Performance of an Al Algorithm in Scoring Respiratory and Non-Respiratory Arousals using Respiratory Inductance Plethysmography Signals

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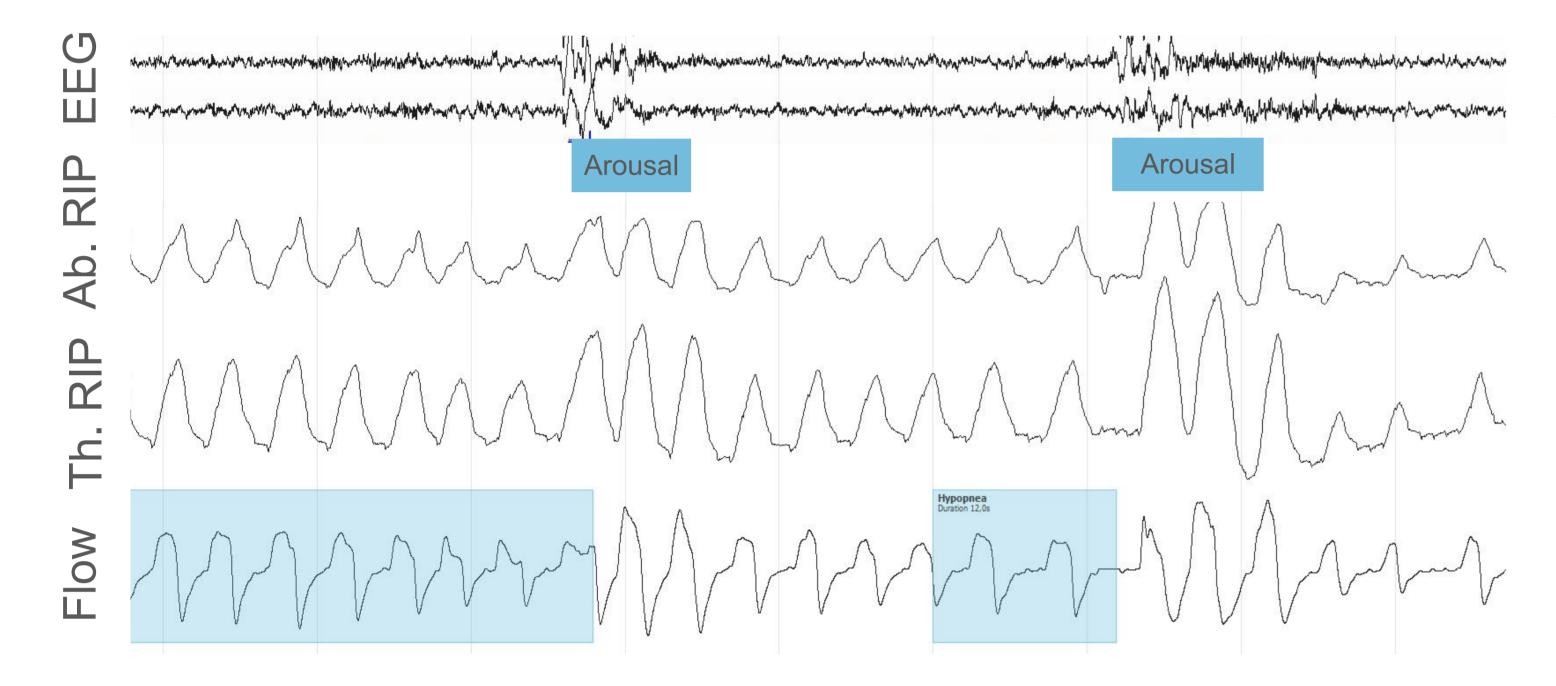
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# Introduction

Arousals are brief awakenings from sleep that can occur spontaneously or in response to stimuli, including respiratory disturbances, limb movements, or environmental factors. They impact sleep architecture and are key to diagnosing sleep disorders, including obstructive sleep apnea (OSA). Arousals can be broadly grouped into (i) respiratory-related arousals, which occur in close temporal proximity to apneas, hypopneas, or flow-limitation events, and (ii) non-respiratory arousals, which arise independently of overt breathing disturbances and may be precipitated by limb movements, spontaneous cortical arousals, or external/environmental stimuli. Both categories provoke a ventilatory response to the arousal, detectable in respiratory sensor traces.<sup>1,2</sup> This study examines the performance of the Nox BodySleep 2.0, a part of the Nox AI Scoring (FDA cleared software medical device DeepResp K241960), in detecting both respiratory-related and non-respiratory arousals across OSA severity levels using respiratory inductance plethysmography (RIP) signals.<sup>3</sup>

The aim of this study was to assess the ability of Nox BodySleep 2.0 to detect both respiratory-related and non-respiratory arousals using RIP signals in a diverse patient population.



<u>Figure 1: Nox BodySleep 2.0 uses only RIP signals to detect both</u> <u>respiratory-related and non-respiratory arousals. EEG signals are shown solely for</u> <u>comparison, illustrating how the arousals scored by Nox BodySleep 2.0 align with</u> <u>typical EEG arousal signatures. Arousals are marked when the probability of</u> <u>arousal exceeds a defined threshold for at least 3 seconds.</u> Ab. RIP = Abdominal RIP signal, Th. RIP = Thoracic RIP signal

# **Results**

Arousal scoring agreement metrics for the Nox BodySleep 2.0 compared to manual scoring, across OSA, and PLMSI severity groups, as well as sleep states can be seen in table 2:

#### <u>Table 2: Performance of the Nox BodySleep 2.0 with regards to scoring arousals</u> <u>overall on a patient level, as well as on an epoch level across OSA and PLMSI</u> <u>severity groups and sleep states (REM vs NREM)</u>

| Class                | Sensitivity%         | Specificity%      | Accuracy%         |
|----------------------|----------------------|-------------------|-------------------|
|                      | Patient Level result | ts, mean [SD]     |                   |
| Overall              | 64.3 [17.3]          | 85.8 [10.1]       | 81.6 [7.1]        |
|                      | Epoch Level Results, | median [95%CI]    |                   |
| AHI < 5              | 59.4 [56.2, 62.6]    | 88.9 [87.6, 90.0] | 83.5 [82.3, 84.7] |
| 5 ≤ AHI < 15         | 58.9 [57.3, 60.6]    | 89.4 [88.8, 90.0] | 84.0 [83.5, 84.6] |
| 15 ≤ AHI < 30        | 63.2 [61.3, 65.0]    | 88.1 [87.3, 88.8] | 82.7 [82.0, 83.2] |
| AHI ≥ 30             | 72.3 [70.4, 74.2]    | 81.1 [79.9, 82.3] | 78.1 [77.3, 78.8] |
|                      | Epoch Level Results, | median [95%Cl]    |                   |
| <b>PLMSI &lt; 15</b> | 66.0 [64.8, 67.2]    | 87.0 [86.5, 87.4] | 81.9 [81.5, 82.3] |
| $PLMSI \ge 15$       | 67.1 [61.6, 72.2]    | 80.6 [77.3, 83.5] | 77.2 [75.2, 79.2] |
|                      | Epoch Level Results, | median [95%CI]    |                   |
| NREM                 | 64.0 [62.7, 65.3]    | 90.0 [90.4, 91.4] | 83.0 [82.6, 83.5] |
| REM                  | 66.8 [65.3, 68.3]    | 86.9 [86.2, 87.6] | 82.3 [81.7, 82.8] |

### Methods

The algorithm was validated using manually scored, clinical sleep recordings from 1,299 adults with suspected sleep disorders. The performance was validated with regards to arousal scoring. Sensitivity, specificity, and accuracy were calculated on a patient level and epoch level. Epoch level results being stratified by apnea-hypopnea index (AHI; AHI < 5,  $5 \le AHI < 15, 15 \le AHI < 30$ , and  $AHI \ge 30$ ), periodic limb movement of sleep index (PLMSI; PLMSI <15 and PLMSI  $\ge 15$ ), and sleep state (rapid eye movement, REM, and non-rapid eye movement, NREM). Agreement for the arousal index (ArI) was additionally analyzed using Bland-Altman bias, limits of agreement (LoA), and intraclass correlation coefficients (ICC). To explore the algorithm's ability to detect non-respiratory arousals, the proportion of scored arousals preceded by respiratory events was assessed, identifying arousals linked to respiratory events versus those from non-respiratory causes.

### **Study Population**

<u>Table 3: Performance of the Nox BodySleep 2.0 with regard to scoring arousals</u> <u>across OSA severity levels. Limits of Agreement (LoA) is shown as 1.96 x</u> <u>standard deviation of error. ICC = Intra Class Correlation.</u>

| AHI Category  | Sample Size (n) | Biasl (LoA)<br>(events/hour) | ICC (95%CI)       |
|---------------|-----------------|------------------------------|-------------------|
| AHI < 5       | 118             | -3.63 (-23.85, 16.59)        | 0.68 [0.57, 0.78] |
| 5 ≤ AHI < 15  | 416             | -3.08 (-22.91, 16.75)        | 0.67 [0.57, 0.76] |
| 15 ≤ AHI < 30 | 344             | -3.61 (-24.95, 17.73)        | 0.54 [0.42, 0.66] |
| $AHI \ge 30$  | 421             | -6.46 (-44.26, 31.34)        | 0.62 [0.53, 0.69] |

#### **Respiratory related arousals:**

Analysis with the Nox BodySleep 2.0 showed that respiratory-related arousals represented 10% to 90% of arousals observed in sleep recordings, with a median of 49%.

This highlights the algorithm's ability to detect **both respiratory and non-respiratory arousals**, capturing diverse arousal profiles across sleep recordings.

### Conclusions

#### <u>Table 1: Overview of sample characteristics shown as absolute values per sex,</u> age and apnea-hypopnea index (AHI) group (N = 1299)

| Characteristic | Mean ± SD   | Unit              |  |
|----------------|-------------|-------------------|--|
| Age            | 48.6 ± 17.0 | years             |  |
| BMI            | 29.5 ± 7.8  | kg/m <sup>2</sup> |  |
| AHI            | 26.9 ± 24.9 | events/hour       |  |
| Sex, M         | 616         | count             |  |
| Sex, F         | 673         | count             |  |
| Sex, Unknown   | 10          | count             |  |

Nox BodySleep 2.0 demonstrates robust and consistent performance in detecting arousals across OSA severity levels, PLMS index levels, and sleep stages (NREM and REM).

Notably, the algorithm captures both respiratory-related and non-respiratory arousals from respiratory signals alone, thereby enabling arousal detection beyond what is typically achievable in home sleep testing without EEG.

This capability positions respiratory signal-based models as a promising solution for more comprehensive arousal profiling in home sleep testing sleep diagnostics.

#### References:

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