Current SDB Digital Health Technologies and Future Trends

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President-elect, AASM
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To Cover

1) Current state of Apps and Gadgets
   - Activity Tracking
   - Sleep
   - OSA

2) Considerations for the Future
Sleep Monitoring Evolves

SLEEP PROBLEMS

- Not a Medical Problem
- Ultra-specialized Medical Problem
- Specialized, but Testable in the Home
- Your Mobile Phone is a Sleep Tester
Sleep Monitoring Evolves (Actual Timeline)
Gold: In-lab Polysomnography

37 y/o man (weight = 270 lbs) in stage REM sleep (2 minutes).
Silver: HSAT with Clear OSA (2m)
These are unscorable on a HSAT (no arousal), but suggestive of sleep-disordered breathing
Prolonged Obstructive Apnea?
(Stardust - 5 minute epoch)
Gadgets: Measuring Activity

“The reliability and validity of most trackers for measuring step count is good.”

Activity Monitors: General Accuracy Issues

"When we tested the leading brand, they gave us over 100 steps for eating cereal. We were getting 1,000 steps by shaving, brushing our teeth, doing things like combing our hair. Creating lots of false positives, false impressions …"
Gadgets Measuring Sleep

• Sleep tracking is a fairly recent area for fitness trackers.
  – They may not track activity particularly well in terms of steps
  – Because they’re largely measuring micro-movements and heart rate, accuracy with which they track subtle sleep patterns is highly contentious.

  – Variability in sleep is high.
    • Thus, sleepers who move may be “awake”
    • People with limited movements reading may be asleep
    • Setting sensitivity will alter the reporting
2015 Review
Consumer Sleep Tracking Devices: A Critical Review

Jeon LEE and Joseph FINKELSTEIN
Johns Hopkins University School of Medicine, Baltimore, USA

BodyMedia FIT, Fitbit Flex, Jawbone UP, Basis Band, Innovative Sleep Solutions SleepTracker, and Zeo Sleep Manager Pro.

3. Discussion

The review identified a critical lack of basic information about the devices: five out of six devices provided no supporting information on their sensor accuracy and four out of six devices provided no information on their output metrics accuracy.
Fitbit Early Data: Sleep

• Fitbit and actigraph differed significantly on recorded TST and SE between each other and polysomnography.
  – Both overestimated sleep efficiency and total sleep time. Sensitivity for accurately identifying sleep was high; specificity for accurately identifying wake was poor.

• They found that the Fitbit overestimated the time participants were asleep by 67 minutes, on average.

Fitbit in Children/Adolescents

- Overestimated sleep (42 min) in Normal mode
- Underestimated sleep (109 min) in Sensitive Mode

**Table:**

<table>
<thead>
<tr>
<th>Mode</th>
<th>Sleep Minutes</th>
<th>Sleep Efficiency (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PSG</td>
<td>421</td>
<td>84</td>
</tr>
<tr>
<td>Normal</td>
<td>463</td>
<td>92</td>
</tr>
<tr>
<td>Sensitive</td>
<td>312</td>
<td>62</td>
</tr>
</tbody>
</table>

Meltzer et al. (2015) *Sleep*
In total, Fitbit offered at least 9 trackers 2008-15 and Jawbone offered at least 6 trackers 2011-15.
2015 – Jawbone Sleep Tracking

Validation of Sleep-Tracking Technology Compared with Polysomnography in Adolescents

Massimiliano de Zambotti, PhD; Fiona C. Baker, PhD; Ian M. Colrain, PhD

1Center for Health Sciences, SRI International, Menlo Park, CA; 2Brain Function Research Group, School of Physiology, University of the Witwatersrand, Johannesburg, South Africa; 3Melbourne School of Psychological Sciences, University of Melbourne, Parkville, Victoria, Australia

ONLY 3+ GENERATIONS BEHIND!

Jawbone UP has good agreement with PSG particularly in the estimation of TST, SE, and SOL in a large sample of healthy adolescent boys and girls without sleep disorders.
2016: Proliferating Sleep Tracking

Table 1. Summary of literature on sleep tracking devices and apps.

<table>
<thead>
<tr>
<th>Study</th>
<th>Device/app</th>
<th>Sleep measure comparators</th>
<th>Population studied</th>
<th>Main results</th>
</tr>
</thead>
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<tr>
<td></td>
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</table>
Mean age 26.1 years;  
range 19–41 years.  
Pts with sleep disorders excluded | Device overestimated TST and SE and underestimated WASO compared to both PSG and actigraphy. Device had high sensitivity (0.978) and low specificity (0.198). Concordance was low in subjects with low SE and TST |
|       |                          |                           |                    |                                                                                                                                                    |
|       | Meltzer et al., 2014 [8] | Fitbit™ Ultra            | PSG and actigraphy | N = 63  
Mean age 9.7 years;  
range 3–17 years;  
39% with AHI > 5 | In ‘normal’ mode device, overestimated TST and SE and underestimated WASO compared to both PSG and actigraphy. In ‘sensitive’ mode, it substantially underestimated TST and SE and overestimated WASO |
|       |                          |                           |                    |                                                                                                                                                    |
|       | De Zambotti et al., 2015 [9] | Jawbone™                | PSG                | N = 65  
Mean age 15.8 years;  
range 12–22 years;  
None had a sleep disorder | Device overestimated TST and SE and underestimated WASO; no difference in SOL. ‘Sleep sleep’ correlated with time in N2 and REM. ‘Light sleep’ with time in N2 and N3 and arousal index |
|       |                          |                           |                    |                                                                                                                                                    |
|       | De Zambotti et al., 2015 [10] | Jawbone™                | PSG                | N = 28  
Mean age 50.1 years;  
Two patients with AHI > 5 | Device overestimated TST and SOL and underestimated WASO. Device had high sensitivity (0.96) and low specificity (0.37) |
|       |                          |                           |                    |                                                                                                                                                    |
|       | Bhat et al., 2015 [15]  | Sleep Time™ app         | PSG                | N = 28  
Mean age 39.5 years;  
range 22–57 years;  
No patients with prior sleep disorders | No correlation between app and PSG SOL, light or deep sleep percentage. App had good sensitivity (0.899) and low specificity (0.50). No detectable difference in awakenings from light vs. deep sleep |
|       |                          |                           |                    |                                                                                                                                                    |
|       | Min et al., 2015 [16]   | Toss ‘N’ Turn™           | PSQI               | N = 27  
Mean age 34 years;  
range 20–59 years.  
One patient with insomnia, two with sleep talking | Significant variation in bedtime, wake time, and sleep duration. Showed 81.48% accuracy for classifying good and poor sleepers |
|       |                          |                           |                    |                                                                                                                                                    |
|       | Toon et al., 2015 [11]  | UP by Jawbone™ and MotionX 24/7™ | PSG and actigraphy | N = 78  
Mean age 8.4 years;  
range 3–18 years.  
41% with mild and 28% with moderate to severe OSA | UP showed no different from PSG in SOL, TST, SE, and WASO. Sensitivity was 0.92 and specificity 0.66. Compared to actigraphy, UP overestimated SOL and underestimated WASO. Smartphone app overestimated TST and SE and underestimated SOL and WASO compared to PSG |

AHI, apnea–hypopnea index, per hour of sleep; OSA, obstructive sleep apnea; PSG, polysomnogram; PSQI, Pittsburgh sleep quality index; pts, patients; REM, rapid eye movement; SE, sleep efficiency; SOL, sleep onset latency; TST, total sleep time; WASO, wake time after sleep onset.

2017 Fitbit Publication

• “In our study, Fitbit Charge 2™ overestimated light sleep and underestimate deep sleep but showed no bias in the estimation of REM sleep and WASO, relative to PSG. It was also able to adequately track sleep cycles across the night.”

Fitbit: Tracking of OSA

“Fitbit’s new Ionic watch has a new hardware component to it: it uses a relative SpO2 sensor… Earlier Fitbit products had sensors that only emitted one wavelength of light: green. This one uses two additional wavelengths, red and infrared.”

Fitbit and OSA

• Supplemental measures can help, but just to track heart rate, movement, and O2 might not necessarily be enough [to diagnose OSA].” And even if algorithms help get a proxy measure of airflow based on heart rate, Stepnowsky says, those algorithmically-divined measurements might not be compatible with how the sleep disorder industry currently scores “breathing events.”
Non-Wearables Assessing Sleep
ResMed S+

S+ by ResMed Personal Sleep Tracker

S+ by ResMed Personal Sleep Tracker is the world's first non-contact sleep system. Designed by the global leaders in sleep, clinically proven S+ connects you to the personalized, expert feedback you need to sleep better, and live better.

Watch Video

$64.99
Was $129.99

Free Shipping on Orders Over $49

ADD TO CART
S+ Data

Hypnogram and Environmental Data

- Deep
- Light
- REM
- Absent
- Wake

Noise | Light | Temperature

Time:
- 11:30 PM
- 12:00 AM
- 12:30 AM
- 1:00 AM
- 1:30 AM
- 2:00 AM
- 2:30 AM
- 3:00 AM
- 3:30 AM
- 4:00 AM
- 4:30 AM
- 5:00 AM
- 5:30 AM
- 6:00 AM
- 6:30 AM
The Bed Can Be A Tracker

Know. Adjust. Sleep.

With SleepIQ® technology, you have the knowledge to adjust for your best sleep. Available on all Sleep Number® beds, with Queen c2 mattress starting at $1,099.98.

WATCH VIDEO
SHOP NOW

ENTER THE SLEEP NUMBER® BED WITH SLEEPIQ® TECHNOLOGY
SleepIQ® technology inside the SLEEP NUMBER® bed tracks and optimizes your sleep, empowering you to make adjustments so you can know your best possible sleep.

There's nothing to wear, nothing to turn on. All you have to do is sleep.

Sleep IQ - Sleep MD Data

- **Heart Rate**: 71 BPM
- **Breathing Rate**: 14 BrPM
- **Sleep Quality**: 78
- **Sleep Duration**: 8h 19m
- **Activity Tracking**: Add an activity about your day.
Apnea Bed?

- This study tested a novel algorithm for sleep apnea screening with a contact-free system based on a piezo-electric sensor (PE system - EarlySense Ltd).

- The novel algorithm detected moderate-to-severe sleep apnea patients with sensitivity of 88% specificity of 89%, and positive predictive value (PPV) of 81%.

- These results together with the convenience of being contact-free make the PE system, with the novel algorithm, suitable for apnea screening at home or hospital setups. It may also be usable for long-term monitoring.

Published in: Computing in Cardiology Conference (CinC), 2016
Date of Conference: 11-14 Sept. 2016
When Smartphones aren’t good enough…

...Get a Geniusphone

Sleep Apps Abound!
Sample of Snoring-Assessment Apps

### TABLE I
SUMMARY OF EVALUATED SMARTPHONE SNORING APPS

<table>
<thead>
<tr>
<th>Snoring app name*</th>
<th>Rating†</th>
<th>Possible to simultaneously play back &amp; view graph?</th>
<th>Possible to localise sound on graph?‡</th>
<th>Continuous playback (sec-by-sec)?</th>
<th>Delayed start option?</th>
<th>Recording sensitivity adjustable?</th>
<th>dB results given?</th>
<th>Snoring events (n) per night given?</th>
<th>Allows notes?</th>
<th>Option to e-mail or print data?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quit Snoring</td>
<td>4.88</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>SnoreMonitorSleepLab</td>
<td>3.88</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>Night Spy – Do you snore...?</td>
<td>3.75</td>
<td>N</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>iSleeping</td>
<td>3.50</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>Sleep Talk Recorder</td>
<td>3.13</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>Sleep Sounds Recorder Plus</td>
<td>3.00</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>SnoreLab</td>
<td>2.75</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>Sleep snore/Apnea/talk Recorder</td>
<td>2.50</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>Dream Talk Pro</td>
<td>2.50</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>iRec – Dreams Recorder</td>
<td>2.25</td>
<td>N</td>
<td>N</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
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<tr>
<td>SleepAssess</td>
<td>2.13</td>
<td>Y</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
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<tr>
<td>SnoreSleep Inspector</td>
<td>2.13</td>
<td>N</td>
<td>N</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
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<tr>
<td>Silencium</td>
<td>1.50</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
</tr>
</tbody>
</table>

*Apps are listed in order of mean author rating. †Apps were rated independently by four authors, on a 0–5 scale. ‡One can click on the graph to view sound waveforms and hear the corresponding sounds. Sec = second; Y = yes; N = no
Real Patient Data – Smart Alarm
Quit Snoring

Snoring: App vs. PSG

<table>
<thead>
<tr>
<th>Subject number, sensitivity threshold setting</th>
<th>Total recording time (hours)</th>
<th>Total snores (n)</th>
<th>Snores per hour (n)</th>
<th>True positive snores on app (n)</th>
<th>False positive snores on app (n)</th>
<th>False negative snores on app (n)</th>
<th>App snoring sensitivity (%)</th>
<th>App snoring positive predictive value (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subject 1, 53 dB</td>
<td>6.3</td>
<td>378</td>
<td>60.00</td>
<td>363</td>
<td>15</td>
<td>17</td>
<td>95.53</td>
<td>96.03</td>
</tr>
<tr>
<td>Subject 1, 55 dB</td>
<td>6.3</td>
<td>344</td>
<td>54.60</td>
<td>329</td>
<td>15</td>
<td>51</td>
<td>86.58</td>
<td>95.64</td>
</tr>
<tr>
<td>Subject 2, 53 dB</td>
<td>7.3</td>
<td>790</td>
<td>108.22</td>
<td>737</td>
<td>53</td>
<td>421</td>
<td>63.64</td>
<td>93.29</td>
</tr>
</tbody>
</table>

PSG = polysomnography

Another Snore App

SnoreLab
The Snoring Analysis App for iPhone

Record, measure and track your snoring with the No.1 snoring analysis app for iPhone:

★ Generates charts of your night's snoring
★ Records snoring sound samples
★ Measures snoring intensity (Snore Score)
★ Tests the effectiveness of snoring remedies
★ Tracks the impact of lifestyle factors

SnoreLab has helped change lives for the better. If snoring impacts your life: download it today!

http://www.snorelab.com/#demo
SnoreLab: Used by a MIT Engineer

CPAP

CPA off at night

Went to bed / wake up 21:45 / 04:53
Time monitoring 7h 3m
Time snoring 30% / 8h 10m
Snore Score 24
Remedies / factors None

Still am sleeping
more comfortable now?
Sleep Apnea Assessment Via App?

• Nakano, Sleep 2014

• 50 patients
  – 10 pts = development; 40 pts = validation

• Smartphone (SH-12C, Sharp Corp) attached to the anterior chest wall over the sternum.

• Acquired ambient sound from the built-in microphone and analyzed it using a fast Fourier transform on a real-time basis.
Nakano, Sleep 2014

• Snoring time measured by the smartphone highly correlated with snoring time measured by PSG (r = 0.93).

• Moreover, the respiratory disturbance index estimated by the smartphone (smart-RDI) highly correlated with the apnea-hypopnea index (AHI) obtained by PSG (r = 0.94).

• The diagnostic sensitivity and specificity of the smart-RDI for diagnosing OSA (AHI ≥ 15) were 0.70 and 0.94, respectively.
Cardiogram App (iOS)

• Health eHeart, an IRB-approved UCSF study, enrolled 6,115 active users of the Cardiogram app for Apple Watch. Heart rate and step counts were collected for a period of 1 to 53 weeks (mean=8.9).

• Mean age was 42.3 ± 12.1, 69% male. 2,230 (36.5%) of participants had hypertension, 1,016 (16.6%) had sleep apnea.

• In the validation set, the DNN predicted prevalent sleep apnea with a c-statistic of 0.902 (95% CI 0.85-0.95; with an optimal operating point yielding 90.4% sensitivity and 59.8% specificity) vs a baseline c-statistic of 0.459 (95% CI 0.39-0.53).

http://circ.ahajournals.org/content/136/Suppl_1/A21042
DeepHeart (Cardiogram App iOS)

• For sleep apnea, DeepHeart achieved an accuracy (c-statistic, or AUC ROC) of 90%, with several attractive operating points. For example, we can detect 52% of sleep apnea (compared to 20% today) with a specificity of 97%. If a specificity of 82% is acceptable, then we can detect even more sleep apnea, about 75% of people.

https://blog.cardiogr.am/screening-for-hypertension-and-sleep-apnea-with-deepheart-416c9bc03efc
UW ApneaApp

New UW app can detect sleep apnea events via smartphone

A Contactless System for Respiratory Event Identification (Abstract)
Rajalakshmi Nandakumar, Shyam Gollakota, Nathaniel Watson
Meeting of the Associated Professional Sleep Societies (SLEEP'15) Oral Presentation

Results: We tested 37 patients (17 female and 20 male, median age = 51) undergoing in-laboratory polysomnography or CPAP titration at UW Medicine Sleep Center at Harborview. We placed a phone in one corner of the bed during the sleep study and then compared device generated respiratory events with events identified by polysomnography. Our algorithm defined respiratory events were highly correlated with manual scoring with an ICC of 0.9978 for central apnea, 0.9582 for hypopnea and 0.9863 for obstructive apnea (all p < 0.00001). The average error in AHI computation was 1.9 events/hour. We accurately classified 32 out of 37 patients between the four-apnea groups with four out of the five misclassifications occurring at the clinically ambiguous boundary between no-apnea and mild-apnea (AHI error < 1 event/hour). Mean and median total sleep time discrepancy with polysomnography was 36 and 27 minutes.

Conclusion: Our system accurately identifies respiratory events using an “off-the-shelf” smartphone in a contactless manner.
SmartCare Sleep App

SmartCare Sleep App

• Researchers at Oxford University in the UK are looking at the smartphone as a platform for detecting sleep apnea.

• The SmartCare Sleep app, is now able to read wireless medical devices, including a wireless pulse oximeter (the finger pulse sensors which are common), through Bluetooth.

• The team selected 856 random patients and found that the screening results from the app were about 90% accurate.

Combo Platter (App+Wearable)

Using four lab-quality sensors, EverSleep tracks over 20 different aspects of your sleep and provides personalized feedback based on your data.

https://www.geteversleep.com/home
https://www.geteversleep.com/technology
Trouble Spots?

EverSleep is the complete all-in-one device that tracks dozens of sleep factors and coaches you with knowledge, tips, tricks, product suggestions and clinical recommendations. EverSleep gives you the power to improve your sleep.

Eversleep is not a FDA cleared medical device and does not claim to diagnose, treat, or cure any disease. Always talk to your physician before starting a sleep improvement program or any other health program. If you think you have a sleep disorder or other medical illness, consult your health care provider for diagnosis and treatment.

https://www.geteversleep.com/technology
The Future is Coming…

• So, there are digital devices and mobile applications that will likely be able to assess OSA in some way; now what?
Efficacy and Safety Issues in Digital OSA Assessment

• 1) Purpose of the Device?
  – Screening vs. Diagnostic vs. Monitoring

• 2) Parameters
  – Discriminate OSA vs. normal breathing
  – Accurately assess the severity of OSA
  – Monitoring severity accurately over time?

• 3) What safety issues are raised?
Maximize Accuracy: HSAT + …

Figure 2—Illustration of the combination of the populations of patients with and without OSA with respect to the AHI cutoff, high pretest probability, true positive, true negative, and false positive results.

The key to the diagram is high pre-test probability; this is not all users.

Defining OSA Severity

• AHI
  – Well, how are you defining AHI?
    • Is it a pause in breathing or a correlative event
  – What kind of hypopnea?
    • Is there a desaturation of 3% vs. 4%, is there an arousals
  – PSG AHI vs. HSAT-based REI (vs. other)
    • What’s the gold standard here?

• But, AHI is just one metric of OSA
  – What about oxygenation?
    • Is it only the low saturation or is it all oximetry?
  – Heart Rate / EKG / PAT?
Device/App Validation

• Likely validate against gold-standard PSG
  – HSAT is common, but not likely gold standard unless measured solely in a “gold standard population”

• Must show ability to discriminate normal/abnormal patients and potentially match severity ranges
What Does the Future Hold?

1) Widely dispersed digital screening methods in sleep-disordered breathing

2) Improved diagnostic methods beyond PSG and HSAT, cheaper and accessible to a broader population than testing is today

3) Increasing expenses for treatment of larger numbers of true positives and removal of increasing numbers of false positives