and associated recorders also include inability of some patients to abide the attendant skin irritation. Bulky or expensive special purpose devices may need to be available and maintained. Removal is required for showering, and so on. Any time a living body needs to have a long term monitoring of a physiologic event that is intermittent or infrequent or both, all these problems come into focus. Therefore, there exists a need for minimally intrusive long-term monitoring of the patient's physiologic events and status. This is particularly indicated in, but not limited to patients with cardiac arrhythmias and vascular syncope to provide sufficient evidence for diagnostic purposes and for research into the causes and effects of such events. Patients have come to accept long term implants of small items for many things, including birth control, for example, like the "Norplant" (TM of Wyeth Laboratories) devices which secrete birth control hormones for perhaps a year before they need replacing. Accordingly it is believed that small device implants for long term implant will be well tolerated by the patient population to be served by this invention.

Many attempts to address some of these problems have been made and met with limited success. The problem has been long existing. The Instromedics approach is seen in the Mills, et al patents (U.S. Pat. Nos. 5,333,616; 5,289,824 and 5,111,396) for a wrist worn monitor for ECG's which include features like patient triggering and microprocessor determination of event types (QRS detection). Wrist worn devices are also shown in the Richner patents issued to assignee Ralin, including U.S. Pat. Nos. 5,226,425 and 5,365,935. Jacobsen, et al in U.S. Pat. No. 5,513,645 describes multiple resolution storage for ECG's (ELA Medical is the assignee), and Snell's U.S. Pat. No. 5,518,801 vaguely describes a patient triggered recording device with multiple sensors and patient triggering (assigned to Pacesetter). InControl's approach is seen in the Yamotov patents, U.S. Pat. Nos. 5,411,031 and 5,313,953 which seems to concentrate on beat to beat timing records, suggests the use of an arrhythmia detector, and does mention the possibility of leadless electrodes for monitoring cardiac signals. Examples of an external monitor/recorders can be found in Segalowicz' patents, including U.S. Pat. No. 5,511,553, and Salo's U.S. Pat. No. 5,417,717. Another well known event recorder is the "King of Hearts" (TM of Inamed) which records pre-event and post-event data.

Monitoring can be done using implantable pulse generators such as pacemakers and other heart stimulating devices or devices with leads in the heart for capturing physiologic parameters, including the ECG. However, the expense and risk from implanting an intracardiac lead and/or a pacemaker with special monitoring functions is something both patients and physicians would prefer to avoid. Such devices, in addition to performing therapeutic operations, may monitor and transmit cardiac electrical signals (e.g., intracardiac electrograms) to an external diagnostic devices typically with leads fixed in the patient's heart, to observe electrical activity of a heart. It is common for implanted cardiac stimulation devices to send intracardiac electrogram signals to a monitoring device, such as an external programmer, to allow a user to analyze the interaction between the heart and the implanted device. Often the user can designate that the communication from the implantable device to the programmer include a transmission of codes which signal the occurrence of a cardiac event such as the delivery of a stimulation pulse or a spontaneous cardiac depolarization.

For example, U.S. Pat. No. 4,223,678, entitled "Arrhythmia Recorder for Use with an Implantable Defibrillator", issued to Langer et al. on Sep. 23, 1980, discloses an arrhythmia record/playback component within an implantable defibrillator. ECG data is converted from analog to digital (A/D) form and stored in a first-in, first-out memory. When the defibrillator detects an arrhythmia event, it disables the memory so that no further ECG data is recorded in the memory until a command is received from an external monitoring device. This command requests the implantable defibrillator to transmit the stored ECG data to the monitoring device via telemetry. Langer et al. in U.S. Pat. No. 4,407,288, entitled "Implantable Heart Stimulator and Stimulation Method", issued Oct. 4, 1983, discloses a programmable, microprocessor based implantable defibrillator which senses and loads ECG data into a memory via a direct memory access operation. A processor analyzes this ECG data in the memory to detect the occurrence of an arrhythmia event affecting a patient's heart. Upon such an event, the defibrillator may generate a therapy to terminate the arrhythmia event and store the ECG data sequence of the event, for transmission to an external monitoring device and later study. In normal circumstances, when no arrhythmia event is occurring, the defibrillator continuously overwrites the ECG data in the memory.

U.S. Pat. No. 4,556,663, entitled "Telemetry System for a Medical Device", granted to D. L. Thompson et al, 1985, teaches a pulse interval telemetry system capable of transmitting analog data, such as sensed intracardiac electrogram signals, without converting analog data to a digital numeric value. The Thompson et al. telemetry system is capable of sequentially transmitting both digital and analog data, individually and serially, in either an analog or a digital format, to a remote receiver. The features and capabilities of these pacemaker/defibrillator devices is now well known, but the problems in long term monitoring for events and adequate recordation remain.
In the December 1992 Vol. 15 edition of PACE (15:588), a feasibility study was done for implantable arrhythmia monitors and reported in an article by Leitch et al. Subcutaneous, Bipolar “Pseudo-ECG” Recordings using an Implantable Monitoring System and at chaired poster presentation of the North American Society of Pacing and Electrophysiology (NASPE) an implantable monitoring system was described using the pacemaker that had been altered to use a point on the can as an electrode and to have an electrode mounted into the connector block thereof. This was presented to NASPE in Munich in 1994 by Brian Lee of Medtronic, Inc. A photograph of the device shown in that poster presentation was published by the American Heart Association Inc. in 1995 by Andrew Krah, M.D. in an article entitled “The Etiology of Syncope in Patients with Negative Tilt Table and Electrophysiological Testing”, pp. 1820 of CIRCULATION, 1995; 1992. The initial thinking for this started in NASPE 1991 in an Abstract published in PACE, 1991; 14:677 authored and titled: Leitch, J.W, Klein, G J, Yee, Lee B B, Kallok, M, Combs, B, Bennett, T: Feasibility of an Implantable arrhythmia Monitor.

Further, a leadless implantable sensor for cardiac emergency warning was described in U.S. Pat. No. 5,404,887 issued to Knowlton et al. which detects heart events through impedance measurement sensed using a coil. See also Yomato et al, U.S. Pat. No. 5,313,953 which describes (in FIG. 26) a large but leadless implant.

With sufficient hardware and connections to the body, numerous other physiologic parameters may be sensed as is pointed out in U.S. Pat. No. 5,464,434 issued to Alt and U.S. Pat. No. 5,464,431 issued to Adams et al.

Accordingly, there still exists a need for a more acceptable recording and monitoring device capable to maintain a data record over a long period of time and highlighting or least capturing those physiologic events that are of interest to a diagnostic, research or therapeutic study, and particularly to those physiologic events that are required for correct diagnosis and therapy. Further, it has herefore been unreasonably expensive and overly invasive to the patient to implant monitors for simple recording functions and particularly to implant intracardiac and intravascular monitors for simple recording functions. Many of the features of this invention are designed to ameliorate both these problems.

BRIEF DESCRIPTION OF THE DRAWINGS
FIGS. 1 and 2 are the exterior side view, interior block diagram, respectively of a prior art device.

FIG. 3 is a block diagram illustrating the main circuit and assembly of a device in accord with a preferred embodiment.

FIGS. 3A-D are block diagrams of preferred embodiment circuits of the implanted device used for monitoring and storing ECGs.

FIGS. 4a, 4b, and 4c are exposed front, side, and back views, respectively of a preferred embodiment of the invention.

FIG. 5 is an illustration of a preferred embodiment of the invention, showing (in dotted line), locations for finwing and stubby lead features.

FIGS. 6a and 6b are front and side views of preferred embodiment cross-sections taken from FIG. 5.

FIGS. 7A, and 7B are front, and cross section views of another preferred embodiment of the invention.

FIG. 8 is a front view of another embodiment of the invention.

FIG. 9 is a drawing of a patient body segment with specific locations referenced thereon.

FIGS. 10A and 10B are front and back views of a testing ECG device for use with this invention.

FIG. 11 is a block diagram of the looping memory and its control circuitry in accord with a preferred embodiment of the invention.

FIG. 12 is a flow chart of the functioning of the recordation of triggered events in a preferred embodiment of the invention.

FIGS. 13a, 13b, 14a and 14b are front and side views of alternate embodiments of the invention.

FIG. 15 is a rough sketch of an inserter tool for implanting the device in accord with this invention.

SUMMARY OF THE INVENTION

Objects of this invention include providing a minimally intrusive implantable system capable of communicating with an external device and having electrodes separated by a fixed distance to measure a substantially electrogram including a signal input means, here shown as an amplifier, a looping memory, and a circuit for controlling the memory, the device having an external configuration and dimensions maximally adapted to such needs.

Numerous features are included to facilitate the implantation, management, and orientation in the body of the implanted device. A preferred data compression scheme is also disclosed as is automatic selection of time periods pre and post triggering.

In its presently most preferred embodiment it provides for long term ECG monitoring, has the capacity to use manual or automatic triggers or both to cause the memory to store events in reserved areas of a looping memory preferably in identifiable memory partitions. It can accept limited programing or mode control and can read out sections of or all of the memory when prompted from the outside by a physician or other user, provided they have the appropriate external device to initiate and receive such transmissions from the implanted inventive device.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Prior to this invention the only consistent use of implantable electrode sensing systems employed leads located in the heart because of the quality of the signal obtained that way. Subcutaneous electrodes (below the skin) have not been demonstrated to be highly effective in producing good monitoring devices, and have not found commercial medical success. A well known example of a system having leads which also contained more than a single electrical contact in the body of the pacemaker was described in U.S. Pat. No. 5,331,966 issued to Bennett et al. in 1994. In column 8 of that patent, several other implantable recording systems are described. The data recording system described in this invention requires only two electrode surfaces.

The closest prior art is described with reference to FIG. 1 and appeared at a NASPE (North American Society of Pacing and Electrophysiology) conference as a poster presentation in 1994. The device 10 was provided with two suture holes 13 and two spaced apart non-lead or leadless electrodes 12 at one and one-quarter inches distance center to center. The device was coated with parafilm indicated by arrow 11 so that the only area of exposure on the body of the pacemaker is the exposed area at the electrode 12a. The other electrode is a metal plug electrode 12b mounted in a connector block 19.

In FIG. 2 the same electrodes 12 supplied signals into the circuitry inside the housing or "can" 18 (FIG. 1) by first
entering a analog to digital conversion and amplifier circuit 14. Data from this circuit 14 was fed to a microcontroller 15 which provided functions of data compression, telemetry control and event capture triggered by patient operation. Telemetry block 16 and RAM memory storage 17 were also provided in this device. The device described in the Yamato et al patent, (U.S. Pat. No. 5,313,953, FIG. 26) is quite complex and in any case, built for deeper implant than in this invention in its preferred uses.

Practical considerations in adopting preferred structure design

A small and easy-to-implant, primarily leadless device or one having a very short lead-like structure, device will require a minimal incision size, which is good for the patient. This can vary if the physician wants to use sutures to hold the device in place or for other reasons as needed. Between ½ and 1 inch incisions are preferred to avoid trauma and scarring. If significant concern exists regarding scarring, both ends can be tapered.

For case of insertion the device should be easy to self-orient, and preferably elongate in shape to maximize signal strength for a given volume by having electrodes spaced out at the ends of the length or longitudinal axis of the device. The larger the device the more electronics and larger the battery volume can be. Both the functionality provided by external electronic circuits and battery volume may be traded for enhanced useful life and minimal complexity when considering the optimum device size. Although it is preferred that the electrodes be widely spaced on opposite ends of an elongate device, variations to this theme may be acceptable for alternative monitoring missions. The primary mission of the preferred implant is long term ECG event monitoring.

Refer now to FIG. 3 in which a circuit model 30 is illustrated in an outline of an implantable device shell 31. Electrodes 32a and 32b bring signal from the body to an input mechanism 38, here drawn as a differential amplifier for simplicity only, the output of which is fed to a QRS detector 36 and an A/D converter 37. Both these circuits 36 and 37 supply output to an arrhythmia detector 39, which in this preferred embodiment supplies the autotrigger signal to the trigger setting circuit 6. The data output from the analog to Digital converter may be converted, compressed, formatted and marked or reformulated if desired in a circuit 45 before the data is ready for input into the memory 34. The Memory control circuits 48 receives input from the A/D converter, with or without conversion and so forth from circuit 35, from the auto triggering determination circuit (here seen as the arrhythmia detection circuit) 39 (which may include input directly from the QRS detector if desired) as well as signals from the trigger setting circuit 6. The trigger setting circuit may also be controlled by a communications unit 5 which operates to receive and decode signals from the outside of the implant 30 that are telemetered or otherwise communicated in by a user. This communications unit 5 will also be able to communicate with the memory controller to request the offloading of memory data for analysis by an outside device. It should contain an antenna a or other transceiver device or circuitry to communicate with an outside device such as device 30A. A clock or counter circuit 7 reports the time since start or real time to the outside interrogator device 30A contemporaneously with a data offloading session so that the events recorded in memory 34 may be time stamped.

 Alternatives to this overall design may be considered, for example by using a microprocessor to accomplish some or all of the functions of circuits 6, 8, 39, and 55 but it is believed that such a design will not provide the power and size savings taught by use of the preferred design.

FIGS. 4a-c illustrate one preferred form 4 of the invention. In this form it has an outer titanium shell 40, in a plastic cap means 44, which together form the exterior of the device. The cap means 44 may be composed of material similar to those used for pacemaker connector blocks as it is in the is case. The two electrodes, 44 and 49, provide metal surface contacts to the body. Electrode 49 is formed as a whole in a paraleine coating over the metal body 40, of the device. The metal electrode 42 is connected via a feedthrough 43 which is itself electrically connected to the circuit board 41. Circuit board 41 contains all the electronics required for the device function and is connected to a battery BA for power. An integrated circuit 46 houses circuitry and intelligence required for the function and the memory M is packaged on the other side of the circuit board. In this preferred form, the invention uses a communications circuit 45 having a telemetry antenna both to indicate from outside the body that a read out is requested of the device, and for communicating data output from said device. Programming of the device or mode setting will also use the communications circuit 45. In an alternative embodiment the cap means 44, Electrode 49 is connected by a conductive connection (not shown in this fig.) to the circuit board. In this embodiment the length “l” is 2¾” and “w” is ¾”. These measurements can be varied within the constraints described. Electrode spacing here is about 1¾”, center to center.

Presently less preferred three or more electrode embodiments are also described with reference to FIGS. 5-8. A third electrode, like electrode 56, can be used to optimize signal strength responsive to changes in device position, heart position, or body position. A transistor or other switch means can switch the electrode configuration automatically based on a determination of signal strength or direction from an outside device through the communications circuit. In order to retain the elongated shape yet provide a well spaced orthogonal position, the third electrode can be mounted on a self-positioning (flexible, rigid, or semi-rigid) stubby lead. An additional variation from the most preferred design could provide for a wing or fin-shaped member 57 or more than one wing (57, 58) that extend substantially in one plane from the main body of the device. Ideally this would be approxi-

 worden 53 and 59). Unless they are constructed so as to spring from the main body outward after insertion into the intended body area, wings like 57 or 58 will require a larger incision than the currently most preferred device, a smooth bodied device. The illustration of the device 50 in FIG. 5 without the dotted line external parts 55, 57, 58, and 60, would be such a most preferred form.

Some other features are also significant and should be noted. A single suture hole 54 (or two or more if desired) can be provided in the cap. Additional suture appendages, like ring 60, having a suture hole 60a, may additionally be provided for more stability. Additionally, a suture may secure the stubby lead to the patient’s tissue if desired. These suture holding means allow the device to be fixedly held in one orientation in the body of the user, whether intramuscular or strictly subcutaneous. Intramuscular pocket implantation is advantageous in that the device may be protected form the outside world by a layer of muscle, which will may provide cosmetic benefits to the patient as well. The exact sites of implant may advantageously be varied from patient to patient for various reasons apparent to the physician. Implant just under the skin now appears to provide the signal
most free of skeletal muscle myopotential or body movement signal interference.

Another important feature of the shape is to have one end of the elongated device tapered to aid in easily inserting under the skin during implantation (as in a blunt dissection procedure). This self-placing tapered tip helps ensure that the device stays positioned properly in alignment with the principal cardiac vectors whether they be the principal R-wave, or P-wave vector or best for both, especially where two sutures would be used at the cap end. It is believed that this taper feature will be better than just a blunt placement with an instrument. Another preferred method of implant could be injection of the tapered end into the body, using a device similar to that described in the U.S. Pat. No. 5,520,660, the Implant Plunger. As a secondary feature the other end from the insertion tip may be blunt or otherwise formed to assist in providing a better directing and pushing surface during insertion. A rough sketch of an alternate tool is provided in FIG. 15, in which a handle unit with a blade 154 makes an insertion into the opening 151 created in the skin, holding the implant 152 between a recess behind the blade and a pushing member 157 until a handle releases the smooth protective chamber 155 advantageously to the end of a suture into the patient beneath the skin with tool 153, which is then retrieved by manipulation of a wire 157, thus accomplishing insertion and securing the implant at the far end 159, rather than at the cap end of the implant. Many variations on this injection and insertion theme can be accommodated within the teachings of this document.

These kinds of instrument assisted insertion are herein referred to generally as insertion via a "trocar" concept. In general this "trocar" concept involves any instrument which encloses the implantable device and contacts the surface of the body or point of incision, starts the incision and allows the device to be inserted thereinto. The trocar is used to make a starting hole/incision using a sharp point and/or cutting edge first. The physician then uses the mechanical advantage provided by the trocar to stretch the incision wide enough to allow the implantable device to fit through the incision and then pushes the device under the skin (or into the muscle, etc.) in one motion. The incision could be enlarged to facilitate suturing if desired.

A preferred form of insertion tool should be fitted with a smooth handle (preferably plastic lined) just wider than the implantable device (but of approximately the same cross-section) to slip the implantable device into, tapered end toward the insertion end of the tool. The bottom of the chamber could be shaped to fit the taper of the implantable device and would move out of the way when the implantable device was pushed by hand or an injecting plunger. The outside of the bottom of the chamber would come to a sharp point and possibly have cutting edges tapered back on both sides from the sharp point, but may not need to cut to the full width, instead it could stretch the initial opening to allow insertion of the implantable device with a push.

Suturing to hold the implant device in place could be done automatically or with surgical staples by some means associated with the tool, the device could be left in the pocket, or it could be held in place by a coating of its surface with a sticky substance or one that adheres to body tissue like silicone rubber, or it could be inserted with a properly shaped Parsonnet pocket, although this would likely interfere with the gathering of signal through the electrodes.

While considering the features of the embodiments illustrated by FIG. 5, it is well to note the electrode configuration. Here the electrode 53 is a conductive or metal plate com-
patible with the patient's body that is on one surface of the cap unit 51, the cap being delineated by dotted line 52. One can construct the device 50 as a solid container having out of body compatible materials. For examples, titanium or other metal or alloy, coated with compatible insulator but exposed for at electrode areas or fitted with conductive electrodes, ceramic having conductive areas thereon, etc. One should have two surface electrode areas separated by a distance (functionally similar, therefore, to electrodes 53 and 59 in FIG. 5) for the device to work. This distance should be at least far enough to achieve good signal but not too far so as to make the size of the implant too large to accommodate. The first devices had electrode separation distances of just over 1/4" center to center and we currently believe the best separation distance to be approximately that. This distance can range between 1/2 and 2 1/2 inches, or even near 4" before becoming impractical.

In the presently preferred embodiment the cross-section is an easy-to-insert rounded rectangular or oval shape to the potential of the device turning over after implant. FIG. 6A shape 61 and FIG. 6B, shape 62 illustrate this concept and the reader may use any similarly functional cross-sections. Our studies have determined that electrodes which are faced outward, toward the skin of the patient, are preferable to face in or other electrode orientations. This may be due to less muscle exposure or movement or other noise sources.

Additional features are illustrated which can assist in preventing medically unintended movement of the device. In FIG. 7A the electrodes are placed so as to be matched on opposite sides of the rectangular, round, or ovoid shaped device and electrically connected in parallel on opposite sides to retain the same signal in spite of flipping or other movement. (This internal circuitry would operate like the op-amp 75 to produce output 76 from electrodes 71–74 as shown to produce this effect.) In surface pacemaker implants, patient populations have been known to play with their implants, often unconsciously and this has been a common enough problem in the pacemaker art to have obtained the name "twiddler's syndrome." These features address this problem. The device of 7A is seen in cross-section in FIG. 7B.

Another feature in a preferred embodiment employs circumferential electrodes on a cylindrically shaped device. In FIG. 8 this device can be seen to also have a body 69 that is tapered on one end 81 and blunt on the other 82. The effect again is to provide a constant signal in spite of likely unwanted rotation of the device, because the electrodes each extend around the device circumference. Here the electrode area positions are illustrated for each end, 65 and 68 for end 81 and positions 66, 67 for end 82. This approach trades-off the protection from muscle noise of the rectangular outward-facing device.

Additional designs for the device shape which would be employed if the circuitry and power needs could be reduced in size are shown in FIGS. 13a, device 130 and 14a, device 140 with side views in the corresponding FIGS. 13 and 14b. These devices have three electrodes each, 1, 2, and 3, to adjust orientation to the best signal if desired, however two electrode forms and forms with windows W for sensors are also contemplated.

Procedure for Non-Invasively Determining Optimal Implant Position and Orientation Prior to the Implant

One of the preferred ways to use the invention is to be careful to assure that the device is implanted in substantially the optimal position and orientation. For obtaining the best ECG signals with a two electrode device this is especially important. A simple and noninvasive determination of the
proper position and orientation prior to implant can be made by
merely employing an external ECG measurement device
using external electrodes (of any of a number of standard
types well known in the field of cardiology). By observing
the ECG at orthogonal electrode orientations in roughly the
positions preferred by the physician/patient, the signal
amplitudes both P and R wave can be monitored until a good
positioning is found and the signals are optimal. It is
preferred that these measurements be made in several typical
patient postures to account for posture variability as well.
The electrodes should be approximately spaced with the
same spacing (within a factor of two or so) as the implant-
able device and with approximately the same diameter
electrodes as the implantable device (a factor of two or so as
well). (The diameter of the external electrodes in most ECG
systems will be smaller than the edge to edge spacing of
the electrodes by greater than roughly a factor of two or so). We
outline two approaches here.

Approach 1

Standard ECG Electrodes: a standard ECG Monitoring
System can be used with the standard electrodes and elec-
trode preparation of the skin. The electrodes are then placed
in orthogonal patterns of the proper electrode spacing over
each candidate implant site (as described in the above
paragraph) per FIG. 9.

Orthogonal measurements over each candidate implant
site (here illustrated as 1, 2, or 3, for example locations for
three electrodes each though two could be used) can be used
to determine the optimal orientation.

One can either simply look at the signal amplitudes using
the orthogonal electrodes and assume a similar implant
orientation will be substantially as “good.” One may try
again until a satisfactory signal at a given location and
orientation is obtained.

For a more exact orientation to produce the absolutely
best and largest R-wave one can do simple vector arithmetic
in the following manner:

If the two orthogonally oriented electrode pairs with a
common electrode produce R-wave Amplitudes A and
B, the optimal orientation will be at the angle=Arc-
Tangent(B/A), where this angle is taken from the
common electrode to the electrode producing R-wave
amplitude A. The same procedure can be followed for
optimizing the P-wave amplitude. One can also use
similar calculations to determine the best compromise
angle for P and R waves.

This Standard ECG approach has the advantage of being
possible using commonly found ECG Monitoring systems,
but has the disadvantage of requiring surface preparation of
the skin, as well as additional calculations or repeated tries
if the “best” orientation is desired.

Approach 2

Hand-Held Device with Fixed Electrode Probes: In this
approach a special device similar to hand-held emergency
heart monitors provided by several manufacturers can be
used to probe the surface locations and orthogonal orienta-
tions that are desired in order to find the optimum orienta-
tion. This device needs to be customized to have electrode
probes which are roughly the same spacing as the implant-
able device and looks like FIG. 10A. The ECG is either
displayed on an attached recording device or display or on
a built-in display such as an LCD monitor. The procedure
can also use a customized hand-held portable ECG monitor
with only slight modifications to produce a satisfactory
result. For example the Micromedical Industries Inc.
(Northbrook, Ill.) Paceview(tm) with the modification
shown in FIG. 10B could be used. It has a raised electrode
assembly constructed on points 93 which support posts 94
and electrodes 95, configured so as to maintain the proper
test position of the electrodes for the device being consid-
ered for implantation. This added structure is on back side
92. Because these additional structures have a spacing
similar to that of the implantable device, the readout on side
91 will produce fine results for placement and orientation
data.

This device 90 has the advantage of not requiring the
placement of surface electrodes over the implant site, is fast
enough to allow a simple sequential test at each orientation
and implant site, and has no wiring or external equipment
required. The ECG can be seen in real time in monitor
window 96.

Functional considerations for the preferred embodiments

In FIG. 3 the inventive system is described as stated
above. The external device 30A is preferably a device that is
commonly called a “programmer” in the pacemaker art,
because it’s usual function is to communicate with and
program implanted devices. Software modifications and
modifications to the telemetry system of device 30A to
accommodate communication with and analysis of data
from device 30 can be made as such data collection will vary
with the programmer type and are within the
discretion of the manufacturer and thus will not be illus-
trated here. Using a programmer will avoid having to have
additional devices cluttering the operating room or clinic by
creating a separate and distinct external communications
device for this invention. The functionality necessary for
mere ECG monitoring and event triggering is minimal, so in
the preferred embodiments that only monitor some form of
ECG or other limited sensory input, a microprocessor can be
and is done away with altogether by using particularized
functional circuits instead of doing the functions in software.

In FIG. 3A, a block diagram of an analog to digital conversion
circuit for use in this invention is shown. The clock
input may advantageously use an output from the
clock circuit 7, input 7I. The input 38C is the analog input
signal from input circuit 38, and the converted output is a
stream of 8 bit digital data words on line 37A, sequenced by
a timing line 37B.

FIG. 3B illustrates the basic parts of circuit 38, addition-
ally indicating the input of gain set bits which can modify
the value of the output of the low noise bipolar amplifier for
output at line 38C, the input to the QRS detector. In this
invention QRS detection is done on the analog signal,
advantageously saving more complex detection after digital
conversion.

In FIG. 3C QRS detect circuit 36 has a 2nd order bandpass
filter with a center frequency preferably in the 20–25 Hz
range. It includes a transconductance amp A1, summing
amp/comparator A2 and resistors Rbp1-3, capacitors Cbp1-4
and selectable resistor R sense connected as shown. R sense
is preferably adjusted during manufacture. Additional con-
rol is provided for QRS sensitivity at line 36C, since the gain
is selectable for this input.

A simple arrhythmia detection circuit 39 is included with
this preferred embodiment, and illustrated in FIG. 3D. The
output from circuit 36 is monitored at a 200 millisecond
blanking interval circuit, controlled by a clock input 72. In
the preferred embodiment, a high rate can be selected
amongst 4, with two selection bits dedicated to do so at input
9d and the low and flatline trigger rates each have one bit to
turn them on or off provided by inputs 9f. These inputs
designated 9d preferably come from a register that holds the
gain the mode and the rate settings, illustrated as register 9
in FIG. 3. Such features may be programmable through
Communication with the implanted device by an external device. Preferred timing for the high rate triggers is 140, 162 and 182 beats per minute, requiring 8 consecutive beats at such a rate to initiate the trigger. Additionally the trigger may be programmed off. The low rate counter/comparator may be programmable to detect low rates of 40 or 30 bpm, requiring 4 consecutive low rate intervals to trigger. Additionally a flat-line trigger can be set to occur after 3 or 4 and 1 half seconds of no QRS detection.

For embodiment that include more sensors and/or electronics, additional sensors could be added to benefit the patient. One particularly useful sensor is an activity sensor based on a single or multi-axis accelerometer, which indicates the level of patient activity and his orientation. By checking for output that indicates the occurrence of a VVS (Vaso Vagal Syncope) episode, for example, the patient falling from an episode) such an addition offers an improved trigger for events that might otherwise be missed by an arrhythmia detector set up like in FIG. 3D. Such a sensor trigger could replace the circuitry of 3D.

Additional circuits may be provided to support additional functions if desired, however in order to reduce size and power is the long term monitoring of the subcutaneous circuit should be kept to a minimum. Such additional circuits could support temperature sensing, oxygen sensing, pressure sensing, respiration sensing, and any other kind of sensing that can be demonstrated to have been known for implanted devices. They may each have their own auto triggers based on sensor output, or depend on manual triggers. Additionally, activity sensing or positional sensing devices can provide additional input for recordation and or autotrigerring functions. As new sensors become available they may also be incorporated into these designs.

In considering size, the maximum dimension of the device need be only the minimum required dimension for good signal to be obtained from the two electrode areas. In our studies we have found useable signal for ECG monitoring at a distance of about 1/2 inch (1 cm). The best minimum electrode distance for current electronics at reasonable prices appears to be from 1/4 inches to 2 inches.

ECG recording functionality for preferred embodiments

The most important function of the simple versions of this invention is the ability to continuously sense and record the subcutaneous (or intramuscular) ECG. The device continuously records and monitors the subcutaneous ECG in an endless loop of memory. In its primary mode the device is triggered to save/retain in memory the last X minutes or seconds of ECG data by the patient subsequent to feeling symptoms of interest (e.g. syncope, palpitations, etc.).

In the preferred embodiment with 128K of memory the device can store 42 or 21 minutes of ECG, which can be reset after offloading by telemetry to an external device for analysis and display. In one form there are four modes settable for patient trigger only and in another form there are autotrigerring. In the patient only (also called “manual”) trigger modes, the patient can capture either one or three events between offloadings at either no compression or at a compression ratio of 1:2 or some other device supported ratio.

When setting the mode of the implant, the physician or attendant can decide whether to record data in a compressed mode or not in the preferred embodiment. If greater detail of the triggered ECG is required than can be developed from compressed data, the physician should select non-compressed recording, thereby limiting the time available to record. In some embodiments sample rate may be modified as well, but this is not preferred.

Compression is preferably done using a known compression algorithm implemented in hardware. Many types are known and software compression could be used if desired too. An excellent and easy to implement example is found in the article Arrhythmia Detection Program for an Ambulatory ECG Monitor by Mueller, copyright 1978, ISA, ISBN 876645, attached to this document as Appendix A. Using this algorithm in one embodiment we have used a pre-trigger time of record of a maximum of 2400 seconds and a maximum post trigger record of 120 seconds, and at the higher sampled or less compressed rate of 1200/60 for a single event and 3600 for events. These time values are obviously only examples and the reader can set whatever time he or his physician feels is appropriate within the ambit of this invention. After such a record is made the device memory locations are full and will be overwritten by the next triggered event since in the preferred embodiment the memory is maintained in a continuous loop.

Additional modes include those with pure autotrigerring, which can mirror the patient triggered only modes if desired. It should be considered that with autotrigerring events, the determination by the device of an event worth recording and the number of taps (advantage of that the trigger is itself will be faster than the patient finding his device for activation or otherwise activating the device, so the pre trigger time record can be smaller. In one preferred embodiment the memory is segmented to allow for 14 autotrigerring and 3 manual triggers. Further detail regarding modes is described with reference to FIGS. 11 and 12.

The patient activated triggering of a preserved form of the recorded ECG signal can be carried out by using a small handheld external device which may be of any number of different forms. A few ways is through a handheld battery powered device which uses a coded radio frequency telemetered signal through the skin to the device, on the press of a button. A simpler device a small handheld used to close a magnetic switch within the implanted device to trigger it by holding the magnet close or patting the area of the body that has the implant a set number of times with the magnet. Other methods for triggering ECG data retention in memory (each of which has i.e. is own advantages for implementation) are to use physical tapping or slapping of the finger or hand on the skin over the device in a particular cadence and/or number of taps (advantage of that the trigger device is needed. With such methods the disadvantage is that the patient needs to memorize the triggering sequence. Matched voice activation with a known command is possible but the complexity at this time of discerning voice commands precludes such activation for the present time, but could be in future devices using this invention. Another approach is light activation through the skin using a light source and receiver, auditory/sonic activation using a handheld auditory/sonic source held over the skin with a microphone receiver in the device. All these methods are patient activated and require patient compliance or cooperation, a feature this device was designed to avoid. Accordingly in conjunction with one of these patient triggers or alone, an automatic activation or trigger for holding a chunk of memory should be included. This could be activated by automatic recognition of an arrhythmia, a heartbeat too fast or too slow, or for any other condition the device may be set up to find.

If a patient trigger is used it is advantageous to provide feedback to the patient indicating whether the attempt to trigger long term storage of the event was successful. To accomplish this the implant should telemeter out a signal that indicates it has recognized a valid trigger. (This of
course requires additional circuitry and usage of the limited available power supply. The external triggering device then notifies the patient via the triggering device or through some known alarm mechanism whether they have or have not properly triggered the implanted device. This notification can be one of any combination of a number of feedback methods including: one or two visual sources such LED’s, an auditory source such as a beeping speaker in one or two tones, or a tactile source such as a vibration. See also U.S. Pat. No. 5,518,001 for other potential trigger-indicator ideas for a hand-held patient activated trigger device.

Features and Construction of the preferred embodiment implantable devices

Referencing now to FIG. 11 in which a block diagram of a functional model 110 of the controller and memory 111 of a preferred embodiment device is illustrated. The memory is generally organized as a continuous loop of, preferably, 8 bit addresses starting at address 0 and looping back around to address 0 through line 124. By telemetry or hard-wired input during manufacture 120, a mode selector 121 is set so as to divide the memory 111 into working segments 111a–d. The address of the start of each of these segments is indicated with lines 112.

Since this device is used for recording physiologic data, after the data is compressed, converted, formatted and is in appropriate digital form, it is continually recorded in the memory 111. The address value at the tip of arrow 122 in the combined memory space 111d, 111c is monitored by a program counter register 113.

The size of each memory segment set in a given mode limits the amount of data available for each triggered event. In the preferred embodiment, using only one program counter set of registers, the flexibility to accommodate two different trigger lengths can be limited. Alternate forms of memory allocation are available. For example, organizing the entire looping memory as one unit and marking each trigger would allow more flexibility but increase the overhead. See for example the memory structure in Enigma, U.S. Pat. No. 5,339,824, FIG. 7, incorporated herein by reference in its entirety.

To use a single program counter the actual trigger address minus the time (in memory location storage events) required to have already stored the amount of data needed for pre event analysis for that trigger is stored as a value in the trigger location register 116 of FIG. 11. If a larger time for pre trigger recording is required by a trigger occurring during an already triggered event (say, a manual trigger follows the occurrence of an auto trigger), the value in the trigger register can be decremented, thus yielding a larger pre trigger time period in the allocated memory segment for this event. A priority system for whether to extend the pre trigger record is simple to implement but again would require additional hardware and is not preferred. In fact the simplest construction ignores any new triggers once a trigger is set until the results of comparing the program counter with the trigger register corresponds to a match in value.

It is preferred to save more data for a manual triggered event than an auto triggered one because upon recovering from an event the patient has enough time to recover, get their wits about them, and find the triggering device. Manual triggering may therefore be set to record in double or multiple sized segments. FIG. 11’s segments 111c and d are joined by looping arrow 122 to give effect to this concept.

Because the memory size is preferably quite limited a time record or first-in-first-out pool record should be kept on order that the newest triggers record only over the oldest events segments. An additional preferred feature allows for a mode that prevents recording over any triggered event segment. This is preferably implemented by a counter which fills for each segment used and has storage for the set number of looping segments. When it is full recording of new events stops.

When a trigger is activated and under the control program of the device is allowed, a signal 115 is permitted by some control gate 117 to allow the program counter address to be loaded into a trigger location address register 116. After loading, each subsequent clock cycle or set of clock cycles depending on the configuration of the device will load the trigger location from 116 into a comparator 118 to compare this location with the program counter address stored in register 113. When comparator 118 finds that they match, an appropriate output is generated to start the next loop via control circuit 119. This control circuit 119 will cause the mode selector to point to the next available loop location effectively placing that into the program counter 113.

The diagrammatic algorithm 100 to indicate the flow of this information is found in the illustration of FIG. 12 in which an electrode signal 101 is input filtered, converted from analog input to digital values, compressed and formatted if desired in step 102 so as to be in appropriate form to store in a memory location designated by a program counter pointer.

This data word’s form could be containing a value representing input signal compressed at various available ratios, and may be mixed with other information like data provided by another sensor or clock data. The data stored will of course carry information related to the signal taken at the sampling rate. Thus lower sampling rates to save power will adversely affect the usefulness or detail of the data. Whatever its preferred form, each data point stored as a word is referred to as a chunk.

Output form step 102 provides the next chunk of data to the next memory location in step 103.

Device checks to see if there is any trigger pending after storing each chunk of data in step 104. If not, the next chunk of data is stored. If there is, the device preferably checks to see if there is another trigger already set and if so either ignores it or resets the value of the reserved looping memory area (like areas 111a–d in FIG. 11) to accommodate a larger trigger or it ignores the trigger if it is smaller or if it indicates a smaller value needs to be stored. If on the other hand, no trigger is already set, then a new trigger location is recorded in the trigger location memory and then the next memory location is written with the next chunk of data. At step 107 if the trigger location is equal in value to the program counter, the device knows that it has gone through the entire loop reserved by the mode selector for this particular event record and then moves on to the next loop location, step 108.

It should be recognized that any of the inventive concepts taught herein may be applied to implantable devices to supplement their other functions, such as a supplemental recording system for a pacemaker, implantable drug pump, etc. Further, known enhancements to telemetric communication can be used to automatically activate offloading
of data to a device located in the patient's home. Such a device could send its received communications to the attending care giver/physician's office at some convenient time, telephonically or otherwise so as to enable close compliance with prescribed follow-up of patient conditions. This invention is not understood to be limited in scope except by the following claims.

What is claimed is:

1. A minimally invasive implant for implantation beneath a skin and into a living body comprising:
   a shell housing means having an inside and an outside, said outside forming a shape and having electrodes for sensing a physiologic parameter of said body, said electrodes located on said outside such that a substantially fixed spacing is maintained between said electrodes on said outside's shape, said electrodes being for electrical connection with the body and wherein said housing shape has a longitudinal dimension exceeding a transverse dimension, said transverse dimension being of a size suitable for insertion into said body with minimal opening requirements to the skin of said body, said minimal opening size being substantially no greater than ½ inch in maximum diameter.

2. An implant as set forth in claim 1 wherein said outside shape has exactly two electrode areas located substantially at opposite ends of said longitudinal dimension.

3. An implant as set forth in claim 2 wherein said input means is a differential amplifier connected between said two electrode areas.

4. An implant as set forth in claim 1 wherein said memory is organized into a continuous loop such that each new datum regarding said physiologic parameter is stored in a subsequent memory location until said memory is full wherein the first location is overwritten and wherein a memory control means marks off segments of said memory such that triggered segments are not overwritten but skipped.

5. An implant as set forth in claim 1 wherein said memory is organized into a set of segments controlled by a mode control means for indicating location addresses of each segment and wherein each segment is organized into a continuous loop such that each new chunk of data regarding said physiologic parameter is stored in a subsequent memory location in a first segment loop until a trigger occurs indicating that an event should be stored, whereupon the trigger location is recorded and compared with a program counter which is updated by one memory chunk location after each new chunk is written, such that when said program counter value compares positively to said trigger location value, said segment loop memory is full whereupon the address of the next available segment is loaded into the program counter and the next chunk of data is stored at that new program counter location.

6. An implantable device as set forth in claim 5 wherein a counter means counts the number of segments holding recorded event data due to triggering events.

7. An implant as set forth in claim 1 wherein said electronic circuitry further comprises a memory controller means for storing data and wherein said memory controller means further comprises a data compression algorithm for directing the accumulation of said data into said memory means in accord therewith.

8. An implant as set forth in claim 7 wherein said memory controller means stores data in accord with a turning point data compression algorithm implemented in hardware.

9. An implant as set forth in claim 1 having an automatic trigger means comprising means for determining if a series of signals representing QRS complexes represents a heart rate that exceeds or falls below a predetermined range of rates.

10. An implant as set forth in claim 9 wherein said autotrigger means is enhanced by an additional sensor means in the device that determines position and movement, such that indications of VVS, are triggered based on output from said sensor means.

11. An implant as set forth in claim 9 wherein said device comprises communication circuit means responsive to patient signals that activate a trigger responsive to patient input.

12. An implant as set forth in claim 9 wherein said autotrigger means is enhanced by an additional sensor means in the device that determines position and movement, such that indications of VVS and other conditions leading to a loss of consciousness are triggered based on output from said position and movement sensor means.

13. An implant as set forth in claim 1 having an automatic trigger means comprising means for determining if a series of signals representing QRS complexes represents a heart rate that exceeds or falls below a predetermined range of rates, and additionally having a patient activatable manual trigger means.

14. An implant as set forth in claim 13 wherein when the trigger is manual, a temporal size of the memory available to be reserved for a recorded event is larger than the temporal memory size available to an automatically triggered event.

15. An implant as set forth in claim 1 wherein the exterior of the device has at least 3 electrodes wherein one is located on an appendage off a main body.

16. An implant as set forth in claim 1 provided with a suture securing means.

17. A device for recording physiologic events for implant into a body, said device being encapsulated in a hermetically sealed housing, having a longitudinal dimension substantially greater than a transverse dimension and wherein a transverse cross-section of the device is substantially elliptical or otherwise substantially flat wherein a substantially flat surface resulting from said substantially elliptical or otherwise flat cross section provides resistance to turning.
while implanted and having two electrodes substantially separated from each other along the longitudinal dimension, and having a memory for said recording.

18. A device as set forth in claim 17 provided with a suture securing means.

19. A device as set forth in claim 17 wherein said device has a shape adapted to be injectable with a trocar-like device, so as to be shaped for slidable mechanical urging against an inner surface of such a trocar-like device.

20. A device as set forth in claim 19 wherein said device additionally has inherent surface characteristics adapted to avoid movement once insertion is complete.

21. An implant as set forth in any of claims 1–6 or 7–20, wherein a sensor provides temperature data for recording in said memory.

22. An implant for recording physiologic events in a body, having a hermetically sealed housing with a longitudinal dimension substantially greater than a transverse dimension and wherein a transverse cross-section of the device is substantially elliptical or otherwise substantially flat wherein a substantially flat surface resulting from said substantially elliptical or otherwise flat cross section provides resistance to turning while implanted, and having sensors within said housing for generating data regarding physiologic conditions within a patient's body and circuit means for storing representations of said conditions in a memory means also within said housing.

* * * * *
LONG-TERM, AMBULATORY PHYSIOLOGICAL RECORDER

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Abstract
A self-contained, compact, long term, ambulatory physiological recorder is designed for mounting directly to the body of a patient, immediately adjacent to the organ or system that is to be monitored, and is adhesively and covertly held in place and comfortably under clothing by the very transducer, skin electrodes that detect the physiological information to be recorded, and thereby increasing continuity and decreasing artifact by obviating the need for numerous and cumbersome, hanging electrode leads as well as unsightly and cumbersome recorder pouches suspended from shoulder straps or belts.
FIG. 3
FIG. 7
LONG-TERM, AMBULATORY PHYSIOLOGICAL RECORDER

BACKGROUND OF THE INVENTION

1. Field of the Invention

Generally speaking, the invention relates to apparatus and processes for long term, ambulatory monitoring and accumulation of human physiological data. More specifically, the invention disclosed herein consists of a miniature, solid state recorder for ambulatory monitoring of body signals over extended periods of time, sealed against moisture and mounted under all clothing, and supported on a bridge between at least two adhesively attached sensor electrodes in conductive contact with the skin. Provision for direct mounting of the solid state recorder is made possible by the recorder’s light weight and flexible structure, and by recent advances in the manufacture of very small memory chips and subminiature solid state, lightweight processor chips incorporated in the invention. The invention not only provides for recording and storing physiological data, but also provides the sensor data input mounts as well as a data output terminal to transfer stored information to a data processing and display unit.

2. Description of the Prior Art

Many and varied long term ambulatory monitoring devices and systems have been developed and marketed over the years with numerous improvements made by applicant herein; most dealing with improved means to provide to the patient a higher and higher accuracy in the assessment of a patient’s risk of sudden death from arrhythmia and other life threatening signal abnormalities. The monitoring process, as applied to electrocardiography, was named after its inventor and pioneer research physicist, Norman J. Holter, President of the Holter Research Foundation of Helena, Montana. Holter’s co-inventor and technical assistant on the original Holter concept was Wilford R. Glasscock. The original Holter concept and invention was assigned to Del Mar Engineering Laboratories of Los Angeles, Calif., under technology license from the Holter Research Foundation dated Apr. 19, 1962, and was filed in the US Patent and Trademark Office by assignee, Del Mar, on Jul. 6, 1962. The application issued as U.S. Patent No. 3,215,136 on Nov. 2, 1965 and taught not only a long term, ambulatory ECG recording technique but also Holter’s data reduction and presentation format promoted under Del Mar’s US registered trademarks Electrocardiograph®, AVSEP®, and Arrhythmograph®. The 136 patent specifically taught a means for processing electrocardiographic signals and more particularly to a means for obtaining large quantities of electrocardiographic signals and to a means for facilitating the processing and observing in graphic form of large volumes of such signals in a short interval of time.

Based on the presentations set forth in the foregoing 136 Holter patent, Del Mar Engineering Laboratories produced for clinical cardiology the first complete Holter Monitoring Systems in 1963 which immediately inspired research activity of pioneer research cardiologists: Dr. Eliot Corday, Dr. Lawrence E. Hinkle, Dr. Herman K. Hellerstein and Dr. John S. Gilson. As a result of several years of clinical testing by these physicians of the Holter Monitoring procedure resulting in numerous publications in medical journals on results emanating from test on hundreds of patients, Holter Monitoring was endorsed and recommended as a new revelation in cardiovascular clinical practice, and was eventually adopted as a standard practice worldwide.

Since 1965, a progression of Holter improvement patents have issued over the years, notably that of Oct. 31, 1978, U.S. Pat. No. 4,123,785, “Recorder for Cardiac Signals with Manually Activated Event Marker” by inventors Issac R. Cherry and Donald L. Anderson of Del Mar Avionics, successor to Del Mar Engineering Labs. The 785 patent disclosed a small, hip side mounted tape recorder for ambulatory recording of cardiac signals over a twenty-four hour interval and included a clock with visual display and a patient event marker. Cardiac signals are simultaneously recorded on two tracks on magnetic tape wherein each event marker function could also be recorded and activated by the patient to denote the happening of a specific event sensed by the patient that can be easily recognized on playback in relation to heart activity at the time. The 785 Cherry et al. patent was followed by yet many other noteworthy inventions.

The foregoing US patents taught many important developments in Holter Monitoring technology but were yet followed by a series of other prior patents of Del Mar Avionics dealing with Holter Monitoring concepts. U.S. Pat. No. 5,352,934, was issued August 1985, titled “Pacemaker Monitoring Recorder and Malfunction Analyzer”, by inventor George J. Kelen, M.D. The Kelen 934 patent disclosed a hip side mounted magnetic tape recorder which detects and records sequential pacemaker spikes in one channel in a waveform compatible with corresponding ECG signals recorded in a second tape channel. The system further includes an analysis module connected to the playback unit for receiving both the ECG and pace spike signals and is adapted to playback both channels of information at 120 times recording speed. An analysis module in the recorder has counters to accumulate the number of paced beats and fusion beats. The system is further configured to sense malfunctions, failure to sense, failure to capture, and abnormal bradycardia.

U.S. Pat. No. 5,109,862 issued May 8, 1992 and was titled “Method and Apparatus for Spectral Analysis of Electrocardiographic Signals,” by inventors George J. Kelen, M.D. and Raphael Henkin, Ph.D. The Kelen 862 patent discloses a signal processing and analysis method and apparatus for plotting and measuring ECG signals where the graphic plots and numeric parameters measured reveal abnormalities of electrical conduction within the heart thought to anticipate abnormal heart rhythm, arrhythmia. The invention employs Fourier analysis of short overlapping segments of ECG signal to create a three dimensional electrocardiogram map.

U.S. Pat. No. 5,205,295, issued Apr. 27, 1993 “Method and Apparatus for Holter Recorder with High Resolution Signal Averageg Capability for Late Potential Analysis,” by inventors Bruce Del Mar and Issac R. Cherry. The Del Mar 295 patent discloses a method for digital signal averaging of selected signals and storing for future playback. The averaged signals, several times per hour in a 24 hour period, are correlated with previously defined correlation coefficients to yield summed results that have eliminated nonrepetitive noise. Information so accumulated enable micropotential analysis of cardiac electrical activity.

Since 1996 digital data storage capacity in lightweight disc drives and printed circuit card, flash memory components has progressed in production to the point where solid-state ambulatory physiological recorders can be made at reasonable cost. They offer an advantage over ambulatory physiological tape recorders having no moving parts and no need for separate analog-to-digital data conversion. Solid-state recording now represents a formidable improvement in the art of ambulatory physiological recording.

Long-term ambulatory physiological and Holter recorders have been conventionally worn in a protective pouch slung
by straps over the shoulder outside the clothing or hung on a person’s belt, again outside the clothing. Many problems and inconveniences can occur while wearing such conventional ambulatory physiological recorders, especially because of the necessary prolonged, continuous recording times involved. Dressing and sleeping become troublesome because of the long wire harness required on existing recorders. Electrodes often get pulled off the chest by the wire harness during sleep and active physical activities. The recorder may also receive rough treatment from dropping to the floor or exposure to other hostile environments. With the invention disclosed herein, compactness and simplicity replace a variety of components and complications. With the new invention disclosed herein, exercise, including walking and running, is unrestricted. The daily routine of sleeping, dressing and bathing need not change! And, for the clinician, this invention can create more reliable long-term monitoring of physiological signal.

SUMMARY OF THE INVENTION

As will be more particularly described herein, the ambulatory data recorder of this invention utilizes compact, contiguous, and high continuity integrated circuitry; A-to-D converters; a CPU operating system; a body/sensor attachment and supported system; printed circuit, flash memory and DC power to record one, or more, channels of physiological signal with optional event marking and optional activity monitoring, as well as means to program specific periods of recording with or without data compression. The recorder is provided with at least two adhesive body sensor chest attachments that not only support the recorder housing but also concomitantly sense cardiac or other body activity; the recorder system may, however, have multiple sensor attachments as well as serial or parallel porting to download recorded data for digital analysis and display of full disclosure or summary data report on a conventional personal computer (PC) or other digital retrieval system. In the preferred embodiment, there are at least three sensor attachments mounted in a triangular manner supporting the CPU recorder therebetween.

OBJECTS OF THE INVENTION

It is a primary object of the invention to provide for a long term, ambulatory physiological data recorder design to obtain more complete and reliable ambulatory physiological recordings by providing a self contained recorder device without electrical leads for mounting on the patient’s skin directly adjacent the organ or system to be monitored.

It is yet another substantial object of the invention to enable a physician to attach a compact recorder system to a patient in an environment that is more convenient and comfortable to wear. Higher electrical continuity and more convenient and comfortable recorder attachment and support objects of the invention are made possible by the simplicity of wearing this novel recorder at the signal source and avoiding recording failures or introduction of artifact attributed to loose rigging of the apparatus on the body.

Yet another object of the invention is the provision for recording ambulatory physiological signals in an unseen, covert fashion;

Still another object is to provide ambulatory physiological recording means and processes without the need to change patient’s daily routine;

Another object is to provide ambulatory physiological recording without restriction to daily exercise or position of the body or limbs, including walking and running;

Yet another object is to reduce the cost of obtaining ambulatory physiological recordings for the patient, the medical practitioner, and the government;

Still another object of the invention is to provide an ambulatory physiological recording system wherein body activity sensors located directly within the recorder can provide information on body orientation and acceleration simultaneously with other sensor data to measure the relationship between physical activity and sensor data throughout the recording period;

Another object is to provide an ambulatory physiological recorder that is pliable and comfortable to wear by having flexibility to fit the contours of the body across electrode sensor locations;

Yet another object is to provide a readily available ambulatory physiological recorder for short-term recording of body signals while undergoing an informal treadmill or improved stress test using a limited number of sensors. The period of recording may be short, but the data analysis can be reported quickly from the digital writeout device, already available for other related purposes. Such a stress test can be conducted in the physician’s office as an adjunct to other long-term physiological monitoring tests.

BRIEF DESCRIPTION OF THE DRAWING

FIG. 1 illustrates a perspective view of a first embodiment of the ambulatory physiological recorder invention.

FIG. 2 illustrates an exploded view of FIG. 1.

FIG. 3 illustrates the preferred placement of the FIG. 1 ambulatory physiological recorder on the body.

FIG. 4 illustrates the embodiment of FIG. 1 with provision for additional multiple sensor leads.

FIG. 5 illustrates a perspective view of a second embodiment of the ambulatory physiological recorder invention.

FIG. 6 illustrates an exploded view of FIG. 5.

FIG. 7 illustrates the preferred placement of the FIG. 5 ambulatory physiological recorder on the body.

FIG. 8 depicts a block diagram of the printed circuit board and components of the invention.

FIG. 9 depicts a block flow diagram of the software recording process of the invention.

DETAILED DESCRIPTION OF A PREFERRED EMBODIMENT

Although the following description of a preferred embodiment will describe a specific embodiment of the invention concept, it will be appreciated that the scope of the invention concept extends to many obvious and similar other embodiments and will be limited by the breadth of the claims alone and not by the description of the preferred embodiment herein. Only when there is an ambiguity of the terms or meaning of a claim as drafted will the description be necessary to interpret the claims. It will be further understood that like numerals on different figures of the Drawing refer to the same element on each figure.

First Embodiment

A perspective view of a first embodiment of the invention is clearly illustrated in FIG. 1 wherein a relatively flat, triangular shaped recorder housing 10 is provided with three adhesive electrode pads, 12, 14, and 16 for comfortable attachment to the skin of a patient to be monitored. Although housing 10 is illustrated in the preferred triangular form of a heart, it can be appreciated that housing 10 could be
virtually any shaped polygon, triangle, square, rectangle, pentagon, hexagon, circle, etc. All the hardware and firmware components of the recorder are totally encapsulated in the water proofed housing 10 and are coupled to electrodes on pads 12, 14, and 16, and are mounted on one or more printed circuit boards (PCB) inside housing 10. Housing 10 is designed with a curved circumferential edge to avoid sharp edge injury or irritation of the device with the patient’s body. Also for ease and comfortable wearing, housing 10 is preferably constructed of a soft, pliant, lightweight, and rugged material, for example a soft plastic or soft rubber. Alternatively, housing 10 may be constructed of harder materials if necessary for durability and covered with a soft textured material such as Santoprene, manufactured by Advanced Elastomer Systems of Akron, Ohio. After a recording has been made, a Personal Computer (PC) or other data analysis system can be coupled to a data output terminal 20 of recorder housing 10, whereby data can be analyzed and archived for later use, and the recorder can be cleared, cleaned and mounted on another patient.

Referring now to FIG. 2, an exploded perspective view of the physical construction of the ambulatory physiological recorder is illustrated. Housing 10 consists of a planar lid 22 attached by screws, adhesive means or “hook and latch” Velcro means to a peripheral housing wall 24 which, in turn, is attached by similar means to a planar base 26 with a printed circuit board 28 suspended therebetween. Three electrode sensors, a ground sensor 30, a positive sensor 32, and a negative sensor 34 residing in pads 12, 14, and 16, respectively, are insertably clipped into respective conductive receptacles 36, 38, and 40. Conductive arm pads 42, 44, and 46 couple electrodes 30, 32, and 34, respectively, to relevant components on PCB 28.

PCB 28 may consist of two or more parallel PCB’s in different embodiments but in all cases performs the function of holding all necessary ambulatory recorder elements. The PCB is powered by one or more removable batteries 48 and 50 and is controlled by a micro processor chip or central processor unit (CPU) 52. Physiological data is recorded in one or more flash memory chips 54 and 56. Once a recording session as been completed, data stored in chips 54 and 56 is passed out through output terminal or universal serial buss (USB) 20 to a typical PC conventionally utilized in data analysis. An event button 58 is also incorporated on PCB 28 to permit the patient to press to data in memory noteworthy or specific “happenings/events” that may occur during the recording process. Event button 58 is positioned immediately under flexible lid 22 and is activated by simply depressing the center of lid 22. Various other electronics, e.g. chips, diodes, transistors, capacitors, inductors, op amps, flip flops, counters, etc., on PCB 28 are conventional in the art and will not therefore be discussed in detail herein.

In a long term ambulatory heart monitoring application, i.e. in a “Holter Monitoring” application, the mounting orientation of the first embodiment 10 of the ambulatory physiological recorder is illustrated in FIG. 3. A typical patient body 60 is depicted with recorder 10 flatly disposed thereon. Ground electrode pad 12, positive electrode pad 14, and negative electrode pad 16 are adhesively and conductively attached to the patient’s chest in a position generally over the heart wherein the positive and negative terminals are in a relative vertical position from top of the heart to the bottom thereof.

For physiological monitoring activities other than Holter (heart) Monitoring, or for more slices of the heart in Holter applications, an adaptation of the first embodiment is indicated in FIG. 4, wherein multiple leads 62, 64, 66, and 68 extend from an input port (not illustrated in the Drawing) adjacent to output port 20, to individual peripheral electrodes 70, 72, 74, and 76, respectively. By such means, the fully self contained ambulatory physiological recorder of FIG. 1 is easily expanded to accommodate more information input channels in addition to the built-in electrodes 30, 32, and 34 illustrated in FIG. 2.

Second Embodiment

FIG. 5 illustrates a perspective view of a second embodiment of the invention uniquely designed to adapt to a female torso more so than a male chest where a woman’s breast might interfere with placement of housing 10 and tightly configured terminal pads 12, 14, and 16, and where the size and unavoidable contact of a woman’s breasts would necessarily cause a great degree of discomfort, especially when worn for period of time.

As opposed to the triangular/heart shaped recorder housing 10 of the first embodiment of FIG. 1, configured for mounting across the chest and over the heart, the second embodiment of FIG. 5 depicts a kidney or bean shaped recorder housing 100 configured for placement and mounting high on the chest above the breast level, and having essentially the same components as the first embodiment of FIG. 1 with the notable exception that the corresponding negative terminal 134 is not in housing 100 but extends down over the heart and between the breast for ease in wearing the recorder for an extended period of time. The second embodiment of FIG. 5 illustrates a first terminal pad 112, a second terminal pad 113, a third terminal pad 106, and a fourth terminal pad 108. First terminal pad 102 serves as a ground terminal, third terminal pad 114 serves as positive terminal (+), and fourth terminal pad 116 serves as a negative terminal (−). Negative terminal 134 on fourth pad 116 attaches physically and electrically by similar adhesive means as with all other terminal pads and is coupled to housing 100 by and input terminal 102 and coupling lead 104. Terminal pad 113 is not a conducting terminal but serves only as an additional adhesive means, in addition to adhesive terminal pads 112 and 114, to support and maintain the ambulatory recorder on the chest of the patient being monitored. Housing 100, in like manner as with housing 10, provides for output of accumulated data at an output terminal 120 to a conventional PC for conventional analysis, evaluation and archival of data.

Referring now to FIG. 6, an exploded, perspective view of the physical construction of the of the second embodiment, ambulatory physiological recorder of FIG. 5 is illustrated. As with the first embodiment, housing 100 consists of a planar lid 122 attached by screws, adhesive means, or hook and latch, Velcro, means to a peripheral housing wall 124, which in turn, is attached by similar means to a planar base 126 with a printed circuit board 128 suspended therebetween. Three electrode sensors, a ground sensor 130, a positive sensor 132, and a negative sensor 134 (hidden) residing in sensor pads 112, 114, and 116, respectively, are insertably snapped into respective conductive receptacles 136, 138, and 140. Conductive arm pads 142 and 144 couple electrodes 130 and 132, respectively, to relevant components on PCB 128.

Again, PCB 128 may consist of two or more parallel PCB’s in different embodiments but in all cases performs the function of holding all necessary ambulatory recorder elements. PCB 128 is powered by one or more removable batteries 148 and 150 and is controlled by a micro processor chip or central processor unit (CPU) 152. Physiological data

is recorded in one or more flash memory chips 154 and 156. Once a recording session as been completed, data stored in chips 154 and 156 is passed out through an output terminal or universal serial buss (USB) 120 to a typical PC conventionally utilized in data analysis. An event button 158 is also incorporated on PCB 128 to permit the patient to press to document in memory noteworthy or specific “happenings/events” that may occur during the recording process. Event button 158 is likewise positioned immediately under flexible lid 122 and is activated by simply depressing the center of lid 122.

Various other electronics, e.g. chips, diodes, transistors, capacitors, inductors, op amps, flip flops, counters, etc. that may be necessary as discrete elements of the PCB in order to perform the long term recording function are conventional in the art and will not hereof be discussed in detail herein.

In a long term ambulatory heart monitoring application, i.e. in a “Holter Monitoring” application, the mounting orientation of the second embodiment 100 of the ambulatory physiological recorder is illustrated in FIG. 7. A typical patient body 60 is depicted with recorder 100 flatly disposed thereon. Ground electrode pad 112, positive electrode pad 114, and non conductive electrode pad 113 are adhesively attached to the patient’s upper chest in a position generally above the breasts with the negative electrode pad 116 positioned below the breasts coupled via lead 104 to recorder housing 100, wherein the positive and negative terminals are in a relative vertical position from top of the heart to the bottom thereof.

Referring now to FIG. 8, a block flow diagram of the functional electronic components of PCB’s 28 and 128 is delineated. It should be understood that although the external appearance of first and second embodiments of the invention are uniquely different, the PCB components and function thereof are identical. Therefor, only PCB 28 will be addressed in this disclosure for ease of description and understanding. The block flow diagram in FIG. 8 is designed for a very small and compact, lightweight digital recorder. The recorder circuit on PCB 28 in FIG. 8 is designed to accommodate and record a variety of physiological signals. The recorder is specifically designed with the concept to be fully “self contained” and mounted immediately adjacent the organ or system which is to be monitored to, among other reasons, diminish electrical lead artifact and discontinuity; the recorder circuit is powered by an internal battery 200 (elements 48 and 50 of FIG. 2), physically possesses its own attached sensor electrode input devices, data storage, data manipulation (micro processor), and data output. The circuit is designed to operate in an ambulatory environment for a recording period of at least twenty four (24) hours. The transducer, electrode sensor, analog signal conditioning and sampling rate can be changed to meet the requirements of the data to be recorded.

The transducers 202, e.g. electrode sensors 30, 32, and 34, utilized in any particular application will depend on the application of varying bioelectric potentials, such as electrocardiograph (ECG), electroencephalograph (EEG), electromyograph (EMG), etc. Transducer 202 would be appropriate skin contact electrodes such as electrode sensors 30, 32, and 34; however, for acceleration, activity or body movement sensors, the transducer would be acceleration sensors; for pressure recording, the transducer would be a pressure transducer; and for skin temperature recording, the transducer would be a thermal type transducer.

Transducer 202 feeds a data signal into an analog signal conditioner 204, the exact elements of which will depend on the transducer type and the recording characteristics desired. These characteristics would include sample rate, resolution, and amount of data to be stored. The signal conditioning function is further characterized by the type of input, the necessary gain, the bandwidth, the signal to noise ratio, the maximum input signal, the maximum output signal, common mode rejection and the operating environment requirement. The primary function of analog signal conditioner 204, however, is to amplify transducer 202 output signal to the level required by an analog to digital converter 206.

Analog to digital converter (A/D) 206 primary function is to sample analog signals on each cycle of a sample clock 208. The A/D output is a digital value represented by one’s and zero’s on a set of parallel lines. In the preferred embodiment, the typical number of lines or bits would be eight (8). A/D converter 206 is in turn connected by an eight bit data bus 210 to a central processor unit (CPU) 212 within micro processor chip 52.

Central processor unit 212 in the preferred embodiment is a standard CPU used in micro processor and controller environments. CPU 212 function is to read instructions stored in a read only memory (ROM) 214 and to execute those instructions. CPU 212 is the heart of any stored program controller. CPU 212 receives and outputs data through a bidirectional data bus 216 through parallel ports, serial ports and other undefined control pins. An output address bus 218 determines which of the devices connected to data bus 216 is to receive data currently on data bus 216. The address also determines from which device CPU 212 will read data. Other control lines determine weather the data is being determined an output or an input to CPU 212 over data bus 216.

Read only memory (ROM) 214 stores program instructions to control operation of CPU 212. The program instructions stored in ROM 214 is referred to as the embedded program code. Several different programs could be stored in ROM 214. An input by an operator through a universal serial bus port (USB) 220 could determine which one of the programs will be executed. Size of memory 214 will vary with the particular microprocessor used; often in the range of 1 k to 64 k bytes, but typically 16 k bytes in the present application.

Random access memory (RAM) 222 is used by the program executed by CPU 212 for temporary storage of data. Typical use of RAM 222 is as a scratch pad memory, buffer memory and program stack.

Flash memory 224 (elements 54 and 56 of FIG. 2) is a type of nonvolatile memory used in digital devices to store large amounts of data in a small volume. Some of the properties of this type of memory are large volumes of data that can be stored in small chips, e.g. 8 megabytes in a chip 20x12.7 mm. Power can be removed from the device and date will be retained. Data must be written to and read from the memory in blocks of data, typically in 512 byte segments; not a very fast memory.

A built in real time clock 226 makes effective system time and data correlation of data digitized for storage.

Referring now to FIG. 9, a flow chart of the software/firmware operation of the ambulatory physiological recorder (identical for both first and second embodiments) succinctly delineates the logic process for recording data by byte. Briefly when the recorder is first powered on and calibrated then mounted onto a patient, data is received from a transducer 202, signal conditioned 204, A/D 206 converted to digital, passes into microprocessor unit 52 to CPU 212 byte by byte to be stored in a temporary buffer until full at which
time the accumulated data bytes are passed to flash memory
224 for a predefined recording period. At the end of the
recording period or when flash memory is full, data is passed
out USB 220 to for example a personal computer (PC) for
later analysis and evaluation. The recorder is then physically
cleaned and electronically cleaned, data erased, and set up
for another patient recording session.

Although the foregoing provides a somewhat detailed
description of the invention disclosed, obvious embodiments, alterations and improvements are considered a
part of the invention as well. The true scope and extent of
the invention concept will be more clearly defined and
delineated by the appended claims.

We claim:

1. A flesh/body mounted, self powered, long-term, ambu-
latory data processor and recorder for accumulation of
physiological and somatic data from a patient, comprising:
environmentally sealed recorder housing means for elim-
nation of moisture, dust, and other contaminants from the
data processing and recording process;
dual function recorder housing mounting means for adhe-
sively holding said recorder housing in a desired position
on the flesh and body of said patient, while concomitantly acting as a data input transducer and
physiological sensor of said somatic data; and
microprocessor system controller means disposed in said
recorder housing for receiving, processing, accumulating, recording, and outputting at least one
channel of said somatic data;
reusable data storage means disposed in said recorder
housing.

2. The recorder housing means according to claim 1,
wherein said housing means is soft, flexible, and compliant
to body tissue movement.

3. The recorder housing means according to claim 2,
wherein said housing means comprises:
a planar lid;
a planar base disposed parallel to said lid, to be placed
adjacent the patient body/flesh to which said recorder is
to be mounted;
a rounded, circumferential seal and wall disposed around the
periphery of and between said lid and base, thereby
enclosing a sealed housing environment therebetween;
and
a printed circuit board extending across said sealed hous-
ing environment for supporting said system micro
processor, memory, and input/output means.

4. The sealed recorder housing according to claim 3,
wherein said base has provision for at least two snap-on
receptacles for recept of at least two snap-on transducer
sensor means and adhesive skin attachment means.

5. The recorder housing mounting means according to
claim 1, wherein said dual function, transducer/attachment
means consists of a snap-on electronic sensor probe sur-
rrounded and attached to the patient skin by an adhesive pad.

6. The recorder housing mounting means according to
claim 5, wherein said sensor/attachment device is further
attached by swivel mount means to said recorder housing,
thereby allowing more comfortable and flexible movement
of the patient's skin to which said recorder is supported.

7. The ambulatory recorder according to claim 1, wherein
said data storage means consists of at least one solid state
flash memory chip.

8. The ambulatory recorder according to claim 1, further
having data output means consisting of a Universal Serial
Bus coupling said micro processor means and data storage
means to an exit port of said recorder.

9. The ambulatory recorder according to claim 1, further
having data output means in the form of an insertable flash
memory card.

10. The ambulatory recorder according to claim 1, wherein
said self powered function of said recorder consists of
at least one battery disposed within said housing.

11. The ambulatory recorder according to claim 1, further
having patient event marking means for indicating time
related specific events contiguous to relevant recorded
somatic data.

12. The ambulatory recorder according to claim 1, further
having the option for data compression for extending peri-
dods of recorded data.

13. The ambulatory recorder according to claim 1, further
having accometer means disposed therein for further
data recording capacity of patient physical activity and body
movement.

14. Hidden and covert apparatus for monitoring and
recording physiological and somatic data from a patient over
an extended period and in an ambulatory environment,
comprising:
a recorder housing;
means attached to said housing for concomitantly sensing
somatic analog signals and also for attaching said
recorder housing directly to the patient's body/skin and
holding said recorder in place during the recording
process;
central processor unit disposed in said housing for
recording, processing, and for converting said somatic
signals from analog to digital data; and
means for storing said digital data.

15. Covert recording apparatus according to claim 14,
wherein said recorder housing is sealed against environmen-
tal contaminants to include water.

16. Covert recording apparatus according to claim 15,
wherein said recorder housing is constructed of a skin soft,
flexible material and capable of bending with the body area
over which the recorder is mounted.

17. Recording apparatus according to claim 14, wherein
said storing means consists of a solid state, digital, flash
memory.

18. Recording apparatus according to claim 14, wherein a
microprocessor controller system and other supporting data
processing and recording electronics are all mounted on at
least one printed circuit board suspended within said
recorder housing.

19. Covert apparatus according to claim 14, further hav-
ning means for a plurality of additional, conventional leads
extending from said recorder housing on one part of the
body to a variety of other parts of the body.

* * * * *
A system and method for obtaining ECG signals from an ambulatory patient are disclosed herein. The system is configured to be inexpensive, small, and robust for outpatient monitoring. The system is configured to be a low power consuming device. The system provides options for a variety of settings and real-time access to the ECG signals being recorded during the recording period.

28 Claims, 7 Drawing Sheets
FIG. 9

FIG. 10
PORTABLE CARDIAC MONITOR

BACKGROUND OF THE INVENTION

The present invention relates to diagnostic medical devices. More particularly, the present invention relates to portable cardiac monitoring devices.

Through a combination of physiology, diet, and life-style factors, millions of people, just in the United States alone, have or will have some form of cardiovascular condition or disease. For many people, unfortunately, early symptoms of cardiovascular conditions are not obvious or even necessarily present. By the time the condition is apparent, it is often already at an advanced stage. At this point, therapeutic treatment options are limited, and such options are likely to carry considerable risks and costs. Early and accurate diagnosis is therefore critical to treat and stop further advance of cardiovascular conditions.

To this end, patients experiencing possible symptoms are encouraged to notify and be examined by health care professionals. Unfortunately, it may not be possible to accurately diagnose a possible condition if symptoms are generic or not present during examination. Alternatively, after a patient has been diagnosed and treatment decided, the patient’s response to the treatment may need to be monitored so as to determine effectiveness and/or to fine-tune the treatment.

However, it is not practical for a health care professional to constantly monitor a patient for a set period of time, nor for a patient to stay at a clinic (or other locations with health care professionals) for a set period of time, merely for purposes of observing possible symptoms or responses. Instead, ambulatory patients are encouraged to be connected to a monitoring device for a set period of time while going about their regular routine.

An example of such a device is a Holter recorder that records cardiac signals of an ambulatory patient for a period of time, such as 24-72 hours. Holter recorders are typically configured to provide heart activity information, and in particular, electrocardiogram (ECG) recordings over a relatively long period of time. Such recordings permit identification of infrequent and transient disturbances of cardiac rhythm, which may aid in diagnosing patients with vague or intermittent symptoms such as dizziness, blackouts, or fainting spells. Such recordings may also quantify and pinpoint times and/or activities associated with a patient’s infrequent symptoms. A physician may be interested not only in the unusual ECG events but also the background rhythm, which may comprise slower or overall responses to influences such as drug treatment, surgery, an implant, or stress. Moreover, a take-home diagnostic device provides more accurate and meaningful ECG recordings since the ambulatory patient is at a home setting (e.g., a natural or real setting) as opposed to an artificial setting (e.g., a doctor’s office).

Effectiveness of ECG recording devices involve not only how well cardiovascular signals are measured and recorded, but also its ease of use and cost-effectiveness. Typical Holter recorders, unfortunately, are not inexpensive. Use of diagnostic devices, especially home diagnostic devices, are also cost-effective and most beneficial for the end-customer (i.e., patients), but may in fact be more costly for medical practitioners due to device purchase and maintenance costs and loss of revenue from future appointments from a given patient. For clinics with budget constraints, spending thousands of dollars for each Holter recorder can be prohibitive.

Ease of use of typical Holter recorders is problematic. The electrode assemblies in typical ambulatory records are reused for many patients, sometimes up to several hundred patients per assembly. The electrode assemblies are not sterilized between uses. Patients can find the idea of having to wear such cables on their skin for up to several days to be unpleasant.

Typical Holter recorders also tend to be large and thus cumbersome for a patient to carry around at all times during the recording period. And even with the large size, typical Holter recorders can be inefficient in power consumption, which further requires use of large batteries. Due to ease of use issues, it is not uncommon for patients to prematurely end the recording period. Alternatively, patients may be reluctant to even commit to the monitoring because of the degree of discomfort and interference with everyday activities.

Thus, there is a need for a small and lightweight monitoring and diagnostic device for obtaining ambulatory ECG signals. There is also a need for a device that can be taken home with an ambulatory patient for up to several days, provide sufficient data for therapeutic or diagnostic use by health care personnel, and is sufficiently robust and comfortable for take-home use. There is still a further need for a device that is inexpensive and is hygienic. Moreover, there is a need for a device that provides a variety of set-up and data optimization features while still being user-friendly.

BRIEF SUMMARY OF THE INVENTION

One embodiment of the invention relates to an ambulatory electrocardiogram (ECG) monitor. The monitor includes a recorder module, and a set of electrode leads coupled to the recorder module. The monitor further includes at least one cover that encases the recorder module. The ECG monitor is approximately 32 mm x 52 mm x 8 mm. The ECG monitor is attachable to patient’s skin during a monitoring period.

Another embodiment of the invention relates to a method for obtaining electrocardiogram (ECG) waveforms from an ambulatory patient. The method includes coupling at least one disposable component to a recorder module, and attaching electrode leads and the recorder module to the ambulatory patient. The method further includes processing inputs from the electrode leads, and storing the processed inputs. The method further includes powering a flash memory for a minimum duration of time necessary to transfer the stored inputs to the flash memory.

Still another embodiment of the invention relates to a circuitry for obtaining electrocardiogram (ECG) signals associated with an ambulatory patient. The circuitry includes a first integrated circuit (IC) configured to accept differential channels of ECG signals, correct out-of-range ECG signals, and store processed ECG signals. The circuitry also includes a second IC in communication with the first IC, the second IC including a microcontroller. The circuitry also includes a third IC in communication with the second IC. The third IC is configured to store the processed ECG signals from the first IC. Each of the second and third ICs is selectively powered in response to an approximately full capacity of the stored processed ECG signals in the first IC. The average current consumption of the circuitry is less than 1 milliamp.

Yet still another embodiment of the invention relates to a portable cardiac recorder. The portable cardiac recorder includes means for delta-sigma modulating cardiac signals from a patient, and means for correcting the cardiac signals that are out-of-range within a data sampling period. The portable cardiac recorder further includes means for annotating certain of the cardiac signals in real-time, and means
for radio frequency (RF) transmitting the cardiac signals. The portable cardiac recorder also includes means for storing the cardiac signals, and means for moisture proofing the recorder.

Other features and aspects of the invention will become apparent from the following detailed description, taken in conjunction with the accompanying drawings which illustrate, by way of example, the features in accordance with embodiments of the invention. The summary is not intended to limit the scope of the invention, which is defined solely by the claims attached hereto.

BRIEF DESCRIPTION OF THE DRAWINGS

The exemplary embodiments will become more fully understood from the following detailed description, taken in conjunction with the accompanying drawings, wherein the reference numerals denote similar elements, in which:

FIG. 1 is an exploded view of one embodiment of an electrocardiogram (ECG) monitor.

FIG. 2 is the ECG monitor of FIG. 1 in an assembled position.

FIG. 3 is a back side of the ECG monitor of FIG. 1, shown with a moisture resistant sealant.

FIG. 4 is a block diagram of circuitry included in the ECG monitor of FIG. 1.

FIG. 5 is an illustration of a data format of data samples obtained by the ECG monitor of FIG. 1.

FIG. 6 is an illustration of the ECG monitor of FIG. 1 attached to a patient.

FIG. 7 is a block diagram of circuitry included in a base station.

FIG. 8 illustrates ECG waveforms obtained by the ECG monitor of FIG. 1 at different stages of signal processing.

FIG. 9 is a more detailed block diagram of circuitry included in the ECG monitor of FIG. 1 associated with a signal clipping feature.

FIG. 10 is a flow diagram illustrating the utilization of the ECG monitor of FIG. 1.

In the drawings, to easily identify the discussion of any particular element or part, the most significant digit or digits in a reference number refer to the figure number in which that element is first introduced (e.g., element 609 is first introduced and discussed with respect to FIG. 6).

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Described in detail below is a system and method for monitoring cardiovascular activity for therapeutic or diagnostic purposes. A portable monitor device is configured to record electrocardiogram (ECG) signals for a set period of time. The portable monitor device is configured to be small, inexpensive, and lightweight. The portable monitor device is configured for at-home or outpatient monitoring of ambulatory patients. Low power consumption and a variety of set-up and recording features are provided via a customized integrated circuit (IC).

The following description provides specific details for a thorough understanding of, and enabling description for, embodiments of the invention. However, one skilled in the art will understand that the invention may be practiced without these details. In other instances, well-known structures and functions have not been shown or described in detail to avoid unnecessarily obscuring the description of the embodiments of the invention.

Referring to FIG. 1, an exploded view of one embodiment of a portable ECG monitor 100 is shown. The ECG monitor 100 includes a first cover 102, and a recorder module 104, and a second cover 106.

The first cover 102, also referred to as an end cover, is configured to slip over approximately half of the recorder module 104. The first cover 102 is hollow with an opening along one side. A cutout 108 is included at the opening edge of the first cover 102. The cutout 108 is shaped to fit around or encircle an annotate button 120 at the recorder module 104.

The recorder module 104 includes batteries 110, a printed circuit board (PCB) 112, a microcontroller integrated circuit (IC) chip 114, a converter IC chip 116, a pin connector 118, the annotate button 120, and a flash memory IC chip (not shown). The batteries 110 are provided at a first side of the recorder module 104. The batteries 110 are configured to power the ECG monitor 100. In one embodiment, the batteries 110 comprise two silver oxide button batteries, each battery having a diameter of approximately 12 millimeters (mm), a thickness of approximately 4 mm, and a voltage of 1.6 volts.

The PCB 112 is provided adjacent to the batteries 110. The microcontroller IC chip 114, converter IC chip 116, and the flash memory IC chip 400 are electrically coupled to the PCB 112. Although not shown, the PCB 112 includes a variety of electrical components such as capacitors, resistors, electrical leads, data bus, etc. typical for function of the recorder module 104.

The annotate button 120 is provided approximately at the center of the recorder module 104. The annotate button 120 is configured to be accessible when the ECG monitor 100 is in an open or closed position. The annotate button 120 is electrically coupled to the converter IC chip 116. In one embodiment, the annotate button 120 is actuated by applying a downward pressure (e.g., pushing). Alternatively, the annotate button 120 can be a switch, a toggle switch, or a variety of other two position devices. The annotate button 120, to be discussed in detail below, is utilized by a health care professional during the initialization or calibration process and/or by the patient to flag certain portions of the ECG data being obtained.

The pin connector 118 is provided at a side of the recorder module 104 opposite the side of the batteries 110. The pin connector 118 is electrically coupled to the PCB 112. In one embodiment, the pin connector 118 is a 30-pin connector. In another embodiment, the pin connector 118 may comprise less or more than 30 pins (e.g., 28 pins, 32 pins, etc.). In still another embodiment, the pin connector 118 may comprise a connection device other than pins as long as it is capable of high-speed communication with a separate computing device (to be discussed below).

The second cover 106, also referred to as an end cover, is configured to slip over the recorder module 104 (the side including the pin connector 118). The second cover 106 is hollow with an opening along one side. The opening includes a cutout 122 that is configured to fit around or encircle the annotate button 120. The cutouts 108 and 122 are symmetrical to each other.

The side of the second cover 106 opposite the cutout 122 includes a set of openings and connection points for a set of electrode leads 124. The second cover 106 is configured to permit the electrode leads 124 to be in electrical contact with the PCB 112 when the second cover 106 is fully slipped over the recorder module 104. The electrode leads 124 are detachable from the ECG monitor 100.
In one embodiment, the electrode leads 124 comprise a set of seven electrode leads. Six leads serve as three differential channel inputs leads. The seventh lead serves as a common or grounding lead. The electrode leads 124 are approximately less than 12 inches in length. Although not shown, the other ends of the electrode leads 124 are configured to continually contact a patient's skin for the duration of the recording period. Various adhesives and electrical contact configurations with the skin are well-known in the art. There may be less or more than seven leads, depending on the cardiac signals desired.

The second cover 106 optionally also includes an opening at the same side as the electrode leads 124 for the pin connector 118. With this additional opening, the pin connector 118 can be accessed with the second cover 106 fully slipped over the recorder module 104. Alternatively, the ECG monitor 100 can be configured such that the pin connector 118 is only accessible when the second cover 106 has been removed.

In one embodiment, the recorder module 104 measures approximately 30 mm x 52 mm x 5 mm, and weighs less than approximately 16 grams. Each of the first and second covers 102, 106 is comprised of molded plastic, such as polypropylene or polyvinyl chloride. It is contemplated that the recorder module 104 may be smaller than discussed above. As the ability to further miniaturize ICs, provide additional circuitry on a single chip, or more efficient power sources become available, the recorder module 104, and by extension, the ECG monitor 160, can be made smaller and/or lighter.

The ECG monitor 100 is shown in FIG. 1 in a disassembled open position. The ECG monitor 100 assembled (in a closed position) is shown in FIGS. 2-3. In particular, FIGS. 1 and 2 illustrate a front view of the ECG monitor 100, and FIG. 3 illustrates a back view of the ECG monitor 100. In FIG. 2, the first and second covers 102, 106 are fully slipped over the recorder module 104. The first and second covers 102, 106 contact each other at an equatorial seam 20. The respective edges of the first and second covers 102, 106 can form a frictional or snap fit with each other to form the equatorial seam 200.

The cutouts 108 and 122 are also configured such that in the assembled position, the cutouts 108 and 122 cinch the annotate button 120. In the assembled position, the electrode leads 124 are also in electrical contact with the PCB 112.

In FIG. 3, the back side of the assembled ECG monitor 100 is shown. After the first and second covers 102, 106 encapsulate the recorder module 104, a moisture resistant device 300 (also referred to as a moisture resistant sealer or sealant) is applied over the equatorial seam 200 and the annotate button 120. The moisture resistant device 300 has, for example, a width of approximately 36 mm. As an example, the moisture resistant device 300 comprises tape having at least one adhesive surface that wraps around the ECG monitor 100 and back onto itself. The tape comprises a waterproof or moisture resistant layer and a thick adhesive layer. In one embodiment, the thick adhesive layer provides adhesive properties and at least a certain amount of sealant properties (to aid in making the ECG monitor moisture resistant). The tape is also flexible enough to allow actuation of the annotate button 120. The moisture resistant device 300 can include polyvinyl chloride material, Mylar™ backing, or polyester backing.

With the moisture resistant device 300 wrapped around the ECG monitor 100, the ECG monitor 100 measures approximately 32 mm x 52 mm x 8 mm or less, and weighs approximately 28 grams or less.

Due to the inexpensiveness of each of the batteries 110, first cover 102, second cover 106, electrode leads 124, and moisture resistant device 300, one or more of these components can be disposable. A set-up kit comprising, for example, the moisture resistant device 300, batteries 110, and a set of the electrode leads 124 may be provided to the doctor, for one-time use with each patient. Utilizing such a kit for each patient addresses hygiene issues, and ensures best possible moisture-resistance and power source for each recording period. The recorder module 104 can be used repeatedly, as discussed in greater detail below.

The ECG monitor 100 includes at least four interfaces: the electrode leads 124, the pin connector 118, the annotate button 120, and a radio frequency (RF) interface. The electrode leads 124 are in electrical contact with an ambulatory patient's skin. The electrode leads 124 are distributed over the patient's chest region to obtain ECG signals in accordance with known ambulatory EKG standards, such as the EC38 standard.

The pin connector 118 permits two-way communication between the ECG monitor 100 and another device. The other device may be a base station or a computing device. Among other things, initiation, calibration, feature selection (e.g., data sampling rate), and recorded data readout are possible via the pin connector 118. Such functions may be carried out without insertion of the batteries 110 in the ECG monitor 100. For example, the pin connector 118 may include a USB connector that mates with a USB connector included in the computing device (e.g., a laptop or general purpose computer), and obtain power to the monitor 100 from the computing device via the USB connection. Alternatively, the pin connector 118 may mate with a connector at the base station, and the base station electrically couples to the computing device via a cable.

The annotate button 120 is utilized by both the health care professional and patient. For the health care professional, the annotate button 120 is first held down, and then the batteries 110 are inserted while the annotate button 120 continues to be depressed. The annotate button 120 remains depressed after battery insertion for some minimum period of time (e.g., 5 seconds or 10 seconds). The recorder module 104 is thus cleared of data (e.g. clears or erases the flash RAM memory shown in FIG. 4) and is reset to start a new recording period. For the patient during his/her recording period, if there is a cardiac event that the patient wishes to flag to the physician who will later view the recorded ECG data signals, the patient can push down the annotate button 120 and a notation will be included with the ECG data signals at that point in time (e.g., real-time annotation of ECG signals). The patient may utilize this annotate feature at any time during the recording period and more than once during the recording period.

A recording period is the time starting immediately after initialization/calibration to when the monitor 100 stops recording for a given patient (because, for example, the batteries 110 can no longer supply sufficient power to the monitor 100, the batteries 110 are removed from the monitor 100, the flash memory IC chip 400 is full, or the electrode leads 124 are removed from the patient). A cardiac event, to be discussed in detail below, can be a variety of actual, perceived, or potential events associated with out-of-the-ordinary cardiac function. As examples, cardiac events can comprise symptoms such as irregular heartbeats, shortness of breath, dizziness, numbness to a section of the patient's body, irregular vision, increased perspiration, increased body temperature, chest pains, headaches, emotional distress, or psychological distress or stress. Cardiac events can
also comprise external or environmental events that may attribute to out-of-the-ordinary cardiac function such as an argument, engaging in strenuous activity, receiving bad news, falling down, etc.

The RF interface is configured for short-range wireless data transmission between the ECG monitor 100 and the base station. The transmission range is less than approximately 12 inches. Real-time ECG data signals with the annotate information are transmitted to the base station. Correspondingly, the base station includes a RF receiver. In one embodiment, the base station is a small device about the size of a pack of cards. The base station is configured to be a conduit or interface between the ECG monitor 100 and a computer. In this manner, a general all-purpose computer can be utilized without the need for specialized circuitry or peripheral device(s). The RF data received by the base station can be provided to the computer via a cable. The RF data waveforms can then be displayed on the computer. The health care professional ensures that the batteries 100 are properly inserted and in working order via the RF interface. Proper adjustment of electrode leads 124 on the patient may also be performed from viewing the ECG waveforms.

It is contemplated that the ECG monitor 100 may have less than four interfaces. For example, the RF interface may be optional if no corresponding RF device (such as the base station) will be utilized. Alternatively, the ECG monitor 100 may include other interfaces to provide communication or functional features.

In FIG. 4, a block diagram of the circuitry included in the recorder module 104 is shown. The converter IC chip 116 is in communication with the microcontroller IC chip 114. The microcontroller IC chip 114 is in communication with a flash memory IC chip 400.

The electrode leads 124 provide the three pairs of differential channel inputs 404. Each pair of differential channel inputs 404 is representative of electrical potential (or physiological signals) sensed at a specified location on an ambulatory patient's chest region. Each pair of differential channel inputs 404 is associated with a set of differential amplifier 406, coupling capacitor 408, nth order delta-sigma modulator 410 (where n=1 to 5), and clip detector 412.

The differential channel inputs 404 are the inputs to three respective differential amplifiers 406. Each of the differential amplifiers 406 is configured to convert its respective pair of differential channel analog inputs 404 into a single-ended analog signal. Each of the differential amplifiers 406 provides a gain of approximately four (to handle up to a 300 mV input).

The outputs of the differential amplifiers 406 are the inputs to three respective coupling capacitors 408. A coupling capacitor 408 is provided between the differential amplifier 406 and the nth order delta-sigma modulator 410. As an example, the capacitance of each coupling capacitor 408 can range from approximately 0.1 μF to 3.3 μF, depending on the low frequency limit of the ECG monitor 100. The three coupling capacitors 408 are provided external to the converter IC chip 116, on the PCB 112.

Each of the clip detector 412 forms a feedback loop to the input of its respective nth order delta-sigma modulator 410. The outputs of the three nth order delta-sigma modulators 410 are inputs to a decimator 414. The decimator 414 is configured to operate in a time-share manner to process outputs of the three nth order delta-sigma modulators 410. Each nth order delta-sigma modulator 410 and the decimator 414 combination is also referred to as an analog-to-digital (A/D) modulator or converter.

For each pair of differential inputs 404, the coupling capacitor 408 and clip detector 412 are configured to detect ECG signals that are out of range to anticipate and correct subsequent ECG signals that are likely to be out of range. The clip detector 412 provides a corrective signal to adjust subsequent ECG signals to be within a diagnostically useful range. When the baseline or zero point of the ECG signals shifts outside of a prescribed signal range such that a positive or negative peak of the ECG signals are clipped, then such signals are considered to be out of range. If out of range signals are not corrected, and merely processed and stored the same way as in-range signals, then the stored out of range signals would store incomplete waveform information and not include the maximum and/or minimum signal inflections representative of actual cardiac electric potential (e.g., be diagnostically useful). Instead, the stored out of range signals would show, for example, a continuous maximum value (a clipped signal), and waveform information such as the actual signal maximum (relative to the rest of the signal), the changes in the signal amplitude, shape of the signal, etc. would not be captured. In contrast, diagnostically useful signals are signals that include ECG maximum and minimum inflection information, signal shape, etc. so that medically useful information is available to a health care professional that reviews the recorded ECG data (to make a diagnosis of a disease or illness, evaluate efficacy of a treatment, etc.).

As an example, an out of range signal could result from a patient's perspiration or when the patient undergoes physical stress due to an extreme cardiac event. The detection and "correction" occurs in less than a data sampling period. For example, when the output signal from the differential amplifier 406 is sixteen successive zeros or ones, then the signals are considered to be out of range. The subsequent analog signals (which have been corrected if out-of-range) are then digitized at the nth order delta-sigma modulator 410.

The digitized bit streams are input to the decimator 414. The decimator 414 is configured to output a high-resolution value for every 64 input bits (when the decimator 414 has a decimation ratio of 64:1). The output of the decimator 414 is a single bit stream that is the input to a first-in-first-out (FIFO) memory 416. Each of the nth order delta-sigma modulator 410 works in conjunction with the decimator 414 (also referred to as a decimation filter) to produce high accuracy samples. The nth order delta-sigma modulator 410 operates at high sample rates. The nth order delta-sigma modulator 410 generates a single bit output data stream that can be used to detect an upcoming saturation (or out of range) limit as well as being the input to the decimator 414.

The switch 417 is actuated by pushing down the annotate button 120. Information about the annotation (or non-annotation) of the switch 417 is associated with time corresponding ECG data in the FIFO memory 416.

The output of the decimator 414 and the switch 417 are also provided as inputs to an RF modulator 418. The RF modulator 418 configures the ECG and annotates signals suitable for RF transmission via a loop antenna 420. The loop antenna 420 and the switch 417 are located external to the converter IC chip 116. The loop antenna 420 provides real-time continuous output that is identical (in substantive content) to the data stored in the FIFO memory 416. Also included in the converter IC chip 116 are clock components 422 to provide timing and synchronization functions associated with processing of the differential channel inputs and data transmission to other circuitry. The clock components 422 include a crystal oscillator operating at 32
KHz, a phase-lock loop (PLL) operating at 16 MHz, and a
timing clock. The crystal oscillator is in communication with a
(watch) crystal located external to the converter. IC chip
116. The crystal oscillator operating at a lower frequency
and then achieving the desired frequency with a PLL pro-
vides total lower power consumption (e.g., on the order of
50 microamp) versus, for example, starting with a 16 MHz
oscillator (which has power consumption of approximately
4 to 5 milliamp).

As shown in FIG. 5, the data format of each sample 500
stored in the FIFO memory 416 is 32 bits (4 bytes) in length.
Of the 32 bits, there are 4 bits of information for each of
the 3 channels (blocks 502, 504, 506), followed by a bit that
indicates the condition of the switch 417 (block 508), and
lastly a negative check bit (block 510, also referred to as a
checksum). For example, the FIFO memory 416 has a
capacity to store up to 16 samples with each sample being
a 32 bit word.

Even though the ECG monitor 100 continuously monitors
the electric potential information from the surface of the
patient's skin throughout the recording period, the ECG
monitor 100 operates on an average current of less than 10
milliamp or less than 1 milliamp. For example, the average
current required can be around 700 microamp. Such low
power consumption is possible due to the low power
requirement of the converter IC chip 116 and selective or
intermittent powering of the chips 114 and 400. This is in
contrast to conventional ambulatory ECG recorders that
consume on average around 50 milliamp of current.

When the FIFO memory 416 is full (or approaching full
capacity), the microcontroller IC chip 114 is powered up. A
DATA READY signal (see FIG. 4) is transmitted from the
FIFO memory 416 to the microcontroller IC chip 114 to turn
on or wake up the microcontroller IC chip 114. The micro-
controller IC chip 114 is configured to transfer the data
serially out of the FIFO memory 416 and then power down
again when the data transfer is complete. A DATA CLOCK
line and a DATA line are utilized by the microcontroller IC
chip 114 to perform the data transfer.

The microcontroller IC chip 114 (also referred to as a
microcomputer or microprocessor) is a programmable
microprocessor that is configured to control transfer of data
from the FIFO memory 416 to the flash memory IC chip
400, control access to the flash memory IC chip 400, and
store certain settings relating to the ECG monitor 100. The
flash memory IC chip 400 is a RAM memory device. During
the recording period, both the microcontroller IC chip 114
and the flash memory IC chip 400 are only powered when
the FIFO memory 416 needs to be emptied because the FIFO
memory 416 is at or near maximum storage capacity. Once
data transfer to the flash memory IC chip 400 is complete,
both the microcontroller IC chip 114 and the flash memory
IC chip 400 are powered down to minimize power con-
sumption.

The microcontroller IC chip 114 temporarily stores the
data from the FIFO memory 416, calculates which portions
of the flash memory IC chip 400 to write the data to, and
writes such data to appropriate portions of the flash memory
IC chip 400. The ADDR, CONTROL, and DATA (8) lines
between the microcontroller IC chip 114 and the flash
memory IC chip 400 are utilized for the data transfer. The
microcontroller IC chip 114 turns on the flash memory IC
chip 400 when a write operation to the flash memory IC
chip 400 is ready to commence (e.g., via the CONTROL line).
Upon completion of the write operation, the microcontroller
IC chip 114 turns off the flash memory IC chip 400, transmits a POWER DOWN signal to the converter IC chip
116 (to indicate that data transfer from the FIFO memory
416 to the flash memory IC chip 400 is complete), and then
turns itself off.

Continuing the example of the FIFO memory 416 con-
taining 16 samples of data and each sample being a 32 bit
word, up to 512 bits of data would be transferred out of the
FIFO memory 416 each time the DATA READY signal is
transmitted. In the case of 128 Hz operation, 16 samples are
acquired 8 times per second, thus the microcontroller IC
chip 114 and flash memory IC chip 400 are turned on 8 times
per second. In the case of 1024 Hz operation, the micro-
controller IC chip 114 and flash memory IC chip 400 are
turned on 64 times per second.

In one embodiment, the microcontroller IC chip 114 is
awake for a time period on the order of approximately 500
μs per duty cycle. The power consumption of the microcon-
troller IC chip 114 during each awake period is on the order
of approximately 20 milliamp, for example, 16 milliamp.
The flash memory IC chip 400 is awake for a time period
shorter than the awake period of the microcontroller IC chip
114 for each duty cycle. The awake period for the flash
memory IC chip 400 is approximately 200 μs. The power
consumption of the flash memory IC chip 400 during each
awake period is on the order of approximately 30 milliamp,
for example, 25 milliamp.

The microcontroller IC chip 114 is also configured to
transmit the prescribed sample rate to the timing clock at the
converter 116 via terminals SR0 and SR1.

Various leads 402 are associated with the pin connector
118. The leads 402 include receiver and transmitter lines to
the microcontroller IC chip 114 (e.g., to specify the sample
rate, or to prescribe the minimum length of time required for
depression of the annotate switch 417 during initialization),
and data bus lines to access the data stored in the flash
memory IC chip 400.

Referring to FIG. 6, the ECG monitor 100 attached to an
ambulatory patient 600 is shown. The electrode leads 124
are placed at various locations on the patient's 600 chest
region. The ECG monitor 100 is also adhered to the patient
600. For example, a second piece of tape that has a double
sided adhesive is placed on the backside of the ECG monitor
100. The side of the ECG monitor 100 with the annotate
button 120 would be accessible by the patient. Alternatively,
the ECG monitor 100 may be transported on a band around
the patient's arm, clamped to the patient's clothing, or
attached to the patient 600 with surgical tape.

A base station 602 may be held close to the ECG monitor
100 for RF communication as the patient monitoring is in
progress. To view the three sets of ECG waveforms, the base
station 602 can be connected to a computer 604, via a cable
such as a USB cable. The computer 604 includes software to
process (if necessary) and display the sample data obtained
from the electrode leads 124.

The RF communication between the receiver module 104
and the base station 602 is configured to be a short-range
link and also very low in power consumption. The transmis-
sion range of the loop antenna 420 is within a couple of
inches and no more than about 12 inches. The RF link can
be configured to not interfere with other possible RF signals
nor FCC mandates. The RF link is further configured to not
interfere with other device(s) inside or around the patient,
such as a pacemaker. The RF link operates at a non-sensitive
frequency, short transmission range, low transmission power,
and/or a different RF modulation scheme to prevent interference issues.

The RF link implemented in the ECG monitor 100 operates at around 20 microamp of current. Alternatively,
LEDs or an infrared communication link may be implemented instead of the RF link, operable around several milliamp of current. FIG. 7 illustrates RF circuitry included in the base station 602. Although not shown, the RF circuitry includes a receiving RF antenna. After the RF antenna receives the RF signal, the RF signal is processed suitable for outputting to the computer 604. An amplifier 700 amplifies the RF signal. The amplified signal is inputted to a detector 702. When the amplified signal is determined to be a plausible RF signal transmitted by the recorder module 104, then the signal is inputted to a filter 704 and a limiter 788. The output of the limiter 706 is the input to the computer 604.

The ECG monitor 100 performs modulation of the ECG signals suitable for storage at the FIFO memory 416 and transmission via the loop antenna 420. In one embodiment, a data serializer circuitry may be included between the RF modulator 418 and the demodulator 414.

In one embodiment, the ECG monitor 100 implements RF modulation using a FM coding scheme. FM coding scheme comprises modulation or coding based on transitions between a signal high and low (or vice versa), as opposed to the high or low values of the signal itself. One bit of modulated output is generated from two successive presubscribed minimum time periods of signal information (e.g., each presubscribed minimum time period referred to as a “bit period”). No more than two bit periods occur without an occurrence of a transition. A transition is considered to be any change in state from an on to off, or vice versa, as opposed to the high or low values of the signal itself.

A data bit of “0” in the modulated output is representative of two successive bit periods of data, where the two bit periods can start and/or end with a transition but there is no transition between the two bit periods. A data bit of “1” in the modulated output is representative of two successive bit periods of data, where the two bit periods can start and/or end with a transition and there is a transition between the start and end points of the two bit periods. A signal or waveform 800 shown in FIG. 8(a) is representative of an input signal to undergo FM coding. A signal or waveform 802 shown in FIG. 8(b) is representative of the input signal 800 of FIG. 8(a) after processing by a limiter or half-wave rectifier, thereby converted to a digital or logic type of signal. Lastly, the signal 802 modulated with FM coding would be represented as three bits of data: 110.

To designate the start of a different data sample, such as the sample 500, a synchronization event or information is included immediately before the start of each data sample. As shown in FIG. 8(c), a synchronization data portion 804 is provided immediately before a data sample 805. The combination of the synchronization data portion 804 and the data sample 805 is collectively referred to as a data frame 806. In FIG. 8(c), each unit of the data frame 806 is designated as a bit period 808. Waveform or signals 810 is representative of a limiter output signal (e.g., the signal 802), and bits 812 are representative of the signals 810 after application of the FM coding scheme.

The synchronization data portion 804 comprises at least a pair of timing or coding violations. Recall with the FM coding scheme, that there would be no more than two successive bit periods without a transition. However, in the synchronization data portion 804, there are 3 successive bit periods without a transition and this happens twice in a row (first sync pattern 814 and second sync pattern 816). In addition, the first and second sync patterns 814 and 816 are followed by 3 sets of 2 bit periods each having a transition (third, fourth, and fifth sync patterns 818, 820, 822). The third, fourth, and fifth sync patterns 818, 820, 822 are collectively referred to as a preset coded sequence. Thus, the synchronization data portion 804 is comprised of 2 “violations” followed by 3 “1”'s, expressed as bits 010111 after FM coding scheme application.

In an alternate embodiment, the synchronization data portion 804 comprises other data patterns recognizable as data sample separators. For example, the synchronization data portion 804 can comprise more or less than one coding violation. As another example, the synchronization data portion 804 need not include a preset coded sequence such as the third, fourth, and fifth sync patterns 818, 820, 822.

The data sample 805 comprises data samples obtained from the ambulatory patient and outputted by the demodulator 414. For example, the data sample 805 can be the data sample 500.

In this manner, analog ECG signals obtained from the patient are encoded for accurate data transfer via a RF communication link. The modulated data further includes annotation information (indicative of the state of the annotate switch 417) and error check information to facilitate use of the ECG signal data at the base station 602 and/or computer 604. At the end of each sample period, a data sample is outputted from the demodulator 414 and is transmitted to each of the FIFO memory 416 and the RF modulator 418. The RF modulator 418 is configured to apply the FM coding to the received data sample and to drive the RF transmission via the loop antenna 420.

In an alternate embodiment, a modulation scheme other than FM coding can be implemented in the ECG monitor 100. As an example, a modified FM (MF/M) coding scheme or any coding scheme that is compatible with RF transmission may be utilized.

Referring to FIG. 9, a detailed block diagram of a portion of the converter IC chip 116 is shown. The circuit blocks associated with detection and correction of out-of-range signals for each channel are shown. This range limiter or clip correction occurs independently at each of the three channels of the ECG monitor 100. During initialization or calibration of the ECG monitor 100, the health care professional specifies whether or not to engage the clip correction feature. Selection of clip correction is specified via RXD and TXD lines to the microcontroller IC chip 114. The microcontroller IC chip 114 includes a certain amount of flash memory to permit programming and retention of certain settings, such as the clip correction feature selection.

Although the clip correction feature is optional, health care personnel reviewing or analyzing the obtained data (e.g., cardiologists) may find the feature to be valuable. Without the clip correction feature, ECG signals can go off-scale for several seconds at a time so that no usable waveform data is recorded for such periods of time. ECG signals can go off-scale (also referred to as being out-of-range) when the baseline or “zero” point of the signal range significantly changes during the recording period. Such significant, and often abrupt, changes to the baseline occurs from events such as: change in electrical potential between different electrodes, change in patient’s skin chemistry (e.g., perspiration), some kind of change to the electrodes itself, the patient shifting body position, patient under stress from some cardiac event, etc. Ambulatory ECG monitors in compliance with the EC38 standard are required to tolerate an input offset between 2 to 300 millivolts. Nevertheless, a normal heartbeat signal is typically on the order of only 1 millivolts. Thus, continuously tracking an input signal on the
order of 1 millivolts in the context of events occurring during the recording period responsible for significant baseline fluctuations and large input signal amplification schemes results in certain ECG signals being out of range for certain periods of time. In contrast, with the clip correction feature activated, an out-of-range ECG signal is brought in range in less than one data sample period.

In FIG. 9, analog signals 900 (the output of the coupling capacitor 408) are the input to the nth order delta-sigma modulator 410. The analog signals 900 are amplified by an amplifier 902 prior to processing at the nth order delta-sigma modulator 410. The output of the nth order delta-sigma modulator 410 is the input to the clip detector 412. The clip detector 412 forms a feedback loop to the input line. The output of the nth order delta-sigma modulator 410 is also the input to the decimator 414.

The nth order delta-sigma modulator (or converter) 410 is configured to output clocked signal bits based on the analog input signals 900. The nth order delta-sigma modulator 410 provides an output bit rate that is higher than the intended output sample rate. In one embodiment, the nth order delta-sigma modulator outputs at 64 times the intended output sample rate. Hence, continuing the earlier example of operating the ECG monitor 100 at a 128 Hz sampling rate, the output of the nth order delta-sigma modulator 410 are 1 bit samples at 8192 Hz (see FIG. 9). In an alternate embodiment, the nth order delta-sigma modulator 410 may comprise an over-sampling converter.

The decimator 414 is configured to bring the one bit samples at the high sample rate (from the nth order delta-sigma modulator 410) to multi-bit samples at a lower sample rate. A decimation ratio associated with the decimator 414 can range between 16:1 to 256:1. Continuing the 128 Hz sampling rate example, the decimator 414 has a 64:1 input to output sample rate ratio. The output of the decimator 414 is 10 bit samples at 128 Hz (see FIG. 9). The decimator 414 (which includes at least one filter) is configured to expand the obtained data to improve accuracy. Accuracy is improved by effectively averaging a large number of single bit input signals or bits (in other words, averaging over a number of data samples).

However, there is a delay of many data samples associated with the averaging function in the decimator 414. Thus, if the output of the decimator 414 was utilized to determine if the obtained ECG signal was out-of-range, then the actual out-of-range condition could not be known until many data samples after the actual point in time when it occurred.

Instead, FIG. 9 illustrates the out-of-range signal detection using the clip detector 412. The detector 412 includes a detector 904, a positive current source 906, and a negative current source 908. The output of the nth order delta-sigma modulator 410 is provided to each of the detector 904 and the decimator 414. The output of the detector 904 is provided to each of the positive and negative current sources 906, 908. The output of each of the positive and negative current sources 906, 908 are combined and fed back to the input line (forms a feedback loop). The input of the nth order delta-sigma modulator 410 are the analog electrical potential signals sensed from the patient’s body surface. The outer surface of the patient’s skin around the chest region (non-invasively) provides signals representative of the electrical potential associated with the patient’s heart muscle activity. The output of the decimator 414 is a digital ECG signal suitable for storage and/or RF transmission.

The detector 904 is configured to detect a prescribed number of successive 1’s or 0’s in the modulator 410 output bit stream. Detection of the prescribed number of successive 1’s indicates that the obtained ECG signal is about to (or has started to) reach the positive maximum of the recordable magnitude range. A series of successive 1’s may occur when the baseline of the obtained ECG signal shifts significantly in the positive direction (e.g., due to perspiration, patient movement, shift in contact point between electrode and patient, etc.) such that the positive peak value of the ECG signal exceeds the capturable range of the monitor 100. Alternatively, a series of successive 1’s may occur when the patient is experiencing an extreme cardiac event such that the positive peak value of the ECG signal exceeds the capturable range of the monitor 100. Instead, the positive peak value of the ECG signal is detected as a “continuous” maximum value, which is digitized as a series of successive 1’s. It is unlikely that the true positive peak value of the ECG signal would be a constant value for such a long period of time. Thus, a “continuous” and constant peak value detected is indicative of a clipped, saturated or out-of-range condition.

Conversely, detection of the prescribed number of successive 0’s indicates that the obtained ECG signal is near or at the negative maximum of the recordable magnitude range. A series of successive 0’s may occur when the baseline of the obtained ECG signal shifts significantly in the negative direction or due to an extreme cardiac event (e.g., due to perspiration, patient movement, shift in contact point between electrode and patient, etc.) such that the negative peak value of the ECG signal cannot be captured by the monitor 100. Similar to the successive 1’s discussed above, a “continuous” and constant negative peak value detected is indicative of a clipped, saturated or out-of-range condition.

In one embodiment, 32 successive 1’s is the prescribed number of 1’s to trigger an out-of-range condition. The 32 successive 1’s indicate that the analog signal obtained from the patient is within approximately 6% of the positive maximum. Similarly, 32 successive 0’s is the prescribed trigger for the negative maximum being within approximately 6%.

If the successive 1’s are detected for a positive maximum out-of-range condition, then the negative current source 908 pulls the current in one direction to bring down the baseline of the incoming analog signals 900 entering the amplifier 902. The negative current source 908 provides a negative current of certain magnitude to cause subsequent analog signals 900 to be within recordable range within less than a data sample period. The negative current source 908 is also configured to provide different magnitudes of negative current depending on the amount of correction required to bring the subsequent signals within the modulator’s 410 active range. In other words, the negative current source 908 provides qualitative and quantitative correction functionality.

If the successive 0’s are detected, then correspondingly the positive current source 906 pulls the current in the other direction to bring the baseline up. Otherwise, the positive current source 906 functions similar to the negative current source 908.

The positive and negative currents sources 906, 908 are configured to generate a positive or negative current, respectively, sufficient to affect the charge of, and thus the voltage across, the corresponding external coupling capacitor 408 by approximately 1 to 40% of its maximum voltage range within the modulator’s 410 clock period. The voltage at a node 910 (the external coupling capacitor 408 terminal connected to the input of the nth order delta-sigma modulator 410) has a voltage range proportional to the maximum voltage range at a node 912 (output of the decimator 414).
For example, the maximum voltage range at the node 912 may be +/−20 mV about a central bias voltage (40 mV total). The resistance at the node 910 can be 5 MΩ.

When at least a preset series of successive 1’s or 0’s is detected at the output of the nth order delta-sigma modulator 410, one of the positive or negative current sources 306, 908 (depending on the 1’s or 0’s detected) is actuated to affect the charge of the corresponding external coupling capacitor 408. This charging, in turn, results in a voltage change at the node 910. The rate of change of voltage at the node 910 is configured such that the new voltage at the node 910 is achieved within a single modulator 410 clock period. The new voltage is a voltage value brought closer to the central bias voltage or null voltage value (scaled down) by approximately 1 to 40% of the full scale (or maximum) voltage range. Continuing the above example of a maximum voltage range of 40 mV at a 128 KHz sampling rate, the voltage change would be between approximately 0.4 mV to 16 mV within a 1/8192 th of a second. For an external coupling capacitor having a capacitance of 1 μF, for example, the current required to affect a voltage change of 0.4 to 16 mV would be between 3.3 to 130 μA, respectively.

Since the modulator 410 outputs are as close as possible to real-time indicators of how extreme in magnitude the analog ECG signals are, continuously monitoring such outputs and introducing offsets to subsequent analog signals as soon as possible allow out-of-range ECG signals to be brought back into range within a very short time period (e.g., within less than the time period of a heartbeat, less than the sampling period, within the A/D modulator clock period, or substantially in real-time).

The heartbeat waveforms during the vast majority of the out-of-range time period is thus accurately recorded (as is done for in-range waveforms), which is useful for diagnostic purposes, even though there is amplitude scale distortion from “forcing” the signals within a useable range. The abrupt shift in the baseline would indicate to the person viewing the recorded data that the clip correction had been implemented.

In another embodiment, it is contemplated that more or less than 32 successive 1’s or 0’s needs to be detected to trigger the clip detector feature. The trigger of the detector 904 can be preset to between 5 to 128 successive 1’s or 0’s. The minimum number of successive 1’s or 0’s required may depend, for example, on how close the input analog signal should be to a maximum (e.g., more or less than 6% of maximum) or how fast clip correction is to be initiated.

Thus the ECG monitor 100 takes analog electrical potential signals associated with a person’s cardiac activity, and processes these signals suitable for storage and/or RF transmission. These signals are A/D converted using nth order delta-sigma modulators 410 and the decimator 414. The addition of the clip detectors 412 and associated circuitry during A/D conversion permit early detection of overflow conditions then would otherwise be possible. The resulting digital output signals at the decimator 414 are highly accurate, lower rate signals than the data bitstream from the nth order delta-sigma modulators 410.

Referring to FIG. 10, a flow diagram illustrates the use of the ECG monitor 100. At a block 1000, the health care professional (e.g., physician, nurse, physician assistant, etc.) initializes the ECG monitor 100 for a new patient. The health care professional inserts new batteries into the recorder module 104; and slides the first and second covers 102, 106 over the recorder module 104. Next, the annotate button 120 is depressed as the batteries are inserted and for some minimum period of time (e.g. 5 seconds or 10 seconds) after battery insertion. This causes the microcontroller IC chip 114 to power up and erase the FIFO memory 416 and the flash memory IP chip 400. In other words, the ECG monitor 100 is reset to record data for a new patient. Since the recorder module 104 is reusable, the recorder module 104 may contain data recorded from a previous patient, which should be erased for the new patient via the initialization process.

At the block 1000, the recorder module 104 or the ECG monitor 100 may be connected to the computer 604 via the pin connector 118. The flash memory IC chip 400 can then be provided with patient identifying information such as the patient’s name, date, case number, brief patient history, etc. Alternatively, patient identifying information need not be included since such information can be provided on a label or tag with the completely recorded recorder module 104.

If the electrode leads 124 are of the disposable variety, then a new set is connected to the ECG monitor 100. Lastly, a new moisture resistant device 300 (also referred to as the tape) is wrapped around the ECG monitor 100.

At the block 1002, the other end of the electrode leads 124 are attached to the patient’s skin at the chest region. The ECG monitor 100 is also attached to the patient (e.g., patient’s chest region) or the patient’s clothing.

The health care professional holds the base station 602 close to the ECG monitor 100 to specify a desired sampling rate, to check that the batteries are functional, and/or to adjust the electrode leads 124 positions on the patient, each via the RF interface or the pin connector 118. It should be understood that these features can also be accomplished by coupling the ECG monitor 100 to the computer 604 (using a cable).

The desired sampling rate is provided to the microcontroller IC chip 114. The health care professional can select from 128 Hz, 256 Hz, 522 Hz, or 1024 Hz sampling rates. The sampling rate would depend, for example, on the degree of sensitivity of ECG data desired, the length of recording time, memory capacity, and/or battery capacity.

Although initiation and calibration are illustrated as separate blocks 1000 and 1002, respectively, one or more of the steps can be performed simultaneously, in different order, or omitted than as discussed above. As an example, the ECG monitor 100 may provide a default sample (or sampling) rate of 128 Hz.

Once initialization and calibration are complete, recording of a patient’s ECG signals starts at a block 1004. The patient is typically free to go about his/her regular routine in an outpatient environment. Such regular routine can include showering, exercising, and sleeping with the attached ECG monitor 100.

During the recording period, if the patient notices an irregular physical symptom or event, he can annotate the corresponding ECG signals being recorded at that same moment in time (block 1006). The patient presses the annotate button 120 which is accessible through the tape. The patient can annotate more than once and at any time during the recording period. Such annotation (or flag) highlights time periods worthy of closer attention or study.

During the recording period, if the flash memory IC chip 400 becomes full, then the microcontroller IC chip 114 turns off the recorder module 104 (including the converter IC chip 116, flash memory IC chip 400, and the microcontroller IC chip 114). This ensures that needless battery usage that could lead to battery leakage and/or damage to the ECG monitor 100 does not occur.

Lastly, at a block 1008, the patient returns to the health care professional to return the recorded ECG monitor 100.
Typically, the patient is instructed to allow the recording to occur for a set period of time (e.g., 24 hours, 48 hours, 72 hours, etc.). The ECG data stored in the flash memory IC chip 400 is retrieved via the pin connector 118 to the base station 602 or the computer 604. Depending on the power source at the base station 602 or the computer 604, no power source is required at the ECG monitor 100 for data readout. For example, if the ECG monitor 100 is accessed via a USB cable, the USB cable can also provide power to the ECG monitor 100.

When the recorded data is displayed (at the computer 604 or printed on paper), three sets of ECG traces corresponding to the three differential channels are provided. These traces also include the annotation condition information. Depending on the software at the computer 604, the displayed traces can be representative of further processed data.

In this manner, a system and method for recording ECG signals for an extended period of time are disclosed herein. ECG signals from an ambulatory patient can be obtained away from a health care professional or hospital setting. The ECG monitor is inexpensive, lightweight, small, and robust. Certain parts of the ECG monitor are disposable, to facilitate hygiene criteria and maximum performance. Although the ECG monitor is diminutive, a wide range of features are provided. Among other things, various sampling rates, optimization of ECG signal obtaining locations on the patient, rapid detection and correction of out-of-range signals, and real-time data output are provided.

While the invention has been described in terms of particular embodiments and illustrated figures, those of ordinary skill in the art will recognize that the invention is not limited to the embodiments or figures described. For example, the recorder module 104 can be encased by a piece cover having a water resistant lid, rather than the first and second covers 102, 106 and the moisture resistant device 300. As another example, the functionalities of the IC chips 116, 114, 400 may be provided on a single IC chip to facilitate further reduction in the size of the ECG monitor. As still another example, the flash memory IC chip 400 may be upgradeable in the recorder module 104 as higher capacity, higher data transfer speed, and/or lower power consuming flash memory chips become available.

One or more aspects of one or more embodiments may be combined to form additional embodiments. The figures provided are merely representational and may not be drawn to scale. Certain proportions thereof may be exaggerated, while other may be minimized. The figures are intended to illustrate various implementations of the invention that can be understood and appropriately carried out by those of ordinary skill in the art. Therefore, it should be understood that the invention can be practiced with modification and alteration within the spirit and scope of the appended claims. The description is not intended to be exhaustive or to limit the invention to the precise form disclosed. It should be understood that the invention can be practiced with modification and alteration. From the foregoing, it will be appreciated that specific embodiments of the invention have been described herein for purposes of illustration, but that various modifications may be made without deviating from the spirit and scope of the invention. Accordingly, the invention is not limited except as by the appended claims and equivalents thereof.

What is claimed is:

1. Circuitry for obtaining electrocardiogram (ECG) signals associated with an ambulatory patient, the circuitry comprising:
   - a first integrated circuit (IC) configured to accept differential channels of ECG signals, process the ECG signals, and store the processed ECG signals, wherein capacitors are coupled to the first IC to correct out-of-range ECG signals;
   - a second IC in communication with the first IC, the second IC including a microcontroller; and
   - a third IC in communication with the second IC, the third IC configured to store the processed ECG signals from the first IC, wherein each of the second and third ICs is selectively powered in response to an approximately full capacity of the stored processed ECG signals in the first IC.

2. The circuitry of claim 1, wherein the first, second, and third ICs are provided in a recorder module weighing less than approximately 16 grams.

3. The circuitry of claim 1, further comprising:
   - an antenna coupled to the first IC, wherein the first IC includes a radio frequency (RF) modulator and the antenna transmits the processed ECG signals in real-time.

4. The circuitry of claim 1, wherein the stored processed ECG signals include data associated with each of the differential channels, a condition of a notation switch, and an error check.

5. The circuitry of claim 1, wherein the first IC includes a clip detector.

6. The circuitry of claim 1, wherein the second IC shuts off power to the first, second, and third ICs when the third IC has reached full storage capacity.

7. The circuitry of claim 1, further comprising:
   - a notation switch coupled to the first IC, wherein the stored processed ECG signals include data associated with a condition of the notation switch.

8. The circuitry of claim 1, wherein the first, second, and third ICs are provided in a recorder module having an average current consumption of less than 1 milliamp.

9. Circuitry for obtaining electrocardiogram (ECG) signals associated with an ambulatory patient, the circuitry comprising:
   - a first integrated circuit (IC) configured to accept differential channels of ECG signals, process the ECG signals, and store the processed ECG signals;
   - a second IC in communication with the first IC, the second IC including a microcontroller; and
   - a third IC in communication with the second IC, the third IC configured to store the processed ECG signals from the first IC, wherein each of the second and third ICs is selectively powered in response to an approximately full capacity of the stored processed ECG signals in the first IC, an antenna is coupled to the first IC, the first IC includes a radio frequency (RF) modulator, and the antenna transmits the processed ECG signals in real-time.

10. The circuitry of claim 9, further comprising:
    - capacitors coupled to the first IC to correct out-of-range ECG signals.

11. The circuitry of claim 9, wherein the antenna transmits within a range of less than approximately 12 inches.

12. The circuitry of claim 9, wherein the stored processed ECG signals include data associated with each of the differential channels, a condition of a notation switch, and an error check.

13. The circuitry of claim 9, wherein the first IC includes a clip detector.
14. The circuitry of claim 9, further comprising: a notation switch coupled to the first IC, wherein the stored processed ECG signals include data associated with a condition of the notation switch,

15. The circuitry of claim 9, wherein the first, second, and third ICs are provided in a recorder module having an average current consumption of less than 1 milliamp.

16. Circuitry for obtaining electrocardiogram (ECG) signals associated with an ambulatory patient, the circuitry comprising:

- a first integrated circuit (IC) configured to accept differential channels of ECG signals, process the ECG signals, and store the processed ECG signals, wherein the first IC includes a clip detector;
- a second IC in communication with the first IC, the second IC including a microcontroller; and
- a third IC in communication with the second IC, the third IC configured to store the processed ECG signals from the first IC,

wherein each of the second and third ICs is selectively powered in response to an approximately full capacity of the stored processed ECG signals in the first IC,

17. The circuitry of claim 16, further comprising: a notation switch coupled to the first IC, wherein the stored processed ECG signals include data associated with a condition of the notation switch.

18. The circuitry of claim 16, wherein the first, second, and third ICs are provided in a recorder module weighing less than approximately 16 grams.

19. The circuitry of claim 16, wherein the stored processed ECG signals include data associated with each of the differential channels, a condition of a notation switch, and an error check.

20. The circuitry of claim 16, wherein the first, second, and third ICs are provided in a recorder module having an average current consumption of less than 1 milliamp.

21. The circuitry of claim 16, further comprising: Capacitors coupled to the first IC to collect out-of-range ECG signals.

22. Circuitry for obtaining electrocardiogram (ECG) signals associated with an ambulatory patient, the circuitry comprising:

- a first integrated circuit (IC) configured to accept differential channels of ECG signals, process the ECG signals, and store the processed ECG signals,
- a second IC in communication with the first IC, the second IC including a microcontroller, and
- a third IC in communication with the second IC, the third IC configured to store the processed ECG signals from the first IC,

wherein each of the second and third ICs is selectively powered in response to an approximately full capacity of the stored processed ECG signals in the first IC, and wherein the second IC shuts off power to the first, second, and third ICs when the third IC has reached full storage capacity.

23. The circuitry of claim 22, further comprising: capacitors coupled to the first IC to correct out-of-range ECG signals.

24. The circuitry of claim 22, further comprising: an antenna coupled to the first IC, wherein the first IC includes a radio frequency (RF) modulator and the antenna transmits the processed ECG signals in real-time.

25. The circuitry of claim 22, wherein the stored processed ECG signals include data associated with each of the differential channels, a condition of a notation switch, and an error check.

26. The circuitry of claim 22, wherein the first IC includes a clip detector.

27. The circuitry of claim 22, further comprising: a notation switch coupled to the first IC, wherein the stored processed ECG signals include data associated with a condition of the notation switch.

28. The circuitry of claim 22, wherein the first, second, and third ICs are provided in a recorder module having an average current consumption of less than 1 milliamp.

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