WatchPAT™ Scoring Guidelines

Leveraging automated scoring with visual oversight

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1. Introduction

The WatchPAT, a device for Home Sleep Apnea Testing (HSAT) based on Peripheral Arterial Tone (PAT™) signal has revolutionized the approach to sleep apnea testing over a decade ago with the introduction of an easy to use, yet comprehensive alternative to traditional diagnostic methods. This technology measures all conventional HSAT indices such as AHI and ODI, and supplements these indices with other critical measures of sleep architecture (total sleep time, REM and NREM sleep time), along with reliable body position, snoring and recently identification of Central Apnea events.

Recently, HSAT has gain much attention and focus as awareness for sleep apnea has grown substantially, while cost constraints from third party payers have limited access to in-lab polysomnography. Even more important are recent data and guidelines, suggesting that sleep apnea contributes to the development and progression of highly prevalent comorbidities including atrial fibrillation, cardiovascular disease, diabetes and congestive heart failure. Its recognition demands an affordable, easy to use method for a reliable diagnostic testing.

In early 2017, published Clinical Practice Guidelines officially recognized PAT-based technologies as technically adequate for HSAT. Nonetheless, the American Academy of Sleep Medicine and most third party payers require manual scoring and review of HSATs. This mandate resonates with traditional roles of sleep professionals, who are trained to score, review, edit and ratify results from sleep studies. This approach is reflected by recent AASM updates on Sleep Apnea Test Scoring Guidelines, which facilitate systematic approaches to scoring and reviewing. WatchPAT technology, however, is unique among HSAT devices in its ability to render a fully automated, validated report, which compares extraordinarily well to gold standard polysomnography. Yet methods for implementing guidelines for scoring and review of WatchPAT recordings are not yet available.

To address the AASM requirement, we conducted a large study (n=455) with a typical mix of patients, who were referred to the Johns Hopkins Sleep Center. The project has developed a streamlined approach for reviewing and editing the automated results from WatchPAT recordings. This booklet will outline the physiologic background for the approach, provide methodology for editing WatchPAT recordings, and describe step by step procedures to allow the sleep professional to comfortably review and confirm a WatchPAT study.

2. Methodology

Cohort was studied in order to generate data base for the project. 455 unselected patients who had been referred to the sleep lab for diagnostic sleep study. The cohort included patients with various comorbidities such as AFIB, Pulmonary, Sleep and Pre-Surgical. For study purposes, the WatchPAT was modified to allow for the recording of the PAT analog signal and PSG together with the conventional full set of channels (EEG, EOG, EMG, SpO2, NAF, Belts, ECG, position and snoring). In addition, WatchPAT automatically scored events were entered into the PSG recording system where PSG was manually scored by Johns Hopkins scorers and reviewed by the sleep experts. Eventually, zzzPAT, the raw data review and scoring software of WatchPAT™, was configured specially to resemble standard PSG software GUI, workflow and scoring methodology.

With the objective to understand AHI scoring, both components of AHI were looked at: first, the agreement between the sleep-wake and hypnogram of both systems was compared at assess Total Sleep Time and REM time. Secondly, to assess the number of events the WatchPAT automated scoring was compared, to the overall study indices (REM AHI and NREM AHI, Total AHI, RDI, ODI, TST etc.). Overall WatchPAT was over-scoring vs manually scored PSG. As a next step, WatchPAT was manually scored until it matched the PSG data. Based on the results – the team developed a WatchPAT editing algorithms led by "delete vs keep events" criteria, "keep existing events" criteria as well as "add missing events" criteria. A thorough flowchart of a per-patient WatchPAT editing events was then developed based on WatchPAT signals (amplitude changes, HR changes, SpO2, snoring, body position changes and actigraphy).

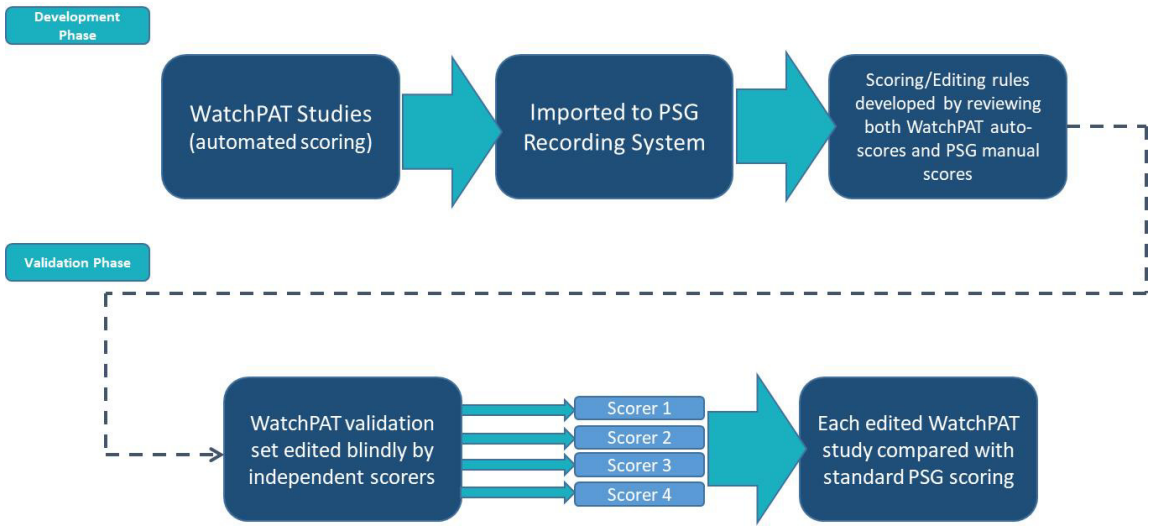


Figure 1: *Study Flow Chart*

3. Basics of PAT

PAT™ - Peripheral Arterial Tonometry, is a non-invasive window into the Autonomic Nervous System at the finger. PAT signal is an accurate measure of the Pulsatile Arterial Volume at the finger and manifests vascular and micro-vascular activity which depends on sympathetic activity. This signal provides critical insight for classifying sleep/wake state and detecting sleep disordered breathing events.

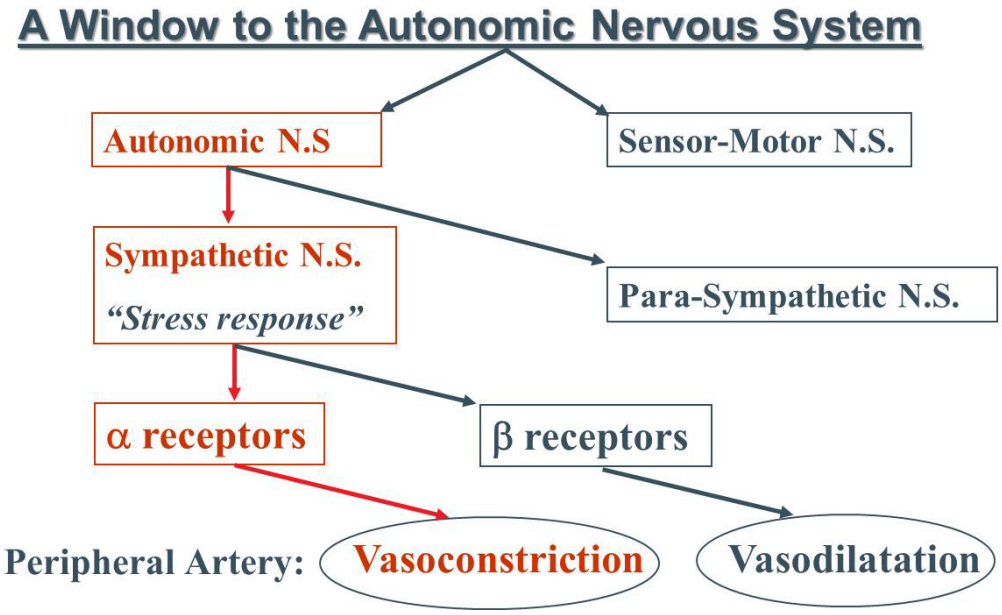


Figure 2: *The Pathophysiology of the PAT signal*

Unlike most peripheral arteries, the arterial walls at the finger and the arteriovenous anastomoses control are solely innervated by the α-adrenergic receptors pathways thus increased sympathetic surge is associated with vasoconstriction at the finger and a PAT amplitude attenuation

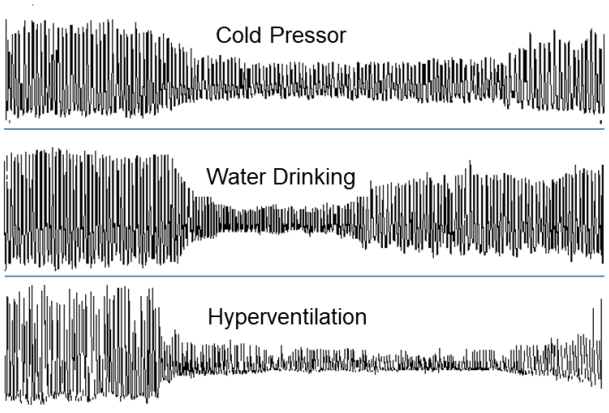


Figure 3: *PAT sympathetic manifestation*

3.1. Sleep Disordered Breathing Detection with PAT

Sleep disordered breathing terminates with Sympathetic surge. Respiratory event is caused either by an upper airway obstruction following the collapse of upper airway wall or central dysfunction in which the brain doesn't send proper signals to the muscles that control breathing. Both are leading to a respiratory event (Apnea episode). During the apnea episode, sympathetic activation causes vasoconstriction and acceleration of the heart rate. This result with attenuation of the PAT signals.

WatchPAT example of OSA

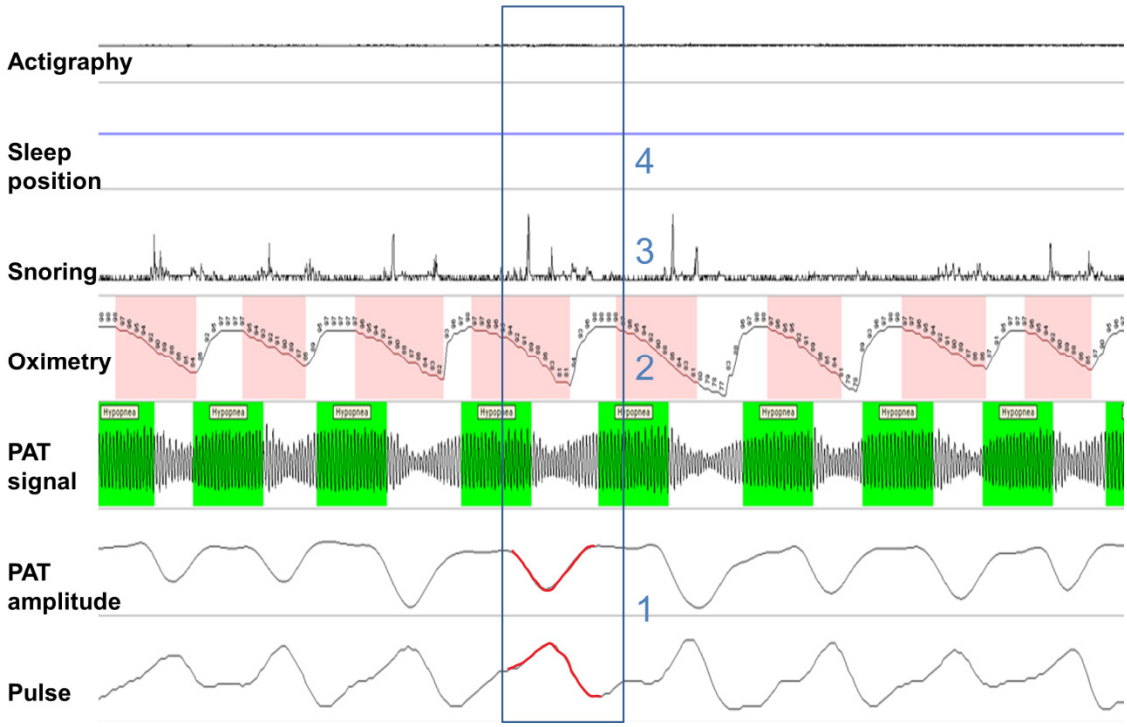


Figure 4: *PAT attenuation with Sleep Disordered Breathing*

1. Reciprocal pattern with the PAT and heart rate signal
    a. PAT amplitude decrease during an event
    b. Heart rate increase during an event
2. Corresponding desaturations
3. Snoring present
4. No positional change

3.2. Sleep Stages Classification with PAT

PAT acts differently in each of the sleep stages. See below figure 5,6,7,8 and Table 1 for PAT and other signals change during different sleep stages.

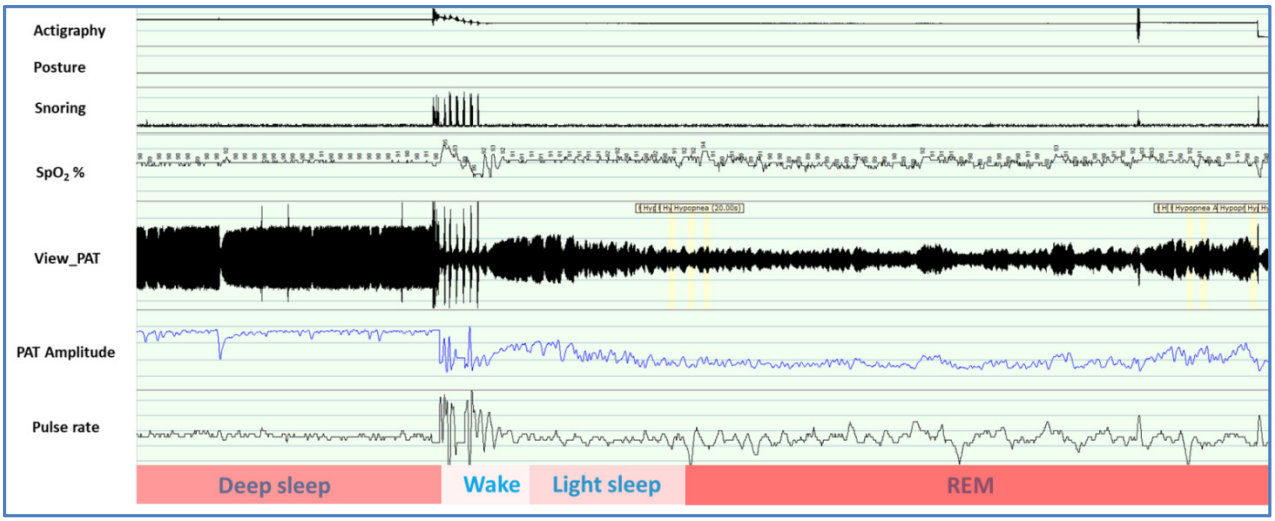


Figure 5: *Change in PAT and other signal in different sleep stages*

Wake

- High variability in heart rate
- High SpO2 levels
- Sporadic SpO2 desats
- Changes in body position (Not in this example)
- Low PAT amplitude, preceding gradual increase when transitioning to sleep

REM

- Irregular heart rate and PAT amplitude
- Heart rate often elevated (lower than in wake)
- Lowest SpO2 values
- Irregular SpO2 fluctuations
- Low PAT amplitude

NREM

- Regular HR and PAT (little fluctuation); Overall increased PAT amplitude, no movements

Table 1*: Sleep Stages*

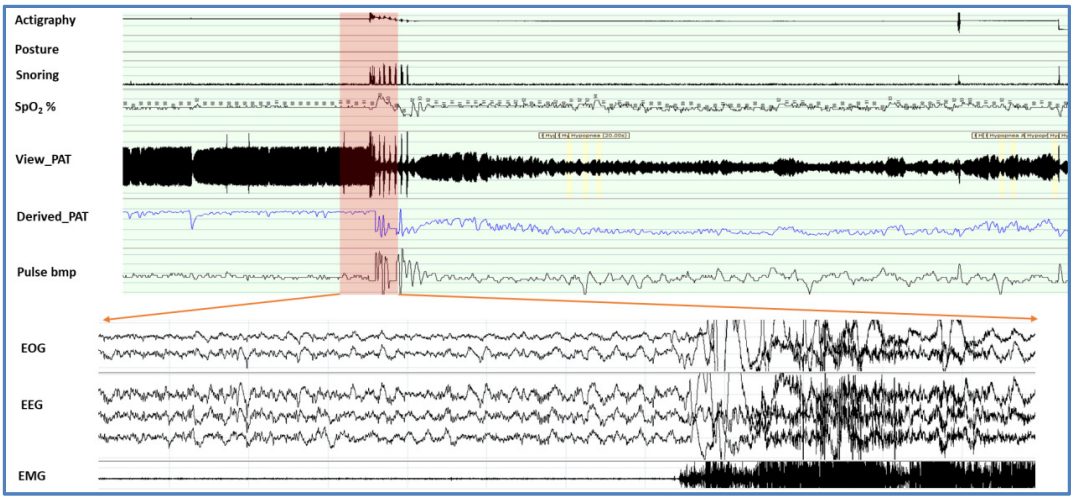


Figure 6: *Changes in signals from* ***Deep Sleep to Wake***

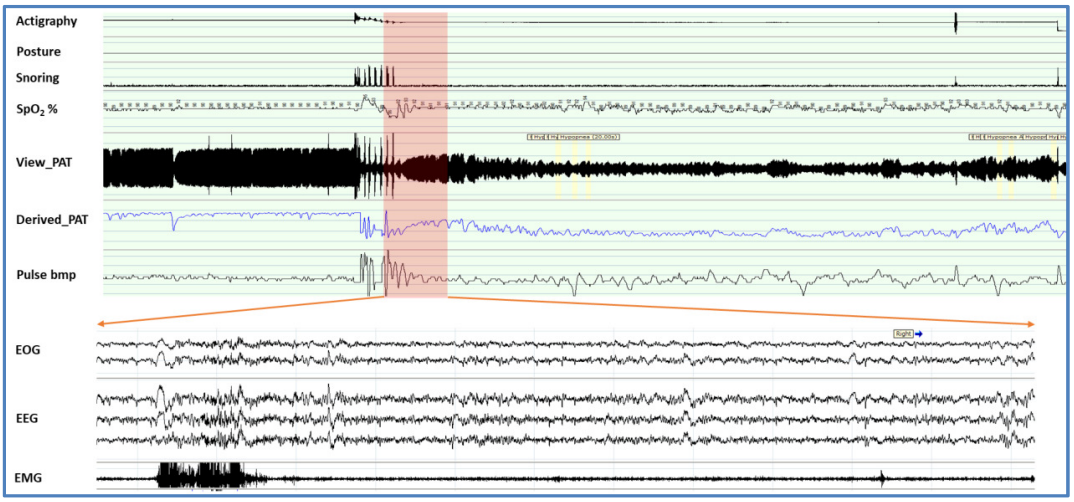


Figure 7: *Changes in signals from* ***Wake to Light Sleep***

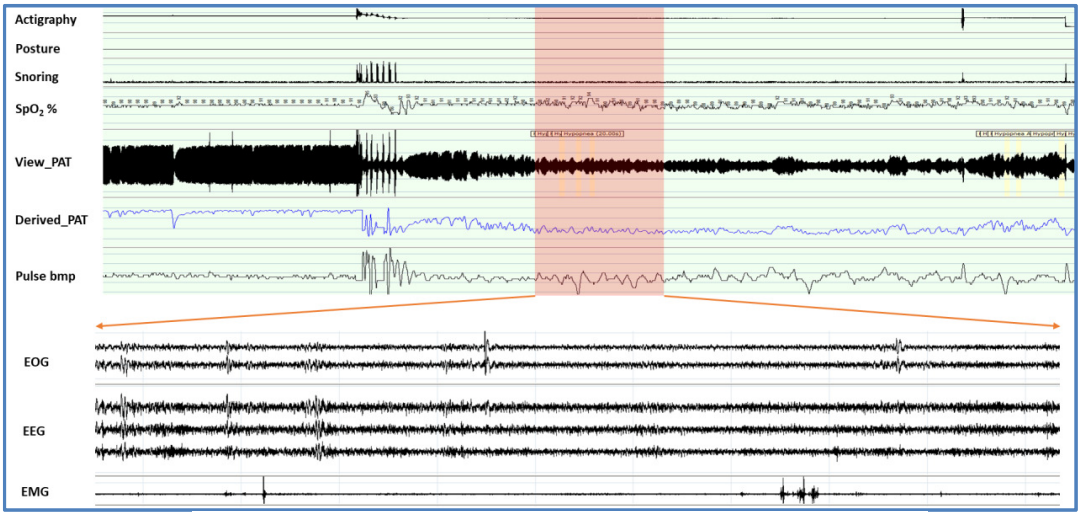


Figure 8: *Changes in signals from* ***Light Sleep to REM***

4. Overview of the Scoring

WatchPAT™ identifies changes in the PAT signal amplitude, heart rate and actigraphy to stage wake, REM and NREM. In brief, the actigraphy and heart rate signals are used to distinguish wake/sleep, while the PAT amplitude and heart rate signal changes are used to identify sleep stages as previously validated (REM vs. NREM). The visual inspection of the PAT amplitude and heart rate allows the end user to visually verify and edit of the staging of wake vs. sleep and REM vs. NREM detection, based on features outlined in below Table 1.

Step by step Scoring Procedure

Step 1: Hypnogram Review and Editing

This step is designed to verify the sleep staging which requires 6 hours of recorded time to obtain accurate results

1. Open WatchPAT signals in zzzPAT
2. Display signals in a 30 to 60 minute time window
3. Review WatchPAT graphic display and identify emblematic periods of Wake and REM based on characteristics of Wake and REM sleep as detailed in Table 1
4. Compare all Wake and REM periods to aforementioned emblematic periods in step 1
5. Adjust sleep stages accordingly if PAT amplitude, heart rate and SpO2 tracings do not show the typical features as outlined in Table 1 and shown in below examples (Example 1 and 2)

Table 1

Wake

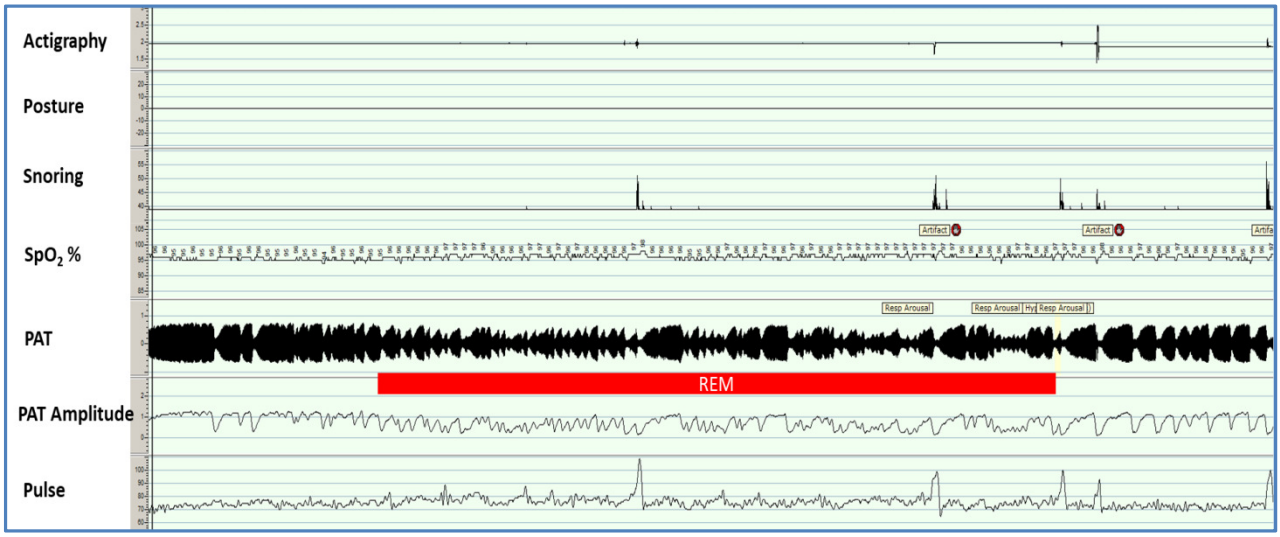
- High variability in heart rate
- High SpO2 levels
- Sporadic SpO2 desats
- Changes in body position
- Low PAT amplitude, preceding gradual increase when transitioning to sleep

REM

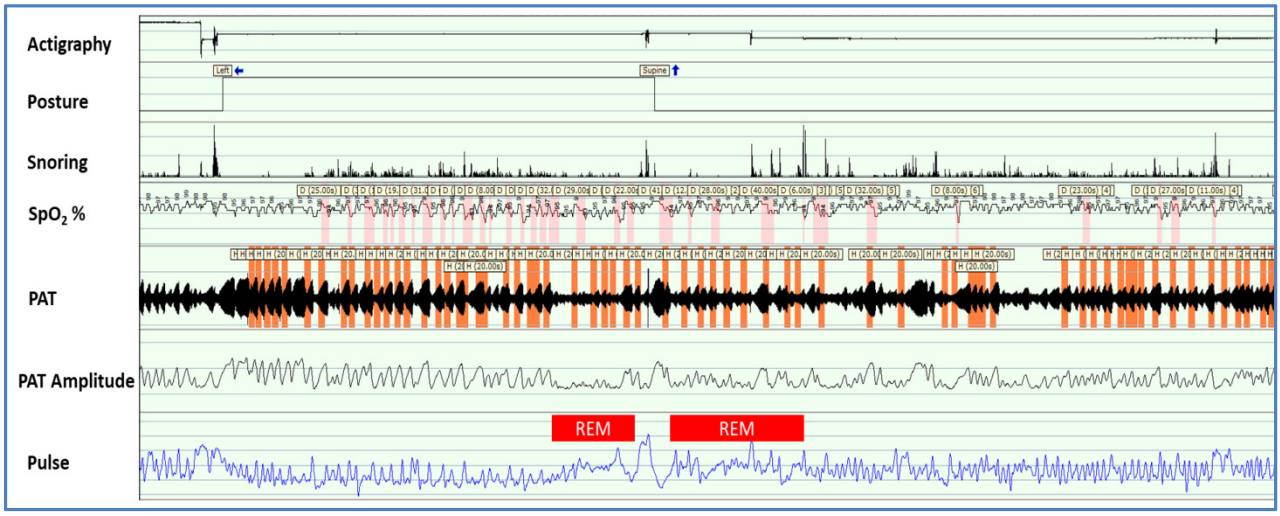
- Irregular heart rate and PAT amplitude
- Heart rate often elevated (lower than in wake)
- Lowest SpO2 values
- Irregular SpO2 fluctuations
- Low PAT amplitude

NREM

- Regular HR and PAT (little fluctuation); Overall increased PAT amplitude, no movements



Example 1: *REM Sleep - Low PAT amplitude – irregular heart rate and SpO2 fluctuations*



Example 2: *Irregular heart rate SpO2 fluctuations – low and irregular PAT amplitude*

Step 2: Sleep Disordered Breathing Event review and editing

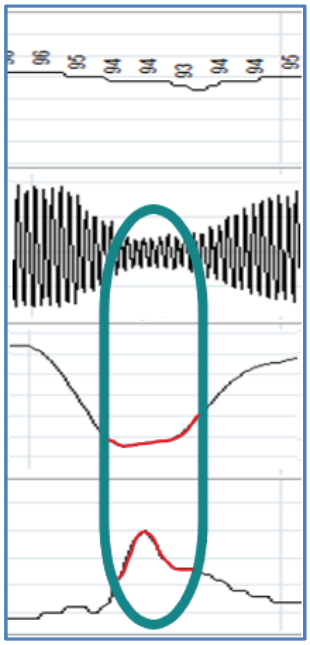
WatchPAT defines events by sympathetic activations and desaturations. Sympathetic activations are defined by PAT amplitude attenuation and heart rate increase.

Apneas and hypopneas are usually terminated with a sympathetic discharge. This discharge is characterized by a decrease in PAT amplitude and increase in the heart rate. This reciprocal pattern response is seen in the PAT amplitude decrease and a heart rate increase (see figure 9).

a. PAT amplitude may vary independent of arousal, in response to changes in vascular tone of the finger. In this case, there is no associated heart rate increase and therefore no typical pattern (see figure 10).

b. Spontaneous arousals can also produce a decrease in PAT amplitude and an increase in heart rate. The pattern of this change, however, differs in several aspects as shown in figure 10 and explained below.

The WatchPAT has algorithms to differentiate apnea and hypopnea events from other events that can produce acute PAT decrease and some HR increase such as PLMs or spontaneous arousals. If the increase in heart rate is minimal, the PAT attenuation is not labeled as an event (Figure 10); however, if there is a significant increase in heart rate and/or a SpO2 re-saturation of ≥ 3%, events are classified as RERAs.



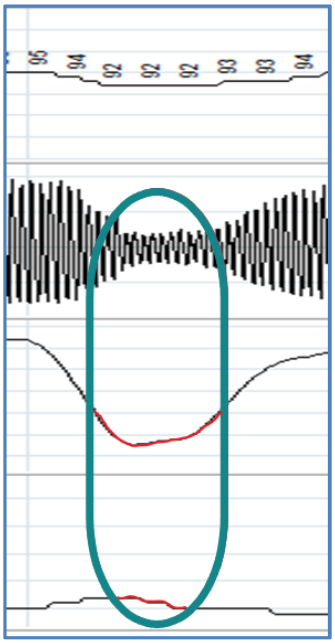


Figure 9: *Typical pattern of PAT Amp attenuation and HR increase*

Figure 10: *Absence of Typical pattern of PAT Amp attenuation and HR increase*

Editing Rules: Sleep Disordered Breathing Event

1. Open the study in zzzPAT for event corrections (10-15 minutes window).

   A. Correct only respiratory events labeled as unclassified or obstructive. Rules for deleting events are less stringent than rules for adding events.

   B. **Delete** event if:

   i. Event does not have the typical pattern of PAT amplitude reduction and HR increase.
   ii. Event is associated with a positional change
   iii. Pattern with a desaturation < 3%, unless there is one of these other hallmarks present: change in snoring pattern or a movement (see Figure 11).

   C. **Add** event if:

   i. Typical Pattern along with a desaturation of ≥ 3% (see Figure 12)
   ii. If 3 or more events are added during Wake, adjust the sleep stage to NREM.

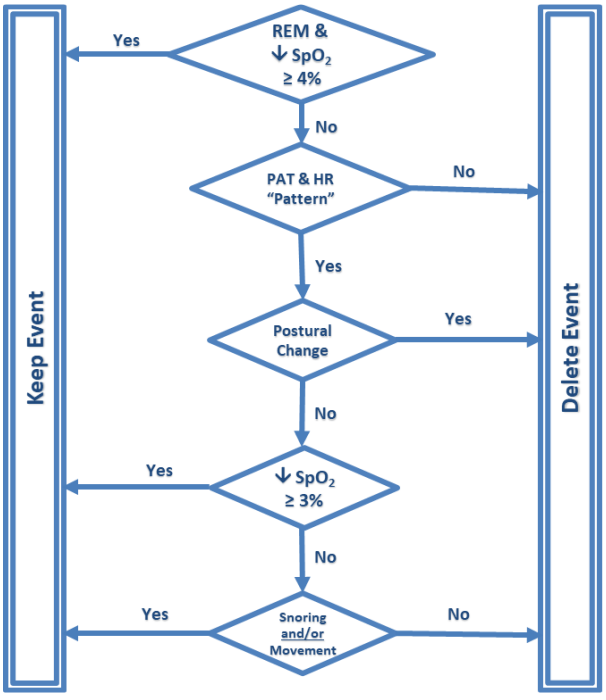


***Figure 11**: Keep and delete events*

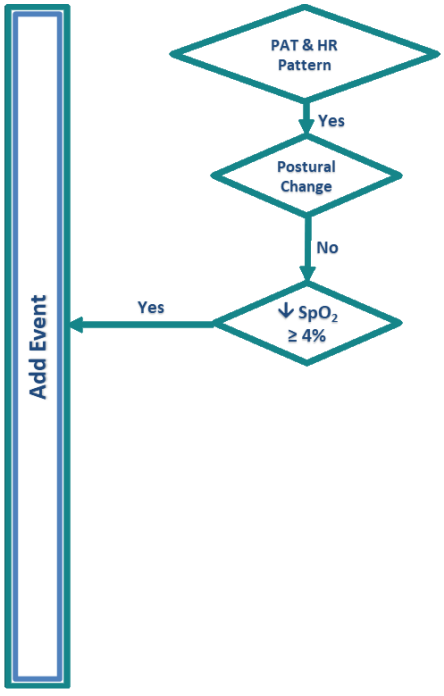
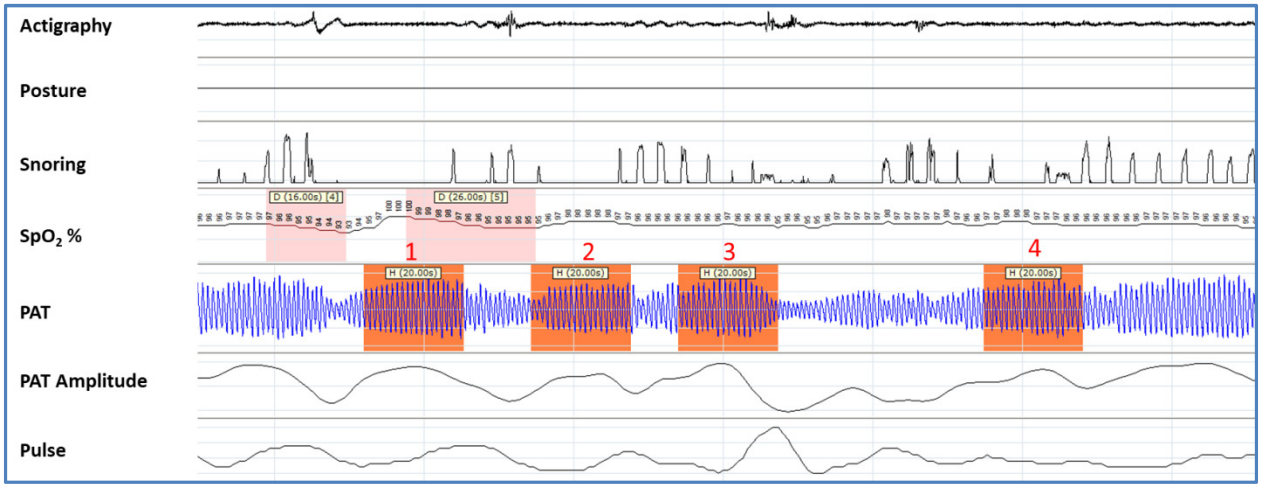


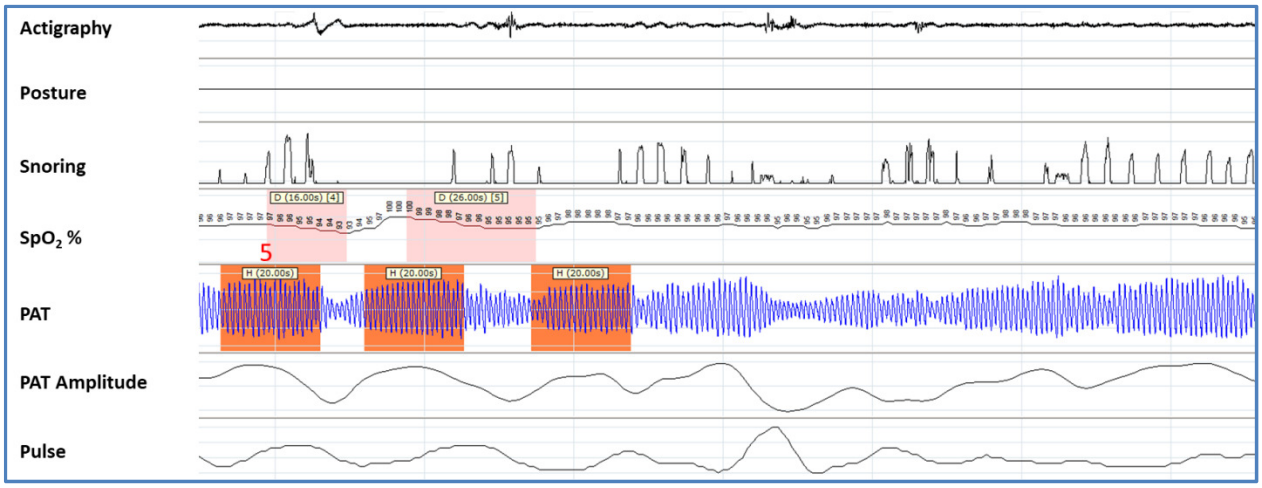
***Figure 12**: Add events*

Example 1:

Before editing



After editing



Event 1 and 2 was kept due to:

- Sleep stage - NREM
- PAT and HR pattern
- No posture change
- ≥ 3% change in SpO2

Event 3 deleted due to:

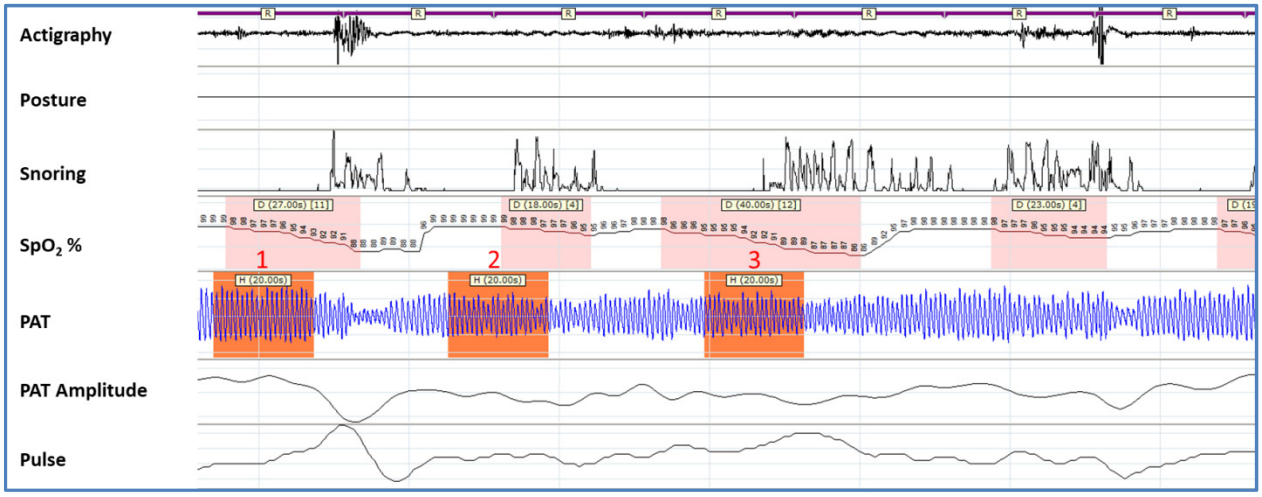
- Sleep stage – NREM
- PAT and HR pattern
- No ≥ 3% change in SpO2
- No snoring

Event 5 added due to:

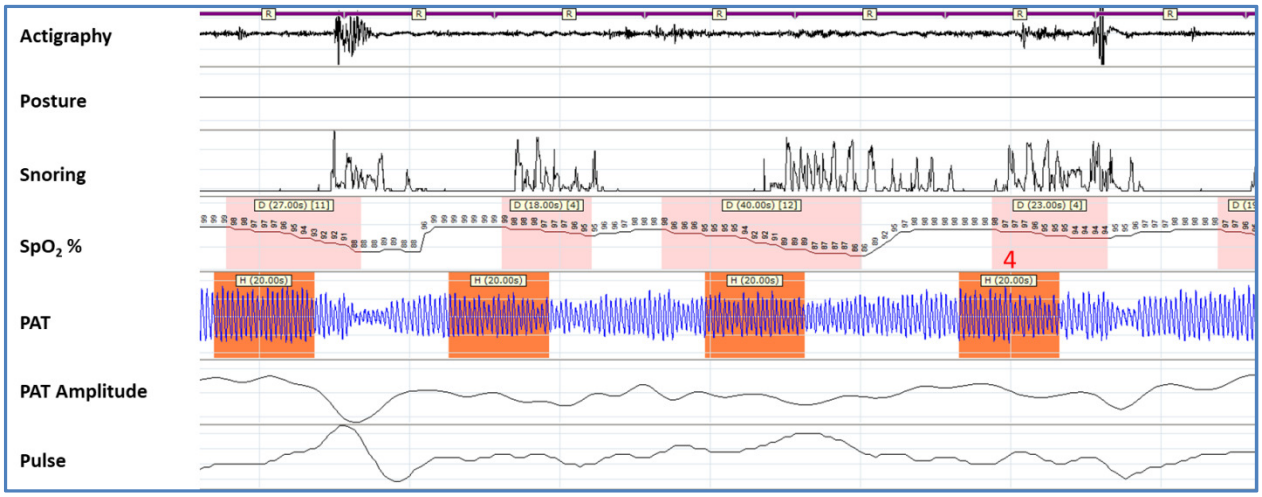
- PAT and HR pattern
- ≥ 4% change in SpO2

Example 2:

Before editing



After editing



Event 1- 2 and 3 was kept due to:

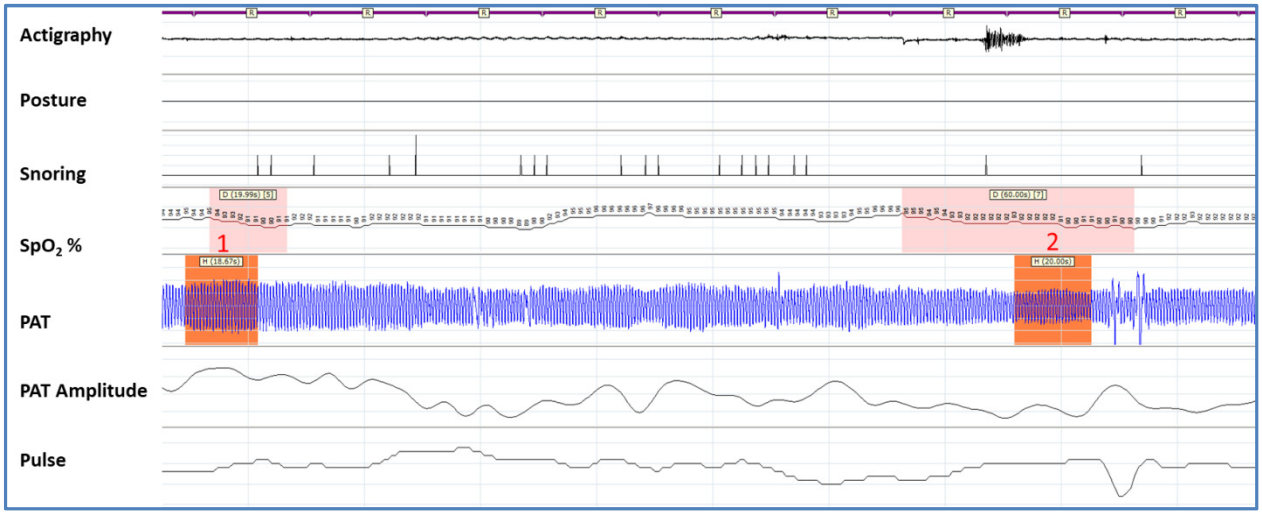
- Sleep stage - REM
- ≥ 4% change in SpO2

Event 4 added due to:

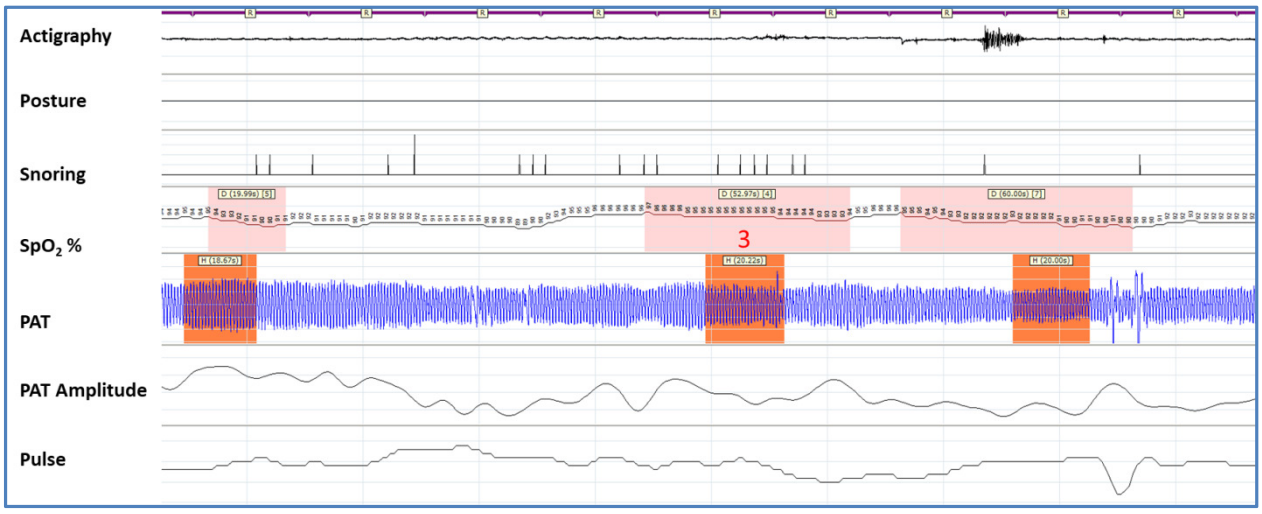
- PAT and HR pattern
- ≥ 4% change in SpO2

Example 3:

Before editing



After editing



Event 1 and 2 was kept due to:

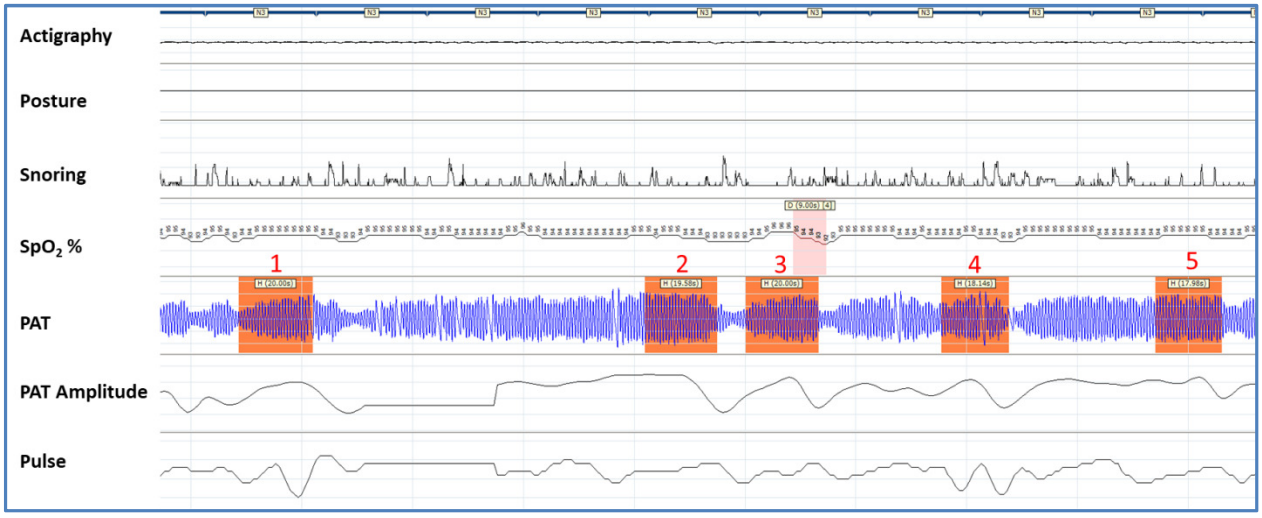
- Sleep stage - REM
- ≥ 4% change in SpO2

Event 3 added due to:

- Sleep stage - REM
- ≥ 4% change in SpO2

Example 4:

Before editing



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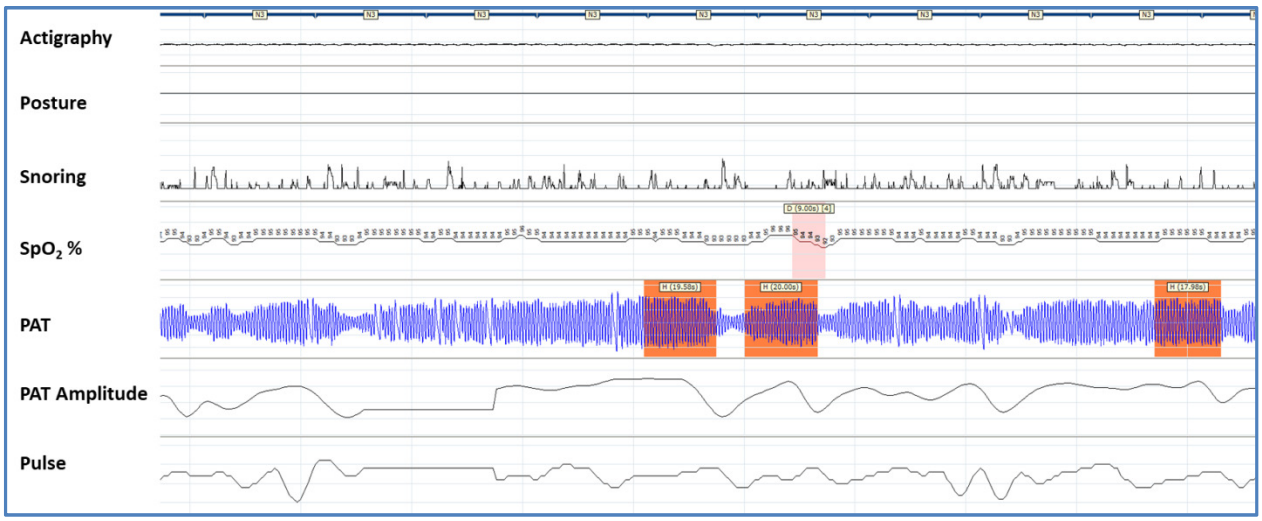


Event 1 and 4 was deleted due to:

- Sleep stage - NREM
- No PAT and HR pattern

Event 2 and 5 kept due to:

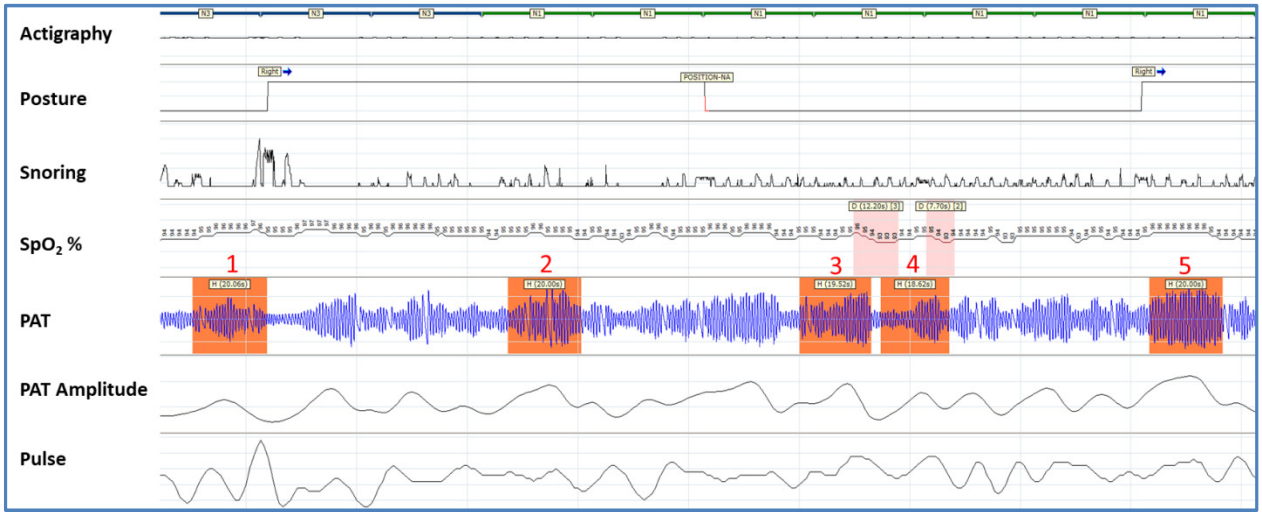
- Sleep stage - NREM
- No ≥ 3% change in SpO2
- Snoring

Event 3 kept due to:

- Sleep stage - NREM
- PAT and HR pattern
- No posture change
- ≥ 3% change in SpO2

Example 5:

Before editing



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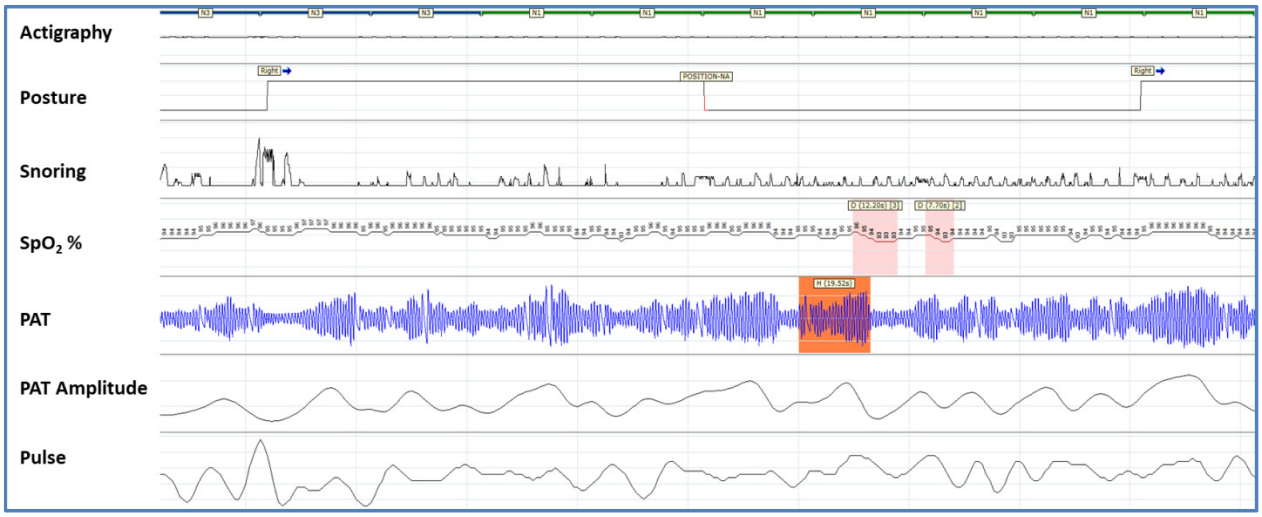


Event 1 was deleted due to:

- Sleep stage - NREM
- PAT and HR pattern
- Posture change

Event 2 and 5 were deleted due to:

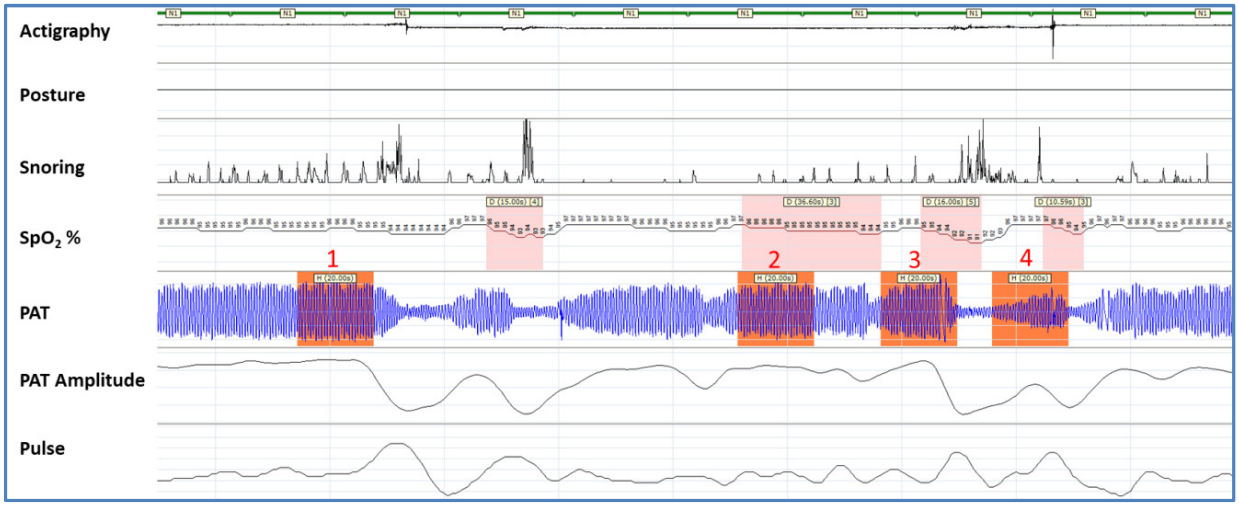
- Sleep stage - NREM
- No PAT and HR pattern

Event 4 was deleted due to:

- Sleep stage - NREM
- PAT and HR pattern
- No posture change
- Only 2% change in SpO2

Example 6:

Before editing



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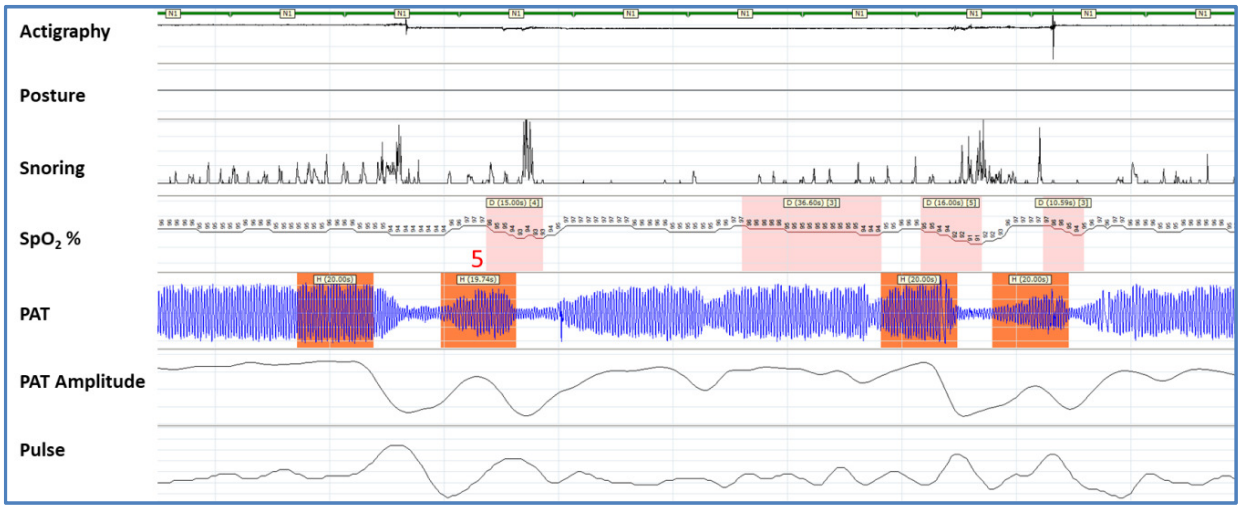

Event 1 was kept due to:

- Sleep stage - NREM
- PAT and HR pattern
- No posture change
- No snoring

Event 3 and 4 were kept due to:

- Sleep stage - NREM
- PAT and HR pattern
- ≥3% change in SpO2

Event 2 was deleted due to:

- Sleep stage - NREM
- No PAT and HR pattern

Event 5 was added due to:

- Sleep stage - NREM
- PAT and HR pattern
- No posture change
- ≥4% change in SpO2

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