SleepView Monitor + SleepView Portal
Clinical Validation Summary

Expanding the reach of your sleep services today and tomorrow
2007

AASM established guidelines for proper **Portable Monitoring (PM)** methodology to be used in **home sleep apnea diagnosis**

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2007

After thorough evaluation of all portable monitoring methodologies and available literature, AASM concluded with guidelines stating:

At a minimum, Portable Monitoring must record the following data with biosensors conventionally used for in-lab PSG:

<table>
<thead>
<tr>
<th>REQUIRED DATA</th>
<th>IN-LAB BIOSENSOR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Airflow</td>
<td>1. Pressure transducer</td>
</tr>
<tr>
<td></td>
<td>2. Strong Recommendation: Additional airflow measurement using thermal biosensor</td>
</tr>
<tr>
<td>Respiratory Effort</td>
<td>3. Calibrated or un-calibrated Respiratory Inductive Plethysmography (RIP) biosensor</td>
</tr>
<tr>
<td>Blood Oxygenation</td>
<td>4. Finger pulse oximetry with fast sampling rate</td>
</tr>
<tr>
<td></td>
<td>5. Heart rate derived from oximetry data</td>
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</table>

Does SleepView meet AASM guidelines?
## SleepView meets AASM Guidelines

<table>
<thead>
<tr>
<th>REQUIRED DATA</th>
<th>IN-LAB BIOSENSOR</th>
<th>SLEEPVIEW BIOSENSOR</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Airflow</strong></td>
<td>1. Pressure transducer</td>
<td>☑️ Pressure transducer</td>
</tr>
<tr>
<td></td>
<td>2. <strong>Strong Recommendation:</strong> Additional airflow measurement using thermal biosensor</td>
<td>☑️ Meets Recommendation: Additional airflow measurement with thermal biosensor</td>
</tr>
<tr>
<td><strong>Respiratory Effort</strong></td>
<td>3. Calibrated or un-calibrated Respiratory Inductive Plethysymography (RIP) biosensor</td>
<td>☑️ Un-calibrated Respiratory Inductive Plethysymography (RIP) biosensor</td>
</tr>
<tr>
<td><strong>Blood Oxygenation</strong></td>
<td>4. Finger pulse oximetry with fast sampling rate</td>
<td>☑️ Finger pulse oximetry with fast sampling rate + high resolution</td>
</tr>
<tr>
<td></td>
<td>5. Heart rate derived from oximetry data</td>
<td>☑️ Heart rate is derived from oximetry data</td>
</tr>
</tbody>
</table>
SleepView meets AASM Guidelines

+ more

- 5 body positions [supine•prone•left•right•upright]
- Snore from airflow
- Auto respiratory event detection
- Estimate of total sleep time
SleepView®

EXCEEDS

AASM guidelines
for Portable Monitoring methodology
for in home sleep apnea diagnosis
2011

New Home Testing Classification System Released

- Details the type of signals measured by home sleep testing devices for diagnosing OSA.
- Categorizes Out-Of-Center (OOC) testing devices based on SCOPER parameters.

SCOPER

- Sleep
- Cardiovascular
- Oximetry
- Position
- Effort
- Respiration
### 2011 SCOPER Defined

<table>
<thead>
<tr>
<th>SLEEP</th>
<th>CARDIOVASCULAR</th>
<th>OXIMETRY</th>
<th>POSITION</th>
<th>EFFORT</th>
<th>RESPIRATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Sleep by 3 EEG channels+ with EOG and chin EMG</td>
<td>More than 1 ECG lead - can derive events</td>
<td>Oximetry (finger or ear) with recommended sampling</td>
<td>Video or visual position measurement</td>
<td>2 RIP belts</td>
</tr>
<tr>
<td>2</td>
<td>Sleep by less than 3 EEG+ with or without EOG or chin EMG</td>
<td>Peripheral arterial tonometry</td>
<td>Oximetry (finger or ear) without recommended sampling (per scoring manual) or not described</td>
<td>Non visual position measurement</td>
<td>1 RIP belt</td>
</tr>
<tr>
<td>3</td>
<td>Sleep surrogate: e.g. actigraphy</td>
<td>Standard ECG measure (1 lead)</td>
<td>Oximetry with alternative site (e.g. forehead)</td>
<td>Derived effort (e.g. forehead versus pressure, FVP)</td>
<td>3</td>
</tr>
<tr>
<td>4</td>
<td>Other sleep measure</td>
<td>Derived pulse (typically from oximetry)</td>
<td>Other oximetry</td>
<td>Other effort measure (including piezo belts)</td>
<td>4</td>
</tr>
<tr>
<td>5</td>
<td>Other cardiac measure</td>
<td>Other oximetry</td>
<td>Other respiratory measure</td>
<td>Other respiratory measure</td>
<td>5</td>
</tr>
<tr>
<td>0</td>
<td>No recording</td>
<td>No recording</td>
<td>No recording</td>
<td>No recording</td>
<td>No recording</td>
</tr>
</tbody>
</table>

**Note:**
- SCOPER Defined
- SleepView CLINICAL VALIDATION
2011

SCOPER Scores of SleepView Monitor

Sleep  Cardiovascular  Oximetry  Position  Effort  Respiration
3*  4  1  2  2  1

*(with web portal)
SleepView® scores HIGH on SCOPER for home testing (OOC) devices for diagnosing OSA
Clinical Studies
White Papers & Publications
2011 Study in collaboration with Cleveland Clinic & John Hopkins Hospital

“Accuracy of Automated Respiratory Scoring Algorithm Using Portable Monitoring”
Foldvary-Schaefer, Nancy D.O. (1), Kaw, Roop M.D. (1), Collop, Nancy M.D. (2), Frederick, Craig (3), Tarler, Matthew Ph.D. (3), Kayyali, Hani (3)
1) Cleveland Clinic, Cleveland, Ohio, 2) Johns Hopkins Hospital, Baltimore, MD, 3) CleveMed, Cleveland, Ohio

SleepView’s Autoscorning of Respiratory Events: 100 patient studies comparison

Correlation Of Over 90%
2012 Study in collaboration with Community Sleep Lab

High Accuracy With In-lab Results
Sensitivity of 100%

SleepView + Portal Home Sleep Testing compared with In-lab Polysomnography
2012 Study in collaboration with Cleveland Clinic

High Accuracy in Total Sleep Time Estimation [95% Correlation]

High Sensitivity & Specificity with In-lab AHI [83%, 100%]

SleepView + Portal Home Sleep Testing compared with In-lab Polysomnography

Expanding the reach of your sleep services today and tomorrow
2012 Study in collaboration with Primary Care Physician offices

Midmark White Paper: “Primary Care and Sleep Apnea Testing - a Pilot Study for Home Testing with SleepView” Thomas D. Schwieterman MD, Hani Kayyali, Kirk Scovill

High Clinical Benefit improved access to patients

Significant Cost Efficiency to payers

SleepView + Web Portal in OR 04 PCP Offices IL 60 Patients CA TX

Expanding the reach of your sleep services today and tomorrow