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Sleep Number Labs

Effortless Detection of Sleep Apnea Using a Smart Bed

Conflict of interest disclosure

With respect to this CME activity,

☐ **No**, I (nor my spouse/partner) do not have a relevant financial relationship.

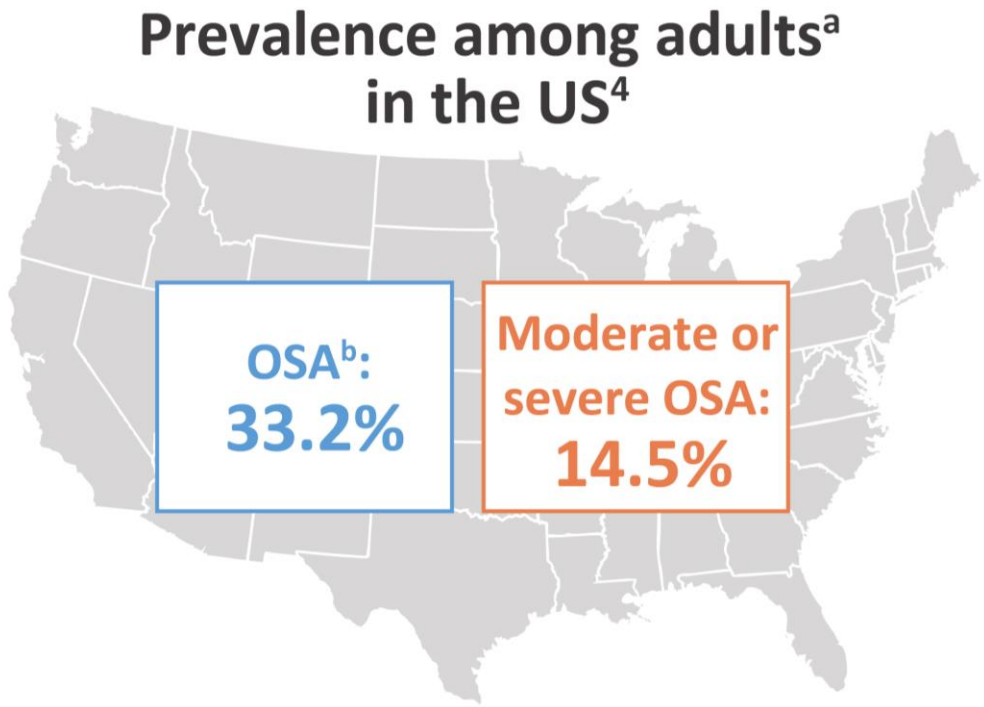
☒ **Yes**, I (and/or my spouse/partner) do have a relevant financial relationship.

Nature of Relevant Financial Relationship (choose all that apply)	**Name(s) of Company or Companies**
___ Consultant	
___ Speaker's bureau	
___ Grant/Research support (secondary investigators need not disclose)	
___ Stock shareholder (self-managed)	
___ Honoraria	
__X_ Full-time/Part-time employee	Sleep Number Corporation
___ Other (describe):	

Sleep apnea overview

- Sleep apnea is a common sleep disorder where a person periodically stops and starts breathing in their sleep
- Types of sleep apnea[1]
  - **Obstructive**
  - **Central**
  - **Mixed**
- The AHI assesses disease severity by the number of complete (apneas) or incomplete (hypopneas) obstructive events per hour of sleep[2]
  - **Mild OSA**: AHI of 5–15 events/hour[3]
  - **Moderate OSA**: AHI of 15–30 events/hour[3]
  - **Severe OSA**: AHI of > 30 events/hour[3]

- Globally, 936 million adults[a] are estimated to have sleep apnea[4]
- An estimated 92% of women and 82% of men with moderate or severe apnea are undiagnosed[5]



[a]Adults aged 30–69 years; [b]Included adults with AHI ≥ 5 events/hr.
AHI, apnea-hypopnea index; OSA, obstructive sleep apnea; US, United States.
[1]Jayaraj R et al. *J Clin Diagn Res*. 2017;11(3):VE01–VE03; [2]Garvey J et al. *J Thorac Dis*. 2015;7(5):920–929; [3]Johns Hopkins Medicine. https://hopkinsmedicine.org/health/wellness-and-prevention/the-dangers-of-uncontrolled-sleep-apnea. 2023. Accessed, July 10, 2023; [4]Benjafield AV et al. *Lancet Respir Med*. 2019;7(8):687–698; [5]Chung F et al. *Curr Opin Anaesthesiol*. 2009;22(3):405–411.

Apnea risk factors, complications, and treatments

Risk factors[1]

- Age > 65 years
- Genetics
- Male sex
- Nasal congestion
- Tobacco and/or alcohol use

Complications

- CV diseases[1]
- Metabolic diseases[1]
- Functional impairment[2]

Treatments

Mechanical[3]
- CPAP
- Oral/dental devices
- Surgical intervention

Behavioral[4]
- Weight loss
- Reduced alcohol and tobacco use
- Sleep position changes

Medical[a]
- HRTs[5]
- Ventilatory stimulants[6]
- Psychotropic drugs[6]

[a]Although positive results for pharmacological interventions exist, evidence is not consistent for use in OSA.
CPAP, continuous positive airway pressure; CV, cardiovascular; HRT, hormone replacement therapy.
[1]Hirani R, Smiley A. *Life*. 2023;13:387; [2]Garvey J et al. *J Thorac Dis*. 2015;7(5):920–929; [3]Chang HP et al. *Kaohsiung J Med* Sci. 2020;36(1):7–12; [4]Kaleelullah RA et al. *Cureus*. 2021;13(1):e12927; [5]Wesstrom J et al. *Acta Obstet Gynecol Scand*. 2005; 84(1):54–57; [6]Arredondo ED et al. *Medicina* (*Kaunas*). 2022;2;58(2):225.

Apnea diagnostic and monitoring tools and trend

Gold standard: PSG

Physician-identified clinical symptoms[a]

Recently approved: HSAT

Unobtrusive monitoring: Smart bed[b]

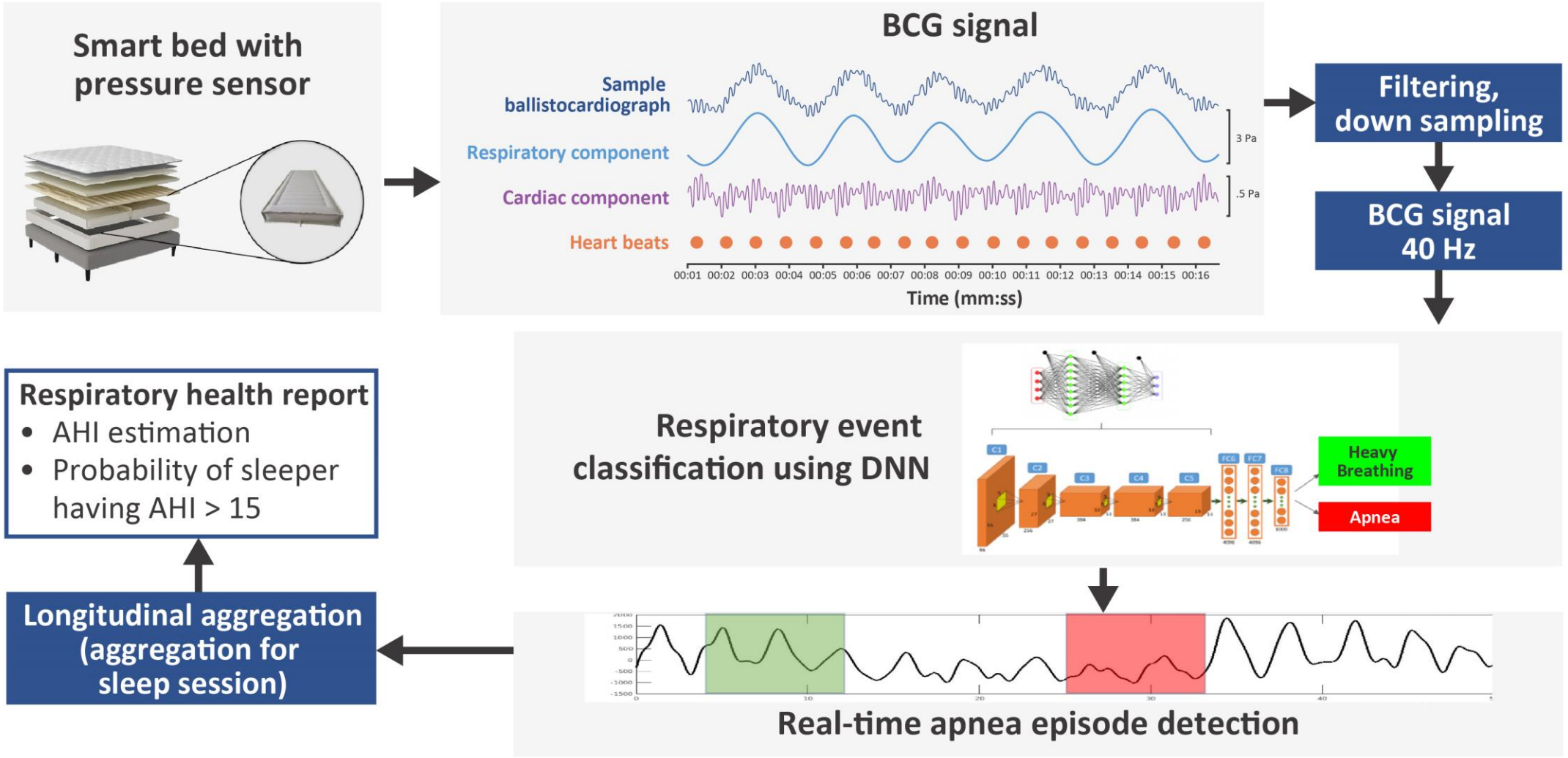
Sleep apnea diagnosis if AHI ≥ 15 events/hour

Sleep apnea monitoring[c]

[a]Symptoms are assessed by questionnaires and/or symptom-scoring scales; [b]The smart bed is validated against PSG;[1] [c]Diagnosis currently requires a physician and PSG or HSAT monitoring.
AHI, apnea-hypopnea index; HSAT, home sleep apnea testing; PSG, polysomnography.

[1]Siyahjani F et al. *Sensors* (*Basel*). 2022;22(7):2605.

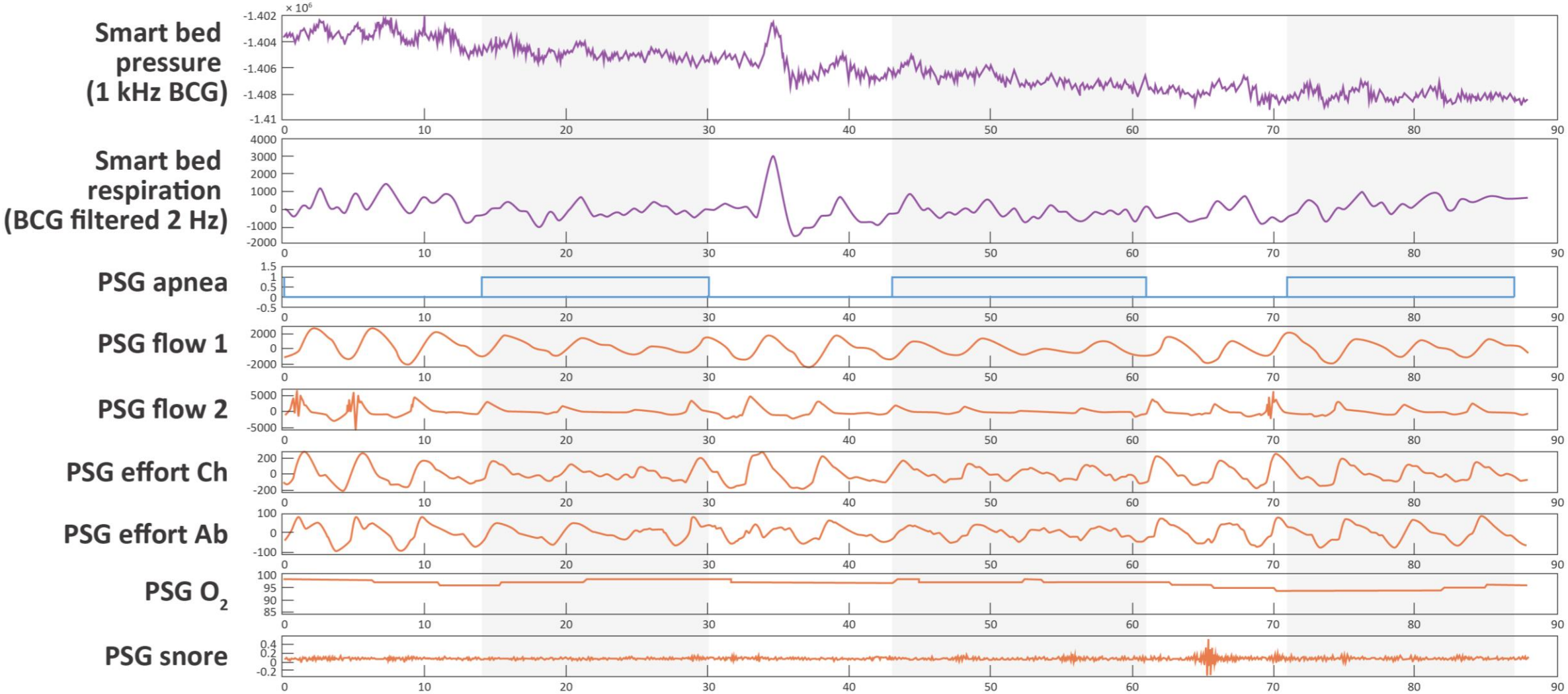
Study design: Detection of sleep apnea using a smart bed[1]



AHI, apnea-hypopnea index; BCG, ballistocardiography; C, convolution layer; DNN, deep neural network; FC, fully connected layer; Hz, hertz; mm:ss, minute:second; Pa, Pascal.

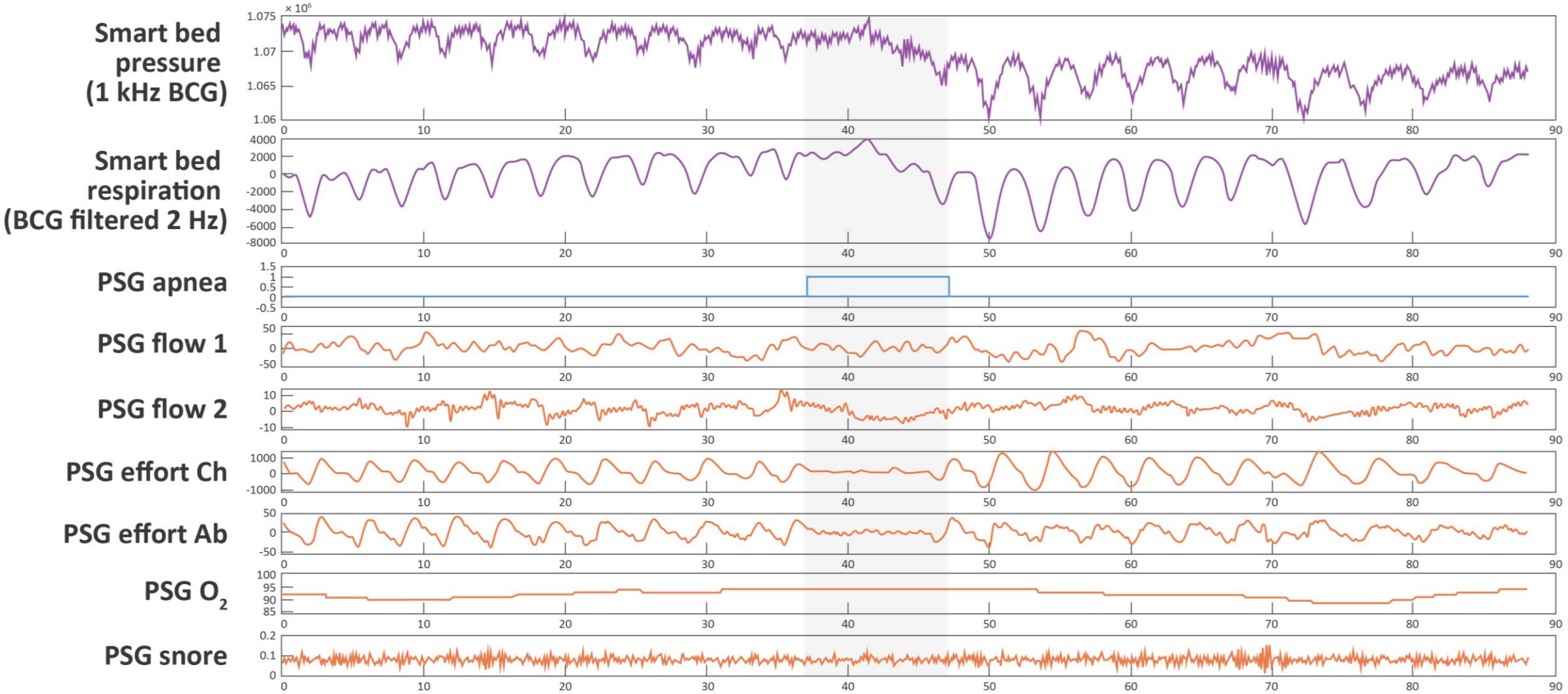
[1]Siyahjani F et al. *Sensors* (*Basel*). 2022;22(7):2605.

Example CSA on PSG and smart bed signals



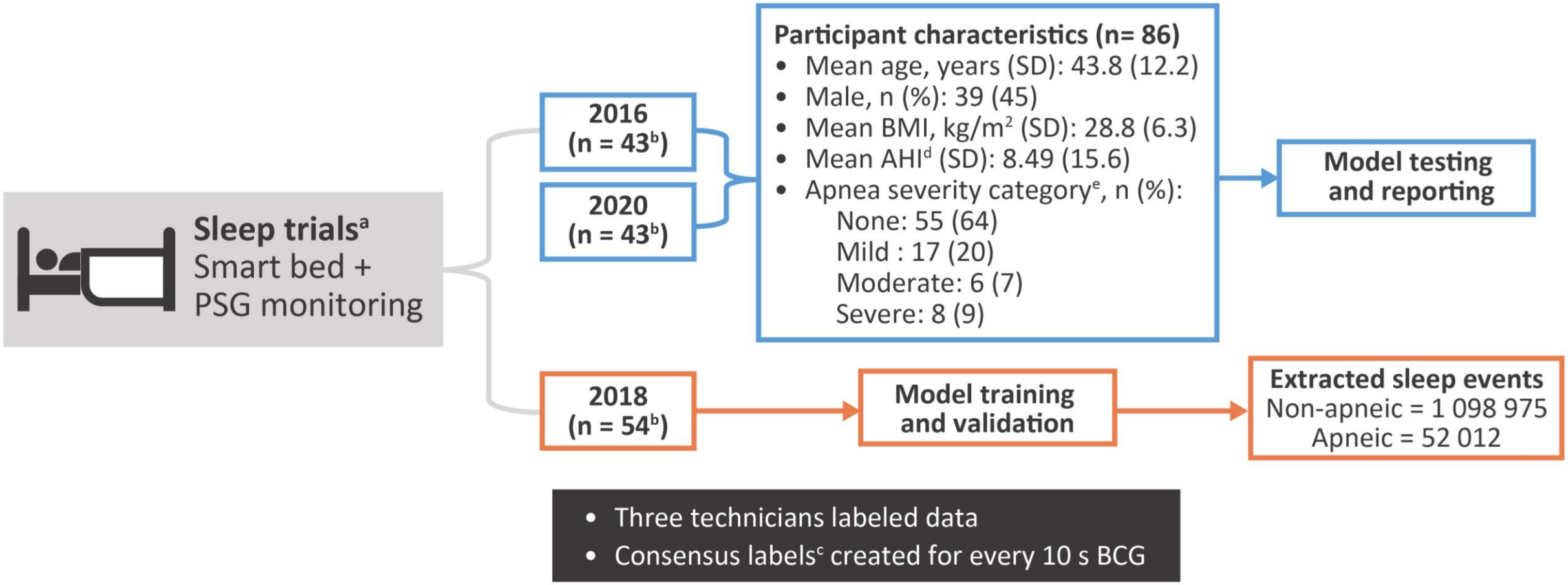
Ab, abdomen; BCG, ballistocardiography; Ch, chest; CSA, central sleep apnea; Hz, hertz; kHz, kilohertz; O_2, oxygen; PSG, polysomnography.

Example OSA on PSG and smart bed signals



Ab, abdomen; BCG, ballistocardiography; Ch, chest; Hz, hertz; kHz, kilohertz; O_2,oxygen; OSA, obstructive sleep apnea; PSG, polysomnography.

Study design: Data collection

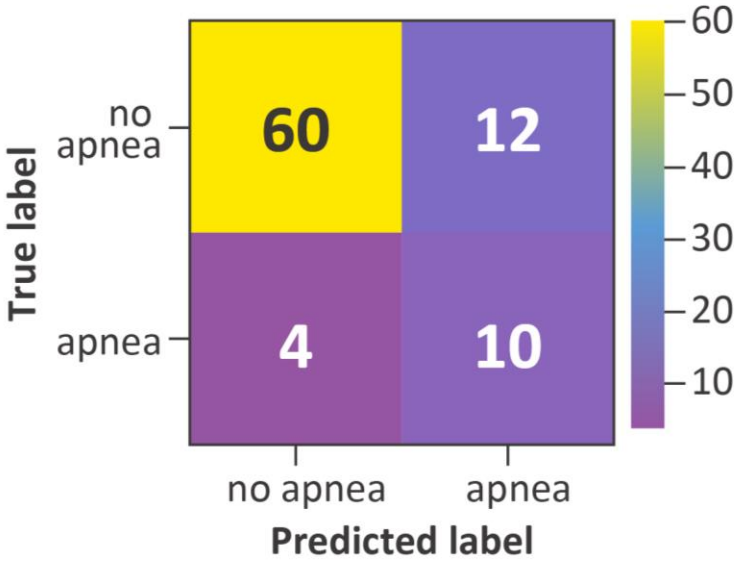


[a]Conducted on healthy participants and those with apnea; [b]Non-overlapping individuals; [c]Labeled by majority vote; [d]AHI was determined by PSG; [e]Apnea severity was determined by participant AHI.

AHI, apnea-hypopnea index; BCG, ballistocardiography; BMI, body mass index; kg/m², kilograms per square meter; PSG, polysomnography; s, second; SD, standard deviation.

Model accuracy: Results on test trials

- **None**: includes participants with AHI < 15
- **Apnea**: includes participants with AHI ≥ 15
- **The sensitivity of model:**
  - **Detecting AHI < 15:** 83%
  - **Detecting AHI ≥ 15:** 71%
  - **Overall accuracy:** 81%



Classification	Precision	Recall	F1 score	Participants, n
No apnea	0.94	0.83	0.88	72
Apnea	0.45	0.71	0.56	14
Macro avg	0.70	0.77	0.72	86
Weighted avg	0.86	0.81	0.83	86

AHI, apnea-hypopnea index; avg, average.

Conclusions

- Apneic events are detectable by smart beds
- Accuracy of the initial models are promising for respiratory monitoring applications

- Future work:
  - Conduct a multi-night, multi-sensor in-home trial for sleep apnea using the smart bed
  - Explore the potential value of additional sensors and smart phone applications with subjective questionnaires for future studies
  - Improve and optimize the model to measure sleep apnea severity and AHI estimates with higher accuracy
  - Develop the capability to distinguish between various respiratory disturbances

AHI, apnea-hypopnea index.

Questions

Disclosures and acknowledgments

- This research was supported by Sleep Number Corporation
- Farzad Siyahjani, Saeed Babaeizadeh, and Faisal Mushtaq are employees of Sleep Number Corporation, Minneapolis, MN, USA
- Medical writing support was provided by Jessica Irons, PhD, from Oxford PharmaGenesis Inc., Newtown, PA, USA, and was funded by Sleep Number Corporation

Supplemental Slides

Model training and validation: 5-fold hold-out accuracy measure

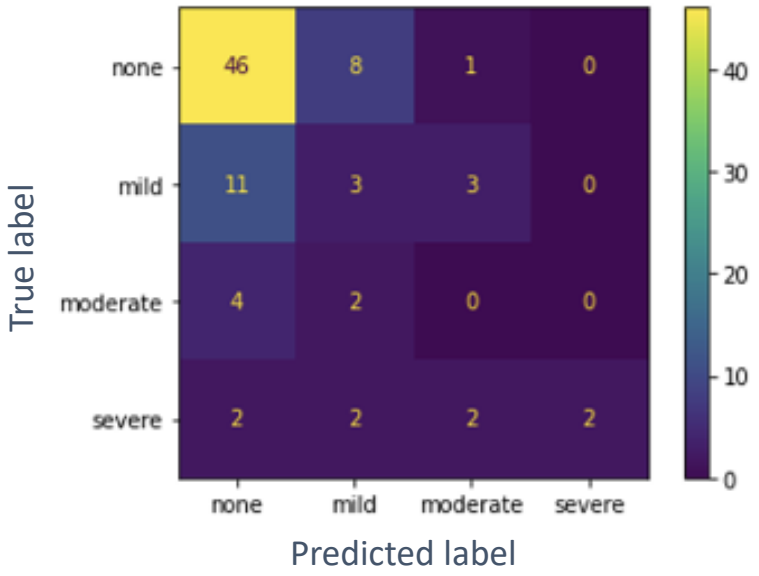
Fold	Balanced accuracy	Accuracy	F1	Precision	Recall	Specificity	TN	FP	FN	TP
1	0.870	0.924	0.493	0.354	0.810	0.930	255 531	19 213	2462	10 541
2	0.875	0.922	0.489	0.378	0.824	0.926	254 640	20 104	2282	10 721
3	0.864	0.895	0.418	0.280	0.830	0.898	246 981	27 763	2201	10 802
4	0.866	0.914	0.463	0.323	0.812	0.919	252 686	22 058	2434	10 569
5	0.847	0.930	0.495	0.368	0.755	0.938	257 937	16 806	3178	9 825
Avg ± SD	0.864 ± 0.01	0.917 ± 0.01	0.471 ± 0.03	0.340 ± 0.04	0.806 ± 0.03	0.922 ± 0.01	253 555 ± 4 130	21 188 ± 4 130	2511 ± 387	10 491 ± 387

Negative samples: 274 744 (10 seconds) = 760 hours
Negative samples: 13 003 (10 seconds) = 36 hours

Avg, average; FN, false negative; FP, false positive; SD, standard deviation; TN, true negative; TP, true positive.

Model accuracy: Results of apnea severity detection on unseen data

- **No apnea**: includes participants with AHI < 5
- **Mild apnea**: includes participants with AHI 5–15
- **Moderate apnea**: includes participants with AHI 15–30
- **Severe apnea**: includes participants with AHI > 30
- Average accuracy: 59%; sensitivity: 0.59; specificity: 0.6; precision: 0.6; F1- score: 0.57

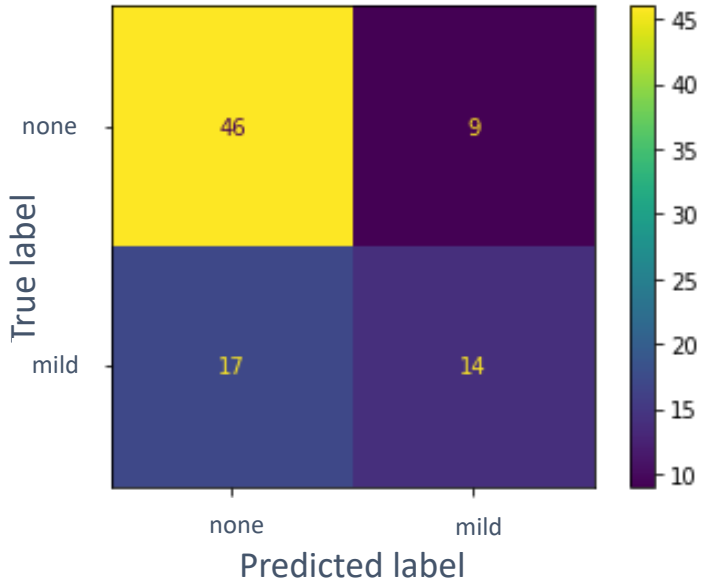


Apnea severity	Precision	Recall	Specificity	F1 score	Participants, n
None	0.73	0.84	0.45	0.78	55
Mild	0.20	0.18	0.82	0.19	17
Moderate	0.00	0.00	0.82	0.00	6
Severe	1.00	0.25	1.00	0.40	8
Macro avg	0.48	0.32	0.77	0.34	86
Weighted avg	0.60	0.59	0.60	0.57	86

AHI, apnea-hypopnea index; avg, average.

Model accuracy: Results of binary classification on AHI < 5 and AHI ≥ 5

- **No apnea:** includes participants with AHI < 5
- **Apnea:** includes participants with AHI ≥ 5
- **Sensitivity of model detecting AHI < 5**: 84%
- **Sensitivity of model detecting AHI ≥ 5**: 45%
- **Overall accuracy**: 70%

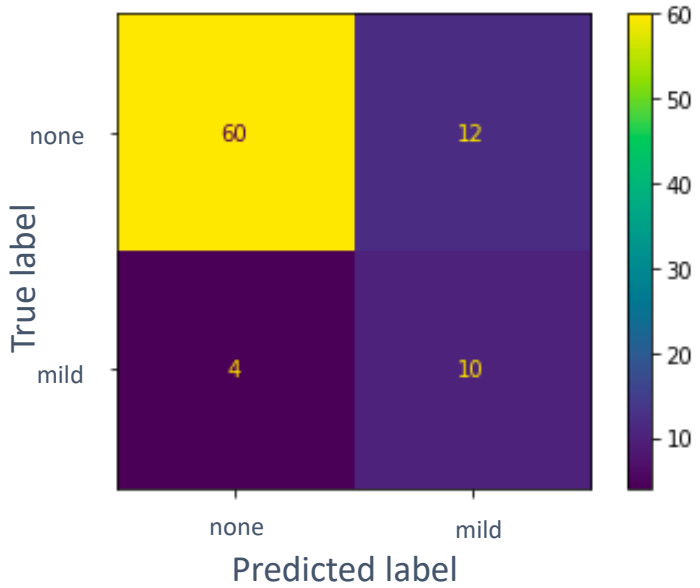


Apnea severity	Precision	Recall	F1 score	Participants, n
AHI < 5	0.73	0.84	0.78	55
AHI ≥ 5	0.61	0.45	0.52	31
Macro avg	0.67	0.64	0.65	86
Weighted avg	0.69	0.70	0.69	86

Fold predictions: AHI < 5: fold 0; AHI ≥ 5: fold 1.
AHI, apnea-hypopnea index; avg, average.

Model accuracy: Results of binary classification on AHI <10 and AHI ≥ 10

- **No apnea:** includes participants with AHI < 10
- **Apnea:** includes participants with AHI ≥ 10
- **Sensitivity of model detecting AHI < 10**: 92%
- **Sensitivity of model detecting AHI ≥ 10**: 40%
- **Overall accuracy**: 90%

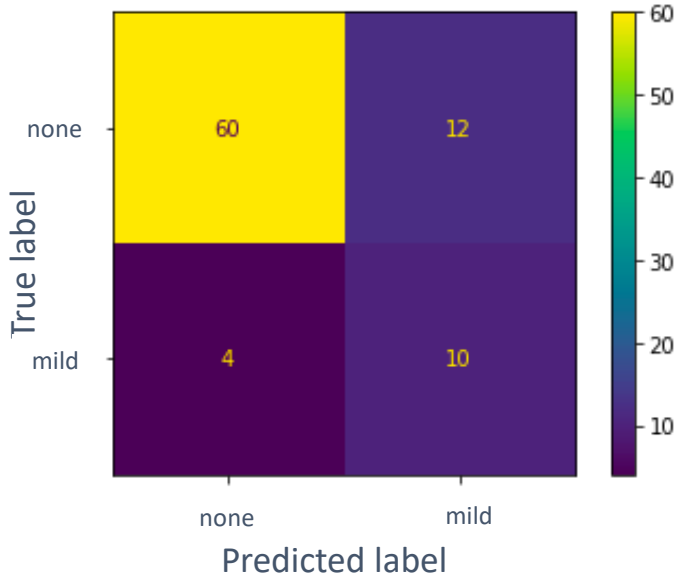


Apnea severity	Precision	Recall	F1 score	Participants, n
AHI < 10	0.84	0.92	0.88	66
AHI ≥ 10	0.62	0.40	0.48	20
Macro avg	0.73	0.66	0.68	86
Weighted avg	0.78	0.80	0.79	86

Fold predictions: AHI < 10: fold 0; AHI ≥ 10: fold 1.
AHI, apnea-hypopnea index; avg, average.

Model accuracy: Results of binary classification on AHI <15 and AHI ≥ 15

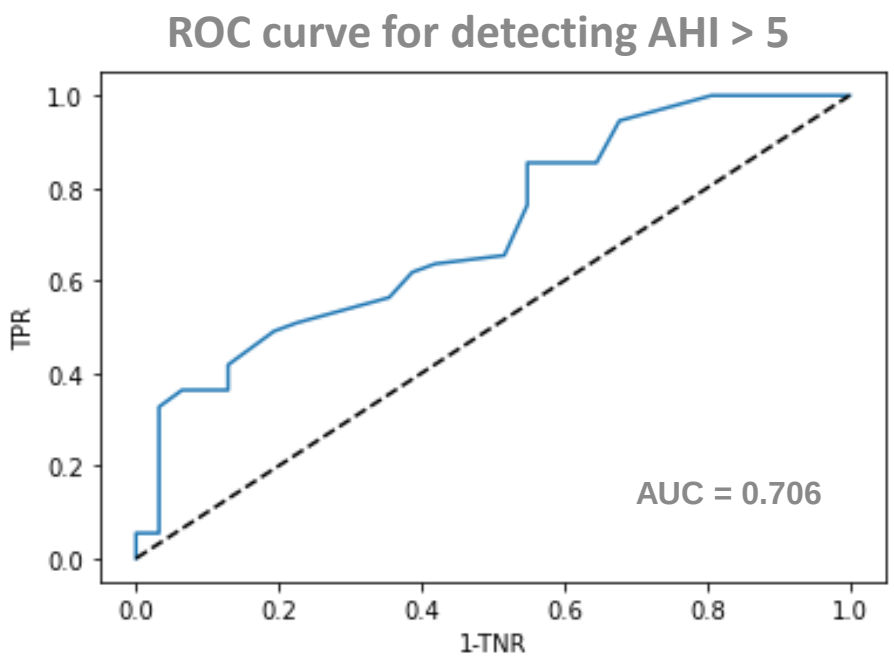
- **No apnea**: includes participants with AHI < 15
- **Apnea**: includes participants with AHI ≥ 15
- **The sensitivity of model detecting AHI < 15:** 83%
- **The sensitivity of model detecting AHI ≥ 15:** 71%
- **Overall accuracy:** 81%

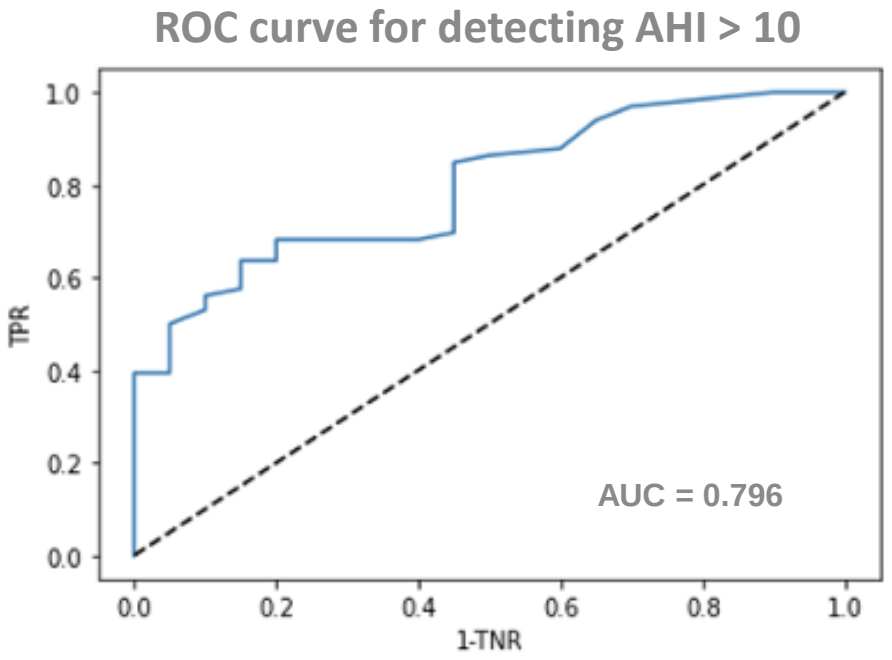


Apnea severity	Precision	Recall	F1 score	Participants, n
AHI < 15	0.94	0.83	0.88	72
AHI ≥ 15	0.45	0.71	0.56	14
Macro avg	0.70	0.77	0.72	86
Weighted avg	0.86	0.81	0.83	86

Fold predictions: AHI < 15: fold 0; AHI ≥ 15: fold 1.
AHI, apnea-hypopnea index; avg, average.

Model performance





AHI, apnea-hypopnea index; AUC, area under the curve; ROC, receiver operating characteristic; TNR, true negative rate; TPR, true positive rate.

Subjective apnea assessments and accuracy

SBQ, BQ, ESS, and KSS questionnaires were analyzed for the highest correlation with known patients who have apnea

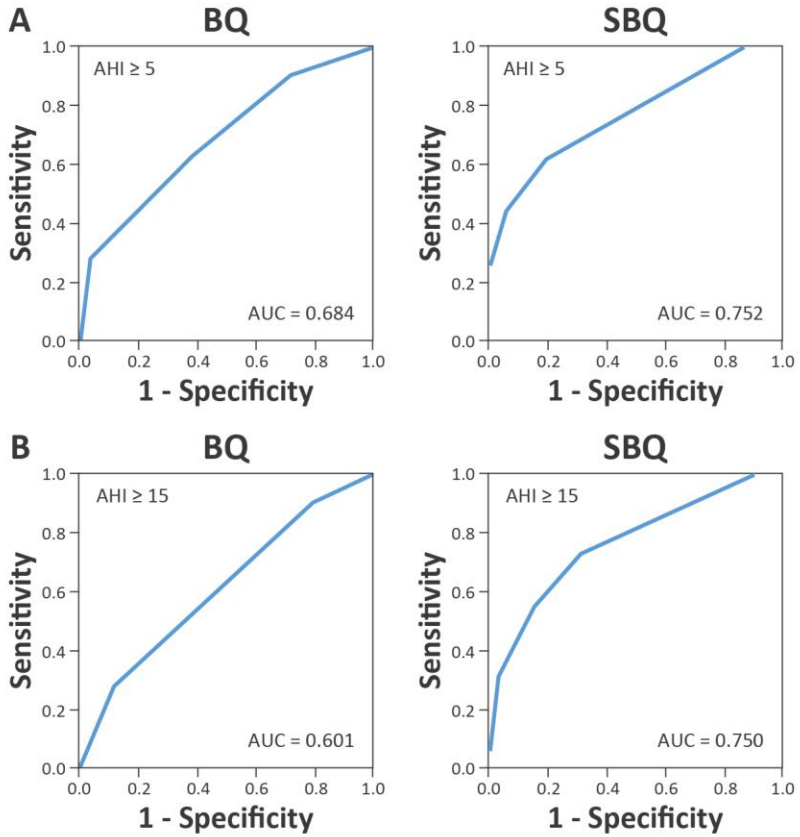
- SBQ and BQ were chosen

SBQ

- Yes/No: 8 questions
  - STOP: 4 questions
  - BANG: 4 questions
- High risk for OSA if 3 or more items are answered “Yes”

BQ

- Composed of 10 questions
  - Evaluate snoring: 5 questions
  - Measure daytime fatigue and sleepiness: 4 questions
  - Records medical history & anthropometric measures such as hypertension and BMI: 1 question
- High risk for OSA if 2 or more categories are positive



BANG, body mass index, age, neck circumference, gender; BMI, body mass index; BQ, Berlin Questionnaire; ESS, Epworth Sleepiness Scale; KSS, Karolinska Sleepiness Scale; AUC, area under the curve; OSA, obstructive sleep apnea; SBQ, STOP-BANG questionnaire; STOP, snoring, tiredness, observed apnea, high blood pressure.

Sample size estimation

Sample size estimation is based on the consideration of the sensitivity and specificity of AHI > 10

The sample size for sensitivity depends on the prevalence “P” which is equal to 11%.
Using P = 0.11 the sample sizes for sensitivity of 0.86 and specificity of 0.75 are:

$$TP + FN = Z^2 \times \frac{Sensitivity \times (1 - Sensitivity)}{W^2}$$

$$TN + FP = Z^2 \times \frac{Specificity \times (1 - Specificity)}{W^2}$$

TP + FN x (P) = 290
TN + FP x (1-P) = 23

Under the assumption of 90% of complete data, the sample size is:
1.12 × (290 + 23) ≈ 315 nights of data.

We require at least 32 sleepers with 10 nights of data based the availability of volunteers.

Z and W are defined as follows: with an assumption of normal distribution and corresponding Z value set to 1.96 to ensure a 95% confidence interval, and 15% maximum acceptable width of the 95% confidence interval denoted as W.
FN, false negative; FP, false positive; TN, true negative; TP, true positive; W, maximum acceptable width of the 95% confidence interval; Z, normal distribution.

Model architecture

- **Input:**
  - In 2018, 10 s 40 Hz smart bed BCG signal segments (n = 54)

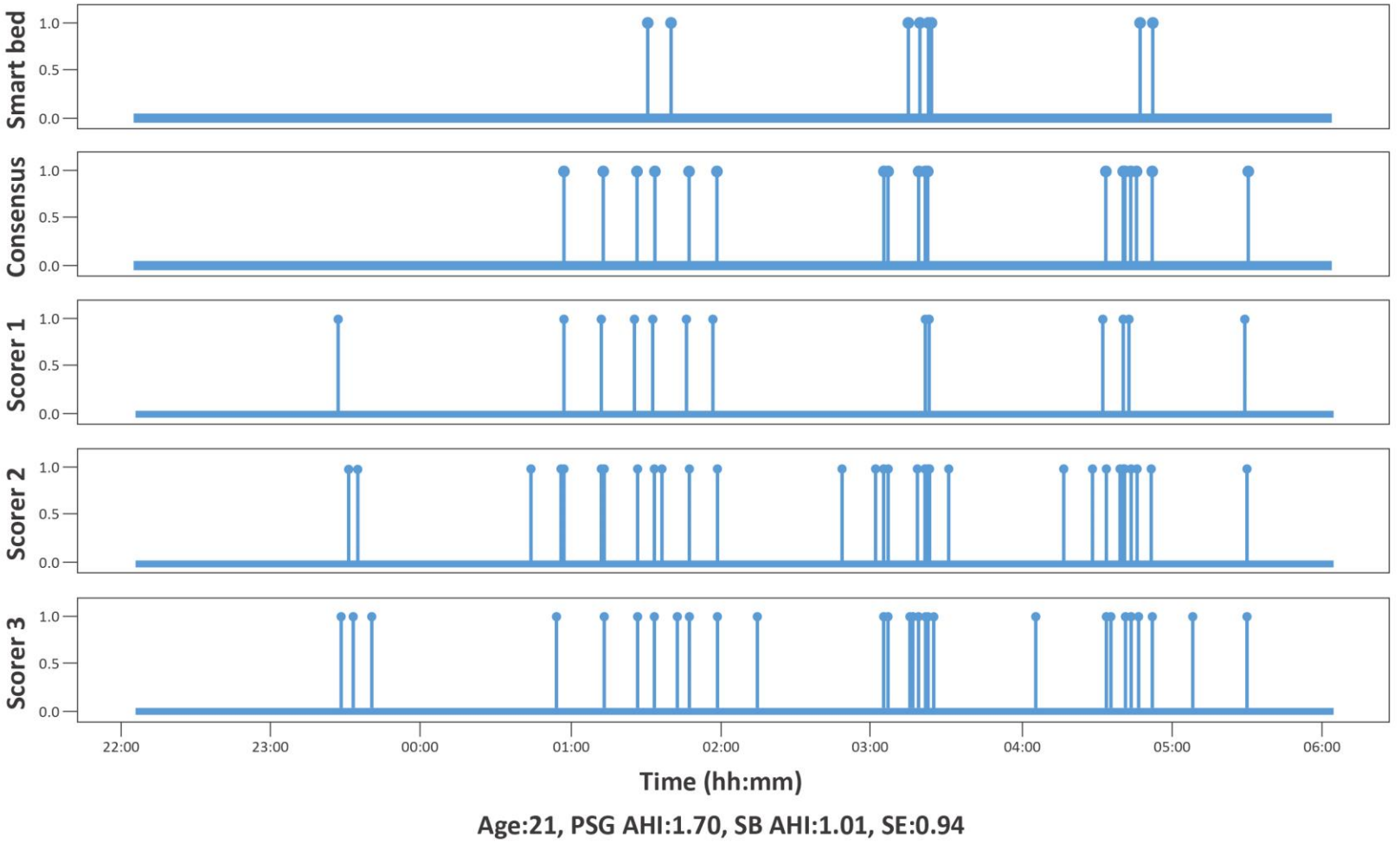
- **Training + validation samples from 2018:**
  - Negative: 1 098 975 samples = 3 050 hr
  - Positive: 52 012 samples = 140 hr

- **Testing samples from 2016 and 2020:**
  - Negative: 274 744 samples = 760 hr
  - Positive: 13 003 samples = 36 hr

```
•Layer (type)                 Output Shape              Param #
•=================================================================
•conv1d_1 (Conv1D)            (None, 398, 128)          512
•_________________________________________________________________
•conv1d_2 (Conv1D)            (None, 396, 128)          49 280
•_________________________________________________________________
•max_pooling1d_1 (MaxPooling1 (None, 19, 128)           0
•_________________________________________________________________
•conv1d_3 (Conv1D)            (None, 17, 128)           49 280
•_________________________________________________________________
•conv1d_4 (Conv1D)            (None, 15, 128)           49 280
•_________________________________________________________________
•dropout_1 (Dropout)          (None, 15, 128)           0
•_________________________________________________________________
•batch_normalization_1 (Batch (None, 15, 128)           512
•_________________________________________________________________
•bidirectional_1 (Bidirection (None, 15, 128)           99 328
•_________________________________________________________________
•time_distributed_1 (TimeDist (None, 15, 16)            2 064
•_________________________________________________________________
•flatten_1 (Flatten)          (None, 240)               0
•_________________________________________________________________
•batch_normalization_2 (Batch (None, 240)               960
•_________________________________________________________________
•dense_2 (Dense)              (None, 64)                15 424
•_________________________________________________________________
•dropout_2 (Dropout)          (None, 64)                0
•_________________________________________________________________
•dense_3 (Dense)              (None, 2)                 130
•=================================================================
•Total params: 266 770
•Trainable params: 266 034
•Non-trainable params: 736
```

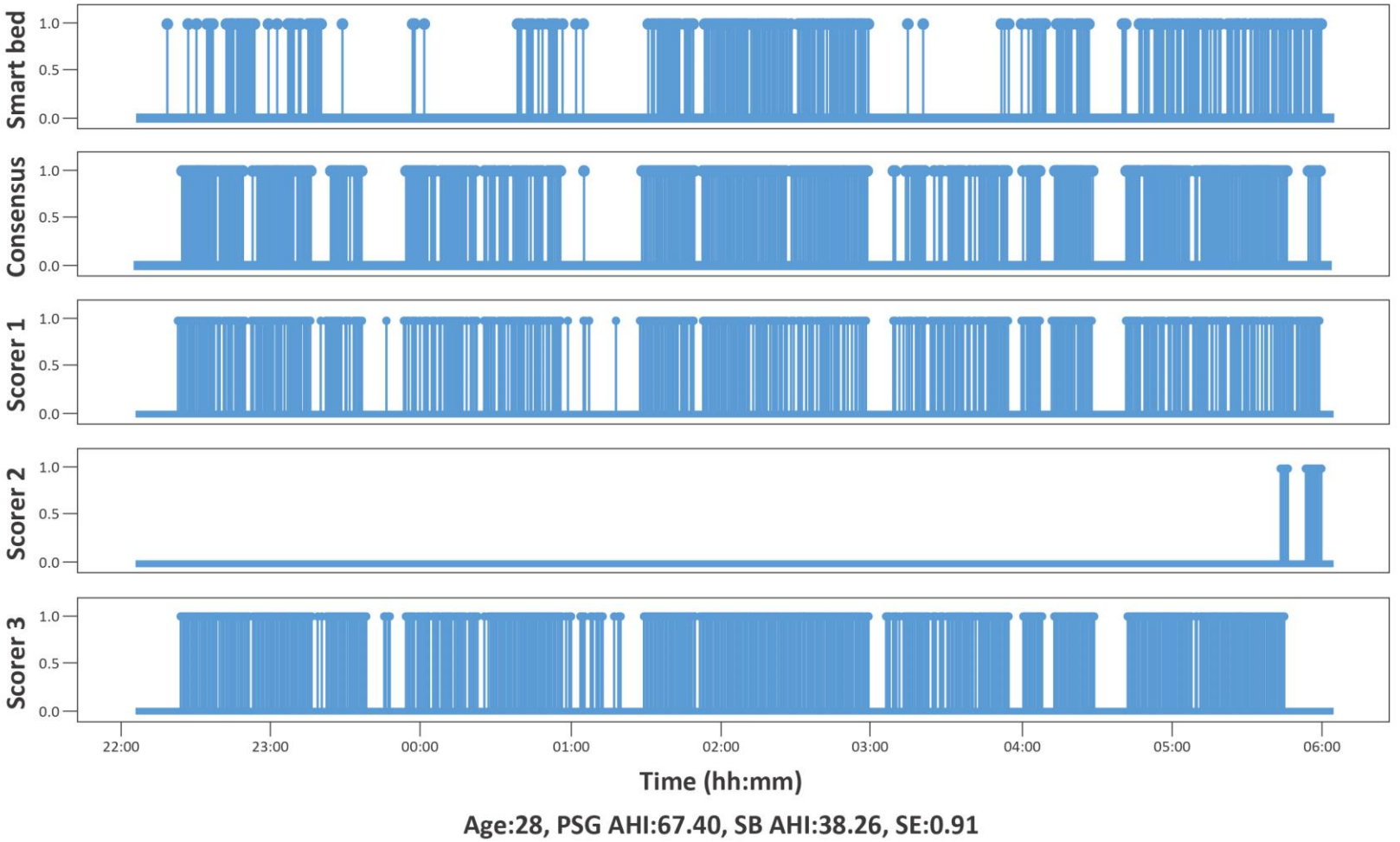
BCG, ballistocardiography; hr, hour; Hz, hertz; param, parameter; s, seconds.

Example apnea detection: Study room 1; April 21, 2016



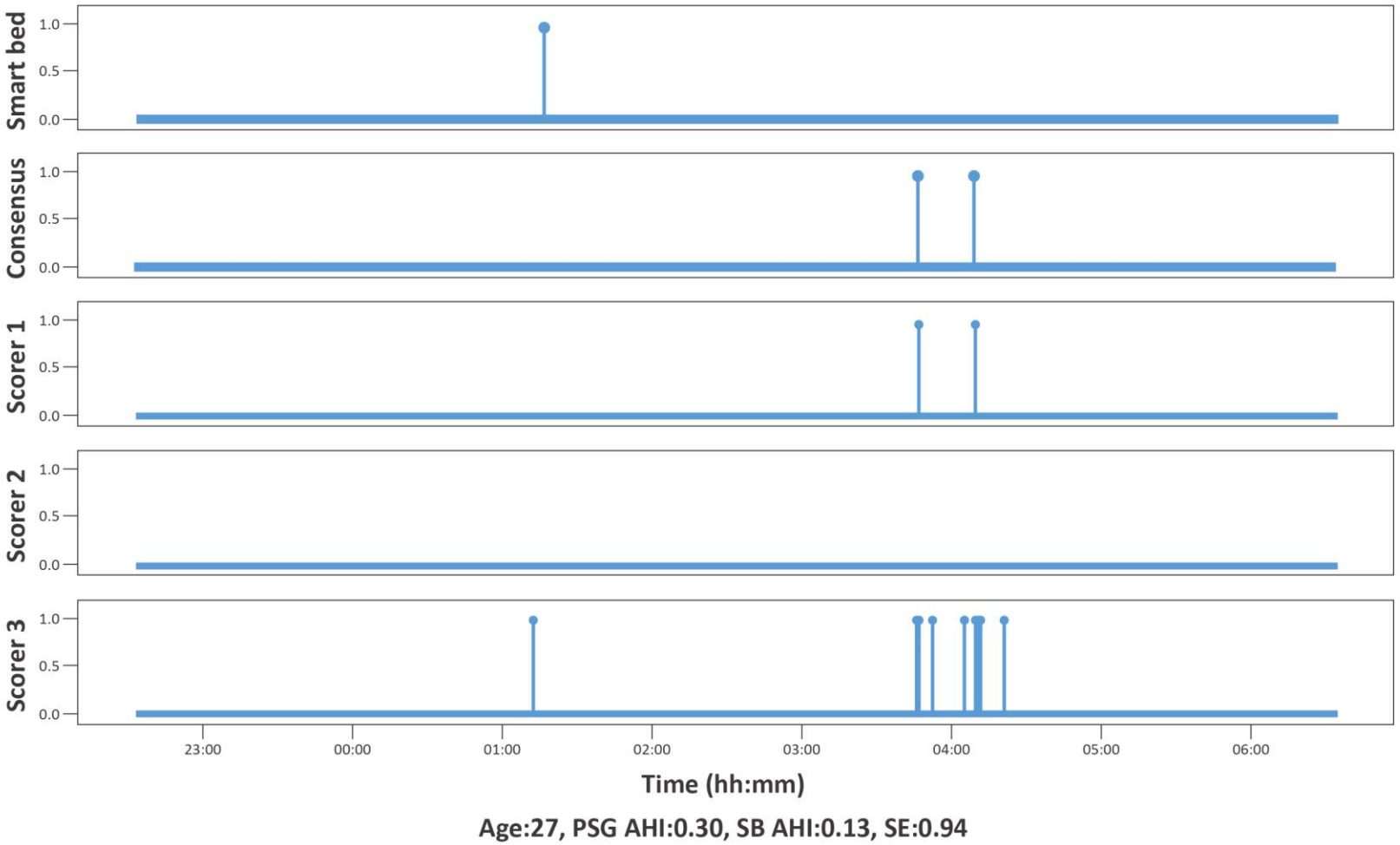
Vertical blue lines indicate episodes of sleep apnea.
AHI, apnea-hypopnea index; hh:mm, hour:minute; PSG, polysomnography; SB, smart bed; SE, standard error.

Example apnea detection: Study room 2; March 21, 2016



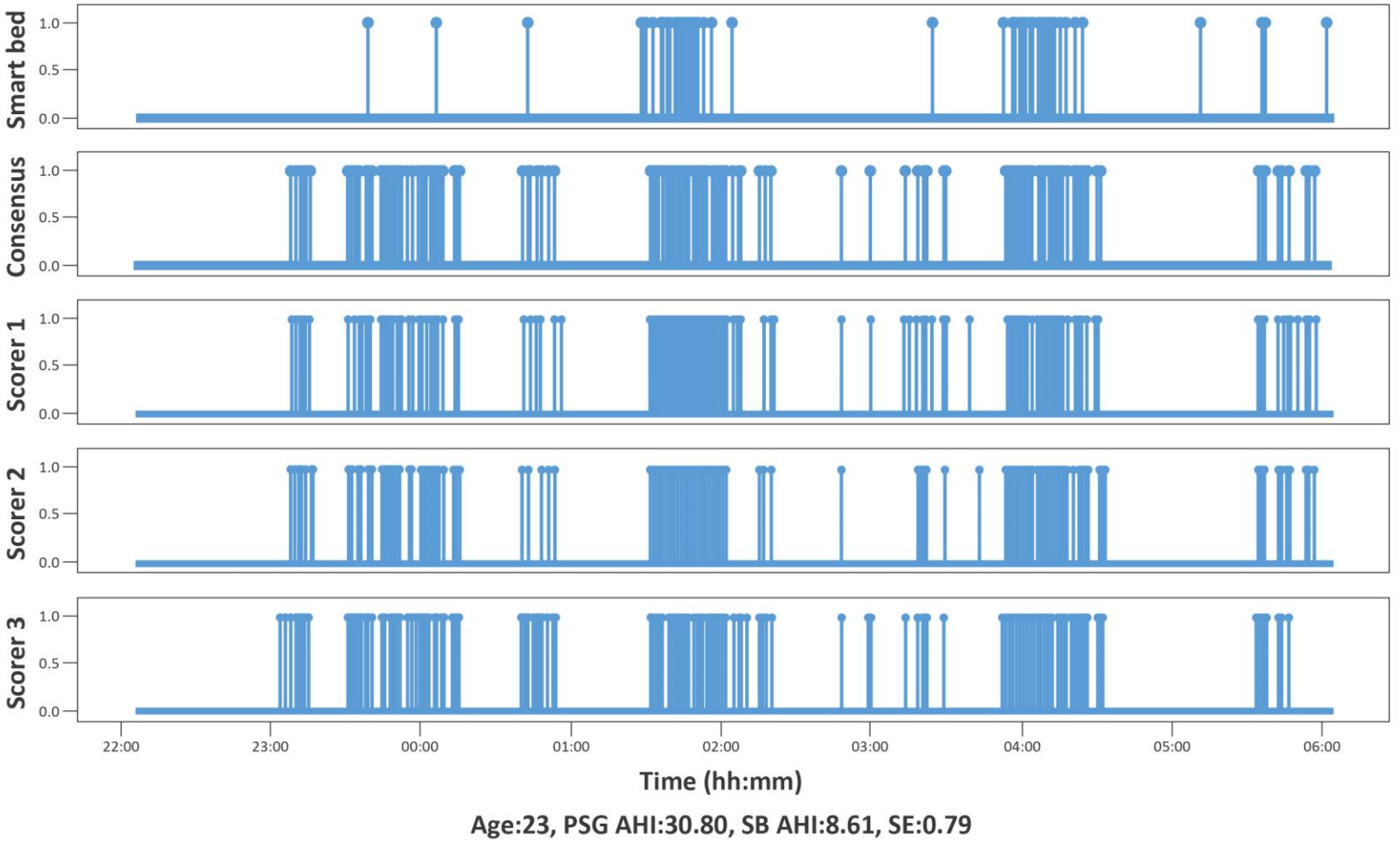
Vertical blue lines indicate episodes of sleep apnea.
AHI, apnea-hypopnea index; hh:mm, hour:minute; PSG, polysomnography; SB, smart bed; SE, standard error.

Example apnea detection: Study room 4; March 14, 2016



Vertical blue lines indicate episodes of sleep apnea.
AHI, apnea-hypopnea index; hh:mm, hour:minute; PSG, polysomnography; SB, smart bed; SE, standard error.

Example apnea detection: Study room 2; March 24, 2016



Vertical blue lines indicate episodes of sleep apnea.
AHI, apnea-hypopnea index; hh:mm, hour:minute; PSG, polysomnography; SB, smart bed; SE, standard error.

Model profiling on TensorFlow lite

Model V1, trained on 20 Hz data

Layer (type)	Output Shape	Param #
== conv1d_1 (Conv1D)	(None, 198, 64)	256
__ dropout_1 (Dropout)	(None, 198, 64)	0
__ conv1d_2 (Conv1D)	(None, 193, 64)	24 640
__ (Batch	(None, 193, 64)	256
__ dropout_2 (Dropout)	(None, 193, 64)	0
__ bidirectional_1	(None, 193, 128)	66 560
__ dropout_3 (Dropout)	(None, 193, 128)	0
__ bidirectional_2	(None, 128)	99 328
__ batch_normalization_2	(None, 128)	512
__ dropout_4 (Dropout)	(None, 128)	0
__ dense_1 (Dense)	(None, 32)	4 128
__ dropout_5 (Dropout)	(None, 32)	0
__ dense_2 (Dense)	(None, 2)	66

==

Total params: 195 746
Trainable params: 195 362
Non-trainable params: 384

CPU (single thread): 64.1 ms
Memory: 4.6 MB

Model V2, trained on 40 Hz data

Layer (type)	Output Shape	Param #
conv1d_1 (Conv1D)	(None, 398, 128)	512
conv1d_2 (Conv1D)	(None, 396, 128)	49 280
max_pooling1d_1 (MaxPooling1	(None, 19, 128)	0
conv1d_3 (Conv1D)	(None, 17, 128)	49 280
conv1d_4 (Conv1D)	(None, 15, 128)	49 280
dropout_1 (Dropout)	(None, 15, 128)	0
batch_normalization_1 (Batch	(None, 15, 128)	512
bidirectional_1 (Bidirection	(None, 15, 128)	99 328
time_distributed_1 (TimeDist	(None, 15, 16)	2 064
flatten_1 (Flatten)	(None, 240)	0
batch_normalization_2 (Batch	(None, 240)	960
dense_2 (Dense)	(None, 64)	15 424
dropout_2 (Dropout)	(None, 64)	0
dense_3 (Dense)	(None, 2)	130

Total params: 266 770
Trainable params: 266 034
Non-trainable params: 736

CPU (single thread): 17.3 ms
Memory: 6.2 MB

CPU, central processing unit; Hz, hertz; MB, megabyte; ms, millisecond; param, parameter; V, version.