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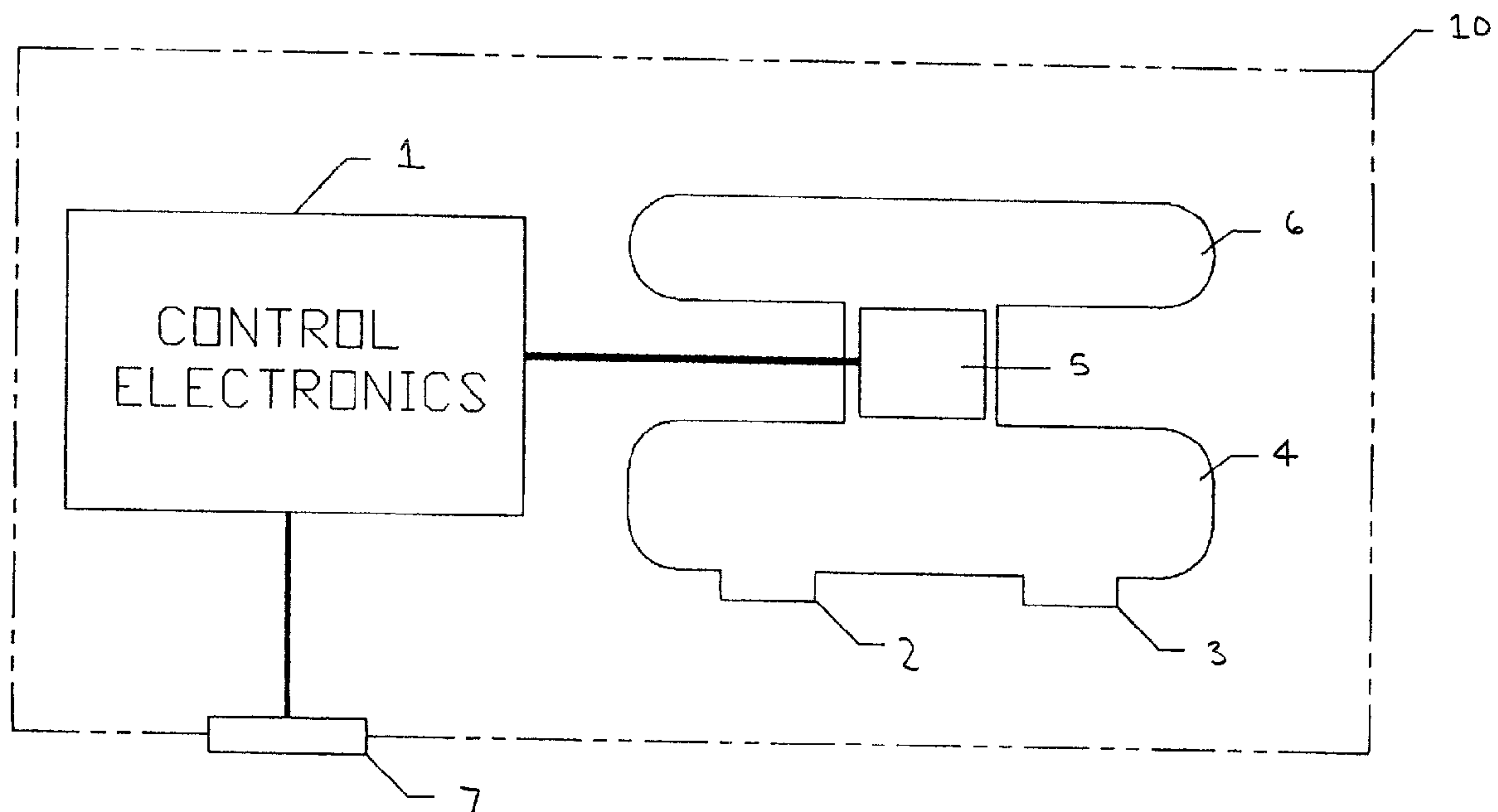
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(54) Titre : APPAREIL D'ASSISTANCE ELECTROHYDRAULIQUE

(54) Title: ELECTROHYDRAULIC ASSIST DEVICE



(57) Abrégé/Abstract:

This invention is directed to a system for a totally implantable circulatory device which combines the following components into a single integrated system: an actuation means for converting energy into a pulsating blood flow, a volume displacement chamber for storage of a volume displacement medium during the diastolic phase of the blood chamber, control electronics for the control and monitoring of the device, and a blood chamber with ports equipped with one-way valves to ensure unidirectional flow of blood from the natural heart through the blood chamber to the systemic and / or pulmonary circulation systems. The integrated system is totally implantable within the chest cavity and requires no physical connections penetrating through the skin to the outside of the body. Due to the location of the device in the human chest, it allows for a reduced conduit length to the natural heart. The size and geometry of the system are suitable for implantation in the chest cavity where the device does not adversely compress adjacent organs, create dead space or limit chest closure after implantation. The overall length of the device is less than 18 cm with an overall thickness less than 4 cm and an overall width less than 12 cm.



ABSTRACT OF THE DISCLOSURE

This invention is directed to a system for a totally implantable circulatory device which combines the following components into a single integrated system: an actuation means for converting energy into a pulsating blood flow, a volume displacement chamber for storage of a volume displacement medium during the diastolic phase of the blood chamber, control electronics for the control and monitoring of the device, and a blood chamber with ports equipped with one-way valves to ensure unidirectional flow of blood from the natural heart through the blood chamber to the systemic and / or pulmonary circulation systems. The integrated system is totally implantable within the chest cavity and requires no physical connections penetrating through the skin to the outside of the body. Due to the location of the device in the human chest, it allows for a reduced conduit length to the natural heart. The size and geometry of the system are suitable for implantation in the chest cavity where the device does not adversely compress adjacent organs, create dead space or limit chest closure after implantation. The overall length of the device is less than 18 cm with an overall thickness less than 4 cm and an overall width less than 12 cm.

Field of the invention

The present invention relates to the field of equipment and prothesis as a circulatory device aid for assisting or replacing the right and/or left ventricle of the natural heart. More particularly, this invention is concerned with a system which integrates several of the major components required for this type of device into one component herein referred to as the Integrated System.

Background of the invention

Clinical experience has shown that the cardiovascular circulation of patients in severe or total heart failure can be sustained with proper ventricular assist devices or total artificial hearts.

For these and other reasons, a number of mechanical circulatory devices have been designed to replace and/or assist the diseased natural heart. Total artificial hearts (TAH) and ventricular assist devices (VAD) have been valuable clinical tools in recent years with their primary benefit as a bridge to transplantation. Currently many of these devices are large requiring multiple implant sites for various components and long tubes and wires to connect these various components, thus they must be located in the abdominal cavity or outside the body.

For the thousands of cases of heart failure, one should aim for long term support rather than support limited in weeks, days or hours. In addition, it is also preferable to have a device capable of assisting or replacing left and/or right ventricle, since in some conditions the natural heart can recover after a period of time with the device used as a booster pump.

It is desirable that such device be implanted in the thoracic cavity. The device must not damage adjacent tissue or traumatize adjacent organs by compression or by excessive local temperatures. The artificial hearts must also avoid skin penetration by connections to the exterior to prevent infections. As well, shortening of the length of the cannulae employed for connecting the device to the natural heart or circulatory system is another desirable requirement for the device.

There has been a great deal of development activity in the area of artificial hearts, and especially for devices to assist the left ventricle (LVADs). Generally, an assist device comprises an elastomeric blood chamber or diaphragm capped cavity. The blood chamber is provided with an inflow and an outflow valve for cannulation to the circulatory system. The blood chamber volume

is controlled with the elastomeric diaphragm or sac which is actuated to oscillate between a systolic and a diastolic position.

Canadian Patent No. 1,188,852 (Robinson) discloses a hydraulically actuated cardiac prosthesis with a hydraulic fluid reservoir, a hydraulic fluid pumping means and a blood pumping chamber with a flexible diaphragm. United States Patent No. 4,222,127 (Donachy et al.) discloses the Pierce-Donachy artificial heart including a blood pump, flexible diaphragm and an inflow and an outflow valves which can be used paracorporeally or intrathoracically. United States Patents Nos. 4,588,404 (Lapeyre) and 5,089,018 (Lapeyre et al.) disclose a biventricular cardiac prosthesis. The device is a sealed case with a dual membrane system for pumping the systemic and pulmonary circulations.

However, a major limitation of these past devices is their physical shape, size, placement of implantation and complexity which increase the surgical complexity of implanting these devices. Power and information transfer requirements of the past devices have also required percutaneous access to the implantation site with its associated risk of infection. These limitations have also had an effect on the length of time that these devices can be implanted.

Recently, devices for transferring power and electrical control signals from an external component to a implanted device without perforating the skin have been developed. This breakthrough has established the potential for a totally implantable devices.

Anatomical fit also has a significant impact on the ease of surgical implantation, organ compression, patient comfort and postoperative complications. The internal body cavity dimensions have been recognized as a prime limitation in the design of implantable, mechanical circulatory devices.

To date no comprehensive fundamental system has been patented that provides for the integration of the major components into a compact, lightweight, totally implantable unit which can be implanted in the chest cavity.

Summary of the Invention

The present invention relates to the field of equipment and prosthesis as a circulatory device aid for assisting or replacing the right and/or left ventricle of the natural heart.

In accordance with the present invention there is provided an integrated system for use in an electrohydraulic ventricular assist device wherein the system is adapted for implantation in the thorax and for cannulation to the blood circulatory system comprising: an internal electronic controller for generating an actuating signal; a blood pumping chamber wherein the blood pumping chamber includes: an inlet port for receiving blood from the blood circulatory system; an outlet port for providing blood to the blood circulatory system; wherein the inlet port and the outlet port are each equipped with a one-way valve to ensure unidirectional flow of blood therethrough; a volume displacement chamber for storing a volume displacement medium; and actuating means for converting the actuating signal into a pulsating rhythmic displacement of the displacement medium wherein the pulsating rhythmic displacement causes a rhythmic unidirectional flow of blood through the blood pumping chamber.

The present invention is also directed to an electrohydraulic ventricular assist device adapted for cannulation to the blood circulatory system comprising: an integrated system means adapted to be implanted in a human thorax proximal to the human heart to replace or assist a ventricle including: an internal electronic controller for generating an actuating signal; and blood pumping means having an inflow blood port and an outflow blood port for cannulation to the blood circulatory system, the pumping means displacing blood through the inflow and outflow ports in response to the actuating signal; wherein the system means has an overall size and geometry such that when placed within the human thorax, the system means do not adversely compress adjacent organs, create dead space or limit chest closure; rechargeable internal battery means adapted for subcutaneous implantation, the rechargeable internal battery means producing an internal supply voltage for the integrated system means; transcutaneous energy transformer (TET) means; first coupling means for connecting the internal battery means to the integrated system means; and second coupling means for connecting the integrated system means to the transcutaneous energy transformer means thereby establishing a communication channel between the TET means and the integrated system means.

It is an object of the present invention to provide a totally implantable circulatory assist device which integrates the main components of the device (actuation means, volume displacement chamber, control electronics and blood pump) into one compact system herein referred to as the Integrated System.

5 It is another object of the present invention to provide an Integrated System which is totally implantable within the chest cavity and requires no physical connections (tubes and wires) through the skin to the outside of the body. The Integrated System is powered by either an implantable battery or a transcutaneous energy transfer system. The Integrated System is controlled and monitored remotely via a transcutaneous information telemetry or by said control electronics. This
10 arrangement results in a reduction of the number of surgical sites required for insertion of the system. As a result, this integration reduces the risk of infection by eliminating the need for direct physical access from outside of the body to inside by perforation of the skin. Furthermore, abdominal implantation and the need for abdominal surgery can be avoided. Thus the diaphragm will not be penetrated and the implant will not cause problems for soft tissue organs in the abdomen
15 such as the spleen, liver, intestine, etc. which are easily disturbed. Placing the Integrated System in the chest cavity further allows for anchoring to the chest cavity ribs, thus preventing critical organ damage, migration, infection and other complications associated with traditional abdominal implantation.

It is another object of the present invention to provide an Integrated System which is of a
20 size and geometry suitable for implantation in the patient's chest cavity without giving rise to any serious clinical disadvantage or inconvenience to the recipient's organs. This will result in a reduction in cannulation lengths to the natural heart, thus reducing hydraulic resistance, kinking, turbulence, separation and recirculation of the blood.

Still another object of the present invention is to provide an Integrated System having an
25 overall thickness of less than 4 cm, an overall length less than 18 cm and an overall width less than 12 cm with sagittal and transverse curvatures compatible to the human anatomy.

It is a further object of the present invention to provide an Integrated System which can be adapted for electrical, thermal, magnetic or mechanical actuation. This will result in the ability to select the best possible actuation means available at the time of design.

It is a further object of the present invention to provide an Integrated System which due to the configuration is suitable for use as a right, left or bi-ventricular device. This will result in a device which can be used in a wider range of patient population and diagnosis.

It is further object of the present invention to provide an Integrated System which due to the integration of the major components allows some components to act as housings for other components. This will result in an overall reduction in amount of housing materials required, thus reducing the volume and weight of the system.

It is a further object of the present invention to provide an Integrated System which due to the integration of the main components allows the volume displacement medium (either fluid or gas) to disperse heat from the actuation means and the control electronics throughout the device and to the circulation system via the pumped blood and contact of the lungs with the volume displacement chambers system.

It is a further object of the present invention to provide an Integrated System which has shorter electrical connections, thus reducing electrical losses.

It is a further object of the present invention to provide an Integrated System which has shorter actuation connections, thus reducing actuation losses.

It is a further object of the present invention to provide an Integrated System which can be secured to the rib cage to prevent migration and organ compression.

It is a further object of the present invention to provide an Integrated System which can be implemented into many different geometrical configurations but at the same time meeting all necessary physical constraints.

Brief Description of the Drawings

These and other features of the invention will become more apparent from the following description in which reference is made to the appended drawings, wherein:

Figure 1 is a schematic diagram of an Integrated System according to the present invention;

Figure 2a is a top plan of an Integrated System in accordance with a first embodiment of the present invention;

Figure 2b is a right elevation of an Integrated System in accordance with a first embodiment of the present invention;

Figure 3a is a top plan of an Integrated System in accordance with a second embodiment of the present invention;

5 **Figure 3b** is a front elevation of an Integrated System in accordance with a second embodiment of the present invention;

Figure 4a is a top plan of an Integrated System in accordance with a third embodiment of the present invention;

10 **Figure 4b** is a front elevation of an Integrated System in accordance with a third embodiment of the present invention;

Figure 5 is a front elevation of an Integrated System in accordance with a fourth embodiment of the present invention.

Description of the preferred embodiment

15 A companion application, now Canadian Patent #2,105,935, was applied for on the same day as the present application.

Referring to the drawings, a schematic diagram and several embodiments of an integrated system for use in an electrohydraulic ventricular assist device (EVAD) are shown. The same reference numbers are used to described the same elements in the various drawings.

20 Figure 1 is a schematic diagram of an integrated system in accordance with the present invention. The Integrated System 10 incorporates the major components of an EVAD into a compact system which ensures convenient implantation into the thorax and direct cannulation to the blood circulatory system. The Integrated System 10 comprises a blood chamber 4 which receives blood via inflow blood port 2 from the body's circulation system. A one-way valve (not shown) in
25 the inflow blood port 2 ensures unidirectional flow of blood into the blood chamber 4. Blood is returned to the body's circulation system through outflow blood port 3. A one-way valve (not shown) in the outflow blood port 3 ensures unidirectional flow of blood out of the blood chamber 4. The system also includes a volume displacement chamber 6. The volume displacement chamber stores a volume displacement medium (fluid or gas). The system further includes actuation means 5

and an internal electronic controller 1 for generating an actuating signal. The actuation means 5 employed in the integrated system 10 can be electrical, thermal, magnetic or mechanical. The internal electronic controller 1 and the actuation means 5 are powered by either an internally implanted battery or a transcutaneous energy transfer system, via hermetic connector 7. The control electronics can also be controlled and monitored remotely via hermitic connector 7 to a transcutaneous information telemetry system. The control electronics 1 generate an actuating signal in response to sensing the status of the blood chamber 4 (*i.e.* full or empty).

In response to the actuating means 5 receiving an actuating signal from the internal electronic controller 1, the actuating means 5 converts said signal into a pulsating rhythmic displacement of said displacement medium in said volume displacement chamber 6. This pulsating rhythmic displacement causes a corresponding rhythmic unidirectional flow of blood through said blood pumping chamber. When connected to a patient's circulatory system, therefore, said system causes blood to flow through said patient's circulatory system.

Figures 2a and 2b depict a top and right side view respectively of an integrated system in accordance with a first embodiment of the present invention. The dark arrows depict the direction of blood flow therethrough.

Figures 3a and 3b depict a top and front view respectively of an integrated system in accordance with a second embodiment of the present invention. The dark arrows depict the direction of blood flow therethrough.

Figures 4a and 4b depict a top and front view respectively of an integrated system in accordance with a third embodiment of the present invention. The dark arrows depict the direction of blood flow therethrough.

Figure 5 depicts a front view of an integrated system in accordance with a fourth embodiment of the present invention. The dark arrows depict the direction of blood flow

therethrough. The embodiment shown in Figure 5 has been designed, fabricated and tested (in vitro and acute in vivo). This version of the device has proven the concepts advantages and confirmed the overall constraints as outlined.

5 Experimental Investigations

In order to determine the size and geometrical constraints of the Integrated System for an intrathoracic placement, thoracic dimensions in cadavers and fit acceptability in live patients has been assessed. To determine the acceptable size of the device for the present invention, some preliminary estimates of the size constraints in the left thoracic cavity were obtained using disc
10 models of varying thickness and diameters. Disks with 2 cm to 6 cm thickness and diameters between 8 cm and 12 cm were placed in the intended implant location of the left anterior chest wall of cadavers, after a chest wall incision. The maximum disk thickness and diameter that could fit into cadaver, without causing organ compression was recorded. Chest cavity dimensions were obtained during the autopsy of nineteen cadavers, eight within 24 hours of death and eleven
15 preserved cadavers. A total of 19 cadavers were used for the experiments, the sizes are given in Table 1.

TABLE 1

Cadavers	n	Height (cm) Mean $\pm$ SEM	Weight (kg) Mean $\pm$ SEM
Fresh			65.6 $\pm$ 9.0
Male	4	175.0 $\pm$ 5.6	88.0 $\pm$ 4.6
Female	4	158.5 $\pm$ 4.2	43.2 $\pm$ 5.0
Preserved	11	174.8 $\pm$ 1.6	70.9 $\pm$ 4.6
Male	10	179.9 $\pm$ 1.4	73.7 $\pm$ 4.0
Female	1	165.0	45.0
Total	19	171.2 $\pm$ 2.3	68.5 $\pm$ 4.6

The cadaveric anatomical dimensions that were measured which are summarized in Table 2.

TABLE 2

Anatomical Dimension	Distance (cm)	Range (cm)
	Mean $\pm$ SEM	
Left ventricular apex to chest wall	2.8 $\pm$ 0.3	1.5 - 3.5
Midline anterior-posterior	10.6 $\pm$ 0.6	6.0 - 14.5
Root of the aorta to the diaphragm	8.6 $\pm$ 0.4	7.0 - 10.0
Sternum length	18.9 $\pm$ 1.2	12.0 - 24.0
Thorax width at 1st rib	15.6 $\pm$ 1.2	10.5 - 21.0
Thorax width at 5th rib	24.6 $\pm$ 0.5	20.0 - 30.0
Thorax width at 9th rib	28.4 $\pm$ 2.2	18.0 - 35.0
Midline to left lateral chest wall	12.2 $\pm$ 0.7	9.5 - 14.0
4th-9th rib vertical midclavicle distance	16.3 $\pm$ 1.8	12.0 - 22.0
Sagittal radius of curvature at 5th rib	11.1 $\pm$ 0.5	9.0 - 12.0
Transverse radius of curvature at 5th rib	9.4 $\pm$ 0.5	8.5 - 10.0

The most critical dimension that defines the configuration of the integrated system was the ventricular apex to the chest wall which was found to be 2.8 $\pm$ 0.3 cm. The sagittal radius of curvature at the 5th rib was found to be 11.1 $\pm$ 0.5 cm and the transverse radius of curvature at the 5th rib was found to be 9.4 $\pm$ 0.5 cm.

An epoxy model of one of the Integrated System configurations was made based on these cadaveric anatomical dimensions. In addition, six sterilizable epoxy version models of this design were available for intraoperative fit trials. Following informed consent, the prototype models were placed in the left chest cavity in patients varying in weight from 65 to 100 Kilograms and heights from 155 to 190 Centimetres who were undergoing various cardiac procedures.

Based on the cadaver fit trials and interoperative patient fit trials the following conclusions were drawn:

1. An integrated system having a thickness of less than 4 cm and a diameter of 11 cm with a sagittal and transverse radius of curvature of 11.1 cm and 9.4 cm respectively could be accommodated in the intrathoracic cavity of the cadavers studied without significant compression of vital structures such as the heart and left pulmonary hilus.
2. With intrathoracic positioning of the integrated system, outflow cannulation could be routed anteriorly over the lungs to the root of the ascending aorta. The length of the inflow cannulation, therefore, would be very short due to its proximity to the left/right ventricular apex.
3. The size of the integrated system could be no larger than 18 cm x 12 cm x 4 cm for the range of human bodies studied.
4. Various other geometrical configurations of the integrated system (as shown in Figures 2 to 5) are feasible, provided that they are within the size and shape constraints outlined above.

5 **THE EMBODIMENTS OF THE INVENTION IN WHICH AN EXCLUSIVE
RIGHT OR PRIVILEGE IS CLAIMED ARE DEFINED AS FOLLOWS:**

1. An integrated system for use in an electrohydraulic ventricular assist device wherein said
system is adapted for implantation in the thorax and for cannulation to the blood circulatory system
10 comprising:

an internal electronic controller for generating an actuating signal;

a blood pumping chamber wherein said blood pumping chamber includes:

an inlet port for receiving blood from said blood circulatory system;

an outlet port for providing blood to said blood circulatory system;

15 wherein said inlet port and said outlet port are each equipped with a one-way valve to
ensure unidirectional flow of blood therethrough;

a volume displacement chamber for storing a volume displacement medium; and

actuating means for converting said actuating signal into a pulsating rhythmic displacement
of said displacement medium wherein said pulsating rhythmic displacement causes rhythmic
20 unidirectional flow of blood through said blood pumping chamber.

2. An integrated system as claimed in claim 1, wherein said system is totally implantable
within the chest cavity and requires no physical connections penetrating through the skin to the
outside of the body.

25 3. An integrated system as claimed in claim 2, having a size and geometry resulting in a
relatively short conduit length to the natural heart.

4. An integrated system as claimed in claim 2, wherein said system has a size and geometry
suitable for implantation in the chest cavity where said device does not adversely compress adjacent
30 organs, create dead space or limit chest closure after implantation.

- 5 5. An integrated system as claimed in claim 1, wherein said system has an overall length less than 18 cm, an overall width less than 12 cm and an overall thickness of less than 4 cm.
6. An integrated system as claimed in claim 1, wherein said system has an overall longitudinal radius of curvature of 11 ± 0.5 cm and a transversal radius of curvature of 9.4 ± 0.5 cm.
7. An integrated system as claimed in claim 1, wherein said system can be adapted for use with
10 an electrical, thermal, magnetic or mechanical actuation means.
8. An integrated system as claimed in claim 1, wherein said system is geometrically configured for use as a left, right or biventricular assist device.
9. An integrated system as claimed in claim 1, including a hermetic connector for connecting a power source to said internal electronic controller.
- 15 10. An integrated system as claimed in claim 1, which uses said volume displacement medium as a means to disperse heat from said actuation means and said internal electronic controller throughout the system to minimize tissue necrosis due to heat.
11. An integrated system as claimed in claim 10, wherein said system disperses heat from said system to said circulatory system via the pumped blood and contact of the lungs with said volume
20 displacement chamber.
12. An integrated system as claimed in claim 1, wherein said system provides for relatively short electrical connections by integration of the components therein into a compact arrangement.
13. An integrated system as claimed in claim 1, wherein said system provides for relatively short actuation connections by integration of the components therein into a compact arrangement.

- 5 14. An integrated system as claimed in claim 2, wherein said system can be secured within the chest cavity to prevent migration and organ compression.
15. An integrated system as claimed in claim 1, wherein said system can be implemented into many different geometrical configurations to meet the requirements of different actuation means, but at the same time meeting all necessary physical constraints.
- 10 16. An electrohydraulic ventricular assist device adapted for cannulation to the blood circulatory system comprising:
- an integrated system means adapted to be implanted in a human thorax proximal to the human heart to replace or assist a ventricle including:
- an internal electronic controller for generating an actuating signal; and
- 15 blood pumping means having an inflow blood port and an outflow blood port for cannulation to the blood circulatory system, said pumping means displacing blood through said inflow and outflow ports in response to said actuating signal;
- wherein said system means has an overall size and geometry such that when placed within the human thorax, said system means do not adversely compress adjacent
- 20 organs, create dead space or limit chest closure;
- rechargeable internal battery means adapted for subcutaneous implantation, said rechargeable internal battery means producing an internal supply voltage for said integrated system means;
- transcutaneous energy transformer (TET) means;
- 25 first coupling means for connecting said internal battery means to said integrated system means; and
- second coupling means for connecting said integrated system means to said transcutaneous energy transformer means thereby establishing a communication channel between said TET means and said integrated system means.

- 5 17. A device as claimed in claim 16, wherein said integrated system means is totally implantable within the chest cavity and requires no physical connections penetrating through the skin to the outside of the body, the chest cavity including a rib cage.
18. A device as claimed in claim 17, wherein said integrated system means has a size and geometry resulting in a relatively short conduit length to the natural heart.
- 10 19. A device as claimed in claim 17, wherein said integrated system means has a size and geometry suitable for implantation in the chest cavity where said device does not adversely compress adjacent organs, create dead space or limit chest closure after implantation.
20. A device as claimed in claim 16, wherein said integrated system means has an overall length less than 18cm, an overall width less than 12 cm and an overall thickness less than 4 cm.
- 15 21. A device as claimed in claim 16, wherein said integrated system means has an overall longitudinal radius of curvature of 11 ± 0.5 cm and a transversal radius of curvature of 9.4 ± 0.5 cm.
22. A device as claimed in claim 16, wherein said integrated system means can be adapted for use with an electrical, thermal, magnetic or mechanical actuation means.
- 20 23. A device as claimed in claim 16, wherein said integrated system means is geometrically configured for use as a left, right or biventricular assist device.
24. A device as claimed in claim 16, wherein said integrated system means uses common housing components to reduce the overall housing material required.
25. A device as claimed in claim 16, wherein said integrated system means further includes a volume displacement chamber for storage of a volume displacement medium wherein said volume

5 displacement medium is used as a means to disperse heat from said actuation means and said internal electronic controller throughout the device to minimize tissue necrosis due to heat.

26. A device as claimed in claim 25, wherein said integrated system means disperses heat from said device to said circulatory system via the pumped blood and contact of the lungs with said volume displacement chamber.

10 27. A device as claimed in claim 16, wherein said integrated system means provides for relatively short electrical connections by integration of the components therein into a compact arrangement.

28. A device as claimed in claim 16, wherein said integrated system means provides for relatively short actuation connections by integration of the components therein into a compact
15 arrangement.

29. A device as claimed in claim 16, wherein said integrated system means can to be secured within the chest cavity to prevent migration and organ compression.

30. A device as claimed in claim 16, wherein said integrated system means can be implanted into many different geometrical configurations to meet the requirements of different actuation
20 means, but at the same time meeting all necessary physical constraints.

FIGURE 1

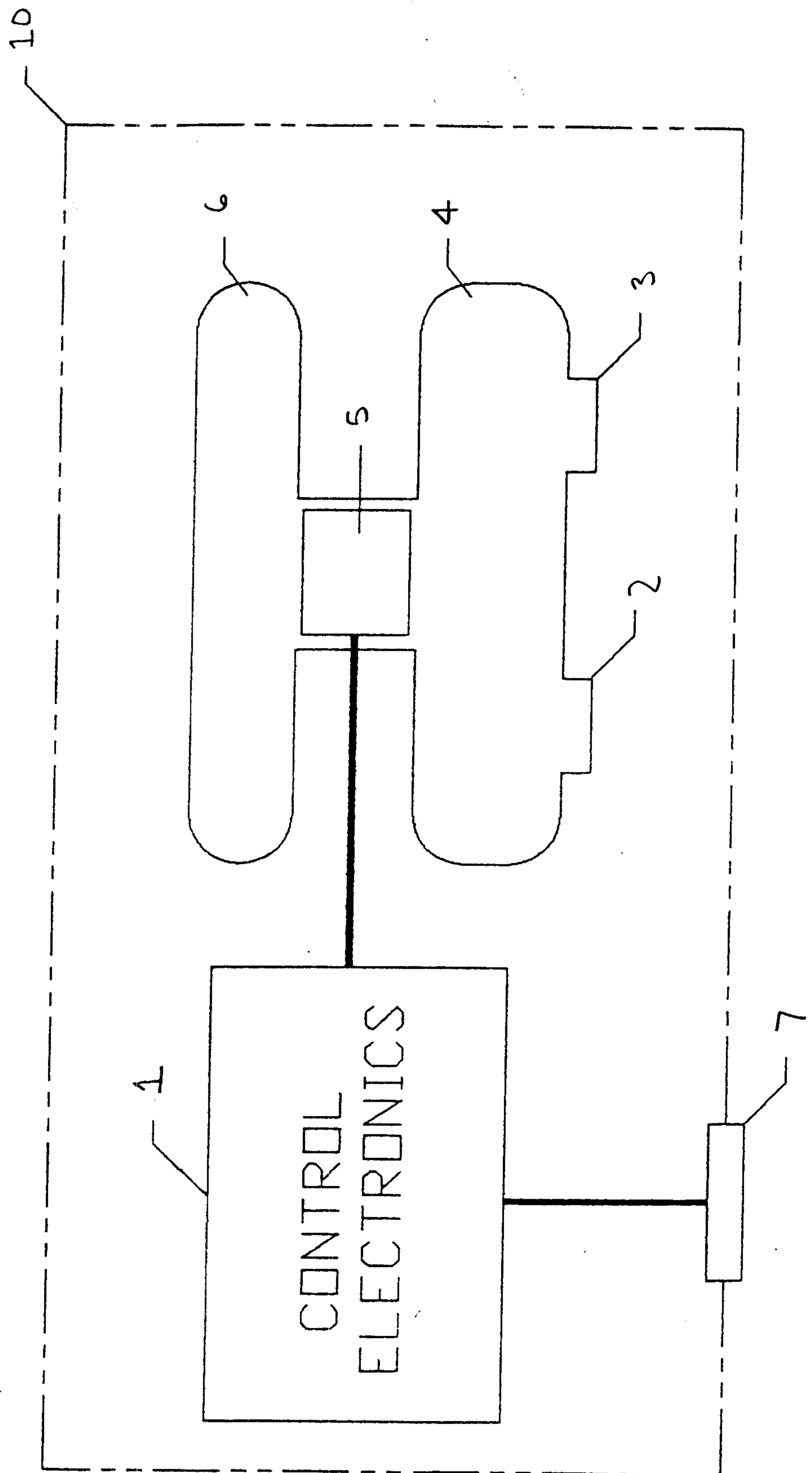
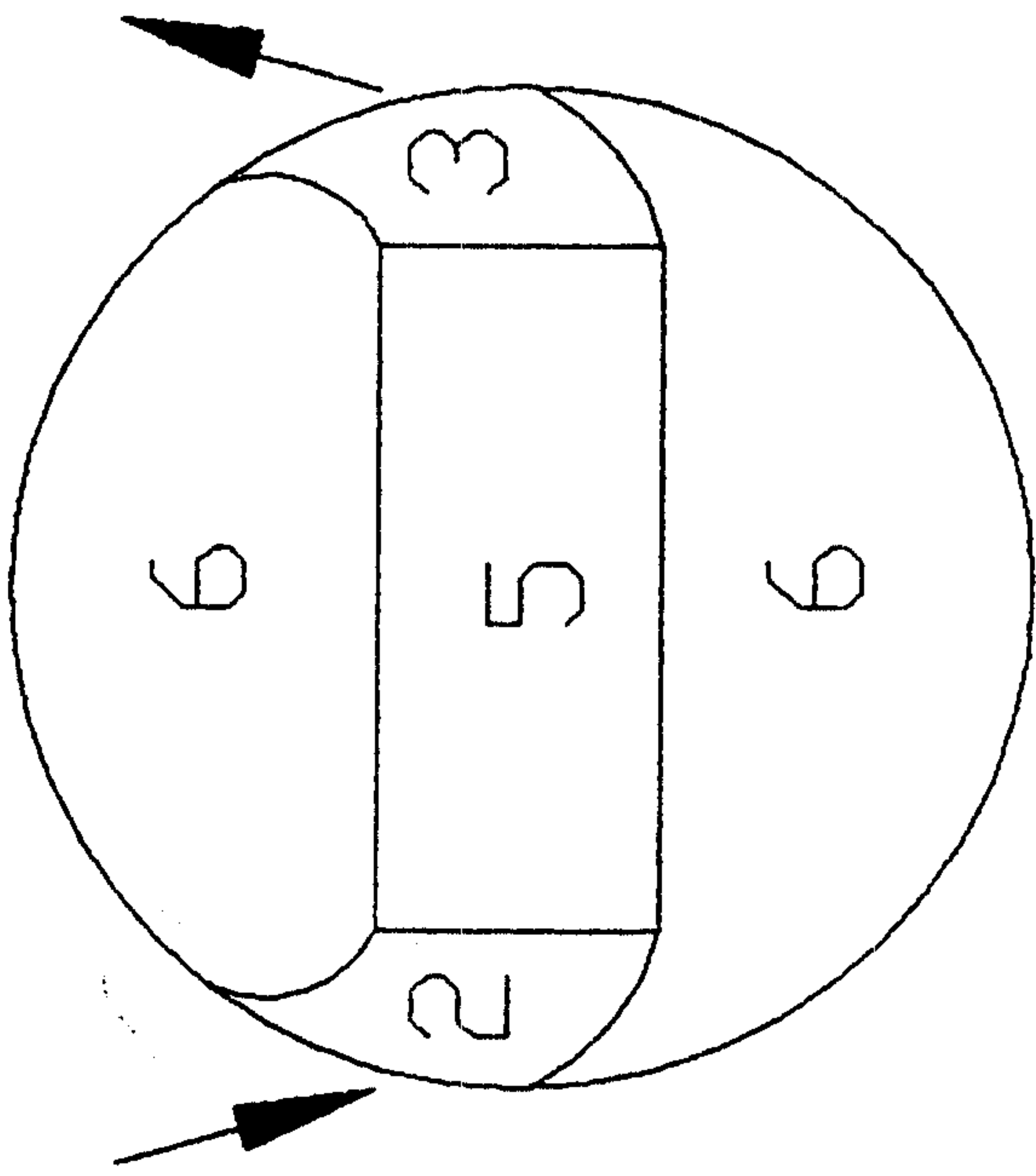


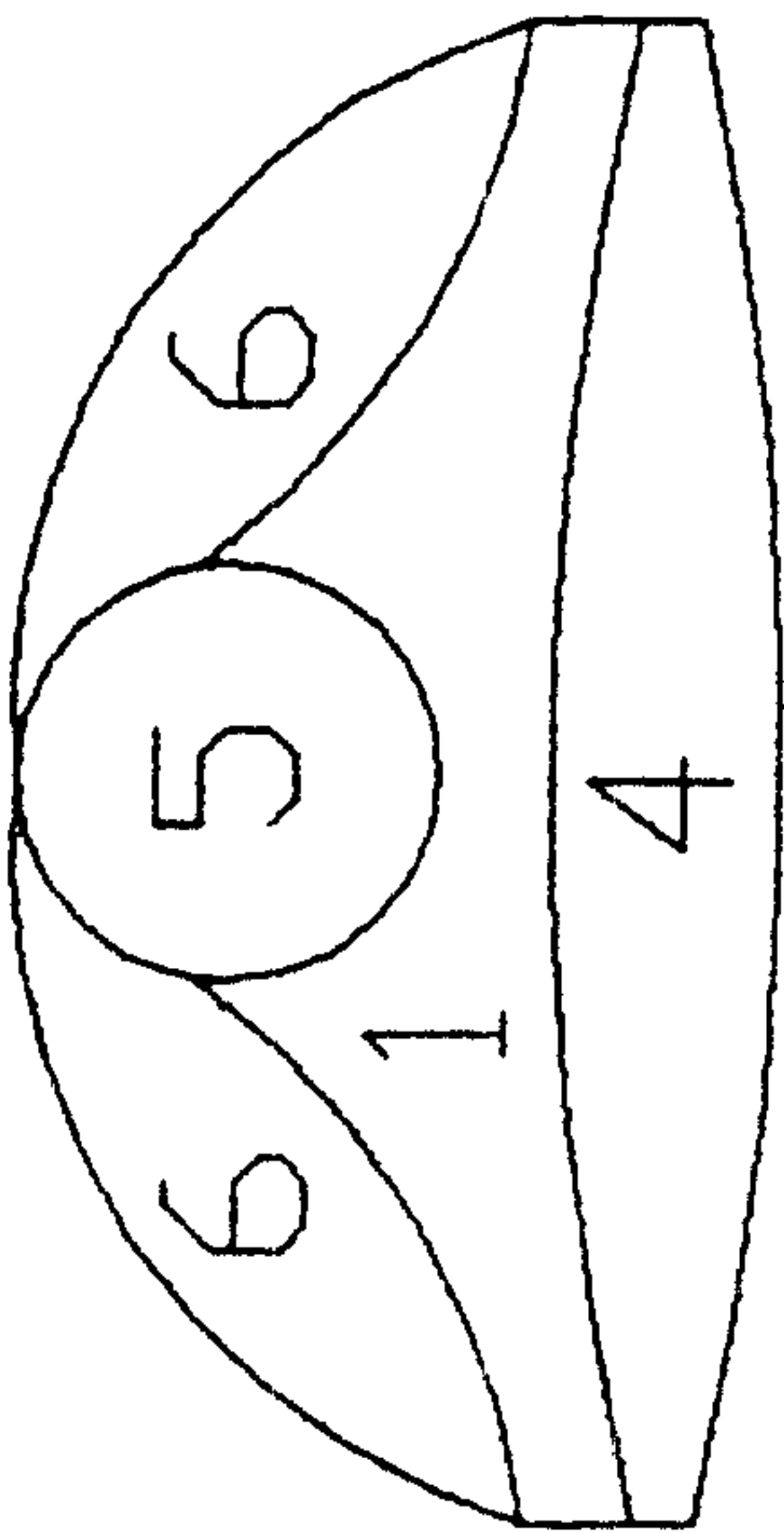
FIGURE 2

Fig 2A



TOP VIEW

Fig 2B

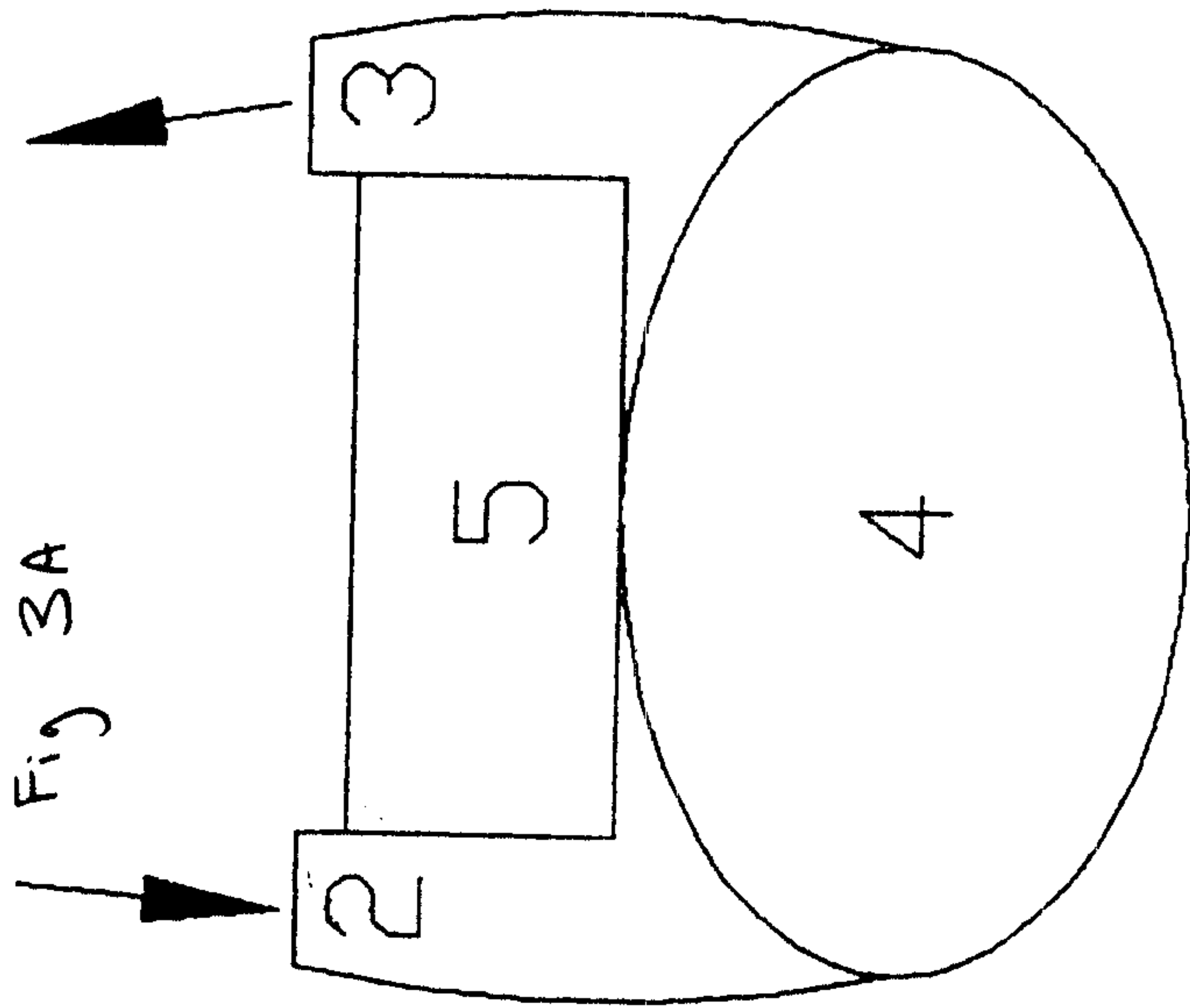


SIDE VIEW

LEGEND

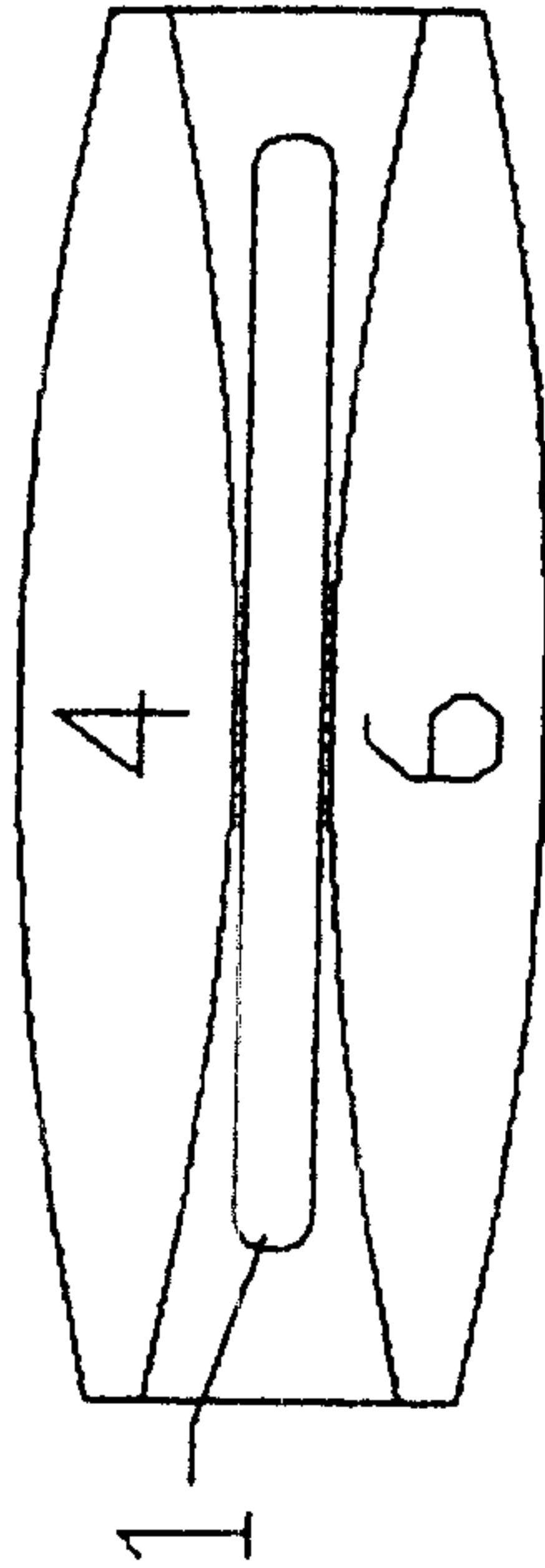
- 1. CONTROL ELECTRONICS
- 2. INFLOW BLOOD PORT
- 3. OUTFLOW BLOOD PORT
- 4. BLOOD CHAMBER
- 5. ACTUATOR
- 6. VOLUME DISPLACEMENT CHAMBER

FIGURE 3



TOP VIEW

Fig 3B



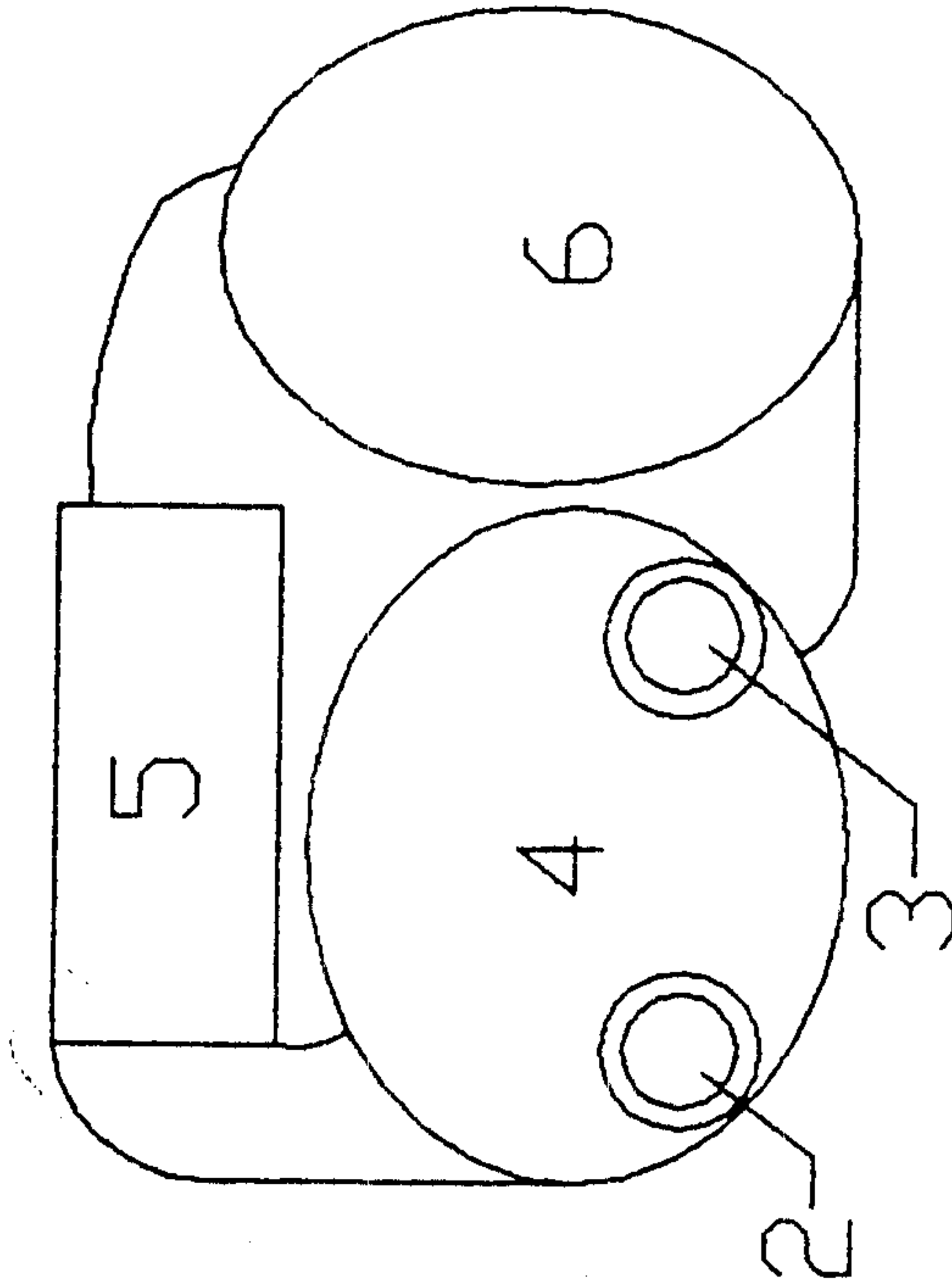
FRONT VIEW

LEGEND

- 1. CONTROL ELECTRONICS
- 2. INFLOW BLOOD PORT
- 3. OUTFLOW BLOOD PORT
- 4. BLOOD CHAMBER
- 5. ACTUATOR
- 6. VOLUME DISPLACEMENT CHAMBER

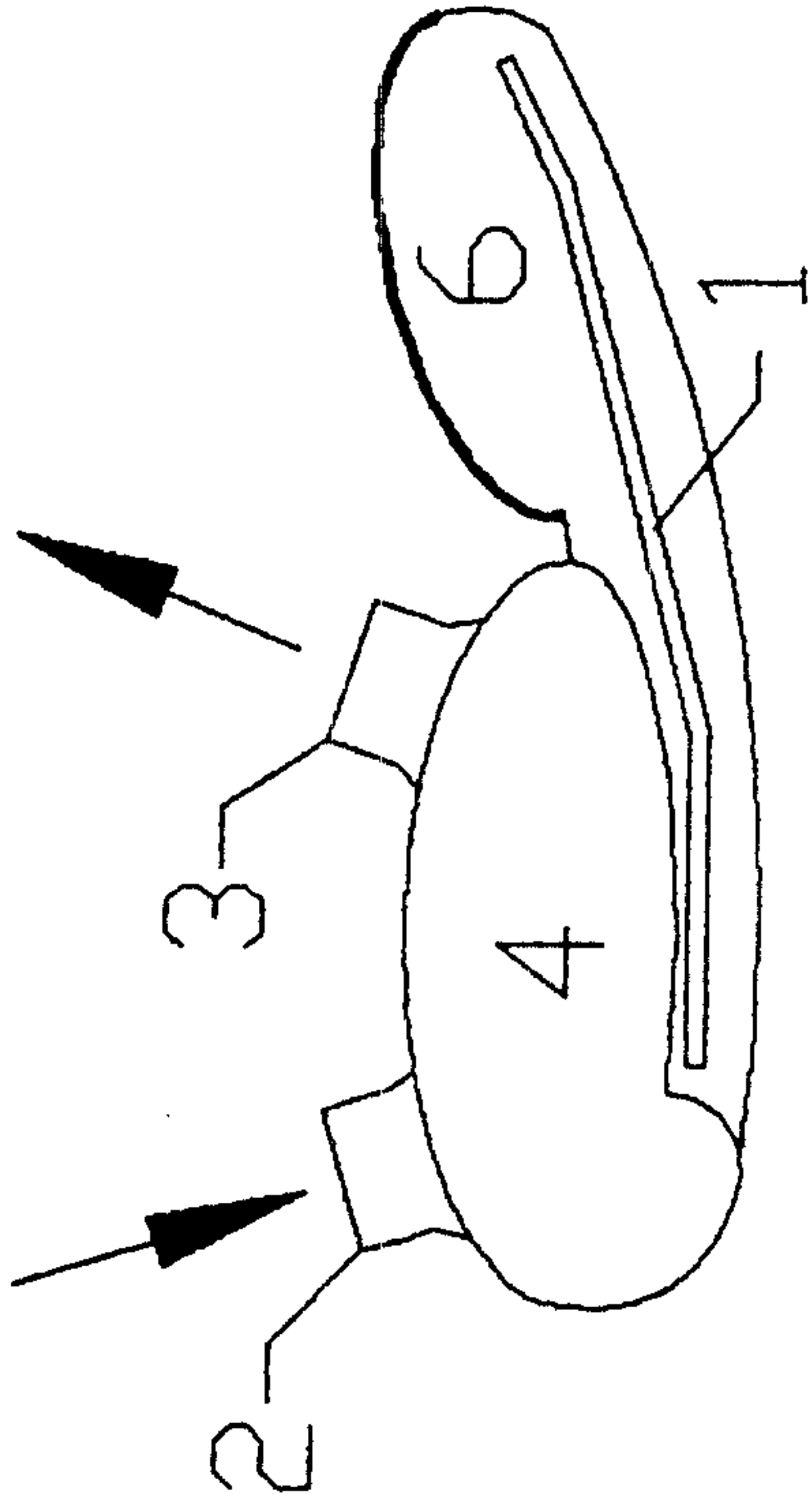
FIGURE 4

Fig 4A



TOP VIEW

Fig 4B

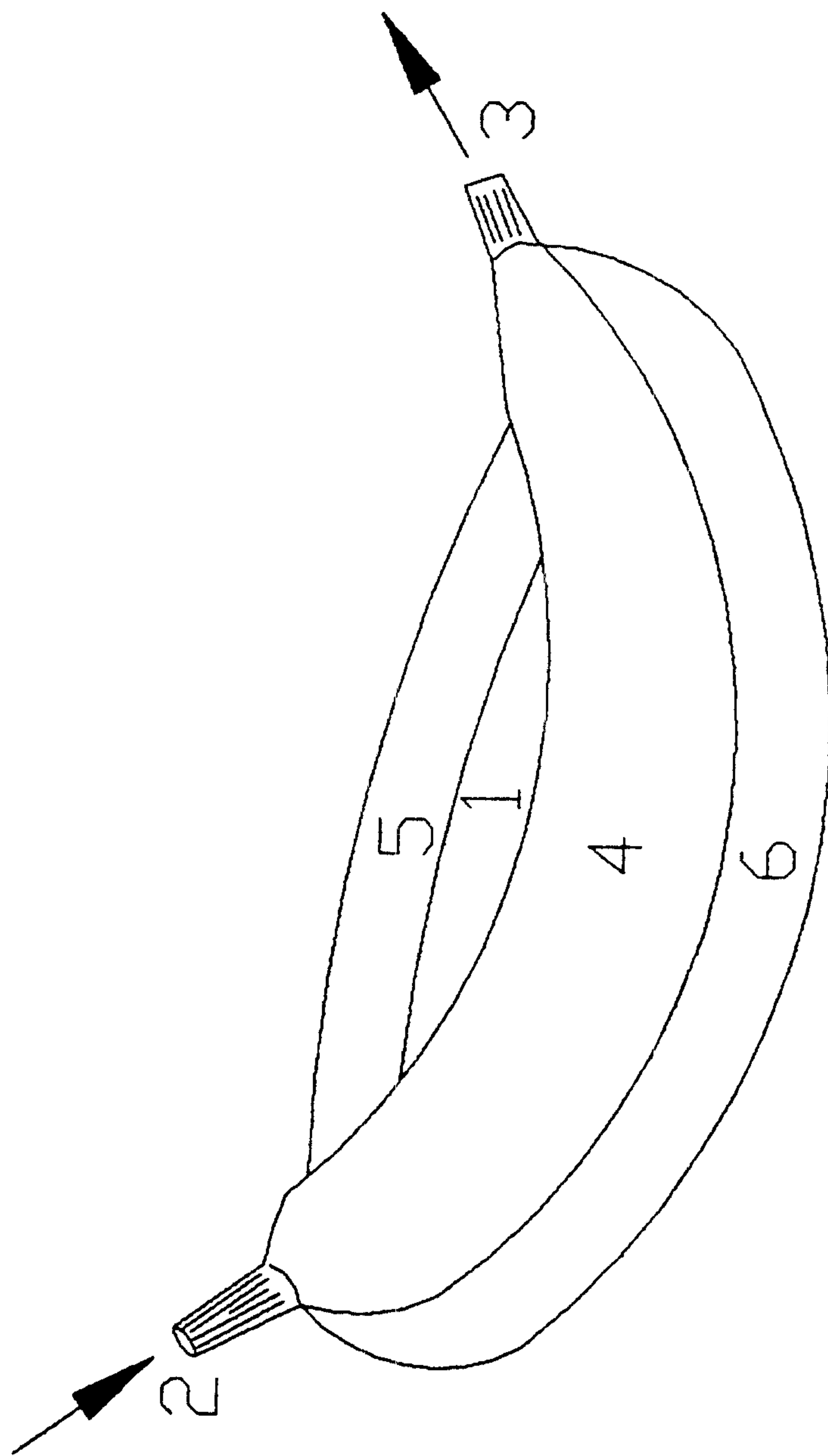


FRONT VIEW

LEGEND

- 1. CONTROL ELECTRONICS
- 2. INFLOW BLOOD PORT
- 3. OUTFLOW BLOOD PORT
- 4. BLOOD CHAMBER
- 5. ACTUATOR
- 6. VOLUME DISPLACEMENT CHAMBER

FIGURE 5



FRONT VIEW

LEGEND

1. CONTROL ELECTRONICS
2. INFLOW BLOOD PORT
3. OUTFLOW BLOOD PORT
4. BLOOD CHAMBER
5. ACTUATOR
6. VOLUME DISPLACEMENT CHAMBER

