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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17/650,835 - Conf. #7707
	Filing Date	February 11, 2022
	First Named Inventor	Derek Dee Deville
	Art Unit	3771
	Examiner Name	Jonathan Wade Miles
	Attorney Docket Number	145404-8001.US07
Sheet **1** of **21**		

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Sheet **2** of **21**		

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Sheet **3** of **21**		

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Sheet **4** of **21**		

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Sheet **5** of **21**		

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Sheet **6** of **21**		

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	Art Unit	3771
	Examiner Name	Jonathan Wade Miles
	Attorney Docket Number	145404-8001.US07
Sheet **10** of **21**		

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Sheet **11** of **21**		

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Sheet **12** of **21**		

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Sheet **13** of **21**		

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Sheet **14** of **21**		

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Examiner Signature		Date Considered	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17/650,835 - Conf. #7707
	Filing Date	February 11, 2022
	First Named Inventor	Derek Dee Deville
	Art Unit	3771
	Examiner Name	Jonathan Wade Miles
	Attorney Docket Number	145404-8001.US07
Sheet **18** of **21**		

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	Attorney Docket Number	145404-8001.US07
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Sheet **20** of **21**		

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Examiner Signature		Date Considered	

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	Art Unit	3771
	Examiner Name	Jonathan Wade Miles
	Attorney Docket Number	145404-8001.US07
Sheet **21** of **21**		

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (2).

☐ See attached certification statement.

☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ None. It is submitted that the Information Disclosure Statement is in compliance with 37 C.F.R. § 1.98 and the Examiner is respectfully requested to consider the listed references. This Information Disclosure Statement is not to be construed as a representation that: (i) a search has been made; (ii) additional information that may be material to the examination of this application does not exist; (iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the cited information is, or is considered to be, material to patentability. In addition, Applicant does not admit that any enclosed item of information constitutes prior art to the subject invention and specifically reserves the right to demonstrate that any such reference is not prior art.

COPIES OF REFERENCES

In accordance with 37 C.F.R. § 1.98(a)(2)(ii), Applicant has not submitted copies of U.S. patents and U.S. patent applications. Applicant submits herewith copies of foreign patents and non-patent literature in accordance with 37 C.F.R. § 1.98(a)(2). Those documents which are marked with a double asterisk (**) next to the Cite No. in the attached form PTO/SB/08 are not supplied because they were previously cited by or submitted to the Office in parent Application No. 16/899,514 filed June 11, 2020 and relied upon in this application for an earlier filing date under 35 U.S.C. § 120. In accordance with 37 C.F.R. § 1.98(d), Applicant has not provided copies of these references.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Paul T. Parker/	Date	2022-04-07
Name/Print	Paul T. Parker	Registration Number	38,264

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APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
17/650,835	**04/07/2022 11:18:34 PM ET**	**145404-8001.US07**

Title of Invention

ASPIRATION THROMBECTOMY SYSTEM AND METHODS FOR THROMBUS REMOVAL WITH ASPIRATION CATHETER

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	7707	FILED BY	Jessica Raucci
PATENT CENTER #	60611038	FILING DATE	02/11/2022
CUSTOMER #	25096	FIRST NAMED INVENTOR	Derek Dee Deville
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	Paul Parker

Documents

TOTAL DOCUMENTS: 12

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
10531883_Petition_for_IPR.pdf	87	Non Patent Literature	1075 KB
10722253_ExpertDeclaration_IANROSS_IPR.pdf	35	Non Patent Literature	1684 KB
10722253_ExpertDeclaration_BRIANBROWN_IPR.pdf	181	Non Patent Literature	4280 KB
10531883_Decision_IPR.pdf	53	Non Patent Literature	482 KB
WO2020023541A1.pdf	65	Foreign Reference	3106 KB

10531883_ExpertDeclaration_IANROSS_IPRa.pdf		35	Non Patent Literature	7100 KB
10531883_ExpertDeclaration_BRIANBROWN_IPRb.pdf		174	Non Patent Literature	2253 KB
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2022-04-07_PAM_1454048001US07-CLM.pdf	(2-6)	5	Claims	29 KB
2022-04-07_PAM_1454048001US07-REM.pdf	(7-7)	1	Applicant Arguments/Remarks Made in an Amendment	15 KB

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New International Application Filed with the USPTO as a Receiving Office

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(71) Applicant: **PENUMBRA, INC.** [—/US]; One Penumbra Place, Alameda, California 94502 (US).

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(54) Title: APPARATUS AND METHODS FOR CONTROLLED CLOT ASPIRATION

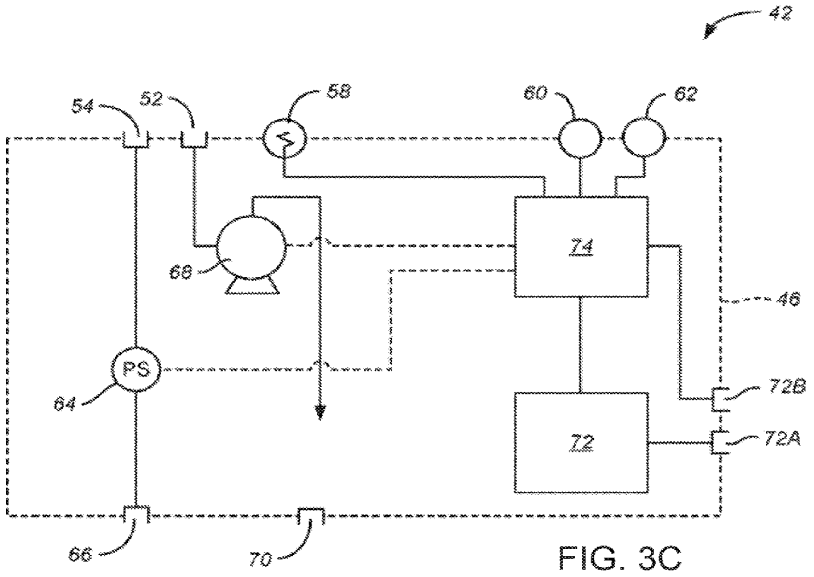

FIG. 3C

(57) Abstract: A vacuum aspiration control system for use with a vacuum source and an aspiration catheter includes a connecting tube configured to connect the vacuum source with a lumen of an aspiration catheter. An on-off valve is operatively coupled to the connecting tube, and a sensing unit is configured to detect flow within the connecting tube and provide a signal representative of flow. A controller receives the signal to decide whether to open or close the valve. The controller may automatically close the valve to stop flow when flow through the connecting tube is unrestricted, or according to a predetermined timing sequence. The controller can further periodically open a closed valve to determine whether flow has entered an acceptable range. The controller can still further engage pulsed aspiration with a pressure manipulation assembly when flow is restricted or occluded.

[Continued on next page]

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APPARATUS AND METHODS FOR CONTROLLED CLOT ASPIRATION

CROSS-REFERENCE TO RELATED APPLICATIONS

[001] This application claims the benefit of US Provisional No. 62/778,708 (Attorney Docket No. 41507-730.102), filed December 12, 2018, and of US Provisional No. 62/702,804 (Attorney Docket No. 41507-730.101), filed July 24, 2018, the entire contents of which are incorporated herein by reference.

BACKGROUND OF THE INVENTION

[002] 1. Field of the Invention. The present invention relates generally to the field of medical devices and methods. More specifically, the invention described herein relates to devices and methods for controlling clot removal from a patient's vasculature by aspiration thrombectomy.

[003] Stroke is a significant cause of disability and death, and a growing problem for global healthcare. More than 700,000 people in the United States alone suffer a stroke each year, and of these, more than 150,000 people die. Of those who survive a stroke, roughly 90% will suffer long term impairment of movement, sensation, memory, or reasoning, ranging from mild to severe. The total cost to the U.S. healthcare system is estimated to be over $50 billion per year.

[004] Stroke may be caused by a blockage in a cerebral artery resulting from a thromboembolism (referred to as an "ischemic stroke"), or by a rupture of a cerebral artery (referred to as a "hemorrhagic stroke"). Hemorrhagic stroke results in bleeding within the skull, limiting blood supply to brain cells, and placing harmful pressure on delicate brain tissue. Blood loss, swelling, herniation of brain tissue, and pooling of blood that results in formation of clot mass inside the skull all rapidly destroy brain tissue. Hemorrhagic stroke is a life-threatening medical emergency with limited treatment options.

[005] Aside from cerebral stroke, thromboembolism throughout the vasculature, in both arterial and venous circulation, is characteristic of numerous common, life-threatening conditions. Examples of potentially fatal diseases resulting from thrombotic occlusion include pulmonary embolism, deep vein thrombosis, and acute limb ischemia. Acute pulmonary embolism is a significant cause of death in the United States, with roughly 300,000 patients dying each year. Pulmonary embolism can be a complication from deep vein thrombosis, which has an annual incidence of 1% in patients 60 years and older. All of the

Penumbra, Inc., Ex. 1004, Page 164 of 394
Penumbra, Inc. v. RapidPulse, Inc.

aforementioned diseases are examples of conditions in which treatment may include aspiration or evacuation of clot and/or blood.

[006] Of particular interest to the present invention, the Penumbra System® mechanical thrombectomy system is a fully-integrated system designed specifically for mechanical thrombectomy by aspiration. It is intended for revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusion. A comparable system designed for the peripheral and coronary vasculature, the Indigo® System is also a mechanical thrombectomy aspiration system, designed for revascularization of patients with thrombotic occlusion of the peripheral vasculature. Both the Penumbra System and the Indigo System are commercially available at the time of filing the present provisional patent application and include aspiration or reperfusion catheters, aspiration tubing, other accessories, and an aspiration pump (sold under the tradename: Pump MAX™ aspiration pump or Penumbra Engine™ aspiration pump) for connection to the aspiration tubing and aspiration catheters. As illustrated in Fig. 1, the Pump MAX™ aspiration pump 10 includes a base unit 12 which encloses a vacuum pump (not shown) which operates off line voltage. The base unit has an on-off switch 14 and a separate knob 16 for adjusting the level of vacuum provided by the pump. The vacuum level can be read on a pressure gauge 18. Blood and clot are drawn into a collection canister 20 from an aspiration tube 22 (shown in broken line) which is connected to a reperfusion catheter (not illustrated) which has been introduced to the vasculature of a patient to aspirate clot. The blood and clot are drawn into the collection canister by a partial vacuum which is provided by a vacuum connector 28 on the base unit 12 which is connected to the vacuum pump, not shown. The vacuum from vacuum connector 28 is applied to a vacuum port 24 on a removable lid 26. The vacuum connector 28 is connected to the vacuum port 24 by an external vacuum tube 30.

[007] Although very effective, clot aspiration using the Indigo System mechanical thrombectomy apparatus or other similar vacuum-assisted thrombectomy systems must sometimes be terminated due to the risk of excessive blood loss by the patient, especially when using large aspiration catheters. During aspiration thrombectomy, when the catheter tip falls out of contact with the thrombus or other occlusive material, the tip is exposed to healthy blood and full flow ensues. Under such conditions, the blood loss rate is excessive, and in some cases, may result in premature termination of the procedure. In one example, during a procedure when the catheter enters healthy blood and full flow ensues, the blood loss rate is in the range of 20-25 cc per second with an 8 French size catheter. With a maximum tolerable blood loss of 300-1000 mL, the catheter cannot run in unrestricted mode for more

Penumbra, Inc., Ex. 1004, Page 165 of 394
Penumbra, Inc. v. RapidPulse, Inc.

than approximately 20 to 50 seconds. When a physician operates the system manually, the aggregate blood loss may reach an unacceptable level before sufficient clot is removed. In addition, reliably identifying whether the tip of the catheter is in contact with clot or is undesirably aspirating healthy, clot-free blood is a significant problem, and such manual control is not optimum.

[008] During other procedures using the Penumbra System, such as, for example, neurovascular procedures for treatment of ischemic stroke, excessive removal of blood is less of a risk, and the primary focus of the procedure is maximization of removal of occlusive material. Optimizing both technique and aspiration control are of upmost importance for successful removal of occlusive material.

[009] Therefore, it would be desirable to provide improved methods and apparatus for controlling the aspiration of thrombus and clot using aspiration catheters in combination with pumping consoles. It would be particularly useful to provide systems and methods which limit blood loss during such aspiration procedures such as by automatically stopping aspiration while the aspiration catheter is not in contact with clot or thrombus. Additionally, it would be desirable to provide systems and methods which optimize system performance, and procedures for removal of occlusive material. At least some of these objectives will be met by the inventions described herein below.

[0010] 2. Description of the Background Art. The Penumbra System® as it is commercially available at the time of filing this provisional patent application is described in a brochure entitled "Science of Aspiration: The Penumbra System® Approach." Relevant patents and patent publications include: US4574812; US5624394; US6019728; US6283719; US6358225; S6599277; US6689089; US6719717; US6830577; US8246580; US8398582; US8465467; US8668665; US9248221; US 2003/0050619; US2010/094201; US2014/323906; US2014/276920; US2016/0220741; US2017/0238950; US2017/049470; WO2014/151209; and WO2010/045178.

SUMMARY OF THE INVENTION

[0011] The present invention provides systems and methods that improve catheter aspiration by enabling a longer procedure, by enhancing the ingestion of occlusive material, or both. In some examples, the amount of fluid flowing through an aspiration catheter under vacuum aspiration is monitored to determine whether the flow is unrestricted, restricted, or clogged. Depending on the determined flow state, the present invention may employ different techniques and methods to improve catheter aspiration. In one example, unrestricted flow is

Penumbra, Inc., Ex. 1004, Page 166 of 394
Penumbra, Inc. v. RapidPulse, Inc.

detected, and aspiration is automatically and temporarily restricted for blood saving purposes. This may beneficially prolong the time available to perform the procedure and thereby allow more complete removal of occlusive material. In another example, restricted flow is detected, and full vacuum aspiration is automatically applied. In yet another example, a clogged catheter is detected, and pulsed aspiration is automatically applied. This may beneficially enhance the ingestion of large, tough, or otherwise troublesome occlusions. Alternatively, pulsed aspiration, full aspiration, or restricted aspiration may be applied on demand by a user of the present invention.

[0012] In one example, the systems and methods of the present invention address the problem of excessive blood loss through dynamic aspiration cycling. The nature and flowability of the material being withdrawn by the aspiration catheter is monitored so that the system can either allow continuous aspiration when in clot, or sampling of extraction rate to determine whether the tip of the catheter is in contact with clot, in order to reduce the risk of excess blood loss. While determining and monitoring of blood flow rate is disclosed in the exemplary embodiments below, other measurements of the flowability and/or structural composition of the aspiration effluent, such as monitoring the collection chamber's volume, monitoring the collection chamber's fill rate, visually monitoring the aspiration tubing (clot is darker than fresh blood), or placing a strain gauge on aspiration tubing, could also be used.

[0013] The systems and methods of the present invention may respond to variations in flow rate, pressure, differential pressure, or other indicators of the composition of the material inside or adjacent to an aspiration catheter in a sub-second time frame to limit the unnecessary aspiration of blood during a thrombectomy procedure. The present invention may be useful with any thrombectomy, embolectomy, atherectomy, or other catheter or probe system where blood and clot are withdrawn wholly or partially by application of a vacuum to the proximal end of any reperfusion, aspiration catheter or probe for the purpose of clot extraction.

[0014] In a first aspect, the present invention provides a vacuum aspiration control system for use with a vacuum source and an aspiration catheter. The system comprises a flexible connecting tube, an on-off valve, a sensing unit, and a controller. The connecting tube is linear in an unconstrained configuration and is configured to connect the vacuum source to an aspiration lumen in the aspiration catheter. The on-off valve is configured to be operatively connected to the connecting tube, and the sensing unit is configured to determine flow rate within the connecting tube and to produce a signal representative of such flow, typically as either unrestricted flow, restricted flow, or clogged. The controller is connected

Penumbra, Inc., Ex. 1004, Page 167 of 394
Penumbra, Inc. v. RapidPulse, Inc.

to receive the signal representative of flow through the connecting tube and to open and close one or more on-off valve(s) in response to the signal. In one example, the controller is configured to automatically close the on-off valve to stop flow through the connecting tube when the signal indicates unrestricted flow, e.g. that primarily healthy blood or blood free of vessel-obstructing clot is flowing through the connecting tube and/or that the catheter is substantially free from contact with clot or other occlusive material. In another example, the controller is configured to initiate pulsed aspiration when the signal indicates a clog, which may be caused by some occlusive material in or adjacent to the catheter or connecting tubing.

[0015] The controller is typically further configured to automatically open the on-off valve at a predetermined interval to sample effluent material through the connecting tube and the valve will typically only remain open if the signal indicates a return to clot. The controller algorithm is capable of deciphering the difference between healthy blood and clot independent of aspiration source and the inner diameter of the attached catheter.

[0016] The sensing unit may comprise any one or more of a variety of sensors, including differential pressure sensors, acoustic (including ultrasonic) flow sensors, optical flow sensors, thermal flow sensors, magnetic flow sensors, sensors which detect circumferential expansion of the connecting tube, and the like. While differential pressures are described in more detail below, it will be appreciated that any sensing unit capable of detecting when flow or extraction rate through the connecting tube is excessive and/or clogged, would be suitable for use in the present invention.

[0017] In exemplary embodiments, the sensing unit comprises a pair of pressure sensors at spaced-apart locations along the connecting tube to measure differential pressure. The controller can calculate flow based on the differential pressure and, from this, determine whether the calculated flow rate indicates unrestricted flow, restricted flow, or a clog.

[0018] In another embodiment, the sensing unit uses optical sensors that measure transmission, absorption, or both of light to characterize the contents flowing through the connecting tube. In one such example, visible light is used determine whether flow contains clot or is primarily clot-free. Typically, flow with clot is darker, which is detectable by optical sensors. Alternatively, the optical sensors may infrared, ultraviolet, visible light, or some such combination to analyze contents within the connecting tubing.

[0019] In another embodiment, the sensing unit uses circumferential expansion sensors to determine the contents flowing through the connecting tube. The internal pressure of the connecting tubing and the contents flowing through it effect the circumference of the connecting tubing. Under strong vacuum, such as during a clog, the tubing may maximally

Penumbra, Inc., Ex. 1004, Page 168 of 394
Penumbra, Inc. v. RapidPulse, Inc.

contract. During high flow of primarily clot-free blood, the tubing may contract only slightly. During restricted flow, the clots and blood may cause a relative expansion of the connecting tubing.

[0020] The on-off valve may also take a variety of specific forms. Typically, regardless of form, the on-off valve will comprise an actuator, such as a solenoid actuator, that is powered to open the valve. The valve itself may take a variety of forms, including a pinch valve, an angle valve, or any one of a variety of other valves that provide actuation. Alternatively, the manual on-off valve may be provided that allows a user to initiate and/or terminate functions and features of the present invention.

[0021] In further exemplary embodiments, the controller may be configured to open the valve and hold the valve open until a flow pattern which indicates unrestricted flow is detected whereupon the controller closes the valve. The controller may be further configured to automatically re-open the on-off valve. For example, in what may be referred to as "sampling mode", the controller may be further configured to periodically sample, or test flow to re-characterize flow and determine if it is safe to recommence aspiration. For example, the controller may periodically test flow by opening the on-off valve for a fixed time interval, in one embodiment 150 milliseconds, to establish a "test" flow. The test flow is characterized and, if it so indicates, the on-off valve may be reopened into a "treatment" mode to allow continued aspiration treatment. If the system characterizes the flow as unrestricted, e.g. excessive, then the system will dwell in a closed configuration for a fixed time interval, in one embodiment between a quarter second and two seconds, before an additional pressure differential sample is taken.

[0022] In other instances, however, the controller may not be configured to automatically reestablish flow when safe conditions have been reached. For example, the controller may be configured to allow a user to reposition the aspiration catheter and, after repositioning, manually open the on-off valve (typically by actuating a switch which causes the controller to open the on-off valve) to resume aspiration treatment. In such instances, the controller may immediately return to the "sampling mode," however, and if the reestablished flow is characterized as unrestricted flow, the controller will again close the on-off valve, and the user can again reposition the aspiration catheter in order to engage clot and manually resume aspiration. Such systems will typically provide a manual switch which allows the user to manually open the on-off valve.

[0023] The controller may be configured to control two or more valves. In one example, the controller controls a first on-off valve between an aspiration catheter and a vacuum source

Penumbra, Inc., Ex. 1004, Page 169 of 394
Penumbra, Inc. v. RapidPulse, Inc.

and a second on-off valve between an aspiration catheter and a pressure source with a pressure at least above that of the vacuum source. The controller may alternate between opening the first on-off valve and the second on-off valve to generate pressure variations within an aspiration catheter or tubing adjacent to such a catheter. The controller may sample flow while the first on-off valve is opened to determine whether an attached catheter is still positioned in clot or otherwise occluded. The controller may hold the first on-off valve open and the second on-off valve closed if no occlusions or clogs are detected.

[0024] In specific embodiments, the vacuum aspiration systems of the present invention comprise a base unit which incorporates at least one on-off valve and the controller. The base unit will typically be configured to be mounted directly on or near a vacuum pump or console and will usually include a connecting cable in order to receive power from the vacuum console or line and optionally exchange information with the controller and the vacuum console. The connecting tube typically has a proximal end configured to connect the vacuum source and distal end configured to connect to the aspiration catheter. In such instances, the vacuum aspiration system will typically further comprise an external unit configured to be secured to the connecting tube at a location between the distal end and the proximal end thereof. Exemplary external units comprise at least a portion of the sensing unit. For example, the sensing unit may comprise a first pressure sensor in the base unit and a second pressure sensor in the external unit. In those instances, the controller will typically be configured to determine if a differential pressure exists based on the signals from the first and the second pressure sensor.

[0025] In a second aspect, the present invention provides a vacuum aspiration method. The vacuum aspiration method comprises engaging a distal end of an aspiration catheter against an occlusion in the blood vessel. A vacuum is applied through an aspiration lumen of the aspiration catheter using a vacuum source coupled to a proximal end of the aspiration lumen by a connecting tube. In this way, portions of clot and other occlusive material may be drawn into the aspiration lumen, through the connecting tube, and into a collection receptacle by the vacuum source. Flow through the connecting tube is sensed, and a valve is automatically closed to stop flow through the connecting tube when the sensed flow exceeds a determined value while the vacuum source remains on. Flow through the connecting tube will be later reestablished by opening the valve, and the steps are repeated until a desired amount of clot has been aspirated.

[0026] In a third aspect, the present invention provides an assembly for generating pressure differentials that may result in pressure pulses to execute an extraction cycle. The

Penumbra, Inc., Ex. 1004, Page 170 of 394
Penumbra, Inc. v. RapidPulse, Inc.

assembly may include a fluid injection apparatus, a mechanical displacement apparatus, gravity induced pressure head, or a combination thereof. A fluid injection apparatus may provide a source of relative positive pressure for a catheter currently or previously under vacuum aspiration. For instance, the fluid may be at a pressure above that of the vacuum aspiration system, between full vacuum pressure and ambient pressure, at ambient pressure, between ambient pressure and systolic pressure, at systolic pressure, or above systolic pressure. The fluid injection apparatus may utilize an aperture, a valve, a pump, a pressure chamber, or some such combination. A mechanical displacement apparatus may physically displace the volume of a catheter system to provide relative increases and decreases of pressure depending on the direction of displacement. In one example, a mechanical displacement assembly assists vacuum recovery after a catheter has had its pressure increased above the pressure of the vacuum source.

[0027] In some embodiments of the present invention, the controller includes an algorithm that is used to interpret pressure sensor signals to determine whether the contents flowing through a catheter should be characterized as unrestricted, restricted, or clogged. Generally, unrestricted flow is a high flow that may be characterized as excessive and may be primarily or completely comprised of healthy blood, clot-free blood, or blood free of vessel-obstructing clot that is not helpful to aspirate, restricted flow may be comprised of a mix of healthy blood and clot or other occlusive material, and a clog may be caused by a clot or other occlusive material within an aspiration catheter, partially within an aspiration catheter, adjacent to an aspiration catheter, or in other connecting tubing attached to the aspiration catheter. In some examples, healthy blood is blood with a low enough proportion of cross-linked fibrin such that it is not sufficiently integrated to cause ischemia or other similar vessel occlusions. When the algorithm detects unrestricted flow, it may cause the system to initiate a sampling mode. When the algorithm detects restricted flow, it may cause the system to enable full vacuum aspiration. When the algorithm detects a clog, it may cause the system to generate a variety of pressure pulses with an extraction cycle. The algorithm may be responsive and adaptable to changing circumstances, such as changing to a catheter of a different size mid-procedure. The algorithm may adjust sampling modes and pressure pulse magnitudes if the catheter state remains static, changes too quickly, changes to slowly, or improves as expected.

[0028] In specific aspects of the method, the present invention may remove clot and other occlusive material from a blood vessel that comprises a vein or an artery. Sensing of flow may comprise one or more of differential pressure measurement, acoustic flow measurement,

Penumbra, Inc., Ex. 1004, Page 171 of 394
Penumbra, Inc. v. RapidPulse, Inc.

optical flow measurement, thermal flow measurement, measurement of circumferential expansion of the connecting tube, and the like.

[0029] In preferred aspects of the method, sensing flow comprises measuring the differential pressure using a first sensor located proximate the vacuum source and a second sensor located on or adjacent the connecting tube between the vacuum source and the aspiration catheter.

[0030] In still further embodiments of the method, the resuming flow through the connecting tube comprises opening the valve for a sub-second interval, detecting when the sensed flow is characterized as acceptable, and automatically resuming flow. Automatically resuming flow typically comprises automatically detecting when the sensed flow can be characterized as acceptable and the valve remains open as long as the flow is so characterized. Alternatively, resuming flow may comprise manually opening the on-off valve.

[0031] In further embodiments of the method, pressure differentials are generated by closing a valve to a vacuum pump, opening a valve to a source of pressure, wherein the pressure is at least above that of the vacuum, and then re-opening the valve to the vacuum pump. Alternatively, or in combination, pressure differentials are generated by mechanical displacement, wherein a volume of a chamber is reduced to increase pressure within a catheter and a volume of the chamber is increased to decreases pressure within a catheter, whereby the actuation of the mechanical displacement chamber results in pressure differentials. The pressure differentials may be tailored to have a specific or dynamic amplitude and frequency that facilitates the removal of clot or other occlusive materials.

BRIEF DESCRIPTION OF THE DRAWINGS

[0032] Fig. 1 illustrates the vacuum console and collection canister of the Penumbra System® mechanical thrombectomy system as described in detail in the Background of the Invention above.

[0033] Fig. 2 is a perspective view of a vacuum console and a blood and clot collection canister with the collection canister received in a mounting region of the vacuum console.

[0034] Fig. 3A is a view of the vacuum console of shown with the collection canister removed.

[0035] Fig. 3B is a detailed view of the on-off switch and a vacuum display region on a top surface of the vacuum console of Fig. 3, shown with the power off.

Penumbra, Inc., Ex. 1004, Page 172 of 394
Penumbra, Inc. v. RapidPulse, Inc.

[0036] Fig. 3C is a schematic representation of the internal components of the vacuum console of Figs. 1 to 3A.

[0037] Fig. 4 illustrates a collection canister.

[0038] Fig. 5 illustrates the embodiment of the collection canister of Fig. 4, shown in an inverted or "upside down" view.

[0039] Fig. 6 is an exploded view of the vacuum canister of Figs. 4 and 5.

[0040] Figs. 7A and 7B illustrate a vacuum console and collection canister, similar to those illustrated previously, having a vacuum aspiration control system attached thereto.

[0041] Figs. 8A and 8B illustrate an external unit of the type suitable for use with the present invention.

[0042] Fig. 9 illustrates an exemplary base unit enclosing an on-off valve and a controller of the type suitable for use in the vacuum aspiration control system, shown in section.

[0043] Fig. 10 illustrates an exemplary external unit showing internal components including a fitting and a pressure sensor, shown in phantom.

[0044] Fig. 11 illustrates an angle valve of the type which may be used as on-off valve in the present invention, shown in section.

[0045] Fig. 12 is an isometric view of an angle valve connected to a coiled tube having pressure sensors at each end thereof mounted on a canister top.

[0046] Fig. 13 illustrates an example of an algorithm suitable for use with the present invention.

[0047] Figs. 14 - 18 illustrate exemplary pulsed fluid injection assemblies suitable for use in the present invention.

[0048] Fig. 19 illustrates a mechanical displacement assembly for manipulating pressure with the present invention.

[0049] Fig. 20 illustrates a graphical representation of one embodiment of pulsed aspiration, where catheter internal pressure is varied over time.

DETAILED DESCRIPTION OF THE INVENTION

[0050] Some embodiments of the inventions of the present application are described below. For clarity, not all features of each actual implementation are described in this specification. In the development of an actual device, some modifications may be made that result in an embodiment that still falls within the scope of the invention.

[0051] Referring to Figs. 2-6, a vacuum system 40 of the type useful with the apparatus and methods for controlled clot aspiration of the present invention will be described. The

Penumbra, Inc., Ex. 1004, Page 173 of 394
Penumbra, Inc. v. RapidPulse, Inc.

vacuum system 40 includes a vacuum console 42 and a blood/clot collection canister 44. The vacuum console 42 comprises an enclosure having a recess 48 which is shaped to removably receive the collection canister 44 as will be described in more detail below.

[0052] Referring to Figs. 3A-3C, the vacuum console 42 is shown with the vacuum canister 44 removed. A post 50 which forms a contiguous portion of the outer surface or wall of the enclosure 46 is formed within the recess 48 and extends upwardly from a bottom plate 56 which acts as a support for the collection canister 44 when it is received within the recess. A vacuum connector 52 and a pressure sensing connector 54 are formed in or on an upper surface of the post 50 and are located so that they will align with a pressure sensing port 104 and a vacuum port 102 (Fig. 5) on the vacuum canister 44 when it is received within the recess 48. One light 58 is located on a wall surface of the enclosure 44 within the recess 48 and is located so that it will illuminate the contents of the collection canister 44 when the system is in use. A second light (not visible in in Fig. 3A) is present on the opposite wall of the recess 48. The vacuum console 42 also has an on-off switch 60 on its upper surface. The on-off switch 60 illuminates when it is on (as shown in Figs. 2 and 3A) and is not illuminated when the system is off (Fig. 3B). Additionally, a pressure display 62 is provided on the upper surface of the enclosure 46. As shown in Figs. 2 and 3A, the display may be a circular light, e.g. having four segments which are sequentially illuminated as the vacuum level within the canister increases. Each quadrant represents the measured vacuum as a percentage of ambient pressure.

[0053] The internal components of the vacuum console 42 are schematically illustrated in Fig. 3C. The primary internal components of the vacuum console include a pressure sensor 64, a pump 68, a power supply 72, and a microprocessor controller 74. The pump 68 has an inlet connected to the vacuum connector 52 on the post 50 of the enclosure 46. Similarly, the pressure sensor 64 is connected to the pressure sensing connector 54 on the post 50. The pump can be turned on by the switch 60 and will draw vacuum through the connector 52 and release removed gas into an interior of the console. The console in turn is vented by a vent 70 on a bottom surface of the enclosure 46.

[0054] The functions of the pump will be controlled by the microprocessor controller 74, and the pressure output from sensor 64 will also go through the microprocessor controller 74. Each of the light 58, switch 60, and display 62 will be connected to the microprocessor controller 74 which is powered by the power supply 72. The power supply 72 is powered through line current connector 72A. The USB connector 72B is powered by microprocessor controller 74. The pump is plugged into an outlet via a power cord that is supplied with the

Penumbra, Inc., Ex. 1004, Page 174 of 394
Penumbra, Inc. v. RapidPulse, Inc.

pump. The power supply converts the AC current from the wall outlet to DC current which is what the microprocessor controller uses to power the pump, switch, lights, USB connector, etc.

[0055] In specific examples, pressure sensor 64 is connected to the microprocessor controller 74 and measures vacuum pressure in the canister through the pressure sensing connector 54. A second pressure sensor (not shown) is also connected to the microprocessor controller 74 and measures ambient pressure outside of the pump enclosure through an internal tube that is routed to a vent in the base of the pump. The microprocessor controller takes the vacuum pressure reading from the pressure sensor 64 and divides it by the ambient pressure reading from the second pressure sensor to calculate the vacuum pressure in the canister as a percent of ambient pressure.

[0056] Referring now to Figs. 4-6, the collection canister 44 has a main body 78 which is typically formed from a polished, clear plastic material which is molded into the illustrated shape. The main body 78 has an open upper end 76 which can be covered by a removable clear plastic lid 80. The clear plastic lid 80 is typically attached by a bayonet connector 82, and a form or other gasket 84 will seal the lid to the open end of the main body 78.

[0057] A groove 94 is formed in one side of the main body 78 and is shaped so that it can be placed over the post 50 in the recess 48 of the enclosure 46 of the vacuum console 42. As best seen in Fig. 5, the pressure sensing port 104 and the vacuum port 102 are located at the upper end of the groove 94 so that they align and connect with the vacuum connector 52 and pressure sensing connector 54 on the post 50 when the canister 44 is in place in the recess 48.

[0058] The pressure sensing port 104 is connected to a tube or lumen which extends upwardly in the main body 48 of the canister 44 and terminates in an upper opening or aperture 106. Similarly, the vacuum port 102 extends upwardly through a much larger lumen or tube and terminates in an open aperture 108 at its upper end. The apertures 106 and 108 are located near the top of the interior of the main body 78 but will be below the bottom of the lid 80 when the lid is in place on the canister 44. Thus, both of the apertures 106 and 108 will be exposed to the interior of the canister 44 but will be maintained well above the mid-section and bottom where the clot and blood are collecting. In this way, the risk of contamination from blood and clot is minimized.

[0059] A filter plate 86, shown as a perforated screen but which could also be a woven screen or other separating member, is held in the mid-section of the interior of the main body 78 of the canister 44. The clot is drawn into the interior of the canister through a connector 110 which is attached to a proximal end of the catheter or other tubing. The clot and blood

Penumbra, Inc., Ex. 1004, Page 175 of 394
Penumbra, Inc. v. RapidPulse, Inc.

are drawn into the interior of the main body 78 by the vacuum which is drawn through the vacuum port 102 by the vacuum console 42, as previously described. As the clot and blood fall downwardly from connector 110 into the canister 44, the clot collects on the upper surface of the filter plate 86 while the blood flows through the perforations in the plate and collects in the bottom of the canister. As the plate is inclined downwardly from a sleeve 88 which is mounted on a post 90 in the interior of the canister, excess blood may flow over an open bypass region 100 (Fig. 4) which is formed on a backside of the plate and allows the blood to flow directly down to the bottom of the canister. Filter body 92 occupies the interior of post 90 and aperture 108 and prevents extracted material from contaminating the interior of enclosure 42. Filter body 92 occupies the interior of post 90 and extends to aperture 108. The filter body can thus prevent extracted material from contaminating the interior of enclosure 42. A groove 94 is formed on a side of the main body 78 of the canister 44 and is received over the post 50 in the recess 48 of the enclosure 46 in order to align the vacuum and pressure sensing connectors and vacuum ports. A gasket 96 is further provided at the seal between the vacuum ports and the vacuum connectors.

[0060] While the exemplary apparatus and methods for controlled clot aspiration described in Figs. 7-19 may be used with the vacuum system 40, as just described, it will be appreciated that the inventions described and claimed herein are not limited to use with any particular vacuum console and instead are useful with any clot or other vascular thrombectomy or aspiration system including a thrombectomy or other vascular aspiration catheter in combination with a vacuum pump or other source where there is a risk of excess blood aspiration, clogging, or both.

[0061] Figures 7A and 7B illustrate one example of an exemplary system 200 for performing controlled clot aspiration in accordance with the principles of the present invention comprises a base unit 210 and an external unit 204. A proximal end of a connecting tube 206 is connected to the base unit 210, and the external unit is secured on or to the connecting tube at a location spaced apart from the proximal end, typically by some distance sufficient to make conclusions about flow. The external unit 204 may be configured to connect directly to a hub or other proximal end of an aspiration catheter or may be configured to be connected in the middle of the connecting tube. The connecting tube is linear in an unconstrained configuration and flexible along its length.

[0062] The base unit 210 may be configured to sit directly atop the lid 26 on the collection canister 44 of the previously described vacuum console 40. Typically, a communication cable extends from the base unit 210 through a portion of connecting tubing

Penumbra, Inc., Ex. 1004, Page 176 of 394
Penumbra, Inc. v. RapidPulse, Inc.

206 to a connection receptacle on the vacuum console 40 so that the base unit may be powered by the vacuum console and optionally can communicate data with the controller within the vacuum console.

[0063] As shown in Fig. 7B, an external unit 204a may include a switch for initiating treatment using the vacuum console 40 and controlled clot aspiration system 200. The switch may also turn off the system, thereby providing a manual override of the algorithm that ensures the system is off with no flow. When the switch is on, the system may immediately enter an algorithm mode where it decides to remain open, enter a sampling mode, or initiate an extraction cycle in response to pressure sensor readings. Further details of the external unit 204a are shown in Figs. 8A and 8B.

[0064] Referring now to Fig. 9, an exemplary base unit 200b may comprise a base unit enclosure 216 having an open interior cavity 218 which receives a number of components. For example, a controller 220, typically including a microprocessor on a printed circuit board, may be mounted within the cavity 218 together with a pressure sensor 224 secured between a tube segment 228 and a proximal end on the connecting tube 206 by a pressure fitting 226. The tube segment 232 may be collapsible and positioned in a pinch valve 228 which is driven by a solenoid 230. Pinch valve 228 may be biased into a closed position by a compressive spring (not visible), unless it is opened by solenoid 230. The base unit 200b further includes a connecting fitting 222 which is configured to be removably secured to a vacuum fitting (not shown) on the lid 26 of the canister 44. The controller 220 is configured to open and close the pinch valve 228 to allow and prevent, respectively, the flow of clot and blood through the tubing segment 232 from the aspiration catheter into the collection canister. Optionally, base unit 200b may include a button (not pictured) in electronic communication with printed circuit board 220, for advanced user control of various parameters of the system. In further embodiments, a base unit of the present invention may house or be in communication with a pressure chamber, a fluid source, additional on-off valves, or some such combination.

[0065] Referring now to Fig. 10, an exemplary external unit 204 includes an external unit enclosure 240 having a flow fitting 242 in an interior cavity thereof. The flow fitting 242 may be connected to portions 206a and 206b of the connecting tubing 206, as shown for example in Figs. 7B, 8A and 8B. A second pressure sensor 246 may be mounted on a printed circuit board 248 and also within an internal cavity of the enclosure 240, and the output of the pressure sensor may be delivered to the controller 220 via a connective cable (not shown) which may be connected via a signal/power connector 250 and a mating signal-power connector 252, which may be a conventional USB port and plug. The connecting cable 206

Penumbra, Inc., Ex. 1004, Page 177 of 394
Penumbra, Inc. v. RapidPulse, Inc.

may have dual lumens, as shown for example in Fig. 9, where one of the lumens can be used to route a communications cable between the external unit and the base unit, while the other lumen accommodates fluid flow. In further embodiments, an external unit of the present invention may house or be in communication with a pressure chamber, a fluid source, additional on-off valves, or some such combination.

[0066] By providing a first pressure sensor 224 in the base unit and a second, axially separated pressure sensor 246 in the external unit 240, the material flow rate through the connecting tube can be calculated based upon measured differential pressure by the controller. The controller may analyze the pressure differentials and flow rate to determine the contents flowing through the aspiration catheter, connective tubing, or both.

[0067] In an exemplary embodiment, the controller characterizes the state of a catheter's contents as unrestricted flow, restricted flow, or clogged. In one example, a high pressure differential between spaced-apart pressure sensors indicates unrestricted flow that may be comprised of primarily healthy, clot-free blood, or blood free of vessel-obstructing clot. In some examples, healthy blood is blood with a low enough proportion of cross-linked fibrin such that it is not sufficiently integrated to cause ischemia or other similar vessel occlusions. Aspirating such healthy blood with full aspiration may result in excessive blood loss that may require the premature termination of the aspiration procedure. In another example, a variable and intermediate or low pressure differential indicates restricted flow that may be comprised of clot, occlusive material, and blood. Such flow may benefit from full aspiration. In another example, a small pressure differential or a pressure differential approaching zero indicates a clog. Such flow, or lack thereof, may benefit from an extraction cycle. The use of differential pressure for detecting increased flow and occlusions, however, is exemplary and other flow measurement and material property measurement techniques will be available within the scope of the present invention.

[0068] Referring now to Fig. 11, instead of the pinch valve 228 shown in the base unit 200, an angle valve 260 may be employed. The angle valve has a connector 262 for being secured to a connector on the vacuum canister (not illustrated) as well as a fitting 266 that may be connected to the connecting tubing 206 which is in turn connected to the aspiration catheter. A solenoid 268 is typically present to open and close valve stem 270 and valve seat 272. In one example, the valves of the present invention open to permit aspiration and close to block aspiration. Alternatively, the valves of the present invention may open to allow fluid to enter the aspiration tubing and/or aspiration catheter and close to block the fluid.

Penumbra, Inc., Ex. 1004, Page 178 of 394
Penumbra, Inc. v. RapidPulse, Inc.

[0069] Referring now to Fig. 12, the pressure sensors may be integrated into a single base unit 276 which may be fixedly attached to a canister cap 278. In this example, a first pressure sensor 282 and a second pressure sensor 284 are attached to opposite ends of a coiled flow tube 280 so that differential pressure may be measured. An angled valve 286 may be secured directly to an outlet of the coiled flow tube 280 in order to provide for the desired on/off flow control.

[0070] The controller 220 in base unit 200 may implement an algorithm that receives and analyzes pressure sensor data to open and close the on-off valve, e.g. a pinch valve 228 (Fig. 9) or an angle valve 286 (Fig. 12) or 260 (Fig. 11). The algorithm receives and analyzes the pressure data input hundreds of times per second. The data are compiled to determine the diameter of the attached catheter, determine the contents flowing through the catheter and aspiration tubing, and to determine the flow rate.

[0071] In one embodiment, the controller 220 implements an algorithm that uses pressure sensor data to analyze the contents flowing through an aspiration catheter and characterizes it as unrestricted flow, restricted flow, or clogged. A catheter with unrestricted is aspirating primarily healthy, clot-free blood, or blood free of vessel-obstructing clot. A catheter with mixed flow is aspirating a combination of clot, occlusive material, and blood. A catheter with little to no flow is clogged or occluded. If the algorithm determines that an excessive amount of blood is being aspirated, as is often the case for a catheter with unrestricted flow, it may restrict aspiration to reduce blood loss. If the algorithm determines that a catheter has restricted flow, it will typically allow full aspiration. If the algorithm determines that a catheter has little to no flow, it may initiate an extraction cycle to help remove any clogs or occlusions. As used herein, the term "clot" should be understood to encompass any occlusive material found in vasculature, such as thrombus, embolus, plaque, occlusive material, vessel blockage, or any other obstructive material. Clot references all such occlusive material for brevity's sake.

[0072] Figure 13 illustrates an example of an algorithm that uses pressure differentials ("ΔP") to determine flowrate and, based on the determined flowrate, controls the on-off valves of the present invention. In the illustrated algorithm logic tree, the first step is to measure max and minimum pressure differential windows over some assessment period and, after the assessment period, take an instantaneous pressure differential and compare it to these max and minimum pressure differential windows, which are incrementally updated. If the instantaneous pressure differential is lower than the minimum pressure differential of the assessment period, the algorithm determines that the system is in clot and instructs the system

Penumbra, Inc., Ex. 1004, Page 179 of 394
Penumbra, Inc. v. RapidPulse, Inc.

to continue full aspiration. On the other hand, if the instantaneous pressure differential is above the minimum pressure differential the algorithm determines whether the instantaneous pressure differential is above the product of the max pressure differential multiplied by a confidence interval, if it isn't the algorithm allows full aspiration, if it is the algorithm restricts aspiration to limit blood loss and enters a sampling state where aspiration is limited to brief surges to make new instantaneous pressure differential readings. In either case, whenever aspiration is allowed, the algorithm continually takes instantaneous pressure differential readings and compares them to the max and minimum pressure differentials collected throughout the procedure. In one example, when unrestricted flow (e.g. open flow) is detected the algorithm triggers a sampling state. In another example, when a clot is detected the algorithm initiates full aspiration or initiates an extraction cycle with pulsed aspiration.

[0073] In one embodiment, the present invention utilizes a correlation algorithm that determines whether a catheter has unrestricted flow, restricted flow, or is clogged, e.g. the catheter's state, based on a correlation between flow rate and such states. In another embodiment, the present invention utilizes a windowing algorithm that analyzes discreet portions of pressure sensor data to establish local minimum and local maximum pressure sensor readings. These windowed minimums and maximums are compared to a global maximum and global minimum across the data set. Given a sudden large delta in pressure readings, the system preferentially makes determinations of a catheter's state according to local minimums and local maximums. Pressure readings below minimums and above maximums signify a change in catheter state, e.g. below a minimum indicates a clogged catheter and above a maximum indicates an unrestricted flow state.

[0074] In an additional embodiment, the present invention utilizes an algorithm emphasizing an analysis of standard deviations across a discreet window of data points. The flow rate is compared to the average and mean flow rate. A small standard deviation indicates a catheter that is clogged or unrestricted, while a large standard deviation indicates a catheter that has restricted flow.

[0075] In one embodiment, a learning algorithm is used to determine the contents flowing through an aspiration catheter. Training data is formed by collecting pressure readings along the length of catheter in a variety of states, e.g. unrestricted flow, restricted flow, or clogged. Numerous pressure readings are recorded for each catheter state, and the algorithm then references those data sets to interpret never seen pressure readings to predict what state the catheter is in.

Penumbra, Inc., Ex. 1004, Page 180 of 394
Penumbra, Inc. v. RapidPulse, Inc.

[0076] In another embodiment, the present invention utilizes an artificial neural network (ANN) that employs a multinomial logistic regression algorithm. The ANN is trained to predict answers by considering numerous training data sets. The training data includes both observed data as inputs and the actual outputs. The inputs are propagated across the ANN, which is comprised of layered nodes that each represent a linear transformation within the solution space. The ANN then "learns" by analyzing the difference between the ANN's calculated output and the actual output. This difference is translated into an error function. The error function is backpropagated across the ANN, whereby the weight of each node is modified according to its contribution to the error function. Weighting is a process of mathematical optimization that establishes which nodes optimally map inputs to their correct outputs. Numerous sets of training data are propagated across the ANN iteratively until the error function reaches convergence, i.e. some acceptable level of tolerance. Once the nodes have been properly weighted, in that the error function has reached convergence, the ANN can accurately predict the output of previously unseen input. Here, that means that the learned ANN can take novel pressure sensor data inputs and accurately predict catheter size and whether a catheter's contents should be classified as unrestricted, restricted, or clogged.

[0077] In some embodiments, the algorithm employs semi-supervised and unsupervised learning to continually update node weights. The algorithm may employ clustering, dimensionality reduction, and reinforcement learning to further improve prediction accuracy. In preferred embodiments, the algorithm can accurately interpret pressure fluctuations associated with switching between catheters of different diameters and filter out pressure fluctuations generated by manual movements of a separator within the aspiration catheter by determining and accounting for the cadence of the movement. Additionally, the present invention may employ an algorithm that uses a combination of the above algorithmic flow analysis techniques.

[0078] The algorithm may initiate a sampling mode when unrestricted flow is detected. In exemplary embodiments, the algorithm can detect a change in flow indicating unrestricted flow within milliseconds. In one embodiment of the sampling mode, the algorithm will cycle off aspiration and then open and close the on-off valve at a predetermined frequency. The sampling state conducts an aspiration surge when the valve is briefly opened and makes an assessment of the pressure sensor readings. Based on this aspiration surge, the algorithm determines whether the system should revert to full aspiration, with the on-off valve in the open position or remain in the sampling state. These sampling surges occur over a

Penumbra, Inc., Ex. 1004, Page 181 of 394
Penumbra, Inc. v. RapidPulse, Inc.

millisecond order of magnitude and ensure that full aspiration occurs only when the system is engaging clot and thus minimizes blood loss.

[0079] In an alternative embodiment, the system is powered on and has a brief delay before the algorithm assesses flow in the aspiration tubing. If the sensors indicate unrestricted flow, then an appropriate delay of time is calculated for which the on-off valve remains shut. After this delay, the on-off valve opens to briefly allow aspiration and take a pressure reading sample in the aspiration tubing to assess whether the system still has unrestricted flow or if it has been positioned into clot or other occlusive material. If the sampling detects unrestricted flow, a new delay is calculated (in some instances, incrementally longer for each consecutive reading up to a threshold). If the sampling detects clot, e.g. restricted flow or a clog, an appropriate delay of time is calculated for which the valve remains open. While open, the system assesses pressure sensors readings at a regular frequency to determine whether the system has been positioned such to cause unrestricted flow. These processes repeat until the procedure is finished.

[0080] An extraction cycle may be useful to clear occlusions in an aspiration catheter or to facilitate the aspiration of clot that are large or otherwise hard to aspirate. An extraction cycle establishes pressure differentials between the aspiration catheter and the vacuum source to generate pressure pulses. In general, these pressure pulses can employ multiple mechanisms to facilitate thrombus ingestion into an aspiration catheter. In one mechanism, the pressure pulse introduces an acceleration component that facilitates the extraction of occlusive material. In another mechanism, the pressure pulse creates a force impulse that breaks static friction momentarily, allowing a lower dynamic friction to ingest thrombus. In yet another mechanism, the pressure pulse moves the thrombus away from the distal tip of the catheter and subsequently rapidly forces contact between the thrombus and the catheter, macerating the thrombus.

[0081] In one example, an extraction cycle alternates between providing vacuum aspiration and relative positive pressure. An extraction cycle is typically initiated when an aspiration catheter is already under full vacuum. When an extraction cycle is initiated, the vacuum on-off valve between the catheter and the aspiration source is closed and the pressure in the aspiration catheter is increased, which may cause a positive pressure pulse and establish a pressure differential between the vacuum source and the catheter. When the on-off valve is then opened, the contents and the distal tip of the aspiration catheter experience the pressure differential as a negative pressure pulse that negatively impacts the structural integrity of any occlusions to a degree that a static force could only achieve with a greater

Penumbra, Inc., Ex. 1004, Page 182 of 394
Penumbra, Inc. v. RapidPulse, Inc.

supply of energy. The amplitude, or magnitude, of these pressure pulses are directly correlated to the pressure differential between an evacuated catheter and a pressure source (for positive pressure pulses) and a pressurized catheter and a vacuum source (for negative pressure pulses). The frequency with which the on-off valve opens and closes may be predetermined or responsive to pressure sensor data. An extraction cycle's pressure pulses may have an amplitude and frequency optimized to extract thrombus and similar occlusions from vasculature.

[0082] Pressure differentials in a catheter may be generated in a number of ways. In one example, pressure is generated by simply closing off a catheter's access to the vacuum source. In another example, pressure is generated by introducing fluid into the catheter, where the fluid is at a pressure between full vacuum and ambient pressure, at ambient pressure, at systolic pressure, or above systolic pressure (Figs. 14-17). In another example, pressure differentials are generated by mechanical displacement of a pressure chamber (Fig. 18).

[0083] An extraction cycle may be automatically initiated when an algorithm of the controller 220 detects a clogged catheter, an occluded catheter, or a catheter positioned in clot. A catheter may be identified as in clogged state when the pressure differentials approach zero. In one example, the controller automatically initiates an extraction cycle after the system has detected a clog lasting for more than 5 seconds. Alternatively, an extraction cycle is initiated, or terminated, on demand by a user. An extraction cycle may provide pressure pulses for a predetermined time period. Alternatively, an extraction cycle assesses pressure sensor data each time the on-off valve opens to assess flow and to determine whether the extraction cycle should continue or end. If an extraction cycle has trouble clearing a clog, it may vary the amplitude and frequency of the pressure pulses. In one example, an algorithm on the controller 220 consults a library of different pressure pulses and chooses from among the library. If a specific amplitude and frequency starts to clear the clog, the algorithm may continue to generate pressure pulses of that frequency and amplitude until the clog is cleared.

[0084] Figure 14 illustrates an example of a fluid system that may be used to generate pressure differentials, and thus pressure pulses. In this example, a fluid introduction unit 290 is attached along a length of the connection tubing 206 with a three-point junction 292. The three-point junction 292 may be positioned between the base unit 210 and the external unit 204 or may be positioned distal to both the base unit 210 and the external unit 204—i.e. in close proximity to an attached aspiration catheter. A fluid injection on-off valve 296 controls the flow of fluid (either liquid or gas) to inject pulses of pressure into the clot flow path that may facilitate the extraction of clot or other occlusive substances. In some instances, the flow

Penumbra, Inc., Ex. 1004, Page 183 of 394
Penumbra, Inc. v. RapidPulse, Inc.

of fluid is introduced directly into the connection tubing 206. In other instances, the flow of fluid first traverses an injection tube 294 before entering the connection tubing 206. The injection tubing 294 may direct the pressure pulse towards the catheter, which may optimize the pressure pulse. In one example, the three-pint junction 292 has a T-joint structure as illustrated in Figure 13. Alternatively, a three-point junction may have a Y-joint structure (not illustrated). The Y-joint may beneficially direct fluid from the fluid introduction unit towards the catheter, which may optimize the pressure pulse in a similar manner to the injection tubing of the prior example.

[0085] Figure 15 illustrates an alternative fluid system that uses a pump 398 that may be connected between a fluid reservoir 390 and an injection valve 396. In one embodiment, the pump 398 cycles on when the injection valve 396 opens. The pump provides work by forcefully injecting fluid from a fluid reservoir 390, through the injection on-off valve 396, into an injection tube 394 and/or connection tubing 306. In this example, the magnitude of the positive pulse of pressure is directly correlated to the throughput (e.g. size) of the pump 398. In a second embodiment, a pressure chamber 397 is positioned between the pump 398 and the injection valve 396. A pressure chamber 397 allows the pump 398 to provide work even when the injection valve 396 is closed. While the injection valve 396 is closed, the pump 398 forcefully injects fluid from the reservoir 390 into the pressure chamber 397, whereby the pressure chamber 397 becomes pressurized. When the injection valve 396 opens, pressure is released from the pressure chamber 397 into the injection tube 394 and/or connection tubing 306. In this embodiment, since the pump 396 can build up pressure over time, the magnitude of the positive pulse of pressure is not directly correlated to the throughput (e.g. size) of the pump 398, thus this embodiment allows for a smaller pump. To provide even greater control over the duration or magnitude of positive pressure pulses, the opening and closing of the injection valve may be throttled or manipulated to modulate rate of injection. Additionally, a pressure sensor may be included in pressure chamber 297 to monitor and control the buildup of pressure.

[0086] Figure 16 illustrates another three-point junction 492 attached along connection tubing 406. The three-point junction 492 may be positioned between the base unit 210 and external unit 204 or may be positioned distal to both the base unit 210 and the external unit 204. A pressure valve 496 controls the generation of positive pulses of pressure from fluid chamber 490. Fluid from the fluid chamber 490 may flow directly into connection tubing 406 or may first traverse an injection tube 494 before entering the connection tubing 406. An aspiration valve 499 controls the application of vacuum aspiration from an attached vacuum

Penumbra, Inc., Ex. 1004, Page 184 of 394
Penumbra, Inc. v. RapidPulse, Inc.

source. In this embodiment, the three-point junction 492 has valves to control both vacuum forces and positive pressure pulses. This allows the three-point junction 492 to alternate between applying vacuum aspiration and pulses of pressure, wherein the pressure is above that of the vacuum source. The aspiration valve 499 and the pressure valve 496 may be opened alternatively, simultaneously, with a delay, or in some overlapping sequence. In one overlapping sequence, one valve starts to open when the other valve is starting to close, whereby there is a brief period where both valves are at least partially open. In other overlapping sequences, sometimes both valves are open and both valves are closed for at least short periods of time.

[0087] In one embodiment, an aspiration valve 499 is positioned between a catheter and an aspiration source to modulate aspiration and a pressure valve 496 is positioned between the catheter and fluid source to modulate fluid injection. The present invention may selectively open and close both aspiration valve 499 and pressure valve 496 to create pressure differentials within the catheter and/or aspiration tubing that result in pressure pulses of a desired amplitude and frequency.

[0088] Figure 17 provides a perspective view of a three-way joint and the components it connects. In this example, a connection tubing 706 acts as a common conduit between a vacuum source 700, a pressure source 790, and an aspiration catheter 750. The connection tubing 706 may have a first end configured to attach, or be placed in fluid communication with, the vacuum source and a second end configured to attach, or be placed in fluid communication with, the aspiration catheter. In one example, the second end is attached to the aspiration catheter with a rotating hemostasis valve. A three-way joint 792 may be positioned proximate to the second end to provide pulses of relative positive pressure near the aspiration catheter 750. In one example, the three-way joint 792 is an angled joint or Y-joint, whereby fluid from the pressure source is directed towards the aspiration catheter 750. In some examples, the three-way joint 792 includes injection tubing 794, which directs fluid from the pressure source towards the aspiration catheter 750. In some examples, the injection tubing 794 extends from the three-way joint into the aspiration catheter, whereby fluid flows from the pressure source into the aspiration catheter 750. In another example, the injection tubing 794 extends from the three-way joint to a position proximate a distal end of the aspiration catheter, as depicted in perspective 751, which provides a zoomed-in perspective of the distal end of the aspiration catheter 750. In this example, the pressure source may cause fluid to flow according to directional arrow 761 and the vacuum source may cause fluid to flow according to directional arrow 760. In some embodiments, the controller may modulate

Penumbra, Inc., Ex. 1004, Page 185 of 394
Penumbra, Inc. v. RapidPulse, Inc.

a vacuum valve 799 and a pressure valve 796, whereby the closing of the vacuum valve 799 and the opening of the pressure valve 796 may result in a relative increase in pressure at a distal tip of an aspiration catheter. Alternatively, the opening of the vacuum valve 799 and the closing of the pressure valve 796 may result in a relative decrease in pressure at the distal tip of the aspiration catheter 750. In some instances, these changes in pressure are transmitted along a length of the aspiration catheter as a pressure pulse. In some embodiments, a controller may close vacuum valve 799 and open pressure valve 796 for a small period of time, thus allowing a minimal volume of fluid from the pressure source 790 to be introduced into a proximal end of aspiration catheter 750 to increase the relative pressure at a distal end of the aspiration catheter 750 before reverting to vacuum by re-opening vacuum valve 799 and closing pressure valve 796. Similarly, a controller may close vacuum valve 799 and open pressure valve 796 for a longer period of time, allowing a larger volume of fluid from the pressure source 790 to be introduced into the aspiration catheter 750 to facilitate movement of obstructive material away from the distal end of aspiration catheter 751 before reverting to vacuum by re-opening vacuum valve 799 and closing pressure valve 796. In some embodiments, the connecting tubing 706 may have a dual lumen along a portion of its length, whereby one lumen accommodates fluid and a second lumen accommodates wiring, which enables the controller to modulate both the vacuum valve 799 and the pressure valve 796.

[0089] Figure 18 illustrates another embodiment of a valve structure that controls both aspiration forces and positive pressure pulses. In this example, a three-point junction 592 attaches to connection tubing 506 and pressure chamber 590. A gate valve 550 translates at axis 570 to block aspiration in a 550A position and to block fluid introduction in a 550B position. The gate valve 550 may provide pulsed aspiration by oscillating back and forth at a predetermined or responsive frequency as controlled by an algorithm in the controller 220. In this example, the three-way gate valve exists at the juncture between the aspiration source, the pressure source, and the catheter. The gate valve 550 translates between blocking the aspiration source and blocking the pressure source to effect pressure pulses of a desired amplitude and frequency.

[0090] In an alternative embodiment, fluid injection does not occur at a three-point juncture, but rather occurs at a more distal region closer the catheter tip. The location of the relative pressure injection may be used to optimize the pressure pulse variation in order to facilitate clot removal. In one embodiment, a distal region of an aspiration catheter includes a valve that can be opened and closed, e.g. the distal valve. In one example, an aspiration valve

Penumbra, Inc., Ex. 1004, Page 186 of 394
Penumbra, Inc. v. RapidPulse, Inc.

is closed, and the distal valve is opened to allow blood to rush into the catheter, which increases the pressure in the catheter and amplifies the pressure differential between the catheter lumen and the vacuum source. Typically, the distal valve is then closed, and the aspiration valve is opened, wherein the pressure differential between the vacuum source and the catheter results in a pressure pulse. In another embodiment, fluid is transferred into an aspiration catheter from another adjacent catheter. For instance, an inner catheter may deliver fluid to an outer aspiration catheter. Alternatively, an outer catheter may deliver fluid to an inner aspiration catheter through a valve structure. In either case, the fluid is delivered along the length of the aspiration catheter, rather than through a proximal end. In a similar manner, an adjacent catheter may offer an additional connection to a vacuum source.

[0091] Figure 19 illustrates a mechanical assembly for generating pressure pulses. In this example a mechanical piston 699 can replace the previous embodiment's injection valves, pressure chambers, pumps, and fluid reservoirs. The stroke of the piston 699 or alternative mechanical device can be controlled to adjust the volume of the catheter resulting in the generation of negative pressure on one stroke and the generation of positive pressure on the other stroke. In general, a mechanical actuation device actuates back and forth to increase and decrease the overall volume of the system. When the device actuates to increase volume, pressure decreases, and when the device actuates to decreases volume, pressure increase. These pressure changes may create, amplify, or assist pressure pulses of an extraction cycle. The piston 699 may be provided in a three-point juncture 692 that attaches to connection tubing 606. Other mechanical means of controlling volume, or pressure, of the catheter include linear motors, stepper/servo motors, cam follower actuators, solenoids, audio exciters, voice coil actuators, diaphragms, peristaltic pumps, rotary vanes, gears, screws, syringes etc. (not pictured).

[0092] High frequency pressure pulses may be enabled by a mechanical method, such as that depicted in Figure 19. To provide high frequency pressure pulses, a catheter must be rapidly pressurized and rapidly evacuated. The fluid injection systems of Figures 14-18 may readily provide a rapid influx of pressure; however, it may take a non-insignificant amount of time for the vacuum source to bring that catheter back to full vacuum. If the next influx of pressure occurs too early, the catheter will not have had time reach full vacuum, or near full vacuum. In this scenario, the pressure differential between the not-quite-evacuated catheter and the pressure source will be lower and the resulting pressure pulses will have a lower amplitude, which may be suboptimal in some scenarios. To avoid low amplitude pressure pulses caused by a high frequency, the present invention may utilize a vacuum recovery

Penumbra, Inc., Ex. 1004, Page 187 of 394
Penumbra, Inc. v. RapidPulse, Inc.

system to reduce the time required to return a catheter to full vacuum after an influx of positive pressure. With a vacuum recovery system, the present invention enables pressure pulses with both a high amplitude and a high frequency.

[0093] Figure 19 illustrates a device that may function as a vacuum recovery system by generating pressure differentials. Alternatively, a vacuum recovery system may utilize a syringe, an evacuated chamber, a second aspiration pump, or some combination of these options. A syringe is a piston actuated device that retracts to increase a system's volume (and thus decrease pressure) and advances to decreases a system's volume (and thus increase pressure). A syringe-like device may beneficially assist not only vacuum recovery but also positive pressure pulse generation. In one example, a syringe is used during an extraction cycle. In such an example, a catheter starts at full vacuum. The vacuum source closes, the syringe advances (to reduce system volume), and, optionally, fluid is injected, which all facilitates the formation of a positive pressure pulse. Next, the vacuum source opens, and the syringe retracts (to increase system volume) to generate a negative pressure pulse, whereby the syringe speeds the catheter's return to near full vacuum. Alternatively, an aspiration pump is configured to selectively prime an evacuated chamber that is opened to the catheter, in addition to an aspiration pump, after each pressure pulse. Together, the aspiration pump and the evacuated chamber more rapidly return a catheter to full vacuum. While the aspiration pump is closed to the catheter, it may be opened to the evacuated chamber to further prime the evacuated chamber between pressure pulses. In a further alternative, a secondary aspiration pump assists a primary aspiration pump to facilitate vacuum recovery after each pressure pulse.

[0094] Figure 20 illustrates a graphical representation of an example pulsation protocol. An extraction cycle may use a pulsation protocol to systemically manipulate the amount of pressure within a catheter to facilitate the extraction of occlusive material. Pressure in a catheter may be manipulated by a variety of methods. For instance, vacuum aspiration may be used to reduce pressure within the catheter and the removal of vacuum suction and/or the introduction of fluid may be used to increase pressure within the catheter. In other instances, a mechanically actuating device may alternate between increasing and decreasing pressure within a catheter. In the example illustrated by Figure 20, at time 0, the catheter has not been subjected to any suction forces and is at atmospheric pressure. From time 0 to time 1, the catheter has lost pressure, lunging from atmospheric pressure to near full vacuum (i.e. near -29.9inHg). From time 1 to time 2, the catheter has gained pressure, which decreases vacuum strength. From time 2 to 3, the catheter has lost pressure, which returned the catheter to near

Penumbra, Inc., Ex. 1004, Page 188 of 394
Penumbra, Inc. v. RapidPulse, Inc.

full vacuum. From time 3 to 4, the catheter has gained pressure and returned to ambient pressure. From time 4 to 5, the catheter has lost pressure, again lunging from atmospheric pressure to near full vacuum. From time 5 to 6, the catheter has gained pressure, which caused the pressure to surge from near full vacuum to above ambient pressure. From time 6 to 7, the catheter has lost pressure, lunging from a pressurized state above atmospheric pressure to near full vacuum.

[0095] A pulsation protocol of the nature illustrated in figure 20 may be executed once or may be repeated several times. In alternative embodiments, the pulsation protocol may include additional time periods with additional pressure variations and pressure patterns. In general, the system's pressure may vary from between near vacuum to above average systolic pressure. The duration of the pulsation protocol may be predetermined or adaptive to pressure sensor readings. For instance, the controller may prolong or shorten a pulsation protocol based on pressure sensor readings. In some examples, the system may remain at a stable pressure state across one or more time periods. For instance, the controller may cause the system to dwell at near full vacuum. The dwell time in each pressure state and the frequency with which the system transitions between pressure states may be optimized to ingest different clot or occlusive material compositions. Although figure 20 illustrates a pulsation protocol with a stable and consistent frequency, in other examples the frequency of a pulsation protocol is variable or some combination of partially stable and partially variable. High amplitude (or high magnitude) pressure pulses may be generated by generating large pressure differentials. For instance, figure 20 illustrates a high amplitude pressure pulse between times 5 and 7. Lower magnitude pressure pulses may be generated by oscillating between less extreme high pressures and low pressures. For instance, the low end of the pressure pulse may not reach near full vacuum, the high end of the pressure pulse may not reach ambient pressure, or both, thereby resulting in a lower magnitude pressure pulse, which may be desirable in some scenarios. The time units of figure 20 may be in second, milliseconds, microseconds, or the like.

[0096] In some examples, an extraction cycle uses a predetermined series of pressure pulses with near full vacuum aspiration before the extraction cycle, between individual pulses of relative positive pressure, and after the extraction cycle. The pressure pulses may be selected from a library of pressure pulses having amplitudes and frequencies that facilitate the extraction of clot and other occlusive material. A series of pressure pulses may vary from one another in terms of frequency, amplitude, or both. For instance, a pulsation protocol may use a series of pressure pulses with a trend where one of the amplitude or frequency rises while

Penumbra, Inc., Ex. 1004, Page 189 of 394
Penumbra, Inc. v. RapidPulse, Inc.

the other diminishes, where both the amplitude and frequency rise or diminish, or where one of the amplitude or frequency rises or diminishes while the other remains constant.

[0097] In some examples, an extraction cycle provides specific pressure pulses based on pressure sensor readings. One such responsive extraction cycle measures pressure within the catheter and then selects one or more pressure pulses optimized for a catheter with those pressure readings. In another responsive extraction cycle, the system cycles through a library of pressure pulse protocols, with time periods of static or full aspiration and occlusion detection after each individual pressure pulse. After the library has been cycled, the system repeats the pressure pulses that were measured to be most successful. The degree of success of a specific pressure pulse is typically commensurate with the amount of increased flow rate after the pressure pulse. The system will continue to cycle down until only a few pressure pulse protocols are in the loop. If the efficacy of the loop begins to diminish, the system will return to the full library and start a fresh cycle.

[0098] In an alternative responsive system, a responsive extraction cycle has three modes: Cycling up, where successive pressure pulses are stronger in terms of amplitude and/or frequency, cycling down, where successive pressure pulses are weaker in terms of amplitude and/or frequency, and maintenance pressure pulses, where pressure pulses have a consistent frequency and amplitude. When the system detects a clogged state, it enters the cycling up mode. When the system detects restricted flow state, it enters the maintenance mode. When the system detects an unrestricted flow state, it enters the cycling down mode. In this way, the system trends towards pressure pulses with an amplitude and frequency that facilitates restricted flow, which is beneficially removing clot and other occlusive material.

[0099] In situations where maximizing the removal of occlusive material eclipses concerns of blood loss, such as in neurovascular stroke procedures, an alternative embodiment according to the invention may be useful. Under these circumstances, as an example, an optimal technique may include positioning the distal end of a catheter in clot, applying full vacuum, and waiting a predetermined period of time before advancing to a next step. The objective may be complete or nearly complete catheter tip engagement of a mass of occlusive material, engagement which essentially clogs the distal end of the catheter and is sometimes referred to as “corking the catheter”. If a clinician has successfully “corked the catheter”, the catheter system may be removed from the vessel, withdrawing the mass of clot or occlusion with it. Alternatively, an extraction cycle may be used to draw an occlusion through the catheter lumen or cause the clot to become deeply latched, or corked, within the catheter attached to the present invention. After the completion of the extraction cycle, the

Penumbra, Inc., Ex. 1004, Page 190 of 394
Penumbra, Inc. v. RapidPulse, Inc.

clot should be removed or corked in the attached catheter so that the catheter together with the clot can safely be removed from the patient.

[00100] In some instances, an extraction cycle may automatically stop or be manually stopped when a clot or other occlusive material clogs a catheter and corks it. For instance, the clot or occlusive substance might be too large or tough to traverse an aspiration catheter, but nonetheless become partially entrained in the aspiration catheter. In such instance, the system may transition to full aspiration to allow the user to remove the corked catheter while dragging the clot or occlusive material out with the catheter. In one example, an extraction cycle is initiated, and the clot or occlusive material still clogs the catheter. The controller may then revert to full aspiration and notify the user of the corking event, whereby the system may prompt the user to remove the catheter. Alternatively, the user may manually turn off an extraction cycle, causing the system to return to full vacuum, and remove the catheter.

[00101] To indicate that the present invention is doing work to remove clots or other occlusive material, one embodiment includes visual and/or auditory signals that indicate the progress of a given extraction cycle. In one example, the start of an extraction cycle is signaled by a flashing blue light, which flashes until the cycle is completed, and, at completion, the light turns to green to indicate completion. In another example, base unit 216 may include a light bar. The light bar fills up incrementally, whereby the light bar progressively "fills up" with light in proportion to the cycle's progress. Alternatively, base unit 216 may include a small screen for displaying images. The small screen may display an animation indicative of loading. Loading animations may execute a repetitive pattern (e.g. spinning circular object) or may execute a single cycle of a prolonged animation (e.g. slowly filling circle). Either in conjunction with visual progress indication or as an alternative to visual progress indication, the system may use auditory cues to signify the extraction cycle's initiation, pulsating phase, and completion. Such auditory cues may include musical notes, beeps, and/or speech. Auditory cues may include updates (e.g. "extracting") or suggestions (e.g. "advance/retract the catheter").

[00102] An algorithm may also control a lighting mechanism, e.g. indicator light 210 (Figs. 7A and 7B), to convey to the user whether the system is in a full aspiration state, an unrestricted flow state, a restricted flow state, a clogged state, a sampling state, or an extracting state. Specific lights may be illuminated to indicate bubbles or that the override switch has been triggered. Additionally, the algorithm may control a piezo acoustic chip that conveys audible information to the physician regarding the state of the effluent and override switch. In one embodiment, the piezo is a surface mounted 4 kHz single tone at 65dB at

Penumbra, Inc., Ex. 1004, Page 191 of 394
Penumbra, Inc. v. RapidPulse, Inc.

10cm. The signals may include sounds and phrases such as tone/pitch changes, beeping patterns, "clogged", "occluded", "clot", "blood", "open flow", etc. One example utilizes a dynamic beeping cadence, where a beeping pattern is steadily increased when an unrestricted flow state is increasing in duration. The speed of the beeps indicates the length of time the system has been in unrestricted flow, alerting the physician to the increasingly problematic nature of the system's positioning. The system may also include a multi-position switch or button to specifically activate different algorithms, mute audio cues, or to prime the system with fluid. Such a feature could be activated by inserting a pin in the base unit 210, which will activate this customizable feature.

[00103] In one embodiment, the system may be manually powered on and conduct aspiration for a predetermined period of time. If the system detects unrestricted flow, then the on-off valve is turned off to stop flow. The attending physician then must reposition the catheter tip into clot and manually trigger a mechanism (such as a foot pedal or manual switch) to initiate further aspiration. This manual trigger overrides the algorithm and allows aspiration to continue. Once the manual trigger is released, the algorithm again monitors flow to allow aspiration so long as the flow is acceptable. If and when the system again detects unrestricted flow, the on-off valve is again closed until the physician repositions the aspiration catheter and manually overrides the controller. This protocol is repeated until the physician completes the procedure.

[00104] Before an aspiration catheter can be used to remove clot and other occlusive material it must be primed with an uncompressible fluid. For instance, a catheter may be filled with saline fluid to remove all the air from the lumen of the catheter. In some embodiments, the present invention automatically primes a catheter, whereby the catheter is filled with fluid to expel all compressible fluids, like air. In one example, the sensors of the present invention monitor catheter contents during use. If compressible fluids are detected, like bubbles, the system may alert the user. In some instances, the system may indicate that the procedure needs to stop so that the catheter can be again primed to remove the air bubbles.

[00105] The foregoing examples are not intended to limit the scope of the invention. All modifications, equivalents and alternatives are within the scope of the invention.

Penumbra, Inc., Ex. 1004, Page 192 of 394
Penumbra, Inc. v. RapidPulse, Inc.

WHAT IS CLAIMED IS:

1. A vacuum aspiration control system for use with a vacuum source and an aspiration catheter, said system comprising:

a connecting tube configured to connect the vacuum source with the aspiration catheter or component thereof;

an on-off valve configured to be operatively coupled to the connecting tube;

a sensing unit configured to detect flow within the connecting tube and to produce a signal representative of such flow; and

a controller configured to receive the signal representative of flow through the connecting tube and to open and close the on-off valve, wherein the controller is configured to automatically close the valve to stop flow through the connecting tube when the signal indicates unrestricted flow.

2. A vacuum aspiration control system as in claim 1, wherein the controller closes the valve when unrestricted flow is detected and periodically opens the valve for a time interval to sample flow, wherein the valve is closed again if unrestricted flow is detected and the valve is held open if unrestricted flow is not detected.

3. A vacuum aspiration control system as in claim 2, wherein the controller includes a sampling delay between closing the valve for unrestricted flow and opening the valve to sample flow.

4. A vacuum aspiration control system as in claim 3, wherein the sampling delay progressively changes in duration when unrestricted flow continues to be detected.

5. A vacuum aspiration control system as in claim 3, wherein the sampling delay increases in duration with each consecutive reading of unrestricted flow.

6. A vacuum aspiration control system as in claim 2, wherein the flow is sampled and a new valve position is determined in a millisecond time frame.

7. A vacuum aspiration control system as in claim 1, wherein the connecting tube is linear in an unconstrained configuration, with a first end configured for attachment to the vacuum source, or component thereof, and a second end configured for attached to the aspiration catheter, or component thereof.

8. A vacuum aspiration system as in claim 1, wherein the sensing unit comprises any one or more of differential pressure sensors, magnetic flow sensors, acoustic flow sensors, optical flow sensors, thermal flow sensors, and sensors to detect circumferential expansion/contraction of the connecting tube.

Penumbra, Inc., Ex. 1004, Page 193 of 394
Penumbra, Inc. v. RapidPulse, Inc.

9. A vacuum aspiration system as in claim 1, wherein the sensing unit comprises a pair of pressure sensors disposed along the connecting tube to measure differential pressure.

10. A vacuum aspiration system as in claim 1, wherein the on-off valve comprises a solenoid actuator comprised of a pinch valve or an angle valve that is powered to open the valve.

11. A vacuum aspiration system as in claim 1, wherein the controller is configured to open the valve and hold the valve open until unrestricted flow is detected whereupon the controller closes the valve.

12. A vacuum aspiration system as in claim 1, wherein the controller closes the valve when the signal indicates unrestricted flow, periodically opens the valve for a time interval to sample flow, and holds the valve open when the signal indicates flow is no longer unrestricted

13. A vacuum aspiration system as in claim 1, wherein the controller closes the valve when unrestricted flow is detected and periodically opens the valve for a time interval to sample flow and determine a new valve position, wherein the new valve position is closed if flow is still unrestricted and the new valve position is open if flow is no longer unrestricted.

14. A vacuum aspiration system as in claim 1, wherein the controller initiates a sampling mode when the signal indicates unrestricted flow, wherein the valve is closed and periodically opened for a time interval to sample flow, wherein the sampling mode ends when the signal indicates that sampled flow is no longer unrestricted.

15. A vacuum aspiration system as in claim 1, wherein the controller is configured to automatically close the valve to stop flow through the connecting tube when the signal indicates unrestricted flow and the controller periodically tests flow by opening the valve for a time interval to establish a test flow and to resume a treatment flow if the test flow is no longer unrestricted.

16. A vacuum aspiration system as in claim 1, wherein the controller is configured to allow a user to manually open the valve until unrestricted flow is detected whereupon the controller closes the valve.

17. A vacuum aspiration system as in claim 16, further comprising a manual switch in communication with the controller to allow a user to manually open the valve.

Penumbra, Inc., Ex. 1004, Page 194 of 394
Penumbra, Inc. v. RapidPulse, Inc.

18. A vacuum aspiration system as in claim 1, wherein the system comprises a base unit which incorporates at least the on-off valve and the controller.

19. A vacuum aspiration system as in claim 18, wherein the connecting tube has a proximal end configured to connect to the vacuum source and a distal end configured to connect to the aspiration lumen in the aspiration catheter, said system further comprising an external unit configured to be secured to the connecting tube at a location between the distal end and the proximal end thereof.

20. A vacuum aspiration system as in claim 19, wherein the external unit comprises at least a portion of the sensing unit.

21. A vacuum aspiration system as in claim 20, wherein the sensing unit comprises a first pressure sensor in the base unit and a second pressure sensor in the external unit, wherein the controller is configured to determine a differential pressure based on signals from the first and second pressure sensors.

22. A vacuum aspiration control system for use with a vacuum source and an aspiration catheter, said system comprising:

a connecting tube configured to connect the vacuum source with an aspiration lumen in the aspiration catheter;

an on-off valve configured to be operatively coupled to the connecting tube;

a sensing unit configured to detect flow within the connecting tube and to produce a signal representative of such flow; and

a controller connected to receive the signal representative of flow through the connecting tube and to open and close the on-off valve, wherein the controller is configured to automatically close the valve to stop flow through the connecting tube when the signal indicates the catheter is aspirating blood free of vessel-obstructing clot.

23. A vacuum aspiration system as in claim 22, wherein the controller is further configured to automatically open the valve to sample flow through the connecting tube and remain open when the signal indicates that the catheter is aspirating blood having vessel-obstructing clot.

24. A vacuum aspiration system as in claim 22, wherein the controller is configured to open the valve and hold the valve open until the controller receives a signal indicating that the aspiration catheter is aspirating blood free of vessel-obstructing clot, whereupon the controller closes the valve.

Penumbra, Inc., Ex. 1004, Page 195 of 394
Penumbra, Inc. v. RapidPulse, Inc.

25. A vacuum aspiration system as in claim 22, wherein the controller is configured to periodically open a closed on-off valve to receive a new signal representative of flow to determine whether the on-off valve should remain closed.

26. A vacuum aspiration control system as in claim 25, wherein the controller includes a sampling delay between closing the valve when the signal indicates the catheter has aspirated blood free of vessel-obstructing clot and opening the valve to sample flow.

27. A vacuum aspiration control system as in claim 26, wherein the sampling delay increases in duration with each consecutive signal indicating that the catheter has been positioned in clot-free blood.

28. A vacuum aspiration system as in claim 22, wherein the sensing unit comprises any one or more of differential pressure sensors, acoustic flow sensors, magnetic flow sensors, optical flow sensors, thermal flow sensors, and sensors to detect circumferential expansion/contraction of the connecting tube.

29. A vacuum aspiration system as in claim 28, wherein the sensing unit comprises a pair of pressure sensors disposed along the connecting tube to measure differential pressure.

30. A vacuum aspiration system as in claim 22, wherein the on-off valve comprises a solenoid actuator that is powered to open the valve.

31. A vacuum aspiration method comprising:

(a) engaging a distal end of an aspiration catheter against an occlusion in a blood vessel;

(b) applying a vacuum through an aspiration lumen of the aspiration catheter using a vacuum source coupled to a proximal end of the aspiration lumen by a connecting tube, whereby portions of the occlusion are drawn into the aspiration lumen, through the connecting tube and into a collection receptacle by the vacuum source;

(c) sensing flow through the connecting tube;

(d) automatically closing a valve to stop flow through the connecting tube when the sensed flow is unrestricted while the vacuum pump remains on;

(e) opening the valve to resume flow through the connecting tube; and

(f) repeating steps (d) and (e) until a desired amount of clot has been aspirated.

32. A vacuum aspiration method as in claim 31, wherein sensing flow comprises any one or more of differential pressure measurement, magnetic flow

Penumbra, Inc., Ex. 1004, Page 196 of 394
Penumbra, Inc. v. RapidPulse, Inc.

measurement, acoustic flow measurement, optical flow measurement, thermal flow measurement, and measurement of circumferential expansion of the connecting tube.

33. A vacuum aspiration method as in claim 31, wherein sensing flow comprises measuring the differential pressure using a first sensor located proximate the vacuum source and a second sensor located in the connecting tube between the vacuum source and the aspiration catheter.

34. A vacuum aspiration method as in claim 31, wherein resuming flow through the connecting tube comprises automatically detecting when the sensed flow is no longer unrestricted and automatically resuming flow.

35. A vacuum aspiration method as in claim 34, wherein automatically detecting when the sensed flow is no longer unrestricted comprises resuming flow for a fixed time interval and detecting during the fixed time interval whether flow is no longer unrestricted.

36. A vacuum aspiration method as in claim 35, including a sampling delay between closing the valve when the sensed flow is unrestricted and resuming flow for a fixed time interval to detect flow.

37. A vacuum aspiration control system as in claim 36, wherein the sampling delay increases in duration with each consecutive signal indicating unrestricted flow.

38. A vacuum aspiration method as in claim 37, wherein resuming flow through the connecting tube comprises manually opening the valve.

39. A dynamic aspiration system for use with a vacuum source, a pressure source, and an aspiration catheter, the system comprising:

a connecting tube configured to place the vacuum source, the pressure source, and the aspiration catheter in fluid communication;

a vacuum source valve;

a pressure source valve; and

a controller configured to modulate the vacuum source valve and the pressure source valve, wherein the controller generates pressure differentials within a lumen of the aspiration catheter by alternating between opening and closing the valves.

40. A dynamic aspiration system for use with a vacuum source, a pressure source, and an aspiration catheter, the system comprising:

a connecting tube configured to place the vacuum source, the pressure source, and the aspiration catheter in fluid communication;

Penumbra, Inc., Ex. 1004, Page 197 of 394
Penumbra, Inc. v. RapidPulse, Inc.

a vacuum source valve;

a pressure source valve;

a sensing unit configured to detect flow within the connecting tube and to produce a signal representative of such flow; and

a controller configured to receive the signal representative of flow through the connecting tube and to modulate both valves, wherein the controller automatically generates pressure differentials within a lumen of the aspiration catheter by alternating between opening and closing both valves when the signal indicates (1) restricted flow, (2) a small pressure differential, (3) a pressure differential approaching zero, or (4) that the aspiration catheter is at least partially clogged.

41. The dynamic aspiration system of claim 39 or 40, wherein the opening of the pressure source valve increases the pressure within the aspiration catheter.

42. The dynamic aspiration system of claim 41, wherein the opening of the pressure source valve increases the pressure at a distal tip of the aspiration catheter.

43. The dynamic aspiration system of claim 41 or 42, wherein the pressure source has a pressure higher than the vacuum source.

44. The dynamic aspiration system of claim 39 or 40, wherein the connecting tubing is linear in an unconstrained configuration, has a length, and includes a first end configured to connect to the vacuum source and a second end configured to connect to the aspiration catheter.

45. The dynamic aspiration system of claim 44, including a three-way joint configured to place the pressure source in fluid communication with the connecting tubing.

46. The dynamic aspiration system of claim 45, wherein the connecting tubing provides a common conduit for the vacuum source and the pressure source.

47. The dynamic aspiration system of claim 45, wherein the three-way joint is located proximate to the second end.

48. The dynamic aspiration system of claim 45, wherein the three-way joint is a T-joint, a Y-joint, or an angled joint.

49. The dynamic aspiration system of claim 45, wherein the three-way joint functions as a hemostatic valve or is incorporated into a hemostatic valve.

50. The dynamic aspiration system of claim 48, wherein the three-way joint includes an angled injection tube that directs fluid from the pressure source towards the second end of the connecting tubing.

Penumbra, Inc., Ex. 1004, Page 198 of 394
Penumbra, Inc. v. RapidPulse, Inc.

51. The dynamic aspiration system of claim 50, wherein the angled injection tube extends from the three-way joint into the lumen of the aspiration catheter.

52. The dynamic aspiration system of claim 50, wherein the angled injection tube extends proximate to a distal end of the aspiration catheter.

53. The dynamic aspiration system of claim 45, wherein the three-way joint is angled to direct fluid from the pressure source towards the second end of the connecting tubing.

54. The dynamic aspiration system of claim 48, wherein the vacuum source valve and the pressure source valve are comprised of a single gate valve at the three-way joint, wherein the gate valve pivots to alternate between restricting the vacuum source and the pressure source.

55. The dynamic aspiration system of claim 45, wherein the three-way joint is connected to a second three-way joint, wherein the second three-way joint is a T-joint, a Y-joint, or an angled joint.

56. The dynamic aspiration system of claim 55, wherein the second three-way joint is configured for attachment to the pressure source and a pressure chamber.

57. The dynamic aspiration system of claims 56, including a pump configured to transfer fluid from the pressure source to the pressure chamber, wherein the pressure chamber becomes pressurized.

58. The dynamic aspiration system of claim 39 or 40, wherein the vacuum source valve is in fluid communication with the vacuum source and the connecting tubing and the pressure source valve is in fluid communication with the pressure source and the connecting tubing, whereby the valves control the vacuum and pressure provided to the aspiration catheter.

59. The dynamic aspiration system of claim 40, wherein the pressure differentials increase in magnitude with each consecutive signal indicating a pressure differential approaching zero or that the catheter is at least partially clogged.

60. The dynamic aspiration system of claim 40, wherein a magnitude of the pressure differentials is held constant when the signal indicates restricted flow.

61. The dynamic aspiration system of claim 40, wherein the frequency and amplitude of pressure differentials is selected from among a library of pressure pulses.

62. The dynamic aspiration system of claim 40, wherein the controller cycles through the library of pressure pulses, and then repeats only those pressure pulses that resulted in increased flow.

Penumbra, Inc., Ex. 1004, Page 199 of 394
Penumbra, Inc. v. RapidPulse, Inc.

63. A dynamic aspiration system for use with a vacuum source, a pressure chamber, and an aspiration catheter, the system comprising:

a connecting tube configured to place the vacuum source, the pressure chamber, and the aspiration catheter in fluid communication;

a vacuum source valve; and

a controller configured to modulate the vacuum source valve and configured to cause the actuation of a piston in the pressure chamber, wherein said modulation and actuation generates pressure differentials in the connecting tubing.

64. The dynamic aspiration system of claim 63, wherein the piston advances to decrease the volume of the connecting tubing and retracts to increase the volume of the connecting tubing, wherein the volume changes results in pressure differentials.

65. The dynamic aspiration system of claim 63, wherein the controller opens the vacuum source valve to decrease pressure and closes the vacuum source valve to increase pressure, wherein the opening and closing of the vacuum source valve results in pressure differentials.

66. The dynamic aspiration system of claim 63, wherein the controller generates pressure differentials within the connecting that cause pressure pulses in a lumen of the aspiration catheter.

67. A dynamic aspiration system for use with a vacuum source, a pressure source, a pressure chamber, and an aspiration catheter, the system comprising:

a connecting tube configured to place the vacuum source, the pressure source, the pressure chamber, and the aspiration catheter in fluid communication;

a vacuum source valve;

a pressure source valve; and

a controller configured to generate pressure differentials in a lumen of the aspiration catheter by opening and closing the valves and by causing the actuation of a piston in the pressure chamber.

68. The dynamic aspiration system of claim 67, wherein the controller increases pressure in the lumen of the aspiration catheter by opening the pressure valve and by actuating the piston in a first direction to reduce system volume.

69. The dynamic aspiration system of claim 67, wherein the controller decreases pressure in the lumen of the aspiration catheter by opening the vacuum valve and by actuating the piston in a second direction to increase system volume.

Penumbra, Inc., Ex. 1004, Page 200 of 394
Penumbra, Inc. v. RapidPulse, Inc.

70. A dynamic aspiration system for use with a vacuum source, a pressure source, a pressure chamber, and an aspiration catheter, the system comprising:

a connecting tube configured to place the vacuum source, the pressure source, the pressure chamber, and the aspiration catheter in fluid communication;

a vacuum source valve;

a pressure source valve;

a sensing unit configured to detect flow within the connecting tube and to produce a signal representative of such flow; and

a controller configured to receive the signal representative of flow through the connecting tube and to generate pressure differentials in a lumen of the aspiration catheter by opening and closing the valves and by causing the actuation of a piston in the pressure chamber.

71. The dynamic aspiration system of claim 70, wherein the controller automatically generates pressure differentials when the signal indicates (1) restricted flow, (2) a small pressure differential, (3) a pressure differential approaching zero, or (4) that the aspiration catheter is at least partially clogged.

72. The dynamic aspiration system of claim 71, wherein the pressure differentials increase in magnitude with each consecutive signal indicating a pressure differential approaching zero or that the aspiration catheter is at least partially clogged.

73. The dynamic aspiration system of claim 71, wherein the magnitude of pressure differentials is held constant when the signal indicates restricted flow.

74. The dynamic aspiration system of claim 71, wherein the frequency and amplitude of pressure differentials is selected from among a library of pressure pulses.

75. The dynamic aspiration system of claim 74, wherein the controller cycles through the library of pressure pulses, and then repeats only those pressure pulses that resulted in increased flow.

76. The dynamic aspiration system of claim 71, wherein the pressure differentials increase in magnitude with each consecutive signal indicating a pressure differential approaching zero or that the catheter is at least partially clogged.

77. The dynamic aspiration system of claim 71, wherein a magnitude of the pressure differentials is held constant when the signal indicates restricted flow.

78. The dynamic aspiration system of claim 71, wherein a frequency and amplitude of pressure differentials is selected from among a library of pressure pulses.

Penumbra, Inc., Ex. 1004, Page 201 of 394
Penumbra, Inc. v. RapidPulse, Inc.

79. The dynamic aspiration system of claim 78, wherein the controller cycles through the library of pressure pulses, and then repeats only those pressure pulses that resulted in increased flow.

80. The dynamic aspiration system of claim 70, wherein the controller increases pressure in the lumen of the aspiration catheter by opening the pressure valve and by actuating the piston in a first direction to reduce a volume of the pressure chamber.

81. The dynamic aspiration system of claim 70, wherein the controller decreases pressure in the lumen of the aspiration catheter by opening the vacuum valve and by actuating the piston in a second direction to increase a volume of the pressure chamber.

82. A dynamic aspiration method comprising:

(a) engaging a distal end of an aspiration catheter against an occlusion in a blood vessel;

(b) applying a vacuum through an aspiration lumen of the aspiration catheter using a vacuum source coupled to a proximal end of the aspiration lumen by a connecting tube, whereby portions of the occlusion are drawn into the aspiration lumen, through the connecting tube and into a collection receptacle by the vacuum source;

(c) sensing flow through the connecting tube; and

(d) automatically generating pressure differentials when a clog or restricted flow is detected.

83. A dynamic aspiration method as in claim 82, wherein sensing flow comprises any one or more of differential pressure measurement, magnetic flow measurement, acoustic flow measurement, optical flow measurement, thermal flow measurement, and measurement of circumferential expansion of the connecting tube.

84. A dynamic aspiration method as in claim 82, wherein sensing flow comprises measuring the differential pressure using a first sensor located proximate the vacuum source and a second sensor located in the connecting tube between the vacuum source and the aspiration catheter.

85. A dynamic aspiration method as in claim 82, including a pressure source in fluid communication with the connecting tube.

86. A dynamic aspiration method as in claim 85, including a pressure valve between the pressure source and the connecting tubing, and a vacuum valve between the vacuum source and the connecting tubing.

Penumbra, Inc., Ex. 1004, Page 202 of 394
Penumbra, Inc. v. RapidPulse, Inc.

87. A dynamic aspiration method as in claim 86, wherein pressure differentials are generated by opening and closing a pressure valve and a vacuum valve in sequence.

Penumbra, Inc., Ex. 1004, Page 203 of 394
Penumbra, Inc. v. RapidPulse, Inc.

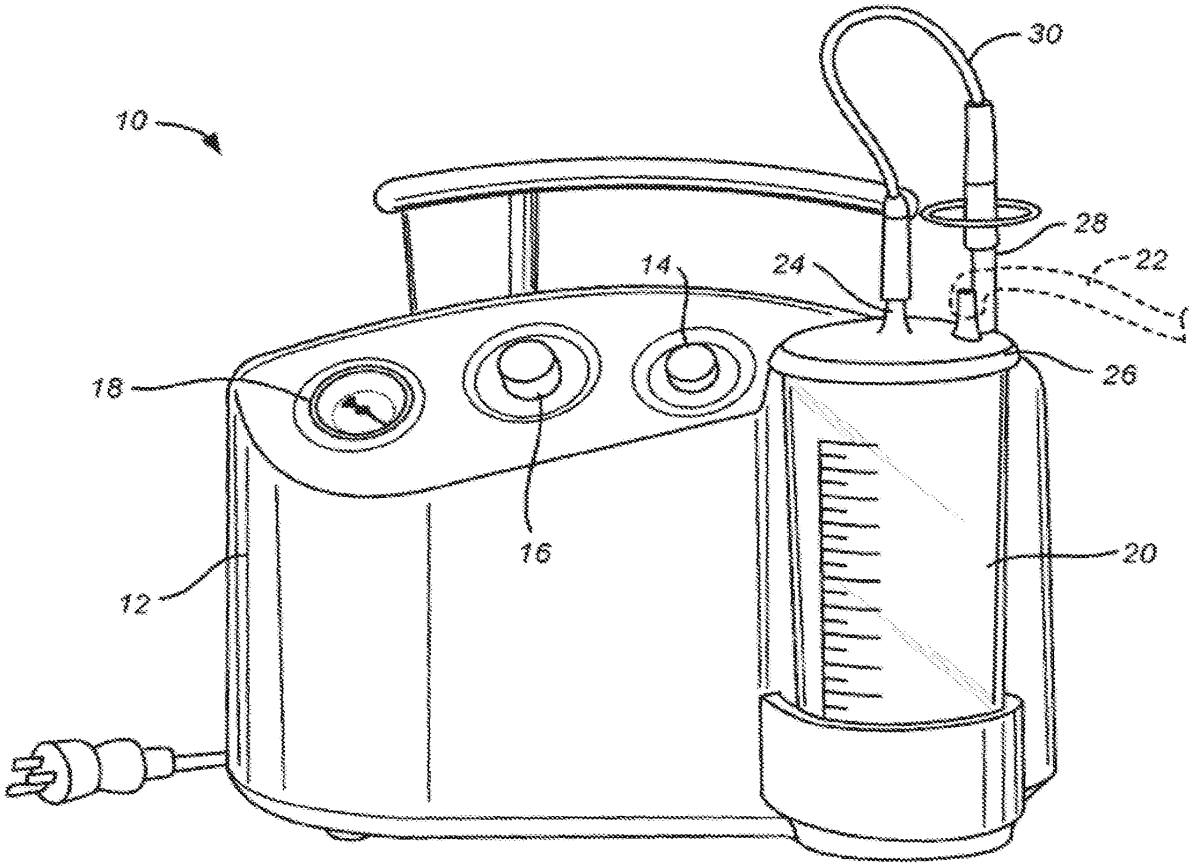


FIG. 1
(PRIOR ART)

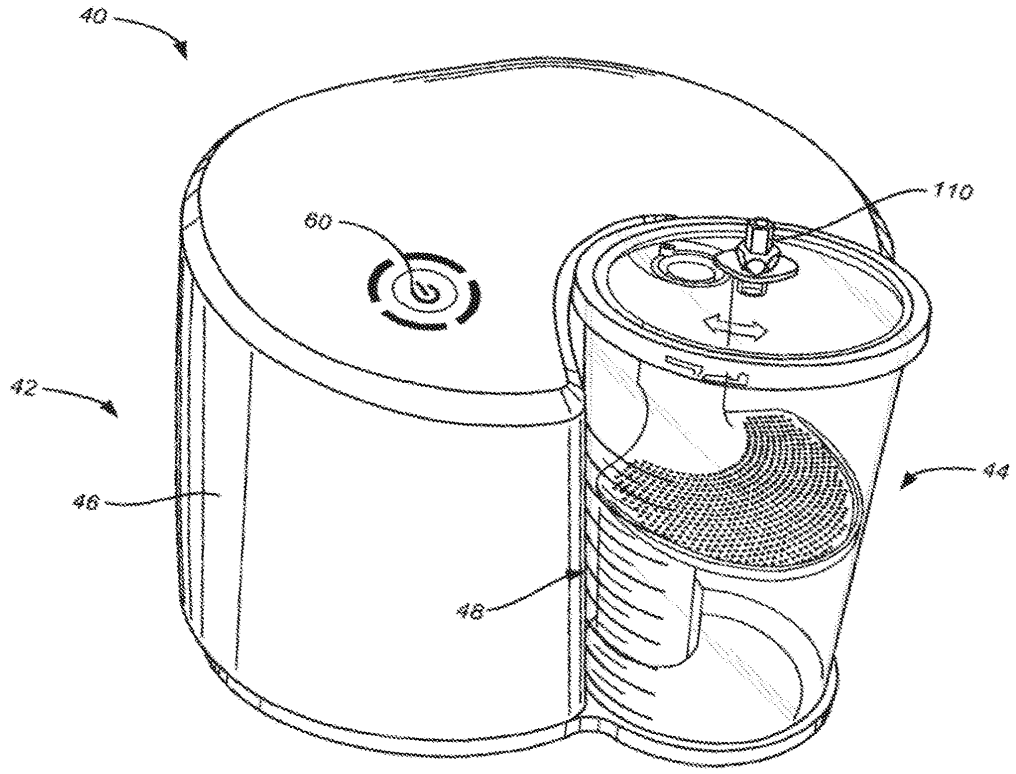


FIG. 2

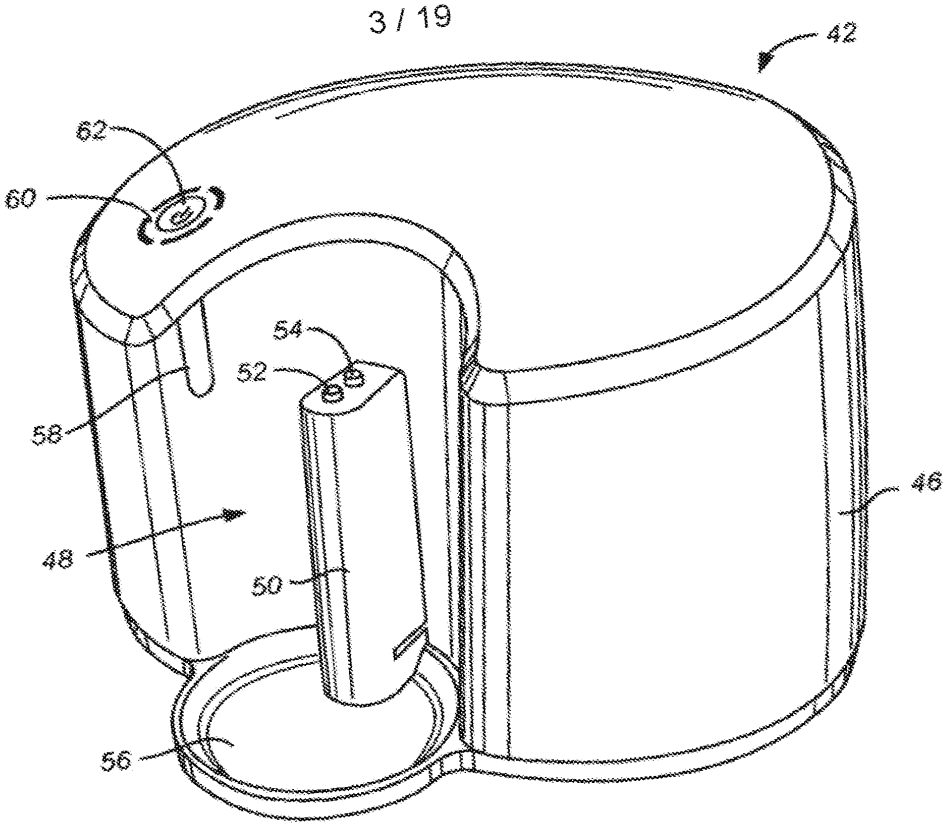


FIG. 3A

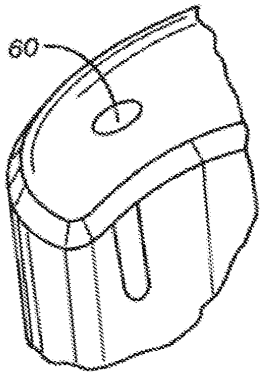


FIG. 3B

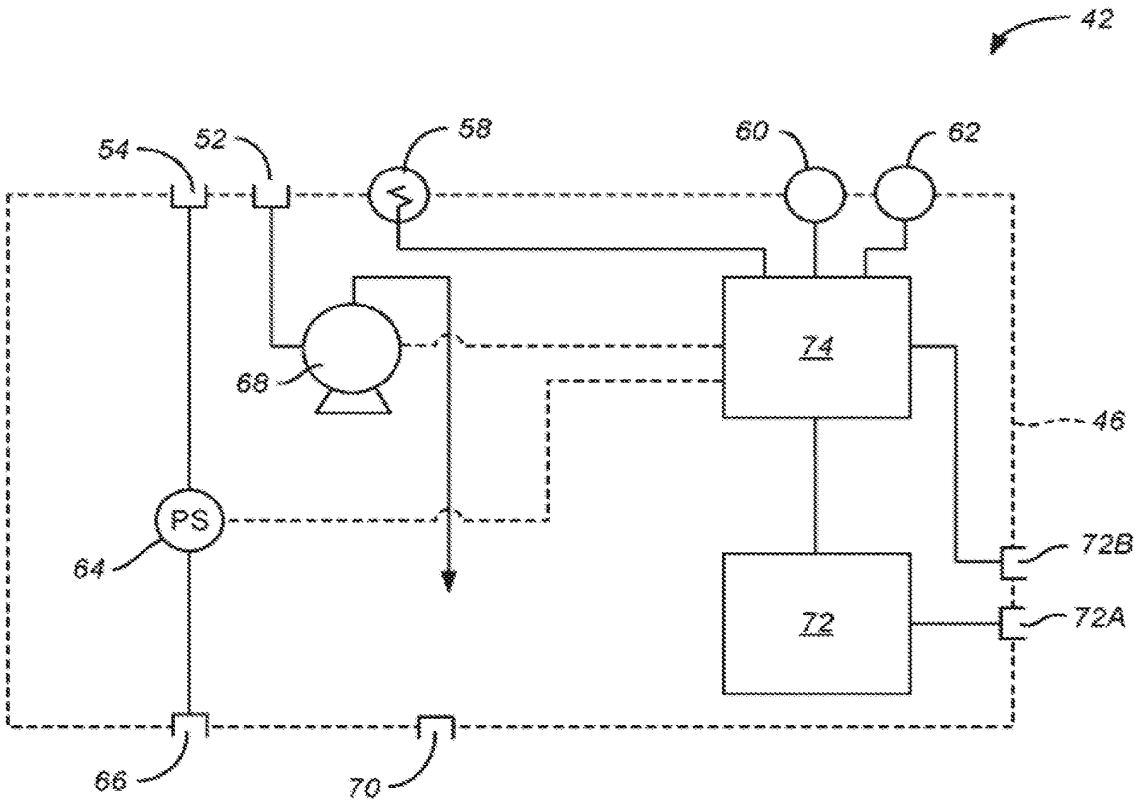


FIG. 3C

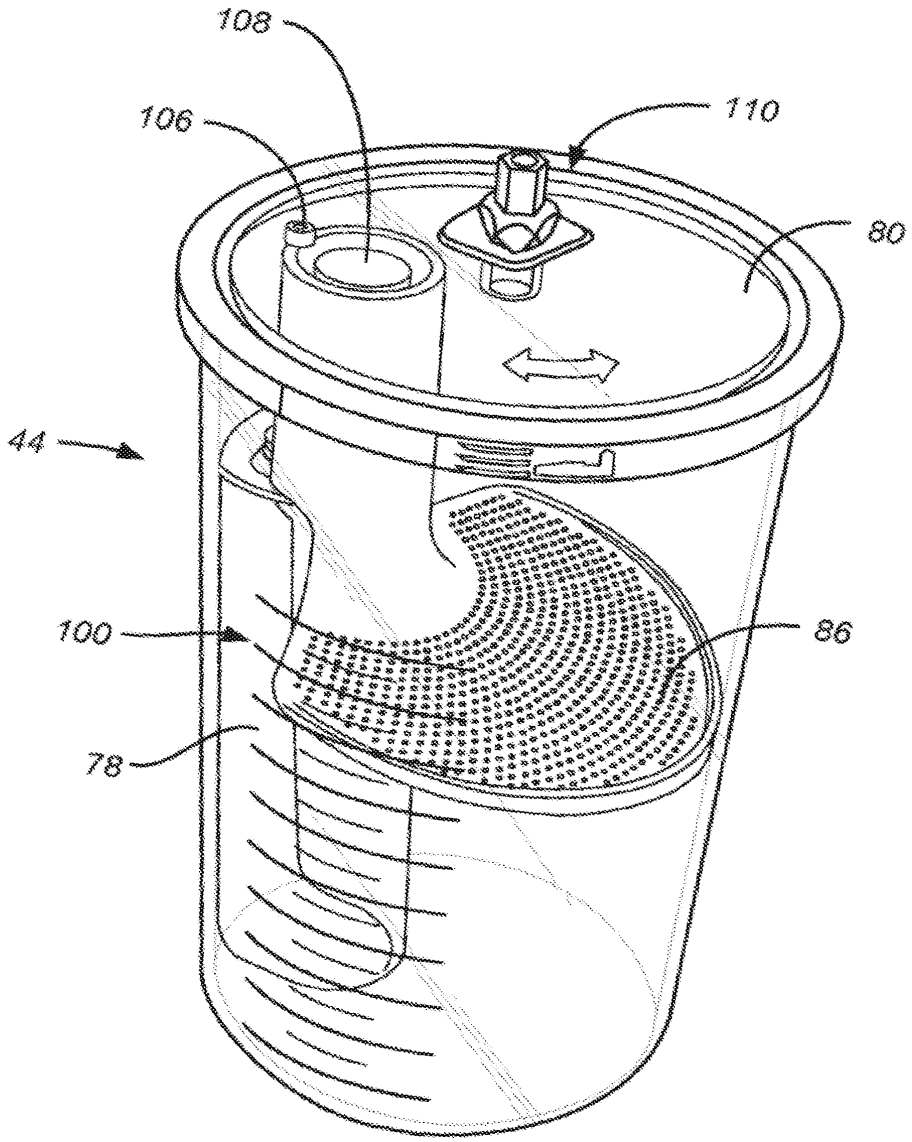


FIG. 4

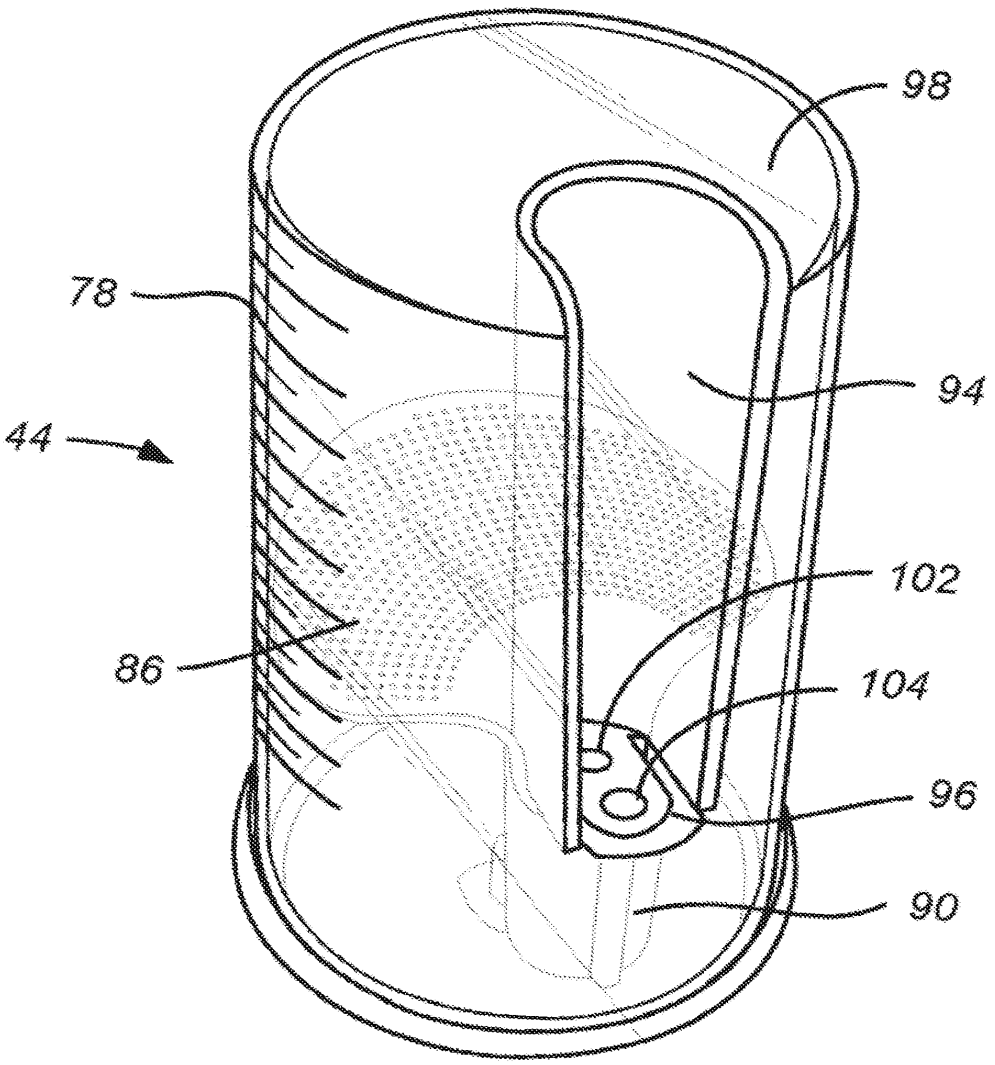


FIG. 5

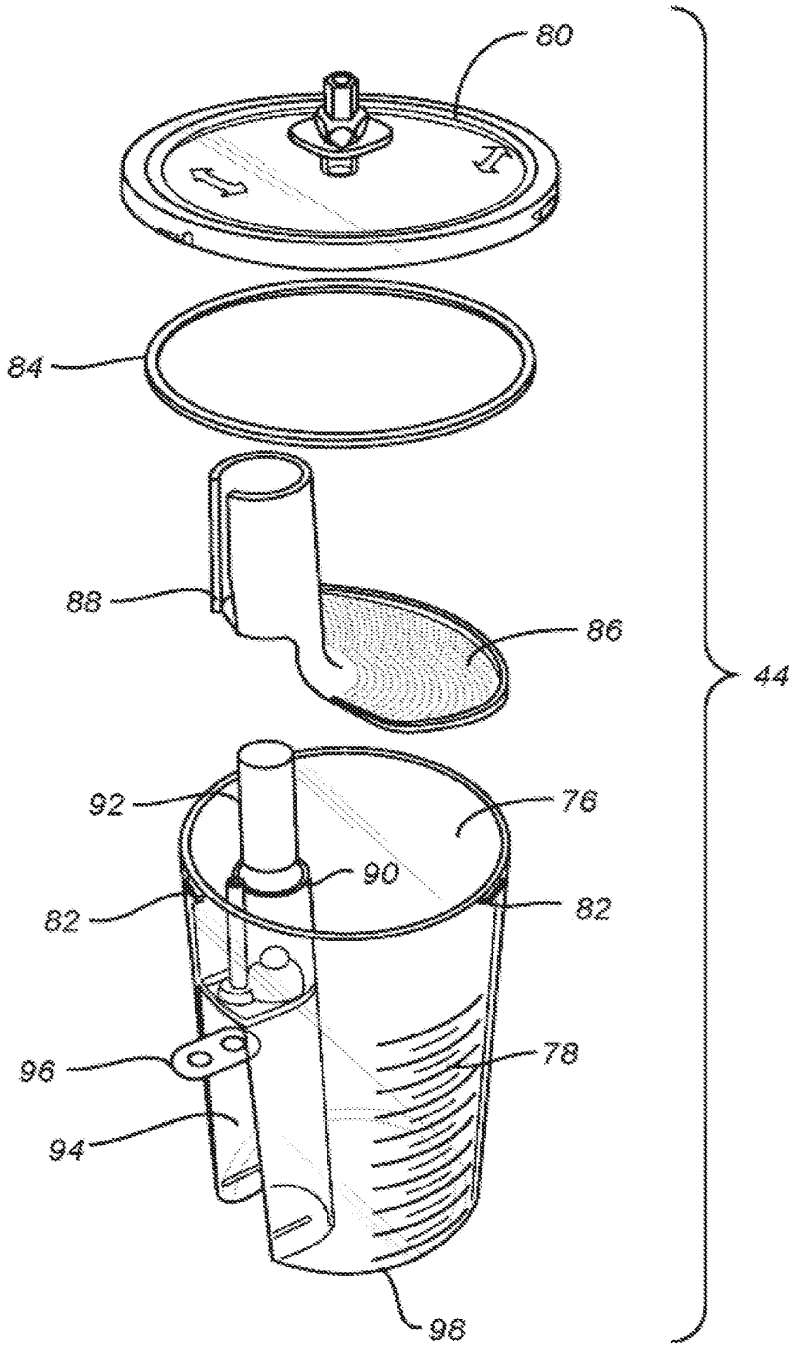


FIG. 6

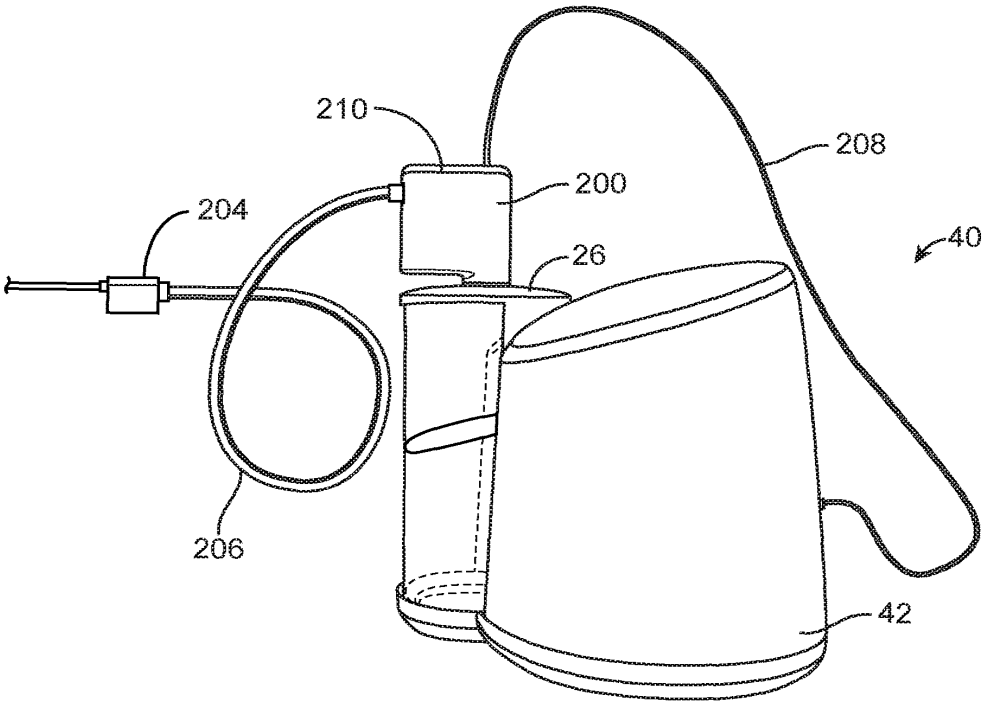


FIG. 7A

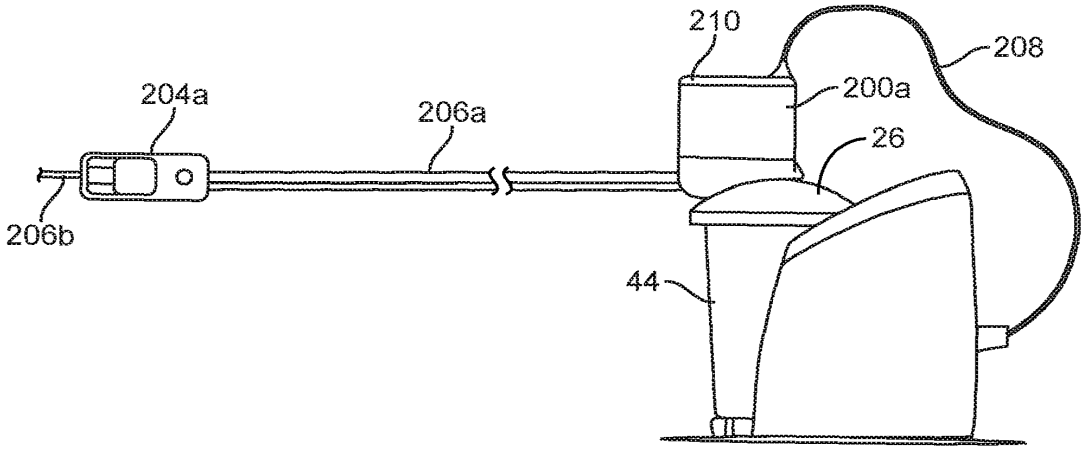


FIG. 7B

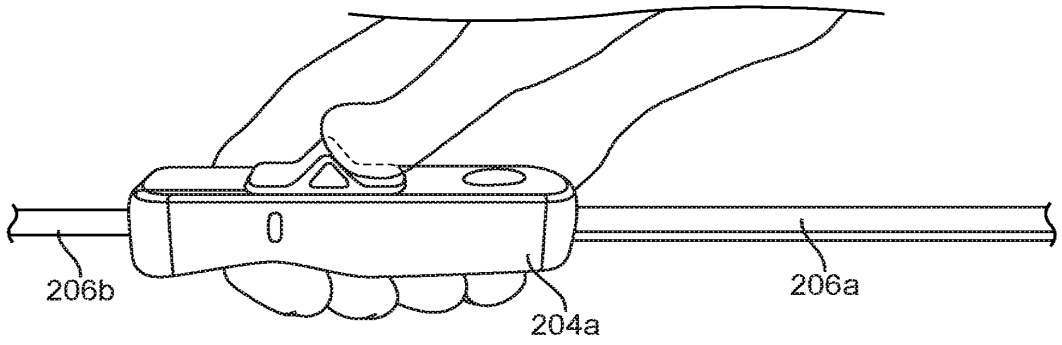


FIG. 8A

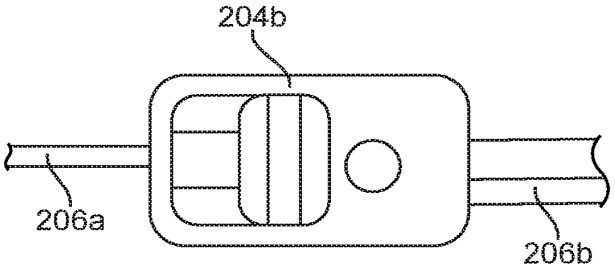


FIG. 8B

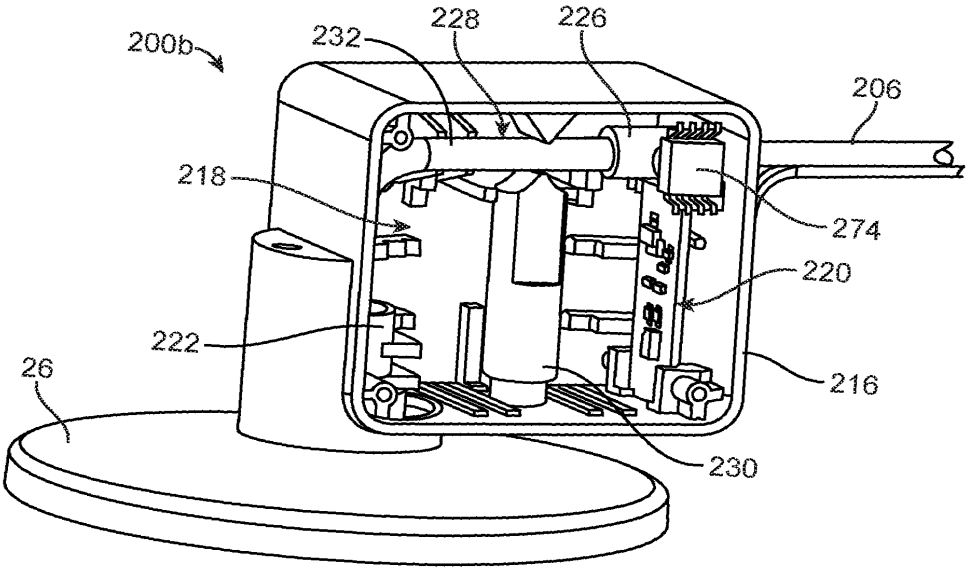

200b
232
228
226
206
218
274
220
222
216
26
230

FIG. 9

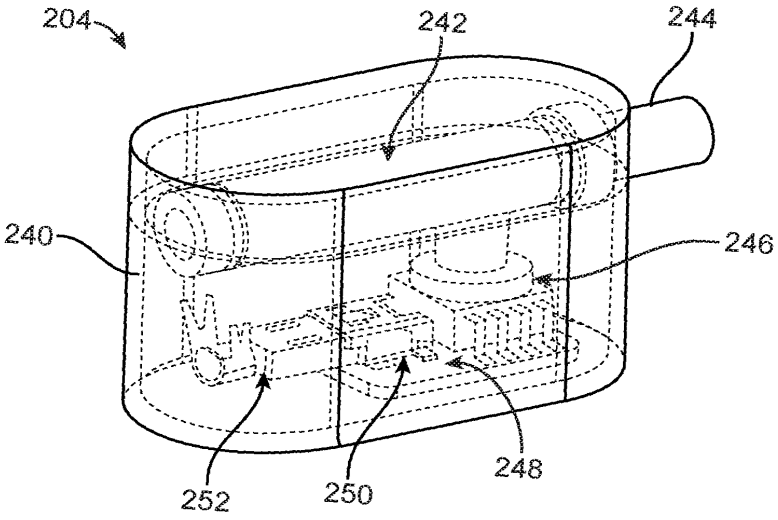

204
242
244
240
246
252
250
248

FIG. 10

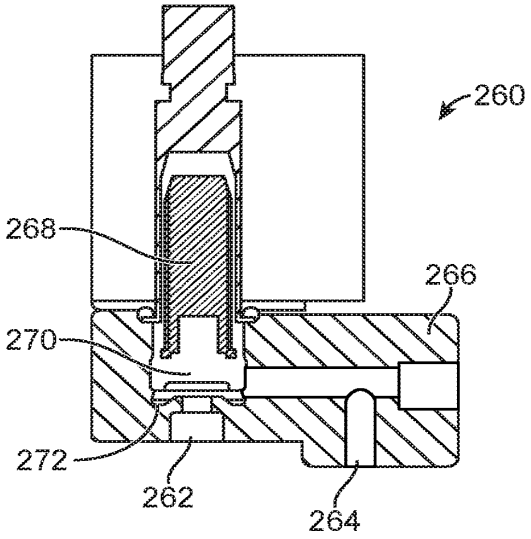


FIG. 11

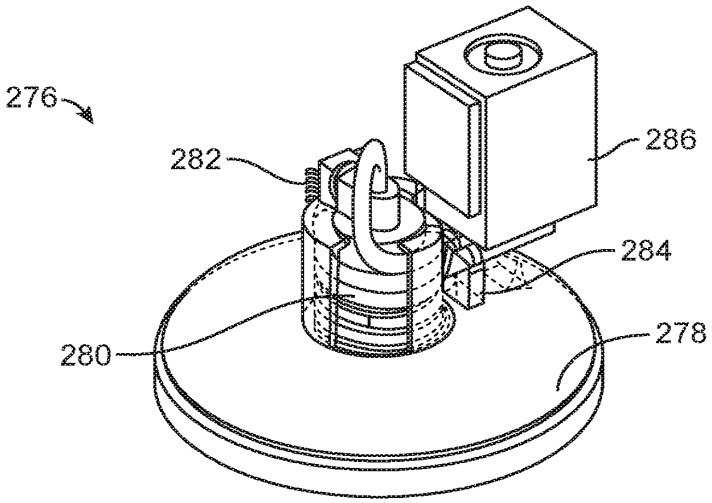
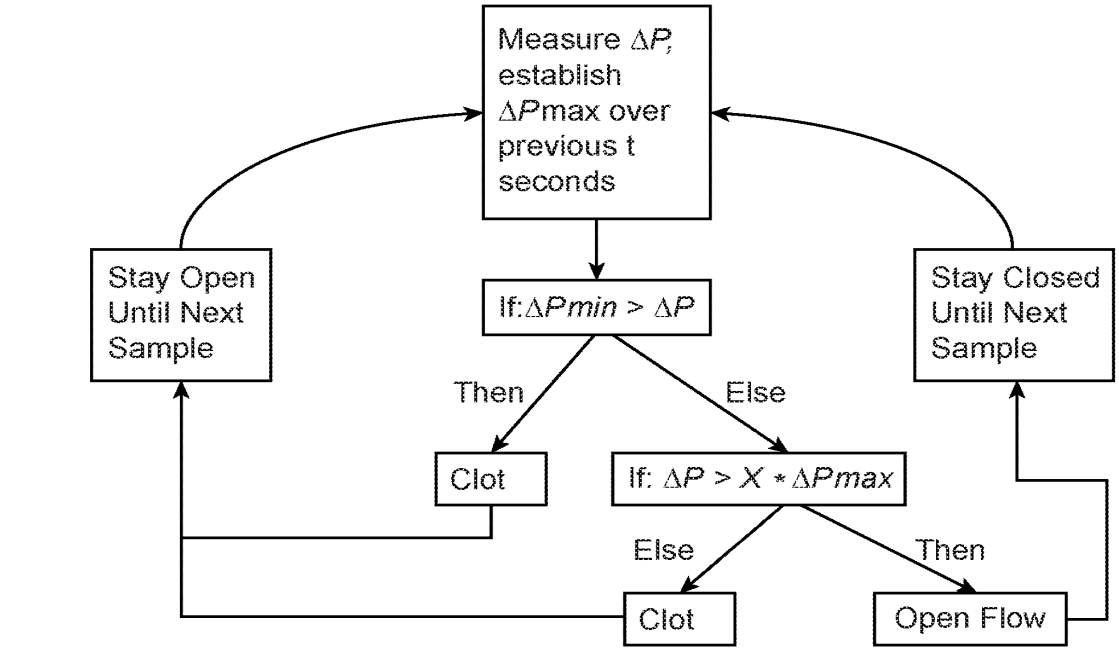


FIG. 12



Variables:
ΔP_{min} = Lower threshold for ΔP
T = Optimized sample period
X = Confidence Multiplier

FIG. 13

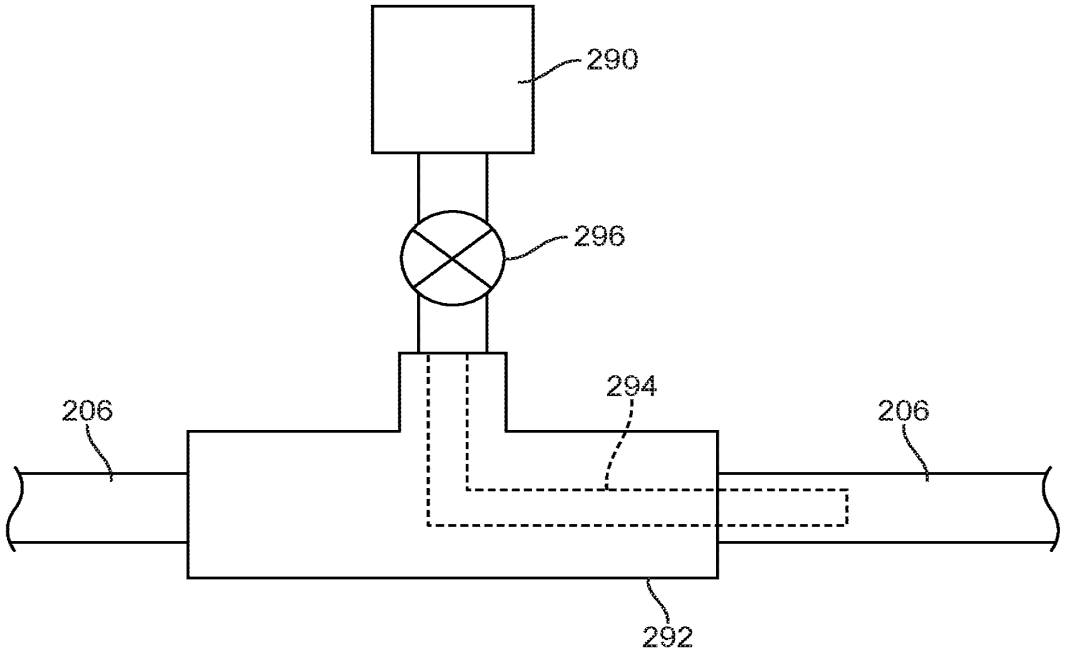


FIG. 14

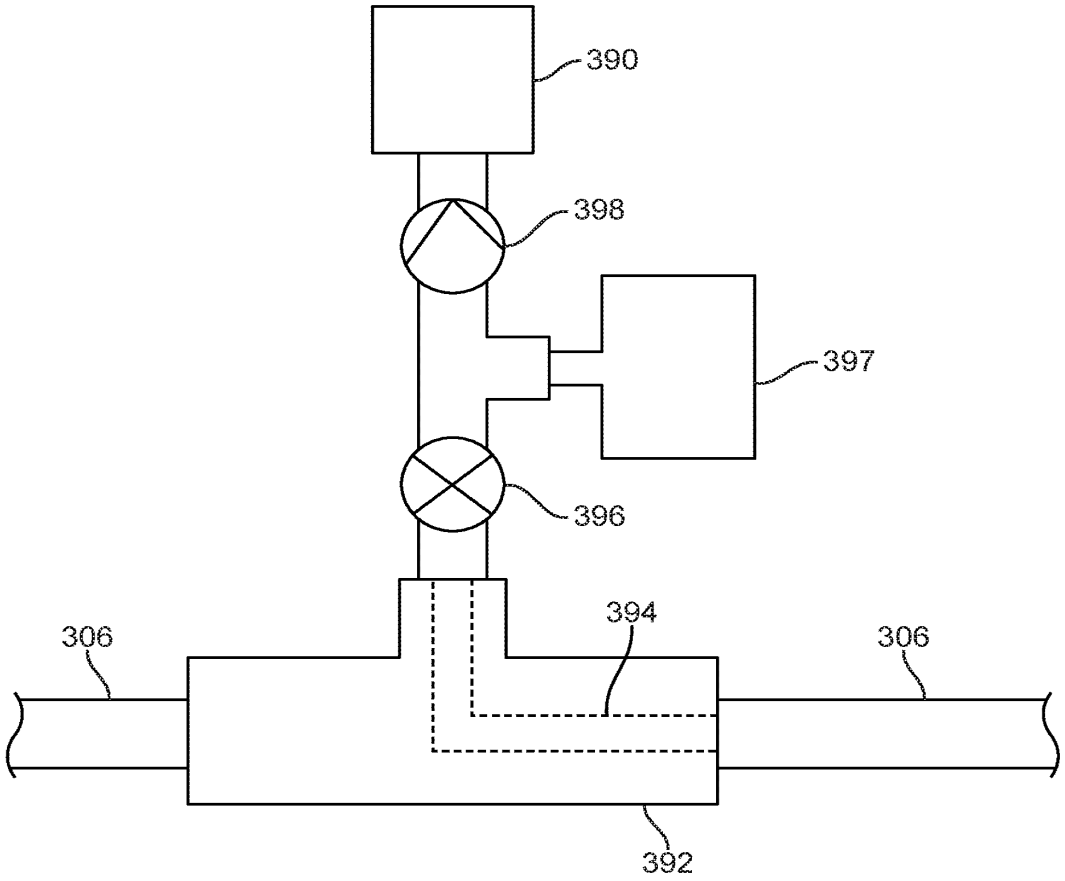


FIG. 15

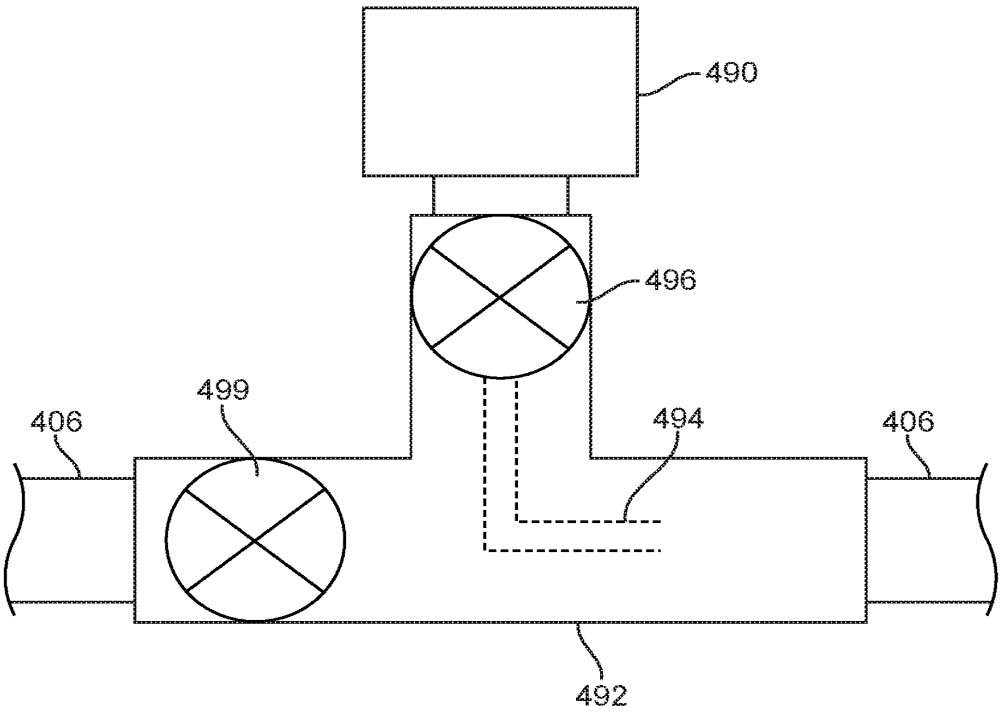


FIG. 16

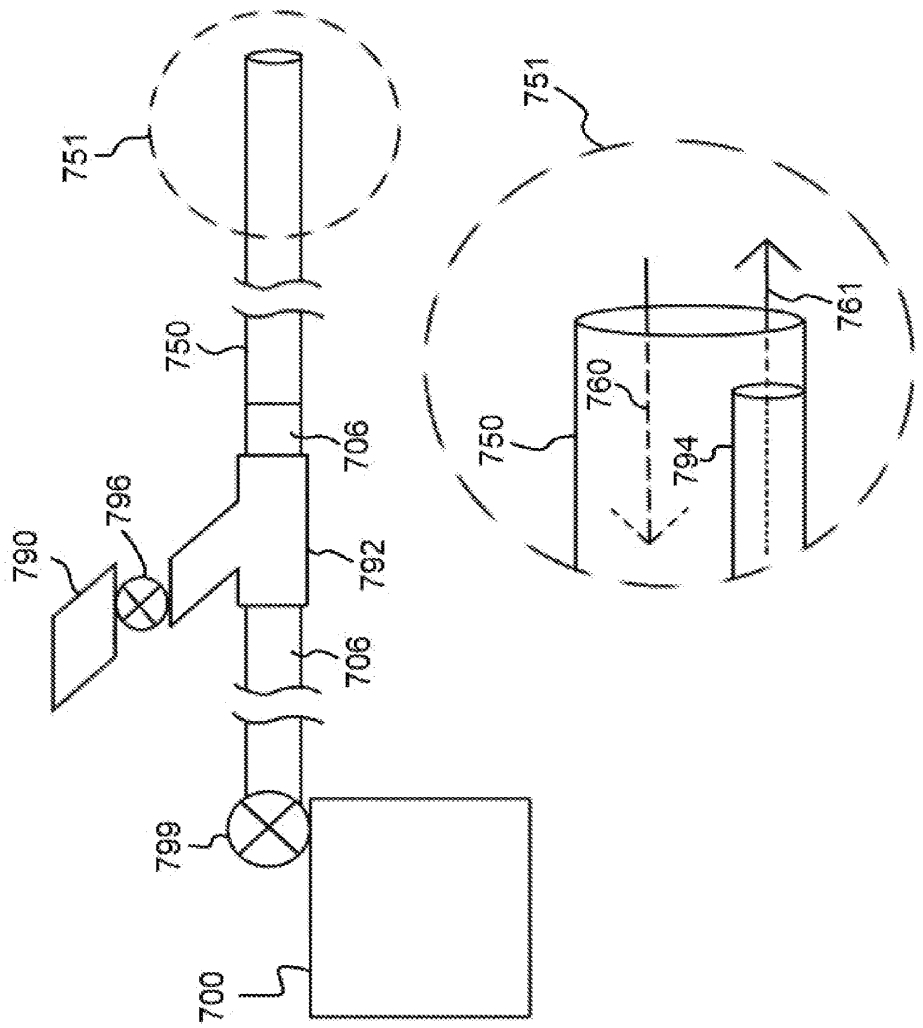


FIG. 17

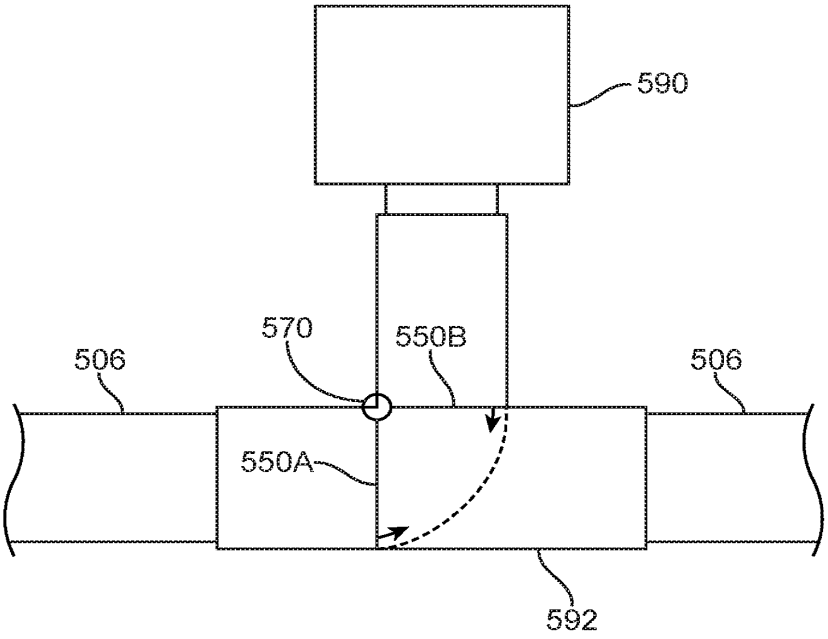


FIG. 18

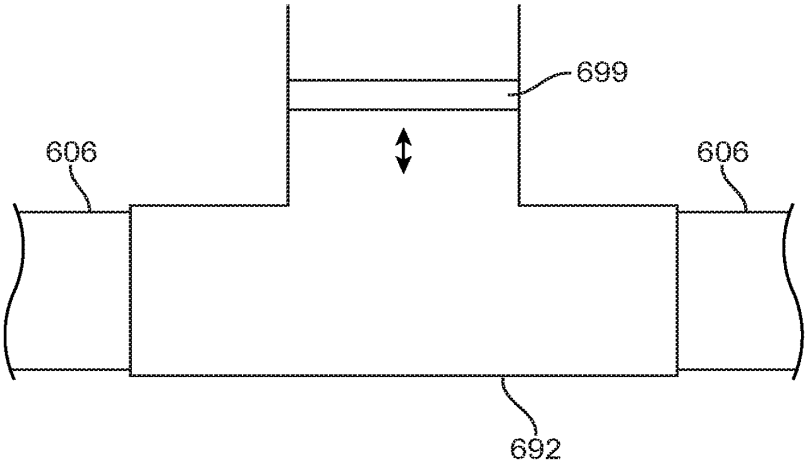


FIG. 19

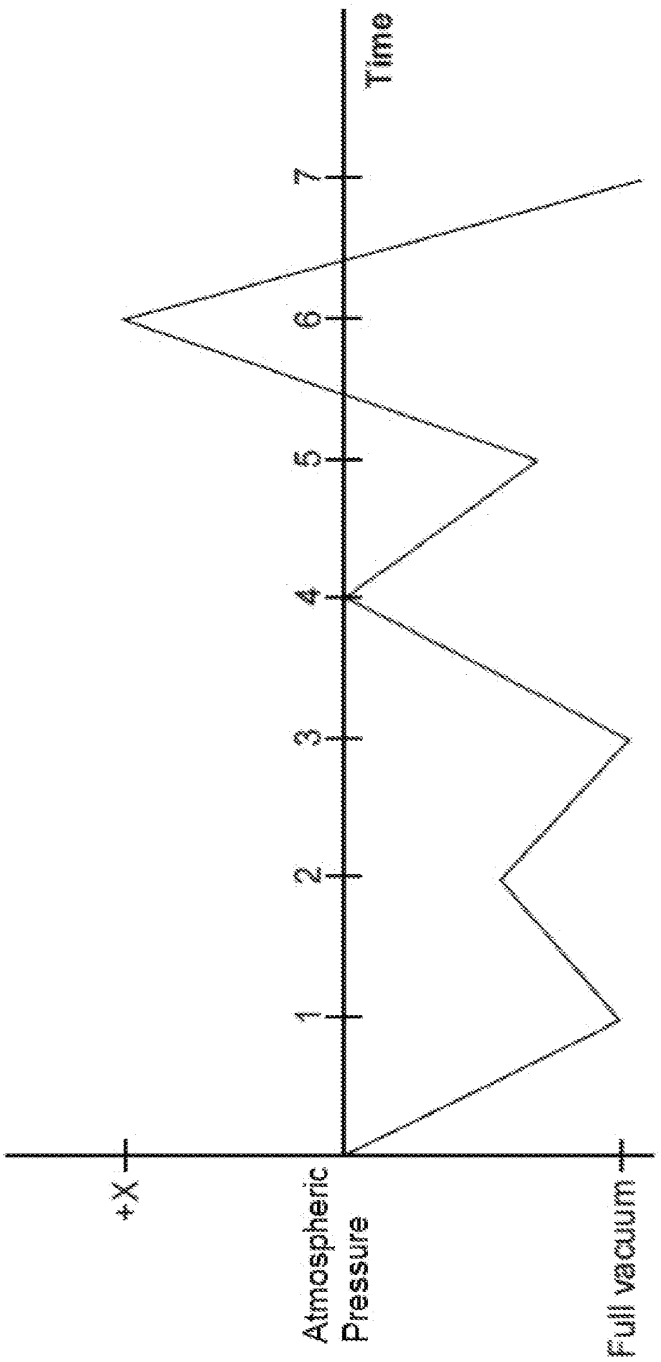


FIG. 20

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US19/43095

A. CLASSIFICATION OF SUBJECT MATTER

IPC - A61B 17/22; A61M 1/00 (2019.01)

CPC - A61B 17/22; A61M 1/0025, 1/0031, 1/0035

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
See Search History document

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X -- Y -- A	US 2016/0367272 A1 (ROUTE 92 MEDICAL, INC.) 22 December 2016; figure 11; paragraphs [0045], [0059]-[0060], [0113]-[0114]	1-7, 18-20, 22, 25, 30-31, 34-35, 39-42, 44-49, 53, 58-60, 82, 85-87 ---------- 8-10, 17, 28-29, 32-33, 55, 56, 61, 62, 70-81, 83-84 ---------- 2-6, 11-16, 21, 23-24, 26-27, 36-38, 50-52, 54, 57
X ---- Y -- A	WO 2018/019829 A1 (NEURAVI LIMITED) 01 February 2018; page 12, lines 27-30; page 23, lines 17-30; figure 25	39, 63-69 ---------- 70-81 ---------- 2-6, 11-16, 23-24, 26-27, 36-38, 50-52, 54
Y	US 2012/0041360 A1 (GERG, J et al.) 16 February 2012; abstract; figure 6; paragraphs [0033]-[0034]	8-9, 28-29, 32-33
Y	US 5,094,961 A (DEL VALLE, R et al.) 10 March 1992; column 4, lines 15-20; claim 20	10

☒ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"D" document cited by the applicant in the international application
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
07 November 2019 (07.11.2019)	04 DEC 2019
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Authorized officer Shane Thomas Telephone No. PCT Helpdesk: 571-272-4300

Form PCT/ISA/210 (second sheet) (July 2019)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US19/43095

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 4,935,005 A (HAINES, SW) 19 June 1990; column 5, lines 55-68; column 6, lines 1-20	17
Y	US 5,536,242 A (WILLARD, KC et al.0 16 July 1996; abstract; figure 1a	55, 56
Y	WO 2014/151209 A1 (VIRGINIA COMMONWEALTH UNIVERSITY) 25 September 2014; abstract; page 5, line 12; page 9, lines 13-31; figures 3A-C	61, 62
A	US 2015/0283309 A1 (INCUVATE, LLC) 8 October 2015; paragraphs [0026], [0034]-[0035]	21
A	US 2015/0327875 A1 (WALK VASCULAR, LLC) 19 November 2015; figure 2; paragraph [0048]	54
A	US 2007/0129679 A1 (BONNETTE, MJ et al.) 07 June 2007; figures 1, 5; paragraphs [0062], [0067]	57

Penumbra, Inc., Ex. 1004, Page 224 of 394
Penumbra, Inc. v. RapidPulse, Inc.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US19/43095

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☒ Claims Nos.: 43
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I: Claims 1-38 are directed toward a vacuum aspiration control system and method for use with a vacuum source and an aspiration catheter comprising an on-off valve and a controller configured to automatically close the valve to stop flow through the connecting tube when the signal indicates unrestricted flow.

Group II: Claims 39-42 and 44-87 are directed toward a dynamic aspiration system for use with a vacuum source, a pressure source, a pressure chamber, and an aspiration catheter comprising a vacuum source valve; a pressure source valve; and generating pressure differentials by alternating between opening and closing both valves.

*** Continued Within Next Supplemental Box ***

1. ☒ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

Penumbra, Inc., Ex. 1004, Page 225 of 394
Penumbra, Inc. v. RapidPulse, Inc.

*** Continued From Box No. III Observations where unity of invention is lacking ***

The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Group I include an on-off valve; and a controller configured to open and close the on-off valve, wherein the controller is configured to automatically close the valve to stop flow through the connecting tube when the signal indicates unrestricted flow while the vacuum pump remains on; opening the valve to resume flow through the connecting tube; and repeating until a desired amount of clot has been aspirated, which are not present in Group II.

Group II include a pressure source, a pressure chamber a vacuum source valve; a pressure source valve; and a controller configured to modulate the vacuum source valve and the pressure source valve, wherein the controller generates pressure differentials by alternating between opening and closing the valves and by causing the actuation of a piston in the pressure chamber when the signal indicates restricted flow, a small pressure differential, a pressure differential approaching zero, or that the aspiration catheter is at least partially clogged, which are not present in Group I.

The common technical features of Groups I and II are a connecting tube configured to connect the vacuum source with the aspiration catheter; a valve; a sensing unit configured to detect flow within the connecting tube and to produce a signal representative of such flow; and a controller configured to receive the signal representative of flow through the connecting tube; (a) engaging a distal end of an aspiration catheter against an occlusion in a blood vessel; (b) applying a vacuum through an aspiration lumen of the aspiration catheter using a vacuum source coupled to a proximal end of the aspiration lumen by a connecting tube, whereby portions of the occlusion are drawn into the aspiration lumen, through the connecting tube and into a collection receptacle by the vacuum source; (c) sensing flow through the connecting tube.

These common technical features are disclosed by US 2016/0367272 A1 to Route 92 Medical, Inc. (hereinafter 'Route 92'). Route 92 discloses a connecting tube configured to connect the vacuum source with the aspiration catheter (an aspiration line 230 (connecting tube) connects an aspiration source 600 with an aspiration catheter 320 located within access sheath 220; figure 11; paragraphs [0111], [0113]); a valve (valve 242; figure 11; paragraph [0117]); a sensing unit configured to detect flow within the connecting tube and to produce a signal representative of such flow (a flow sensor 275 that senses flow in the aspiration line 230; figure 11; paragraph [0113]); and a controller configured to receive the signal representative of flow through the connecting tube (a flow sensor 275 that senses flow in the aspiration line 230, coupled to a controller that controls the level of aspiration; figure 11; paragraph [0113]); (a) engaging a distal end of an aspiration catheter against an occlusion in a blood vessel (aspiration catheter 320 can be positioned with the distal tip at the face of the occlusion in the artery; paragraphs [0126]-[0127]); (b) applying a vacuum through an aspiration lumen of the aspiration catheter using a vacuum source coupled to a proximal end of the aspiration lumen by a connecting tube (aspiration is applied through the aspiration catheter 320 using aspiration source 600 fluidly coupled to the proximal end of the aspiration catheter 320 via aspiration line 230 (connecting tube); figure 11; paragraphs [0126]-[0127]), whereby portions of the occlusion are drawn into the aspiration lumen (the clot is aspirated using the aspiration catheter 320; paragraph [0127]), through the connecting tube and into a collection receptacle by the vacuum source (the aspirated material, and thus the clot, are aspirated into a receptacle or blood collection reservoir by the aspiration source 600; figure 11; paragraphs [0111], [0113]-[0114]); (c) sensing flow through the connecting tube (a flow sensor 275 that senses flow in the aspiration line 230 (connecting tube); figure 11; paragraph [0113]).

Since the common technical features are previously disclosed by the Route 92 reference, the common features are not special and so Groups I and II lack unity.

Docket No.: 145404-8001.US07
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Derek Dee Deville et al.

Application No.: 17/650,835 | Confirmation No.: 7707

Filed: February 11, 2022 | Art Unit: 3771

For: **ASPIRATION THROMBECTOMY SYSTEM AND METHODS FOR THROMBUS REMOVAL WITH ASPIRATION CATHETER** | Examiner: Jonathan Wade Miles

PRELIMINARY AMENDMENT

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

Commissioner:

Prior to examination on the merits, please amend the above-identified U.S. patent application as follows:

Amendments to the Claims are reflected in the listing of claims beginning on page 2 of this paper.

Remarks begin on page 7 of this paper.

Penumbra, Inc., Ex. 1004, Page 227 of 394
Penumbra, Inc. v. RapidPulse, Inc.

AMENDMENTS TO THE CLAIMS

Please amend claims 1, 11, 17, and 19. Following is a complete listing of the claims pending in the application.

1. (Currently Amended) An aspiration thrombectomy system, comprising:

an aspiration catheter having a proximal portion, a distal end and a lumen extending through the catheter;

a vacuum source fluidically coupled to the catheter;

a vacuum valve connected between the vacuum source and the proximal portion of the catheter to control a vacuum flow in the catheter lumen;

a vent valve fluidically coupled to the proximal portion of the catheter, the vent valve being configured to control a flow of a vent fluid in the catheter lumen; and

a controller configured to open and close the vacuum valve and the vent valve in a predetermined cycle to change a level of vacuum at the distal end of the ~~aspiration~~ catheter and to control fluid flow in and out from the distal end of the catheter.

2. (Original) The system of claim 1, further comprising a vent fluid source, and wherein:

the vent fluid source is configured to provide vent fluid at a pressure greater than atmospheric pressure; and

the controller is configured to cyclically open and close the vacuum valve and the vent valve to change a level of negative pressure and positive pressure at the distal end of the catheter during each cycle.

3. (Original) The system of claim 2 wherein the controller is configured to cyclically open and close the vacuum valve and the vent valve such that movement of the fluid column at the distal end of the catheter is limited to a positive amount of exit flow

from approximately 0.001 ml to approximately 1.0 ml before fluid is drawn back into the catheter lumen.

4. (Original) The system of claim 2 wherein the controller is configured to cyclically open and close the vacuum valve and the vent valve such that movement of the fluid column at the distal end of the catheter is limited to a positive amount of exit flow of approximately 0.1 ml to approximately 0.5 ml before fluid is drawn back into the catheter lumen.

5. (Original) The system of claim 1 wherein the controller is configured to cyclically open and close the vacuum valve and the vent valve in a repeated cycle comprising an off-off state in which the vacuum valve is closed while the vent valve is closed.

6. (Original) The system of claim 1 wherein:

the controller is configured to cyclically open and close the vacuum valve and the vent valve in a cycle comprising (a) a first off-off state in which the vacuum valve is closed while the vent valve is closed, (b) a vacuum-only state following the first off-off state in which the vacuum valve is open while the vent valve is closed, (c) a second off-off state following the vacuum-only state in which the vacuum valve is closed while the vent valve is closed, and (d) a vent-only state following the second off-off state in which the vacuum valve is closed while the vent valve is open; and

the cycle is repeated.

7. (Original) The system of claim 6 wherein the cycle is repeated at a frequency of 2 Hz to 12 Hz.

8. (Original) The system of claim 1 wherein the vacuum valve and the vent valve are solenoid pinch valves.

9. (Original) The system of claim 1 wherein the vacuum valve and the vent valve are cammed pinch valves.

10. (Original) The system of claim 1 wherein the controller is configured to cyclically open and close the vacuum valve and the vent valve such that an amount of momentum transfer from the fluid column in the catheter lumen is sufficient to unstick thromboembolic material at the distal end of the catheter.

11. (Currently Amended) A method for removing thromboembolic material ~~from a person using aspiration~~, comprising:

aspirating thromboembolic material from a person using the system of claim 1 by -

(a) positioning ~~a~~the distal end of ~~a~~the catheter at least proximate to thromboembolic material in a blood vessel of the person;

(b) applying a vacuum through ~~a~~the lumen of the catheter such that a vacuum flow draws at least a portion of the thromboembolic material into the catheter lumen; and

(c) controlling ~~a~~the vacuum valve fluidically coupled to the vacuum source and the catheter and ~~a~~the vent valve fluidically coupled to a vent fluid source and the catheter such that a level of vacuum at the distal end of the ~~aspiration~~ catheter changes and thereby controls flow in and out from the distal end of the catheter.

12. (Original) The method of claim 11 wherein:

the vent fluid source is configured to provide the vent fluid at a pressure greater than atmospheric pressure; and

controlling the vacuum valve and the vent valve comprises cyclically opening and closing the vacuum valve and the vent valve to change a level of negative pressure and positive pressure at the distal end of the catheter during each cycle.

13. (Original) The method of claim 12 wherein controlling the vacuum valve and the vent valve comprises limiting movement of a fluid column in the catheter lumen at the distal end of the catheter to a positive amount of exit flow within a range of a length of the fluid column that exits the distal end of the catheter.

14. (Original) The method of claim 13 wherein limiting movement of the fluid column at the distal end of the catheter comprises stopping a distal flow through the catheter lumen and reapplying the vacuum through the catheter lumen such that the positive amount of exit flow is approximately 0.5 mm to approximately 30 mm of the fluid column before fluid is drawn back into the catheter lumen.

15. (Original) The method of claim 12 wherein controlling the vacuum valve and the vent valve comprises limiting movement of a fluid column in the catheter lumen at the distal end of the catheter to a positive amount of exit flow within a range of volume of fluid that exits the distal end of the catheter.

16. (Original) The method of claim 15 wherein limiting movement of the fluid column at the distal end of the catheter comprises stopping a distal flow through the catheter lumen and reapplying the vacuum through the catheter lumen such that the positive amount of exit flow is approximately 0.001 ml to approximately 1.0 ml before fluid is drawn back into the catheter lumen.

17. (Currently Amended) The ~~system~~ method of claim 15 wherein limiting movement of the fluid column at the distal end of the catheter comprises stopping a distal

flow through the catheter lumen and reapplying the vacuum through the catheter lumen such that the positive amount of exit flow is approximately 0.1 ml to approximately 0.5 ml before fluid is drawn back into the catheter lumen.

18. (Original) The method of claim 11, further comprising cyclically opening and closing the vacuum valve and the vent valve in a repeated cycle including an off-off state in which the vacuum valve is closed while the vent valve is closed.

19. (Currently Amended) The ~~system~~ method of claim 11, further comprising:

cyclically opening and closing the vacuum valve and the vent valve in a cycle including (a) a first off-off state in which the vacuum valve is closed while the vent valve is closed, (b) a vacuum-only state following the first off-off state in which the vacuum valve is open while the vent valve is closed, (c) a second off-off state following the vacuum-only state in which the vacuum valve is closed while the vent valve is closed, and (d) a vent-only state following the second off-off state in which the vacuum valve is closed while the vent valve is open; and

repeating the cycle.

20. (Original) The method of claim 19 wherein the cycle is repeated at a frequency of 2 Hz to 12 Hz.

REMARKS

Prior to examination, please amend claims 1, 11, 17, and 19 as set forth above. Accordingly, claims 1-20 are currently pending in this application.

If the Examiner has any questions or believes a telephone conference would expedite prosecution of this application, the Examiner is encouraged to contact the undersigned attorney at (206) 359-3258.

Please charge any underpayment or credit any overpayment to our Deposit Account No. 50-0665, under Order No. 145404-8001.US07 from which the undersigned is authorized to draw.

Dated: 2022 - April - 07

Respectfully submitted,

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Attorney for Applicant

PTO/SB/06 (09-11)
Approved for use through 1/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 17/650,835	Filing Date 02/11/2022	☐ To be Mailed

ENTITY: ☐ LARGE ☑ SMALL ☐ MICRO

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA		RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A		N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A		N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*		x $50 =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*		x $240 =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).				
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))					
* If the difference in column 1 is less than zero, enter "0" in column 2.				TOTAL	

APPLICATION AS AMENDED - PART II

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT	04/07/2022	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 20	Minus	** 20	= 0		x $50 =	0
	Independent (37 CFR 1.16(h))	* 1	Minus	*** 3	= 0		x $240 =	0
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	0

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=		x $0 =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=		x $0 =	
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.	SLIE
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".	/SHARON M WEST/
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".	
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.	

This collection of information is required by 37 CFR 1.16. 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, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/650,835	02/11/2022	Derek Dee Deville	145404-8001.US07	7707

25096 7590 03/31/2022

PERKINS COIE LLP - SEA General
PATENT-SEA
P.O. BOX 1247
SEATTLE, WA 98111-1247

EXAMINER	
CENTRAL, DOCKET	

ART UNIT	PAPER NUMBER
OPAP	

NOTIFICATION DATE	DELIVERY MODE
03/31/2022	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):

patentprocurement@perkinscoie.com

Decision Granting Request for Prioritized Examination (Track I)	**Application No.** 17/650,835	**Applicant(s)** Deville et al.	
	Examiner CHERYL P GIBSON BAYLOR	**Art Unit** OPET	**AIA (FITF) Status** Yes

1. THE REQUEST FILED 11 February 2022 IS **GRANTED** .

The above-identified application has met the requirements for prioritized examination

A. ☑ for an original nonprovisional application (Track I).
B. ☐ for an application undergoing continued examination (RCE).

2. **The above-identified application will undergo prioritized examination**. The application will be accorded special status throughout its entire course of prosecution until one of the following occurs:

A. filing a **petition for extension of time** to extend the time period for filing a reply;

B. filing an **amendment to amend the application to contain more than four independent claims, more than thirty total claims** , or a multiple dependent claim;

C. filing a **request for continued examination** ;

D. filing a notice of appeal;

E. filing a request for suspension of action;

F. mailing of a notice of allowance;

G. mailing of a final Office action;

H. completion of examination as defined in 37 CFR 41.102; or

I. abandonment of the application.

Telephone inquiries with regard to this decision should be directed to CHERYL GIBSON BAYLOR at (571)272-3213. In his/her absence, calls may be directed to Petition Help Desk at (571) 272-3282.

/CHERYL GIBSON BAYLOR/ Paralegal Specialist, OPET	

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APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
17/650,835	02/11/2022	3783	830	145404-8001.US07	20	2

CONFIRMATION NO. 7707

FILING RECEIPT

25096
PERKINS COIE LLP - SEA General
PATENT-SEA
P.O. BOX 1247
SEATTLE, WA 98111-1247

OC000000131889074

Date Mailed: 02/18/2022

Receipt is acknowledged of this non-provisional utility patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF FIRST INVENTOR, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection.

Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please submit a written request for a corrected Filing Receipt, including a properly marked-up ADS showing the changes with strike-through for deletions and underlining for additions. If you received a "Notice to File Missing Parts" or other Notice requiring a response for this application, please submit any request for correction to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections provided that the request is grantable.

Inventor(s)

Derek Dee Deville, Coral Gables, FL;
Matthew A. Palmer, Miami, FL;
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Applicant(s)

RapidPulse, Inc., Miami, FL;

Power of Attorney: None

Domestic Priority data as claimed by applicant

This application is a CON of 16/899,514 06/11/2020
which is a CON of 16/681,564 11/12/2019 PAT 10722253
which is a CON of 16/516,232 07/18/2019 PAT 10531883
which claims benefit of 62/701,086 07/20/2018
and claims benefit of 62/750,011 10/24/2018
and said 16/899,514 06/11/2020
is a CON of PCT/US2019/042546 07/19/2019
and said 16/516,232 07/18/2019
claims benefit of 62/701,086 07/20/2018

and claims benefit of 62/750,011 10/24/2018

Foreign Applications for which priority is claimed (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see http://www.uspto.gov for more information.) - None.
Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.

Permission to Access Application via Priority Document Exchange: Yes

Permission to Access Search Results: Yes

Applicant may provide or rescind an authorization for access using Form PTO/SB/39 or Form PTO/SB/69 as appropriate.

If Required, Foreign Filing License Granted: 02/16/2022

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 17/650,835**

Projected Publication Date: 05/26/2022

Non-Publication Request: No

Early Publication Request: No
** **SMALL ENTITY** **
Title

ASPIRATION THROMBECTOMY SYSTEM AND METHODS FOR THROMBUS REMOVAL WITH ASPIRATION CATHETER

Preliminary Class

604

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: No

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Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application

serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at http://www.uspto.gov/web/offices/pac/doc/general/index.html.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, http://www.stopfakes.gov. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4258).

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Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

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Penumbra, Inc., Ex. 1004, Page 239 of 394
Penumbra, Inc. v. RapidPulse, Inc.

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Penumbra, Inc., Ex. 1004, Page 240 of 394
Penumbra, Inc. v. RapidPulse, Inc.

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number: 17/650,835

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY FEE($)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	80		N/A	
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	350		N/A	
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	400		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	20 minus 20 =	*	x 50 =	0.00	OR		
INDEPENDENT CLAIMS (37 CFR 1.16(h))	2 minus 3 =	*	x 240 =	0.00			
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			0.00			
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				0.00			
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	830		TOTAL	

APPLICATION AS AMENDED - PART II

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY ADDITIONAL FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE($)
AMENDMENT A	Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE($)	ADDITIONAL FEE($)	OR	RATE($)	ADDITIONAL FEE($)
AMENDMENT B	Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

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Doc Code: TRACK1.REQ
Document Description: TrackOne Request

PTO/AIA/424 (04-14)

CERTIFICATION AND REQUEST FOR PRIORITIZED EXAMINATION UNDER 37 CFR 1.102(e) (Page 1 of 1)

First Named Inventor:	Derek Dee Deville	Nonprovisional Application Number (if known):	
Title of Invention:	ASPIRATION THROMBECTOMY SYSTEM AND METHODS FOR THROMBUS REMOVAL WITH ASPIRATION CATHETER		

APPLICANT HEREBY CERTIFIES THE FOLLOWING AND REQUESTS PRIORITIZED EXAMINATION FOR THE ABOVE-IDENTIFIED APPLICATION.

1. The processing fee set forth in 37 CFR 1.17(i)(1) and the prioritized examination fee set forth in 37 CFR 1.17(c) have been filed with the request. The publication fee requirement is met because that fee, set forth in 37 CFR 1.18(d), is currently $0. The basic filing fee, search fee, and examination fee are filed with the request or have been already been paid. I understand that any required excess claims fees or application size fee must be paid for the application.
2. I understand that the application may not contain, or be amended to contain, more than four independent claims, more than thirty total claims, or any multiple dependent claims, and that any request for an extension of time will cause an outstanding Track I request to be dismissed.
3. The applicable box is checked below:

I. ☑ Original Application (Track One) - Prioritized Examination under § 1.102(e)(1)

i. (a) The application is an original nonprovisional utility application filed under 35 U.S.C. 111(a). This certification and request is being filed with the utility application via EFS-Web.

---OR---

(b) The application is an original nonprovisional plant application filed under 35 U.S.C. 111(a). This certification and request is being filed with the plant application in paper.

ii. An executed inventor's oath or declaration under 37 CFR 1.63 or 37 CFR 1.64 for each inventor, **or** the application data sheet meeting the conditions specified in 37 CFR 1.53(f)(3)(i) is filed with the application.

II. ☐ Request for Continued Examination - Prioritized Examination under § 1.102(e)(2)

i. A request for continued examination has been filed with, or prior to, this form.
ii. If the application is a utility application, this certification and request is being filed via EFS-Web.
iii. The application is an original nonprovisional utility application filed under 35 U.S.C. 111(a), or is a national stage entry under 35 U.S.C. 371.
iv. This certification and request is being filed prior to the mailing of a first Office action responsive to the request for continued examination.
v. No prior request for continued examination has been granted prioritized examination status under 37 CFR 1.102(e)(2).

Signature /Paul T. Parker/	Date 2022-02-11
Name (Print/Typed) Paul T. Parker	Practitioner Registration Number 38,264

Note: *This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. Submit multiple forms if more than one signature is required.**

☑ *Total of 1 forms are submitted.

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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.

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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.

ASPIRATION THROMBECTOMY SYSTEM AND METHODS FOR THROMBUS REMOVAL WITH ASPIRATION CATHETER

CROSS-REFERENCE TO RELATED APPLICATION(S)

[0001] This application is a continuation of U.S. Patent Application Serial No. 16/899,514, filed on June 11, 2020, which is a continuation of:

- U.S. Patent Application Serial No. 16/681,564, filed on Nov. 12, 2019, now U.S. Patent No. 10,722,253, issued July 28, 2020, which is a continuation of U.S. Patent Application Serial No. 16/516,232, filed on July 18, 2019, now U.S. Patent No. 10,531,883, issued January 14, 2020, which claims the benefit of U.S. Provisional Application Serial Nos. 62/701,086, filed July 20, 2018, and 62/750,011, filed October 24, 2018; and
- International Application No. PCT/US2019/042546 under 35 U.S.C. § 120, filed July 19, 2019, which designated the United States and under 35 U.S.C. § 119 claims the priority of U.S. Patent Application Serial No. 16/516,232, filed on July 18, 2019, which claims the benefit of U.S. Provisional Application Serial Nos. 62/701,086, filed July 20, 2018, and 62/750,011, filed October 24, 2018.

The disclosures of the foregoing related applications are hereby incorporated herein by reference in their entireties.

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH

[0002] Not Applicable

TECHNICAL FIELD

[0003] The present systems, apparatuses, and methods lie in the field of thrombus removal. The present disclosure relates to an aspiration thrombectomy system and methods for thrombus removal with aspiration catheter.

BACKGROUND

[0004] Ischemic strokes are usually caused by a blood clot that blocks or plugs a blood vessel in the brain. This blockage prevents blood from flowing to the brain. Within minutes, brain cells begin to die, which, if not treated rapidly, causes brain damage or death. The costs associated with removing a clot are significant. Most treatments involve thrombectomy: the removal of the clot by aspiration, mechanical retrieval, or some combination thereof.

[0005] Removal by aspiration is effected by placing a source of vacuum, e.g., an aspiration or vacuum catheter, upstream of the clot and drawing the clot into or against the distal end of the catheter. Conceptually, aspiration is effective but some significant problems occur in practice. The basic configuration for an aspiration catheter includes a length of hollow catheter having a proximal end fluidically connected to a vacuum or suction pump. In this configuration, operation of the suction pump causes fluid and particulates at the distal end of the catheter to enter the distal opening of the hollow lumen and travel to the proximal end of the lumen near or into the suction pump. Conventional aspiration catheters are threaded through a balloon guide catheter. In one exemplary procedure, the balloon of the guide catheter is guided into the internal carotid artery of the brain. The balloon is inflated to occlude the vessel. The aspiration catheter is threaded through the balloon guide catheter and out the distal end of the guide catheter past the balloon. The distal end of the aspiration catheter is advanced to the clot that is occluding the brain vessel. Suction connected to the aspiration catheter is turned on to cause flow reversal. Ideally, this system aspirates the clot entirely out of the neurovasculature and to the proximal end of the aspiration catheter so that extraction and re-establishment of blood flow could be confirmed. In practice, however, this rarely occurs.

[0006] Thrombi are frequently of a larger diameter than the catheter being used to aspirate them. For aspiration to be successful, the thrombus must deform to conform to the inner diameter of the aspiration catheter. During conventional aspirations, it is common for applied vacuum to partially draw a thrombus into the distal opening of the aspiration catheter's lumen, thereby deforming some of the thrombus to the catheter's inner diameter. At this point, the thrombus becomes lodged completely within, partially within, or at the distal opening of the aspiration catheter, a condition that can be referred to as corked or corking.

In effect, the distal end becomes a suction cup grasper for the clot. When this situation occurs, a surgeon's only option is to use the aspiration catheter as a fishing line to pull the clot back through the balloon guide and out of body. The other option is not viable, that is, reversing the suction to pressurize the clot and eject it forcibly and uncontrollably out of the distal opening of the aspiration catheter. Such action is dangerous to the patient for many reasons, the primary one being that forcibly and uncontrollably ejecting the clot may cause the clot to move further distally within the vessel in which it was originally lodged. That distal movement would not only cause the clot to be further within the vessel — i.e., in an even smaller diameter of the vessel than when it was originally lodged — but it could permanently lodge the clot into that vessel, making it impossible to remove, or it could burst the vessel. Those of skill in the art know that these situations are to be avoided because of the serious potential risks to the patient.

[0007] Even when the surgeon uses the aspiration catheter to fish out the clot, there is no assurance that the entirety of the clot will be removed. Pieces of the clot can break off during movement, when that occurs, the pieces re-embolize within the same vessel or within different vessels that might be even more difficult to remove.

[0008] When all or most of the clot is drawn out from the patient, it is difficult to confirm that the entire thrombus was removed. A significant disadvantage of current thrombus removal devices is the inability of a surgeon to ascertain thrombus capture/removal without the full withdrawal of a given therapeutic device from a patient's anatomy. Even systems capable of fully aspirating a given thrombus are problematic, because the reservoirs into which aspirated contents are deposited are located outside of the sterile field in an operating room setting. This location, outside the sterile field, makes it difficult or impossible for physicians operating aspiration catheters to easily visualize and appraise aspirated thrombus material.

[0009] To confirm thrombus removal can require the surgeon to attempt aspiration again. The aspiration and balloon guide catheters have to be cleaned out, access to distal anatomy has to be re-established, and, when the aspiration catheter finally is located back at the embolism site, the same issues may be present again with whatever embolus material remains. A disadvantage of these procedures is the significant increase in procedure time,

which not only significantly increases the cost (as each minute in an operating room is expensive), it also increases the surgeon's stress, which decreases the success rate of the operation.

[0010] First-pass recanalization rate is a metric used to determine the efficacy of thrombectomy systems. Most current systems offer rates of between 30% and 60%. A system that increases the first-pass recanalization rate is valuable and desirable.

[0011] Even with an attempt to maintain vacuum pressure utilizing manual periodic cycling, prior art systems are not capable of avoiding positive pressures at the distal end of the catheter. Prior art systems are not able to react quickly enough to keep the distal end of the catheter from experiencing a positive pressure. When positive pressure exists at the distal end of the lumen, liquid from inside the lumen exits out from the distal end of the catheter in a distal direction. This is referred to as forward flow. The prior art do not have a fast enough reaction time to quell forward flow. Forward flow, therefore, can and does remove thrombi off of the distal end and risk sending thrombi further distally in the vasculature. Such systems cannot guarantee removing all forward flow eliminating positive pressure at the distal end of the catheter.

[0012] Thus, a need exists to overcome the problems with the prior art systems, designs, and processes as discussed above.

SUMMARY

[0013] The systems, apparatuses, and methods described provide an aspiration thrombectomy system and methods for thrombus removal with an aspiration thrombectomy system that overcome the herein fore-mentioned disadvantages of the heretofore-known devices and methods of this general type and that provide such features with increased first-pass recanalization rate by completely pulling the embolus out and, thereby, reducing the instance of aspiration catheter obstruction/clogging by the embolus.

[0014] The systems, apparatuses, and methods provide an aspiration thrombectomy system that completely vacuums up the clot so that clots are no longer dragged out of vasculature while half hanging out of a catheter tip. The aspiration thrombectomy system moves the vacuumed clot all the way to the proximal end of the vacuum channel and allows

the surgeon to confirm recanalization of the vessel in which the clot formerly resided (for example, by injecting contrast through the catheter that remains in place after clot removal) and provides structure to indicate to the surgeon that the thrombus has been removed and that flow has been restored.

[0015] The systems, apparatuses, and methods provide an aspiration thrombectomy system that can be coupled with conventional aspiration catheters to significantly increase the efficacy of such catheter and pump systems. Vacuum level is indicated herein in two different ways:

1) as the absolute level of pressure, where a "high vacuum" approaches zero absolute pressure. This is the "absolute pressure" way of measuring vacuum. A perfect vacuum would be zero, and atmospheric pressure would be indicated by measuring the height of a column of mercury that can be supported by a standard atmosphere (760 mm Hg). Hence, lower values indicate an increased level of vacuum relative to the ambient atmospheric pressure.

2) The pressure relative to atmospheric pressure may be indicated. This way of measuring pressure relative to a standard atmospheric pressure is known as "gage pressure." The most common way of measuring pressure in the vacuum realm (below atmospheric pressure) is by using a gage calibrated so that one atmosphere reads zero (standard atmospheric pressure), and the highest possible level of vacuum would be indicated as "29.92 inches of mercury" Common mechanical vacuum gauges work this way, so this usage has become common.

Herein, the "gage pressure" is used as method of indicating vacuum level; i.e., "zero inches of mercury" means atmospheric pressure, no suction at all. A high number (e.g., 25" Hg) means a high level of vacuum suction. (The highest possible level of vacuum measured this way would be 29.92" Hg.) "Vacuum" as used herein is a condition below normal atmospheric pressure. In the instant application, the units of pressure for vacuum is pounds per square inch ("PSI").psi"), inches of mercury, or mmHg. Depending on the context of use of the word vacuum, a "high" vacuum is referred to herein as a low pressure that is lower than atmospheric pressure. Vacuum also refers to a negative pressure(s) and a pressure above

atmospheric pressure is referred to as a positive pressure. In some instances, however, use of the word "high" with respect to pressure can mean a greater negative or can mean a greater positive based on the context. Likewise, use of the words "low" or "lower" with respect to pressure can mean a lesser negative or can mean a lesser positive based on the context

[0016] Thrombi are frequently of a larger diameter than the catheter being used to aspirate them. In order for aspiration to be successful, the thrombus must deform to conform to the inner diameter of the aspiration catheter. During conventional aspirations, it is common for applied vacuum to partially draw a thrombus into the distal opening of the aspiration catheter's lumen. At this point, the thrombus becomes stuck with some of the thrombus resting within the catheter's inner diameter and some of the thrombus protruding from the distal end.

[0017] The systems, apparatuses, and methods provide an aspiration thrombectomy system with an unclogging structure and technique that temporarily halts vacuum at the distal end of the aspiration catheter, pushes the thrombus distally out of the lumen, and then re-applies vacuum —an occlusion-vacuum-pressure sequence of operation. Upon re-application of the vacuum, the thrombus accelerates back into the catheter and deforms to a diameter allowing it to be completely aspirated. Each halting of the vacuum, thrombus pushing, and reapplication of the vacuum is controlled by the surgeon.

[0018] The systems and methods operate an aspiration/suction catheter with a mechanism to stop the vacuum and then press the distal fluid column in reverse, i.e., a positive displacement without a check valve, referred to herein as a column shift. All functions can be controlled with a single handle, including vacuum shut off and column shift while limiting the amount and the force for the column shift. When the controller is actuated, a positive amount of exit flow is created without possibility of overshooting. The exiting movement of fluid is limited to a specific volume and/or pressure and is automatically and precisely controlled. It is the user who controls when the column shift occurs and when it returns. A trap is disposed at an exit to catch and display the thrombus. A vent can be opened to atmosphere to clear fluid in the trap and show what thrombus remains.

[0019] With the foregoing and other objects in view, there is provided, a vacuum catheter for removing an object from within a human vessel comprising a vacuum tube defining an interior vacuum channel comprising a proximal opening for receiving application of vacuum and a distal capture opening fluidically connected to the proximal opening, the distal capture opening configured to receive therein the object responsive to application of the vacuum, and comprising an intermediate section between the proximal opening and the distal capture opening, and a vacuum interruption controller comprising a body through which a portion of the intermediate section passes and an extrusion compressor movably disposed with respect to the body towards and away from the portion of the intermediate section such that, in a rest state, the extrusion compressor does not occlude the vacuum channel and, in an actuated state, the extrusion compressor first occludes the vacuum channel and then moves fluid disposed between the portion of the intermediate section and the distal capture opening a given distance distally towards the distal capture opening.

[0020] In accordance with another feature, there is provided a vacuum pump selectively applying vacuum to the proximal opening.

[0021] In accordance with a further feature, the vacuum tube has a proximal portion and which further comprises a catheter body surrounding the vacuum tube and configured to steer at least the proximal portion of the vacuum tube.

[0022] In accordance with an added feature, the vacuum tube has a proximal portion sized to fit within the Circle of Willis in a brain and the object is a blood clot adjacent the Circle of Willis.

[0023] With the foregoing and other objects in view, there is provided, a clot removal system comprising a catheter having a distal end and defining a lumen filled with a liquid column having a proximal portion and a distal portion, a controllable vacuum valve, a vacuum source fluidically connected to the vacuum valve, a controllable vent valve having a vent liquid input, a vent fluid source containing a vent liquid and fluidically connected to the vent valve to retain the vent liquid at the vent fluid input, a manifold connected to the catheter, to the vacuum valve, and to the vent valve, the manifold fluidically connecting the proximal portion of the liquid column in the lumen to the vacuum source through the vacuum valve and to the vent fluid source through the vent valve, a controller connected to the

vacuum valve and the vent valve and configured to selectively open and close the vacuum valve and the vent valve such that, responsive to opening the vacuum valve, the vacuum source is fluidically connected to the liquid column in the lumen and, responsive to opening the vent valve, the vent fluid source is fluidically connected to the liquid column in the lumen, the controller configured to cyclically open and close the vacuum valve and the vent valve to change a level of vacuum at the distal end and prevent forward flow of the distal portion out from the distal end during each cycle.

[0024] With the objects in view, there is also provided a clot removal system comprising a catheter having a distal end and defining a lumen filled with a liquid column having a proximal portion and a distal portion, a controllable vacuum valve, a vacuum source fluidically connected to the vacuum valve, a controllable vent valve having a vent liquid input, a vent fluid source containing a vent liquid and fluidically connected to the vent valve to retain the vent liquid at the vent fluid input, a manifold connected to the catheter, to the vacuum valve, and to the vent valve, the manifold fluidically connecting the proximal portion of the liquid column in the lumen to the vacuum source through the vacuum valve and to the vent fluid source through the vent valve, a controller connected to the vacuum valve and the vent valve and configured to selectively open and close the vacuum valve and the vent valve such that responsive to opening the vacuum valve, the vacuum source is fluidically connected to the liquid column in the lumen and responsive to opening the vent valve, the vent fluid source is fluidically connected to the liquid column in the lumen, the controller configured to cyclically open and close the vacuum valve and the vent valve in a repeated cycle comprising a double-closed state in which the vacuum valve is closed and the vent valve is closed to change a level of vacuum at the distal end and prevent forward flow of the distal portion out from the distal end during each cycle, and a time of the double-closed state is no greater than approximately 30 ms.

[0025] With the objects in view, there is also provided a clot removal system comprising a catheter having a distal end and defining a lumen filled with a liquid column having a proximal portion and a distal portion, a vacuum source, a vent liquid source, and a vacuum and vent control system configured to cyclically connect or disconnect the vacuum source

and the vent liquid source to change a level of vacuum at the distal end and substantially prevent forward flow.

[0026] With the objects in view, there is also provided a clot removal system comprising a catheter having a distal end and defining a lumen filled with a liquid column having a proximal portion and a distal portion, a vacuum source, a vent liquid source, and a vacuum and vent control system configured to cyclically fluidically connect to the proximal portion at least one of vacuum from the vacuum source, vent liquid from the vent liquid source, and neither the vacuum nor the vent liquid, and thereby change a level of vacuum at the distal end and substantially prevent forward flow.

[0027] In accordance with another feature, the controller is configured to cyclically open and close the vacuum valve and the vent valve in a repeated cycle comprising a double-closed state in which the vacuum valve is closed and the vent valve is closed.

[0028] In accordance with a further feature, a time of the double-closed state is no greater than 30 ms.

[0029] In accordance with an added feature, the controller is configured to cyclically open and close the vacuum valve and the vent valve in a repeated cycle comprising a vent-only state in which the vacuum valve is closed and the vent valve is open.

[0030] In accordance with an additional feature, a time of the vent-only state is no greater than 50 ms.

[0031] In accordance with yet another feature, the controller is configured to selectively open and close the vacuum valve and the vent valve cycle in a repeated cycle comprising a vacuum-only state in which the vacuum valve is open and the vent valve is closed, a first double-closed state in which the vacuum valve is closed and the vent valve is closed, a vent-only state in which the vacuum valve is closed and the vent valve is open, and a second double-closed state in which the vacuum valve is closed and the vent valve is closed.

[0032] In accordance with yet a further feature, a time between an opening of the vent valve and a closing of the vent valve is between approximately 10 ms and approximately 50 ms.

[0033]

[0034] In accordance with yet an added feature, a period of the cycle is between approximately 6 Hz and approximately 16 Hz.

[0035] In accordance with yet an additional feature, a period of the cycle is between approximately 8 Hz and 12 Hz.

[0036] In accordance with again another feature, the change in the level of vacuum at the distal end is greater than approximately 15 inHg in no greater than approximately 50 ms.

[0037] In accordance with again another feature, the change in the level of vacuum at the distal end is greater than approximately 20 inHg and no greater than approximately 30 ms; and

[0038] In accordance with again another feature, the change in the level of vacuum at the distal end is greater than approximately 25 inHg and no greater than approximately 20 ms.

[0039] In accordance with again an added feature, the lumen has an internal diameter of between approximately 0.038" and approximately 0.106" and the controller is configured to cyclically open and close the vacuum valve and the vent valve at a frequency of between 2 and 16 Hz.

[0040] In accordance with again an additional feature, the lumen has an internal diameter of between approximately 0.068" and approximately 0.088" and the controller is configured to cyclically open and close the vacuum valve and the vent valve at a frequency of between 2 and 16 Hz.

[0041] In accordance with still another feature, the controller is configured to cyclically open and close the vacuum valve and the vent valve in a repeated cycle and prevent forward flow of the distal portion out from the distal end during each cycle by regulating timing of the vent valve. In accordance with still a further feature, the controller is configured to cyclically open and close the vacuum valve and the vent valve to retain a level of pressure at the distal end at less than physiological pressure.

[0042] In accordance with a concomitant feature, there is provided a shaft and the vacuum valve and the vent valve are mounted together on the shaft.

[0043] Operation of a ROAR process as described hereinbelow successfully removes thrombi for two reasons. First, the ROAR effect overcomes the static friction of a clot that is fixed or "stuck" on the catheter tip while under constant suction. The ROAR process provides an oscillating/alternating displacement that causes the clot to "shuttle" back and forth to overcome static frictional force. Second, there is a morcellation of the clot that overcomes different clot morphologies as well as overriding volume and diameter constraints of the small, fixed luminal volume dictated by the micro-anatomic environment.

[0044] The systems and methods described and shown herein react quickly enough to keep pressure at the distal end from going positive. By cycling the vacuum and vent valves at a sufficiently fast rate, a pressure measurement at a rate of one thousand samples per section at the distal end of the catheter lumen proves that the distal end of the ROAR catheter does not experience positive pressure and substantially quells forward flow. The timing between operating the vacuum and vent valves can be adjusted so that physical mechanisms that would cause distal end positive pressure can be avoided in both the open flow condition and in the corked condition.

[0045] In accordance with an exemplary embodiment, the distal portion of the liquid column exiting the distal end is limited to no more than approximately 2 microliters.

[0046] In accordance with an exemplary embodiment, a clot removal system comprises a catheter having a distal end and defining a lumen filled with a liquid column having a proximal portion and a distal portion, a vacuum source, a vent fluid source containing a vent liquid, and a vacuum and vent control system configured to cyclically fluidically connect to and disconnect from the proximal portion at least one of vacuum from the vacuum source and vent fluid from the vent fluid source, and thereby change a level of vacuum at the distal end and substantially prevent the distal portion of the liquid column from exiting the distal end.

[0047] In accordance with an exemplary embodiment, a clot removal system comprises a catheter having a distal end and defining a lumen filled with a liquid column having a

proximal portion and a vacuum and vent control system configured to cyclically connect to and disconnect from the proximal portion vacuum and vent fluid to create therein a forward flow pressure pulse and thereby reverse flow in the liquid column and substantially prevent the forward flow pressure pulse from reaching the distal end.

[0048] In accordance with an exemplary embodiment, a clot removal system comprises a catheter having a distal end and defining a lumen filled with a liquid column having a proximal portion and a vacuum and vent control system configured to cyclically connect to and disconnect from the proximal portion vacuum and vent fluid to create therein a forward flow pressure pulse and, before the forward flow pressure pulse reaches the distal end, reverse flow in the liquid column and thereby substantially prevent the forward flow pressure pulse from reaching the distal end.

[0049] In accordance with an exemplary embodiment, a clot removal system comprises a catheter having a distal end and defining a lumen filled with a liquid column having a proximal portion and a vacuum and vent control system configured to cyclically connect to and disconnect from the proximal portion vacuum and vent fluid and thereby allow the liquid column to move and stop to create therein a forward flow pressure pulse and, before the forward flow pressure pulse reaches the distal end, alternate control to reverse flow in the liquid column and thereby control the forward flow pressure pulse by substantially preventing the forward flow pressure pulse from reaching the distal end.

[0050] In accordance with an exemplary embodiment, the controller is configured to change the level of vacuum at the distal end in a cycle while simultaneously preventing distal movement of the distal portion of the liquid column.

[0051] In accordance with an exemplary embodiment, the controller is configured to selectively open and close the vacuum valve and the vent valve cycle in a repeated cycle comprising a first state in which the vacuum valve is open and the vent valve is closed, a second state in which the vacuum valve is closed and the vent valve is closed, a third state in which the vacuum valve is closed and the vent valve is open, and a fourth state in which the vacuum valve is closed and the vent valve is closed.

[0052] In accordance with an exemplary embodiment, a clot removal system comprises a catheter defining a lumen filled with a liquid column from a proximal portion to a distal end and a water hammer controller configured to alternatively connect vacuum and/or fluid at atmospheric or body or lower pressure to the lumen, thereby allowing the liquid column to move and stop to create therein a water hammer and, before the water hammer reaches the distal end, alternate control to reverse flow and thereby control the water hammer by substantially preventing the water hammer from reaching the distal end.

[0053] In accordance with an exemplary embodiment, a clot removal system comprises a catheter with a lumen, a vacuum source, a controllable vacuum valve, a vent fluid source, a controllable vent valve, a manifold connected to the catheter, to the vacuum valve, and to the vent valve, and a controller controlling the vacuum valve and the vent valve.

[0054] In accordance with an exemplary embodiment, the controller is configured to modulate the vacuum valve and the vent valve in a cycle that, responsive to vacuum being applied to the catheter, the compliance of the catheter causes a reduction in volume such that, when the vacuum is closed and the vent is open, the compliance acts as a spring and the lumen ingests vent fluid in a distal direction and, before a momentum induced by the ingested fluid reaches the distal end of the catheter, the controller modulates the valves to reverse a direction and quell movement of the fluid of the fluid and prevent the fluid from exiting the distal end of the catheter.

[0055] In accordance with an exemplary embodiment, a clot removal system comprises a catheter having a lumen, a substantially incompressible connection tube having interior lumen with a proximal end and a distal end fluidically connected to the lumen, a vacuum source, and a vacuum/vent manifold comprising a manifold chamber having an output fluidically connected to the proximal end, a vacuum line fluidically connected to the manifold and to the vacuum source to present vacuum from the source to the manifold chamber, and a vent line fluidically connected to the manifold and to a fluid bath at atmospheric pressure.

[0056] In accordance with an exemplary embodiment, the clot removal system comprises a fixed cycle with plurality of pinch valves and plurality of cams mechanically coupled to the valves so that orientations of the cams cannot be changed.

[0057] In accordance with an exemplary embodiment, the time within which the forward flow pulse is quelled is no greater than approximately 20 ms.

[0058] In accordance with an exemplary embodiment, a clot removal system comprises a pulsatile vacuum controller configured to alternatively connect vacuum and/or fluid at atmospheric/body/slightly lower than body/slightly higher than body pressure to the lumen and thereby allow the liquid column to move and stop to create therein a forward flow pressure pulse and (before the forward flow pressure pulse reaches the distal end, alternating control to reverse flow and thereby) control the forward flow pressure pulse by substantially preventing the forward flow pressure pulse from reaching the distal end.

[0059] With the foregoing and other objects in view, there is provided, a clot removal system comprising a catheter having a proximal end and a distal end and defining a lumen configured to be filled with a liquid column having a proximal portion, a vacuum pump configured to supply vacuum, a vent container holding a vent liquid, a vent valve configured to fluidically communicate with the vent liquid in the vent container and with the proximal portion of the liquid column at the proximal end of the catheter, a vacuum valve configured to fluidically communicate with the vacuum from the vacuum pump and with the proximal portion of the liquid column at the proximal end of the catheter, and a controller configured to carry out a pre-determined pattern of opening and closing the vent and vacuum valves to change a level of vacuum at the distal end and, while changing the level of vacuum at the distal end, to substantially prevent forward flow of the liquid at a distal end of the liquid column.

[0060] With the objects in view, there is also provided a clot removal system comprising a catheter having a proximal end and a distal end and defining a lumen configured to be filled with a liquid column having a proximal portion, a vacuum pump configured to supply vacuum, a vent liquid container holding a vent liquid, a vent valve configured to fluidically communicate with the vent liquid in the liquid container and with the proximal portion of the liquid column at the proximal end of the catheter, a vacuum valve configured to fluidically communicate with the vacuum from the vacuum pump, and with the proximal portion of the liquid column at the proximal end of the catheter, and a controller configured to carry out a pre-determined cycle of opening and closing the vent and vacuum valves to change a level

of vacuum at the distal end and, during each cycle, to substantially prevent forward flow of liquid at the distal end of the liquid column.

[0061] In accordance with another feature, the liquid at the distal end of the liquid column is one or more of albumin, d5W water, normal saline, half-normal saline, lactated Ringer's solution, and blood, and mixtures thereof.

[0062] In accordance with a further feature, there is provided a manifold comprising the vent valve, the vacuum valve, and an output and an extension line fluidically connecting the proximal end of the catheter to the output of the manifold.

[0063] In accordance with an added feature, a portion of the pre-determined pattern includes a time period where both the vent and vacuum valves are closed.

[0064] In accordance with an additional feature, the controller is configured to open and close the vent and vacuum valves in a repeated cycle comprising a double-closed state in which both the vent and vacuum valves are closed.

[0065] In accordance with yet another feature, a time of the double-closed state is no greater than 30 ms.

[0066] In accordance with yet a further feature, the controller is configured to open and close the vent and vacuum valves in a repeated cycle comprising a vent-only state in which the vacuum valve is closed and the vent valve is open, and a time of the vent-only state is no greater than 50 ms.

[0067] In accordance with yet an added feature, the controller is configured to repeatedly and periodically carry out the pre-determined pattern.

[0068] In accordance with yet an additional feature, the controller is configured to selectively open and close the vent and vacuum valves in a repeated cycle comprising a vacuum-only state in which the vacuum valve is open and the vent valve is closed, a first double-closed state in which the vacuum valve is closed and the vent valve is closed, a vent-only state in which the vacuum valve is closed and the vent valve is open, and a second double-closed state in which the vacuum valve is closed and the vent valve is closed.

[0069] In accordance with again another feature, the controller is configured to selectively open and close the vent and vacuum valves in a repeated cycle comprising a vacuum-only state in which the vacuum valve is open and the vent valve is closed, followed by a first double-closed state in which the vacuum valve is closed and the vent valve is closed and a time of the first double-closed state is no greater than 30 ms, followed by a vent-only state in which the vacuum valve is closed and the vent valve is open, followed by a second double-closed state in which the vacuum valve is closed and the vent valve is closed.

[0070] In accordance with again a further feature, a time between an opening of the vent valve and a closing of the vent valve is between approximately 10 ms and approximately 50 ms.

[0071] In accordance with again an added feature, a frequency of the cycle is between approximately 6 Hz and approximately 16 Hz.

[0072] In accordance with still another feature, a frequency of the cycle is between approximately 8 Hz and 12 Hz.

[0073] In accordance with still a further feature, the change in the level of vacuum at the distal end is one of greater than approximately 15 inHg and occurs in no greater than approximately 50 ms, greater than approximately 20 inHg and occurs in no greater than approximately 30 ms, and greater than approximately 25 inHg and occurs in no greater than approximately 20 ms.

[0074] In accordance with still an added feature, the lumen has a diameter of between approximately 0.038" and approximately 0.106" and the controller is configured to repeatedly and periodically carry out the pre-determined pattern of opening and closing the vent and vacuum valves at a frequency of between 2 and 16 Hz.

[0075] In accordance with still an additional feature, the lumen has an internal diameter of between approximately 0.068" and approximately 0.088" and the controller is configured to repeatedly and periodically carry out the pre-determined pattern of opening and closing the vent and vacuum valves at a frequency of between 6 and 12 Hz.

[0076] In accordance with another feature, the controller is configured to open and close the vent and vacuum valves in a repeated cycle of the pre-determined pattern and prevent forward flow of the distal portion out from the distal end during each cycle by regulating timing of the vent valve.

[0077] In accordance with a further feature, the controller is configured to open and close the vacuum valve and the vent valve in a repeated cycle of the pre-determined pattern to retain a level of pressure at the distal end at less than physiological pressure.

[0078] In accordance with an added feature, the controller is one of a mechanical valve controller and an electronic valve controller.

[0079] In accordance with a concomitant feature, there is provided a shaft and the vent and vacuum valves are cam-driven valves with respective cams mounted together on the shaft.

[0080] With the foregoing and other objects in view, there is provided, a clot removal system comprising a catheter comprising a proximal end, a distal end, and controller operating parameters and defining a lumen configured to be filled with a liquid column having a proximal portion, a vacuum source configured to supply vacuum, and a controller configured to carry out a control pattern of turning on and off the vacuum based upon the controller operating parameters and configured to receive the controller operating parameters in an automatic response to the catheter being operatively connected to at least one of the vacuum source and the controller and, responsive to the connection, to carry out the control pattern to change a level of vacuum at the distal end of the catheter.

[0081] With the objects in view, there is also provided a clot removal system comprising a catheter comprising a proximal end, a distal end, and controller operating parameters and defining a lumen configured to be filled with a liquid column having a proximal portion, a vacuum source configured to supply vacuum, a vacuum modulator configured to fluidically communicate with the vacuum from the vacuum source and with the proximal portion of the liquid column at the proximal end of the catheter, and a controller configured to carry out a control pattern of modulating the vacuum modulator based upon the controller operating parameters and configured to receive the controller operating parameters in an automatic

response to the catheter being operatively connected to at least one of the vacuum modulator and the controller and, responsive to the connection, to carry out the control pattern to change a level of vacuum at the distal end of the catheter.

[0082] With the objects in view, there is also provided a clot removal system comprising a catheter comprising a proximal end, a distal end, and controller operating parameters and defining a lumen configured to be filled with a liquid column having a proximal portion, a vacuum source configured to supply vacuum, a vent container holding a vent liquid, a vent valve configured to fluidically communicate with the vent liquid in the liquid container and with the proximal portion of the liquid column at the proximal end of the catheter, a vacuum valve configured to fluidically communicate with the vacuum source and the proximal portion of the liquid column at the proximal end of the catheter, and a controller configured to carry out a control pattern of opening and closing the vent and vacuum valves based upon the controller operating parameters and configured to receive the controller operating parameters in an automatic response to the catheter being operatively connected to at least one of the vent valve, the vacuum valve, the vacuum source, and the controller and, responsive to the connection, to carry out the control pattern to change a level of vacuum at the distal end of the catheter.

[0083] With the objects in view, there is also provided a clot removal system comprising a catheter comprising a proximal end, a distal end, and controller operating parameters and defining a lumen configured to be filled with a liquid column having a proximal portion and a distal end, a vacuum source configured to supply vacuum, a vent container holding a vent liquid, a vent valve configured to fluidically communicate with the vent liquid in the liquid container and with the proximal portion of the liquid column at the proximal end of the catheter, a vacuum valve configured to fluidically communicate with the vacuum source and the proximal portion of the liquid column at the proximal end of the catheter, and a controller configured to carry out a control pattern to change a level of vacuum at the distal end of the catheter and, while changing the level of vacuum at the distal end of the catheter, to substantially prevent forward flow of the liquid at the distal end of the liquid column and configured to operate the vent and vacuum valves based upon the controller operating

parameters in an automatic response to the catheter being operatively connected to at least one of the vent valve, the vacuum valve, the controller, and the vacuum source.

[0084] In accordance with another feature, the controller operating parameters are stored in the catheter and are provided to the controller responsive to the connection.

[0085] In accordance with a further feature, the catheter comprises an extension line having a first end connected to the catheter and a second end connected to at least one of the vacuum source and the controller and comprising the controller operating parameters and, responsive to the connection configured to provide the controller operating parameters to the controller and fluidically connecting the proximal end of the catheter with the vacuum source.

[0086] In accordance with an added feature, the controller is part of the vacuum source and the controller is configured to receive the controller operating parameters in the automatic response to the catheter being operatively connected to the vacuum source.

[0087] In accordance with an additional feature, the controller is separate from the vacuum source and the controller is configured to receive the controller operating parameters in the automatic response to the catheter being operatively connected to the controller.

[0088] In accordance with yet another feature, the extension line comprises additional controller operating parameters and, responsive to the connection is configured to provide the additional controller operating parameters to the controller.

[0089] In accordance with yet a further feature, the controller operating parameters comprise a catheter identifier and the controller is configured to receive the catheter identifier in the automatic response to the catheter being operatively connected to at least one of the vacuum source and the controller and, responsive to the connection, to carry out a pre-determined control pattern associated with the catheter identifier to change the level of vacuum at the distal end of the catheter.

[0090] In accordance with yet an added feature, the controller is part of the vacuum source and the controller is configured to receive the catheter identifier in the automatic response to the catheter being operatively connected to the vacuum source.

[0091] In accordance with yet an additional feature, the controller is separate from the vacuum source and the controller is configured to receive the catheter identifier in the automatic response to the catheter being operatively connected to the controller.

[0092] In accordance with again another feature, the controller operating parameters comprise a catheter identifier and the catheter comprises an extension line having a first end connected to the catheter and a second end connected to at least one of the vacuum source and the controller, comprising the catheter identifier, and, responsive to the connection, the extension line is configured to provide the catheter identifier to the controller and fluidically connects the proximal end of the catheter with the vacuum source.

[0093] In accordance with again a further feature, the controller is part of the vacuum source and the controller is configured to receive the catheter identifier in the automatic response to the extension line being operatively connected to the vacuum source.

[0094] In accordance with again an added feature, the controller is separate from the vacuum source and the controller is configured to receive the catheter identifier in the automatic response to the extension line being operatively connected to the controller.

[0095] In accordance with again an additional feature, the controller is configured to repeatedly and periodically carry out the control pattern.

[0096] In accordance with still another feature, the controller is one of a mechanical valve controller and an electronic valve controller.

[0097] In accordance with still a further feature, there is provided a control element operatively connected to the controller and, responsive to actuation of the control element, the controller carries out the control pattern.

[0098] In accordance with still an added feature, the controller is part of the vacuum source and the extension line fluidically connects the proximal end of the catheter to the vacuum source or the controller is separate from the vacuum source and is removably coupleable to the vacuum source and the extension line fluidically connects the proximal end of the catheter to the controller.

[0099] In accordance with still an additional feature, the operative connection of the catheter to the at least one of the vacuum source and the controller is an identification sub-assembly.

[0100] In accordance with another feature, the identification sub-assembly is disposed at the connection between the catheter and the extension line.

[0101] In accordance with a further feature, the operative connection of at least one of the catheter and the extension line to the at least one of the vacuum source and the controller is an identification sub-assembly.

[0102] In accordance with an added feature, the identification sub-assembly is at least one of an inductive sensor and sensed part, an RFID tag and reader, an NFC tag and reader, a 1-wire detection system, a 2-wire detection configuration, a Bluetooth low energy device, metallic touch pads, at least one passive resistor configuration, and at least one hall sensor.

[0103] In accordance with an additional feature, the identification sub-assembly is at least one of a manual user interface in which the user communicates to the controller which controller operating parameters to use with the catheter, a QR code and a QR code reader in which the QR code provided with the catheter communicates to the controller which controller operating parameters to use with the catheter, a bar code and a bar code reader in which the bar code provided with the catheter communicates to the controller which controller operating parameters to use with the catheter, and a punch-card and punch-card reader in which the punch-card provided with the catheter communicates to the controller which controller operating parameters to use with the catheter.

[0104] In accordance with yet another feature, the identification sub-assembly comprises a reader disposed at least one of at the vacuum source, at the controller as part of the vacuum source, and at the controller separable from the vacuum source.

[0105] In accordance with yet a further feature, the catheter comprises an extension line having a first end connected to the catheter and a second end opposite the first end and the operative connection of the catheter is an identification sub-assembly comprising a reader disposed at least one of, at the extension line, at the vacuum source, at the controller

as part of the vacuum source, at the controller separate from the vacuum source, and at the controller separable from the vacuum source.

[0106] In accordance with yet an added feature, a manifold comprising the vacuum modulator and an output and an extension line fluidically connecting the proximal end of the catheter to the output of the manifold.

[0107] In accordance with yet an additional feature, there is provided an extension line operatively connected to at least one the vacuum modulator and the controller and fluidically connecting the proximal end of the catheter to at least one the vacuum modulator and the controller.

[0108] In accordance with again another feature, the operative connection of the catheter to the at least one of the vacuum modulator and the controller is an identification sub-assembly.

[0109] In accordance with again a further feature, a portion of the control pattern includes a time period where both the vent and vacuum valves are closed.

[0110] In accordance with again an added feature, the controller is configured to repeatedly and periodically carry out the control pattern with the vent and vacuum valves.

[0111] In accordance with again an additional feature, the controller is configured to open and close the vent and vacuum valves in a repeated cycle comprising a vent-only state in which the vacuum valve is closed and the vent valve is open, and a time of the vent-only state is no greater than 50 ms.

[0112] In accordance with still another feature, the lumen has a diameter of between approximately 0.038" and approximately 0.106" and the controller is configured to repeatedly and periodically carry out the control pattern of opening and closing the vent and vacuum valves at a frequency of between approximately 2 Hz and approximately 16 Hz.

[0113] In accordance with still a further feature, there is provided an extension line operatively connected to at least one of the vent valve, the vacuum valve, and the controller and fluidically connecting the proximal end of the catheter to at least one of the vent valve, the vacuum valve, and the controller.

[0114] In accordance with still an added feature, the operative connection of the catheter to the at least one of the vent valve, the vacuum valve, the vacuum source, and the controller is an identification sub-assembly.

[0115] In accordance with still an additional feature, the controller operating parameters comprises catheter identifiers, the catheter is one of a plurality of different catheters each having one of the catheter identifiers, and the controller is configured to store a plurality of pre-determined control patterns of opening and closing the vent and vacuum valves, each of the plurality of pre-determined control patterns being associated with one of the catheter identifiers and operate the vent and vacuum valves according to the pre-determined control pattern associated with the one catheter identifier in an automatic response to each of the catheters being operatively connected to the at least one of the vent valve, the vacuum valve, the controller, and the vacuum source.

[0116] In accordance with still an additional feature, the catheter is one of a plurality of different catheters each having a given set of the controller operating parameters and the controller is configured to receive the given set of the controller operating parameters and operate the vent and vacuum valves in the control pattern based upon the given set of controller operating parameters in an automatic response to each of the catheters being operatively connected to the at least one of the vent valve, the vacuum valve, the controller, and the vacuum source.

[0117] In accordance with still an additional feature, the change in the level of vacuum at the distal end of the catheter is one of greater than approximately 15 inHg and occurs in no greater than approximately 50 ms, greater than approximately 20 inHg and occurs in no greater than approximately 30 ms, and greater than approximately 25 inHg and occurs in no greater than approximately 20 ms.

[0118] In accordance with a concomitant feature, the controller is configured to open and close the vacuum and vent valves in a repeated cycle of the control pattern to retain a level of pressure at the distal end of the catheter at less than physiological pressure.

[0119] Although the systems, apparatuses, and methods are illustrated and described herein as embodied in an aspiration thrombectomy system and methods for thrombus

removal with aspiration catheter, it is, nevertheless, not intended to be limited to the details shown because various modifications and structural changes may be made therein without departing from the spirit of the invention and within the scope and range of equivalents of the claims. Additionally, well-known elements of exemplary embodiments will not be described in detail or will be omitted so as not to obscure the relevant details of the systems, apparatuses, and methods.

[0120] Additional advantages and other features characteristic of the systems, apparatuses, and methods will be set forth in the detailed description that follows and may be apparent from the detailed description or may be learned by practice of exemplary embodiments. Still other advantages of the systems, apparatuses, and methods may be realized by any of the instrumentalities, methods, or combinations particularly pointed out in the claims.

[0121] Other features that are considered as characteristic for the systems, apparatuses, and methods are set forth in the appended claims. As required, detailed embodiments of the systems, apparatuses, and methods are disclosed herein; however, it is to be understood that the disclosed embodiments are merely exemplary of the systems, apparatuses, and methods, which can be embodied in various forms. Therefore, specific structural and functional details disclosed herein are not to be interpreted as limiting, but merely as a basis for the claims and as a representative basis for teaching one of ordinary skill in the art to variously employ the systems, apparatuses, and methods in virtually any appropriately detailed structure. Further, the terms and phrases used herein are not intended to be limiting; but rather, to provide an understandable description of the systems, apparatuses, and methods. While the specification concludes with claims defining the systems, apparatuses, and methods of the invention that are regarded as novel, it is believed that the systems, apparatuses, and methods will be better understood from a consideration of the following description in conjunction with the drawing figures, in which like reference numerals are carried forward.

BRIEF DESCRIPTION OF THE DRAWINGS

[0122] The accompanying figures, where like reference numerals refer to identical or functionally similar elements throughout the separate views, which are not true to scale, and which, together with the detailed description below, are incorporated in and form part of the specification, serve to illustrate further various embodiments and to explain various principles and advantages all in accordance with the systems, apparatuses, and methods. Advantages of embodiments of the systems, apparatuses, and methods will be apparent from the following detailed description of the exemplary embodiments thereof, which description should be considered in conjunction with the accompanying drawings in which:

[0123] FIG. 1 is a fragmentary, perspective view of an exemplary embodiment of a controller for a thrombectomy aspiration catheter in an unactuated state;

[0124] FIG. 2 is a fragmentary, perspective, longitudinal cross-sectional view of the controller of FIG. 1;

[0125] FIG. 3 is an enlarged, diagrammatic, side elevational view of a compression cam assembly of the controller of FIG. 1;

[0126] FIG. 4 is a fragmentary, longitudinal cross-sectional view of the controller of FIG. 1 with a compression roller removed;

[0127] FIG. 5 is a fragmentary, longitudinal cross-sectional view of the controller of FIG. 1 in an actuated state;

[0128] FIG. 6 is a fragmentary, enlarged, perspective view of a portion of an extrusion compressor of the controller of FIG. 1;

[0129] FIG. 7 is a fragmentary, perspective view of the controller of FIG. 1 in the actuated state;

[0130] FIG. 8 is a fragmentary, perspective and partially longitudinal cross-sectional view of the controller of FIG. 7;

[0131] FIG. 9 is a fragmentary, perspective and longitudinal cross-sectional view of the controller of FIG. 1 in an intermediate actuated state with the compression roller occluding the aspiration catheter and partially rolled to cause fluid column shift;

[0132] FIG. 10 is a fragmentary, longitudinal cross-sectional view of the controller of FIG.

[0133] FIG. 11 is a fragmentary, perspective and longitudinal cross-sectional view of the controller of FIG. 1 in the actuated state with the compression roller occluding the aspiration catheter and fully rolled to cause fluid column shift;

[0134] FIG. 12 is a fragmentary, longitudinal cross-sectional view of the controller of FIG. 11;

[0135] FIG. 13 is a longitudinal cross-sectional view of the controller of FIG. 9 with the compression roller and the aspiration catheter removed;

[0136] FIG. 14 is a fragmentary, perspective and longitudinal cross-sectional view of the controller of FIG. 1 in the unactuated state and diagrammatically connected to a distal portion of the aspiration catheter with a thrombus lodged in a distal opening of a vacuum channel;

[0137] FIG. 15 is a fragmentary, perspective and longitudinal cross-sectional view of the controller of FIG. 12 in the actuated state with the column shift that distally dislodges the thrombus from the distal opening of the vacuum channel;

[0138] FIG. 16 is a fragmentary, enlarged, perspective and longitudinal cross-sectional view of a distal portion of the controller of FIG. 1 and an exemplary embodiment of a vacuum booster disposed between the controller and a distal extent of the aspiration catheter with the vacuum booster in an energized state;

[0139] FIG. 17 is a fragmentary, enlarged, perspective and longitudinal cross-sectional view of the controller and the vacuum booster of FIG. 16 with the vacuum booster in a relaxed state;

[0140] FIG. 18 is a fragmentary, enlarged, perspective and partially transparent view of a proximal portion of the controller of FIG. 1 and an exemplary embodiment of a thrombus trap;

[0141] FIG. 19 is a fragmentary, enlarged, perspective view of the controller and thrombus trap of FIG. 18 with the intermediate shell of the thrombus trap removed;

[0142] FIG. 20 is a fragmentary, enlarged, perspective view of the controller and thrombus trap of FIG. 18;

[0143] FIG. 21 is a fragmentary, perspective and longitudinal cross-sectional view of the controller of FIG. 16, and the thrombus trap of FIG. 18;

[0144] FIG. 22 is a fragmentary, longitudinal cross-sectional view of an exemplary embodiment of a volume changing controller;

[0145] FIG. 23 is a vacuum circuit diagram of an exemplary embodiment of a vacuum booster and vacuum booster control device;

[0146] FIG. 24 is a cycle flow diagram of the operation of exemplary embodiments of the controller with the vacuum booster and the thrombus trap;

[0147] FIG. 25 is a perspective view of an automatic aspiration thrombectomy system to be connected distally to an aspiration catheter and proximally to vacuum and vent lines and with a cam housing removed;

[0148] FIG. 26 is a fragmentary, top plan view of the aspiration thrombectomy system of FIG. 25 with diagrammatic illustration of the aspiration catheter and the vacuum and vent lines;

[0149] FIG. 27 is an elevational view of a proximal side of the aspiration thrombectomy system of FIG. 25;

[0150] FIG. 28 is an elevational view of a bearing side of the aspiration thrombectomy system of FIG. 25;

[0151] FIG. 29 is a perspective and longitudinally cross-sectional view of the aspiration thrombectomy system of FIG. 25 with a vacuum valve in a closed state, a vent valve in an open state, and a flag of a positional reset assembly in a zero reset state;

[0152] FIG. 30 is a longitudinally cross-sectional view of the aspiration thrombectomy system of FIG. 29;

[0153] FIG. 31 is an enlarged cross-sectional view of a valve and cam set of the aspiration thrombectomy system of FIG. 25 with the cam in a rotational position to set an intermediate closing of the valve;

[0154] FIG. 32 is an enlarged cross-sectional view of the valve and cam set of FIG. 31 with the cam in a rotational position to close the valve;

[0155] FIG. 33 is a cross-sectional view of the aspiration thrombectomy system of FIG. 25 along section line 33-33 in FIG. 30 with the cam housing removed;

[0156] FIG. 34 is a perspective view of the aspiration thrombectomy system of FIG. 25 with the motor assembly housing removed;

[0157] FIG. 35 is a top plan view of the aspiration thrombectomy system of FIG. 26 with the motor assembly housing removed;

[0158] FIG. 36 is an elevational view of the aspiration thrombectomy system of FIG. 27 with the motor assembly housing removed;

[0159] FIG. 37 is an elevational view of the bearing side of the aspiration thrombectomy system of FIG. 28 with the motor assembly housing removed;

[0160] FIG. 38 is a perspective view of the aspiration thrombectomy system of FIG. 25 with the cam housing;

[0161] FIG. 39 is a top plan view of the aspiration thrombectomy system of FIG. 26 with the cam housing;

[0162] FIG. 40 is an elevational view of the aspiration thrombectomy system of FIG. 27 with the cam housing;

[0163] FIG. 41 is an elevational view of the bearing side of the aspiration thrombectomy system of FIG. 28 with the cam housing;

[0164] FIG. 42 is a fragmentary, partially hidden, perspective view of an exemplary embodiment of a rotational pintle valve to be employed with the aspiration thrombectomy system in a first valve state;

[0165] FIG. 43 is a fragmentary, cross-sectional view of the valve of FIG. 42;

[0166] FIG. 44 is a fragmentary, partially hidden, perspective view of the valve of FIG. 42;

[0167] FIG. 45 is a fragmentary, partially hidden, perspective view of the valve of FIG. 42 in a second valve state;

[0168] FIG. 46 is a fragmentary, cross-sectional view of the valve of FIG. 45;

[0169] FIG. 47 is a diagrammatic, cross-sectional view of an exemplary embodiment of an aspiration thrombectomy system;

[0170] FIG. 48 is a graph of an exemplary embodiment of a waveform for operating the system of FIG. 47 with a ROAR process to quell pressure pulses;

[0171] FIG. 49 is a graph illustrating an exemplary embodiment of one cycle of a waveform operation of a vacuum valve and a vent valve of the system of FIG. 47;

[0172] FIG. 50 is a graph illustrating pressure curves at a proximal portion and a distal portion of a lumen of a catheter of the system of FIG. 47 operating with the waveform of FIG. 49;

[0173] FIG. 51 is a graph illustrating the waveforms of FIG. 49 and 50 combined together in time;

[0174] FIG. 52 is a graph of an exemplary embodiment of a waveform for operating the system of FIG. 47 with a ROAR process to quell pressure pulses;

[0175] FIG. 53 is a graph illustrating positions of the vacuum and vent valves of the system of FIG. 47 for tuning the valves to create a ROAR effect;

[0176] FIG. 54 is a fragmentary, longitudinal cross-sectional view of a proximal manifold connector assembly for the system of FIG. 47;

[0177] FIG. 55 is a block diagram of an exemplary embodiment of a self-contained, aspiration thrombectomy system;

[0178] FIG. 56 is a block diagram of the system of FIG. 55 with an exemplary embodiment of a proximal manifold connector assembly having remote controls;

[0179] FIG. 57 is a perspective view of an exemplary embodiment of a self-contained, aspiration thrombectomy system with a collection canister and a vent liquid reservoir indicated diagrammatically;

[0180] FIG. 58 is a fragmentary, perspective view of a cassette connection assembly of the system of FIG. 57;

[0181] FIG. 59 is a top plan view of the system of FIG. 57;

[0182] FIG. 60 is a left side elevational view of the system of FIG. 57;

[0183] FIG. 61 is a right side elevational view of the system of FIG. 57;

[0184] FIG. 62 is a perspective view of an exemplary embodiment of a self-contained, aspiration thrombectomy system with a collection canister and a hanging vent liquid reservoir indicated diagrammatically;

[0185] FIG. 63 is a left side elevational view of the system of FIG. 62;

[0186] FIG. 64 is a right side elevational view of the system of FIG. 62;

[0187] FIG. 65 is a top plan view of the system of FIG. 62;

[0188] FIG. 66 is a front elevational view of the system of FIG. 57;

[0189] FIG. 67 is a fragmentary, front perspective view of cassette connection assembly and the hanging vent liquid reservoir of the system of FIG. 57;

[0190] FIG. 68 is a top plan view of an exemplary embodiment of a valve cassette for the systems of FIGS. 57 to 67 with hidden line views of fluid lumens;

[0191] FIG. 69 is a bottom plan view of the valve cassette of FIG. 69;

[0192] FIG. 70 is a bottom perspective view of the valve cassette of FIG. 69;

[0193] FIG. 71 is a bottom perspective view of the valve cassette of FIG. 69; and

[0194] FIG. 72 is a diagrammatic illustrated of an exemplary embodiment of a self-contained, aspiration thrombectomy system.

DETAILED DESCRIPTION

[0195] As required, detailed embodiments of the systems, apparatuses, and methods are disclosed herein; however, it is to be understood that the disclosed embodiments are merely exemplary of the systems, apparatuses, and methods, which can be embodied in various forms. Therefore, specific structural and functional details disclosed herein are not

to be interpreted as limiting, but merely as a basis for the claims and as a representative basis for teaching one skilled in the art to variously employ the systems, apparatuses, and methods in virtually any appropriately detailed structure. Further, the terms and phrases used herein are not intended to be limiting; but rather, to provide an understandable description of the systems, apparatuses, and methods. While the specification concludes with claims defining the features of the systems, apparatuses, and methods that are regarded as novel, it is believed that the systems, apparatuses, and methods will be better understood from a consideration of the following description in conjunction with the drawing figures, in which like reference numerals are carried forward.

[0196] In the following detailed description, reference is made to the accompanying drawings which form a part hereof, and in which are shown by way of illustration embodiments that may be practiced. It is to be understood that other embodiments may be utilized and structural or logical changes may be made without departing from the scope. Therefore, the following detailed description is not to be taken in a limiting sense, and the scope of embodiments is defined by the appended claims and their equivalents.

[0197] Alternate embodiments may be devised without departing from the spirit or the scope of the invention. Additionally, well-known elements of exemplary embodiments of the systems, apparatuses, and methods will not be described in detail or will be omitted so as not to obscure the relevant details of the systems, apparatuses, and methods.

[0198] Before the systems, apparatuses, and methods are disclosed and described, it is to be understood that the terminology used herein is for the purpose of describing particular embodiments only and is not intended to be limiting. The terms "comprises," "comprising," or any other variation thereof are intended to cover a non-exclusive inclusion, such that a process, method, article, or apparatus that comprises a list of elements does not include only those elements but may include other elements not expressly listed or inherent to such process, method, article, or apparatus. An element proceeded by "comprises ... a" does not, without more constraints, preclude the existence of additional identical elements in the process, method, article, or apparatus that comprises the element. The terms "including" and/or "having," as used herein, are defined as comprising (i.e., open language). The terms "a" or "an", as used herein, are defined as one or more than one. The term

"plurality," as used herein, is defined as two or more than two. The term "another," as used herein, is defined as at least a second or more. The description may use the terms "embodiment" or "embodiments," which may each refer to one or more of the same or different embodiments.

[0199] The terms "coupled" and "connected," along with their derivatives, may be used. It should be understood that these terms are not intended as synonyms for each other. Rather, in particular embodiments, "connected" may be used to indicate that two or more elements are in direct physical or electrical contact with each other. "Coupled" may mean that two or more elements are in direct physical or electrical contact (e.g., directly coupled). However, "coupled" may also mean that two or more elements are not in direct contact with each other, but yet still cooperate or interact with each other (e.g., indirectly coupled).

[0200] For the purposes of the description, a phrase in the form "A/B" or in the form "A and/or B" or in the form "at least one of A and B" means (A), (B), or (A and B), where A and B are variables indicating a particular object or attribute. When used, this phrase is intended to and is hereby defined as a choice of A or B or both A and B, which is similar to the phrase "and/or". Where more than two variables are present in such a phrase, this phrase is hereby defined as including only one of the variables, any one of the variables, any combination of any of the variables, and all of the variables, for example, a phrase in the form "at least one of A, B, and C" means (A), (B), (C), (A and B), (A and C), (B and C), or (A, B and C).

[0201] Relational terms such as first and second, top and bottom, and the like may be used solely to distinguish one entity or action from another entity or action without necessarily requiring or implying any actual such relationship or order between such entities or actions. The description may use perspective-based descriptions such as up/down, back/front, top/bottom, and proximal/distal. Such descriptions are merely used to facilitate the discussion and are not intended to restrict the application of disclosed embodiments. Various operations may be described as multiple discrete operations in tum, in a manner that may be helpful in understanding embodiments; however, the order of description should not be construed to imply that these operations are order dependent.

[0202] As used herein, the term "about" or "approximately" applies to all numeric values, whether or not explicitly indicated. These terms generally refer to a range of numbers

that one of skill in the art would consider equivalent to the recited values (i.e., having the same function or result). In many instances these terms may include numbers that are rounded to the nearest significant figure. As used herein, the terms "substantial" and "substantially" means, when comparing various parts to one another, that the parts being compared are equal to or are so close enough in dimension that one skill in the art would consider the same. Substantial and substantially, as used herein, are not limited to a single dimension and specifically include a range of values for those parts being compared. The range of values, both above and below (e.g., "+/-" or greater/lesser or larger/smaller), includes a variance that one skilled in the art would know to be a reasonable tolerance for the parts mentioned.

[0203] It will be appreciated that embodiments of the systems, apparatuses, and methods described herein may be comprised of one or more conventional processors and unique stored program instructions that control the one or more processors to implement, in conjunction with certain non-processor circuits and other elements, some, most, or all of the functions of the systems, apparatuses, and methods described herein. The non-processor circuits may include, but are not limited to, signal drivers, clock circuits, power source circuits, and user input and output elements. Alternatively, some or all functions could be implemented by a state machine that has no stored program instructions, or in one or more application specific integrated circuits (ASICs) or field-programmable gate arrays (FPGA), in which each function or some combinations of certain of the functions are implemented as custom logic. Of course, a combination of these approaches could also be used. Thus, methods and means for these functions have been described herein.

[0204] The terms "program," "software," "software application," and the like as used herein, are defined as a sequence of instructions designed for execution on a computer system or programmable device. A "program," "software," "application," "computer program," or "software application" may include a subroutine, a function, a procedure, an object method, an object implementation, an executable application, an applet, a servlet, a source code, an object code, any computer language logic, a shared library/dynamic load library and/or other sequence of instructions designed for execution on a computer system.

[0205] Herein various embodiments of the systems, apparatuses, and methods are described. In many of the different embodiments, features are similar. Therefore, to avoid redundancy, repetitive description of these similar features may not be made in some circumstances. It shall be understood, however, that description of a first-appearing feature applies to the later described similar feature and each respective description, therefore, is to be incorporated therein without such repetition.

[0206] Described now are exemplary embodiments. Referring now to the figures of the drawings in detail and first, particularly to FIGS. 1 to 13, there is shown a first exemplary embodiment of a one-handed controller 10 for an aspiration thrombectomy system 1 utilizing a vacuum tube 2. The controller 10 comprises a first handle part 20 and a second handle part 40. The first handle part 20 is connected to and holds the vacuum tube 2 and, therefore, is also referred to as a handle base. The second handle part 40 moves with respect to the first handle part 20 and, therefore, the second handle part 40 is also referred to as a compressor-actuator 40.

[0207] In an exemplary embodiment, the first handle part 20 has a distal tube anchor 22 and a proximal tube anchor 24. In this embodiment, the distal and proximal tube anchors 22, 24 are in the form of hollow tubes through which the vacuum tube 2 traverses. The distal and proximal tube anchors 22, 24 hold the vacuum tube 2 therein substantially without compressing the vacuum tube 2 (and thereby does not reduce or close the inner vacuum channel 3). The vacuum tube 2 can be of many materials, including latex, silicone, Pebax®, polyurethane, polyvinyl chloride, or other synthetic rubber. Exemplary sizes for the vacuum tube 2 have an inner diameter (I.D.) of approximately 0.055 to 0.095 inches. One exemplary embodiment for retaining the vacuum tube 2 is an adhesive that bonds the material of the vacuum tube 2 to the interior lumens of the tubular tube anchors 22, 24. In this exemplary embodiment, the vacuum tube 2 is fixed to the first handle part 20. In an alternative embodiment, the first handle part 20 is a clamshell having two first handle part halves (not illustrated) that open to receive the cylindrical vacuum tube 2 and, when closed thereupon, the tube anchors 22, 24 tightly grip the vacuum tube 2 therein substantially without closing or occluding the vacuum channel 3 of the vacuum tube 2. In one exemplary clamshell embodiment, the first handle part 20 is split horizontally at the dashed line in FIG. 2 with a

hinge, allowing a portion of the vacuum tube 2 to be inserted into and removed from the distal and proximal tube anchors 22, 24. A lock secures the vacuum tube 2 therein until the user desires removal. The hinge is useful to allow the surgeon to reposition the controller 10 along the vacuum tube 2.

[0208] The exemplary embodiment of the distal and proximal tube anchors 22, 24 are separated from one another over a distance. Between the distal and proximal tube anchors 22, 24 of the first handle part 20 is a compression floor 26. When installed within the first handle part 20, the vacuum tube 2 lays against the compression floor 26 between the distal and proximal tube anchors 22, 24 substantially without closing or occluding the vacuum channel 3. FIG. 13 illustrates the compression floor 26 of first handle part 20 with the vacuum tube 2 removed.

[0209] The first handle part 20 has a hollow interior that defines a set of parallel lateral walls 32 on either side of the vacuum tube 2. The first handle part 20 comprises a compression cam assembly 30 that permits the second handle part 40 to move in two directions with respect to the first handle part 20. More specifically, in the exemplary embodiment, the compression cam assembly 30 comprises a set of slots 34 formed in the lateral walls 32 of the first handle part 20. As shown in the enlarged view of FIG. 3, these slots 34 have a vertical extent 35 and an angled extent 36. The vertical extent 35 has a vertical length and the angled extent 36 has a vector length that is comprised of a second vertical extent 37 and a horizontal extent 39. Accordingly, as explained below, the slots 34 provide a cam surface for movement of the second handle part 40 in the same shape as the slot 34.

[0210] In the exemplary embodiment, to contact the first and second handle parts 20, 40 together, the second handle part 40 has a hollow interior into which the first handle part 20 is inserted and projects. (In an alternative embodiment, the first handle part 20 has a hollow interior into which the second handle part 40 is inserted and projects.) A width between interior facing lateral surfaces of the hollow compartment of the second handle part 40 is approximately equal to the width of the exterior surfaces of the lateral walls 32 such that the second handle part 40 can move up and down on the first handle part 20 tightly but smoothly with little or substantially no friction. In comparison, the length between interior

facing longitudinal surfaces of the hollow compartment of the second handle part 40 is greater than the length of the exterior surfaces of the longitudinal walls 38. The difference in length is sufficiently long enough to allow the second handle part 40 to move along the horizontal extent 39 longitudinally parallel with the vacuum tube 2 throughout the horizontal extent 39.

[0211] Movement of the compressor-actuator 40 with respect to the handle base 20 follows the slots 34 by providing the compressor-actuator 40 with bosses 42 protruding from the interior facing surfaces of the lateral walls 42 of the hollow compartment of the compressor-actuator 40; one circular boss 42 is associated with each of the slots 34. In this way, movement of the compressor-actuator 40 is guided by and restricted by the shape of the slots 34. In an unactuated state of the controller 10, shown in FIGS. 1, 2, and 4, the bosses 42 reside at the end of the vertical extent 35, which in the exemplary embodiment is at the uppermost end of the slot 34. (It is noted that the embodiment shown in FIGS. 1 to 13 provide four slots 34 and four bosses 42. This number is merely exemplary. The cam surface of the slots 34, the extents 35, 36 of the slots 34, and the cam follower of the bosses 42 can take any form or shape that causes the controller to operate as described herein.) As seen most clearly in FIG. 4, a distance A between an interior of the proximal longitudinal wall 38 of the compressor-actuator 40 and an exterior of the proximal wall of the first handle part 20 is longer than the horizontal extent 39 (i.e., 1A1 > 1391). When the compressor-actuator 40 is fully actuated as shown in FIG. 5, the bosses 42 travel to the opposite (lowermost) end of the slot 34. The compressor-actuator 40, therefore, has traveled a vertical distance equal to the vertical movement of the bosses 42 within the vertical and angled extents 35, 36 and has traveled a horizontal distance equal to the horizontal extent 39. The exemplary embodiments of the first and second handle parts 20, 40 have the interior surface of the distal longitudinal wall of the compressor-actuator 40 touching the exterior surface of the distal longitudinal wall of the handle base 20, this touch being indicated with arrows B in FIG. 4 (i.e., 1B1 = 0). When the compressor-actuator 40 is fully actuated, therefore, these two distal longitudinal walls separate to a distance equal to the horizontal extent 39. Likewise, the distance between an exterior surface of the proximal longitudinal wall of the handle base 20 and an interior surface of the proximal longitudinal wall of the compressor-actuator 40 shortens from A by a length equal to the horizontal extent 39 (i.e., (A-1391)), which is

illustrated in FIG. 5. Alternately, a four-bar linkage could be provided to join 20 and 40 to create the same motion as the cam slots and bosses.

[0212] What becomes apparent from movement of the compressor-actuator 40 following the slots 34 is how an extrusion compressor 50 connected to the compressor-actuator 40 operates during this movement. The exemplary embodiment of the extrusion compressor 50 in FIGS. 1, 2 and 4 to 13 has the extrusion compressor 50 project from an interior surface of a ceiling of the hollow compartment of the compressor-actuator 40 downwards towards the handle base 20. In particular, the extrusion compressor 50 projects downwards towards the compression floor 26 of the handle base 20. The extrusion compressor 50 has a base 52 attached to the second handle part 40. A flex arm 54 projects from the base 52 and extends towards the compression floor 26. In the exemplary embodiment, the flex arm 54 is thinner than the base 52. A material from which the base 52 and flex arm 54 are made is not substantially rigid and, therefore, responsive to moving downwards to have a portion of the extrusion compressor 50 touch the compression floor 26 before the entire vertical movement of the compressor-actuator 40 is complete, the flex arm 54 flexes. Example materials for the base 52 and flex arm 54 include ABS, polycarbonate and Nylon®, polypropylene, polyurethane, or other thermoplastic or thermoplastic elastomer and/or fiber filled ABS, polycarbonate and Nylon®. At a distal end of the flex arm 54 is a gear flange 56 shaped to hold thereat a compression roller 60. The gear flange 56 has axle ports in which an axle 62 of the compression roller 60 resides. When installed between the interior sides of the gear flange 56, the compression roller 60 becomes fixed to the gear flange 56 in all directions except for rotational movement of the compression roller 60 about a rotation axis 64 of the roller 60; in other words, the roller 60 is allowed to rotate about the axis 64.

[0213] It is noted that the extrusion compressor 50 shown is an exemplary embodiment. Different mechanical structures performing the same function can be used. For example, the base 52 and flex arm 54 can be replaced with a single beam that is hinged to the ceiling of the interior hollow of the compressor-actuator 40 and biased with a bias device (e.g., a spring) towards the compression floor 26 such that the point of the compression roller 60 touches the vacuum tube 2 as shown in FIG. 2 enough to grip the

vacuum tube 2 but substantially not reduce the cross-sectional area of the vacuum channel 3.

[0214] Rotation of the roller 60 is dependent upon how the roller 60 moves towards the vacuum tube 2 and along the vacuum tube 2. In this regard, the compression roller 60 has an exterior contact surface 66 that contacts the vacuum tube 2 in various ways when the compressor-actuator 40 is moved towards the handle base 20. As shown in FIG. 6, a longitudinal cross-section of the exterior surface 66 is approximately in the shape of a nautilus (alternatively, the shape can be cylindrical). The exterior surface 66 has a contact point 67, which is in contact with the exterior surface of the vacuum tube 2 in the unactuated state of the compressor-actuator 40 as shown in FIG. 2 (the vacuum channel 3 is unoccluded with a substantially patent and open cross-section). As the compressor-actuator 40 is actuated, the compressor-actuator 40 travels along the vertical extent 35. This moves the contact point 67 towards the compression floor 26. When the compressor-actuator 40 has travelled along the entirety of the vertical extent 35, as shown in FIGS. 7 and 8, the contact point 67 has moved against the vacuum tube 2 to occlude the vacuum channel 3 completely. At the stage where the bosses 42 are at this transition point from the vertical extent 35 to the angled extent 36, the contact point 67 is as far towards the compression floor 26 as it can move in that direction — because the thickness of the vacuum tube 2 prevents further movement of the contact point 67 towards the compression floor 26.

[0215] In a procedure where the vacuum tube 2 is used in a thrombectomy, the vacuum channel 3 will be filled with a fluid, i.e., blood. When the vacuum channel 3 is completely occluded, the blood that fills up the vacuum channel 3 from the contact point 67 of the compression roller 60 distally to the distal end of the vacuum channel 3 defines a column of fluid, which fluid is not compressible. The controller 10 is configured to apply the extrusion compressor 50 and the compression roller 60 to move this column of fluid a shift distance 70 in the distal direction. An exemplary volume of the shift distance is approximately 0.001 ml to approximately 1.0 ml, in particular, approximately 0.1 ml to approximately 0.5 ml. An exemplary length of the shift distance 70 is approximately 0.5 mm to approximately 30 mm, in particular, approximately 0.5 mm to approximately 15 mm. To effect such a movement, the compressor-actuator 40 is moved further in the direction towards the handle base 20,

which means that that the bosses 42 travel along and through to the end of the angled extent 36. Because the contact point 67 is already as far towards the compression floor 26 as it can move in that direction (i.e., when the bosses 42 are at the transition point from the vertical extent 35 to the angled extent 36), the extrusion compressor 50 has no other way to move than to flex the flex arm 54 and/or to roll the compression roller 60. The contact surface 66 of the compression roller 60 is shaped to roll (counterclockwise in the views of FIGS. 2 and 8 to 12) against an upper surface of the vacuum tube 2. FIGS. 9 and 10 illustrate the rolling start of the compression roller 60 at a point where the bosses 42 are approximately halfway to the distal end of the slot 34 within the angled extent 36. (It is noted that limitation of the computer software that generates FIG. 9 to 12 do not allow for displaying a realistic view of how the vacuum tube 2 compresses as the compression roller 60 rotates. These figures, therefore, illustrate an approximation of the compression roller 60 rolling on and over the shift distance 70 of the vacuum tube 2.) The contact point 67 of the compression roller 60 is offset from the rotation axis 64 towards the contact surface 66. This forms an over center, or toggle, such that the initial rolling motion of the compression roller must first force the contact point 67 over the center of the rotation axis 64. In such a configuration, not only does the compression roller 60 roll once the bosses 42 of the compression-actuator 40 start traveling in the angled extent 37, but there is also a tactile feedback transmitted to the compression-actuator 40 once the axle 62 moves slightly forward. This feedback, when felt by the user, indicates to the user that the contact surface 66 of the compression roller 60 has rolled onto a portion of the vacuum tube 2 and, as it moves along the vacuum tube 2, squeezes that portion to translate the fluid column in the distal direction of the vacuum tube 2. With complete movement of the compression-actuator 40 towards the handle base 20 as shown in FIGS. 11 and 12, the compression roller 60 has completed its defined rotation over the vacuum tube 2 and, in doing so, has squeezed a segment of the vacuum channel 3 from proximal to distal over the length to shift the fluid column distally to a length equal to the shift distance 70.

[0216] To return the controller 10 to the initial, unactuated state shown in FIGS. 1 and 2, for example, a bias device 12 is interposed between any surface of the interior hollow of the compression-actuator 40 and any surface of interior hollow of the handle base 20. In the exemplary embodiment shown in FIGS. 2 and 8, the bias device 12 is disposed between the

surface of the ceiling within the interior hollow of the compression-actuator 40 and an upper surface of the proximal tube anchor 24. This configuration for the bias device 12 is merely exemplary and any return spring or similar mechanical device can be placed and used. When the user releases pressure on the compression-actuator 40, the flex arm 54 and/or the bias device 12 causes the compression-actuator 40 to return to the initial, unactuated state. This action rolls the compression roller 60 in the opposite direction (i.e., the progression from FIG. 11 to FIG. 9 to FIG. 8). As the distal end of the vacuum channel 3 experiences positive pressure from the patient and also from the increase in volume as the crushed tube rebounds, the fluid column retreats proximally back into the vacuum channel 3 and, when the compression roller 60 releases from the vacuum tube 2 to cease occluding the vacuum channel 3, vacuum being placed in the vacuum channel 3 from a vacuum pump 80 proximal to the controller 10 automatically reestablishes and draws the fluid column through the segment of the vacuum tube 2 within the controller 10.

[0217] As set forth herein, the vacuum tube 2 is sized to lay against the compression floor 26 on one side and to have the point of the compression roller 60 touch the outer surface of the vacuum tube 2 just slightly enough to grip the vacuum tube 2 but substantially not reduce the cross sectional area of vacuum channel 3. In an embodiment where the vacuum tube 2 is not fixed within the handle base 20, the compression roller 60 is provided with a non-illustrated bias device that biases the compression roller 60 rotationally into a position shown in FIG. 2. This bias compensates in a situation where the vacuum tube 2 is not touching the compression roller in the unactuated position of the compressor-actuator 40.

[0218] With a configuration as described, the controller 10 is to be used with a vacuum tube 2 that is or is part of a thrombectomy aspiration catheter. Such use is described with regard to FIGS. 14 and 15, in which the vacuum lumen 3 is shown as being an aspiration controller that, distal to the controller 10, is threaded through vasculature and up to a thrombus 4, which in the form of a blood clot, that has corked within or at the distal opening of the vacuum channel 3. On the proximal side of the controller 10, the vacuum channel 3 is fluidically connected to the vacuum pump 80. As indicated above, thrombi typically are trapped at the end of an aspiration catheter and removing the entire catheter from the patient

when that occurs is not desirable. The inventors have discovered that removal of the catheter can be prevented using the controller 10. More particular, when the distal end of the vacuum tube 2 is clogged by a thrombus, the controller 10 is actuated to occlude all flow through the vacuum channel 3. This occurs by the first movement of the compressor-actuator 40 towards the handle base 20. The controller 10 is actuated to cause the fluid column to shift distally to the shift distance 70. This imparts a controlled reversal of flow to the fluid column within the vacuum channel 3 that slightly translates the thrombus to a prescribed shift distance 70 distally relative to the distal opening of the vacuum channel 3. During a third and final phase, the user releases actuation of the controller 10 to reset the fluid column within the vacuum channel 3 and, once again, allows the fluid to flow freely. The inventors have discovered that such movement causes either a repositioning of the thrombus or a deformation of the thrombus or both and that this movement allows the thrombus to pass entirely into and through the vacuum channel 3 where such passage was not possible before.

[0219] Operation of the controller 10 is explained with regard to the system cycle diagram of FIG. 24.

- **State 1**: Normal aspiration is occurring. The vacuum channel 3 is not occluded. The controller 100 is in a rest state where the vacuum pump 80 is connected to the vacuum channel 3.
- **Transition A — Occlusion**: Thrombus 4 occludes distal end of vacuum channel 3. Unclogging controller 10 actuates to occlude vacuum channel 3 and stop vacuum flow distal of the controller 10.
- **State 2**: Flow through the vacuum channel 3 has stopped.
- **Transition B — Unclogging**: Controller 10 continues actuation to cause reverse flow in vacuum channel 3 for a metered volumetric column shift.
- **State 3**: Flow reversal stops.
- **Transition C — Return Column Shift**: Controller 10 is reversed to return column and accelerate thrombus 4 into catheter tip by reconnecting the vacuum pump 80 to the vacuum channel 3.
- **Return to State 1 and Repeat**: Normal aspiration occurs.

[0220] The inventors further discovered that greater accelerations of the thrombus into the catheter provide proportionally quicker aspirations. A magnitude of the thrombus' impact velocity, and therefore its kinetic energy, when it impacts the aspiration catheter's distal tip, affects the amount of the thrombus that is deformed to fit within the diameter of the vacuum channel 3. When a catheter is extended to a thrombus that is lodged in a vessel, e.g., a vessel within the brain, the controller 10 is not needed until the thrombus 4 is stuck at the distal opening of the vacuum channel 3. Thus, the thrombus does not have any distance to move in order to accelerate towards the opening of the vacuum channel 3. Imparting the shift distance to the thrombus as described maximizes the kinetic energy of the thrombus at the point when it impacts the catheter's tip. The thrombus' acceleration (and therefore its kinetic energy) are generated by a pressure differential between intracranial pressure and the effective aspiration pressure at the catheter's tip. For the thrombus to accelerate, both it and the fluid column within the catheter system must attain a velocity. After catheters are occluded, the fluid velocity within the catheter is substantially zero. In conventional catheter architecture, the pressure that attempts to accelerate this fluid column is provided solely by an external vacuum pump. Significantly, however, this pressure is reduced by head losses in the tubing connecting the vacuum pump to the catheter's proximal end. Accordingly, conventional catheters must be fished out of the vasculature entirely because the thrombus is corked within the distal opening of the vacuum channel.

[0221] This disadvantage is removed by the controller 10. After the distal opening of the vacuum channel 3 is occluded by the thrombus, the fluid velocity within the catheter is substantially zero. The controller 10 is used to unclog the vacuum channel 3 and displace the thrombus 4 distally out from the distal opening. Then, the controller 10 re-applies vacuum. Upon re-application of vacuum, the fluid column accelerates and the thrombus 4 accelerates back into the vacuum channel 3. With such acceleration, the thrombus is deformed to a diameter allowing it to be aspirated. With one or just a few applications to displace the thrombus by the shift distance 70 with the controller 10, the vacuum channel 3 becomes unclogged and the thrombus 4 accelerates sufficiently to be completely aspirated through and out of the vacuum tube 2. With the controller 10, the head losses in the tubing are minimized, thereby allowing the thrombus to accelerate to a much greater extent than in conventional product architectures.

[0222] Realizing that acceleration of the thrombus proximally is a desirable trait, it becomes possible to enhance acceleration in the proximal direction when deactuation of the controller 10 occurs to re-establish vacuum. To maximize the acceleration of the thrombus and the fluid column within the vacuum channel 3 for the purpose of maximizing the thrombus' kinetic energy upon its impact with the distal tip of the vacuum tube 2, a vacuum booster 100, illustrated in FIG. 16, is fluidically connected to the vacuum channel 3 of the vacuum tube 2. In general, the vacuum booster 100 applies suction to the fluid column in a region of the aspiration catheter's proximal end to maximize acceleration of the catheter's fluid column at a user-selected time. This exemplary embodiment of the vacuum booster 100 comprises a booster body 110 defining a plunger bore 112, a plunger 120 housed within the bore 112, and a bias device 130. The plunger bore 112 is shaped to define a vacuum chamber 114 and an ambient chamber 116. In the exemplary embodiment, the vacuum chamber 114 is cylindrical and has a first inner diameter and the ambient chamber 116 is cylindrical and has a second inner diameter larger than the first inner diameter. The vacuum chamber 114 has a volume that is smaller than a volume of the ambient chamber 116.

[0223] The plunger 120 has a vacuum piston 122 and an ambient piston 124, which is connected to the vacuum piston 122 through a rod 123. In the exemplary embodiment, the vacuum piston 122 has a diameter substantially equal to the first inner diameter of the vacuum chamber 114 and is able to move within the vacuum chamber 114. The ambient piston 124 has a diameter substantially equal to the second inner diameter of the ambient chamber 116 and is able to move within the ambient chamber 116. Between the vacuum piston 122 and the ambient piston 124 is a pressure chamber 118 in which is located the rod 123 connecting the two pistons 122, 124 together, for example, in the shape of an asymmetric dumbbell. To seal the pressure chamber 118 off from both the vacuum chamber 114 and the ambient chamber 116, a vacuum seal 126 is disposed between the vacuum piston 112 and the wall of the vacuum chamber 114 and an ambient seal 128 is disposed between the ambient piston 124 and the wall of the ambient chamber 116. The booster body 110 defines the pressure chamber 118 and a pressure port 119 that fluidically connects the pressure chamber 118 to a boost control valve or switch 150. This connection is illustrated diagrammatically in FIG. 23.

[0224] The vacuum chamber 114 operatively communicates with the vacuum channel 3 at a connection 140. The plunger 120 and the bias device 130 are disposed such that, when the bias device 130 is in a relaxed state, the vacuum piston 122 is at a given distance from the connection 140 to the vacuum channel 3; this relaxed state is illustrated in FIG. 17. In the relaxed state, the spring is at a steady state — there is no potential energy stored in the spring. With regard to pressure, in the relaxed state, both the pressure chamber 118 and the ambient chamber 116 are at ambient pressure, i.e., they are substantially equal. When the plunger 120 is moved towards the vacuum channel 3 into an energized state (which is shown in FIG. 16), the bias device 130 (e.g., in the form of a spring that is stretched) thereby stores strain energy that is directed to move the plunger 120 away from the connection 140. Such movement, when it occurs, creates suction within the vacuum chamber 114 and the vacuum channel 3 that communicates with the vacuum chamber 114.

[0225] To actuate the embodiment of the pneumatically actuated vacuum booster 100, the pressure chamber 118 is connected to the vacuum pump 80 (the vacuum source) through a relatively high impedance conduit 152. The pressure chamber 118 is also connected to the boost control valve 150, which is connected to ambient pressure but is normally open to prevent flow from the pressure chamber 118 to the environment (Patm). When the vacuum booster 100 is in a cocked state (FIG. 16), the boost control valve 150 is open (as shown) and, as such, the vacuum pump 80 is able to significantly lower pressure within the pressure chamber 118. When the boost control valve 150 is actuated (i.e., connecting the pressure chamber 118 to the ambient environment), pressure equalization occurs between the pressure chamber 118 and the ambient chamber 116. An impedance of a connection between the pressure chamber 118 and the boost control valve 150 is designed to be substantially less than the impedance between the pressure chamber 118 and the vacuum pump 80 such that, upon actuation of the boost control valve 150 (i.e., closure), rapid pressure equalization is possible.

[0226] Operation of the vacuum booster 100 is explained with regard to the system cycle diagram of FIG. 24.

- **State 1**: Normal aspiration is occurring. The vacuum channel 3 is not occluded. The controller 100 is in a rest state where the vacuum pump 80 is connected to the

vacuum channel 3. The vacuum booster 100 is in the cocked state. The thrombus trap 200 is operating without bleed purge.

- **Transition A — Occlusion**: Thrombus 4 occludes distal end of vacuum channel 3. Unclogging controller 10 actuates to occlude vacuum channel 3 and stop vacuum flow distal of the controller 10.
- **State 2**: Flow through the vacuum channel 3 has stopped.
- **Transition B — Unclogging**: Controller 10 continues actuation to cause reverse flow in vacuum channel 3 for a metered volumetric column shift.
- **State 3**: Flow reversal stops.
- **Transition C — Vacuum Boost**: Vacuum booster 100 actuated to re-initiate flow in nominal direction and accelerate thrombus 4 into catheter tip. Shortly before, at the same time, or shortly thereafter, controller 10 opens vacuum channel 3 to reinitiate vacuum of pump 80 for fluid flow and aspiration of thrombus 4 into thrombus trap 200. Simultaneously or thereafter, controlled purging or automatic purging of thrombus trap 200 occurs allowing inspection of thrombus 4.
- **Return to State 1 and Repeat**: Vacuum booster 100 and self-purging trap 200 are de-actuated. Normal aspiration occurs.

[0227] During the occlusion and column shift phases in the operation of the controller 10, the plunger 120 is held in the energized state, with the plunger 120 raised to place the vacuum piston 122 closer to the connection 140. During or immediately upon the end of the reversal phase, the plunger 120 is released, generating suction within the locally communicating lumen of the vacuum channel 3 and thereby accelerating the fluid column proximally in the vacuum direction. What fluid is begin drawn into or towards the vacuum chamber has an effect on the efficiency of the vacuum booster 100. More specifically, if the fluid arrives only from downstream of the vacuum booster 100 when actuated, then the fluid column will not accelerate proximally as desired. When the controller 10 occludes the vacuum channel 3, fluid into and towards the vacuum chamber 114 will arrive substantially from upstream of the vacuum channel 3, thereby accelerating the fluid column in the desired direction. In an intermediate stage where fluid arrives from both upstream and downstream, the downstream portion can be limited, for example, by placing a non-illustrated check valve

between the thrombus trap 200 and the connection 140, in particular, between the connection 140 and the controller 10. The check valve can be external or can use the occlusive function of unclogging handle.

[0228] The following description summarizes the forces in a pneumatic embodiment of the vacuum booster 100. In an un-cocked state of the plunger 120, the pressure chamber 118 and the ambient chamber 116 are at ambient pressure and the bias device 130 is in substantially in the relaxed state, storing little or no strain energy. In a cocked state of the plunger 120, the pressure chamber 118 is caused by the boost control valve 118 to be at a significantly lower pressure than the ambient chamber 116. The geometries of the chambers 114, 116, 118 and the pistons 122, 124, and the characteristics of the bias device 130 are selected such that, in this configuration, a force created by the pressure difference across the ambient (larger) piston is significantly greater than the force required to expand the spring. As such, when the given pressures are held, the piston and spring system translates upwards into a "cocked" position. When the vacuum booster 100 is actuated, the pressure chamber 118 is allowed to rapidly equalize to ambient pressure. With no net force input from the ambient piston 124 (the larger of the two pistons), any motion of the piston and spring system are now caused by the actions of the bias device 130 and the pressure differential across the smaller, vacuum piston 122. The geometries of the chambers 114, 116, 118 and the pistons 122, 124, and the characteristics of the bias device 130 are selected such that the bias device's restoring force in the cocked configuration is much higher than an opposing force caused by the pressure difference across the smaller vacuum piston 122, which is disposed between ambient pressure and a pressure within the vacuum channel 3. As such, when the vacuum booster 100 is actuated and the pressure chamber 118 is allowed to equalize to ambient pressure, the piston and spring system energetically drives "downwards", generating a negative displacement and a dramatic pressure decrease within the vacuum chamber 114 and thereby the vacuum channel 3 of the aspiration device.

[0229] As indicated herein, current thrombus removal devices are not able to inform the surgeon that the thrombus has been removed without full withdrawal of the device from a patient's anatomy. Surgeons do not have an ability to view the reservoirs into which aspirated contents are deposited, not only because the reservoirs are located outside of the

sterile field in an operating room setting, but also because the removed thrombus is present within a significant quantity of blood contained in the reservoir.

[0230] To overcome an inability to visualize the thrombus actually retrieved, a visualization-aiding thrombus trap 200 is provided and shown in FIGS. 18 to 21. The thrombus trap 200 is placed in-line with the aspiration system, in particular, the vacuum channel 3. In the exemplary embodiment, the thrombus trap 200 is within the catheter operator's immediate vicinity between the aspiration catheter and the vacuum source, in particular, between the controller 10 and the vacuum pump 80, so that the surgeon can see the thrombus trap 200 during use of the controller 10. In use, all aspirated material flows through the thrombus trap 200.

[0231] The thrombus trap 200 comprises a container having an inflow section 210 having an input orifice 212 fluidically connected to the vacuum channel 3, a transparent intermediate trap section 220 in which the thrombus is trapped, and an outflow section 230 fluidically connected to the vacuum pump 80. In operation, aspirated material and fluid travel from the vacuum channel 3 past the controller 10 through the inflow section 210 and into the trap section 220. The trap section 220 contains a trap filter 222 that is, in an exemplary embodiment, a screen or a filter through which all aspirated flow must pass. The filter 222 is configured to stop and capture thrombus material therein but allow the passage of air and fluid with minimal impedance therethrough and, thereby out of the outflow section 230 to the vacuum pump 80 and any associated vacuum pump reservoir 82. In the exemplary embodiment of FIGS. 18 to 22, the filter 222 is in the form of a grating or screen having orifices sufficiently large enough for fluid and air to pass therethrough but sufficiently small enough to substantially prevent the thrombus from passing across the filter 222 from an inflow or trap chamber 224 of the trap section 220 to an outflow chamber 226 of the trap section 220. As used herein, the term "filter" includes any structure that is able to separate fluid from particulate matter by allowing the fluid to pass through the structure while preventing the particular matter from passing through. Other exemplary embodiments of the filter 222 include perforated polymer, textile, or sintered semi-permeable polymer. The outflow section 230 has an output orifice 232 that fluidically connects the outflow chamber 226 to the vacuum pump 80 for directly receiving the vacuum generated.

[0232] The container of the thrombus trap 200 is sealed when closed and in use during a surgical procedure. In an exemplary embodiment, the thrombus trap 200 can be taken apart and opened for removal of the thrombus out of the trap chamber 224 and inspection by the surgeon or pathologist, as well as for sterilization when the thrombus trap 200 is reusable.

[0233] It is noted that when a thrombus 4 is captured in the trap chamber 224, whether or not vacuum is still being applied, the trap chamber 224 is also filled with blood. Thus, the thrombus 4 cannot be visualized even if the entirety of the thrombus trap 200 is transparent for viewing inside by a user. To assist with visualization of the thrombus 4 contained within the trap chamber 224, the thrombus trap 200 is configured to temporarily purge itself of fluids that visually impede inspection of captured thrombus material. In an exemplary embodiment, therefore, the inflow section 212 is formed with an intake bleed valve 214 fluidically connected to the vacuum channel 3 and to the trap chamber 224. The bleed valve 214 is configured to operate in a closed mode, in which any flow of air and/or fluid through the bleed valve 214 and into the trap chamber 224 (or vacuum channel 3) is fully restricted, and a bleed mode, in which the bleed valve 214 intakes a fluid, in particular, ambient air. (Alternatively, if desired, in the bleed mode, the bleed valve 214 can intake a clear liquid such as saline.) During the closed mode operation, the exit of the bleed valve 214 is closed and aspirated materials are unhindered to flow through the thrombus trap 200 from the input orifice 212 and out the output orifice 232 away towards the vacuum source, leaving aspirated thrombus and other solid matter in the trap chamber 224. Accordingly, when the surgeon has captured a thrombus 4 in the trap chamber 224 during a thrombectomy procedure, the surgeon can immediately visualize that thrombus 4 by setting the bleed valve 214 into the bleed mode, which, due to a relatively larger size of the bleed valve's 214 input opening and to a decreased resistance to the vacuum by opening to ambient air, causes the vacuum pump to draw ambient air rapidly into the trap chamber 224 and thereby evacuate all fluid from the trap chamber 224. During inspection, the bleed valve 214 can be configured to occlude the fluidic connection between the trap chamber 224 and the vacuum channel 3. Actuation of the bleed valve 214 can be separate from the controller 10 or mechanically connected to the controller 10 so that, when the controller 10 is in an unactuated state where aspiration is occurring, a bleed switch on the controller can activate the bleed valve 214.

The rapid inflow of air into the trap chamber 224 is directed by the descending pressure gradient between the outside environment and the relatively low pressure existing within the volume existing between the trap chamber 224 and the vacuum pump 80. As such, while the bleed 214 valve is open, airflow displaces fluids from the volume of the thrombus trap 200, leaving the volume mostly full of transparent air, instead of opaque blood. This temporary transparency allows for easier inspection of the material caught by the filter 222. The surgeon then can view the thrombus 4 unobstructed within the trap chamber 224. During this examination, the control of the bleed valve 214 (which can be a mechanical or a processor-based controller) can cause the vacuum pump 80 to reduce vacuum or to shut off completely, at least until the surgeon is ready to continue the thrombectomy procedure if continuation is desired. When the bleed valve 214 is set back to the closed mode and re-connection of the trap chamber 224 to the vacuum channel 3 occurs, normal aspiration resumes. Alternatively the bleed valve can be connected to a fluid flush line such as a saline drip bag.

[0234] Inspection of the thrombus 4 may be enhanced by providing the thrombus trap 200 with optical filters optimized for visual contrast, transparent trap enclosures as described, built-in magnification or visualization systems, lighting, and/or sensor-based thrombus-detection methods.

[0235] In the exemplary configuration, the vacuum booster 100 is disposed upstream of the thrombus trap 200 and is on a side of controller 10 opposite the thrombus trap 200 as shown in FIG. 21. Accordingly, to maintain efficacy of the thrombus trap 200 as a terminus for all aspirated thrombi 4, vacuum booster configurations that might entrap or significantly damage or macerate the thrombus are less desirable. One exemplary embodiment of a gentler vacuum booster 200, instead of the piston design of FIGS. 16 and 17, couples a section of the tubing of the vacuum tube 2 having a deformable interior volume with a mechanical actuation mechanism. This mechanism is able to collapse and expand the interior cross-section of a length of the vacuum channel 3 to provide an increase or a decrease in pressure along that length. Another mechanical embodiment for the vacuum booster having no pneumatic actuation takes energy for vacuum boost from energy imparted by actuation of the controller 10 or from a separate energy input. For example, as user

depresses a lever in the controller 10 that occludes flow and temporarily causes the column shift, the lever's motion also cocks and releases a spring-loaded piston that creates the vacuum boost. Another exemplary embodiment of the vacuum booster places a screen between the vacuum chamber 114 of the vacuum booster 100 and the vacuum channel 3 of the aspiration system. This screen allows fluid communication between the two interior volumes but occludes particulate matter from entering the piston bore defined by the vacuum chamber 114. A further exemplary embodiment that guards against clogging/accidental maceration of the thrombus alters the piston configuration of FIGS. 16 and 17 by having the connection 140 be a flexible diaphragm mechanically disposed between the surface of the vacuum piston 122 and the opening into the vacuum channel 3. The diaphragm can be contained in and cross the actual opening of the vacuum channel 3, for example. Such a membrane transmits volumetric displacement while excluding all flow. The membrane can be separate from the vacuum piston 122, fluidically coupled thereto, or attached. In each of these configurations, the volume through which the fluid column flows is unhindered to prevent entrapping or damaging the thrombus 4 when traveling thereby, whether the vacuum booster 100 is in an energized state or a resting state.

[0236] Both the vacuum booster and the blood-purging clot trap rely on the timely and controlled application of either vacuum or ambient pressures to specific parts of the device, namely the bleed valve 214 of the thrombus trap 200 or the plunger 120 of the vacuum booster 100. The self-unclogging thrombectomy aspiration catheter described and shown herein can be provided with additional features actuated by the same user input as the self-unclogging function, e.g., at or by the controller 10, but which serve to either open or occlude additional conduits for vacuum or atmospheric pressure air that control device features such as the self-purging thrombus trap 200 and/or the vacuum booster 100.

[0237] The vacuum channel 3 of the vacuum tube 2 (and any other tubing within the catheter) can be coated with a hydrophobic coating, such as carnauba wax, for example, to decrease head loss during aspiration.

[0238] With an appropriate pressure sensor (for example, a piezoelectric diaphragm transducer, an electromagnetic diaphragm transducer, a strain-gage diaphragm transducer, or a MEMS pressure integrated circuit transducer), the controller 10 can determine when

the vacuum channel 3 is clogged by a thrombus and automatically perform the unclogging procedures described herein. In an exemplary embodiment, a computer connected to the sensor can detect a pressure drop and lack of flow associated with a thrombus clog in or at the vacuum channel 3. When the clog is detected, the sensor triggers the sequence that halts application of vacuum in the vacuum channel 3 and carries out the column shift sequence. With respect to visualization of the thrombus 4 in the device, another exemplary embodiment of a sensor includes an optical sensor that detects the presence of the thrombus in either or both of the distal opening of the vacuum channel 3 and the thrombus trap 200. In the latter configuration, the optical sensor associated with the trap section 220 detects when the thrombus 4 is present and cause purging of fluid by opening the bleed valve 214.

[0239] As set forth herein, the vacuum tube 2 can be made from various materials. Some materials for the vacuum tube 2 have a relatively lower compression strength, such as latex, silicone, and other synthetic rubbers. Other materials for the vacuum tube 2 have a relatively higher compression strength, such as Pebax®, polyurethane, and polyvinyl chloride. Because the vacuum tube 2 within the controller 10 is subject to expansion when positively pressured in the vacuum channel 3 and is subject to contraction when negative pressured, this flexible attribute of the material from which the vacuum tube 2 is made could possibly contribute to a less effective column shift. In order to reduce these effects of pressure (both positive and negative) on the vacuum tube 2, the vacuum tube 2 can be reinforced with a braid or coil or other mechanical structure to support the portion of the vacuum tube 2 within the controller 10 against pressure changes. Where the vacuum tube 2 is made from a material with a relatively lower compression strength, the section of the vacuum tube 2 that resides within the controller 10 is made as short as possible to minimize the expansion/contraction effects.

[0240] An alternative embodiment to the controller 10 of FIG. 1, which indirectly operates on the vacuum channel 3 through the compression roller 60, is shown in FIG. 22. In the exemplary embodiment of FIG. 22, the extrusion compressor is replaced with a volume changing controller 300 that is directly fluidically connected to the vacuum channel 3 of the vacuum tube 3. The volume changing controller 300 has a barrel body 310 with an

interior 311 defining an input orifice 312 fluidically connected to the vacuum channel 3. The barrel body 310 also defines a plunger orifice 314, a pump orifice 316, and a purge orifice 318. A plunger 320 sealably connects to the interior 311 of the barrel body 310 movably towards and away from the input orifice 314. When in the position shown in FIG. 22, vacuum applied by the vacuum pump 80 is connected to the distal opening of the vacuum channel 3 for aspiration of material. When a thrombus becomes clogged at the distal opening, the surgeon presses the plunger 320 inwards. In a first portion of the inwards motion, a surface of the plunger 320 seals off the pump orifice 316 to stop the application of vacuum to the vacuum channel 3. In a second portion of the inwards motion, the plunger 320 moves all fluid contained within the interior 311 and the vacuum channel 3 distally to cause the column shift. Reversal of the plunger reverses the column shift and reapplies vacuum to the vacuum channel 3.

[0241] The plunger 320 can also be used to control purging of the thrombus trap 200. The plunger is provided with a purge conduit 322. When the plunger 320 is placed in a purge position, the plunger 320 closes off the vacuum channel 3 from the vacuum pump 80 and fluidically connects the pump orifice 316 to the purge orifice 318 through the purge conduit 322. In this position, a fluid connected to the purge orifice, e.g., ambient air, is drawn through the purge conduit 322, through the purge orifice 318, and into the thrombus trap 200.

[0242] Operation of the volume changing controller 300 is explained with regard to the system cycle diagram of FIG. 24.

- **State 1**: Normal aspiration is occurring. The vacuum channel 3 is not occluded. The volume changing controller 300 is in a rest state where the vacuum pump 80 is connected to the vacuum channel 3.
- **Transition A — Occlusion**: Thrombus 4 occludes distal end of vacuum channel 3. Controller 300 actuates (plunges) to occlude vacuum channel 3 and stop vacuum flow distal of the controller 300.
- **State 2**: Flow through the vacuum channel 3 has stopped.
- **Transition B — Unclogging**: Controller 300 continues to plunge to cause reverse flow in vacuum channel 3 for a metered volumetric column shift.
- **State 3**: Flow reversal stops.

- **Transition C — Return Column Shift**: Controller 300 is reversed to return column and accelerate thrombus 4 into catheter tip by reconnecting the vacuum pump 80 to the vacuum channel 3.
- **Return to State 1 and Repeat**: Normal aspiration occurs.

[0243] FIGS. 25 to 41 illustrate an exemplary embodiment of an aspiration thrombectomy system 400 operating with an automatic, rapid, and repeated onset of pressure change. An aspiration catheter 410 is diagrammatically indicated in FIG. 26 leading from distal orifices of a pair of valves 420, 440, which in this exemplary embodiment are pinch valves 420, 440. One of these valves is a pinch valve 420 to control vacuum flow and is connected between the aspiration catheter 410 and the aspiration pump (e.g., vacuum pump 80). The other of these valves is a pinch valve 440 to control vent flow and is connected to a supply of vent liquid. In an exemplary embodiment, the vent liquid can be any of albumin, d5W water, normal saline, half-normal saline, and lactated Ringer's solution, to name a few. The vent liquid can also be any other biocompatible fluid such as contrast media or tissue plasminogen activator (tPa). With such fluids, the catheter 410 can perform different functions. For example, switching the vent liquid to contrast media after it is believed that a clot has been successfully removed allows the surgeon to inject that media into the vessel to confirm removal of the clot. This is significant because the catheter 410 changes from the aspiration function to the contrast injection function without any significant movement within the vasculature. With standard aspiration catheters where a clot becomes lodged in the distal end, the entire catheter needs to be removed from the patient and, if contrast needs to be injected at the site, the catheter needs to be reintroduced through the vasculature just to perform this visualization. The vent liquid can be at atmospheric pressure or at a higher or lower than atmospheric pressure.

[0244] In an exemplary configuration, these valves 420, 440 are mounted to a base 401. Operatively associated with the pinch valves 420, 440 are respective cams, a vacuum cam 430 and a vent cam 450. These cams 430, 450 are connected to a cam shaft 460. A first shaft end 462 of the cam shaft 460 is fixedly connected to a shaft bearing 470 in a freely rotatable manner. The shaft bearing 470 has a bearing body 472 mounted to the base 401. A second shaft end 464 of the cam shaft 460 is connected to a shaft drive assembly 500.

The shaft drive assembly 500 comprises a motor 510, a transmission or gear box 520, a shaft coupler 530, and a motor controller assembly 550.

[0245] The transmission 520 has an output shaft 522. To connect the transmission 520 to the cam shaft 460, a first coupler end 532 of the shaft coupler 530 is connected to the output shaft 522 and a second coupler end 534 of the shaft coupler 530 is connected to the second shaft end 464. In this manner, rotation of the motor 510 corresponds to a rotation (at the same or different speed based upon the gearing of the transmission 520) of the cam shaft 460 with a corresponding rotation of the vacuum and vent cams 430, 450.

[0246] Control of the motor 510 originates from the motor controller assembly 550, which comprises a controller 560, a positional encoder 570 and a positional reset assembly 580. In an exemplary embodiment, the controller 560 is a microcontroller that has a user interface (UI) comprising user inputs that include, for example, control buttons to operate the aspiration thrombectomy system 400 in various states, examples of which are described in further detail below. The controller 560 with the UI is illustrated diagrammatically in FIG. 30. To isolate parts from fluid, in the exemplary embodiment, the motor 510, the transmission 520, the shaft coupler 530, and the motor controller assembly 550, 560, 570, 580 are contained in a motor assembly housing 552. The connection of the motor assembly housing 552 to the cam shaft 460 is sealed fluidically with a shaft seal 554. Similarly, the cams 430, 450, the cam shaft 460, and the shaft bearing 470 are covered with a cam housing 466. The controller 560 is indicated in FIG. 30 as separate from the motor assembly housing 552 (either wired or wireless) but it can also be integrated into or attached to the motor assembly housing 552. In a wireless configuration, the controller 560 can be an app on a computer or smartphone, for example, with all of the UI being available through a touchscreen.

[0247] The vacuum and vent cams 430, 450 are fixed rotationally to the cam shaft 460. These cams 430, 450 have various cam profiles to operate the valves 420, 440. It is desirable to know the exact rotational position of the cams 430, 450 and, therefore, cam shaft 460, so that the controller 560 can set the valves 420, 440 in whatever state that is desired. Because the motor 510 rotates freely and can end its rotation at any rotational position, it is desirable to know the exact rotational position of the cam shaft 560 at all given times. Accordingly, the motor controller assembly 550 includes the positional encoder 570

associated with the motor 510. With this association, the controller is provided with information on the exact rotational state of the cam shaft 460 and, therefore, the cams 430, 450. The positional encoder 570 comprises an encoder disk 572 and an encoder circuit 574. The encoder 570 is able to detect and report out to the controller 560 the current relative rotational position of the motor 510 at any point in time.

[0248] Those of skill in the art know that the motor 510 and/or the positional encoder 570 can drift in use. To account for and correct any drift, the motor controller assembly 550 comprises the positional reset assembly 580. This positional reset assembly 580 assigns a single rotational position of the cam shaft 460 as a reset point and every time that position crosses a zero-line the positional encoder resets the position of the motor 510 to zero, which in turn allows the system to know the absolute position of the cam shaft 460. In an exemplary embodiment, the positional reset assembly 580 comprises a photodiode 582 and a flag or interrupter 584. As shown in FIG. 30, the flag 584 is fixed to the shaft coupler 530. The photodiode 582 is placed at the path of the flag 584 so that the flag 584 interrupts the photodiode 582 once for each rotation of the cam shaft 460. This exemplary embodiment allows for immediate correction of any skipped steps of the encoder 570.

[0249] The exemplary embodiment of the pinch valves 420, 440 is explained with regard to FIGS. 31 to 33 using the vent pinch valve 440. Each valve 420, 440 comprises a valve body 422, 442 defining a vacuum or vent lumen 424, 444. An elastomeric tube 426, 446 is secured within the lumen 424, 444 at each end of the tube 426, 446. Exemplary embodiments for this connection include but are not limited to fusing, compression sealing, and fixation with an adhesive. Accordingly, the tube 426, 446 spans an extent of the lumen 424, 444 with an intermediate portion of the tube 426, 446 unattached to the lumen 424, 444. A lumen of the tube 426, 446 fluidically connects a distal end of the lumen 424, 444 (to the left of FIGS. 31 and 32) to the proximal end of the lumen 424, 444 (to the right of FIGS. 31 and 32). The intermediate section of the valve body 422, 442 defines a follower connection in which is movably secured a cam follower 421. A first end of the cam follower 421 is biased against the outer surface of the cam 430, 450 with a non-illustrated bias device or is simply trapped in place. The opposing second end of the cam follower 421 rests against the intermediate portion of the tube 426, 446. Accordingly, when moved by the cam 430,

450 towards the tube 426, 446, as shown in FIG. 32, the cam follower 421 fluidically seals off the lumen of the tube 426, 446 and, when allowed to return away from the tube 426, 446, as shown in FIG. 31, the cam follower 421 opens the lumen of the tube 426, 446. In the exemplary embodiment, the cam follower 421 is pill-shaped but it can be formed in any shape to provide the function of closing off the tube 426, 446.

[0250] Both a vacuum line 402 and a vent line 404 are connected through the selectively openable valves 420, 440 to a proximal end of the aspiration catheter 410. In operation, the vacuum cam 430 and the vent cam 450 push down on the respective cam followers 421, which pinch down the short sections of tubing 426, 446, each respectively fluidically connected to the vacuum line 402 and the vent line 404. When the vacuum line 402 is open and the vent line 404 is closed, vacuum is drawn on the aspiration catheter 410. When the distal end of the catheter 410 is clogged with a clot, the closure raises a vacuum level within the catheter 410 to full (the greatest current vacuum generated by the vacuum pump). This closure creates a delta in pressure between the internal lumen of the catheter 410 and the environment external to the catheter 410, which change squeezes down the body of the catheter 410 both radially and longitudinally (e.g., the diameter and length become incrementally smaller). This change also draws out a small volume of liquid from within the lumen of the catheter 410. In an exemplary embodiment, the volume is approximately 0.2 ml. The end effect is the creation of a spring-like force within the catheter 410 that wants to expand the catheter 410 back to its steady state, but when the vacuum line 402 is closed off, that cannot happen. Thus, the vacuum is stored as potential energy until the vent line 404 is opened (as can be seen in FIG. 26, for example, the vacuum and vent lines 402, 404 are connected together distal of the valves 420, 440). When the vent line 404 is opened, there is an in-rush of fluid because of the pressure delta. This rush of fluid balances the radial force of the catheter 410 and draws in fluid to create a distally directed momentum in the column of fluid residing in the catheter 410 distal of the valves 420, 440. The momentum causes a small amount of fluid to move through a distal portion of the catheter 410 and create a small distal movement of the clot that is stuck in the distal opening at the end of the catheter 410. Once the clot is no longer stuck at the distal opening, it is able to be moved proximally into and through the catheter 410 with subsequent vacuum imparted to the catheter 410. Repeated selective actuation of vacuum and venting

macerates the clot at the distal opening, thereby reforming it into a state where it can be completely drawn into the lumen of the catheter 410 and out of the vasculature. The flow of fluid forward in this exemplary embodiment is intentional, which is in contrast to other exemplary embodiments herein where substantially no forward flow occurs.

[0251] The system 400 can be operated in various modes to remove clots in the vasculature. Rotation of the cams are measured in degrees, a full rotation being 360° of movement. In a first exemplary embodiment, the vacuum cam 430 is configured to establish vacuum in the catheter 410 through approximately 220° of rotation. The vent cam 450 is configured to have venting on through approximately 80° of rotation. The configuration of the cams 430, 450 stop both venting and vacuum between each respective application of vacuum and venting, for example, with a 30° rotation. This configuration, therefore results in operation states according to Table 1 below.

State	Vacuum	Venting	Cam Angle
Off	0	0	0 to +30
Vac	1	0	+30 to +250
Off	0	0	+250 to +280
Vent	0	1	+280 to 0

Table 1

As soon as the vent is opened, there is an in-rush of fluid to balance out the vacuum pressure, then the vent line 404 is closed and the vacuum line 402 is opened, suddenly causing a rapid decrease in pressure that serves to forcefully pull the clot to the catheter. It is desirable, therefore, to close both vacuum and vent lines before resuming vacuum.

[0252] In another exemplary embodiment, the vacuum cam 430 is configured to establish vacuum in the catheter 410 through approximately 220° of rotation. The vent cam 450 is configured to have venting on through approximately 80° of rotation. Thus, there is created, in a desirable second exemplary configuration, a pause between vacuum draw in the catheter and venting of the catheter and another pause between venting of the catheter and resuming vacuum draw in the catheter. In this exemplary configuration, the pause can be through approx. 30° of rotation. To create a purge state, where vacuum and venting occur

simultaneously, the vent cam 450 has a small inwards depression in a position of the vent cam 450 that occurs during a long vacuum-on stage (e.g., between +30° to +250°). The extent of the venting is configured to not provide a significant change in pressure or change in the vacuum energy but, instead, is configured to create a single rotation position of the cams 430, 450 where the motor control assembly 550 can stop rotation of the cam shaft 460 in that orientation where both the vacuum line 402 and the vent line 404 are connected to the catheter 410, which allows the user to purge out any air that might be present in the system (e.g., in the vacuum line 402, the vent line 404, and/or the catheter 410). The extent of the depression can be such that it only partially opens the vent to reduce the amount of vent liquid that is drawn in during this purge state. This purging can be a known position of the cam rotation and is placed in that position to ensure that all lines in the system 400 are cleared of air. Such a configuration results in operation states according to Table 2 below.

State	Vacuum	Venting	Cam Angle
Off	0	0	0 to +30
Vac	1	0	+30 to +120
Purge	1	1	+120 to +140
Vac	1	0	+140 to +250
Off	0	0	+250 to +280
Vent	0	1	+280 to 0

Table 2

[0253] A third alternative configuration for operation of the system 400 can include a full-time vacuum with a pulsed venting including the operating states according to Table 3 below.

State	Vacuum	Venting	Cam Angle
Vac	1	0	0 to +120
Purge	1	1	+120 to +150
Vac	1	0	+150 to 0

Table 3

An opposite configuration to the states of Table 3 can including a full-time venting with a vacuum overlap.

[0254] A fourth alternative configuration for operation of the system 400 can include a vacuum during venting, which configuration includes the operating states according to Table 4 below.

State	Vacuum	Venting	Cam Angle
Purge	1	1	0 to +30
Vac	1	0	+30 to +250
Off	0	0	+250 to +280
Vent	0	1	+280 to 0

Table 4

An opposite configuration to the states of Table 3 can include a full-time venting with a vacuum overlap.

[0255] A fifth alternative configuration for operation of the system 400 can include a venting during vacuum, which configuration includes the operating states according to Table 5 below.

State	Vacuum	Venting	Cam Angle
Off	0	0	0 to +30
Vac	1	0	+30 to +250
Purge	1	1	+250 to +280
Vent	0	1	+280 to 0

Table 5

[0256] In further alternative configurations, there can be a variation overlapping of venting and vacuum, which would delete one or more of the OFF states in any of the state tables above.

[0257] The cam-driven valves 420, 440 allow the positional encoder driven motor to create positions for vacuum, venting, off, and purge. The motor controller assembly 550

allows the cams 420, 440 to be controlled by any frequency, e.g., they can be set to move through the various states at any given speed, for example, at 4 Hz. The frequency at which the motor runs may be more appropriate to run at lower frequencies such as 0.5 Hz, 1 Hz, or 2 Hz. Alternatively, it may be more effective to run at higher frequencies such as 8 Hz, 12 Hz, or 16 Hz. The motor control assembly 550 can also dynamically change the rate of cam shaft 460 rotation to sweep the frequency of rotation. In exemplary embodiments, the step in speed is in a range from 1 Hz to approximately 4 Hz, the change in increment is between approximately 0.25 seconds to approximately 5 seconds, and the range of rotation is between approximately 2 Hz to approximately 12 Hz. One example for the step, increment, and range is 2 Hz and 1 second increments in the following progression 2 Hz/4/6/8/10/12/10/8/6/4/2/... Another example is 4 Hz with 0.5 sec increments in the following progression 4 Hz/8/12/8/4/... In exemplary embodiments, the system uses the higher frequencies in the 8 Hz to 12 Hz range, which has been observed to have less movement of the proximal end of a clot stuck at the distal end of the catheter 410. Alternatively, further increments can be used to sweep the frequency through complex forms, such as sine, sawtooth, stepped, and pulsing variations.

[0258] In an exemplary alternative to the pinch valves 420, 440, the valves can be solenoid-driven pinch valves or voice coil actuators. In another exemplary alternative, a rotational pintle valve can be used, as shown in FIGS. 42 to 46. The first valve state shown in FIGS. 42 to 44 can, for example, be a vacuum-on/vent-off state and the second valve state shown in FIGS. 45 and 46 can be a vacuum-off/vent-on state.

[0259] It has been determined that the most rapid onset of vacuum and venting is desirable. To create this rapid onset, the cams 430, 450 start vacuum and venting, respectively, with a cliff 452 in the shape of the cam 430, 450. Sudden creation of vacuum creates a rapid decrease of pressure inside the catheter 410, which draws the clot aggressively against the distal end of the catheter 410. Venting, as described above, creates a distal momentum that unsticks the clot and repetition of the vacuum and venting causes mechanical maceration of the clot at the distal opening until the clot completely enters the lumen of the catheter 410 and is removed from the vasculature. Therefore, the instant system 400 can be described as a Rapid Onset Aspiration Repeater or ROAR.

[0260] The control carried out by the motor controller assembly 550 has a selection of user-actuated buttons. In an exemplary embodiment, one button causes both vacuum and venting to be shut off, i.e., off operation. One button causes vacuum to occur in a continuous manner, i.e., manual control. One button causes venting to occur in a continuous manner, i.e., manual control. One button causes the cam shaft 460 to rotate the cams 430, 450 to the position in which the vacuum and vent lines 402, 404 can be purged, i.e., the purge function. One button causes the system to run or pulse repeatedly according to a desired set of states (e.g., according to any of Tables 1 to 5) along with a selection of any number of sets for step, increment, and range. As such, if the surgeon desires to use the system 400 as a simple thrombectomy device, the surgeon can just use the vacuum button. In this condition, the encoder 570 assists to have the cam shaft 460 to rotate to a position in which vacuum is open. The vacuum pump runs with a fully open vacuum until the surgeon releases the button. If the surgeon wants to purge or inject contrast, for example, then the surgeon can use the vent button to have the encoder 570 assist to rotate the cam shaft 460 to a position in which the vent is open. Likewise, the off button rotates the cam shaft 460 to a position where the cams 430, 450 close both the vacuum and vent lines 402, 404. The purge button causes rotation of the cam shaft 460 to a position where the cams 430, 450 allow simultaneous vacuum and venting.

[0261] In an exemplary embodiment of the run or ROAR mode, rotation of the cam shaft 460 is between approximately 0.5 Hz and approximately 25 Hz, further, approximately 6 Hz and approximately 16 Hz, in particular, between approximately 8 Hz and approximately 12 Hz. In this exemplary ROAR cycle, the cam shaft 460 is rotated for between approximately 10 seconds and approximately 30 seconds and, during that time, the motor controller assembly 550 causes the motor 410 to sweep through frequencies between approximately 2 Hz and approximately 12 Hz.

[0262] As set forth above, the elastomeric tube 426, 446 is attached to distal and proximal locations of the valve lumen 424, 444. Compliance in the system 400 distal of the vacuum valve (described above as including reduction of the diameter and/or length of the catheter 410 as well as compliance of the tube 426, 446) when vacuum is applied to the catheter 410 and a clot is stuck at the distal end determines how much fluid is drawn out

when the system 400 is under full vacuum and, conversely, how much fluid rushes back into the system 400 when that state is released. In other words, with a greater amount of compliance distal of the valves 420, 440, momentum imparted to the stuck clot by the column of fluid increases. It is desirable to have a minimal amount of momentum transfer from the fluid column to the stuck clot to unstick the clot sufficiently so that the next vacuum cycle macerates the clot against the distal end of the catheter 410 and causes it to enter the lumen of the catheter 410 and be removed from the vessel. To minimize this compliance (which is fixed for a given catheter 410), this tube 426, 446 is made as short as possible to still allow valve operation by the cam follower. Compliance as used herein refers to mechanical compliance of the catheter 410 and the tube 426, 446; it does not refer to any air that might be in the system 400, which air is purged before use as set forth herein. This desire for a reduction in compliance is one reason the valving system is connected directly to the proximal end of the catheter 410. This close connection minimizes overall compliance. In an exemplary embodiment, the valving system can be located away from the catheter 410 and, in such a case, substantially non-compliant tubing is desired. This configuration may experience lower performance due to the excess compliance.

[0263] To determine the status of a clot at the distal end of the catheter 410, the system 400 is put in the ROAR mode. If there are no sensors associated with the system 400, a surgeon cannot distinguish the situation when a clot is corked during ROAR or not. The surgeon has to turn off ROAR and visualize whether the catheter is corked (in which nothing is being drawn in by the catheter 410) or is not corked (in which blood is being drawn into the catheter 410). With the different situations of aborting pulse based on flow and pulsing until not corked, it is hard to know when a clot is corked.

[0264] The vent line 404 is connected to a vent liquid reservoir (not illustrated), which can contain for example, any of albumin, d5 water, normal saline, half-normal saline, and lactated ringers. When a fluid is used to vent the system 400, as described above, all air can be purged out of the system 400. Additionally, knowing that a given amount of vent liquid is used at various stages of clot removal can allow the user to correlate removal of a clot into the catheter after being stuck at the distal end to a rate of vent liquid use. In other words, the amount of vent liquid is different when the clot corked from when it is not corked. Thus,

a user or a sensor can look at or measure vent liquid use to determine to turn off the system. If the catheter 410 is aspirating without obstruction (uncorked), then a significant flow of blood will exit the system 400. If the catheter 410 is aspirating while corked, then no blood will appear at the vacuum exit. During a ROAR operation and the catheter 410 is uncorked, the user/sensor will detect some blood at the vacuum exit. Finally, during the ROAR operation when the catheter 410 is corked, the vacuum exit will receive some fluid that is a combination of both blood and vent liquid and, in this state, the flow rate of the vent liquid can indicate if the catheter is corked or uncorked.

[0265] If a surgeon visualizes free flow during vacuum and see a captured clot (for example, in the thrombus trap 200), then the surgeon has the ability to perform a contrast injection with the catheter 410 to confirm revascularization without moving or removing the aspiration catheter 410. This is in contrast to current state-of-the-art aspiration catheters where the catheter removes the clot by holding the clot corked on the end and the surgeon retracts the entire catheter to drag out the corked clot. The increased ability of a smaller diameter catheter to be able to fully ingest or secure a better grip on the clot by drawing a greater amount of it into the catheter is a significant benefit. Many clots are deep enough into the anatomy that it is difficult to get large catheters to the site of the clot. If a smaller diameter catheter can have increased effectiveness through ROAR than a greater number of clots can be accessed and retrieved.

[0266] It is noted that one desirable goal to achieve with the system 400 is to fully ingest a clot and bring it back a standard aspiration canister (in a typical thrombectomy end reservoir) or into the thrombus trap 200. When using a standard aspiration canister and the thrombus trap 200, the system 400 can use the vent liquid to flush the thrombus trap 200 through the intake bleed valve 214 instead of using air. This allows retention of vacuum pressure in the aspiration canister.

[0267] Turning now to embodiments that create maceration but without the forward flow, FIG. 47 illustrates diagrammatically an exemplary embodiment of an aspiration thrombectomy system 600 that operates in a ROAR mode. The system 600 comprises a vacuum source 610 fluidically connected to an input of a controllable vacuum valve 620. (Parts of the vacuum source 610, such as the collection canister, are not illustrated in FIG.

47 for reasons of clarity but are detailed below.) The vacuum valve 620 is fluidically connected to a vacuum input 632 of a manifold 630. The connection can be direct or through a conduit, such as silicone tubing. A vent fluid source or reservoir 640 containing a vent liquid 642 is fluidically connected to a controllable vent valve 650. The vent liquid 642 can be, for example, any of albumin, d5 water, normal saline, half-normal saline, and lactated ringers, to name a few. As used herein, "controllable" means that the device is able to be selected between various states, the selection including analog and/or digital switching. One exemplary embodiment is a digital switching between an open position and a closed with a single command (e.g., a change of bit 1/0). The entire working channel of the aspiration thrombectomy system 600 is to be free from air or other gaseous bubbles during use.

[0268] The vent fluid source 640 has a sufficient amount of vent liquid in the reservoir that will not end during a given surgical procedure and this prevents any possibility of air entering the system. If the vent fluid source 640 is flexible, such as with fluid supplied by a parenteral fluid containment bag or an intravenous therapy bag, the gas-free container will shrink as the vent liquid 642 is used. If the vent fluid source 640 is inflexible and has an air or gas pocket, as in a replaceable/removable and sterilizable container, the conduit that transfers the vent liquid 642 from the vent fluid source 640 to the vent valve 650 is at a level within the reservoir to keep the input of that conduit submerged within the vent liquid 642 throughout a given procedure.

[0269] A ROAR catheter 660 defines a working lumen 662 fluidically connecting a distal end 664 thereof to a proximal manifold connector assembly 670 at a proximal end of the ROAR catheter 660, which assembly 670 is described in greater detail below. The ROAR catheter 660 is configured to operate in relatively small vessels. Thus, in an exemplary embodiment, the lumen has an internal diameter of between approximately 0.038" and approximately 0.106" and, in particular, an internal diameter of between approximately 0.068" and approximately 0.088". The proximal manifold connector assembly 670 fluidically connects the lumen 662 to the interior of the manifold 630 and, thereby, the manifold 630 fluidically connects the lumen 662 to the vacuum source 610 through the vacuum valve 620 and to the vent fluid source 640 through the vent valve 650. In use within a vessel, the lumen 662 is filled with a liquid column having a proximal portion and a distal portion. Depending

on the context used with respect to the catheter 660, the proximal and distal portions of the liquid column can be a given amount (e.g., less than 20 microliters or less than 5 microliters), can be a given length (e.g., a few mm or cm) or it can be an instance of the column that is approximated by using statistical flow analyses. For example, when discussing whether a distal portion of the fluid column exits the distal end of the lumen 662, that distal portion is a measurable distance at the distal end of the liquid column equal to an instance of liquid present at the plane of the lumen distal exit. In the realm of statistical analysis in this example, the distal portion is a last distal finite element in a finite element analysis (FEA) of the liquid column. Here, the system 600 is used to substantially prevent forward flow. The term "forward flow" is used herein to define an amount of liquid in the lumen 662 that exits the distal end 664 in a distal direction. Forward flow is defined as greater than 6 microliters of fluid (approximately 1 mm of catheter length of ID 0.071" = 5.7 [IL) . Less forward flow is also included in this definition. For example, the amount of forward flow can be restricted to no greater than 2 microliters or, in a particularly beneficial embodiment, forward flow is approximately zero microliters. In each case, no forward flow means that substantially no liquid exits the distal end 664 in the distal direction.

[0270] Operation of the aspiration thrombectomy system 600 occurs through a controller 700, which can be an analog controller or a digital controller. Examples of the analog controller are shown in FIGS. 25 to 46. An example of a digital controller is described in further detail below. One exemplary configuration for a digital controller is a microcontroller manufactured by Microchip Technology, Inc. The controller 700 is operatively connected to each of the vacuum valve 620 and the vent valve 650 (and to a vacuum motor as described below). The controller 700 selectively opens and closes the vacuum and vent valves 620, 650 such that, when the vacuum valve 620 is opened, the vacuum source 610 is fluidically connected to the liquid column in the lumen 662 and, when the vent valve 650 is opened, vent liquid 642 is fluidically connected to the liquid column in the lumen 662. The timing of these valves is significant so that the controller 700 can change a level of vacuum at the distal end 664 and prevent the distal portion of the liquid column in the lumen 662 from exiting the distal end 664 -- substantially no forward flow. There are two significant actions that contribute to forward flow when operating the valves 620, 650: compliance of the catheter system and the water hammer effect. Each will be discussed in turn. Exemplary

configurations of the vacuum and vent valves is shown in FIGS. 25 to 36 in FIGS. 42 to 46. Configurations for the valves include spool valves, pinch valves, rotary valves, and rotary valve having a pintel design.

[0271] To explain timing of the valves to eliminate forward flow, reference is first made to the system depicted in the diagram of FIG. 47. It is noted that the ROAR catheter 660 is a flexible body and, therefore, it has compliance both in the radial direction and in the longitudinal direction. When the distal end 664 is corked with a thrombus (as shown in FIG. 47), vacuum is being applied to the lumen 662. Compliance of the catheter 660, therefore, causes reduction in the diameter of the catheter and reduction in the length of the catheter. When the catheter 660 corked, no flow occurs in the lumen. By having pressure lower than atmosphere within the lumen 662, the catheter 660 shrinks and reduces (shortens radially and longitudinally). This shrinkage acts like a spring squeezing down on the lumen in the catheter — in other words, it is a storage of potential energy. If the vacuum source is then cut off (e.g., the vacuum valve 620 is closed) and the vent valve 650 is opened to the vent fluid source 640, then the catheter 660 elongates and acts as a piston pulling against the vent liquid 642. Further, the vent liquid 642 is at a higher pressure (e.g., atmospheric pressure or slightly elevated by having a higher physical position than the patient) than the fluid in the lumen 662. Consequently, an amount of the vent liquid 642 enters through the vent valve 640 into the manifold 630 and then into the lumen 662 through the proximal manifold connector assembly 670. As the vent liquid 642 flows in and the catheter 660 expands to its normal or free steady state, momentum is created in the fluid column directed towards the distal end 664, referred to herein as a pressure pulse or pressure wave. In other words, a "pressure pulse" or "pressure wave" is momentum within a column of fluid that can act to move a distal portion of the fluid column in the catheter lumen distally out from a distal end of the catheter. This term relates to a given cycle of the vacuum and vent valves 620, 650 and is not limited to a single pressure transmission with that cycle. A pressure pulse, therefore, can include multiple pressure differentials with a given cycle of the vacuum and vent valves 620, 650. Thus, by adjusting a timing of the vacuum and vent valves to match a compliance and length of a particular catheter system (which can include the catheter and also the manifold and valves and other lumens in line with the catheter), a ROAR effect can be achieved for that catheter. In particular, one way to achieve the ROAR effect and prevent

forward flow of the distal portion out from the distal end during each cycle is by regulating a timing of the vent valve 650.

[0272] Prior art aspiration thrombectomy systems periodically open and close a vacuum valve. Fluid rushes into the distal end of the catheter while the vacuum valve is open and vacuum is being applied to the fluid column. When the vacuum valve is closed, liquid rushing proximally through the lumen stops by hitting the closed vacuum valve. This causes pressure to build at the vacuum valve and create a bounce-back wave that carries momentum distally towards the distal end and ejects an amount of fluid distally from the distal end of the catheter. This action is referred to as a water hammer effect. The prior art repetitively opens and closes that vacuum valve. Thus, an amount of liquid ejects in a periodic manner out of the distal opening in those devices. This forward flow phenomena is undesirable in the area of thrombus removal because, when liquid is allowed to eject from the distal end and the physician is causing the distal end to approach the thrombus, the liquid could or will move the thrombus further distally, or it could break the thrombus up to allow arterial pressure to push the broken pieces further downstream, e.g., into smaller brain arterial vessels. It would be, therefore, desirable to entirely prevent any distally directed pressure pulse reaching the distal end of the aspiration catheter in a thrombus aspiration removal system. As described herein, the system 600 has a response to the water hammer effect that is tuned to achieve a maximum water hammer effect without causing forward flow, which response achieves the most effective engagement and disruption of the thrombus.

[0273] Proximal and distal pressure measurement devices 690, 692 are illustrated diagrammatically in FIG. 47. In this exemplary embodiment, the proximal pressure measurement device 690 is adjacent or within the proximal manifold connector assembly 670 and/or within the proximal portion of the fluid column, and the distal pressure measurement device 692 is adjacent or within the distal end 664 or within the distal portion of the fluid column. An exemplary embodiment for measurement devices 690, 692 include a pressure transducer manufactured by TransducersDirect.com.

[0274] Measurement in the fluid column of the catheter 660 at or adjacent the manifold 630 and adjacent the distal end 664 reveals a time delay in travel of the pressure pulse — the pressure rises at the manifold 630 first and then pressure rises at the distal end 664

later. By knowing the time delay and the distance between the sensors, the speed of the wave can be calculated. By knowing the distance from the most distal sensor to the tip of the catheter 660, the time it will take for the wave to travel to the distal tip can be calculated. This information can be used by the controller to time the valves properly to stop the pressure pulse. If the pressure pulse is allowed to travel all the way to the distal end 664, then a distal portion of the fluid column in the lumen 662 will exit the distal end 664, e.g., forward flow. If, during this time, the distal end 664 is corked with a thrombus 4, that pressure pulse could or will eject the thrombus 4 distally. Alternatively, if the distal end 664 is approaching a thrombus 4, any pressure pulse exiting the distal end 664 could or will move the thrombus 4 further distally. Movement of the thrombus 4 in a distal direction before or after it has been captured and corked at the distal end 664 of the catheter 660 is to be avoided. Therefore, the pressure pulse needs to be reversed or stopped before that pressure pulse reaches a point where it could move the thrombus 4 either further downstream or off of the distal end 664 in the distal direction. Such reversal is referred to herein as "quelling" the pressure pulse.

[0275] Operation of the aspiration thrombectomy system 600 with the ROAR effect does not produce the same results as prior art catheters. When operated with the distal end 664 unobstructed, the vacuum valve 620 and the vent valve 650 are periodically opened and closed. Fluid rushes into the distal end 664 of the catheter 660 and into the canister of the vacuum source 610 while the vacuum valve 620 is open and vacuum is being applied to the fluid column. When the vacuum valve 620 is closed, the sudden stop of flow creates the pressure wave generated as described above due to the water hammer effect from the closing of the vacuum valve 620. The controller 700 is timed to control the vacuum and vent valves 620, 650 to create the ROAR effect even when the distal end 664 is open to vasculature and, therefore, any distally directed pressure pulse in the aspiration thrombectomy system 600 is quelled so that substantially no forward flow occurs during a thrombus retrieval procedure. Through experimentation, net flow of liquid at the distal end 664 remains positive in the proximal direction — in other words, while operating with the ROAR effect in the corked or un-corked state, liquid either moves through the distal end 664 towards the vacuum source (when un-corked) or does not flow at all (when corked). In both circumstances, substantially no liquid exits the distal tip 610.

[0276] To accomplish the ROAR effect, the change in the level of vacuum at the distal end is at least approximately 15 inHg, further, at least approximately 20 inHg, and, in particular, at least approximately 25 inHg. A time for the change in the level of vacuum from low to high or from high to low at the distal end is no greater than approximately 50 ms, further, no greater than approximately 30 ms, and, in particular, no greater than approximately 20 ms. This change can be referred to as a maximum pressure delta. Various combinations of these variables include a change in the level of vacuum of approximately 15 inHg and a time for that of no greater than 50 ms, or the change in the level of vacuum of approximately 20 inHg and a time for that change of no greater than 30 ms, or the change in the level of vacuum of approximately 25 inHg and a time for that change of no greater than 20 ms.

[0277] The ROAR catheter 660 is operated to quell all pressure pulses in an exemplary embodiment according to the graph of FIG. 48. The state of the vacuum valve 620 is shown in the waveform at the top of the graph and the state of the vent valve 650 is shown in the waveform at the bottom of the graph. The repetitive cycle starts at time 0 with the valve starting to open in this exemplary embodiment. At time 1, the vacuum valve 620 is fully open and the vent valve 650 is closed. Vacuum continues until time 2, when the vacuum valve 620 starts to close. Closing of the vacuum valve 620 is not instantaneous and, therefore, the vacuum valve waveform decreases at a sharp angle and is fully closed at time 3. After the vacuum valve 620 is closed, at time 4, the vent valve 650 starts to open. This closing of the vacuum valve 620 initiates a water hammer and the closing of the vacuum valve 620 and subsequent opening of the vent valve 650 causes vent liquid 642 to enter the manifold 630 (and possibly the proximal end of the lumen 662). The potential energy stored in the compliant catheter 660 is also allowed to release due to the change in pressure from the negative pressure generated by the vacuum source 610 to the relatively larger pressure (e.g., arterial) existing in the vent fluid source 640. This combination of events initiates a pressure pulse at time 2 that travels distally through the lumen 662 towards the distal end. If there was no further change in the valves 620, 650, then liquid in the column will eject out from the distal end 664, i.e., forward flow. However, as shown in FIG. 48, after a relatively short vent-open time compared to the vacuum-on time, the vent valve 650 is closed (at time 7) and, shortly thereafter, the vacuum valve 620 is opened. This means that, while the

pressure wave is travelling distally along the length of the lumen 662 of the catheter 660, when the vent valve 650 is closed to turn the vent liquid 642 off and the vacuum valve 620 is opened to turn vacuum back on (time 0 of the repeating waveform), switching of these valves 620, 650 causes vent liquid 642 to cease entering the manifold 630 and to move the fluid in the manifold 630 and in the lumen 662 proximally into the collection canister 612 of the vacuum source 610 (see, e.g., FIG. 55). Thus, a reverse momentum is imparted within the fluid column. This reverse momentum is sufficiently large enough to prevent the pressure pulse from ever reaching a point where the distal portion of fluid in the lumen 662 exits the distal end 664 — thereby quelling the pressure pulse and preventing forward flow. The ROAR effect, therefore, retains a level of pressure at the distal end at less than or equal to physiological pressure. The area 690 of the two waveforms shown in FIG. 48 includes a time at which the pressure pulse has been quelled. The waveforms repeat in a periodic manner to continue the distal-then-proximal momentum pulse without ever allowing the distal portion to exit the distal end 664 of the catheter 660. The rapid change in pressure at the catheter tip from near full vacuum to nearly zero vacuum pressure is the ROAR effect. Under the ROAR effect, pressure at the distal end 664 can rise to just short of being arterial pressure and reversal of that rise is, then, started due to the reestablishment of vacuum. This allows the aspiration thrombectomy system 600 to approach a thrombus 4 without imparting distal movement to the thrombus 4 and to retain the corked thrombus 4 at the distal end 664 without any distal movement of the thrombus 4 caused by a change in pressure within the fluid column.

[0278] Another exemplary embodiment for creating the ROAR effect with the catheter 660 utilizing the vacuum valve 620 and the vent valve 650 is shown in the waveforms of FIG. 49, which are repeated at an exemplary rate of between approximately 1 Hz and approximately 250 Hz, further, between approximately 2 Hz and approximately 20 Hz, still further, between approximately 4 Hz and approximately 12 Hz, in particular, between approximately 6 Hz and approximately 8 Hz. At time 1, the vacuum valve 620 is in the open/on position and the vent valve 650 is in the closed/off position. At approximately time 2, the vacuum valve 620 starts transitioning to the closed/off position. At approximately time 3, the vacuum valve 620 is closed/off. At time 4, the vent valve 650 starts to open and at approximately time 5, the vent valve 650 is fully open. The vent valve 650 remains open

while the vacuum valve 620 is closed until time 6, at which the vent valve 650 starts to close. The vent valve 650 is closed at approximately time 7. The vacuum valve 620 starts to open at time 8 and is partially open at approximately time 9. The vacuum valve 620 is full open when near the bottom extent of the curve in the graph. This process is repeated periodically, which in this example is at 10 Hz.

[0279] In what is referred to herein as static aspiration, the distal end 664 of the catheter 660 is pushed against a thrombus 4 while suction is applied to the catheter 660. The lower pressure in the catheter 660 creates a force on the clot 4 equal to a pressure differential across the clot 4 multiplied by the area of the inner diameter of the catheter 660. It is this force that "sticks" the clot 4 to the distal end 664 of the catheter 660 in an attempt to retrieve the clot 4 entirely.

[0280] In the ROAR cycle, suction is applied to the clot by rapidly opening a valve, causing a rapid rise in vacuum pressure. The source of suction is then turned off and a vent fluid source is rapidly opened. This relieves the vacuum present in the catheter 660, which again rapidly changes the pressure applied to the clot. The vent valve 650 is then rapidly closed and the vacuum valve 620 is rapidly opened. This cycle is repeated multiple times per second. For example, the period for repetition is between approximately 2 Hz and approximately 16 Hz, in particular, between approximately 8 Hz and approximately 12 Hz. The rapid drop of pressure across the clot 4 when the vacuum valve 620 is opened causes the clot 4 to accelerate into the lumen 662 of the catheter 660. The release of vacuum pressure when the vent valve 650 is opened causes the clot 4 to rebound back from the catheter 660. When the vacuum is applied again, the clot 4 once again accelerates towards the catheter 660. These accelerations and rebounds cause the distributed mass of the clot 4 to oscillate. The large internal accelerations of the distributed mass from the oscillation creates internal forces in the clot 4 that are high enough to exceed the tensile strength of the clot 4 and cause it to fail. The torn pieces of clot 4 are then aspirated all the way through the catheter 660 and into the vacuum collection canister 612. To maximize forces in the clot, the pressure differential across the clot and the rate at which this differential pressure is applied is maximized. The higher the rate at which this force is applied to the clot, the higher the internal acceleration of the distributed mass of the clot, and thus the higher the internal

forces within the clot, and thus the higher the likelihood of the clot to tear. The times for the pressure change in both the up and down directions are about 20 ms either way. At 8 Hz, for example, each cycle is 125 ms and at 12 Hz each cycle is 83ms. The greater the frequency of the cycle, the greater the number of these impacts that the catheter can have to interact with the clot. Using higher frequencies is, therefore, better, but only up to a point where there is not enough time to cause an effective enough pressure delta within each cycle.

[0281] During operation of the catheter 660 with the ROAR effect, measurement of the pressure pulse can be undertaken with the proximal and distal pressure measurement devices 690, 692. The graph of FIG. 50 illustrates pressure sensed by these devices 690, 692 during the exemplary 10 Hz pulse present in FIG. 49 (FIG. 51 illustrates the graphs of FIGS. 49 and 50 superimposed on one another). The pressure sensed by the proximal pressure measurement device 690 starts at the lower pressure value (approximately at -13 psi) and the pressure sensed by the distal pressure measurement device 692 starts at a higher pressure value (approximately at -11 psi). This represents a partially corked system where an incomplete seal of the thrombus simulant to the catheter allows some flow by creating a slightly lower pressure at the distal measurement. At time 4, vacuum is off and the vent valve 650 starts to open. Accordingly, vacuum in the lumen 662 starts to be relieved. This means that pressure at the proximal pressure measurement device 690 starts to increase, which is evidenced by the upwards curve starting at approximately 4'. A short while later, as the change in pressure propagates distally down the catheter 660, pressure at the distal pressure measurement device 692 starts to increase, which is evidenced by the upwards curve starting at approximately 4". At time 6, the vent valve 650 starts to close and, therefore, no more vent liquid 642 is entering the manifold 630 to add to or augment the fluid column in the lumen 662. Pressure at the proximal pressure measurement device 690, nonetheless, continues to rise as the vacuum (negative pressure) is entirely removed or is compensated by the pressure of the vent liquid 642. Pressure at the proximal pressure measurement device 690 peaks and, as shown in FIG. 50, the pressure at the peak is at a positive pressure of approximately 2 psi — this occurs even though the aspiration thrombectomy system 600 does not actively apply any positive pressure to the fluid or the lumen 662. Rather, this level of pressure being > 0.0 psi is due to the momentum of the fluid

traveling within the lumen 662. Thus, a positive pressure within the lumen 662 is acceptable but it needs to be suppressed before arriving at distal end. At time 8, the vent valve 650 has already closed and the vacuum valve 620 starts to open at approximately the time of peak pressure at the proximal pressure measurement device 690. Opening of the vacuum valve 620 drops pressure within the lumen 662 and stops pressure at the proximal pressure measurement device 690 from going any higher (if not stopped at this level, then it is possible that pressure at the distal pressure measurement device 692 would be > 0.0 psi, which means distal forward flow will occur out from the distal end). Quelling of the pressure pulse is proven by review of the pressure track of the distal pressure measurement device 692. As can be seen in the graph of FIG. 50, the pressure increase at the distal pressure measurement device 692 follows the pressure increase at the proximal pressure measurement device 690. At time 8, pressure recorded at the distal pressure measurement device 692 is still negative (approximately at -5 psi), but is rising. With continued operation of vacuum to and past time 9 (when the vacuum valve 620 is fully open), the peak pressure measured at the distal end 664 by the distal pressure measurement device 692 is less than 0.0 psi (horizontal dashed line), which means that the pressure pulse is quelled and that liquid from the distal portion does not exit the distal end 664, in other words, substantially no forward flow. The ROAR effect allows the clot simulant to remain sealed to the catheter and the system 600 is able to achieve the full vacuum of -13 psi at both measurements. Because the distal pressure is relieved almost to zero but then shortly arrives at the full -13 psi vacuum, the pressure delta illustrated is approximately 13 psi.

[0282] As described herein, it is possible to force flow from the distal end 664 of the catheter 660 while cycling between vacuum and vent. The rapid switching between vacuum and vent creates forward flow pressure pulses in the fluid column that, if not managed, will force the fluid column out of the distal end 664 of the catheter 660. The waves move through the fluid column at a very high speed through the medium. The speed is primarily a function of the density of the fluid, the compliance of the system (the bulk modulus), and the length of the fluid column. To prevent these waves from forcing the fluid column out of the catheter, the system is considered as a whole and the parameters of the valve switching cycle are set such that the forces that cause the fluid column to flow are controlled. To ensure that the fluid column does not exit the distal end 664 of the catheter 660, it is important that the

catheter 660, any extension tube that connects to the catheter 660, the controller 700, and the valving sequence be tuned as a system.

[0283] The goal of the tuning process is at least two-fold: prevent the pressure waves generated during ROAR operation from causing forward flow and optimize the ROAR effect. The length of the fluid column is critical to the tuning of the system. The pressure wave moves rapidly within the fluid column. The time for the wave to reach the distal tip of the catheter is a function of this speed and the length of the fluid column. The speed is a function of the density of the fluid in the column and the bulk modulus of the catheter and extension. The bulk modulus refers to the compliance of the system: both the radial and the longitudinal flexibility of the catheter and the extension tube. The density of the fluid column is not as significant a variable as the bulk modulus unless it changes greatly, such as is the case if the fluid column has gaseous (air) bubbles in it. It is thus, important, to have all air purged from the system prior to implementing ROAR operation. For a given catheter and extension tube configuration, the bulk modulus and the length of the system is fixed. Compliance can be added to the system to change the speed and thus tune the timing of the pressure wave. A flexible length of tubing could be added in-line with the relatively stiff catheter and extension, for example. This flexible length of tubing expands as the pressure pulses occur during ROAR operation. This decreases the bulk modulus of the system and reduces the speed, thus slowing down the pressure wave and increasing its transit time to the distal tip of the catheter. Compliance can be added in other ways as well, such as by including a piston backed by a spring in a bore that communicates with the catheter lumen such that the pressure wave displaces the piston, which increases compliance of the system. By manipulating the compliance and the valve timing, the system can be tuned for many different combinations of catheters and extension lines. Careful tuning results in achieving a resonant condition. If the suction and release pulses in the catheter are tuned to match a natural frequency of the clot, enhanced ROAR effect can be achieved.

[0284] Tuning can happen statically or dynamically. A statically tuned system is tuned so that the catheter 660 (and any extension tube that connects to the catheter 660) is mated to the controller 700 with a fixed valving sequence (such as the exemplary configuration shown in FIGS. 29 and 30). The controller 700 senses the presence of the catheter 660

when it is attached and verifies that it is the correct one for the tuned sequence of that controller 700. If the correct catheter is not sensed, the tuned sequence does not initiate. A dynamically tuned system is, in comparison, tuned during operation. Prior to operation, a valve sequence is initiated that creates a series of pressure pulses in the catheter 660. Sensors, such as strain gauges, on the catheter 660 and/or an extension tube detect these pulses and are used to adjust parameters of the controller 700 for operation to create the ROAR effect. The catheter 660 contains and transmits critical data, such as its length, to the controller 700. Using this tuning, any catheter, within limits, could be used without causing the fluid column to flow from the distal end 664 during ROAR operation. Alternatively, the catheter 660 and the extension can be tuned at the manufacturer and the specifics of the valve timing can be transmitted to the controller 700 by the catheter 660.

[0285] In an exemplary embodiment, the valve sequence is as follows:

the vacuum valve 620 is closed;

a time later the vent valve 650 is opened;

a time later the vent valve 650 is closed;

a time later the vacuum valve 620 is opened; and

a time later the sequence is repeated.

When the vent valve 650 is opened, a bit of vent liquid 642 enters the system and creates a pressure pulse. If the vent valve 650 is not closed, and the vacuum valve 620 is not opened before the pulse reaches the distal end 664 of the catheter 660, the fluid column will exit the distal end 664 of the catheter 660 as forward flow. To prevent the fluid column from exiting the catheter 660, it is this time -- the time that it takes for the pressure pulse to traverse the catheter -- for which the system must be tuned. Additionally, the pressure pulse from closing the vacuum valve 620 in a flow condition will cause a pressure increase that must be quelled by opening the vent valve 650 before it causes forward flow.

[0286] Tuning is accomplished by selecting appropriate times for the vacuum cycle and the vent cycle. In this regard, the vacuum cycle includes Vacon time 622, Vacon duration 624, Vacoff time 626, and Vacoff duration 628 and the vent cycle includes Vnton time 652,

Vnton duration 654, Vntoff time 656, and Vntoff duration 658. Accordingly, tuning is explained with reference to FIG. 52. A cycle time is the duration of the repetition of the entire cycle. At 8 Hz, the cycle time is 125 ms and at 12 Hz, the cycle time is 83.33 ms. The cycle time is determined by adding the Vacon duration 624, the Vnton duration 654 and the first and second times in the cycle that both the vacuum and vent valves 620, 650 are off, referred to as the "double-off' or "double-closed" times or states. The cycle time is optimized by the dynamics or the resonance of a particular catheter 660. The Vacon duration 624 must be long enough for the system to pump down to full vacuum and the longer the vacuum is on during a particular cycle, the better the aspiration of the thrombus 4. In this embodiment, opening only the vacuum valve is referred to as the "vacuum-only" state. The first double-off time, which is the time after the vacuum is turned off (vacuum valve 620 closed) up until the time that venting begins (vent valve 650 opens), has an effect on the extent to which forward flow occurs. As this is a short time, such forward flow is referred to as flow burping. Through experimentation, an exemplary embodiment of an 0.071" inner diameter catheter 660 experiences flow burping when the first double-off time is greater than approximately 30 ms; the longer the double-off time, the greater flow burping. During ROAR operation, the first double-off time is about 10 ms; therefore, this is significantly less than the flow burping threshold, which means that substantially all forward flow is quelled. The Vnton duration 654 is determined by a maximum time that occurs before a corked clot 4 is dropped from forward flow. A ratio between the Vnton duration 654 and the second double-off time is a compromise for the longest Vnton time 654 and a minimum of the first double-off time. In this embodiment, opening only the vent valve is referred to as the "vent-only" state. Finally, with respect to the second double-off time, the vent valve 650 is off (fully closed) before the vacuum valve 620 is opened and vacuum recommences.

[0287] The calculation is explained further with regard to the valve position graphs in FIG. 53. Starting from the left of the graph at Vacon time 622, the vent valve 650 is closed and the vacuum valve 620 is open. The Vacon duration 624 is long enough for the system 600 to pump down to full vacuum (between approximately 10 ms and approximately 50 ms, in particular, approximately 30 ms). The longer the Vacon duration 624, the better the catheter 660 performs because of increased flow rate in the proximal direction. There is a compromise based on achieving a higher frequency for more hits/sec on the clot 4. In an

exemplary embodiment, the Vacon duration 624, calculated from the Vacon time 622 to the Vacoff time 626, is between approximately 40% and approximately 60% of the cycle time 629. As set forth above, the cycle time 629 is a minimum determined by summation of Vacon duration 624 plus the first and second double-off times 625, 627 plus the Vnton duration 654. The Vnton duration 654 is short enough to fill the lumen with vent liquid without causing forward flow (between approximately 10 ms and approximately 50 ms, in particular, approximately 30 ms). The first double-off time 625 is set based upon when open flow burping occurs. The maximum value for the first double-off time 625 applies to either of the periods from the Vacoff time 626 to the Vnton time 652 or the Vacoff time 626 to the Vacon time 622' whichever is shorter. Each of these values are optimized by the dynamics/resonance/compliance/length of the particular catheter 660 and extension set.

[0288] From this, some observations can be made. When the vent is opened, a pressure pulse is generated. It is important to stop the pressure pulse before it reaches the distal end. If the pressure pulse is not stopped before it reaches the distal end, the catheter 660 will experience forward flow. The way to stop the pressure pulse is to either close the vent and/or turn the vacuum back on if the vacuum was off prior to venting. If the vacuum remains on, then there is a need to turn the vent off. Or, if the vacuum does not remain on, the vent is turned off and the vacuum is turned back on before the pressure pulse makes it to the distal end 664. In other words, the vent needs to be closed before the pressure pulse makes it to the distal end 664 and the vacuum has to be turned on. So, the condition of merely opening the vacuum valve 620 when the vent valve 650 is opened may not be enough to quell the pressure pulse because of the low resistance between the vent and the vacuum; the vent will overwhelm the vacuum so the vacuum cannot have an effect over the length of the catheter. The time that it takes for the pressure pulse to propagate to the tip of the catheter 660 and then cause forward flow is used to define the time that the vent valve 650 is left open. The time that the vent is left open is selected to be shorter than the time it takes for the pressure pulse to propagate to the distal end 664.

[0289] In an exemplary embodiment illustrated diagrammatically in FIG. 55, all portions of the aspiration thrombectomy system 600 except for the ROAR catheter 660 are incorporated into the body 601 of the vacuum source 610. In particular, the vacuum source

610 comprises the body 601, a collection canister 612, and a vacuum motor 614. The vacuum motor 614 is fluidically connected to an outlet of the collection canister 612 and the input of the collection canister 612 is fluidically connected to a vacuum side of the manifold 630. Accordingly, vacuum generated by the vacuum motor 614 imparts vacuum within the collection canister 612 to draw fluid into the collection canister 612 from the manifold 630 but not into the vacuum motor 614. The vacuum valve 620 present at the manifold 630 prevents input fluid received at the manifold 630 from entering the collection canister 612 and closes off the manifold 630 from vacuum generated by the vacuum motor 614. The vent fluid reservoir 640 containing the vent liquid 642 is fluidically connected to a vent side of the manifold 630. The vent valve 650 present at the manifold 630 closes off the manifold 630 from the vent liquid 642 and prevents liquid within the manifold 630 from entering the vent fluid reservoir 640 (as pressure in the manifold 630 is typically lower than pressure within the reservoir 640, liquid from the manifold 630 will not typically enter the reservoir 640). In summary, a catheter input port 631 of the manifold 630 is fluidically connected to the collection canister 612 through the vacuum valve 620 and is fluidically connected to the vent liquid 642 in the reservoir 640 through the vent valve 650. The catheter input port 631 is fluidically connected to the downstream end of the proximal manifold connector assembly 670. The upstream end of the proximal manifold connector assembly 670 is fluidically connected to the proximal end of the catheter 660.

[0290] Direct connection of the catheter 660 to the aspiration thrombectomy system 600 is explained with regard to FIGS. 54 and 55. The proximal manifold connector assembly 670 connects the proximal end 666 of the ROAR catheter 660 to the manifold 630. In an exemplary embodiment shown in FIG. 54, the proximal manifold connector assembly 670 comprises a male luer lock fitting 672 connected to the manifold 630 (shown in dashed lines), either removably or integrally. The assembly 670 includes a ROAR identification (ID) sub-assembly 680. The exemplary embodiment of the ID sub-assembly 680 shown in FIG. 54 comprises an inductive sensing device or sensor 682 connected to the manifold 630. The inductive sensor 682 detects the presence of an inductive sensed part 684 that is present in or integral with the proximal manifold connector assembly 670. In an exemplary embodiment where the manifold 630 can be used with various different ROAR catheters 660, each of the types of ROAR catheters has a unique inductive sensed part 684 and the inductive sensor

682 of the manifold 630 is able to determine which type of ROAR catheter 660 is attached. Accordingly, with an appropriate communication of the ROAR catheter 660 type to the controller 700, the controller 700 is able to operate the ROAR catheter 660 according to its own unique configuration to produce the ROAR effect for every one of the different ROAR catheters 660 that are used. When the sensor 682 does not detect a sensed part 684 and the aspiration thrombectomy system 600 is, nonetheless, operated, the controller 700 will automatically prevent ROAR operation of aspiration thrombectomy system 600 and that connected catheter will only be operated as a standard vacuum catheter.

[0291] Indirect connection of the catheter 660 to the aspiration thrombectomy system 600 is explained with regard to FIGS. 56. The proximal manifold connector assembly 670 can simply be a fitting 672 as shown in FIG. 54 or it can be or include a separate extension line 674 between the catheter input port 631 and whatever catheter 660 (standard or ROAR) that is to be used along with the aspiration thrombectomy system 600. In an exemplary embodiment of the extension line 674, not only does the extension line 674 comprise a lumen extension for aspiration through the catheter 600, the extension line 674 also comprises system controls for operating the aspiration thrombectomy system 600. These controls include, for example, turning on and off the vacuum motor 614 and turning on the ROAR operation (e.g., one button for each of these or an on/off switch for vacuum and a push-to-start button for ROAR). As shown in the diagram of FIG. 56, the extension line 674 has a distal end that is able to connect to both standard catheters and ROAR catheters 600 -- as both can be used with the aspiration thrombectomy system 600. When the standard catheter is connected to the extension line 674, the aspiration thrombectomy system 660 only acts as a standard vacuum pump and ROAR is disabled. When a ROAR catheter 660 is connected to the extension line 674, identification sub-assemblies in the ROAR catheter 660 and the extension line 674 inform the system 600 which ROAR catheter 660 and which extension line 674 are connected.

[0292] In the exemplary embodiments with digital control of the vacuum and vent valves 620, 650, a processor and memory in the controller 700 stores the identification data and, upon identification of a particular ROAR catheter (e.g., different lengths, different outer diameters, different materials), the controller 700 loads the valve sequence and operates

the vacuum and vent valves 620, 650 according to the characteristics of the particular catheter connected to the vacuum source 610. In one exemplary embodiment, the identification data can be preprogrammed at the manufacturer for all ROAR catheters 660 that currently exist. Thus, with direct connection of the ROAR catheter 660 to the system 600, the controller 700 can operate without receiving any information other than the identity of the catheter 660. If a ROAR extension line 674 is used between the ROAR catheter 660 and the controller 700 (in other words, an extension line that is ROAR compatible and is able to inform the system 600 of its augmentary characteristics to those of the ROAR catheter 660 to which it is connected), the controller 700 can operate without receiving any information other than the identity of the catheter 660 and the identity of the intermediate extension line 674 because connection with the ROAR extension line 674 allows the system 600 to detect which particular one of the different ROAR catheters 660 has been connected to the distal end of the ROAR extension line 674 and then to operate ROAR in a predefined manner appropriate for that particular ROAR catheter 660 with the ROAR extension line 674. In the case of RFID or near field communication (NFC), the chip embedded in the ROAR catheter 660 is programmed with the specific valve timings required by that catheter 660. The controller 700 reads these values and functions properly for that catheter 660. This ensures future compatibility with new generation catheters that require different tuning, which tuning would not be known at the time the controller 700 is programmed at the manufacturer. If the catheter to be used is not a ROAR catheter 660, then ROAR should not be used with that catheter because of the high probability of forward flow at the distal end. Accordingly, the system 600 automatically prevents use of the ROAR effect when a non-ROAR catheter is connected to the distal end of the ROAR extension line 674 or is connected directly to the system 600 or is connected to the distal end of a non-ROAR extension line 674.

[0293] The identification sub-assemblies include various measures present at least at the proximal end of the ROAR catheter 660 (e.g., the inductive sensing system 682, 684 or a 1-wire detection system, such as a DALLAS Semiconductor encryption chip, RFID, Bluetooth low energy (BLE), metallic touch pads, a simple passive design based upon resistors (in series for catheter and extension, to name a few). In the sub-assemblies, there can be two or more electrical contacts. For example, there can be three contacts including

power, ground, and a signal using a Hall sensor. In a two-contact configuration, there can be a 2-wire configuration using resistors and mechanical switches. Resistance can be measured between two contacts and, depending on the resistance, a state of the switch can be detected. Power and signal can be combined on one line (plus an additional ground line) to create a "one-wire" connection, for example, using a DALLAS chip mentioned above. An identification sub-assembly also can be present at the distal connection (e.g., a Luer fitting) of the extension line 674 (to contact with the identification sub-assembly at the proximal end of the ROAR catheter 660) and extend back through the extension line 674 to a communication connection with the vacuum source 610, e.g., the proximal manifold connector assembly 670. Therefore, the aspiration thrombectomy system 600 has an ability to sense/detect when a ROAR catheter 660 is connected as differentiated from a standard catheter (i.e., not ROAR). Connection of the ROAR catheter 660 enables use of the ROAR function; connection of a non-ROAR catheter (or, e.g., to a side port of a rotating hemostasis valve (RHV)) disables use of the ROAR function and only normal aspiration is available. Where the identification sub-assembly includes electrical contacts in the ROAR catheter 660, the conductive connection to the vacuum motor 614 can utilize one or more coils of the ROAR catheter 660 as one of these conductors. Alternatively, two or more conductors can be wrapped within the ROAR catheter 660. Alternatively, or additionally, conductors can be bonded on the outside of the ROAR catheter 660.

[0294] In addition to the exemplary embodiments where the system 600 already stores the operating parameters for performing aspiration and automatically uses those parameters when the ROAR catheter 660 and/or the extension line 674 is connected or where the ROAR catheter 660 or the extension line 674 provides the operating parameters for performing aspiration, the user can be provided with selectable programs in the controller. These selectable programs can be, in one exemplary embodiment, programmed where the controller 700 is manufactured. The user has an instruction manual associating the particular ROAR catheter 660 and/or the extension line 674 being used with a code that loads in the operating parameters, such as pressures, delays, timing. Instead of an instruction manual, these operating parameters can be manually entered by the user instead of through the selectable program(s), for example, by reading the information the instructions for use (IFU) or the packaging of the system 600, or ROAR catheter 660, or extension line 674. In addition,

if the user has a desired method of operation (for example, to increase a particular timing), the user can enter the parameter(s) directly through a user interface on the system 600. In other exemplary embodiments, a code supplier (e.g., a QR code, a barcode, or an RFID chip) could be on the packaging of one or more of the components and the user presents that code supplier to the controller for reading. In this regard, the system 600 comprises a bar-code reader and/or a QR code reader and/or an RFID communication device. With a display on the system 600, in another exemplary embodiment, the screen presents parameters to the user and those parameters could be fixed or alterable by the user. In other words, the user could accept or alter the parameters shown. In a particularly inexpensive embodiment, the parameters can be "stored" on a punch card that is supplied with the ROAR catheter 660 or the extension line 674 and the system 600 has a punch card reader. In this embodiment, the user inserts the inexpensive card (e.g., provided with a covering that protects it from liquids present in the operating room) into the card reader and the controller 700 utilizes the parameters on the card or utilizes a code on the card, which code is associated with a set of stored parameters.

[0295] All of these embodiments could present the operator with a choice of alternative programs or parameters, or the system 600 could list the parameters that are about to be utilized separately on a display screen and then allow the operator to select those parameters or alter the provided parameters. Similarly, operators are able to store parameters/programs into empty memories within the controller 700. The stored information provided by the catheter, the extension line, the card, the code, etc., could be either ROAR parameters or, alternatively, the information can be characteristics of the catheter and the extension line so that the controller 700 could make compensations to provide a predefined ROAR waveform at catheter tip. In other words, rather than offer up stored ROAR programs, the catheter and the extension line could simply give information to the controller 700 so that the timing and pressures could be modified for each catheter/extension line combination to achieve the predefined ROAR pressure/time profile. By storing either compensation parameters or actual time/pressure parameters, the controller 700 is able to allow future catheters and extensions not yet available. Further, chips, resistors, RFIDs, or BLE could be used to prevent use of the system 600 with catheters not provided by the manufacturer of

the system 600, and/or to present a warning or alarm condition to the operator so that they know that the catheter and/or extension is not supported by the system 600.

[0296] One exemplary embodiment of the proximal manifold connector assembly 670 comprises the extension line 674 having a system control board 676 with remote controls 678 illustrated in FIG. 56. An exemplary embodiment of the remote control 678 is a mechanical slide switch that turns vacuum on or off based upon a longitudinal position. This can be a two position switch with a button for ROAR operation. Alternatively, a three-position switch can be provided. In a forward position, the vacuum is off, in a middle or intermediate position the vacuum is on, and in a rear position ROAR operation takes place. When the remote switch is connected, any control buttons on pump are disengaged but the pump can have an "emergency off' switch on the pump that allows the user to turn off the pump if desired regardless of the operation of the remote controls. LEDs can be provided on the remote controls 678 and/or on the body 601. These LEDs can, for example, be: Red = off, Green = Vacuum on, Blinking Green = ROAR, Blinking Red = Error, Blue = vent/purge. In an exemplary embodiment, a mechanical redundant pinch valve is present against catheter that, when actuated, pinches closed the lumen of the catheter. In the exemplary embodiment, the distal end of the proximal manifold connector assembly 670 that connected to the ROAR catheter 660 comprises a luer lock part that connects to another luer lock part on the ROAR catheter 660. In various exemplary embodiments, the switch is passive (e.g., a simple mechanical switch) or it is an active switch (e.g., capacitive, pressure, magnetic). In such a case, the switch is powered by wires through the extension line 674. In an alternative embodiment, the switch is a separate module that attaches to the extension line 674 and is, for example, battery-powered.

[0297] A first benefit of the aspiration thrombectomy system 600 is that, with such a configuration, the same vacuum source 610 can be used with all catheters that previously could be connected to any surgical aspiration devices/vacuum pumps. A second advantage relates to security for enacting the ROAR effect. In such a configuration, users are persuaded to connect the proximal end of the ROAR catheter 660 to the distal end of the proprietary extension line 674. This is beneficial for various reasons. First, ROAR will not work unless the two unique ROAR parts are directly connected and a positive ROAR ID is

established. Second, if a standard rotating hemostasis valve is connected between the ROAR catheter 660 and the extension line 674 (for whatever reason that the surgeon/nurse may have), then identification will be negative and ROAR will be disabled. There is a risk that fluid contained within lumens of such rotating hemostasis valves will enter into the ROAR catheter's fluid column and, thereby, introduce air bubbles, which need to be purged entirely from the system for use. An RHV 609 increases the probability of air remaining in the lumens or entering the fluid system. See FIG. 72. Thus, a particularly desirable configuration for the ROAR catheter 660 is a direct connection between the proximal end of the ROAR catheter 660 and a distal end of the proprietary extension line 674. There is also an issue of safety to ensure that the ROAR effect is utilized only with ROAR catheters 660. As described above, each ROAR catheter 660 has a particular set of characteristics related to compliance and, therefore, operation of the vacuum and vent valves 620, 650 is set for that characteristic set. The system 600 is set to react with a particular ROAR configuration based upon the physical characteristics of the ROAR catheter 600 connected, such as length and lumen size. Therefore, the system 660 is tuned/programmed to store a given ROAR setting for each ROAR catheter 660.

[0298] However, it is possible that new ROAR catheters 660 and new ROAR extension lines 674 are created after the system 600 or the controller 700 are put into the field. Providing the identity of the ROAR catheter 660 or the ROAR extension line 674 would, therefore, not be sufficient to permit operation of those components properly. Thus, in an additional or alternative embodiment, each of the ROAR catheters 660 and the ROAR extension lines 674 are provided with a memory device (e.g., a DS28E07 EEPROM memory chip) that, when connected to the system 600, provides the controller 700 with the variables necessary for that ROAR catheter 660 and/or that ROAR extension line 674 to operate with the ROAR effect. Example variables that are stored in the memory of each of the ROAR catheters 660 and the ROAR extension lines 674 include, but are not limited to, the frequency of the waveform cycle, a time in the cycle at which the vacuum turns on (Vacon time 622), a duration of the vacuum (Vacon duration 624), a time in the cycle at which the vacuum turns off (Vacoff time 626), a duration that the vacuum is off (Vacoff duration 628), a time in the cycle at which the vent turns on (Vnton time 652), a duration of the vent (Vnton duration 654), a time in the cycle at which the vent turns off (Vntoff time 656), and/or a

duration that the vent is off (Vntoff duration 658). By being able to provide such information to the controller 700, the system 600 can utilize any future ROAR catheter 660 and/or ROAR extension line 674 that might be created for use with the system 600.

[0299] An exemplary embodiment of a self-contained aspiration thrombectomy system 600 is shown in FIGS. 57 to 71. The system 600 has an exterior body 601 containing therein a vacuum motor 614, the controller 700, and controls for the vacuum and vent valves 620, 650 (exemplary embodiments of the controls for the valves are shown in FIG. 29 and FIGS. 42 to 46). The vacuum motor 614 is fluidically connected to a collection canister 612 (shown diagrammatically with dashed lines). The body 601 houses a set of system controls 676 (in an alternative embodiment, the controls 676 can be located on/also located on the extension line 674). In this exemplary embodiment, there are three buttons: off, purge, and ROAR/Vac. (The purge function will be described in further detail below.) On a side opposite the collection canister 612 is a vent fluid reservoir 640 (shown diagrammatically with dashed lines) containing therein vent liquid 642. As mentioned above, the fluid path of the catheter 660 is to be free from bubbles/air at all times during a surgical procedure.

[0300] The body 601 has cassette connection assembly 602 on a front face thereof. The cassette connection assembly 602 protrudes from the front face and has an exterior shape substantially the same as a cassette 710 that will be attached thereto. The vacuum and vent valves 620, 650 protrude from the front face 608 of the cassette connection assembly 602 and, in an exemplary embodiment, are centered within respective depressions of the cassette connection assembly 602. In this embodiment, the vacuum and vent valves 620, 650 are pistons that have at a distal-most end thereof a pinching structure. In this exemplary embodiment, the pinching structure is substantially in the shape of a standard slot screwdriver. As the vacuum and vent pistons extend out from the depression a given distance (e.g., 8 mm), the slot presses against tubing (in the cassette 710) to close off the lumen within the respective vacuum or vent hose. Closing off the hose acts as a shut¬off of the respective valve and releasing away from the hose acts to open the vacuum or vent, respectively. Thus, if the hoses for each of the vacuum and vent lines are placed directly in front of the pistons, the valves 620, 650 will control vacuum and vent according to the ROAR process described herein. (As described below, the cassette 710 positions those

hoses in this manner.) In between the valves 620, 650 is a boss 604 protruding from the front face 608 of the cassette connection assembly 602. The boss 604 has an exterior surface with a given shape, e.g., a raceway, and orientation wings 605. At the end of the boss 604 is a rotating lock 606 in the shape of half circle or half oval. The rotating lock 606 has a central pivot to allow it to rotate 90 degrees from the position shown in FIGS. 57 to 67. In the rotated orientation, therefore, the rotating lock 606 defines lower surfaces (opposite the front face 608 of the cassette connection assembly 602) that are perpendicular to the protruding extent of the boss 604. These lower surfaces are set at a distance to define a gap between the lower surface of the rotating lock 606 and the front face 608 of the cassette connection assembly 602. Also present on the front face 608 of the cassette connection assembly 602 is/are conductive connectors 618. The conductive connectors 618 are used to detect when a cassette 710 is present and locked on the cassette connection assembly 602. Detection of the cassette 710 can be made by mechanical measures (such as a pogo pin) or a combination of mechanical and optical and electrical measures.

[0301] A cassette 710 is removably connected to the cassette connection assembly 602 and an exemplary embodiment of this cassette 710 is illustrated in FIGS. 68 to 71. As shown in FIG. 68, the cassette 710 has an interior orifice 712 with a shape corresponding to the given shape of the boss 604. The boss 604 and interior orifice are matched in shape so that the cassette 710 can fit onto the boss 604 and slide down thereon until the rear face of the cassette 710 aligns with and/or touches the front face 608 of the cassette connection assembly 602. The rear face of the cassette 710 is depicted in FIG. 69. In the view of FIG. 69, pockets 714 corresponding in shape to the orientation wings 605 are present in the interior surface of the cassette 710 at the interior orifice 712. In this regard, when the cassette 710 is slid down the boss 604, there is only one orientation in which the cassette 710 can approach the front face 608 in a lower-most position e.g., as in a key within a keyhole. This placement insures that the distal end effectors of the vacuum and vent valves 620, 650 are always aligned with vacuum valve area 720 and the vent valve area 750 within the cassette 710.

[0302] When the "T" shape of the boss 604 and wings 605 are matched with the interior T-shape of the orifice 712, three connections are made possible. First, as set forth above,

the distal end effectors of the vacuum and vent valves 620, 650 are aligned with vacuum and vent valve areas 720, 750 within the cassette 710. Second, conductive connectors 718 on a rear face of the cassette 710 are aligned with and make contact with respective conductive connectors 618 adjacent the boss 604. These connectors 718, 618 can be, for example, respective pads and pogo pins to insure positive electrical connection when the rotating lock 606 is used to lock the cassette 610 onto the body 611. With appropriate electrical connections, these connectors 718, 618 can inform the controller 700 that the cassette 710 is installed and ready for use and which kind of cassette 710 is installed if it is associated with a particular ROAR catheter 660 and needs identification. Finally, the rotating lock 606 is located above the front face 608 of the cassette connection assembly 602 and the bottom surfaces of the rotating lock 606 are above the outer front face 716 of the cassette 710. A protrusion distance of the boss 604 is configured to place bottom surfaces of the rotating lock 606 (those surfaces facing the front face 608) at a distance approximately equal to the thickness of the cassette 710 such that, with rotation of the lock 606, the bottom surfaces of the lock 606 engage the outer front face 716 of the cassette 710, thereby pressing the cassette 710 firmly in place against the front face 608 to touch the connectors 718, 618 together and locking the cassette 710 to the body 601. The quarter-turn rotating lock 606 secures the cassette 710 on the body 601 and also provides a cam force that holds the cassette 710 thereon, in particular, while the valves 620, 650 actuate against vacuum and vent tubing present within the cassette 710. In an exemplary embodiment, a non-illustrated switch is integrated in the rotating lock 606, the switch detecting the quarter-turn and, with the electrical connectors 718, 618, verifying that the system 600 is armed and ready for use.

[0303] In a particularly efficient configuration, the cassette 710 can be removable, replaceable, and disposable as an entire set including the junction box shown in FIGS. 68 to 71 and a tubing set. The cassette 710 has as set of relatively short whips of tubing including a first tubing whip 722 fluidically connected to the collection canister 612 of the vacuum source 610 and a second tubing whip 752 fluidically connected to an intake of the vent valve 650, and an extension whip that can be the extension line 674 or it can be a short tubing to be connected directly to the catheter 660. Once connected, this efficient configuration allows the system of lumens to be automatically cleared of air/bubbles. By

locating the vent liquid above all of the lumens (such as with the bag 640 in FIG. 67), the catheter 660, and the collection canister, opening the output of the vent fluid reservoir 640 will fill all interior lumens and clear the system of any air/bubbles before use. If desired, a cam lock can be mechanically connected to the vacuum motor 614 (either temporarily or fixed) and the motor 614 can be operated to actively draw all air into the collection canister and thereby purge the system 600. As an alternative to the front-loaded configuration of the cassette 710, the cassette 710 can be connected or molded as a part of a bottom of the disposable collection canister 612. In this configuration, two disposable parts can be provided together in a sterile packaging and disposed of in one piece. With a vent fluid reservoir that is either a hard container (FIGS. 57 to 61) or a bag (FIGS. 62 to 67), the vent liquid 642 can be part of the cassette 700 with all lumens pre-filled with saline and part of a single disposable package. The vent fluid reservoir 640 and the collection canister 612 can either or both be part of a disposable cassette 700 system. All of the disposable parts used in a catheter procedure can be integrated together in one disposable package.

[0304] As explained previously, it is important for the system to be purged of air to achieve the ROAR effect. Purging can be achieved in several ways. The two main methods used to purge the system are forced purged and dribble purge. The forced purge method involves submerging the tip of the extension line 674 into sterile fluid such as saline and while submerged activating the "purge" function. The controller 700 will then alternatively open one or both of the control valves for a predetermined time and sequence to pull the sterile fluid through the extension line 674 and valves and displace all the air that may have been in the system. Once this purge process is complete, both valves will close and the extension line 674 with a full fluid column can be connected to the catheter which has also be de-aired and ROAR applied. In comparison, the dribble method relies on a small positive pressure (created by gravity, squeezing the fluid bag, pressurizing the vent fluid tank, or a peristaltic pump or any similar measures) to allow the vent fluid to dribble through the lumens and, thus, flood them. In an exemplary case of the dribble purge system, the vent fluid source 640 is higher than the exit of the extension line 674 and the vent liquid path does not contain any air traps.

[0305] For the dribble method, the purge cycle is initiated by pressing the purge button and, in an exemplary embodiment, is performed by the controller 700. With the vacuum valve 620 closed, the vacuum source 610 is turned on and the vacuum vessel is pumped down to a desired vacuum level. The vent valve 650 is opened and vent liquid 642 is allowed to flood the vent line and the extension line 674. To ensure that all air is removed from the manifold 630, the vacuum valve 620 is opened momentarily while the vent valve 650 is also open. This allows the vent liquid 642 to be drawn from the vent fluid source 640 and from the extension line 674, and through the vacuum manifold passageways thus purging them of air. The vent valve 650 is left open for a period of time after the vacuum valve 620 closes to ensure that the quantity of fluid that the vacuum cycle removed from the extension line 674 is replenished. This cycle of vent liquid flow and momentary vacuum can be repeated several times to ensure complete purging. The purge pump can be a peristaltic pump, a pressurized cuff around a flexible vent liquid container (such as an IV bag), and/or a vent fluid canister pressurized by using the exhaust from the vacuum source 610.

[0306] The presence of bubbles in the fluid system adversely affects the water-hammer effect. Accordingly, the system 600 facilitates or automatically purges air from the fluid lumens. In an exemplary embodiment, bubble sensors (either optical, ultrasonic, or fluid-pressure-profile based) are incorporated into the system 600 to facilitate this purging or to automatically engage a purging function (e.g., under operator control to prevent purging when the catheter 660 is present in the bloodstream). There are various measures for bubble detection. For example, an optical sensor could be placed in the cassette 710 to sense the presence of bubbles. With a sensor coupled to the vacuum source 610, a slow rise in pressure can be sensed to prevent using the incorrect catheter or extension. The specific compliance of a catheter 660 or an extension line 674 is among the parameters used to program or compensate the system 600. A user-feedback indication informs the user when the system has been sufficiently purged. In an exemplary embodiment, the compliance of the catheter 660 and the extension line 674 are controlled to be below some optimum range. Also, pressure-rise information is used to modify the ROAR settings, for example, to detect corking and provide an optimum pressure profile for that condition.

[0307] The exemplary configurations of the aspiration thrombectomy system 600 described and shown provide various significant benefits. Before describing these additional benefits, reference is made to FIG. 72, which illustrates one exemplary embodiment of the aspiration thrombectomy system 600 with extension lines 674, and catheters 660. The aspiration thrombectomy system 600 comprises the vacuum source 610 with the collection canister 612, the vent liquid reservoir 640 with the vent liquid 642, the manifold 630, and the proximal manifold connector assembly 670. Removably connected to the proximal manifold connector assembly 670 is a ROAR extension line 674. Next to the ROAR extension line 674 is an off-the-shelf extension line 674' usable both with the system 600 by connecting through the proximal manifold connector assembly 670 and with conventional surgical vacuum sources. The ROAR extension line 674 comprises the system controls 676, which are also shown on a top surface of a frame of the system 600. Also shown is a ROAR catheter 660 and an off-the-shelf aspiration catheter 660'. With proximal Luer connectors, both catheters 660, 660' can be used with either extension line 674, 674'.

[0308] There are several topologies for the disposable, reusable, and limited-reuse components of the aspiration thrombectomy system 600 as described and shown herein. The vacuum source 610 can be a limited-reuse component that plugs into a reusable electronics/power-supply system, such as the frame in FIG. 72. The valve-element cassette 710 includes pinch-tubes and, therefore, it is a single-use only component. Alternatively, the valving components can be reusable, for example, where the valve actuator is separate, either in a separate semi-reusable module, or part of the pump/control system. The different kinds of valves (e.g., rotary, trumpet) that have different ways to separate the disposable/reusable portions of the system 600. The valve actuators can be part of a reusable portion or part of a limited-reuse portion (e.g., along with a pump module). Alternatively, the valve-actuators can be a second limited-reuse module. The cassette 710 with the valve elements can include a diaphragm or piston that is actuated by a mechanical actuator in the reusable part of the system 600. With such modularity, the architecture of the system 600 becomes adaptable to use with any vacuum source, even a household vacuum system (which could include a vacuum pressure regulator to ensure uniformity of the system 600. The power source for the system 600 may be a rechargeable battery or a replaceable module attached to the system 600, in which case the latter does not require sterility.

Alternatively, the power source is a primary battery included as part of the disposable components, which could include disposable pumping elements.

[0309] The various configurations permit multiple product topologies specifically targeted at different use cases. For example, one topology is a minimum-recurring-cost system with only the tubing set being disposable. Alternatively, another topology is a system requiring minimum capital cost and incorporating modules whose costs are easily amortized for each surgical case.

[0310] Various additional safety measures can be added to the system 600. For example, a liquid level detector can be provided at or with the vent fluid reservoir 640 to confirm that vent liquid 642 is within the tank or pouch, to indicate a warning to the user when the level of vent liquid is low, and to prevent operation of the system 600 if the vent liquid about to run out or is empty. In the configurations with the cassette 710, the system 600 will not start unless the cassette 710 is in place and is correctly installed. The system 600 can have a purging function that is used to fill the various lumens of the catheter 660, the extension line 674, and any tubing connecting the vent fluid reservoir 640 and the collection canister 612 before use. It is noted that the system 600 should not be operated if air is present anywhere in the lumens. Thus, the controller 700 can operate the system to draw in vent liquid 642 and fill the various lumens in a pre-use setup phase. This could include having the vacuum motor 614 operate in reverse to apply positive pressure for purging the various lumens. Alternatively, the controller 700 could actuate a peristaltic pump to purge vent fluid through the lumens. The controller 700 can be programmed, during operation of the system 600, to detect peaks of use during ROAR. If these peaks are not sharp, then a conclusion that air is present in the system can be determined. Bubble detectors (i.e., ultrasonic) can be added to the system such that they straddle the tubing in the cassette and provide feedback to the controller to ensure that the tubing has been properly purged. With such a conclusion, the controller 700 can be programmed to cease operation and start an auto-purge routine to flush the various lumens with an external liquid source or from the vent fluid reservoir 640.

[0311] It is noted that various individual features of the inventive processes and systems may be described only in one exemplary embodiment herein. The particular choice

for description herein with regard to a single exemplary embodiment is not to be taken as a limitation that the particular feature is only applicable to the embodiment in which it is described. All features described herein are equally applicable to, additive, or interchangeable with any or all of the other exemplary embodiments described herein and in any combination or grouping or arrangement. In particular, use of a single reference numeral herein to illustrate, define, or describe a particular feature does not mean that the feature cannot be associated or equated to another feature in another drawing figure or description. Further, where two or more reference numerals are used in the figures or in the drawings, this should not be construed as being limited to only those embodiments or features, they are equally applicable to similar features or not a reference numeral is used or another reference numeral is omitted.

[0312] The foregoing description and accompanying drawings illustrate the principles, exemplary embodiments, and modes of operation of the systems, apparatuses, and methods. However, the systems, apparatuses, and methods should not be construed as being limited to the particular embodiments discussed above. Additional variations of the embodiments discussed above will be appreciated by those skilled in the art and the above-described embodiments should be regarded as illustrative rather than restrictive. Accordingly, it should be appreciated that variations to those embodiments can be made by those skilled in the art without departing from the scope of the systems, apparatuses, and methods as defined by the following claims.

CLAIMS

I/We claim:

1. An aspiration thrombectomy system, comprising:

an aspiration catheter having a proximal portion, a distal end and a lumen extending through the catheter;

a vacuum source fluidically coupled to the catheter;

a vacuum valve connected between the vacuum source and the proximal portion of the catheter to control a vacuum flow in the catheter lumen;

a vent valve fluidically coupled to the proximal portion of the catheter, the vent valve being configured to control a flow of a vent fluid in the catheter lumen; and

a controller configured to open and close the vacuum valve and the vent valve in a predetermined cycle to change a level of vacuum at the distal end of the aspiration catheter and to control fluid flow in and out from the distal end of the catheter.

2. The system of claim 1, further comprising a vent fluid source, and wherein:

the vent fluid source is configured to provide vent fluid at a pressure greater than atmospheric pressure; and

the controller is configured to cyclically open and close the vacuum valve and the vent valve to change a level of negative pressure and positive pressure at the distal end of the catheter during each cycle.

3. The system of claim 2 wherein the controller is configured to cyclically open and close the vacuum valve and the vent valve such that movement of the fluid column at the distal end of the catheter is limited to a positive amount of exit flow from approximately 0.001 ml to approximately 1.0 ml before fluid is drawn back into the catheter lumen.

4. The system of claim 2 wherein the controller is configured to cyclically open and close the vacuum valve and the vent valve such that movement of the fluid column at the distal end of the catheter is limited to a positive amount of exit flow of approximately 0.1 ml to approximately 0.5 ml before fluid is drawn back into the catheter lumen.

5. The system of claim 1 wherein the controller is configured to cyclically open and close the vacuum valve and the vent valve in a repeated cycle comprising an off-off state in which the vacuum valve is closed while the vent valve is closed.

6. The system of claim 1 wherein:

the controller is configured to cyclically open and close the vacuum valve and the vent valve in a cycle comprising (a) a first off-off state in which the vacuum valve is closed while the vent valve is closed, (b) a vacuum-only state following the first off-off state in which the vacuum valve is open while the vent valve is closed, (c) a second off-off state following the vacuum-only state in which the vacuum valve is closed while the vent valve is closed, and (d) a vent-only state following the second off-off state in which the vacuum valve is closed while the vent valve is open; and

the cycle is repeated.

7. The system of claim 6 wherein the cycle is repeated at a frequency of 2 Hz to 12 Hz.

8. The system of claim 1 wherein the vacuum valve and the vent valve are solenoid pinch valves.

9. The system of claim 1 wherein the vacuum valve and the vent valve are cammed pinch valves.

10. The system of claim 1 wherein the controller is configured to cyclically open and close the vacuum valve and the vent valve such that an amount of momentum transfer

from the fluid column in the catheter lumen is sufficient to unstick thromboembolic material at the distal end of the catheter.

11. A method for removing thromboembolic material from a person using aspiration, comprising:

positioning a distal end of a catheter at least proximate to thromboembolic material in a blood vessel of the person;

applying a vacuum through a lumen of the catheter such that a vacuum flow draws at least a portion of the thromboembolic material into the catheter lumen; and

controlling a vacuum valve fluidically coupled to the vacuum source and the catheter and a vent valve fluidically coupled to a vent fluid source and the catheter such that a level of vacuum at the distal end of the aspiration catheter changes and thereby controls flow in and out from the distal end of the catheter.

12. The method of claim 11 wherein:

the vent fluid source is configured to provide the vent fluid at a pressure greater than atmospheric pressure; and

controlling the vacuum valve and the vent valve comprises cyclically opening and closing the vacuum valve and the vent valve to change a level of negative pressure and positive pressure at the distal end of the catheter during each cycle.

13. The method of claim 12 wherein controlling the vacuum valve and the vent valve comprises limiting movement of a fluid column in the catheter lumen at the distal end of the catheter to a positive amount of exit flow within a range of a length of the fluid column that exits the distal end of the catheter.

14. The method of claim 13 wherein limiting movement of the fluid column at the distal end of the catheter comprises stopping a distal flow through the catheter lumen and reapplying the vacuum through the catheter lumen such that the positive amount of exit flow

is approximately 0.5 mm to approximately 30 mm of the fluid column before fluid is drawn back into the catheter lumen.

15. The method of claim 12 wherein controlling the vacuum valve and the vent valve comprises limiting movement of a fluid column in the catheter lumen at the distal end of the catheter to a positive amount of exit flow within a range of volume of fluid that exits the distal end of the catheter.

16. The method of claim 15 wherein limiting movement of the fluid column at the distal end of the catheter comprises stopping a distal flow through the catheter lumen and reapplying the vacuum through the catheter lumen such that the positive amount of exit flow is approximately 0.001 ml to approximately 1.0 ml before fluid is drawn back into the catheter lumen.

17. The system of claim 15 wherein limiting movement of the fluid column at the distal end of the catheter comprises stopping a distal flow through the catheter lumen and reapplying the vacuum through the catheter lumen such that the positive amount of exit flow is approximately 0.1 ml to approximately 0.5 ml before fluid is drawn back into the catheter lumen.

18. The method of claim 11, further comprising cyclically opening and closing the vacuum valve and the vent valve in a repeated cycle including an off-off state in which the vacuum valve is closed while the vent valve is closed.

19. The system of claim 11, further comprising:

cyclically opening and closing the vacuum valve and the vent valve in a cycle including (a) a first off-off state in which the vacuum valve is closed while the vent valve is closed, (b) a vacuum-only state following the first off-off state in which the vacuum valve is open while the vent valve is closed, (c) a second off-off state following the vacuum-only state in which the vacuum valve is closed while the vent valve is closed, and (d) a vent-only state following the

second off-off state in which the vacuum valve is closed while the vent valve is open; and

repeating the cycle.

20. The method of claim 19 wherein the cycle is repeated at a frequency of 2 Hz to 12 Hz.

ABSTRACT

A clot removal system comprises a catheter, a vacuum source, and a controller. The catheter comprises a proximal end, a distal end, and controller operating parameters and defines a lumen configured to be filled with a liquid column having a proximal portion. The vacuum source is configured to supply vacuum. The controller is configured to carry out a control pattern of turning on and off the vacuum based upon the controller operating parameters and is configured to receive the controller operating parameters in an automatic response to the catheter being operatively connected to at least one of the vacuum source and the controller and, responsive to the connection, to carry out the control pattern to change a level of vacuum at the distal end of the catheter.

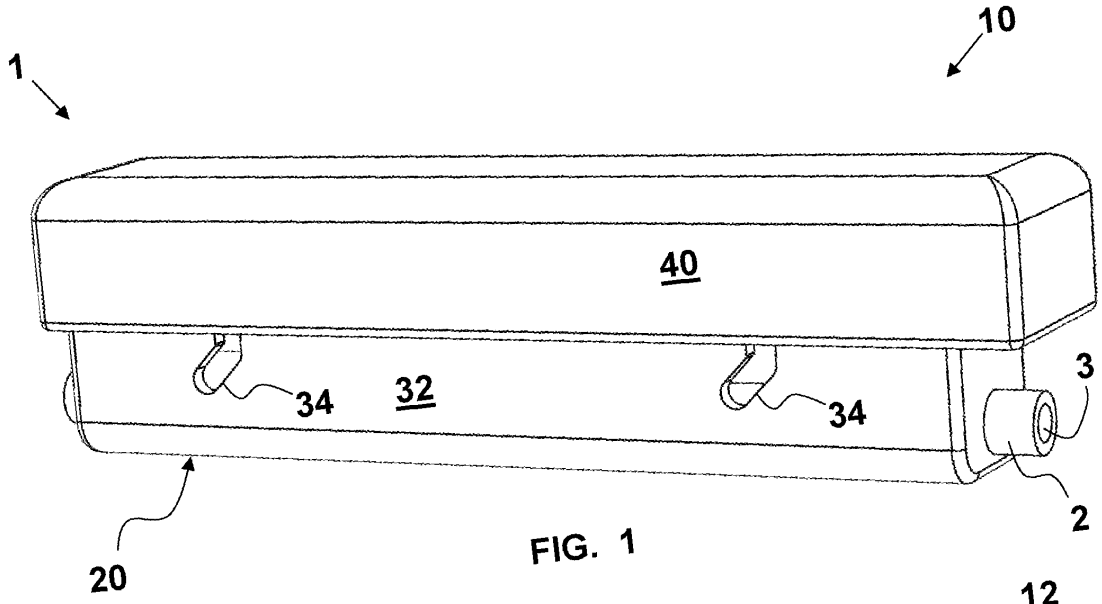


FIG. 1

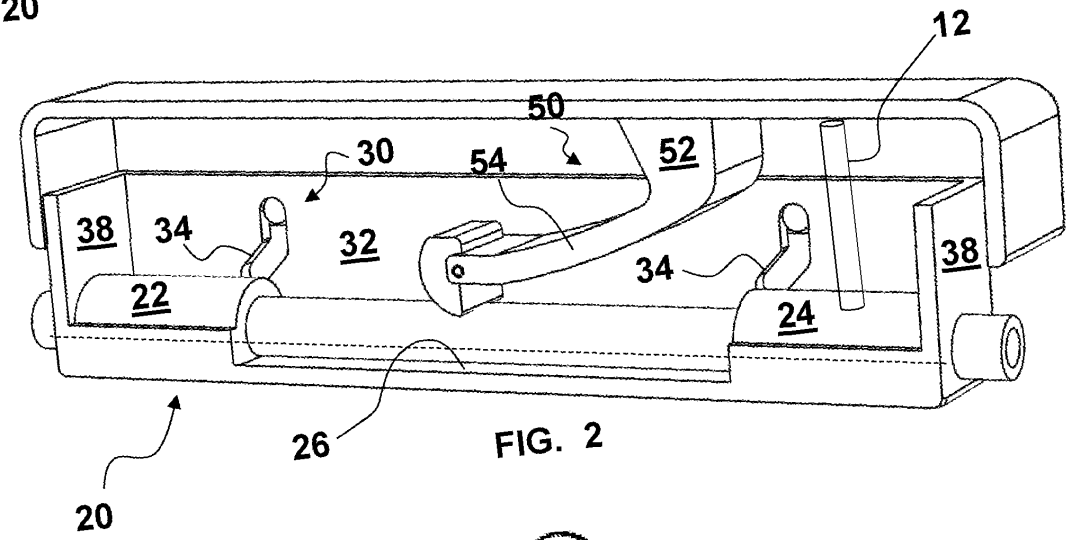


FIG. 2

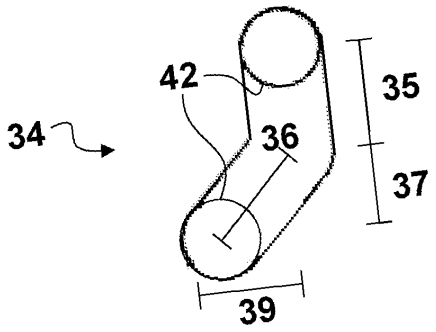


FIG. 3

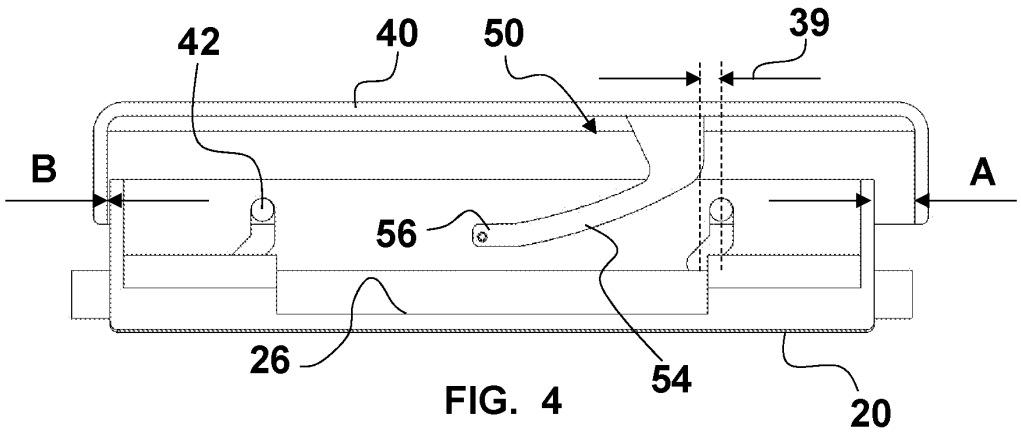


FIG. 4

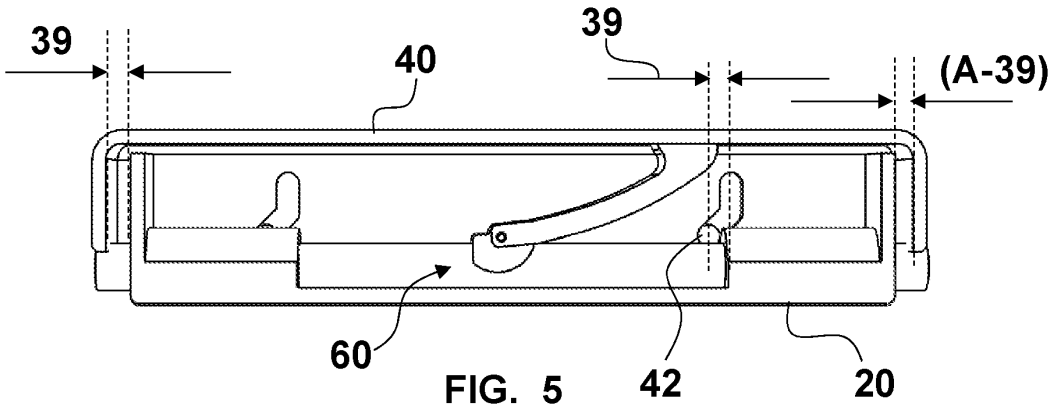


FIG. 5

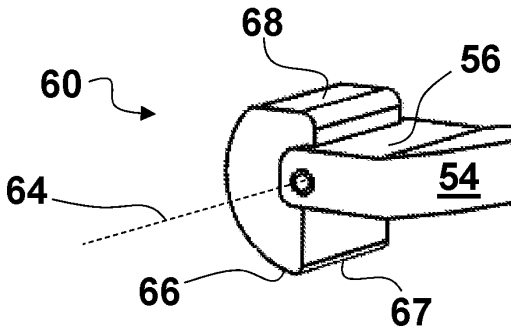


FIG. 6

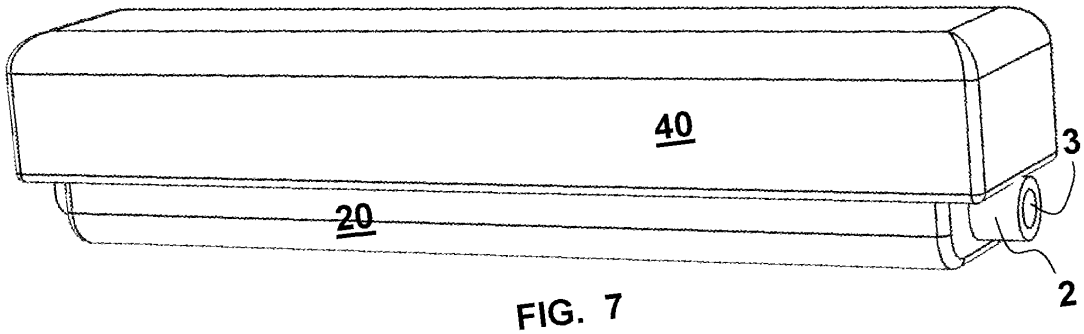


FIG. 7

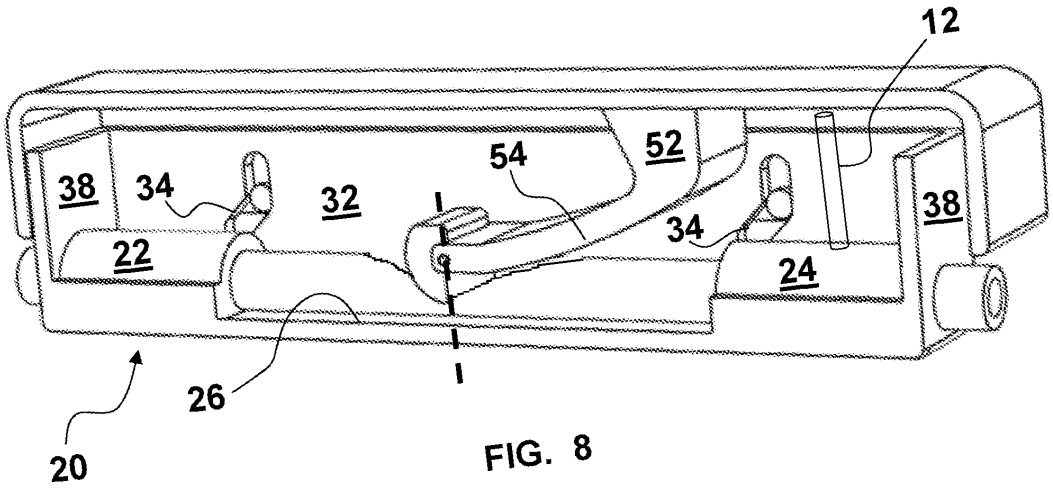


FIG. 8

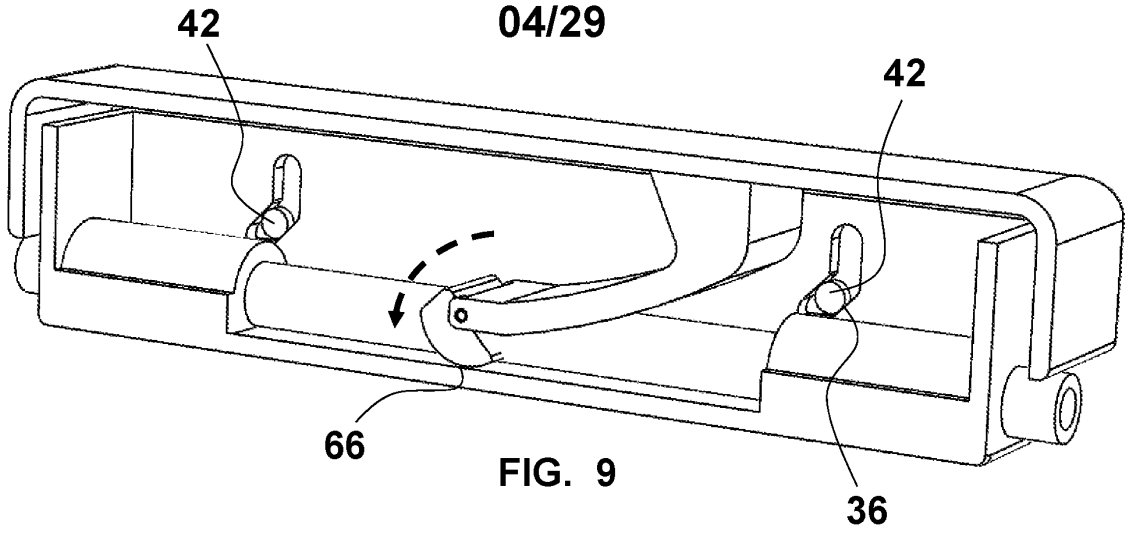


FIG. 9

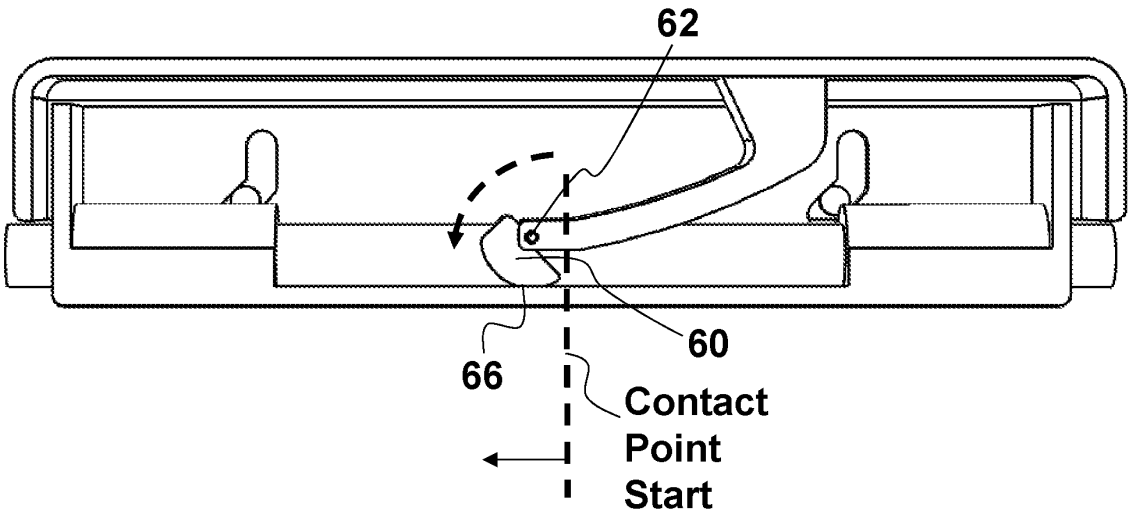


FIG. 10

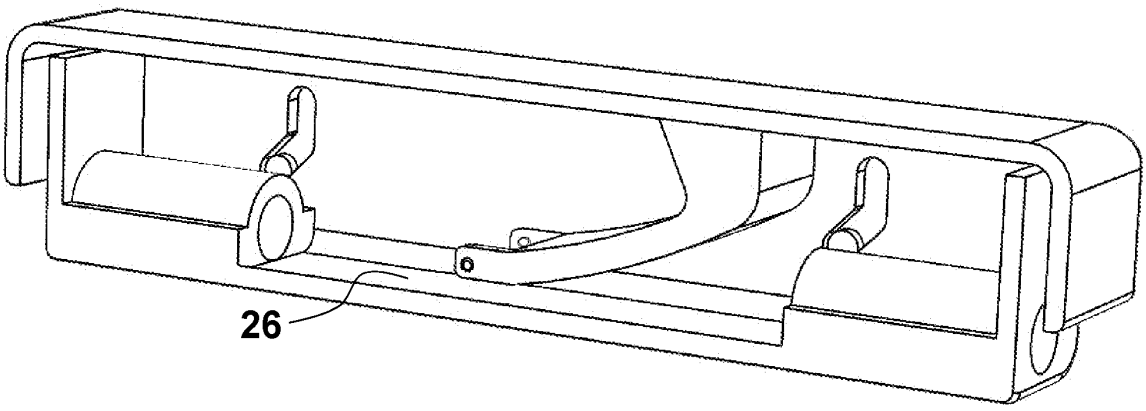


FIG. 13

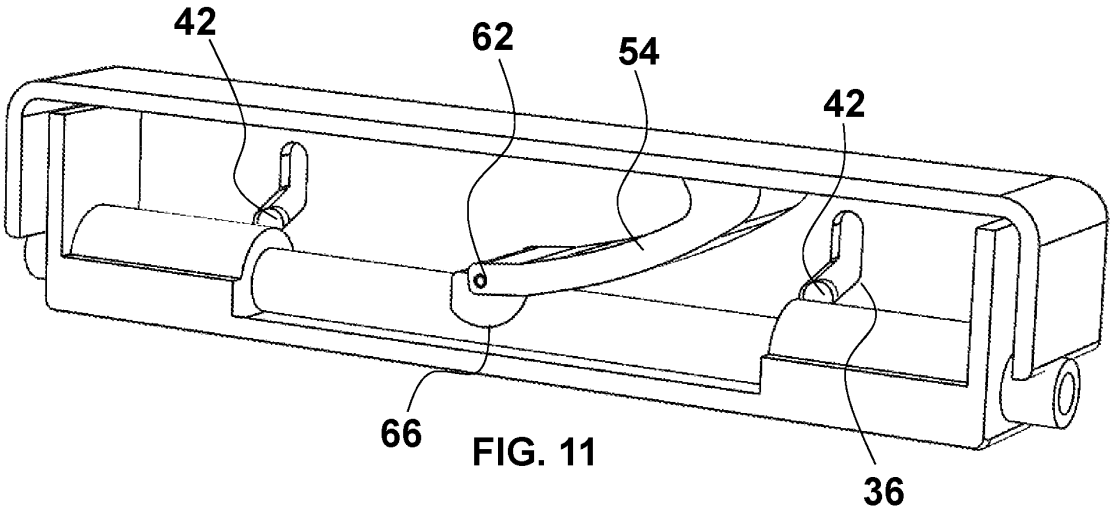


FIG. 11

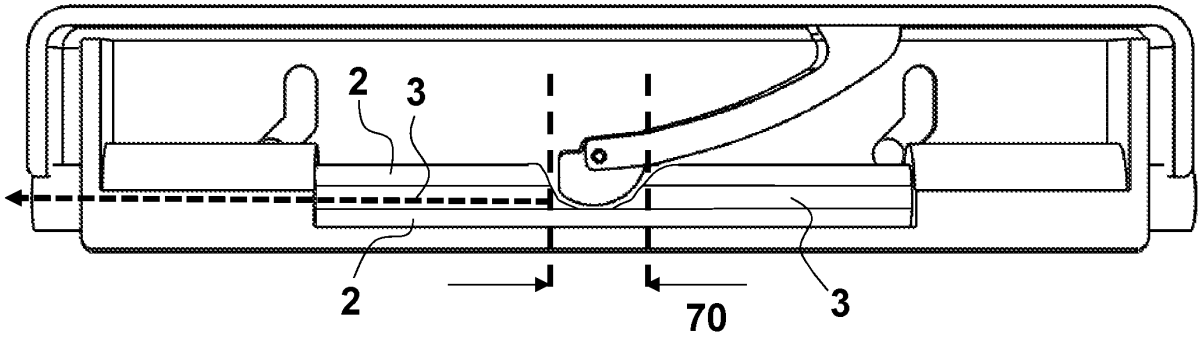


FIG. 12

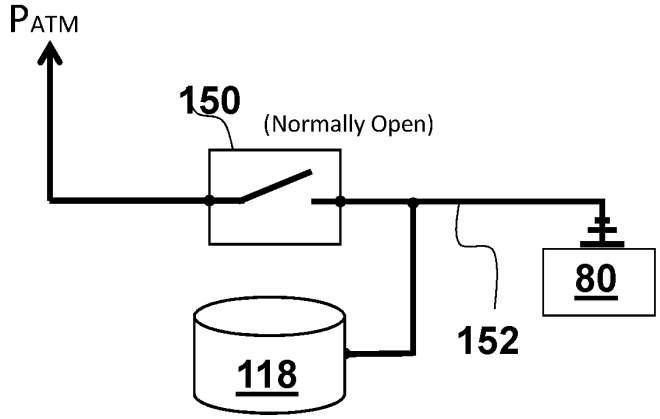


FIG. 23

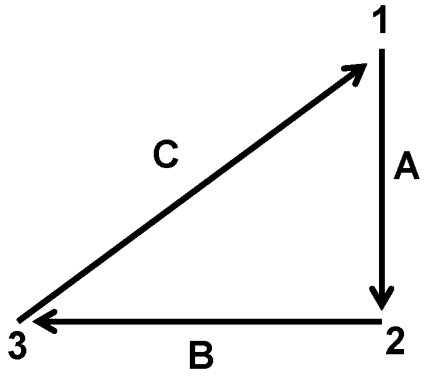


FIG. 24

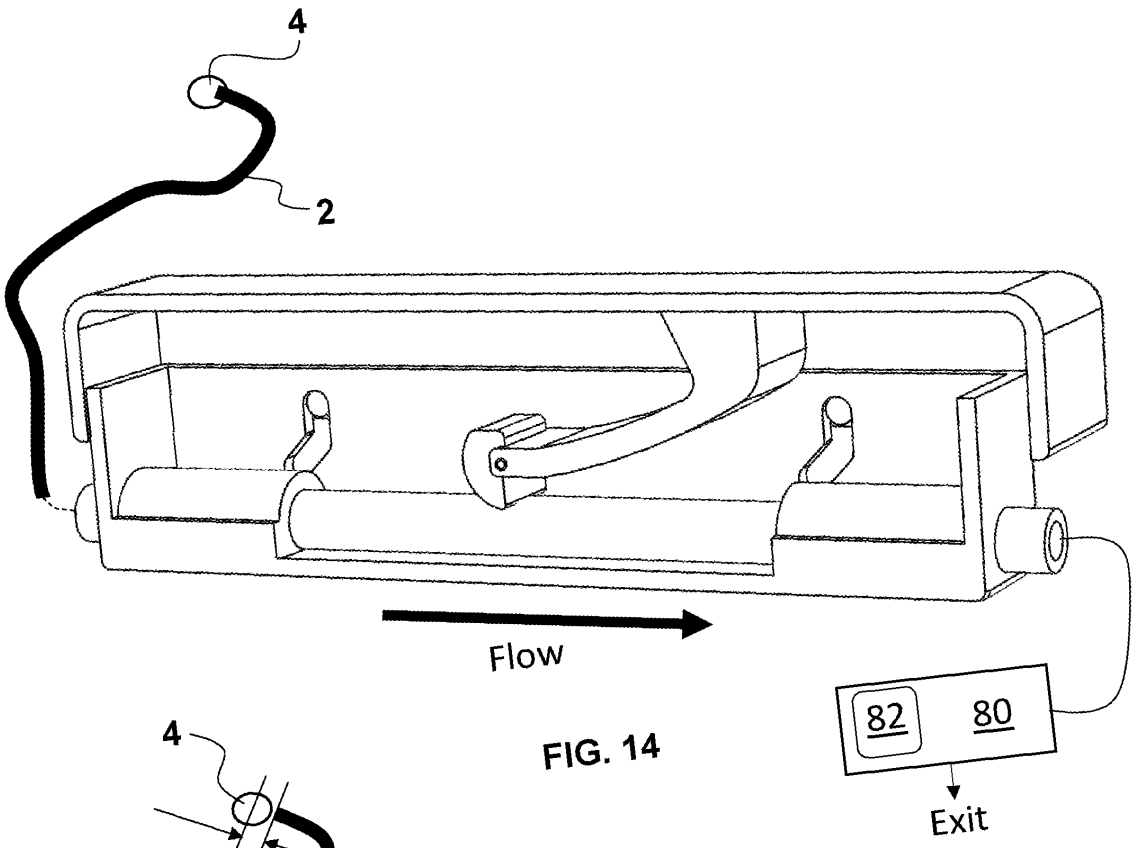


FIG. 14

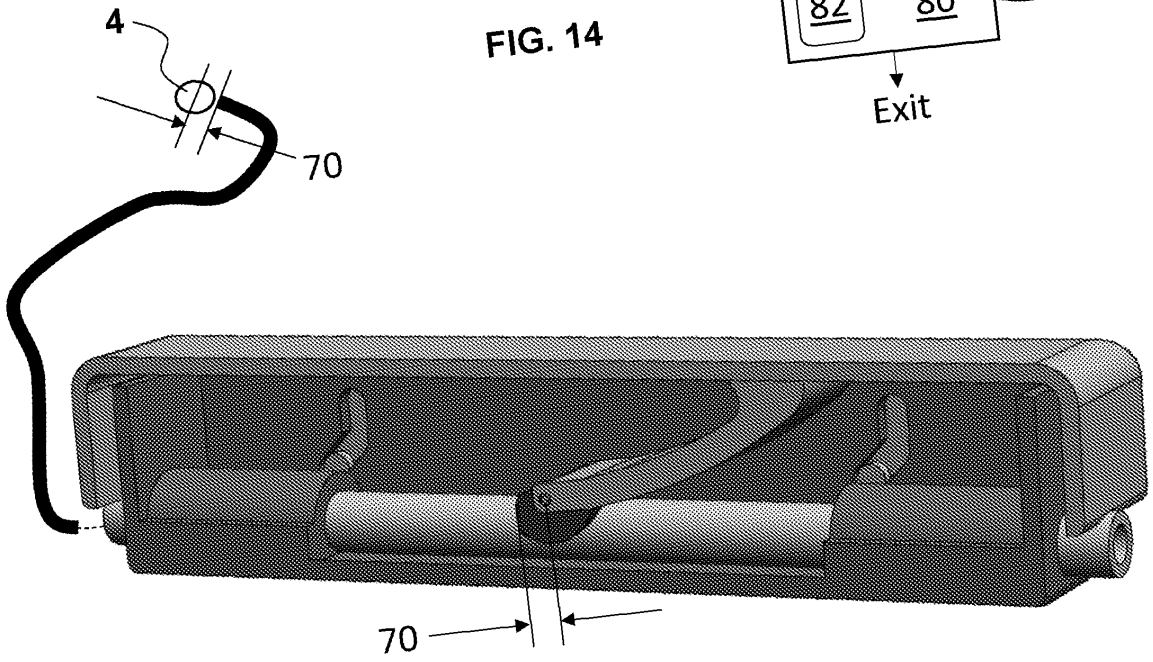
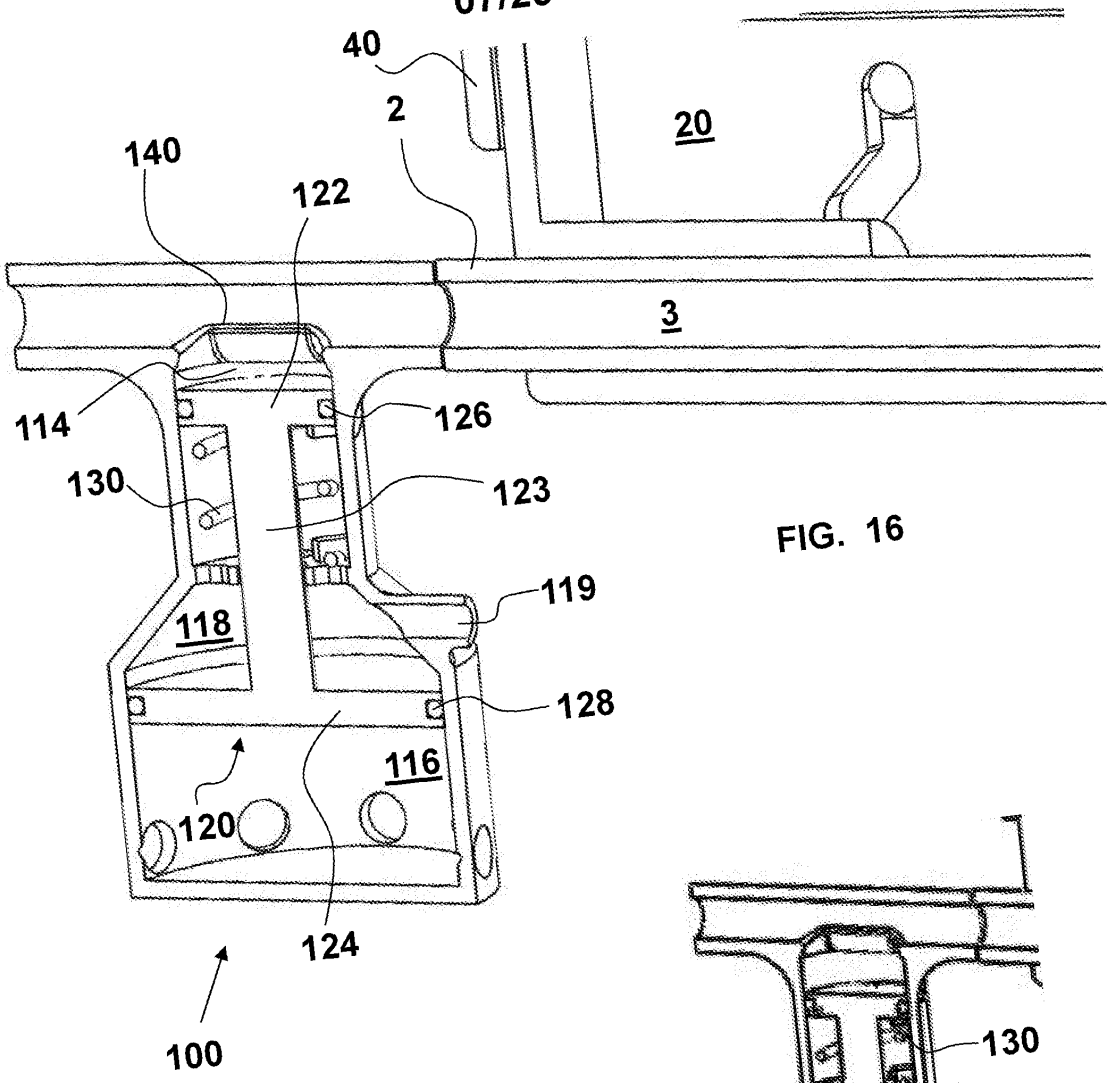


FIG. 15


40
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20
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122
3
114
126
130
123
119
118
128
116
120
124
100

FIG. 16

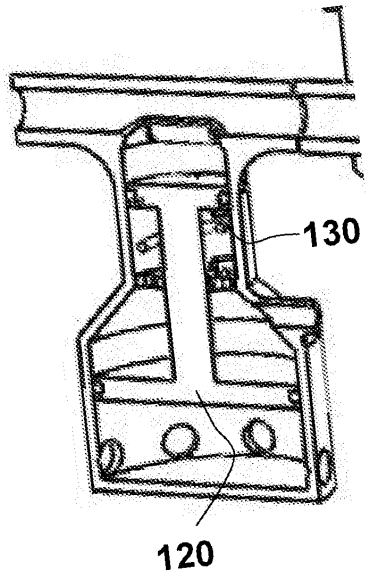

130
120

FIG. 17

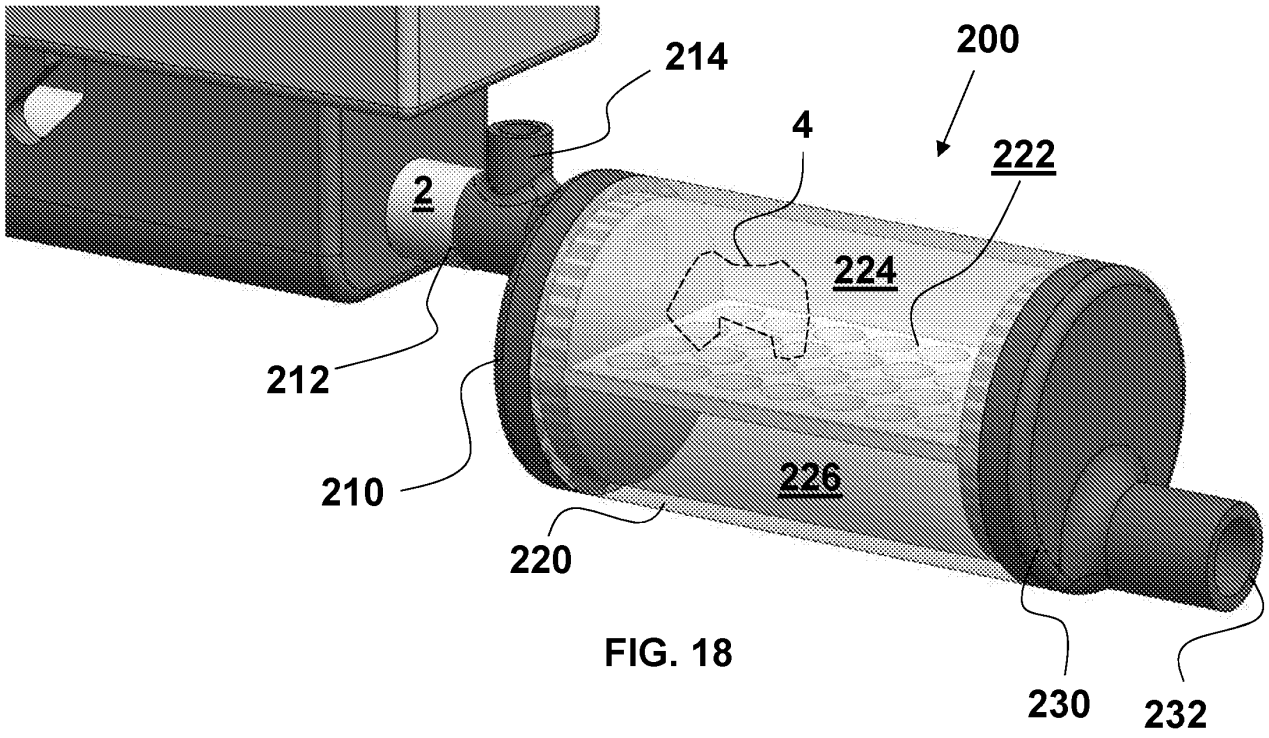


FIG. 18

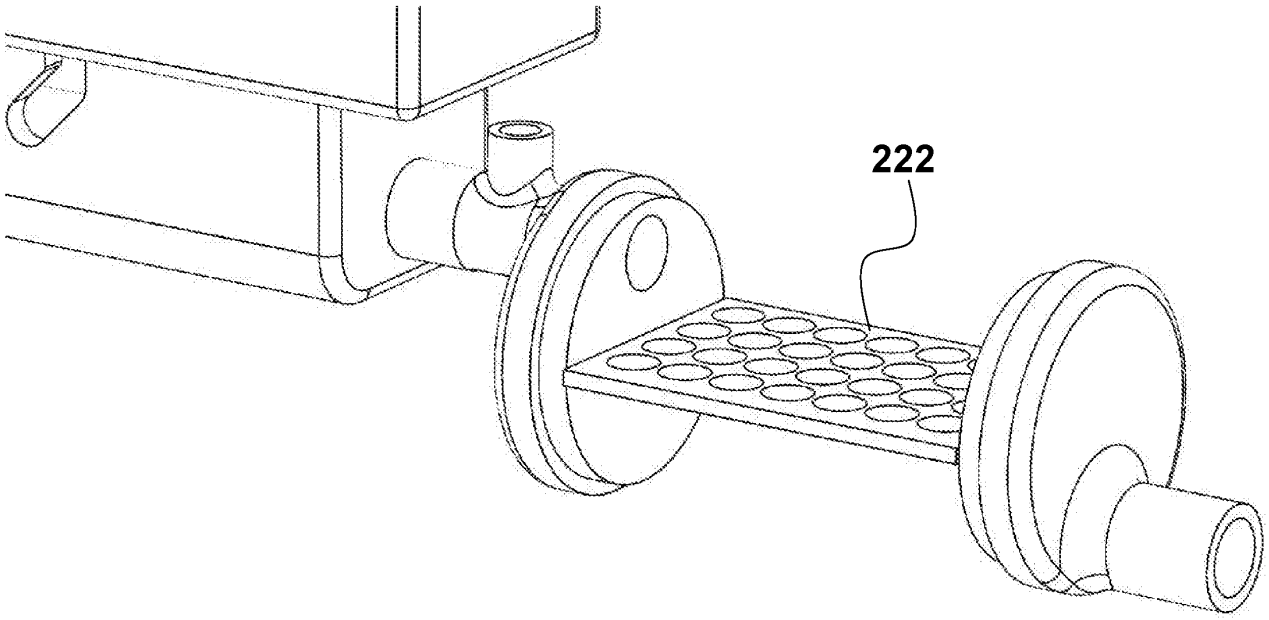


FIG. 19

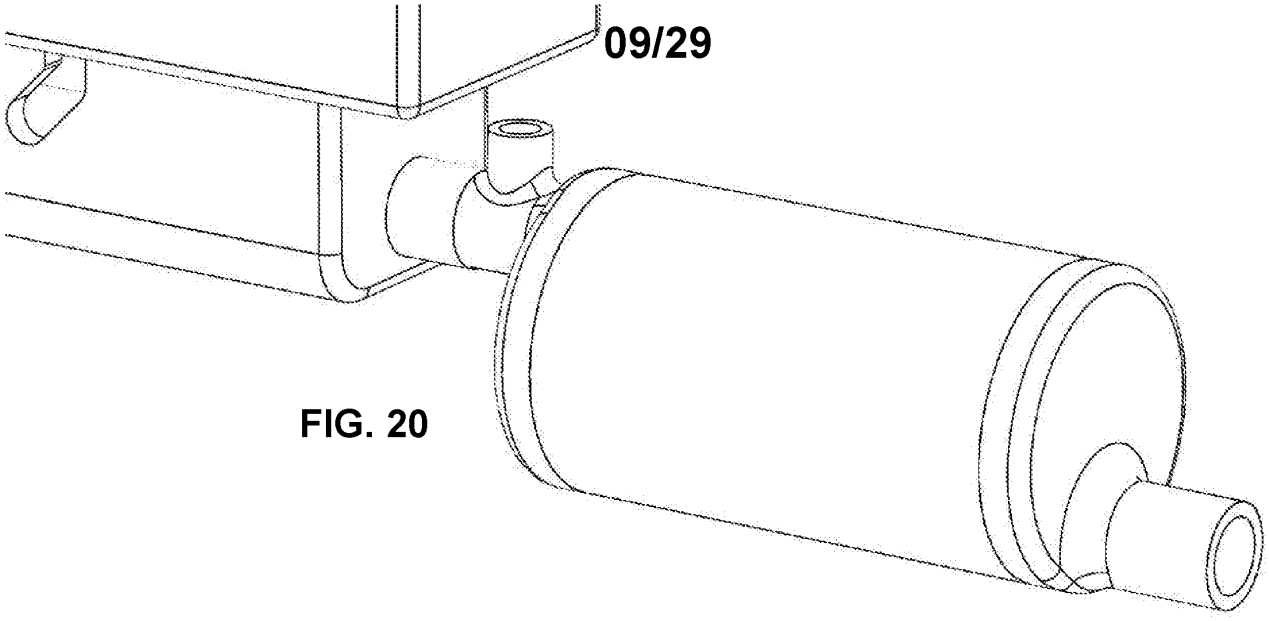


FIG. 20

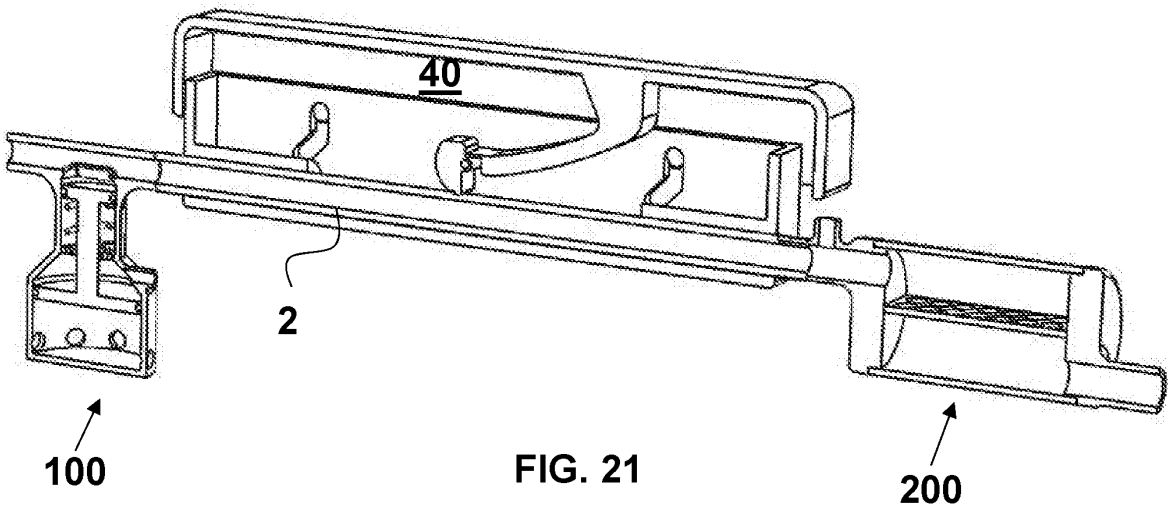


FIG. 21

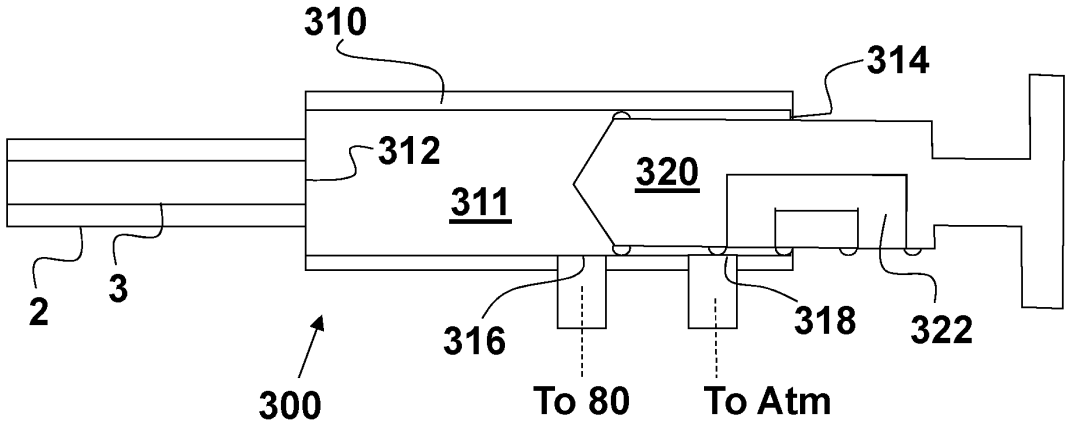


FIG. 22

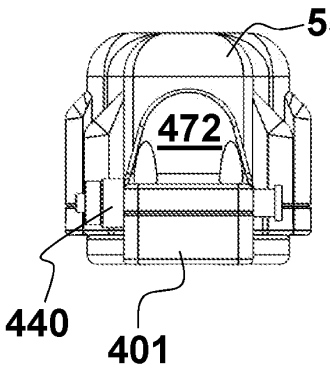


FIG. 28

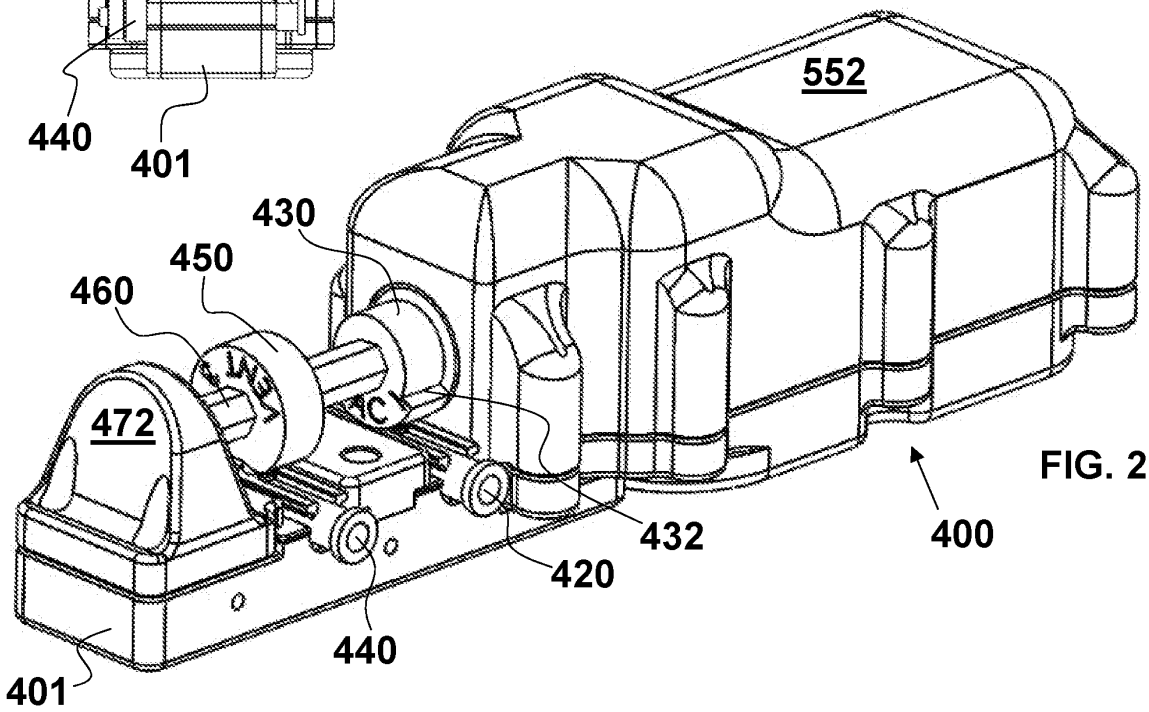


FIG. 25

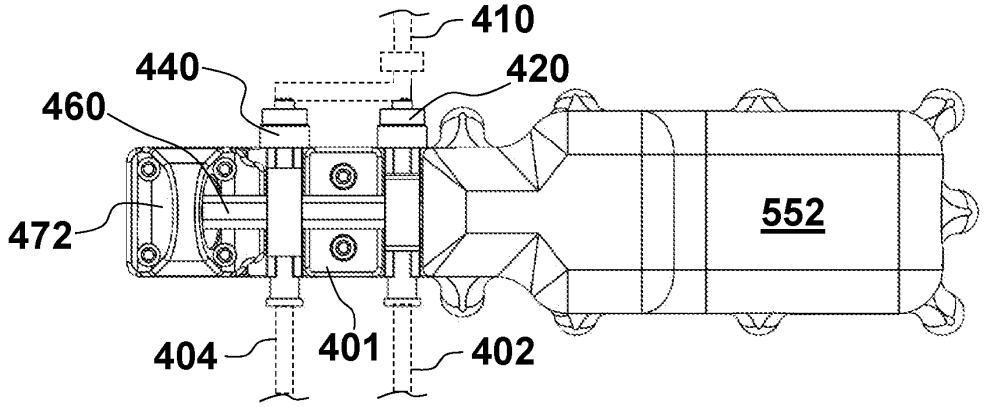


FIG. 26

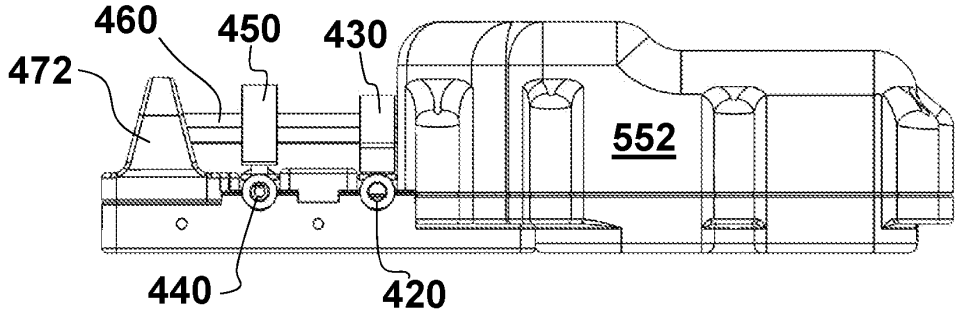
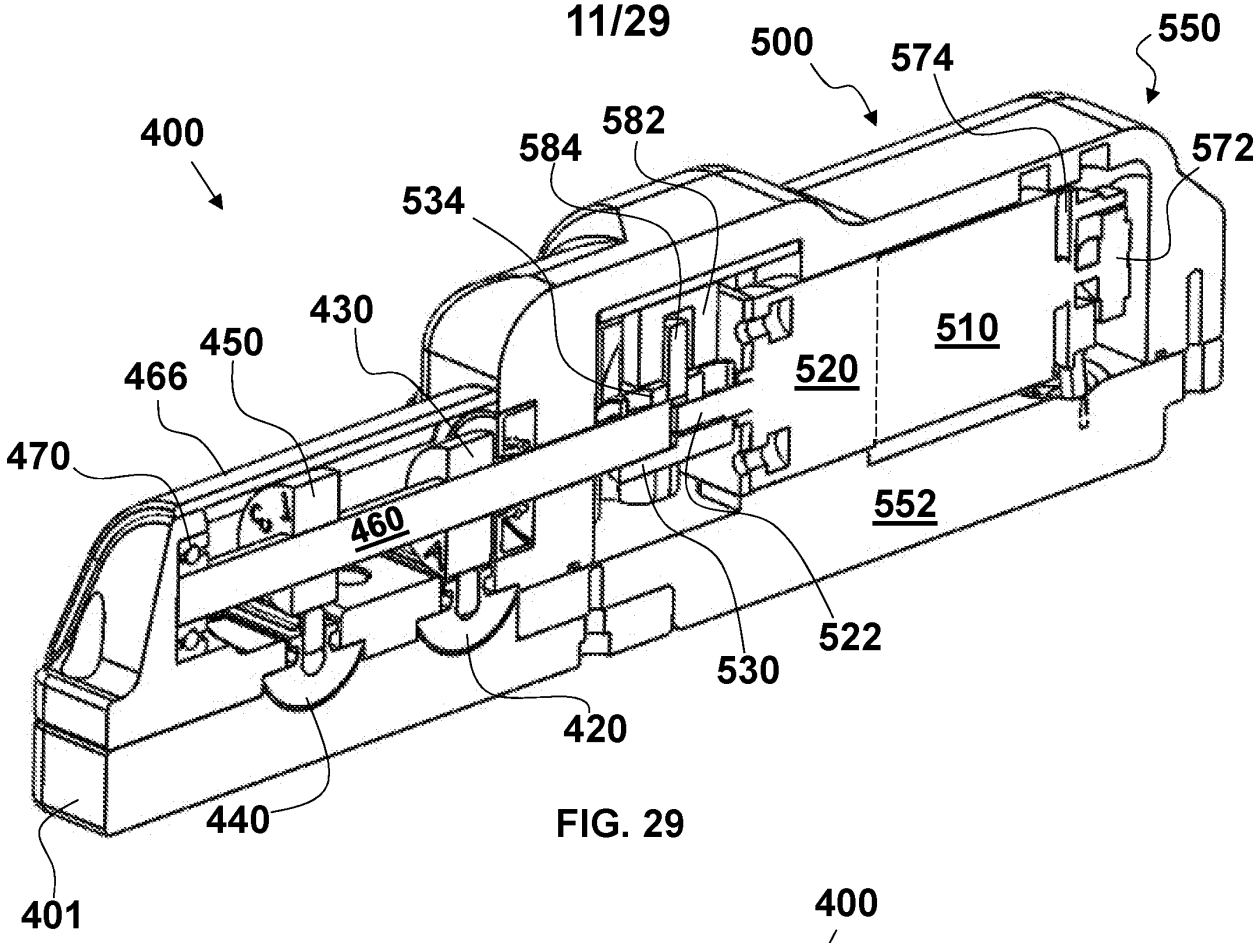


FIG. 27


400
500
574
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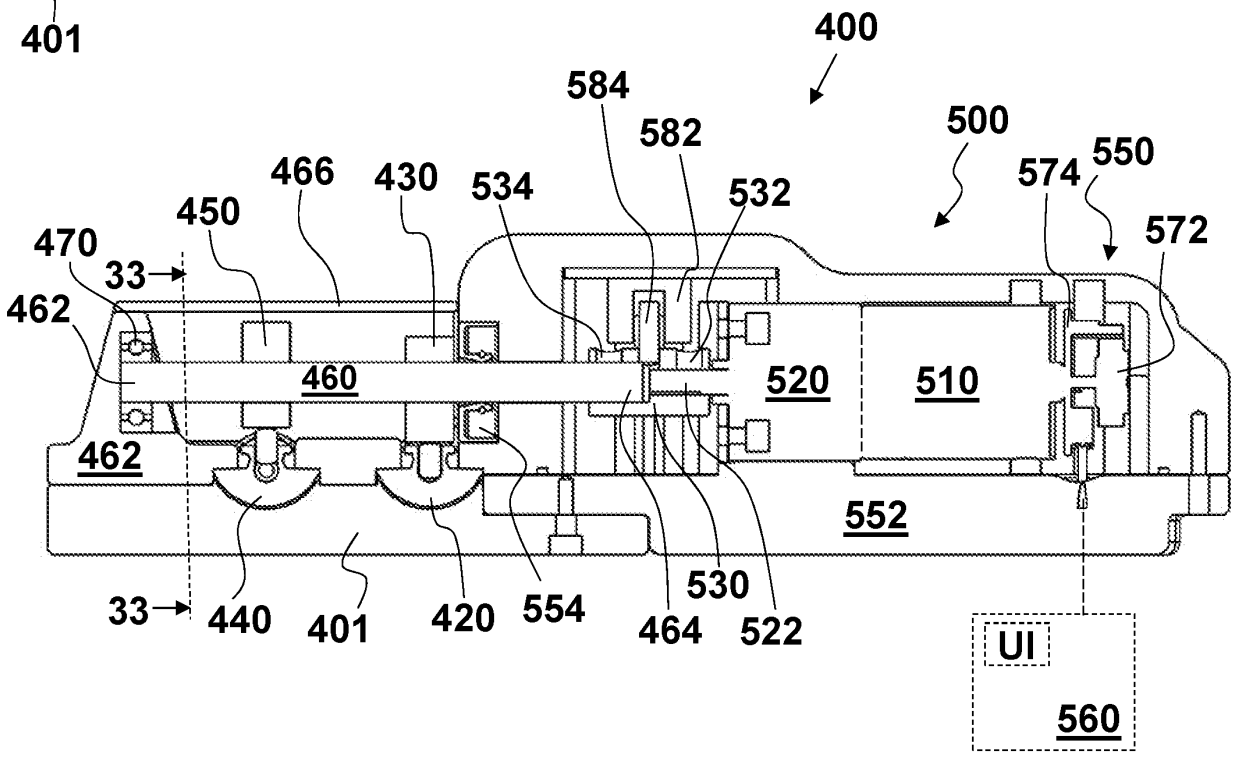
420
440
401

FIG. 29


400
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560

FIG. 30

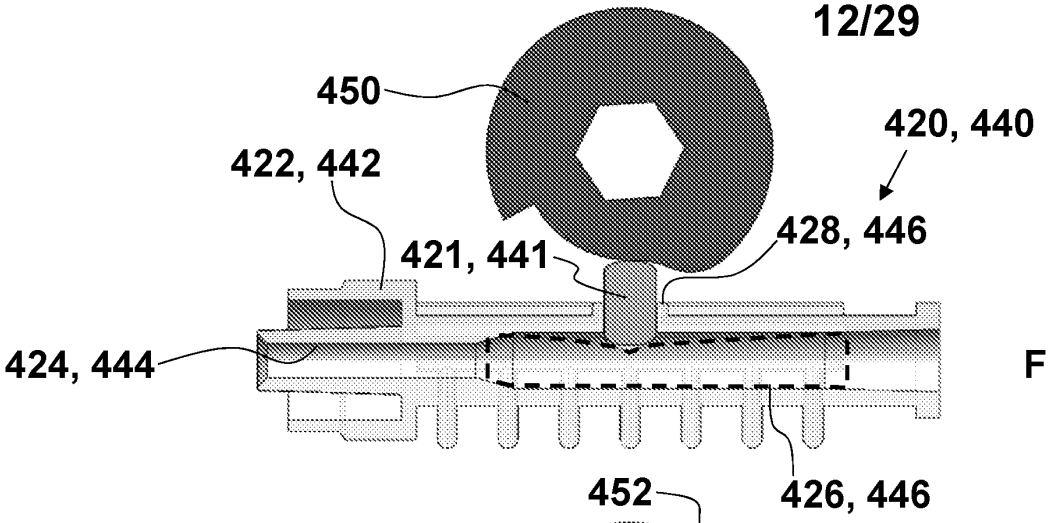


FIG. 31

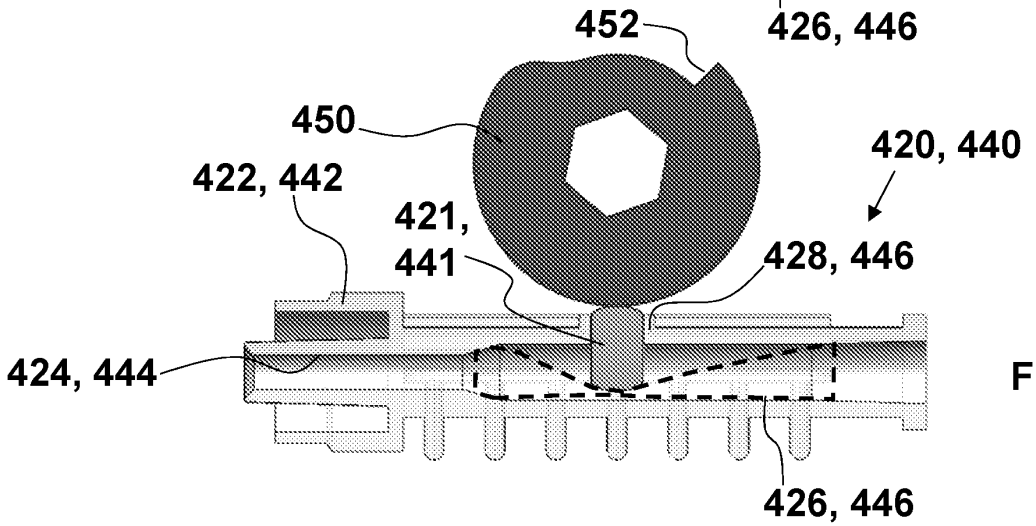


FIG. 32

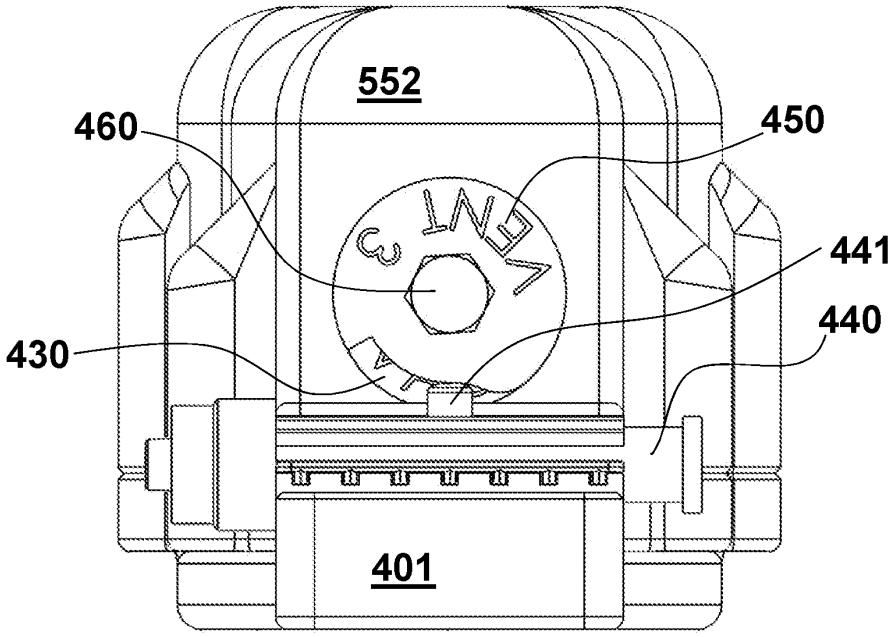


FIG. 33

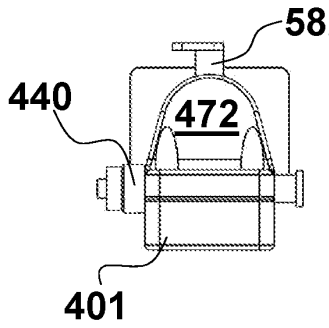


FIG. 37

FIG. 34

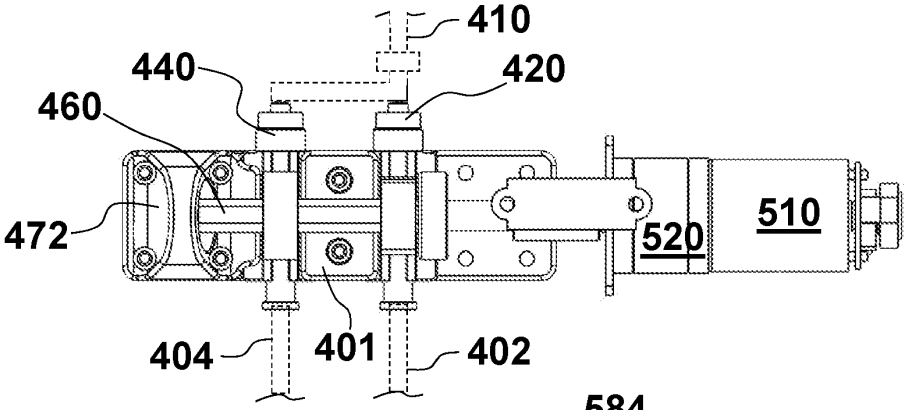


FIG. 35

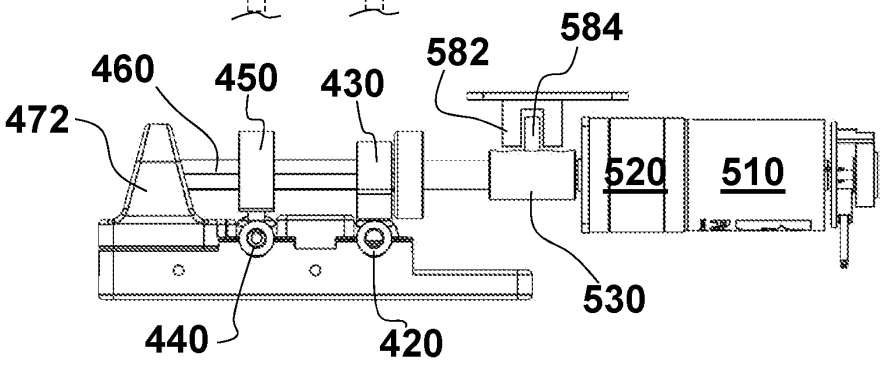


FIG. 36

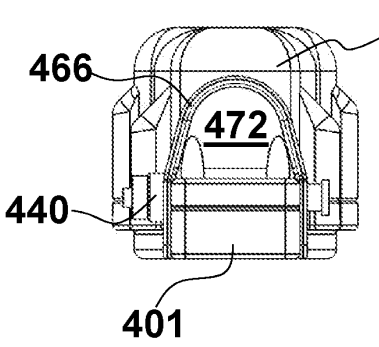


FIG. 41

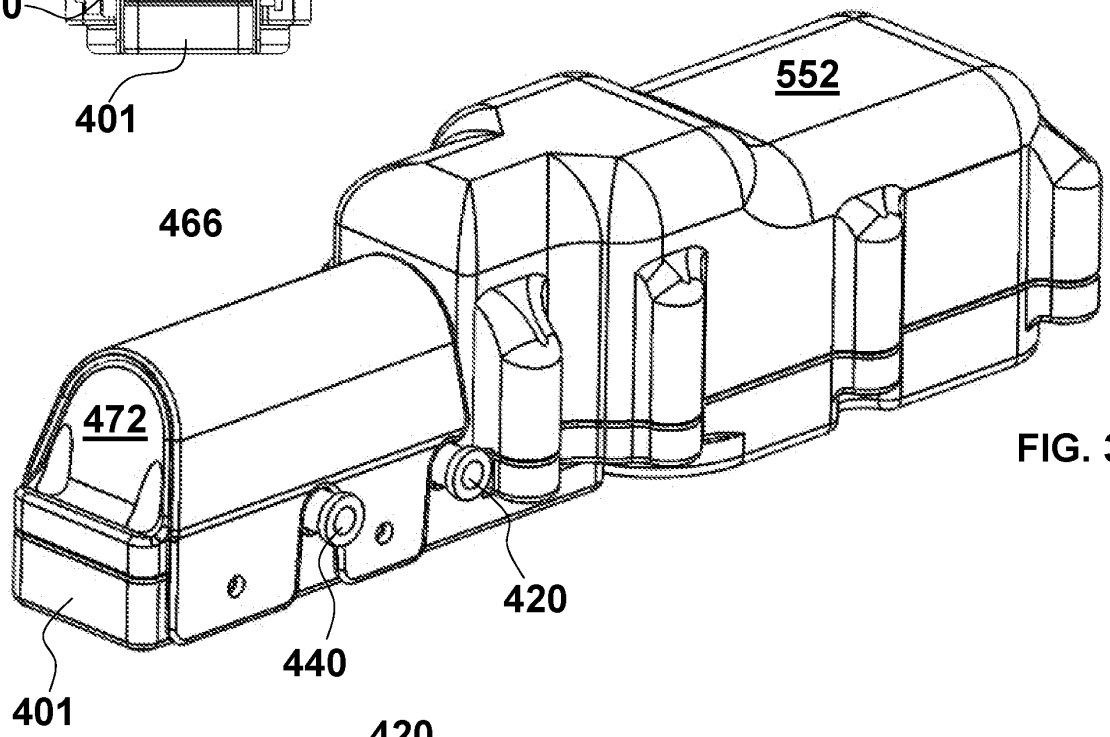


FIG. 38

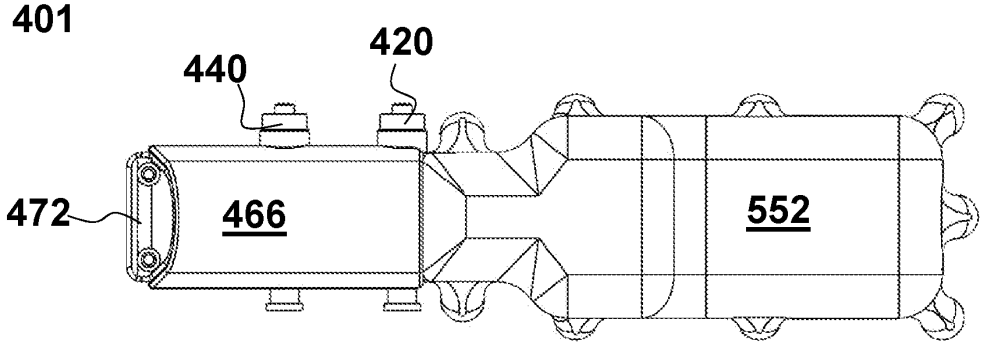


FIG. 39

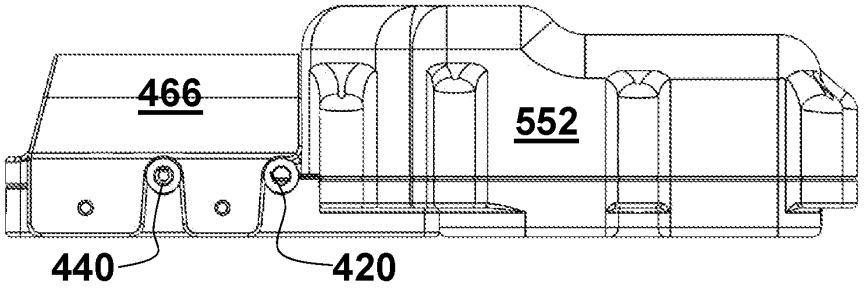


FIG. 40

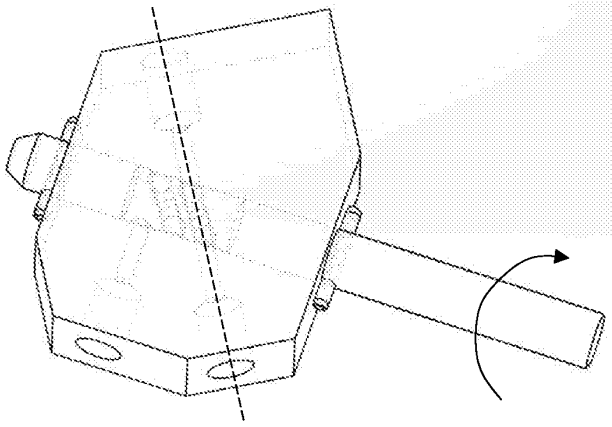


FIG. 42

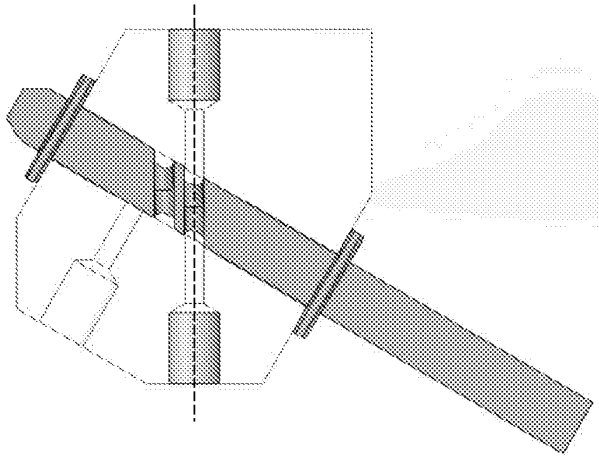


FIG. 43

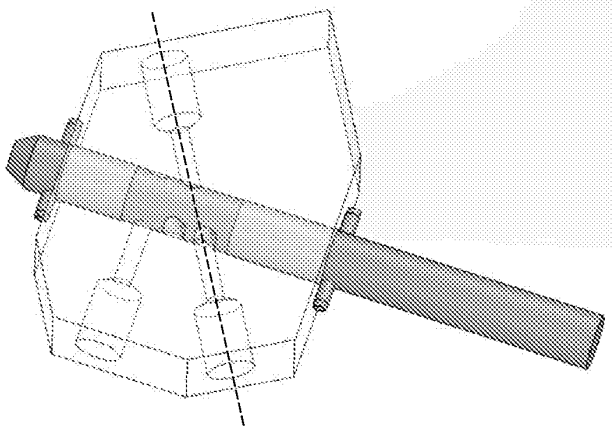


FIG. 44

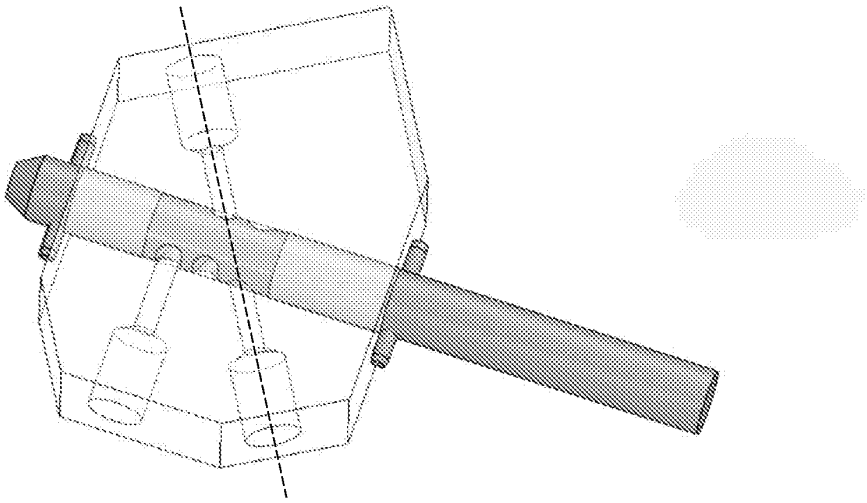


FIG. 45

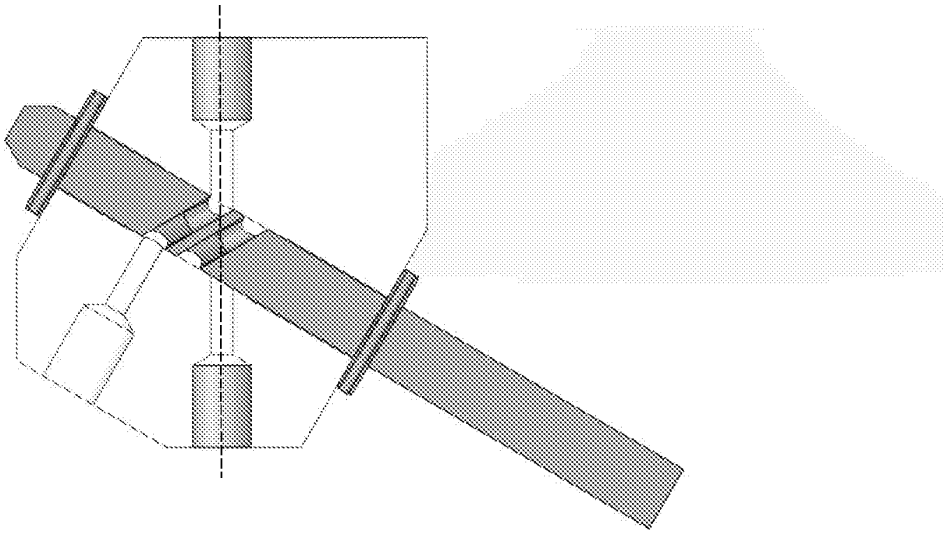
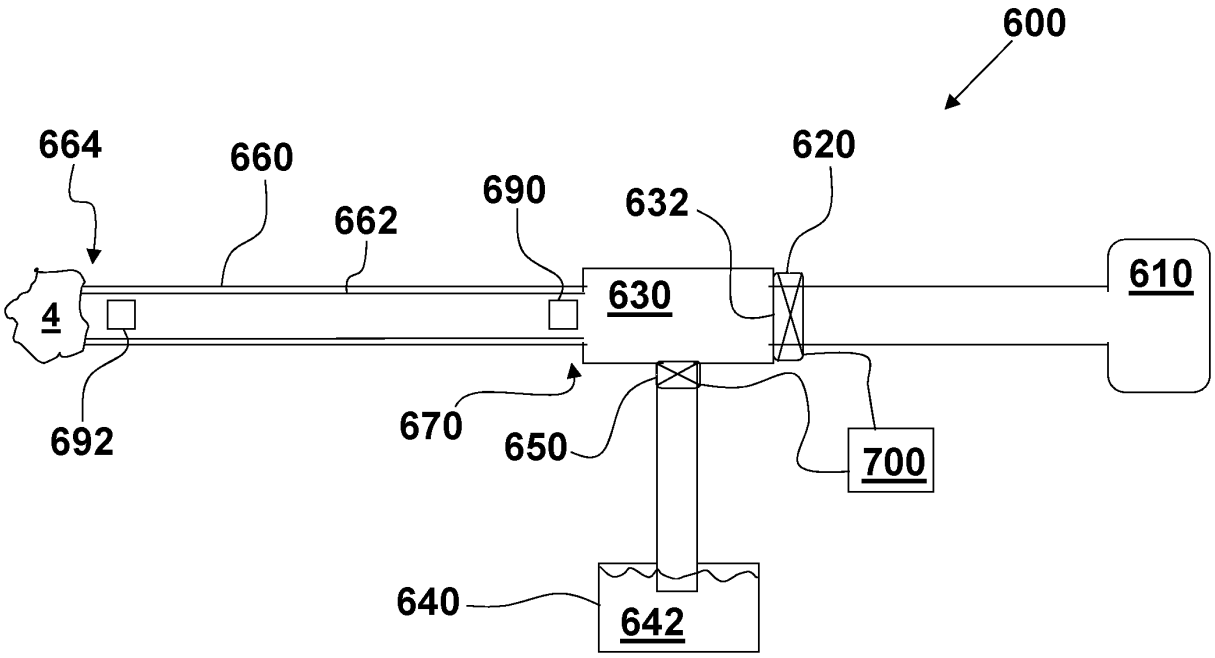


FIG. 46


600
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662
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632
620
610
4
630
692
670
650
700
640
642

FIG. 47

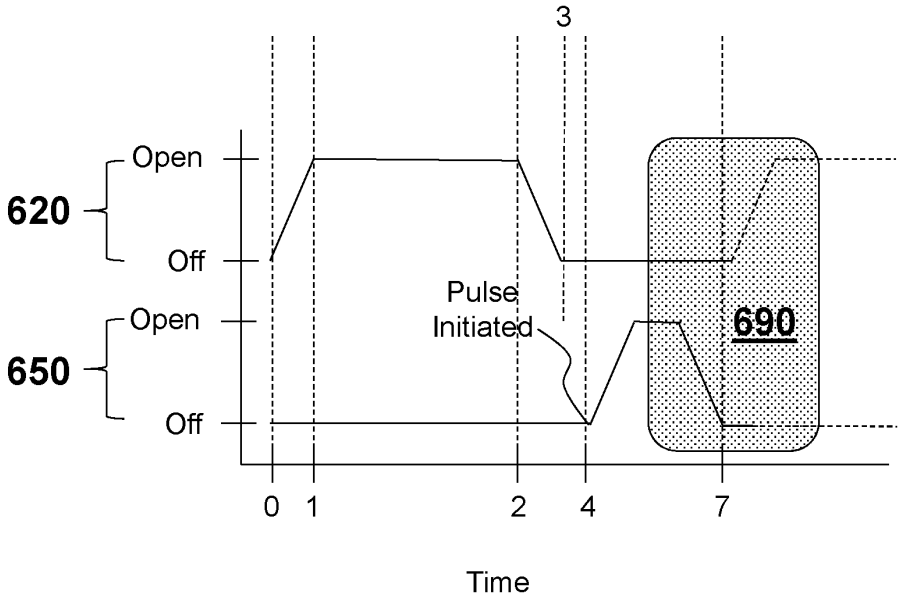
3
620
Open
Off
650
Open
Off
Pulse
Initiated
690
0
1
2
4
7
Time

FIG. 48

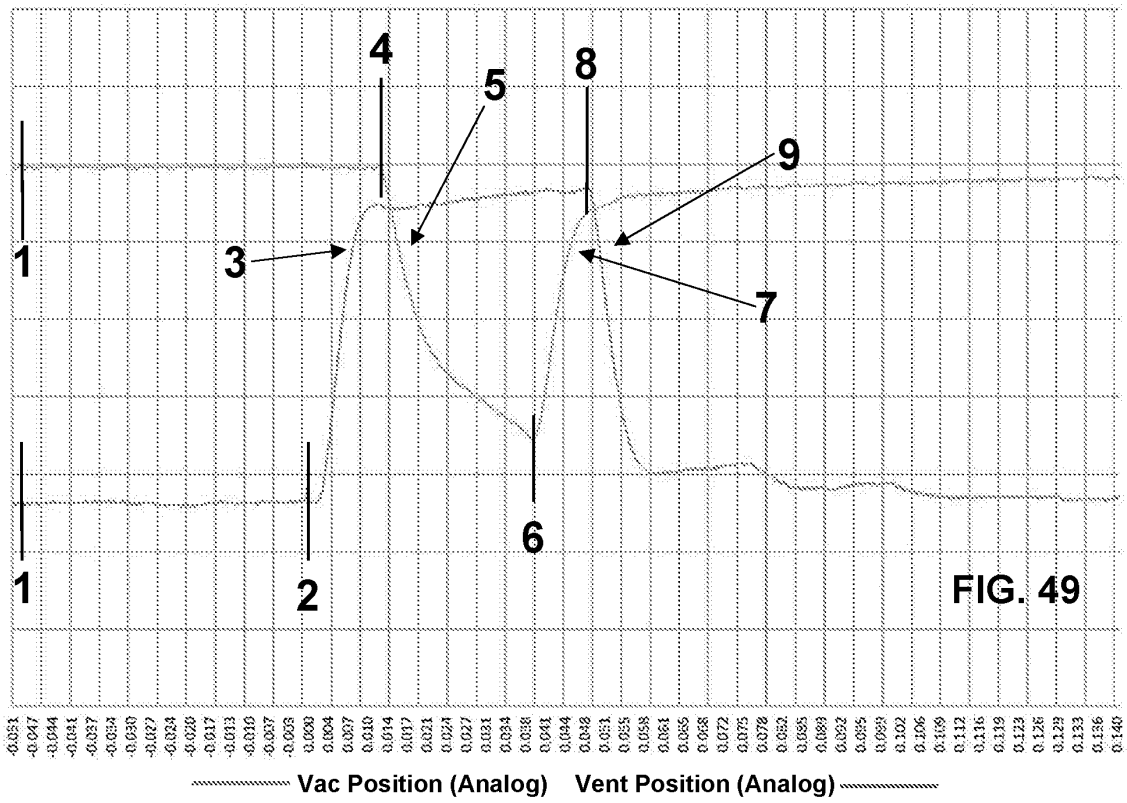
4
5
8
9
1
3
7
6
1
2
Vac Position (Analog)
Vent Position (Analog)

FIG. 49

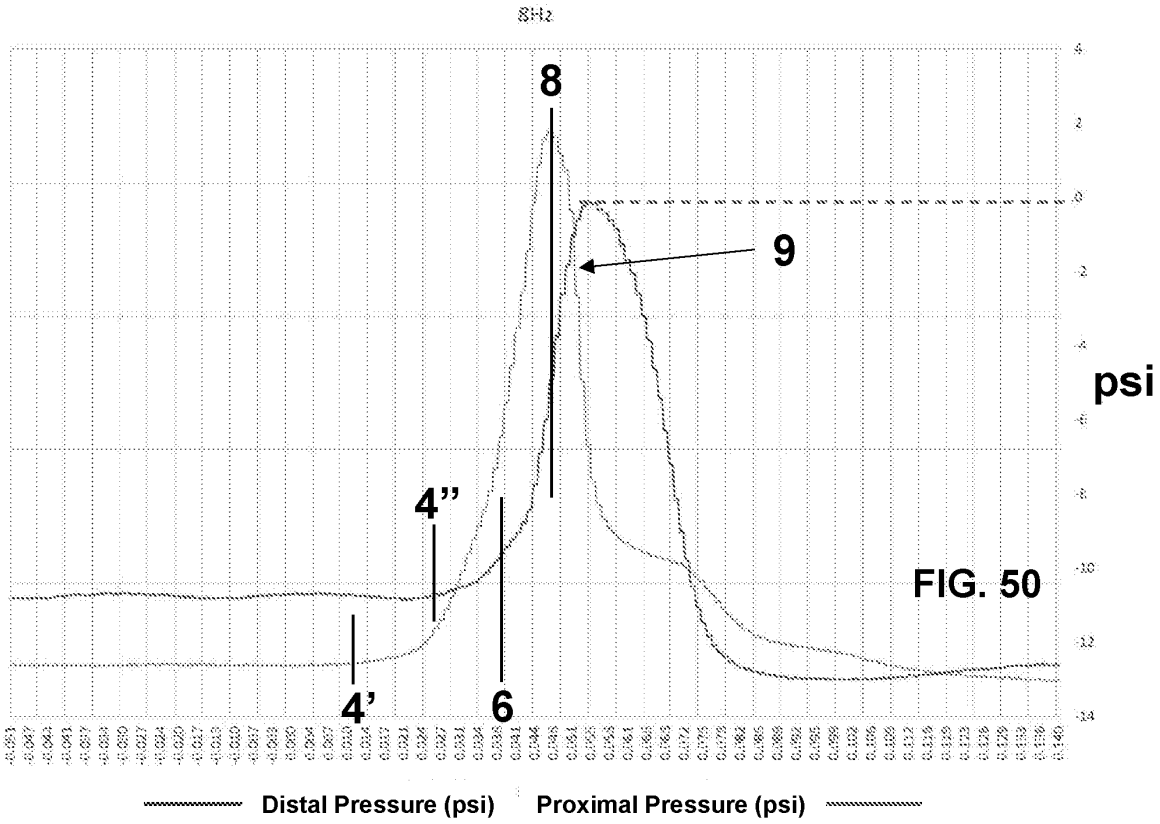
8Hz
8
9
psi
4”
4’
6
Distal Pressure (psi)
Proximal Pressure (psi)

FIG. 50

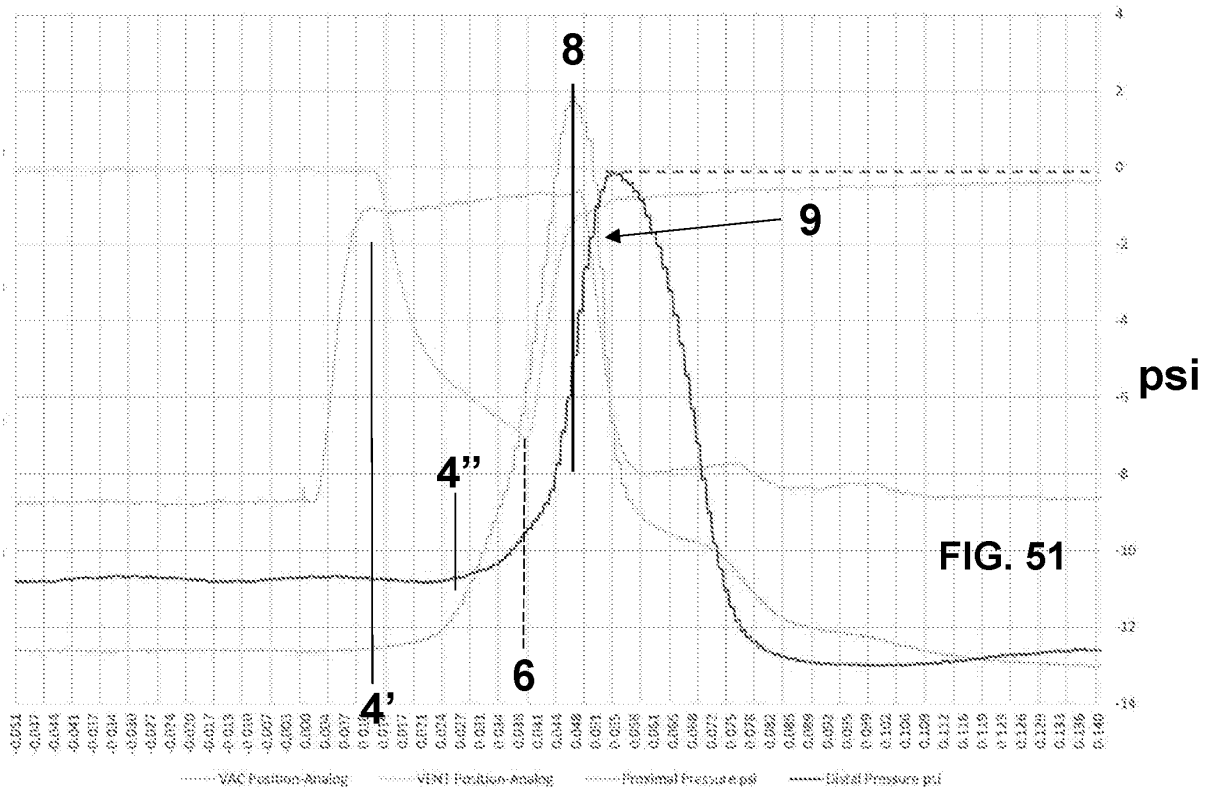

FIG. 51

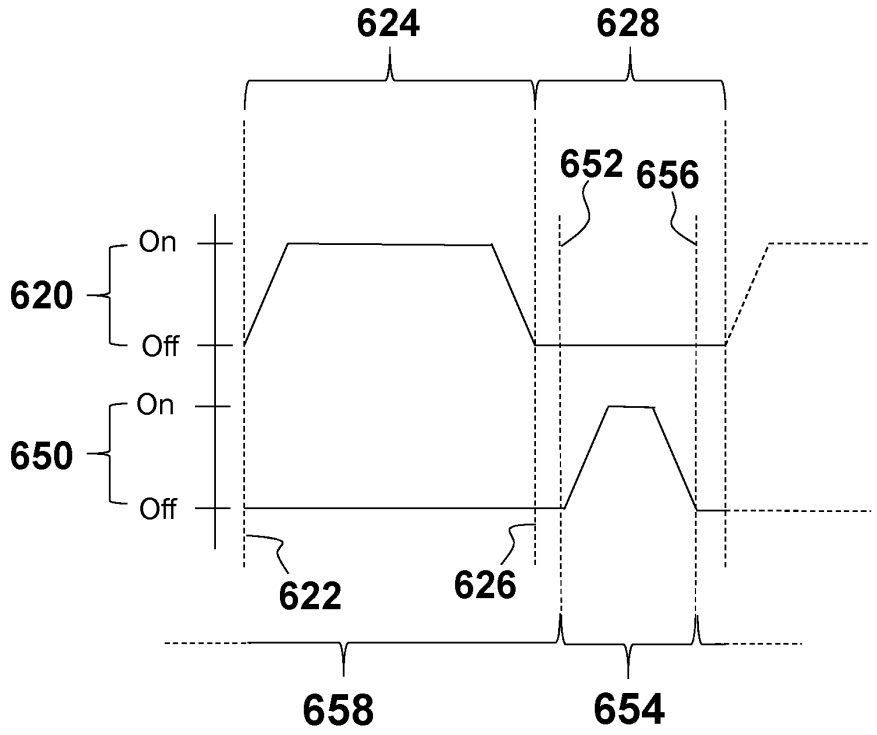

FIG. 52

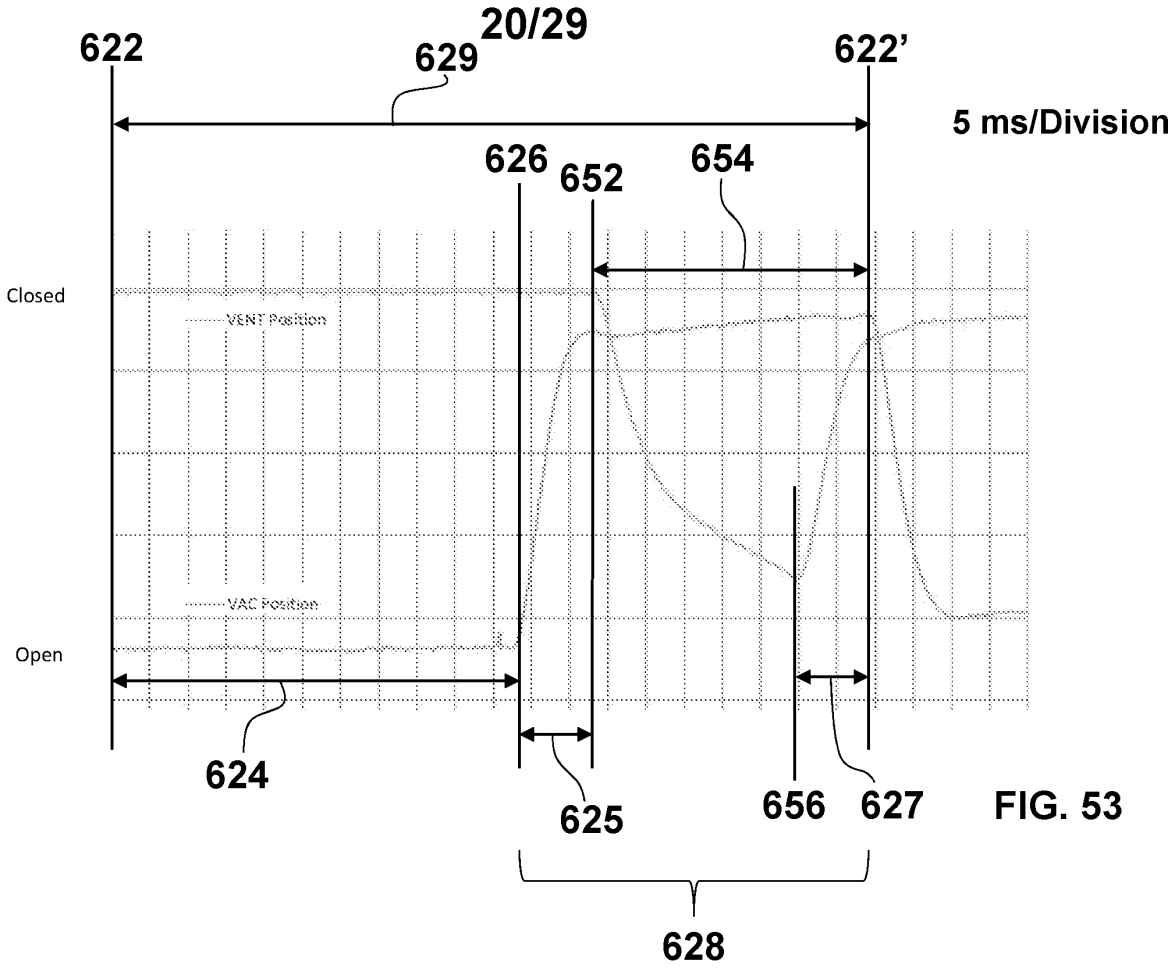
622
629
622'
5 ms/Division
626
652
654
Closed
VENT Position
VAC Position
Open
624
625
656
627
628

FIG. 53

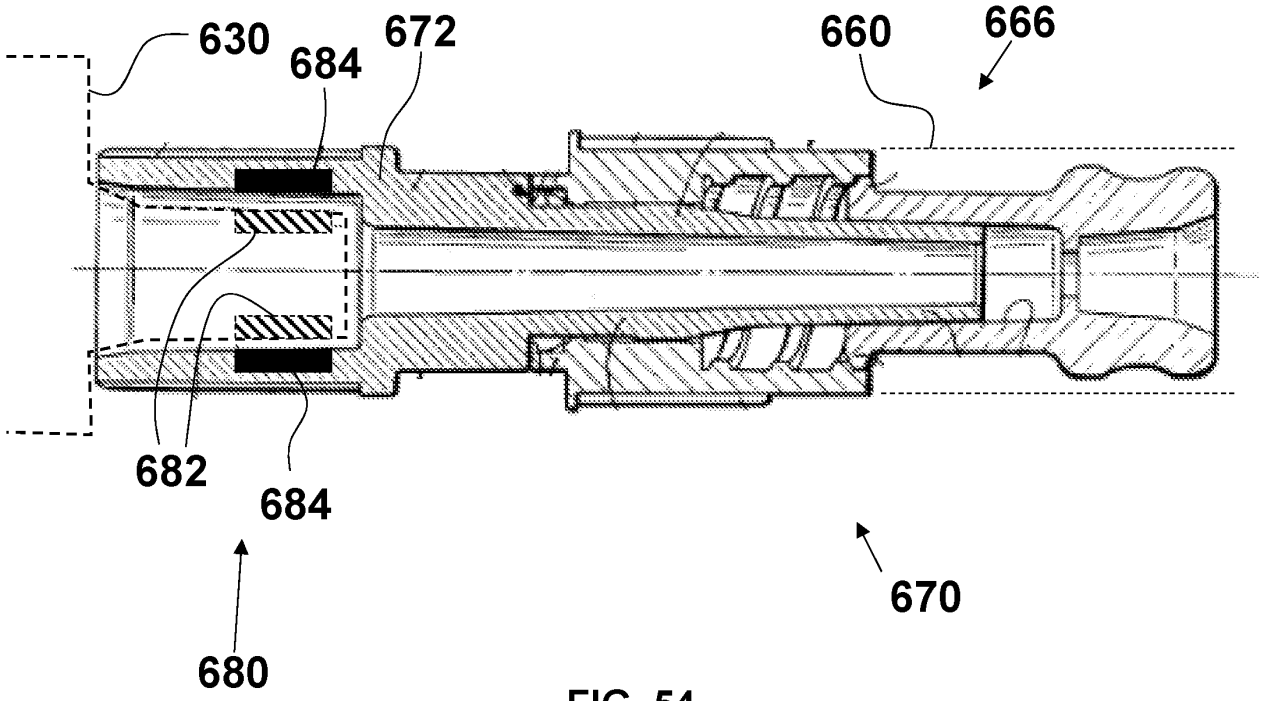
630
684
672
660
666
682
684
680
670

FIG. 54

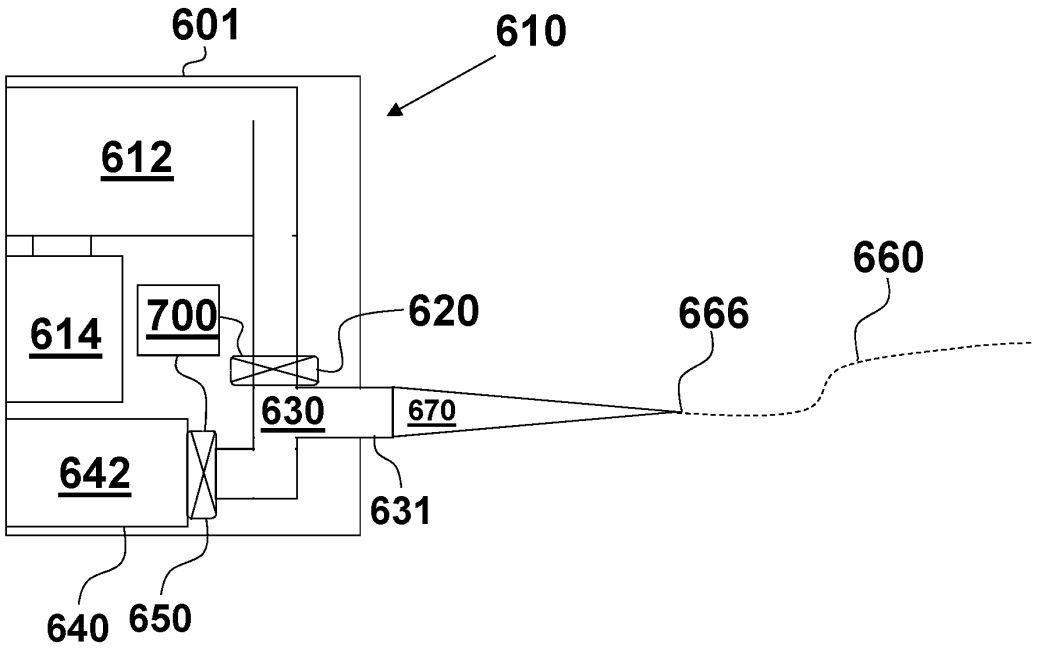
601
610
612
614
700
620
660
666
630
670
642
631
640
650

FIG. 55

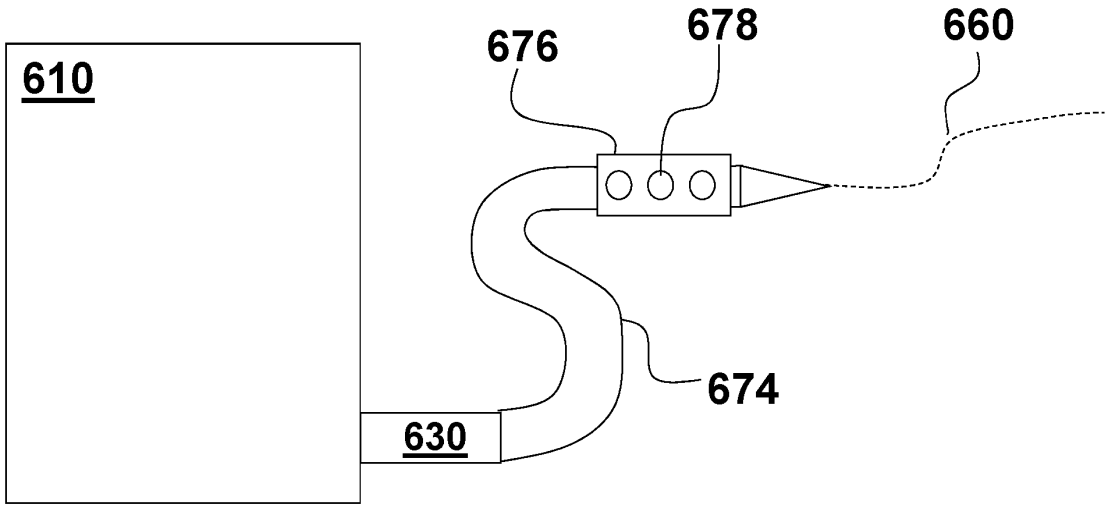
610
676
678
660
674
630

FIG. 56

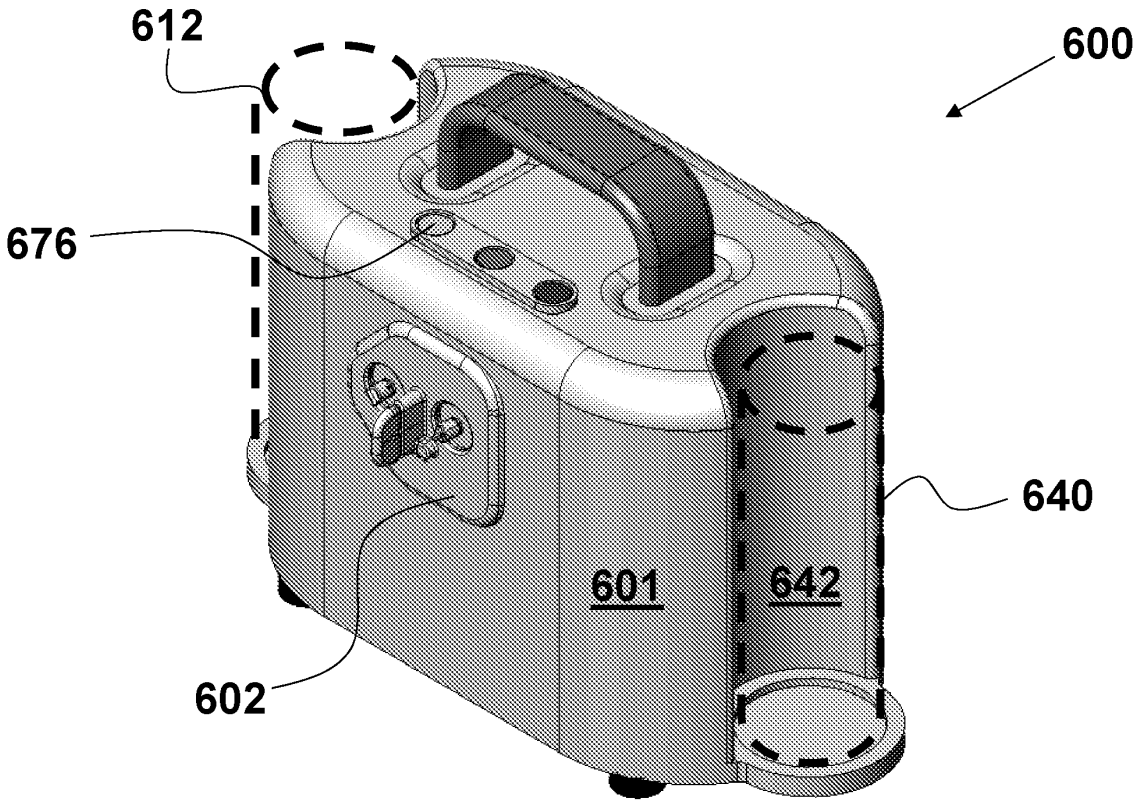

FIG. 57

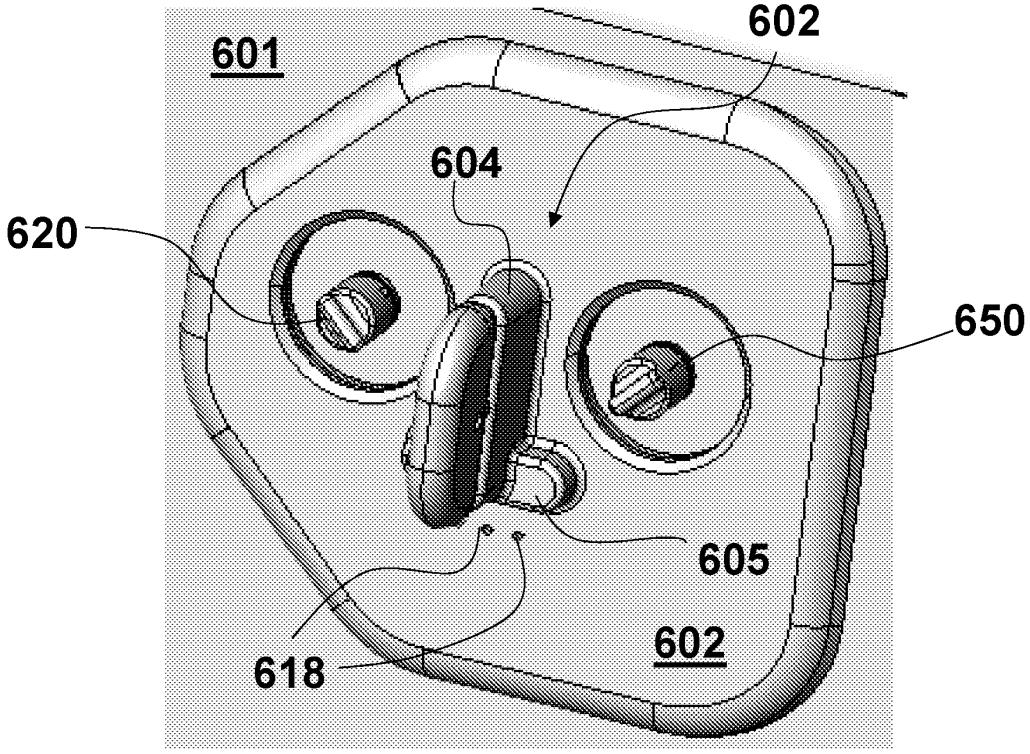

FIG. 58

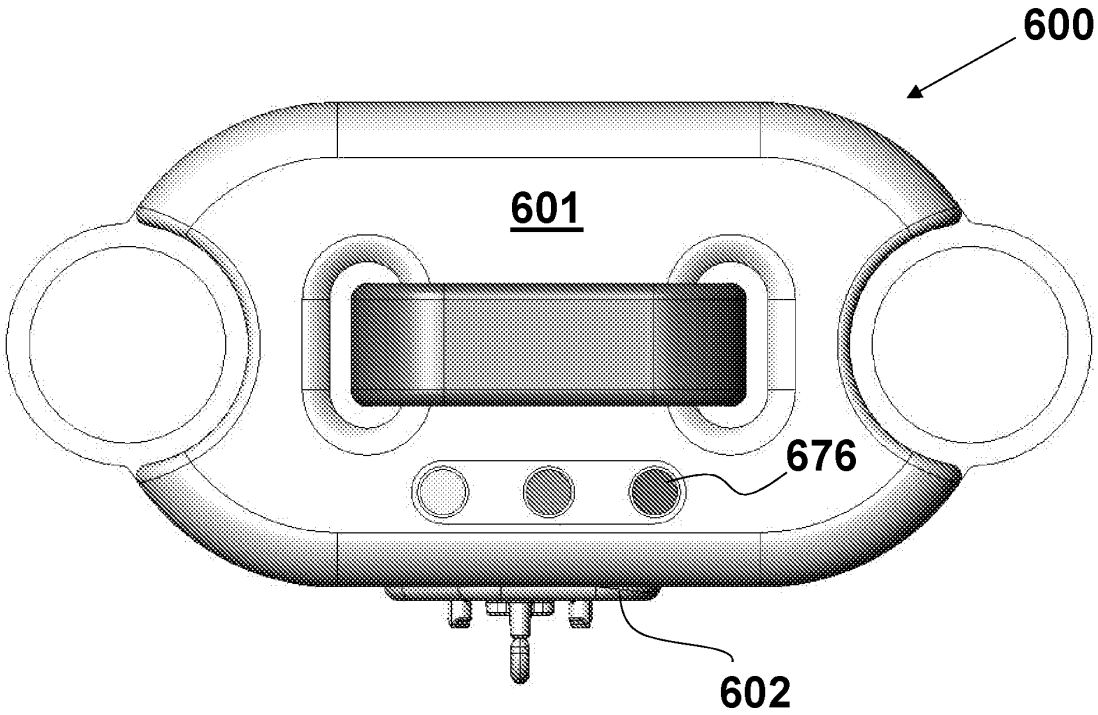

FIG. 59

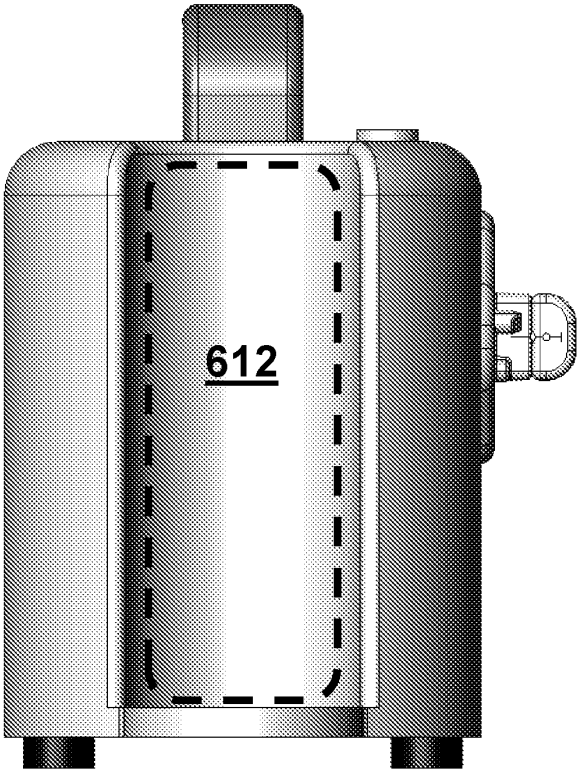

FIG. 60

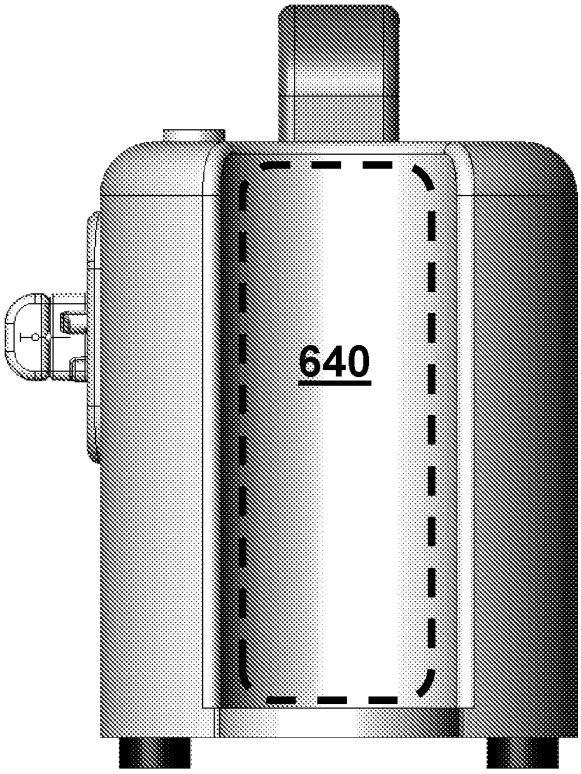

FIG. 61

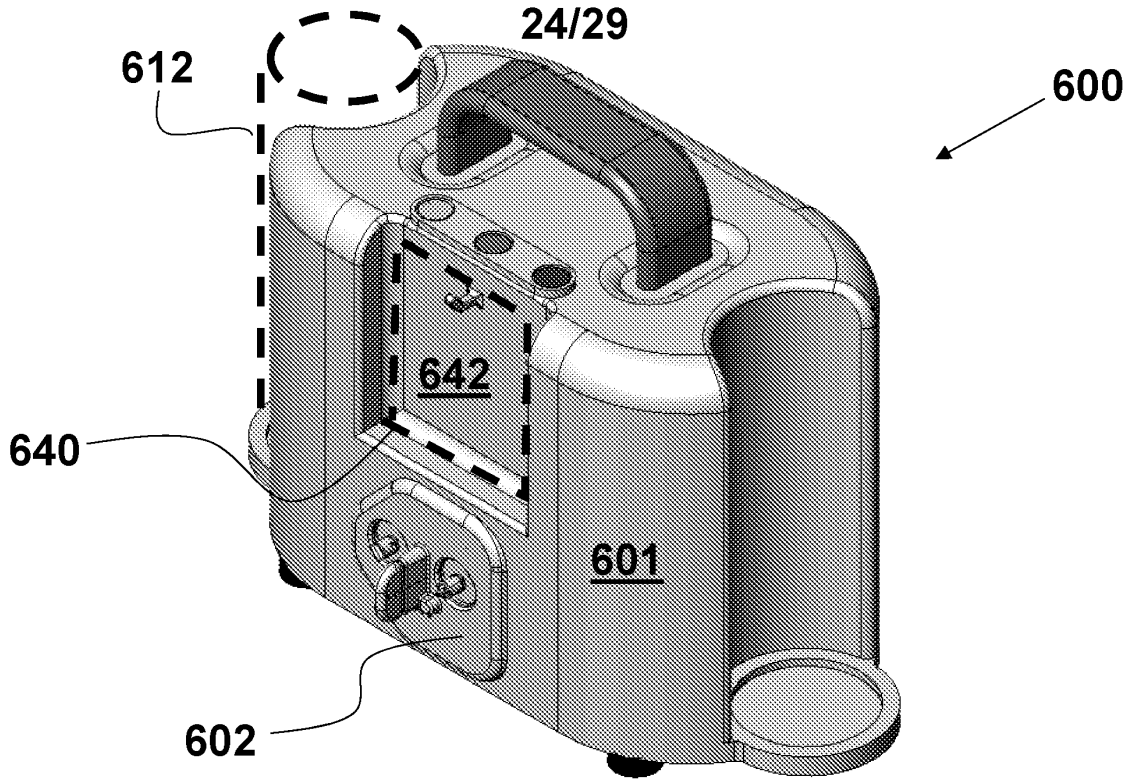

FIG. 62

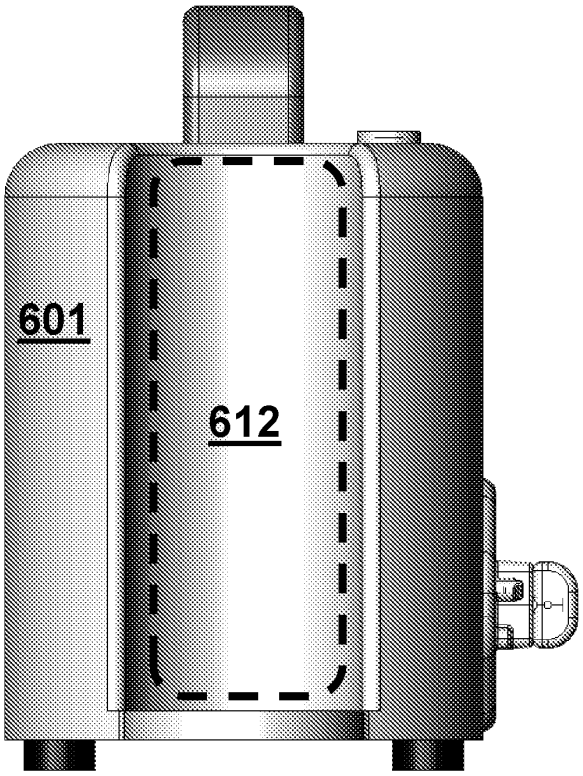

FIG. 63

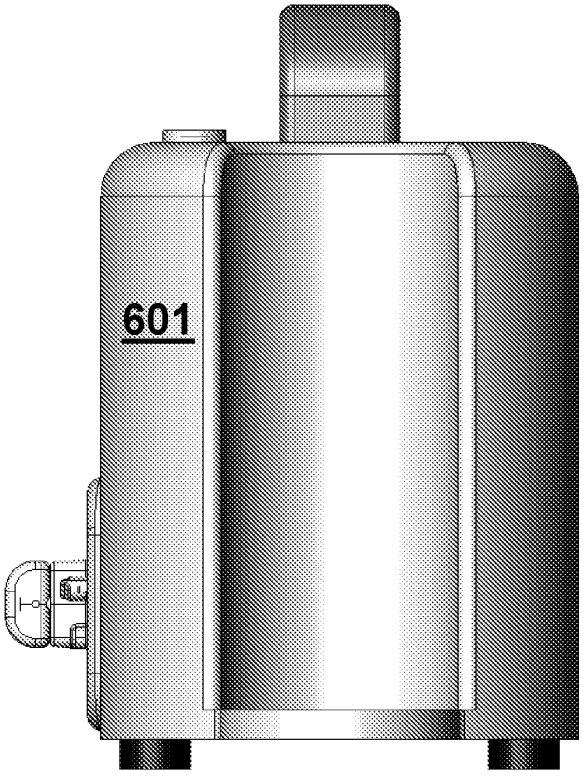

FIG. 64

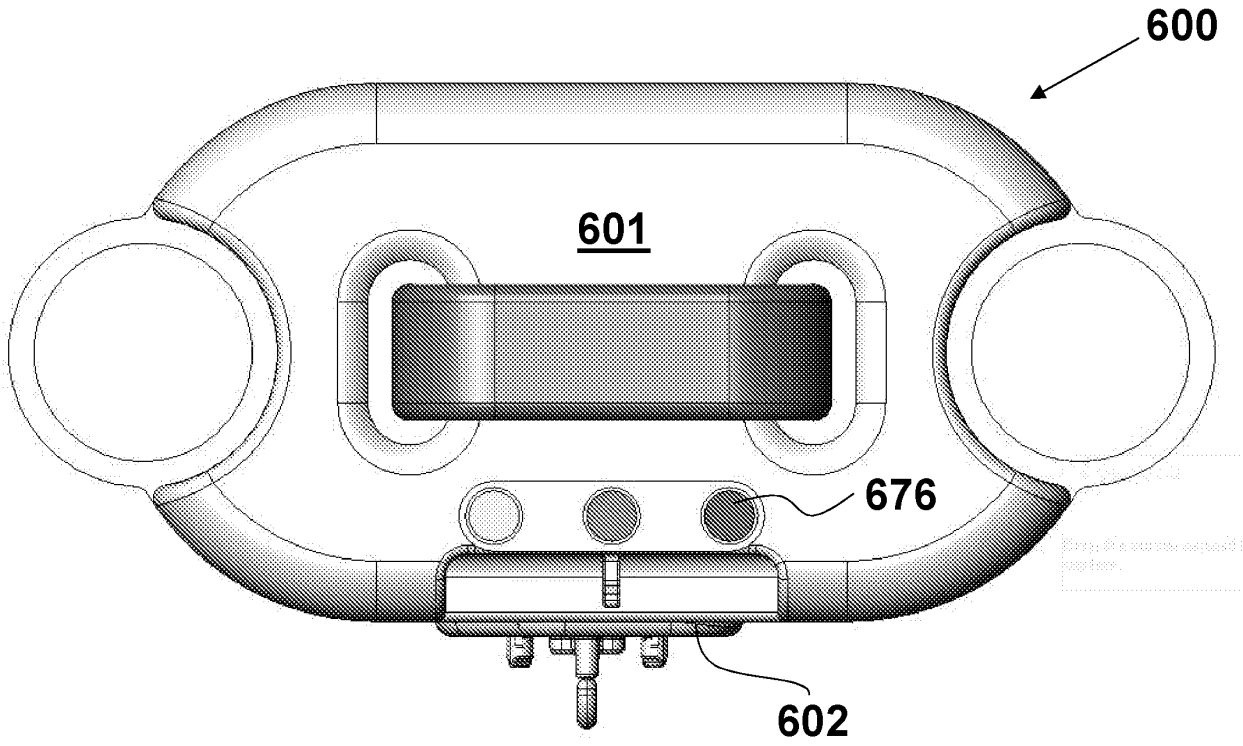

FIG. 65

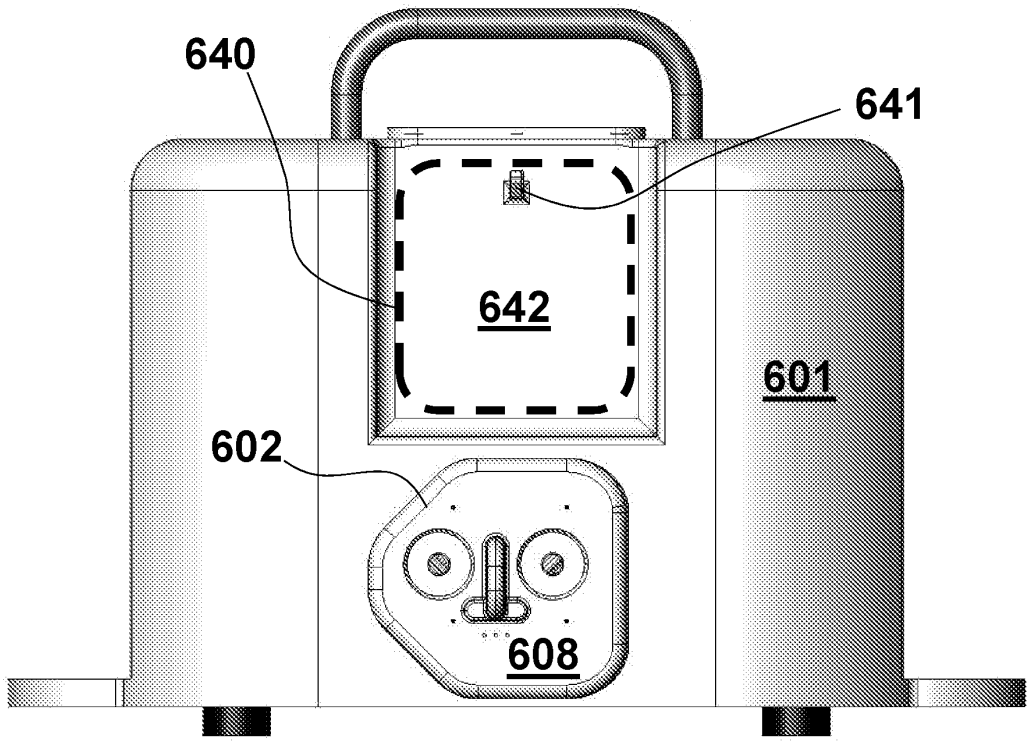

FIG. 66

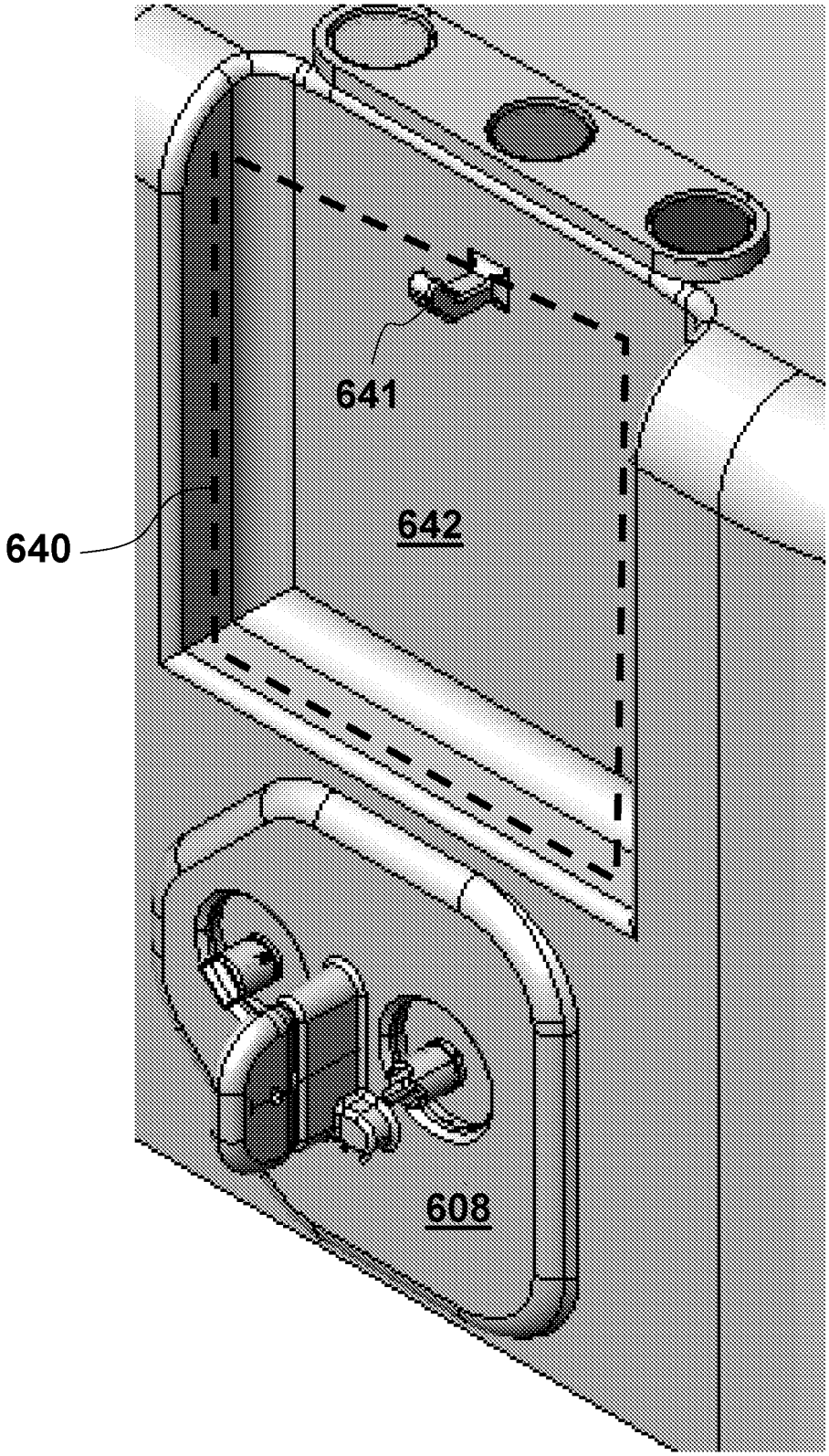

FIG. 67

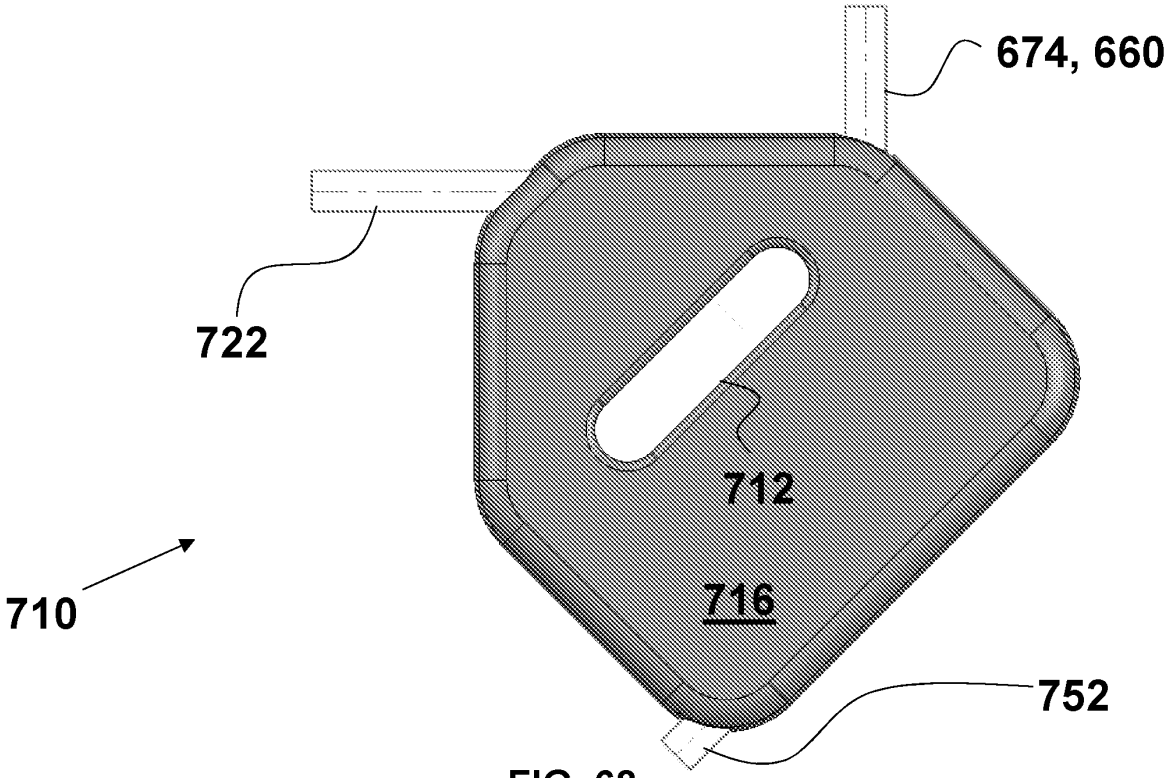

FIG. 68

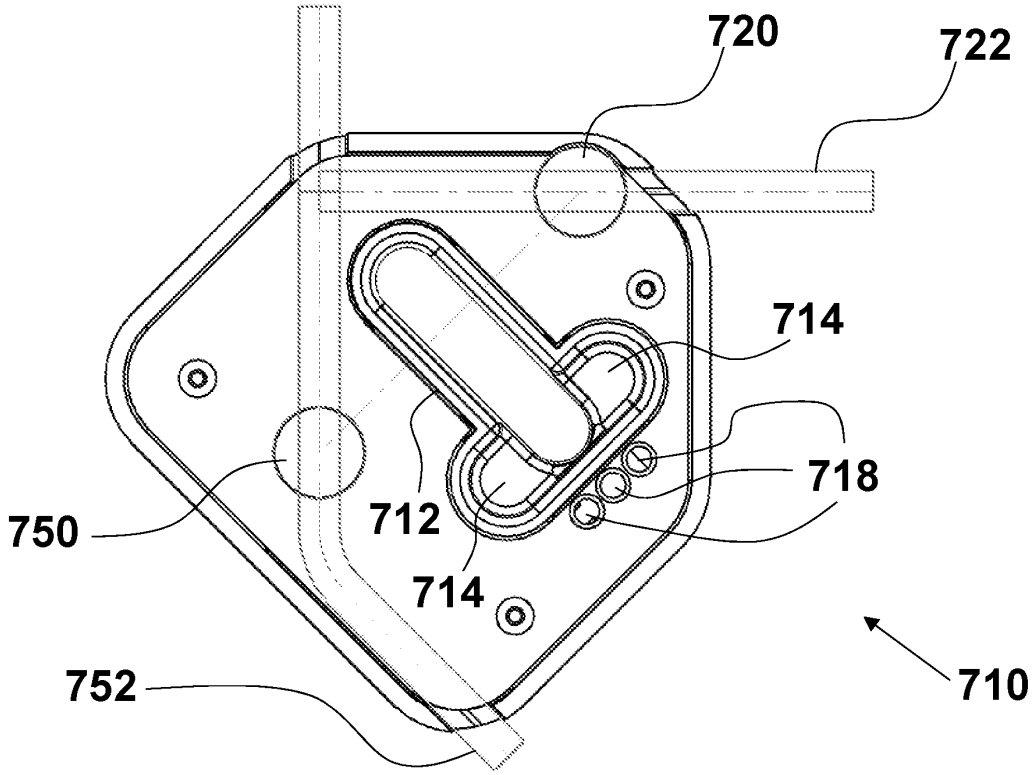

FIG. 69

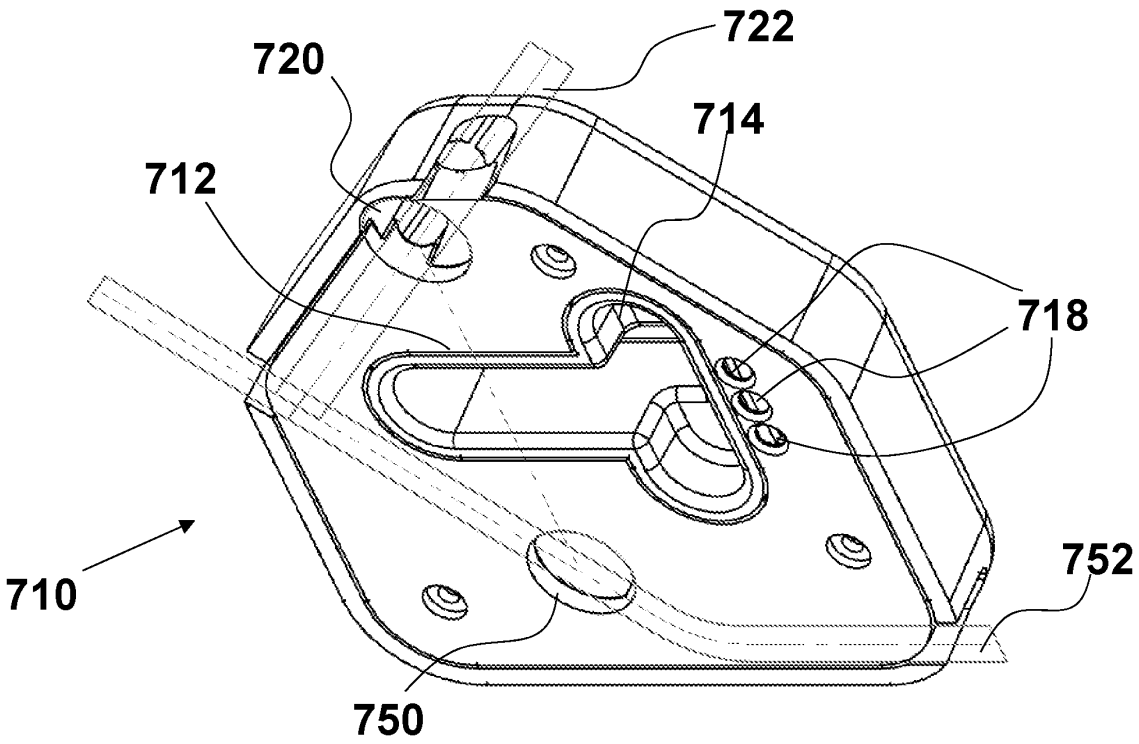

FIG. 70

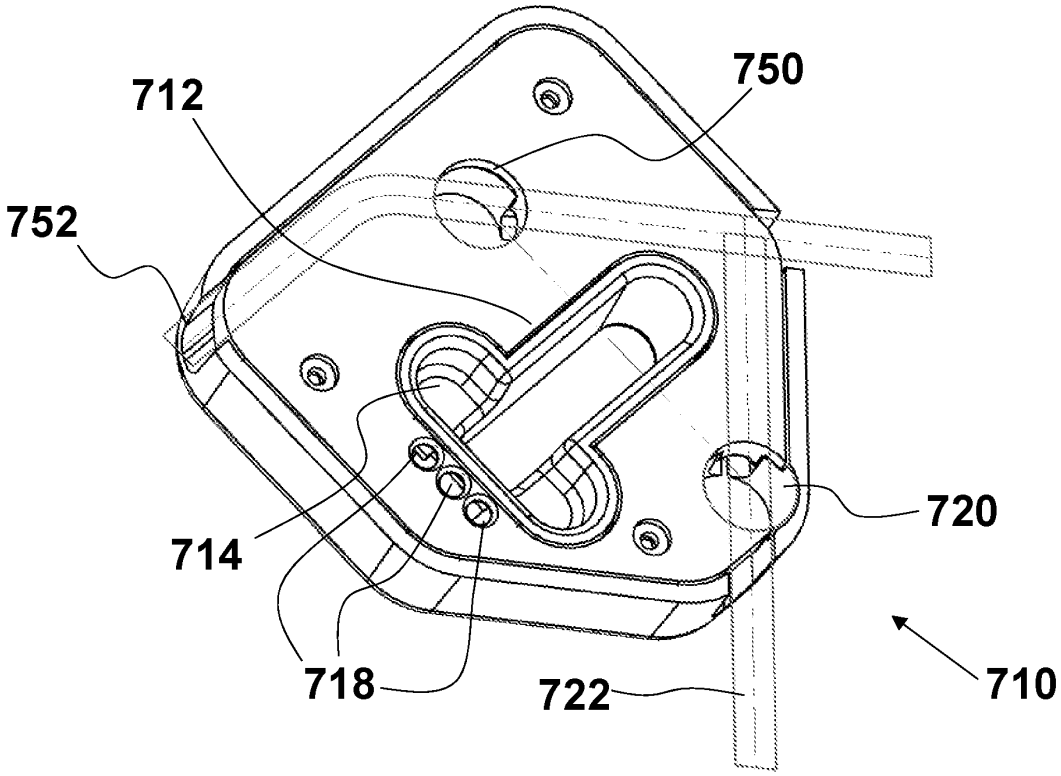

FIG. 71

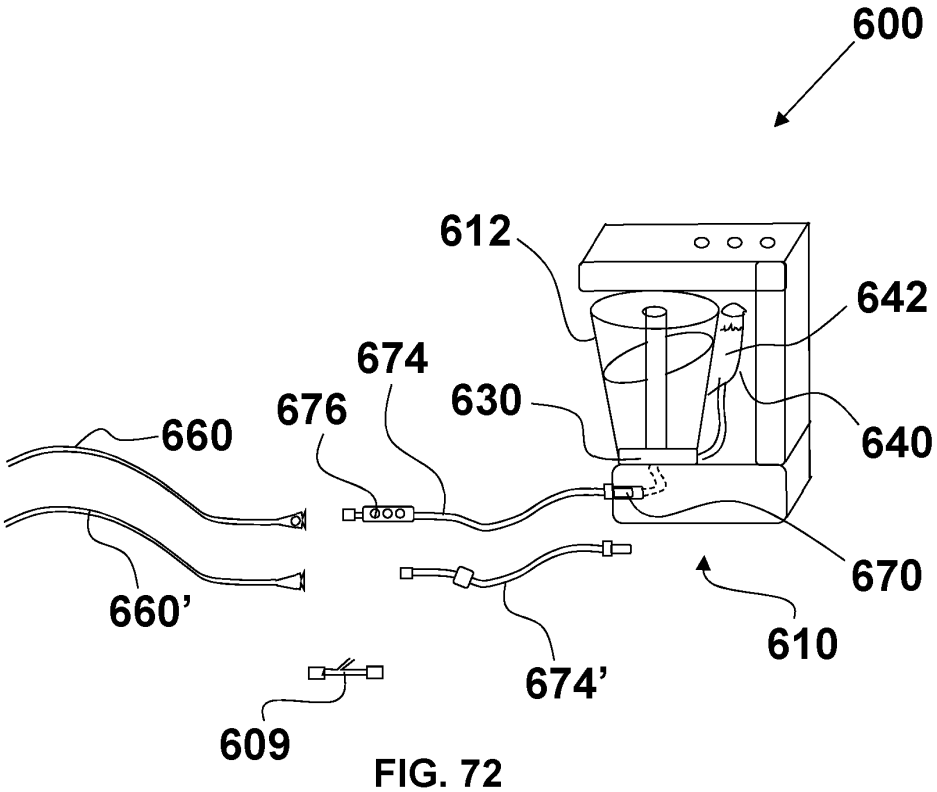

FIG. 72

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DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

Title of Invention	ASPIRATION THROMBECTOMY SYSTEM AND METHODS FOR THROMBOSIS REMOVAL WITH ASPIRATION CATHETER

As the below named inventor, I hereby declare that:

This declaration is directed to:

- [■] The attached application, or
- [ ] United States application or PCT international application number _____ filed on _____.

The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

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LEGAL NAME OF INVENTOR

Inventor: Derek Dee Deville Date (Optional): 6/9/20

Signature: _____

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

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LEGAL NAME OF INVENTOR

Inventor: Matthew A. Palmer Date (Optional): _____

Signature: _____

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LEGAL NAME OF INVENTOR

Inventor: William T. Bates Date (Optional): 06/09/2020

Signature: _____

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LEGAL NAME OF INVENTOR

Inventor: M. Sean McBrayer Date (Optional): 6/9/2020

Signature: _____

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LEGAL NAME OF INVENTOR

Inventor: Eric Petersen Date (Optional): 6/9/2020

Signature: Eric Petersen

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LEGAL NAME OF INVENTOR

Inventor: Richard Cartledge Date (Optional) :_____

Signature: _____

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I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

WARNING:

Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.

LEGAL NAME OF INVENTOR

Inventor: THOMAS O. BALES, Jr. Date (Optional): 6/9/2020

Signature: _____

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. 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 1.11 and 1.14. This collection is estimated to take 1 minute 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, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

PTO/AIA/01 (06-12)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

Title of Invention	ASPIRATION THROMBECTOMY SYSTEM AND METHODS FOR THROMBOSIS REMOVAL WITH ASPIRATION CATHETER

As the below named inventor, I hereby declare that:

This declaration is directed to:

- [■] The attached application, or
- [ ] United States application or PCT international application number _____ filed on _____.

The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

WARNING:

Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.

LEGAL NAME OF INVENTOR

Inventor: Carlos Rivera Date (Optional): 6/10/2020

Signature: _____

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. 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 1.11 and 1.14. This collection is estimated to take 1 minute 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, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
17/650,835	**02/11/2022 08:29:04 PM ET**	**145404-8001.US07**

Title of Invention

ASPIRATION THROMBECTOMY SYSTEM AND METHODS FOR THROMBUS REMOVAL WITH ASPIRATION CATHETER

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	7707	FILED BY	Jessica Raucci
PATENT CENTER #	60528906	FILING DATE	-
CUSTOMER #	25096	FIRST NAMED INVENTOR	Derek Dee Deville
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	Paul Parker

Documents

TOTAL DOCUMENTS: 7

DOCUMENT		PAGES	DESCRIPTION	SIZE (KB)
2022-02-11_ADS_1454048001US07.PDF		11	Application Data Sheet	2175 KB
2022-02-11_Track1Request_1454048001US07.PDF		2	TrackOne Request	136 KB
2022-02-11_Application_1454048001US07.PDF		98	-	515 KB
2022-02-11_Application_1454048001	(1-92)	92	Specification	492 KB

US07-SPEC.pdf				
2022-02-11_Application_1454048001US07-CLM.pdf	(93-97)	5	Claims	25 KB
2022-02-11_Application_1454048001US07-ABST.pdf	(98-98)	1	Abstract	12 KB
2022-02-11_Drawings_1454048001US07.PDF		29	Drawings-only black and white line drawings	2307 KB
2022-02-11_Declarations_1454048001US07.PDF		8	Oath or Declaration filed	875 KB

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
2022-02-11_ADS_1454048001US07.PDF	1111B3859E4DFBB06ECAACECBC62665C33331388188EE276EB7252A94D34D9CF437B8C8DA7A29C55BDE21EB4F1CB2D13142401C20D0B8B2EF5619235196545 4A
2022-02-11_Track1Request_1454048001US07.PDF	09FFF57EC140E6E723D848A7B81E946B90FF5C08E3D634C2C63C9457BB9B3A55E5EFD8604E52B0021254612CB30144BF032854E55E3E833131C652C3EFC05BE2
2022-02-11_Application_1454048001US07.PDF	74FCF17F6984288C1354784D7C77898C02E5499166664999660A12E469E6E64CABD9743ECF9CD1834D4B946521F02353D456B10DB618CEAA61597C008B5836D9
2022-02-11_Application_1454048001US07-SPEC.pdf	4676215649BCF5582AF6D1CF75C4E5804A65EE59ABAB5462D2AFF127B4B7EC3506290FC1A8379F792306E4F1717EED1A409EEDD31B4E2970A059E61B56C6D431

2022-02-11_Application_1454048001US07-CLM.pdf	223106AAEC366AD0E2326DBB84EA29967227643EFA2AFA770A387438B6BED3A3E40E34E5C847FE24F23FC9054FAC09841D5BE6387107C1BE99777922EBEE4DD4
2022-02-11_Application_1454048001US07-ABST.pdf	777B35879502BDF2EFE3D9EC27488D1AE45AD269242E1385F157D3C0C1531F6AC0F41516164D61C183CF933A090297953F91E3CFA8A3813011AB9F0800B07891
2022-02-11_Drawings_1454048001US07.PDF	080B2F382FABC8F8BD44E0ACABEBC2B3C7C427225C6D426B7B53CDC8BE225D840AEB62DEE444DD0600C88C055198813FC3C63041E98BABFF37A9827352BF83CD
2022-02-11_Declarations_1454048001US07.PDF	BBC519E4E74CEB4F60DF027F66F044AE00C670F446B1AB1B3719D7D524F025B4692E0A922CA6056246AB9E25180D46A6C838658A037C3E48922415 6B2268F6A2

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

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ELECTRONIC PAYMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
17/650,835	02/11/2022 08:29:04 PM ET	145404-8001.US07

Title of Invention

ASPIRATION THROMBECTOMY SYSTEM AND METHODS FOR THROMBUS REMOVAL WITH ASPIRATION CATHETER

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	7707	FILED BY	Jessica Raucci
PATENT CENTER #	60528906	AUTHORIZED BY	Paul Parker
CUSTOMER #	25096	FILING DATE	-
CORRESPONDENCE ADDRESS	-	FIRST NAMED INVENTOR	Derek Dee Deville

Payment Information

PAYMENT METHOD	PAYMENT TRANSACTION ID	PAYMENT AUTHORIZED BY
CARD / 8743	E20222AK30403825	Jessica Raucci

PRE-AUTHORIZED ACCOUNT	PRE-AUTHORIZED CATEGORY
500665	37 CFR 1.16 (National application filing, search, and examination fees); 37 CFR 1.17 (Patent application and reexamination processing fees); 37 CFR 1.19 (Document supply fees); 37 CFR 1.20 (Post issuance fees); 37 CFR 1.21 (Miscellaneous fees and charges)

FEE CODE	DESCRIPTION	ITEM PRICE($)	QUANTITY	ITEM TOTAL($)
2830	PROCESSING FEE, EXCEPT IN PROVISIONAL APPLICATIONS	70.00	1	70.00
2817	REQUEST FOR PRIORITIZED EXAMINATION	2100.00	1	2100.00
2111	UTILITY PATENT APPL. SEARCH FEE	350.00	1	350.00
4011	BASIC FILING FEE- UTILITY	80.00	1	80.00

2311	EXAMINATION OF ORIGINAL PATENT APPLICATION	400.00	1	400.00

TOTAL AMOUNT: **$3,000.00**

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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	145404-8001.US07
	Application Number	
Title of Invention	ASPIRATION THROMBECTOMY SYSTEM AND METHODS FOR THROMBUS REMOVAL WITH ASPIRATION CATHETER	

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.)

Inventor Information:

Inventor 1 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Derek	Dee	Deville	

Residence Information (Select One) ● US Residency ○ Non US Residency ○ Active US Military Service

City	Coral Gables	State/Province	FL	Country of Residence	US

Mailing Address of Inventor:

Address 1	6500 Oak Lane		
Address 2			
City	Coral Gables	State/Province	FL
Postal Code	33156	Country	US

Inventor 2 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Matthew	A.	Palmer	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	Miami	State/Province	FL	Country of Residence	US

Mailing Address of Inventor:

Address 1	12790 SW 64 Court		
Address 2			
City	Miami	State/Province	FL
Postal Code	33156	Country	US

Inventor 3 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	William	T.	Bales	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	145404-8001.US07
	Application Number	
Title of Invention	ASPIRATION THROMBECTOMY SYSTEM AND METHODS FOR THROMBUS REMOVAL WITH ASPIRATION CATHETER	

City	Miami	State/Province	FL	Country of Residence	US

Mailing Address of Inventor:

Address 1	7630 Southwest 54 Avenue		
Address 2			
City	Miami	State/Province	FL
Postal Code	33143	Country	US

Inventor 4 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	M.	Sean	McBrayer	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	Coral Gables	State/Province	FL	Country of Residence	US

Mailing Address of Inventor:

Address 1	6940 Sunrise Drive		
Address 2			
City	Coral Gables	State/Province	FL
Postal Code	33133	Country	US

Inventor 5 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Eric		Peterson	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	Homestead	State/Province	FL	Country of Residence	US

Mailing Address of Inventor:

Address 1	27025 Southwest 197 Avenue		
Address 2			
City	Homestead	State/Province	FL
Postal Code	33031	Country	US

Inventor 6 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Richard		Cartledge	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	Boca Raton	State/Province	FL	Country of Residence	US

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	145404-8001.US07
	Application Number	
Title of Invention	ASPIRATION THROMBECTOMY SYSTEM AND METHODS FOR THROMBUS REMOVAL WITH ASPIRATION CATHETER	

Mailing Address of Inventor:

Address 1	2268 Acorn Palm Road		
Address 2			
City	Boca Raton	**State/Province**	FL
Postal Code	33432	**Country**	US

Inventor 7 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Thomas	O.	Bales	Jr.

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	Miami	**State/Province**	FL	**Country of Residence**	US

Mailing Address of Inventor:

Address 1	4745 Southwest 80th Street		
Address 2			
City	Miami	**State/Province**	FL
Postal Code	33145	**Country**	US

Inventor 8 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Carlos		Rivera	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	Cooper City	**State/Province**	FL	**Country of Residence**	US

Mailing Address of Inventor:

Address 1	5817 Southwest 120th Avenue		
Address 2			
City	Cooper City	**State/Province**	FL
Postal Code	33330	**Country**	US

All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the **Add** button. Add

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	25096

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	145404-8001.US07
	Application Number	
Title of Invention	ASPIRATION THROMBECTOMY SYSTEM AND METHODS FOR THROMBUS REMOVAL WITH ASPIRATION CATHETER	

Email Address	patentprocurement@perkinscoie.com	Add Email	Remove Email

Application Information:

Title of the Invention	ASPIRATION THROMBECTOMY SYSTEM AND METHODS FOR THROMBUS REMOVAL WITH ASPIRATION CATHETER		
Attorney Docket Number	145404-8001.US07	**Small Entity Status Claimed**	☒
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	29	**Suggested Figure for Publication (if any)**	

Filing By Reference:

Only complete this section when filing an application by reference under 35 U.S.C. 111(c) and 37 CFR 1.57(a). Do not complete this section if application papers including a specification and any drawings are being filed. Any domestic benefit or foreign priority information must be provided in the appropriate section(s) below (i.e., "Domestic Benefit/National Stage Information" and "Foreign Priority Information").

For the purposes of a filing date under 37 CFR 1.53(b), the description and any drawings of the present application are replaced by this reference to the previously filed application, subject to conditions and requirements of 37 CFR 1.57(a).

Application number of the previously filed application	Filing date (YYYY-MM-DD)	Intellectual Property Authority or Country

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 and will not** be the subject of an application filed in another country, or under a multilateral international 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).
Either enter 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	25096		

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	145404-8001.US07
	Application Number	
Title of Invention	ASPIRATION THROMBECTOMY SYSTEM AND METHODS FOR THROMBUS REMOVAL WITH ASPIRATION CATHETER	

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, 365(c), or 386(c) or indicate National Stage entry from a PCT application. Providing benefit claim 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.
When referring to the current application, please leave the "Application Number" field blank.

Prior Application Status	Pending	Remove

Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
	Continuation of	16899514	2020-06-11

Prior Application Status	Patented	Remove

Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
16899514	Continuation of	16681564	2019-11-12	10722253	2020-07-28

Prior Application Status	Patented	Remove

Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
16681564	Continuation of	16516232	2019-07-18	10531883	2020-01-14

Prior Application Status	Expired	Remove

Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
16516232	Claims benefit of provisional	62701086	2018-07-20

Prior Application Status	Expired	Remove

Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
16516232	Claims benefit of provisional	62750011	2018-10-24

Prior Application Status	Expired	Remove

Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
16899514	Continuation of	PCT/US2019/042546	2019-07-19

Prior Application Status	Patented	Remove

Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
PCT/US2019/042546	Continuation of	16516232	2019-07-18	10531883	2020-01-14

Prior Application Status	Expired	Remove

Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
16516232	Claims benefit of provisional	62701086	2018-07-20

PTO/AIA/14 (01-22)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	145404-8001.US07
	Application Number	
Title of Invention	ASPIRATION THROMBECTOMY SYSTEM AND METHODS FOR THROMBUS REMOVAL WITH ASPIRATION CATHETER	

Prior Application Status	Expired		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
16516232	Claims benefit of provisional	62750011	2018-10-24
Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the **Add** button.			Add

Foreign Priority Information:

This section allows for the applicant to claim priority to a foreign application. 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. When priority is claimed to a foreign application that is eligible for retrieval under the priority document exchange program (PDX)[i] the information will be used by the Office to automatically attempt retrieval pursuant to 37 CFR 1.55(i)(1) and (2). Under the PDX program, applicant bears the ultimate responsibility for ensuring that a copy of the foreign application is received by the Office from the participating foreign intellectual property office, or a certified copy of the foreign priority application is filed, within the time period specified in 37 CFR 1.55(g)(1).

			Remove
Application Number	Country[i]	Filing Date (YYYY-MM-DD)	Access Code[i] (if applicable)
Additional Foreign Priority Data may be generated within this form by selecting the **Add** button.			Add

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications

☐ This application (1) claims priority to or the benefit of an application filed before March 16, 2013 and (2) also contains, or contained at any time, a claim to a claimed invention that has an effective filing date on or after March 16, 2013.
NOTE: By providing this statement under 37 CFR 1.55 or 1.78, this application, with a filing date on or after March 16, 2013, will be examined under the first inventor to file provisions of the AIA.

PTO/AIA/14 (01-22)
Approved for use through 05/31/2024. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	145404-8001.US07
	Application Number	
Title of Invention	ASPIRATION THROMBECTOMY SYSTEM AND METHODS FOR THROMBUS REMOVAL WITH ASPIRATION CATHETER	

Authorization or Opt-Out of Authorization to Permit Access:

When this Application Data Sheet is properly signed and filed with the application, applicant has provided written authority to permit a participating foreign intellectual property (IP) office access to the instant application-as-filed (see paragraph A in subsection 1 below) and the European Patent Office (EPO) access to any search results from the instant application (see paragraph B in subsection 1 below).

Should applicant choose not to provide an authorization identified in subsection 1 below, applicant **must opt-out** of the authorization by checking the corresponding box A or B or both in subsection 2 below.

NOTE: This section of the Application Data Sheet is **ONLY** reviewed and processed with the **INITIAL** filing of an application. After the initial filing of an application, an Application Data Sheet cannot be used to provide or rescind authorization for access by a foreign IP office(s). Instead, Form PTO/SB/39 or PTO/SB/69 must be used as appropriate.

1. Authorization to Permit Access by a Foreign Intellectual Property Office(s)

A. Priority Document Exchange (PDX) - Unless box A in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the European Patent Office (EPO), the Japan Patent Office (JPO), the Korean Intellectual Property Office (KIPO), the State Intellectual Property Office of the People's Republic of China (SIPO), the World Intellectual Property Organization (WIPO), and any other foreign intellectual property office participating with the USPTO in a bilateral or multilateral priority document exchange agreement in which a foreign application claiming priority to the instant patent application is filed, access to: (1) the instant patent application-as-filed and its related bibliographic data, (2) any foreign or domestic application to which priority or benefit is claimed by the instant application and its related bibliographic data, and (3) the date of filing of this Authorization. See 37 CFR 1.14(h)(1).

B. Search Results from U.S. Application to EPO - Unless box B in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the EPO access to the bibliographic data and search results from the instant patent application when a European patent application claiming priority to the instant patent application is filed. See 37 CFR 1.14(h)(2).

The applicant is reminded that the EPO's Rule 141(1) EPC (European Patent Convention) requires applicants to submit a copy of search results from the instant application without delay in a European patent application that claims priority to the instant application.

2. Opt-Out of Authorizations to Permit Access by a Foreign Intellectual Property Office(s)

☐ A. Applicant **DOES NOT** authorize the USPTO to permit a participating foreign IP office access to the instant application-as-filed. If this box is checked, the USPTO will not be providing a participating foreign IP office with any documents and information identified in subsection 1A above.

☐ B. Applicant **DOES NOT** authorize the USPTO to transmit to the EPO any search results from the instant patent application. If this box is checked, the USPTO will not be providing the EPO with search results from the instant application.

NOTE: Once the application has published or is otherwise publicly available, the USPTO may provide access to the application in accordance with 37 CFR 1.14.

PTO/AIA/14 (01-22)
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	145404-8001.US07
	Application Number	
Title of Invention	ASPIRATION THROMBECTOMY SYSTEM AND METHODS FOR THROMBUS REMOVAL WITH ASPIRATION CATHETER	

Applicant Information:

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

Applicant 1 Remove

If the applicant is the inventor (or the remaining joint inventor or inventors under 37 CFR 1.45), this section should not be completed. The information to be provided in this section is the name and address of the legal representative who is the applicant under 37 CFR 1.43; or the name and address of the assignee, person to whom the inventor is under an obligation to assign the invention, or person who otherwise shows sufficient proprietary interest in the matter who is the applicant under 37 CFR 1.46. If the applicant is an applicant under 37 CFR 1.46 (assignee, person to whom the inventor is obligated to assign, or person who otherwise shows sufficient proprietary interest) together with one or more joint inventors, then the joint inventor or inventors who are also the applicant should be identified in this section.

Clear

● Assignee	Legal Representative under 35 U.S.C. 117	Joint Inventor
Person to whom the inventor is obligated to assign.	Person who shows sufficient proprietary interest	

If applicant is the legal representative, indicate the authority to file the patent application, the inventor is:

Name of the Deceased or Legally Incapacitated Inventor:

If the Applicant is an Organization check here. ☒

Organization Name	RapidPulse, Inc.		
Mailing Address Information For Applicant:			
Address 1	13755 Southwest 119th Avenue		
Address 2			
City	Miami	**State/Province**	FL
Country	US	Postal Code	33186
Phone Number		Fax Number	
Email Address			

Additional Applicant Data may be generated within this form by selecting the Add button. Add

Assignee Information including Non-Applicant Assignee Information:

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

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Assignee 1

Complete this section if assignee information, including non-applicant assignee information, is desired to be included on the patent application publication. An assignee-applicant identified in the "Applicant Information" section will appear on the patent application publication as an applicant. For an assignee-applicant, complete this section only if identification as an assignee is also desired on the patent application publication.

Remove

If the Assignee or Non-Applicant Assignee is an Organization check here. ☐

Prefix	**Given Name**	Middle Name	**Family Name**	Suffix

Mailing Address Information For Assignee including Non-Applicant Assignee:

Address 1			
Address 2			
City		**State/Province**	
Country i		Postal Code	
Phone Number		Fax Number	
Email Address			

Additional Assignee or Non-Applicant Assignee Data may be generated within this form by selecting the Add button. Add

Signature:

Remove

NOTE: This Application Data Sheet must be signed in accordance with 37 CFR 1.33(b). **However, if this Application Data Sheet is submitted with the INITIAL filing of the application and either box A or B is not checked in subsection 2 of the "Authorization or Opt-Out of Authorization to Permit Access" section, then this form must also be signed in accordance with 37 CFR 1.14(c).**

This Application Data Sheet **must** be signed by a patent practitioner if one or more of the applicants is a **juristic entity** (e.g., corporation or association). If the applicant is two or more joint inventors, this form must be signed by a patent practitioner, **all** joint inventors who are the applicant, or one or more joint inventor-applicants who have been given power of attorney (e.g., see USPTO Form PTO/AIA/81) on behalf of **all** joint inventor-applicants.

See 37 CFR 1.4(d) for the manner of making signatures and certifications.

Signature	/Paul T. Parker/			Date (YYYY-MM-DD)	2022-02-11
First Name	Paul T.	Last Name	Parker	Registration Number	38,264

Additional Signature may be generated within this form by selecting the Add button. Add

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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 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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 the Freedom of Information Act requires disclosure of these records.

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 CooperationTreaty.

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 inspections 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.