ORIGINAL ARTICLE

The use of combined thermal/pressure polyvinylidene fluoride film airflow sensor in polysomnography

Meir Kryger · Todd Eiken · Li Qin

Abstract

Background The technologies recommended by the American Academy of Sleep Medicine (AASM) to monitor airflow in polysomnography (PSG) include the simultaneous monitoring of two physical variables: air temperature (for thermal airflow) and air pressure (for nasal pressure). To comply with airflow monitoring standards in the sleep lab setting thus often requires the patient to wear two sensors under the nose during testing. We hypothesized that a single combined thermal/pressure sensor using polyvinylidene fluoride (PVDF) film responsive to both airflow temperature and pressure would be effective in documenting abnormal breathing events during sleep.

Methods Sixty patients undergoing routine PSG testing to rule out obstructive sleep apnea at two different sleep laboratories were asked to wear a third PVDF airflow sensor in addition to the traditional thermal sensor and pressure sensor. Apnea and hypopnea events were scored by the sleep lab technologists using the AASM guidelines (CMS option) using the thermal sensor for apnea and the pressure sensor for hypopnea (scorer 1). The digital PSG data were also forwarded to an outside registered polysomnographic technologist for scoring of respiratory events detected in the PVDF airflow channels (scorer 2).

Results The Pearson correlation coefficient, r, between apnea and hypopnea indices obtained using the AASM sensors and the combined PVDF sensor was almost unity for the four calculated indices: apnea–hypopnea index (0.990), obstructive apnea index (0.992), hypopnea index (0.958), and central apnea index (1.0). The slope of the four relationships was virtually unity and the coefficient of determination (r^2) was also close to 1. The results of intraclass correlation coefficients (>0.95) and Bland–Altman plots also provide excellent agreement between the combined PVDF sensor and the AASM sensors.

Conclusion The indices used to calculate apnea severity obtained with the combined PVDF thermal and pressure sensor were equivalent to those obtained using AASM-recommended sensors.

Keywords Sleep apnea · Polysomnography · Nasal pressure · Monitoring · Thermistor · PVDF

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Introduction

The technologies recommended to monitor airflow in polysomnography (PSG) include the simultaneous monitoring of two physical variables: air temperature and air pressure [1]. These methods which have been used for decades consist of a thermal sensor method for detecting apnea events and a nasal/oral pressure sensor for detecting hypopnea events [2]. The response time of a conventional thermistor sensor is sufficiently fast enough for detecting and displaying waveforms consistent with apnea events, but too slow for displaying hypopnea episodes. The response time of an airflow pressure monitor is faster than a thermistor and is therefore more suitable for displaying waveforms consistent with hypopnea events [2, 3].

To comply with airflow monitoring standards in the sleep lab setting typically requires the patient to wear two sensors under the nose during testing [1]. Typically, a nasal/oral thermistor sensor is placed on the patient first as it is the smaller of the two sensors, and a nasal/oral nasal pressure cannula is then placed on top of the thermistor. Alternatively, new combination sensor devices have been manufactured to help accomplish this dual sensing methodology. Some of the problems encountered in the sleep lab while using multiple sensors include patient discomfort due to multiple sensors being placed under or in the nose, reduced sensitivity of the thermal sensor due to the airflow pressure cannula being placed on top of the thermal sensor and reduced nasal flow due to the nasal cannula placement, and increased testing costs resulting from disposable cannula requirements. These and other potential problems encountered while using dual methods of airflow monitoring during clinical PSG could be resolved if a single method of airflow monitoring were capable of capturing both hypopnea and apnea events with the same degree of sensitivity as thermal and pressure sensing methods.

A relatively new single type of combined thermal/pressure sensor using polyvinylidene fluoride (PVDF) film has been developed which has a faster response time than traditional thermal devices and a comparable response time to pressure-based airflow devices. The sensor appears to produce signals that more accurately display changes in airflow. The PVDF signal is proportionally linear to the differences in temperature and pressure. The single PVDF device can detect both nasal and oral airflow. The output of the sensor can be split into two different signals, each filtered in such a manner to optimize waveform displays consistent with hypopnea events in one channel and apnea events in the other. The purpose of this study was to compare the ability of a PVDF device (Dymedix Corp, Shoreview, MN, USA), a traditional thermal sensor to detect and display apnea events, and a traditional nasal/oral pressure sensor to detect and display hypopnea events.

Methods

A total of 60 patients undergoing routine PSG testing to rule out obstructive sleep apnea at two different sleep laboratories were asked to wear a third PVDF airflow sensor (Dymedix Diagnostics) in addition to the traditional thermal and sensors. The subjects signed an informed consent form before participating in the study. The project was approved by United Hospital, St. Paul, MN, USA and Noran Neurological Clinic, Blaine, MN, USA.

Routine digital polysomnography was performed (E-Series, Compumedics, Charlotte, NC, USA and XLTEK, Natus Medical Inc., San Carlos, CA, USA). Right and left

electrooculograms; frontal, central, and occipital EEG; submental chin and bilateral anterior tibialis electromyogram; ECG; airflow, thoracic, and abdominal respiratory effort; and oximetry were recorded. Abdominal and chest wall effort was recorded using respiratory inductance plethysmography belts (SleepSense SLP Corp, St Charles, IL, USA). A total of four airflow channels were recorded during each test: thermal sensor—apnea, pressure sensor—hypopnea, PVDF—apnea, and PVDF—hypopnea. A PVDF sensor was first placed on the upper lip of the patient, then a traditional thermal sensor and a nasal/oral pressure cannula were placed on the upper lip as well.

The thermal sensor used was a thermocouple (Ambu Sleepmate®, Ambu, Corp. Ballerup, Denmark) whose signal was acquired with a high-frequency filter (HFF) of 15 Hz and a low-frequency filter (LFF) of 0.1 Hz. The pressure sensing system used was comprised of a cannula system (Pro-Flow® nasal cannula, Phillips/Respironics, Monroeville, PA, USA) plugged into the pressure transducer port which is built into the XL-TEK PSG system electrode input box. The pressure signal was acquired with HHF of 15 Hz and LLF of 0.05 Hz.

A combined PVDF sensor (Dymedix Corp) was used. The PVDF thermal data were acquired with a HFF of 15 Hz and LFF of 0.1 Hz. The PVDF pressure data were acquired with a HFF of 15 Hz and LFF of 0.05 Hz. The sampling rate for all the pressure and thermal sensor channels was 100 Hz.

Sleep was manually staged in 30-s epochs using standard criteria by registered polysomnographic technologists employed at the sleep labs. Apnea and hypopnea events were scored by the sleep lab technologists in a routine manner using the thermal sensor for apnea and the pressure sensor for hypopnea (scorer 1). After the patients were processed through the sleep lab, the digital PSG data were forwarded to an outside registered polysomnographic technologist for scoring of respiratory events detected in the PVDF airflow channels (scorer 2). Scorer 1 respiratory event scoring results displayed within the PSG data were removed prior to PVDF event scoring by scorer 2. Respiratory events were defined by the American Academy of Sleep Medicine criteria [1]. For hypopnea, we used the Centers for Medicare Services mandated definition of hypopnea (CMS option) defined as a 30 % or greater reduction in airflow (nasal pressure) amplitude, accompanied by a 4 % or greater desaturation and a duration of at least 10 s.

Statistical methods

Data analyses were undertaken using Excel (Microsoft, Redmond WA, USA) and SAS, version 9.2 (SAS Institute, Cary, NC, USA). Continuous data were expressed as mean (SD and range). Patient characteristics

considered were age, sex, BMI, and apnea–hypopnea index (AHI). The sleep breathing indices are compared between the combined PVDF sensor and the AASM-recommended sensors using Pearson correlation coefficients, intraclass correlation coefficients (ICC), and Bland–Altman plots [4].

Results

Subjects

The 60 subjects, mean age 49.9 years (SD 13.6, range 24–84 years) and mean BMI 34.8 (SD 8.1, range 19.9–67.4), were made up of 32 females and 28 males. The mean AHI (using the AASM-recommended sensors) was 29.8 (SD 29.9, range

0.4–116). Thus, the sample included both sexes and a diverse range of age, BMI, and AHI.

Detection of events

The utility of the combined sensor in yielding indices, which are important since they are the metrics used to describe disease severity, was excellent. The Pearson correlation coefficient, r, was almost unity for the four calculated indices: AHI (0.990), obstructive apnea index—OAI (0.991), hypopnea index—HI (0.958), and central apnea index—CAI (0.999). The slope of the four relationships was virtually unity and the coefficient of determination (r^2) was close to unity as shown next.

Figure 1(a) shows the relationships between indices obtained by the combined sensor (on the vertical axes)
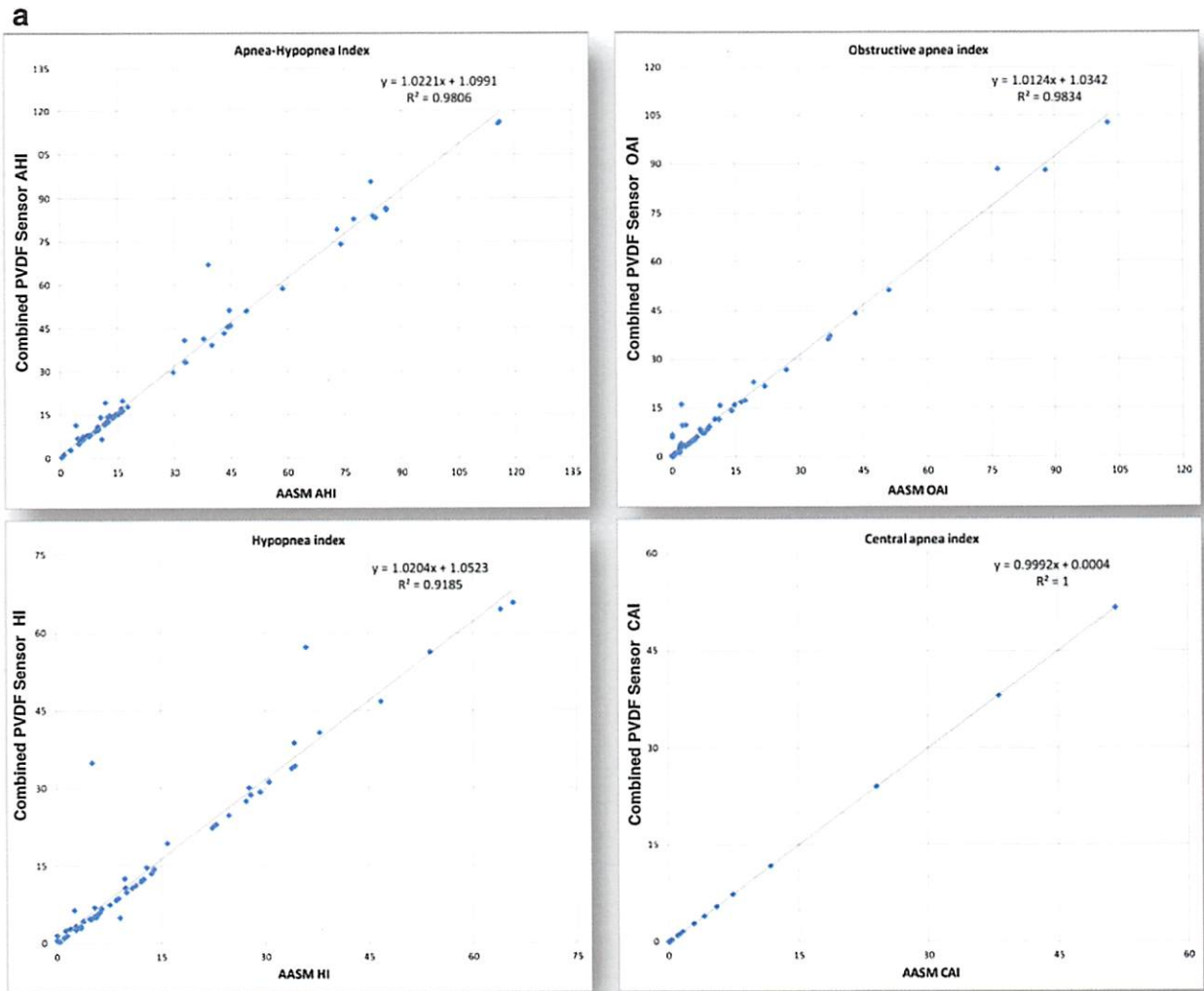
Fig. 1 a Sleep breathing event indices using AASM-recommended separate temperature and pressure sensors versus the combined thermal/pressure polyvinylidene fluoride film airflow sensor. Central apneas were found in 17 of the 60 subjects. **b** Differences (combined AASM) plotted against the mean of using combined and AASM sensors for sleep breathing event indices. The *solid line* is the mean difference, and the *dotted lines* are the limits of agreement which are mean difference±2 SDs
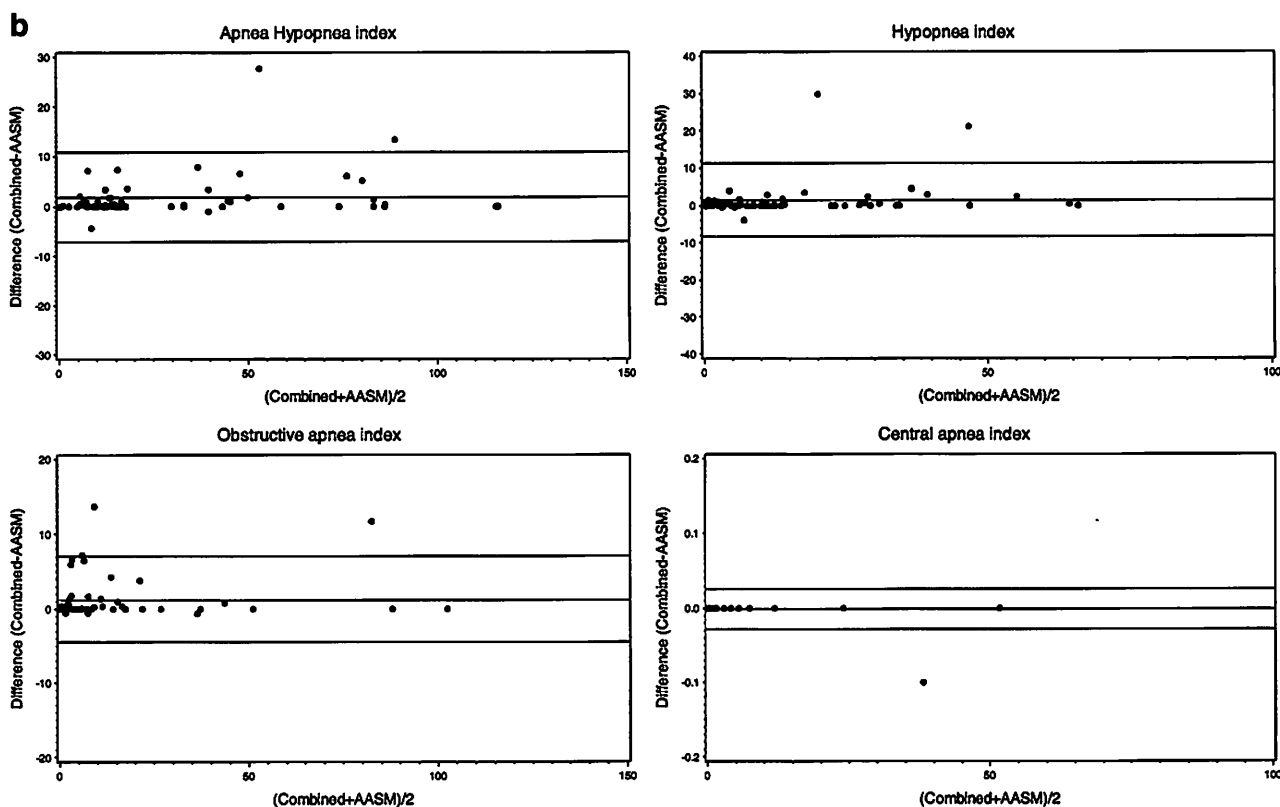
b

Fig. 1 (continued)

versus the AASM-recommended sensors (on the horizontal axes). There is an excellent correlation between the two.

Additionally, we also calculate ICCs which compare total variability among patients, measurement variability, and measurement error. Table 1 gives the ICC results of AHI, OAI, HI, and CAI between the combined PVDF sensor and the AASM-recommended sensors. All ICC results show that these two sensors agree to each other very well (ICCs>0.95). For example, for apnea–hypopnea index, the ICC of 0.988 (95 % CI, 0.980–0. 993) indicates that measures of AHI taken from either

Table 1 Agreement between AASM-recommended separate temperature and pressure sensors and the combined thermal/pressure polyvinylidene fluoride film airflow sensor

Index	ICC (95 % CI)
Apnea–hypopnea index	0.988 (0.980, 0.993)
Obstructive apnea index	0.990 (0.983, 0.994)
Hypopnea index	0.954 (0.925, 0.972)
Central apnea index	1.000 (1.000, 1.000)

AASM or combined sensor have a very high level of agreement, i.e., they are almost exactly the same.

Bland–Altman plots (Fig. 1(b)) demonstrate small upward bias (overestimation on average) for AHI, OAI, and HI in the combined PVDF sensor. For AHI and HI, positive biases are generated most for those with higher levels, but for OAI, biases could happen at any levels. These two sensors have almost the same results for CAI.
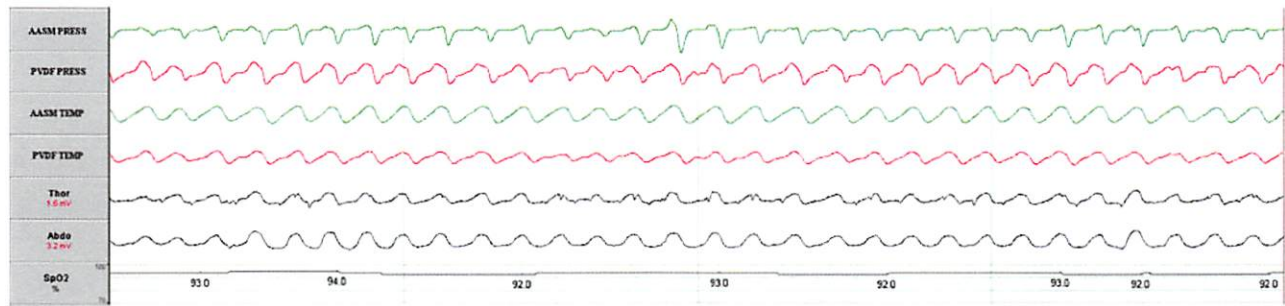
Discussion

This study shows that a combined sensor that responds rapidly to two physical properties, temperature and pressure, can accurately determine the metrics required to document sleep apnea using the AASM criteria. The CMS criteria have not changed even though the AASM manual has been recently updated. In our study, all Pearson correlation coefficients, intraclass correlation coefficients, and Bland–Altman plots provide strong evidence that the combined PVDF sensor and the AASM-recommended sensors agree to each other very well.

PVDF film converts one form of energy (heat and mechanical) into another (electrical). PVDF, as used in

Fig. 2 This figure shows normal breathing. Notice the PVDF and AASM waveforms are synchronous and practically identical. A mild degree of flow limitation is noted in both the AASM and PVDF PRESS channels (time base, 2 min)

the combined oronasal airflow sensors and respiratory effort belt sensors, is a polarized fluoropolymer whose electrons are aligned (similar to a magnet), and any force that disturbs this alignment causes the film to generate a measurable voltage. Thus, PVDF exhibits both piezoelectric (responding to mechanical changes) and pyroelectric properties (responding to thermal changes).

The piezoelectric output from the film is an electric current caused by mechanical forces which include pressure changes from changing oral or nasal airflow and changes in stress/strain from the changes in length caused by abdomen and ribcage movement in inspiration and expiration. The amplitude and frequency of the signal is directly proportional (linear) to the mechanical deformation of the PVDF film. The resulting deformation causes a change in the surface charge density of the film so that a voltage is generated.

The pyroelectric output from the film is an electric current resulting from applied temperature changes caused by the differences in the temperature of the airstream during inspiration versus expiration. The output current is proportional to the rate of temperature change (linear). In addition, as the film is heated and cooled, the resultant expansion and contraction induces secondary piezoelectric signals.

PVDF sensors are extremely sensitive and fast, and thus, signal conditioning is required in order to obtain a useful output voltage. However, no additional external power supply is required to generate or amplify the signal.

Thus, the sensors used in this research are PVDF films containing polymer chains (ferroelectric polymers) that respond to changes in electrical fields (ferroelectric behavior), mechanical stretch or stress (piezoelectric behavior), and temperature (pyroelectric behavior). Such films and sensors based on such materials are now widely used in medicine [5–12]. Such films have been validated in sensors that respond to respiratory efforts during polysomnography [13].

The two signals obtained from the PVDF sensor are virtually identical to those obtained using the AASM-recommended sensors. Figures 2, 3, and 4 show the equivalence of the sensors.

There have been few recent advances in the technology used to document abnormal breathing events during sleep. The basic technology to monitor respiratory effort (respiratory inductance plethysmography) was described in 1981 and remained the technology recommended by the standard manual last published in 2007 [1]. Other sensors have more recently been validated and are now considered acceptable
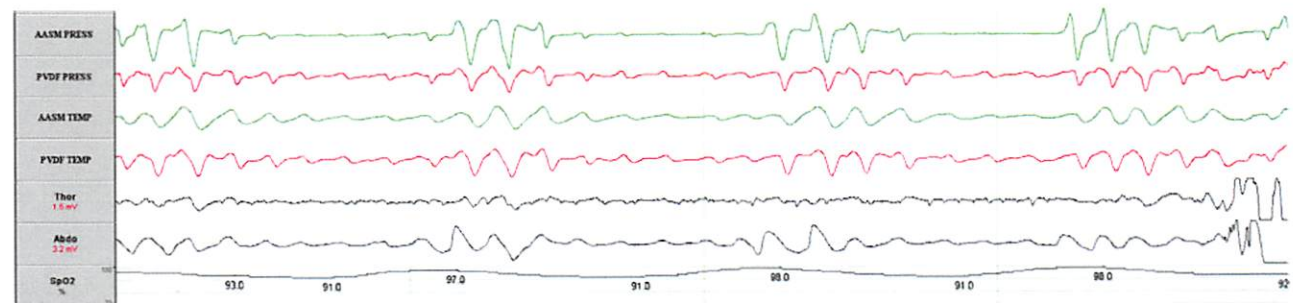
Fig. 3 This and the following figures show the simultaneous recording of AASM-recommended nasal pressure and thermistor (*green lines*) and outputs from the combined PVDF pressure and airflow temperature (*red lines*). This figure shows multiple AASM hypopnea events (CMS option) defined as a 30 % or greater reduction in airflow (nasal pressure) amplitude, accompanied by a 4 % or greater desaturation and a duration of at least 10 s. Notice the hypopnea events are also clearly demonstrated in the PVDF PRESS tracing (time base, 2 min)
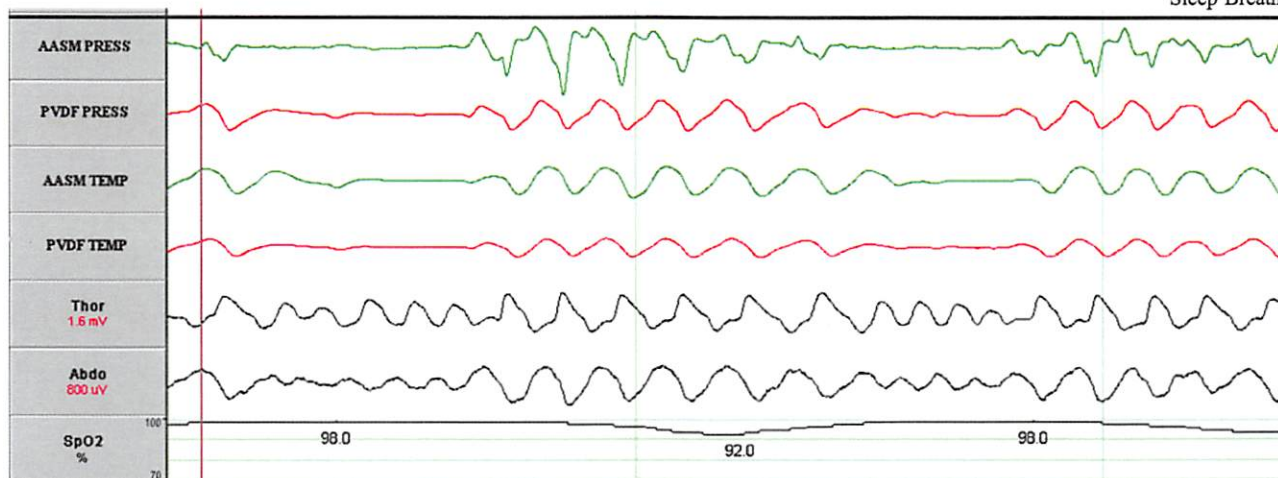
Fig. 4 This figure shows two AASM apnea events defined as a 90 % or greater reduction in airflow (temperature) amplitude and a duration of at least 10 s. Notice the apnea events are also clearly demonstrated in the PVDF TEMP tracing as well as all other airflow channels (time base, 2 min)

[13]. Until about 1997, thermistors were the most widely used sensors used to document airflow. The measurement of nasal pressure was then introduced [14, 15]. The thermal sensor remains the recommended sensor to detect apneas, and nasal pressure remains the recommended sensor to detect hypopneas, and most laboratories use two separate sensor systems [1]. This study shows the utility of using a single PVDF sensor that responds to airstream temperature and pressure in polysomnography.

A potential limitation of this research is that the AASM has very recently changed the recommended scoring rules for hypopnea, suggesting that a 3 % rather than a 4 % desaturation be the desaturation metric used to document the event [16]. In practical terms, clinical labs in the USA will continue to report AHI using the CMS criteria (the preferred rule in the previous edition that employs the 4 % desaturation) because that is what is required by CMS, Medicaid, and many insurance companies in order to be reimbursed for apnea treatment. Although our hypopnea event scoring methods may not be relevant to the new manual, they are very relevant to clinical practice. In fact, the new manual, recognizing this, includes the following: "Note 1. If necessary, the number of hypopneas using a definition requiring a ≥30 % drop in flow for ≥10 seconds that is associated with ≥4 % desaturation may additionally be reported to qualify a patient for PAP reimbursement (eg. Medicaid or Medicare patients)."

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