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Aber

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[54] **BLOOD PUMP BEARING SYSTEM**

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[73] Assignee: **The United States of America as represented by the Administrator of the National Aeronautics and Space Administration**, Washington, D.C.

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Related U.S. Application Data

[63] Continuation-in-part of application No. 08/153,595, Nov. 10, 1993, Pat. No. 5,527,159, and a continuation-in-part of application No. 08/451,709, May 26, 1995, Pat. No. 5,678, 306.

[51] **Int. Cl.⁶** F04B 35/04
[52] **U.S. Cl.** **417/423.12**; 417/356; 384/907.1
[58] **Field of Search** 417/355, 356, 417/423.12; 384/246, 245, 244, 907.1, 913

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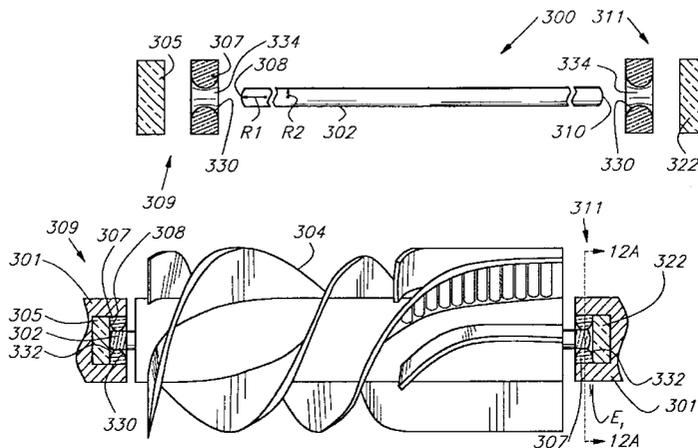
[57] **ABSTRACT**

Methods and apparatus are provided for a blood pump bearing system within a pump housing to support long-term high-speed rotation of a rotor with an impeller blade having a plurality of individual magnets disposed thereon to provide a small radial air gap between the magnets and a stator of less than 0.025 inches. The bearing system may be mounted within a flow straightener, diffuser, or other pump element to support the shaft of a pump rotor. The bearing system includes a zirconia shaft having a radiused end. The radiused end has a first radius selected to be about three times greater than the radius of the zirconia shaft. The radiused end of the zirconia shaft engages a flat sapphire endstone. Due to the relative hardness of these materials a flat is quickly produced during break-in on the zirconia radiused end of precisely the size necessary to support thrust loads whereupon wear substantially ceases. Due to the selection of the first radius, the change in shaft end-play during pump break-in is limited to a total desired end-play of less than about 0.010 inches. Radial loads are supported by an olive hole ring jewel that makes near line contact around the circumference of the shaft to support high speed rotation with little friction. The width of olive hole ring jewel is small to allow heat to conduct through to thereby prevent heat build-up in the bearing. A void defined by the bearing elements may fill with blood that then coagulates within the void. The coagulated blood is then conformed to the shape of the bearing surfaces.
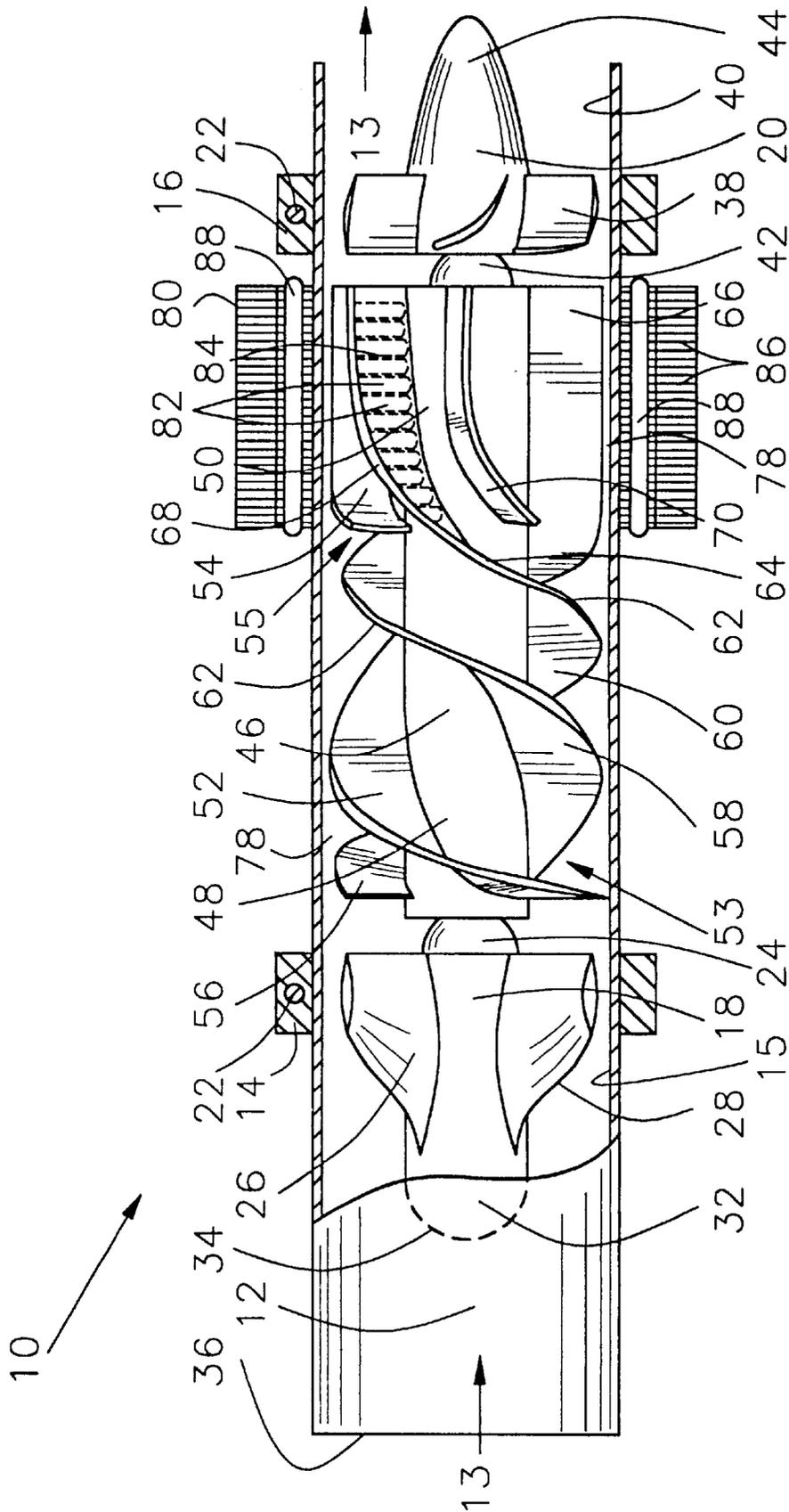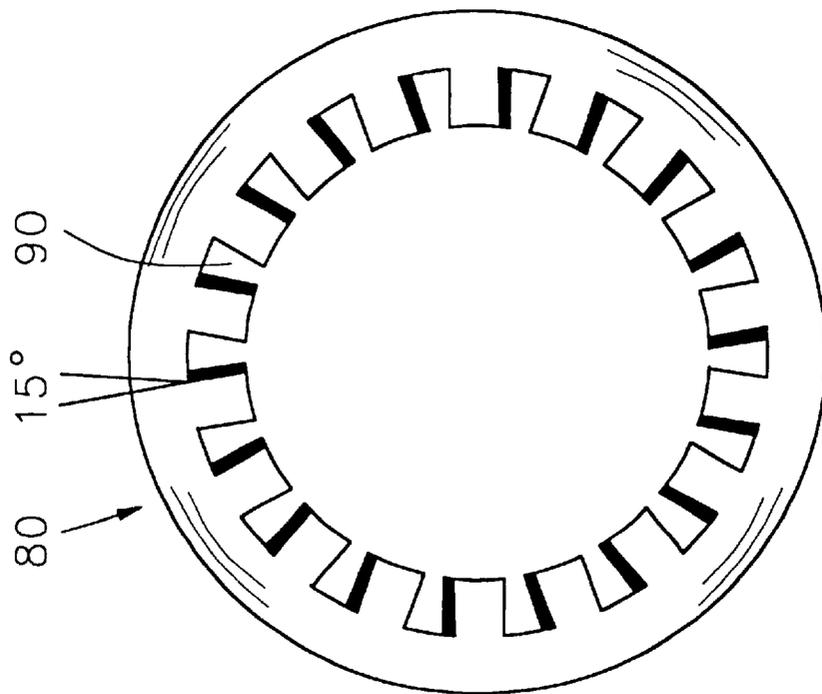
9 Claims, 11 Drawing Sheets
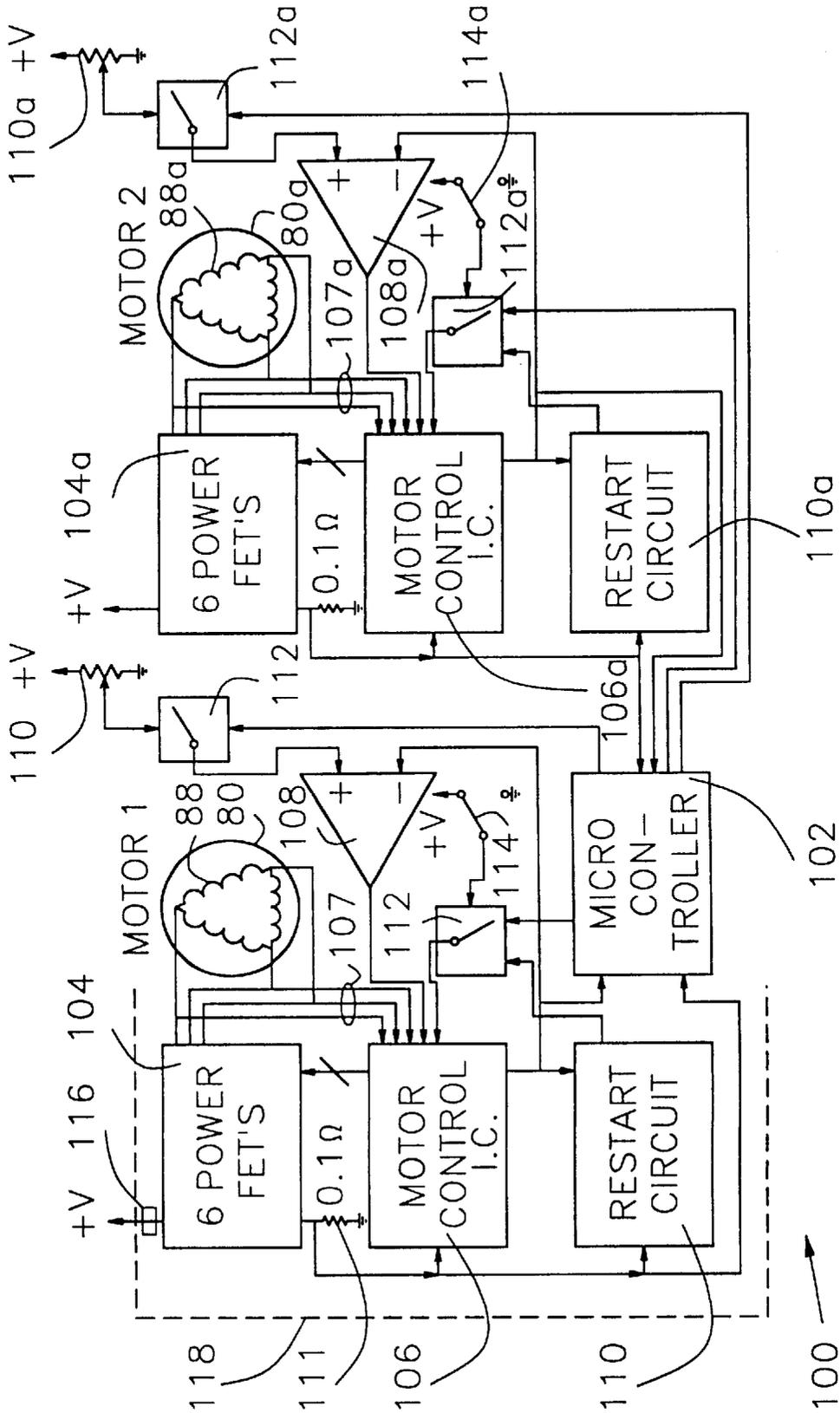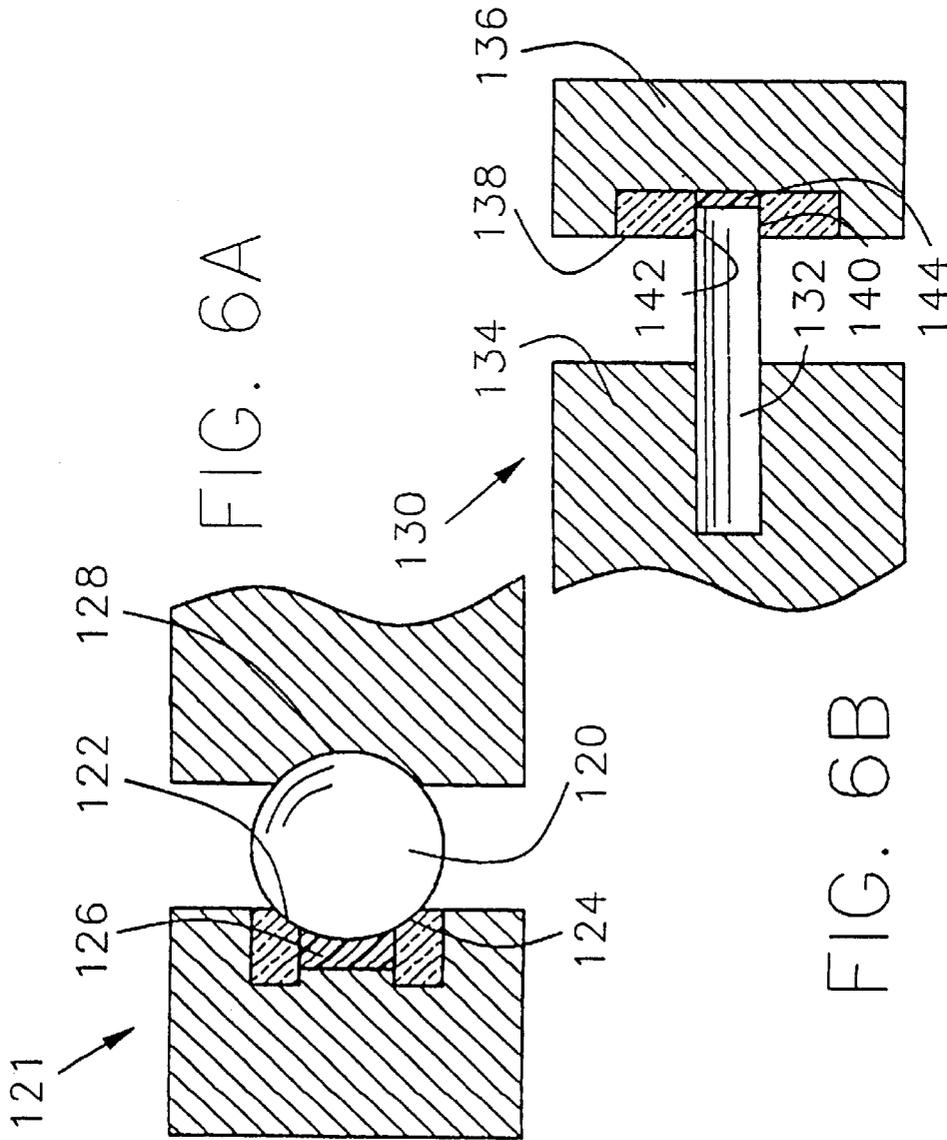
FIG. 1

FIG. 2A

FIG. 2
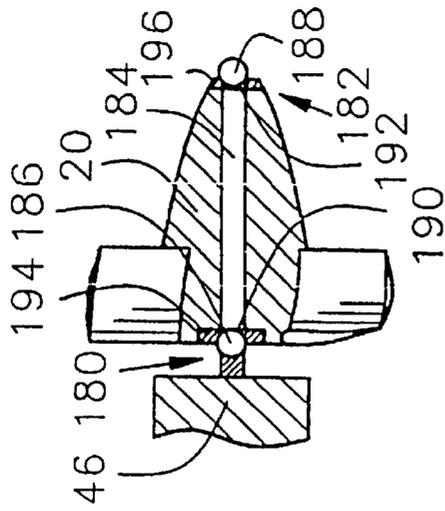
FIG. 4

FIG. 3

FIG. 5

FIG. 6F

FIG. 6A

FIG. 6B

FIG. 6C

FIG. 6D

FIG. 6E

FIG. 7

TABLE OF PUMP COMPONENTS

PARAMETER	FLOW STRAIGHTENER	INDUCER	IMPELLER	DIFFUSER
ENTRANCE ANGLE (DEGREES)				
PRESENT PREFERENCE	90	10	15	15
PREFERRED RANGE	80–90	10–20	10–25	10–25
OUTLET ANGLE (DEGREES)				
PRESENT PREFERENCE	90	20	90	90
PREFERRED RANGE	80–90	10–25	80–90	80–90
PREFERRED MIDPOINT	N/A	35	N/A	
MIDPOINT RANGE	N/A	30–45	N/A	
MAX THICKNESS (INCHES)	0.030	0.035	0.070	0.040
AXIAL CLEARANCE (INCHES)				
PRESENT PREFERENCE	0.040	0.040	N/A	0.025
PREFERRED RANGE	N/A	0.010–0.050	N/A	0.010–0.050
RADIAL CLEARANCE (INCHES)				
PRESENT PREFERENCE	0	0.005	0.005	0
PREFERRED RANGE	N/A	0.003–0.015	0.003–0.015	N/A
LENGTH (INCHES)	0.300	0.400	0.675	0.300
WRAP (DEGREES)				
PRESENT PREFERENCE	N/A	240	N/A	N/A
PREFERRED RANGE	N/A	200–300	N/A	N/A
NUMBER OF BLADES				
PRESENT PREFERENCE	4	3	6	6
PREFERRED RANGE	2–4	2–6	2–6	5–8
OVERLAP (DEGREES)				
PRESENT PREFERENCE	N/A	120	N/A	N/A
PREFERRED RANGE	N/A	100–200	N/A	N/A

FIG. 8

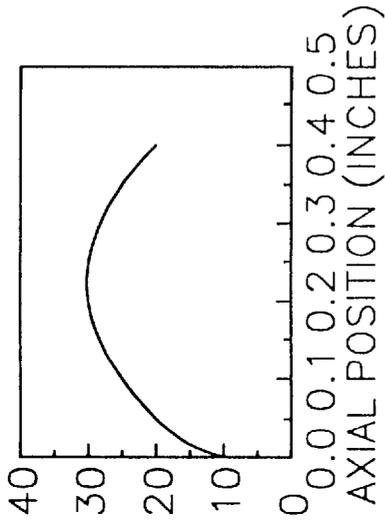# AXIAL FLOW PUMP TEST MATRIX

Test variables TEST #	No 1 BLADE TIPS (IMPELLER)	No 2 RADIAL CLEARANCE	No 3 AXIAL CLEARANCE	No 4 # OF BLADES (IMPELLER)	No 5 # OF BLADES (STATOR)	No 6 IMPELLER LENGTH
1	FLAT	0.013"	0.025"	6	5	0.675"
2	ROUNDED	0.013"	0.025"	6	5	0.675"
3	SEE NOTE A	0.026"	0.025"	6	5	0.675"
4	"	0.039"	0.025"	6	5	0.675"
5	"	SEE NOTE B	0.050"	6	5	0.675"
6	"	"	0.075"	6	5	0.675"
7	"	"	SEE NOTE C	4	5	0.675"
8	"	"	"	2	5	0.675"
9	"	"	"	SEE NOTE D	4	0.675"
10	"	"	"	"	3	0.675"
11	"	"	"	"	2	0.675"
12	"	"	"	"	SEE NOTE E	0.338"
13	FLAT	0.009"	0.025"	6	5	0.675"
14	FLAT	0.005"	0.025"	6	5	0.675"
15	FLAT	0.009"	0.025"	2	5	0.675"
16	FLAT	0.005"	0.025"	2	5	0.675"

NOTES:

A - USE OPTIMUM BLADE TIP GEOMETRY FROM TESTS 1 AND 2
B - USE OPTIMUM RADIAL CLEARANCE FROM TESTS 1 - 4
C - USE OPTIMUM STATOR/ROTOR CLEAREANCE FROM TESTS 1 - 6
D - USE OPTIMUM NUMBER OF IMPELLER BLADES FROM TESTS 1-8
E - USE OPTIMUM NUMBER OF STATOR BLADES FROM TESTS 1-11

Test Conditions:
- 5 Liters/Minute against 100 mmHg
- 20 minute duration
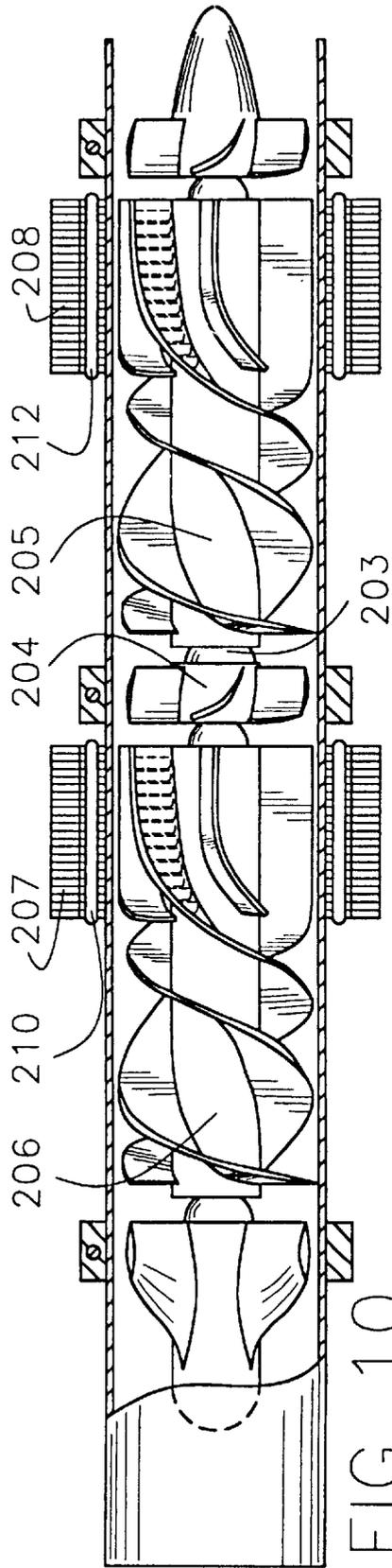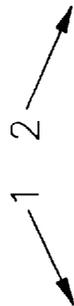- 500 ml Bovine blood

ANGLE OF
ATTACK
(DEGREES)

40

30

20

10

0
  0.0 0.1 0.2 0.3 0.4 0.5
  AXIAL POSITION (INCHES)

FIG. 9

FIG. 10

FIG. 11

FIG. 12

FIG. 12A

FIG. 14A

FIG. 14B

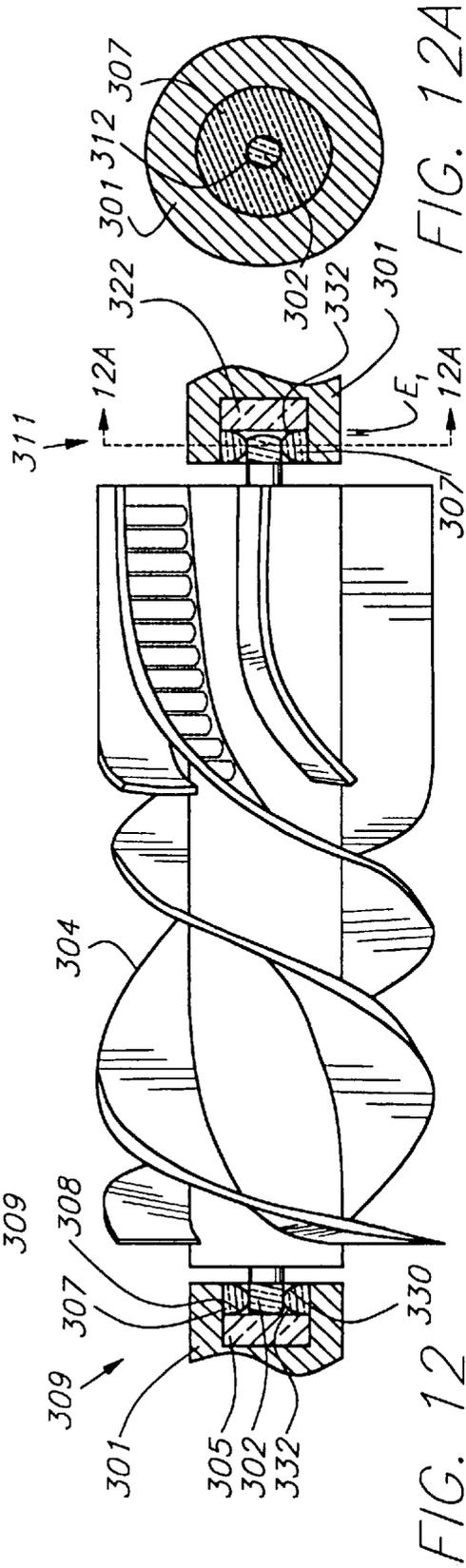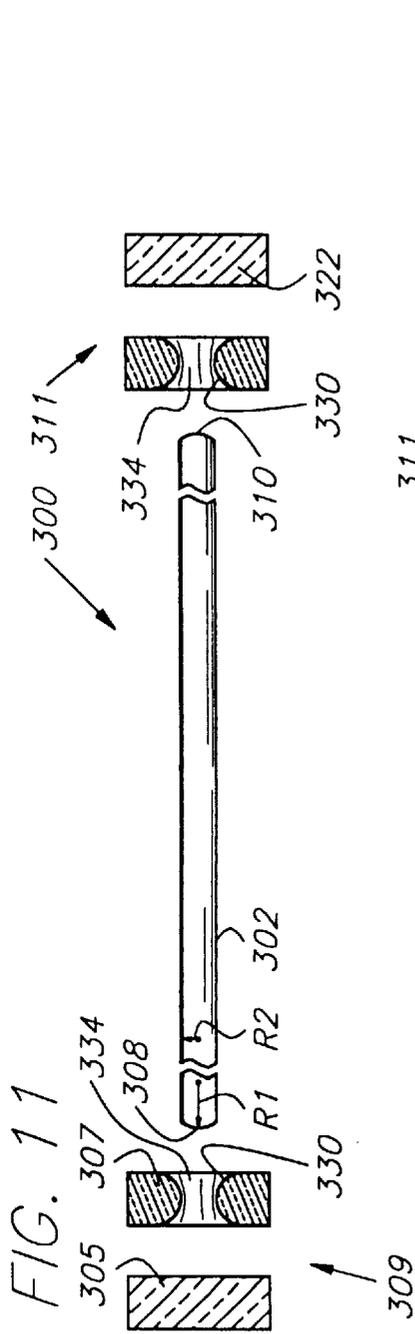*FIG. 13*

BLOOD PUMP BEARING SYSTEM

This application is a continuation-in-part of U.S. application Ser. No. 08/153,595 filed Nov. 10, 1993, U.S. Pat. No. 5,527,159 and of U.S. application Ser. No. 08/451,709 filed May 26, 1995 U.S. Pat. No. 5,678,306.

ORIGIN OF THE INVENTION

The invention described herein was made in the performance of work under a NASA contract and is subject to the provisions of Section 305 of the National Aeronautics and Space Act of 1958, Public Law 85-568 (72 Stat. 435; 42 U.S.C. 2457).

1. Technical Field

The present invention relates generally to rotary blood pumps. More specifically, the present invention relates to a ventricle assist device having a bearing system for supporting long-term high speed rotor rotation with minimal friction and heat build-up.

2. Background Art

Ventricle assist devices are frequently used to boost blood circulation to assist a heart which still functions but is not pumping sufficient blood for adequate circulation. The estimated need for a reliable long-term ventricle assist device (VAD) is presently projected at between 50,000 and 100,000 patients per year in the United States alone.

At the present time, rotary blood pumps are often the preferred type of pump for use as a ventricle assist device as compared to other more complex types of pumps which may use pistons, rollers, diaphragms, compliance chambers, and so forth. This is at least partially because rotary pumps may be manufactured in larger numbers at a relatively lower cost and are typically less complex than other types of pumps. The more complex pumps, on the other hand, may cost up to $50,000 per unit. Furthermore, availability of large numbers of complex pumps, as is required by the sizeable population that could benefit from such pumps, is limited by high manufacturing, operating, and maintenance costs. Therefore, rotary blood pumps are increasingly used not only for ventricular assist applications, but also for cardiopulmonary bypass procedures and percutaneous cardiopulmonary support applications in emergency cases.

Clinical uses of rotary pumps are normally limited to a few days owing to shortcomings of the devices. A non-comprehensive list of such problems or shortcomings would include the following: (1) blood damage which may occur when blood comes into contact with rotor bearings due to bearing heat or being forced through small clearances, (2) the need for bearing purge systems which may require percutaneous (through the skin) saline solution pump systems, (3) bearing seizure resulting from the considerable thrust and torque loads, or from dried blood sticking on the bearing surfaces, (4) problems of blood damage (hemolysis) and blood clotting (thrombosis) caused by relative rotational movement of the components of the pump, (5) pump and control size and shape limitations necessary for implantation or convenient mobility, (6) weight limitations for implantation to avoid tearing of implant grafts due to inertia of sudden movement, (7) difficulty in coordinating and optimizing the many pump design parameters which may affect hemolysis, (8) high power consumption that requires a larger power supply, (9) motor inefficiency caused by a large air gap between motor windings and drive magnets, (10) heat flow from the device to the body, (11) complex Hall Effect sensors/electronics for rotary control, (12) the substantial desire for minimizing percutaneous (through the skin) inser-

tions including support lines and tubes, (13) large pump and related hose internal volume which may cause an initial shock when filled with saline solution while starting the pump, and other problems.

Existing bearing systems for externally used rotary blood pumps may have small rolling element bearings such as ball bearings. Rolling element bearings require a shaft seal to prevent blood entering the bearing voids between the rolling elements. If blood enters the bearing voids, it coagulates and may cause bearing seizure by interfering with the rolling elements. Shaft seals complicate pump design, decrease pump reliability, and reduce pump life.

Some implantable blood pumps utilize pivot bearings. Pivot bearings can operate immersed in blood without a blood seal. However, to maintain the precise rotation required in blood pumps to minimize red blood cell damage, such pivot bearings utilize complicated shaft pre-load mechanisms to eliminate shaft end-play. Shaft pre-load mechanisms are prone to seizure by coagulated blood. They also increase bearing wear.

Other blood pump bearing systems utilize journal bearings flushed with fluids such as saline solution or blood. Journal bearings have minimal wear, but require a separate thrust bearing that complicates pump design. Journal bearings require fluid pressure to support the loads. If the pump utilizes saline solution rather than blood as the bearing fluid, then pump design is significantly complicated by the need for a separate reservoir, flow lines, and the like. If the pump utilizes blood as bearing fluid, then potential pump seizure caused by coagulated blood is a serious concern. In addition, blood flow through a journal bearing is exposed to a high shear environment. The high shear environment may damage the blood or generate micro-clots that are washed into the patients blood stream. Finally, journal bearings of the size used in blood pumps require very precise alignment that increase manufacturing complexity, and increase costs.

Although a significant amount of effort has been applied to solving the problems associated with rotary pumps, there is still a great demand for a safe, reliable, and durable blood pump that may be used for longer term applications.

The following patents describe attempts made to solve problems associated with rotary blood pumps including ventricle assist devices.

U.S. Pat. No. 4,625,712 to R. K. Wampler discloses a full-flow cardiac assist device for cardiogenic shock patients which may be inserted into the heart through the femoral artery and driven via flexible cable from an external power source. A catheter attached to the pump supplies the pump bearings with a blood-compatible purge fluid to prevent thrombus formation and introduction of blood elements between rotating and stationary elements. Due to the very small diameter of the pump, rotational speeds on the order of 10,000 to 20,000 rpm are used to produce a blood flow on the order of about four liters per minute.

U.S. Pat. No. 4,957,504 to W. M. Chardack discloses an implantable blood pump for providing either continuous or pulsatile blood flow to the heart. The pump includes a stator having a cylindrical opening, an annular array of electromagnets disposed in a circle about the stator concentric with the cylindrical opening, a bearing carried by the stator and extending across the cylindrical opening, and a rotor supported by the bearing. The rotor is in the form of an Archimedes screw and has a permanent magnet in its periphery which lies in the same plane as the circular array of electromagnets and is driven in stepper motor fashion.

U.S. Pat. No. 4,944,722 to J. W. Carriker discloses a percutaneously insertable intravascular axial flow blood

pump with a rotor extension and drive cable fitting so designed that the thrust bearing surfaces of the purge seal and cable fitting can be pre-loaded.

U.S. Pat. No. 4,817,586 to R. K. Wampler discloses an intravascular flow blood pump with reduced diameter having blood exit apertures in the cylindrical outside wall of the pump housing between the rotor blades and the rotor journal bearing.

U.S. Pat. No. 4,908,012 to Moise et al. discloses an implantable ventricular assist system having a high-speed axial flow blood pump. The pump includes a blood tube in which the pump rotor and stator are coaxially contained, and a motor stator surrounding the blood duct. A permanent magnet motor rotor is integral with the pump rotor. Purge fluid for the hydrodynamic bearings of the device and power for the motor are preferably percutaneously introduced from extra-corporeal sources worn by the patient.

U.S. Pat. No. 4,779,614 to J. C. Moise discloses an implantable axial flow blood pump which includes a magnetically suspended rotor of relative small diameter disposed without bearings in a cylindrical blood conduit. Neodymium-boron-iron rotor magnets allow a substantial gap between the static motor armature and the rotor. Magnetically permeable strips in opposite ends of the pump stator blades transmit to Hall sensors variations in an annular magnetic field surrounding the rotor adjacent the ends of the pump stator blades.

U.S. Pat. No. 5,049,134 to Golding et al. discloses a seal free centrifugal impeller supported in a pump housing by fluid bearings through which a blood flow passageway is provided.

U.S. Pat. No. 4,382,199 to M. S. Isacson discloses a hydrodynamic bearing system for use with a left ventricle assist device. The bearings are formed by the fluid in the gap between the rotor and the stator.

U.S. Pat. No. 4,135,253 to Reich et al. discloses a centrifugal blood pump provided with a magnetic drive system which permits a synchronous magnetic coupling with a separate power unit disposed immediately adjacent the pump housing but outside of the skin surface. The pump has a single moving part which includes the combination of an impeller connected to a magnetic drive rotor. The magnetic drive system floats on a fluid surface of saline solution.

U.S. Pat. No. 4,507,048 to J. Belenger discloses a centrifugal blood pump with a bell shaped housing having a suction inlet at the apex and a tangential outlet adjacent the base. A conical rotator is driven by spaced permanent magnets embedded in the base of the rotator and an externally generated rotating magnetic field.

U.S. Pat. No. 4,688,998 to Olsen et al. discloses a pump with a magnetically suspended and magnetically rotated impeller. The impeller may be configured for axial flow with a hollow, cylindrical-type impeller with impeller vanes on the internal surface thereof. The impeller includes a plurality of internally embedded, permanent magnets that cooperate with electromagnets for drive and position control of the impeller.

U.S. Pat. No. 4,763,032 to Bramm et al. discloses a magnetic rotor bearing for suspending a rotor for an axial or radial-centrifugal blood pump in a contact-free manner, and comprising a permanent and electromagnetic arrangement.

U.S. Pat. No. 4,846,152 to Wampler et al. discloses a miniature high-speed intravascular blood pump with two rows of rotor blades and a single row of stator blades within a tubular housing. The rotor's first row has no provision for

a variable pitch blade but produces a mixed centrifugal and axial flow by increasing hub diameter. The rotor's second row, axially spaced and having an axial distance between the first row, produces a purely axial flow. The stator blades are reverse twisted to straighten and slow the blood flow.

U.S. Pat. No. 4,944,748 to Bramm et al. discloses an impeller in a blood pump supported by permanent magnets on the impeller and pump housing and stabilized by an electromagnet on the housing. The impeller is rotated magnetically and stator coils in the housing are supplied with electric currents having a frequency and amplitude adjusted in relation to blood pressure at the pump inlet

U.S. Pat. No. 4,994,078 to R. K. Jarvik discloses an electrically powered rotary hydrodynamic pump having motor windings and laminations disposed radially about an annular blood channel and having a motor rotor disposed therein such that an annular blood channel passes through the gap between the motor rotor and the windings.

U.S. Pat. No. 5,055,005 to Kletschka discloses a fluid pump with an electromagnetically driven rotary impeller levitated by localized opposed fluid forces.

In spite of the effort evidenced by the above patents, there remains the need for an improved rotary pump for use as a ventricle assist device that is reliable, compact, requires limited percutaneous insertions, and produces fewer blood damage problems such as hemolysis and thrombosis. A bearing system for an improved rotary pump should reliably and precisely support the rotor for long-term, maintenance free, low friction operation without the need for bearing seals and lubrication. Those skilled in the art will appreciate the present invention which addresses these and other problems.

STATEMENT OF THE INVENTION

The present invention provides a blood pump bearing system for precisely supporting high-speed rotation of a rotor within a housing through which blood is pumped. The bearing system includes a shaft to support the rotor. The shaft has a circumference defined by a first radius. The shaft terminates at a shaft end that has a radiused surface defined by a second radius. The second radius is greater than the first radius and preferably is about three times greater. A shaft end bearing surface mounted to the housing operates to contact the shaft end for supporting axial loads on the shaft. The shaft end bearing surface and the shaft end form a pivot bearing. A shaft circumferential bearing mounted to the housing has an aperture therethrough for receiving the circumference of the shaft. The shaft circumferential bearing is operable to support radial loads on the shaft. The shaft circumferential bearing prevents radial but not rotational movement between the shaft end bearing surface and the shaft end that comprise the pivot bearing.

The shaft end bearing surface is preferably comprised of a first material that is harder than a second material that forms the shaft end. For this reason, wear occurs on the shaft end to quickly produce a flat surface on the radiused surface of the shaft end. After the flat surface is large enough to support axial thrust loads, wear substantially ceases to occur. At that time, the flat surface preferably has a diameter of less than about 0.025 inches. The second radius is selected such that the change of shaft axial end-play due to creation of the flat surface is preferably less than about 0.005 inches. The total shaft axial end-play after break-in is preferably less than about 0.010 inches.

The shaft end bearing surface includes a flat planar surface that contacts the radiused surface of the shaft end

prior to break-in of the bearing and that contacts the created flat surface after bearing break-in.

The shaft circumferential bearing further comprises a curved inner surface that defines the aperture for receiving the shaft. This curved inner surface makes line contact along the circumference of the shaft. This line contact is very small to thereby minimize friction and heat build-up in the blood pump bearing system as the rotor rotates. The locus of line contact has a width of less than about 0.010 inches. The shaft circumferential bearing may comprise a commercially available jewel typically known as an olive hole ring jewel by those skilled in the art. The jewel bearing preferably has a substantially doughnut-shaped or toroidal curved inner surface portion that defines the aperture. The olive hole ring jewel preferably has a width as measured parallel to an axis of the shaft that is as narrow as possible to allow for heat transfer through the bearing. Preferably the width is less than about 0.035 inches and tailor bearing jewels may be obtained with significantly smaller widths. The radial clearance between the shaft circumference bearing and the circumference of the shaft is about 0.0001–0.0002 inches.

A void is formed between the shaft end and the shaft end bearing into which blood may leak between the circumference of the shaft and the shaft circumference bearing. This blood coagulates and becomes trapped in the void. Additional blood is then prevented from flowing into the void.

The blood pump bearing system shaft may be integral to the rotor section, it may be a single separate shaft mounted at both ends, or it may comprise two end sections.

The present invention also provides a method and apparatus for a rotary blood pump electromagnetic drive and includes a pump housing defining a blood flow path therethrough. A first stator having a first stator field winding is used to produce a first stator magnetic field. A first rotor is mounted within the pump housing for rotation in response to the first stator magnetic field. The first rotor carries a blade thereon to propel blood through the pump housing along the blood flow path. At least one magnet is secured to the first rotor and produces a first rotor magnetic field that passes through the first stator field winding during rotation of the first rotor to thereby induce a back emf within the first stator field winding. Back emf sensor circuitry connecting to the first stator field winding senses back emf produced during the rotation of the first rotor within the pump housing. In one embodiment of the present invention, at least one magnet is implanted in each of a plurality of impeller blades to produce rotational movement of the rotor.

The rotary pump also includes, in a preferred embodiment, an inducer portion of the rotor having a plurality of inducer blades equidistantly disposed about a circumference of the rotor with each inducer blade having a variable pitch along its axial length. An interconnection blade portion connects at least one of the inducer blades to at least one impeller blade to form a continuous blade extending through the inducer and impeller portions of the rotor.

An object of the present invention is to provide an improved rotary blood pump.

Another object of the present invention is to provide axial and radial support of a high-speed spinning impeller used to increase or sustain blood flow for a cardiac patient.

A further object is to provide an improved control circuit for controlling a rotor within the pump in response to a back emf produced in stator windings.

Another object is to provide an improved rotor bearing for which cross-linked blood forms a bearing surface and blood seal.

Yet another object of the present invention is to provide a method for optimizing pump parameters to reduce blood hemolysis to minimum.

Yet another object of the present invention is to provide a highly reliable, low friction bearing to support the rotor for high speed operation while limiting bearing temperature without the need for bearing lubrication.

A feature of the present invention is a reduced air gap between permanent magnets on the rotor and the stator winding.

Another feature of the present invention is an impeller having a variable pitch blade.

Another feature of the present invention is a back emf integrated circuit for controlling rotor operation.

Yet another feature of the present invention is a rotor shaft having a radiused end with a radius greater than the radius of the shaft circumference and preferably about three times greater.

Yet another feature of the present invention is an olive hole ring jewel to support the rotor shaft along a low friction, low heat, near line contact surface around the circumference of the rotor shaft.

Yet another feature of the present invention is a near point contact between the radiused end of the rotor shaft and a flat endstone produced when the radiused end is worn during break-in of the pump to form a small flat of the precise size necessary to support thrust loads after which wear substantially ceases thereafter.

An advantage of the present invention is improved rotor control.

Another advantage of the present invention is quantifiably reduced damage to blood.

Yet another advantage of the present invention is an elimination of the need for a bearing purge system requiring saline carrying tubes penetrating through the skin.

Yet another advantage of the present invention is the avoidance of the need for bearing seals, blood forced through close tolerance moving components, excessive bearing heat, corrosive bearing components, pre-load mechanisms, and bearing lubrication.

Other objects, features and intended advantages of the present invention will be readily apparent by the references to the following detailed description in connection with the accompanying drawings and claims.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is an elevational view, partially in section, of a rotary blood pump in accord with the present invention;

FIG. 2 is an elevational view of a stator showing stator laminations stacked together to form a skewed stator;

FIG. 2A is an elevational view indicating the skewed path of stator field windings through the stator;

FIG. 3 is an elevational view, partially in section, of an alternative embodiment rotary blood pump having distinct impeller and inducer blades;

FIG. 4 is an elevational view, in section, of a portion of an impeller showing non-radiused blade tips;

FIG. 5 is a block diagram of a control system including a back emf integrated circuit and a microprocessor;

FIG. 6A is an elevational view, partially in section, of a ball-socket rotor bearing having a bearing chamber filled with bio-compatible material;

FIG. 6B is an elevational view, partially in section, of a shaft journal rotor bearing having a bearing chamber filled with bio-compatible material;

FIG. **6C** is an elevational view, partially in section, having a rotor bearing washed from increased blood flow caused by bend in the pump housing;

FIG. **6D** is an elevational view, partially in section, showing a cross-section of a rotor bearing shaft having blood flow passages along the shaft periphery;

FIG. **6E** is a cross-sectional view along line **6E—6E**;

FIG. **6F** is an elevational view, partially in section, of a rotor bearing for supporting the rotor in cantilevered fashion;

FIG. **7** is a chart showing optimum pump parameter components determined from methods of optimizing pump parameters to minimize hemolysis;

FIG. **8** shows the test matrix of the present invention for optimizing pump parameters to minimize hemolysis while maximizing pump efficiency;

FIG. **9** is a graph showing change in inducer blade pitch along the axial length of the inducer;

FIG. **10** is an elevational view, in section, of two axially spaced pumps for separate or combined operation in accord with the present invention;

FIG. **11** is an elevational view, partially in section, of components of a bearing system in accord with the present invention;

FIG. **12** is an elevational view, partially in section, of components of the invention supporting a blood pump rotor in accord with the present invention;

FIG. **12A** is a cross-sectional view along the line **12A—12A**;

FIG. **13** is an enlarged elevational view, partially in section, of one end of a rotor bearing system in accord with the present invention;

FIG. **14A** is an enlarged elevational view, in section, showing point contact at end of the radiused shaft prior to pump break-in; and

FIG. **14B** is an enlarged elevational view, in section, showing a flat worn on the radiused shaft after pump break-in in accord with the present invention.

While the invention will be described in connection with the presently preferred embodiments, it will be understood that it is not intended to limit the invention to these embodiments. On the contrary, it is intended to cover all alternatives, modifications, and equivalents as may be included in the spirit of the invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention describes a rotary blood pump which has an improved rotor control system. The rotary pump has pump blade geometry optimized by a method of the present invention to provide high pump efficiency while minimizing hemolysis and thrombus (hemolysis is defined quantitatively hereinafter). The pump requires less than 10 watts of power to pump 5 liters/minute against a pressure head of 100 mm Hg. A preferred embodiment of the pump weighs 53 grams and has a length of 75 mm and a diameter of 25 mm. An index of hemolysis of from 0.003 to 0.005 g/100 liters pumped has been achieved, although using the method of this invention, further reductions are possible. For reference, a standard roller pump has an index of hemolysis of 0.06 g/100 liters. Published articles concerning aspects of the present invention are hereby incorporated by reference and include the following: (1) "In Vitro Performance of the Baylor/NASA Axial Flow Pump", *Artificial Organs,* 1993

Volume 17, number 7, page 609–613; (2) "Development of Baylor/NASA axial flow VAD, *Artificial Organs,* 1993, Volume 17, page 469.

Referring now to the drawings, and more particularly to FIG. **1**, there is a shown a rotary blood pump **10** in accord with the present invention. Blood pump **10** includes a preferably metallic tubular pump housing **12** which is, in a preferred embodiment, a straight-sided cylinder. Pump housing **12** has a smooth inner bore wall **15** to minimize thrombus formation. Pump housing **12** defines an axial blood flow path **13** therethrough in the direction indicated by blood flow arrows shown in FIG. **1**.

Front and rear clamps **14** and **16**, respectively, are used to secure flow straightener **18** and diffuser **20** within pump housing **12**. Pump housing **12** is sufficiently thin-walled so that the tightening of clamps **14** and **16** with clamp screws **22** locally deforms pump housing **12** about flow straightener **18** and diffuser **20** to affix these components in position. The clamps provide a very convenient means of securing the rotor assembly. Alternatively, other means for securing these components could be used such as spot welding, fasteners, interference fit, and so forth.

Flow straightener **18** serves two basic functions (1) it straightens blood flow to reduce hemolysis while improving pump efficiency (2) it provides a support structure for front ball-socket bearing assembly **24** as discussed hereinafter. By straightening the flow of blood as it initially flows into the entrance **36** of pump **10**, hydraulic efficiency is increased. Straightening the blood flow reduces turbulence to increase the pump pressure. FIG. **7** lists optimal values and permissible pump parameter ranges of values for flow straightener **18** and other pump components.

Flow straightener **18** preferably has four fixed blades **26** but may have from two to four blades. Too many blades impede blood flow while too few blades reduce pump efficiency. For purposes of lowering thrombosis, the front edge **28** of blades **26** is sloped from inner housing wall **15** to flow straightener hub **32** so that blood trauma by contact with blades **26** is minimized. Also to reduce blood trauma, flow straightener hub **32** is cylindrical with a round leading surface **34**. Surface **34** may also be hyperbolical or generally bullet-shaped for this purpose. An alternative embodiment flow straightener **18a** is shown in FIG. **3** and does not have the sloping front edge blades.

The preferred angle of attack of blades **26** is 90° i.e. the blades would intersect a plane transverse to cylindrical housing **12** at an angle of 90°. This reference for the angle of attack or pitch of the blades will be used throughout this specification.

Flow straightener **18** is preferably metallic but may also be formed of plastic. If formed of plastic and secured in place by clamp **14**, it is necessary to reinforce flow straightener **18** with, for instance, metallic supports to prevent plastic creep deformation. The plastic creep deformation phenomena might otherwise eventually cause flow straightener **18** to come loose from clamp **14**. Reinforcement is also necessary with respect to other clamped plastic pump components.

Diffuser **20** also has two basic purposes: (1) it de-accelerates and redirects the outflow at blood flow path exit **40** axially to boost pump performance and (2) it serves as a support structure for rear rotor bearing **42**. Diffuser **20** preferably has from **5** to **8** fixed blades **38** with 6 blades being the presently preferred optimum number. Blades **38** are fixably engaged with pump housing **12** after rear clamp **16** is tightened as by screw **22**.

To perform the function of de-acceleration and axial redirection of blood flow, each diffuser blade **38** has an entrance angle of from about 10° to 25° for slowing the blood down and an outlet angle of from about 80° to 90° for redirecting blood flow in an axial direction. Presently preferred blade geometry is listed in FIG. **7** and includes an entrance angle of 15° and an outlet angle of 90°. Tail cone **44** of diffuser **20** is hyperbolical or generally bullet shaped to reduce turbulence or wake of blood flow from pump **10** so as to minimize blood damage from such turbulence. Somewhat surprisingly, it was found that increasing the number of fixed blades tends to decrease hemolysis.

Rotor **46** is supported for rotary movement with pump housing **12** by front and rear bearings **24** and **42**, respectively. Rotor **46** is divided into two portions along its axis based on the type and function of the blades disposed thereon. Inducer portion **48** of rotor **46** is disposed in the front part, with respect to blood flow direction, of rotor **46** closest to pump inlet **36**. Impeller portion **50** is disposed in the rear part of rotor **46** closest to pump outlet **40**. It has been found that including an inducer portion in an axial flow pump, along with an impeller portion, significantly reduces hemolysis.

FIG. **3** shows an alternative embodiment pump **10***a* of the present invention which provides for two distinct sets of axially spaced blades which more clearly distinguish the inducer portion of the rotor from the impeller portion of the rotor. Corresponding components of pump **10** and **10***a* are given the same number, with the difference of an "a" suffix to distinguish the components for comparison purposes as necessary. A reference to one number is therefore a reference to its corresponding number in this specification, unless otherwise stated. Where components are substantially different between the two pump versions, completely new numbers are assigned. In pump **10***a,* inducer portion **48***a* is separated from impeller portion **50***a* of rotor **46***a* by gap **49***a* which is preferably less than 0.10 inches. Inducer blade **52***a* may be tapered (not shown) at forward end **56***a* so that blade **52***a* has a smaller radial length at forward end **56***a,* perhaps even blending into hub **73**. However, using the method of the present invention, it has been found that a continuous blade pump has even more reduced levels of hemolysis than the non-continuous blade pump **10***a*. Thus, pump **10** shown in FIG. **1** is the presently preferred embodiment.

Inducer blades **52** on inducer **53** have a variable pitch along their axial length. FIG. **9** shows an inducer blade angle profile that plots angle of attack in degrees versus axial position on inducer **53** in inches. It was found that the inducer portion **48** reduced hemolysis by approximately 45% from a pump design without the inducer. Hydraulic efficiency was also increased as the rotation speed required to pump 5 liters/min of blood at 100 mm Hg. dropped from 12,600 rpm to 10,800. The inducer blades pre-rotate the blood before it enters the main pumping blades (i.e. impeller blades **54**) to reduce hemolysis.

Inducer blades **52** also achieve a pumping action that effectively produces a two-stage, increased efficiency pump. Optimum inducer blade geometry for minimal hemolysis and maximum pump efficiency is listed for specific parts of inducer blade **52** in the chart of FIG. **7**. Thus, the entrance angle of leading end **56** of inducer blade **52** is preferably 10° but has a preferred range from about 10° to 20°. The shallow entrance angle effectively engages the blood for movement but does not damage it. The pitch of inducer blade **52** continues to change along its axial length and preferably is about 30° at midpoint **58** of the blade. The tailing end **60** of inducer blade **52** preferably has an outlet angle of 20°. This

variable pitch is described in FIG. **9** which shows how pitch varies versus axial length of inducer **53**. As well, it is desired that inducer blades have a wrap of preferably 240° around rotor **46**. The presently preferred overlap of each blade over other blades is 120° or a 50% overlap. The chart of FIG. **7** provides a complete listing of relevant pump parameter values including preferred ranges of operation. Outside of these ranges, pump efficiency drops and/or blood damage is more likely to occur.

Pump **10** includes an interconnecting blade portion **62** which is not included in pump **10***a*. Although the two-stage pump **10***a* produces significantly reduced hemolysis and efficient pump operation as compared to a single stage pump, it has been discovered that by interconnecting inducer blades **52** with impeller blades **54** with interconnecting blade portion **62**, hemolysis may be reduced to even lower levels while maintaining efficient pump operation.

Impeller blades **54** on impeller **55** have an entrance angle in leading end region **64** of preferably 20°. This may be seen more clearly in FIG. **3** which has no interconnecting blade portion **62**. The entrance angle preferably smoothly tapers to an optimum preferred outlet angle of 90° at blade tailing end region **66**. The optimum ranges of operation for the entrance and outlet angles is given in FIG. **7**.

Impeller blades **54** include axially longer impeller blades such as longer blade **68** and axially shorter impeller blades such as shorter blade **70**. The alternate long and short blade arrangement on impeller **55** accommodates multiple magnetic poles for electric motor operation as discussed hereinafter, and still maintains adequate flow area through impeller **55**. Presently, the preferred number of impeller blades is six, but a range from two to six blades provides a range of permissible pump efficiency. If impeller **55** included six axially longer blades, such as longer blade **68**, flow area through impeller portion **50** would be restricted to such an extent that the blades actually begin to block the flow they are intended to produce.

Using the method of this invention, it was unexpectedly discovered that hemolysis does not necessarily increase with the number of blades, as anticipated. The alternating long-short blade arrangement of the six bladed impeller of the present invention does not cause hemolysis any more significantly than a two-bladed impeller. In some cases, an impeller with four long blades may cause more hemolysis than either a two or six bladed impeller. It is possible that the degree of hemolysis depends more on the number of long blades rather than the total number of blades.

FIG. **4** shows a portion of impeller **55** in cross-section to illustrate substantially flat, non-radiused blade tips **72**. It has been unexpectedly found, using the method of this invention, that flat or substantially flat, non-radiused blade tips have substantially the same pump response but do not produce significantly different results from rounded or radiused blade tips with respect to hemolysis. It was anticipated that flat blade tips would produce higher hemolysis. Because flat blade tips are less expensive to manufacture in conjunction with magnets to be used in the blades as discussed hereinafter, flat blade tips comprise the presently preferred embodiment. Further test results are discussed in greater detail in the previously noted articles incorporated herein by reference.

FIG. **4** also illustrates a preferred rotor hub **73** with outside diameter **74** compared to overall outside diameter **76** of inducer **53** and/or impeller **55**. The preferred ratio is 0.48 although a range of 0.45 to 0.55 permits excellent pump operation. If the hub is smaller than permitted by this range,

blood becomes excessively swirled and may tend to recirculate within pump **10** in the wrong flow direction to possibly damage the blood as well as reduce pump efficiency. If the hub is too large so as to be outside of this range, the hub tends to block flow through pump **10**.

The radial clearance **78** between inducer **53** and/or impeller **55** with respect to pump housing **12** inner wall **15** is preferably in the range of about 0.003 inches to 0.015 inches. Using a test matrix as per the method of this invention, it was unexpectedly discovered that smaller radial clearances lowered hemolysis. It was expected that smaller clearances would produce greater blood damage due to higher sheer stresses on the blood. The presently preferred radial clearance **78** is 0.005 inches. Axial clearances between components such as flow straightener **18**, rotor **46**, and diffuser **20** are shown in FIG. **7**. Axial clearances should be within the ranges shown to improve pump efficiency and to reduce hemolysis.

In order to reduce air gap between stator **80** and magnets **82**, the magnets are preferably sealingly mounted within impeller blades **54**. Reducing the air gap between stator **80** and magnets **82** increases motor efficiency, because magnetic flux is not as diffused as occurs in motor designs with large air gaps. The preferred radial spacing or air gap between magnets **82** and stator **80** is from 0.01 inches to 0.025 inches. Magnets **82** are preferably rare earth magnets because of the higher magnetic flux produced by such magnets. Each magnet **82** is encapsulated into an individual pocket **84** to eliminate corrosion. Because magnets are individualized, motor torque and rotor weight can be easily adjusted in the manufacturing stage to provide motors that are tailored to the type of pump performance necessary without producing excessive pump weight.

Field winding **88** generates a magnetic field to rotate rotor **46**. Stator **80** is comprised of individual stator laminations **86** to eliminate eddy currents that generate heat and reduce efficiency. Heat flow from pump **10** is directed both into the blood stream and into the tissues surrounding pump **10**. In this way, the blood is not heated in a manner that may damage the blood and, as well, the surrounding tissues do not have to absorb all the heat. Heat conductive flow paths using thermally conductive material, such as the metal of the stator or thermally conductive gel, may be used to provide approximately the desired ratio of heat flow to tissues compared to the heat flow to the blood.

As illustrated in FIG. **2**, stator **80**, comprised of individual laminations **86**, is stacked in a presently preferred skewed manner such that pathways **90** provide a motor winding pathway that is offset from the rotor axis **92**. The skew of laminations **86** may or may not correspond in some manner with the offset angle or changing offset angle of the row of magnets **82** and is not limited to the position shown in FIG. **2**. A skewed stator **80** is also indicated in FIG. **2A** which shows an offset path from axis **92** which field windings **88** travel through stator **80**. The skewing angle or offset from the rotor axis is used to optimize performance. The skewing angle of stator **80** may be variable rather than fixed along its length. While skewed stator **80** is the presently preferred embodiment, other factors or combinations of factors (e.g. small air gap, magnet orientation, etc.), as discussed, produce excellent pump and motor performance without a skewed stator.

An axial force is produced on rotor **46** during rotation which can be varied by moving stator **80** axially along pump housing **12**. Stator **80** is axially adjustable for this purpose and could be fixed in position during manufacturing for

optimal performance given the number of magnets to be used and other factors discussed hereinafter. The axial force produced hereby can be used to offset thrust created during pumping to reduce the load on front or rear bearing assemblies **24** and **42**, respectively, as desired. The axial positioning of stator **80** may also be used to optimize electrical motor efficiency.

Referring to FIG. **5**, a block diagram of control system **100** of the present invention is shown. Note that control system **100** may operate two motors **1** and **2** such as shown in FIG. **10**. For some applications either for implantation or for external use, it may be desirable to have two pumps connected either in parallel or series. Thus, control system **100** can be easily configured for this purpose if desired. In addition, magnets (not shown) may be placed in the inducer hub to provide a secondary motor in the case of primary motor or controller failure. Various other back-up and redundancy configurations may be used.

For instance, in an axially spaced pump configuration shown in FIG. **10**, motors **1** and **2** are axially displaced from each other and may be operated separately or in conjunction with each other as control system **100** regulates power, as discussed hereinafter, to axially spaced stators **207** and **208** containing stator windings **210** and **212**, respectively. Ball-socket bearing **203**, or another bearing discussed hereinafter, on modified diffuser **204** rotatably supports rotor **205** of motor **2** which is axially spaced from rotor **206** of motor **1**. Diffuser **204** acts as a flow straightener when independent operation of motor **2** is desired. Control system **100** may be used to operate both motors simultaneously or to turn one motor on if micro-controller **102** senses a motor has failed. Micro-controller **102** may be programmed for pulsatile motor operation or continuous speed motor operation of one or more motors, as desired.

If only one pump is to be used, extra components may be removed. In FIG. **5**, except for micro-controller **102**, most components are duplicated to allow operation of two motors. For convenience, reference to corresponding components will be made to one number with the corresponding component having an "a" suffix. Control system **100** operates either manually or by micro-control as discussed subsequently so it may be used for test purposes if desired.

Control system **100** applies current to stator windings **88**. Preferably stator **80** includes three stator windings **88**. Stator **80** generates a rotating magnetic field which rotor **46**, containing magnets **82**, follows to produce motion. The motor stator may be three phase "Y" or "Delta" wound. The operation of the brushless D.C. motor of the present invention requires a proper sequence of power to be applied to stator windings **88**. Two stator windings **88** have power applied to them at any one time. By sequencing the voltage on and off to the respective stator windings **88**, a rotating magnetic field is produced.

A preferred embodiment three-phase motor requires a repetitive sequence of six states to generate a rotating magnetic field but other commutation schemes could be used as well. The six states are produced by electronic commutation provided by power F.E.T.'s **104**. If Motor **1** were sequenced through the six electrical states at a controlled frequency without feedback, its operation would be that of a stepper motor. In such a mode of operation, the motor rapidly loses its ability to generate torque as the rpm's increase.

Control system **100** detects back electromotive force or back emf to control motor operation. Whenever a conductor, such as field winding **88**, is cut by moving magnetic lines of

force, such as magnets **82**, a voltage is induced. The voltage will increase with rotor speed. It is possible to sense this voltage in one of the three stator windings **88** because only two of the motor's windings are activated at any one time, determine rotor **46** position, and to activate commutator switches **104**. The circuitry is much simpler and more reliable than Hall Effect sensors which have been used in the past. Although a back emf control is the presently preferred embodiment, a Hall effect driven commutation scheme could also be used.

Back emf integrated circuit **106** provides sensors for detecting the back emf from lines indicated at **107** and operates commutation switches **104** accordingly. A presently preferred back emf integrated circuit includes a ML4411 motor controller integrated circuit. Each commutation switch F.E.T. is preferably turned all the way on or off for maximum power efficiency.

Back emf integrated circuit **106** also provides start up mode operation when the back emf is not present or large enough for detection. From zero to approximately 200 rpm's, motor **1** operates in stepper motor fashion as described hereinbefore. Motor speed is controlled with difference amplifier **108** which may take its speed signal from either micro-controller **102** or speed adjust pot **110** as selected by switch **112**. A speed detection signal is available from back emf integrated circuit **106** for this purpose.

Restart circuit **110** and micro-controller **102** monitor voltage developed across sense resistor **111** (present preference is about 0.1 ohms) and the frequency signal from back emf integrated circuit **106** to determine whether motor **1** should be restarted i.e. due to sudden increase or decrease in current or frequency. Switch **113** may be used to select between use of restart circuit **110**, micro-controller **102**, or a manual restart switch **114**. Controller **102** may be programmed to produce an alarm signal if there are sudden changes in power consumption or frequency as may occur if heart strength weakens or improves. To protect the electronics from electromagnetic interference (EMI), ferrite beads **116** are used with wires to an external power supply. The electronics are preferably hermetically sealed in case **118** which is formed of a high mu material to limit EMI.

Referring now to FIG. **11** through FIG. **14B**, there is shown a presently preferred bearing system embodiment **300** in accord with the present invention. While bearing system **300** is exemplified within an axial flow pump, it could also be used in a radial flow pump configuration, such as a centrifuge, or a mixed flow pump. The long life of the bearing system lends itself to use either in long-term implanted blood pumps or short-term external devices. While bearing system **300** is especially suited for blood pumps, it may also be used in fluid pumps or motors to reliably support high rotor speeds with little friction for long life. Preferably, bearing system **300** is comprised of ceramics, as discussed hereinafter. However, if wanted for particular conditions, bearing system **300** may comprise materials such as hardened metals.

Bearing system **300** is comprised of three basic components that include a shaft, an endstone, and an olive ring jewel. Representative elements in FIG. **11** disclose shaft **302**, endstone **305**, and olive hole ring jewel **307**. In the presently preferred embodiment, bearing system **300** utilizes the same bearing components on front bearing assembly **309** as on rear bearing assembly **311** to thereby support both ends of a rotor, such as rotor **304**. However, differences between front bearing assembly and rear bearing assembly are preferably designed to develop after break-in of bearing system

300, as discussed hereinafter. Front bearing assembly **309** and rear bearing assembly **311** may be mounted in the pump casing or to pump flow elements such as the diffuser, straightener, and the like discussed herein. Such mountings are referred to generally in FIG. **12** as component **301**. Bearing components, such as endstone **305**, could be monolithically formed within pump flow elements **301** if those elements are formed of the necessary materials.

Shaft **302** of bearing system **300** may comprise a solid shaft mounted or affixed through the rotor **304**. Alternatively, shaft **302** may be comprised of two end sections that are mounted within appropriately sized but oppositely situated cavities in rotor **304**. In FIG. **13**, one of such shaft end segments is denoted as shaft end section **306**. As well, shaft **302** may be monolithically constructed with rotor **304** or a portion thereof so that it forms a one piece unit.

Preferably, shaft **302** is comprised of zirconia, whereas endstone **305** and olive hole ring jewel **307** are preferably formed of sapphire. The fact that sapphire is a somewhat harder material than zirconia is used to advantage as discussed subsequently.

In the presently preferred embodiment of shaft **302**, radiused end surfaces **308** and **310** are formed on front and rear bearing assemblies **309** and **311**, respectively. The remainder of shaft **302** is preferably cylindrical along its length but could have tapering portions or portions with other cross-sectional shapes. Because the sapphire material forming endstone **305** is somewhat harder than the zirconia of shaft **302**, radiused surface **308** in front bearing **309** wears but endstone **305** experiences substantially no wear. Designing the bearing system to wear only on radiused surface **308** is preferable because this design results in less friction after break-in as compared to designing wear to occur on endstone **305**, or on both endstone **305** and radiused surface **308**. Furthermore, because front bearing assembly **309**, rather than rear bearing assembly **311**, supports the thrust load, rear bearing assembly **311** experiences little wear.

The radius of curvature R1 indicated in FIG. **11** of radiused end surface, such as surface **308** as compared to the radius of curvature R2 of the circumference **312** as shown in FIG. **12** is preferably about three to one. However, any ratio larger than about one to one could be used. The selection of the radius of curvature R1 in this manner provides that the wear occurs very quickly during initial break-in. In fact, referring to FIG. **14**, rapid wear begins almost immediately during initial rotation at contact point **318** on radiused surface **308** of shaft end section **302** of front bearing assembly **309**. Wear then tapers off essentially to zero wear once bearing surface area **320** becomes large enough to support the thrust load. In other words, true point contact occurs during initial bearing operation of front bearing **309**, but wear of radiused surface **308** results in a small flat or bearing surface area **320** after an initial break-in period to effect a near point contact.

While the surface area of point contact **318** between radiused surface **308** and endstone **305** may have an area with a diameter of a few angstroms, the diameter D1 of the wear flat or bearing surface **320** is preferably less than about twenty-five thousandths (0.025) of an inch. Since little, if any, axial load is placed on rear bearing assembly **311**, little, if any, wear occurs on the radiused shaft end **310**. This is one distinction between front and rear bearing assemblies **309** and **311**, respectively.

The selection of the radius of curvature R1 also affects the change in end-play E1 of shaft **302**, shown proportionately

overly large in FIG. **12**. The change in end-play E1 between before and after break-in is indicated at least somewhat more proportionately in FIG. **14A** and FIG. **14B**, where the width of the end portion that is worn off to create wear flat or bearing surface **320** is about the same as the line width designated as E1. Preferably, change E1 is designed to be less than five thousandths (0.005) of an inch. As suggested by FIG. **14A** that presents a greatly enlarged view of shaft **302**, change E1 is a relatively small change in axial play. It will be understood that increasing the radius of curvature R1 will produce the necessary size bearing surface area **320** to support axial thrust with a relatively smaller change E1 in end-play of shaft **302**. Thus, the overall change in length of shaft **302** due to wear is minimized by using a shaft end radius R1 significantly larger than shaft radius of circumference R2. This results in extremely stable shaft end-play and axial clearances between pump components throughout the life of the pump. Stable shaft end-play maintains low levels of blood clotting and damage. Preferably, the shaft end-play after break-in is less than ten thousandths (0.010) of an inch.

The purpose of rear endstone **322** is mainly to secure and minimize impeller movement during handling and due to patient mobility. Rear endstone **322** therefore completes bearing system **300** to provide a sturdy, precise, and simple assembly.

Olive hole ring jewels, such as jewel **307**, may be commercially purchased or specially made. Olive hole ring jewels are normally used in components of precision instruments such as relatively slow moving visually readable needle indicators of analog meter movements such as volt meters, and the like. However, in a preferred embodiment of the present invention, olive hole ring jewel **307** is used to support high speed rotation of shaft **302** with very little friction. Olive hole ring jewel **307** has a doughnut-shaped or torroidial inner surface portion **330** that makes line contact, or near line contact, around circumference **312** of shaft **302** as indicated in cross-section in FIG. **12A**. In FIG. **14A**, cross-sectional points **319** and **321** of inner surface portion **330** contact shaft **302**. Of course, points **319** and **321** lie on the circle indicated as circumference **312** of the cross-section shown in FIG. **12A**.

Inner surface **330** also defines aperture **334** (see FIG. **11**) that receives circumference **312** of shaft **302**. Little bearing heat is produced because of the very low friction between zirconia shaft **302** and jewel **307** due to the near line contact that is made around the circumference **312** of shaft **302**. The locus of the width of the near line contact, as measured parallel to the axis of rotor **304**, is preferably less than about ten thousandths (0.010) of an inch.

Radial loads produced due to high speed rotation of rotor **304** are much smaller than axial loads so that virtually no wear occurs around zirconia rotor shaft **302**. Even when the pump components were disassembled for inspection after significant running time, no wear could be detected during microscopic examination of shaft **302** where shaft **302** contacts olive hole ring jewel **307**. The radial clearance between shaft **302** and olive hole ring jewel **307** is preferably in the range of about one ten-thousandths to two ten-thousandths (0.0001–0.0002) of an inch.

Olive hole ring jewel **307** maintains extremely precise impeller rotation and yet allows for axial shaft movement. No pre-load mechanism is required because bearing system **300** is designed to run with a small amount of shaft end-play. The shaft end-play after break-in is preferably less than about ten thousandths (0.010) of an inch. Fluid pressure is

not needed to support bearing loads because the bearing loads at circumference **312** and inner curved surface **330** contact each other. This bearing system therefore eliminates the need for an external reservoir or complex fluid porting arrangements or other forced fluid methods as used with other bearing systems. Blood trauma and potential of clotting is therefore reduced as compared with bearing systems that force blood through small clearances.

Another feature of olive hole ring jewel **307** is a relatively narrow width W as indicated in FIG. **13** that permits heat conduction through olive hole ring jewel **307**. Width W is measured parallel to axis of rotation of rotor **304**. While commercially available olive hole ring jewels may be purchased with a width of less than thirty-five thousandths (0.035) of an inch, specially made jewels may be formed with an even smaller width as desired. The advantage of a small width W of olive ring jewel **307** is that the heat produced by bearing system **300** is not insulated by jewel **307** so as to continue increasing. Instead, the heat conducts outwardly into the blood to provide a cool running bearing. The lower bearing temperature reduces the likelihood of bearing seizure, increases bearing life, and reduces the possibility of thrombus formation when blood contacts the bearings. It will be observed that a minimum thickness of jewel **307** is preferably required to support radial forces acting on shaft **302** on circumference **312** and/or to maintain jewel **307** in contact with circumference **312** of shaft **302**.

Bearing system **300** requires no shaft seals. Instead, the outer surfaces of shaft **302**, endstone **305**, and olive hole ring jewel **307**, define void **332** as indicated in FIG. **14A** and FIG. **14B**. Void **332** may be made very small by selecting radius R1 to be significantly larger than radius R2. Any blood that enters void **332** coagulates quickly due to bearing heat to form a smooth and stable surface that conforms to radiused surface **308**. Due to the conforming shape, coagulated blood does not interfere with shaft rotation. Once coagulated, the blood cannot leave void **332** to enter the blood stream. Furthermore, any coagulated blood in void **332** acts to further stabilize end play of shaft **302**. Radius R2 of shaft **302** may be made quite small if desired to reduce even further any friction created by coagulated blood. Certain other advantages of a void such as void **332** over attempts to seal or wash bearings with saline fluids are discussed hereinafter in connection with other bearing embodiments. However, FIG. **11** through FIG. **14B** disclose the presently preferred bearing system configuration embodiments.

In another bearing embodiment having a void for blood, FIG. **6A** discloses a ball-socket bearing configuration. The bearings are comprised of bio-compatible material such as ceramic material. The ball-socket bearing **121** may be configured as shown in FIG. **1** or in other configurations. Ball **120** is preferably secured by some securing means such as glue, welding, or other means along edge **128**. Ball **120** could be molded into one component or split and secured as is known in the art. Ball **120** has a spherical surface **122** that engages a mating seat spherical surface **124**. A void or bearing chamber **126** is filled with bio-compatible material to prevent blood from coming into this area and stagnating. In this embodiment, bearing chamber **126** is left empty and allowed to fill with blood. The blood cross-links due to bearing heat and takes on a soft, pliable, plastic texture. The cross-linked blood may perform, to some extent, a bearing surface function. The cross-linked blood then prevents other blood from entering the bearing and stagnating.

In an alternative bearing configuration, shaft-journal bearing **130** provides that shaft **132** is secured to component **134**, which may be rotor **46**, for rotation with respect to a second

component 136, which may be diffuser 20. Journal sleeve 138 has a cylindrical bearing receiving surface 140 for engaging cylindrical shaft bearing surface 142. Biocompatible material in bearing chamber 144 is preferably cross-linked blood, as discussed hereinbefore, which has leaked into this chamber, heated up, and solidified.

Another embodiment of a shaft-journal bearing would include a shaft (not shown) extending through rotor 46 and engaging respective sleeves on flow straightener 18 and diffuser 20. As well, the flow straightener and/or diffuser, or relevant portions thereof, may be made from a suitable material, such as zirconia, with the bearing surfaces being formed or machined directly into that material. In a similar manner, the bearing surfaces of bearing 121, 130, or other bearings could be machined into a bearing mount component in this way.

To avoid the problem of blood stagnation in the region of the bearing, several bearing washing configurations, using directed blood flow or pump differential pressures, may also be used as part of the present invention. Referring to FIG. 3, there is shown a means for using a pump pressure differential for washing bearing 150 which includes shaft 152 and journal sleeve 153. High pressure region 154 produces a blood flow through passage 156 to wash bearing 150 and exit to lower pressure region 158. Thus, blood is prevented from stagnating behind bearing 150.

Another bearing embodiment (not shown) would include a pressure fed journal bearing to form a hydrodynamic film that supports the shaft and loads so that the bearing surfaces do not touch. Shaft 152 would be slightly undersize with respect to a journal sleeve for this purpose, and a pressure fed flow passage may be directed through such a hydrodynamic journal bearing from high pressure region 154 to low pressure region 158.

FIG. 6C illustrates another bearing washing method by producing bend 160 in pump housing 12. This places bearing 162 in a high velocity flow area. Blood flow through bend 160 washes the bearing members which include a male portion 164 and mating member 166. Other configurations for this type arrangement may be used but the general principle is as shown. The flow straightener is removed in this embodiment but may be included in another embodiment where it does not necessarily need to act as a bearing support.

FIG. 6D and 6E illustrate yet another alternative bearing arrangement embodiment. In this embodiment, a bearing shaft 170 extends through journal sleeve 172. Bearing shaft 170 has an oblong, or substantially oval transverse cross-section as shown in FIG. 6E. This configuration produces flow paths 174 through journal sleeve 172 so as to flush the bearing and prevent blood stagnation. Shaft 170 could also be fluted so as to have spirals, slots, or in some other manner form flow paths 174 along its periphery within sleeve 172.

FIG. 6F shows a bearing configuration wherein rotor 46 is cantilevered with respect to diffuser 20 using two bearings 180 and 182. Shaft 184 extends between the two bearings. Each bearing includes a rotating ball surface, 186 and 188, mating with a socket surface 190 and 192, respectively. Socket surfaces 190 and 192 are formed in ceramic material sleeves 194 and 196, respectively. The bearings are "zero tolerance" bearings. Thus, either shaft 184 which runs through diffuser 20, or the diffuser 20 itself must provide a take up mechanism that keeps each ball surface 186 and 188 tightly engaged with respective socket surfaces 190 and 192. For this purpose, diffuser 20 could be made of compressible material. Alternatively, diffuser 20 could receive injection molding around sleeves 194 or 196.

As another alternative, either a passive or active, or a combination passive-active magnetic bearing suspension system (not shown) could be used to rotatably mount rotor 46 whereby rotor 46 would be axially positioned and/or bearing surfaces would be suspended with respect to each other using magnetic force.

The method of the present invention is illustrated in FIG. 8 which shows a test matrix for optimizing the pump parameters which are believed to affect hemolysis. This method enables optimization of pump parameters as discussed hereinafter with a minimum number of tests. Although this matrix is designed for a blood pump with no inducer or flow straightener, it is believed the method of the present invention is clearly illustrated with this example and may be used to improve most other blood pump designs with respect to hemolysis, thrombus, pump efficiency, cost, and other important factors. Using this approach, it is possible to thoroughly investigate many parameters in an organized, methodical approach to achieve highly desired goals such as optimum pump performance and minimum hemolysis.

To apply this method, it was first necessary to identify the pump parameters that were believed to affect hemolysis. The variables are listed at the headings of the test matrix and include blade tip shape, radial clearance, axial clearance, number of blades, and impeller length. To judge effectively the impact of each variable on hemolysis, the method of the present invention requires that all pump dimensions be held constant while only one variable is changed. As shown in the matrix of FIG. 8, 16 different tests are used. Preferably, each test is made at least three different times to provide statistical results and check consistency.

The information learned in initial tests is used later in the matrix. For example, tests 1 and 2 compare the effects of flat and round blade tip geometries. The least hemolytic of the two is then used in all remaining tests. If there is no statistically significant difference, then the result that provides superior hydrodynamic performance is used. If there is no hydrodynamic difference, then the least expensive parameter to manufacture is used. Test conditions are constant for each parameter. All tests were made using bovine blood at a flow of 5 liters/min against 100 mm Hg. The duration of each test was 20 minutes. The pump circulates blood through a test loop having a 500 cc blood reservoir which was conveniently a 500 cc blood bag. The 500 cc blood bag is preferably changed after each version of each parameter is tested.

In order to compare various impeller and stator blade geometries within a reasonable time period, a stereolithography technique was used to quickly realize the complex shapes. This technique relies on a laser beam that scans the surface of a liquid acrylic polymer. The polymer hardens under the influence of the laser, and layer by layer a solid shaped is formed from the liquid surface.

To compare hemolysis results, an index of hemolysis (IH) is used. This is defined as the amount of hemoglobin liberated in grams per 100 liters of blood pumped against 100 mm Hg. In equation form:

$$IH = \Delta Hb \times V \times (1 - Ht) \times \frac{100}{(\text{Flow} \times \text{Time})}, \qquad (1)$$

where:

IH equals amount of hemoglobin liberated in grams per 100 liters of blood pumped against 100 mm Hg;

Ht is the hematocrit in decimal percent;

V is the blood volume in liters;

ΔHb is the amount of hemoglobin liberated in a fixed time period in grams/liter;

Flow is the flow rate in liters per minute; and

Time is the total time in minutes at that flow rate.

The final results are seen in the matrix of FIG. **8** and other more detailed factors of testing in accord with the method of this invention are discussed more thoroughly in the articles which have been named previously and incorporated herein by reference.

As to manufacturing and usage considerations, Pump **10** is preferably manufactured using materials designed to be buoyant inside the body to make the completed pump neutrally buoyant or approximately neutrally buoyant. This minimizes stress on stitches or other means used to position the pump within the body. Thus, the rotor, rotor blades, and/or other components may be made with lightweight material having sufficient thickness to produce a buoyant effect.

Pump **10** has numerous uses as a blood pump including use as a portable blood pumping unit for field service or for other clinical applications involving other fluids. It could, for instance, be used in a compact heart-lung machine. Due to the small volume and size of pump **10**, it can be placed close to a patient to minimize shock caused when initiating blood pump operation using saline solution. Larger pumps, with larger volume, may be awkward to move close by a patient to eliminate this shock.

Thus, the blood pump of the present invention, optimized using the method of the present invention has many advantages over the prior art. For instance, there are no blood seals which require bearing purge systems. The bearing system has been found to require no maintenance for long-term, reliable operation. No Hall Effect sensors are required which may tend to limit motor control reliability due to their complexity. As well, pump **10** provides low power consumption and produces very low levels of hemolysis.

The foregoing disclosure and description of the invention is illustrative and explanatory thereof, and it will be appreciated by those skilled in the art, that various changes in the size, shape and materials as well as in the details of the illustrated construction, reliability configurations, or combinations of features of the various rotary pump elements of the present invention may be made without departing from the spirit of the invention.

What is claimed is:

1. A blood-pump bearing system for rotatably supporting a rotor section that is rotatable with respect to a housing through which blood is pumped, said bearing system comprising:

a shaft for rotatably supporting said rotor section, said shaft having a circumference defined by a first radius, said shaft terminating at a shaft end, said shaft end comprising a radiused surface defined by a second radius, said second radius being greater than said first radius;

an endstone mounted to said housing having a flat planar surface operable to contact said radiused surface of said shaft end;

a shaft circumferential bearing mounted to said housing and having an aperture therethrough for receiving said circumference of said shaft, said shaft circumferential bearing being operable to support radial loads acting on said shaft, said shaft circumferential bearing comprising a curved inner surface that defines said aperture, said curved inner surface being operable for making near line contact along said circumference of said shaft as said shaft rotates, wherein said shaft circumferential bearing comprises an olive hole ring jewel;

wherein a void is formed between said shaft end and said endstone into which pumped blood that leaks between said circumference of said shaft and said shaft circumferential bearing coagulates;

a plurality of individual magnets disposed on said rotor along a path that defines at least a portion of a helix; and

a stator mounted to said housing.

2. The pump bearing system of claim **1**, wherein:

said second radius is about three times said first radius.

3. The pump bearing system of claim **1**, wherein:

said endstone is comprised of a first material, said shaft end is comprised of a second material of less hardness than said first material such that wear occurs on said radiused surface of said shaft end to produce a flat surface thereon.

4. The pump bearing system of claim **1**, wherein:

said flat surface has a diameter less than about 0.025 inches.

5. The pump bearing system of claim **1**, wherein:

said second radius is selected such that change of shaft axial end-play due to creation of said flat surface is less than about 0.005 inches.

6. The pump bearing system of claim **1**, wherein:

said near line contact has a locus with a width of less than about 0.010 inches.

7. The pump bearing system of claim **1**, wherein:

said olive hole ring jewel has a width as measured parallel to an axis of said shaft of less than about 0.035 inches to promote heat transfer through said olive hole ring jewel.

8. The pump bearing system of claim **1**, wherein said shaft is axially movable to the extent that end-play of said shaft is less than about 0.010 inches.

9. The pump bearing system of claim **1**, wherein radial clearance between said shaft circumferential bearing and said circumference of said shaft is about 0.0001–0.0002 inches.

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