

[54] **RESPIRATORY DEVICE AND PROCEDURE**

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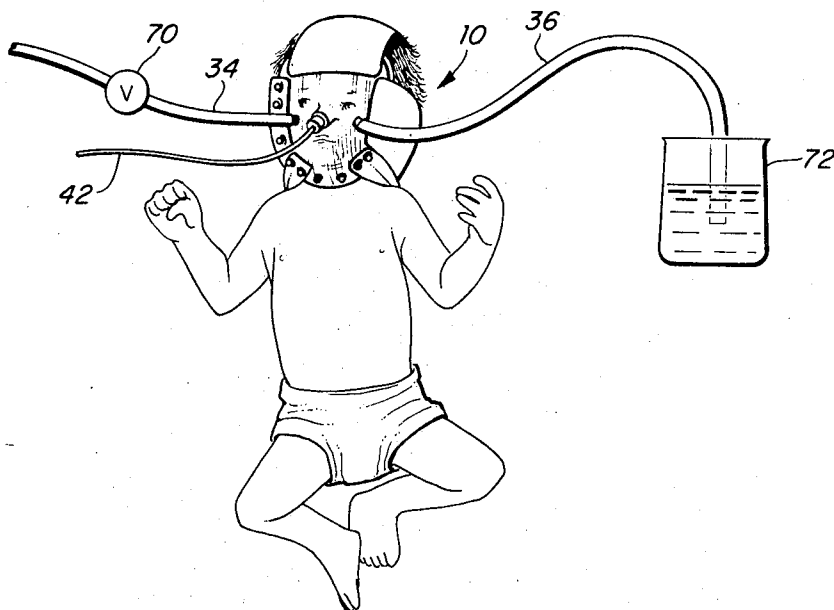
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[57] **ABSTRACT**

Applying positive end expiratory pressure breathing assistance to, for example, an infant by enclosing the infant's face in a gas-tight mask, providing inhalation air into the mask, and restricting the passage for exhaled air from the mask, such as by immersing the end of the passage in a liquid, to maintain a positive pressure above ambient pressure in the passage, and hence within the mask.

9 Claims, 3 Drawing Figures



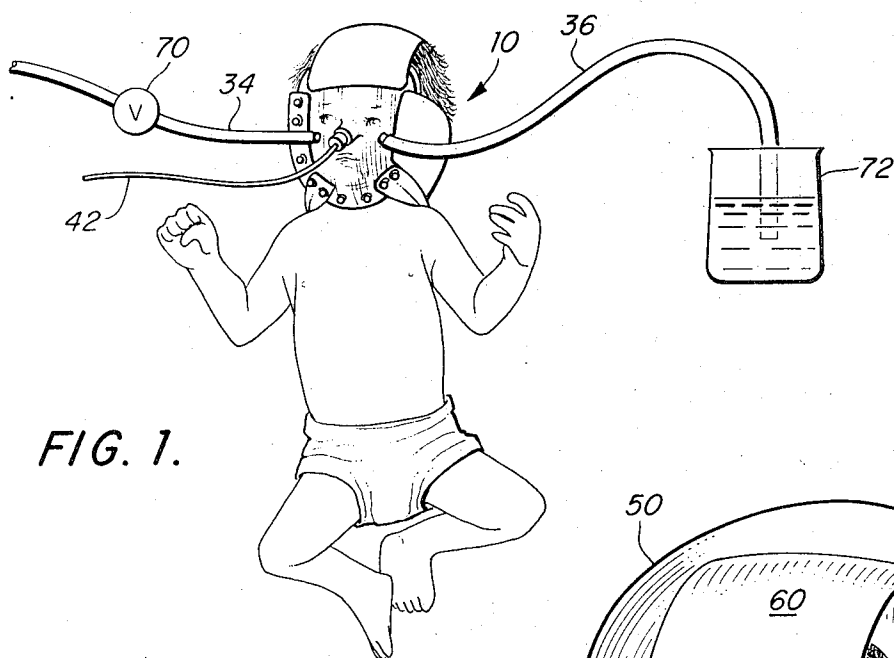


FIG. 1.

FIG. 2.

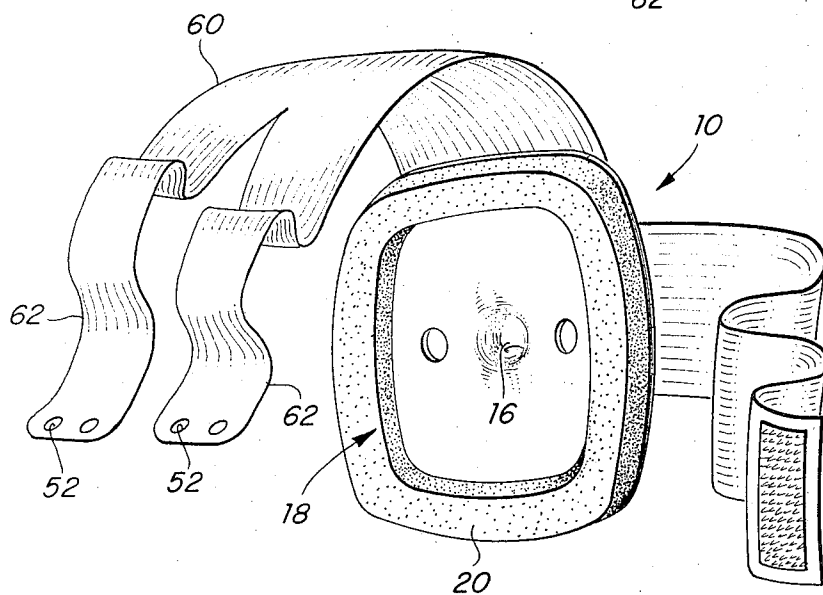
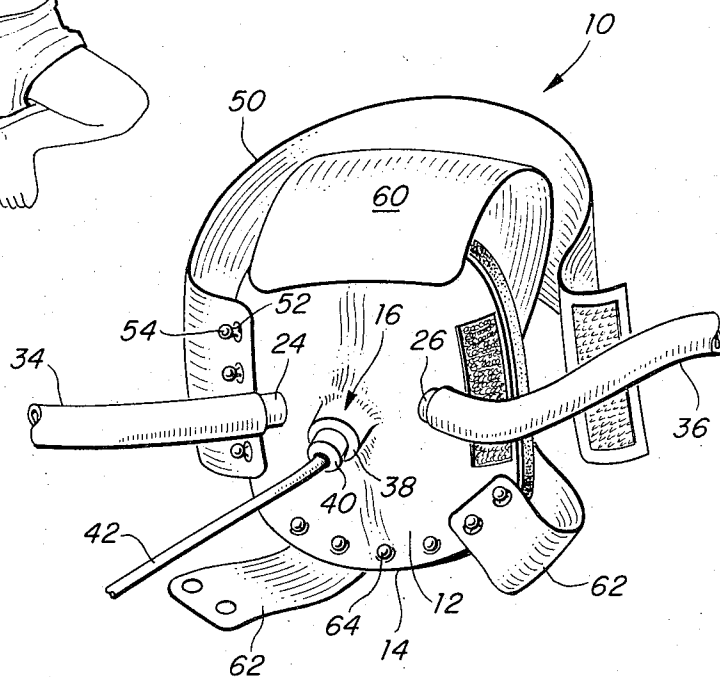


FIG. 3.

RESPIRATORY DEVICE AND PROCEDURE

FIELD OF INVENTION

This invention relates to respiration, and particularly to assisting spontaneous human breathing, especially in infants.

BACKGROUND OF INVENTION

Respiratory distress syndrome (RDS) has been a large contributing factor to infant mortality, particularly among prematurely born infants. This affliction is characterized, in general, by an inability of the alveolus of the lungs to sustain inflation in the absence of positive air pressure (giving rise to "pulmonary atelectasis"). Recently proposed forms of treatment rely on supplying and maintaining "positive pressure" in the lungs during the breathing cycle. For example, Lewey, in "Volume Limited Paediatric Respirator," *Bio-Medical Engineering*, p. 419 (Sept. 1969), describes a specially designed mechanical respirator which supplies positive pressure during the inhalation part of the respiratory cycle, but which requires 1/2 mm of water negative pressure to be produced by the infant to trigger its respiratory cycle. Although the use of respirators has somewhat improved the infant's chances of survival, among small infants the mortality rate of infants so treated remains in the range of 50 to 60 percent. Moreover, the Lewey respirator employs a nose mask which fits over the infant's nose and which, when tightened to a gas-tight seal, has been found to produce "welts" on the infant's face which limit to a few hours the useful time for this respirator method.

It has also been reported that some success has been achieved by inserting a tube directly into an infant's trachea, and connecting external intake and exhaust conduits to the tube. The exhaust or exhalation conduit is kept at a positive pressure, such as by constricting its air escape port, and intake air for inhalation is supplied from a suitable air or oxygen-enriched air supply. The maintenance of positive pressure can be observed, e.g., by bubbling some exhaust gases through water. Such a procedure differs from the aforesaid respirators in that the infant continues to breathe spontaneously, and, according to an article by Gregory et al., "Treatment of the Idiopathic Respiratory-Distress Syndrome with Continuous Positive Airway Pressure," *The New England Journal of Medicine*, Vol. 284, p. 1,333 (1971), this increases the infant's chances of survival. However, insofar as this method relies on the insertion of a tube into the trachea, not only is there the potential for physical damage to the infant, but such a procedure makes no provision for expelling secretions which build up in the trachea or lungs. Unless the infant is artificially "coughed" at intervals, the build-up of such secretions can plug the tube or lungs or both.

SUMMARY OF INVENTION

It is therefore an object of this invention to provide a therapeutic procedure for infants afflicted with RDS, which enables a positive pressure to be applied at the expiratory or exhalation part of the respiration cycle, for days at a time without causing any physical internal or external damage to the infant.

Another object is to provide a diagnostic procedure for determining if an infant's respiratory distress is due to cardiac or pulmonary disease.

A further object is to provide a mask for carrying out these procedures.

The invention features a procedure for applying positive end expiratory pressure to a person, such as an infant afflicted with or suspected to be afflicted with RDS, to assist the infant's spontaneous breathing. According to the invention, a mask comprising an enclosure constructed to enclose the face of, for example, an infant between his forehead and his chin and having a peripheral sealing region, an inhalation tube in to the enclosure, and an exhalation tube out of the enclosure is secured to the infant to form an air-tight seal at the peripheral sealing region. Air (oxygen-enriched, if desired) is supplied to the enclosure continuously through the inhalation tube while the exterior end of the exhalation tube is immersed in a liquid, e.g., such as water, so that air exhaled by the infant must bubble out through the water, therefore causing a positive pressure above ambient pressure to be maintained in the exhalation tube. As a result, positive pressure is maintained also in the enclosure, and hence in the infant's lungs, to counteract RDS.

In a preferred embodiment, the mask includes an additional aperture through which, e.g., a flexible tube may be inserted, usually through the infant's nose, into his stomach to exhaust air entering the stomach from the positive pressure enclosure maintaining ambient pressure in the infant's stomach.

A preferred mask has a translucent plastic portion, generally conforming to the contours of the infant's face but spaced from it, covering the face, and a soft, resilient sealing material (e.g., a closed cell silicone rubber foam) about the peripheral sealing region, and may be secured to the person by adjustable straps.

Other objects, features and advantages will appear to one skilled in the art from the following description of a preferred embodiment of the invention, taken together with the attached drawings thereof, in which:

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a diagrammatic illustration showing treatment of an infant in accordance with the invention;

FIG. 2 is a perspective view of the outside or front of the mask of FIG. 1; and,

FIG. 3 is a perspective view of the inside or rear of this mask.

DESCRIPTION OF PREFERRED EMBODIMENT

The figures show an infant's mask 10 having a translucent plastic facepiece 12 which is a maximum of about 5 inches wide, and a maximum of about 6 inches high. The facepiece is contoured so as to approximate, more or less, the contours of the infant's face, being, e.g., rounded along the bottom of the chin 14 and jutting forward at the nose portion 16. The concave interior of the mask defines an enclosure which has, at the nose portion 16, a maximum depth of about 2 inches. The facepiece may be of a somewhat flexible material but should be self-supporting and capable of withstanding the applied air pressures. A 1/16 inch thick polycarbonate is useful, particularly because it is translucent and hence allows for constant visual observation of the patient and its hardness avoids scratches which might damage somewhat its optical properties.

Disposed around the periphery of facepiece 12 is an approximately 1 inch wide molding 18, which is fabricated of a soft, resilient, air-tight material, and has an

inner annular surface 20 defining a sealing region. The resilience enables the molding to follow the contours of an infant's face, while the softness assures that the pressure of the molding against the skin necessary to maintain a gas-tight seal will not injure or bruise the infant's face. A particularly useful material is closed cell silicone rubber foam (for example, that manufactured by Dow-Corning under the trade designation "medical grade silicone-rubber TRV foam, MDX-4-4521"). In addition to forming gas-tight seals, the material has a "spongy" texture, so that it does not tend to slip along the skin.

Formed integrally with the facepiece 12 are flanges 24, 26 over which are secured, respectively, an inhalation tube 34 and an exhalation tube 36 (both formed e.g., of "Tigon"). A third flange 38 contains an air-tight plug 40, through which protrudes, in FIG. 1, a thin flexible tube 42. A flexible fastening strap 50 is secured at one end by a "velcro" closure to facepiece 12, and has perforations 52 near its other end by which it is hooked to the studs 54 secured to facepiece 12. A second strap 60 is secured to the forehead region of the mask by a "velcro" closure (not shown) and has perforations 52 near its other bifurcated end by which the sub-straps 62 are hooked to the studs 64 secured to the chin region of facepiece 12.

When the mask is in use, as shown in FIG. 1, the inhalation tube 34 is connected, through a suitable regulator or valve 70, to a source of air or oxygen-enriched air at above ambient pressure. The outer end of exhalation tube 36 is immersed in a beaker of water 72. The thin flexible tube 42 is open to ambient pressure at its outer end, and its inner end is inserted through the infant's nose into the stomach.

Because of the location of exhalation tube 36 in a beaker of water, a back or end pressure of about 6-10 cm. of water (with a properly sized and elongated tube 36) is applied to the exhalation tube, so that a positive pressure above ambient is maintained at all times within the enclosure of the mask, and hence also within the lungs of the infant. The air flow into the inhalation tube is sufficient to continually exhaust spent air and supply fresh air to the enclosure.

Not only because of the softness of molding material 18 but also because the full-face nature of the mask distributes the force applied to keep an air-tight seal about the mask over a large area of the infant's face, this mask may be kept on the infant's face for days (with periodic removal for 10-15 minutes every 4 hours) without causing bruising or even noticeable discomfort to the infant. The translucent facepiece 12 enables constant visual monitoring of the infant's condition. The use of "velcro" closures on the straps combine a tight fit between mask and face with practically instantaneous detachability of the straps and removal of the mask in an emergency. The bubbling of exhaust gases through the beaker also provides a visual check that adequate air pressure is being maintained within the mask.

Besides exhausting the stomach, the tube 42 may also be used, if desired, for feeding the infant directly into its stomach (rather than intravenously).

In addition to its usefulness in treating RDS, the mask also provides a useful diagnostic tool, such as for distinguishing certain cardiac diseases commonly found in infants from RDS. Certain cardiac diseases lead to build-up of fluid adjacent to the aveolus, and interfere

with gas exchange and hence simulate the symptoms of RDS. However, in these infants, oxygenation worsens after application of a mask thus distinguishing this infant from one afflicted with RDS, since in the latter case the use of the mask would significantly improve aeration of the blood. The mask has the advantage that unlike prior tracheally inserted tubes, it can be applied for rapid diagnosis.

Other embodiments will occur to those skilled in the art and are within the following claims.

What is claimed is:

1. A device for use in applying positive end expiratory pressure to a person comprising a mask with a gas-tight enclosure capable of substantially enclosing a person's face between forehead and chin, an inhalation tube for supplying air to the enclosure and means to supply air continuously to said enclosure through said inhalation tube, an exhalation tube for directing exhaled air at above ambient pressure out of the enclosure, means for maintaining a positive pressure in said exhalation tube, whereby a positive pressure is maintained in said mask at all times and an additional aperture for gaining access to said enclosure without interrupting the gas-tight seal of said enclosure, said additional aperture having a length of unrestricted flexible tube passing therethrough of a length suitable for insertion into a person's stomach.

2. A device according to claim 1 wherein said enclosure and said tubes are formed of a translucent plastic.

3. A device according to claim 2 including a layer of soft resilient sealing material disposed about the inner periphery of the enclosure so as to be located between the enclosure and face, said material being conformable to the contours of a face in a gas-tight seal.

4. A device according to claim 3 wherein said resilient material is a closed-cell silicone rubber foam.

5. A device according to claim 3 wherein said plastic enclosure is generally shaped to conform to the contours of an infant's face, and the sealing material is of a thickness sufficient to prevent contact of the plastic and the face when the mask is secured in gas-tight seal.

6. A device according to claim 1 including at least one adjustable fastening strap for securing the mask said strap being of sufficient length to surround a head and being detachably mounted at at least one side of said mask and secured to the other side thereof.

7. A device according to claim 6 including a first flexible sealing strap located to be secured to the mask at opposite sides of the face, and a second strap located to be secured to the mask at the forehead and chin.

8. A method of assisting spontaneous breathing of a person by applying positive end expiratory pressure, said method comprising the steps of:

providing a mask comprising an enclosure constructed to enclose a person's face between forehead and chin and having a peripheral sealing region, an inhalation tube into said enclosure, an exhalation tube out of said enclosure and an additional aperture in said mask, said additional aperture having a flexible unrestricted tube of a length suitable for insertion into the person's stomach passing through said aperture,

securing said mask to the face of said person to form an air-tight seal at said peripheral sealing region

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sealing the person's nose and mouth within the enclosure,
maintaining a positive pressure in the lungs during the entire breathing cycle by supplying air continuously to said enclosure through the inhalation tube and maintaining a positive pressure above ambient pressure in the exhalation tube, and
locating one end of said unrestricted tube in the person's stomach and exhausting air therefrom through said aperture.
9. A device for use in applying positive end expiratory pressure to a person comprising a mask with a gas-tight enclosure capable of substantially enclosing a person's face between the forehead and chin, an inhalation

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tube for supplying air to the enclosure, an exhalation tube for directing exhaled air at above ambient pressure out of the enclosure, said exhalation tube having a free end immersed in a liquid to maintain a positive pressure in said exhalation tube whereby a positive pressure is maintained in said mask at all times, and an additional aperture for gaining access to said enclosure without interrupting the gas-tight seal of said enclosure, said additional aperture having a flexible unrestricted tube passing therethrough of a length suitable for insertion into a person's stomach to exhaust air therefrom.

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