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A fluidic-controlled, miniature respirator with a new positive airway pressure device

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Continuous positive airway pressure (CPAP) has proved to be a very helpful tool in the treatment of RDS [1, 2, 3]. In many cases the improvement in gas exchange as well as in lung mechanics, which can be achieved by CPAP, is sufficient to substitute for artificial ventilation [4, 5]. This method has also become a valuable technique for weaning patients from the respirator. Since its introduction by Gregory many modified CPAP devices have been constructed. Their development shows a tendency (a) to simplify the devices and (b) to make them safer [6, 7, 8]. The conventional CPAP-apparatus is rather large, bulky and complicated for use with premature infants. The tubing and apparatus hinders the general management of the patient and prevents transport. A large dead-space endangers sufficient alveolar ventilation. A conventional CPAP-system does not allow immediate transition to other forms of ventilatory assistance as provided by respirators i.e. that a rapid change from CPAP to IPPV is not possible with systems in use nowadays. There are only very few pediatric respirators that really can cope with the specific demands of artificial ventilation of the newborn [9, 10]. Common to all existing pediatric ventilators is a rather complicated handling, a very complex electronic or pneumatic circuitry which is difficult to deal with [11] and last but not least a high price. It would therefore be very useful to have a simple apparatus for daily use, which included all the respiratory modes

Curriculum vitae

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mentioned above with a maximum of simplicity and reliability.

We developed a simple and versatile respirator of miniature dimensions. According to the morphological structure the respirator consists of two systems: one to supply the air and the other to control it (Fig. 1 a and 1 b).

1.1 Air-supply system

It contains a flow-meter, a flow-divider and a part called the regulator. The regulator is a tube with the same diameter as the tracheal tube fitted with one end onto it. The other free end of the regulator can be occluded by a valve-mechanism. It consists of a balloon, which occludes the tube when inflated

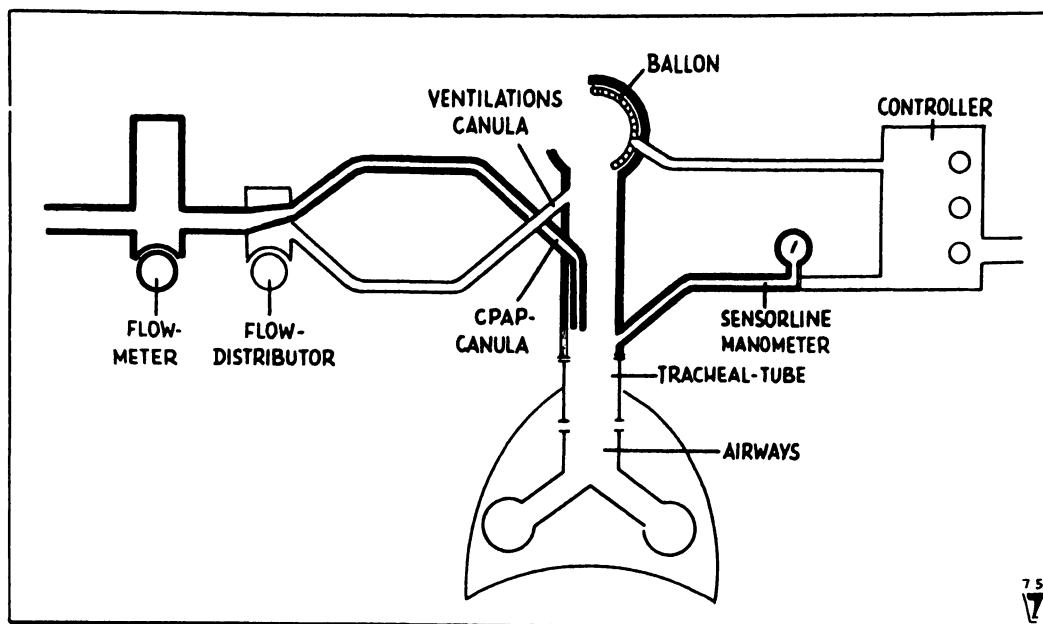


Fig. 1 a. Principal structure of the apparatus. Parts needed for CPAP in heavy print.

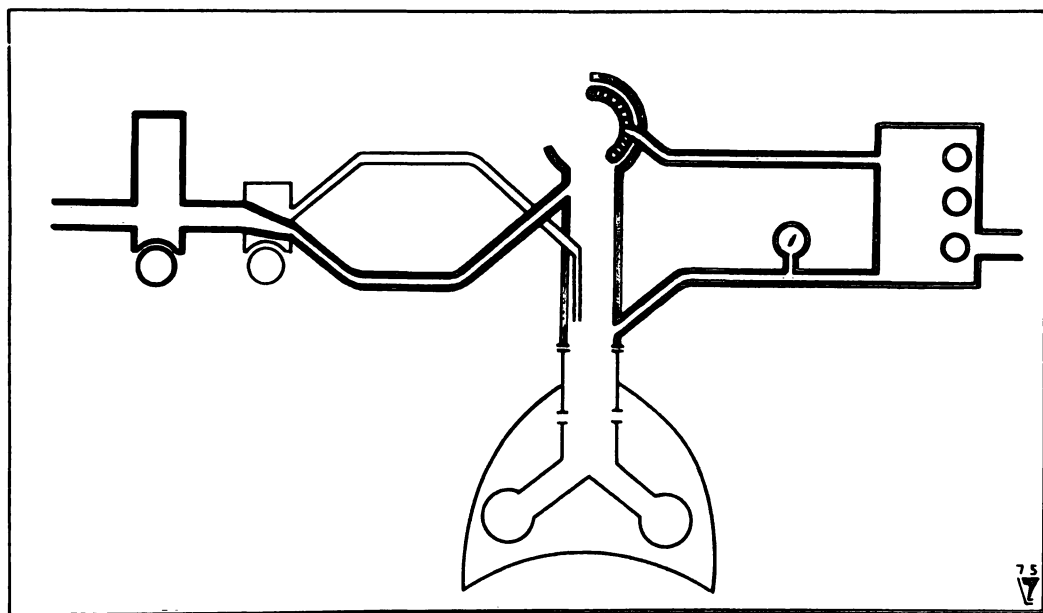


Fig. 1 b. Principal structure of the apparatus. Parts needed for mechanical ventilation in heavy print.

and does not offer any resistance to expiration when deflated. Two canulas are fitted into the lumen of the regulator: one is parallel pointing in the direction of the lung (CPAP-canula), the other points to the open end of the tube at a small acute angle (Ventilation-canula).

1.2 Control-system

It comprises a sensor-line connected to a manometer and the so-called "controller", which consists of fluidic-circuits [12]. The sensorline has to enter the tracheal-tube at least 3 cm below the

CPAP-canule to avoid measuring the negative pressure due to the Venturi effect. The sensorline feeds information about the tracheal pressure changes into the fluidic-circuits the output of which controls the balloon. Thus the control system functions as a feed-back-loop. The fluidic circuit is constructed to provide controlled ventilation and to guarantee safety by a pressure limiting device. 600 liters of pressurized gas are needed to operate the fluidic circuits for half an hour.

According to the function we distinguish between a CPAP-system and one for mechanical ventilation. Both can be combined. By definition CPAP is then called PEEP [13].

2.1 CPAP-system

Fig. 1 a shows the necessary parts (in heavy print): flowmeter, CPAP-canula of the regulator and manometer. An oxygen-air-mixture rationed by the flowmeter passes through the CPAP-canula into the airways. Because the preset flow is greater than the volume ventilated per minute, a part of this flow escapes even during the inspiratory phase at the open end of the regulator. During expiration the direction of the insufflated air has to be changed by the patient's expiratory flow and the dynamic pressure necessary for it manifests itself as a constant positive airway pressure. The airflow

(supplying the canula) is regulated to obtain the desired CPAP as indicated by the manometer. The distribution of flow during the breathing cycle can be seen in Fig. 2 a (inspiration) and 2 b (expiration).

2.2 System for mechanical ventilation

In this mode the airsupply- and the control-system are necessary for operation (Fig. 1 b in heavy print). As mechanical ventilation can be combined with a positive airway pressure we choose to describe the combined function. The inspiratory flow is set on the flowmeter. The flow-divider divides it into two partial flows: one passes through the CPAP-canula, the other through the ventilation canula. The division is made to obtain a flow through the CPAP canula resulting in the desired positive airway pressure. Consequently the remaining flow passes through the ventilation canula and leaks into the open air without any effect as long as the valve-mechanism is open. The moment the valve-mechanism closes due to the inflating of the balloon, the total flow is directed into the lungs. Inspiration lasts as long as the balloon occludes the cross-section of the regulator. When it collapses, expiration begins during which the flow through the CPAP-canula keeps up a positive airway pressure. For flow distribution see Fig. 3 a (inspiration) and 3 b (expiration). CPAP and inspiratory flow

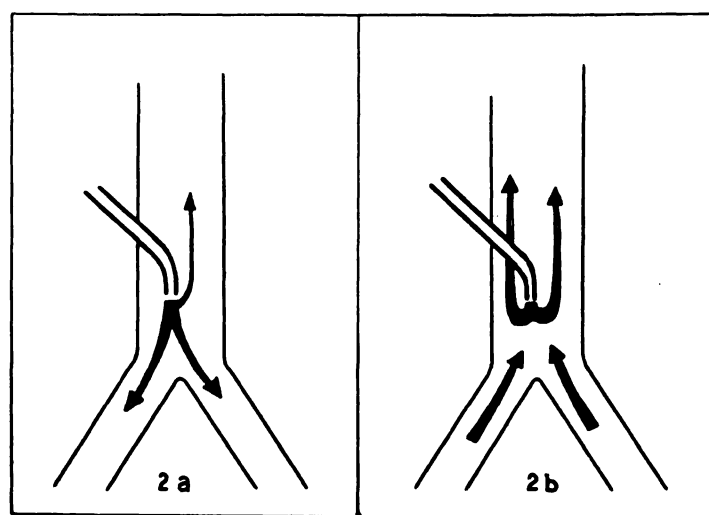


Fig. 2 a, 2 b. Flow distribution during CPAP assisted ventilation a) at inspiration, b) at expiration.

can be regulated independently by flowmeter and flow-divider. Frequency and duration of inspiration (I:E ratio) can be set on the controller. The ventilating volume delivered is dependent on inspiratory flow and I:E ratio, as in all respirators of the "constant-flow-generator"-type as long as the preset safety-pressure is not reached. The control modes are time cycled/pressure limited or pressure cycled/time limited.

2.3 Sighing

A slight modification allows sighing in an open system. It can be brought about by allowing the airflow used for inflating the balloon to pass through the CPAP canula. The airflow must be sufficiently great to create the pressure necessary for hyperinflation. It is also possible to combine sighing with CPAP.

3 Methods

3.1 Test with a lung model

The lung model used in our experiments consisted of a 5 litre glass bottle filled with 2 litres of water thus giving a compliance of 3 ml/cm water (independent of respirator pressure and — rate). A tracheal resistance of 20 cm water/l/sec was simulated by an orifice connected to the neck of the

bottle. Airway pressure was recorded by means of an electromanometer. Under these conditions measurements were made to optimize different variables like diameter of the regulator, velocity and angly of inflow and pressure-rise-velocity (dp/dt).

3.2 Clinical Tests

The CPAP device was tested on an anencephalic newborn, 3 days of age, 2800 g, with clinical signs of dyspnoea to obtain flow-pressure-ratios. CPAP and mechanical ventilation with PEEP were tested on a 3 months old baby, 4 kg, during the postoperative phase after a partial correction of an anomalous pulmonary venous drainage had been performed. The pressure curves were obtained from the tracheal tube at a distance of 7 cm from the mouth.

4 Results

4.1 Lung model results

The variables which affect the amount of CPAP produced were found to be:

4.1.1 Diameter of the tube Table I shows that CPAP is inversely correlated to the diameter of a tube and flow dependent.

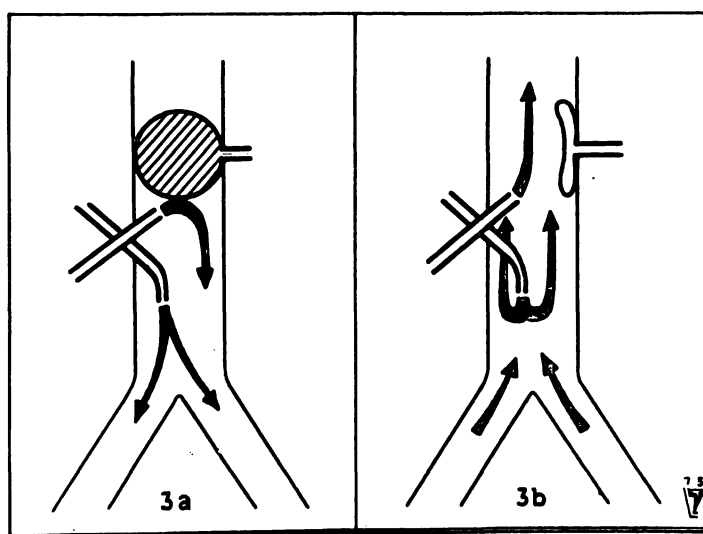


Fig. 3a, 3b. Flow distribution during mechanical ventilation with PEEP a) at inspiration, b) at expiration.

Tab. I.	tube diameter	3	4	litres/min
	2 mm	30	40	cm water
	3 mm	10	18	
	4 mm	4	8	

Tab. II.	canula diameter	2,	6	litres/min.
	0.9 mm	3.5	24.5	cm water
	1.5 mm	1.5	9.5	

4.1.2 Angle of inflow

A correlation was found between the pressure in a tube, obtained by an airflow through a canula, and the angle of inflow, with its maximum (and positive value) when directed towards the lung and its minimum (and negative value) when directed oppositely (Venturi effect) (Fig. 4).

4.1.3 Velocity of inflow

The thinner the canula (i.e the greater the flow velocity) the higher the CPAP produced. Canulas with a diameter of 0.8 mm or less have a very high resistance and the driving pressure necessary to obtain a certain flow velocity may enhance disconnection of the tubing. The results with a set of these variables are shown in Tab. II.

4.1.4 Pressure-rise-velocity (dp/dt)

For a sighing manoeuvre it is necessary to obtain a certain pressure within a certain period of time. Fig. 5 shows pressure-time curves at various flow-rates, in a 3 mm wide tube. The inflow is parallel to the tube, the canula diameter 0.9 mm. At flow-rates ranging from 3 to 7 litres/min 90% of the maximum pressure can be achieved within 0.5 sec.

4.2 Clinical results

Fig. 6 shows the CPAP obtained at various flow-rates tested in the anencephalic newborn. The results were reproducible. Fig. 7 depicts the pressure curve of the intubated baby's breathing cycle unassisted by any respiratory device, whereas Fig. 8 shows the CPAP curve using the apparatus

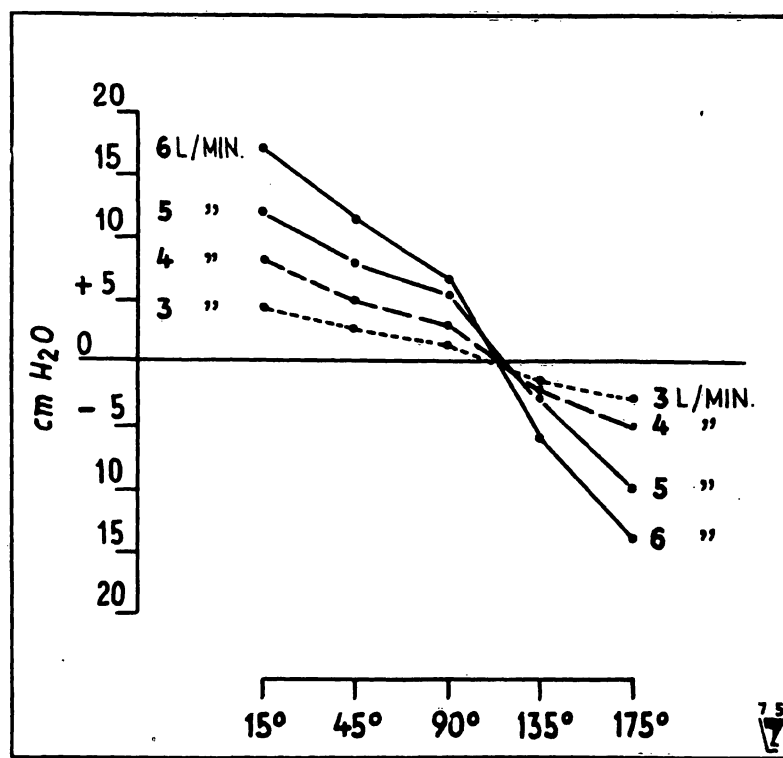


Fig. 4. Positive pressure obtained in 3 mm tube with a canula of 0.9 mm at various angles and flow-rates.

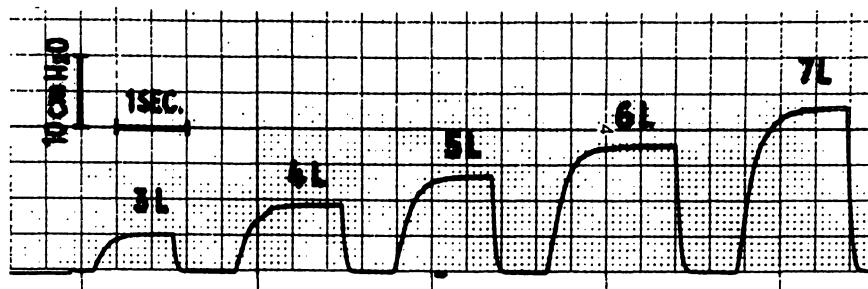


Fig. 5. Time-pressure-curves obtained in a 3 mm tube at various flow rates. Canula diameter 0.9 mm, parallel to the tube. X-axis: 1 cm = 1 sec. Y-axis: 1 mm = 1 cm water.

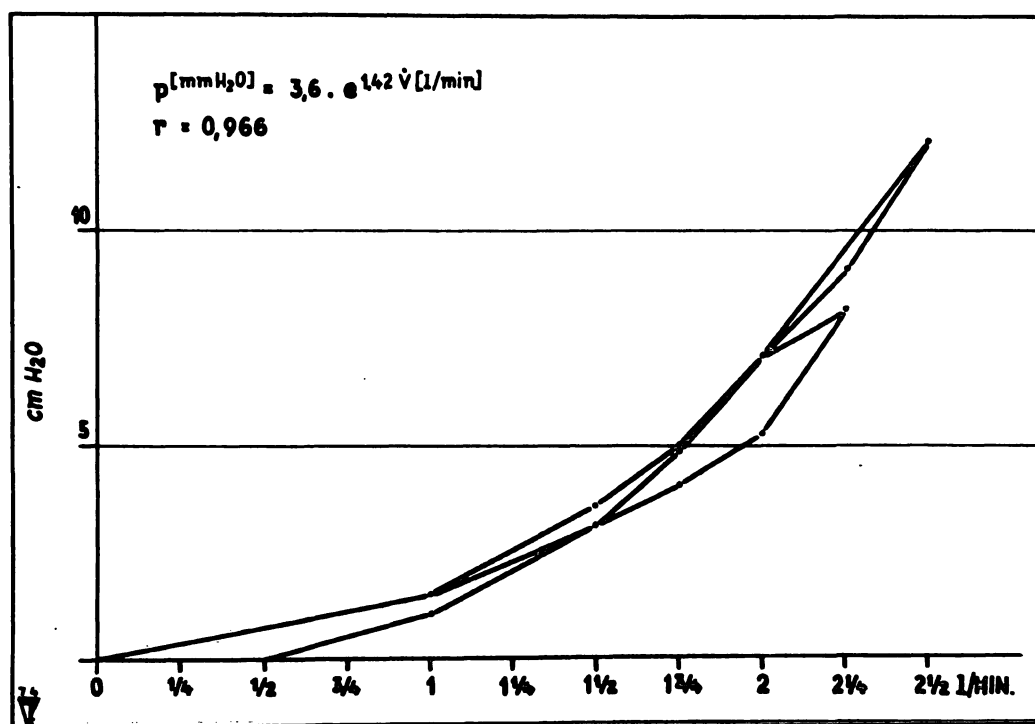


Fig. 6. CPAP obtained in an anencephalic newborn at various flow-rates. 3 mm tube, 0.9 mm canula-diameter.

described. Pressure curves of sighing combined with CPAP are shown in Fig. 9. In this case sighing was achieved by means of the valve-mechanism. The total airflow needed for it was approximately 2 litres to result in a positive pressure of 27 cm water.

5. Discussion

The respirator is considered to meet [a] all essential criteria for pediatric ventilatory assistance and [b] offers some additional advantages. [a] Breathing

rates up to 100/min can be obtained. The infant can be sighed as rarely as once every 3 minutes. Tidal volume can be regulated to as little as 5 ml and as much as 100 ml. The inspiratory flow necessary for it lies between 1–4 litres/min. The unit can be used to apply positive airway pressure. The control modes depend on the fluidic circuits used. Our controller allows controlled ventilation in two modes, time cycled/pressure limited and pressure cycled/time limited. Any oxygen-mixer and humidifier can be integrated into the system. [b] This respirator is characterized by its miniature

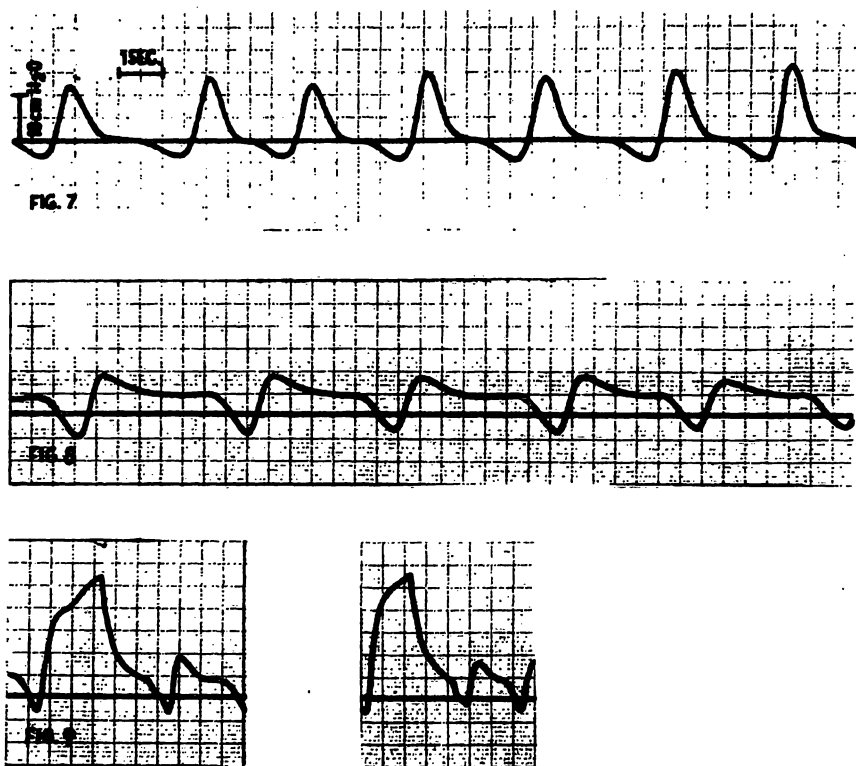


Fig. 7. Time-pressure-curve during spontaneous ventilation and

Fig. 8. Time-pressure-curve during CPAP assisted ventilation.

Fig. 9. Time-pressure-curve of sighing and CPAP in a closed system.

dimensions, versatility and its safe and simple construction. In addition there is no apparatus deadspace because the patient's expired air leaks out into the atmosphere directly at the end of the tracheal tube. This means rebreathing is completely prevented even if the tubings are disconnected. Furthermore, the regulator and tubing supplying the air can be made disposable and therefore steril. Miniature dimensions were made possible by use of fluidic elements for the controller ($10 \times 10 \times 5$ cm) and a simply structured regulator (2 cm^3). Due to this fact the respirator is easily transportable and allows free access to the infant. Treatment of neonatal respiratory difficulties takes place in the labour ward, during transport and in the neonatal unit. As each location has its specific demands and facilities, adaptability is advantageous: in the labour ward the regulator supplied with oxygen by two flowmeters constitutes an always and immediately available CPAP- and mechanical ventilation device with or without PEEP, if the pediatrician's thumb functions as a controller. As soon as the fluidic

controller is available, the child is ready for transport to the neonatal unit, where heater, humidifier and oxygen-mixer are added for longterm ventilation. The pressure-rise-velocity as demonstrated in Fig. 5 meets the requirements for sighing in an open system. Because CPAP and sighing are achieved in an open system dangerous pressure can only be brought about if the flow-setting is gravely erroneous, but the blockage of an expiratory limb, resulting in a steady pressure rise, cannot occur in this system. Thus in the application of CPAP and sighing the constant leakage offers maximum security and enables tracheal suction at any time. Except for two membrane valves the respirator contains no moving parts. Only information in form of pressure changes is fed into the fluidic circuits, the output of which are again pressure changes. Therefore the only source of energy required for running the respirator is highly pressurized gas. This justifies an expectation of high technical reliability. At the present stage an adequate supply of gas for transportation

is endangered by the high gas consumption of the fluidic circuits. This problem will be solved by

developing an integrated fluidic circuit for this particular application.

Summary

A simple and miniature respirator was developed providing controlled ventilation and application of a positive airway pressure. The positive airway pressure is achieved by an airflow through a canula into the airways. During expiration the direction of this insufflated air-flow is changed and the dynamic pressure necessary for it manifests itself as a positive airway pressure. Mechanical ventilation functions according to the principle of the Ayre-T-Piece: flow direction and, therefore ventilation, is controlled by occlusion of the expiratory limb. Occlusion is brought about by inflating a balloon. The inflation of the balloon is controlled by fluidic-circuits. They allow setting of frequency, duration of inspiration and pressure limit. As the above mentioned system for creating a positive airway pressure is integrated, mechanical ventilation with PEEP is achieved.

Tests on a lung model were performed to establish the variables which influence the amount of positive pressure produced by an air-flow through a canula into a tube. Results indicate that the positive pressure obtained is in-

versely correlated to the diameter of tube and canula and varies with the angle of inflow (Tab. I, II, Fig. 4). The pressure-rise-velocity depicted in Fig. 5 suggests that sighing is possible in an open system. On an anencephalic newborn pressure-flow-ratios were established (Fig. 6). Pressure-time curves during spontaneous breathing, CPAP assisted breathing and sighing combined with CPAP* were recorded in a 3 month old baby (Fig. 7, 8, 9).

The discussion states the technical performance of the respirator (frequency 100/min–1/3 min., tidal volume 5–100 ml, controlled ventilation with pressure limitation, application of PEEP) and additional advantages (no apparatus deadspace, disposable i.e. sterile air supply-system, the miniature dimensions 10 × 10 × 5 cm, versatility and simple therefore technically reliable construction).

* Nowadays called IMV (Intermittant Mandatory Ventilation)

Key-words: CPAP, fluidic controller, IPPV, miniature respirator, respirator, transport.

Zusammenfassung

Ein Fluidik-kontrollierter Miniaturrespirator mit einer neuen Vorrichtung für positiven Atemwegsdruck

Wir entwickelten einen einfachen und kleinen Respirator, der kontrollierte Beatmung und die Anwendung eines positiven Atemwegsdruckes ermöglicht. Der positive Atemwegsdruck wird mittels eines Luftstrahles, der aus einer Kanüle kommt in die Atemwege strömt, erzielt. Während der Expiration wird die Richtung des Luftstromes geändert und der dafür notwendige dynamische Druck manifestiert sich als positiver Atemwegsdruck. Die mechanische Ventilation beruht auf dem Prinzip des Ayre-T-Rohres: die Strömungsrichtung des Atemgases und damit die Ventilation wird durch die Okklusion des expiratorischen Schenkels kontrolliert. Die Okklusion erfolgt durch das Aufblasen eines Ballones und wird durch Fluidik-elemente gesteuert. Jene ermöglichen eine Einstellung der Frequenz, Inspirationsdauer und der Druckgrenze. Da die oben erwähnte Vorrichtung darin integriert ist, ist eine mechanische Beatmung mit PEEP möglich.

An Hand eines Lungenmodells wurde untersucht, welche Variablen die Höhe des positiven Druckes beeinflussen, der durch einen Luftstrom aus einer Kanüle in einem

Tubus entsteht. Die Ergebnisse zeigen, daß der erzielte positive Druck eine negative Korrelation zum Durchmesser des Tubus und der Kanüle aufweist und mit dem Einstromwinkel variiert (Tab. I, II, Fig. 4). Die in Fig. 5 dargestellte Druckanstiegsgeschwindigkeit macht deutlich, daß eine Seufzeratmung in einem offenen System möglich ist. An einem anencephalen Neugeborenen wurde die Abhängigkeit des Druckes vom Flow untersucht (Fig. 6). Druckzeitkurven wurden während Spontan und CPAP-assistierter Atmung und während kombinierter CPAP-Seufzeratmung* bei einem 3 monatigem Säugling aufgezeichnet (Fig. 7, 8, 8). Die Diskussion befaßt sich mit dem technischen Vermögen des Respirators (Frequenz 100/min–1/3 min, Atemzugvolumen 5–100 ml, kontrollierte Beatmung mit Druckbegrenzung, Anwendung von PEEP) und zusätzlichen Vorteilen (kein Geräte-Totraum, Einmalgerät d.h. steriles Luftzufuhrsystem, kleine Ausmaße, Vielseitigkeit und einfache, deshalb verlässliche Konstruktion).

* In der Literatur derzeit als IMV (= Intermittant Mandatory Ventilation) bezeichnet.

Schlüsselwörter: Fluidiksteuerung, Miniaturrespirator, positiver Atemwegsdruck (CPAP), positive Druckbeatmung, Transport.

Résumé

Un respirateur de format très réduit, à contrôle liquide et doté d'un nouveau dispositif de pression positive de la voie aérienne

Un respirateur simple et de format très réduit a été mis au point pour assurer une ventilation contrôlée et une pression positive de la voie aérienne. Cette pression est fournie par un flux d'air à travers une canule dans les voies aériennes. La direction de ce flux d'air insufflé est modifiée durant l'expiration et la pression dynamique que cela nécessite se manifeste comme étant une pression positive de la voie aérienne. La ventilation mécanique fonctionne selon le principe du Ayre-T-Piece: la direction du flux et, par suite, la ventilation sont contrôlées par l'occlusion du membre expiratoire. L'occlusion est provoquée par le gonflement d'un ballon contrôlé par des circuits liquides qui permettent d'établir la fréquence, la durée de l'inspiration et la limite de pression. L'intégration du système mentionné ci-dessus et créateur d'une pression positive de la voie aérienne assure une ventilation mécanique avec PEEP (positive end expiratory pressure).

Des tests sur un modèle pulmonaire ont été effectués afin d'établir les variables qui influencent la mesure de pression

positive produite par un flux d'air à travers une canule jusque dans un tube. Les résultats indiquent que la pression positive obtenue est inversement proportionnelle au diamètre du tube et de la canule et qu'elle varie avec l'angle de l'influx (Tab. I, II, Fig. 4). La rapidité de la hausse de pression représentée à la Fig. 5 semble prouver que le soupir est possible dans un système ouvert. Des rapports proportionnels de flux de pression ont été établis sur un nouveau-né anencéphale (Fig. 6) On a également enregistré chez un bébé de 3 mois des courbes de temps de pression pendant la respiration spontanée, la respiration soutenue par la CPAP (pression positive continue de la voie aérienne) et le soupir combiné avec la CPAP (Fig. 7, 8, 9).

La discussion amène à constater la performance technique du respirateur (fréquence 100/min—1/3 min., volume de flux 5–100 ml, ventilation contrôlée avec limitation de pression, application du PEEP) et les avantages additionnels (appareil sans espace mort, système d'apport d'air disponible, c.à.d. stérile, dimensions réduites 10 × 10 × 5 cm, versatilité et construction simple, donc d'une technique sûre).

Mots-cles: contrôleur liquide, CPAP, IPPV, respirateur, respirateur miniature, transport.

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