ECG Patch Monitors for Assessment of Cardiac Rhythm Abnormalities

S. Suave Lobodzinski*

Department of Electrical and Biomedical Engineering, California State University, Long Beach, CA, USA

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ABSTRACT

The primary goal of long-term monitoring is the improvement of diagnostic yield. Despite the clear utility of Holter monitoring in clinical cardiology, issues of relatively low diagnostic yield, cost and inconvenience have motivated the development of ultra-portable devices referred to as ECG patch monitors. Although the "gold standard" for assessing cardiac rhythm abnormalities remains a 12-lead Holter, there is an increasing interest in portable monitoring devices that provide the opportunity for evaluating cardiac rhythm in real-world environments such as the workplace or home. To facilitate patient acceptance these monitors underwent a radical miniaturization and redesign to include wireless communication, water proofing and a patch carrier for attaching devices directly to the skin. We review recent developments in the field of "patch" devices primarily designed for very long-term monitoring of cardiac arrhythmic events. As the body of supporting clinical validation data grows, these devices hold promise for a variety of cardiac monitoring applications. From a clinical and research standpoint, the capacity to obtain longitudinal cardiac activity data by patch devices may have significant implications for device selection, monitoring duration, and care pathways for arrhythmia evaluation and atrial fibrillation surveillance. From a research standpoint, the new devices may allow for the development of novel diagnostic algorithms with the goal of finding patterns and correlations with exercise and drug regimens.

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Indications for monitoring

Cardiac monitoring may be necessary for diagnostic evaluation of patients with any of the following symptoms or conditions:

1. The need to assess treatment effectiveness in individuals with baseline high frequency, reproducible, sustained, symptomatic premature ventricular complexes, supraventricular arrhythmias or ventricular tachycardia.
2. Autonomic cardiac neuropathy associated with diabetes mellitus; or
3. Idiopathic hypertrophic or dilated cardiomyopathy.
4. In individuals with pacemakers, a need to assess paroxysmal symptoms, myopotential inhibition, pacemaker medicated tachycardia, anti-tachycardia pacing device functioning, rate-responsive physiologic pacing function.
5. Symptoms suggestive of Prinzmetal's angina.
6. Post-myocardial infarction with left ventricular dysfunction.

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* Address reprint requests S. Suave Lobodzinski, PhD, Department of Electrical and Biomedical Engineering, California State University, Long Beach, CA 90840.
E-mail address: suavelobodzinski@gmail.com.

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7. Symptoms consistent with rhythm disturbances (e.g., frequent palpitation, syncope, unexplained dizziness).

Typically if any of the above conditions is encountered, Holter monitoring is used. However, intermittent cardiac event monitors (i.e., external loop recorders) and external intermittent cardiac event monitors with real-time data transmission and analysis are considered medically necessary for any of the following conditions:

1. To document an arrhythmia in persons with a non-diagnostic Holter monitor, or in persons whose symptoms occur infrequently (less frequently than daily) such that the arrhythmia is unlikely to be diagnosed by Holter monitoring.
2. To document ST-segment depression for suspected ischemia.
3. To document the impact of initiating drug therapy for an arrhythmia.
4. To document the recurrence of an arrhythmia after discontinuation of drug therapy.
5. To document the results after an ablation procedure for arrhythmia.
6. To evaluate syncope and lightheadedness in persons with a non-diagnostic Holter monitor, or in persons whose symptoms occur infrequently (less frequently than daily) such that the arrhythmia is unlikely to be diagnosed by Holter monitoring.

**Current state of the art ECG patch monitoring technologies for assessment of cardiac rhythm abnormalities**

Ideally ECG path monitor (EPM) devices would combine the features of the present-day Holter and event/loop recorders with real-time data transmission and analysis capabilities. This is however not yet technologically possible. The present-day mix of FDA cleared EPMs are limited by their data acquisition capabilities (typically single-channel electrogram), adhesive materials that limit the device on-skin longevity and communication capabilities. Some EPM can be categorized as a single-lead “Holter-like devices,” exemplified by Zio Patch, some as post-symptom event recorders with data transmission and yet another as event/loop recorders with pre-symptom capabilities in addition to data transmission such as NUVANT. An overview of a typical EPM system architecture illustrates the technologies used in patch monitor designs.

A typical ECG path monitor (EPM) architecture is shown in Fig 1. The EPM be functionally divided into two subsystems. The first subsystem is responsible for processing of both analog and digital ECG data. It is implemented as a System on a Chip (SoC) self-contained processor, that has three primary constituents: an Analog Front-End (AFE) for ECG signal acquisition, amplification and filtering, a 12-bit Analog to Digital Converter (ADC) that converts the analog ECG signal into a digital format, and a custom Digital Signal Processing (DSP). DSP is responsible for various ECG processing tasks such as signal filtering, feature extraction, waveform analysis and motion artifact removal. The artifact removal is aided by an accelerometer, which provides time-dependent data on the patient’s movements. Typically, fast and excessive motion triggers ECG measurement artifacts, often rendering the signal unreadable. DSP either ignores or heavily filters unreadable ECG segments when excessive motion is encountered. The second, SoC, is dedicated to wireless data transmission and features a low-power Bluetooth Low Energy (BLE) processor, which is responsible for transmitting the data from the ECG SoC and accelerometer to a remote BLE enabled device, such as a smart phone, tablet or notebook computer. The two SoC subsystems are interconnected through a Serial Peripheral Interface Data Bus (SPI). Other EPM sensors that include three-axis accelerometer for patient activity monitoring and a MicroSD memory card for data logging are interfaced to the BLE SoC through a second SPI interface. The system is powered by two 3.7-V coin lithium polymer (Li-Po) batteries with a total capacity of 400 mAh.

**ECG patch monitor data processing**

The ECG SoC is a sophisticated processor capable of real-time data processing tasks such as QRS and optimized R-wave detection. The QRS complex is detected using an algorithm based on derivative or band-power extraction. The accurate R peak value detection is accomplished by a continuous wavelet transform algorithm optimized for reduction of the motion artifacts. The data from the sensors can be sampled individually or simultaneously depending on the mode of operation. The power consumption of the EPM has been estimated to be 1 mA at 3.7 V during streaming of ECG data, heart rate and acceleration data simultaneously.

**Patient interface**

EPM electronics is attached to the skin via an adhesive carrier with embedded wet gel electrodes. In a typical present-day configuration, EPM may feature up to three ECG leads. The electrodes within the patch are closely spaced (about 80 mm) to facilitate the placement of the adhesive patch on the body.
surface as shown in Fig 3. The adhesive carrier is typically optimized to last up to 14 days on the skin.

Clinical EPM devices

A number of new EPM devices have recently been announced in various news releases, engineering conference proceedings or Web pages. We have restricted our review to two most representative examples—a ZIO Patch Recorder, which could be best categorized as a single-lead Holter and NUVANT/PiiX event recorder with a data transmission capability. Zio Patch can only continuously record the ECG data, while NUVANT/PiiX performs ECG analysis in real time, stores only the arrhythmic events and transmits some to the caregivers. Both devices that received FDA clearance are now commercially available to the healthcare providers worldwide. Unlike traditional ECG devices, the electrograms acquired from closely spaced EPM electrodes cannot be directly compared to any of the ECG leads in either standard 12-, Mason-Likar or EASI lead configurations commonly used in Holter monitoring. Rather, typical EPM signals from the left pectoral region closely resemble the data obtained by implantable devices, such as the Zio Patch as shown in Fig 2 and characterized by the narrower QRS complexes and suppressed signal morphology.

Zio patch recorder

According to the manufacturer (Zio Patch from iRhythm Technologies of San Francisco, CA), it is a waterproof single-use, long-term cardiac rhythm monitor that provides continuous monitoring for up to 14 days (Fig 3).

The Zio Patch is a single-channel EPM recorder with a memory of up to 14 days of stored rhythms. The frequency response of Zio Patch is 0.15–34 Hz, input impedance is greater than 3 MΩ, differential range is ±1.65 mV and the resolution is 10 bits.

The Zio Patch uses a patch carrier that is placed on the left pectoral region. The patch does not require patient activation. However, a button on the patch can be pressed by the patient to mark a symptomatic episode. The manufacturer states that it is indicated for use in patients who may be asymptomatic or who may suffer from transient symptoms (e.g., anxiety, dizziness, fatigue, light headedness, palpitations, pre-syncope, shortness of breath, and syncope). At the end of the recording period, the patient mails back the patch in a prepaid envelope to a central monitoring station. A report is provided to the ordering physician within a few days.

The Zio ECG Utilization Service (ZEUS) system is a comprehensive system that processes and analyzes received ECG data captured by long duration, single-lead, continuous recording diagnostic devices, such as the Zio Patch. The ZEUS...
system uses beat-by-beat QRS detection and a sophisticated rhythm analysis algorithm to detect up to 10 categories of rhythms. ZEUS runs on a cloud-computing platform and can be used to analyze up to 14 days of ECG data more rapidly and accurately than traditional systems. The data processed by the ZEUS algorithm are reviewed by a certified cardiacographic technician to help ensure high accuracy and quality. iRhythm has received Food and Drug Administration (FDA) 510(k) clearance for both the Zio Patch, and the companion ZEUS algorithm and software system.9

NUVANT Mobile Cardiac Telemetry (MCT) system—system overview

The NUVANT® Mobile Cardiac Telemetry (MCT) System is a patient-friendly, wireless-enabled arrhythmia monitor designed to support more effective and timely assessment of suspected non-lethal cardiac arrhythmias, such as atrial fibrillation, in ambulatory patients. It consists primarily of the PiiX® wearable monitoring device, the zLink® portable data transmission device and a Patient Trigger Magnet to enable on-demand collection of ECGs (recordings of heart rhythm). In combination with interpretation services provided by the Corventis Monitoring Center, as well as secure online access to data (for prescribing physicians only), NUVANT MCT enables patient- and physician-friendly arrhythmia detection for up to 30 days at a time (Fig 4).

NUVANT MCT utilizes the water-resistant, wireless and low-profile PiiX sensor to collect data and identify non-lethal cardiac arrhythmias. The sensor samples the ECG Signal at 200 Hz with a resolution of 10 bits. Each PiiX device lasts for up to 7.5 days. Patients in need of longer monitoring
access to ECG information within the recording period need to through the entire recording period. The authors stated, the patch can yield a high-quality artifact-free ECG recording lacking.

patients with detected arrhythmias (60.3% of all patients), 29.9%

The mean wear time was 7.6 ± 3.6 days, and the median diagnostic yield was greater when data from the entire Zio Patch beyond 48 hours for all arrhythmia types.

The authors concluded that, extended monitoring with the Zio Patch for clinical experience [with the Zio Patch] is currently lacking at the present time.

The authors stated that it is not known how well patients can tolerate the patch for 1 to 2 weeks, and whether the patch can yield a high-quality artifact-free ECG recording through the entire recording period. The authors stated, furthermore, that “the clinical implications of not having access to ECG information within the recording period need to be determined.” Documented clinical experience in the scientific literature with NUVANT is lacking at the present time.

Rosenberg et al. compared the Zio Patch with a 24-hour Holter monitor in 74 consecutive patients with paroxysmal atrial fibrillation (AF) referred for Holter monitoring for detection of arrhythmias. The Zio Patch was well tolerated, with a mean monitoring period of 10.8 ± 2.8 days (range, 4–14 days). Over a 24-hour period, there was excellent agreement between the Zio Patch and Holter for identifying AF events and estimating AF burden. Although there was no difference in AF burden estimated by the Zio Patch and the Holter monitor, AF events were identified in 18 additional individuals, and the documented pattern of AF (persistent or paroxysmal) changed in 21 patients after Zio Patch monitoring. Other clinically relevant cardiac events recorded on the Zio Patch after the first 24 hours of monitoring, including symptomatic ventricular pauses, prompted referrals for pacemaker placement or changes in medications. As a result of the findings from the Zio Patch, 28.4% of patients had a change in their clinical management. The authors concluded that the Zio Patch was well tolerated, and allowed significantly longer continuous monitoring than a Holter, resulting in an improvement in clinical accuracy, the detection of potentially malignant arrhythmias, and a meaningful change in clinical management. Moreover, they stated that further studies are necessary to examine the long-term impact of the use of the Zio Patch in AF management. The study concluded that the promising data from this pilot study suggest that the Zio Patch device may represent a more convenient and efficient method of outpatient arrhythmia detection than current methods using Holter monitors, event recorders, or mobile cardiac outpatient telemetry. A second head-to-head randomized comparison for all symptomatic indications has just been completed, with results expected in late 2013.

In another study, Turakhia et al. evaluated compliance, analyzable signal time, interval to arrhythmia detection, and diagnostic yield of the Zio Patch, in 26,751 consecutive patients. The mean wear time was 7.6 ± 3.6 days, and the median analyzable time was 99% of the total wear time. Among the patients with detected arrhythmias (60.3% of all patients), 29.9% had their first arrhythmia and 51.1% had their first symptom-triggered arrhythmia occur after the initial 48-hour period. Compared with the first 48 hours of monitoring, the overall diagnostic yield was greater when data from the entire Zio Patch wear duration were included for any arrhythmia (62.2% vs 43.9%, p < 0.0001) and for any symptomatic arrhythmia (9.7% vs 4.4%, p < 0.0001). For paroxysmal atrial fibrillation (AF), the mean interval to the first detection of AF was inversely proportional to the total AF burden, with an increasing proportion occurring after 48 hours (11.2%, 10.5%, 20.8%, and 38.0% for an AF burden of 51% to 75%, 26% to 50%, 1% to 25%, and <1%, respectively). The authors concluded that, extended monitoring with the Zio Patch for ≤14 days is feasible, with high patient compliance, a high analyzable signal time, and an incremental diagnostic yield beyond 48 hours for all arrhythmia types.

Clinical experience with ECG patch monitors

So far, the clinical outcomes and cost-effectiveness of extended cardiac monitoring by means of the Zio Patch, the ZEUS, NUVANT systems and similar devices have not been shown to be superior to other available approaches. Mittal et al. noted that “clinical experience [with the Zio Patch] is currently lacking.” The author stated that it is not known how well patients can tolerate the patch for 1 to 2 weeks, and whether the patch can yield a high-quality artifact-free ECG recording through the entire recording period. The authors stated, furthermore, that “the clinical implications of not having access to ECG information within the recording period need to be determined.” Documented clinical experience in the scientific literature with NUVANT is lacking at the present time.

In conclusion, although still considered experimental by some, long-term monitoring with the EPM for ≤14 days is feasible. Patch ECG Monitors offer patient-friendly, well-tolerated non-obtrusive, electrode and lead wire-free very long-term recording
capabilities. These new devices allowed significantly longer continuous monitoring than a Holter, resulting in an improvement in clinical accuracy, the detection of potentially malignant arrhythmias, and a meaningful change in clinical management. Further studies are necessary to examine the long-term impact of the use of EPM in AF and other arrhythmia management. As EPM devices get more popular in the market place, we can expect the improvements in their functionality and capabilities.

Statement of Conflict of Interest

The author declare that there are no conflicts of interest.

REFERENCES