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SUPPLEMENT ARTICLE

Seizure detection at home: Do devices on the market match the needs of people living with epilepsy and their caregivers?

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Abstract

In patients with epilepsy, the potential to prevent seizure-related injuries and to improve the unreliability of seizure self-report have fostered the development and marketing of numerous seizure detection devices for home use. Understanding the requirements of users (patients and caregivers) is essential to improve adherence and mitigate barriers to the long-term use of such devices. Here we reviewed the evidence on the needs and preferences of users and provided an overview of currently marketed devices for seizure detection (medically approved or with published evidence for their performance). We then compared devices with known needs. Seizure-detection devices are expected to improve safety and clinical and self-management, and to provide reassurance to users. Key factors affecting a device's usability relate to its design (attractive appearance, low visibility, low intrusiveness), comfort of use, confidentiality of recorded data, and timely support from both technical and clinical ends. High detection sensitivity and low false alarm rates are paramount. Currently marketed devices are focused primarily on the recording of non–electroencephalography (EEG) signals associated with tonic-clonic seizures, whereas the detection of focal seizures without major motor features remains a clear evidence gap. Moreover, there is paucity of evidence coming from real-life settings. A joint effort of clinical and nonclinical experts, patients, and caregivers is required to ensure an optimal level of acceptability and usability, which are key aspects for a successful continuous monitoring aimed at seizure detection at home.

KEYWORDS

acceptability, epilepsy, mHealth, seizure detection, usability, wearables

1 | INTRODUCTION

Recent years have seen the rapid emergence of a new approach to health care, making use of the wealth of data constantly collected by smartphones and wearable devices such as smartwatches. This new paradigm, termed mobile health or mHealth, opens new possibilities for continuous monitoring of factors related to health status in the patient's home environment and to use this information to inform the management of their health conditions.[1] For people with epilepsy

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(PWE) and their caregivers, one potential application of mHealth technology would be to continuously detect seizures in real time (or close to real time) and use information about seizure occurrences to inform treatment decisions and to improve patient safety. Key requirements for the adoption of mHealth approaches include objective evidence that the technology is reliable and has suitable performance characteristics[2] and that the technology addresses the needs of patients and their caregivers.[3] In this contribution, we examine the specific instance of wearable devices for seizure detection. We briefly comment on the rationale and use-cases, followed by a survey of the literature on what PWE and their caregivers want from seizure-detection devices, subsequently review the literature on seizure-detection device performance, and finally, examine whether current evidence sufficiently addresses the needs of patients and carers.

Key Points

- Seizure detection at home is being explored by an increasing number of marketed devices
- Understanding user (patient and/or caregiver) needs is essential for long-term adherence to seizure-detection devices
- Device design, comfort of use, and seizure-detection performance are key aspects affecting device usability
- There is still low evidence of real-life, ambulatory usability of currently marketed seizure detection devices

2 | SEIZURE DETECTION AT HOME: WHY?

Seizures are the primary symptom of epilepsy, and treatment aims to prevent their occurrence so that the complications, which include death, injury, disability, and loss of independence, among others, are also prevented.[4] Optimal treatment can reduce the medical and psychosocial burden imposed by seizures and improve quality of life.[5] Moreover, patients wish to be free of the risks and limitations they impose, as well as avoid the associated fear and uncertainty that accompany them.[6]

Therefore, to most effectively treat PWE, we must accurately identify seizures. In addition to diagnosing these seizures at onset of epilepsy, we must accurately determine whether they have stopped once therapy is prescribed, and whether riskier motor behaviors have stopped should seizures not be completely abolished. As seizures are the key indicator of disease, it is sensible to employ the most reliable methods of ascertainment. However, the method presently used to assess the effectiveness of therapy is unchanged from that used for centuries: We ask patients, their families, and/or witnesses whether the patients are experiencing seizures, and rely on this historical information for our medical decisions. If we are told that seizures are still happening, then we may raise the dose of medication, add a new medication, or even advise nonpharmacological therapies (eg, neurostimulation, brain surgery, dietary therapies). If we are told that seizures have stopped, then we leave well enough alone.

However, why do we depend on flawed information when studies suggest that the patient's history is unreliable?[7–11] A survey of patients and their families revealed that both cast doubt on the reliability of their own reporting.[9] Twenty-eight percent of patients thought they never noticed daytime seizures, and 47% thought they noted fewer than half of their daytime seizures (n = 157 patients). Sixty-four percent of patients reported never noticing nighttime seizures, and 79% thought they missed a majority of nocturnal seizures (n = 107 patients). Family members reported a better impression of their own accuracy but believed that they too were often unreliable. One can conclude that our primary reporters of symptoms, when asked, are dubious about the quality of the data they provide, upon which our treatments are based.

Objective measures confirm the unreliability of the patient history. In an ambulatory study that included 552 long-term electroencephalography (EEG) studies from 502 patients, unreliability of reporting was common, confirming patient beliefs.[10] Forty-seven of 552 EEG recordings contained focal seizures, but patients reported seizures in only 29 of these records; only 61.7% of EEG recordings with seizures were believed by patients to contain seizures. In addition, generalized spike-wave bursts, even prolonged ones, often went unrecognized. Looking at the opposite aspect, gauging whether symptoms were truly seizures, only 132 patient alarms out of a total of 986 alarms were associated with an electrographic seizure on EEG. Although patients were undoubtedly overreporting some symptoms because of instructions given at the time of recording, there is little doubt that most of the symptoms were suspected to be epilepsy related. Hence, ambulatory EEG confirms that patients underreport seizures, and suggests that some symptoms reported as a seizure may well not be seizures. This raises the possibility that physicians at times may overtreat patients, prescribing antiepileptic therapy for nonepileptic symptoms (or perhaps very mild symptoms that might not warrant further therapy).

The combination of underdiagnosis and overdiagnosis can lead to unnecessary complications and restrictions. The patient who is thought to have well-controlled seizures but who, in reality, has ongoing unreported seizures may be at continued risk for injury and death. This same patient might be permitted to drive a motor vehicle, posing a risk to both patient and the public.[12] The patient who reports symptoms

that are misinterpreted as seizures might have higher doses of medication prescribed and experience more side effects.[13] Greater postural or gait imbalance induced by drugs might cause falls, and higher doses may have more adverse cognitive or psychiatric effects. If a woman of childbearing age becomes pregnant, a fetus may have increased risk of adverse teratogenic or developmental effects with higher drug doses or polytherapy. We may not properly judge the efficacy of medication in uncontrolled patients who we know to be uncontrolled. We might falsely believe that an existing or new therapy is better or worse than it really is, and rationalize treatment decisions when relying on flawed data.

In addition to detecting and counting seizures with an objective alternative to seizure diaries, home seizure detection in real time might have other uses. It could help protect PWE against seizure-related harms. For example, it could be employed as a seizure alarm to summon help or to activate a protective device,[14] or to activate therapy, as in a closed-loop stimulation device.[15] A seizure alarm seems a highly compelling use-case, but in our opinion the seizure-counting use-case is equally compelling, given that evidence suggests that self-reported or carer-reported seizure diaries are extremely unreliable.[7,11] Hence, both patient safety and treatment decisions based on seizure diaries could be greatly enhanced by a reliable and easy-to-use seizure-detection device (Table 1).

3 | SEIZURE DETECTION AT HOME: HOW?

EEG shows well-known features associated with seizures. Multiple automated real-time seizure-detection algorithms have been developed based on continuously recorded EEG. Many other physiological features associate with seizures, including motor activity and changes in autonomic parameters. Motor activity can be detected with video, accelerometers, and electromyography. Autonomic changes include alteration in heart rate parameters detectable with electrocardiography or photoplethysmography (PPG), a technique to detect changes in blood volume noninvasively in the skin using light transmission.[16] Autonomic output can also be monitored using electrodermal activity (EDA). EDA is a complex and incompletely understood electrical property of the skin, which is believed in part to reflect activity in the sympathetic nervous system.[17] Seizure- detection devices have typically used single modalities or combinations of EEG,[18] video,[19] accelerometry (ACM),[20] electromyography,[21] electrocardiography (ECG),[22] PPG, and EDA.[23] We will not review here the vast literature on changes in these parameters in association with seizures.

TABLE 1 Limitations to the current method of relying on patient and caregiver seizure diaries

Criteria for assessing diagnosis and treatment efficacy relies on flawed data
Patients and families often do not notice seizures
Patients and families report symptoms that may not be seizures
This is particularly true for nocturnal seizures (which pose greater SUDEP risk) and nonconvulsive seizures (which may be subtle and go unnoticed)
Treatment decisions thereby rely on unreliable data
Patient are assumed to have seizures under control due to failure to note seizures; this may put patients at risk, as necessary treatment changes are not implemented (eg, allowed to drive when seizures are not controlled, increased SUDEP risk)
Patients may be considered uncontrolled when the reported symptoms are not epileptic; this may put patients at risk due to unnecessary adjustments in treatment and lead to unnecessary activity restrictions (eg, advice to stop driving, more side effects)

4 | WHAT DO PWE AND THEIR CAREGIVERS WANT FROM SEIZURE-DETECTION DEVICES?

In the context of living with a chronic condition primarily characterized by unpredictable events and often not amenable to optimal control, PWE identify many unmet needs that may be supplemented by new technologies in their daily life.[3,24] Studies have highlighted that key needs, for both PWE and caregivers, are (a) improving safety, (b) improving clinical and self-management, and (c) providing reassurance.[3,24–27] Figure 1 shows the views of PWE and their caregivers on how digital tools can answer their needs. Accuracy and timing of seizure detection are paramount in this context, as false alarms and false short-term predictions can increase distress and have a detrimental impact on PWE and caregivers.[3,24,27–29] Overall, PWE are willing to use wearable devices for continuous health monitoring.[3,30,31] However, a lot of attention should be given to device design in order to address the requirements and preferences of PWE and caregivers, since these factors influence acceptance and long-term engagement, which is essential to allow novel technologies to successfully meet the needs of PWE. Multiple factors have been explored in studies investigating user preferences[3,24,25,27–34] and, to a lesser extent, direct experiences with digital tools[32,34]; these are summarized below. Unobtrusiveness is also a desired feature, so that the detection device does not call unwanted attention to the user.

1. Device design, form, and features are the most important factors driving user preferences. An attractive **appearance** is essential. When continuous tracking is required, devices should look familiar, similar to those commonly used in daily life by healthy individuals,[30] fashionably designed, and not awkward in size and shape.[24] Wires, stickers,

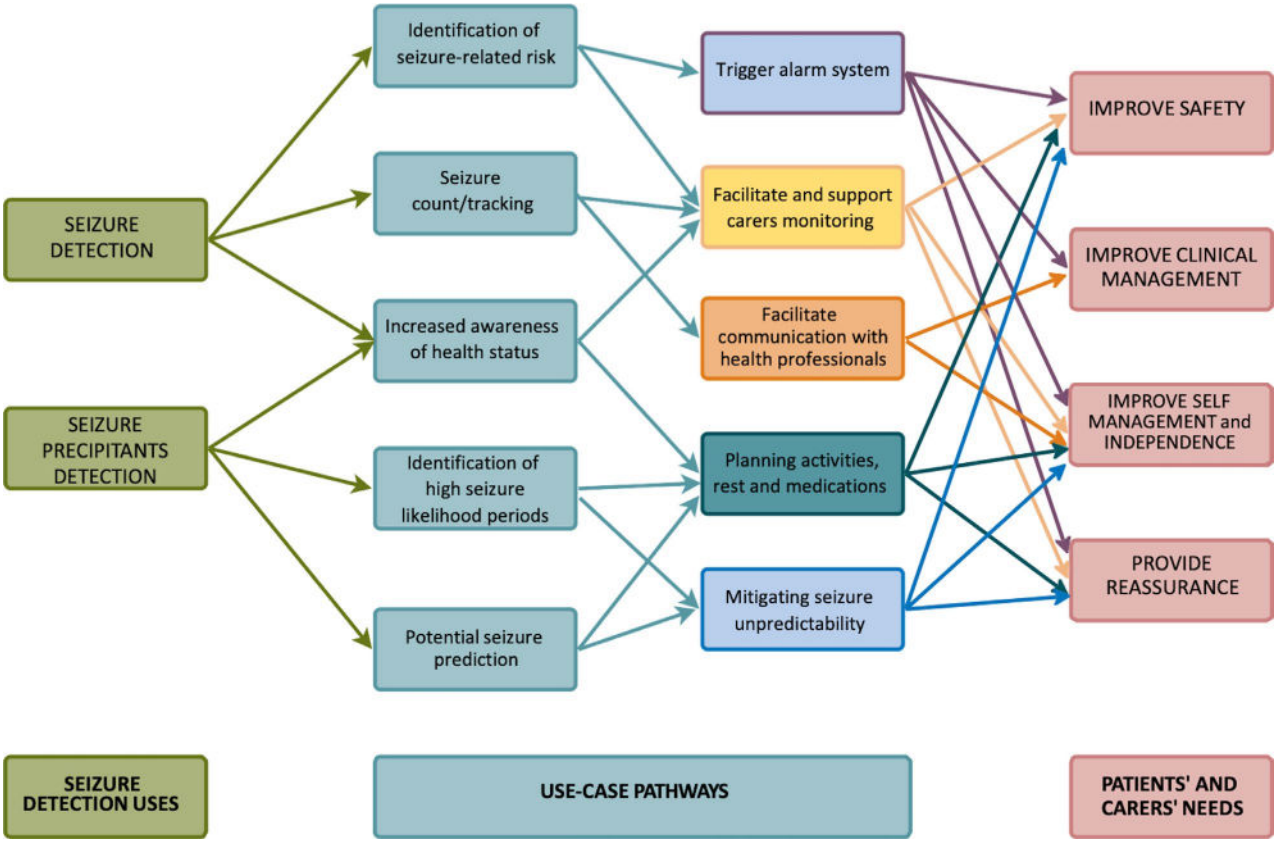

FIGURE 1 Seizure-detection devices applications in relation to the needs of people with epilepsy and their caregivers

patches, bulky or cumbersome shapes, as well as the presence of flashing lights lead to unwanted **visibility**.[32] Discreet, inconspicuous devices that can be worn and covered with clothes are largely favored.[30] However, in the context of exclusively night-time or home use, appearance and visibility are less important and sensors under the mattress and more unconventional designs may be considered acceptable.[3,30,32] **Intrusiveness** is another important factor influencing user acceptance. The number of alerts and interactions required with the device should be kept to a minimum and automated; passive data gathering and sharing is preferable.[3,32] Altogether, users indicate that a device should be socially acceptable, as wearing a device that looks unfamiliar, visible, and intrusive may disclose their condition to others and lead to discrimination, heightened experience of stigma, as well as to self-stigma, as a constant reminder of their state. Ideally a device should also serve other functions (eg, indicate the time) and be integrated with other technological devices (eg, music player) often used in a person's daily life beyond that of a health-monitoring device.

2. **Comfort and usability** are additional important factors. Being undisturbed by the device during routine activity and sleep, as well as the possibility to easily wear, position, and remove it are crucial requirements.[27,30] Potential for customization and choice related to personal preferences (eg, time to get alerts, feedback), a long battery life, and the possibility of being waterproof are further advantages.[24,26,28-30,32]
3. **Confidentiality** in data collection, privacy, and security matters has been rarely addressed in studies investigating users' experiences, despite their significance in this field. Concerns about the information not being kept confidential and concerns related to data safety have been expressed by patients and caregivers in several studies,[3,26,29,30,32] highlighting the potential consequences that privacy breach could have on users' daily life and restrictions of freedom (eg, driving, work, and insurance). Users require the information about where data are hosted, who manages them, the ethics of data ownership and use, and what measures are in place to maintain data security to be systematically provided and explicitly consented.[35]
4. **Support** might be required by PWE and caregivers,[3,24] covering different aspects: Technical support to improve device usability and addressing potential malfunctions, and clinical support[26,30,36] to discuss the data collected and receive feedback. Technical support teams are fundamental and need to be easily identifiable and accessible. A third aspect to be considered is financial support for device purchase. Although some studies have indicated that patients would be willing to contribute to the

cost of the device,[30] others have highlighted the importance of financial assistance to allow the technology to be accessible.[3,31]

5. **Additional features** include integrating information by tracking multiple parameters simultaneously, including mood, behavior, and cognition, to identify major seizure precipitants; this is a very important topic among PWE.[3] The desire to acquire a holistic view of personal health trajectories is related to a major need, that of seizure risk assessment and prediction.[30,37] Finally, there is a demand for devices dedicated to the detection of non-motor seizures, as these seizures may severely affect quality of life and might often be difficult to fully control.[3,28,31]

Another important feature is reliability and lack of significant false detections. Not only do patients and physicians desire devices that detect seizures with reasonable sensitivity, but the specificity must also be high. The ratio of true-positive to false-positive detections must be high. A device that either triggers an alarm or engages a therapeutic intervention cannot afford too many false-positive detections. Frequent false alarms that summon help will lead either to failure to heed alarms or discontinuation of device use. Frequent activation of unnecessary intervention might similarly lead to discontinuation of device use, although the nature of the intervention might affect this decision. For example, in the pivotal trial for a responsive neurostimulation device,[38] the goal was to detect epileptiform activity and then stimulate cortex to abort seizures. The system parameters detected and stimulated a median of ~2800 episodes per day, or approximately 84 000 stimuli per month, in a subject population that reported a median of 8.7 seizures per month. Although the detection rate, and hence, stimulation rate, vastly exceeded seizure frequency (10 000:1 ratio), the benign, asymptomatic nature of the intervention makes this detection algorithm tolerable, and it was proven beneficial. In contrast, a seizure-detection algorithm that automatically alerts carers or emergency medical services cannot have such low specificity, and detections must be reliably associated with seizures or the device could not be used.

5 | WHAT DEVICES FOR SEIZURE DETECTION AT HOME ARE CURRENTLY AVAILABLE, AND WHAT IS THE EVIDENCE FOR THEIR DETECTION PERFORMANCE?

We report here a brief market survey conducted at the end of 2019. To identify candidate devices, we searched PubMed and EMBASE for "(seizure* OR epilep*) AND (detection OR alarm OR monitor) AND (device* OR technology OR mHealth)." We also referred to online seizure-detection device catalogs (https://aanvalsdetectie.nl/index.shtml and https://www.epilepsy.com/deviceapedia-listing-page) as well as our personal knowledge of the field. We excluded invasive, implanted devices such as NeuroPace,[39] since such devices are subjected to intense study and scrutiny. We report here devices aimed at seizure-detection applications, with either medical device approval, or evidence published in peer-reviewed journal articles to support claims of seizure-detection performance, or both (Table 2). Moreover, we evaluated the studies' key features and the clinical validation phase of each seizure-detection device based on Reference 40 (Table S1). We encountered numerous devices and systems marketed for seizure detection that had neither medical device approval nor published evidence, which we do not discuss further here. We also do not discuss the large literature on seizure detection, based on various sensor modalities, using devices not currently being marketed as seizure detectors. The many devices and systems not mentioned here for the preceding reasons use mostly sensor modalities similar to devices discussed later, although automated seizure detection using video (eg, Ref. 41) is not discussed below, because to the best of our knowledge there are no such devices currently on the market. We do not endorse or recommend any of the devices discussed and we draw attention to the risks that some devices are being marketed as seizure detectors without adequate evidence and/or without medical device approval.

6 | DEVICES APPARENTLY AIMED AT SEIZURE-DETECTION APPLICATIONS BUT WITHOUT MEDICAL DEVICE APPROVAL OR WITHOUT EVIDENCE PUBLISHED IN PEER-REVIEWED JOURNAL ARTICLES

6.1 | EmFit

The EmFit (EmFit Corp., Austin TX) is a thin sheet placed under the bed mattress, which incorporates a piezoelectric transducer to measure repetitive motion. Device parameters can be set to allow automated event detection. It does not have approval or clearance as a medical device. In a study of 45 subjects in the epilepsy monitoring unit (EMU), 23 of 78 seizures (of all types) were detected by the EmFit, including 12 of 16 generalized tonic-clonic seizures (GTCSs).[42] False-alarm rate was not reported in this study. In another study of 14 subjects, EmFit had a median sensitivity of 21% and a median false alarm rate of 0.03 per night.[43] In another single-center, prospective study conducted in an adult EMU, comprising 51 patients (3741 recording hours), 16 of 18 GTCSs were detected by the device, with a false-alarm rate

TABLE 2 Overview of currently marketed devices for seizure detection, with either published evidence on device performance or medical device approval

Device	Company	Signals	Placement	Seizure types targeted	Medical device approval	Evidence on device performance	Sensitivity[a]	False- alarm rate[a]
EmFit	EmFit, Corp., Austin, TX	Movement	Under mattress sheet	Seizures with motor features (in bed)	No	42–44	21%-89%	0.03-0.55/night
EpiHunter	EpiHunter NV, Hasselt, Belgium	Single-channel EEG	EEG headset	Absence seizures	EU Class I	45	99.60%	5/d
MedPage	MedPage Ltd, Corby, UK	Audio (bed movement noise)	Under mattress microphone	TCS (in bed)	No	46–47	11.1%-62.5%	4.2/d
Smartwatch Inspyre	Smart Monitor, San Jose, CA	ACM	Wristwatch	TCS	No	48–50	31%-92.3%	NR
Empatica Embrace	Empatica Inc, Cambridge MA, US	ACM, EDA, Temperature, Gyroscope	Wristwatch	TCS	FDA Class II; EU Class IIa	23,53–54,56–58	93%-100%	0.11-0.58/d
Brain Sentinel SPEAC	Brain Sentinel, San Antonio, TX, US	sEMG	Device strapped to biceps	TCS	FDA Class II	62–64	76%-95%	0.014-2.52/d
SeizureLink	Brain Sentinel, San Antonio, TX, US	sEMG	Device strapped to biceps	TCS	EU Class I	65	93.8%	0.67/d
Nightwatch	Livassured, Leiden, Netherlands	ACM, PPG	Upper arm bracelet	Nocturnal seizures with motor features	EU Class I	43	86%	0.25/night
Epi-Care Free/ Epi-Care Mobile	Danish Care Technology ApS, Sorø, Denmark	ACM	Wristwatch	TCS	EU Class I	34,66	90%	0.1-0.2/d

Abbreviations:ACM, accelerometry; EDA, electrodermal activity; PPG, photoplethysmography; sEMG, surface electromyography; TCS, tonic-clonic seizure.

[a]Reported metrics for the seizure types targeted by the device.

of 0.13 per day (out-of-bed events were excluded from the analysis).[44]

6.2 | EpiHunter

The EpiHunter (EpiHunter, NV) is a single-channel wearable EEG recorder, consisting of a small amplifier system in a lightweight box attached to a headband. It has a CE marking in the European Union as a Class I medical device (Class I indicates an "inactive" device that touches intact skin only). It is intended for the automatic detection of absence seizures using EEG analyzed in real time with an automated detection algorithm. At the current time there are only conference presentations of data supporting the algorithm's performance, tested on a single frontal EEG channel derived from standard scalp EEG. In eight patients in whom a total of 141 hours of data were recorded including 279 absences, the system had a sensitivity of 99.6% with five false alarms per day.[45]

6.3 | MedPage

The MedPage MP5 (MedPage Ltd) is an under-the-mattress microphone system intended to record the sound of seizure-related movements during the night. To the best of the authors' knowledge, it does not have medical device approval or clearance. In one study,[46] 64 patients were studied in the EMU for a total of 1528 hours, during which time eight GTCSs were recorded. Five of these eight were detected (63% sensitivity), with a false-alarm rate of 4.2 per day. In a pediatric study in the EMU, only one convulsive seizure was detected by the MP5 device, out of 23 seizures recorded. False-alarm rate was not reported.[47]

6.4 | SmartWatch Inspyre

The SmartWatch Inspyre (SmartMonitor) is a wristwatch-type device containing an accelerometer that detects repetitive motion using an automated algorithm. It does not have medical device approval or clearance. The first study prospectively assessing performance of this device assessed 40 adults in an EMU. Sensitivity parameters were tested and fine-tuned on the study investigators (simulating repetitive movements) and first patients. Seven of eight GTCSs were detected by the device, and 204 false alarms (due to various non–seizure-like movements) were generated (false-alarm rate not reported). Detection latency from onset of the tonic phase of a GTCS was in the range of 5 to 43 seconds.[48] In another study of 62 patients in the EMU with simultaneous video-EEG and SmartWatch Inspyre recording, 10 patients had 13 GTCSs, of which 12 were automatically and correctly identified by the watch and detection algorithm.[49] Forty-nine other seizure types were recorded, but detection performance for these other seizures is not reported. A false-alarm rate is not reported, but 81 false alarms were registered during the data-collection period. A further study also analyzed device performance on 41 patients (aged 5 to 41 years), using predefined sensitivity thresholds. Sensitivity was lower than in previous studies (31% of 51 GTCSs, 16% of all seizures), and no information on false-positive alarms was described.[50] Quality of life measures were assessed in 10 adolescent patients wearing the SmartWatch for 6 months. Overall, the wearable device was well accepted, despite barriers related to technical difficulties, false alarms, and the burden of adding another aspect to their epilepsy care.[51]

7 | DEVICES WITH MEDICAL DEVICE APPROVAL AND EVIDENCE PUBLISHED IN PEER-REVIEWED JOURNAL ARTICLES

7.1 | Empatica Embrace

Empatica Inc (Cambridge, MA) have developed wrist-worn devices with incorporated multimodal sensors (gyroscope, ACM, EDA, temperature, and photoplethysmography). The E4 watch is currently marketed for research studies. On the other hand, the Embrace (incorporating gyroscope, ACM, EDA, and temperature) runs an embedded machine-learning algorithm for detection of GTCSs, based on variation in the detected sensor signals. The wristwatch device links via Bluetooth to a smartphone app (Alert App) that then alerts designated caregivers. Embrace received U.S. Food and Drug Administration (FDA) Section 510(k) clearance as a Class II device (moderate- to high-risk device) in 2018 for adults[52] and in 2019 for children older than 6 years of age.[53] According to its FDA clearance, the Embrace has the following indications and functionalities:

"The Embrace is a prescription only device that is indicated for use as an adjunct to seizure monitoring of adults and children age 6 and up in home or healthcare facilities during periods of rest. The device is worn on the wrist and senses Electrodermal Activity (EDA) and motion data to detect patterns that may be associated with generalized tonic-clonic seizures in patients with epilepsy or at risk of having epilepsy. When a seizure event is detected, Embrace sends a command to a paired wireless device that is programmed to initiate an alert to a designated caregiver. The System records and stores data from Accelerometer, EDA, and Temperature sensors for subsequent review by a trained healthcare professional.[53]" In the European Union, this device has Class IIa clearance, which denotes a noninvasive device-monitoring physiological process, but it is notable that this level

of clearance specifically excludes monitoring physiological processes where variations could result in immediate danger.

The performance characteristics of Embrace and other Empatica devices has been described in a number of publications. In a single-center study, a prototype device measuring EDA and ACM was used in 80 patients in the EMU, totaling 4213 hours (127 days) of recorded time. A semi–patient-specific algorithm (trained on recording data from the seven patients with GTCSs, using leave-one-seizure-out cross-validation) achieved 94% sensitivity (detecting 15/16 GTC), with a false-alarm rate of 0.74 per day.[23] In a multicenter study of 69 patients during admission to the EMU,[54] a total of 5928 hours of data were collected during simultaneous video-EEG and signal collection from E3, E4, and iCalm devices. Therefore, each patient was evaluated for an average of 3.6 days, which is typical for EMU admission. Of these 69 patients, 22 experienced a total of 55 GTCSs. This is a very high seizure rate compared to the broad population of PWE[55] but is probably typical of patients admitted to the EMU. In this study, multiple detection algorithms were investigated offline (not in real time); the best performing algorithm had a sensitivity of 94.55% (correctly detecting 52 of 55 events) but also incorrectly detected 50 events as GTCSs when in fact there had been no seizure (ie, false alarms). This equates to 0.2 false alarms per day on average. The median latency between actual seizure onset and algorithmic seizure detection was 29.3 seconds (range 14.8-151 seconds). From the detection algorithm, it was also possible to make an estimate of seizure duration and compare with the seizure duration estimated from video-EEG data; this comparison showed a correlation of $r = .73$, which could be considered highly correlated.

Of interest, these data were not used in submission for FDA clearance. A second data set was used, combined with a single invariant detection algorithm that was identical for all patients, again evaluating data offline. These data and the related analysis were intended to provide detection sensitivity of 100%, and are mentioned in a review written by the Empatica team[56] and described in outline in the FDA submission[53] but not separately published in peer-reviewed literature. These data comprise 6530 hours of simultaneous video-EEG and signal collection from the Embrace in 135 patients during EMU admission, including a total of 40 GTCSs. Using an algorithm achieving 100% sensitivity (all 40 seizures were correctly detected), the false-alarm rate was 0.43 per day.

Empatica data described above were all collected in EMUs. Although approved and indicated only for seizure detection during periods of rest, data have been presented at conferences regarding detection performance during outpatient "real world" experience, including during periods of activity. In 27 outpatients, a total of 2286 hours of Empatica sensor data were collected and compared with seizure diary data collected by the patient and/or caregivers.[57] Therefore, each patient was monitored for an average of 3.5 days. During this time, a total of 111 GTCSs were recorded in the patients' seizure diaries, a very high seizure rate. In this study, multiple detection algorithms were evaluated offline and tuned; the best-performing algorithm achieved sensitivity of 93% (103 of 111 seizures were correctly detected). Detection sensitivity was lower for events occurring during activity: 40 of 46 events during activity were correctly detected (87%) vs 63 of 65 events during rest (97%). Overall, the false-alarm rate was 0.58 per day. In another conference presentation, data were presented from three patients who had collected Embrace data for more >1 year each.[58] In total, the three patients collected data for 1609 days, experiencing 330 GTCSs in total, a high seizure rate. Sensitivity was 100% in two patients and 97% in the third; false-alarm rate varied from 0.11 per day to 0.32 per day. False alarms were all in the daytime, and only one nocturnal event was missed in the entire data set. One case has been described of probable sudden unexpected death in epilepsy (SUDEP) occurred in a 20-year-old patient while wearing the Embrace, despite an alarm being issued by the device.[59]

7.2 | Brain sentinel SPEAC

The SPEAC device marketed by Brain Sentinel (San Antonio, TX) is a lightweight box that attaches to an adhesive pad containing three pre-gelled electrodes, which are in turn attached to the belly of the biceps muscle. It detects surface electromyography (sEMG) signals. It is intended to be used during rest only. SPEAC was classified as a Class II device by the FDA following an application under section 513(f)(2) in 2017[60] and was cleared under Section 510(k) in 2018 for use in adults.[61] The device links via a laptop and router to online services. According to its FDA clearance,[61] the SPEAC system has the following indications and functionalities: "The SPEAC system is indicated for use as an adjunct to seizure monitoring in adults in the home or healthcare facilities during periods of rest. The system records and stores surface electromyographic (sEMG) data for subsequent review by a trained healthcare professional. The device is to be used on the belly of the biceps muscle to analyze sEMG signals that may be associated with generalized tonic-clonic (GTC) seizures. When sEMG signal patterns associated with a unilateral, appendicular, tonic extension that could be associated with a GTC seizure are detected, the SPEAC system sends adjunctive alarms to alert caregivers. Adjunctive alarms may be disabled by a physician order while continuing to record sEMG data for subsequent review."

The performance characteristics of the SPEAC system have been reported in a cohort of 199 patients admitted to the EMU.[62] In these patients, 9237 hours of simultaneous

video-EEG and SPEAC sEMG data were recorded, including 46 GTCSs. Analyzing data offline, the detection algorithm correctly detected 35 of 46 GTCS (sensitivity 76%), with a false-alarm rate of 2.52 per day, and a median latency between video-EEG seizure onset and event detection by the SPEAC system of 12.8 seconds (range 0.78-25.1 seconds). The authors report that during the study it became apparent that in some cases the device had been improperly placed and was not correctly attached to the belly of the biceps. Hence, a subgroup analysis was carried out for the "properly placed" patients, comprising a subset of 149 patients recorded for a total of 7369 hours and experiencing in total 29 GTCSs. In this subset, the sensitivity was 100%, with a false-alarm rate of 1.52 per day and a median latency for event detection of 13.9 seconds (range 0.78-25.1 seconds). The authors comment that false alarms were not evenly distributed across subjects and were typically related to movement or loose connection of electrodes.

In a subset of these data, an algorithm was developed to automatically estimate the durations of tonic phase, clonic phase, and total GTCS duration, using frequency components of the recorded sEMG signal.[63] Compared to human expert evaluation of these durations using video-EEG data, there was no significant difference in the durations estimated by the automated algorithm and the human expert.

A very small real-world experience with SPEAC has been reported at a conference,[64] including 20 patients during a total of 495 days of monitoring either at home or in a hospital setting. Three GTCSs were detected (one at home), none of which were reported by the patients; the sensitivity seizure detection in this cohort compared to seizure diaries was not reported. False-alarm rate varied from 0.3-0.5 per day and was adjusted during the study by physicians.

7.3 | SeizureLink

A second seizure-detection device based on surface electromyography (EMG), SeizureLink, was formerly known as Epileptic seizure Detector Developed by IctalCare (EDDI) and was acquired in 2017 by Brain Sentinel (San Antonio TX). The device attaches to the patient's biceps and gives real-time alarms in the occurrence of a convulsive seizure, by connecting wirelessly to an audible alarm monitor or other devices. This device received CE marking in 2013 (still under the name of EDDI). Its seizure-detection performance was assessed in an EMU-based prospective multicenter study involving 71 consecutive patients with epilepsy and 3928.6 recording hours. The device detected 30 of 32 GTCSs recorded (sensitivity 93.8%), with a median seizure-detection latency of 9 seconds. False-alarm rate was 0.67/d.[65]

7.4 | Nightwatch

The Nightwatch device marketed by Livassured is an armband with a lightweight box incorporated, which includes sensors for three-axis ACM and PPG. It is intended for use during night-time sleep. To the authors' knowledge, it does not have FDA approval or clearance, but has a CE mark as a Class I medical device in the European Union. The Nightwatch uses a combination of change in heart rate estimated from the PPG signal and motion estimated from ACM to automatically detect seizures with major motor components using an embedded algorithm.

In a study of 34 adult outpatients with intellectual disability living in a long-term care center, 1826 nights of monitoring with the Nightwatch device and simultaneous video were recorded, capturing 809 seizures with prominent motor features (generalized tonic-clonic, generalized tonic lasting >30 seconds, hyperkinetic, or others including clusters lasting >30 minutes of short myoclonic/tonic seizures). Events were recorded in seizure diaries by caregivers, and in addition, simultaneously acquired video of all detected events was reviewed by the research team to establish false-alarm rate. Furthermore, to objectively estimate the sensitivity independently of the seizure diaries, the entire night of video was reviewed for 10% of all nights of recording. In this study, the device and embedded algorithm achieved a sensitivity of 86% and a false-alarm rate of 0.25 per night.[43]

7.5 | Epi-Care Free/Epi-Care Mobile

The Epi-Care device marketed by Danish Care Technology ApS (Sorø, Denmark) is small lightweight box containing a three-axis accelerometer attached to a wrist strap. It is intended to detect GTCS based on motion patterns. When a seizure is detected, the device triggers an alarm on a portable base unit (Epi-Care Free) or sends a message to a caregiver via a wirelessly connected Android smartphone (Epi-Care Mobile). To the authors' knowledge, it does not have FDA approval or clearance, but has a CE mark as a Class I medical device in the European Union. Seventy-three patients were studied with video-EEG and Epi-Care Free in the EMU for a total of 4878 hours, experiencing a total of 39 GTCSs.[66] Thirty-five GTCSs were detected (sensitivity 90%) with 0.2 false alarms per day. In an out-of-hospital study, 112 users of Epi-Care Free or Mobile were asked to complete a questionnaire, of whom 71 returned a completed questionnaire. Users reported a 90% median sensitivity and 0.1 false alarms per day, but an important caveat of this study is that there was no objective independent validation of questionnaire responses.[34]

TABLE 3 Do currently marketed devices match the needs of users?

	Appearance		Visibility		Intrusiveness		Comfort	Usability		
Devices	**Familiar shape**	**Small size**	**Discreet**	**Wearable under the clothes (under the mattress)**	**No interactions required**	**Automated data collection**	**Easily wearable and removable**	**Easy to use**	**Long battery life (>12 hours)**	**Customization/ waterproof**
Emfit	✓	**n.a.**	**n.a.**	✓	✓	✓	**n.a.**	**n.a.**	**n.a.**	**n.a.**
EpiHunter	✗	✗	✗	✗	✓	✓	✓	✓	✗	✗
MedPage	✓	**n.a.**	**n.a.**	✓	✓	✓	**n.a.**	**n.a.**	**n.a.**	**n.a.**
SmartWatch Inspyre	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Empatica Embrace	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Brain Sentinel SPEAC	✗	✗	✗	✗	✓	✓	✓	✓	✓	✗
SeizureLink	✗	✓	✓	✓	✓	✓	✓	✓	✓	✗
Nightwatch	✗	✓	✓	✓	✓	✓	✓	✓	✓	✗
Epi-Care Free / Epi-Care Mobile	✓	✓	✓	✓	✓	✓	✓	✓	✓	✗

✓ yes; ✗ no; ? not found; FAR, false alarm rate; n.a., not applicable.

8 | DO CURRENTLY MARKETED DEVICES MATCH USER NEEDS?

A considerable and growing body of literature has focused on biosensors for seizure detection, and a number of consumer-grade devices, readily available for purchase to patients and caregivers, are promoted as seizures detectors. We compared the requirements and wants of PWE and caregivers with current market offers. The characteristics of the devices were evaluated in light of the views of patients and caregivers. Table 2 summarizes this process. For a device to satisfy the need to improve safety and provide reassurance to self and others, we assume that automation and continuous real-time detection are essential requirements. A further assumed requirement is that they must provide an acceptable above-chance detection accuracy and an acceptable false-alarm rate (FAR). At the current time, only a few studies have asked PWE what would be acceptable sensitivity and FAR for seizure detection devices.[27,31,37] Overall, these studies indicate that for the technology to be acceptable, the detection sensitivity should be above 90% and the FAR should be limited to one per week or 0.14 per day, a combination not currently met by any of the devices considered (Table 3). However, it seems highly likely that criteria for acceptable performance would vary between people. For example, a person with infrequent seizures might want a high sensitivity and very low FAR, because if the person has only four seizures per year, missing even one would be significant and false alarms every few days would be intolerable, whereas a person with dozens of seizures per year might be willing to accept several being missed and false alarms every few days. Furthermore, using seizure-detection devices to satisfy the need to improve clinical and self-management, evaluate treatment effectiveness, and guide treatment changes might not require a high sensitivity or a low FAR: The clinician needs to know whether there has been objective evidence of a change in seizure occurrence rate, which requires only that a change in seizure rate can be reliably detected rather than accurately detecting every event without false alarms. Future work should focus on developing rigorous criteria for acceptable detection accuracy for different seizure rates and for different use-cases (eg, seizure alarm use-case vs treatment-monitoring use-case).

A key evidence gap for current devices is their performance accuracy for focal-onset seizures (or any seizure type without major motor features), since almost all evidence is specific to GTCSs. The authors are aware of several ongoing studies using wearable devices in focal seizures, and evidence in this domain is anticipated soon.

Objective assessment of seizure detection performance has been carried out somewhat naively in all the published studies reviewed here. Typically, the detection sensitivity and false-alarm rate are compared to a gold standard over the same

	Support						Detection accuracy	
Confidentiality/ Data privacy policy	Technical	Clinical (data visualization)	Additional parameters (contextual information)	Different seizure types captured	For continuous (night and day) recording	Real time detection	High detection sensitivity (≥90%)	Low FAR (one/ week or 0.14/24 hours)
✓	✓	✓	✗	✓	✗	✓	✗	✓
✓	✓	✗	✗	✗	✓	✓	✓	✗
✓	✓	n.a.	✗	✗	✗	✓	✗	✗
✓	✓	✓	✓	✗	✓	✓	✗	✗
✓	✓	✓	✗	✗	✓	✓	✓	✗
✓	✓	✓	✗	✗	✗	✓	✗	✗
✓	✓	✓	✓	✗	✓	✓	✓	✗
?	✓	✓	✗	✓	✗	✓	✗	✗
✓	✓	✓	✗	✗	✓	✓	✓	✗

time period (usually EMU-based video-EEG, or video only in some studies, or self-reported seizure diary). No effort is made to test whether the device performance is above chance, that is, whether the device and algorithm have a performance significantly superior to a naive or random detector. For example, a device and algorithm can have a high sensitivity by chance alone if it has a long detection window or a high false-alarm rate, or both. To assess whether detection performance is above chance, the detection performance of the device and algorithm needs to be compared with the detection performance of random events similarly distributed in the data. This is an important evidence gap at the current time.

The opinion of patients and caregivers on specific devices was assessed in some studies. The possibility of increasing safety and improving the independence of both patients and caregivers was praised for some devices (SmartWatch Inspyre,[51] Nightwatch[43]) despite concerns about false alarms and additional burden to epilepsy care (SmartWatch Inspyre[51]). Similar studies reported device design and form to be overall acceptable and comfortable (Nightwatch,[43] Epi-Care Free/ Mobile[34]) except for specific context (eg, Brain Sentinel SPEAC during sleep[62]).

Overall, the evidence assessed in this work indicates that PWE put considerable emphasis on the need for devices to be attractive, comfortable, not obviously "medical" devices, and to be highly usable and nonintrusive. At the current time, several of the devices discussed herein do not seem to have focused on such key features. Nonetheless, there is every possibility that effective technology could be incorporated into greatly preferable form factors. Additional important factors related to data confidentiality and to technical support are less easy to comment on, since confidentiality requirements may differ between jurisdictions, and technical support for users is impossible to evaluate without direct user experience. Finally, recording the trajectory of additional parameters and contextual information that may act as seizure triggers and precipitants is strongly advocated by both patients and caregivers.

9 | CONCLUSION

There is a real need for more reliable ascertainment of seizures, both for diagnostic and therapeutic purposes. At the current time, several seizure-detection devices have medical device approval in the United States or Europe (or both) and have published objective evidence regarding device performance. Our survey of the literature and devices suggest that many more devices may achieve medical device approval in the future and may be accompanied by future published evidence. In addition, there is valuable published evidence about user needs in this specific setting. This seems an encouraging starting point and grounds for future optimism. To meet the needs of people living with epilepsy and their caregivers and ensure tools that can significantly

improve their quality of life, future works should focus on demonstrating the validity and usefulness of data collected in daily life and real-world conditions, as the majority of the current evidence is collected from hospital environments. A joint effort of experts engaged in this field of technological development and users' advisory boards is required to ensure an optimal level of acceptability and usability, which is a key aspect for patients' engagement when long-term use is expected and desired. Finally, to prevent false assumptions and expectations of perfect seizure-detection and seizure-risk mitigation, there is a compelling need to provide the users with balanced information highlighting both the advantages and disadvantages of each technology. We anticipate that home seizure detection will open new avenues to improve both the safety and treatment of people with epilepsy, with our imagination being the only limiting factor.

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CONFLICT OF INTEREST

None of the authors has any conflict of interest to disclose. We confirm that we have read the Journal's position on issues involved in ethical publication and affirm that this report is consistent with those guidelines.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.

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