

Response to Exhibit A-1
Responsive Chart for U.S. Patent No. 11,351,356 over HeartMate III: Pump Design for a Centrifugal LVAD with a Magnetically Levitated Rotor (“Bourque 2001”)

The following chart represents Miracor’s preliminary response to Defendants’ Invalidity Chart (“the invalidity chart”), identified as Exhibit A-1, for the application of “Bourque 2001” (also, “the reference;” K. Bourque, et al., “HeartMate III: Pump Design for a Centrifugal LVAD with a Magnetically Levitated Rotor,” ASAIO Journal 2001, 47:401-405) to U.S. Patent No. 11,351,356 (“the ’356 patent”). Defendants assert without evidence or explanation that Bourque 2001 is prior art to the ’356 patent. Miracor does not agree with or acquiesce to this assertion and reserves all rights to refute the status of Bourque 2001 as prior art.

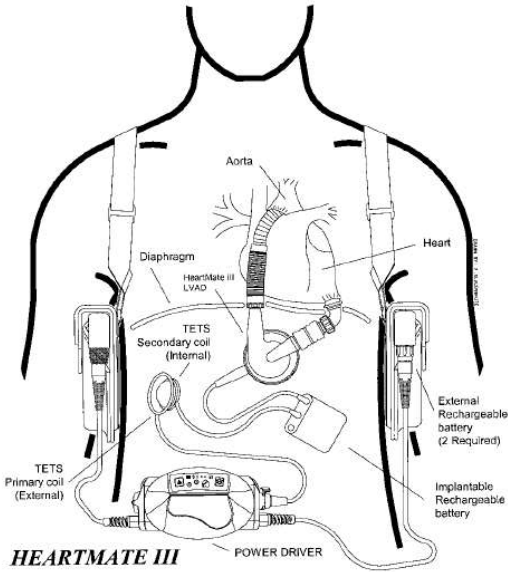
Defendants assert that they apply the apparent claim constructions set forth in Miracor’s Initial Infringement Contentions. Defendants appear not to apply those apparent claim constructions, not to apply the apparent claim constructions set forth in Defendants’ Initial Noninfringement Contentions, and not to apply the plain and ordinary meaning of the claim terms. Nothing in this chart conveys agreement or acquiescence with any meaning that Defendants attempt to convey for any claim term.

The invalidity chart fails to comply with LPR 2.3(b)(2). In particular, Defendants provide no detailed statement of whether the reference anticipates or renders obvious any claim. Instead Defendants assert that each element is disclosed, and if an element is not disclosed it is inherent, and if it is not inherent it can be found in one of the other cited references. Also, the invalidity chart provides no reason to combine any elements from different references.

The invalidity chart fails to comply with LPR 2.3(b)(3). In particular, Defendants do not identify where specifically in each alleged item of prior art each element of the asserted claims are found. All of the elements are met with a conclusory recitation that the reference discloses the claim element. Some of these recitations are followed by quotes from the reference, many of which do not include the relevant claim elements. At best, Defendants simply identify portions of the various references that they apparently believe disclose or render obvious various claim elements without explanation of how these disclosures correspond to the claim elements. Next, each element is met with an assertion that even if the element is not disclosed, it is inherent or obvious in combination with any of the other references, without any reasons given in support of this assertion. Miracor does not respond to Defendants’ arguments regarding combinations with other references as such a response would fall outside of LPR 2.5. This compliance with the rules does not indicate any agreement, acquiescence or waiver with respect to Defendants’ arguments regarding combinations with other references.

Because of Defendants’ failure to explain its purported invalidity positions, Miracor is limited in its ability to respond to them. Miracor reserves all rights to further respond should Defendants be allowed to expand their contentions. In the initial responsive chart

below, Miracor states as best it can, given Defendants' contentions, whether the reference includes the relevant claim element. Miracor may modify its response to each claim element subject to further explanation or definition by Defendants.

U.S. Patent No. 11,351,356			
#	Claim Element	Bourque 2001	Miracor's Response as to Whether the Element is Present in the Reference
1	[PRE] A method for assisting the blood circulation of a heart in a body, comprising:	<p>Bourque 2001 discloses "a method for assisting the blood circulation of a heart in a body, comprising" at least under the apparent construction and scope of the claims as set forth in Miracor's Initial Infringement Contentions and to the extent the asserted claims are found to be not indefinite.</p> <p>Bourque 2001 at fig. 3</p>  <p>Figure 3. HeartMate III LVAD implanted configuration. TETS, transcutaneous energy transmission system.</p>	<p>Yes, subject to the limitations stated at the top of this document and the comments made throughout. Miracor may modify its response to this claim element subject to further explanation or definition by Defendants.</p>

	<p>Bourque 2001 at page 403 ABT-MIR-00000024 Materials and Methods</p> <p>Bourque 2001 at page 403 ABT-MIR-00000024 For in vitro characterization, the pump was attached to a mock physiologic laboratory flow loop. Although this loop is generally equipped to simulate vascular compliance, and can even be configured with a pulsatile pump to represent a beating ventricle, the steady-state results reported here reflect time invariant measurements recorded after changed flow conditions had settled. Tests were repeated with several working fluids, including water, a blood analog aqueous solution (40% glycerin), and whole bovine blood. Flow measurements were made with an ultrasonic flow probe (Transonic Systems, Ithaca, NY), and pressure measurements were made with solid-state, catheter-type pressure transducers (Cobe Cardiovascular, Arvada, CO). Speed and motor parameters were set and controlled using software specifically designed to develop the HeartMate III. All measurements were automatically processed and recorded using Labview (National Instruments, Austin, TX).</p> <p>For in vivo testing, a young bovine model (,100 kg) was used (Figure 6). Surgeries were performed at the University of Pittsburgh McGowan Center for Artificial Organ Development in accordance with Guide for the Care and Use of Laboratory Animals.⁹ The pump was implanted with routine surgical techniques via left ventricular apical cannulation and anastomosis to the descending aorta.</p> <p>Bourque 2001 at page 405 ABT-MIR-00000024 The progress of HeartMate III from concept, through design, and into animal studies has been rapid, and the successful performance has been very encouraging.</p>	
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		<p>To the extent it is found that Bourque 2001 does not expressly disclose this limitation, the limitation is inherent. And to the extent it is found that Bourque 2001 does not anticipate this claim, Bourque 2001 renders it obvious, standing alone, in combination with the knowledge of a person of ordinary skill in the art, and/or in combination with one or more other prior art references identified in the cover pleading of Defendants’ Initial Invalidity Contentions.</p>	
	[1a] delivering a heart assist pump device to the heart	<p>Bourque 2001 discloses “delivering a heart assist pump device to the heart” at least under the apparent construction and scope of the claims as set forth in Miracor’s Initial Infringement Contentions and to the extent the asserted claims are found to be not indefinite.</p> <p>Bourque 2001 at Abstract ABT-MIR-00000024 A long-term, compact left ventricular assist device (LVAD), the HeartMate III, has been designed and fabricated, featuring a centrifugal pump with a magnetically levitate rotor.</p> <p>Bourque 2001 at page 401 ABT-MIR-00000024 The advent of the left ventricular assist device (LVAD) has provided significant benefit to certain [congestive heart failure] patients since becoming clinically available.</p> <p>Bourque 2001 at page 404 ABT-MIR-00000024 It was a fundamental goal of the HeartMate III mechanical design to achieve optimal pumping performance and to enclose a sophisticated motor in the simplest possible way, this being the best means of achieving success.</p> <p>Bourque 2001 at fig. 3.</p>	<p>No. Bourque 2001 does not disclose or suggest a heart assist pump device that is deliverable or delivered to the heart. Instead, the pump is located in the “least obtrusive position,” spaced apart from the heart and connected to the heart by what Bourque 2001 calls an “inflow cannula” which does not meet the recitations of the claimed “inflow tube” of the claimed “heart assist pump device.” Bourque 2001 at 402.</p> <p>Bourque 2001’s “inflow cannula” is part of what Bourque 2001 calls an “inflow subassembly” comprising “a section that partially decouples the position ... of the heart from the pump and facilitates pump recovery at explant.” <i>Id.</i> at 402. In vivo bovine testing involved similar</p>

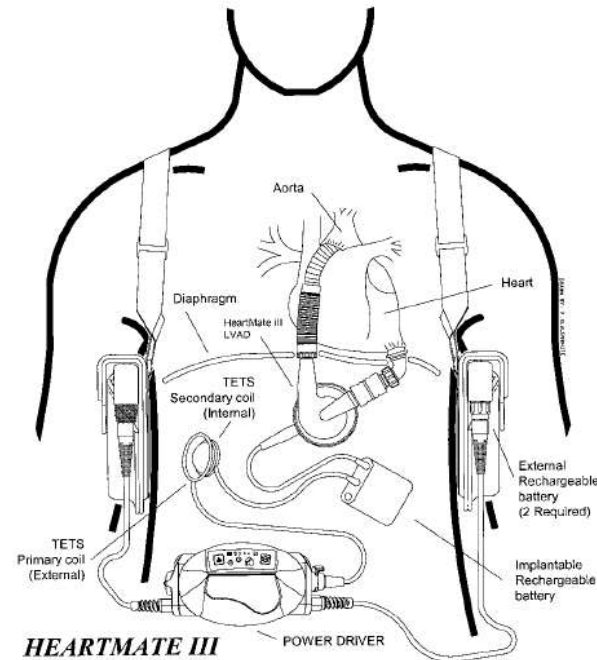


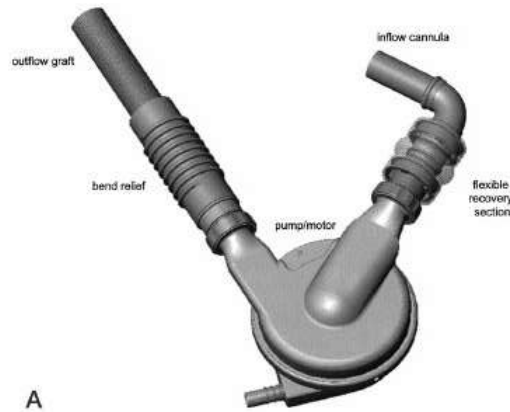
Figure 3. HeartMate III LVAD implanted configuration. TETS, transcutaneous energy transmission system.

cannulation that spaces the “heart assist pump device” away from the heart. *Id.* at 403. Miracor may modify its response to this claim element subject to further explanation or definition by Defendants.

Bourque 2001 at page 403 | ABT-MIR-00000024

For in vitro characterization, the pump was attached to a mock physiologic laboratory flow loop. Although this loop is generally equipped to simulate vascular compliance, and can even be configured with a pulsatile pump to represent a beating ventricle, the steady-state results reported here reflect time invariant measurements recorded after changed flow conditions had settled. Tests were repeated with several working fluids, including water, a blood analog aqueous solution (40% glycerin), and whole bovine blood. Flow measurements were made with an ultrasonic flow probe (Transonic Systems, Ithaca, NY), and pressure measurements were made with solid-state, catheter-type pressure transducers (Cobe Cardiovascular, Arvada, CO). Speed and

		<p>motor parameters were set and controlled using software specifically designed to develop the HeartMate III. All measurements were automatically processed and recorded using Labview (National Instruments, Austin, TX).</p> <p>For in vivo testing, a young bovine model (,100 kg) was used (Figure 6). Surgeries were performed at the University of Pittsburgh McGowan Center for Artificial Organ Development in accordance with Guide for the Care and Use of Laboratory Animals.⁹ The pump was implanted with routine surgical techniques via left ventricular apical cannulation and anastomosis to the descending aorta.</p> <p>To the extent it is found that Bourque 2001 does not expressly disclose this limitation, the limitation is inherent. And to the extent it is found that Bourque 2001 does not anticipate this claim, Bourque 2001 renders it obvious, standing alone, in combination with the knowledge of a person of ordinary skill in the art, and/or in combination with one or more other prior art references identified in the cover pleading of Defendants’ Initial Invalidity Contentions.</p>	
	<p>[1b] so that a suction end of an inflow tube of the heart assist pump device is inserted into a ventricle of the heart</p>	<p>Bourque 2001 discloses “so that a suction end of an inflow tube of the heart assist pump device is inserted into a ventricle of the heart” at least under the apparent construction and scope of the claims as set forth in Miracor’s Initial Infringement Contentions and to the extent the asserted claims are found to be not indefinite.</p> <p>Bourque 2001 at 401 ABT-MIR-00000024</p> <p>The HeartMate III pump...comprises an upper housing that includes the inflow and outflow channels and the upper half of the volute;...an inflow subassembly that includes a left ventricular (LV) cannula and a section that partially decouples the position and motion of the heart from the pump and facilitates pump recovery at explant.</p> <p>Bourque 2001 at fig. 1A</p>	<p>No. Defendants’ bare citation in support fails to comply with LPR 2.3(b)(3) and does not specifically identify a suction end of an inflow tube, nor does it specifically identify the insertion of such a suction end into a ventricle of the heart. Moreover, Defendants do not identify an “inflow tube”—as explained below, Bourque 2001 does not disclose or suggest an inflow tube meeting the recitations of this claim.</p>



A

Bourque 2001 at fig. 3.

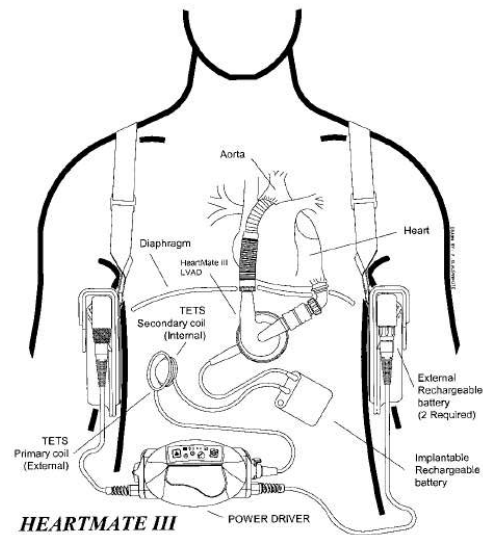
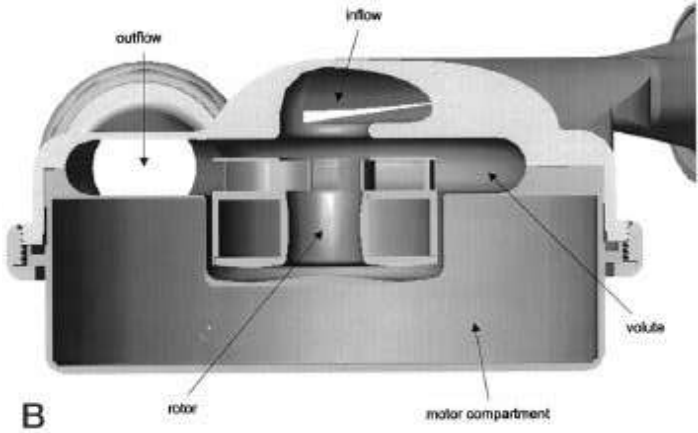
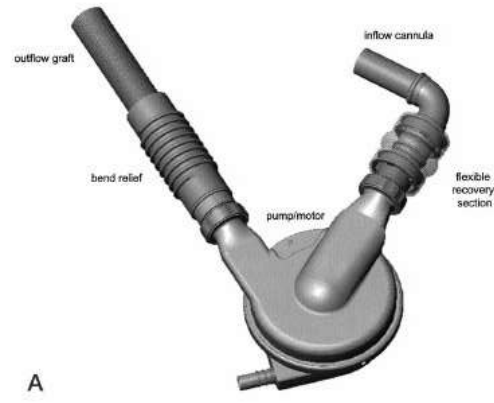


Figure 3. HeartMate III LVAD implanted configuration. TETS, transcutaneous energy transmission system.

To the extent it is found that Bourque 2001 does not expressly disclose this limitation, the limitation is inherent. And to the extent it is found

Miracor may modify its response to this claim element subject to further explanation or definition by Defendants.

		that Bourque 2001 does not anticipate this claim, Bourque 2001 renders it obvious, standing alone, in combination with the knowledge of a person of ordinary skill in the art, and/or in combination with one or more other prior art references identified in the cover pleading of Defendants' Initial Invalidity Contentions.	
	[1c] while a magnetically driven rotor of the heart assist pump device is positioned outside the ventricle of the heart,	<p>Bourque 2001 discloses “while a magnetically driven rotor of the heart assist pump device is positioned outside the ventricle of the heart” at least under the apparent construction and scope of the claims as set forth in Miracor’s Initial Infringement Contentions and to the extent the asserted claims are found to be not indefinite.</p> <p>Bourque 2001 at fig. 1B</p>  <p>Bourque 2001 at fig. 1A</p>	Yes, subject to the limitations stated at the top of this document and to the comments made throughout. Miracor may modify its response to this claim element subject to further explanation or definition by Defendants.



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Bourque 2001 at fig. 3

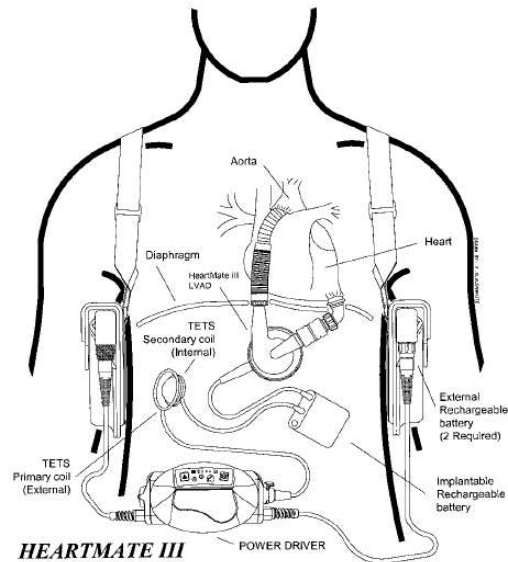
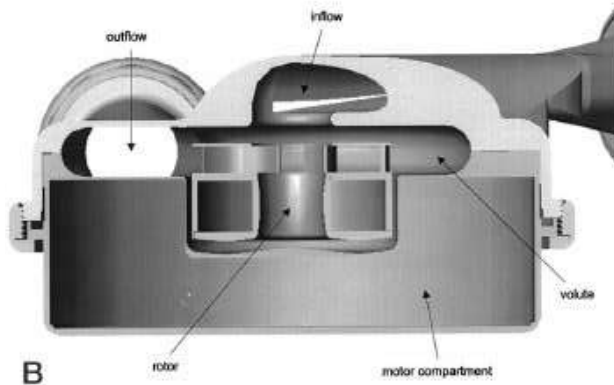
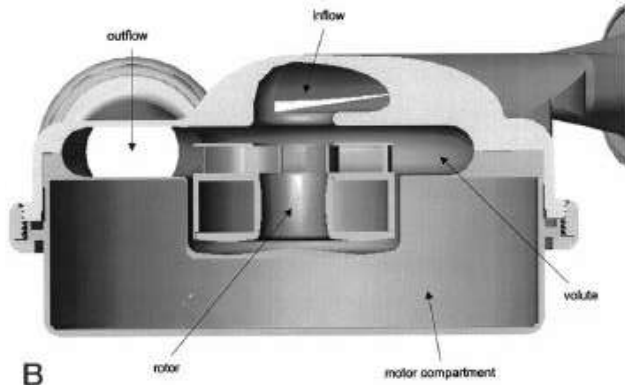
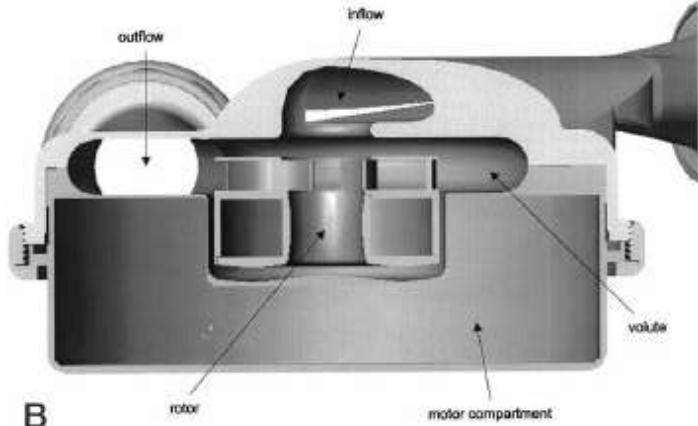
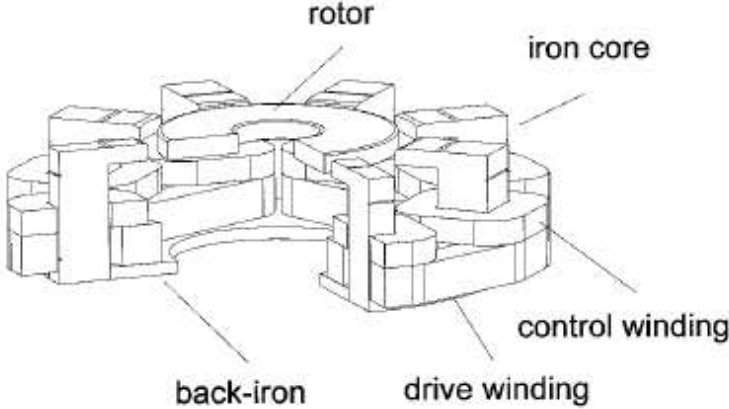


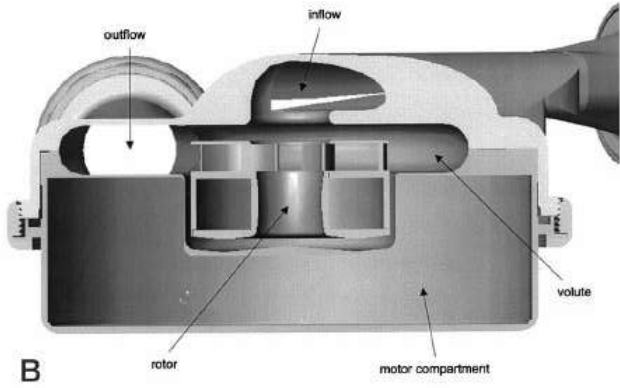
Figure 3. HeartMate III LVAD implanted configuration. TETS, transcutaneous energy transmission system.

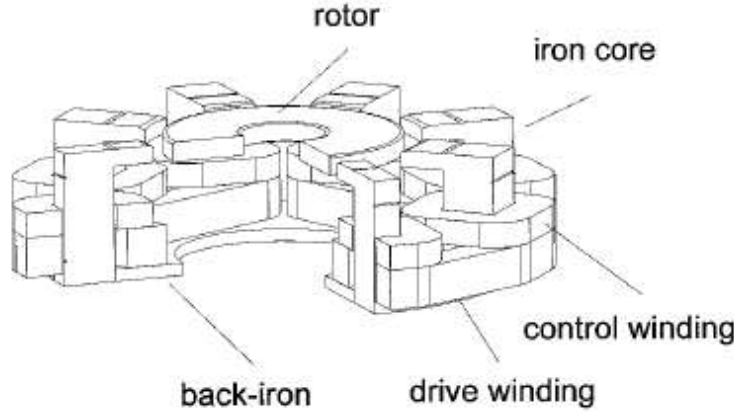
		<p>To the extent it is found that Bourque 2001 does not expressly disclose this limitation, the limitation is inherent. And to the extent it is found that Bourque 2001 does not anticipate this claim, Bourque 2001 renders it obvious, standing alone, in combination with the knowledge of a person of ordinary skill in the art, and/or in combination with one or more other prior art references identified in the cover pleading of Defendants’ Initial Invalidity Contentions.</p>	
	<p>[1d] wherein the magnetically driven rotor is axially aligned with the inflow tube,</p>	<p>Bourque 2001 discloses “wherein the magnetically driven rotor is axially aligned with the inflow tube” at least under the apparent construction and scope of the claims as set forth in Miracor’s Initial Infringement Contentions and to the extent the asserted claims are found to be not indefinite.</p> <p>Bourque 2001 at fig. 1B</p>  <p>To the extent it is found that Bourque 2001 does not expressly disclose this limitation, the limitation is inherent. And to the extent it is found that Bourque 2001 does not anticipate this claim, Bourque 2001 renders it obvious, standing alone, in combination with the knowledge of a person of ordinary skill in the art, and/or in combination with one or more other prior art references identified in the cover pleading of Defendants’ Initial Invalidity Contentions.</p>	<p>No. Bourque 2001 does not disclose a magnetically driven rotor axially aligned with the inflow tube. Defendants do not identify a rotor axis, nor do Defendants identify an inflow tube or an inflow tube direction. Miracor notes that, in the figures presented, the rotor axis appears to be orthogonal to what Bourque 2001 calls the “inflow cannula.”</p>

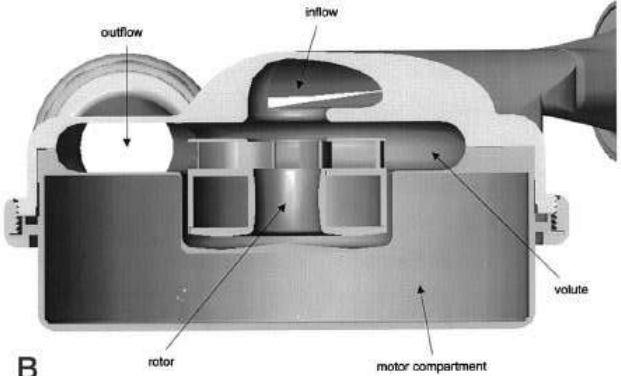
<p>[1e] and [the magnetically driven rotor] is rotatable within a surrounding rotor housing of the heart assist pump device to act upon blood flowing from the inflow tube toward the magnetically driven rotor</p>	<p>Bourque 2001 discloses “and [the magnetically driven rotor] is rotatable within a surrounding rotor housing of the heart assist pump device to act upon blood flowing from the inflow tube toward the magnetically driven rotor” at least under the apparent construction and scope of the claims as set forth in Miracor’s Initial Infringement Contentions and to the extent the asserted claims are found to be not indefinite.</p> <p>Bourque 2001 at page 401 ABT-MIR-00000024 The HeartMate III pump...comprises...a lower housing that includes the lower half of the volute and a cavity for the rotor, in which the motor is enclosed.</p> <p>Bourque 2001 at fig. 1B</p>  <p>To the extent it is found that Bourque 2001 does not expressly disclose this limitation, the limitation is inherent. And to the extent it is found that Bourque 2001 does not anticipate this claim, Bourque 2001 renders it obvious, standing alone, in combination with the knowledge of a person of ordinary skill in the art, and/or in combination with one or more other prior art references identified in the cover pleading of Defendants’ Initial Invalidity Contentions.</p>	<p>No. Defendants’ bare citation in support fails to comply with LPR 2.3(b)(3), does not specifically identify a flow of blood, and does not specifically identify any acting on the flowing blood by the rotor. Miracor may modify its response to this claim element subject to further explanation or definition by Defendants.</p>
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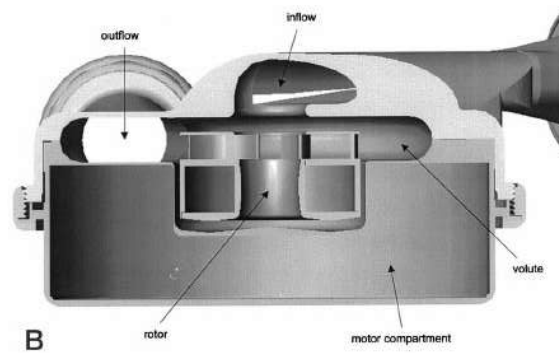
<p>[1f] the magnetically driven rotor being rotatable about a central axis</p>	<p>Bourque 2001 discloses “the magnetically driven rotor being rotatable about a central axis” at least under the apparent construction and scope of the claims as set forth in Miracor’s Initial Infringement Contentions and to the extent the asserted claims are found to be not indefinite. Bourque 2001 at fig. 1B</p>  <p>Bourque 2001 at page 402 ABT-MIR-00000024 To orient the pump in the least obtrusive position...it was decided that the rotational axis of the pump’s rotor should be perpendicular to the body’s long axis.</p> <p>To the extent it is found that Bourque 2001 does not expressly disclose this limitation, the limitation is inherent. And to the extent it is found that Bourque 2001 does not anticipate this claim, Bourque 2001 renders it obvious, standing alone, in combination with the knowledge of a person of ordinary skill in the art, and/or in combination with one or more other prior art references identified in the cover pleading of Defendants’ Initial Invalidity Contentions.</p>	<p>No. Defendants’ bare citation in support fails to comply with LPR 2.3(b)(3) and does not specifically identify a central axis. Miracor may modify its response to this claim element subject to further explanation or definition by Defendants.</p>
<p>[1g] and [the magnetically driven rotor]</p>	<p>Bourque 2001 discloses “and [the magnetically driven rotor] being rigidly coupled to a first magnetic device” at least under the apparent construction and scope of the claims as set forth in Miracor’s Initial</p>	<p>No. Defendants’ bare citation in support fails to comply with LPR 2.3(b)(3), does not</p>

<p>being rigidly coupled to a first magnetic device</p>	<p>Infringement Contentions and to the extent the asserted claims are found to be not indefinite.</p> <p>Bourque 2001 at page 402 ABT-MIR-00000024 The HeartMate III motor includes drive and levitation in a single magnetic structure as show in Figure 4.</p> <p>Bourque 2001 at page 401 ABT-MIR-00000024 a rotor that includes an impeller and passively magnetic elements;</p> <p>Bourque 2001 at fig. 4</p>  <p>Figure 4. HeartMate III motor, drive, and levitation (control) in a single magnetic structure.</p> <p>To the extent it is found that Bourque 2001 does not expressly disclose this limitation, the limitation is inherent. And to the extent it is found that Bourque 2001 does not anticipate this claim, Bourque 2001 renders it obvious, standing alone, in combination with the knowledge of a person of ordinary skill in the art, and/or in combination with one or</p>	<p>specifically identify a first magnetic device, and does not specifically identify a rigid coupling. Miracor may modify its response to this claim element subject to further explanation or definition by Defendants.</p>
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		more other prior art references identified in the cover pleading of Defendants' Initial Invalidity Contentions.	
	[1h] that [the first magnetic device] is located within the surrounding rotor housing	<p>Bourque 2001 discloses “that [the first magnetic device] is located within the surrounding rotor housing” at least under the apparent construction and scope of the claims as set forth in Miracor’s Initial Infringement Contentions and to the extent the asserted claims are found to be not indefinite.</p> <p>Bourque 2001 at page 402 ABT-MIR-00000024 The HeartMate III motor includes drive and levitation in a single magnetic structure as show in Figure 4.</p> <p>Bourque 2001 at page 401 ABT-MIR-00000024 The HeartMate III pump...comprises an <i>upper housing</i> that includes the inflow and outflow channels and the upper half of the volute; a <i>lower housing</i> that includes the lower half of the volute and a cavity for the rotor, in which the motor is enclosed; a <i>rotor</i> that includes an impeller and passively magnetic elements...</p> <p>Bourque 2001 at figs. 1B</p> 	<p>No. Defendants’ bare citation in support fails to comply with LPR 2.3(b)(3) and does not specifically identify a first magnetic device, and thus does not specifically identify a first magnetic device within the surrounding rotor housing. Miracor may modify its response to this claim element subject to further explanation or definition by Defendants.</p>

		<p>To the extent it is found that Bourque 2001 does not expressly disclose this limitation, the limitation is inherent. And to the extent it is found that Bourque 2001 does not anticipate this claim, Bourque 2001 renders it obvious, standing alone, in combination with the knowledge of a person of ordinary skill in the art, and/or in combination with one or more other prior art references identified in the cover pleading of Defendants' Initial Invalidity Contentions.</p>	
	<p>[1i] [the first magnetic device is] at a position axially adjacent to the magnetically driven rotor</p>	<p>Bourque 2001 discloses “[the first magnetic device is] at a position axially adjacent to the magnetically driven rotor” at least under the apparent construction and scope of the claims as set forth in Miracor’s Initial Infringement Contentions and to the extent the asserted claims are found to be not indefinite.</p> <p>Bourque 2001 at fig. 4</p>  <p>Figure 4. HeartMate III motor, drive, and levitation (control) in a single magnetic structure.</p> <p>Bourque 2001 at fig. 1B</p>	<p>No. Defendants’ bare citation in support fails to comply with LPR 2.3(b)(3) and does not specifically identify a first magnetic device, and thus does not specifically identify an axially adjacent position of a first magnetic device. Miracor may modify its response to this claim element subject to further explanation or definition by Defendants.</p>

		 <p>To the extent it is found that Bourque 2001 does not expressly disclose this limitation, the limitation is inherent. And to the extent it is found that Bourque 2001 does not anticipate this claim, Bourque 2001 renders it obvious, standing alone, in combination with the knowledge of a person of ordinary skill in the art, and/or in combination with one or more other prior art references identified in the cover pleading of Defendants' Initial Invalidity Contentions.</p>	
	<p>[1j] wherein the heart assist pump device further includes: a second magnetic device axially aligned with the inflow tube</p>	<p>Bourque 2001 discloses “wherein the heart assist pump device further includes: a second magnetic device axially aligned with the inflow” at least under the apparent construction and scope of the claims as set forth in Miracor’s Initial Infringement Contentions and to the extent the asserted claims are found to be not indefinite.</p> <p>Bourque 2001 at fig. 1B</p>	<p>No. Defendants’ bare citation in support fails to comply with LPR 2.3(b)(3), does not identify the claimed inflow tube, does not specifically identify a second magnetic device, does not identify a direction or axis of an inflow tube, and thus does not specifically identify an axially aligned position of a second magnetic device with respect to an inflow tube as recited in the claim. Miracor notes that</p>



Bourque 2001 at fig. 4

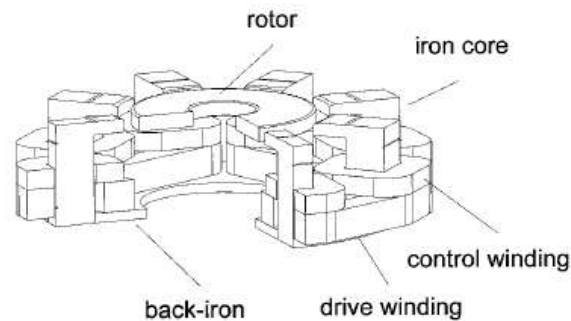
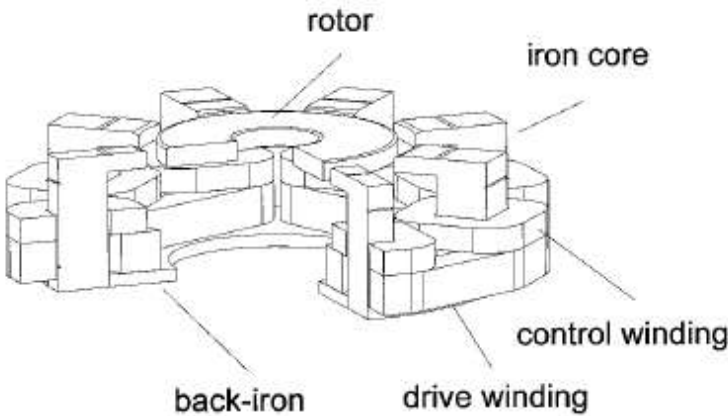
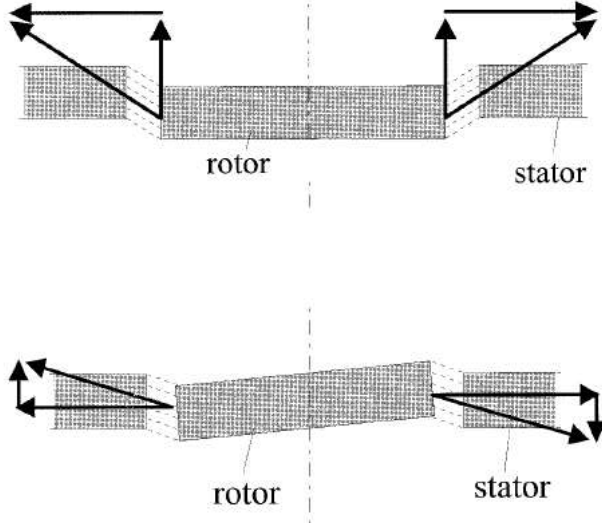


Figure 4. HeartMate III motor, drive, and levitation (control) in a single magnetic structure.

To the extent it is found that Bourque 2001 does not expressly disclose this limitation, the limitation is inherent. And to the extent it is found that Bourque 2001 does not anticipate this claim, Bourque 2001 renders it obvious, standing alone, in combination with the knowledge of a person of ordinary skill in the art, and/or in combination with one or more other prior art references identified in the cover pleading of Defendants' Initial Invalidity Contentions.

the portion of Bourque 2001's Fig. 1B labeled as "inflow" appears to be orthogonal to Bourque 2001's motor. Miracor may modify its response to this claim element subject to further explanation or definition by Defendants.

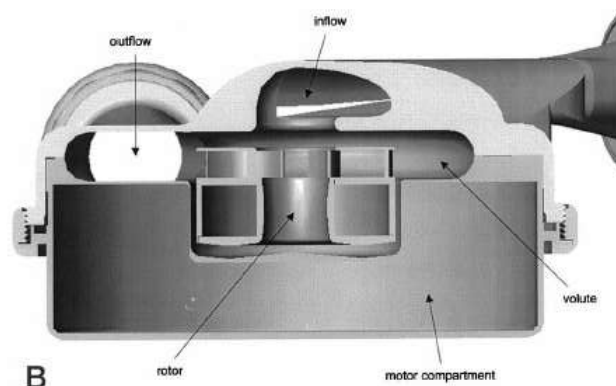
<p>[1k] and [the second magnetic device is] positioned to magnetically drive rotation of the magnetically driven rotor via a magneto coupling with the first magnetic device</p>	<p>Bourque 2001 discloses “and [the second magnetic device is] positioned to magnetically drive rotation of the magnetically driven rotor via a magneto coupling with the first magnetic device” at least under the apparent construction and scope of the claims as set forth in Miracor’s Initial Infringement Contentions and to the extent the asserted claims are found to be not indefinite.</p> <p>Bourque 2001 at fig. 4</p>  <p>Figure 4. HeartMate III motor, drive, and levitation (control) in a single magnetic structure.</p> <p>Bourque 2001 at page 402-403 ABT-MIR-00000024 The HeartMate III motor includes drive and levitation in a single magnetic structure as shown in Figure 4. The rotor is passively magnetically levitated in the axial-translational and transverse-rotational degrees of freedom (Figure 5) and actively magnetically levitated in the remaining degrees of freedom.</p> <p>Bourque 2001 at fig. 5</p>	<p>No. Defendants’ bare citation in support fails to comply with LPR 2.3(b)(3), does not specifically identify a second magnetic device, does not specifically identify a first magnetic device, and thus does not specifically identify a position for a second magnetic device to magnetically drive rotation of the magnetically driven rotor via a magneto coupling with the first magnetic device. Miracor may modify its response to this claim element subject to further explanation or definition by Defendants.</p>
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		 <p>Figure 5. Passive magnetic levitation. Above, Restoration force when axially displaced. Below, Restoration force when tilted.</p> <p>To the extent it is found that Bourque 2001 does not expressly disclose this limitation, the limitation is inherent. And to the extent it is found that Bourque 2001 does not anticipate this claim, Bourque 2001 renders it obvious, standing alone, in combination with the knowledge of a person of ordinary skill in the art, and/or in combination with one or more other prior art references identified in the cover pleading of Defendants' Initial Invalidity Contentions.</p>	
	<p>[11] while [the second magnetic device is] being spaced apart and sealed from both the magnetically driven rotor and</p>	<p>Bourque 2001 discloses “while [the second magnetic device is] being spaced apart and sealed from both the magnetically driven rotor and the first magnetic device” at least under the apparent construction and scope of the claims as set forth in Miracor’s Initial Infringement Contentions and to the extent the asserted claims are found to be not indefinite.</p> <p>Bourque 2001 at fig. 1B</p>	<p>No. Defendants’ bare citation in support fails to comply with LPR 2.3(b)(3), does not specifically identify a second magnetic device, and does not specifically identify a first magnetic device or a seal. Defendants’ argument that</p>

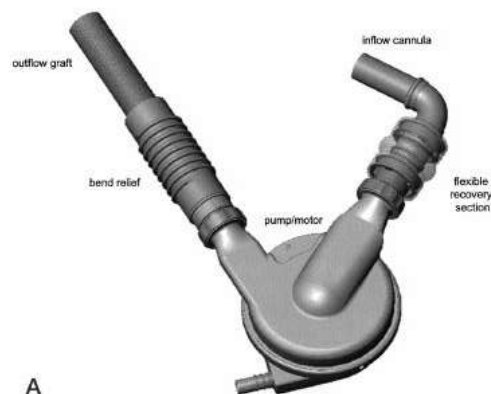
<p>the first magnetic device</p>	<div data-bbox="672 211 1291 592" data-label="Image"> </div> <p>Bourque 2001 at page 401 ABT-MIR-00000024 The rotor is magnetically suspended, eliminating contact between moving parts and consequently extending wear life indefinitely. It is anticipated that this design will profoundly increase reliability.</p> <p>Bourque 2001 at page 402-403 ABT-MIR-00000024 The HeartMate III motor includes drive and levitation in a single magnetic structure as shown in Figure 4. The rotor is passively magnetically levitated in the axial-translational and transverse-rotational degrees of freedom (Figure 5) and actively magnetically levitated in the remaining degrees of freedom.</p> <p>Bourque 2001 at page 402 ABT-MIR-00000024 By creating a similar opening in the lower half of the rotor, a second backflow path underneath the rotor results, eliminating what would have been an accumulation of stagnant blood there, and relieving the upward thrust load on the rotor. However, both of these backflows consume hydraulic power without contributing to physiologic perfusion. Thus, the clearances above and below the rotor were chosen to balance reduced hydraulic efficiency with sufficient washing of</p>	<p>elements can be found in a different reference fails to comply with the relevant rules because Defendants do not identify with specificity where such elements can be found in that different reference. Miracor does not further respond to Defendants' arguments regarding combination with other references as such a response would fall outside of LPR 2.5. Miracor's compliance with the rules does not indicate any agreement, acquiescence or waiver with respect to Defendants' arguments regarding combinations with other references. Miracor may modify its response to this claim element subject to further explanation or definition by Defendants.</p>
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		<p>blood contacting surfaces... [T]he gaps permit up to 7X gravitational loads in any direction without contact between the rotor and housing.</p> <p>To the extent it is found that Bourque 2001 does not expressly disclose this limitation, the limitation is inherent. And to the extent it is found that Bourque 2001 does not anticipate this claim, Bourque 2001 renders it obvious, standing alone, in combination with the knowledge of a person of ordinary skill in the art, and/or in combination with one or more other prior art references (e.g., Schob '618 Ex. A-5) identified in the cover pleading of Defendants' Initial Invalidity Contentions. For example, a person of ordinary skill in the art would know that if a magnet comes into contact with blood, it can adversely affect the blood so as to become toxic or lethal, or cause corrosion, and that therefore the magnet must be sealed from the blood. Further, a person of ordinary skill in the art would have been motivated to combine Bourque 2001 with one or more other references identified in the cover pleading of Defendants' Initial Invalidity Contentions (e.g., Schob '618 Ex. A-5) with a reasonable expectation of success because each of these references contains familiar elements within the similar fields of endeavor to address similar known problems according to known methods which would yield predictable results.</p>	
	<p>[1m] and a blood outflow port positioned radially adjacent the magnetically driven rotor such that blood driven by the magnetically driven rotor is configured to exit the surrounding</p>	<p>Bourque 2001 discloses “and a blood outflow port positioned radially adjacent the magnetically driven rotor such that blood driven by the magnetically driven rotor is configured to exit the surrounding rotor housing in a direction substantially perpendicular from the inflow tube and the central axis of the magnetically driven rotor,” at least under the apparent construction and scope of the claims as set forth in Miracor’s Initial Infringement Contentions and to the extent the asserted claims are found to be not indefinite.</p> <p>Bourque 2001 at fig. 1B</p>	<p>No. Defendants’ bare citation in support fails to comply with LPR 2.3(b)(3) and does not specifically identify a direction of blood exiting the housing or a direction of the inflow tube or an axis for the rotor—as a result, there is no indication that the “blood driven by the magnetically driven rotor is configured to exit the surrounding rotor housing in a</p>

rotor housing in a direction substantially perpendicular from the inflow tube and the central axis of the magnetically driven rotor,



Bourque 2001 at fig. 1A

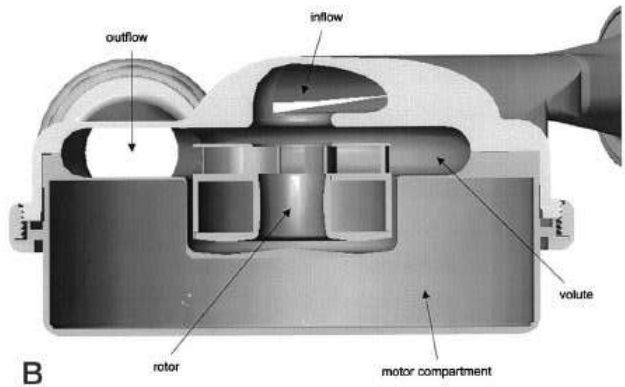


To the extent it is found that Bourque 2001 does not expressly disclose this limitation, the limitation is inherent. And to the extent it is found that Bourque 2001 does not anticipate this claim, Bourque 2001 renders it obvious, standing alone, in combination with the knowledge of a person of ordinary skill in the art, and/or in combination with one or more other prior art references identified in the cover pleading of Defendants' Initial Invalidity Contentions.

direction substantially perpendicular from the inflow tube and the central axis of the magnetically driven rotor." Miracor notes that, to the extent the relevant directions can be estimated, blood exiting through the outflow appears to be flowing substantially parallel to the portion labeled as "inflow cannula" in Bourque 2001's Fig. 1A. Miracor may modify its response to this claim element subject to further explanation or definition by Defendants.

	<p>[1n] wherein the magneto coupling orients the magnetically driven rotor so that, in response to rotation of the magnetically driven rotor, the magnetically driven rotor remains entirely spaced apart from the surrounding rotor housing by the blood flowing from the inflow tube and to the blood outflow port; and</p>	<p>Bourque 2001 discloses “wherein the magneto coupling orients the magnetically driven rotor so that, in response to rotation of the magnetically driven rotor, the magnetically driven rotor remains entirely spaced apart from the surrounding rotor housing by the blood flowing from the inflow tube and to the blood outflow port; and” at least under the apparent construction and scope of the claims as set forth in Miracor’s Initial Infringement Contentions and to the extent the asserted claims are found to be not indefinite.</p> <p>Bourque 2001 at page 401 ABT-MIR-00000024 The rotor is magnetically suspended, eliminating contact between moving parts and consequently extending wear life indefinitely. It is anticipated that this design will profoundly increase reliability.</p> <p>Bourque 2001 at page 402-403 ABT-MIR-00000024 The HeartMate III motor includes drive and levitation in a single magnetic structure as shown in Figure 4. The rotor is passively magnetically levitated in the axial-translational and transverse-rotational degrees of freedom (Figure 5) and actively magnetically levitated in the remaining degrees of freedom.</p> <p>Bourque 2001 at page 402 ABT-MIR-00000024 By creating a similar opening in the lower half of the rotor, a second backflow path underneath the rotor results, eliminating what would have been an accumulation of stagnant blood there, and relieving the upward thrust load on the rotor. However, both of these backflows consume hydraulic power without contributing to physiologic perfusion. Thus, the clearances above and below the rotor were chosen to balance reduced hydraulic efficiency with sufficient washing of blood contacting surfaces. Backflow clearances were further constrained by the stiffness of the magnetic suspension (passive in the axial direction, actively controlled in the radial direction), which describes the levitation system’s capacity to counteract imposed</p>	<p>No. Defendants’ bare citation in support fails to comply with LPR 2.3(b)(3), does not specifically identify the first or second magnetic devices or the magneto coupling as discussed above and thus does not specifically identify the magneto coupling orienting the rotor, and does not identify the inflow tube or blood outflow port as discussed above and thus also does not specifically identify the blood flowing from the inflow tube and to the blood outflow port as recited in the claim. Miracor may modify its response to this claim element subject to further explanation or definition by Defendants.</p>
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		<p>deviations of rotor position; the gaps permit up to 7X gravitational loads in any direction without contact between the rotor and housing.</p> <p>Bourque 2001 at page 402 ABT-MIR-00000024 The pump components were designed to achieve the desired flow paths, accommodate the motor, and provide convenient reliable connections in the simplest, most cost effective way.</p> <p>To the extent it is found that Bourque 2001 does not expressly disclose this limitation, the limitation is inherent. And to the extent it is found that Bourque 2001 does not anticipate this claim, Bourque 2001 renders it obvious, standing alone, in combination with the knowledge of a person of ordinary skill in the art, and/or in combination with one or more other prior art references identified in the cover pleading of Defendants' Initial Invalidity Contentions.</p>	
	<p>[1o] connecting an external control unit to the heart assist pump device for regulating operation of the second magnetic device to thereby magnetically drive the rotation of the magnetically driven rotor via the magneto coupling with the first magnetic device,</p>	<p>Bourque 2001 discloses "connecting an external control unit to the heart assist pump device for regulating operation of the second magnetic device to thereby magnetically drive the rotation of the magnetically driven rotor via the magneto coupling with the first magnetic device," at least under the apparent construction and scope of the claims as set forth in Miracor's Initial Infringement Contentions and to the extent the asserted claims are found to be not indefinite.</p> <p>Bourque 2001 at fig. 1B</p>	<p>No. Defendants' bare citation in support fails to comply with LPR 2.3(b)(3), does not specifically identify a first or second magnetic device or magneto coupling as discussed above, and does not specifically identify any regulation of the second magnetic device by the shelf mounted electronics. Defendants' argument that elements can be found in a different reference fails to comply with the relevant rules because Defendants do not identify with specificity where such elements can be found in</p>

		 <p>Bourque 2001 at page 403 ABT-MIR-00000024</p> <p>The electronics for power and control of the LVAD and for data acquisition resided on a shelf and alongside the cages containing the calves. The animals were continuously monitored for general welfare, and certain parameters such as arterial pressure, pump and pulmonary artery volume flow rates, pump speed, and blood chemistry (including plasma free hemoglobin) were periodically recorded. In two animals, measurement of pressure head throughout the duration of the studies were made with flocked carotid lines and fluid filled LV catheters.</p> <p>Bourque 2001 at fig. 3.</p>	<p>that different reference. Miracor does not further respond to Defendants' arguments regarding combination with other references as such a response would fall outside of LPR 2.5. Miracor's compliance with the rules does not indicate any agreement, acquiescence or waiver with respect to Defendants' arguments regarding combinations with other references. Miracor may modify its response to this claim element subject to further explanation or definition by Defendants.</p>
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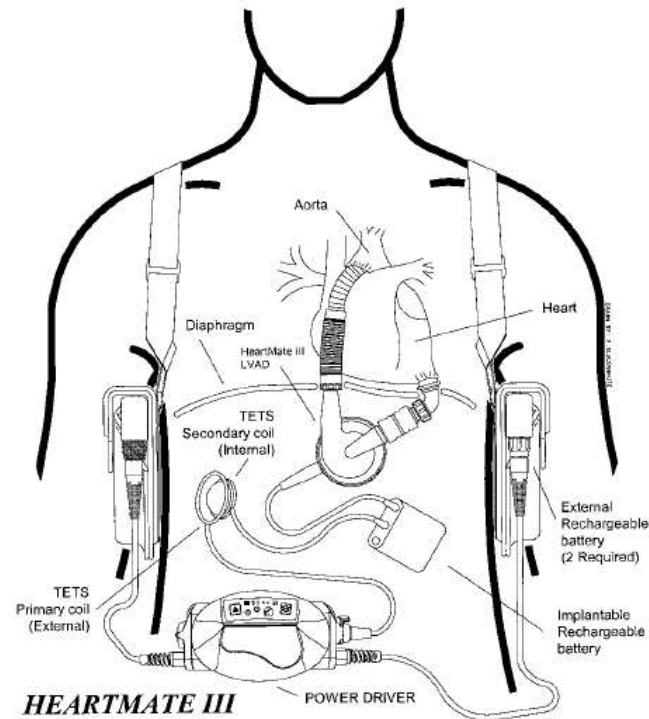


Figure 3. HeartMate III LVAD implanted configuration. TETS, transcutaneous energy transmission system.

Bourque 2001 at page 403 | ABT-MIR-00000024

For in vitro characterization, the pump was attached to a mock physiologic laboratory flow loop. Although this loop is generally equipped to simulate vascular compliance, and can even be configured with a pulsatile pump to represent a beating ventricle, the steady-state results reported here reflect time invariant measurements recorded after changed flow conditions had settled. Tests were repeated with several working fluids, including water, a blood analog aqueous solution (40% glycerin), and whole bovine blood. Flow measurements were made

	<p>with an ultrasonic flow probe (Transonic Systems, Ithaca, NY), and pressure measurements were made with solid-state, catheter-type pressure transducers (Cobe Cardiovascular, Arvada, CO). Speed and motor parameters were set and controlled using software specifically designed to develop the HeartMate III. All measurements were automatically processed and recorded using Labview (National Instruments, Austin, TX).</p> <p>For in vivo testing, a young bovine model (,100 kg) was used (Figure 6). Surgeries were performed at the University of Pittsburgh McGowan Center for Artificial Organ Development in accordance with Guide for the Care and Use of Laboratory Animals.⁹ The pump was implanted with routine surgical techniques via left ventricular apical cannulation and anastomosis to the descending aorta.</p> <p>To the extent it is found that Bourque 2001 does not expressly disclose this limitation, the limitation is inherent. And to the extent it is found that Bourque 2001 does not anticipate this claim, Bourque 2001 renders it obvious, standing alone, in combination with the knowledge of a person of ordinary skill in the art, and/or in combination with one or more other prior art references identified (e.g., Schob '705 Ex. A-6, Bearnson '066 Ex. A-20) in the cover pleading of Defendants' Initial Invalidity Contentions. For example, a person of ordinary skill in the art would know that per Earnshaw's Theorem, magnetic levitation requires constant power and an active control system to keep the levitation stable. Further, a person of ordinary skill in the art would have been motivated to combine Bourque 2001 with one or more other references identified in the cover pleading of Defendants' Initial Invalidity Contentions (e.g., Schob '705 Ex. A-6, Bearnson '066 Ex. A-20) with a reasonable expectation of success because each of these references contains familiar elements within the similar fields of endeavor to address similar known problems, according to known methods which would yield predictable results.</p>	
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	<p>[1p] the external control unit being positioned exterior to the body while the inflow tube of the heart assist pump device is in the heart.</p>	<p>Bourque 2001 discloses “the external control unit being positioned exterior to the body while the inflow tube of the heart assist pump device is in the heart” at least under the apparent construction and scope of the claims as set forth in Miracor’s Initial Infringement Contentions and to the extent the asserted claims are found to be not indefinite.</p> <p>Bourque 2001 at page 403 ABT-MIR-00000024 The pump was implanted with routine surgical techniques via ventricular apical cannulation and anastomosis to the descending aorta. The electronics for power and control of the LVAD and for data acquisition resided on a shelf and alongside the cages containing the calves.</p> <p>Bourque 2001 at fig. 3.</p>	<p>No. Defendants’ bare citation in support fails to comply with LPR 2.3(b)(3) and does not specifically identify an inflow tube, the location of an inflow tube, or the presence in the heart of an inflow tube. Miracor may modify its response to this claim element subject to further explanation or definition by Defendants.</p>
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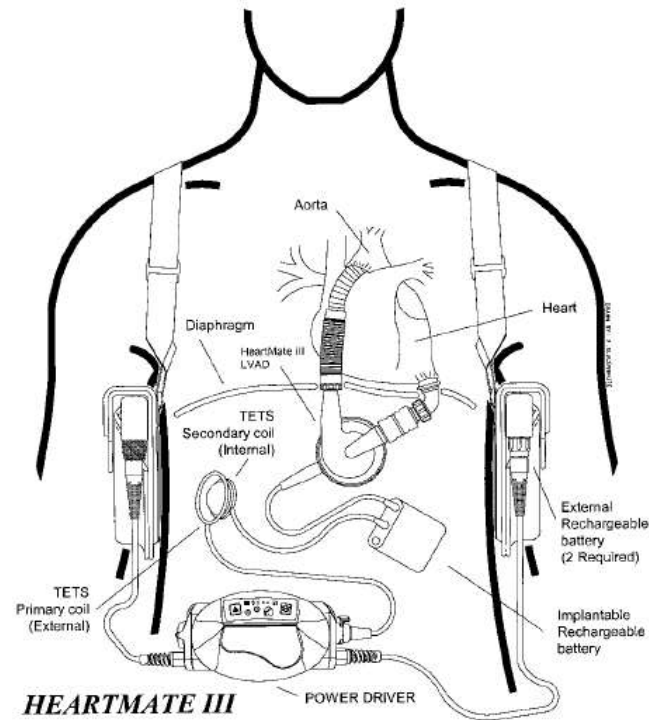
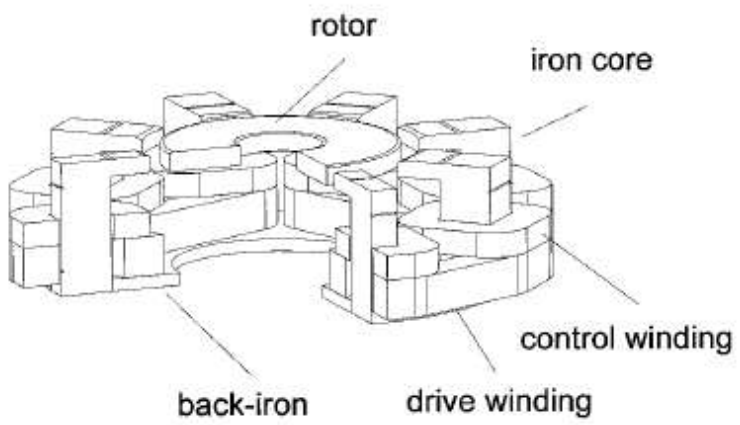


Figure 3. HeartMate III LVAD implanted configuration. TETS, transcutaneous energy transmission system.

To the extent it is found that Bourque 2001 does not expressly disclose this limitation, the limitation is inherent. And to the extent it is found that Bourque 2001 does not anticipate this claim, Bourque 2001 renders it obvious, standing alone, in combination with the knowledge of a person of ordinary skill in the art, and/or in combination with one or more other prior art references identified in the cover pleading of Defendants' Initial Invalidity Contentions.

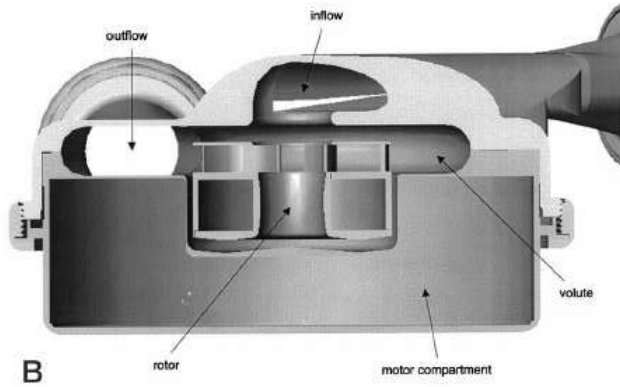
2 ¹	The method of claim 1, wherein in response to the rotation of the magnetically driven rotor via the magneto coupling, guide surfaces of the magnetically driven rotor produce centrifugal flow components.	<p>Bourque 2001 discloses “The method of claim 1, wherein in response to the rotation of the magnetically driven rotor via the magneto coupling, guide surfaces of the magnetically driven rotor produce centrifugal flow components.” at least under the apparent construction and scope of the claims as set forth in Miracor’s Initial Infringement Contentions and to the extent the asserted claims are found to be not indefinite.</p> <p>Bourque 2001 at page 401 ABT-MIR-00000024 A long-term, compact left ventricular assist device (LVAD), the HeartMate III, has been designed and fabricated, featuring a centrifugal pump with a magnetically levitated rotor.</p> <p>Bourque 2001 at page 402 ABT-MIR-00000024 An opening in the shroud (<i>i.e.</i>, the cover across the top of the blades on the rotor) permits fluid leaving the inflow conduit to enter the impeller. This results in a backflow path from the trailing edges of the blades (where the pressure is relatively high), over the shroud, and back to the leading edges of the blades. By creating a similar opening in the lower half of the rotor, a second backflow path underneath the rotor results, eliminating what would have been an accumulation of stagnant blood there, and relieving the upward thrust load on the rotor.</p> <p>Bourque 2001 at fig. 4</p>	No. Defendants’ bare citation in support fails to comply with LPR 2.3(b)(3), does not identify the method of claim 1, and does not specifically identify the magneto coupling, for the reasons discussed with respect to claim 1 above. Miracor may modify its response to this claim, subject to further explanation or definition by Defendants.
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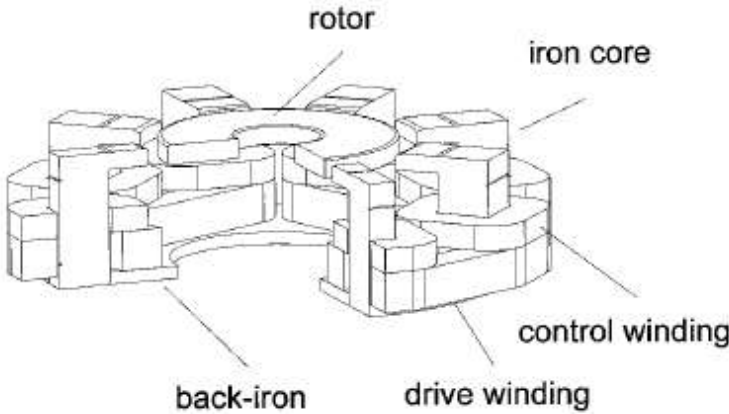
¹ Miracor does not assert this claim in its LPR 2.2 Initial Infringement Contentions, but certain asserted claims depend from this claim.

		 <p>Figure 4. HeartMate III motor, drive, and levitation (control) in a single magnetic structure.</p> <p>To the extent it is found that Bourque 2001 does not expressly disclose this limitation, the limitation is inherent. And to the extent it is found that Bourque 2001 does not anticipate this claim, Bourque 2001 renders it obvious, standing alone, in combination with the knowledge of a person of ordinary skill in the art, and/or in combination with one or more other prior art references identified in the cover pleading of Defendants' Initial Invalidity Contentions.</p>	
3 ²	[3a] The method of claim 2, wherein the surrounding rotor housing comprises at least one sealing wall between the first	<p>Bourque 2001 discloses “The method of claim 2, wherein the surrounding rotor housing comprises at least one sealing wall between the first magnetic device and the second magnetic device” at least under the apparent construction and scope of the claims as set forth in Miracor’s Initial Infringement Contentions and to the extent the asserted claims are found to be not indefinite.</p> <p>Bourque 2001 at fig. 1B</p>	No. Defendants’ bare citation in support fails to comply with LPR 2.3(b)(3), does not identify the method of claim 2 or specifically identify the first or second magnetic device for the reasons discussed above with respect to claims 1 and 2,

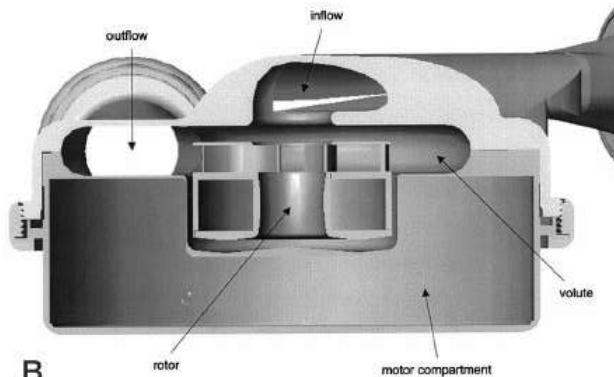
² Miracor does not assert this claim in its LPR 2.2 Initial Infringement Contentions, but certain asserted claims depend from this claim.

magnetic device and the second magnetic device	<div data-bbox="682 207 1297 592" data-label="Image"> </div> <p data-bbox="541 646 1444 1287">To the extent it is found that Bourque 2001 does not expressly disclose this limitation, the limitation is inherent. And to the extent it is found that Bourque 2001 does not anticipate this claim, Bourque 2001 renders it obvious, standing alone, in combination with the knowledge of a person of ordinary skill in the art, and/or in combination with one or more other prior art references (e.g., Schob '618 Ex. A-5) identified in the cover pleading of Defendants' Initial Invalidity Contentions. For example, a person of ordinary skill in the art would know that if a magnet comes into contact with blood, it can adversely affect the blood so as to become toxic or lethal, or cause corrosion, and that therefore the magnet must be sealed from the blood. Further, a person of ordinary skill in the art would have been motivated to combine Bourque 2001 with one or more other references identified in the cover pleading of Defendants' Initial Invalidity Contentions (e.g., Schob '618 Ex. A-5) with a reasonable expectation of success because each of these references contains familiar elements within the similar fields of endeavor to address similar known problems according to known methods which would yield predictable results.</p>	<p data-bbox="1472 207 1860 1174">and does not specifically identify a sealing wall. Defendants' argument that elements can be found in a different reference fails to comply with the relevant rules because Defendants do not identify with specificity where such elements can be found in that different reference. Miracor does not further respond to Defendants' arguments regarding combination with other references as such a response would fall outside of LPR 2.5. Miracor's compliance with the rules does not indicate any agreement, acquiescence or waiver with respect to Defendants' arguments regarding combinations with other references. Miracor may modify its response to this claim element subject to further explanation or definition by Defendants.</p>
[3b] and the first magnetic device is positioned	Bourque 2001 discloses "and the first magnetic device is positioned between the second magnetic device and the magnetically driven rotor" at least under the apparent construction and scope of the claims as set	No. Defendants' bare citation in support fails to comply with LPR 2.3(b)(3) and does not

	<p>between the second magnetic device and the magnetically driven rotor.</p>	<p>forth in Miracor’s Initial Infringement Contentions and to the extent the asserted claims are found to be not indefinite.</p> <p>Bourque 2001 at fig. 1B</p>  <p>To the extent it is found that Bourque 2001 does not expressly disclose this limitation, the limitation is inherent. And to the extent it is found that Bourque 2001 does not anticipate this claim, Bourque 2001 renders it obvious, standing alone, in combination with the knowledge of a person of ordinary skill in the art, and/or in combination with one or more other prior art references identified in the cover pleading of Defendants’ Initial Invalidity Contentions.</p>	<p>specifically identify, for example, a first magnetic device, a second magnetic device, or a position of a first magnetic device with respect to a second magnetic device. Accordingly, Defendants do not identify a first magnetic device that is positioned between the second magnetic device and the magnetically driven rotor. Miracor may modify its response to this claim element subject to further explanation or definition by Defendants.</p>
4	<p>The method of claim 3, wherein the first magnetic device rotates together with the magnetically driven rotor relative to the</p>	<p>Bourque 2001 discloses “The method of claim 3, wherein the first magnetic device rotates together with the magnetically driven rotor relative to the surrounding rotor housing,” at least under the apparent construction and scope of the claims as set forth in Miracor’s Initial Infringement Contentions and to the extent the asserted claims are found to be not indefinite.</p> <p>Bourque 2001 at page 401 ABT-MIR-00000024</p>	<p>No. Defendants’ bare citation in support fails to comply with LPR 2.3(b)(3), does not identify the method of claim 3, and does not specifically identify a first magnetic device, for the reasons discussed with respect to claims 1-3 above.</p>

	<p>surrounding rotor housing.</p>	<p>The rotor is magnetically suspended, eliminating contact between moving parts and consequently extending wear life indefinitely.</p> <p>Bourque 2001 at page 401 ABT-MIR-00000024 The HeartMate III pump...comprises...a <i>rotor</i> that includes an impeller and passively magnetic elements.</p> <p>Bourque 2001 at page 402-403 ABT-MIR-00000024 The HeartMate III motor includes drive and levitation in a single magnetic structure as show in Figure 4. The rotor is passively magnetically levitated in the axial-translational and transverse-rotational degrees of freedom...and actively magnetically levitated in the remaining degrees of freedom.</p> <p>Bourque 2001 at fig. 4</p>  <p>Figure 4. HeartMate III motor, drive, and levitation (control) in a single magnetic structure.</p> <p>Bourque 2001 at page 404 ABT-MIR-00000024</p>	<p>Miracor may modify its response to this claim element subject to further explanation or definition by Defendants.</p>
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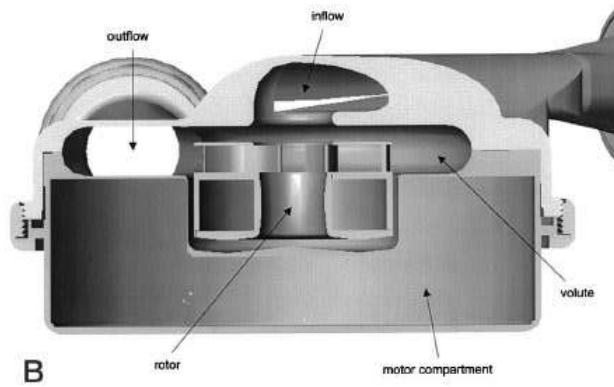
		<p>The very simple main flow path is a consequence of the motor's 'J' core configuration...which places an imaginary plane near the mid-height of the pump, below which are confined the motor and levitation elements, and above which the hydrodynamic elements are permitted free reign.</p> <p>To the extent it is found that Bourque 2001 does not expressly disclose this limitation, the limitation is inherent. And to the extent it is found that Bourque 2001 does not anticipate this claim, Bourque 2001 renders it obvious, standing alone, in combination with the knowledge of a person of ordinary skill in the art, and/or in combination with one or more other prior art references identified in the cover pleading of Defendants' Initial Invalidity Contentions.</p>	
5	<p>The method of claim 1, wherein the external control unit controls the second magnetic device in response to measurement values indicative of cardiac output of the heart.</p>	<p>Bourque 2001 discloses "The method of claim 1, wherein the external control unit controls the second magnetic device in response to measurement values indicative of cardiac output of the heart," at least under the apparent construction and scope of the claims as set forth in Miracor's Initial Infringement Contentions and to the extent the asserted claims are found to be not indefinite.</p> <p>See analysis of [10].</p> <p>To the extent it is found that Bourque 2001 does not expressly disclose this limitation, the limitation is inherent. And to the extent it is found that Bourque 2001 does not anticipate this claim, Bourque 2001 renders it obvious, standing alone, in combination with the knowledge of a person of ordinary skill in the art, and/or in combination with one or more other prior art references identified in the cover pleading of Defendants' Initial Invalidity Contentions.</p>	<p>No. See above. Defendants' bare citations in support fail to comply with LPR 2.3(b)(3) and do not specifically identify at least the alleged external control unit, the second magnetic device, measurement values indicative of cardiac output of the heart or controlling a second magnetic device in response to measurement values indicative of cardiac output of the heart. The citations to Bourque 2001 do not teach or suggest the method as claimed. Defendants' citations without sufficient analysis do not teach or suggest at least connecting an external control unit to a heart assist pump device for regulating operation of a second magnetic device to thereby magnetically drive the</p>

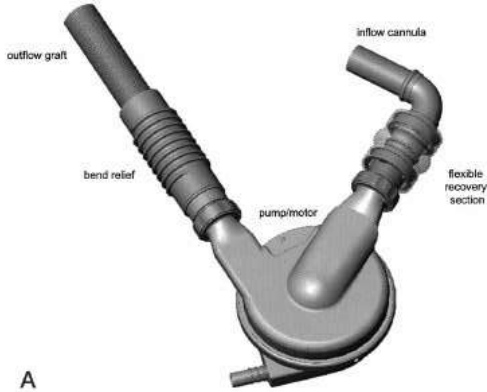
			rotation of a magnetically driven rotor via a magneto coupling with a first magnetic device, wherein the external control unit controls the second magnetic device in response to measurement values indicative of cardiac output of the heart. See responses to claim 1. Miracor may modify its response to this claim element subject to further explanation or definition by Defendants.
6	The method of claim 1, wherein both the magnetically driven rotor and first magnetic device are entirely spaced apart from the surrounding rotor housing by a gap during rotation of the magnetically driven rotor.	<p>Bourque 2001 discloses “The method of claim 1, wherein both the magnetically driven rotor and first magnetic device are entirely spaced apart from the surrounding rotor housing by a gap during rotation of the magnetically driven rotor,” at least under the apparent construction and scope of the claims as set forth in Miracor’s Initial Infringement Contentions and to the extent the asserted claims are found to be not indefinite.</p> <p>Bourque 2001 at fig. 1B</p>  <p>Bourque 2001 at page 401 ABT-MIR-00000024</p>	No. See above. Defendants’ bare citations in support fail to comply with LPR 2.3(b)(3) and do not specifically identify at least the first magnetic device, the surrounding rotor housing or the gap. The citations to Bourque 2001 do not teach or suggest the method as claimed. Defendants’ citations without sufficient analysis do not teach or suggest at least wherein both the magnetically driven rotor and first magnetic device are entirely spaced apart from the surrounding rotor housing by a gap during rotation of the magnetically driven rotor. See responses to claim 1. Miracor may modify its response to this claim element subject to further explanation or definition by Defendants.

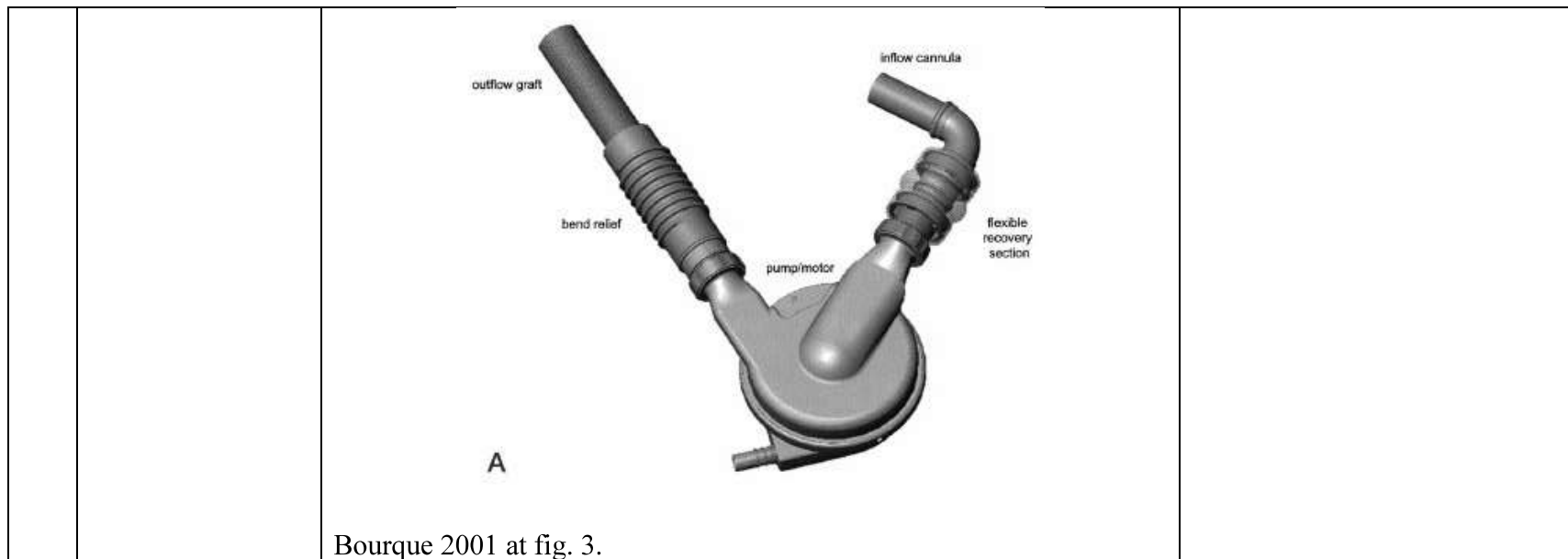
		<p>The rotor is magnetically suspended, eliminating contact between moving parts and consequently extending wear life indefinitely. It is anticipated that this design will profoundly increase reliability.</p> <p>Bourque 2001 at page 402-403 ABT-MIR-00000024 The HeartMate III motor includes drive and levitation in a single magnetic structure as shown in Figure 4. The rotor is passively magnetically levitated in the axial-translational and transverse-rotational degrees of freedom (Figure 5) and actively magnetically levitated in the remaining degrees of freedom.</p> <p>Bourque 2001 at page 402 ABT-MIR-00000024 By creating a similar opening in the lower half of the rotor, a second backflow path underneath the rotor results, eliminating what would have been an accumulation of stagnant blood there, and relieving the upward thrust load on the rotor. However, both of these backflows consume hydraulic power without contributing to physiologic perfusion. Thus, the clearances above and below the rotor were chosen to balance reduced hydraulic efficiency with sufficient washing of blood contacting surfaces... [T]he gaps permit up to 7X gravitational loads in any direction without contact between the rotor and housing.</p> <p>To the extent it is found that Bourque 2001 does not expressly disclose this limitation, the limitation is inherent. And to the extent it is found that Bourque 2001 does not anticipate this claim, Bourque 2001 renders it obvious, standing alone, in combination with the knowledge of a person of ordinary skill in the art, and/or in combination with one or more other prior art references identified in the cover pleading of Defendants' Initial Invalidity Contentions.</p>	
7	The method of claim 1, further comprising	Bourque 2001 discloses "The method of claim 1, further comprising providing feedback signals to the external control unit from one or more sensors," at least under the apparent construction and scope of the	No. Defendants' bare citation in support fails to comply with LPR 2.3(b)(3), does not

providing feedback signals to the external control unit from one or more sensors.	<p>claims as set forth in Miracor’s Initial Infringement Contentions and to the extent the asserted claims are found to be not indefinite.</p> <p>See analysis of [1o].</p> <p>Bourque 2001 at page 403 ABT-MIR-00000024</p> <p>For in vitro characterization, the pump was attached to a mock physiologic laboratory flow loop. Although this loop is generally equipped to simulate vascular compliance, and can even be configured with a pulsatile pump to represent a beating ventricle, the steady-state results reported here reflect time invariant measurements recorded after changed flow conditions had settled. Tests were repeated with several working fluids, including water, a blood analog aqueous solution (40% glycerin), and whole bovine blood. Flow measurements were made with an ultrasonic flow probe (Transonic Systems, Ithaca, NY), and pressure measurements were made with solid-state, catheter-type pressure transducers (Cobe Cardiovascular, Arvada, CO). Speed and motor parameters were set and controlled using software specifically designed to develop the HeartMate III. All measurements were automatically processed and recorded using Labview (National Instruments, Austin, TX).</p> <p>For in vivo testing, a young bovine model (,100 kg) was used (Figure 6). Surgeries were performed at the University of Pittsburgh McGowan Center for Artificial Organ Development in accordance with Guide for the Care and Use of Laboratory Animals.⁹ The pump was implanted with routine surgical techniques via left ventricular apical cannulation and anastomosis to the descending aorta.</p> <p>To the extent it is found that Bourque 2001 does not expressly disclose this limitation, the limitation is inherent. And to the extent it is found that Bourque 2001 does not anticipate this claim, Bourque 2001 renders it obvious, standing alone, in combination with the knowledge of a</p>	identify the method of claim 1 for the reasons discussed with respect to claim 1 above, and does not specifically identify signals from sensors that are provided to an external control unit. Miracor may modify its response to this claim element subject to further explanation or definition by Defendants.
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		person of ordinary skill in the art, and/or in combination with one or more other prior art references identified in the cover pleading of Defendants' Initial Invalidity Contentions.	
10	The method of claim 1, wherein the external control unit is configured to regulate operation of the second magnetic device based on a fixed control value.	<p>Bourque 2001 discloses "The method of claim 1, wherein the external control unit is configured to regulate operation of the second magnetic device based on a fixed control value," at least under the apparent construction and scope of the claims as set forth in Miracor's Initial Infringement Contentions and to the extent the asserted claims are found to be not indefinite.</p> <p>See analysis of [1o].</p> <p>To the extent it is found that Bourque 2001 does not expressly disclose this limitation, the limitation is inherent. And to the extent it is found that Bourque 2001 does not anticipate this claim, Bourque 2001 renders it obvious, standing alone, in combination with the knowledge of a person of ordinary skill in the art, and/or in combination with one or more other prior art references identified in the cover pleading of Defendants' Initial Invalidity Contentions.</p>	<p>No. Defendants' bare citation in support fails to comply with LPR 2.3(b)(3), does not identify the method of claim 1 or a second magnetic device for the reasons discussed with respect to claim 1 above, and does not specifically identify any regulation of a second magnetic device by the shelf mounted electronics. Defendants do not indicate any fixed control value. Defendants' argument that elements can be found in a different reference fails to comply with the relevant rules because Defendants do not identify with specificity where such elements can be found in that different reference. Miracor does not further respond to Defendants' arguments regarding combination with other references as such a response would fall outside of LPR 2.5. Miracor's compliance with the rules does not indicate any agreement, acquiescence or</p>

			waiver with respect to Defendants' arguments regarding combinations with other references. Miracor may modify its response to this claim element subject to further explanation or definition by Defendants.
12	The method of claim 1, wherein the second magnetic device is positioned closer to the blood outflow port than the second magnetic device is positioned relative to the suction end of the inflow tube.	<p>Bourque 2001 discloses "The method of claim 1, wherein the second magnetic device is positioned closer to the blood outflow port than the second magnetic device is positioned relative to the suction end of the inflow tube," at least under the apparent construction and scope of the claims as set forth in Miracor's Initial Infringement Contentions and to the extent the asserted claims are found to be not indefinite.</p> <p>Bourque 2001 at fig. 1B</p>  <p>Bourque 2001 at fig. 1A</p>	<p>No. See above. Defendants' bare citations in support fail to comply with LPR 2.3(b)(3) and do not specifically identify at least the second magnetic device, the blood outflow port, the suction end or the inflow tube. The citations to Bourque 2001 do not teach or suggest the method as claimed. Defendants' citations without sufficient analysis do not teach or suggest at least wherein the second magnetic device is positioned closer to the blood outflow port than the second magnetic device is positioned relative to the suction end of the inflow tube. See responses to claim 1. Miracor may modify its response to this claim element subject to further explanation or definition by Defendants.</p>

		 <p>To the extent it is found that Bourque 2001 does not expressly disclose this limitation, the limitation is inherent. And to the extent it is found that Bourque 2001 does not anticipate this claim, Bourque 2001 renders it obvious, standing alone, in combination with the knowledge of a person of ordinary skill in the art, and/or in combination with one or more other prior art references identified in the cover pleading of Defendants' Initial Invalidity Contentions.</p>	
13	The method of claim 1, wherein the heart assist pump device is a catheter device.	<p>Bourque 2001 discloses “The method of claim 1, wherein the heart assist pump device is a catheter device,” at least under the apparent construction and scope of the claims as set forth in Miracor’s Initial Infringement Contentions and to the extent the asserted claims are found to be not indefinite.</p> <p>Bourque 2001 at 401 ABT-MIR-00000024 The HeartMate III pump...comprises an upper housing that includes the inflow and outflow channels and the upper half of the volute;...an inflow subassembly that includes a left ventricular (LV) cannula and a section that partially decouples the position and motion of the heart from the pump and facilitates pump recovery at explant.</p> <p>Bourque 2001 at fig. 1A</p>	<p>No. Defendants’ bare citation in support fails to comply with LPR 2.3(b)(3) and does not identify the method of claim 1, for the reasons discussed with respect to claim 1 above. Miracor may modify its response to this claim element subject to further explanation or definition by Defendants.</p>



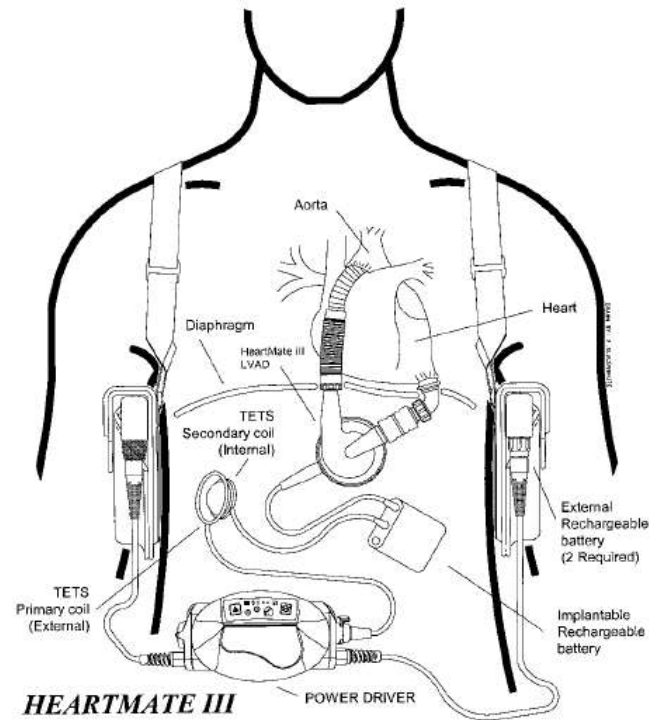


Figure 3. HeartMate III LVAD implanted configuration. TETS, transcutaneous energy transmission system.

To the extent it is found that Bourque 2001 does not expressly disclose this limitation, the limitation is inherent. And to the extent it is found that Bourque 2001 does not anticipate this claim, Bourque 2001 renders it obvious, standing alone, in combination with the knowledge of a person of ordinary skill in the art, and/or in combination with one or more other prior art references identified in the cover pleading of Defendants' Initial Invalidity Contentions.