

[54] CONTINUOUS NEGATIVE PRESSURE
CHAMBER FOR INFANTS

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[51] Int. Cl.² A61M 16/00; A61H 31/00[58] Field of Search 128/1 B, 298, 30, 30.2,
128/28, 20, 204, 145.7, 145.6, 145.8, 145.5

[56] References Cited

UNITED STATES PATENTS

2,314,955	3/1943	Slater	128/30
2,572,787	10/1951	Wallin	128/30
2,822,803	2/1958	Huxley	128/30

Primary Examiner—Richard A. Gaudet

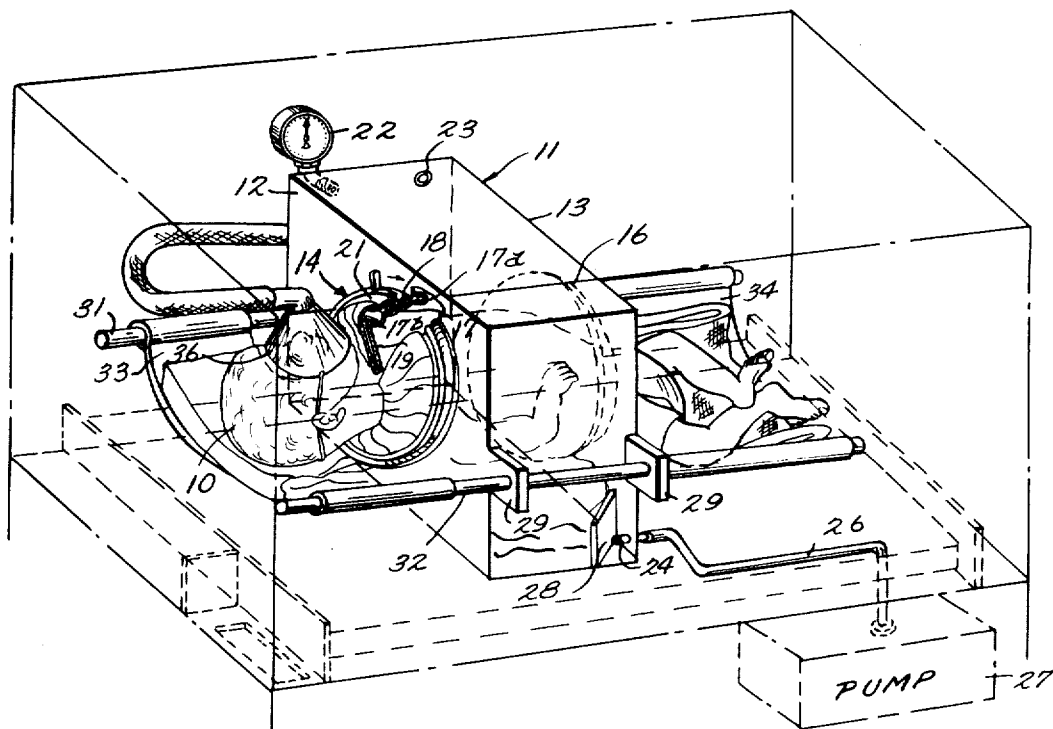
Assistant Examiner—Henry J. Recla

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[57] ABSTRACT

A continuous negative pressure chamber for treating infants having Idiopathic Respiratory Distress Syndrome including an enclosure with two of the opposed walls of the enclosure each having an opening aligned with each other and each mounting an adjustable iris diaphragm for adjustably engaging the neck and pelvic area of an infant placed in the chamber. A pressure manometer as well as a pressure relief valve are mounted to the chamber. The chamber has a vacuum inlet to which a vacuum source means is connected for producing a continuous negative pressure in the chamber.

6 Claims, 4 Drawing Figures



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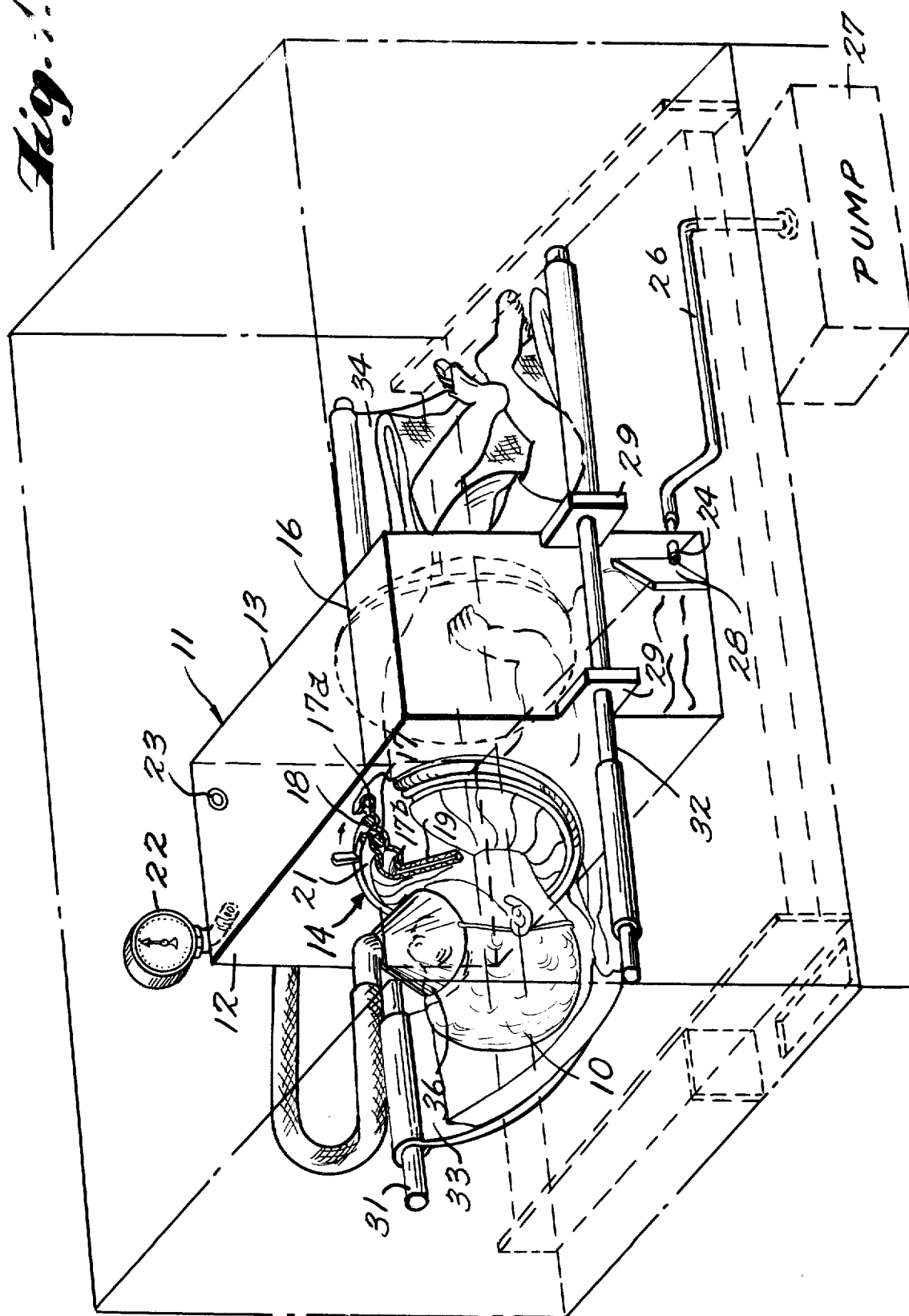


Fig. 2.

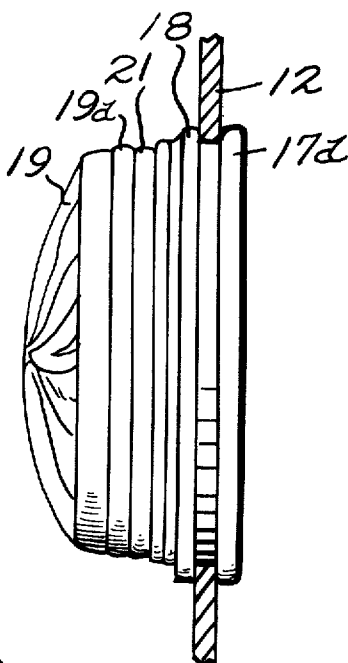


Fig. 3.

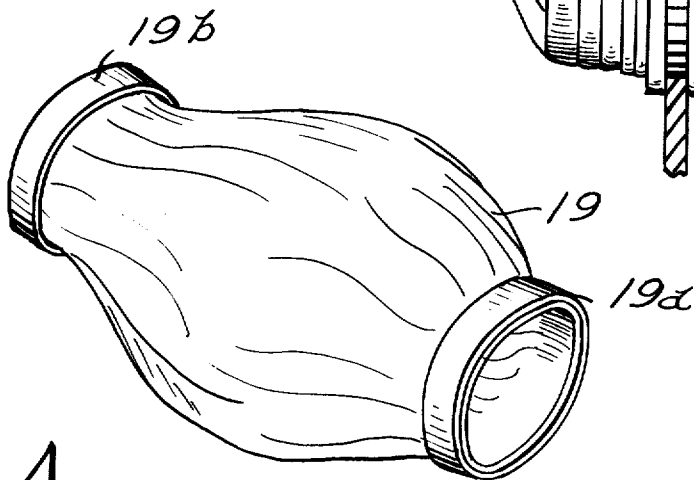
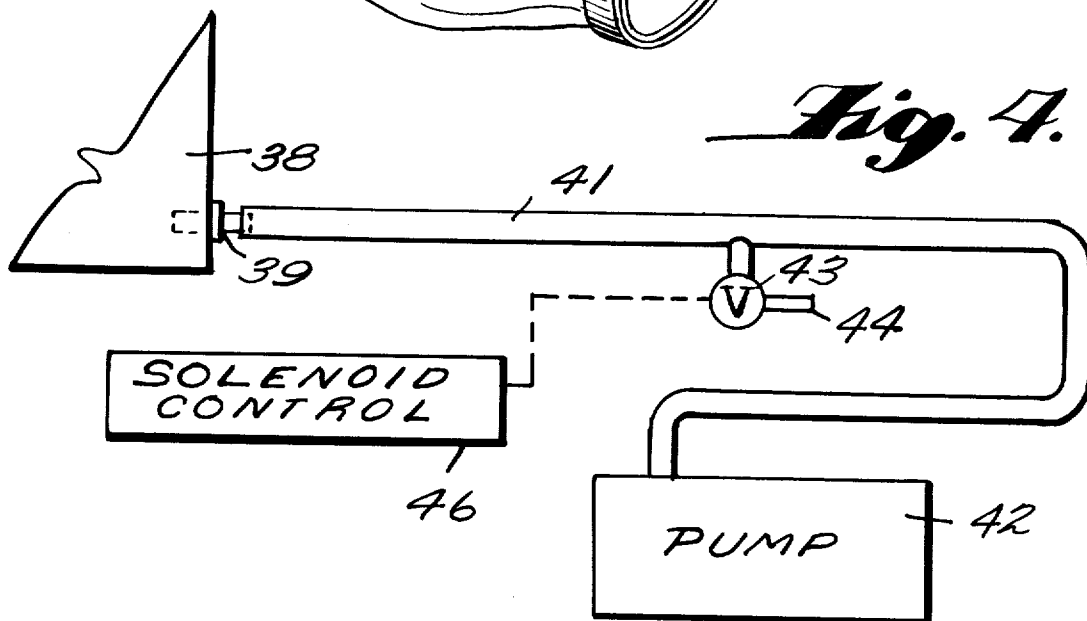


Fig. 4.



CONTINUOUS NEGATIVE PRESSURE CHAMBER FOR INFANTS

BACKGROUND OF THE INVENTION

This invention pertains to a continuous negative pressure chamber and in particular to such apparatus for treating infants having Idiopathic Respiratory Distress Syndrome.

Thousands of new born infants die each year with the Idiopathic Respiratory Distress Syndrome. This condition usually affects premature infants which are born before their lungs are fully developed. In such infants the alveolar walls are not fully developed and the surface tension of the material on the walls is too high, causing the lungs of the infants to collapse.

Various techniques have been utilized to treat this condition in the prior art. These prior art techniques include, for example, the use of positive pressure administered to the infant to expand the lungs with the positive pressure being administered through an endotracheal tube or sealed head chamber. Recently, a new successful treatment in new borns with this disease is the use of a continuous negative pressure around the body except the head, in order to expand their lungs. The effectiveness of treatment utilizing either positive pressure or negative pressure is usually expressed as the partial pressure of arterial oxygen in the blood, conventionally expressed as PaO_2 . While there are no proven differences between constant positive and constant negative pressure, either in relative increase of PaO_2 or in possible circulatory changes, continuous negative pressure has the advantages that it avoids the use of an endotracheal tube or a tight face mask.

The experiments that have been tried in the prior art with application of continuous negative pressure have involved modifications to conventional intermittent negative pressure respirators. These negative pressure respirators are conventional devices which are quite complicated and expensive and which vary the pressure over the thorax area of a patient from atmospheric pressure to a slightly negative pressure. An example of one such respirator is that disclosed in U.S. Pat. No. 2,314,955 to Slater. Modification of these conventional respirators to provide continuous negative pressure involve, of course, changing them over from intermittent negative pressure operation to continuous negative pressure operation. Use of these modified respirators entails enclosing all of the infant's body except its head in the respirator. This has the drawbacks of restricting access to the infant and entailing loss of negative pressure every time the patient needs cleaning or care. There is the further difficulty of transferring the patient in and out of the unit which may compromise the well-being of a very sick infant.

OBJECTS AND SUMMARY OF THE INVENTION

It is an object of this invention to provide a continuous negative pressure chamber for treating infants having Idiopathic Respiratory Distress Syndrome.

It is a more specific object of this invention to provide a negative pressure chamber for enclosing only the thorax area and upper abdomen of an infant for applying a negative pressure to expand the infant's lungs.

It is another object of this invention to provide a continuous negative pressure chamber enclosing the thorax area and upper abdomen of an infant of simple design and construction and of a size such that it may be

placed together with the infant within the confines of a conventional incubator chamber.

Briefly, in accordance with one embodiment of the invention there is provided a continuous negative pressure chamber comprising an enclosure with two opposite walls of the enclosure being spaced apart from each other a distance corresponding approximately to the distance between an infant's neck and pelvic area with the opposed walls having openings therein. An adjustable iris diaphragm is provided in each of the opposed walls for adjustably engaging the neck and pelvic area of an infant placed in the chamber. A pressure manometer is mounted to the chamber for providing an indication of the air pressure therein and a pressure relief valve is mounted to the chamber for relieving the pressure in the chamber if the pressure exceeds a predetermined limit. The chamber includes a vacuum inlet and a vacuum source means is provided which is connected to the inlet for producing a continuous negative pressure in the chamber.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a schematic illustration of a continuous negative pressure chamber in accordance with the invention showing an infant placed therein and illustrating the infant with the negative pressure chamber enclosing the thorax and upper abdomen of the infant placed within a conventional incubator chamber.

FIG. 2 is a side view of the adjustable iris closures provided for adjustably engaging the neck and pelvic area of the infant.

FIG. 3 is a schematic illustration of the flexible cylindrical sheet material used to form the iris of FIG. 2.

FIG. 4 is a schematic illustration showing the controls connected to the vacuum inlet of the chamber in accordance with another embodiment of the invention for cyclically varying the magnitude of continuous negative pressure maintained in the chamber.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Turning now to FIG. 1, there is shown in diagrammatic form one embodiment of the invention. A chamber or enclosure 11 is provided which has opposed top and bottom walls and opposed side walls. The chamber 11 also has a front 12 and a back 13, each of which has a central opening therein. The openings are aligned with each other along the axis of the enclosure 11 and are fitted with adjustable iris diaphragms 14 and 16. The adjustable iris diaphragms 14 and 16 can be of the type described in U.S. Pat. No. 2,695,605, or of any other suitable construction for adjustably engaging a portion of an infant's body to seal the enclosure 11 to the infant's body. In accordance with the particular embodiment of the invention illustrated in FIG. 1, the diaphragms 14 and 16 are of identical construction so that only diaphragm 14 will be particularly described. The diaphragm 14 includes a stationary frame structure 17 supported in the front 12 of enclosure 11 by means of inside flange 17a and a exterior ring 18 which may be made of an elastic material such as rubber. A closure material 19 is provided (more particularly shown in FIG. 3) which is tubular-shaped flexible sheet material having elastic rings 19a and 19b disposed at either end. The frame structure 17 has an annular rim 17b to which one end of the closure 19 is held by one of the elastic rings. The closure material 19 is then folded back upon

itself and its other end secured by means of the other elastic ring to an outer collar 21. The closure material 19 thus forms an iris diaphragm which is adjustable by rotation of the collar 21 with respect to the stationary frame structure 17.

In accordance with the embodiment of the invention shown in FIG. 1, a manometer 22 is provided attached, for example, to one of the side walls of the enclosure or chamber 11 and functioning to provide an indication of the pressure of the air within the enclosure 11. A pressure relief or pop-off valve 23 is also provided mounted, for example, in the side wall of the enclosure 11 and functioning to relieve the pressure in the enclosure if the pressure exceeds a predetermined limit.

The enclosure 11 has a vacuum inlet 24 connected by means such as tubing 26 to a high flow vacuum source which is illustrated in FIG. 1 as a pump 27. A baffle 28 is provided within the enclosure 11 adjacent the vacuum inlet 24 to prevent materials which might be present in the enclosure 11, such as diapers in the bottom of the enclosure for example, from occluding the vacuum inlet 24.

In the arrangement illustrated in FIG. 1 the side walls of the enclosure 11 have projecting tabs 29 which mount rod members 31 and 32. The rod members 31 and 32 both project past the front and back walls of the enclosure 11. Flexible material such as tape, cloth, or diapers, for example, may be wrapped around the projecting portions of the rods 31 and 32 to form hammock-like supports 33 and 34 as illustrated in FIG. 1.

To place an infant having Idiopathic Respiratory Distress Syndrome into the chamber or enclosure 11, the adjustable iris diaphragms 14 and 16 are adjusted to their maximum open position and an infant is inserted lengthwise through the iris diaphragms to the position illustrated in FIG. 1 by the infant 10. The front and back walls 12 and 13 of the enclosure 11 are spaced with respect to each other a predetermined distance such that the iris diaphragm 14 is adjacent the infant's neck and the iris diaphragm 16 is adjacent the pelvic area of the infant. In practice, the front and back walls 13 and 12 of the enclosure 11 are spaced with respect to each other a distance of approximately 15 centimeters. With the infant 10 in position the iris diaphragms 14 and 16 are adjusted by rotating the rotatable collars thereof such as collar 21 of diaphragm 14 so as to close the iris of closure material 19 about the neck and pelvic area of the infant. With the dimensions and arrangement of the enclosure 11 as illustrated and described with reference to FIG. 1, the negative pressure chamber or enclosure 11 encloses only the thorax and upper abdomen of the infant. The infant's head is free as is its pelvic area so that the infant may be cleaned or nursing care administered to the infant without removing it from the chamber 11 thus preventing an interruption of the negative pressure within the chamber 11. Thus an oxygen mask 36 may be applied to the infant if necessary. The leads of monitoring equipment and an umbilical arterial catheter may be passed through one of the irises, such as iris diaphragm 16 for example.

The enclosure or chamber 11 can be made of any suitable material but is preferably made of a transparent material such as plexiglass so that the enclosed thorax and upper abdomen of the infant may be visually observed. Also, with an enclosure 11 made of plexiglass, X-rays may be taken of the infant while its thorax is enclosed in the chamber 11.

In operation, the pump 27 is utilized to establish a negative pressure with reference to atmospheric pressure within the chamber or enclosure 11 on the order of between 4 and 15 centimeters of H₂O. The amount of negative pressure required as well as the length of time an infant needs to have the negative pressure applied to its thorax depends upon the severity of the Idiopathic Respiratory Distress Syndrome with which the infant is afflicted and can be monitored by monitoring the partial pressure oxygen tension (PaO₂) in the infant's blood. The entire negative pressure chamber or enclosure 11 in accordance with the invention is suitably dimensioned so that it may be placed within a standard incubator unit 37. Normally, the negative pressure chamber in accordance with this invention should always be utilized within an incubator inasmuch as the flow of air around the infant's thorax and the air leaks through the irises 14 and 16 produce a cooling effect which would be deleterious to an infant if not utilized within an incubator in which the air was heated. Alternatively, instead of being utilized within an incubator the negative pressure chamber in accordance with this invention may be placed under an array of infrared lights or other heat-producing elements.

Turning now to a consideration of FIG. 4 there is shown in diagrammatic form a portion of the vacuum supply means to a negative pressure chamber in accordance with another embodiment of the invention. Infants having the Idiopathic Respiratory Distress Syndrome are subject to what is described as apnea, in which the infant just suddenly stops breathing. Usually all that is required to get an infant out of an apnic spell is to physically jolt the infant or to alter the pressure or pattern of air supply to an infant for breathing. In accordance with the embodiment of the invention schematically illustrated in FIG. 4, the magnitude of negative air pressure within the negative pressure chamber is automatically altered in order to prevent such apnic spells.

Thus in FIG. 4 a negative pressure chamber or enclosure 38 (identical for example to the enclosure 11 shown in FIG. 1) has a vacuum inlet 39 connected via a tube or pipe 41 to a vacuum pump 42. A valve 43 is connected to the tube 41 and includes an inlet 44 to the atmosphere. The valve 43 has suitable control means for effecting the opening and closing of the valve 43, which control means are illustrated by the solenoid control apparatus 46, as shown in FIG. 4. In operation, when the valve 43 is open, the pump 42 through tube 41 is still producing a negative pressure within the chamber 38 in the same manner as described before with reference to the apparatus illustrated in FIG. 1 as long as the resistance of inlet 44 is higher than that of tube 41. When, however, the solenoid control 46 is actuated to close the valve 43, air does not enter through the inlet 44 but passes only through the tube 41 to the pump 42, thus increasing the magnitude of negative pressure produced within the chamber 38 by the pump 42. The rate of an amount of negative pressure variation within the chamber 38 depends upon the size of the valve 43, the inlet 44 and the tube 41, as well as the length of time the valve 43 remains open or closed. In accordance with one embodiment of the invention, the solenoid control 46 is operated to close the valve 43 in a cyclical fashion at a rate ranging from 2 or 3 per minute to 30 or 40 openings per minute. The solenoid control 46 can hold the valve 43 closed for a length of time

which is also adjustable ranging from a fraction of a second to several seconds. The length of time the valve 43 must remain closed in order to produce the desired pressure variations in the negative pressure within the chamber 38 depend upon the characteristics and capacity of the pump 42 and the leaks present in the box.

With the arrangement of the invention shown in FIG. 4, continuous negative pressure is still maintained about the thorax of the infant at all times; the magnitude of the negative pressure is varied. Further, in accordance with the embodiment of the invention shown in FIG. 4, the maximum negative pressure to which the infant is subjected can be increased since the maximum will not be continuously applied to the infant. Thus, maximum negative pressures on the order of 25 centimeters of H₂O can be applied to the infant's thorax with no deleterious effects as long as the infant is not exposed to this maximum negative pressure for too long a period. In a typical application of the embodiment of the invention diagrammatically illustrated in FIG. 4 the negative pressure in the negative pressure chamber 38 might be varied at a rate of 20 variations a minute from a minimum negative pressure of 10 centimeters of H₂O to a maximum negative pressure of 25 centimeters of H₂O. This variation is sufficient to prevent apnea while still continuously maintaining negative pressure about the thorax of an infant to maintain the infant's lungs in an inflated condition.

Thus, what has been described is a negative pressure chamber for use in treating infants having Idiopathic Respiratory Distress Syndrome. Although the invention has been described with reference to particular preferred embodiments, it should be obvious that modifications and additions to the particular preferred embodiments disclosed are well within the capability of those skilled in the art without departing from the true spirit and scope of the invention.

What is claimed is:

1. A continuous negative pressure chamber for treating infants having Idiopathic Respiratory Distress Syndrome comprising an enclosure having a top, a bottom, two spaced side walls and a front and a back spaced with respect to each other and made of a material which is visually transparent and also transparent to X-rays, said front and back being spaced from each other a distance of approximately 15 centimeters, which corresponds to the distance between an infant's neck and

pelvic area, said front and back each having an opening aligned with each other and mounting an adjustable iris diaphragm for adjustably engaging the neck and pelvic area of an infant placed in the enclosure, a pressure manometer mounted to said enclosure for providing an indication of the air pressure therein, a pressure relief valve mounted to said enclosure for relieving the pressure in said enclosure if the pressure exceeds a predetermined limit, a vacuum inlet to said enclosure, and vacuum source means connected to said inlet for producing a continuous negative pressure in said enclosure, and heating means external to said enclosure for heating air within and surrounding said enclosure so that air flow through said iris diaphragms does not produce a deleterious cooling effect.

2. A continuous negative pressure chamber in accordance with claim 1 wherein said enclosure includes a baffle placed inside said enclosure adjacent said vacuum inlet to prevent materials which might be contained within said enclosure from occluding said vacuum inlet.

3. A continuous negative pressure chamber in accordance with claim 1 including a rod member mounted to each of said side walls and extending parallel to said side walls and perpendicularly to said front and back and projecting predetermined distances beyond the front and back, whereby material may be wrapped around the projecting rod members to provide support for the head and lower body portion of an infant placed in the chamber.

4. A continuous negative pressure chamber in accordance with claim 1 wherein said vacuum source means is adjustable to provide a continuous negative pressure within said enclosure within the range of 2-15 centimeters of H₂O.

5. A continuous negative pressure chamber in accordance with claim 1 wherein said vacuum source means comprises a continuous vacuum pump and including a selectively operable valve connecting the vacuum pump to said vacuum inlet, and further including control means for cyclically opening and closing said valve for cyclically varying the magnitude of continuous negative pressure maintained within said enclosure.

6. A continuous negative pressure chamber in accordance with claim 1 wherein said heating means comprises an incubator surrounding said enclosure.

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