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Assessment of the technical usability and efficacy of a new portable dry-electrode EEG recorder: First results of the HOME^{ONE} study

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HIGHLIGHTS

- Technical usability and efficacy of a new portable dry-electrode EEG recorder was assessed.
- New dry-electrode EEG device was shown to have technical comparability to conventional EEG devices.
- New dry-electrode EEG device allows for sufficiently reliable clinical evaluation.

ABSTRACT

Objectives: The *HOME* project is intended to provide evidence of diagnostic and therapeutic yield of a patient-controlled EEG home-monitoring for neurological outpatients.
Methods: This study evaluated the technical and practical usability and efficacy of a new portable dry-electrode EEG recorder in comparison to conventional EEG devices based on technical assessments and inter-rater comparisons of EEG record examinations of office-based practitioners and two experienced neurologists.
Results: The technical assessment was based on channel-wise comparisons of band power values derived from power spectra as observed in two recording modalities. Slight yet significant differences were observed only in the Delta-frequency band (1.5–4 Hz). The fraction of automatically detected artifact segments was larger in the new portable recordings than in conventional recordings (20% vs. 11%, median). Overall, 93% of raters' stated diagnostic findings gathered from conventional devices were concordant with stated diagnostic findings gathered from the new portable device.
Conclusion: The new EEG device was shown to have technical comparability to and a high concordance rate of diagnostic findings with conventional EEG devices.
Significance: The new portable dry-electrode EEG device is suitable to meet the *HOME* projects' goal of establishing a patient-controlled EEG home-monitoring in the routine care of neurological outpatients.
Trial registration: DRKS DRKS00012685. Registered 09 August 2017, retrospectively registered.

1. Introduction

Electroencephalography (EEG) plays a central role in diagnosing epileptic and other disorders of the central nervous system (CNS) (Smith, 2005; Shahwan et al., 2010; Britton and Benarroch, 2006). While (standard) routine outpatient EEGs last between 20 and 30 min (Deutsche Gesellschaft für Klinische

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Neurophysiologie - DGKN, 2006; Sinha et al., 2016; Flink et al., 2002), a recent study showed that increasing the average duration to 45 min or longer increases the accuracy of an epilepsy diagnosis by approximately 20% and the event capture rate by approximately 30% (Burkholder et al., 2016). Thus, implementing an EEG home-monitoring system for neurological outpatients is a highly promising approach to increase detection rate and diagnostic accuracy (Burkholder et al., 2016). In addition, Lobello et al. (2006) pointed out that "a prolonged outpatient EEG would increase the sensitivity for detecting abnormalities when compared with the standard 20-min EEG but would not require the intensive resources needed for inpatient monitoring" (p. 265).

The *HOME* project (**HO**me-**M**onitoring and **E**ducation) conducted by the authors is intended to provide evidence of diagnostic and therapeutic yield of EEG home-monitoring of neurological outpatients, and to implement a patient-controlled EEG home-monitoring as part of routine outpatient care for diagnostic purposes as well as for therapeutic management (see Neumann et al., 2018 for the study protocol). The first part of the *HOME* project is the HOME^{ONE} study, which consists of two phases: (1) HOME^{ONE} pilot study phase and (2) HOME^{ONE} feasibility study phase. The HOME^{ONE} pilot study is intended to confirm the technical and practical usability and efficacy of an EEG system for the purpose of EEG home-monitoring neurological outpatients.

Kam et al. (2019) reviewed studies that compared signal quality between wet and dry EEG systems and concluded "that dry electrodes show comparable performance to wet electrodes in stationary environments" (p. 120). In addition, the authors reviewed studies that compare wireless wet-electrode EEG systems and stationary wet-electrode EEG systems and concluded that movement artifacts (might) reduce signal quality. Nevertheless, the classification performance of the wireless wet-electrode EEG systems was still satisfactory. However, the literature on direct comparisons of wireless dry-electrode EEG systems and other wireless EEG systems is sparse. This is particularly true concerning studies that take place in an everyday environment of an office-based practitioner. This is to be expected since, to the best of our knowledge, there are only very few devices available on the market that meet the technical and legal needs (as described below) to be appropriate for home-monitoring of neurological outpatients.

An EEG system that is appropriate for home-monitoring must fulfill various technical and legal needs, which can be worked out and tested step by step. According to Pinho et al. (2017), such a system shall have the following features: "wireless connectivity, dry-electrodes, signal resolution, sampling frequency, comfort, portability, signal artefact attenuation, event detection and event prediction" (p. 565). For practical reasons and clinical acceptability, we added four additional needs: (1) an integrated and structured medical reporting system, (2) the full coverage of the 10–20 system for electrode placement, (3) patient friendliness, i.e., patients should be able to place the EEG device independently without the help of medical staff, and (4) at least for the European Healthcare sector the device must be CE certified (Neumann et al., 2018). These needs greatly restrict the number of candidate devices. One device that meets most of these requirements is the Fourier One™ EEG headset (Nielsen Tele Medical GmbH, Magdeburg/Germany). Although the current version of the Fourier One™ EEG headset does not provide all required features—specifically, signal artefact attenuation, event detection, and event prediction—these features have been developed and will be implemented in future versions of the EEG headset. The missing features are not crucial for the purpose of the HOME^{ONE} pilot study phase, which is designed simply to evaluate the technical usability and efficacy of a patient-controlled portable EEG device in comparison to conventional EEG devices (and the Fourier One™ headset is one promising device available on the market). During the HOME^{ONE} pilot study phase, we assess the new EEG device against conventional (permanently installed) EEG devices used by participating office-based practitioners. Since ambulatory (or mobile) EEG devices are often associated with more artifacts and poorer quality (see for instance Oliveira et al., 2016), we decided to start with a direct comparison of the new (mobile) EEG device with those stationary devices that are used by the participating office-based practitioners. These permanently installed EEG devices provide a stronger reference point (with respect to the technical assessment) as it would have been the case with other ambulatory (mobile) devices. With respect to the technical quality, Kam et al. (2019) conducted a systematic comparison of a state-of-the-art wet EEG system and the new Fourier One™ EEG Headset.

This article reports the results of the HOME^{ONE} pilot study phase only, in which two EEG devices—conventional EEG devices (used by office-based neurologists) and a newly developed dry-electrode EEG recorder—were used within the practices of neurologists, who held everything equal except for the type of EEG. This study evaluates the technical and practical usability and efficacy of the new portable dry-electrode EEG recorder in comparison to conventional EEG devices based on pairs of recordings from 87 outpatients.[1] Office-based practitioners and two experienced neurologists (RD, HF) examined the EEG records and made technical assessments.

2. Method

The HOME^{ONE} pilot study was designed as an intra-individual comparison of the output of different EEG recording systems (see Neumann et al., 2018 for the study protocol). It was intended to evaluate the efficacy and technical and practical usability of a new portable dry-electrode EEG recorder, which was developed for use as an outpatient EEG home-monitoring system in the future.[2] For 87 unsystematically selected patients in the outpatient practices of 14 neurologist, brain waves were measured with two different EEG systems (the practices' conventional EEG system and the portable EEG system) for a period of 20 min each. Both EEG recordings were performed during a single consultation (in sequence) with all other things being equal. To avoid operator errors, both devices were applied by medical-technical assistants. Patients were fully informed and gave their written consent for the extra examination.

The office-based practitioners were responsible for the selection and the information of the patients. This study includes 87 patients (47 male and 40 female, aged between 19 and 92, with an average age of 52 years) who, according to the judgment of the practicing neurologist, have a suspected or manifest disease giving rise to the medical indication to record an EEG (first or repeated) within the framework of usual statutory care (i.e., billing numbers EBM 16310 or 16311). Those patients who have to be treated after the first EEG without delay due to hazard prevention were not included in the study.

Approximately 80 percent of the patients already had at least one EEG examination prior to this study. Approximately 55 percent of the participants reported a good cap fit and good wearing comfort. Another approx. 40 percent of the patients reported minor discomfort mainly as a result of mild feeling of pressure and/or poking caused by the dry-electrodes.

The assessment was based on two components: (1) a technical assessment and (2) an intra- and inter-rater evaluation. The tech-

[1] Note that we collected EEG recordings from 124 patients but received suitable pairs of recordings (one each from the portable dry-electrode and the conventional EEG) from only 87 patients.

[2] For the present HOME^{ONE} study, we did not implement tele-monitoring capabilities due to lacking statutory regulation in the outpatient sector. The device, however, is prepared for transmitting telemedical signals in real time.

nical assessment was based on the comparison of the two types of recorded EEGs by means of spectral analyses combined with computerized detection of artifacts. These analyses focused on the spectral structure in terms of the power observed in bands at the clinically used frequencies. This part of the study was designed to investigate whether the signal quality of dry-electrode recordings is technically acceptable and comparable to conventional wet-electrode recordings.

Each EEG record was evaluated by three raters: the office-based practitioners (responsible for diagnosis and treatment decisions) and two independent assessors (clinical physicians with long standing expertise in EEG from the University Department of Neurology, Magdeburg).[3] The former served as control group,[4] while the latter enabled intra- and inter-rater evaluations regarding practical usability and feasibility. The office-based practitioners evaluated the EEG recordings of their respective patients and documented their diagnostic findings and therapeutic consequences before and after the EEGs. The two clinical physicians evaluated all EEG recordings (after pseudonymization of all data) independently from each other; they did not have access to the evaluation of the office-based practitioners nor further information on the patients. Thus, the evaluations of the two clinical physicians were based exclusively on the recorded EEG signals, and, in particular, were blind to the clinical issue.

2.1. EEG recording setup

2.1.1. Physicians' offices – wet electrode EEG

The 14 participating neurologists used their own equipment to record EEGs with wet electrodes. This meant that in sum, the wet electrode EEG recordings were acquired with seven different devices (Appendix A.3: Table A1), sampling rates, and resolutions. The EEGs were recorded referentially from all 19 Ag/AgCl electrodes as specified by the international 10–20 electrode system (Jesper, 1958) plus left and right ear lobes. Electrode impedances were kept below 10 KOhm.

2.1.2. Physicians' offices – dry-electrode EEG

The Fourier One™ EEG headset (Nielsen TeleMedical, Magdeburg/Germany) consists of spring-loaded dry silver electrodes magnetically attached to a dedicated headset covering all 19 electrodes of the international 10–20 system plus left and right mastoids. An electronic module connected to the headset acquires the EEG data and transmits it wirelessly to a computer, as shown in Fig. 1. The digitization rate was 500 Hz with 24 bit resolution (LSB 0.04 uV). Electrode impedances ranged from 0.05 to 8 MOhm, with a mean of 0.375 MOhm.

2.2. The technical assessment

Before any analysis, all wet electrode EEG recordings were resampled to the sampling rate of the Fourier One™ recorder (500 Hz) using the Matlab routine *resample* with spline interpolation. Next, all EEGs were recalculated to a common average reference montage in order to avoid differences caused by different reference electrode locations applied in the wet EEG recordings. Using the Matlab version R2015b (The Mathworks) programming

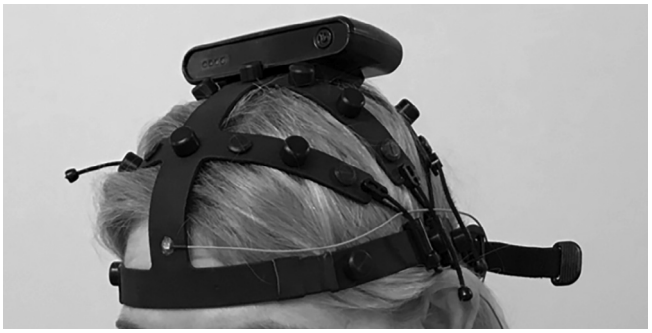

Fig. 1. Fourier One™ EEG headset.

platform, spectral analysis was conducted according to the (Welch, 1967) procedure. For this purpose, each EEG signal was split into consecutive 2-second segments with 50% overlap. Each segment was windowed with a Bartlett (=triangle) function. Power spectral analysis was carried out by means of the Fast Fourier Transform (FFT) algorithm. For each segment, spectral band power values were computed for four frequency bands: Delta (1.5–4 Hz), Theta (4–8 Hz), Alpha (8–13 Hz), and Beta (13–30 Hz). Before the estimation of the final spectra, segments were labeled and rejected as artifacts if either their signal amplitudes or band power values exceeded thresholds as derived from the total signal's statistic. The ratio of rejected artifact segments was separately determined for both recording modalities.

Finally, for each EEG channel, the difference between each subject's band power values was statistically evaluated using the Wilcoxon signed-rank test. The resulting levels of significance were subsequently corrected for multiple comparisons by applying the false discovery ratio (FDR) as suggested by Benjamini and Yekutieli (2001).

2.3. Inter- and intra-rater assessment and description of used variables

All raters assessed the EEG records with respect to their overall quality (“good,” “limited,” or “insufficient”). An EEG record was considered “good” quality if the interpretation was not significantly compromised by technical artifacts, biological artifacts, nor any other technical aspect. EEG records with artifacts were rated as “limited” if the artifacts caused uncertainty regarding diagnosis or therapy but did not prevent the rater from deriving diagnostic findings in the first place. The EEG record quality was considered “insufficient” if the raters were not able to state a diagnostic finding.

In addition to this quality assessment, all raters had to provide their diagnostic finding in a free text field. We decided to use a free text field in this pilot study because we wanted to receive as much information as possible without restricting the evaluation to a set of predetermined answers.[5] Considered examples of (free text) diagnostic findings were “normal” or “abnormal”. In case of abnormality, the finding was supplemented by the type of abnormality (for example epileptiform activity/generalized slowing/focal slowing). Based on this free text, a binary criterion was derived: whether or not a diagnostic finding was provided. From a methodological perspective, this criterion served as a consistency check for the quality assessment.

In a next step, an independent assessor determined the concordance of each patient's diagnostic findings from the three raters. This assessor performed:

[3] The terms “office-based practitioner” and “clinical physician” are related to the German health care system that is divided into outpatient care, inpatient care (the hospital sector), and rehabilitation facilities. Officebased practitioners work in outpatient care. All participating physicians are board certified neurologists. The two clinical physicians are specialists in neurology, working at the university hospital.

[4] In contrast to the clinical physicians, the office-based practitioners knew each patient's medical history, the EEG device used for each record, and the order of EEG recordings (making the data not independent). Thus, we contrasted the office-based practitioners' data to that of the clinical physicians.

[5] However, we deem a structured medical reporting system (SRS) necessary in routine outpatient EEG home-monitoring as it is shown that SRS contributes to quality assurance.

(1) an intra-rater comparison of the stated diagnostic findings per patient, gathered from the conventional EEG device compared with that from the new dry-electrode EEG recorder, and
(2) an inter-rater comparison, both pairwise and all three raters together, for each EEG record system separately.

Each of these comparisons led to three possible judgments: the diagnostic findings were (1) concordant, (2) clinically irrelevantly discordant, or (3) clinically relevantly discordant.

We calculate Cohen's kappa (Cohen, 1960) as measure of inter-rater reliability, as it is a commonly used reliability measure in this context (Pieper et al., 2017; Benbadis et al., 2009; Halford et al., 2015; Grant et al., 2014). In addition, we calculate percentage agreement rates.

The literature on inter-rater reliability of EEG evaluations shows kappa values of 0.5–0.9 (Benbadis et al., 2009; Stroink et al., 2006; Azuma et al., 2003; van Donselaar et al., 1992). The variance of the kappa values can be influenced by different factors (e.g., the level of experience of the rater (Piccinelli et al., 2005) or specific EEG findings (Grant et al., 2014)).

3. Results

In this section, we will first report the results of the technical evaluation and then the results of the inter- and intra-rater assessments.

3.1. Technical assessment

As shown in Fig. 2, the Theta-, Alpha-, and Beta-band power values of the two EEG modalities closely resembled each other with no significant differences in any of the electrode locations. In the Delta band, mild yet statistically significant differences (values of dry recordings > wet recordings) were observed in all locations. This presumably was caused by non-prominent, movement-related artifacts in the Fourier One™ recordings that were not detected by the automatic procedure. This is in line with the rating of the visual assessments, which reported a slightly worse overall EEG quality of the Fourier One™ recordings. This explanation is further supported by the fraction of automatically-rejected artifact segments: 10.6% in the conventional EEG but 20.4% (median) in the dry-electrode recordings. This difference is statistically significant ($p < .0001$, $Z = 18.6$, Wilcoxon signed-rank test).

3.2. Inter- and intra-rater assessments

3.2.1. Overall quality assessment

The following analyses are based on the raters' overall quality assessment of the EEG recordings of 87 patients. These assessments were provided by 14 office-based practitioners, who evaluated the EEG recordings for their own patients, and by two clinical physicians, who evaluated all EEG recordings of all patients included in this study. Unfortunately, we have not received complete data for all patients from the office-based practitioners, so we could include only their 68 conventional EEG evaluations and 58 dry-electrode EEG evaluations in the corresponding analyses. Table 1 shows the overall quality assessments. Samples of EEG recordings assessed as good, limited, or insufficient are provided in Appendix A.1. In addition, in Appendix A.2 we provide samples of EEG recordings of three patients which show (1) a diagnostic finding on both EEG systems, (2) a diagnostic finding on the new EEG device but not on the conventional EEG device, and (3) a diagnostic finding on the conventional EEG device but not on the new EEG device.

We first analyzed the stated overall quality assessments of the clinical physicians and, in a second step, compared these results with the assessments of the office-based practitioners. Both clinical specialists assessed the overall quality of the new EEG device to be significantly different (inferior) than that of the conventional EEG devices. Table 2 shows the results of chi-square tests.

Clinical physicians agreed 83% of the time about the overall quality of the conventional EEG records (Cohen's kappa $= 0.1624$, 95% confidence interval: $[-0.0863; 0.4111]$). This means that the observed agreement rate was only slightly above the expected overall random agreement probability (79%). The low Kappa value alongside a high value of observed percentage agreements is a well-known effect in the literature (Wongpakaran et al., 2013), referred to as the "Kappa paradox" (Cicchetti and Feinstein, 1990; Gwet, 2014). Table 3 illustrates the paradox.

Meanwhile, clinical physicians agreed 70% of the time about the overall quality of the new portable dry-electrode EEG records (expected overall random agreement probability = 48%, Cohen's kappa $= 0.4244$, 95% confidence interval: $[0.2371; 0.6117]$). According to Landis and Koch (1977), this represents a moderate agreement among the raters.

3.2.2. Diagnostic finding provided

In a next step, we analyzed whether a diagnostic finding was provided or not. We did not have information on why the office-based practitioners were not able to report diagnostic findings on several cases, so in the following section, we focus only on the clinical physicians. Thus, the following analysis includes the same 174 EEG recordings (87 pairs) as the analysis in Section 3.2.1. Table 4 shows the number of cases for which the clinical physicians provided a diagnostic finding (or not).

Both clinical physicians provided diagnostic findings for almost all EEG records (> 93%, Table 4), even though there was a considerable number of EEG records (especially of the new EEG device) assessed to be of limited or insufficient quality (c.f. Table 1).

For diagnostic findings provided from the conventional EEG records, we observed a relative agreement rate of 98.8% among clinical physicians (expected overall random agreement probability = 96.6%, Cohen's kappa $= 0.6615$, 95% confidence interval: $[0.039; 1.284]$), i.e., a substantial agreement among the raters.

For diagnostic findings provided from the new portable dry-electrode EEG device, we observed a relative agreement rate of 96.6% among clinical physicians (expected overall random agreement probability = 90.1% (Cohen's kappa $= 0.6506$, 95% confidence interval: $[0.2829; 1.0182]$), also representing substantial agreement among the raters.

3.2.3. Comparison of provided diagnostic findings

In the following, we analyze whether the provided diagnostic findings are concordant between the conventional and dry-electrode EEG recorders. We start with an intra-rater comparison (performed by an independent assessor) of the stated diagnostic findings per patient, gathered from a conventional EEG device compared with that from the new portable dry-electrode EEG recorder. This analysis comprises diagnostic findings from 14 neurologists (12 office-based practitioners and 2 clinical physicians). While the clinical physicians assessed all 174 EEG records, leading to 87 pairwise comparisons, the number of EEG pairs assessed by the office-based practitioners varied between 1 and 8 pairs.

First, the independent assessor compared the two stated diagnostic findings per patient from both clinical physicians and classified each pair according to three possible outcomes: (1) concordant, (2) clinically irrelevantly discordant, or (3) clinically relevantly discordant. In a second step, the independent assessor performed the same evaluation on the stated diagnostic findings

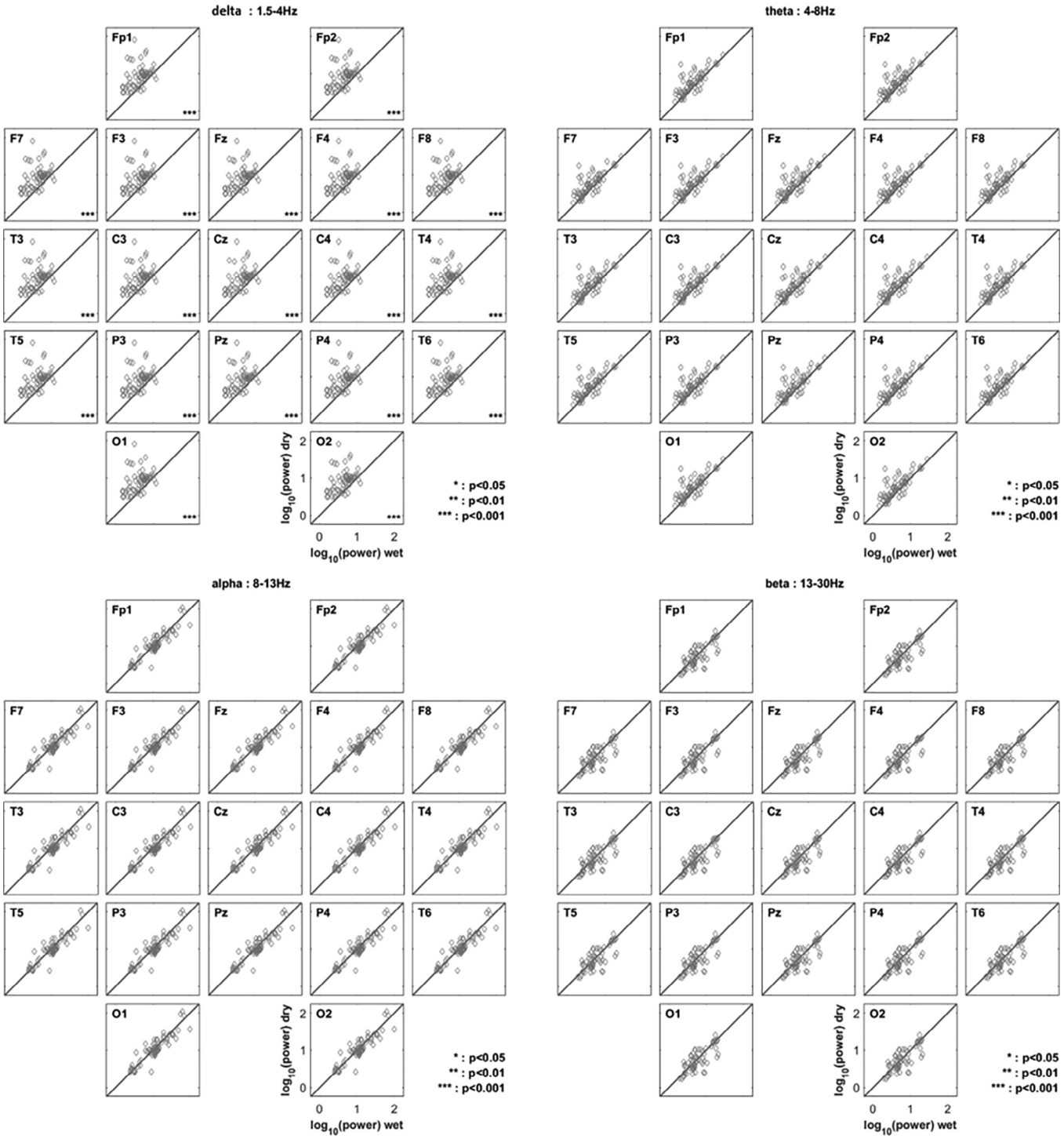

Fig. 2. Logarithmic spectral band power values of all subjects for both recording systems shown for each 10–20 electrode location. Each diamond represents one pair of wet (x-axis) and dry (y-axis) electrode values. The thin gray line indicates identity.

Table 1
Data from overall quality assessment.

	Office-based practitioners		Clinical physician 1		Clinical physician 2	
Quality assessment	conv. EEG	new EEG	conv. EEG	new EEG	conv. EEG	new EEG
good	60	33	77 (63)	46 (34)	77 (62)	54 (42)
limited	8	25	9 (5)	37 (24)	9 (6)	31 (16)
insufficient	0	0	1 (0)	4 (0)	1 (0)	2 (0)

Numbers in brackets show the clinical physicians' assessments of those 68 conventional and 58 new dry-electrode EEG records that were completely evaluated by the office-based practitioners.

Table 2
Analyses of the overall quality assessments from 2 clinical physicians (CP) and 14 office-based physicians (OBP).

Chi-square test	Chi-square statistic	P-value
CP_1 conv. vs. new EEG	26.66 (20.46)	< 0.00001 (0.000006)
CP_2 conv. vs. new EEG	16.47 (7.65)	0.000265 (0.005689)
OBP conv. vs. new EEG	15.90	0.000067

Numbers in brackets correspond to those 68 conventional and 58 new dry-electrode EEG records that were completely evaluated by the office-based practitioners.

Table 3
Agreement among clinical physicians regarding the overall quality given in a contingency table, conventional EEGs.

		CP_1			Marginal totals
		good	limited	insufficient	
CP_2	good	70	6	1	77
	limited	7	2	0	9
	insufficient	0	1	0	1
Marginal totals		77	9	1	87

Table 4
Diagnostic finding provided (yes/no).

	Clinical physician 1		Clinical physician 2	
Diagnostic finding provided	conv. EEG	new EEG	conv. EEG	new EEG
yes	86	81	85	84
no	1	6	2	3

per patient from the office-based practitioners. Table 5 shows the results of these evaluations.

Overall, the independent assessor classified the majority (more than 80%) of stated diagnostic findings as concordant, and less than 7% as clinically relevantly discordant.[6] Thus, the intra-rater percentage agreements ranged from 0.9318 (OBP) to 0.9643 (CP_2). A comparison of the distribution of the independent assessor's possible judgments per rater showed that these distributions were not significantly different. Table 6 shows the results of the chi-square tests.

We interpret this result as a first indication that both EEG recording systems perform similarly given that few diagnostic findings are clinically relevantly discordant.

In a second step, the independent assessor performed inter-rater comparisons, both pairwise and with all three raters together, for each EEG record system separately. Tables 7 and 8 show the results of these evaluations.

Based on the inter-rater comparison of the stated diagnostic findings gathered from conventional EEG devices, we first analyzed whether the resulting distribution of the independent assessor's judgments differed significantly; they did not ($\chi^2 = 10.8999$, $p = 0.0915$). The same held true for the independent assessor's judgments based on the EEG recordings gathered from the new portable dry-electrode EEG ($\chi^2 = 7.5971, p = 0.2691$).

In addition, we compared the independent assessor's judgments of the inter-rater comparison based on EEG recordings gathered from conventional EEG devices compared with those from the new portable dry-electrode EEG device. Table 9 shows the results.

The "between devices" analysis of the assessors inter-rater comparisons found no significant differences between the two EEG devices. This is interpreted as a further indication that the two EEG recording systems perform similarly.

[6] Note: Discordant diagnostic statements may have resulted from different possible reasons: technical reasons, particular time point of the EEG recording, and mistakes by the rater, among others.

Table 5
Independent assessor's comparisons of stated diagnostic findings per patient.

Independent assessor's possible judgments:	Clinical physician 1 conv. vs. new EEG	Clinical physician 2 conv. vs. new EEG	Office-based practitioners conv. vs. new EEG
concordant	65	73	35
clinically irrelevantly discordant	12	9	6
clinically relevantly discordant	3	2	3
comparison not possible*	7	3	43**

* A comparison was not possible in cases in which at least one EEG record was assessed as insufficient and/or no diagnostic finding was stated.
** In 42 of 43 cases, we received no diagnostic finding from office-based practitioners (the free text field was empty).

Table 6
Analyses on independent assessor's comparison of stated diagnostic findings.

Chi-square test	Chi-square statistic	P-value
CP_1 vs. CP_2 vs. OBP	2.3254	0.6762
CP_1 vs. CP_2	0.9954	0.6079
CP_1 vs. OBP	0.5989	0.7412
CP_2 vs. OBP	1.8511	0.3963

Note: Cases in which a comparison was not possible were excluded from these analyses.

Table 7
Independent assessor's inter-rater comparisons of stated diagnostic findings (conventional EEG records).

Conventional EEG records				
	CP_1 vs. CP_2	CP_1 vs. OBP	CP_2 vs. OBP	CP_1 vs. CP_2 vs. OBP
concordant	76	44	43	42
clinically irrelevantly discordant	11	8	9	10
clinically relevantly discordant	0	6	6	6
comparison not possible*	0	29	29	29

* A comparison was not possible in cases in which at least one EEG record was assessed as insufficient and/or no diagnostic finding was stated.

Table 8
Independent assessor's inter-rater comparisons of stated diagnostic findings (dry-electrode EEG records).

Dry-electrode EEG records				
	CP_1 vs. CP_2	CP_1 vs. OBP	CP_2 vs. OBP	CP_1 vs. CP_2 vs. OBP
concordant	74	47	44	44
clinically irrelevantly discordant	11	7	8	10
clinically relevantly discordant	2	6	8	6
comparison not possible*	0	27	27	27

* A comparison was not possible in cases in which at least one EEG record was assessed as insufficient and/or no diagnostic finding was stated.

Table 9
Analysis of independent assessoŕs inter-rater comparison.

Chi-square test	Chi-square statistic	P-value
conv.(CP_1 vs. CP_2) vs. new(CP_1 vs. CP_2)	2.03	0.3630
conv.(CP_1 vs. OBP) vs. new(CP_1 vs. OBP)	0.13	0.9362
conv.(CP_2 vs. OBP) vs. new(CP_2 vs. OBP)	0.32	0.8512
conv.(CP_1 vs. CP_2 vs. OBP) vs. new(CP_1 vs. CP_2 vs. OBP)	0.01	0.9937

Note: Cases in which a comparison was not possible were excluded from these analyses.

4. Discussion

The HOME^{ONE} study was intended to evaluate the technical and practical usability and efficacy of a new portable dry-electrode EEG recorder (Fourier One™) in comparison to conventional EEG devices. As part of the larger *HOME* project, the confirmation of usability and efficacy is a necessary step for reaching the *HOME* projecťs ultimate goal: the establishment of patient-controlled EEG home-monitoring of neurological outpatients.

A patient-controlled EEG home-monitoring has the potential to increase the accuracy of diagnosis and the event capture rate while using fewer resources than is needed for inpatient monitoring. However, EEG devices have to meet technical and practical requirements to be useful for this end. These requirements greatly restrict the number of suitable devices. This pilot study investigated the Fourier One™ EEG headset, which is CE-certified as a medical device and used within the *HOME* project.

As the first step of our project, the HOME^{ONE} pilot study was conducted as an intra-individual comparison to evaluate the technical quality of EEG recordings gathered from the new portable dry-electrode EEG device relative to the quality of recordings from conventional EEG devices as recorded in numerous doctor's offices under routine conditions. We used spectral analyses combined with a computerized detection of artifacts to compare the two types of recorded EEGs. No differences were observed in the clinically relevant frequency bands Theta (4–8 Hz), Alpha (8–13 Hz), nor Beta (13–30 Hz). Quantitatively, mild yet statistically significant differences occurred in the Delta (1.5–4 Hz) frequency band. This most likely was caused by the higher susceptibility of the Fourier One™ device to artifacts, since the automatic procedure to detect artifacts fails when there are only mild distortion patterns that hardly exceed the amplitude of the ongoing background activity. In accordance with the reports of the participating neurologist, artefacts as observed in the Fourier One™ recordings are often characterized by low frequency, low amplitude fluctuations, which consequently add to the physiological Delta activity. Nevertheless, according to the doctors' reports, these underlying mild artifacts are easy to distinguish from physiological activity and thus do not hinder the visual assessment, as demonstrated by the corresponding evaluation results.

The neurologists also reported that the conventional wet EEG recordings slightly outperformed the Fourier One™ recordings in terms of the technical quality (as subjectively derived from the neurologists' visual assessment). This aligned with the result of the automatic artifact detection, which—using the same algorithm in all EEGs—observed more artifacts in the dry recordings.

In addition to these technical assessments, we used intra- and inter-rater comparisons to evaluate the stated quality assessments and diagnostic findings of 14 office-based practitioners as well as those of two clinical physicians. We found agreement among raters that the overall quality of the new portable dry-electrode EEG device was assessed to be significantly lower than the overall quality of the conventional EEG devices. However, the stated diagnostic findings based on EEG recordings gathered from the new portable dry-electrode EEG device were not significantly different from findings that were determined from conventional EEG recordings. In more detail, the observed inter-rater reliability aligned with the literature, which reports moderate to almost perfect reliability for EEG evaluations (Benbadis et al., 2009; Stroink et al., 2006; Azuma et al., 2003; van Donselaar et al., 1992). In particular, the two almost equally experienced clinical physicians showed very high agreement rates. The observed intra-rater percentage agreements were similar to those reported in studies analyzing whether raters agreed with themselves when rereading EEG recordings (Grant et al., 2014; Little and Raffel, 1962).

Summarizing the data from the HOME^{ONE} pilot study, we conclude that the new portable dry-electrode EEG device is well suited for use in everyday neurological outpatient practice. Despite the slightly worse overall technical signal quality, demonstrated by the technical and visual comparisons, the dry electrode recordings allow for a sufficiently reliable clinical evaluation. However, further testing is necessary to fully evaluate the new EEG device and to confirm that the ultimate goal of the *HOME* project -a patient-controlled EEG home-monitoring of neurological outpatients- is attainable. While the HOME^{ONE} pilot study we report here, was intended to evaluate the technical usability and efficacy of the new portable dry under "optimal" conditions (in comparison to conventional devices), it is the aim of the ongoing HOME^{ONE} feasibility study (second phase of the HOME^{ONE} study) to assess patients' acceptability and feasibility of the EEG home-monitoring and will provide insights into the extent diagnostic and therapeutic yields can be expected. We also expect insights on possible drawbacks regarding the usability of the new EEG device.

Declarations

Ethics approval and consent to participate

The ethics committee of the Faculty of Medicine of the Otto-von-Guericke-University Magdeburg has reviewed and approved all patient information, data management and outcomes related activities of this research project (Reference number: 25/16). Patients provided their written consent to participate in the study prior to any examination.

Consent for publication

Not applicable. This manuscript does not contain participant data.

Availability of data and material

Not applicable.

Authors' contributions

TN, HH, and BPR drafted the manuscript. TN and MS conducted the quantitative analyses. TN, HH, BPR designed the study. AB, UB have coordinated the study and the collaboration with the participating neurologists. RD and HF helped to design the study and performed the reference evaluation of the recorded EEGs. All authors critically revised and finally approved the manuscript.

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Declaration of Competing Interest

HH and AB act as consultants for Nielsen Tele Medical. All other authors declare that they have no competing interests.

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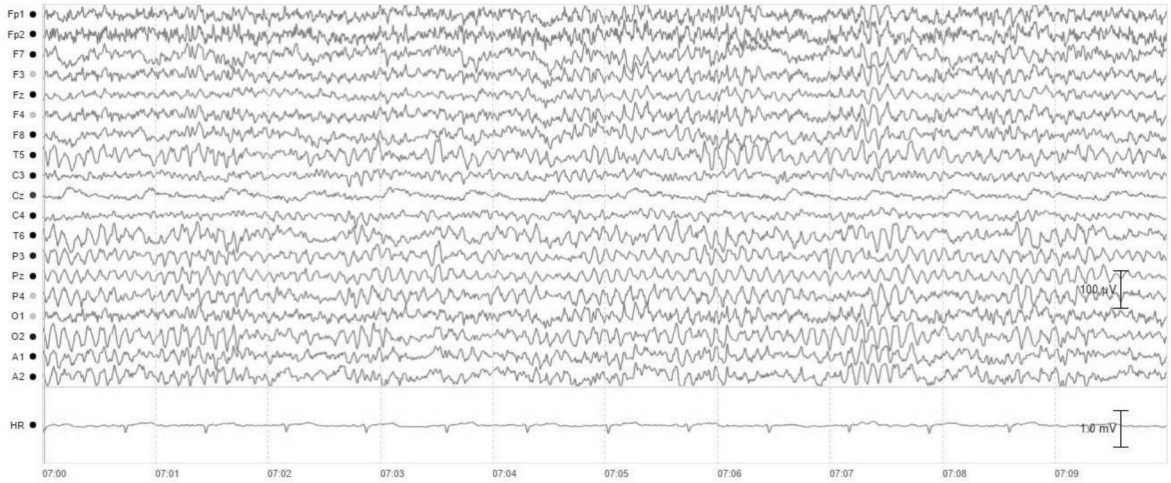
Disclaimer

The statements presented in this publication are solely the responsibility of the authors and do not necessarily represent the views of the funding institution and/or of any of the institutions mentioned above.

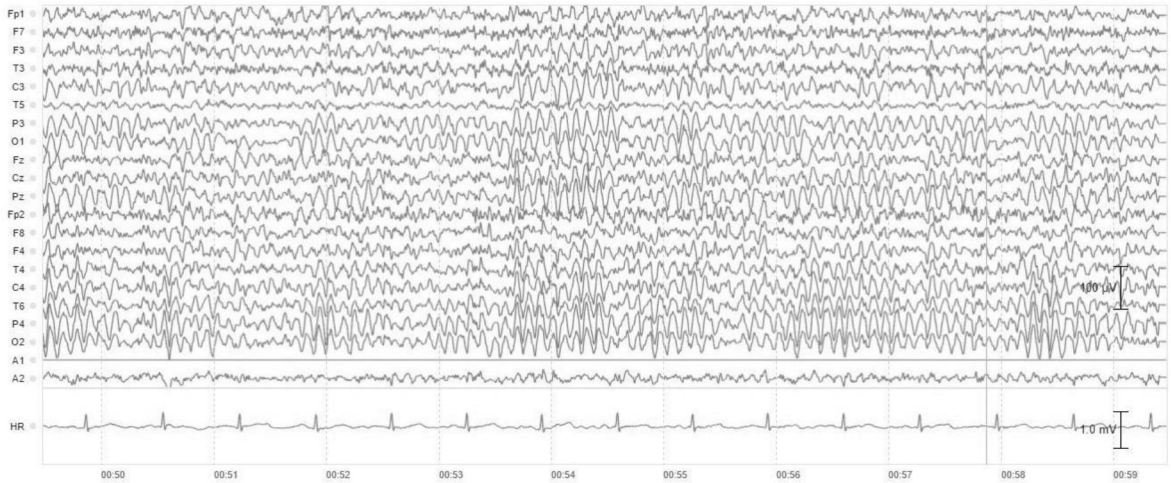
Appendix A

A.1. Samples of EEG traces (with respect to the quality assessment)

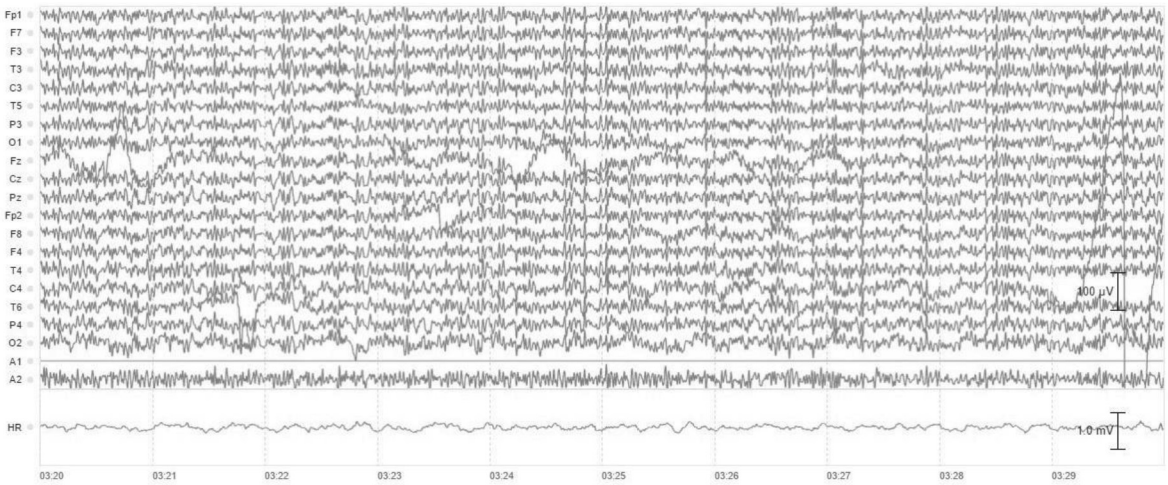
(1) Sample recorded with the **new** portable dry-electrode **EEG recorder** assessed as **good** quality



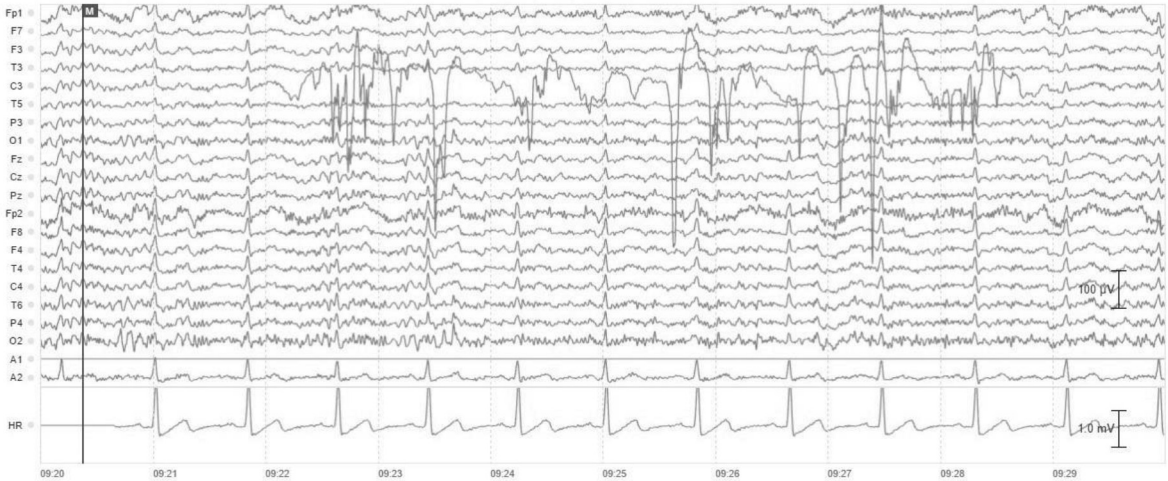
(2) Sample recorded with the **conventional EEG recorder** assessed as **good** quality



(3) Sample recorded with the **new** portable dry-electrode **EEG recorder** assessed as **limited** quality

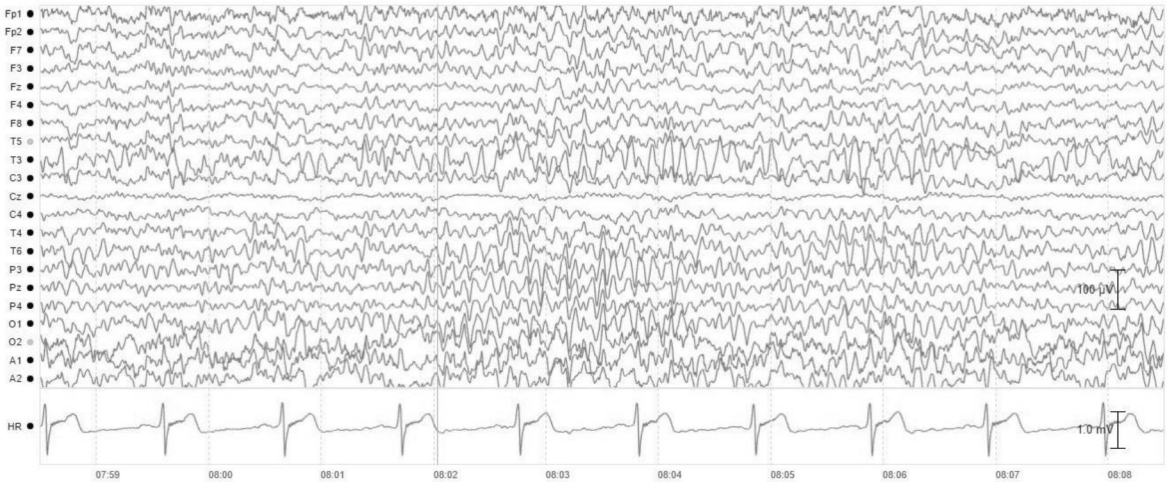


(4) Sample recorded with the **conventional EEG recorder** assessed as **limited** quality

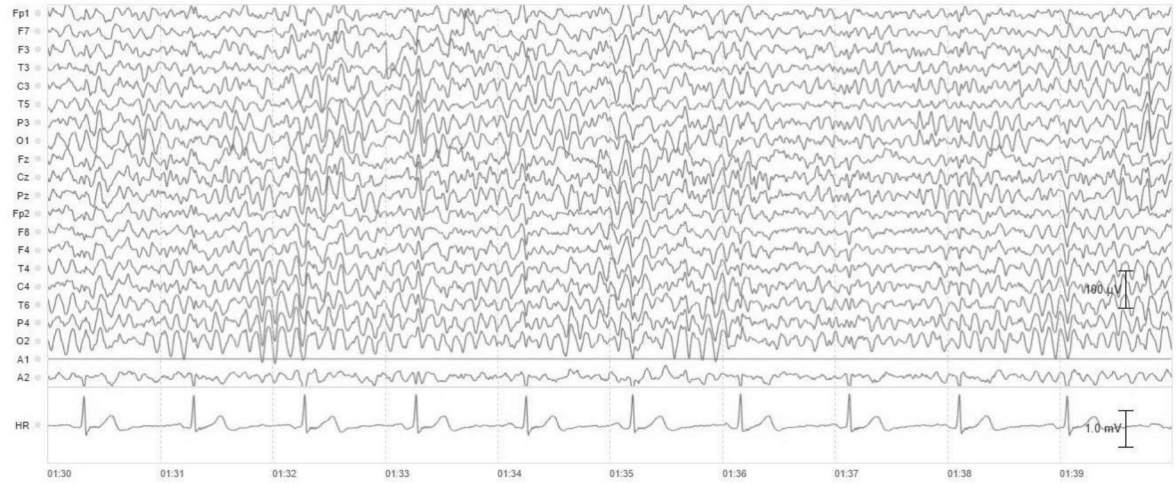


A.2. Samples of EEG traces (with respect to diagnostic finding)

(1) Samples of EEG traces of a patient which show a diagnostic finding on both EEG recorders:
(a) **New** portable dry-electrode **EEG recorder** (considered as abnormal, finding: focal theta-activity in the left temporo-central region)

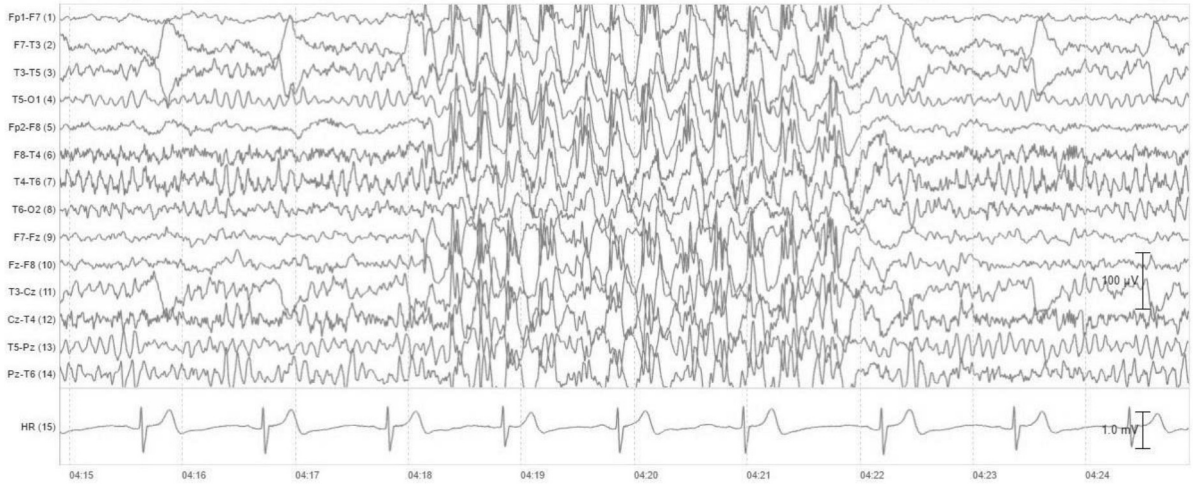


(b) Conventional EEG recorder (considered as abnormal, finding: focal theta-activity in the left temporo-central region)

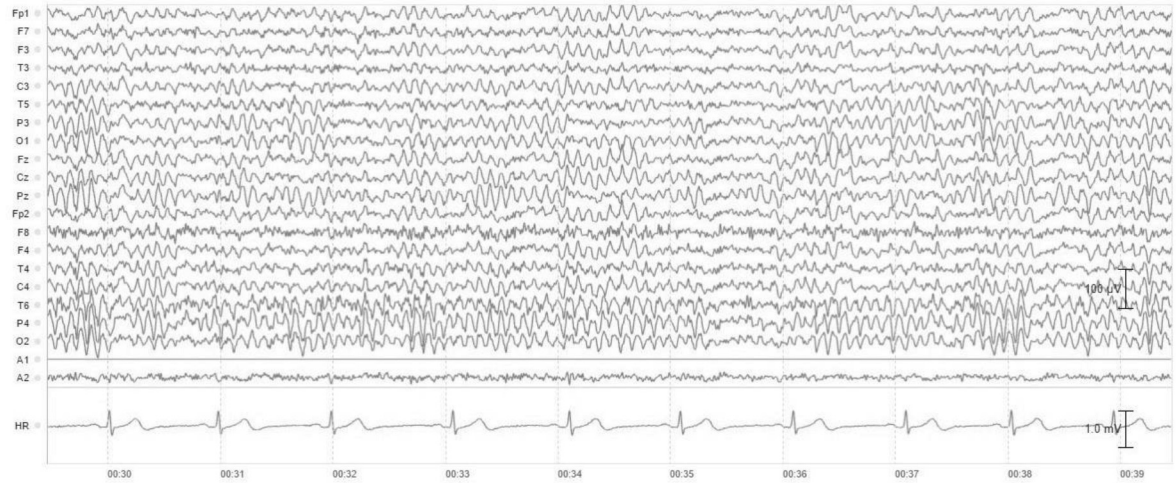


(2) Samples of EEG traces of a patient which show a diagnostic finding on the new dry-electrode EEG recorder but not on conventional EEG recorder:

(a) **New** portable dry-electrode **EEG recorder** (considered as abnormal, finding: fronto-temporal generalized 3/sec spike-wave pattern)

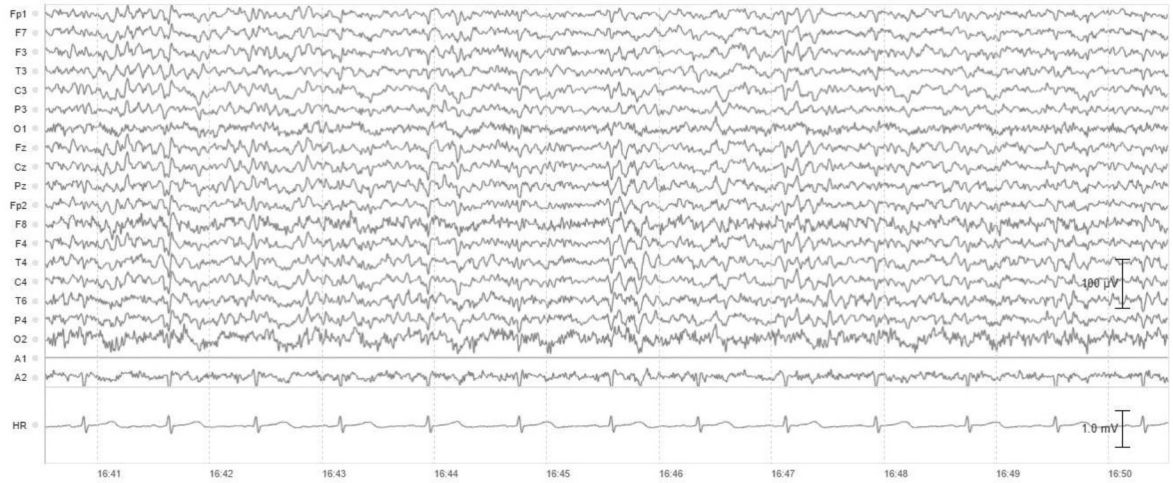


(b) Conventional EEG recorder (considered as normal EEG without any pathological activity)

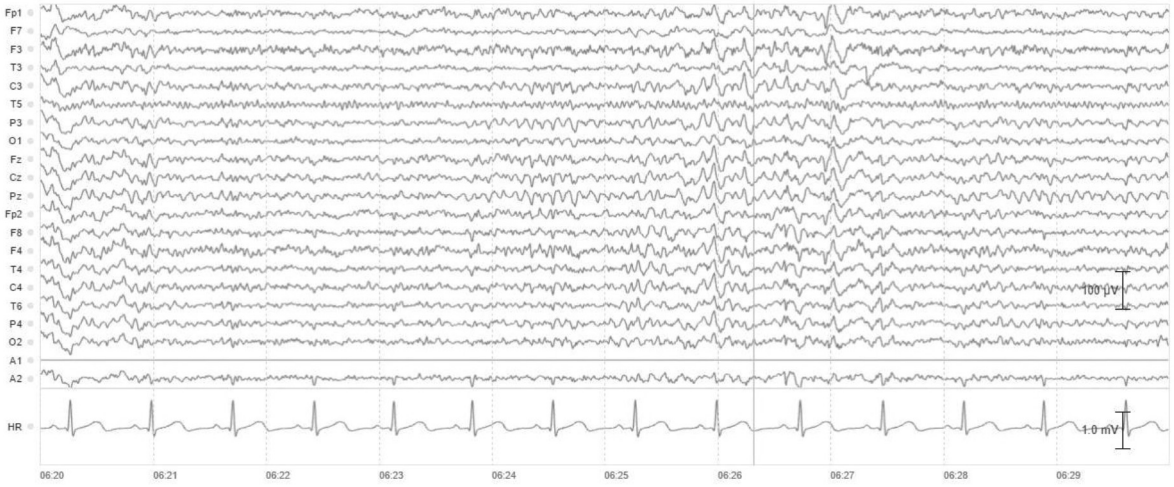


(3) Samples of EEG traces of a patient which show a diagnostic finding on the conventional EEG recorder but not on the new dry-electrode EEG recorder:

(a) **New** portable dry-electrode **EEG recorder** (considered as normal EEG without any pathological activity)



(b) **Conventional EEG recorder** (considered as abnormal, finding: left temporal dysrhythmia)



A.3. Table

See Table A1.

Table A.1
Recording devices and specifications applied by the various neurologists.

Device	Sampling rate [Hz]	Resolution [Bit]	Amplitude resolution (least significant bit) [uV]
Schwarzer EPAS	200	16	0.1
Schwarzer EPAS	256	16	0.1
Nihon Kohden Neurofax	200	16	0.1
Walter Graphtek PL 230	256	16	0.5
Walter Graphtek PL 230	512	16	0.5
Sigma Neurowerk DB 26	128	16	0.125
Sigma Neurowerk DB 26	256	16	0.125

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