



# Clinical validation of a low-power and wearable ECG patch for long term full-disclosure monitoring

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## Abstract

**Background:** Detection of intermittent atrial fibrillation (AF) is done using a 24-h Holter. Holter recordings are powerful but lack the comfort and have limited recording times resulting in under diagnosing of intermittent AF.

**Objective:** Within this work we evaluated and compared a novel miniaturized three-channel ECG monitoring patch versus a 24-h Holter system.

**Methods:** Both patients with a chronic AF rhythm ( $n = 5$ ) as well as patients with an AF rhythm that underwent electrical reversion ( $n = 5$ ) were equipped with both a 24-h Holter and ECG patch.

**Results:** Alignment of raw data of both ECG systems allowed cross-correlation analysis. Overall good correlations of up to 85% were obtained. RR-interval analysis of both systems resulted in very high correlations of 99% and higher. AF analysis showed correct identification of AF on both ECG systems.

**Conclusions:** The performance of our ECG patch matches that of the 24-h Holter and could provide a suitable tool for long-term monitoring applications.

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## Keywords:

Low power; ECG; Holter; ECG patch; Full disclosure

## Introduction

Atrial fibrillation (AF) is the most common heart rhythm disorder, with increasing incidence with age. It is a cardiac arrhythmia that often proceeds asymptomatic and can cause severe comorbidities such as embolic stroke. Short episodes of AF (48 h) are sufficient for thrombus formation in the left atrial appendage which can dislocate and cause severe (cerebral) damage. For these reasons, the management of AF puts a high burden on healthcare costs, accounting for up to 6.5 billion dollar in the US [1–3]. It is therefore essential that the diagnosis of AF occurs as early as possible. The problem here, however, is that it is a disease that can manifest in intermittent episodes (i.e. paroxysmal AF), making detection very challenging. For decades, the gold standard method for investigation of patients with suspected arrhythmias, including AF, in the ambulatory setting is the 24-h Holter monitor.

This method has already proven its beneficial effect in many occasions. However, with its current form factor, there are some limitations in its use and applicability. Due to the short measurement period (i.e. 24 h) of the Holter monitor, its diagnostic yield is reported to range from 15% to 39%. This is due to the fact that intermittent periods of paroxysmal AF, which do not manifest during the 24-h monitoring period, remain unnoticed [4–13]. Event recorders and 7-day electrocardiogram (ECG) monitors have due to their longer measurement period a higher diagnostic yield. However, like the 24-h Holter monitor they contain a lot of cables and are therefore rather cumbersome to wear [4,5,11,13,14]. The highest diagnostic yield is achieved with implanted devices, such as loop recorders [7]. But due to high costs and invasive character they are limited to a certain subset of patients. Therefore, new non-invasive diagnostic devices capable of monitoring for longer time periods, with a high quality and comfort are needed. These devices will have to be made small, with few or no electrodes/cables and without losing diagnostic accuracy. In addition, to provide optimal patient follow-up, they will need to be equipped with wireless communication capabilities. Patches would be able to exhibit

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these properties and would have additional advantages and reduced lead-noise sensitivity due to fixed leads. Such devices have recently been developed and have already been proven to capture more significant arrhythmias compared to 24-h Holter monitoring [1,3,15–17]. However, most of the time, these devices are limited to single lead ECG information and are not completely optimized for low-power applications causing a reduction in monitoring time. A comparison between commercial patch systems and our ECG application can be found in the work of Lobodzinski *et al.* and Buxi *et al.* [15,16,18].

In this work, we compared an innovative low-power ECG patch from Imec versus a gold standard 24-h Holter monitor on raw signal quality, clinical significance, lead redundancy and AF detection performance.

## Materials and methods

### Reference Holter system

A Seer Light Holter from General Electric Company (GE) Healthcare (Little Chalfont, United Kingdom) was used as gold standard medical device and served as a reference system. Dimensions of this device are 8.5 cm × 5.4 cm × 1.5 cm, with a total weight of 72 g; it is worn by the patient in a pouch. A connector cable provides seven leads resulting in three full disclosure bipolar ECG channels. The system has a digital sampling rate of 125 frames per second and an analog to digital (A/D) conversion of 10 bits, with 8 ms sampling. A voltage peak-to-peak input range within 16 mV and recordings are made with a bandwidth between 0.05 Hz and 40 Hz. The

device is equipped with an event button and memory card for local storage. Device set-up and interrogation are done by infrared communication with the provided Seer Light connect device. In Fig. 2, one can see how the 24-h Holter is attached to the human body.

### Architecture ECG patch

Imec's low power ECG patch [18] consists of 2 stacked printed circuit board (PCB) modules, a sensor board and a radio/controller board. Together, the stacked modules with the housing measure 4.9 cm × 3.2 cm × 1.9 cm, with a total weight of 25 g (including battery). Depending on the measurement requirements a larger battery can be used resulting in a slight increase of total weight. Fig. 1 shows the overall architecture of the proposed ECG patch monitor and its photograph. The system contains Imec's proprietary ultra-low power (40 μW), low noise (80 nV/√Hz) three-channel ECG analog front-end ASIC with electronically selectable gain/bandwidth and on-chip 12 bit ADC and a 3D accelerometer ADXL326 by Analog Devices. A microcontroller (TI MSP430F1611) is used to control the system and streaming the data to a 2.4 GHz Radio (Nordic nRF24L01), or storing the data on a micro SD card. The system also contains an optional digital signal processing (DSP) unit, called CoolBio, which is not used in the current study. For the purpose of this study the micro SD card was used for data storage. However, the Nordic radio has the ability to transmit all recorded data with low-power to a receiving unit for the duration of the recording. Transmitted data can either be real-time ECG data as well as the processed data from the on-chip digital signal processor. For the duration of this study this radio feature was only used to

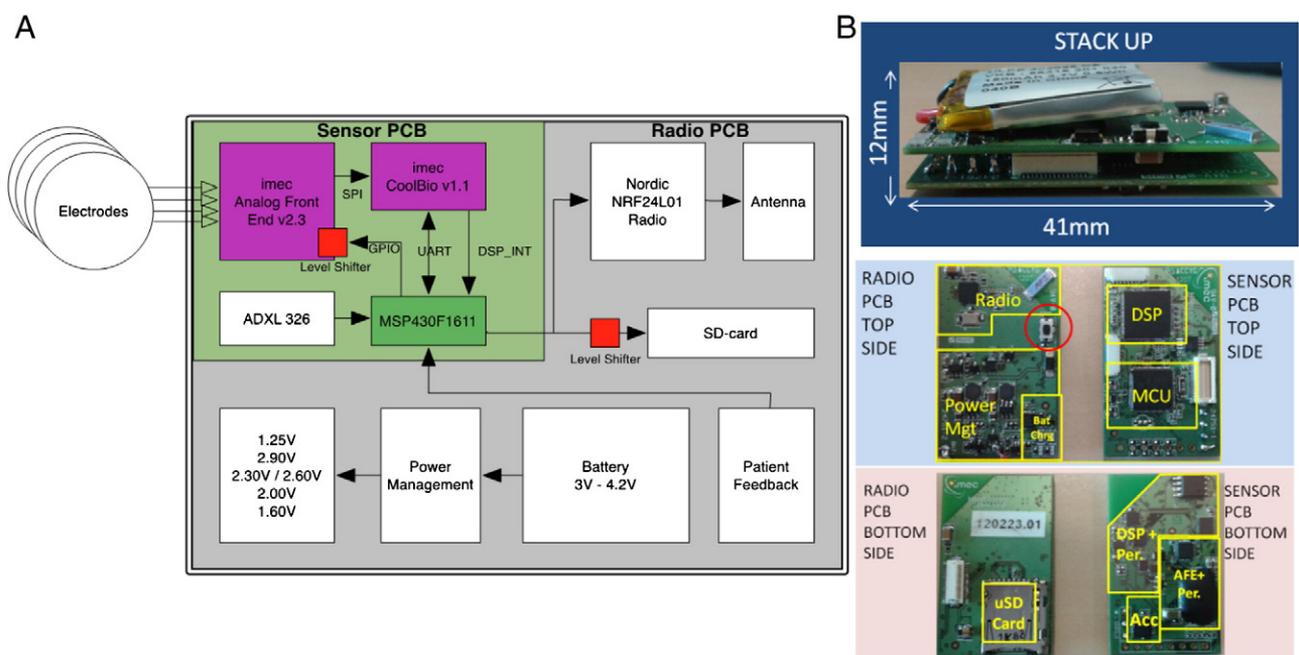


Fig. 1. A: The system architecture with the different modules of the low-power ECG patch. B: A photograph of the two stacked modules. DSP, Digital Signal Processor; MCU, Microcontroller; uSD Card, micro SD-card; Acc, Accelerometer; AFE + Per., Analog Front End and additional circuitry; DSP + Per., peripheral circuitry connected to the DSP unit.

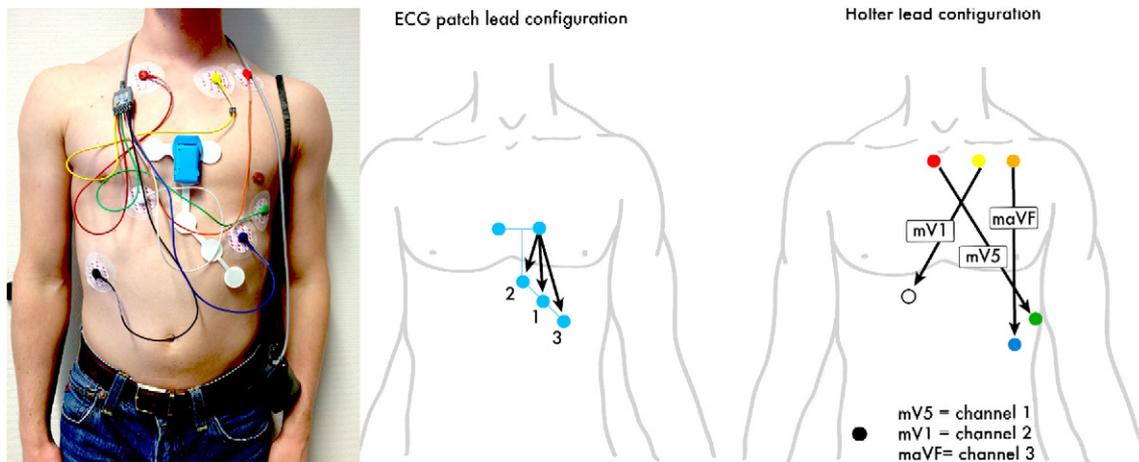


Fig. 2. Left: Photograph of the measurement setup for a subject wearing the reference Holter system and the ECG patch for validation purposes. Middle: Unconventional lead configuration of the ECG patch. Right: Lead configuration of the reference Holter monitor from General Electric Company (GE) Healthcare (Little Chalfont, United Kingdom).

check the integrity of the signal but had no added value for the data collection.

The system is powered by a single-cell Li-polymer battery, which supplies a voltage from 3.2 to 4.2 V. This enables the device to measure up to 48 h when recording to SD card and up to seven days when streaming via radio.

The patch records full disclosure ECG signals of up to three (unconventional) leads, together with tissue-contact impedance and a 3D-accelerometer for physical activity monitoring. By measuring tissue-contact impedance, the patch provides real-time information on the sensor contact quality. This can be used to evaluate data quality and to filter (adaptive filtering) for motion artifacts. The device is also equipped with an event button to record symptomatic events. The event button can be either a mechanical button (located on the lower right part of the device) or a software algorithm based on accelerometer input (tapping motion). To attach the device to the human body, it is clicked in an integrated disposable patch with fixed electrode position. In Fig. 2 one can see how the ECG patch is attached to the human body and the lead configuration of both the ECG patch and reference Holter system.

### Study setup

Patients ( $n = 5$ ) in whom a diagnostic ECG showed an AF rhythm and patients ( $n = 5$ ) with AF, who were admitted to our hospital for electrical reversion to normal sinus rhythm, were equipped with the Seer Light 24-h Holter monitor. In addition, the patients were also equipped with our ECG patch monitor. For the former group, both devices were attached for about 24 h. For the latter group, both devices were attached two to three hours before the electrical reversion, detached during the reversion (to prevent system damage) and reattached after reversion for another two to three hours. Holter data were analyzed by specialized nurses and validated by cardiologists following standardized procedures.

### Signal analysis and statistics

The analog front-end in the ECG patch is configured for a sample rate of 512 Hz, with bandwidth from 0.5 Hz (1st

order highpassfilter) to 200 Hz (2nd order lowpassfilter). The reference device uses a sample rate of 125 Hz. Raw data were offline analyzed afterwards. Since sampling rates and initial startup moments were different for both devices a proper alignment was required. These alignment algorithms were developed in MATLAB® 8.1 (The MathWorks Inc., Natick, MA, USA). First, raw ECG signals were fragmented into sections of 5 mins at random intervals. After beat-detection, using a Mexican-hat continuous wavelet transform (CWT) algorithm, the RR-interval was obtained. These RR intervals were subsequently cross-correlated between both signals. Next, these fragment signals could be aligned and the temporal delay between both signals could be determined allowing full data alignment and calculation of the exact ‘real’ sampling frequencies required for accurate re-sampling of both signals.

After this alignment procedure, the following actions were performed in signal comparison [1]: a normalized absolute-value cross correlation (xcorr) of raw signal (1 = complete correlation, 0 = no correlation) for each lead compared to each other, resulting in a total of 9 combinations [2]. After calculating the RR-intervals from all leads, they were correlated for a more clinically relevant correlation (1 = complete correlation, 0 = no correlation) [3]. Finally, the entire dataset was fragmented in sequential fragments of 5 min and in each segment a standardized detection algorithm of AF was applied, i.e. the Linker Algorithm [19,20]. If this algorithm indicated the presence of AF, a score of 2 is obtained for that entire 5 min section. Applying this standardized algorithm on both unconditioned signals provides insight on data quality and the ability to detect AF between both devices. Since both devices each have three leads, the option of a majority vote is possible to indicate the presence or absence of AF.

### Results

In this section, the results of the alignment, cross correlations and AF analysis are shown. All analyses were based on the raw ECG signals without any pre-processing or filtering. As proof of concept, one example of each case will

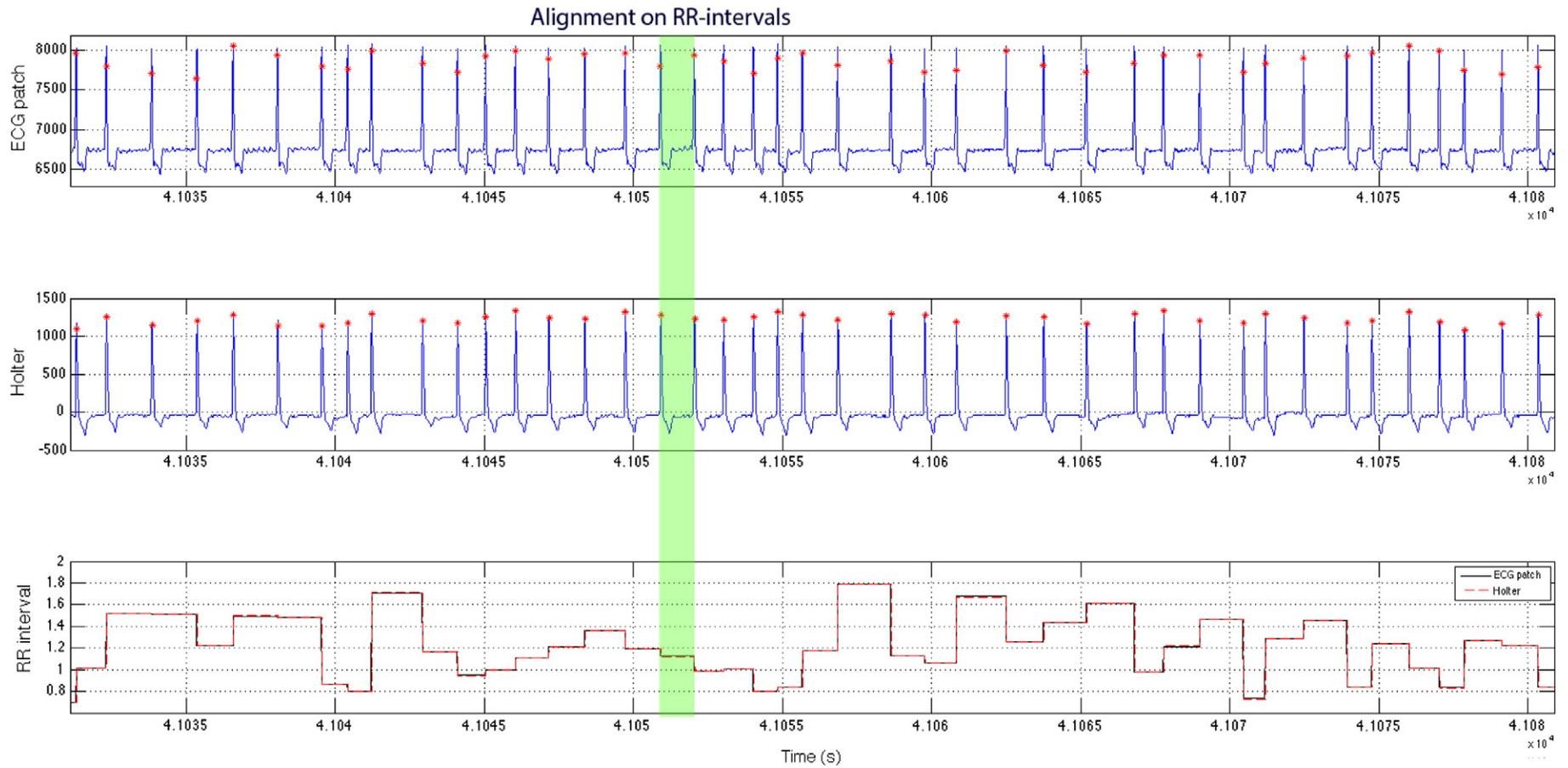


Fig. 3. Results on an alignment set of ECG data from both the ECG patch and the Holter system. Peak detection and RR-interval analysis allows cross-correlation analysis to align both signals based on RR intervals. Based on the obtained delay, the ECG patch could be delayed in order to match the alignment of the Holter. Upper graph: RR-intervals of the ECG patch. Middle graph: The ECG signal obtained from the Holter. Lower graph: Aligned RR-intervals. The green translucent bar shows the alignment of the two ECG traces and the corresponding RR-interval.

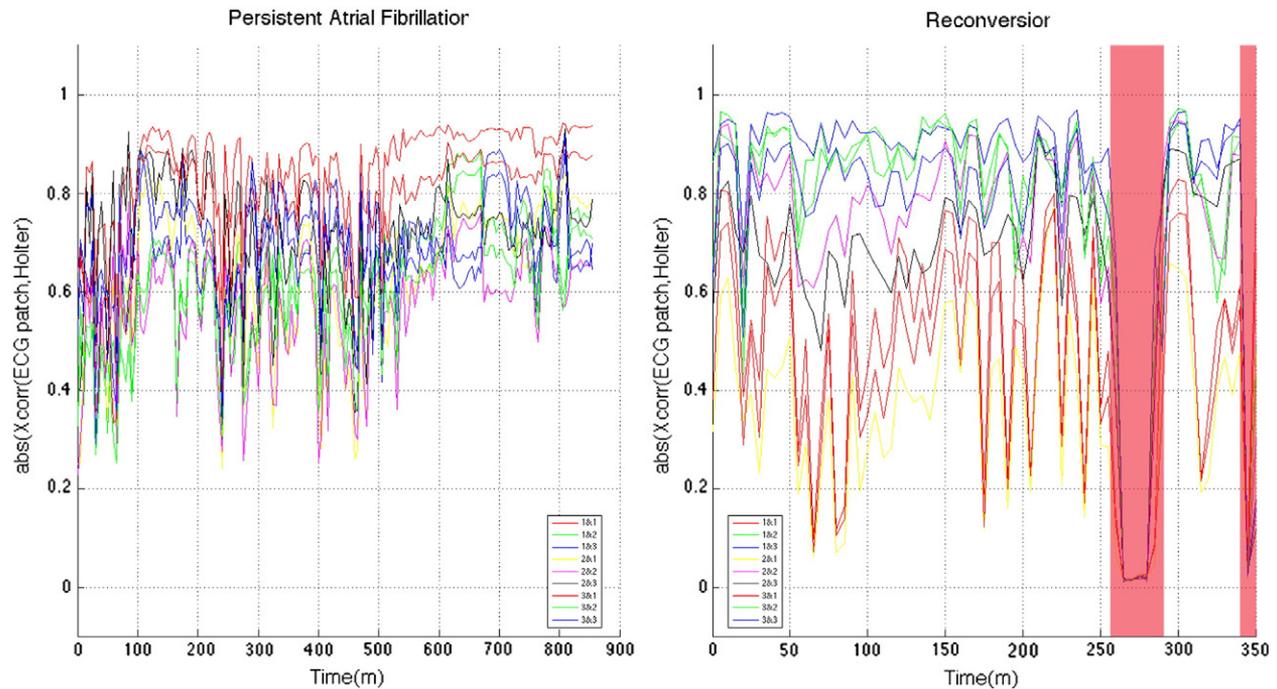


Fig. 4. Cross correlation results of raw ECG signals. All leads of the ECG patch were compared to the Holter leads, resulting in nine different correlations. The correlations were made absolute indicating that 1 represents a perfect correlation and 0 represents no correlation. Left panel: Cross correlations of a patient suffering from persistent AF. Right: Cross correlations of a patient undergoing cardiac reconversion. The red translucent bar indicates the disconnection of the system during the electrical reconversion and at the end of the recording.

be discussed in detail: one for a subject with persistent AF and one for a subject undergoing cardiac reconversion. For all the other recorded subjects, only the means are given.

#### Signal alignment

Cross correlation of the RR-intervals showed the highest peak after 26.244 s, indicating the temporal offset of the ECG patch towards the Holter device (data not shown). The exact real sample rate was also determined using this approach: arbitrarily assuming the ECG patch to have a sample rate exactly equal to its nominal value of 512 Hz, the real sample rate of the Holter system was calculated as 124.987 Hz (compared to a nominal value of 125 Hz). The obtained results of the RR-interval correlation and the corresponding raw ECG signal alignment are shown in the upper and lower panel of Fig. 3, respectively.

The sampling frequencies and temporal offset varied for all recordings, therefore a new alignment procedure was needed for each recording. The success of alignment was determined on the mathematical outcome of the cross correlation and confirmed by manually measuring the RR-intervals at random recording intervals.

#### Cross correlation of raw ECG signals

After the alignment procedure, a cross correlation of all combinations of the ECG signals was performed. Here fore, all three leads of both the Holter and ECG patch signals were compared with each other, resulting in nine cross-correlations (Fig. 4). For the patients with persistent AF, the example showed the best result for the combination of Holter lead 1 and ECG patch lead 1, with an xcorr of 0.85. When

this combination is looked in more detail, one can see that there are great similarities in both the QRS morphology and RR-intervals, but a clear difference in signal amplitude (Fig. 5). The worst correlation was obtained in the combination for ECG patch lead 3 with Holter lead 1, with an xcorr of 0.23. For this combination, one can see great dissimilarities in ECG morphology and amplitude, and only the RR-intervals remain the same (Fig. 5). The other lead combinations for the persistent AF patient are shown in Table 1. Focusing on the total population of persistent AF and taking into account the best lead configuration for each subject, a mean correlation of  $0.89 \pm 0.05$  was obtained. For the reconversion subjects similar results were obtained pre- and post-reconversion. In all these recordings, again lead 1 of both devices showed the best correlation (Fig. 4).

#### Cross correlation of RR-interval analysis

To compare the clinical performance of the ECG patch to the Holter system, an analysis was made based on the recorded QRS complexes (i.e. RR-intervals). Fig. 6 shows the result of RR-interval cross-correlation for lead 1 of both devices. A cross correlation of 0.9968 was obtained with minor deviations in the signal. For the patients suffering from persistent atrial fibrillation, a mean overall RR-interval cross correlation of  $0.9977 \pm 0.0012$  was obtained. In addition, data of the subjects who were admitted to the hospital with AF and underwent reconversion showed an xcorr of 0.9912 in the pre-reconversion state and an xcorr of 0.9952 post reconversion. In the example subject, both devices were disconnected in the time window from 258 to 270 min. The noise collected in this time window was

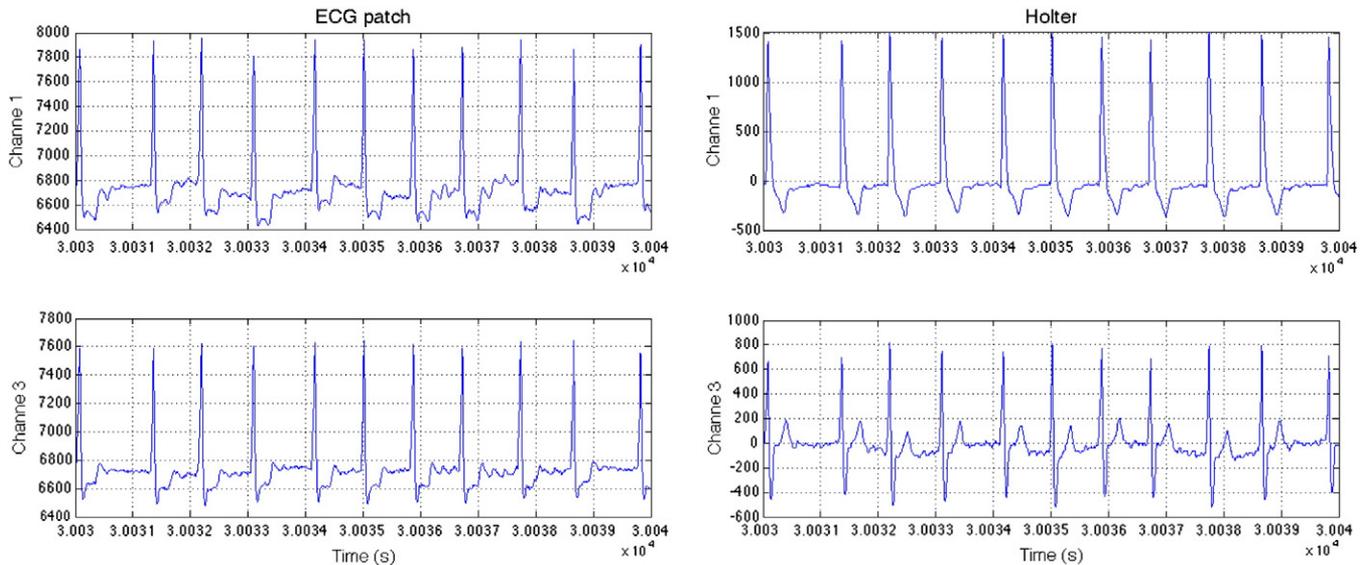


Fig. 5. The highest and lowest cross correlations between the ECG patch and the Holter. The aligned ECG results of lead 1 and lead 3 of the ECG patch are shown on the left, and for the Holter system on the right. Lead 1 of the ECG patch had the highest correlation with lead 1 of the Holter ( $xcorr = 0.8569$ ), while lead 1 of the ECG patch had the worst correlation with lead 3 of the Holter ( $xcorr = 0.2315$ ). Comparing lead 3 of the ECG patch with lead 3 of the Holter resulted in an overall reduced correlation ( $xcorr = 0.4031$ ).

not considered as relevant information and was left out from the analysis.

#### Atrial fibrillation analysis

In order to assess the viability of the ECG patch system as a clinical tool, a comparison was made in the performance of an AF algorithm on the raw ECG data. The well-known Linker algorithm was used [19,20]. An episode of AF is represented by a score of 2, while normal sinus rhythm is represented by a score of 0. In order to perform AF analysis, the signals from all ECG leads were fragmented into 5-min blocks. Each block of aligned ECG traces was analyzed using the Linker algorithm [19,20]. If within such a block the rhythm went back to normal sinus rhythm or did have irregularities in signal quality, the entire 5-min fragment was given a score of 0. Fig. 7 shows the results for the patients suffering from persistent AF, for all three leads of both systems. In all cases, the ECG patch system had a better overall performance compared to the reference Holter system. In all cases, a drop to 0 was caused by a loss of signal quality or false peak detection instead of normal sinus rhythm. A majority vote was performed and if the result of the analysis (a score of 2 or 0) was equal to a score of 2 for more than two of the three leads, this would favor the majority and the majority vote of the signal was considered

as the true signal, and would be considered as AF in this case (score of 2). In all subjects with persistent AF, the majority vote of our analysis resulted in 100% AF detection for both devices. When the reversion subjects are considered, one can see that in the pre-reversion period, the algorithm indicated 100% AF burden (Fig. 7). After reversion to normal sinus rhythm, the score of the algorithm dropped to 0. Also here the presence of a majority vote corresponded with the initial diagnosis. A clinical reference was made based on the standard Holter readings and they conformed 100% to the findings of the ECG patch.

#### Discussion

With the increasing prevalence of cardiovascular rhythm disorders, the tools for their diagnosis need to further evolve in order to expand the functionalities of the Holter system, the current gold standard. The most important aspects that need to be improved are the measurement time and miniaturization, in order to favor patient comfort. Within this study, the raw signal quality of a medical reference system, a 24-h Holter, was compared with a new three lead patch system from Imec. In total 10 subjects were analyzed, from which five were suffering from persistent AF and five were admitted to the hospital for reversion of AF. The study focused on three different aspects: (1) comparing raw signal quality between both systems, (2) cross correlation of the obtained RR-intervals between both systems and (3) comparison of the ability to detect AF using the same standard algorithm on both signals.

The alignment procedure was crucial before signal comparison could be made. Since the recordings lasted for 24 h and both systems did not have a synchronized clock, the alignment was done based on the RR-intervals. In all

Table 1

Matrix representing the different leads for both the ECG patch and the Holter system. The combination results in cross correlations of the entire recording time.

	ECG patch Lead 1	ECG patch Lead 2	ECG patch Lead 3
Holter Lead 1	0.8569	0.5953	0.2315
Holter Lead 2	0.6317	0.3148	0.6162
Holter Lead 3	0.7711	0.3749	0.4031

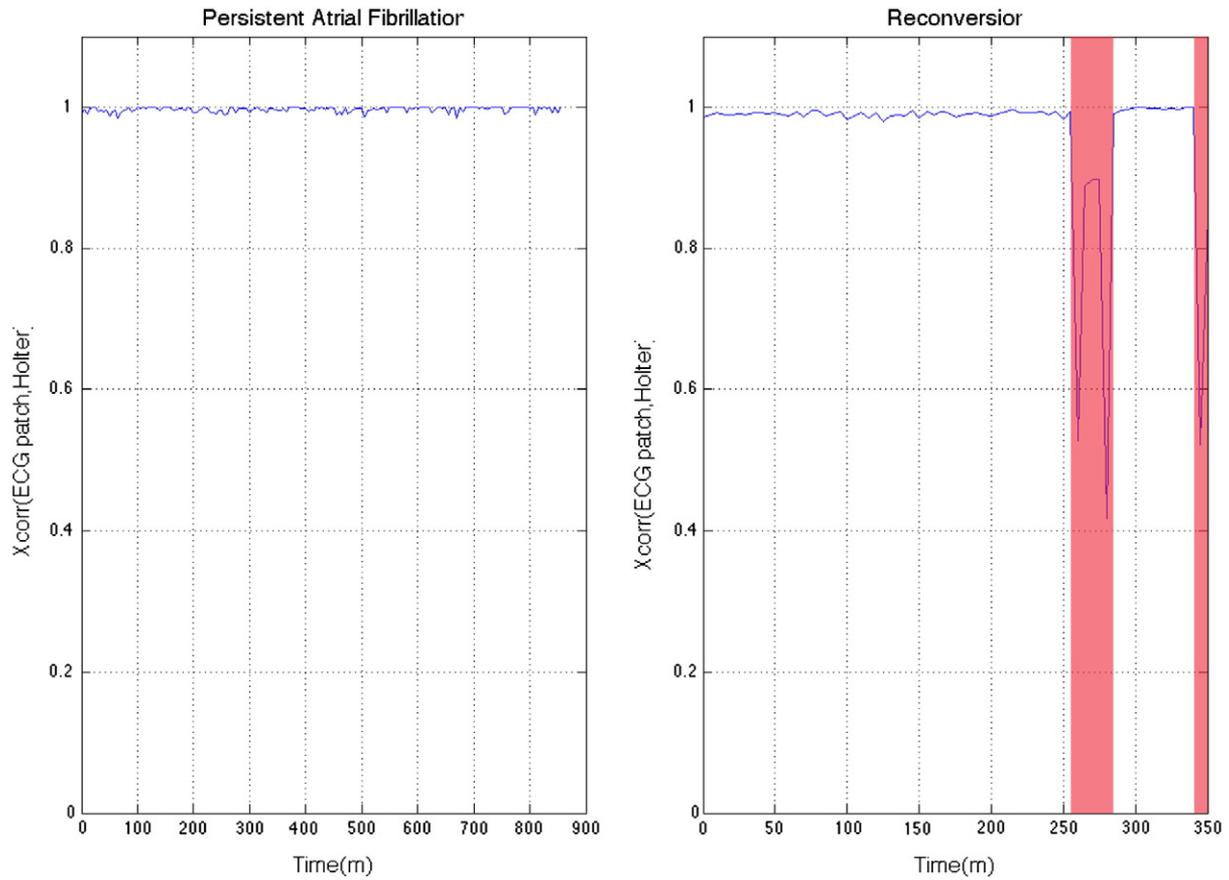


Fig. 6. Cross correlation results of RR-interval analysis. Graphs only show lead 1 of both the ECG patch and the Holter system. Similar results were obtained for all the other leads (data not shown). Left: A high correlation was obtained for the patient with persistent AF ( $xcorr = 0.9968$ ). Right: Very high correlation was obtained for the reversion patient ( $xcorr\text{-pre-reversion} = 0.9912$ ,  $xcorr\text{-post-reversion} = 0.9952$ ).

subjects, a good signal alignment was obtained. However, due to the use of leads in the reference system, there were sometimes long periods of motion artifacts, making the alignment difficult. Another limitation of the alignment procedure can be present in subjects with perfect RR-intervals (i.e. pacemaker rhythm), since their RR-intervals do not vary significantly.

The cross correlation of the raw ECG traces between different lead combinations of the Holter system and the

ECG patch showed both similarities and differences in all cases. Since the ECG patch system is using three non-conventional lead configurations and the positioning of the Holter leads is not completely the same as the ECG patch electrodes, this results in different morphologies of the QRS signal, both in shape and in amplitude. In case of good correlation, there are clear similarities (Fig. 5), while poor correlations were accompanied by great morphological differences due to the different vectors that are recorded.

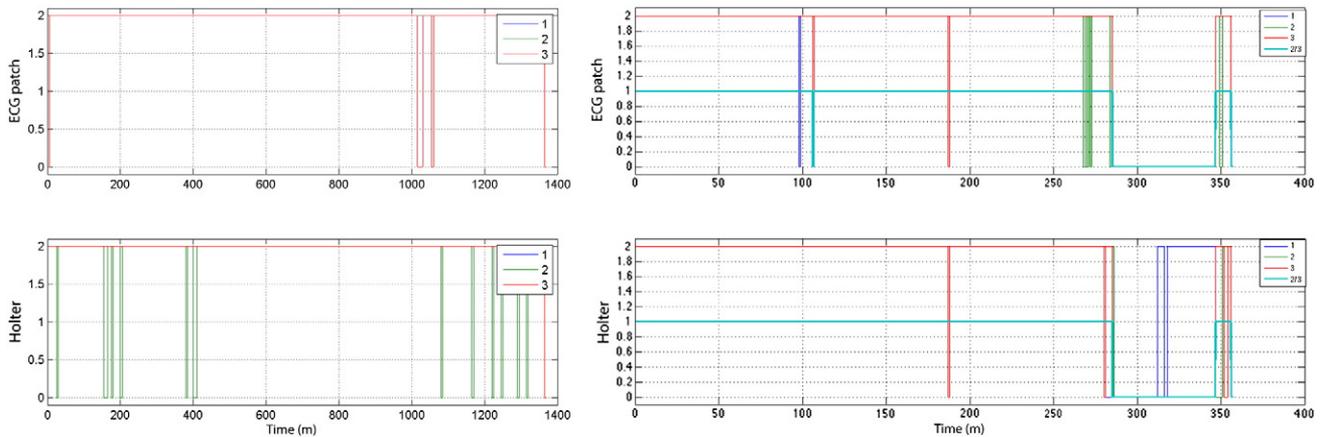


Fig. 7. AF detection. Left: The outcome of the Linker algorithm [19,20] for the patient with persistent AF. A score of 2 represents the presence of AF while a score of 0 indicates normal sinus rhythm or noise. Right: The results for the reversion patient. A majority vote was applied to indicate the accuracy of the system.

However, this does not indicate failing of the system, but rather makes it difficult to assess and compare the functionality and performance of both systems based on the correlation of raw signals. It is more an indication on the overall signal comparison and at the areas where the correlation drops to a score of 0, it is worth to investigate the cause. In all cases there was noise present in one or more leads, resulting in signal differences. The results for the obtained signals from the reversion subjects also showed good correlations. During the reversion both systems were disconnected to prevent electrical damage, which results in a drop of the correlation. After reversion, all subjects were back in normal sinus rhythm and the overall raw data correlation increased and approximated a score of 0.

A more important and relevant parameter to compare the functionality of both systems, is by focusing on the RR-intervals, which are independent on the signal morphology and amplitude and solely rely on the intervals between the R peaks of two adjacent QRS-complexes. The cross correlation between all leads of both systems indicated a very good correlation above 99%. The small differences, which were observed, were due to the down sampling of the ECG patch to 125 Hz and some noise artifacts which could result in wrong peak detection resulting in differences in RR-intervals. When comparing the overall correlation of the RR-intervals of the different subjects, a very good correlation of  $0.9977 \pm 0.0012$  was obtained. This indicates that both systems have the same performance in QRS detection ability and that general algorithms have nearly the same performance on both signals. For the reversion subjects similar results were obtained, both for the AF episodes as well as for the normal sinus rhythm. Since the ECG patch has the ability to monitor multiple leads, it is possible to combine the three signals in a sample-by-sample sum of squares approach to enhance the R-peak detection.

To further investigate the application ability of the ECG patch, the ECG traces were analyzed to obtain a diagnosis for normal sinus rhythm or AF. All the obtained Holter results were in parallel analyzed by a cardiologist using the standard analysis procedure. For the persistent AF patients, it was found that these subjects were 100% in AF. For the patients undergoing electrical reversion, the results showed that they were in AF before the treatment and returned back to sinus rhythm afterwards. To verify these clinical findings based on only the Holter data, all raw ECG tracings were analyzed with an AF algorithm. Since the major focus is on the performance differences between the Holter system and the ECG patch, a well-known AF algorithm (i.e. the Linker algorithm) was used [19,20]. Because of computational limitations in the post-processing and analysis of all ECG traces with this algorithm, the data were segmented into blocks of 5 min, which were consecutively analyzed by the algorithm. Every time a score of 0 was obtained, a cardiologist was asked to review these fragments and distinguish between, (1) normal sinus rhythm, (2) AF and (3) noise. In all cases, the drop in AF score to 0 was due to noise. Since both signals have three leads, it is possible to create a majority vote allowing to strengthen the clinical diagnosis. In all cases, both the Holter and ECG patch

showed 100% AF in the group of patients suffering from persistent AF. Similar results were obtained in the patient population who underwent reversion. Here, 100% of the time the subjects were in AF prior to reversion and 100% in sinus rhythm after reversion.

The proposed study has some limitations that should be taken into account. The main purpose of this study was to compare the developed hardware functionalities and the acquisition of raw data of a new ECG patch versus the medically approved gold standard Holter system. The ECG patch has additional features for motion artifact reduction and on-chip beat detection capabilities, however, these features were not applied in this study since the main focus was on raw-data comparison. Additional digital signal processing on the raw data will further improve the signal quality and therefore also the diagnostic power for future applications. Additionally, the experiments took place in a small patient population with little diversity in the nature of their arrhythmias. Also the comparison between both systems based on different electrode positions is rather difficult since the ECG patch records the ECG vectors in a non-conventional way. However, the layout of these patch systems is variable and can be changed into any form factor towards future applications.

## Conclusion

Within this work we compared the measurement functionality and the hardware performance of a proprietary developed ECG patch with a medical gold standard 24-h Holter device. Based on the obtained results, it was difficult to conclude the functionality between both devices on raw signal quality, since electrode positions were at different locations. However, the main focus was on the detection of rhythm disorders (i.e. AF), the detection of QRS peaks and RR-interval analysis. The application of a standardized AF algorithm on the recordings resulted in good correlation between both devices. Based on the obtained results in ten subjects, one can conclude that the new ECG patch has the same performance as a medical gold standard Holter. It is important to state that the ECG patch in its current form factor will not replace the Holter, but extends the functionalities in cases where long-term comfortable monitoring is required. Important to note is that the ECG patch has been used in its basic structure without the capabilities of digital signal processing to compensate for motion artifacts and on chip beat detection. Additional improvements in electronics miniaturization and patch optimization, both in layout and in adhesives, should enhance stability on the chest wall and further improve the performance during physical activity.

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