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RESEARCH ARTICLE

# Home recording of 3-Hz spike–wave discharges in adults with absence epilepsy using the wearable Sensor Dot

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## Abstract

**Objective:** Home monitoring of 3-Hz spike–wave discharges (SWDs) in patients with refractory absence epilepsy could improve clinical care by replacing the inaccurate seizure diary with objective counts. We investigated the use and performance of the Sensor Dot (Byteflies) wearable in persons with absence epilepsy in their home environment.

**Methods:** Thirteen participants (median age = 22 years, 11 female) were enrolled at the university hospitals of Leuven and Freiburg. At home, participants had to attach the Sensor Dot and behind-the-ear electrodes to record two-channel electroencephalogram (EEG), accelerometry, and gyroscope data. Ground truth annotations were created during a visual review of the full Sensor Dot recording. Generalized SWDs were annotated if they were 3 Hz and at least 3 s on EEG. Potential 3-Hz SWDs were flagged by an automated seizure detection algorithm, (1) using only EEG and (2) with an additional postprocessing step using accelerometer and gyroscope to discard motion artifacts. Afterward, two readers (W.V.P. and L.S.) reviewed algorithm-labeled segments and annotated true positive detections. Sensitivity, precision, and F1 score were calculated. Patients had to keep a seizure diary and complete questionnaires about their experiences.

**Results:** Total recording time was 394 h 42 min. Overall, 234 SWDs were captured in 11 of 13 participants. Review of the unimodal algorithm-labeled recordings resulted in a mean sensitivity of .84, precision of .93, and F1 score of .89. Visual review of the multimodal algorithm-labeled segments resulted in a similar F1 score and shorter review time due to fewer false positive labels. Participants reported that the device was comfortable and that they would be willing to wear it on demand of their neurologist, for a maximum of 1 week or with intermediate breaks.

**Significance:** The Sensor Dot improved seizure documentation at home, relative to patient self-reporting. Additional benefits were the short review time and the patients' device acceptance due to user-friendliness and comfortability.

**KEYWORDS**

epilepsy, machine learning, seizure detection, seizure underreporting, wearable devices

## 1 | INTRODUCTION

Typical absence seizures are short-lasting seizures characterized by 3-Hz (range = 2.5–4 Hz) spike–wave discharges (SWDs) on the electroencephalogram (EEG) and brief loss of awareness clinically.[1] Absence seizures appear in idiopathic generalized epilepsies[2,3] and hinder the patient in daily life activities. Although sometimes called "benign," absence epilepsy may be associated with cognitive difficulties[4] and mood disorders,[5] and variable remission rates have been reported.[6–8] Refractory absence seizures have a considerable impact on those affected and society as a whole.

Current clinical management of epilepsy is based on in-hospital video-EEG recordings. At home, it is quite challenging for the patient to self-report their seizures in a diary, due to seizure unawareness or recall bias.[9] Recent research in people with absence epilepsy has shown both underreporting (only 26% of all absences) and overreporting (only 24% of reported absences had an EEG correlate) of seizures.[10] Even lower sensitivities, of 6%–14% for patient self-reporting of absence seizures,[11–13] have been reported. Optimal treatment is difficult when decision-making is based on incorrect seizure frequency estimates. Therefore, the epilepsy community has been looking for new ways to record absence seizure frequency accurately.

Tremendous research has been done into the development of small devices with different types of sensors that can be worn in daily life and that are able to monitor seizures.[14–16] Regarding detection of absence seizures, a few devices[17,18] have been studied, in addition to our own research on the Sensor Dot.[3] The studied devices are EEG-based wearables that have been validated in the controlled setting of an epilepsy-monitoring unit. Although it is essential to compare the performance of a novel device to the gold standard video-EEG (acquired within the hospital environment), the challenge lies in assessing the value of the data recorded at home. Everyday life goes hand in hand with limitations such as obscured signal quality due to movement artifacts, and the patient's willingness and consistency in wearing the device.

The latter is arguably the most important step to study during the development of seizures detection devices, because perfect performance is pointless if patients are not willing to wear it. Previous research showed that seizure detection devices worn in daily life can make a patient feel exposed and vulnerable, but simultaneously, can also validate epilepsy symptoms.[4] Hence, it is indispensable that people with epilepsy are involved in the full process of designing a seizure detection device and that their feedback, such as the need for discreet and unobtrusive wearables,[5] is taken into account.

**Key Points**

- The Sensor Dot with machine learning algorithm can be used to accurately detect 3-Hz SWDs in patients with absence epilepsy at home
- An algorithm using EEG and movement data from accelerometer and gyroscope reduces the amount of data needed to review, by filtering out motion artifacts
- The Sensor Dot can be boxed and sent to the patient to enable remote monitoring
- Adult patients are willing to wear the device for 24 h at home, which could improve clinical management

Previously, we have shown in a phase 2 study[6] that different neurologists can recognize 3-Hz SWDs on the two-channel Sensor Dot EEG.[3] Here, we present the first phase 4 study[19] investigating the performance and usability of the Sensor Dot for detection of 3-Hz SWDs in patients with absence epilepsy in the home environment.

## 2 | MATERIALS AND METHODS

### 2.1 | Study design

This was a duo-center prospective study to evaluate the accuracy of the Sensor Dot in combination with our detection algorithm in detecting 3-Hz SWDs in the patient's home environment. Through questionnaires, we collected patient feedback on the use of the Sensor Dot in daily life. The ethical committees of UZ/KU Leuven and University Hospital Freiburg approved this study.

### 2.2 | Participants

We enrolled 13 patients in University Hospital Leuven and University Hospital Freiburg between March 15 and June 15, 2022. Patients were eligible for inclusion if they

had refractory absence epilepsy and previously participated in the in-hospital phase of SeizeIT2 (clinicaltrials.gov NCT04284072). All patients gave written informed consent.

## 2.3 | Sensor Dot

Participants received the medical device Byteflies kit (Byteflies) via post, containing two EEG-based Sensor Dots (wearable recording devices, to be used alternately every 24 h or to have one spare in case of technical issues), the 4-Wire Cradle with adhesive, the Docking Station, and four Ambu BRS neonatal electrocardiography adhesive electrodes (Ambu) to be used as behind-the-ear EEG electrodes. The device is a small (24.5 × 33.5 × 7.73 mm; 6.3 g) biopotential amplifier with a battery life of 24 h. Participants received instructions on paper and if necessary via phone call on the installation of the Byteflies kit. They were also instructed on how to place the electrodes on the mastoid bone behind the ears, two on each side of the head, approximately 5 cm apart (Figure 1). Electrodes on the same side had to be connected to create two ipsilateral, one left and one right, EEG channels (sampled at 250 Hz). The Sensor Dot has an accelerometer and gyroscope to measure movement. After every recording, the Sensor Dot had to be placed in the docking station to upload the data to the certified Byteflies cloud.

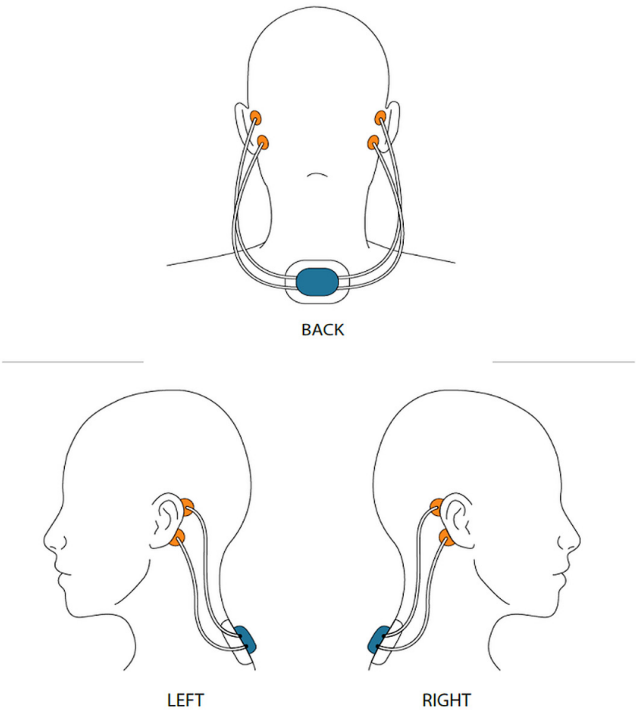


**FIGURE 1** Setup of Sensor Dot device with adhesive electrodes attached behind the ears and the Sensor Dot attached on the neck/upper back.

Participants were instructed to use the Sensor Dot for 1 day at home, preferably on a quiet day to limit the presence of artifacts. They were instructed to record at least 24 h but were free to choose when to start and stop recording so that participating in the study would not interfere with daily activities if they did not want it to. Participants who wanted to use the device for >1 day were allowed to do so. In this case, Sensor Dots had to be changed every day due to battery capacity of approximately 24 h. Patients could easily take another charged Dot out of the Docking station to continue recording. Electrodes had to be changed when they came loose or when the electrodes started to feel uncomfortable for the patient.

## 2.4 | Algorithm development

We previously published the development of our new pipeline for semiautomatic absence seizure detection in the home environment. In Chatzichristos et al.,[20] the detection algorithm was presented, without and with a postprocessing step. The algorithm presented in Swinnen et al.[13] was the starting point and underwent modifications to consider the artifacts during daily life such as those caused by movement and flat lines due to disconnection of electrodes. Performance metrics were calculated and are defined below. The metrics were compared to the ground truth and are based on true positives (TPs; if the algorithm detection occurred between the EEG onset and end of the seizure), false negatives (FNs; if there was a seizure but no overlap with an algorithm detection), and false positives (FPs; if there was an algorithm detection but no seizure, FPs within 3 s of each other were counted as one FP).

- Sensitivity: TPs / (TPs + FNs), indicates the number of 3-Hz SWDs that were correctly detected
- Precision: TPs / (TPs + FPs), indicates whether a labeled segment was actually a 3-Hz SWD
- FPs/h: calculated over all seizures and median across patients

First, we employed a unimodal approach using behind-the-ear EEG with minor modifications from the algorithm in Swinnen et al. For instance, whereas the zero crossings were previously calculated from the filtered signals, they were now computed on the raw signal, as it was more discriminative.

Second, we added a multimodal postprocessing step to this algorithm, which in addition to behind-the-ear EEG now also employed the accelerometer and gyroscope. This was done to counteract the many FPs caused by the segments with artifacts due to movement.

Another difference in the home-based study is the data used for training the model. Previously, in-hospital data of the patient were used to train the algorithm. In the current study, we could choose three different paths: training with (1) data of the first day of home recording of the patient, annotated by a neurologist (only if the patient recorded for multiple days); (2) hospital data of the patient; or (3) data of home recordings from other patients, annotated by a neurologist, and hospital data of the test patient. Here all recordings were analyzed following the third approach.

## 2.5 | Visual review of Sensor Dot signals

To constitute a ground truth to which to compare the algorithm performance as well as the subsequent visual review, the full Sensor Dot recording was reviewed by a PhD student (L.S.) with 2 years of experience in reading two-channel EEG. All 3-Hz SWDs of at least 3 s were annotated and presented to an epileptologist for confirmation.

Second, both algorithms (i.e., with and without multimodal postprocessing) were applied to the recordings, and detections made by the algorithms (from here on the "algorithm-labeled segments") were reviewed independently by an epileptologist (W.V.P.) and a PhD student (L.S.), who annotated onset and ending of each 3-Hz SWD of ≥3 s. The annotations of the visual review by the two readers were compared to the ground truth, and sensitivity, precision, and F1 score (harmonic mean of sensitivity and precision, ranging from 0 [poor] to 1 [excellent]) were calculated. The time needed to review the files was tracked as well.

Additionally, an expert in behind-the-ear EEG visually determined onset and ending of periods with artifacts on Sensor Dot EEG, in line with the paper by Radüntz.[21] Movement and electronic artifacts as well as flat lines were annotated with a start and stop label. The percentage of time with insufficient signal quality was calculated relative to the total recording time.

## 2.6 | Questionnaires

Patients received (daily, in case they recorded for >1 day) a questionnaire on paper using predefined statements about technical failures and possible side effects, and one questionnaire at the end of recording about their experience (Table S1). The statements in the questionnaires were answered, respectively, with yes/no or on a Likert-type scale from 0 (no) to 10 (absolutely) with additional space for free text comments. Patients who recorded for 1 day had to fill out both questionnaires at the same time. Additionally, patients were asked to write down whether they had had any epileptic seizures (yes/no), how many, and at what time and to give a description of this event. Seizures reported in the diary were compared to seizures on Sensor Dot EEG and a TP was pragmatically defined by taking into account a larger time frame and description of the event for comparison.

# 3 | RESULTS

Thirteen adult patients were enrolled. Median age of patients was 22 years (range = 17–46 years, 11 female). All participant information is summarized in Table 1.

Total time of recording was 394 h 42 min (median across patient recordings = 22 h 47 min). Although we recommended recording for approximately 24 h, the participant was free to choose when to start and stop recording, which resulted in varying recording durations. One participant experienced premature battery depletion and therefore switched the Sensor Dot after 8 h to use another Dot, which then recorded for 16 h. A second participant used two Dots to record subsequently for approximately 10 and 14 h. No reason was noted. Four participants recorded for two full days.

As the ground truth, we recorded 234 SWDs of 3 Hz with time duration of ≥3 s in 11 patients. Two of 13 patients did not have any SWDs on the day of recording, neither on Sensor Dot recording nor reported in the seizure diary. These recordings were only considered in the calculation of FPs/h and precision of the algorithm detection and subsequent visual review.

The time to review a full 24-h file as ground truth was on average 55 min 31 s (median = 52 min 54 s).

## 3.1 | Algorithm performance

We present performance of the algorithm over the total of 234 SWDs of 3 Hz with a duration of ≥3 s. Second, we provide the patient-specific means and medians. Compared to the ground truth of 234 SWDs, the unimodal algorithm detected the SWDs with a total sensitivity of .87 (median across patients = .96, mean = .91), 4.03 FPs/h (median = 1.15 FPs/h, mean = 3.20 FPs/h), and precision of .11 (median = .15, mean = .31). The multimodal algorithm gave a total sensitivity of .86 (median = .94, mean = .84), 2.29 FPs/h (median = .56 FPs/h, mean = 1.77 FPs/h), and precision of .18 (median = .47, mean = .46). Details of per patient results are shown in Table 2.

**TABLE 1** Participant information.

| Subject | Center | Sex | Age, years | Epilepsy syndrome | Current ASM | Past ASMs |
|---|---|---|---|---|---|---|
| SUBJ-4-388 | UKF | F | 21 | JAE | BRV, LTG | LEV |
| SUBJ-1a-391 | UZL | M | 17 | JAE | BRV, LTG | ESM, VPA |
| SUBJ-1a-412 | UZL | F | 22 | JAE | ESM, LTG, LEV, VPA | BRV, CLB, LCM |
| SUBJ-1a-416 | UZL | F | 22 | JAE | LTG | BRV, LEV, VPA |
| SUBJ-1a-417 | UZL | F | 23 | JAE | BRV, ESM, LTG | ESM, LEV |
| SUBJ-1a-421 | UZL | M | 26 | JAE | ESM, LTG, VPA | BRV, LCM, LEV, OXC, PER, TPM |
| SUBJ-4-422 | UKF | F | 32 | JME | BRV, LTG, PER | ESM, LTG, LEV, VPA, PER, TPM, ZNS |
| SUBJ-1a-431 | UZL | F | 23 | JAE | BRV, ESM | LTG, LEV |
| SUBJ-1a-465 | UZL | F | 19 | CAE | ESM, LTG | LEV, OXC |
| SUBJ-4-475 | UKF | F | 18 | JME | LTG, LEV, PER | LTG, LEV, PER |
| SUBJ-1a-478 | UZL | F | 46 | JAE | LCM, VPA | ESM, LTG, LEV, TPM |
| SUBJ-4-484 | UKF | F | 21 | Jeavons syndrome | BRV, VPA, PER | BRV, LTG, LEV, VPA |
| SUBJ-4-487 | UKF | F | 25 | JAE | LTG, ZNS | ESM, LTG, ZNS |

Abbreviations: ASM, antiseizure medication; BRV, brivaracetam; CAE, childhood absence epilepsy; CLB, clobazam; ESM, ethosuximide; F, female; JAE, juvenile absence epilepsy; JME, juvenile myoclonic epilepsy; LCM, lacosamide; LEV, levetiracetam; LTG, lamotrigine; M, male; OXC, oxcarbazepine; PER, perampanel; TPM, topiramate; UKF, University Hospital Freiburg; UZL, University Hospital Leuven; VPA, valproate; ZNS, zonisamide.

## 3.2 | Performance of visual review of algorithm-labeled segments by readers

Afterward, all detections made by the algorithms were provided to the readers. Review of the unimodal algorithm-labeled segments by the readers resulted in an average overall sensitivity of .84, precision of .93, and F1 score of .89, compared to the ground truth of 234 SWDs. Second, visual review of the multimodal (postprocessing) algorithm-labeled segments resulted in an average total sensitivity of .83, precision of .94, and F1 score of .88. Note that because the algorithms only detected 87% and 86% of all SWDs, respectively, the sensitivity of the readers over the total number of SWDs may only have the same or lower values. The detailed summary of all TPs, FNs, and FPs is given in Table S2.

Because all recordings had a variable duration, the time needed to review a single file was weighted to a 24-h file. The time to review was shorter for the multimodal algorithm-labeled files (mean = 3 min 38 s, median = 1 min 38 s) compared to unimodal algorithm-labeled files (mean = 4 min 51 s, median = 3 min 15 s). A 3-Hz SWD on Sensor Dot, as detected by the algorithm and subsequently by the readers, is shown in Figure 2.

## 3.3 | Device deficiency

The number of EEG periods obscured by artifacts on both EEG channels was on average 19% of the total recording (median = 10%, interquartile range [IQR] = 7%–16%). The number with one-sided obscured signal, meaning that the EEG is still readable on the remaining channel, was on average 9% (median = 5%, IQR = 2%–10%).

There were a few recordings with very low signal quality. In one recording, the left channel was obscured 48% of the time with artifacts resembling SWDs (Figure 3), probably due to disconnection of the left-side electrodes. These artifacts resulted in 21.06 FPs/h for this particular recording when analyzed with the unimodal algorithm. Review time of this recording was longer than usual, approximately 18 min. The multimodal algorithm could filter these segments out as artifacts, and the FPs/h were considerably reduced to 14.50 FPs/h and a review time of 13 min.

Examples of the most common types of artifacts are presented in Figure S3.

## 3.4 | Patient feedback

Eleven of 13 participants completed the questionnaires. All seizure diaries were empty, except one, in which the participant reported having had four absence seizures. None of these reported seizures coincided with SWDs on Sensor Dot EEG. Two participants reported having "woken up during the night but did not know why" and "probably had some absences." As they could not specify a time and the reports may have been guesses, they were not taken into account.

The first questionnaire consisted of statements regarding technical issues and adverse events. Pain or irritation

**TABLE 2** Summary of all per-patient metrics (TPs, FPs, sensitivity, precision, and FPs/h) of the respective absence detection algorithm and the total length of recordings and total seizures.

| | Recording | | Unimodal algorithm | | | | | Multimodal algorithm | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Subject | Length | Seizures | TPs | FPs | Sensitivity | Precision | FPs/h | TPs | FPs | Sensitivity | Precision | FPs/h |
| SUBJ-4-388 | 24:10:52 | 1 | 1 | 77 | 1.00 | .01 | 3.18 | 1 | 41 | 1.00 | .02 | 1.70 |
| SUBJ-1a-391[a] | 30:40:47<br>22:41:07 | 95 | 74 | 88 | .78 | .46 | 1.65 | 74 | 85 | .78 | .47 | 1.59 |
| SUBJ-1a-412 | 24:22:42 | 23 | 20 | 24 | .87 | .45 | .98 | 20 | 22 | .87 | .48 | .90 |
| SUBJ-1a-416 | 23:47:28 | 72 | 69 | 21 | .96 | .77 | .88 | 68 | 17 | .94 | .80 | .71 |
| SUBJ-1a-417[a] | 22:21:20<br>22:56:45 | 5 | 5 | 954 | 1.00 | .01 | 21.06 | 5 | 657 | 1.00 | .01 | 14.50 |
| SUBJ-1a-421 | 21:19:48 | 3 | 2 | 59 | .67 | .03 | 2.77 | 1 | 12 | .33 | .08 | .56 |
| SUBJ-4-422[a] | 31:14:26<br>24:02:03 | 2 | 2 | 6 | 1.00 | .25 | .11 | 1 | 2 | .50 | .33 | .04 |
| SUBJ-1a-431 | 9:32:56 | 2 | 2 | 11 | 1.00 | .15 | 1.15 | 2 | 0 | 1.00 | 1.00 | .00 |
| SUBJ-1a-465[a] | 23:34:06<br>23:23:26 | 0 | 0 | 245 | N/A | .00 | 5.22 | 0 | 0 | N/A | N/A | .00 |
| SUBJ-4-475 | 22:47:46 | 6 | 5 | 79 | .83 | .06 | 3.47 | 5 | 61 | .83 | .08 | 2.68 |
| SUBJ-1a-478 | 24:58:23 | 2 | 2 | 0 | 1.00 | 1.00 | .00 | 2 | 0 | 1.00 | 1.00 | .00 |
| SUBJ-4-484[a] | 10:16:33<br>13:52:39 | 0 | 0 | 21 | N/A | .00 | .87 | 0 | 0 | N/A | N/A | .00 |
| SUBJ-4-487 | 18:39:19 | 23 | 22 | 6 | .96 | .79 | .32 | 22 | 5 | .96 | .81 | .27 |

*Note*: Durations of recordings per used Sensor Dot are given.

Abbreviations: FP, false positive; N/A, not available; TP, true positive.

[a]Patients who recorded for >1 day.

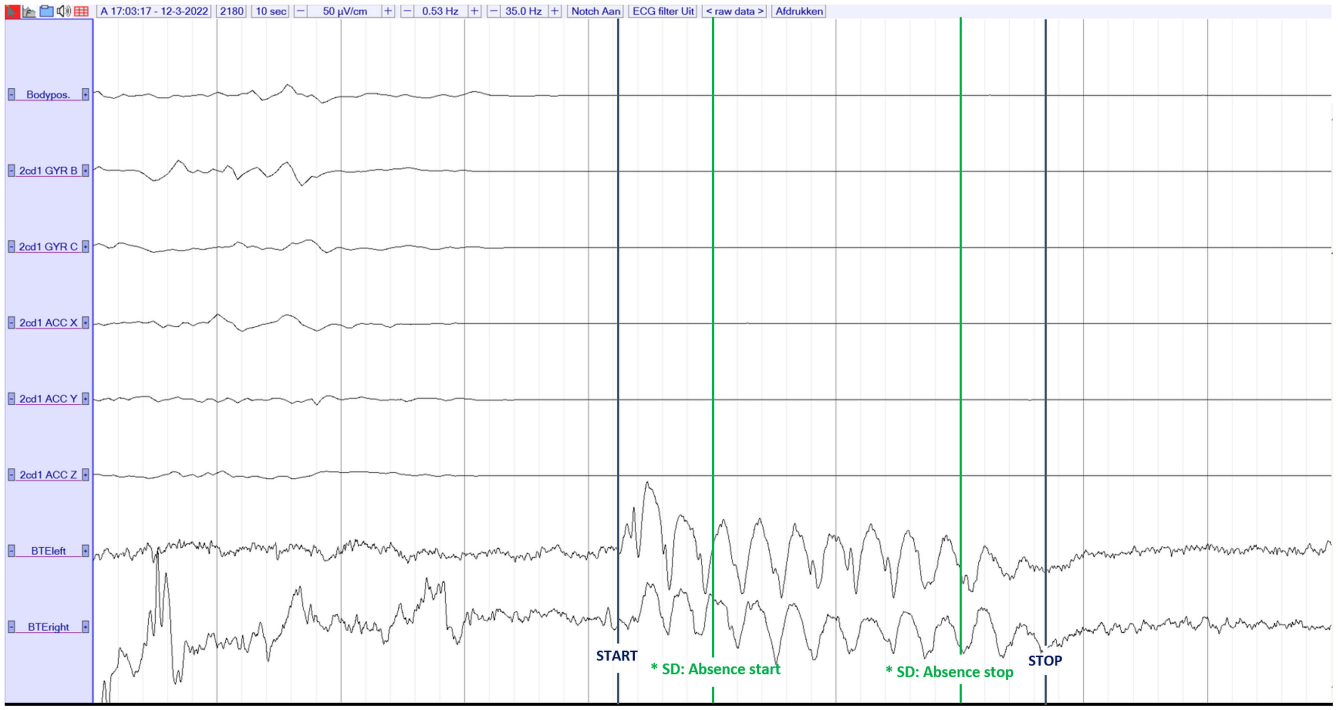


**FIGURE 2** Example of an algorithm-detected 3-Hz spike–wave discharge of ≥3 s on Sensor Dot recording. The recording includes the following channels (from top to bottom): gyroscope in three different axes, accelerometer in three different axes, the left electroencephalographic (EEG) channel, and the right EEG channel. Filters used for all channels were high pass filter of .53 Hz, low pass filter of 35 Hz, and notch filter of 50 Hz. The sensitivity of the Sensor Dot EEG was 50 µV/cm. The detections made by the algorithm are in green and indicated with an asterisk*; the annotations made by the reviewer are in blue. Signals in accelerometer and gyroscope show interruption of movement during the absence seizure. SD, Sensor Dot.

caused by the device was reported twice (13%). The Sensor Dot came loose or was detached in only one case (6%). No one reported having had issues for which help was needed. However, it was reported four times that an error occurred that the participant could fix (25%). These errors included having to reattach electrodes because of wrongful placement initially, replacing the device with a spare one because it did not start recording, multiple attempts to connect the Docking Station to Wi-Fi, and having to reconnect the electrode cables to the wire cradle holding the device.

The end questionnaire focused on several topics: motivation to wear the device, design and comfort, the preferred duration of monitoring, and potential stigmatization. The statements and response median scores (on a Likert-type scale from 0 to 10) and IQRs are displayed in Table 3.

We found that for every patient, the motivation to wear the device was finding the right medication and dose and consequently becoming seizure-free. As such, they hoped they would soon be able to resume their daily activities, for example, driving a car.

Regarding comfort and design of the wearable Sensor Dot with third party Ambu electrodes, seven patients (64%) found it easy to apply. Three patients (27%) reported that assistance with attaching the behind-the-ear electrodes was needed; however, besides this the setup was unproblematic. One patient was neutral. The wearable device was deemed an improvement over wearing an ambulatory EEG cap or visiting the hospital when living far away. Two participants (18%) reported forgetting they wore the device. Two other participants (18%) found it uncomfortable to wear during the day. There were mixed reactions about the length of the wires. Two (18%) found them too long and felt they were getting in the way, whereas another person (9%) found them too short, which limited them in their movements. A third group of participants (73%) reported no complaints concerning the wires and said they could move well. During the night, the wearable setup was overall comfortable to sleep with. Three participants (9%) felt a bit bothered by the device, while turning in their sleep or because the placement on the back was uncomfortable. The main barrier to wearing the wearable setup were side effects. Two participants (18%) reported redness, itching, and irritation of the skin caused by the adhesives. Both patients recorded for 1 day. Four other patients (36%) suggested not wanting to wear it for a long period due to sensitivity to patches and skin irritation. Six patients (55%) experienced limitations in daily life activities like playing sports and difficulties with showering. Three participants

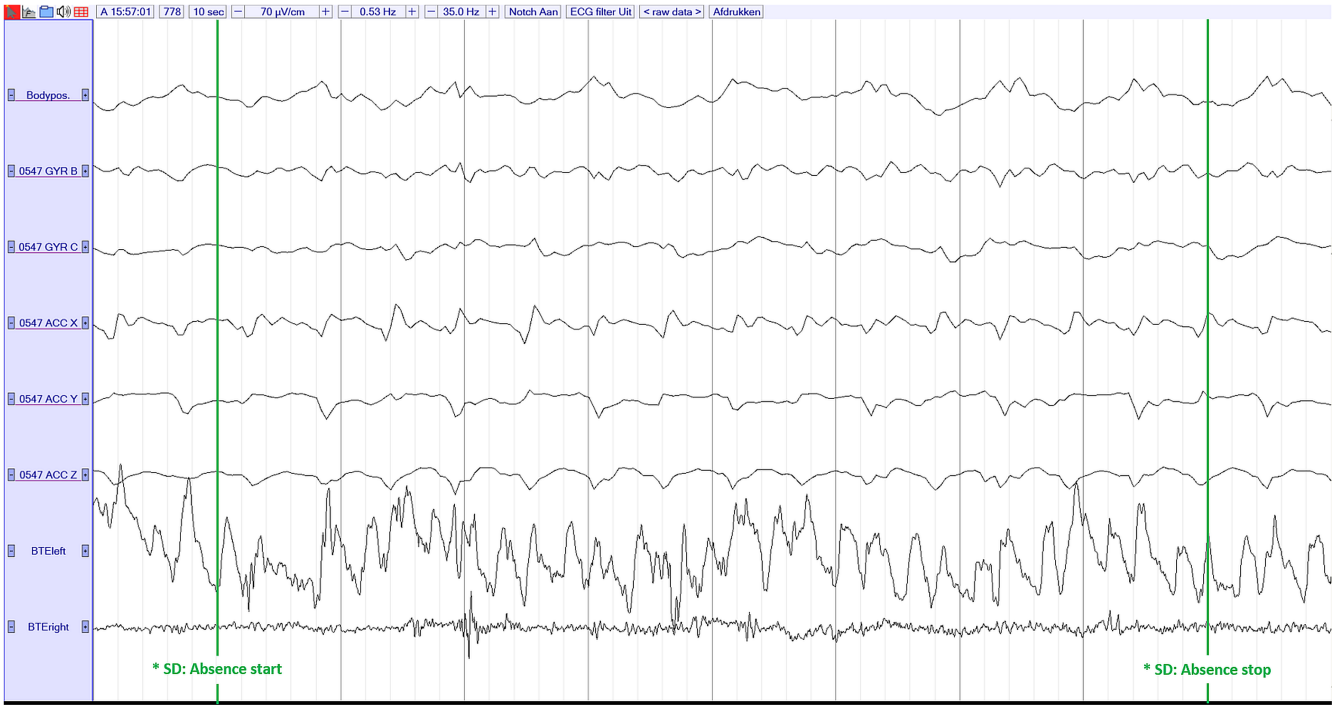


**FIGURE 3** Artifacts due to electrode disconnection on the left channel, labeled as 3-Hz spike–wave discharge by unimodal detection algorithm (green), probably due to resemblance to spike–wave discharges. When using the algorithm with multimodal postprocessing, this segment was not detected as a seizure. The recording exists of the following channels (from top to bottom): gyroscope in three different axes, accelerometer in three different axes, the left electroencephalographic (EEG) channel, and the right EEG channel. Filters used for all channels were high pass filter of .53 Hz, low pass filter of 35 Hz, and notch filter of 50 Hz. The sensitivity of the Sensor Dot EEG was 70 µV/cm. The detections made by the algorithm are in green and indicated with an asterisk*. SD, Sensor Dot.

**TABLE 3** Result scores of end of recording questionnaire: median and IQR of responses based on a Likert-type scale ranging from 0 (no) to 10 (absolutely).

| Question/statement (0 = no, 10 = absolutely) | Median | IQR |
|---|---|---|
| If the Sensor Dot could help you and your neurologist to quickly find the correct medication, diagnosis, and/or treatment (with improved quality of life), would you then wear the Sensor Dot in your everyday life? | 10 | 6.5–10 |
| What is the maximum amount of time that you would want to wear the Sensor Dot (including the electrodes)? (never/<1 week/1 week/2 weeks/3 weeks/4 weeks) | 1 week | <1 week–2 weeks |
| I'm worried about how I look while wearing the device; I feel tense or on edge | 5 | 3–8 |
| It's easy to use the device, and the instructions are very clear | 9 | 8.5–10 |
| It was comfortable to wear the device during the day | 7 | 7–8.5 |
| It was comfortable to wear the device during the night | 8 | 6.5–10 |
| I'd be willing to use the device again if my neurologist would ask | 9 | 8.25–10 |
| I'm very good at using smartphones and/or tablets | 9 | 8.5–10 |

Abbreviation: IQR, interquartile range.

(27%) reported being anxious that something would break off or come loose and that they would crush the device. These barriers influenced the preferred duration of monitoring with the Sensor Dot. The majority ($n = 8$, 73%) noted that they wanted to wear the device for 1 week or less, mainly because of side effects. Three patients (27%) suggested wearing it with intermediate breaks to reduce irritation, to shower, and to be able to plan activities outside of the monitoring period.

Another recurring topic was feeling observed and the opinion of others. Five patients (45%) noted that the wearable setup was still relatively visible. They found it

uncomfortable and embarrassing to have to keep explaining to other people why they wore it. They felt it was perceived as "weird" and "abnormal." Four participants (36%) did not consider this an issue, because they could hide the wires and the device by covering it with their longer hair. In line with this, another participant (9%) reported being more likely to wear it during winter, because she would sweat less and could cover the wires.

## 4 | DISCUSSION

We have shown that people with absence epilepsy are able and willing to use the wearable seizure detection device, Sensor Dot, at home. Our machine-learning absence detection algorithm could detect 3-Hz SWDs of ≥3 s in the Sensor Dot recordings with a high sensitivity of .86. Consequent clinical review of these algorithm-labeled segments maintained a high sensitivity of .83 and increased precision to .94.

We present here the first phase 4 (recording of 234 SWDs at home) validation of a wearable device for people with absence epilepsy. In the prior in-hospital study,[13] multiple neurologists could, with the assistance of an algorithm, recognize 3-Hz SWDs of ≥3 s with a median sensitivity of .83, precision of .89, and F1 score of .87, compared to the gold standard video-EEG. Here, as the study was performed in the patient's home, there was no clear gold standard such as video-EEG for comparison with semiautomatic and subsequent visual review annotations. Additionally, participants were not able to correctly self-report any absence seizures, and hence this could not be used as a ground truth. Therefore, annotations of the review of the entire 24-h recordings were used.

We recommended the patients use the Sensor Dot on a quiet day at home; however, we naturally noticed artifacts obscuring the signal at certain times in the EEG (Figure 3). There were various reasons for artifacts, for example, movement, disconnection of an electrode, and wrongful placement of behind-the-ear electrodes, which led to more muscle artifacts. The small drop in sensitivity in the visual review compared to automatic detection could also be explained by artifacts covering the SWDs. Other SWDs were only nearly 3 s and therefore occasionally missed. The algorithms could only detect one additional 3-Hz SWD of ≥3 s other than those initially annotated by the expert.

In this study, we prioritized higher performance over real time detection, because in absence epilepsy, the greatest potential offered by wearables is generating an objective and accurate seizure diary. With our semiautomatic method, the neurologist has the possibility to visually check and quantify the SWDs that were detected by the algorithm. Moreover, this brief visual review improves the precision of SWD detection to a near-perfect score of .93–.94, reflecting the clinical value.

Objectively counting seizures would mean a positive shift in clinical decision-making. Yet, a major concern for implementation of wearable devices in clinical practice is the time needed to review the acquired signals.[8] We have overcome that barrier, as we have shown that review of 24 h of wearable recordings, after use of our absence detection algorithm, can be performed in <5 min, compared to approximately 1 h to review the full recording. Especially when accelerometer and gyroscope were used to discard alarms that were coinciding with significant movement, the number of labels was substantially decreased and thus review time. Previously, we reported in our hospital-based validation that the review could be performed in 5–10 min.[13] This shows that training and experience in reading two-channel EEG has an additional positive effect on review time.

Using a multimodal approach versus a unimodal one decreased review time, and importantly, in the recordings without seizures the multimodal approach did not label any segments, whereas the unimodal approach resulted in numerous FPs (Table 2). Performance of the visual review using both approaches remained, however, similar. Adding movement data does not seem to alter experts' decision-making. Possibly, as EEG is the main modality to identify absence seizures, less attention was given to the accelerometer and gyroscope data. Moreover, SWDs that were not annotated by the readers were usually covered in muscle artifact. Concomitant movement on accelerometer would only consolidate the decision not to label it as a seizure.

Overall, participants were willing to use the Byteflies kit, which is in line with previous research on wearable technology.[22] We suggested wearing the device 1 day at a time at home. This persuaded many to participate in this trial, keeping in mind that stigmatization due to visibility of the device to the outside world is still a concern. Olsen and colleagues[23] previously found that wearables made people with epilepsy feel exposed and vulnerable. Unfortunately, detection of absence seizures is not possible without EEG, but participants who reported being able to cover the electrodes and device with their hair or clothes felt less on edge or worried. The participants reported being willing to wear the device for <1 week to a maximum of 2 weeks, possibly with intermediate breaks. Although epilepsy professionals prefer (ultra)long-term monitoring, 1 day of objectively recording 3-Hz SWDs in a patient is probably sufficient to optimize clinical management. This provides the person with epilepsy some autonomy to choose which day they will wear the device and reduces fear about stigmatization.

The wearable setup was comfortable for the participants during day and night, although there were some complaints about the length of the wires and the adhesives causing redness and irritation. In this study, we have used commercially available Ambu adhesive electrodes, because the dedicated Byteflies hydrogel electrodes were under development at the time of this research. With the dry-electrode-based version, we[24] have shown that long-term monitoring is not feasible due to the aforementioned side effects. These side effects are commonly caused by adhesive patches,[25] and further improvement in terms of biocompatibility of these electrodes and patches is necessary. Furthermore, the wearable device is designed so that it can be placed on the neck, back, or shoulder of the person. The person can consequently select a location that is most comfortable.

A permanent limitation in automated detection of absence seizures at home is the lack of knowledge about the presence of a clinical correlate during the SWD. Even during video-EEG monitoring, noticing a decrease in awareness during an absence seizure of mere seconds is challenging. It remains unclear whether only clinical seizures in absence epilepsy should be treated. A commonly used threshold to separate clinical from subclinical absence seizures is SWDs with a duration of 3 s or more. We also used this threshold here. Meritam Larsen et al.[26] found in their data-driven study that the range of duration of typical absence seizures in patients who did not undergo antiseizure medication (ASM) withdrawal is between 2.75 and 26 s, which corroborates the 3 s rule. Also the International League Against Epilepsy reports typical absence seizures to usually have a duration of 3–20 s.[1] In the multimodal algorithm, we used accelerometer and gyroscope to filter out movement artifacts. These modalities may give an idea about the possible interruption of activities during an absence seizure, although this should be interpreted with caution. Recently, it was shown that machine-learning approaches could be used in determining impaired behavior during electrographic absence seizures, based on features derived from the full or high-density EEG.[27] Further research may open the door to implementing such strategies in long-term wearable absence seizure detection.

## 5 | CONCLUSIONS

We have demonstrated that the patient can handle the Sensor Dot for at least 1 day at home. SWDs of 3 Hz with a duration of at least 3 s, which appear to be the best biomarker for absence seizures, can be detected with high accuracy by reviewers, when an automated algorithm is used as an assistive tool. Our future research will focus on the potential benefit of using the Sensor Dot in the clinical management of patients with absence epilepsy. We would obtain a baseline absence seizure frequency. At least 5 half-lives after a change in ASM, we would repeat the EEG measurement, with the aim of obtaining seizure freedom as soon as possible on the lowest dose of ASM possible.

### AUTHOR CONTRIBUTIONS

Lauren Swinnen, Andreas Schulze-Bonhage, Matthias Dümpelmann, Maarten De Vos, and Wim Van Paesschen contributed to the conception and design of the study. Lauren Swinnen, Christos Chatzichristos, Miguel Bhagubai, and Wim Van Paesschen performed data analysis. All authors contributed to data interpretation. Victoria Broux and Nicolas Zabler contributed to the acquisition of data. Lauren Swinnen drafted the original manuscript and prepared the figures. All authors critically revised the manuscript for important intellectual content.

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### CONFLICT OF INTEREST STATEMENT

None of the authors has any conflict of interest to disclose.

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## SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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