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(54) **METHOD OF ASSESSING RESPIRATORY EFFORT**

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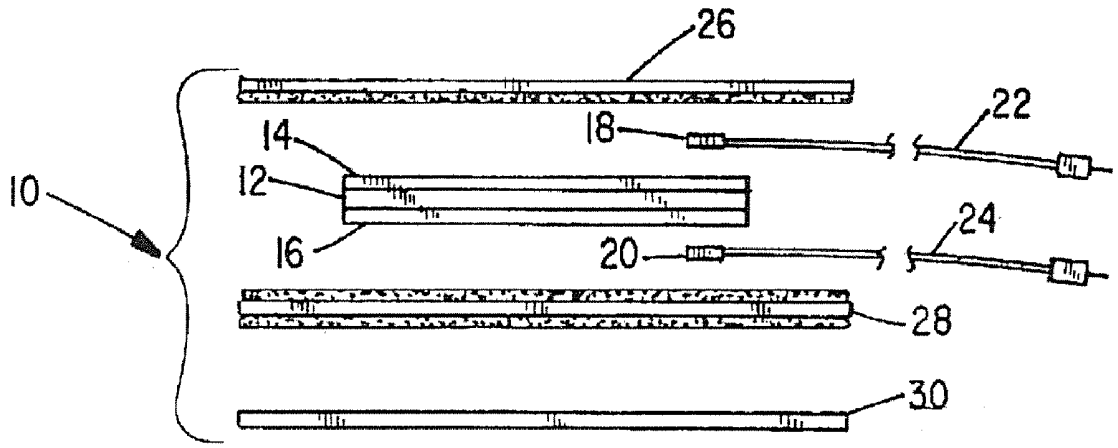
(57) **ABSTRACT**

A method of measuring a patient's respiratory effort that does away with the need for body encircling belts comprises a PVDF sensor sandwiched between a covering layer of a single sided adhesive tape strip and a bottom layer of a double sided adhesive tape strip arranged such that the sensor may be adhesively affixed to a person undergoing a sleep study and where electrical leads cooperating with the PVDF sensor are adapted to be connected to a physiological data collection device such as a PSG machine or a HST monitor.



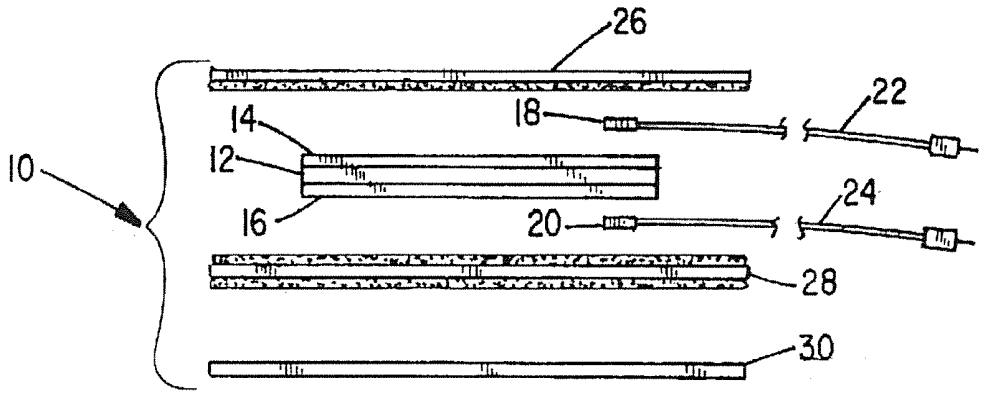


FIG. 1

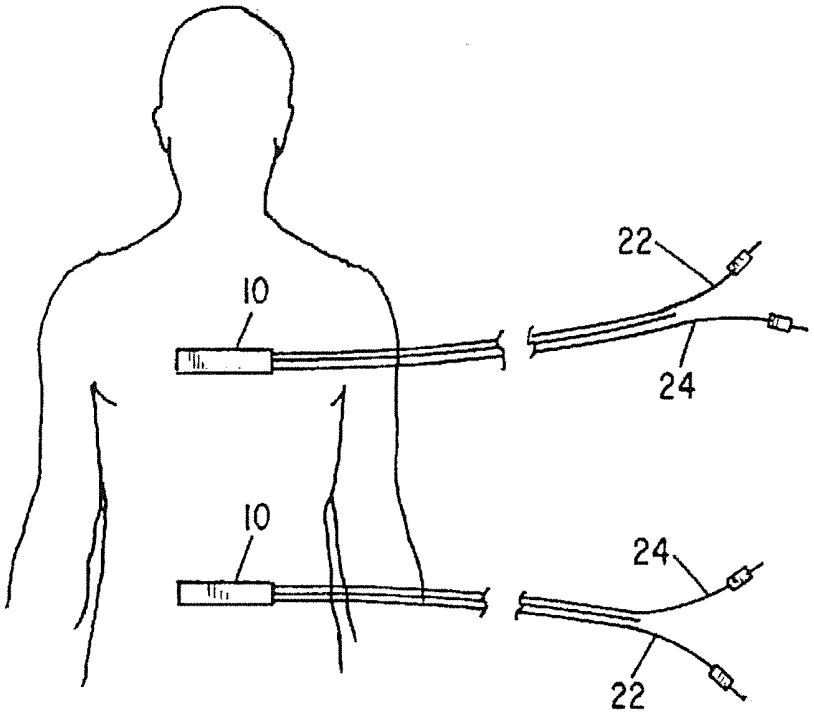


FIG. 2

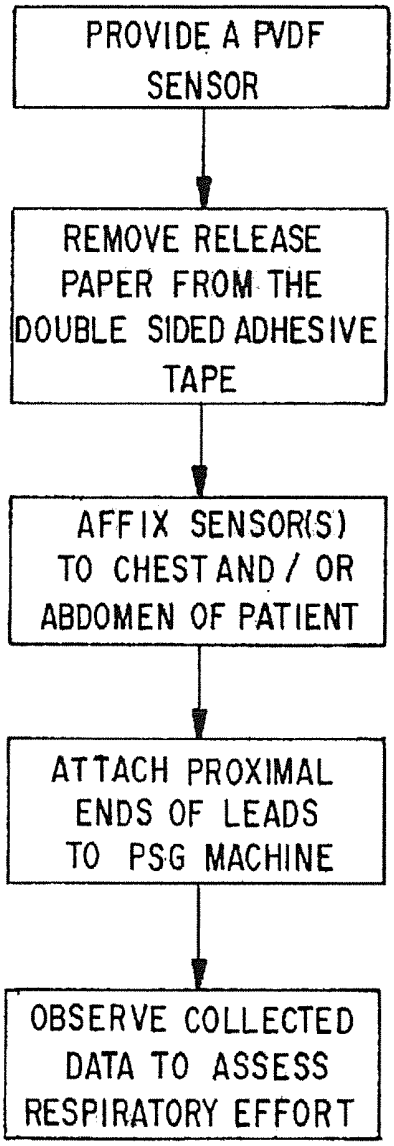

PROVIDE A PVDF SENSOR
REMOVE RELEASE PAPER FROM THE DOUBLE SIDED ADHESIVE TAPE
AFFIX SENSOR(S) TO CHEST AND / OR ABDOMEN OF PATIENT
ATTACH PROXIMAL ENDS OF LEADS TO PSG MACHINE
OBSERVE COLLECTED DATA TO ASSESS RESPIRATORY EFFORT

FIG. 3

METHOD OF ASSESSING RESPIRATORY EFFORT

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] None

STATEMENT RE FEDERALLY SPONSORED RESEARCH

[0002] None

BACKGROUND OF THE INVENTION

[0003] I. Field of the Invention

[0004] This invention relates generally to methods of conducting sleep studies on patients to assess apnea and more particularly to a method for assessing respiratory effort that obviates the need for conventional RIP Belts.

[0005] II. Discussion of the Prior Art

[0006] In conducting sleep studies on patients suspected of episodes of sleep apnea, it is customary to apply a number of sensors to the patient for detecting such things as respiratory air flow, snoring, rapid eye movement, leg twitches, heart rate, and respiratory effort. Conventionally, respiratory inductance plesmography belts (RIP belts) are used to monitor respiratory effort. The RIP belts incorporate a body encircling band incorporating a somewhat sinusoidally bent wire. A high frequency signal is applied and as the patient breathes, chest or abdominal movement causes a measurable modulation of the applied signal that is delivered over electrical leads to a polysomnograph (PSG) machine, along with outputs from the other sensors where by abnormal sleep events can be assessed. Such RIP Belts have been found to suffer from a number of problems, not the least of which is the breakage of the undulating inductance wire that necessitates a redo of the sleep study. Additionally, RIP belts have the potential to reverse polarity of the output waveform should the patient move so as to fold the elastic RIP belt a certain way. Cleaning the reusable belt can also be problematic as water will affect and corrode the embedded wire over time.

[0007] Dymedix Corporation of Shoreview, Minn. introduced to the market a respiratory effort belt to replace a RIP Belt. Instead of a variable inductance element, it incorporated a piezoelectric element that generates a measurable signal when subjected to changes in force on the element as the patient's chest and/or abdomen changes in circumference due to breathing. The piezoelectric element in the Dymedix belt is a strip of polyvinylidene fluoride (PVDF) polymer disposed on a predetermined surface of the body-encircling belt. The film is metalized on its two major surfaces and electrical leads are conductively attached to the metallization to convey signals to a PSG machine. Further information may be obtained from published U.S. Patent Application No. 2008/0275356A1. The present invention provides a method of assessing respiratory effort of a patient that eliminates the need for a belt configuration in conducting a sleep study.

SUMMARY OF THE INVENTION

[0008] A method of detecting, identifying, monitoring and assessing a sleeping patient's respiratory effort involves the steps of providing a sensor comprising a flat strip of PVDF polymer having a metallized layer on its opposed major surfaces to which are conductively attached a pair of insulated electrical leads. The metallized strip and the distal end portions of the leads are sandwiched between a layer of double sided adhesive tape and a layer of single sided adhesive tape. This construction allows the sensor to be adhesively affixed to the patient's skin on the chest and/or abdominal area. The proximal ends of the leads are then connected to a physiological data collection device, such as a PSG machine or a home sleep test (HST) monitor or other suitable physiological data collection device whereby electrical signals due to changes in thoracic or abdominal circumference resulting from breathing are generated and analyzed for purposes of screening or diagnosing sleep disordered breathing abnormalities.

DESCRIPTION OF THE DRAWINGS

[0009] The foregoing features, objects and advantages of the invention will become apparent to those skilled in the art from the following detailed description of a preferred embodiment, especially when considered in conjunction with the accompanying drawings in which:

[0010] FIG. **1** is an exploded view of a sensor used in carrying out the method of the present invention;

[0011] FIG. **2** is a schematic drawing of a person's torso with the sensor of FIG. **1** attached; and

[0012] FIG. **3** is a process flow diagram of the steps for carrying out the method of the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENT

[0013] Referring to FIG. **1**, there is indicated generally by Numeral **10** a piezoelectric sensor used in carrying out the method of the present invention. It is seen to comprise a strip of a PVDF polymer **12** on whose major surfaces are deposited metallization layers **14** and **16**. The PVDF strip is preferably rectangular and may be about 6 centimeters long and 2 centimeters wide. Affixed to the metallization layers by a suitable conductive adhesive are conductive tabs **18** and **20** to which insulated electrical leads **22** and **24** are conductively joined. A strip of single sided adhesive tape **26** whose length and width dimensions exceed those of the PVDF polymer strip **12** is laminated with a layer **28** of a double sided adhesive tape strip. Without limitation, the adhesive strips may be of a length in a range between 6 and 24 centimeters and may be of a width in a range between 2 and 4 centimeters. The PVDF strip with the metallization layers **14** and **16** and distal end portions of the electrical leads **22** and **24** are effectively sandwiched between the tape layers **26** and **28**. A strip of silicone coated release paper **30** protects the integrity of the adhesive on the double sided tape strip **28** prior to application of the sensor **10** to a patient in the course of a sleep study.

[0014] Referring to FIG. **2**, two such sensors **10** may be placed on a person, one being appended to the chest area and the other to the abdominal area.

[0015] Referring to the flow diagram of FIG. **3**, in use, the release paper layer **30** is first removed from the sensor module **10** exposing the adhesive on the lower surface of the double sided adhesive tape strip **28** and thus allowing the sensor to be affixed to the patient's skin either one of the chest area or the abdominal area as shown in FIG. **2**. A second such sensor **10** may then be adhesively affixed to the other of the chest or abdominal areas. Once the sensors **10** are affixed to the patient, their associated leads **22** and **24** may be plugged into a suitable physiological data collection device, e.g., a PSG machine or a HST monitor as the case may be.

[0016] As the patient breathes, the circumference of the chest and abdominal areas will expand during inhalation and will fall during exhalation. The resulting stretching and recovery of the PVDF polymer layer **12** causes a voltage to be applied to the leads **22** and **24** creating a signal proportional to the force exerted on the transducer. The signal is recorded and/or displayed for analysis by a medical professional who can then assess the patient's respiratory effort.

[0017] It will be immediately recognized that the need for a body encircling belt is obviated. Upon completion of the sleep study, the sensor may be readily removed from the patient and disposed of.

[0018] It is apparent that there has been provided in accordance with this invention a disposable sensing device for sensing respiratory effort. While the invention has been described in combination with a specific embodiment thereof, it should be evident that many modifications and variations will become apparent to those skilled in the art from what is described herein. Accordingly, it is intended to embrace all such alternatives, modification and variations as fall within the spirit and broad scope of the appended claims.

What is claimed is:

1. A method of detecting, identifying, monitoring and assessing respiratory effort of a person comprising the steps of:

a. providing a sensor including a flat strip of a PVFD polymer of a predetermined length dimension having a layer of metallization on opposed major surfaces thereof and with first and second elongated, conductive, insulated leads individually in electrical contact at a first end with the layers of metallization, said metallized flat strip being sandwiched between a layer of single sided adhesive tape and a layer of double sided adhesive tape;

b. adhesively affixing the sensor to the skin of the person proximate either the chest or the abdomen; and

c. connecting a second end of the first and second leads to a physiological data collection device whereby electrical signals due to changes in thoracic or abdominal circumference resulting from breathing are generated and analyzed for either screening or diagnosing sleep disordered breathing abnormalities.

2. The method of claim **1** wherein one side of the double-sided adhesive tape is provided with a covering layer of a silicone release paper and further comprising a step of removing the release paper to expose the adhesive on the one side prior to affixing the sensor on the person.

3. The method of claim **1** wherein the physiological data collection device is a PSG machine.

4. The method of claim **1** wherein the physiological data collection device comprises a home sleep test recorder.

5. The method of claim **1** wherein said predetermined length dimension is in a range from 6 centimeters to 24 centimeters.

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专利名称(译)	评估呼吸努力的方法		
公开(公告)号	US20160045155A1	公开(公告)日	2016-02-18
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[标]申请(专利权)人(译)	DYMEDIX		
申请(专利权)人(译)	DYMEDIX CORPORATION		
当前申请(专利权)人(译)	DYMEDIX CORPORATION		
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外部链接	Espacenet USPTO		

摘要(译)

一种测量不需要身体环绕带的患者呼吸努力的方法包括夹在单面胶带条的覆盖层和双面胶带条的底层之间的PVDF传感器，其布置成使得传感器可以粘附地附接到正在进行睡眠研究的人，并且其中与PVDF传感器协作的电导线适于连接到诸如PSG机或HST监视器的生理数据收集装置。