Evaluation of wearable epileptic seizure monitors

by

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“This thesis is dedicated to my loving parents,

(Evaresto and Betty Rukasha).”

ABSTRACT

The research presented in this thesis contributes to the evaluation and future evolution of wearable epilepsy seizure monitoring devices with a systematic literature review and three research studies that include two device evaluation studies, and a survey of stakeholder opinions and experiences of wearable epilepsy monitoring devices.

The thesis comprises background literature relevant to epilepsy, wearable technology, seizure monitoring and device evaluation. This review is followed by chapters for the systematic literature review and the three research studies.

The systematic review is focused on evaluations of wearable epilepsy seizure monitors in the academic literature. It demonstrates that although there are over 3000 works in the literature proposing and evaluating novel and incremental approaches to epilepsy seizure detection, there are very few that report evaluations of available devices and, amongst studies that do report evaluations, there is a lack data for important metrics such as false alarm rates as well as other details that would support reproducibility.

The first device evaluation study contributes an assessment of the 'photoplethysmography' optical heart rate performance of the medical-grade Empatica E4 data streaming wrist-worn wearable that is based on the Empatica Embrace epilepsy monitor. Heart rates were acquired from the E4 and a reference electrocardiogram (ECG) chest strap monitor for four participants during treadmill walking and 12 hours of free-living. Mean Absolute Percentage Errors (MAPEs) and correlations are reported and demonstrate variable performance that includes negative correlation with the reference. This finding contributes insights into the poor seizure detection performance of studies that have relied on wrist-worn heart rate sensing during motor seizures.

The second study reports device evaluation results for the Empatica Embrace wrist-worn seizure monitor. No other studies in the literature have evaluated the interfaces of wearable seizure monitors. Eight of the Embrace display indications were assessed for 'guessabilty' by fourteen computer science participants who also performed a heuristic evaluation of the interface. The guessability results demonstrate confusion between different interface indications. The heuristic evaluation identified i) concerns about accessibility and reliance on recall and ii) satisfaction in terms of the minimal aesthetic of a simple light pattern interface.

The third and final study reports opinions and experiences of wearable epilepsy monitors reported by 61 respondents comprising 36 individuals with epilepsy, 14 carers, and 11 healthcare professionals. Overall, survey responses indicate that stakeholders have mixed opinions of wearable epilepsy seizure monitors and a degree of concern, particularly in terms of false alarms, missed seizures and other aspects of device reliability, as well as concerns about costs.

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May God continue to bless you all (Amen).

DECLARATION OF AUTHORSHIP

I declare that the work presented in this thesis is my own. Where I have consulted and collaborated with others, this has been acknowledged.

DISSEMINATIONS

Journal article

- Rukasha, T., Woolley, S., Kyriacou, T. and Collins, T. Evaluation of Wearable Electronics for Epilepsy: A Systematic Review. Electronics, 2020, 9(6), p.968.

Conference papers

- Rukasha, T., Woolley, S., Kyriacou, T. and Collins, T. Evaluation of Wearable Epileptic Seizure Monitors, Virtual Doctoral Symposium, BCS Human-Computer Interaction Conference, Keele University, 6 July 2020.

- Rukasha, T., Woolley, S., Kyriacou, T. and Collins, T. Wearable Epilepsy Seizure Monitor User Interface Evaluation: An Evaluation of the Empatica 'Embrace' Interface, ACM International Joint Conference on Pervasive and Ubiquitous Computing, New York, NY, USA, 14 September 2020.

- Rukasha, T., Woolley, S., Kyriacou, T. and Collins, T. Heart Rate Performance of a Medical-Grade Data Streaming Wearable Device. The IEEE/ACM international conference on Connected Health: Applications, Systems and Engineering Technologies (CHASE), Washington, D.C, 17 December 2020.

Presentations

- An Evaluation of the Empatica 'Embrace' Interface, School PGR Symposium, Keele University, 15 April 2021.

- Research Progress, Software and Systems Engineering Research Meeting, Keele University, 19 August 2020.

- Findings of a Systematic Review of Wearables for Epilepsy, Software, and Systems Engineering Research Meeting, Keele University, 20 November 2019.

- Wearable Evaluations and Piloting the E4 Wristband, Software and Systems Engineering Research Meeting, Keele University, 28 August 2019.

- Epileptic Seizure Prediction, Detection and Recording with the use of Sensor Technologies, progress so far and work to be completed, Software and Systems Engineering Research Meeting, Keele University, 21 November 2018.

- Epileptic Seizure Prediction, Detection, and Recording with the use of Sensor Technologies and hints and tips on how to survive your first-year progress report, Computer Science Journal Club, Keele University, 21 November 2018.

- Epileptic Seizure Prediction, Detection, and Recording with the use of Sensor Technologies, Literature Review, Postgraduate Computing Research Day, Keele University, 11 April 2018.

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LIST OF ABBREVIATIONS

AED	Anti-Epileptic Drug
BTCS	Bilateral Tonic-Clonic Seizures
CPS	Complex Partial Seizures
CS	Clonic Seizures
ECG	Electrocardiogram
EDA	Electrodermal Activity
EEG	Electroencephalography
EMG	Electromyography
EMU	Epilepsy Monitoring Units
FAR	False Alarm Rate
FN	False Negative
FP	False Positive
FS	Focal Seizures
FTCS	Focal Tonic-Clonic Seizures
GPS	Global Positioning System
GTCS	Generalized Tonic-Clonic Seizures
HCI	Human-Computer Interaction
HRV	Heart Rate Variability
ICC	Intraclass Correlations
kNN	K-Nearest Neighbour
LED	Light-Emitting Diode
MAPE	Mean Absolute Percentage Error
MS	Myoclonic Seizures
MTS	Myoclonic-Tonic Seizures
NB	Naïve Bayes
NPV	Negative Predictive Value
PMS	Predominantly Motor Seizures
PNMS	Predominantly Non-Motor Seizures
PPG	Photoplethysmography
PPV	Positive Predictive Value
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PS	Partial Onset Seizures
PSSUQ	Post-Study Systems Usability Questionnaire
RF	Random Forest
SUDEP	Sudden Unexpected Death in Epilepsy
SVM	Support Vector Machine
TCS	Tonic-Clonic Seizures
TLS	Temporal Lobe Seizures
TN	True Negative
TP	True Positive
TS	Tonic Seizures
vEEG	Video Electroencephalography

CHAPTER 1
INTRODUCTION

This chapter outlines the background and motivation for the research and summarises the research questions and original contributions before closing with a summary of the thesis structure.

1.1. Background

Epilepsy is a neurological disorder marked by abnormal electrical discharges in the brain that can induce epileptic seizures; states of altered or diminished consciousness and involuntary body movements [Merriam-webster, 2020]. Epileptic seizures that involve body movement can induce significant injuries. Additionally, sudden unexpected death in epilepsy (SUDEP) occurs in 1 in every 1000 individuals with epilepsy per year [Epilepsysociety.org.uk, 2021].

Epileptic seizures can be triggered by stimuli, for example, flashing lights and sudden noises or fever, lack of sleep, tiredness, or stress and avoiding these triggers can help reduce seizures [Epilepsy Society, 2020]. Individuals with epilepsy are typically prescribed Anti-Epileptic Drugs (AEDs) however, more than 30% of individuals with epilepsy experience drug-resistant seizures [Sheng et al., 2018].

In clinical practice, electroencephalography (EEG) is used to diagnose and assess epileptic conditions, but EEG sensing is not practicable in everyday living, and research into wearable EEG monitoring [Casson, 2019] is at an early stage. Wearable monitoring devices for real-world seizure monitoring could benefit the hailing of timely care for individuals and also provide data to inform care and manage their treatment. Seizure monitoring devices based on consumer-grade health trackers are now becoming available. These devices typically incorporate electrodermal activity (EDA) sensors, tri-axis accelerometers, and skin temperature and optical heart rate sensors.

1.2. Research Motivation

The research reported in this thesis was motivated by the lack of evaluations of wearable epilepsy monitors reported in the literature. Although there are many studies evaluating novel and incremental approaches to epilepsy seizure detection, relatively few report evaluation data. In particular, there is a lack of research reporting evaluations based on real-world use of wearable seizure monitors, a lack of independent research evaluations, a lack of usability and qualitative evaluations, and a lack of rigour in data reporting.

1.3. Research Questions

The research questions that guided the research are as follows:

Q1. What evaluation evidence for available wearable epilepsy seizure monitors is reported in the academic literature?

Q1.1 What methods are used?

Q1.2 What evaluation data is reported?

Q2. How accurate and reliable are the wearable sensors used for epilepsy seizure monitoring?

Q3. To what extent do wearable user interface designs affect usability?

Q4. What are user and stakeholder opinions and experiences of wearable devices for epilepsy seizure monitoring?

1.4. Original Contributions

The original contribution of this thesis are as follows:

i. A systematic literature review demonstrating a lack of evaluations of available wearable seizure monitoring devices, a lack of details in reported studies, a lack of qualitative studies and a lack of evaluations based on real-world use of devices. The work was published in MDPI Electronics, 9(6), p.968, Evaluation of Wearable Electronics for Epilepsy: A Systematic Review. [Rukasha, T., Woolley, S., Kyriacou, T. and Collins, T, 2020].

ii. The first empirical device study contributes a heart rate performance evaluation of a data-streaming Empatica E4 device (a device based on the Empatica Embrace seizure monitor). The work was presented at the CHASE 2020: The Fifth IEEE/ACM Conference on Connected Health: Applications, Systems, and Engineering Technologies, December 2020, in Washington D.C., USA. Heart Rate Performance of a Medical-Grade Data Streaming Wearable Device [Rukasha, T., Woolley, S. and Collins, T, 2020].

iii. The second empirical study reports device interface evaluation results for the Empatica Embrace wrist-worn epileptic seizure monitor. The work was published in ACM, p.12-16, and presented at the UbiComp/ISWC '20: 2020 ACM International Joint Conference on Pervasive and Ubiquitous Computing Virtual Event in Mexico (pp. 110-114). Wearable Epilepsy Seizure Monitor User Interface Evaluation and Evaluation of the Empatica 'Embrace' Interface [Rukasha, T., Woolley, S. and Collins, T, 2020].

iv. The third study contributes an unpublished survey of stakeholder opinions and experiences of epilepsy seizure monitoring devices.

1.5. Structure of the thesis

The thesis is presented as follows:

Chapter 1 presents a summary of the research background and motivation, the research questions, and the original contribution.

Chapter 2 surveys the background literature relevant to epilepsy, wearable technology, seizure monitoring, and device evaluation.

Chapter 3 presents a systematic review of wearable electronics for epilepsy seizure detection.

Chapter 4 presents heart rate performance evaluations for the Empactica E4 data-streaming wearable device (a device based on the Empatica Embrace seizure monitor).

Chapter 5 presents the results of a 'guessability' experiment and a heuristic evaluation of the Empatica Embrace seizure monitor user interface.

Chapter 6 presents a survey of stakeholder opinions and experiences based on questionnaires for i) individuals with epilepsy, ii) carers, and iii) healthcare professionals. These questionnaires were made available via the Epilepsy Action charity website.

Chapter 7 presents the summary and conclusions from the research and provides future research ideas.

CHAPTER 2
BACKGROUND LITERATURE REVIEW

2.1. Introduction

This chapter surveys the background literature relevant to epilepsy, wearable technology, seizure monitoring, and device evaluation.

2.2. Epilepsy

Epilepsy is a neurological disorder affecting 50 million people worldwide [WHO. Epilepsy, 2019]. While seizures can be controlled with anti-epileptic drugs (AEDs), more than 30% of individuals with epilepsy have drug-resistant seizures [Sheng et al., 2018]. The timely detection of seizures is important in hailing assistance that can reduce the potential for injuries and SUDEP events [Van de Vel et al., 2016, Van Andel et al., 2016].

The onset of epileptic seizures is associated with autonomic changes, for example, flushing and sweating [Wannamaker et al., 1985, Baumgartner et al., 2001] that have the potential to be detected by temperature and EDA sensors. But seizure types and their presentation vary considerably. Convulsive seizures involve repeated involuntary contractions and relaxations of muscles that appear as repetitive, rhythmic, and shaking motions. This motor activity makes them potentially recognisable with accelerometer sensors. In contrast, nonconvulsive seizures can be difficult to detect and they can appear as simple absences or losses in muscle strength.

Seizure types and presentations is summarised below:

- Tonic Seizures (TS) are associated with contractions of the muscles.
- Clonic Seizures (CS) are associated with repeated contractions and relaxation of muscles.
- Tonic-Clonic Seizures (TCS) associated with stiffening followed by shaking.
- Myoclonic Seizures (MS) are associated with twitching regions of muscles.
- Atonic seizures are associated with loss of muscle strength.
- Absence seizures are associated with individuals appearing detached or inattentive.

The management and treatment of epilepsy relies on the assessment of seizure presentation and frequency, but patient self-reports and carer recall can be unreliable [Bruno et al., 2018] and patient seizure diaries can underestimate seizure frequency [Meritam et al., 2018, Fisher et al., 2012]. In a review of seizure reporting technologies Bidwell et al. [2015], highlighted "*a strong need for better distinguishing between patients exhibiting generalized and partial seizure types as well as achieving more accurate seizure counts*".

2.3. Epilepsy Triggers and Auras

Epilepsy **triggers** vary from person to person. For some people knowing their seizure triggers enables them to reduce the number of seizures they experience. Examples of seizure triggers

include tiredness and lack of sleep, stress, alcohol, not taking medication flashing lights, missing meals, and illnesses that raise body temperature [Epilepsy Society, 2020, Epilepsy Action, 2020].

An **aura** is a feeling/warning an individual with epilepsy may experience before a seizure. There are different types of auras (olfactory aura, visual aura, sound aura, somatosensory aura, temperature aura). An example of an aura is the smell of a putrid odour of burned or rotten fish [Acharya et al., 1998].

2.4. Anti-Epileptic Drugs (AEDs)

Anti-epileptic drugs (AEDs) are prescribed to individuals with epilepsy to control seizures and are effective for 70% of individuals [Sheng et al., 2018]. However, AEDs do not cure epilepsy and they cannot stop a seizure once it has started [Epilepsy Society, 2020]. Additionally, AEDs are associated with side effects including dizziness, drowsiness, fatigue, unsteady walking, slurred speech, nausea, and acne. Some neurological side effects are more serious than others, for example, "*permanent vision loss, anaemia, and liver failure and shedding of skin*" [Stacey et al., 2008]. Where AEDs do not stop seizures, other treatment can be attempted. For example, neurosurgery or medical-dietary treatment such as the ketogenic diet may be considered on their own or alongside AED treatment [Epilepsy Society, 2020].

2.5. Seizure Monitoring Devices

For epileptic individuals, the hailing of timely care with automated messages at seizure onset has the potential to reduce injuries and, potentially, save lives. Epilepsy seizure detection, patient monitoring and wearable technology are active areas of research.

2.5.1. Stakeholder Attitudes and Preferences

A qualitative study on patient views of seizure prediction devices conducted by Schulze-Bonhage et al. [2010], reported that 94% of their participants preferred wearable monitoring devices but were opposed to EEG or intracranial electrodes. Additionally, a study conducted by Hoppe et al. [2015] exploring attitudes and preferences about future devices for seizure detection, reported 90% acceptability for wrist-worn devices as compared to 68% acceptability for "*intelligent clothes*" and 30% acceptability for "*scalp electrodes"*. Similarly, a qualitative study on multimodal sensor devices conducted by Simblett et al. [2020] reported wearable sensors to be preferable to EEG sensors.

Individuals with epilepsy and carers may be willing to use wearable devices for continuous long-term monitoring [Bruno et al., 2020], but they have concerns about device appearance and stigmatisation, and this influences device acceptance [Beck et al., 2020]. However, individuals with epilepsy are "*willing to use wearables based on the hope that the technology will validate their seizures*" in everyday living at home without the need for hospitalization [Beck et al., 2020].

A qualitative study on the needs and preferences of patients and caregivers conducted by Herrera-Fortin et al. [2021], reported that 82% of caregivers considered using wearable devices for continuous patient seizure monitoring, and over 50% of individuals with epilepsy and carers were willing to use a wrist-worn monitor continuously. A few individuals with epilepsy and carers were not so willing to wear smart clothing, a band worn around the torso, a band worn around the arm, or a leg, headband/hat, camera, microphone, and electrode glued to the skin [Herrera-Fortin et al., 2021].

2.5.2. Consumer Epilepsy Monitors

There has been long-standing interest from individuals and carers in consumer-grade at-home devices that can detect and monitor epilepsy seizures during the day and night. Figure 2.1 shows examples of Google shopping results for epilepsy seizure monitoring devices, for example, mattress sensors (which, as non-wearable sensors, are beyond the scope of this research), with prices ranging from less than £200 to more than £1000. There are also some wearable devices designed to detect seizures and alert caregivers.

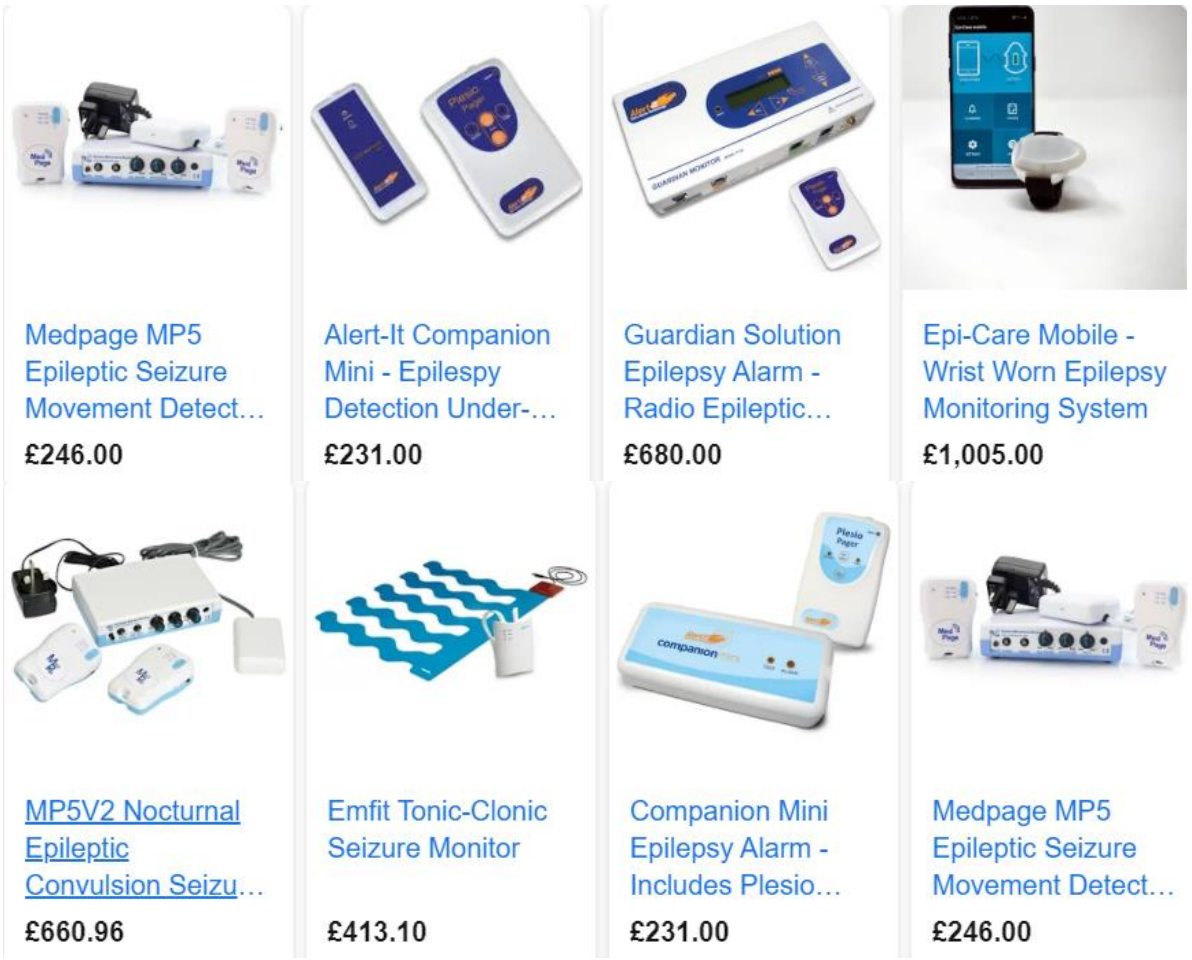


Figure 2.1: Examples of Google shopping results for epilepsy seizure monitoring devices and prices from May 2021.

2.5.3. Wearable Seizure Sensors, Devices and Challenges

Wrist-worn wearable health trackers have increased in popularity in the last decade. For example, Fitbit and Garmin devices are popular for activity tracking, step counting, and heart rate monitoring. Data-streaming versions of these types of wrist-worn devices are also available to researchers, for example, the Empatica E4 wristband and the Biovotion (now Biofourmis) Everion. Like the consumer-grade devices, these devices typically incorporate temperature sensors, conductivity sensors for electrodermal activity (EDA), three-axis accelerometers, and LEDs and photodiodes for photoplethysmography (PPG) pulse wave detection. Wearable epilepsy seizure monitors based on wrist- and arm-worn sensor configurations, as illustrated in Figure 2.2, are now available to detect and report seizures and alert carers. These devices also typically incorporate accelerometers and EDA, heart rate and temperature sensors and, sometimes, gyroscopes and GPS receivers to detect rotational movement and location, respectively.

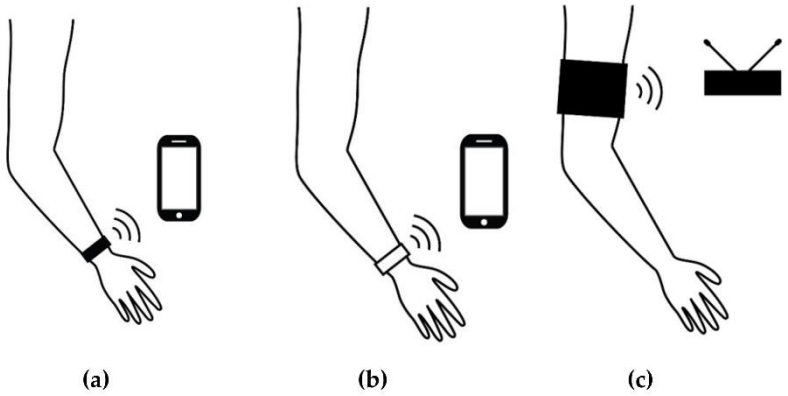


Figure 2.2: Wearables and apps for epilepsy seizure detection.

(a) Wrist-worn sensing device and companion app.
(b) App using sensed data from a compatible consumer wrist-worn tracker.
(c) Non-wrist wearable with a base station.

Signals detected from sensors can be used to detect seizures and 'preictal' periods before seizures and can also be used to locate, report, and log seizure events. However, it is difficult to reliably detect seizures in everyday life [Johansson et al., 2018], because it is very difficult to disambiguate seizures from the many normal (seizure-like) rhythmic movements of everyday living, such as teeth brushing. These everyday seizure-like movements can result in false alarms that may require repeated and prompt cancellations throughout the day, distracting the wearer and, potentially, disincentivising use.

Epilepsy seizures such as absence seizures and complex partial seizures (which can appear similar to absence seizures but affect only one brain lobe) are especially challenging to detect. In a study conducted by Elger & Hoppe [2018] on diagnostic challenges in epilepsy, the authors reported that all available techniques for monitoring seizures with subtle motor signs have limitations. They observed that the automatic detection of seizures such as complex partial seizures *"will require multimodal approaches that combine the measurement of ictal*

autonomic alterations (e.g., heart rate) and of characteristic movement patterns (e.g., accelerometery)".

2.5.4. Available Wearable Seizure Monitors

Table 2.1 summarises available wearable seizure-detecting devices, for example, the Brio epilepsy monitor detects heart rate changes (at the time of writing, £499) [Epilepsy Alarms, 2019], Epilert (price on inquiry) [Epilert.io, 2020], PulseGuard (subscriptions from £250 and £675) [Alert-it Care Alarm Technology, 2019], and the Open Seizure Detector App (free) [Open Seizure Detector, 2021] for use with specified consumer-grade wearables such as the Garmin smartwatch. Wearable seizure-detecting devices that are available also include the Embrace seizure-detecting wrist-worn sensor, developed by Empatica [Empatica Inc, 2020]. Embrace is a maturing product that is sold with a monthly alert service subscription (subscriptions, at the time of writing, are £9.90 – £44.90 per month). Empatica also markets an 'E4' (previously 'E3') data-streaming version of their Embrace device that provides researchers with access to the raw sensor data that can be used to test seizure-detecting algorithms. The Empatica E4, at the time of writing, is an FDA-approved class 2a medical-grade device which, Empatica reports, has been used in 'over 1000 studies and trials' [Empatica Inc. 2020]. It is a data streaming device similar to the Embrace, comprising PPG, temperature, EDA, and accelerometer sensors, and is used by researchers for physiological data acquisition for a variety of healthcare applications, as well as for epileptic seizure detection research.

Also, as shown in Table 2.1, other devices reported in the literature include the Epi-Care free [Danish Care Technology, 2020], NightWatch [LivAssured, B.V (NightWatch), 2020], and SmartWatch [Smart Monitor (SmartWatch Inspyre), 2020]. Epi-Care free is a wrist-worn (or ankle-worn) sensor incorporating an accelerometer, gyroscope, and GPS to detect seizure motor activity and send alerts to family members or telecare services (subscriptions, at the time of writing, are £1399 and £1519 per year). The NightWatch sensor is an armband wearable that senses pulse and activity to detect and report nocturnal seizures, the device was not available to purchase, it was just for people to use and provide feedback, now it is available for purchase through the Epilepsy Alarms webpage (at the time of writing, are £1249). The Smart Monitor's SmartWatch is a seizure detector that makes use of wearable heart rate and activity data (originally from prototype wearable devices and now the app, named 'Inspyre', can access data from compatible Apple and Samsung Galaxy and Gear watches) and summon help to the GPS location of the wearer (subscriptions, at the time of writing, are from £9.99 to £29.99 per month).

Table 2.1: Wearable epilepsy detection devices/apps.

Wearable device	Sensors	Manufacturer/ Supplier	Software/ Applications	Hardware	Device Price Examples
E4/ Embrace 2	PPG Temperature EDA Accelerometer Gyroscope (Embrace 2)	Empatica Inc./Srl, USA/ Italy)	Alert App Mate App	Wristband Bluetooth connection to a smartphone Changing dock USB Cable	**E4** $1690. **Embrace 2** $249
Smart Monitor (SmartWatch Inspyre App)	3-axis Accelerometer Heart rate	Smart Monitor, USA	Smart monitor App Web Portal	Wristband Changing dock Apple or Android Phone	**Samsung Frontier** £279.99–£301.49. **Samsung Galaxy Watch Active** £219.99–£241.49. **Samsung Gear Sport** £249.99–£271.49. **Pulse Companion** £599.00
Epi-Care free	3-axis accelerometer	Danish Care Technology ApS, Denmark	Epi-Care App.	Wristband Smartphone Pager	**Epi-Care mobile.** £1519. **Epi-Care standard** £1399
PulseGuard	Accelerometer Heart rate	Alert-it Care Alarm Technology, UK	Sends alerts to a pager.	Wristband Pager iPad	**PulseGuard Mk-II Package** £675.00. **PulseGuard Mk-II Package** £25.00
Brio	Heart rate	Epilepsy Alarms, UK		Wristband	£449
NightWatch	PPG Accelerometer	LivAssured B.V., Netherlands/	Night watch online portal	Armband	£1249
Epilert	Heart rate Temperature Accelerometer EDA	Epilert USA	Epilert App	Wristband Smartphone	Price on enquiry
Open Seizure Detector (App)	Accelerometer	Open Seizure Detector	Open Seizure Detector phone app	Wristband Apple or Android Phone	Open-source

2.6. Wearable Sensing Performance

Optical heart rate acquisitions from wrist-worn PPG sensors are known to lack reliability during periods of activity due to the interfering effects of motion artefacts [Oniani et al., 2018, Couceiro et al., 2014]. But despite accuracy concerns, the opportunity to achieve continuous, unobtrusive, low-cost patient monitoring and to incentivize patients toward positive health behaviours has resulted in many clinical research and healthcare applications of consumer-grade wearables, despite manufacturers not making no medical device claims [Oniani et al., 2018].

Bent et al. [2020] conducted a study on "*investigating sources of inaccuracy in wearable optical heart rate sensors*" and reported wearable heart rate recording accuracies of consumer-grade (Fitbit Charge 2, Apple Watch 4, Garmin Vivosmart 3, and Xiaomi Mi Band)

and ‘research-grade’ data-streaming wearables (Everion and Empatica E4) and observed that “*absolute error during activity was, on average, 30% higher than during rest*” and “*Consumer-grade wearables were found to be more accurate than research-grade wearables at rest*.” Walking activity was reported to result in heart rate estimates above the true heart rate and typing activity was reported to result in heart rate estimates lower than the true heart rate. Wearing devices too tightly was also reported to affect the performance.

Although not directly within the scope of this research it is interesting that the work of Bent et al. [2020] has been recently criticised by Colvonen [2021]. Bent et al. [2020] had reported that *“Overall, we did not find statistically significant differences in HR or HRV accuracy across skin tones.”* Colvonen criticised the study methodology including the small number of participants and the use of a subjective skin tone scale, and commented that the finding is in contrast to previously reported studies finding wearables using green light technology had larger errors rates in tracking heart rate and energy expenditure for individuals with darker skin tones, especially if exercising stating that *“I am concerned their findings on skin tone are not accurate and will be used to limit or misrepresent future research on inaccuracies of skin tone in wearable devices”*. Concerns about technology performances for persons of colour have also been reported by Hankerson et al. [2016].

Data Missingness

Data missingness occurs when devices fail to log sensed data. Missingness has been reported to be caused by ‘technical errors’ (for example, signal reception failures) and human factors (for example, patients shifting the device because of discomfort) [Ramgopal et al., 2014, Leijten., 2018, Johansson et al., 2018]. Missingness is a problem that is increasingly recognised, but few studies quantify the missingness [Collins et al., 2021].

Missingness is calculated from actual samples and expected samples. The calculation used to determine missingness (%) is shown below.

$$\text{Missingness \%} = 100 - \text{Actual \# Samples}/\text{Expected \# Samples} * 100 \qquad (1)$$

Bent et al [2020], reported the heart rate *missingness* for the Fitbit Charge 2, Apple Watch 4, and Xiaomi Mi Band 3. Missingness was “*mostly unchanged between rest and activity for the Apple Watch*”. During physical activity, missingness was highest for the Fitbit Charge 2 (10.4%) and lowest for the Xiaomi Mi Band 3 (-14.2% which was negative because samples exceeded the expected number for the specified sampling rate). At rest, the missingness was highest for the Fitbit Charge 2 (18.7%) and lowest for the Apple Watch 4 (2.7%). Epilepsy Seizure Detection Performance Metrics

Figure 2.2 summarises seizure detections in terms of true/false and positive/negative outcomes and the related sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV), and the associated formulae, including the false alarm rate (FAR), is summarised in Equations (1) – (6). PPV is also known as precision.

Sensitivity = TP/ (FN + TP) (2)

Specificity = TN/ (TN + FP) (3)

Positive Predictive Value (PPV) = TP/ (TP + FP) (4)

Negative Predictive Value (NPV) = TN/ (FN + TN) (5)

Accuracy = (TP + TN)/ (TP + TN + FP + FN) (6)

False Alarm Probability = FP/day (7)

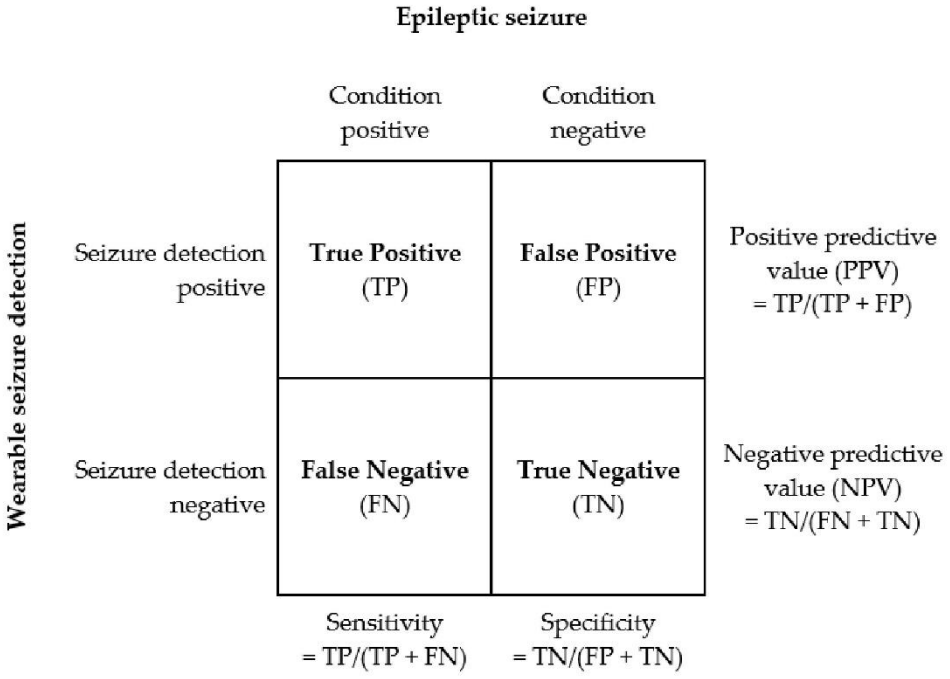


Figure 2.3: Seizure detection performance metrics.

2.7. Wearable Interface Design

Clear communication of detected seizures is important. A correctly interpreted wearable seizure monitor display could provide important information to individuals and carers about possible seizures, and also remove some of the burden and worries about seizure reporting.

Wrist-worn devices have small screen sizes which limits the amount of information that can be displayed. Human-Computer Interaction (HCI) researchers have suggested some ways to improve the user experience of wrist-worn devices, for example.

A study conducted on interface design by Motti et al. [2016], reported "*current work either lack user studies or are limited to user tests in controlled environments usually conducted with a small sample of participants in a laboratory setting. By being executed in controlled environments, little is known about the user interaction in the wild*." The authors also reported that participants concern such about device battery power (low durability, charging, and problems during setup) and overall quality (e.g., fragile, not sturdy, bulky).

A qualitative analysis of epilepsy patient opinions of wearables conducted by Simblett et al. [2020] reported that for the devices to be widely adopted, they must be acceptable and easy to use for patients. The presence of wires, bulky size, discomfort, and need for support, make devices less appealing with opinions strongly influenced by how visible the device was, whilst wearing it in public.

2.8. Heuristic Evaluation

Heuristic evaluation is a usability inspection method where expert evaluations examine a user interface, heuristics are suitable for evaluating and examining most user interfaces for design problems, by judging their compliance with a set of principles [Hermawati et al., 2016, Aitta et al., 2008].

Jakob Nielsen's ten usability heuristics [Nielsen et al., 1994] are a set of established and popular heuristics consisting of 1) visibility of system status, 2) match between system and the real world, 3) user control and freedom, 4) consistency and standards, 5) error prevention, 6) recognition rather than recall, 7) flexibility and efficiency of use, 8) aesthetic and minimalist design, 9) help users recognize, diagnose, and recover from error, and 10) help and documentation.

2.9. Thematic Analysis

Thematic analysis is a common form of qualitative analysis. The processes are summarised in Table 2.2 which shows the phases of thematic analysis [Braun, V. and Clarke, V., 2006].

Table 2.2: Phases of thematic analysis [Braun, V. and Clarke, V., 2006].

Phase	Description of the process
1. Familiarising	Transcribing data, reading and re-reading the data, noting down initial ideas.
2. Generating	Coding interesting features of the data in a systematic fashion across the entire data set, collating data relevant to each code.
3. Searching	Collating codes into potential themes, gathering all data relevant to each potential theme.
4. Reviewing	Checking if the themes work with the coded extracts and the entire data set, generating a thematic ‘map’ of the analysis.
5. Defining and naming themes	Ongoing analysis to refine the specifics of each theme, and the overall story the analysis tells, generating clear definitions and names for each theme
6. Producing	The final opportunity for analysis. Selection of vivid, compelling extract examples, the final analysis of selected extracts, relating of the analysis to the research question and literature, producing a scholarly report of the analysis.

NVivo is a software application for the coding and thematic analysis of qualitative research data [Qualitative Data Analysis Software | NVivo. 2021]. It is popularly used by qualitative researchers, including in health and care qualitative analyses. For example, NVivo has been

used in a qualitative study undertaken to provide a detailed account of individuals view about emergency care, conducted by [McKinlay et al., 2020], for data management and two separate studies conducted by Thompson et al. [2020] and Mathieson et al. [2020], to assess patients views on the care services, device design preference, and usability. NVivo was used in this research as a tool to analyse the data collected from the questionnaires to organize and analyse.

2.10. Summary

This chapter summarised the background literature relevant to wearable epilepsy monitoring devices. The next chapter is a systematic literature review of the evaluation of wearable electronics for epilepsy.

CHAPTER 3
SYSTEMATIC LITERATURE REVIEW

3.1. Introduction

This chapter comprises a systematic literature review of the Evaluation of Wearable Electronics for Epilepsy. It addresses the research question RQ1: What evaluation evidence for available wearable epilepsy seizure monitors is reported in the academic literature? and the sub-questions: RQ1.1: What methods are used? RQ1.2: What evaluation data is reported?

A systematic literature review is a methodologically rigorous review and synthesis of research literature that incorporates a systematic and repeatable search strategy and the application of inclusion and exclusion criteria such as year of publication and paper title (Kitchenham et al., 2009).

A systematic search strategy aims to identify all relevant literature with search strings constructed as below:

- Identify major terms and synonyms by terms that are used in the research questions.
- Identify different spellings and include any word variation of each search term.
- Use the Boolean operator "OR" to link alternate words and synonyms.
- Use the Boolean operator "AND" to link major terms.

This chapter contributes a systematic review of literature from 1 January 2005 to 31 October 2019 that evaluates available wearable epilepsy monitoring devices. The primary studies comprising evaluations were collated according to preferred reporting items for systematic reviews and meta-analyses (PRISMA) guidelines. This work was published in a 2020 MDPI Electronics Journal, paper entitled Evaluation of Wearable Electronics for Epilepsy: A Systematic Review (Rukasha et al., 2020).

3.2. Methodology

A systematic review of primary studies evaluating available wearable seizure-detecting devices spanning almost fifteen years (from 1 January 2005 to 31 October 2019, when the review was initiated) was conducted with an evidence-based methodology [Kitchenham et al., 2004, Kitchenham et al., 2015] and following PRISMA guidelines [Moher et al., 2009].

3.2.1. Search Strategy

Technology and medical digital libraries were used to identify primary studies, digital libraries, for example, Association for Computing Machinery (ACM), Institute of Electrical and Electronics Engineers (IEEE) Xplore Digital Library, Medline, ScienceDirect, and Wiley Online Library.

The keyword search string below was evolved to identify primary studies relevant to wearable epilepsy sensing devices:

> *(“wearable” OR “smart watch” OR “smartwatch” OR “wrist-worn” OR “wrist worn” OR “wristworn” OR “wristband” OR “armband”) AND (“epileptic” OR “epilepsy”).*

3.2.2. Eligibility Criteria and Selection

Studies were eligible for selection if they met all three of the following inclusion criteria:

i. Primary studies in peer-reviewed literature.
ii. Studies where the main theme is evaluation of available wearable electronics for epilepsy seizure detection.
iii. Studies reporting quantitative and/or qualitative assessment data.

The relevant papers were assessed for quality according to screening criteria including rigour, credibility, and relevance [Dybå et al., 2008].

Papers were identified by using the search string and were filtered according to the eligibility criteria in a phased inspection process. First paper titles were inspected, and duplicates removed. For example, from the titles alone, prospective studies and review papers could be identified and excluded. The abstracts of the remaining papers were inspected and checked against the inclusion criteria. Finally, the remaining papers were inspected in detail to identify the final selection.

3.3. Results

Following the PRISMA systematic review guidance outlined in Figure 3.1, a total of 12 papers satisfied the eligibility criteria. A second researcher checked the screening and eligibility of papers, and a third researcher moderated the results.

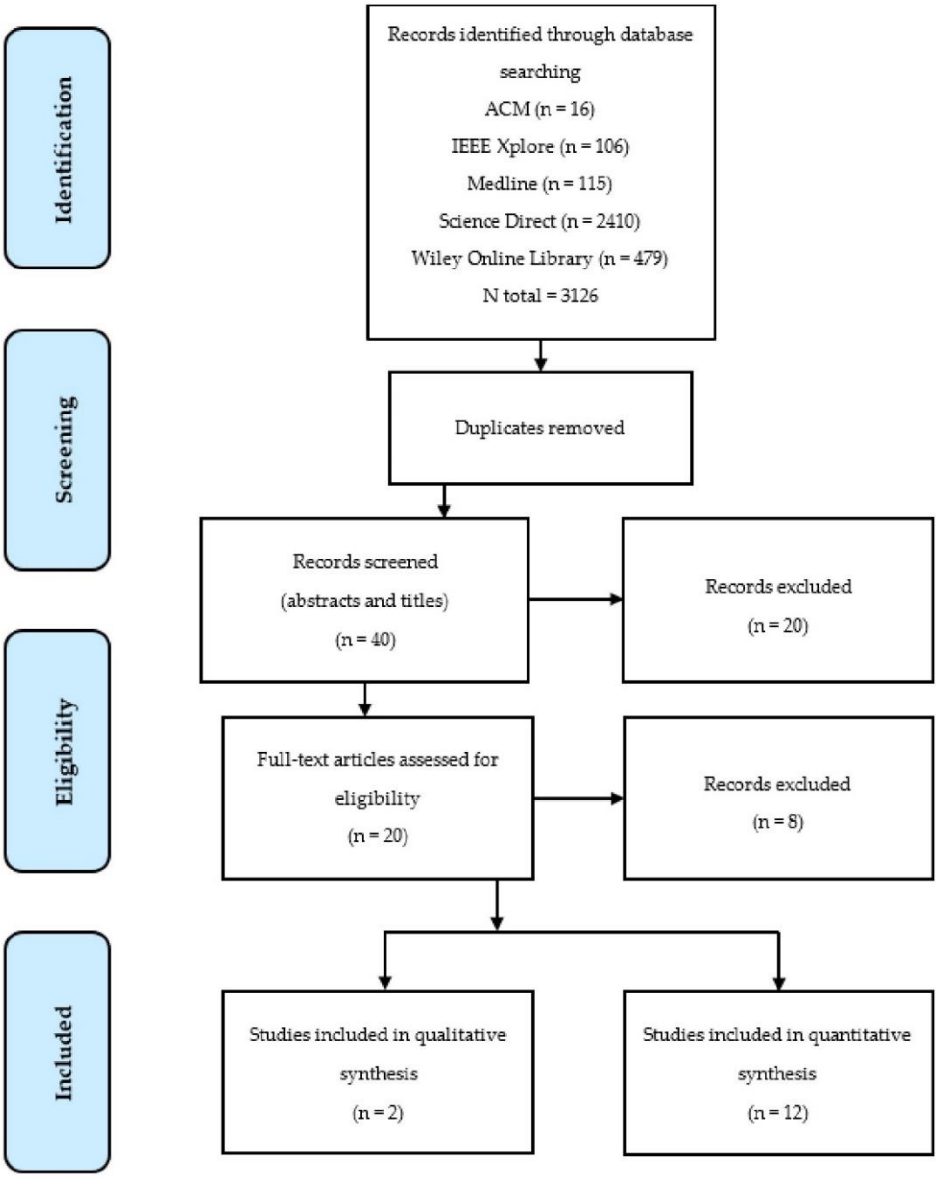


Figure 3.1: Flow diagram of the systematic review according to preferred reporting items for systematic reviews and meta-analyses (PRISMA) guidelines.

As summarised in Table 3.1, all 12 studies reported qualitative assessments (8 conducted in clinical settings and 4 in free-living conditions). Two of the 12 studies also reported qualitative assessments. While the search process did initially identify qualitative papers on wearable devices for epilepsy, some of these studies [e.g., Kramer et al., 2011, Ozanne et al., 2017] were assessments of perceptions about the potential of such devices rather than assessments of actual use. No studies reported solely qualitative assessment data for the real use of available wearable devices for seizure detection.

Table 3.1: Overview of studies and participant numbers.

No. Studies = **14**		
No. Quantitative = **12**		**No. Qualitative** = **2**
Clinical setting = 8	Free-living = 4	-
No. participants/patients = 341	No. participants/patients = 169	No. participants/patients = 104
TOTAL = 510		TOTAL = 104

3.3.1. Quantitative Studies

3.3.1.1. Clinical Setting

Eight of the 12 quantitative studies were conducted in clinical settings. All eight were studies with data gathered from epileptic inpatients and outpatients; none were two-arm or controlled studies with healthy participants. Most studies compared recorded device data with other clinical reference recordings, including EEG, vEEG, electromyography (EMG), and ECG. The studies are summarised in Table 3.2 in terms of the devices used, the number of participants, the number of seizures detected (where specified) and the study duration. As shown in the summary in Table 3.2, four of the studies used Empatica E3, E4, and Embrace devices, three used Smart Monitor's evolving SmartWatch device, and one used the Epi-Care free device. The number of patient participants varied from 3 to 135. A study [Al-Bakri et al., 2018] with three participants selected 1 h recorded segments rather than continuous recordings. Otherwise, observation durations varied within studies [Al-Bakri et al., 2018, Velez et al., 2016, Beniczky et al., 2013] as well as between studies from 17 h to 487 days, and two studies [Regalia et al., 2019, Patterson et al., 2015] did not report durations. The total number of seizures detected in the studies varied from 7 and 55 and, across all studies, a total of 226 seizures were reported as detected. Only one study [Al-Bakri et al., 2018] did not report the number of detected seizures.

Table 3.2: Clinical setting studies with the number of seizures and their duration.

Clinical Settings				
Study	**Device**	**No. Participants**	**No. Seizures Detected**	**Duration**
Heldberg et al., 2015	E3	8	55	23 days
Al-Bakri et al., 2018	E4	3	unspecified	4–5 days (1 h intervals)
Vandecasteele et al., 2017	E4	11	47	29 days
Regalia et al., 2019	Embrace and E4	135	40	unspecified
Lockman et al., 2011	SmartWatch	40	7	487 days
Patterson et al., 2015	SmartWatch	41	30	unspecified
Velez et al., 2016	SmartWatch	30	12	1–9 days
Beniczky et al., 2013	Epi-Care free	73	35	17–171 hours
-	-	TOTAL = 341	TOTAL = 226	-

Table 3.3 summarises the performance assessments of the studies. The reporting of performance metrics was variable and sparse across most of the studies. For example, false alarm rates for only three studies could be identified. The studies using the Empatica E3 and E4 implemented machine learning detection methods (kNN: k-nearest neighbour; RF: random forest; NB: naïve Bayes; SVM: support vector machine). Regalia et al. [2019] made a brief reference to previously unpublished assessments with 135 patients and 22 seizures with 100% sensitivity and a FAR of 0.42 per day for a “fixed and frozen” algorithm. No methodology, sensitivity, or other assessment information was provided, and the paper largely focused on compiling and comparing other Empatica wristband performance indicators. Heldberg et al. [2015] reported the sensitivity and specificity for two different classifiers. Vandecasteele et al. [2017] compared the performance of SVM classifiers on hospital ECG with wearable ECG and E4 PPG recordings. PPG motion artefacts (which would have been largely induced by the seizures themselves) made more than half of the seizures undetectable via this approach and resulted in a poor sensitivity of 32%. The studies encompassed different seizure types but with TCS and ‘motor’ seizures often included. Dramatically different performance results were observed. For example, sensitivities of 100% and 16% were reported by Regalia et al. [2019] and Patterson et al. [2015], respectively. Notably, the latter paper [Patterson et al., 2015] comprised many (undetected) nonmotor seizures.

The levels of patient activity and any movement constraints were not generally explicitly reported and, in any case, are difficult to convey. However, in the clinical setting, worn sensors usually benefit from reduced interference from activities of daily living. For example, the good wearable performance for the small study [Al-Bakri et al., 2018] was achieved from recordings taken simultaneously with EEGs, i.e., when patients would be inactive.

Table 3.3: Performance assessments in clinical settings.

Authors/ No. Participants	Device	Seizure	Sensitivity	Specificity	FAR	PPV/ R	Detection Latency
Heldberg et al., 2015 8 participants	E3	PNMS, PMS	89.1% (kNN) 87.3% (RF)	93.1% (kNN) 95.2% (RF)	-	-	-
Al-Bakri et al., 2018 3 participants	E4	-	84% (NB) (preictal sleep) 78% (NB) (preictal wake)	79% (NB) (preictal sleep) 80% (NB) (preictal wake)	-	-	-
Vandecasteele et al., 2017 11 participants	E4 (PPG)	TLS, CPS	32% (SVM)	-	1.80 per hour	1.43 %	-
Regalia et al., 2019 135 participants	E4 and Embrace	GTC	100%	-	0.42 per day	-	-
Lockman et al., 2011 40 participants	SmartWatch	TCS	87.5%	-	-	-	-
Patterson et al., 2015 41 participants	SmartWatch	TS, GTC, MS, MTS, PS	16%	-	-	-	-
Velez et al., 2016 30 participants	SmartWatch	TCS	92.3%	-	-	-	-
Beniczky et al., 2013 73 participants	Epi-Care free	TCS	90%	-	0.2 per day	-	55 s

Seizure Abbreviations: CPS: complex partial seizures, **GTC:** generalized tonic-clonic, **MS:** myoclonic seizures, **MTS:** myoclonic-tonic seizures, **PMS:** predominantly motor seizures, **PNMS:** predominantly nonmotor seizures, **PS:** partial-onset seizures, **TCS:** tonic-clonic seizures, **TLS:** temporal lobe seizures, **TS:** tonic seizures. **Classifier Abbreviations: kNN:** k-nearest neighbour; **NB:** naïve Bayes; **RF:** random forest; **SVM:** support vector machine. **Other Abbreviations: FAR:** False Alarm Rate; **PPV/R:** Positive Predictive Value/Rate.

Smart Monitor's SmartWatch was used in three of the eight clinical assessments. Patterson et al. [2015] reported the lowest sensitivity 16% overall: 31% for GTCS and 0% for MS in a study of 41 patients aged 5–41 years. Lockman et al. [2011], did not record false positives "*because these are well known*" and did report 204 false alarm occurrences in their SmartWatch study with 40 patients between 'March 2009 and June 2010' but did not specify a FAR or confirm the duration of actual usage within the study period. Velez et al. [2016] referred to 81 false alarms but also did not specify a FAR (and one cannot be estimated because of the varying durations of use from 1–9 days). Beniczky et al. [2013] reported a sensitivity of 90% and a FAR of 0.2 per day in a study with 73 participants with GTC seizures who were monitored for 17–171 hours. An average detection latency of 55s was reported.

3.3.1.2. Free-Living Environment

Four of the 12 quantitative studies report free-living environment evaluations. These studies are summarised in Tables 3.4 and 3.5 and comprise 169 participants and 850 seizures.

Table 3.4: Free-living studies with the number of seizures and duration.

Free-Living Settings				
References	**Device**	**Participants**	**No. Seizures Detected**	**Duration**
Onorati et al., 2017	E3 and E4	69	32	247 days
Van de Vel et al., 2014	Epi-Care free	1	9	19 nights
Meritam et al., 2018	Epi-Care free	71	-	15 months median (24 days to 6 years)
Arends et al., 2018	NightWatch	28	809	1826 nights
-	-	TOTAL = 169	TOTAL = 850	-

Table 3.5: Performance metrics in a free-living setting.

Study/No. of Participants	Device	Seizure	Sensitivity	Specificity	FAR	PPV/R	Detection Latency
Onorati et al., 2017 69 participants	E3 and E4	BTCS, FTC	83.64% (Classifier I) 92.73% (Classifier II) 94.55% (Classifier III)	-	0.29 per day (Classifier I) 0.21 per day (Classifier II) 0.20 per day (Classifier III)	-	31.2 s (Classifier I) 29.3 s (Classifier II) 29.3 s (Classifier III)
Van de Vel et al., 2014 1 participant	Epi-Care free	TS, CS, TCS	41%	-	0.05 per night	-	-
Meritam et al., 2018 71 participants	Epi-Care free	BTCS	90% BTCS median	-	0.1 per day median	-	-
Arends et al., 2018 28 participants	NightWatch	MS, TC, TCS, Hyperkinetic	86% median	-	0.25 per night median	49% median	-

Seizure Abbreviations: BTCS: bilateral tonic-clonic seizures, **CS:** clonic seizures, **FTC:** focal tonic-clonic, **FS:** focal seizures, **MS**: myoclonic seizures, **TCS**: tonic-clonic seizures, **TS:** tonic seizures. **Other Abbreviations: FAR:** false alarm rate, **PPV/R:** positive predictive value/rate.

Onorati et al. [2017] reported a range of classifier performances for the E3 and E4 with sensitivities from 83.64% to 94.55% and FARs of between 0.2 and 0.29 per day. Van de Vel et al. [2014] and Meritam et al. [2018] both reported Epi-Care free evaluations with 71 and 1 participants, respectively. For the 71 patients, a sensitivity of 90% and an FAR of 0.1 per day were reported. Arends et al. [2018] reported a sensitivity of 86% for the NightWatch arm-worn nocturnal seizure monitor, an FAR of 0.25 per night, and a PPV of 49%.

3.3.2. Qualitative Studies

Only two studies provided qualitative assessment data for device evaluations. Both studies also reported quantitative evaluations that were included in the earlier sections. Summaries of patient and stakeholder views and observations are listed in Table 3.6.

Table 3.6: Qualitative studies.

Study/ No. Participants	**Stakeholder Views and Observations**	
	Benefits	**Barriers/Concerns**
Arends et al., 2018 33 qualitative carer respondents	• Timely responses to urgent situations. • Offers carers more freedom. • Helps carers give better care. • More autonomy for individuals with epilepsy.	• Skin irritation. • Armband not fitting properly. • Poor signal reception.
Meritam et al., 2018 71 qualitative patient respondents	• Good overall device satisfaction (5.5/7) • Easy to use. • Clear alarm signals. • Timely alerts enabled a 40% reduction in injuries. • Feeling of security and a decreased psychological burden.	• High false alarm rate. • Skin irritation or discomfort. • Low effectiveness for detecting seizures. • Unstable sensor communication and interference issues. • Limited battery life and lack of water resistance. • 10% of patients stopped using the device for device-related reasons.

Arends et al. [2018] evaluated the NightWatch night-time upper arm seizure monitor using a multifactor questionnaire with 33 carer stakeholder respondents comprising 30 nurses, 2 parent carers, and 1 ‘not specified’. Meritam et al. [2018] performed a qualitative evaluation of the Epi-Care free monitor with 71 patient participants aged 7–72 years using a post-study

systems usability questionnaire (PSSUQ) comprising 13 questions and requiring a 1 – 7 Likert-scale responses from participants on aspects on monitor usability. Both studies identified concerns in terms of (a) physical intrusion, e.g., discomfort or irritation, and (b) performance concerns, e.g., signal reception or detection failures. Participants in both studies agreed with the benefits of the monitors in terms of the potential for improved responses to seizure events and the potential for improved care outcomes.

3.3.3. Data Failures—Missing and Unusable Data

In addition to missed seizures caused by algorithms failing to detect seizures in acquired data, seizures can also be missed when data are not recorded, not received, or not usable (for example, if they are so corrupted as to be unusable). There were limited discussions of data failures or the "missingness" of data in the studies. Examples are summarised in Table 3.7.

Table 3.7: Missing data.

Studies	Device	Participants	Data Failures	Reasons
Vandecasteele et al., 2017	E4	11	PPG motion artefacts	Motion artefacts "PPG signal was drastically affected ... 55% of the seizures could not be detected because of motion artefacts ... no reliable Heart rate could be extracted"
Velez et al., 2016	SmartWatch	30	3 occasions	2× wireless communication failures and 1× device not worn during a seizure
Beniczky et al., 2013	Epi-Care free	73	"15 times"	"Device deficiencies" (including 2× "technical error", 11×" battery failure")

3.4. Discussion and Conclusion

This review aimed to collate and analyse qualitative and quantitative assessments of wearable electronics for epilepsy seizure monitoring that are available to individuals and researchers. Although there are over 3000 works in the literature discussing, proposing, and evaluating novel and incremental approaches to epilepsy seizure detection, there are very few that report evaluation data and, as observed previously [Jory et al., 2016], none that report comparative results of large-scale studies. In terms of the Oxford Centre for Evidence-Based Medicine 2011 Levels of Evidence 1–5 scale [OCEBM Levels of Evidence Working Group.,

2020], none of the reviewed studies would qualify as the highest level of evidence (Level 1), and most would rank as Level 3 or below.

The diversity of the reviewed studies in terms of motor and nonmotor seizure types and levels of patient activity/freedom of movement is matched by the diversity of results including, for example, very high and very low sensitivities. Across the reviewed works there was a lack of full detail, including details required to establish important metrics such as sensitivity, specificity and FARs. Given the importance of timely alerts for seizure detection and the anxiety and alarm fatigue associated with high FARs, both FAR and detection latency, should be reported. Details important to reproducibility should also be reported, for example, device firmware, and app version numbers [Woolley et al., 2019]. Ideally, the frequency, duration, impact, and cause of all data recording failures (resulting in the 'missingness' of data) would also be provided in all performance assessment studies [Collins et al., 2021].

The review highlights that there are opportunities for improvements in device performance and, ideally, monitors would be sensitive across the range of seizure types whilst maintaining acceptably low false alarm rates. Ideally, future seizure sensing systems and algorithms would benefit from detailed qualitative and quantitative assessments of their performance. However, assessing technology in critical health scenarios is not easy. Clinical assessments are onerous and resource-expensive undertakings, and their timescales are at odds with the iterative updating of digital technologies. Free-living assessments require investments in time and resources, and they present additional difficulties in terms of truth data.

Since the period of the review (1 January 2005 to 31 October 2019) other works have been published, for example, a comparison of wearable seizure detection devices study conducted by Verdru et al. [2020] suggests that wearable devices that combine multimodal measurements may give the most accurate detection of TCS. Authors in the same study reviewed 16 wearable seizure detection devices and "*observed a significant inconsistency in the description of performance measures*". Bruno et al. [2020] conducted a study and reported that device satisfaction is affected by the seizure detection performance, device appearance and comfort of use.

In the next chapter further investigation on medical-grade data streaming wearable device is carried out by evaluating the heart rate performance of the Empatica E4 wrist-worn sensor device for detecting epileptic seizures.

CHAPTER 4
HEART RATE PERFORMANCE OF A MEDICAL GRADE DATA STREAMING WEARABLE DEVICE

4.1. Introduction

This chapter addresses RQ2: How accurate and reliable are the wearable sensors used for epilepsy seizure monitoring? It presents results from a study that acquired participant heart rates during treadmill walking and 12-hrs of everyday living, comparing estimates from the Empatica E4 data streaming wearable with a Polar H10 ECG chest strap sensor. Heart rate (RR interval) performance of the Polar H10 chest strap has been validated in previous research [Gilgen-Ammann et al., 2019] and the device has been used as a heart rate reference in studies similar to this, for example, studies conducted by Müller et al. [2019] and Weaver et al. [2019].

Even in well-resourced clinical studies, it is challenging to test the performance of seizure detecting wearables because it requires the recruitment and observation of epileptic individuals in laboratory environments where EEG and/or other truth data can be achieved. But seizures are intermittent and should not be provoked, so it may take very many hours of clinical resources to capture enough seizures for device evaluation. An alternative to seizure-monitoring evaluation is the evaluation of sensing performance. If wearable sensing devices are to perform well at detecting and monitoring seizures, they should perform well at recording their sensed values. However, reliable heart rate sensing is challenging during activity [Oniani et al., 2018].

4.2. Background

The onset of a seizure is associated with changes in temperature, perspiration, and heart rate [Wannamaker et al., 1985, Baumgartner et al., 2001]. These changes have the potential to be detected by wearable skin temperature, EDA, and optical pulse PPG sensors, respectively.

Optical heart rate acquisitions from wrist-worn PPG sensors are known to lack reliability during periods of activity due to the interfering effects of motion artefacts [Oniani et al., 2018, Couceiro et al., 2014]. However, the opportunity to achieve continuous, unobtrusive, low-cost patient monitoring and to incentivize patients toward positive health behaviours, has resulted in many clinical research and healthcare applications of consumer-grade wearables, despite manufacturers making no medical device claims.

The E4 is a data streaming device like Empatica Embrace Food and Drug Administration (FDA)-approved wearable epilepsy monitor, comprising PPG, temperature, EDA, and accelerometer sensors, and is used by researchers for physiological data acquisition for a variety of healthcare applications as well as for epileptic seizure detection research.

Empatica Inc. is a US company that "*design and develop artificial intelligent (AI) systems to monitor human health through wearable sensors*" [Empatica Inc., 2020]. The Empatica E4, at

the time of writing, is a class 2a medical-grade device used in *"over 1000 studies and trials"* [Empatica Inc., 2020] and has provided researchers with access to the raw sensor data which can be used to test seizure-detecting algorithms. It is similar to the Empatica Embrace seizure monitor.

Improvements in version reporting [Collins et al., 2019] and standardized reporting practices [Nelson et al., 2020] have been recommended to support the reproducibility of findings from studies using wearable devices. Bent et al. [2020] reported on the wearable heart rate recording accuracies of 'consumer-grade' Fitbit Charge 2, Apple Watch 4, Garmin Vivosmart 3, and Xiaomi Miband, wearables and 'research-grade' data-streaming Biovotion (now Biofourmis) Everion and Empatica E4 wristbands. The authors observed that "*absolute error during activity was, on average, 30% higher than during rest*" and that "*consumer-grade wearables were found to be more accurate than research-grade wearables at rest*." The study provides summarized statistics, but no examples of heart rate recordings or signal behaviours, as provided here.

4.3. Methodology

Healthy participants, as summarised in Table 4.1, were recruited according to ethical approval for 'Wearable Technology Performance Evaluation' from Keele University (NS-190021). Participants were asked to complete questions on demographic information, their age range, gender, height (cm), and weight (kg). In total, seven participants were recruited but because of data missingness and COVID19 limitations on laboratory access, only two sets of four participant data acquisitions were achieved for i) treadmill walking P_T 01-P_T04 and ii) 12 hours of free-living P_D01-P_D04. Participants wore a Polar H10 ECG chest strap sensor and an E4 wristband on their non-dominant wrist. The ethical documentation for the study (approval, participant information, consent form) is provided in Appendix A together with version information [Collins et al., 2019, Woolley et al., 2019] and other study details.

Table 4.1: Participant summary (P_T (Participant treadmill) and P_D (Participant 12 hours of free-living)).

Participants	Gender	Age	Height (cm)	Weight (kg)	BMI
P_T01	F	>50	160	60	23
P_T02	M	30-40	165	80	29
P_T03	M	30-40	180	91	28
P_T04	F	30-40	170	66	22
P_D01	F	>50	160	60	23
P_D02	M	30-40	180	91	28
P_D03	F	30-40	170	66	22
P_D04	M	40-50	175	70	23

Each participant took part in a treadmill activity that lasted 20-30 minutes in Keele University's Physiotherapy laboratory. Participants were asked to complete and sign a consent form. The participants wore the E4 and Embrace on their non-dominant hand (the manufacturer's recommended region of the wrist). The walking speeds for the treadmill: moderate, fast, and

vigorous walking [Collins et al., 2019, Grant et al., 2008, Tackas et al., 2014], as shown in Table 4.2 and were performed on a h/p/ cosmos Pulsar treadmill.

Table 4.2: Treadmill walking activity schedule.

Time (minutes)	**20**	**20**	**20**
Activity	Moderate Walking 3.2 km/h	Fast Walking 4.8 km/h	Vigorous Walking 6.4 km/h

There were 2 minutes of standing with arms down before the moderate walking for each participant. The heart rate reading was collected using the Polar H10 ECG chest strap sensor and E4 wristband at a sampling rate of 1 bpm, the heart rate data was downloaded from the Polar Flow and Empatica E4 Connect apps converted into .csv files and imported into Excel. The date and time stamps for the Empatica E4 connect .csv files were converted from Epoch to Unix Timestamp. The heart rate vs time graphs were used to display the Polar H10 ECG chest strap sensor and E4 wristband heart rate during the treadmill activity and 12-hours of free-living for each participant.

Bland-Altman plots were used to compare the Polar H10 and E4 heart rates acquired from the treadmill activity and the 12-hours of free-living. Bland-Altman 'difference plots' of the difference between acquisitions plotted against their average values, are popularly used in biomedical research studies. If devices are in perfect agreement, all plotted data would lie on the central axis (i.e., difference=0). The vertical spread of data points indicates the extent of disagreement between device acquisitions and how this varies with average values.

Mean absolute percentage errors (MAPEs) were calculated for the heart rate acquisitions from the treadmill activity and the 12-hours of free-living. As, shown in equation 8, Mean absolute percentage error (MAPE) is the average of the absolute error as a percentage of the reference (Polar H10) value.

$$MAPE = \frac{100}{n} \sum_{i=1}^{n} \left| \frac{R_i - D_i}{R_i} \right| \quad (8)$$

where, n = number of observations, R_i = Reference value (Polar H10), D_i = Device value (E4).

Correlation describes the strength of agreement between variables. Correlation value indications: 1 = perfect agreement 0 = no agreement -1 = perfect disagreement.

$$\text{Correlation} = \frac{\Sigma_{i=1}^{n}(R_i - \overline{R_i})(D_i - \overline{D_i})}{\sqrt{\Sigma_{i=1}^{n}(R_i - \overline{R_i})^2}\sqrt{\Sigma_{i=1}^{n}(D_i - \overline{D_i})^2}} \quad (9)$$

Investigation of the effects of rhythmic arm movement: To explore the effects of rhythmic arm movement on heart rate and seizure detection, all participants were asked to perform each of the five simple rhythmic arm movements for 20 seconds (as listed in Table 4.3) after the treadmill activity.

Table 4.3: Normal rhythmic movements.

Time (seconds)	**20**	**20**	**20**	**20**	**20**
Activity	Wiping of Shirt	Shaking bottle	Fanning motion with your hands	Tapping pen	Moving arm up and down

The rhythmic movements used in this study, have been reported in the literature as examples of movements mis-detected as motor seizure movements. In a study conducted by Lockman et al. [2011] to determine if a wrist-worn motion detector could detect tonic-clonic seizures, the authors reported wiping of one's shirt, shaking a bottle, fanning motions with your hands, tapping a pen, and moving the arm up and down as non-seizure movements.

4.4. Results

In terms of equivalence testing, there is no universal agreement on 'acceptable' ranges, however, MAPEs over 10% are the level often taken as the upper bound for "acceptable" errors [Collins et al., 2011].

The acquired treadmill and 12-hours of free-living heart rate recordings are summarised in Figures 4.1 and 4.2, respectively. The treadmill corresponding MAPE and correlation is summarised in Table 4.3. The recordings showed the heart rate recording vs time.

For treadmill walking, heart rate MAPE was between 7.2% and 29.2%, and correlation between 0.6 and -0.5, indicating moderate agreement and strong disagreement, respectively as shown in Table 4.4.

Table 4.4: MAPES and Correlation for the treadmill.

Participant	**Activity**	**Correlation**	**MAPE**
P_T01	Treadmill	0.4 (0.44 / 0.36)	19.17%
P_T02		0.61 (0.64 / 0.58)	7.21%
P_T03		**-0.53 (-0.44 / -0.61)**	29.25%
P_T04		0.32 (0.54 / -0.02)	10.54%

During 12-hour, everyday living acquisitions, heart rate estimate MAPE was between 5.3% and 13.5% and correlation between 0.7 and 0.1, indicating good to poor agreements, as shown in Table 4.5. Two E4 12-hour recordings failed to maintain connectivity for any usable data acquisition and there were several prolonged periods of missing data for P_D01-4. More data was missing from the 12-hour free-living activity because of the different movements in a free-living environment and participants had to keep the smartphones, (with the app always connected to them) close to them.

Table 4.5: MAPES and Correlation for 12-hour everyday living.

Participant	Activity	Correlation	MAPE
P_D01	12-hour everyday living	0.11 (0.2 / 0.01)	13.45%
P_D02		0.21 (0.27 / 0.15)	13.54%
P_D03		0.66 (0.69 / 0.63)	7.86%
P_D04		0.59 (0.6 / 0.58)	5.32%

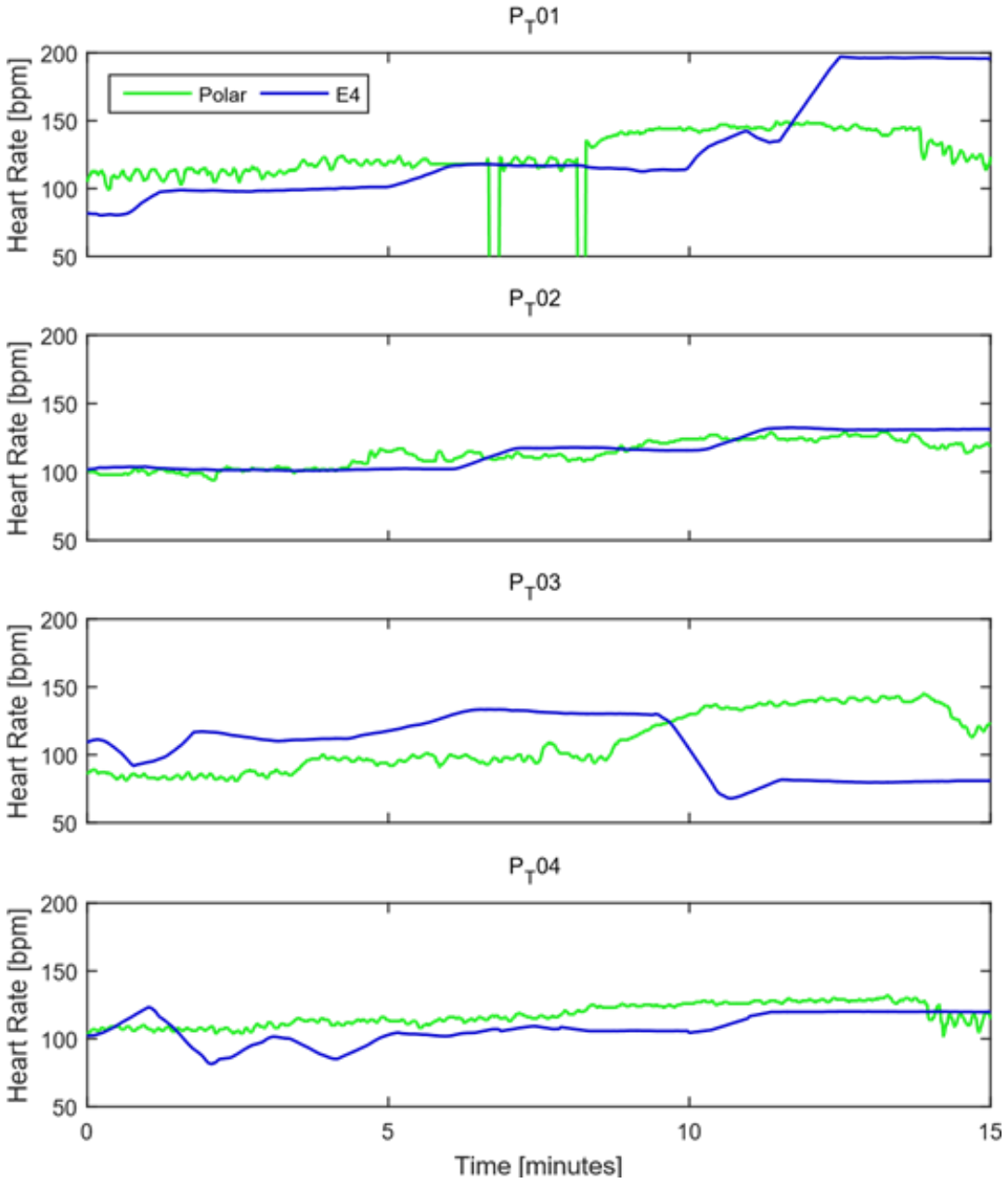


Figure 4.1: Treadmill heart rates for participants P_T01-4.

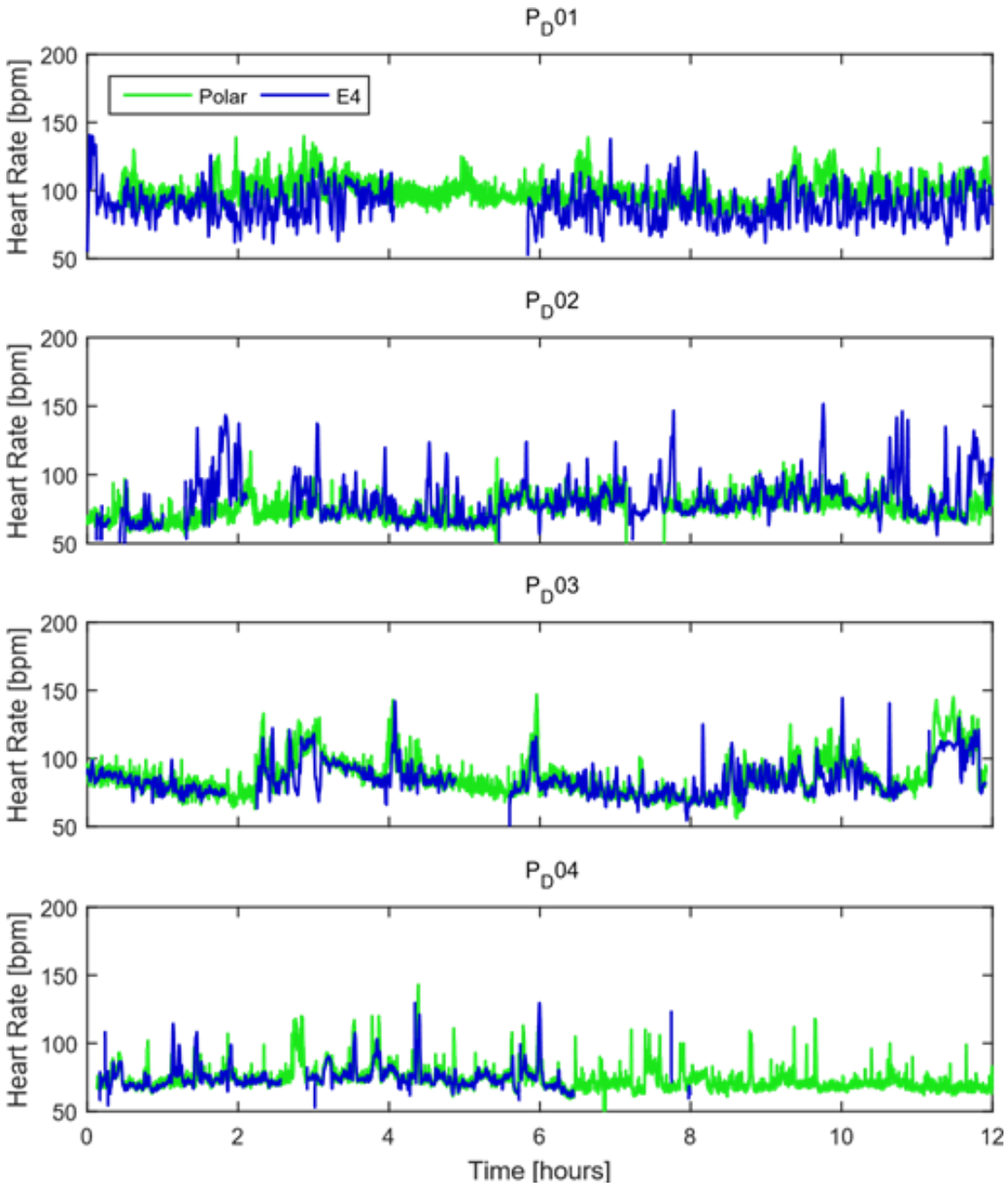


Figure 4.2: 12-hour everyday living heart rates for participants P_D01-4 (Data missingness is indicted by the disappearances of the plotted data, e.g., the missing blue line in Figure 4.2 for participant P_D01 there is 2 hours missingness).

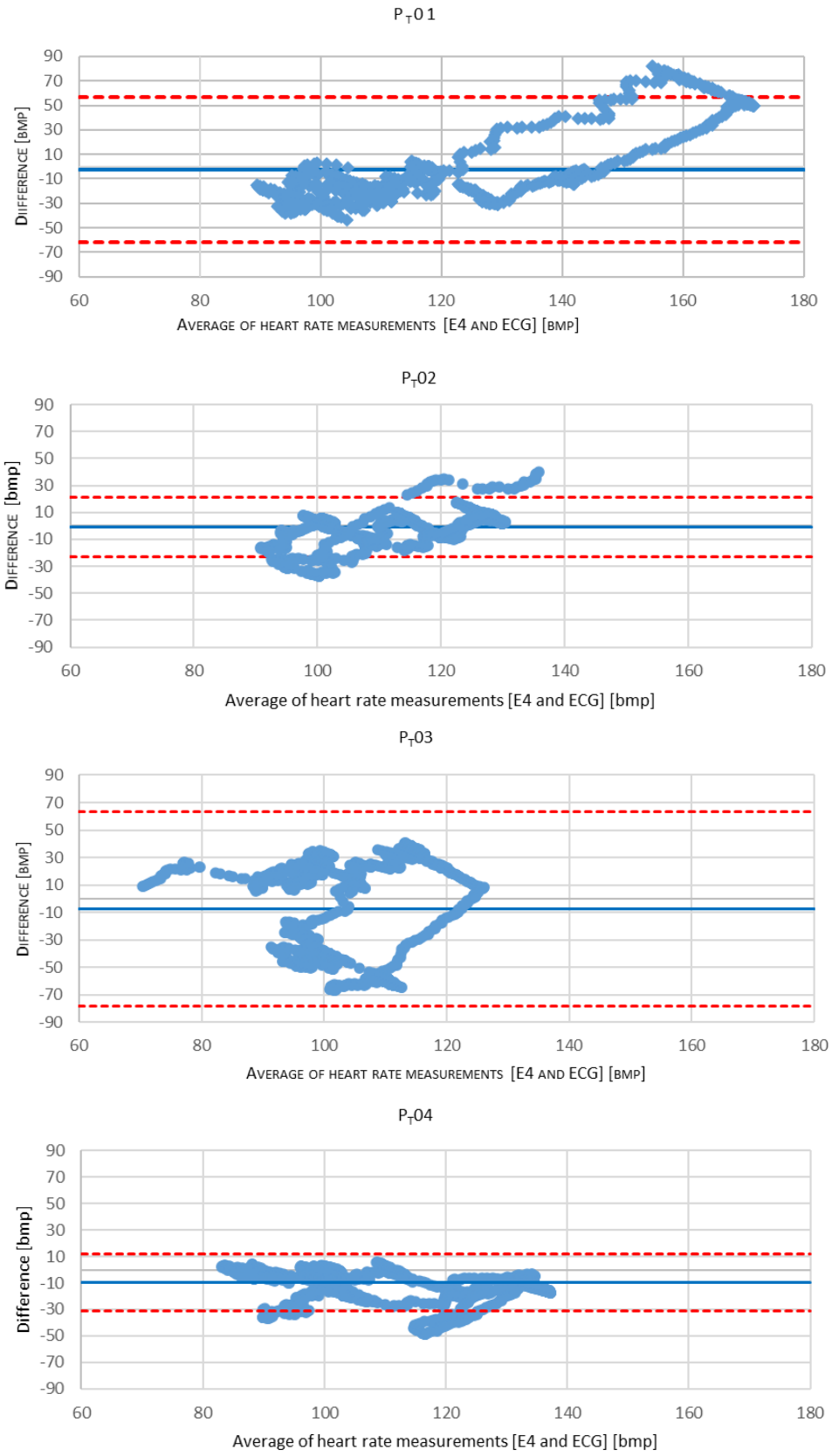


Figure 4.3: Bland-Altman plots for the E4 compared with the ECG chest strap for treadmill activities.

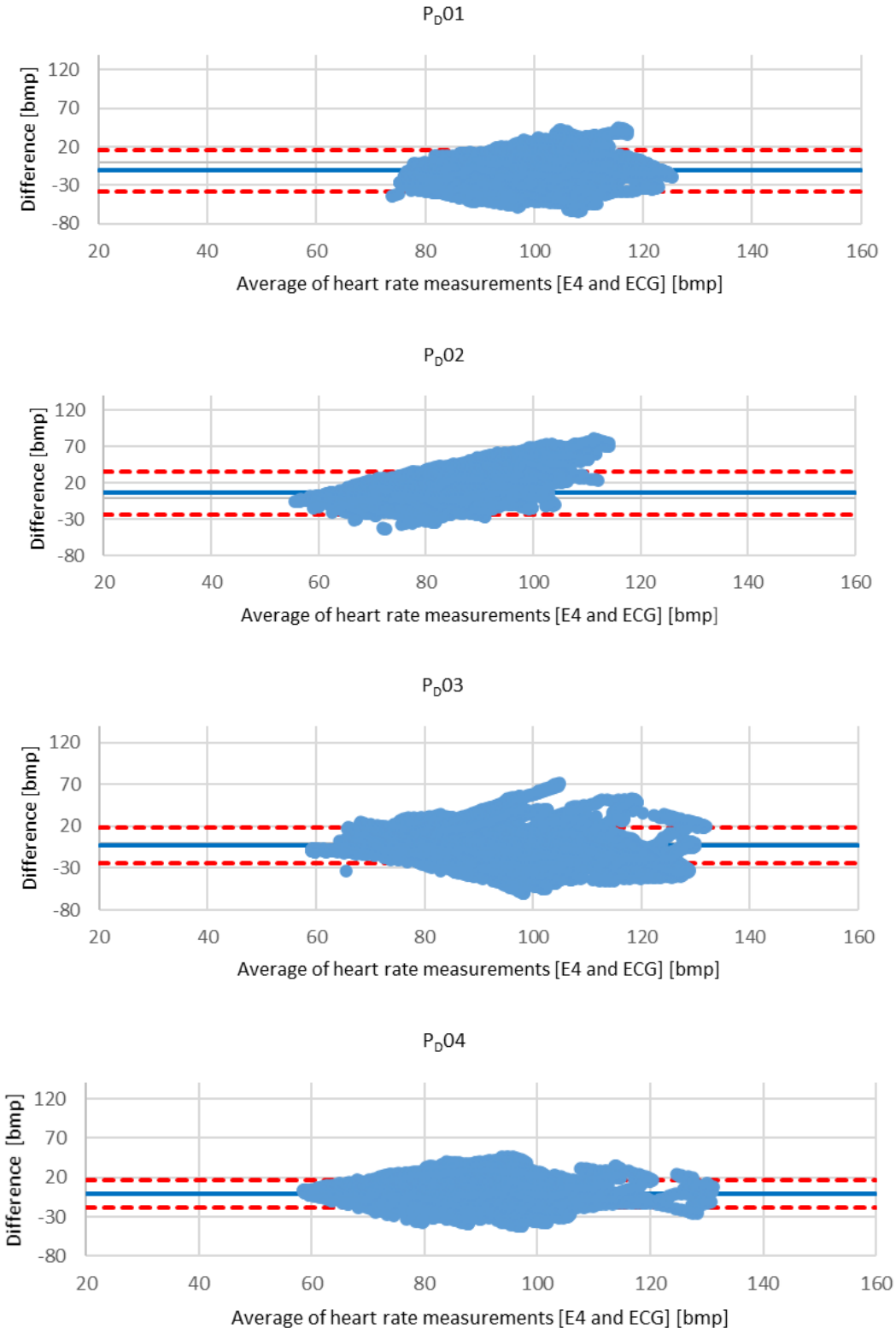


Figure 4.4: Bland-Altman plots for the E4 compared with the ECG chest strap for 12-hours free living.

Exploration of the Effects of Rhythmic Movements

Activities involving rhythmic arm movements can cause false alarms [Lockman et al., 2011, Velez M. et al 2016]. Some seizure false alarms occurred during and after the rhythmic movements, but due to latency, it was impossible to know which activity caused the alert. The exploration provided an insight into the potential for frequent false alarms during everyday rhythmic activity, and also the problem of achieving robust heart rate sensing during rhythmic arm movements. However, the exploration revealed the difficulty in achieving control and consistency of motor movements between participants (for example, participants used very variable amounts of vigour and displacement in making the movements).

Other lessons learnt from the rhythmic movement exploration were that there needs to be substantially more than 20 seconds for movements, each movement needs a clearly defined start and stop time and there should be pauses between activities (particularly after treadmill walking) for heart rates to return to baseline.

4.5. Discussion and Conclusion

The disagreement between the E4 wristband and the Polar H10 ECG chest strap sensor was large enough to be evident, even in this small study, with treadmill MAPE ranging from 7.2% to 29.2%, and correlation between 0.6 and -0.5, indicating moderate agreement and strong disagreement, respectively, and 12-hour everyday living MAPE from 5.3% to 13.5% and correlation between 0.7 and 0.1, indicating good to poor agreement [Koo et al., 2016].

In the absence of motion artefacts, PPG heart rate estimates may perform reliably and could be used, for example, to detect 'preictal' epileptic seizure onset heart rate variations. However, attempting to detect heart rate variations during activity or during a motor seizure could produce unreliable results as, for example, reported by Vandecasteele et al. [2017].

Despite these challenges, wearable epilepsy seizure detecting devices offer important opportunities to reduce injuries and save lives. However, researchers using data streaming research and medical-grade wearables should be aware of device performance during periods of activity. As underlying technologies mature, it is important to see improvements in both signal acquisition and algorithm performance. The E4 continuously disconnected from the app and that caused a problem as the experiment had to be stopped and restarted or postponed to another day. More time was required to do more experiments and to be able to get more data for the data analysis.

This empirical study addressed RQ2: How accurate and reliable are the wearable sensors used for epilepsy seizure monitoring? The results agree with other reports in the literature that there are accuracy and reliability issues with wrist-worn PPG heart rate sensing during activity. Additionally, this study demonstrates that accuracy issues are not limited to consumer-grade devices. The implications arising from these findings are that future studies may include data of low accuracy, and datasets that incorporate low accuracy data may be generated and reused. Ideally there will be improvements in device performance and in understanding of device accuracy amongst researchers, users, and health professionals.

In the next chapter further investigation on small screens and minimal interfaces of wearable devices is carried out using the light pattern interface of the Empatica Embrace wrist-worn epileptic seizure monitor for eight interface displays.

CHAPTER 5
USER INTERFACE EVALUATION

5.1. Introduction

This chapter addresses RQ3: To what extent do wearable user interface designs affect usability? It presents results from a study on wearable interface evaluation and contributes a novel reflection on the interface requirements of wearer user and non-wearer user stakeholders.

The work presented comprises two components which assess the light pattern interface of the Empatica Embrace wrist-worn epileptic seizure monitor: the 'guessability' of eight Embrace interface display state and a heuristic analysis from the fourteen participant evaluators. The results indicate satisfaction with the aesthetic of the minimal light interface but confusion between different patterns and concerns about accessibility, and reliance on recall.

5.2. Background

The challenge of achieving useful and unambiguous information delivery via the small screens of mobile devices is well recognised [Motti et al., 2016]. In a study investigating how variations in the screen shape and screen size of smartwatches conducted by Kim [2017] reported that *"large screens positively influence information quality by simultaneously increasing both the hedonic (perceived attractiveness) and pragmatic (perceived control) qualities of smartwatches"*. In contrast, a screen size evaluation study by Raptis et al. [2013] reported that mobile device screen size did not have a significant effect on usability (assessed with SUS), but that *"prior experience and desire for the device did have a significant effect*" and users are more efficient during information seeking tasks when using larger screens.

Achieving useful and unambiguous information delivery via the very small screens and minimal interfaces of wearable devices poses further design challenges [Xu et al., 2015, Zhang et al., 2016]. In a study comparing wearable devices, Kaewkannate et al. [2016] reported that the most common criticisms of wearable devices, is that they *"cannot display information but require a smartphone to send the metric data and reports".* But for wearables, it is especially important that devices are aesthetically acceptable [Fortmann et al., 2013] and, particularly in the case of health-condition monitoring, it is important that devices are discreet [Simblett et al., 2020] and do not stigmatize wearers [Johansson et al., 2018].

Minimal interface indicators may very quickly become familiar to individuals, who wear the devices every day. But, in critical healthcare applications, there are often other stakeholder users beyond the wearer users, during critical episodes such as an epileptic seizure, the wearer may be incapacitated or confused for some extended period during and after the event. Examples of non-wearer stakeholder users include a parent or grandparent, teacher, caregiver, colleague, classmate, friend, or First Aid responder. These non-wearer stakeholders may normally have little reason to observe the interface or respond to low priority indications

such as ‘Battery Low’, however, the correct identification of a seizure (‘Unusual Event Detected’) indication could be an important source of seizure detection. A correctly interpreted display could also provide some reassurance about automated messaging that could reduce the responder’s burden of seizure reporting. Likewise, the misinterpretation of a non-seizure display as a seizure could have consequences that, like false alarms in general, can disincentivize users.

The Empatica Embrace epilepsy seizure monitor [Empatica Inc. 2020] has a multicolour LED interface that includes blinking and rotating animations indicating a range of conditions and states as indicated by the illustrations in Figure 5.1.

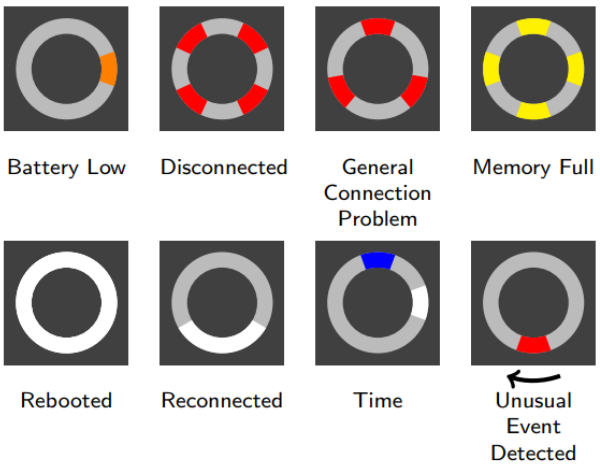
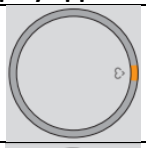
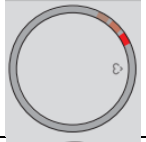
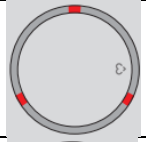
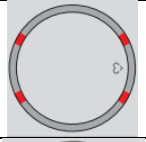
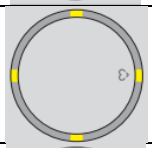
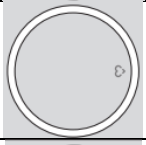
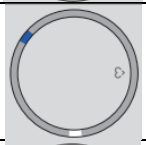
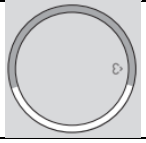


Figure 5.1: Embrace epilepsy monitor LED interface examples.

Table 5.1: The PowerPoint animations questionnaire interface displays, questions and answers, used to check the responses.

Display appearance	Description	Meaning
	Orange dot blinking	Low Battery
	Red spinning circle	Seizure Detected
	Red triangle (3 red dots)	Connection Problem
	Red X (4 red dots)	Embrace Disconnected
	Yellow cross (4 yellow dots)	Embrace Memory is Full
	White circle	Embrace Restarted
	White and blue lights	Time
	White ‘smile’	Embrace Connected

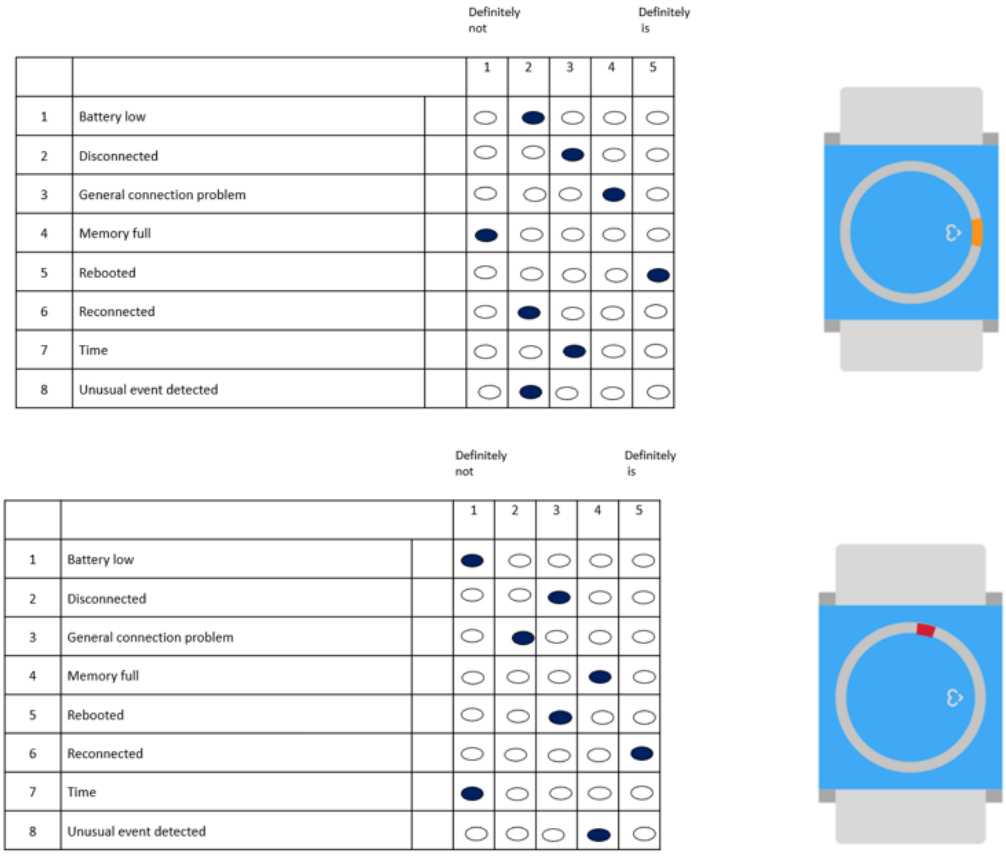


Figure 5.2: The PowerPoint animations questionnaire interface participant response example.

The PowerPoint animations questionnaire interface had a scale of 1 - 5 (1 = definitely isn't, 2 = isn't, 3 = neutral, 4 = is, 5 = definitely is). The PowerPoint animations questionnaire interface was made up of 8 slides with one Embrace epilepsy monitor LED interface on each slide. Figure 5.2 shows an example of how the participants were asked to complete the questionnaire.

5.3. Methodology

Fourteen Computer Science students and researchers with confirmed experience in the heuristic evaluation were recruited according to Keele University Faculty of Natural Sciences Research Ethics Committee approval (NS-200058) to evaluate the LED interface of the Empatica Embrace wearable seizure monitor. Participants comprised two academic staff members, three PhD researchers, and four masters and five undergraduate Computer Science students. All participants gave their consent to having their responses audio recorded. The study was conducted in March 2020 immediately before the COVID19 lockdown. Each participant was allocated a participant ID (P01-P14). For repeatability [Collins et al., 2019, Woolley et al., 2019], the device version was an Empatica Embrace wristband EMB-MB-S (purchased 26th February 2019 with firmware version current between 11th to 13th March 2020). The ethical documentation (approval, participant information, consent form), the questionnaire is included in Appendix B.

The study comprised two components:

Interface State Guessability: In the first component, the participants were asked to guess on a scale of 5 - 1 (5 = definitely is and 1 = definitely isn't) what each of eight LED interface patterns signified: Battery Low, Disconnected, General Connection Problem, Memory Full, Rebooted, Reconnected, Time and Unusual Event Detected. The LED patterns were displayed in random order (indicated in Figure 2).

The question participants were asked for each of 8 LED patterns was: *'What do you think this interface display indicates? "Please tell me on a scale of 5-1 (5 = definitely is and 1 = definitely isn't) how confident you are that this display indicates each condition". For example, participants were shown the Disconnected LED Pattern display, and asked to guess to report on the 5-1 scale how confident they were that it was or wasn't the Battery Low indication, then again on the scale 5-1 how confident they were that it was or wasn't the Disconnected indication, and again on the scale 5-1 how confident they were that it was or wasn't the General Connection Problem, and so on for all 8 indications. This process was repeated for all 8 of the LED interface patterns.*

Participants were shown the interface display animations and asked to identify the meaning of each. They were asked to complete the PowerPoint animations questionnaire interface displays. The participants were showed the correct answers (as shown in Table 5.1) to the PowerPoint animations questionnaire interface displays and were asked their opinions based on their answers.

i. **Heuristics Evaluation:** In the second study, the participants were shown the correct answers for each condition and asked to complete a heuristic evaluation based on Neilsen's 10 Usability Heuristics for User Interface Design [Nielsen et al., 1994]: 1) visibility of system status, 2) match between system and the real world, 3) user control and freedom, 4) consistency and standards, 5) error prevention, 6) recognition rather than recall, 7) flexibility and efficiency of use, 8) aesthetic and minimalist design, 9) help users recognize, diagnose, and recover from an error, and 10) help and documentation.

The heuristics evaluation took approximately 15-20 minutes and took place in March 2020.

5.4. Results

i. **Interface State Guessability:** The Guessability results are illustrated with Box Plots in Figure 5.3, summarising the participant interface guesses (5 = definitely is, 1 = definitely isn't). Correct instances are shaded in green, 'x' marks mean, bar marks median and box and whiskers indicate the interquartile range and max/min, respectively.

Ideally, the correct LED patterns (shaded in green) would have averaged close to 5 and all incorrect conditions would have averaged close to 1. Table 5.1 shows the participant evaluations for each of the 10 Nielsen user interface design heuristics [Nielsen et al., 1994]. The heuristics from all 14 participants was based on the LED patterns as shown in Figure 5.1.

Overall, the participants' evaluators to question 1 reported the LED as visible and clear but most identified ambiguities.

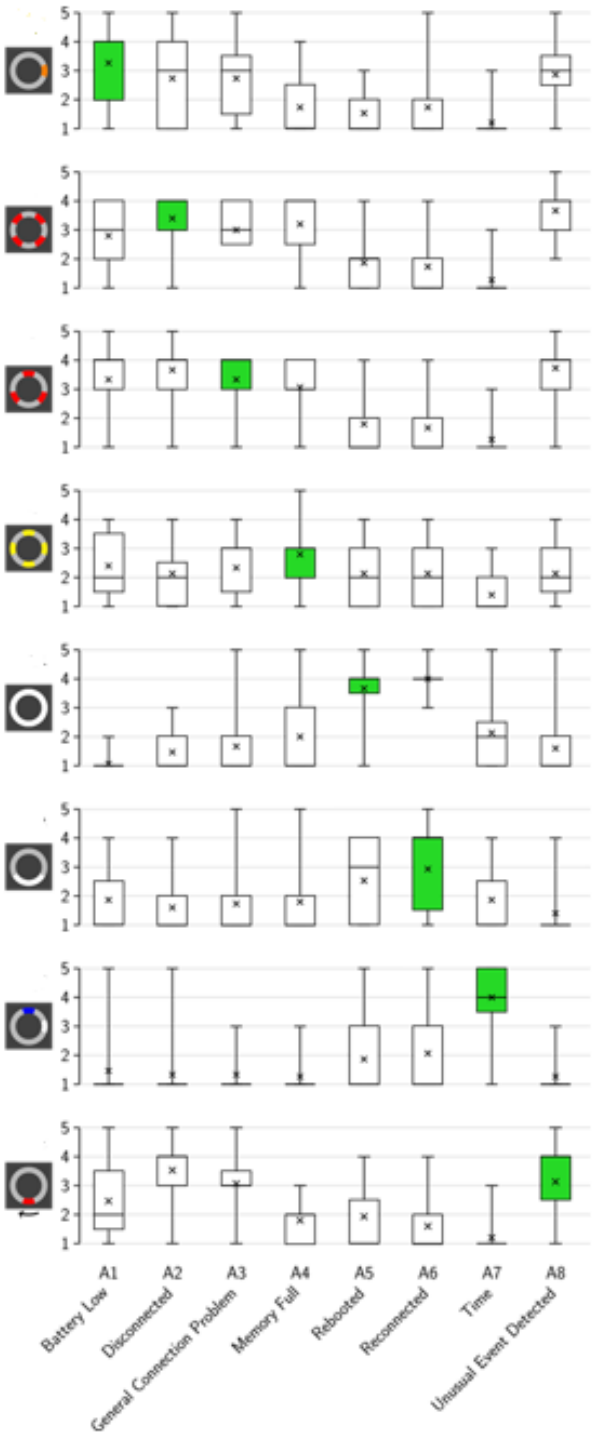


Figure 5.3: Eight Embrace Guessability Box Plots.
(The correct responses are shown highlighted in green)

ii. **Heuristics Evaluation:** All fourteen completed a heuristics evaluation of the interface using Jakob Nielsen's [1994] 10 Interface Design Heuristics. A summary of the evaluation responses is provided in Table 5.2. Seven participants reported experience of using wearable health trackers.

Table 5.2: User interface design heuristics [Jakob Nielsen. 1994] with summarized descriptions and participant evaluations.

Heuristics	Participant Evaluations
Visibility of system status: The system keeps users informed of what is going on, through appropriate feedback within a reasonable time.	Some evaluators reported the LEDs as visible and clear but most identified ambiguities. *"About half the LEDs made sense."* *"Once the user knows the patterns it could be readable." "To the unversed person, it seems confusing..."*
Match between system and the real world: The system should speak the users' language and follow real-world conventions in a natural and logical order.	Several evaluators reported a good match for the red colour and a warning condition. Opinions varied about the use of white and orange LEDs. The time interface was thought to be intuitive. There was uncertainty about the animations. *"The system does not speak our language or use conventional symbols/signs."* *"Red indicates a serious problem."* *"Some animations matched real-world... most do not."*
User control and freedom: Support undo and redo and have an "emergency exit".	Most participants felt that this heuristic was not applicable, but one evaluator suggested customization control.
Consistency and standards: Users should not have to wonder about meanings (the device should follow conventions).	Evaluators generally agreed on the internal consistency of the LED displays but did not agree on a consistent standard beyond the use of red for warning. *"LEDs don't seem consistent with other products I am aware of."*
Error prevention: A design that avoids errors and requests user confirmations.	Most evaluators agreed that, although it is clear when an error or problem has occurred, it was not clear what the error condition was. *"Where the LED shows red, this is most obvious that there is an issue, but difficult to discern what the error it is."* There were also concerns about the accessibility of the display for colour blind individuals
Recognition rather than recall: Users should not have to remember information from one part of the dialogue to another.	Although there were some intuitive elements of the interface, most evaluators felt the interface relied largely on recall. *"The problem is having to remember what it means..."* *"You would have to rely on memorizing the LED patterns..."*
Flexibility and efficiency of use: Support for inexperienced and experienced users.	Evaluators agreed that the interface was efficient and international.
Aesthetic and minimalist design: Dialogues should not contain irrelevant information.	Some evaluators liked the minimalist aesthetic, but most felt it was too minimalistic. *"Possibly too minimalistic with such a variety of meanings..."* *"A lack of text may make it hard to remember the meanings..."*
Help users recognize, diagnose, and recover from errors: Error messages should specify the problem and suggest a solution.	Evaluators expressed different opinions but generally agreed that displays were recognizable if LED patterns were learned, but no indications were given about recovery. *"If users know the meanings, displays are distinct."* *"There is little help provided for the user, if they don't know what the lights mean, they won't know what to do."*
Help and documentation: The system should provide help and documentation).	Participants agreed that there was no help available via the interface. *"None is provided on the interface leading to a reliance on recall or reference to a manual."*

5.5. Discussion and Conclusion

Interface State Guessability: As demonstrated in Figure 5.3 by the number of average guess values between 2 and 4, as well as the similarity of scores between some interface displays, participants found it difficult to disambiguate between sets of conditions. For example, participants could not discern between the orange and red Battery Low, Disconnected and General Connection Problem light patterns: all three received averages of 2.5 to 3.5 (3 = unsure) no matter which pattern was displayed. Similarly, the white Rebooted and Reconnected LED patterns were confused with each other. The Time display was the most recognized. Only one participant was confident the Time display was not Time, and, at most, one participant guessed that Battery Low, Disconnected, and General Connection Problem, were Time indicators. Unfortunately, **the spinning red Unusual Event Detected display that can signify a seizure was not guessed well** and was confused with Battery Low, Disconnected, and General Connection Problem. When displayed, to participants the **Unusual Event Detected display received an average score for the correct answer of 3.13 (3 = unsure)** which was lower than the (incorrect) Disconnected guess that received an average of 3.53. Overall, for four out of the eight displays, at least one incorrect answer had a higher average guess score than the correct answer.

Heuristics Evaluation: In Table 5.1, the heuristic evaluation feedback summarises the opinions amongst participant evaluators that, on the one hand, recognize the simplicity, clarity, and potential memorability of the display and, on the other, raises concerns about the reliance on recall and the potential for confusion. For example, one evaluator observed that the interface was *"Quite aesthetically pleasing but as intuitive as a Star Trek control panel".* The use of colour, e.g., *"Red indicates a serious problem"* was appropriate as a real-world convention but some concerns were raised about accessibility for individuals with colour-vision deficiencies.

Minimal light pattern displays have a pleasing aesthetic but can be confusing to users lacking familiarity with the interface. Ideally, each displayed pattern could be correctly guessed, especially the one that could indicate a seizure. There is a need for further research and improvements in the design of interface displays for wearable devices and particularly for devices used in critical health monitoring scenarios with different wearer user and non-wearer user stakeholders.

This empirical study addressed RQ3: To what extent do wearable user interface designs affect usability? The results findings provided insights into usability of the user interface, for example, on one hand recognizing the simplicity, clarity, and potential memorability of the display and, on the other, identifying concerns about the reliance on recall and the potential for confusion about the device state communication. The implications of the findings are that individuals and caregivers (including, for example, colleagues and co-workers) may fail to identify important device communications such as a seizure event detected. Ideally, there is scope for improvements in user interface design for wearable device and understanding amongst researchers, users, and health professionals about the usability of the user interface design devices.

In the next chapter, further investigation is conducted on the opinions and any experiences of wearable and non-wearable monitoring devices or apps. Opinions and experiences from individuals with epilepsy, aged 18 or over, carers or other stakeholders with an interest or responsibility for individuals with epilepsy and healthcare professionals.

CHAPTER 6
STAKEHOLDER OPINION AND EXPERIENCE OF EPILEPSY WEARABLE MONITORING DEVICES

6.1. Introduction

This chapter addresses RQ4: What are user and stakeholder opinions and experiences of wearable devices for epilepsy seizure monitoring? It presents results from stakeholder opinions and experiences of epilepsy monitoring devices and presents the results of a survey of individuals, carers, and healthcare professionals.

The survey was distributed by Epilepsy Action as shown in Figure 6.1.

Figure 6.1: Opinions of wearable devices for epilepsy seizure detection survey distributed by Epilepsy Action.

6.2. Motivation and Background

The motivation for the study was the lack of evaluation studies, specifically the lack of qualitative studies and evaluations based on real-world use, identified in the initial systematic literature review performed at the outset of this research [Rukasha et al. 2020] as well as the observations of Brun et al. [2018]. Brun et al. [2018] reported *"there is a limited number of investigations exploring the willingness of individuals with epilepsy to use digital technologies for seizure detection and factors influencing their attitudes*."

Seizure tracking has relied on patients recall and self-reporting, this has been reported in clinical practice to be unreliable [Cook et al., 2013]. Monitoring devices are generally designed to communicate 'alerts' for carers to attend to individuals who may be experiencing a seizure [Langan et al., 2005], especially when individuals are regularly monitored at night [Fisher et al., 12].

Epilepsy Action is a charity that aims to improve the lives of individuals affected by epilepsy, give advice, improve healthcare, fund research and campaign for change. It also provides researchers with the opportunity to survey the epilepsy community (i.e., individuals, carers, healthcare professionals and other stakeholders) [epilepsy.org.uk., 2020], as shown in Figure 6.2.

Figure 6.2: Epilepsy Action website page (https://www.epilepsy.org.uk/research/take-part/projects- you-can-take-part-in/wearable-devices).

6.3. Methodology

As shown in Figure 6.3, the study was entitled 'Opinions of wearable devices for epilepsy seizure detection' and was approved by the Keele University Faculty of Natural Sciences Research Ethics Committee (NS-200056). The permission was also sought and granted by Epilepsy Action and informed consent was obtained from all participants. Participants were provided with a Participant Information Sheet and consented by completing the (anonymous) questionnaire ('I permit to use quotes from my responses'). The ethical documentation (approval, participant information, consent form), the questionnaires for individuals with epilepsy, carers and healthcare professionals are included in Appendix C.

There were three separate questionnaires and inclusion criteria, summarised in Table 6.1.

Figure 6.3: Epilepsy Action website questionnaire.

Table 6.1: Summary of questionnaires and inclusion criteria.

Questionnaire	Respondents (Inclusion criteria)	Demographic/ Introductory questions	Epilepsy monitoring questions	PSSUQ
Individuals	Individuals with epilepsy, aged 18 or over	Gender Age range How long have you had epilepsy? (years) Age at diagnosis Fitness level Seizures (type/s, frequency, duration, and recovery)	Use of (any) wearables. Use of epilepsy monitors (wearable and non-wearable, past and present)	✓
Carers	Carers and stakeholders with interest or responsibility for individuals with epilepsy	Current role Relationship to individual/s with epilepsy (age, gender, seizures)	Use of (any) wearables. Use of epilepsy monitors (wearable and non-wearable, past and present)	✓
Healthcare professionals	-	Current role Relationship to individual/s with epilepsy (age, gender, seizures)	Use of (any) wearables. Use of epilepsy monitors (wearable and non-wearable, past and present)	✓

The Post-Study System Usability Questionnaire (PSSUQ) is a popular usability questionnaire that was used as an alternative to SUS (System Usability Scale) to assess usability and differentiate usability in terms of system usefulness, information quality, and interface quality. Participants only completed the PSSUQ if they had experiences of using wearable devices. The PSSUQ was also preferred because it was used in a similar qualitative evaluation of the Epi-Care free monitor study by Meritam et al. [2018]. The PSSUQ incorporates 16 items grouped as follows: system usefulness, information quality, and interface design, as shown in Table 6.2.

Table 6.2: The System Usefulness (SU), Information Quality (IQ), and Interface Quality (INQ) questions in the PSSUQ.

System Usefulness (SU) Questions	
SU1:	Overall, I am satisfied with how easy it is to use this system. **(SATISFACTION)**
SU2:	It was simple to use this system. **(SIMPLE)**
SU3:	I was able to complete the tasks and scenarios quickly using this system. **(EASE OF USE)**
SU4:	I felt comfortable using this system. **(COMFORT)**
SU5:	It was easy to learn to use this system. **(EASY TO LEARN)**
SU6:	I believe I could become productive quickly using this system. **(PRODUCTIVE)**
Information quality (IQ) Questions	
IQ1:	The system gave error messages that clearly told me how to fix problems. **(FIX PROBLEMS)**
IQ2:	Whenever I made a mistake using the system, I could recover easily and quickly. **(RECOVER)**
IQ3:	The information such as online help, on-screen messages, and other documentation provided with this system was clear. **(CLARITY)**
IQ4:	It was easy to find the information I needed. **(INFORMATION)**
IQ5:	The information was effective in helping me complete the tasks and scenarios. **(EFFECTIVE**)
IQ6:	The organization of information on the system screens was clear. **(SCREEN)**
Interface quality (INQ) Questions	
INQ1:	The interface of this system was pleasant. **(PLEASANT)**
INQ2:	I liked using the interface of this system. **(LIKE)**
INQ3:	This system has all the functions and capabilities I expect it to have. **(FUNCTIONS AND CAPABILITIES)**
INQ4:	Overall, I am satisfied with this system. **(SATISFACTION)**

PSSUQ scores range from 1 indicating a strong agreement to 7 indicating a strong disagreement. The lower the score, the better the performance and satisfaction, a score of 4 represents a neutral response. The study timescale of the response period was from 29 February 2020 to the end of November 2020.

6.4. Survey Results

A total of 61 responses were received from the 3 different questionnaires. Eleven (of 36) individuals, seven (of 14) carers and four (of 11) healthcare professionals completed the PSSUQ, as shown in sections 6.4.5, 6.4.6 and 6.4.7. There were more responses from individuals between 20 - 29 years (12 responses) and 50 – 59 (8 responses) and fewer responses from under 20 years (2 responses) and 60 and overs (2 responses), as compared to healthcare professionals and carers who reported several individuals in their care of various age ranges from birth – 80+ years. The survey showed that individuals (particularly carers)

demonstrated interest in using epilepsy monitoring devices but concerns about devices not recording seizures, (missing seizures) and these were some of the reasons they stopped using the devices.

- 36 individuals (11 PSSUQ responses)
- 14 carers (7 PSSUQ responses)
- 11 healthcare professionals (4 PSSUQ responses)

6.4.1. Survey Results for Individuals

Thirty-three (of 36) responders specified their gender, 20 female and 13 males There was a spread of ages from under 20 to over 60. Thirty-three (of 36) responders specified their age range, with half of the responders being 20-59, the majority of the participants were 20 and over, between 20-40, as shown in Figure 6.4.

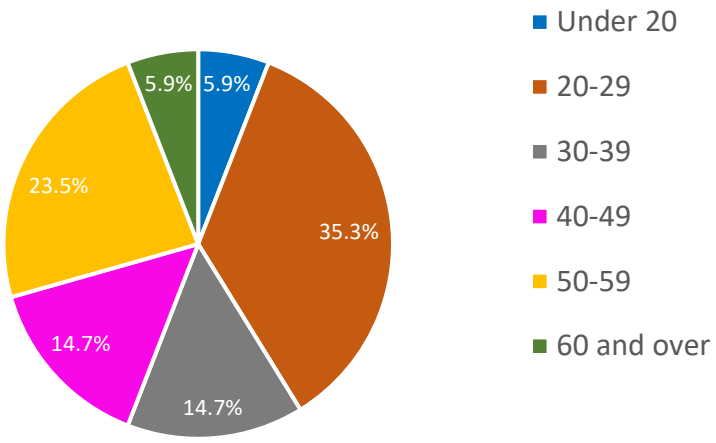


Figure 6.4: Age ranges reported by responding individuals with epilepsy.

6.4.2. Survey Results for Carers

Thirteen (of 14) carers identified themselves, as (two) partners, (eleven) carers and (one) a friend. Carers reported taking care of 1 - 5 individuals with epilepsy, both male and female. Carers reported individuals using the devices or apps for a period between 1 - 6 months or more and between 1 - 3 years.

6.4.3. Survey for Healthcare Professionals

Eleven healthcare professionals responded (ten epilepsy nurses and one neurologist). The healthcare professionals reported caring for 1 – 8000 adults both male and female. Healthcare professionals reported individuals using or having used wearable epilepsy monitoring devices/apps for 1 - 4 years or more.

6.4.4. Combined Thematic Analysis

Thematic analysis was used as a method for identifying, analysing, and reporting patterns (themes) in responses from the Individuals (P), Carers (C), and Healthcare Professionals (H). Several themes emerged from the qualitative sampling of participant comments from the open-ended questions.

Responses from Individuals

i. **Fitness and general level of activity** (**Q.** Please comment on your fitness and general level of activity, e.g., "regular desk working with occasional walking and jogging" or "intermittent vigorous work and regular gym/football" or "regular moderate activity such as gardening and housework).

   Thirty-three (of 36) individuals responded. The responses varied from active to inactive person, who reported a general level of activity as house chores, walking or desk work, for example,

   "Unemployed usually walk 3 miles a day plus housework …" P04.

   "Regular moderate activity such as gardening and housework" P17.

   "Regular - gym a few times a week and regular walking and yoga" P19.

   "Run marathons - run every other day at least use gym for yoga, cycling, Swimming…" P32.

ii. **Seizure frequency and recovery period** (**Q.** Broadly, please tell us about the seizures. How frequent are they and how long do they last? On average, how long does it take for full recovery from a seizure?).

   Thirty-three (of 36) individuals responded. The reported seizure frequency and recovery varied. The seizure frequency reported by individuals with epilepsy varied depending on their seizures. The frequency was from twice a week to once every following month. The full recovery period was similar for each response, the recovery period ranged from just a few hours to 1-8 days, for example,

   "My seizures usually last for 5 minutes and I generally take me 8 days to fully recover" P02.

   "Tonic-clonic average 3 minutes usually 3-4 a year.... takes 3-8 hours to recover" P03.

   "Once a month for a major seizure and once or twice a week for the smaller types, full recovery from a major seizure will take up to 24 hours ...." P06.

   "1 every 3 months which last anywhere up to 5 mins...takes me around a week to fully recover..." P12.

iii. **Why you chose the device?** (**Q.** If you are CURRENTLY using a wearable epilepsy monitoring device, please tell us why you chose it),

Eight (of 36) individuals responded. The individuals reported different reasons for why they chose the devices, from being able to get assistance and for health reasons, for example,

"…helps me get in contact with my parents while I am unconscious. It reassures me to know someone knows" P02.

"..... for fall detections" P05.

"My medical ID bracelet makes me feel secure" P10.

"I bought the watch to go with the phone it had nothing to do with health reasons other than a step counter" P35.

iv. Emergency contacts and relationship (**Q.** How many emergency contacts do you have. What is your relationship with them)?

From the 28 (of 36) responses from individuals referred to their parents and partners as their carers'. Individuals reported between 1 - 8 emergency contacts, for example,

"1 and it is my wife" P15.

"8- friends, flatmates, family" P20.

"1 my partner and carer" P22.

"Only my epilepsy specialist, and 111" P24.

Responses from Carers

v. Alarm messages (**Q.** Do you receive the alarm messages from the individual's wearable epilepsy monitoring devices or apps, if so, please tell us your opinion of the messages)

Five (of 14) carers reported receiving alarm messages, that were clear and simple to understand, providing the individual's location which made it easier to locate them, when they required assistance, for example,

"Yes, I like the messages as they are simple and tell me what I need to know. Time and location" C04.

"Yes. The message is clear and has a link to Google Maps app. It's up to the recipient to check the person's location" C08.

Responses from Individuals and Carers

vi. Types of seizures (**Q.** What types of seizures do they have (Please select all that apply))

Thirty-three (of 36) individuals reported different types of seizures they have; the most frequent seizures were TCS and absence/atonic seizures. All 14 carers responded, they reported the most frequent seizures were myoclonic/tonic and absence/atonic seizures, as shown in Figures 6.6.

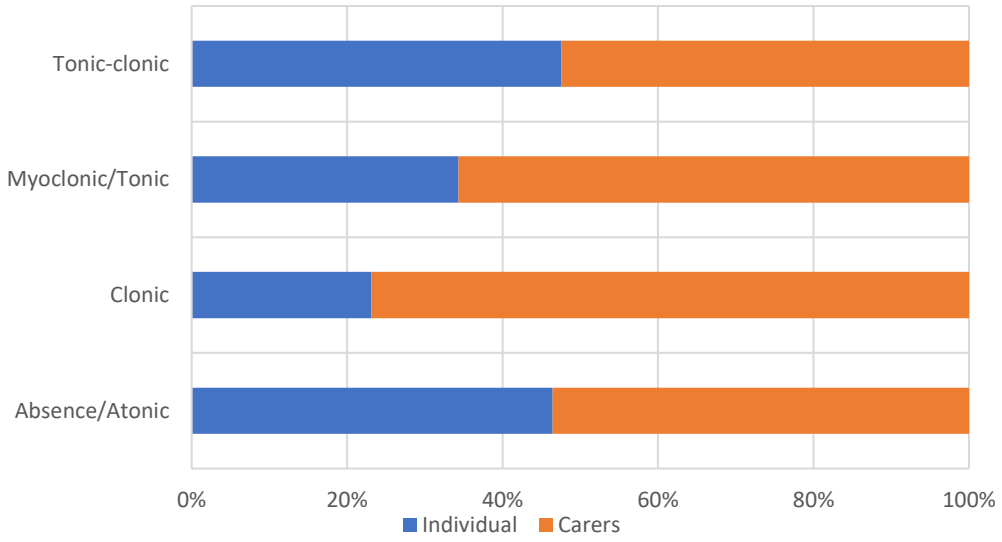


Figure 6.5: Types of seizures reported by individuals and carers (outer max 100%).

Responses from Carers and Healthcare Professionals

vii. **Individuals with epilepsy in your care** (**Q.** Please tell us how many individuals with epilepsy are in your care (What are their ages and gender)

Eleven (of 14) carers reported taking care of around 1 – 4 individuals with epilepsy, both male and female of different age ranges from 1 – 40 years. Nine (of 11) healthcare professionals reported taking care of around 1 – 8000 children and adults with epilepsy, of different age ranges, 0 – 80+, for example,

"1, 18 months female" C02.

"4, 1) my dad 81, 2) my other son 20, 3) my daughter in law 19, 4) my son with epilepsy" C13.

"Age 16 up to 80+! Two nurses cover a population of 8000 patients" H06.

"2000 adults variable ages" H10.

viii. **Recommended devices** (**Q.** Are these devices that you recommended? What is your opinion of the device?)

Five (of 14) carers responded saying they recommended devices for example:

"Yes, knowing we will be alerted if our son stops breathing during a seizure at night has allowed everyone to relax and get better rest at night. The monitor only detects seizures where his heart rate or oxygen levels change out if normal parameters however so many seizures are missed" C07.

"Yes, both. Seizario works outdoors where the Careline doesn't. Falls are detected (including false alarms when the user drops it!). Seizario: The person's location can also

be detected through Google Maps but requires user and recipients to have location switched on all the time and a Smartphone. Available for iPhone or Android. Free to download - no in-app purchases required. Regular updates. False alarms may be cancelled by the user. Text message alert system" C08.

Six (of 11) healthcare professionals that responded saying they have recommended devices such as Embrace wrist-worn devices (https://www.empatica.com/en-gb/embrace2/), Epi-care wrist-worn sensor (https://danishcare.co.uk/epicare-free) and V-SOS Vodaphone fall detector watch (https://www.vodafonefaf.ie/collections/new-in/products/vodafone-v-sos-gps-watch-tracker). Other respondents explained that they did not recommend devices.

"Empatica, Embrace, I phone - with fall alarm, VSOS watch by Vodaphone, Refer to telecare services for general fall alarms and bed sensors" H10.

"We do not recommend or fund any epilepsy device as none are registered as medical devices due to not being 100% accurate. We do signpost patients to the information on Epilepsy Action website, however" H06.

ix. Wearable epilepsy monitoring devices or apps used IN THE PAST (**Q.** Please tell us about any wearable epilepsy monitoring devices or apps that the individuals with epilepsy used IN THE PAST (i.e., devices that they no longer use))

Seven (of 36) responses from the individuals reported the use of wearable monitoring devices such as Buddi fall detector (https://www.buddi.co.uk/) and Apple watch. There were Five (of 14) responses from carers who also reported individuals in their care using devices such as Epi-care wrist-worn sensor, Embrace wrist-worn device and a mattress sensor. Four (of 11) responses from healthcare professionals with individuals in their care using Brio epilepsy monitor ((Brio - Epilepsy Alarms UK, 2021)), Embrace wrist-worn device and PulseGuard sensor (https://pulseguard.org/).

"I was given the Buddi by Rochdale council and I put it on my wrist and the pendant around my neck. The wrist band would detect a fall and the pendant would alert the Buddi team and my emergency contacts" P14.

"Just the app on my phone and watch but it was always screwing up" P25.

"Previously used mattress alarm which was slow to detect tonic-clonic seizures and did not detect other seizure types. Currently, use a Sats monitor overnight to detect potential issues mainly from a SUDEP concern" C11.

We used to have one that was an app on both my sons' phone and watch but it would send out false alarms and other times it would not send an alert when he needed us. One time it didn't send an alert and my son went into epi status and needed quick intervention via hospital and ambulance" C13.

"falls pendant alarm" H03.

"PulseGuard" H08.

x. **Non-wearable epilepsy monitoring devices used IN THE PAST (Q.** Please tell us about any non-wearable epilepsy monitoring devices that the individuals with epilepsy used IN THE PAST (i.e., devices that they no longer use))

Two (of 36) individuals responded saying they have not used any device in the past. Four (of 14) carers responded saying the individuals they care for have used mostly mattress/bed sensors, although they were not very effective due to the sensor not detecting "convulsive seizures" (C11). Six (of 11) healthcare professionals reported caring for individuals who have used different types of non-wearable devices such as mattress sensors, fall alarms and alert mats.

"Mattress sensor. It seemed good but didn't work when both of us were in bed" C04.

"Bed mattress alert which alerts every time he moved in his sleep" C12.

"bed sensor unreliable with false alarms did not work well in double beds" H08.

"young epilepsy app- doesn't seem to update anymore" H11.

Responses from Individuals, Carers and Healthcare Professionals

xi. **Wearable epilepsy monitoring devices or apps CURRENTLY USED** (**Q.** Do the individual/s with epilepsy CURRENTLY use wearable epilepsy monitoring devices or apps? (If the individual/s do not use any wearable epilepsy monitoring devices please proceed to question 6). If they do, i) please tell us (if you know) which devices or apps they use.)

Seven (of 36) responses from individuals reported currently using monitoring devices, four (of 14) carers and nine (of 11) healthcare professionals reported caring for individual who are currently using monitoring devices, such as smartphones, medical wristbands, smartwatches, and armbands.

"I wear a medical ID bracelet and also have all my medical history on my phone for emergency purposes" P10.

"I have a Samsung watch galaxy 3 with a medical app on but not sure about it and not sure if good" P35.

"Yes. Empatica Embrace" C01.

"Seizario; connected to a Careline" C08.

"Seizario app, Embrace Empatica watch and apps, Epihunter, NightWatch" H03.

"Various - some have PulseGuard which they have bought privately or fall alarms" H06.

xii. **Stopped using the devices or apps (Q.** Please tell us of any reason you know why they stopped using the devices or apps (Please select all that apply))

Eight (of 36) individuals, five (of 14) carers and six (of 11) healthcare professionals responded. Some of the reasons mentioned for no longer using the device/app were because the device broke or stopped working, it generated falls alarms and the device was too slow at detecting

seizures, as shown in Figure 6.7. Two (of 36) individual reported other reasons they stopped using the devices/apps as shown below.

".....The council stopped funding it because I was moving away" (P14).

"The ambulance people didn't relise its (sic) for them" (P35)

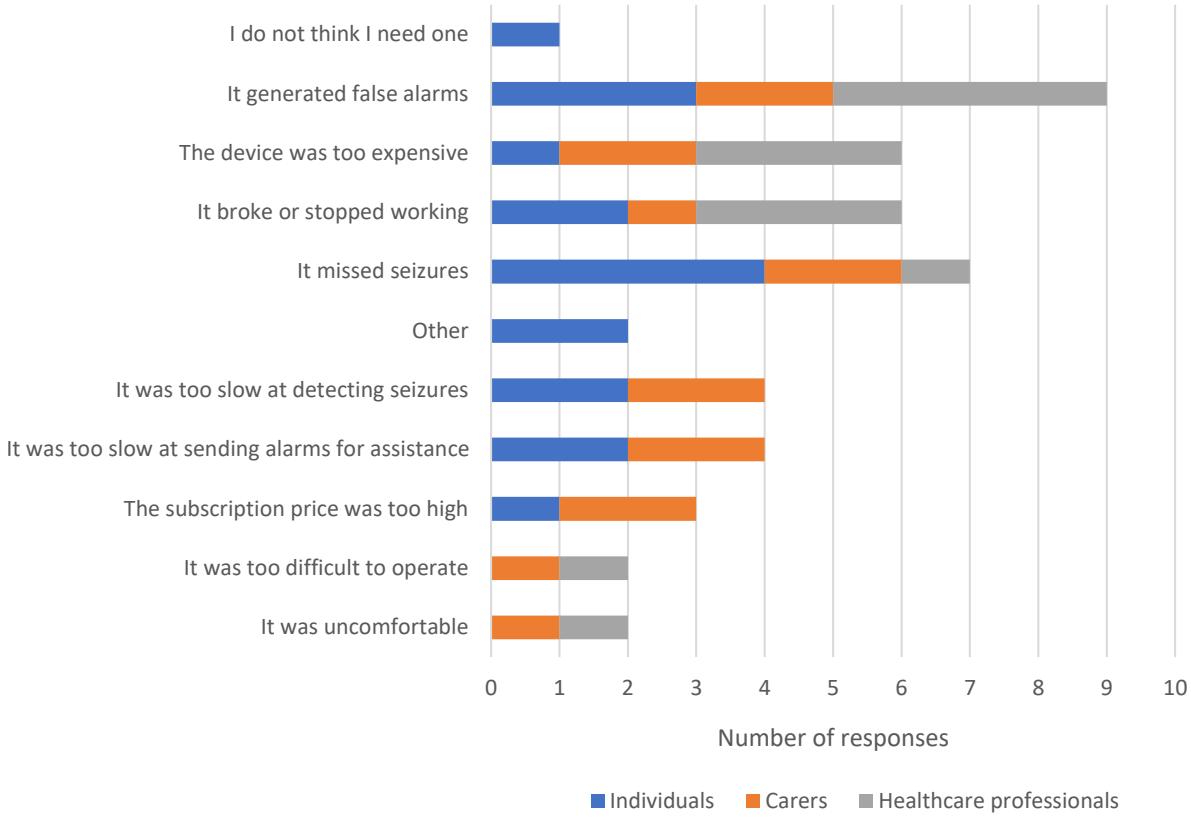


Figure 6.6: Reasons reported for stopping use of device/apps (Total of 19 respondents, 8 individuals,5 carers and 6 health professionals).

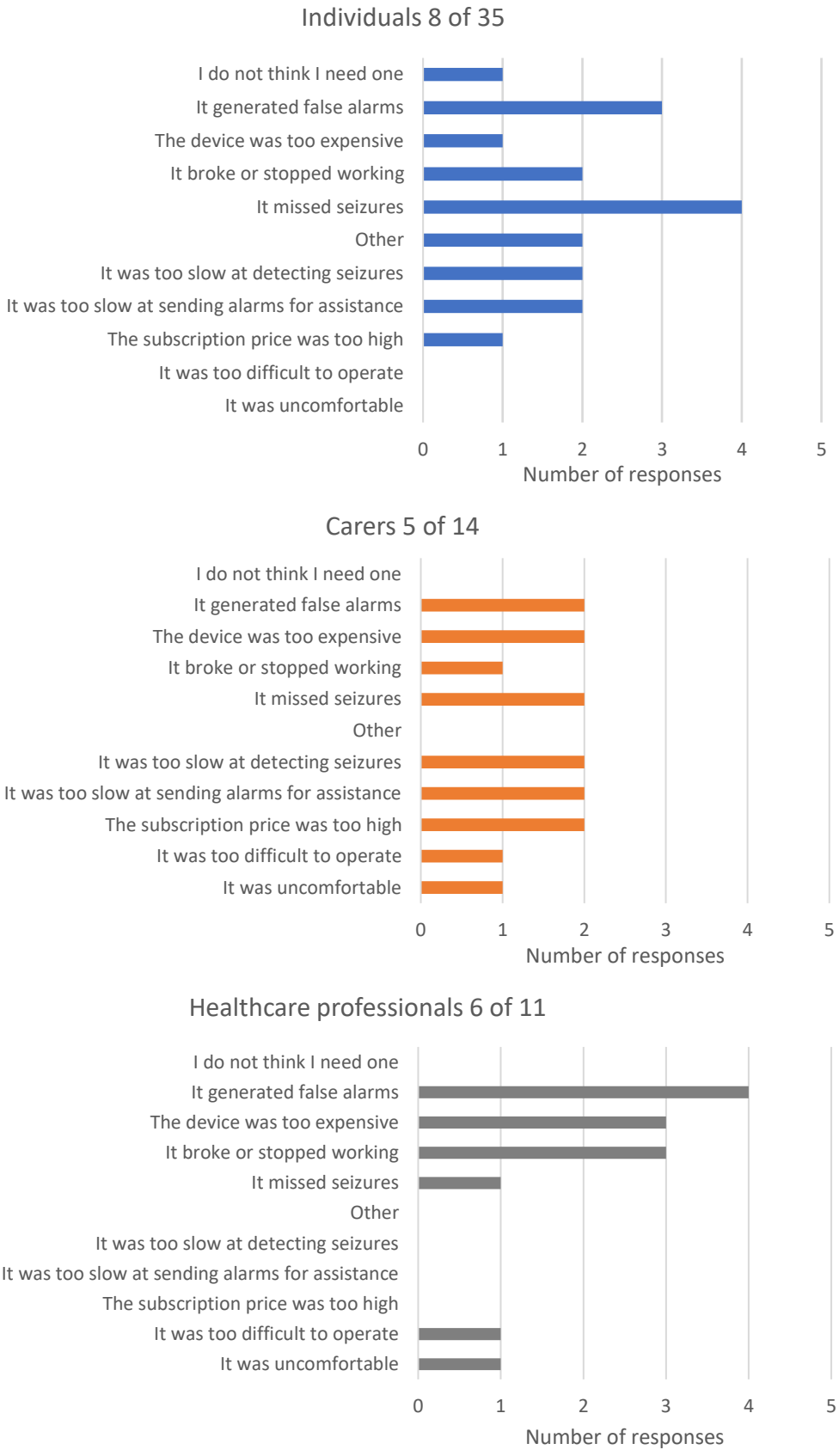


Figure 6.7: Reasons reported for stopping use of device/apps (Total of 19 respondents, 8 individuals,5 carers and 6 health professionals (separated according to survey))

xiii. False Alarms (**Q.** We are particularly interested in false alarms. Please share any opinions or experiences you may have with false alarms).

Concerns were expressed about false alarms 18 (of 61) responses made reference to false alarms, being, stressed, worrying and annoying, as the examples listed below,

"It was very sensitive and went off every time I got on the bus" P14.

"It's annoying because when you do have a seizure it doesn't' always pick it up or if it does then sometimes people dismiss it as the alarm screwing up" P25.

"In a false alarm, the user can ring the recipient or where they haven't noticed, the recipient may phone the user. There have been a couple of false alarms where the app has just appeared to send a text for no reason. But we would rather have a false alarm than no alarm" C08.

"When my son self-regulated it would go off when he removed due to irritation when the device had moved around his limb when he got up in the night to go to the toilet or eat" C12.

"False alarms are mostly associated with bed sensors rather than wearables. Epihunter might detect numerous subclinical seizure activity and for some patients, this might be quite stressful" H03.

"We have occasional false alarms on bed monitors, but most parents would rather have one of those than miss a seizure" H11.

xiv. The benefit of having seizures monitored (**Q.** In your opinion, what is the benefit of having seizures monitored by wearable epilepsy monitoring devices or apps (please select all that apply))

Twenty-eight (of 36) individuals, all 14 carers and all 11 healthcare professionals responded, they reported different benefits to have their seizures reported, as shown in Figure 6.8.

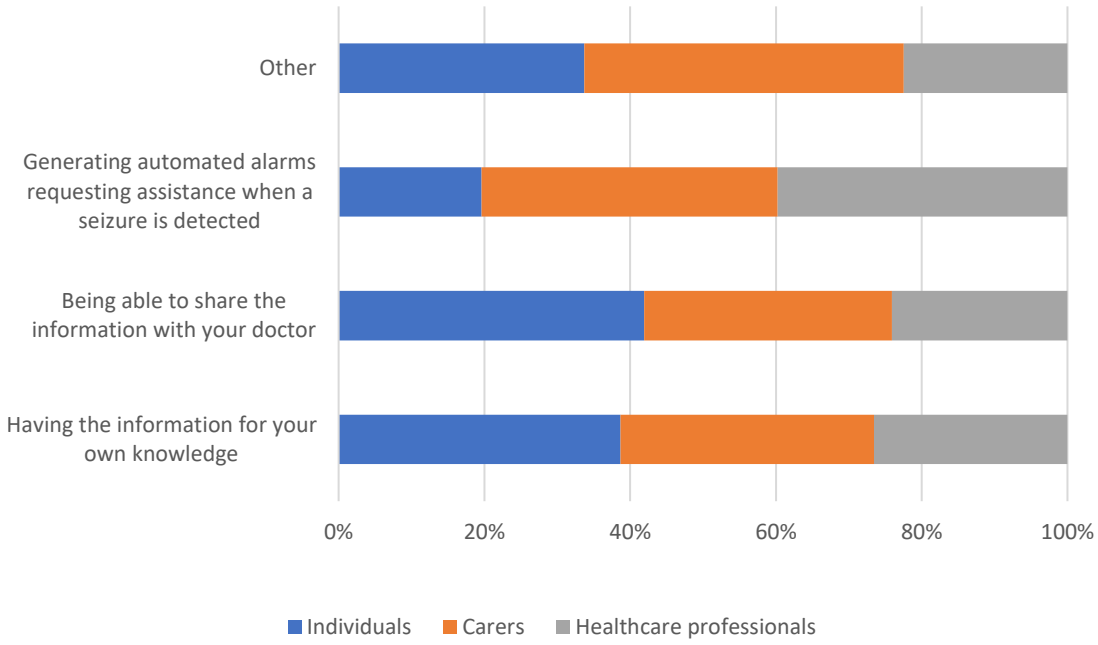


Figure 6.8: Summary of 53 of 61 responses for the benefits of having seizures monitored by wearable epilepsy monitoring devices (outer max 100%).

xv. Currently used non-wearable epilepsy monitoring devices (**Q.** Please tell us about any non-wearable epilepsy monitoring devices (like mattress sensors) that the individuals with epilepsy CURRENTLY use)

One (of 36) individual responded saying they use anti-suffocation pillows. Two (of 14) carers responded saying the individuals they care for use anti-suffocation pillows and bed alarms. Seven (of 11) healthcare professionals reported caring for individuals who use different types of non-wearable devices such as mattress sensors, fall alarms, alert mats, and audio monitoring devices.

"I use anti suffocation pillows so that I'm safe during bed and I also have adapted lights so that I can eliminate strong lights" P02.

. "I have just ordered a bed alarm as my daughter has had cluster seizures and we have been told she could have tonic-clonic" C02.

"They currently use anti suffocation pillows" C04.

"Brio, NightGuard, bed movement sensors, audio monitoring, CCTV" H03.

"most families of children with nigh-time seizures have a mattress sensor. These are available via a charity. The family self refers to apply" H09.

6.4.5. PSSUQ for 11 (of 36) individuals' responses.

Figures 6.9 summarises the 11 (of 36) individuals' responses, indicating a wide spread of opinions and a significant amount of dissatisfaction. There is a low level of satisfaction and a significant amount of strong dissatisfaction, a strong dissatisfaction particularly for the effectiveness of information quality. The response shows a much higher degree of satisfaction with liking the monitoring device, interface quality.

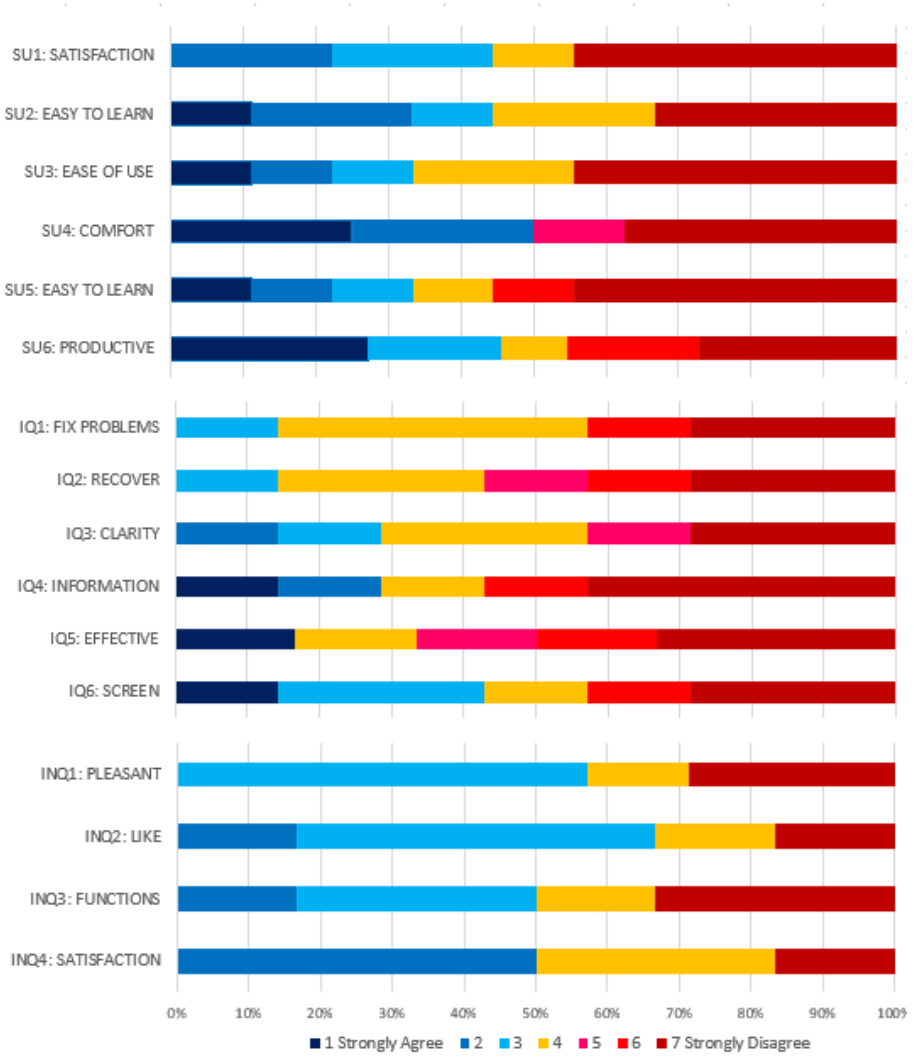


Figure 6.9: Summary of 11 (of 36) individuals PSSUQ responses for System Usefulness (SU), Information Quality (IQ) and Interface Quality (INQ).

6.4.6. PSSUQ for seven (of 14) carers responses

Figure 6.10 summarises the seven (of 14) carers responses, indicating a wide spread of opinions, half of the carers being satisfied, and half being dissatisfied. The carers indicated a higher level of satisfaction for the system usability and a fair satisfaction for information quality and interface quality. The details of the carers' responses are included in the appendix.

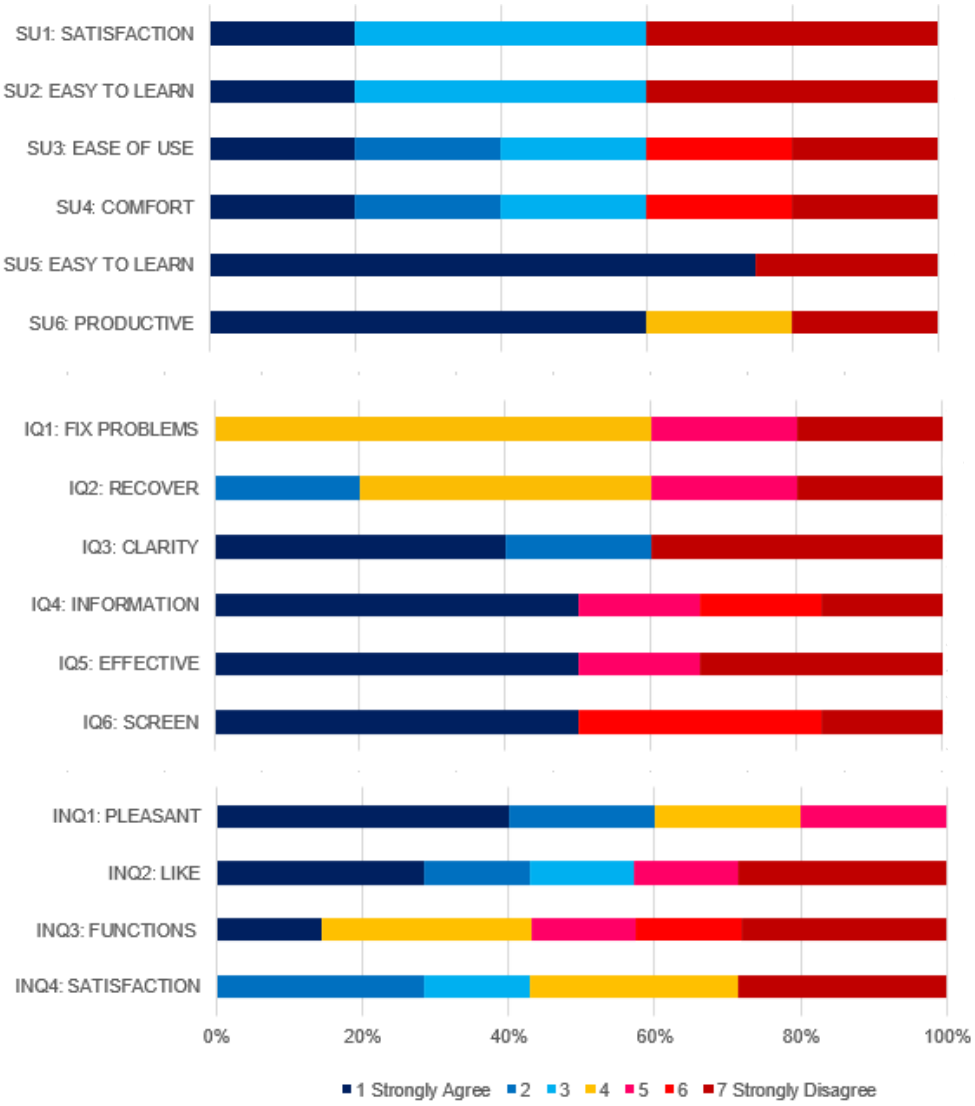


Figure 6.10: Summary of seven (of 14) carers PSSUQ responses for System Usefulness (SU), Information Quality (IQ) and Interface Quality (INQ).

6.4.7. PSSUQ from four of 11 healthcare professionals' responses

The responses from four (of 11) healthcare professionals for system usefulness indicated a wide spread of options and a fair amount of dissatisfaction. The responses presented a significant dissatisfaction for the information quality, clarity and interface quality, functions, as shown in Figure 6.11. The results of the healthcare professionals' responses are included in the appendix.

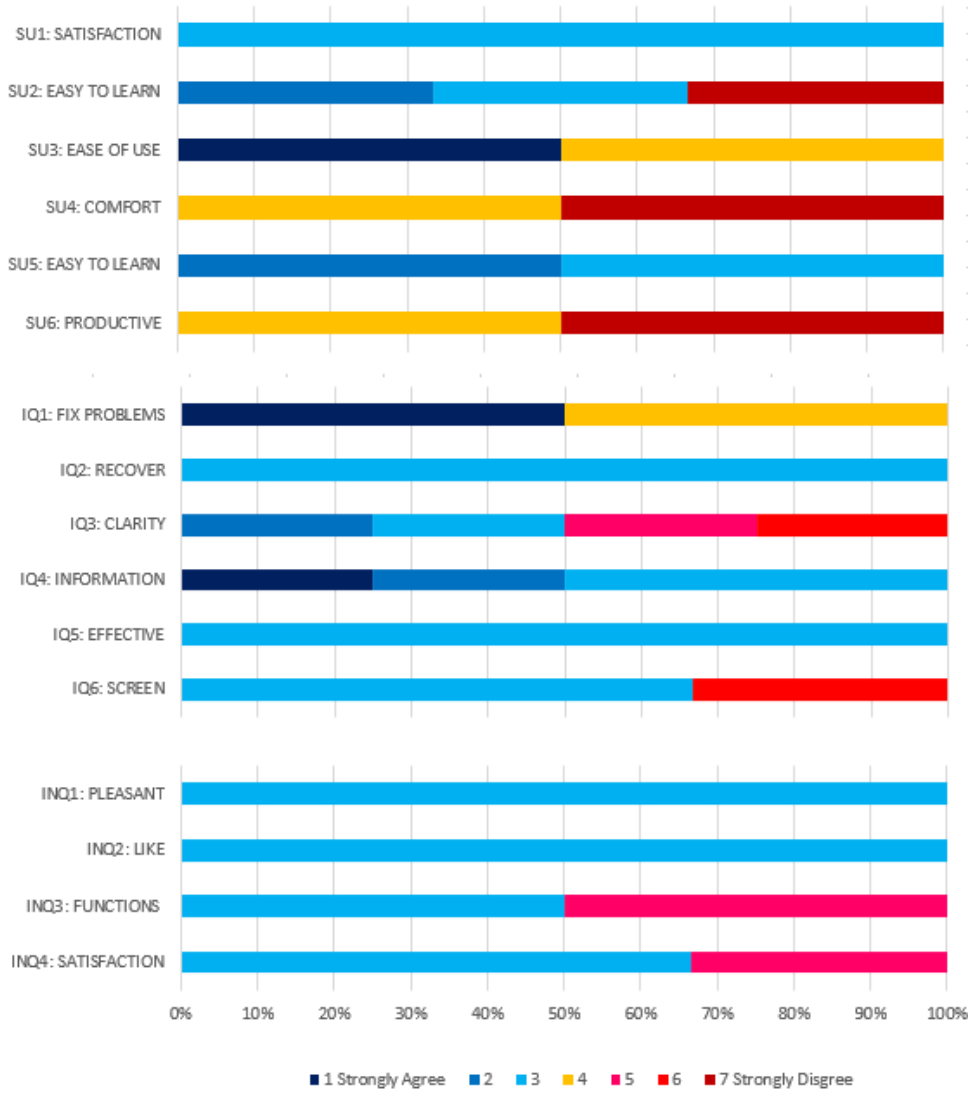


Figure 6.11: Summary of Four (of 11) healthcare professionals PSSUQ responses for System Usefulness (SU), Information Quality (IQ) and Interface Quality (INQ).

Summary PSSUQ Scores

Table 6.3 lists the mean and standard deviation (SD) PSSUQ scores. As shown, individuals' overall PSSUQ mean score of 4.58 indicates less satisfaction than the "neutral" value of 4. The component scores of 4.55, 4.83 and 4.11 indicate mild dissatisfaction and neutral opinions for system usefulness and information quality and interface quality, respectively.

The carers' overall mean PSSUQ score of 3.78 indicates mild satisfaction close to neutral. The responses indicated slightly more satisfaction amongst carers than individuals. System usefulness achieved the lowest (best) satisfaction of 3.59 from carers whereas the most satisfaction amongst individuals was interface quality. Both individuals and carers agreed that information quality was the least satisfying aspect.

The healthcare professionals' overall PSSUQ mean of 3.49 suggests mild satisfaction close to neutral with information quality the most satisfying aspect. However, with only four responses from healthcare professionals, it would be inappropriate to make conclusions.

Table 6.3: Individuals, carers, and healthcare professionals PSSUQ scores by subscale.

Scale	Individuals (n=11) Mean (SD)	Carers (n=7) Mean (SD)	Healthcare professionals (n=4) Mean (SD)
System usefulness **(SU1 – SU6)**	***4.55 (2.32)***	3.59 (2.53)	3.79 (1.93)
Information quality **(IQ1 – IQ6)**	***4.83 (1.95)***	3.91(2.47)	3.20 (1.52)
Interface quality (**INQ1 – INQ4)**	***4.11 (1.85)***	3.84 (2.32)	3.50 (0.93)
Overall	**4.58 (2.11)**	**3.78 (2.43)**	**3.49 (1.57)**

Abbreviation: SD: Standard Deviation.

6.4.8. Additional comments and suggestions from respondents

The last question of the three questionnaires sought any additional comments and suggestions from respondents. The responses show a diversity of opinions. Below are some of responses examples from the individuals, carers, and healthcare professionals reported about the wearable epilepsy monitoring devices,

> *"It kept a record of a very nasty night of status epilepticus where I had 6 seizures and no regaining of consciousness in between." P24.*
>
> *"If there was something else, I could use I would try it as long as it's affordable but until then I'm just stuck." P25.*
>
> *"That the devices can seem good on paper. But they are so expensive that my partner wouldn't get one. If it was (sic) recommended by his doctor, he would probably use one." C05.*
>
> *"Are there any that detect focal epilepsy where there are no falls, but the recipient might eg (sic) bite their tongue or suffer absences/confusion." C08.*
>
> *"Need to be affordable, reliable, easy to use with a backup plan when they break. Try before you buy would be good." H06.*
>
> *"The main benefit appears to be, that they provide reassurance and confidence for the family, that a seizure can be detected. Taking away the daily anxiety around the unpredictability of a seizure." H09.*

6.5. Discussion and Conclusion

The survey was limited to a total of 61 responses, only 11 of which were healthcare professionals and 14 carers. The questionnaire was active during the COVID19 lockdown, and it is expected that this had an impact on the number of responses. The lockdown also meant that there were no opportunities to engage with individuals and healthcare professionals.

Nineteen of the 61 participants responded to the question about stopping the use of monitoring devices/apps. The most reported reason was the generation of false alarms (9 responses) followed by missed seizures (7 responses), and device failure (6 responses) and expense (6 responses).

The mean and standard deviation PSSUQ scores were calculated from survey respondents with experience of using wearable epilepsy monitors or receiving alarm or alert message. These included 11 of 36 individuals, 7 of 14 carers, and 4 of 11 healthcare professionals. The results, summarised in Table 6.3, indicate that mean levels of satisfaction were close to neutral (close to 4 on a scale from 1=strongly satisfied to 7=strong dissatisfied); slightly below neutral for individuals and slightly neutral above for carers and health professionals, but with quite a large spread of opinions indicated by individual and carer standard deviations greater than two.

This empirical study addressed RQ4: What are user and stakeholder opinions and experiences of wearable devices for epilepsy seizure monitoring? The results provided insights into a range of concerns from stakeholders and identified mixed levels of satisfaction in device performance both within and between stakeholders. These findings have implications for the design of future devices and can inform and prioritise future designs.

Overall, survey responses indicate that stakeholders have mixed opinions of the wearable epilepsy seizure monitors, and a degree of concern, particularly in terms of reliability, false alarms and missed seizures. However, wearable epilepsy monitoring technology is still evolving, and it is not unusual for early adopters to be disappointed by the performance of early systems.

In the next chapter, conclusions and further research recommendations are summarised.

CHAPTER 7
CONCLUSIONS AND FURTHER RESEARCH

7.1. Introduction

The overarching aim of this research was to contribute toward future wearable epileptic seizure monitoring and to the literature evaluating these devices. This chapter reflects on the research questions and the methodologies used as well as the study outcomes and implications. These reflections are structured according to each of the four research questions. The chapter concludes with conclusions and recommendations for further research.

7.2. Reflections Related to Research Question One (RQ1)

RQ1: What evaluation evidence for available wearable epilepsy seizure monitors is reported in the academic literature?

- RQ1.1: What evaluation data is reported?
- RQ1.2: What methods are used?

The first research question (RQ1) underpinned the direction of the systematic literature review. The sub-questions further focused the aims of the review toward the specifics of reported evaluation data and the methods used for reported studies.

Performing the systematic literature helped to define the research direction by identifying gaps in the field that motivated and informed the empirical studies. The review itself was challenging because of the rigour required by the PRISMA systematic review process and because of the large number of papers that required inspection for the sift stage. However, on reflection, the systematic review methodology worked well in terms of motivating and underpinning subsequent research and empirical studies. The implications of the review findings are significant. The lack of evaluations in the literature and the paucity of reported data mean that clinical and health technology communities are uninformed and unguided in their efforts toward technology advances and future clinical studies and applications.

7.3. Reflections Related to Research Question Two (RQ2)

RQ2: How accurate and reliable are the wearable sensors used for epilepsy seizure monitoring?

The second research question (RQ2) informed the direction of the first empirical study exploring device performance. This research question was motivated by the finding of the literature review which identified a lack of evaluation studies in the literature.

The experimental methodology of directly comparing wrist-worn PPG heart rate with chest strap ECG heart rate has been used in other device evaluation studies [Takacs et al., 2014].

Acquisitions from *both* treadmill walking and 12-hrs free-living have also been published in prior work [Collins et al., 2019] but had not been reported for a data streaming wearable (nor an epilepsy monitoring device). The data collection process, particularly for the 12-hrs free-living, was challenging because of repeated difficulties maintaining the connectivity of the data-streaming E4, for example, when participants moved out of range of the smartphone. The COVID19 pandemic also affected the study and limited opportunities for repeating recording attempts.

The exploration of rhythmic movement effects attempted during this study was not pursued beyond the initial investigation but was reported in the thesis for completion. The investigation demonstrated that false alarms do occur during everyday types of rhythmic movements like wiping one's shirt, shaking a bottle, fanning motions with hands, and tapping a pen. However, the difficulty of replicating precise choreographed movements across participants (i.e., the problem of controlling the experiment) proved challenging and for this reason further investigation of false alarms and heart rate accuracy during rhythmic movements was not pursued. On reflection this outcome might have been foreseen, however, the investigation did provide some meaningful insights into the practicalities of seizure sensing and, for example, the potential latency of alarm messages.

Overall, on reflection, the study succeeded in demonstrating accuracy failings of PPG heart rate estimation during activity that would, for example, explain failures in investigations relying solely on PPG-acquired estimates during motor seizures. Unfortunately, researchers may assume better performance of wearable PPG heart rate estimation, and particularly of medical grade data streaming wearable devices like the E4. The implication of this is that future studies may include data of low accuracy, and datasets that incorporate low accuracy data may be generated and reused. There is scope for improvements both in device performance and understanding of device accuracy amongst system designers, researchers and health professionals.

7.4. Reflections Related to Research Question Three (RQ3)

RQ3: To what extent do wearable user interface designs affect usability?

The third research question (RQ3) was motivated by the lack of seizure monitor evaluation studies and wearable user interface design studies in the literature. This research question informed the direction of the second empirical study evaluating the wearable user interface design of the Empatica Embrace.

There is very little evaluation of wearable interfaces in the literature, this made the study design decisions challenging. The methodology adopted comprised two components, i) an innovative experimental assessment of the guessability of each interface state, and ii) a heuristic evaluation based closely on Jakob Nielsen's User Interface Design Heuristic Evaluation which is more usually used for non-wearable interface design evaluations of mobile and desktop apps.

The COVID19 pandemic also affected this study and limited opportunities for recruiting more participants. On reflection the study methodology succeeded in evaluating aspects of the

usability of the user interface, for example, on one hand recognizing the simplicity, clarity, and potential memorability of the display and, on the other, identifying concerns about the reliance on recall and the potential for confusion about the device state communication. The implications of the findings are that individuals and caregivers (including, for example, colleagues and co-workers) may fail to identify important device communications such as a seizure event detected. There is scope for improvements in wearable interface designs and improved understandings amongst system designers, researchers, and health professionals about the usability of these wearable interfaces.

7.5. Reflections Related to Research Question Four (RQ4)

> RQ4: What are user and stakeholder opinions and experiences of wearable devices for epilepsy seizure monitoring?

The fourth research question (RQ4) informed the direction of the third empirical study exploring stakeholders' experiences and opinions on wearable epilepsy seizure monitors. This research question was motivated by the lack of qualitative assessments and evaluations based on stakeholder opinions and real-world experiences of devices, as identified in the systematic literature review.

The methodology comprised a survey (delivered via Epilepsy Action) of stakeholders' experiences and opinions of wearable devices and a PSSUQ usability questionnaire. The PSSUQ is a popular and well-established post-study usability questionnaire that had been used by one of the qualitative seizure monitoring studies identified in the systematic review [Meritam et al., 2018].

The methodology worked well, and the support of Epilepsy Action was very beneficial. On reflection preparation for this study could have started earlier to allow more time for the ethics and permission processes for both the university and Epilepsy Action charity, as well as for the preparation of the three separate questionnaires. Initiating the survey before studies one and two would have allowed more time for preparation and processes, and also more time for acquiring stakeholder responses. However, given the COVID19 pandemic and the significant challenges faced by all healthcare professionals, it was pleasing that the survey achieved 11 healthcare professional responses and an overall total of 61 stakeholder responses.

The findings provided insights into a range of concerns from stakeholders and identified mixed levels of satisfaction in device performance both within and between stakeholders. These findings have implications for the design of future devices and can inform and prioritise future designs.

7.6. Conclusions

The main conclusions from the research are summarised in this section.

The systematic literature review demonstrated a lack of evaluation of available wearable seizure monitoring devices, a lack of details in reported studies, a lack of qualitative studies and a lack of evaluations based on real-world use of devices. Across the reviewed works there was a lack of full detail, including details required to establish important metrics such as sensitivity, specificity, and false alarm rates. Ideally, future seizure sensing systems and algorithms would benefit from detailed qualitative and quantitative assessments of wearable epilepsy seizure device performance. However, clinical, and free-living assessments of wearable epilepsy device performance, require investments in time and resources, their timescales are at odds with the iterative updating of digital technologies, and they present additional difficulties in terms of truth data.

The first empirical study demonstrated a lack of wearable heart rate accuracy during activity. In the absence of motion artefacts, PPG heart rate estimates may perform reliably and may be used, for example, to detect 'preictal' epileptic seizure onset heart rate variations. However, researchers should be aware that attempting to detect heart rate variations during activity or during a motor seizure could produce unreliable results as it did for Vandecasteele et al. [2017]. Despite these challenges, wearable epilepsy seizure detecting devices offer important opportunities to reduce injuries and save lives. However, researchers using data streaming research and medical-grade wearables should be aware of device performance during periods of activity and should be cautious regarding the accuracy of wearable heart rate datasets acquired during activity.

The second empirical study, interface evaluation, demonstrated confusions and concerns about interface display indications. The conclusion of this study was that there is a need for clearer and more intuitive interface designs for wearable seizure monitors, particularly for devices used in critical health monitoring scenarios with different wearer user and non-wearer user stakeholders.

The findings from the third empirical study, surveying epilepsy stakeholders, demonstrated mixed opinions of wearable epilepsy seizure monitors and a degree of concern about missed seizures and dissatisfaction about false alarms that leads to some individuals abandoning use of the devices. Most individuals reported that having seizure information for themselves and to share with their doctor was beneficial, but far fewer reported automated alarms as beneficial. In contrast healthcare professionals felt that sharing data about seizures was less beneficial but both carers and healthcare professionals felt that automated alarms were beneficial.

In terms of stakeholder levels of satisfaction based on experience, the satisfaction of individuals was lower than that of carers and healthcare professionals. Of course, wearable epilepsy monitoring technology is still evolving, and it is not unusual for early adopters to be disappointed by the performance of early systems. However, the opinions and experiences of stakeholders and early adopters are important to the evolution of better systems, and is, currently, lacking in the literature.

Reflecting on the study outcomes and their connected contributions to the overall aim of the research: In reflecting on the research as a whole, the overarching aim to contribute toward future wearable epileptic seizure monitoring was underpinned by the systematic literature review that identified i) a lack of device performance evaluations in the literature and a lack of consistent and complete data reporting, and ii) a lack of evaluations based on real-world stakeholder opinions and experiences. The first and second empirical studies contributed directly to i) with assessments of device heart rate acquisition and interface design. The third and final empirical study contributed to ii) with insights into a range of opinions, concerns and priorities from stakeholders and identifying mixed levels of satisfaction in terms of device performance. The studies can also be seen as evaluations of wearable seizure monitors from the inside out, that is, from an evaluation of the internal heart rate sensor performance, through to an evaluation of the physical device interface and, further beyond, to the opinions and experiences of stakeholders.

Contribution to future digital healthcare design: The findings of this thesis contribute to the digital healthcare design community by i) highlighting the lack of evaluation studies (which may itself motivate further investigations), ii) increased awareness of the inaccuracy of optically sensed heart rate during movement and the importance of accuracy for seizure detection using wearable epilepsy seizure monitors, iii) informing the design of future wearable interface designs and providing a guessability method to identify the meaning of displayed states, iv) informing future designers and developers of stakeholder opinions, concerns and levels of satisfaction about wearable epilepsy seizure monitors.

7.7. Recommendations for Further Research

Further research is needed to contribute towards the performance, reliability, and usability of wearable epileptic seizure monitoring devices. The following further research recommendations are proposed based on the results presented in this thesis.

Currently there is a lack of evaluation information in the literature. Further evaluations of available seizure monitors are recommended. Ideally, these studies will also report more complete details about data quality and device performance and provide more detailed information about assessments, including device model and version numbers as well as detailed contextual information about the wearers and their activity.

Future investigations need to be conducted into wearable epilepsy seizure monitor performance for non-motor seizures such as absence seizures. Ideally, future work should also include an evaluation of the intrinsic performance of wearable epilepsy seizure monitors and improving wearable epilepsy seizure monitors sensing performance for diverse cohorts of users.

Further research is also recommended for the design of interface displays for wearable seizure monitors (and other critical health monitoring devices), so that the displays are more intuitive and understandable. Ideally this will involve usability studies with significant cohorts of representative stakeholders.

Additionally, there is much scope for further research evaluating available wearable seizure monitors. In particular, further qualitative studies are recommended for eliciting stakeholder opinions and experiences from real-world experiences of device usage.

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APPENDIX

Appendix A: Study One:
Appendix A.1: The version details for the devices used in the experiment.
Appendix A.2: Ethical documentation (approval, participant information, consent form).

Appendix B: Study Two:
Appendix B.1: The ethical documentation (approval, participant information, consent form).
Appendix B.2: Questionnaire.

Appendix C: Study Three:
Appendix C.1: The ethical documentation (approval, participant information, consent form).
Appendix C.2: Questionnaires for individuals with epilepsy, carers, and healthcare professionals.

Appendix D: Papers

- **Appendix D.1:** The International BCS Human-Computer Interaction Conference
- **Appendix D.2:** Evaluation of Wearable Electronics for Epilepsy: A Systematic Review
- **Appendix D.3:** IEEE/ACM International Conference on Connected Health: Applications, Systems and Engineering Technologies (CHASE)
- **Appendix D.4:** Ubiquitous Computing/ International Semantic Web Conference

Appendix E: Posters

- **Appendix E.1:** IEEE/ACM International Conference on Connected Health: Applications, Systems and Engineering Technologies (CHASE)
- **Appendix E.2:** Ubiquitous Computing/ International Semantic Web Conference (UBICOMP/ISWC)

Appendix A: Study One: Heart Rate Performance

Appendix A.1: The version details for the devices used in the experiment

The Embrace wristband version EMB-MB-S, data acquired via Alert app version 2.1.1 and Mate app version 4.3.7.

The E4 wristband version SP069-B-20150001, data acquired via E4 real-time app version 2.1.1 (8202) and E4 Manager version 2.0.3 (5119).

The treadmill was an h/p/cosmos Pulsar treadmill, h/p/cosmos Sports & Medical Gmbh, Nussdorf Traunstein, Germany. (cos100420b; ID: X239W80479043; OP19: 0319 1139).

The Polar H10 chest heart rate monitor (FCC ID: INW1W; Model: 1W; IC: 6248A-1W; SN: C7301W0726005; ID: 14C00425; Firmware: 2.1.9 and data acquired via Polar Beat 2.5.3.

Appendix A.2: Ethical documentation

Approval

Keele University FNS Non-psychology Faculty Research Ethics Committee

naturalsciences.ethics@keele.ac.uk

6th March 2020

Dear Tendai,

Project Title:	Wearable User Interface Evaluation
REC Project Reference:	NS-200058
Type of Application	Main application

Keele University's Faculty of Natural Sciences Non-psychology Research Ethics Committee reviewed the above project application.

Favourable Ethical opinion
The members of the Committee gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Conditions of the favourable opinion
The favourable opinion is subject to the following conditions being met prior to the start of the project.

1.	NONE

Reporting requirements
The University's standard operating procedures give detailed guidance on reporting requirements for studies with a favourable opinion including:

- Notifying substantial amendments
- Notifying issues which may have an impact upon ethical opinion of the study
- Progress reports (where required)
- Notifying the end of the study

Approved documents
The documents reviewed and approved are:

Document	Version	Date
Application form	2	06/03/20
Consent form	2	06/03/20
Participant information form	2	06/03/20

Yours sincerely,

Professor Clare Holdsworth
Lead Reviewer

Participant Information Sheet

Information Sheet

Wearable Technology Evaluation

Invitation

Keele University students and staff are invited to take part in the research study. The research will be undertaken by Computer Science researchers in the Centre for Computer Science Research at Keele University. The research is undertaken by PhD researcher Tendai Rukasha (lead supervisor Dr S Woolley and co-supervisor Dr T Kyriacou).

Please take time to read this Information Sheet carefully and if there is anything that is unclear and needs further explanation please do get in touch, the contact details are at the end of the information sheet.

Aims of the Research

The aim of the research is to evaluate the E4 wristband, a commercial wearable technology used to record physiological signals.

This research will further help epileptic seizure prone individuals to avoid dangerous and embarrassing seizures episodes that will be of harm to themselves as well as other individuals around them.

Why have I been invited?

As students'/staff members at Keele University, you have been invited to participate in a research study based in the Centre for Computer Science Research. Keele University staff/students are more accessible to the research; this is why you are being invited to participate in the research.

Do I have to take part?

Participating in this assessment will not affect the participants' daily life as well as their studies, this is completely voluntary. If you do decide to take part, you will be provided with information and instruction handbook regarding the wristband. There will be advice and instructions on how to use the wristband and discussing the specific events that should be recorded down by each participant regarding their daily activities.

Information sheet for recording daily events, general specifications and additional information, will be required and should be filled in the daily log.

You will have an opportunity to ask questions and, if you are satisfied to proceed, you will be asked to sign a consent form. You will be free to withdraw from this study without giving reasons. If you elect to withdraw you will have to notify the researcher 2 weeks after participation and your data will be withdrawn and destroyed.

What will happen if I take part?

Participation will involve wearing 4 E4 wristbands and complete a brief questionnaire at the end of the assessment, for recording age range, height, weight, perceived fitness, physical activity level and general comments. You will also be asked to attend a 10-15 min interview and complete a daily log that you will be provided with.

Participation will also involve wearing a Polar H10 pro chest strap for 30min whilst walking on the treadmill.

What are the benefits (if any) of taking part?
The assessment will assist in Keele future research work, the ethical approval process and in advancing the quality effectiveness and efficiency of sensor technology for epileptic seizures. Participating in this assessment will not affect the participants' daily life as well as their studies, this is completely voluntary.

What are the risks (if any) of taking part?
There are no risks expected from the use of the commercial, Empatica E4 wristband and the Polar H10 pro chest strap, however, if you were to experience any discomfort or have any concern at all regarding the E4 wristband and the Polar H10 pro chest strap, you must immediately discontinue use. The commercial, Empatica E4 wristband is completely risk assessed and has a CE certification for health, safety and environment and FCC certification for electromagnetic interference from the device under limits. In the event of any abnormal recordings that may indicate a possible health condition, you will be provided with all your data and advised to discuss these with your GP.

How will information about me be used?
The recordings gained from the E4 wristband app (real-time app) and the Polar H10 pro chest strap app (Polar beat app) and all completed questionnaires, interview answers and the daily log will be held securely, as required by research processes, for a minimum of five years.

Who will have access to information about me?
All information obtained during the assessment will remain confidential. All participant names will be replaced with numerical identifiers and all data will be anonymous in publication. The recordings gained from the E4 wristband, Polar H10 pro chest strap and all completed questionnaires, interview answers and daily log/diary will be held securely, as required by research processes. All personally identifiable data will be destroyed after a minimum of five years. Only the Centre for Computer Science Research lead supervisor and co-supervisor will have access to the study data. Any paper records will be stored in a locked filing cabinet and all electronic data will be stored on secure, password protected drives.

Who is funding and organising the research?
This phase of the research is unfunded.

What if there is a problem?
If you have a concern about any aspect of this study, you may wish to speak to the principal researcher who will do their best to answer your questions. You should contact the principal investigator, T Rukasha t.rukasha@keele.ac.uk. Alternatively, if you do not wish to contact the principal investigator you may contact the lead supervisor Dr S I Woolley s.i.woolley@keele.ac.uk or co-supervisor Dr T Kyriacou t.kyriacou@keele.ac.uk

PLEASE NOTE: E4 IS NOT WATERPROOF, PLEASE TAKE EXTRA PRECAUTION WHEN HANDLING LIQUIDS WHILST WEARING THE E4

Consent Form

CONSENT FORM

Wearable Technology Evaluation

Name and contact details of Principal Investigator: Tendai Rukasha, School of Computing and Mathematics, Keele University, ST55BG. Email: t.rukasha@keele.ac.uk

As a student/staff at Keele University, you have been invited to participate in this study. You should only participate if you want to. Participation is voluntary and will be of no advantage or disadvantage to your studies. Before you decide whether you want to take part, please take time to read the Information Sheet, listen to the instruction regarding the use of the systems and please ask if there is anything that is not clear or if you would like more information.

Please tick the box if you agree with the statement

1. I have read and understood the Information Sheet and have been provided with an opportunity to ask any questions.

2. The nature of the research has been explained to my satisfaction. I understand what is expected of me and any questions I had have been answered to my satisfaction.

3. I understand that if I experience any discomfort, I will immediately discontinue its use.

4. I understand that if I decide that I no longer wish to participate in this project, I can notify the researchers up to 2 weeks after participation and my data will be withdrawn and destroyed.

5. I consent to the processing of my data for the purposes of this research study and for its use in anonymized form in the dissemination of study findings and in research publication.

6. I understand that recorded data will be stored in electronic format. All information relating to this study is to remain confidential and it will only be used for the research. I understand that all data will be preserved for a minimum of 5 years in accordance with research requirements.

_____	_____	_____
Name	Date	Signature

_____	_____	_____
Name	Date	Signature

Appendix B: Study Two: Interface Evaluation

Appendix B.1: The ethical documentation

Approval

Keele University FNS Non-psychology Faculty Research Ethics Committee
naturalsciences.ethics@keele.ac.uk

Keele UNIVERSITY

6th March 2020

Dear Tendai,

Project Title:	Wearable User Interface Evaluation
REC Project Reference:	NS-200058
Type of Application	Main application

Keele University's Faculty of Natural Sciences Non-psychology Research Ethics Committee reviewed the above project application.

Favourable Ethical opinion
The members of the Committee gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Conditions of the favourable opinion
The favourable opinion is subject to the following conditions being met prior to the start of the project.

1.	NONE

Reporting requirements
The University's standard operating procedures give detailed guidance on reporting requirements for studies with a favourable opinion including:

- Notifying substantial amendments
- Notifying issues which may have an impact upon ethical opinion of the study
- Progress reports (where required)
- Notifying the end of the study

Approved documents
The documents reviewed and approved are:

Document	Version	Date
Application form	2	06/03/20
Consent form	2	06/03/20
Participant information form	2	06/03/20

Yours sincerely,

Professor Clare Holdsworth
Lead Reviewer

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Participant Information Sheet

PARTICIPANT INFORMATION SHEET

Wearable User Interface Evaluation

Name and Contact Details of Researcher: Tendai Rukasha, t.rukasha@keele.ac.uk

Supervisors: Dr Sandra I Woolley, s.i.woolley@keele.ac.uk and

Dr Theocharis Kyriacou, t.kyriacou@keele.ac.uk

Invitation
As a student or member of staff with user interaction design experience and expertise, we would like to invite you to take part in our research study. Participating in the research study is entirely up to you. Before you decide we would like you to understand why the research is being done and what it would involve for you. The research will be undertaken in the Centre for Computer Science Research at Keele University.

Please take time to read this participant information sheet. If there is anything that is unclear and needs further explanation, please ask.

Research Summary
This study is concerned with wearable user interface evaluation; it is part of a programme of PhD research relevant to wearable devices. The evaluation will take approximately 15-20 minutes of your time.

What is the purpose of the research?
The aim of the research is to evaluate wearable user interface designs, identify usability issues and contribute toward recommendations for future devices.

Why have I been invited?
You have been invited to participate because you are a student or member of staff with user interaction design experience and expertise at Keele University,

Do I have to take part?
Participating in this research study is completely voluntary. If you do decide to take part, you will be requested to respond to the questionnaires, an audio recorder will be used to record their responses and the researcher will complete the questionnaires based on the participants' responses.

What will happen if I take part?
Participation will involve a brief discussion on your use and opinion of wearable devices/trackers and to perform an evaluation of an interface design. An audio recorder will be used to record the participant's responses.

What are the possible disadvantages, burdens and risks (if any) of taking part?
There are no risks expected from taking part in this study.

What are the possible advantages or benefits (if any) of taking part?
Participants will not receive direct personal benefit from participating but society may benefit from advances wearable user interface designs.

Will my data be kept confidential?
No identifying comments will be published. The anonymous responses will be collated and will be made available on request to other researchers for the purpose research towards new technology.

You can find out more about how we use your information
https://www.keele.ac.uk/privacynotices/privacynotice-researchparticipants/ or by contacting the University's Data Protection Officer at dpo@keele.ac.uk.

If you have a concern about any aspect of this research study, you may wish to speak to the researcher Tendai Rukasha t.rukasha@keele.ac.uk. Alternatively you may contact the supervisor Dr Sandra I Woolley s.i.woolley@keele.ac.uk or Dr Theocharis Kyriacou t.kyriacou@keele.ac.uk

Who has reviewed the study?
This study has been reviewed by Keele University Research Ethics Committee (Ethics REC: NS200058).

Thank you
Thank you for taking time to read this information sheet and for considering volunteering for this research.

Consent Form

CONSENT FORM

Wearable Technology Evaluation

Name and contact details of Principal Investigator: Tendai Rukasha, School of Computing and Mathematics, Keele University, ST55BG. Email: t.rukasha@keele.ac.uk

As a student/staff at Keele University, you have been invited to participate in this study. You should only participate if you want to. Participation is voluntary and will be of no advantage or disadvantage to your studies. Before you decide whether you want to take part, please take time to read the Information Sheet, listen to the instruction regarding the use of the systems and please ask if there is anything that is not clear or if you would like more information.

Please tick the box if you agree with the statement

1. I have read and understood the Information Sheet and have been provided with an opportunity to ask any questions.
2. The nature of the research has been explained to my satisfaction. I understand what is expected of me and any questions I had have been answered to my satisfaction.
3. I understand that if I experience any discomfort, I will immediately discontinue its use.
4. I understand that if I decide that I no longer wish to participate in this project, I can notify the researchers up to 2 weeks after participation and my data will be withdrawn and destroyed.
5. I consent to the processing of my data for the purposes of this research study and for its use in anonymized form in the dissemination of study findings and in research publication.
6. I understand that recorded data will be stored in electronic format. All information relating to this study is to remain confidential and it will only be used for the research. I understand that all data will be preserved for a minimum of 5 years in accordance with research requirements.

_____	_____	_____
Name	Date	Signature

_____	_____	_____
Name	Date	Signature

Appendix B.2: Questionnaire

Keele UNIVERSITY

QUESTIONNAIRE

The aim of the research is to evaluate the E4 wristband, a commercial wearable technology used to record physiological signals.

Date:

Reference #:

Age Range

<20 ☐

20-30 ☐

30-40 ☐

40-50 ☐

>50 ☐

Gender

Female ☐

Male ☐

Other ☐

Occupation

Student ☐

Staff ☐

Height (cm)

.....

Weight (kg)

.....

Appendix C: Study Three: Stakeholders Opinion and Experiences

Appendix C.1: The ethical documentation

Approval

Keele University FNS Non-psychology Faculty Research Ethics Committee
naturalsciences.ethics@keele.ac.uk

Keele UNIVERSITY

5th March 2020
Dear Tendai,

Project Title:	A Survey of Stakeholder Opinions and Experiences of Wearable Devices for Epilepsy Seizure Detection
REC Project Reference:	NS-200056
Type of Application	Amendment
Amendment Reference:	NS-200063
Amendment Date:	5th March 2020

Keele University's Faculty of Natural Sciences Non-Psychology Research Ethics Committee reviewed the above amendment.

Favourable Ethical opinion
The members of the Committee gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Conditions of the favourable opinion
The favourable opinion is subject to the following conditions being met prior to the implementation of the amendment:

1.	NONE

Reporting requirements
The University's standard operating procedures give detailed guidance on reporting requirements for studies with a favourable opinion including:

- Notifying substantial amendments
- Notifying issues which may have an impact upon ethical opinion of the study
- Progress reports (where required)
- Notifying the end of the study

Approved documents
The documents reviewed and approved are:

Document	Version	Date
Application form	2	05/03/20
Epilepsy Action research resource application	2	05/03/20
Amendment form	1	05/03/20
Participant information sheet	1	05/03/20

Yours sincerely,

Professor Clare Holdsworth
Lead Reviewer

Participant Information

PARTICIPANT INFORMATION SHEET

A Survey of Stakeholder Opinions and Experiences of Wearable Devices for Epilepsy Seizure Detection

Researcher: Tendai Rukasha, t.rukasha@keele.ac.uk

Supervisors: Dr Sandra I Woolley and Dr Theocharis Kyriacou

Invitation

We would like to invite you to take part in our research study. Participating in the research study is entirely up to you. Before you decide we would like you to understand why the research is being done and what it would involve for you. The research will be undertaken by researchers in the Centre for Computer Science at Keele University.

Please take time to read this participant information sheet. If there is anything that is unclear and needs further explanation please do get in touch, the contact details are at the end of the participant information sheet.

Research summary

This study is concerned with opinions and experiences of wearable devices for epilepsy. We are seeking participants who are people with epilepsy, carers, family, friends, 'alarm receivers'* and healthcare professionals.

Participation in the research would require you to complete an online questionnaire linked from the Epilepsy Action website which will take approximately 15 minutes of your time.

(*i.e., anyone receiving SMS messages or alerts from epilepsy monitoring devices).

What is the purpose of the research?

This research study aims to collect and analyse opinions and experiences of wearable devices that will contribute to the evaluation and future developments of seizure-detecting wearables.

Why have I been invited?

You are invited to participate in this study via Epilepsy Action if you are aged 18 years or older and if you are an individual with epilepsy, a healthcare professional or other epilepsy stakeholders, or a career, family member, friend or colleague of an individual with epilepsy.

Do I have to take part?

Participating in this research study is completely voluntary.

What will happen to me if I take part?

If you do decide to take part, you will be asked to complete an online questionnaire about your epilepsy or that of the individuals in your care/ network and to answer questions about your opinions and any experiences of wearable devices for seizure detection.

Participation will involve completing an online questionnaire linked on the Epilepsy Action website. The questionnaire will take approximately 15 minutes to complete. You will be required to complete the questionnaires by 31 May 2020.

Note: You are welcome to complete more than one online questionnaire. For example, if you are a healthcare professional who has epilepsy, you are welcome to fill out both applicable questionnaires.

What are the possible disadvantages, burdens and risks (if any) of taking part?

There are no anticipated risks associated with completing the online questionnaires.

What are the possible advantages or benefits (if any) of taking part?

Participants will not receive direct personal benefit from participating but society (or a sub-group of society) may benefit from the research contribution toward wearable devices for epilepsy.

Will my data be kept confidential?

No identifying comments will be published. Anonymous questionnaire responses will be collated and will be made available, on request, to other researchers investigating technologies for epilepsy. All data will be stored securely for 10 years in line with Keele University research requirements. You can find out more about how we use your information here https://www.keele.ac.uk/privacynotices/privacynotice-researchparticipants/ or by contacting the University's Data Protection Officer at dpo@keele.ac.uk.

Who has reviewed the study?

This study has been reviewed by Keele University Faculty of Natural Sciences (non-Psychology) Research Ethics Committee (Ethics Reference Number: NS-200056).

Contact information

If you have a concern about any aspect of this research study, you may wish to speak to the researcher Tendai Rukasha t.rukasha@keele.ac.uk. Alternatively, you may contact the supervisor Dr Sandra I Woolley s.i.woolley@keele.ac.uk

If you have a concern or complaint that is not resolved by the researcher or their supervisor, you may elect to contact the approving Research Ethics Committee via their administrator at naturalsciences.ethics@keele.ac.uk (Telephone. 01782 733615).

Thank you for taking the time to read this information sheet and for considering participation in the study.

Appendix C.2: Questionnaires for individuals with epilepsy, carers, and healthcare professionals. Questionnaire for People with Epilepsy Aged 18 and Over

Questionnaire for people with epilepsy aged 18 and over

Keele UNIVERSITY

I am, Tendai Rukasha, a Computer Science PhD candidate at Keele University researching wearable epilepsy monitors. I am supervised by Drs Sandra Woolley and Theocharis Kyriacou.

If you are a person with epilepsy, aged 18 or over, we would really like to know your opinions and any experiences of wearable and non-wearable monitoring devices or apps.

We would be grateful if you would complete this questionnaire. We are looking for your opinions and experiences - we are not asking you to take part in any trials. We welcome all opinions and please feel free to tell us of any experiences that inform your opinions.

The results of this questionnaire will be published and shared with Epilepsy Action. No identifying comments will be published and no quotes from responses will be used without permission. Full participant information details are available.

Note: You are welcome to complete more than one online questionnaire. For example, if you are a healthcare professional or carer who has epilepsy, you are welcome to fill out both applicable questionnaires.

Thank you very much for your help.

Tendai Rukasha (t.rukasha@keele.ac.uk).

ABOUT YOU AND YOUR EPILEPSY

1. Gender

Mark only one oval.

- ◯ Female
- ◯ Male
- ◯ Other: _____

2. Age Range

Mark only one oval.

- ◯ Under 20
- ◯ 20-29
- ◯ 30-39
- ◯ 40-49
- ◯ 50-59
- ◯ 60 and over

3. How long have you had epilepsy? (years). _____

4. What age were you when you received a formal diagnosis of epilepsy? (years). _____

5. Please comment on your fitness and general level of activity, e.g., "regular desk working with occasional walking and jogging" or "intermittent vigorous work and regular gym/football" or "regular moderate activity such as gardening and housework". _____

6. What types of seizure have you had in the last 5 years? (Please select all that apply). _____

Tick all that apply.

- ☐ Tonic
- ☐ Clonic
- ☐ Tonic-clonic
- ☐ Myoclonic
- ☐ Atonic
- ☐ Absence
- ☐ I haven't had any
- ☐ I am not sure
- Other: ☐ _____

7. Broadly, please tell us about the seizures. How frequent are they and how long do they last? On average, how long does it take for full recovery from a seizure?

_____

_____

WEARABLE DEVICES OR APPS

8. Please tell us about any wearable epilepsy monitoring devices or apps and any other wearable activity monitoring devices (like Fitbits) that you CURRENTLY use.

_____

_____

9. If you are CURRENTLY using a wearable epilepsy monitoring device, please tell us why you chose it.

_____

_____

10. How many emergency contacts do you have? What is your relationship with them?

_____

_____

11. Please tell us about any wearable epilepsy monitoring devices that you used IN THE PAST (i.e., devices that you no longer use). (If you have not previously used any devices please proceed to question 14).

_____

_____

12. How long did you use the wearable epilepsy monitoring devices or apps IN THE PAST?

_____

_____

13. Please tell us of any reason why you stopped using the devices or apps? (Please select all that apply).

Tick all that apply.

- ☐ It broke or stopped working
- ☐ It was uncomfortable
- ☐ It was too difficult to operate
- ☐ It generated false alarms
- ☐ I do not think I need one
- ☐ It missed seizures
- ☐ It was too slow at detecting seizures
- ☐ It was too slow at sending alarms for assistance
- ☐ The device was too expensive
- ☐ The subscription price was too high
- Other: ☐ _____

14. We are particularly interested in false alarms. Please share any opinions or experiences you may have with false alarms.

15. In your opinion, what are the benefits of having your seizures monitored by wearable epilepsy monitoring devices or apps? (Please select all that apply).

Tick all that apply.

- [ ] Having the information for your own knowledge
- [ ] Being able to share the information with your doctor
- [ ] Generating automated alarms requesting assistance when a seizure is detected Other:

NON-WEARABLE DEVICES

16. Please tell us about any non-wearable epilepsy monitoring devices (like mattress sensors) that you CURRENTLY use.

17. Please tell us your opinions and experiences from ANY PAST USE of nonwearable epilepsy monitoring devices.

POST-STUDY USABILITY QUESTIONNAIRE

If you have any experience of using a wearable epilepsy monitoring device or if you receive alarm/alert messages.

Please reflect on this use and complete this usability questionnaire, otherwise please go to question 19.

Overall, I was satisfied with how easy was it to use epilepsy monitoring devices or apps.

Mark only one oval.

	1	2	3	4	5	6	7	
Strongly Agree	◯	◯	◯	◯	◯	◯	◯	Strongly Disagree

It was simple to use epilepsy monitoring devices or apps.

Mark only one oval.

	2	2	3	4	5	6	7	
Strongly Agree	◯	◯	◯	◯	◯	◯	◯	Strongly Disagree

I was able to complete the tasks quickly using epilepsy monitoring devices or apps.

Mark only one oval.

	3	2	3	4	5	6	7	
Strongly Agree	◯	◯	◯	◯	◯	◯	◯	Strongly Disagree

I felt comfortable using epilepsy monitoring devices or apps.

Mark only one oval.

	4	2	3	4	5	6	7	
Strongly Agree	◯	◯	◯	◯	◯	◯	◯	Strongly Disagree

It was easy to learn to use epilepsy monitoring devices or apps.

Mark only one oval.

	5	2	3	4	5	6	7	
Strongly Agree	◯	◯	◯	◯	◯	◯	◯	Strongly Disagree

I believe I could become productive quickly using epilepsy monitoring devices or apps.

Mark only one oval.

	6	2	3	4	5	6	7	
Strongly Agree	◯	◯	◯	◯	◯	◯	◯	Strongly Disagree

Epilepsy monitoring devices or apps gave error messages that clearly told me how to fix problems.

Mark only one oval.

1 2 3 4 5 6 7

Strongly Agree ◯ ◯ ◯ ◯ ◯ ◯ ◯ Strongly Disagree

Whenever I made a mistake using epilepsy monitoring devices or apps, I could recover easily and quickly.

Mark only one oval.

2 2 3 4 5 6 7

Strongly Agree ◯ ◯ ◯ ◯ ◯ ◯ ◯ Strongly Disagree

The information (such as online help, on-screen messages, and other documentation) provided with epilepsy monitoring devices or apps was clear.

Mark only one oval.

3 2 3 4 5 6 7

Strongly Agree ◯ ◯ ◯ ◯ ◯ ◯ ◯ Strongly Disagree

It was easy for me to find the information I needed.

Mark only one oval.

4 2 3 4 5 6 7

Strongly Agree ◯ ◯ ◯ ◯ ◯ ◯ ◯ Strongly Disagree

The information was effective in helping me complete the tasks.

Mark only one oval.

5 2 3 4 5 6 7

Strongly Agree ◯ ◯ ◯ ◯ ◯ ◯ ◯ Strongly Disagree

The organisation of information on the epilepsy monitoring devices or apps screens was clear.

Mark only one oval.

6 2 3 4 5 6 7

Strongly Agree ◯ ◯ ◯ ◯ ◯ ◯ ◯ Strongly Disagree

The interface of epilepsy monitoring devices or apps was pleasant.

Mark only one oval.

7 2 3 4 5 6 7

Strongly Agree ◯ ◯ ◯ ◯ ◯ ◯ ◯ Strongly Disagree

I liked using the interface of epilepsy monitoring devices or apps.

Mark only one oval.

8 2 3 4 5 6 7

Strongly Agree ◯ ◯ ◯ ◯ ◯ ◯ ◯ Strongly Disagree

Epilepsy monitoring devices or apps have all the functions and capabilities I expect them to have.

Mark only one oval.

9 2 3 4 5 6 7

Strongly Agree ◯ ◯ ◯ ◯ ◯ ◯ ◯ Strongly Disagree

Overall, I am satisfied with epilepsy monitoring devices or apps.

Mark only one oval.

10 2 3 4 5 6 7

Strongly Agree ◯ ◯ ◯ ◯ ◯ ◯ ◯ Strongly Disagree

19. Are there are any comments or suggestions you would like to share with us about wearable and non-wearable epilepsy monitoring devices.

20. Permission to use quotes. We will never use any quotes from questionnaires unless we have your permission. Please indicate your preference below.

I give permission to use quotes from my responses.

Mark only one oval.

◯ Yes

◯ No

THANK YOU VERY MUCH FOR YOUR TIME.

Questionnaire for carers, family, friends, and alarms receivers* of individuals with epilepsy.

I am, Tendai Rukasha, a Computer Science PhD candidate at Keele University researching wearable epilepsy monitors. I am supervised by Drs Sandra Woolley and Theocharis Kyriacou.

If you are a carer or other stakeholder with an interest or responsibility for individuals with epilepsy, we would really like to know your opinions and any experiences of wearable and non-wearable monitoring devices or apps.

We would be grateful if you would complete this questionnaire. We are just looking for your opinions and experiences –we are not asking you to take part in any trials. We welcome all opinions and please feel free to tell us of any experiences that inform your opinions.

The results of this questionnaire will be published and shared with Epilepsy Action. No identifying comments will be published and no quotes from responses will be used without permission. Full participant information details are available.

Note: You are welcome to complete more than one online questionnaire. For example, if you are a healthcare professional or carer who has epilepsy, you are welcome to fill out both applicable questionnaires.

Thank you very much for your help.

Tendai Rukasha (t.rukasha@keele.ac.uk).

(*i.e., anyone receiving SMS messages or alerts from epilepsy monitoring devices).

ABOUT YOU AND YOUR ROLE

1. What is your current role? Please tell us your relationship to the individual/s with epilepsy.

2. Please tell us how many individual/s with epilepsy are in your care? (What are their ages and gender?).

3. What types of seizures do they have? (Please select all that apply).

Tick all that apply.

- [ ] Tonic
- [ ] Clonic
- [ ] Tonic-clonic
- [ ] Myoclonic
- [ ] Atonic
- [ ] Absence

Other: [ ] _____

WEARABLE DEVICES OR APPS

4. Do the individual/s with epilepsy CURRENTLY use wearable epilepsy monitoring devices or apps? (If the individual/s do not use any wearable epilepsy monitoring devices please proceed to question 6). If they do, i) please tell us (if you know) which devices or apps they us.

_____

_____

and ii) are these devices that you recommended? What is your opinion of the device?

_____

_____

5. Do you receive the alarm messages from the individual/s wearable epilepsy monitoring devices or apps? If so, please tell us your opinion of the messages?

_____

_____

6. Please tell us about any wearable epilepsy monitoring devices or apps that the individual/s with epilepsy used IN THE PAST (i.e., devices that they no longer use). (If they have not used any wearable epilepsy monitoring devices please proceed to question 9).

_____

_____

7. How long did they use the wearable epilepsy monitoring devices or apps IN THE PAST?

_____

_____

8. Please tell us of any reason you know why they stopped using the devices or apps? (Please select all that apply).

Tick all that apply.

- [ ] It broke or stopped working
- [ ] It was uncomfortable
- [ ] It was too difficult to operate
- [ ] It generated false alarms
- [ ] It missed seizures
- [ ] It was too slow at detecting seizures
- [ ] It was too slow at sending alarms for assistance
- [ ] The device was too expensive
- [ ] The subscription price was too high

Other: [ ] _____

9. We are particularly interested in false alarms. Please share any opinions or experiences you may have with false alarms.

_____

_____

10. In your opinion, what is the benefit of having seizures monitored by wearable epilepsy monitoring devices or apps? (please select all that apply).

Tick all that apply.

- [ ] Having the information for your/their knowledge
- [ ] To share information with individual/s with epilepsy in my care
- [ ] Generating automated alarms requesting assistance when a seizure is detected Other:

11. Please tell us YOUR OWN OPINION of wearable epilepsy monitoring devices or apps.

_____

_____

NON-WEARABLE DEVICES

12. Please tell us about any non-wearable epilepsy monitoring devices (like mattress sensors) that the individual/s with epilepsy CURRENTLY use.

_____

_____

13. Please tell us about any non-wearable epilepsy monitoring devices that the individual/s with epilepsy used IN THE PAST (i.e., devices that they no longer use).

_____

_____

POST-STUDY USABILITY QUESTIONNAIRE

If you have any experience of using wearable epilepsy monitoring devices or if you receive alarm/alert messages.

Please reflect on this experience and complete this usability questionnaire, otherwise please proceed to question 15.

Overall, I was satisfied with how easy it was to use epilepsy monitoring devices or apps.

Mark only one oval.

	1	2	3	4	5	6	7	
Strongly Agree	◯	◯	◯	◯	◯	◯	◯	Strongly Disagree

It was simple to use epilepsy monitoring devices or apps.

Mark only one oval.

	1	2	3	4	5	6	7	
Strongly Agree	◯	◯	◯	◯	◯	◯	◯	Strongly Disagree

I was able to complete the tasks quickly using epilepsy monitoring devices or apps.

Mark only one oval.

	2	2	3	4	5	6	7	
Strongly Agree	◯	◯	◯	◯	◯	◯	◯	Strongly Disagree

I felt comfortable using epilepsy monitoring devices or apps.

Mark only one oval.

	3	2	3	4	5	6	7	
Strongly Agree	◯	◯	◯	◯	◯	◯	◯	Strongly Disagree

It was easy to learn to use epilepsy monitoring devices or apps.

Mark only one oval.

	4	2	3	4	5	6	7	
Strongly Agree	◯	◯	◯	◯	◯	◯	◯	Strongly Disagree

I believe I could become productive quickly using epilepsy monitoring devices or apps.

Mark only one oval.

	5	2	3	4	5	6	7	
Strongly Agree	◯	◯	◯	◯	◯	◯	◯	Strongly Disagree

Epilepsy monitoring devices or apps gave error messages that clearly told me how to fix problems.

Mark only one oval.

	6	2	3	4	5	6	7	
Strongly Agree	◯	◯	◯	◯	◯	◯	◯	Strongly Disagree

Whenever I made a mistake using epilepsy monitoring devices or apps, I could recover easily and quickly.

Mark only one oval.

	7	2	3	4	5	6	7	
Strongly Agree	◯	◯	◯	◯	◯	◯	◯	Strongly Disagree

The information (such as online help, on-screen messages and other documentation) provided with epilepsy monitoring devices or apps was clear.

Mark only one oval.

	8	2	3	4	5	6	7	
Strongly Agree	◯	◯	◯	◯	◯	◯	◯	Strongly Disagree

It was easy for me to find the information I needed.

Mark only one oval.

	9	2	3	4	5	6	7	
Strongly Agree	◯	◯	◯	◯	◯	◯	◯	Strongly Disagree

The information was effective in helping me complete the tasks.

Mark only one oval.

	10	2	3	4	5	6	7	

Strongly Agree ◯ ◯ ◯ ◯ ◯ ◯ ◯ Strongly Disagree

The organisation of information on the epilepsy monitoring devices or apps screens was clear.

Mark only one oval.

1 2 3 4 5 6 7

Strongly Agree ◯ ◯ ◯ ◯ ◯ ◯ ◯ Strongly Disagree

The interface of epilepsy monitoring devices or apps was pleasant.

Mark only one oval.

2 2 3 4 5 6 7

Strongly Agree ◯ ◯ ◯ ◯ ◯ ◯ ◯ Strongly Disagree

I liked using the interface of epilepsy monitoring devices or apps.

Mark only one oval.

3 2 3 4 5 6 7

Strongly Agree ◯ ◯ ◯ ◯ ◯ ◯ ◯ Strongly Disagree

Epilepsy monitoring devices or apps have all the functions and capabilities I expect them to have.

Mark only one oval.

4 2 3 4 5 6 7

Strongly Agree ◯ ◯ ◯ ◯ ◯ ◯ ◯ Strongly Disagree

Overall, I am satisfied with epilepsy monitoring devices or apps.

Mark only one oval.

5 2 3 4 5 6 7

Strongly Agree ◯ ◯ ◯ ◯ ◯ ◯ ◯ Disagree Agree

15. Are there any comments or suggestions, you would like to share with us about wearable and non-wearable epilepsy monitoring devices?

16. Permission to use quotes. We will never use any quotes from questionnaires unless we have your permission. Please indicate your preference below.

I give permission to use quotes from my responses.

Mark only one oval.

◯ Yes

◯ No

THANK YOU VERY MUCH FOR YOUR TIME.

Questionnaire for healthcare professionals.

I am, Tendai Rukasha, a Computer Science PhD candidate at Keele University researching wearable epilepsy monitors. I am supervised by Drs Sandra Woolley and Theocharis Kyriacou.

If you are a healthcare professional, we would really like to know your opinions and any experiences of wearable and non-wearable monitoring devices or apps.

We would be grateful if you would complete this questionnaire. We are just looking for your opinions and experiences – we are not asking you to take part in any trials. We welcome all opinions and please feel free to tell us of any experiences that inform your opinions.

The results of this questionnaire will be published and shared with Epilepsy Action. No identifying comments will be published and no quotes from responses will be used without permission. Full participant information details are available.

Note: You are welcome to complete more than one online questionnaire. For example, if you are a healthcare professional or carer who has epilepsy, you are welcome to fill out both applicable questionnaires.

Thank you very much for your help.

We recognise That healthcare workers are busy during this critical time.

Tendai Rukasha (t.rukasha@keele.ac.uk).

ABOUT YOU AND YOUR ROLE

1. What is your current role?

Mark only one oval.

- ◯ Neurologist
- ◯ Epilepsy Nurse
- ◯ General Practitioner
- ◯ Other: _____

2. Please tell us how many individual/s with epilepsy are in your care? (What are their ages and gender?).

_____

_____

3. What types of seizures do they have? (Please select all that apply).

Tick all that apply.

- ☐ Tonic
- ☐ Clonic
- ☐ Tonic-clonic
- ☐ Myoclonic
- ☐ Atonic
- ☐ Absence
- ☐ Other: _____

WEARABLE DEVICES OR APPS

4. Do the individual/s with epilepsy CURRENTLY use wearable epilepsy monitoring devices or apps? (If the individual/s do not use any wearable epilepsy monitoring devices please proceed to question 7). If they do, i) please tell us (if you know) which devices or apps they use.

_____

_____

and ii) are these devices that you recommended? What is your opinion of the devices?

5. Please tell us about any wearable epilepsy monitoring devices or apps that the individual/s with epilepsy used IN THE PAST (i.e., devices that they no longer use). (If they have not used any wearable epilepsy monitoring devices please proceed to question 8).

6. How long did they use the wearable epilepsy monitoring devices or apps IN THE PAST?

7. Please tell us of any reason you know why they stopped using the devices or apps. (Please select all that apply).

Tick all that apply.

- [ ] It broke or stopped working
- [ ] It was uncomfortable
- [ ] It was too difficult to operate
- [ ] It generated false alarms
- [ ] It missed seizures
- [ ] It was too slow at detecting seizures
- [ ] It was too slow at sending alarms for assistance
- [ ] The device was too expensive
- [ ] The subscription price was too high
- [ ] Other: _____

8. We are particularly interested in false alarms. Please share any opinion or experience you may have with false alarms.

9. In your opinion, what is the benefit of having seizures monitored by wearable epilepsy monitoring devices or apps? (Please select all that apply).

Tick all that apply.

- [ ] Having the information for your/their own knowledge
- [ ] To share information with individual/s with epilepsy in my care
- [ ] Generating automated alarms requesting assistance when a seizure is detected Other:

10. Please tell us YOUR OWN OPINION of wearable epilepsy monitoring devices or apps.

NON-WEARABLE DEVICES

11. Please tell us about any non-wearable epilepsy monitoring devices (like mattress sensors) that the individual/s with epilepsy CURRENTLY use.

12. Please tell us about any non-wearable epilepsy monitoring devices that the individual/s with epilepsy used IN THE PAST (i.e., devices that they no longer use).

POST-STUDY USABILITY QUESTIONNAIRE

If you have any experience of using wearable epilepsy monitoring devices or if you receive alarm/alert messages.

Please reflect on this experience and complete this usability questionnaire otherwise please proceed to question 14.

Overall, I was satisfied with how easy it was to use epilepsy monitoring devices or apps.

Mark only one oval.

	1	2	3	4	5	6	7	
Strongly Agree	◯	◯	◯	◯	◯	◯	◯	Strongly Disagree

It was simple to use epilepsy monitoring devices or apps.

Mark only one oval.

	2	2	3	4	5	6	7	
Strongly Agree	◯	◯	◯	◯	◯	◯	◯	Strongly Disagree

I was able to complete the tasks quickly using epilepsy monitoring devices or apps.

Mark only one oval.

	3	2	3	4	5	6	7	
Strongly Agree	◯	◯	◯	◯	◯	◯	◯	Strongly Disagree

I felt comfortable using epilepsy monitoring devices or apps.

Mark only one oval.

	4	2	3	4	5	6	7	
Strongly Agree	◯	◯	◯	◯	◯	◯	◯	Strongly Disagree

It was easy to learn to use epilepsy monitoring devices or apps.

Mark only one oval.

	5	2	3	4	5	6	7	
Strongly Agree	◯	◯	◯	◯	◯	◯	◯	Strongly Disagree

I believe I could become productive quickly using epilepsy monitoring devices or apps.

Mark only one oval.

	6	2	3	4	5	6	7	
Strongly Agree	◯	◯	◯	◯	◯	◯	◯	Strongly Disagree

Epilepsy monitoring devices or apps gave error messages that clearly told me how to fix problems.

Mark only one oval.

	7	2	3	4	5	6	7	
Strongly Agree	◯	◯	◯	◯	◯	◯	◯	Strongly Disagree

Whenever I made a mistake using epilepsy monitoring devices or apps, I could recover easily and quickly.

Mark only one oval.

	8	2	3	4	5	6	7	
Strongly Agree	◯	◯	◯	◯	◯	◯	◯	Strongly Disagree

The information (such as online help, on-screen messages, and other documentation) provided with epilepsy monitoring devices or apps was clear.

Mark only one oval.

	1	2	3	4	5	6	7	
Strongly Agree	◯	◯	◯	◯	◯	◯	◯	Strongly Disagree

It was easy for me to find the information I needed.

Mark only one oval.

	2	2	3	4	5	6	7	
Strongly Agree	◯	◯	◯	◯	◯	◯	◯	Strongly Disagree

The information was effective in helping me complete the tasks.

Mark only one oval.

	3	2	3	4	5	6	7	
Strongly Agree	◯	◯	◯	◯	◯	◯	◯	Strongly Disagree

The organization of information on the epilepsy monitoring devices or apps screens was clear.

Mark only one oval.

	4	2	3	4	5	6	7	
Strongly Agree	◯	◯	◯	◯	◯	◯	◯	Strongly Disagree

The interface of epilepsy monitoring devices or apps was pleasant.

Mark only one oval.

	5	2	3	4	5	6	7	
Strongly Agree	◯	◯	◯	◯	◯	◯	◯	Strongly Disagree

I liked using the interface of epilepsy monitoring devices or apps.

Mark only one oval.

	6	2	3	4	5	6	7	
Strongly Agree	◯	◯	◯	◯	◯	◯	◯	Strongly Disagree

Epilepsy monitoring devices or apps have all the functions and capabilities I expect them to have.

Mark only one oval.

	7	2	3	4	5	6	7	
Strongly Agree	◯	◯	◯	◯	◯	◯	◯	Strongly Disagree

Overall, I am satisfied with epilepsy monitoring devices or apps.

Mark only one oval.

	8	2	3	4	5	6	7	
Strongly Agree	◯	◯	◯	◯	◯	◯	◯	Strongly Disagree

14. Are there any comments or suggestions, you would like to share with us about wearable and non-wearable epilepsy monitoring devices?

15. Permission to use quotes. We will never use any quotes from questionnaires unless we have your permission. Please indicate your preference below.

I give permission to use quotes from my responses.

Mark only one oval.

Appendix D: Papers

Appendix D.1: The International BCS Human-Computer Interaction Conference

Evaluation of Wearable Epileptic Seizure Monitors

Tendai Rukasha
Keele University
Staffordshire ST5 5BG, UK
t.rukasha@keele.ac.uk

Wearable health devices that detect epileptic seizures have the potential to hail timely assistance for individuals, inform their treatment and assist care and self-management. New wearable seizure-detecting devices are becoming available to individuals, carers and researchers but there is scope for improvements in device performance and for more evaluations in the research literature. This position paper outlines research that includes a review of the evaluation literature and both quantitative and qualitative device evaluations.

Keywords: wearable devices, health technology, usability, epilepsy, seizure detection.

1. INTRODUCTION

Epilepsy is a neurological disorder that affects 50 million people worldwide. It is characterised by seizures that can present in very different ways, for example, from short absences to protracted convulsions. Although seizures can be controlled with antiepileptic drugs, 30% of people with epilepsy have drug-resistant seizures (Sheng et al., 2018). The onset of a seizure is associated with changes in temperature, perspiration and heart rate (Wannamaker et al.,1985; Baumgartner et al., 2001). These changes have the potential to be detected by wearable skin temperature, electrodermal activity (EDA) and optical pulse 'photoplethysmography' (PPG) sensors, respectively. During a seizure, rhythmic shaking movements or the lack of movement can be detected via signals from a wearable accelerometer. Wearable seizure-detecting devices that include these sensors are now becoming available to individuals, carers, healthcare professionals and researchers. However, reliable seizure detection is difficult in everyday life and devices can miss seizures and produce false alarms (Johansson et al., 2018).

2. RESEARCH SCOPE

The PhD research surveys and evaluates wearable epileptic seizure monitoring devices with the aim of contributing toward improving future device designs and evaluations.

2.1 Research Directions

The aims and objectives are as follows:

- To survey and evaluate wearable seizure monitor performance.
- To identify issues in wearable interface design and recommend improvements.
- To collect and analyse the opinions and experiences of people with epilepsy, carers, family, friends, alarm receivers and healthcare professionals.

The research questions that guide the research aims and objectives:

(i) How to evaluate the performance of wearable devices for epilepsy seizure monitoring?
(ii) To what extent do wearable user interface designs affect usability?
(iii) What are epilepsy stakeholders' perceptions and experiences of consumer wearable devices?

Systematic literature review. A systematic literature review of wearable seizure-monitoring device evaluations was performed and has been published in MDPI electronics journal (Rukasha et al., 2020). The devices and apps available are summarised in Figure 1. Published evaluations reported varying levels of detail about performance metrics such as sensitivity, specificity, positive predictive and negative predictive values, and false alarm rates for detecting different types of epileptic seizures.

Proceedings of BCS HCI 2020. Keele University, UK.

The review demonstrated that despite a very large body of research into novel methods for seizure detection, there is a lack of research reporting evaluation data for available devices, and, in particular, there is a lack of studies reporting on real-world use and experiences of epilepsy stakeholders.

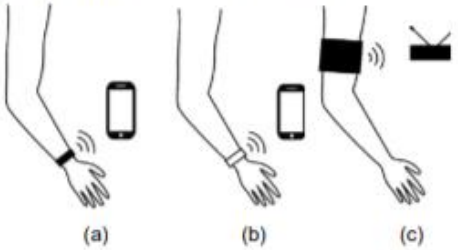

Figure 1. *Wearables and apps for epilepsy seizure detection: (a) dedicated wrist-worn sensing device and companion app (e.g., Embrace (Empatica) and Epi-Care free (Danish Care Technology) devices); (b) app using sensed data from a compatible consumer wrist-worn tracker (e.g., the SmartWatch Inspyre app (Smart Monitor) with an Apple or Samsung device); (c) a nonwrist wearable with a base station (NightWatch (LivAssured, B.V) device).*

Study One – Performance evaluation: Even in well-resourced clinical studies, it is still very challenging to test the performance of seizure-detecting wearables because it requires the recruitment and observation of epileptic individuals into laboratory environments where EEG and/or other truth data can be achieved. But, seizures are intermittent and should not be provoked, so it may take very many hours of clinical resource to capture a sufficient number of seizures for device evaluation.

An alternative to seizure-monitoring evaluation is the evaluation of sensing performance. If wearable sensing devices are to perform well at detecting and monitoring seizures, they should perform well at recording their sensed values. However, reliable heart rate sensing is challenging during activity [Oniani, 2018].

In this study, heart rate sensing evaluations were completed for 12-hour everyday living and 15-minute treadmill activity data collections. An Empatica E4 wrist-worn wearable (a research version of an Empatica Embrace epileptic seizure monitor) and the Polar ECG chest strap were used in testing. Figure 2 shows an example of the different recorded heart rates from both devices worn by the same participant during 12-hour everyday living

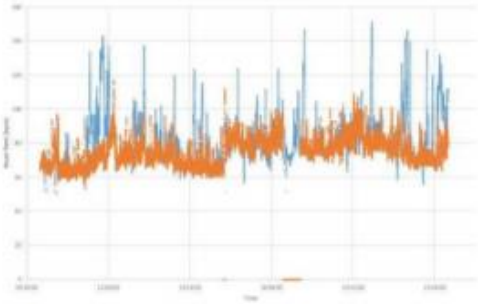

Figure 2. *Example concurrent acquisitions of 12-hour everyday living heart rate recordings from a E4 wearable (blue line) and a Polar ECG chest strap (orange line).*

Study Two – Interface Evaluation: This study involved a heuristic evaluation (using Neilsen's Usability Heuristics for User Interface Design [Neilsen, 1994]) of the minimal circular coloured light LED interface of the Empatica 'Embrace' wearable epilepsy seizure monitor.

Minimal interface indicators and alerts can quickly become familiar to individuals wearing devices every day. But, in critical healthcare applications there can be other 'stakeholder users' acting in support during episodes when the wearer may be incapacitated or confused [Rukasha, 2020b].

A number of participants assessors with HCI experience were recruited to perform a heuristic evaluation and to try to guess the meaning of different light patterns. Figure 3 shows box plot results for the light pattern indicating an "unusual event detected", i.e., reporting a potential seizure. As demonstrated by the example, assessors lacked confidence about the meaning of the display and had difficulties disambiguating between sets of possible conditions.

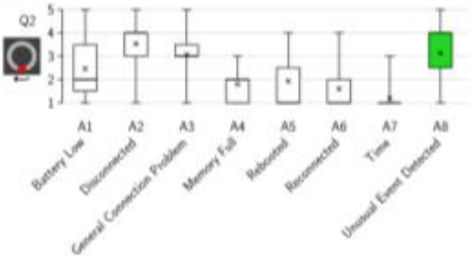

Figure 3. *Box Plot Responses of Guessed Interface Visualisation: Likert scale responses (5=Definitely is and 1= Definitely isn't): Q2: Displayed "Unusual event detected", the correct answer (A8) is shaded green.*

Study Three – Stakeholder Evaluations: With Keele University ethical approval, a survey of stakeholder opinions and experiences collection is currently in progress. Three questionnaires survey

opinions and experiences for i) people with epilepsy, ii) carers, and iii) healthcare professionals. These questionnaires are available at the time of writing on the Epilepsy Action charity website, https://www.epilepsy.org.uk/research/takepart/projects-you-can-take-part-in/wearabledevices. Epilepsy Action is a charity that improves the lives of people affected by epilepsy, by giving advice, improve healthcare and fund research and campaign for change.

3. DISCUSSION

The findings of the research so far indicate that there is enthusiasm for wearable epilepsy seizure monitoring among individuals, carers and health professionals but there are also concerns about performance and false alarm rates.

The review of the literature highlighted the lack of both qualitative and quantitative published research evaluating the devices. This research aims to contribute to the area.

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Appendix D.2: Evaluation of Wearable Electronics for Epilepsy: A Systematic Review

electronics

MDPI

Review

Evaluation of Wearable Electronics for Epilepsy: A Systematic Review

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Abstract: Epilepsy is a neurological disorder that affects 50 million people worldwide. It is characterised by seizures that can vary in presentation, from short absences to protracted convulsions. Wearable electronic devices that detect seizures have the potential to hail timely assistance for individuals, inform their treatment, and assist care and self-management. This systematic review encompasses the literature relevant to the evaluation of wearable electronics for epilepsy. Devices and performance metrics are identified, and the evaluations, both quantitative and qualitative, are presented. Twelve primary studies comprising quantitative evaluations from 510 patients and participants were collated according to preferred reporting items for systematic reviews and meta-analyses (PRISMA) guidelines. Two studies (with 104 patients/participants) comprised both qualitative and quantitative evaluation components. Despite many works in the literature proposing and evaluating novel and incremental approaches to seizure detection, there is a lack of studies evaluating the devices available to consumers and researchers, and there is much scope for more complete evaluation data in quantitative studies. There is also scope for further qualitative evaluations amongst individuals, carers, and healthcare professionals regarding their use, experiences, and opinions of these devices.

Keywords: wearable electronics; epilepsy; seizure detection; smart watch; systematic review

1. Introduction

Epilepsy is a neurological disorder affecting 50 million people worldwide [1]. While seizures can be controlled with antiepileptic drugs, more than 30% of people with epilepsy have drug-resistant seizures [2]. The timely detection of seizures is important in hailing assistance that can reduce the potential for injuries and sudden unexpected death in epilepsy (SUDEP) events [3,4]. This paper reviews the literature relevant to qualitative and quantitative assessments of the wearable electronics available to individuals and researchers for the detection of epilepsy seizures.

The onset of epileptic seizures is associated with autonomic changes including flushing, sweating, and heart rate changes [5,6] that have the potential to be detected by wearable temperature, electrodermal activity (EDA), and optical pulse "photoplethysmography" (PPG) sensors, respectively. The seizures themselves can be convulsive or nonconvulsive. Convulsive seizures involve repeated involuntary contractions and relaxations of muscles that appear as repetitive, rhythmic, shaking motions. The pronounced motor activity of convulsive seizures makes them potentially recognisable with accelerometery. In contrast, nonconvulsive seizures can be difficult to detect; they can appear as simple absences or losses in muscle strength. Seizure types are described according to their type of presentation as tonic, clonic, tonic-clonic, myoclonic, atonic, and absence as summarised below:

- Tonic seizures (TS) associated with contractions of the muscles;
- Clonic seizures (CS) associated with repeated contractions and relaxation of muscles;
- Tonic-clonic seizures (TCS) associated with stiffening followed by shaking;
- Myoclonic seizures (MS) associated with twitching regions of muscles;
- Atonic seizures associated with loss of muscle strength;
- Absence seizures associated with individuals appearing detached or inattentive.

The management and treatment of epilepsy relies on the assessment of seizure presentation and frequency, but patient self-reports and carer recall can be unreliable [7] and patient seizure diaries can underestimate seizure frequency [8,9]. In a review of electroencephalography (EEG) and other seizure reporting technologies for epilepsy treatment, Bidwell et al. [10] highlighted "a strong need for better distinguishing between patients exhibiting generalized and partial seizure types as well as achieving more accurate seizure counts" but concluded that high false positive seizure detection rates meant that most technologies failed to surpass patient self-reporting performance.

Whilst EEG is used in clinical laboratory settings for seizure assessment and diagnosis, new research toward wearable ambulatory EEG sensing [11] offers future opportunities for assessment and monitoring beyond the clinical environment. However, currently, despite "great interest in the use of wearable technology across epilepsy service users, carers, and healthcare professionals" [7], the monitoring of seizures outside the clinic, in real-world settings and during the activities of everyday living, is limited to the sensing afforded by a small set of available wearable epilepsy seizure-sensing devices. Additionally, some nonwearable devices are available, for example, sensors designed to attach to a bed or mattress to detect night-time seizures; however, the focus of this review is on wearable devices.

1.1. Wearable Electronics for Epilepsy Seizure Detection

There has been strong interest and market growth in wrist-worn wearable health and well-being devices [12] incorporating digital thermometers for temperature, conductivity sensors for EDA, micro-electromechanical systems (MEMS) for accelerometery, and light-emitting diodes (LEDs) and photodiodes for PPG pulse wave detection [13], as well as new advances toward flexible skin-inspired sensors [14]. Despite reliability concerns related to ambulatory sensing [15], wearable devices are increasingly used in clinical and healthcare applications. Low- and mid-range wearable devices typically comprise optical PPG pulse, EDA, temperature, and three-axis accelerometer sensors [16–19]. As illustrated in Figure 1, wearable electronics for epilepsy seizure detection, based on wrist- and arm-worn sensor configurations, are now available to individuals and researchers for the purpose of detecting and reporting seizures and alerting carers for timely assistance. Additional sensors such as gyroscopes and GPS (global positioning system) receivers can detect rotational movements and location, respectively. Signals from these sensors can be used to detect "preictal" periods before a seizure by electrodermal activity and heart rate changes, or, during the seizure, shaking motor movements (or lack of movement during absences), and can be used to locate, report, and log seizure events. It is, however, difficult to reliably detect seizures in everyday life [20], and the challenge of disambiguating seizures and normal everyday (seizure-like) movements such as teeth brushing may result in false alarms that require repeated cancellations and which may disincentivise uptake among patients.

Table 1 summarises the currently available wearable consumer seizure-detecting devices that have been evaluated in the literature. These include the Embrace seizure-detecting wrist-worn sensor, developed by Empatica [21]. Embrace is a maturing product that is available to consumers via device purchase and monthly subscription (subscriptions, at the time of writing, are £9.90–£44.90 per month). Empatica also market an "E4" (previously "E3") research version of their Embrace device that provides researchers with access to the raw sensor data that can be used to test seizure-detecting algorithms. Also, as shown in Table 1, other devices reported in the literature include the Epi-Care

free [22], NightWatch [23], and SmartWatch [24]. Epi-Care free is a wrist-worn (or ankle-worn) sensor incorporating an accelerometer, gyroscope, and GPS to detect seizure motor activity and send alerts to family members or telecare services (subscriptions, at the time or writing, are £995 and £1115 per year). The NightWatch sensor is an armband wearable that senses pulse and activity to detect and report nocturnal seizures. The Smart Monitor SmartWatch is a seizure detector that makes use of wearable heart rate and activity data (originally from prototype wearable devices and now the app, named "Inspyre", can access data from compatible Apple and Samsung Galaxy and Gear watches) and summon help to the GPS location of the wearer (subscriptions, at the time of writing, are from £9.99 to £24.99 per month). Other wearable consumer products for epilepsy seizure detection include Brio, Epilert (no longer available), Pulse Companion, and Open Seizure Detector (App). However, these devices have not been assessed in the literature.

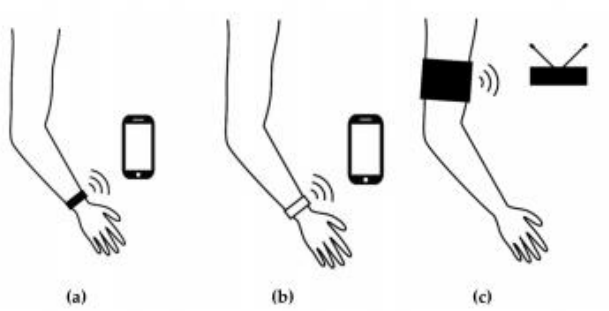

Figure 1. Wearables and apps for epilepsy seizure detection: (**a**) dedicated wrist-worn sensing device and companion app (e.g., Embrace and Epi-Care free); (**b**) app using sensed data from a compatible consumer wrist-worn tracker (e.g., the SmartWatch Inspyre app with an Apple or Samsung device); (**c**) a non-wrist wearable with a base station (NightWatch).

Table 1. Wearable electronics for epilepsy seizure detection.

Device	Sensors	Manufacturer/Supplier	Software/Applications	Hardware/Platform
Embrace/Embrace 2 E4	Accelerometer PPG Temperature EDA Gyroscope (Embrace 2)	Empatica Inc./Srl (Boston, USA/Milan, Italy)	Alert App Mate App	Apple/Android Smartphone
Epi-Care free	Accelerometer Gyroscope	Danish Care Technology ApS (Sorø, Denmark)	Epi-Care App	Apple/Android Smartphone
NightWatch	Accelerometer PPG	LivAssured B.V. (Leiden, The Netherlands)	NightWatch online portal	Dedicated base station
Smart Monitor (SmartWatch/Inspyre App)	Accelerometer PPG	Smart Monitor (San Jose, USA)	Smart Monitor App Web Portal	Apple/Android Smartphone and compatible Samsung and Apple Watches

Detection Performance

Figure 2 summarises seizure detections in terms of true/false and positive/negative outcomes and the related sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV), and the associated formulae, including the false alarm rate (FAR), are summarised in Equations (1)–(6).

$$\text{Sensitivity} = TP/(FN + TP) \quad (1)$$

$$\text{Specificity} = TN/(TN + FP) \quad (2)$$

$$\text{Positive Predictive Value (PPV)/Precision} = TP/(TP + FP) \quad (3)$$

$$\text{Negative Predictive Value (NPV)} = TN/(FN + TN) \quad (4)$$

$$\text{Accuracy} = (TP + TN)/(TP + TN + FP + FN) \quad (5)$$

$$\text{False Alarm Probability} = FP/\text{day} \quad (6)$$

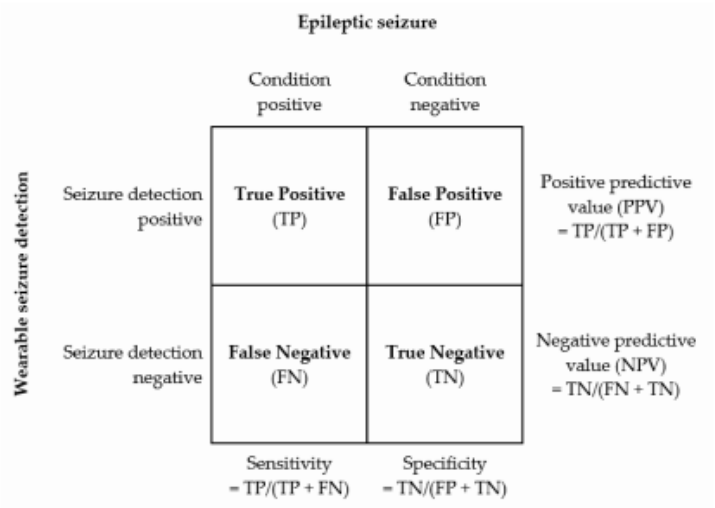

Figure 2. Seizure detection performance metrics.

Ideally, assessments of wearable devices would present results for these metrics for significant numbers of subjects over sufficient duration for testing detection of a substantial number of seizures of different types. In addition, assessments would also ideally support repeatability by clearly specifying test conditions, device models, and, also, version information [25]. Given the importance of timely alerts for seizure detection and the need to reduce the anxiety and alarm fatigue associated with high false alarm rates (FARs), detection latency and FARs should also be reported.

2. Method

A systematic review of primary studies evaluating wearable seizure-detecting devices spanning almost fifteen years (from 1 January 2005 to 31 October 2019, when the review was initiated) was conducted with an evidence-based methodology [26,27] and in accordance with PRISMA guidelines [28]. A requirement of the review was that devices were identified and available to individuals or researchers (i.e., not unavailable, proof-of-concept, laboratory prototypes).

2.1. Search Strategy

Both technology and medical digital libraries were used to identify primary studies. These were Association for Computing Machinery (ACM), Institute of Electrical and Electronics Engineers (IEEE) Xplore Digital Library, Medline, ScienceDirect, and Wiley Online Library.

The keyword search string below was evolved to identify primary studies relevant to wearable epilepsy sensing devices:

("wearable" OR "smart watch" OR "smart watch" OR "wrist-worn" OR "wrist worn" OR "wrist worn" OR "wristband" OR "armband") AND ("epileptic" OR "epilepsy").

2.2. Eligibility Criteria and Selection

Studies were eligible for selection if they met all three of the following inclusion criteria:

1. Primary studies in peer-reviewed literature;
2. Studies where the main theme is consumer wearable electronics for epilepsy seizure detection;
3. Studies reporting quantitative and/or qualitative assessment data.

The relevant papers were assessed for quality according to screening criteria including rigour, credibility, and relevance [29].

3. Results

Following the PRISMA systematic review guidance outlined in Figure 3, a total of 12 papers satisfied the eligibility criteria. A second researcher checked the screening and eligibility of papers and a third researcher moderated the results.

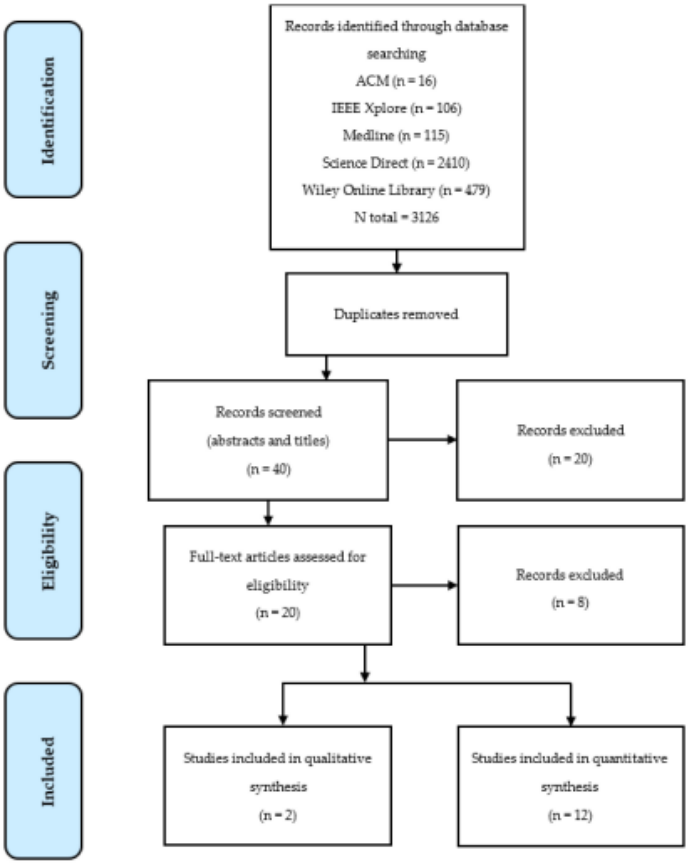

Figure 3. Flow diagram of the systematic review according to preferred reporting items for systematic reviews and meta-analyses (PRISMA) guidelines.

As summarised in Table 2, all 12 studies reported qualitative assessments (8 conducted in clinical settings and 4 in free-living conditions). Two of the 12 studies also reported qualitative assessments. While the search process did initially identify qualitative papers on wearable devices for epilepsy, some of these studies [30,31] were assessments of perceptions about the potential of such devices rather than assessments of actual use. No studies reported solely qualitative assessment data for the real use of available wearable devices for seizure detection.

Table 2. Overview of studies and participant numbers.

No. Studies = 12		
No. Quantitative = 12		**No. Qualitative = 2**
Clinical setting = 8	Free-living = 4	-
No. participants/patients = 341	No. participants/patients = 169	No. participants/patients = 104
TOTAL = 510		TOTAL = 104

3.1. Quantitative Studies

3.1.1. Clinical Setting

Eight of the 12 quantitative studies were conducted in clinical settings. All eight were evaluation studies [32–39] with data gathered from epileptic inpatients and outpatients; none were two-arm or controlled studies with healthy participants. Most studies compared recorded device data with other clinical reference recordings, including EEG, video EEG (vEEG), electromyography (EMG), and electrocardiogram (ECG). The studies are summarised in Table 3 in terms of the devices used, the numbers of participants, the numbers of seizures detected, and, where specified, the study duration. As shown in the summary in Table 3, four of the studies used Empatica E3, E4, and Embrace devices, three used Smart Monitor's evolving SmartWatch devices, and one used the Epi-Care free. The numbers of patient participants varied from 3 to 135. A study [33] with three participants selected 1 h recorded segments rather than continuous recordings. Otherwise, observation durations varied within studies [33,38,39] as well as between studies from 17 h to 487 days, and two studies [35,37] did not report durations. The total number of seizures detected in studies varied from 7 and 55 and, across all studies, a total of 226 seizures were reported as detected. Only one study [33] did not report the number of detected seizures.

Table 3. Clinical setting studies with number of seizures and duration.

Clinical Settings				
Study	**Device**	**No. Participants**	**No. Seizures Detected**	**Duration**
Heldberg et al., 2015 [32]	E3	8	55	23 days
Al-Bakri et al., 2018 [33]	E4	3	unspecified	4–5 days (1 h intervals)
Vandecasteele et al., 2017 [34]	E4	11	47	29 days
Regalia et al., 2019 [35]	Embrace and E4	135	40	unspecified
Lockman et al., 2011 [36]	SmartWatch	40	7	487 days
Patterson et al., 2015 [37]	SmartWatch	41	30	unspecified
Velez et al., 2016 [38]	SmartWatch	30	12	1–9 days
Beniczky et al., 2013 [39]	Epi-Care free	73	35	17–171 hours
-	-	TOTAL = 341	TOTAL = 226	-

Table 4 summarises the performance assessments of the studies. The reporting of performance metrics was variable and sparse across most of the studies. For example, false alarm rates for only three studies could be identified. The studies using the Empatica E3 and E4 implemented machine learning detection methods (kNN: k-nearest neighbour; RF: random forest; NB: naïve Bayes; SVM: support vector machine). Regalia et al., 2019 [35] made brief reference to previously unpublished assessments with 135 patients and 22 seizures with 100% sensitivity and an FAR of 0.42 per day for a "fixed and frozen" algorithm. No methodology, sensitivity, or other assessment information was provided,

and the paper largely focused on compiling and comparing other Empatica wristband performance indicators. Heldberg et al., 2015 [32] reported the sensitivity and specificity for two different classifiers. Vandecasteele et al. [34] compared the performance of SVM classifiers on hospital ECG with wearable ECG and E4 PPG recordings. PPG motion artefacts (which would have been largely induced by the seizures themselves) made more than half of the seizures undetectable via this approach and resulted in a poor sensitivity of 32%. The studies encompassed different seizure types but with TCS and "motor" seizures often included. Dramatically different performance results were observed. For example, sensitivities of 100% and 16% were reported by the authors of [35] and [37], respectively. Notably, the latter paper [37] comprised a large number of (undetected) nonmotor seizures. The levels of patient activity and any movement constraints were not generally explicitly reported and, in any case, are difficult to convey. However, in the clinical setting, worn sensors usually benefit from reduced interference from activities of daily living. For example, the good wearable performance for the small study in [33] was achieved from recordings taken simultaneously with EEGs, i.e., when one would expect patients to be inactive.

Table 4. Performance assessments in clinical settings.

Authors/ No. Participants	Device	Seizure	Sensitivity	Specificity	FAR	PPV/R	Detection Latency
Heldberg et al., 2015 [32] 8 participants	E3	PNMS, PMS	89.1% (kNN) 87.3% (RF) 84% (NB)	93.1% (kNN) 95.2% (RF) 79% (NB)	-	-	-
Al-Bakri et al., 2018 [33] 3 participants	E4	-	(preictal sleep) 78% (NB) (preictal wake)	(preictal sleep) 80% (NB) (preictal wake)	-	-	-
Vandecasteele et al., 2017 [34] 11 participants	E4 (PPG)	TLS, CPS	32% (SVM)	-	1.80 per hour	1.43%	-
Regalia et al., 2019 [35] 135 participants	E4 and Embrace	GTC	100%	-	0.42 per day	-	-
Lockman et al., 2011 [36] 40 participants	SmartWatch	TCS	87.5%	-	-	-	-
Patterson et al., 2015 [37] 41 participants	SmartWatch	TS, GTC, MS, MTS, PS	16%	-	-	-	-
Velez et al., 2016 [38] 30 participants	SmartWatch	TCS	92.3%	-	-	-	-
Beniczky et al., 2013 [39] 73 participants	Epi-Care free	TCS	90%	-	0.2 per day	-	55 s

Seizure Abbreviations: CPS: complex partial seizures, GTC: general tonic-clonic, MS: myoclonic seizures, MTS: myoclonic-tonic seizures, PMS: predominantly motor seizures, PNMS: predominantly nonmotor seizures, PS: partial onset seizures, TCS: tonic-clonic seizures, TLS: temporal lobe seizures, TS: tonic seizures. Classifier Abbreviations: kNN: k-nearest neighbour; NB: naïve Bayes; RF: random forest; SVM: support vector machine. Other Abbreviations: FAR: False Alarm Rate; PPV/R: Positive Predictive Value/Rate.

Smart Monitor's SmartWatch was used in three of the eight clinical assessments. Patterson et al. [37] reported the lowest sensitivity (16% overall: 31% for general tonic-clonic (GTC) and 0% for MS) in a study of 41 patients aged 5–41 years. Citing Lockman et al. [36], the authors did not record false positives "because these are well known". Lockman et al. [36] did report 204 false alarm occurrences in their SmartWatch study with 40 patients between "March 2009 and June 2010" but did not specify an FAR or confirm the duration of actual usage within the study period. Velez et al. [38] referred to 81 false alarms but also did not specify an FAR (and one cannot be estimated because of the varying durations of 1–9 days). Beniczky et al. [39] reported a sensitivity of 90% and an FAR of 0.2 per day in a study with 73 participants with GTC seizures who were monitored for 17–171 hours. An average detection latency of 55 s was reported.

3.1.2. Free-Living Environment

Four of the 12 quantitative studies report free-living environment evaluations. These studies are summarised in Tables 5 and 6 and comprise 169 participants and 850 seizures.

Table 5. Free-living studies with number of seizures and duration.

Free-Living Settings				
References	**Device**	**Participants**	**No. Seizures Detected**	**Duration**
Onorati et al., 2017 [40]	E3 and E4	69	32	247 days
Van de Vel et al., 2014 [3]	Epi-Care free	1	9	19 nights
Meritam et al., 2018 [8]	Epi-Care free	71	-	15 months median (24 days to 6 years)
Arends et al., 2018 [41]	NightWatch	28	809	1826 nights
-	-	TOTAL = 169	TOTAL = 850	-

Table 6. Performance metrics in a free-living setting.

Study/No: of Participants	Device	Seizure	Sensitivity	Specificity	FAR	PPV/R	Detection Latency
Onorati et al., 2017 [40] 69 participants	E3 and E4	BTCS, FTC	83.64% (Classifier I) 92.73% (Classifier II) 94.55% (Classifier III)	-	0.29 per day (Classifier I) 0.21 per day (Classifier II) 0.20 per day (Classifier III)	-	31.2 s (Classifier I) 29.3 s (Classifier II) 29.3 s (Classifier III)
Van de Vel et al., 2014 [3] 1 participant	Epi-Care free	TS, CS, TCS	41%	-	0.05 per night	-	-
Meritam et al., 2018 [8] 71 participants	Epi-Care free	BTCS	90% BTCS median	-	0.1 per day median	-	-
Arends et al., 2018 [41] 28 participants	NightWatch	MS, TC, TCS, Hyperkinetic	86% median	-	0.25 per night median	49% median	-

Seizure Abbreviations: BTCS: bilateral tonic-clonic seizures, CS: clonic seizures, FTC: focal tonic-clonic, FS: focal seizures, MS: myoclonic seizures, TCS: tonic-clonic seizures, TS: tonic seizures. Other Abbreviations: FAR: false alarm rate, PPV/R: positive predictive value/rate.

Onorati et al. [40] reported a range of classifier performances for the E3 and E4 with sensitivities from 83.64% to 94.55% and FARs of between 0.2 and 0.29 per day. Van de Vel et al. [3] and Meritam et al. [8] both reported Epi-Care free evaluations with 71 and 1 participants, respectively. For the 71 patients [8], a sensitivity of 90% and an FAR of 0.1 per day were reported. Arends et al. [41] reported a sensitivity of 86% for the NightWatch arm-worn nocturnal seizure monitor, an FAR of 0.25 per night, and a PPV of 49%.

3.1.3. Data Failures—Missing and Unusable Data

In addition to missed seizures caused by algorithms failing to detect seizures in acquired data, seizures can also be missed when data are not recorded, not received, or not usable (for example, if they are so corrupted as to be unusable). There were limited discussions of data failures or the "missingness" of data in the studies. Examples are summarised in Table 7.

Table 7. Missing data.

Studies	Device	Participants	Data Failures	Reasons
Vandecasteele et al., 2017 [34]	E4	11	PPG motion artefacts	Motion artefacts "PPG signal was drastically affected … 55% of the seizures could not be detected because of motion artefacts … no reliable HR could be extracted"
Vélez et al., 2016 [38]	SmartWatch	30	3 occasions	2× wireless communication failures and 1× device not worn during seizure
Beniczky et al., 2013 [39]	Epi-Care free	73	"15 times"	"Device deficiencies" (including 2× "technical error", 11× "battery failure")

3.2. *Qualitative Studies*

Only two studies provided qualitative assessment data for device evaluations. Both of these studies also reported quantitative evaluations that were included in the earlier sections. Summaries of patient and stakeholder views and observations are listed in Table 8.

Table 8. Qualitative studies.

Study/ No. Participants	Stakeholder Views and Observations	
	Benefits	**Barriers/Concerns**
Arends et al., 2018 [41] 33 qualitative carer respondents	• Timely responses to urgent situations. • Offers carers more freedom. • Helps carers give better care. • More autonomy for people with epilepsy.	• Skin irritation. • Armband not fitting properly. • Poor signal reception.
Meritam et al., 2018 [8] 71 qualitative patient respondents	• Good overall device satisfaction (5.5/7) • Easy to use. • Clear alarm signals. • Timely alerts enabled 40% reduction in injuries. • Feeling of security and a decreased psychological burden.	• High false alarm rate. • Skin irritation or discomfort. • Low effectiveness for detecting seizures. • Unstable sensor communication and interference issues. • Limited battery life and lack of water resistance. • 10% of patients stopped using the device for device-related reasons.

Arends et al., 2018 [41] evaluated the NightWatch night-time upper arm seizure monitor using a multifactor questionnaire with 33 carer stakeholder respondents comprising 30 nurses, 2 parent carers, and 1 "not specified". Meritam et al., 2018 [8] performed a qualitative evaluation of the Epi-Care free monitor with 71 patient participants aged 7–72 years using a post-study systems usability questionnaire (PSSUQ) comprising 13 questions and requiring a 1–7 Likert-scale response from participants on aspects on monitor usability.

Both studies identified concerns in terms of (a) physical intrusion, e.g., discomfort or irritation, and (b) performance concerns, e.g., signal reception or detection failures. Participants in both studies agreed with the benefits of the monitors in terms of the potential for improved responses to seizure events and the potential for improved care outcomes.

4. Discussion

The aim of this review was to collate and analyse qualitative and quantitative assessments of wearable electronics for epilepsy seizure monitoring that are available to individuals and researchers. Although there are over 3000 works in the literature discussing, proposing, and evaluating novel and incremental approaches to epilepsy seizure detection, there are very few that report evaluation data and, as observed previously [42], none that report comparative results of large-scale studies. In terms of the Oxford Centre for Evidence-Based Medicine 2011 Levels of Evidence 1–5 scale [43], none of the reviewed studies would qualify as the highest level of evidence (Level 1), and most would rank as Level 3 or below.

The diversity of the reviewed studies in terms of motor and nonmotor seizure types and levels of patient activity/freedom of movement is matched by the diversity of results including, for example, very high and very low sensitivities.

Across the reviewed works there was a lack of full detail, including details required to establish important metrics such as false alarm rates (FARs) and details important to reproducibility such as device, firmware, and app version numbers [44]. Ideally, the frequency, duration, impact, and cause of all data recording failures (resulting in the "missingness" of data) would also be provided in all performance assessment studies. There was also a lack of detail regarding the performance of the devices themselves in terms of seizure detection and estimation of key parameters such as heart rate. In a recent study [45], researchers compared consumer-grade and research-grade heart rate (HR) and heart rate variability (HRV) estimating wearables (including the Empatica E4 and two other HR sensing devices) and observed that "while the research-grade wearables are the only wearables that provide users with raw data that can be used to visualize PPG waveforms and calculate HRV, the HR

measurements tended to be less accurate than consumer-grade wearables. This is especially important for researchers and clinicians to be aware of when choosing devices for clinical research and clinical decision support." [45] This very difficult problem of achieving accurate and reliable continuous sensor data in nonsedentary scenarios is highly significant and worthy of more attention if researchers are to develop robust methods and make valid conclusions from acquired data.

Wearable electronic devices for epilepsy seizure detection have the potential to improve patient outcomes and to afford carers more freedom. However, the technology is still evolving. There are opportunities for improvements in system reliability and algorithm detection performance and, ideally, monitors would be sensitive across the range of seizure types whilst maintaining acceptably low false alarm rates. Ideally, future seizure sensing systems and algorithms would benefit from detailed qualitative and quantitative assessments of their performance. However, we should appreciate that assessing technology in critical health scenarios is not easy. Clinical assessments are onerous and resource-expensive undertakings, and their timescales are at odds with the iterative updating of digital technologies. Free-living assessments in particular require investments in time and resources, and they present additional difficulties in terms of truth data.

5. Conclusions

There is much scope for further research and improved performance reporting of wearable devices for epilepsy seizure detection and monitoring. There is a lack of qualitative studies eliciting feedback and stakeholder recommendations from real-world experiences of device usage. Ideally, future studies will report on the data quality and reliability of the sensing devices and provide much more detailed information regarding assessments, including device model and version numbers as well as detailed contextual information about the wearers and their activity.

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Abbreviations

The following abbreviations are used in this manuscript:

BTCS	Bilateral tonic-clonic seizures
CPS	Complex partial seizures
CS	Clonic seizures
ECG	Electrocardiogram
EDA	Electrodermal activity
EMG	Electromyography
FN	False negative
FNV/R	False negative value/rate
FP	False positive
FPV/R	False positive value/rate
FS	Focal seizures
FTC	Focal tonic–clonic
GTC	General tonic-clonic
HRV	Heart rate variability

kNN	k-nearest neighbour
MS	Myoclonic seizures
MTS	Myoclonic-tonic seizures
NB	Naïve Bayes classifier
NPV/R	Negative predictive value/rate
PMS	Predominantly motor seizures
PNMS	Predominantly non-motor seizures
PPG	Photoplethysmography
PPV/R	Positive predictive value/rate
PRV	Pulse rate variability
PS	Partial onset seizures
RF	Random forest
SUDEP	Sudden unexpected death in epilepsy
SVM	Support vector machine
TCS	Tonic-clonic seizures
TLS	Temporal lobe seizures
TN	True negative
TP	True positive
TPV/R	True positive value/rate
TS	Tonic seizures
vEEG	Video electroencephalogram

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Appendix D.3: IEEE/ACM International Conference on Connected Health: Applications, Systems and Engineering Technologies (CHASE)

Poster: Heart Rate Performance of a Medical-Grade Data Streaming Wearable Device

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ABSTRACT

Wrist-worn devices afford convenient and unobtrusive heart rate sensing, however, motion artifacts can lead to unreliable data recordings. This paper evaluates heart rate estimates acquired during treadmill walking and 12 hours of everyday living from a medical-grade Empatica E4 data streaming wristband wearable compared to a Polar H10 chest strap ECG sensor. For treadmill walking, heart rate Mean Absolute Percentage Errors (MAPEs) were between 7.2% and 29.2%, and IntraClass Correlations (ICCs) between 0.6 and -0.5, indicating moderate agreement and strong disagreement, respectively. During 12-hour everyday living acquisitions, heart rate estimate MAPEs were between 5.3% and 13.5% and ICCs between 0.7 and 0.1, indicating good to poor agreements.

CCS CONCEPTS

• **Applied computing** → **Consumer health**.

KEYWORDS

wearable devices, heart rate monitoring

ACM Reference Format:
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1 INTRODUCTION

Optical heart rate acquisitions from wrist-worn photoplethysmography (PPG) sensors are known to lack reliability during periods of activity due to the interfering effects of motion artifacts [3, 7]. However, the opportunity to achieve continuous, unobtrusive, low-cost patient monitoring and to incentivize patients toward positive health behaviors has resulted in many clinical research and healthcare applications of consumer-grade wearables, despite manufacturers making no medical device claims.

The Empatica E4, at the time of writing, is a class 2a medical-grade device used in *"over 1000 studies and trials"* [4]. It is a data streaming device similar to Empatica's Embrace FDA-approved wearable epilepsy monitor, comprising PPG, temperature, conductivity and accelerometer sensors, and is used by researchers for physiological data acquisition for a variety of healthcare applications, as well as for epileptic seizure detection research. Despite many studies proposing novel and incremental contributions for seizure detection, there are few studies evaluating wearable seizure monitoring devices in the literature [8].

Improvements in version reporting [2, 10] and standardized reporting practices [6] have been recommended to support the reproducibility of findings from studies using wearable devices. Bent et al. [1] reported on the wearable heart rate recording accuracies of 'consumer-grade' Fitbit Charge 2, Apple Watch 4, Garmin Vivosmart 3, and Xiaomi Miband, wearables and 'research-grade' data-streaming Biovotion Everion and Empatica E4 devices, and observed that *"absolute error during activity was, on average, 30% higher than during rest"* and that *"Consumer-grade wearables were found to be more accurate than research-grade wearables at rest."* The study provides summarized statistics, but no examples of heart rate recordings or signal behaviors as provided here.

2 METHOD AND MATERIALS

Healthy participants were recruited with ethical approval (KUFREC NS-190021) for wearable data recording during i) treadmill walking at speeds of 3.2, 4.8 and 6.4 km/h for five minutes at each speed, and ii) 12 hours of everyday living. Participants wore a Polar H10 ECG chest strap sensor and an E4 wristband on their non-dominant wrist. Heart rate data was downloaded from the Polar Flow and Empatica E4 Connect apps. [1]

3 RESULTS

Acquired treadmill and 12-hour everyday living heart rate recordings are summarized for participants P_T01-04 and P_D01-04 in Figure 1, and the corresponding Mean Absolute Percentage Errors (MAPEs) and IntraClass Correlations (ICCs) are summarized in Table 1. Periods of data missingness affected the E4 and, to a lesser extent, the Polar recordings. Two E4 12-hour recordings failed to maintain connectivity and there were some periods of missing data for P_D01-4.

CHASE 2020, Dec 17–18, 2020, Virtual Conference

ACM ISBN 978-1-4503-XXXX-X/18/06…$15.00
https://doi.org/10.1145/1122445.1122456

[1] Material details: (i) Empatica E4 wristband SP069-B-20150001, with E4 real-time app v 2.1.1 (8202), E4 Manager version 2.0.3 (5119) (ii) Polar H10 chest heart rate monitor FCC ID: INWIW, with Polar Flow and Polar Beat App version 3.4.0 (iii) Treadmill: h/p/cosmos Pulsar treadmill.

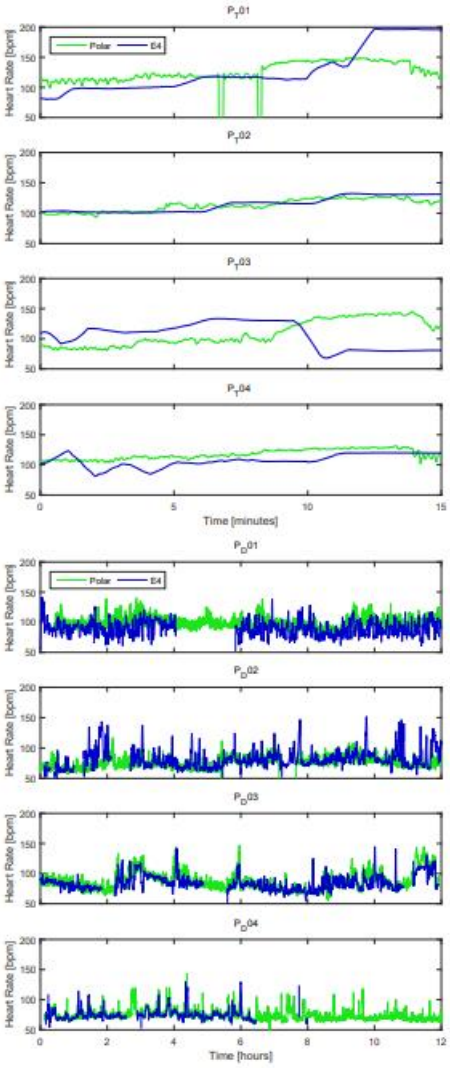

Figure 1: (top) Treadmill heart rates for participants P_T01-4, (bottom) 12-hour everyday living heart rates for participants P_D01-4.

4 DISCUSSION AND CONCLUSIONS

The disagreement between the E4 wristband and the Polar chest strap was large enough to be evident, even in this small study, with treadmill MAPEs ranging from 7.2% to 29.2%, and ICCs between 0.6 and -0.5, indicating moderate agreement and strong disagreement, respectively, and 12-hour everyday living MAPEs from 5.3% to 13.5%

Table 1: MAPEs and ICCs

Participant	Activity	ICC (upper/lower bounds)	MAPE
P_T01	Treadmill	0.4 (0.44 / 0.36)	19.17%
P_T02		0.61 (0.64 / 0.58)	7.21%
P_T03		-0.53 (-0.44 / -0.61)	29.25%
P_T04		0.32 (0.54 / -0.02)	10.54%
P_D01	12-hour	0.11 (0.2 / 0.01)	13.45%
P_D02		0.21 (0.27 / 0.15)	13.54%
P_D03		0.66 (0.69 / 0.63)	7.86%
P_D04		0.59 (0.6 / 0.58)	5.32%

and ICCs between 0.7 and 0.1 indicating good to poor agreement [5]. In the absence of motion artifacts, PPG heart rate estimates may perform reliably and could be used, for example, to detect 'preictal' epileptic seizure onset heart rate variations. However, attempting to detect heart rate variations during activity or during a motor seizure could produce unreliable results as reported in [9].

Despite these challenges, wearable epilepsy seizure detecting devices offer important opportunities to reduce injuries and save lives. However, researchers using data streaming research- and medical-grade wearables should be aware of device performance during periods of activity. As underlying technologies mature, we can hope to see improvements in both signal acquisition and algorithm performance.

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Appendix H.4: Ubiquitous Computing/ International Semantic Web Conference

Wearable Epilepsy Seizure Monitor User Interface Evaluation

An Evaluation of the Empatica 'Embrace' Interface

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ABSTRACT

Wearable health devices have the potential to incentivize individuals in health-promoting behaviors and to assist in the monitoring of health conditions. Wearable epilepsy seizure monitoring devices are now evolving that can support individuals and their caregivers via the automated sensing, reporting and logging of epileptic seizures. This work contributes a novel reflection on the interface requirements of wearer users and non-wearer stakeholder users. We evaluate the "guessability" of the light pattern interface of the Empatica Embrace wrist-worn epileptic seizure monitor and provide box plot results for eight interface indications. We also report summarised feedback from a heuristic analysis with fourteen participant evaluators. The results indicate some satisfaction with the minimal aesthetic of a simple light pattern interface as well as some concerns about confusion between different indications, accessibility and reliance on recall.

CCS CONCEPTS

• **Human-centered computing** → **Interaction design**.

KEYWORDS

Wearable Computing; Interface Evaluation; Health Technology; Epilepsy Monitoring; Heuristic Evaluation; Usability

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UbiComp/ISWC '20 Adjunct, September 12–16, 2020, Virtual Event, Mexico

ACM ISBN 978-1-4503-8076-8/20/09.
https://doi.org/10.1145/3410530.3414382

1 INTRODUCTION

Patient monitoring systems capable of accurate recording in the real-world, during the activities of everyday living, create opportunities to make real-time assessments of patient well-being, respond to potentially critical events and support clinical decision making [8].

Epilepsy is a neurological condition that affects 50 million people worldwide [11]. While antiepileptic drugs can control the seizures of many individuals, more than 30% of people with epilepsy have drug-resistant seizures [9]. Epileptic seizure types vary considerably between convulsive and non-convulsive seizures including 'tonic' and 'clonic' muscular contractions and relaxations, 'atonic' losses of muscle strength and 'absence' episodes where individuals can lapse awareness and appear detached. For epileptic individuals, the hailing of timely care with automated messages at seizure onset has the potential to reduce injuries and, potentially, save lives.

Epilepsy seizure detection and wearable patient monitoring are active areas of research but there is currently a lack of work evaluating the seizure monitoring technologies currently available to individuals and researchers [7]. This work makes a novel contribution to this area.

Wearable Device Interfaces

Achieving useful and unambiguous information delivery via the small screens and minimal interfaces of wearable devices poses interesting design challenges [5, 13, 14]. At the same time, it is important that devices are aesthetically acceptable [3] and, particularly in the case of health-condition monitoring, it is important that devices are discreet [10] and do not stigmatize wearers [4].

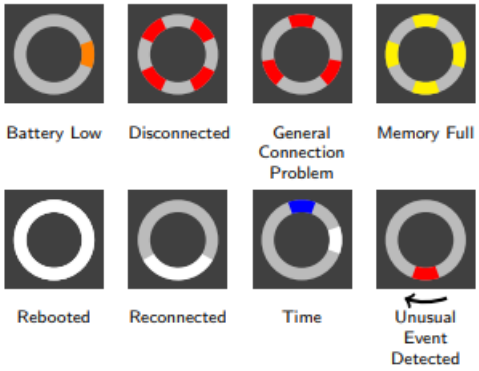

Figure 1: Embrace LED Interface Examples.

Minimal interface indicators may very quickly become familiar to individuals wearing devices every day. But, in critical healthcare applications there are often other *stakeholder users* beyond the *wearer users* and, during critical episodes such as an epileptic seizure, the wearer may be incapacitated or confused for some extended period of time during and after the event.

Examples of non-wearer stakeholder users include a parent or grandparent, teacher, caregiver, colleague, classmate, friend, or First Aid responder. These non-wearer stakeholders may normally have little reason to observe the interface or respond to low priority indications such as "Battery Low". However, the correct identification of a seizure ("Unusual Event Detected") indication could be an important source of seizure corroboration. A correctly interpreted display could also provide some reassurance about automated messaging that could reduce the responder's burden of seizure reporting and messaging. Likewise, the misinterpretation of a non-seizure display as a seizure could have consequences that, like false alarms in general, can disincentivize users.

The Empatica Embrace

The Empatica Embrace epilepsy seizure monitor is one of the few currently available wearable epilepsy seizure monitors [2]. It has a multicolor LED (light-emitting diode) interface that includes blinking and rotating animations indicating a range of conditions and states as indicated by the illustrations in Figure 1. Compared to visually-richer displays the LED interface has benefits in terms of aesthetics, internationalization and energy consumption, but has potential drawbacks in terms of usability.

2 EVALUATION

Method and Materials

Fourteen Computer Science students and researchers experienced in heuristic evaluation were recruited according to Keele University Faculty of Natural Sciences Research Ethics Committee approval (NS-200058) to evaluate the LED interface of the Empatica Embrace wearable seizure monitor. For repeatability [1, 12], the device version was an Empatica Embrace wristband EMB-MB-S (purchased 26th February 2019 with firmware version current between 11th to 13th March 2020).

Participants comprised two academic staff members, three PhD researchers, and four masters and five undergraduate Computer Science students. Seven participants reported ownership or experience of using wearable health trackers.

Participants were shown each of the eight animated interface indications shown in Figure 1 and were asked to guess on a scale of 5-1 (5 = definitely is and 1 = definitely isn't) what each of eight LED interface patterns signified: Battery Low, Disconnected, General Connection Problem, Memory Full, Rebooted, Reconnected, Time and Unusual Event Detected. The LED patterns were displayed in random order (indicated by Figure 2 labels Q1-Q8). On completion, participants were shown the correct answers for each condition and asked to complete a heuristic evaluation based on Neilsen's 10 Usability Heuristics for User Interface Design [6]: 1) visibility of system status, 2) match between system and the real world, 3) user control and freedom, 4) consistency and standards, 5) error prevention, 6) recognition rather than recall, 7) flexibility and efficiency of use, 8) aesthetic and minimalist design, 9) help users recognize, diagnose, and recover from error, and 10) help and documentation. Participant evaluations were audio recorded and summarized.

3 RESULTS

Figure 2 presents box plot results for the 5-1 (5 = definitely is and 1 = definitely isn't) Likert scale guesses for each of the eight Embrace LED interface examples illustrated. Ideally, the correct LED patterns (shaded in green) would have averages close to 5 and the all incorrect conditions would have averages close to 1.

Table 1 summarizes the participant evaluations for each of the 10 Nielsen user interface design heuristics [6].

4 DISCUSSION

As demonstrated in Figure 2 by the quantity of average guess values between 2 and 4, as well as the similarity of scores between some interface displays, participants found it difficult to disambiguate between sets of conditions. For example, participants could not discern between the orange and red

Table 1: User Interface Design Heuristics [6] with Summarized Descriptions and Participant Evaluations.

Heuristics	Participant Evaluations
Visibility of system status: The system keeps users informed of what is going on, through appropriate feedback within reasonable time.	Some evaluators reported the LEDs as visible and clear but most identified ambiguities. "About half the LEDs made sense." "Once the user knows the patterns it could be readable." "To the unversed person it seems confusing..."
Match between system and the real world: The system should speak the users' language and follow real-world conventions in a natural and logical order.	Several evaluators reported a good match for the red color and a warning condition. Opinions varied about the use of white and orange LEDs. Time interface was thought to be intuitive. There was uncertainty about the animations. "The system does not speak our language or use conventional symbols/signs" "Red indicates a serious problem." "Some animations matched real world... most do not."
User control and freedom: Support undo and redo and have an "emergency exit".	Most participants felt that this heuristic was not applicable but one evaluator suggested customization control.
Consistency and standards: Users should not have to wonder about meanings (device should follow conventions).	Evaluators generally agreed on the internal consistency of the LED displays but did not agree on a consistent standard beyond the use of red for warning. "LEDs don't seem consistent with other products I am aware of."
Error prevention: A design that avoids errors and requests user confirmations.	Most evaluators agreed that, although it is clear when an error or problem has occurred, it was not clear what the error condition was. "Where the LED shows red, this is most obvious that there is an issue, but difficult to discern what the error it is." There were also concerns about the accessibility of the display for color blind individuals.
Recognition rather than recall: Users should not have to remember information from one part of the dialog to another.	Although there were some intuitive elements of the interface, most evaluators felt the interface relied largely on recall. "The problem is having to remember what it means..." "You would have to rely on memorizing the LED patterns..."
Flexibility and efficiency of use: The system should be able to efficiently cater for both inexperienced and experienced users.	Evaluators agreed that the interface was efficient and international.
Aesthetic and minimalist design: Dialogues should not contain information which is irrelevant.	Some evaluators liked the minimalist aesthetic, but most felt it was too minimalistic. "Possibly too minimalistic with such a variety of meanings..." "A lack of text may make it hard to remember the meanings..."
Help users recognize, diagnose, and recover from errors: Error messages should specify the problem and suggest a solution.	Evaluators expressed different opinions but generally agreed that displays were recognizable if LED patterns were learned, but no indications were given about recovery. "If users know the meanings, displays are distinct." "There is little help provided for the user, if they don't know what the lights mean, they won't know what to do."
Help and documentation: The system should provide help and documentation (easy to search, focused on the user's task, list steps to be carried out, and should not be too large)	Participants agreed that there was no help available via the interface. "None is provided on the interface leading to a reliance on recall or reference to a manual."

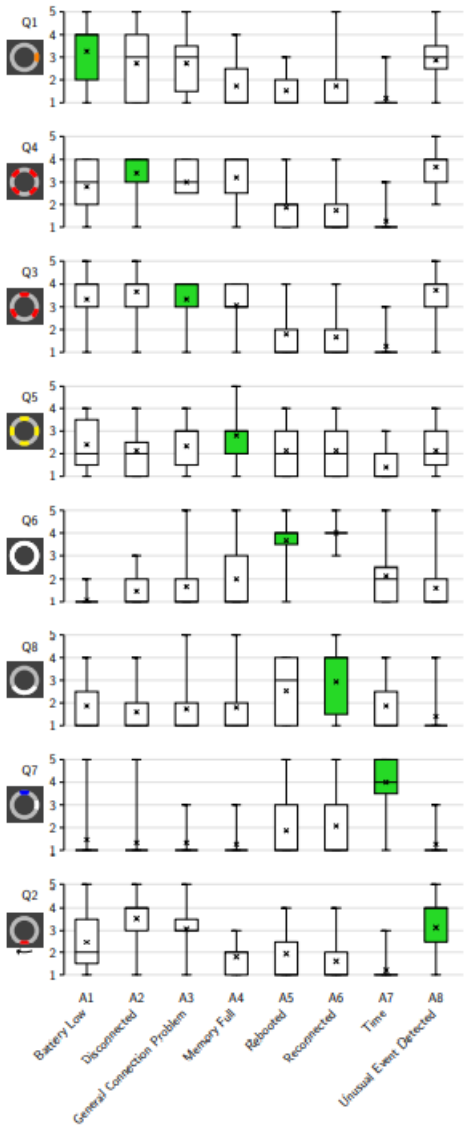

Figure 2: Guessability Box Plots. Participant interface guesses (5 = definitely is, 1 = definitely isn't). Correct instances are shaded in green, "x" marks mean, bar marks median and box and whiskers indicate interquartile range and max/min, respectively.

Battery Low, Disconnected and General Connection Problem light patterns: all three received averages of 2.5 to 3.5 (3 = unsure) no matter which pattern was displayed. Similarly, the white Rebooted and Reconnected LED patterns were confused with each other.

The Time display was the most recognized display. Only one participant was confident the Time display was not Time and, at most, one participant guessed that Battery Low, Disconnected and General Connection Problem, were Time indicators.

Unfortunately, the spinning red Unusual Event Detected display that can signify a seizure was not guessed well and was confused with Battery Low, Disconnected and General Connection Problem. When displayed, to participants the Unusual Event Detected display received an average score for the correct answer of 3.13 (3 = unsure) which was lower than the (incorrect) Disconnected guess that received an average of 3.53. Overall, for four out of the eight displays, at least one incorrect answer had a higher average guess score than the correct answer.

In Table 1, the heuristic feedback summarises the opinions amongst participant evaluators that, on the one hand, recognize the simplicity, clarity and potential memorability of the display and, on the other, raises concerns about the reliance on recall and the potential for confusion. For example, one evaluator observed that the interface was "Quite aesthetically pleasing but as intuitive as a Star Trek control panel". The use of color, e.g., "Red indicates a serious problem" was seen as appropriate as a real-world convention but some concerns were raised about accessibility for individuals with color-vision deficiencies.

5 CONCLUSIONS

Minimal light pattern displays have a pleasing aesthetic but can be confusing to users lacking familiarity with the interface. Ideally, each displayed pattern could be correctly guessed from the set of possible meanings.

There is need for further research and improvements in the design of interface displays for wearable devices and particularly for devices used in critical health monitoring scenarios with wearer users and non-wearer user stakeholders.

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Tendai Rukasha thanks Evaresto Rukasha and Betty Rukasha for funding the PhD research.

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Appendix E: Posters

Appendix E.1: IEEE/ACM International Conference on Connected Health: Applications, Systems and Engineering Technologies (CHASE)

Heart Rate Performance of a Medical-Grade Data Streaming Wearable Device

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Introduction

Wrist-worn devices afford convenient and unobtrusive heart rate sensing, however, motion artifacts can lead to unreliable data recordings. This paper evaluates heart rate estimates acquired during treadmill walking and 12 hours of everyday living from a medical-grade Empatica E4 data streaming wristband wearable compared to a Polar H10 chest strap ECG sensor.

Optical heart rate acquisitions from wrist-worn photoplethysmography (PPG) sensors are known to lack reliability during periods of activity due to the interfering effects of motion artifacts [1], [2]. However, the opportunity to achieve continuous, unobtrusive, low-cost patient monitoring and to incentivize patients toward positive health behaviors has resulted in many clinical research and healthcare applications of consumer-grade wearables, despite manufacturers making no medical device claims.

The Empatica E4 is a class 2a medical-grade device used in *"over 1000 studies and trials"* [3]. It is a data streaming device similar to Empatica's Embrace FDA-approved wearable epilepsy monitor, comprising PPG, temperature, conductivity and accelerometer sensors, and is used by researchers for physiological data acquisition for a variety of healthcare applications, as well as for epileptic seizure detection research. Despite many studies proposing novel and incremental contributions for seizure detection, there are few studies evaluating wearable seizure monitoring devices in the literature [4].

Improvements in version reporting [5], [6] and standardized reporting practices [7] have been recommended to support the reproducibility of findings from studies using wearable devices. Bent et al. [8] reported on the wearable heart rate recording accuracies of 'consumer-grade' Fitbit Charge 2, Apple Watch 4, Garmin Vivosmart 3, and Xiaomi Miband, wearables and 'research-grade' data-streaming Biovotion Everion and Empatica E4 devices, and observed that *"absolute error during activity was, on average, 30% higher than during rest"* and that *"Consumer-grade wearables were found to be more accurate than research-grade wearables at rest."* The study provides summarized statistics, but no examples of heart rate recordings or signal behaviors as provided here.

Method and Materials

Healthy participants were recruited with ethical approval (KUFREC NS-190021) for wearable data recording during i) treadmill walking at speeds of 3.2, 4.8 and 6.4 km/h for five minutes at each speed, and ii) 12 hours of everyday living. Participants wore a Polar H10 ECG chest strap sensor and an E4 wristband on their non-dominant wrist. Heart rate data was downloaded from the Polar Flow and Empatica E4 Connect apps.

Results

Acquired treadmill and 12-hour everyday living heart rate recordings are summarized for participants P_T01-04 in Figure 1 and P_D01-04 in Figure 2, and the corresponding Mean Absolute Percentage Errors (MAPEs) and IntraClass Correlations (ICCs) are summarized in Table I. Periods of data missingness affected the E4 and, to a lesser extent, the Polar recordings. Two E4 12-hour recordings failed to maintain connectivity and there were some periods of missing data for P_D01-4.

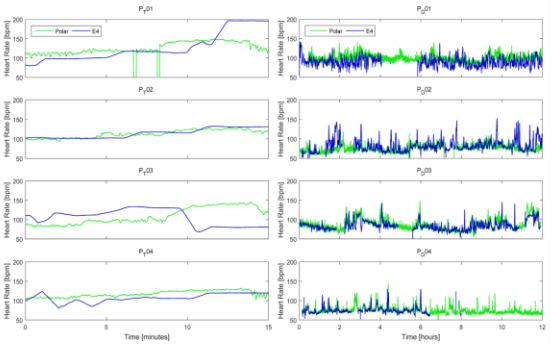

Fig 1. Treadmill heart rates for participants P_T01-4.

Fig. 2. 12-hour everyday living heart rates for participants P_D01-4.

Table 1
MAPEs and ICCs for treadmill and 12-hour everyday living

Participant	Activity	ICC (upper/lower bounds)	MAPE
P_T01	Treadmill	0.4 (0.44/0.36)	19.17%
P_T02		0.61 (0.64/0.58)	7.21%
P_T03		-0.53 (-0.44/-0.61)	29.25%
P_T04		0.32 (0.54/-0.02)	10.54%
P_D01	12-hour	0.11 (0.2/0.01)	13.45%
P_D02		0.21 (0.27/0.15)	13.54%
P_D03		0.66 (0.69/0.63)	7.86%
P_D04		0.59 (0.6/0.58)	5.32%

Discussion and Conclusions

The disagreement between the E4 wristband and the Polar chest strap was large enough to be evident, even in this small study, with treadmill MAPEs ranging from 7.2% to 29.2%, and ICCs between 0.6 and -0.5, indicating moderate agreement and strong disagreement, respectively, and 12-hour everyday living MAPEs from 5.3% to 13.5% and ICCs between 0.7 and 0.1, indicating good to poor agreement [9].

In the absence of motion artifacts, PPG heart rate estimates may perform reliably and could be used, for example, to detect 'preictal' epileptic seizure onset heart rate variations. However, attempting to detect heart rate variations during activity or during a motor seizure could produce unreliable results as, for example, reported by Vandecasteele et al. [10].

Despite these challenges, wearable epilepsy seizure detecting devices offer important opportunities to reduce injuries and save lives. However, researchers using data streaming wearables should be aware of device performance during periods of activity. As underlying technologies mature, we can hope to see improvements in both signal acquisition and algorithm performance.

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Appendix E.2: Ubiquitous Computing/ International Semantic Web Conference (UBICOMP/ISWC)

Wearable Epilepsy Seizure Monitor User Interface Evaluation
An Evaluation of the Empatica 'Embrace' Interface

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S.I Woolley, Keele University, UK
T. Collins, Manchester Metropolitan University, UK

Introduction

Patient monitoring systems capable of accurate recording in the real world, during the activities of everyday living, create opportunities to make real-time assessments of patient well-being, respond to potentially critical events and support clinical decision making [1].

Epilepsy is a neurological condition that affects 50 million people worldwide [2]. While antiepileptic drugs can control the seizures of many individuals, more than 30% of people with epilepsy have drug-resistant seizures [3]. Epileptic seizure types vary considerably between convulsive and non-convulsive seizures including 'tonic' and 'clonic' muscular contractions and relaxations, 'atonic' losses of muscle strength and 'absence' episodes where individuals can lapse awareness and appear detached. For epileptic individuals, the hailing of timely care with automated messages at seizure onset has the potential to reduce injuries and, potentially, save lives.

Epilepsy seizure detection and wearable patient monitoring are active areas of research but there is currently a lack of work evaluating seizure monitoring technologies currently available to individuals and researchers [4]. This work makes a novel contribution to this area.

Achieving useful and unambiguous information delivery via the small screens and minimal interfaces of wearable devices poses design challenges. At the same time, it is important that devices are aesthetically acceptable and, particularly in the case of health-condition monitoring, it is important that devices are discreet and do not stigmatize wearers.

Minimal interface indicators can quickly become familiar to individuals wearing devices every day. But, in critical healthcare applications there are other stakeholder users or observers beyond wearer users, for example, caregivers, family members or colleagues.

Method and Materials

Fourteen Computer Science students and researchers experienced in heuristic evaluation were recruited according to Keele University Faculty of Natural Sciences Research Ethics Committee approval (NS-200058) to evaluate the LED interface of the Empatica Embrace wearable seizure monitor.

Participants comprised two academic staff members, three PhD researchers, and four masters and five undergraduate Computer Science students. Participants were shown each of the eight animated interface indications shown in Figure 1 and were asked to guess on a scale of 5-1 (5 = definitely is and 1 = definitely isn't) what each of eight LED interface patterns signified: Battery Low, Disconnected, General Connection Problem, Memory Full, Rebooted, Reconnected, Time and Unusual Event Detected.

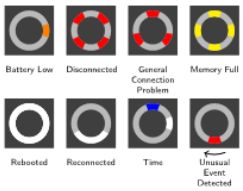

Figure 1: Embrace LED Interface Examples.

On completion, participants were shown the correct answers for each condition and asked to complete a heuristic evaluation based on Neilsen's 10 Usability Heuristics for User Interface Design [5]: 1) visibility of system status, 2) match between system and the real world, 3) user control and freedom, 4) consistency and standards, 5) error prevention, 6) recognition rather than recall, 7) flexibility and efficiency of use, 8) aesthetic and minimalist design, 9) help users recognize, diagnose, and recover from error, and 10) help and documentation.

Results

Figure 2 presents box plot results for the 5-1 (5 = definitely is and 1 = definitely isn't) LED interface guesses. Ideally, the correct LED patterns (shaded in green) would have averages close to 5 and the incorrect conditions would be close to 1.

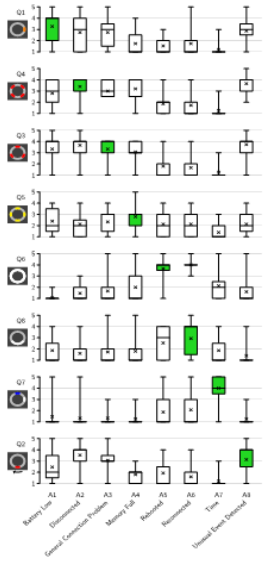

Figure 2. Guessability Box Plots. (5=definitely is, 1=definitely isn't). Correct instances are shaded in green, 'x' marks mean, bar marks median and box and whiskers indicate interquartile range and max/min, respectively.

Conclusions & Further Work

The Time display was the most recognized display. Only one participant was confident the Time display was not Time and, at most, one participant guessed that Battery Low, Disconnected and General Connection Problem, were Time indicators. Unfortunately, the spinning red Unusual Event Detected display that can signify a seizure was not guessed well and was confused with Battery Low, Disconnected and General Connection Problem.

Minimal light pattern displays have a pleasing aesthetic but can be confusing to users lacking familiarity with the interface. Ideally, each displayed pattern could be correctly guessed from the set of possible meanings.

Improvements in the design of interface displays for wearable devices and particularly for devices used in critical health monitoring scenarios with wearer users and non-wearer user stakeholders.

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