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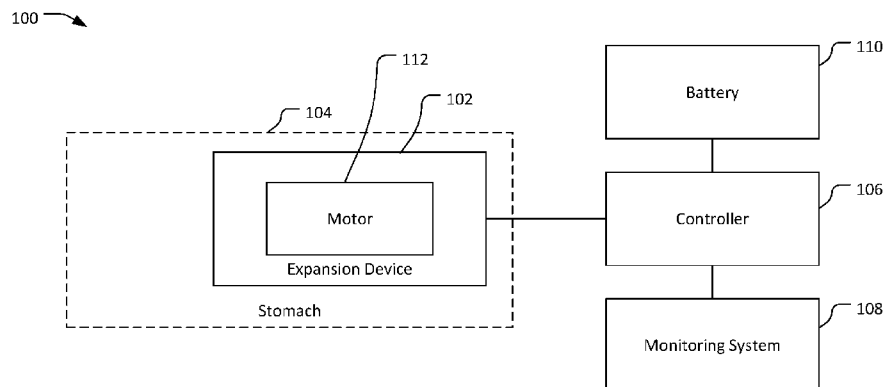


FIG. 1

(57) Abstract: Disclosed are systems and methods for dynamic occupational satiety stimulation. The system includes a device that includes at least one outer arm, a motor, and a controller that operates the motor to actuate the at least one outer arm. The controller operates the motor to pre-prandially extend the at least one outer arm away from a body of the device, and the controller further operates the motor to post-prandially contract the at least one outer arm.

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FEEDING BEHAVIOR CHANGE INDUCED BY DYNAMIC OCCUPATIONAL SATIETY STIMULATOR

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority to U.S. Provisional Patent Application No. 63/523,903, filed on June 28, 2023, which is incorporated herein by reference in its entirety.

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH

[0002] Not Applicable

BACKGROUND

[0003] The present disclosure relates generally to systems and methods for dynamic satiety stimulation. More specifically, the present disclosure relates to systems and methods for dynamically stimulating satiation by occupying a volume of a subject's stomach during feeding to reduce food intake and obesity.

[0004] Obesity is a global health concern, with a rising prevalence that poses substantial social and economic challenges. It is often managed clinically through a combination of behavioral interventions, surgical and endoscopic interventions, and pharmacotherapy. However, each of these conventional interventions have been shown to have limitations that limit their long-term efficacy. For example, traditional diet and exercise treatments have been shown to have poor weight loss efficacy and often result in complete weight regain within 3-5 years. In contrast, bariatric surgeries (*e.g.*, sleeve gastrectomy, Jejunoileal Bypass, Vertical Gastroplasty, Gastric Banding, and Roux-en-Y Gastric Bypass) have been shown, to result in total weight loss of over 25% after 12 months, or effective weight loss of over 40%. However, the invasive nature and potential for severe complications of these procedures limit their application.

[0005] Moreover, oral pharmacological therapies (*e.g.*, Xenical, Qsymia, and Contrave, must be taken daily and result in a low total weight loss of 5-10% over the course of 52-56 weeks). Similarly, injectable drugs, such as, *e.g.*, Saxenda, Wegovy, and IMCIVREE require frequent dosing and result in a low total weight loss of 6-12.5% in a year. Further, endoscopic interventions, such as, *e.g.*, intragastric balloon and endoscopic suturing, can result in 25-40% effective weight loss in 6-12 months. The lower weight loss efficacy, in comparison to bariatric surgeries, has prevented endoscopic interventions from being a widely adopted as a viable obesity treatment alternative. In addition, static intragastric balloons, which maintain a constant volume, typically result in accommodation and plateauing of weight loss in large mammals, thus limiting their long-term efficacy pertaining to weight loss.

[0006] Accordingly, there is a need for improved treatment methods to cause higher weight loss over longer periods of time and address one or more of the challenges discussed above concerning conventional static treatments.

SUMMARY

[0007] The present disclosure overcomes the aforementioned drawbacks by providing systems and methods for dynamic satiety stimulation and appetite management to treat obesity by occupying a volume of a subject's stomach with a device. By contacting and/or deflating the device after feeding (*i.e.*, postprandially), accommodation to the expanded volume of the device and weight loss plateauing can be avoided. That is, the dynamic satiety stimulation systems described herein can pre-prandially expanded and post-prandially contracted to retain the benefits of occupational satiety stimulation without experiencing a loss of stimulation over time due to accommodation. Accordingly, the present disclosure provides systems and methods of using dynamic expansion devices to maintain weight loss over time, thus offering an effective and non-invasive alternative to conventional obesity intervention techniques.

[0008] In accordance with one aspect of the disclosure, a system is provided for dynamically inducing gastric satiety in a subject. The system includes a device that includes at least one outer arm, a motor, and a controller that operates the motor to actuate the at least one outer arm. The controller operates the motor to pre-prandially extend the at least one outer arm away from a body of the device, and the controller further operates the motor to post-prandially contract the at least one outer arm.

[0009] In accordance with another aspect of the disclosure, a system is provided for dynamically inducing gastric satiety in a subject. The system includes a balloon, a percutaneous endoscopic gastrostomy (PEG) tube coupled to the balloon, a pump coupled to the PEG tube and in fluid communication with the balloon, and a valve coupled to the PEG tube and in fluid communication with the balloon. The balloon is configured to be pre-prandially inflated with the pump, and the balloon is configured to be post-prandially deflated with the valve.

[0010] In accordance with yet another aspect of the disclosure, a method of dynamically inducing gastric satiety in a subject is provided. The method includes implanting a percutaneous endoscopic gastrostomy (PEG) tube into a stomach of the subject and deploying a balloon into the stomach of the subject through the PEG tube, the balloon coupled to a pump and a valve via the PEG tube. The method further includes pre-prandially inflating the balloon with the pump to induce gastric satiety and post-prandially deflating the balloon with the valve.

[0011] The foregoing and other aspects and advantages of the present disclosure will appear from the following description. In the description, reference is made to the accompanying drawings that form a part hereof, and in which one or more embodiments are shown by way of illustration. These embodiments do not necessarily represent the full scope of the invention, however, and reference is therefore made to the claims and herein for interpreting the scope of the invention. Like reference numerals will be used to refer to like parts from Figure to Figure in the following description.

BRIEF DESCRIPTION OF THE DRAWINGS

[0012] Various objects, features, and advantages of the disclosed subject matter can be more fully appreciated with reference to the following detailed description of the disclosed subject matter when considered in connection with the following drawings, in which like reference numerals identify like elements.

[0013] FIG. 1 is a block diagram of an example dynamic satiety stimulator system, in accordance with aspects of the present disclosure.

[0014] FIG. 2 is a schematic diagram of implanting the example system of FIG. 1 within a region of interest of a subject, in accordance with aspects of the present disclosure.

[0015] FIG. 3 is an exploded view of an expansion device of the example system of FIG. 1, in accordance with aspects of the present disclosure.

[0016] FIG. 4 is a side view of the expansion device of FIG. 3 in a contracted configuration, in accordance with aspects of the present disclosure.

[0017] FIG. 5 is a perspective view of the expansion device of FIG. 3 in an expanded configuration, in accordance with aspects of the present disclosure.

[0018] FIG. 6 is an isometric view of the expansion device of FIG. 3 enclosed by an elastic cover, in accordance with aspects of the present disclosure.

[0019] FIG. 7 is a cross-sectional view of the expansion device of FIG. 6 taken through line 7-7 in FIG. 6, in accordance with aspects of the present disclosure.

[0020] FIG. 8 is a block diagram of another example dynamic satiety stimulator system, in accordance with aspects of the present disclosure.

[0021] FIG. 9 is a schematic diagram of implanting a balloon within the region of interest of a subject using a percutaneous endoscopic gastrostomy (PEG) tube, in accordance with aspects of the present disclosure.

[0022] FIG. 10 is an exploded view of a valve of the example dynamic satiety stimulator system of FIG. 8, in accordance with aspects of the present disclosure.

[0023] FIG. 11 is an isometric view of the valve of FIG. 10, in accordance with aspects of the present disclosure.

[0024] FIG. 12 is a side view of the valve of FIG. 10, in accordance with aspects of the present disclosure.

[0025] FIG. 13 is a schematic illustration view of the PEG tube of FIG. 9, in accordance with aspects of the present disclosure.

[0026] FIG. 14 is a detail view of the PEG tube of FIG. 13, in accordance with aspects of the present disclosure.

[0027] FIG. 15 is a flowchart of non-limiting example steps for a method of selectively stimulating satiety in a subject, in accordance with aspects of the present disclosure.

[0028] FIG. 16 is a flowchart of non-limiting example steps for a method of selectively stimulating satiety in a subject using a balloon system, in accordance with aspects of the present disclosure.

[0029] FIG. 17A is a free body diagram of forces on inner and outer arms of an expansion device, in accordance with aspects of the present disclosure.

[0030] FIG. 17B is a free body diagram depicting forces on a slide ring of the expansion device of FIG. 17A, in accordance with aspects of the present disclosure.

[0031] FIG. 18 is a plot illustrating actuation force of an expansion device as a function of open diameter for different inner arm lengths, in accordance with aspects of the present disclosure.

[0032] FIGS. 19A-19D are a series of free body diagrams of forces on different portions of an outer arm of an expansion device, in accordance with aspects of the present disclosure.

[0033] FIG. 20A is a plot illustrating contact angle of different covers of an expansion device as a function of open diameter, in accordance with aspects of the present disclosure.

[0034] FIG. 20B is a plot illustrating elongation ratio of different covers of an expansion device as a function of open diameter, in accordance with aspects of the present disclosure.

[0035] FIG. 21 is a plot illustrating actuator force of an expansion device with a cover as a function of open diameter, in accordance with aspects of the present disclosure.

[0036] FIG. 22 is a schematic illustration of an expansion device with a cover coupled to a control terminal, in accordance with aspects of the present disclosure.

[0037] FIG. 23A is a plot illustrating volume rate of a balloon as a function of time for different tubing lengths, in accordance with aspects of the present disclosure.

[0038] FIG. 23B is a plot illustrating balloon volume as a function of time for different tubing lengths, in accordance with aspects of the present disclosure.

[0039] FIG. 24A is a plot illustrating volume rate of a balloon as a function of time for different tubing diameters, in accordance with aspects of the present disclosure.

[0040] FIG. 24B is a plot illustrating balloon volume as a function of time for different tubing diameters, in accordance with aspects of the present disclosure.

[0041] FIG. 25A is a top plan view of an example housing for a valve of a dynamic balloon satiety stimulation system, in accordance with aspects of the present disclosure.

[0042] FIG. 25B is an isometric view of the example housing of FIG. 25A, in accordance with aspects of the present disclosure.

[0043] FIG. 26A is an isometric view of a corner tubing of a PEG tubing assembly, in accordance with aspects of the present disclosure.

[0044] FIG. 26B is schematic diagram of the corner tubing of FIG. 26A, in accordance with aspects of the present disclosure.

[0045] FIG. 26C is a schematic illustration of the PEG tubing assembly of FIG. 26A coupled to a valve in an airflow system, in accordance with aspects of the present disclosure.

[0046] FIG. 27 is a schematic illustration of an experimental setup for testing the durability of a dynamic balloon satiety stimulation system, in accordance with aspects of the present disclosure.

[0047] FIG. 28 is a detail view of a balloon expanded within a water tank of the experimental setup of FIG. 27.

[0048] FIG. 29A is an isometric view of a water sensor holder of the experimental setup of FIG. 27 including five strips, in accordance with aspects of the present disclosure.

[0049] FIG. 29B is a schematic diagram of an inner strip of the water sensor holder of FIG. 29A, in accordance with aspects of the present disclosure.

[0050] FIG. 29C is a schematic diagram of an outer strip of the water sensor holder of FIG. 29A, in accordance with aspects of the present disclosure.

[0051] FIG. 30A is a plot illustrating intra-balloon pressure over time measured in-vivo, in accordance with aspects of the present disclosure.

[0052] FIG. 30B is a plot illustrating intra-balloon pressure measured at different balloon volumes in a partition tank system, in accordance with aspects of the present disclosure.

[0053] FIGS. 31A-31C are a series of plots illustrating inflation cycle testing of condom balloons, in accordance with aspects of the present disclosure.

[0054] FIGS. 32A-32C are a series of plots illustrating inflation cycle testing of latex balloons, in accordance with aspects of the present disclosure.

[0055] FIGS. 33A-33C are a series of plots illustrating inflation cycle testing of polyvinyl chloride (PVC) balloons, in accordance with aspects of the present disclosure.

[0056] FIG. 34 is a schematic diagram of a PEG clip coupled to a PEG tube that is used to place a balloon in a subject's stomach, in accordance with aspects of the present disclosure.

[0057] FIG. 35 is a plot illustrating balloon inflation times measured with different tightness levels of the PEG clip of FIG. 34, in accordance with aspects of the present disclosure.

[0058] FIG. 36 is a top view of a printed circuit board (PCB) of an example dynamic balloon satiety stimulation system, in accordance with aspects of the present disclosure.

[0059] FIG. 37 is a schematic diagram of a circuit for controlling the example dynamic balloon satiety stimulation system of FIG. 36, in accordance with aspects of the present disclosure.

[0060] FIG. 38 is a plot illustrating balloon volume changes measured over time in vitro due to scheduled inflation cycles, in accordance with aspects of the present disclosure.

[0061] FIG. 39 is a schematic flowchart illustrating a process of assembling a dynamic balloon satiety stimulation system and performing durability testing, in accordance with aspects of the present disclosure.

[0062] FIG. 40A is a top and front isometric view of an example PEG tube cap, in accordance with aspects of the present disclosure.

[0063] FIG. 40B is a schematic diagram of the example PEG tube cap of FIG. 40A, in accordance with aspects of the present disclosure.

[0064] FIG. 40C is a bottom and front isometric view of the example PEG tube cap of FIG. 40A, in accordance with aspects of the present disclosure.

[0065] FIG. 41A is a plot illustrating expansion device diameter measured over time, in accordance with aspects of the present disclosure.

[0066] FIG. 41B is a series of schematic illustrations of a pig stomach during an expansion cycle of the expansion device of FIG. 41A, in accordance with aspects of the present disclosure.

[0067] FIG. 41C is a series of X-ray images of the expansion device of FIG. 41A in vitro during an expansion cycle, in accordance with aspects of the present disclosure.

[0068] FIG. 42A is a schematic illustration of a balloon deployed within a pig stomach via a PEG tube, in accordance with aspects of the present disclosure.

[0069] FIG. 42B is a schematic illustration of expansion of the pig stomach due to inflation of the balloon of FIG. 42A, in accordance with aspects of the present disclosure.

[0070] FIG. 43 is a plot illustrating air pressures in balloons measured over time during different test runs, in accordance with aspects of the present disclosure.

[0071] FIG. 44 is a plot illustrating changes food intake as a result of implanting a balloon within a pig's stomach and selectively inflating and deflating the balloon on a meal schedule, in accordance with aspects of the present disclosure.

DESCRIPTION

[0072] Before any aspects of the disclosure are explained in detail, it is to be understood that the present disclosure is not limited in its application to the details of construction and the arrangement of components set forth in the following description or illustrated in the following drawings. The present disclosure is readily extended to other aspects and implementations and may be practiced or carried out in various ways. Also, it is to be understood that the phraseology and terminology used herein is for the purpose of description and should not be regarded as limiting. The use of “including,” “comprising,” or “having” and variations thereof herein is meant to encompass the items listed thereafter and equivalents thereof as well as additional items. Unless specified or limited otherwise, the terms “mounted,” “connected,” “supported,” and “coupled” and variations thereof are used broadly and encompass both direct and indirect mountings, connections, supports, and couplings. Further, “connected” and “coupled” are not restricted to physical or mechanical connections or couplings.

[0073] As used herein in the context of computer implementation, unless otherwise specified or limited, the terms “component,” “system,” “module,” “controller,” “framework,” and the like are intended to encompass part or all of computer-related systems that include hardware, software, a combination of hardware and software, or software in execution. For example, a component may be, but is not limited to being, a controller device, a process being executed (or executable) by a controller device, an object, an executable, a thread of execution, a computer program, or a computer. By way of illustration, both an application running on a computer and the computer can be a component. One or more components (or system, module, and so on) may reside within a process or thread of execution, may be localized on one computer, may be distributed between two or more computers or other controller devices, or may be included within another component (or system, module, and so on).

[0074] In the methods described herein, the steps can be carried out in any order without departing from the principles of the disclosure, except when a temporal or operational sequence is explicitly recited. Recitation in a claim to the effect that first a step is performed, and then several other steps are subsequently performed, shall be taken to mean that the first step is performed before any of the other steps, but the other steps can be performed in any suitable sequence, unless a sequence is further recited within the other steps. For example, claim elements that recite “Step A, Step B, Step C, Step D, and Step E” shall be construed to mean step A is carried out first, step E is carried out last, and steps B, C, and D can be carried out in any sequence between steps A and

E, and that the sequence still falls within the literal scope of the claimed process. A given step or sub-set of steps can also be repeated.

[0075] Furthermore, specified steps can be carried out concurrently unless explicit claim language recites that they be carried out separately. For example, a claimed step of doing X and a claimed step of doing Y can be conducted simultaneously within a single operation, and the resulting process will fall within the literal scope of the claimed process.

[0076] The term “substantially” as used herein refers to a majority of, or mostly, as in at least about 50%, at least about 60%, at least about 70%, at least about 80%, at least about 90%, at least about 95%, at least about 96%, at least about 97%, at least about 98%, at least about 99%, at least about 99.5%, at least about 99.9%, at least about 99.99%, or at least about 99.999% or more.

[0077] The following discussion is presented to enable a person skilled in the art to make and use aspects of the disclosure. Various modifications to the illustrated configurations or processes will be readily apparent to those skilled in the art, and the generic principles herein can be applied to other aspects and applications within the scope of the present disclosure and the understanding of one of skill based thereon. Thus, the present disclosure is not intended to be limited to particular embodiments or aspects shown, but is to be accorded the widest scope consistent with the principles and features disclosed herein. The following detailed description is to be read with reference to the figures, in which like components or elements in different figures have like reference numerals. The figures, which are not necessarily to scale, depict selected aspects and configurations or processes and are not intended to limit the scope of the disclosure. Skilled artisans will recognize that the examples provided herein have many useful alternatives and fall within the scope of the disclosure.

[0078] In accordance with aspects of the present disclosure, mechanisms (which can, for example, include systems, methods, and media) for using dynamic and/or occupational satiety stimulation to treat obesity via appetite regulation are provided.

[0079] Generally, the present disclosure provides systems, methods, and media for using a dynamic satiety stimulation system that prevents accommodation and leads to improved long-term weight loss. Further, a dynamic satiety stimulation system can be implemented as a non-invasive solution that increases subject satisfaction and comfort in comparison with conventional surgical obesity interventions (*e.g.*, sleeve gastrectomy, Jejunioileal Bypass, Vertical Gastropasty, *etc.*). For example, a dynamic satiety stimulation system can be endoscopically positioned within a region of interest of a subject, such as a subject's stomach, and an expansion device of the system can be dynamically expanded prior to feeding (*i.e.*, pre-prandially) and contracted after feeding (*i.e.*, post-prandially). That is, the expansion device can be expanded to occupy a greater volume within the

subject's stomach to stimulate satiation and reduce food intake while eating, and the expansion device can then be contracted to prevent the subject from accommodating to the satiation stimulation provided by the expanded configuration of the expansion device. Satiation stimulation during feeding can in turn lead to post-prandial hunger suppression (*i.e.*, satiety). Accordingly, aspects of the present disclosure provide systems, methods and media for stimulating satiety within a subject to reduce overall food intake to treat obesity.

[0080] In some non-limiting examples, a dynamic satiety stimulation system may be provided as an endoscopically implantable device that is coupled to a controller and/or a monitoring system. For example, the implantable device can be surgically and/or endoscopically positioned within a subject's stomach. The controller (*e.g.*, an external controller) can be configured to operate the system to selectively expand (*e.g.*, pre-prandially) and contract (*e.g.*, post-prandially) the device such that the device occupies a variable volume within the subject's stomach. In some examples, the device contacts walls of the subject's stomach to stimulate satiety while in an expanded configuration, which in turn regulates appetite and food intake while eating. Further, the controller and/or the monitoring system can monitor the pressure and/or volume of the subject's stomach, and the monitoring system may include one or more control algorithms that the controller executes to determine when the device should be expanded and/or contracted, as will be discussed below in greater detail. Regulating food intake by stimulating satiety can lead to more effective weight loss, which helps to treat obesity. Further, the dynamic aspects of the satiety stimulation system can prevent the subject from accommodating to satiety stimulation, leading to improved weight loss over time.

[0081] In some examples, a dynamic satiety stimulation system can be implemented as a motorized expansion device that includes one or more expandable arms that can be manipulated to change the device's size and volume within a subject's stomach. In particular, an expansion device can be a capsule that is endoscopically inserted within a stomach of a subject, and the device can be coupled to an external controller. In some aspects, the controller can be configured to actuate the one or more expandable arms to pre-prandially extend outward such that the device comprises a volume within the subject's stomach. Similarly, the controller can be configured to actuate the one or more expandable arms to post-prandially contract inward to prevent the subject's stomach from accommodating to the volume of the device in the expanded configuration. To accomplish this, the device can include a motor (*e.g.*, an electric motor, a rotary motor, a brushless direct current (DC) motor, *etc.*) that is in communication with the controller, meaning that the controller can operate the motor to selectively expand and contract the expandable arms. In some aspects, the controller can be coupled to a monitoring or control system which can be configured to control

expansion/contraction of the extendable arms and stimulate satiety during feeding. For example, the monitoring system can be configured to monitor satiety by measure relevant biosignals and/or hormone levels of the subject to ensure that deployment of the device is appropriate. Therefore, using a dynamic satiety stimulation system in accordance with aspects of the present disclosure can lead to decreased food intake while preventing accommodation.

[0082] FIG. 1 illustrates a dynamic satiety stimulation system 100 to reduce food intake during feeding using a motorized expansion device 102. As discussed above, overeating can be a significant contributing factor to obesity, and appetite management can be used to reduce overall food intake. In particular, food intake can be regulated by inducing satiation (*i.e.*, inhibiting appetite) during feeding (*e.g.*, by occupying a volume of a subject's stomach and/or contacting walls of a subject's stomach). However, conventional methods of occupational satiety stimulation utilize static devices that maintain a constant volume and often result in weight loss plateauing as the subject gradually accommodates to the static occupational volume over time. In contrast the, present disclosure includes a dynamic system with a motorized expansion device 102 which can be selectively adjust a volume occupied thereby to maintain long term satiety stimulation.

[0083] With continued reference to FIG. 1, the expansion device 102 can be implanted within an area of interest of a subject (*i.e.*, a subject's stomach 104). The expansion device 102 can be coupled to a controller 106 that can be located externally with respect to the subject's stomach 104. It is contemplated that the controller 106 may be an electronic controller, a programmable logic controller (PLC), a computer, or an application specific device comprising a microprocessor, memory, and communication components, such as transceivers, wireless communication devices, *etc.* Such devices can be configured to communicate via network communications, internet protocols, through cellular communications or other types of communications included as part of the controller 106. Moreover, the controller 106 can be coupled to a monitoring system 108 and/or a battery 110, although it is contemplated that the battery 110 may be included within the expansion device 102 in some examples.

[0084] In some aspects, the expansion device 102 can comprise a variable volume that is selectively adjusted by the controller 106 and/or the monitoring system 108 in response to determining that one or more conditions have been met. The monitoring system 108 may be a passive system that records physiological activity of the subject (*e.g.*, stomach distension, gastric emptying rate, and/or other relevant parameters), or the monitoring system 108 can include one or more control algorithms that the controller 106 can execute to regulate expansion and contraction of the expansion device 102. In particular, actuation of the expansion device 102 can be performed at predetermined time intervals that are stored within the monitoring system 108. For example, an

operator can upload a predetermined meal schedule to the monitoring system 108 including directions to pre-prandially expand the expansion device 102 and post-prandially contract the expansion device 102. The monitoring system 108 may use the controller 106 to extend the expansion device 102 at predetermined meal times (*e.g.*, breakfast, lunch, and dinner) and contract the expansion device 102 after a predetermined period following each meal. An example meal schedule can include a first period where the expansion device 102 is maintained within an expanded configuration (*i.e.*, during a meal), and a second period where the expansion device 102 is maintained within a contracted state (*i.e.*, between meals). More specifically, the monitoring system 108 can store a first cycle characterized by a one-hour period in which the expansion device 102 is held in an expanded configuration followed by a four-hour period in which the expansion device 102 is held in a contracted configuration. This first cycle can be repeated three times (*i.e.*, corresponding to three meals taken at regular intervals during a single day) before being followed by a second cycle characterized by a nine-hour period in which the expansion device 102 is held in a contracted configuration (*i.e.*, corresponding to a sleep period). It is contemplated that the monitoring system 108 can be programmed to include alternative meal schedules (*e.g.*, intermittent fasting cycles, alternative fasting cycles, cycles with more than three meals a day, *etc.*).

[0085] Further, the monitoring system 108 may also be configured to record and/or analyze physiological markers of the subject related to hunger and satiety to determine when to actuate the expansion device 102. In particular, the monitoring system 108 can may be configured to detect episodic appetite signals and/or measure concentrations of appetite related arising from a subject's gastrointestinal tract, including appetite stimulating hormones (*e.g.*, ghrelin) and appetite inhibiting hormones (*e.g.*, cholecystokinin (CCK), peptide YY (PYY) and glucagon-like peptide-1 (GLP-1)). The monitoring system 108 can establish threshold values for detected appetite stimulating and/or inhibiting hormones that can be used to determine if the expansion device 102 should be expanded and/or contracted, respectively. For example, the monitoring system 108 may determine that a concentration of an appetite stimulating hormone in a subject is greater than a first threshold value, indicating that the subject is experiencing hunger. Accordingly, the monitoring system 108 can cause the controller 106 to expand the expansion device 102 to occupy a greater volume of the subject's stomach 104, thus stimulating satiation. Satiation stimulation may result in the release of appetite inhibiting hormones, and the monitoring system 108 can determine if concentrations of such appetite stimulating hormones in the subject are greater than a second threshold value. If the second threshold value is exceeded, the monitoring system 108 can cause the controller 106 to contract the expansion device 102 to prevent the subject's stomach from accommodating to the volume of the expansion device 102 in an expanded configuration. Thus, the monitoring system

108 can include a variety of control algorithms to control expansion and contraction of the expansion device 102.

[0086] With continued reference to FIG. 1, the expansion device 102 may include a motor 112 that is configured to drive the expansion device 102 to selectively expand and contract to achieve the dynamic occupation of the subject's stomach 104. In some aspects, the motor 112 is in electronic communication with the controller 106 (*e.g.*, via wired communication and/or wireless communication), and the controller 106 is configured to actuate the motor to selectively expand or contract the expansion device 102. It is contemplated that any suitable motor may be included within the expansion device 102, including, for example, brushless DC motors, coreless motors, piezo motors, servo motors, step motors, and/or any combination thereof.

[0087] Referring specifically to FIG. 2, a schematic diagram is illustrated of implanting the expansion device 102 within the stomach 104 of a subject. As discussed above, the expansion device 102 may be surgically and/or endoscopically implanted within the subject's stomach 104. Specifically, the expansion device 102 may be directly inserted into the stomach 104 via a percutaneous endoscopic gastrostomy (PEG) tube, or the expansion device 102 may be inserted into the stomach via the subject's esophagus 114. For example, the expansion device 102 may be provided as a capsule that is swallowed and deposited within the stomach 104. Thus, the expansion device 102 can be non-invasively implanted within the subject's stomach 104, which can increase patient comfort in comparison to conventional surgical implantation methods.

[0088] In some examples, an expansion device includes one or more expandable components that are configured to be selectively actuated by a motor between an expanded configuration and a contracted state to dynamically adjust a volume of the expansion device. In the non-limiting example illustrated in FIG. 2, the expansion device 102 can include a body 116 that can define a substantially cylindrical profile including a distal or first end 118 and a proximal or second end 120. Further, the expansion device 102 can include at least one outer arm 122 that is coupled (*e.g.*, via a hinge) to the body 116 at the first end 118, the at least one outer arm 122 being moveable between an expanded position and a contracted position.

[0089] Relatedly, the expansion device 102 can further include at least one inner arm 124 (*e.g.*, a rib or strut) that is coupled to the at least one outer arm 122 and a runner or slide ring 126 that is configured to slide along the body 116. That is, the motor 112 can drive the slide ring 126 to move along the body 116 toward the first end 118, which in turn causes the inner arm 124 to push the outer arm 122 outward (*i.e.*, away from the body 116), thus achieving a deployed or expanded configuration. Correspondingly, the motor 112 can drive the slide ring 126 to move along the body 116 toward the second end 120, thus causing the outer arm 122 and the inner arm 124 to contract

and return to a contracted configuration. Additional aspects of the expanded and contracted configurations of the expansion device 102 will be discussed below in greater detail. In some examples, the expansion device 102 can be maintained in the contracted configuration during implantation and can be selectively actuated between the expanded and contracted configuration after having been positioned within the stomach 104 to dynamically stimulate satiety.

[0090] Referring now to FIG. 3, an exploded view is illustrated of a non-limiting implementation of the expansion device 102. As discussed above, the at least one outer arm 122 can be coupled to the body 116 at the first end 118, and the at least one outer arm 122 can extend toward the second end 120. The body 116 may include a head 128 at the first end 118, and the at least one outer arm 122 can be coupled to the head 128. It is contemplated that the at least one outer arm 122 may be part of a plurality of outer arms (*e.g.*, between 2 and 10 outer arms). Further, the outer arm 122 may be provided as any suitable shape (*e.g.*, a rectangular arm, a triangular arm, a cylindrical arm, *etc.*). In some examples, at least one rail 130 can be coupled to the head 128 and may extend toward the second end 120. The at least one rail 130 may be provided as a fastener (*e.g.*, a threaded bolt or screw) that can be configured to couple the first end 118 of the body 116 with the second end 120 of the body 116, as will be discussed below. In the non-limiting example, the at least one rail 130 includes two rails 130 that extend between the first end 118 and the second end 120 of the body 116.

[0091] Further, the motor 112 and a central shaft 132 can be coupled to the second end 120 of the body 116, the central shaft 132 defining a central or longitudinal axis A1 and extending toward the first end 118 (see FIG. 4). In some aspects, the longitudinal axis A1 is defined by the body 116, meaning that the longitudinal axis A1 extends between the first end 118 and the second end 120. Further, the motor 112 may be integral with the second end 120 of the body 116, or the motor 112 can be removably coupled to the second end 120. The motor 112 may include a gearbox 134 that is configured to increase the output torque that is provided to the central shaft 132. To that end, the central shaft 132 can be coupled to and rotated by the motor 112, meaning that the central shaft 132 can serve as a drive shaft to actuate the expansion device 102 between the expanded and contracted configurations, as will be discussed below. In some aspects, the central shaft 132 is provided as a fastener (*e.g.*, a threaded bolt or screw) or a molded component.

[0092] Further, a housing 136 can be slipped over the motor 112, the central shaft 132, and the gearbox 134 to protect and secure the components. That is, the housing 136 can be used to retain the motor 112, the central shaft 132, and the gearbox 134 along a radial direction. In addition, a pad 138 can be coupled (*e.g.*, via adhesives, fasteners, magnets, *etc.*) to the second end 120 of the body 116 to secure the motor 112 in an axial or longitudinal direction. Put another way, the motor

112 can be axially secured between the housing 136 and the bottom pad 138. In some examples, the pad 138 can include one or more apertures 140 in which fasteners can be received to secure the pad 138 to the motor 112 and/or the housing 136. It is contemplated that the housing 136 and/or the pad 138 may be manufactured from any suitable material or combination of materials, *e.g.*, a polymer, thermoplastic polyurethane (TPU), nylon, aluminum, titanium, stainless steel, rubber, epoxy, *etc.*

[0093] With continued reference to the non-limiting example illustrated in FIG. 3, the central shaft 132 can receive the slide ring 126 thereon. Specifically, the slide ring 126 can include a bore 142 that can be sized to correspond to a diameter of the central shaft 132. In some examples, the bore 142 is threaded such that the slide ring 126 can be screwed onto the central shaft 132, or the expansion device 102 can include a threaded fastener 144 (*e.g.*, a threaded nut) that is configured to be inserted into the bore 142 before the slide ring 126 is received on the central shaft 132. That is, the threaded fastener 144 can be disposed within the bore 142 (*e.g.*, between the slide ring 126 and the central shaft 132) to allow the slide ring 126 to slide along the central shaft 132. In this way, the slide ring 126, the central shaft 132, and the threaded fastener 144 can define a lead screw mechanism in which rotational motion of the central shaft 132 (*i.e.*, rotation provided by the motor 112) can be translated into linear motion of the slide ring 126. For example, the motor 112 can be used to rotate the central shaft 132 in a first (*e.g.*, clockwise) direction to move the slide ring 126 toward the first end 118. Correspondingly, the motor 112 can be used to rotate the central shaft 132 in a second (*e.g.*, counterclockwise) direction to move the slide ring 126 toward the second end 120 of the body 116.

[0094] As discussed above, the at least one inner arm 124 is rotatably coupled to the at least one outer arm 122 and the slide ring 126. It is contemplated that the at least one inner arm 124 may be part of a plurality of inner arms (*e.g.*, between 2 and 10 inner arms), and that each inner arm 124 may be coupled to a corresponding outer arm 122. Further, the at least one inner arm 124 can be provided as any suitable shape or combination of shapes (*e.g.*, a rectangular arm, a triangular arm, a cylindrical arm, *etc.*). The at least one inner arm 124 can be configured to transfer the linear motion of the slide ring 126 (*i.e.*, linear motion caused by rotation of the central shaft 132) into an compressive and/or tensile force that can be applied on the at least one outer arm 122, as discussed below.

[0095] Referring now to FIG. 4, a side view is illustrated of the assembled expansion device 102 in the contracted configuration. As shown, the arms 122, 124 may be arranged substantially parallel with respect to the central shaft 132 in the contracted configuration, meaning that the arms 122, 124 can be compressed against the body 116 to minimize the volume of the expansion device

102. With additional reference to FIG. 2, the expansion device 102 may comprise between about 1% and about 65% of a volume of the stomach 104, or between about 1% and about 30% of a volume of the stomach 104, or between about 1% and about 10% of a volume of the stomach 104, or between about 1% and about 5% of a volume of the stomach 104, or less than about 5% of a volume of the stomach 104 in the contracted configuration.

[0096] Referring specifically to FIG. 4, the rails 130 can extend through the housing 136 and can be received within the apertures 140 defined by the pad 138, thereby holding the housing 136 and the pad 138, along with the motor 112 and the gearbox 134, in place along the axial direction (*i.e.*, a direction that is parallel with respect to the central shaft 132). In some examples, the expansion device 102 defines a first length L1 that extends between the first end 118 and the second end 120 along the axial direction, and the at least one outer arm 122 defines a second length L2 that is measured along the axial direction. In some examples, the second length L2 of the at least one outer arm 122 is between about 25% and about 100% of the first length L1 of the expansion device 102, or between about 25% and about 50% of the first length L1 of the expansion device 102, or between about 30% and about 40% of the first length L1 of the expansion device 102, or about 35% of the first length L1 of the expansion device 102.

[0097] As discussed above, the expansion device 102 can define a larger volume by expanding or deploying the at least one outer arm 122. Referring now to FIG. 5, a perspective view is illustrated of the expansion device 102 in the expanded configuration. In particular, the motor 112 can be used to rotate the central shaft 132 and slide the slide ring 126 toward the first end 118 (*i.e.*, via the lead screw mechanism). Moving the slide ring 126 toward the first end 118 can compress the at least one inner arm 124 between the at least one outer arm 122 and the slide ring 126, thus causing the inner arm 124 to rotate outward from the body 116 (*i.e.*, about a circumferential direction that is perpendicular with respect to the axial direction and the radial direction). In particular, the at least one inner arm 124 can be coupled to the slide ring 126 at a first hinge joint 146 which can allow the inner arm 124 to rotate about the circumferential direction. This rotation of the inner arm 124 can transfer the linear motion of the slide ring 126 to the outer arm 122. Specifically, the inner arm 124 can press the outer arm 122 radially outward (*i.e.*, away from the body 116) and axially upward (*i.e.*, toward the first end 118), thus expanding the outer profile of the device 102. Correspondingly, the inner arm 124 can also pull the outer arm 122 radially inward (*i.e.*, toward from the body 116) and axially downward (*i.e.*, toward the second end 120) to contract the device 102. The at least one inner arm 124 can be coupled to the at least one outer arm 122 at a second hinge joint 148 formed by the at least one outer arm 122. In some aspects, the second

hinge joint 148 can be a pin joint such that a pin 150 couples the at least one outer arm 122 to the at least one inner arm 124.

[0098] Due to the lead screw mechanism provided by the slide ring 126 and the central shaft 132, it is contemplated that the volume of the expansion device 102 in the expanded configuration can be finely tuned or adjusted as desired. That is, the expansion device 102 may be actuatable into one or more intermediate expansion states that exist between a fully expanded state and a fully contracted state. To accomplish this, the motor 112, which may be provided as a brushless DC motor and/or a step motor, can be selectively actuated to finely adjust the position of the slide ring 126 along the central shaft 132. The linear motion of the slide ring 126 causes the at least one inner arm 124 to apply a compressive and/or tensile force on the at least one outer arm 122, which can change the profile of the expansion device 102. This advantageously allows the expansion device 102 to be expanded based on the subject's particular anatomy to improve, comfort, satisfaction, and chronic implantation efficacy. With additional reference to FIG. 2, the expansion device 102 may comprise between about 1% and about 75% of a volume of the stomach 104, or between about 10% and about 50% of a volume of the stomach 104, or between about 30% and about 50% of a volume of the stomach 104, or between about 15% and about 30% of a volume of the stomach 104, or about 20% of a volume of the stomach 104, or less than about 30% of a volume of the stomach 104 in the expanded configuration.

[0099] In some examples, an expansion device can include an elastic or deformable cover that completely encloses, or encapsulates, the device to ensure the safety of the subject after implanting the device. In particular, a cover can be used to encapsulate expandable components of a device to protect tissue (*e.g.*, walls of a subject's stomach) when the device is actuated between an expanded configuration and a contracted configuration. Referring now to the non-limiting example illustrated in FIG. 6, the expansion device 102 can be encapsulated by a cover 152 that extends from the first end 118 to the second end 120. The cover 152 can be configured to protect the expansion device 102 from the harsh environment of the stomach 104 while providing a smooth surface for the expansion device 102 (*i.e.*, reducing friction with the tissue of the stomach 104, see, *e.g.*, FIG. 2). Relatedly, the cover 152 can be deformable (*i.e.*, elastic), meaning that the cover 152 can stretch and contract along with the expansion and contraction of the at least one outer arm 122. In this way, the cover 152 can maintain a tight fit around the expansion device 102 and ensure that the expansion device 102 remains in place after implantation. The elastic material of the cover 152 may also provide a degree of cushioning for the expansion device 102, which can help reduce any discomfort or irritation caused by movement of the expansion devices 102 within the stomach 104 (see FIG. 2). It is contemplated that the cover 152 can comprise any suitable material, such as, *e.g.*,

elastomers, polymers, latex, epoxy, silicone, ceramic, titanium-based alloys, zirconium-based alloys, ceramic compositions, and/or another biocompatible material.

[00100] Referring now to FIG. 7, a cross-sectional view is illustrated of the expansion device 102 enclosed by the cover 152. As shown, the cover 152 can be stretched by the at least one outer arm 122 when in the expanded state, which can increase the volume of the expansion device 102. While the cover 152 can generally define a linear path between adjacent outer arms 122, the cover 152 may be deformed inward (*i.e.*, toward the body 116) due to contact with surrounding stomach tissue. For example, stomach tissue may push the cover 152 inward such that the cover 152 defines a generally curved or arcuate path between adjacent outer arms 122, as indicated by dashed line 154. Such deformation can create an indentation angle β (*i.e.*, an angle formed between the normal linear path of the cover 152 and a line tangent to the deformed arcuate path 154 where the cover 152 contacts the at least one outer arm 122). In some examples, the material of the cover 152 has a tensile strength that is sufficient to prevent the indentation angle β from being greater than 90 degrees, which in turn can prevent tissue from being grasped or pinched by the at least one outer arm 122 during contraction. In this way, a motorized expansion device can be used to selectively stimulate satiety within a subject.

[00101] However, a dynamic satiety system can also be implemented as an intragastric balloon system including a balloon that can be selectively inflated and deflated to occupy a variable volume of a subject's stomach to stimulate satiety. Specifically, a balloon can be introduced to a subject's stomach endoscopically (*e.g.*, via a PEG tube), and a pump can be used to pre-prandially inflate the balloon and post-prandially deflate the balloon to stimulate satiety while preventing the subject from accommodating to the inflated volume of the balloon. A valve can also be used to regulate airflow within an intragastric balloon system (*e.g.*, during balloon inflation and/or deflation). In some examples, a controller can be used to selectively actuate a pump, and the controller may be coupled to a monitoring system for regulating inflation of a balloon to improve satiety stimulation efficacy, as well as subject comfort and satisfaction.

[00102] FIG. 8 illustrates another example dynamic satiety stimulation system 200 to reduce food intake during feeding using an intragastric balloon 202. In particular, the balloon 202 can be implanted within an area of interest of a subject (*i.e.*, a subject's stomach 204), and the balloon 202 can be an inflatable device that is configured to expand and contract within the stomach 204 to stimulate satiety. Accordingly, the balloon 202 may be made of a flexible and durable material (*e.g.*, latex, rubber, silicone, *etc.*) that can withstand the acidic environment of the stomach 204 and the mechanical stresses associated with inflation and deflation. In some examples, the balloon 202 may be designed to remain within the stomach for a predetermined period, such as several

weeks or months, to provide ongoing satiety stimulation. Further, the balloon 202 can be coupled to a controller 206 which can be used to selectively inflate and deflate the balloon to dynamically stimulate satiety. The controller 206 can be coupled to a monitoring system 108 that can passively record physiological activity of the subject and/or store one or more control algorithms to regulate balloon inflation. In some aspects, the controller 206 and the monitoring system 208 may be similar to the controller 106 and the monitoring system 108, respectively of the system 100 (see FIG. 1), as discussed below.

[00103] In addition, the balloon 202 can be coupled to a PEG tube 210 that can place the balloon 202 in fluid communication with a pump 212 and/or a valve 214. That is, the PEG tube 210 can serve as a fluid conduit between the balloon 202, the pump 212, and/or the valve 214. In some examples, the pump 212 can be provided as an air pump (*e.g.*, a commercially available air pump) that can be actuated to inflate the balloon 202. Correspondingly, the valve 214 can be implemented as an exhaust valve that can be closed to maintain pressure within the balloon 202 and opened to deflate the balloon 202. In some examples, the pump 212 also includes a separate exhaust valve, or the valve 214 can be incorporated within the pump 212. Further, the pump 212 and the valve 214 can be controlled by the controller 206, meaning that the pump 212 and the valve 214 can be in electronic communication with the controller 206. Similar to the controller 106 (see FIG. 1), it is contemplated that the controller 206 may be an electronic controller, a programmable logic controller (PLC), a computer, or an application specific device comprising a microprocessor, memory, and communication components, such as transceivers, wireless communication devices, *etc.* Such devices can be configured to communicate via network communications, internet protocols, through cellular communications or other types of communications included as part of the controller 206.

[00104] In some aspects, the controller 206 can be configured to switch the system 200 between a plurality of states or modes to dynamically adjust a volume of the balloon 202, prevent accommodation, and reduce power consumption. For example, the system 200 may begin in a first or setup mode to allow the system 200 to be put in place (*e.g.*, inserting the PEG tube 210, deploying the balloon 202 within the subject's stomach 204, programming the controller 206 and/or the monitoring system 208 with a feeding schedule for the subject, *etc.*). The system 200 can also include a second or snooze mode that is configured to conserve energy between active operations. The snooze mode may correspond to a time period in which the subject does not eat such as, for example, between scheduled mealtimes and/or when the subject is sleeping.

[00105] At or immediately before a scheduled feeding time (*i.e.*, pre-prandially), the controller 206 can switch the system 200 into a third or inflation mode in which the balloon 202 is inflated.

For example, the controller 206 can control the pump 212 to inflate the balloon 202 to a particular volume within the stomach 204. Specifically, the controller 206 can actuate a pump switch 216 to activate the pump 212. In some aspects, the pump switch 216 can be a power diode, a metal oxide semiconductor field-effect transistor (MOSFET), a bipolar junction transistor (BJT), a reed switch, an insulated-gate bipolar transistor (IGBT), or the like. Further, the controller 206 can keep the valve 214 closed in the inflation mode to prevent air from exiting the balloon 202. In particular, the valve 214 can include a motor 218 (*e.g.*, an electric motor, a rotary motor, a brushless direct current (DC) motor, *etc.*) that can be in electronic communication with the controller 206 such that the controller 206 can control the motor 218 to selectively open and close the valve 214, as will be discussed below in greater detail. In some examples, the controller 206 uses a control circuit 220 (*e.g.*, an H-bridge) to rotate the motor 218 in a particular direction to open or close the valve 214, the control circuit 220 being coupled to the motor 218.

[00106] Once the balloon 202 has been inflated to desired pressure and/or volume, the controller 206 can switch the system 200 into a fourth or hold mode to maintain the pressure in the balloon 202. In some aspects, the hold mode corresponds to a predetermined mealtime period (*e.g.*, one hour) such that the volume of the balloon 202 is maintained to stimulate satiation during feeding. In the hold mode, the controller 206 can turn the pump 212 off (*e.g.*, by actuating the pump switch 216) and hold the valve 214 closed to prevent air from exiting the balloon 202. After the predetermined mealtime (*i.e.*, post-prandially), the controller 206 can switch the system 200 into a fifth or deflate mode to deflate the balloon 202. Specifically, the controller 206 can keep the pump 212 turned off and activate the motor 218 to rotate in a first direction (*i.e.*, a counterclockwise or backward direction) to open the valve 214. In this way, air from the balloon 202 can be exhausted by the valve 214, thereby deflating the balloon 202 and preventing the subject from accommodating to the inflated balloon volume.

[00107] After deflation is completed, (*i.e.*, after the valve 214 is opened for a predetermined time and/or until the pressure in the balloon 202 falls below a threshold value), the controller 206 can activate the motor 218 to rotate in a second direction (*i.e.*, a clockwise or forward direction) to close the valve 214, and the controller 206 can switch system 200 back into the snooze mode to conserve power. This may be particularly advantageous if any components of the system 200 use batteries, as conserving power can increase battery life longevity. To that end, the system 200 can include one or more batteries 222 for powering the components thereof. For example, the pump 212 can be coupled to a first battery 222A and a second battery 222B, the controller 206 can be coupled to a third battery 222C, and the motor 218 can be coupled to a fourth battery 222D. In some aspects, the batteries 222 are provided as high-capacity batteries, rechargeable batteries,

lithium batteries, alkaline batteries, or any combination thereof. However, it is contemplated that any of the components of the system 200 may include wired connections to other power sources (*e.g.*, electrical outlets or portable battery packs).

[00108] With continued reference to FIG. 8, the balloon 202 can include a sensor 224 therein that can be configured to detect one or more parameters related to the inflation and deflation of the balloon 202. For example, the sensor 224 can be configured to detect air flow rate into and out of the balloon 202 and/or a pressure within the balloon 202. Accordingly, the sensor 224 may be an environmental sensor, a pressure sensor, a flow sensor, another suitable sensor, and/or any combination thereof. The sensor 224 can send digital signals to the controller 206, which can process the signals and control the operation of the system 200 based on the detected pressure. In some examples, the controller 206 provides pressure data from the sensor 224 to the monitoring system 208 to regulate inflation and deflation of the balloon 202.

[00109] As discussed above, the monitoring system 208 may be similar to the monitoring system 108 (see FIG. 1), meaning that the monitoring system 208 may be a passive system that records physiological activity of the subject and/or may include one or more control algorithms (*e.g.*, cycles corresponding to pre-set feeding schedules and/or appetite related hormone concentration) to regulate inflation and deflation of the balloon 202. In some examples, the monitoring system 208 can be programmed to include one or more pressure thresholds, such as a first or maximum pressure threshold and a second or minimum pressure threshold. In the inflation mode, the sensor 224 can continuously provide balloon pressure to the controller 206 and the monitoring system 208, and the monitoring system 208 can determine a moving average of the pressure within the balloon 202 (*e.g.*, a moving average of the latest 10 recorded pressure values) during inflation. After determining that the moving average of the pressure within the balloon 202 exceeds the first pressure threshold, the monitoring system 208 can use the controller 206 to turn off or deactivate the pump 212 and switch the system 200 into the hold mode. In this way, the monitoring system 208 can improve balloon inflation accuracy, and therefore satiety stimulation, while ensuring the safety of the subject by preventing bursting due to excessive balloon pressure.

[00110] Referring now to FIG. 9, a schematic diagram is illustrated of implanting the balloon 202 within the stomach 204 of a subject. As discussed above, the balloon 202 may be surgically and/or endoscopically implanted within the subject's stomach 204. In some aspects, the 202 may be delivered into the stomach 204 in a deflated state to facilitate its passage through the PEG tube 210. Once the balloon 202 is positioned within the stomach 204, it may be inflated to occupy a portion of the stomach's volume. The inflation of the balloon 202 may be provided by the pump 212, which can be fluidly coupled to the PEG tube 210. The pump 212 may be configured to inflate

the balloon 202 pre-prandially, thereby inducing gastric satiety by occupying a portion of the stomach's volume during feeding. After feeding, the balloon 202 may be deflated (*e.g.*, by opening the valve 214, see FIG. 8) to reduce the occupied volume within the stomach 204. This dynamic inflation and deflation of the balloon 202 may induce gastric satiety by occupying a portion of the stomach's volume during feeding and then reducing the occupied volume after feeding, thereby preventing the stomach 204 from accommodating to the fully expanded volume of the balloon 202.

[00111] When deflated, the balloon 202 may be configured to occupy between about 1% and about 25% of a volume of the stomach 204, or between about 1% and about 10% of a volume of the stomach 204, or between about 1% and about 5% of a volume of the stomach 104, or less than about 5% of a volume of the stomach 204. When inflated, the balloon 202 may comprise between about 10% and about 75% of a volume of the stomach 204, or between about 10% and about 50% of a volume of the stomach 204, or between about 15% and about 30% of a volume of the stomach 204, or about 20% of a volume of the stomach 204, or less than about 30% of a volume of the stomach 204.

[00112] As discussed above, a balloon in a dynamic satiety stimulation system can be deflated by using a motor to open a valve that is in fluid communication with the balloon. In some aspects, a valve can be a valve assembly including a motor that can be used to move a piston within a valve body to selectively block or unblock an aperture defined by a housing. Referring to FIGS. 10 and 11, a non-limiting example is illustrated of the valve 214 (*e.g.*, a valve assembly), which includes the motor 218. The valve 214 can further include a piston 226 coupled to the motor 218, a housing 228 that at least partially encases the piston 226, and a cap 230 coupled to the housing 228. The motor 218 can define a first end 232 of the valve 214, and the cap 230 can define a second end 234 of the valve 214 opposite the first end 232. In some examples, the motor 218 is an electric motor (*e.g.*, a brushless DC motor) that is capable of rotating in two directions (*i.e.*, clockwise and counterclockwise). As illustrated in FIG. 10, the motor 218 can include a shaft 236 that extends toward the second end 234, the shaft 236 being rotatable by the motor 218. The shaft 236 may be integral with the motor 218, or the motor 218 and the shaft 236 can be formed as a separate components.

[00113] Further, the shaft 236 can be received within a first bore 238 defined by the piston 226. Thus, rotational motion of the shaft 236 (*i.e.*, rotation provided by the motor 218) can be transferred to the piston 226 to adjust a position of the piston 226 within the valve 214. To that end, the piston 226 may be a threaded component (*e.g.*, a screw or bolt) that includes threads 240 on an outer surface thereof. Relatedly, the housing 228 can include a second bore 242 that extends longitudinally therethrough, and the piston 226 can be received at least partially within the second

bore 242. In some examples, the second bore 242 can also be threaded, meaning that the second bore 242 can define grooves 244 to engage with the threads 240 of the piston 226. Accordingly, the piston 226 can be rotated in a first direction (*i.e.*, clockwise) within the second bore 242 to move the piston 226 closer to the second end 234 and in a second direction (*i.e.*, counterclockwise) within the second bore 242 to move the piston 226 closer to the first end 232. In some examples, the cap 230 is also threaded such that the cap 230 can also be screwed into the second bore 242 (*i.e.*, into a side of the second bore 242 opposite to the side in which the piston 226 is received). In this way, the cap 230 can serve as a bolt-stopper to prevent the piston 226 from falling out of the second bore 242.

[00114] With continued reference to FIG. 10, the housing 228 can define an aperture 246 that extends therethrough in a direction that is perpendicular with respect to the second bore 242 (*e.g.*, a radial direction). The aperture 246 can define a fluid pathway through the valve 214, and the aperture 246 can be in selective fluid communication with the balloon 202 (*e.g.*, via the PEG tube 210, see FIG. 9). To close the valve 214, the motor 218 can be rotated in the first direction to move the piston 226 toward the second end 234 and block the aperture 246, thereby preventing air from exiting the valve 214 via the aperture 246. Accordingly, the piston 226 can be configured to provide an airtight and/or watertight seal within the second bore 242 of the housing 228. Further, and as discussed above, the valve 214 can be closed during at least the inflation and hold modes. Correspondingly, the valve 214 can be opened by rotating the motor 218 in the second direction to move the piston 226 toward the first end 232 and unblock the aperture 246, thereby reestablishing the fluid communication path through the valve 214. That is, the valve 214 can be opened to allow air to be exhausted therethrough, such as during the deflation mode. Accordingly, rotation of the motor 218 can allow precise metering through the aperture 246, which in turn provides greater control over the rate of deflation of the balloon 202 and allows the valve 214 to regulate airflow in the system 200 (see FIG. 9).

[00115] Referring now to FIG. 11, the valve 214 may define a substantially cylindrical outer profile, meaning that the motor 218, the housing 228, and the cap 230 are substantially cylindrical. Further, the housing 228 can serve, at least partially, as a protective casing for the motor 218 and the piston 226, thereby ensuring proper alignment and operation of the valve 214. Moreover, the motor 218, the housing 228, and the cap 230 may each be made of a durable and biocompatible material that can withstand the mechanical stresses associated with the operation of the valve 214. For example, the motor 218, the housing 228, and the cap 230 may each comprise a polymer, thermoplastic polyurethane (TPU), nylon, aluminum, titanium, stainless steel, rubber, epoxy, and/or any combination thereof.

[00116] Referring now to FIG. 12, the valve 214 may include one or more additional protective components to ensuring proper alignment and operation of its components. As discussed above, the motor 218 may draw power from a variety of power sources, including the batteries 222 (see FIG. 8) and/or a wired power source. In the illustrated non-limiting example, the motor 218 is coupled to wires 248 at the first end 232 of the valve 214. To protect the wires 248, shrink tubing 250 can be placed over the first end 232. The shrink tubing 250 can also be used to cover the motor 218 and at least a portion of the housing 228 to align and protect the components. It is contemplated that the components of the valve 214 may be secured to one another in any suitable way, including, for example, fasteners, adhesives, magnets, epoxy, *etc.* For example, epoxy can be applied at the interface formed between the motor 218 and the housing 228, and the shrink tubing 250 can be placed over the epoxy to further secure the connection between the motor 218 and the housing 228.

[00117] Further, it is contemplated that a PEG tube may comprise any suitable shape(s) and/or material(s) to facilitate air exchange within a dynamic satiety stimulation system. In some examples, a PEG tube can include multiple branches or sections to couple different components of to one another. For example, a PEG tube may include a double lumen to place a pump in fluid communication with a valve and a balloon to allow the balloon to be selectively inflated and deflated within a subject's stomach. Referring to the non-limiting example of FIG. 13, the PEG tube 210 can include multiple tubing sections, including a first tubing section 252 defining a pump end 254, a second tubing section 256 coupled to the first tubing section 252 and defining a balloon end 258, and a third tubing section 260 coupled to the first tubing section 252 and defining a valve end 262. In some examples, the first tubing section 252 is coupled to each of the second tubing section 256 and the third tubing section 260. That is, the first and second tubing sections 252, 256 can provide a pathway for the flow of air between the pump end 254 and the balloon end 258 (*i.e.*, between the balloon 202 and the pump 212), and the first and third tubing sections 252, 260 can provide a pathway for the flow of air between the pump end 254 and the valve end 262 (*i.e.*, between the pump 212 and the valve 214, see FIG. 8). To establish these fluid pathways, the first tubing section 252 may define a double lumen to receive portions of the second and third tubing sections 256, 260.

[00118] FIG. 14 illustrates a detail view of the interface between the tubing sections 252, 256, 260, with the first tubing section 252 depicted as being transparent. The first tubing section 252 may define a larger diameter than the second and third tubing sections 256, 260, which allows the second and third tubing sections 256, 260 to be at least partially inserted into the first tubing section 252. In some examples, the first tubing section 252 is bifurcated to define a double lumen. In particular, the second tubing section 256 can be coupled to a first channel or lumen 264 defined by

the first tubing section 252, and the third tubing section 260 can be coupled to a second channel or lumen 266 defined by the first tubing section 252. This configuration can allow for the separate and controlled flow of air through each tubing section, facilitating the precise operation of the system. However, in some examples, the first tubing section 252 may include a single lumen such that the second and third tubing sections 256, 260 are coupled to the same single lumen defined by the first tubing section 252.

[00119] FIG. 15 illustrates a method of dynamically expanding and contracting a device within a region of interest of a subject (*e.g.*, a subject's stomach) to stimulate satiety and reduce food intake during feeding, according to some aspects of the present disclosure. As discussed above, obesity can be managed by reducing total caloric intake, which can be achieved by reducing the amount of food eaten during meals. To help a subject reduce their food intake, a device can be placed within a subject's stomach and expanded to occupy a portion of the stomach. Contact with walls of the stomach can release appetite suppressing hormones, thus stimulating satiety. Further, dynamically adjusting the volume of the device within the subject's stomach can prevent the subject from accommodating to the expanded volume of the device, which can improve weight loss over time in comparison with conventional static occupational satiety stimulation techniques.

[00120] For example, a process 300 of stimulating satiety with an implantable device can include first placing the device within a region of interest of the subject at step 302. As discussed above, a device may be implanted surgically, endoscopically (*e.g.*, via a subject's esophagus or a small incision made in the subject's abdomen), or via a capsule that a subject swallows. In particular, a device may be implanted through a PEG tube that is inserted into a subject's stomach. At step 304, the process 300 can include pre-prandially expanding the device to occupy a volume of the subject's stomach and induce satiation during feeding. In some aspects, pre-prandially expanding the device can include a variety of sub-steps to execute one or more control processes (*e.g.*, pre-programmed meal time schedules, threshold exceeding concentrations of appetite stimulating hormones, threshold exceeding pressures, manual expansion, *etc.*) to confirm that expansion is appropriate. Accordingly, the process 300 may further include detecting and analyzing parameters related to the device and/or the subject's stomach to determine if expansion is appropriate. In addition, pre-prandially expanding the device may include actuating a combination of switches, valves, and/or motors to achieve a desired volume. The device can be held in an expanded state during feeding and/or for a predetermined time period (*e.g.*, one hour).

[00121] At step 306, the process 300 can include post-prandially contracting the device to prevent the subject's stomach from accommodating to the expanded volume of the device. In some aspects, the device is contracted after a predetermined time has elapsed from expansion (*e.g.*, one

hour), or the device can be contracted after determining a concentration of appetite suppressing hormones in the subject exceeds a threshold level. That is, the device can be contracted after the subject feels satiated, thereby helping the subject to reduce their food intake. Therefore, the dynamic satiety stimulation systems disclosed herein can dynamically occupy a volume of a subject's stomach to stimulate satiety while preventing weight loss plateau due to accommodation (*i.e.*, a loss of stimulation over time). In this way, the dynamic satiety stimulation systems can improve weight loss outcomes and provide non-invasive alternatives to traditional surgical interventions to treat obesity.

[00122] It is contemplated that the process 300 may be compatible with a variety of different devices, such as the motorized expansion head and/or an intragastric balloon devices discussed above. For example, FIG. 16 illustrates a method of operating a dynamic satiety stimulation system that includes a balloon positioned within a subject's stomach to stimulate satiation during feeding, according to some aspects of the present disclosure. In some aspects, the process 400 can include first implanting a PEG tube into a stomach of the subject and deploying a balloon into the stomach through the PEG tube. As discussed above, the system may include a controller to switch the system between a variety of different modes (*e.g.*, a setup mode, a snooze mode, an inflation mode, a hold mode, and a deflation mode). Accordingly, at step 402, the process 400 can include switching the system into the setup mode, which can include implanting the PEG tube and/or deploying the balloon. Other aspects of the system can also be adjusted during the set up mode, including programming a monitoring system with one or more control algorithms (*e.g.*, establishing a mealtime schedule and/or balloon pressure threshold levels).

[00123] At step 404, the process 400 can include determining if it is time for the subject to eat (*i.e.*, mealtime). It is contemplated that mealtimes may be scheduled (*i.e.*, time periods that are pre-programmed into the monitoring system), or mealtimes may be determined based on concentrations of appetite related hormones within the subject. If the system determines that it is not mealtime, the controller can switch the system into the snooze mode at step 406. The snooze mode may be an idle or low power mode to limit power consumption. However, if the system instead determines that it is mealtime, the process 400 can include pre-prandially inflating the balloon with the pump to induce gastric satiety by switching the system into the inflation mode at step 408. In the inflation mode, the controller can turn on the pump (*e.g.*, an air pump) and hold the valve closed to allow the balloon to be inflated.

[00124] During the inflation mode, the process 400 can further include detecting a pressure within a balloon and determining a moving average of the pressure within the balloon during a predetermined time period. For example, the system can include a sensor that provides balloon

pressure data to the controller and/or the monitoring system. This balloon pressure data can be input to one or more control algorithms provided by the monitoring system. Specifically, process 400 can include determining if the moving average of the pressure within the balloon is at or above a threshold pressure, and/or determining if a predetermined time period (*e.g.*, five minutes) has elapsed since the start of inflation. If neither of these conditions are met, the system can be maintained in the inflation mode, or the process 400 can include switching the system into the hold mode at step 410 if either condition is met. That is, the controller can be used to turn the pump off and hold the valve closed to maintain a desired pressure within the balloon if a pressure threshold is reached or a predetermined time period has elapsed since the start of inflation. In some aspects, the system is maintained in the hold mode while the subject is eating or for another predetermined time period (*e.g.*, one hour).

[00125] After this time period has elapsed or the subject has finished eating, the process 400 can include post-prandially deflating the balloon with the valve by switching the system into the deflation mode at step 414. In the deflation mode, the controller can keep the pump turned off and open the valve to allow air to be exhausted from the balloon, which in turn causes the volume of the balloon to decrease. The process 400 can then return to step 404, and the steps 404, 406, 410, 412, and/or 414 can be repeated to selectively inflate and deflate the balloon to stimulate satiety and help the subject reduce overall food intake. In this way, the process 400 can increase the efficacy of balloon inflation to induce satiety by preventing the subject from accommodating to the inflated state of the balloon. Therefore, the dynamic balloon satiety stimulation system disclosed herein can dynamically occupy a volume of a subject's stomach to stimulate satiety while preventing weight loss plateau due to accommodation (*i.e.*, a loss of stimulation over time). In this way, the dynamic satiety stimulation system can improve weight loss outcomes and provide non-invasive alternatives to traditional surgical interventions to treat obesity.

EXAMPLE

[00126] To experimentally demonstrate the feasibility and advantages of the systems and methods provided herein, experimental dynamic satiety stimulation systems were created that included the architecture described above with respect to FIGS. 2 and 8.

[00127] *Example 1*

[00128] *Overview*

[00129] The obesity epidemic presents significant social and economic challenges. From 1994 to 2020, the obesity rate in the United States rose by 100%, with over 40% of the adult population now considered obese. The medical expenses associated with obesity in the U.S. alone cost more

than \$170 billion annually. The lack of an effective obesity treatment contributes to the ongoing rising obesity prevalence. Currently, there are five main categories of obesity treatments: diet and exercise, surgery, endoscopic intervention, and oral or injectable drugs. However, each approach has its own limitations.

[00130] Traditional diet and exercise treatments have been shown to have poor weight loss efficacy and often result in complete weight regain within 3-5 years. Bariatric surgeries, such as sleeve gastrectomy, Jejunioileal Bypass, Vertical Gastropasty, Gastric Banding, and Roux-en-Y Gastric Bypass, can result in total weight loss of over 25% after 12 months or effective weight loss of over 40%. However, their invasive nature and potential for severe complications limit their application. Oral drugs, such as Xenical, Qsymia, and Contrave must be taken daily and result in a low total weight loss of 5-10% over the course of 52-56 weeks. Injectable drugs, such as Saxenda, Wegovy, and IMCIVREE require frequent dosing and result in a low total weight loss of 6-12.5% in a year. Endoscopic interventions, such as intragastric balloon, endoscopic suturing, AspireAssist can result in 25-40% effective weight loss in 6-12 months. However, the lower weight loss efficacy compared to bariatric surgeries prevents endoscopic interventions from being a viable alternative. In conclusion, the current obesity treatments lack either efficacy or minimal invasiveness.

[00131] To address the need for an effective weight loss treatment with both high efficacy and minimal invasiveness, intragastric balloons, temporary balloon placed within the stomach, were considered. This procedure is minimally invasive, but its efficacy has been limited. A study on a swine model found that satiety induction was only effective in the first week after balloon placement. Over the course of the first week, food intake was reduced by 50%. However, in the following weeks, food intake increased at the same rate as the control group. A similar trend was also observed in human trials of intragastric balloons, where the effect of inducing feelings of fullness decreased over time.

[00132] This observation led to the hypothesis that the cause of the loss of efficacy was due to the accommodation of the balloon in the stomach, which resulted in a loss of stimuli. Satiety factors are released by the gastrointestinal tract and enter the bloodstream or stimulate the vagus nerve to send satiety signals to the brain. The gastric muscles relax, and the gastric cavity expands in response to ingested food, a process known as gastric accommodation. With a static placement of the balloon, the stomach is forced to accommodate the balloon's volume, resulting in the loss of stimuli. To increase the occupational satiety induction efficacy, simulating natural feeding behavior and satiety signal induction was proposed. The intragastric stimulator can be delivered via the esophagus and expand before meals and shrink back to a minimal volume after meals. Two

stimulators have been developed using motorized and balloon technology, and the functionality of these stimulators has been validated through testing on a swine model.

[00133] *Materials and Methods*

[00134] *Motorized Expansion Head*

[00135] A motorized expansion stimulator was developed as a capsule capable of being delivered endoscopically to the stomach and subsequently expanded during the meal. The mechanical model of the skeleton device and the sliding connector are shown in FIGS. 17A and 17B. The slider with a threaded inner bore A was hinged with four inner arms AB. A leadscrew was connected to a motor that spins and applies actuation force F_a on the slider, causing the four outer arms CD to expand with the displacement of the slider.

[00136] Minimizing the actuation force F_a can reduce power consumption. Actuation force F_a works against force F , which can be applied on each arm by the surrounding tissue, to expand the stomach. The expansion of the device resulted in an increased volume of the stomach and a stretched protection cover. It was assumed that the force F was applied perpendicular to the center axis of the expansion head, which applied force on the stomach wall to expand the volume. In the skeleton device, the amount of force needed was dependent on the total force needed to expand the volume (F_{vol}) and the number of arms (N_{arm}), which is four in this example. This relationship is described as:

$$F = \frac{F_{vol}}{N_{arm}} \quad (1)$$

[00137] To determine the volume force needed to expand the stomach, clinical data was used from where a balloon was inflated inside the stomach. The energy delivered by expanding the radius of the gastric cavity by dr is equal to the energy needed to expand the volume of the balloon (PdV). The volume of the gastric balloon is proportional to the square of the radius r , the length of the balloon which is lumped into a factor of α that can be obtained from the maximum volume, and diameter of the balloon placed inside the stomach ($V = \alpha r^2$). Therefore, the volume force needed to expand the stomach can be calculated as:

$$F_{vol} = P \frac{dV}{dr} = 2P\alpha r \quad \square \quad (2)$$

[00138] From the free body diagram of the slider illustrated in FIG. 17B, the actuation force (F_a) can be seen to be equal to the projection of the compression force N_{AB} to the axis of the device. For a given θ , angle ψ can be derived using Eqn. 3.

$$\psi = \sin^{-1} \left(\frac{l_{BD} \sin \theta}{l_{AB}} \right) \quad (3)$$

[00139] Angle $\phi = \pi - \theta - \psi$. In this design, $l_{AB} + l_{BD} = l_{CD}$ was set, thus at the folded state $l_{AD} = l_{CD}$. With actuation force F_a pushes the slider and expands the system, the distance slider travels is defined as stroke length $s = l_{CD} - l_{AD}$:

$$s = l_{CD} - l_{AB} \sin(\phi) / \sin(\theta) \quad (4)$$

[00140] According to the virtual work principle, the actuation force F_a and F_{total} can be related as shown in Eqn. 5:

$$F_a ds = F_{vol} \cos(\theta) l_{CD} d\theta \quad (5)$$

[00141] Utilizing the equations above equations, the below equation was derived:

$$\frac{d\theta}{ds} = \frac{1/l_{BD} + (l_{AB}^2 - (l_{CD} - s)^2 - l_{BD}^2) / (2 * l_{BD} * (s - l_{CD})^2)}{(1 - \cos(\theta))^2)^{0.5}} \quad (6)$$

[00142] Using Eqns. 2, 5 and 6, the actuation force was determined with different inner arm l_{AB} lengths at $l_{CD} = 5\text{cm}$. As shown in FIG. 18, the peak actuation force with $l_{AB} = 1, 1.5, 2\text{cm}$ is 63, 60, 104 N respectively. Further, l_{AB} is set as 1.5cm to minimize the load on the motor.

[00143] FIG. 19A illustrates a free body diagram of the outer beam, FIG. 19B illustrates a free body diagram of right part of the outer beam, FIG. 19C illustrates a free body diagram of the left part of the outer beam, and FIG. 19D illustrates a free body diagram of half of the pin at hinge point B.

[00144] After calculating the F_a , the maximum stresses within the structure were determined. The following stresses were considered: inner arm AB compression stress and buckling load, outer arm CD maximum bending stress, pin bending stress at hinge connection B, and leadscrew buckling load. These forces are depicted in FIGS. 19A-19D. Specifically, FIG. 19A illustrates a free body diagram of the outer beam, FIG. 19B illustrates a free body diagram of right part of the outer beam, FIG. 19C illustrates a free body diagram of the left part of the outer beam, and FIG. 19D illustrates a free body diagram of half of the pin at hinge point B.

[00145] The outer arm CD was modeled as a beam pivoted at D (see FIG. 19A), and parts BD and CB of the outer arm were considered separately. The torque and compression force at the cross-section was a function of x , the distance from the cross-section to the pivoted point D or B (see FIGS. 19B and 19C). Via the balance of force along the axis of actuation as shown in FIG. 19C, the compression force in the inner arm AB is:

$$N^{AB} = \frac{F_a}{\cos(\psi) N_{Arm}} \quad (7)$$

The compression stress in the arm AB is:

$$\sigma_{compression}^{AB} = \frac{N_{max}^{AB}}{A_{AB}} \quad (8)$$

The inner arm was modeled as a 1.5mm by 1.5mm square column with both ends pivoted. The buckling load was calculated from Euler's critical load equation:

$$F_{critical} = \frac{\pi^2 EI_{AB}}{l_{AB}^2} \quad (9)$$

Where E is the Young's Modulus of the material and I_{AB} is the cross-section moment of inertia whose value depends on width a and height d of the inner arm:

$$I_{AB} = \frac{ad^3}{12} \quad (10)$$

The critical compression stress considering the buckling is F_{critical}/ad. Similarly, the steel leadscrew was also considered for its buckling load:

$$F_{leadscrew} = \frac{4\pi^2 EI_{leadscrew}}{l_{leadscrew}^2} \quad (11)$$

Where I_{leadscrew} is the moment of inertia of the cross-section, the leadscrew is modeled as a column with both ends fixed, results in the factor 4 at the numerator. For BD in the outer arm, the axial force balance is:

$$N^{BD} = N^{AB} \cos(\phi) - F \sin(\theta) \quad (12)$$

The bending torque derived from free body diagram is:

$$M^{BD} = (l_{BD} - x)N^{AB} \sin(\phi) - (l_{CD} - x)F \cos(\theta) \quad (13)$$

For CB in the outer arm, the axial force balance gives the compression force:

$$N^{CB} = F \sin(\theta) \quad (14)$$

$$M^{CB} = (l_{CD} - x)F \cos(\theta) \quad (15)$$

The maximum bending stress can be derived from the following equation:

$$\sigma_{bending}^{CD} = \frac{hM_{max}^{CD}}{2I_{CD}} \quad (16)$$

Where I_{CD} is the moment of the inertia of the arm CD, whose value depends on height h and width b of the arm:

$$I_{CD} = \frac{bh^3}{12} \quad (17)$$

The compression stress in the arm CD is:

$$\sigma_{compression}^{CD} = \frac{N_{max}^{CD}}{bh} \quad (18)$$

In the calculation, the maximum stress in arm CD was defined as:

$$\sigma^{CD} = \sigma_{compression}^{CD} + \sigma_{bending}^{CD} \quad (19)$$

The maximum stresses in the connection pins at joints A and B were also determined. Half of the pin, which has a length of $2l$, was modeled as a cantilever beam under a uniform load of $NAB/2l$, as illustrated in FIG. 19D, for symmetry purposes. The torque in the pin can be obtained by:

$$M_{pin} = -\frac{(l-x)^2 N^{AB}}{2l} \quad (20)$$

The maximum bending stress in the pin can be expressed as:

$$\sigma_{pin} = \frac{r_{pin} M_{pin}^{max}}{I_{pin}} \quad (21)$$

Where r_{pin} is the radius of the pin, and the moment of inertia of the pin I_{pin} is:

$$I_{pin} = \frac{\pi r_{pin}^4}{4} \quad (22)$$

Table 1: The value of stresses in the skeleton motorized expansion head.

Parameters			
Maximum actuation force F_a (N)	60	60	60
Outer arm width b (mm)	4	4	4
Outer arm thickness h (mm)	2	2	3
Inner arm width a (mm)	2	2	2
Inner arm height d (mm)	1	1.5	1
Inner and outer arm material	Al 6061	Al 6061	Al 6061
Arms material yield strength (MPa)	240	240	240
Pin diameter at pivoted connection A r_{pin} (mm)	0.75	0.75	0.75
Pin material	Steel 304	Steel 304	Steel 304
Pin material yield strength (MPa)	250	250	250
Leadscrew length $l_{leadscrew}$ (mm)	30	30	30
Leadscrew diameter (mm)	3	2	2

Leadscrew material	Steel 304	Steel 304	Steel 304
Max inner compression stress $\sigma_{compression}^{AB}$ (MPa)	8.2	5.5	8.2
Max outer arm stress σ^{CD} (MPa)	58	58	26
Max pin stress σ_{pin} (MPa)	37	37	37
Critical stress of buckling for inner beam (MPa)	249	559	249
Critical load of buckling leadscrew (N)	17790	3514	3514
Arm strength sufficient	Yes	Yes	Yes
Pin strength sufficient	Yes	Yes	Yes
Leadscrew strength sufficient	Yes	Yes	Yes

[00146] Through this analysis, various stresses present in the system were determined. These values have been calculated and listed in Table 1 above. The yield strength of steel 304 and Al 6061 is 205 and 276 MPa. To ensure the system's strength, the following conditions can be balanced: the maximum compression strength in the inner arm can be less than the inner arm material's yield strength; the maximum compression strength in the inner arm can be less than the inner arm's critical buckling stress; the maximum stress in the outer arm can be less than the outer arm material's yield strength; the maximum stress in the connection pins can be less than the pin material's yield strength; and the maximum actuation force can be less than the leadscrew's buckling load. As shown in Table 1, any one of the three material/geometric parameter sets can provide sufficient strength.

[00147] Further, an elastic latex cover was added onto the motorized skeleton to ensure protection against fouling and gastric contents. There were two main factors to consider when evaluating the cover's performance: maximum elongation and protection for the tissue. The design was provided to ensure that the cover did not exceed its maximum elongation rate, which is between 300-650% for latex rubber. When the covered device is surrounded by the tissue, tissue may push into the cover with an indentation angle β , as illustrated in FIG. 7. When $\beta > 90^\circ$, the tissue may be positioned under the arm and may be grasped when the device collapses. The critical contact angle of safety is set at 90 degrees. This ensures that the tissue was not grasped when the device contracts. Additionally, the impact of the protective cover on the strength guidelines was also evaluated.

The tensile stress of stretching the cover is:

$$\sigma = eG \quad (23)$$

Where G is the tensile strength of the material, e is the elongation ratio. The force due to the elongation is:

$$F_{stretch} = wL\sigma \quad (24)$$

Where w is the width of the cross-section of the cover and t is the thickness. The energy cost to stretch the material is calculated using the difference between the surface area of the cover before and after stretching:

$$E_{stretch} = \int wteGL_0 de = wtL_0G \cdot \frac{1}{2}e^2 = \frac{1}{2}GtS_t e^2 = \frac{1}{2}GtS_t \left(\sqrt{\frac{S}{S_t}} - 1\right)^2 \quad (25)$$

[00148] Here the L_0 is the total length of the cross-section, S_t is the surface area in its neutral state, S is the surface area of the cover after stretching. In Eqn. 25, t was assumed to be a constant. The actuation force needed to expand with a cover was obtained by considering the contribution of pressure applied by the stomach tissue and the energy needed to stretch the cover. The area of the cover when the arm open angle is θ :

$$S_0 = l_{CD}^2 2\sqrt{2} \sin(\theta) \left(1 + 2\sin\left(\frac{\theta}{2}\right)\right) + S_t \quad (26)$$

The force needed to stretch the cover can be obtained from the virtual work principle, where the input of work is used to increase stretching energy:

$$\begin{aligned} F_{stretch} &= \frac{dE_{stretch}}{dr} = \frac{d}{dr} \left(\frac{1}{2} EtS_t \left(\sqrt{\frac{S_0}{S_t}} - 1 \right)^2 \right) \\ &= Et l_{CD} \left(1 - \sqrt{\frac{S_t}{S_0}} \right) \sqrt{2} \left(1 + \sin\left(\frac{\theta}{2}\right) + \tan(\theta) \cos\left(\frac{\theta}{2}\right) \right) \end{aligned} \quad (27)$$

Thus, the total force for the actuation calculation is:

$$F_{total} = F_{vol} + F_{stretch} \quad (28)$$

With F_{total} replacing F_{vol} in Eqn. 1 and conducting the internal stress analysis, the stresses in the new condition can be calculated. After the head expands in the stomach, the tissue will compress the cover and push into the space between the arms. The new surface area can be obtained from:

$$S = l_{CD}^2 \frac{\beta}{\sin(\beta)} 2\sqrt{2} \sin(\theta) \left(1 + 2\sin\left(\frac{\theta}{2}\right)\right) + S_t \quad (29)$$

The tissue pushed into the cover is a volume of:

$$\Delta V = \left(\frac{2}{3} + 2\sqrt{2} \sin(\theta) \right) l_{CD}^3 \sin^2(\theta) \frac{\beta - \sin(2\beta)/2}{\sin^2(\beta)} \quad (30)$$

By assuming S_i is relatively small and can be dropped when calculating $\sqrt{\frac{S}{S_0}}$, the elongation ratio

where S_0 is used as the new neutral state is:

$$\sqrt{\frac{S}{S_0}} - 1 \approx \sqrt{\frac{\beta}{\sin(\beta)}} - 1 \quad (31)$$

$$P\Delta V = \frac{1}{2}EtS_0\left(\sqrt{\frac{S}{S_0}} - 1\right)^2 \quad (32)$$

$$\frac{P\left(\frac{2}{3} + 2\sqrt{2}\sin(\theta)\right)l_{CD}\sin(\theta)}{\sqrt{2}Et(1 + 2\sin(\theta/2))} = \left(\sqrt{\frac{\beta}{\sin(\beta)}} - 1\right)^2 / \left(\frac{\beta - \sin(2\beta)/2}{\sin^2(\beta)}\right) \quad (33)$$

In the range from 0 to $\pi/2$, the right-hand side of the equation can be approximated as:

$$\left(\sqrt{\frac{\beta}{\sin(\beta)}} - 1\right)^2 / \left(\frac{\beta - \sin(2\beta)/2}{\sin^2(\beta)}\right) \approx 0.0105\beta^3 \quad (34)$$

[00149] By calculating angle β 's and the elongation ratio as a function of opening diameter, commercially available latex rubbers were evaluated, including a condom (thickness 0.08mm) and a 646Q balloon (thickness 0.4mm). The results, illustrated in FIGS. 20A and 20B, indicated that either a single or double layer of 646Q balloon could achieve a maximum contact angle of less than 90 degrees and an elongation rate of less than 100%. Thus, a single layer of 0.4mm thick latex rubber (646Q balloon) was found to be an ideal solution, as it provided sufficient tissue protection while using the minimum amount of material. The actuation force with a single layer cover is shown in FIG. 21, with l_{AB} set as 1.5cm. With the addition of the cover, the peak actuation force was 1059N. The results of the stress analysis indicated that Titanium Ti-6Al-4V was suitable for the construction of the arms and pins to ensure sufficient strength. On the other hand, Steel 304 can be used for the leadscrew material.

Table 2: The value of stresses in a single 646Q balloon covered motorized expansion head.

Parameters		
Maximum actuation force F_a (N)	1059	1059
Outer arm width b (mm)	4	4
Outer arm thickness h (mm)	2	2
Inner arm width a (mm)	2	2

Inner arm height d (mm)	1	1
Inner and outer arm material	Al 6061	Titanium Ti-6Al-4V
Arm material yield strength (MPa)	240	880
Pin diameter at pivoted connection A r_{pin} (mm)	0.75	0.75
Pin material	Steel 304	Titanium Ti-6Al-4V
Pin material yield strength (MPa)	250	880
Leadscrew length $l_{leadscrew}$ (mm)	30	30
Leadscrew diameter (mm)	3	2
Leadscrew material	Steel 304	Steel 304
Max inner compression stress $\sigma_{compression}^{AB}$ (MPa)	130	130
Max outer arm stress σ^{CD} (MPa)	451	451
Max pin stress σ_{pin} (MPa)	562	562
Critical stress of buckling for inner beam (MPa)	249	416
Critical load of buckling leadscrew (N)	3514	3514
Arm strength sufficient	No	Yes
Pin strength sufficient	No	Yes
Leadscrew strength sufficient	Yes	Yes

[00150] In addition, efforts were made to make the device as compact as possible. To achieve this, the smallest leadscrew and motor that can provide sufficient actuation force were sought. An online calculator was used to convert actuation load into torque load, and the N20-6V DC motor is selected for its compact size and availability of gearboxes with different ratios. The leadscrew and nut were chosen to be #5-40 UNC thread. The Al6061 was selected as the prototype material due to its machinability. The Tormach 440 PCNC was used to manufacture the inner and outer arms, while the housing was 3D printed with a Formlab 3D printer. The bottom plate was cut out of a 1/8inch thick Al6061 slab using an OMAX water jet. The resulting prototype is depicted in FIG. 22, and a condom was selected as the protective cover. More details of the fabrication can be found in Table 3 below.

Table 3. Device actuation system data

Maximum load (N)	1059
Leadscrew type	#5-40 UNC
Leadscrew pitch diameter (mm)	3.175
Leadscrew pitch (mm)	0.635
Screw-nut type	Steel-Bronze
Coefficient of friction	0.04
Torque load (mN*m)	175
Motor model	N20 6V
Motor stall torque (mN*m)	0.7
Gear-box ratio	298
Output torque (mN*m)	108
Sufficient actuation	Yes

[00151] In the *ex vivo* validation, a fully-grown pig's stomach (130kg) was utilized to test the stimulator's functionality of expansion. The device was operated using an Arduino Motor Shield Rev3 and an Arduino Uno microcontroller, which are illustrated in FIG. 22. To ensure that the device could expand freely and consistently, a series of tests were conducted by holding the expand button on the terminal for intervals of 5, 10, 15, and 20 seconds, repeating three times. Subsequently, the expansion head was placed in the pig's stomach and activated the expand button for 20 seconds, followed by pressing the contract button for 20 seconds to evaluate its performance.

[00152] In the *in vivo* studies, Yorkshire swine were obtained from Cummings School of Veterinary Medicine at Tufts University (Grafton, USA) and the experiments were pre-approved by the Massachusetts Institute of Technology Committee on Animal Care. The experiments were conducted in accordance with the approved protocols and all appropriate precautions were taken to ensure the welfare of the animals. Pigs were sedated with an intramuscular injection of Midazolam 0.25mg/kg with Dexdomitor 0.03mg/kg and after intubation, anesthesia was maintained with isoflurane (1-3% in oxygen). After the experiment, pigs were returned to their pen and sedation was reversed intramuscularly with the reversal agent Atipamazole. If intubated, the pig was closely monitored until extubation and then is followed by monitoring of the recovery process until the pig was standing and considered bright, alert, and responsive. During the experiment, the pig was placed on a heated operating table with the additional thermal support of a heated blanket. Ophthalmic ointment was applied to both eyes. Once the pig was placed on isoflurane (1-2%) and oxygen (1-3%) either via a face mask or an endotracheal (ET) tube, it was then connected to an anesthesia monitoring machine in order to monitor vital signs every 15

minutes until returned to the pen. The motorized expansion head was delivered to a female pig of 95 kg through a 2cm incision on the stomach, with the aid of upper endoscopy and X-ray imaging to evaluate the expansion and contraction of the device in the stomach.

[00153] *Intragastric Balloon*

[00154] An alternative method of inducing satiety is through the placement of a gastric balloon in the stomach. This balloon can inflate to create satiety and then deflate to prevent stomach accommodation. The procedure involved implanting a subject with a Percutaneous Endoscopic Gastrostomy (PEG) tube and delivering the balloon endoscopically to the stomach. The balloon was connected to a portable system (*i.e.*, an air pump) via the PEG tube, as illustrated in FIG. 9.

To optimize the inflation system, the pressure equation was derived by integrating the Euler equation along the streamline. This equation (Eqn. 35) takes into account the stagnation pressure of the air pump (P_{stag}), air density (ρ), airflow rate (u), blade diameter (D_{blade}), blade width (b), volume rate (Q), pump input voltage (V) and current (I), pressure loss coefficients in the connections (k_{tot}), inner cross-section area of the tube (A), tube length (L), dynamic viscosity of air (μ), and blade angle (γ). The pressure loss was broken down into three components and written on the left-hand side of the equation: due to the blade (second term), connections (third term), and along the tubing (fourth term).

$$P_{stag}(V, I) - \frac{\rho \mu \cot \gamma}{\pi D_{blade} b} Q - \frac{1}{2} k_{tot} \rho \left(\frac{Q}{A} \right)^2 - \frac{32 \mu L}{D^2} \cdot \frac{Q}{A} = P_{balloon} \quad (35)$$

[00155] A commercially available air pump was used with a 65kPa stagnation pressure at 7.4V input voltage (Delinx Inc.). To determine the main source of pressure loss, an order of magnitude analysis was conducted. In the analysis, the cross-section of inflation tubing was set to have a 2mm inner diameter and the pump fills a 1L balloon in 60s. The results showed that the pressure loss due to connections was negligible considering a typical loss factor k_{tot} is about 10 to 1 (Eqn. 36), while the pressure loss along the tubing was significant, reaching up to 30% of the stagnation pressure (Eqn. 37).

$$f_{loss-connection} = \frac{P_{loss-connection}}{P_{stagnation}} = \frac{\rho Q^2}{2 P_{stag} A^2} \approx 0.004 \quad (36)$$

$$f_{loss-tubing} = \frac{P_{loss-tubing}}{P_{stagnation}} = \frac{32 \mu Q}{D^2 A P_{stag}} \approx 0.3 \quad (37)$$

[00156] To further quantify the impact of tubing length and inner diameter on the inflation system, Eqn. 35 was numerically solved using a finite difference method on MATLAB. Results showed that as tubing length increased, the volume rate decreased and the balloon volume was smaller after 60s of inflation (see FIGS. 23A and 23B). Additionally, alterations in the tubing inner

diameter resulted in a significant change in both volume rate and volume over time (see FIGS. 24A and 24B). Considering these factors, a Polyurethane inflation tube was selected with a 3mm outer diameter, 1.6mm inner diameter and 1.5m length as the inflation tube.

[00157] A valve was developed to regulate the airflow in the system. The housing was created by cutting an 11mm diameter McMaster FR4 rod into 25.5mm segments using a band saw. A 5/16inch tap was used to drill and thread the inner wall of the rod, forming a hollow cylindrical shape. This design allows the screw and motor-gearbox to open and close the valve. A hole, 10mm from the top, was drilled perpendicular to the axis of the housing using a drill press. The soft tubing was inserted into this hole, and a piston was added to clamp the tubing and regulate airflow. The design of the housing is illustrated in FIGS. 25A and 25B, which depict a top view and an isometric view of the housing, respectively.

[00158] The valve components were assembled by inserting the shaft of the motor-gearbox into the complementary bore of the piston. The loose fit between the shaft and bore allows the piston to rotate with the shaft while moving along the housing axially. The motor ports were soldered with two wires. The housing was then placed onto the motor-gearbox, with the piston inside. Application of epoxy was used to secure the connection between the housing and the motor-gearbox, and shrink tubing was placed on top for added protection. A 5/16inch bolt stopper was inserted into the other end of the housing to create a tight clamp between the piston and bolt. The shrink wrap at the motor-gearbox end was also sealed with epoxy to protect its moving parts. The soft tubing was inserted through the drill-pressed hole in the housing. When the motor-gearbox rotates, the soft tubing is either clamped or unclamped. The valve was tested for airtightness during balloon inflation and deflation to ensure proper functioning.

[00159] The tubing (*i.e.*, the PEG tube) includes a bifurcation that serves as a link between the motor, valve, and balloon to regulate airflow. A 3-inch piece of 5.5mm diameter Delinx soft tubing and two 3-inch pieces of 3mm tubing were cut. The two pieces of 3mm tubing were inserted at least 0.5 inches deep into one end of the soft tubing. Epoxy was used to ensure a secure connection between the tubes, and shrink tubing was added to ensure an airtight seal. The final product was a bifurcation that connects the air pump to the soft tubing channel on one end, and the 3mm tubing pieced to the valve and balloon for inflation on the other.

[00160] Further, and as illustrated in FIGS. 26A and 26B, a 90-degree tube was 3D printed to accommodate the angles in the box assembly and prevent tubing collapse during routing. The tube was attached directly to the motor with epoxy to ensure an airtight seal, as illustrated in FIG. 26C. The other end of the 90-degree tube was connected to the bifurcation using soft tubing. An additional 3D-printed tube was also incorporated into the valve: one end of the tube was fitted with

soft tubing, while the second end was fitted with 3mm tubing secured using duct tape. The system was tested by inflating and deflating the balloon to verify that the connections were airtight with the addition of the 3D-printed tubes.

[00161] Given that the balloon will remain in the stomach once inserted, it is crucial to select a material that can withstand repeated inflation cycles for at least 3 months. To determine the balloon's durability, a series of tests were conducted on various types of balloons in a simulated stomach environment. The durability experiment involved several components, including a balloon, a water tank, an acrylic plate, a water sensor, a water sensor holder, a lid, a power supply, a digital multimeter, and a laptop, as shown in FIGS. 27 and 28.

[00162] To prepare the water tank for the experiment, these steps were followed: first, the water level on the side of a 5L transparent plastic tank was marked with increments of 0.25L. Then, 0.25L of water was added at a time to the tank and marked the tank's water level until it reached 4.5L. An acrylic plate was secured as the partition at the 2.5L mark to prevent the balloon from floating post-inflation. The partition was large enough to block the balloon but didn't prevent water from flowing freely. Two openings were cut on the lid, one on the edge for water sensor placement and the other for the balloon tube to go through. These components ensured accurate measurements of the balloon's durability.

[00163] For the experiment, Songhe water sensors were used, which have three pins: input, ground, and signal. The pins were connected using female-to-male jumper wires and then placed the wires through heat shrink tubing to ensure waterproof protection. Next, epoxy was applied on the connections to secure them in place, hot air was blown to shrink the tubing, and the epoxy was let dry for 5 minutes. To hold the water sensor in place, a holder was fabricated according to the dimensions and specifications illustrated in FIGS. 29A-29C. FIG. 29A depicts the assembled holder, FIG. 29B depicts a side view of an inner strip of the holder, and FIG. 29C depicts a side view of an outer strip of the holder. The water sensor was then placed into the holder, which allowed accurate measurements of the balloon's durability in the simulated stomach environment to be collected.

[00164] Once the tank, lid, and water sensors were prepared, the balloon was passed through the hole cut out on the lid and placed underneath the partition in the water tank. Using the holder, the water sensor was hung in the interior of the tank and water was added until it reached the bottom of the water level sensor, which was approximately 2.5L. To minimize evaporation, the lid was closed. 3.3V was supplied to the water sensor and the signal terminal was connected to the positive terminal of the digital multimeter (DMM), making sure the power source, multimeter, and water sensor were all connected to the same ground. After connecting the DMM to a computer

with the EasyDMM software installed, the device was turned on and the data was recorded using the autosave function. As the experiment could take multiple days, the computer was connected to a power source and the automatic sleep mode was turned off.

[00165] Before conducting the durability tests, the tank setup was confirmed to accurately simulate the stomach environment in terms of confinement. To achieve this, in vivo experiments were conducted to find that the pressure inside the balloon in real situations could range from approximately 96 kPa (uninflated) to 101 kPa (at full inflation) (see FIG. 30A). The in vivo test graph illustrated in FIG. 30A was then compared with the partition-tank system graph illustrated in FIG. 30B, and it was found that by inflating the balloon from 0L to 1.5L, it was possible to create a pressure inside the balloon that ranged from approximately 98 kPa to 106 kPa. These results confirmed that the partition-tank system could simulate confinement comparable to the real stomach, which allowed accurate and meaningful durability tests to be conducted on the balloon.

[00166] To test the durability of each balloon, the balloon was repeatedly inflated and deflated until it burst or leaked inside the tank. The water level sensor monitored the condition of the balloon, inflation and deflation cycles resulted in regular alterations in water levels. Any burst or leakage of the balloon resulted in an irregular change in the water level. The water level change was recorded to count the number of cycles the balloon endured and the point at which it failed. The 20-inch PVC balloon was selected among three candidate materials, which included a latex condom and an 18-inch latex balloon, based on its performance in the durability test. As shown in FIGS. 31A-32B the condom and latex balloon remained functional for only about 30 and 100-200 cycles in the pH7 environment, respectively, while the PVC balloon survived over 2000 cycles in a pH2 environment (see FIGS. 33A-33C). The pH2 environment is created by mixing Acetic acid with water. These results indicated that the PVC balloon was the most durable of the three materials and could withstand repeated inflation and deflation cycles for an extended period of time.

[00167] Further tests were conducted to verify that placing PEG clip to the PEG tube would not interfere with the inflation of the balloon. As illustrated in FIG. 34, after placing the PEG tube onto the subject, the clip is used to clamp the tube, thus avoiding the exit of gastric content through the PEG tube. The PEG tube connected to the balloon passed through a PEG clip with six levels, providing eight different tightness levels ranging from no clamp to the tightest level. The clamp levels, from least to most tight, were as follows: no clamp, sham, level 1, level 2, level 3, level 4, level 5, and level 6.

[00168] To measure the effect of the PEG clip on balloon inflation, experiments were conducted and the results were recorded, which are illustrated in FIG. 35. The findings indicated that the time it took to increase the water level by 1.5 L was approximately 100 seconds for all levels of

tightness, except for level 6, where the time increased to approximately 200 seconds. These results suggest that clipping the PEG tube at any level from 1-5 will not affect the inflation of the balloon. However, using level 6 may cause a significant delay in the time it takes to inflate the balloon, which may impact the results of future experiments. Therefore, it was concluded that using a PEG clip with a tightness level of 5 or lower to ensure that the inflation of the balloon is not affected by the clip.

[00169] Moreover, a Teensy 3.2 board and a custom PCB board were employed to control the inflation and deflation of a PVC balloon located inside a pig's stomach. The balloon was inflated prior to feeding time to occupy the stomach and induce satiety, thereby reducing the amount of food taken by the pig during the meal. After eating, the balloon was deflated, and the device entered a dormant state until the next feeding time. The design of the device, including its airflow and wiring, as illustrated in FIGS. 36 and 37. The inflation tube was placed inside the PVC balloon and the other end was connected to a bifurcation. This bifurcation split into two channels, one connecting to the pump and the other to the valve, providing control of the inflation, hold, and deflation stages.

[00170] The BME280 pressure sensor breakout was integrated with the Teensy board through an I2C bus. The sensor continuously sent digital signals reflecting the current pressure inside the balloon. The control function maintained a record of the latest 10 readings and calculated the moving average as the current pressure within the balloon. When the moving average reached the predetermined threshold pressure, the inflation pump was automatically turned off to ensure the safety of the subject. The valve and pump were powered by lithium batteries, with the valve powered by a 3.7V battery and the pump by two 3.7V batteries connected in series to produce a 7.4V voltage. Two analog I/O ports on the Teensy 3.2 were connected to the H-bridge controlling the valve, enabling the motor to rotate and move the piston, opening and closing the soft tubing channel. The pump was controlled by a MOSFET switch connected to one analog I/O port. The PCB board file and circuit schematics are illustrated in FIGS. 36 and 37, respectively.

[00171] Relatedly, the device operates in five distinct modes: Initial Delay, Inflation, Hold, Deflation, and Snooze. Inflation, Hold, and Deflation make up a single cycle of inducing satiety, while the Initial Delay compensates for the time needed to set up the device on the subject. The Snooze mode is a low-power consumption sleep state. A feeding schedule was created for the subject, and the feeding times were input into the Teensy 3.2. A control algorithm was programmed to inflate and deflate the balloon according to the pre-set feeding schedule. To conserve energy, a Snooze library was integrated that allows the Teensy 3.2 to enter sleep mode between active operations. The feeding times of the pig were entered into the control algorithm before device

setup, and were used to calculate the timing and duration of each Snooze period. Throughout the day, the device transitioned through different modes based on the set feeding times.

The device operated in the following sequence:

1. Upon initial activation, the device enters an Initial Delay mode, in which it is set to Snooze until the next scheduled feeding time. This delay allows for the preparation of the device and its deployment. The time remaining until the next feeding time is pre-entered into the device before it is set to Snooze.

2. At the scheduled feeding time, the device is awoken from Snooze mode and begins inflating the balloon. During inflation, the valve is closed by rotating the valve motor forward and the pump motor is activated to pump air into the balloon. Inflation stops either when the inside the balloon reaches the set threshold or the pre-determined inflation time has elapsed.

3. After the balloon is inflated to the desired pressure, the device enters a Hold status, in which the pump motor stops pumping air into the balloon and the valve remains closed to maintain the balloon's pressure. The Hold status lasts for one hour.

4. The device then enters a Deflation mode, during which the pump motor remains at a low voltage and the valve motor rotates in a backward direction to open the valve and deflate the balloon. This process takes approximately 5 seconds. The device then returns to Snooze mode until the next scheduled feeding time.

5. The Teensy Snooze library is utilized to put the device into a low-power status. The Snooze Alarm function is used to periodically wake the device up every hour to prevent any malfunction in time calculation.

[00172] The stopping mechanism of the inflation process involves both pressure and time thresholds. Based on preliminary in vivo studies, it was determined that a pressure of 103,000 Pa was ideal to accommodate the anatomy of the pig's stomach, corresponding to a balloon volume of 1-2L depending on body weight. Any readings above 130,000 Pa or below 80,000 Pa were considered outliers and are filtered out. If the moving average exceeds 103,000 Pa, the inflation was stopped. The time threshold for inflation was set at 1 minute, which was the estimated time for the balloon to reach 2L. If either the pressure or time threshold was exceeded, the inflation process was terminated.

[00173] The Teensy Snooze library provides three snooze options: Sleep, Deep Sleep, and Hibernate. The Deep Sleep function and Snooze Alarm were used to set the Freescale Kinetis processor in the Teensy board to a low-power mode and later wake it up. The procedure to configure the Snooze function was as follows:

1. Include the Snooze library header:

```
#include <Snooze.h>
```

2. Load the desired driver classes:

```
SnoozeTouch touch;
```

```
SnoozeDigital digital;
```

```
SnoozeTimer timer;
```

3. Install the Timer and Digital drivers to the SnoozeBlock:

```
SnoozeBlock config(timer, digital);
```

4. Configure the drivers, typically by changing certain parameters:

```
timer.setTimer(5000); // milliseconds
```

```
digital.pinMode(21, INPUT_PULLUP, RISING); // pin, mode, type
```

```
digital.pinMode(22, INPUT_PULLUP, RISING); // pin, mode, type
```

5. Provide the SnoozeBlock to the desired Snooze function from the Snooze class:

```
Snooze.sleep( config );
```

```
Snooze.deepSleep( config );
```

```
Snooze.hibernate( config );
```

[00174] An in vitro test was performed to evaluate the functionality and sleep-wake behavior of the system. During the test, the balloon was positioned under the partition in the water tank to simulate the stomach environment. The control algorithm was loaded into the Teensy board and programmed to inflate the balloon at 8am, 12pm, and 5pm, hold the volume for 1 hour after each inflation, and then deflate it. This mimicked the pig's feeding schedule in the in vivo experiments, and the volume change of the balloon was recorded by monitoring the water level. The DMM multimeter was turned on and the water sensor data was recorded using EasyDMM. The device was allowed to run for three days, and the recorded water level sensor data was analyzed to confirm normal inflation behavior. FIG. 38 illustrates the data collected by the water level sensor over a three-day interval during the in vitro experiment. Each spike in the graph represents a complete inflation-hold-deflation cycle. The results indicated that the system can operate stably for 2 days with 3 cycles per day.

[00175] A portable pack was designed for an in vivo survival study to investigate whether the prototyped device can decrease satiety in swine. Given the need for space efficiency, the device was condensed to ensure ease of use. The flow of the integration process is depicted in FIG. 39. Initially, parts were mounted onto the PCB manufactured by OSH Park and code that automates timed inflation and deflation was uploaded onto the Teensy 3.2 microcontroller. Next, the balloon and container were uploaded. Lubrication was injected into a 1.5 meter long 1.8mm inflation tube, through which four thin wires for the air pressure sensor are threaded. The wires are soldered onto

the air pressure sensor, which is then inserted into the balloon. The balloon was sealed with epoxy to maintain its airtightness. Two holes were cut out of the container, one for wiring and the other for the tubes, and four batteries, the PCB, a power switch, and a motor were placed inside. Finally, the balloon air pressure sensor wires were connected to the PCB and a 90-degree tube was used to facilitate airflow in harsh bending angles. To ensure the durability of the compact system, *in vitro* tests were performed. First, a horizontal partition was placed inside a 5L box and positioning the balloon below the divider. The box was filled with water, allowing a water level sensor to detect any changes in balloon volume as it inflates and deflates. The data from both the water level sensor and air pressure sensor was monitored and recorded externally using a computer.

[00176] The preliminary *in vivo* study in swine models involved the use of a balloon with an internal air pressure sensor, an Arduino Uno board with four gator pins, a power source, a pump to inflate and deflate the balloon, and a PEG tube. The study began by deploying an overtube into the pig. A fishing wire was then delivered through the PEG tube into the stomach and retrieved using a clip in the endoscope. PAM oil was applied to the balloon to reduce friction before delivering the balloon system into the stomach. The fishing wire was attached to the inflation tube, opposite the balloon. To prevent fluid and debris from entering the airflow system, a tube cap was inserted into the tube at the end away from the balloon.

[00177] The tube cap is illustrated in FIGS. 40A-40C. The fishing wire was then pulled from the PEG tube until the 3mm tube exited the PEG tube, providing access to the system. After the balloon was placed into the stomach of the pig, the inflation tube was subsequently connected to the portable pack. A PEG clip was used to stop the exit of gastric content through the PEG tube. The portable pack was secured onto the back of the pig using bandages. The PEG tube was flushed with saline once a day and the bandages on the pig were changed twice a week.

[00178] *Results*

[00179] As shown in FIG. 41A the motorized stimulator expanded from a diameter of 20mm to 80mm in 20 seconds. The stimulator was placed inside the pig's stomach and its expansion and contraction behavior was monitored. The results demonstrated that the stimulator was capable of expanding against the weight of the gastric tissue, as illustrated in FIG. 41B. During the *in vivo* validation, an endoscopy video and X-ray images (see FIG. 41C) were taken to observe the device during expansion. These images demonstrate how the stimulator is able to push against the gastric tissue and expand.

[00180] An *in vivo* test was performed to validate the air balloon stimulator. As shown in FIGS. 42A and 42B, the inflation tube can be passed through the PEG tube, and the PEG clip can be used

to prevent the overflow of gastric content. After placement, the balloon was inflated for 1 minute via the inflation tube, resulting in the visible expansion of the abdomen.

[00181] The functionality of the device was further validated through the collection of air pressure data within the balloon. The balloon contained an air pressure sensor that recorded levels of inflation in the stomach. As illustrated in FIG. 43, the collected data showed a consistent increase in air pressure, demonstrating the compatibility of the air balloon stimulator with the PEG tube and clip. The air pressure data displayed a consistent increase and trajectory in all three tests above the baseline, thereby validating the air balloon system in vivo.

[00182] To evaluate the effectiveness of the device in reducing food intake, a feeding behavior study was conducted using a swine model. A 40 kg Yorkshire swine was purchased from Cummings School of Veterinary Medicine at Tufts University (Grafton, USA), and the study was pre-approved by the Massachusetts Institute of Technology Committee on Animal Care to ensure animal welfare. All approved protocols were followed and all appropriate precautions were taken to guarantee the swine's well-being. To start the experiments, a PEG tube was placed in the sedated swine, which was allowed to recover for two days before deploying the stimulator. Throughout the study, the swine was fed twice a day, at 08:30 AM and 01:30 PM, with 1360g (3lbs) of pellets each time. During the 30-minute feeding period, the amount of food consumed was monitored and the remaining food was weighed, which was later returned to the pig in accordance with the Massachusetts Institute of Technology Committee on Animal Care's policy.

[00183] The experiment comprised three types of days: control, sham, and measuring. During control days, the pig had the PEG tube but not the satiety stimulator. On sham days, the satiety stimulator was placed within the pig, but it remained inactive. Measuring days involved expanding the satiety stimulator twice a day in the pig's stomach at 08:30 AM and 01:30 PM. The valve closed the air channel, held the air for 30 minutes, and subsequently deflated. On the morning of days 3, 7, and 10, the pig was sedated to allow for bandage exchange and was only fed at 01:30 PM. The device was deployed into the pig on the third day of the experiment and removed on the thirteenth day. To offset the growth factor of the pig, measuring days and sham days were mixed when the device was placed on the pig. The experiment schedule is presented in Table IV and the 30 minutes food intakes are illustrated in FIG. 44.

[00184] As shown in FIG. 44, the mean food intake during control, sham, and measuring meals were 268g, 284g, and 94g, respectively, with corresponding standard deviations of 133g, 144g, and 118g. The p-values between control-measuring, sham-control, and sham-measuring were 0.8, 0.02, and 0.01, respectively. The study revealed a significant decrease in food intake during the measuring meals, where the balloon was expanded prior to feeding. The reduction in food intake

was over 60% compared to the control and sham groups (p-value < 0.05). However, no significant changes were observed in feeding behavior due to the presence of the balloon in the stomach, as indicated by the small differences in food intake between the sham and control groups and a very large p-value. Based on this result, it can be concluded that the inflation of the balloon prior to the meal was the sole factor responsible for the observed changes in feeding behavior.

Table IV. The feeding schedule during the feeding behavior experiment.

Day	1	2	3	4	5	6	7	8	9
Type	Control	Control	Sham	Measuring	Sham	Measuring	Sham	Measuring	Sham
Day	10	11	12	13	14	15	16	17	18
Type	Sham	Measuring	Sham	Control	Control	Control			

[00185] *Discussion*

[00186] The development of two dynamic satiety stimulators for endoscopic delivery, designed to promote feelings of fullness over the course of several weeks, was recorded. These stimulators expand pre-meal to stimulate satiety and then contract post-meal to prevent gastric accommodation and loss of stimulation. Two non-limiting example methods have been developed for stomach expansion: a motorized expansion head and a balloon approach. The motorized expansion head featured a system with four arms driven by a DC motor to expand against gastric tissue. A latex cover was added to protect the tissue from being grasped by the arms during contraction. This approach has been validated in a swine model and shown to expand freely within the stomach. The balloon stimulator system included a PVC balloon delivered endoscopically, a PEG tube allowing inflation, and a portable pack for controlling inflation and deflation. Prior to a meal, the portable pack inflated the balloon and held the air for the duration of the meal. After the meal, the pack released the air and allowed the balloon to collapse within the stomach. The balloon also had an internal pressure sensor to monitor gas pressure and avoid over-inflation, ensuring safety. To minimize energy costs and extend operation time, the balloon was programmed to enter sleep mode during non-active times. A feeding behavior study in a swine model showed a 60% average reduction in food intake with the activation of the balloon stimulator.

[00187] Static intragastric balloons (*i.e.*, those that do not change in volume) appear to be associated with accommodation with plateauing of weight loss in large mammals. In contrast, the present disclosure provides an endoscopically administered gastric resident device that has been

shown to support dynamic satiety induction to approximate the natural satiety induction process associated with episodic meal ingestion. The device expands pre-prandially and occupies the gastric cavity, then shrinks to a minimal volume after the meal. Two gastric residency and dynamic expansion mechanisms have been developed based on motorized and balloon approaches. The system is programmed to stimulate satiety autonomously over the course of treatment without manual assistance. Thus, systems and methods are provided for dynamically inducing gastric satiety by temporarily expanding a device in the gastric cavity prior to eating and contracting the device after eating. The system includes multiple implementations that may include, as non-limiting examples, an expandable balloon device and a motorized expansion head device.

[00188] Method examples described herein can be machine or computer-implemented at least in part. Some examples can include a computer-readable medium or machine-readable medium encoded with instructions operable to configure an electronic device to perform methods as described in the above examples. An implementation of such methods can include code, such as microcode, assembly language code, a higher-level language code, or the like. Such code can include computer readable instructions for performing various methods. The code may form portions of computer program products. Further, in an example, the code can be tangibly stored on one or more volatile, non-transitory, or non-volatile tangible computer-readable media, such as during execution or at other times. Examples of these tangible computer-readable media can include, but are not limited to, hard disks, removable magnetic disks, removable optical disks, *e.g.*, compact disks and digital video disks, magnetic cassettes, memory cards or sticks, random access memories (RAMs), read only memories (ROMs), and the like.

[00189] As used in the claims, the phrase "at least one of A, B, and C" means at least one of A, at least one of B, and/or at least one of C, or any one of A, B, or C or combination of A, B, or C. A, B, and C are elements of a list, and A, B, and C may be anything contained in the Specification.

[00190] The present invention has been described in terms of one or more preferred embodiments, and it should be appreciated that many equivalents, alternatives, variations, and modifications, aside from those expressly stated, are possible and within the scope of the invention.

WHAT IS CLAIMED IS:

1. A system for dynamically inducing gastric satiety in a subject, comprising:
a device that includes at least one outer arm;
a motor; and
a controller that operates the motor to actuate the at least one outer arm,
wherein the controller operates the motor to pre-prandially extend the at least one outer arm away from a body of the device, and
wherein the controller operates the motor to post-prandially contract the at least one outer arm.
2. The system of claim 1, wherein the device is a capsule that is endoscopically inserted within a stomach of the subject.
3. The system of claim 2, wherein the device is configured to occupy at least 25% of a volume of the stomach of the subject when the at least one outer arm is extended.
4. The system of claim 1, wherein the device further includes at least one inner arm that is coupled to the at least one outer arm and a slide ring of the device.
5. The system of claim 4, wherein the slide ring is moveable along a longitudinal axis defined by the body such that moving the slide ring toward a distal end of the device causes the at least one outer arm to move away from the body.
6. The system of claim 5, wherein the device further includes a central shaft that is coupled to the motor, and wherein the motor rotates the central shaft to move the slide ring along the longitudinal axis.
7. The system of claim 1, further comprising an elastic cover that encapsulates the device.
8. The system of claim 1, wherein the controller is coupled to a monitoring system that is configured to monitor satiety in the subject.

9. A system for dynamically inducing gastric satiety in a subject, comprising:
a balloon;
a percutaneous endoscopic gastrostomy (PEG) tube coupled to the balloon;
a pump coupled to the PEG tube and in fluid communication with the balloon; and
a valve coupled to the PEG tube and in fluid communication with the balloon,
wherein the balloon is configured to be pre-prandially inflated with the pump, and
wherein the balloon is configured to be post-prandially deflated with the valve.

10. The system of claim 9, wherein the valve includes:
a motor;
a piston; and
a threaded cap,
wherein the valve is selectively opened and closed to regulate airflow in the system.

11. The system of claim 10, wherein the PEG tube defines a double lumen including a first lumen that couples the valve to the pump and a second lumen that couples the balloon to the pump.

12. The system of claim 9, wherein the pump is coupled to a controller, the controller configured to automatically inflate and deflate the balloon at predetermined time intervals.

13. The system of claim 9, wherein the PEG tube is delivered endoscopically to a stomach of the subject and the balloon is placed within the stomach of the subject.

14. The system of claim 13, wherein the balloon comprises at least 25% of a volume of the stomach of the subject when inflated.

15. A method of dynamically inducing gastric satiety in a subject, comprising:
implanting a percutaneous endoscopic gastrostomy (PEG) tube into a stomach of the subject;
deploying a balloon into the stomach of the subject through the PEG tube, the balloon coupled to a pump and a valve via the PEG tube;
pre-prandially inflating the balloon with the pump to induce gastric satiety; and
post-prandially deflating the balloon with the valve.
16. The method of claim 15 further comprising detecting a pressure within the balloon and determining a moving average of the pressure within the balloon during a predetermined time period.
17. The method of claim 16, further comprising turning the pump off when the moving average of the pressure within the balloon reaches a predetermined threshold.
18. The method of claim 15, wherein inflating and deflating the balloon are performed according to a predetermined meal schedule.
19. The method of claim 15, further comprising holding the valve closed to maintain a pressure within the balloon.
20. The method of claim 15, wherein deflating the balloon includes deactivating the pump and activating a motor to open the valve.

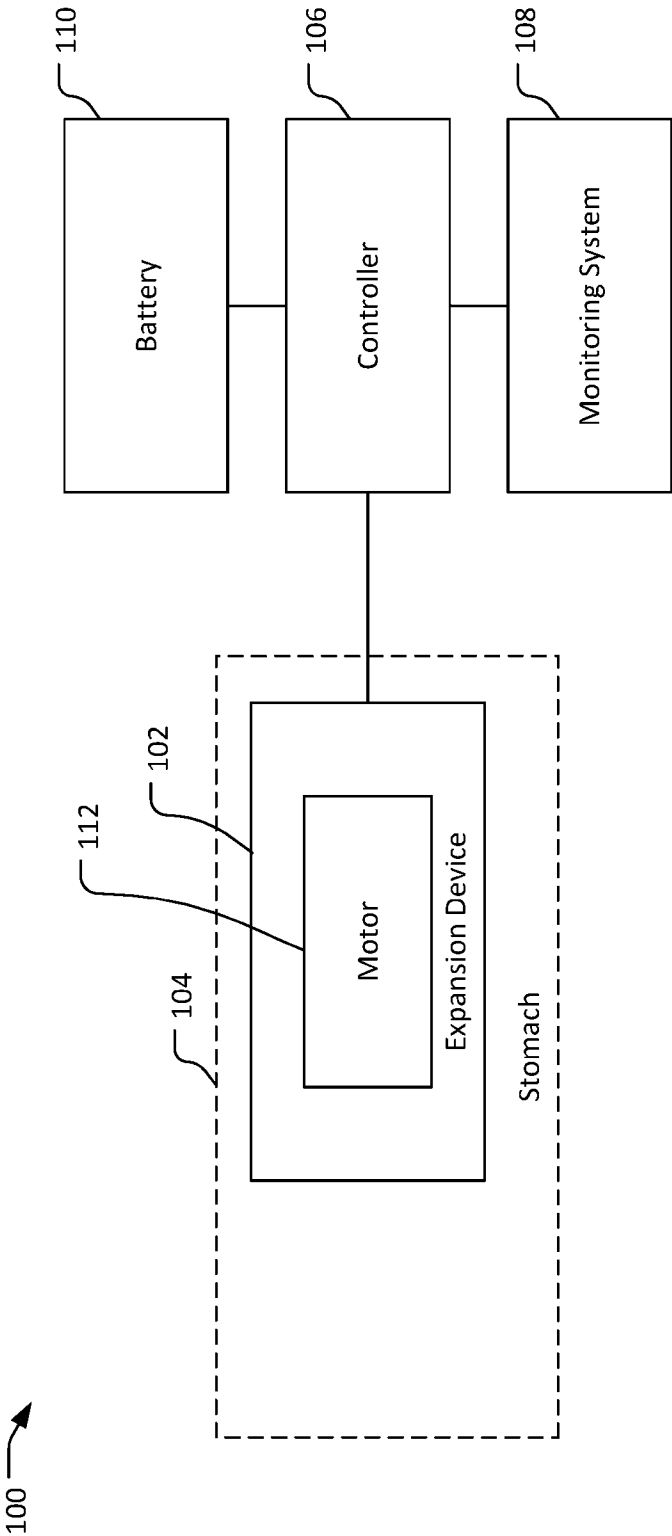


FIG. 1

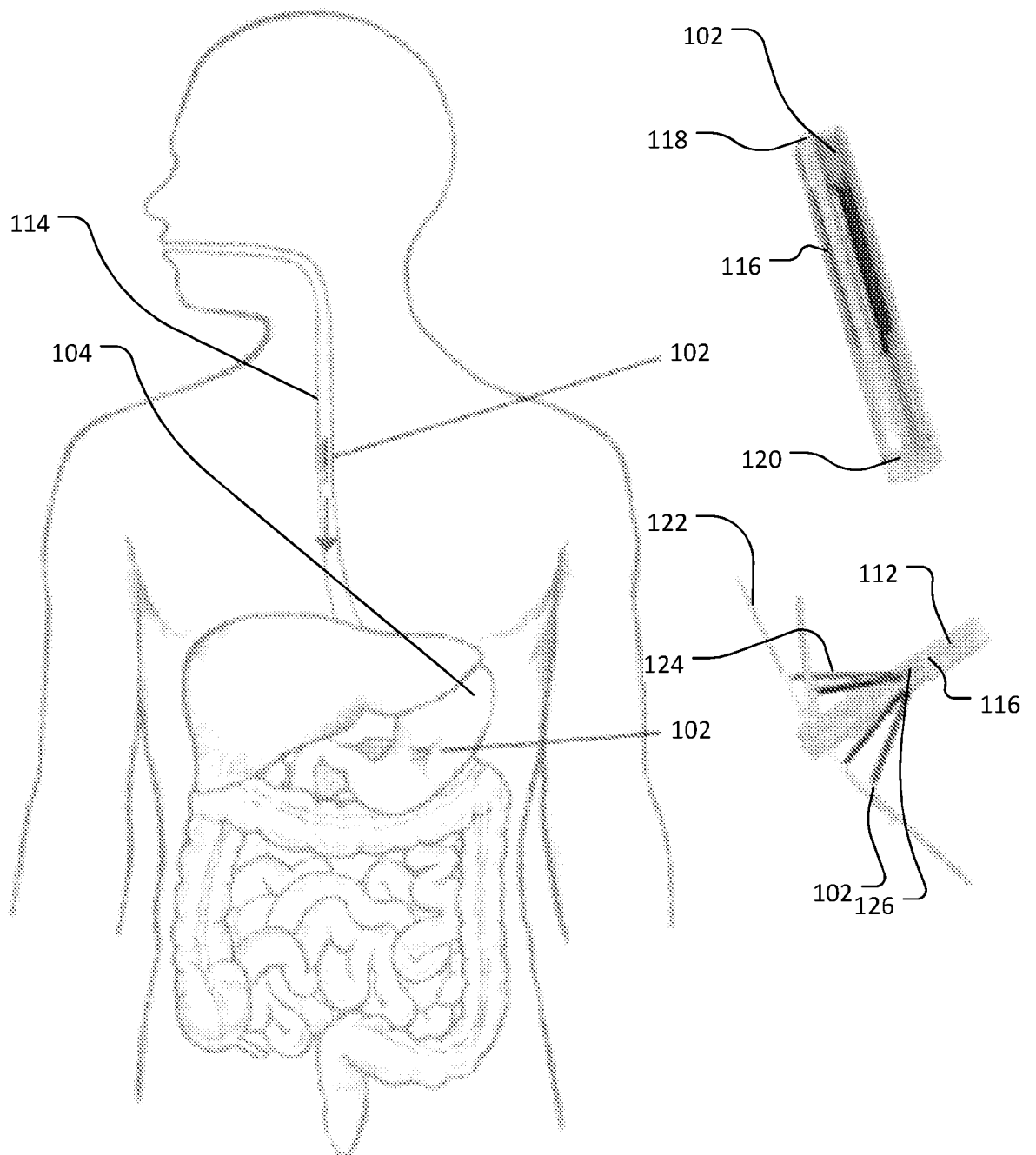


FIG. 2

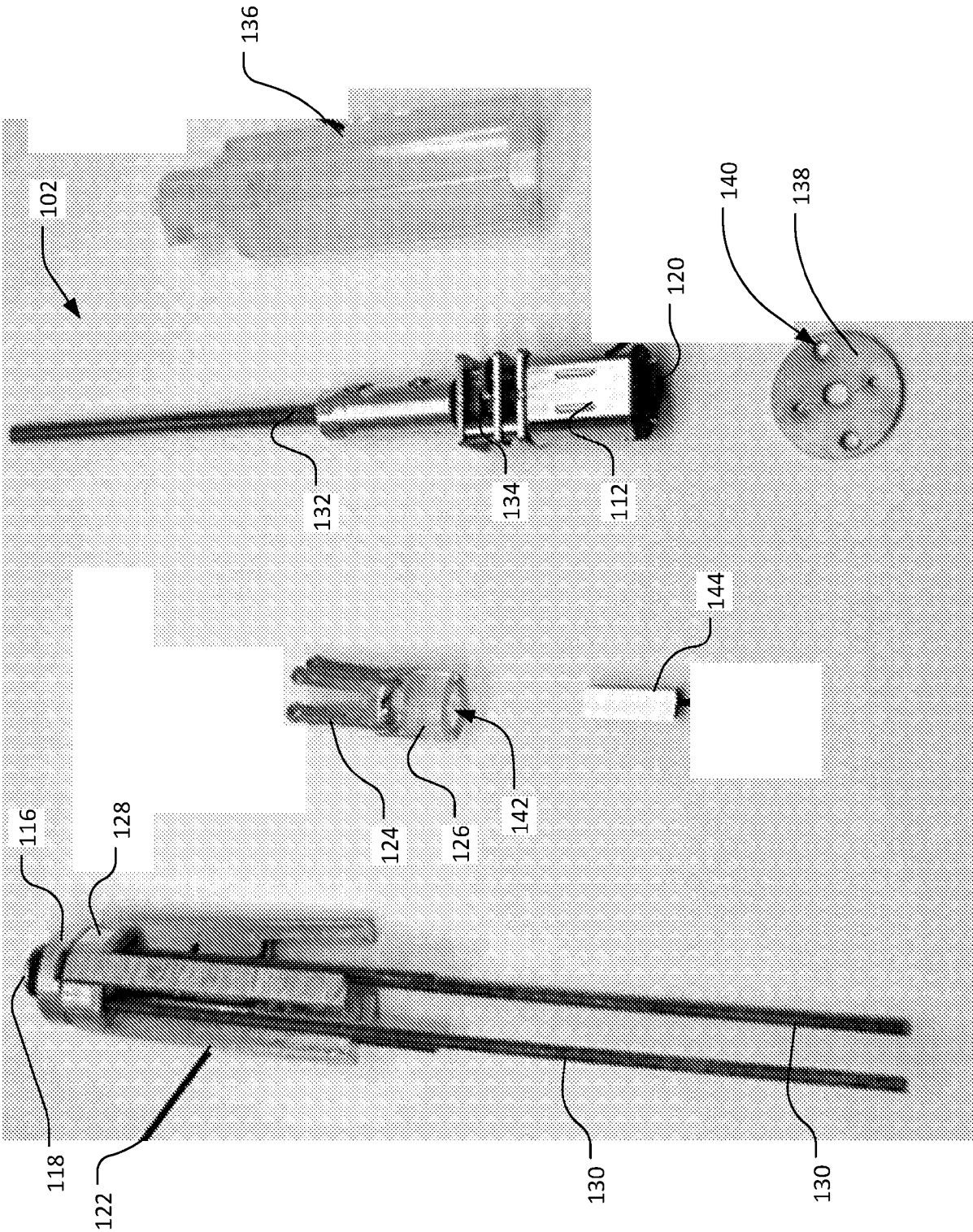


FIG. 3

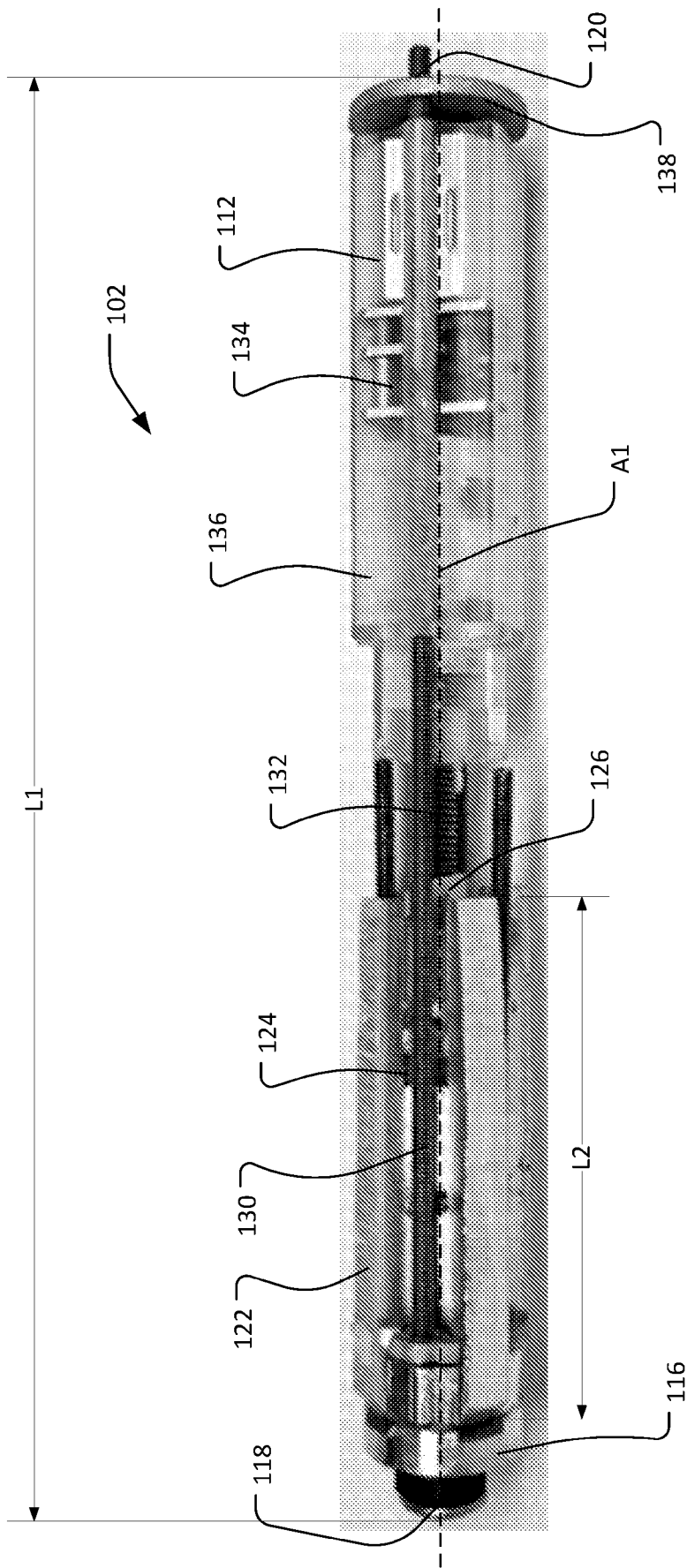


FIG. 4

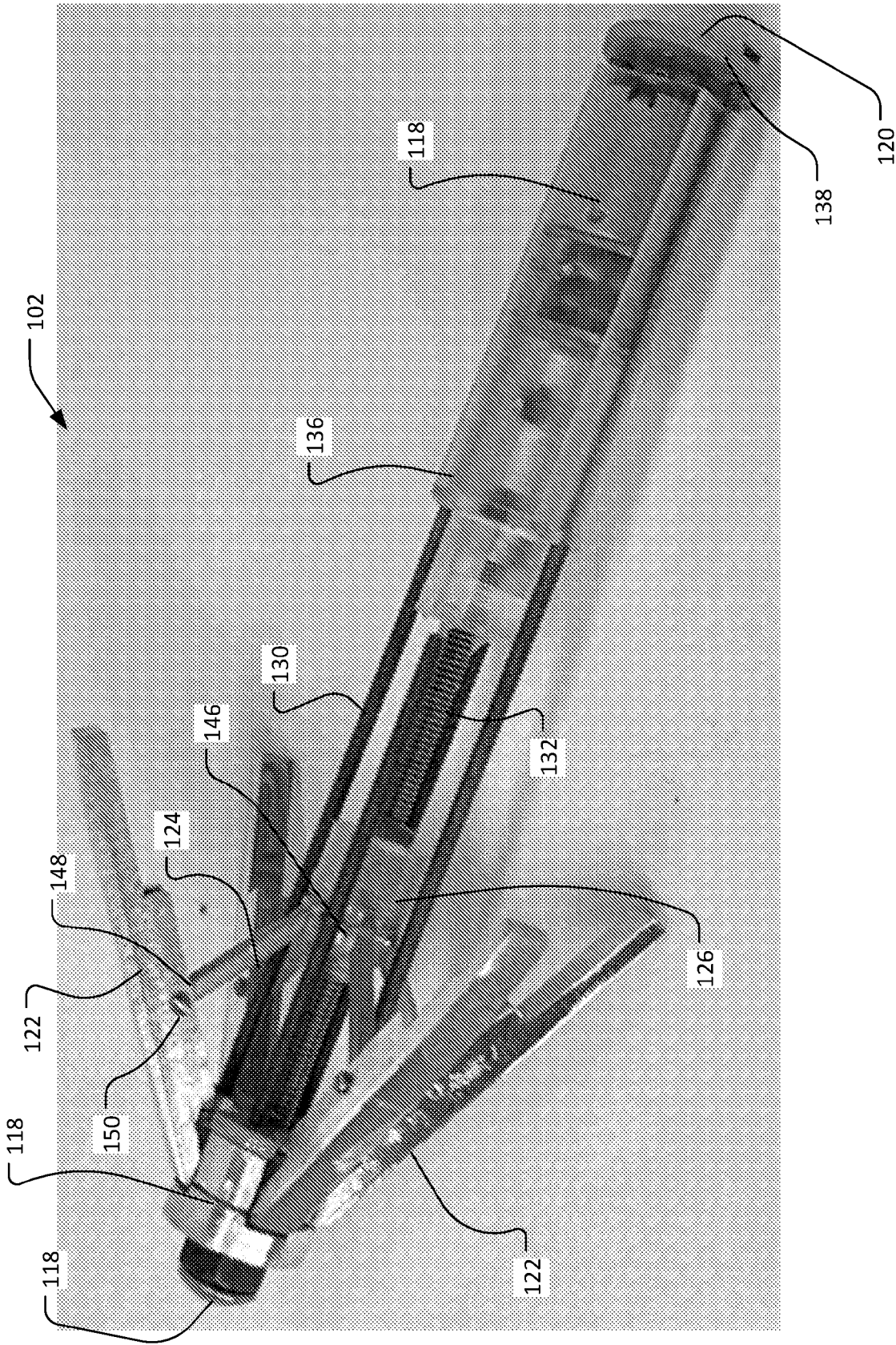


FIG. 5

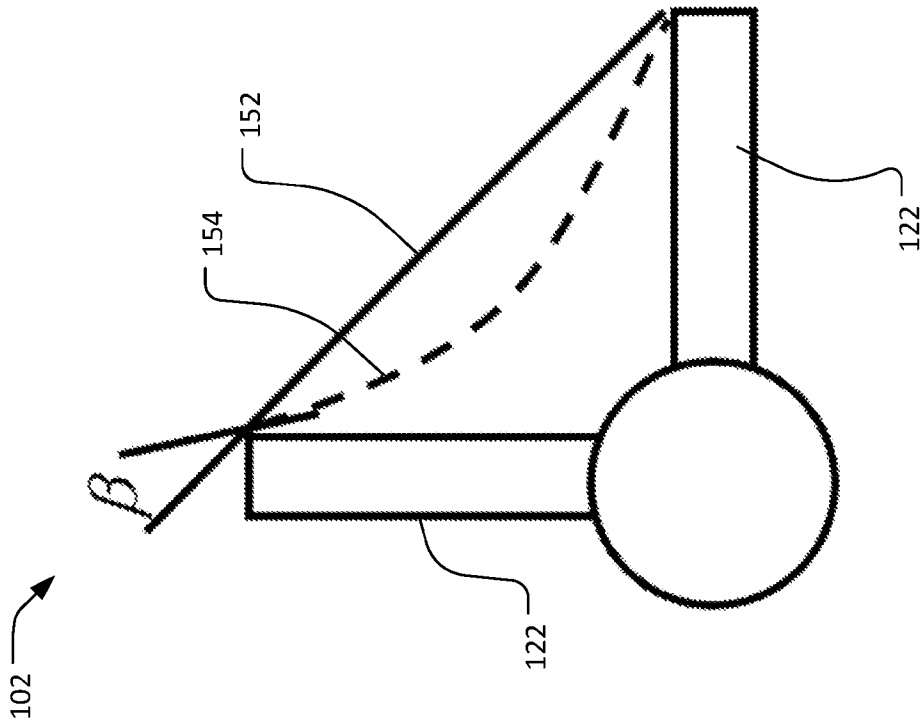


FIG. 7

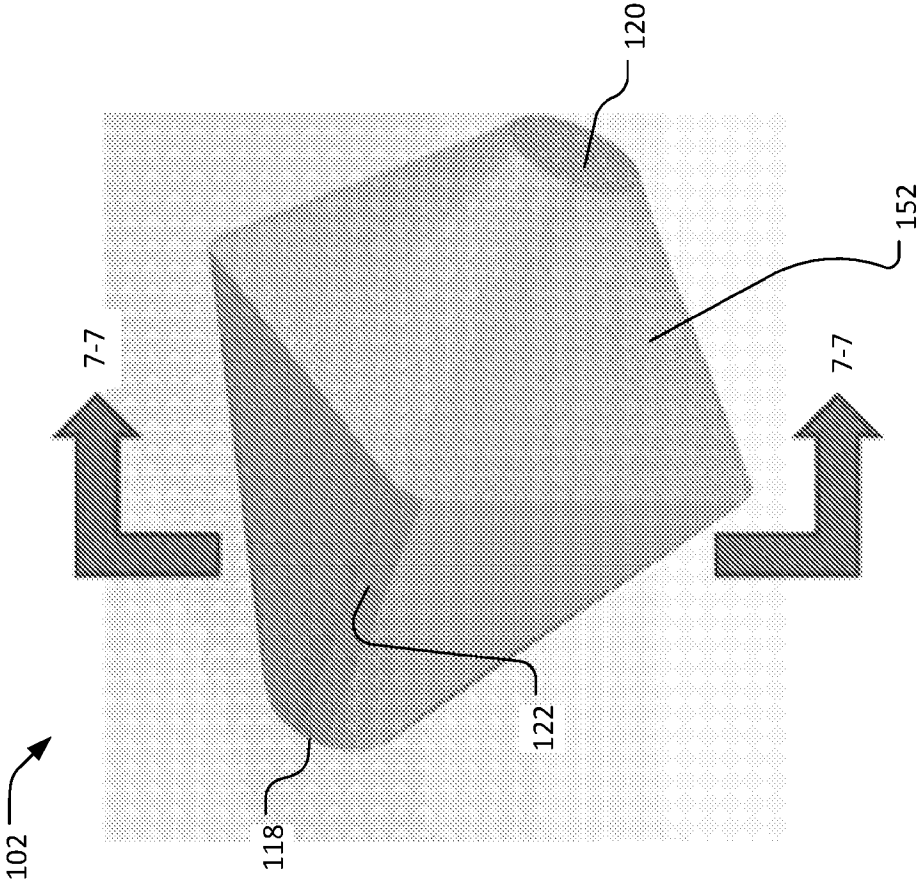


FIG. 6

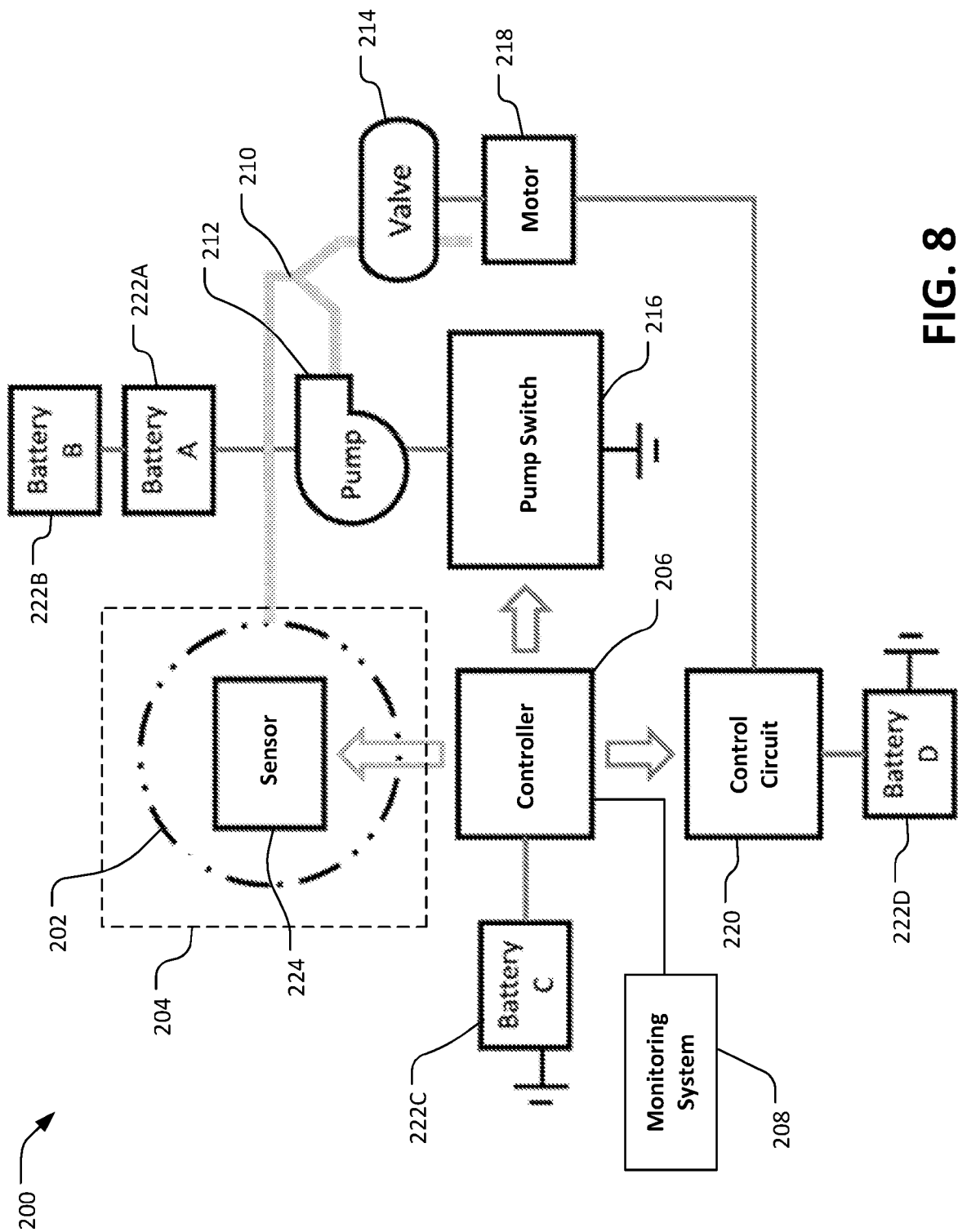


FIG. 8

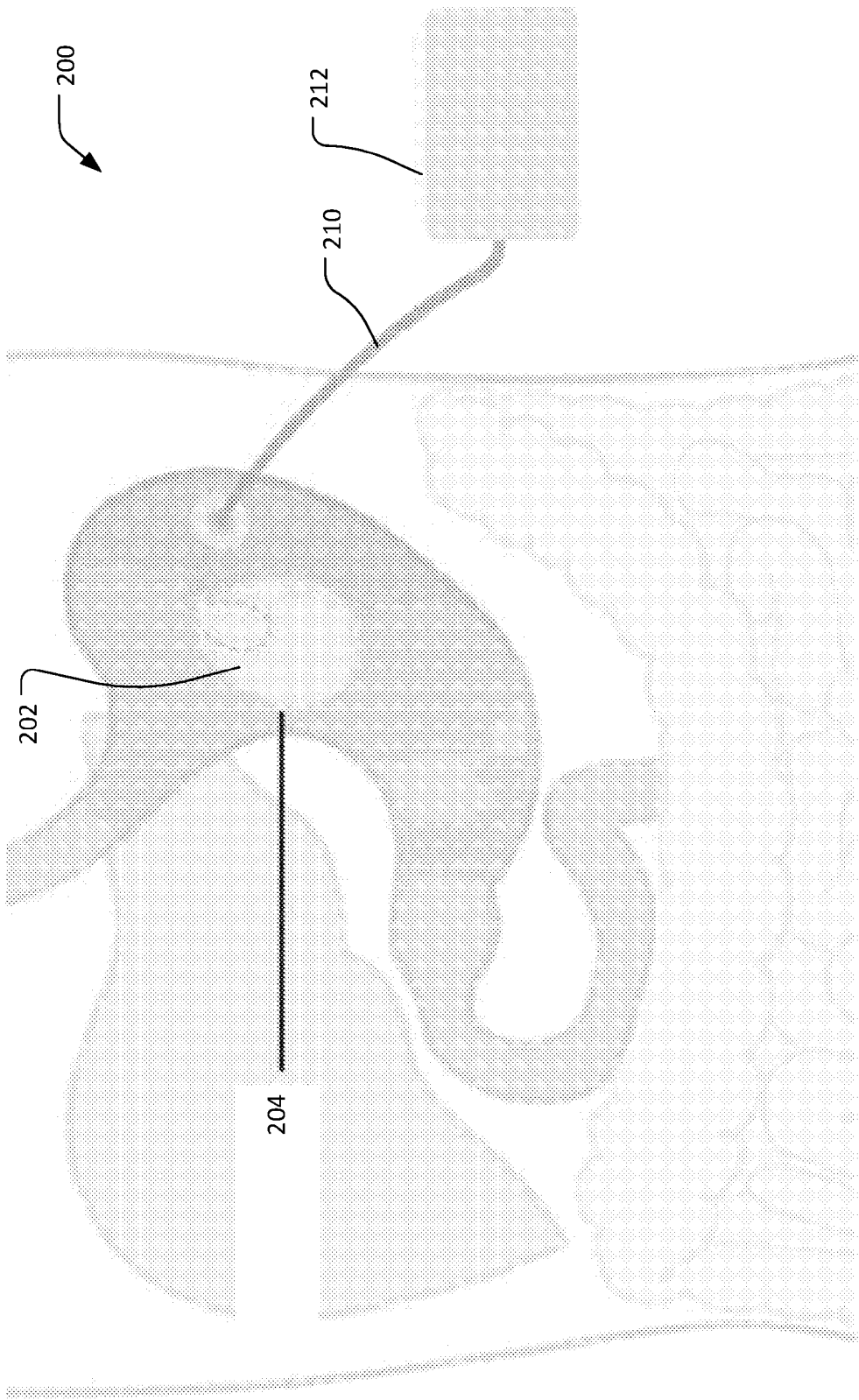


FIG. 9

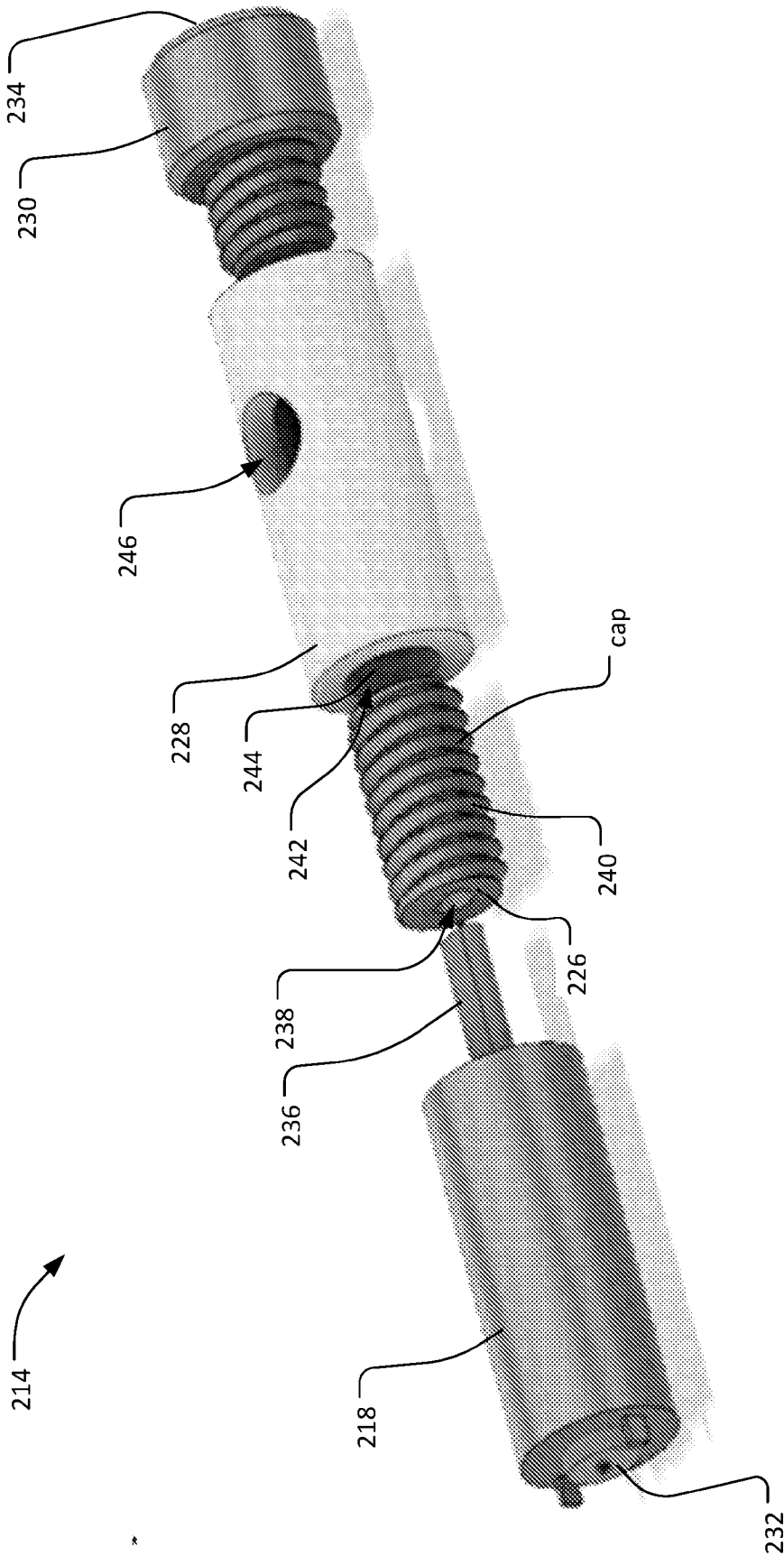


FIG. 10

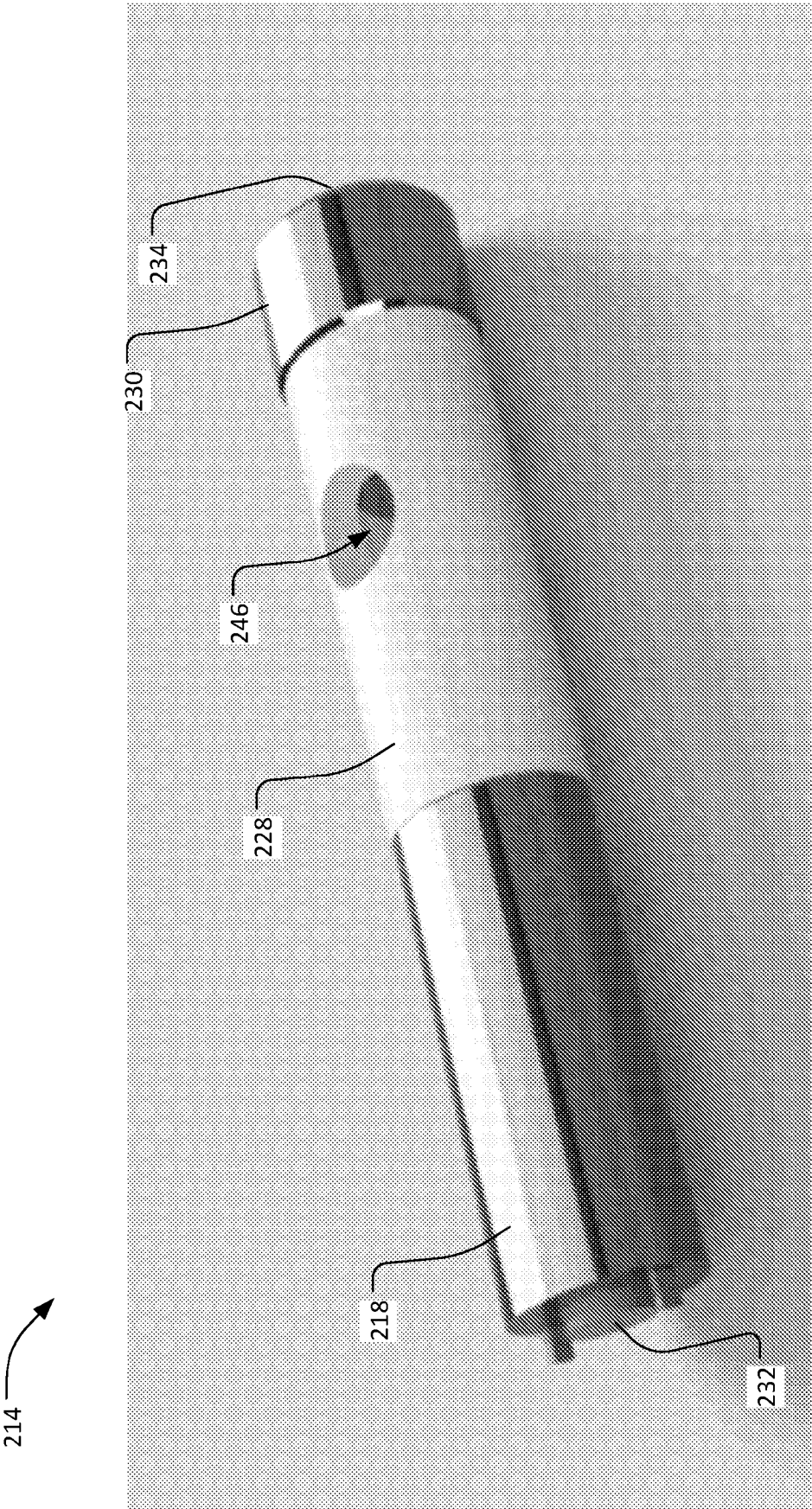


FIG. 11

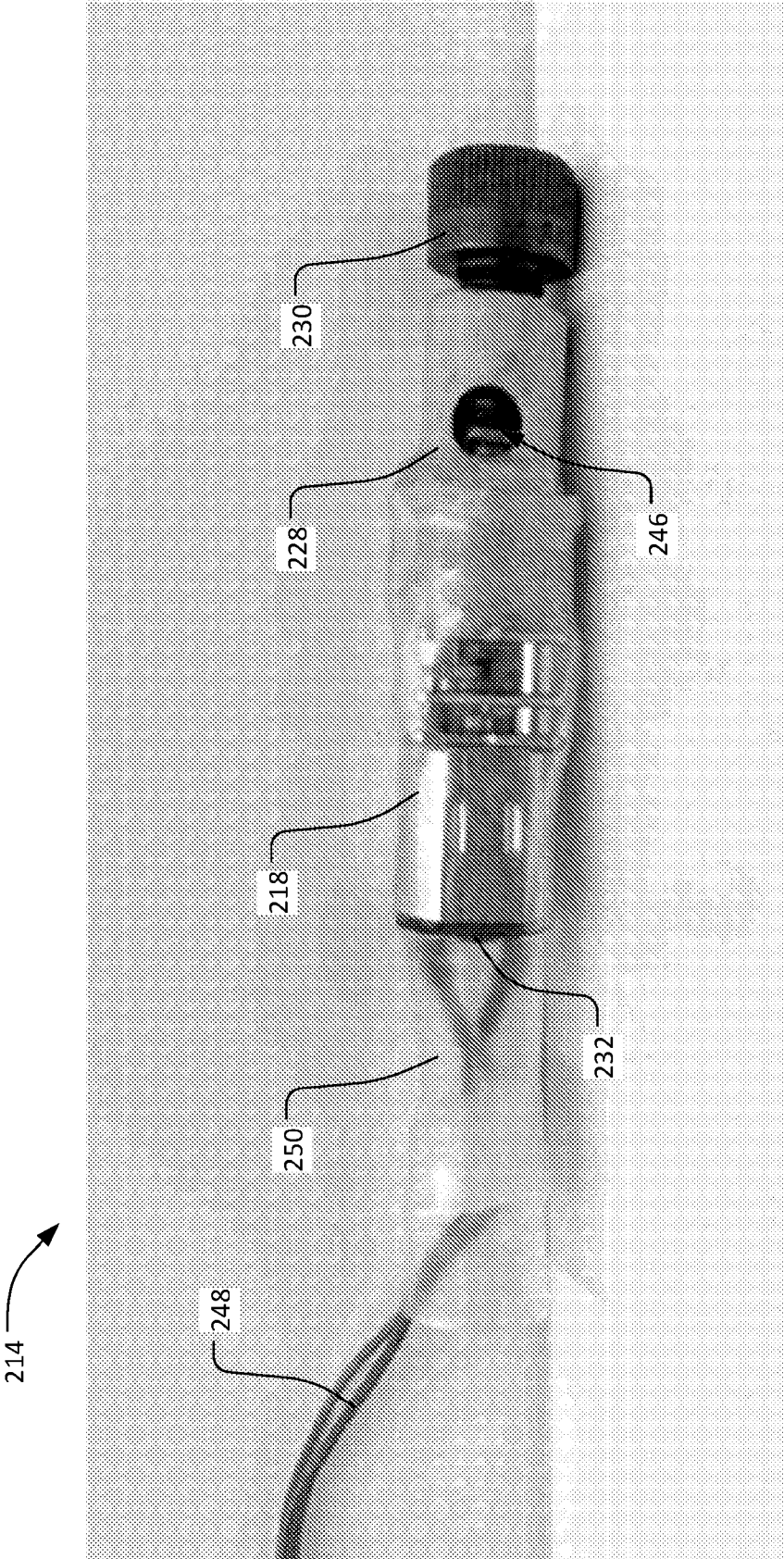


FIG. 12

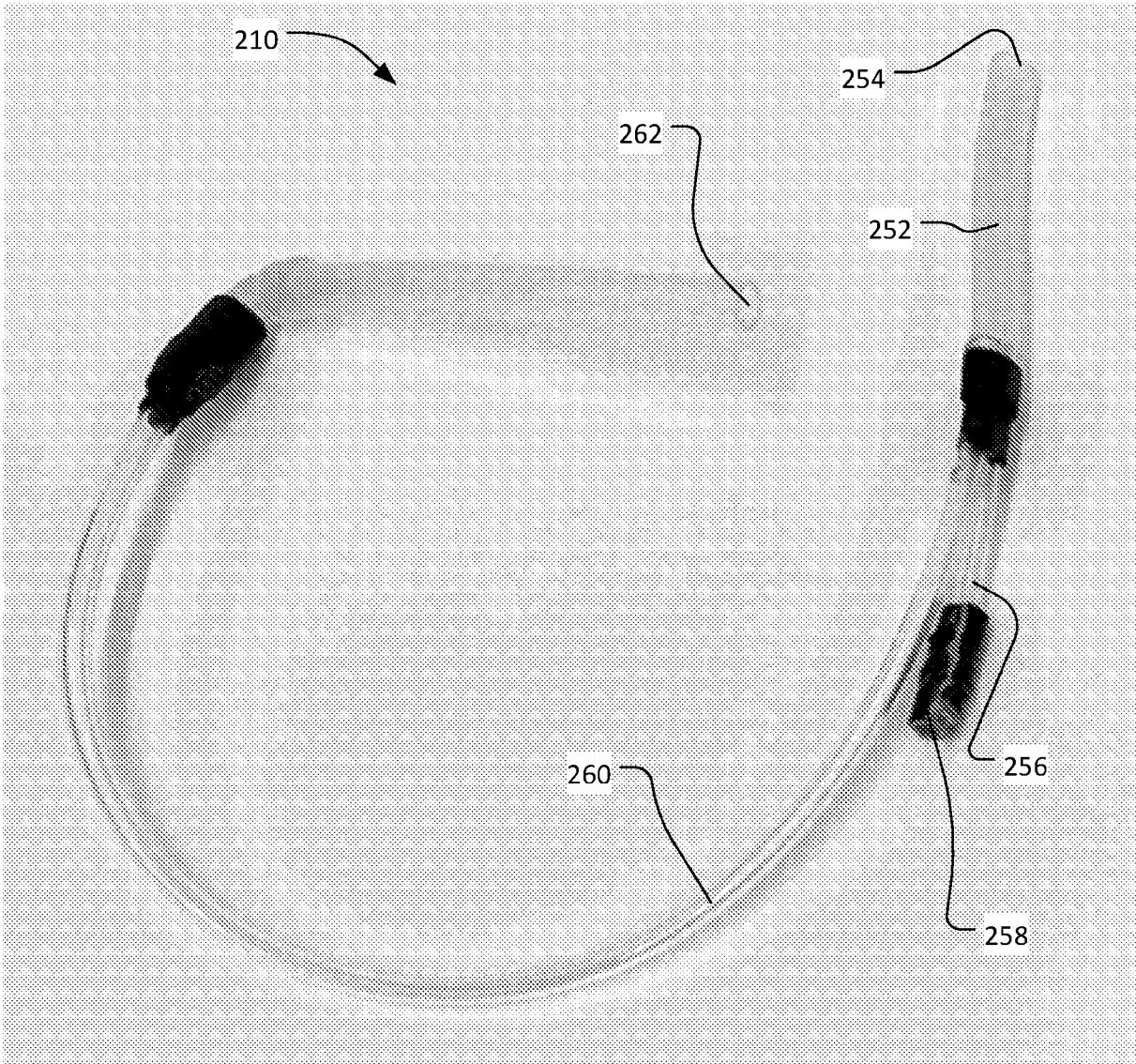


FIG. 13

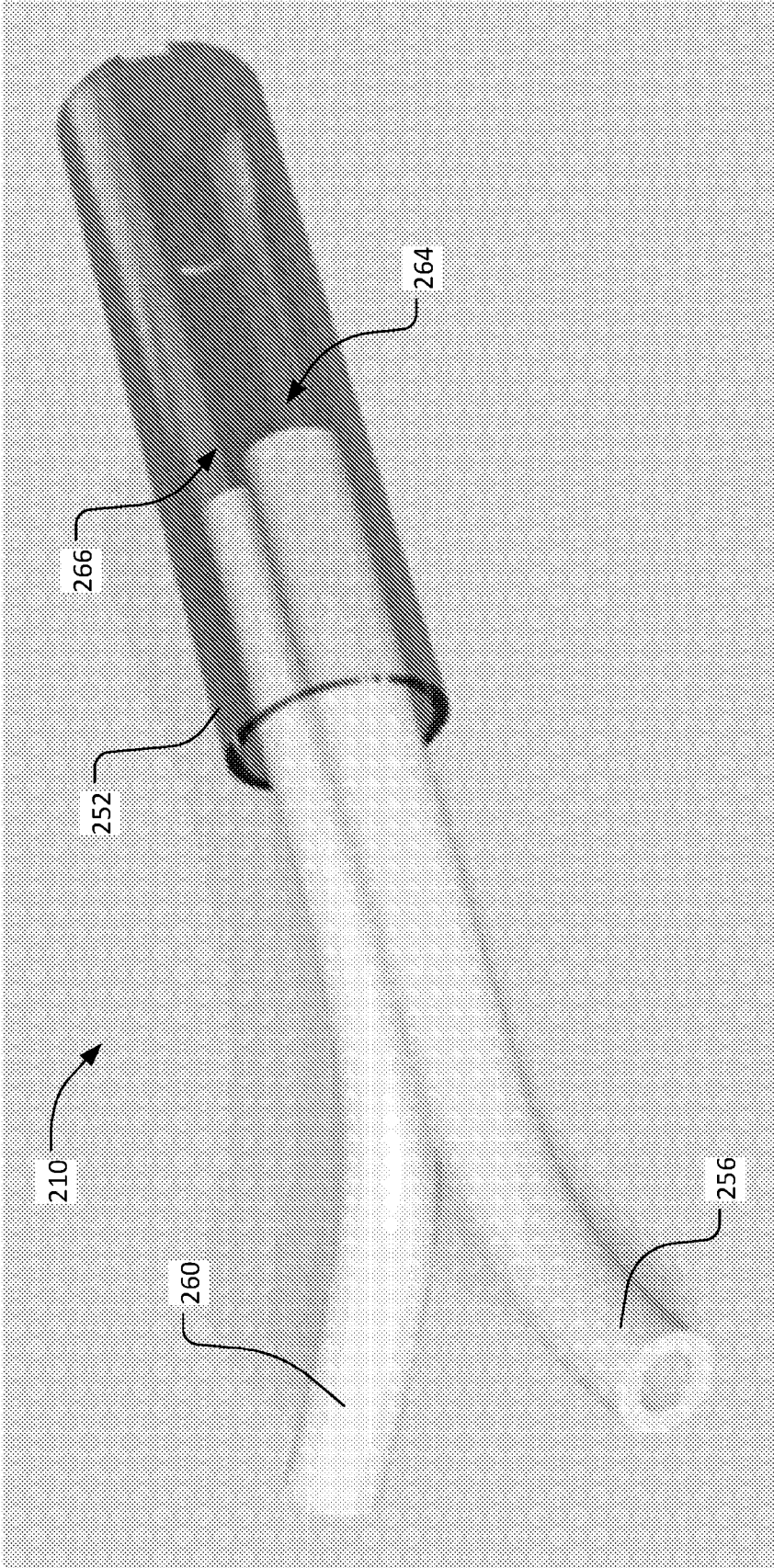
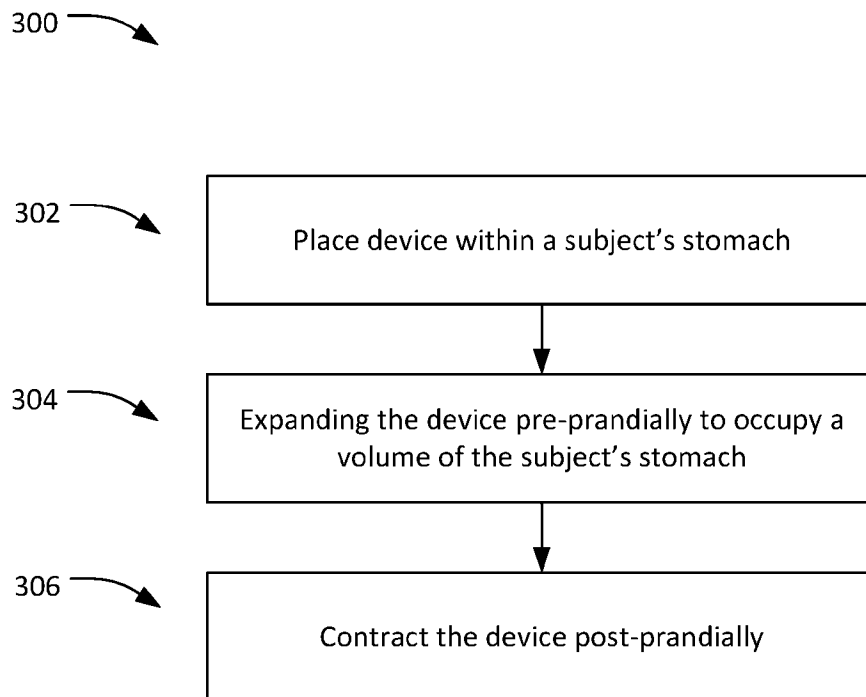


FIG. 14

**FIG. 15**

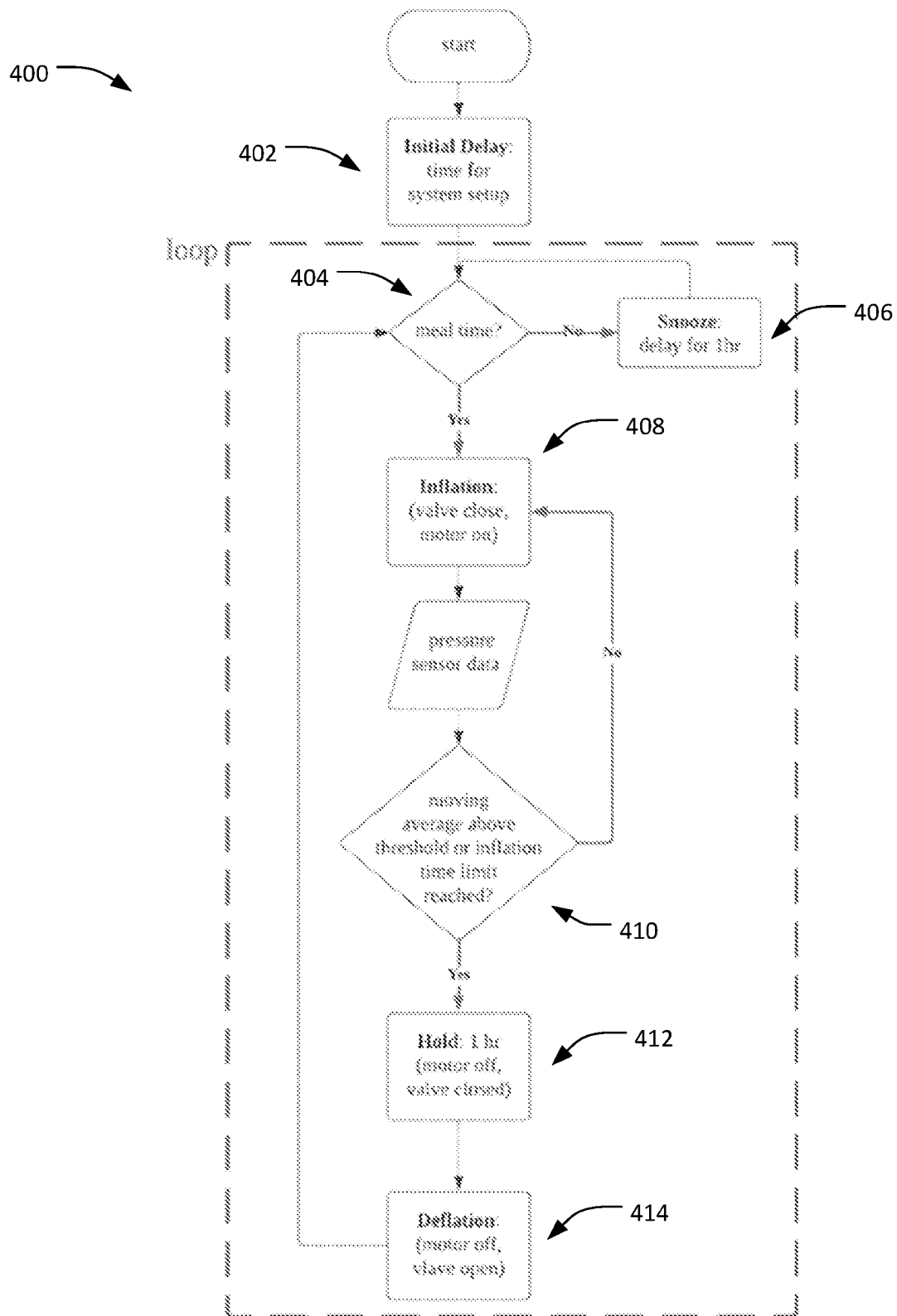


FIG. 16

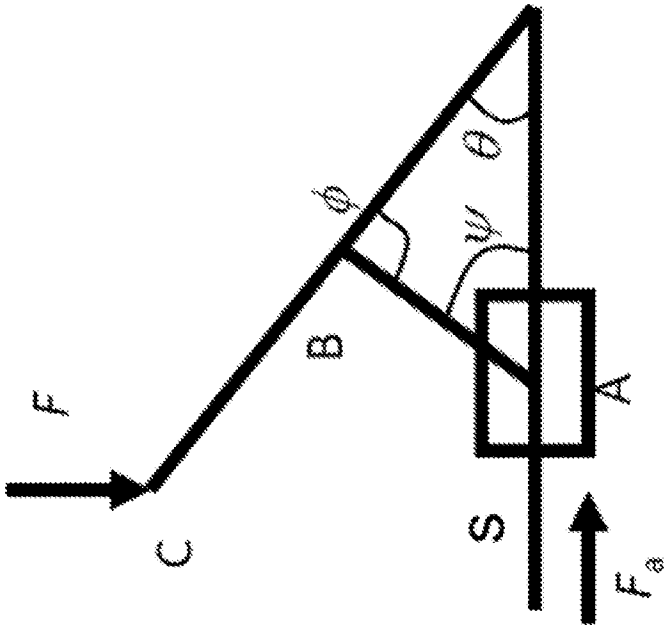


FIG. 17A

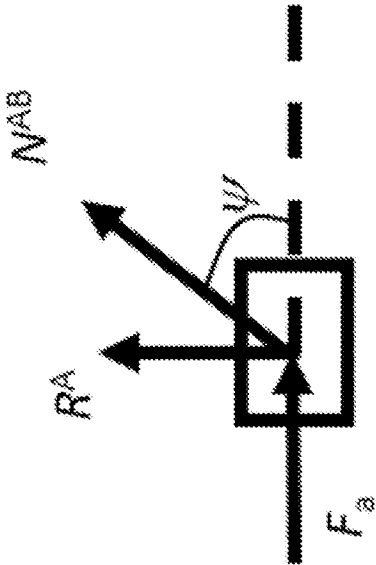


FIG. 17B

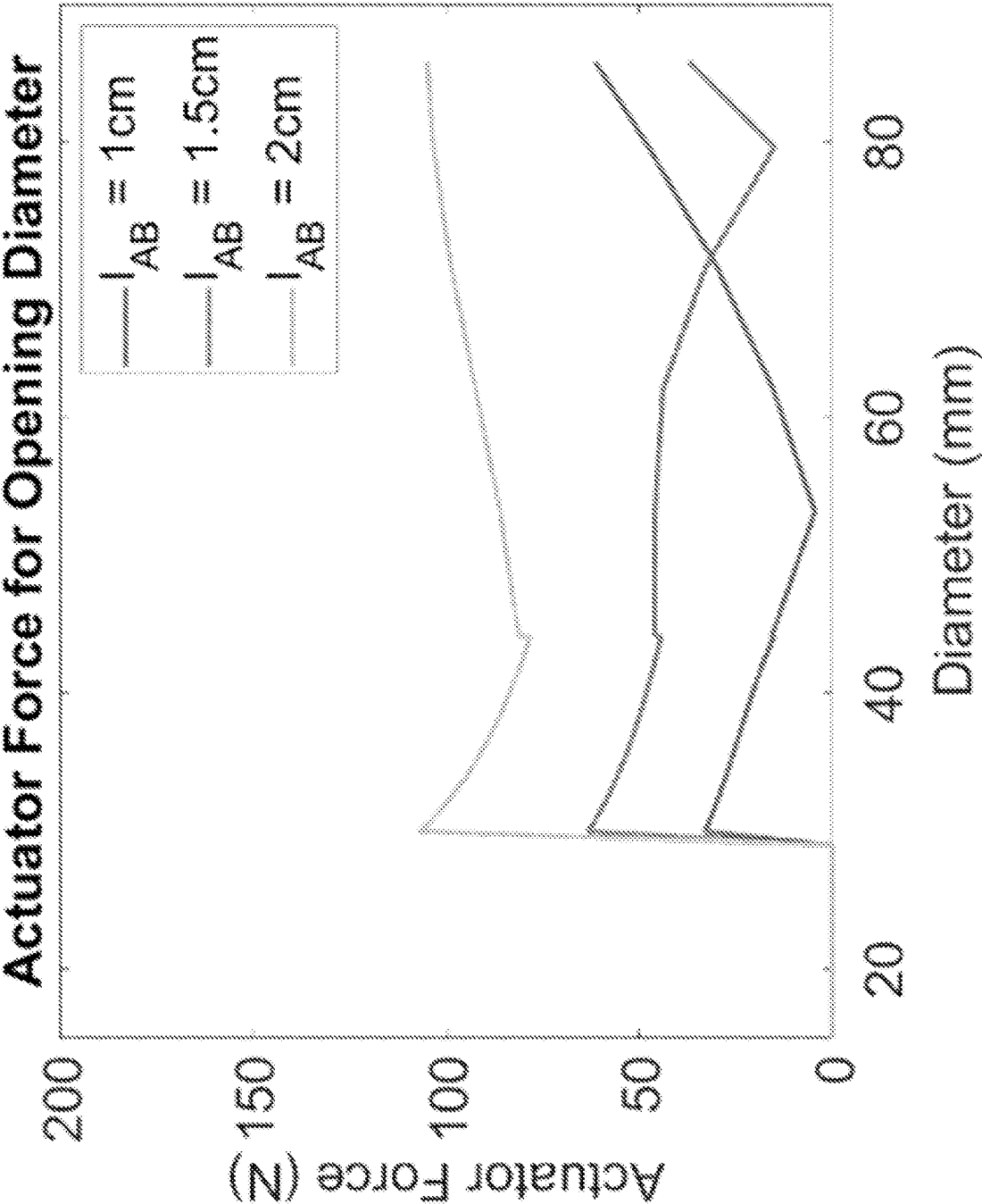


FIG. 18

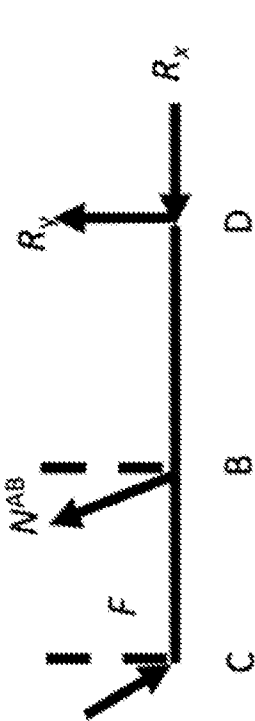


FIG. 19A

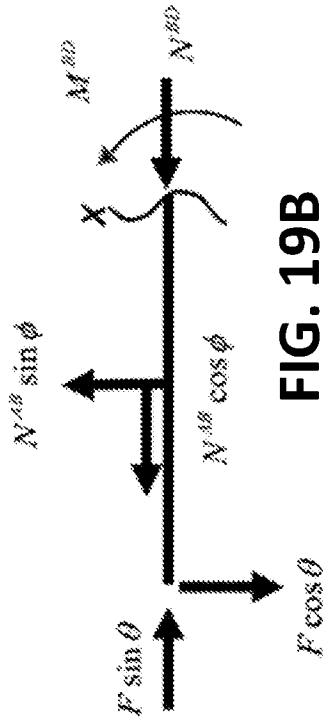


FIG. 19B

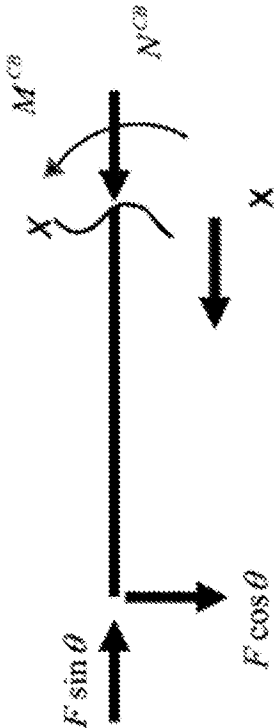


FIG. 19C

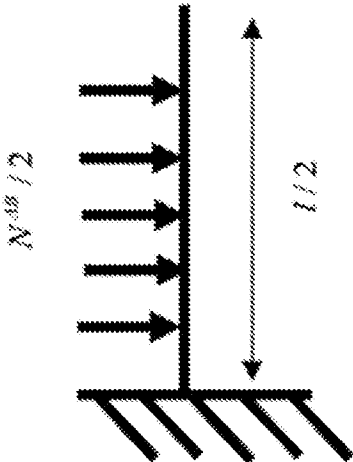


FIG. 19D

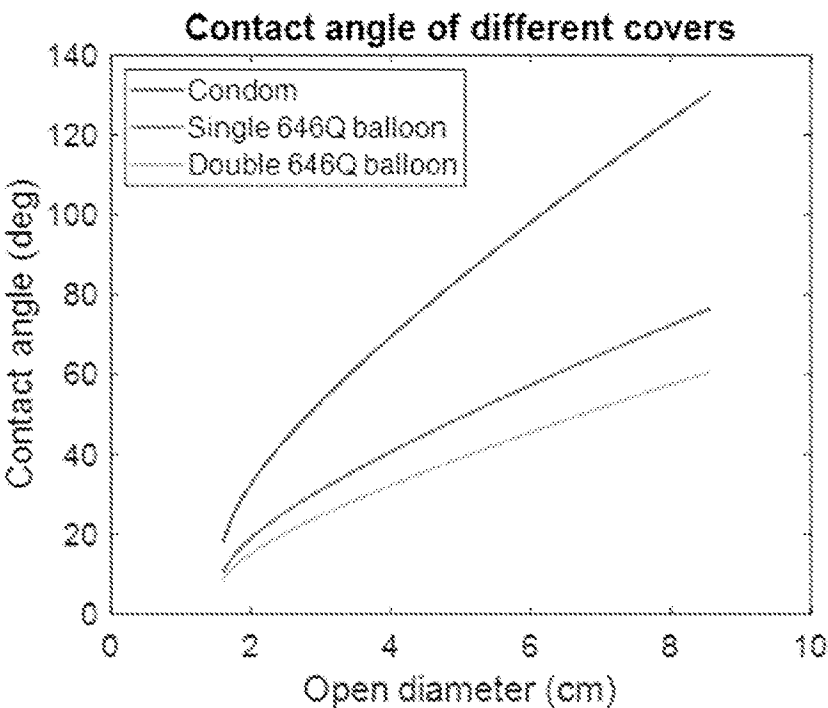


FIG. 20A

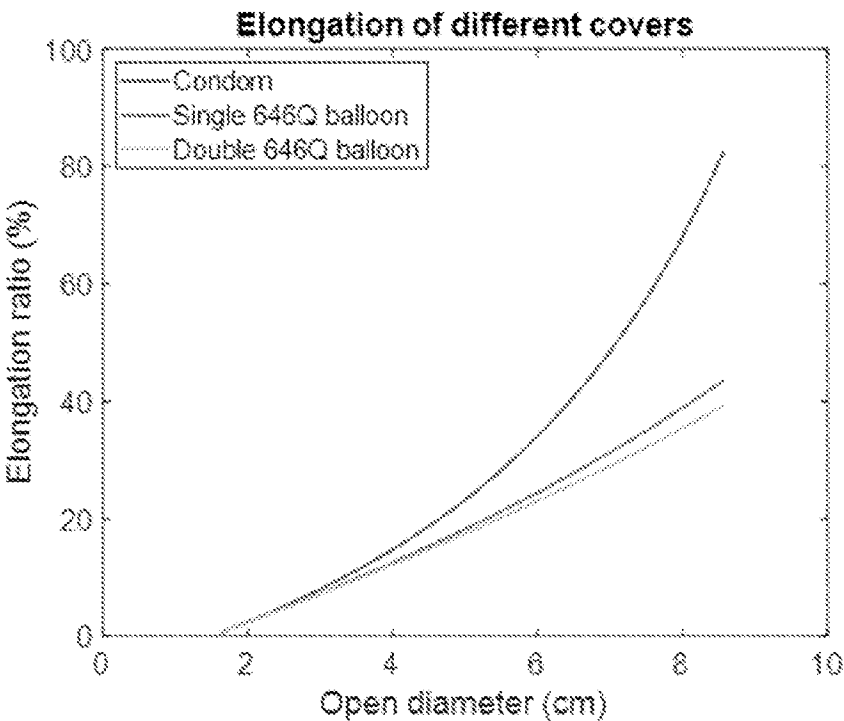


FIG. 20B

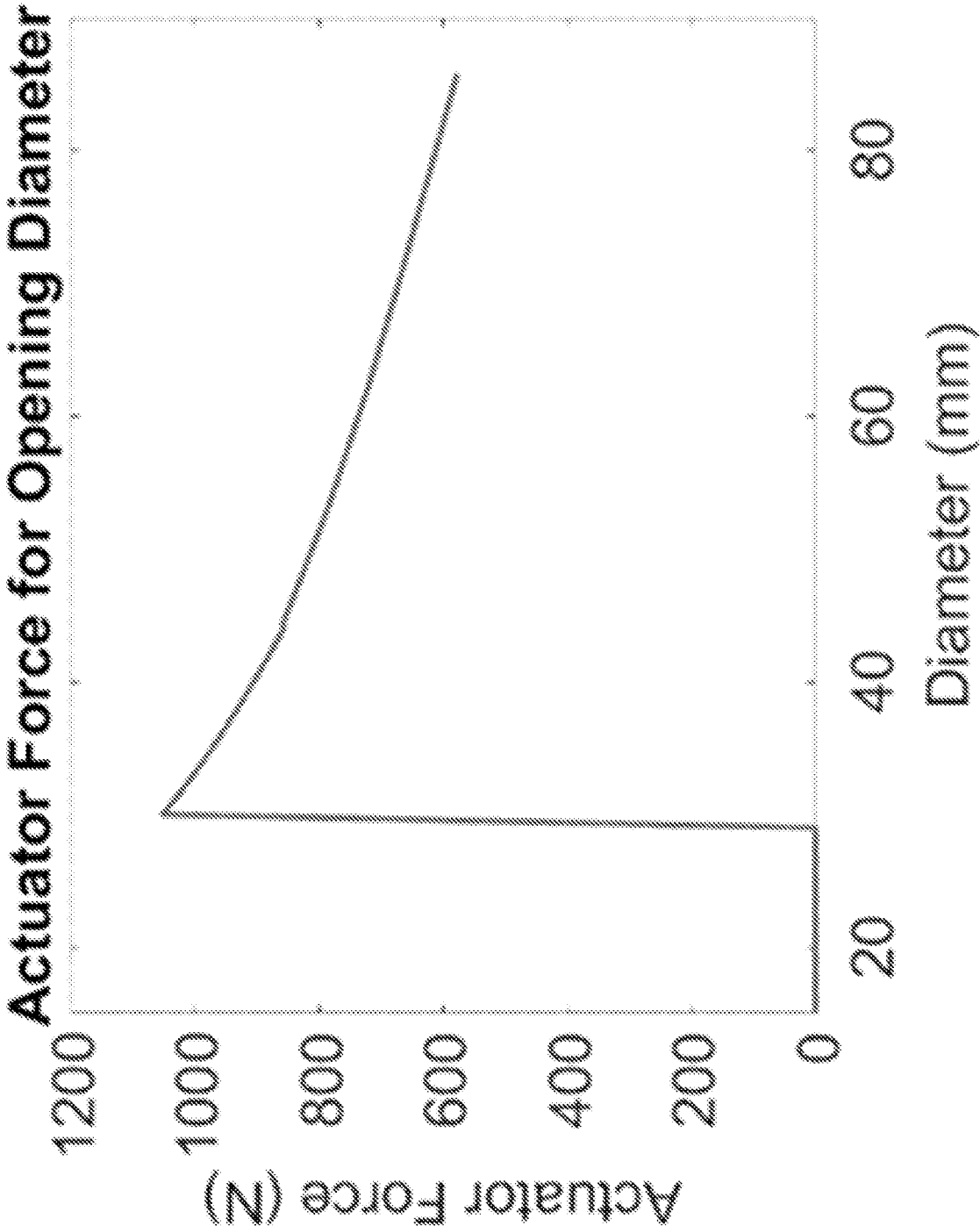


FIG. 21

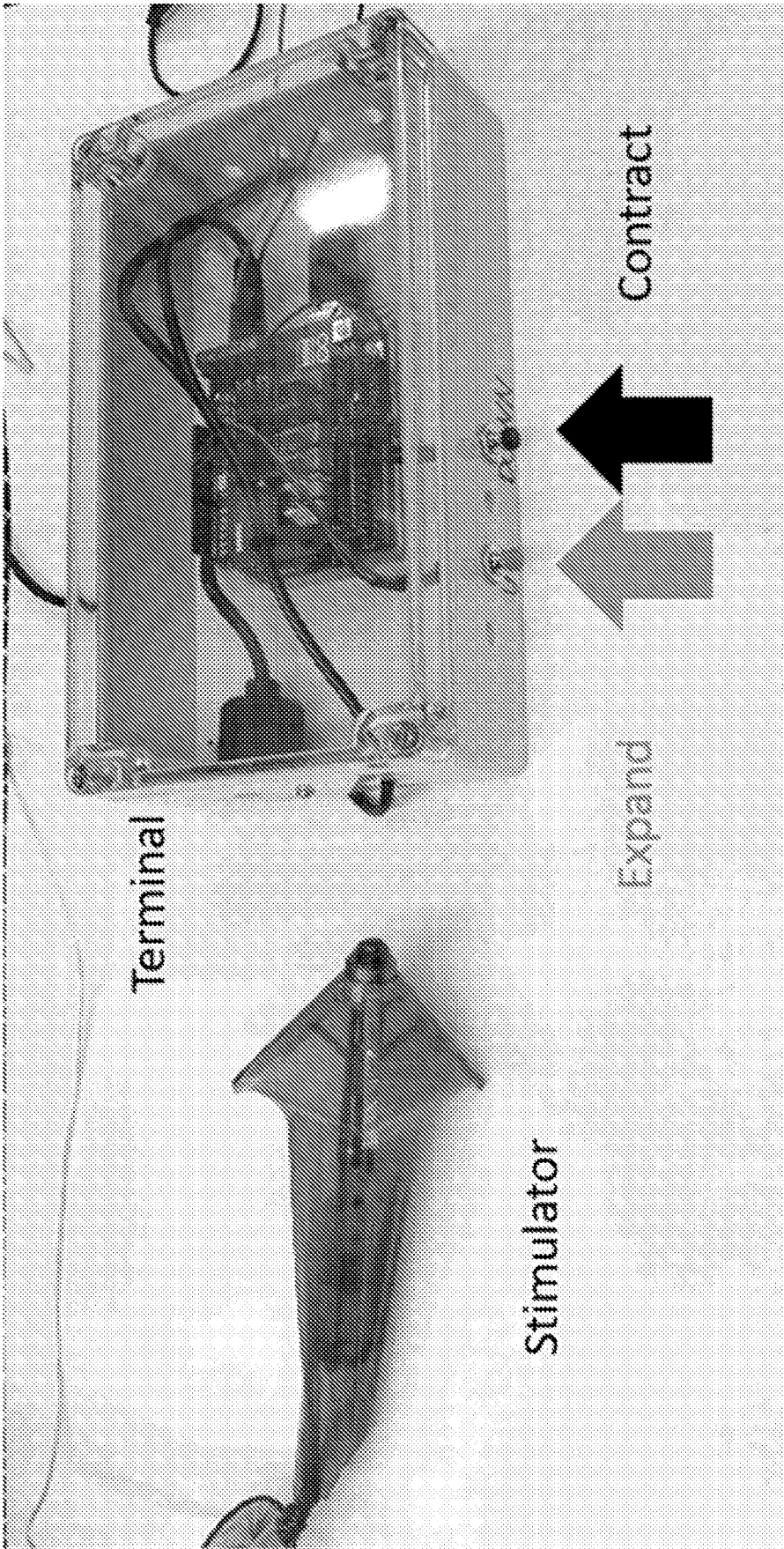
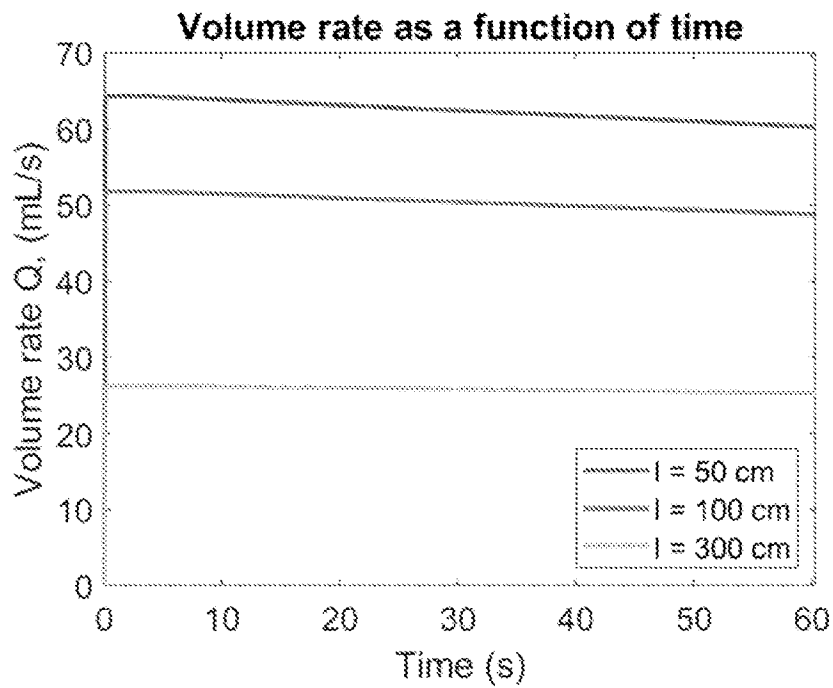
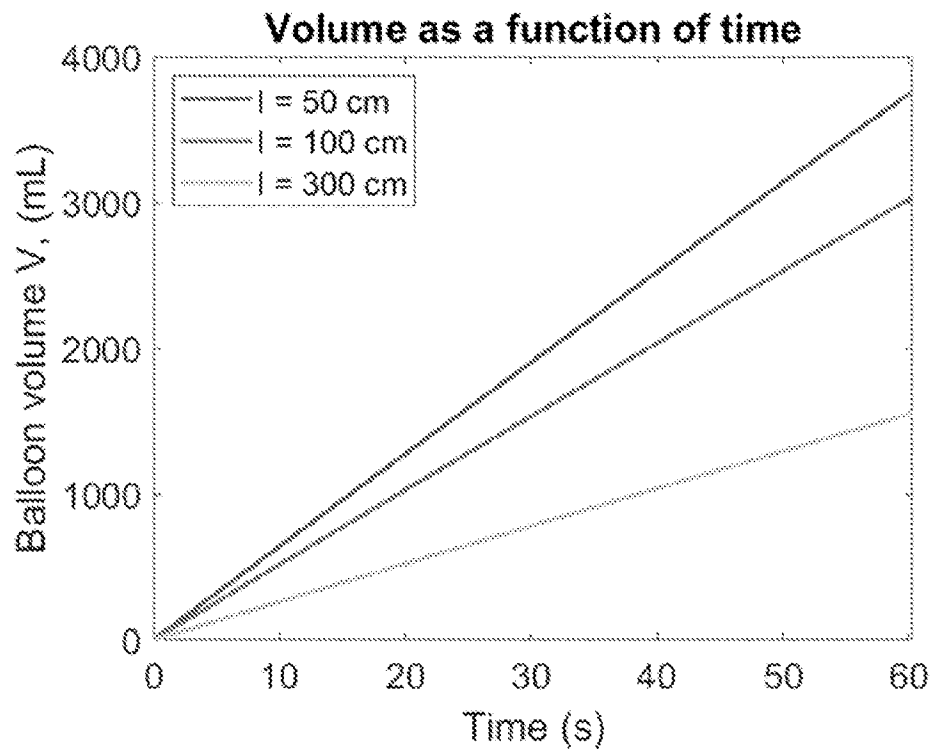


FIG. 22

**FIG. 23A****FIG. 23B**

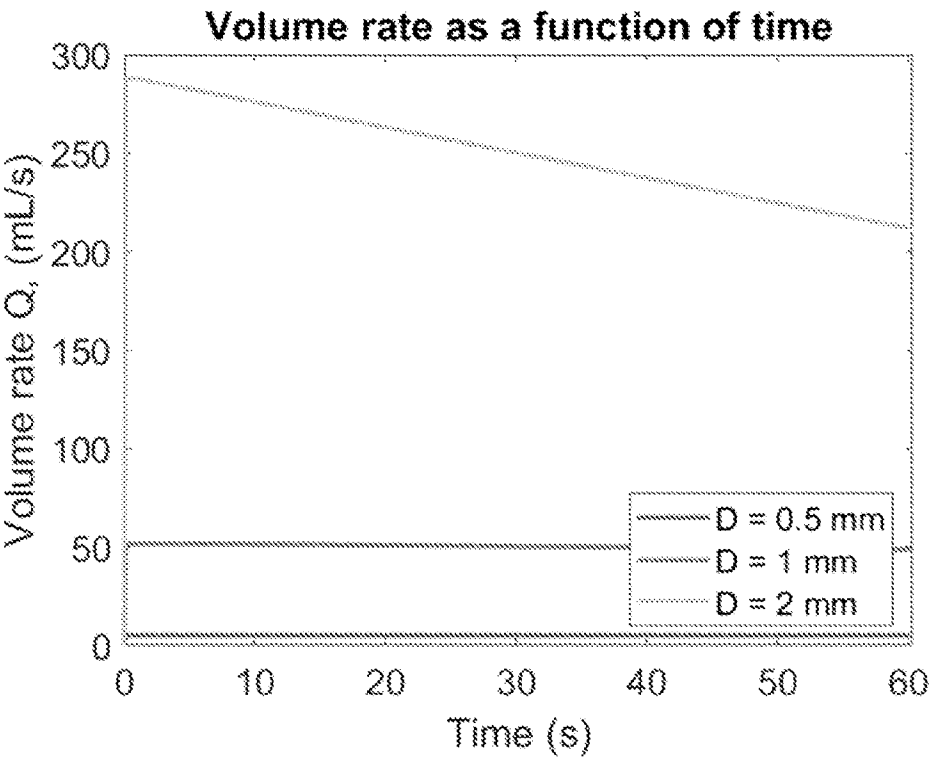


FIG. 24A

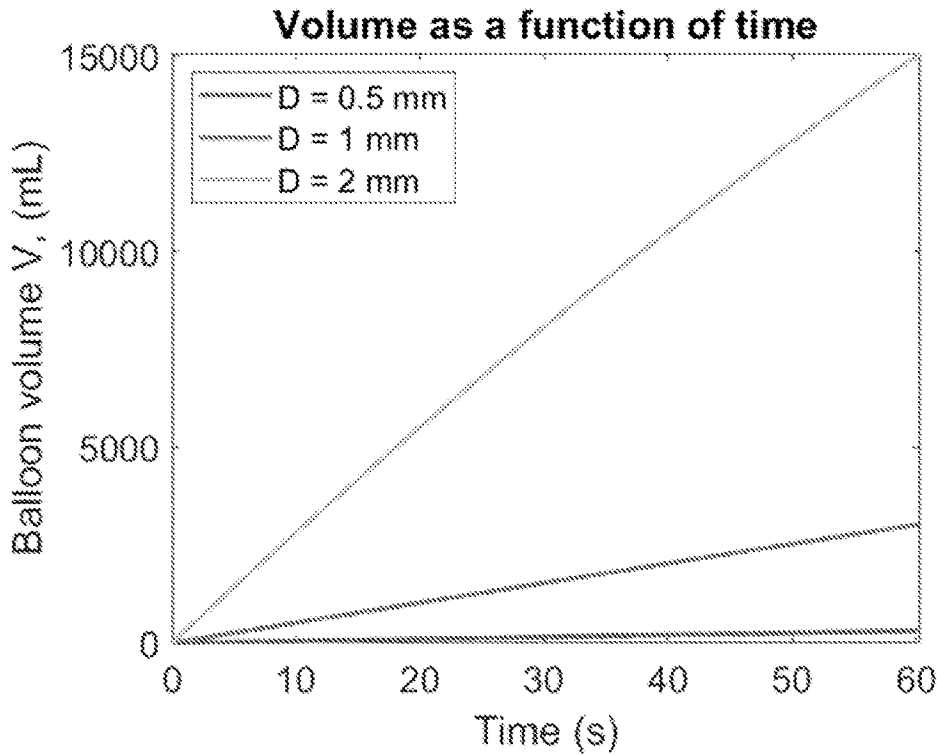


FIG. 24B

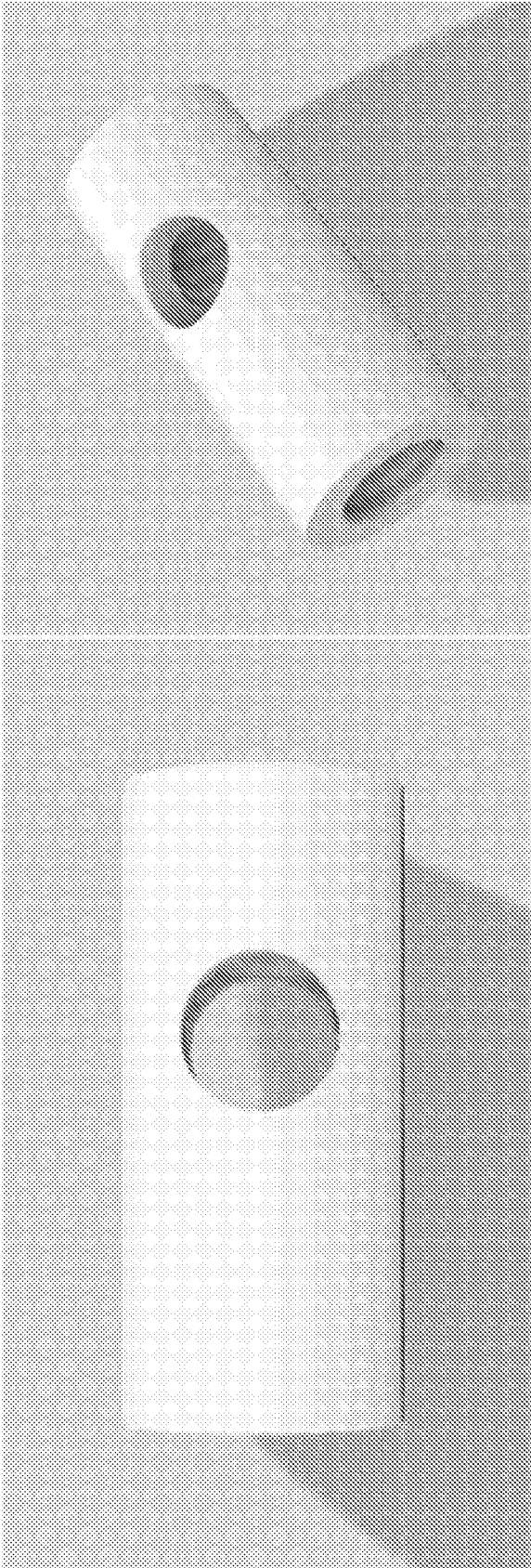


FIG. 25A

FIG. 25B



FIG. 26A

FIG. 26B

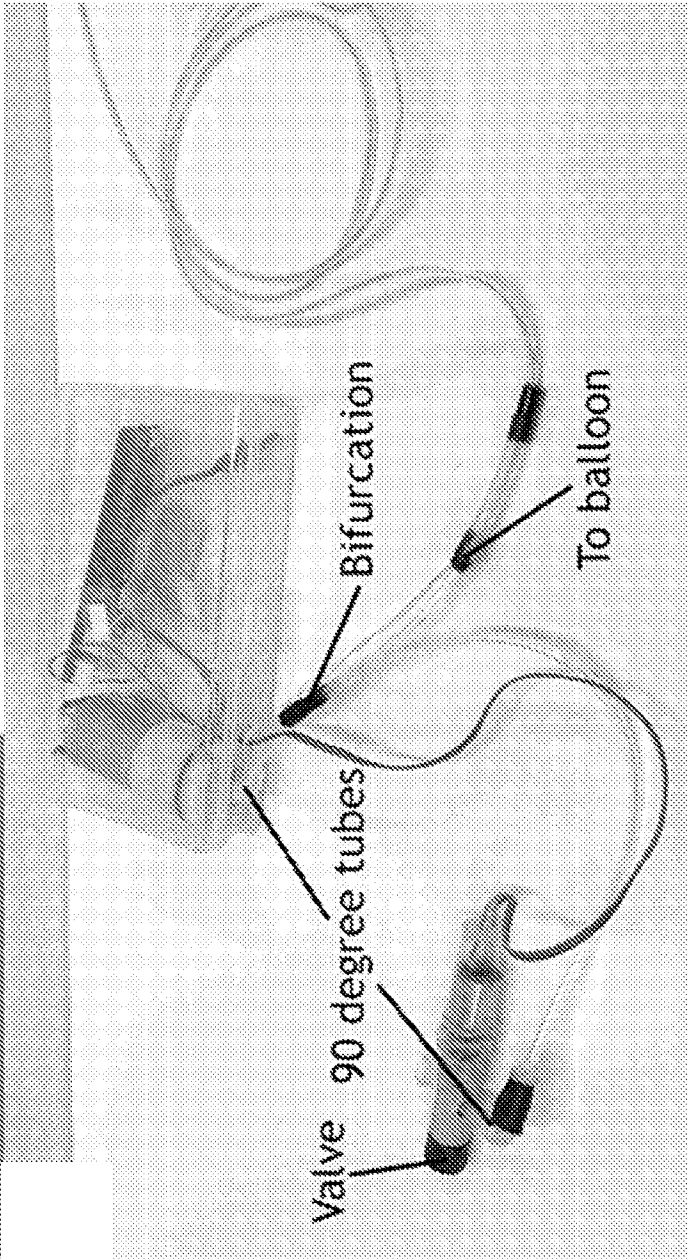
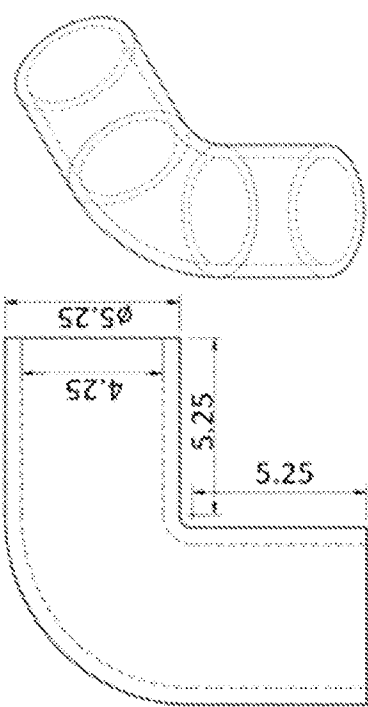


FIG. 26C

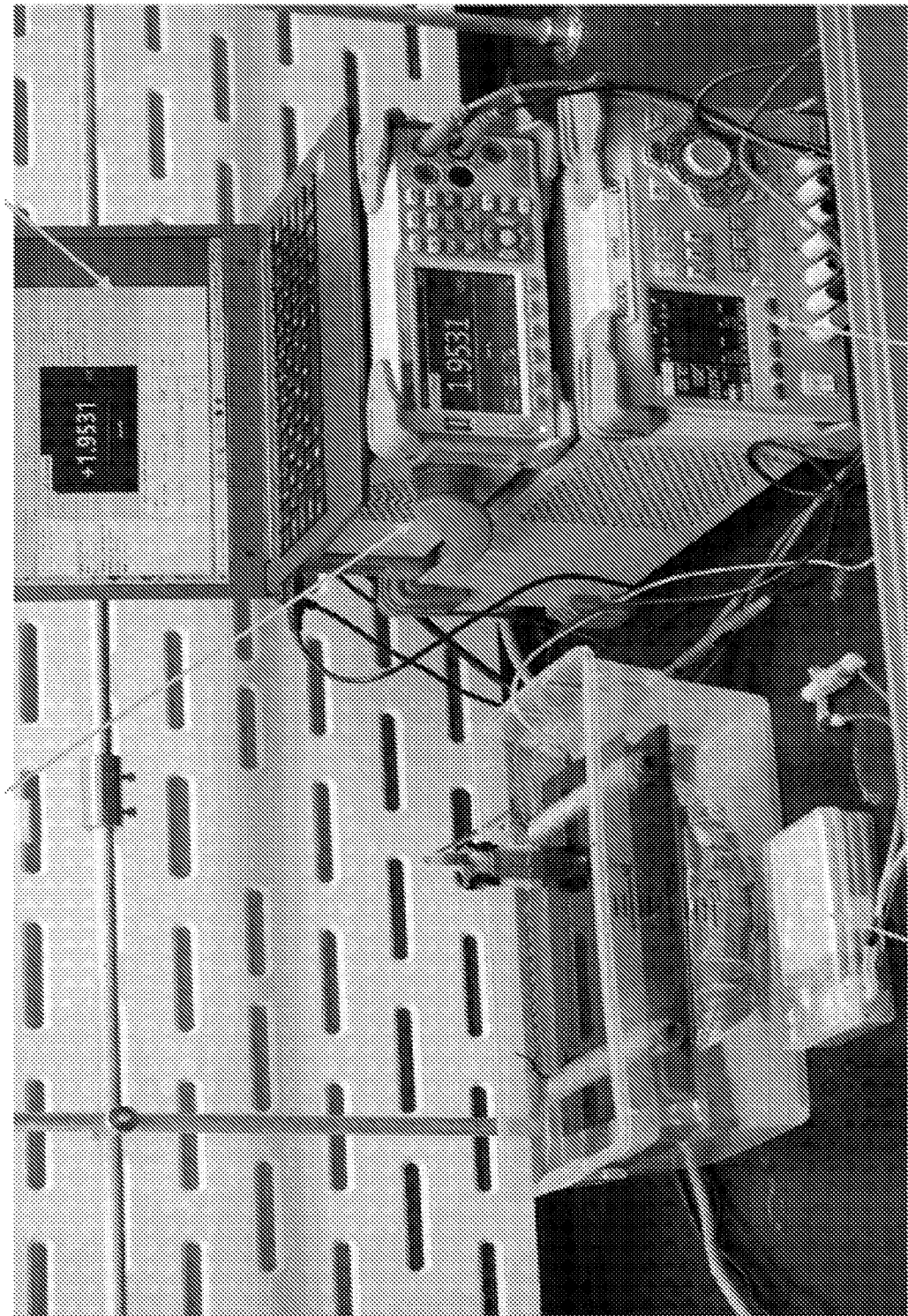


FIG. 27

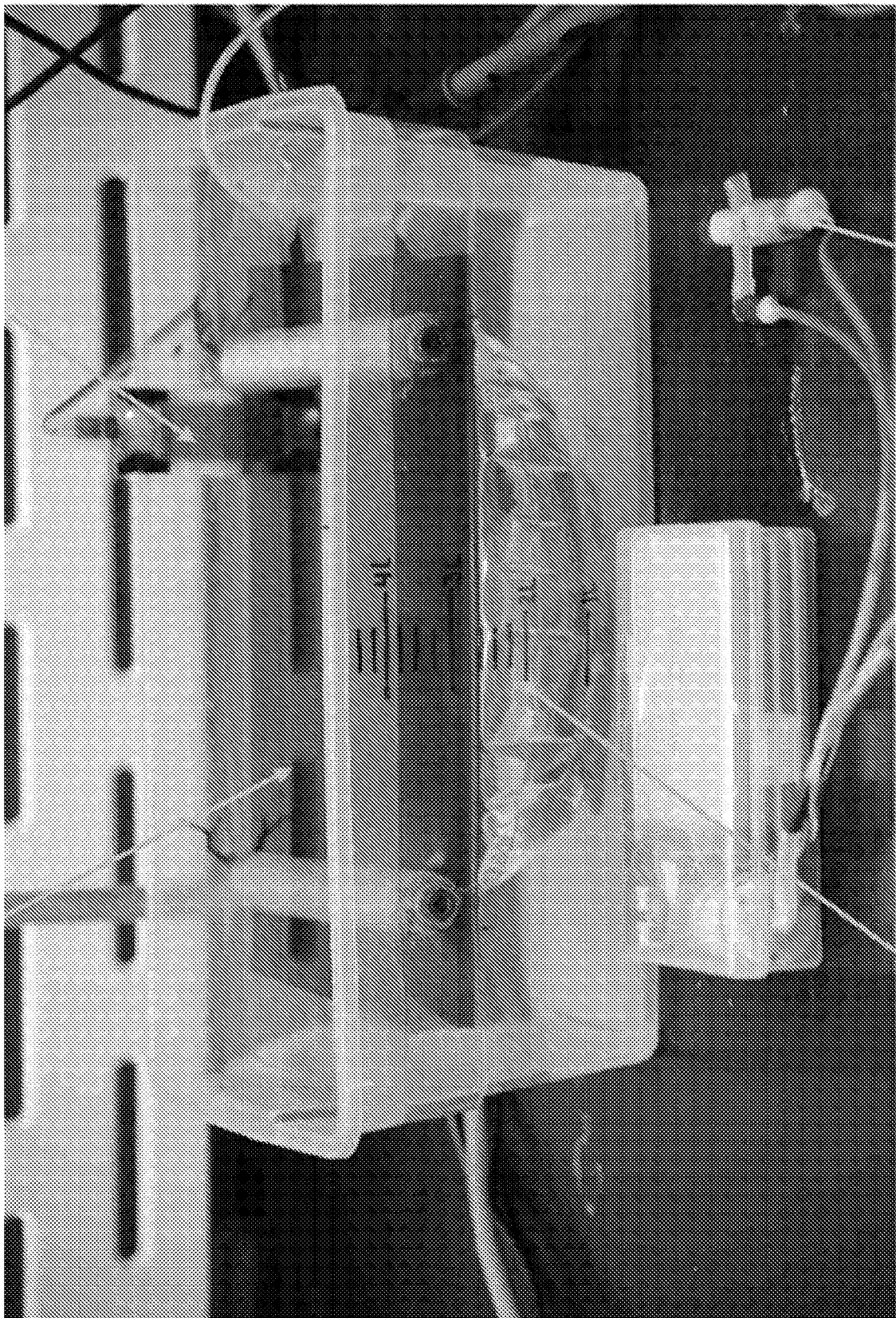


FIG. 28

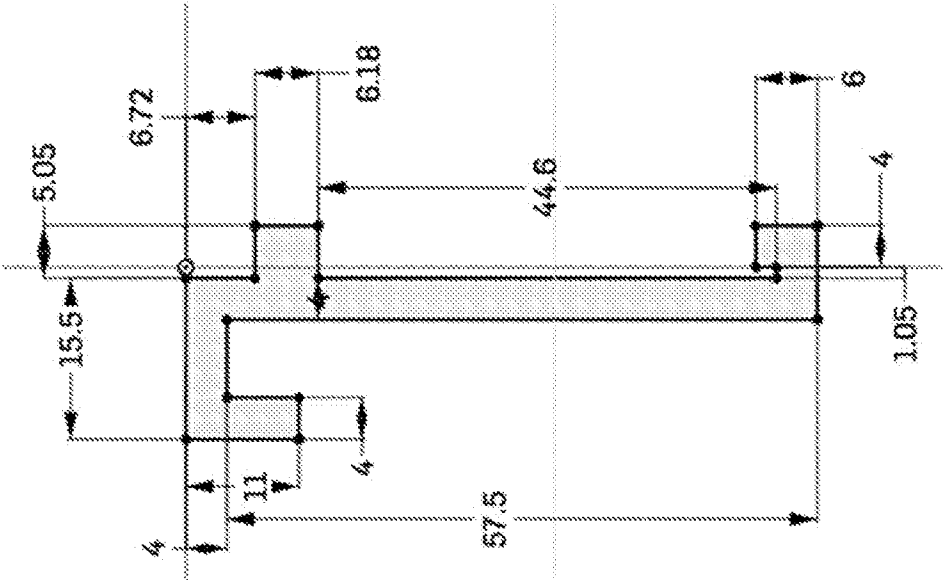


FIG. 29C

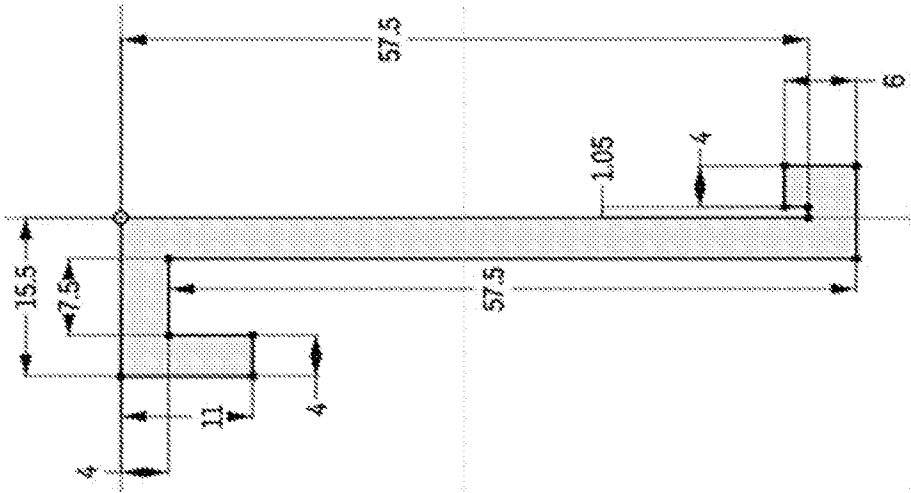


FIG. 29B

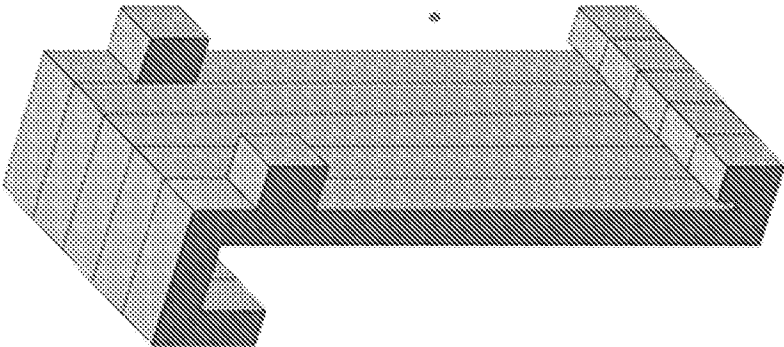
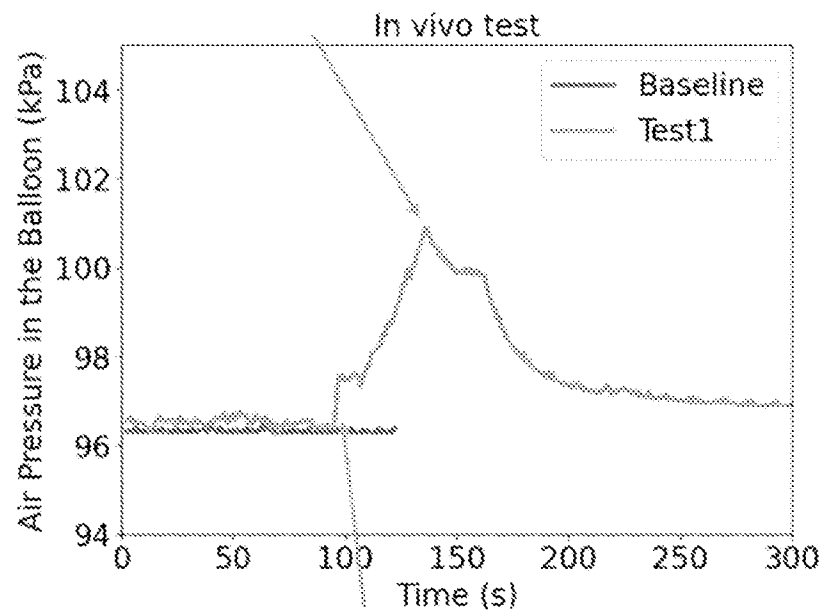
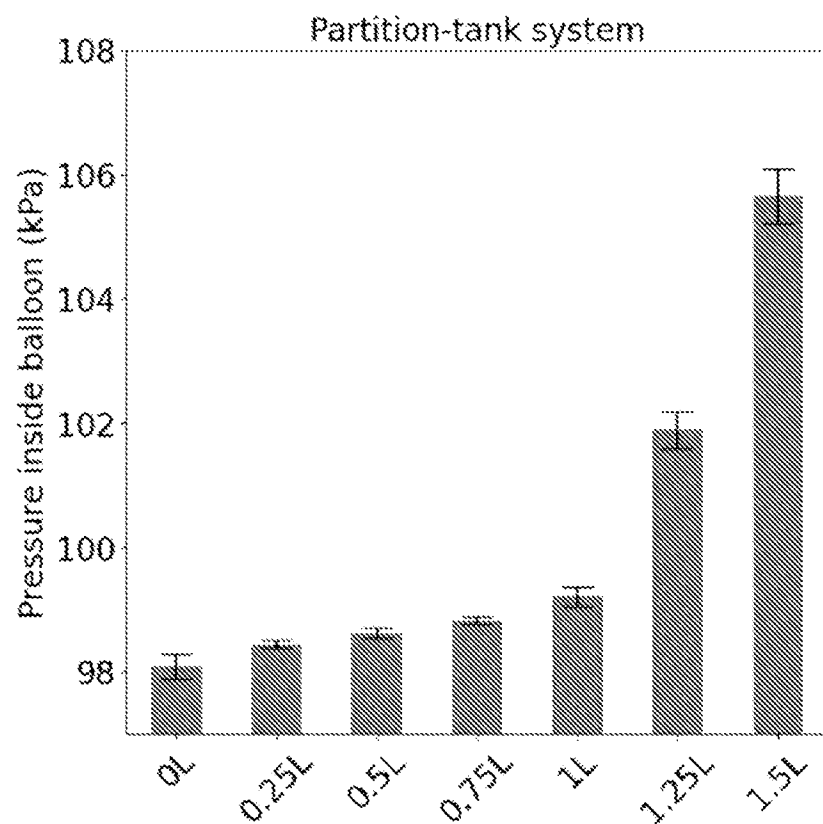


FIG. 29A

**FIG. 30A****FIG. 30B**

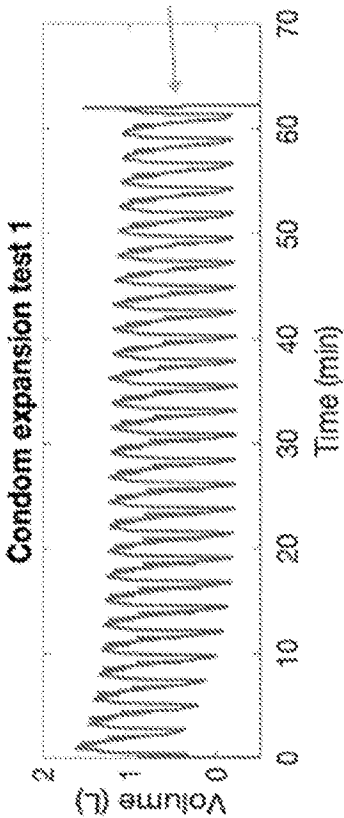


FIG. 31A

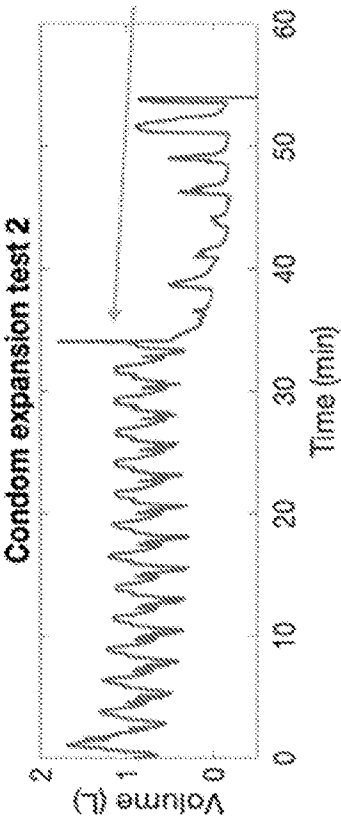


FIG. 31B

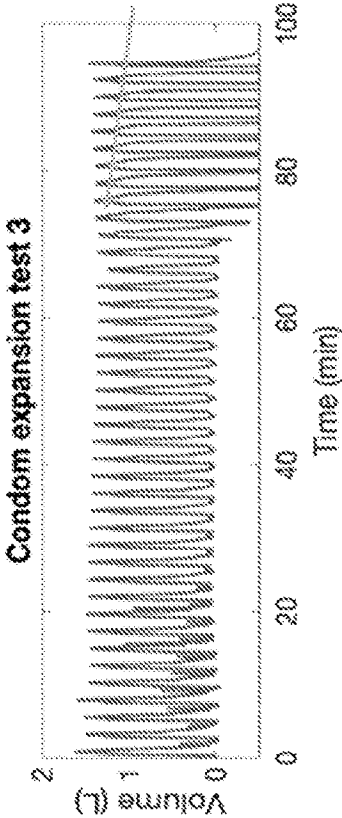


FIG. 31C

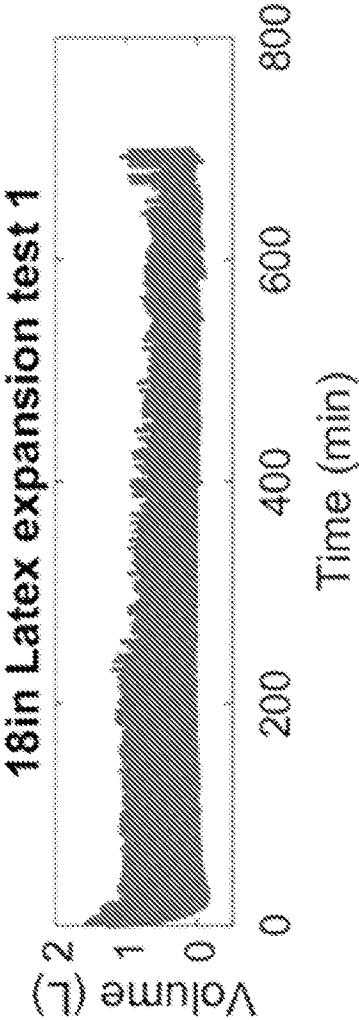


FIG. 32A

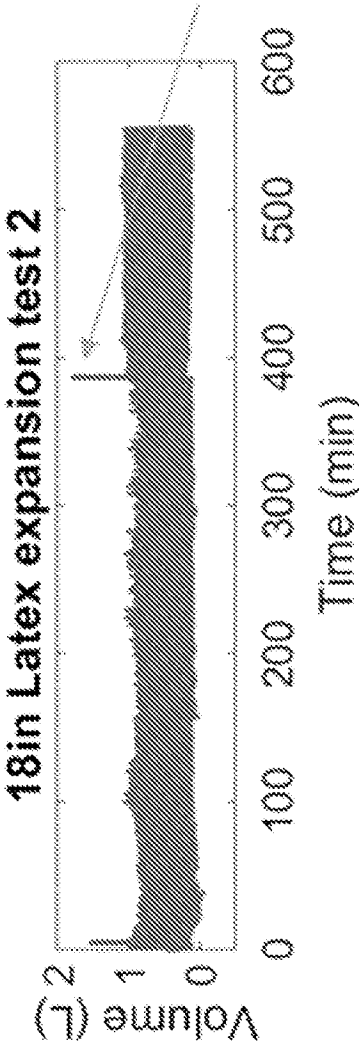


FIG. 32B

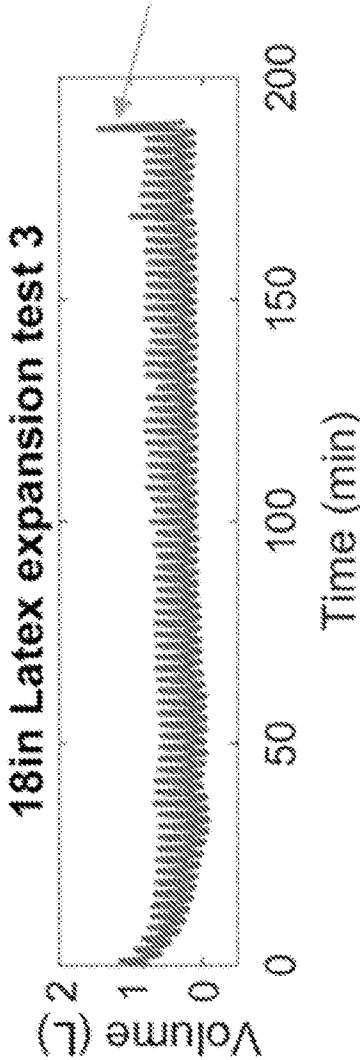


FIG. 32C

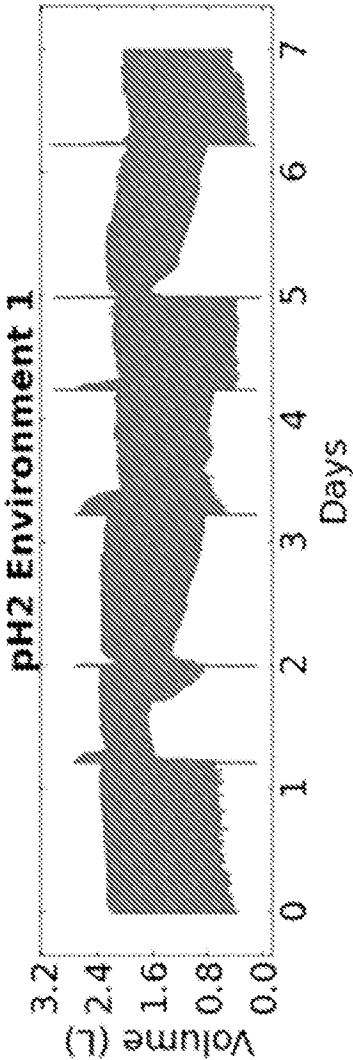


FIG. 33A

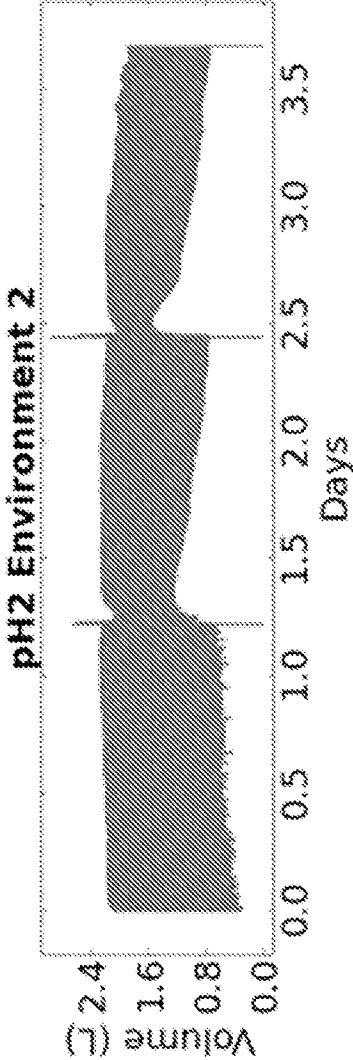


FIG. 33B

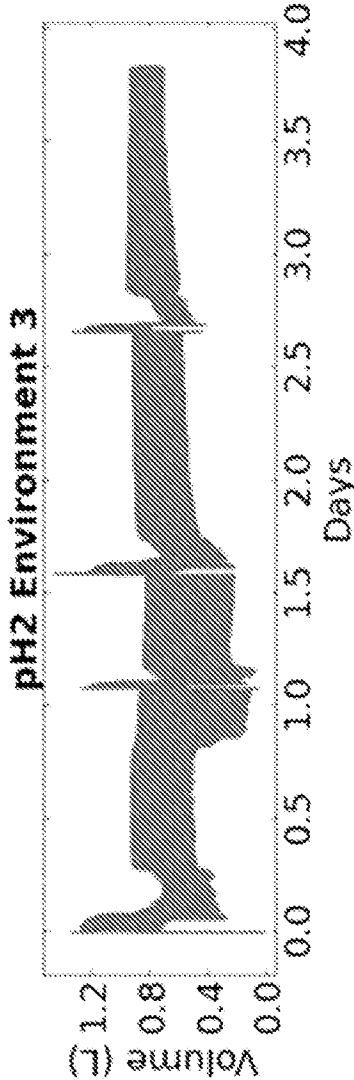


FIG. 33C

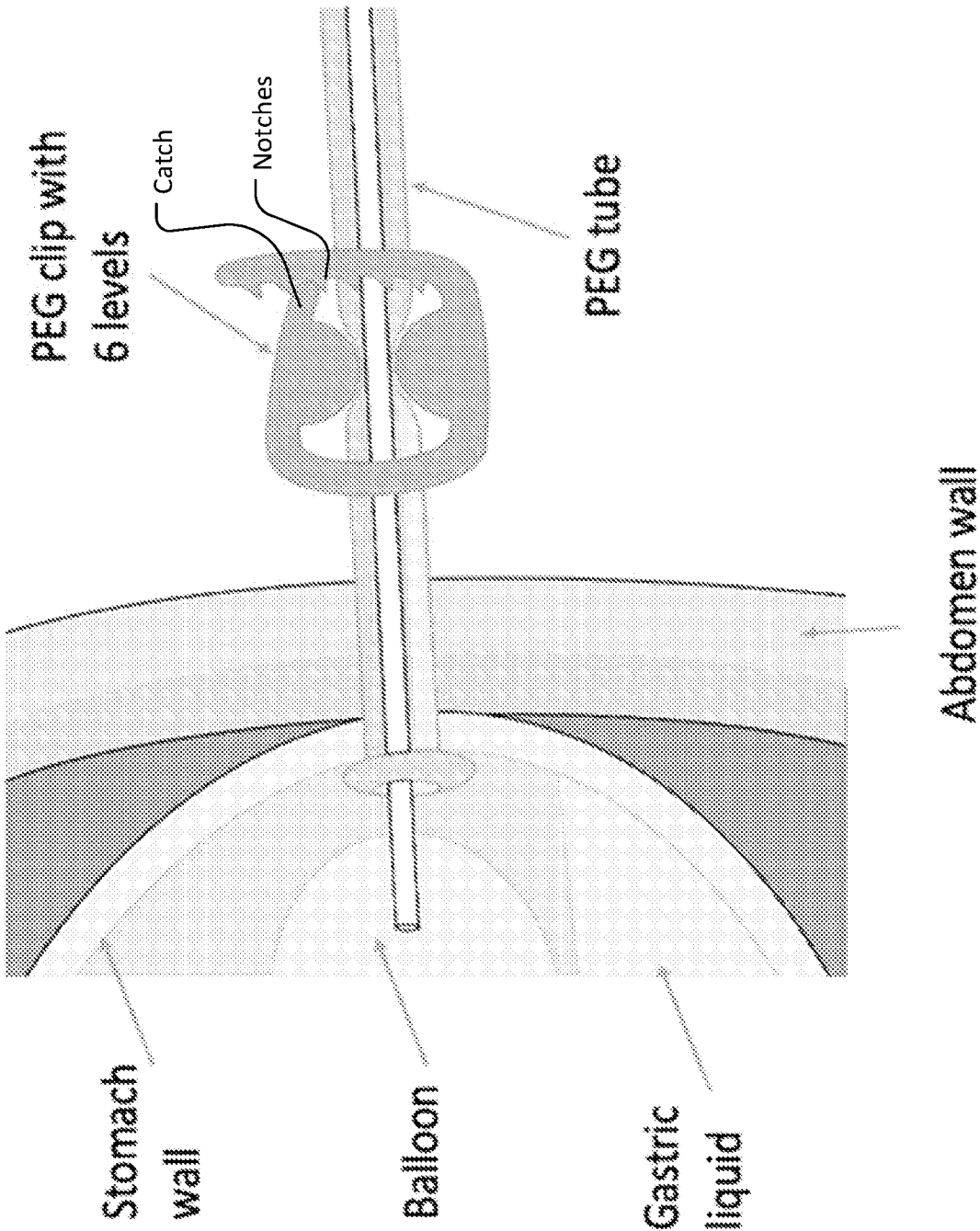
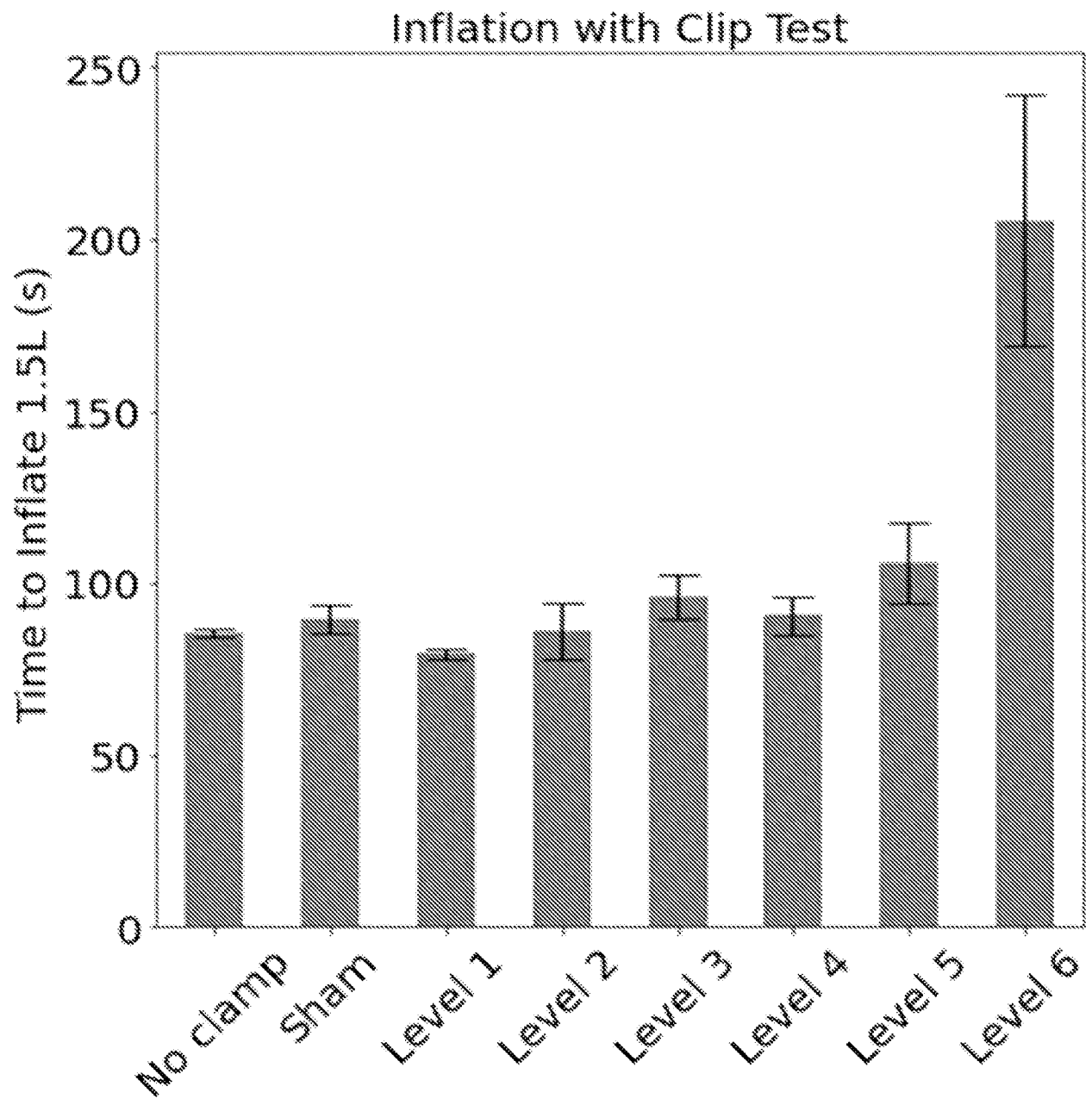


FIG. 34

**FIG. 35**

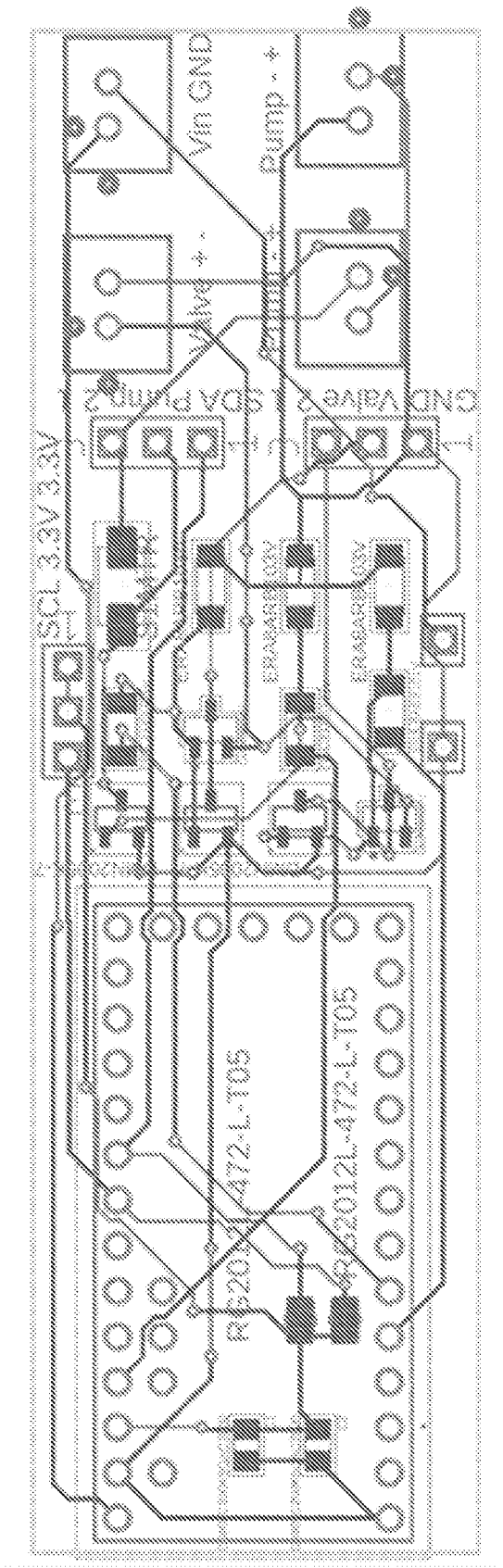


FIG. 36

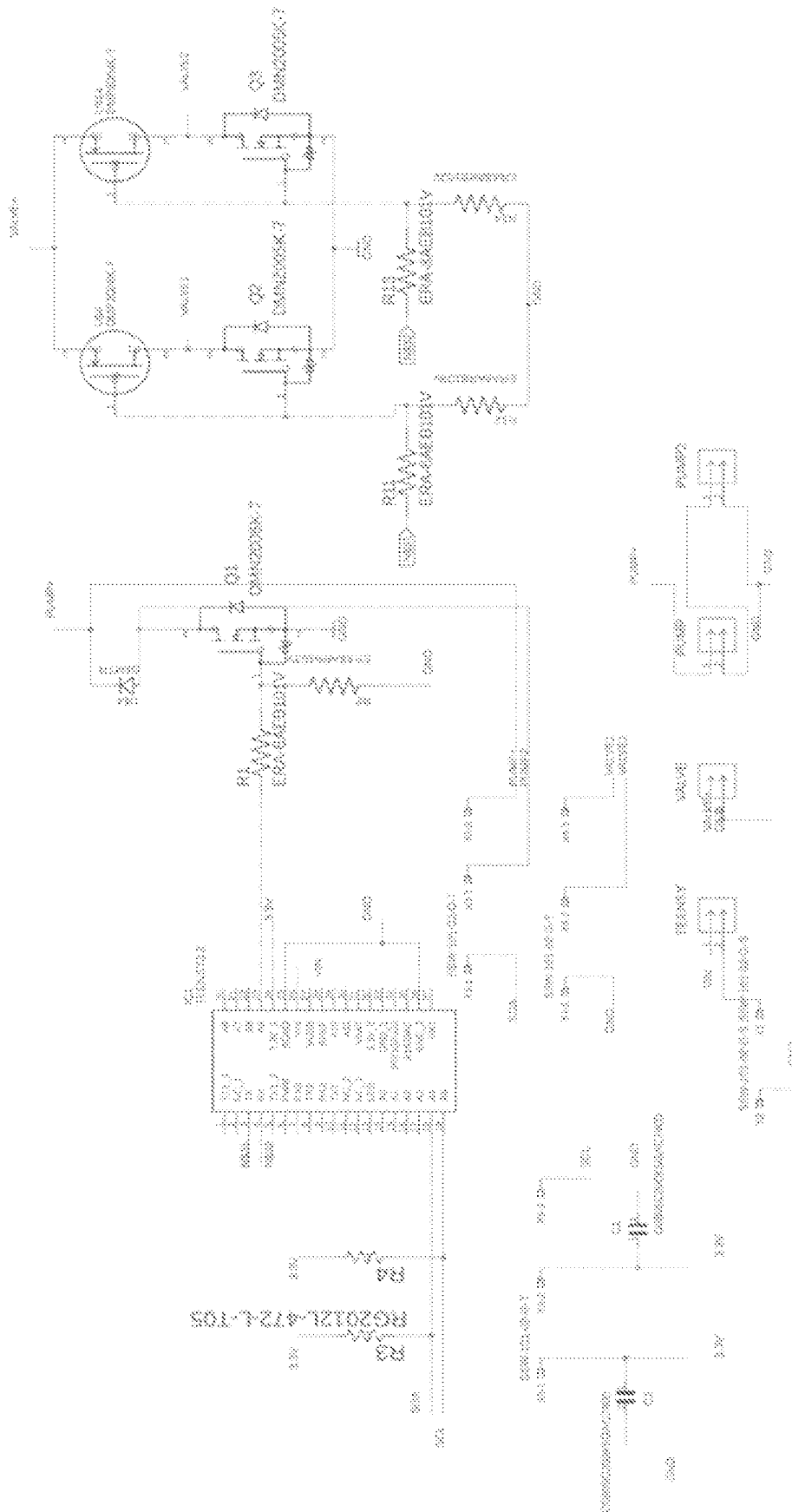


FIG. 37

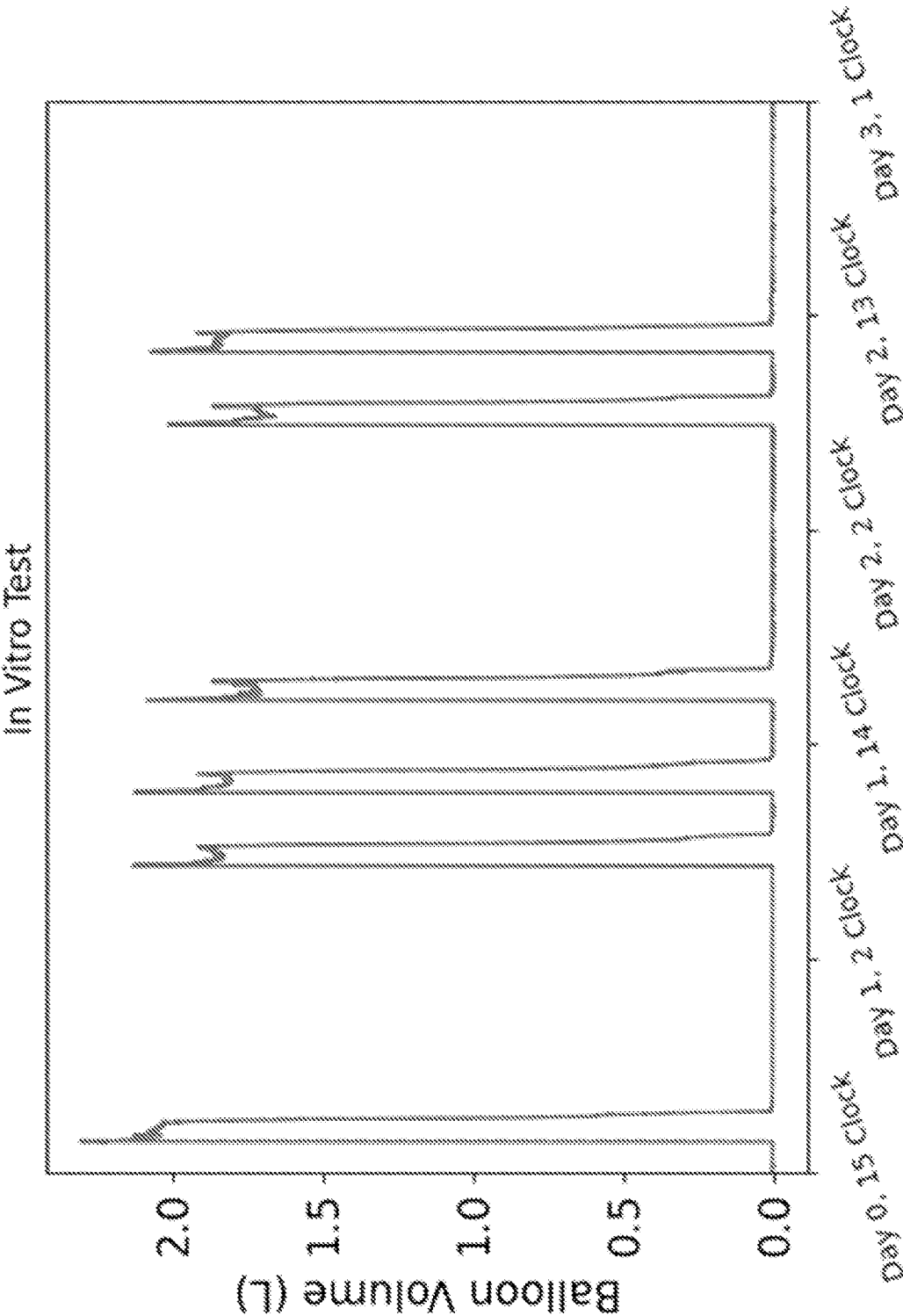


FIG. 38

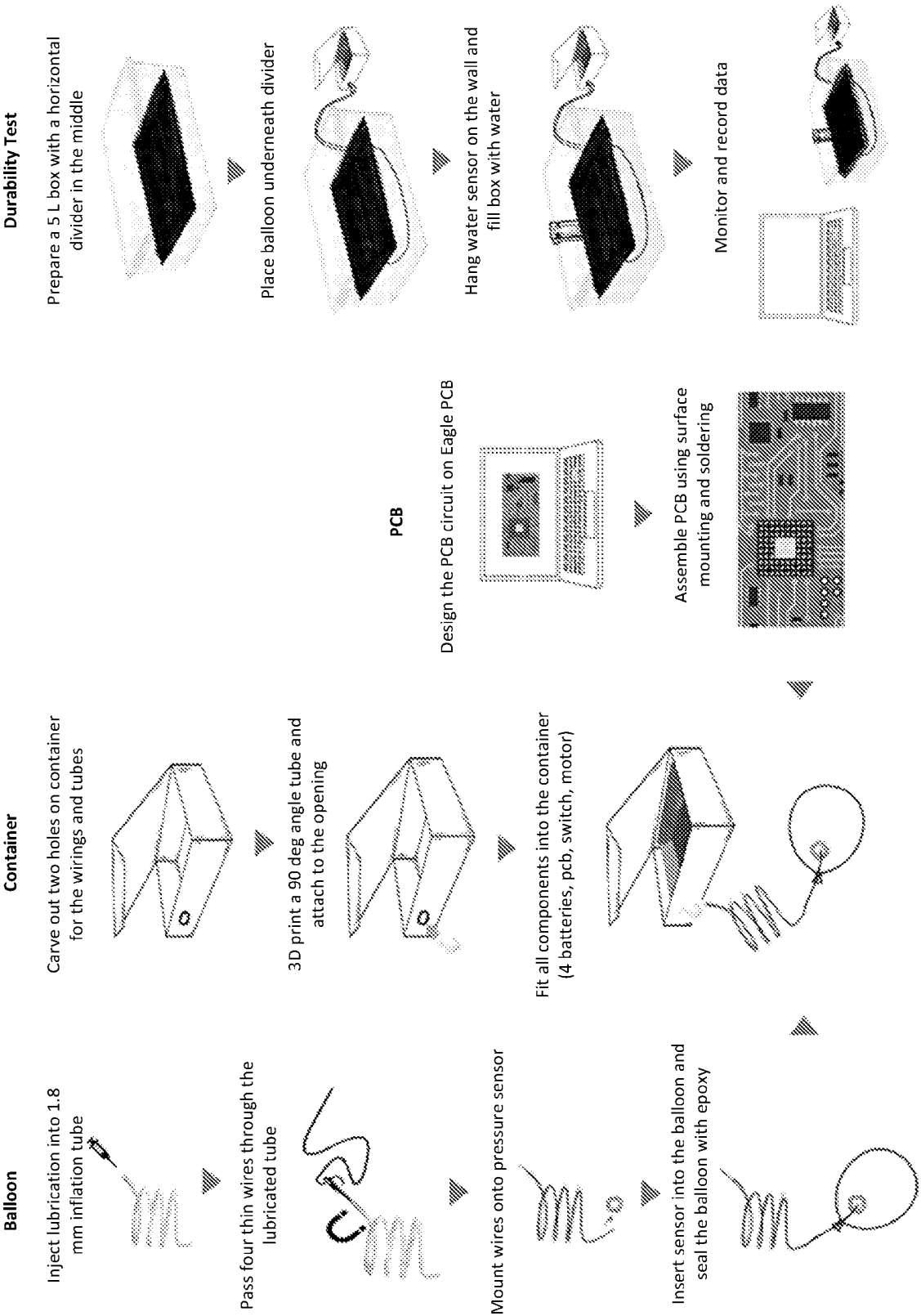


FIG. 39

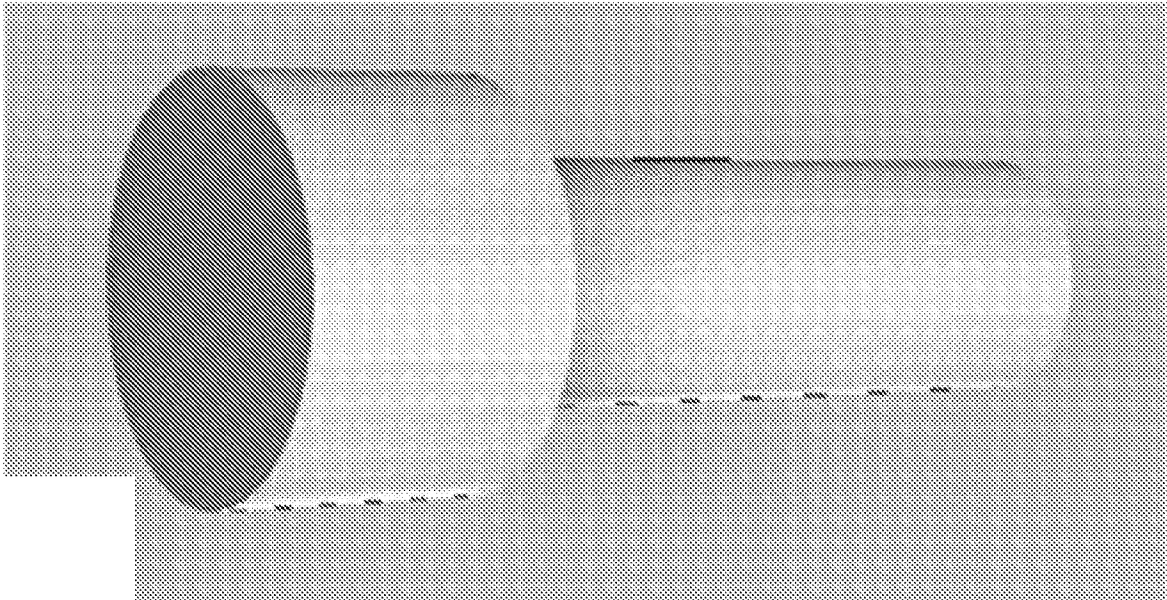


FIG. 40A

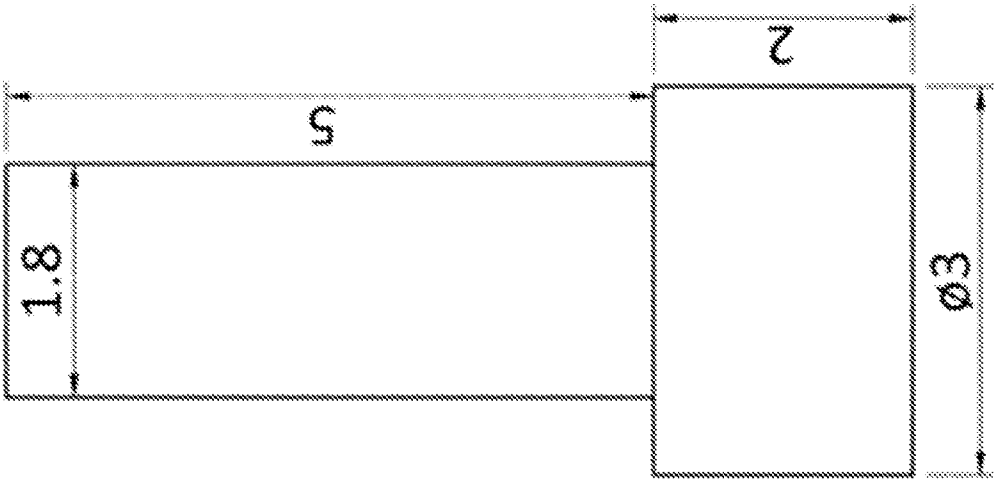


FIG. 40B

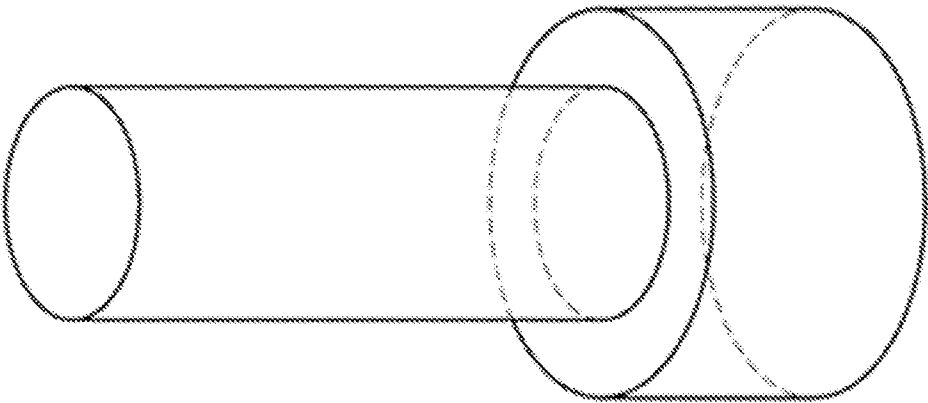


FIG. 40C

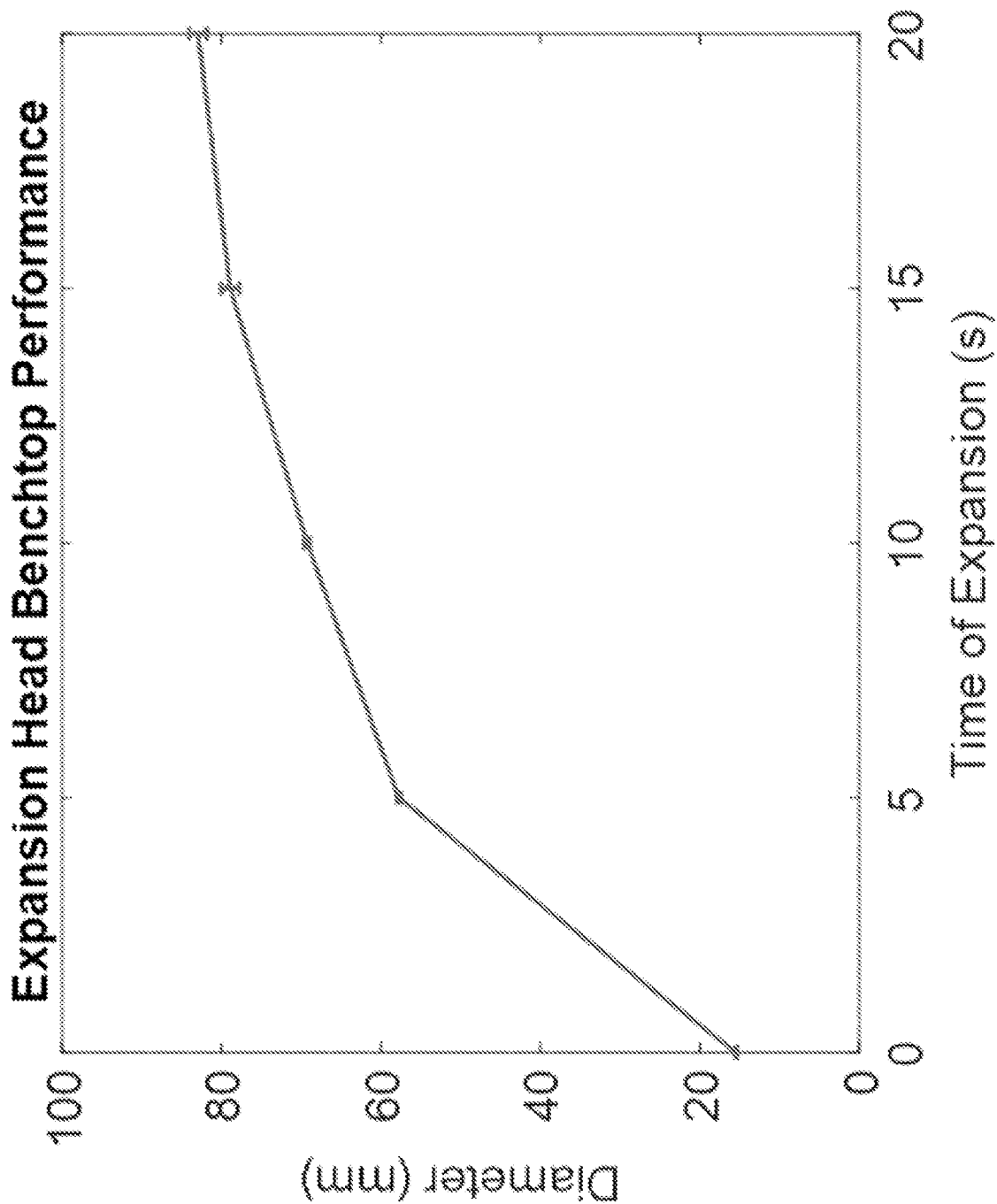
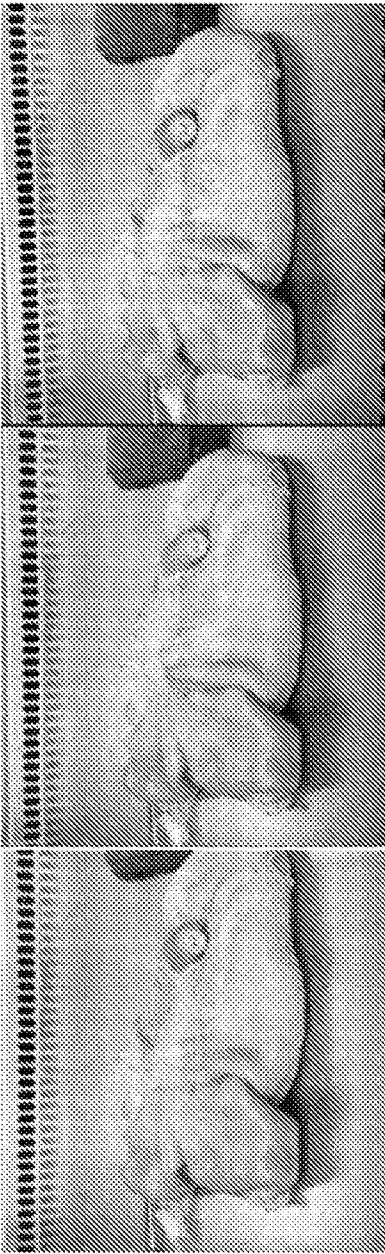


FIG. 41A



0s-closed 20s-open 40s-closed

FIG. 41B

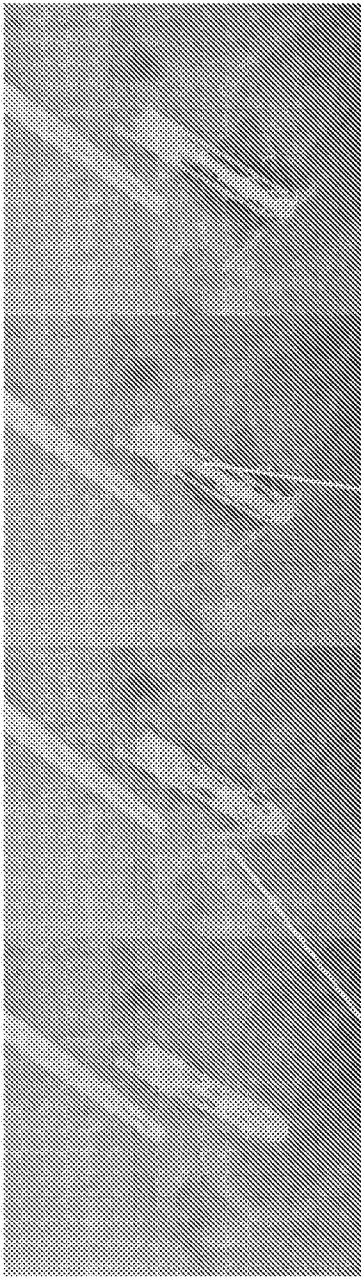


FIG. 41C

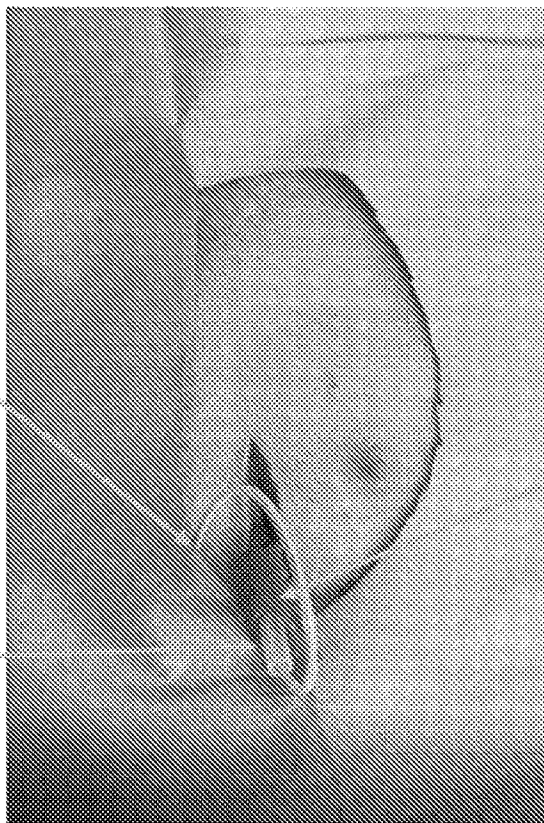


FIG. 42A

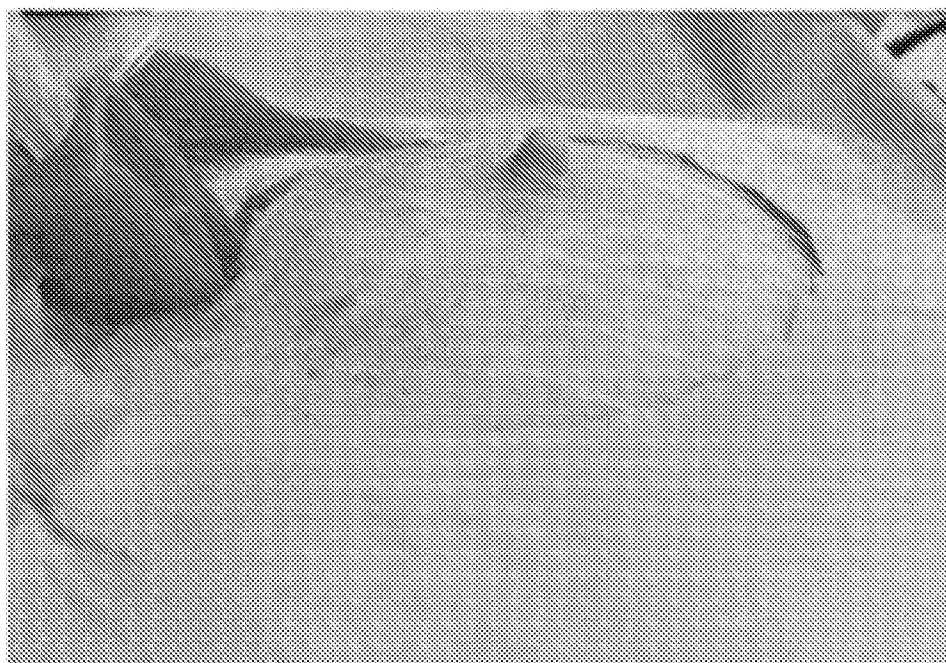
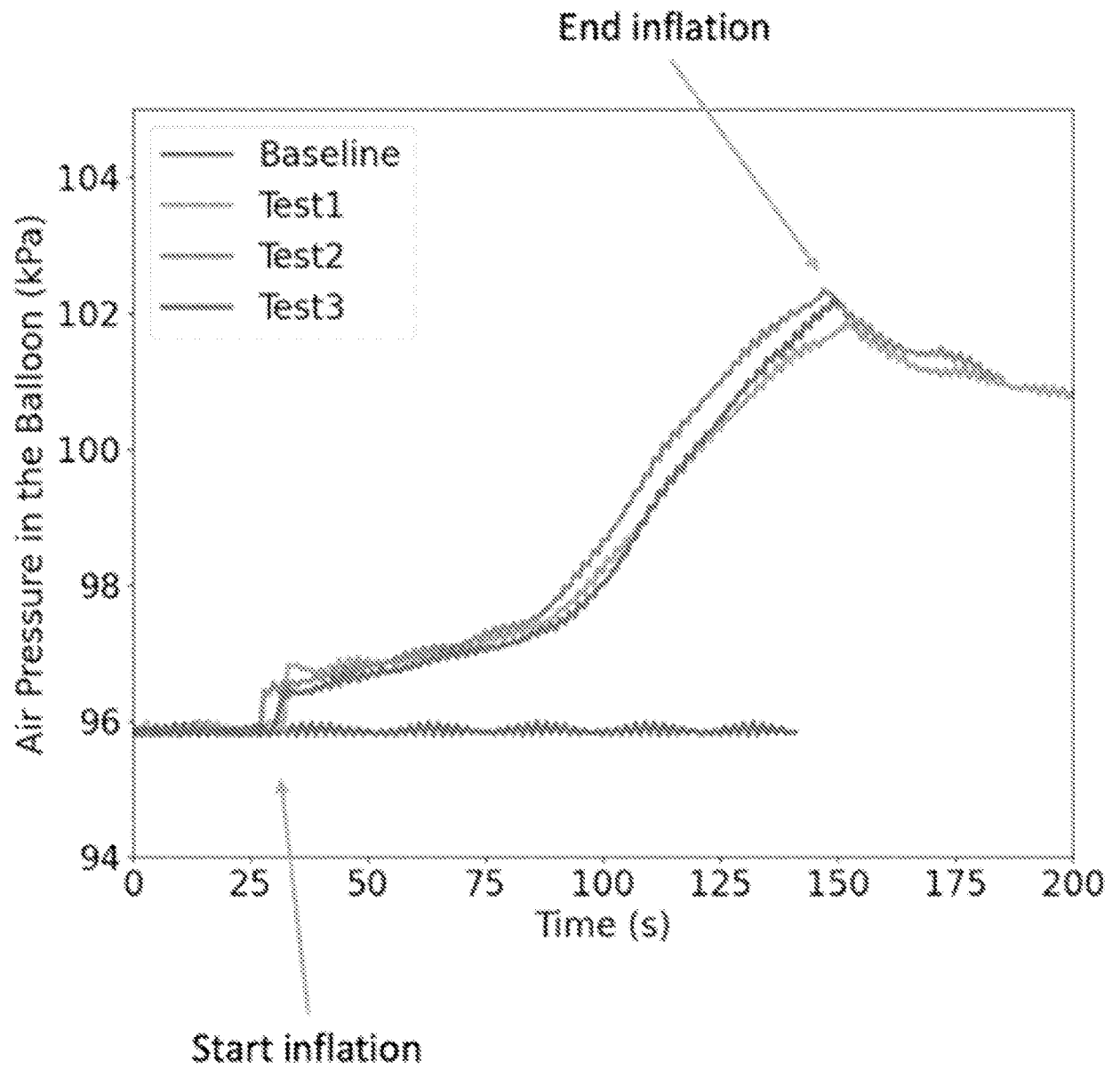
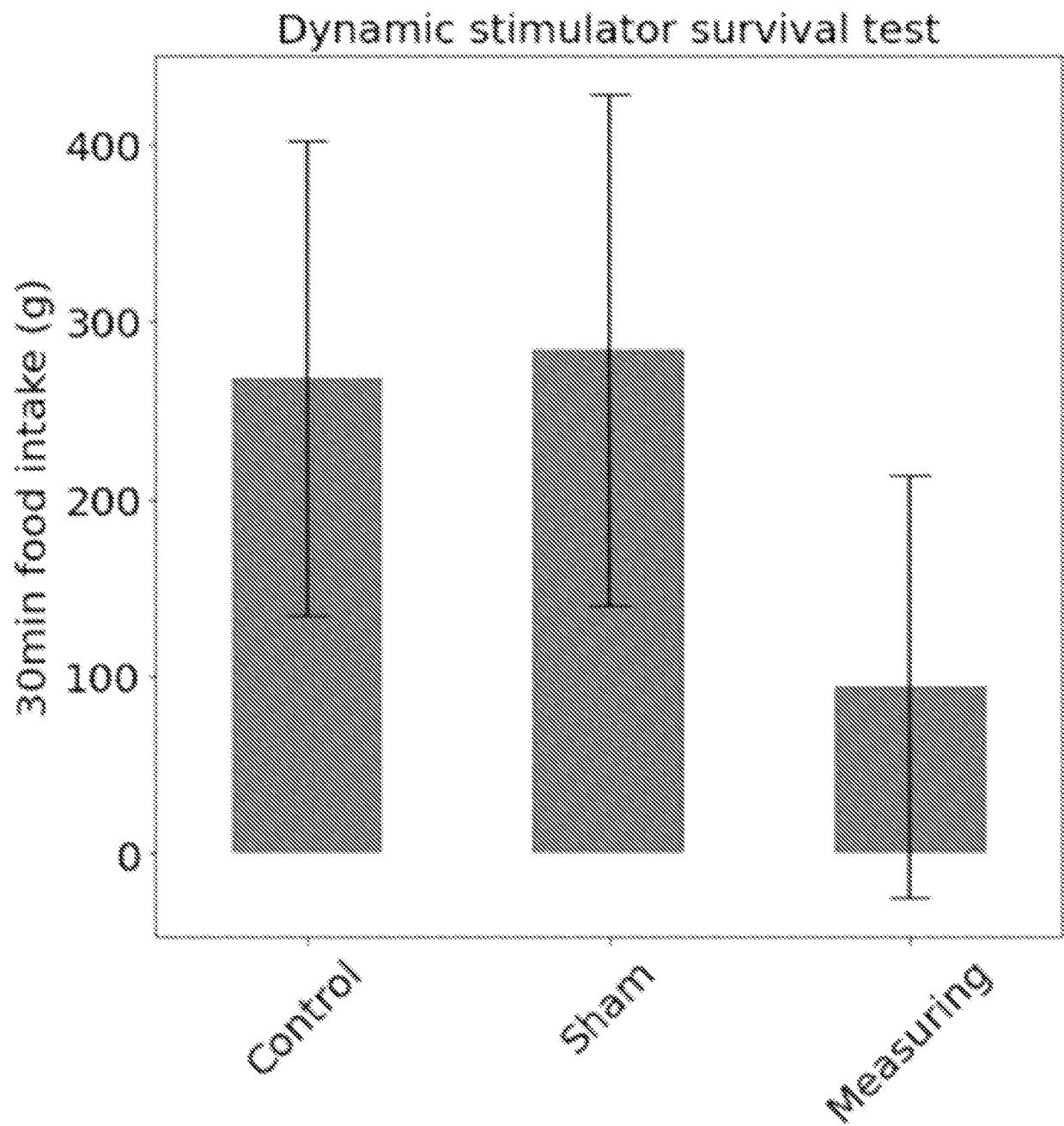


FIG. 42B

**FIG. 43**

**FIG. 44**