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New devices for very long-term ECG monitoring

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Abstract

Present day 24-h Holter monitors have been shown to miss many arrhythmias that may occur infrequently or under specific circumstances. The advancement in electronic and adhesive technologies have enabled the development of first generation wearable long-term 14-day patch ECG monitors that attach directly to the skin and require no electrodes and wires to operate. This new technology is unobtrusive to the patients and offers them unprecedented mobility. It enables very long-term monitoring of critical patients while they are carrying out daily activities. The monitors are waterproof, offer good adhesion to the skin and can operate as either recorders or wireless streaming devices. (Cardiol J 2012; 19, 2: 210–214)

Key words: Holter monitoring, wireless ECG patch, body sensor, long-term monitoring, ECG

Introduction

This review paper describes the representative wearable electrocardiogram (ECG) devices in both recording and wirelessly transmitting categories. A brief overview of their potential applications to the arrhythmia monitoring, ST-T segment changes and management is also provided.

The limitations of the traditional Holter recorders are well known [1] in the literature. Rapidly progressing medical device technology may soon overcome these limitations however and future Holters may have the following characteristics:

- very long recording periods — weeks or even months to accurately capture the arrhythmic episodes, ST changes and long-term dynamic ECG patterns;
- there will be no wires or electrodes on the patient chest;
- very small size will make “wearing” these devices finally possible;
- wireless communication capability for instantaneous reporting of cardiac events during the monitoring period;
- user attachable, water proof patch form;
- extensive signal processing capability for accurate arrhythmia detection and ECG waveform analysis;
- multiple sensors such as accelerometer, temperature, etc., will be included along the ECG application specific integrated circuit (ASIC);
- wireless recharging and/or energy harvesting capability.

The major shortcomings of standard 24 h Holters include poor detection rates of transient arrhythmic events.

Senatore et al. [2] studied incidence of asymptomatic recurrences of atrial fibrillation (AF) by daily transtelephonic (TT) ECG monitoring, as compared with standard ECG and 24-h Holter recording, in patients who underwent radiofrequency catheter ablation (RCA) of AF. Long-term TT ECG was better than standard ECG and 24-h Holter recordings in evaluating AF relapses after RCA, thus decreasing the short-term success of ablation from 86% to 72%. The authors concluded that the absence of symptoms should not be interpreted as absence of AF, as 50% of patients were asymptomatic during at least one AF episode.

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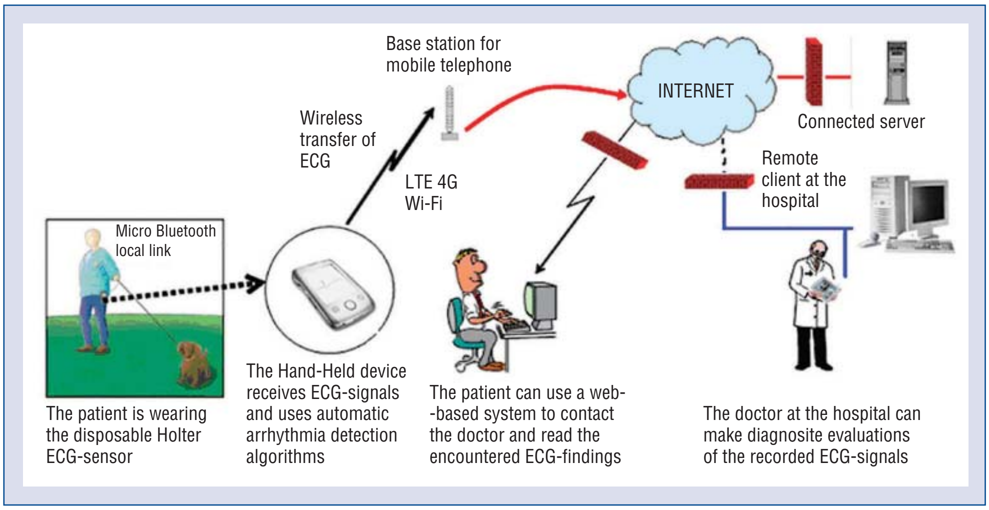

Figure 1. The wearable Patch ECG Monitors runs on a cloud computing platform. The ECG data is transmitted locally from the free living subject wearing a sensor patch to a gateway Hand-Held device via a micro Bluetooth wireless link. The Hand-Held device has enough computing power to perform automatic arrhythmia detection. The alarms together with ECG data are transferred via a fast wireless Internet link to the processing servers where the data is further analyzed and stored. The patient and the doctor access the ECG records on the server via specialized client applications. Adapted from [9].

Piorkowski et al. [3] compared TT ECG every 2 days and serial 7-day Holter as 2 methods of follow-up after AF catheter ablation to determine the ablation success. The success rate in terms of freedom from AF was 70% on a symptom-only-based follow-up; using serial 7-day Holter it decreased to 50% and on TT monitoring to 45%, respectively. Transtelephonic ECG and serial 7-day Holter were equally effective in determining long-term success and to detect asymptomatic patients

Dagres et al. [4] investigated the influence of Holter duration on the detection of recurrences after ablation for AF and reported that a 24-h Holter would have detected 59%, a 48-h Holter 67% and a 72-h Holter 80% of patients with recurrences, whereas a 4-day recording would have detected 91% of the recurrences that were detected with the complete 7-day recording.

Hanke et al. [5] studied the accuracy of cardiac rhythm assessment after surgical ablation therapy as compared to implantable cardiac rhythm monitoring (IMD) device (Reveal XT 9525). Rhythm control readings were derived simultaneously from 24HM Holter and IMD at 3-month intervals with a total recording of 2021 h for 24HM and 220 766 h for IMD. Sinus rhythm was documented in 53 readings of 24HM, but in only 34 of these instances by the IMD in the time period before 24HM readings (64%, $p < 0.0001$), reflecting a 24HR Holter sensitivity of 0.60 and a negative predictive value of 0.64 for detecting AF recurrence. The authors concluded that for "real-life" cardiac rhythm documentation, continuous heart rhythm surveillance instead of any conventional 24HM follow-up strategy is necessary. This is particularly important for further judgment of ablation techniques, devices as well as anticoagulation and antiarrhythmic therapy.

Jabaudon et al. [6] reported that 7-day ambulatory ECG monitoring using an event-loop recording device would detect otherwise occult episodes AF and atrial flutter after acute stroke or transient ischemic attack.

Recent technological advances resulted in development of single use, wearable ECG monitoring devices capable of continuously recording ECG signals for 7, 14 day or even longer periods. Such devices comprise a pressure sensitive adhesive patch with an embedded electronic circuit attached to the patient's chest. The idea behind the wearable Patch ECG Monitors (PEM) is to record ECG signals without visible electrodes and lead wires.

Typical PEM features a very low power, ASIC, wireless network interface and an extremely small footprint. Wearable Patch ECG Monitors may also include motion, temperature and impedance sensors [7, 8]. Together, these sensors provide more patient information than standard 3-lead Holter recorders as shown in Figure 1.

Numerous academic and commercial institutions are presently engaged in development and

Figure 2. Single lead Zio Patch long term wearable ECG recording device comprises two sensors placed 82 mm from each other.

commercialization of PEMs, which fall into two broad categories: (1) recording devices only and (2) recording and transmitting devices [10, 11]. In this paper we'll discuss most representative devices currently commercially available from these two broad categories.

Recording only PEM — single lead

The most representative device in this category is Zio Patch from iRhythm Technologies of San Francisco, California [12]. As per manufacturer's data, it is a waterproof single use, long-term cardiac rhythm monitor that provides continuous monitoring for up-to-14 days (Fig. 2).

By providing a longer time period of continuous recording, the Zio Patch improves the likelihood of capturing arrhythmias and provides for an equal or higher diagnostic yield versus other devices on the market.

The Zio Patch is indicated for use on patients who may be asymptomatic or who may suffer from transient symptoms such as palpitations, dizziness, light-headedness, pre-syncope and syncope, shortness of breath, anxiety and fatigue. The Zio Patch constantly records the heart's electrical activity and was designed to be worn comfortably during normal daily activities, including showering and sleep. The ease of use and inconspicuousness of the Zio Patch helps increase the likelihood that a patient will wear the device for the entire prescribed monitoring period. If the patient has a symptom, they can mark the time of the symptom by pushing a button on the Zio Patch to allow their physician to correlate their symptom with the rhythm of their heart. At the end of the patient's monitoring period, the patient sends the Zio Patch to the iRhythm's processing center for analyzis. Upon receipt of the Zio Patch, iRhythm will provide the physician with a comprehensive easy-to-read report.

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 ten 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 is reviewed by a Certified Cardiographic 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.

Figure 3. Piix multi-sensor, waterproof patch placed on the patient's chest.

Recording and wirelessly transmitting PEM — single lead

NUVANT Mobile Cardiac Telemetry (MCT) System by Corventis, San Jose, California, revolves around the chest worn PiiX electrocardiograph, a high precision single lead ECG, which sends readings to a mobile phone based device for further transmission of the data to a hosted application for clinician's access. The NUVANT MCT System has been designed with a specific focus on ambulatory arrhythmia monitoring, the NUVANT MCT System leverages the low profile form factor, advanced algorithms and multi-sensor capabilities of the PiiX wearable platform to enable continuous monitoring for a broad set of arrhythmias, including AF, as well as patient falls that may be associated with arrhythmias. Patients can also trigger the collection of an ECG, on-demand, upon experiencing symptoms, further aiding in the correlation of symptoms with the ECG (Fig. 3).

All ECGs are transmitted to the Corventis Monitoring Center via the wireless-enabled zLink, for review and response by trained cardiographic technicians as shown in Figure 4. Physicians receive prompt notification of urgent events as well as actionable information in the form of Episode Reports, Daily Reports and End of Use Reports via fax, email and/or the secure www.corventis.com website. Using this information, a physician can diagnose symptomatic and asymptomatic cardiac arrhythmias and proactively manage patients remotely from anywhere across the globe. Corventis has received FDA 510(k) clearance for the NUVANT MCT System.

Other single lead transmitting PEMs include Curvus [13] WIN Human Recorder [14], and Taumaz [15].

Recording and wirelessly transmitting PEM — three lead

Another noteworthy 3-lead device has been developed by IMEC and the Holst Centre [16]. This innovative PEM integrates an ultra-low power ECG chip and a Bluetooth Low Energy (BLE) radio (Fig. 5).

The patch fuses power-efficient electronics and standardized communication. The ECG patch records up to 3 lead ECG signals, tissue-contact impedance and includes a 3D-accelerometer for physical activity monitoring. The data are processed and analyzed locally, and relevant events and information are transmitted through BLE wireless link. The PEM is capable of monitoring, processing and communication on a minimal energy budget. When computing and transmitting the heart rate, the entire system consumes 280 μA at 2.1 V, running continuously for 1 month on a 200 mAh Li-Po battery. When transmitting accelerometer data (at 32 Hz) on top of the heart rate, the power consumption remains below 1 mA in continuous operation, giving about 1 week of autonomy. The PEM uses a communication gateway to mobile devices such as smart phones and tablets. At the heart of the patch is an ECG SoC, a mixed signal ASIC. It is custom designed integrated circuit to provide ECG monitoring and signal processing at extremely low power consumption. In addition to monitoring 1- to 3--lead ECG, the PEM also monitors the contact impedance, providing real-time information on the sensor contact quality. The impedance data can then be used to evaluate the quality of the ECG measurement and to aid in filtering motion artifacts.

The ECG SoC has been designed to run algorithms for motion artifact reduction (based on

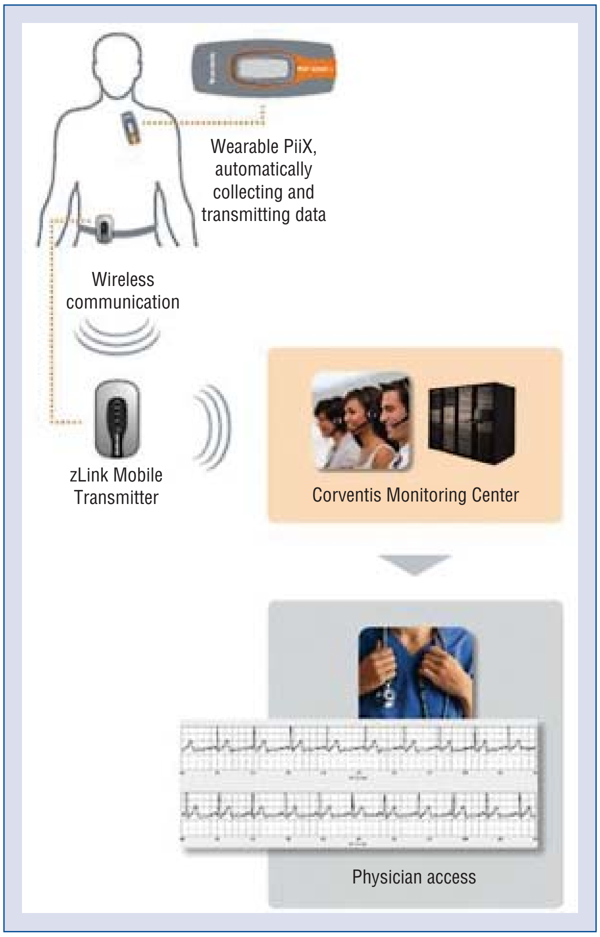

Figure 4. Workflow of the NUVANT Mobile Cardiac Telemetry (MCT) System. The ECG data is recorded by the PiiX patch and sent wirelessly to zLink Mobile Transmitter, which forwards it to the monitoring center. Physicians access the data in the monitoring center via a client application.

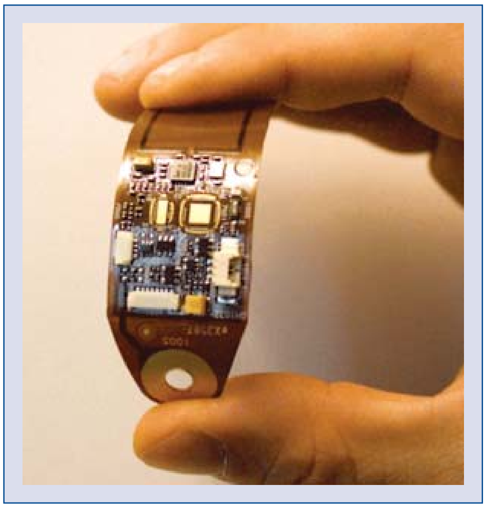

Figure 5. The flexible circuit board of the 3-lead PEM developed by IMEC.

adaptive filtering or principal component analyzis) and beat-to-beat heart rate computation (based on discrete or continuous wavelet transforms). It has additional computation power to run application-specific algorithms such as epileptic seizure detection or arrhythmia monitoring. The built-in 12-bit ADC is capable of adaptive sampling — sampling the QRS segments at high frequency, and the rest of the ECG at a lower frequency thus achieving a data compression ratio of up to 5. IMEC PEM is still undergoing further development and is not available commercially.

Other 3-lead PEMs include V-Patch [17] and Novosense [18].

Conclusions

Patch ECG Monitors offer patient friendly, non-obtrusive, electrode and lead wire free recording environment. PEMs' ability to record ECG data for very long-time periods will allow clinicians to better diagnose arrhythmic events. Present day devices are limited to maximum of 3-leads and these still require a periodic replacement of the electrodes [8]. Of particular interest would be studies analyzing the sensitivity and specificity of the recordings. Another potential limitation of these devices is their problematic measurement artifact immunity and their ability to measure discernible QRS and P waveforms in the presence of noise. As the devices get more popular in the market place, we can expect the improvements in their functionality and more accurate data acquisition. On balance, we can reasonably expect the Patch ECG Monitor technology to evolve and result in wearable 12-lead devices in a near future.

Conflict of interest: none declared

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