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(54) Benævnelse: **Indretning til at påføre et pulserende tryk til en lægemiddelindretning**

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This invention relates to an apparatus enabling a predetermined pulsating pressure to be applied on a medical device.

In the description below, the term "medical device" is to be understood as meaning a tube, a catheter, a combination or any other medical device.

Conceptually, the cardiovascular system is a closed, pressurized hydraulic system internally lined with endothelial cells. The functioning of these endothelial cells is regulated by cardiac pulsation, which causes pressure variations in the vessels and therefore a shear force on said cells, which stimulates them. These tangential forces of the shear stress are essential for maintaining endothelial function including vascular tone by nitric oxide synthesis (NOS), coagulation of the blood, the inflammatory response, immunity, atherosclerosis, angiogenesis and apoptosis. The endothelial function is very important since it controls embryogenesis, morphogenesis, organogenesis as well as maintenance of a healthy body.

Any intervention on this system, such as, for example, a pathology or a surgical operation, causes an endothelial dysfunction with consequences that may be dramatic.

In the field of circulatory assistance, numerous pulsating apparatuses are currently used. Among these, it is possible to cite, for example, external enhanced counterpulsation, left ventricular assist devices, intra aortic balloon pump, and so on.

However, the current pulsating apparatuses require, in order to create this pulsating function, consoles equipped with sophisticated computer systems, electrocardiograms, cardiopulmonary monitors, alarms, and so on. However, these consoles are very expensive, large and require trained care personnel as well as engineers and technicians for proper operation.

Document US 2001/016676 describes a system preventing condensation in an intra aortic balloon pump.

The invention is therefore intended to simplify the existing apparatuses owing to a new apparatus intended to apply a predetermined pulsating pressure on a medical device.

Said apparatus for applying a predetermined pulsating pressure on a medical device includes:

- drawing means suitable for drawing fluid from a high-pressure continuous flow fluid source;

- conversion means suitable for converting said fluid into a low-pressure pulsating flow fluid;

- at least one application means for applying said fluid, in a low-pressure pulsating flow on said medical device; and

- means for discharging said fluid.

The apparatus of the invention also includes an enclosure, said enclosure being:

- suitable for being temporarily attached to the high-pressure continuous flow fluid source, to draw a finite fluid volume;

- attached to the drawing means to enable the drawing of the finite fluid volume contained therein; and

- attached to the discharge means to create a closed fluid circuit.

Said apparatus has the advantage of being much simpler and smaller in size than the existing consoles. It is therefore less expensive to produce and operate.

The apparatus of the invention has the advantage of creating the pulsatility applied on the medical device owing to a simple high-pressure continuous flow fluid source. This fluid source may be that present in any medical chamber, for example pressurized liquid or gas bottles.

The presence of the enclosure enables a finite volume of high-pressure fluid to be drawn. Then, once said fluid volume has been drawn, the attachment between the enclosure, therefore the apparatus of the invention, and the fluid source may be eliminated. The apparatus of the invention then becomes an autonomous apparatus.

The attachments of the enclosure to the drawing means and the discharge means may be permanent or not.

As the discharge means are connected to said enclosure, the apparatus of the invention has a closed fluid circuit. There is therefore no fluid loss. The apparatus of the invention may be portable insofar as the volume drawn is sufficient to supply the entire enclosure - conversion means - application means - discharge means circuit.

In one embodiment of the invention, the apparatus of the invention includes, in addition, a hollow body having two ends and, from the periphery to the center of the hollow body, an outer wall, a hollow chamber and a flexible membrane defining a through passage joining both ends, suitable for inserting a

medical device, said application means passing through said outer wall, leading to the hollow chamber and being suitable for applying a pulsating pressure on the flexible membrane and the discharge means from the hollow chamber and also passing through said outer wall.

During operation, the medical device is inserted into the through passage and the fluid, in a low-pressure pulsating flow, is applied, through the hollow chamber, on the flexible membrane. The flexible membrane undergoes a compression/decompression movement that it transmits to the medical device. The medical device is then a pulsating device.

In another embodiment, the apparatus of the invention also comprises an enclosure, as defined above, as well as a hollow body as defined above.

In one embodiment of the apparatus of the invention, said conversion means is a piston-spring and compartment system.

This piston-spring assembly associated with a compartment is a relatively simple system enabling a high-pressure continuous fluid source to be converted into rhythmic low-pressure fluid pulsations (see below).

In one embodiment, said conversion means is controlled electromechanically.

The presence of an electromechanical control enables an operator to control the operation of the pistons-springs and, thus, to choose the pulsation frequency as well as the pressure desired.

In one embodiment, the apparatus of the invention also comprises monitoring and alarm means. These monitoring and alarm means enable, for example, any fluid leak to be detected, the oxygen content in the patient's blood or the heart rate of the patient to be measured, and an alarm to be activated in the event of danger and/or the pulsations of the apparatus to be stopped.

In a particular embodiment, the electromechanical control and/or the monitoring and alarm means record a history of events by creating, for example, a database so as to be capable of being interrogated later by an operator.

The invention will be easier to understand in reference to the appended drawings, wherein:

- figure 1 is a schematic representation of a first apparatus enabling a pulsating pressure to be applied;

- figure 2 is a schematic representation of an apparatus of the invention, in which the apparatus includes an enclosure; and

- figure 3 is a schematic representation of a second apparatus including a hollow body.

In the drawings, the same reference numbers (units and tens) designate corresponding structures from one figure to another, with the hundreds digit distinguishing the different alternatives.

In the drawings, the circulation of fluid is schematically represented by arrows.

Figure 1 schematically represents an apparatus 101 in a longitudinal cross-section. This apparatus, schematically represented with a generally elongate form, successively includes, from one end to the other: drawing means 2, conversion means 3, fluid discharge means 104, which, in this embodiment, discharges the fluid to the outside of the apparatus, and application means 105.

The drawing means 2 and the application means 105 will generally but not necessarily be extended by a high-pressure cord connecting the drawing means to the fluid source and by a low-pressure cord connecting the application means to the medical device.

The drawing means 2 may be in the form of a tube (having a general trapezoid shape in figure 1) having two ends. The first end 6 of the drawing means 2 is suitable for being hermetically attached by means of a high-pressure cord or directly on a gas bottle or on a gas intake present along the wall of the medical chamber. The second end 7 of the drawing means 2 is attached to the conversion means 3.

The drawing means 2 and the conversion means 3 may be made in a single piece.

The conversion means 3, in the embodiment of figure 1, includes an assembly of pistons 8A (high-pressure piston, placed inside the compartment) and 8B (low-pressure piston, placed outside the compartment) and springs 9A (high-pressure spring, which is a traction spring) and 9B (low-pressure spring, which is a compression spring) inserted in a tube 10 placed on either side of a compartment 11 having two inlets. The pistons 8A and 8B, during operation, regularly open or close the inlets of the compartment 11. One end of the tube 10 is attached to the drawing means 2 and the other end is formed, in this figure, by the application means 105. The conversion means 3 may be controlled electromechanically (control not shown in this figure 1).

The discharge means 104 is located on a portion of the tube 10 on the side of the end formed by the application means 105. This discharge means 104 may, for example, be a one-way valve.

During operation, if the apparatus 101 is used with a medical balloon device, the application means 105, which, in this embodiment, is an end of the tube 10, is connected, by means of a low-pressure cord or not, to a fluid connector port (not shown), itself connected to the balloon of the medical device. The drawing means 2 is attached, by means of the high-pressure cord or not, to a high-pressure continuous flow fluid source, for example a gas bottle (not shown here). This fluid source may have a pressure of between 0.5 and 30 bars. A possible operation is as follows: high-pressure fluid, drawn from the high-pressure continuous flow fluid source enters the compartment 11, pushing the high-pressure piston 8A toward the inside of the compartment 11. Then, when the pressure inside the compartment 11 becomes equal to that of the high-pressure fluid, the high-pressure spring 9A, which acts opposite the direction of the continuous fluid flow, pulls the piston 8A toward the outside of the compartment 11, closing the compartment 11. On the other side of the compartment 11, the low-pressure piston 8B is then pushed toward the outside of the compartment 11 by the difference in pressure between the compartment 11 and the interior of the tube 10. Fluid leaves the compartment 11 toward the tube 10 with a lower pressure than that of the compartment 11. As the pressure in the compartment 11 decreases, the low-pressure spring 9B pushes the low-pressure piston 8B toward the compartment 11. A low-pressure fluid pulsation has thus been created. A sequence of the operation has been described, but it must be understood that this piston-spring-compartment is in perpetual equilibrium and regularly creates low-pressure fluid pulsations toward the application means 105.

In a preferred embodiment, the piston-spring-compartment system is coupled to an electromechanical control. Thus, according to information provided by an operator to the electromechanical control, the frequency of the pulsations and the pressure of each pulsation may be chosen by programming said data on said control. For example, the pulsation rate may be between 10 and 300 beats per minute. This rate may also be regulated according to the heart rate of the patient.

In the case of a medical balloon device, the fluid then flows in a pulsed manner from the application means 105, passing through the fluid connector port,

to the balloon of the medical device in order to be discharged by the discharge means. The subsequent inflation/deflation of the balloon causes a pulsating pressure on the medical device.

This figure 1 shows a single application means 105. However, the apparatus may have one or more application means. For example, when the medical device is a combination, it is possible to envisage having first application means at the pants level (with a first frequency and pulsation pressure) and second application means at the belt level (with a second frequency and pulsation pressure) and third application means at the shirt level (with a third frequency and pulsation pressure).

Figure 2 shows an embodiment of the invention that differs from that of figure 1 in that the apparatus of the invention 201 has an enclosure 12 and the discharge means 204 is connected to this enclosure 12.

The enclosure 12 is schematically represented in the form of a cube having two protuberances 12A and 12B, on two opposite sides, representing accesses to the enclosure. At least the end 12B is an access capable of being in a hermetically closed or open position. The first protuberance 12A is attached to the end 6 of the drawing means 2 and the second protuberance 12B is suitable for being attached to the high-pressure continuous flow fluid source.

In this embodiment, the apparatus 201 is attached to the high-pressure continuous flow fluid source by means of the enclosure 12, on the side of end 12B. During operation, the end 12B is open and a finite volume of fluid is drawn from the fluid source and enclosed in the enclosure 12 by a hermetic closure of the end 12B. Then, said enclosure 12 is detached from the fluid source. Thus, the apparatus 201 becomes autonomous.

To improve the autonomy of this apparatus 201, the discharge means 204 is connected to said enclosure 12, and thus a closed fluid circuit is created (it is obvious that compressor means should be envisaged for pushing the fluid arriving from the low-pressure discharge means in the high-pressure enclosure 12).

During operation, if the apparatus 201 of the invention is used with a medical balloon device, the piston-spring-compartment system delivers fluid from the enclosure 12 as a low-pressure pulsed flow. If the trajectory of a fluid pulsation is described, it flows through the application means 205 and the fluid connector port so as to inflate the balloon of the medical device. Then, this fluid pulsation returns to the discharge means 204, where it is directed, by

compression, toward the enclosure 12, while a new pulsation leaves the application means 205 toward the balloon of the medical device.

Figure 3 shows another embodiment of the apparatus that differs from that of figure 1 in that the apparatus 301 includes a hollow body 13 attached to said application means 305. This hollow body 13, cylindrical, preferably with a circular cross-section, has an outer wall 14 and two ends 15 and 16. Inside this hollow body 13 is a membrane 17, flexible, itself cylindrical, connecting the two ends 15 and 16, and defining a through-passage 18. Between the outer wall 14 and the flexible membrane 17, a hollow chamber 19 is created.

This embodiment makes it possible to create a pulsating movement on a balloon-free medical device, for example, a tube, as explained below.

Because of the presence of this hollow body 13, the application means 305 is not connected to a fluid connector port but passes through the outer wall 14 and reaches the hollow chamber 19, the discharge means 304 from the hollow chamber 19 also passes through the outer wall 14. For example, the discharge means 304 may be in a position diametrally opposed to that of the application means 305.

When the apparatus 301 is not in operation, the through passage 18 may be occupied by a bar and, at each end 15, 16, caps may be placed to hermetically close the through passage 18. The presence of this bar and these caps eliminates any presence of a vacuum in the apparatus enabling a pulsating pressure to be applied when it is not in operation. Thus, no contaminant of any type will contaminate the apparatus of the invention.

During operation, the bar and the caps are removed from the apparatus 301. In place of the bar, a medical device is inserted, and then the fluid source (not shown) is opened.

The low-pressure pulsating fluid coming from the conversion means 3 circulates through the application means 305 to the hollow chamber 19. Two operations are then envisaged:

In the first, the pulsation of low-pressure fluid entering the hollow chamber 19 exerts a pressure at a location on the flexible membrane 17, which pressure is reflected on the medical device. Then, the fluid goes into the hollow chamber 19 and the medical device is no longer subjected to pressure. The discharge means 304 then serve only to purge the apparatus of any fluid. This operation is

repeated in each pulsation; a medical device subject to pulsating compression/decompression movements is thus obtained.

In the second mode of operation, the low-pressure fluid pulsation represents a volume of fluid greater than the capacity of said hollow chamber 19, which has the effect of compressing the flexible membrane 17 against the medical device. Then, the discharge means 304 is opened and the hollow chamber 19 is emptied of this excess fluid, and the membrane 17 is no longer compressed against the walls of the medical device. This operation is repeated with each pulsation; thus, again, a medical device subject to pulsating compression/decompression movements is obtained.

This invention is not limited to the embodiments described and illustrated. For example, in the conversion means, a valve system may be envisaged in place of the piston-spring system. Similarly, an embodiment of the apparatus of the invention may involve an association of the enclosure 12 and the hollow body 13.

Patentkrav

1. Apparat til at påføre et forudbestemt pulserende tryk på en lægemiddelindretning omfattende:

- udtrækningsorgan (2) der er egnet til at udtrække væske fra en højtryks-kontinuerlig væskestrømningskilde;

- forarbejdningsorgan (3) der er egnet til at omdanne væsken til en lavtryks-pulserende væskestrøm;

- mindst ét tilførselsorgan (105) til at tilføre væsken, i en lavtryks-pulserende strøm på lægemiddelindretningen; og

- organ til udledning (104; 204) af væsken,
kendetegnet ved at apparatet yderligere omfatter et indelukke (12), hvilket indelukke er:

- egnet til midlertidig fastgørelse til den højtryks-kontinuerlige væskestrømkilde, til at udtrække et slutvæskevolumen;

- fastgjort til udtrækningsorganet (2) for at muliggøre udtrækningen af slutvæskevolumenet indeholdt deri; og

- fastgjort til udledningsorganet (204) for at danne et lukket væskekredsløb.

2. Apparat til at påføre et forudbestemt tryk på lægemiddelindretningen ifølge krav 1, **kendetegnet ved at** det yderligere omfatter et hult legeme (13) der har to ender (15, 16) og, fra periferien til midten af det hule legeme, en ydervæg (14), et hult kammer (19) og en fleksibel membran (17) der definerer en gennemgående passage der samler begge ender, som er egnet til at indsætte en lægemiddelindretning, hvilket tilførselsorgan (105) passerer gennem den ydre væg, der fører til det hule kammer og som er egnet til at påføre et pulserende tryk på den fleksible membran og udladningsorganet der kommer fra det hule kammer og også passerer gennem den ydre væg.

3. Apparat til at påføre et forudbestemt tryk på en lægemiddelindretning ifølge et hvilket som helst af de ovennævnte krav, **kendetegnet ved at** forarbejdningsorganet (3) er et stempel-fjeder- og kassesystem.

4. Apparat til at påføre et forudbestemt tryk på en lægemiddelindretning ifølge et hvilket som helst af de ovennævnte krav, **kendetegnet ved at** forarbejdningsorganet (3) styres elektromekanisk.

5. Apparat til at påføre et forudbestemt tryk på en lægemiddelindretning ifølge et hvilket som helst af de ovennævnte krav, **kendetegnet ved at** det yderligere omfatter overvågnings- og alarmorgan.

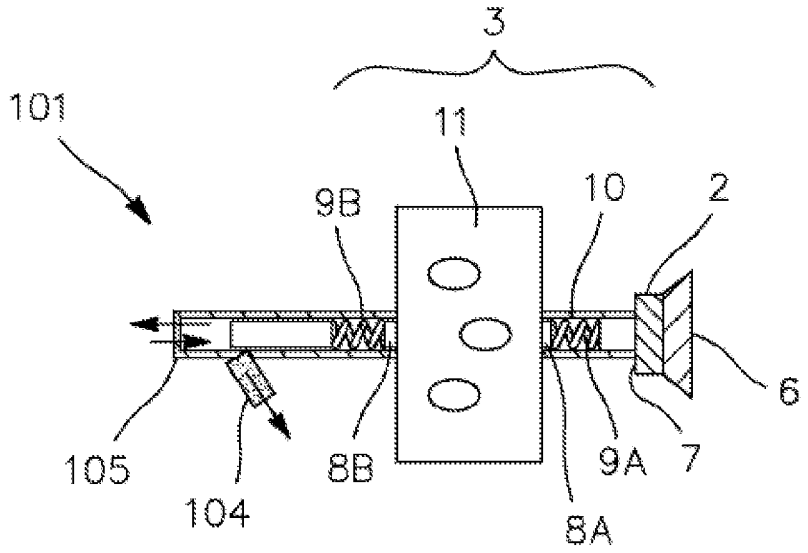

FIG. 1

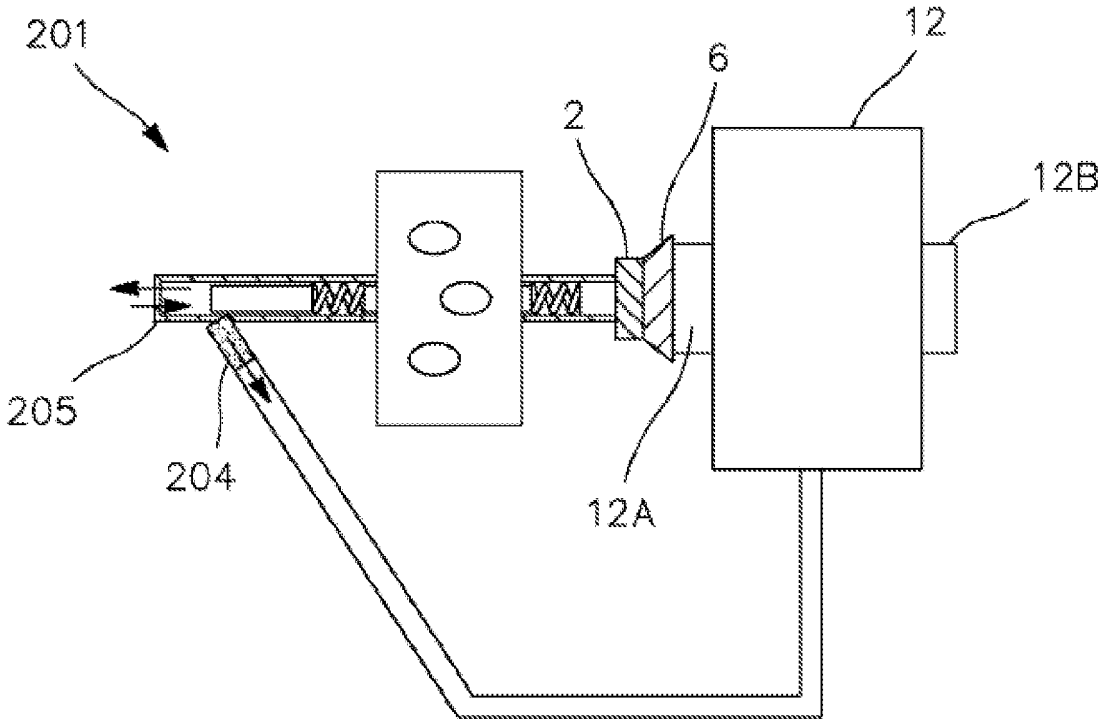

FIG. 2

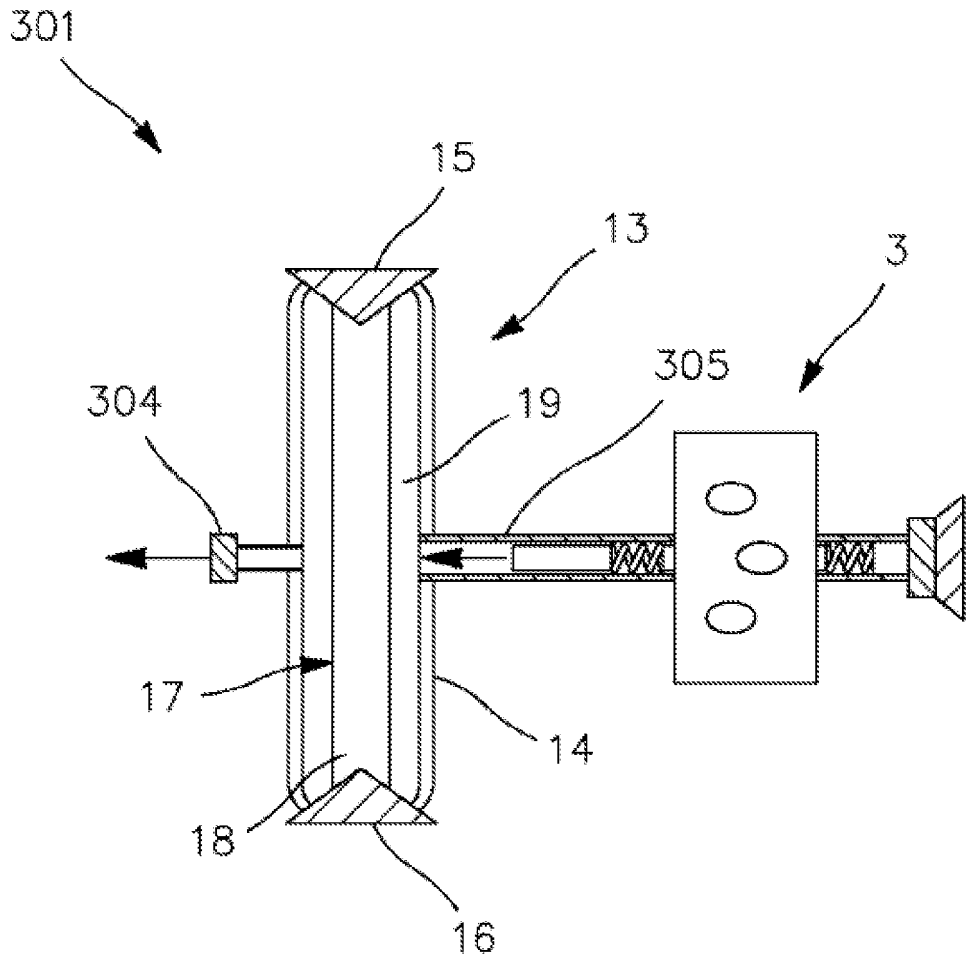

FIG. 3