



ePatch® - A Clinical Overview

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ePatch® - A Clinical Overview

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We help ideas meet the real world



ePatch® - A Clinical Overview

ePatch Research Unit*

I. WHY DELTA DESIGNED THE EPATCH

Since the first Holter recorders were invented in the 1940s there has been a tremendous development in the capabilities for ambulatory ElectroCardioGraphic (ECG) monitoring. A detailed overview of the different monitoring techniques is provided in [1] and [2]. Many applications of the older technologies induce significant issues related to patient comfort, duration of the monitoring period, and the integrity of the recorded data. The event and loop recorders only store ECG data when either a patient trigger system or an automatic event detection system is activated. This prevents full disclosure and investigation of potential dangerous but asymptomatic events which were not correctly detected by the automatic algorithms. This situation is overcome by the continuous Holter and telemetry systems. However, the nature of these systems induces significant issues related to patient comfort and compliance with wearing the systems for extended periods of time. The selection of monitoring technique in each situation was thus a compromise between sufficient diagnostic information from adequate continuous monitoring on one hand, and patient comfort and compliance on the other. The DELTA ePatch system was created to fit right in the middle of this compromise: The ePatch was designed to provide reliable high quality continuous ECG monitoring for long periods of time without any patient discomfort or impairment of normal daily life activities.

The results of a patient satisfaction survey based on ePatch recordings from 169 different patients clearly illustrate how the comfort and daily activity level is not altered by wearing the ePatch system (see Fig. 1). This is achieved due to the “wear and forget” principle that was a key factor during the design phase. As illustrated in Fig. 2, the ePatch system is placed on the chest and consists of two parts: 1) The single-use ePatch electrode, and 2) the reusable ePatch sensor. To increase the comfort, the two

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How did the ePatch recording affect your daily activities?

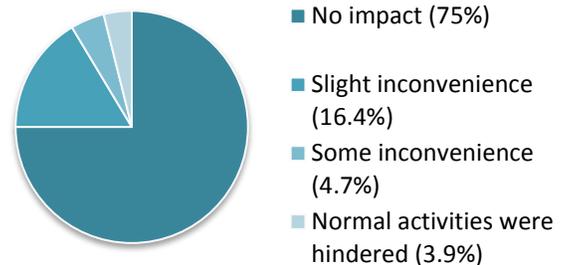


Figure 1. Results from a patient satisfaction survey on 169 different patients undergoing up to 24 hours of continuous ePatch recording. Approximately half of the patients were hospitalized, and the other half were wearing the ePatch system ambulant in their own homes.

parts are connected directly without any cables. The ePatch is thus capable of providing the same clinical information as regular Holter or telemetry equipment. However, this information is gained in a much less intrusive way. This reveals an opportunity to monitor new patient populations, deploy large-scale screening programs, intensified follow-up on known cardiac patients as well as post-operative monitoring, possibilities of close cardiac surveillance of patients in their own homes, and improved surveillance and guidance in rehabilitation and exercise programs.

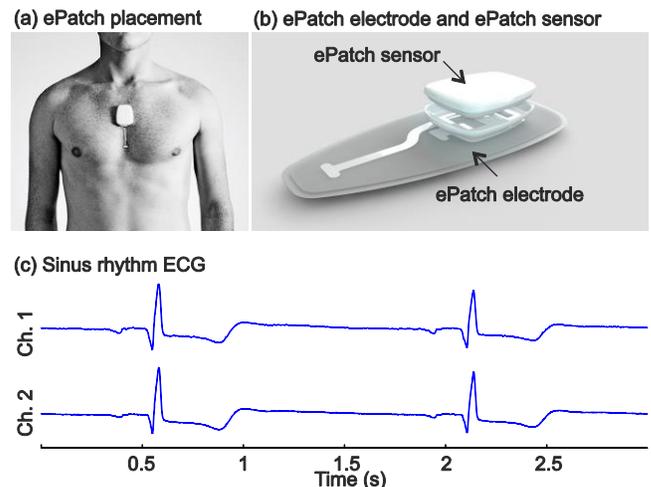


Figure 2. (a) Illustration of the CE marked and FDA approved ePatch system placed on the chest. (b) The ePatch sensor and the ePatch electrode before assembly. The ePatch will automatically start recording after mounting of the system. (c) Illustration of normal sinus rhythm ECG recorded with the ePatch system.

II. CLINICAL INTERPRETATION OF ePATCH ECGS

Reliable interpretation and high quality of the recorded ECG signals are the primary conditions for a successful diagnosis and treatment of the patients. The ePatch ECGs can be visualized and analysed in the exact same ways as ECGs recorded with traditional equipment. Several commercially CE marked and FDA approved Holter analysis software systems are available for regular rhythm analysis of ECG recorded with the ePatch system, e.g. [3] and [4]. An example of a Heart Rate (HR) trend curve, and two ECG strips from a healthy test subject is provided in Fig. 3. This test subject is recruited from a fitness study [5], and the high HR observed in the last hours of the recording is due to high intensity exercise in a fitness centre. It is clearly observed how the HR drops during the night. The relatively low mean HR indicates the fitness level of this test subject. The different stages of sleep are also observed as short peaks in the HR trend curve during the night. The recording illustrates a case of Normal Sinus Rhythm (NSR) with only a few SupraVentricular Ectopic Beats (SVEBs). An example of NSR is illustrated in the first ECG strip and an episode of two SVEBs is illustrated in the second ECG strip. Additional examples of clinical ECGs recorded with the ePatch system are provided in section IV.

The user-friendly design of the ePatch implies that the placement of the electrodes is different from the standard Holter/telemetry electrode locations. In addition, the distance between the recording sites is slightly shorter. This induces small changes in the appearance of the recorded ECGs. However, a variety of clinical studies have demonstrated the possibility of recording of diagnostic relevant ECG using prototype patch devices [6], [7], [8], [9]. To further confirm the clinical quality, diagnostic yield and recognizable appearance of clinically relevant heart rhythms, a number of different clinical studies were conducted with the novel ePatch system. The purpose of the first study was to confirm that individual ECG strips extracted from long-term recordings obtained with the ePatch system can be used for heart rhythm analysis. This application scenario is similar to the traditional Holter analysis applied today, where selected ECG strips are extracted by an experienced ECG technician and provided to the referring medical doctor together with a general description of the findings in the recording. Two medical doctors conducted an individual assessment of seven-second ECG strips which were selected by an experienced ECG technician from 25 randomly selected admitted patients. As illustrated in Fig. 4, the result was that the two medical doctors found as much as 98.5% and 99.5% of the

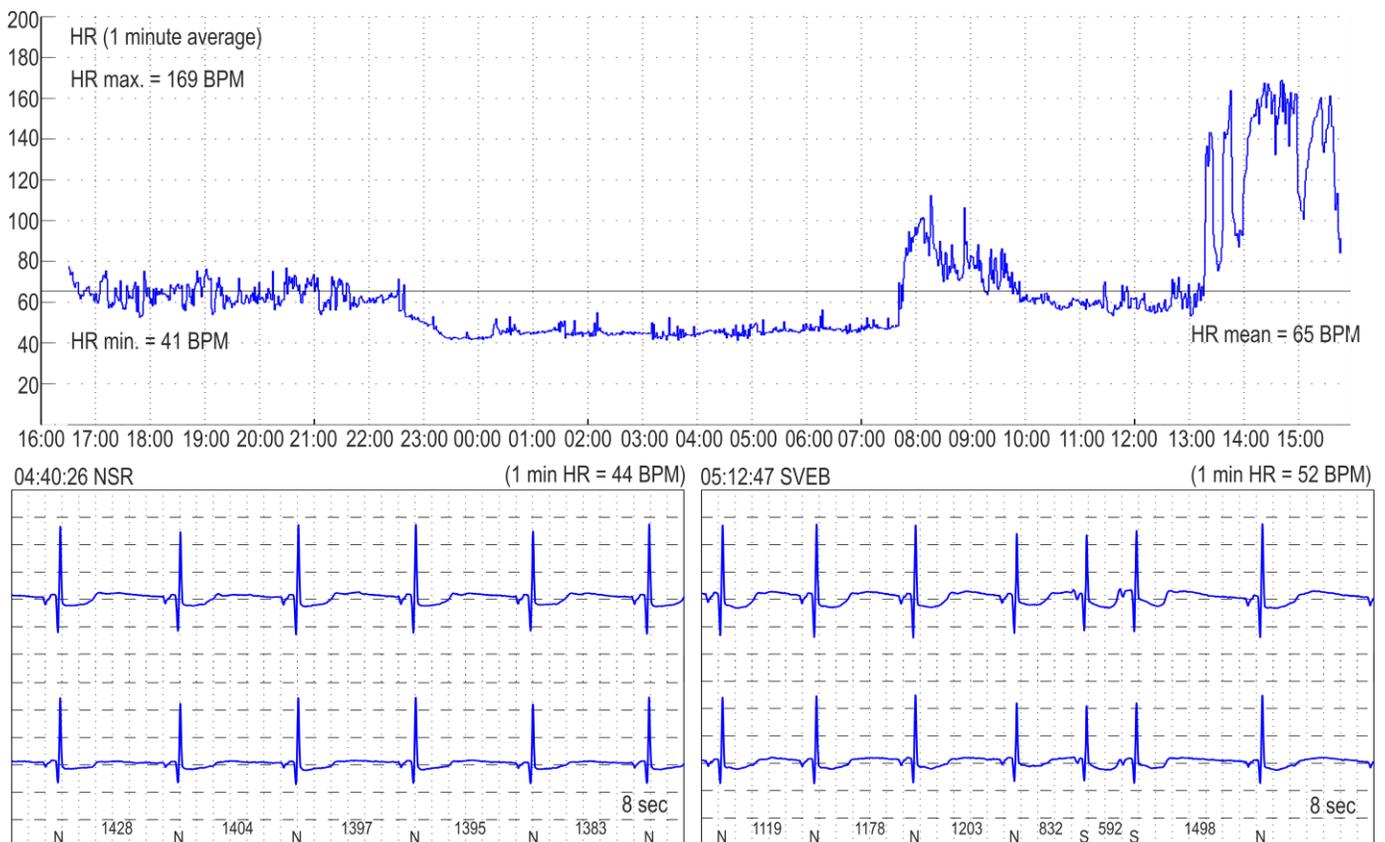


Figure 3. Example of a HR trend curve from a healthy test subject recruited from a fitness study [5]. The HR clearly drops during the night, and increases rapidly in the morning. The different stages of sleep are observed from the short HR peaks during the night. The last couple of hours with relatively high HR were recorded during heavy exercise. The lower plot illustrates two ECG strips extracted from the recording. The first strip illustrates NSR during the night, and the second ECG strip illustrates two SVEB beats.

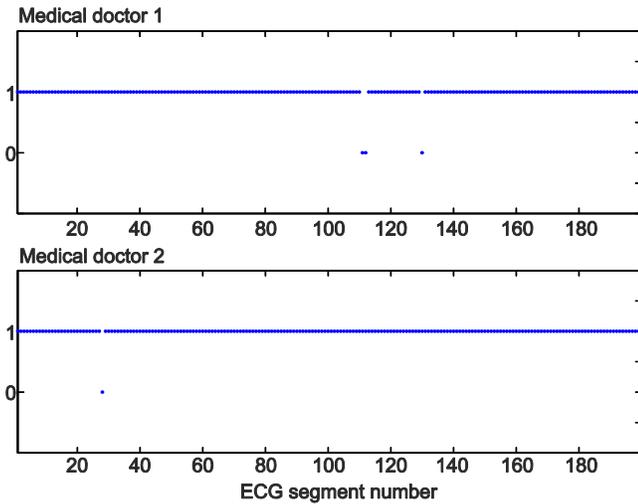


Figure 4. Result from a clinical study investigating the usefulness of two channel ePatch ECG for heart rhythm analysis. Eight segments were selected from 25 different patients, yielding a total of 200 ECG segments. Each of the 200 segments was independently evaluated by two medical doctors. The score 1 indicates that the medical doctor found the segment useful for heart rhythm analysis, whereas the score 0 indicates that he did not find the segment useful for rhythm analysis [10].

segments useful for rhythm analysis [10].

In another clinical study, the overall diagnostic information from a 24-hour ePatch recording was compared with the diagnostic information from simultaneous monitoring with regular telemetry equipment [11]. This comparison was conducted by a cardiologist using 11 randomly selected admitted patients. The cardiologist selected relevant alarm events from the telemetry recording, and these were compared with the same time period of the ePatch recordings to confirm the presence of the arrhythmia event in the ePatch recordings. An example of these comparisons is provided in Fig. 5. The general heart rhythm and HR trend curves were compared as well. For all patients, the same diagnostic information was extracted from the two monitoring techniques. The clinically relevant

TABLE 1. SUMMARY OF CLINICAL FINDINGS USING ePATCH ECG RECORDED ON 169 DIFFERENT PATIENTS. THE RIGHT COLUMN INDICATES THE NUMBER OF PATIENTS THAT DISPLAYED EACH ARRHYTHMIA TYPE.

Arrhythmia type	Number
Atrial flutter (AFL)	5
Atrial fibrillation (AF)	14
Atrio-ventricular block (AV block)	4
Sino-atrial block (SA block)	3
Supraventricular tachycardia (ST)	2
Supraventricular ectopic beats (SVEBs)	50
Ventricular ectopic beats (VEBs)	44

heart rhythms and beats observed in this investigation included NSR, Atrial Fibrillation (AF), paroxysmal AF, pauses, Ventricular Ectopic Beats (VEBs), and SVEBs. Furthermore, ventricular frequencies up to 150 Beats Per Minute (BPM) were represented. This study indicates that ECGs recorded with the ePatch system contain the same diagnostic information as traditional telemetry systems.

In a third clinical study, data from the CE marked ePatch was applied as the primary ECG source. The ECG data was analysed by experienced ECG technicians using the CE marked MyDarwin software [4]. This implies that solely the ECG recorded with the ePatch was analysed in order to gain information about the patients. The study enrolled 169 patients from two different patient groups: 1) 84 patients admitted after apoplexy, and 2) 85 patients that were monitored in their homes as a part of an ambulant PolySomnoGraphy (PSG) recording. A total summary of the overall arrhythmia findings is provided in Table 1. Overall, 17 significant findings were reported (12 in the apoplexy group and five in the ambulant group).

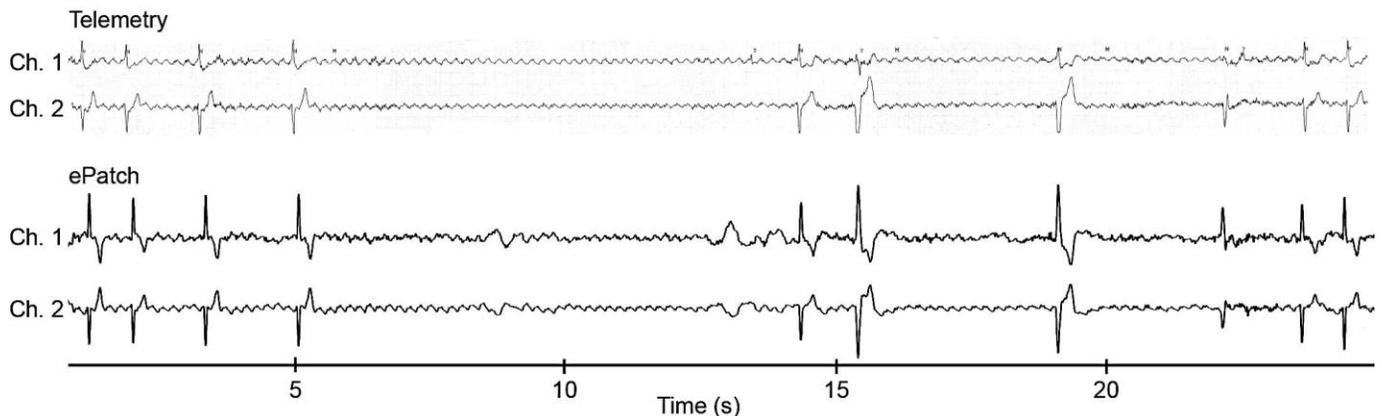


Figure 5. Example of comparison between an alarm event from the traditional telemetry equipment and the corresponding time in the ePatch recording. This case illustrates an episode with 9 seconds pause. The two telemetry ECG channels are provided in the upper traces. The two ePatch ECG channels are provided in the lower traces.

III. CLINICAL USABILITY OF THE ePATCH

As mentioned earlier, the key design goals of the ePatch system were to develop a reliable, safe, comfortable ECG recording system which is easy to use for both the patients and the healthcare providers. This has been accomplished both by the easy handling and mounting of the system, and the cable free design.

A. Mounting of the ePatch

The simple mounting of the ePatch system is illustrated in Fig. 6. The mounting consists of six easy steps: 1) The ePatch sensor and the ePatch electrode are easily attached by clicking the two parts together; 2) The protective plastic back liner is removed from the electrode to expose the adhesive part; 3) The electrode is attached to the skin in the correct position; 4) The assistive front liner is removed from the electrode; 5) The corners of the electrode are carefully pressed to ensure firm adhesion to the skin; and 6) The patient can wear normal clothing immediately after the mounting and throughout the entire recording period. The simple mounting procedure even facilitates the possibility for patients to mount the ePatch and conduct an ambulatory recording themselves, for instance before a follow-up consultation. After the mounting, the ePatch sensor will automatically start recording. Of course, the skin should be

How long time did you spend on mounting the ePatch?

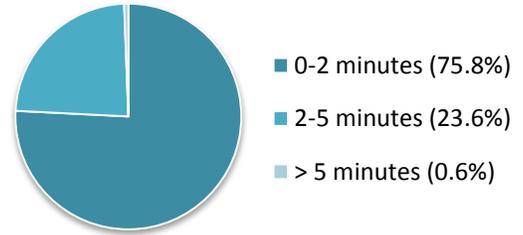


Figure 7. Results from a survey on the mounting time for the ePatch system. The nurses from this survey conducted a total of 169 ePatch recordings during a period of approximately six months.

prepared before mounting. This preparation follows the known procedure from other ECG equipment. The results from a clinical study including a total of 169 patients and three different hospital units show that more than 75% of the recordings were mounted in less than two minutes, and more than 99% were mounted in less than five minutes (see Fig. 7). After the recording, the ePatch system is easily removed from the chest. The ePatch sensor and the ePatch electrode are separated, and the data is extracted from the sensor using a standard USB cable. Studies show that the removal of the ePatch system is conducted in less than two minutes in more than 99% of the recordings.

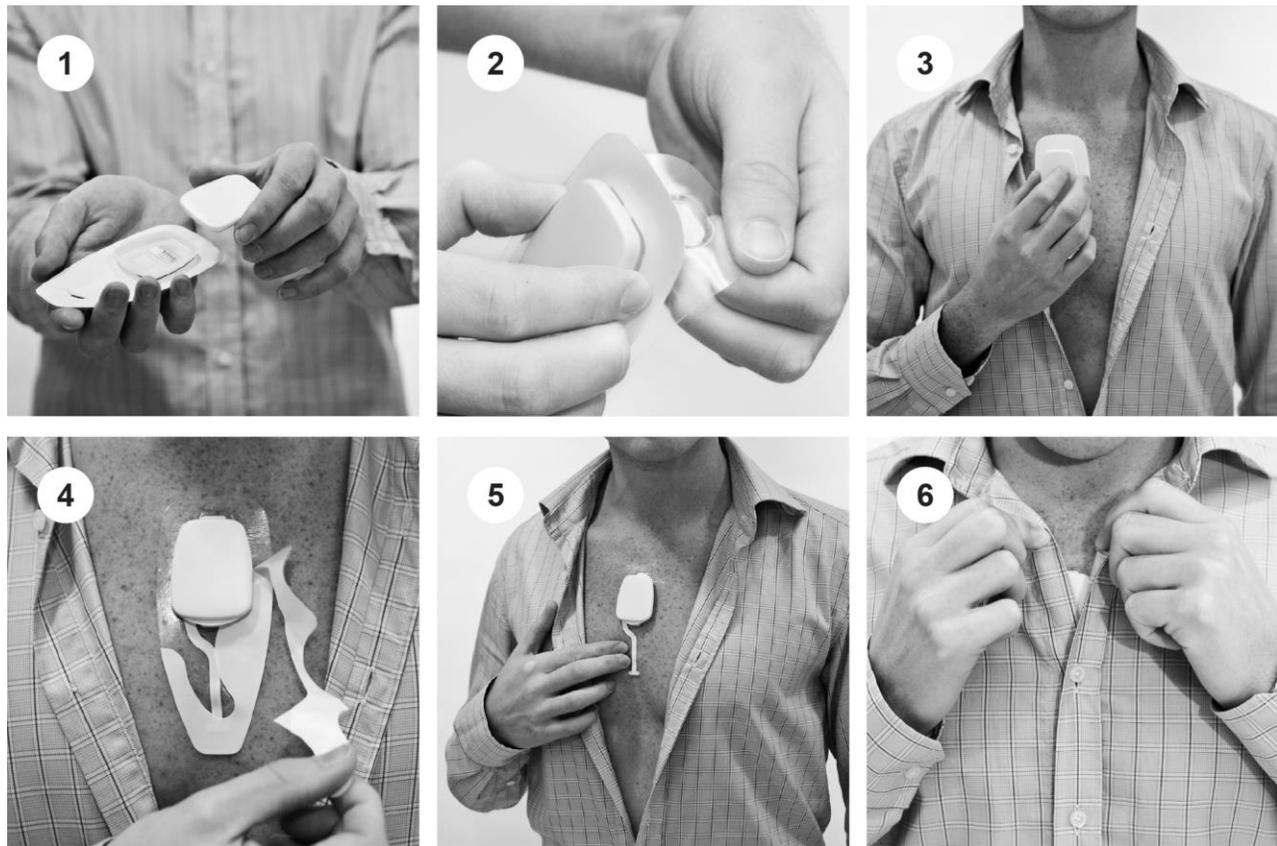


Figure 6. Mounting of the ePatch is carried out in six easy steps: 1) Attach the ePatch sensor to the ePatch electrode by clicking them together; 2) Remove the back liner from the electrode to expose the adhesive part; 3) Place the adhesive electrode in the correct position; 4) Remove the assistive front liner from the electrode; 5) Press carefully around the corners of the electrode to ensure firm adhesion to the skin; and 6) The patient wears normal clothing immediately after mounting and throughout the entire duration of the recording.

B. Patient and Healthcare Provider Satisfaction

The results from a user satisfaction survey based on the 169 ePatch recordings clearly show how the design goals are reached by the ePatch system: 83.6% of the nurses indicated that the ePatch was simpler than the traditional ECG equipment (see Fig. 8). It was also indicated by 75% of the patients that they experienced no impact on their ability to perform normal daily life activities during the recording period (see Fig. 1). Only 3.9% of the patients experienced to be hindered in normal daily activities. Furthermore, another clinical study enrolling 50 patients admitted for cardiac surveillance shows that 92.5% of the patients answering the questionnaire regarding their satisfaction with wearing the ePatch system answered to be “very satisfied”. The remainder patients indicated to be “satisfied”. None of the patients were “dissatisfied” or “very dissatisfied”. Fourteen patients also made additional comments regarding either their non-awareness of wearing the ePatch system or that they preferred the ePatch over the traditional telemetry equipment which was worn simultaneously. These results demonstrate the simplicity of the system and the satisfaction with using the system – from both a patient and healthcare provider point-of-view.

IV. EXAMPLES OF CLINICAL ECGS

This section contains some interesting cases of clinical ECGs recorded with the ePatch system. Each example is illustrated by use of raw unfiltered ECG data recorded with a CE marked ePatch system. Each heart beat is automatically detected with DELTA’s proprietary embedded algorithm. The ECG strips are visualized with standardized square sizes to indicate time and amplitude (two vertical squares indicate 1mV and five horizontal squares indicate 1s). The HR trend curves contain one minute HR averages. Each Lorenz plot indicates the relationship between the current RR interval (time between two subsequent heart beats) and the subsequent RR interval for one hour of the recordings.

How did you find the application of the ePatch compared to traditional ECG equipment?

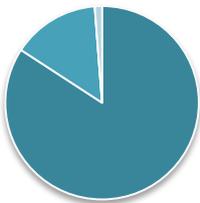


Figure 8. Results from a clinical study regarding the nurse evaluation of the ePatch system compared to traditional ECG equipment: 83.6% of the nurses from three different regular hospital units found the ePatch system simpler than the traditional ECG equipment. A total of 169 ePatch recordings were evaluated for this survey.

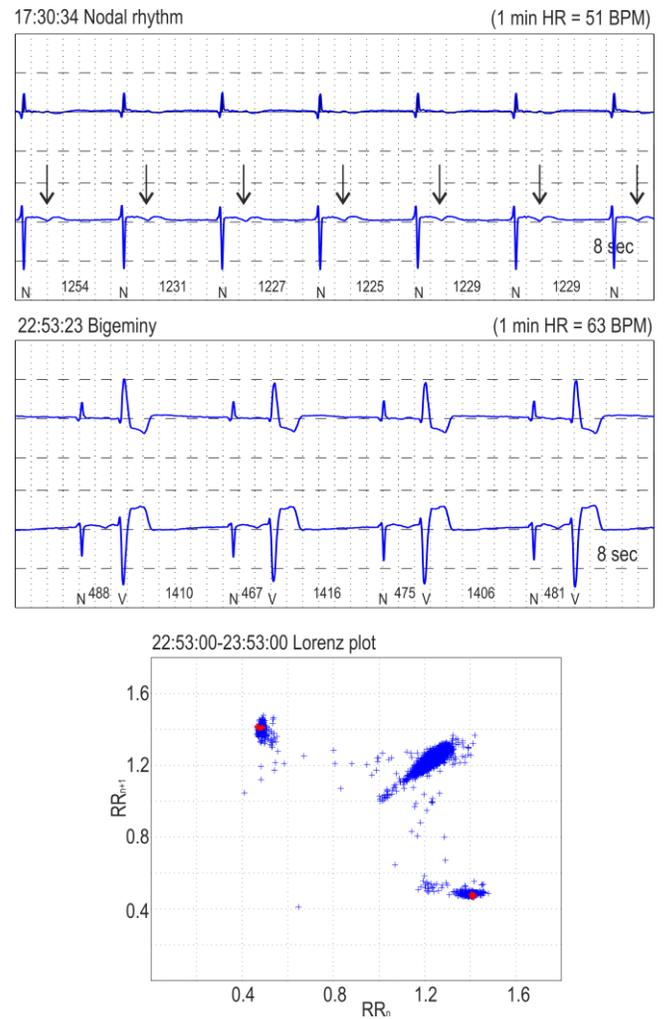


Figure 9. Clinical ECG strips from a patient with nodal rhythm. The retrograde P-waves positioned after the QRS complex are marked with black arrows in the first ECG strip. The lower ECG strip illustrates a case of bigeminy for the same patient. The bigeminy present during this hour is also observed from the Lorenz plot where the red marks indicate the heart beats from the second ECG strip.

Fig. 9 illustrates ECG strips and a Lorenz plot recorded from a patient with nodal rhythm. The nodal rhythm is clearly observed from the first ECG strip. The recording is furthermore described by a high number of VEBs which often are present as bigeminy. This is illustrated in the second ECG strip. The bigeminy is also observed from the Lorenz plot. The red marks in the Lorenz plot indicate the heart beats that are illustrated in the second ECG strip.

Fig. 10 illustrates an overview of a recording on a patient that suffers from paroxysmal AF. The irregular heart rhythm is clearly observed from the first ECG strip, and a case of AF termination, including the sinus recovery period, is represented in the second ECG strip. During the first hour of the recording, there are three shifts from AF to NSR. This is also observed from the sudden drops in the HR trend curve.

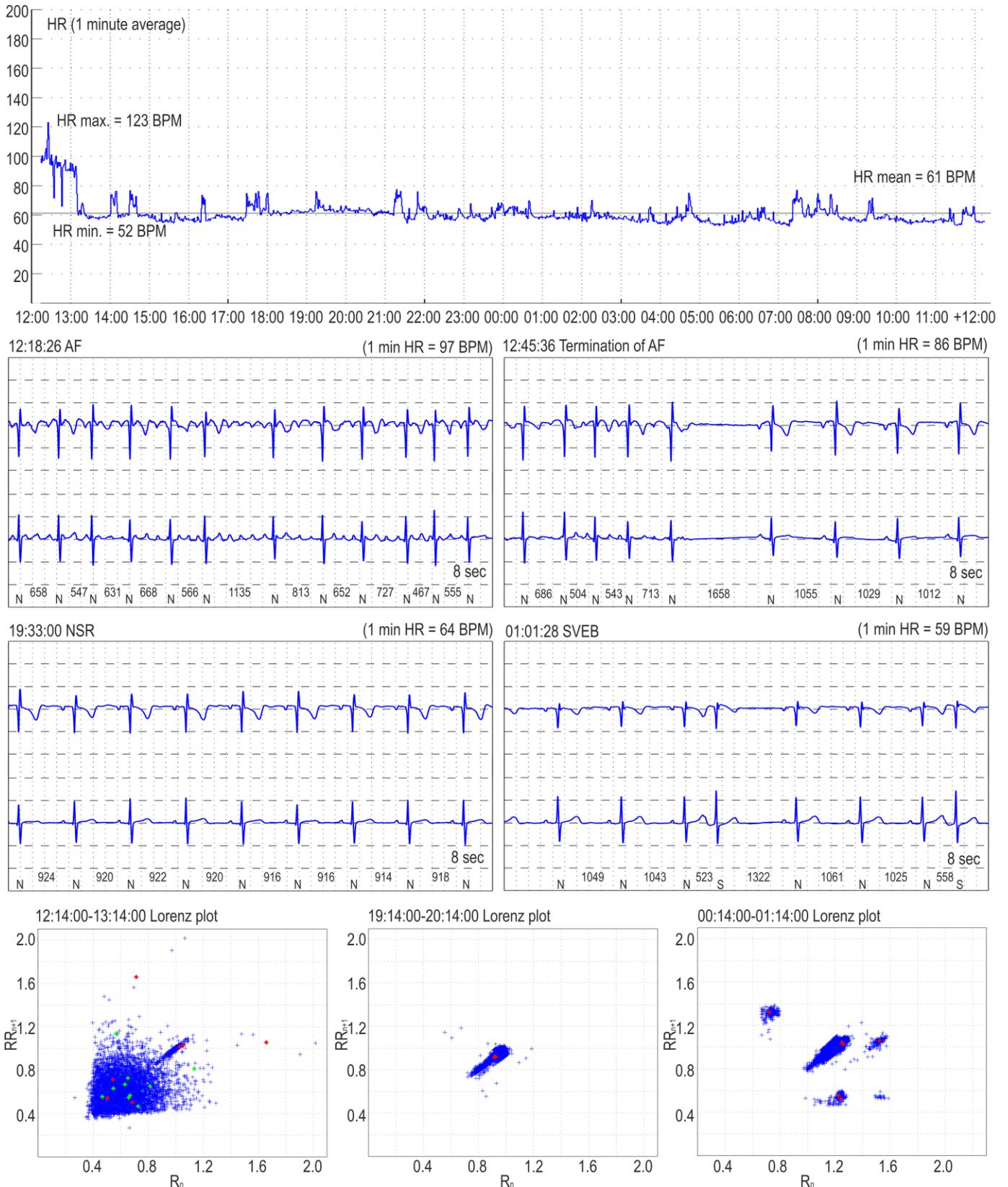


Figure 10. Overview of a clinical ECG recording from a patient with paroxysmal AF. The HR trend curve indicates a high HR in the first hour with a few drops. This part of the recording represents episodes of paroxysmal AF, and the drops in the HR curve represent episodes of NSR. The first ECG strip illustrates a period with AF. The heart beats in this strip are illustrated with green marks in the left Lorenz plot. The red marks in the left Lorenz plot indicate the beats from the second ECG strip that illustrates a case of AF termination. It is observed that the first beats from this ECG strip are placed in the “chaotic AF region” of the Lorenz plot. The sinus recovery period causes two beats to be located away from most other beats, and the last 3 beats are located in the “cigar shaped” area of the Lorenz plot that represents periods of NSR. The third ECG strip illustrates a period of NSR. These beats are indicated by red marks in the middle Lorenz plot. The last ECG strip illustrates a period with two SVEBs. The red marks on the right Lorenz plot illustrate the beats from this ECG strip. The right Lorenz plot generally illustrates that this hour of data contains a very high number of SVEBs.

The first Lorenz plot in Fig. 10 represents both the irregular nature of RR intervals during episodes of AF as well as a “cigar shaped” group of RR intervals which represent the episodes of NSR. The green marks in the first Lorenz plot indicate the heart beats that are illustrated in the first strip. The red marks in the first Lorenz plot indicate the heart beats from the second ECG strip (AF termination episode). The combination from AF to sinus recovery to NSR is observed from the red marks in the first Lorenz plot. The second Lorenz plot is taken from one hour of the recording with primarily NSR and only a few SVEBs. The ECG strip with NSR is marked with red in the second Lorenz plot. The third Lorenz plot is from one hour with a very high

number of SVEBs. This is observed from the four distinct areas in the Lorenz plot. Again, the red marks indicate the heart beats represented in the fourth ECG strip.

An overview of a recording with primarily NSR is illustrated in Fig. 11. The recording contains scattered VEBs as illustrated in the first ECG strip. The second ECG strip illustrates a period of NSR. The patient also has two episodes of 2nd degree AV block during the night. An example of this is illustrated in the third ECG strip. At the end of the recording there is an episode of sinus tachycardia. An ECG segment from the one minute with the highest average HR is presented in the fourth strip. A slight decrease in the HR is observed during the night.

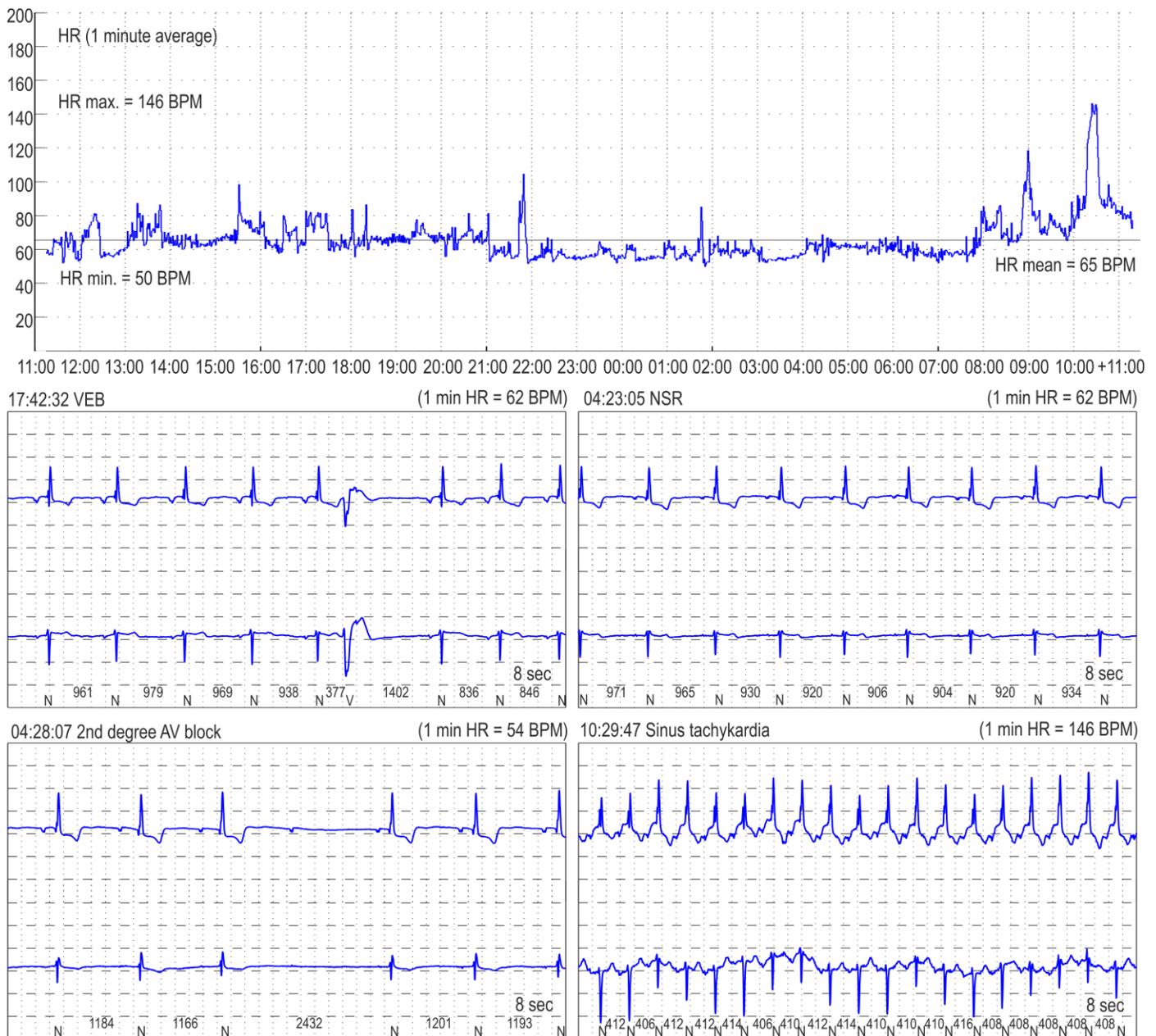


Figure 11. Overview of a clinical ECG recording from a patient with primarily NSR. The recording has scattered VEBs, as illustrated in the first ECG strip, and two cases of 2nd degree AV block, as illustrated in the third ECG strip. The second strip illustrates a period of NSR, and the fourth strip illustrates a data segment from the period with the highest one minute HR.

Another interesting clinical example is illustrated in Fig. 12. This patient suffers from AF during the entire duration of the recording. It is observed from the three Lorenz plots that the nature of the irregularity of the RR intervals differs from the one observed for the patient in Fig. 10. The two ECG strips illustrate examples of AF with different ventricular frequencies. The first strip has a relatively low frequency. The heart beats from this strip are illustrated by red marks in the second Lorenz plot. The second ECG strip illustrates a period of relatively high ventricular frequency. The heart beats from this strip are illustrated by red marks in the third Lorenz plot. It is observed how the different ventricular frequencies are located in different regions of

the Lorenz plots.

The last clinical example is provided in Fig. 13. This patient suffers from AF with a high number of VEBs that are often present as bigeminy.

These clinical examples illustrate how ECG recorded with the ePatch system can be applied to diagnose and monitor patients with different kinds of rhythm disorders. Together with the described results from the clinical studies regarding the ePatch interpretability, this demonstrates that the ePatch system is easily used as a substitute for traditional ECG equipment (e.g. Holter or telemetry recorders). Moreover, the high patient satisfaction facilitates the possibility of very long-term monitoring, and

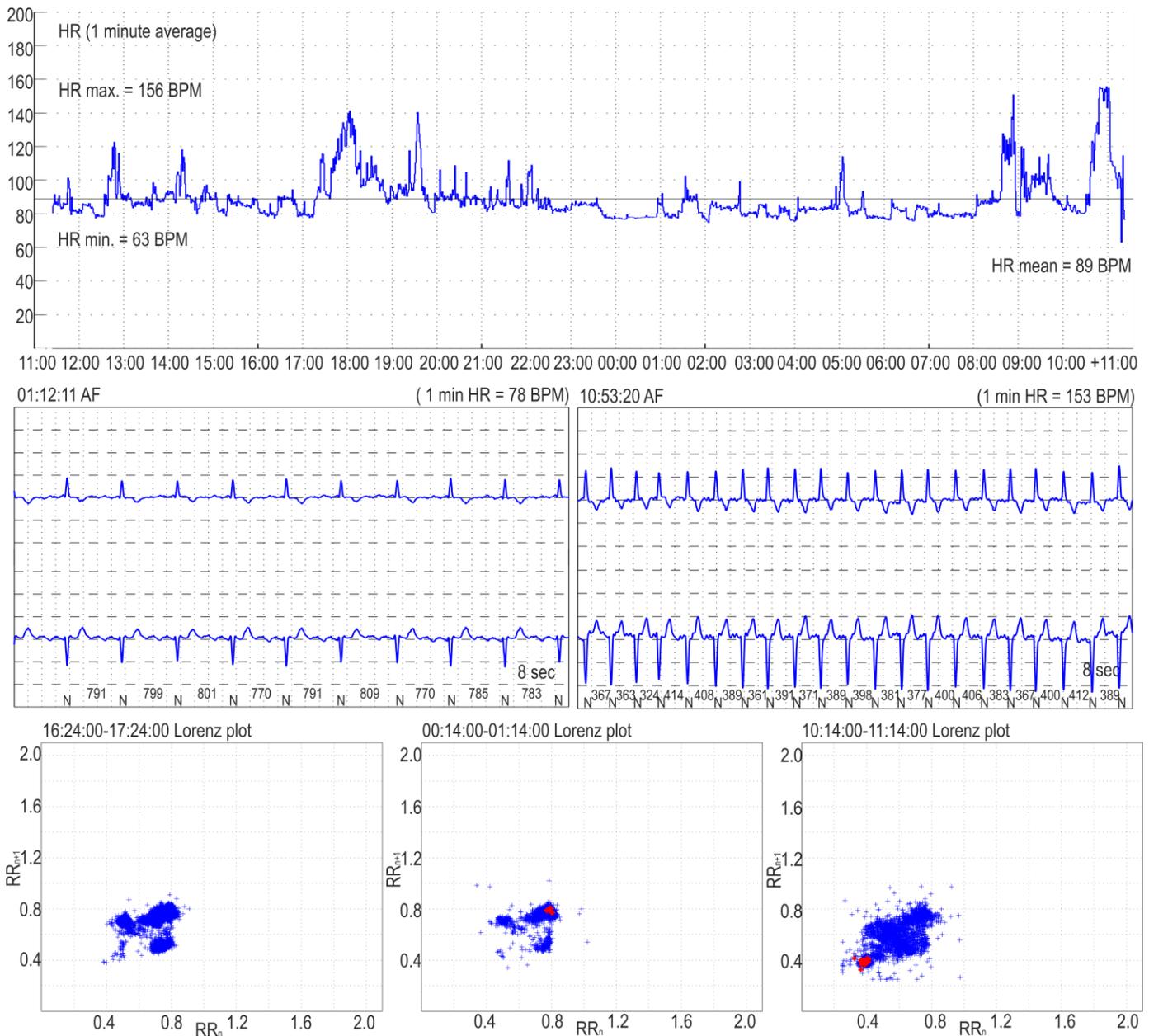


Figure 12. This patient suffers from AF, and the irregularity of the QRS complexes is observed in the three Lorenz plots. The two ECG strips illustrate AF with different ventricular frequencies. The red marks in the second and third Lorenz plots correspond to the heart beats illustrated in the two ECG strips.

consequently improved diagnosis and treatment for a high number of patients where ECG monitoring is not conducted today, or is limited by patient compliance or other obstacles related to the healthcare system.

V. TECHNICAL SPECIFICATIONS OF THE ePATCH

The adhesive ePatch electrode is bio-compatible and contains the skin contact points that allow the recording of bio-potentials. The ePatch sensor contains all the electronic parts, a rechargeable battery, data storage module, a signal processing module, and equipment for wireless data transmission. The ePatch is placed on the chest of the patient, and the recording of high quality ECG starts automatically after the mounting of the system.

The ePatch is shower proof, it is easily worn under

normal clothing, and it can thus be applied during most normal daily life activities. The unique modular design of the ePatch system allows easy adaptation and customization to match the specific needs in every monitoring situation. The current standard EU version of the ePatch is CE approved for 24-hour ambulatory ECG recording. It is able to record two ECG channels with a sampling frequency of 512 Hz, and a bit resolution of 12 bits. The current US version is FDA approved for ambulatory recording of two ECG channels for 72 hours with a sampling frequency of 256 Hz. One of the major advantages of the ePatch system is the possibility of continuous ECG recording for long periods of time. All ECG data can be stored, and full disclosure of the recorded data is therefore possible. This ensures that no critical events are lost. After the recording, the data is transferred to a computer with fast data transmission using a USB cable. The ECG can then be analysed offline.

The next generation of the ePatch will be available during the fall 2014. This generation can record a varying number of channels (one to three) for multiple days with a bit resolution of up to 16 bits, and a user-defined sampling frequency from 128 Hz to 1024 Hz. Furthermore, the next generation is born with additional recording modalities, e.g. accelerometers for activity estimation and adaptive quality assurance. There is also possibility of real-time embedded signal processing and real-time transmission of e.g. ECG strips, events or HR trend curves. The data can either be analysed offline after the recording, or it can be wirelessly transmitted to for instance a central monitoring station (e.g. regular hospital telemetry equipment, monitoring of cardiac patients in their own homes). This transmission is secure and follows standard protocols for transmission of private information. Each ECG file is stored in the proprietary ePatch File System (EFS) format, and can be converted to other formats to allow analysis with commercial software, e.g. [3] and [4].

VI. OTHER RESEARCH ACTIVITIES

Research activities related to the ePatch platform have been carried out and are still ongoing. Some of them have already been presented in this paper. These studies were primarily related to the usefulness of two ECG channels recorded on the sternum with the novel ePatch ECG recorder. Research is also conducted to investigate the correlation between ECG recorded with the ePatch placed in different chest locations and the standard 12-lead ECG. This particular investigation will provide knowledge about the morphological content of ECGs recorded with the ePatch in various chest locations. A schematic overview of the experimental set-up is provided in Fig. 14. The ePatch is placed in three different locations: X, Y and Z. Each ePatch sensor records two ECG channels (X1, X2, Y1, Y2, Z1, and Z2). Simultaneous recordings were conducted using standard 12-lead ECG equipment. An example of the recorded ECGs is provided in Fig. 15. The experiment was conducted on 10 healthy volunteers. As observed from Fig.

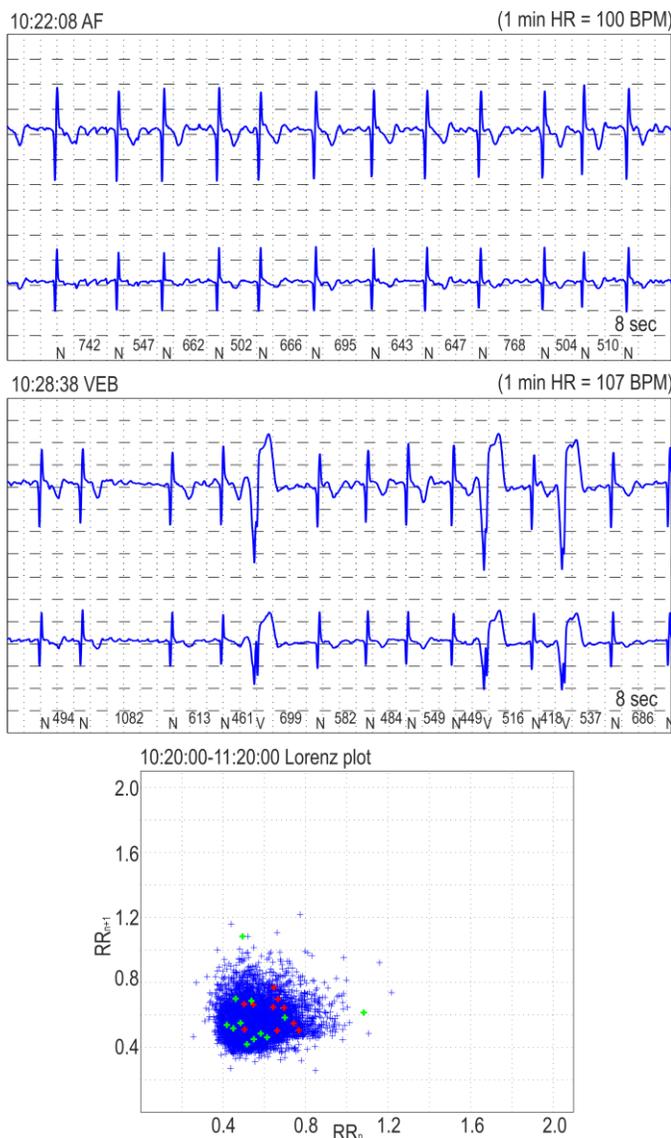


Figure 13. Clinical ECG strips from a patient with AF and a high number of VEBs. The irregular nature of the RR intervals is observed from the Lorenz plot. The red marks in the Lorenz plot represent the heart beats included in the upper ECG strip, whereas the green marks represent the heart beats included in the lower ECG strip.

15, the similarity is highest between Y1 and V2. This may indicate that the morphological information from V2 could also be extracted from the ePatch lead Y1. The mean correlation between Y1 and V2 for the 10 test subjects was found to be 0.8715 with a standard deviation of 0.1232. Further research is conducted to explore the potential for reconstruction of some of the standard leads in the 12-lead ECG system based on information from ePatch sensors placed in different chest locations.

Besides these studies, a number of research projects have already obtained benefits from the advantages gained from this technology. One study includes the application of the ePatch system for automatic classification of acute stress [12]. Another study is related to automatic assessment of the overall quality of long-term ECG recordings obtained using patch type ECG recorders [13]. A third study applies different features based on the T-wave amplitude to estimate fitness level of the test subjects [5]. A fourth study investigated the relation between heart rate variability obtained with photoplethysmography (PPG) and ECG on the sternum [14]. Furthermore, DELTA has participated in a number of larger projects where the possibilities with the ePatch platform were investigated. One of these studies include the European REACTION project that aimed at finding solutions for online diabetes management and therapy in different healthcare settings [15]. During this project, the ePatch was successfully tested in the primary care setting. The ePatch was applied to monitor high risk patients for heart rhythm abnormalities. Other ongoing

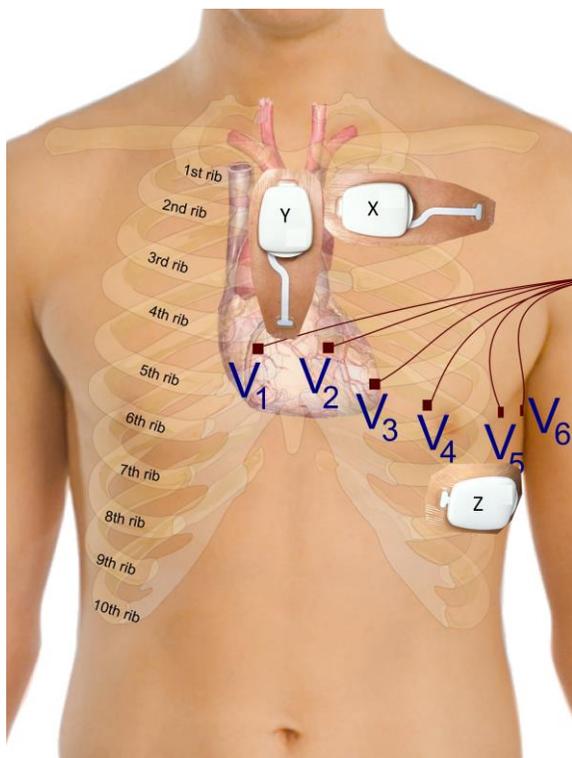


Figure 14. Illustration of the experimental set-up. Three ePatch recorders were placed in various chest locations, and simultaneous recordings from the three ePatch sensors and the standard 12-lead ECG equipment were obtained from 10 healthy test subjects. Modified from [16].



Figure 15. Illustration of ECG example from the three ePatch ECG recorders and the standard 12-lead ECG equipment. The top six traces illustrate the two channels from each of the three ePatch sensors, and the lower 12 traces illustrate the traditional 12-lead ECG. A high similarity is observed between Y1 and V2.

research activities are related to areas like design of automatic algorithms for real-time analysis of the ePatch ECG signals, implementation of new sensor modalities, and investigation of new potential areas where all the advantages of the ePatch system provide benefits and possibilities that were not present with the older technologies.

VII. SUMMARY AND CONCLUSIONS

The novel CE marked and FDA approved ePatch ECG monitor was designed to overcome the disadvantages with older ambulatory ECG recorders. The ePatch system thus allows continuous recording of high quality ECG for extended periods of time without patient discomfort and impairment of normal daily life activities. The usability of the ePatch system has been evaluated in a number of clinical studies. These studies include both investigations of the clinical usefulness of the ECG signals recorded with the system and the user satisfaction. The studies clearly indicate the potential for the application of this system for

future ECG monitoring. This opens the possibilities of applying the ePatch for a wide range of situations, e.g. tele-monitoring of patients at home, rehabilitation programs, large-scale screening programs, and follow-up on known cardiac or high risk patients.

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