Aetna considers actigraphy testing/measurement (e.g., the Actiwatch, AW-64, and Emfit; not an all-inclusive list) experimental and investigational for the following indications (not an all-inclusive list) because there is insufficient scientific evidence in the medical literature to support its use in clinical practice:

- Detection of seizures during sleep
- Diagnosis of hypertension
- Diagnosis of sleep disorders (e.g., central disorders of hypersomnolence, insomnia, periodic limb movements of sleep, sleep-disordered breathing, and sleep-wake disturbance)
- Evaluation of depression
- Evaluation of disruptive mood dysregulation disorder
- Evaluation of motor fluctuations in persons with Parkinson's disease
- Evaluation of post-traumatic stress disorder
- Evaluation of schizophrenia
- In the setting of opioid detoxification

*Please see amendment for Pennsylvania Medicaid at the end of this CPB.*
• Screening for idiopathic rapid eye movement (REM) sleep behavior disorder

Aetna considers accelerometry (e.g., the Kinesia, and the Tremerometer) experimental and investigational for the following indications (not an all-inclusive list) because there is insufficient scientific evidence in the medical literature to support its use in clinical practice.

• Evaluating functional ability in the elderly
• Differential diagnosis of tremor syndromes
• Evaluating sleep disturbances in Parkinson's disease
• Gait analysis in persons with hip osteoarthritis
• Measuring disease activity in children with eczema
• Monitoring of physical activity during rehabilitation of persons with stroke
• Monitoring of physical activity in critically ill persons; and after stroke
• Monitoring of physical motion and muscle activity to quantify kinematics of movement disorder symptoms (e.g., tremor)

Aetna considers an epilepsy monitoring system utilizing accelerometry and heart rate monitoring experimental and investigational for diagnosing nocturnal epilepsy and for all other indications.

See also
CPB 0004 - Obstructive Sleep Apnea in Adults
(../1_99/0004.html)
CPB 0330 - Multiple Sleep Latency Test (MSLT)
, and (../300_399/0330.html)

Background
Actigraphy Testing

Actigraphy is the process of measuring physical movement of an individual over time to assess the degree of motor activities. Actigraphy has been used for monitoring body movement during sleep to detect sleep disorders by using a portable device known as an actigraph, which is worn on the individual’s wrist or ankle. An example of an actigraphy device is the Actiwatch.

Actigraphy testing consists of a small portable device (actigraph) that senses physical motion and stores the resulting information. Actigraphy testing has been predominantly used in research studies to evaluate rest-activity cycles in patients with sleep disorders, to determine circadian rhythm activity cycles, and to determine the effect of a treatment on sleep. The actigraph is most commonly worn on the wrist, but can also be worn on the ankle or trunk of the body. Actigraphy testing is based on the assumption that movement is reduced during sleep compared with wakefulness and that activity level can be used as a diagnostic indicator for sleep disorders.

The Actiwatch™ (Mini-Mitter Co., Inc., Bend, OR) is a battery-operated device that has received 510(k) premarket notification from the U.S. Food and Drug Administration (FDA) to be used to automatically collect and score data for sleep parameters, analyze circadian rhythms, and assess activity in any instance where quantifiable analysis of physical motion is desired. Thus, the manufacturer was not required to submit to the FDA the evidence of efficacy that is necessary to support a premarket approval application.

According to the manufacturer’s website, the Actiwatch utilizes a motion sensor known as an “accelerometer” to monitor the occurrence and degree of motion and produces a small signal. The magnitude and duration of the signal depends on the amount of motion. The activity signals are amplified and
digitized and stored as activity counts. Recordings can be conducted for days or weeks on patients in their own homes. When the recording period is complete, the stored movement data can be transferred to a computer for analysis. Data may be expressed graphically as actograms or reported numerically as total activity counts per epoch, thereby estimating sleep latency, total sleep time, number and frequency of awakenings, and “sleep efficiency.” The Actiwatch has been proposed as a diagnostic parameter for a number of sleep disorders including insomnia, restless legs syndrome/periodic limb movement disorder, circadian-rhythm disorders, and sleep apnea.

Methods of assessing sleep complaints have included history from the patient and bed partner, use of sleep history questionnaires, sleep-wake diaries, actigraphy and polysomnography (PSG). However, a review of the literature produced few validation studies that incorporated large sample sizes, typical sleep clinic patients, or comparisons with subjective reports of sleep parameters. There is little agreement among authors concerning methods for effective assessment and subsequent differential diagnosis of sleep disorders (Kushida et al, 2001; Bjorvatn et al, 2001). Furthermore, some of the research studies failed to find relationships between sleep measures and health-related symptoms.

Practice guidelines for actigraphy established by the Standards of Practice Committee of the American Academy of Sleep Medicine (AASM) (Littner et al, 2003) stated that actigraphy testing is reliable and valid for detecting sleep in normal, healthy populations. However, the guidelines stated that actigraphy testing is not indicated for the routine diagnosis, assessment, or management of any of the sleep disorders. A 2007 update of the AASM guidelines (Morgenthaler et al, 2007) only recommended actigraphy as a “standard” to estimate total sleep time in persons with obstructive sleep apnea syndrome (OSA) "when PSG is
unavailable” and, consistent with the 2003 guideline, as "a way to assist in determining sleep patterns in normal, healthy adult populations." The recommendations of the AASM are categorized as standards, guidelines, or options. Standards describe a "generally accepted patient-care strategy, which reflects a high degree of clinical certainty." The term standard generally implies the use of Level 1 evidence (defined as blind, prospective comparison of results obtained by actigraphy to those obtained by a reference standard on an appropriate spectrum of subjects and number of patients, which directly addresses the clinical issue), or overwhelming Level 2 evidence (defined as comparison of results obtained by actigraphy to those obtained by a reference standard but blinding not specified, not prospective, or on a limited spectrum of subjects or number of patients). Guidelines reflect "a moderate degree of clinical certainty", and implies the use of Level 2 evidence or a consensus of Level 3 evidence (defined as a comparison of results obtained by actigraphy to the mean value of a reference standard, but not direct within-subject comparison, or otherwise methodologically limited). Options reflect "uncertain clinical use" and imply either inconclusive or conflicting evidence or conflicting expert opinion. According to these guidelines, actigraphy is a standard "generally accepted patient care strategy .... reflecting a high degree of clinical certainty" for estimating total sleep time in OSA when PSG is unavailable. Given limitations of the evidence, all the other clinical indications for actigraphy that were considered were classified as guidelines ("moderate degree of clinical certainty") or options ("uncertain clinical use"). The guideline summarized limitations of the existing data on actigraphy, noting that "few studies" actually specified whether investigators were blinded to the results of other studies, and most of these lacked a description of blinding. The guideline also found that few of the studies reviewed had provided technical details related to the administration and scoring of actigraphy. The AASM Standards of Practice Committee indicated the need for additional research in the following areas:
• Comparison of results from different actigraphy devices and the variety of algorithms used to evaluate actigraphy data in order to further establish standards of actigraphy technology.

• Additional study addressing the reliability and validity of actigraphy compared to reference standards, such as polysomnography, and the circadian rhythms of basic physiologic functions, such as temperature, cortisol, and melatonin levels.

• Research is needed to establish standards for setting start and stop times of the sleep and wake periods when using actigraphy, including techniques such as event markers or sleep diaries, and other methods in the study of populations where these techniques may not be valid.

• More research is needed to assess the reliability of actigraphy under various clinical circumstances, and to determine what parameters may be used to assess the quality of actigraphic data.

• There is a need for well-designed studies that include technical details related to the administration and scoring of actigraphy. The guideline stated that "in much of the existing literature, there is an inadequate description of whether visual inspection of data is performed, how missing data is handled, and other important decisions made in the analysis of actigraphy data."

• Further work is needed to clarify the relative and unique contributions of actigraphy, polysomnography and sleep logs in the diagnosis of sleep disorders and measurement of treatment effects.

• The guidelines stated that the use of actigraphy in hypersomnia populations, especially as an adjunct to the Multiple Sleep Latency Test, should be tested to establish an evidence-based recommendation for the use of actigraphy in the clinical evaluation and management of hypersomnia.
According to a review by Sadeh and Acebo (2002), actigraphy is less useful for documenting sleep-wake in persons who have long motionless periods of wakefulness (e.g., insomnia patients) or who have disorders that involve altered motility patterns (e.g., sleep apnea). The authors stated the pitfalls of actigraphy testing are: (i) validity has not been established for all scoring algorithms or devices, or for all clinical groups; (ii) actigraphy is not sufficient for diagnosis of sleep disorders in individuals with motor disorders or high motility during sleep; and (iii) the use of computer scoring algorithms without controlling for potential artifacts can lead to inaccurate and misleading results.

It is difficult to establish actigraphy testing standards at the present time, given the variety of different actigraphs available, the different technology and algorithms for detecting movement, and the lack of standardized units of activity measures. Thus, it is not clear how actigraphic information would be used in the treatment and management of patients with sleep disorders (Edinger et al, 2004). Patients who lie still but are awake for prolonged periods of time will have their sleep time overestimated. Similarly, patients with excessive movements during sleep may be considered to be awake and have an underestimation of sleep time. Additional research comparing actigraphic methodology is needed to establish standards of actigraphy testing.

The Watch_PAT 100 is a portable device that measures peripheral arterial tonometry, pulse oximetry, and actigraphy. Although there are published studies suggesting that the Watch_PAT may be useful in diagnosing OSA (Pillar et al, 2003; Ayas et al, 2003; and Bar et al, 2003), there is currently insufficient scientific evidence in the medical literature to support its use for the diagnosis of obstructive sleep apnea (OSA).
Ayas et al (2003) assessed the accuracy of the Watch_PAT100 to diagnose OSA. A total of 30 adult subjects with and without suspected OSA simultaneously had a standard in-laboratory PSG and wore the Watch_PAT100 during a full-night recording. PSG sleep and respiratory events were scored according to standard criteria. Watch_PAT data were analyzed with an automated computerized algorithm which calculated the frequency of respiratory events per hour of actigraphy measured sleep using a combination of peripheral arterial tonometry (PAT) signal attenuation, desaturation on pulse oximetry, and changes in heart rate. This yielded a PAT apnea hypopnea index (AHI). Mean age was 47.0 +/- 14.8 years, mean body mass index 31.0 +/- 7.6 kg/m², mean PSG AHI 23 +/- 23.9 events per hour, and mean PAT AHI 23 +/- 15.9 events per hour. There was a significant correlation between PAT AHI and AHI by PSG (r = 0.87, p < 0.001). To assess sensitivity and specificity of the Watch_PAT, the authors constructed receiver operator characteristic (ROC) curves using a variety of AHI threshold values (10, 15, 20, and 30 events per hour). Optimal combinations of sensitivity and specificity for the various thresholds were 82.6/71.4, 93.3/73.3, 90.9/84.2, and 83.3/91.7, respectively. The authors concluded that the Watch_PAT is a device that can detect OSA with reasonable accuracy. Thus, the Watch_PAT may be a useful method to diagnose OSA. They noted that "prior to widespread use of the device, further studies are needed. These include verification of accuracy and ease of use in an ambulatory setting, studies in other medical centers, and studies including more patients with non-respiratory causes of sleep fragmentation. Nevertheless, the Watch_PAT may become a useful technology to diagnose and manage patients with OSA".

Moreover, a technology assessment on portable monitoring devices for diagnosing OSA prepared for the Agency for Healthcare Research and Quality (AHRQ, 2004) evaluated the evidence on the clinical value of Watch_PAT. It found that the
quality of evidence to be fair for the study by Bar et al (2003), while the quality of evidence is poor for the studies by Pillar et al (2003) and Ayas et al (2003). It concluded that the new body of evidence does not materially change earlier findings regarding in-home devices for diagnosing OSA -- there is inadequate to support the use of unattended portable multi-channel sleep testing for the diagnosis of OSA. Furthermore, Acebo and LeBourgeois (2006) stated that although actigraphy maybe suitable for documenting and evaluating some sleep disorders, its role in clinical diagnosis is limited.

In a prospective randomized study with blinded analysis, Garcia-Diaz et al (2007) ascertained the utility and reliability of a respiratory polygraphy (RP) device with actigraphy in the diagnosis of sleep apnea-hypopnea syndrome (SAHS). A total of 62 patients with suspected SAHS were enrolled in the following 2 RP studies: (i) one in the sleep laboratory (sleep laboratory RP [LRP]), simultaneously with polysomnography; and (ii) the other at home (home RP [HRP]). To study the inter-observer reliability of RP, 2 manual analyses were carried out by 2 different researchers. In LRP, when the respiratory disturbance index was calculated using the total sleep time estimated by actigraphy (RDI) as a denominator, the sensitivity ranged between 94.6 % and 100 %, and the specificity between 88 % and 96.7 % for the different cut-off points of the apnea-hypopnea indexes studied. When the respiratory disturbance index was calculated according to the total recording time (RDITRT), the sensitivity was slightly lower (91.6 % to 96.9 %) and the specificity was similar (92 % to 96.7 %). In HRP, the sensitivity of the RDI ranged between 83.8 % and 95.8 %, and the specificity between 92 % and 100 %, whereas, when the RDITRT was used, the sensitivity was between 83.8 % and 87.5 %, and the specificity was between 94.7 % and 100 %. With regard to inter-observer reliability, the intra-class correlation coefficient for the RDI of the two analyses of the RP was 0.99 for both LPR and HPR. The authors concluded that
HPR is an effective and reliable technique for the diagnosis of SAHS, although it is less sensitive than LRP. Furthermore, wrist actigraphy improves the results of HRP only slightly.

Paquet and associates (2007) assessed the ability of actigraphy compared to PSG to detect wakefulness in subjects submitted to 3 sleep conditions with different amounts of wakefulness: a nocturnal sleep episode and 2 day-time recovery sleep episodes, one with placebo and one with caffeine (200 mg). A second objective was to compare the ability of 4 different scoring algorithms (2 threshold algorithms and 2 regression analysis algorithms) to detect wake in the 3 sleep conditions. A total of 15 healthy subjects aged between 20 and 60 years (7 males and 8 females) were included in this study. An epoch-by-epoch comparison between actigraphy and PSG showed a significant decrease in actigraphy accuracy with increased wakefulness in sleep conditions due to the low sleep specificity of actigraphy (generally less than 50%). Actigraphy over-estimated total sleep time and sleep efficiency more strongly in conditions involving more wakefulness. Compared to the 2 regression algorithms, the 2 threshold algorithms were less able to detect wake when the sleep episode involved more wakefulness, and they tended to alternate more between wake and sleep in the scoring of long periods of wakefulness resulting in an over-estimation of the number of awakenings. The authors concluded that the very low ability of actigraphy to detect wakefulness casts doubt on its validity to measure sleep quality in clinical populations with fragmented sleep or in situations where the sleep-wake cycle is challenged, such as jet-lag and shift-work.

Sitnick and colleagues (2008) compared actigraphy with videosomnography in preschool-aged children, with special emphasis on the accuracy of detection of night-time awakenings. A total of 58 subjects wore an actigraph for 1 week and were videotaped for 2 nights while wearing the actigraph. Participants were solitary sleepers, studied in their homes. One group (n = 22) was diagnosed with autism,
another group (n = 11) had developmental delays without autism, and a third group (n = 25) were typically developing children; age ranged from 28 to 73 months (mean age of 47 months); 29 boys and 29 girls. Nocturnal sleep and wakefulness were scored from simultaneously recorded videosomnography and actigraphy. The accuracy of actigraphy was examined in an epoch-by-epoch comparison with videosomnography. Findings were 94 % overall agreement, 97 % sensitivity, and 24 % specificity. Statistical corrections for overall agreement and specificity resulted in an 89 % weighted-agreement and 27 % adjusted specificity. The authors concluded that actigraphy has poor agreement for detecting nocturnal awakenings, compared with video observations, in preschool-aged children.

Gschliesser et al (2009) compared periodic leg movement (PLM) counts obtained with PSG to those obtained from 2 actigraphical devices (Actiwatch and PAM-RL). A total of 24 patients underwent full-night actigraphy with Actiwatch from both legs and simultaneous PSG. Out of these patients, 10 had additional actigraphy with PAM-RL. Bilateral and unilateral PLM indices (PLMI) for both actigraphical devices were calculated for time in bed and compared to polysomnographic PLMI. Additionally, a comparison between the 2 different actigraphical devices was performed. Overall, PLMI obtained with Actiwatch were significantly lower than those obtained with PSG (21.2 +/- 25.6/hr versus 34.4 +/- 30.7/hr; p < 0.001), whereas the PLMI from PAM-RL were significantly higher than in PSG (63.6 +/- 39.3/hr versus 37.0 +/- 33.5/hr; p = 0.009). In direct comparison, Actiwatch gave significantly lower PLMI than the PAM-RL (p = 0.005). The correlations between Actiwatch and PSG (rho = 0.835, p < 0.001), PAM-RL and PSG (rho = 0.939, p < 0.001), and Actiwatch and PAM-RL (rho = 0.915, p < 0.001) were significant. Unilateral actigraphy compared to standard PSG gave less consistent findings. When comparing different settings of the PAM-RL, manual threshold setting resulted in PLMI that were no longer different from PSG (p = 0.074), in
contrast to the default threshold setting. The authors concluded that the Actiwatch under-estimated and the PAM-RL over-estimated PLMI compared to PSG. Whereas PLMI obtained with the 2 actigraphical devices and PSG were highly correlated, they differed in mean values. Thus, PSG, actigraphy and also the different actigraphical devices can not be interchanged in longitudinal studies, and actigraphy should not be used for diagnostic decision-making based on PLM indices. The best approximation to PSG PLMI was achieved by using manual threshold setting with the PAM-RL.

In a review on ambulatory monitoring of sleep disorders, Tahmasian et al (2010) noted that actigraphy can not stand alone as a diagnostic tool for all clinical groups; especially so with those diagnosed with sleep disorders with significant motility or long catatonic periods of wakefulness during sleep.

Perez Lloret et al (2010) compared activity level in the "off-state", "on-state", and dyskinetic periods as evaluated either by a physician during a levodopa challenge or by a 72-hr on-off diary self-evaluation in the ambulatory setting. Finally, the effect of daily activities on motor activity in Parkinson's disease (PD) and healthy controls was further explored. The study was conducted in 3 consecutive phases: (i) for phase I, in which the on-state, off-state, and dyskinesia were evaluated using actigraphy, recordings were made during standard acute levodopa challenge in 9 dyskinetic PD patients; (ii) for phase II, a different set of 16 dyskinetic PD patients was monitored in the ambulatory setting for 72 consecutive hrs by actigraphy and a standardized on-off diary; and (iii) for phase III, 62 PD patients and 14 age- and sex-matched healthy controls wore an actigraph and completed a daily activities diary for 7 days. No differences in activity level between on-state and off-state during the acute levodopa challenge (phase I) or the 72-hr ambulatory period (phase II) were found. Activity during dyskinesia periods was significantly higher than during on-state periods without
dyskinesia (p < 0.01). During the phase III study, dyskinetic PD patients and healthy controls showed higher actigraphy-measured activity as compared to de novo, stable, or fluctuating PD (p < 0.0001), which remained unchanged by daily activities performed during the study period. Tremor UPDRS scores did not correlate with activity level. The authors concluded that these results confirm the lack of specificity of simple wrist-worn actigraphy and further suggested it may be suitable for dyskinesia assessment but not for on-state and off-state evaluation.

Pjrek and colleagues (2012) evaluated the differential effects of opioid detoxification with methadone or buprenorphine on activity, circadian rhythm, and sleep. A total of 42 consecutive inpatients with opiate addiction were switched to either methadone or buprenorphine and gradually tapered down over the course of 2 to 3 weeks. There were no significant differences in co-medication (lofexidine, quetiapine, and valproic acid) between the methadone and buprenorphine groups. Patients in the methadone group showed 11% lower activity and were 24 minutes phase delayed as compared with buprenorphine-treated patients, whereas the latter had 2.5% lower sleep efficiency and 9% shorter actual sleep time. These significant group differences were most pronounced for the lowest doses (less than or equal to 20% of maximum individual daily dose, i.e., at the end of withdrawal representing late withdrawal effects). Furthermore, for the total sample, these investigators found a significant decrease in the relative amplitude of the sleep-wake cycle and worsening of all actigraphic sleep parameters from the higher (100% to 20%) to the lowest doses (20% to 0%). The acrophase of the circadian rhythm displayed a phase advance (-88 minutes) from the highest (100% to 80%) to the lower doses (80% to 0%) in methadone-treated patients. The authors concluded that opioid tapering with methadone or buprenorphine leads to characteristic changes of the rest-activity cycle, but further study is needed to validate these findings.
Plante (2014) stated that periodic limb movements of sleep (PLMS) are repetitive, stereotyped movements that can disrupt sleep and result in insomnia, non-restorative sleep, and/or daytime sleepiness. Currently, PSG is the gold standard and only clinically acceptable means of quantifying PLMS. Leg-worn actigraphy is an alternative method of measuring PLMS, which may circumvent many of the economic and technical limitations of PSG to quantify nocturnal leg movements. However, the use of leg actigraphy as a diagnostic means of assessing PLMS has not been systematically evaluated. In this review, the use of leg-worn actigraphy to measure PLMS was systematically evaluated, using both qualitative and quantitative assessment. Findings demonstrate significant heterogeneity among a limited number of studies in terms of type of actigraph utilized, position of the device on the lower extremity, and methods employed to count PLMS. In general, common accelerometers vary in their sensitivity and specificity to detect PLMS, which is likely related to the technical specifications of a given device. A current limitation in the ability to combine data from actigraphs placed on both legs is also a significant barrier to their use in clinical settings. The author concluded that further research is needed to determine the optimal methods to quantify PLMS using leg actigraphy, as well as specific clinical situations in which these devices may prove most useful.

Burton et al (2013) noted that altered physical activity is an important feature of depression. It is manifested in psychomotor retardation, agitation and withdrawal from engagement in normal activities. Modern devices for activity monitoring (actigraphs) make it possible to monitor physical activity unobtrusively but the validity of actigraphy as an indicator of mood state is uncertain. These researchers performed a systematic review of digital actigraphy in patients with depression to investigate the associations between measured physical activity and depression. Studies were identified from Medline, EMBASE and Psycinfo databases and included if they were either case control or longitudinal studies.
of actigraphy in adults aged between 18 and 65 diagnosed with a depressive disorder. Outcomes were day-time and night-time activity and actigraphic measures of sleep. These investigators identified 19 eligible papers from 16 studies (412 patients). Case control studies showed less day-time activity in patients with depression (standardized mean difference -0.76, 95% confidence interval [CI]: -1.05 to -0.47). Longitudinal studies showed moderate increase in day-time activity (0.53, 0.20 to 0.87) and a reduction in night-time activity (-0.36, -0.65 to -0.06) over the course of treatment. The authors concluded that actigraphy is a potentially valuable source of additional information about patients with depression. However, there are no clear guidelines for use of actigraphy in studies of patients with depression. Moreover, they stated that further studies should investigate patients treated in the community; additional work to develop algorithms for differentiating behavior patterns is also needed.

Khawaja et al (2014) noted that patients with post-traumatic stress disorder (PTSD) frequently complain of sleep disturbances such as insomnia and nightmares. Evaluation of sleep disturbances is often difficult due to the subjective nature of the complaints. Polysomnography and other sleep studies are generally not indicated in the evaluation of insomnia or nightmares associated with PTSD. Actigraphy has been used in research to evaluate sleep disturbances in patients with PTSD. These researchers reviewed the literature on the use of actigraphy in evaluation of sleep problems in patients with PTSD. A literature search for articles on the topic was conducted on PubMed using the search algorithm (actigraphy [Title/Abstract] OR actigraphic[Title/Abstract]) AND PTSD [Title/Abstract]. Out of 11 search results, 9 studies in which application of actigraphy had relevance to the primary objective and outcome in PTSD patients with sleep problems were selected for review. These investigators also handpicked 1 additional article from personal communication with their colleagues who had performed some of these studies. The authors concluded that actigraphy has been used to evaluate
circadian rhythm sleep disorders. Use of actigraphy in psychiatry clinics is uncommon. There are no data to support that there are specific actigraphic sleep related findings in PTSD patients.

Geoffroy et al (2015) performed a meta-analysis of published actigraphy studies to identify whether any abnormalities in the reported sleep profiles of remitted BD cases differ from controls. A systematic review identified independent studies that were eligible for inclusion in a random effects meta-analysis. Effect sizes for actigraphy parameters were expressed as standardized mean differences (SMD) with 95 % CI. Nine of 248 identified studies met eligibility criteria. Compared with controls (n = 210), remitted BD cases (n = 202) showed significant differences in SMD for sleep latency (0.51 [0.28 to 0.73]), sleep duration (0.57 [0.30 to 0.84]), wake after sleep onset (WASO) (0.28 [0.06 to 0.50]) and sleep efficiency (-0.38 [-0.70 to 0.07]). Moderate heterogeneity was identified for sleep duration (I² = 44 %) and sleep efficiency (I² = 44 %). Post-hoc meta-regression analyses demonstrated that larger SMD for sleep duration were identified for studies with a greater age difference between BD cases and controls (β = 0.22; p = 0.03) and non-significantly lower levels of residual depressive symptoms in BD cases (β = -0.13; p = 0.07). The authors concluded that the findings of this meta-analysis of sleep in remitted BD highlighted disturbances in several sleep parameters. They stated that future actigraphy studies should pay attention to age-matching and levels of residual depressive symptoms.

Martin and Hakim (2011) stated that to record sleep, actigraphic devices are worn on the wrist and record movements that can be used to estimate sleep parameters with specialized algorithms in computer software programs. With the recent establishment of a Current Procedural Terminology code for wrist actigraphy, this technology is being used increasingly in clinical settings as actigraphy has the advantage of providing objective information on sleep habits in
the patient's natural sleep environment. Actigraphy has been well-validated for the estimation of night-time sleep parameters across age groups, but the validity of the estimation of sleep-onset latency and day-time sleeping is limited. Clinical guidelines and research suggested that wrist actigraphy is particularly useful in the documentation of sleep patterns prior to a multiple sleep latency test, in the evaluation of circadian rhythm sleep disorders, to evaluate treatment outcomes, and as an adjunct to home monitoring of sleep-disordered breathing. Actigraphy has also been well-studied in the evaluation of sleep in the context of depression and dementia. The authors concluded that although actigraphy should not be viewed as a substitute for clinical interviews, sleep diaries, or overnight polysomnography (PSG) when indicated, it can provide useful information about sleep in the natural sleep environment and/or when extended monitoring is clinically indicated.

The authors also noted the limitations of wrist actigraphy:

- Although actigraphy is an objective measure of sleep vs wakefulness, it has not been validated for measuring sleep stages. Actigraphy is also prone to over-estimating sleep in certain patient groups. A discussion of the limitations of this technology is warranted. When comparing actigraphy's ability to assess sleep parameters to the "gold standard" of PSG, it has shown excellent concordance in the measurement of total sleep time (TST) among healthy subjects, with a sensitivity of greater than 90%. However, the ability to detect sleep is substantially reduced in patients with disturbed sleep (i.e., those who have frequent arousals and reduced TST).
- With actigraphy, because sleep is inferred from lack of movement, subjects who are awake but lie motionless can be classified incorrectly as being asleep, and thus the technique is biased toward over-estimating TST,
which may lead to incorrectly minimizing the severity of sleep disturbances. This may present a specific challenge for patients with insomnia, and may partially explain the limited validity of wrist actigraphy for estimating sleep-onset latency (SOL). This may also be a concern among individuals who are hospitalized or bed bound, because these individuals may not have as much activity during wakefulness.

- The process of scoring wrist actigraphy data is substantially simplified when a concurrent sleep diary is maintained by the patient. This enables the clinician to determine the key period for analyzing sleep parameters. Typically, the time window between the patient's bedtime and morning rise time is considered the “major sleep period” and used for analysis. In the absence of such documentation, actigraphy can still provide an useful estimate of sleep habits over a 24-hour period, but parameters such as TST and WASO may be of more limited use.

The authors concluded that key limitations remain the absence of validation studies with many of the commercially available devices and the use of actigraphy in the assessment of daytime sleeping.

Montgomery-Downs et al (2012) stated that the web-based Fitbit, available at a markedly reduced price and with several convenience factors compared to standard actigraphy, may be an acceptable activity measurement instrument for use with normative populations. However, Fitbit has the same specificity limitations as actigraphy; both devices consistently misidentify wake as sleep and thus over-estimate both sleep time and quality.

Camargos et al (2013) noted that sleep disorders are common in patients with Alzheimer's disease (AD). An important aspect of intervention studies in patients with sleep disorders is the
choice of assessment strategy. These researchers presented a literature review concerning assessment strategies for measuring sleep in intervention studies with AD patients, with a focus on actigraphy (wrist actigraphy). A total of 37 articles were selected for this review, having analysis of sleep/nocturnal rhythm disturbances by actigraphy as the primary or secondary outcome. The advantages and limitations of actigraphy were discussed vis-à-vis PSG and subjective interventions. The following methodological aspects were addressed: impact of experimental design and patient setting, inclusion and exclusion criteria, placement of the actigraphy device, adherence to the regimen, duration of recordings and the choice of sleep parameters. The authors concluded that their analyses suggested that the methods used in intervention studies encompassing sleep disorders and dementia could be improved by increasing accuracy of diagnosis, categorization of sleep disturbances, adherence to actigraphy, and by clearly defining the variables and endpoints in each study. Furthermore controlling variables that could interfere with sleep and describing the data processing and analysis might improve interpretation of results.

O'Brien et al (2016) examined the agreement between actigraphy-estimated and self-reported sleep duration in obese individuals; these investigators had 63 treatment seeking overweight/obese participants who completed the Pittsburgh Sleep Quality Index (PSQI) and reported sleep duration for weekends and weekdays, and compared their reports to 7 days of actigraphy. Actigraph TST correlated $r = 0.20$ to $0.31$ with self-report and the absolute discrepancy averaged 51 to 54 minutes. Only 20 of the 32 subjects (62.5 %) classified as short sleepers (less than 7 hours/night) by actigraphy were similarly classified by self-report. Poor sleep quality was associated with greater absolute discrepancy between actigraphy and self-report. The authors concluded that the weak correlations between self-report and actigraph should be considered in future efforts to increase sleep duration to promote weight loss in obese individuals.
Luna and colleagues (2017) noted that previous studies using actigraphy to monitor recovery after total knee arthroplasty (TKA) have reported activity as maximum and average count/min, but not utilized the full potential of the data by stratifying activity into various intensities or analyzed the individual development in activity over time. These investigators described a novel methodology using actigraphy data to describe specific activity-intensities potentially affected by surgery and patients with poor rehabilitation trajectories. Actigraphy data from 10 patients scheduled for primary unilateral TKA were recorded pre-operatively and for 3 weeks post-operatively. Data were individualized by comparing pre- and post-operative values, and activity intensities stratified by division into 5 percentiles (10th, 25th, 50th, 75th and 90th). Changes in activity were assessed visually and by non-parametric testing. Individualized recovery trajectories were described by the gradient of the regression line of post- versus pre-operative physical activity over the study period. Total knee arthroplasty had a negative impact on all activity intensities with gradual improvement towards pre-operative values during the study period. The inter-individual variation increased with intensified activity. Identification of individual patients with positive, neutral or negative activity trajectories was possible. The authors concluded that the methodology should be considered in future interventional studies to improve rehabilitation strategies.

Athavale and associates (2017) noted that actigraphy can assist in the detection of periodic limb movements in sleep. Although several actigraphs have been previously reported to accurately detect periodic limb movements, many are no longer available; of the existing actigraphs, most sample too infrequently to accurately detect periodic limb movements. These researchers used advanced signal analysis to validate a readily available actigraph that has the capability of sampling at relatively high frequencies. They simultaneously recorded polysomnography and bilateral ankle actigraphy in 96 consecutive patients presenting to the authors’ sleep
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laboratory. After pre-processing and conditioning, the bilateral ankle actigraphy signals were then analyzed for 14 simple time, frequency and morphology-based features. These features reduced the signal dimensionality and aided in better representation of the periodic limb movement activity in the actigraph signals. These features were then processed by a Naïve-Bayes binary classifier for distinguishing between normal and abnormal periodic limb movement indices. These researchers trained the Naïve-Bayes classifier using a training set, and subsequently tested its classification accuracy using a testing set. From these experiments, using a periodic limb movement index cut-off of 5, the authors found that the Naïve-Bayes classifier had a correct classification rate of 78.9 %, with a sensitivity of 80.3 % and a specificity of 73.7 %. They concluded that the algorithm developed in this study has the potential of facilitating identification of periodic limb movements across a wide spectrum of patient populations via the use of bilateral ankle actigraphy.

Actigraphy for Diagnosis of Hypertension

Ramos and colleagues (2018) evaluated the association between actigraphy-based measures of sleep and prevalent hypertension in a sample of U.S. Latinos. These researchers analyzed data from 2,148 participants of the Sueno Sleep Ancillary Study of the Hispanic Community Health Study/Study of Latinos (HCHS/SOL), who underwent 1 week of wrist actigraphy to characterize sleep duration, sleep efficiency, sleep fragmentation index, and day-time naps. Insomnia was defined as an Insomnia Severity Index of greater than or equal to 15. Hypertension was defined based on self-reported physician diagnosis. Survey linear regression was used to evaluate the association of sleep measures with hypertension prevalence. Sensitivity analyses excluded participants with an AHI of greater than or equal to 15 events/hour. The mean age was 46.3 ± 11.6 years, and 65 % of the sample consisted of women. The mean sleep duration was 6.7 ± 1.1 hours; 32 % of the sample had hypertension. After adjusting for age, sex,
ethnic background, site, and AHI, each 10 % reduction in sleep efficiency was associated with a 7.5 % (95 % CI: -12.9 to -2.2; p = 0.0061) greater hypertension prevalence, each 10 % increase in sleep fragmentation index was associated with a 5.2 % (95 % CI: 1.4 to 8.9; p = 0.0071) greater hypertension prevalence, and frequent napping was associated with a 11.6 % greater hypertension prevalence (95 % CI: 5.5 to 17.7; p = 0.0002). In contrast, actigraphy-defined sleep duration (p = 0.20) and insomnia (p = 0.17) were not associated with hypertension. These findings persisted after excluding participants with an AHI of greater than or equal to 15 events/hour. The authors concluded that independent of sleep-disordered breathing, these researchers observed associations between reduced sleep continuity and day-time napping, but not short sleep duration, and prevalent hypertension.

**Actigraphy for Evaluation of Disruptive Mood Dysregulation Disorder**

In a pilot study, Delaplace and colleagues (2018) examined the clinical characteristics and motor activity profile during sleep periods of children and adolescents presenting with disruptive mood dysregulation disorder (DMDD). A total of 21 youths (mean age ± standard deviation, 11.7 ± 3 years) wore a wrist actigraph for 9 consecutive days (including both school days and non-school days), to measure sleep parameters: sleep latency, sleep efficiency and the number and duration of periods of wakefulness after sleep onset (WASO). These researchers divided the night-time actigraphy recording sessions into 3 sections and compared the first and last thirds of the night. All the study participants had a psychiatric co-morbidity (primarily attention deficit hyperactivity disorder, depressive disorder or anxiety disorder). On non-school days, bedrest onset and activity onset were shifted later by about 1 hour. There was no significant difference between school days and non-school days with regard to the total sleep time. Sleep efficiency was significantly greater on non-school days.
Sleep was fragmented on both school days and non-school days. The mean number of episodes of WASO was 24.9 for school days and 30.9 for non-school days. Relative to the first third of the night, these investigators observed a significantly greater number of episodes of WASO during the last third of the night, a period associated with a larger proportion of rapid eye movement (REM) sleep. The authors concluded that sleep appeared to be fragmented in the study population of youths with DMDD. The greater frequency of WASO in the last third of the night pointed to a possible impairment of the motor inhibition normally associated with REM sleep. These preliminary findings need to be validated by well-designed studies.

In a systematic review and meta-analysis, Tazawa et al (2019) examined the usefulness of actigraphy in evaluating depressive and/or bipolar disorder symptoms. These researchers selected studies that used actigraphy to compare either patients versus healthy controls, or pre- versus post-treatment data from the same patient group. Common actigraphy measurements, namely daily activity and sleep-related data, were extracted and synthesized. A total of 38 studies (n = 3,758) were included in the analysis. Compared with healthy controls, depressive patients were less active (SMD = 1.27, 95 % CI: 0.97 to 1.57, p < 0.001) and had longer wake after sleep onset (SMD = -0.729, 95 % CI: -1.20 to -0.25, p = 0.003). Total sleep time (SMD = -0.33, 95 % CI: -0.55 to -0.11, p = 0.004), sleep latency (SMD = -0.22, 95 % CI: -0.42 to -0.02, p = 0.032), and wake after sleep onset (SMD = 0.22, 95 % CI: -0.39 to -0.04, p = 0.015) were longer in euthymic/remitted patients compared to healthy controls. In pre- and post-treatment comparisons, sleep latency (SMD = -0.85, 95 % CI: -1.53 to -0.17, p = 0.015), wake after sleep onset (SMD = -0.65, 95 % CI: -1.20 to -0.10, p = 0.022), and sleep efficiency (SMD = 0.77, 95 % CI: 0.29 to 1.24, p = 0.002) showed significant improvement. The authors found significant differences between healthy controls and mood disorders patients for some actigraphy-measured modalities.
Specific measurement patterns characterizing each mood disorder/status were also found. These investigators noted that additional actigraphy data linked to severity and/or treatment could enhance the clinical utility of actigraphy. However, the authors stated that the limitations of this study included: sample sizes for each outcome were small; and the type of actigraphy devices and patients' illness severity differed across studies. It was possible that hospitalizations and medication influenced the outcomes.

**Actigraphy for Screening of Idiopathic Rapid Eye Movement (REM) Sleep Behavior Disorder**

Stefani and colleagues (2018) evaluated the utility of multi-modal low-cost approaches including actigraphy in identifying patients with idiopathic rapid eye movement (REM) sleep behavior disorder (iRBD). A total of 70 patients diagnosed with sleep disorders causing different motor manifestations during sleep (iRBD, sleep apnea, restless legs syndrome) and 20 subjects without any relevant motor manifestation during sleep, underwent video-polysomnography (vPSG) and 2 weeks of actigraphy, completed 6 validated RBD screening questionnaires, and sleep apps use was assessed. Actigraphy was analyzed automatically, and visually by 7 blinded sleep medicine experts who rated as "no", "possible", and "probable" RBD. Quantitative actigraphy analysis distinguished patients from controls, but not between patients with different types of motor activity during sleep. Visual actigraphy rating by blinded experts in sleep medicine using pattern recognition identified vPSG confirmed iRBD with 85% to 95% sensitivity, 79% to 91% specificity, 81% to 91% accuracy, 57.7% ± 11.3% positive predictive value (PPV), 95.1% ± 3.3% negative predictive value (NPV), 6.8 ± 2.2 positive likelihood ratio (PLR), 0.14 ± 0.05 negative likelihood ratio (NLR) and 0.874-0.933 area under the ROC curve (AUC); AUC of the best performing questionnaire was 0.868. Few patients used sleep apps; therefore, their potential utility in the evaluated patients' groups was limited. The authors
concluded that these findings indicated that experts in sleep medicine were able to recognize the activity patterns of iRBD with simple visual analysis of actigraphy. They stated that actigraphy is a promising screening method, which outperformed questionnaires alone according to results obtained. These researchers stated that actigraphy in conjunction with little clinical information might prove useful as a first-step to identify iRBD in the general population, to select patients who will undergo vPSG for confirming diagnosis of early-stage α-synucleinopathy.

One potential drawback of this study was the age difference between groups, as patients’ groups were not matched. However, these investigators thought this was not a drawback as they aimed to compare different motor activities during sleep, which have per se different age prevalence. While these investigators showed that providing simple clinical information was useful, they did not evaluate the impact of each single clinical variable. Actigraphy was not systematically performed during vPSG, so that registered activity could not be systematically compared with electromyographic (EMG) activity during vPSG. This was done only in some patients. Visual analysis performed by raters who were not experts in sleep medicine would probably not be as accurate, and it may require a specific training.

Actigraphy for Evaluation of Sleep Disorders and Circadian Rhythm Sleep-Wake Disorders

On behalf of the American Academy of Sleep Medicine (AASM), Smith and colleagues (2018) established clinical practice recommendations for the use of actigraphy in adult and pediatric patients with suspected or diagnosed sleep disorders or circadian rhythm sleep-wake disorders. The AASM commissioned a task force of experts in sleep medicine to develop recommendations and assigned strengths based on a systematic review of the literature and an assessment of the evidence using the Grading of Recommendations
Assessment, Development and Evaluation (GRADE) process. The task force provided a summary of the relevant literature and the quality of evidence, the balance of benefits and harms, patient values and preferences, and resource use considerations that support the recommendations. The AASM Board of Directors approved the final recommendations. The following recommendations are intended as a guide for clinicians using actigraphy in evaluating patients with sleep disorders and circadian rhythm sleep-wake disorders, and only apply to the use of FDA-approved devices. Each recommendation statement is assigned a strength ("Strong" or "Conditional"). A "Strong" recommendation (i.e., "We recommend...") is one that clinicians should follow under most circumstances. A "Conditional" recommendation (i.e., "We suggest...") reflects a lower degree of certainty regarding the outcome and appropriateness of the patient-care strategy for all patients. The ultimate judgment regarding any specific care must be made by the treating clinician and the patient, taking into consideration the individual circumstances of the patient, available therapeutic options, and resources.

- We suggest that clinicians use actigraphy to estimate sleep parameters in adult patients with insomnia disorder. (Conditional).
- We suggest that clinicians use actigraphy in the assessment of pediatric patients with insomnia disorder. (Conditional).
- We suggest that clinicians use actigraphy in the assessment of adult patients with circadian rhythm sleep-wake disorder. (Conditional).
- We suggest that clinicians use actigraphy in the assessment of pediatric patients with circadian rhythm sleep-wake disorder. (Conditional).
- We suggest that clinicians use actigraphy integrated with home sleep apnea test devices to estimate total sleep time during recording (in the absence of alternative objective measurements of total sleep time).
in adult patients suspected of sleep-disordered breathing. (Conditional).

- We suggest that clinicians use actigraphy to monitor total sleep time prior to testing with the Multiple Sleep Latency Test in adult and pediatric patients with suspected central disorders of hypersomnolence. (Conditional).

- We suggest that clinicians use actigraphy to estimate total sleep time in adult patients with suspected insufficient sleep syndrome. (Conditional).

- We recommend that clinicians not use actigraphy in place of electromyography for the diagnosis of periodic limb movement disorder in adult and pediatric patients. (Strong).

Assessment of periodic limb movement disorder (PLMD) was not addressed in previous clinical practice guidelines; however, there is a growing interest in tests conducted out of the sleep center, and studies have examined if actigraphy devices placed on the ankle or foot are a viable alternative to in-laboratory EMG in conjunction with polysomnography (PSG) (as required by current diagnostic criteria). The Task Force (TF) compared actigraphy to EMG for the assessment of periodic limb movements in adult and pediatric patients, to examine if actigraphy could be used in place of EMG during PSG to evaluate the periodic limb movements of sleep index (PLMSI) and diagnose PLMD. The TF identified 5 studies (4 adult, 1 pediatric), 1 of which did not provide mean and standard deviation (SD) values and 1 of which used 2 actigraphy comparators. The small number of studies and sample heterogeneity precluded meta-analysis. Across the studies, the PLMSI as measured by actigraphy differed significantly from EMG measures in both adult and pediatric populations, demonstrating that actigraphy does not produce reliable estimates of periodic limb movements. The overall quality of evidence was moderate due to low sample size and imprecision. The TF determined that the potential for over-
estimating or under-estimating PLMSI could lead to potentially unnecessary treatment or to missed cases of PLMD. In addition, without evaluation of simultaneous EEG, the evaluation of arousals from sleep is not possible with actigraphy alone. Thus, the TF concluded that the potential harms of misclassification out-weighed the benefits of ease of monitoring with actigraphy versus EMG during PSG. Based on clinical expertise, the TF determined that the vast majority of patients would not use actigraphy in place of EMG, given the poor correspondence between the PLMSI as measured with actigraphy versus gold-standard EMG during PSG. The recommendation against using actigraphy in place of EMG for the diagnosis of PLMD is primarily a result of the unreliable estimates of periodic limb movement and the potential for misdiagnosis.

**Actigraphy for Evaluation of Schizophrenia**

Wee and colleagues (2019) stated that actigraphy is a non-invasive method of monitoring circadian rhythms and motor activity. These investigators reviewed extant evidence until September 2018 pertaining to actigraphy use in schizophrenia, its clinical/biological correlates and posit future research directions. Within 38 included studies involving 2,700 subjects, patients with schizophrenia generally have lower motor activity levels, poorer sleep quality and efficiency, increased sleep fragmentation and duration compared with healthy controls. Lowered motor activity and longer sleep duration in patients were associated with greater severity of negative symptoms. Less structured motor activity and decreased sleep quality were associated with greater severity of positive symptoms, worse cognitive functioning involving attention and processing speed, illness chronicity, higher antipsychotic dose, and poorer quality of life (QOL). Correlations of actigraphic measures with biological factors are sparse with inconclusive results. The authors concluded that future studies with larger sample sets may adopt a multi-modal, longitudinal approach that examines both motor and sleep
activity, triangulates clinical, actigraphic and biological measures to clarify their inter-relationships and inform risk prediction of illness onset, course, and treatment response over time.

Accelerometry

Individuals with movement disorders including essential tremor and PD often exhibit tremor, bradykinesia and dyskinesias, which can change rapidly and affect quality of life. Research to develop new treatments for these disorders is ongoing and advent in new therapies requires methodologies that can reliably quantify movement. Available methods include accelerometry, spirometry, volumetry, handwriting assessment, handicap/disability scales, as well as handicap/disability questionnaires.

Accelerometry was first suggested in the 1970s, but has only been refined during the past 2 decades. Direct measurement by accelerometry has seen the introduction of the successful implementation of low-power, low-cost electronic sensors that have been employed in clinical and home environments for the constant monitoring of patients (and their controls). The qualitative and quantitative data provided by these sensors enable engineers, clinicians and physicians to work together to help patients with movement disorders in overcoming their physical disability (Godfrey et al, 2008).

In April 2007, Cleveland Medical Devices Inc. (Cleveland, OH) received clearance from the FDA to market Kinesia to be used for monitoring physical motion and muscle activity to quantify kinematics of movement disorder symptoms such as tremor and assess activity in any instance where quantifiable analysis of motion and muscle activity is desired. Kinesia, a quantitative motor assessment system, is a compact wireless system that uses accelerometers and gyroscopes to monitor 3-dimensional motion. The device is worn on the wrist and finger of the patient and can be used to monitor upper
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extremity movement disorder symptoms and their fluctuations. Motion and electromyography information from the patient is wirelessly telemetered to a computer for display and analysis. The Kinesia software also integrates videos, which guide the patient through tasks known to elicit symptoms, similar to instructions given by a physician when evaluating upper extremity motor symptoms. Tasks completed for evaluating tremor are automatically scored on a 0 to 4 scale, which correlated to the Unified Parkinson’s Disease Rating Scale (UPDRS).

Although feasible methods for monitoring movement are available, evidence-based clinical applications of accelerometry in patients with PD have generated mixed results. In particular, there is insufficient evidence that the use of accelerometry is associated with improved health outcomes in PD patients.

Manson and colleagues (2000) noted that new treatments are now becoming available for the management of levodopa-induced dyskinesias (LID) in PD. However, assessment of their effectiveness is limited by the inadequacies of current methods of dyskinesia measurement. The aim of this study was to develop and validate a portable device capable of objectively measuring dyskinesias during normal daily activities. A portable device was developed based on a tri-axial accelerometer, worn on the shoulder, and a data recorder that can record LID. A computer program plots raw acceleration and acceleration over 0.5 Hz frequency bands against time. The acceleration in the different bands can then be compared with the raw acceleration trace, enabling identification and exclusion of confounding activities such as tremor and walking, which have a characteristic appearance on the trace. The validity of this device was assessed on 12 patients and 8 age-matched controls by comparing accelerations in the 1 to 3 Hz frequency band with established clinical dyskinesia rating scales. While wearing the monitor, subjects were video-recorded sitting and during dyskinesia
provocation tasks, including mental activation tasks, eating, drinking, writing, putting on a coat, and walking. The dyskinesias were graded with both modified abnormal involuntary movement (AIM) and Goetz scales. The clinical ratings were then compared with the mean acceleration scores. Acceleration in the 1 to 3 Hz frequency band correlated well against both scales, during all individual tasks. Acceleration produced by normal voluntary activity (with the exception of walking, which produced large accelerations, even in controls) was small compared with dyskinetic activity. With walking excluded, the mean acceleration over the rest of the recording time correlated strongly with both the modified AIM (Spearman's rank \( r = 0.972, p < 0.001 \)) and Goetz \( (r = 0.951, p < 0.001) \) scales. The authors concluded that this method provides an accurate, objective means for dyskinesia assessment, and compares favorably with established methods currently used.

Keijzers et al (2003) developed an objective and automatic procedure to assess the severity of LID in patients with PD during daily life activities. A total of 13 patients were continuously monitored in a home-like situation for a period of approximately 2.5 hrs. During this time period, patients performed approximately 35 functional ADL. Behavior of the patients was measured using tri-axial accelerometers, which were placed at 6 different positions on the body. A neural network was trained to assess the severity of LID using various variables of the accelerometer signals. Neural network scores were compared with the assessment by physicians, who evaluated the continuously video-taped behavior of the patients off-line. The neural network correctly classified dyskinesia or the absence of dyskinesia in 15-min intervals in 93.7, 99.7, and 97.0 % for the arm, trunk, and leg, respectively. In the few cases of mis-classification, the rating by the neural network was in the class next to that indicated by the physicians using the AIMS score (scale 0 to 4). Analysis of the neural networks revealed several new variables, which are relevant for assessing the severity of LID. The results
indicated that the neural network can accurately assess the severity of LID and could distinguish LID from voluntary movements in daily life situations.

On the other hand, findings from other studies did not support the use of accelerometry in evaluating PD patients. Hoff et al (2001) developed parameters for objective ambulatory measurements of LID in patients with PD. A total of 23 PD patients with mild-to-severe LID were submitted to a standardized protocol of 1-min recordings during rest, talking, stress, and 4 activities of daily life (ADL). Patients were simultaneously monitored with portable multi-channel accelerometry (4 pairs of bi-axial sensors mounted onto the most affected arm, leg, and at the trunk) and recorded by video. The severity of LID was assessed with a modified Abnormal Involuntary Movement Scale (m-AIMS). The signals were analyzed, and every 1/8-second interval the amplitude was obtained of the dominant frequency within 1 to 4 Hz and 4 to 8 Hz frequency bands (Amp 1 to 4 and Amp 4 to 8). For both measures, convergent validity, reproducibility, and responsiveness were determined. In the absence of voluntary movements, a significant relation was found between Amp 1 to 4 and Amp 4 to 8 and m-AIMS. Repeated measurements during rest showed a high reproducibility (intra-class correlation coefficient [ICC] = 0.90 [Amp 1 to 4] and 0.86 [Amp 4 to 8]). The extent to which LID increased with talking and stress correlated significantly (p = 0.02) between the objective and clinical measures (ICC for differences = 0.67). During ADL, LID occurred in a similar frequency band as voluntary movements and only Amp 1 to 4 and Amp 4 to 8 of the trunk and leg sensor remained highly correlated with m-AIMS. The authors noted that although objective measures of LID are reliable and responsive, they failed to distinguish LID from voluntary movements. These measures are of value only when obtained during rest (all sensor sites) or during ADL when derived from those body segments that are normally not involved in these ADL tasks (trunk and leg).
Thielgen et al (2004) extended the use of accelerometry to PD patients in a clinical rehabilitation program, and examined its practability with respect to the results of the treatment and patients' compliance. The methodology was tested on 30 patients (17 males, 13 females). The mean age was 64.8 years (s = 8.9). The Hoehn-Yahr index ranged from 1 to 3 (m = 2.3, s = 0.7) and the overall UPDRS between 10 and 74 (m = 42.9, s = 18.1). The data recording included: (i) the registration of tremor under standardized conditions of rest and postural tremor test with and without distraction; (ii) a standard protocol to obtain reference values for body position and movement; and (iii) the 24-hr monitoring. A total of 21 patients could be recorded a second time, on average 18 days after the first recording. Between the 2 registrations, patients received individually tailored drug treatment supplemented with specific activating physiotherapy, ergotherapy measures, and individual psychotherapeutic counseling. Changes between 1st and 2nd recording were evident for the 3 tremor variables, but significant only for the 24-hr ambulatory monitoring. The between and within-subjects correlations of the tremor variables were rather low except the correlations between occurrence and amplitude (between-subjects 0.87; within-subjects 0.67). Conditions of rest and postural tremor test showed a correlation with corresponding segments of the ambulatory monitoring of about 0.50 for the tremor occurrence. The best prediction of the daytime monitoring was made by the tremor tests with distraction, whereas the night segment was best predicted by the standard protocol.

Hoff et al (2004) noted that shortcomings of existing assessment methods in PD have led to the development of continuous ambulatory multi-channel accelerometry for the assessment of the core features of PD. Although measures for hypokinesia, bradykinesia, and tremor have been validated in groups of patients with PD, it is unclear whether this method is able to detect "on" with or without dyskinesias, and "off" in
individual PD patients. This study addressed the accuracy of objective ambulatory accelerometry in detecting motor complications in 15 PD patients, using a self-assessment scale as gold standard. Measures for hypokinesia, bradykinesia, and tremor showed limited sensitivity (0.60 to 0.71) and specificity (0.66 to 0.76) for motor complications in individual PD patients. In the group of PD patients, comparing the "on" with the "off" state yielded statistically significant differences for tremor only. Objective dyskinesia measures correlated with time spent with dyskinesias (r = 0.89). The authors stated that although validated for the measurement of hypokinesia, bradykinesia, and tremor, continuous ambulatory multi-channel accelerometry currently can not detect "on" and "off" in individual PD patients.

In a review on accelerometry, Kavanagh and Menz (2008) noted that despite significant progress in the use of accelerometry to evaluate gait patterns, there are several areas of scientific and clinical importance that are yet to be fully explored: (i) the validity of accelerometer-based approaches to motion assessment is scarcely reported. There is considerable potential to enhance gait measurement with accelerometers by the addition of rate gyroscopes, magnetometers and electrogoniometers, (ii) despite the frequently cited benefit of employing accelerometer-based gait analysis to test under "real world" conditions, few studies have actually assessed gait patterns over extended duration, under real-life environmental conditions. The use of accelerometry to assess gait when negotiating various walking surfaces and other environmental challenges, both indoors and outdoors, may improve the understanding of how subjects behave when performing normal daily activities. Although preliminary studies have been undertaken to evaluate gait in clinical populations, few studies have examined if therapeutic interventions (e.g., orthoses, footwear and physiotherapy) or pharmacotherapies (e.g., l-dopa and botulinum toxin) can aid in normalizing
acceleration patterns when walking. Given their portability and relatively straightforward data processing requirements, accelerometers may enable more detailed gait outcome measurement in large-scale clinical trials of patients with balance and mobility impairments.

Burke and colleagues (2009) stated that electromyography or accelerometry can be used to evaluate tremor frequency, rhythmicity, and amplitude in the work-up of patients with essential tremor, but are not part of the routine evaluation.

In a systematic review of accelerometry-based measures for monitoring of physical activity after stroke, Gebruers and colleagues (2010) evaluated the clinimetric properties and clinical applicability of different accelerometry-based measurement techniques in persons with stroke. A systematic search of literature was performed using a specific search strategy by means of different electronic databases until October 2008 (PubMed, EMBASE, CINAHL, Cochrane Library of Clinical Trials). A first selection was made by means of title and abstract. A second selection was performed by means of predefined inclusion criteria: (i) accelerometry in stroke population, (ii) application of accelerometry in patients with stroke including clinimetric properties. The exclusion criteria were (i) dysphagia, (ii) new engineering techniques or software alterations, (iii) secondary sources, and (iv) Case studies. The clinimetric properties and applicability of accelerometry were described based on the included publications. A total of 25 articles (4 randomized controlled trials) were included. The information of the publications was divided into (i) gait, cadence, and ambulatory activity; (ii) upper-extremity activity; and (iii) topics related to stroke other than upper or lower extremity. Accelerometry was shown to be valid and had good test-retest reliability in a large number of settings. Many studies demonstrated correlations between accelerometry and common stroke scales. Trunk movements were measured as an outcome of disturbed gait.
The vertical asymmetry index especially was able to differentiate between persons with stroke and healthy controls. Persons with stroke showed less ambulatory activity, measured as steps per day, than sedentary controls. Tri-axial accelerometry was able to distinguish between varying activity levels. Upper-extremity use was lesser in persons with stroke. It was impossible to calculate a minimal clinical difference for arm use by a uni-axial accelerometer. Evidence was presented that finger-tapping and sit-to-stand measured by accelerometers could be used to define recovery from stroke. The authors concluded that the literature concerning accelerometry incorporated into stroke research is young, limiting the ability to draw consistent conclusions. Nonetheless, the available evidence suggested that accelerometers yield valid and reliable data about the physical activity of patients with stroke. They stated that more research is needed to investigate clinimetric properties like predictive value and responsiveness further before implementing accelerometry in clinical trials as an outcome for change.

Cheung et al (2011) reviewed studies that used accelerometers to classify human movements and appraised their potential to determine the activities of older patients in hospital settings. All studies that validated the use of accelerometers to classify human postural movements and mobility were included. Studies included participants from any age group. All types of accelerometers were included. Outcome measures criteria explored within the studies were comparisons of derived classifications of postural movements and mobility against those made by using observations. Based on these criteria, a total of 54 studies were selected for detailed review. Data were extracted by the first author and included characteristics of study participants, accelerometers used, body positions of device attachment, study setting, duration, methods, results, and limitations of the validation studies. The accelerometer-based monitoring technique was investigated predominantly on a small sample of healthy adult participants in a laboratory setting. Most studies applied
multiple accelerometers on the sternum, wrists, thighs, and shanks of participants. Most studies collected validation data while participants performed a pre-defined standardized activity protocol. The authors concluded that accelerometer devices have the potential to monitor human movements continuously to determine postural movements and mobility for the assessment of functional ability. They stated that future studies should focus on long-term monitoring of free daily activity of a large sample of mobility-impaired or older hospitalized patients, who are at risk for functional decline.

Bento et al (2012) reviewed the use of accelerometry as an objective measure of physical activity in adults and elderly people. A systematic review of studies on the use of accelerometry as an objective measure to assess physical activity in adults were examined in PubMed Central, Web of Knowledge, EBSCO and Medline databases from March 29 to April 15, 2010. The following keywords were used: "accelerometry," "accelerometer," "physical activity," "PA," "patterns," "levels," "adults," "older adults," and "elderly," either alone or in combination using "AND" or "OR." The reference lists of the articles retrieved were examined to capture any other potentially relevant article. Of 899 studies initially identified, only 18 were fully reviewed, and their outcome measures abstracted and analyzed. Eleven studies were conducted in North America (United States), 5 in Europe, 1 in Africa (Cameroon) and 1 in Australia. Very few enrolled older people, and only 1 study reported the season or time of year when data were collected. The articles selected had different methods, analyses, and results, which prevented comparison between studies. The authors concluded that there is a need to standardize study methods for data reporting to allow comparisons of results across studies and monitor changes in populations. These data can help design more adequate strategies for monitoring and promotion of physical activity.
In a validity study, Item-Glatthorn et al (2012) evaluated the concurrent validity of an accelerometry-based system (IDEEA (a)) with a criterion instrument (Gaitrite(b)) for the evaluation of spatio-temporal gait variables in orthopedic patients. A total of 26 men with unilateral hip osteoarthritis (mean age +/- SD, 54 +/- 9 years) were included in this study. Patients were asked to walk at normal and fast velocities while gait cycle, swing, double support, step length, cadence and speed were concomitantly recorded with the 2 instruments. Concurrent criterion-related validity was examined using intra-class correlation coefficients and Bland-Altman limits of agreement. Intra-class correlation coefficients were acceptable for all gait parameters (range of 0.815 to 0.997), except step length (0.783). Limits of agreement were low for gait cycle, swing and cadence, though relatively high for double support, step length and speed. A significant bias between the 2 measuring instruments was consistently observed. The authors concluded that in patients with hip osteoarthritis, quantitative gait analysis with the IDEEA accelerometry system was satisfactory for the main temporal gait parameters, while double support, step length and walking speed quantifications were invalid. They stated that IDEEA should be used with caution, and modifications of the system are recommended for improved use in clinical practice and research.

The Tremorometer is a physiologic recording system using accelerometers that generates precision tremor frequency and amplitude information. Caligiuri and Tripp (2004) described the results of the Tremorometer, a hand-held device, for quantifying tremor in the upper extremity. The specific aims of the study were to evaluate: (i) the reliability of the device to record tremor frequency and amplitude; (ii) the relationship between observer ratings of tremor severity and spectral power derived from the instrument; (iii) the effects of limb posture on tremor properties recorded by the instrument; and (iv) whether scores from the instrument can discriminate types of tremor with sufficient accuracy to be
of diagnostic value. Results from 242 subjects with tremor showed significant effects of limb posture on tremor frequency detected by the device that could not be revealed using traditional observer severity ratings. Subjects with tremor associated with idiopathic Parkinson's disease were distinguished from patients with drug-induced parkinsonian tremor with 83 % accuracy. These and other findings on instrument validity demonstrated that tremor assessment can be performed using standard quantitative procedures that overcome many of the limitations inherent in subjective observer ratings. The authors concluded that the portability of the Tremorometer made it a useful tool for multi-site collaborative studies in community settings. However, there is insufficient evidence that the Tremerometer improve therapeutic responses for the purpose of decreasing tremor in patients with tremor. Well-designed studies are needed to ascertain its clinical value.

Wootton et al (2012) evaluated the validity of accelerometer data, its responsiveness to change, and the practicality and acceptability of accelerometers when used as an outcome measure in a clinical trial. This study used data collected from 336 subjects of the Softened Water Eczema Trial (SWET). Accelerometer data were compared with 3 standardized scales: (i) Six Area, Six Sign Atopic Dermatitis (SASSAD) severity score, (ii) Patient Oriented Eczema Measure (POEM), and (iii) Dermatitis Family Impact (DFI). Spearman's rank testing was used for correlations. Only 70 % of trial participants had complete data, compared with 96 % for the primary outcome (eczema severity - SASSAD). The convergent validity of accelerometer data with other measures of eczema severity was poor: correlation with SASSAD 0.15 (p = 0.02), and POEM 0.10 (p = 0.13). Assessing for divergent validity against quality of life measures, the correlation with the DFI was low (r = 0.29, p < 0.0001). Comparing the change scores from baseline to week 12 for SASSAD, POEM, and DFI with the change in accelerometer scores these researchers
found low, negative correlations ($r = -0.02, p = 0.77$; $r = -0.12, p = 0.06$; and $r = -0.01, p = 0.87$, respectively). In general, the units were well-tolerated, but suggestions were made that could improve their usability in children. The authors concluded that actigraphy did not correlate well with disease severity or quality of life when used as an objective outcome measure in a multi-center clinical trial, and was not responsive to change over time. They stated that further work is needed to establish why this might be, and to establish improved methods of distinguishing between eczema-related and eczema-nonrelated movements.

Verceles and Hager (2015) stated that medical management of critically ill patients often incorporates prolonged bed rest, which, in combination with the underlying illness, results in global muscle weakness and atrophy. Recent evidence has demonstrated improvements in clinical and functional outcomes when exercise and physical activity are incorporated early in the management of patients in the intensive care unit (ICU). Accurate monitoring of ICU patients' physical activity is essential for proper prescription and escalation of activity levels. The use of accelerometry in critically ill, hospitalized patients with poor functional mobility is limited. In this review, these investigators focused on the few studies assessing the use of accelerometry to measure physical activity in the care of mechanically ventilated adult ICU patients. The selected literature demonstrated that accelerometry correlates well with direct observation in reporting frequency and duration of various types of physical activity (rolling, sitting up, transferring, walking), but cannot differentiate various intensities of activity or whether movements are voluntary or involuntary with respect to effort. The authors concluded that although accelerometry may serve as a useful adjunct in reporting temporality of physical activity in critically ill patients, other objective information may be needed to accurately record frequency, duration, and intensity of activity in this population.
Skender and colleagues (2016) reviewed accelerometer wear methods and correlations between accelerometry and physical activity (PA) questionnaire data, depending on participant characteristics. These investigators included 57 articles about PA measurement by accelerometry and questionnaires. Criteria were to have at least 100 participants of at least 18 years of age with manuscripts available in English. Accelerometer wear methods were compared. Spearman and Pearson correlation coefficients between questionnaires and accelerometers and differences between genders, age categories, and body mass index (BMI) categories were assessed. In most investigations, requested wear time was 7 days during waking hours and devices were mostly attached on hips with waist belts. A minimum of 4 valid days with wear time of at least 10 hours per day was required in most studies.

Correlations \((r = \text{Pearson, } \rho = \text{Spearman})\) of total questionnaire scores against accelerometer measures across individual studies ranged from \(r = 0.08\) to \(\rho = 0.58\) \((p < 0.001)\) for men and from \(r = -0.02\) to \(r = 0.49\) \((p < 0.01)\) for women. Correlations for total PA among participants with ages less than or equal to 65 ranged from \(r = 0.04\) to \(\rho = 0.47\) \((p < 0.001)\) and from \(r = 0.16\) \((p = 0.02)\) to \(r = 0.53\) \((p < 0.01)\) among the elderly (greater than or equal to 65 years). Few studies investigated stratification by BMI, with varying cut-points and inconsistent results. Investigations reviewed in this study compared PA scores of questionnaires with PA measures from accelerometers. In the 57 investigations, correlations between questionnaires and accelerometry were weak-to-moderate. This finding was in agreement with previous reviews. Unlike questionnaires, accelerometers are not suitable for long-term measurements and thus seasonable activities can be captured only through repeated administration. This is expected to reduce correlations. There are further aspects that limit PA measurement by accelerometry (e.g., the devices not being able to cover stationary activities, strength training, or cycling). Also, water-based activities can also lead to misclassifications in individual PA measurement in cases where the sensors are not water-proof or not worn during that activity.
Furthermore, the wearing of an accelerometer itself may promote PA. The authors concluded that there were no clear patterns in correlations between PA questionnaires and accelerometry by gender, age, BMI, or wear time. However, correlations appeared to be slightly stronger among men compared to women and younger versus older populations. Due to differences in the dimensions studied by each method, it is advised that studies use both questionnaires and accelerometers to gain the most complete information. Furthermore, due to the low number of studies in patient groups, continued research to identify the best combination of wear methods is needed.

Accelerometry for Differential Diagnosis of Tremor Syndromes

Bove and colleagues (2018) stated that there is no consensus on criteria for accelerometric diagnosis of tremor syndromes. These researchers enrolled 20 patients with essential tremor (ET), 20 with dystonic tremor (DT), and 20 with classic Parkinsonian tremor (PD-T), all meeting accepted clinical criteria. All the patients underwent dopamine transporter imaging (by means of single-photon emission computed tomography [SPECT] ) and tri-axial accelerometric tremor analysis. The latter revealed group-wise differences in tremor frequency, peak dispersion, spectral coherence, unilaterality and resting versus action tremor amplitude. From the above, 5 diagnostic criteria were extrapolated for each condition; ROC curves, depicting criteria-based scoring of each tremor type, showed negligible declines in specificity for scores of greater than or equal to 4 in patients with ET or DT and scores of greater than or equal to 3 in patients with PD-T, thus providing a simple scoring method (accelerometrically derived) for differential diagnosis of the principal tremor syndromes. The authors concluded that accelerometry provided objective and precise linear measurements of tremor occurrence, frequency and amplitude, eliminating potential bias deriving from patient perceptions and clinical over-sights. They stated that this
approach may aid in distinguishing various tremor syndromes through a criteria-based scoring method, although further prospective validation is needed.

The authors stated that a drawback of this study was the divergence between the 3 groups in terms of age (the patients with DT being notably younger) and disease duration (those with ET being afflicted for the longest time). These differences may both be explained by the younger age at onset of ET and DT, relative to PD-T. However, it is worth considering that in ET patients, tremor frequency could change as the disease progresses, and that these investigators considered only patients with a long disease duration. Accordingly, a more homogeneous sample in terms of age and disease duration should be selected for future studies.

Accelerometry for Evaluating Sleep Disturbances in Parkinson's Disease

McGregor and colleagues (2018) noted that sleep disturbances are common in PD. These investigators used the Parkinson's KinetiGraph (PKG), an objective movement recording system for PD to evaluate night-time sleep in 155 people aged over 60 and without PD (controls), 72 people with PD (PwP) and 46 subjects undergoing PSG (36 with sleep disorder and 10 with normal sleep). The PKG system uses a wrist-worn logger to capture acceleration and derive a bradykinesia score (BKS) every 2 mins over 6 days. The BKS ranges from 0 to 160 with higher scores associated with lesser mobility. Previously, these researchers showed that BKS of greater than 80 were associated with day-time sleep and used this to produce scores for night-time sleep: Efficiency (percent time with BKS greater than 80), Fragmentation (average duration of runs of BKS greater than 80) and Sleep Quality (BKS greater than 111 as a representation of atonia). There was a fair association with BKS score and sleep level as judged by PSG. Using these PKG scores, it was possible to distinguish between normal and abnormal PSG studies with
good selectivity (86 %) and sensitivity (80 %). The PKG's sleep scores were significantly different in PD and controls and correlated with a subject's self-assessment (PDSS 2) of the quality, wakefulness and restlessness. Using both the PDSS 2 and the PKG, it was apparent that sleep disturbances were apparent early in disease in many PD subjects and that subjects with poor night-time sleep were more likely to have day-time sleepiness. This system shows promise as a quantitative score for assessing sleep in Parkinson's disease.

The authors concluded that the combined sleep score (CSS) showed promise as a quantitative score for assessing sleep in PD. Moreover, they stated that further study is needed to understand its relationship to sleep architecture, although the SQ (the percent of the NP with BKS greater than 110) score showed promise in this respect. They stated that further studies are also needed to examine if the CSS or similar accelerometry scales could be developed as a tool to predict those subjects who do or do not need PSG.

Accelerometry for Monitoring of Physical Activity during Rehabilitation of Persons with Stroke

In a longitudinal observational study, Joseph and colleagues (2018) examined the feasibility of using accelerometers to monitor physical activity in persons with stroke admitted to in-patient rehabilitation. Volume and intensity of physical activity were assessed with accelerometers throughout the rehabilitation period. Indicators of feasibility included processes (recruitment, protocol adherence and participants' experiences) and scientific feasibility, which assessed the accelerometers' ability to detect change in physical activity among stroke survivors who ambulate independently and those who are dependent on a mobility device. A total of 27 out of 31 eligible individuals participated in this study, with 23 (85 %) completing it. In total, 432 days of rehabilitation were monitored and valid physical activity data were obtained for 408 days (94 %). There were no indications that the
measurement interfered with participants’ ability to participate in rehabilitation. Despite the subjects' ambulation status, the number of steps and time spent in moderate-to-vigorous physical activity increased significantly across the first 18 days of rehabilitation, whereas sedentary time was unchanged. The authors concluded that the findings of this study supported the feasibility of using accelerometers to capture physical activity behavior in survivors of stroke during in-patient rehabilitation.

Epilepsy Monitoring System

For epileptic seizures, seizure frequency is the primary indicator and measure on which to base treatment (AAP, 2014). Many patients are asked to maintain seizure diaries for this purpose, but evidence has shown that the self-reported data is unreliable. Due to the high-cost of video electroencephalography (EEG) monitoring in an inpatient epilepsy monitoring unit (EMU) and the unreliability of patient paper seizure diaries, there is a need for a less costly, objective, diagnostic tool to track patient seizure count and frequency. Therefore, diagnostic event monitoring tools are being developed that are to be worn by the patient in order to capture seizure event data.

The epilepsy event monitoring system is a device that includes an adhesive patch connected to a sensor that will continuously detect and record ECG and 3-axis accelerometer motion data which communicates to a base station hub and then notifies a caregiver (AAP, 2014). The system is being specifically developed to address the unmet need of objective, non-invasive, discrete seizure monitoring, reporting and notification.

Several clinical trials are ongoing. The Epilepsy Institute of the Netherlands Foundation (SEIN) and the University Medical Center Utrecht (UMCU) are sponsoring a clinical trial in the home environment of 60 epilepsy patients to investigate the sensitivity and positive predictive value of a multimodal sensor
system (‘LivAssured’) for the detection of nocturnal motor seizures. Subjects included in this study are children and adolescents living at home, or adults with a mental impairment living in long-term care facilities, who are diagnosed with major motor seizures (defined as tonic-clonic, generalized tonic, hypermotor or series of myoclonic seizures) with minimal nocturnal motor seizure frequency (one per week). The primary outcome of the study will be the detection rate of epileptic nocturnal seizures by the combination of heart rate and accelerometry analysis and the added value of video and audio detection.

Cyberonics (2014) is conducting a pilot observational study to evaluate a prototype device designed to collect ECG and accelerometer data in children and adults with epilepsy. The investigational system is composed of a sensor, patch, hub, and caregiver application. The sensor is applied externally during periods of nocturnal sleep for up to 7 nights. Results of this study are pending. The primary outcome of the study is to collect usability data from the intended use population of people with epilepsy and their caregivers.

Van de Vel et al (2014) stated that for long-term home monitoring of epileptic seizures, the measurement of extra-cerebral body signals such as abnormal movement is often easier and less obtrusive than monitoring intra-cerebral brain waves with EEG. Non-EEG devices are commercially available but with little scientifically valid information and no consensus on which system works for which seizure type or patient. These investigators evaluated 4 systems based on efficiency, comfort, and user-friendliness and compared them in 1 patient suffering from focal epilepsy with secondary generalization. The Emfit mat, Epi-Care device, and Epi-Care Free bracelet are commercially available alarm systems, while the VARIA (Video, Accelerometry, and Radar-Induced Activity recording) device is being developed by the authors’ team and requires off-line analysis for seizure detection and does so by presenting the 5 % or 10 % (patient-specific) most abnormal
movement events, irrespective of the number of seizures per night. As the authors chose to mimic the home situation, they did not record EEG and compared their results to the seizures reported by experienced staff who monitored the patient on a semi-continuous basis. This resulted in sensitivity (sens) of 78 % and false detection rate (FDR) of 0.55 per night for Emfit; sens 40 % and FDR 0.41 for Epi-Care; sens 41 % and FDR 0.05 for Epi-Care Free; and sens 56 % and FDR 20.33 for VARIA. Good results were obtained by some of the devices, even though, as expected, non-generalized and non-rhythmic motor seizures (involving the head only, having a tonic phase, or manifesting mainly as sound) were often missed. The Emfit mat was chosen for the patient, also based on user-friendliness (few set-up steps), comfort (contactless), and possibility to adjust patient-specific settings. The authors concluded that when in need of a seizure detection system for a patient, a thorough individual search is still required, which suggests the need for a database or overview including results of clinical trials describing the patient and their seizure types.

In a pilot study, Van de Vel and colleagues (2016) examined the effectiveness of the VARIA system (video, accelerometry, and radar-induced activity recording) and validation of accelerometry-based detection algorithms for nocturnal tonic-clonic and clonic seizures developed by these researchers. They presented the results of 2 patients with tonic-clonic and clonic seizures, measured for about 1 month in a home setting with 4 wireless accelerometers (ACM) attached to wrists and ankles. The algorithms were developed using wired ACM data synchronized with the gold standard video-EEG and then run off-line on the wireless ACM signals. Detection of seizures was compared with semi-continuous monitoring by professional caregivers (keeping an eye on multiple patients). The best result for the 2 patients was obtained with the semi-patient-specific algorithm, which was developed using all patients with tonic-clonic and clonic seizures in the authors’ database with wired ACM. It gave a mean sensitivity of 66.87 % and false detection rate of 1.16 per night. This included 13
extra seizures detected (31 %) compared with professional caregivers’ observations. The authors concluded that while the algorithms were previously validated in a controlled video-EEG monitoring unit with wired sensors, these researchers showed the first results of long-term, wireless testing in a home environment. These preliminary findings need to be validated by well-designed studies.

Milosevic et al (2016) examined the application of feature selection methods and their influence on distinguishing nocturnal motor seizures in epileptic children from normal nocturnal movements using accelerometry signals. These investigators studied 2 feature selection methods applied one after the other to reduce the complexity and computation costs of least-squares support vector machine (LS-SVM) models. Simultaneous feature selection analyses were performed for each seizure type individually and jointly. Starting from 140 features, a filter method based on mutual information was applied to remove irrelevant and redundant features. The obtained subset was further reduced through a wrapper feature selection strategy using an LS-SVM classifier with both forward search and backward elimination. The discriminative power of each feature subset was evaluated on the test data in terms of the area under the receiver operating characteristic curve, sensitivity, and false detection rate per hour. The authors showed that, by using only a filter method for feature selection, it was possible to obtain classification results of comparable or slightly reduced performance with respect to the complete feature set. They stated that the attained results could facilitate further development of accelerometry-based seizure detection and alarm systems.

CPT Codes / HCPCS Codes / ICD-10 Codes

Information in the [brackets] below has been added for clarification purposes. Codes requiring a 7th character are represented by "+":

Proprietary
<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
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<tr>
<td>CPT codes not covered for indications listed in the CPB:</td>
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<tr>
<td>0381T</td>
<td>External heart rate and 3-axis accelerometer data recording up to 14 days to assess changes in heart rate and to monitor motion analysis for the purposes of diagnosing nocturnal epilepsy seizure events; includes report, scanning analysis with report, review and interpretation by a physician or other qualified health care professional.</td>
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<td>0382T</td>
<td>review and interpretation only</td>
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<tr>
<td>0383T</td>
<td>External heart rate and 3-axis accelerometer data recording from 15 to 30 days to assess changes in heart rate to monitor motion analysis for the purposes of diagnosing nocturnal epilepsy seizure events; includes report, scanning analysis with report, review and interpretation by a physician or other qualified health care professional.</td>
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<td>0533T - 0536T</td>
<td>Continuous recording of movement disorder symptoms</td>
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<td>Code</td>
<td>Code Description</td>
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<td>-------------------------------------------------------------------------------------------------------------------------------------------------</td>
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<tr>
<td>95803</td>
<td>Actigraphy testing, recording, analysis, interpretation and report (minimum of 72 hours to 14 consecutive days of recording)</td>
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<td>Opioid dependence</td>
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<td>Schizophrenia, schizotypal disorder, delusional disorders and brief psychotic disorder</td>
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<td>Major depressive disorder, single episode, unspecified</td>
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<td>Essential and other specified forms of tremor</td>
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<td>G40.001 - G40.919</td>
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<td>Sequelae of cerebrovascular disease</td>
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<td>R56.00</td>
<td>Convulsions, not elsewhere classified</td>
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<td>R59.9</td>
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<td>Z04.8</td>
<td>Encounter for examination and observation for other specified reasons [diagnosis of central disorders of hypersomnolence, insomnia, and sleep-disordered breathing]</td>
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</table>

The above policy is based on the following references:

**Actigraphy Testing**


8. Bjorvatn B, Holsten F, Skeidsvoll H. Periodic limb movements in sleep--can and should this condition be treated?. Tidsskr Nor Laegeforen. 2001;121(18):2169-2172.


12. Camargos EF, Louzada FM, Nóbrega OT. Wrist actigraphy for measuring sleep in intervention studies with Alzheimer's disease patients: Application,


Accelerometry


Epilepsy Monitoring System


AETNA BETTER HEALTH® OF PENNSYLVANIA

Amendment to
Aetna Clinical Policy Bulletin Number: 0710 Actigraphy and Accelerometry

There are no amendments for Medicaid.