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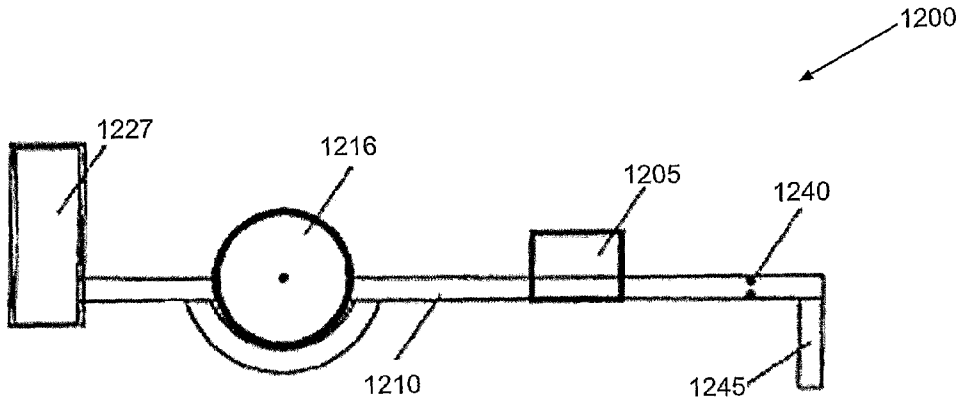
(54) **Title:** SYSTEM FOR DETECTING AN OCCLUSION IN A TUBE



(57) **Abstract:** Systems and methods for detecting an occlusion in a fluid delivery device are disclosed. The system includes a fluid delivery tube, an occlusion detection sensor configured to be coupled to the fluid delivery tube and further configured to detect occlusion within the fluid delivery tube. The fluid delivery tube includes an occlusion detection portion. The occlusion detection sensor is further configured to detect alteration of a shape of the occlusion detection portion when at least one condition occurs within the fluid delivery tube.

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SYSTEM FOR DETECTING AN OCCLUSION IN A TUBE

CROSS-REFERENCE TO RELATED APPLICATION

[0001] The present application claims priority to U.S. Provisional Patent Application No. 60/812,549 to Yodfat, filed June 8, 2006, and entitled "Method and System for Detecting an occlusion in a Tube." The present application also relates to Israel Patent Application No. 171813. The disclosures of the above applications are incorporated herein by reference in their entireties.

BACKGROUND OF THE INVENTION

Field of the invention

[0002] The present invention relates generally to a medical device for delivering fluids to a patient. Specifically, the invention relates to a small, low-cost, portable infusion device that can be used to transcutaneously deliver therapeutic fluids to a patient. The present invention also relates to systems and methods for detecting an occlusion in a fluid passageway in the infusion device that includes disposable and reusable parts.

Background

[0003] Conventional methods and systems for detecting an occlusion in a fluid delivery tube are based on a detection of tube's radial expansion. The expansion is caused by an elevation of an upstream pressure that is caused by a downstream occlusion. Exemplary conventional systems are disclosed in U.S. Patent No. 4,373,525 to Kobayashi and U.S. Patent No. 6,423,035 to Ras et al. Other conventional systems and methods for detecting an occlusion are disclosed in

U.S. Patent No. 4,369,780 to Sakai ("Sakai"), U.S. Patent No. 6,149,394 to Allen ("Allen"), U.S. Patent No. 6,830,558 to Flaherty et al. ("Flaherty").

[0004] Sakai discloses a magnet sensitive element for the detection of a flexible tube expansion. Allen discloses an apparatus and a method for detecting an occlusion using a portion of tube, which has a thinner wall section. When a downstream occlusion occurs, pressure elevation causes expansion of the thinner wall section of the tube. Flaherty discloses an apparatus and a method for detecting an occlusion by means of a sensor assembly that includes a resilient diaphragm having one surface positioned against the flow path's tube and a chamber wall positioned adjacent to the second surface of the diaphragm. A first electrode is positioned in the diaphragm, a second electrode is positioned in a fixed location and an impedance meter measures impedance between electrodes. In response to fluid flow conditions occurring in the flow path's tube, the second surface of the diaphragm expands and an electrical signal is provided accordingly.

[0005] However, most conventional systems and methods do not reliably detect an undesirable occlusion in the tube. The existing occlusion detectors are not sensitive enough and fail to detect partial occlusions. Further, most conventional detectors require a long lag time before alarming the patient of the occlusion. Additionally, they are expensive to produce and bulky.

[0006] Thus, there is a need for less expensive, accurate and sensitive systems and methods for the detection of partial and/or full occlusion(s) that may occur in the fluid infusion system.

SUMMARY OF THE INVENTION

[0007] The present invention relates to systems and methods for detecting an occlusion in a fluid passageway. An occlusion of a fluid passageway (e.g., a fluid delivery tube) is a common phenomenon, which can be caused by various reasons, e.g., aggregation of molecules of a therapeutic fluid, interference of a therapeutic fluid with tissue (for example, when the fluid is delivered by a subcutaneous insertion), tube kinking, cannula apposition etc. Occlusions occurring in an infusion device could be life threatening, and thus, there is a need to reliably detect occlusion at an early stage and alarm the patient before occurrence of any hazardous events associated with such occlusion.

[0008] In some embodiments of the present invention, detection and monitoring of occlusions within a passageway of a therapeutic fluid is especially advantageous in infusion devices or infusion pumps that can be configured to be attached to the body of a patient. Such attachment can be via adhesives and in this situation the fluid infusion device is designed as a dispensing patch unit. This dispensing patch unit or simply dispensing unit may have a reusable part and a disposable part. The reusable part includes components of a fluid metering system, electronic circuitry and other components (e.g., more expensive components of the system). The disposable part includes a downstream portion of the fluid delivery tube that can be configured to be monitored for occlusions and in which an occlusion is most likely to be detected.

[0009] In some embodiments, the present invention includes an infusion pump which propels therapeutic fluid through a flexible fluid delivery tube. The infusion pump can be configured to include an occlusion detection system. An occlusion causes an elevation of pressure and results in an expansion of the fluid delivery tube, which can be used for detecting the occlusion. In some embodiments, occlusions can be detected by measuring elevation of pressure or volume at discrete locations of fluid delivery tube.

[0010] In some embodiments, the present invention's occlusion detection is based on a downstream occlusion. The downstream occlusion causes elevation of upstream pressure within the fluid delivery tube. If the fluid delivery tube is short, pressure elevation is detectable immediately upon occlusion. In case of an elastic expandable tube, pressure elevation can be associated with an immediate radial expansion of tube which is also detectable.

[0011] In some embodiments of the invention, a short conducting tube is used for delivering a therapeutic fluid from a reservoir to the body of a patient. The tube can be made of a flexible material (e.g., silicone rubber, butyl rubber, polyurethane, etc.). During operation of the pump (whether continuous or not), a downstream occlusion can cause an increase in the fluid pressure and fluid volume in the tube.

[0012] In other embodiments of the invention, a portion of the tube can be deliberately weakened to allow immediate expansion and increase in diameter of the weakened tube portion. The weakening could be implemented by providing a portion of the delivery tube with a thinner wall or by using a stiffer tube on the remainder of the tube.

[0013] In some embodiments of the invention, an increase of the tube's diameter can be detected using an optical device or means. Such optical devices can be a combination of light detectors, and/or light collecting arrays that can be configured to detect light passing through the fluid delivery tube. As the light passes through the tube, the light detector device (e.g., CCD light collecting array) detects a change in light path as the light passes through the tube's expanded portion. In some embodiments, the light detector devices can include a light-collecting array and a light-emitting source, which can be positioned on the same or opposite sides of the tube's expanded portion.

[0014] In alternate embodiments of the invention, the expansion of the tube can be detected by the Bourdon effect. The Bourdon effect is a difference between the pressure inside a tube and the pressure outside the tube. If the inside pressure is greater than the outside pressure, the tube will expand. In these embodiments, the present invention can be configured to include an L-shape protrusion extending from the tube having a blind end. This change spatial configuration of the tube according to pressure elevations. In another embodiment, the light-emitting and collecting sources are positioned on the same side of the L-shape protrusion and optically sense conformation changes and corresponding pressure elevations.

[0015] In alternate embodiments of the present invention, occlusions can be electrically detected by a pressure sensor. Yet in other alternate embodiments, pressure elevation can be detected by a variation in capacitance. The system in the present invention can be configured to include a scissors-like assembly having one arm embracing the fluid delivery tube and a tail portion having one or more (preferably two) electrically conductive surfaces. A rise in pressure causes the tube diameter to change and, consequently, capacitance changes between the conductive surfaces. In some embodiments, capacitance measurement can be used for measuring quanta of the delivered therapeutic fluid (e.g., doses of basal and bolus insulin) as well as low pressure that is caused by fluid leakage.

[0016] In some embodiments, the present invention relates to a fluid delivery device for delivering therapeutic fluid to a patient. The system includes a fluid delivery tube and an occlusion detection sensor configured to be coupled to the fluid delivery tube and further configured to detect occlusion within the fluid delivery tube. The fluid delivery tube includes an occlusion detection portion. The occlusion detection sensor is further configured to detect

alteration of a shape of the occlusion detection portion when at least one condition occurs within the fluid delivery tube.

[0017] In alternate embodiments, the present invention relates to a method of detecting an occlusion using a fluid delivery device for delivering therapeutic fluid to a patient. The fluid delivery device includes a fluid delivery tube having an occlusion detection portion and an occlusion detection sensor configured to be coupled to the fluid delivery tube. The method includes steps of delivering therapeutic fluid through the fluid delivery tube and detecting alternation of a shape of the occlusion detection portion of the fluid delivery tube when at least one condition occurs within the fluid delivery tube.

[0018] Further features and advantages of the invention, as well as structure and operation of various embodiments of the invention, are disclosed in detail below with references to the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWNGS

[0019] The present invention is described with reference to the accompanying drawings. In the drawings, like reference numbers indicate identical or functionally similar elements. Additionally, in most cases, the left-most digit(s) of a reference number identifies the drawing in which the reference number first appears.

[0020] FIG. 1 illustrates an exemplary embodiment of a dispensing unit, according to the present invention.

[0021] FIGS. 2A-2B illustrate exemplary embodiments of a disposable part and a reusable part of the dispensing unit, according to the present invention.

[0022] FIGS. 3A-3C are longitudinal cross-sectional views of an exemplary tube with optical means for detecting an occlusion and having a light-collecting array and a light-emitting source positioned on the opposite sides of the tube, according to the present invention.

[0023] FIGS. 4A-4C are transverse cross-sectional views of an exemplary tube with optical means for detecting an occlusion and having a light-collecting array and a light-emitting source positioned on the opposite sides of the tube, according to the present invention.

[0024] FIGS. 5A-5C are longitudinal cross-sectional views of an exemplary tube with optical means for detecting an occlusion and having a light-collecting array and a light-emitting source positioned on the same side of the tube, according to the present invention.

[0025] FIG. 6 is a cross-sectional view of an exemplary tube having a pressure sensor configured to detect occlusion, according to the present invention.

[0026] FIGS. 7A-7B illustrate an exemplary tube having a pressure sensor and two levers for detecting an occlusion using variant capacitance, according to the present invention.

[0027] FIGS. 8A-8B illustrate an exemplary tube configured to be embraced by levers that are further configured to pivot around an axle for detecting an occlusion using variant capacitance, according to the present invention.

[0028] FIGS. 9A-9B are longitudinal cross-sectional views of an exemplary tube having an L-shaped tubular protrusion constituting a Burdon gauge and having a light-collecting array and a light-emitting source positioned on the opposite sides of the tubular protrusion, according to the present invention.

[0029] FIGS. 10A-10B are transversal cross-sectional views of an exemplary tube having an L-shaped tubular protrusion constituting a Burdon gauge and having a light-collecting array

and a light-emitting source positioned on the opposite sides of the tubular protrusion, according to the present invention.

[0030] FIGS. 11A-11B are longitudinal cross-sectional views of an exemplary tube having an L-shaped tubular protrusion constituting a Burdon gauge and having a light-collecting array and a light-emitting source positioned on the same side of the tubular protrusion, according to the present invention.

[0031] FIG. 12 illustrates an exemplary embodiment of a dispensing unit, according to the present invention.

[0032] FIG. 13 illustrates an exemplary tube having partial and/or complete occlusions.

[0033] FIGS. 14A-14C illustrate exemplary pressure-time graphs representing fluid delivery tube's pressure, where the tube includes a pulsating pumping mechanism, according to the present invention.

[0034] FIG. 15 illustrates an exemplary tube having a valve and an occlusion detector, according to the present invention.

[0035] FIGS. 16A-16C illustrate exemplary pressure-time graphs representing fluid delivery tube's pressure, where the tube includes a pulsating pumping mechanism and a valve, according to the present invention.

DETAILED DESCRIPTION OF THE INVENTION

[0036] FIG. 1 illustrates an embodiment of a fluid delivery device 100 having a dispensing unit 101, according to the present invention. In some embodiments of the invention, the fluid delivery device includes a dispensing unit configured to be adherable to the skin of the patient, and a separate remote control unit (not shown). In this situation the dispensing unit can

be referred to as a dispensing patch unit. In the further description the term dispensing unit is equally applicable to an adherable to the skin (i.e. patch unit) and non-adherable to the skin dispensing units. The dispensing unit 101 is configured to include a disposable part 103 and a reusable part 102. This configuration of the fluid delivery device 100 is disclosed in Israel Patent Application No. 171813, disclosure of which is incorporated herein by reference in its entirety.

[0037] One of the advantages of this configuration is that the relatively expensive components of the dispensing unit 101 are contained within the reusable part 102 and less expensive components are contained within the disposable part 103. By virtue of this provision the use of the device 100 is more economical for the patient.

[0038] FIG. 2A illustrates the two parts of the dispensing unit 101. A reusable part 102 is configured to be operatively coupled to a disposable part 103. In some embodiments, the dispensing unit 101 can be configured to include an occlusion sensor, discussed below. The occlusion sensor can be a pressure sensor, a capacitance sensor, an optical sensor, or other type of sensor. In some embodiments, the occlusion sensor includes a reusable portion 204, and can be configured to include a disposable portion 205. The disposable portion 205 can be configured to be included in the reusable part 102 and/or disposable part 103 of the dispensing unit 101. Upon coupling the reusable part 102 and disposable part 103 (shown in FIG. 2B), the unit 101 including the occlusion sensor becomes operative. The unit 101 also includes a printed circuit board 214 ("PCB"). The PCB 214 includes a processor and other electronic components. Once the unit 101 becomes operative, the sensor is activated and configured to detect an occlusion in the fluid delivery tube. Also, the PCB 214 is configured to begin collecting data, processing, and performing data analysis.

[0039] FIG. 2B illustrates the reusable part 102 coupled to the disposable part 103. The disposable part 103 contains a reservoir 227. A delivery tube 217 connects an inlet portion 228 and an outlet portion 229. The inlet portion 228 is in flow communication with reservoir 227. The outlet portion 229 is connected to a subcutaneous cannula (not shown). The delivery tube 217 is placed between a stator plate 215 of the disposable part 103 and a peristaltic pump rotary wheel 216 within the reusable part 102.

[0040] Rotary wheel 216 rotates rollers that squeeze the delivery tube 217 against the stator plate 215. Thus, the therapeutic fluid is periodically pumped from the reservoir 227 via the inlet portion 228 to the delivery tube 217 and then via outlet portion 229 to the cannula (not shown). The device 100 further includes an occlusion sensor 225, which is configured to be placed near the outlet portion 229. The sensor 225 is configured to detect occlusion occurring downstream in the outlet portion 229 and/or in the cannula. In some embodiments, the dispensing unit 101 can include an alternative pumping mechanism, e.g., a syringe pump, piston pump, or any other pump suitable for these purposes.

[0041] FIGS. 3A-4C illustrate longitudinal and cross-sectional views of a delivery tube 310 configured with an optical device sensor for detecting an occlusion. The fluid delivery tube 310 includes a dedicated region 320. The dedicated region 320 is configured to be defined by sidewalls 322. The sidewalls 322 are configured to be manufactured from a more expendable elastic material than the rest of the tube. The optical device 300 further includes a light-collecting array 332 and a light-emitting source 331 (shown in FIGS. 4A-4C). The array 332 and the source 331 are configured to be positioned on opposite sides of the fluid delivery tube 310. The source 331 is configured to emit light 301 toward the array 332. Because emitted light 301 encounters the fluid delivery tube 310 on its path, the fluid delivery tube 310 casts a shadow on the array

332 (illustrated by the dark-colored or shaded zones 334 in FIGS. 4A-4C). The zones over which the delivery tube 310 do not cast a shadow are designated as light-colored zones 333 in FIGS. 4A-4C. When downstream occlusion occurs, it induces radial expansion of the dedicated region 320. This is illustrated in FIGS. 3B-3C and FIGS. 4B- 4C. Because of such expansion, the shadow cast by the expanded region 320 is greater than the shadow cast by the unexpanded region 320, thus, this causes the dark-colored zones 334 to expand and light-colored zones 333 to contract. The expansion of zones 334 and the contraction of zones 333 are configured to be detected by the light-collecting array 332. A processor (not shown) is configured to collect and interpret data as partial and/or full occlusion, based on such detection. The present invention is also configured to interpret reduction of tube's size as leakage of fluid from the tube. Further, periodic change in tube's diameter can be interpreted as a normal pulsating fluid delivery. In some embodiments, the sensibility of the occlusion detection method above can be adjusted by changing the distance between the light-emitting source 331 and the light-collecting array 332.

[0042] FIG. 5A illustrates yet another preferred embodiment of an optical detection device for detecting pressure variation in the fluid delivery tube 510. The optical device includes a light-collecting array 542 and a light-emitting source 541. The array 542 and the source 541 are configured to be positioned on the same side of a dedicated region 520. In this embodiment, the light emitted by the light-emitting source 541 is configured to be reflected by the opposite side of the dedicated region 520 and then sensed by the light-collecting array 542.

[0043] FIGS. 5B and 5C illustrate downstream occlusion detection in the fluid delivery tube 510. In some embodiments, an upstream pressure elevation in the tube 510 is configured to induce a radial expansion of the dedicated region 520. A beam of light 543 emitted by the light-emitting source 541 is reflected at a particular angle. The angle of reflection is configured to vary

in proportion to a curvature of the dedicated region 520. The beam 543 is consequently configured to be detected by the light collecting array 542. A processor (not shown) collects light beam 543 reflection data and is configured to interpret it as occlusion or any other tube condition, such as leakage. In some embodiments, reduction of tube's size can be interpreted as leakage. Additionally, periodic change in tube's diameter can also be interpreted as a normal pulsating fluid delivery.

[0044] FIG. 6 illustrates another embodiment of the present invention, in which radial expansion is sensed by a pressure sensor 609. A housing 608 surrounds at least a portion of a fluid delivery tube 610. The tube 610 is configured to be coupled to the pressure sensor 609. The pressure sensor 609 is configured to be positioned in close proximity to a wall 607 of the tube 610. The pressure sensor 609 can be configured to be electrically coupled to at least one resistor that may be arranged in a Wheatstone bridge (not shown in FIG. 6).

[0045] When a downstream occlusion occurs, an upstream pressure in the fluid delivery tube 610 causes radial expansion of the tube wall 607. The radial expansion of the tube wall 607 is configured to cause deformation of the pressure sensor 609 (an exemplary pressure sensor can be a Metrodyne Microsystems's MPS-1060 sensor, or any other sensor). This deformation further alters sensor's 609 resistance. A processor (not shown in FIG. 6) configured to be coupled to the system can interpret such change as occlusion.

[0046] FIGS. 7A-B illustrate another embodiment of the present invention's system for monitoring pressure changes in the delivery tube 710 and fluid delivery tube's wall 707 expansion. The system includes two levers 711, 721 configured to embrace at least a portion of tube's wall 707. The levers 711, 721 further include tail portions 731, 741, respectively. The tail portions 731, 741 are configured to include electrically conductive regions 733, 735,

respectively. In some embodiments, the electrically conductive regions 733, 735 are configured to be metallic plates. As such, the conductive regions 733, 735 are configured to form a capacitor. The capacitance of which is configured to change in accordance with the distance between the regions 733 and 735. Thus, when the fluid delivery tube 710 expands due to a downstream occlusion, it displaces levers 711, 721, which in turn affect the distance between the conductive regions 733, 735. Hence, the capacitance of the capacitor formed by the conductive regions 733 and 735 changes accordingly. In some embodiments, a processor (not shown in FIG. 7) configured to be coupled to the system is configured to interpret such change in capacitance. Based on the amount of the change, the processor can estimate the change in a diameter of the fluid delivery tube 710. The processor can further determine whether the change in the diameter is a result of a downstream occlusion in the fluid delivery tube 710, a leakage in the tube, or a normal pulsating delivery of a therapeutic fluid through the tube 710.

[0047] FIGS. 8A-8B illustrate another embodiment where a wall 807 of the fluid delivery tube 810 is configured to be embraced by levers 840, 842. The levers 840, 842 are configured to pivot around an axis 843. In the embodiment shown in FIG. 8, the levers 840, 842 are configured to have a scissors-like shape. As can be understood by one skilled in the art, other types of arrangement of levers 840, 842 are possible. Similarly to the embodiment illustrated in FIGS. 7A-7B, the levers 840, 842 are configured to include tail portions 831, 841. The tail portions 831, 841 are configured to include conductive regions 833, 835. Similarly to the embodiment of FIGS. 7A-7B, the conductive regions 833, 835 are configured to form a capacitor once current is passed through the regions 833, 835. Capacitance of this capacitor depends on the distance between the conductive regions 833, 835. As such, variation in the distance between regions 833, 835 causes variation of capacitance in the capacitor formed by the regions 833, 835. A processor

(not shown in FIGS. 8A-8B) can be configured to be coupled to the system 800 and can be further configured to interpret variation in the distance between the regions 833, 835 as variation of pressure in tube 810. Thus, the processor can be configured to interpret change of pressure in the fluid delivery tube 810 as either downstream occlusion, leakage in the tube, normal pulsating delivery of the fluid, or any other condition in the tube.

[0048] FIGS. 9A-9B and 10A-10B illustrate longitudinal and cross sectional views of an exemplary fluid delivery tube 910, according to the present invention. In the illustrated embodiments, an L-shaped tubular protrusion 930 is configured to extend from the fluid delivery tube 910. The protrusion 930 further includes a first end 950 and a second end 960. First end 950 of the tubular protrusion 930 is configured to be closed (i.e., it is a blind end) and the second end 960 is configured to be open such that fluid communication is allowed between tube 910 and tubular protrusion 930. As can be understood by one skilled in the art, the tubular protrusion 930 can be configured to be a Bourdon gauge that can be further configured to change its configuration in response to pressure variation in fluid delivery tube 910. In some embodiments, such variation of tubular protrusion's configuration can be detected by various methods, e.g., optical detection methods, force and pressure sensing methods.

[0049] The fluid delivery tube 910 further includes a light-collecting array 942 (in some embodiments, the array can be a small CCD sensor) and a light-emitting source 941 (shown in FIGS. 10A-10B). The array 942 and the source 941 are configured to be located on the opposite sides of the protrusion 930 and specifically on the opposite sides of the closed end 950, as illustrated in FIGS. 9A-9B. Thus, the protrusion 930 is configured to block the light 932 emanating from the source 941 to the ligh-collecting array 942.

[0050] FIGS. 10A-10B are cross-sectional views of the fluid delivery tube 910 illustrated in FIGS. 9A-9B, respectively. As illustrated in FIGS. 10A-10B, the light collecting array 942 includes a shaded portion 934 and an illuminated portion 933. The shaded portion 934 represents a portion of the light collecting array 942 that is blocked by the protrusion 930 of the tube 910. The illuminated portion 933 represents a portion of the light collecting array 942 that is not currently blocked by the protrusion 930. Because of downstream occlusions (or any other conditions occurring in the tube), locations of the shaded portion 934 and the illuminated portion 933 on the light collecting array 942 may change, as shown in FIGS. 10A-10B. The location change is caused by the movement of the closed end 950. The movement of the closed end 950 is caused by rising pressure within the tube 910 (e.g., pressure rise caused by a Bourdon effect occlusion within the tube 910). FIG. 9A (and corresponding FIG. 10A) illustrates that there is substantially no pressure change within the tube 910 and, hence, no downstream occlusion has occurred in the tube 910. This is illustrated by the closed end 950 have a substantially curved shape, as illustrated in FIG. 9A. FIG. 9B (and corresponding FIG. 10B) illustrates that there is increase and/or other change in pressure within the tube 910 that may be caused by a downstream occlusion or any other effect. Such change in pressure causes the closed end 950 to become substantially straight, as illustrated in FIG. 9B. Thus, as the closed end 950 becomes substantially straight, its shadow (produced as a result of the light 933 emitted by the light source 941 towards light collecting array 942) shifts along the light collecting array 942, as illustrated in FIGS. 10A-10B. In some embodiments, a processor (not shown in FIGS. 9A-10B) can be configured to be coupled to the system 900 and interpret shifting of the shaded portions 934 as caused by a downstream occlusion, normal pulsating operation, leakage in the tube, or any other conditions.

[0051] FIGS. 11A-11B are longitudinal views of another embodiment of the tube 1110. The tube 1110 includes protrusion 1130. Protrusion 1130 includes a closed end 1150 and an open end 1160. The open end 1160 communicates with the main tube 1110. In this embodiment, a light collecting array 1142 and a light-emitting source 1141 are located at the same side of the protrusion 1130 and, more specifically, on the same side of the closed end 1150. Similarly to FIGS. 9A-10B, light beam 1132, emitted by the source 1141, is reflected off of a surface of the closed end 1150 of the protrusion 1130. The reflected light beam 1132 is collected by the light collecting array 1142.

[0052] As the pressure in the tube 1110 changes, the closed end 1150 of the protrusion 1130 is configured to become straight (FIG. 11B) as opposed to substantially curved (FIG. 11A). Such change causes the angle and the location of reflection formed by the light beam 1132 on the surface of the closed end 1150 to change. As shown in FIG. 11A, light beam 1132 emitted by the source 1141 hits the closed end 1150 at location A and is collected at location AA on the light collecting array 1142. Once the closed end 1150 straightens, the light beam 1132 hits the closed end 1150 at location B and is collected at location BB on the light collecting array 1142, as illustrated in FIG. 11B. A processor (not shown in FIGS. 11A-11B) may be configured to be coupled to the system 1100 and interpret such change of collection location as downstream occlusion, normal pulsating delivery of fluid through the tube 1110, leakage in the tube 1110, or any other condition occurring in the system 1100 that causes change of location.

[0053] FIG. 12 illustrates an exemplary dispensing unit 1200, according to the present invention. The dispensing unit 1200 includes a reservoir 1227 that contains therapeutic fluid (e.g. insulin), a cannula 1245, a pump 1216, a delivery tube 1210, and an occlusion sensor 1205. The therapeutic fluid is configured to be delivered to the patient through the cannula 1245. As can be

understood by one skilled in the art, the occlusion sensor 1205 can be a pressure sensor, a capacitance sensor, an optical sensor, or any other suitable sensor. The occlusion sensor 1205 is configured to detect an occlusion occurring in the tube 1210. As illustrated in FIG. 13, such an occlusion 1240 can be a partial occlusion 1241, 1242 (where occlusions 1241 and 1242 differ by a degree of actual occlusion in the tube 1210; in the shown example, occlusion 1242 is greater than occlusion 1241) or a complete occlusion 1243. As can be understood by one skilled in the art, the tube 1210 can have one or more occlusions 1240 occurring at the same time. In some embodiments, the therapeutic fluid can be delivered to the patient via a pulsating pumping mechanism. Waves generated by the pulsating mechanism in the fluid delivery tube 1210 can be depicted in pressure-time plots, as illustrated in FIGS. 14A-14C.

[0054] As shown in the FIGS. 14A-14C, y-axis of the plots corresponds to pressure exerted by the fluid in the fluid delivery tube and x-axis corresponds to time over which such pressure is exerted. Since therapeutic fluid is delivered by a pulsating mechanism, a substantially non-occluded delivery of the fluid to the patient can be represented by curve A1 having equally spaced peaks (corresponding to pulses generated by the pulsating mechanism) on the pressure-time plot. This is illustrated in FIGS. 14A-14C. In some embodiments, a threshold pressure setting may be set by the system that indicates above which pressure occlusion in the tube 1210 begins to occur. This is illustrated by a line 1401 in FIGS. 14A and 14B. As can be understood by one skilled in the art, threshold setting can be adjusted according to the desired setting of the system. During a substantially non-occluded delivery of the therapeutic fluid, the heights of all of the equally spaced peaks are configured to be below the threshold line 1401, as illustrated on the plot in FIG. 14A. Mild occlusion (e.g., 40% of the tube is occluded) is normal during operation

of the system 1200. Periods of mild occlusion are illustrated by a curve A2 in FIG. 14A. The peaks' heights of the curve A2 are slightly higher than the threshold line 1401. In some embodiments, the system 1200 may choose to ignore detection of a mild occlusion by the sensor 1205. Yet, in other alternate embodiments, the sensor 1205 may be configured to various degrees of occlusions and the system 1200 can be configured to act as desired.

[0055] FIG. 14b is another pressure-time plot illustrating a substantially non-occluded delivery of fluid (represented by curve A1) and delivery of fluid during periods of partial occlusions 1241, 1242 and full occlusions 1243 of the tube 1210 (FIG. 13). Periods of partial and/or full occlusions of the delivery tube are illustrated by curve B. Because tube 1210 is experiencing an occlusion (whether partial or full), fluid delivery through tube 1210 becomes sporadic. As such, this causes fluid built-up, which corresponds to an increase in fluid pressure inside the tube 1210. Thus, the pressure-time curve representing fluid delivery through the tube loses its periodicity and symmetry, as illustrated in FIG. 14B. Because of rise in amplitude of the pressure, curve B crosses threshold line 1401 indicating an occlusion condition within tube 1210. The occlusion sensor 1205 is configured to detect these changing patterns of curve B and supply signals indicative of the occlusion in the tube 1210 to a processor (not shown in FIG. 12). The processor (and/or other electronic components) can be configured to process and interpret these signals and generate a warning and/or an alarm to the patient.

[0056] In some embodiments, the system 1200 can be configured to detect low-flow conditions within the delivery tube 1210. Low-flow conditions may occur when the pulsating flow through the tube 1210 is lower than is set by the system. In some embodiments, the low-flow conditions may occur when there is a leak in the tube 1210. FIG. 14C is a pressure-time plot

illustrating monitoring of flow conditions within the tube 1210. FIG. 14C illustrates curve A1 that corresponds to substantially non-occluded delivery of the fluid and curve C that corresponds to a low-flow condition. As can be seen from FIG. 14C, peaks in curve C have a significantly lower height than peaks in curve A1, which is indicative of a low flow condition in the tube 1210.

[0057] FIG. 15 illustrates another exemplary fluid delivery system 1500, according to the present invention. Similar to the fluid delivery system shown in FIG. 12, the fluid delivery system 1500 includes a reservoir 1527, a pump 1516, a fluid delivery tube 1510 and an occlusion sensor 1505. Additionally, the fluid delivery system 1500 also includes a control valve 1555. The control valve 1555 has a closed and an open state. In the closed state, the valve 1555 does not allow any fluid to be delivered through the tube 1510. In the open state, the valve 1555 allows fluid delivery through the tube 1510. In some embodiments of the present invention, a processor (not shown in FIG. 15) can be configured to be coupled to the valve 1555 and to control opening and closing of the valve 1555 based on operation of the pump 1516.

[0058] FIG. 16A is a pressure-time plot illustrating operation of the pump 1516 shown in FIG. 15. In some embodiments, the valve 1555 operation can be configured to be synchronized with a normal operation of the pump 1516. This is illustrated by the curve A in FIG. 16A. The "normal" operation of the pump 1516 is characterized by a substantially non-occluded delivery of the fluid through the tube 1510. As illustrated in FIG. 16A, curve A includes periods of pressure alteration when pressure inside the tube begins to rise during pumping operating of the pump 1516. During this time, the valve 1555 remains closed. This is illustrated by segments 1625 (a, b, c). When pumping operation halts and the valve 1555 remains closed, the pressure reaches an upper limit, i.e., a plateau 1627 (a, b, c). As soon as the valve 1555 is opened, i.e.,

occurring at the end of plateaus 1627, the pressure inside the tube 1510 begins to drop. This is illustrated by the segments 1629 (a, b, c). During "normal" operation of the pump, curve A is periodic in nature and the amplitude of each period is substantially the same throughout the curve.

[0059] FIG. 16B is a pressure-time plot illustrating operation of the pump 1516 during total or partial occlusion occurring within the tube 1510. FIG. 16B includes a curve B, representing operation of the pump 1516 during total occlusion (FIG. 13), and a curve C representing operation of the pump 1516 during partial occlusion (FIG. 13). Similar to the discussion of FIGS. 14A-14C, curves B and C do not have the same periodicity or substantially the same amplitude, as curve A shown in FIG. 16A. The severity of change in periodicity and amplitude is dependent on the severity of occlusion occurring within the tube 1510. As the occlusion in the tube 1510 increases, the periodicity of the curve decreases and the amplitude increases (as shown by curve B, representing total occlusion).

[0060] FIG. 16C is a pressure-time plot illustrating operation of the pump 1516 when air is present in the tube 1510 and a very mild occlusion occurs. FIG. 16C includes a curve E, representing operation of the pump 1516 when a large amount of air is present in the tube 1510, and a curve D, representing operation of the pump 1516 when a small amount of air is present in the tube 1510. As shown in FIG. 16C, when air is present in the tube 1510, the pressure inside the tube decreases, which is illustrated by the decreasing amplitude. However, if more air is present in the tube 1510, the amplitude is greater (as illustrated by curve E). In some embodiments, valve 1555 can be configured to provide high sensitivity required for occlusion detection sensors even when there is a fluid leak or air is present in the tube 1510. The valve 1555 can be configured to enhance signals corresponding to variation in pressure within the tube

1510. This improves sensitivity of occlusion detection and allows detection of variety of flow conditions, including partial or full occlusion or lack of fluid in the reservoir/leakage.

[0061] In some embodiments of the present invention, the fluid delivery device discussed above with regard to FIGS. 1-16C is configured to be attached to the patient. As explained above, the device can be configured to be a patch unit adherable to the skin of the patient. The fluid delivery device is configured to pump therapeutic fluid to the patient using a dispensing unit having a pumping mechanism. The dispensing unit is controlled by a remote control unit.. The dispensing unit is configured to communicate with the remote control unit. The dispensing unit includes a delivery tube having an inlet portion and an outlet portion, where the inlet portion is configured to be coupled to a reservoir containing therapeutic fluid, as discussed above with regard to FIGS. 1-16C. The dispensing unit also includes a peristaltic pump having a stator plate and rotary wheel with rollers, wherein the stator plate and the rollers are configured to squeeze the fluid delivery tube. In some embodiments, the peristaltic pump can be configured to pump fluid from the reservoir via the inlet portion of the tube to the outlet portion upon squeezing the fluid delivery tube. The dispensing unit also includes an occlusion sensor that can be configured to be located near the outlet portion of the fluid delivery tube, as discussed above with regard to FIGS. 1-16C. The sensor can be configured to detect occlusion within the fluid delivery tube.

[0062] Example embodiments of the methods and components of the present invention have been described herein. As noted elsewhere, these example embodiments have been described for illustrative purposes only, and are not limiting. Other embodiments are possible and are covered by the invention. Such embodiments will be apparent to persons skilled in the relevant art(s) based on the teachings contained herein. Thus, the breadth and scope of the

present invention should not be limited by any of the above-described exemplary embodiments, but should be defined only in accordance with the following claims and their equivalents.

What is claimed is:

1. A fluid delivery device for delivering therapeutic fluid to a patient comprising:

a fluid delivery tube;

an occlusion detection sensor configured to be coupled to said fluid delivery tube and further configured to detect occlusion within said fluid delivery tube;

said fluid delivery tube includes an occlusion detection portion; and

said occlusion detection sensor is further configured to detect alteration of a shape of said occlusion detection portion when at least one condition occurs within said fluid delivery tube.

2. The fluid delivery device according to claim 1, further comprises a reservoir coupled to said fluid delivery tube and configured to deliver therapeutic fluid to the patient via said fluid delivery tube.

3. The fluid delivery device according to claim 2, which comprises a dispensing unit configured to pump therapeutic fluid from said reservoir, wherein said dispensing unit includes

a peristaltic pump having a stator plate and rotary wheel with rollers, wherein said stator plate and said rollers are configured to squeeze said fluid delivery tube;

said peristaltic pump is configured to pump fluid from said reservoir via an inlet portion of said fluid delivery tube to an outlet portion of said fluid delivery tube upon squeezing said fluid delivery tube.

4. The fluid delivery device according to claim 1, wherein said at least one condition is a change in fluid pressure within said fluid delivery tube.

5. The fluid delivery device according to claim 4, wherein said occlusion detection portion is configured to expand when said fluid pressure increases within said fluid delivery tube.

6. The fluid delivery device according to claim 4, wherein said occlusion detection portion is a protrusion extending from said fluid delivery tube; and

wherein said protrusion is configured to change its orientation with respect to said fluid delivery tube when said fluid pressure increases within said fluid delivery tube.

7. The fluid delivery device according to claim 4, wherein said occlusion detection sensor further comprises a light emitting source and a light collecting array;

wherein said light emitting source is configured to emit light and said light collecting array is configured to collect said light.

8. The fluid delivery device according to claim 7, wherein said light emitting source is configured to emit light toward said occlusion detection portion and said occlusion detection portion is configured to reflect said light towards said light collecting array at a reflection angle.

9. The fluid delivery device according to claim 8, wherein said occlusion detection sensor is configured to determine whether there is occlusion within said fluid delivery tube based on said angle of reflection.

10. The fluid delivery device according to claim 7, wherein said light emitting source is configured to emit light toward said occlusion detection portion and said occlusion detection portion is configured to block at least a portion of said light.

11. The fluid delivery device according to claim 10, wherein said light collecting array is configured to detect an amount of light blocked by said occlusion detection portion and based on said amount determine whether there is occlusion within said fluid delivery tube.

12. The fluid delivery device according to claim 7, wherein said light emitting source and said light collecting source are configured to be located on the same side of said occlusion detection portion.

13. The fluid delivery device according to claim 7, wherein said light emitting source and said light collecting source are configured to be located on opposite sides of said occlusion detection portion.

14. The fluid delivery device according to claim 4, wherein said occlusion detection sensor further comprises movable capacitance plates;

wherein said occlusion detection portion is configured to change a distance between said movable capacitance plates based on said change of said fluid pressure within said fluid delivery tube.

15. The fluid delivery device according to claim 14, wherein said occlusion detection sensor is configured to determine an occlusion within said fluid delivery tube based on said distance between said movable capacitance plates.

16. The fluid delivery device according to claim 1, wherein said occlusion detection sensor is configured to detect conditions selected from a group consisting of: no occlusion, partial occlusion, and total occlusion.

17. The fluid delivery device according to claim 1, further comprising an alarm device configured to alert the patient when said occlusion detection sensor detects an occlusion within said fluid delivery tube.

18. The fluid delivery device according to claim 1, wherein said occlusion detection sensor is configured to detect normal delivery of therapeutic fluid to the patient based on a predetermined pressure value of the fluid associated with said normal delivery.

19. The fluid delivery device according to claim 18, wherein said normal delivery is a pulsating delivery.

20. The fluid delivery device according to claim 1, wherein said occlusion detection sensor is configured to detect leakage of therapeutic fluid from said fluid delivery tube based on a pressure of the fluid dropping below a threshold pressure value.

21. The fluid delivery device according to claim 1, wherein said occlusion detection sensor is configured to detect presence of air within said fluid delivery tube.

22. The fluid delivery device according to claim 1, further comprising a control valve, wherein said control valve is configured to control delivery of the therapeutic fluid in said fluid delivery tube for variation of pressure thereof.

23. The fluid delivery device according to claim 22, wherein said control valve is configured in such a manner that when it is closed, the pressure of the therapeutic fluid inside said fluid delivery tube increases, and when said control valve is open, the pressure of the therapeutic fluid inside said fluid delivery tube decreases.

24. The fluid delivery device according to claim 23, wherein during a normal operation of the fluid delivery device, said increase and said decrease of said pressure inside said fluid delivery tube are periodic.

25. The fluid delivery device according to claim 3, in which said dispensing unit comprises a reusable part configured to be operatively coupled to a disposable part.

26. The fluid delivery device according to claim 25, wherein said occlusion detection sensor is configured to be included in said reusable part and/or said disposable part;

wherein when said reusable part and said disposable part are operatively coupled together, said occlusion detection sensor is configured to become operative;

said reusable part is further configured to include said peristaltic pump and electronic components configured to collect data, process and perform data analysis;

said disposable part is further configured to include said reservoir and said fluid delivery tube.

27. A method of detecting an occlusion using a fluid delivery device for delivering therapeutic fluid to a patient, the fluid delivery device including a fluid delivery tube having an occlusion detection portion and an occlusion detection sensor configured to be coupled to the fluid delivery tube, the method comprising the steps of:

delivering therapeutic fluid through the fluid delivery tube;

detecting alternation of a shape of the occlusion detection portion of the fluid delivery tube based on at least one condition which occurs within the fluid delivery tube.

28. The method according to claim 27, further comprising sensing an occlusion within the fluid delivery tube based on the alteration of the shape of the occlusion detection portion.

29. The method according to claim 27, wherein the fluid delivery device further includes a reservoir coupled to the fluid delivery tube and configured to deliver therapeutic fluid to the patient via the fluid delivery tube.

30. The method according to claim 29, wherein the fluid delivery device is configured to pump therapeutic fluid from the reservoir, and comprises

a peristaltic pump having a stator plate and rotary wheel with rollers, wherein the stator plate and the rollers are configured to squeeze the fluid delivery tube;

the peristaltic pump is configured to pump fluid from the reservoir via an inlet portion of the fluid delivery tube to an outlet portion of the fluid delivery tube upon squeezing the fluid delivery tube.

31. The method according to claim 27, wherein the at least one condition is a change in fluid pressure within the fluid delivery tube.

32. The method according to claim 31, further comprising

detecting expansion of the occlusion detection portion when the fluid pressure increases within the fluid delivery tube.

33. The method according to claim 31, wherein the occlusion detection portion is a protrusion extending from said fluid delivery tube; and

wherein the protrusion is configured to change its orientation with respect to the fluid delivery tube when the fluid pressure increases within the fluid delivery tube.

34. The method according to claim 31, wherein the occlusion detection sensor further includes a light emitting source and a light collecting array.

35. The method according to claim 34, further comprising

using the light emitting source to emit light toward the occlusion detection portion; and

using the light collecting array to collect light reflected off of the occlusion detection portion;

wherein the light is reflected at a reflection angle.

36. The method according to claim 35, further comprising

determining whether there is occlusion within the fluid delivery tube based on the angle of reflection.

37. The method according to claim 34, further comprising

using the light emitting source to emit light toward the occlusion detection portion; and

using the light collecting array to collect at least a portion of the light passing by or through the occlusion detection portion.

38. The method according to claim 37, further comprising

determining whether there is occlusion within the fluid delivery tube based on the amount of light collected by the light collecting array.

39. The method according to claim 34, wherein the light emitting source and the light collecting source are configured to be located on the same side of the occlusion detection portion.

40. The method according to claim 34, wherein the light emitting source and the light collecting source are configured to be located on opposite sides of the occlusion detection portion.

41. The method according to claim 31, wherein the occlusion detection sensor further includes movable capacitance plates.

42. The method according to claim 41, further comprising

detecting change in distance between the movable capacitance plates based on the change of the fluid pressure within the fluid delivery tube; and

determining whether there is occlusion within the fluid delivery tube based on the distance between the movable capacitance plates.

43. The method according to claim 27, further comprising

using the occlusion detection sensor, detecting conditions within the fluid delivery tube, wherein the conditions are selected from a group consisting of: no occlusion, partial occlusion, and total occlusion.

44. The method according to claim 27, further comprising

alerting the patient when occlusion is detected within the fluid delivery tube.

45. The method according to claim 27, further comprising

detecting normal delivery of therapeutic fluid to the patient based on a predetermined pressure value of the fluid during the normal delivery.

46. The method according to claim 45, wherein the normal delivery is a pulsating delivery.

47. The method according to claim 27, further comprising

detecting leakage of therapeutic fluid from the fluid delivery tube based on a pressure of the fluid when it drops below a threshold pressure value.

48. The method according to claim 27, further comprising

detecting presence of air within said fluid delivery tube.

49. The method according to claim 27, further comprising

using a control valve to control delivery of the therapeutic fluid in said fluid delivery tube for variation of the pressure thereof.

50. The method according to claim 49, wherein when the control valve is closed, the pressure of the therapeutic fluid inside the fluid delivery tube increases, and when the control valve is open, the pressure of the therapeutic fluid inside the fluid delivery tube decreases.

51. The method according to claim 50, wherein during a normal operation of the fluid delivery device, the increase and the decrease of the pressure inside the fluid delivery tube are periodic.

52. The method according to claim 30, wherein the fluid delivery device comprises a reusable part configured to be operatively coupled to a disposable part.

53. The method according to claim 52, wherein the occlusion detection sensor is locatable in the reusable part and/or the disposable part;

wherein when the reusable part and the disposable part are operatively coupled together, the occlusion detection sensor is configured to become operative;

the reusable part is further configured to include the peristaltic pump and electronic components configured to collect data, process and perform data analysis;

the disposable part is further configured to include the reservoir and the fluid delivery tube.

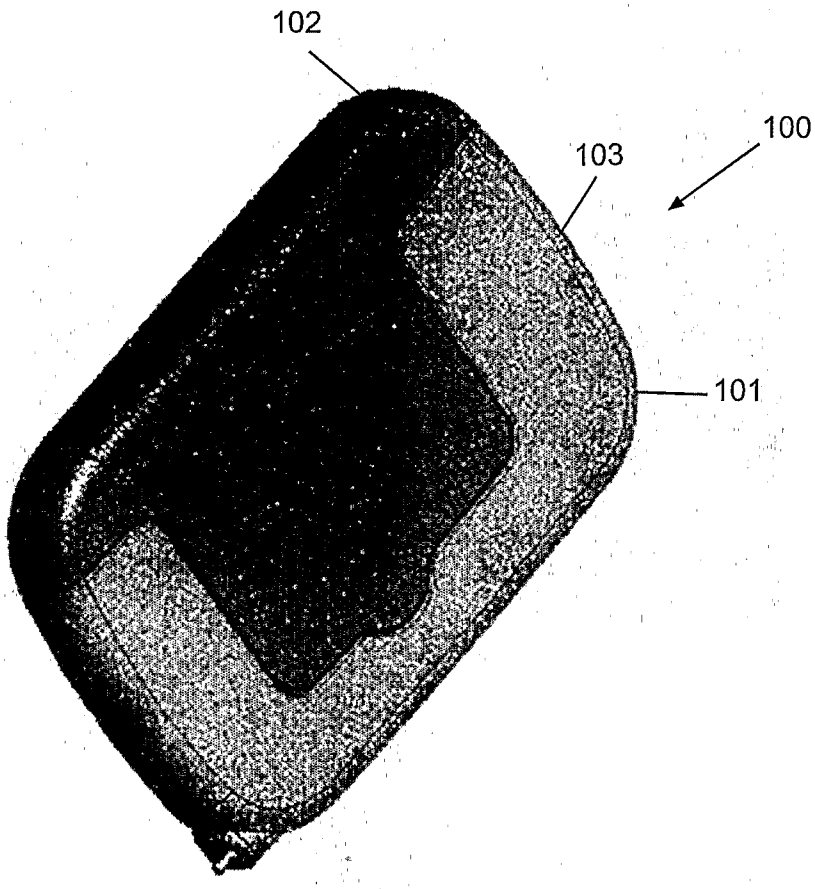

Fig. 1

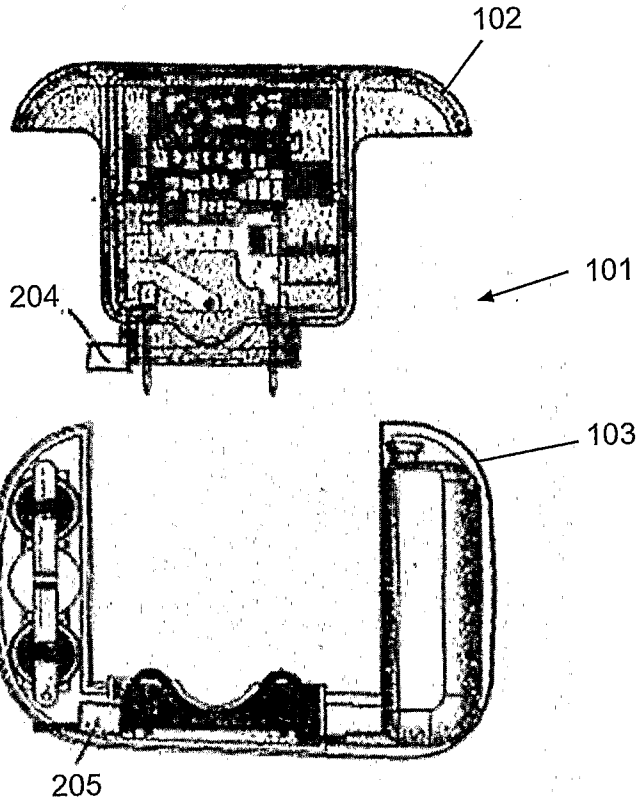
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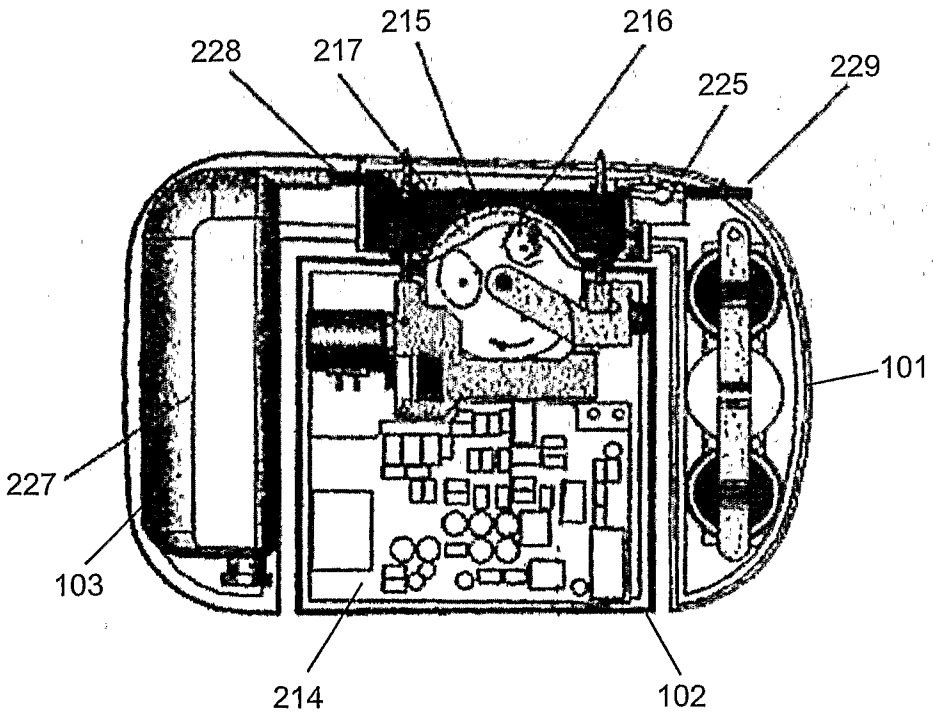
Fig. 2A


228
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103
214
102

Fig. 2B

Fig. 3A

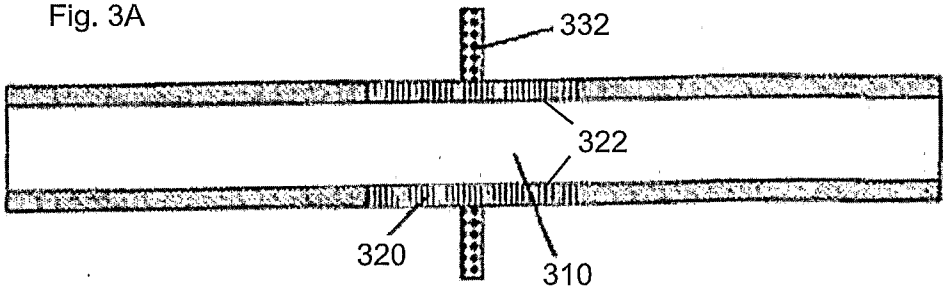


Fig. 3B

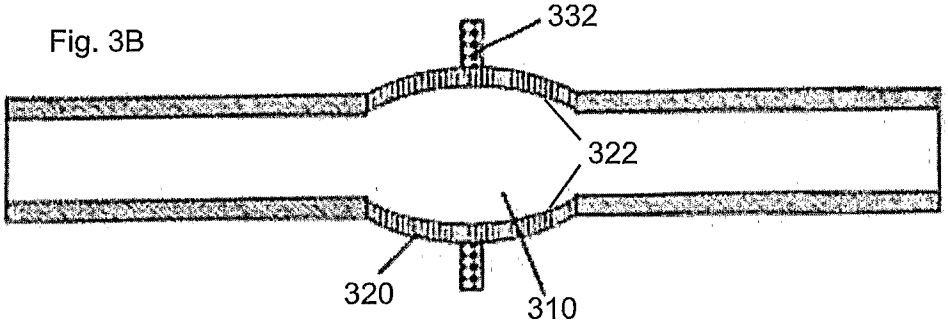
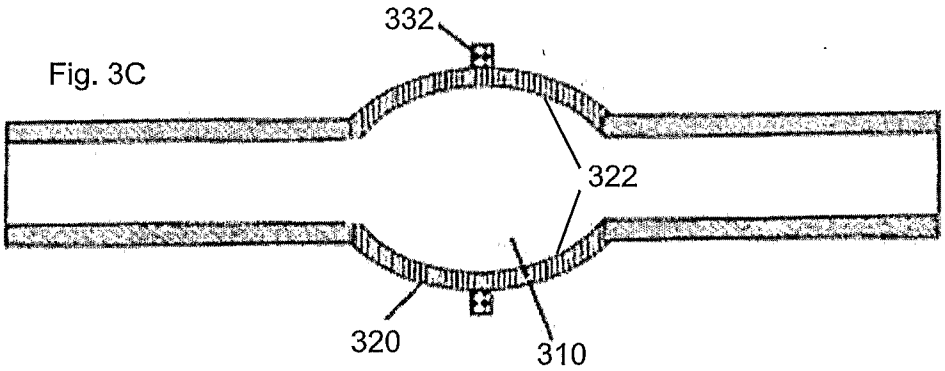


Fig. 3C



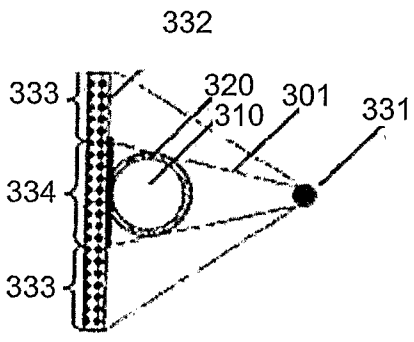


Fig. 4A

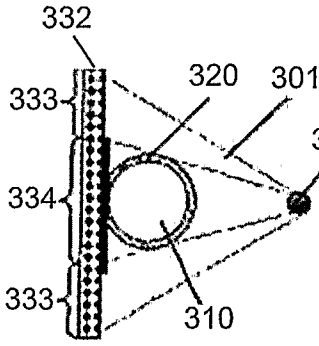


Fig. 4B

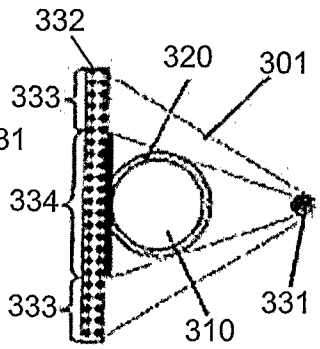


Fig. 4C

Fig. 5A

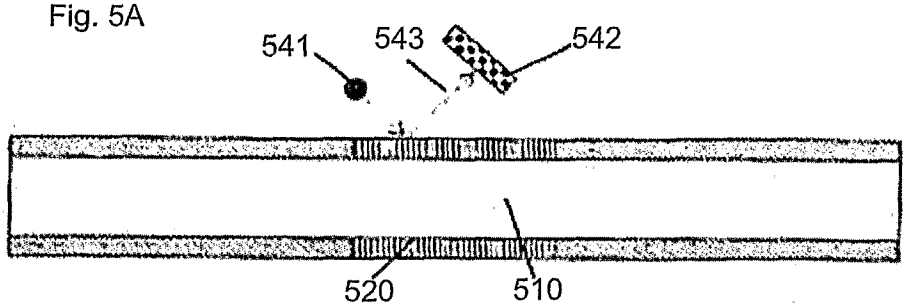


Fig. 5B

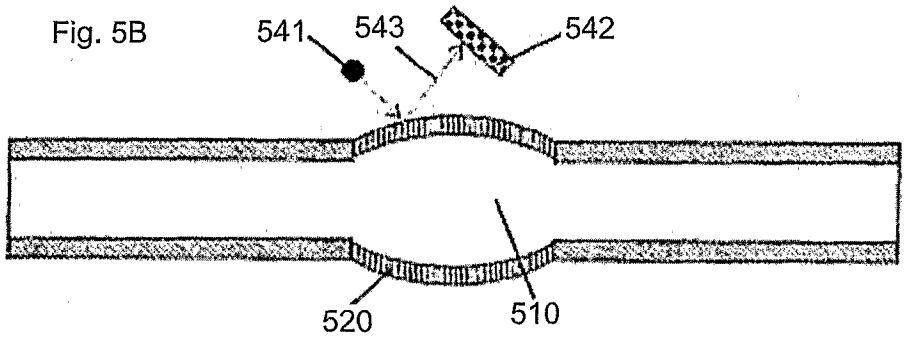
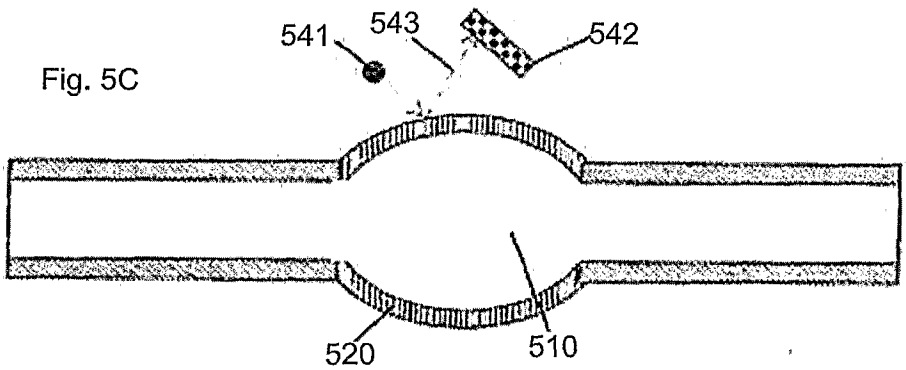


Fig. 5C



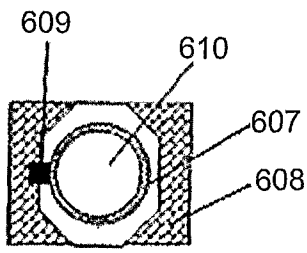


Fig. 6

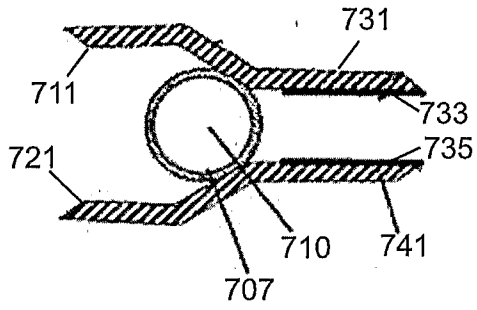


Fig. 7A

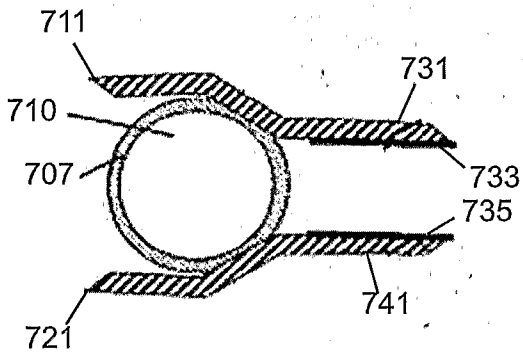


Fig. 7B

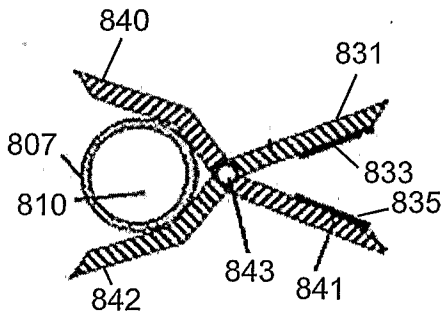


Fig. 8A

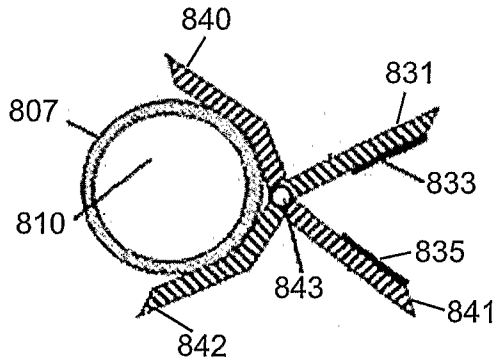


Fig. 8B

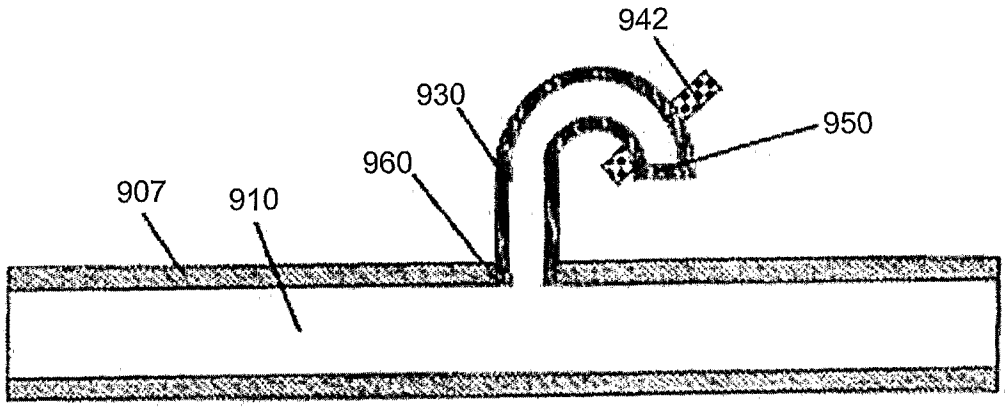


Fig. 9A

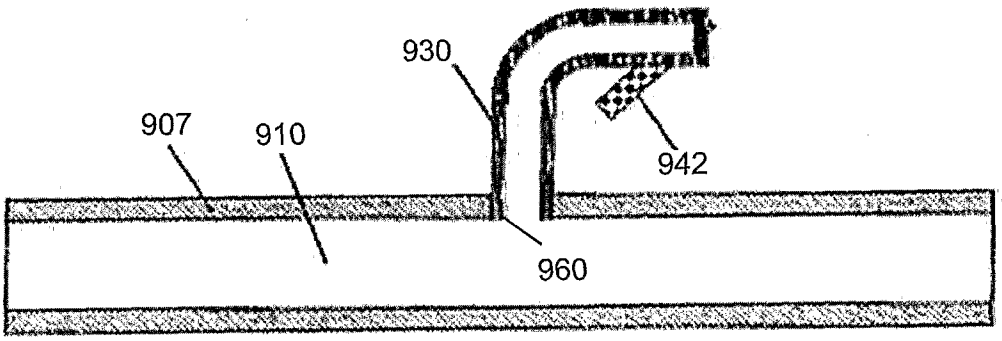


Fig. 9B

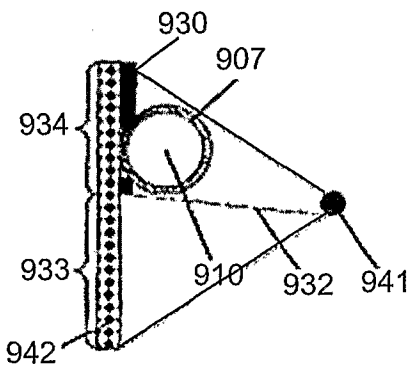


Fig. 10A

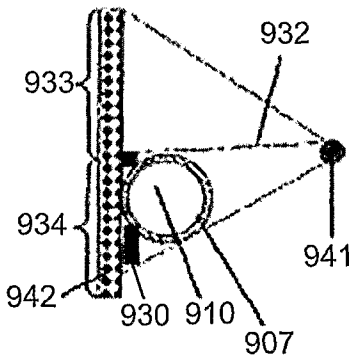


Fig. 10B

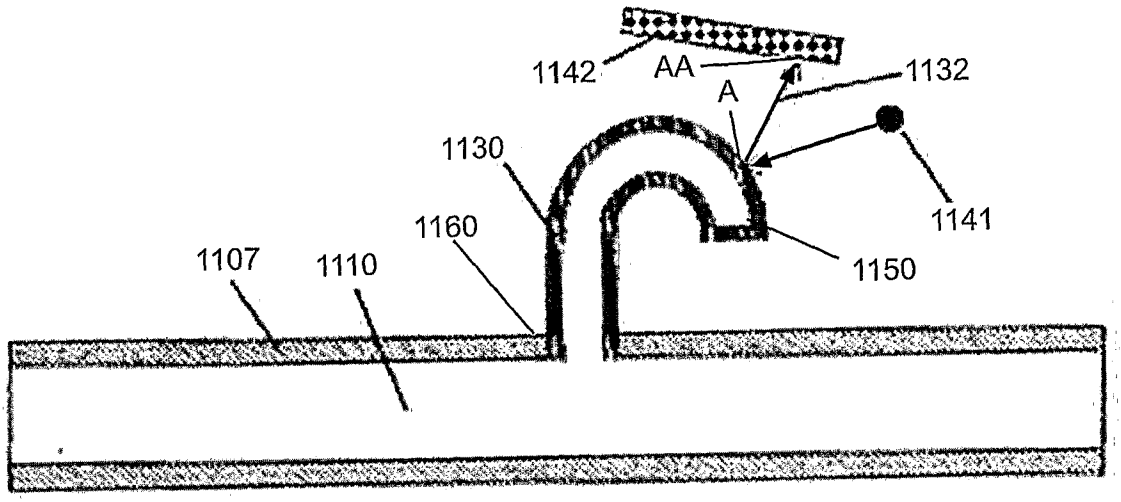


Fig. 11A

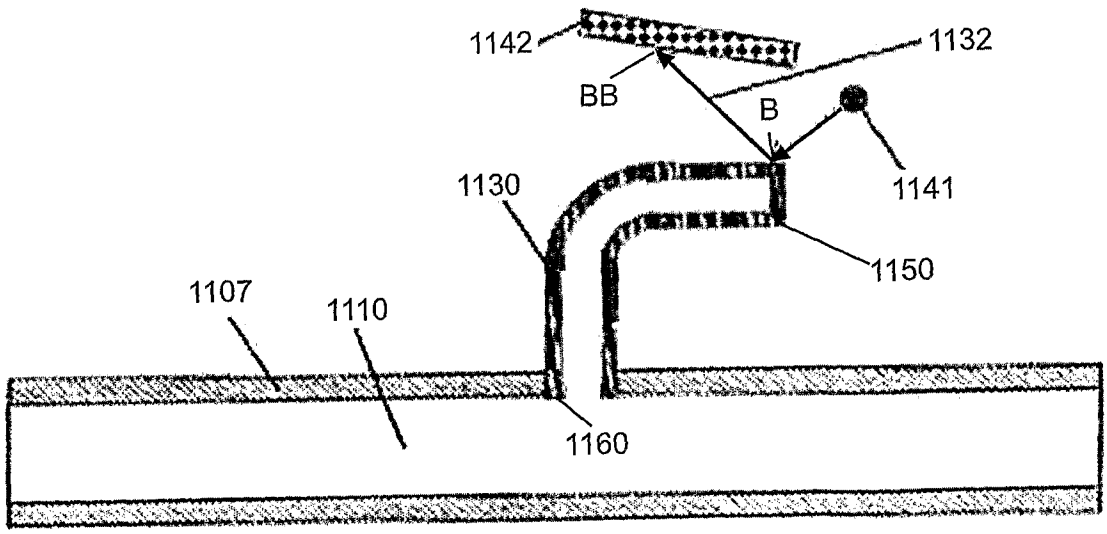


Fig. 11B

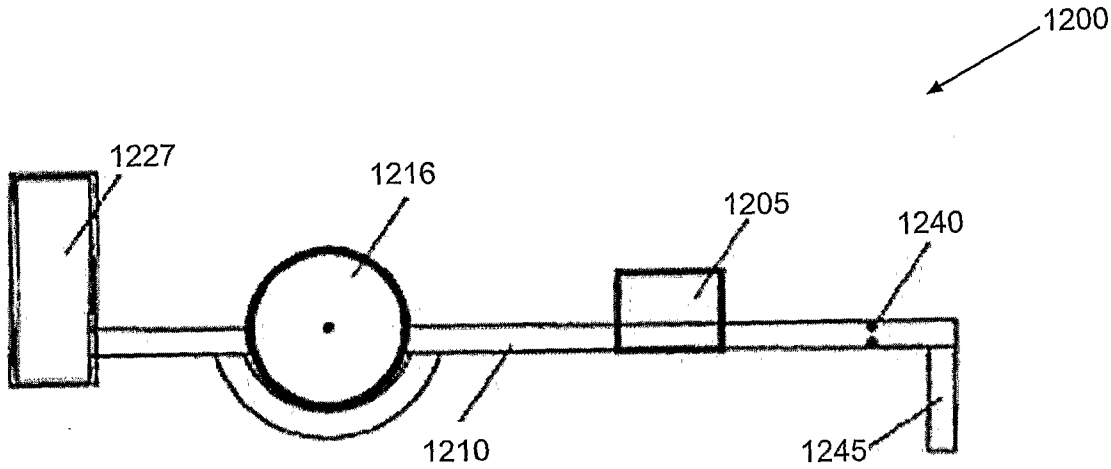


Fig. 12

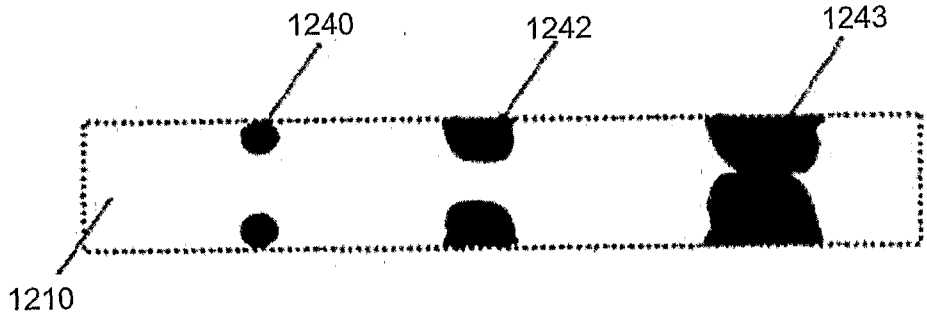


Fig. 13

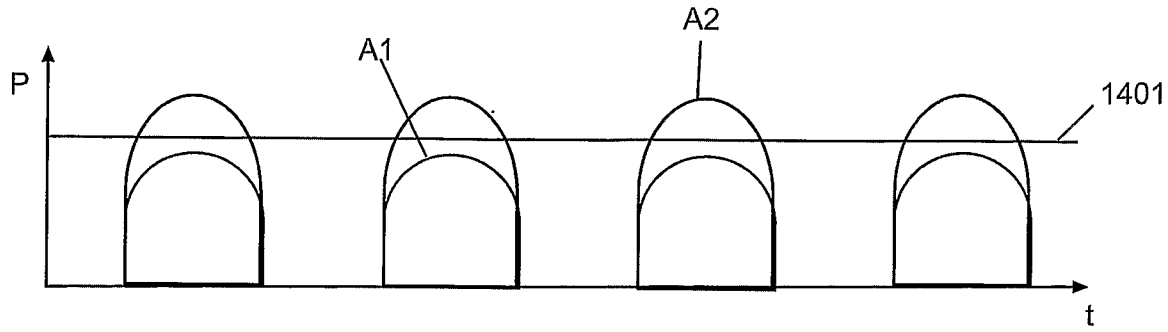


Fig. 14A

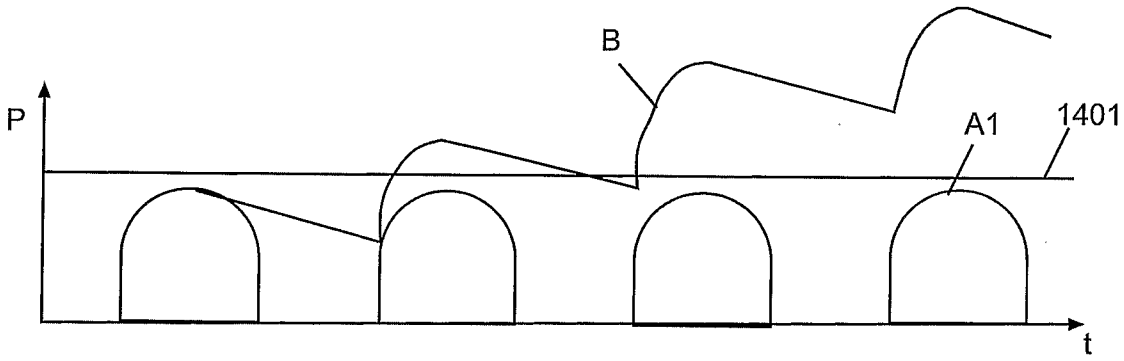


Fig. 14B

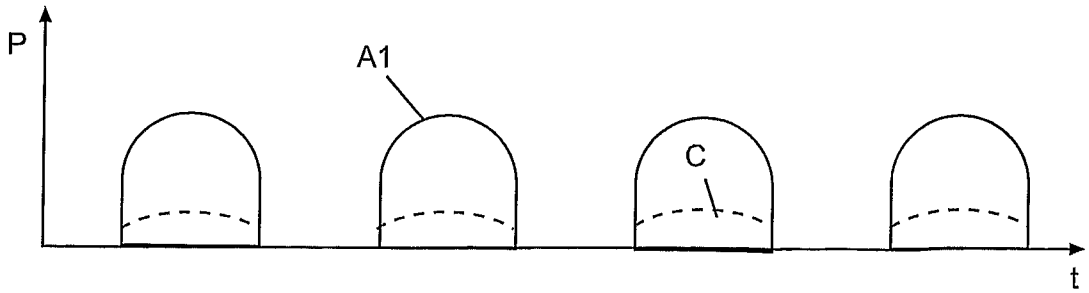


Fig. 14C

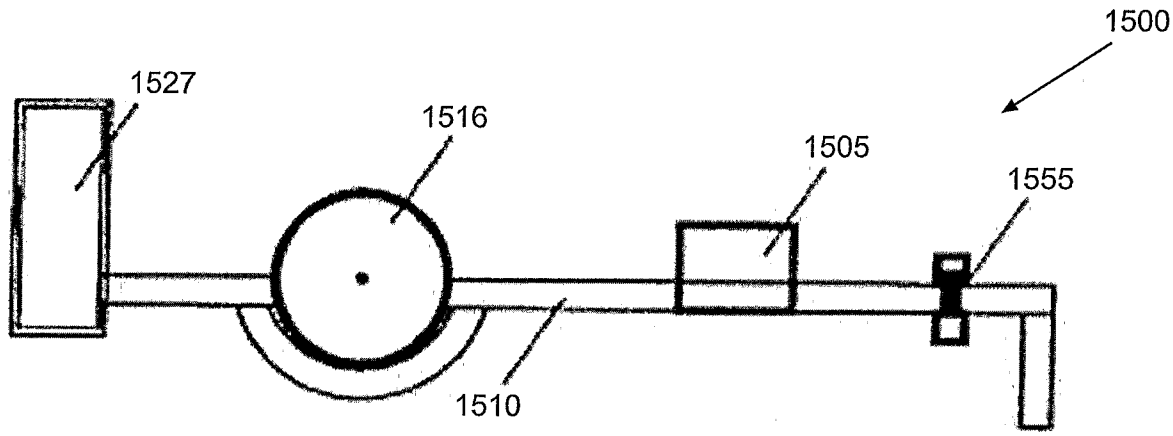


Fig. 15

Fig. 16A

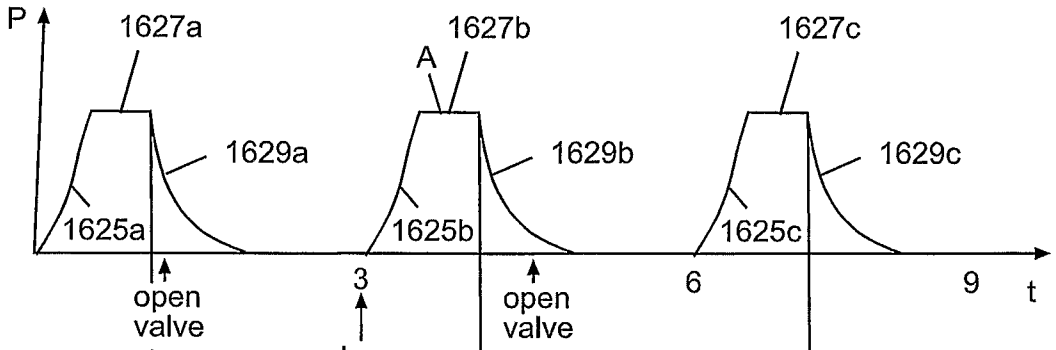


Fig. 16B

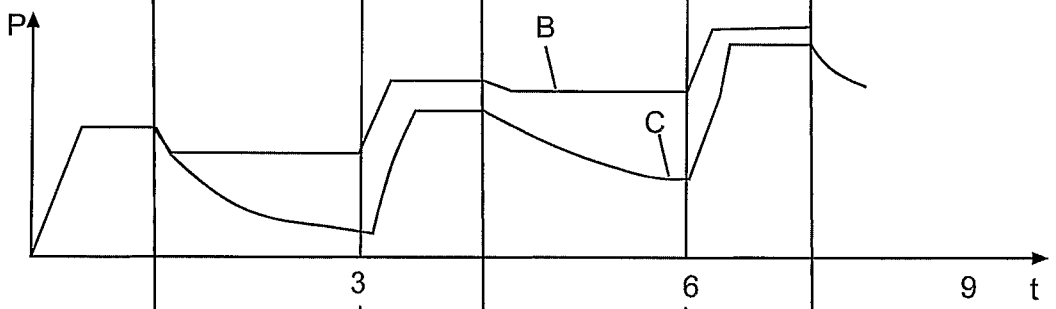
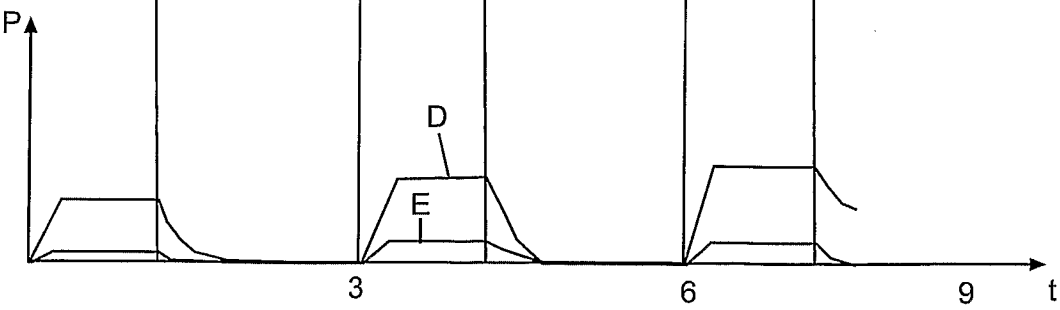


Fig. 16C



INTERNATIONAL SEARCH REPORT

International application No
PCT/IL2007/000684

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M5/168

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

B. FIELDS SEARCHED

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

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

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 98/04301 A (PATIENT SOLUTIONS INC [US]) 5 February 1998 (1998-02-05) figures 1-19	1,2, 4-13,21
A	page 12, line 31 - page 16, line 14	16-19
X	US 2005/178206 A1 (MALMSTROM JAMES A [US] ET AL) 18 August 2005 (2005-08-18) figure 5 paragraph [0047] - paragraph [0055] paragraph [0082] - paragraph [0086]	1,2,4-13
X	US 2003/167035 A1 (FLAHERTY J CHRISTOPHER [US] ET AL FLAHERTY J CHRISTOPHER [US] ET AL) 4 September 2003 (2003-09-04) cited in the application	1,2,4-6, 14-18, 20,21
A	figures 1-9 paragraph [0033] - paragraph [0053] paragraph [0068]	22-24

-/--

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

[X] See patent family annex.

* *Special categories of cited documents :*

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
18 September 2007	27/09/2007

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Reinbold, Sylvie

INTERNATIONAL SEARCH REPORT

International application No
PCT/IL2007/000684

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 720 721 A (DUMAS CHRIS [US] ET AL) 24 February 1998 (1998-02-24) figures 1-8 column 3, line 51 - column 8, line 16	1-4,25, 26
E	EP 1 818 664 A (HOFFMANN LA ROCHE [CH]; ROCHE DIAGNOSTICS GMBH [DE]) 15 August 2007 (2007-08-15) figures 1-9 paragraph [0027] paragraph [0044] - paragraph [0045] paragraph [0058] - paragraph [0060]	1,2,4,5, 7-17,20, 25

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 27-53

The methods of claims 27-53 are carried within a human body, these methods are during a medical therapy (delivering a therapeutic fluid through the fluid delivery tube). These methods are forming part of a therapeutic procedure and can therefore not be regarded as an invention which is susceptible of industrial application.
The application does not meet the requirement of Rule 39.1 (iv), because these claims are a method of treatment of the human body.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IL2007/000684

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 27-53
because they relate to subject matter not required to be searched by this Authority, namely:

see FURTHER INFORMATION sheet PCT/ISA/210

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

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

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

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

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/IL2007/000684

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9804301 A	05-02-1998	AU 737494 B2	23-08-2001
		AU 3733797 A	20-02-1998
		EP 0956057 A1	17-11-1999
		JP 3450337 B2	22-09-2003
		JP 2001523120 T	20-11-2001
		NO 990263 A	24-03-1999
		NZ 333874 A	29-09-2000
		US 6110153 A	29-08-2000
		US 5853386 A	29-12-1998
US 2005178206 A1	18-08-2005	NONE	
US 2003167035 A1	04-09-2003	NONE	
US 5720721 A	24-02-1998	AT 213172 T	15-02-2002
		AU 5723896 A	21-11-1996
		DE 69619282 D1	21-03-2002
		DE 69619282 T2	19-09-2002
		EP 0959920 A1	01-12-1999
		JP 3917655 B2	23-05-2007
		JP 11505449 T	21-05-1999
		WO 9634648 A1	07-11-1996
		US 5514102 A	07-05-1996
EP 1818664 A	15-08-2007	WO 2007093064 A1	23-08-2007