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Optical Fiber-Based Sleep Apnea Syndrome Sensor

*Seiko Mitachi, Ken Satoh, Kumiko Shimoyama,
Makoto Satoh and Takeshi Sugiyama*

Abstract

A noninvasive sleep apnea syndrome (SAS) sensor using optical fibers, the “F-SAS sensor,” has been evaluated in a clinical application ranging in age from 13 to 78 years and with BMIs of 19.2–39.3. The respiratory disturbance index (RDI) from the F-SAS sensor corresponded well with the apnea hypopnea index (AHI) from polysomnography (PSG). Concurrent measurement of the RDI and the AHI had a correlation coefficient of 0.71. This means that the F-SAS is well-suited for preliminary SAS screening. They would also be useful for screening potential SAS sufferers during normal sleep at home. Then, we have succeeded in downsizing F-SAS sensor and have recognized that it is highly correlated with PSG and pulse oximetry. Next, we applied the compact F-SAS sensor to examining SAS diagnosis in a child patient (2–12 years) and report on improved pediatric analysis. The analysis results revealed the correlation value to be $R = 0.87$ was a significant improvement over the correlation value of $R = 0.697$ between the AHI obtained by a sleep apnea syndrome examination apparatus (SAS 2100) and RDI obtained by the conventional F-SAS sensor.

Keywords: optical fiber sensors, sleep apnea syndrome, SAS, F-SAS sensor, noninvasive, plastic optical fiber

1. Ordinal size of F-SAS sensors and application to adults

1.1 Introduction

Sleep apnea syndrome (SAS) has been identified as a risk factor for traffic accidents because it can cause excessive daytime sleepiness. As shown in **Figure 1**, the probability of a traffic accident for ordinary people is about 5% while that for SAS sufferers range from about 7–25% depending on the level of the apnea–hypopnea index (AHI), which indicates the severity of sleep apnea. Given this finding, the Japanese government requires train drivers and airplane pilots to get periodic SAS check-ups.

The prevalence of SAS sufferers in Japan is estimated to be 4%: 2.0 million and 2.8 million yet to be identified. The polysomnography (PSG) test commonly used for diagnosing SAS is a bothersome and uncomfortable examination as shown in **Figure 2**.

In contrast, a previously developed sleep apnea syndrome (SAS) sensor using optical fibers, the “F-SAS sensor,” is non-invasive and non-restrictive [1–4].

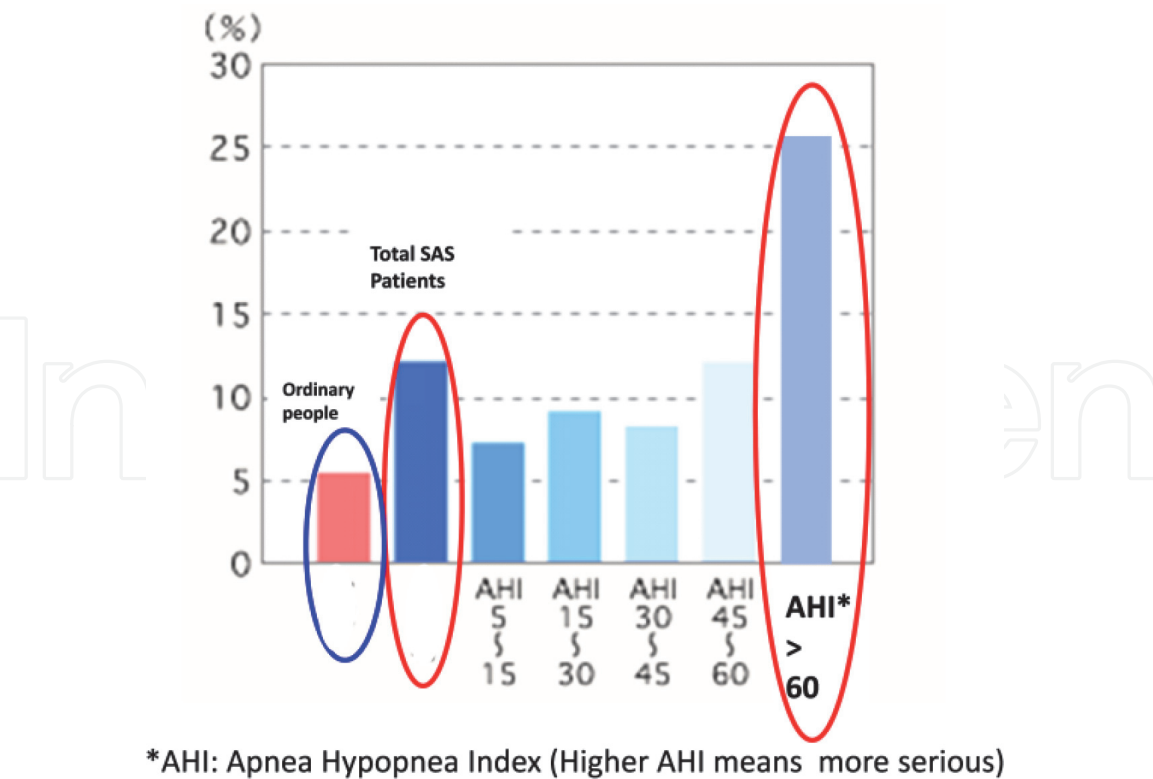


Figure 1.
Probability of traffic accident for various AHI levels of Japanese adults.

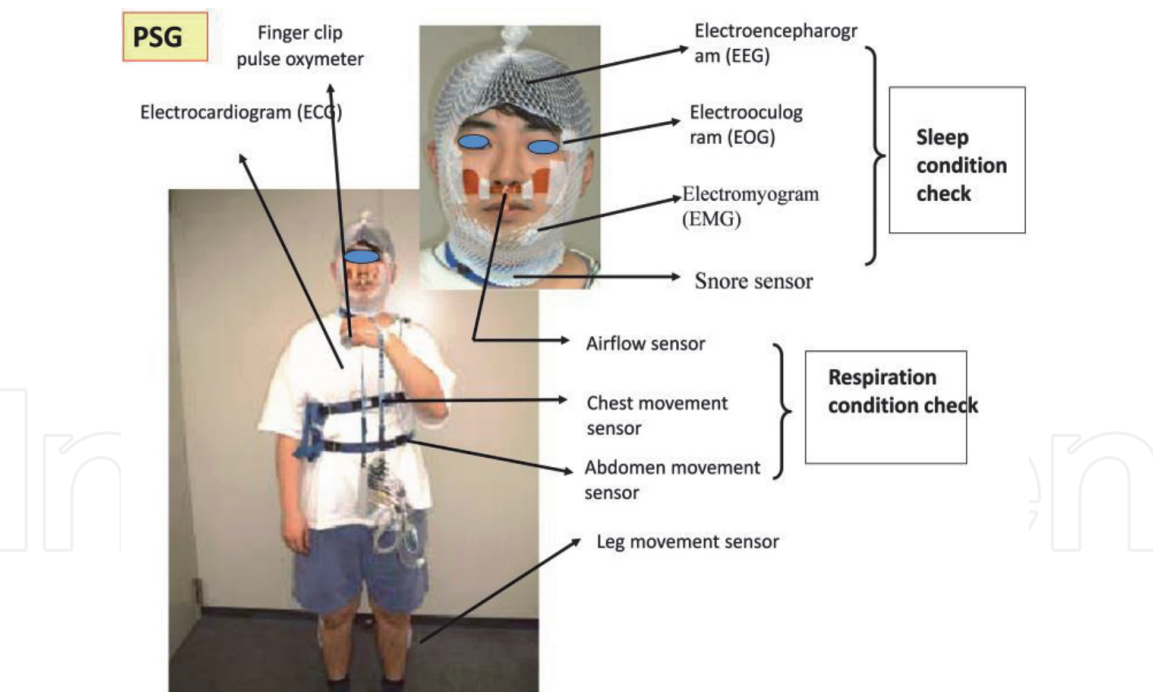


Figure 2.
Subjects ready for PSG test.

It is both quiet and compact and thus potentially useful for screening potential SAS sufferers during normal sleep at home.

This paper describes the F-SAS sensor and the measurement principle. It then describes its application in a hospital setting and in hotels [5, 6]. Under the assistance of the “Beautiful Fukushima Next-Generation Medical Industry Agglomeration Project,” in Japan, we have succeeded in downsizing the F-SAS sensor and have recognized that it highly correlates with polysomnography (PSG) and pulse

oximetry (PLSX). The F-SAS sensor is promising for screening latent SAS patients (Sleep Apnea Syndrome patients) during usual sleep.

On the other hands, obstructive sleep apnea syndrome (OSAS) in children is a disease in which respiratory arrest during sleep is frequently observed due to narrowing of the upper airways, such as due to tonsil hypertrophy, growth disorders, and a lowered quality of life (QOL) such as from having a decreased ability to learn. We reviewed the improvement made to pediatric analysis software by using the F-SAS sensor and report it [7–11]. Further, we report on a comparison of sleep events with the conventional F-SAS sensor and polysomnography (PSG) in children [9].

1.2 F-SAS sensor system

Figure 3 shows plastic optical fiber sheets and physics of measurement. Fibers interspaces are narrower one and wider one within several centimeters. Commercially available SI plastic optical fibers (CK10) were used. Physical principle is to measure the deviation of output optical power from fiber sheet by micro-bending loss and/or bending loss. **Figure 4** is the experimental response for intentional apnea. One pulse wave form means one breath in and out. Flat parts indicate the apnea after breath in or out. Narrower fiber interspaces POF sheet is more sensitive than the wider one. As shown in **Figure 5**, a plastic optical fiber (POF) sensor sheet is simply placed under the bottom bed sheet. There is no need for the subject to wear any special clothing or devices. The measurement data is transmitted to a remote location for analysis and diagnosis. The measurement principle is illustrated in **Figure 3**. The deviation in the output optical power from the POF sheet due to micro-bending loss and/or bending loss caused by the lateral pressure change created by the motion of the person's chest during respiration is measured.

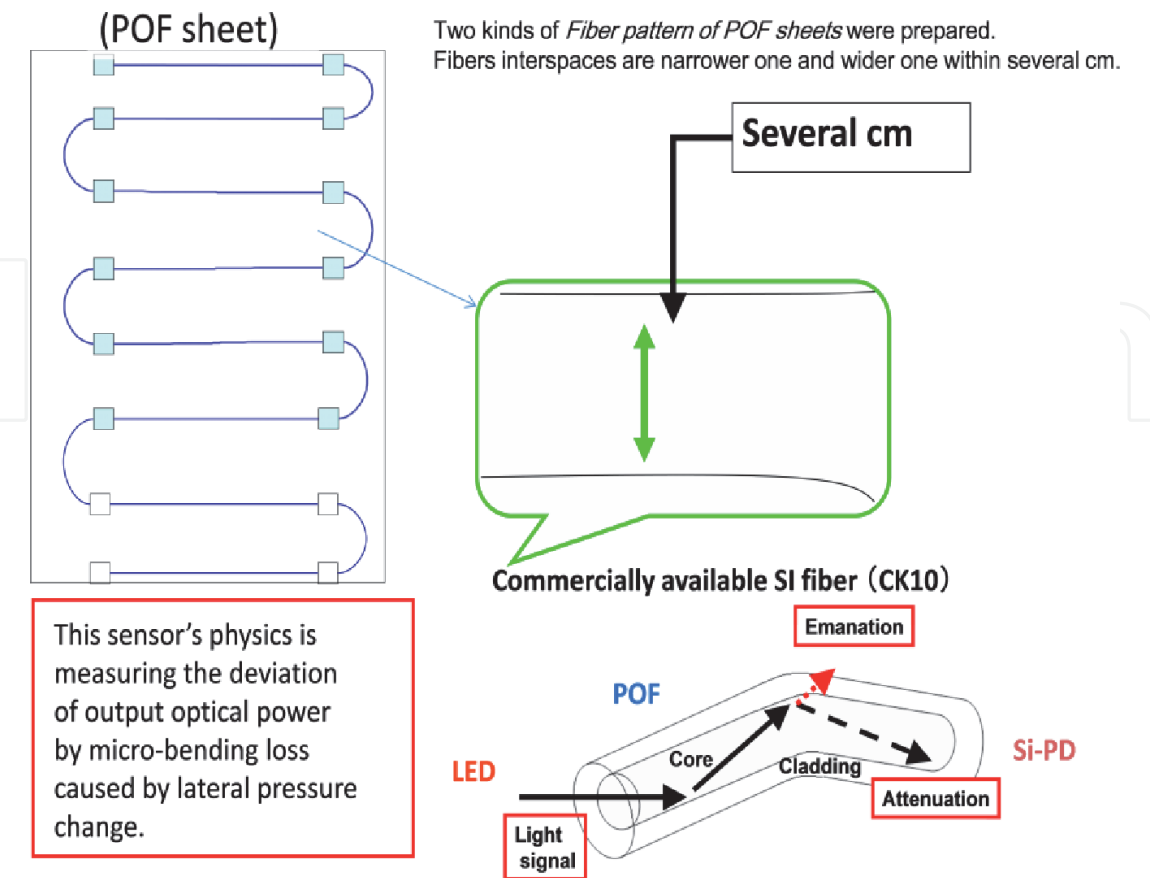


Figure 3.
Measurement principle.

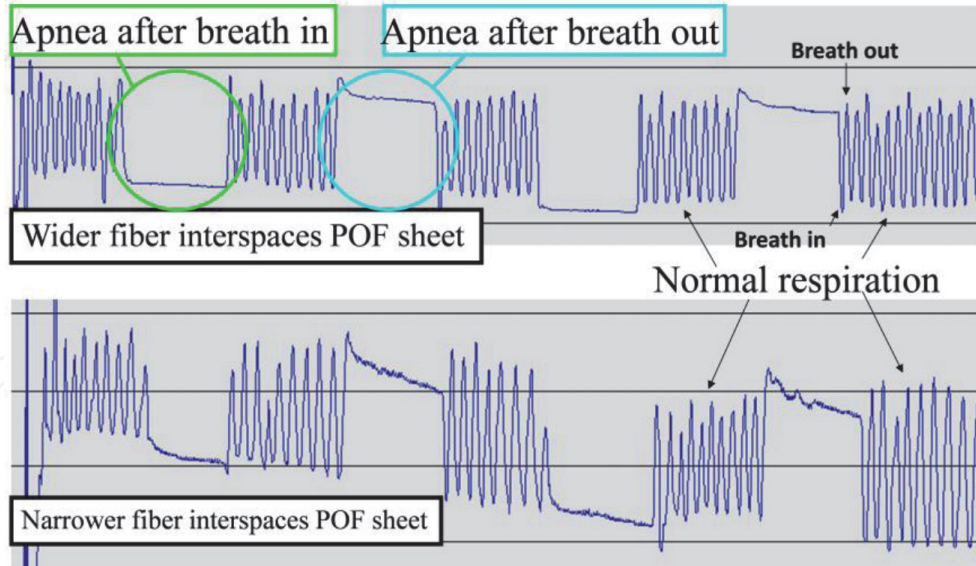


Figure 4.
Example measurement results for intentional apnea.

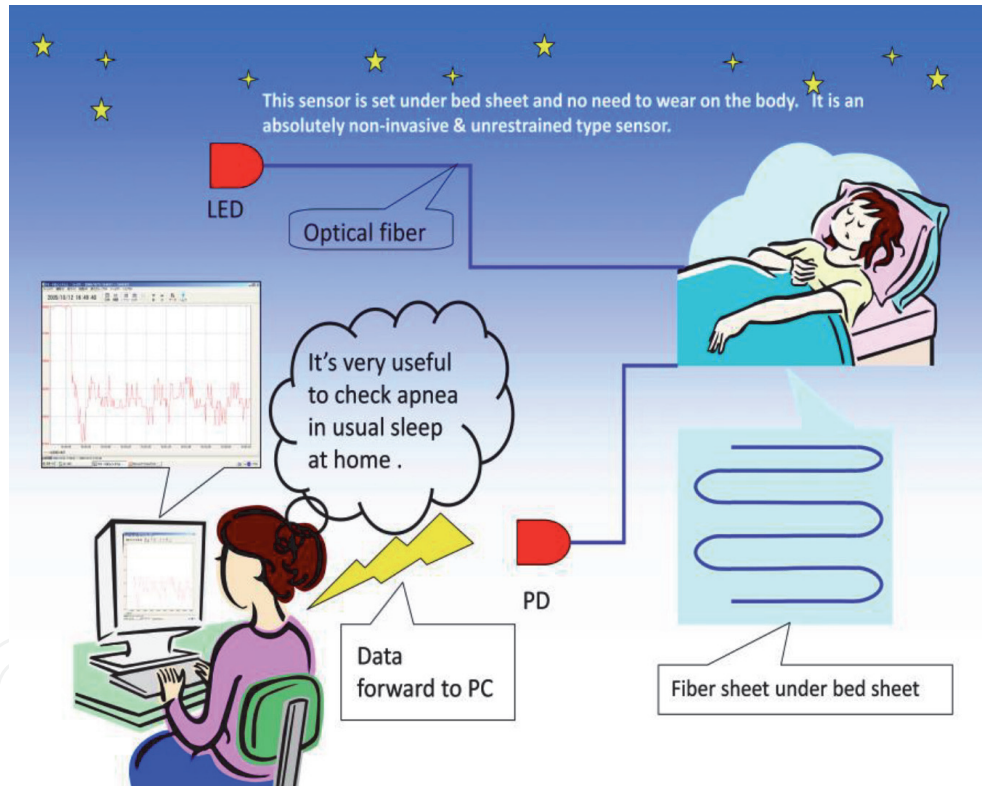


Figure 5.
Overview of F-SAS sensor system.

The theoretical formula for irregular bending loss of multimode optical fibers was given by Furuya and Suematsu [12]. As shown by Eq. (1), R_1 decreases/increases depending on the stress increase/decrease with expansion/contraction of the chest by respiration. Therefore, the stress increases/decreases, and transmission loss L_m increases/decreases.

$$L_m = 2500 N \overline{(1/R_1)^2} W^2 \frac{1}{\Delta} \exp \left[- \left(\frac{\overline{W}}{d} \right)^2 \Delta \right] (dB / km) \quad (1)$$

N : Average number of bends per meter, $\overline{(1/R_1)^2}$: Mean square of fiber curvature, \overline{W} : Correlation length, d : core diameter, Δ : Relative refractive index difference.

Example measurement results for intentional apnea are shown in **Figure 4**. One pulse wave-form corresponds to one breath in and out. The flat parts indicate apnea after breathing in or out. Results are shown for a POF sheet with narrow fiber spacing and for one with wider spacing. The one with narrower spacing was more sensitive. As shown in **Figure 6**, the sensor system comprises a SI-POF (240/250 micron, NA = 0.5) sheet, an optical power meter (9 V DC) with a Si photodiode, an LED (650 nm) built-in controller, a microcomputer (5 V DC), a memory card, and a small liquid crystal display panel. Input power is 12 V DC from AC commercial power.

Commercially available Si plastic fibers (ESCA CK10, Mitsubishi Rayon Co., Ltd.) are used. The sheet is packed between the bottom sheet and the bed. The user initiates operation by simply pushing the SW button and then sleeps on the bed as usual without wearing any electrodes. While sleeping, the user can freely roll over, change body position, and go to the toilet. The user ends operation upon awaking by again pushing the SW button. The measurement data are automatically stored on the memory card (SD card), which is attached to the side of the controller. The data for more than 200 nights can be stored; the data for each night is stored in a separate file with an automatically generated sequential file name. As necessary, the data can be analyzed at remote site or on site by inserting the SD card into a PC running a specially developed data analysis program. For one night's data file, it takes about 1 second to plot the signals for normal respiration, apnea, hypopnea, body motion, rolling over, and sleeping body position, and to generate the respiratory disturbance index (RDI).

A clinical application of this F-SAS sensor system was conducted at JR Sendai Hospital and in Tsukuba University Hospital in Japan using 20 subjects with ages from 13 to 78 and with BMIs of from 19.2 to 39.3. The POF sheet and PSG were used concurrently. The F-SAS sensor data were automatically analyzed by using the specially developed data analysis program to plot the signals for normal respiration,

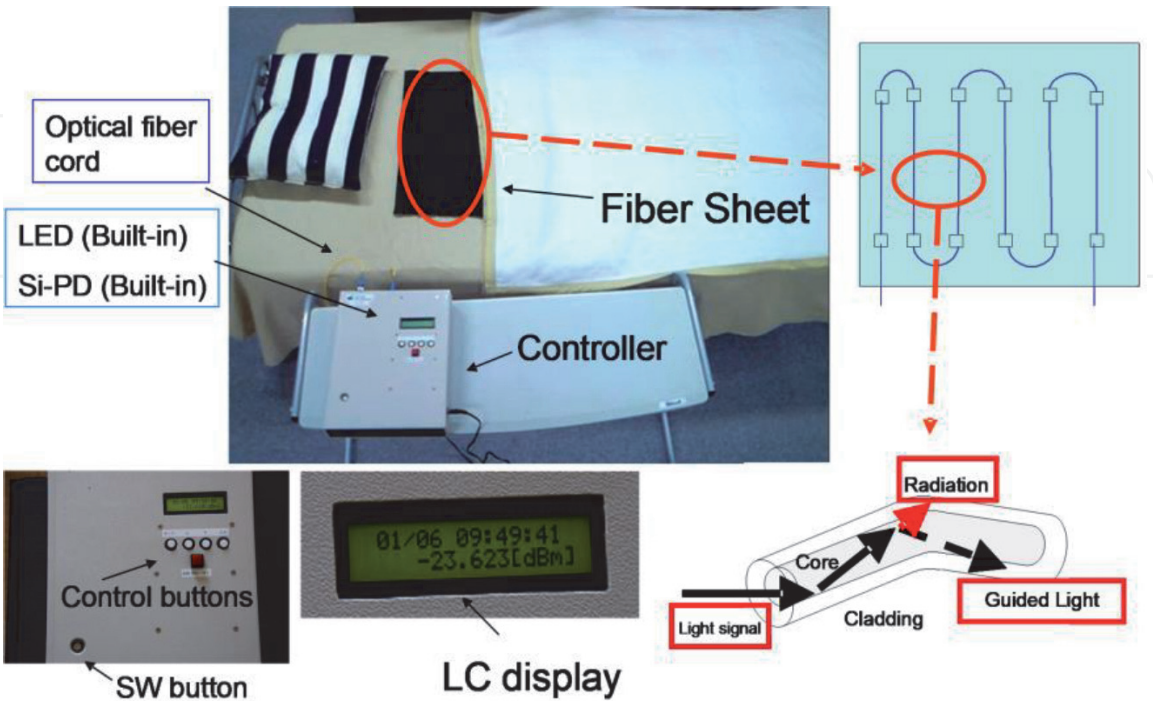


Figure 6.
Sensor system components and configuration.

apnea, hypopnea, body motion and rolling over independently from the PSG analysis. The example respiration waveforms for the F-SAS sensor and PSG are shown in **Figure 7** exhibits good consistency. The correlation coefficient between the AHI from the PSG and the RDI from the F-SAS was 0.71 in the region of AHI from 0 to 85.9 as shown in **Figure 8**. For AHI values from 0 to 20, the correlation coefficient was much better 0.89. In contrast, it was 0.57 for AHI values from 20 to 85.9. This means that the F-SAS sensor is more accurate and sensitive for milder degrees of SAS. The RDI from the F-SAS sensor was smaller than the AHI from the PSG for moderate and severe degrees of SAS because of the bigger difference between the sleeping time and the time in bed. This means that the F-SAS sensor is better suited for screening than for diagnosis. In fact, in a separate study of at-home use, potential SAS sufferers from among 19 ordinary people were identified by using this

Subject : age 46 (male) BMI: 30.9 Measured date: 17th Sep. 2008 at JR Sendai Hospital

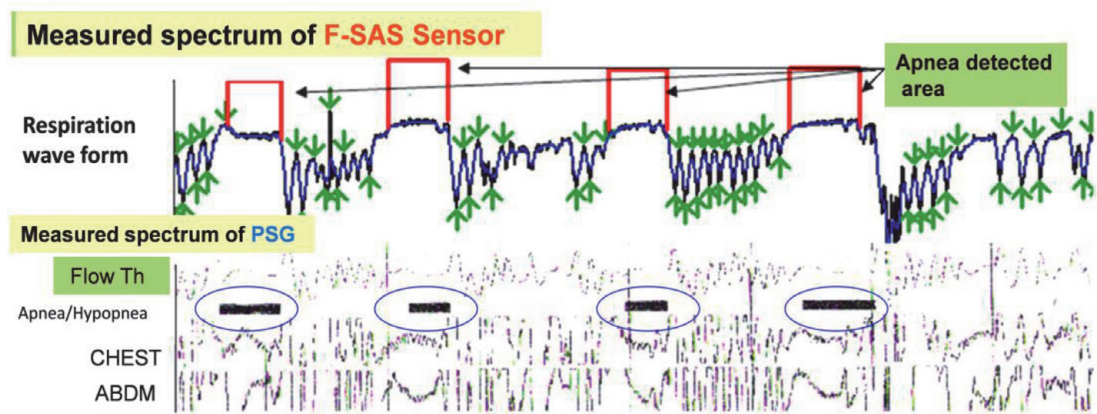


Figure 7.
Example respiration waveforms for F-SAS sensor and PSG [3] from 0 to 85.9 ($R = 0.71$).

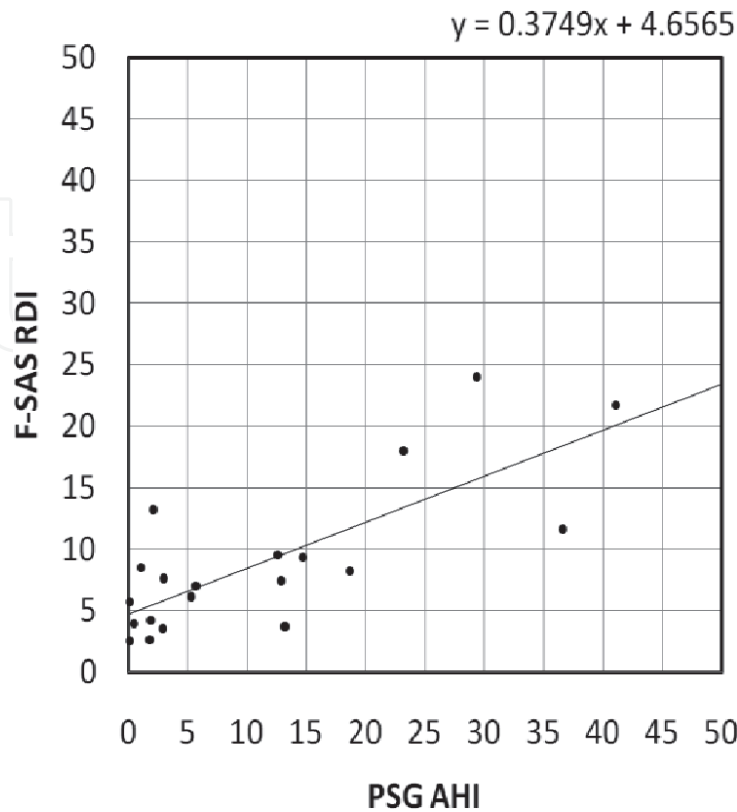


Figure 8.
Correlation between AHI by PSG and RDI from F-SAS for AHI values.

F-SAS sensor system. Definitive diagnoses made in the JR Sendai Hospital for the four potential sufferers were that three had mild cases and one had a moderate case.

The apnea and hypopnea distributions from the PSG and the F-SAS sensor for one night for a severe SAS sufferer (**Figure 9**) show good accordance. **Table 1** shows the reliability of the F-SAS sensor in comparison with PSG under the American Academy of Sleep Medicine (AASM) criteria published in 2001 [13]. It had good sensitivity of 0.909.

1.3 Application to other areas

A multi-channel F-SAS sensor system has been developed and done field test in a hotel, full medical check-up and clinical test in pediatrics. **Figure 10** shows the

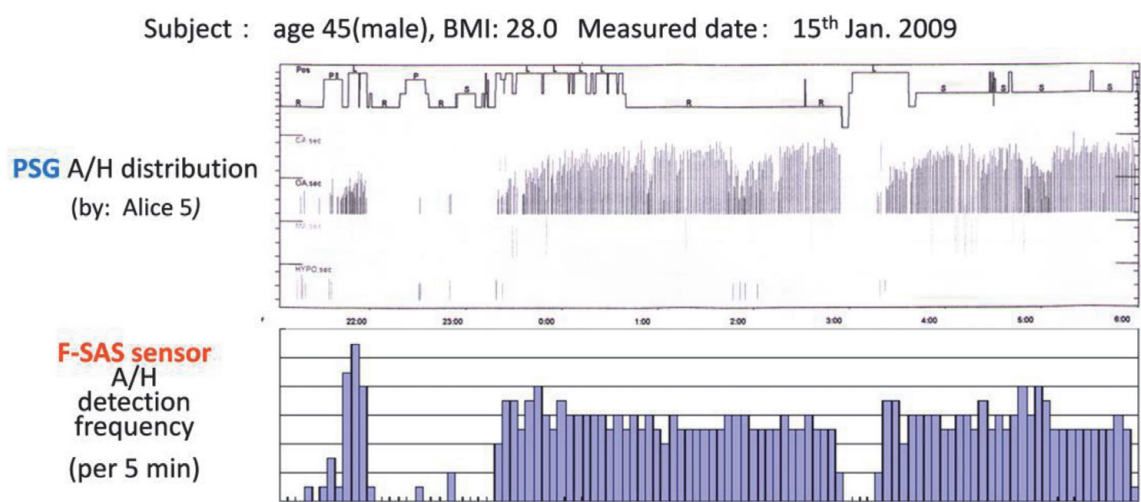


Figure 9.
Apnea and hypopnea distributions from PSG and F-SAS sensor for one night for severe SAS sufferer.

	PSG(AD)	PSG(NAD)	Total
F-SAS (AD)	10	4	14
F-SAS (NAD)	1	5	6
Total	11	9	20

POF sheet (400x900mm: 20 Subjects)

Sensitivity	0.909
Specifity	0.111
False negative rate	0.091
False positive rate	0.444
Positive predictive value	0.714
Negative predictive value	0.833
Likelihood ratio for a negative finding	1.023

PSG(AD): $AHI \geq 5$
F-SAS (AD): $RDI \geq 5$
AD: Appreciable Disease
NAD: No Appreciable Disease

Table 1.
Reliability of F-SAS sensor in comparison with PSG under AASM criteria published in 2001 [13].



Figure 10.
Clinical test of multichannel system of F-SAS sensor in pediatrics.

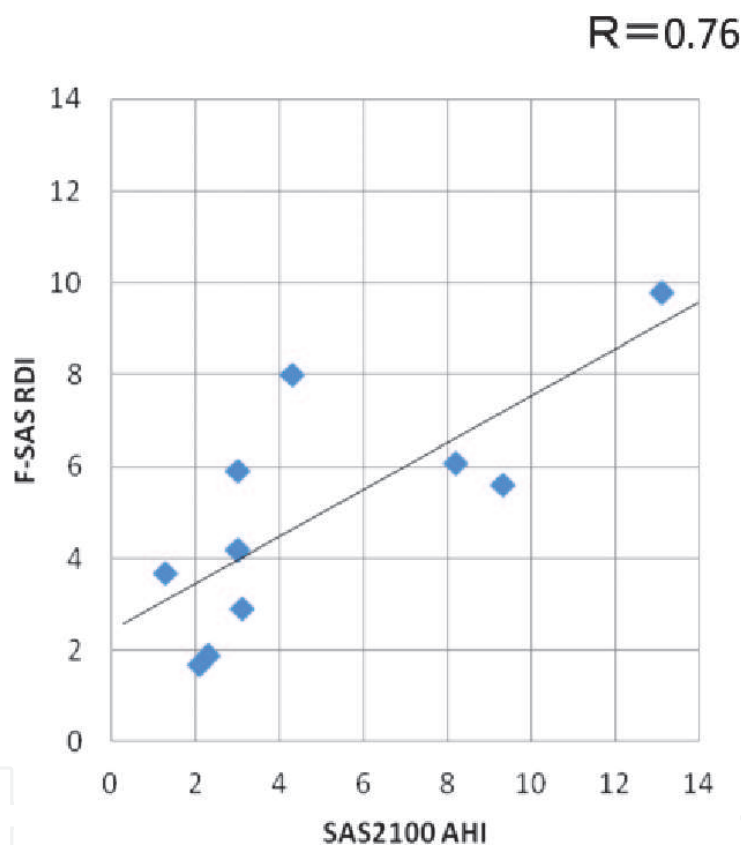


Figure 11.
Correlation between AHI of SAS2100 of the Yamanashi University Hospital (subjects: 11 children of age 2~10 y) as a reference and RDI of F-SAS sensor [11].

installation of the system in the pediatric ward. A correlation coefficient of 0.76 was obtained for 11 infantile subjects (**Figure 11**).

2. Downsizing the F-SAS sensor

Under the assistance of the “Beautiful Fukushima Next-Generation Medical Industry Agglomeration Project,” in Japan, we have succeeded in downsizing the F-SAS sensor as shown in **Figure 12** and have recognized that it highly correlates with polysomnography (PSG) and pulse oximetry (PLSX). The F-SAS sensor is promising for screening latent SAS patients (Sleep Apnea Syndrome patients) during usual sleep.

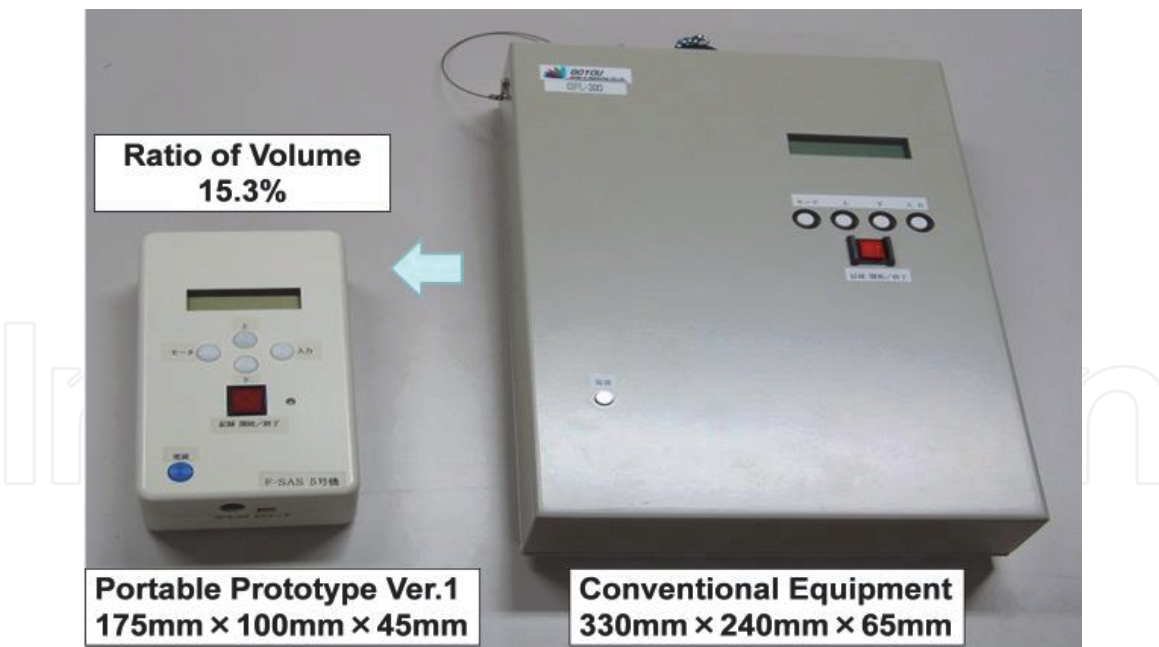


Figure 12.
 Portable prototype and original F-SAS sensor.

2.1 Measuring procedure

Under the agreement of the ethical committee of Tohoku Rosai Hospital in Japan and the following two conditions, coincident measurements of PLSX and F-SAS sensors were taken for an overnight medical checkup screening.

1. Subjects were 33 men and 8 women (age: 55.7 ± 7.49 , BMI: 25.6 ± 4.2 , ESS: 6.9 ± 3.5), and as shown in **Figures 6** and **13–16**, an optical fiber sheet was set under the bed pad, respiratory motion of the chest was measured, and arterial blood oxygen saturation was measured by PLSX from February 16, 2012 to September 7, 2016 in Tohoku Rosai Hospital, Sendai in Japan.
2. Next, conditions for 68 men and 8 women (age: 52.5 ± 20.5 , BMI: 24.8 ± 6.8 , ESS: 6 ± 6) were measured by using the downsized F-SAS sensor (controller is 16.8% and weight is 19% less than before) with a conventional PLSX from March 12, 2013 to January 11, 2016, in Tohoku Rosai Hospital, Sendai in Japan.
3. Finally, the clinical examination was carried out in the Department of Sleep Medicine, University of Tsukuba in Japan. Candidates were chosen from both healthy subjects and those suspected to be severe SAS patients who were definitive diagnosed by PSG and complied with F-SAS sensor clinical tests. Clinical test periods were from September 25, 2013 to February 12, 2014, and measurements were taken for 35 SAS patients including healthy subjects. Simultaneously parallel used measurements were taken with a PSG system, Alice 5, and a compact F-SAS sensor system-Ver. 1 and 2, as shown in **Figures 15** and **16**.

2.2 Results and discussion

The analytical results of RDI (Respiratory disturbance index, Pro-AHI; Provisional Apnea Hypopnea Index) by the conventional F-SAS sensor and ODI3% (oxygen desaturation index: 3%) of PLSX [5] are shown in **Figure 17**.

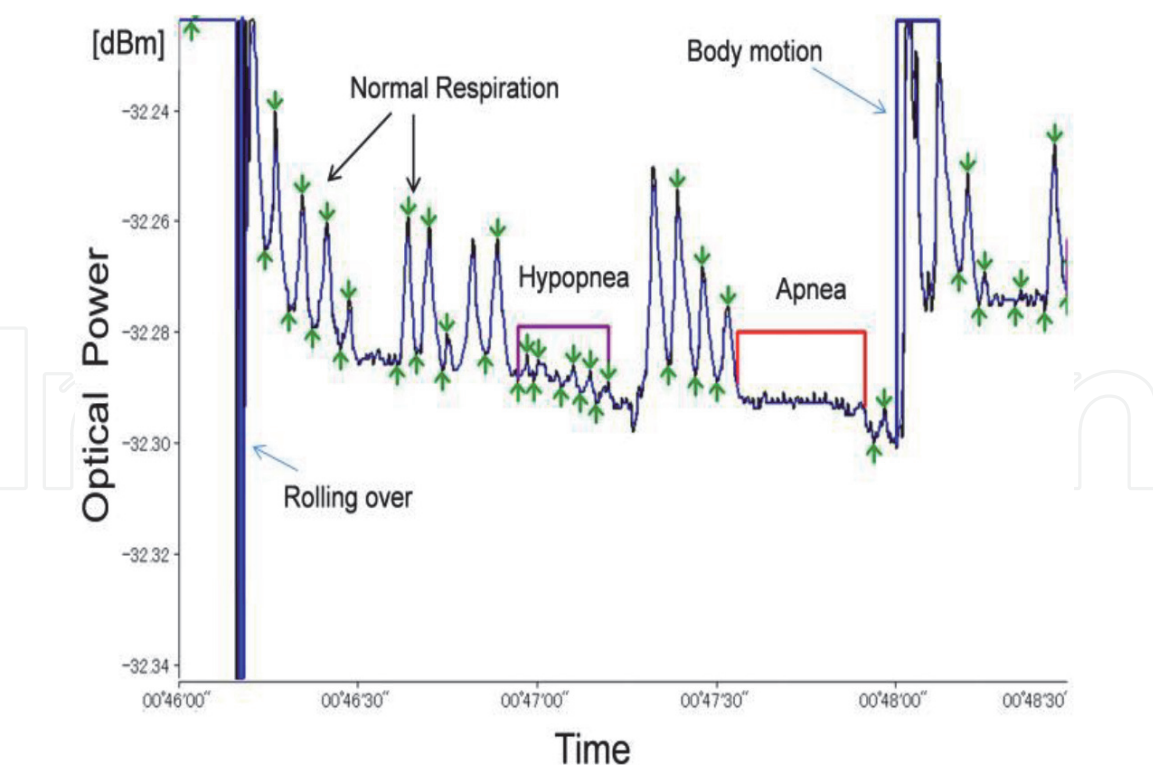


Figure 13.
A measured example by conventional F-SAS sensor.



Figure 14.
F-SAS sensor for used.



Figure 15.
Compact F-SAS sensor system (175 × 100 × 45 mm, 390 g, voltaic drive during electric outage)
(before improvement).



Figure 16.
Compact F-SAS sensor system (175 × 100 × 45 mm, 390 g, voltaic drive during electric outage)
(after improvement).

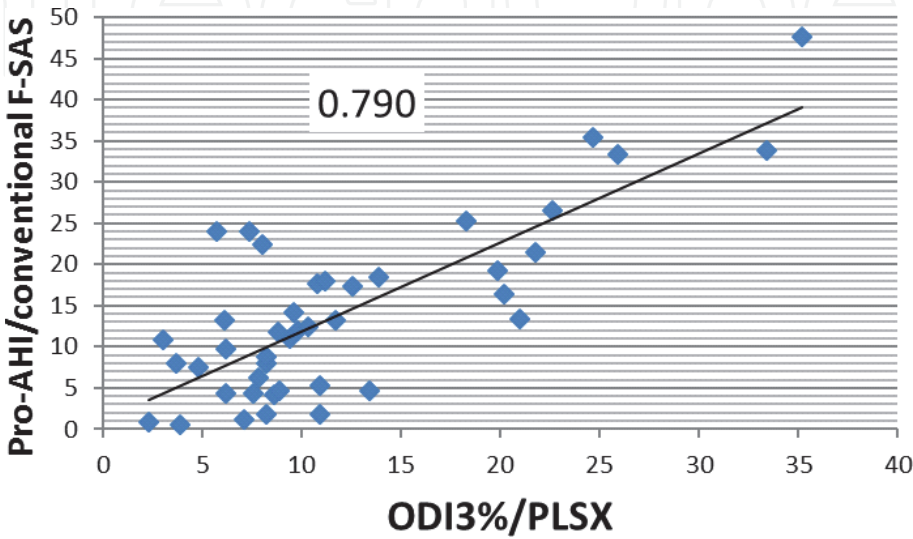


Figure 17.
Correlation between conventional F-SAS sensor's pro-AHI and ODI₃% of PLSX.

Thirty-eight of the 42 examinees show Pro-AHI > 5 and were suspected of SAS. The coincident measurement of ODI3% and Pro-AHI shows significant correlation ($r = 0.79, p < 0.01$). Seventeen examinees with Pro-AHI were over 10 and were eventually given SAS outpatient consultation. Four of them received a complete checkup by PSG and were given CPAP (Continuous Positive Airway Pressure) therapy. Next, a comparison of the analytical data of RDI (Pro-AHI) by the compact F-SAS sensor system and the coincident measurement of ODI3% by PULSOX are shown in **Figure 18**. Out of 76 examinees, 56 were Pro-AHI > 5 and were suspected of SAS. The coincident measurement of PULSOX, Pro-AHI, and ODI3% shows good correlation ($r = 0.796, p < 0.01$). The 32 examinees were consulted during SAS outpatient screening. In this manner, both the conventional type and the compact

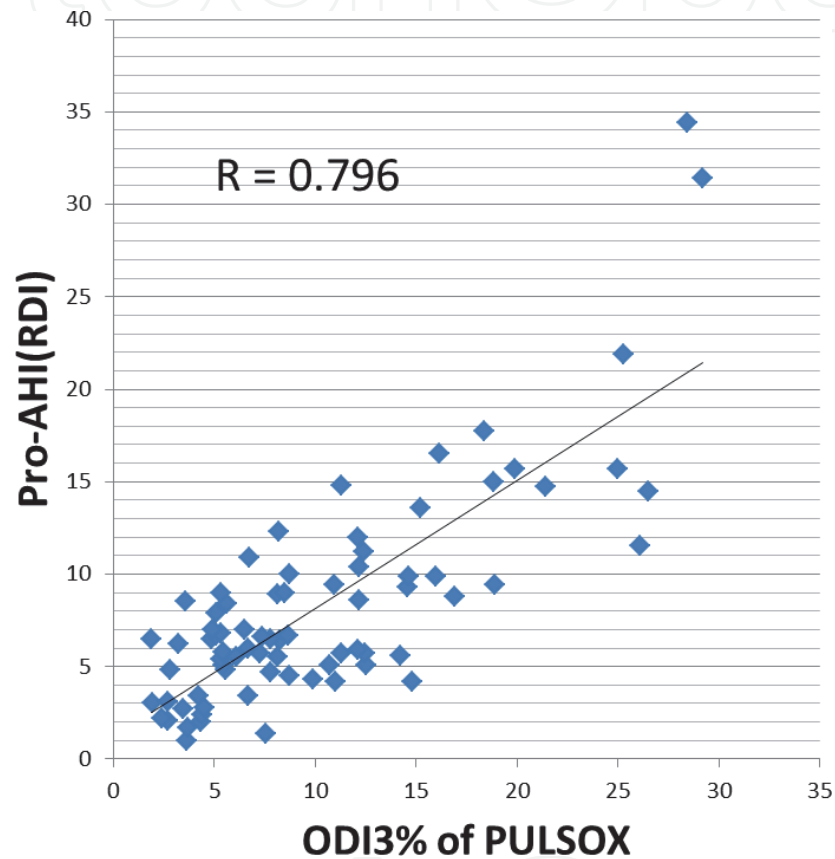


Figure 18.
Correlation between the portable F-SAS sensor's pro-AHI and ODI3% of PULSOX.

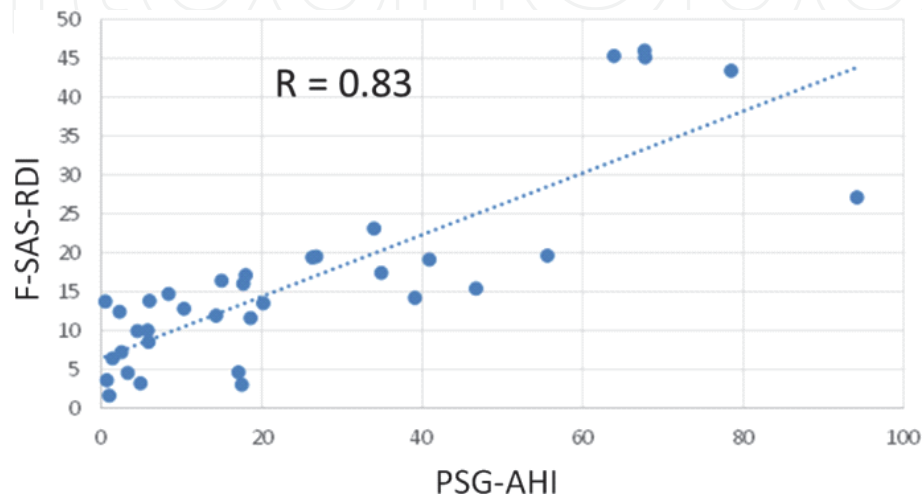


Figure 19.
Correlation between the portable F-SAS sensor's pro-AHI and AHI of PSG.

type F-SAS sensors are very useful for SAS screening during a complete medical checkup.

Finally, we demonstrate the results of simultaneous measurement with the portable F-SAS sensor and PSG (Alice5). Healthy subjects and SAS patients diagnosed by full PSG were included as examinees. There is a significant correlation between AHI by PSG, the gold standard for diagnosis of SAS, and Pro-AHI by the compact F-SAS sensor, as shown in **Figure 19** ($r = 0.83$).

3. Application to children

The compact F-SAS sensor is made portable by it having only 15.3% of the volume of a conventional F-SAS sensor, as is shown in **Figure 20**. Under the approval of the Ethics Committee at the Dept. of Pediatrics at the University of Yamanashi, the subject wore a portable sleep apnea syndrome examination apparatus (SAS 2100) while a plastic optical fiber sheet was placed under the subject's bed. The subject's apnea/hypopnea index (AHI) was measured by the SAS 2100 and the respiratory disturbance index (RDI) was measured with new analysis software developed for the compact F-SAS sensor.

Further, this type of F-SAS sensor and Alice PDX of Philips-Respironics GK, a PSG device used to inspect sleep for OSAS diagnosis, were used for measurement. **Figure 21** below shows a diagram of the F-SAS sensor and PSG (Alice PDX).

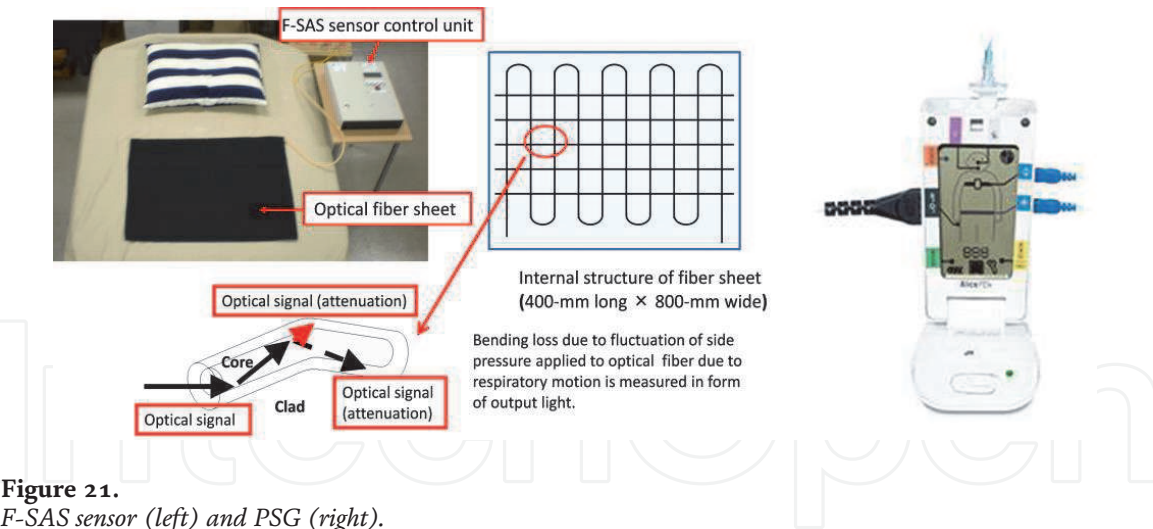
3.1 Results

Their correlation value was then obtained. The new analysis software was made up of a new algorithm that is difficult to use when the number of body movements per hour exceeds a certain number, and it analyzes the RDI by checking both the gasping judgment and weakness judgment against the data from a seriously ill patient. In this study, we improved the algorithm for severe markers in children (2–12 years old) and aimed to expand the application area to the compact F-SAS sensor. We compared severe markers obtained with the compact F-SAS sensor and existing simple polysomnography (PSG) (SAS 2100 manufactured by Nihon Kohden).

In this study, 27 data collected by the compact F-SAS sensor were analyzed by using the new analysis software, which were a severe marker caused by RDI, severe markers with periodic distribution, severe markers due to gasping respiratory



Figure 20.
Comparison of compact F-SAS sensor and conventional one (left) and SAS 2100 (right).

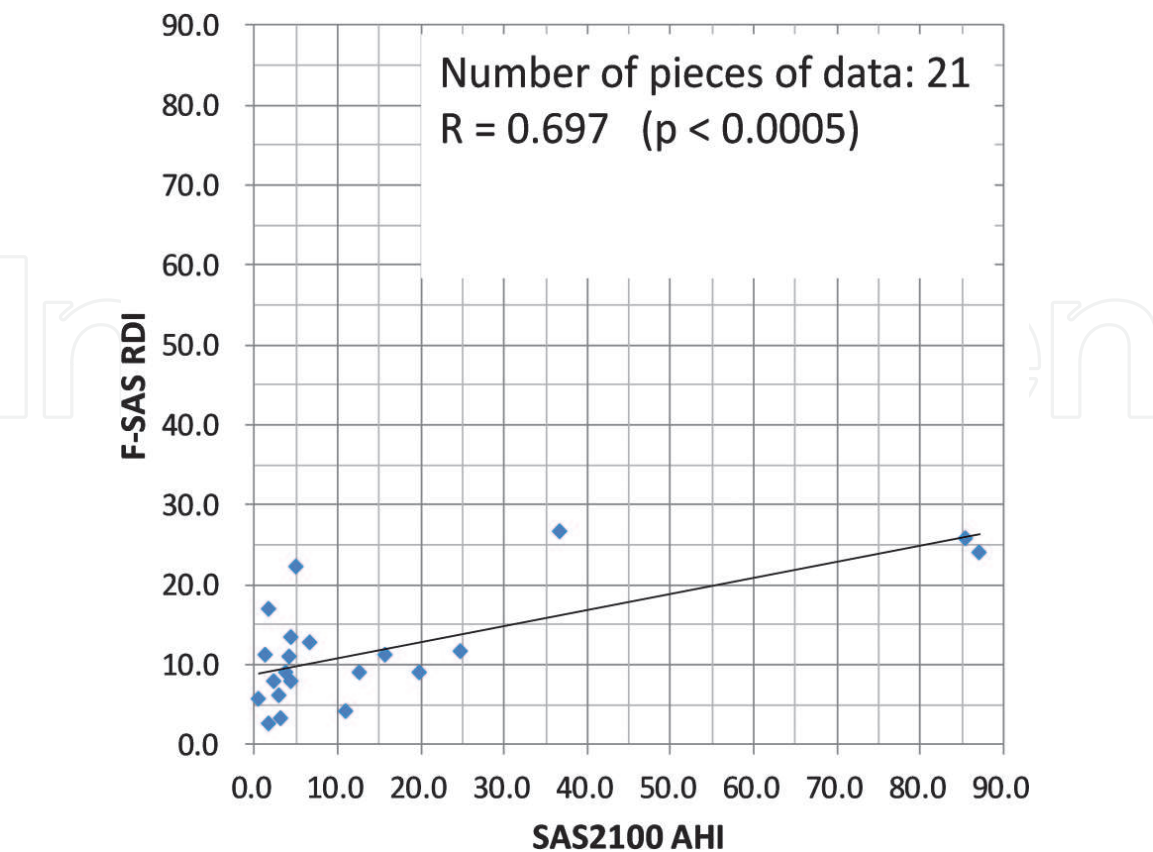


frequency, severe markers due to hypopnea, and severe marker due to body movement frequency. The results are shown below. Before introducing the markers, the correlation value of R was 0.697 as shown in **Figure 22**.

After introducing the severe markers obtained by RDI, $R = 0.58$ as shown in **Figure 23**. RDI 10 or more was considered as a serious patient and examined.

After introducing the severe markers due to gasping respiratory frequency, $R = 0.76$ as shown in **Figure 24**. We divided the total number of detected low respiration times by total landing time, and assumed that one with a high number of low respirations per hour is a serious one.

After introducing the severe markers due to hypopnea, and $R = 0.87$ after introducing the severe markers due to body movement frequency, as shown in **Figure 25**.



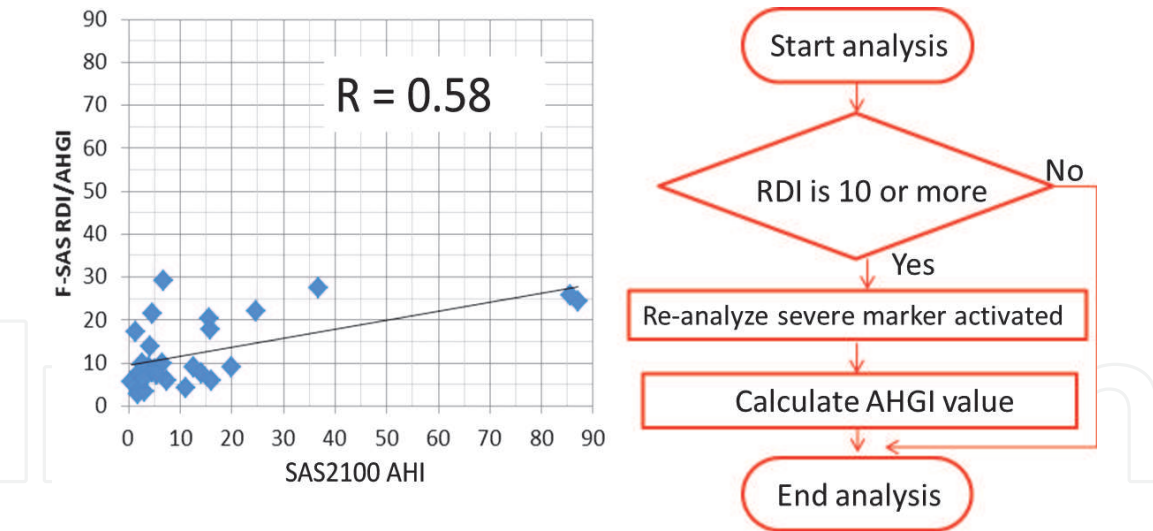


Figure 23. Scatter diagram of F-SAS RDI/AHGI and SAS 2100 AHI after introduction of severe marker that is RDI 10 or more was considered as a serious patient and examined.

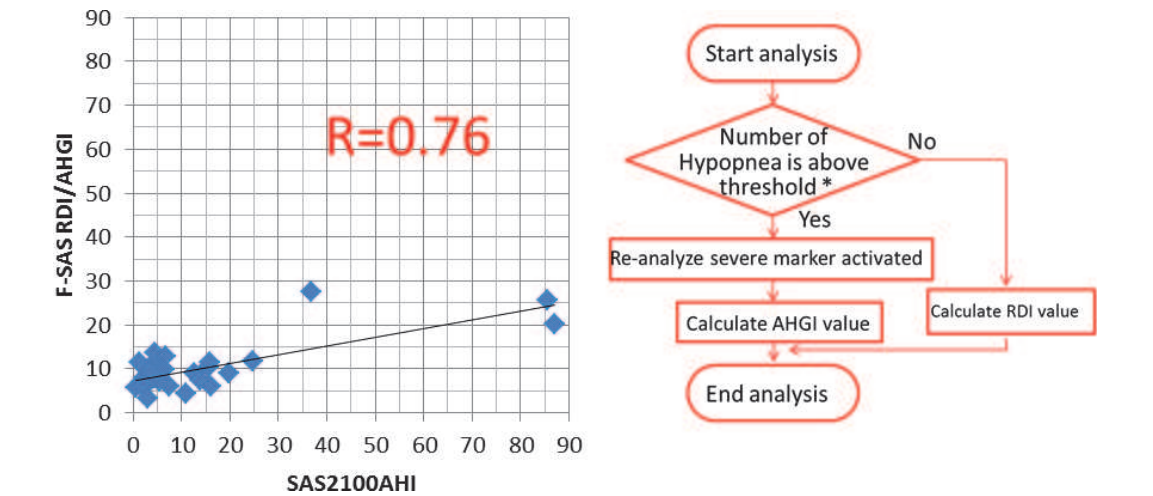


Figure 24. Scatter diagram of F-SAS RDI/AHGI and SAS 2100 AHI of severe marker algorithm with the number of hypopnea.

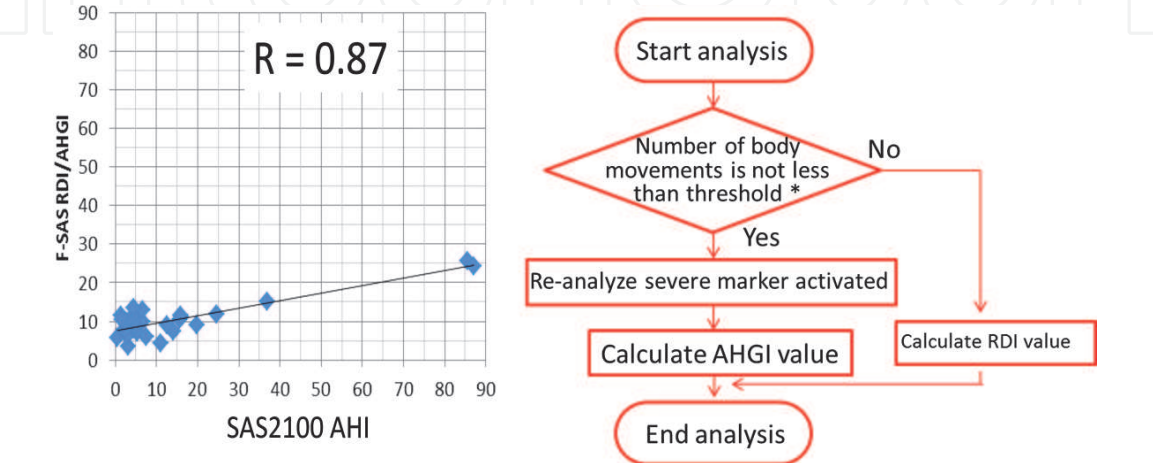


Figure 25. Scatter diagram of F-SAS RDI/AHGI and SAS 2100 AHI of severe marker algorithm based on body movement frequency.

We divided the total number of detected body movements by total bedtime, and assumed that one with more body movements per hour is a serious one.

Finally, we summarized as shown in **Table 2**. Sever markers were as *RDI*, *Periodic distribution*, *Candle breathing frequency*, *Low breathing frequency* and *Number of body movements*. As a result, *Number of body movements* showed best data of correlation value is 0.87.

The analysis results revealed the correlation value to be $R = 0.87$, which is a significant improvement over the correlation value of $R = 0.697$ between AHI obtained by SAS 2100 and RDI obtained by the conventional F-SAS sensor. From this, the software using the new algorithm effectively analyzes the RDI. In the future, to further improve the sensitivity of the compact F-SAS sensor, the remaining gap between the AHI and RDI in seriously ill patients must be bridged. To do this, algorithms will need to be developed that allow the analysis software of F-SAS sensors to capture highly disturbed respiration in seriously ill patients.

We improve the accuracy of the software used for analysis with the F-SAS sensor for child development. This was done for the development of PSG equipment of Philips Respironics GK used in a pediatric clinical trial at Yamanashi University School of Medicine for the purpose of comparing apneic events between the pediatric F-SAS sensor and PSG. That is, the respiratory events were judged and compared from the waveform data at bedtime, which is the analysis result of the F-SAS sensor and PSG. On the basis of the definition of the scoring rule of children for sleeping respiratory events, proposed by the American Academy of Sleep

Severe marker	Correlation value
RDI	0.58
Periodic distribution	0.67
Candle breathing frequency	0.52
Low breathing frequency	0.76
Number of body movements	0.87

Table 2.
Correlation value in each severe marker.

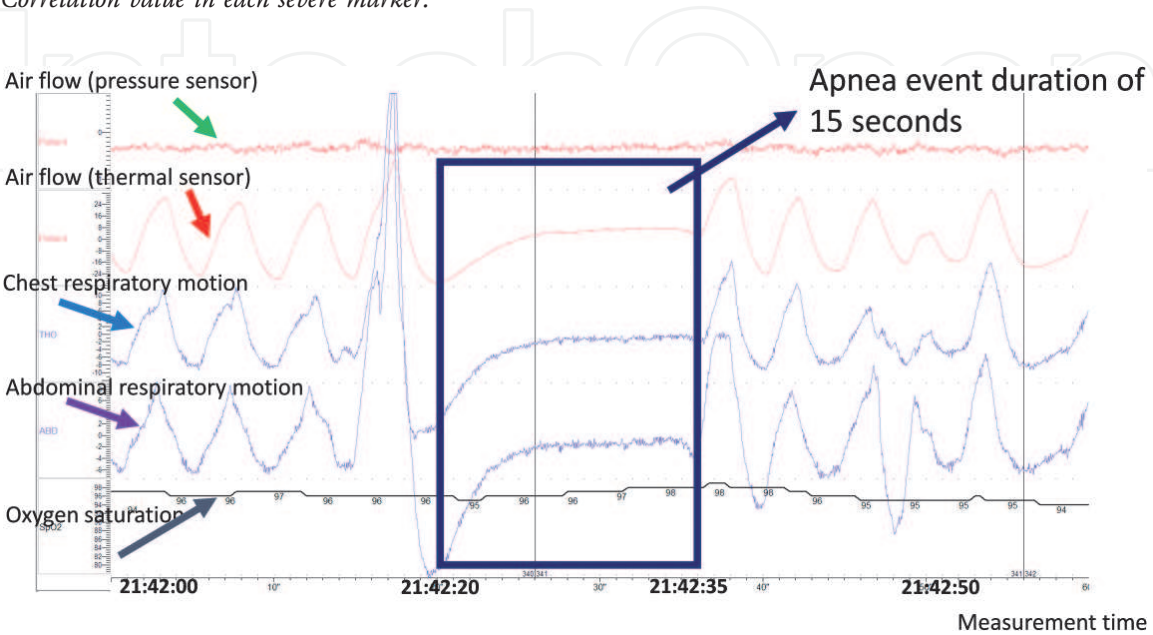


Figure 26.
Measurement analysis result of PSG (apnea waveform).

Apnea event start time (F-SAS)	Apnea event duration (F-SAS) [sec]	Apnea event start time (PSG)	Apnea event duration (PSG) [sec]
21:30:12	18	21:23:20	18
21:49:12	15	21:42:20	15
22:02:12	13	21:55:20	13
22:52:50	12	22:45:58	12
22:56:54	12	22:50:02	12

Table 3.
Results of apnea events comparison between F-SAS sensor and PSG.

Medicine (AASM) in 2007, apnea events were judged from the waveforms of PSG. The analysis results are as shown in **Figure 26**.

The subject was a boy, aged 4 years and 0 months. The measurement comparison time was 21:18:39 to 23:36:24. His height was 99.1 cm, and his weight was 16.6 kg. The respiration cycle was 6 seconds/turn. Concerning the maximum amplitude of the thermal sensor, which was 24 (unit unknown), a drop of 90% or more can be seen for 15 seconds. **Table 3** shows that all five apnea event durations of F-SAS and PSG were consistent. As a result of comparing apneic events between F-SAS sensor and PSG, five apneic events in five out of five matched. In this subject, all apnea events could be detected by the F-SAS sensor.

4. Conclusions

Clinical application of the F-SAS sensor showed that the respiratory disturbance index (RDI) from the F-SAS sensor corresponded well with the apnea-hypopnea index (AHI) from polysomnography under the AASM criteria published in 2001. The concurrently measured RDI and AHI had a correlation coefficient of 0.71. This means that the F-SAS sensor is well suited for preliminary SAS screening. The sensor would also be useful for screening potential SAS sufferers during normal sleep at home and for SAS screening of and monitoring of the respiration and heartbeat of neonates. Also we demonstrated through a detailed examination by PLSX and PSG (Alice5) that PLSX data and PSG (Alice5) data are well correlated with those of the F-SAS sensor. The F-SAS sensor is effective for SAS screening during a full overnight medical check-up.

Further, a good correlation value of 0.87 was obtained between the RDI calculated by a new compact F-SAS sensor analysis system using an algorithm for severely ill children and AHI calculated by using the SAS 2100. Also, by comparing the sleep-event results of the F-SAS sensor with those of the PSG, it was observed that apnea sleep events matched. This suggests that it might be valid applied to diagnosing sleep apnea with the pediatric F-SAS sensor. We further analyze the subject data for further improvement.

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Author details

Seiko Mitachi^{1*}, Ken Satoh², Kumiko Shimoyama³, Makoto Satoh⁴ and Takeshi Sugiyama⁵

¹ Graduate School of Bionics, Computer and Media Sciences of Tokyo University of Technology, Tokyo, Japan

² Ohu University, Koriyama, Japan


³ University of Tsukuba Hospital, Tsukuba, Japan

⁴ Sleep Center of University of Tsukuba, Tsukuba, Japan

⁵ Ichinomiyanishi Hospital, Japan

*Address all correspondence to: mitachi@stf.teu.ac.jp

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