

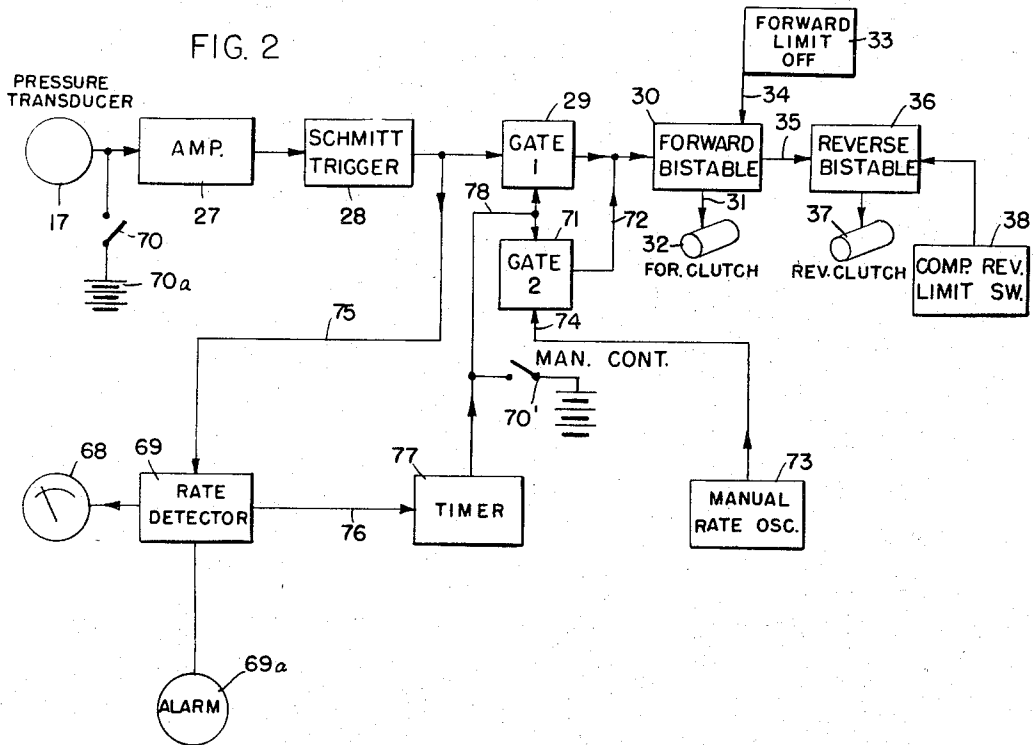
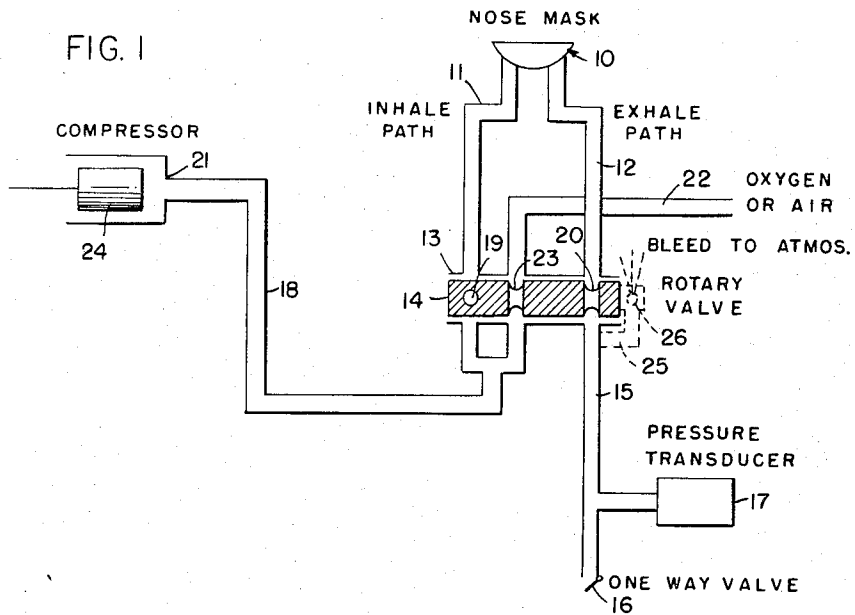
Dec. 12, 1967

D. L. CARLSON  
RESPIRATORY AUGMENTOR WITH ELECTRONIC  
MONITOR AND CONTROL

3,357,428

Filed Dec. 23, 1963

2 Sheets-Sheet 1



INVENTOR:

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*Dawson, Titton, Fallon, Lungmus & Alexander*

ATT'YS

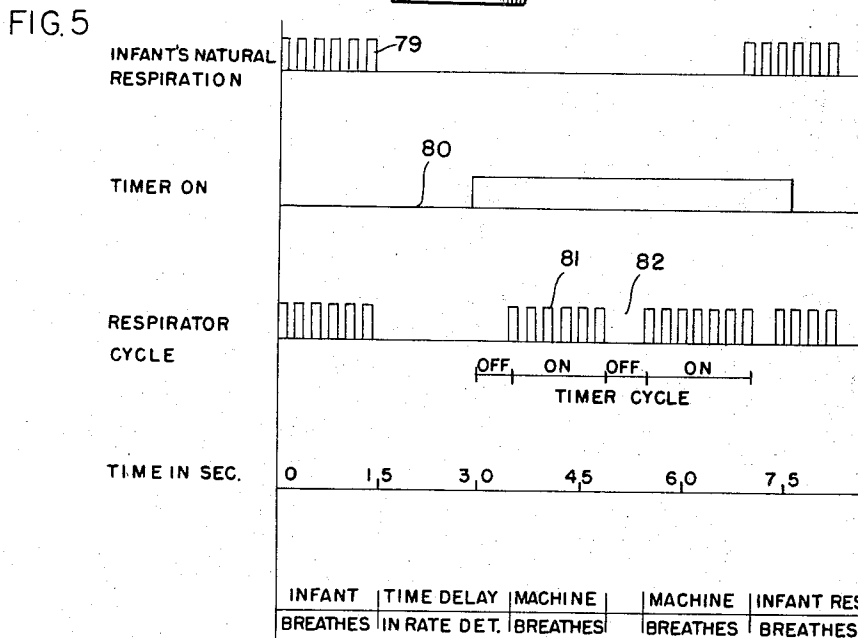
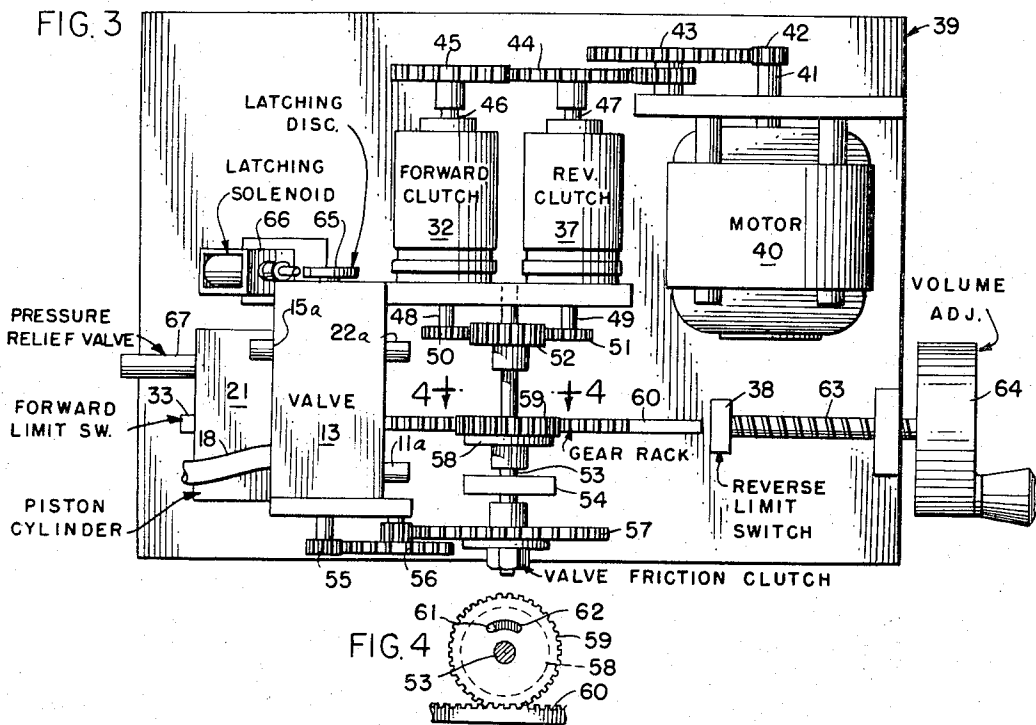
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## RESPIRATORY AUGMENTOR WITH ELECTRONIC MONITOR AND CONTROL

David L. Carlson, Ames, Iowa, assignor, by mesne assignments, to the United States of America as represented by the Secretary of the Department of Health, Education, and Welfare

Filed Dec. 23, 1963, Ser. No. 332,369

14 Claims. (Cl. 128—145.8)

This invention relates to a respiratory augmentor, and, more particularly, to a device capable of ameliorating the respiratory distress syndrome in infants.

One condition in infants that requires respiratory augmenting is when the infant lacks sufficient strength to maintain life while a Hyaline membrane is sometimes present in the lungs shortly after birth. This is particularly true of prematurely born infants, and frequently the baby is incapable of expanding his lungs sufficiently to maintain the necessary respiration rate. The provision of apparatus for augmenting respiration and synchronization with the infant's natural attempt thus constitutes an important object of the invention.

Another object is to provide a mechanism which provides forced breathing in the event of failure of natural breathing.

Still another object is to provide apparatus which functions to challenge and stimulate the infant to return to a predetermined respiration rate whenever the natural rate falls therebelow.

Other objects and advantages of the invention may be seen in the details of construction and operation set down in this specification.

The invention is explained in conjunction with an illustrative embodiment in the accompanying drawing, in which—

FIG. 1 is a schematic picturization of the respiration circuit employed in the practice of the invention;

FIG. 2 is a schematic diagram of the electronic circuitry associated with the mechanical respiration circuit;

FIG. 3 is a top plan view of the mechanical portion of the apparatus and which incorporates most of the elements represented schematically in FIG. 1;

FIG. 4 is an elevational view, partially in section, onto enlarged scale, of the portion of the apparatus of FIG. 3 seen along the sight line 4—4 applied to FIG. 3; and

FIG. 5 is a graph of respiratory function against time, featuring one of the modes of operation of the invention.

In the illustration given and with particular reference to FIG. 1, the numeral 10 designates generally a nose mask which is adapted to be installed over the face of an infant (not shown) whose respiratory efforts are to be augmented by the inventive mechanism. The mask can be seen in greater detail in the copending, co-owned application of John B. Buck, Serial No. 351,182, filed March 11, 1964, now replaced by continuation-in-part application Serial No. 557,184 filed June 13, 1966, and reference may be had to that application for details of the mask not herein given. It is believed sufficient to state that infants normally are "nose breathers", and a mask fitted to the infant's nose leaves the mouth available for feeding, vomiting, mucous aspiration, etc.

Connected to the face mask are a pair of conduits 11 and 12 which provide, respectively, paths for inhalation and exhalation. The other ends of the conduits 11 and 12 are connected to a valve generally designated 13 which is arranged to assume two different positions, one for inhalation and one for exhalation.

In the condition shown, the valve 13 has its spool 14 positioned or disposed so as to couple the exhalation conduit 12 to a conduit 15 which terminates in a check valve

16. Interposed in the conduit 15 is a pressure transducer 17 which is arranged to be sensitive to negative pressure, i.e., subatmospheric pressure such as is developed when the infant starts to inhale. When this occurs, the check valve 16 remains closed and the sensing of the negative pressure in the conduit 15 by the transducer 17 provides a signal that initiates repositioning of the spool 14 so as to connect the inhalation conduit 11 with the compressor conduit 18—this via the flow passage 19 in the spool 14. During this repositioning of the spool 14, the flow path 20 which heretofore has coupled the conduits 15 and 12 is rotated out of alignment with the conduit so as to prevent inspiration of air via the exhalation conduit 12.

Coupled to the compressor conduit 18 is a compressor 21 which is optimally a positive displacement device such as the cylinder and piston unit schematically illustrated in FIG. 1. The positive displacement unit 21, during the exhalation portion of the respiratory cycle, draws a predetermined volume of air or oxygen through the conduit 18 by virtue of being coupled to the supply conduit 22 and the alignment of the flow ports 23 in the spool 14.

Movement of the piston 24 of the positive displacement unit 21 forces air through the inhalation conduit 11 so that the infant is relieved of the work of expanding his lungs to inhale. The natural elasticity or resiliency of the lungs is relied upon in the practice of this invention to develop the exhalation.

Also illustrated in FIG. 1 is a branch or bleed conduit 25 which is coupled to the transducer conduit 15 for the purpose of returning the pressure in the conduit 15 to atmospheric pressure after the spool 14 has been positioned for the inhalation phase of the respiratory cycle. This is achieved through providing a flow bore 26 in the spool 14 so that a negative pressure does not continue to exist in the transducer conduit 15 and thereby interfere with the subsequent operation of the transducer 17. Exemplary of the equipment useful in the practice of the invention, the pressure transducer may be catalog No. PM 97 of the Statham Instrument Company, of Los Angeles, California, which incorporates a diaphragm and bridge circuit of the strain gauge type.

Now referring to FIG. 2 and particularly the upper portion thereof, the electronic circuitry useful in controlling the operation just described is seen. Again, the pressure transducer is designated 17 and it is electrically coupled to an amplifier 27 so as to increase the magnitude of the signal voltage provided by the transducer 17. Advantageously, the output of the amplifier 27 is coupled to a Schmitt trigger 28 which provides a sharp pulse corresponding to the transducer signal.

The output pulse of the Schmitt trigger 28 is coupled to the input of an electronic gate 29 which, in the particular type of operation under consideration at the present, merely passes the signal to a first or forward bistable circuit 40 which may be of the Eccles-Jordan, or "flip-flop" type. Such a circuit is bistable and develops an output signal as at 31 in response to the signal from the gate 29 to energize a forward clutch 32. The clutch 32 is effective to reposition the spool 14 of the rotary valve 13 and to move the piston 24 of the positive displacement unit 21 in a direction to expel air into the inhalation conduit 11, i.e., move to a condition of no displacement.

The functioning of the first bistable circuit 30 is terminated when the piston 24 reaches the end of its travel, i.e., to a position of no displacement, wherein it energizes a limit switch schematically illustrated at 33. The limit switch 33 delivers a signal at 34 changing the condition of the first bistable circuit 30 and thereby delivers an output pulse via the line 35 to a second or reverse bistable circuit 36. The circuit 36, in response to the signal at 35, actuates a reverse clutch 37 which repositions the spool 14 of the rotary valve 13 and retracts the piston 24—the

retraction continuing until the second limit switch 38 is engaged—whereupon the second bistable circuit 36 is converted to its alternate condition where the output is unused and the entire electromechanical system is ready for another signal from the pressure transducer 17.

The mechanical apparatus referred to in connection with the description of the electronic circuitry of FIG. 2 can be seen in plan view in FIG. 3, and reference is now made to that view. In the particular illustration given, the numeral 39 designates generally a base or frame for supporting the mechanical elements and which can be incorporated into a chassis (not shown) housing the electrical elements previously referred to. Supported on the frame 39 is a motor 40 equipped with an output shaft 41. The shaft 41 has fixed thereto a spur gear 42 which provides the beginning of a gear train generally designated 43 terminating in a pair of spur gears 44 and 45 associated, respectively, with the reverse clutch 37 and the forward clutch 32 hereinbefore referred to in connection with FIG. 2. The clutches 32 and 37 are operably associated with gear shafts 46 and 47 and their axial continuations 48 and 49 which also carry spur gears 50 and 51. The gears 50 and 51 engage a driven gear 52 fixed to a shaft 53 suitably journaled in pedestal 54 provided as part of the frame 39. It will be apparent from the description thus far that the shaft 53 will rotate in one of two directions depending upon which of the clutches 32 and 37 is actuated by the electronic circuitry of FIG. 2.

The rotary valve 13 is also seen in FIG. 3 and the spool is equipped with a gear as at 55 for actuation by the shaft 53 through a gear train generally designated 56. Interposed in the gear train is a friction clutch 57 so that only a small amount of the rotational movement of the shaft 53 is utilized for positioning or repositioning the spool 14.

The shaft 53 carries a disk 58 fixed to it and has a pinion gear 59 journaled thereon. The pinion gear 59 cooperates with a rack 60 which is fixed to the piston 24 provided interiorly of the unit 21. The interrelationship of the disk 58 and the pinion gear 59 can be seen in FIG. 4, wherein the disk 58 is equipped with an axially extending pin 60 positioned within an arcuate slot 62 provided in the pinion gear 59. Thus, the pin 60 and slot 62 provide a lost motion linkage whereby the initial 10° or so of movement of the shaft 53 are not used for turning the pinion gear 59 but only for the purpose of positioning the spool 14 of the valve 13. After the initial small arcuate movement of the shaft 53, the pin 60 reaches one end of the slot 62 and under the urging thereof rotates the pinion gear 59 to reciprocate the rack 60.

Also seen in FIG. 3 are the forward and reverse limit switches 33 and 38, respectively. The reverse limit switch 38 is seen to be mounted on a threaded shaft 63 which terminates in a dial handle 64 useful in positioning the reverse limit switch for different amounts of retraction of the piston 24. It will be appreciated that although the inspired volume of air is normally small, of the order of 5–20 cc., the volume variation can be important to the infant and thus the degree of displacement in the positive displacement device 21 becomes meaningful. Initially, the tidal volume is ascertained for the purpose of positioning the reverse limit switch 38, and useful in this connection is the respiration meter described in the co-pending, co-owned application of Arp and Griffith, Serial No. 337,778, filed January 15, 1964.

To correlate the showing in FIG. 3 with that of FIG. 1, the inhalation conduit is coupled to the valve 13 as at 11a while the oxygen or air conduit 22 is coupled to the fitting 12a. The compressor conduit 18 is also seen in FIG. 2, while the exhalation conduit is adapted to be coupled to the fitting 12a. The transducer conduit 15 is adapted to be coupled to the fitting 15a. Additionally, the valve spool 14 is equipped with a latching disk as at 65 which is immobilized by engagement with the arm of the latching solenoid 66 so that the spool 14 is locked in position except

just prior to initial movement of the piston 24. The solenoid 66 provides a positive lock against spool rotation when the volume is adjusted. The solenoid 66 is responsive for unlatching the disk 65 to signals from the forward bistable circuit 30 which is also used for energizing the clutch 32.

The apparatus thus far described is that portion of the invention used for merely augmenting the natural respiratory effort of the infant, i.e., for relieving the infant of the burden of expanding his own lungs to inhale, which, it will be appreciated, can be critical since the period of life of the Hyaline membrane may be several days, during which the infant must labor to breathe. A summary of the operation in this aspect of the invention is set down below.

#### *Operation during augmenting*

An operating cycle starts with a negative pressure (with respect to the atmosphere) developed in the nose mask 10, by the infant's respiratory efforts. A one-way valve 16 prevents outside air from entering the transducer conduit 15 during this phase. The transducer 17 is then actuated by the pressure differential which triggers the electronic system (see FIG. 2). The amplified, sharpened pulse developed by the transducer 17 is applied through the first flip-flop circuit 30 to actuate the forward clutch 32 on the metering compressor 21 and the valve 13.

The valve spool 14 rotates in such a way as to close the exhalation path 20 and the air inlet to the compressor 23 as well as opening the inhalation path 19 to the compressor. Air is then forced into the lungs by the compressor. Completing its travel, the piston 24 actuates the forward limit switch 33, turning off the forward clutch 32 and triggering the reverse bistable circuit 36 to energize the reverse clutch 37. Upon this occurrence, the valve spool 14 is repositioned to the condition shown in FIG. 1, which closes the intake path 19 and opens the exhalation path 20. Simultaneously with this, the air supply path 23 is opened. Elastic contraction of the infant's lungs forces the respired air out. Positive pressure relative to the atmosphere opens the one-way valve 16, allowing the expired air to be exhausted to the atmosphere. The path 23 is also opened by the valve action from the air or air-oxygen supply to the compressor, allowing the compressor to be recharged. A breathing cycle is complete and the device is again ready to detect the infant's next inspiratory effort.

Advantageous in the practice of the invention is a compressor of the positive displacement type utilizing a piston wherein a tight piston seal is maintained by a rolling diaphragm. The stroke of the piston is adjustable, being determined by the position of the reverse limit switch 38, affording a method of varying piston displacement from zero to 40 cc. Maximum output pressure is limited to 30 cm. of water by a pressure release valve 67 (see FIG. 3), to insure that no damage can occur to the infant's lungs.

The forward and reverse limit switches 33 and 38, respectively, trigger the electronic system to disconnect current from the appropriate magnetic clutches 32 and 37. The forward and reverse clutches 32 and 37 drive the piston in and out by means of a rack and pinion arrangement 60 and 59, respectively. Initial forward rotation of the shaft 53 by the forward clutch 32 rotates the valve spool 14. After a fraction of a revolution, the valve core or spool 14 is rotated the necessary 90° and a friction clutch 57 then allows the forward clutch to rotate further without advancing the valve spool 14. A solenoid latch 66 prevents inadvertent movement of the valve spool 14. This solenoid is energized during the initial portion of the forward cycle as just described.

The electronic system provides the sensing and timing functions for the compressor and valve, and also it provides supervisory and control functions as well as supplying power for both the mechanical and electronic components. This is illustrated in FIG. 2 utilizing component blocks with the design being based upon binary type cir-

cuitry. All timing functions occur as a result of a pulse being received.

A step output from the nasal pressure transducer to the amplifier 27 and Schmitt trigger 28 triggers a first flip-flop circuit 30 controlling the forward clutch 32 on the positive displacement device 21. Completion of the device 21 metering action energizes the reverse clutch 37 and reverses the forward flip-flop 30 to its initial state for the next respiratory cycle. When the compressor returns to its initial position, the reverse clutch flip-flop 36 is reset.

The supervisory function just referred to makes use of the circuitry shown in the lower portion of FIG. 2 and includes a respiration rate meter 68 and a rate detector 69 coupled to an alarm which alerts attending personnel should natural respiration cease. An automatic timing sequence determines if the infant's failure to inspire is temporary. If no respiratory attempts are evident, the supervisory and control portion of the apparatus initiates forced respiration at a rate determined by a control setting on the front panel (not shown) of the equipment.

With reference to FIG. 2, the manual control of the device and breathing will now be described. Through the use of manually depressible switch 70 coupled to a suitable voltage source as at 70a, a signal is delivered to the input of the amplifier to simulate the output of the transducer 17. This mode of manual control requires a signal for each cycle of the equipment and is used primarily for testing the operability of the equipment and for priming the positive displacement device, as with oxygen or other useful gas.

Where there is a complete failure of inspiratory effort on the part of the infant, the manual rate oscillator 73 may be employed wherein the operator selects a desired breathing rate which is used to control the rate of operation of the oscillator 73. Pulses from the oscillator 73 are delivered to the second gate 71 as at 74, and the gate 71 thereupon energizes the forward flip-flop 30 via a signal through line 72, the first gate 29 being locked in its "Off" position through closing switch 70'. The manual rate oscillator 73 thus provides a controlled series of signals equivalent to manually depressing the switch 70 (but through a different path).

When, however, the infant is still capable of respiratory effort but this is inadequate, the portion of the FIG. 2 circuit shown in the lower left-hand portion is employed to augment the respiratory effort.

For this purpose, the sub-circuitry includes the rate detector 69 which is coupled by means of line 75 to the output of the Schmitt trigger 28. The rate detector includes a control (not shown) capable of adjustment to a predetermined rate or value of breathing effort which is deemed minimal for the infant—say, seventy inspirations per minute. The actual breathing rate will be reflected on the ratemeter 68. When, however, the natural rate drops below that set on the detector 69, a signal is delivered at the input 76 of the timer 77 which delivers an output pulse or signal at 78 for the purpose of blocking the first gate 29 and energizing the second gate 71 as was the case with the manual control utilizing switch 70. The automatic mode of augmentation when the infant's respiratory effort is present but inadequate, is summarized in FIG. 5. The upper series of pulses denote the infant's natural respiration, and it is seen that there is a cessation at 79. When the infant ceases to breathe, the rate detector 69 starts the timer 77. A fifteen-second delay as at 80 allows the infant to commence breathing within fifteen seconds without initiating the forced cycle. The delay time is adjustable through the provision of suitable components in an RC circuit in the detector. When, however, the infant's natural breathing rate does not increase or begin, as the case may be, the timer connects the manual rate oscillator 73 to the forward bistable circuit 30 for fifteen seconds as at 81 in FIG. 5, then disconnects it for five seconds as at 82 to determine

if the stimulation was successful. If it was, the timer disconnects and normally amplified respiration continues. The timing chart in FIG. 5 shows a hypothetical cycle of an infant's discontinuing respiration and then, after two stimulation periods, beginning again. When the timer is operating, the alarm 69a sounds, notifying the medical personnel of respiration failure.

While in the foregoing specification a detailed description of an embodiment of the invention has been put down for the purpose of explanation, many variations in the details herein given may be made by those skilled in the art without departing from the spirit and scope of the invention.

I claim:

1. A respiratory augmentor, comprising a pair of conduits providing paths for inhalation and exhalation of air and terminating at one end in a face mask, valve means in said conduits, means for providing a predetermined volume of air to said inhalator conduit, and sub-atmospheric pressure-sensing means operably associated with said exhalation conduit, said pressure-sensing means being coupled to said valve means for interconnecting said air providing means with said face mask upon initiation of inhalation, said valve means including a spool-equipped casing and means for rotating said spool between alternative positions coupling said face mask with said pressure-sensing means and said means for providing gas under pressure, said exhalation conduit terminating in check valve means, and means operably associated with said exhalation conduit for communicating the portion thereof between said valve means and said check valve means with the atmosphere when said spool is in the position coupling said face mask with said means for providing gas under pressure.
2. The structure of claim 1 in which said pressure-sensing means includes an electro-mechanical transducer, said means for providing gas under pressure including a positive displacement device, and electrically-actuated clutch means interconnected between said transducer and device, said clutch means being operative to actuate said valve means for interconnecting said face mask with said device before any substantial movement of said device.
3. The structure of claim 2 in which said clutch means includes limit switch means responsive to the action of said positive displacement device for reversing the action of said device and for connecting said face mask with said pressure-sensing means.
4. The structure of claim 3 in which said device comprises a cylinder and piston unit, said limit switch means comprising a pair of limit switches, one switch providing the above-mentioned reversal and connection while the other switch is adjustably positioned relative to said piston for varying the stroke of said piston.
5. The structure of claim 4 in which said valve means is equipped with latch means immobilizing said valve means against actuation except just prior to initial movements of said piston.
6. A respirator augmentor, comprising a frame equipped with two-position valve means, a pair of conduits coupled to said valve means and terminating in a nose mask adapted to be secured about the nose of a patient, one conduit providing an exhalation path and the other an inhalation path, a positive displacement device mounted on said frame and coupled to said valve means for delivering a predetermined quantity of air to said nose mask in one position of said valve means, means including valve activating means and a transducer mounted on said frame and conduit means coupling said transducer to said valve means for response to the initial stage of inhalation, whereby to actuate said valve means to said one position and actuate said device to deliver said quantity of air to said nose mask, and means operably associated with said conduit means for establishing atmospheric pressure therein during the one position of said valve means.

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7. The structure of claim 6 in which electro-mechanical means are interposed between said transducer and said device for interconnecting the same, said electro-mechanical means including a gate circuit for delivering an actuation signal to said device upon receipt of an actuation signal from said transducer, and a second gate circuit coupled to said device and first-mentioned gate circuit for blocking the delivery of said actuation signal from said transducer and for delivering an actuation signal responsive to external control.

8. The structure of claim 6 in which electromechanical means are interposed between said transducer and device for interconnecting the same, said electromechanical means including an inhalation rate detector, and means operably associated with said detector for actuating said device independently of said transducer whenever said inhalation rate falls below a predetermined value.

9. The structure of claim 8 in which said independently actuating means includes a timing circuit for intermittently actuating said device at a rate at least equal to said predetermined value until the infant's natural inhalation rate is at least equal to said predetermined value.

10. In respiratory augmenting equipment for infants, means including a mask, inlet and exhaust conduits connected to said mask, valve means interposed in each of said conduits, a positive displacement device connected to said inlet conduit via said valve means for delivering a controlled volume of air to said mask, means including a transducer for sensing inhalation effort of an infant and means connecting said transducer to said device for initiating action of said device to cause said device to deliver said volume to the infant to relieve the infant of the work attendant on inhalation while utilizing the resiliency of the infant's lungs to expel air therefrom, and means including a breathing rate detector interposed between said transducer and said device for signalling a reduction in the natural breathing rate below a predetermined value.

11. In respiratory augmenting equipment for infants, means including a mask, inlet and exhaust conduits connected to said mask, valve means interposed in each of said conduits, a positive displacement device connected to said inlet conduit by a said valve means for delivering a controlled volume of air to said mask, means including a transducer for sensing inhalation effort of an infant and means connecting said transducer to said device for initiating action of said device to cause device to deliver said volume to the infant to relieve the infant of the work attendant on inhalation while utilizing the resiliency of

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the infant's lungs to expel air therefrom, and means including a breathing rate detector interposed between said transducer and said device for signaling a reduction in the natural breathing rate below a predetermined value, means including a gate circuit coupled to said device for actuating said device independently of said transducer and at a rate at least equal to said predetermined value.

12. The structure of claim 11 in which means including an oscillator is coupled to said gate circuit for actuating said device independently of said detector.

13. The structure of claim 11 in which means including a timing circuit is coupled to said gate circuit and detector for intermittently actuating said device for discrete periods, with the actuating rate during each period being at least equal to said predetermined value whereby the infant is permitted to regain a natural breathing rate at least equal to said predetermined rate between said periods.

14. The structure of claim 11 including a timing circuit interconnected between said detector and device for actuating said device independently of said transducer and at a rate at least equal to said predetermined valve whenever the infant's natural breathing rate is less than said predetermined value, said timing circuit being operative to actuate said device for periods of the order of about 10-20 seconds with intervening periods of non-actuation of the order of 5 seconds to permit the infant's natural breathing rate to reach at least said predetermined rate, said detector being operative upon such occurrence to deactuate said timing circuit.

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RICHARD A. GAUDET, *Primary Examiner.*

CHARLES F. ROSENBAUM, *Examiner.*

UNITED STATES PATENT OFFICE  
CERTIFICATE OF CORRECTION

Patent No. 3,357,428

December 12, 1967

David L. Carlson

It is hereby certified that error appears in the above numbered patent requiring correction and that the said Letters Patent should read as corrected below.

In the heading to the printed specification, lines 4 to 7, for "assignor, by mesne assignments, to the United States of America as represented by the Secretary of the Department of Health, Education, and Welfare" read -- assignor to Iowa State University Research Foundation, Inc., Ames, Iowa, a corporation of Iowa --.

Signed and sealed this 25th day of February 1969.

(SEAL)

Attest:

Edward M. Fletcher, Jr.

Attesting Officer

EDWARD J. BRENNER

Commissioner of Patents