

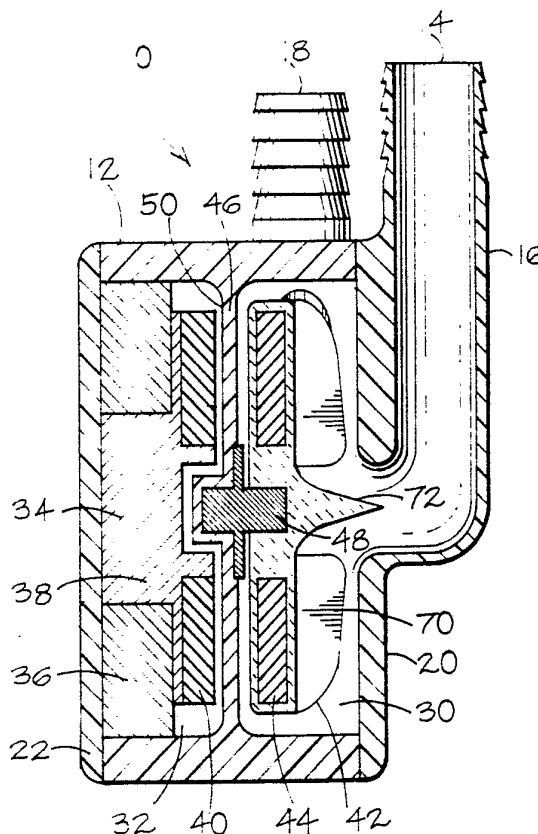


INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(21) International Application Number: PCT/US91/06049 (22) International Filing Date: 23 August 1991 (23.08.91) (30) Priority data: 573,425 24 August 1990 (24.08.90) US (71) Applicant: BAYLOR COLLEGE OF MEDICINE [US/US]; One Baylor Plaza, Houston, TX 77030 (US). (72) Inventors: FELDMAN, Louis ; 2810 Conway, Houston, TX 77025 (US). NOON, George, P. ; 9010 Sandringham, Houston, TX 77024 (US). DeBAKEY, Michael, E. ; 5325 Cherokee, Houston, TX 77005 (US). FERNANDEZ, Juan, A. ; 8125 Ithaca, Houston, TX 77017 (US).		(74) Agent: LAUNER, Charlene, A.; Fulbright & Jaworski, 1301 McKinney #5100, Houston, TX 77010-3095 (US). (81) Designated States: AT (European patent), AU, BE (European patent), CA, CH (European patent), DE (European patent), DK (European patent), ES (European patent), FR (European patent), GB (European patent), GR (European patent), IT (European patent), JP, LU (European patent), NL (European patent), SE (European patent). Published <i>With international search report.</i>

(54) Title: CARDIAC ASSIST CENTRIFUGAL PUMP**(57) Abstract**

A cardiac assist centrifugal pump (10) used for pumping human blood that may be surgically implanted in a patient or used extracorporeally. The pump (10) consists of two chambers (30 and 32) isolated from each other, one houses an electric motor (34) the other an impeller (42). The impeller (42) is rotatably fastened to the floor of the impeller chamber (30) by a stabilizing pin (48) used to eliminate float and other irregular motion of the impeller (42) which may cause damage to the blood cells. A face seal (62) is used to prevent blood collecting in low flow areas of the impeller (42) which may cause blood clots to form. A magnetic coupler (40 and 44) is used to transfer the motor's rotational power to the impeller (42) and to assist in maintaining the sealing integrity of the face seal (62) over prolonged and continuous operation of the pump (10).



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⁺ Any designation of "SU" has effect in the Russian Federation. It is not yet known whether any such designation has effect in other States of the former Soviet Union.

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CARDIAC ASSIST CENTRIFUGAL PUMP

BACKGROUND OF THE INVENTION

1. Field of the Invention

5 This invention relates to continuous delivery blood pumps, and more particularly a cardiac assist centrifugal blood pump that may be implanted in a body cavity or used extracorporeally.

2. Description of the Related Technology

10 Heart disease severe enough to require some means of cardiac support will affect tens of thousands of people a year. The most effective treatment is cardiac transplantation, however, there is a large backlog of patients waiting for donor hearts because the number of potential recipients far outnumber donors. If the condition of these patients deteriorates before a donor heart becomes available,
15 mechanical support systems must be used to keep the patients alive.

20 Mechanical cardiac support systems in current use are mounted external to the patient's body. These systems require external power sources which usually are housed in large consoles and require tubes and wires through the skin to the cardiac pump mounted inside the patient's body. Connection of the patient to all of this equipment virtually immobilizes him. In some instances the equipment is so cumbersome that it cannot be used in smaller patients such as children

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and may not be tolerated well even by adult patients. In addition, infection around the body entry of the tube and wires are common. This type of infection is difficult to treat and, also, the body's immunization systems commonly cause failure of the mechanical assist mechanisms.

5 Not all cardiac patients require a heart transplant. There are cardiac patients who have some ventricular function but whose cardiac output is below that which will maintain sufficient blood circulation. These patients may function normally with a relatively small
10 augmentation of their cardiac output. What is needed is a small, implantable, tether-free cardiac pumping device.

SUMMARY OF THE INVENTION

The present invention is a centrifugal pump that may be implanted in a cardiac patient's body to assist the heart in maintaining
15 adequate blood circulation to sustain his life. This invention has low power consumption and may be powered from portable batteries attached to the patient's body. Thus a patient, not having sufficient cardiac circulation by his own heart, may function normally by means of the invention.

20 When pumping body fluids, especially blood, the pump system must be sterilizable to limit the risk of infection to the patient. The materials used in the pump must not trigger the body's immunological defense system nor be adversely affected by corrosive elements normally found in the body. In dealing with blood, any device used
25 must not destroy red blood cells ("hemolytic") or create blood clots ("thrombogenic"). In addition, small size, low power requirements and minimal heat generation are important features of any device that may be implanted in a cardiac patient's body and powered through the skin or by batteries.

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It is therefore an object of the present invention to provide a cardiac centrifugal pump including two separate chambers and an isolator, such as a wall, preventing liquids and gases from communicating between chambers. One chamber houses part of a magnetic coupler and a pump impeller which propels the blood. The second chamber contains a motor and the other part of the magnetic coupler. Thus, the present invention eliminates the need for rotary seals which are used to prevent fluids from getting into the motor. Rotary seals tend to wear out and leak.

Another object of the present invention is the use of a stabilizing pin to rotatably attach the impeller to the impeller chamber. Without this stabilizing pin the impeller would "float" in the blood in the chamber because there is no direct mechanical coupling between the impeller and the motor shaft. This floating action may make the impeller motion erratic and cause the spinning impeller to "lift" and hit the cover of the centrifugal pump housing with disastrous consequences. Thus, the stabilizing pin prevents irregular impeller motion within the impeller chamber. Irregular impeller motion within the impeller chamber may cause hemolysis.

Yet another object of the present invention is the use of a thin stainless steel sheet to stiffen the wall separating the impeller chamber from the motor chamber. The magnetic coupler requires close proximity for efficient operation, therefore, the distance between coupling magnets must be very short. Close spacing of the coupling magnets can only be reliably used when the rigidity and dimensional integrity of the isolator separating the two chambers is maintained.

Still another object of the present invention is the use of a face seal between the back of the impeller and the isolating wall face located in the impeller chamber. Significant failures are caused in centrifugal pumps used in blood by clots forming in the impeller chamber. The

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clot forms at the center of rotation where there is an area of low flow ("stasis"). The present invention uses a face seal to prevent blood from reaching the center of rotation of the stabilizing pin means. The face seal consists of two parts, a stabilizing pin which has a flange and an
5 ultra high molecular weight polyethylene disk or more preferably, a ceramic disk which rides on the raised rib, or more preferably an elastomer. The disk may be press fitted into a cavity machined into the back of the impeller. In addition, the integrity of this seal is maintained by the magnetic force keeping the two parts together, thus,
10 making up for wear and improving the seal tolerances with use. Further, a second rib or elastomer may be placed between the first rib or elastomer and the shaft of the stabilizing pin.

Yet still another object of the present invention is the use of a nose cone on the front face of the impeller for gentler handling of blood
15 as it flows onto the impeller blades. Blood is easily damaged and care in minimizing blood cell bruising will reduce hemolytic effects.

A further object of the present invention is the use of a motor with low temperature rise and materials of low friction coefficient so as to reduce the effects of heating. Blood exposed to temperatures of 45
20 degrees C will be hemolyzed. The present invention has not exceeded 35 degrees C during tests and is within safe operating temperature limits for human blood.

Yet a further object of the present invention is implanting the pump in the abdominal cavity of the cardiac patient and using batteries
25 to power the pump motor. The batteries may be externally worn by the patient with electrical connections formed through the patient's skin. Alternatively, the batteries may be internally mounted in the abdominal cavity and recharged by an inductive energy transfer means. The patient's abdomen performs its intended function as a membrane seal
30 without foreign objects protruding through it.

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5 Still a further object of the present invention is to use the pump either internally or extracorporeally as a heart-lung machine during open heart surgery. Such uses are as a standby pump in cardiac catheterization, retrieval of donor hearts from remote locations, and in cardiopulmonary bypass surgery in place of a roller pump.

10 The present invention is a cardiac assist centrifugal pump that may be implanted directly in a patient's body or used externally ("extracorporeally"). The present invention consists of a housing, a motor, an impeller, an inlet manifold including an inlet and an outlet. The housing is divided into two chambers, one houses the motor and the other the impeller. Magnetic coupler is used to transfer the rotational power of the motor to the impeller of the pump. The impeller is rotatably attached to a wall of the impeller chamber, the wall located between the impeller and motor chambers, by a stabilizing pin. This stabilizing pin prevents irregular impeller motion which may cause hemolysis.

15 Other and further objects, uses, features and advantages which are included within the scope of the claims of this invention will become readily apparent to those skilled in the art after reading the following description of a present exemplary embodiment of the invention, given for the purpose of disclosure and taken with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

25 FIG. 1 is a side elevation view of a preferred embodiment of the present invention;

FIG. 2 is a front elevation view of a preferred embodiment of the present invention;

FIG. 3 is a view taken along the line 3-3 of FIG. 1;

FIG. 4 is a view taken along the line 4-4 of FIG. 2;

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FIG. 5 is an exploded sectional view of a preferred embodiment of an impeller and pin assembly of the present invention;

FIG. 6 is an assembled sectional view of the impeller and pin assembly of FIG. 5.

5 DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring now to the drawings, and particularly to Figs. 1 and 2, the reference 10 generally indicates a cardiac assist centrifugal pump of the present invention that may be implanted in a patient's body or mounted extracorporeally. The cardiac assist pump 10 comprises a housing 12 having an inlet 14, an inlet manifold 16, an outlet 18, an impeller chamber cover 20 and a motor chamber cover 22. The covers 20 and 22 may be secured to the housing 12 by screws 24.

As best seen in Fig. 4, the housing 12 of the cardiac assist pump 10 has two chambers, an impeller chamber 30 and a motor chamber 32. The chambers 30 and 32 are isolated from each other and do not allow the transmission of either liquids or gases between chambers. Normally, body fluids such as blood flows through the impeller chamber 30 entering at the inlet 14 and exiting at the outlet 18. The motor chamber 32 is a gas and liquid tight housing for an electric motor 34. The electric motor 34 comprises a stator 36 and a rotor 38. The rotor 38 has magnets 40 fixedly attached thereto. An impeller 42, in the impeller chamber 30, has magnets 44 imbedded therein. The impeller magnets 44 are in close proximity with the rotor magnets 40 for the purpose of efficiently coupling the rotational energy of the motor 34 to the impeller 42.

In the present invention, the rotational energy of the motor 34 is transmitted to the impeller 42 by a magnetic coupler comprised of closely coupled magnets 40 and 44. Thus, the impeller chamber 30 and the motor chamber 32 may be totally isolated from each other.

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Integral to housing 12 is a thin wall 46 which separates the chambers 30 and 32. The impeller 42 is attached to the wall 46 by a stabilizing pin assembly 48. The wall 46 may be made, for example, from polycarbonate plastic laminated with a thin stainless steel sheet 50. The stainless steel sheet 50 may be used to reinforce the wall 46. Use of polycarbonate plastic laminated with stainless steel is a preferred embodiment of the wall 46 of the present invention, but any material or combination thereof having suitable stiffness to properly support and keep in alignment the impeller 42 is claimed. The stainless steel sheet 50 does not affect the magnetic coupling of magnets 40 and 44.

The stabilizing pin assembly 48 prevents irregular motion of the impeller 42. Any irregular motion of the impeller 42 may cause hemolysis. If the impeller 42 was not position stabilized with respect to the impeller chamber 30, then the impeller 42 could float in the blood and hit the cover 20 with disastrous consequences. The present invention accomplishes a stable positional relationship between the impeller 42, the cover 20 and impeller chamber 30 by using of the stabilizing pin assembly 48. The pin assembly 48 is attached to the wall 46 which isolates the impeller chamber 30 from the motor chamber 32.

Referring now to Fig. 5, the pin assembly 48 includes a machined stainless steel shaft 52 having upper and lower threaded ends 57 and 55, respectively, a thin flange 53 machined between both threaded ends 55 and 57, a disk 54, and ball bearing bushings 56. The disk 54 may be made of ultra high molecular weight polyethylene or, more preferably, ceramic. The outside diameter of the flange 53 matches the outside diameter of the disk 54. The inside diameter of the disk 54 matches the outside diameter of the shaft 52 and fits rotatably over it. The ball

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bearing bushings 56 fit rotatably over the shaft 52 and are secured thereto by a locking nut 58 on the upper threaded end 57.

The stabilizing pin assembly may be press fitted into a precisely machined cavity 60 in the back of the impeller 42. The lower threaded
5 end 55 is fixedly attached to the wall 46 and steel sheet 50 by a locking nut 59. The bottom face of the flange 53 forms a seal in cooperation with the wall 46 and steel sheet 50. The impeller 42 may freely rotate about the axis of the stabilizing pin 48 without lifting or otherwise adversely moving in the impeller chamber 30.

10 Prior art centrifugal pumps have failed due to blood clot formation. Blood clots form at the center of impeller rotation where there is an area of low flow ("stasis"). The present invention includes a face seal 62 which prevents blood from reaching the stabilizing pin assembly 48, thus, eliminating an area of possible stasis. The face seal
15 62 is comprised of a raised rib or elastomer 64 located on the outer circumference of the top face of the flange 53 and the bottom face of the disk 54. The disk 54 rides on the raised rib or, more preferably, an elastomer 64 creating a rotating seal that is further aided by the attractive magnetic forces between magnets 40 and 44. A second rib or,
20 more preferably, a second elastomer 65 may be placed between the first rib or elastomer 64 and the shaft of the stabilizing pin. Most preferably, the elastomer are biolor or silicon O-rings. The attractive magnetic forces will maintain the integrity of the face seal 62 by compensating for any wear of the raised rib 64 and disk 54 faces.

25 Referring now to Figs. 3 and 6, the impeller 42 front comprises, as a preferred embodiment, six vanes 70 and a nose cone 72. The nose cone 72 allows the blood to gently flow across the face of the impeller 42 while being accelerated by the vanes 70.

30 Materials used in the impeller assembly of the present invention may be, for example, ultra high molecular weight polyethylene or, more

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preferably, ceramic. This material is blood compatible and has excellent abrasion resistant qualities. The motor 34 may be, for example, an Inland Motor, DC brushless model BM 1501. This motor is small, light weight, adequate power and long life. The pancake type geometry
5 allows compact packaging in the motor chamber 32.

The present invention, therefore, is well adapted to carry out the objects and attain the ends and advantages mentioned as well as others inherent therein. While a presently preferred embodiment of the invention has been given for the purpose of disclosure, numerous
10 changes in the details of construction and arrangement of parts will readily suggest themselves to those skilled in the art and which are encompassed within the spirit of the invention and the scope of the appended claims.

What is claimed is:

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CLAIMS:

1. A cardiac assist centrifugal pump that may be connected to a patient and run continuously by means of an electric motor powered by batteries, comprising:

a housing, said housing having an impeller chamber and a motor chamber;

means for isolating said chambers from each other, whereby liquids and gases cannot communicate between said chambers;

means for blood inlet connected to said impeller chamber;

means for blood outlet from said impeller chamber, whereby said outlet means attaches to said impeller chamber in the area of maximum blood velocity from said impeller chamber;

a centrifugal impeller in said impeller chamber, whereby said impeller accelerates the blood flow from said inlet to said outlet means;

a stabilizing pin rotatably attached to said impeller and fixedly attached to said chamber isolating means, whereby said stabilizing pin prevents irregular impeller motion within said impeller chamber;

a face seal, between said impeller and said isolating means, whereby said face seal prevents blood from accumulating around said stabilizing pin;

an electric motor having a rotor and stator, said motor positioned inside said housing motor chamber; and

means for magnetically coupling said motor rotor to said impeller, whereby said motor's rotational power is transmitted to said impeller.

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2. The pump of claim 1, wherein the isolating means between the two chambers consists of a wall between the two chambers, said wall comprising a thin stainless steel stiffening sheet laminated with a polycarbonate wall material.

3. The pump of claim 1, wherein said inlet means includes an inlet manifold attached to an impeller chamber cover, whereby said inlet manifold directs blood flow onto said impeller front face.

4. The pump of claim 1, wherein said centrifugal impeller comprises six vanes attached to the front of said impeller extending outwardly from the center of its rotation axis.

5. The pump of claim 1, wherein said stabilizing pin comprises:

a stainless steel shaft having threaded top and bottom ends;

a flange fixed to said shaft and biased toward the bottom end of said shaft;

ball bearing bushings rotatably mounted on said shaft above said disk, whereby said disk and

said ball bearing bushings freely rotate about said shaft;

a first nut engaging the threaded top end of said shaft, said first nut securing said ball bearing bushings and said disk to said shaft; and

a second nut engaging the threaded bottom end of said shaft, whereby said stabilizing pin assembly is attached to said isolating means located between said chambers.

6. The pump of claim 5 wherein said disk is ceramic.

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7. The pump of claim 1, wherein said face seal comprises:
a flange fix mounted to the shaft of said stabilizing pin
and biased toward the bottom end of said shaft;
an elastomer located on the outer circumference of the top
face of said flange; and
a disk rotatably mounted on said shaft above the top face
of said flange, whereby the face of said disk is in communication
with said elastomer and free to rotate axially about said shaft.
8. The pump of claim 7, wherein said disk is ceramic.
9. The pump of claim 7, wherein the elastomer is a biolor or
silicon O-ring.
10. The pump of claim 7, further comprising a second
elastomer on the top face of said flange between the outer
circumference of said shaft and said shaft of said stabilizing pin.
11. The pump of claim 1, wherein said magnetic coupling
means comprises:
first permanent magnets fixed to said motor rotor; and
second permanent magnets attached to said impeller,
whereby said first magnets are in magnetic communication with
said second magnets for the purpose of transferring rotational
power from said electric motor to said impeller.
12. The pump of claim 1, wherein said stabilizing pin and face
seal assembly is press fitted into a machined cavity in the back of said
impeller.

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13. A cardiac assist centrifugal pump that may be connected to a patient and run continuously by means of an electric motor powered by batteries, comprising:

a housing, said housing having an impeller chamber and a motor chamber;

means for isolating said chambers from each other, whereby liquids and gases cannot communicate between said chambers;

means for blood inlet connected to said impeller chamber;

an inlet manifold, said inlet manifold attached between said housing impeller chamber and said blood inlet means;

means for blood outlet from said impeller chamber, whereby said outlet means attaches to said impeller chamber in the area of maximum blood velocity from said impeller chamber;

a centrifugal impeller in said impeller chamber, whereby said impeller accelerates the blood flow from said inlet to said outlet means;

a stabilizing pin rotatably attached to said impeller and fixedly attached to said chamber isolating means, whereby said stabilizing pin prevents irregular impeller motion within said impeller chamber;

a face seal, between said impeller and said impeller chamber isolating means, whereby said face seal prevents blood from accumulating around said stabilizing pin;

an electric motor having a rotor and stator, said motor inside of said housing motor chamber; and

means for magnetically coupling said motor rotor to said impeller, whereby said motor's rotational power is transmitted to said impeller.

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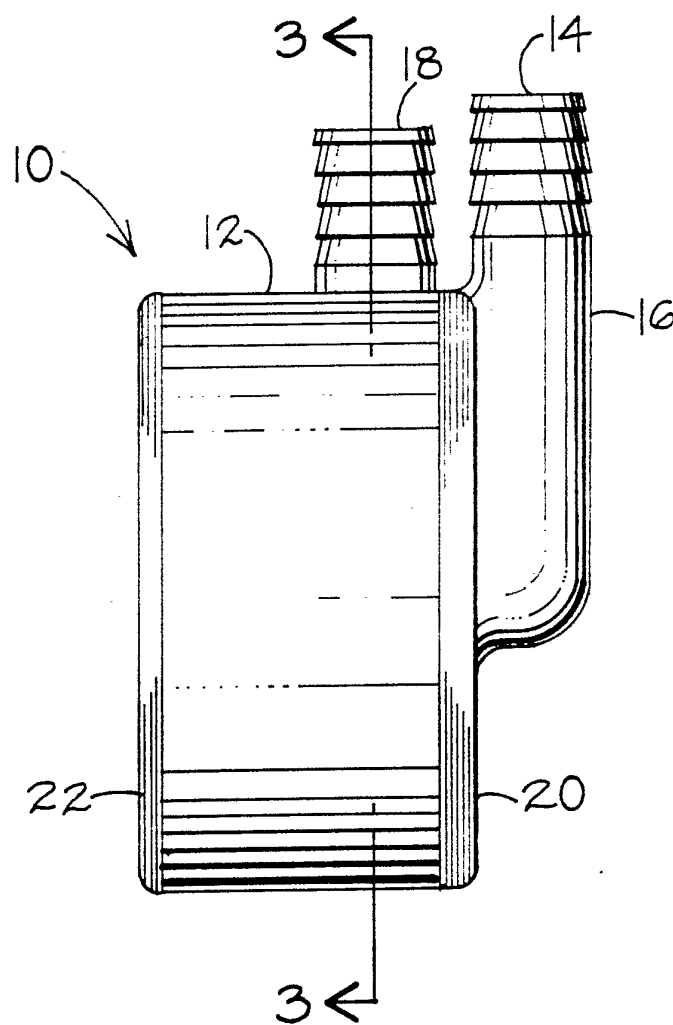


Fig. 1

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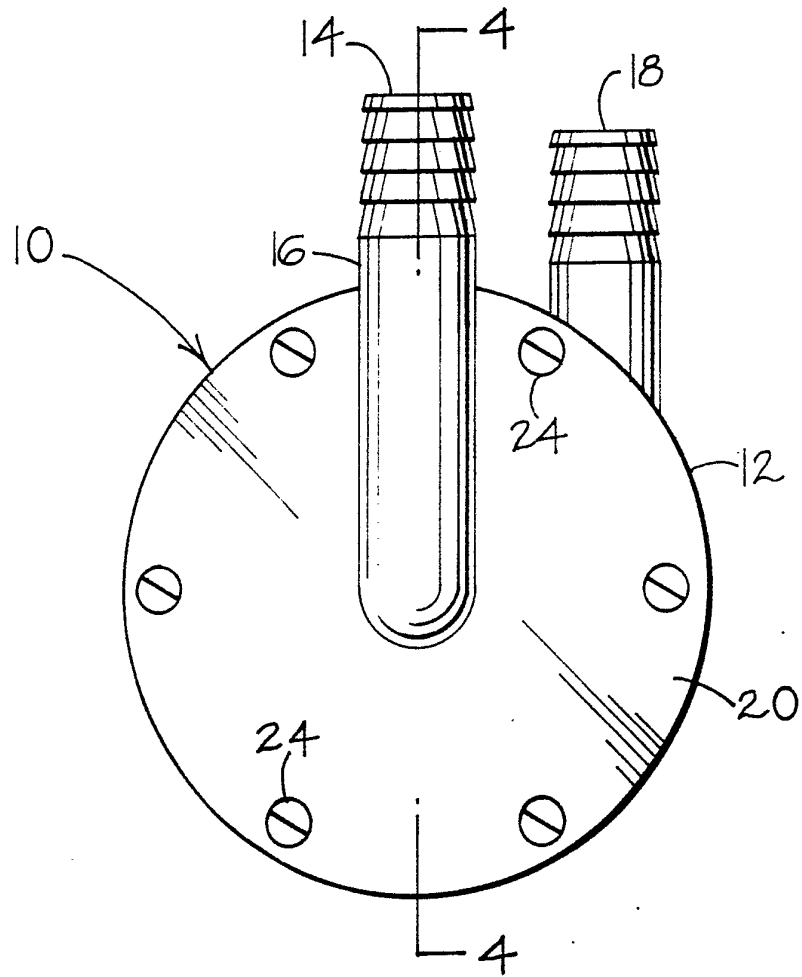


Fig. 2

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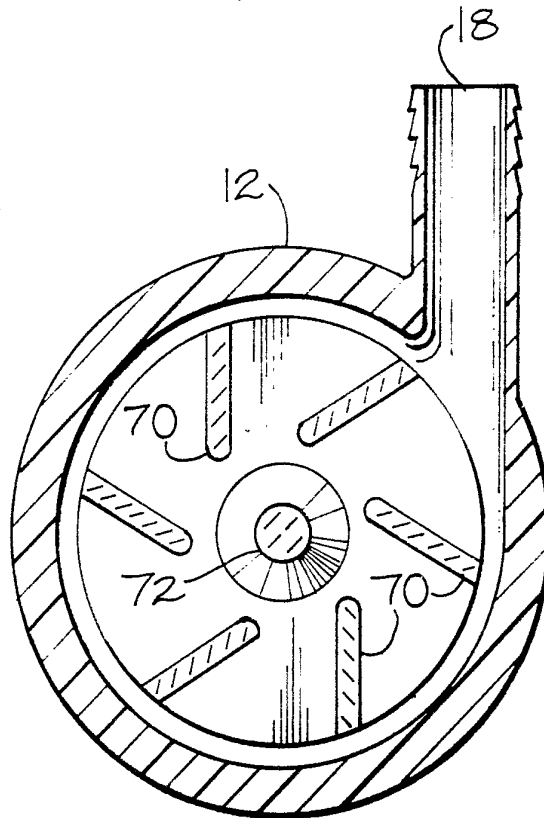


Fig. 3

SUBSTITUTE SHEET

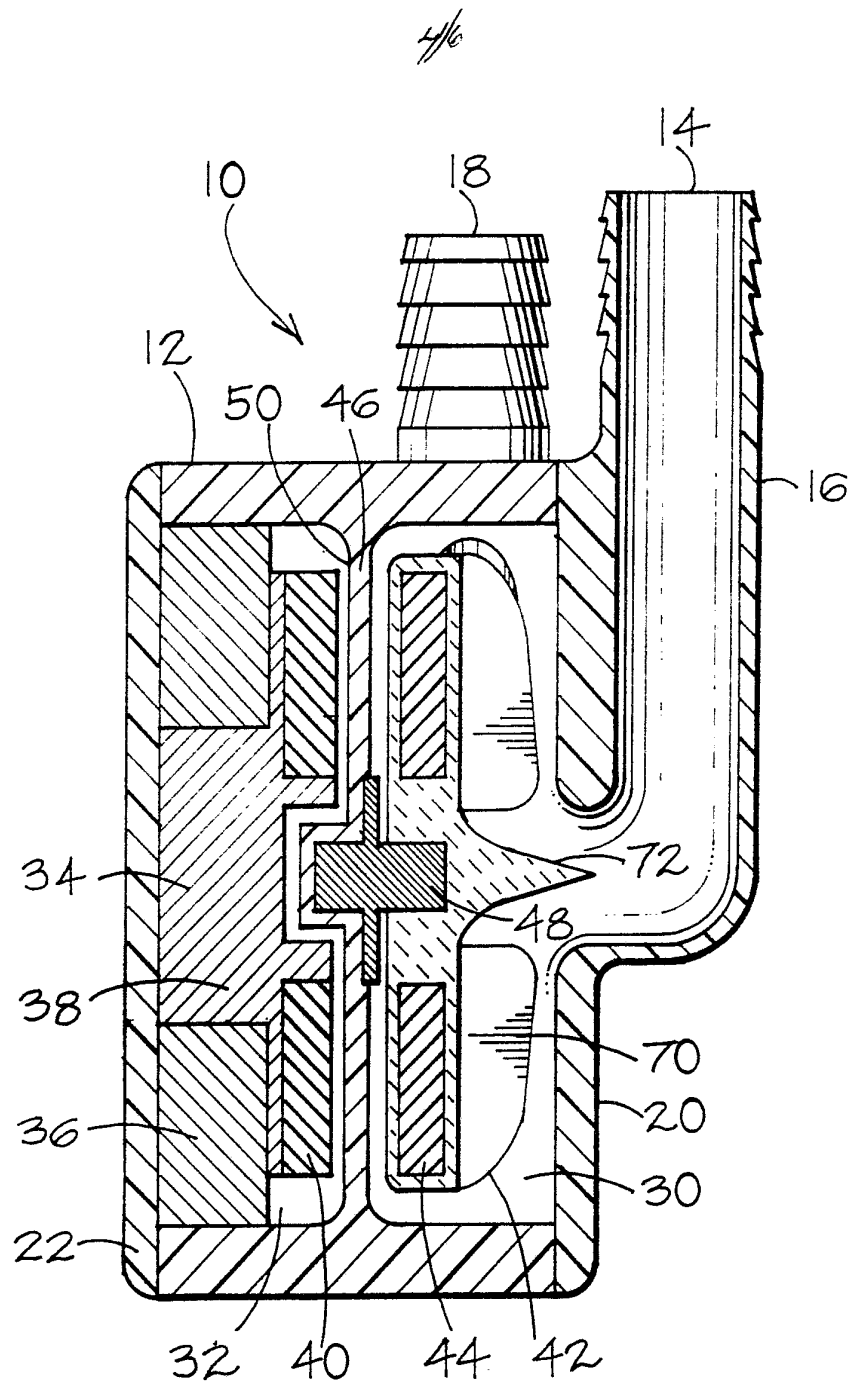


Fig. 4

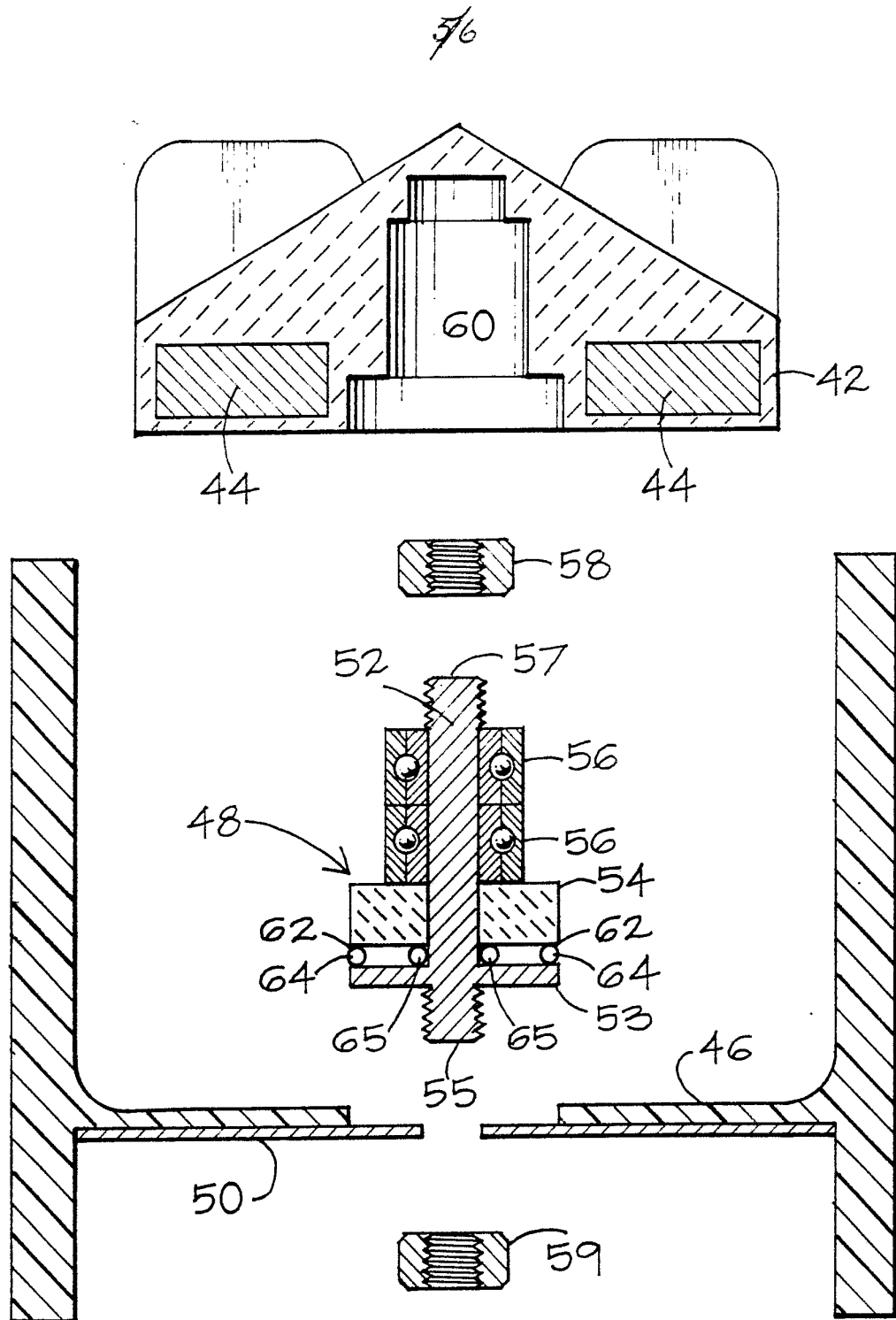
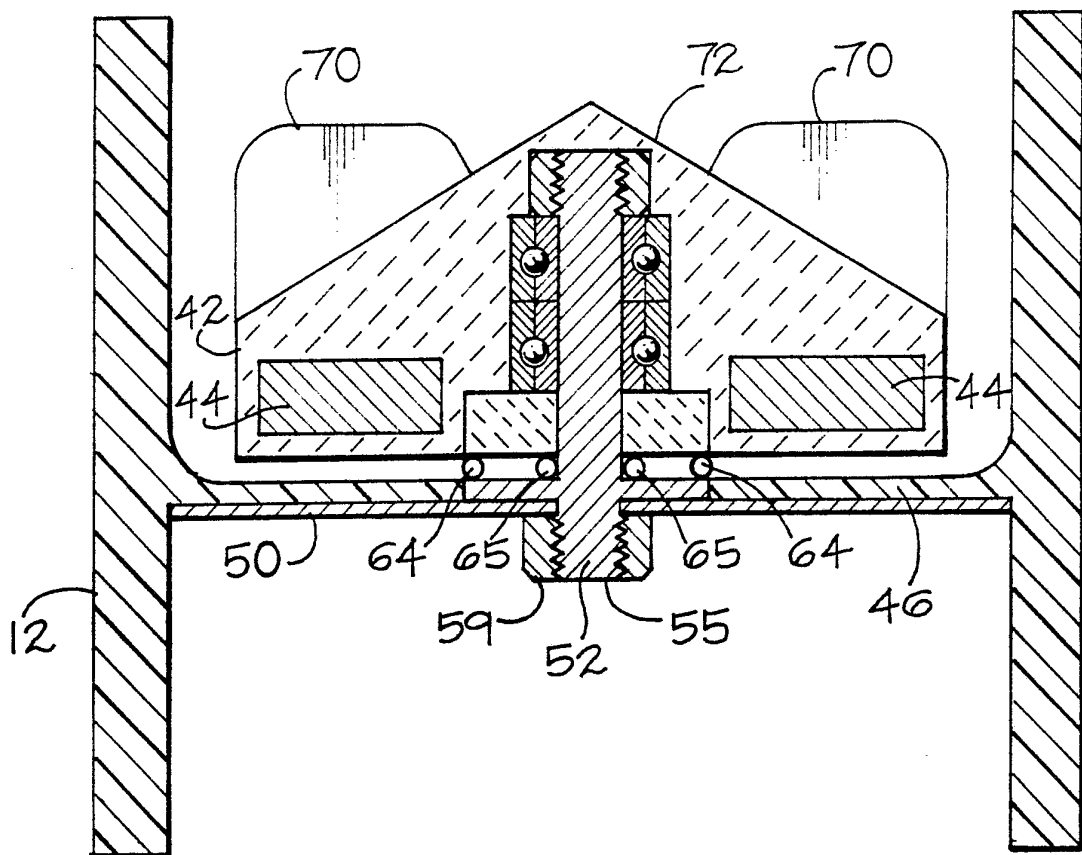


Fig. 5

SUBSTITUTE SHEET

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*Fig. 6*

SUBSTITUTE SHEET

INTERNATIONAL SEARCH REPORT

International Application No. PCT/US91/06049

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) ⁶ According to International Patent Classification (IPC) or to both National Classification and IPC IPC (5): A61N 1/362 U.S. CL: 600/016														
II. FIELDS SEARCHED Minimum Documentation Searched ⁷ <table style="width: 100%; border: none;"> <tr> <td style="width: 30%; border: none;">Classification System</td> <td style="border: none;">Classification Symbols</td> </tr> <tr> <td style="border: none; padding: 5px;">U.S. CL.</td> <td style="border: none; padding: 5px;">600/016-018 623/3</td> </tr> </table> Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched ⁸			Classification System	Classification Symbols	U.S. CL.	600/016-018 623/3								
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III. DOCUMENTS CONSIDERED TO BE RELEVANT ⁹ <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 10%; font-size: x-small;">Category [*]</th> <th style="width: 70%; font-size: x-small;">Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²</th> <th style="width: 20%; font-size: x-small;">Relevant to Claim No. ¹³</th> </tr> </thead> <tbody> <tr> <td style="text-align: center; vertical-align: top;">Y</td> <td>US, A, 3,932,068 ZIMMERMAN 13 JANUARY 1976 (See entire document).</td> <td style="text-align: center; vertical-align: top;">1-4,11-13</td> </tr> <tr> <td style="text-align: center; vertical-align: top;">Y</td> <td>US, A, 3,411,450 CLIFTON 19 NOVEMBER 1968 (See col.5, lines 58-67).</td> <td style="text-align: center; vertical-align: top;">1-4,11-13</td> </tr> <tr> <td style="text-align: center; vertical-align: top;">Y</td> <td>US, A, 4,226,574 VILLETTE 07 OCTOBER 1980 (See entire document).</td> <td style="text-align: center; vertical-align: top;">2</td> </tr> </tbody> </table>			Category [*]	Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³	Y	US, A, 3,932,068 ZIMMERMAN 13 JANUARY 1976 (See entire document).	1-4,11-13	Y	US, A, 3,411,450 CLIFTON 19 NOVEMBER 1968 (See col.5, lines 58-67).	1-4,11-13	Y	US, A, 4,226,574 VILLETTE 07 OCTOBER 1980 (See entire document).	2
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* Special categories of cited documents: ¹⁰ "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier document but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art. "&" document member of the same patent family														
IV. CERTIFICATION <table style="width: 100%; border: none;"> <tr> <td style="width: 50%; border: none;"> Date of the Actual Completion of the International Search 28 OCTOBER 1991 International Searching Authority ISA/US </td> <td style="width: 50%; border: none;"> Date of Mailing of this International Search Report 18 NOV 1991 Signature of Authorized Officer JOHN LACYK </td> </tr> </table>			Date of the Actual Completion of the International Search 28 OCTOBER 1991 International Searching Authority ISA/US	Date of Mailing of this International Search Report 18 NOV 1991 Signature of Authorized Officer JOHN LACYK										
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