

[54] **APPARATUS FOR INTRA-AORTAL BALLOON PULSATION**

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128/53, 64 X

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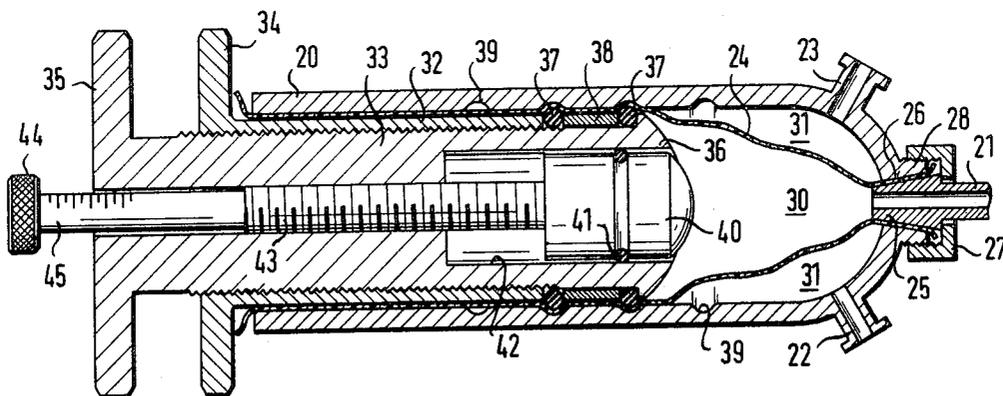
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[57] **ABSTRACT**

An apparatus for aiding the heart in its pulsation wherein a balloon means is inserted into the aorta and which is inflated and deflated in accordance with the diastolic and systolic cycles of the heart comprising a chamber having a pumping section connected with the balloon, and a driving section, a source of excess pressure and a source of low pressure, control means for alternately coupling the source of excess pressure and the source of low pressure to the driving section, a membrane separating the pumping section and the driving section and being constructed for pumping the entire volume of the pumping section into the balloon during the phase when the source of high pressure is connected and for driving the entire volume of the driving section into the low pressure source when the low pressure source is connected to the driving section.

22 Claims, 2 Drawing Figures



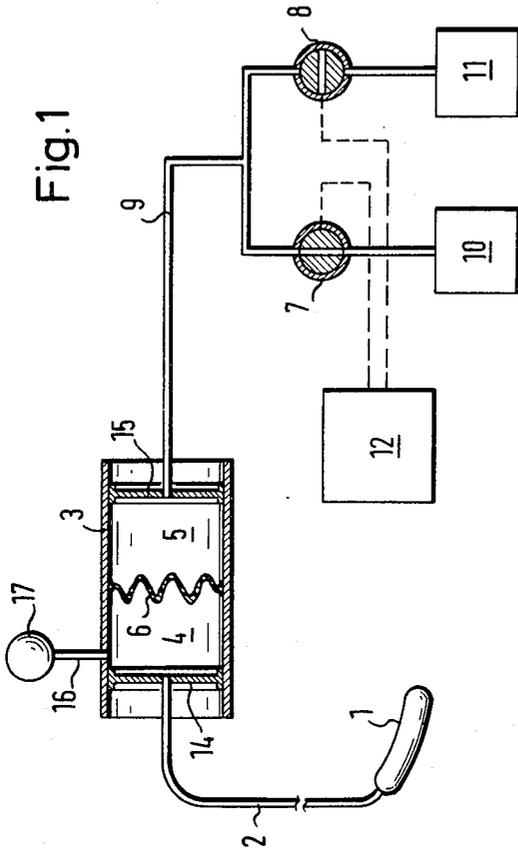


Fig. 1

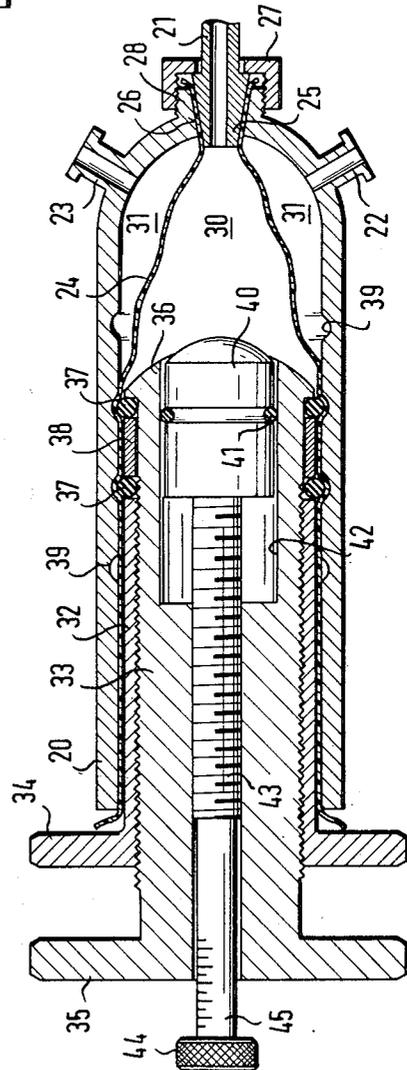


Fig. 2

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APPARATUS FOR INTRA-AORTAL BALLOON PULSATION

FIELD OF THE INVENTION

The present invention relates to an arrangement for intra-aortal balloon pulsation controlled by the electrical action of the heart and aiding the work of the heart, such arrangement having a separating chamber which separates the balloon circuit from the driving gas circuit and wherein in the separating chamber a membrane is arranged the stroke or displacement of which is adjustable to adapt it to the filling volume of the balloon or other conditions which exist in this connection.

BACKGROUND OF THE INVENTION

Balloon pulsing systems have been developed for relieving the heart muscle and to improve the coronary blood supply in the event of a shock, that is, when the blood pressure falls so deep that the self-supply of the heart cannot be anymore secured and, as a result, the contraction capability of the heart muscle and the resultant pumping volume of the heart falls to extremely dangerous low levels. Such devices operate according to the principle of arterial counter — pulsation according to which during the systole cycle the pressure in the arteries will fall by evacuating the balloon and thereby the pressure work on the heart is reduced. On the other hand, during the diastole cycle the balloon becomes blown up which increases the diastolic pressure and thereby an increased coronary blood flow is attained.

A system of the above-described type became known from the publication "Trans-American Society for Artificial Internal Organs", 1969, pages 400-405. An essential part of the above-described arrangement is a separating chamber wherein a movable membrane divides the separating chamber into a driving chamber and into a filling chamber, that is, the membrane separates the driving gas circuit from the balloon circuit. The balloon circuit which comprises the balloon, a feed conduit and the filling chamber, becomes filled with a helium gas. The separating chamber has fixed outer dimensions. Within this separating chamber there is a movable membrane arranged. The membrane itself is a rigid member made from elastic material and supported by a ring about its circumference. For the adjustment of the magnitude of the volume which is displaced during a membrane cycle an adjustable projection is provided which limits the displacement of the membrane within the separating chamber.

Due to such construction the volume of the separating chamber normally is larger than is necessary in the individual case. When the rigid membrane abuts against the projection, there is still a quite large "dead volume" of the separating chamber available. Such dead volume must be, however, during the compression and during the relaxation or decompression phase placed under excess or below atmospheric pressure, respectively. As a result, such known arrangement operates relatively slow. In order to reach the necessary pulsation speed one must use in the above-described known system a gas having an extremely low density, such as helium.

The use of helium as filling gas for the balloon is, however, not without danger. Helium is not resorbed by the blood. In the event there is a sealing defect in the

balloon or in the feed conduit, then the helium will flow into the blood path and the danger of an embolism might arise.

The adjustability of the filling or pumping volume is, on the other hand, a necessary condition for a technically usable device. More particularly, the diameter and the magnitude of the balloon used in each individual case must be selected in accordance with the diameter and the dimensions of the individual aorta. The volume of the balloon used in each case and the associated feed conduit determines at the same time the volume of the filling chamber which, obviously, must become variable in each case.

SUMMARY OF THE INVENTION

It is, therefore, an object of the present invention to provide an improved balloon pulsation system for aiding the heart in its work in which the filling volume can be adjusted and the pulsation speed can be increased to such an extent that gases can be used as operating mediums which can be resorbed by the blood, so that the danger of an embolism is eliminated in the event there is a sealing defect in the system.

According to the present invention the volume of the separating chamber is adjustable, that is, variable, and the membrane is constructed in such a manner that during the excess pressure phase it displaces the entire volume of the part of the separating chamber serving as the filling or pumping chamber, while during the reduced pressure phase it displaces the entire volume of the separating chamber serving as the driving chamber.

According to the present invention it becomes possible to obtain an optimum subdivision of the volume of the separating chamber. Such optimum is arrived at when during the abutting of the membrane to the wall portions of the filling chamber of the separating chamber the balloon becomes just completely filled and during the abutting of the membrane onto the wall portions of the separating chamber serving as the driving chamber the balloon becomes evacuated just to the necessary extent.

According to a further feature of the present invention the membrane is fixedly spanned in the separating chamber and comprises a synthetic foil which is in the position to apply itself in a relatively short time against the wall portions of the separating chamber. The membrane according to the present invention has a very slight mass so that relatively small accelerating forces are necessary to bring about its pulsating movements. As a result, the operating speed of the transmitting member becomes further increased.

BRIEF DESCRIPTION OF THE DRAWING

The invention will become more readily apparent from the following description of a preferred embodiment thereof shown, by way of example, in the accompanying drawing, in which:

FIG. 1 is a schematic representation of the principle of operation of the arrangement according to the present invention; and

FIG. 2 is a preferred structural illustration of a separating chamber according to the present invention, in cross section.

DESCRIPTION OF THE PREFERRED EMBODIMENT

With reference to FIG. 1 it is seen that a double circuit balloon pulsation system principally comprises the following elements: a balloon 1 which is to be inserted into the aorta, a feed conduit 2 connecting the balloon 1 to a separating chamber 3 having a section 4 which functions as the filling or pumping chamber of the balloon 1 and another section 5 which functions as the driving chamber, the filling chamber 4 and the driving chamber 5 being separated by a membrane 6, a feed conduit 9 which by means of valves 7 and 8 alternately can be connected to an excess pressure reservoir 10 or to a low pressure reservoir 11, as well as an electronic control unit 12 which operates both valves 7 and 8. This general construction is known from prior devices and from the above-mentioned publication.

The present invention is primarily concerned with the construction of the separating chamber 3. The volume of this separating chamber 3 which is put together from the partial volumes of the driving chamber 5 and of the filling chamber 4 is adjustably constructed by providing the possibility of movement for the end walls 15 and 14 so that a volume sub-division can be had always in an optimum manner. During an optimum volume sub-division the balloon 1 is just about full when the membrane 6 lies completely over the wall of the filling chamber 4. As a result, the pressure in the driving chamber 5, that is, also the pressure in the excess pressure reservoir 10 then can be selected as high as desired without this having any effect on the pressure in the balloon 1. The selection of the high pressure in the driving chamber 5 has, however, primary importance from the viewpoint of speed with which the balloon 1 can be filled. At an optimum volume sub-division during the low pressure phase, that is when the membrane 6 lies against the wall portions of the driving chamber 5, the balloon 1 becomes reduced just to the desired volume.

The filling chamber 4 has a pressure indicator 17 connected thereto by means of a conduit 16 which makes it possible to follow the pressure conditions within the balloon circuit.

While in the prior art devices the feed conduit for the filling of the driving chamber 5 is coupled to the high pressure reservoir 10 and to the low pressure reservoir 11 by means of an electro-magnetically controlled three-way valve, it has been found, that the illustrated application of a pair of separate two-way valves 7 and 8 leads to substantial advantages in that they are having a much shorter switching time. This is explained by the fact that in a three-way valve during the switching there is always a time period during which all three paths of the valve are coupled with each other so that a short circuiting of the high pressure and low pressure may be present. This advantage is eliminated by the application of a pair of parallel-connected two-way valves and, at the same time, the effective switching time is substantially reduced. This measure of application of two-way valves as explained above contributes also substantially to the increase of the operating speed of the entire system.

The preferred structural construction of the separating chamber is illustrated in FIG. 2. A hollow cylinder 20 which is closed at one end thereof has at such closed

end a connecting piece 21 where the driving pressure is applied thereto, while the connecting piece 23 is provided for the coupling of the pressure indicating means 17. Within the cylinder 20 a hose-like membrane 24 is arranged. On the sealed end of the cylinder 20 the membrane is spanned between a cone portion 25 of the connecting piece 21 and a cone-shaped bore 26 cooperating therewith. The screw cap 27 which is screwed onto a threaded end piece 28 provides for a good securing of the membrane 24.

At the other end the cylinder shaped membrane 24 is pressed against the inner walls of the cylinder 20 by an insert means hereinafter described. In this manner within the cylinder 20 by the membrane 24 the two partial chambers 30 and 31 are formed. The partial chamber 30 within the cylinder-shaped membrane serves as the driving chamber while the partial chamber 31 between the membrane 24 and the wall of the cylinder 20 serves as the filling chamber for the balloon 1.

The accurate positioning of the volume of the separating chamber is accomplished by an insert means which forces the membrane 24 onto the wall portions of the cylinder 20. Such insert means comprises an outer hollow cylinder 32 and an inner hollow cylinder 33. The outer hollow cylinder 32 has on its inner side a thread cooperating with a corresponding thread on the outer side of the hollow cylinder 33. By means of two outer discs 34 and 35 both hollow cylinders 32 and 33 can be moved by being threaded with respect to each other. By rotating these two discs 34 and 35 in opposite direction the end portions of both hollow cylinders 32 and 33 of which the inner hollow cylinder 33 at one end thereof has a ring-like outwardly increasing projection 36, become tensioned with respect to each other and, as a result, a pair of sealing rings 37 which are separated by each other by means of a spacing ring 38, become pressed against the wall portions of the cylinder 20. In the wall portions of the cylinder 20 there are in correspondence with the distance between the two sealing rings 37 ring-like grooves 39 provided. The sealing rings 37 lie against the membrane 24 in these grooves 39 and thereby a secured feeding of the insert means within the cylinder 20 is accomplished.

By displacing the insert means over a path defined between a pair of adjacent grooves 39 a coarse adjustment of the separating chamber can be obtained. The fine adjustment or correction of the volume of the separating chamber can be accomplished by means of a piston 40 displaceably mounted within the hollow cylinder 33. The piston 40 is sealed by means of a sealing ring 41 within the bore 42. By rotating a stem 43 by means of a disc 44, the piston 40 can be brought to any desired position at a great accuracy. On the upper end of the stem 43 there is a scale 45 provided on which the fine correction of the volume can be read off.

For the membrane 24 a polyurethane hose can be used having a thickness of about 0.2mm.

From the above, it is apparent that although the invention has been described hereinbefore with respect to a certain specific embodiment thereof, it is evident that many modifications and changes may be made without departing from the spirit of the invention. Accordingly, by the appended claims, we intend to cover all such modifications and changes as fall within the true spirit and scope of this invention.

We claim:

1. An apparatus for aiding the heart in its pulsation wherein a balloon means is inserted into the aorta and which is inflated and deflated in accordance with the diastolic and systolic cycles of the heart comprising a chamber means having a pumping chamber, means connecting said pumping chamber with the balloon means, and a driving chamber, a source of excess pressure and a source of low pressure, means for alternately coupling said source of excess pressure and said source of low pressure to said driving chamber, a membrane means separating said pumping chamber and said driving chamber, said chamber including means for positioning and controlling the size of the membrane means for pumping the entire volume of said pumping chamber into said balloon means during the phase when said source of high pressure is connected and for driving the entire volume of said driving chamber into said low pressure source when said low pressure source is connected.

2. The apparatus as claimed in claim 1, wherein means are provided for adjusting the volume of said pumping chamber, and means are provided for adjusting the volume of said driving chamber.

3. The apparatus as claimed in claim 1, wherein said membrane is made from a foil of synthetic material and is adapted to abut against the wall portion of said pumping chamber when said high pressure source is operated and, to lie against the wall portions of said driving chamber when said low pressure source is operated, the flexing of said membrane means occurring in a very short period of time.

4. The apparatus as claimed in claim 1, wherein said membrane means is made from a foil of polyurethane material having a wall thickness of about 0.2mm.

5. The apparatus as claimed in claim 1, wherein said balloon means connecting said balloon to said pumping chamber, and said pumping chamber constitute a balloon circuit and are filled with a gas which is capable of being resorbed by the blood.

6. The apparatus as claimed in claim 5, wherein said gas filling the balloon circuit is acetylen.

7. The apparatus as claimed in claim 1, wherein said means for alternately coupling said high and low pressure sources to said driving chamber comprises a pair of two-way valves, a pair of conduits each leading to one of said pressure sources, one of said valves being associated with a predetermined one of said pressure sources, and means for controlling the alternate opening and closing of said valve means so that at one instant of the time only one of said sources is connected to said driving chamber.

8. The apparatus as claimed in claim 7, wherein said controlling means is operating said pair of valve means in accordance with the heart beat and includes means for electrically picking up the heart rate during the systolic and diastolic cycles of the heart operation.

9. The apparatus as claimed in claim 1, wherein said chamber comprises a hollow cylinder having means closing one end thereof, and insert means being inserted into said hollow cylinder at the other end thereof, said membrane means extending along said insert means and the wall portions of said hollow cylinder and being secured at the closed end of said hollow cylinder, said membrane means being a hose-shaped flexible material, said membrane means with its inside

wall portions defining said driving chamber, said closing means of said hollow cylinder communicating said driving chamber with said high or low pressure source, the outer side of said membrane means with the wall portions of said hollow cylinder defining said pumping chamber.

10. The apparatus as claimed in claim 9, wherein said insert means comprises an outer hollow cylinder and an inner cylinder, thread means on said outer cylinder of said insert means and thread means on said inner cylinder of said insert means, said outer cylinder and said inner cylinder being movable along a common axis over said cooperating thread means of the respective cylinders, a ring-like projection on said inner cylinder of said insert means, sealing means provided between said outer and said inner cylinder of said insert means, said insert means being movable axially in said hollow cylinder of said chamber for adjusting thereby the volume of said pumping and said driving chambers.

11. The apparatus as claimed in claim 10, wherein said outer hollow cylinder of said chamber has groove means formed on the inner wall thereof, said sealing means being forced into said groove means and defining predetermined volume positions of said insert means.

12. The apparatus as claimed in claim 11, wherein said insert means comprises a piston means, said means being mounted coaxially with said insert means, the front portion of said piston means communicating with said driving chamber, means for adjusting the position of said piston means thereby adjusting the volume of said pumping and said driving chamber.

13. The apparatus as claimed in claim 12, wherein said means for adjusting said position of said piston means comprises a threaded bar means passing through a threaded passage in said inner hollow cylinder of said insert means, and an indicating operating means at the end of said threaded bar means for indicating the fine adjustment to said driving chamber and said pumping chamber.

14. A separating device for separating the driving and pumping circuits in an apparatus for aiding the heart in its pulsation wherein a balloon means is inserted into the aorta and which is inflated and deflated in accordance with the diastolic and systolic cycles of the heart, said separating device having a pumping chamber adapted to be connected with the balloon, and a driving chamber adapted to be connected to a source of excess pressure or to a source of low pressure, a membrane means separating said pumping chamber and said driving chamber, said chamber including means for positioning and controlling the size of the membrane means for pumping the entire volume of said pumping chamber when connected to said balloon during the phase when said source of high pressure is connected and for driving the entire volume of said driving chamber into said low pressure source when connected to said low pressure source.

15. The separating device as claimed in claim 14, wherein means are provided for adjusting the volume of said pumping chamber, and means are provided for adjusting the volume of said driving chamber.

16. The separating device as claimed in claim 14, wherein said membrane is made from a foil of synthetic material and is adapted to abut against the wall portion

of said pumping chamber when said high pressure source is operated and, to lie against the wall portions of said driving chamber when said low pressure source is operated, the flexing of said membrane means occurring in a very short period of time.

17. The separating device as claimed in claim 14, wherein said membrane means is made from a foil of polyurethane material having a wall thickness of about 0.2mm.

18. The separating device as claimed in claim 14, wherein said separating device comprises a hollow cylinder having means closing one end thereof, and insert means being inserted into said hollow cylinder at the other end thereof, said membrane means extending along said insert means and the wall portions of said hollow cylinder and being secured at the closed end of said hollow cylinder, said membrane means being a hose-shaped flexible material, said membrane means with its inside wall portions defining said driving chamber, said closing means of said hollow cylinder adapted to communicate said driving chamber with said high or low pressure source, the outer side of said membrane means with the wall portions of said hollow cylinder defining said pumping chamber.

19. The separating device as claimed in claim 18, wherein said insert means comprises an outer hollow cylinder and an inner cylinder, thread means on said outer cylinder of said insert means and thread means on said inner cylinder of said insert means, said outer cylinder and said inner cylinder being movable along a common axis over said cooperating thread means of

the respective cylinders, a ring-like projection on said inner cylinder of said insert means, sealing means provided between said outer and said inner cylinder of said insert means, said insert means being movable axially in said hollow cylinder of said chamber for adjusting thereby the volume of said pumping and said driving chambers.

20. The separating device as claimed in claim 19, wherein said outer hollow cylinder of said chamber has groove means formed on the inner wall thereof, said sealing means being forced into said groove means and defining predetermined volume positions of said insert means.

21. The separating device as claimed in claim 20, wherein said insert means comprises a piston means, said piston means being mounted coaxially with said insert means, the front portion of said piston means communicating with said driving chamber, means for adjusting the position of said piston means thereby adjusting the volume of said pumping chamber and said driving chamber.

22. The separating device as claimed in claim 21, wherein said means for adjusting said position of said piston means comprises a threaded bar means passing through a threaded passage in said inner hollow cylinder of said insert means, and an indicating operating means at the end of said threaded bar means for indicating the fine adjustment to said driving chamber and said driving chamber.

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