

UTILITY PATENT APPLICATION TRANSMITTAL (Small Entity)

(Only for new nonprovisional applications under 37 CFR 1.53(b))

Docket No.
P201384.US.02

Total Pages in this Submission

COMMISSIONER FOR PATENTS

P.O. Box 1450
Alexandria, VA 22313-1450

Transmitted herewith for filing under 35 U.S.C. 111(a) and 37 C.F.R. 1.53(b) is a new utility patent application for an invention entitled:

Fatigue testing system for prosthetic devices

and invented by:

Benjamin McCloskey
Craig Weinberg, Ph.D.
Steven Weinberg, Ph.D.

If a **CONTINUATION APPLICATION**, check appropriate box and supply the requisite information:

☐ Continuation ☐ Divisional ☐ Continuation-in-part (CIP) of prior application No.: _____

Which is a:

☐ Continuation ☐ Divisional ☐ Continuation-in-part (CIP) of prior application No.: _____

Which is a:

☐ Continuation ☐ Divisional ☐ Continuation-in-part (CIP) of prior application No.: _____

Enclosed are:

Application Elements

1. ☒ Filing fee as calculated and transmitted as described below
2. ☒ Specification having 28 pages and including the following:
 - a. ☒ Descriptive Title of the Invention
 - b. ☒ Cross References to Related Applications (if applicable)
 - c. ☐ Statement Regarding Federally-sponsored Research/Development (if applicable)
 - d. ☐ Reference to Sequence Listing, a Table, or a Computer Program Listing Appendix
 - e. ☒ Background of the Invention
 - f. ☒ Brief Summary of the Invention
 - g. ☒ Brief Description of the Drawings (if filed)
 - h. ☒ Detailed Description
 - i. ☒ Claim(s) as Classified Below
 - j. ☒ Abstract of the Disclosure

Petitioner's Exhibit 1009
VIVITRO v. BDC
IPR2024-00320

UTILITY PATENT APPLICATION TRANSMITTAL
(Small Entity)

(Only for new nonprovisional applications under 37 CFR 1.53(b))

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Total Pages in this Submission

Application Elements (Continued)

3. ☒ Drawing(s) *(when necessary as prescribed by 35 USC 113)*
- a. ☒ Formal Number of Sheets 9
- b. ☐ Informal Number of Sheets _____
4. ☒ Oath or Declaration
- a. ☒ Newly executed *(original or copy)* ☐ Unexecuted
- b. ☐ Copy from a prior application (37 CFR 1.63(d)) *(for continuation/divisional application only)*
- c. ☐ With Power of Attorney ☐ Without Power of Attorney
- d. ☐ DELETION OF INVENTOR(S)
Signed statement attached deleting inventor(s) named in the prior application,
see 37 C.F.R. 1.63(d)(2) and 1.33(b).
5. ☐ Incorporation By Reference *(usable if Box 4b is checked)*
The entire disclosure of the prior application, from which a copy of the oath or declaration is supplied under Box 4b, is considered as being part of the disclosure of the accompanying application and is hereby incorporated by reference therein.
6. ☐ CD ROM or CD-R in duplicate, large table or Computer Program (Appendix)
7. ☒ Application Data Sheet (See 37 CFR 1.76)
8. ☐ Nucleotide and/or Amino Acid Sequence Submission *(if applicable, all must be included)*
- a. ☐ Computer Readable Form (CFR)
- b. ☐ Specification Sequence Listing on:
- i. ☐ CD-ROM or CD-R (2 copies); or
- ii. ☐ Paper
- c. ☐ Statement(s) Verifying Identical Paper and Computer Readable Copy

Accompanying Application Parts

9. ☐ Assignment Papers (cover sheet & document(s))
10. ☐ 37 CFR 3.73(B) Statement (when there is an assignee)
11. ☐ English Translation Document (if applicable)
12. ☐ Information Disclosure Statement/PTO-1449 ☐ Copies of IDS Citations
13. ☐ Preliminary Amendment
14. ☐ Return Receipt Postcard (MPEP 503) (Should be specifically itemized)
15. ☐ Certified Copy of Priority Document(s) (if foreign priority is claimed)
16. ☐ Certificate of Mailing
- ☐ First Class ☐ Express Mail (Specify Label No.): electronically filed

Petitioner's Exhibit 1009
VIVITRO v. BDC
IPR2024-00320

**UTILITY PATENT APPLICATION TRANSMITTAL
(Small Entity)**

(Only for new nonprovisional applications under 37 CFR 1.53(b))

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Accompanying Application Parts (Continued)

17. ☒ Applicant claims small entity status. See 37 CFR 1.27.
☐ (Optional) Small Entity Statement(s) - Specify Number of Statements Submitted: _____
18. ☐ Additional Enclosures (*please identify below*):

Request That Application Not Be Published Pursuant To 35 U.S.C. 122(b)(2)

19. ☐ Pursuant to 35 U.S.C. 122(b)(2), Applicant hereby requests that this patent application not be published pursuant to 35 U.S.C. 122(b)(1). Applicant hereby certifies that the invention disclosed in this application has not and will not be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication of applications 18 months after filing of the application.

Warning

An applicant who makes a request not to publish, but who subsequently files in a foreign country or under a multilateral international agreement specified in 35 U.S.C. 122(b)(2)(B)(i), must notify the Director of such filing not later than 45 days after the date of the filing of such foreign or international application. A failure of the applicant to provide such notice within the prescribed period shall result in the application being regarded as abandoned, unless it is shown to the satisfaction of the Director that the delay in submitting the notice was unintentional.

20. ☐ Other:

Petitioner's Exhibit 1009
VIVITRO v. BDC
IPR2024-00320

UTILITY PATENT APPLICATION TRANSMITTAL
(Small Entity)

(Only for new nonprovisional applications under 37 CFR 1.53(b))

Docket No.
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Fee Calculation and Transmittal

CLAIMS AS FILED

For	#Filed	#Allowed	#Extra	Rate		Fee
Total Claims	31	- 20 =	11	x	\$26.00	\$286.00
Indep. Claims	4	- 3 =	1	x	\$110.00	\$110.00
Multiple Dependent Claims (check if applicable) ☐						\$0.00
Total # of Pages in Specification		28	Total # of Drawing Sheets		9	
Total # of Pages	37	Application Size Fee				\$0.00
Basic Fee						\$165.00
Search Fee						\$270.00
Examination Fee						\$110.00
OTHER FEE (specify purpose)						\$0.00
TOTAL FILING FEE						\$941.00

☐ A check in the amount of _____ to cover the filing fee is enclosed.
☒ The Director is hereby authorized to charge and credit Deposit Account No. **04-1415**
as described below.

- ☒ Charge the amount of **\$941.00** as filing fee.
☒ Credit any overpayment.
☒ Charge any additional filing fees required under 37 C.F.R. 1.16 and 1.17.
☐ Charge the issue fee set in 37 C.F.R. 1.18 at the mailing of the Notice of Allowance,
pursuant to 37 C.F.R. 1.311(b).

☐ Payment by credit card. Form PTO-2038 is attached.

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

Dated: **5 March 2010**

Customer Number: **20686**

cc:


Signature

Brad J. Hattenbach, Registration No. 42,642
DORSEY & WHITNEY LLP
Republic Plaza Building, Suite 4700
370 Seventeenth Street
Denver, Colorado 80202
(303) 629-3400
(303) 629-3450 fax

Petitioner's Exhibit 1009
VIVITRO v. BDC
IPR2024-00320

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	P201384.US.02
		Application Number	Not Yet Assigned
Title of Invention	Fatigue testing system for prosthetic devices		
The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76. This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.			

Secrecy Order 37 CFR 5.2

☐	Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)
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Applicant Information:

Applicant 1					
Applicant Authority		☒ Inventor	☐ Legal Representative under 35 U.S.C.	☐ Party of Interest under 35 U.S.C.	
Prefix	Given Name	Middle Name	Family Name	Suffix	
	Benjamin		McCloskey		
Residence Information (Select One)		☒ US Residency	☐ Non US Residency	☐ Active US Military Service	
City	Evergreen	State/Province	CO	Country of Residence i	US
Citizenship under 37 CFR 1.41(b) i		US			
Mailing Address of Applicant:					
Address 1		29726 Bronco Road			
Address 2					
City	Evergreen	State/Province	CO		
Postal Code	80439	Country i	US		
☒ All Inventors Must be Listed - Additional Inventor Information listed below.					

Applicant 2					
Applicant Authority		☒ Inventor	☐ Legal Representative under 35 U.S.C.	☐ Party of Interest under 35 U.S.C.	
Prefix	Given Name	Middle Name	Family Name	Suffix	
	Craig		Weinberg	Ph.D.	
Residence Information (Select One)		☒ US Residency	☐ Non US Residency	☐ Active US Military Service	
City	Denver	State/Province	CO	Country of Residence i	US
Citizenship under 37 CFR 1.41(b) i		US			
Mailing Address of Applicant:					
Address 1		4132 Decatur Street			
Address 2					
City	Denver	State/Province	CO		
Postal Code	80211	Country i	US		
☒ All Inventors Must be Listed - Additional Inventor Information listed below.					

Applicant Information: (continued)

Applicant							
Applicant Authority		☒ Inventor		☐ Legal Representative under 35 U.S.C.		☐ Party of Interest under 35 U.S.C.	
Prefix	Given Name		Middle Name		Family Name		Suffix
	Steven				Weinberg		Ph.D.
Residence Information (Select One) ☐ US Residency ☐ Non US Residency ☐ Active US Military Service							
City	League City		State/Province	TX	Country of Residence ⁱ		US
Citizenship under 37 CFR 1.41(b) ⁱ							
Mailing Address of Applicant:							
Address 1		916 Davis Road					
Address 2							
City	League City			State/Province	TX		
Postal Code		77573		Country ⁱ	US		
☐ All Inventors Must be Listed - Additional Inventor Information listed below.							

Applicant							
Applicant Authority		☐ Inventor		☐ Legal Representative under 35 U.S.C.		☐ Party of Interest under 35 U.S.C.	
Prefix	Given Name		Middle Name		Family Name		Suffix
Residence Information (Select One) ☐ US Residency ☐ Non US Residency ☐ Active US Military Service							
City			State/Province		Country of Residence ⁱ		
Citizenship under 37 CFR 1.41(b) ⁱ							
Mailing Address of Applicant:							
Address 1							
Address 2							
City				State/Province			
Postal Code				Country ⁱ			
☐ All Inventors Must be Listed - Additional Inventor Information listed below.							

Applicant							
Applicant Authority		☐ Inventor		☐ Legal Representative under 35 U.S.C.		☐ Party of Interest under 35 U.S.C.	
Prefix	Given Name		Middle Name		Family Name		Suffix
Residence Information (Select One) ☐ US Residency ☐ Non US Residency ☐ Active US Military Service							
City			State/Province		Country of Residence ⁱ		
Citizenship under 37 CFR 1.41(b) ⁱ							
Mailing Address of Applicant:							
Address 1							
Address 2							
City				State/Province			
Postal Code				Country ⁱ			
☐ All Inventors Must be Listed - Additional Inventor Information listed below.							

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	P201384.US.02
		Application Number	Not Yet Assigned
Title of Invention	Fatigue testing system for prosthetic devices		

Correspondence Information:

Enter either Customer Number or complete the Correspondence Information section below.
For further information see 37 CFR 1.33(a).

☒ An Address is being provided for the Correspondence Information of this application.	
Customer Number	20686
Email Address	docketing-dv@dorsey.com
Email Address	
Email Address	

Application Information:

Title of the Invention	Fatigue testing system for prosthetic devices		
Attorney Docket Number	P201384.US.02	Small Entity Status Claimed	☒
Application Type	NonProvisional		
Subject Matter	Utility		
Suggested Class (if any)		Sub Class (if any)	
Suggested Technology Center (if any)			
Total Number of Drawing Sheets (if any)	9	Suggested Figure for Publication (if any)	3

Publication Information:

☐ Request Early Publication (Fee required at time of Request 37 CFR 1.219)
☐ Request Not to Publish. I hereby request that the attached application not be published under 35 U.S.C. 122(b) and certify that the invention disclosed in the attached application has not been and will not be the subject of an application filed in another country, or under a multilateral agreement, that requires publication at eighteen months after filing.

Representative Information:

Representative information should be provided for all practitioners having a power of attorney in the application. Providing this information in the Application Data Sheet does not constitute a power of attorney in the application (see 37 CFR 1.32). Enter either Customer Number or complete the Representative Name section below. If both sections are completed the Customer Number will be used for the Representative Information during processing.

Please Select One:	☒ Customer Number	☐ US Patent Practitioner	☐ Limited Recognition (37 CFR 11.9)	
Customer Number	20686			
Prefix	Given Name	Middle Name	Family Name	Suffix
	Brad	J.	Hattenbach	
Registration Number	42,642			
Prefix	Given Name	Middle Name	Family Name	Suffix
Registration Number				

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	P201384.US.02
		Application Number	Not Yet Assigned
Title of Invention	Fatigue testing system for prosthetic devices		

Domestic Priority Information:

This section allows for the applicant to claim benefit under 35 U.S.C. 119(e), 120, 121, or 365(c) or indicate National Stage entry from a PCT application. Providing this information in the application data sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78(a)(2) or CFR 1.78(a)(4), and need not otherwise be made part of the specification.

Prior Application Status			
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
This application	35 U.S.C. § 119(e) to	61/158,185	2009-03-06

This section allows for the applicant to claim benefit under 35 U.S.C. 119(e), 120, 121, or 365(c) or indicate National Stage entry from a PCT application. Providing this information in the application data sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78(a)(2) or CFR 1.78(a)(4), and need not otherwise be made part of the specification.

Prior Application Status			
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)

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Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)

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Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)

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Prior Application Status			
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	P201384.US.02
		Application Number	Not Yet Assigned
Title of Invention	Fatigue testing system for prosthetic devices		

Foreign Priority Information:

This section allows for the applicant to claim benefit of foreign priority and to identify any prior foreign application for which priority is not claimed. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55(a).

Application Number	Country i	Parent Filing Date (YYYY-MM-DD)	Priority Claimed
			☐ Yes ☐ No

This section allows for the applicant to claim benefit of foreign priority and to identify any prior foreign application for which priority is not claimed. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55(a).

Application Number	Country i	Parent Filing Date (YYYY-MM-DD)	Priority Claimed
			☐ Yes ☐ No

This section allows for the applicant to claim benefit of foreign priority and to identify any prior foreign application for which priority is not claimed. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55(a).

Application Number	Country i	Parent Filing Date (YYYY-MM-DD)	Priority Claimed
			☐ Yes ☐ No

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Application Number	Country i	Parent Filing Date (YYYY-MM-DD)	Priority Claimed
			☐ Yes ☐ No

This section allows for the applicant to claim benefit of foreign priority and to identify any prior foreign application for which priority is not claimed. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55(a).

Application Number	Country i	Parent Filing Date (YYYY-MM-DD)	Priority Claimed
			☐ Yes ☐ No

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	P201384.US.02	
		Application Number	Not Yet Assigned	
Title of Invention	Fatigue testing system for prosthetic devices			

Assignee Information:

Providing this information in the application data sheet does not substitute for compliance with any requirement of part 3 of Title 37 of the CFR to have an assignment recorded in the Office.

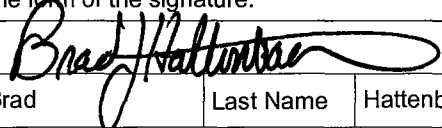
Assignee 1	Biomedical Device Consultants and Laboratories of Colorado, LLC			
If the Assignee is an Organization check here. ☐				
Prefix	Given Name	Middle Name	Family Name	Suffix
Mailing Address Information:				
Address 1	4060 Youngfield Street			
Address 2				
City	Wheat Ridge	State/Province	CO	
Country i	US	Postal Code	80033	
Phone Number		Fax Number		
Email Address				

Assignee				
If the Assignee is an Organization check here. ☐				
Prefix	Given Name	Middle Name	Family Name	Suffix
Mailing Address Information:				
Address 1				
Address 2				
City		State/Province		
Country i		Postal Code		
Phone Number		Fax Number		
Email Address				

Assignee				
If the Assignee is an Organization check here. ☐				
Prefix	Given Name	Middle Name	Family Name	Suffix
Mailing Address Information:				
Address 1				
Address 2				
City		State/Province		
Country i		Postal Code		
Phone Number		Fax Number		
Email Address				

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	P201384.US.02
		Application Number	Not Yet Assigned
Title of Invention	Fatigue testing system for prosthetic devices		

Signature:

A signature of the applicant or representative is required in accordance with 37 CFR 1.33 and 10.18. Please see 37 CFR 1.4(d) for the form of the signature.					
Signature				Date (YYYY-MM-DD)	2010-03-05
First Name	Brad	Last Name	Hattenbach	Registration Number	42,642

This collection of information is required by 37 CFR 1.76. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 23 minutes to complete, including gathering, preparing, and submitting the completed application data sheet form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1451. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

TITLE

Fatigue testing system for prosthetic devices

INVENTORS

Benjamin McCloskey of Evergreen, Colorado

Craig Weinberg of Denver, Colorado

Steven Weinberg of League City, Texas

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of priority pursuant to 35 U.S.C. § 119(e) of U.S. provisional application no. 61/158,185 filed 6 March 2009 entitled "Apparatus and method for fatigue testing of prosthetic valves," which is hereby incorporated herein by reference in its entirety.

TECHNICAL FIELD

[0002] The technology described herein relates to systems and methods for fatigue testing of prosthetic devices, in particular, but not limited to, prosthetic vascular and heart valves, under simulated physiological loading conditions and high-cycle applications.

BACKGROUND

[0003] Prior prosthetic valve testing apparatus and methods typically use a traditional rotary motor coupled with mechanisms to produce regular sinusoidal time varying pressure field conditions. To accurately simulate physiologic conditions and/or produce a more desirable test condition, especially at accelerated testing speeds, a non-sinusoidal time dependent pressure field may be desired. This is not easily accomplished with a mechanistic approach. Furthermore, current systems employ a flexible metallic bellows or conventional piston and cylinder as drive members to provide the pressure actuation. Flexible metallic bellows are not ideal because they require high forces to operate and resonate at frequency, necessitating the use of larger driving systems and limiting the available test speeds. Piston and cylinder arrangements are not ideal because the seals employed in these systems are subjected to friction and thus have severely limited life in high cycle applications.

[0004] The information included in this Background section of the specification, including any references cited herein and any description or discussion thereof, is included for technical reference purposes only and is not to be regarded subject matter by which the scope of the invention is to be bound.

SUMMARY

[0005] A design for a fatigue testing system for cyclic, long-term testing of various types of prosthetic devices (e.g., cardiac valves, vascular valves, stents, atrial septal defect

technologies, vascular linings, and others) is designed to impart a repeating loading condition for the test samples during a test run. However, the system is also designed to be variable in its abilities so it can accurately test multiple technologies. Thus, the system may be variably configured depending upon the device being tested to impart a particular loading profile to repeatedly expose the prosthetic device being tested to desired physiological loading conditions during a testing run. The purpose is to simulate typical or specific physiologic loading conditions on a vascular or heart prosthetic valve, or other prosthetic technology, at accelerated frequency over time to determine the efficacy, resiliency, and wear of the devices.

[0006] Fatigue testing is accomplished by first deploying the prosthetic device in an appropriately sized sample holder, e.g., a rigid or flexible tube, canister, housing or other appropriate structure for holding the device being tested. The sample holder is then placed between two halves of a test chamber that together form a reservoir for a working fluid. The test chamber is in turn mounted to a drive system. The sample holder and valve being tested are then subjected to physiological appropriate conditions which may include: pressure, temperature, flow rate, and cycle times.

[0007] An implementation of a drive system for the fatigue testing system may include a linear actuator or magnetic-based drive motor coupled to a flexible rolling diaphragm. The drive system is coupled to a lower opening in the test chamber and is in fluid communication with the fluid reservoir in the test chamber. The flexible rolling diaphragm (or "rolling bellow") is reciprocally moveable to pressurize and depressurize fluid and interacts with the lower section of the fluid reservoir to provide a motive force to drive the working fluid through its cycles within the test chamber, including the sample holders.

[0008] Testing and test conditions are controlled by a control computer that permits both input of test conditions and monitors feedback of the test conditions during a testing run. Computer system control may be either an open loop control that requires user intervention in the event a condition falls outside pre-set condition parameters or a closed loop control system in which the computer monitors and actively controls testing parameters to ensure that the test conditions remain within the pre-set condition parameters.

[0009] The fatigue tester is capable of simulating physiologic conditions on prosthetic devices at an accelerated rate. The fatigue tester may also be configured to create either sinusoidal or non-sinusoidal pressure and/or flow waveforms across the prosthetic devices. Pressure waveforms may also be applied that produce a pre-defined pressure gradient over time to a prosthetic device being tested.

[0010] In one exemplary implementation, a device for simultaneous cyclic testing of a plurality of prosthetic devices is composed of a test chamber, a drive motor and a fluid displacement member. The test chamber is pressurizable and has a fluid distribution

chamber with a first manifold defining a plurality of ports configured to receive and fluidically couple with a first end of each of a respective plurality of sample holders. The fluid distribution chamber also defines an aperture in a lower face in fluid communication with a pressure source. The test chamber also has a fluid return chamber with a second manifold disposed opposite and spaced apart from the first manifold of the fluid distribution chamber. The manifold of the return chamber defines a plurality of ports configured to receive and fluidically couple with a second end of each of the respective plurality of sample holders. A fluid return conduit both structurally and fluidily connects the fluid distribution chamber to the fluid return chamber. The test chamber also has a compliance chamber which provides a volume for holding a gas or an elastic material that compresses under a pressure placed upon fluid in the test chamber and allows fluid in the test chamber to occupy a portion of the volume. The drive motor is configured to operate cyclically, acyclically, or a combination of both. The fluid displacement member is connected with and driven by the drive motor to provide the pressure source that increases and decreases a pressure on fluid in the test chamber. In this manner, cyclic and acyclic fluid pressures may be maintained throughout the test chamber.

[0011] This Summary is provided to introduce a selection of concepts in a simplified form that are further described below in the Detailed Description. This Summary is not intended to identify key features or essential features of the claimed subject matter, nor is it intended to be used to limit the scope of the claimed subject matter. A more extensive presentation of features, details, utilities, and advantages of the present invention is provided in the following written description of various embodiments of the invention, illustrated in the accompanying drawings, and defined in the appended claims.

BRIEF DESCRIPTION OF THE DRAWINGS

[0012] FIG. 1 is a combined isometric view and schematic diagram of an exemplary implementation of a fatigue testing system and a corresponding control system.

[0013] FIG. 2A is a front elevation view of the fatigue testing system of FIG. 1.

[0014] FIG. 2B is an enlarged view of the motor support in the area surrounded by the circle labeled 2B in FIG. 2A.

[0015] FIG. 3 is a partial cross sectional view of a test chamber of the fatigue testing system taken along line 3-3 of FIG. 1.

[0016] FIG. 4A is an isometric view in cross section of a portion of the fatigue testing system of FIG. 1 detailing a flexible rolling diaphragm pump connected to a linear piston drive system in a down stroke position.

[0017] FIG. 4B is an isometric view in cross section of a portion of the fatigue testing system of FIG. 1 detailing a flexible rolling diaphragm pump connected to a linear piston drive system in an upstroke position.

[0018] FIG. 5A is an isometric view in cross section of a portion of the test chamber of the fatigue testing system detailing an isolation valve in an open position.

[0019] FIG. 5B is an isometric view in cross section of a portion of the test chamber of the fatigue testing system detailing the isolation valve in a closed position.

[0020] FIG. 6 is a schematic diagram in cross section of an alternative implementation of a test chamber for use in a fatigue testing system.

[0021] FIG. 7 is a graph depicting three exemplary pressure control waves for generation by test control software to provide pressure across a sample device being tested.

[0022] FIG. 8 is a schematic diagram of a software and hardware implementation for controlling a fatigue testing system.

[0023] FIG. 9 is a schematic diagram of an exemplary computer system for controlling a fatigue testing system.

DETAILED DESCRIPTION

[0024] The system of the present invention generally includes a linear actuator or magnetic based drive coupled to a flexible rolling bellows diaphragm to provide variable pressure gradients across test samples mounted in a test chamber housing a fluid reservoir. These components operate together to act as a fluid pump and, when combined with a fluid control system, provide the absolute pressure and/or differential pressure and flow conditions necessary to cycle test prosthetic devices mounted in the test chamber. The flexible rolling diaphragm thrusts toward the lower section of the test chamber to provide a motive force to drive the working fluid through cycles within the test chamber. The flexible diaphragm is coupled to a lower opening in the test chamber and is reciprocally moveable to pressurize and depressurize fluid within the lower section of the main housing. The flexible rolling bellows diaphragm drive system has a very low inertia as compared to other drive systems, e.g., a metal bellows or a standard piston-in-cylinder drive. The flexible diaphragm is highly compliant with low resistance to axial deformation across its entire axial range of motion.

[0025] Plural sample holder tubes are coupled in parallel across the test chamber which has plural fluid distribution channels in communication with each of the sample holders. The lower distribution chamber of the test chamber has a single fluid reservoir in fluid flow communication with each of the plurality of sample holders. The distribution chamber includes a manifold with a plurality of fluid outlet ports, and each fluid outlet port communicates with an inflow opening of a test holder. The upper return chamber of the test

chamber includes a similar manifold with a plurality of fluid inflow ports and compliance chambers. Each fluid inflow port communicates with an outflow opening of a respective sample holder. A central return flow channel is provided between the return chamber and the distribution chamber of the test chamber reservoir to provide a return flow of the working fluid from the outflow section of the sample holders. A throttle control and a check valve are disposed at the inflow and outflow ends of the central return flow channel, respectively, to regulate fluid flow during testing. The throttle control serves to partially regulate the pressure across the prosthetic devices being tested as well as the return flow of the working fluid in the fluid test chamber.

[0026] These components operate together to provide a differential pressure and flow conditions necessary to cycle the prosthetic device. The internal conditions, which may include, among other things, temperature, differential pressure, and system pressure, are electrically communicated to monitoring and controlling software on a test system computer. The motion of the fluid pump and therefore the system dynamics are controlled via test system control software. The pressure field resulting from the pump motion is easily controlled and can be set as a simple sine wave or as any complex user created waveform.

[0027] One exemplary implementation of a fatigue testing system 100 for any of a variety of prosthetic devices is depicted in FIGS. 1 through 5B. The fatigue testing system 100 may be understood as having two primary components, a test chamber 106 and a drive motor 105. The fatigue testing system 100 may be both partially mounted upon and housed within a base housing 157 formed and supported by a number of frame members 102. In the implementation shown, the drive motor 105 is housed within the base housing 157 while the test chamber 106 is supported on a base plate 111 forming a top surface of the base housing 157. The base housing 157 may be open on its sides or enclosed with removable panels as desired. A number of leveling feet 101 may be attached to the bottom of the base housing 157 to provide for leveling of the fatigue testing system 100 and thereby assist in creating consistent operating conditions across each of the multiple sample chambers of the fatigue testing system 100 as further described below.

[0028] In the embodiment shown in FIGS. 1 and 2A with greater detail shown in FIG. 2B, the drive motor 105 may be a linear motor. The linear drive motor 105 is mounted vertically on a motor stabilizer 104 and is centered underneath the test chamber 106. The lower end of the drive motor 105 is supported by a spring 103 that interfaces with a horizontal foot 104a of the motor stabilizer 104 that extends underneath the linear drive motor 105. A lower shaft extension 156 is attached to and extends downwardly from a thrust rod 108 of the linear drive motor 105, through the spring 103, and through a bearing-lined aperture in the foot 104a of the motor stabilizer 104 where it is secured on the underside of the foot 104a as shown in FIG. 2B. The spring 103 is mounted concentrically about the lower

shaft extension 156 and abuts the lower end of the thrust rod 108 of the linear motor 105 to support the weight of the thrust rod 108 of the linear drive motor 105 when the linear drive motor 105 is in an unpowered state. Further, in the event of a power failure during operation, the spring 103 prevents the thrust rod 108 from dropping quickly and causing an extremely large pressure gradient across test samples in the test chamber 106, which could damage the test samples.

[0029] The upper end of the linear drive motor 105 is fixed to a motor support plate 109 that is in turn supported by several frame members 102 of the base housing 157. An aperture in the motor support plate 109 provides for passage of the upper end of the thrust rod 108 for alignment and mechanical connection with components interfacing with the test chamber 106. It should be noted that while a linear drive motor 105 is depicted in the figures, other types of motors, for example, a regular DC motor or a voice coil, may be used to offer alternate functionality than the linear drive motor 105 of desired for a particular prosthetic device. The number of cycles completed during a test session may be monitored by a cycle counter (not shown) that monitors the motion of the thrust rod 108 of the linear motor 105, which may be affixed to the motor support plate 109.

[0030] Several linkage components are provided between the drive motor 105 and the test chamber 106 as shown to best advantage in FIGS. 2A and 3. These components together form the drive member for creating a driving pressure on fluid in the system. An upper shaft extension 112 is fixed to and extends from an upper end of the thrust rod 108 and further extends axially within a cylinder 113. The cylinder 113 is supported about the upper shaft extension 112 within an alignment collar 107. The alignment collar 107 is further supported by a pair of alignment mounts 155 that are fixed to and extend upward from the motor support plate 109. The alignment collar 107 ensures that the cylinder 113 and the drive motor 105 maintain axial alignment.

[0031] A central aperture in the bottom of the cylinder 113 receives the upper shaft extension 112. This aperture in the bottom wall of cylinder 113 is lined with a bearing 162 to provide a low friction interface between the cylinder 113 and the upper shaft extension 112 as the upper shaft extension 112 moves within the cylinder 113 as further described below. A piston 114 in the shape of an inverted cylindrical cup may be mounted to the top of the upper shaft extension 112 for axial displacement within the cylinder 113 as the linear drive motor 105 drives the upper shaft extension 112 up and down.

[0032] The fluid drive member can be sized based on the volumetric requirements of the test chamber 106 or test samples. Depending on the volume displacement required for a particular application, the cylinder 113 and corresponding piston 114 may be swapped out for sizes of larger or smaller diameter. The cylinder 113 and corresponding piston 114 may thus be provided in a variety of diameters in order to provide different volume displacements

for a given stroke, and thereby pressure differentials, within the test chamber 106 depending upon the type of sample being tested or the particular testing protocol being implemented.

[0033] The top edge of the cylinder 113 extends radially to form a flange 113a that interfaces with a bottom surface of a drive adapter 117. The drive adapter 117 may also be provided in a variety of alternative different sizes to interface with different types of cylinders 113 of various diameters. Thus, corresponding drive adapters 117 and alignment collars 107 are similarly swapped for adjustment to the size of the cylinder 113. For example, as shown in FIG. 3, the aperture in the drive adapter 117 is shaped as a frustum with a wider upper mouth toward the test chamber 106 and walls that then taper to a smaller opening at the interface with the top of the cylinder 113. In another embodiment with a larger diameter cylinder 113, the drive adapter 117 may have a larger diameter lower opening defining more sharply angled sidewalls of the frustum-shaped aperture and, in some embodiments, might even be cylindrical to accommodate a larger cylinder 113 of a common diameter.

[0034] In one implementation, the fluid drive member has a flexible diaphragm drive system as illustrated in FIGS. 3, 4A, and 4B. The diaphragm 115 may be a cap-like or cup-like member constructed of a non-reactive and flexible thin rubber, polymeric or synthetic based material. The flexible diaphragm 115 is highly compliant with low resistance to axial deformation across its entire axial range of motion within the cylinder 113 and the aperture in the drive adapter 117. However, alternative configurations of the diaphragm 115 may be employed so long as the configuration is capable of low friction and low resistance to deformation under the influence of the piston 114. The outer diameter of the sidewalls 114a of the piston 114 is slightly smaller than the inner diameter of the cylinder 113 to provide a uniform gap therebetween. The gap is designed to be large enough to allow the sidewall of the diaphragm 115 to fold in half against itself, i.e., evert, within this gap when the sidewalls 114a of the piston 114 are positioned within the sidewalls of the cylinder 113. It may thus be noted that in operation flexible diaphragm 115 will operate as a rolling bellows when the linear drive motor 105 is actuated.

[0035] Many advantages of a low friction flexible diaphragm 115 as opposed to a rigid metallic bellows or traditional piston and cylinder drive may be appreciated. The lateral surfaces of the diaphragm 115 evert between the sidewalls 115a of the piston 115 and the sidewalls of the cylinder 113 as the piston 114 reciprocates within the cylinder 113 and drive adapter 117. However, this eversion occurs with very low friction and low heat generation, and exerts very little resistance to piston 114 movement. As such, the drive motor can operate with a low driving force for either small or large displacements requiring low current draw and thus low energy expenditure. The flexible diaphragm 115 is highly compliant with low resistance to axial deformation across its entire axial range of motion. Alternative

configurations of the diaphragm 115 may also be employed so long as the configuration is capable of very low friction and very low resistance to deformation under the influence of the piston 114.

[0036] The cup-shaped flexible diaphragm 115 is mounted on top of the piston 114. The end wall of the diaphragm 115 is held against the top of the piston 114 by a rigid, disk-shaped cap 116, which is fastened to the upper shaft extension 112 via fastener 158 (e.g., a set screw threaded within the upper extension shaft 112). A flange surface 115a extends radially outward and circumferentially around the opening to the cavity of the cup-shaped diaphragm 115. This flange surface 115a is sandwiched between the flange surface 113a of the cylinder 113 and the bottom surface of the drive adapter 117 to maintain a pressure seal between the test chamber 106 and the drive components. In view of FIG. 3, the tapering of the frustum-shaped wall defining the aperture in the drive adapter 117 to an opening of comparable diameter to the diameter of the sidewalls forming the cylinder 113 becomes apparent, i.e., the need for corresponding surfaces between the flange of the cylinder 113 and the bottom surface of the drive adapter 117 to retain the flange surface 115a of the diaphragm 115.

[0037] A top surface of the drive adapter 117 is fastened to a plenum 118 that defines a center cylindrical aperture aligned coaxially with the aperture of the drive adapter 117 and the cavity defined by the cylinder 113. As shown in FIGS. 4A and 4B, a plurality of ports may be defined within the sidewall of the plenum 118 to provide fluid fill, drainage, or other functionality within the linkage components below the test chamber 106. For the sake of clarity, the plenum 118 shown in FIG. 3 depicts only a single sidewall port 143 that, in this embodiment, is used as a fluid inflow port. However, additional ports may be defined within the plenum 118 if desirable (see, e.g., FIGS. 4A and 4B). If not in use for a particular test configuration, the sidewall ports 143 in the plenum 118 may be plugged. The plenum 118 may be of constant diameter to interface with an aperture in the base plate 111 of the base housing 157. For this reason it can now be understood why in some embodiments the opening in the top surface of the drive adapter 117 may be of a larger diameter than the opening in the bottom surface of the drive adapter 117 as the drive adapter 117 mates with a constant diameter plenum 118 in contrast to a variable diameter cylinder 113.

[0038] As previously indicated, the test chamber 106 sits atop of the base plate 111 on the base housing 157. The foundation of the test chamber 106 may in some embodiments include a gate guide plate 120 that also defines a central aperture that is coextensive in diameter with and concentrically aligned with the aperture in the base plate 111. A distribution chamber 126 is supported by the gate guide plate 120. The gate guide plate 120, the distribution chamber 126, and the base plate 111 may all be fastened together via bolts (not shown) extending upward from the underside of the base plate 111. A pair of

gate seals 160 may be positioned between the gate guide plate 120 and the distribution chamber 126. The gate seals 160 may be a set of stacked O-rings surrounding the central apertures in the gate guide plate 120 and the distribution chamber 126. The gate seals 160 may be slightly recessed within corresponding annular grooves formed in a bottom surface of the distribution chamber 126 and a top surface of the gate guide plate 120.

[0039] A shallow flat channel 159 of a width at least slightly greater than the diameter of the gate seals 160 may be formed to extend radially from the center aperture within the top surface of the gate guide plate 120. A flat rectangular knife or gate valve 119, shown to best advantage in FIGS. 5A and 5B, may be positioned within the channel in the gate guide plate 120. The gate valve 119 is shown in a radially withdrawn, open position in FIG. 5A, such that there is an open passage between the center apertures defined within the gate plate 120 and the distribution chamber 126. In this position, the gate seals 160 press against each other to create a fluid tight seal about the central apertures.

[0040] In a closed state as depicted in FIG. 5B, the gate valve 119 is pushed radially inward such that the flat plate forming the gate valve 119 extends completely across the center apertures and is sealed between the gate seals 160 to fluidically separate the gate guide plate 120 and the linkage elements below it from the rest of the test chamber 106 above it. Closure of the gate valve 119 thus allows for easy maintenance of the drive motor 105 or the piston driver 114 (e.g., replacement of the flexible bellows diaphragm 115) without having to drain the test chamber 106.

[0041] As previously noted, the distribution chamber 126 is positioned on top of the gate guide plate 120. The distribution chamber 126 defines a much wider but shallow cavity with an interior bottom wall that slants radially inward until it reaches a common diameter with the aperture of the gate plate 120. In this embodiment, one or more resistive heaters 130 may be embedded within the bulk of the distribution chamber 126 underneath the fluid cavity defined by distribution chamber 126. In one embodiment a separate heater 138 may be located immediately beneath each sample holder 129 (as further described below) to aid in the uniformity of heat distribution within the fluid in the test chamber 106.

[0042] A distribution chamber manifold 153 is mounted to a top surface of the distribution chamber 126, for example, by bolting the two surfaces together about the perimeter. The distribution chamber manifold 153 may form a conical diverter surface 122 that extends downward into the cavity of the distribution chamber 126. A center bore 164 extends through the distribution chamber manifold 153, including through the diverter 122. This center bore forms part of a return flow path 128 as further described below. The distribution chamber manifold 153 may further define a plurality of bores 166 spaced about the perimeter of the distribution chamber manifold 153. In the embodiment shown in FIGS. 1 through 3, eight perimeter bores 166 are defined at a uniform radial distance from the center

and are equiangularly spaced apart. However, in alternative embodiments, there may be greater or fewer perimeter bores 166 and different or non-uniform spacing may be implemented if desired. A sample inlet tube 147 forming the bottom half of a sample holder 129 is connected within and seals against each of the perimeter bores 166 of the distribution chamber manifold 153.

[0043] Similarly, a lower conduit wall 124(2) of a telescoping center conduit 124 mounts within and seals against the center bore 164 in the distribution chamber manifold 153. A one-way valve 127 or similar check valve is positioned within the center bore 164 of the distribution chamber manifold 153 below the lower conduit wall 124(2) of the center conduit 124. The second half of the center conduit 124 is formed as a cylindrical upper conduit wall 124(1) with an inner diameter substantially the same as an outer diameter of the lower conduit wall 124(2) such that the center conduit 124 can be expanded or contracted in length. One or more center seals 161, for example, in the form of O-rings mounted within annular recesses in the outer surface of the lower conduit wall 121(2) provide a fluid tight seal interface with the interior surface of the upper conduit wall 124(1).

[0044] Each of the sample holders 129 is also composed of a sample outlet tube 148 that sits atop a respective sample inlet tube 147. The actual test sample 130 (e.g., a prosthetic device) may be sandwiched between the sample inlet tube 147 and sample outlet tube 148 to hold it in place within the test chamber 106. In other embodiments (not shown) each of the sample holders 129 may be an integral unit with a test sample 130 mounted within by any of a variety of means that may be specific to the nature of the particular test sample 130.

[0045] A return chamber manifold 154 is positioned atop each of the sample outlet tubes 148 and the upper conduit wall 124(1) of the center conduit 124. The return chamber manifold 154 defines corresponding perimeter bores 167 for mating with each of the sample outlet tubes 148 and a center aperture 165 for mating with the upper conduit wall 124(1) of the center conduit 124. Each of the interfaces between the sample outlet tubes 148 and the center conduit 124 with the return chamber manifold 154 is configured to provide a fluid tight seal between the components.

[0046] A return chamber 136 is mounted on top of the return chamber manifold 154 in a similar manner as the distribution chamber 126 is mounted to the distribution chamber manifold 153. The return chamber 136 defines one or more compliance chambers 135 which, in the embodiment of FIGS. 1-3, are composed of cavities associated respectively with each of the sample holders 129. As used herein, "compliance" refers to the ability of the cavities forming the compliance chambers 135 to absorb some of the pressure placed upon the fluid in the test chamber 106 and further to control recoil toward the original volume dimensions upon removal of the compressive force. The compliance chambers 135 assist in

minimizing the effects of large and quickly changing pressure gradients across test samples 130 placed within the test chamber 106. In some implementations, the compliance chambers 135 may merely contain air or another gas. The air or other gas may be indirect contact with the working fluid in the test chamber 106 or a membrane may be provided within the compliance chambers 135 to separate the air or gas from the working fluid. In other embodiments, the compliance chambers 135 may house a porous material or an elastomeric material. In each case, the purpose of the compliance chambers is to act as a resilient spring force to dampen the effects of large, quickly changing pressure gradients within the test chamber 106.

[0047] The return chamber 136 further defines separate return conduits 168 that are in fluid communication with respective pairs of the sample holders 129 and compliance chambers 135. A respective throttle valve 132 is housed within the return chamber 136 and placed between each respective return conduit 168 and a central return basin 133 that empties into the center return conduit 124. Each of the throttle valves 132 may be operably raised or lowered to restrict or enlarge the fluid flow passage between the return conduits 168 and the central return basin 133 and assist in the regulation of the pressure across the test samples 130 in the sample holders 129.

[0048] The return chamber 136 may also define a number of bores variously in communication with the return conduits 168, the compliance chambers 135, the central return basin 133. For example, system input bores 121 may be provided for relatively direct access to each of the sample holders 129 via the return conduits 168. The system input bores 121 may be used for a variety of purposes, for example, for the placement of sensing or diagnostic equipment or for access to the test samples 130 in the sample holders 129. In a particular example, when testing a valve design with removable valve leaflets, the system input 121 could be used to access the sample holder 129 and remove and replace the valve leaflets while leaving the permanent valve mounting structure in place within the sample holder 129. This obviates the need to disassemble the test chamber 106 for replacement of components of the test samples 130.

[0049] An access port 125 may also be associated with each of the compliance chambers 135. The access port 125 may be used for the attachment and introduction of sensing equipment or for providing additional air or gas pressurization to the compliance chambers 135. Additional sensors may further be placed in access ports positioned for communication with the central return basin 133. For example, as shown in FIG. 3, a temperature transducer 139 and a water level sensor 144 may be placed in communication with the central return basin 133. It should be understood that any number of other sensor devices could also be placed in contact with or introduced within the test chamber 106 by any of the various apertures, bores, or ports provided within the return chamber 136.

[0050] The various sensors of the fatigue testing system 100 may be operably connected to a data acquisition (DAQ) device 141. An amplifier and control system 140 may also be connected with the drive motor 105 to provide output control of the same. In some embodiments, the DAQ device 141 and amplifier/control system 140 may be mounted within the base frame 157. An air source 131 connected in line with a pressure regulator 134 may also be under control of the control system 140. These components are, in turn, either directly or indirectly operably connected to a microprocessor-based computer 142. All systems may also be connected to an uninterrupted power supply (UPS) 143.

[0051] Software provided on the computer 142 can direct the system controller 140 to provide full closed-loop control based on feedback measurements received from the DAQ device 141 coupled with the sensors. In one example of this functionality, software may be configured to control the driving amplitude and velocity of the drive motor 105 based upon differential pressure transducer feedback. The system 100 may therefore compensate for any changes during the high cycle testing cycle providing the test samples 130 with the most optimal testing conditions. An automated test interface may be provided as part of the fatigue testing system 100 to run the test chamber 106 without direct management, ensuring proper testing conditions and safety mechanisms. The test interface may be configured to provide closed-loop control based off any system measurement feedback.

[0052] An implementation of operation of the exemplary fatigue testing system 100 of FIGS. 1-5B may be understood as follows. Initially, test samples 130 need to be placed within the test chamber 106. In order to introduce test samples 130, the sample holders 129 must be accessed. The adjustment nuts 146 on the top of the return chamber 136 may be rotated to raise the adjustment posts 145 from their tightened positions within the distribution chamber manifold 153 and distribution chamber 126. Once the return chamber 136 and return chamber manifold 154 are raised, the sample holders 129 may be removed and replaced with alternate sample holders or, as shown in this embodiment, samples positioned between sample inlet to 147 and sample outlet to 148, may be removed and replaced with new samples 130. The adjustment nuts 146 may then be tightened to lower the return chamber 136 and return chamber manifold 154 back into contact with the sample holders 129 to create fluid-tight flow path through each of the sample holders 129 between the distribution chamber 126 and the return chamber 136. Note that when the return chamber 136 and return chamber manifold 154 are raised, the center conduit 124 telescopes upward with the upper conduit wall 124(2) sliding along the exterior of the lower conduit wall 124(1), thus maintaining a fluid-tight connection within a center conduit 124.

[0053] In many applications, it may be desirable to monitor the pressure gradient across the sample holder 129. For such purposes, a conduit with a sensing device, for example, a pressure transducer, may be placed in a conduit that is attached at one end to a monitor

outlet port 149 in the sample inlet tubes 147 and a monitor inlet port 150 on the sample outlet tubes 148. In an alternative implementation, individual sensors (e.g., pressure transducers) may be attached directly to each of the monitor outlet ports 149 and monitor inlet ports 150 to measure absolute pressure at each of these locations. The absolute pressure data may be collected by the data acquisition component 141 and transferred to the computing device 142 for calculation of the pressure differential by taking the difference between the absolute pressure values on either end of the sample holders 129.

[0054] Presuming that the correct size of cylinder 113 and corresponding drive adaptor 117 are already attached, the fatigue testing system 100 may be charged with the desired type and amount of working fluid through any one of the inflow ports 143 in the plenum 118. The working fluid may be water, saline, a saline/glycerin solution, a glycerin/water solution, a blood analog or substitute, or other type of fluid. In some embodiments, the working fluid may be selected to simulate one or more attributes of human blood, such as density, viscosity or temperature. For example, in certain instances, physiological saline which does not simulate the viscosity of blood, but simulates density, may be used. In other cases saline/glycerin solution may be employed to simulate blood viscosity.

[0055] Depending upon the particular test samples 130 and desired testing conditions and dynamics, the fatigue system 100 may be filled with fluid up to an appropriate or desired level in the compliance chambers 135. Once fluid has been filled to a desired level, in some scenarios, the fatigue testing system 100 may be additionally pressurized with air or another gas via an air source 131, e.g., an air compressor or sealed pressurized volume, connected to the air inlet 152 in the return chamber 136 or via the compliance access ports 125 in the compliance chambers 135. In some embodiments, a pressure regulator 134 may be interposed between the air source 131 and the air inlet 152 to regulate the pressure within the test chamber 106. Alternatively, the system 100 can be pressurized by first sealing the system 100 and then changing the position of the fluid driving piston 114 such that the available volume is decreased.

[0056] The working fluid temperature is controlled via the fluid heaters 138 and the temperature transducer 139. Upper and lower temperature bounds may be set in the test software. At startup the system 100 will begin to heat until the upper bound is reached. As the input temperature falls below the lower bound, the heaters 138 are again activated, thus maintaining a mean temperature within acceptable bounds. This mean temperature is typically set to 37° C to simulate physiologic conditions.

[0057] Once the system is filled with fluid, heated, and properly pressurized, testing operations under control of the computer 142 may be initiated. The computer 142 may control the operations of the linear drive motor 105 to move the piston 114 and thus the

diaphragm 115 up and down within the cylinder 113 and drive it after 117 to cyclically increase and decrease the pressure within the test chamber 106. Under computer control and depending upon the size of the cylinder 113, the linear drive motor 105 may cause the thrust rod 108 and the attached upper shaft extension 112 to move up and down thereby moving the cylinder 113 and diaphragm 115 up and down to create a displacement of any size, small or large, to change the pressure within the test chamber 106. The rolling or eversion of the diaphragm 115 exerts very little resistance to piston 14 movement. Thus, power requirements on the linear drive motor 105 are small and current draw is minimized.

[0058] Fluid flow 110 through the test chamber 106 is indicated by the dashed lines initiating at the drive adaptor 117 traveling through the plenum 118 and then through the sample holders 129 to exit through the return conduit 168, the central return chamber 133, and the center conduit 124. Fluid flow can be prevented from moving upward in the center conduit 124 by the one-way valve 127 housed within the distribution chamber manifold 153. The conical diverter 122 helps direct fluid flow from the piston 114 regularly and uniformly to each of the sample holders 129 about the perimeter of the test chamber 106.

[0059] The compliance chambers 135 provide excess volume area for fluid to move into when the piston 114 performs a compression stroke. As the pressure of the gas in the compliance chamber 135 increases, the volume occupied by the gas decreases to provide additional volume for displacement of the liquid working fluid within the test chamber 106. The throttle valves 132 restrict the rate of return flow of fluid within the test chamber 106 into the central return basin 133. The combination of the compliance chambers 135 and the throttle valves 132 help control undesirable pressure loading or pressure spikes within the sample holder 129 and consequent adverse effects on the test samples 130 when the piston 114 moves in a decompression stroke. The compliance chambers 135 and the throttle valves 132 also generally help tune the test conditions across the sample holder 129. In addition to selecting the piston size, the displacement range, frequency, and waveform settings, the system equilibrium pressure, and other settings, the compliance chambers 135 and the throttle valves 132 may be adjusted as an additional aid in fine-tuning appropriate differential pressure across the test samples 130 in the sample holder 129.

[0060] As the piston 114 moves downward in decompression stroke, pressure on the one-way valve 127 is released and fluid flow through the center conduit 124 is initiated at a controlled rate depending upon the position of the throttle valves 132. In this way, on the downward stroke, the pressure in the test chamber 106 returns to an initial level and excess volume returns to the compliance chambers 135. It should be noted that the compliance chambers 135 may be configured in a variety of different ways. In addition to merely containing a volume of air or other gas to act as an air spring, a membrane could be provided between the liquid and the air or other gas or alternatively the space could be filled

with a porous foam or other elastomeric material, thereby reducing or otherwise adjusting the spring factor provided by the compliance chamber 135.

[0061] The dynamics of the system 100 can be controlled through the stroke pattern, frequency, and volume of the piston 114, the flow setting of the throttle valves 132, and the spring force of the compliance chambers 135. Additionally, the working fluid in the test chamber 106 may be preset to a base or ambient pressure using a separate pressure source. For example, an air/gas source 131 (e.g., and air compressor or gas tank) may be connected to and pressurize a fluid reservoir (not shown) in fluid contact with the working fluid in the test chamber 106. A pressure regulator 134 may be positioned between the air source 131 and the introduction into the test chamber 106 for controlling the desired system pressure. Alternatively, a pressurized gas may be introduced directly into the compliance chambers 135 through access ports 125, into the central return basin 133 through inlet 152, or through any other port (e.g., one of the sidewall ports 143 in the plenum 118) for charging the test chamber to an appropriate base pressure for proper function of the system 100 for the particular test configuration.

[0062] An alternate embodiment of a test chamber 206 for a fatigue testing system 200 is shown in FIG. 6. The test chamber 206 consists generally of a lower chamber composed of a distribution chamber 226, a flow conditioning chamber 272, and a manifold 253, and an upper chamber composed of a return chamber 236, a manifold 254 and a central compliance chamber 235. A fluid flow pathway 210 extends from the lower chamber to the upper chamber which passes through a plurality of sample holders 229 holding the device samples 230 being tested and a return fluid flow pathway 228 extends from the upper chamber to the lower chamber to return fluid from the upper chamber to the lower chamber in preparation for a following cycle. A check valve 227 is inline with the return fluid flow pathway 228 between the upper and lower chambers to regulate back flow through the test chamber 206. A controllable central throttle valve 232 is also in-line with the upper and lower chambers to regulate the differential pressure across the test samples 230 during operation.

[0063] The fluid drive member, i.e., the piston 214, is provided within the cylinder 213 to pressurize and drive the working fluid upward through the drive adapter 217 and the plenum 218. The piston 214 is mounted on the shaft extension 212 extending through the bearing 262 from the thrust rod of the linear motor (not shown). The flexible diaphragm is mounted on the piston 214 as in the prior embodiment and held in place by a cap 216. The diaphragm 15 is preferably a cap-like member constructed of a non-reactive and flexible thin rubber, polymeric or synthetic based material. The lateral surfaces of diaphragm 215 roll or evert as the piston 214 reciprocates within the cylinder 213 and drive adapter 217 between which the circumferential flange of the diaphragm is sealed. These components are affixed

to the support plenum 218 and maintain the pressure seal along the circumference of the diaphragm 215. The plenum 218 serves as a mounting point for the drive system. The plenum 218 may also include fluid ports for pressure monitoring and system draining.

[0064] During the primary or pressurization portion of a test cycle, the piston 214 moves in a positive direction toward the test chamber 206 and creates an initial pressurization and the working fluid flows up through the base plate 211 into the distribution chamber 226. The working fluid impinges upon a generally conical flow baffle 222 and is directed radially outward to flow straighteners 271. The fluid is blocked from entering the central return conduit 224 by a one-way exit valve 227. The working fluid then passes from the distribution chamber 226 and into a flow conditioning chamber 272, wherein it passes through a flow straighteners 271, aligning the flow along the axis of the sample holders 229. Sample adapters 247, 248 attach the sample holders 229 to the distribution manifold 253 and the return manifold 255, allowing the sample holders 229 to be connected to the test chamber 206 in a leak free manner.

[0065] A collateral pressure-sensing conduit 269 may be coupled to the sample holder 229 and direct a fluid flow pathway toward a pressure transducer 270 that serves to monitor the differential pressure gradient across the test sample 330 within the sample holder 229. The differential pressure transducers 270 monitor the pressure field across each test sample 230 in the sample holders 229 during the testing cycle. Flexible or rigid tubing 269 is connected to the upper and lower sample adapters 247, 248, with the opposite ends of the conduit 269 being connected to the differential pressure transducer 270. Additional monitoring transducers can be introduced through the sensor ports 221 and other ports built into the return chamber 236 as necessary.

[0066] Once the fluid flow has exited the sample holders 229 it flows into the return manifold 254 and return chamber 236. The working fluid passes around a throttle valve 232 and a return fluid flow is communicated through return conduit 224 to the lower chamber during a secondary or depressurization portion of the test, thus completing the first portion of the test cycle. The throttle valve 232 is connected to the throttle valve handle 232a, which runs through a fluid-tight fitting on top of compliance chamber cap 221. The throttle valve handle 232a is adjustable, such as by a threaded coupling to the cap 221 on the compliance chamber 235. The throttle valve 232 can be adjusted up or down, increasing or decreasing the resistance to fluid returning to the central return conduit 224 to aid in controlling the differential pressure across the test sample 230. The amount of gas or the elasticity of the elastomeric material inside the compliance chamber 35 allows the user to control the damping of the system and provides an additional tool calibrate the ideal test conditions for the particular prosthetic device. In the embodiment of FIG. 6, a single compliance chamber 235 is axially centered over the test chamber 206 and provides a compliance

volume for all of the sample holders 230 in the test chamber 235. Similarly, in this embodiment only a single throttle valve 232 is provided to control the return flow of the working fluid through the center return conduit 224.

[0067] Figure 7 provides examples of three different pressure control signals generating three different cyclical pressure waveforms 300 across a prosthetic device being tested. Because of the vertical orientation of the displacement components, the term "upstroke" is synonymous with a pressurization stroke of the piston, i.e., that which exerts a positive pressure across the prosthetic device being tested and the term "down stroke" is synonymous with a depressurization stroke of the pump, i.e., that which exerts a negative pressure across the prosthetic device being tested. Typical test systems are only capable of driving the fluid with a regular sine wave 306. A non-regular pressure waveform may be desirable for testing of certain devices as it allows the user to control the rate of pressurization in the test system and optimize the test conditions, while maintaining a desired operating frequency. Two exemplary non-regular waveforms having short upstrokes 308 and down strokes 310, respectively, are illustrated in FIG. 7. However, any arbitrary pressure waveform may be generated and can be utilized to drive the motor and thereby the piston.

[0068] During the primary or pressurization portion of the testing cycle, i.e., that portion of the waveforms 302 having positive stroke percentage values, fluid is moved past the prosthesis within the housing tube. In an exemplary implementation in which valve prostheses are tested, the positive upstroke forces the valve prosthesis to the open state. During a secondary or depressurization portion of the test cycle, i.e., that portion of waveforms 304 having negative stroke percentage values, the flow is reversed and the valve prostheses 30 are closed. As the secondary portion of the cycle begins, the fluid moves through the throttle valves into the central return conduit and back into the distribution chamber through the one-way valve. During return flow, the valve prosthesis remains closed due to the flow reversal and differential pressure present between the distribution chamber and the return chamber. The drive system returns to its starting position and the process is repeated, cycling the prosthetic devices. A single test cycle consists of completion of both the primary portion 302 and secondary portion 304 of the test cycle such that the prosthetic device passes through one open and-closed cycle.

[0069] The exemplary pressure waveforms 306, 308, 310 depicted in FIG. 7 may be generated by the fatigue testing system or by other mechanical mechanisms. It is envisioned that alternative mechanical or electromechanical systems, such as those including gearing or cams to drive a pump, may be employed in a manner that generates the variable pressure waveforms as depicted in FIG. 7, in which the pressure gradients are variable over time.

[0070] As indicated above, the proposed technology may be integrated with system monitoring and controlling software. The computer software can be used to record and analyze data while controlling the dynamics of the system, as outlined in the exemplary process 400 shown FIG. 8. Data is first obtained by system hardware 402, i.e., the system sensors 406, and then processed through data acquisition hardware 408 and transmitted to the system computer for processing and formatting for presentation by the system software 404.

[0071] All system inputs and outputs may be continuously monitored and directed into software-based control and alarm system modules, allowing the system to automatically reconfigure or halt if any signal deviates outside of the user set bounds. The real-time data stream may be utilized for three primary purposes: data logging and graphing, alarm condition indication, and test system control. The data logging and plotting subroutine 410 generates graphs and plots of pertinent signals while also creating a data file to allow for test documentation and off-line analysis.

[0072] The alarm condition subroutine 412 analyzes data to determine if any of the test inputs or control signals have deviated outside of user defined alarm magnitudes. If an alarm is triggered, i.e. an alarm parameters exceeds its bounds as determined in operation 414, an alarm sequence is initiated as indicated in operation 416. This sequence could trigger a number of events. In one sequence, the software may halt the test system in a specific manner; in another alarm sequence, the test software may notify the operator; in yet another alarm sequence, the system may be halted and the user notified. As can be appreciated, there are a number of actions that are available as part of an alarm sequence and these sequence steps could be dependent on a number of parameters including the specific test samples and/or the specific test protocol.

[0073] The control loop subroutine 418 further monitors the control parameters based on a user defined target input signals and/or parameters. Exemplary user set parameters may include pressure input parameters 428 and motor drive waveform parameters 430. Each of these parameters may be set as static or variable. If the control loop determines that the real-time sensor data received is outside the bounds of the user parameters as determined in operation 420, then the software adjusts the input control parameters provided to the hardware control systems as indicated in operation 422. As one example, test system pressure may be set as the control parameter; therefore, the software will continually adjust the dynamics of the pressure regulator 424 to maintain the desired pressure. In another example, the displacement of the driver may be the control parameter; therefore, the software will continually adjust the system dynamics for the motor control 426 to maintain the desired displacement. Again, as one can appreciate, the closed-loop control of the test system can be applied to myriad parameters.

[0074] FIG. 9 illustrates an exemplary computer system 500 configured as part of the fatigue testing system as described herein. In one implementation, the computer system 500 typically includes at least one processing unit 502 and memory 504. Depending upon the exact configuration and type of the computer system 500, the memory 504 may be volatile (e.g., RAM), non-volatile (e.g., ROM and flash memory), or some combination of both. The most basic configuration of the computer system 500 need include only the processing unit 502 and the memory 504 as indicated by the dashed line 506.

[0075] The computer system 500 may further include additional devices for memory storage or retrieval. These devices may be removable storage devices 508 or non-removable storage devices 510, for example, memory cards, magnetic disk drives, magnetic tape drives, and optical drives for memory storage and retrieval on magnetic and optical media. Storage media may include volatile and nonvolatile media, both removable and non-removable, and may be provided in any of a number of configurations, for example, RAM, ROM, EEPROM, flash memory, CD-ROM, DVD, or other optical storage medium, magnetic cassettes, magnetic tape, magnetic disk, or other magnetic storage device, or any other memory technology or medium that can be used to store data and can be accessed by the processing unit 502. Alarm monitoring, data acquisition, and closed loop control software modules may be stored on the storage device for execution by the processing unit 502 using any method or technology for storage of data, for example, computer readable instructions, data structures, and program modules.

[0076] The computer system 500 may also have one or more communication interfaces 512 that allow the system 500 to communicate with other devices. The communication interface 512 may be connected with a network. The network may be a local area network (LAN), a wide area network (WAN), a telephony network, a cable network, an optical network, the Internet, a direct wired connection, a wireless network, e.g., radio frequency, infrared, microwave, or acoustic, or other networks enabling the transfer of data between devices. Data is generally transmitted to and from the communication interface 512 over the network via a modulated data signal, e.g., a carrier wave or other transport medium. A modulated data signal is an electromagnetic signal with characteristics that can be set or changed in such a manner as to encode data within the signal.

[0077] The computer system 500 may further have a variety of input devices 514 and output devices 516. Exemplary input devices 514 may include sensors, a keyboard, a mouse, a tablet, and/or a touch screen device. Exemplary output devices 516 may include a display and speakers. Such input devices 514 and output devices 516 may be integrated with the computer system 500 or they may be connected to the computer system 500 via wires or wirelessly, e.g., via IEEE 802.11 or Bluetooth protocol. These integrated or peripheral input and output devices are generally well known and are not further discussed

herein. Other functions, for example, handling network communication transactions, may be performed by an operating system in the nonvolatile memory 504 of the computer system 500.

[0078] The technology described herein may be implemented as logical operations and/or modules in one or more systems. The logical operations may be implemented as a sequence of processor-implemented steps executing in one or more computer systems and as interconnected machine or circuit modules within one or more computer systems. Likewise, the descriptions of various component modules may be provided in terms of operations executed or effected by the modules. The resulting implementation is a matter of choice, dependent on the performance requirements of the underlying system implementing the described technology. Accordingly, the logical operations making up the embodiments of the technology described herein are referred to variously as operations, steps, objects, or modules. Furthermore, it should be understood that logical operations may be performed in any order, unless explicitly claimed otherwise or a specific order is inherently necessitated by the claim language.

[0079] In some implementations, articles of manufacture are provided as computer program products that cause the instantiation of operations on a computer system to implement the invention. One implementation of a computer program product provides a computer program storage medium readable by a computer system and encoding a computer program. It should further be understood that the described technology may be employed in special purpose devices independent of a personal computer.

[0080] All directional references (e.g., proximal, distal, upper, lower, upward, downward, left, right, lateral, longitudinal, front, back, top, bottom, above, below, vertical, horizontal, radial, axial, clockwise, and counterclockwise) are only used for identification purposes to aid the reader's understanding of the present invention, and do not create limitations, particularly as to the position, orientation, or use of the invention. Connection references (e.g., attached, coupled, connected, and joined) are to be construed broadly and may include intermediate members between a collection of elements and relative movement between elements unless otherwise indicated. As such, connection references do not necessarily infer that two elements are directly connected and in fixed relation to each other. The exemplary drawings are for purposes of illustration only and the dimensions, positions, order and relative sizes reflected in the drawings attached hereto may vary.

[0081] The above specification, examples and data provide a complete description of the structure and use of exemplary embodiments of the invention. Although various embodiments of the invention have been described above with a certain degree of particularity, or with reference to one or more individual embodiments, those skilled in the art could make numerous alterations to the disclosed embodiments without departing from the

spirit or scope of this invention. Other embodiments are therefore contemplated. It is intended that all matter contained in the above description and shown in the accompanying drawings shall be interpreted as illustrative only of particular embodiments and not limiting. Changes in detail or structure may be made without departing from the basic elements of the invention as defined in the following claims.

CLAIMS

What is claimed is

1. A device for simultaneous cyclic testing of a plurality of prosthetic devices comprising
a pressurizable test chamber further comprising
a fluid distribution chamber having a first manifold defining a first plurality of ports configured to receive and fluidicly couple with a first end of each of a respective plurality of sample holders and defining an aperture in a lower face in fluid communication with a pressure source;
a fluid return chamber having a second manifold disposed opposite and spaced apart from the first manifold of the fluid distribution chamber and defining a second plurality of ports configured to receive and fluidicly couple with a second end of each of the respective plurality of sample holders;
a fluid return conduit both structurally and fluidly connecting the fluid distribution chamber to the fluid return chamber; and
a compliance chamber providing a volume for holding a gas or elastomeric material that compresses under a pressure placed upon fluid in the test chamber and allows fluid in the test chamber to occupy a portion of the volume;
a drive motor configured to operate cyclically, acyclically, or a combination of both ;
and
a fluid displacement member connected with and driven by the drive motor to provide the pressure source that increases and decreases a pressure on fluid in the test chamber; whereby cyclic and acyclic fluid pressures are maintained throughout the test chamber.
2. The device of claim 1 further comprising a plurality of sample holders, each configured to hold a respective prosthetic device, mounted between the first manifold of the fluid distribution chamber and second manifold of the fluid return chamber, and mounted within a respective pair of the first plurality of ports and the second plurality of ports, whereby the prosthetic device is placed in fluid communication with the distribution fluid chamber and the return fluid chamber.
3. The device of claim 1, wherein
the compliance chamber comprises a plurality of compliance chambers formed as cavities within the fluid return chamber; and
a respective one of the plurality of compliance chambers is positioned substantially above each of the second plurality of ports and between each of the second plurality of ports and the fluid return conduit.

4. The device of claim 1, wherein each of the sample holders defines a first port on a first side of a test sample position and a second port on a second side of the test sample position; wherein the first port and the second port are configured to receive one or more sensor devices.

5. The device of claim 4 further comprising a pressure transducer in fluid communication with the first port and the second port in one of the sample holders configured to measure a pressure gradient across a test sample positioned within the one of the sample holders.

6. The device of claim 1 further comprising a one-way valve positioned within the fluid return conduit that prevents fluid flow through the fluid return conduit when the fluid displacement member increases pressure on fluid in the test chamber.

7. The device of claim 1, wherein the fluid return conduit is positioned along an axial center of the test chamber.

8. The device of claim 1, wherein the fluid return conduit further comprises an inner conduit wall having an outer diameter and attached to one of the fluid distribution chamber or the fluid return chamber;

an outer conduit wall having an inner diameter larger than the outer diameter of the inner conduit and attached to the other of the fluid distribution chamber or the fluid return chamber, wherein the inner conduit wall is received within the outer conduit wall; and

a seal member positioned between the inner conduit wall and the outer conduit wall to create a fluid-tight seal therebetween; wherein

the fluid return conduit is configured to telescopically lengthen or shorten.

9. The device of claim 8 further comprising a plurality of adjustment posts positioned between the fluid distribution chamber and the fluid return chamber and operable to adjust a separation distance between the fluid distribution chamber and the fluid return chamber.

10. The device of claim 1 further comprising a computer control system connected with the drive motor and a sensor positioned within the test chamber, wherein the computer control system is configured to operate one or more of the following:

an alarm module for alerting a user or arresting operation of the device upon receipt of data from the sensor that is outside a preset parameter; or

a closed loop feedback module for adjusting operation of the drive motor upon

receipt of data from the sensor to maintain a pressure profile within the test chamber according to a preset parameter.

11. The device of claim 1 further comprising
a heater positioned in the test chamber for heating fluid within the test chamber; and
a temperature sensor positioned within the test chamber to measure temperature of fluid within the test chamber.

12. The device of claim 1, wherein the fluid displacement member comprises a flexible diaphragm.

13. The device of claim 1, wherein the drive motor comprises a linear motor.

14. The device of claim 13 further comprising
a mounting structure connected to and supporting the linear motor in a vertically mounted position; and
a spring supported by the mounting structure, and interfacing with an end of a shaft of the linear motor extending from a lower end of the linear motor, wherein
the spring prevents the shaft from dropping downward from the linear motor when the linear motor is in an unpowered state.

15. The device of claim 1, wherein the fluid displacement member further comprises a flexible rolling bellows connected to a shaft of the linear motor.

16. The device of claim 15 further comprising
a drive adapter coupled to the either directly or indirectly to the distribution chamber and in fluid communication with the aperture in the lower face of the fluid distribution chamber, wherein

the drive adaptor defines an aperture with an upper diameter congruent with a diameter of the aperture in the lower face of the fluid distribution chamber;

the rolling bellows is further attached to a piston connected to the shaft of the linear motor and the piston moves axially within a cylinder;

the cylinder defines an opening of a diameter that is substantially the same as a diameter of an end wall of the rolling bellows;

the cylinder is coupled to the drive adapter and a circumferential flange of the rolling bellows is held therebetween; and

the aperture defined in the drive adaptor has a lower diameter congruent with the diameter of the opening in the cylinder.

17. A test chamber for cyclic testing of a prosthetic device in a variable pressurized environment comprising

- a fluid distribution chamber having a first manifold defining a first port configured to receive and fluidically couple with a first end of a sample holder and a lower face defining an aperture for communicating with a fluid pressure source;
- a fluid return chamber having a second manifold disposed opposite and spaced apart from the first manifold of the fluid distribution chamber and defining a second port configured to receive and fluidically couple with a second end of the sample holder;
- a fluid return conduit both structurally and fluidly connecting the fluid distribution chamber to the fluid return chamber; and
- a compliance chamber providing a volume for holding a gas or elastomeric material that compresses under a pressure placed upon fluid in the test chamber and allows fluid in the test chamber to occupy a portion of the volume.

18. The test chamber of claim 17, wherein the compliance chamber is defined as a cavity within the fluid return chamber.

19. The test chamber of claim 18, wherein the fluid return chamber defines a port providing fluid communication between an outer surface of the fluid return chamber and the cavity forming the compliance chamber.

20. The test chamber of claim 17 further comprising a sample holder configured to hold a prosthetic device, mounted between the first manifold of the fluid distribution chamber and second manifold of the fluid return chamber, and mounted within the first port and the second port, whereby the prosthetic device is placed in fluid communication with the distribution fluid chamber and the return fluid chamber.

21. The device of claim 20, wherein the sample holder defines a first port on a first side of a test sample position and a second port on a second side of the test sample position; wherein the first port and the second port are configured to receive one or more sensor devices.

22. The device of claim 17, further comprising a porous material at least partially filling the compliance chamber.

23. The device of claim 17, further comprising an elastomeric membrane separating at least a portion of the compliance chamber from fluid in the fluid return chamber.

24. The device of claim 17, wherein the compliance chamber is positioned substantially above the second port and between the second port and the fluid return conduit.

25. A pressurization system for a fluid test chamber for cyclic pressure testing of a of a prosthetic device comprising
a linear drive motor that displaces a shaft in an axial direction;
a flexible diaphragm connected with and driven axially by the shaft of the linear motor that cyclically increases and decreases a pressure on a fluid in the fluid test chamber;
wherein active control of the linear drive motor provides an ability to create small and large fluid displacements with consequent variable effect of a fluid pressure of the fluid in the fluid test chamber.

26. The system of claim 25, wherein the flexible diaphragm further comprises an elastomeric rolling bellows connected to a shaft of the linear motor.

27. The system of claim 25, further comprising
a cylinder that defines an opening of a diameter that is substantially the same as a diameter of an end wall of the rolling bellows; and
a piston connected to the shaft of the linear motor, wherein
the end wall of the rolling bellows is attached to the piston;
the piston and the end wall of the rolling bellows move axially within the cylinder to create the fluid displacements.

28. A computer-readable medium having computer-executable instructions for performing a computer process implementing a fatigue testing system for cyclic testing of a plurality of prosthetic devices, the instructions comprising causing the computer to
receive sensor data from one more sensors placed in a pressurizable fluid test chamber of the fatigue testing system;
determine whether the sensor data is within a preset control boundary;
if so, return to the receive operation;
if not, adjust control parameters for controlling a linear motor driving an elastomeric rolling bellows that cyclically changes the pressure in the pressurizable fluid test chamber;
and
transmit an adjusted control signal based upon the adjusted control parameters to adjust operation of the linear motor.

29. The computer-readable medium of claim 28, further comprising instructions for causing the computer to

- determine whether the sensor data is within a preset alarm boundary;
- initiate an alarm function if the sensor data falls outside the preset alarm boundary;

and

- output an alarm indicator for perception by a user; transmit an alarm control signal to override a standard control signal to the linear motor, or both.

30. The computer-readable medium of claim 28, further comprising instructions for causing the computer to

- store the sensor data;
- receive user input regarding parameters for data logging, data graphing, or both;
- create data presentation incorporating a data log, a data graph, or both in accordance with the parameters; and
- output the presentation for perception by a user.

31. The computer-readable medium of claim 28, wherein the sensor data comprises one or more of the following types of data: single point pressure data, differential pressure data, fluid temperature data, fluid level data; fluid viscosity data, fluid turbulence data, pressure cycle data, or motor cycle data.

ABSTRACT

A fatigue testing system provides simultaneous cycle testing for a plurality of prosthetic devices under simulated physiological loading conditions. A plurality of sample holders containing test samples of prosthetic devices is positioned between a distribution chamber and a return fluid chamber to form an integrated test chamber. A reciprocating linear drive motor operates a rolling bellows diaphragm to cyclically pressurize fluid within the test chamber and drive the pressurized fluid through the prosthetic devices being tested. The test chamber defines a return flow conduit in fluid communication with each of the sample holders, the return fluid chamber, and the distribution chamber. Compliance chambers and throttle valves associated with each of the sample holders regulate the pressure gradient and back pressure across the prosthetic devices being tested.



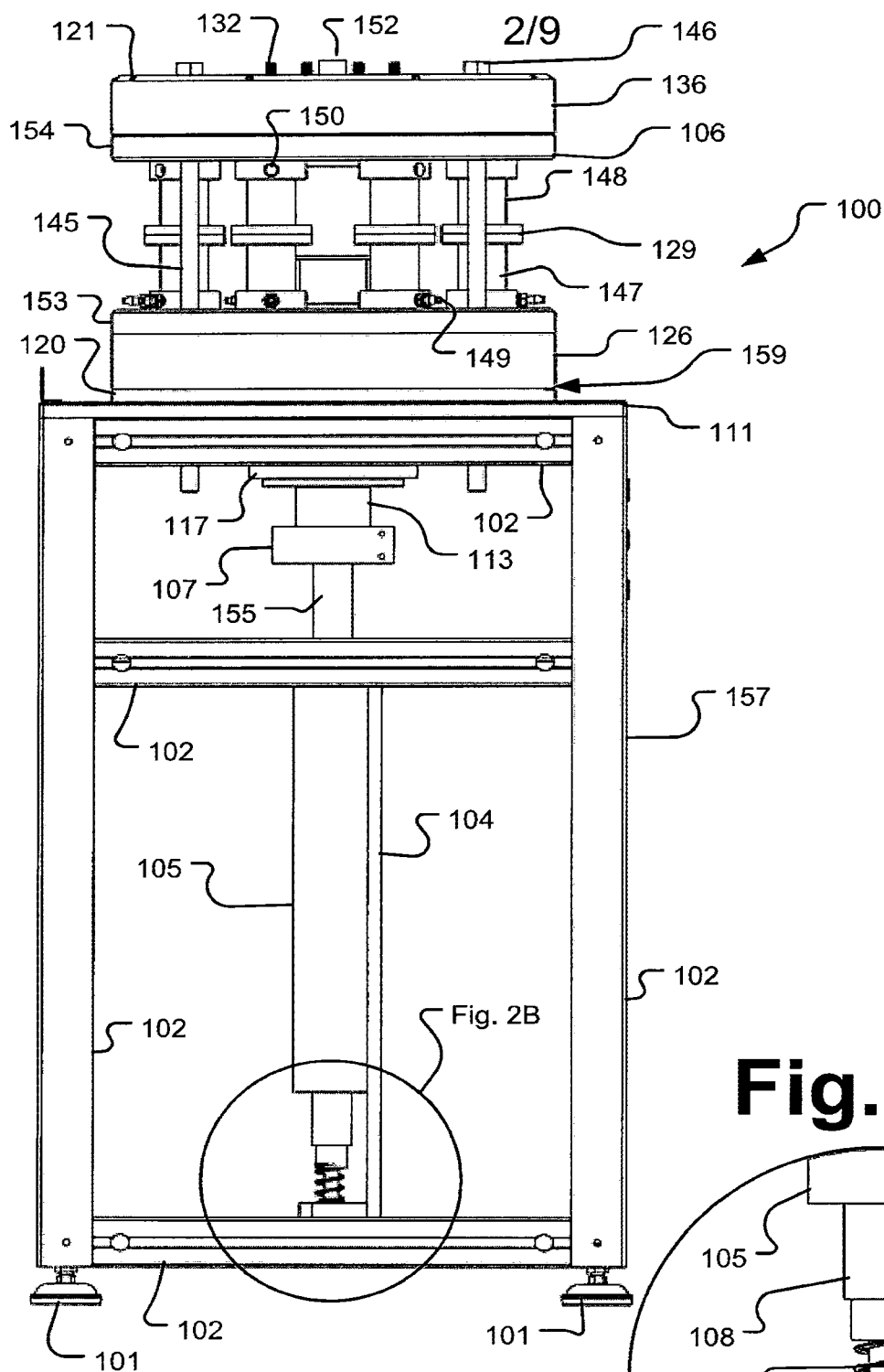
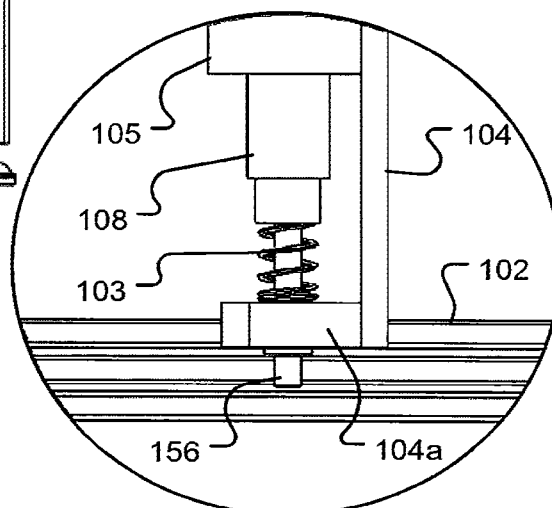


Fig. 2A

Fig. 2B



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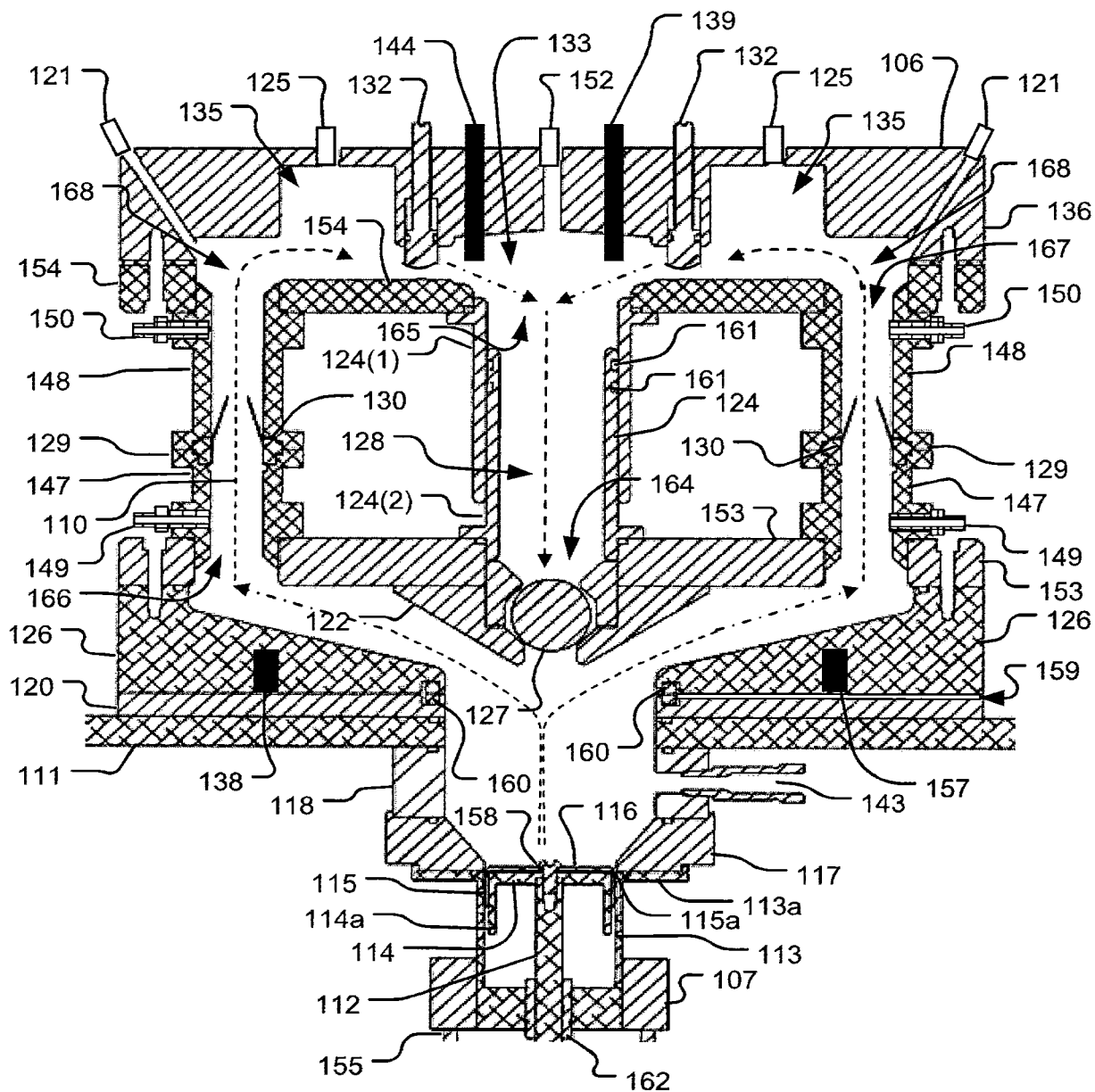


Fig. 3

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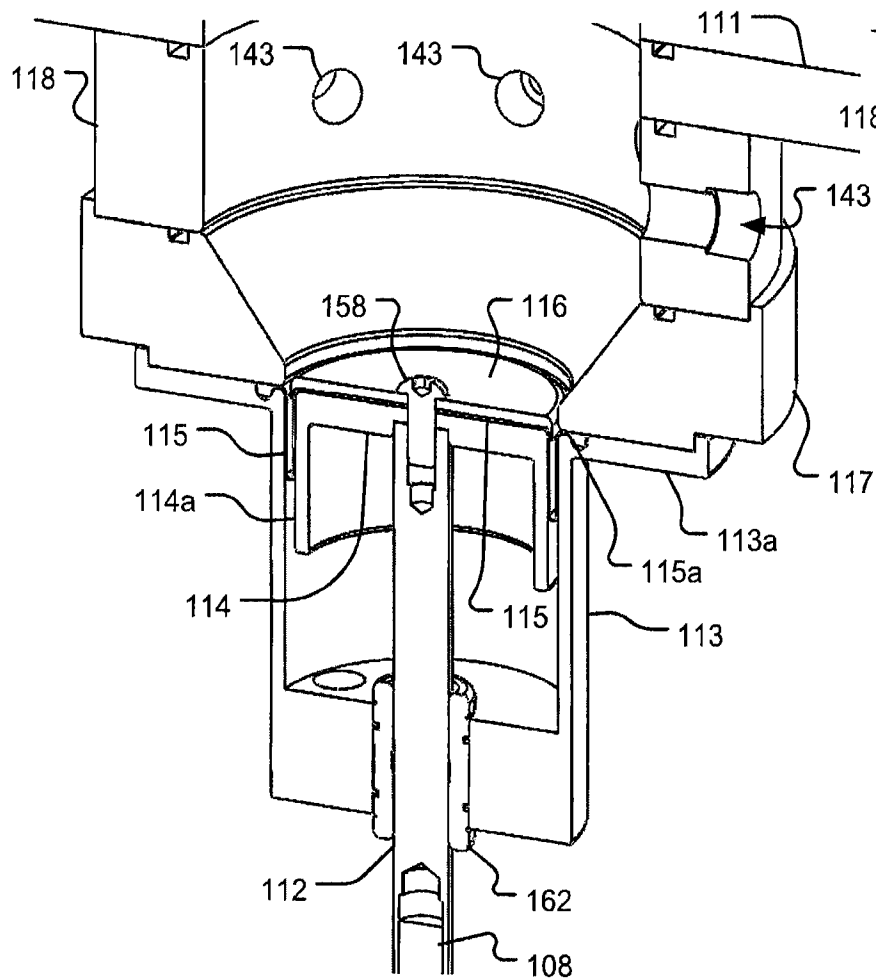


Fig. 4A

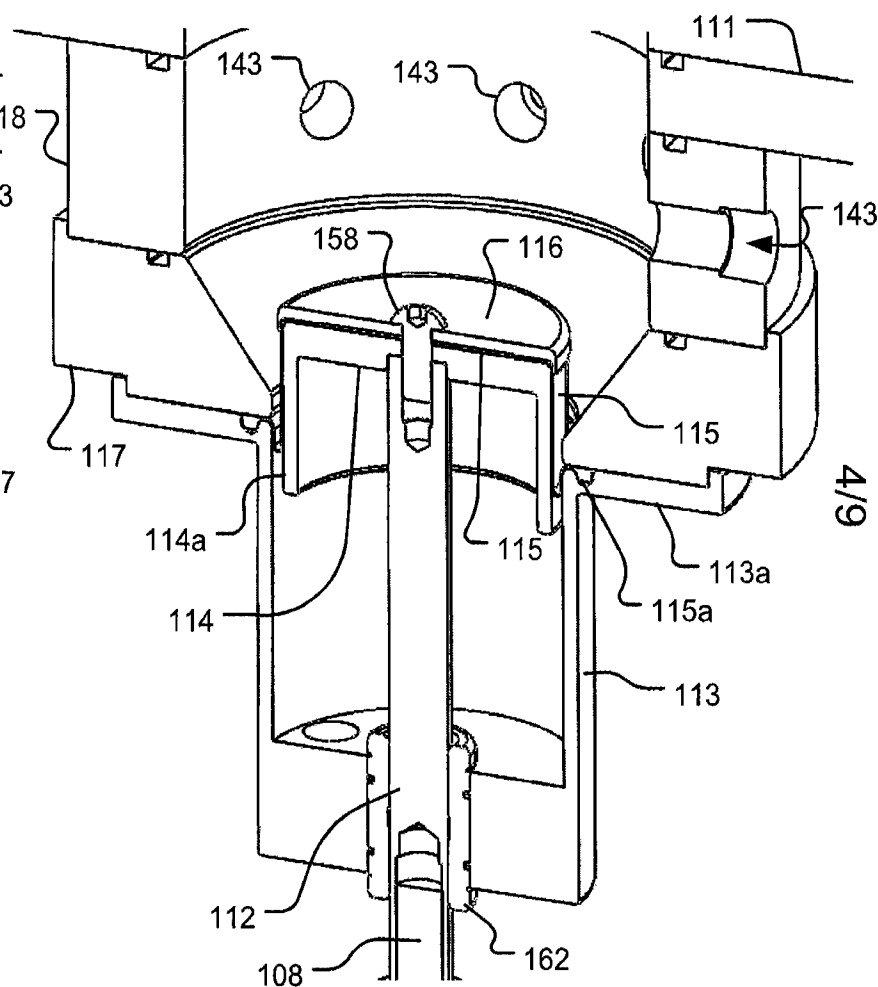
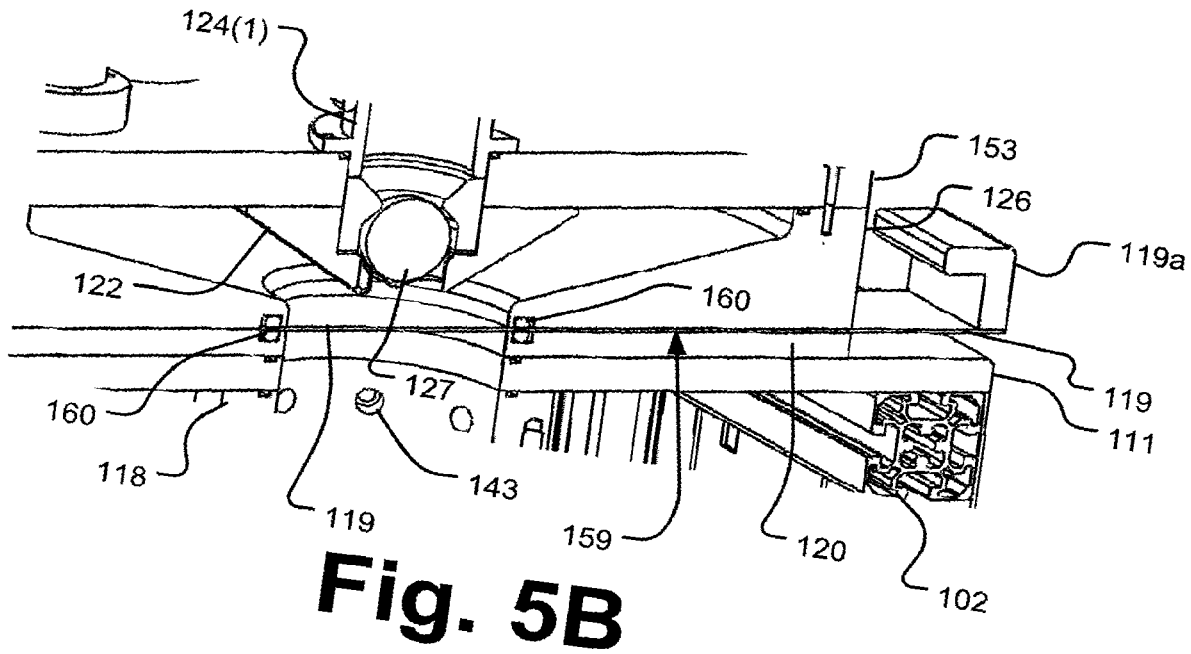
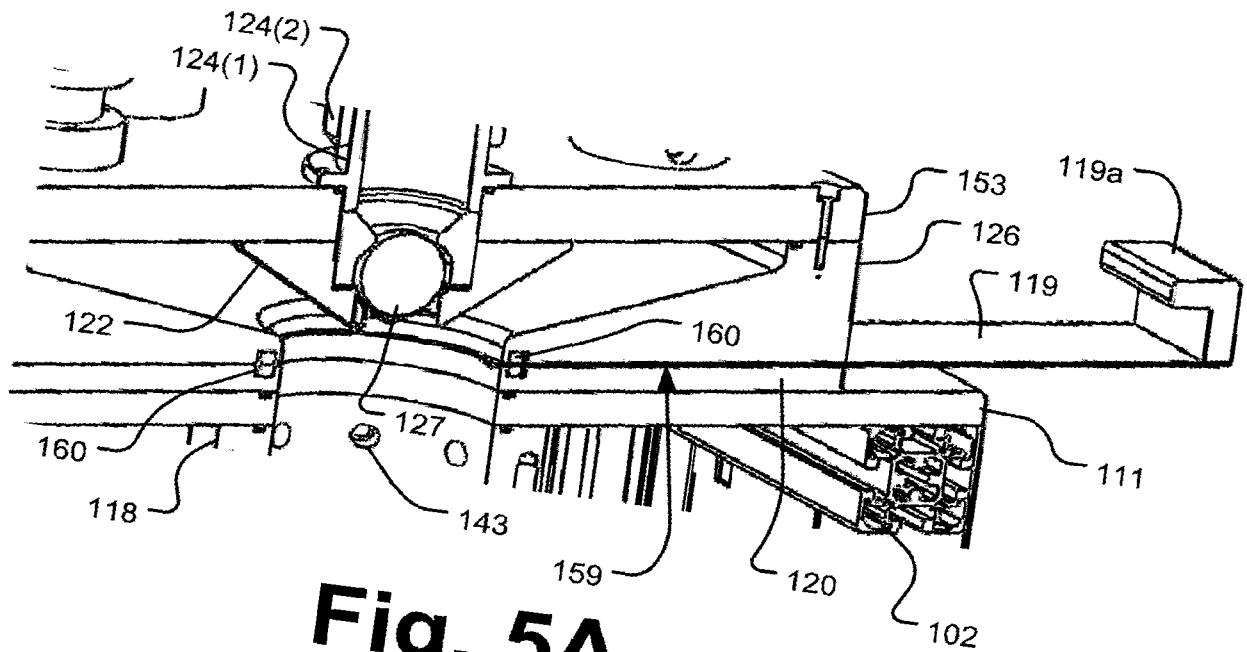


Fig. 4B

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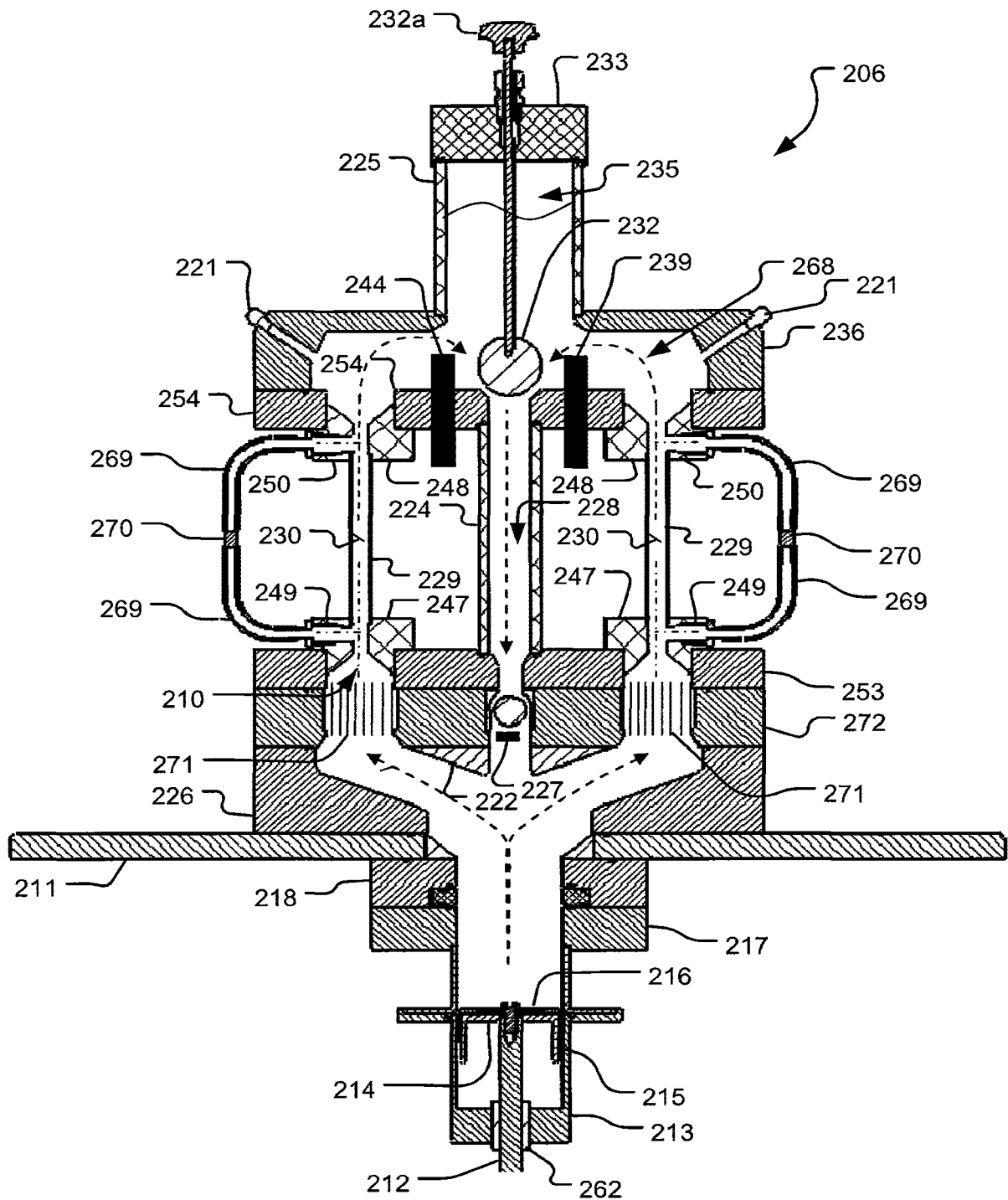


Fig. 6

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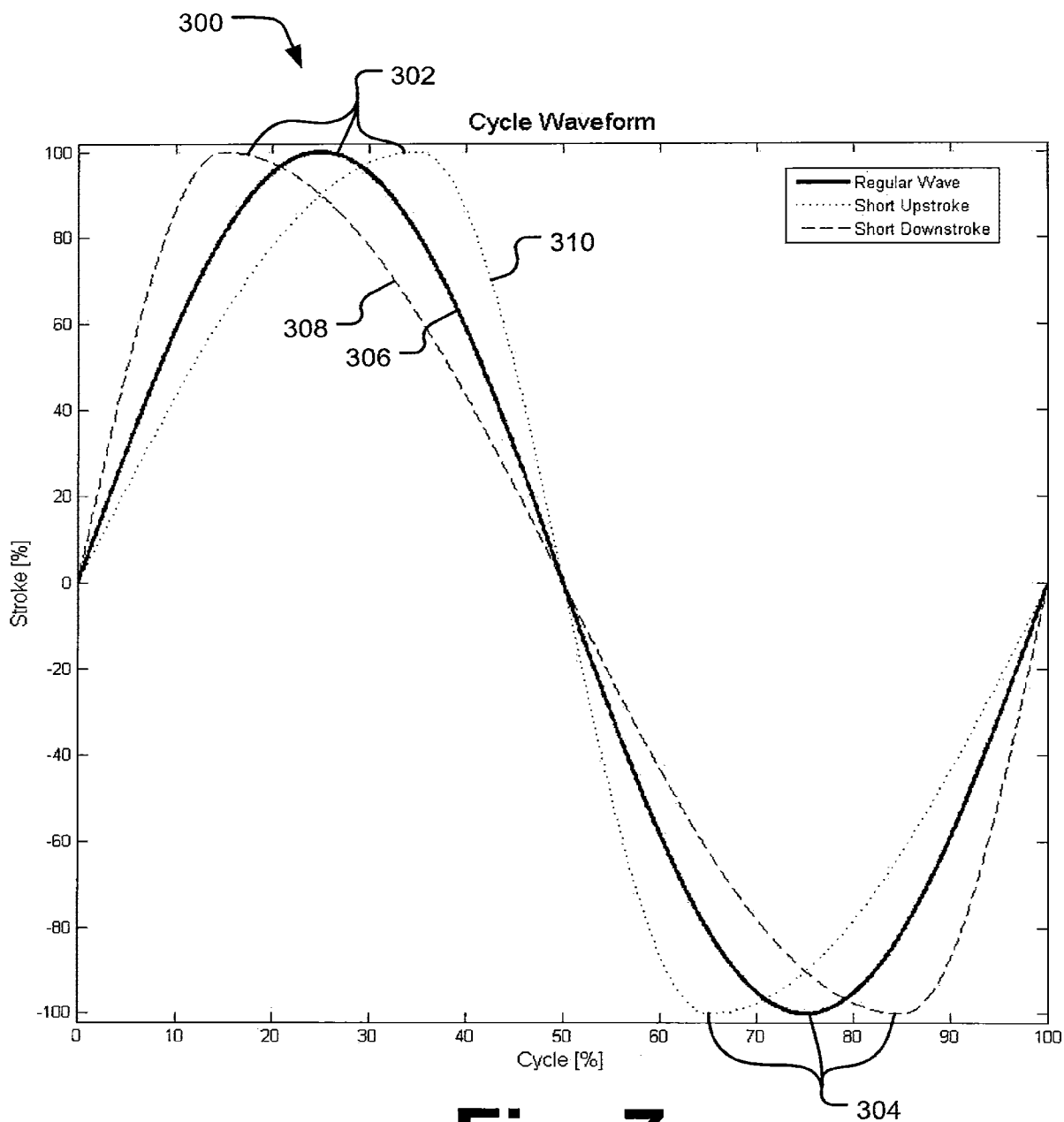


Fig. 7

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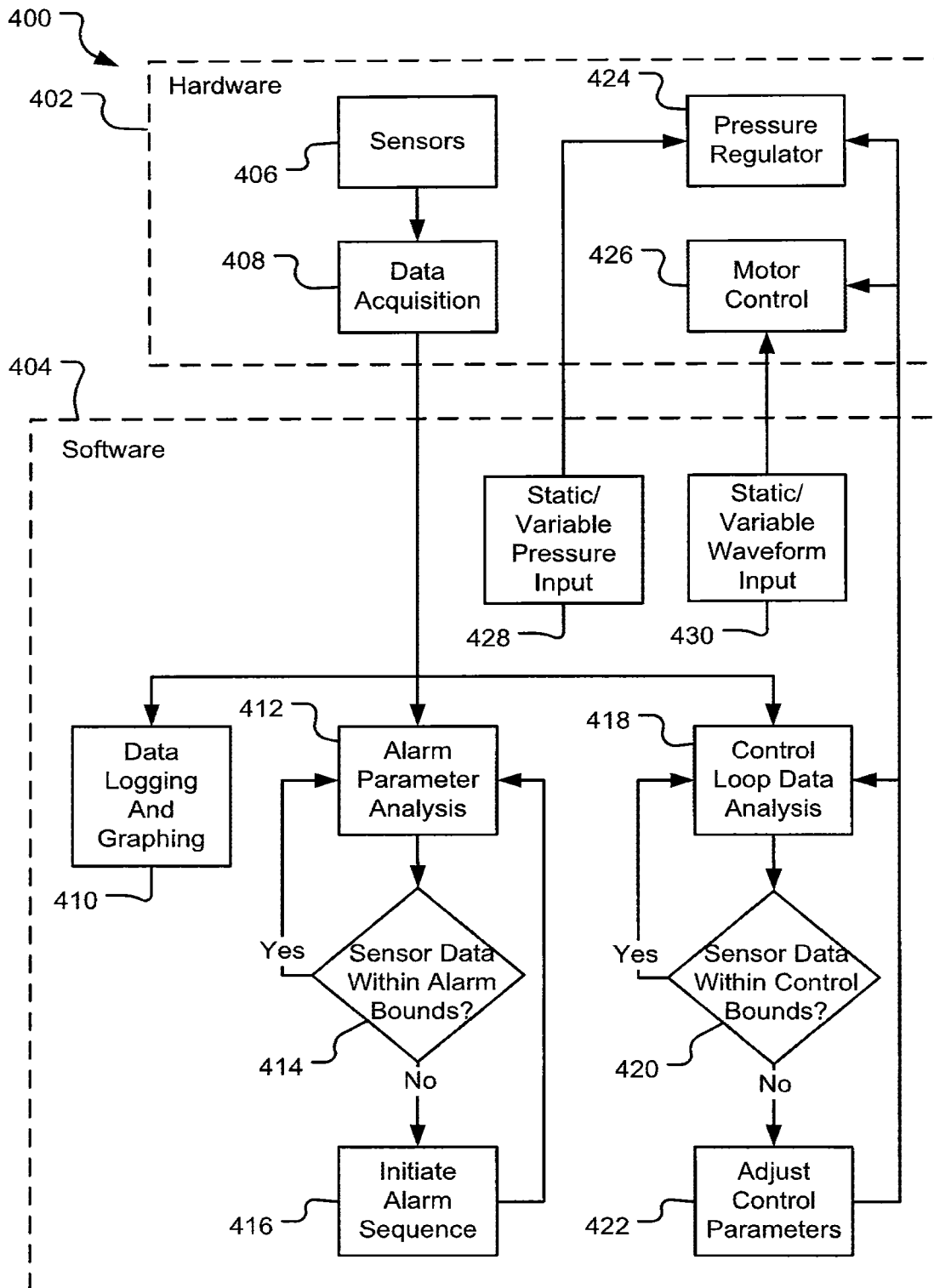


Fig. 8

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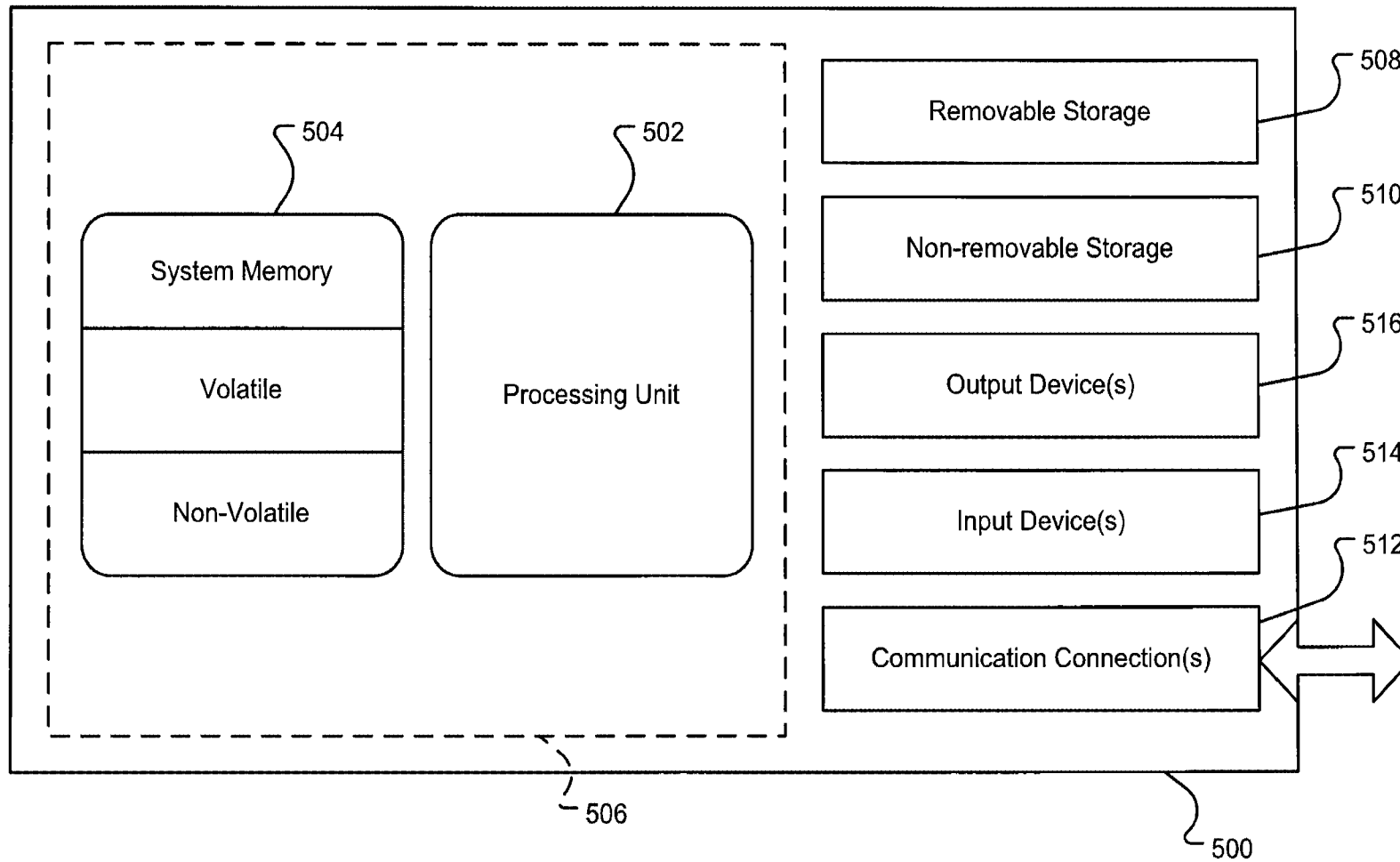


Fig. 9



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12/718,316	03/05/2010	Benjamin McCloskey	P201384.US.02	4620

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DORSEY & WHITNEY, LLP - Denver
INTELLECTUAL PROPERTY DEPARTMENT
1400 Wewatta Street
Suite 400
DENVER, CO 80202-5549

EXAMINER

JAHANGIR, NAEEM M

ART UNIT	PAPER NUMBER
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4125

NOTIFICATION DATE	DELIVERY MODE
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01/03/2013

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing-dv@dorsey.com
docketingDV@dorsey.foundationip.com

Office Action Summary	Application No.	Applicant(s)	
	12/718,316	MCCLOSKEY ET AL.	
	Examiner	Art Unit	
	NAEEM M. JAHANGIR	4125	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3/5/2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 1-31 is/are pending in the application.
- 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 1-31 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 11/4/10 6/13/11.

- 3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. ____.
- 4) ☐ Other: ____.

Petitioner's Exhibit 1009
VIVITRO v. BDC
IPR2024-00320

DETAILED ACTION***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claim 1, 17, 25, 28, are rejected under 35 U.S.C. 102(b) as being anticipated by Vilendrer (US 5670708).

Regarding claim 1, Vilendrer teaches “The fatigue tester 10 generally includes a plurality of prosthesis containing tubes 18, manifolds 20 and 22, bellows 24 and 26 and linear voice-coil drive motors 28 and 30. A plurality of transducers, including a compliance transducer 32, temperature transducer 34, pressure transducer 38, and linear displacement transducers 40 and 42 are coupled to the fatigue tester 10. The pressure transducer 38, and linear displacement transducers 40 and 42 are also coupled to the microprocessor-based controller 12 (see FIGS. 1, 2 and 5) to provide feedback for closed loop servo control.....(Column 3, Lines: 40-59)”.

Vilendrer also teaches, “The tube 18 is connected in-line to a fluid flow circuit of the fatigue tester 10. Generally, a continuous fluid conduit or passage is formed between bellows 24 and 26, manifolds 20 and 22, and tubes 18 (see FIGS. 5-7)..... (column 4, Lines:36-52)”.

As to claim 17, “Vilendrer teaches, “A fluid such as saline may be selected to simulate fluids encountered in vitro. The manifolds 20 and 22 are preferably constructed from a non-corrosive material such as polypropylene, polytetrafluoroethylene, or stainless steel (Column 4, Lines: 49-52)”.

“Referring to FIG. 7, those skilled in the art will appreciate that one or more tubes 18 may be coupled to the first and second manifolds 20 and 22, wherein radial bores in each manifold form a fluid passage 62 between a plurality of outlet passages 64 and a central longitudinal bore or inlet 66. The plurality of tubes 18 are sealably connected to corresponding outlet passages 64 and the bellows 24 and 26 are connected to the inlet 66 of the manifolds 20 and 22 respectively (Column 4, Lines: 53-61)”.

As to claim 25, Vilendrer teaches, “The pressure within the fluid conduit is measured via a pressure transducer. The pressure is monitored by the microprocessor-based controller and used as part of the closed loop servo control. To ensure long term test reliability, an uninterruptable power supply is connected to the microprocessor-based controller...(Column 4, Lines: 52-57)”.

Art Unit: 4125

Vilendrer teaches "The linear drive motors are coupled to linear displacement transducers which are connected to the microprocessor-based controller. The microprocessor-based controller operates the linear driven pumps over a frequency range from 0 to over 6000 cycles/minute under closed loop control (Column 2, Lines: 29-33)".

As to claim 28, Vilendrer teaches, "The compliance transducer controller 16 is also coupled to the microprocessor-based controller 12 by electrical leads of known construction, wherein a proportional analog signal is transmitted to a data acquisition board (not shown) contained within the microprocessor-based controller 12 for direct processing by the computer (Column 4, Lines:15-21)".

Claim Rejections - 35 USC § 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 103 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

AS to Claims 2, 3, 4, 6, 7, 8, 10, 11, 12, 13, 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vilendrer, Kent. (US Patent No. 5670708) hereinafter Vilendrer, and in view of Murphy Pickard (US Patent No. 4682491) Pickard hereinafter (Pickard).

As to Claim 2, Pickard teaches "a test chamber is provided for insertion into a flow channel with the mounting structure for the prosthetic heart valve comprising a shuttle into which one or two heart valves may be mounted..... valve may become desiccated when it is not in position within the flow channel (Column 2, Lines:11-23) .

As to Claim 3, Pickard teaches, the device as defined in claim 1 as set forth above. Pickard also teaches "this circulatory loop includes an intake chamber that receives a saline fluid through a fluid inlet under the cyclical action of a pump, the stroke of which acts as a heart beat. The intake chamber has first and second orifices that are in fluid communication, respectively, with first and second test chambers" (Column 3 Lines: 12-18).

As to Claim 4, Pickard teaches, the device as defined in claim 1 as set forth above. “a pump cyclically drives a fluid through the loop, and flow meters and pressure sensors monitor the test. A data processor monitors and processes the flow data and controls the pump to create a desired flow waveform. The test can also be visually and optically monitored (Abstract)”.

As to Claim 6, Pickard teaches, the device as defined in claim 1 as set forth above. Pickard also teaches “each test chamber is in fluid communication with a respective restriction chamber flow orifice by a conduit means that conducts fluid between restriction chamber flow orifice and the test chamber in a direction depending on the positioning of a prosthetic valve (Column 3 Lines 37-41).

As to Claim 7, Pickard teaches, the device as defined in claim 1 as set forth above. Pickard also teaches “A fluid pressure compensation chamber is associated with each conduit between the respective chamber and the restriction chamber and each includes a fluid.....Suitable flow measuring elements are provided to measure the velocity and volume of fluid flow through the conduits” (Column 3 Lines 46-57).

As to Claim 8, Pickard teaches, the device as defined in claim 1 as set forth above. Pickard also teaches “an inflow shaper 258 is then mounted against flange 256 with inflow shaper 258 having a converging inner wall 260 that.....an outflow shaper 270 is provided to configure the flow path after fluid is passed through the heart valve without flow shaper 270 having tapered side wall 272 similar to inflow shaper side wall 260” (Column 11 Lines 26-38).

As to Claim 10, Pickard teaches, the device as defined in claim 1 as set forth above. Pickard also teaches “In order to monitor the flow channel, various sensors are provided in addition to the flow meter noted above. In the preferred embodiment, a pair of pressure sensors are provided for each test chamber so that a pressure sensor is located on each side of the heart valve”..... “to this end, a computer may be interfaced with the various sensors and pressure regulating devices to automatically control the simulated circuit loop described above” (Column 4, Lines 25-45)

As to Claim 11, Pickard teaches, the device as defined in claim 1 as set forth above. Pickard also teaches “In the preferred embodiment, a pair of pressure sensors are provided for each test chamber so that a pressure sensor is located on each side of the heart valve” (Column 4, Lines 27-29).

As to Claim 12, Pickard teaches, the device as defined in claim 1 as set forth above. Pickard also teaches, “a monitor 48 senses the location of the piston in pump 46 for purposes of controlling the volumetric displacement of pump 46. To this end, piston reservoir 50 is filled with fluid which communicates with circulatory loop 18 through an intake opening 52 extending between reservoir 50 and circulatory loop 18” (Column 7 Lines 43-49).

As to Claim 13, Pickard teaches, the device as defined in claim 1 as set forth above. Pickard also teaches, “in order to provide variation in resistance to fluid flow, a motor 324 is provided to rotate element 320. Motor 324 has a square shaped shaft 326 which is received in a square shaped opening 328 at one end of valve element 306 so that, as shaft 326 turns, valve element 306 is rotated so that restriction element 320 varies the effective flow cross-section for the restrictive flow path through restriction chamber 130. Motor 324 is preferably a step motor controlled by computer 102” (Column 11 Lines 68 through Column 12 Lines 8).

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As to Claim 15, Pickard teaches, the device as defined in claim 1 as set forth above. Pickard also teaches, "Motor 324 has a square shaped shaft 326 which is received in a square shaped opening 328 at one end of valve element 306 so that, as shaft 326 turns, valve element 306 is rotated so that restriction element 320 varies the effective flow cross-section for the restrictive flow path through restriction chamber 130" (Column 12 Lines 2-7).

Claims 18, 19, 20, 21, 22, 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vilendrer, Kent (US 5670708) (hereinafter Vilendrer) in view of Murphy Pickard (US Patent No. 4682491) Pickard hereinafter (Pickard) and further in view of Kruse et al (US 20030235804).

Kruse et al. teaches all the limitations of the base claims as outlined above. But **In claim 18** Pickard fails to clearly specify "elastomeric material that compresses under a pressure placed upon fluid in the test chamber and allows fluid in the test chamber to occupy a portion of the volume.

However, Kruse et al. teaches, "to test the stents under more appropriate loads and load distributions, the stents are assembled into stented test structures with a flexible material membrane supported by the stent.....the stented test structures are similar to closed prosthetic valves with flexible leaflets." (Column 5 Paragraph 0061).

It would be obvious to a skilled in the art to modify the above testing for elastomeric material that compresses under a pressure placed upon fluid in the test chamber and allows fluid in the test chamber, as taught by pickard in view of testing the blood circulation by limiting the amount of back flow in the veins thought by Kruse.et al.

In claim 19 Pickard does not teach explicitly about the fluid return chamber defines a port providing fluid communication between and outer surface of the fluid return chamber. However, Kruse et al. teaches "the outer surface of stent 270 can be covered with a fabric to facilitate implantation of the valve or for convenience of handling" (Column 5, Paragraph 0057).

It would be obvious to a skilled in the art to modify the above testing for Fatigue prosthetic devices, as taught by pickard "about the fluid return chamber defines a port providing fluid communication between and outer surface of the fluid return chamber".

In view of testing the blood circulation by limiting the amount of back flow in the veins thought by Kruse.et al.

In claim 20, Pickard does not teach between the first manifold of the fluid distribution chamber and second manifold of the fluid return chamber.

However, Kruse et al. teaches "a corresponding testing apparatus includes a cyclic pressure applicator, a conduit connected to the cyclic pressure applicator, and a stented test structure mounted within the conduit to receive cyclic fluid pressures from the cyclic pressure applicator" (Abstract).

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It would be obvious to a skilled in the art to modify the above testing for Fatigue prosthetic devices, as taught by pickard “about the first manifold of the fluid distribution chamber and second manifold of the fluid return chamber” in view of testing the Fluid conduit 476 includes a flow restrictor 498 mounted within the lumen of fluid conduit 476 to provide for better control of the pressure applied to stented test structure thought by Kruse.et al.

In claim 21, Pickard did not disclose explicitly the sample holder defines first side of a test and second side of the test sample position.

However, Kruse et al. teaches, “one-way flow through or around the stented test structure is to provide a more rapid equilibration of the fluid from the upstream chamber to the downstream chamber in testing apparatuses with a configuration having a fluid loop”(Column 7 Paragraph77).

It would be obvious to a skilled in the art to modify the above testing for Fatigue prosthetic devices, as taught by pickard “about the sample holder on a first side of a test and second side of the sample position” in view of testing the Fluid conduit 476 includes a flow restrictor 498 mounted within the lumen of fluid conduit 476 to provide for better control of the pressure applied to stented test structure thought by Kruse.et al.

In claim 22

Pickard does not disclose “free edges open in response to fluid pressure to allow limited flow through the flexible membrane in the forward direction. The length of the free edges can be adjusted to yield the desired amount of flow”.

However, Kruse et al. teaches, “Desirable approaches for forming the stented test structure generally depend on the material used to form the flexible membrane. For example, flexible membranes formed from tissue materials can be sutured to the stent, or the tissue can be sutured together to form sheaths into which the stent is inserted” (Column 8 Paragraph 0079).

It would be obvious to a skilled in the art to modify the above testing for Fatigue prosthetic devices, as taught by pickard “in response to fluid pressure to allow limited flow through the flexible membrane in the forward direction” In view of desirable approaches the stented structure base on material used on flexible membrane thought by Kruse et al.

In Claim 23 Pickard fail to disclose an elastomeric membrane separating at least one a portion from fluid in the return chamber.

However, Kruse et al. teaches “the stented test structure includes a stent and a flexible membrane extending within the lumen defined by the stent with the flexible membrane having a plurality of contours connecting to the stent along the scallops. A corresponding testing apparatus includes a cyclic pressure applicator, a conduit connected to the cyclic pressure applicator, and a stented test structure mounted within the conduit to receive cyclic fluid pressures from the cyclic pressure applicator” (Abstrac) .

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It would be obvious to a skilled in the art to modify the above testing for Fatigue prosthetic devices, as taught by Kruse the flexible membrane substantially blocks flow of the fluid in a backward direction and does not fully open upon application of the fluid pressure in a forward direction.

In claim 24, Pickard does not teach the compliance is positioned substantially above the second port and between the second port and the fluid return conduit.

But Kruse et al. teaches “a corresponding testing apparatus includes a cyclic pressure applicator, a conduit connected to the cyclic pressure applicator, and a stented test structure mounted within the conduit to receive cyclic fluid pressures from the cyclic pressure applicator” (abstract).

It would be obvious to a skilled in the art to modify the above testing for Fatigue prosthetic devices, as taught by Pickard, the compliance is positioned substantially above the second port and between the second port and the fluid return conduit in view of heart valves function as check valves, which open for flow in one direction and close in response to pressure differentials taught by Kruse et al. .

In claim 26, Pickard fail to disclose the flexible diaphragm further comprises and elastomeric rolling bellows connected to a shaft of the linear motor.

Kruse teaches “The cyclic pump can be any suitable pump including, for example, a piston driven diaphragm pump or other cyclic pump structure, such as a Harvard-style piston pump, a cam actuated piston pump or an electromagnetic actuator” (Column paragraph 0090).

It would be obvious to a skilled in the art to modify the above testing for Fatigue prosthetic devices, as taught by Pickard, the flexible diaphragm further comprises and elastomeric rolling bellows connected to a shaft of the linear motor, in view of a piston driven diaphragm pump or other cyclic pump structure, such as a Harvard-style piston pump, a cam actuated piston pump or an electromagnetic actuator taught by Kruse et al.

In claim 27, Kruse does not teach a piston connected to the linear motor wherein the end wall of the rolling bellows is attached to the piston.

However Pickard teaches “in order to provide variation in resistance to fluid flow, a motor 324 is provided to rotate element 320. Motor 324 has a square shaped shaft 326 which is received in a square shaped opening 328 at one end of valve element 306 so that, as shaft 326 turns, valve element 306 is rotated so that restriction element 320 varies the effective flow cross-section for the restrictive flow path through restriction chamber 130. Motor 324 is preferably a step motor controlled by computer 102” (Column 11 Line 68 and Column 12 Line1-8).

It would be obvious to a skilled in the art to modify the above testing for Fatigue prosthetic devices, as taught by Kruse et al displacement on the diaphragm by the piston and the corresponding fluid pressures on the stented test structure. In view of Fluid is driven through circulatory loop 18 in a pulsatile or cyclical manner thought by Pickard.

In claim 29, Kruse does not explicitly discussed about a preset alarm boundary and output an alarm indicator for perception by user.

Pickard teaches “automatic monitors may also be used within the test chamber to monitor the position of the mounting element so that proper registration of the heart valve within the flow channel may be automatically attained. Similarly, a step motor may be used to drive the position of the restriction means in the restriction chamber, and an electronic monitor may output the position of the restriction element for automatic processing. To this end, a computer may be interfaced with the various sensors and pressure regulating devices to automatically control the simulated circuit loop described above” (Column 4 Line 35-45) .

It would be obvious to a skilled in the art to modify the above testing for Fatigue prosthetic devices, as taught by Kruse et al with a variable frequency and stroke volume of diaphragm, a sinusoidal pressure waveform was generated that could be controlled in both amplitude and frequency, in view of signals corresponding to fluid flow velocity are likewise transmitted to analog/digital converter 103 from first flow module 134 and second flow module 140, and the amount of resistance in restriction chamber 130 is received by analog/digital converter 103 from resistance monitor 152 thought by Pickard.

In claim 30, Kruse et al. does not teach explicitly storing the sensor data, parameters for data logging, data graphing or both incorporating a data log with the output presentation for perception by a user.

But Pickard teaches “A data processor monitors and processes the flow data and controls the pump to create a desired flow waveform. The test can also be visually and optically monitored” (Abstract).

It would be obvious to a skilled in the art to modify the above testing for Fatigue prosthetic devices, as taught by kruse the flexible membrane substantially blocks flow of the fluid in a backward direction and does not fully open upon application of the fluid pressure in a forward direction, in view of a data processor monitors and processes the flow data and controls the pump to create a desired flow waveform taught by packard.

In claim 31, Kruse et al. fail to teach explicitly the sensor data comprises one or more types of data.

But Pickard teaches, “the present invention, a computer interface and control system is provided so that the preferred method is directed toward a simulated circulatory system that has a flow channel containing a test fluid and which includes a selectably adjustable fluid restriction element in the flow channel, a compensation chamber which provides both an excess fluid compensation reservoir and which may be adjusted to selectively apply pressure to the fluid in the flow channel, and that includes a pulsatile pump having a selectable adjusted period, amplitude and duty cycle for driving the fluid in a selected waveform through the flow channel” (Column 5 Line 53-65). .

Art Unit: 4125

It would be obvious to a skilled in the art to modify the above testing for Fatigue prosthetic devices, as taught by kruse, a polymer flexible membrane is formed directly in contact with the stent, in view of the computer first uses interactive processing of the flow rate and channel pressure data to calculate the actual fluid flow and pressure waveform through the flow channel to compare this waveform to the desired waveform and generate waveform error data according thereto. taught by packard.

Vilendrer (US 5670708), Murphy Pickard (US Patent No. 4682491) and Kruse et al (US 20030235804) are analogous art because they are from the same field of endeavor and contain overlapping structural and functional similarities. They relate to "Fatigue testing for prosthetic devices". They all contain functional similarities because they all contain "Fatigue testing for Prosthetic". They all contain functional similarities because they contain a fatigue tester for simulating physiological lodging condition.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NAEEM M. JAHANGIR whose telephone number is (571)270-7055.

The examiner can normally be reached on Mon-Fri 730AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gray David can be reached on 571-272-2119. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/David M Gray/
Supervisory Patent Examiner,
Art Unit 2852

/N. M. J./
Examiner, Art Unit 4125



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/718,316	03/05/2010	Benjamin McCloskey	P201384.US.02	4620

20686 7590 05/08/2013
DORSEY & WHITNEY, LLP - Denver
INTELLECTUAL PROPERTY DEPARTMENT
1400 Wewatta Street
Suite 400
DENVER, CO 80202-5549

EXAMINER

JAHANGIR, NAEEM M

ART UNIT	PAPER NUMBER
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2856

NOTIFICATION DATE	DELIVERY MODE
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05/08/2013

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing-dv@dorsey.com
docketingDV@dorsey.foundationip.com

<i>Applicant-Initiated Interview Summary</i>	Application No. 12/718,316	Applicant(s) MCCLOSKEY ET AL.	
	Examiner NAEEM M. JAHANGIR	Art Unit 2856	

All participants (applicant, applicant's representative, PTO personnel):

(1) John Fitzgerald. (3) Brad J. Hattenbach.

(2) NAEEM M. JAHANGIR. (4) Craig Weinberg.

Date of Interview: 29 April 2013.

Type: ☒ Telephonic ☐ Video Conference
 ☐ Personal [copy given to: ☐ applicant ☐ applicant's representative]

Exhibit shown or demonstration conducted: ☒ Yes ☐ No.
 If Yes, brief description: _____.

Issues Discussed ☐101 ☐112 ☒102 ☐103 ☐Others
 (For each of the checked box(es) above, please describe below the issue and detailed description of the discussion)

Claim(s) discussed: 1.

Identification of prior art discussed: 4682491 and 5670708.

Substance of Interview
 (For each issue discussed, provide a detailed description and indicate if agreement was reached. Some topics may include: identification or clarification of a reference or a portion thereof, claim interpretation, proposed amendments, arguments of any applied references etc...)

Applicant's arguments regarding the prior art and the proposed amendment to the instant claims were found persuasive.

Applicant recordation instructions: The formal written reply to the last Office action must include the substance of the interview. (See MPEP section 713.04). If a reply to the last Office action has already been filed, applicant is given a non-extendable period of the longer of one month or thirty days from this interview date, or the mailing date of this interview summary form, whichever is later, to file a statement of the substance of the interview

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

☒ Attachment

/NAEEM M JAHANGIR/ Examiner, Art Unit 2856	
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Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews

Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

DO NOT PLACE IN FILE

FOR DISCUSSION PURPOSES ONLY

U.S. Patent Application No. 12/718,316

Examiner Interview 29 April 2013

Claim 1 (proposed amendment)

A device for simultaneous accelerated cyclic testing of a plurality of valved prosthetic devices comprising

a pressurizable test chamber further comprising

a fluid distribution chamber having a first manifold defining a first plurality of ports configured to receive and fluidicly couple with a first end of each of a respective plurality of sample holders and defining an aperture in a lower face in fluid communication with a pressure source;

a fluid return chamber having a second manifold disposed opposite and spaced apart from the first manifold of the fluid distribution chamber and defining a second plurality of ports configured to receive and fluidicly couple with a second end of each of the respective plurality of sample holders;

a fluid return conduit both structurally and fluidly connecting the fluid distribution chamber to the fluid return chamber; and

a compliance chamber providing a volume for holding a gas or elastomeric material that compresses under a pressure placed upon fluid in the test chamber and allows fluid in the test chamber to occupy a portion of the volume;

a drive motor configured to operate cyclically, acyclically, or a combination of both ; and

a fluid displacement member connected with and driven by the drive motor to provide the pressure source that increases and decreases a pressure on fluid in the test chamber; whereby cyclic and acyclic fluid pressures are maintained throughout the test chamber.

Discussion Topics

- 1) Vilrendrer
 - a) Device is for testing radial dilation of stents and grafts, not valves; it would not work to test valves
 - b) Compliance Transducer = Laser micrometer; it measures distensibility (i.e., compliance of tubes); not a compliance chamber as described and claimed

2) Pickard

- a) Not an accelerated testing system (e.g., 15 Hz); Discloses a real time system (e.g., 1 Hz) for testing heart valves immediately before implantation (can't simulate cardiac environment at high speed).
- b) Purpose of compliance in Pickard system is to mimic circulatory system
- c) Purpose of compliance in present invention is to prevent kinetic energy of fluid flow from translating into high static fluid pressure

3) Kruse

- a) Discloses a testing system for a valve frame; it is not designed to test leaflet wear
- b) System is designed to operate at atmospheric pressure
- c) No fluid flow through the frame

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.	: 12/718,316	Confirmation No.	: 4620
First Applicant	: Benjamin McCloskey	Art Unit	: 4125
Filed	: 5 March 2010	Examiner	: Jahangir, Naeem M.
Title	: FATIGUE TESTING SYSTEM FOR PROSTHETIC DEVICES		
Docket No.	: P201384.US.02	Customer No.	: 20686

AMENDMENT A AND RESPONSE TO OFFICE ACTION
INCLUDING INTERVIEW SUMMARY

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Commisioner:

In response to the Office action dated 3 January 2013, please consider the following remarks and amend the above-identified application as follows:

Amendments to the Claims begin on page 2 of this paper.

Remarks begin on page 8 of this paper.

CLAIMS

This listing of claims replaces all prior versions and listings of claims in this application. New terms are presented in underline text and deleted terms are indicated in ~~strikethrough~~ text or are enclosed in [[double brackets]].

What is claimed is:

1. (Currently Amended) A device for simultaneous accelerated cyclic testing of a plurality of valved prosthetic devices comprising
 - a pressurizable test chamber further comprising
 - a fluid distribution chamber having a first manifold defining a first plurality of ports configured to receive and fluidically couple with a first end of each of a respective plurality of sample holders and defining an aperture in a lower face in fluid communication with a pressure source;
 - a fluid return chamber having a second manifold disposed opposite and spaced apart from the first manifold of the fluid distribution chamber and defining a second plurality of ports configured to receive and fluidically couple with a second end of each of the respective plurality of sample holders;
 - a fluid return conduit both structurally and fluidily connecting the fluid distribution chamber to the fluid return chamber; and
 - a compliance chamber providing a volume for holding a gas or elastomeric material that compresses under a pressure placed upon fluid in the test chamber and ~~and~~; allows fluid in the test chamber to occupy a portion of the volume;
 - a drive motor configured to operate cyclically, acyclically, or a combination of both; and
 - a fluid displacement member connected with and driven by the drive motor to provide the pressure source that increases and decreases a pressure on fluid in the test chamber; whereby cyclic and acyclic fluid pressures are maintained throughout the test chamber.

2. (Original) The device of claim 1 further comprising a plurality of sample holders, each configured to hold a respective prosthetic device, mounted between the first manifold of the fluid distribution chamber and second manifold of the fluid return chamber, and mounted within a respective pair of the first plurality of ports and the second plurality of ports, whereby the prosthetic device is placed in fluid communication with the distribution fluid chamber and the return fluid chamber.

3. (Original) The device of claim 1, wherein
the compliance chamber comprises a plurality of compliance chambers formed as
cavities within the fluid return chamber; and
a respective one of the plurality of compliance chambers is positioned substantially
above each of the second plurality of ports and between each of the second plurality of ports
and the fluid return conduit.
4. (Original) The device of claim 1, wherein each of the sample holders defines a
first port on a first side of a test sample position and a second port on a second side of the test
sample position; wherein the first port and the second port are configured to receive one or
more sensor devices.
5. (Original) The device of claim 4 further comprising a pressure transducer in fluid
communication with the first port and the second port in one of the sample holders configured to
measure a pressure gradient across a test sample positioned within the one of the sample
holders.
6. (Original) The device of claim 1 further comprising a one-way valve positioned
within the fluid return conduit that prevents fluid flow through the fluid return conduit when the
fluid displacement member increases pressure on fluid in the test chamber.
7. (Original) The device of claim 1, wherein the fluid return conduit is positioned
along an axial center of the test chamber.
8. (Original) The device of claim 1, wherein the fluid return conduit further
comprises
an inner conduit wall having an outer diameter and attached to one of the fluid
distribution chamber or the fluid return chamber;
an outer conduit wall having an inner diameter larger than the outer diameter of the inner
conduit and attached to the other of the fluid distribution chamber or the fluid return chamber,
wherein the inner conduit wall is received within the outer conduit wall; and
a seal member positioned between the inner conduit wall and the outer conduit wall to
create a fluid-tight seal therebetween; wherein
the fluid return conduit is configured to telescopically lengthen or shorten.

9. (Original) The device of claim 8 further comprising a plurality of adjustment posts positioned between the fluid distribution chamber and the fluid return chamber and operable to adjust a separation distance between the fluid distribution chamber and the fluid return chamber.

10. (Original) The device of claim 1 further comprising a computer control system connected with the drive motor and a sensor positioned within the test chamber, wherein the computer control system is configured to operate one or more of the following:

an alarm module for alerting a user or arresting operation of the device upon receipt of data from the sensor that is outside a preset parameter; or

a closed loop feedback module for adjusting operation of the drive motor upon receipt of data from the sensor to maintain a pressure profile within the test chamber according to a preset parameter.

11. (Original) The device of claim 1 further comprising
a heater positioned in the test chamber for heating fluid within the test chamber; and
a temperature sensor positioned within the test chamber to measure temperature of fluid within the test chamber.

12. (Original) The device of claim 1, wherein the fluid displacement member comprises a flexible diaphragm.

13. (Original) The device of claim 1, wherein the drive motor comprises a linear motor.

14. (Original) The device of claim 13 further comprising
a mounting structure connected to and supporting the linear motor in a vertically mounted position; and

a spring supported by the mounting structure, and interfacing with an end of a shaft of the linear motor extending from a lower end of the linear motor, wherein

the spring prevents the shaft from dropping downward from the linear motor when the linear motor is in an unpowered state.

15. (Original) The device of claim 1, wherein the fluid displacement member further comprises a flexible rolling bellows connected to a shaft of the linear motor.

16. (Original) The device of claim 15 further comprising
a drive adaptor coupled to the either directly or indirectly to the distribution chamber and
in fluid communication with the aperture in the lower face of the fluid distribution chamber,
wherein

the drive adaptor defines an aperture with an upper diameter congruent with a diameter
of the aperture in the lower face of the fluid distribution chamber;

the rolling bellows is further attached to a piston connected to the shaft of the linear
motor and the piston moves axially within a cylinder;

the cylinder defines an opening of a diameter that is substantially the same as a
diameter of an end wall of the rolling bellows;

the cylinder is coupled to the drive adaptor and a circumferential flange of the rolling
bellows is held therebetween; and

the aperture defined in the drive adaptor has a lower diameter congruent with the
diameter of the opening in the cylinder.

17. (Currently Amended) A test chamber for accelerated cyclic testing of a valved
prosthetic device in a variable pressurized environment comprising

a fluid distribution chamber having a first manifold defining a first port configured to
receive and fluidicly couple with a first end of a sample holder and a lower face defining an
aperture for communicating with a fluid pressure source;

a fluid return chamber having a second manifold disposed opposite and spaced apart
from the first manifold of the fluid distribution chamber and defining a second port configured to
receive and fluidicly couple with a second end of the sample holder;

a fluid return conduit both structurally and fluidly connecting the fluid distribution
chamber to the fluid return chamber; and

a compliance chamber providing a volume for holding a gas or elastomeric material that
compresses under a pressure placed upon fluid in the test chamber ~~and~~ allows fluid in the test
chamber to occupy a portion of the volume.

18. (Original) The test chamber of claim 17, wherein the compliance chamber is
defined as a cavity within the fluid return chamber.

19. (Original) The test chamber of claim 18, wherein the fluid return chamber defines
a port providing fluid communication between an outer surface of the fluid return chamber and
the cavity forming the compliance chamber.

20. (Original) The test chamber of claim 17 further comprising a sample holder configured to hold a prosthetic device, mounted between the first manifold of the fluid distribution chamber and second manifold of the fluid return chamber, and mounted within the first port and the second port, whereby the prosthetic device is placed in fluid communication with the distribution fluid chamber and the return fluid chamber.

21. (Original) The device of claim 20, wherein the sample holder defines a first port on a first side of a test sample position and a second port on a second side of the test sample position; wherein the first port and the second port are configured to receive one or more sensor devices.

22. (Original) The device of claim 17, further comprising a porous material at least partially filling the compliance chamber.

23. (Original) The device of claim 17, further comprising an elastomeric membrane separating at least a portion of the compliance chamber from fluid in the fluid return chamber.

24. (Original) The device of claim 17, wherein the compliance chamber is positioned substantially above the second port and between the second port and the fluid return conduit.

25. (Currently Amended) A pressurization system for a fluid test chamber for accelerated cyclic pressure testing of a of a valved prosthetic device comprising
a linear drive motor that displaces a shaft in an axial direction;
a flexible elastomeric rolling bellows diaphragm connected with and driven axially by the shaft of the linear motor that cyclically increases and decreases a pressure on a fluid in the fluid test chamber; wherein active control of the linear drive motor provides an ability to create small and large fluid displacements with consequent variable effect of a fluid pressure of the fluid in the fluid test chamber.

26. (Canceled)

27. (Currently Amended) The system of claim 25, further comprising
a cylinder that defines an opening of a diameter that is substantially the same as a diameter of an end wall of the rolling bellows diaphragm; and
a piston connected to the shaft of the linear motor, wherein
the end wall of the rolling bellows diaphragm is attached to the piston;

the piston and the end wall of the rolling bellows diaphragm move axially within the cylinder to create the fluid displacements.

28. (Canceled)

29. (Canceled)

30. (Canceled)

31. (Canceled)

REMARKS & ARGUMENTS

The Applicant provides the following remarks and argument for consideration in further examination of the present application and explanation of the amendments presented herein.

Interview Summary

Applicant thanks the Examiner and Supervisory Examiner John Fitzgerald for their time on 29 April 2013 and participation in a telephone interview with the undersigned and Craig Weinberg, Ph.D., one of the inventors. Initially the difference between the “compliance transducer” (i.e., a laser micrometer used to measure radial dilation of stents and grafts) disclosed in Vilrendrer and the Applicant’s use of a “compliance chamber” was discussed. The examiners agreed that the Vilrendrer structure is completely different and for a different purpose than the structure of Applicant’s claims 1 and 17 and, for at least this reason, the rejections of claims with this feature in view of Vilrendrer would be withdrawn.

Dr. Weinberg further discussed the differences between the invention claimed in claims 1 and 17 and the prior art references of record, namely, Vilrendrer, Pickard, and Kruse et al.. Dr. Weinberg noted that the Vilredrer device is designed for testing radial dilation of stents and grafts, not cardiac, vascular, or other prosthetic biologic valves. Dr. Weinberg further noted the Vilrendrer device would not work to test the wear of valve leaflets though opening and closing of the valve in view of the need to push fluid from both ends into the tubes holding the prosthetic stents or grafts.

Dr. Weinberg next discussed the difference between Pickard and the present claims. Pickard discloses a real time system (e.g., 1 Hz) for testing heart valves immediately before implantation. Pickard is thus not an accelerated testing system (e.g., ≥ 5 Hz) like the presently claimed invention and trying to cycle the Pickard system faster would frustrate the purpose of the test it is trying to perform (i.e., characterizing valve performance in a simulated circulatory system under which the valve is to be used) while not being able to perform the accelerated wear testing of the claimed invention. Dr. Weinberg also discussed the different purpose of compliance between the two systems. In the Pickard system, compliance is used to shape the systemic pressure waveform to mimic the circulatory system distensibility (e.g., capillaries) and characterize the prosthetic heart valve performance. In contrast, the purpose of the compliance chamber(s) as claimed in the devices of independent claims 1 and 17 is to prevent or minimize the kinetic energy of fluid flow from translating into high static fluid pressure in the test system during the accelerated frequency testing.

Dr. Weinberg finally discussed the differences between Kruse et al. and the claimed invention. Kruse et al. discloses a testing system for evaluation of the valve prostheses frame. The Kruse et al. device is not designed to test or determine leaflet wear (i.e., life-cycle wear of the prosthesis leaflets resulting from the opening and closing of the leaflets during a cardiac cycle). Notably, the system disclosed in Kruse et al. is not interested in fluid flow through the prostheses nor opening and closing of the leaflets. A closed membrane is placed across the frame to include the commissure posts in order to place significant fluid pressure on the frame to test the fatigue resistance to deformation of the frame under back pressures anticipated during clinical use over time. In the preferred embodiment in Kruse et al., the native prosthesis leaflets are replaced with flexible membranes that have significant differences from the native prosthesis leaflets to limit or cease flow when positive pressure is applied. Thus, no fluid flow is required through the membrane or valve component in the Kruse et al. system. In contrast, the valve leaflets are the structures being tested by the claimed invention and thus the presence of fluid flow through the leaflets is necessary in order for the valve test article to open and close functionally..

In view of these comments, the examiners stated that it was likely that the references were improperly applied and that claims 1 and 17 are likely allowable in view of the references.

Claim Amendments

Claims 1, 17, and 25 are amended to clarify that the claimed systems and devices are for the accelerated cyclic testing of valved prosthetic devices.

Claim 25 is further amended to provide proper antecedent basis for claim 27 by incorporating the subject matter of claim 26.

Claim 26 is canceled herein and the subject matter thereof is incorporated into claim 25.

Claims 28-31 are canceled herein without prejudice to or disclaimer of the subject matter presented therein.

Claim Rejections – 35 U.S.C. § 102

Claims 1, 17, 25 and 28 are rejected in the Office action pursuant to 35 U.S.C. § 102 as anticipated by Vilendrer (US Patent No. 5,670,708). It appears that the examiner may misunderstand claims 1 and 17, which require, *inter alia*, a compliance chamber. As shown and described in the specification, a compliance chamber 135 is a cavity associated with a sample holder that absorbs some of the pressure placed upon the fluid in the test chamber and help control recoil to the original volume dimensions. (See ¶ 0046.) The compliance chamber assist in minimizing the effects of large and quickly changing pressure gradients across test samples.

(Id.) The examiner points to the compliance transducer (32) in Vilrendrer as a structure meeting this claim limitation. To the contrary, the compliance transducer (32) is a laser scanning micrometer used to measure the diameter of the prosthetic tubes to determine the amount of dilation when the tubes being tested are placed under cyclic pressures. Thus, the compliance transducers of Vilrendrer have absolutely no relevance to the structure or function of the compliance chamber of independent claims 1 and 17. For at least this reason, Applicant requests that the rejection of claims 1 and 17 in view of Vilrendrer be withdrawn.

With respect to claim 25, Applicant respectfully submits that the first paragraph of the examiner's rejection has no relevance to the claimed linear drive motor and a flexible diaphragm. Applicant is uncertain of the reason for the examiner's recitation of the quoted passage from Vilrendrer (col. 2, ll. 52-57) to the claim. [Applicant notes that the examiner actually cited col. 4, ll. 52-57 for this passage in the Office action.]

With respect to the second paragraph of the rejection of claim 25, the examiner recites a passage from Vilrendrer regarding the drive system used in the system disclosed therein. However, the examiner provides no explanation of how the drive system for a stent dilation test system has any relationship to the pressurization system presented in independent claim 25.

Vilrendrer discloses a prosthesis fatigue test system that, *inter alia*, employs the use of two metal bellows, one on each end of the system to drive the system. Claim 25 specifically provides for the use of a flexible rolling bellows diaphragm. As set forth in the Declaration of Craig Weinberg Ph.D. filed in conjunction with this response, the problems with metal bellows technology as disclosed in Vilrendrer are particularly avoided by the system of claim 25. He states that metal bellows require large driving forces to achieve large fluid displacements during compression. (Id. at ¶ 6.) This in turn requires large electromagnetic driver(s) that impart operating challenges such as increased heat generation from the driver, increased operating stresses on adjacent components, and increased physical size requirements for the driver and system. (Id.)

In addition, metal bellows possess their own spring constant and effective mass. (Id. at ¶ 7.) During cyclic, oscillatory motion the metal bellows therefore responds as a standard mass-spring system with a respective vibrational natural frequency and subsequent harmonic response, producing undesirable excitation of the test prostheses under evaluation and/or limitations in the system operating frequency. (Id.)

In contrast, these problems are avoided through the use of a flexible rolling bellows diaphragm as provided in claim 25. Larger displacements for generating higher system flow rates can be achieved without any need for increased force requirements to the driver beyond

the loading requirements of the test prostheses under evaluation. (Id. at ¶ 8.) Additionally, a rolling bellows diaphragm does not have an effective spring constant and, therefore, does not respond as a mass-spring system nor possess a natural frequency. (Id.) Dr. Weinberg also notes further benefits of the rolling bellows diaphragm in view of other types of drive systems.

Further, in consideration of the incorporation of the elements of claim 26 into claim 25 by amendment herein, and in view of the rejection of claim 26 in view of Pickard and Kruse et al., Applicant makes the following additional observations. The system described in the Kruse et al. is for evaluation and testing of heart valve frames (referred to in Kruse et al. as a “valve stent”) and describes a preferred embodiment that has limited or no system fluid flow through the test article. (Weinberg Dec., ¶ 10.) This technology therefore does not require the larger driver / diaphragm displacements. The Kruse et al. diaphragm merely flexes in and out and generates very small displacements. (Id.) Such a diaphragm does not operate like a rolling bellows diaphragm and would not be applicable to the system of claim 25 in which much larger displacements are achieved. Use of a rolling bellows diaphragm allows the system of claim 25 to test larger valved prostheses and achieve higher system flow to facilitate better opening of the test article. (Id.)

Further, with respect to Pickard, a piston pump is disclosed to drive the disclosed system. A piston pump may be adequate for a real-time (i.e., ~1 Hz) valve performance test system. However, it has significant drawbacks in the context of an accelerated test system such as claimed in claim 25. For example, the United States Food & Drug Administration (FDA) and other regulatory agencies, require that the valved prostheses be loaded through 200,000,000 test cycles for biologic prostheses or 600,000,000 test cycles for synthetic prostheses. (Id. at ¶ 11.) This extremely high cycle requirement prohibits the use of a standard piston with seal(s) as a driver since because O-rings, cup seals, and other standard seal structures wear out before the completion of a single test run. (Id.) Further, the friction caused by the interference between the piston, seal, and chamber generate heat within the test system and additional wear on the components and driver (Id.). A rolling bellows diaphragm avoids all of these inherent problems in other drive systems in the context of a prosthetic test environment requiring large displacement and extremely high test cycles. (Id.)

For these reasons, Applicant submits that Vilendrer (alone or in combination with Pickard and/or Kruse et al.) does not disclose the system of claim 25. Further, none of the benefits of the system of claim 25 can be achieved by such Vilendrer. Applicant therefore requests that the rejection of claim 25 be withdrawn.

Claim 28 is canceled herein. Therefore, the examiner’s rejection of the same is moot.

The Applicant therefore requests reconsideration and withdrawal of the rejection of claims 1, 17, and 25 under 35 U.S.C. § 102.

Claim Rejections – 35 U.S.C. § 103

Claims 2-4, 6-8, 10-13 and 15 are rejected in the Office action pursuant to 35 U.S.C. § 103 as obvious in view of Vilendrer (US Patent No. 5,670,708) in combination with Pickard (US Patent No. 4,682,491).

Dependent claims 2-4, 6-8, 10-13 and 15 depend upon and contain all the limitations of independent claims 1 or 17 as applicable. For at least the reasons discussed above in connection with independent claims 1 and 17, the Applicant respectfully submits that dependent claims 2-4, 6-8, 10-13 and 15 are allowable. The Applicant makes this statement without waiving any independent bases for patentability in claims 2-4, 6-8, 10-13 and 15. The Applicant reserves the right to separately argue the patentability of dependent claims 2-4, 6-8, 10-13 and 15 in a subsequently filed response, if necessary.

With particular respect to claims 7 and 8, contrary to the examiner's assertion, the claimed structures of a fluid return conduit that is axially oriented along a center of the device and a return fluid conduit that telescopes are not disclosed in any of the cited references. For these additional reasons, Applicant submits that claims 7 and 8 are allowable.

With respect to claim 15, contrary to the examiner's assertion, none of the references disclose the claimed structure of a flexible rolling bellows. For this additional reason, Applicant submits that claim 15 is allowable.

Claims 18-23 are rejected under 35 USC § 103(a) as obvious in view of Vilendrer in combination with Pickard and Kruse et al. (U.S. Publication No. 2003/0235804).

Dependent claims 18-23 depend upon and contain all the limitations of independent claim 17 as applicable. For at least the reasons discussed above in connection with independent claim 17, the Applicant respectfully submits that dependent claims 18-23 are allowable. The Applicant makes this statement without waiving any independent bases for patentability in claims 18-23. The Applicant reserves the right to separately argue the patentability of dependent claims 18-23 in a subsequently filed response, if necessary.

With particular respect to claim 18, Applicant notes the basis for rejection cited by the examiner has little or no direct relationship to the claimed structure. In fact, the argument appears to be directed to the last clause of claim 17. However, the cited passage in Kruse et al. has nothing at all to do with the compliance chamber of claim 17, much less the further limitation on the compliance chamber in claim 18. Applicant therefore submits that the examiner failed to make a prima facie case of obviousness with respect to claim 18.

With particular respect to claims 22 and 23, contrary to the examiner's assertion, the cited passage in Kruse has nothing at all to do with the material or design of a compliance chamber. For this additional reason, Applicant submits that claims 22 and 23 are allowable.

Claims 24, 26, 27 and 29-31 appear to be rejected under 35 USC § 103(a) as obvious in view of Pickard in combination with Kruse et al. However, the examiner does not explicitly state this as grounds for the rejection. Applicant assumes that this is the case because the only references mentioned in the detailed statements of reasons for rejection are Pickard and Kruse et al.

Claims 26 and 29-31 are canceled herein. Therefore, the examiner's rejection of the same is moot.

Dependent claims 24 and 27 depend upon and contain all the limitations of independent claims 17 or 25 as applicable. For at least the reasons discussed above in connection with independent claims 17 and 25, the Applicant respectfully submits that dependent claims 24 and 27 are allowable. The Applicant makes this statement without waiving any independent bases for patentability in claims 24 and 27. The Applicant reserves the right to separately argue the patentability of dependent claims 24 and 27 in a subsequently filed response, if necessary.

Although claim 26 is canceled herein, because the elements thereof are incorporated into claim 25 (addressed above), Applicant makes the following further statements with respect to Pickard and Kruse et al. which form the basis of the rejection. Applicant initially notes that Pickard does not disclose a flexible diaphragm as suggested in the rejection. Pickard discloses a pump (46) that is described as a piston pump. The differences and deficiencies of a piston pump as compared to the claimed rolling bellows diaphragm (now in claim 25) are discussed above with respect to claim 25. The examiner cites a passage in Kruse et al. that refers to alternate types of pumps that could be used in the system, none of which are rolling bellows. Therefore, Applicant submits that since Pickard and Kruse et al. in combination fail to render claim 26 obvious, for the same reasons the combination thereof would not render claim 25 as amended obvious.

With respect to claim 27, Applicant submits that the argument presented by the examiner based upon the cited passage in Pickard (i.e., a motor with a square shaft that rotates a valve element to provide flow restriction) has nothing at all to do with the design of the piston and rolling bellows set forth in the claim. Further, as discussed above with respect to claim 25, Kruse et al. does not disclose a rolling bellows, but instead discloses a metal bellows, which has significant deficiencies in the context of providing clinically relevant test results as stated by Dr. Weinberg in his declaration and as discussed above with respect to claim 25. Finally, the

combination of Kruse et al. with Pickard would defeat the purpose of Pickard. As noted by Dr. Weinberg in the interview, Pickard is a real-time valve function test system with a circulatory loop while Kruse et al. is not interested in flow through the prosthetic device, but rather wants to create a high static pressure on a single side of the valve frame for the purpose of frame deformation. For these additional reasons, Applicant submits that claim 27 is allowable.

For these additional reasons, the Applicant requests reconsideration and withdrawal of the rejection of claims 24 and 27 under 35 U.S.C. § 103.

Claims Not Addressed

Applicant notes that the examiner fails to address claims 5, 9, 14, and 16 in any way in the detailed action. However, the examiner indicates on the summary sheet that each of these claims is rejected. In view of the examiner's failure to provide a detailed rationale for the rejection of these claims, Applicant submits that the examiner has failed to meet the burden for making a prima facie case of either anticipation or obviousness with respect to any of these claims. See M.P.E.P §§ 2121 & 2142. Withdrawal of the rejection for failure to meet this burden is therefore requested.

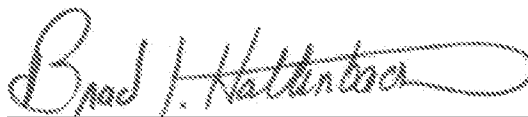
Conclusion

Claims 1-25 and 27 are currently pending in the application. Applicant has fully responded to the objections and rejections in the Office action dated 3 January 2013 and believes that claims 1-25 and 27 are in a condition for allowance. Applicant therefore requests that a timely Notice of Allowance be issued in this case.

This response is submitted within the first month following the shortened statutory period for response. Accordingly, please consider this document a petition for a one-month extension of time. The appropriate fees are paid contemporaneously herewith. Applicant believes that no additional fees or petitions beyond these noted are due with this filing. However, should any such fees or petitions be required, please consider this a request therefor and authorization to charge Deposit Account No. 04-1415 as necessary.

If the Examiner should require any additional information or amendment, please contact the undersigned attorney. If the Examiner believes any issues could be resolved via a telephone interview, the Examiner is invited to contact the undersigned at the telephone number listed below.

Respectfully submitted this 10th day of May 2013

A handwritten signature in black ink, appearing to read "Brad J. Hattenbach", written over a horizontal line.

Brad J. Hattenbach, Esq.
Registration No. 42,642
Customer No. 20686

DORSEY & WHITNEY LLP
1400 Wewatta Street
Suite 400
Denver, Colorado 80202
303-269-3400 (TEL)
303-269-3450 (FAX)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.	: 12/718,316	Confirmation No.	: 4620
First Applicant	: Benjamin McCloskey	Art Unit	: 4125
Filed	: 5 March 2010	Examiner	: Jahangir, Naeem M.
Title	: Fatigue testing system for prosthetic devices		
Docket No.	: P201384.US.02	Customer No.	: 20686

DECLARATION OF CRAIG WEINBERG, Ph.D. UNDER 37 C.F.R. § 1.132

Mail Stop Amendment
Commissioner for Patents
U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

I, CRAIG WEINBERG, having a residence at 4132 Decatur Street, Denver, Colorado 80211 and being a U.S. citizen, hereby declare as follows:

1. I am a named inventor on the patent application captioned above and am an owner and president of the assignee of the application, Biomedical Device Consultants and Laboratories of Colorado, LLC. I have held this position for over 7 years.
2. I have a Ph.D. in Mechanical/Biomedical Engineering from the University of Colorado - Boulder (2003).
3. My primary expertise is with the cardiovascular system and my research experience is focused on statistically based experimental design and analysis, cardiovascular system experimental modeling, and control system algorithm development. My doctoral thesis was in the area of ultrasound imaging, experimental fluid dynamics and flow visualization. Additional research and development experience includes vascular implants (synthetic and biologic), endovascular implants, radio-frequency tissue treatments (tissue fusion, division, and coagulation), control system logic development, and management of acute and chronic preclinical animal studies.
4. I participated in the preparation of the subject patent application captioned above and have also reviewed the pending claims in this application and the references cited by the examiner in the Office action dated 3 January 2013.
5. The examiner cites the Vilendrer reference in the Office action as disclosing a similar system as the system of claim 25 of our application. I would note particularly that the Vilendrer system employs the use of two metal bellows on each end of the system to drive the

system. The use of metal bellows is something that we intentionally avoided in the design of the system of claim 25.

6. Metal bellows technology requires a substantially increasing force during compression, once beyond the initial, relatively small displacement, to increase the bellows compression. Therefore to achieve higher flow rates through larger displacements as required for testing some larger sized valved prosthetic devices (such as tested by the claimed invention) and to ensure full opening and closing performance of the test article, one must provide a larger electromagnetic driver(s) for a metal bellows that can generate the necessary higher forces during operation. Consequently, further challenges to the test equipment result from this factor such as increased heat generation from the driver, increased operating stresses on adjacent components, and increased physical size requirements for the driver and test system.

7. In addition, metal bellows possess their own spring constant and effective mass. During cyclic, oscillatory motion the bellows therefore responds as a standard mass-spring system with a respective vibrational natural frequency and subsequent harmonic response. This characteristic can impact the operation of the test system by producing undesirable excitation of the valved test prosthesis(es) under evaluation and/or impart artificial limitations in the system operating frequency.

8. By utilizing a flexible elastomeric rolling bellows diaphragm technology as provided in claim 25, higher system flow generated by large displacements can be achieved without any need for increased force requirements to the driver beyond the loading requirements of the valved test prosthesis(es) under evaluation. No incremental load considerations are necessary for the motion of the rolling bellows. Furthermore, a flexible rolling bellows diaphragm does not possess an effective spring constant; therefore, the rolling bellows does not respond as a mass-spring system nor possess its own natural frequency. These points combine to an added benefit of requiring a smaller electromagnetic driver(s), fewer system component stresses, and no operational or frequency restrictions stemming from the prior art metal bellows component.

9. The examiner secondarily identified the system in the Kruse et al. reference as using a diaphragm to drive a prosthetic test system.. The system described in the Kruse et al. is for evaluation and testing of heart valve frames (referred to in Kruse et al. as a "valve stent") and describes a preferred embodiment that has limited to no system flow through the test article. Therefore, the Kruse et al. system does not require the large driver / diaphragm displacements since the opening and closing of the test article leaflets are not desired. The

diaphragm in the Kruse et al. system performs in a manner similar to a loudspeaker cone, with the diaphragm merely flexing inward and outward with respect to a fixed circumferential position. Such a diaphragm does not have a rolling interface along the diaphragm like a rolling bellows and would not be applicable to the system of claim 25 in which much larger displacements are achieved using the rolling bellows diaphragm. This allows the system of claim 25 to test larger valved prosthetic devices that require larger fluid volume flows.

10. Additionally, test requirements for valved endovascular prostheses, as outlined by the United States Food & Drug Administration (FDA) and all worldwide regulatory agencies, provide that the valved prosthesis(es) be loaded through 200,000,000 – 600,000,000 cycles. This extremely high cycle requirement prohibits the use of a standard piston with seal(s) as used in the Pickard reference (which is a real-time, not accelerated system) to provide a driving member, since seal technologies such as O-rings, cup seals, and others do not have an anticipated life-duration equivalent to one test run. Moreover, standard seal technologies function by interference between the seal and the piston cylinder. The amount of interference is a delicate balance of providing adequate pressure on the seal-cylinder interface to prohibit the leaking of working fluid while recognizing that the resulting pressure will create friction and require additional input force to overcome and increase the wear of the seals during operation. This friction can also generate heat in the test system and additional wear and stresses on the components and driver.

11. Since a rolling bellows diaphragm does not generate a fluid seal by an interference fit and contact between a piston and piston cylinder as with classic seals, the shortcomings of classic seals such as friction and inadequate life-span during a test run are overcome. Thus, the rolling bellows overcomes the problems of prior driver technologies used in these test systems requiring extremely high test cycles.

12. I declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that the making of willful false statements and the like are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful statements may jeopardized the validity of the application or any patent issuing thereon.

Dated: 10 May 2013

By: _____

Craig Weinberg, Ph.D.



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NOTICE OF ALLOWANCE AND FEE(S) DUE

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1400 Wewatta Street
Suite 400
DENVER, CO 80202-5549

EXAMINER

FITZGERALD, JOHN P

ART UNIT

PAPER NUMBER

2856

DATE MAILED: 09/06/2013

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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12/718,316

03/05/2010

Benjamin McCloskey

P201384.US.02

4620

TITLE OF INVENTION: FATIGUE TESTING SYSTEM FOR PROSTHETIC DEVICES

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	\$890	\$300	\$0	\$1190	12/06/2013

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: **Mail** Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or **Fax** (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

20686 7590 09/06/2013
DORSEY & WHITNEY, LLP - Denver
INTELLECTUAL PROPERTY DEPARTMENT
1400 Wewatta Street
Suite 400
DENVER, CO 80202-5549

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/718,316	03/05/2010	Benjamin McCloskey	P201384.US.02	4620

TITLE OF INVENTION: FATIGUE TESTING SYSTEM FOR PROSTHETIC DEVICES

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	\$890	\$300	\$0	\$1190	12/06/2013

EXAMINER	ART UNIT	CLASS-SUBCLASS
FITZGERALD, JOHN P	2856	073-037000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

- ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

- (1) the names of up to 3 registered patent attorneys or agents OR, alternatively,
- (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 _____
2 _____
3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

- ☐ Issue Fee
- ☐ Publication Fee (No small entity discount permitted)
- ☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above)

- ☐ A check is enclosed.
- ☐ Payment by credit card. Form PTO-2038 is attached.
- ☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)

- ☐ Applicant certifying micro entity status. See 37 CFR 1.29
- ☐ Applicant asserting small entity status. See 37 CFR 1.27
- ☐ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see form PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/718,316	03/05/2010	Benjamin McCloskey	P201384.US.02	4620

20686 7590 09/06/2013
DORSEY & WHITNEY, LLP - Denver
INTELLECTUAL PROPERTY DEPARTMENT
1400 Wewatta Street
Suite 400
DENVER, CO 80202-5549

EXAMINER

FITZGERALD, JOHN P

ART UNIT PAPER NUMBER

2856

DATE MAILED: 09/06/2013

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 572 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 572 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	Application No. 12/718,316	Applicant(s) MCCLOSKEY ET AL.	
	Examiner JOHN FITZGERALD	Art Unit 2856	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 10 May 2013.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.
2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.
3. ☒ The allowed claim(s) is/are 1-25 and 27. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

- a) ☐ All b) ☐ Some *c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|--|
| 1. ☐ Notice of References Cited (PTO-892) | 5. ☐ Examiner's Amendment/Comment |
| 2. ☒ Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date <u>5/10/13</u> | 6. ☒ Examiner's Statement of Reasons for Allowance |
| 3. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 7. ☐ Other _____. |
| 4. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____. | |

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DETAILED ACTION

Response to Arguments

1. Applicant's arguments, see pages 8-14 and Affidavit filed by the inventor, filed 10 May 2013, with respect to all pending claims have been fully considered and are persuasive. The previous rejection of all claims under the prior art has been withdrawn.

Allowable Subject Matter

2. Claims 1-25 and 27 are allowed over the Prior Art of record.

3. The following is an examiner's statement of reasons for allowance: All of the Prior art found typically only disclosed testing arrangements for simulated vascular structures, not heart valves or valved prosthetics, having all of the elements and connectivity recited in instant independent claim 1, not the disclosed chamber to perform the testing of the posthetic device, as recited in instant independent claim 17 and the pressurization system recited in instant independent claim 25, wherein accelerated testing is capable of being performed, and elastomeric rolling bellows are employed.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Primary Examiner John Fitzgerald whose telephone number is

Art Unit: 2856

(571) 272-2843. The examiner can normally be reached on Monday-Friday from 7:00 AM to 3:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Hezron Williams, can be reached on (571) 272-2208. The central fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/John Fitzgerald/
Primary Examiner, Art Unit 2856
8/30/13