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Lang

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[54] **DEVICE FOR COMBINED MONITORING AND STIMULATION OF RESPIRATION**

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[21] Appl. No.: **177,580**

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 886,429, Dec. 18, 1969, abandoned.

[30] **Foreign Application Priority Data**

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Feb. 15, 1971 Germany 2107099
Feb. 15, 1971 Germany 2107098

[52] **U.S. Cl.** ..... **128/2 R,** 128/2.08, 128/30.2, 340/279

[51] **Int. Cl.** **A61b 5/08**

[58] **Field of Search** ..... 128/2.1 R, 30, 30.2, 25 R, 128/DIG. 17, 2.08, 145.8; 340/279

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Attorney, Agent, or Firm—Fleit, Gipple & Jacobson

[57] **ABSTRACT**

A device for monitoring and automatically stimulating respiration including means for directly monitoring respiratory activity via the respiratory tract, a sensor for converting the monitored respiratory activity into cyclical electrical signals indicative of the respiration depth and frequency, and electronic counter means for counting the electrical signals generated by the sensor and for generating a signal when a predetermined number of electrical signals have been counted. The device also includes an alarm relay, integrating timing means for triggering the alarm relay in the event that no signal is received from the counter within a predetermined time period, and respiration stimulator means activated by the alarm relay upon the triggering thereof for automatically reestablishing respiration. Means are also provided to clear mucus from the passage between the respiratory tract and the sensor, and further to ensure that shallow breathing is not mistaken for reestablished normal breathing.

12 Claims, 3 Drawing Figures

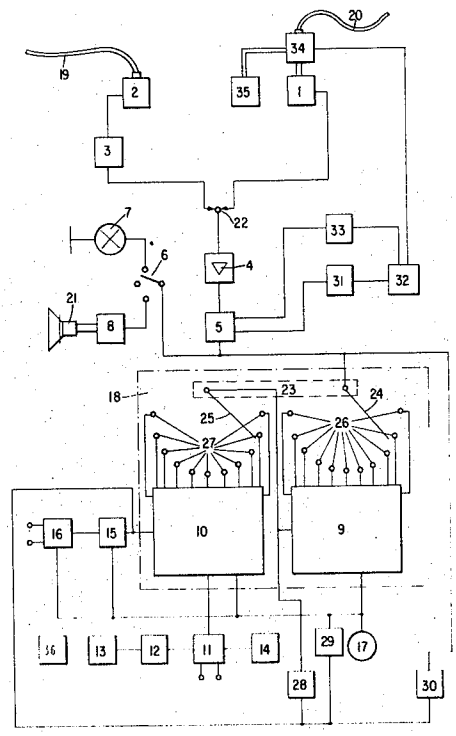


Fig. 1

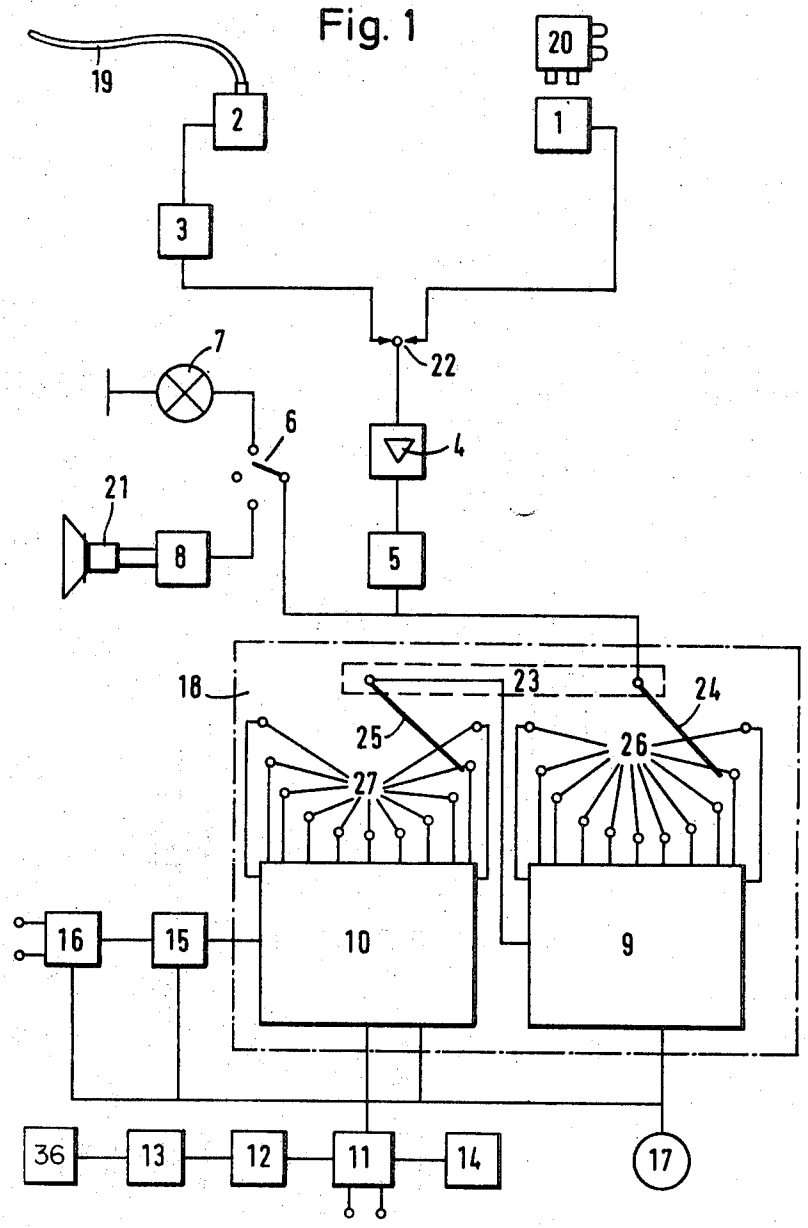


Fig. 2

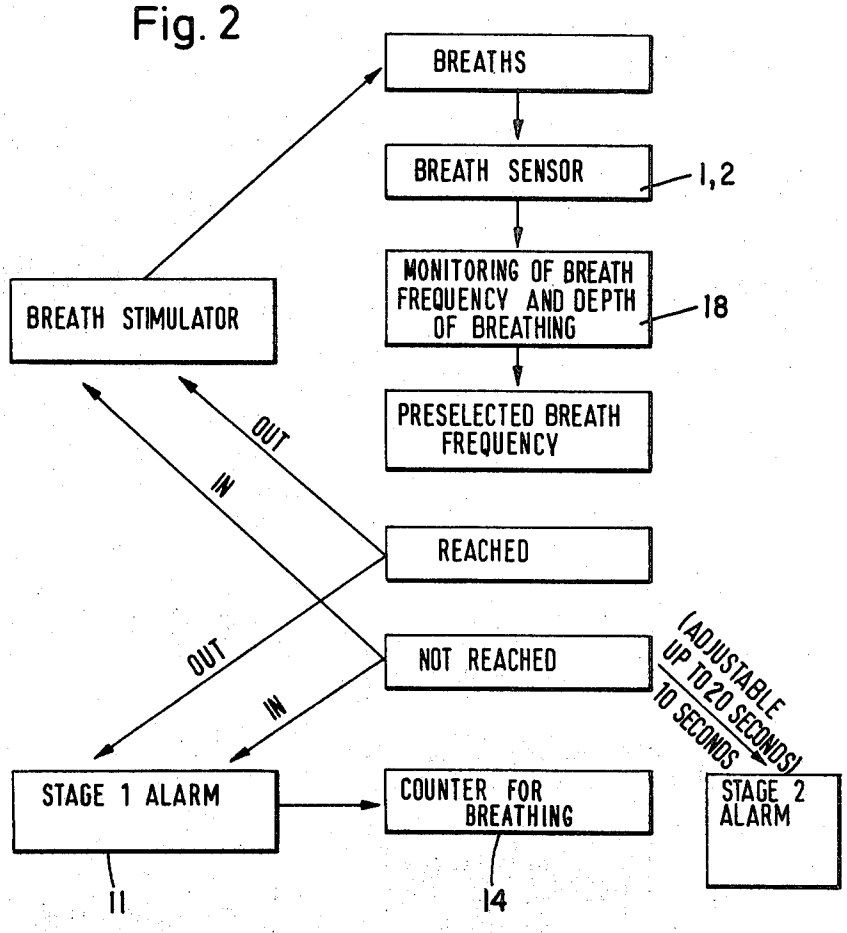
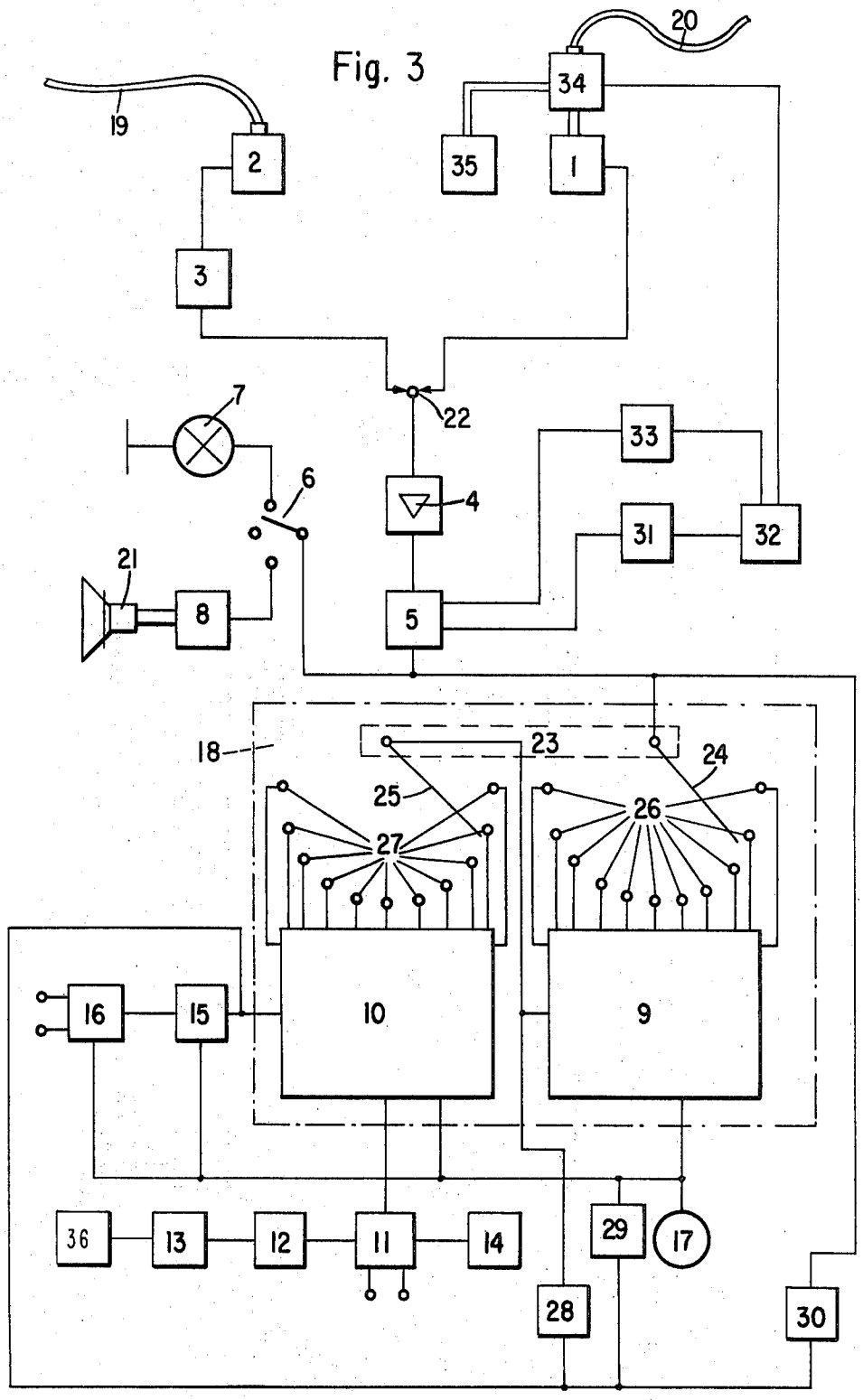

BREATHS
BREATH SENSOR
1,2
MONITORING OF BREATH FREQUENCY AND DEPTH OF BREATHING
18
BREATH STIMULATOR
PRESELECTED BREATH FREQUENCY
OUT
IN
REACHED
OUT
IN
NOT REACHED
(ADJUSTABLE UP TO 20 SECONDS)
10 SECONDS
STAGE 1 ALARM
COUNTER FOR BREATHING
STAGE 2 ALARM
11
14

Fig. 3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DEVICE FOR COMBINED MONITORING AND STIMULATION OF RESPIRATION

RELATED APPLICATIONS

This application is a continuation-in-part of U.S. Pat. application Ser. No. 886,429, filed Dec. 18, 1969, and now abandoned.

BACKGROUND OF THE INVENTION

In recent years, there has been decided progress in the care of premature and newborn infants. In contrast to the previous situation, it is now possible to keep even premature infants alive, if only the still very immature organs can be relieved of load or stimulated to the extent that the performance required of these organs can be achieved. A problem that lies at the heart of the matter is adequate spontaneous respiration.

Apparatus has been developed in this art that attempt, for the monitoring, to detect the breathing activity through movements of the thorax by means of respiratory belts, changes of electric conductivity, and so forth. The electronic apparatus thus far developed constitute an advance in the monitoring of endangered children, and they also have led to a certain relief of the nursing personnel. Unfortunately, however, they are easily subject to disturbance from all movements of the children, that is, movements are erroneously recorded as inhalations. In the case of usually restless premature infants in the incubator, for whom these monitoring devices are primarily developed, such a drawback must be considered substantial. And if there is respiratory failure, the oxygen deficiency is threatening in a relatively short time, strongly increasing the restlessness of these children annd manifesting the condition in increased motility.

Since these random movements are recorded in the prior art monitoring apparatus as "inhalations," there is a delay in triggering the alarm up to the point at which the child has become devoid of tonus because of serious hypoxemia. From this instant of alarm signalling until the monitoring personnel arrives and artificial respiration is initiated, there is a substantial loss of valuable time. And in animal experiments of recent years, it has been shown that even respiratory cessation of short duration (above 60 seconds), especially when there is already a slight hypoxia, can lead to brain damage which can cummulatively lead to observable defects. Unfortunately, threatening pulmonary ventilation disturbance through shallowness of respiration (e.g. in the respiratory distress syndrome) cannot be detected in time by these known instruments.

The most varied kinds of statistics show, unfortunately, and especially in premature infants, that there is a shockingly high incidence of brain damage, a substantial proportion being caused by inadequate spontaneous respiration with hypoxia. Respiratory failure in the premature is mostly caused by immaturity of the respiratory center, and can be relieved immediately by the simplest of measures, for example, manual slapping of the infant or repeated short-duration rhythmic compression of the thorax.

The objective of the present invention is to develop an electronic apparatus for combined automatic monitoring and stimulation of respiration, ensuring a high degree of safety for the infant being monitored, and at the same time relieving the nursing personnel of work load.

SUMMARY OF THE INVENTION

According to the present invention, the problems of the prior art are solved in that sensors consisting of thermistors or pressure sensitive elements convert respiration to electric signals. The electric signals are counted on electronic counters preset to count a specific number of breaths. The output of the counter is fed to integrating timing circuits that trigger an alarm relay if the desired standard respiratory frequency is not attained. When triggered, the alarm relay switches on a respiration stimulator that consists of a rhythmically inflatable belt or cuff. The inventive apparatus has a plurality of electronic counters for counting exhalations and a corresponding number of timing circuits so that respiration can be monitored and the desired standard respiratory frequency can be established. By determination of the respiration (e.g., by the expired air) by means of thermistors or by a pressure sensitive sensor (Pitran, piezoelectric or photoelectric measuring transducer), not only the respiratory frequency but also the depth of respiration can be measured semiquantitatively and utilized for monitoring the infant. A special adapter that fits the nose of the child or a sound tube with adapter that can be introduced into the nose or mouth, carries the flow of respiratory air to the sensor. By means of the apparatus of the invention the dangers of the prior art are avoided. In the prior art, the magnitude of respiration is measured indirectly by thoracic movements, by an expansion measuring strip or by electric conductivity, and may result in mistaking the child's movements for "inhalation" which can then lead to delayed alarm after respiratory failure, just as it can result in unreliably reported threatening shallowness of respiration.

With the inventive system, the first alarm relay (alarm I) simultaneously switches on the respiration stimulator which consists of a pulse generator that rhythmically initiates respiratory activity via supplementary devices. For stimulation of breathing, an inflatable belt can be positioned around the chest or any other part of the child's body, the valve controlling the inflation of such belt being rhythmically actuated by the pulse generator. Spontaneous breathing on the part of the child can be stimulated by the belt. Breathing can also be initiated by rhythmic pain or heat stimuli, produced by electric stimulation of the skin, nerves or muscles, or by thermal stimuli via skin or mucosa. The desired respiratory depth can be adjusted by setting the threshold value of an adjustable threshold value amplifier to the required level.

In a further advantageous embodiment of the present invention, there is provision for a second integrating timing circuit that triggers a second alarm (nurses' alarm) if after the initiation of the respiration stimulator by the first alarm circuit and the first timing circuit, spontaneous respiration has not been reestablished after a specific, predetermined time. The alarm triggering that is controlled by the second timing circuit can be stopped only by means of a manually actuated key.

It is further advantageous to selectively actuate acoustic or optical indicator devices by the electric signals delivered from the respiration snesor, to permit monitoring of individual exhalations.

The device of the present invention reliably detects respiratory failure and respiratory shallowness, and eliminates such deficiencies by automatic stimulation, an alarm being triggered upon unsuccessful stimulation of respiration. The apparatus of the invention thus attains a reliability that is not afforded by the known prior art devices. The combination of monitoring and stimulation of respiration in the device of the invention by eliminating travel time on the part of nursing personnel, makes possible the early treatment of respiratory failure and the resultant prevention of hypoxidosis in 90 to 95 percent of the cases.

Expecially in prematurely born children, irregular respiration is frequently observed, and this condition may unpredictably lead to respiratory failure. Before the onset of respiratory failure, however, there is frequently an irregular gasping, and there is the possibility that there will only be a respiration consisting of two or three gasps after stimulation by the prior art devices. Such defective respiration leads to no essential improvement, and on the contrary usually ends in a deterioration of oxygen supply to the patient being monitored. If a respiration monitoring device is constructed as is known in the prior art, with alarm triggering independent of the number and depth of the inhalations, there is the great danger that in gasping breath there will be a delayed alarm or that an existing alarm will be cut off. Such could well result in increased oxygen deficiency for the infant, and, as a consequence, brain damage.

With the present invention, the detection of respiration is by means of expired air and hence such defective respiration can be reliably reported. Accordingly, a further object of the invention is to provide a respiration monitor which will detect gasping respiration, and which is so arranged that gasping will not delay triggering of the alarm.

This problem is solved by providing a respiration monitoring device with an electronic counter for determination of respiration in combination with an electric zero setter, timing member, pulse generator and blocking circuits. A timing member that is connected after the electronic counter triggers the four following functions after the elapse of a predetermined time: blocking the input of the timing member; electronic zeroing of the counter; actuation of a time-delayed pulse generator that sends a pulse to the input of the electronic counter; and lifting the block on the input of the timing member. The four described functions have the effect that, depending upon the preselected respiration frequency, at least 4, 8, 16 or 32 minus one exhalations are required to extinguish the alarm that has been set off.

In the apparatus of the invention, it has been repeatedly observed that false alarms are set off by penetration of mucus into the sound tube or nose adapter introduced for the monitoring of respiration. A further object of the invention is the elimination of this defect, and such is eliminated with a blow-through device for the respiration monitoring apparatus which consists of a two-way valve connected to a breath sensor and an expander valve associated with a gas tank or fan. The sound tube or adapter serving to transmit pressure fluctuations and air flow that occur in breathing can be connected either to the breath sensor or the blow-through device by means of an intermediate two-way valve. Penetration of mucus or fluid into the sound tube that serves for transmission of the breathing to the sensor, after a short set interval, leads to brief switching of the electromagnetic two-way valve, by an electronic switch. This brief switching on of a blow-through device leads to a cleaning of the sound tube. In actuation of the two-way valve, an electronic blocking circuit at the same time prevents disturbances that would occur in the switching of the two-way valve caused by air movements from being recorded in the breathing sensor and erroneously reported as inhalation. Advantageously, both in start up of the monitoring device and in manual cutoff of an alarm after respiratory failure, there is an automatic cleaning of the sound tube by preliminary blowing.

The foregoing objects and advantages of the present invention will be more fully understood when reference is made to the following description taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a block diagram of the circuitry of the apparatus of the present invention;

FIG. **2** is a schematic diagram illustrating the function of the invention according to FIG. **1**; and

FIG. **3** is a block diagram of the circuitry of the device of the present invention with gasping respiration safety and blow-through device.

DETAILED DESCRIPTION OF THE DRAWINGS

Into the nose or mouth of the child to be monitored, there is introduced a suitable, optimally fitted nose adapter **20** or mouth adapter **19.** The respective adapter elements lead the flow of respiratory air directly or via a sound tube to a breath sensor **1,2.** The breath sensor receives the respiratory air flow and converts the same to electric signals. As suitable sensors there may be used thermistors **1** or pressure sensitive measuring transducers **2** (according to principles of piezoelectricity or photoelectricity), or pressure sensitive transistors (Pitrans). Both possibilities are indicated in FIG. **1.** The sensitivity of thermistor **1** can be enhanced by preconnection of a preheated thermistor, which at the same time makes selective detection of the expired air possible.

Between amplifier **4** and the pressure sensitive sensor **2,** there is an active filter **3.** This filter has a feedback amplifier and selectively separates out all interfering frequencies. Only frequencies produced by the breathing are introduced into amplifier **4** for amplification. For example, interfering pulses caused by noise are filtered out. The analog signal of sensor **1,2** is amplified in amplifier **4** and is converted by the threshold value amplifier **5** (Schmidt trigger) into a digital signal. The threshold value amplifier is adjustable, to adapt the threshold value to a predetermined minimum depth of respiration so that no signal is transmitted in the event of shallow breathing. If the depth of respiration is above the threshold level, a signal from the threshold value amplifier **5** is simultaneously transmitted to the respiratory frequency control unit **18** and to an optical and acoustic indicator unit **6,7,8,21.** In this way, the signal can be brought selectively by switch **6** to lamp **7** or the sine generator **8** which generates an acoustic frequency and results in an audible signal via speaker **21.**

The signal derived from the threshold value amplifier **5** is applied to respiratory frequency control unit **18** including an electronic counter **9** comprised of a plurality

of electronic counting units in the form of flip-flop circuits. Beyond the electronic counter **9** there is a timing circuit (Miller integrator) **10** connected to the counter output. The desired breathing frequency (exhalations per minute) can be set by a preselector switch **23** which at the same time sets the counter **9** and timing circuit **10** associated therewith by means of switches **24** and **25.** Depending upon the setting for respiratory frequency, a specific number of exhalations (4–32 per minute) is counted by the electronic counter **9,** and after counting, a signal is developed which is sent to timing circuit **10** associated with the counting device **9.** The respiratory frequency control thus consists in determining whether the predetermined number of exhalations occur within the predetermined time given by timing circuit **10.** The timing circuit is so tuned to electronic counter **9** that a signal is sent to alarm relay **11** and to the second timing (e.g., **10** to **20** seconds) circuit **15** if the predetermined standard time has elapsed without any exhalations count by the electronic counter **9** corresponding to the setting.

If the chosen values for breathing frequency and/or depth of respiration are not attained, alarm relay **11** (alarm stage I) is energized by the first timing circuit **10** and at the same time the pulse generator **12** (multivibrator) is switched on to control magnetic valve **13** for the respiration stimulator **36.** The respiratory failures are counted by the electromechanically functioning counter **14,** and are recorded. The respiratory failures recorded by counter **14,** and successfully treated failures, can be evaluated in terms of therapy, prognosis and diagnosis.

Along with the alarm relay **11,** the first timing circuit **10** energizes the second timing circuit **15** (Miller integrator) which, when its preestablished time interval has elapsed, energizes the second alarm relay **16** (alarm stage II). The alarm set off by the second alarm relay **16** can only be interrupted by means of a cutoff key **17.** The use of key **17** also results in the reset of the respiratory frequency control unit **18** and the second timing circuit **15** to zero. The second timing circuit **15** is adjustable to a time of 10–20 seconds. If during this time there is no adequate spontaneous respiration as a result of stimulation, the second alarm relay **16** is set off. This alarm relay **16,** as already noted, can only be restored to its initial setting by by manual depression of key **17.** If adequate spontaneous respiration develops before the termination of the stimulation time the timing circuits **10** and **15** and the electronic counter **9** are reset to zero, along with alarm relay **11,** and hence pulse generator **12** for the respiration stimulator **36** is disconnected along with its appurtenant magnetic valve **13.**

The circuit is so arranged that if there is current failure, alarm relays **11** and **16** are always energized. The respiratory frequency control unit is designed in such a way that the frequency can be set at 15 to 140 exhalations per minute.

The operation of the device of the present invention will now be explained with reference to FIG. **2.** The individual exhalations of the child are detected by breath sensor **1** or **2** which delivers electric signals to the respiration frequency control **18** of the apparatus as indicated by the arrows in the schematic diagram. Four or more exhalations serve for the determination of respiratory frequency. As shown by the schematic diagram, reaching the standard breath frequency leads to cutoff of the respiration stimulator and of alarm relay **11** (alarm stage I).

If it happens that the standard respiratory frequency is no longer reached, e.g., in extreme respiratory shallowness, slowing or cessation, the respiration stimulation and alarm stage I are switched on, with simultaneous recording of respiratory failure by an incorporated counter **14.** Breathing frequency higher than the established standard leads only to triggering of the alarm if at the same time a significant shallowness of respiration occurs and inadequate ventilation results. In most cases, indicated by the arrow in the schematic, respiration stimulation results in the reestablishment of spontaneous respiration of the premature infant or patient. The individual exhalations are detected then by the breath sensor, signals are delivered to the respiration frequency control **18,** and when the standard frequency is attained, the respiration stimulator and alarm stage I are cut off. If, in rare instances, e.e., with long-lasting hypoxia, a period of 10 seconds (adjustable to 20 seconds) elapses without the reestablishment of spontaneous respiration during stimulation, alarm stage II is tripped (activating the central alarm facility and lighting up of alarm cutoff key **17**). This alarm can then only be cut off manually by the depression of the light key **17** by an attendant. Alarm stage I, after a brief interval, is triggered during shallow respiration or during respiratory failure and serves primarily for monitoring the respiration of small children, school age children and adults, and may be used even if the stimulator is not used.

As shown in the block diagram of FIG. **3,** the electric signals from the sensor **1** or **2** pass via the amplifier **4** to the threshold value amplifier **5** and respiration frequency control unit **18.** The signal is delivered to an electronic counter **9** that contains electronic counting units consisting of flip-flop circuits. A timing circuit **10** (Miller integrator) is connected after elelctronic counter **9,** and is adapted to receive the counter input. By this timing circuit **10,** it can be determined whether the predetermined number of exhalations have occurred within a preestablished time given by the circuit. The desired respiration frequency (exhalations per minute) is set through a preselector switch **23** which simultaneously, by means of the switching levers **24, 25,** set the counter **9** and the timing circuit **10** associated therewith. Depending upon the respiration frequency setting, a specific number of exhalations (**4–32**) is counted by electronic counter **9,** and after the counting, a signal is applied to the associated timing circuit **10,** setting it to zero. The respiration frequency control involves determining whether the predetermined number of exhalations occur within the predetermined time given by timing circuit **10.** The timing circuit is so tuned to the electronic counter **9** that a signal to relay **11** is transmitted if the predetermined standard time has elapsed without the electronic counter **9** counting the number of exhalations for which it is set. If the standard value for respiration frequency is not reached, alarm relay **11** is triggered by timing circuit **10.**

The gasping respiration safety operates at the same time that alarm relay **11** is triggered. Four processes are initiated in succession by the respiration safety, and simultaneously with the triggering of alarm relay **11.** First, the input of timing circuit **10** is electronically blocked by blocking circuit **28;** second the electronic zero-setting device **29** for the counting circuit **9** is ener-

gized; third, a pulse is applied to the input of the electronic counter **9** by a time delayed pulse generator **30**; and fourth, the blocking of the input of the timing circuit **10** is removed.

After the completion of these processes, **4, 8, 16** or **32** exhalations minus one are necessary for the renewed setting of timing circuit **10** to zero i.e., for extinguishing the alarm. This means for the child being monitored, that depending upon the preestablished respiration frequency, there must be at least 3, 7, 15 or 31 normal exhalations to deactivate the triggered alarm. In this way, a very high monitoring safety is attained for the patient.

The automatic blow-through device operates as follows. The automatically controlled blow-through device (pertubator) for the respiration monitoring apparatus is shown in the block circuit diagram of FIG. **3.** The respiratory air of the patient passes via sound tube **20** to two-way valve **34** and breath sensor **1.** If the sound tube is clear, air movements occurring in expiration will be converted by the sensor to electric signals and carried via amplifier **4** and Schmidt trigger **5** to the counting circuit **18,** there determining whether the respiratory frequency is adequate by means of the associated timing circuit. A timing member **31** (e.g., Miller integrator) is connected with Schmidt trigger **5,** controlling a monostable flip-flop **32.** The "on" time of this flip-flop determines the switching time of the electromagnetic two-way valve **34.** At the same time, the monostable flip-flop **32** controls an electronic blocking circuit **33** connected to the Schmidt trigger **5.**

If the child breathes regularly and if the sound tube is free of mucus, the air displacement or pressure fluctuation occurring in expiration exceeds a threshold and causes a response by the respiration sensor. The signals of the sensor are electrically amplified and delivered via Schmidt trigger **5** to the electronic device of the respiration monitoring apparatus. With adequate respiration, timing member **31** is always reset to zero by Schmidt trigger **5.**

If, however, the sound tube to the nose or throat is filled with mucus or fluid, the threshold is not reached, and there is no electric signal from respiration sensor **1** strong enough to activate Schmidt trigger **5.** Hence, timing member **31** is not reset to zero by the Schmidt trigger **5.** After a few seconds (adjustable) the timing member **31** sends a pulse through flip-flop **32.** This flip-flop then briefly energizes the two-way gas valve **34** and thereby connects the sound tube with the expander valve associated with a gas tank or fan **35.** Valve **34** can take the form of any conventional electrically operated valve which, in one position, communicates the tube **20** with the sensor **1,** and which, in the other position, communicates tube **20** with the tank or fan **35.** A blow-through (cleaning) of the sound tube **20** is thereby effected. At the same time, Schmidt trigger **5** is electrically blocked by monostable flip-flop **32** via blocking circuit **33** until valve **34** has been de-energized for a time, and thereby no electric signal of disturbance from sensor **1,** caused by switching of valve **34,** can reach Schmidt trigger **5.**

Above, a specific embodiment of the present invention has been described. It should be appreciated, however, that this embodiment is described for purposes of illustration only and that numerous alterations and modifications may be practiced by those skilled in the art without departing from the spirit and scope of the invention. Accordingly, it is the intent that the present invention not be limited by the above but be limited only as defined in the appended claims.

What is claimed is:

1. A device for automatically monitoring and stimulating respiration, the device comprising: means for directly monitoring respiratory activity via the respiratory tract; said means including at least one sensor means for converting the monitored respiratory activity into electrical signals indicative of the respiration frequency; electronic counter means said at least one sensor means for counting the electrical signals generated by said sensor and for issuing a signal when a predetermined number of electrical signals have been counted; an alarm relay; first integrating timing means for receiving the signals issued by said electronic counter means and for triggering said alarm relay in the event that no signal is received from said counter means within a predetermined time period; and respiration stimulator means activated by said alarm relay upon the triggering thereof for automatically reestablishing respiration.

2. The device recited in claim **1,** in which said counting means comprises a plurality of counters, and said first integrating timing means comprises a corresponding number of timing circuits, and further comprising means for delivering the electrical signals generated by said sensor to one of said counters, and for delivering the signal issued by said one counter to a corresponding one of said timing circuits.

3. The device recited in claim **1,** in which said respiration stimulator means comprises a rhythmically inflatable belt, a magnetic valve means controlling the inflation of said belt, and a pulse generator means for actuating said magnetic valve.

4. The device recited in claim **1,** in which said respiration stimulator means comprises heating elements for establishing normal respiration by way of thermal stimuli.

5. The device recited in claim **1,** and further comprising a second alarm relay and means for triggering said second alarm relay in the event that respiration is not automatically reestablished by said respiration stimulator means after a predetermined time period.

6. The device recited in claim **5,** and further comprising a second timing means connected after said first timing means for energizing said second alarm relay after the elapse of said predetermined time period.

7. The device recited in claim **1,** and further comprising a gasping respiration saftety including an electronic zeroing means connected to said counter means; a pulse generator means for putting a predetermined count on said counter means; and a blocking circuit means for blocking the input to said first timing means.

8. The device recited in claim **7,** wherein said first timing means is connected after said electronic counter means and initiates, in succession, the blocking of the input of said first timing means, the electronic zero setting of said counter means by said electronic zeroing means, the energizing of said pulse generator to deliver a pulse to the input of said electronic counter, and the removal of the blocking of the input of said first timing means.

9. The device recited in claim **1,** and further comprising a blow-through device including a two-way valve in combination with said sensor means and a source of pressurized gas.

10. The device recited in claim 9, and further comprising a sound tube serving for transmission of respiratory activity, said tube being selectively connected by said two-way valve either to said means sensor or to said blow-through device.

11. The device recited in claim 9 and further including an electronic circuit means for switching said valve in the event of penetration of mucus or fluid into said sound tube.

12. The device recited in claim 9, and further including a second blocking circuit, means actuated simultaneously with the actuation of said two-way valve, for blocking signals developed in the operation of said two-way valve from being erroneously detected as respiration.

* * * * *