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Comparative study of a single lead ECG in a wearable device

Rebecca Funston, PhD [a], Austin Gibbs, MD [b], Jordan Diven, MEng [a], Jonathan Francey, MEng [a], Holly Easlea, BSc [a], Stacey Murray, BSc [a], Matthew Fitzpatrick, MSc [a,*], Adrian Condon, BEng [a], Andrew R.J. Mitchell, MD [b]

[a] B-Secur, Queen's Road, Belfast BT3 9DT, UK
[b] The Allan Lab, Jersey General Hospital, St. Helier, Jersey

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ABSTRACT

Background: Technological advances have led to electrocardiograph (ECG) functionality becoming increasingly accessible in wearable health devices, which has the potential to vastly expand the clinician's ability to monitor, diagnose, and manage cardiac health conditions. However, achieving the high signal quality necessary to make an accurate and confident diagnosis is inherently challenging on consumer device-acquired ECGs. Effective signal conditioning is crucial to make ECG data from wearable devices clinically actionable.

Objective: This study evaluates the heart rate (HR) performance of ECG data collected on the HeartKey® Test Watch, a single lead, dry electrode wrist wearable, against data acquired on two criterion devices: the Bittium® Faros 180, a gold standard wet electrode ambulatory monitoring device, and the HeartKey Chest Module.

Methods: ECG data was simultaneously acquired on three devices during a multi-stage protocol (sitting, walking, standing) designed to reflect the motion noise of real-life scenarios. Raw ECGs from the HeartKey Test Watch and HeartKey Chest Module were processed through HeartKey software, and the accuracy of the outputted heart rate data was compared to that of the criterion device at each stage of the protocol. A beat rejection analysis was performed to provide insight into the degree of high-frequency noise present in ECGs recorded on the HeartKey Test Watch.

Results: Data acquired on the HeartKey Test Watch and processed by HeartKey software generated HR metrics that closely matched that of the criterion devices throughout the protocol. Bland-Altman analysis showed a mean absolute HR difference of 0.74, 1.21, 0.80 bpm during the sitting, walking, and standing stages respectively, which is within the ± 10% or ±5 bpm range required by ANSI EC13. ECG data from the HeartKey Test Watch had a higher beat rejection rate relative to the HeartKey Chest Module (8.5% vs ~0%) due to the excessive high-frequency noise generated during the motion-based protocol.

Conclusion: HeartKey software demonstrated highly accurate HR performance, comparable to that of the criterion Faros device, when processing challenging ECG data acquired on a single lead, dry electrode wrist wearable during both non-motion and motion-based protocols.

Introduction

The integration of ECG functionality into everyday consumer devices is transforming our approach to cardiac healthcare. By continuously monitoring heart function over extended periods of time, wearable devices generate a plethora of diagnostic data that can be called upon when needed [1]. Access to such pre-existing ECG data saves both time and resources for the clinician. Given the mounting clinical burden facing global healthcare in the post-COVID-19 era, this approach is incredibly valuable [2]. Additionally, as wearable ECG devices are unobtrusive and typically offer superior user comfort relative to the Holter devices typically employed for out-of-hospital heart monitoring [3], they are ideal for the detection and long-term periodic monitoring of transient arrhythmias, such as atrial fibrillation, which manifest infrequently and inconsistently.

However, extracting actionable clinical data from consumer device-acquired ECGs is challenging for two reasons. Firstly, the increased impedance of a dry electrode device leads to greater noise interference. Secondly, if the device is to be worn at peripheral locations on the body, such as the wrists or hands, the amplitude of the resulting ECG signal

* Corresponding author.
E-mail address: Matthew.Fitzpatrick@B-Secur.com (M. Fitzpatrick).

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will be low. Combined, these issues produce data in which the diagnostically relevant ECG waveforms can be buried under noise. Effective signal conditioning software capable of removing this excessive noise is vital in unlocking the clinical value of user-collected data [4,5]. Although numerous ECG wrist wearables and their accompanying software have been reported to effectively process acquired data to output accurate ECG health metrics, they require the user to remain stationary during the collection protocol to minimize motion artefacts, which significantly limits the everyday utility of the technology [6–8]. In this study, we highlight the ability of HeartKey Signal Processing algorithms to extract high-quality data from challenging ECGs collected on a dry electrode wrist wearable during non-motion and motion-based protocols.

Materials and methods

Overview of ECG hardware

ECG data was simultaneously collected on three different devices during the testing protocol. The HeartKey Chest Module, a single lead, dry electrode ECG device, was securely strapped to the subject's torso in a configuration akin to that of the Angle of Louis electrode placement used in 12-lead ECG recordings. The HeartKey Test Watch, a single lead, dry electrode wrist wearable, was fitted to the subject's left wrist. Bittium® Faros 180, an FDA 510(k) cleared, CE marked class IIa medical device, was set up in a lead II position using Ambu® BlueSensor wet electrodes to enable the acquisition of a high-quality chest ECG signal (Fig. 1). A Holter device is considered the industry gold standard for ambulatory ECG monitoring, and in this case, we utilised the Faros Holter device as the criterion. The HeartKey Chest Module acted as an extra reference device from which the performance of the HeartKey Test Watch could be compared.

Multi-stage ECG collection protocol

The data collection protocol was designed to evaluate the performance of the wearable devices when subjected to differing levels of induced motion artefacts, which will invariably effect ECG signal quality and the algorithms' ability to extract accurate health metrics. The active testing protocol lasted a total of 4 min per subject and was divided into four distinct stationary or motion-based phases performed consecutively, consisting of; i) 1-min resting baseline while sitting upright, ii) 1-min light walk at 3 km/h, iii) 1-min brisk walk at 4 km/h, and iv) 1-min resting recovery while standing. A ProForm Performance 750 treadmill was used to maintain control over the subject's walking speed. The timing of each activity was strictly enforced to ensure that the datasets acquired from each subject were directly comparable and that the subjects did not undergo any excess, unnecessary strenuous activity. Subjects wore the devices while the protocol was explained to allow for a short settle time.

Study population and exclusion criteria

A total of 14 participants were recruited for this study, 7 males and 7 females, with an age range of 20–42 years. Details of the testing protocol were fully disclosed to each subject prior to their participation in the study. Exclusion criteria included subjects with allergies to plasters, pregnant women, those with pre-existing heart conditions, and those under the age of 18.

Data processing

Data collected on the Bittium Faros 180 was processed using the embedded Faros software, generating an R-R interval series which is then fed into the HeartKey Heart Rate algorithm to generate a HR output. Data acquired on the HeartKey Chest Module and HeartKey Test Watch was streamed through the HeartKey software, which contains several distinct stages designed to autonomously process and interpret raw ECG data and output several useful ECG metrics (Fig. 1). To ensure robust algorithm performance across different hardware sources, the initial filtering step uses a combination of low- and high-pass filters to remove a broad range of noise artefacts, including baseline wander, muscle activity, respiration, and powerline interference. The conditioned ECG signal is then passed through the HeartKey QRS Detection algorithm. Upon successful identification of QRS locations, an R-R interval series is calculated and inputted into the HeartKey Heart Rate algorithm. HR is calculated over a moving median window of nine R-R intervals in real time. As standard QRS accuracy measurements employ a wide error window (+/− 150 ms), the precise location of detection within the QRS complex is not important, only that this location remains consistent from beat-to-beat. Looking at this in isolation could mask variation in where the algorithm picks up the beat. Therefore, performance was evaluated between devices using HR metrics. HeartKey provides an indicator of ECG signal quality and will only generate a HR value if the signal is deemed to be of sufficient quality.

Results

Throughout each stage of the testing protocol, the HR performance of ECG data collected on the HeartKey Test Watch and processed using HeartKey software closely matched that of the criterion Faros device (Fig. 2).

HR data was derived from the Faros R-R series and compared to the HeartKey Test Watch HR data using Bland-Altman analysis. Bland-Altman analysis evaluates mean difference bias between two inputs and estimates an agreement interval within which 95% of future

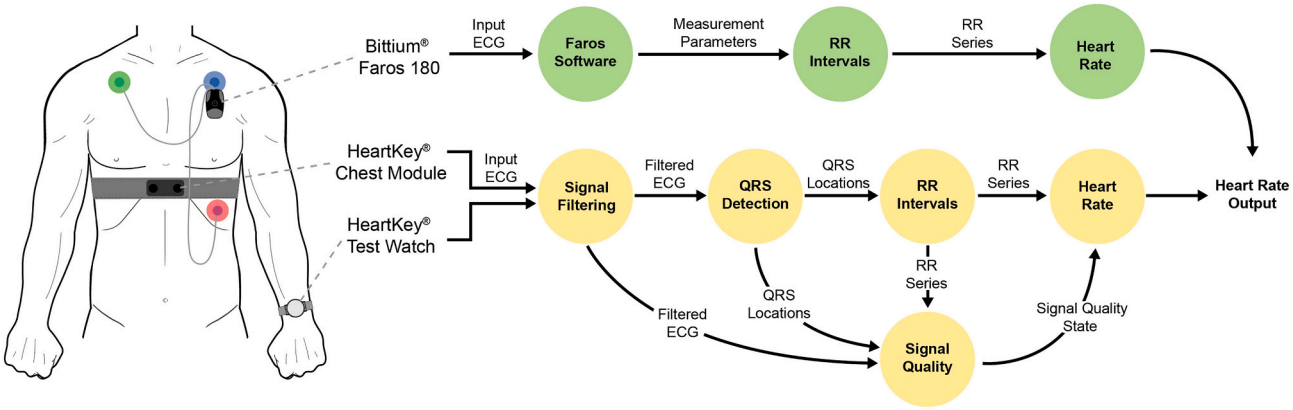

Fig. 1. Configuration of the three devices used in this study and the flow of ECG data through the corresponding algorithms to generate a HR output.

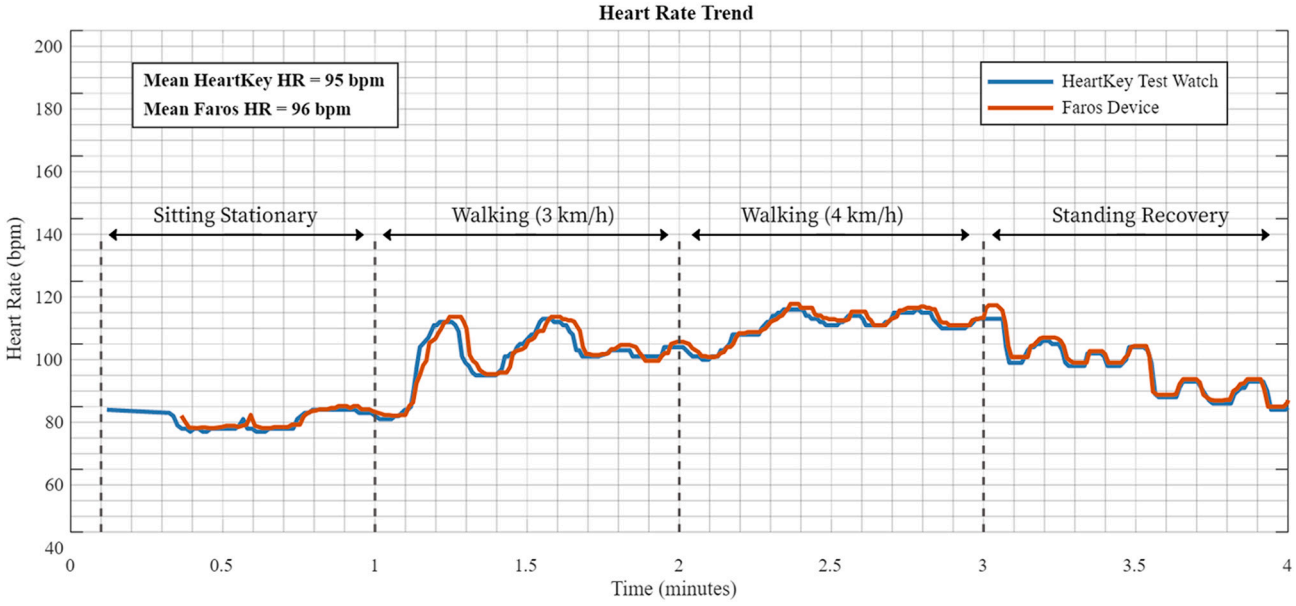

Fig. 2. HR trend comparison of the HeartKey Test Watch and the criterion Faros device through the various phases of the protocol for a single participant (S054).

differences between the two inputs shall fall. Reported confidence intervals (CIs) are that of the absolute mean difference between HR generated on the criterion Faros device and the HeartKey Test Watch. Table 1 provides a statistical overview of the Bland-Altman analysis.

Sitting baseline analysis

During the sitting baseline period, the HeartKey Test Watch had an Absolute Mean HR difference of 0.74 bpm relative to the Faros device and a Mean Absolute Percentage Error (MAPE) of 1.31% when averaged across all subjects. The narrow CI range on the Bland-Altman plot of −2.89 bpm to 1.70 bpm further highlights the close performance of the two devices.

Walking and standing recovery analysis

Over both walking periods, the relative performance of HeartKey Test Watch data is slightly poorer when compared to the sitting protocol, although still well within the ±10% or ±5 bpm range required by ANSI EC13. The HeartKey Test Watch had an Absolute Mean HR difference of 1.21 bpm and a MAPE of 1.17% averaged over the entire subject cohort. Bland-Altman analysis revealed a larger CI range of −5.60 to 3.19 bpm. Fig. 3 shows the difference in signal quality for ECG data acquired and processed on the Faros device to ECG data acquired on the HeartKey Test Watch and processed with HeartKey software during the walking phase. It should be noted that Faros peak annotations were taken directly from the device (i.e., not generated by the HeartKey QRS Detection algorithm), hence, the peak location may not be exactly on the R peak. During the standing recovery period, the HR performance of HeartKey Test Watch data improved, with an Absolute Mean HR difference of 0.80 bpm, a MAPE of 1.43% when averaged across all subjects and a decreased CI range (−3.72 to 2.36 bpm) relative to the walking phases.

Discussion

Accurate and reliable QRS detection is fundamental as this serves as the basis from which more complex HeartKey algorithms operate, including HR, Heart Rate Variability (HRV), Physiological Stress, and Arrhythmia Analysis. An ECG signal that has retained a high degree of noise after conditioning can therefore have a significant impact on the generation of downstream HeartKey metrics. HeartKey software employs adaptive morphology-based selection parameters and proprietary measurements of noise to appraise the quality of each individual beat and will only allow HeartKey to generate a HR value if it is deemed to be of sufficient quality (i.e., a correct QRS morphology not severely contaminated by noise). Table 2 shows the number of beats rejected by

Table 1
HR data results divided per testing section for the entire subject cohort ($N = 14$). Separate walking periods were analysed together for simplicity.

Protocol	Device	Min HR (bpm)	Max HR (bpm)	Mean HR (bpm)	SD	Absolute Mean Difference (bpm)	Mean Lower CI Range	Mean Upper CI Range
Sitting Baseline	Bittium Faros 180	54	103	78	13.5	**0.74**	−2.89	1.70
	HeartKey Chest Module	52	103	78	13.7			
	HeartKey Test Watch	52	103	77	13.5			
Walking (3-4 km/h)	Bittium Faros 180	78	129	101	13.9	**1.21**	−5.60	3.19
	HeartKey Chest Module	77	128	100	13.9			
	HeartKey Test Watch	77	127	100	13.5			
Standing Recovery	Bittium Faros 180	72	114	96	15.8	**0.80**	−3.72	2.36
	HeartKey Chest Module	71	113	96	15.6			
	HeartKey Test Watch	71	113	95	15.5			

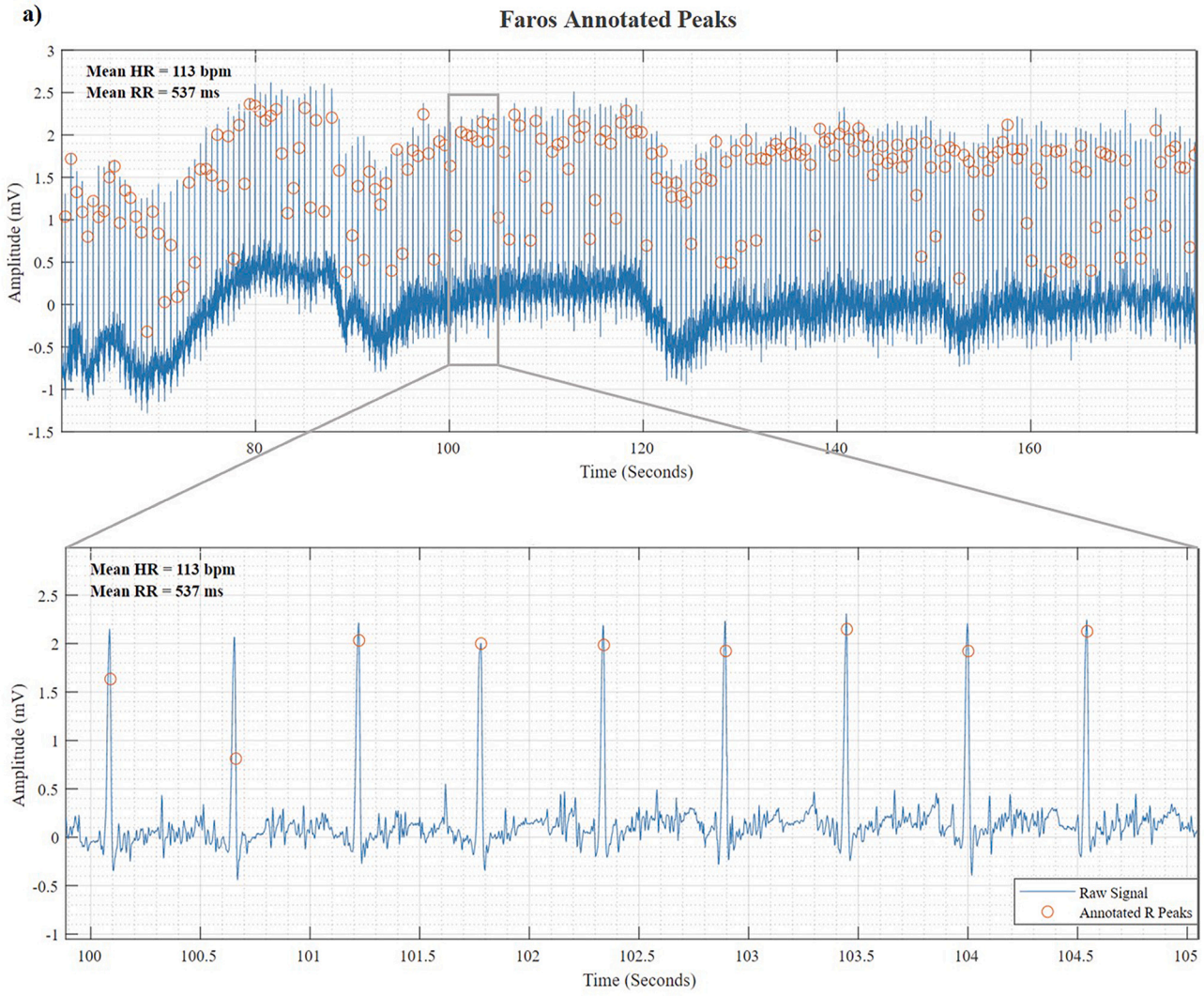

Fig. 3. Walking phase ECG data of participant S026; (a) acquired on the Faros device and processed using the embedded software (annotated R peaks generated by Faros software), and (b) acquired on the HeartKey Test Watch and processed through HeartKey Software (includes a filtering step). Beats rejected by HeartKey due to insufficient quality are shown.

HeartKey throughout each stage of the protocol due to elevated signal noise. As data from Faros device was processed using embedded Faros software and does not provide beat rejection analysis, the HeartKey Chest Module was used as the criterion for this assessment.

Being securely strapped to the torso, ECG data collected on the HeartKey Chest Module has a larger signal amplitude and is less prone to motion-derived noise artefacts, resulting in high signal quality and only a single noise-rejected beat throughout the entire collection protocol. Conversely, the optimal protocol for ECG acquisition on the HeartKey Test Watch involves the subject sitting in a stationary position while placing the thumb and forefinger of their right hand on the face of the watch in a more uncontrolled manner. This leads to considerably greater motion-derived signal noise which, in combination with the low wrist ECG amplitude, makes it difficult to differentiate a QRS complex from a noise artefact. The lowest percentage number of rejected noise beats (3.4%) was observed during the sitting protocol, as would be expected. The enhanced motion during walking phases led to more than a 3-fold increase in the percentage of noise-rejected beats. Upon returning to a stationary position, the percentage of rejected beats again decreased from 10.9% to 8.4%. Over the whole protocol, a total beat rejection rate of 8.5% was observed.

Conclusion

In this small-scale pilot study ($N = 14$), ECG data acquired on the dry electrode, Lead I HeartKey Test Watch and processed using HeartKey software displayed analogous HR performance relative to the Bittium Faros 180 – an industry standard wet electrode, Lead II ambulatory monitoring device. Bland-Altman analysis showed that throughout the entire testing protocol, featuring several scenarios intended to reflect real-life use, the absolute mean HR difference between devices was small (0.74 bpm (sitting), 1.21 bpm (walking), 0.80 bpm (standing)). Processed data collected on the HeartKey Test Watch performed to a high standard in most subjects. In several subjects, particularly those with a low wrist ECG amplitude, the signal quality was poor at times. An average of 8.5% of HeartKey rejected beats were observed for the HeartKey Test Watch, whereas the HeartKey Chest Module had ~0%, which is to be expected from the less-stable wrist-based ECG. Although signal quality decreased during the walking phase of the protocol, HeartKey's ability to correctly reject noise artefacts prevented the HR algorithm from using these as inputs, enabling accurate HR performance to be maintained.

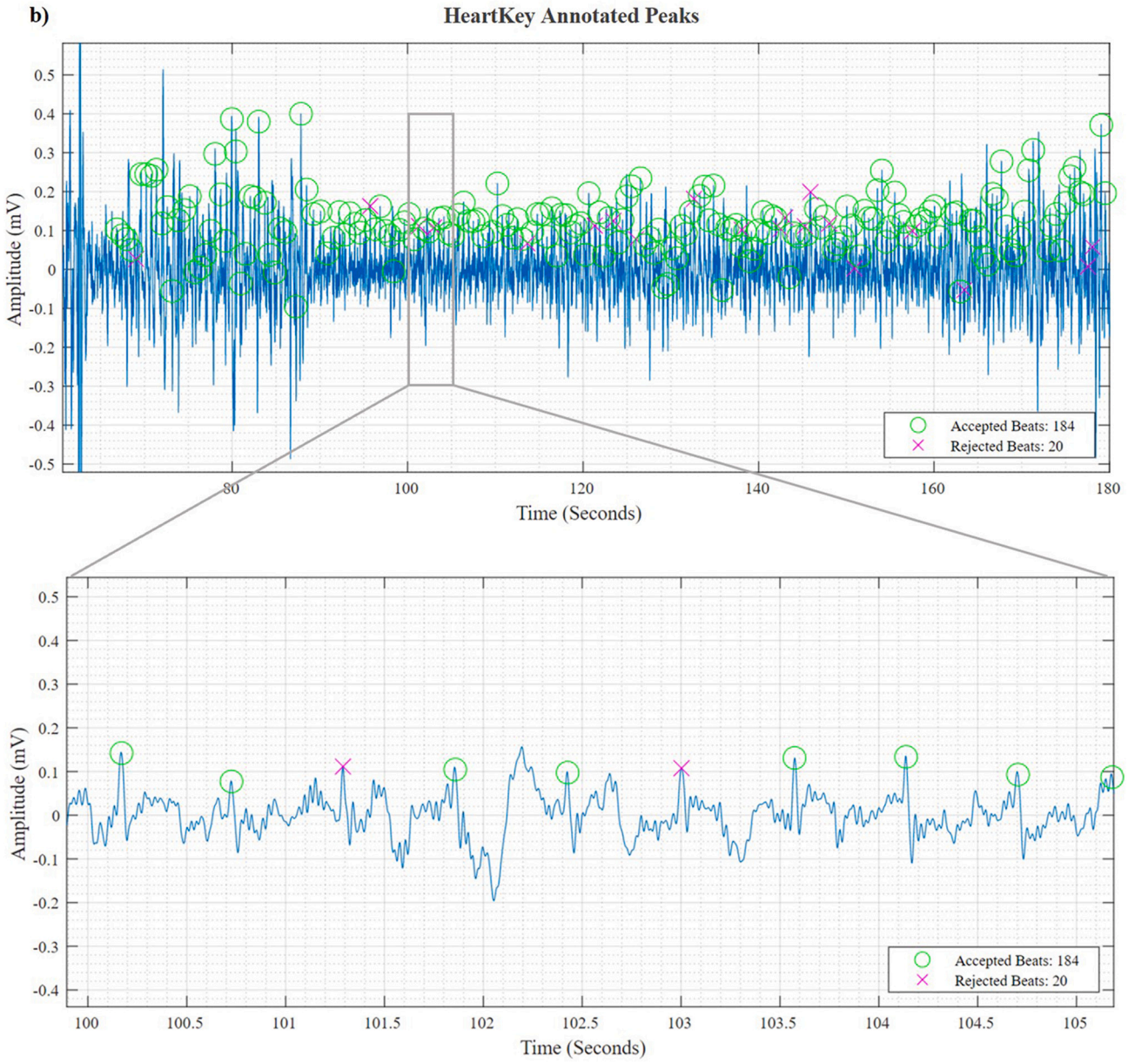

Fig. 3. (*continued*).

Table 2
The number of HeartKey rejected beats observed for the full study cohort ($N = 14$) throughout the collection protocol due to poor signal quality for the HeartKey Chest Module and The HeartKey Test Watch.

	HeartKey Chest Module			HeartKey Test Watch		
	Sitting	Walking	Standing	Sitting	Walking	Standing
Total Beats Detected	1013	2634	1226	923	2535	1217
Noise Beats Rejected	0	1	0	32	267	100
Mean % of Beats Rejected	0	~ 0	0	3.4	10.9	8.4

Conflicts of interest

Rebecca Funston is Director of RAQAC, B-Secur, Ltd. (e-mail: rebecca.funston@b-secur.com). Dr. Austin Gibbs is Lab Director, The Allan Lab, Jersey General Hospital, and is a Consultant to B-Secur, Ltd. (e-mail: austin@theallanlab.com). Jordan Diven is Validation Team Lead, B-Secur, Ltd. (e-mail: jordan.diven@b-secur.com). Jonathan Francey is Head of Algorithm Development, B-Secur, Ltd. (e-mail: jonathan.francey@b-secur.com). Holly Easlea is Senior Clinical Manager, B-Secur, Ltd. (e-mail: holly.easlea@b-secur.com). Matthew Fitzpatrick (corresponding author) is Scientific Writer, B-Secur, Ltd. (e-mail: matthew.fitzpatrick@b-secur.com, postal address: B-Secur Ltd. Catalyst Inc., The Innovation Centre, Queen's Road, Belfast, BT3 9DT, UK). Stacey Murray is Clinical Research Lead, B-Secur, Ltd. (e-mail: stacey.murray@b-secur.com). Adrian Condon is Chief Technical Officer B-Secur, Ltd. (e-mail: acondon@b-secur.com), mitchogj@gmail.comDr. Andrew RJ Mitchell is Consultant Cardiologist & Head of Research, The Allan Lab, Jersey General Hospital and is a Consultant to B-Secur, Ltd. (e-mail: andy@theallanlab.com).

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Ethics

This study was conducted in accordance with the Declaration of Helsinki. Proprietary data was collected at B-Secur HQ (Queen's Road, Belfast). Data was managed in-line with European General Data Protection Regulation (GDPR). Enrolled subjects provided informed consent prior to study participation.

CRediT authorship contribution statement

Rebecca Funston: Supervision, Project administration, Writing – original draft, Writing – review & editing. **Austin Gibbs:** Methodology, Writing – review & editing. **Jordan Diven:** Validation, Formal analysis, Software, Data curation, Investigation. **Jonathan Francey:** Software, Methodology, Writing – review & editing. **Holly Easlea:** Project administration, Writing – review & editing. **Stacey Murray:** Writing – review & editing, Project administration. **Matthew Fitzpatrick:** Writing – original draft, Writing – review & editing, Visualization. **Adrian Condon:** Supervision. **Andrew R.J. Mitchell:** Methodology, Writing – review & editing.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jelectrocard.2022.08.004.

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