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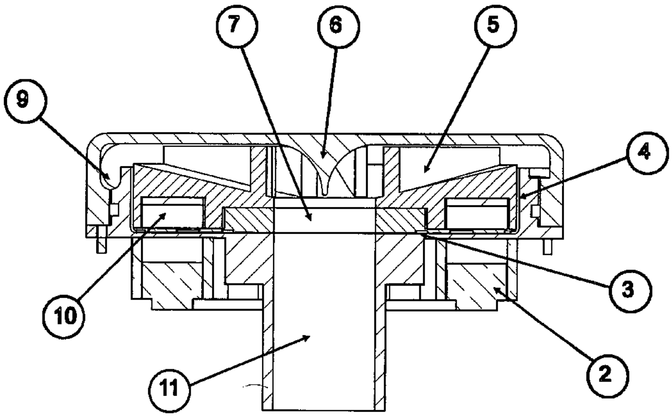

Fig. 1

(57) Abstract: The invention relates to a centrifugal blood pump apparatus comprising a housing having an inlet port, an outlet port and a pump chamber connecting these ports and an impeller located in the pump chamber and rotatable around an axis of rotation being coaxial with the inlet port, the impeller having a central axial opening, communicating with the inlet port, several blades and free spaces between the blades, the free spaces being radially open and communicating with the central axial opening and with the outlet port via a volute surrounding the impeller and a magnetic drive, driving the impeller by means of a magnetic field interacting with permanent magnets integrated in the impeller and a bearing for the impeller, in particular a hydrodynamic bearing, preferably by means of several spiral grooves or tilted pads in a lower end face of the impeller opposite to a mating inner surface of a lower wall of the pump chamber or in a mating inner surface of the lower wall of the pump chamber opposite to a lower end face of the impeller wherein each of the blades of the impeller has an axial abutting face directly opposing an upper wall of the pump chamber, in particular forming free spaces between the blades being open in axial direction and covered by the said upper wall of the pump chamber.

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Centrifugal blood pump apparatus

The invention relates to a centrifugal blood pump apparatus comprising a housing having an inlet port, an outlet port and a pump chamber connecting these ports and an impeller located in the pump chamber and rotatable around an axis of rotation being coaxial with the inlet port, the impeller having a central axial opening, communicating with the inlet port, several blades and free spaces between the blades, the free spaces being radially open and communicating with the central axial opening and with the outlet port via a volute surrounding the impeller and a magnetic drive, driving the impeller by means of a magnetic field interacting with permanent magnets integrated in the impeller and a bearing system for the impeller.

Such a bearing system may be formed as a hydrodynamic bearing realized for example by means of several spiral grooves in a lower end face of the impeller opposite to a mating inner surface of a lower wall of the pump chamber or in a mating inner surface of the lower wall of the pump chamber opposite to a lower end face of the impeller. A tilted pad bearing is also a known kind of hydrodynamic bearing.

A blood pump apparatus of this kind is for example known from the document US 2005/0287022 and typically used to bridge a patient to heart transplantation, to a heart recovery or to provide long term assistance.

Unfortunately, many of the current devices clinically available are too large and prone to mechanical failure due to contacting parts. In particular the apparatus known from the above-mentioned document comprises a driven rotor on a first side of an impeller that is magnetically coupled to the rotor and an inlet port formed as a channel on a second side of the rotor. As a consequence this apparatus has a long extension in the direction of the axis of rotation. Furthermore the impeller suspension by a single hydrodynamic bearing is not ideal to withstand shock situation to avoid contact between rotating parts of the apparatus, in particular the impeller and the housing or pump chamber.

It is an object of the invention to provide a small, long term, wear free and reliable blood pump apparatus that can be used to treat end stage heart failure. Preferably it is an object of the invention to use such an apparatus as a left ventricular assist device, a right ventricular assist device, or indeed in a dual device configuration to provide biventricular assistance. Furthermore it is an object of the invention to provide a blood pump apparatus that may also be used as an extracorporeal apparatus for example during a cardio pulmonary bypass situation during heart surgery or for extracorporeal membrane oxygenation patients. Preferably it is an object of the invention to provide high stiffness to the impeller and thus a high resistance against displacement in shock situations.

According to the invention each of the blades of the impeller has an axial abutting face directly opposing an upper wall of the pump chamber, in particular forming free spaces between the blades being open in axial direction and covered by the said upper wall of the pump chamber.

In former designs, in particular the design of the mentioned document the blades of an impeller are encapsulated between a top and a bottom cover. In this design according to the invention the top cover on top of the blades is omitted and thus the axial length of the apparatus may be reduced. In the apparatus according to the invention the blades of the impeller are positioned directly opposite the upper wall of the pump chamber, which is preferably formed by the upper wall of the housing. Accordingly this wall forms a cover for the rotating free spaces between the blades of the impeller. In operation of the pump apparatus a gap is maintained between the axial abutting end faces of the blades and the covering upper wall of the pump chamber.

According to the invention the axial length of the apparatus may be reduced in comparison to the known state of the art. In particular the design of an axially open impeller reduces the forces exerted to the impeller in direction to the stator of the magnetic drive.

In a preferred embodiment of this invention the central opening of the impeller communicates with an inlet port being formed as a channel or cannula ending in the lower wall of the pump chamber and being surrounded by at least a part of the magnetic drive, in particular an axial flux motor-stator. In this construction the stator coils of the magnetic drive and the channel / cannula are on the same side of the impeller thus furthermore reducing the axial length of the apparatus in comparison to the state of the art.

According to the invention it is possible to adjust the force in axial direction by adjusting the attractive force between the ferromagnetic stator of the motor and permanent magnets in the impeller. This may be performed by stator current adjustment / control or by construction, in particular the number of poles and/or the cross sectional area of the motor stator teeth. The stiffness of the axial drive may be controlled this way and by an additional magnetic suspension as it is explained later.

Furthermore it is preferred that the central opening of the impeller is formed as a through hole, meaning that the opening extends through the total length of the impeller. The through hole is ending opposite to the upper wall of the pump housing. In a preferred construction the upper wall has a tapered tip protruding from the upper wall into the through hole thus directing flowing blood from the inlet port to the free spaces between the blades. By use of such a tip the blood is redirected from a direction parallel to the axis of rotation in the cannula / channel to a direction radial to this axis in the through hole of the impeller.

The side walls of the tip may be formed like a parable or quarter-circular when regarded in a cross section parallel to the axis of rotation.

In a preferred embodiment the height of the free spaces between the blades decreases with increasing radius. This may be achieved for example if the upper face of the impeller carrying the blades is lower near the axis of rotation and higher at the outer circumference (with regard to the lower axial abutting face of the impeller), in particular the upper face being conically formed, in particular formed like a funnel into the inlet channel/cannula. Such a construction provides a bigger radial cross section of the free space between the blades on the entry side in comparison to the exit side. Furthermore this construction provides the possibility to enlarge the closed surface area of the outer circumference of the impeller in comparison to former constructions known in the art.

A radial journal bearing may be provided between the outer radial circumference of the impeller (in particular its lower part, being near to the magnetic drive) and the circumferential wall of the pump chamber, in particular between the outer radial circumference of the impeller and an inner circumferential wall of the volute and the pump chamber, preferably in combination with the afore-mentioned construction of decreasing height of the free spaces with increasing radius.

The radial journal bearing may be realized by the fact that the impeller is eccentrically arranged within the cross section of the pump housing. In particular this may be achieved by positioning the axis of rotation that is given by the magnetic drive eccentrically in the pump housing. The radial journal bearing separates the rotating impeller from the non-moving housing by means of a blood film between the above-mentioned circumferential walls. Preferably the blood is circulating around the impeller through the radial journal bearing and an axial hydrodynamic bearing due to the pressure difference between entry and exit side of the impeller and in case of a spiral groove bearing due to its active pumping capability.

Furthermore, the impeller may be stabilized by two kinds of hydrodynamic bearings: the radial journal bearing may be provided in addition to an axial hydrodynamic bearing, in particular as initially mentioned a spiral groove bearing or a tilted pad bearing. The shock-resistance of such an apparatus is improved. In an embodiment of the invention the impeller is fully fluid-suspended, i.e. floating in blood when rotated. In this embodiment the impeller is suspended by hydrodynamic bearings without any full-contact bearings. This suspension may be assisted by an additional magnetic suspension / bearing as described later which is the preferred embodiment.

The radial extension of an apparatus may be furthermore reduced by the fact that the height of the volute in axial direction is increased with decreasing distance to the outlet port, in particular by simultaneously maintaining the width of the volute and the gap between the axial abutting face of the inner wall of the volute and the upper wall of the pump chamber. Preferably the height of the volute increases in the direction of the lower wall of the pump chamber.

The type of volute, in particular a volute with increasing height in axial direction used in connection with the invention may be any of the following kinds:

1) A single volute, i.e. a volute that is characterized by a continuously increasing cross section from the volute tongue position in circumferential direction to the outlet port. Such a common volute is known for generating a minimal radial force on the impeller in combination with said given impeller for the design operational flow rate. An increased radial force is observed for off-design operational flow rates. The direction of the force on the impeller is not constant for the different operational flow rates. The hydraulic efficiency that is achievable with this volute type is higher than for a mixed or circular volute and comparable to the double volute.
2) A double volute, i.e. a single volute that is characterized by a splitter that is introduced in the flow channel of the volute and thereby creating two flow channels for a section of the circumference. Such a volute is known for

generating a minimal radial force on the impeller for all operational points. The direction of the force is approximately constant for all operational points. The hydraulic efficiency that is achievable with this volute type is higher than for a mixed or circular volute and comparable to the single volute.

3) A circular volute, i.e. a volute that is characterized by a constant cross section area around the circumference of the pump. The resulting radial force is elevated compared to a single and double volute and approximately constant in direction for all operational points. The hydraulic efficiency that is achievable with this volute type is lower than for the other mentioned volute types.

4) A mixed volute, i.e. in the context of this invention a volute that is characterized by a constant cross section area for parts of the circumference and an increasing cross section area for the remaining part of the circumference. The radial force that is achievable with this volute type is lower than for the circular volute type and not as constant in direction for all operational flow rates. The hydraulic efficiency that is achievable with this volute type is higher than for the circular volute and lower than for the single and double volute.

In another improvement the lower end face of the impeller is formed by a cover covering at least one, in particular several recesses in the impeller in which at least one, in particular several permanent magnets are arranged. The magnets in these recesses may be preferably the ones of the magnetic drive. The spiral grooves of a hydrodynamic axial bearing may be arranged in this cover if such a spiral groove bearing is provided. These recesses or additional recesses in the impeller may also include additional permanent magnets for the aforementioned additional magnetic suspension of the impeller – if such additional suspension is used.

Regardless whether the spiral grooves of an axial hydrodynamic bearing are positioned in the mentioned cover or in the lower wall of the pump casing these grooves may have a width being bigger than the distance between the grooves thus reducing the risk of hemolysis. Furthermore these grooves may have no direct radial connection to the inner hole of the impeller.

In particular in order to achieve a high total force capacity in the pump apparatus in a preferred embodiment of the invention several additional pairs of permanent magnets distributed around the axis of rotation and provided in the housing and the impeller respectively are used for an additional magnetic suspension of the impeller. These additional magnets provide a force exerted to the impeller in an axial direction that is at least partially compensating the attractive force between impeller and magnetic drive. Accordingly this non avoidable attractive force needs not to be compensated by the hydrodynamic bearing alone.

As a consequence such an additional magnetic suspension improves force capacity and thus reduces the risk of touchdown of the impeller in a shock situation.

The compensating force may be given by means of repelling magnets positioned in the lower wall of the pump casing and the lower part of the impeller or by means of attracting magnets being arranged in the axial abutting faces of the blades and the upper wall of the pump chamber.

Mostly preferred in combination with an otherwise complete hydrodynamic suspension but also possible with attractive bearing magnets an active tilt control may be realized. This may be done by at least three additional position sensors disposed in the non-moving part of the apparatus and facing a rotating conductive or magnetic section of the impeller thus providing the possibility to capture a signal proportional to the distance between sensor and magnets i.e. proportional to tilt. Additional coils may be integrated in the stator part of the magnetic drive in order to provide a tilt compensating current in these coils in dependence of the signal.

These tilt compensating coils may be positioned on the stator teeth in an axial direction between the coils of the magnetic drive and the permanent magnets of the drive. Furthermore these coils may be individually set under current.

In particular in combination with an additional magnetic suspension, in particular for improving the stiffness of the impeller even further in the magnetic drive, stator teeth may be used having at least the axial length of the stator coils thus providing a higher attractive motor force that still may be compensated by the hydrodynamic bearing and the magnetic suspension. This improves motor efficiency. Additionally, the pole face area of the stator teeth is increased which yields lower losses and a higher driving torque at the expense of a higher axial attractive force, in particular it may be increased to a value of $9.8mm^2$ for each tooth for a 12 coil configuration. The pole face area corresponds to a coil thickness (the lower the coil thickness, the higher the pole face area) and the coil thickness may in this case particularly be down to 2.1mm.

In case that the impeller is only suspended by means of a hydrodynamic bearing without additional magnetic suspension and without active tilt control the stator teeth of the magnetic drive may be shorter than the axial length of the coils surrounding the stator teeth. In such a case the attractive force is lower compared to the afore-mentioned embodiment and may be compensated by the hydrodynamic bearing alone. It is even possible to omit stator teeth at all in such a case. Particularly here, the pole face area may be decreased to $8.0mm^2$ for each tooth for a 18 coil configuration. The corresponding coil thickness may be chosen up to 1.5mm.

In another preferred embodiment the upper wall of the housing is formed as a removable cover of the pump housing. Removal of this cover provides access to the impeller.

Preferable the outlet port comprises a connecting member or flange to which exchangeable port-pieces are mountable. This provides the possibility to change the port pieces in dependence of the requested application. For this purpose the cross section of the connecting member or flange may be rectangular or square. A port piece may fit on one side to this rectangular or square cross section having a circular or elliptical cross section on the other side, in particular on the exit side.

Embodiments are shown in the figures.

All the Figures 1 to 3 show the essentials of the inventive construction of an axially thin rotary blood pump apparatus with a fully suspended impeller having free spaces between the impeller blades being open in axial and radial direction. A channel 11 is provided for blood entering the through hole in the impeller, being redirected from an axial direction into a radial direction by means of the cone 6 emerging from the upper wall of the pump chamber into the through hole and being discharged via the volute 9 into the exit of the apparatus. In the circumferential direction of the impeller the surrounding volute increases in axial height. The impeller may be driven by an axially aligned motor (axial flux) which may create, by design, an adjustable force in the axial direction through the attractive force of the ferromagnetic stator 2 (not fully shown) and the rotor permanent magnets 10.

According to the first embodiment of Figure 1 the impeller is fully blood suspended by means of an hydrodynamic axial spiral groove bearing 3 providing grooves 15 in the lower end face of the impeller as shown in Figure 4 and by means of a radial journal bearing 4 for which the impeller 5 is eccentrically positioned in the pump chamber. This embodiment only provides passive tilt control due to hydrodynamic forces. Accordingly only the hydrodynamic bearing compensates the attractive force on the impeller. In this embodiment preferably a circular volute may be used, providing the advantage that a radial force approximately constant in direction is able to stabilize the impeller in radial direction and increase radial stiffness.

Figure 2 shows an improvement in which an additional magnetic suspension of the impeller is provided for higher force capacity and motor efficiency. In a preferred configuration, a tilted pad bearing, as shown in Figure 5, may be used instead of a spiral groove bearing 3 at the same location. According to this Figure 5 the lower surface of the impeller has several sloped areas forming several tilted pads A as known in the art to provide another type of hydrodynamic bearing. All other features correspond to Figure 1. Co-working pairs of repelling magnets 12a and 12b are disposed in the lower wall of the pump chamber and the lower part of the impeller respectively. Accordingly the attractive force of the magnetic drive may be compensated in this embodiment by means of the hydrodynamic bearings and the additional magnetic suspension. A bigger teeth lengths and larger pole face area may be used in the stator of the magnetic drive compared to the embodiment of Figure 1. In this embodiment preferably a single volute may be used, providing the advantage that the hydraulic efficiency is maximal.

Figure 3 shows an embodiment in which pairs of attractive magnets 8a/8b are used instead of the repelling magnets of Figure 2. The magnets are disposed in the abutting faces of the blades of the impeller and the upper wall of the pump housing. Accordingly also in this embodiment the attractive force of the magnetic drive may be compensated by means of an axial hydrodynamic bearing and the additional magnetic suspension. A higher teeth lengths and larger pole face area may be used in the stator of the magnetic drive compared to the embodiment of Figure 1.

Furthermore this Figure 3 shows an active tilt control that may be provided also in the embodiment of Figure 1 creating another possible embodiment. If a tilt control is employed in the embodiment of Figure 3, a spiral groove bearing 3 is used to benefit from a pumping effect that generates a washout of the secondary flow path. If an active tilt control is omitted creating yet another possible embodiment, a hydrodynamic tilted pad bearing is required to benefit from its elevated tilt restoration capacity. This active tilt control comprises at least three position sensors 1 for providing a signal proportional to the tilt of the impeller. For this purpose the sensor may face a magnetic or conductive section of the impeller, for example a magnet of the drive. The signal is used to control the current in the coils of the magnetic drive or to control the current in additional tilt-control-coils provided in that stator. In this embodiment preferably a single volute may be used, providing the advantage that the hydraulic efficiency is maximal.

The magnets, in particular one of a pair of the additional magnetic suspension of the impeller may be several single magnets, in particular segmented magnets or magnet rings.

Figure 6 shows in a crossectional view the volute 14 surrounding the impeller. As mentioned for Figure 1 to 3 the height of the volute increases with decreasing distance to the outlet port. The volute type may be one of the afore-mentioned four kinds. This outlet port may have a connecting member or flange of rectangular cross section to which exchangeable port-pieces are mountable as shown in Figure 7. Different port pieces may be used according to the requested application of the apparatus.

In all the afore-mentioned embodiments the impeller may be rotated by an axial flux motor that, in one instance, may include a tilt control, in particular by controlling the current through the stator coils or additional tilt-control coils in dependence of the measured signal of at least three tilt sensors 1.

Instead of an axial spiral groove bearing (SGB) a tilted pad bearing (TPB) 3 may be used in all possible embodiments, as mentioned for Figure 2.

The design of the motor stator and the motor impeller plays an important role in achieving a highly stiff axial drive and suspension system. Here, an optimal point between motor efficiency, smooth motor operation and the stiffness may be found.

For an axial flux motor, the axial force changes with the air gap d between the stator teeth and motor impeller permanent magnets 10 as shown in Figure 8. To achieve a significant total positive stiffness in the axial direction, the negative stiffness of the axial flux motor is to be reduced. The stiffness of the motor is a nonlinear relationship to the gap distance d. Also, the stiffness can be significantly adjusted by changing the pole number in the motor rotor and/or the cross sectional area of the motor stator teeth.

Further the stiffness is a function of saturation effects in the motor impeller and stator. While adjusting the saturation in the stator yoke and/or the back iron of the impeller, the axial force and stiffness of the motor can be controlled. Care must be taken to not increase the saturation in the motor stator and rotor above an acceptable level which would yield a drop in efficiency and torque generation. If the cross sectional area of the motor stator teeth is reduced, a reduction of motor axial force and stiffness results.

A smaller pole number reduces the negative stiffness of the motor, contributing to a maximized positive system stiffness. On the other hand, smooth motor operation is improved by a high pole number combined with a defined slot number/ coil number in the motor stator; one preferred embodiment could use a combination of 18 slots and 16 poles.

For this embodiment, in order to achieve a total positive stiffness, the axial force created by the motor is adjusted by coils that are longer than the stator teeth and thus increasing the distance d as shown in Figure 9. This yields a low force and a low stiffness. However, longer teeth, in particular longer than the axial length of the coils would result in a smaller air gap between the stator teeth and rotor magnets, which improves motor efficiency.

Another embodiment could use such a motor stator configuration with a reduced pole number in the motor rotor, for example 12 slots and 10 poles. Consequently, the distance d is reduced but the negative stiffness and the force magnitude remains tolerable. This embodiment is the preferred embodiment because of an increased motor efficiency.

In particular to counteract the attractive force by the motor and shock forces in the same axial direction, magnets or ferrous material 8b in the impeller blades, in particular in the abutting faces of the blades, and a ferrous metal ring or magnet ring 8a of opposing pole (to create an attractive force) in the casing create a counteracting axial bias force in addition to the hydrodynamic bearing (SGB or TPB), allowing even higher axial forces by the motor and thus a smaller air gap between the impeller and stator teeth 2, as shown in Figure 3.

A similar effect may be created by orientating same pole magnets 12a / 12b in the lower face of the impeller and in the casing lying opposite to it so as to produce a repelling force which is supported by the hydrodynamic bearing to counteract higher axial forces produced by the motor, as already shown in Figure 2.

Permanent magnets may be integrated in the blades and the opposing casing or in the lower face of the impeller and the opposing casing or in both positions.
The magnets in the impeller blades should be located as close to the rotational axis as possible so as to reduce the rotor's moment of inertia. This will reduce the moment of inertia and thus power requirements in cases where impeller rotation is operated with speed pulses.

The configuration of permanent magnets as described above may improve the stiffness in the axial direction. A segmented permanent magnet, in particular radially segmented magnet bearing may be employed. The magnets may be magnetized in axial direction and two rings may be used which yield a steeper force curve, according to Figure 9.

Passive permanent magnets configurations commonly use designs like PM1 of Figure 9. The segmented approach of magnets like PM2 of Figure 9 may be used for the configuration of permanent magnets in the motor casing side or with permanent magnets on the opposite side.

To further increase the total stiffness, the motor stator and the permanent magnets may be misaligned in the casing according to Figure 10 / System 2. This increases the positive stiffness effect of the permanent magnets when compared to the negative stiffness of the motor. The total axial force should always have a maximal positive slope. When all forces balance, the impeller will be in fixed position.

The permanent magnets play also an important role for the radial stiffness of the suspension and drive system. It has been found that the motor radial stiffness is negligible for the axial flux motor configurations assumed in this invention. The permanent magnets on the other hand produce a significant radial force that can bias the hydrodynamic journal bearing. A biased hydrodynamic bearing will work in a stable manner. The biasing force may be created through a slightly eccentric operation of the impeller in the casing which results in a misalignment of the permanent magnets in the stator and in the rotor. By this misalignment a magnetic radial force on the impeller is created which points into the direction of minimal film thickness.

The spiral groove bearing as shown in Figure 4 is preferably inwardly pumping and partially grooved. It may be optimized for washout and suspension capacity by having a groove geometry that has the inner radii rounded but the outer not.
Like any hydrodynamic bearing, the force and stiffness increases with a reduced gap between the moving and stationary walls. The washout production is a major benefit of this bearing as thrombus formation has been seen to occur in secondary flow paths of rotary blood pumps. The washout reduces the residence time of cells in this region and thus reduces the risk of thrombus formation. The spiral groove bearing is inwardly pumping and preferably possesses a step restriction 15 close to the center, in particular in the low shear region. The inflow 11 of the pump runs through a large through hole 7 in the middle of the impeller to improve washout and avoid stagnation areas. Furthermore, the possible speed pulsing of the rotor during operation leads to a changing operating film thickness between the impeller and stator, thus further assists in washing out this region.

A tilted pad bearing (TPB, Figure 5) may also be used as an alternative hydrodynamic axial bearing. The tilt restoration capacity is bigger compared to the spiral groove bearing and thus it can be used for an embodiment where axial force capacity and washout flow generation play a minor role compared to tilt restoration capacity. The axial abutting surface of the impeller or the corresponding casing surface is equipped with inclined surface sections, the pads A. Through these pads, a number of narrowing hydrodynamic bearing gaps are created when the impeller rotates.

External gyroscopic accelerations, radial hydrodynamic bearings through eccentric rotor operation, an uneven volute pressure distribution, or other forces creating tilting forces may cause impeller touchdown through unwanted tilt movement. The introduced design possesses in one embodiment at least three position sensor 1 to measure the tilting of the rotor and the motor then acts as active control. This may be done by controlling the current in the stator 2, in particular in the stator coils or in additional tilt-control coils.

The pump's impeller has a unique compact design due to the 'inverted' flow stream which allows implementing the impeller blades 5 into the rotor body itself while enough space still remains for the magnet ring 10 of the motor rotor, in particular integrated into the lower face of the impeller. A top shroud in this design is not necessary anymore. This design leads to a significantly reduced size of the impeller and hence of the overall size of the pump, particularly in the axial dimension. The flow may, after passing the hole in the impeller be directed away from the center by a cone 6, which increases the hydraulic efficiency and avoids stagnation in the center.

The volute 14 can be circular or a mixed circular-single type to create an additional hydraulic bias force in the radial direction acting on the impeller, whilst still maintaining high volute efficiency. The radial bias forces, from the volute, are thereby acting in almost the same direction for all operating flow rates. This fact makes the hydraulic force created by the volute-impeller configuration suitable as a bias force resulting in a stable impeller operation and increased radial stiffness. In a heart assist configuration, the pump routinely operates at changing flow rates and at off-design points due to the residual heart function. For one embodiment, the volute can be of a double volute type including a splitter of the volute flow path.

Such a volute is more hydraulically efficient and for almost creating no radial bias force for design and off-design flow rates. In this case, the permanent magnets create the only significant radial bias force which will result in a less stiff radial suspension but in more efficient device. In a further embodiment, the volute type can be a single volute which results in a less stiff and stable suspension in the radial direction but is the most simple, efficient and compact version.

The cross section area of the single and double volute segment varies through an increase in the axial dimension (height) while maintaining a constant dimension in the radial direction (width), thus maintaining radial compactness.
In this configuration also a substantially square volute throat cross sectional area may be provided. A transition piece 13 or diffusing section can be optionally placed separately from the pump (i.e. as part of the connecting outflow cannula), to improve manufacturability. Furthermore, this diffuser section 13 can be modified to have a smaller cross sectional throat or outlet area for inclusion in the device configured for the right ventricular assist device (RVAD) application. The smaller area will create a higher resistance to flow and thus reduce the outlet pressure from the device, as required by the pulmonary circulation to which the RVAD connects.

The journal bearing 4 is a hydrodynamic bearing that supports the free floating impeller in the radial direction.

The high stiffness of the suspension and drive system in the radial direction is ensured by a radial bias force and the nature of the hydrodynamic bearing. Through a radial hydraulic force constant in direction generated by the volute design, the direction of the total radial bias force is almost constant. By adding a bias force through the permanent magnet design, the amplitude of this bias force becomes more significant leading to a stiffer radial suspension. The probability of an uncontrolled movement of the impeller in the circumferential direction has been dissolved. The increased stiffness is thus a result of the fact that any shock or unbalancing radial force will be balanced either by the total bias force or by an increase in hydrodynamic bearing force, depending on direction. A hydrodynamic bearing force is naturally characterized by an increasing stiffness when the moving wall closes the distance to the stationary wall.

The journal bearing 4 can possess grooves, in particular in the circumferential area of the impeller or the volute side wall which increase the cross-flow through the circumferential gap. As the impeller spins at a radially eccentric position, pressure differences emerge across the journal bearing which are transferred to the bottom surface of the rotor creating unwanted tilting moments. These pressure differences occur due to circumferentially varying flow resistance in the radial clearance. The design of the journal bearing grooves further offers the possibility of higher flow in the small gap section, thus counteracting the emerging pressure differences.

The integrated inflow cannula is suitably sized for the RVAD application, with an extension piece available to connect to the device inlet to extend the inflow to the centre of the left ventricular cavity for the left ventricular (LVAD) application.
The innovative design of this pump allows it to be compact and small in size as a consequence of the proposed improvements.

List of references

1. Position sensor(s)
2. Axial flux motor stator, in one embodiment including an active tilt control algorithm
3. Hydrodynamic spiral groove bearing
4. Hydrodynamic journal bearing
5. Impeller blades
6. Cone
7. Impeller
8. a) Permanent magnets in casing on opposite side of motor stator, b) Permanent magnets in impeller blades
9. Volute channel increased in axial direction

10. Motor rotor magnets
11. Inlet tube
12. a) Permanent magnets in casing at motor stator side, b) Permanent magnets in motor rotor
13. Exchangeable diffuser section
14. Volute
15. Step restriction of spiral groove bearing
16. Edges of grooves of spiral groove bearing

s: Stiffness (Change of force)
PM: Permanent magnetic bearing
d: distance
MS: Motor stator
F: Force

The invention provides the following advantages/features:

1. The stator teeth of the axial flux motor do not necessarily extend through the entire coil set (distance d is increased) so that the axial attractive force and stiffness of the motor is reduced, thus the SGB and/or any other axial bearing does not need to compensate for large axial forces and negative stiffness. Also, the total system stiffness is positive.

2. The motor attraction force may be offset by a set of permanent magnets in the casing and in the rotor. These magnets are arranged either on the opposite side to the motor location (attracting) or on the same side as the motor (repelling). The magnets can be segmented into numerous single rings which allow a higher and adjustable positive stiffness of the entire system. This avoids touchdowns in axial direction or the creation of instantly minor fluid gaps.

3. The air gap difference between PM and motor stator and rotor respectively is chosen to maximize total stiffness in the axial direction. This avoids touchdowns in axial direction or the creation of instantly minor fluid gaps.

4. The motor rotor pole number is chosen to maximize total stiffness in the axial direction. This avoids touchdowns in axial direction or the creation of instantly minor fluid gaps.

5. The cross sectional area of the motor stator teeth is adjusted to find the best operation point of the motor stator in terms of motor efficiency and total system stiffness. This avoids touchdowns in axial direction or the creation of instantly minor fluid gaps.

6. The motor rotor back iron geometry and therefore the saturation level in the back iron is designed to find the best operation point of the motor in terms of motor efficiency, exerted axial force and total system stiffness. This avoids touchdowns in axial direction or the creation of instantly minor fluid gaps.

7. Conventional volute sections extend in the radial direction, contributing to a larger overall pump diameter. However to save radial space, the volute section is extended in the axial direction. The volute is either a full single volute or a circular volute for half of the circumference, then completed by a single volute transition to the outlet section, a complete circular volute (no extension in axial direction) or a double volute.

8. A large radial stiffness is ensured through the combination of hydraulic and magnetic bias forces. This increases the stability of rotor operation and decreases the probability for impeller touchdown or instantly minor fluid gaps in the radial direction.

9. In one embodiment, the combination of a spiral groove bearing, journal bearing, and axial flux motor *with* active tilt prevention/restoration to provide a completely levitated rotary blood pump impeller.

10. The combination of a spiral groove bearing and axial flux motor, *with* the motor actively controlled/oriented so that it can restore/reduce tilt. Combating tilt and maintaining rotor SGB operation parallel to the casing surface promotes the counteraction of larger axial forces and a creation of a desired flow according to the design of the SGB.

11. The SGB is inwardly pumping and has a step restriction at a smaller inner radius. A hole in the centre promotes washout of the SGB gap. The step restriction at the inner radius is beneficial with respect to blood damage, as the shear stress generated at this inner radius is lower than, say, a restriction at the outer radius of an outwardly pumping SGB. The ratio of ridge to gap width is less than 1 which produces a reduced region of high shear stress between the casing and ridges. The groove depth is also deep enough such that the path of the blood cells in the groove is not subjected to high shear stresses. This yields the desired washout flow according to the SGB design and lower shear rate. In the embodiments with PM, the SGB serves primarily as source for the desired washout of the secondary flow path.

12. The diffuser section is separated from the casing to ease manufacturing. This also enables an alternate diffuser to be used for the device that is configured as an RVAD. Thus the manufacture and assembly of the whole pump is exactly the same, with just a different diffuser. The diffuser for the RVAD application has a smaller cross sectional area to create an additional pressure drop and thus a suitable outflow pressure for the pulmonary circulation. This technique also allows for the maintenance of impeller rotational speed to the same value as the LVAD application, which consequently maintains sufficient SGB/TPB and JB force capacity, at the expense of device efficiency. Furthermore, washout of the small clearance gaps is maintained, as the pressure at the periphery of the rotor is just as high as in the LVAD application, and thus backflow through these gaps is maintained.

13. Inflow cannula section is suitably short for the RVAD application. That is, the inflow does not extend to far into the thin walled and small chamber so as to be occluded

by the ventricular septum. This means, there is no need to do any modifications concerning the inlet cannula like for other devices. As this length is sub-optimal for LVAD assistance, an extension cannula is provided to relocate the inflow to the centre of the LV cavity.

Claims

1. Centrifugal blood pump apparatus comprising
    a. a housing having an inlet port, an outlet port and a pump chamber connecting these ports and
    b. an impeller located in the pump chamber and rotatable around an axis of rotation being coaxial with the inlet port, the impeller having a central axial opening, communicating with the inlet port, several blades and free spaces between the blades, the free spaces being radially open and communicating with the central axial opening and with the outlet port via a volute surrounding the impeller and
    c. a magnetic drive, driving the impeller by means of a magnetic field interacting with permanent magnets integrated in the impeller and
    d. a bearing for the impeller, in particular a hydrodynamic bearing, preferably by means of several spiral grooves or tilted pads in a lower end face of the impeller opposite to a mating inner surface of a lower wall of the pump chamber or in a mating inner surface of the lower wall of the pump chamber opposite to a lower end face of the impeller

    wherein
    e. each of the blades of the impeller has an axial abutting face directly opposing an upper wall of the pump chamber, in particular forming free spaces between the blades being open in axial direction and covered by the said upper wall of the pump chamber.

2. Apparatus according to claim 1, **wherein** the central opening of the impeller communicates with an inlet port being formed as a channel ending in the lower wall of the pump chamber and being surrounded by the magnetic drive, in particular an axial flux motor.

3. Apparatus according to claim 1 or 2, **wherein** the central opening of the impeller is formed as a through hole ending opposite to the upper wall of the pump housing, the upper wall having a tapered tip protruding from the upper wall into the through hole thus directing flowing blood from the inlet port to the free spaces between the blades.

4. Apparatus according to any of the preceeding claims, **wherein** the height of the free spaces between the blades decreases with increasing radius.

5. Apparatus according to claim 4, **wherein** the upper face of the impeller carrying the blades is conically formed.

6. Apparatus according to any of the preceeding claims, **wherein** a radial journal bearing is formed between the outer radial circumference of the impeller and the pump chamber, in particular an inner circumferential wall of the volute and the pump chamber, preferably by eccentrically arranging the impeller within the cross section of the pump chamber.

7. Apparatus according to any of the preceeding claims, **wherein** the height of the volute in axial direction is increasing with decreasing distance to the outlet port, in particular by simultaneously maintaining the width of the volute and the gap between the axial abutting face of the inner wall of the volute and the upper wall of the pump chamber.

8. Apparatus according to any of the preceeding claims, **wherein** the lower end face of the impeller is formed by a cover covering several recesses in the impeller in which permanent magnets, in particular permanent magnets of the magnetic drive are arranged.

9. Apparatus according to claim 8, **wherein** the spiral grooves of the hydrodynamic bearing are arranged in the cover.

10. Apparatus according to any of the preceeding claims, **wherein** magnets are arranged in the impeller and the pump housing for providing an axial force at least partially compensating the attractive force between the impeller and

magnetic drive and /or for biasing a radial journal bearing, in particular by means of pairs of repelling magnets disposed in the lower part of the impeller and the lower wall of the pump housing respectively and/or by means of attractive pairs of magnets in the axial abutting faces of the blades and the upper wall of the pump chamber respectively.

11. Apparatus according to any of the preceeding claims, **wherein** sensors are provided in the non-moving part of the apparatus, in particular in a wall of the pump housing for capturing a signal proportional to the distance between the sensors and a rotating magnet or a conductive section in the impeller, in particular a signal proportional to the tilt of the impeller, the signal being used to control a tilt-compensating current through at least one tilt-compensation coil in the magnetic drive.

12. Apparatus according to any of the preceeding claims, **wherein** the upper wall of the housing is formed as a removable cover of the pump chamber, providing access to the impeller.

13. Apparatus according to any of the preceeding claims, **wherein** the outlet port comprises a connecting member or flange to which exchangeable port-pieces are mountable.

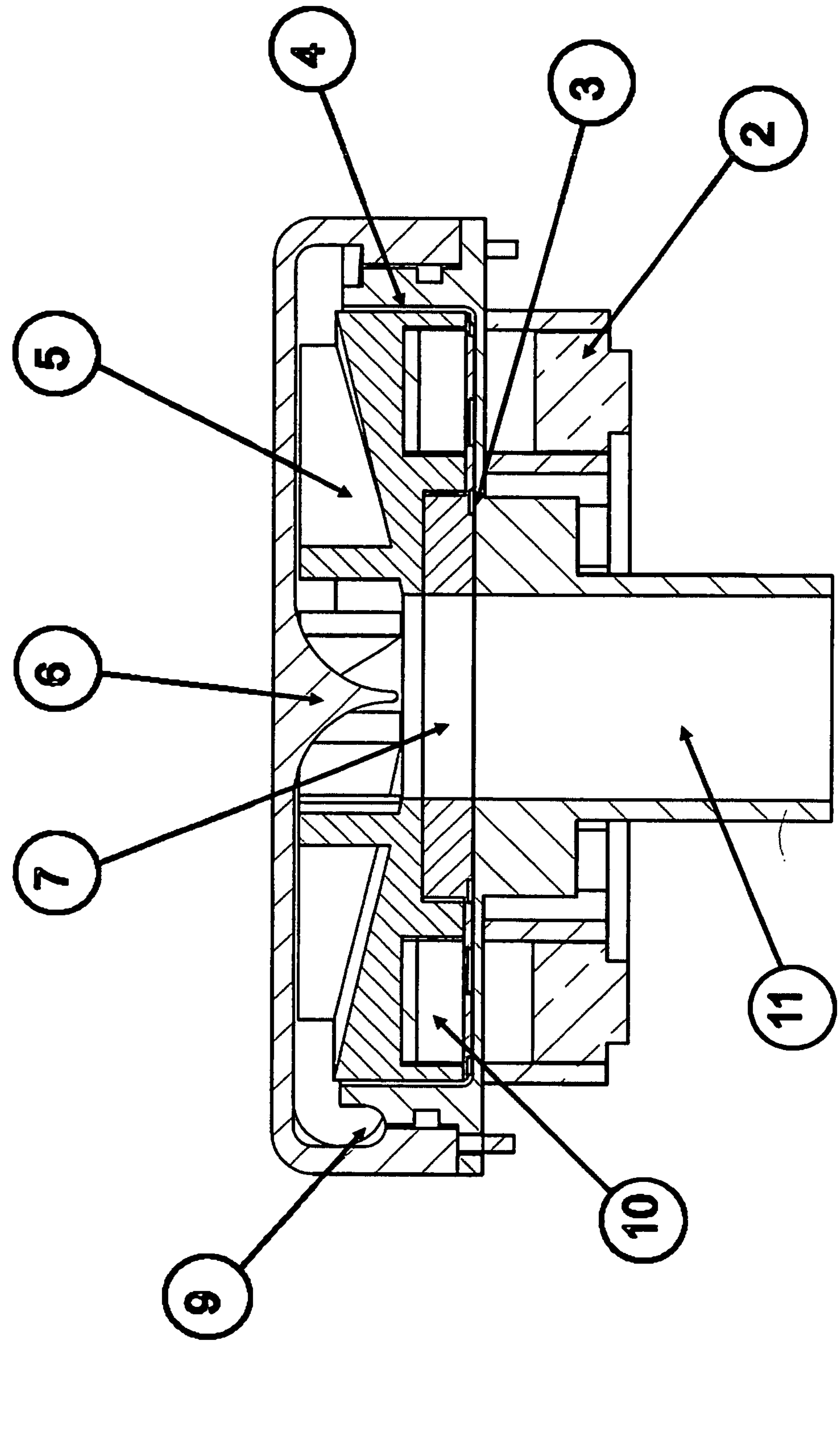

Fig. 1

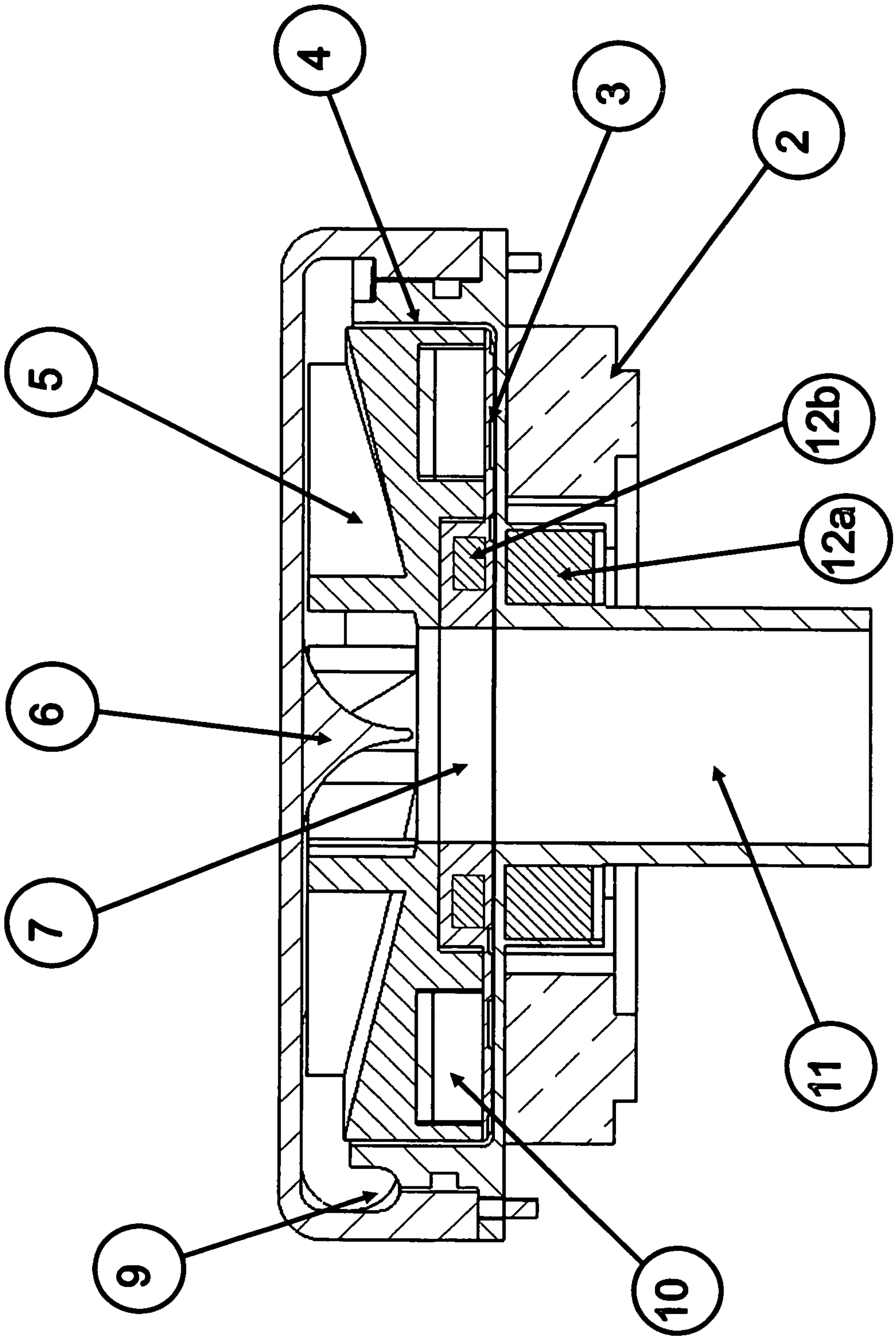

Fig. 2

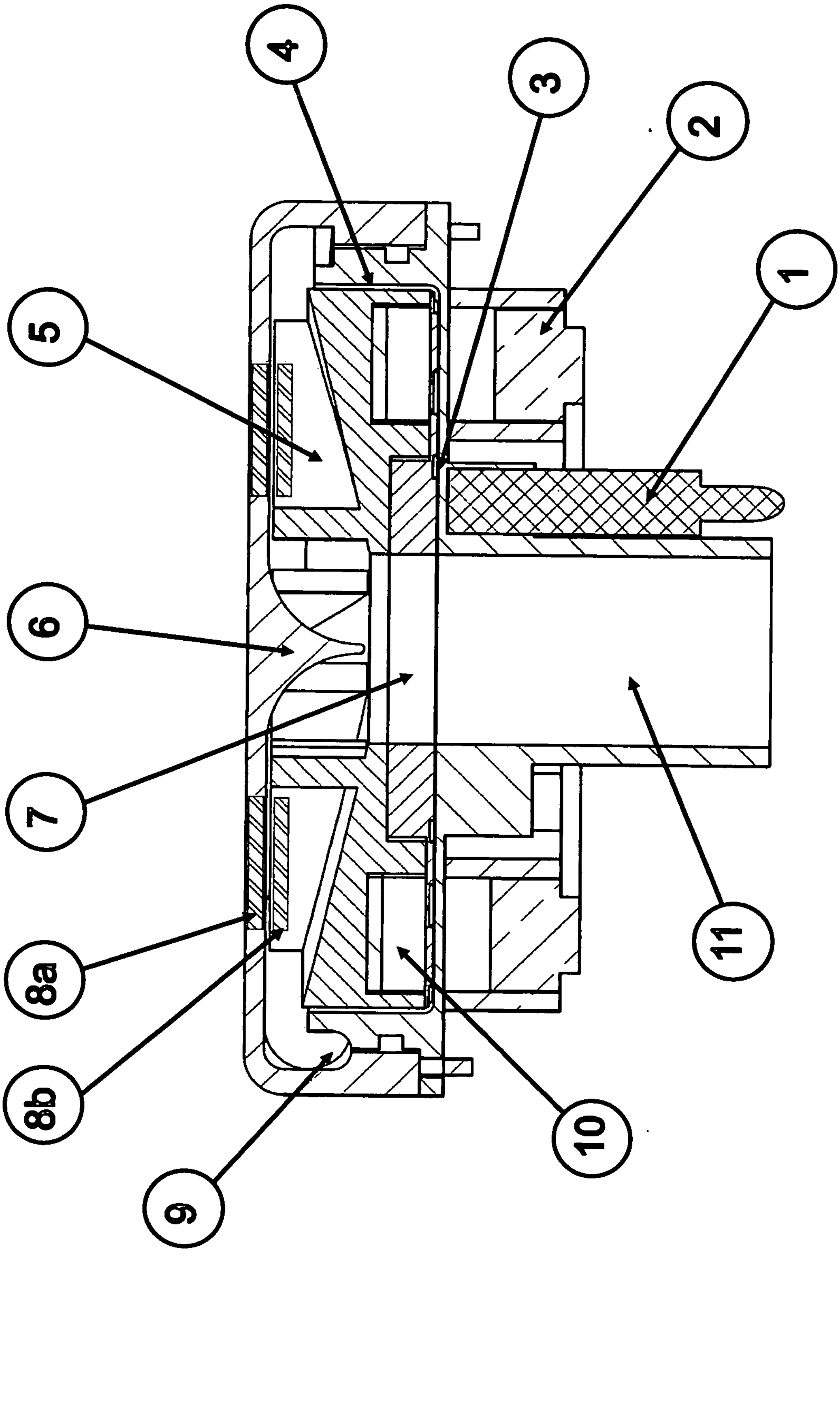

Fig 3

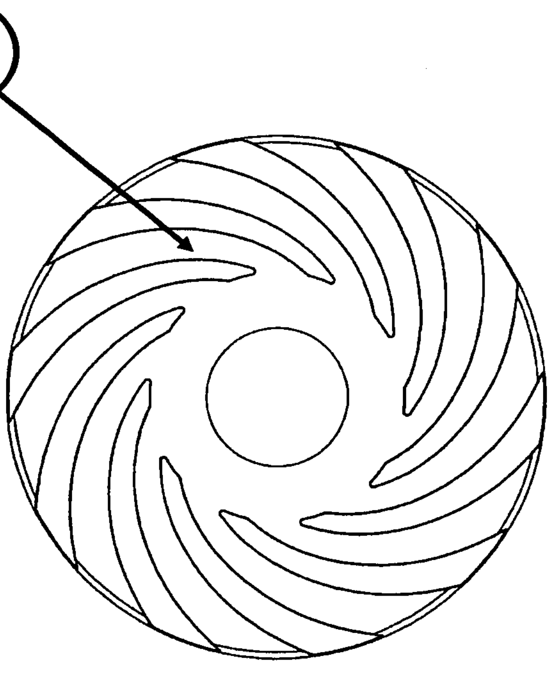

Fig. 4

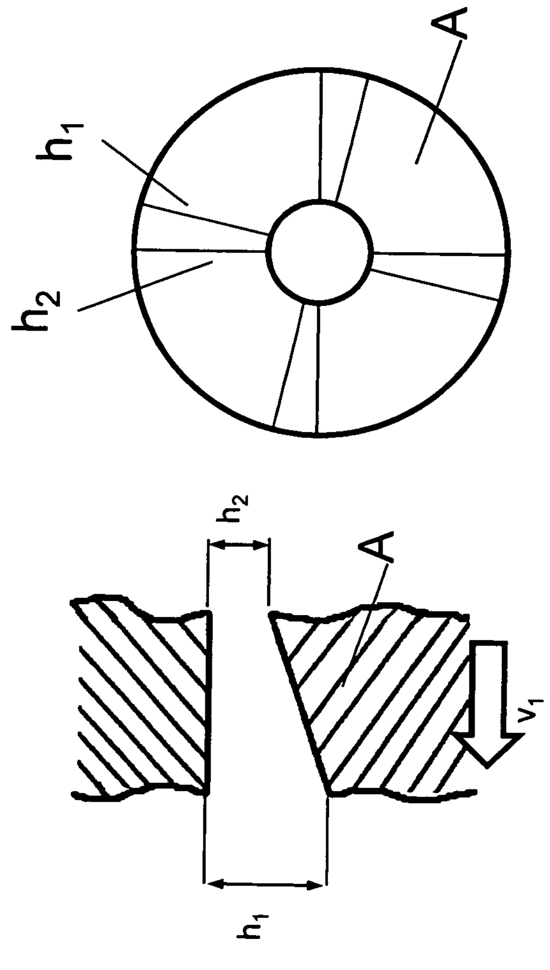

Fig. 5

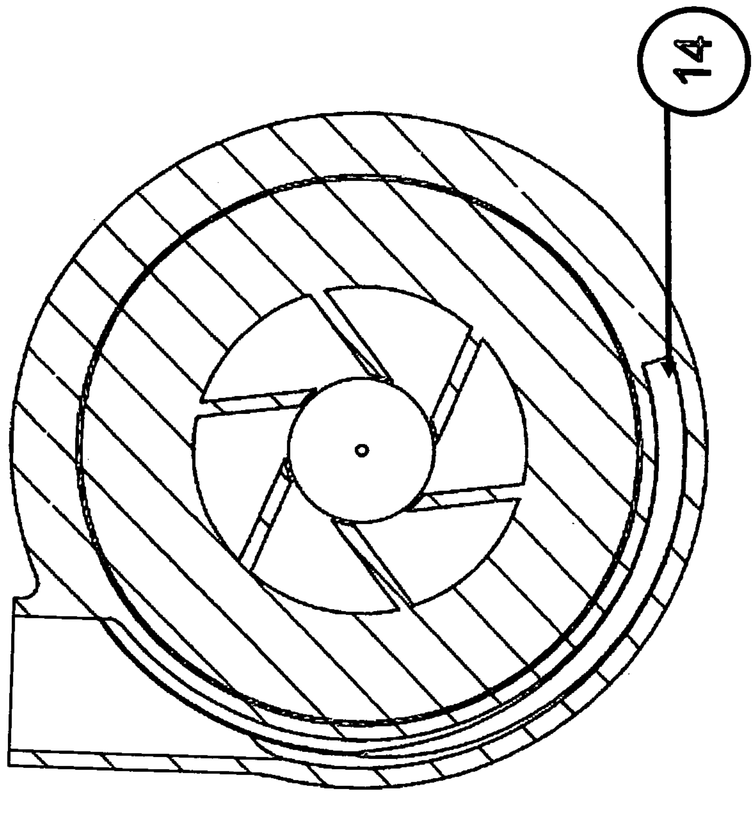

Fig. 6

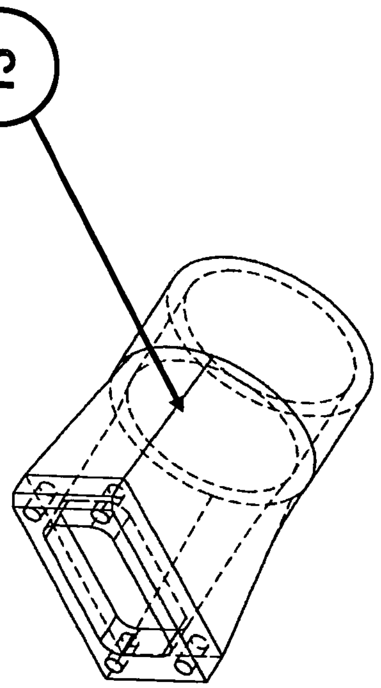

Fig. 7

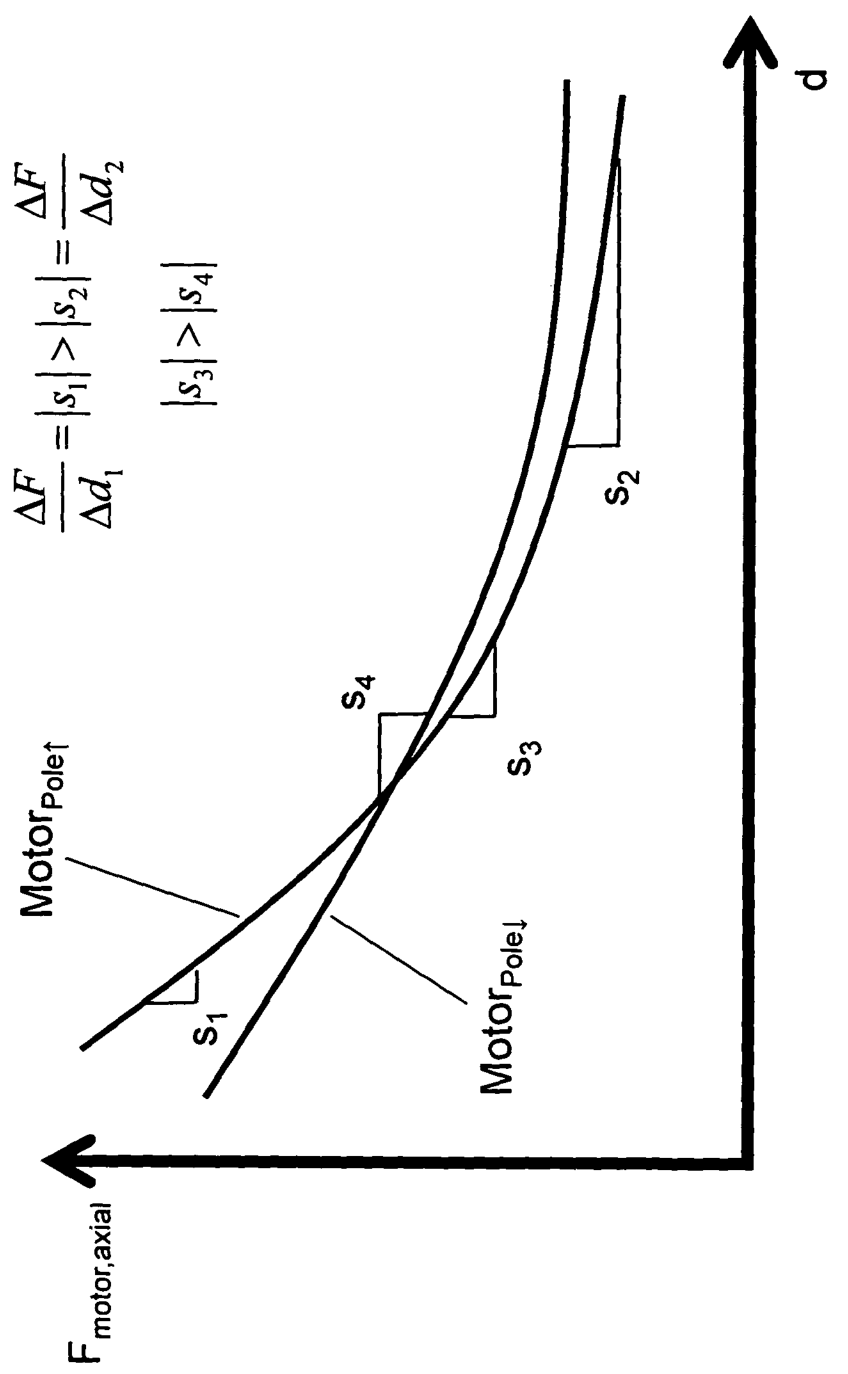
$\frac{\Delta F}{\Delta d_1} = |s_1| > |s_2| = \frac{\Delta F}{\Delta d_2}$
$|s_3| > |s_4|$
$F_{motor,axial}$
d
$Motor_{Pole\uparrow}$
$Motor_{Pole\downarrow}$
s_1
s_2
s_3
s_4

Fig. 8

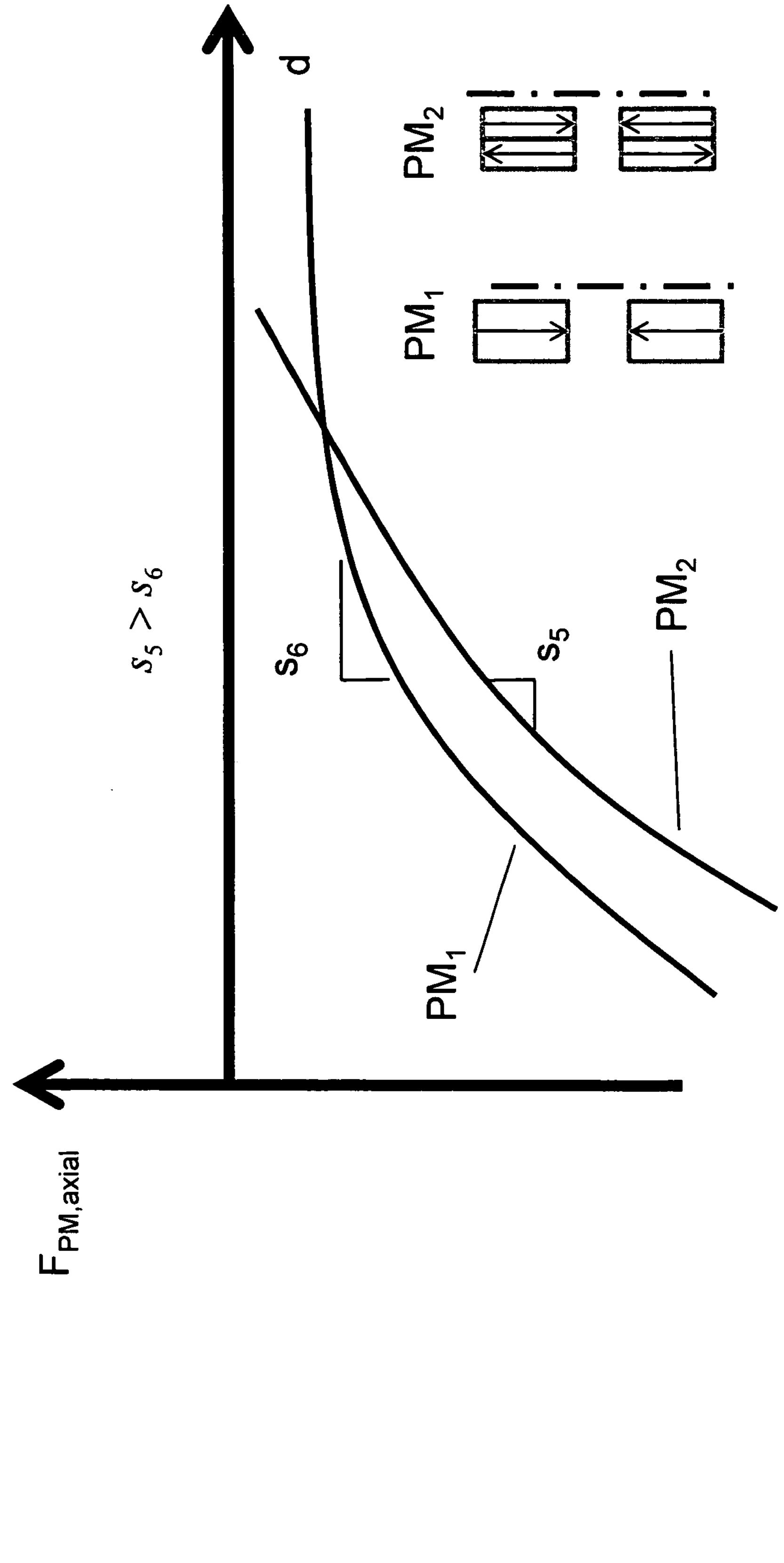

Fig. 9

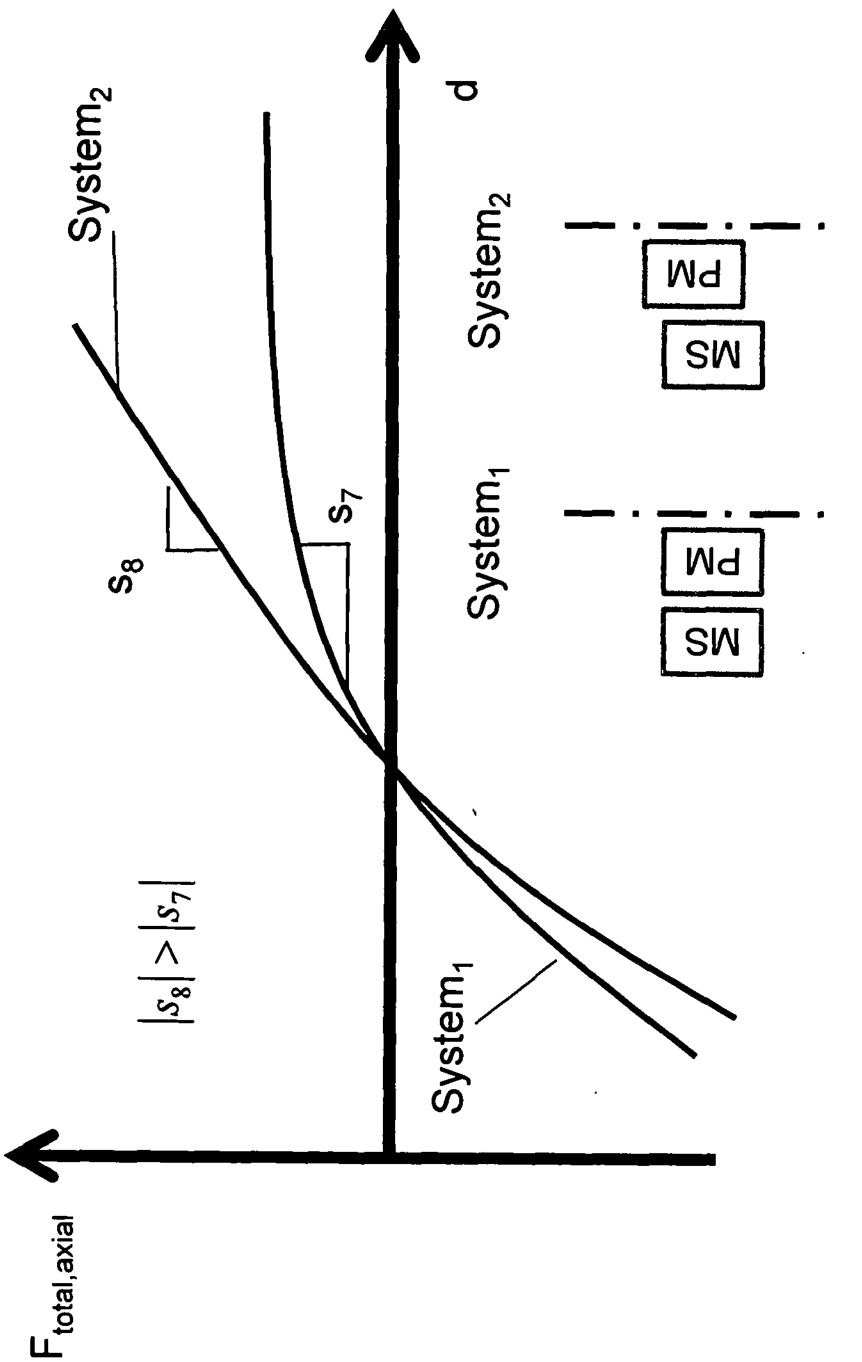

Fig. 10

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2012/002722

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M1/10
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2008/136979 A1 (HEARTWARE INC [US]) 13 November 2008 (2008-11-13) paragraphs [0009], [0010], [0052] - [0082] figures 1, 9-11, 16 -----	1-4,7-9, 12,13
X	WO 00/32256 A1 (IMPELLA CARDIOTECH AG [DE]; SIESS THORSTEN [DE]) 8 June 2000 (2000-06-08) page 5, line 9 - page 8, line 4 figures 1-4 -----	1,3-5
X	WO 2007/084339 A2 (HEARTWARE INC [US]) 26 July 2007 (2007-07-26) paragraphs [0037] - [0064] figures 1-8 -----	1-3,8, 10,12
	-/--	

[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
19 March 2013	27/03/2013

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Schlaug, Martin

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INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2012/002722

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2001/002234 A1 (WOODARD JOHN C [AU] ET AL) 31 May 2001 (2001-05-31) paragraphs [0071], [0072], [0117] - [0132] figures 1-3, 7-11 -----	1-3,6,8, 12
X	US 5 947 703 A (NOJIRI TOSHIHIKO [JP] ET AL) 7 September 1999 (1999-09-07) column 7, line 10 - column 9, line 44 column 16, line 56 - column 17, line 23 figures 1-6, 11, 12, 32 claims 1-8 -----	1,3,10, 11

1

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP2012/002722

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2008136979 A1	13-11-2008	EP 2145108 A1	20-01-2010
		JP 2010525871 A	29-07-2010
		US 2009234447 A1	17-09-2009
		WO 2008136979 A1	13-11-2008
WO 0032256 A1	08-06-2000	AT 281191 T	15-11-2004
		AU 1554000 A	19-06-2000
		CA 2349483 A1	08-06-2000
		DE 29821565 U1	15-06-2000
		EP 1135182 A1	26-09-2001
		JP 4018342 B2	05-12-2007
		JP 2002531184 A	24-09-2002
		US 6623475 B1	23-09-2003
		WO 0032256 A1	08-06-2000
WO 2007084339 A2	26-07-2007	AU 2007207782 A1	26-07-2007
		CA 2636418 A1	26-07-2007
		EP 1977110 A2	08-10-2008
		JP 2009523488 A	25-06-2009
		JP 2012210415 A	01-11-2012
		KR 20080085911 A	24-09-2008
		US 2007280841 A1	06-12-2007
		US 2008021394 A1	24-01-2008
		US 2008031725 A1	07-02-2008
		US 2012063942 A1	15-03-2012
		WO 2007084339 A2	26-07-2007
US 2001002234 A1	31-05-2001	US 2001002234 A1	31-05-2001
		US 2002018713 A1	14-02-2002
		US 2004028525 A1	12-02-2004
		US 2005281685 A1	22-12-2005
US 5947703 A	07-09-1999	NONE	