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PocketECG: A new continuous and real-time ambulatory arrhythmia diagnostic method

Marek Dziubiński

Medicalgorithmics S.A., Warsaw, Poland

Abstract

This article presents a new approach to ambulatory arrhythmia monitoring, one which can be viewed as a natural evolution of the existing non-invasive methods for diagnosing heart rhythm abnormalities. This new method combines the real-time capabilities of modern mobile cardiovascular telemetry systems with a quantitative way of reporting measured findings and continuous storage of the ECG data typical of Holter monitoring systems. It further combines this with a symptom-reporting capability typical of event monitoring applications. Combining all these features produces a single device which could be described as the ultimate arrhythmia diagnostic tool. (Cardiol J 2011; 18, 4: 454–460)

Key words: arrhythmia, atrial fibrillation, outpatient, monitoring, diagnosis, stroke, syncope

Introduction

Ambulatory monitoring is used to diagnose syncope and palpitations, and identify ventricular ectopy and non-sustained ventricular tachycardia [1]. Atrial fibrillation (AF) has become the commonest indication for ambulatory monitoring, especially to monitor the safety and efficacy of pharmacological and non-pharmacological therapies [2, 3], or to identify asymptomatic AF as an underlying cause of cryptogenic stroke [4, 5].

Ambulatory arrhythmia monitoring was invented by Norman J. Holter [6] in 1949 for diagnosing patients with suspected cardiac arrhythmias. Initially, the device had very large batteries and the tape recorder weighed roughly 75 lbs (35 kg). Clinical use of the device began in the early 1960s [6]. It could record a single lead signal for less than 24 h. The clinical need for time-extended monitoring has resulted in technological advances over the past 50 years. Today, clinicians utilize the latest mobile data transmission technologies, the internet, advanced digital signal processing techniques and artificial intelligence including artificial neural network self-learning algorithms.

Today, clinicians can benefit from real-time access to data and can choose for how long a study should be carried out. Based on the generated results, the monitoring session can be terminated at any time — after a day, a week or even a month — once the conclusive data has been collected. Also, the latest mobile telephony network technologies allow for the transmission of large packets of data, making the devices truly mobile and simpler to use for the patients.

Review of non-invasive ambulatory arrhythmia diagnostic methods

Holter monitoring (HM) systems

HM is a continuous monitoring device that stores the entire ECG signal in memory for further analysis when the patient returns the device to the healthcare provider. Today's HM systems utilize small and lightweight recorders that allow for monitoring over several days or even up to two weeks.

Address for correspondence: Marek Dziubiński, PhD, Medicalgorithmics S.A., ul. Żurawia 22, 00–515, Warszawa, Poland, tel: +48 600 942 992, fax: +48 825 12 49, e-mail: m.dziubinski@medicalgorithmics.com

Storage capacity of the memory cards used by the modern devices is no longer the technological limitation of the monitors. After collecting the data, the digitized ECG signal is downloaded onto a computer and automatically processed using advanced data processing software. The process is supervised by a trained specialist. The biggest advantage of the Holter system is its ability to access continuous ECG data and quantitative representation of the analysis results. HMs automatically recognize PQRST complexes morphology and count all pathological and normal beats. This allows for reporting of the results in a numerical format, where a single page of the report presents results of analysis performed on thousands of heartbeats. The numerical summary is supported by selected ECG sample examples and the entire report normally covers no more than a few pages, which saves the physician's time, and is thus cost-effective. Another advantage of HM is its ease of use for the patient — the recording does not require the patient to transmit the data or charge the batteries of the monitor.

The biggest limitation of this monitoring method is an inability to access the ECG data in real time — the recording duration has to be determined in advance. Another limitation of HM for an extended period of time is ECG signal quality and lack of compliance from the patient, something that is a particular problem for monitoring sessions longer than 24/48 h [7, 8]. Since this monitoring method does not allow for accessing data in real time, it is impossible to control the recording quality, making it impractical to use the devices for an extended period of time [1, 9–12].

Event monitoring: Non-looping memory (EMNL) systems

EMNLs are patient-activated intermittent monitoring systems that do not require the patient to constantly wear electrode patches. Once the symptomatic event occurs, the device should be attached to the patient's skin e.g. chest, thumbs, wrists, etc. to store the relevant ECG data. Then the stored data has to be transmitted via a telephone to the healthcare provider for analysis. The biggest advantage of this type of device is that they are comfortable for the patient and are suitable for patients with sensitive skin, or for patients unable to manage the electrode patches. Normally, EMNLs have up to 6 min of memory, and can be used for an extended period of time and allow for almost real-time access to the data, which is another advantage of this monitoring method.

The biggest limitation of the intermittent non-looping memory monitor is the delay in recording the symptomatic ECG data: when the patient feels the symptom, places the monitor, and then presses the button, it is often too late to capture the event. This type of monitor is not intended to capture pre-event data. Another limitation of EMNLs is related to compliance, in that they require some level of technical skill from the patient. The patient has to be able to transmit the ECG through a landline phone, by playing the frequency modulated signal. Also, the patient has to remember to have the monitor with him/her at all times [13]. Used infrequently, patients can forget how to use the device. Another limitation is inability to capture asymptomatic events and inability to report arrhythmias in a quantitative/numerical format. The latter means that in cases of frequent transmission, the clinician requires a lot of time to interpret the final/summary report.

Event monitoring: Looping memory (EML) systems

EMLs are also patient-activated (symptomatic) intermittent monitoring systems. The device has a built-in looping memory in which the ECG signal is constantly stored, with the oldest ECG samples being overwritten by the newest. EMLs overcome the biggest limitation of EMNLs in that they allow for transmission of the pre-event signal, recovered from the internal looping memory buffer. The intermittent looping memory monitors are used for diagnosing patients with infrequent symptoms [14, 15], drug management, etc. In order to capture the pre-event information, the patient has to wear the monitor constantly with electrode patches attached to the skin, which may cause irritation and allergic reactions. Other limitations of EMLs are similar to the limitations of the non-looping monitoring systems and include:

- limited internal memory, meaning inability to store continuous ECG;
- inability to automatically capture asymptomatic events;
- patient compliance: data has to be sent trans-telephonically;
- inability to report arrhythmias in a quantitative format: reports may be extensive in size;
- high cost of report interpretation: the physician has to review a significant number of reported ECG strips;
- interaction from the patient may be required to charge the batteries of the monitor.

Atrial fibrillation auto-trigger monitoring (AFM) systems

The next step in the evolution of the intermittent monitoring systems is represented by AFMs. This type of device is used for real-time monitoring over an extended period in order to detect infrequent arrhythmias. The devices allow for storage and transmission of symptomatic and limited types of asymptomatic events [16]. Similarly to EMLs, this type of monitor has a built-in looping memory for storing pre-event data, but also a built-in Central Processor Unit that operates a simple ECG analysis algorithm for measuring the patient's heart rate (HR). Based on the HR or R-R interval criteria, the algorithm triggers storage of an event, i.e. when the rate or the R-R interval falls below or exceeds a specified threshold, or is irregular, then the software makes a decision to record an ECG strip. All the stored events are daily transmitted to a healthcare provider. The algorithms embedded in the AFM devices operate in real time, and do not have the capability to recognize morphology of the PQRST complexes. So, they cannot be used to detect ventricular arrhythmias, which is their significant limitation compared to the Holter systems. The inability to classify the ECG morphology does not allow for robust discrimination of the real ECG beats from artifacts and other ECG disturbances, and may lead to inaccurate measurements of HR or R-R intervals. Except for the ability to store/transmit some of the asymptomatic events, the limitations of AFMs are similar to the limitations of EMLs and include:

— limited internal memory means inability to store continuous ECG;
— potential skin irritation caused by the electrode patches;
— patient compliance: data has to be sent trans-telephonically;
— inability to report arrhythmias in a quantitative format: the reports may be extensive in size in case of frequent transmissions;
— high cost of report interpretation: the physician has to review a significant number of reported ECG strips;
— interaction from the patient is required to charge the batteries of the monitor.

Mobile cardiac telemetry (MCT) systems

The newest incarnation of intermittent ECG monitoring system is the MCT. Mobile cardiac telemetry systems, as with all other intermittent monitors, are used for real-time monitoring over an extended period of time. MCTs are similar to AFMs, but have a larger built-in memory that can store more than 24 h of data. In addition, the device periodically triggers transmission of 30 s ECG strips, so called 'trending strips'. These strips are sent every 10 min and are used for creating HR and AF burden trends. Similarly to AFM devices, MCTs utilize a simple real-time ECG interpretation algorithm that detects a limited number of arrhythmias based on the rate and R-R interval criteria. Patients have the capability to transmit symptomatic events in a similar manner to all other intermittent monitoring systems. Another advantage of the MCT devices is the fact that they use the mobile telephony network infrastructure for data transmission. This makes them simpler to use for the patient, because there is no need to record events and then send them via a landline phone to the monitoring center/healthcare provider.

The transmission of the digital files uses file transfer protocol and does not degrade the ECG quality, which is another advantage of this technology. Also, once an event is detected, then the transmission/upload is performed inside or outside the patient's home, assuming sufficient mobile network coverage. This means that the patient can be truly mobile and minimizes any delay between event occurrence and actual transmission. The biggest advantage of the MCT device is its ability to produce basic quantitative information regarding HR and AF burden. This is useful for monitoring post--AF-ablation patients, patients undergoing antiarrhythmic drug therapy, or for detecting asymptomatic AF [12]. Yet at the same time the methodology used for obtaining the quantitative information, i.e. the methodology used for constructing the HR and AF burden trends, is controversial and may be misleading for the interpreting physician. This could be considered as the biggest disadvantage of MCTs. The MCT trends are calculated from the *trending strips* — ECGs of 30 s duration transmitted every 10 min. This means that in fact the quantitative trending information is extrapolated from 5% of the actual ECG signal, which has significant numerical consequences. The problem has been described in the sampling theorem formulated by Theodor Nyquist in 1924 [17, 18]. The *sampling condition* introduced by Nyquist requires that in case of uniform sampling intervals (e.g. 10 min in the case of MCT trends), the sampled components, i.e. the AF episodes or sections with constant HR, should have duration equal to or longer than $2 \times 10 = 20$ min. If some of the episodes/sections with constant rate are shorter than 20 min, then the extrapolated trend is affected by so-called '*aliasing* error'. This means that if the *sampling condition* is not satisfied, then it is not possible in general to discern an unambiguous signal — in this case the AF burden or HR trend. Any component of the trends shorter than 20 min is indistinguishable from components longer than 20 min.

The *aliasing* error may be illustrated by the following example: if the 30 s ECG sample used for creating one value of the trend contains AF with HR above 180 bpm, then it will be assumed that 10 min of the data contain constant AF with a rate of 180 bpm, while in fact the duration of the episode may have been only 30 s. If similar aliasing errors were repeated several times a day, e.g. if 30 out of a total of 144 *trending strips* transmitted per day contained AF with a rate above 180 bpm, then it would be represented by the MCT trends as 300 min = 5 h of AF with a rate above 180 bpm, while in fact the duration of AF with 180 bpm could be only 15 min.

Another example is detection of paroxysmal AF: AF episodes, if not captured by the *trending strips,* would remain as undetected, which would lead to potentially significant underestimation of the total AF burden. If, similarly as in the first example, 30 out of 144 *trending strips* did not contain AF, then the trend would show 300 min = 5 h of non-AF signal, which is 21% of the total time per day, while in fact it could be only 15 min of non-AF signal, which is 1% of 24 h. Other limitations of MCTs are similar to the limitations of the other intermittent monitoring systems and include:
— potential skin irritation caused by the electrode patches;
— high cost of report interpretation: the physician has to review a significant number of ECG strips included in the summary report;
— interaction from the patient is required to charge the batteries of the monitor.

PocketECG: A new continuous and real-time ambulatory arrhythmia diagnostic method

The 'PocketECG' method utilizes a newly developed real-time and self-learning ECG interpretation algorithm [19] that has the capability of detecting QRS complexes and classifying the heartbeats' morphology in real time with a delay not exceeding 3.5 s. The algorithm's efficacy has been measured using standard ECG signas databases [20–22] in accordance with the ANSI/AAMI EC57:1998/(R)2003 requirements. AF detection efficacy yields are: AF Se, AF+P: 94.6% and 95.1% respectively. QRS detection and morphology classification efficacy yields are: QRS Se, QRS+P, VEB Se and VEB+P: 99.6%, 99.7%, 93.5% and 93.5% respectively for the AHA database [22] and 99.6%, 99.5%, 94.1% and 91.4% respectively for the MIT-BIH database [22].

Technical challenges of the new approach

The achieved efficacy is comparable to that of the most effective Holter system. However, these results are generated in real-time with a 3.5 s delay, while the Holter applications work in an *offline setup* — the signal has to be collected first and then processed. Obtaining this level of accuracy in a *real-time setup* is a major technical challenge, and from a digital signal processing algorithm design perspective it is a more complex challenge. The complexity is caused by the fact that the algorithm has to have the ability to automatically learn the signal and create its own morphology templates, based on which all classification decisions are made autonomously. Prior to creating the templates, one of the crucial elements of the preprocessing stage is an effective way of discriminating useful ECG signal from disturbances and broadband noise. The developed ECG interpretation engine utilizes an unpredictability measure (UM) algorithm [23] — a technique used in advanced psychoacoustics and perceptual audio coding applications. The UM algorithm can be successfully applied to ECG preprocessing, because the ECG signal has a quasi-periodic character similar to that of audio waveforms. This means that the chaotic/random phase of complex numbered spectrum components represents parasite noise and therefore can be distinguished using the UM method. The unpredictability value of the complex numbered spectral bin is calculated in the following way:

$$\alpha_k^t = \frac{\sqrt{\left(r_k^t \cdot \cos\Phi_k^t - \hat{r}_k^t \cdot \cos\hat{\Phi}_k^t\right)^2 + \left(r_k^t \cdot \sin\Phi_k^t - \hat{r}_k^t \cdot \sin\hat{\Phi}_k^t\right)^2}}{r_k^t - \left|\hat{r}_k^t\right|}$$

For r_k^t denoting spectral magnitude and Φ_k^t denoting phase, both at time t, while $\hat{r}_k^t$ and $\hat{\Phi}_k^t$ represent the predicted values of Φ_k^t, and are referred to the past information — calculated for two previous signal sample frames:

$$\alpha_k^t = \begin{cases} \hat{r}_k^t = r_k^{t-1} + \left(r_k^{t-1} - r_k^{t-2}\right) \\ \Phi_k^t = \Phi_k^{t-1} + \left(\Phi_k^{t-1} - \Phi_k^{t-2}\right) \end{cases} \Rightarrow \begin{cases} \hat{r}_k^t = 2 \cdot r_k^{t-1} - r_k^{t-2} \\ \Phi_k^t = 2 \cdot \Phi_k^{t-1} - \Phi_k^{t-2} \end{cases}$$

Spectrum of three consecutive periods of ECG is shown in the upper part of Figure 1. The UM graph calculated for all spectrum bins is shown in the lower part of Figure 1.

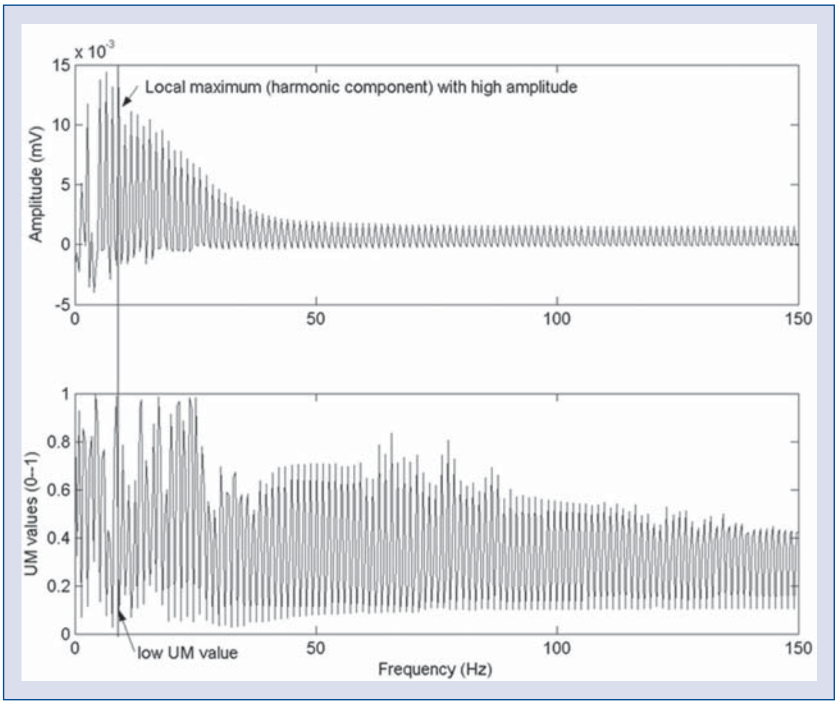


Figure 1. Spectrum (upper) and unpredictability measure (UM) graph (lower) of clean ECG waveform.

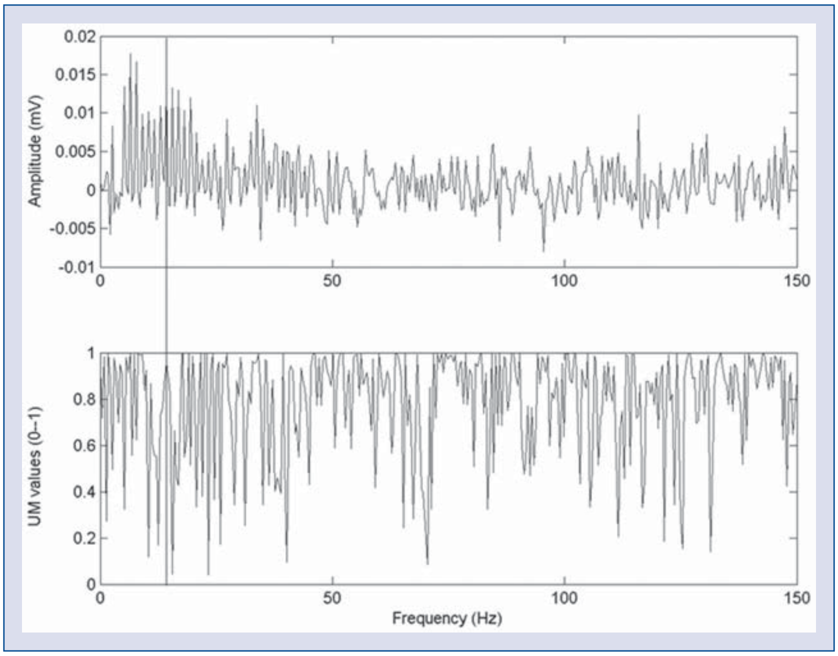
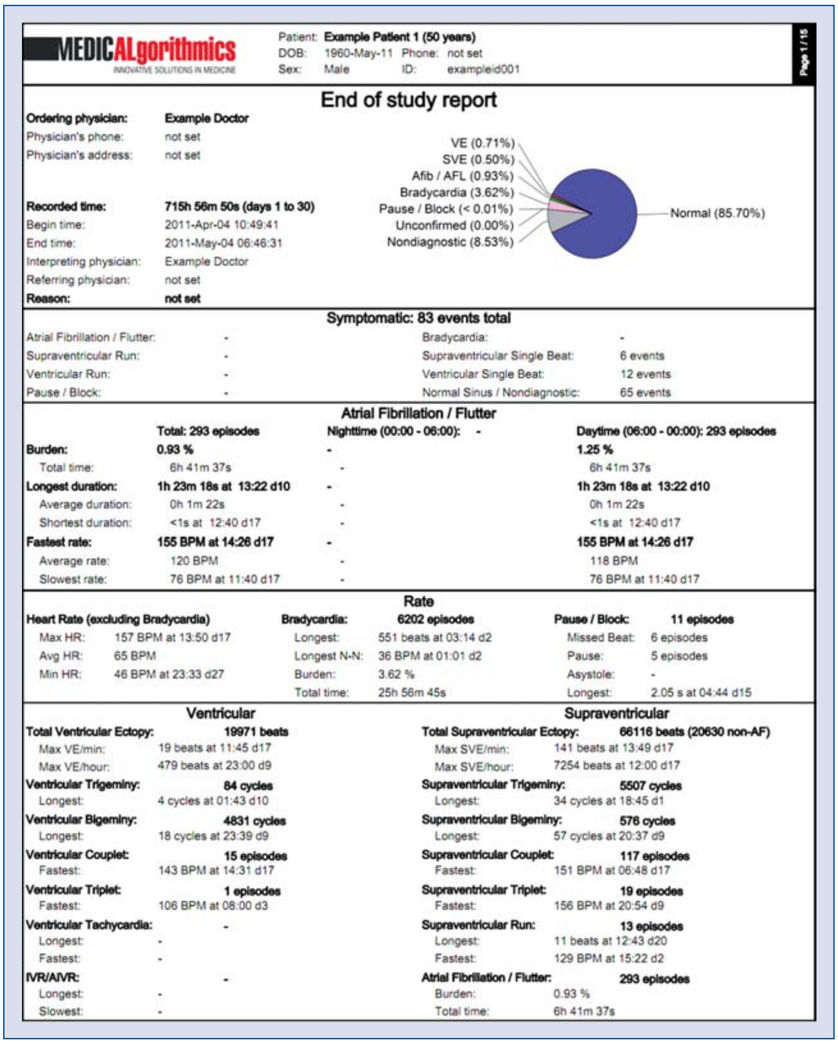


Figure 2. Spectrum (upper) and unpredictability measure (UM) graph (lower) of noisy ECG waveform.

The spectrum and the UM curve of the same signal, but contaminated with artificially added Gaussian white noise, are shown in Figure 2.

It can be seen that the local maxima of the spectrum from the upper part of Figure 1 correspond with the local minima (low UM values) from the lower part of Figure 1. In the noisy signal from Figure 2, the high magnitude level of the spectrum bins presented in the upper part does not correspond with the low UM values shown in the lower part. Since the



MEDICALgorithmics INNOVATIVE SOLUTIONS IN MEDICINE

Patient: **Example Patient 1 (50 years)**
DOB: 1960-May-11 Phone: not set
Sex: Male ID: exampleid001

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End of study report

Ordering physician:	**Example Doctor**
Physician's phone:	not set
Physician's address:	not set
Recorded time:	**715h 56m 50s (days 1 to 30)**
Begin time:	2011-Apr-04 10:49:41
End time:	2011-May-04 06:46:31
Interpreting physician:	Example Doctor
Referring physician:	not set
Reason:	**not set**

Symptomatic: 83 events total

Atrial Fibrillation / Flutter:	-	Bradycardia:	-
Supraventricular Run:	-	Supraventricular Single Beat:	6 events
Ventricular Run:	-	Ventricular Single Beat:	12 events
Pause / Block:	-	Normal Sinus / Nondiagnostic:	65 events

Atrial Fibrillation / Flutter

	Total: 293 episodes	**Nighttime (00:00 - 06:00): -**	**Daytime (06:00 - 00:00): 293 episodes**
Burden:	**0.93 %**	**-**	**1.25 %**
Total time:	6h 41m 37s	-	6h 41m 37s
Longest duration:	**1h 23m 18s at 13:22 d10**	**-**	**1h 23m 18s at 13:22 d10**
Average duration:	0h 1m 22s	-	0h 1m 22s
Shortest duration:	<1s at 12:40 d17	-	<1s at 12:40 d17
Fastest rate:	**155 BPM at 14:26 d17**	**-**	**155 BPM at 14:26 d17**
Average rate:	120 BPM	-	118 BPM
Slowest rate:	76 BPM at 11:40 d17	-	76 BPM at 11:40 d17

Rate

Heart Rate (excluding Bradycardia)		**Bradycardia:**	**6202 episodes**	**Pause / Block:**	**11 episodes**
Max HR:	157 BPM at 13:50 d17	Longest:	551 beats at 03:14 d2	Missed Beat:	6 episodes
Avg HR:	65 BPM	Longest N-N:	36 BPM at 01:01 d2	Pause:	5 episodes
Min HR:	46 BPM at 23:33 d27	Burden:	3.62 %	Asystole:	-
		Total time:	25h 56m 45s	Longest:	2.05 s at 04:44 d15

Ventricular		**Supraventricular**	
Total Ventricular Ectopy:	**19971 beats**	**Total Supraventricular Ectopy:**	**66116 beats (20630 non-AF)**
Max VE/min:	19 beats at 11:45 d17	Max SVE/min:	141 beats at 13:49 d17
Max VE/hour:	479 beats at 23:00 d9	Max SVE/hour:	7254 beats at 12:00 d17
Ventricular Trigeminy:	**84 cycles**	**Supraventricular Trigeminy:**	**5507 cycles**
Longest:	4 cycles at 01:43 d10	Longest:	34 cycles at 18:45 d1
Ventricular Bigeminy:	**4831 cycles**	**Supraventricular Bigeminy:**	**576 cycles**
Longest:	18 cycles at 23:39 d9	Longest:	57 cycles at 20:37 d9
Ventricular Couplet:	**15 episodes**	**Supraventricular Couplet:**	**117 episodes**
Fastest:	143 BPM at 14:31 d17	Fastest:	151 BPM at 06:48 d17
Ventricular Triplet:	**1 episodes**	**Supraventricular Triplet:**	**19 episodes**
Fastest:	106 BPM at 08:00 d3	Fastest:	156 BPM at 20:54 d9
Ventricular Tachycardia:	**-**	**Supraventricular Run:**	**13 episodes**
Longest:	-	Longest:	11 beats at 12:43 d20
Fastest:	-	Fastest:	129 BPM at 15:22 d2
IVR/AIVR:	**-**	**Atrial Fibrillation / Flutter:**	**293 episodes**
Longest:	-	Burden:	0.93 %
Slowest:	-	Total time:	6h 41m 37s

Figure 3. Example of front page of summary report of PocketECG, the new arrhythmia diagnostic method.

sinusoidal components forming the clean, quasi-periodic ECG waveform contain the most signal energy, they are reflected by the UM values close to zero. Hence, the UM weighted noise energy estimate for time t can be estimated in the following way:

$$E^t = \left(1 - \frac{\sum_{k=1}^{K}\left(1-\alpha_k^t\right)\cdot\left|X_k^t\right|^2}{\sum_{k=1}^{K}\left|X_k^t\right|^2}\right)\cdot\sum_{k=1}^{K}\left|X_k^t\right|^2$$

where: X is the ECG block spectrum, t is the time instance, k is the spectrum bin index and E the is noise energy estimate.

Advantages and disadvantages of the new arrhythmia diagnostic method

The main advantage of the new method is that it combines the main advantages of the continuous method of Holter diagnostics with the advantages of all the real-time, intermittent diagnostic solutions. The new method automatically recognizes PQRST morphology and counts all of the pathological and normal beats. The report format of the new method is presented in Figure 3. The device streams the entire ECG signal through the mobile telephony network for instant access. The system allows for reporting the results in a numerical format, similarly to Holter applications, where the front page of the report summarizes the analysis of results of hundreds of thousands of heartbeats collected over several weeks (Fig. 3).

The report can be supported by selected ECG examples, as in the Holter systems. This way of presenting the diagnostic results saves the physician's time, hence reducing the report interpretation cost. Patients have the capability to mark symptomatic events, similarly as with all the reviewed intermittent monitoring systems. But correlation of the symptomatic events with the asymptomatic events is summarized using the numerical format on the front page of the report (see the Symptomatic section in Fig. 3). Since it is a real-time method, it allows for remote and real-time access to the beat--by-beat, hourly and daily HR and AF burden data.

It is especially useful for monitoring post-AF--ablation patients, patients undergoing antiarrhythmic drug therapy, or for detecting asymptomatic AF. It also allows for real-time access to detailed analysis results related to all other arrhythmias, including supraventricular and ventricular events (Fig. 3). All of the arrhythmia statistics, including AF burden and AF rate analysis, are based on the detection of single ECG beats, similarly as in the Holter applications i.e. the results are not extrapolated from limited/sampled data. The limitations of the PocketECG system include:

— potential skin irritation caused by the electrode patches;
— required interaction from the patient to charge the batteries of the monitor.

Conclusions

The new continuous and real-time ambulatory arrhythmia diagnostic system presented in this article overcomes most of the limitations typical of the existing non-invasive ambulatory arrhythmia diagnostic methods. It provides numerical/quantitative reporting capabilities and access to a continuous ECG signal, similarly to the Holter applications, combined with the capability of monitoring patients over an extended period and with the capability to access the data and the diagnosis results in real-time.

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