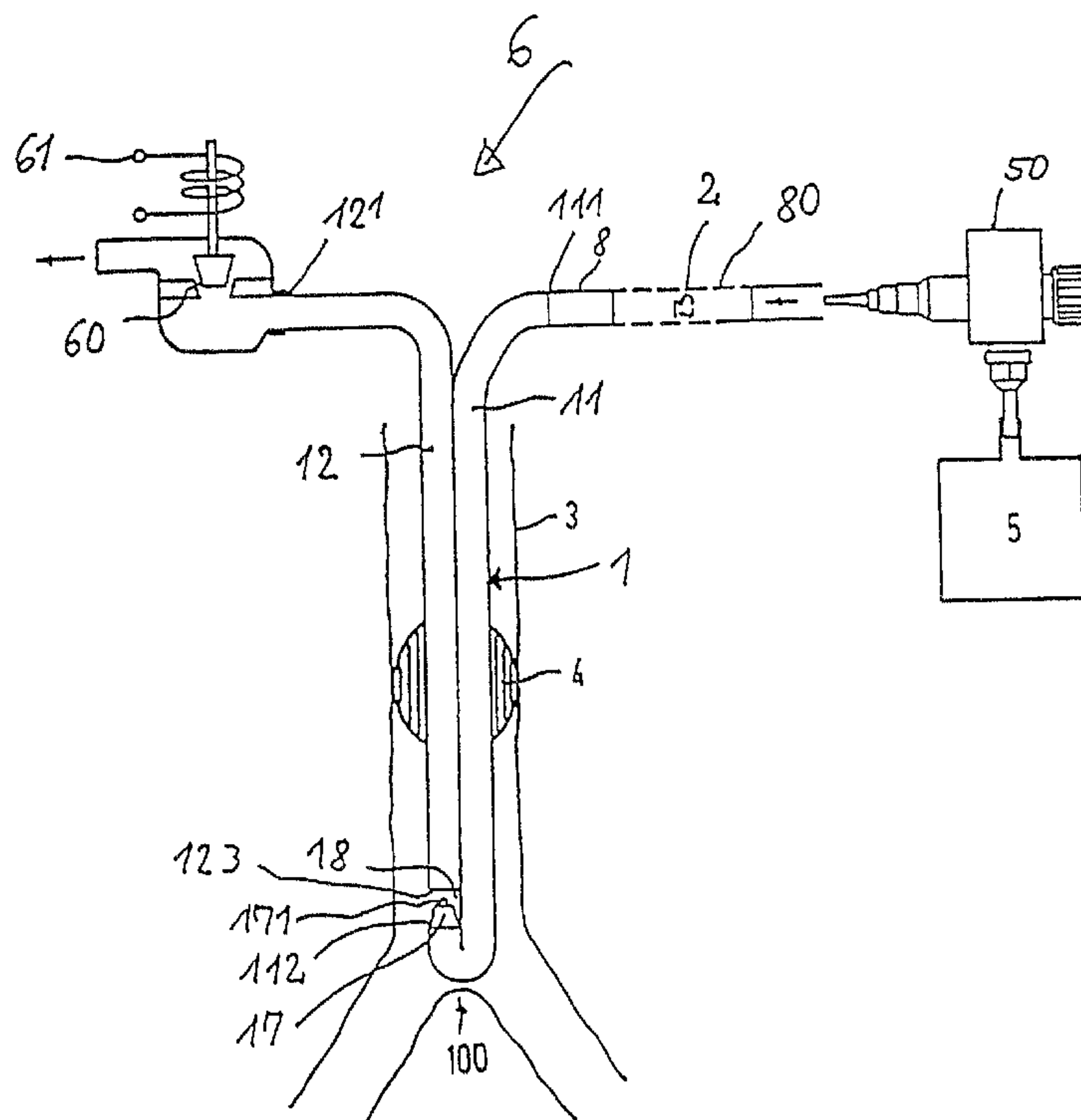




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(54) Titre : TUBE ENDO-TRACHEAL OU DE TRACHEOTOMIE MUNI D'UN DISPOSITIF POUR LA RESPIRATION
(54) Title: TRACHEAL OR TRACHEOTOMY TUBE AND BREATHING INSTALLATIONS FITTED THEREWITH



(57) **Abrégé/Abstract:**

The invention relates to a double-barrelled tube with a respiratory (11) and an inhaling (12) passage for the mechanically controllable respiration of a patient in which the inhaling passage connected to a respiratory gas source is fitted at the distal outlet with a nozzle directed towards the distal outlet aperture of respiratory passage. The respiratory passage is connected at the proximal outlet with an exhalation valve (60) which can be opened and closed by means of an electrical control device. The electrical control device is connected to an electrocardiograph or a blood pressure measuring instrument so that respiration may be effected synchronously with the pulse rate using the respiratory gas fed to the inhalation passage with a retrograde flow of respiratory gas. Inhalation may take place in either the systole or the diastole.



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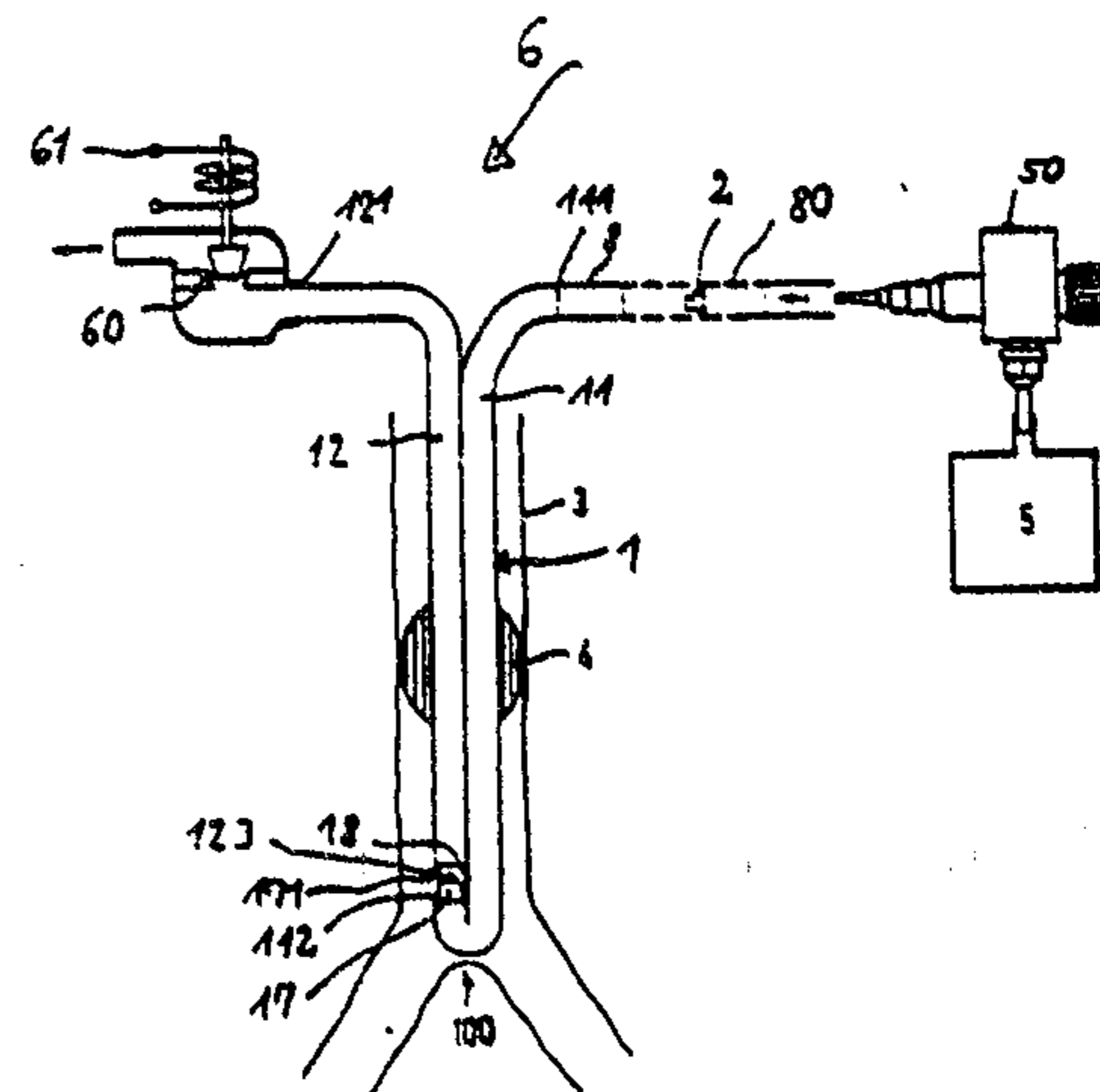
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(54) Title: TRACHEAL OR TRACHEOTOMY TUBE AND BREATHING INSTALLATIONS FITTED THEREWITH

(54) Bezeichnung: TRACHEAL- ODER TRACHEOSTOMIE-TUBUS UND DAMIT AUSGESTATTETE BEATMUNGSANLAGEN

(57) Abstract

The invention relates to a double-barrelled tube with a respiratory (11) and an inhaling (12) passage for the mechanically controllable respiration of a patient in which the inhaling passage connected to a respiratory gas source is fitted at the distal outlet with a nozzle directed towards the distal outlet aperture of the respiratory passage. The respiratory passage is connected at the proximal outlet with an exhalation valve (60) which can be opened and closed by means of an electrical control device. The electrical control device is connected to an electrocardiograph or a blood pressure measuring instrument so that respiration may be effected synchronously with the pulse rate using the respiratory gas fed to the inhalation passage with a retrograde flow of respiratory gas. Inhalation may take place in either the systole or the diastole.



(57) Zusammenfassung

Die Erfindung befasst sich mit einem doppelumigen Tubus mit einem Respirationslumen (11) und einem Inspirationslumen (12) für eine maschinelle steuerbare Beatmung eines Patienten, bei dem das an eine Atemgasquelle angeschlossene Inspirationslumen am distalen Austritt mit einer Düse ausgestattet ist, die auf die distale Austrittsöffnung des Respirationslumens gerichtet ist. Das Respirationslumen ist am proximalen Ausgang mit einem Expirationsventil (60) verbunden, das mittels eines elektrischen Steuergerätes offenbar und schliessbar ist, wobei das elektrische Steuergerät an einen Elektrokardiographen oder ein Blutdruckmessgerät angeschlossen ist, so dass die Beatmung mit dem über das Inspirationslumen zugeführten Atemgas pulssynchron mit einem retrograden Atemgasfluss durchführbar ist. Die Inspiration kann entweder in der Systole oder in der Diastole erfolgen.

SPECIFICATION

The invention relates to a tube for introduction into the respiratory tract of a patient, especially orotracheal or nasotracheal tubes or tracheostomy tubes for controllable mechanical ventilation of a patient, with a distal end insertable into the respiratory tract and a proximal end provided with connectors and two continuous passages extending essentially from the proximal to the distal end of the tube, one of the two passages serving as a fresh passage in ventilation or breathing and the other of the two passages serving as an inspiration passage for additional or sole administration of fresh gas.

Tracheal and tracheostomy tubes are used for artificial ventilation of a human being in conjunction with ventilators usually comprising an expiration valve and a fresh gas source. The invention therefore consists in an improvement on the tube with a ventilator for improving breathing and for reducing the residual gas remaining in the respiratory tract by using a tube with an improved function.

Artificial ventilation of a human being is normally conducted at the natural respiratory rate. In the various methods of high-frequency ventilation, respiratory rates in the range of the heart rate are also used, without any synchronization of the ventilation phases with the heart action.

The conventional ventilators known heretofore, with a controllable expiration valve and fresh gas supply controllable by means of an electrically controllable pressure-reduction valve, require one tube with a single passage (ventilation tube) or a tube with two passages (inspiration passage, expiration passage) so designed that the gas flow in one

passage has no effect on that in the other passage; see DE 25 35 191 A1, AT 389 818. For all practical purposes, known ventilators can be influenced only by damming up the fresh gas source, whereupon any alveolar gas residue remains in the tube in each cycle and has a disadvantageous effect.

The goal of the invention is to eliminate this disadvantage of ventilators with double-lumen tubes. In addition, the control of ventilation is to be effected as a function of
10 signals delivered by an electrocardiograph or a blood pressure monitor for example.

According to the present invention, there is provided a tube for introduction into a respiratory tract of a patient for controlling a ventilation of said patient, with a distal end capable of being introduced into the respiratory tract and a proximal end provided with connections, and two passages extending essentially from the proximal end to the distal end of the tube, with one of the two passages serving as a ventilation passage during ventilation and
20 breathing and the other of the two passages serving as an inspiration passage for administering a fresh gas, characterized by the fact that each of the two passages has a distal outlet opening, the distal outlet opening of the inspiration passage being directed at the distal outlet opening of the ventilation passage, the distal outlet opening of the inspiration passage being tapered to form a nozzle and terminating in a nozzle outlet opening directed at the distal outlet opening of the ventilation passage.

In a preferred embodiment of the tube, the inspiration
30 passage is bent at approximately 180° in the vicinity of

the distal end of the tube and directed at or into the distal outlet opening of the ventilation passage and through the ventilation passage to the proximal end of the tube. Preferably, in the tube according to the invention one of the two passages has a cross section smaller than that of the other of the two passages in the tube and the passage with the cross section that is larger than that of the other passage serves as the ventilation passage for ventilation and breathing, and the passage with the cross
10 section that is smaller than that of the other passage serves as the inspiration passage for the additional or sole supply of fresh gas.

Preferably, the tube according to the invention, which can be designed as an orotracheal, nasotracheal, or tracheostomy tube, has two passages so designated that conventional ventilation can be conducted through the ventilation passage (from example, intermittent positive pressure ventilation, or IPPV). In addition, endotracheal and endobronchial suctioning can be performed through this
20 passage both with conventional disposable suction catheters and with a bronchoscope. The inspiration passage, made with a smaller cross section than that of the ventilation passage, is intended for additional or sole supply of fresh gas to the patient. Both the additional and sole gas supply through the inspiration passage can be provided intermittently, preferably on expiration, or constantly or continuously, but as a function of the fresh phase with a different current, also termed flux or flow. The distal end of the tube, which is placed in the trachea, is designed so
30 that the inspiration passage narrows to form a jet and its opening or openings point or extend toward or into the open

distal outlet end of the ventilation passage. In other words, the nozzle-shaped distal end of the inspiration passage "blows" into the outlet opening of the ventilation passage, namely in the expiration direction through the ventilation passage at the proximal end of the tube, in other words out of the trachea and hence out of the patient. At the proximal end of the tube, outside the trachea, both passages in the tube have connections (connectors) for the connecting lines to the fresh gas
10 sources, valves, or other equipment being used.

Preferably, as a result of the design according to the invention for the distal end of the inspiration passage, which serves to supply the fresh gas, in the shape of a nozzle, the gas flowing through the inspiration passage is deflected through 180° so that it is guided from the distal end of the tube into the ventilation passage of the tube in the direction of its proximal end and flows toward the proximal end. To achieve a jet effect using the jet pump principle, the cross sectional area of the inspiration
20 passage of the tube is reduced at the distal end up to the nozzle outlet opening, preferably by approximately one-half.

Preferably, when the tube according to the invention is used for the ventilation of a patient, as a result of a continuous supply of fresh gas through the smaller passage, the dead space during ventilation can be considerably reduced, i.e. the volume of residual gas that is not expired is reduced considerably. In order to improve ventilation during mechanical ventilation of a patient, it
30 is even possible with the tube according to the invention

to reduce the space, thus increasing carbon dioxide elimination by administering a continuous retrograde or expiratory retrograde fresh gas flow through the smaller tube passage.

Preferably, in the tubes according to the invention, with two passages of different sizes, the larger passage is intended to permit both unimpeded conventional ventilation and spontaneous breathing by the patient. In addition, the larger passage is intended to allow cleaning up the bronchi with suction catheters or with a bronchoscope. The smaller passage of the tube is used to supply the fresh gas. It cross sectional area is therefore selected so that with each size of tube correct for the patient, up to five times the spontaneous fresh minute volume can be supplied with assumed pressures as behind commercially available flow regulators associated with fresh gas sources.

Preferably, for example, the following cross-sectional ratios can be given as guidelines; larger passage (fresh passage) to smaller passage (inspiration passage) to nozzle outlet opening, 8:2:1. In tubes for adults, the cross sectional area of the larger passage should correspond to that of a conventional tube with an inside diameter of 7 mm, i.e. approximately 38.5 mm^2 . The smaller passage of the tube at 9.6 mm^2 then corresponds to an inside diameter of a conventional tube with an inside diameter of 3.5 mm. The cross-sectional area of the nozzle outlet opening of the smaller passage in this example is then 4.8 mm^2 .

Preferably, the tube is characterized by the fact that one of the two passages has a smaller cross section than the

other of the two passages of the tube, and the passage with the cross section that is larger relative to the passage of the other serves as the ventilation passage for ventilation and breathing, the passage with the cross section that is smaller than the other passage serving as the inspiration passage for fresh gas supply.

Preferably, the tube is characterized by the fact that the ventilation passage serves for introducing an element selected from the group including a suction catheter and a
10 bronchoscope.

Preferably, the tube is characterized by the fact that one of the two passages has a smaller cross section than the other of the two passages of the tube, and the passage with the cross section that is larger than that of the other passages serves as the ventilation passage for ventilation and breathing, the passage with the cross section that is smaller than that of the other passage serving as the inspiration passage for fresh gas supply, the distal outlet opening of the inspiration passage being tapered to form a
20 nozzle and terminating in the nozzle outlet opening directed at the distal outlet opening of the ventilation passage, and the nozzle outlet opening having ratios of approximately 8:2:1 to one another.

Preferably, the tube is characterized by the fact that the distal outlet opening of the inspiration passage is bent in a vicinity of the distal end of the tube by approximately 180° and is directed at the distal outlet opening of the ventilation passage and through the ventilation passage to the proximal end of the tube.

Preferably, the tube is characterized by the fact that the distal outlet opening of the ventilation passage runs diagonally to a lengthwise axis (X) of the tube, in such manner that the distal end of the tube is beveled unilaterally in a vicinity of the ventilation passage toward the distal end of the tube.

Preferably, the tube is characterized the fact that the nozzle outlet opening of the inspiration passage is located off center relative to the distal outlet opening of the
10 ventilation passage near he periphery of the ventilation passage.

Preferably, the tube is characterized by the fact that the ventilation passage and the inspiration passage are divided from one another by a partition in tube.

Preferably, the tube is characterized by the fact that the nozzle outlet opening of the inspiration passage is located outside the distal outlet opening of the ventilation passage and outside the ventilation passage.

Preferably, the tube is characterized by the fat that the
20 nozzle outlet opening of the inspiration passage partially projects into the ventilation passage through the distal outlet opening of the ventilation passage.

Preferably, the tube is characterized by the fact that the nozzle outlet opening of the inspiration passage and the distal outlet opening of ventilation passage abut one another at a point where the outlet opening of the ventilation passage running diagonally to lengthwise axis

(X) of the tube terminates at the partition of the tube and the nozzle outlet opening of the inspiration passage is located.

Preferably, the tube is characterized by the fact that, to form the nozzle of the inspiration passage and the nozzle outlet opening at the distal end of the tube, a nozzle-shaped piece is connected with the tube as an extension of the inspiration passage, forming a nozzle channel which continues the inspiration passage.

- 10 Preferably, the tube is characterized by the fact that the nozzle-shaped piece is bent at right angles twice forming two legs, so that a flow path of the inspiration passage is deflected through 180°.

Preferably, the tube is characterized by the fact that the nozzle outlet opening formed by nozzle shaped piece for the inspiration passage runs beveled in a plane which is at an angle to or perpendicular to a bevel of the distal outlet opening of the ventilation passage.

- 20 Preferably, the tube is characterized by the fact that the nozzle-shaped piece having said two legs is inserted with one of the legs into an open end of the inspiration passage at the distal end of the tube and is latched to a wall of the tube.

Preferably, the tube is characterized by the fact that the nozzle-shaped piece having said two legs is inserted with one of the legs into an open end of the inspiration passage

at the distal end of the tube and is glued to a wall of the tube.

Preferably, the tube is characterized by the fact that the nozzle-shaped piece is made in the form of a nozzle ring and fitted on the distal end of the tube, with one or more nozzle outlet openings being formed on the inside of the nozzle ring and the ventilation passage running through the nozzle ring.

10 Preferably, the tube is characterized by the fact that a pressure sensor is mounted near the distal end of the tube.

Preferably, the tube is characterized by the fact that the pressure sensor (S) mounted near the distal end of the tube is mounted externally on or in a wall of the tube in a position for measuring the pressure outside the tube.

20 Preferably, the tube is characterized by the fact that the pressure sensor (S) is provided equipped with an integrated electronic measured value detection and signal processing for a continuous measurement of a central airway pressure prevailing in the trachea of the patient, which is connectable through a line with a control device for a ventilator to control the ventilator as a function of the central airway pressure prevailing in the trachea of the patient.

Preferably, the tube is characterized by the fact that near the distal end of the ventilation passage, the cross section of the ventilation passage is reduced by 10 to 25%

for a short distance relative to a lengthwise extend of the ventilation passage.

Preferably, the tubes can be made with or without a cuff. The cuff can be inflatable (balloon) or unfold by itself (so-called "foam cuff"). When no cuff is provided, so-called "gills" can be used which are wafer-thin membranes or structures made of silicone, arranged in a circle around the shaft of the tube for sealing.

10 Preferably, the tube themselves are made of a tissue-compatible plastic, for example PVC, preferably a plastic that does not change in the body even when left there for a long period of time and can be disposed of in an environmentally safe manner after use. It is also possible to use spiral-reinforced tubing made of rubber or silicone. For optimum utilization of the cross-sectional area of the tube, its wall should be as thin as possible.

20 Preferably, to achieve a jet effect with the aid of the nozzle formed at the distal end of the inspiration passage as well as the deflection of the flow in the inspiration passage in the direction of the ventilation passage, entering the distal end thereof, the nozzle outlet opening of the inspiration passage can project slightly into the outlet opening, i.e. into the ventilation passage, or be arranged in front of the outlet opening of the ventilation passage or directly adjoining it. The arrangement of the outlet opening of the ventilation passage and the nozzle outlet opening of the inspiration passage should leave sufficient space for entrainment of the expired gas, but at the same time must not block the outlet opening of the

10a

ventilation passage so that unimpeded flow is possible during ventilation and a suction catheter can also be passed through the ventilation passage of the tube, for example.

Preferably, to achieve a Venturi effect which increases the volume of gas drawn out of the respiratory tract, a bead (short reduction of the cross-sectional area up to about 25%) can be located in the (distal) inlet area of the ventilation passage near the patient.

- 10 Preferably, the nozzle-shaped element that forms the nozzle at the distal end of the tube of the inspiration passage that is near the patient likewise consists of a tissue-compatible plastic that can be disposed of in an environmentally safe manner, with a harder material being used than for the tube itself. The nozzle or the nozzle-shaped body has a defined seat relative to the tube, for example by means of a snap closure; it is also glued or welded to the tube.

- 20 Preferably, the double-lumen tube according to the invention with a nozzle at the distal outlet of the inspiration passage, which blows into the ventilation passage from the distal end thereof, can be used to support ventilation with a continuous retrograde fresh gas flow or an exhalational retrograde fresh gas flow or for ventilation with a continuous retrograde fresh gas flow. Fresh gas can be air or oxygen supplied from a gas source, additionally equipped with a flowmeter for compressed air or oxygen. Mechanical ventilation in addition to the double-lumen tube inserted into the trachea of a patient

10b

and the fresh gas source also requires a controllable expiration valve connected to the proximal end, in other words the end of the larger passage of the tube away from the patient. The expiration valve, the fresh gas source, a pressure reduction valve in the fresh gas supply, and a tube constitute a ventilator.

Preferably, according to the present invention there is provided a ventilator system for electrically controlling mechanical ventilation of a patient, as described above, 10 with the ventilation passage of the tube being connected at its proximal end to a controllable expiration valve and with inspiration passage being connected at its proximal end to a fresh gas source.

Preferably, controlled or assisted ventilation is performed in the usual manner through the ventilation passage, in other words the larger passage on the tube. To improve ventilation, i.e. to increase carbon dioxide elimination by reducing dead space, a continuous, preferably exhalation fresh gas flow can be added through the inspiration passage 20 of the tube. Basically, air or oxygen can be fed continuously into the smaller passage of the tube using the ventilator. Then, besides the double-lumen tube, only one flowmeter is needed for compressed air or oxygen as fresh gas from the fresh gas source.

Preferably, for ventilation with a continuous retrograde gas flow, according to the invention an electrical control device is provided for the controllable expiration valve associated with the proximal outlet of the ventilation passage of the tube. The control device utilizes electrical

10c

signals delivered from the ventilator and opens the expiration valve for continuous retrograde gas flow during the exhalation phase, i.e. whenever the expiration valve is in the "open" position.

Preferably, the inspiratory oxygen concentration of the continuous or exhalational retrograde gas flow can also be identical with the respiratory oxygen concentration supplied through the ventilator or the fresh unit, i.e. through the fresh gas source. This is accomplished by
10 connecting the flowmeter for the continuous or exhalational retrograde gas flow to the air/oxygen mixer of the fresh gas source or to a separate air/oxygen mixer with the same setting. The fresh gas for the continuous or exhalational retrograde gas flow can be heated and moistened in the same way as is done for a gas delivered by a ventilator. In particular, ventilation of a patient with a ventilator using the double-lumen tube according to the invention is possible with a continuous retrograde fresh gas flow. If, to support ventilation with a continuous retrograde gas
20 flow, one begins at the level of a fraction of the required minute volume and the continuous retrograde gas flow is increased with a simultaneous reduction of conventional ventilation up to a multiple of the minute volume originally required for conventional ventilation, a point is eventually reached at which conventional ventilation using the fresh passage of the tube can be completely suspended. All of the fresh gas then flows through the inspiration passage of the tube into the trachea and is distributed, with the expiration valve closed, into the
30 lungs - inspiration - or escapes with the expiration valve open together with the gas that flowed into the lung during

10d

the inhalation phase, outward through the ventilation passage of the tube - expiration. This type of ventilation is termed ventilation with a continuous retrograde gas flow.

Preferably, in its simplest form, ventilation with a continuous retrograde gas flow can be performed manually. Then the fresh gas source is connected to the smaller passage of the tube (fresh gas flow 10 l/min for example) and the person administering ventilation manually closes
10 the outer opening of the fresh passage of the tube (inhalation phase) for 3 seconds for example and then releases it again (exhalation phase), for example for 3 seconds as well, so that a minute volume of 5 liters is obtained in this example.

Preferably, in theory, any conventional ventilator with a time-controlled expiration valve and fresh gas source can be used for ventilation with a continuous retrograde gas flow. The gas connections of the ventilator are then not used and the device is merely supplied with current. The
20 inspiration passage of the tube is connected with the fresh gas source and the ventilation passage of the tube is connected through a connecting hose with the expiration valve. On the ventilator the inhalation/exhalation ratio and the respiratory rate or the inhalation and exhalation times can be adjusted directly. The level of the required continuous retrograde gas flow for efficient carbon dioxide elimination then depends on the respiratory rate and the inhalation/exhalation ratio. The mean airway pressure critical for oxygenation is adjusted by changing the
30 inhalation/exhalation ratio and the PEEP valve or the PEEP

10e

function of the ventilator. Therefore a suitable time-controlled expiration valve is required. The task of a time-controlled expiration valve with positive end exhalation pressure function also be supplied by an expiration valve that is independent of a ventilator, said valve being usable in cases when ventilation with a continuous retrograde fresh gas flow is conducted exclusively in patient.

10 Preferably, the double-lumen tube according to the invention and the principle of ventilation with a continuous retrograde gas flow with a ventilator reduce the dead space when ventilating a patient in such a way that ventilation can be conducted at respiratory rates that are much higher than those conventionally employed. It is then possible according to the invention, by conducting ventilation with a continuous retrograde gas flow and using the tube designed according to the invention, to work at respiratory rates that correspond to the human heart rate. According to the invention therefore the double-lumen tube
20 is used in a ventilator that makes it possible to perform ventilation with a continuous retrograde gas flow that is EKG - triggered and in synchronization with the pulse.

Preferably, the ventilator is characterized by the fact that the electrical control device for the expiration valve is connected to an electrocardiograph or blood pressure measuring device and, depending on output signals delivered by the electrocardiograph or blood pressure measuring device, expiration valve is controllable in such fashion that a ventilation of the patient with fresh gas supplied
30 through the inspiration passage of the tube is capable of

being performed, synchronized with a pulse, with a retrograde flow.

Preferably, according to the invention the electrical control device receives the output signals from conventional electrocardiographs or blood pressure monitors to close and open the expiration valve which is available in conventional ventilators or as a device by itself in synchronization with the pulse.

10 Preferably, with a ventilator system equipped according to the invention, the inspiration phase can be synchronized with the systole. This measure is capable of lowering the afterload of the left ventricle, which is hemodynamically favorable in left ventricular heart failure (e.g. myocardial infarction). It is also possible to synchronize the inhalation phase with the diastole, and as a result the right ventricle does not have to eject the blood against a high vascular resistance into the pulmonary circulation compressed by the respiratory pressure. This measure reduces the load on the right ventricle which has an
20 advantageous effect in all conditions involving acutely elevated pulmonary vascular resistance, e.g. pulmonary embolism.

Preferably, the ventilator system is, characterized by the fact that expiration valve is controllable as a function of a pulse frequency and an adjustable inhalation/exhalation ratio.

Preferably, the ventilator system is characterized by the fact hat an electrically controllable pressure-reduction

10g

valve is provided in a supply line for the fresh gas to the inspiration passage of the tube, with the fresh gas having a flow into the inspiration passage that is freely selectable and controllable during inhalation and exhalation.

Preferably, the ventilator system is characterized by the fact that the electrically controllable pressure-reduction valve is connected to the electronic control device connected to an electrocardiograph or blood pressure
10 measuring device, and is controllable as a function of signals delivered by the electrocardiograph or blood pressure measuring device.

Preferably, the ventilator system is characterized by the fact that the flow of fresh gas is adjustable to a minute volume required for a carbon dioxide elimination by controlling the pressure-reduction valve with the aid of a control device and the flow of fresh gas is adjustable to a mean airway pressure that is critical for oxygenation by controlling the pressure-reduction valve with the aid of
20 the control device.

Preferably, the ventilator system is characterized by the fact that the electrical control device is equipped with an electronic signal preparation for the electrical signal delivered by the electrocardiograph or blood pressure measuring device, and with an electronic evaluation for a processed received signal and an electronic control for a control signal to be delivered to the expiration valve, as well as operating elements for operating modes and display elements.

10h

Preferably, the ventilator system is characterized by the fact that the electrical control device for the expiration valve has operating elements for changing the time ratio from an inhalation to an exhalation as well for an alternative selection of synchronization of the inhalation with a contraction of an heart muscle of the patient, or with a relaxation of the heart muscle.

10 Preferably, the ventilator system is characterized by the fact that the electrical control device is automatically switchable upon recognition of an improper functioning of a mechanical ventilation or of the electrocardiograph.

Preferably, the ventilator system is characterized by the fact that the electrical control device is connected to the pressure sensor integrated into the tube, near the distal end of the tube to monitor the central airway pressure.

20 Preferably, the ventilator system is characterized by the fact that a defined positive end-expiratory pressure (PEEP) for the patient is adjustable by controlling the expiration valve for a partial opening by means of the electrical control device.

Preferably, the ventilator system is characterized by the fact that the electrocardiograph or blood pressure measuring device supplying signals for the electrical control device is replaced by an impulse generator supplying corresponding signals with an adjustable clock frequency of the signals.

Preferably, the ventilator system is characterized by the fact that the expiration valve is part of a conventional ventilator with a fresh gas source.

Preferably, the ventilator system is characterized by the fact that the electrical control device is connected with the expiration valve to form a structural unit.

Preferably, integration of an electrocardiograph into the ventilator makes it possible, using the signals from the electrocardiograph, to control the expiration valve
10 connected to the larger passage of the tube in such a way that ventilation takes place in synchronization with the pulse, using a fresh gas supplied through the inspiration passage of the tube, a so-called pulse-synchronized positive pressure ventilation. The control device for the expiration valve is also equipped with functions for changing the time relationship from inspiration to expiration (inhalation/exhalation ratio) and for the alternative selection of synchronization of inhalation with a contraction of the heart muscle (systolic inhalation) or
20 with its relaxation (diastolic inhalation).

Preferably, in another embodiment of the invention, an electrically controllable valve, especially a pressure-reduction valve, is provided, arranged in the supply line from the fresh gas source to the inspiration passage of the tube, and the fresh gas flowing to the inspiration passage of the tube can be metered with its aid so that the gas flow during inhalation and gas flow during exhalation may be freely selected.

10j

Preferably, during mechanical ventilation with a continuous retrograde gas flow, a constant fresh gas flow can be set for the sake of simplicity. Advantageously, however, there is the possibility of adjusting the magnitudes of the continuous fresh gas flow for the inhalation phase and for the exhalation phase separately. The electrically controllable pressure-reduction valve is provided for this purpose. The inhalation gas flow can be adjusted to the minute volume required for carbon dioxide elimination and
10 the exhalational gas flow can be adjusted to the mean airway pressure critical for oxygenation.

The design of the tube according to the invention as well as a system according to the invention for pulse-synchronized ventilation with retrograde gas flow will now be described and explained with embodiments.

Figure 1 is a schematic diagram of a ventilator system;

Figure 2 is a view of a double-lumen tube with nozzle;

20 Figure 3 is a partial cross section DD in Figure 6 of the distal end area of the tube;

Figure 4 is view EE in Figure 2;

Figure 5 shows cross section FF in Figure 2;

Figure 6 is a top view of the end area of the tube according to Figure 2;

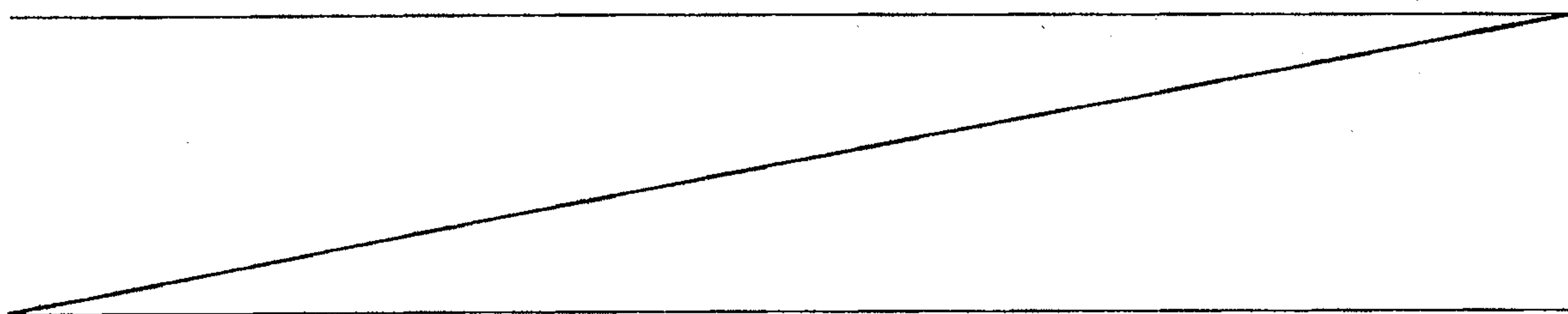


Figure 7 is a nozzle-shaped body for insertion into the inspiration passage of the tube according to Figure 2, in a top view;

Figure 8 is a cross section GG through the nozzle-shaped body according to Figure 7;

Figure 9 is a side view of the nozzle-shaped body according to Figure 7;

Figure 10 is a view Y of the nozzle-shaped body according to Figure 7;

Figure 11 is a partial lengthwise section of the distal end area of the tube, with the nozzle-shaped body according to Figures 7 to 10 inserted;

Figure 12 is a partial lengthwise section through the distal end area of the tube, with insertion of a varied nozzle-shaped body and bead formation;

Figure 13 is a section similar to section EE in Figure 2 of the end of the tube according to Figure 12;

Figure 14 is a cross section through the tube according to Figure 12 corresponding to Figure 5;

Figure 15 is a view of a double-lumen tube in a double-tube design;

Figure 16 is a cross section KK through the tube according to Figure 15;

Figure 17 is a view of a double-lumen tube with an annular nozzle mounted at the distal end of the tube;

Figure 18 is a partial lengthwise section through the distal end area of the tube according to Figure 7 along section MM in Figure 19;

Figure 19 is a view I of the distal end of the tube according to Figure 17;

Figure 20 is a cross section LL of the tube according to Figure 17;

Figure 21 is a block diagram of a control device for the ventilator system according to Figure 1;

Figure 22 is a functional diagram of the control device with ventilator;

Figure 23 is a diagram showing the control of the expiration valve by means of signals from an electrocardiograph;

Figure 24 is the design and functional diagram of the control device for control according to Figure 23;

Figure 25 is a functional diagram of a control device with integrated expiration valve for control according to Figure 23;

Figure 26 is a schematic diagram of a control device for the expiration valve with an integrated clock.

Figure 1 shows schematically a ventilator 6 with double-lumen tube 1, fresh gas source 5 with flowmeter 50, and a controllable pressure reduction valve 2 in gas supply line 80 to tube 1 and an electrically controllable expiration valve 60 with electrical connections 61.

Tube 1 inserted into the trachea 3 of a patient up to carina 100 has two continuous passages 11 and 12, of which passage 11 used as the inspiration passage has a smaller

cross section than passage 12 used as the ventilation passage. The ventilator system 6 shown is suitable for controlled mechanical ventilation of a patient. The double-lumen tube according to Figure 1 has an inflatable cuff 4 for holding and sealing in trachea 3. Inspiration passage 11 is connected on the inlet side, in other words proximal end 11, through a connector 8 and through flowmeter 50 to a fresh gas source 5. The fresh gas is under a desired positive pressure. Ventilators with tubes not according to the invention are known.

Ventilation passage 12 is connected on the output side, i.e. at proximal end 121, with electrically controllable expiration valve 60.

In the vicinity of distal end of tube 1, near carina 100, inspiration passage 11 and exhalation passage 12 are connected together by a nozzle 17 formed at the distal end 112 of the inspiration passage. Conical nozzle 17 has its nozzle outlet opening 171 or nozzle mouth close to or at outlet opening 123 of ventilation passage 12, so that an open annular space 18 remains between the nozzle outlet and the distal end of ventilation passage 12 and/or the inside wall of ventilation passage 12. With expiration valve 60 closed, the fresh gas, which is under pressure, fills the lung through inspiration passage 11 of tube 1, emerging at nozzle 17. With expiration valve 60 open, the fresh gas flows through nozzle 17 into ventilation passage 12 from the distal end and outward through ventilation passage 12 and expiration valve 60. During this process, the gas in the lung is simultaneously expelled by the vacuum prevailing in free annular space 18 through ventilation passage 12 and expiration valve 60. Nozzle 17 at the distal end of inspiration passage 11 is arranged so that it is directed at the distal end of the ventilation passage and blows into the ventilation passage from the nozzle of the inspiration passage, in the exhalation direction.

Between gas source 5 and inspiration passage 11 of tube 1, an electrically controllable pressure reduction valve 2, shown by the dashed lines, can be inserted which makes it

possible to provide different fresh gas pressures for the inhalation phase and the exhalation phase. In this way, the exhalation process can be accelerated timewise for example.

The additional design of ventilator system 6 according to the invention according to Figure 1 for controlled mechanical ventilation consists in controlling expiration valve 60 as a function of a signal from an electrocardiograph. The system thus equipped then makes it possible to perform ventilation with positive pressure in synchronization with the heart cycle. For example, the efficiency of the failing left ventricle can be improved by systolic inhalation, so-called afterload reduction and diastolic exhalation, so-called minimization of preload reduction. Likewise, in situations with acute right ventricular failure the right ventricle can be relieved by diastolic inhalation and systolic exhalation.

Depending on the therapeutic goal, electrically controllable expiration valve 60 and/or electrically controllable pressure-reduction valve 2 can be controlled by signals controlled in turn by medical instruments, as for example an electrocardiograph, or by a clock that replaces these devices.

In Figures 2 to 6, a double-lumen tube 1, suitable for use in controlled mechanical ventilation with a continuous retrograde gas flow, is shown. Tube 1 has two through passages 11, 12 separated from one another by a partition 14; see Figure 5. The through passages have different sizes, with the larger passage serving as a ventilation passage for unimpeded conventional ventilation as well as spontaneous breathing by the patient, and in addition must be sufficiently large in cross section to permit introduction of a suction catheter or bronchoscope. Smaller passage 11 serves as the inspiration passage for supplying the fresh gas. Tube 1 is long enough so that regardless of the size of the tube or patient, a portion of the shaft of the tube projects from the patient and is suitable for fastening, preferably with adhesive or hook-and-loop fasteners. The length 1 of an average tube is 220 mm for example. In the vicinity of the distal end 19 of the tube, at a

slight distance from the latter, an inflatable tube cuff is provided. Tube cuff 4 is supplied with inflating air through an air supply duct 42 formed in the wall of tube 10; see Figure 5. In the vicinity of the proximal end of tube 1, control balloon 40 is mounted with a connection 43 through air supply hose 41 to the output 44 of air channel 42. At the proximal end 121 of larger passage 12, a suitable connecting stub 7 is provided. At the proximal outlet 11 of inspiration passage 11 a connecting stub 8 is likewise provided that, for the sake of improved handling, is connected through a supply tube 15 with the proximal input of the inspiration passage. At the distal end 19 of tube 1, inspiration passage 11 is designed to be tapered in the form of a nozzle, see Figures 3 and 4, with the nozzle channel of nozzle 17 being bent at 180° so that nozzle outlet opening 171 points at the open distal end 122 of ventilation passage 12. The fresh gas flow flowing through inspiration passage 11, see Figure 3, in the direction of arrow a is guided at the distal end of tube 19 by the design of nozzle 17 with a cross section that decreases relative to the cross section of inspiration passage 11 toward the outlet of the nozzle, with a simultaneous deflection by 180° in the direction of ventilation passage 12, with simultaneous acceleration, and flows in the direction of arrow b, i.e. in the opposite direction, from the distal end of the tube into fresh passage 12. For those cases in which the expiration valve (see Figure 1) is closed at the proximal outlet of passage 12, the gas flowing in the direction of arrow b into the ventilation passage, after filling ventilation passage 12, can escape through distal outlet opening 123 of ventilation passage in the direction of arrow c and reach the lung. When the expiration valve is open at the proximal outlet of ventilation passage 12, on the other hand, the gas flow moving in the direction of arrow b into ventilation passage 12 from the distal end thereof entrains the exhalation gas coming from the lungs and clears the lungs well to remove exhalation gas and improve ventilation considerably, i.e. increase carbon dioxide elimination by reducing dead space.

In the example shown in Figures 2 to 6, the design of distal end 112 of inspiration passage 11 with a nozzle is shown, with deflection of the flow channel with the aid of a

nozzle-shaped piece 9 inserted into the distal end of the tube and inspiration passage 11. Nozzle-shaped piece 9 has a leg 90 abutting the wall of tube 10 internally, so that a flow channel continuing inspiration passage 11 is formed between partition 14 and leg 90. Nozzle-shaped piece 9, as an extension of leg 90, is made hook-shaped with a shorter leg 94 guided around the distal end of the partition, leaving a space forming nozzle channel 17a. Nozzle channel 17a terminates with a flow direction that runs axially parallel to lengthwise axis X of the tube. The outlet opening 171 of the nozzle channel and hence of the inspiration passage 11 at the distal end is shown doubled outward in the example shown in Figure 3, making improved outward flow in arrow direction c during inhalation possible. In addition, nozzle outlet opening 171 of inspiration passage 11 is located at the periphery of the cross section of ventilation passage 12 so that an outlet opening 123 that is as large as possible remains for ventilation passage 12. This outlet opening 123, for example in the example shown, can have a diameter ϕ of 5.9 mm. Tube wall 10 should be as thin as possible; when a suitable material is selected, for example PVC, it can be 1.2 mm. Outlet opening 123 must also be large enough to permit unimpeded introduction of a suction catheter through ventilation passage 12 to evacuate the respiratory tract. For this reason, outlet opening 123, also beveled, for example at 45° relative to the lengthwise axis X of tube 1, in such fashion that the tip of the tube is tapered at one end toward distal end 19. In this manner as well, outlet opening 123 is made larger. It is also possible, by further separation of distal outlet opening 123 of ventilation passage 12 and distal outlet opening 171 of inspiration passage 11, to increase the outlet area, with reference being made for example to the embodiment shown in Figure 11, where outlet openings 123 and 171 contact one another only in foot area FP at partition 14.

Nozzle-shaped piece 9 is mechanically engaged in the vicinity of tube wall 10 by means of a projecting locking nose 91 that engages a recess 13 in the tube wall. In addition, tubular-shaped piece 9 is glued or sealed in the area of tube wall 10.

For the double-lumen tube to function well, especially with good ventilation and gas direction, the sizes of the cross sections of the ventilation passage, the inspiration passage, and the nozzle outlet opening, individually and in relation to one another, are critical. The cross section of the inspiration passage must be sufficiently large to permit a fresh gas supply sufficient for up to five times the spontaneous minute ventilation to pass through at usual pressure. The cross section of the ventilation passage must permit unimpeded conventional ventilation or spontaneous breathing by the patient, and the passage of a suction catheter. Under these circumstances, a ratio of cross section C of the ventilation passage to the cross section A of the inspiration passage to the size B of nozzle outlet opening 171 of the inspiration passage of approximately 8:2:1 is provided. Cross sections A, B, C, as stated above, are evident from the cross sections shown in Figures 4 and 5 for the catheter according to Figure 2. With an inside diameter of ventilation passage 12 corresponding to a conventional tube with an inside diameter of 7 mm, the cross-sectional area C is approximately 38.5 mm^2 , cross-sectional area A is approximately 9.6 mm^2 , and nozzle outlet area B is approximately 4.8 mm^2 . Accordingly, the outside diameter \bar{r} of tube 1 is approximately 11 mm.

As connectors for inspiration passage 11, preferably those with integrated tapping stubs for monitoring airway pressure or gas composition can be used, possibly also for the proximal entrance of ventilation passage 12.

In Figures 7 to 10, another version of a nozzle-shaped piece 9 for insertion into inspiration passage 11 for forming a nozzle outlet opening at the distal end of tube 1 is shown. The nozzle-shaped piece likewise has a long leg 90 for insertion into inspiration passage 11 from the distal end 19 of the tube, as shown in Figure 11, while tube wall 10 is expanded outward corresponding to the thickness of leg 90 in order to continue inspiration passage 11 with the same cross section at the beginning of the nozzle-shaped piece. The nozzle-shaped piece also has leg 94 bent at 90° , which leads to a bend in the flow channel by 180° and ends with a bevel 95 at the outlet opening. The channel

enclosed by short leg 94 has a cross section that tapers and narrows toward end 95, thanks to additional bends 94a. In connection with partition 14, the closed flow channel for the fresh gas in the direction of arrow a is then formed; see Figure 11. To anchor nozzle-shaped piece 9 to tube 1, externally on the longer leg, projecting locking hook 91 and stop lug 92 with receiving pocket 93 for locking, see Figure 11, are formed on tube wall 10. Depending on the arrangement of nozzle outlet opening 171 formed by nozzle-shaped piece 9, mounted at the tube end, according to Figure 11, for inspiration passage 11, and the design of nozzle outlet opening 123 of ventilation passage 12, corresponding ventilation is made possible as indicated by arrows c and b for the fresh gas supplied through inspiration passage 11.

Figure 12 shows another variation on a nozzle-shaped piece 9 for forming the nozzle-shaped constriction at the distal end of the inspiration passage and nozzle outlet opening 171, inserted at the distal end 19 of tube 1. In this case, only a relatively short nozzle-shaped section has its long leg 9 inserted into the expanded end of the tube into inspiration passage 11 and glued therewith.

To achieve a Venturi effect, intended to increase the volume of gas entrained by gas flow b from the respiratory tract, near distal outlet opening 123 of ventilation passage 12 a bead 16a can be impressed into the ventilation passage for reducing the cross section by means of a notch 16 in wall 10 of the tube. A reduction of the cross section by up to about 25% can be achieved in this manner.

Figure 13 is a view of the distal end 19 of the tube in cross section, where H represents the cross-sectional area of ventilation passage 12 reduced by bead 16a.

Figure 15 shows a design of double-lumen tube with two pipes brought together to form one tube, containing the smaller inspiration passage 11 and the larger ventilation passage 12. The two pipes containing the passages are connected together by strips 20 and strips

45, 46 in the vicinity of inflatable tube cuff 4. In addition, the pipes forming tube 1, see the cross section in Figure 16, can be permanently connected to one another by gluing in contact area 22. It is also possible to weld them together in this area by using a suitable plastic, for example by using solvents. In tube 1 according to Figure 15, outlet opening 171 of the end of the nozzle-shaped inspiration passage that is bent to an angle of 180° is located a short distance from the distal outlet opening 123 of ventilation passage 12, so that a free outward flow of the gas emerging from the nozzle outlet opening 171 into the lungs can take place with the expiration valve closed, and distal outlet opening 123 is sufficient to pass a suction catheter through and also, with the expiration valve open, the gas flow from nozzle outlet opening 171 can blow directly into outlet opening 123 into large ventilation passage 12.

Figure 17 shows another embodiment of double-lumen tube 1 according to the invention, in which the distal end of tube 1 is provided with an annular nozzle-shaped section that forms both the tapering nozzle outlet channel at the distal end for inspiration passage 11 and also outlet opening 123 of ventilation passage 12 at the distal end.

Figure 19 shows view I according to Figure 17 looking at the distal end of the tube with nozzle-shaped piece 9. In Figure 18, axial lengthwise section MM shows in Figure 18 the distal end area of the tube in cross section and the annular molded part 9, which is attached externally to tube wall 10 and fits over it, and internally forms a tapering annular space with a plurality of nozzle outlet openings 171. Inner nozzle annular wall 96 also forms the limit for outlet opening 123 of the ventilation passage. At a slight distance from distal end 19 of tube 1, once again in the vicinity of ventilation passage 12, a notch 16 is provided to form a bead 16a that reduces the cross section partially and over a short distance.

Figure 20 shows that the tube in the middle area, see cross section LL in Figure 17, has continuous fresh passage 12 with cross section C and continuous inspiration passage 11 with cross section A, of a size sufficient to perform its functions.

For pulse-synchronized ventilation with a continuous retrograde gas flow, expiration valve 60 of ventilator 6 according to Figure 1 is controlled by means of a control device. For pulse-synchronized ventilation, the control device is connected to an electrocardiograph EKG whose EKG signal is received by the control device, processed electronically, and used as the control signal for the expiration valve.

Figure 21 is a block diagram of the functional layout. The control device forms a connection between the EKG or the blood pressure measuring device and the expiration valve of a ventilator and delivers the control signal to open or close the expiration valve. The basic system of a ventilator system for pulse-synchronized ventilation is shown schematically in Figure 22 and includes the following parts: a gas source, a double-lumen tube with a nozzle at the distal end of the inspiration passage, an expiration valve, a control device, and an electrocardiograph or blood pressure measuring device. The ventilator system can be equipped with conventional EKG units or blood pressure measuring devices as well as commercially available ventilators with an expiration valve, for example a Siemens Servo Ventilator 900C* in conjunction with the electronic adaptable control device according to the invention and in conjunction with the double-lumen tube according to the invention, with a nozzle outlet at the distal end of the inspiration passage and permits pulse-synchronized ventilation for anesthesia, intensive care, and emergency medicine.

The charts for pulse-synchronized ventilation are shown in Figure 23. Curve I shows the EKG signals with the QRS complexes obtained by the EKG. The time duration AZ calculated from time interval AZ between two QRS complexes corresponds to the duration of one fresh cycle. Curve II shows the changes in pressure in the aorta and in

* trademarks

the left ventricle. Curve III shows systolic inhalation and curve IV shows diastolic inhalation.

In order to perform pulse-synchronized ventilation, the contraction time (systole) of the heart must be determined. The beginning of systole can be derived from the QRS complex of the electrocardiogram. There is no defined technical signal for the end of systole. Therefore, the following estimate is performed: a heart period consists of three phases: contraction, relaxation, and the resting period, with each of these phases occupying approximately one-third of the total period between two heart beats with normal heart activity. The time for systole is therefore assumed to be one-third of the time between two heartbeats, i.e. between two successive QRS complexes. In order to obtain a defined synchronization, the ratio between inhalation and exhalation can be varied. During systolic ventilation, the beginning of inhalation is determined from the QRS complex of the EKG signal. The duration of systole is determined from the pulse frequency, which in turn is determined by the interval of the respective previous QRS complex, and from the adjusted inhalation/exhalation ratio. At the end of systole, a switch is made to exhalation and a new QRS signal is awaited to start a new inhalation.

In diastolic inhalation, exhalation is started with a QRS complex in the EKG signal. The moment of beginning of inhalation is determined from the pulse frequency, which is determined from two previous QRS complexes, as well as from the I/E ratio. When this point is reached, a switch is made to inhalation. Then the next QRS complex is awaited again. In systolic ventilation, therefore, the beginning of the inhalation phase is synchronous with the QRS complex, while in diastolic ventilation the end of inhalation is synchronous with the QRS complex.

During inhalation, the expiration valve is closed and the fresh gas flows into the lungs. During exhalation, the expiration valve is open and the alveolar gas is entrained and carried away from the lungs by the flow of fresh gas.

The functional design of the control device for performing pulse-synchronized ventilation according to Figure 23 is shown in Figure 24. The control device contains signal preparation, evaluating electronics, control electronics, and display elements and operating elements (key recognition). The signal-preparation electronics has the task of receiving the electrical EKG signal delivered by the electrocardiograph or blood pressure measuring device, encoding it, and displaying the QRS complex in order then to deliver a defined control pulse to the evaluation electronics. The signal preparation electronics contains a threshold value detector and a timer which provides a control pulse with the necessary length and amplitude. This makes it possible to use EKG devices with analog or digital signals. In this way it is possible to use all commercial EKG units or blood pressure measuring devices for the ventilator system according to the invention for pulse-synchronized ventilation.

The evaluation electronics is the central component of the control device. The evaluation electronics contains the following functional units: central processing unit, clock, RAM, interfaces for inputs and outputs, timer, interruption-control circuit, and possibly a read-only memory (ROM). The evaluation electronics receives the pulse delivered by the signal preparation electronics and, from the duration of the AZ interval of two QRS complexes, calculates the duration between two heartbeats. The evaluation electronics is also connected with the operating elements, with which the inhalation/exhalation ratio as well as the operating mode may be determined, and it monitors the display elements. In the evaluation electronics, the duration of inhalation and exhalation corresponding to the set inhalation/exhalation ratio is determined, as well as the time between the EKG signals and the operating mode to be used. The evaluation electronics transmits the required signal for opening and closing the expiration valve. Control for the expiration valve is provided as a function of the pulse frequency (EKG signals) and the set predetermined inhalation/exhalation ratio (I/E ratio). With the I/E ratio, the ventilation cycle can be synchronized with the systole or diastole. In contrast to

a EKG trigger with initially adjustable, then fixed delay, with the control device and its control according to the invention, independence from the heart rate is ensured. It is possible to perform ventilation with a freely selectable frequency. The ratio between the inhalation and exhalation time is adjustable, for example in a range from 1:4 to 4:1. The duration of inhalation and exhalation is determined by the set I/E ratio. The correct point in time for switching from inhalation to exhalation, i.e. the opening of the expiration valve, results from the set mode (systolic or diastolic inhalation) and the set I/E ratio.

The control electronics performs the necessary adjustments to the control signal supplied by the evaluation electronics, in order to control the expiration valves of commercially available ventilators. The key recognition of the control device makes it possible to use operating elements to set the ratio of inhalation to exhalation. In addition, operating elements are provided for adjusting the operating mode. Key recognition is detected in the evaluation electronics and changed.

The control device also has display elements for displaying the operating mode, the set I/E ratio. In addition, incoming QRS complexes (EKG signals) as well as the position of the expiration valve are displayed. All the display elements are controlled by the central evaluation electronics of the control device. The evaluation electronics of the control device require an external program.

The control device distinguishes between two operating modes.

- "Systolic" operating mode: inhalation takes place during systole.
- "Diastolic" operating mode: inhalation takes place during diastole.

It is possible to switch between the two operating modes by means of operating elements; for this purpose the evaluation electronics can be controlled by key recognition; see Figure 24.

In the "diastolic" operating mode, immediately after an EKG signal is recognized (QRS complex), the expiration valve is opened; see Figure 23, curve IV.

Depending on the I/E ratio, the expiration valve is then closed again after a certain period of time t_a , so that inhalation takes place during diastole. After the next QRS complex arrives, the expiration valve is opened again.

In the "systolic" operating mode, following recognition of the QRS complex, the expiration valve is closed; see Figure 23, curve III. In this operating mode, depending on the I/E ratio, the expiration valve is opened again after a certain period of time t_b , so that inhalation takes place during systole. After the next QRS complex arrives, the expiration valve is closed again.

The control device monitors the actual functionality itself. In order to achieve maximum safety, the monitoring functions of the connected ventilator system are active. If improper functioning of the ventilator system is detected, the control device is switched off automatically and the conventional ventilator begins independently to provide conventional ventilation.

The evaluation electronics of the control device constantly tests the times for inhalation and exhalation and the arrival of new EKG signals. Only when several correct ventilation cycles have been recorded does the control unit take over the monitoring of the ventilator. Then the shutoff to the ventilator is closed, indicated by a pilot light. In the event of power failure, the shutoff disconnects the control device from the ventilator, which then starts operating independently again.

In the event of an absence of EKG signals, continuation of conventional ventilation with the ventilator is likewise initiated without control by the control device, until new EKG pulses reach the control device.

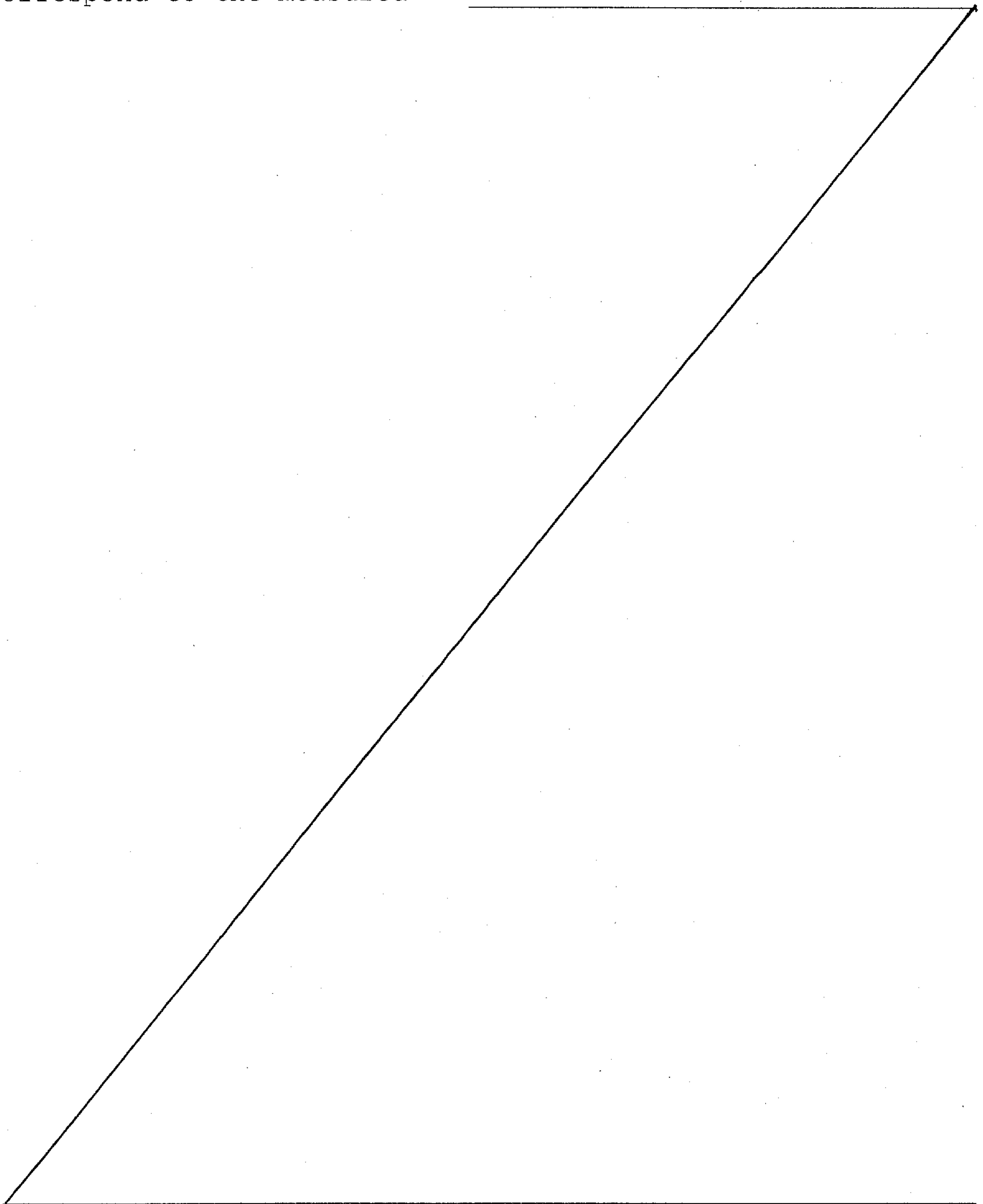
10 To avoid dangerous pressures in the lungs, the inhalation time is monitored. In cases of excessive inhalation times, the ventilator likewise automatically takes over control once again, i.e. the control device is switched off. In those cases in which the EKG pulses arrive too rapidly, efficient ventilation is no longer guaranteed. In this case as well, the control device can shut off automatically and the conventional ventilator automatically takes over further ventilation. In the event of EKG pulses following one another at intervals that are too short, however, several such short pulses must follow one another to trigger a shutoff, since only then do they indicate a prolonged state.

To monitor the central airway pressure, the tube is provided near the distal end, on the outside, with a pressure sensor, especially an electronic pressure sensor, equipped with an electronic device for signal processing of the measured values detected. In addition, the electronic pressure sensor can supply the recorded measured value of the central airway pressure in the trachea to the control device. Then the control device, in addition to the given safety mechanism can monitor the function of the overall system and correct it as necessary. In addition, it is possible with the aid of the central airway pressure measured continuously in the trachea using the tube with integrated pressure sensor and the electrical signals obtained therefrom, to operate the ventilator system as a function of the prevailing central airway pressure of the patient. In particular, it is possible to supply the electrical signals, corresponding to the central airway

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25a

pressure determined, to the ventilator system to actuate a trigger for a defined pressure drop in the ventilator system. With continuously controlled mechanical ventilation of a patient, the electrical signals recorded, which correspond to the measured



central airway pressure, can be fed into the ventilator system to control the pressure limitation and upper pressure limit functions, so that the ventilator system, when a predetermined pressure is reached, either shuts off the supply of fresh gas or switches to exhalation. In particular, capacitive pressure sensors with integrated electronic signal processing are suitable, manufactured as ready-to-install modules. The pressure sensors operate using the difference principle, i.e. pressure differences are determined and converted into electronic signals. The analog signals from the measured parameters are converted into digital signals with the aid of an analog-digital converter, amplified, and evaluated in microprocessors. These electronics are designed in the form of a chip and connected with the pressure sensor as a measurement sensor to form a small module, measuring $9 \times 1.2 \times 0.8$ mm for example, so that they can be mounted or installed easily on the outside of the tube wall.

The control device can also be designed according to the invention in such fashion that it is capable of controlling the expiration valve in such manner that a definite positive-end expiratory pressure (PEEP) can be adjusted for the patient.

In order to adjust the PEEP, the expiration valve is opened only partially, so that a corresponding certain residual pressure PEEP remains in the airways.

The PEEP can be adjusted using the operating elements in the evaluation electronics of the control device; see Figure 24. The evaluation electronics is capable of calculating the degree of opening of the expiration valve that is then required. This extension stage for the adjustment of the PEEP can be used on all ventilators that have a controllable expiration valve.

When pressure sensors are used in conjunction with the tube, it is possible to design the control device so that it can measure the exhalation pressure with the aid of the pressure sensors on the exhalation leg of the ventilator build-up, and this measurement signal is

used in evaluation to increase the reliability of the overall system. In addition, it is also possible to use the pressure sensors to monitor the adjusted PEEP.

While in conventional ventilators the expiration valve has heretofore formed a single unit with the fresh gas source and the corresponding operating and adjusting elements, and the control device according the invention is connected in addition, it is also possible to equip the control device according to the invention directly with an expiration valve of its own. In this manner, the expiration valve together with the control device is
10 independent of the ventilator system and can likewise perform ventilation itself.

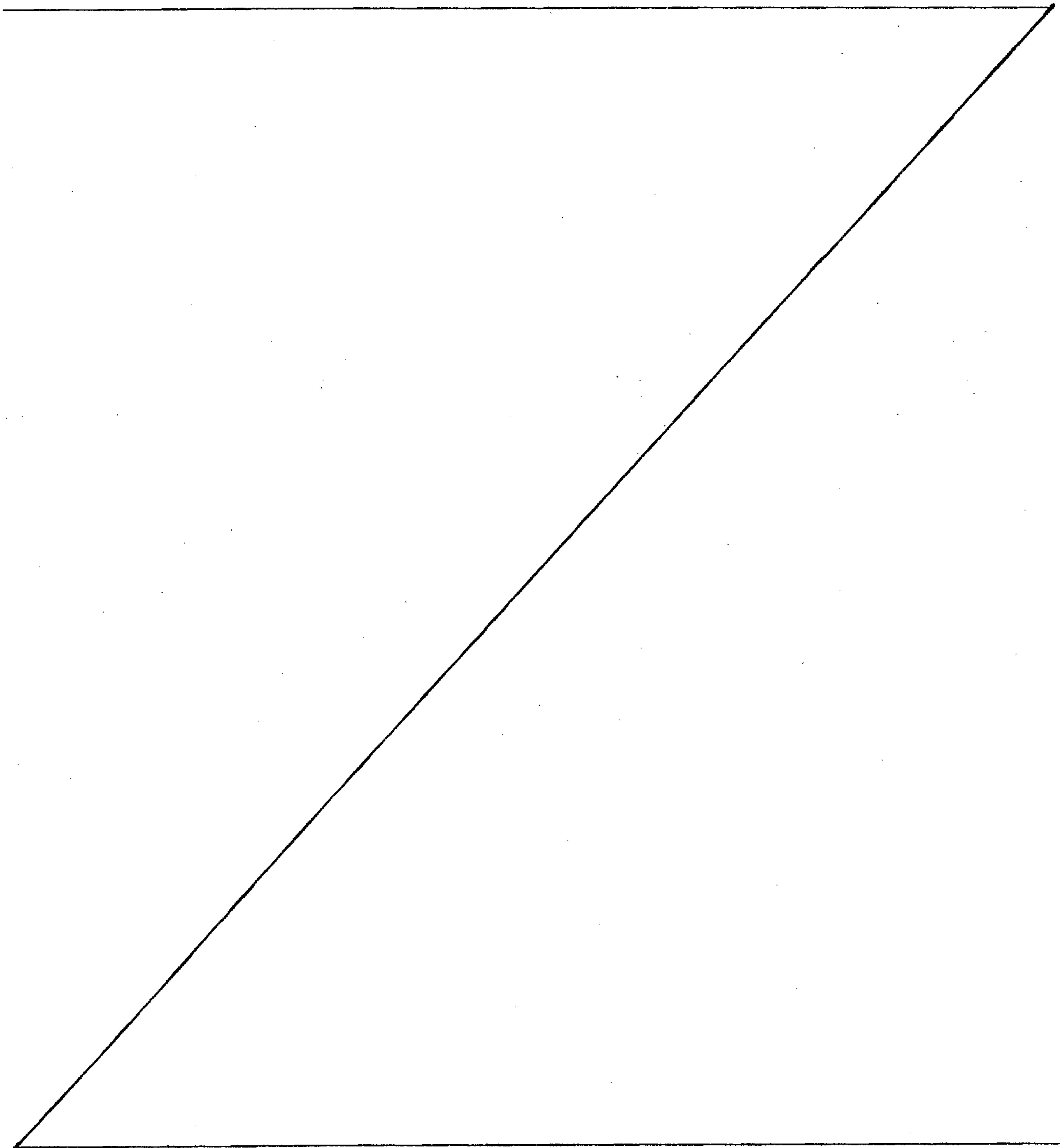
Figure 25 shows schematically the diagram of a control device with an internal expiration valve 60. The double-lumen tube 1 with ventilation passage 12 and inspiration passage as well as nozzle 17 at the transition of the distal end of the inspiration passage to the exhalation passage is used, with the aid of the control device, for pulse-synchronized ventilation with a retrograde gas flow. With an oxygen/air mixer, the correct gas mixture is
20 selected from the oxygen/air supply, the desired fresh gas flow can be set with the flow regulator, and fed through line 80 to inspiration passage 11. The control device which uses the EKG signals obtained from the electrocardiograph EKG unit to control ventilation, controls directly the expiration valve 60 mounted at the proximal outlet of ventilation passage 12. An arrangement according to Figure 25 permits pulse-synchronized ventilation with continuous exhalational retrograde flow only with an expiration valve, but without a conventional ventilator. In order to be able
30 to operate the control device completely independently, i.e. even without a EKG unit or blood pressure measuring

device, according to the invention an internal impulse generator is provided that is associated with the control device. The design of a control device with an external impulse generator is shown in the block diagram in Figure 26. Instead of an electrocardiogram or blood pressure measuring device, an impulse generator is provided. The pulses generated by the impulse generator are picked up by the evaluation electronics. From impulse generator frequency and the set I/E ratio, the evaluation electronics
10 calculates the time for opening and closing the expiration valve. The operating elements and the evaluation electronics can be used to adjust the impulse generator frequency of example between 2/min and 200/min. The control unit with the impulse generator can be integrated for example into the system according to Figure 25, so that the EKG device shown there can be eliminated. In this manner it is possible to provide a ventilator system that may be used as a stand-alone version, in other words without a conventional ventilator. When an impulse generator is used
20 in conjunction with the control device, see Figure 26, non-pulse-synchronized ventilation with a continuous exhalation retrograde gas flow is also possible.

The control device according to the invention, in the various expansion stages, serves to control pulse-synchronized ventilation with continuous retrograde gas flow in conjunction with a double-lumen tube, in which the inspiration passage is equipped at the distal end with a nozzle that blows into the distal outlet opening of the ventilation passage. With the aid of the control device, an expiration valve that is provided either externally in a commercially available ventilator or is connected internally directly with
30 the control device, see Figure 25, is opened and closed. The control for the exhalation device is provided pulse-synchronously, so that inhalation takes place during either systole or diastole. In order to record the phases of the heart, the control device is connected with an EKG unit or a blood pressure measuring device.

28a

The control device is designed so that it can also be operated as a stand-alone device with an integrated expiration valve and its own impulse generator (asynchronous); see Figure 26. In addition, the residual pressure in the airways can be adjusted with this device. Direct measurement and control of central airway pressure using pressure sensors is also possible.



WHAT IS CLAIMED IS:

1. A tube for introduction into a respiratory tract of a patient for controlling a ventilation of said patient, with a distal end capable of being introduced into the respiratory tract and a proximal end provided with connections, and two passages extending essentially from the proximal end to the distal end of the tube, with one of the two passages serving as a ventilation passage during ventilation and breathing and the other of the two passages serving as an inspiration passage for administering a fresh gas, characterized by the fact that each of the two passages has a distal outlet opening, the distal outlet opening of the inspiration passage (11) being directed at the distal outlet opening (123) of the ventilation passage (12), the distal outlet opening of the inspiration passage (11) being tapered to form a nozzle and terminating in a nozzle outlet opening (171) directed at the distal outlet opening (123) of the ventilation passage (12).

2. A tube according to claim 1, characterized by the fact that one of the two passages has a smaller cross section than the other of the two passages of the tube, and the passage with the cross section that is larger relative to the passage of the other serves as the ventilation passage for ventilation and breathing, the passage with the cross section that is smaller than the other passage serving as the inspiration passage for the fresh gas.

3. A tube according to any one of claims 1 and 2, characterized by the fact that the ventilation passage

serves for introducing an element selected from the group including a suction catheter and a bronchoscope.

4. A tube according to claim 1, characterized by the fact that one of the two passages has a smaller cross section than the other of the two passages of the tube, and the passage with the cross section that is larger than that of the other passage serves as the ventilation passage for ventilation and breathing, the passage with the cross section that is smaller than that of the other passage serving as the inspiration passage for the fresh gas, the distal outlet opening of the inspiration passage (11) being tapered to form a nozzle and terminating the nozzle outlet opening (171) directed at the distal outlet opening (123) of the ventilation passage (12), with the size of the cross section of the ventilation passage, the inspiration passage, and the nozzle outlet opening having ratios of approximately 8:2:1 to one another.

5. A tube according to any one of claims 1 to 4, characterized by the fact that the distal outlet opening of the inspiration passage (11) is bent in a vicinity of the distal end (19) of the tube (1) by approximately 180° and is directed at the distal outlet opening (123) of the ventilation passage (12) and through the ventilation passage (12) to the proximal end of the tube (1).

6. A tube according to claim 1 or 2, characterized by the fact that the distal outlet opening (123) of the ventilation passage (12) runs diagonally to a lengthwise axis (X) of the tube, in such manner that the distal end

(19) of the tube is beveled unilaterally in a vicinity of the ventilation passage toward the distal end of the tube.

7. A tube according to any one of claims 1, 4, 5 and 6, characterized by the fact that the nozzle outlet opening (171) of the inspiration passage (11) is located off center relative to the distal outlet opening (123) of the ventilation passage near the periphery of the ventilation passage (12).

8. A tube according to any one of claims 1 to 7,
10 characterized by the fact that the ventilation passage (12) and the inspiration passage (11) are divided from one another by a partition (14) in the tube (1).

9. A tube according to any one of claims 1, 4, 5, 6 and 7, characterized by the fact that the nozzle outlet opening (171) of the inspiration passage is located outside the distal outlet opening (123) of the ventilation passage and outside the ventilation passage.

10. A tube according to any one of claims 1, 4, 5, 6 and 7, characterized by the fact that the nozzle outlet opening
20 (171) of the inspiration passage partially projects into the ventilation passage (12) through the distal outlet opening (123) of the ventilation passage (12).

11. A tube according to claim 8, characterized by the fact that the nozzle outlet opening (171) of the inspiration passage (11) and the distal outlet opening (123) of the ventilation passage (12) abut one another at a point where the outlet opening (123) of the ventilation passage running

diagonally to lengthwise axis (X) of the tube terminates at the partition (14) of the tube (1) and the nozzle outlet opening (171) of the inspiration passage is located.

12. A tube according to any one of claims 1 and 4 to 11, characterized by the fact that, to form the nozzle of the inspiration passage and the nozzle outlet opening (171) at the distal end (19) of the tube (1), a nozzle-shaped piece (9) is connected with the tube as an extension of the inspiration passage (11), forming a nozzle channel (17a)
10 which continues the inspiration passage (11).

13. A tube according to claim 12, characterized by the fact that the nozzle-shaped piece (9) is bent at right angles twice forming two legs (90, 94), so that a flow path of the inspiration passage (11) is deflected through 180°.

14. A tube according to claim 13, characterized by the fact that the nozzle outlet opening (171) formed by the nozzle-shaped piece (9) for the inspiration passage (11) runs beveled in a plane which is at an angle to or perpendicular to a bevel of the distal outlet opening (123)
20 of the ventilation passage (12).

15. A tube according to claim 13, characterized by the fact that the nozzle-shaped piece (9) having said two legs (90, 94) is inserted with one (90) of the legs into an open end of the inspiration passage (11) at the distal end (19) of the tube (1) and is latched to a wall of the tube.

16. A tube according to claim 13, characterized by the fact that the nozzle-shaped piece (9) having said two legs

(90, 94) is inserted with one (90) of the legs into an open end of the inspiration passage (11) at the distal end (19) of the tube (1) and is glued to a wall of the tube.

17. A tube according to one any one of claims 12 to 14, characterized by the fact that the nozzle-shaped piece (9) is made in the form of a nozzle ring and fitted on the distal end (19) of the tube (1), with one or more nozzle outlet openings being formed on the inside (96) of the nozzle ring and the ventilation passage (12) running
10 through the nozzle ring.

18. A tube according to any one of claims 1 to 17, characterized by the fact that a pressure sensor (S) is mounted near the distal end (19) of the tube (1).

19. A tube according to claim 18, characterized by the fact that the pressure sensor (S) mounted near the distal end (19) of the tube (1) is mounted externally on or in a wall of the tube in a position for measuring a pressure outside the tube.

20. A tube according to claim 18 or 19, characterized by
20 the fact that the pressure sensor (S) is provided, equipped with an integrated electronic measured value detection and signal processing for a continuous measurement of a central airway pressure prevailing in the trachea of the patient, which is connectable through a line with a control device for a ventilator to control the ventilator as a function of the central airway pressure prevailing in the trachea of the patient.

21. A tube according to any one of claims 1 to 20, characterized by the fact that near the distal end of the ventilation passage (12), the cross section of the ventilation passage (12) is reduced by 10 to 25% for a short distance relative to a lengthwise extent of the ventilation passage.

22. A ventilator system for electrically controlling mechanical ventilation of a patient with fresh gas, with a tube insertable into a respiratory tract of the patient,
10 according to one of the claims 1 to 21, with the ventilation passage of the tube (1) being connected at its proximal end to a controllable expiration valve (60) and with an inspiration passage (11) being connected at its proximal end to a fresh gas source (5).

23. A ventilator system according to claim 22, characterized by the fact that an electrical control device is provided to control expiration valve (60).

24. A ventilator system according to claim 23, characterized by the fact that the electrical control
20 device for the expiration valve (60) is connected to an electrocardiograph or blood pressure measuring device and, depending on output signals delivered by the electrocardiograph or blood pressure measuring device, the expiration valve (60) is controllable in such fashion that a ventilation of the patient with fresh gas supplied through the inspiration passage (11) of the tube (1) is capable of being performed, synchronised with a pulse, with a retrograde flow.

25. A ventilator system according to claim 23 or 24, characterized by the fact that the expiration valve (60) is controllable as a function of a pulse frequency and an adjustable inhalation/exhalation ratio.

26. A ventilator system according to one of claims 22 and 23, characterized by the fact that an electrically pressure-reduction valve (2) is provided in a supply line for the fresh gas to the inspiration passage (11) of the tube (1), with the fresh gas having a flow into the
10 inspiration passage that is freely selectable and controllable during inhalation and exhalation.

27. Ventilator system according to claim 26, characterized by the fact that the electrically controllable pressure-reduction valve is connected to the electronic control device connected to an electrocardiograph or blood pressure measuring device, and is controllable as a function of signals delivered by the electrocardiograph or blood pressure measuring device.

28. A ventilator system according to claim 26 or 27,
20 characterized by the fact that the flow of fresh gas is adjustable to a minute volume required for a carbon dioxide elimination by controlling the pressure-reduction valve with the aid of a control device, and the flow of fresh gas is adjustable to a mean airway pressure that is critical for oxygenation by controlling the pressure-reduction valve with the aid of the control device.

29. A ventilator system according to claim 22 or 28, characterized by the fact that the electrical control

device is equipped with an electronic signal preparation for the electrical signal delivered by the electrocardiograph or blood pressure measuring, and with an electronic evaluation for a processed received signal and an electronic control for a control signal to be delivered to the expiration valve (60), as well as operating elements for operating modes and display elements.

30. A ventilator system according to claim 23 or 29, characterized by the fact that the electrical control
10 device for the expiration valve (60) has operating elements for changing the time ratio from an inhalation to an exhalation as well for an alternative selection of synchronization of the inhalation with a contraction of a heart muscle of the patient, or with a relaxation of the hearth muscle.

31. A ventilator system according to any one of claims 23 to 30, characterized by the fact that the electrical control device is automatically switchable upon recognition of an improper functioning of a mechanical ventilation or
20 of the electrocardiograph.

32. A ventilator system according to claim 31, characterized by the fact that the electrical control device is connected to the pressure sensor integrated into the tube, near the distal end of the tube to monitor the central airway pressure.

33. A ventilator system according any one of claims 23 to 32, characterized by the fact that a defined positive end-expiratory pressure (PEEP) for the patient is adjustable by

controlling the expiration valve for a partial opening by means of the electrical control device.

34. A ventilator system according to claim 24, characterized by the fact that the electro-cardiograph or blood pressure measuring device supplying signals for the electrical control device is replaced by an impulse generator supplying corresponding signals with an adjustable clock frequency of the signals.

10 35. A ventilator system according to any one of claims 23 to 34, characterized by the fact that the expiration valve is part of a conventional ventilator with the fresh gas source.

36. A ventilator system according to any one of claims 23 to 34, characterized by the fact that the electrical control device is connected with the expiration valve to form a structural unit.

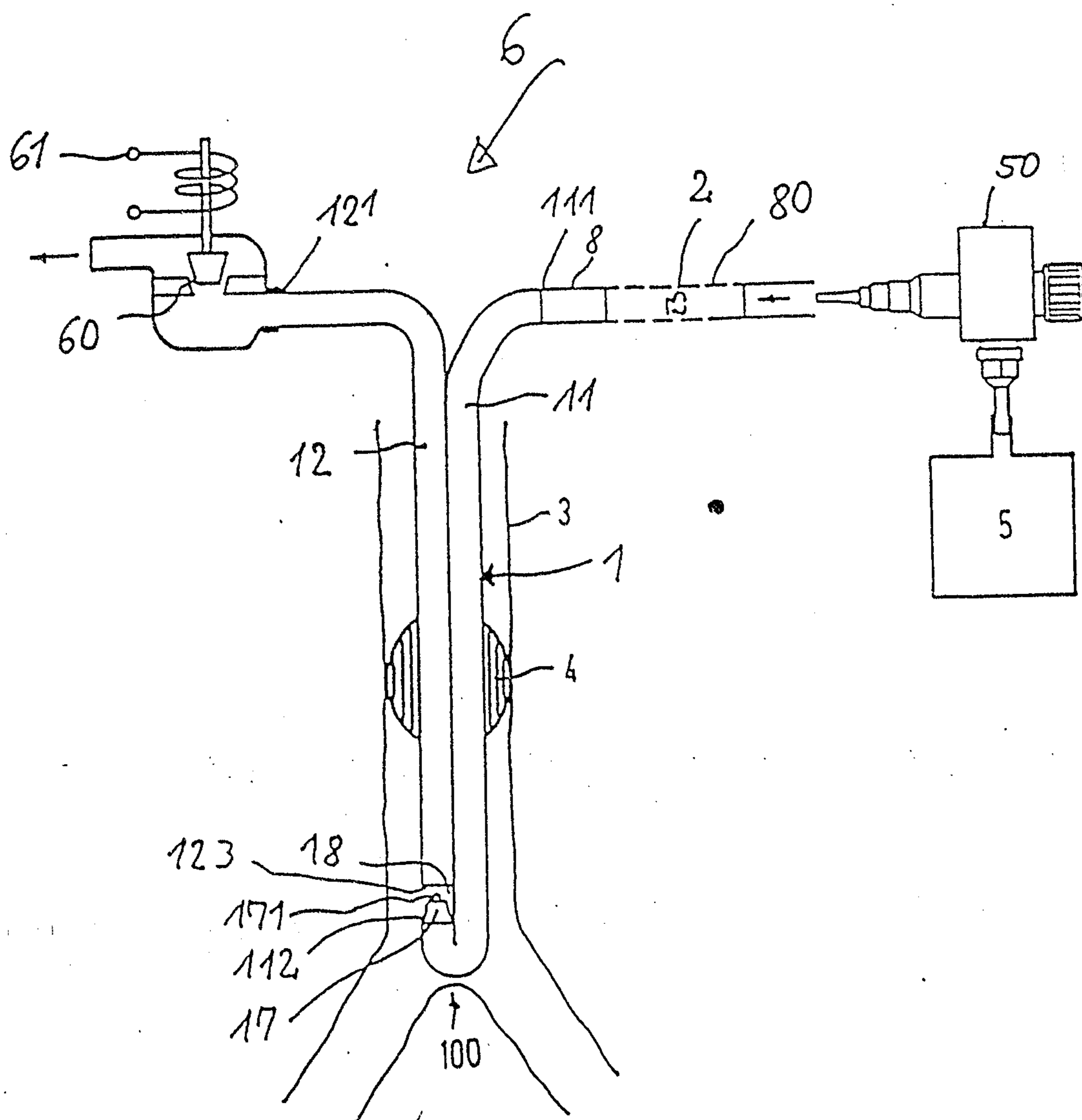
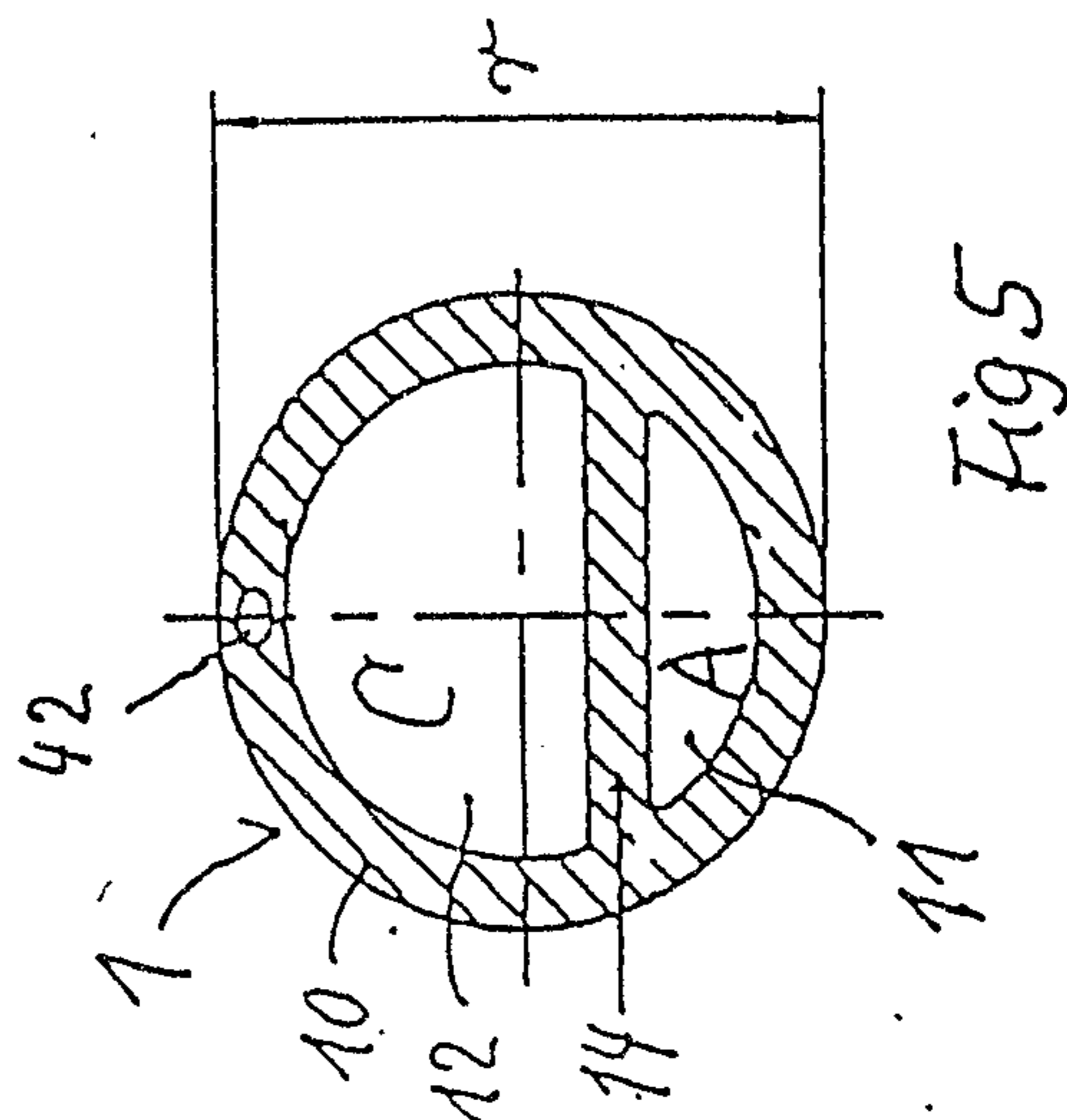
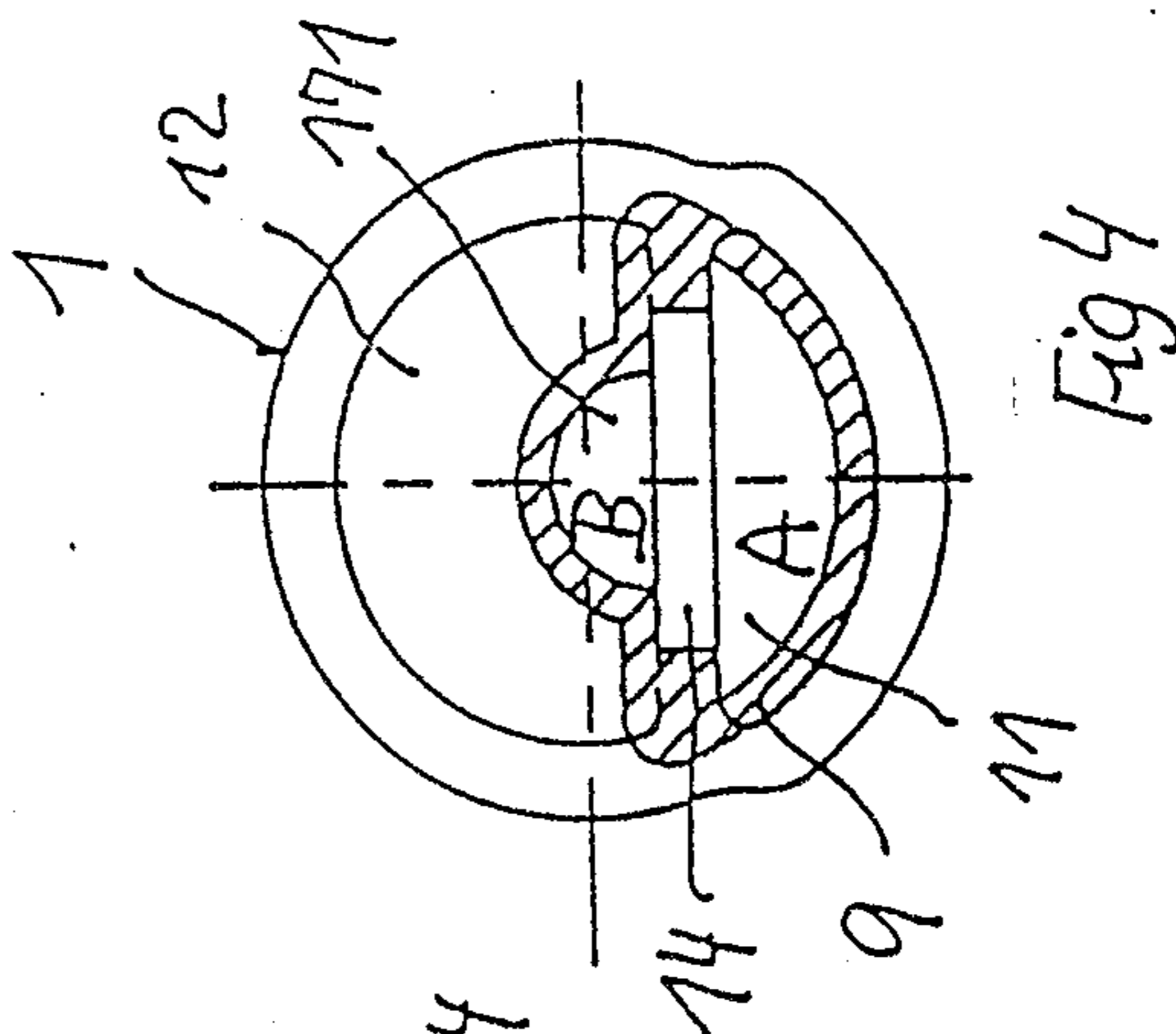
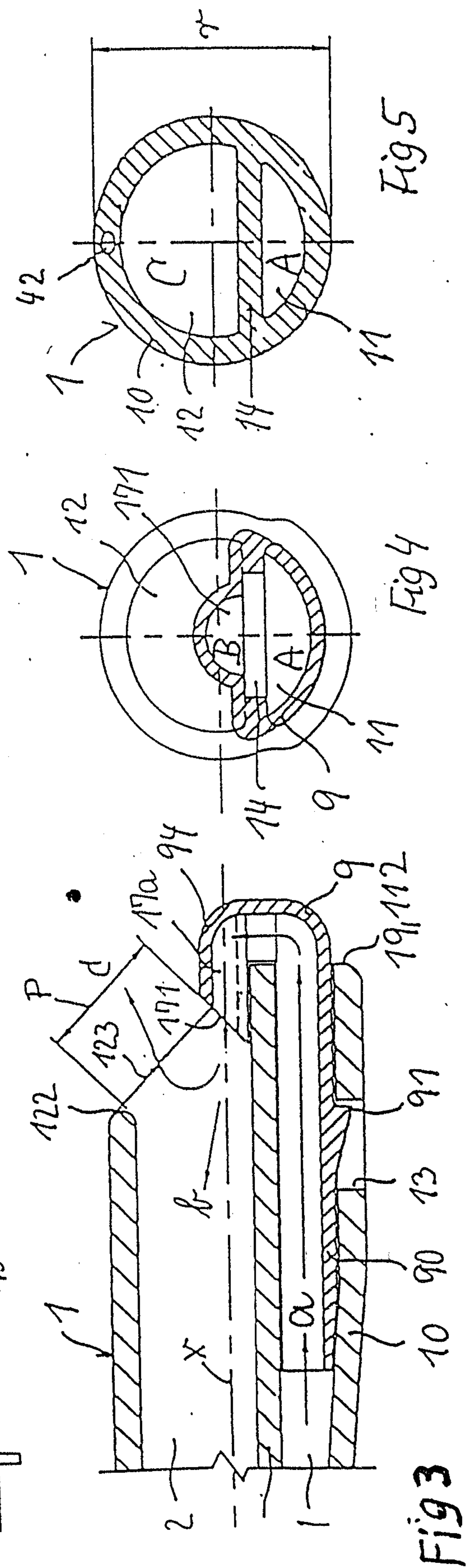
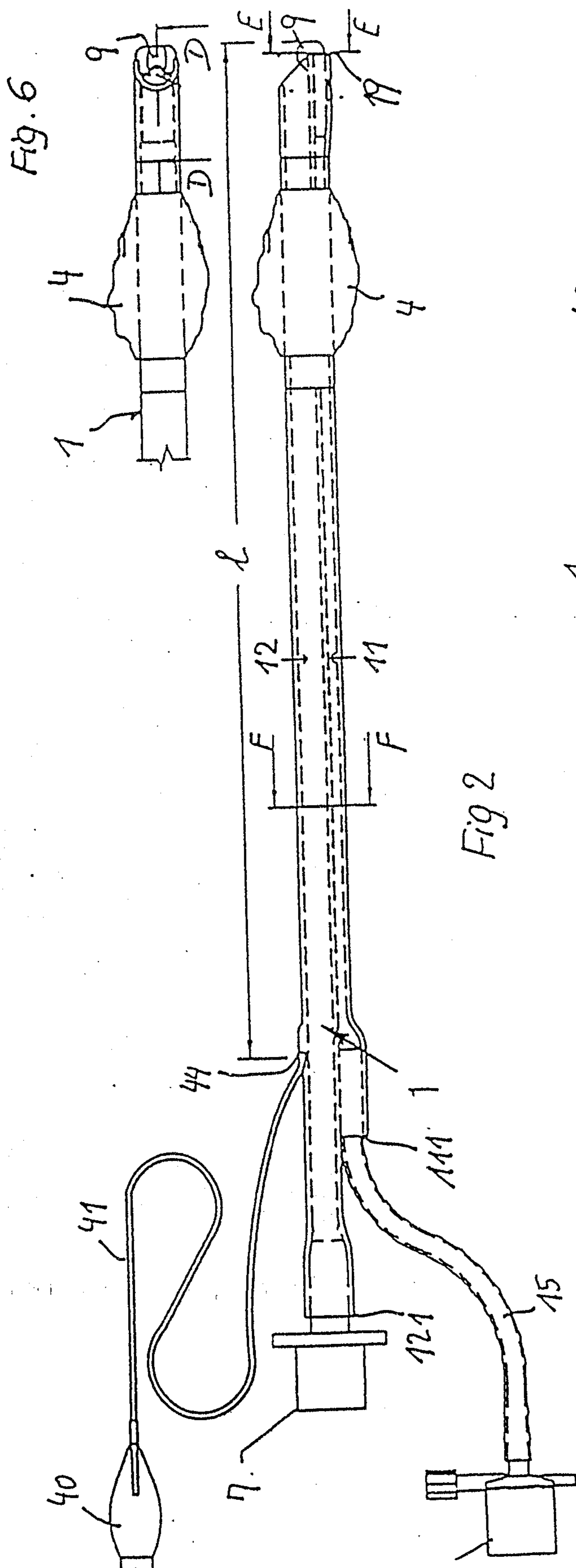
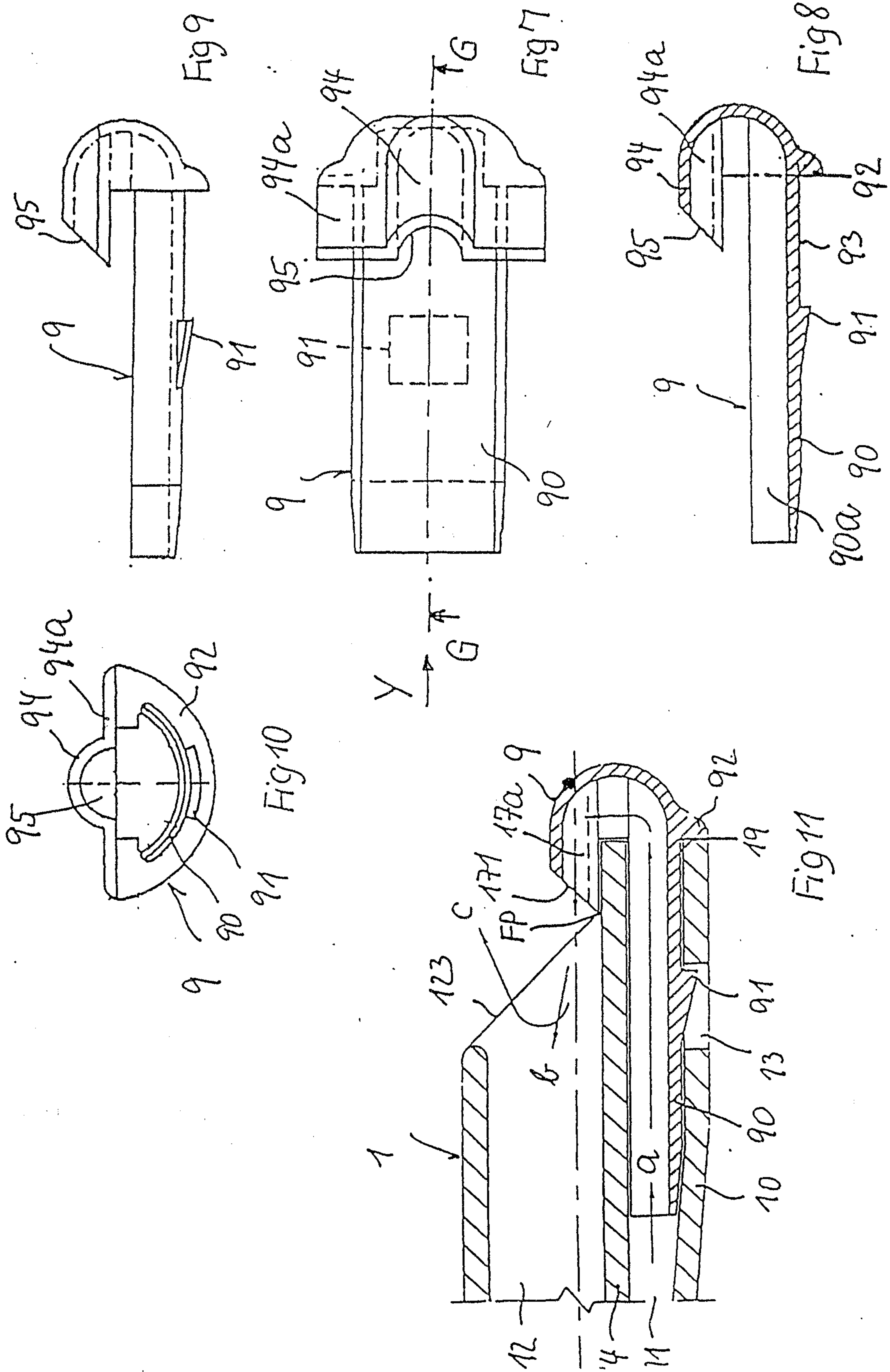


Fig. 1





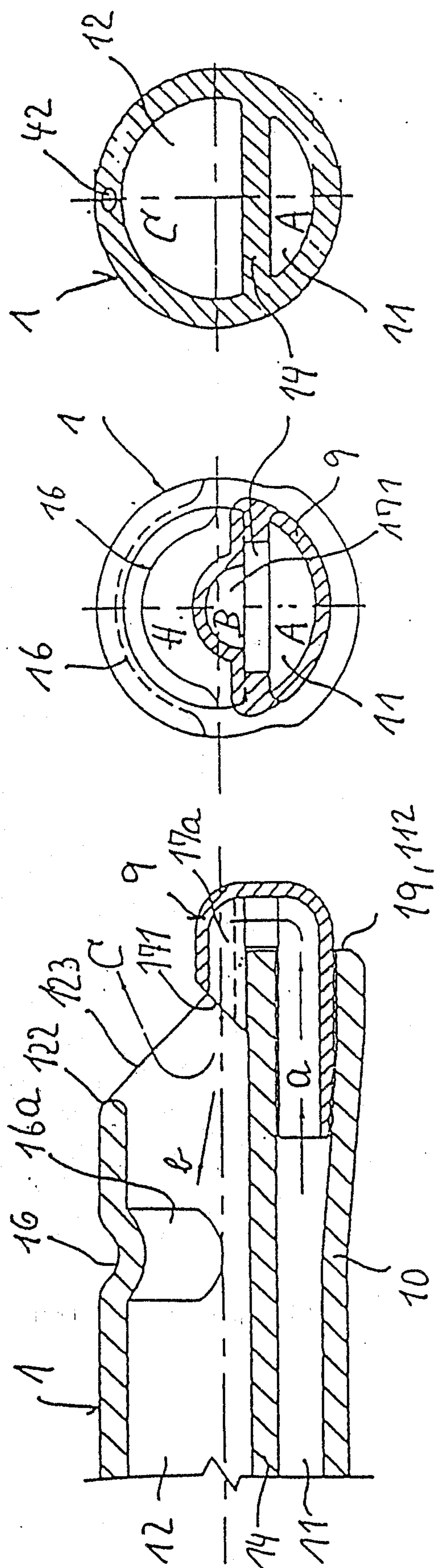


Fig 14

Fig 13

Fig 12

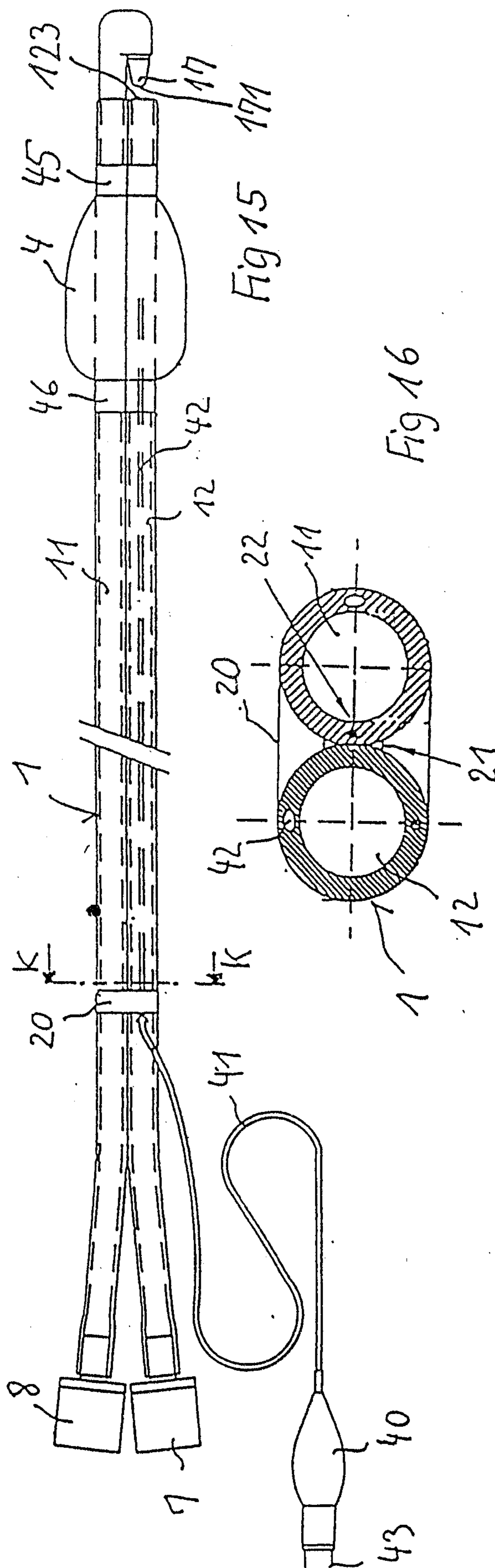


Fig 15 1971

Fig 16

43 40

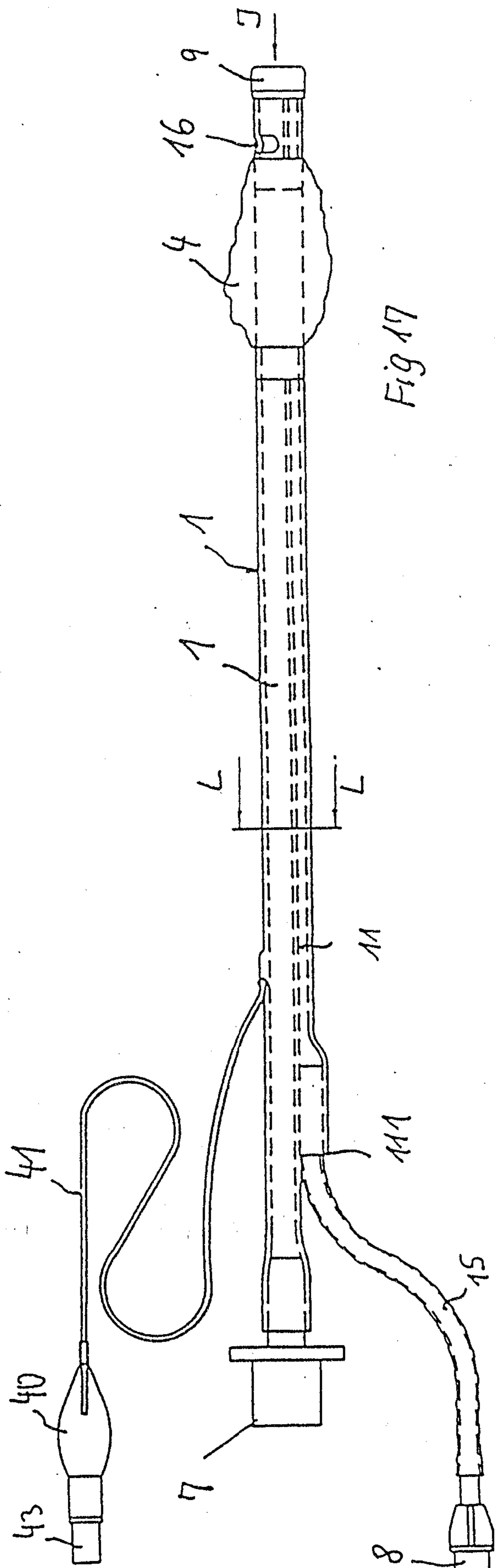


Fig. 17

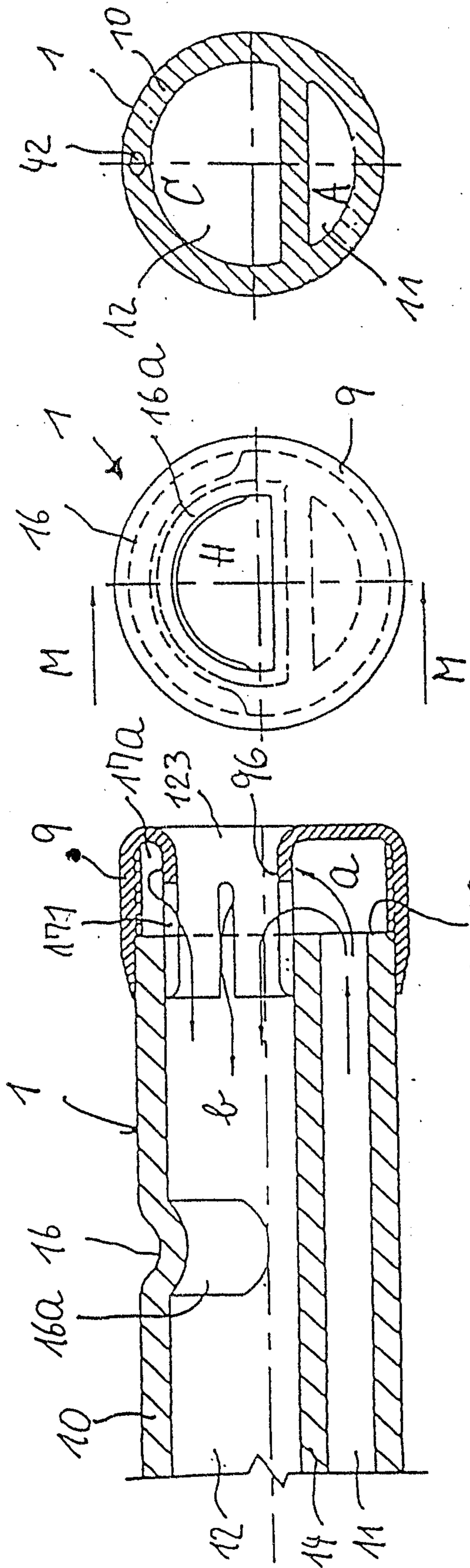
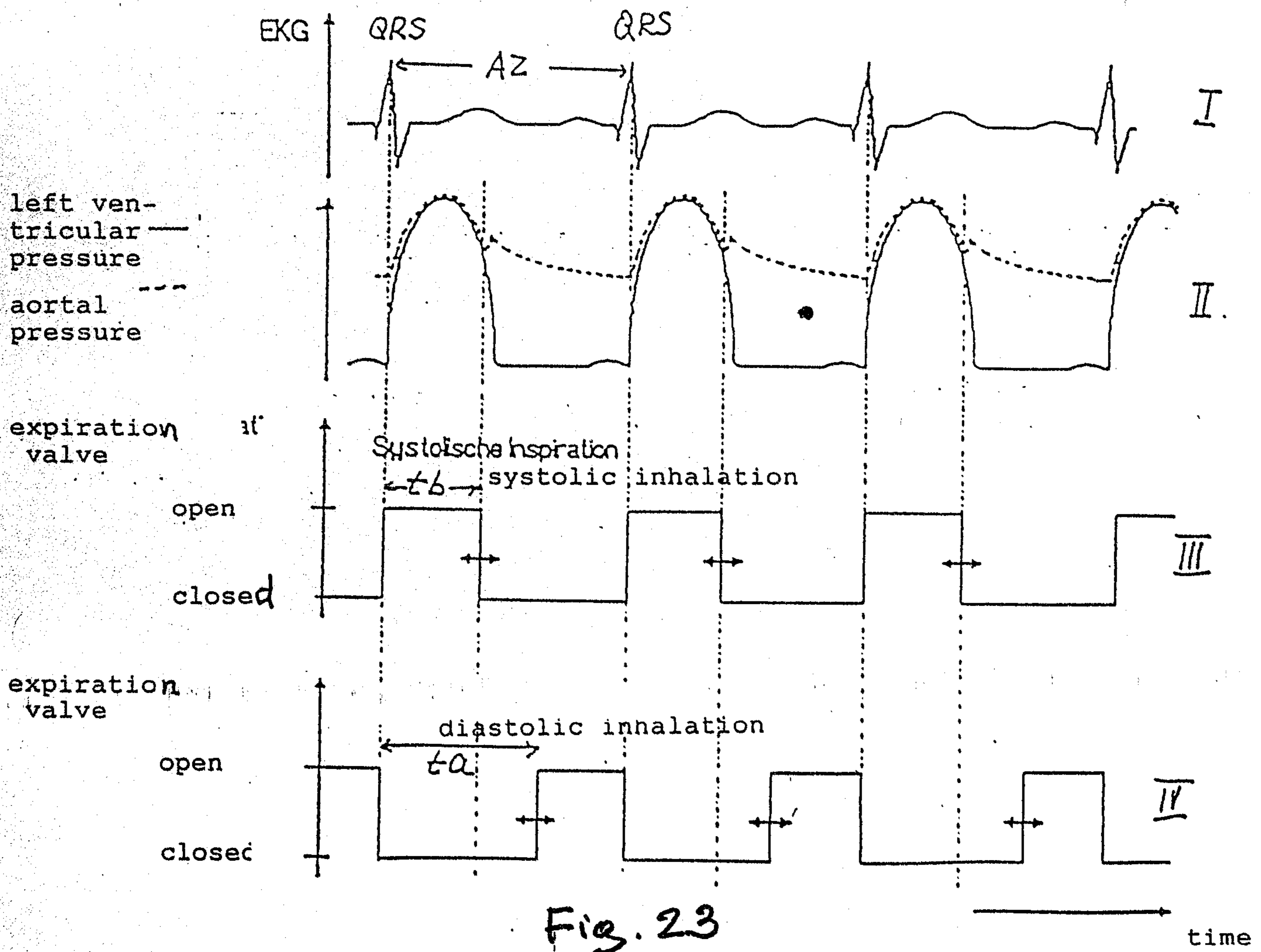
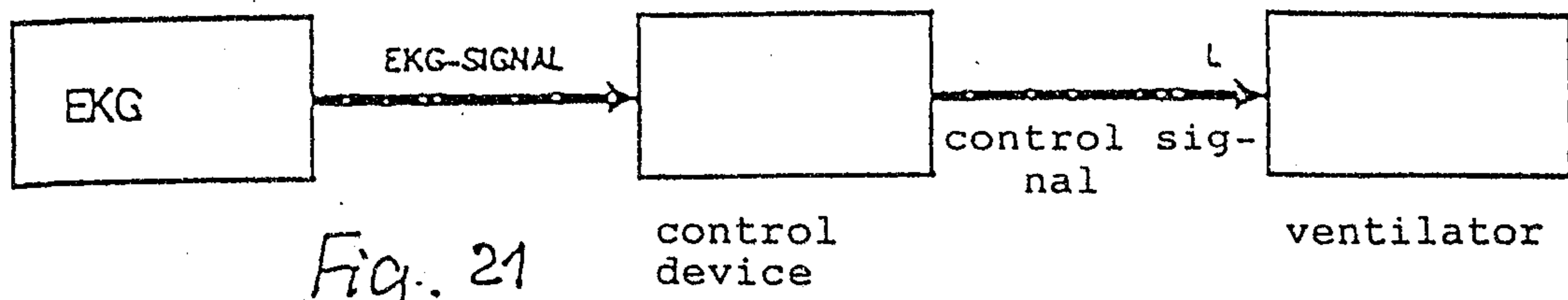


Fig 20

Fig 19

Fig 18



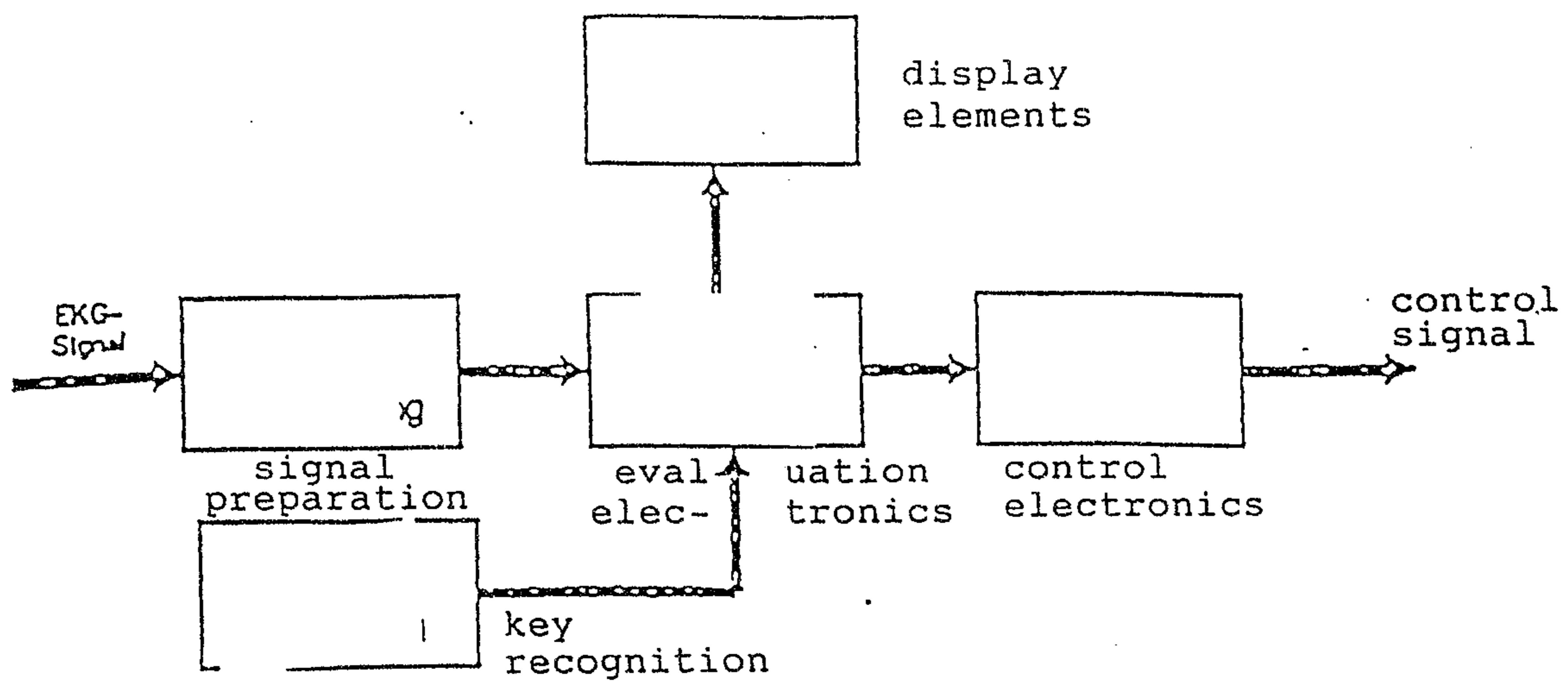


Fig. 24

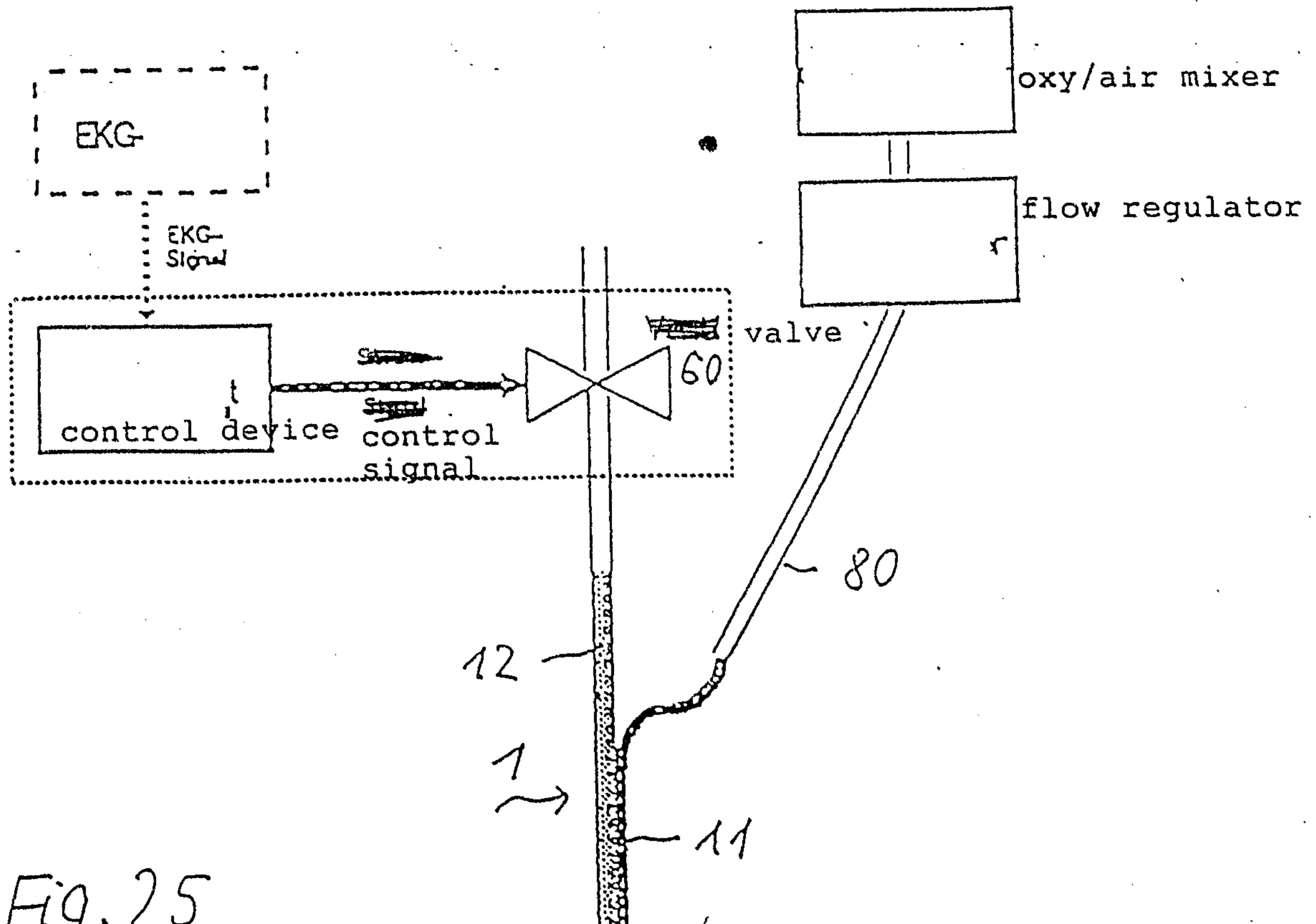


Fig. 25

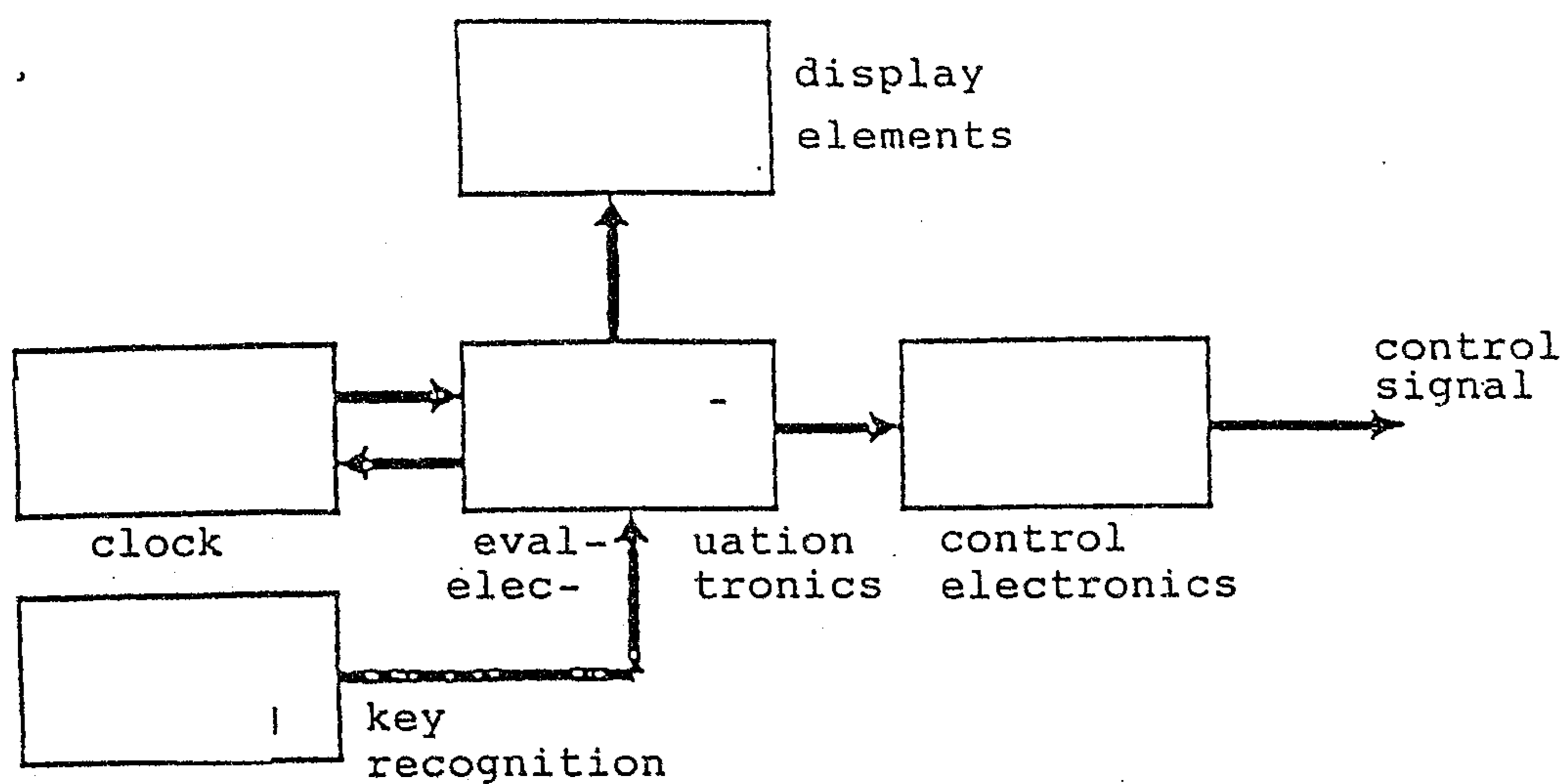


Fig. 26

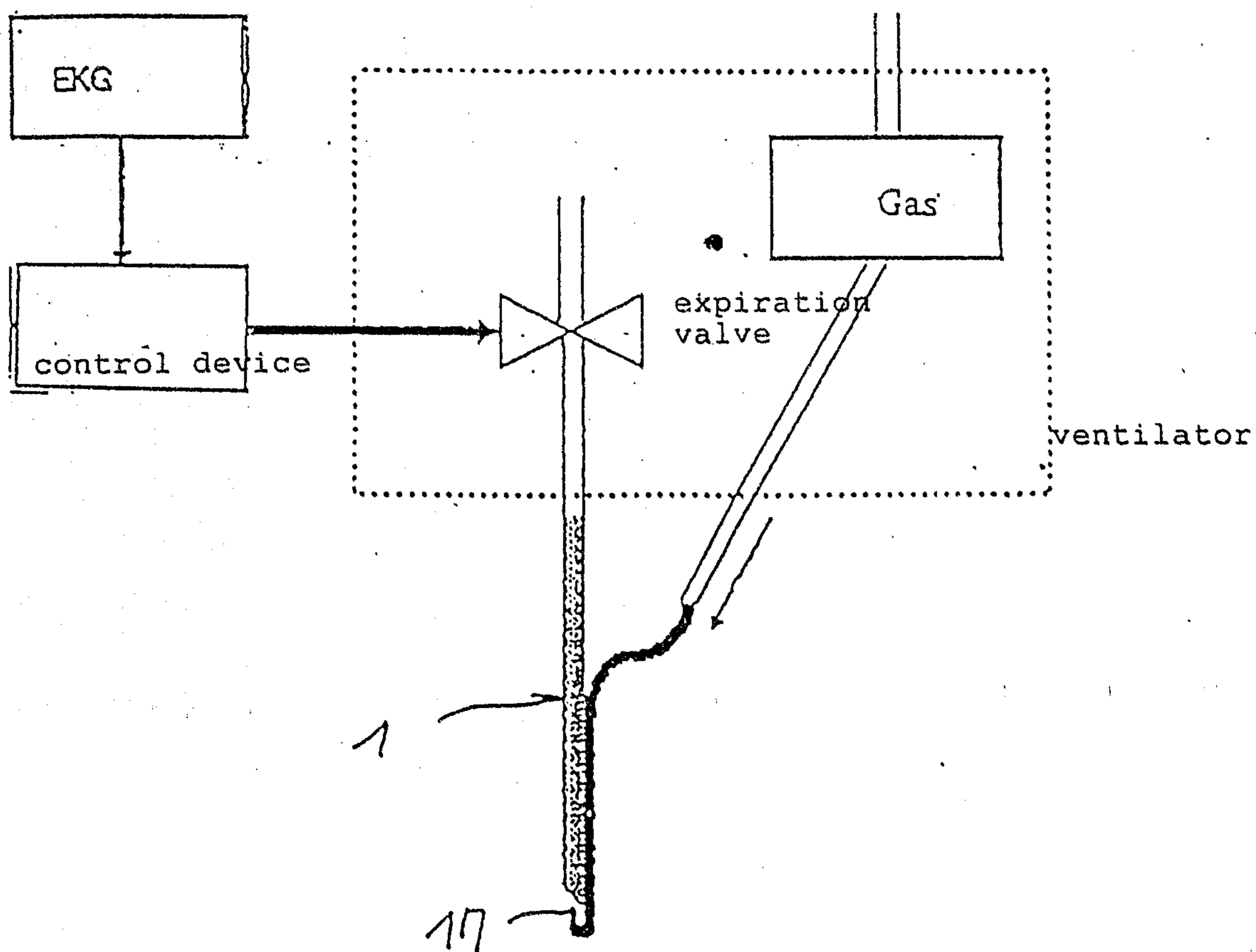


Fig. 22

