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Sensors Capabilities, Performance, and Use of Consumer Sleep Technology

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INTRODUCTION

Sleep is a fundamental human need supporting the proper functioning of mind and body.^{1–7} Being able to measure and accurately quantify sleep is critical to characterize the sleep processes supporting health and those implicated in disease as well as to understand how and to what extent sleep (a modifiable behavior) can be enhanced to promote healthy living, mitigate or slow the occurrence of clinical conditions, and improve cognitive functioning and performance.

The current gold standard for measuring sleep is polysomnography (PSG), a multichannel recording of scalp cortical brain activity, muscle tone, and eye movement activity (see Kryger and colleagues⁸). To clinically evaluate the presence of sleep disorders, PSG also may include other signals, such as the measurement of airflow and respiratory efforts, leg movements, oxygen saturation, snoring, and body position. PSG is used mainly in the laboratory setting and, occasionally, in nonlaboratory environments (ambulatory PSG). PSG

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CONFLICT OF INTEREST

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allows an in-depth characterization of sleep physiology, from the sleep macrostructure (the dynamics of wake and sleep stage distribution across the night via manual standard classification of sleep/wake and sleep stages across the night) to a finer analysis of specific features of sleep, via the quantitative analysis of cortical electroencephalographic (EEG) signals.⁸ Despite the vision of sleep as a central nervous system (CNS) phenomenon (a state of brain activation), it is important to understand that overall physiology goes through sleep.⁹ Although not used for classic standard sleep scoring, additional biosignals can be collected simultaneously as part of PSG and can provide information about the state of bodily systems at night as well as serving as peripheral correlates of cortical events (eg, arousals) and the clinical manifestation of sleep disorders (eg, transient respiratory events). Among the additional signals, the most commonly recorded is the electrocardiogram (ECG), from which beat-to-beat heart rate (HR) can be extracted and its variability quantified as an indication of cardiac autonomic nervous system (ANS) functioning (see de Zambotti and colleagues⁹). Beat-to-beat blood pressure, respiratory rate, skin conductance, and body temperature also can be collected. Thus, PSG can truly offer a complete, detailed picture of the physiologic state of sleep.

Outside the laboratory, actigraphy is considered as the accepted alternative to PSG.¹⁰ Actigraphy can measure objective day-to-day variation in an individual's sleep/wake activity, which, for example, allows understanding of whether an individual sleeps more during the weekend compared with weekdays, potential seasonal variations in sleep, regularities/abnormalities in bed times and rising times, how sleep varies across different geolocations, and so forth. Actigraphy provides an indirect measure of sleep, a crude estimation of an individual sleep/wake patterns by using a motion sensor, usually embedded in a wristwatch, to estimate patterns of motion and classify periods as wake or sleep. Compared with PSG, actigraphy is limited in detecting wake, particularly when sleep is highly disrupted or in the presence of sleep disturbances and in situations in which people are lying in bed but not moving. In those cases, actigraphy misclassifies wake as sleep (for limitations and use of actigraphy, see Sadeh¹⁰).

Both PSG and actigraphy are research/clinical tools, and their applicability on a large scale is limited, having a relatively high cost, using specialized equipment including dedicated software platforms for data analysis, and requiring specific expertise and trained personnel to operate them.

With the recent boom in new consumer sleep technologies (CSTs), possibly due to advancements in sensor capabilities, communication protocols (eg, Bluetooth), data analysis techniques, data storage (eg, cloud environment), and meeting the consumer market demand for devices of low cost, low power consumption, and small size, it is now becoming possible to track users' behaviors, physiology, and sleep 24/7 with minimal obtrusiveness. CSTs have several limitations, however. Data usually are extracted via proprietary algorithms that have not been independently validated. Limited validation exists for the summary post-processed data, and no current validation exists on the direct sensor outputs of CSTs, with companies currently not releasing raw data. Users can access their summary data via dedicated mobile app or Internet-based platforms. Some third-party services (eg, Fitabase) aiming at a more clinical/research use of CSTs, do exist and simplify study implementation, data collection,

and monitoring: post-processed data can be obtained with a greater time resolution (eg, 30-s epochs), and there is some control on the CSTs algorithm used (algorithm version), although raw data are still not provided. Some CSTs companies also provide an open application programming interface, which allows a more advanced use of wearable operating systems despite not directly accessing the sensors' readings.¹¹

CSTs usually are wristwatches or other wearable types of devices (clips, rings, and so forth) with embedded accelerometer and/or additional sensors (eg, photoplethysmography (PPG), temperature, and skin conductance sensors [discussed later]). Noncontact CSTs also exist (termed, *nearables*) and there is a new emerging line of wearables based on the recordings of EEG signals using dry electrodes. Although development of these devices is on the rise, they still do not reach high numbers of users and, to date, are still far from large-scale implementation and usefulness in the field of sleep and circadian science.¹¹

CSTs now are widely used by the general population and increasingly used in clinical and research studies (mainly viewed as an alternative to standard actigraphy), linking CST-measured sleep (eg, sleep duration) and sleep-related outcomes (eg, night-time resting HR) with several biopsychosocial factors, performance, and behaviors. Despite recognizing the potential of CSTs, it is important to realize that CSTs pose critical challenges for their implementation in science given the unregulated and uncontrolled nature of an industry product.

There are a growing number of initiatives aimed at providing standards and regulations in using CSTs. In a recent review, de Zambotti and colleagues highlighted the performance, use, and challenges of these devices in the field of sleep and circadian science, by introducing guidelines on how to evaluate and use CSTs.¹¹ The American Academy of Sleep Medicine (AASM) recently published a position statement warning about the challenges in using CSTs and setting a high bar for their adoption in sleep medicine as a diagnostic tool.¹² A summary of the 2018 International Biomarkers Workshop on Wearables in Sleep and Circadian Science promoted by the Sleep Research Society also has been released.¹³ The expert panel's recommendations include best practices and guidelines for evaluating and using CSTs. The Consumer Technology Association recently released some standards for CSTs, which include definitions of terminology and methods for calculating basic sleep metrics and features used in sleep tracking.^{14–16} Importantly, the Food and Drug Administration (FDA) launched a precertification program (Software Precertification Pilot Program, <https://www.fda.gov/medical-devices/digital-health/digital-health-software-precertification-precert-program>), a new regulatory model to face the rapid expansion of digital health technology on the market that can potentially “replace the need for a premarket submission in some cases and allow for decreased submission content and/or faster review of marketing applications for software products in other cases.” Some of the major players in the CSTs (eg, Fitbit and Apple) currently are involved in the FDA precertification program. This new model focuses more on the developer rather than the product per se and allows the public to provide inputs on the program through an open public docket (<https://www.regulations.gov/comment?D5FDA-2017-N-4301-0001>).

From a scientific point of view, it is fundamental to understand whether and under which circumstances outcomes from CSTs can be trusted and, therefore, how to interpret outcomes from studies already adopting these consumer devices. This review highlights the rationale and the capability behind wearable sleep trackers and describes what wearable sensors can truly record and the meaning of the derived physiologic measures. Finally, a general overview of the current use and potential use of CSTs to investigate relationships between sleep, health, and performance is provided, considering their limitations due to potential errors in sleep quantification.

CONSUMER SLEEP TECHNOLOGIES: SENSORS CAPABILITY AND PHYSIOLOGIC MEANING OF BIOSIGNALS

Rudimental versions of CST sensors have been used since the second half of the past century to monitor the functioning of different physiologic systems (see Holter¹⁷) and behaviors, such as physical activity, outside the laboratory/clinical setting.

In the context of sleep monitoring, a first motionbased generation of sleep trackers (ie, using accelerometry to estimate patterns of motion and sleep/wake) and a second multisensory generation (ie, using a combination of accelerometry and other features extracted by different biosignals to improve the detection of sleep/wake patterns and sleep stages) can be distinguished. The newer generation of multisensory CSTs aims to collect information about sleep macrostructure, specifically about wake, light (commonly referred as PSG N1 + N2), deep (commonly referred as PSG N3), and rapid eye movement (REM) sleep (see de Zambotti and colleagues¹¹), providing users with a day-by-day feedback on their sleep, sleep-related physiology, and fitness. In most cases, sleep trackers can measure motion and the night-time plethysmography signal, with some of them also collecting information about skin/body temperature and electrodermal activity (skin conductance). This article provides a summary of the main types of physiologic signals the CSTs are capable of collecting for sleep measurement, along with an overview of the physiologic meaning of these signals, processing pipelines, and related challenges (Table 1). For a more exhaustive overview on signals used in sleep analysis, see the article by Roebuck and colleagues.¹⁸

The multisensory capability of the new generation of CSTs has the potential to (1) theoretically, advance the accuracy in sleep tracking by enhancing the capability of algorithms for sleep/wake patterns and sleep stage detection—this is possible thanks to a combination of motion with a broad range of features obtained from different biosignals showing sleep stage-dependent changes (the most common features used by CSTs for sleep tracking are based on the analysis of HR and its variability)—and (2) enable assessment of the functioning of other body systems (eg, cardiac ANS function) during sleep, making a more naturalistic investigation of processes like restoration and recovery possible, as well as the detection of abnormalities in cardiac rhythms, potentially expanding their use as diagnostic tools. See Matar and colleagues¹⁹ for a schematic overview of the physiologic changes (HR and its variability, respiratory pattern, and motion) occurring when transitioning between PSG-defined sleep stages. See also articles by de Zambotti and colleagues,^{9,11} Willemsen and colleagues,²⁰ and Faust and colleagues²¹ for further details

about ANS dynamics during sleep and development and performance of automatic algorithms for measuring sleep/wake and sleep stages based on CNS and ANS information. For instance, Willemen and colleagues²⁰ used features of cardiorespiratory and movement signals to discriminate sleep stages, reaching an accuracy ranging from 69% (wake-REM-N1N2-N3; Cohen kappa = .56) to 92% (sleep/wake; Cohen kappa = .69). Similarly, Herlan and colleagues²² constructed an algorithm to discriminate wake and sleep based on skin conductance level (SCL) and skin conductance responses (SCRs), reaching an overall accuracy of 86% (97% sensitivity and 75% specificity).

Although there is a strong theoretic basis for applying a multidimensional approach to sleep staging, it is challenging for CSTs to implement this approach for several reasons. CSTs target gold-standard PSG-level accuracy, whereas (1) PSG is based on experts' manual-visual scoring of sleep records and (2) PSG does not provide an absolute reference point.¹¹ For example, high and variable levels of agreement between experts in scoring sleep records (usually highest for REM sleep and wake, followed by N3 and N2 sleep, with the poorest agreement for N1 sleep) exist and may pose severe challenges for algorithm development.²³ Furthermore, although methodological guidelines for validating CSTs have begun to appear (see de Zambotti and colleagues¹¹ and Depner and colleagues¹³), specific academic standards for validation metrics (eg, threshold for accuracy for sleep and wake classification) currently do not exist.

The use of ANS signals to estimate CNS (EEG)-based sleep staging is still in its infancy, even within the academic field. ANS-based sleep staging relies on the complex and still largely unexplored sleep CNS-ANS dynamics,⁹ and the current performance of academic-based automatic algorithms using 1 or more laboratory-grade peripheral signals (respiration, motion, and ECG) as well as when based on automatic analysis of EEG signals do not fully match PSG-level manual sleep staging.^{20,21,24} The use of commercial sensors from CSTs adds further complexity. For example, common ANS metrics used by CSTs for sleep staging, that is, HR variability (HRV) features, may differ according to whether they are obtained by analyzing the electrical activity of the heart (ECG) or by analyzing blood flow (using a PPG-type sensor).²⁵ Also, obtaining a high signal-to-noise ratio when using commercial unobtrusive sensors in noncontrolled laboratory conditions is challenged by several potential sources of artifacts due to environmental features (eg, ambient temperature) and other factors (eg, sensor shift) that often cannot be monitored (see Table 1).

To date it is still unclear what advancements can be made using peripheral information to classify EEG-based sleep/wake and sleep staging. Improvements in hardware solutions, sensors integration, and signal processing techniques and more collaboration between academia and industry are among the crucial requirements for further advancing the field.

The types of information that CSTs can collect are continuously increasing. For instance, impressive technological advancements have been made in the field of electrochemical sensors able to detect metabolites, electrolytes, and hormones (eg, catecholamines, antioxidants, and cortisol) from sweat, tears, saliva, and skin interstitial fluid.¹¹⁵ Moreover, other environmental features indexing or influencing sleep patterns and their physiology, such as ambient temperature, humidity, and noise, also are monitored by some devices.¹¹⁶

CSTs, including microphones for ambient noise measurement, also may be used to assess sleep-related behaviors, such as snoring.¹⁸ A useful feature included in some CSTs is the event marker button, which allows a user to highlight the presence of the stimulus of interest directly within the recording (eg, event markers have been used extensively in actigraphy literature to mark lights-off and lights-on times).¹¹⁷ Finally, promising developments in data processing (including real-time computation) in all these signals are possible due to the increasing implementation of machine learning techniques, such as random decision forests (see Jeng and colleagues¹¹⁸).

ACCURACY OF CONSUMER SLEEP TECHNOLOGIES FOR MEASURING SLEEP AND SLEEP-RELATED OUTCOMES: THE IMPORTANCE OF BIASES IN THE CONTEXT OF BIG DATA

There are a growing but limited number of studies testing the accuracy of CSTs against gold-standard PSG, and these studies used different CST devices (different brands and models), in a variety of different samples (healthy and clinical) and under different conditions (see de Zambotti and colleagues¹¹ for a detailed review of performance and limitations of sleep-tracking CSTs). These validation studies are performed on post-processed CSTs outcomes; the accuracy of CSTs direct sensor readings is still largely unknown. Overall, CSTs compared with PSG perform better in detecting sleep (higher sensitivity) than wake (relatively lower specificity), with a general tendency to overestimate PSG total sleep time (TST) and underestimate PSG wake time at night. This limitation is in line with the performance of standard actigraphy. The performance of CSTs was not dissimilar from the performance of research/clinical-grade actigraphy in studies in which individuals simultaneously wore CSTs and standard actigraphy and their performance was tested against PSG (see de Zambotti and colleagues¹¹). This pattern may change with the new generation of multisensory CSTs, in which the use of sleep-tracking algorithms based on multifeatures is in the early stages and may still have room for improvement.

Evidence indicates that CST devices used with different settings (eg, sensitive mode) than normal had the poorest performance. Moreover, few CST devices have been tested against PSG for accuracy in estimating sleep stages (light, deep, and REM sleep), with the poorest performance for deep sleep (PSG N3) classification. Distinguishing N3 sleep from N2 sleep even from PSG using AASM rules is challenging: N3 is discriminated from N2 by the visual recognition of a greater presence of slow wave sleep (>20% of the epoch). Possibly, with future advances in knowledge of precise rhythmic changes in peripheral signals, such as HRV linked with sleep stages and/or specific sleep events like slow waves,⁹ there may be improvements in CSTs' detection of sleep stages.

Less evidence is currently available for the performance of CSTs in measuring sleep-related physiology. By evaluating a CST wristband, de Zambotti and colleagues previously found that the device underestimated overnight ECG-derived HR by 0.88 beats per minute (bpm), an error that was very small and constant across hours of the night.¹¹⁹ When testing a similar CST device model in adults,¹²⁰ no differences were found between CST-derived HR and

ECG-derived HR (0.09 bpm mean difference), although greater levels of error were found in those participants in the lower (<50 bpm) or higher (>80 bpm) ranges of HR.

The access to physiologic metrics on a high temporal resolution (eg, beat-to-beat HR) from CSTs is limited or not available. Thus, the performance of CSTs in measuring sleep-related physiology like sleep HRV is unknown. There are also other potential limitations in CSTs performance, including poor detection of daytime naps, unclear reliability over time, and potential for device failures, as reviewed elsewhere by de Zambotti and colleagues.¹¹

Most validation studies are done in the laboratory (using single-night PSG device comparison in convenient samples), which is not the expected setting for using CSTs. Given the impracticality of running at-home PSG validation studies, new paradigms for at-home validation need to be explored. Comparisons between CSTs with standard actigraphy or sleep diaries may provide some insight in the CSTs performance but are questionable as a means of determining CSTs' core validity. Currently, sleep outcomes measured via PSG according to the AASM guidelines¹²¹ should be considered as the only ground truth. A multidisciplinary effort is needed to face this critical barrier.

There is a rapid adoption of CSTs without proper consideration of the implications. Several factors can affect device accuracy, which is particularly critical when using multisensory CSTs. Although alterations to the pattern of motion are responsible for PSG device discrepancies in motion-only-based devices, alterations to 1 or multiple features (eg, motion and autonomic features) used to score wake, sleep, and sleep stages potentially can affect performance in multisensory devices and can have a profound effect on data outcomes. Table 2 shows some of the potential factors affecting CSTs' accuracy. Factors highlighted in Table 2 may not be directly responsible for the inaccuracy of CSTs but may reflect other hidden factors (eg, greater device inaccuracy as a function of developmental age may reflect a change in the pattern of motion with age or an age-dependent change in the relation between electrocortical activity and autonomic functioning during the night). It also is important to consider that factors implicated in PSG device inaccuracy may vary in different CST devices models and samples (eg, children vs adults).

Fig. 1 highlights the potential issue of nonconstant biases (different level of error) over time. It is critical to raise awareness that individuals' day-to-day variations in true sleep may be misrepresented by CSTs. It cannot be assumed that the performance of CSTs is always valid and that the same level of accuracy is achieved every day, because conditions vary (eg, sleeping with a bed partner and having a variable amount of wake time) and between different people. In the figure, the hypothetical TRUE pattern of sleep in red and the hypothetical wearable pattern in gray have different levels of concordance at different times. The source of inaccuracy could be due to myriad different factors, as described previously, and also could include changes in behavior or condition (eg, caffeine or alcohol consumption, physical exercise, fever, and menstrual cycle phase). These factors may alter not only individual physiology but also the output measures of sleep and other variables CSTs use to score sleep, potentially having an impact on the bias of the device.

In summary, although CSTs hold a lot of promise, there is still a need to further understand their limitations, particularly given the growing use of CSTs in the field, with limited experimental control and generating overwhelming big data sets. These data give incredible power for analyses but high complexity in study outcomes interpretation not only for healthy sleepers but also when using CSTs to track or evaluate a clinical disorder or influence treatment decisions. Understanding the level of accuracy (and of the bias) of a specific CST is particularly critical when considering its potential use in precision medicine and integration in the health care Internet of Things.

POTENTIAL USE OF CONSUMER SLEEP TECHNOLOGIES IN THE CONTEXT OF DISEASE RECOGNITION AND INTERVENTION AND IN GATHERING INSIGHT INTO THE RELATIONSHIPS BETWEEN SLEEP, HEALTH, AND PERFORMANCE

The previous sections discuss the sensors used by CSTs, their limitations, and factors that could affect their performance. Next, the potential of CSTs for use in a wide range of applications is discussed. Although the limitations need to be kept in mind, CSTs hold promise for the continuous passive monitoring of sleep and related physiology, an important step in advancing biomedical research and personalized health.¹³⁹ CSTs integrated with ecological momentary assessments (EMAs) (see Bertz and colleagues,¹⁴⁰ Colombo and colleagues,¹⁴¹ Seppala and colleagues,¹⁴² and Shiffman and colleagues¹⁴³), powered by the widespread use of electronic diaries and self-report data collection via mobile technology, allow the study of sleep in relation to a wide range of life factors (eg, physical activity, alcohol consumption, and stress) implicated in sleep health and performance in daily life. The main advantage is the combination of objective and subjective data (multimethod) in real life (ecologically valid), contextualized in time (avoiding recall biases), and over prolonged periods (longitudinal). Also, toward the push for precision medicine, data-driven approaches to digital phenotyping of specific individuals' health profiles (see Jain and colleagues¹⁴⁴) could be a reality and lead to enhancement in early detection and management of diseases. Following that, there is a need for different analytical methods and computational skills to deal with the growing amount, variety, and complexity of longitudinal, integrated data sets.

Mobile technology also can be viewed as a tool for implementing intervention, as in the case of cognitive behavioral therapy (CBT) for insomnia (discussed later). In addition, smartphones offer a direct way to communicate with participants (eg, by sending notifications or messages to ensure adherence and protocol compliance) and also could be considered as wearable devices. Smartphones are constantly carried by the users and are capable of providing additional sensory outputs, such as global positioning system geolocation, as well as collecting additional data, such as app usage (eg, social media), call and text message logs (eg, time and duration), and screen usage. Smartphones also have integrated internal sensory capability to quantify relevant metrics among those described in Table 1 (eg, phone camera can be used to track pulse waveform from an individual's finger and to calculate HRV metrics; snoring episodes can be detected through the microphone).

The next section highlights some of the sleeprelevant areas in which CSTs currently are used. Study outcomes need to be interpreted cautiously when considering that CSTs outcomes may be affected by myriad unpredictable factors having an impact on their accuracy (discussed see Table 2, for example). Privacy, security vulnerabilities, and ethical questions also need to be considered.

Health

Sleep is implicated in the regulation of many biological processes, including autonomic, metabolic, immune, and cardiovascular (CV) functioning.^{1–6} Wearables, implantable devices, and other type of electronics, including CSTs, are of growing interest for CV monitoring (see Hong and colleagues¹⁴⁵). The simultaneous continuous collection of sleep (eg, sleep duration¹⁴⁶), cardiac physiology (eg, resting HR¹⁴⁷), and integrated data and factors implicated in CV health may lead to better recognition and management of CV disease (CVD) conditions, albeit with the challenge of translating complex big data sets into useful clinical information.

For example, recent results (preprint) from Teo and colleagues¹⁴⁸ showed significant relationships between CST-derived sleep outputs (TST and sleep efficiency [SE]) and several markers of CVD (body mass index [BMI], total cholesterol, resting HR, waist circumference, waist-to-height ratio, and high-density lipoprotein) as well as sample demographics (age, gender, ethnicity, and socioeconomic and lifestyle factors). These relationships were absent when using subjective instead of CST-derived sleep outcomes. Other studies linked CST-derived sleep measures with BMI in adults^{149,150} and obesity in adolescence.¹⁵¹

The use of wearable technology–based analytical platforms is increasing. For example, Cardiogram (Cardiogram, Inc., San Francisco, CA, USA) applies artificial intelligence (AI) algorithms to data obtained from commercial devices (eg, Apple Watch, Wear OS, Garmin, and Fitbit devices). Initial data collected in collaboration with the University of California, San Francisco (see Health eHeart Study: <http://www.health-eheartstudy.org>), showed the potential of this approach to screen for several conditions (high cholesterol, diabetes, hypertension, sleep apnea, and atrial fibrillation) associated with elevated CV risk.^{152,153} Any effort allowing large-scale affordable early detection of CV risk profiles could be translated in more effective treatments and reductions in the socioeconomic impact of CVDs.

AI (machine learning) applied to CST data (HR cosinor analysis outputs, sleep measures, and activity data) also have been promising in predicting mood state and mood-related episodes (depressive episode, manic episode, hypomanic episode, or no episode), as assessed via self-reported electronic assessments in patients with major depressive and bipolar disorders.¹⁵⁴ These results using continuous passive wearable data collection potentially can expand the capability of previously explored mood prediction models based on mobile built-in sensors. Trained AI algorithms and large data sets available in public repositories may be useful tools to advance the use of AI in precision medicine.

The use of CSTs outcomes has shown to be promising in several other areas of health monitoring and health care, linking CST-derived sleep measures and related physiologic data with a broad range of health outcomes, including self-reported pediatric asthma impact in adolescent patients with asthma,¹⁵⁵ patient-reported outcomes in adult patients with diabetes,¹⁵⁶ and health outcomes in astronauts in an 8-month simulated Mars mission.¹⁵⁷ These results should be viewed cautiously at this early stage of CSTs application, when the need to understand whether CSTs measure true sleep and under which circumstances CSTs measure biases (errors) challenge the validity and interpretation of study outcomes.

Sleep Disorders

In 2003 (and in the 2007 update³⁶), the AASM included the use of actigraphy in sleep medicine practice, such as in the assessment of sleep patterns in patients with insomnia, to provide diagnosis of circadian rhythm disorders and to evaluate the outcome of sleep treatments. The same AASM article included several applications in which the use of actigraphy is not recommended, for instance in the diagnosis of sleep-disordered breathing (SDB) or of periodic limb movements. Regarding the use of CSTs, the AASM has clearly stated, “CSTs cannot be utilized for the diagnosis and/or treatment of sleep disorders at this time.”¹² Nevertheless, some attempts to test CSTs accuracy in the evaluation of sleep disorders have been made. Although mixed results have been reported for insomnia disorders,^{122,158} studies focusing on central disorders of hypersomnolence^{127,128} or SDB generally showed that sleep trackers cannot detect, with sufficient accuracy, sleep patterns in these conditions.^{132,136,159,160} Moreover, as showed in a recent review,¹⁶¹ smartphone applications for obstructive sleep apnea (OSA) monitoring cannot fulfill the required standards for diagnosis, even in cases where multiple external sensors (eg, sound, position, and oxygen saturation) are combined.

Although CSTs limitations are clearly emphasized in the published guidelines, the diagnostic accuracy of these devices is continuously improving. For instance, in a recent article, Camci and colleagues¹⁶² developed a prescreening tool to detect respiratory issues during sleep by combining a smartwatch (Gear S3 [Samsung Electronics Co., Ltd., Suwon, Korea]) with a microphone app (the Smart Voice Recorder [Smartmob, LLC., Seattle, WA, USA]). Other studies have developed systems to predict apnea events within 1 minute to 3 minutes prior to the event using a wearable multisensory suite, which collects ECG, respiration, heart sounds, and oxygen saturation data.¹⁶³ They were able to correctly discriminate 16 out of 17 participants as OSA patients or healthy sleepers. The combination of sleep tracker and smartphone apps also has been tested, with mixed results, as a screening tool for insomnia, to provide Internet-based CBT (iCBT)^{158,164–166} or to assess the effect of interventions on sleep patterns.^{167,168} Although studies have not yet validated any sleep trackers for circadian rhythm disorder, a recent article described the social jet lag and chronotype in approximately 50,000 individuals wearing a smartwatch.¹⁶⁹

In summary, although CSTs cannot currently be used for the diagnosis and/or treatment of sleep disorders,¹² further technological improvements may, in the near future, allow their use as a supporting tool for assessing sleep conditions and facilitate online treatments.

Academic Performance

Sleep plays a key role in cognitive functions, and it is consistently shown that its quantity and quality affect academic performance in students of different ages.¹⁷⁰ College students typically have irregular sleep/wake patterns,¹⁷¹ which is a modifiable factor. In 1 randomized-trial, Chu and colleagues¹⁷² propose a mobile sleep-management learning system based on self-regulated learning strategies to improve sleep quality in undergraduate students. The system is composed of a wearable device (no product name reported) connected to a smartphone app, which provides information, feedback, and tips about a participant's sleep. Participants used the system for 2 weeks and showed self-reported sleep improvement. No academic performance or objective sleep data were reported. Notwithstanding the limitations of this study, a potential application of CSTs is to help students of different ages keep track of their sleep/wake patterns and to provide them feedback or iCBT treatment in order to improve their sleep and, eventually, their academic performance. Another potential application of wearable sensors is to predict academic performance in students. For example, Sano and colleagues¹⁷³ collected self-reported and physiologic data (accelerometer, skin conductance, and skin temperature) in 66 college students using a combination of wearable sensors (Q Sensor [Affectiva, Boston, MA, USA]) and smartphone app. Using a machine learning approach, they were able to classify, with 67% to 92% of accuracy (depending on how many features were included), students with high grade point average (GPA) or low GPA. A similar approach, but only based on a smartphone app, was developed by Dartmouth College to successfully predict cumulative GPA in college students.¹⁷⁴

These studies show the potential of CSTs, alone or in combination with smartphone apps, to modify sleep/wake cycles or to predict academic performance in college students, and, therefore, could be used to plan individualized interventions. These applications, however, also have intrinsic privacy issues that need to be addressed carefully.

Sports Performance

Sleep plays a key role in sports performance. Several observations converge to support the idea that sleep loss and poor sleep quality impair sport performance, whereas good sleep quality seems to improve it.¹⁷⁵ These observations seem particularly important for professional athletes, who often are traveling, playing at night, and participating in competition with tight schedules.¹⁷⁶ Over the past few decades, several interventions have been proposed to deal with the constant circadian shift and reduced time and quality of sleep that athletes experience.¹⁷⁷ In recent years, CSTs have been proposed as a tool to improve sleep in athletes, for example, by providing feedback about sleep.¹⁷⁸ Little investigation has been carried out, however, to assess the reliability and the impact of CSTs on improving sleep and circadian rhythms in athletes (see Sargent and colleagues¹⁷⁹). Differently, CSTs and other wearable sensors and mobile applications are used to manage athletes' training loads based on the assessment of their physiologic parameters during sleep and immediately after awakening (eg, morning HRV has been found to discriminate overtraining states) (see Plews and colleagues¹⁸⁰) and mobile applications are increasingly used by professional and amateur athletes to set their own training based on their HRV-derived fitness level and recovery (see Altini and colleagues¹⁸¹).

Given the growing number of wearable devices used by the general population as well as elite athletes, there is a need for further studies to investigate the potential usefulness of CSTs as a tool to improve sleep and, consequently, sports performance in athletes.

Work Stress and Performance

Whereas poor sleep quality and sleep disturbances typically are considered consequences of work-related demands and psychosocial factors (for a review, see Linton and colleagues¹⁸²), several multiwave and daily diary studies focused on the reciprocal relationship between sleep and work-related outcomes.¹⁸³ For instance, higher-than-usual sleep quality and duration were associated with morning affect (in terms of higher positive activation and serenity and lower negative activation and fatigue) in a sample of 166 employees, controlling for gender, age, position, and trait affect.¹⁸⁴ The recovery model proposed by Demerouti and colleagues¹⁸⁵ identifies sleep quality as the main recovery activity that directly predicts the psychological and energetic states in the morning. In turn, the feeling of being physically and mentally recovered in the morning is positively related to work outcomes, such as daily task performance, personal initiative, and organizational citizenship behavior (see Binnewies¹⁸⁶).

From a research-oriented perspective, the relationship between sleep and work-related outcomes has been investigated almost exclusively using self-report techniques. Thus, CSTs may offer the opportunity to replicate and integrate these findings using a multimethod approach (eg, CSTs combined with EMAs) more suitable to measure multifaceted phenomena, such as work stress and workplace performance.^{187,188} From a more practical point of view, the information collected by these types of sensors embedded in commercially available devices may be used by employers and safety managers to promote employees' health and well-being and optimize the workforce productivity. For instance, some evidence suggests that smartwatch-derived sleep quality may predict so-called fitness to work (eg, psychomotor vigilance and drowsiness).¹⁸⁹

Recently, a team of researchers at Dartmouth College has developed a classification system that uses information passively recorded by smartphones (eg, location and ambient light), wearable sensors (eg, HRV, physical activity, and sleep) and Bluetooth beacons (eg, time spent at work and number of breaks) to discriminate between lower performers and higher performers.¹⁹⁰ The classifier has been trained and tested against a battery of job performance surveys administered 3 times per week on 554 employees over 2 months to 8.25 months, showing an area under the receiver operating characteristic curve of 0.83. Importantly, several sleep features (eg, light/deep sleep duration and awakenings during sleep) showed different patterns in lower performers and higher performers.

Safety

Another potential application of CSTs is aimed at reducing sleepiness-related errors and injuries. A significant portion of errors made at work is linked (at least subjectively) to sleepiness, sleep problems, and poor sleep hygiene,¹⁹¹ with shift work and professional driving (see Folkard and colleagues¹⁹²) among the occupations most exposed to safety risks associated with sleep problems.¹⁹³ Sleep quality measured using wrist-worn actigraphs was

used by Mollicone and colleagues¹⁹⁴ to compute a fatigue scale able to predict drivers' performance and safety (ie, frequency of hardbraking events). A predicting model for driver alertness was proposed by focusing on the circadian variation of CST metrics (eg, HR and HRV).^{195,196} The use of wrist-worn wearable data also has been explored to potentially detect instances of distracted driving.¹⁹⁷ Other attempts of using consumer wearable technology to detect driving-related vigilance levels have focused on the use of EEG and/or electrooculography types of signals (see Zheng and colleagues¹⁹⁸). Overall, this is a promising area of investigation with CSTs, although their usefulness in improving driver safety requires further research.

SUMMARY

CSTs allow longitudinal and real-time monitoring of human physiology and behavior and environmental factors and can be considered an integrated part of the mobile health revolution. The use of CSTs in biomedical research is on the rise and shows great potential in providing new insight into the role of sleep in human functioning in health and disease. The multisensory capability of CSTs and their easy integration with EMAs and other digital technologies could lead to endless possibilities. However, the understanding of functioning, sensor capability, accuracy of CSTs outcomes, is still rudimentary. Also, privacy and ethical implications of CSTs require further attention. These issues need to be addressed in order to properly implement and use CSTs in biomedical research.

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KEY POINTS

- Consumer sleep technologies (CSTs) are largely unregulated. Understanding the rationale behind the technology, the challenges, and the limitations of CSTs is critical for an informed and proper adoption of these technologies in research and clinical applications.
- CSTs have a growing number of sensor capabilities, with multisensory devices having the potential of advancing the accuracy in sleep tracking and also enabling assessment of the functioning of other body systems, such as autonomic functioning.
- CSTs have the potential to advance understanding of sleep and its importance in health, disease, safety, and human performance.

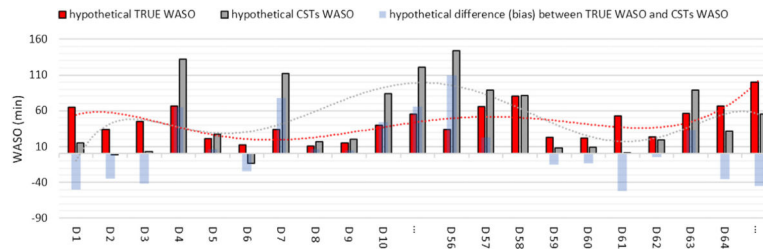


Fig. 1. Simulation of hypothetical sleep data for an individual over time. In the graph, the TRUE day-to-day variation in WASO, a main parameter of interest in sleep research, is provided in red. In gray, the hypothetical WASO obtained from CSTs is displayed by accounting for the randomly generated biases (distance between TRUE WASO and CST-derived WASO), in blue. The level of concordance between TRUE WASO and CSTs WASO changes over time.

Table 1

Consumer sleep technologies: sensors, techniques, and biosignals used in for sleep measurement and quantification

	Signals and Physiologic Meaning	Biosensors and Measurement	Signal Processing and Real-time Processing	Confounders and Challenges	Relevant Post-processed Metrics
Motion/activity	Physical activity can be defined as any type of bodily movement produced by the skeletal muscles and resulting in energy expenditure. ²⁶ Physical activity and body movements are recorded most commonly in terms of acceleration (ie, change in speed over time), expressed in gravitational acceleration units ($1g = 9.81 \text{ m/s}^2$), using a sampling frequency in the human motion range, for example, between 1 Hz and 25 Hz. ²⁷ Physical activity intensity (eg, low, moderate, and vigorous) can be expressed in activity counts per minute using predefined cutoff points. ²⁸	Acceleration due to body movements, specifically during sleep, is mainly measured using wrist-mounted, waist-mounted, or hip-mounted accelerometers. In sleep research, nondominant wrist sites have shown better accuracy than other locations. ²⁹ The small size and light weight of wrist-worn accelerometers make them ideal tools for long-term 24 h/d monitoring. ³⁰ Activity monitors may include 1 (monoaxial) to 3 (triaxial) accelerometers, typically consisting of a piezoelectric element whose deformations are converted into proportional voltage changes. ²⁷	Several validated proprietary (eg, Philips Respironics [Bend, Oregon] and publicly available algorithms (see Van Hees and colleagues ³¹ and Sadeh and colleagues ³²) have been proposed to obtain a binary classification (ie, 1 = sleep and 0 = wake) of activity epochs, congruent with PSG. Signal processing includes band-pass filtering (removal of irrelevant types of movement [eg, higher than 25 Hz]), rectification (eg, signal conversion into absolute values), and integration (conversion into digital raw counts at a prefixed frequency). The resulting signal is averaged or summed over time epochs (usually 1 min) to be expressed in terms of “activity counts.” ²⁷ Each epoch’s value is compared with a predefined threshold (eg, 20 counts) on which the epoch is scored as wake, and under which it is scored as sleep. In most commercial actigraphs, the signal processing is automatically performed by the sensor’s firmware and only a summary of activity/sleep metrics is presented to the user (see Albinali and colleagues ³³).	The main limitation in sleep monitoring through actigraphy is due to the definition of sleep as a lack of movement. This implies that motionless wake intervals are classified incorrectly as sleep (low measurement specificity), leading to overestimated TST and SE, and to underestimated SOL and WASO, especially in individuals with sleep disturbances. ¹⁰ Further limitations concern the inability to discriminate sleep stages, ³⁴ several sources of artifacts (eg, active bed partner, waterbed, movement disorders), and the need of sleep logs to determine the time window within which motionless intervals are interpreted as sleep. ^{30,35}	Epochs scored as sleep and wake can be used to compute widely assessed sleep parameters, such as TST, SE, SOL, and WASO, as well as number of awakenings, matching the standard guidelines of the AASM for calculating the standard PSG parameters in both nonclinical and clinical settings. ³⁶ Actigraphy also can be used to objectively estimate TIB. Although self-report information is still the most used method to determine bedtime and wake-up time, some algorithms (see van Hees and colleagues ³⁷) have recently been proposed to detect these time intervals. The same information may be used to understand potential circadian alterations in sleep timing. On a different time scale, the night-to-night variability in sleep measures (eg, standard deviation) could be an important metric to consider, because it reflects the regularity of sleep/wake patterns, and it is particularly useful in the context of insomnia disorders. ³⁸ A composite measure has been proposed based on a combination of SOL, TST, WASO, and number of awakenings in order to provide an objective index of sleep disturbance and to discriminate good sleepers and insomniacs (the discriminant score). ³⁹
Cardiac function (ECG)	The ECG is the biosignal measured by the surface recording of the cardiac electrical activity. ⁴⁰ In the ECG, heart cycles are represented by patterns of electric potentials ranging from tenths of microvolts to more than 1 mV. Each	A 12-lead ECG is the standard configuration used in cardiology, ⁴¹ but more basic ECG configurations require 2 electrodes plus a ground electrode (usually Ag/AgCl) placed on proximal (chest) or distal sites (arms and legs). Portable ECGs have been used	The heart periods are estimated by measuring the time intervals (milliseconds) between consecutive R peaks (RR intervals or IBIs). Several algorithms (see Benitez and colleagues ⁴⁶) have been proposed for an accurate detection of the R-wave peaks	Artifacts in the ECG signal originate mainly from movements, technical failures or ectopic beats (eg, arrhythmia), resulting in spurious quantifications of IBIs (eg, missing or double beats) and, thus, into biased estimations of HR and HRV	ECG is the gold standard method for measuring HR and HRV, with the latter representing variations in heart periods over time. ⁴⁵ HR and HRV originate from autonomic innervations of the sinus-atrial node, with vagally mediated cholinergic synapses exerting a tonic inhibitory effect on HR. ⁴⁰ HRV metrics are derived from the IBI time series and frequently

Signals and Physiologic Meaning	Biosensors and Measurement	Signal Processing and Real-time Processing	Confounders and Challenges	Relevant Post-processed Metrics
<p>potential represents a specific event occurring in the heart: the atrial depolarization (P wave), the ventricular depolarization (QRS complex), and its repolarization (T wave).⁴⁰</p>	<p>since the 1960s,¹⁷ Modern wireless ECG sensors simply require 2 dry electrodes placed on the chest (see Parak and colleagues⁴²), making them suitable to be implemented into smart wearable clothes (see Grossman⁴³). Similarly, electrodes are embedded into chest belts for HR monitors.⁴⁴ Although a sampling rate of 250 Hz is recommended to detect R waves, a lower sampling rate (100 Hz) may still be used with appropriate interpolation techniques.⁴⁵</p>	<p>in order to precisely measure IBIs. The IBI time series is the raw signal from which HR and HRV metrics are computed. Instantaneous HR is simply computed by converting the IBIs' length into frequency expressed in beats per minute (instantaneous HR = $1/IBI \times 60,000$). In cases of HR monitors, such algorithms may be included in the device firmware and the user can be provided with a real-time update—in most cases with a slight delay—of his/her HR (see Ruha and colleagues⁴⁶).</p>	<p>metrics.⁴⁰ Various artifact detection algorithms, usually based on adaptive and moving thresholds, have been proposed (see Berntson and colleagues⁴⁸) and implemented into signal processing software (see Kaurmann and colleagues⁴⁹). Thus, the main challenge for HR monitors and ECG-based wearable sensors is to detect artifacts with an acceptable accuracy. A combination of automatic and manual procedures is recommended.⁵⁰ Overall, in the analysis of HRV, any potential factors leading to phasic (eg, a sudden sound) and/or tonic (eg, b-blockers) cardiac oscillations within the frequency range of interest (0–0.4 Hz), potentially can invalidate the physiologic meaning of the HRV metrics of interest.</p>	<p>expressed through variability statistics, such as the root mean square of successive differences in IBIs, expressed in milliseconds. Alternative analyses may be performed on the power spectrum density of the IBIs time series, using time-to-frequency transformations (eg, fast Fourier transform) to estimate the power associated with different frequency bands. In particular, HRV in the high frequency range (0.15–0.4 Hz) is considered as an index of vagal cardiac control.⁴⁵ Sleep is characterized by marked decreases in HR and increases in vagally mediated HRV, with several studies showing different HRV patterns depending on sleep stages, arousals, awakenings and body movements, and HRV synchrony with EEG activity (see de Zambotti and colleagues⁹). Consequently, the unobtrusive monitoring of HRV using CSTs may represent a unique opportunity to investigate sleep patterns and sleep quality (see Fonseca and colleagues⁵¹), with HRV-type features among the key features used by current CSTs to classify wake, sleep, and sleep stages.</p>
<p>Cardiac function (plethysmogram)</p>	<p>A standard PPG sensor uses a light source to illuminate the tissue and a photodetector to record variations in the reflected light intensity. The light source typically uses red or green light-emitting diodes, because shorter wavelengths are more strongly absorbed by skin melanin.⁵⁴ The site of PPG measurement, as in the case of pulse oximetry in clinical settings⁵² (PPG-derived pulse oximetry uses red and infrared light frequencies to estimate blood oxygen saturation, SpO₂, in peripheral blood vessel⁵⁵), PPG, however, can be applied to several sites of the body, such as earlobes, forehead, arms, and wrists, with wristband PPG among the most used by CSTs sensors.⁵⁶</p>	<p>Regular features in the PPG waveform (usually the systolic peak or its onset) are used to measure pulse intervals (ie, time distances between consecutive pulse peaks) for computing HR and HRV measures.²⁵ When focusing on the pulsatile (AC) component, preprocessing procedures include filtering, smoothing, and detrending of blood volume pulse raw data.⁵⁷ Real-time signal processing is often included in most commercial PPG CSTs, which are able to show beat-to-beat instantaneous pulse rate or, more frequently, average pulse rate values computed over time windows of a few seconds (see Spierer and colleagues⁵⁸).</p>	<p>The same sources of artifacts and recommendations made for ECG-derived HR and PPG signals, with motion artifacts recognized as the most critical, especially in peripheral measurement sites.⁵⁹ Furthermore, the agreement between ECG-derived and PPG-derived HRV metrics depends on physiologic processes, such as the pulse transit time (ie, the delay between a given R wave and the corresponding pulse wave), which is affected by both dispositional (eg, blood pressure, arterial stiffness, and age) and situational variables (eg, respiratory effort and mental stress).²⁵ Finally, environmental factors</p>	<p>In most PPG applications, the pulsatile AC component is used to measure pulse rate and its variability as surrogates of HR and HRV (for a review, see the article by Schäfer and Vagedes²⁵). Thus, PPG data can be used to potentially assess sleep patterns as in the case of ECG (see Beattie and colleagues⁶¹ and Fonseca and colleagues⁶²). In addition to pulse intervals, other features of the PPG waveform (eg, the systolic peak amplitude, the ratio between the 2 areas separated by the diastolic notch inflection) may provide useful information to improve sleep stage classification.⁶³ Currently, time spent in light, deep, and REM sleep have become common metrics calculated from the new generation of multisensory CSTs by mainly combining motion-like and PPG features. Deep sleep information, in particular, potentially is useful to quantify homeostatic pressure and its</p>

	Signals and Physiologic Meaning	Biosensors and Measurement	Signal Processing and Real-time Processing	Confounders and Challenges	Relevant Post-processed Metrics
	<p>⁵² The typical PPG waveform shows a first positive peak corresponding to the systole, followed by a negative peak (diastolic notch), and a third positive peak corresponding to the diastole.⁵³ (Fig. 1).</p>			<p>influencing vasodilation, such as ambient temperature, also may lead to biased measures.⁶⁰ This is extremely important when considering that PPG-derived HR and HRV metrics are among the features used by CSTs to classify wake, sleep, and sleep stages.</p>	<p>night-time dissipation. Limited evidence, however, supports the accuracy of CSTs in estimating these measures (see de Zambotti and colleagues¹¹). Finally, the DC component may be used to estimate patterns of respiration (leading to paced changes in blood volume pulse amplitude), vasodilation, and sympathetic-induced vasoconstriction (eg, in association with sleep arousals) to provide a more complete overview of the autonomic activity while sleeping.⁵² PPG also might be used to indicate whether an individual is wearing the device or not.</p>
Respiration	<p>The respiratory system is a complex network of structures including muscles (eg, diaphragm) and airways (eg, trachea and larynx) through which the oxygenated air reaches the lungs, where it is exchanged with carbon dioxide (see Cacioppo and colleagues⁴⁶). Although several respiratory parameters (eg, air flow rate, lung volume, gas exchange, breathing temperature) can be measured, noninvasive, measures of RR (expressed in cycles per minute), inhalation and exhalation duration, and respiratory effort are among the most commonly used in psychophysiology and sleep research.</p>	<p>RR may be measured using noncontact-based (eg, optical, thermal, or radar sensors) or contact-based techniques (eg, nasal microphones and thermistors).⁶⁴ Among the latter, common wearable monitors are PPG sensors and respiratory belts. Respiratory belts measure increases in thoracic/abdominal volume due to inhalations using a variety of techniques, such as strain gauges, mercury-filled tubes, inductive coils, and piezoelectric devices.⁴⁰</p>	<p>The data obtained through respiratory belts require only relatively simple processing procedures, such as band-pass filtering the signal (eg, 6–40 cycles per minute) to remove artifacts due to movements unrelated to respiration.⁶⁵ In contrast, the RR estimation from pulse intervals requires more complex procedures.⁶⁶ Most algorithms doing these procedures are based on the existing relationship between HR and respiration (ie, RSA). Because RSA diminishes in some conditions (eg, stress, exercise, and in the elderly), however, other strategies focus on the DC component of the PPG signal.⁶⁷</p>	<p>Biased measures derived from thoracic or abdominal belts may rise mainly from ceiling effects and loss of data due to tight and large belt fitting, respectively.⁴⁰ To prevent these problems, calibration techniques have been suggested.⁶⁵ PPG-derived respiratory measures are affected by the same sources of artifacts (eg, movements), described previously.</p>	<p>Besides RR, several respiratory metrics may be computed in both the time (eg, inspiratory and expiratory duration, inspiration/expiratory ratio) and frequency domain (spectral analysis).⁴⁰ In sleep monitoring, RR has been used for discriminating sleep stages, with non-REM sleep (in particular, deep sleep) characterized by more stable and regular respiratory amplitude and frequency, and other morphologic and variability features have shown to provide useful information.^{20, 51, 68} Moreover, when recorded simultaneously with IBIs, RSA estimates may be used as a parasympathetic indicator (see Cacioppo and colleagues⁴⁶). Finally, clinical applications, such as RR and SpO2 monitoring for the assessment of OSA, is of growing use and may have clinical utility.⁶⁹</p>
ST	<p>ST is the temperature (in degrees Celsius [°C] or Fahrenheit [°F]) recorded on the skin surface, reflecting both the CT and the peripheral hemodynamic status.⁷⁰ CT is the result of several thermoregulatory processes mediated by central and peripheral thermosensory neurons and thermoeffector Romanovsky⁷¹). CT typically ranges between 36.5°C and</p>	<p>Thermometers can be classified according to their degree of invasiveness and contact required. Invasive methods, such as oral and rectal sensors, are used for CT measurement.⁷⁰ In contrast, ST can be measured through noninvasive methods, such as surface thermistors (transducers whose resistance is sensitive to temperature changes), and noncontact sensors, such as infrared thermopile (using thermocouples to measure</p>	<p>Depending on the type of thermometer and its sampling rate, different calibration and preprocessing procedures (eg, lowpass filtering) are necessary to obtain the ST time series (see Shusterman and colleagues⁷⁵ and Keränen and colleagues⁷⁹). Mean ST values can be computed over time intervals (eg, 1 min), and several formulas may be applied to estimate mean ST by weighting the values</p>	<p>ST is affected by several confounding factors, including hemodynamic dysfunction, medications, and environmental temperature.⁷³ For instance, mean ST measures have shown to be biased by cool environments and subjects wearing heavy clothes.⁸¹ In the case of sleep, the heat flow to the environment may be limited by the use of bed covers.⁷² When the sensor is embedded</p>	<p>Sleep is associated with decreased heat production, increased heat loss and peripheral vasodilation, leading to lower average CT and higher peripheral ST compared with daytime.⁷² Consequently, several ST measures can be used in sleep research, such as average body ST,⁸² blood flow measures expressed by the distal-proximal ST gradient,⁸³ and ST phasic decreases due to sympathetically mediated vasoconstriction.⁷³ Wrist ST has been suggested as a promising index of circadian rhythms, because it showed</p>

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<p>38.5°C, and it expresses the momentary balance between heat production and heat loss.⁷² Differently, peripheral ST is a low-varying signal showing spontaneous oscillations between 32°C and 35°C within the 0.01–2.00 Hz range, partially due to blood flow, blood pressure, and respiration.^{73–75}</p>	<p>temperature-related infrared radiations).⁷⁶ Miniaturized wireless digital thermometers (eg, iButtons [iButtonLink, LLC, Whitewater, WI, USA]) also are increasingly used, especially in sleep research, with the main advantage of allowing simultaneous recordings of ST over multiple sites.⁷⁷ Different sites are affected by different sources of heat, with proximal ST (measured on the trunk and the proximal limb parts) more affected by CT, and distal/peripheral ST (measured on the feet, toes, hands, fingers, and ears) out of phase with CT and more affected by blood flow and environmental temperature.⁷⁸</p>	<p>recorded over multiple sites (see Choi and colleagues⁸⁰). Finally, spectral analyses also have been proposed to distinguish sources of ST variability (cardiac output, respiration, and so forth), although small ST variations may not be distinguishable from external thermal noise.⁷⁴</p>	<p>in CSTs, the recorded temperature may be affected by the device itself and the included sources of heat.⁷⁹</p>	<p>relatively marked changes concurrent with bedtime and awakening.⁸⁴ Moreover, wrist ST sensors increasingly are included in wearable accelerometers to classify wear and non-wear time intervals, providing information on participants' compliance (see Zhou and colleagues⁸⁵).</p>
<p>EDA EDA is a general term to describe changes in the electrical properties (ie, resistance, potential difference, and conductivity) of the skin surface, as a function of the secretory activity of eccrine sweat glands.^{40, 86} Whereas thermoregulation is the primary function of eccrine gland activity, phasic EDA measures, such as SCRs and NSSCRs, are widely used as indices of sympathetically mediated arousal.⁸⁷ Skin conductance is expressed in microsiemens or micromho. Similarly to ST, it varies in a low-frequency range, typically showing 1 to 3 NS-SCRs whose amplitude frequently ranges from 0.1 msiemen to 1.0 msiemen and whose latency frequently falls between 1 s and 3 s.^{40, 86}</p>	<p>Skin conductance measurements are based most commonly on the exosomatic method, using 2 electrodes (usually Ag/AgCl) between which a weak constant voltage (or current) is passed, and the conductance is recorded as the reciprocal of the skin resistance.⁸⁸ A sampling frequency of at least 20 Hz is recommended.⁸⁹ EDA is usually measured on the nondominant hand, over skin sites showing the highest sweat glands density: the thenar eminences of palms and soles, and the volar surfaces of the phalanges.⁹⁰ Wrist EDA is thermoregulatory rather than psychophysiological processes.⁸⁶ Although the NaCl or KCl isotonic paste is recommended,⁸⁸ dry electrodes also are suitable to record EDA in most cases, and they are increasingly included into CSTs wearable recording systems, including wristbands,⁹¹ gloves,⁹² and socks.⁹³</p>	<p>Similarly to the previously described signals, a combination of visual inspection and automatic artifacts correction procedures is recommended for processing raw EDA signal.⁸⁶ Low-pass filters of approximately 5 Hz may be used to exclude high-frequency noise (see Bach⁹⁴). Then, the tonic (SCL) and the phasic component (SCRs or NS-SCRs) of the signal should be analyzed separately, to avoid overestimating SCL due to ongoing or overlapping SCRs.⁹⁴ Several analytical strategies have been proposed for SCRs detection, including trough-to-peak, deconvolution and model-based analyses.^{94, 95} A major challenge is the implementation of similar procedures into real-time processing algorithms to be implemented in wearable sensors.</p>	<p>Artifacts in the EDA signal may originate from mechanical pressures on the electrodes, loss of contact (especially with dry electrodes and during ambulatory monitoring), environmental temperature, humidity and dryness, and SCRs due to the subject's activity (eg, respiratory effort) or environmental factors (eg, external sounds).^{86, 96} The measurement site is particularly important, because different body locations may show very different patterns of responsiveness.⁹⁷ Finally, because reliable EDA measurements require the preservation of the skin electrical properties, simple subjects' actions (eg, hand washing) may introduce noise or attenuate the recorded signal.⁴⁰</p>	<p>When focusing on sleep monitoring, both thermoregulatory and nonthermoregulatory origins of EDA are of interest. Sleep is characterized by ST (in particular, wrist ST) increases.^{72, 84} Coherently, increased SCL and relatively frequent SCL rises (called storms) have been observed, especially in the earlier part of the night,⁹⁸ with more pronounced increases in wrist than palmar SCL.⁹⁹ Because these rises tend to disappear in REM sleep (during which thermoregulatory processes are inhibited), they have been associated with thermal sweating.⁹⁶ It is still unclear if EDA measures may be used for sleep stage classification/differentiation.²² Other potential uses of EDA should be explored. Variations in sympathetically mediated finger and palmar EDA may be used as indices of presleep and nocturnal arousals, possibly involved in sleep disturbances.¹⁰⁰ Phasic fluctuations in wrist EDA have been used in combination with motion features for seizure detection.¹⁰¹ Wearable SCL signals also could be a heat for hot flash detection. A hot flash is a heat dissipation response characterized by cutaneous vasodilation and sweating, a hallmark of the menopausal transition, objectively</p>

Signals and Physiologic Meaning	Biosensors and Measurement	Signal Processing and Real-time Processing	Confounders and Challenges	Relevant Post-processed Metrics
<p>Environmental light</p> <p>Light is particularly critical for all circadian processes, particularly for sleep. Light exposure is the most important environmental cue (zeitgeber) that regulates circadian rhythms in mammals.^{104, 105} Light quantification also can be useful to evaluate the relation between light exposure and sleep. For instance, diurnal bright light treatments have shown positive effects on sleep quality,¹⁰⁶ whereas environmental light during synchronization between light exposure and the endogenous clock have been associated with poorer sleep quality.^{107, 108}</p>	<p>Light exposure may be measured in terms of illuminance (1 lux = 1 lumen/m²), color temperature (in kelvins) and spectral power distribution. In sleep research, light exposure is mostly measured using standard equipment for illuminance (eg, luxmeters, photodiodes, and other photo detectors) and light color detection (eg, photo radiometers). Because the circadian and the visual system are affected by different lighting features,¹⁰⁹ however, the use of calibrated devices for measuring person-specific light exposure has been recommended in this field of research.¹⁰⁷ For instance, a head-worn device (the Daysimeter; see Miller and colleagues¹¹⁰) using photosensors, accelerometers, and temperature sensors have been developed to study circadian activity and light exposure.¹¹⁰ Nevertheless, these types of sensors may not be ideally comfortable for long-term continuous sleep monitoring. As an alternative, wearable devices measuring ambient light through small embedded sensors (eg, photodiodes¹¹¹) might be preferred.</p>	<p>Sensor light usually can process wavelengths in the range of 400–1100 nm, with different intensity, depending on the type of sensor (see Kamisalic and colleagues¹¹²). Some sensors are specific for different wavelengths (eg, blue spectrum: 400–500 nm, green spectrum: 500–600 nm, red spectrum: 600–700 nm), allowing to analyze differences in the environmental light. Other sensors have been developed to measure ultraviolet lights (290–400 nm). Several measures can be derived from these sensors, for example, intensity, duration, and timing of light exposure. In most applications, where only light intensity is measured, environmental light is recorded directly by the sensor and converted to current or voltage. Light intensity is averaged over epochs of time based on the device sampling frequency. Alternatively, the information can be encoded using a binary classification (ie, light on/light off) similarly to actigraphic classification.</p>	<p>Although light detection may be relatively easy to perform in some applications involved in sleep monitoring, when the light detector is contained into a wearable sensor the measurement may be affected by several factors. For instance, a major problem of wristworn light detectors is the occlusion by long sleeves and bed linens. Consequently, the light sensors should be directed outward and set for maximal sensitivity to light (see Borazio and colleagues¹¹³).</p>	<p>Light recorded during sleep monitoring is useful to improve sleep detection. Actigraphy-based sleep scoring relies on the determination of sleep time periods, usually defined as the time between lights-off and lights-on. Self-report sleep diaries often are used to determine these times, but light (as well as potentially the use of event markers and to some extent ST) can be used as adjunctive information for determining individual bedtime and wake-up times. Several light features may be taken into account when investigating the role of light on sleep and circadian functioning. These include the light quantity (ie, illuminance), spectrum, spatial distribution, timing, and duration.¹⁰⁹ Specific metrics to investigate circadian processes also have been proposed, such as the phasors, representing the magnitude and phase relationship between behavioral (ie, activity-rest) and light data (ie, light-dark) measured by the same sensor.^{110, 114}</p>

Abbreviations: CT, core body temperature; EDA, electrodermal activity; IBI, interbeat interval; NS, nonspecific; RR, respiratory rate; RSA, respiratory sinus arrhythmia; SCL, skin conductance level; SOL, sleep-onset latency; ST, skin temperature; TIB, time spent in bed; WASO, wake after sleep onset.

Example of factors affecting the biases (level of inaccuracy) of consumer sleep technologies outcomes compared with gold-standard polysomnography

Table 2

Factors Affecting the Biases	Main Findings for Factors Affecting Consumer Sleep Technologies–Polysomnography Biases (Consumer Sleep Technologies’ Level of Inaccuracy in Estimating Sleep)
True (PSG-defined) sleep	<p>Worse true sleep leads to worse CST performance. Evidence suggests a greater bias and/or shifting (from overestimation to underestimation or vice versa) in PSG-CST devices biases and/or greater dispersion of the biases for WASO estimation as a function of increases in PSG WASO. This effect was evident in midlife women with and without a <i>DSM</i> (Fourth Edition) insomnia diagnosis (greater device inaccuracy in those women with greater amount of WASO),^{123,124} adult patients with unipolar major depressive disorder,¹²⁵ adults with insomnia,¹²⁶ patients with suspected central disorders of hypersomnolence,^{127,128} and healthy adolescents.^{119,129}</p> <p>In a study of healthy adolescents, investigators found a shifting (from overestimation to underestimation) in PSG-CST device bias for light sleep (N1 N2) as a function of PSG light sleep.¹²⁹ In testing several CST devices in healthy young adults, Mantua and colleagues¹³⁰ showed a shifting from underestimation to overestimation of deep (N3) sleep as a function of the PSG deep sleep. In another study, investigators found a shifting from overestimation to underestimation in PSG-CST device biases for deep and REM sleep, as a function of the PSG values of these parameters, in healthy adults.¹²³ Overall, the dependency of PSG-CST device biases in sleep stages estimation as a function of the amount of time spent in the respective PSG sleep stage seems to be a common finding from the multisensory CSTs (see also Cook and colleagues^{127,128}).</p> <p>These findings are extrapolated mainly from the interpretation of the Bland-Altman plots and/or regression analyses of the biases.</p>
Demographics	<p>Age affects CSTs performance. In a study testing CST performance in different age groups, investigators found a greater CST wrist-worn device inaccuracy for TST (overestimation ~70 min), WASO (underestimation ~54 min), and SE (overestimation ~14%) in adolescents (13–18 y) compared with school-age (6–12 y) and preschool (3–5 y) children.¹³¹ Similar results were provided by other investigators.¹³² In¹³³ PSG-CST devices, however, discrepancies were greater in prepubertal children (9–11 y) compared with postpubertal adolescents (17–19 y) for WASO (~24 min vs ~13 min) and SE (~5% vs ~3%). It is unclear whether the different pattern was due to the use of a different CST device or to the sample used (in the study by Pesonen and Kuula,¹³³ adolescents had a higher variability in their sleep compared with children). Within the adolescence period, another study showed a greater and/or shifting (overestimation to underestimation or vice versa) in PSG-CST device biases for TST, WASO, SE, and SOL as a function of age. Overall, there was a greater device inaccuracy in older compared with younger adolescents, in both male and female participants.¹³⁴</p> <p>Age and BMI also have been found to be related to PSG-CST device biases for TST and SE (greater overestimation of these measures with advancing age and in those with lower BMI), in a sample of adults with different sleep disorder diagnoses, including breathing-related sleep disorders, hypersomnia, and parasomnia.¹³⁵</p>
Device position	<p>In evaluating the performance of a CST wearable ring in adolescents, the device position affected the performance of the device. PSG device discrepancies for light and REM sleep were significant when individuals were wearing the device on the ring finger compared with the index and the other fingers.¹²⁹ It is unclear to what extent factors like sweating, tightness/looseness, and position of the device affect the device accuracy.</p>
Clinical status	<p>Greater PSG-CST device discrepancies in those individuals with greater severity or presence of sleep disorders. Meltzer and colleagues¹³⁶ divided a sample of children and adolescents (3–18 y) based on their sleep AHI to form 3 groups: no OSA (no OSA; AHI <1.5), mild OSA (1.5–5), and moderate/severe OSA (AHI >5). There was a progressive decrease in performance of the CST device as a function of the SDB status, with those categorized as moderate/severe OSA having the poorest performance for TST (overestimation ~76 min), WASO (underestimation ~66 min), and SE (overestimation ~16%) estimation compared with PSG. Although no differences were found according to clinical status for these variables, Toon and colleagues¹³² found PSG-CST device differences in SOL estimation (significant underestimation of ~10 min) in children with primary snoring compared with those with mild and moderate/severe OSA. Kang and colleagues¹³⁷ found a greater CST device overestimation of PSG TST (~33 min vs ~7 min) and SE (~8% vs ~2%) in adults meeting <i>DSM</i> (Fifth Edition) criteria for insomnia disorder compared with good sleepers, with only 39.4% of insomnias vs 82.4% of good sleepers having PSG device biases ~30 min for TST and ~5% for SE.</p> <p>Despite the absence of a control group, a pilot study evaluating the performance of CSTs in 7 presymptomatic and early symptomatic Huntington gene carriers found wide PSG-CST device discrepancies for TST (>75 min overestimation) and SE (>15% overestimation).¹³⁸</p>

Abbreviations: AHI, apnea-hypopnea index; *DSM*, diagnostic and statistical manual of mental disorders; SOL, sleep-onset latency; WASO, wake after sleep onset.