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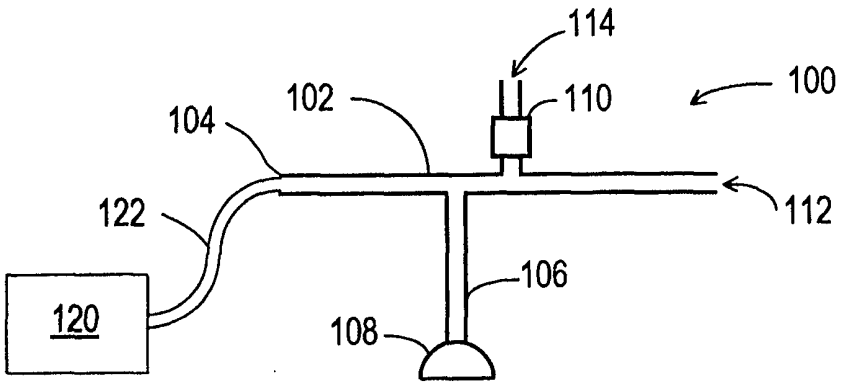
(54) Title: APPARATUS FOR CONTROLLED VENTILATION OF A PATIENT

(57) Abstract

An apparatus (100) for producing pause in a respiratory cycle of an infant or a patient unable to perform a voluntary breath hold manoeuvre, includes a manifold (102) having an inlet port (104) adapted to be connected to a source of air or other breathable gas (120), an occluded outlet port (112), a face mask (108) connected to the manifold, and a pressure limiting valve (110) connected to the manifold. A pause in the patient's respiratory cycle is induced by inflating the lungs synchronously with natural inspiration to a volume greater then normal end tidal inspiration for several closely spaced respiratory cycles. The inflation is accomplished by fitting the face mask to a patient, and occluding the outlet port to introduce the pressurized air into the patient's lungs. After a few cycles of full breaths, the breathing rhythm of an infant or a patient naturally pauses for a period of several seconds, during which an image, e.g., a scanned x-ray image, can be made of lungs, and/or adjacent organs.



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TITLE: APPARATUS FOR CONTROLLED VENTILATION OF A PATIENT

BACKGROUND OF THE INVENTION

Field of the invention:

This invention relates to apparatus for controlling breathing of infants and other patients in connection with pulmonary diagnostic procedures and more particularly to apparatus for producing a pause in breathing of an infant or patient to permit visualization of the lungs.

Brief description of the prior art:

Imaging of internal structures of the chest and lungs by means of x-rays has long been an essential procedure in diagnosis of diseases and disorders of the lungs. With the development of modern techniques such as computerized tomography (CT) anatomical information obtainable by such imaging techniques has become especially useful. At present, high resolution computed tomography (HRCT) of the chest is capable of providing anatomic detail similar to that available from pathologic sections of the lung. However, HRCT scanning using the instruments generally available to clinical practice requires voluntary breath holding by the patient in order to minimize motion-related artifacts which are accentuated on the thin slices obtained for HRCT. As

performed in adults and older children, the technique also involves voluntary inspiration to near full lung inflation before breath holding to minimize any non-inflated volumes and to distend and better display the pulmonary airways, vessels, and parenchyma. In addition, expiratory HRCT scans are desirable to identify air-trapping and differentiate causes for mosaic lung attentuation.

In infants and small children, i.e., up to the age of about 4 or even 6, who cannot cooperate with breath holding or have difficulty in such cooperation, the usefulness of HRCT has been limited due to motion artifacts. Similar problems are encountered with adults who cannot follow instructions, e.g., unconscious, mentally impaired, or confused individuals. The use of ultrafast electron beam scanners, which are capable of presenting single sections of the chest in as short a period as 0.1 second, decreases problems related to patient cooperation. However, ultrafast scanners are available at only a few clinical centers. Furthermore, the use of ultrafast scanners does not in itself address the need for obtaining images near full lung inflation and deflation.

At present, motion-free inspiratory and expiratory HRCT images in infants and young children can only be obtained under general anesthesia and intubation to provide the necessary control of respiration. Ideally, HRCT scans in these children should be acquired less invasively.

A procedure for producing a forced expiration in infants has been disclosed in U.S. Patent 5,513,647, to Robert G. Castile, the entire disclosure of which is incorporated herein by reference. According to the procedure disclosed in U.S. Patent 5,513,647, sleeping or sedated infants are fitted with a chest compression vest and a face mask to influence and alter their natural breathing pattern in order to obtain diagnostic information regarding lung function. Under automatic control, the infant's inhalations are augmented by gentle overpressure of air synchronized with the infant's natural inhalations so that the infant effectively inhales to near full lung capacity for several successive inspirations. This increase in ventilation produces a mild hypocarbia (i.e., decrease in blood carbon dioxide level) which decreases pulmonary drive, and the rapid chest expansion produces a vagally mediated pause in spontaneous respiratory effort (the Hering-Breuer response). The augmented supply of air also assures that all organs are amply provided with oxygen. After a relatively few augmented inhalations, the infant ordinarily naturally pauses its breathing. Thereupon, the equipment senses the pause, inflates the infant's lungs to maximum capacity, and activates the compression vest to produce a maximum forced exhalation. The rate of flow, recorded by a pneumotachograph, is a useful measure of the infant's lung function. This procedure and equipment has

proved to be of great clinical value in the treatment of children afflicted with cystic fibrosis.

However, such equipment is evidently not suitable for imaging because the pause in the infant's breathing pattern is immediately exploited to inflate and compress the infant's lungs. Accordingly, there is no interval of lung immobility during which an image of the lungs might be acquired. Furthermore, the automatic breathing control equipment is complex and combined with flow measuring equipment to produce a physiological measurement. Consequently it is not readily portable nor adaptable to other situations in which a simpler device would be useful.

Accordingly, a need has continued to exist for a simple apparatus that can be used to induce an infant to pause its breathing for period of time long enough to acquire an image of the lungs, e.g., by HRCT, magnetic resonance imaging (MRI) or the like.

SUMMARY OF THE INVENTION

The need for a simple apparatus usable by a physician or operator to induce a pause in the breathing cycle of an infant has now been met by the apparatus of the invention which consists essentially of a manifold, adapted to be connected to a source of breathable air, that is in fluid communication with a face mask and is provided with a pressure-limiting valve and an outlet port that can be

occluded by the physician or operator. The operator closes the outlet port during the infant's inhalations to provide augmented inspirations synchronized with the infant's natural breathing rhythm. The pressure is controlled by the pressure-limiting valve, which is adjusted to provide a pressure calculated to inflate the lungs to about full lung capacity. After a few such full breaths, the infant is temporarily satiated and naturally pauses its breathing for several seconds. When the breathing pause occurs, the physician or another operator can trigger the operation of the imaging instrument, e.g., a CT scanner, MRI scanner, x-ray camera or the like.

Accordingly, it is an object of the invention to provide a method of causing an infant to pause its breathing naturally.

A further object is to provide an apparatus that can be used by a physician to induce an infant to pause its breathing.

A further object is to provide an apparatus that can assist a physician in obtaining an image of an infant's lungs.

A further object is to provide an apparatus that can be used to induce a pause in an infant's breathing during which a CT scan of the lungs or other organs can be obtained.

A further object is to provide an apparatus that can be used to induce a pause in an infant's breathing during which an MRI scan of the lungs or other organs can be obtained.

A further object is to provide an apparatus for producing respiratory pauses in a patient at specific desired levels of lung inflation.

A further object is to provide a simple and portable apparatus that a medical practitioner can use to control the ventilation of an infant or adult who is not capable of voluntarily executing a breathhold maneuver.

Further objects of the invention will become apparent from the disclosure that follows.

BRIEF DESCRIPTION OF THE DRAWING

Figure 1 illustrates an embodiment of the apparatus of the invention having an outlet port adapted for manual occlusion.

Figure 2 illustrates an embodiment of the apparatus of the invention having an outlet control valve.

DETAILED DESCRIPTION OF THE INVENTION AND PREFERRED EMBODIMENTS

The combination of physiological principles with modern radiological instruments permits the collection of images by means of HRCT, MRI and the like in infants and very young children that are similar in quality to those obtainable in

older children and adults, who can voluntarily hold their breath at different lung volumes.

According to the invention, images can be obtained in infants by a "stop ventilation" technique in which the infant is induced to pause its breathing for a brief period of time, whereupon the lungs can be inflated to a desired volume and an image, e.g., an HRCT scan, can be obtained in the short interval before the infant resumes normal tidal breathing.

The physiological basis for "capturing" the infant's ventilation and inducing a pause depends, as discussed above, on a combination of a step increase in ventilation, which produces mild hypocarbia, thereby reducing respiratory drive, and rapid chest expansion, which produces a vagally mediated pause in spontaneous respiratory effort (the Hering-Breuer response).

In order to induce a pause in an infant's breathing the infant must be provided with augmented inspirations for a few cycles of breathing in order to decrease the natural stimuli for breathing and provide sufficient oxygen to last through the pause. Thereupon the infant's natural reflexes will cause its breathing to stop until the levels of the blood gases return to values that again stimulate breathing, whereupon the infant naturally starts breathing again.

In order to accomplish the increased ventilation leading to a pause in respiration, an infant is fitted with a face mask, surrounding its nose and mouth, which is connected to a

source of breathable air capable of supplying a flow of air sufficient for breathing at a pressure sufficient to inflate the lungs to about full capacity. The source of air should be capable of supplying air at a pressure of about 25-30 centimeters of water above atmospheric pressure. According to the invention, the air is conveniently supplied to the mask through a manifold provided with an inlet port adapted to be connected to the source of air, a controllable outlet port and a pressure-limiting relief valve. The manifold may be a simple tube leading from the air supply to an open end, with the face mask and pressure-limiting valve connected to the tube through T-fittings. The outlet port, or open end of the air supply tube, may be of such a size that it can be simply occluded by the operator's thumb or finger. Alternatively, the outlet port can be provided with a valve that can be opened and closed by the operator, either directly, by a mechanical action, or indirectly, e.g., through an electrical actuator and appropriate manually-operated switch.

Figure 1 illustrates a breathing controller 100 of the invention having a manifold 102 with an inlet port 104. The inlet port 104 is connected to a source of pressurized air 120 by air supply tube 122. The source of air 120 should be capable of supplying an air flow at a volume to provide sufficient air for normal breathing of the patient and at a pressure that can inflate the lungs of the patient to maximum

volume in a brief period of time. The air from the source 120 flows through the manifold 102 to an outlet port 112. A connecting conduit 106 connects the manifold 102 to the facemask 108. The outlet port 112 allows the air to flow out of the manifold when it is open to the atmosphere. The outlet port 112 is of such a size that it can be closed manually by an operator, e.g., by pressing a thumb or finger over the port 112. A pressure relief or pressure-limiting valve 110 automatically opens when the pressure in the manifold exceeds a preset value and vents the manifold 102 to the atmosphere through exhaust port 114.

In order to produce a pause in an infant's respiration and obtain an image of the infant's lung at a predetermined degree of inflation, the infant is first placed in a state of sleep, either naturally or by sedation. The face mask 108 is then fitted about the infant's nose and mouth and sealed to the extent necessary around the edges. Ordinarily a face mask having a soft, compressible edge provides an adequate seal, with only minor leaks, that is suitable for imaging procedures. However, if a more thorough seal is desired, it can be achieved by the use of medical putty. With the air flowing from the supply 120 through the manifold 102 or tube to the open outlet port 112 the pressure in the manifold 102 is essentially atmospheric, and the infant can breath naturally, inhaling and exhaling through the face mask conduit 106 via the outlet port 112. The infant is then

positioned within the imaging apparatus, e.g., an HRCT scanner.

In order to induce a pause in the infant's natural breathing rhythm, the operator of the breathing control apparatus closes the outlet port 112 in synchrony with the infant's spontaneous inspiratory breaths. The port is closed generally at the beginning of an inspiration and held closed until the infant has taken a full breath. The pressure in the manifold rises to a pressure predetermined by the setting of the pressure-limiting valve 110. Typically the pressure-limiting valve 110 is set to provide a pressure of about 25-30 centimeters of water, preferably about 25 centimeters of water, over atmospheric pressure. Such a pressure assures that the infant's lungs will be inflated to near full lung capacity. When the infant has taken a full breath as determined by observation and/or the opening of the pressure-limiting valve 110, the operator opens the outlet port 112 and allows the infant to exhale. The outlet port 112 is then closed again and the infant is induced to take a second full breath. After a few full breaths, typically 4-5, the blood gas levels reach values such that the infant experiences no need to breathe, as discussed above. Accordingly, the infant's breathing pauses, and the lungs are in a quiescent state. At this time, the infant's lungs can be inflated to full capacity by closing the outlet port 112 and holding it closed for a few seconds. The operator then actuates the

imaging device either directly or by signaling the operator of the imaging device. As soon as the image has been taken the outlet port 112 is opened and the infant is allowed to breathe normally. If an image of the lungs at their end-expiration volume is desired, the outlet port 112 is left open when the infant pauses in breathing and the infant is allowed to exhale to resting volume. The image is then taken at the resting volume and the infant resumes normal breathing after a few seconds. Evidently, it is also possible to inflate the infant's lungs to any desired intermediate volume if images are needed under intermediate conditions. Such intermediate inflation may be achieved, for example, by adjusting the pressure limit on the pressure-limiting valve, or by fitting a pressure gauge to the manifold and manually inflating the lungs to a predetermined pressure.

The technique of taking images of the infant's lungs in a quiescent state is especially useful with rapid sectional or spiral CT scanners.

An alternate embodiment of the breathing control apparatus of the invention is illustrated in Figure 2. The breathing control apparatus 200 of Figure 2 is generally similar to that illustrated in Figure 1. A source of pressurized breathable air 220 provides a stream of breathable air to the apparatus through air supply tube 222. The air enters the manifold 202 through inlet port 204. A face mask 208 is connected to manifold 202 through face mask

conduit 206. A pressure-limiting valve 210 opens at a preset pressure to vent the manifold 202 to the atmosphere through exhaust port 214. In the embodiment of Figure 2, an outlet control valve 216 is provided to open and close the outlet port 212. The outlet control valve 216 is opened and closed in rhythm with the infant's breathing in order to produce enhanced inhalations leading to a pause in the infant's breathing. The operator may open and close the outlet control valve 216 manually or by a mechanical or electrical valve operator as is conventional in the art of pneumatic control.

Although the schematic illustrations in the drawings show the face mask and pressure relief valve connected to a central manifold, the skilled practitioner will understand that the manifold is merely a chamber for placing the elements of the apparatus into fluid communication. Accordingly, the pressure-limiting valve could be connected to the face mask conduit 106 or 206, or could be integrated into the face mask itself. Similarly, although the bias flow arrangement illustrated, wherein the air flows from the inlet port to the outlet port and the face mask is connected through a side tube, is believed to be the most convenient, other arrangements are not excluded. For example, the outlet port could be located between the source of air and the face mask.

Other measuring instruments can also be incorporated into the apparatus of the invention. For example, sensors to monitor the level of carbon dioxide in the exhaled air, pressure sensors to measure and/or record pressure, or a pneumotachometer to measure and/or record gas flow rate could be placed in the face mask or adjacent air conduits.

Although the procedure is best performed by inflating the lungs for several successive respiratory cycles, it is not excluded that some normal respiratory cycles may be interspersed with the cycles containing augmented inspirations. The augmented inspirations should preferably be closely spaced, however, for maximum efficacy in performing the procedure.

Although the stopped ventilation procedure is especially useful in visualizing the lungs themselves, adjacent abdominal organs such as the liver and spleen are also moved by the action of the diaphragm. Consequently, scanned images of such organs are also degraded by respiratory motion in patients that cannot voluntarily hold their breath. Therefore, the apparatus and procedure of the invention are also useful in obtaining images of other organs that are moved by a patient's natural breathing.

Furthermore, although the invention is described above in connection with its use to induce respiratory pauses in infants, the apparatus can also be used for the same purpose with adults who cannot follow instructions, e.g.,

unconscious, mentally impaired, or confused persons. Accordingly, high resolution images of the lungs and other organs can be obtained in such individuals as well.

The ventilation apparatus is also useful in assisting breathing in persons who are having difficulty in breathing because of a medical emergency or trauma, if a source of air is available. In addition to natural air, air enriched in oxygen, pure oxygen, or air containing other therapeutically useful gases, such as anesthetic agents, or x-ray contrast agents, can be used as a breathable gas in the apparatus of the invention. Accordingly, the apparatus is useful in hospitals for breathing assistance and resuscitation procedures.

The invention having now been fully described, it should be understood that it may be embodied in other specific forms or variations without departing from its spirit or essential characteristics. Accordingly, the embodiments described above are to be considered in all respects as illustrative and not restrictive, the scope of the invention being indicated by the appended claims rather than by the foregoing description, and all changes which come within the meaning and range of equivalency of the claims are intended to be embraced therein.

I CLAIM:

1. An apparatus for controlled ventilation of a patient consisting essentially of

a manifold having an inlet port adapted to be connected to a source of breathable gas,

a face mask in fluid communication with said manifold,

a pressure relief valve in fluid communication with said manifold, and

an outlet port in fluid communication with said manifold, said outlet port being adapted to be manually occluded by an operator.

2. The apparatus of Claim 1 wherein said outlet port is adapted to be occluded by an operator's digit.

3. The apparatus of Claim 1 additionally comprising an outlet valve capable of occluding said outlet port.

4. The apparatus of Claim 3 wherein said outlet valve is adapted to be operated manually.

5. The apparatus of Claim 3 wherein said outlet valve is adapted to be operated electrically.

6. A method for obtaining an image of organs moved by a patient's natural breathing in a patient that cannot voluntarily perform a breathhold maneuver comprising

1.) inflating the lungs of a patient synchronously with natural tidal inspiration to a lung volume greater than that reached at end tidal inspiration for a plurality of closely spaced respiratory cycles until the patient's natural tidal breathing pauses, whereby said lungs and organs adjacent to said lungs become immobile, and

2.) during said pause in breathing forming an image of selected ones of said lungs and said adjacent organs.

7. The method of Claim 6 wherein said image is formed by computerized tomographic x-ray procedures.

8. The method of Claim 6 wherein said image is formed by magnetic resonance imaging.

9. The method of Claim 6 wherein said patient is a child that cannot voluntarily perform a breathhold maneuver.

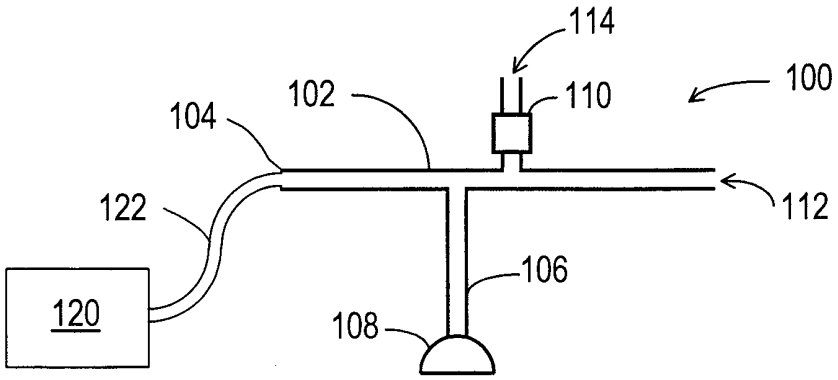
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Fig. 1

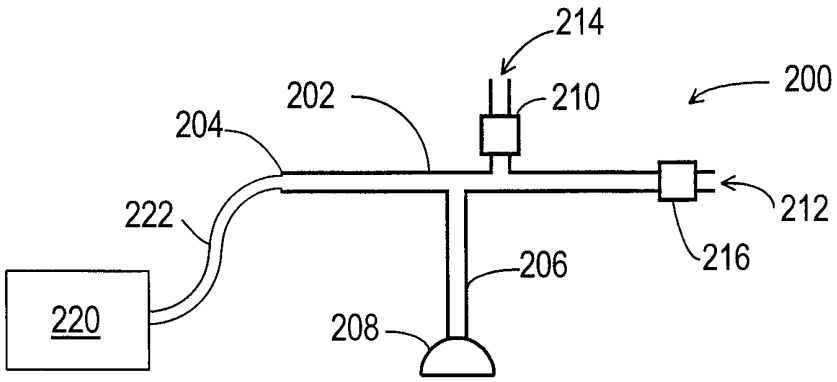
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Fig. 2

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US98/22408

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61B 6 00; A61M 16/00
US CL :128/200.24, 204.18, 204.21, 204.23, 912; 600/410, 431
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/200.24, 204.18, 204.21, 204.23, 912

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

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APS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5,513,647 A (CASTILE) 07 May 1996, entire document.	1-9
Y	US 5,551,419 A (FROEHLICH et al) 03 September 1996, entire document.	1-5
Y	US 5,720,282 A (WRIGHT)24 February 1998, entire document.	1-5
A	US 5,271,401 A (FISHMAN) 21 December 1993, col. 7 lines 50-56, and col. 8 lines 3-11.	6-9
A	US 5,732,702 A (MUELLER) 31 March 1998, col. 1 lines 37-49.	6-9

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

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