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Published in:
CARDIOTECHNIX 2013

Publication date:
2013

[Link back to DTU Orbit](#)

Citation (APA):

Saadi, D. B., Fauerskov, I., Osmanagic, A., Sheta, H. M., Sørensen, H. B. D., Egstrup, K., & Hoppe, K. (2013). Heart rhythm analysis using ECG recorded with a novel sternum based patch technology. In *CARDIOTECHNIX 2013: Proceedings of the International Congress on Cardiovascular Technologies* (pp. 15-21). SciTePress.

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Heart Rhythm Analysis using ECG recorded with a Novel Sternum based Patch Technology

- A Pilot Study

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Keywords: Long-term ECG monitoring, home cardiac monitoring, sternum ECG, patch ECG recorder

Abstract: According to the World Health Organization, cardiovascular diseases are the number one cause of death globally. Early diagnosis and treatment of many of these patients depend on ambulatory electrocardiography recordings. Therefore a novel wireless patch technology has been designed for easy, reliable long-term ECG recordings. The device is designed for high compliance and low patient burden. This novel patch technology is CE approved for ambulatory ECG recording of two ECG channels on the sternum. This paper describes a clinical pilot study regarding the usefulness of these ECG signals for heart rhythm analysis. A clinical technician with experience in ECG interpretation selected 200 noise-free 7 seconds ECG segments from 25 different patients. These 200 ECG segments were evaluated by two medical doctors according to their usefulness for heart rhythm analysis. The first doctor considered 98.5% of the segments useful for rhythm analysis, whereas the second doctor considered 99.5% of the segments useful for rhythm analysis. The conclusion of this pilot study indicates that two channel ECG recorded on the sternum is useful for rhythm analysis and could be used as input to diagnosis together with other clinical tests and medical history.

1 INTRODUCTION

According to the World Health Organization (2013), cardiovascular diseases (CVDs) are the number one cause of death globally. They state that CVDs were responsible for 30% of all deaths in 2008.

CVDs are not only lethal, but they are also associated with a high economic burden on the healthcare system. Furthermore, diseases like ischemic stroke can have high human costs and decrease significantly the quality of life. Early diagnosis and treatment of cardiac related diseases is therefore crucial. For more than hundred years, the 12-lead electrocardiogram (ECG) has served as the “gold standard” for diagnosis of different heart conditions, including arrhythmias (Mittal, Movsowitz and Steinberg, 2011). The well-chosen and standardized selection of electrode positions allows a full investigation of different projections of the electrical activity of the heart. This allows a

careful investigation of the heart in different “spatial plans”.

However, for some conditions, it is more important to obtain long-term information about the general rhythm of the heart from a rhythm analysis. In this case, an ambulatory long-term ECG recording is desired. Some examples of conditions that are not sufficiently managed by baseline 12-lead ECG recordings are paroxysmal atrial fibrillation (AF), non-sustained ventricular tachycardia, unexplained episodes of syncope, and diagnosis of other cardiac symptoms not explained by a baseline 12-lead resting ECG (Mittal et al., 2011), (Zimetbaum and Goldman, 2010). It is, however, important to notice the different possibilities with a standard 12-lead ECG and an ambulatory recording. Some of the main advantages of ambulatory ECG recordings are long monitoring period, detection of paroxysmal and asymptomatic arrhythmias, remote monitoring of the patient and correlation between specific symptoms and the ECG signals.

It is however still important that the ambulatory long-term ECG recordings have a sufficient quality for analysis of specific ECG patterns. Some of the key features in rhythm analysis include the depolarization of the atria (the P-wave) and the depolarization of the ventricles (the QRS complex). An example of a short unfiltered ECG segment recorded with the ePatch is provided in Figure 1.

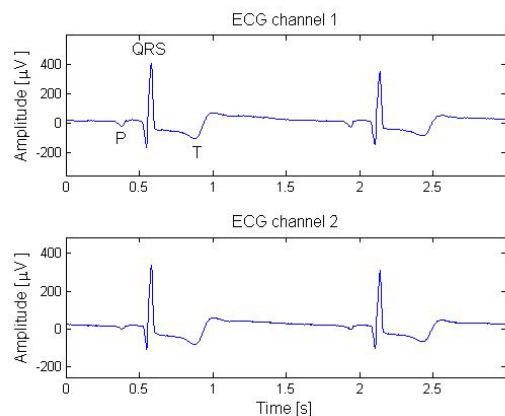


Figure 1: Illustration of a normal sinus rhythm ECG recorded with the novel ePatch technology. The important ECG markers are indicated in channel 1 for one heart cycle. The ECG is raw without any digital filtering.

A number of different long-term ambulatory monitoring techniques are accepted today. One of the most commonly applied ambulatory ECG recorders is the HOLTER monitor.

1.1 Traditional HOLTER Analysis

The HOLTER monitor typically records 2 – 3 ECG leads continuously for 24 – 48 hours (Zimetbaum and Goldman, 2010). During a traditional HOLTER recording, a medical technician attaches the electrodes and the HOLTER recorder to the patient. The electrodes are attached to the recorder through wires. After the monitoring period, the recorder with the ECG data is returned to the hospital or healthcare facility. At the hospital, a specially trained nurse looks through the recorded data using automatic software and generates a report for the referring medical doctor. This report contains a general description of the rhythm during the recording, any special findings, and a number of descriptive ECG “snippets” displaying the different rhythms found during the recording. The report serves as input to the diagnosis together with other clinical tests and the medical history of the patient. If the recording is of sufficient quality, the following parameters may be determined based on a traditional HOLTER

recording: Average heart rate and heart rate range, quantification of atrial and ventricular ectopic beats, and determination of whether AF is present – including information about pattern of AF initiation and termination, shortest and longest duration of AF, heart rate during AF and AF burden (Mittal et al., 2011).

However, this monitoring technique possesses a number of disadvantages including cables that affect the ability to perform some daily activities during the recording and the lack of real-time data transmission and analysis. Furthermore, the relatively short monitoring duration might not be sufficient for investigation of infrequent arrhythmias (Zimetbaum and Goldman, 2010), (Rosenberg, Samuel, Thosani and Zimetbaum, 2013). To account for some of these disadvantages, a novel wireless ECG patch technology was designed.

1.2 The ePatch Technology Platform

The ePatch heart monitoring platform is designed according to a “wear and forget” principle. Thus, the device is designed to be reliable, safe, comfortable and easy to use for both the patient and the healthcare professionals. The ePatch is designed as a technology platform that can be customised to account for the needs in a high variety of situations. Some of the advantages and possibilities with this novel technology platform are listed below:

- Possibility of multi-sensor design with e.g. accelerometer recordings for activity estimation.
- Splash proof design: Patients can shower while wearing the ePatch.
- No cables are needed to connect the electrodes to the recording device. This highly increases the patient comfort and decreases the patient burden.
- Possibility of wireless data transmission and/or local data storage. The platform can be adapted to any desired communication protocol.
- Home monitoring of cardiac patients that might reduce hospitalizations.
- Possibility of long-term monitoring due to the expected higher patient comfort and compliance with wearing the device.
- Module design allows easy adaptation to different applications.
- Real-time embedded signal processing, e.g. automatic detection of cardiac events.

In this pilot study, the focus is to investigate the application of the ePatch for heart rhythm analysis. The ePatch version applied in this study is CE approved for 24 hour ambulatory ECG recordings, and the ECG signals are stored locally on an internal memory. An illustration of the applied ePatch is provided in Figure 2. As observed from Figure 2, the ePatch is placed at the sternum.

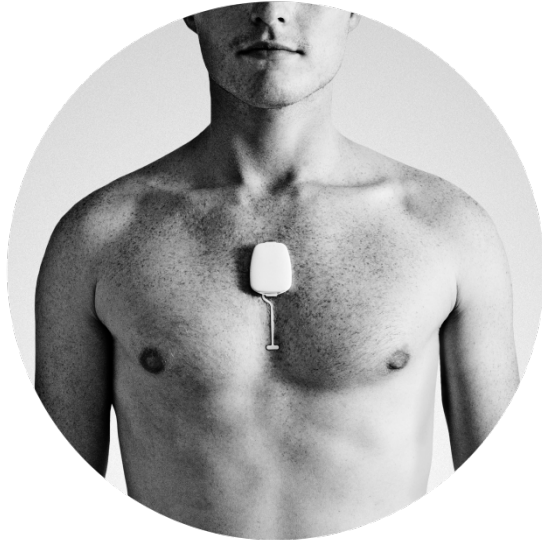


Figure 2: Illustration of the placement of the ePatch electrode and sensor on the sternum.

The ePatch system consists of two parts: 1) A bio-compatible, single-use adhesive electrode with multiple skin contact points that is attached directly to the skin surface (this part is termed the ePatch electrode) and 2) A reusable device that contains a rechargeable battery, electronic parts, data storage module, equipment for wireless data transmission, and a signal processing module (this part is termed the ePatch sensor). The ePatch sensor is attached directly on the ePatch electrode. This makes the system completely free of cables. This is designed so that patients can perform normal daily activities during the recording. Furthermore, the ePatch is easily worn under normal clothing and the cable free design makes it possible for the patient to easily change clothes during the recording. This patch design also facilitates a very small and light weight construction that minimizes the awareness of the system while wearing it. The two ECG channels are measured as bipolar derivations from the multiple skin contact points, cf. Figure 3.

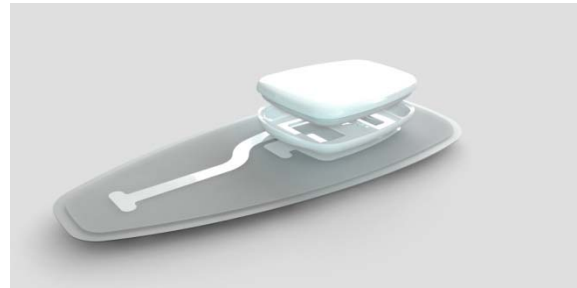


Figure 3: Illustration of the ePatch electrode and sensor before assembly. The ePatch version applied in this study records two ECG channels using bipolar derivations from the multiple skin contact points in the ePatch electrode.

The placement of the ePatch electrode results in a shorter distance between the bipolar recording electrodes. This might influence the quality of the ECG signal. This reservation toward the quality of ECG signals recorded using patch technologies with near-field recording electrodes was also stated by Mittal et al. (2011). However, Rosenberg et al. (2013) compared the ability of a patch type ECG recorder to recognize episodes of AF with a traditional 24-hours HOLTER recording. They found an excellent agreement between the patch recorder and the HOLTER recorder for both AF episode detection and AF burden estimation during a 24 hour recording in 74 consecutive patients.

The selected electrode placement furthermore changes the different projections of the cardiac vector, and hereby changes the appearance of the ECG slightly. This might induce issues regarding the medical professional's ability to recognize different heart rhythms and hereby reduce the practicability of the system. On the other hand, the advantages of this placement are expected to include the benefits of reduced artefacts from large muscles and large movements of electrodes and wires. Furthermore, several studies have shown promising results with experimental ECG recorders placed at a midsternal location. Two research groups, (Janata, Lemmert, Russell, Gehman, Fleischhackl, Robak, Pernicka, Sterz and Gorgels, 2008) and (Lemmert, Janata, Erkens, Russell, Gehman, Nammi, Crijns, Sterz and Gorgels, 2011), conducted studies where 7 seconds noise free HOLTER recordings were visually compared with 7 seconds noise free ECG recordings from a prototype device developed by Phillips Healthcare. Janata et al. (2008) investigated different placements of the experimental device and compared the ability to recognize the presence of P waves, PR time, ventricular morphology (QRS width ≤ 0.12 seconds or prolonged), and rhythm

diagnosis. They found that for the presence of P waves, PR time and general rhythm diagnosis, the device location had a significant influence, and that a midsternal location was optimal. They generally obtain a good agreement between the two devices. Lemmert et al. (2011) investigated the ability to visually recognize ventricular ectopic beats (VEBs) and ventricular fibrillation (VF) with ECGs recorded with the prototype device and EASI lead. The authors found a very high accuracy between the two devices for recognition of VEBs and VEB configuration counts. The results furthermore showed a perfect agreement between the two devices for the recognition of VF. The recognition of pace spikes was better on the standard device. Furthermore, studies conducted by Puurtinen, Viik and Huttinen (2009), indicate that, with respect to P-wave amplitude, the optimal placement of closely spaced bipolar electrodes is diagonally above the standard 12-lead precordial leads V1 and V2.

A review of the literature thus indicates a strong potential for the recording of relevant ECG signals on the sternum. However, the described systems are not completely comparable to the ePatch system and it is therefore desirable to investigate the practical usefulness of two ECG channels recorded with the novel ePatch technology placed at the sternum. This investigation is thus the focus of this clinical pilot study. During the study, the analysis of the recorded ECG signals is performed in a setting fairly similar to the setting for the traditional HOLTER or telemetry recordings.

2 METHODS AND DESIGN

This study includes ECG data segments from 25 different hospitalized patients. The choice of hospitalized patients ensures a realistic amount of abnormal beat morphologies and abnormal heart rhythms. Each of the patients was monitored with an ePatch for approximately 24 hours. All patients were simultaneously monitored with the regular telemetry equipment at the hospital department. The ePatch ECG signals were recorded using a sampling frequency of 512 Hz and a resolution of 12 bits. In compliance with IEC 60601-2-47, the ePatch front end had an analog bandpass filter between 0.67 and 40 Hz. The study was conducted in accordance with the principles of Good Clinical Practice (GCP) (Research Ethics Committee ID: S-20120132). All patients were informed about the study and signed a written consent form before their inclusion in the study. The patients were furthermore questioned

about any discomfort and their general satisfaction with wearing the system. They were asked regarding their level of satisfaction on an analog scale from “very satisfied” to “very dissatisfied”. The study included 15 males and 10 females. The mean Body Mass Index (BMI) was 27.5 with a standard deviation of 6.3. The mean age was 71.7 years with a standard deviation of 13.0 years.

As mentioned, the purpose of the study was to investigate whether two channel ECG signals recorded with the ePatch placed at the sternum is useful for heart rhythm analysis. In a realistic setting, a medical technician with speciality in HOLTER or telemetry analysis extracts relevant ECG segments that are provided to the referring medical doctor. This step was also performed in this study. An experienced nurse was asked to extract 7 seconds ECG segments where the interpretation of the ECG signal was not hindered by noise, in other words, the data should be of sufficient signal quality. The definition of sufficient signal quality was thus based on a subjective judgement by an experienced ECG analyzer. This is somehow similar to the extraction of ECG snippets during a traditional HOLTER analysis. The ECG segments were provided to both the nurse and the medical doctors without any form of digital filtering, that is, the analysis was based on raw ECG signals. A total of 8 segments were extracted from each patient according to the scheme illustrated in Figure 4.

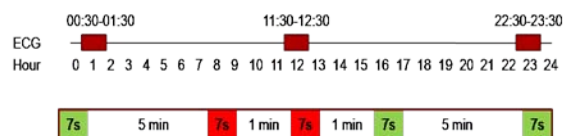


Figure 4: Illustration of the data extraction and selection process. The red marks on the top panel indicate the three one hour segments that were extracted for the study for a recording of exactly 24 hours. The bottom panel illustrates the process of selection of 7 seconds segments from the extracted data. Green segments are selected for the study, whereas red segments are excluded.

For each patient, three hours of data was considered. The three hours were extracted as 1 hour in the beginning, 1 hour in the middle, and 1 hour at the end of the recording. The first and last 30 minutes were, however, not considered to ensure that artefacts from mounting and removal of electrodes did not affect the extracted data. The three hours of extracted data for a recording of exactly 24 hours is illustrated by red colour marks in Figure 4. This ensures that a patient is only excluded from the

analysis if the general signal quality is insufficient throughout the recording.

The 7 seconds ECG segments are extracted from these three hours of data according to the following scheme: 1) If the current 7 seconds data segment is considered noise free, it is selected for the study, and a new 7 seconds segment is investigated 5 minutes later. 2) If the current 7 seconds data segment is not considered noise free, it is excluded from the study, and a new 7 seconds segment is investigated 1 minute later. 3) If it is not possible to extract 8 segments of sufficient signal quality within these three hours of data, the patient is excluded from the study.

The data was selected with a custom designed Graphical User Interface (GUI) using MATLAB R2012B. The GUI provided an illustration of 7 seconds of two channel ECG data, and the nurse was asked to use two check boxes to choose between “noise free segment” and “noise disturbed segment”. The study included a total of 200 two channel ECG segments.

After selection of the 200 ECG segments, two medical doctors with experience in ECG

interpretation performed an independent individual evaluation of each of the ECG segments according to the usefulness for heart rhythm analysis.

The medical evaluation of each segment was conducted using another GUI designed in MATLAB R2012B. This GUI is illustrated in Figure 5. The two channel ECG signal is visualized and the medical doctor was asked to choose between two check boxes, indicating the usefulness of the ECG segment for rhythm analysis.

3 RESULTS

Each ECG segment was evaluated according to the usefulness for heart rhythm analysis. The score “good” indicates that the ECG segment was found useful for heart rhythm analysis, whereas the score “bad” indicates that the ECG segment was not considered useful for rhythm analysis. The evaluation from both medical doctors is illustrated in Figure 6.

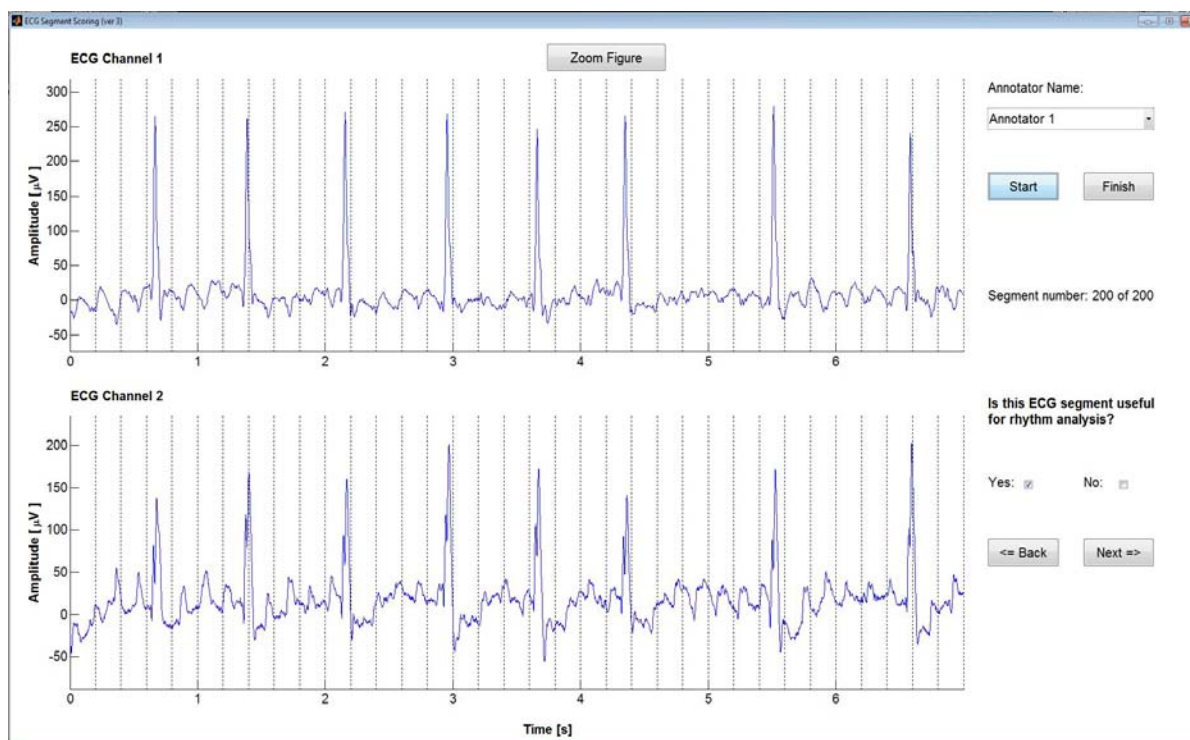


Figure 5: Illustration of the designed GUI used for the medical doctor evaluation of each 7 seconds ECG segment. The two channel ECG segment was visualized on a computer screen, and the medical doctor was asked to check one of the check boxes dependent on his evaluation of the relevance of the current ECG segment for rhythm analysis. Note, that this segment illustrates a case of AF.

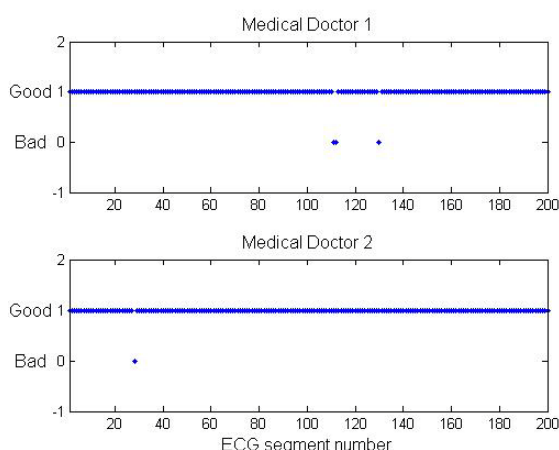


Figure 6: Illustration of the evaluation from both medical doctors for each of the 200 ECG segments. The score “1” is “good” and indicates that the ECG segment was considered useful, whereas the score “0” indicates that the ECG segment was not considered useful for rhythm analysis.

Table 1: Results from the evaluation for ECG segment relevance for rhythm analysis from the two medical doctors.

Segments marked as “good”	Number	Percentage
Medical doctor 1	197	98.5%
Medical doctor 2	199	99.5%
Both medical doctors	196	98%
At least one medical doctor	200	100%

As observed from Figure 6, the doctors did not agree on the segments that were not useful for rhythm analysis. This is also illustrated in Table 1 that contains the percentage of “good” ECG segments for each doctor, the percentage of ECG segments considered as “good” by both doctors and the percentage of segments considered as “good” by at least one of the doctors.

Of the 25 patients, 22 indicated that they were very satisfied with wearing the device, 1 indicated to be satisfied, and 2 did not answer the question. Furthermore, several patients mentioned that they did not even notice that they were wearing it.

4 DISCUSSION

Both medical doctors indicated that more than 98% of the selected ECG segments were diagnostically meaningful to them, and that the ECG could help toward a rhythm analysis and diagnosis of the patient. It should, of course, be stated that the diagnosis of the patient would contain results from

other relevant clinical tests, medical history, review of the entire long-term ECG recording, and general comments from the nurse preparing the ECG report for the referring medical doctor. The diagnosis is not imagined to be based solely on the 7 seconds ECG segments investigated in this study. However, the results from this pilot study are very promising and indicate the potential for this novel device for ambulatory cardiac monitoring.

The fact that the “bad” segments were not the same for both medical doctors, could indicate a certain degree of inter reader variability. The number of doctors could be increased in a future study to investigate the true inter reader variability. For the purpose of this pilot study, it is, however, considered sufficient with the evaluation by two medical doctors. It should also be stated that even using the “worst case” of judging all segments evaluated as “bad” by at least one of the doctors as a “bad” segment, still results in 98% of the segments being useful. Furthermore, a traditional HOLTER recording might also contain segments of data that is not useful for rhythm analysis. In a real life situation, cases of doubt about a diagnosis are solved by discussion and consensus with other doctors. This is also expected to be the case when ePatch ECG signals are applied for rhythm analysis.

Another interesting finding is the generally high patient satisfaction with wearing the system. This is one of the expected advantages of this novel technology. The high patient comfort is expected to allow very long-term monitoring in the future. This could increase the likelihood of detecting paroxysmal and infrequent arrhythmias. The higher patient comfort is also expected to increase the compliance with wearing the system, and a high patient compliance is necessary for reliable monitoring results (Ackermans, Solosko, Spencer, Gehman, Nammi, Engel and Russell, 2012).

The focus of this pilot study was to obtain preliminary knowledge about the overall applicability of ECG signals recorded with the ePatch on the sternum. Future studies might include more direct comparisons between ECG signals recorded synchronously with the ePatch and traditional HOLTER recordings. Future studies might also investigate the ability to correctly detect specific ECG features, e.g. the presence of the P-wave.

The future possibilities of this type of long-term ambulatory ECG recorders seem to be very high in areas like home monitoring, screenings, and follow-up consultations. However, the knowledge about the practical application of these new technologies is

still relatively limited due to the lack of large-scale applications of the technology in everyday clinical situations. This study contributes to the currently limited amount of knowledge about the usability of these patch type ECG recorders. Further investigations could be conducted to investigate the usefulness for specific cardiac conditions on a larger database. Furthermore, in this study, only noise free ECG segments were presented to the medical doctors. This mimics the everyday selection of representative ECG “snippets” for the referring medical doctor and serves the purpose of this study. However, large-scale studies should be conducted to investigate the general level of artefacts and signal quality with this new patch technology.

5 CONCLUSIONS

This clinical pilot study indicates the medical usefulness of two channel ECG signals recorded at the sternum using the novel ePatch technology for heart rhythm analysis. Furthermore, the 25 included patients provided positive declarations regarding their experience with the device. Further studies should be conducted to establish possible new application areas for this new technology and to determine the general quality of the signal and the vulnerability to different types of artefacts.

ACKNOWLEDGEMENTS

The clinical study was supported by funding from the Danish Business Innovation Fund. The authors wish to thank the clinical staff at the Department of Medical Research, OUH Svendborg hospital, for conducting the clinical recordings.

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