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Sleep devices: wearables and nearables, informational and interventional, consumer and clinical

Matt T. Bianchi*

Neurology Department, Massachusetts General Hospital, Wang 720, Boston, MA 02114, United States Division of Sleep Medicine, Harvard Medical School, Boston, MA, 02115, United States

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ABSTRACT

The field of sleep is in many ways ideally positioned to take full advantage of advancements in technology and analytics that is fueling the mobile health movement. Combining hardware and software advances with increasingly available big datasets that contain scored data obtained under gold standard sleep laboratory conditions completes the trifecta of this perfect storm. This review highlights recent developments in consumer and clinical devices for sleep, emphasizing the need for validation at multiple levels, with the ultimate goal of using personalized data and advanced algorithms to provide actionable information that will improve sleep health.

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Wang 7 Neurology, Massachusetts General Hospital, 55 Fruit Street, Boston, MA 02114, United States.

E-mail address: mtbianchi@partners.org.

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Abbreviations: AASM, American Academy of Sleep Medicine; BCG, ballistocardiogram; CPC, cardiopulmonary coupling; EEG, electroencephalogram; EMG, electromyogram; EOG, electroculogram; ECG, electrocardiogram; FDA, Food and Drug Administration; HFC, high frequency coupling; HSAT, home sleep apnea test; LFC, low frequency coupling; OSA, obstructive sleep apnea; NREM, non-REM; PAP, positive airway pressure; PSG, polysomnography; REM, rapid eye movement.

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1. Introduction

Wearable technology is not new to sleep medicine, but never before has the situation been so promising to combine hardware and software capabilities to realize the potential for such technology to positively impact sleep health. Wrist-worn actigraphy has been used for decades, mainly in research settings, but also in some clinical circumstances, as an adjunct to diaries for understanding rest-activity patterns over days or weeks [1]. The past decade has seen an acceleration of consumerfacing technology for sleep tracking, initially with actigraphy type devices but additional sensors are now commonplace. The implied benefit of sleep tracking has been one of "knowledge is power", that is, measuring sleep would lead to insights or patterns that an individual could use to improve sleep. More recent advancements have seen the growth of devices that more actively "intervene", beyond the indirect approaches allowed by purely tracking approaches. Recent reviews in the area of consumer sleep tracking have highlighted the need for improved validation, including the contrast between strong marketing claims of consumer devices versus the relative paucity of available validation [2-4]. However, the consumer appetite for these products seems undaunted by validation uncertainties, even as companies and products rise and fall in recent years. Since our 2012 summary of sleep monitoring devices [5], five of the six consumer trackers on the market that we reviewed at that time no longer exist today. Even in the past year, we have seen the demise of popular trackers such as Hello Sense, Jawbone, and Basis (which was acquired by Intel, and subsequently had a safety recall for overheating; Intel has since dissolved its wearable division). By contrast, large companies have moved into this space, with Nokia acquiring Withings, ResMed acquiring Biancamed (and now spun off as SleepScore Labs), Apple acquiring Beddit, and Google's Verily announcing a phenotyping cohort of 10,000 adults that includes home sleep tracking.

Technology advances in the clinical arena also continue, though at a slower pace that is not surprising given the distinctly different landscape of regulated versus consumer markets. Nevertheless, the hardware aspects of sleep tracking share much in common between the healthcare and consumer areas, and the sensor improvements driven by consumer advancements will be relevant for clinical applications as well. Improvements in computational capacity combined with increased availability of training datasets are likely to foster improved algorithm performance that will simultaneously benefit consumer and clinical sleep devices alike.

2. Overview of Sleep Physiology

Measuring sleep with polysomnography (PSG) involves a variety of physiological streams recorded through surface sensors, including electroencephalogram (EEG), electromyogram (EMG), electrooculogram (EOG), thoracic movement (chest and abdomen belts), airflow measures, oximetry, and electrocardiogram (ECG). The sleep stages are scored according to standard visual criteria based on the EEG, EOG, and EMG sensors. Leg movements are scored according to anterior tibialis EMG sensors on each leg. Respiratory events are scored using a combination of effort (belts), airflow changes, and oxygen desaturation levels. The ECG is used to detect arrhythmias, but is not part of scoring, although extensive literature regarding heart rate variability in sleep suggests potential utility of extracting additional features from this channel in particular [6].

Scoring continues to be performed manually, through implementation of rules for visual identification of stages and clinically relevant events like periodic limb movements or sleep disordered breathing. In an era of automation and excitement about classifier algorithms (whether we are referring to machine learning, deep learning, or artificial intelligence), it has been elegantly argued that sleep scoring is ripe for a transition to automation [7]. Whether this occurs in a clinical context or not, there is little doubt it will continue to dominate the analysis of portable devices, if only because of the scale and desire for rapid/ immediate results. Beyond the need for inexpensive and scalable solutions, issues of inter-rater reliability and lack of quantification for features like spectral power are among important reasons to consider automation. Automation also facilitates higher-order analytics, like event-triggered crosschannel analysis which may help stratify events currently

| Table 1 – Consumer sleep device examples. | | | |
|---|-------------------|-------------|--|
| Product/ Company | Sensors | Location | |
| "Wearable" | | | |
| AppleWatch | Accel, HR | Wrist | |
| Biostrap | Accel, HR | Wrist, foot | |
| - | (respiration) | | |
| Dreem | EEG | Headband | |
| E4 (Empatica) | Accel, HR, GSR | Wrist | |
| Fitbit | Accel, HR | Wrist | |
| Garmin | Accel, HR | Wrist | |
| Vivosmart | | | |
| Hexoskin | Accel, ECG, | Shirt | |
| | respiration | | |
| Misfit | Accel, HR | Wrist | |
| Muse | EEG | Headband | |
| Oura | Accel, HR | Finger | |
| SensMi | GSR | Wrist | |
| Sleep Shepherd | EEG | Headband | |
| Whoop | Accel, HR | Wrist | |
| Xiaomi Mi | Accel, HR | Wrist | |
| "Nearable" | | | |
| Beddit | BCG, respiration, | On mattress | |
| | movement | | |
| EarlySense | BCG, respiration, | Under | |
| | movement | mattress | |
| Eight (mattress | BCG, respiration, | On mattress | |
| cover) | movement | | |
| EmFit | BCG, respiration, | Under | |
| | movement | mattress | |
| RestOn (Sleepace) | BCG, respiration, | On mattress | |
| | movement | | |
| S+ (ResMed) | Respiration, | Near bed | |
| | movement | | |
| Withings Aura | BCG, respiration, | Under | |
| | movement | mattress | |

Accel, accelerometry; BCG, ballistocardiogram; ECG, electrocardiogram; EEG, electroencephalography; GSR, galvanic skin response; HR, heart rate.

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