Journal of Electrocardiology 55 (2019) 54–58

Contents lists available at ScienceDirect

Journal of Electrocardiology

journal homepage: www.jecgonline.com

Single lead patch recording systems: The expanding role for long-term ECG recording systems

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Keywords:
Atrial fibrillation
ECG recording
ECG device
Ambulatory monitoring
Holter monitor

Introduction

The assessment of rhythm symptoms often requires a symptom-to-rhythm ECG correlation ideally using a multi lead recording system with up to 12 skin surface electrodes connected to a separate recording device. Such skin surface devices generally record data with conventional memory allowing up to 2 weeks of recording. Some devices use a flash memory technology with recording occurring not continuously but only on patient activation with partitioning of the memory to some period of time programmable before and after activation. Hand-held recording systems are available but only acquire the signal close to coincident or after symptom onset [1,2]. These systems would not be as useful for symptoms that occur unpredictably, for rhythms that occur without symptoms, or to look at premonitory rhythms prior to symptom onset. Advances in technology allow for leadless single lead ECG patch-like recording systems [3]. These have been validated against conventional Holter recording devices with results showing similar quality of data and analytic potential [4,5].

Methods

We present four cases that each exemplify a different issue with these systems and suggest possible future directions of patch like single lead recording systems. The same single lead patch-like recording device was used in all cases (CardioSTAT, iCentia, Quebec, QC, Canada) [6]. At either end of the device there is a conventional male terminus electrode snap type pin and in the center there is a button for patients to press for activation to record symptoms for later correlation with ECG rhythm. The device has an inter-electrode distance of 12 cm and is enclosed in a thermoplastic elastomer (Fig. 3A). The device is a continuous recorder with commercially available recording software for off-line analysis. The analysis provides data on all ECG recording beats, magnitude of noise signal, with identification of all arrhythmias as well as graphical display of heart rate trends along with standard APB and VPB counts.

Case series

Case 1

A 32-year-old man with atypical chest pain and rare palpitations in an avid triathlete was having symptoms while swimming. No abnormal rhythms or abnormalities were seen on an 18 min Bruce protocol stress to a peak rate of only 80% age-predicted. Echo and stress echo imaging was normal. While wearing the device he engaged in high-end athletic swimming efforts. First recording positioning was horizontal just below the angle of Louis on his sternum. The recording signal showed a high quality signal with no observed difference on recordings of ectopy or non-sustained atrial rhythms on land or water (Fig. 1A, B). During peak swimming efforts with aggressive upper arm movement and pectoralis activation, noise artifact was created. A repeat system was given to him only now with the lead configuration placed vertically on the sternum. The same noise artifact is seen while actively swimming. On the cessation of swimming sinus tachycardia was observed with good P-wave morphology (Fig. 1C). In this case palpitations that occurred with symptom activation post swimming were associated with low-grade isolated atrial ectopy.

Case 2

A 68-year-old woman presented with documented asymptomatic rate impaired atrial fibrillation with normal echo assessed left ventricular function. The 14-day Holter shows her elevated rate in continuous atrial fibrillation with daily nocturnal slowing occurring (Fig. 2A). The mean rate in atrial fibrillation is 115 bpm. Diurnal variation allowed for nocturnal rates in the 70–75 bpm range. The patient wore the device while in her hot tub. The device was activated for symptoms that occurred while she was in the hot tub (Fig. 2B). Her diary states "… a squirrel fell off a branch and landed in the tub. This shocked me I was in a panic felt my heart racing…". Not surprisingly, the ECG seen in atrial fibrillation with this sudden startle and she presented with a very sudden racing heart rate of 150 bpm, sustained for 4 min. Consequent to this phenomenon she

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https://doi.org/10.1016/j.jelectrocard.2019.03.004

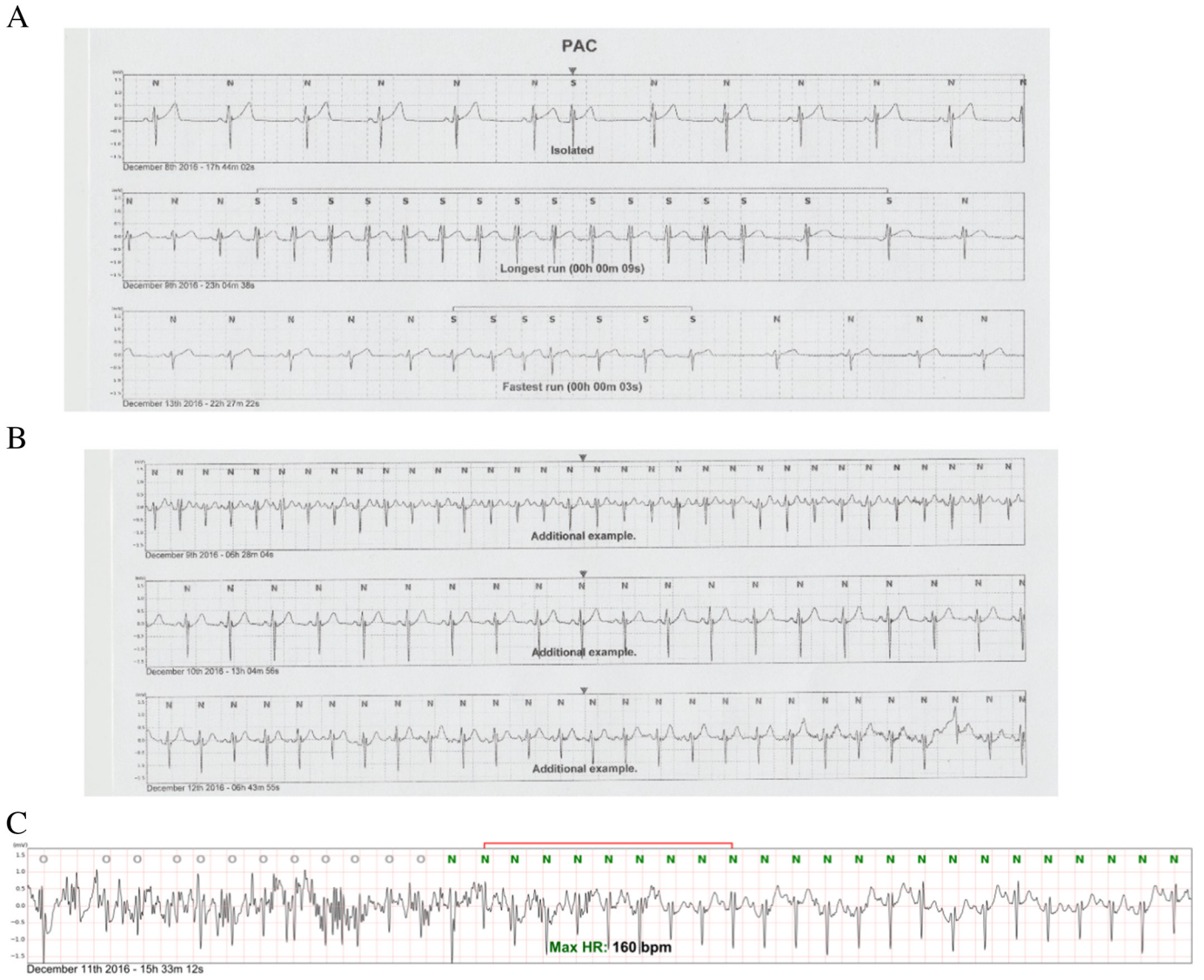

Fig. 1. Recordings of patient (A) swimming in water, (B) running on land and (C) with device patched in horizontal position across sternum. There is no significant chance in signal quality, refer to text for further discussion.

was willing to have initiation of beta-blocker therapy for symptoms and prognosis.

Case 3

A 92-year-old woman with remotely documented bouts of atrial fibrillation on metoprolol 25 mg twice a day presented with episodes of loss of consciousness. She had significant cognitive impairments and was unable to give a history. According to her caregiver she had the sudden onset of non-responsiveness with confusion after the event. Her cognitive impairments also made it impossible to use any chest wall lead recording system and instead the device system was placed in an inter-scapular location (Fig. 3A). This still allowed adequate recording of atrial activity and QRS (Fig. 3B). Over a two-week period, normal sinus node mechanism was seen with 18% of the time heart rate below 60 bpm and mild sinus node dysfunction. Total APB burden was 35 APB per hour with rare bouts of non-sustained atrial tachycardia of 29 beats at 102 bpm. No atrial fibrillation was seen and there were no prolonged pauses. On 3 occasions her caregiver activated the device as instructed for symptoms that were not entirely like index symptoms with still P-wave seen in her usual first-degree heart block but no abnormal rhythm at the time. She was subsequently placed on empiric anti-seizure medications with no further episodes.

Case 4

An embolic stroke of an unknown source occurred in a 66-year-old man with hypertension and normal echocardiogram with normal left atrial size. Neuroimaging with an MRI confirmed an acute middle cerebral artery territory embolic ischemic stroke. CT angiogram of the extracranial and intracranial arteries was unremarkable. An initial 48-hour Holter monitor revealed sinus rhythm with no episodes of atrial fibrillation. The device was worn for 2 weeks during which no arrhythmias were observed. APB frequency was 10 per hour. A second two-week device recording detected 9 episodes of non-sustained atrial fibrillation (total duration 2 h; longest single episode 75 min). All atrial fibrillation events were nocturnal and asymptomatic, and occurred in a de novo fashion with no antecedent atrial tachyarrhythmia (Fig. 4A, B). Based on this result, the likely etiology of the patient's stroke was identified and antiplatelet therapy was switched to anticoagulant therapy for maximum secondary stroke prevention.

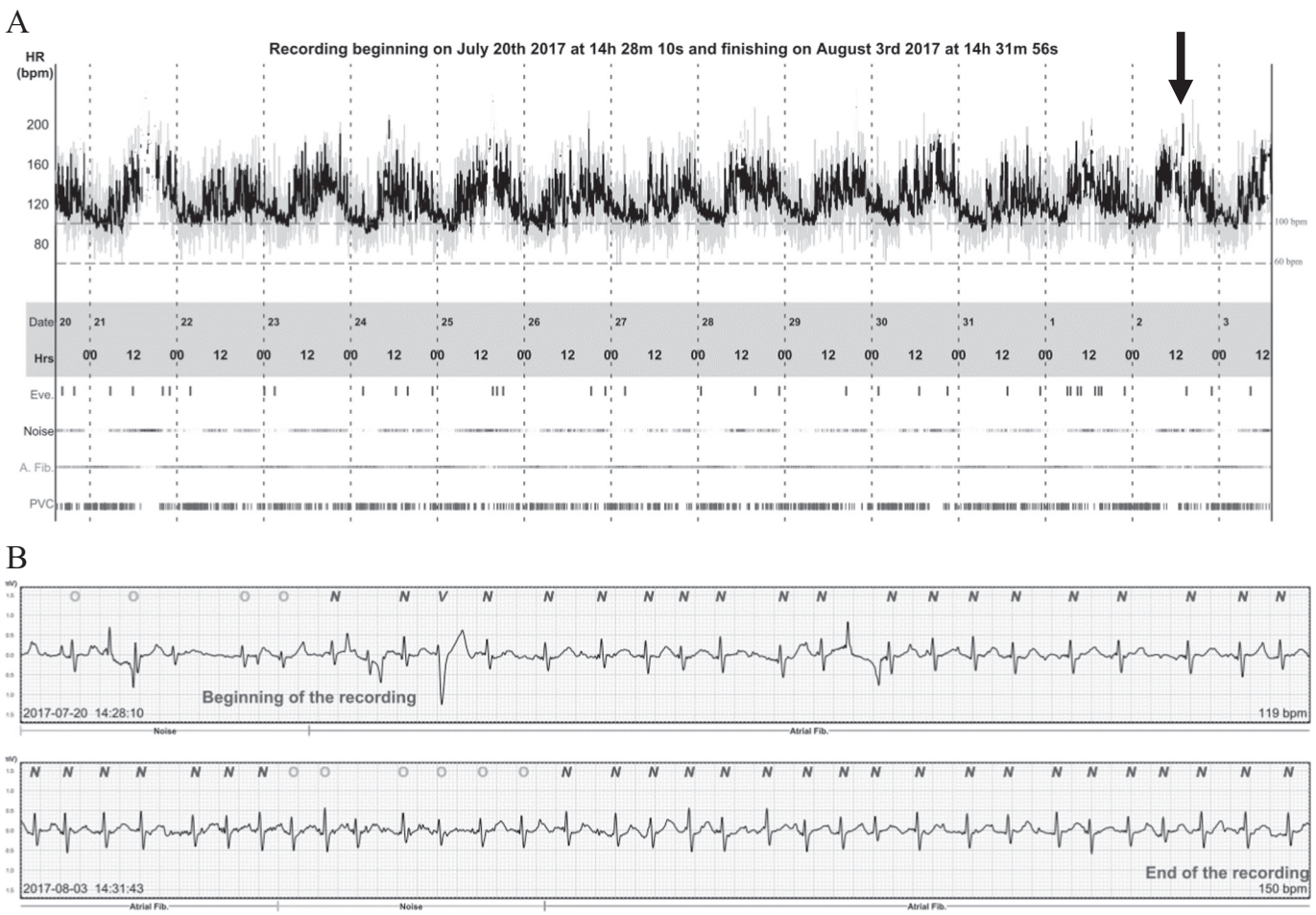

Fig. 2. (A) 14 day recording with horizontal markers for heart rate; labels include date and hour (Hrs), event activation (Eve), noise signal (Noise), atrial fibrillation label (A. Fib) and premature ventricular contractions/wide complex beat (PVC). The arrow indicates event onset. (B) ECG detail of the event.

Discussion

Leadless recording systems, when compared to multi lead Holter devices, provide patients with greater utility and ease of use while providing clinicians with recordings of equivalent signal quality. The system used in this study is capable of heart recordings in aquatic environments as in case 1, or recreationally as in case 2. Although preliminary, this suggests that these types of devices may have an important role in exploring symptoms that occur in aquatic environments and perhaps have a particular role for surveillance in particular forms of channelopathies that may be related or exacerbated in aquatic activities [7]. In all cases the devices allowed for symptom rhythm correlation that helped guide therapy. In these cases, waterproof leadless recording systems allowed ease of use for long-term monitoring in both bathing aquatic environments and activities of daily living.

The optimal lead location for leadless systems is not established. Smith et al. suggests vertical placement may be particularly important for identification of P-wave morphology [4]. In case 1 we assess that two different lead configurations in the same patient and the same environment had no change in signal quality. Importantly, there was noise artifact related to pectoralis muscle activation in this configuration during his more extreme exercise efforts. Case 3 suggests that when needed, even an unusual lead location on a patients' back may be clinically warranted and yield valid data. This suggests increased utility for such recording systems in patients or perhaps the pediatric population who may have an inability to cooperate with a chest wall placed recording system.

The lead array described in this report is a 12 cm band. It is possible alternative placement locations applied systematically could increase the amplitude of QRS, P or T waves. In one study of 16 different possible single lead configurations the optimal interelectrode distance was at least 8 am aligned diagonally along the cardiac axis [8]. We cannot make any comparative statements about efficacy, tolerability or possible utility in aquatic environments with other similar patch-like systems. Such systems now available include both 2- electrode (Zio™ patch, Carnation Ambulatory Monitor™ patch) and 3-electode (Novi™ patch) configurations. This is not an exhaustive list as there may be other devices now or in the future in the marketplace.

Case 4 is an example of how prolonged post-stroke ECG monitoring with wearable devices can improve the detection of paroxysmal atrial fibrillation, as supported by recent trials [9,10]. It is recognized that some embolic ischemic stroke or TIA events may be the first manifestation of atrial fibrillation (in approximately 12% of ischemic strokes [11]), which may be paroxysmal, subclinical and evade detection by routine short-duration ECG monitoring. Thus, a subset of patients with embolic stroke of undetermined source may have occult atrial fibrillation that may benefit from anticoagulant therapy for maximum stroke protection. However, for brief atrial fibrillation episodes lasting less than 24 h, the minimum amount of atrial fibrillation that warrants anticoagulation is currently unknown, and randomized data on the efficacy of anticoagulation for brief atrial fibrillation is currently lacking. Frequent atrial premature ectopic beats and clinical factors (left atrial enlargement, older age, high CHADS2 score, elevated atrial natriuretic

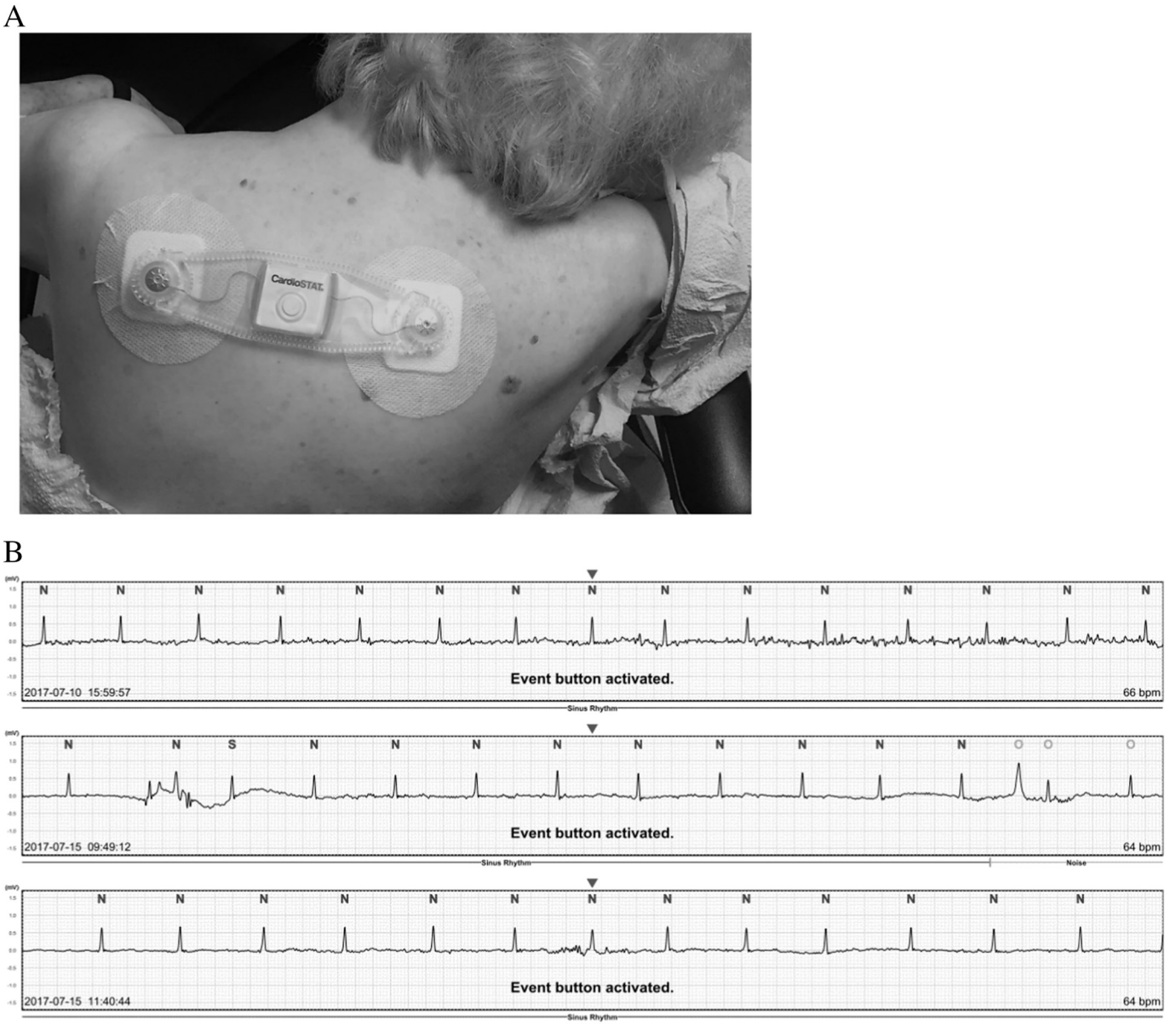

Fig. 3. (A) Photo of inter scapular device placement on patient. (B) Rhythm tracing following events as activated on the device by the patients' caregiver. Note that this intrascapular position provides reasonable signal amplitude and signal to noise ratio.

peptide levels) may predict a greater likelihood of atrial fibrillation detection [12].

Limitations

Leadless single lead ECG recording systems are relatively new and do have limitations. Not all software systems are necessarily capable of providing analysis with simultaneous pacemaker systems. No manufacturer will claim that the systems are waterproof and our use of this device in aquatic environments is off-label. The use of any single lead system means that there will be no backup recording capabilities in the event of any partial or complete lead detachment. Multi lead Holter systems do have such redundancy available and therefore in critical situations or, in patients who have implanted devices in place, the use of conventional Holter multi lead systems may still be important. Patch like recording systems with multi lead recording capabilities will likely increase. Post ectopic beat repolarization changes may be important, and having a multi lead system may allow one to see abnormalities more clearly. For isolated ventricular ectopy morphology analysis (pre-ablation), or ischemia identification, a 12 lead Holter may be preferable for more precise assessment of the ECG signal. Lastly, single lead recording systems generally use manufacturer specific algorithms for data analysis which, may be done offline from the site where the patient receives the system and therefore issues of confidentiality related to the data loading onto the cloud or other Internet-based platforms may be of concern.

Conclusion

The use of single lead, leadless ECG recording devices will expand the role of ambulatory monitoring. The ease of use for such devices combined with the relative ease of use in aquatic environments will likely increase monitoring capabilities. Optimal lead placement remains unclear with unusual lead locations still able to provide viable data tailored to clinical context.

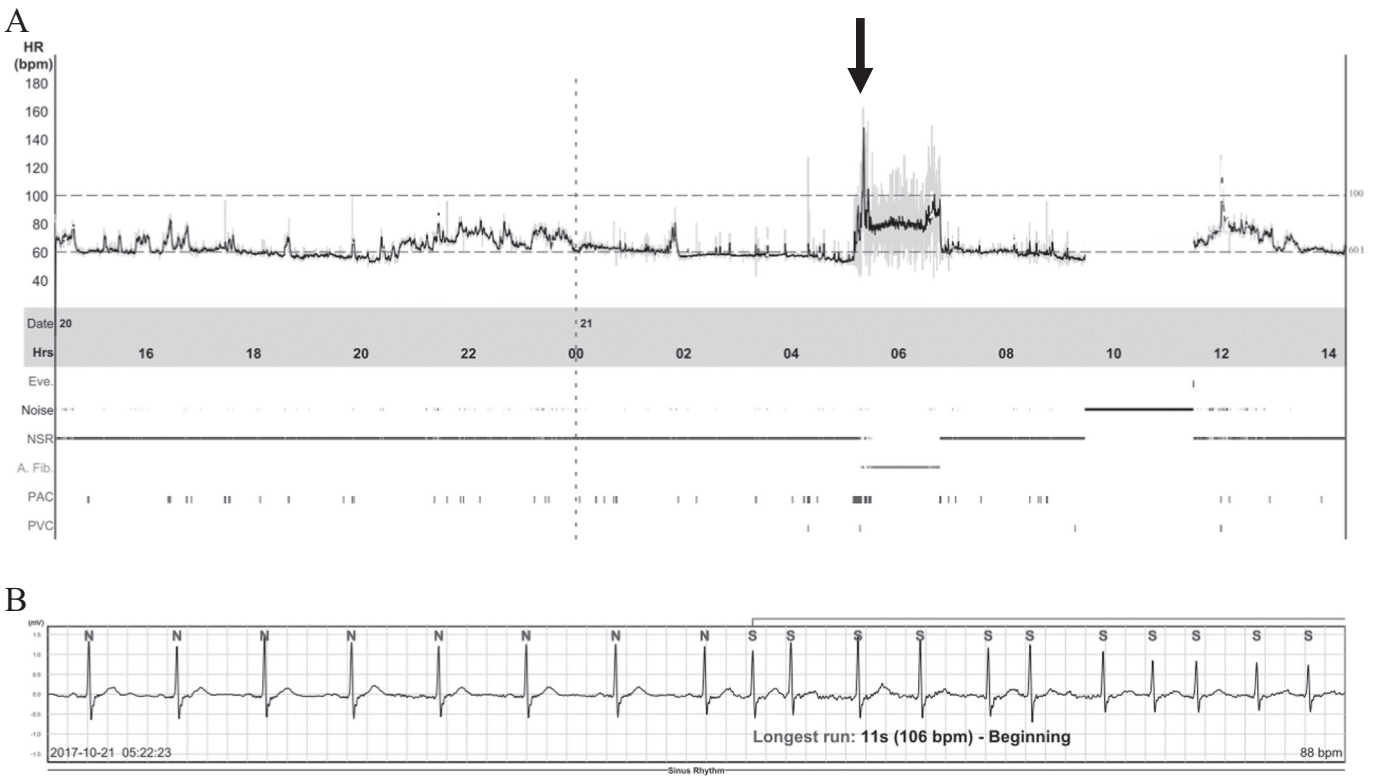

Fig. 4. (A) 24 h recording with horizontal markers for heart rate; labels include date and hour (Hrs), event activation (Eve), noise signal (Noise), normal sinus rhythm (NSR), atrial fibrillation label (A. Fib), premature atrial contractions (PAC) and premature ventricular contractions/wide complex beat (PVC). The arrow indicates event onset. (B) ECG detail of the event.

Funding

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Declarations of interest

None.

Acknowledgements

Authors wish to thank Maya Newman for her efforts on this paper.

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