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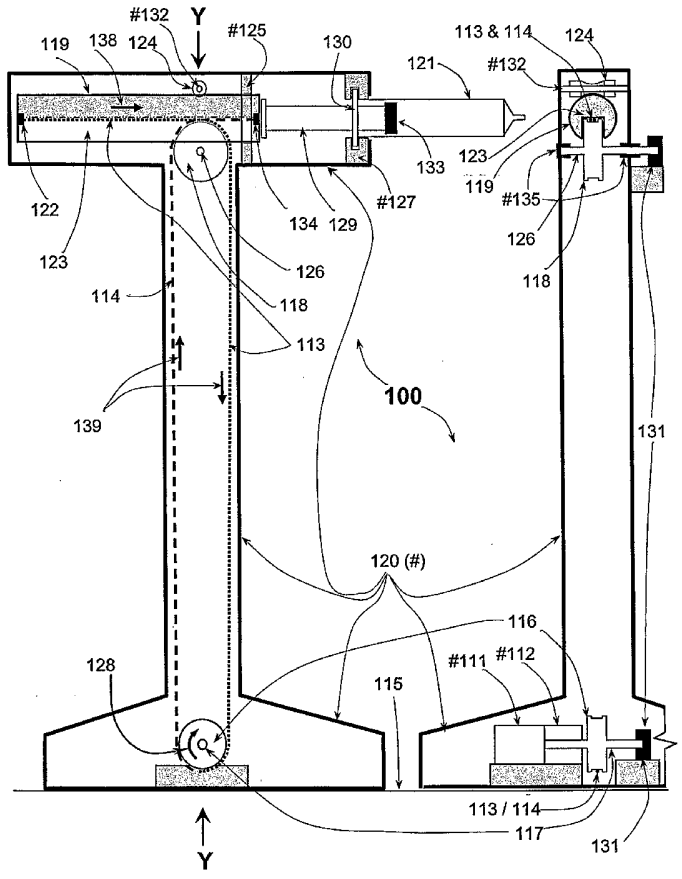
(54) Title: MEDICAL FLUID INJECTOR



(57) Abstract: An injector unit for injecting a patient with fluid during a medical injection procedure. The injector unit comprise a head portion configured to receive a fluid container containing (121). The head portion also houses a mean (119) to inject fluid from the container. A base portion support the injector unit on a substantially planar surface (115) and is adapted to house a drive (111) to provide motive force to the injecting means. An elongate body supports the head portion above the base and houses a drive transfer means, in the form of a flexible cables (113, 114) between the drive and the injecting means.

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"Medical fluid injector"

Field of the Invention

The present invention relates to an injector unit for injecting a fluid into a patient in a medical injection procedure. In particular, the present invention relates to the construction of such an injector unit including a means for injecting fluid from the injector unit in a controlled and efficient manner which is suitable for use in a variety of applications.

Background of the Invention

Many medical diagnostic and therapeutic procedures require a patient to be injected with a fluid under the administration of a physician or similarly trained person. Many forms of fluid pumps have been developed to perform this function that generally employ a variety of actuating mechanisms to control the administration of the fluid to the patient. Infusion pumps have been employed for slow/gradual administration of a fluid medication to a patient over time for instances such as pain management and the like. For procedures such as angiography, computed tomography, ultrasound and NMR/MRI, powered injectors have been developed for pressurised injection of fluids such as imaging contrast media into a patient.. In this regard, powered injectors have typically been designed to control the delivery of the contrast media at a controlled pressure and flow rate.

In most medical fluid pumps, particularly powered injectors, the fluid is contained and expelled from either syringes, soft bags, peristaltic tubes, or a combination of these. These fluid containers are typically secured to or retained within the body of the injector system, at which point the actuating mechanisms are initiated to deliver the fluid to the patient. The actuating mechanisms are typically driven by motors in combination with reduction gearboxes to control the flow of fluid from the container, and in the case of injectors employing syringe-type fluid containers, lead screws and complicated drive shafts are often combined to expel the fluid.

As such, most existing injector units are relatively large and heavy in order to house the various components necessary to perform their function, particularly units that employ two or more syringe-type delivery containers. Therefore, the mobility of

existing units is limited, which is an issue where such units must be transported around various sites in a hospital or clinical environment. Further, as the various components of the units, such as drive shafts and the like, are generally manufactured from a high proportion of ferrous material, such units are generally not ideally suited for use in the vicinity of Magnetic Resonance Imaging ("MRI") scanners as they become adveresly attracted to the magnetic force, and can have an adverse impact on the quality of the resulting image.

As a result, devices for use in MRI applications typically locate the ferrous motors and/or lead screws near the floor of the MRI room, where the magnetic field is relatively weak, to reduce the adverse affects they may have on the resulting image. However, this then requires transference of the motive force from the motor located in the base of the unit, to the syringe or fluid vessel located at the top or head of the unit, which is typically approximately 1 metre above the floor so as to be closer and more convenient to the patient and operator. Transferring motive force over such a distance is difficult to achieve without loss of motive power, particularly if the unit employs a tilting head portion and there is some interaction between the tilting motion of the head, and the motion of the drive transfer. As most units are battery powered they must operate at a high level of efficiency to maximise usage between charges and any inefficiency in the drive mechanism, due to friction losses and the like, requires frequent recharging of the battery.

As a result of the above, medical fluid injector units compatible with MRI are generally very expensive and complicated devices. One such device, "Spectris", manufactured and distributed by Medrad Inc. of Indianola, Pa, U.S.A., is described in US Patent No. 5,494,036 and US Patent Application Publication No. US 2003/0050555. This unit is designed specifically for use with MRI and has its motor/gearbox located either external to the injector unit or in the base of the unit, and orientated vertically thereby intersecting a significant portion of the magnetic field associated with an MRI procedure. The device employs flexible rotating drive shafts within flexible tubes (also known as Bowden shafts) to transfer rotational motive power from the motor/gearbox some distance to a lead screw pushing on the syringe(s) provided in the head of the unit. Such a drive means has disadvantages as it requires specialised manufacture procedures and is therefore costly to produce and has limited availability, and also exhibits high friction losses (i.e. poor efficiency), limited life, limited flexibility of the cable, and elasticity in the power transfer of the cable. The

Spectris also employs lead screws in the head which are not efficient, are heavy, and for use with MRI must be non-magnetic which also adds to the cost if the unit.

There is therefore a need to provide an injector unit which is arranged in a manner which ensures efficient transference of motive force throughout the unit as well as good weight distribution to provide improved mobility of the unit. There is also a need to provide an injector unit than can be readily used in an MRI environment without adversely affecting the quality of the resultant image.

Further to this, in order to control the delivery of fluid to a patient during a medical procedure, there is a need to monitor and control the fluid pressure in the system to ensure safe fluid delivery as well as to detect restrictions, blockages, or poor placement of the needle within the patient.

Still further, most existing injector units can only accommodate one size and/or type of syringe which restricts the choice of syringes that can be used as well as the volume of fluid that is to be delivered. Such units also typically restrict the user to the use of proprietary syringes which are often considerably more expensive. In injector units where a variety of sized syringes can be used, special adaptors are often required which can be tedious to change and are sometimes misplaced or inadvertently discarded with the disposable syringe. Alternative types and/or sized syringes have differing bores and the injector unit must be programmed for correct speed and stroke of compression in order to accurately deliver the desired flow and volume for each particular syringe. Some injectors may be able to recognize a limited choice of proprietary adaptors or coded syringes, however no current injector units can accept standard (pre-filled or disposable) syringes, in a variety of sizes, without changing hardware or adaptors. Furthermore no existing injector units are able to automatically recognize the syringe size directly, and adjust flow and stroke accordingly.

Any discussion of documents, acts, materials, devices, articles or the like which has been included in the present specification is solely for the purpose of providing a context for the present invention. It is not to be taken as an admission that any or all of these matters form part of the prior art base or were common general knowledge in the field relevant to the present invention as it existed before the priority date of each claim of this application.

Summary of the Invention

Throughout this specification the word "comprise", or variations such as "comprises" or "comprising", will be understood to imply the inclusion of a stated element, integer or step, or group of elements, integers or steps, but not the exclusion of any other element, integer or step, or group of elements, integers or steps.

According to a first aspect, the invention is an injector unit for injecting a patient with fluid during a medical injection procedure, the injector unit comprising:

a head portion configured to receive at least one fluid container containing said fluid for injection, and housing an injecting means operable to eject fluid therefrom;

a base portion configured to support said injector unit and adapted to house a drive means for providing motive force to operate said injecting means; and

an elongate body portion, for supporting said head portion in a position relative to said base portion and for housing a drive transfer means for transferring motive force from said drive means to said injecting means, the drive transfer means comprising at least one cable extending between said drive means and said injecting means.

In one embodiment, the at least one fluid container is a syringe having a plunger disposed therein, and the injecting means comprises at least one elongate rod element which is movable in an axial direction to contact and depress the plunger of the syringe to eject the fluid therefrom. The elongate rod element may be arranged along at least one roller such that the axial movement of the elongate rod element is axial rolling movement and is guided by the at least one roller. The elongate rod element has a proximal end and a distal end, with the proximal end being the end which contacts the plunger of the syringe to eject the fluid therefrom. In this regard, the proximal end of the elongate rod element may have a closed face to ensure that even force is applied to the plunger of the syringe.

In one embodiment, the drive means comprises a motor. The motor can provide a substantially rotary motive force to an associated drive shaft. A first end of a first cable may be attached to the drive shaft and a second end to the distal end of the elongate rod element. In this regard, the first cable may be arranged to extend along a length of the axis of the elongate rod element. In this arrangement, rotation of the drive shaft in a first direction causes an increase in tension in the first cable causing the first cable to move in a first direction, thereby moving said elongate rod element in an axial

direction to contact and depress the plunger into said syringe to expel the fluid therefrom. By ensuring that the first cable is connected to the distal end of the elongate rod element to extend along a length of the axis of the elongate rod member, virtually all the cable tension is exerted squarely onto the syringe and associated plunger. This should result in all parts bearing relatively very light loads so resulting in long life and greater efficiency of the injector unit.

This arrangement allows the motor, and where appropriate an associated gearbox and lead screw, to be located in the base portion of the unit. Such a base unit can be placed on or very near the floor, so avoiding most of the magnetic field associated with MRI scanners. Such an arrangement further overcomes the high centre of gravity problem associated with conventional units and provides a stable unit able to be readily transported in a safe and reliable manner.

In another embodiment, the drive transfer means may comprises a second cable attached at a first end to the drive shaft and at a second end to the proximal end of the elongate rod element. The second cable may also be arranged to extend along a length of the axis of the elongate rod element, in a direction opposite to the first cable to optimise force transferral from the second cable to the elongate rod element. In such an arrangement, rotation of the drive shaft in the first direction releases tension in the second cable causing the second cable to move in the first direction. Further, rotation of the drive shaft in a direction opposite to the first direction causes a decrease in tension in the first cable and an increase in tension in the second cable, thereby causing the elongate rod element to move in an axial direction away from the plunger of the syringe to enable removal of the spent syringe.

Each of the first and the second cables may be attached at their respective first ends to a reel fixed to the drive shaft. By arranging the system such that the cable is driven directly from the reel on the output of the motor/gearbox, there is no need to provide a customary lead screw arrangement and thereby greatly improving reliability, longevity and efficiency of the system, as well as simplifying the design, manufacture, and cost of the injector unit. In another embodiment where a lead screw arrangement may be employed, each of the first and second cables may be attached at their respective first ends to a nut, driven by a lead screw in contact with the drive shaft of the motor.

The first and/or second cables may be in the form of a wire, chain, belt or cord. They may be made from a non-stretchable, non-metallic and/or non-conductive material. In this regard, the first and/or second cables may be made from a para-aramid fibre (such as Kevlar®) or carbon fibre.

In another embodiment, the head portion is able to be tilted in relation to the base portion and/or the elongate body portion. As the present invention does not employ drive shafts and the like to transfer the motive force, the head portion of the unit is able to tilt with virtually no affect on cable tension, and without resulting in movement of the pusher or syringe plunger. Further, this arrangement ensures that there is no tendency for the head portion to tilt unexpectedly, or loss of system power due to tilting of the head when the unit is in operation.

The structural components of the injector unit may be constructed from non-conductive materials such as plastics, resins or composite materials, thereby further reducing electromagnetic interaction between the unit and an MRI scanner.

Most existing injectors require expensive custom designed and built bases to accommodate the components such as the mechanics and electronics necessary for such devices. In one embodiment of the present invention, a low cost conventional chair base portion may be provided to support the unit. The base portion may support either a single or double elongate body portion, for instances where single or double syringes are provided. A brake system may be also provided to prevent wheeled pumps from rolling undesirably on smooth floors, and which can be incorporated into conventional chair bases.

In this aspect of the invention, the axial position and/or speed of the elongate rod element may be readily monitored to determine the flow rate of the fluid expelled from the syringe. The axial position and/or speed of the elongate rod element may be monitored by measuring the rotational speed of the drive shaft and/or at least one of the rollers which guide the elongate rod element. In this regard, the rotational speed may be measured by a rotational encoder or potentiometer. In such an arrangement, the rotational encoder or potentiometer type sensor may be coupled directly to the motor/gearbox drive shaft located in the base portion of the unit to ensure shielding of the control electronics from EMI. Thus, the invention avoids any sensors and/or conductive wires in the head portion or elongate body portion of the unit (as is common

with existing injector units) which are a particular problem in the vicinity of an MRI scanner due to EMI and shielding problems.

In an alternative embodiment, for sensing fluid pressure in the syringe in order to detect restriction or blockages, or poor needle placement, a sensor is provided to measure the tension in the first cable. The sensor may comprise an arm hingedly mounted at one end to the injector unit for deflecting the first cable, and the tension in the first cable may be determined by measuring the force applied by the first cable against the arm. The free end of the arm may comprise a roller which contacts the first cable to deflect the cable, and the force applied by the first cable against the arm may be measured by a force sensor. In this regard, the measured tension in the first cable is directly proportional to the syringe fluid pressure.

With this arrangement, large forces can be measured with relatively small force sensors, enabling the use of relatively cheap conventional sensors, for example of the piezo type which are very compact, light weight, and not affected by magnetic fields. Further, the deflection force being measured can be matched (apportioned) to the sensor sensitivity simply by choosing the degree of deflection in the cable, and/or the position of the roller along the cable (regardless of the magnitude of the syringe force and pressure). In this regard, the system can be easily calibrated (i.e. adjusted for accuracy) simply by adjusting the degree of deflection in the cable, and/or the position of the roller along the cable. Further, as the cable tension is directly proportional to the syringe fluid pressure, errors associated with existing lead screw methods which include screw and torsion friction errors are eliminated. Also, where the unit is used in close proximity to EMI (e.g. near a medical scanner) by extending the cable (and perhaps employing rollers) the force sensor can be located almost anywhere in the unit (e.g. in the base portion of the unit and/or in a screened enclosure) thereby avoiding or reducing errors caused by induced voltages from the EMI in the sensor.

In yet another embodiment for sensing fluid pressure in the syringe, the proximal end of the elongate rod element may have a sensor for determining contact with, and/or pressure applied to, the plunger of the syringe. The sensor may be a fluid filled bag located on a contact surface of the proximal end of the elongate rod element in fluid communication with a pressure transducer for measuring fluid pressure within the fluid filled bag. In this regard, the fluid pressure measured in the fluid filled bag is directly proportional to the pressure of the fluid expelled from the syringe.

In this arrangement, pressure at the transducer is accurately representative of the syringe pressure (ignoring the friction of the syringe piston), and ignores friction errors associated with the drive means. The sensitivity of the transducer may be readily selected by varying the surface area of the fluid filled bag, thereby controlling the ratio of the syringe pressure to the transducer pressure. In this regard, by using a non-conductive fluid such as an oil with the sensing system of this embodiment, the system is immune to EMI. Further, the present embodiment ensures that very small pressures are accurately measured, thereby enabling the injector unit to detect when the advancing injecting means first touches the syringe plunger.

In yet another embodiment for sensing fluid pressure in the syringe, the syringe is supported within the head portion on a sliding base which is free to move in an axial direction for a fixed distance. The axial direction may be substantially co-axial with said axial movement of the at least one elongate rod element and the fixed distance, may be a distance of between up to 10 mm. In this arrangement, contact between said elongate rod element and the plunger of the syringe may cause movement of said sliding base in the axial direction. The sliding base may be in direct or indirect contact with a force sensor which senses forces associated with said axial movement of said sliding base. In this regard, the force sensor may be a load cell, strain gauge or piezo cell in direct contact with the sliding base. In this arrangement, the force sensed by the force sensor associated with movement of the sliding base of the syringe support is directly proportional to the pressure of the fluid ejected from the syringe, and detects initial contact between the elongate rod element and the plunger of the syringe to enable priming of the injector unit.

In each of the above embodiments, the injector unit can be controlled by an electronic control system which controls the injection of the fluid into a patient in response to the above sensed pressure conditions associated with the injection procedure. In this regard, the electronic system is able to precisely control pump flow by continuously adjusting pressure to meet the inherent resistance, yet safely limit pressure with compromised flow in the event of an uncharacteristic restriction or blockage to flow. Unlike most existing injector unit types, the flow control system of the present invention employs analog feedback techniques which greatly simplify the circuitry, produce little electromagnetic radiation, and are relatively immune to any EMI from the surrounding environment.

In yet another embodiment, each syringe is received in the head portion by a syringe holder, comprising a base portion for securing said syringe holder to said injector unit; at least two arms, each arm being mounted to said base portion at a first end, with at least one of said arms being hingedly mounted to said base portion at said first end, and each arm further having a gripping element secured to a second end; and a biasing element arranged between said at least two arms for biasing said arms into a holding position, wherein a body of the syringe is securely held between said gripping elements of said arms.

The first ends of the at least two arms may be mounted to axles provided in the base portion of the syringe holder. The axles may be fixed to the base portion and arranged in a parallel relationship to ensure that when the arms are in the holding position, the syringe is axially aligned with the injecting means. To ensure symmetrical movement of the arms with respect to the base such that any diameter syringe will be axially aligned with the injecting means, each axle may have a gear element mounted thereon such that gear elements of adjacent axles mesh together.

The biasing element may be an extension spring stretched between the at least two arms. The biasing force of the extension spring may be sufficient to firmly hold the syringe in position during ejection of the fluid retained therein, whilst enabling manual separation of the arms to remove the syringe therefrom following ejection of the fluid.

The surfaces of the gripping elements which contact the body of the syringe may be shaped to conform to the body of the syringe. In this regard, the contact surfaces of the gripping elements may have a substantially concave surface. In another form, the contact surfaces of the gripping elements may be provided with two concave surfaces, one concave surface having a radius substantially equal to the largest suitable syringe diameter, and the other concave surface having a diameter substantially equal to the smallest suitable syringe diameter. In yet another form, the gripping elements may be substantially V-shaped in cross-section. The contact surfaces of the gripping elements may also have grooves provided therein to conform with flanges provided on the body of the syringe. The contact surfaces of the claws may be moulded from or coated with a soft plastic to facilitate gripping of the syringe. In another embodiment, the gripping

elements may be detachable from the arms of the syringe holder, such that the gripping elements may be interchangeable to suit different types and styles of syringes.

The arms of the syringe holder can be separated to receive a variety of syringes having variable barrel diameters, to retain the syringe in an axially aligned arrangement with the injecting means. A sensor may be provided to measure the distance of separation of the arms to determine the barrel diameter of the syringe retained therein. The distance of separation of the arms may be determined by measuring the angle of at least one of the arms with respect to the base portion of the syringe holder. In this regard, a rotational sensor may be coupled to at least one arm of the syringe holder to measure the angle of the arm with respect to the base portion.

The control circuitry of the injector unit may determine the barrel diameter of the syringe based on the measured distance of separation of the arms, and control the injecting means accordingly. In one form, the control circuitry may control the injecting speed and stroke of the injecting means in relation to the determined barrel diameter of the syringe to ensure the correct flow rate of fluid is delivered from the syringe. In another form, the control circuitry may cease operation of the injecting means if the determined barrel diameter of the syringe is inconsistent with the medical procedure being performed.

According to a second aspect, the invention is a syringe holder for an injector unit, comprising:

a base portion for securing said syringe holder to said injector unit;

at least two arms, each arm having a first end and a second end, said first ends of each arm being mountable to said base portion, with at least one of said arms being hingedly mountable to said base portion at said first end, and each said second end having a gripping element attached thereto; and

a biasing element arranged to bias said arms into a holding position for holding the syringe between said gripping elements of said arms.

In one embodiment of this second aspect, the first ends of the at least two arms may be mounted to axles provided in the base portion of the syringe holder. The axles may be fixed to the base portion and arranged in a parallel relationship to ensure that when the arms are in the holding position, the syringe is axially aligned with the injecting means. To ensure symmetrical movement of the arms with respect to the base

such that any diameter syringe will be axially aligned with the injecting means, each axle may have a gear element mounted thereon such that gear elements of adjacent axles mesh together.

The biasing element may be an extension spring stretched between the at least two arms. The biasing force of the extension spring may be sufficient to firmly hold the syringe in position during ejection of the fluid retained therein, whilst enabling manual separation of the arms to remove the syringe therefrom following ejection of the fluid.

The surfaces of the gripping elements which contact the body of the syringe may be shaped to conform to the body of the syringe. In this regard, the contact surfaces of the gripping elements may have a substantially concave surface. In another form, the contact surfaces of the gripping elements may be provided with two concave surfaces, one concave surface having a radius substantially equal to the largest suitable syringe diameter, and the other concave surface having a diameter substantially equal to the smallest suitable syringe diameter. In yet another form, the gripping elements may be substantially V-shaped in cross-section. The contact surfaces of the gripping elements may also have grooves provided therein to conform with flanges provided on the body of the syringe. The contact surfaces of the claws may be moulded from or coated with a soft plastic to facilitate gripping of the syringe. In another embodiment, the gripping elements may be detachable from the arms of the syringe holder, such that the gripping elements may be interchangeable to suit different types and styles of syringes.

The arms of the syringe holder can be separated to receive a variety of syringes having variable barrel diameters, to retain the syringe in an axially aligned arrangement with the injecting means. A sensor may be provided to measure the distance of separation of the arms to determine the barrel diameter of the syringe retained therein. The distance of separation of the arms may be determined by measuring the angle of at least one of the arms with respect to the base portion of the syringe holder. In this regard, a rotational sensor may be coupled to at least one arm of the syringe holder to measure the angle of the arm with respect to the base portion.

The control circuitry of the injector unit may determine the barrel diameter of the syringe based on the measured distance of separation of the arms, and control the injecting means accordingly. In one form, the control circuitry may control the

injecting speed and stroke of the injecting means in relation to the determined barrel diameter of the syringe to ensure the correct flow rate of fluid is delivered from the syringe. In another form, the control circuitry may cease operation of the injecting means if the determined barrel diameter of the syringe is inconsistent with the medical procedure being performed.

According to a third aspect, the invention is a method of operating an injector unit for injecting a patient with fluid during a medical injection procedure, comprising:

loading the injector unit with a container containing said fluid for injection;

sensing a parameter associated with the container; and

controlling the delivery of said fluid from the container in response to said sensed parameter.

In one embodiment of this aspect, the injector unit can be as described herein with reference to the first aspect of the invention.

In one embodiment, the step of loading the injector unit may comprise loading a fluid filled syringe into a syringe holder of the injector unit. The syringe holder may comprise at least two arms for securely retained the syringe in position for injecting by the injector unit. In this regard, the syringe may have a plunger disposed therein for ejecting the contained fluid from the syringe.

The step of sensing a parameter associated with the container may comprise sensing a barrel diameter of the syringe which is indicative of the volume of the syringe. The barrel diameter of the syringe may be sensed by determining a distance of separation between the at least two arms of the syringe holder holding the syringe. In this regard, the distance of separation of the arms may be determined by measuring the angle of at least one of the arms with respect to a base portion of the syringe holder. In one form, a rotational sensor may be coupled to at least one of the arms of the syringe holder to measure the angle of the arm with respect to the base portion.

The step of controlling the delivery of the fluid from the container may comprise controlling the speed and stroke of the plunger within the syringe to deliver an appropriate volume and/or flow rate of fluid from the syringe proportional to the measured barrel diameter of the syringe. In this regard, the speed and stroke of the plunger may be controlled by a control system of the injector unit which controls a

drive mechanism for engaging with the plunger to eject fluid from the syringe. The drive mechanism may comprise a motor which operates a push-rod that engages the plunger, and the speed and stroke of the plunger may be controlled by controlling the speed of the motor.

According to a fourth aspect, the invention is an injector unit for injecting a patient with fluid during a medical injection procedure, comprising:

a holder mechanism for receiving and securing in position a fluid container for injection;

an injecting means for ejecting fluid from said fluid container; and

a sensor for measuring a force applied by the injecting means to the holder mechanism.

In one embodiment of this aspect, the fluid container is a syringe having a plunger disposed therein. The holder mechanism may be attached to said injector unit such that it is free to move, for a predetermined distance, along the axis of the syringe. The predetermined distance may be a distance of up to 10 mm.

The injecting means may comprise at least one elongate rod element which is movable in an axial direction to contact and apply force to the plunger of the syringe to eject fluid therefrom. The at least one elongate rod element may be driven by a motor under control of a control system of the injector unit. In this regard, the force applied to the plunger of the syringe is also transferred to the holder mechanism, causing the holder mechanism to move in a direction along the axis of the syringe.

The sensor may be in contact with the holder mechanism such that movement of the holder mechanism generates a force upon said sensor. In this regard, the sensor may be a load cell, strain gauge and/or a piezo cell, capable of efficiently measuring forces. The force sensed by the sensor can be proportional to the fluid pressure delivered by the syringe and can provide an indication of any problems associated with the injection procedure, such as blockages, incorrect syringe placement and the like. As such, in response to the forces sensed by the sensor, the injecting means may be controlled to ensure that the procedure is operating efficiently and that the fluid pressure delivered by the syringe is within acceptable and safe limits.

Brief Description of the Drawings

By way of example only, preferred embodiments of the invention are now described with reference to the accompanying drawings, in which:

Fig. 1 depicts a sectional side view of an injector unit arrangement having motive power source arranged in the base of the unit in accordance with one embodiment of the present invention;

Fig. 2 shows a cross-section view of the injector unit of Fig. 1 through section Y-Y;

Fig. 3 reveals a side view of an alternative embodiment of the injector unit of Figs. 1 and 2, employing a tilting head arrangement;

Fig. 4 shows the injector unit of Fig. 1, in combination with a monitoring system for monitoring the tension of the drive cable to determine fluid pressure in the syringe in accordance with one embodiment of the present invention;

Fig. 5A shows a sectional side view of a sliding base syringe holder arrangement employing a means for measuring syringe pressure in accordance with one embodiment of the present invention;

Fig. 5B is a front view of the sliding base syringe holder arrangement of Fig. 5A;

Fig. 6 shows a side view of the sliding base syringe holder of Figs. 5A and 5B employing a means for measuring syringe pressure according to another embodiment of the present invention;

Fig. 7 shows a side view of a syringe holder employing an alternate means for measuring syringe pressure in accordance with another embodiment of the present invention;

Fig. 8 shows a side view of a system for detecting contact between a pump pusher and a syringe plunger, in accordance with an embodiment of the present invention;

Fig. 9 depicts a sectional side view of an injector unit arrangement having an alternative motive power source arranged in the base of the unit in accordance with another embodiment of the present invention;

Fig. 10 shows a cross-sectional view of the injector unit of Fig. 9 through plane B-B;

Fig. 11 depicts a sectional side view of an injector unit arrangement having an alternative motive power source arranged in the base of the unit in accordance with yet another embodiment of the present invention;

Fig. 12 shows a cross-sectional view of the injector unit of Fig. 11 through plane C-C;

Fig. 13 depicts a sectional side view of an injector unit arrangement having an alternative motive power source arranged in the base of the unit in accordance with still yet another embodiment of the present invention;

Fig. 14 shows a cross sectional view of the injector unit of Fig. 13 through plane D-D;

Fig. 15 depicts a sectional front view of a peristaltic pump injector unit according to yet another embodiment of the present invention;

Fig. 16 shows a cross-sectional view of the injector unit of Fig. 15 through plane E-E;

Fig. 17A shows an exploded oblique view of a syringe holder in accordance with one embodiment of the present invention;

Fig. 17B shows an oblique view of the assembled syringe holder of Fig. 17A, with a syringe above ready to be loaded into the holder;

Fig 18A shows the syringe holder of Figs 17A and 17B having removable claws in accordance with an embodiment of the present invention;

Fig 18B shows the syringe holder of Fig. 18A with removable claws attached;

Figs 18C(i) to (v) show a variety of flanged syringes adapted for use with the injector unit of the present invention.

Figs 18D(i) to (iii) show a variety of plungerless syringes adapted for use with the injector unit of the present invention;

Fig. 18E shows a side view of a syringe holder having alternative slotted claws for holding flanged syringes;

Fig. 18F is a front view of the syringe holder of Fig. 18E;

Fig. 18G shows a three-dimensional oblique view of the syringe holder of Figs. 18E and 18F.

Fig. 18H shows a front view of the syringe holder of Fig. 18G;

Fig. 18I shows two pairs of alternate claws having grooves to support flanged syringes suitable for use with a syringe holder of the present invention;

Fig. 18J shows a front view of a syringe holder employing either of the two alternate slotted claws of Fig 18I to hold a loaded syringe;

Fig. 18K shows an alternative grooved claw having a conical entry taper in accordance with another embodiment of the present invention;

Fig. 18I shows an alternative view of the grooved claw of Fig 18K;

Fig. 19 shows an oblique three-dimensional view of the syringe holder and syringe of Figs. 17A and 17B, showing the syringe clamped in the holder restrained by force sensing cables, and having the pusher primed ready for immediate pumping;

Figs. 20A - 20C show front views of three different sized syringes clamped in the syringe holder as shown in any one of Figs. 17A to 19, securely held, and on axis with the pusher ready for pumping;

Fig. 21A shows an oblique three-dimensional view of a syringe holder in accordance with any one of Figs. 17A to 19, with the addition of restraints to support the holder arms as well as prevent them from opening, particularly under heavy loads and syringe pressures;

Fig. 21B shows a side view of the syringe holder of Fig. 21A further showing the restraints for supporting the holder arms, and revealing a rotational sensor coupled to one arm of the holder, enabling measurement of the syringe barrel diameter;

Figs. 21C and 21D show front and side views respectively of an alternate syringe size encoder which can be employed with any of the syringe holders of Figs. 17A - 19;

Figs. 21E and 21F reveal front and oblique three-dimensional views respectively of an alternative sliding syringe holder mounted in its chassis and restrained by twin cables, enabling pressure measurements;

Fig 21G further shows the arrangement of Figs 21E and 21F, particularly showing the cable deflection;

Fig. 22 shows a three-dimensional oblique view of a dual pedestal injector unit in accordance with one embodiment of the present invention;

Fig 22A and 22B show in more detail the injector head , cover shape, pusher, and claw arrangement of the injector unit of Fig. 22;

Fig. 23 shows a cross sectional view of a base of the injector unit of Fig. 22 having a releasable central brake post to prevent the unit from rolling undesirably on smooth floors;

Fig. 24 shows a simplified schematic of an analog system for controlling the injector unit motor speed and syringe flow, in accordance with an embodiment of the present invention.

Fig. 25 shows typical simplified waveforms of various parameters of Figs. 24 and 26; and

Fig. 26 reveals an improved means for controlling syringe flow, employing a force sensor, and able to more precisely limit syringe pressure yet continue pumping should a restriction occur.

Preferred Mode of Carrying out the Invention

Referring to Fig. 1 an injector system 100 is shown, removably positioned on a floor 115 of a room, for example an isolated room suitable for performing an MRI procedure. The injector system 100 comprises a rigid, one-piece chassis 120 which houses the various components of the injector system. The chassis 120 is configured such that it is capable of removably receiving a fluid filled syringe 121 at an upper portion or head of the injector system 100 at a height convenient for use by an operator and/or the patient. A pair of jaws 127 is provided within the head of the chassis 120 to receive and retain a flange 130 of the syringe 121 to secure the syringe 121 in a desired position for use. In order to expel the contents of the syringe 121, a pusher system 119 is provided in the head of the chassis 120 which is actuated to advance in the direction of arrow 138, thereby compressing the syringe plunger 129 and piston 133 into the body of the syringe 121.

As shown more clearly in Fig. 2, positioned within the chassis 120 and located at the base of the injector system 100 adjacent the floor 155 of the room, is a motor 111 with integral reduction gearbox 112. The motor 111 and gearbox 112 provides the actuating force for driving the syringe pusher system 119 thereby causing expulsion of the contents of the syringe 121. A taut cable 113 (shown as a dotted line) and a retract cable 114 (shown as a dashed line) is provided between the motor 111 and pusher system 119 to efficiently transfer motive force generated by the motor to the pusher system to cause the syringe plunger 129 to move within the body of the syringe 121 as desired. At one end, the taut cable 113 is connected to a reel 116 which in turn is fixed to the output shaft 117 of the motor/gearbox 111/112 to receive the motive force

therefrom. The taut cable 113 is then drawn over a cable/pusher roller 118 for at least a ¼ of a turn and is fixed at its other end to a rear axis of the pusher system 119 at anchor point 122. As shown more clearly in Fig. 2, the roller 118 is supported within the chassis 120 along an axial shaft 126 by chassis mounted bearings 135 and is free to rotate about its axis. Similarly, the retract cable 114 is also attached at one end to the reel 116 to receive motive force from the motor/gearbox 111/112 via the output shaft 117. The retract cable 114 is also drawn over the roller 118 for at least a ¼ of a turn but in the opposite direction to the taut cable 113 such that it is fixed at its other end to a front, inside axis of the pusher system 119 at anchor point 134. The cables 113/114 can be made from a non conductive material to avoid interference with any environmental magnetic field which may be associated with an MRI scanner, and can be made of non-conductive cord or reinforced belt material such as Kevlar, carbon fibre, or similar to reduce EMI interaction. To avoid slippage of the cables 113/114 on the reel 116, the cables 113/114 may be wound several times around the perimeter of reel 116. Alternatively, cables 113/114 could be anchored by means of a clamp (not shown) at a central point on the reel 116. It will be appreciated that whilst the term cable is used in this description, a wire, belt, chain, cord, line, or similar non-stretchable flexible material could be used to perform this function and still fall within the scope of the present invention.

To advance the pusher system 119 in the direction indicated by arrow 138, the motor/gearbox 111/112 causes reel 116 to rotate in a clockwise direction (as indicated by arrow 128 of Fig. 1) thereby pulling the taut cable 113 in a downward direction, and releasing retract cable 114 in an upward direction, as shown by cable tension and movement directions arrows 139. The tension present in cable 113 is transferred directly onto the pusher system 119 in the direction indicated by arrow 138, thereby causing compression of the syringe plunger 129, which in turn pushes syringe piston 133 expelling the contents of the syringe 121.

To retract the pusher system 119, the motor/gearbox 111/112 reverses direction thereby causing reel 116 to rotate in a counter-clockwise direction. This action pulls cable 114 in a downward direction and releases cable 113 in an upward direction (whilst not allowing any slack in the cable) thereby retracting the pusher system 119 away from the syringe plunger 129. The cables 113 and 114 are each preferably one continuous length between the attachment points 122 and 134. Although not

illustrated, it will be appreciated that the pusher system 119 has a closed face in front of attachment point 134 to ensure even force is applied to the syringe plunger 129.

To facilitate controlled advancing and retracting movement of the pusher system 119 in relation to the stationary roller 118, a deep slot 123 is provided in the pusher system 119 which extends substantially the full length of the pusher system to accommodate the roller 118. The slot 123 is slightly wider than roller 118, and has a depth equal to half the diameter of the pusher system 119, so that cables 113 and 114 lie along the axis of pusher system 119. A top roller 124 is also provided and supported within the chassis 120 along an axial shaft 132 and is free to rotate about its axis. The top roller 124 is shaped to conform with the top surface of the pusher system 119 such that movement of the pusher system 119 is guided by cable roller 118 and the top roller 124. A circular bush 125 is also provided, which generally forms a circular ring through which the cylindrical pusher system can slide axially, to further control the movement of the pusher system 119.

As the taut cable 113 pulls directly along the axis of the pusher system 119 and the corresponding syringe 121 and syringe plunger 129, virtually all the cable tension is transferred squarely to the syringe plunger 129, with very little force or friction transferred to the roller 124 and bush 125. Although roller 118 bears significant load from the cables 113 and 114, low friction bearings 135 support the roller 118 in the chassis 120 to conserve any energy losses of the system.

In essence, the actuation system of the injector unit 100 makes it possible to arrange the motor 111 and gearbox 112 so as they are oriented horizontally with respect to each other, and thus can be located proximal the floor 115. This arrangement reduces the amount of weight distributed towards the top of the pump, and significantly avoids interfering with most of the magnetic field associated with MRI (Magnetic Resonance Imaging) scanners. Further, as the taut cable 113 is driven directly from the reel 116 fixed to the output shaft 117 of the motor/gearbox 111/112, there is no need to employ a conventional lead screw arrangement to facilitate dispensing of the syringe 121, thereby greatly improving the efficiency of the system and simplifying the design, manufacture, and cost of injector unit 100.

Further, as the taut drive cable 113 is attached directly to the pusher system 119 at attachment point 122, the position (and speed) of the pusher system 119 can be easily

monitored by coupling an absolute rotational sensor 131 (such as a potentiometer or absolute encoder) at any point along the cable 113 or 114. In Fig. 2, sensor 131 is shown in two alternate locations, either coupled to the roller 118 in the head of the chassis 120, or coupled to the reel 116 down in the base of the chassis 120. In an MRI environment, the latter position may be preferable to assist in shielding the base and control electronics to avoid MRI, and so that it is further away from the sensitive bore area of any associated MRI Scanner which may affect the image quality. Currently available absolute potentiometers or encoders for use as sensor 131 usually have a limited rotation of around 360 degrees or less, and hence the circumference (i.e. diameter) of the associated roller 118 or reel 116 is chosen to give the desired rotation to suit the required pusher system 119 travel.

In instances where very precise control of fluid flow rate and volume is required, a second encoder may be coupled to the motor itself, before the gearbox. Such an additional encoder cannot provide an indication of absolute position of the pusher system 119, as is the case with sensor 131, and especially not in the event of power interruption or control failure, however it can provide a secondary indication of syringe movement (eg for safety purposes), which could allow an overall control system to detect slippage, stretch, or excess speed/flow in the drive system.

The arrangement of the present invention substantially reduces the chances of EMI between the injector unit 100 and any associated medical scanner (not shown) by employing non conductive cables 113/114, eliminating the presence of conductive wires through the pedestal of the unit, and/or by locating sensors 131 in the base of the unit as described above. By constructing the pedestal and base sections of chassis 120 from a non-conductive material, such as a plastics material, a resin or a composite material.

An alternative embodiment of an injector unit is shown in Fig. 3. In this embodiment, the injector unit 101 performs the same function as injector unit 100 of Figs. 1 and 2, and where appropriate, the same reference numerals have been used to refer to similar components of the injector unit. Generally, the injector unit 101 has the additional benefit of having a tilting head portion 140 mounted atop of the pedestal of the chassis 141, which has been truncated at section 149 for illustrative purposes, and which could be any length convenient for the application.

The tilting head portion 140 is provided to enable the syringe tip 137 (outlet) to be angled up, to expel any air present at the tip, or down during injections, so that any small bubbles of air in the syringe 121 will be expelled last, and typically go no further than the tube 133 connecting the unit 101 to the patient. This movement is shown by the arrows 144 and the dotted outline 142. Controls for controlling the operation of the unit 101 (not shown) are mounted on the head portion 140 of the unit, and the ability to tilt the head portion provides greater visibility of, and access to, such controls by an operator.

The actuating mechanism of the injector unit 101, as described above in relation to the injector unit 100, accommodates tilting movement of the head portion 140. In this regard, as the head portion 140 is tilted about a pivot 145, whilst the cables 113 and 114 are both flexed, they are unaffected in terms of length and tension, with the result that roller 118, pusher system 119, and syringe plunger 129 are not actuated when the head is tilted, regardless of whether the unit 101 is operational or not. It should also be noted that when high loads are applied to the cables 113 and 114 (e.g. during an injection procedure) there is no tendency for the head to tilt inadvertently because all tension is applied through the centre of the pivot 145, resulting in no net rotational force on the head 140. This also overcomes the need to provide an additional locking means to lock the head portion 140 at an appropriate head tilt angle as is found on some existing pumps.

Alternative actuating mechanisms suitable for an injector unit of the present invention are shown in Figs. 9 to 16 and will be described generally below.

In Figs. 9 and 10, injector unit 190 is shown having the same head and syringe actuating arrangements as described above in relation to Figs. 1 to 3. However, in this arrangement, an alternate means of driving the taut cable 113 is shown. A motor/gearbox 191 is located in the base of the unit 190 and is coupled to a lead screw arrangement 192, on which nut 193 travels up and down as lead screw 192 is rotated by motor/gearbox 191. Motor/gearbox 191 is fixed to the chassis 196 by fixed mounting blocks 197, whilst the top end of lead screw 192 is supported to the chassis by bearing block 198. The cable 113 is attached to nut 193 at clamp 199, and rides over roller 118, and is attached to the rear axis of pusher system 119 at clamp 122. Roller 118 is free to rotate about its axis on axle 126 in the same manner as described above, and pusher system 119 reciprocates along its axis (as indicated by arrow 138), also in the manner

as previously described. A freewheeling roller 200 is located in the base of the injector unit 190 and spins on shaft 201 which is fixed to the chassis 196 by mounting blocks 197. Cable 114 is attached to nut 193 at clamp 199 (in practice is a continuation of cable 113), and is guided around and under motor/gearbox 191 by roller 200, then up and over the top of roller 118, then is attached to the axis of the front of pusher system 119 at clamp 134. As described previously, pusher system 119 has a closed face.

As nut 193 is caused to move in a downward position by lead screw 192, cable 113 is pulled down, which in turn pulls pusher system 119 forward, compressing syringe plunger 129. Simultaneously cable 114 is released by nut 199 as it is propelled down, allowing pusher 119 to travel forward, but not allowing cable 114 to become slack. Arrows 139 indicate cable movements during advancement of pusher 119. To retract pusher 119, the motor/gearbox 191 and lead screw 192 reverses direction, causing nut 199 to travel up, pulling on cable 114 whilst releasing cable 113, causing pusher 119 to retract away from the syringe. It will be appreciated that the actuating system of unit 190 operates in a substantially identical manner as that described in relation to unit 100 and 101, with the difference being the manner the motive force applied to the cables 113/114.

In Figs. 11 and 12, injector unit 210 is shown using the same motor/gearbox 111/112, and syringe mounts 127, as those described in relation to units 100 and 101. In this arrangement, reel 116 drives a taut cable (or belt, or chain etc) 211 which in turn drives a slotted gear 212 located in the head portion of the unit 210. A pusher system 213, similar in arrangement to that described in relation to Figs. 1 to 3, is provided which has a slot 214 formed along its underside to engage with toothed gear 212. The top of slot 214 has a continuous line of gear teeth 215 along the axis of pusher 213 which mesh with gear 212. As gear 212 rotates it drives the pusher 213 back and forth along its axis, as indicated by arrow 217. Pusher 213 is also guided by top roller 124, and circular bush 125 (in the same manner as previously described) to ensure controlled axial movement and hence controlled fluid flow from the syringe 121. As motor/gearbox 111/112, reel 116, and roller 212 rotate clockwise (indicated by arrows 216), pusher 213 is driven forward, compressing syringe plunger 129. Likewise if motor/gearbox 111/112, reel 116, and roller 212 were to rotate counter-clockwise, pusher 213 is retracted away from syringe plunger 129. As in the unit described in relation to Figs. 1 and 2, this unit 210 of a syringe pump is well suited to an MRI environment.

In Figs. 13 and 14, yet another injector unit 220 is shown having a motor 221 provided in the base, with syringe 121 mounted removably in the top of chassis 222 by jaws 127. In this arrangement, motor 221 (which can incorporate a gearbox – not shown) and pulley 223, drive a belt (or cable, or chain) 224, which turns a top pulley 225 located on a driving shaft 226. At one end of the driving shaft there are provided driving gears 227 which engage with a lead screw 228 such that rotational motion of the driving shaft 226 is transferred to the lead screw 228. As in the previous embodiments, pusher 229 is only able to move axially, guided by circular bush 125 at the front, and nut 230 at the rear and has a slot 231 provided along its entire right side, as is shown clearly in Fig. 14.

A block 232 is attached to chassis 222 and fits loosely into slot 231 to prevent pusher 229 from rotating about its axis during actuation. Depending on the direction of rotation of the motor 221, lead screw 228 drives nut 230 and pusher 229 back or forth along their axes, compressing or retracting from syringe plunger 129. Whilst this injector unit 220 provides an alternative system for actuating the syringes, it may not be ideally used in some circumstances, such as where mobility of the unit is required, as having a lead screw and gears etc in the head portion of the unit causes it to be "top heavy" and more difficult to manoeuvre. Further, as most lead screws are ferrous such a unit may not be ideally suited in an MRI environment, however it is envisaged that lead screw 228 could be fabricated from a non ferrous material such as brass.

In Figs. 15 and 16 yet another embodiment of an injector unit 240 is shown which employs a peristaltic type medical fluid pump having an elastic tube 241 mounted removably in the pump head, and squeezed in a continuous peristaltic motion by three rollers 249 to deliver fluid. A motor/gearbox 242 is located in the base of a rigid chassis/pedestal 243 and a pulley 244 (preferably toothed pulley, or sprocket, reel, etc) is fixed to motor/gearbox 242 to drive a continuous belt 245 (preferably a toothed belt, cable, chain, cord, etc). In this regard, motive force is transferred from the motor/gearbox 242 to a top pulley 246. A conventional peristaltic pump unit 247 is mounted at the top of chassis/pedestal 243 comprising a wheel 248 having 3 rollers 249 squeezing tube 241 against housing 250. As can be seen in Fig. 16 pump wheel 248 is coupled to top pulley 246 which is rotated by the motive force from motor/gearbox 242 via belt 245. It should be noted that with the motor/gearbox 242 mounted horizontally and located very close to the floor this invention is ideally suited to an MRI

environment for reasons discussed above. Under these circumstances the belt/cable/cord 245 and chassis/pedestal 243 would preferably be fabricated from non-conductive materials. Rotational sensor 251 is a very useful option for monitoring pump rotation, thereby providing measurement of pump volume and flow. Rotational sensor 251 could be coupled to top shaft 253, although for a medical imaging environment sensor 251 would preferably be located in the base, coupled to motor/gearbox 242 (as shown in Fig. 16) to enable easier screening from EMI, and to be further away from the scanner (not shown).

For injector units such as those described above, it is highly beneficial to be able to sense and limit the delivery pressure of the fluid injected therefrom. Such an ability enables the detection of any restrictions or blockages present in the system, the detection of poor needle placement within the patient and the ability to reduce injury to patients should the needle be misplaced, the ability to limit pressure for patients having frail blood vessels, and/or the ability to simply avoid bursting the syringe and tube.

One system for performing this function is described in relation to the injector unit 102 of Fig. 4. This system generally senses the tension present in the aforementioned cable 113 to sense the fluid delivery pressure from the pump. The cable tension may be sensed at any point between the reel 116 and the roller 118 by deflecting the taut cable 113 just a few degrees around a small roller 179 mounted on a hinged arm 182, which hinges at pivot 184. A conventional low force sensor 183 is used to sense a portion of the force on roller 179 which will be directly proportional to cable 113 tension, and fluid pressure in syringe 121. It should be noted that the force on roller 179 and on sensor 183 of Fig. 4 can very easily be designed and/or calibrated (i.e. adjusted for accuracy) simply by either: adjusting the degree of deflection in the cable 113; adjusting the position of the roller 179 with respect to reel 116 and roller 118; and/or adjusting the position of sensor 183 relative to the arm pivot 184. It will also be appreciated that the cable tension could also be measured between roller 118 and anchor point 122.

The above described embodiment permits a wide range of force sensor types and sensitivities, and also permits simple calibration of the system for accurate pressure measurements. In all cases actual syringe pressure will be a multiple of sensor force which can be readily calibrated.

An alternative means of measuring fluid pressure in the syringe 121 is shown in Figs. 5(a) and 5(b). In this embodiment, the syringe 121 is mounted to the chassis 120 on a sliding base 162 and the forces associated with the sliding base are measured to determine the fluid pressure in the syringe.

In order to support the sliding base 162, the chassis 120 is provided with an extension 165 which includes a plurality of guides 163 formed therein. The syringe 121 is mounted between a pair of fingers 161 of the sliding base 162, and the sliding base 162 is free to slide along an axis parallel to the axis of the syringe 121 under action of the pusher system 119. As shown, the guides 163 support the sliding base 162 and limit the axial movement of the sliding base.

As the sliding base 162 moves under action of the pusher system 119, the forward end of the sliding base 162 bears force onto a conventional force sensor 164 such as a load cell, strain gauge, or a piezo cell mounted on the chassis extension 165 such that the sliding base is only able to move a few millimetres. As the syringe plunger 129 is pushed forward all the opposing force is borne by the syringe flange 130, which in turn is applied to force sensor 164 via the sliding base 162, thus measuring a force in proportion to the fluid pressure within the syringe. Friction losses in sliding base 162 and guides 163 can be made negligible with the use of low friction materials, ball bearing slides, or rollers (not shown) to guide and support sliding base 162, thereby allowing more sensitive and accurate measurements of the syringe pressure.

Further, the instant of initial contact by the pusher system 119 on syringe plunger 129 can be reliably detected through the force sensor 164, allowing semi-automatic priming of the injector unit (i.e. advancing the pusher system 119 to the point where it touches the syringe plunger, and pausing the pusher system 119 ready for immediate injection with any further advancement).

In an alternative system, also shown in Fig. 5A, syringe force and pressure can be monitored through dual taught restraining cables 147 attached to the sliding holder fingers 161 at points 158. The tension in the either or both of the cables 147 can be measured by various means, such as the deflection system as described in relation to Fig. 4, and is proportional to syringe pressure. It should be noted that by arranging the twin cables 147 such that they are equal in length, located on a plane about the syringe

axis, and equidistant from the syringe 121 axis, then there is no tendency for the syringe and holder to tilt off axis whilst under pressure. This provides a very basic sliding base system, virtually free of torsion, and therefore free of almost all friction.

It will also be appreciated that if pressure sensing is not required, the force sensor 164 can be replaced with a simple micro switch or optical switch/interrupter (not shown) to detect only initial contact by the pusher system 119 on the syringe plunger 129. As such, this sensing means could be employed with existing injector units to provide enhanced control of the system for improved use and patient benefit.

Fig. 6 shows an alternative embodiment of the system shown in relation to Figs. 5A and 5B, for measuring syringe pressure. As in the previous embodiment, a sliding base 162 is provided upon which the syringe is secured between a pair of fingers 161, and the sliding base 162 is restrained only by a single taut cable 166 which is attached to the sliding base 162 at point 159, whilst the other end of cable 166 is fixed to the chassis 165 at point 168. Tension in the cable 166 is in proportion to syringe pressure and is sensed by roller 172 which deflects cable 166 by a few degrees. Roller 172 is mounted on the end of swing arm 170 which is allowed to freely hinge from pivot 171, which is mounted on chassis 165. Force sensor 173 is also mounted on rigid chassis 165 and senses the force on the arm 170 and roller 172, thereby sensing a proportion of cable tension and syringe 121 fluid pressure.

Cable 166 could alternatively use twin cables, as in Fig. 5A, which would be attached to two points 158 on fingers 161, in which case the twin cables 166 would preferably lay parallel to the axis of the syringe 121. A pair of rollers adjacent to the pusher system 119 would permit the twin cables to take a 90 degree turn down to the base of the injector unit where they are joined into one cable (as shown later in Fig 19) which is then deflected with roller 172 (located elsewhere on the lower chassis 120 – not shown) then attached to the chassis, wherein the pressure would be measured in the same manner as Fig. 6. This twin cable arrangement significantly reduces friction in the sliding base 167 because all force is restrained in line with the force applied to the syringe 121. It should also be noted that tension in the cable(s) 166 can be monitored elsewhere in the injector unit by simply extending the cable sensor (via fixed rollers if necessary) and terminating the cable elsewhere to the rigid chassis 120. This way, for example, in an MRI environment, the force sensor 173 could be located towards the base of the injector unit, away from EMI.

As mentioned above, in an MRI environment, the cable 166 would preferably be made of strong non-conductive material such as Kevlar. It should also be noted that as sensor 173 in Fig 6 is only measuring a fraction of the force on the syringe, the system enables use of a low force, low cost, readily available sensor such as piezo-type sensor. More embodiments of sliding base syringe holders are revealed in Figs. 17 to 21(e) and discussed below, any of which may be coupled with a force sensor as revealed above in Figs. 5 or 6 means for measuring pressure.

Another alternative system 105 for sensing fluid pressure is revealed in Fig. 7. This system 105 employs a small soft "bag" 181 mounted on the front face of the pusher system 119 forming an interface with the syringe plunger 129. A thin flexible pressure tube 182 connects the bag 181 to a conventional fluid pressure transducer 183, and the whole system is filled with fluid (not shown). As the pusher system 119 is actuated against the syringe plunger 129 to facilitate fluid expulsion from the syringe 121, fluid pressure within the bag 181 increases and is applied to transducer 183, thereby providing an accurate representation of syringe pressure. It will be noted that the sensitivity of the transducer 183 is dependant on the surface area of bag 181 and can be adjusted as required. Such a system is particularly sensitive in that very small pressures can be detected, thereby also enabling the injector system to detect when the advancing pusher first touches the syringe to enable priming of the injector system prior to use. To enable the system 105 to be employed in a high EMI environment, the fluid filling bag 181, tube 182, and transducer 183 would be a non-conductive type such as oil.

In Fig. 8, there is shown a further embodiment 106 of the system 105 of Fig. 7, wherein a smaller fluid or air filled bag 185 is employed to only detect contact between the pusher system 119 on syringe plunger 129. Bag 185 is located in a central recess 189 on the face of pusher system 119, and is inflated so as to protrude beyond the face of pusher system 119. As the pusher system 119 approaches syringe plunger 129, the bag 185 is compressed, causing an increased pressure through tubing 187 to transducer 188 which in turn relays a signal to the injector unit control circuitry (not shown) allowing detection of first touch between pusher system 119 and syringe plunger 129 to determine priming of the injector unit. Transducer 188 could be located some distance from the head portion 140 (for example in the base of the injector unit protected from EMI), and/or replaced with a simple pressure operated switch or similar.

It will be understood by those familiar with the art that in all the above inventions for sensing fluid pressure in the syringe (Figs. 4 to 8) actual syringe pressure must be calculated after considering many proportional factors, such as, the surface area of the syringe piston 133, area of the bag 181, the sensitivity of the sensors 164, 173, and 183, the degree of deflection of the cable 166 and 113, the position of the rollers 172, 174 and 179, the length of the cable 113, the position of sensors 173 and 183 on the arm, etc.

In injector units that employ syringe-type delivery devices, the manner in which the syringe is secured and supported within the unit is important to ensure controlled and safe delivery of the necessary fluid to the patient. In this regard, Figs. 17 to 21G describe various embodiments for performing this task to enable such units to accept a wide variety of syringe sizes and types, both proprietary and standard disposable syringes, without the need for any special adaptors. Each of these embodiments is applicable to any cylindrical syringe having a rear flange that can be supported by the unit.

In Fig. 17, there is shown an exploded three dimensional exterior view of a syringe holder 260 according to one embodiment of the present invention, which is shown in its assembled form in Fig. 18 with syringe 121 oriented for loading. The holder 260 generally comprises two claws 261 which are mounted on hinged arms 262 and fixed to two axles 263. The axles 263 are supported within a base 264 such that claws 261 are able to pivot as indicated by arrows 277 of Fig. 18. An extension spring 265 is extended between the two arms 262 in the manner as shown and attached to each arm at points 275. The spring 265 acts to provide a force to the two arms 262 to bias the claws 261 together in order to securely hold the syringe barrel 271 between the two claws 261. The spring 265 is chosen such that the force stored within the spring 265 is strong enough to firmly hold the syringe 121 whilst pumping, but weak enough to allow manual separation of the claws 261 to load and/or remove the syringe 121 once emptied.

In order to ensure that the arms 262 are always angled symmetrically with respect to base 264 regardless of the degree of separation of the claws 261 and diameter of syringe barrel 271, two closely meshed gears 266 are fixed to their respective axles 263. The gears 266 assist in ensuring that syringe 121 is always aligned with the axis

267 of the pump pusher 268 regardless of syringe barrel 271 diameter. Syringe 121 is aligned as shown and loaded into the holder 270 by first hand separating claws 261, then lowering the syringe 121 in the direction indicated by arrow 272 between the claws 261, which when released spring back together to securely and accurately hold the syringe 121 in line with the axis 267 of pusher 268. To remove the syringe the spring loaded claws 261 are simply hand separated, and the syringe is raised up clear of claws 261. It is envisaged that claw opening and closing could be motorised for convenience or more secure holding of the syringe (not shown).

The base 264 of holder 260 may be fixed to the chassis of the unit, however for sensing purposes, as described in relation to Figs. 5 and 6 above, the base 264 in Fig. 18 can slide longitudinally parallel to the pusher and syringe axis 267. As in Figs. 5 and 6, the base 264 may be closely supported along either side by two horizontal channel shaped guides 269 which are both aligned parallel with axis 267 and fixed to the pump chassis to allow base 264 to slide parallel to the pusher and syringe axis 267 (as indicated by arrow 278). If required to slide, base 264 would preferably be fabricated from rigid low friction material such as Teflon or acetyl to minimise friction errors in sensing. Alternatively, conventional ball slides or rollers could be used between base 264 and fixed guides 269.

It will be appreciated that claws 261 can expand to accommodate a wide range of syringe barrel 271 diameters, whilst holding all sizes securely, and on axis 267 with the pusher 268. It should also be noted that the opposing inside faces 273 of claws 261 are also parallel to the syringe axis 267 regardless of claw 261 separation. The profile of claw faces 273 could take many forms depending on the range of syringe types & sizes to be accommodated.

As virtually all existing syringes consist of a cylindrical barrel with a flange 130 at the rear which may vary in relation to diameter and perimeter shape (ovoid, circular, etc), syringe 121 is loaded with its flange 130 against the rear (as viewed) faces of claws 261. This prevents the syringe barrel 271 from sliding forward through claws 261 during delivery. As such, this arrangement ensures that substantially all conventional syringes can be used with the injector unit and restrained therein. Further, this arrangement enables easy rotation of a loaded syringe about its axis, thereby providing convenient connection/disconnection of associated tubing.

As shown in Figs. 18(a) and 18(b) the claws 261 of Figs. 17A and 17B can be detachable/removable. In this regard, the detachable claws 350 have hollow receptacles 351 at their ends which are configured to slide over and attach to the ends of arms 262. Such an arrangement enables easy replacement and changing of the claws 350 to suit different types and sizes of syringes, and/or to enable the cover of the injector unit to be removed, as will be discussed in more detail below.

To facilitate increased and effective gripping by the syringe holder 260, the syringes may be configured in a variety of ways, as shown in Figs 18(c)(i)-(v). All syringes shown are of the type having a barrel 357, plunger 358, and flanges 359. Fig. 18(c)(i) shows a syringe having flanges 359 in the form of lugs projecting from the barrel at spaced intervals around the circumference of the barrel, whilst Figs 18(c)(ii)-(iv) show syringes having single, double and triple flanges 359 formed on their barrels. By providing syringes for use by an injector unit having a variety of flange configurations 359, syringes can be categorised for delivering specific drugs. This may be necessary where some drugs/fluids require administration at certain flow rates and conditions, which may not correspond with the capabilities of the injector unit.

In order to ensure that the appropriate drugs/fluids are administered by the appropriate injector units, the claws of the syringe holders are configured in order to only accept a specific type of syringe. As the claws 350 of the syringe holder 260 as shown in Figs 18A and 18B are interchangeable, the manner in which the syringe holder can be adapted to receive only a specific type of syringe can be readily applied. This aspect of the invention is shown in Figs. 18(e) and 18(f) in which a special syringe holder 374 having slotted claws 375 which have slots 378 designed to accept only the flanges 359 of correspondingly flanged syringe 357. Arrows 385 indicate how the syringe 357 is loaded into claws 375 so that the syringe axis is aligned with cross 383a. In this arrangement, the claws 375 are fixed to arms 262 which are fixed to and pivot about their respective axles 263, however, as discussed above, it is also envisaged that the claws 375 could be removable and interchangeable with the arms 262. The manner in which the syringe holder operates is substantially as described previously with regard to Figs. 17A and 17B.

It should be noted that multiple flanges provided on the syringe and corresponding slots or grooves in the holding claws substantially improves the grip by the holder on the syringe under heavy loads. In this regard, under load the arms 262 are

pushed forward against rubber stops 380 which grip the arms preventing them from opening under load, thereby securely holding the syringe in position for fluid delivery. Axles 263 pivot and slide in holes (at axles 263) in the holder frame 376 which is fabricated from a rigid metal box section having four vertical sides only. Two slotted slides 377 are attached to the base of frame 376 by screws 379, and are fabricated from low friction material such as Teflon or polypropylene. Slides 377 have slots 378 in either end to allow the whole assembly of holder 374 to slide freely along the axis of the syringe for sensing purposes as discussed previously and described later in relation to Fig. 21(c). Under load, holder 374 and the associated syringe 357 are restrained by cables 381 and 382 which are attached to frame 376 symmetrically about the syringe axis at points 386 and 387 for the purpose of sensing, also described later in Fig. 21(c).

Fig. 18(g) shows a three dimensional oblique view of the claws 375, arms 262, and axles 263 only of the syringe holder 374 in Figure 18(e) and (f). Fig. 18(h) shows a front view of syringe 357, claws 375, arms 262, and axles 263 only of the syringe holder 374 in Figure 18(e) and (f).

As discussed previously, Fig. 18(i) shows replacement claws 389 (or 390) which may be used as alternatives for claws 375 in Fig's 18(e) and (f) for securely holding syringe 357 having different configurations and administration requirements. In the embodiment shown, claws 390 in Fig 18(i) are quite short, thereby providing adequate support for a single flanged syringe and allowing better visibility of the syringe. Fig. 18(j) shows a front view of claws 389 and 390 holding a flanged syringe 354.

With regard to Figs. 18(k) and 18(l), there is shown a claw 393 suitable for holding a single flanged syringe (only one of 2 symmetrical claws are shown). To load a flanged syringe such as 353 of Fig. 18(c)(ii) into a pair of conical claws 393 the syringe is positioned in the usual manner. If the flange of the syringe is located at the rear of claws 393 the operator need only pull the syringe forward forcing the jaws open and allowing the flange to slip into grooves 394.

The manner in which the syringe holder described above can be used to enhance fluid flow control from the syringes will be discussed in relation to Fig. 19. In this figure, a syringe 121 is removably clamped between claws 261 of holder 280, with pusher 268 advanced to contact the syringe plunger 129, resulting in the injector unit being primed ready for immediate fluid release. In this position, syringe 271 is

restrained by the holder 280 firmly against the considerable forces possible under high pressure compression typically found with imaging contrast injectors. Even if arms 262 should flex slightly under load it has been found that claws 261 tend to clamp the syringe even tighter adjacent to the rear flange area. As discussed previously, the base of the syringe holder 280 is able to slide freely parallel to the syringe axis. Optional twin cables 279 in Fig. 19 are attached at points 259 symmetrically to each arm 262 of holder 280, preferably on the same plane as the syringe axis. Cables 279 may be attached to a force sensor at some point behind and preferably on axis with the pusher (not shown), or fed over twin rollers 292, and at some point preferably below the pusher, are joined together into one cable 258 which is attached to a force sensor 257. In this arrangement, as discussed previously, the force exerted on the syringe 121 can be readily determined to provide an indication of the fluid pressure in the syringe as described in relation to Figs. 4 to 6. Alternatively cable 258 may be clamped to the chassis, and its tension measured in the same manner as that shown in Fig. 6, i.e. by using a small force sensor to monitor a small deflection in the cable.

An alternative manner in which the syringe holders of the present invention can be used to aid in fluid flow control is shown in Figs. 21 (e) - (g). Here is shown an arrangement, including the sliding syringe holder 374 restrained by cables 281 and 282 for the purpose of measuring the force on the syringe (not shown) as previously described for Fig. 18(e) and (f). In this arrangement, the syringe holder 374 is able to slide freely parallel to the pusher axis 267 on chassis angles 411. Attached to the base of sliding holder 374 are two low friction slides 377 which have slots 378 which fit and slide along the inner edges of chassis angles 411. Restraining cables 281 and 282 (described previously for Fig. 18(e) and (f)) are attached to sliding holder frame 376 of holder 374 at points 386 and 387. It should be noted in Fig. 21(e) that cables 281 and 282 should lie on the same plane as the syringe axis to avoid any torsional forces on the holder 374. Cables 281 and 282 pass freely through holes 412 in chassis wall 413, over the face 419 of force sensor 414, and are terminated at points 415 and 416 to a rigid bar 418 across the rear of chassis angles 411. Sensor 414 is fixed to chassis angle 411 by screws 417. Note that cable 281 is deflected slightly by sensor 414, thus a small proportion of cable tension (and therefore pusher force and syringe pressure) is measured by sensor 414. Note that only one cable of the pair 281 and 282 need a force sensor 414 to monitor syringe force, as long as the associated control system (not shown) takes into account that each cable bears half the force. This system provides a

simple and accurate means to measure syringe pressure, as well as detect the moment of first contact of the syringe plunger 129 (shown in Fig. 21(e) by the pusher 268).

Another advantage of the syringe holders of the present invention is the ability of the holders to accommodate a wide variety of sizes of syringes. Most syringes are made with a bore and length having similar proportions to the nominal capacity, and are available in standard sizes common to most major manufacturers. Figs. 20 (a) (b) and (c) show the inside faces 273 of claws 261 are shaped to comfortably support both the largest and smallest diameter syringes required. Fig. 20(a) shows holder 294, a front view of the present invention holding a relatively large diameter syringe. Fig. 20(b) shows a front view of the same holder 294 holding a medium diameter syringe, whilst Fig. 20(c) shows a front view of holder 294 holding a small diameter syringe. In all cases the syringe flange 130 can be seen at the rear of claws 261. The faces 273 of claws 261 are preferably shaped as illustrated, with two parallel concave troughs having radii approximately matching the largest and smallest diameter syringes to which the holder is intending to accommodate. For syringe radii in between it should be noted that the claws 261 support the syringe barrel 271 in at least four approximately symmetrical points around the barrel 271 perimeter, and over the full length of claws 261, thereby ensuring the syringe barrel 271 is held firmly, and always aligned with pusher axis 267 (the axis 267 is shown in Figs. 17b and 21a). It will be appreciated by those familiar with the art that claws 261 could take many different shapes, the most obvious being "V" grooves. In any regard, regardless of the barrel diameter of the syringe 271, the syringe holder is capable of aligning a variety of sized syringes from the largest to the smallest diameter with the axis of the pusher, as indicated by dotted centreline 291, and height lines "H" to ensure controlled and efficient delivery of fluid to a patient.

Claws 261 are preferably moulded from or coated with soft plastic (particularly important for holding fragile glass syringes) and reinforced internally within by rigid metal fingers (not shown) extending from their respective arms 262, or in the case of Fig. 18(a) & (b) receptacles 351. Deep radial grooves (as shown previously in Figs. 18(i), (k), & (l) may be moulded into the inside faces of claws 261 to accommodate varying syringe flanges as discussed previously. A tab extension (not shown) could also be added to the top of one or both claws 261 to aid separation of the claws 261 during hand loading of the syringe. Thereby loading and unloading of the syringe need only require one hand and takes only seconds. Syringe 121 can be rotated in any

orientation, and generally no twisting or locking is required, unlike most existing holders. Holder arms 262, axles 263, gears 266, and guides 269 should be fabricated from strong materials such as stainless steel (non-magnetic for MRI).

Whilst most syringe designs comprise a barrel and a plunger to expel the fluid from the barrel, Fig. 18(d)(i) shows an alternative syringe design 360 having no flanges on the barrel, and no plunger on the piston 363. A similar syringe 361 is shown in Fig. 18(d)(ii) also having no plunger, but having a flange 365. In order to use such syringes 360 and 361 in an injector unit of Figs. 1 to 16, an extended pusher 364 is required which extends into the syringe to contact and move the piston 363. As discussed in detail above, syringe 361 having a flange can be accepted by the syringe holders of the present invention, however syringe 360 cannot, and must be held within an adaptor such as 366 in Fig. 18(d)(iii) to secure it in position for use. The adaptor 366 is essentially a transparent tube 369 having an open front portion through which the syringe 360 is inserted, and a flange 367 at the rear which can be supported within the syringe holders of the present invention. A catch 368 of adaptor 366 holds the syringe 362 inside adaptor 366 whilst the extended pusher 364 drives the piston 363.

Whilst the syringe holders described above can be employed in most injector units used for administering fluid to a patient, some specific applications may require the injectors to operate at particularly high pressures, particularly injectors used for X-ray, Computerised Tomography (CT), and MRI contrast. For these applications it may be necessary to further strengthen the syringe holders so that they will not fail under high delivery pressures. As shown in Fig. 21a, the syringe 121 is shown unloaded and above holder 297 for clarity. In this arrangement, two robust restraints 281 are provided adjacent the arms 262, and are attached to the rigid guides 269, effectively forming an extension of the injector chassis. Two thin resilient rubber pads 282 are fixed to the rear face of the restraints 281, upon which the holder arms 262 are pressed firmly when the injector is pumping fluid. Fig. 21(b) shows a side view of Fig. 21(a) having syringe 121 securely mounted in holder 298. It can be seen from Fig. 21(b) that when the injector is pumping under high pressure, pusher 268 compresses syringe plunger 129, and forces barrel 271 and its flange 130 forward as indicated by arrow 287, exerting substantial load on the claws 261 and arms 262. Arms 262 and base 264 are free to slide in the axis of the pusher and syringe until arms 262 press firmly against pads 282, as indicated by arrow 287.

In this regard, the restraints 281 with pads 282 act to support the arms 262 when under heavy load, and ensure syringe 121 cannot be dislodged or inadvertently removed because arms 262 and claws 261 cannot separate whilst arms 262 are pressed against and firmly gripped by fixed rubber pads 282 which are attached to the robust restraints 281 which are firmly attached to or form part of the rigid pump chassis.

In some applications, such as pain control or the administration of chemotherapy drugs, it is important that the syringe cannot physically be removed during fluid delivery. In such circumstances it may be necessary to replace the rubber pads 282 with toothed plates (not shown) that mesh with corresponding teeth provided in the arms 262. The teeth would ideally be meshing "saw tooth" in section (not shown) ensuring the arms could not be separated whilst under load. It can be seen that once the pusher 268 is retracted arms 262 are no longer pressed against pads 282, and hence claws 261 are now easily separated allowing removal of the syringe 121 (of Fig. 21(a) and (b)).

To assist this separation a short extension spring could be added between the sliding base 264 and injector chassis (not shown). Note that holder base section 264 could be fixed to or be part of the injector chassis 269, and the very small sliding action of arms 262 could be achieved by axles 263 sliding along their axis.

In accordance with another aspect of the present invention, it will be appreciated by those familiar with the art that, in order for a syringe injector unit to deliver correct flow and volume for a particular syringe, pusher 268 travel and speed must first be calculated with reference to the internal bore of the syringe barrel. In almost all cases bore diameter increases with syringe volume, and bore is reliably indicated by measuring barrel outer diameter.

In Fig. 21b, a rotational sensor 288, such as a slotted vane, potentiometer or absolute digital encoder is shown, coupled to one arm 262 of the syringe holder via axle 263. Bracket 289 attaches the body of the sensor to the sliding base 264 forming a point of reference for sensor 288. It can be seen that the sensor 288 is able to measure arm angle, which is directly proportional to syringe diameter. This information enables the control circuitry (not shown) of the present invention to:

(a) Measure the syringe barrel 271 diameter and hence adjust pusher speed and stroke appropriate for the syringe, thereby delivering the correct flow and volume, and

(b) detect when a syringe is being loaded, or removed, thereby respond with an appropriate menu, pusher retraction, or alarm, etc., and/or

(c) measure the approximate syringe size and automatically prompt the operator to identify the exact syringe type or brand from a limited range pre-programmed into and identified by the pump control system.

Figs. 21(c) and 21(d) show front and side views of a vane encoder 405 coupled to a syringe holder of the present invention to enable the unit to operate only when the correct syringe, having the desired diameter, is loaded into the syringe holder of the unit. This ensures that the pump control system compresses the syringe at the appropriate speed and pressure suitable for the desired application.

The vane encoder 405 consists of a vane 406 fixed to the arm shaft 263, such that it is able to rotate with the arm shaft as the syringe holder opens and closes. An optical interrupter 409 is also provided which receives the outer perimeter of the vane 406 as the vane rotates. Vane 406 has a very narrow slit 407 which is adjusted so that the slit 407 coincides with the fine beam of interrupter 409 only when the correct diameter syringe is loaded into the syringe holder. If the slit 407 does not coincide with the beam of the optical interrupter 409 following loading of the syringe, then the injector is not permitted to operate. For the sake of clarity, other components of the holder have been omitted from Fig. 21c and 21d. It should also be noted that several sets of vane and interrupter could be coupled to one holder, thus allowing the pump to identify several different size syringes, and safely operate with several specific sizes.

It will be appreciated that in each of the above described embodiments, the syringe holders could be fixed to the chassis of the injector unit, particularly in cases where sensing of syringe force is not required, or is achieved by alternative means. Further, the syringe holders could be motorized to open and close either automatically or when instructed by the operator. Such an arrangement would also improve the security and safety of the syringe and the motive power required to operate the holder arms 262 could be provided by a conventional electric motor, which, for MRI injectors, could be located in the base of the unit and coupled to the syringe holder via taut cables. Alternatively the syringe holder(s) could be opened and closed directly (not

shown) with the aid of a pneumatic or hydraulic piston, or Shape Memory Alloy wires which extend and shorten with the application of an electric current.

Many existing contrast injector units employ two syringes – one for the contrast agent, and the other for a saline flush to "push" the drug through the connecting tubing and the patient's veins. In this regard, each of the above described embodiments could be duplicated to form such a multiple channel injector. As a result, multiple independent drive systems would be required, and as the drive systems of the above described embodiments are located in the pedestal and base of the unit, a multiple channel injector would require multiple pedestals. Having two relatively thin pedestals also permits the use of readily available, low cost PVC or aluminium tubing.

Fig. 22a shows such a dual pedestal unit 300 employing a standard multi leg chair base 304. In this arrangement, unit 300 has a head 301 supporting two syringes 302, two separate inclined pedestals 303, and a common base 304 fitted with castor wheels 310. A centre post 305 is located in the central hole of the chair base 304, and extends part way up to meet and support the two inclined pedestals 303 at attachment point 306. In this regard, a brake arrangement can be readily provided in post 305 to provide stability to the unit, as shown in Fig. 23 and discussed below.

Figs. 22(a) and 22(b) show the preferred novel shape and configuration of external cover 293 for a dual syringe injector 420. A control panel 421 is shown on the upper rear of cover 293. Below that the twin pushers 268 protrude from the rear of two recessed troughs 401. Syringe holder claws 389 can be seen attached to their corresponding arms 262, which protrude from notches 400 in cover 293. This shape and troughs 401 freely shed any liquid spills or leaks from the syringes etc. Fig. 22(b) in particular, shows a close up view of the pushers 268, recessed troughs 401, and holder claws 389.

It should be noted that although many of the injector units described above have been shown without wheels, it is highly desirable for medical fluid pumps to be manoeuvrable, and hence be wheeled from location to location. Fig. 23 of the present invention illustrates a cross sectional view of a brake system 307 which could be incorporated into the base of any wheeled syringe injector unit to discourage the unit from rolling as required.

In the embodiment shown, a base hub 308 forms the centre of legs 304 and castor wheels 310. A rigid brake post 311 slides vertically (indicated by arrow 312) inside hub 308 which is preferably mounted inside the base of centre post 305. A rubber foot 314 is attached to the bottom end of brake post 311 providing friction with the floor 115, thereby discouraging the unit from rolling when stationary. An extension spring 316 pushes brake post 311 and foot 314 down against the floor 115 for extra friction if required. Spring tension must be chosen so that there is no tendency for the brake post to lift the castors off the floor. An alternative to spring 316 would be to simply make post 311 from heavy metal, and /or attach heavy cylindrical weights to post 311 (not shown). A lever or cable (not shown) could be attached to the top end of post 311 to lift the post 311 and rubber foot 314 up off the floor to release the brake when the operator wishes to move the pump. Preferably, the brake release means would be incorporated into the manoeuvring handle of the unit (not shown). Such a breaking arrangement is particularly useful in an MRI environment where the unit may be attracted to the magnetic field of the scanner.

The manner in which the various components of the injector unit are controlled can be appreciated by referring to the simplified electronic control circuit of Figure 24. There is shown a circuit for controlling the motor drive to achieve smooth and precise control of syringe fluid flow, as well as limiting syringe pressure by reducing flow should a restriction or the like occur.

As shown, motor 111 may be mechanically coupled to the syringe by various means as previously. Sensor 330 (in this example a resistive potentiometer) is also mechanically coupled to the syringe drive (coupling indicated by dotted line 331) thereby sensing syringe position (i.e. position of the piston in relation to the syringe). Power Amplifier 332 drives the motor 111 with a voltage "E" proportional to the difference between the Integrator 333 output voltage "C", and the syringe position voltage "D". Under normal unrestricted conditions the integrator voltage "C" rises in a linear and constant manner (set by variable resistor flow control 334), and the power amplifier 332 drives the syringe with a relatively steady voltage "E", maintaining a steady compression of the syringe, producing a constant flow, as illustrated in Figure 25 up to time T2. Should the syringe plunger position (and therefore flow) slow then potentiometer voltage "D" will fall behind integrator voltage "C", in which case power amplifier 332 will detect and amplify the difference, thereby applying more drive to the motor until the plunger and voltage "D" catches up with "C".

Supply current to power amplifier 332 flows from supply voltage "S" through sense resistor 335, and given an efficient amplifier 332 is essentially equal to motor 111 current, which is proportional to motor power output and syringe pressure. Hence the voltage across resistor 335 is proportional to syringe pressure, and is sensed at point "A". Voltage "A" is fed proportionately to amplifier 336 by resistive divider network 337. Offset (i.e. baseline output voltage) of amplifier 336 is set by variable potentiometer (pot) 338 so that under normal conditions (i.e. unrestricted flow from the syringe) the output from amplifier 336 (voltage "B") is "below" ground (i.e. if permitted would be negative, but in this case limited to ground voltage). Hence pot 338 sets the "threshold" point at which voltage "B" begins to rise, and as such determines the pressure at which amplifier 336 becomes active, and where pressure is limited. Gain of amplifier 336 and hence response of the system is set by feedback resistor 339.

At rest, the plunger position is determined by voltage "R" which is derived from a pot control for the operator, enabling manual adjustment of the start position for the plunger. Under normal conditions voltage "B" rests at ground (i.e. zero volts). Fluid flow is determined by the slope (or rate of rise) of voltage "C", which is in turn is determined by current 323 to integrator 333, which is controlled by the product of flow resistor 334 and the voltage across it (being the difference between the fixed reference voltage "R" (the operator's plunger position control) and amplifier output 336 voltage "B"), all of which are quite steady for a given start position, flow setting, and unrestricted flow. Should flow resistor 334 setting be reduced then integrator current 323 is reduced, and voltage "C" rises at a reduced rate causing reduced drive to the motor, and reduced flow from the syringe. Switch 340 starts the pump by opening, and terminates the integration and pumping by closing, discharging capacitor 341.

Figure 25 shows simplified waveforms for various parameters of the circuit in Fig. 24 (and later Fig. 26) with respect to time in relation to managing a situation where pressure restriction is sensed in the system. Normal operation is shown from the start time T1, until T2 when an abnormal restriction occurs in the flow from the syringe outlet. At time T4 the restriction is cleared, and by T5 normal flow is resumed. Referring to both Figs. 24 and 25, circuit operation and waveforms are described in greater detail as follows:

When switch 340 is opened integrator output at "C" begins to ramp up linearly with a slope controlled by the setting of Flow control 334 and the voltage across it. The voltage at "B" is normally zero (ground), however should syringe pressure rise above the preset limit (as seen by waveform "E" at time T3) the voltage at "B" begins to rise, reducing the voltage across Flow resistor 334, and thereby reducing the slope of the ramp at "C", thereby reducing drive to the motor and syringe until pressure is reduced down to or below the preset limit set by pot 338. The feedback loop process will continuously reduce drive down to zero if necessary (in the case of a complete blockage of flow) until pressure is controlled. Should the blockage clear (as shown at time T4), the feedback loop will reduce the voltage at "B" back to zero, and normal current 323 and syringe flow are resumed at time T5. Once the syringe is empty switch 340 is closed (shown at time T6) and voltage "C" quickly returns to the reference voltage, driving the motor in reverse, retracting the pusher back to the start.

Fig. 26 reveals simplified circuit 325 which is very similar to 320 in Fig 24 except network 337 has been substituted by a piezo resistive force sensor 183 mounted in a pump 102. Almost any force sensor including those described in relation to Figs. 4 to 8 could be substituted for 337 in Fig. 24. It will however be appreciated that should a different type of sensor be used for 183 in Fig. 26, extra interface circuitry may be required to incorporate the sensor. It should also be noted that with circuit 325 more precise control of the fluid flow is possible as sensors such as 183 can measure syringe pressure more directly than that shown in network 337 of Fig. 24.

In Fig. 25 waveforms "A" to "F" apply equally to Figures 24 and 26. In circuit 325 of Fig. 26 voltage "A" from sensor 183 is representative of pressure, and is amplified by 336 which has pressure limit (DC offset) adjustment at 338. As in Fig 24, amplifier 336 output "B" is normally at zero volts, unless a restriction to fluid flow occurs (time T2), in which case "B" begins to rise, reducing integrator current and reducing the "slope" or rise of voltage "C" (from time T3), thereby reducing drive to the motor and flow from the syringe until pressure is stabilized (as shown by waveform "E") or reduced. When the restriction is cleared (time T4) pressure and flow return to normal (after time T5).

It should be noted that force sensor 183 in Fig. 26 could be located at various alternative positions for sensing syringe pressure as has been described in relation to Figs. 4, 5, 6, ,19 and Figs. 21 (f) and 21 (g).

It should also be noted in Fig. 26 that the syringe position potentiometer 330 is mechanically coupled (represented by dotted line 343) to the syringe pusher roller 118 (rather than coupled to the motor as indicated in Fig. 24), providing more accurate monitoring of syringe piston movement, thereby more precise control of fluid flow. In Fig. 26 injector unit 102 is shown by way of example, and operates in the manner as described in relation to Fig. 4. Note that the motor 111, gearbox 112, and reel 116 are shown as one assembly in Fig. 26.

It should be noted in Fig. 25, the dotted curve in waveform E (Syringe pressure) clearly shows that had no limit been set the pressure would have drastically exceeded the desired level.

Waveform "F" in Fig. 25 clearly shows that both circuits 320 and 325 maintain consistent flow unless the set pressure limit is breached, during which time flow is reduced but continues as close as possible to the desired flow, and within the maximum permissible set by the pressure limit. In this manner all safety concerns are met, and the pumping is allowed to continue or even resume normal flow should the restriction clear, as preferred for most medical fluid pumps.

It will be appreciated that the electronic control system described above in relation to Figs. 24 to 26, is particularly suited to a medical scanner environment such as an MRI scanner environment. In this regard, unlike most control and drive systems employed in existing injector units, the above described electronic control system drives the motor with direct current (DC) which eliminates electromagnetic radiation found in most existing pulse width modulated pumps. Also, the analog circuits of the present invention employ no clocking or switching and operate at virtually DC frequencies, and hence are relatively immune to any EMI from the scanner because it only induces relatively high frequencies. As the above described control system has no computer, software, touch screens, pulse width modulation, or digital control circuitry, its operation is unlikely to be corrupted, which is of particular benefit in the high EMI environment of medical scanners. The above described control systems lend themselves easily to the use of digitally controlled flow resistors such as binary thumbwheel switches or digitally selected flow resistors, providing precise control of flow, without susceptibility to EMI.

The above described injector systems provide many improvements over existing medical fluid pumps, particularly for use in a medical scanner environment. Various means for improved transfer of motive power from the motor and base to the top mounted pump device are revealed. The present invention allows heavy and often ferrous motor and drive components to be mounted in the base, improving pump stability, as well as reducing magnetic interaction and EMI between the pump and other equipment nearby. Most of the novel drive transfer means revealed dispense with the large metal components such as lead screws and drive shafts commonly found in existing pumps. Various novel improvements in drive efficiency and monitoring accuracies are revealed. The present invention provides several low cost, reliable, and non-elastic means for transferring motive power from motor to syringe. The preferred drive embodiments permit the head unit to be tilted without affecting the drive transfer means between base and head.

Other inventions revealed permit the use non-conductive cable to sense parameters such as plunger movement and syringe pressure, allowing essential sensors to be located in the base, thereby avoiding the use of wires and again reducing magnetic interaction and EMI between the pump and other equipment nearby. Furthermore novel embodiments permit accurate measurement of high forces utilizing relatively low cost sensors.

Various other novel drives are revealed for syringe and peristaltic pumps having the motor in the base which are particularly suited to an MRI environment. Most of the drive means revealed permit the use of absolute position rotational sensors which allow precise monitoring and do not lose track of their position if the control system errs, or power is interrupted.

Various improved means for detecting contact between pusher and syringe are revealed, providing precise, consistent, and reliable operation compared to existing methods. Some contact sensor embodiments are immune to EMI and as such particularly advantageous in an MRI environment.

At least one present invention reveals a novel means for holding syringes in a medical pump, supporting a wide variety of types and sizes without the need for special adaptors or modifications as found in most existing syringe pumps. One embodiment of the novel holder is able to detect the presence of a syringe, as well as measure its

diameter and thereby permit the control system to adjust compression speed and stroke appropriately. Various embodiments of the novel holders also exhibit novel means for monitoring syringe pressure, some means particularly suited to pumps used with medical scanners. At least one embodiment of the present syringe holders is able to withstand very high loads making it particularly suited to contrast injectors. A syringe mounted in another novel holder is difficult or impossible to remove until the pumping is complete.

A novel dual pedestal pump is revealed which is particularly suited to dual syringe pumps, is easily fitted to a conventional single holed base, and permits the use of readily available rigid tubing.

A novel braking system is revealed which prevents the pump from rolling undesirably due to attraction from the scanner, sloping floor, etc.

A novel electronic control system is revealed which maintains precise control of flow, yet should a restriction occur is able to maintain maximum possible flow whilst keeping pressure within safe limits. The circuit is particularly suited to medical scanner environments such as MRI and CT because it produces virtually no EMI, and is also relatively immune to EMI from scanners. This system also lends itself to switch or digitally selected resistors for accurate control of flow, without susceptibility to EMI.

It will be understood by those familiar with the art that any one or many of the inventions described above could be applied to any standard medical fluid pump, and used in any other environment. It will also be understood that various combinations of the above revealed inventions are possible, depending on the application.

It will be appreciated by persons skilled in the art that numerous variations and/or modifications may be made to the invention as shown in the specific embodiments without departing from the spirit or scope of the invention as broadly described. The present embodiments are, therefore, to be considered in all respects as illustrative and not restrictive.

CLAIMS:

1. An injector unit for injecting a patient with fluid during a medical injection procedure, the injector unit comprising:

a head portion configured to receive at least one fluid container containing said fluid for injection, and housing an injecting means operable to eject fluid therefrom;

a base portion configured to support said injector unit and adapted to house a drive means for providing motive force to operate said injecting means; and

an elongate body portion, for supporting said head portion in a position relative to said base portion and for housing a drive transfer means for transferring motive force from said drive means to said injecting means, the drive transfer means comprising at least one cable extending between said drive means and said injecting means.

2. An injector unit according to claim 1, wherein the at least one fluid container is a syringe having a plunger disposed therein.

3. An injector unit according to claim 2, wherein the injecting means comprises at least one elongate rod element which is movable in an axial direction to contact and depress the plunger of the syringe to eject the fluid therefrom.

4. An injector unit according to claim 3, wherein the elongate rod element is arranged to travel along at least one roller and the axial movement of the elongate rod element is axial rolling movement.

5. An injector unit according to claim 4, wherein the elongate rod element has a proximal end and a distal end, the proximal end being the end which contacts the plunger of the syringe to eject the fluid therefrom.

6. An injector unit according to claim 5, wherein the proximal end of the elongate rod element has a closed face to ensure that even force is applied to the plunger of the syringe.

7. An injector unit according to any one of the preceding claims, wherein the drive means comprises a motor that provides a substantially rotary motive force to an associated drive shaft.

8. An injector unit according to claim 7, wherein a first cable is attached to the drive shaft at a first end and to the distal end of the elongate rod element at a second end.

9. An injector unit according to claim 8, wherein the first cable is arranged to extend along a length of the substantially axis of the elongate rod element

10. An injector unit according to claim 9, wherein rotation of the drive shaft in a first direction increases tension in said first cable causing said first cable to move in said first direction, thereby moving said elongate rod element in an axial direction to contact and depress the plunger into said syringe to expel the fluid therefrom.

11. An injector unit according to claim 10, wherein said drive transfer means comprises a second cable attached at a first end to the drive shaft and at a second end to the proximal end of the elongate rod element.

12. An injector unit according to claim 11, wherein the second cable is arranged to extend along a length of the axis of the elongate rod element, in a direction opposite to said first cable.

13. An injector unit according to claim 12, wherein rotation of said drive shaft in said first direction releases tension in said second cable causing said second cable to move in said first direction.

14. An injector unit according to claim 13, wherein rotation of said drive shaft in a direction opposite to said first direction causes a decrease in tension in said first cable and an increase in tension in said second cable, thereby causing said elongate rod element to move in an axial direction away from said plunger.

15. An injector unit according to claim 14, wherein both the first and the second cables are attached at respective first ends to a reel fixed to the drive shaft.

16. An injector unit according to claim 14, wherein both the first and second cables are attached at respective first ends to a nut, driven by a lead screw in contact with the drive shaft of the motor.

17. An injector unit according to any one of the preceding claims, wherein the first and second cables may be in the form of a wire, chain, belt or cord are made from a non-stretchable and/or non-metallic and/or non-conductive material.

18. An injector unit according to claim 17, wherein the first and second cables are made from Kevlar or carbon fibre.

19. An injector unit according to any one of the preceding claims, wherein the head portion is able to be tilted in relation to the base portion and the elongate body portion.

20. An injector unit according to claim 10, wherein the axial position and/or speed of the elongate rod element is monitored to determine the flow rate of the fluid expelled from the syringe.

21 An injector unit according to claim 20, wherein the axial position and/or speed of the elongate rod element is monitored by measuring the rotational speed of the drive shaft.

22. An injector unit according to claim 20, wherein the axial position and/or speed of the elongate rod element is monitored by measuring the rotational speed of at least one of the rollers which guide the elongate rod element.

23. An injector unit according to claims 21 or 22, wherein the rotational speed is measured by a rotational encoder or potentiometer.

24. An injector unit according to claim 10, wherein a sensor is provided to measure the tension in the first cable to determine the pressure of fluid expelled from the syringe.

25. An injector unit according to claim 24, wherein the sensor comprises an arm hingedly mounted at one end to the injector unit for deflecting the first cable, and the tension in the first cable is determined by measuring the force applied by the first cable against the arm.

26. An injector unit according to claim 25, wherein the free end of the arm comprises a roller which contacts the first cable to deflect the cable.

27. An injector unit according to claim 25, wherein the force applied by the first cable against the arm is measured by a piezo-electric sensor.

28. An injector unit according to claim 25, wherein the measured tension in the first cable is directly proportional to the syringe fluid pressure.

29. An injector unit according to claim 5, wherein the proximal end of the elongate rod element has a sensor for determining contact with, and/or pressure applied to, the plunger of the syringe.

30. An injector unit according to claim 29, wherein the sensor is a fluid filled bag located on a contact surface of the proximal end of the elongate rod element in fluid communication with a pressure transducer for measuring fluid pressure within the fluid filled bag.

31. An injector unit according to claim 30, wherein the fluid pressure measured in the fluid filled bag is directly proportional to the pressure of the fluid expelled from the syringe.

32. An injector unit according to claim 3, wherein the syringe is supported within the head portion on a sliding base which is free to move in an axial direction for a fixed distance.

33. An injector unit according to claim 32, wherein said axial direction is substantially co-axial with said axial movement of the at least one elongate rod element.

34. An injector unit according to claim 33, wherein said fixed distance, is a distance of up to 10 mm.

35 An injector unit according to claim 34, wherein contact between said elongate rod element and the plunger of the syringe causes movement of said sliding base in the axial direction.

36. An injector unit according to claim 35, wherein the sliding base is in contact with a force sensor which senses forces associated with said axial movement of said sliding base.

37. An injector unit according to claim 36, wherein the force sensor is a load cell, strain gauge or piezo cell in direct contact with said sliding base.

38. An injector unit according to claim 36, wherein the force sensor is a load cell, strain gauge or piezo cell in indirect contact with said sliding base via a cable connecting said force sensor to the sliding base.

39. An injector unit according to claims 37 or 38, wherein the force sensed by the force sensor is directly proportional to the pressure of the fluid ejected from the syringe.

40. An injector unit according to claim 37 or 38, wherein the force sensed by the force sensor detects initial contact between the elongate rod element and the plunger of the syringe to enable priming of the injector unit.

41. An injector unit according to any one of the preceding claims, wherein the injector unit is controlled by an electronic control system which controls the injection of the fluid into a patient in response to the sensed pressure conditions associated with the injection procedure.

42. An injector unit according to claim 2, wherein each syringe is received in the head portion by a syringe holder, the syringe holder comprising:

a base portion for securing said syringe holder to said injector unit;

at least two arms, each arm having a first end and a second end, said first ends of each arm being mountable to said base portion, with at least one of said arms being hingedly mounted to said base portion at said first end, and each said second end having a gripping element attached thereto; and

a biasing element arranged to biasing said arms into a holding position for holding the syringe between said gripping elements of said arms.

43. An injector unit according to claim 42, wherein the first ends of the at least two arms are mounted to axles provided in the base portion.

44. An injector unit according to claim 43, wherein the axles are fixed to the base portion and arranged in a parallel relationship to ensure that when the arms are in said holding position, the syringe is axially aligned with the injecting means.

45. An injector unit according to claim 44, wherein each axle has a gear element mounted thereon such that gear elements of adjacent axles mesh to ensure symmetrical movement of the arms with respect to said base.

46. An injector unit according to claim 42, wherein the biasing element is an extension spring.

47. An injector unit according to claim 46, wherein the extension spring is stretched between the at least two arms.

48. An injector unit according to claim 47, wherein the biasing force of the extension spring is sufficient to firmly hold the syringe in position during ejection of the fluid retained therein, whilst enabling separation of the arms to remove the syringe therefrom following ejection of the fluid.

49. An injector unit according to claim 44, wherein said arms are separated to receive a variety of syringes having variable barrel diameters, to retain the syringe in an axially aligned arrangement with the injecting means.

50. An injector unit according to claim 42, wherein the surfaces of said gripping elements which contact the body of the syringe are shaped to conform to the body of the syringe.

51. An injector unit according to claim 50, wherein the contact surfaces of the gripping elements have a substantially concave surface.

52. An injector unit according to claim 51, wherein the contact surfaces of the gripping elements are provided with two concave surfaces, one concave surface having a radius substantially equal to the largest suitable syringe diameter, and the other concave surface having a diameter substantially equal to the smallest suitable syringe diameter.

53. An injector unit according to claim 50, wherein the contact surfaces of the gripping elements have grooves provided therein to conform with flanges provided on the body of the syringe.

54. An injector unit according to claim 50, wherein the gripping elements are detachable from the arms.

55. An injector unit according to claim 54, wherein the gripping elements are interchangeable to suit different types of syringes.

56. An injector unit according to claim 50, wherein the gripping elements are substantially V-shaped in cross-section.

57. An injector unit according to claim 50, wherein the contact surfaces of the claws are moulded from or coated with a soft plastic.

58. An injector unit according to claim 49, wherein a sensor is provided to measure the distance of separation of the arms to determine the barrel diameter of the syringe retained therein.

59. An injector unit according to claim 58, wherein the distance of separation of the arms is determined by measuring the angle of at least one of the arms with respect to the base portion.

60. An injector unit according to claim 59, wherein a rotational sensor is coupled to at least one arm of the syringe holder to measure the angle of the arm with respect to the base portion.

61. An injector unit according to claim 58, wherein the control circuitry of the injector unit determines the barrel diameter of the syringe based on the measured distance of separation of the arms and controls the injecting means accordingly.

62. An injector unit according to claim 61, wherein the control circuitry controls the injecting speed and stroke of the injecting means in relation to the determined barrel

diameter of the syringe to ensure the correct flow rate of fluid is delivered from the syringe.

63. An injector unit according to claim 62, wherein the control circuitry ceases operation of the injecting means if the determined barrel diameter is inconsistent with the medical procedure being performed.

64. A syringe holder for an injector unit, comprising:

a base portion for securing said syringe holder to said injector unit;

at least two arms, each arm having a first end and a second end, said first ends of each arm being mountable to said base portion, with at least one of said arms being hingedly mounted to said base portion at said first end, and each said second end having a gripping element attached thereto; and

a biasing element arranged to biasing said arms into a holding position for holding the syringe between said gripping elements of said arms.

65. A syringe holder according to claim 64, wherein the first ends of the at least two arms are mounted to separate axles provided in the base portion.

66. A syringe holder according to claim 65, wherein the axles are arranged parallel to each other such that when the arms are in said holding position, the syringe is axially aligned with an injecting means of the injector unit and is able to rotate freely about its axis.

67. A syringe holder according to claim 66, wherein each axle has a gear element mounted thereon such that gear elements of adjacent axles mesh to ensure symmetrical movement of the arms with respect to said base.

68. A syringe holder according to claim 64, wherein the biasing element is an extension spring.

69. A syringe holder according to claim 68, wherein the extension spring is stretched between the at least two arms.

70. A syringe holder according to claim 69, wherein the biasing force of the extension spring is sufficient to firmly hold the syringe in position during ejection of

the fluid retained therein, whilst enabling separation of the arms to remove the syringe therefrom following ejection of the fluid.

71. A syringe holder according to claim 64, wherein said arms are separated to receive syringes having variable barrel diameters, such that the syringes are retained in an axially aligned arrangement with an injecting means of the injector unit.

72. A syringe holder according to claim 64, wherein the surfaces of said gripping elements which contact the body of the syringe are shaped to conform to the body of the syringe.

73. A syringe holder according to claim 72, wherein the contact surfaces of the gripping elements have a substantially concave surface.

74. A syringe holder according to claim 73, wherein the contact surfaces of the gripping elements are provided with two concave surfaces, a first concave surface having a radius substantially equal to the largest suitable syringe diameter, and a second concave surface having a diameter substantially equal to the smallest suitable syringe diameter.

75. A syringe holder according to claim 72, wherein the contact surfaces of the gripping elements have grooves provided therein to conform with flanges provided on the body of the syringe.

76. A syringe holder according to claim 72, wherein the gripping elements are detachable from the arms.

77. A syringe holder according to claim 76, wherein the gripping elements are interchangeable to suit different types of syringes.

78. A syringe holder according to claim 72, wherein the gripping elements are substantially V-shaped in cross-section.

79. A syringe holder according to claim 72, wherein the contact surfaces of the claws are moulded from, or coated with, a soft plastic.

80. A syringe holder according to claim 71, wherein a sensor is provided to measure the distance of separation of the arms to determine the barrel diameter of the syringe retained therein.

81. A syringe holder according to claim 80, wherein the distance of separation of the arms is determined by measuring the angle of at least one of the arms with respect to the base portion.

82. A syringe holder according to claim 81, wherein a rotational sensor is coupled to at least one arm of the syringe holder to measure the angle of the arm with respect to the base portion.

83. A syringe holder according to claim 80, wherein control circuitry of the injector unit determines the barrel diameter of the syringe based on the measured distance of separation of the arms and controls the injecting means accordingly.

84. A syringe holder according to claim 83, wherein the control circuitry controls the injecting speed and stroke of the injecting means in relation to the determined barrel diameter of the syringe to ensure the correct flow rate of fluid is delivered from the syringe.

85. A syringe holder according to claim 83, wherein the control circuitry ceases operation of the injecting means if the determined barrel diameter is inconsistent with the medical procedure being performed.

86. A method of operating an injector unit for injecting a patient with fluid during a medical injection procedure, comprising:

loading the injector unit with a container containing said fluid for injection;

sensing a parameter associated with the container; and

controlling the delivery of said fluid from the container in response to said sensed parameter.

87. A method according to claim 86, wherein the step of loading the injector unit comprises loading a fluid filled syringe into a syringe holder of the injector unit.

88. A method according to claim 87, wherein the syringe is securely retained between at least two arms of syringe holder.

89 A method according to claim 88, wherein the syringe has a plunger disposed therein for ejecting the contained fluid from the syringe.

90. A method according to claim 89, wherein the step of sensing a parameter associated with the container comprises sensing a barrel diameter of the syringe.

91. A method according to claim 90, wherein the barrel diameter of the syringe is sensed by determining a distance of separation between the at least two arms of the syringe holder holding the syringe.

92. A method according to claim 91, wherein the distance of separation is determined by measuring the angle of at least one of the arms with respect to a base portion of the syringe holder.

93. A method according to claim 92, wherein a rotational sensor is coupled to at least one of the arms of the syringe holder to measure the angle of the arm with respect to the base portion.

94. A method according to claim 90, wherein the step of controlling the delivery of the fluid from the container comprises controlling the speed and stroke of the plunger within the syringe to deliver an appropriate volume and/or flow rate of fluid from the syringe proportional to the measured barrel diameter of the syringe.

95. A method according to claim 94, wherein the speed and stroke of the plunger is controlled by a control system of the injector unit which controls a drive mechanism for engaging with the plunger to eject fluid from the syringe.

96. A method according to claim 95, wherein the drive mechanism comprises a motor which operates a push-rod that engages the plunger, and the speed and stroke of the plunger is controlled by controlling the speed of the motor.

97. An injector unit for injecting a patient with fluid during a medical injection procedure, the injector unit comprising:

a holder mechanism for receiving and securing in position a fluid container for injection;

an injecting means for applying a force to said fluid container to eject said fluid therefrom; and

a sensor for measuring a force applied by the injecting means to the holder mechanism.

98. An injector unit according to claim 97, wherein the fluid container is a syringe having a plunger disposed therein.

99. An injector unit according to claim 98, wherein the holder mechanism is attached to said injector unit such that it is free to move, for a predetermined distance, along the axis of the syringe.

100. An injector unit according to claim 99, wherein the predetermined distance is up to 10 mm.

101. An injector unit according to claim 99, wherein the injecting means comprises at least one elongate rod element which is movable in an axial direction to contact and apply force to the plunger of the syringe to eject fluid therefrom.

102. An injector unit according to claim 101, wherein the at least one elongate rod element is driven by a motor under control of a control system of the injector unit.

103. An injector unit according to claim 101, wherein the force applied to the plunger of the syringe is also experienced by the holder mechanism, causing the holder mechanism to move in a direction along the axis of the syringe.

104. An injector unit according to claim 103, wherein the sensor is in contact with the holder mechanism such that movement of the holder mechanism generates a force upon said sensor.

105. An injector unit according to claim 104, wherein the sensor is a load cell, strain gauge or a piezo cell.

106. An injector unit according to claim 104, wherein the force sensed by the sensor is proportional to the fluid pressure delivered by the syringe.

107. An injector unit according to claim 106, wherein the injecting means is controlled in response to the force measured by the sensor, to ensure that the fluid pressure delivered by the syringe is within acceptable limits.

108. An injector unit for injecting a patient with fluid during a medical injection procedure, the injector unit comprising:

at least one fluid container containing said fluid for injection;

an injecting means operable to eject fluid from said at least one fluid container;

a drive means for providing motive force to operate said injecting means; and

a drive transfer means for transferring motive force from said drive means to said injecting means, the drive transfer means comprising at least one cable extending between said drive means and said injecting means.

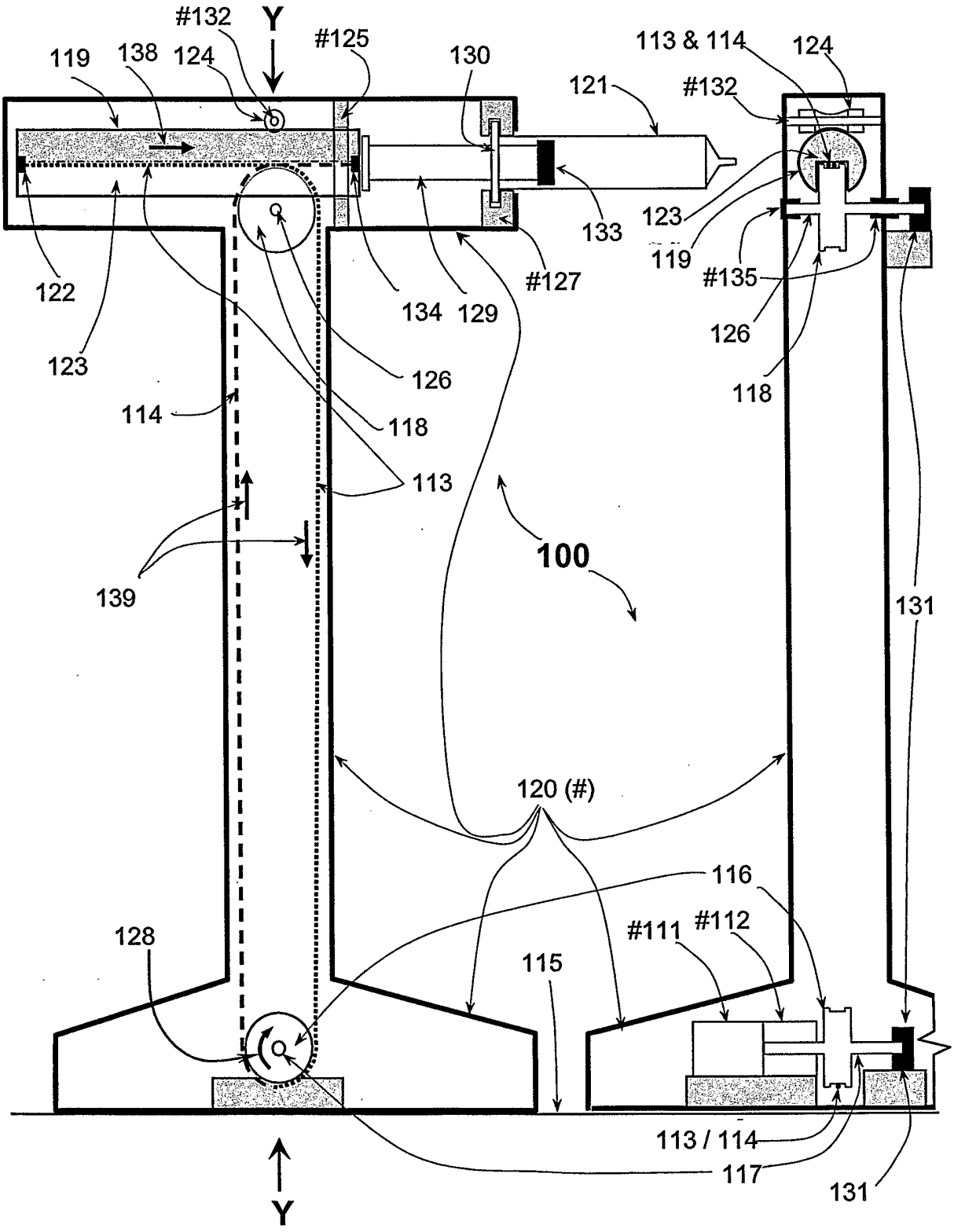
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Fig 1.

Fig 2.

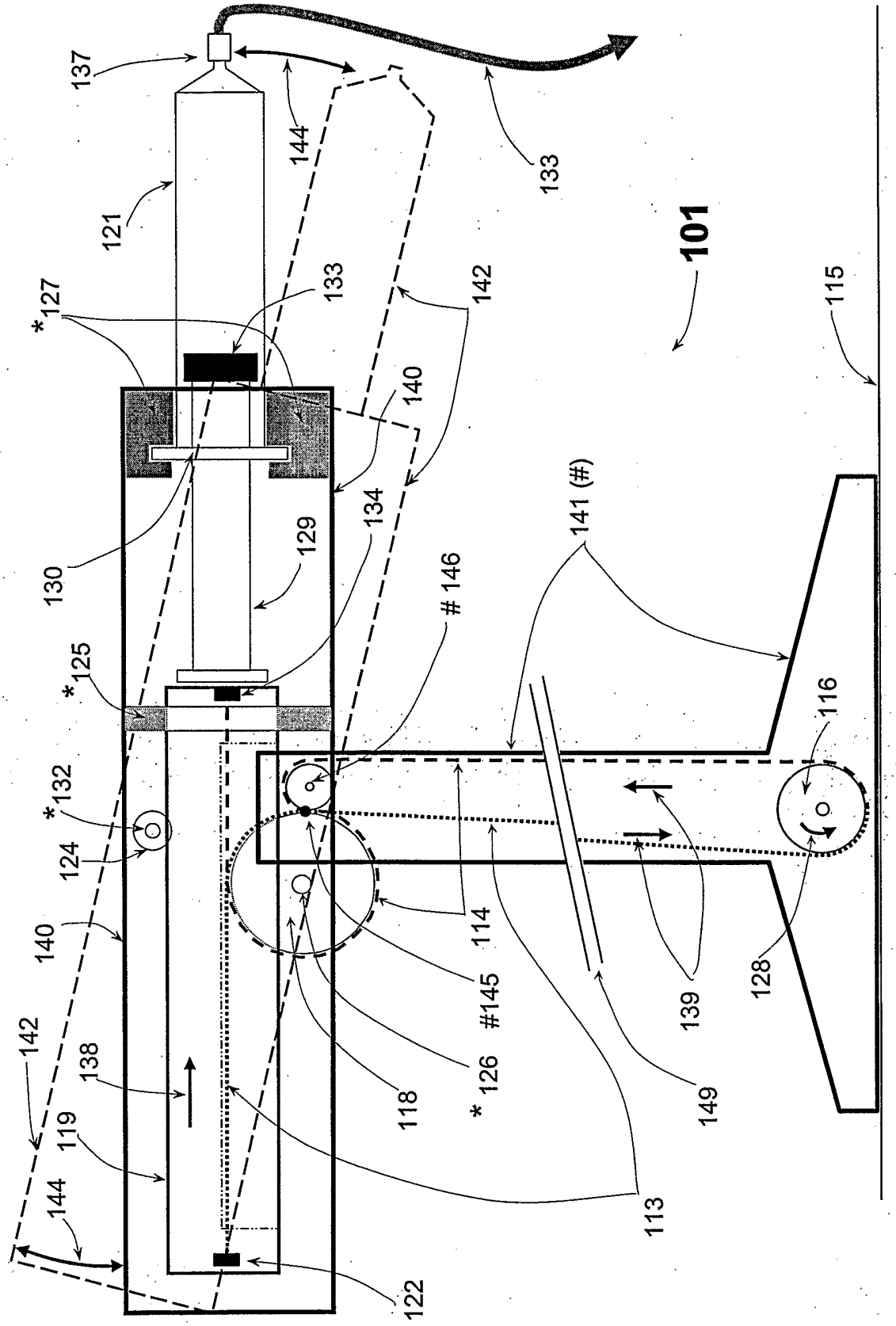
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Fig. 3

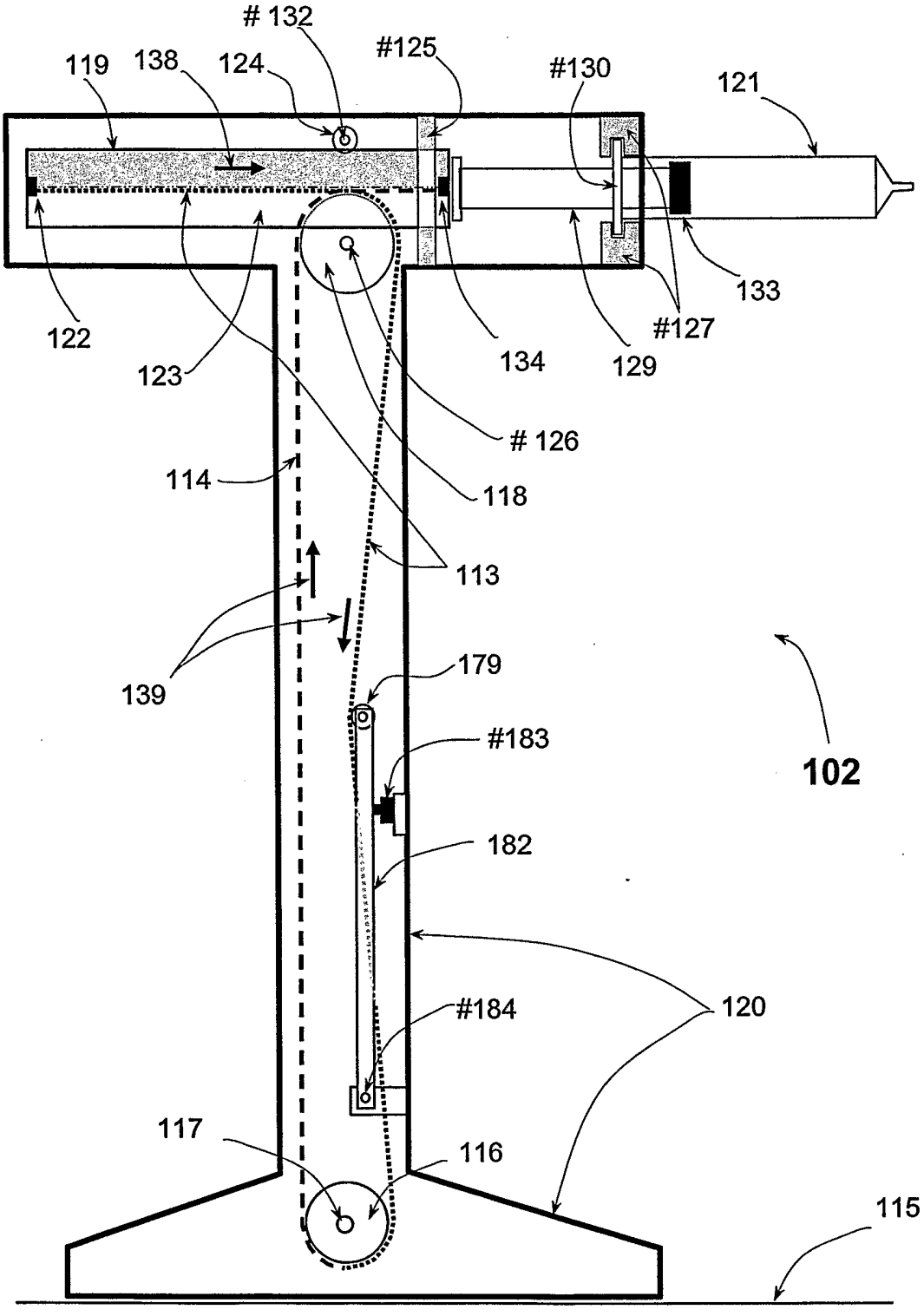
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Fig. 4

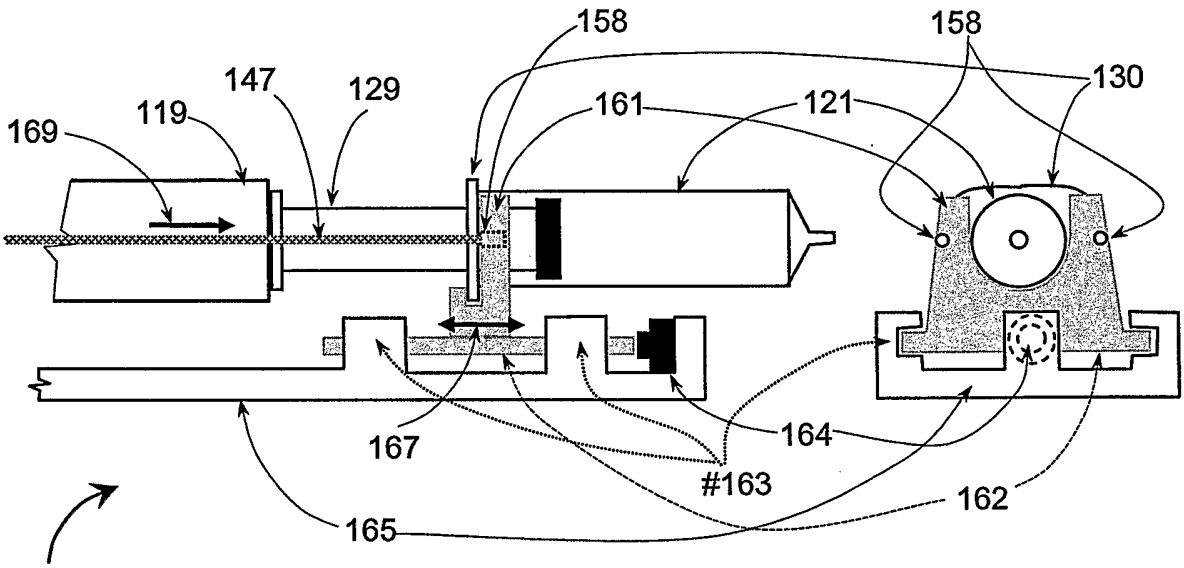

Figure 5 (a)

Figure 5(b)

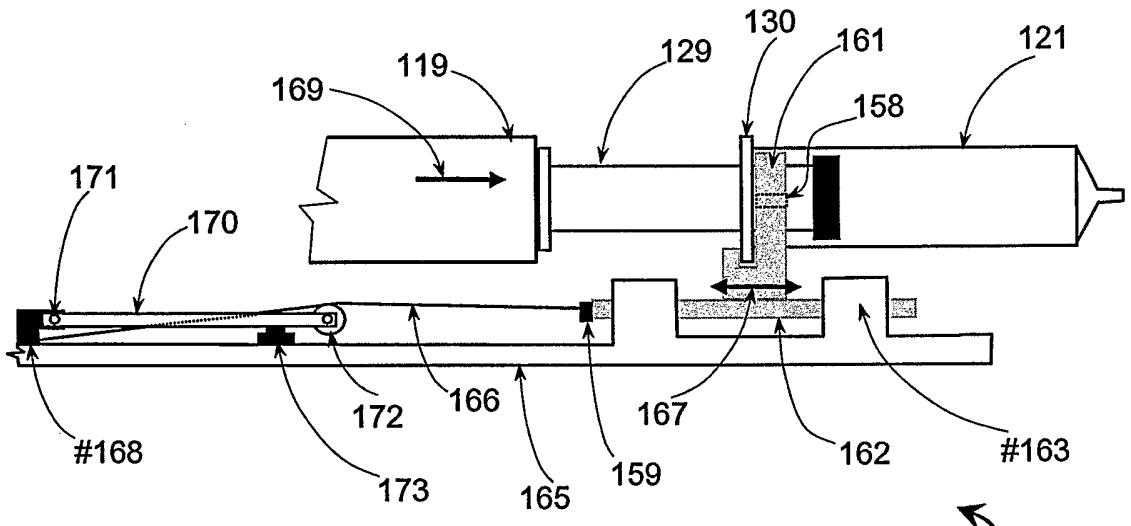

Figure 6

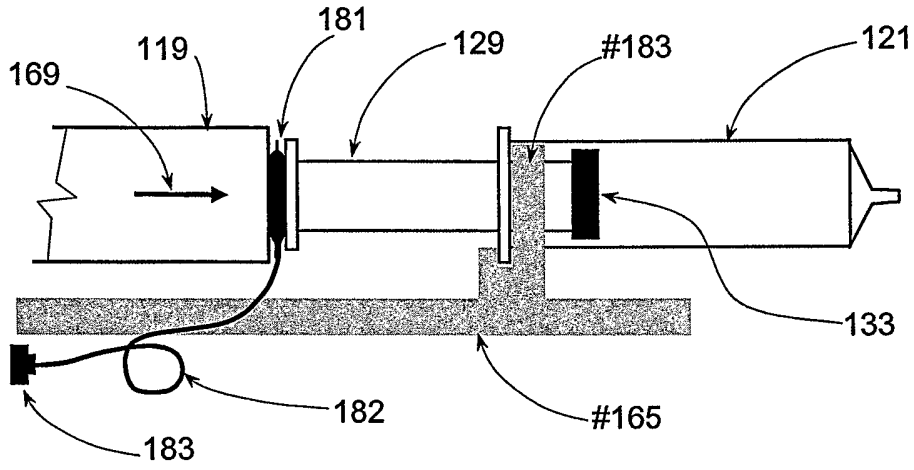

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Figure 7

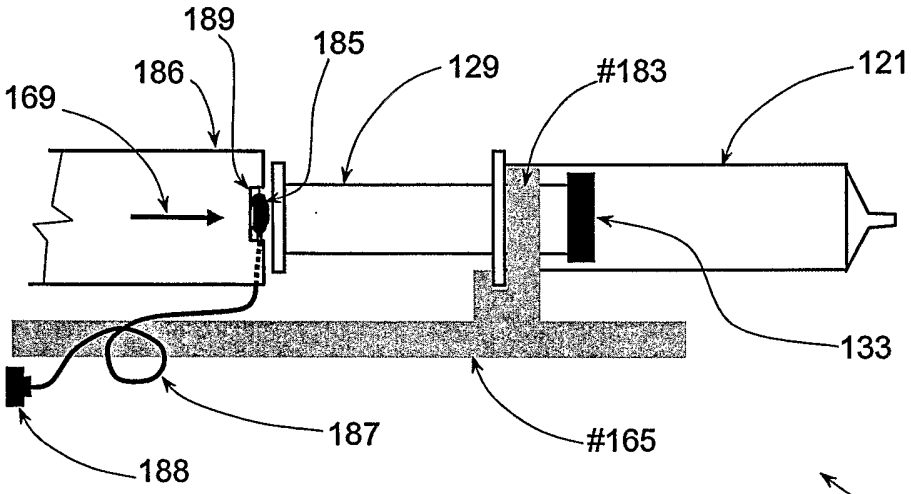

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Figure 8 :

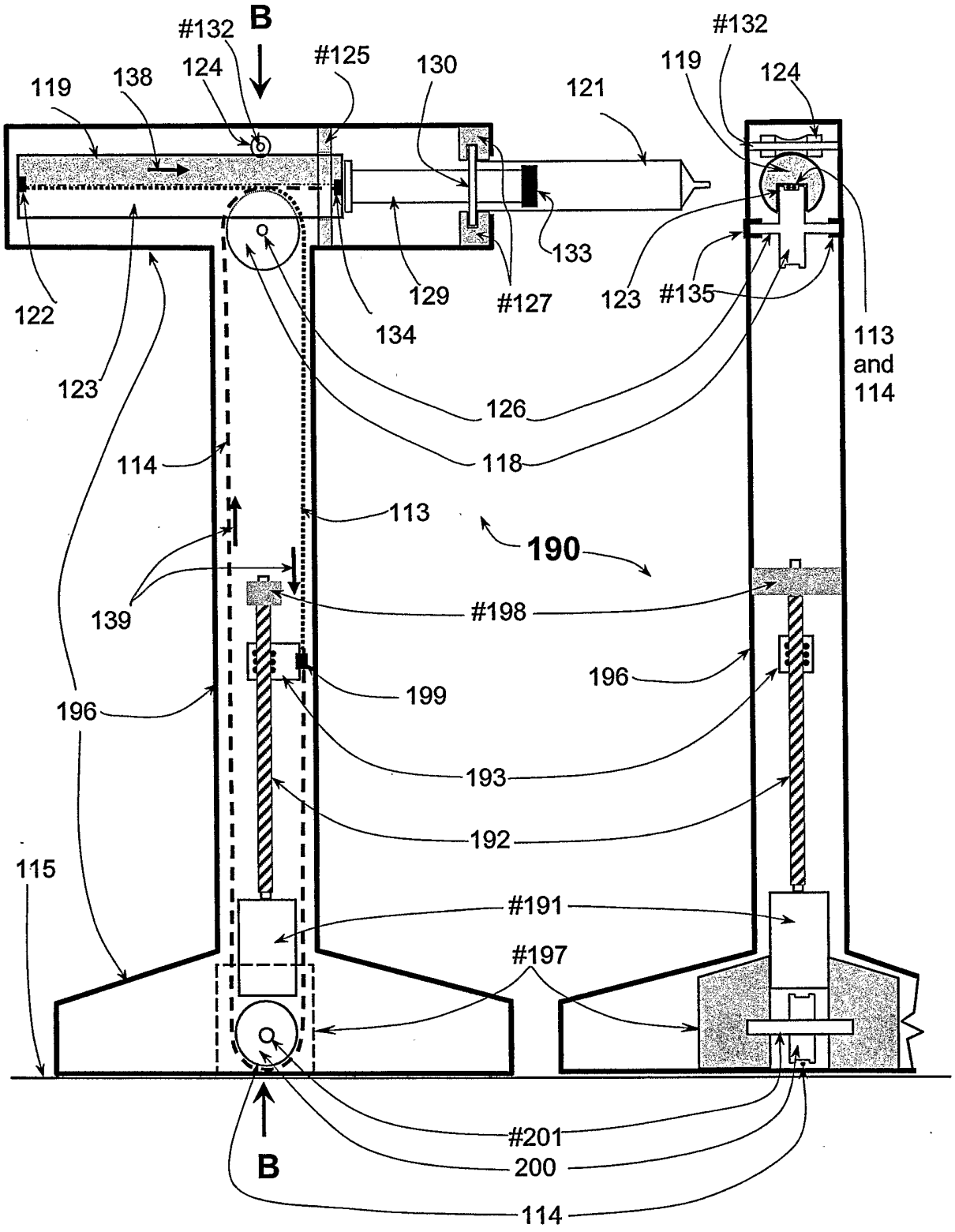
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Fig 9

Fig 10

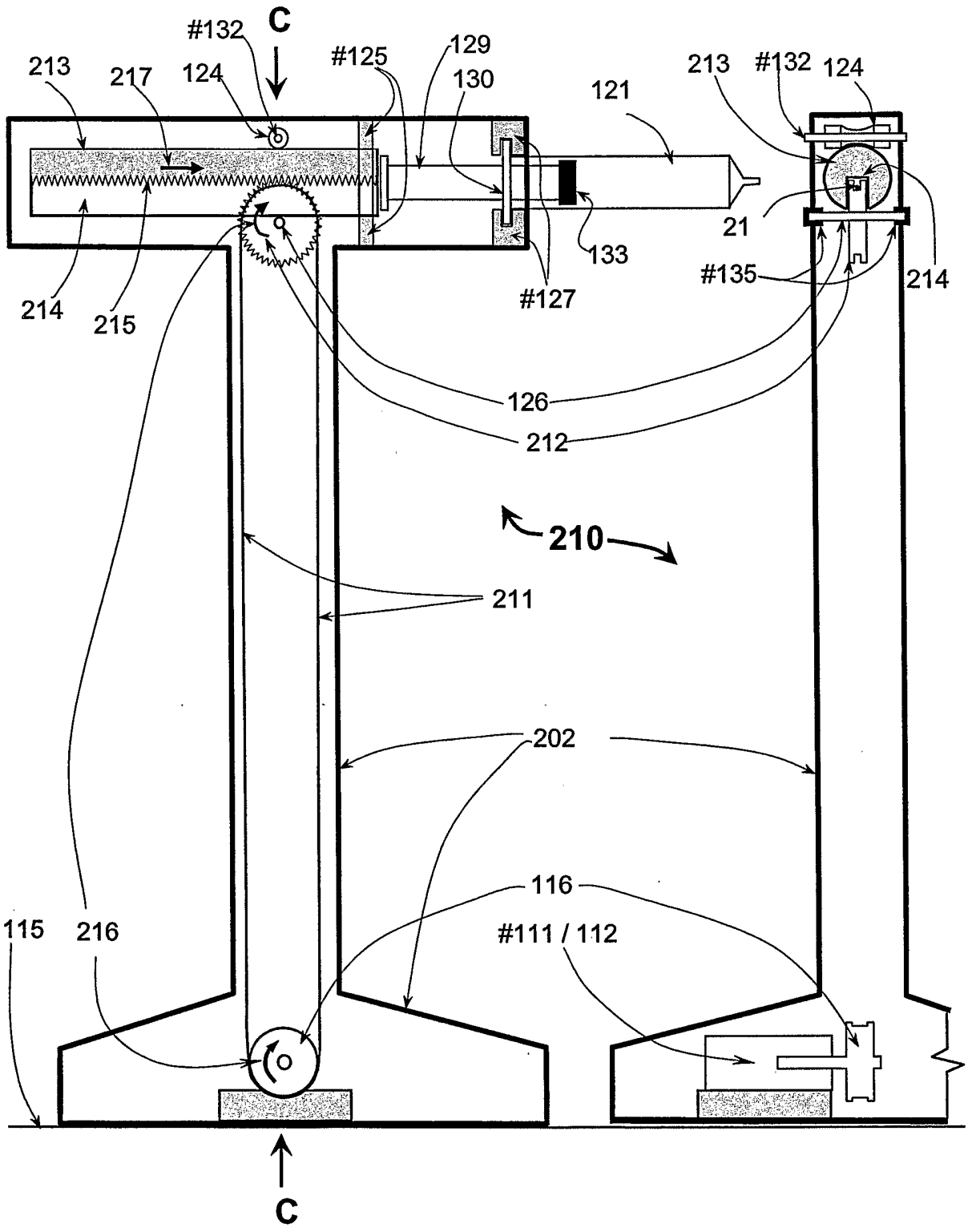
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Fig 11

Fig 12

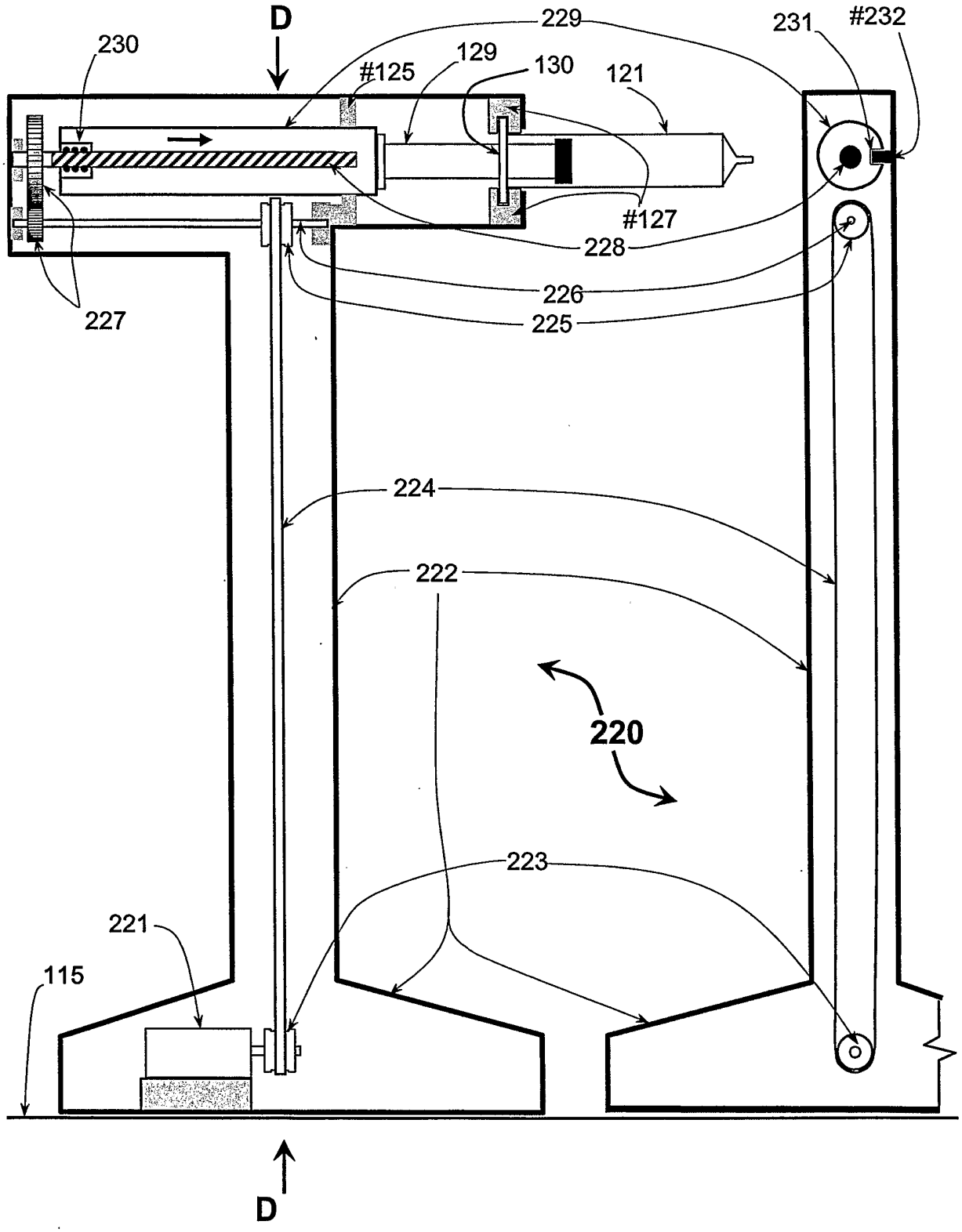
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Fig 13

Fig 14

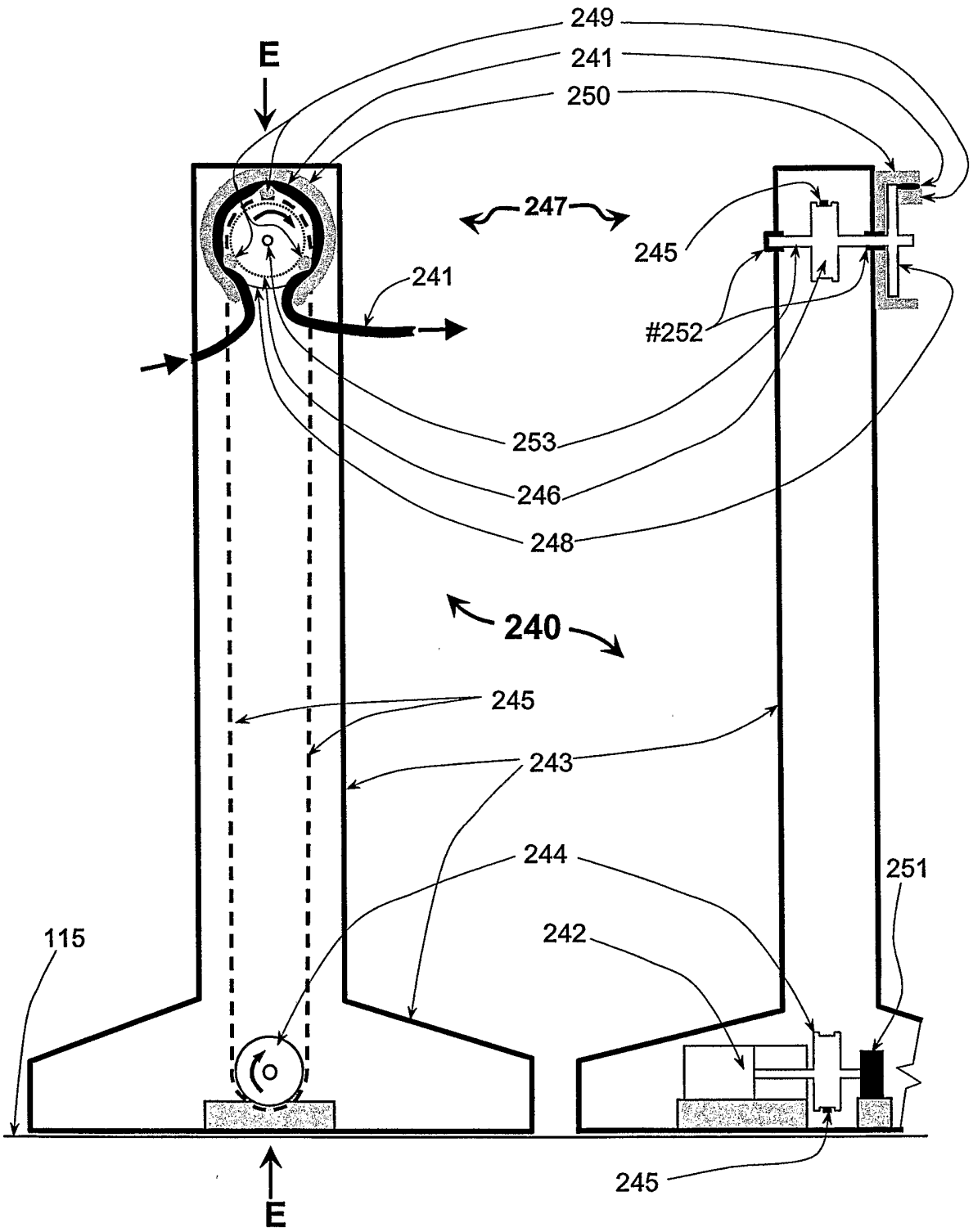
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Fig 15

Fig 16

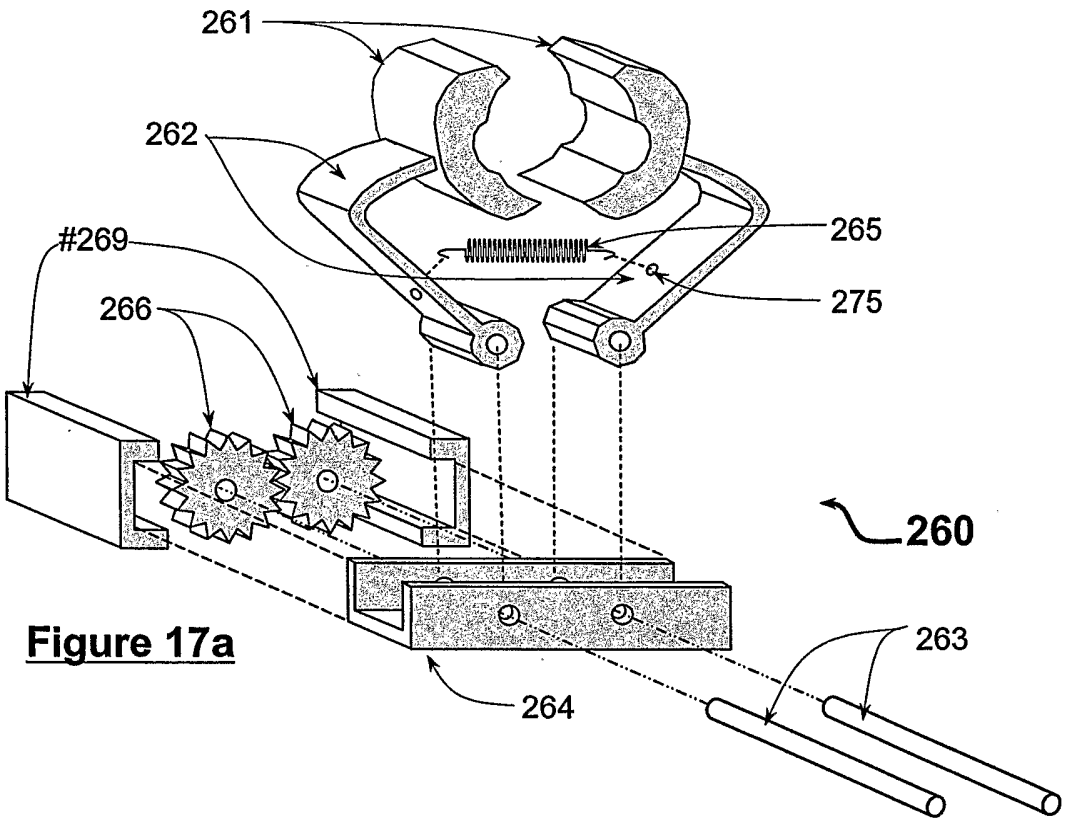


Figure 17a

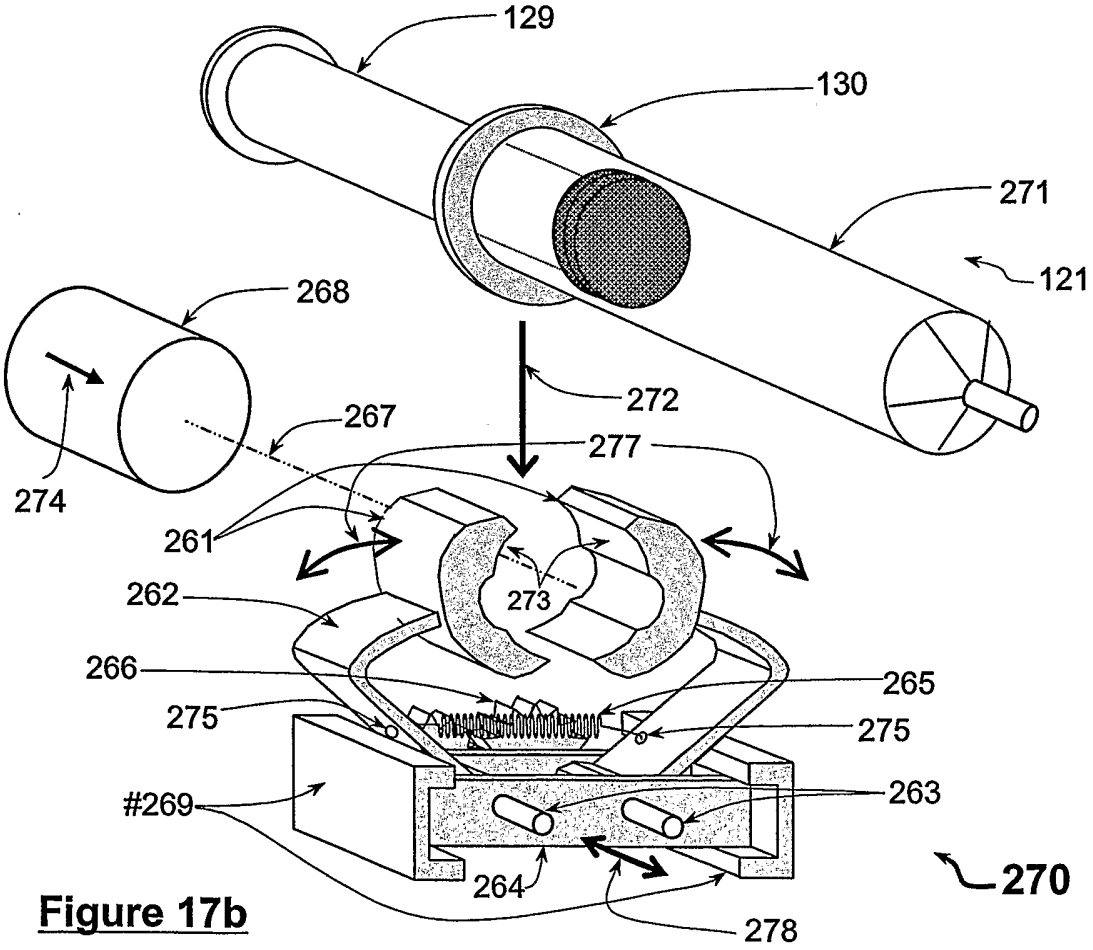


Figure 17b

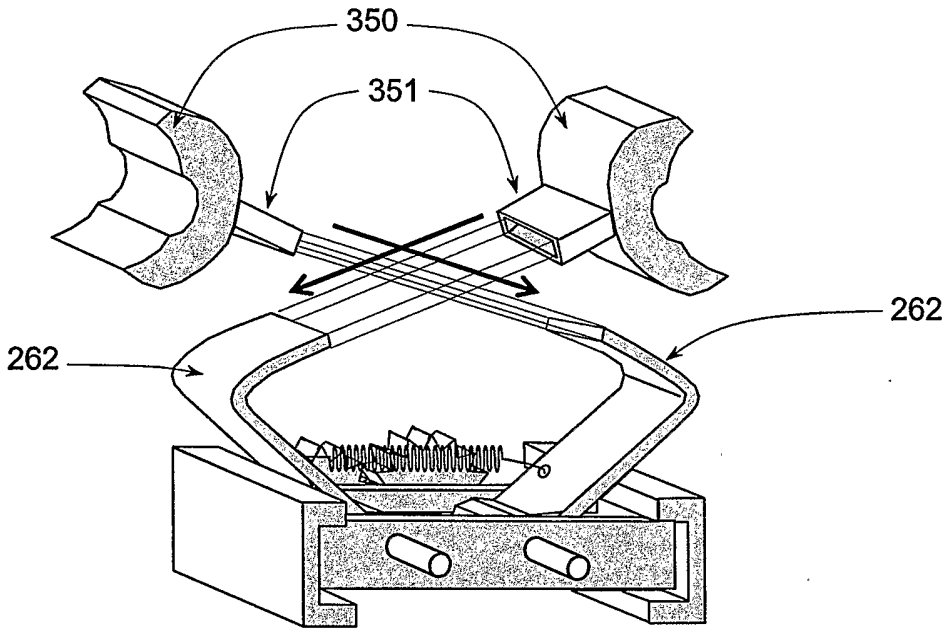


Fig.18(a)

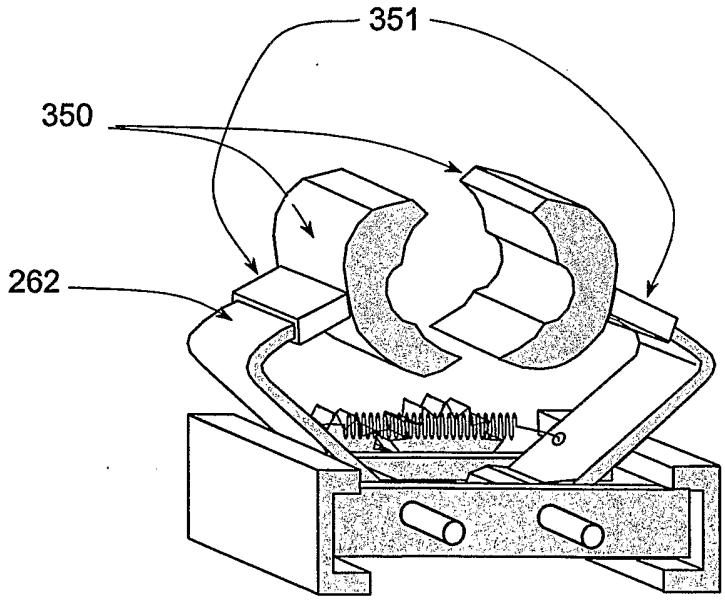


Fig.18(b)

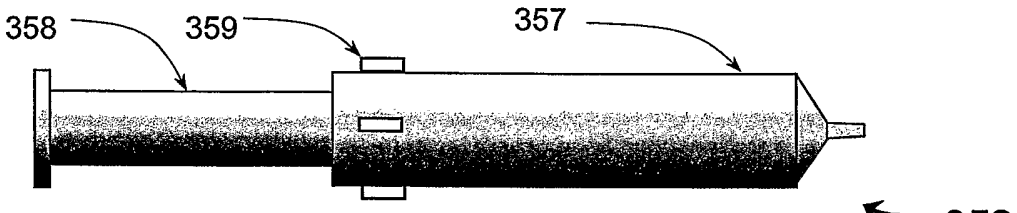


Figure 18(c)(i)

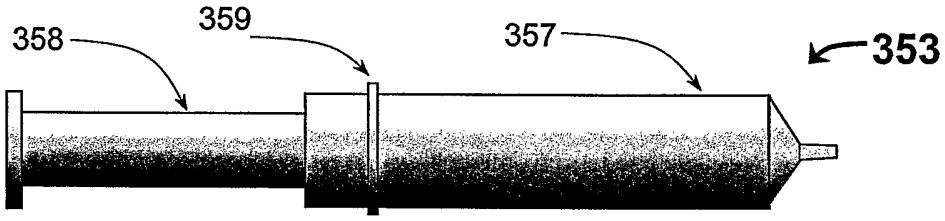


Figure 18(c)(ii)

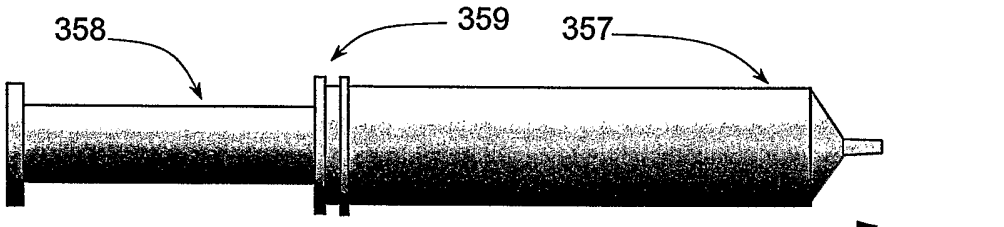


Figure 18(c)(iii)

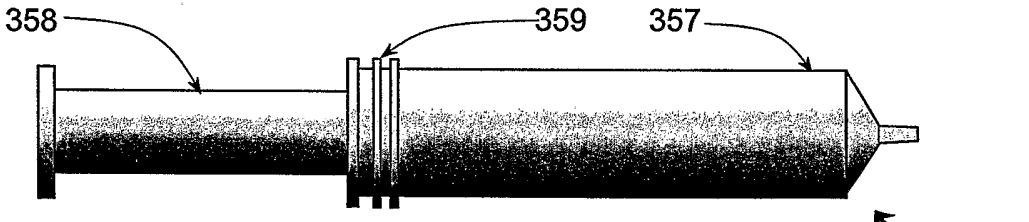


Figure 18(c)(iv)

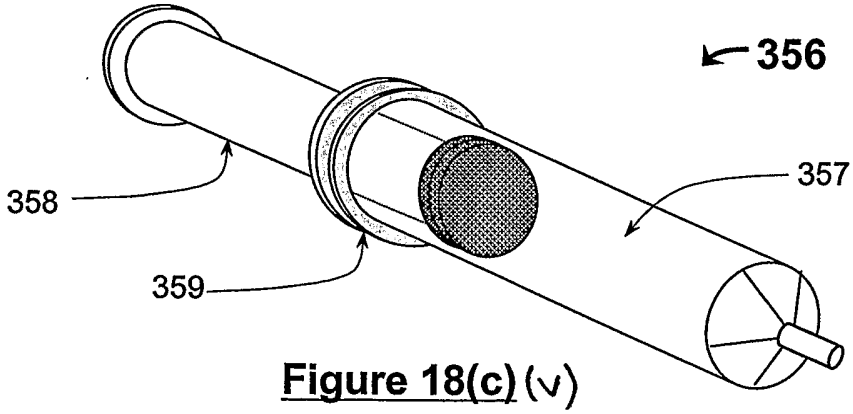


Figure 18(c)(v)

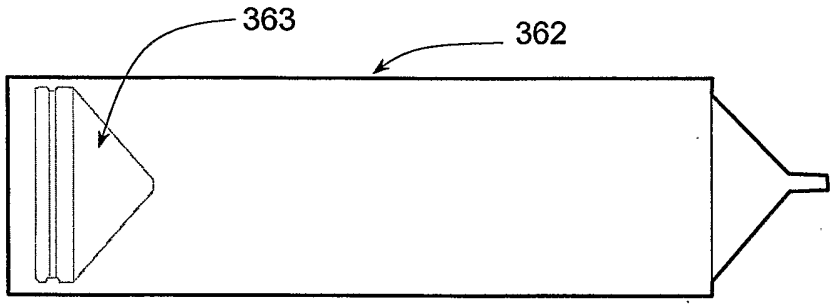


Figure18(d)(i)

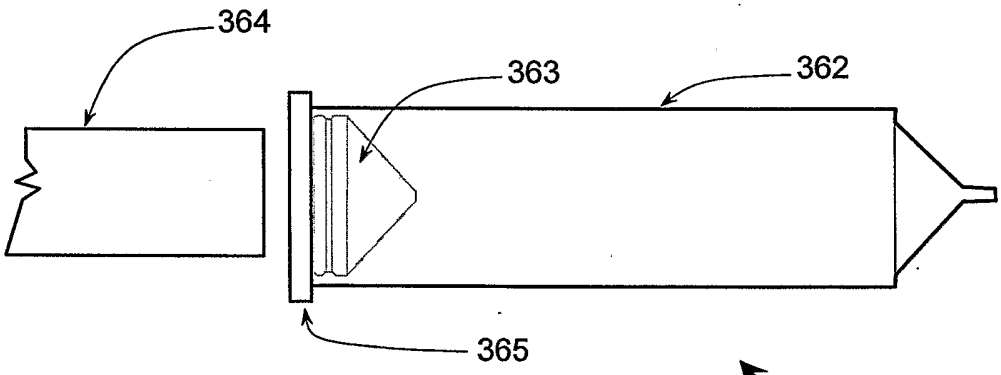


Figure18(d)(ii)

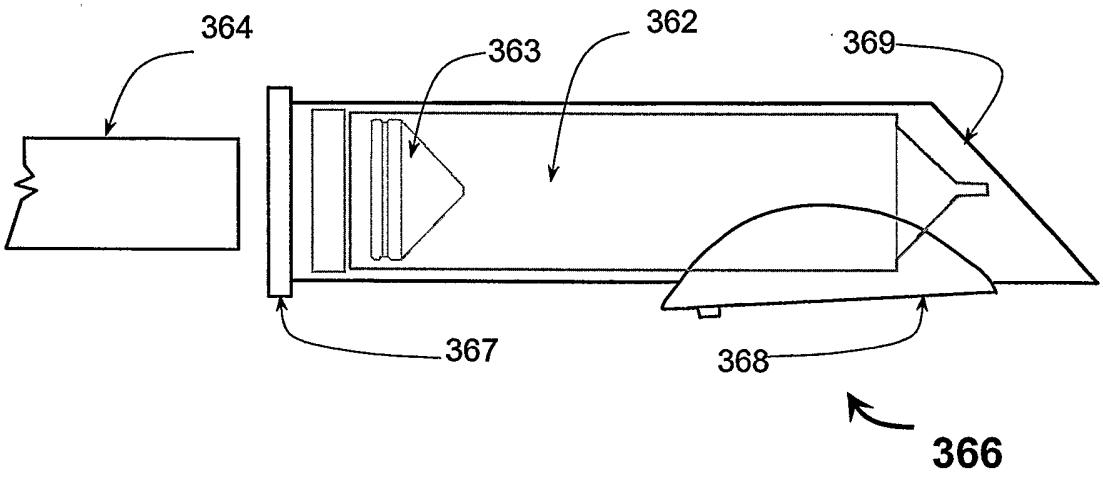


Figure18(d)(iii)

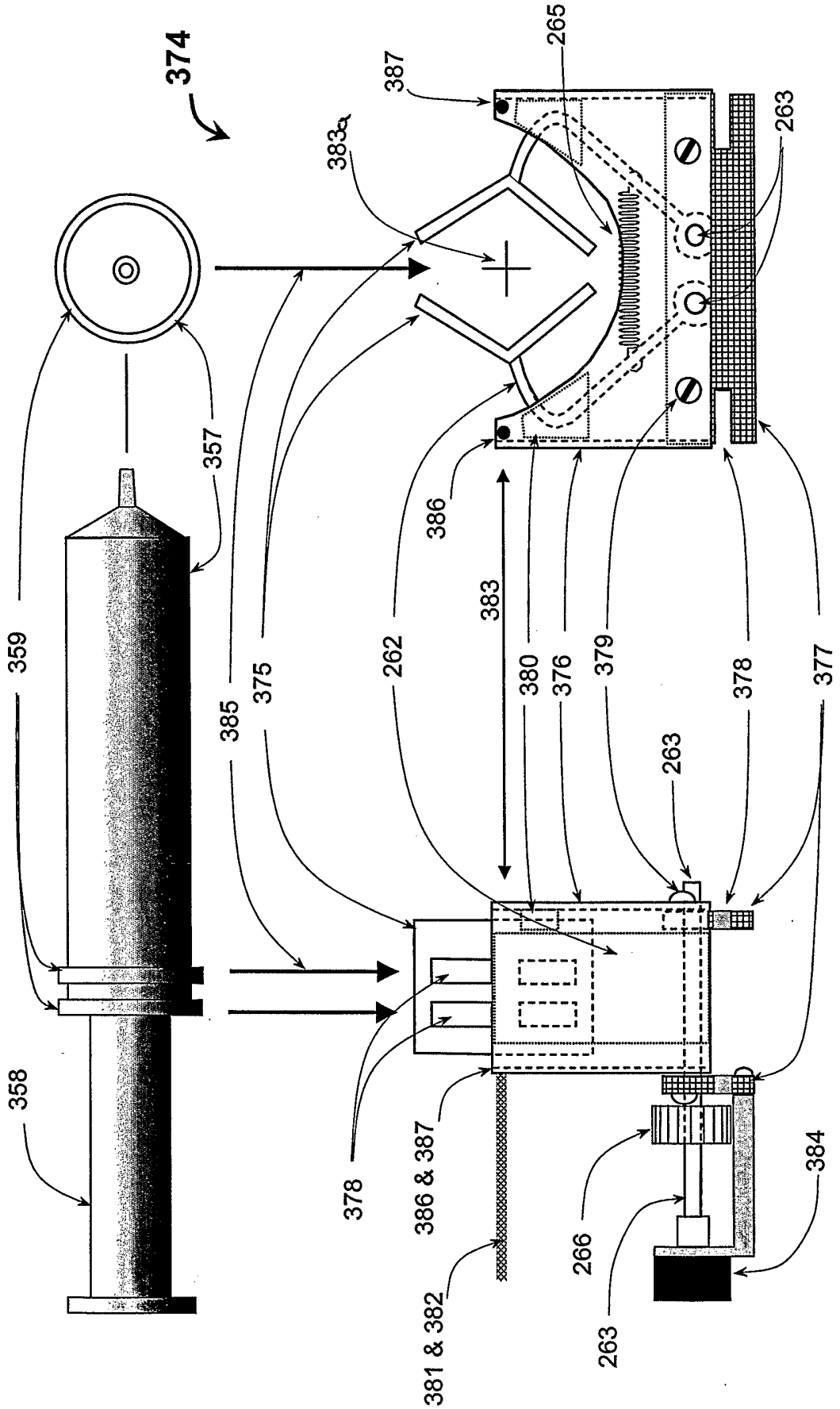


Figure 18(f)

Figure 18(e)

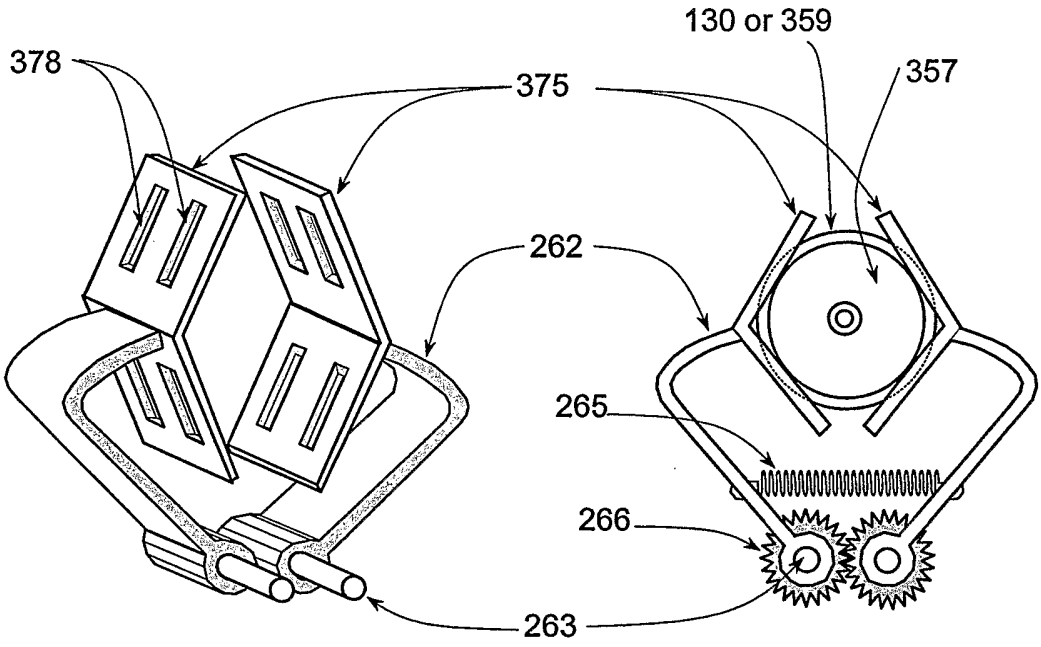


Figure 18(g)

Figure18(h)

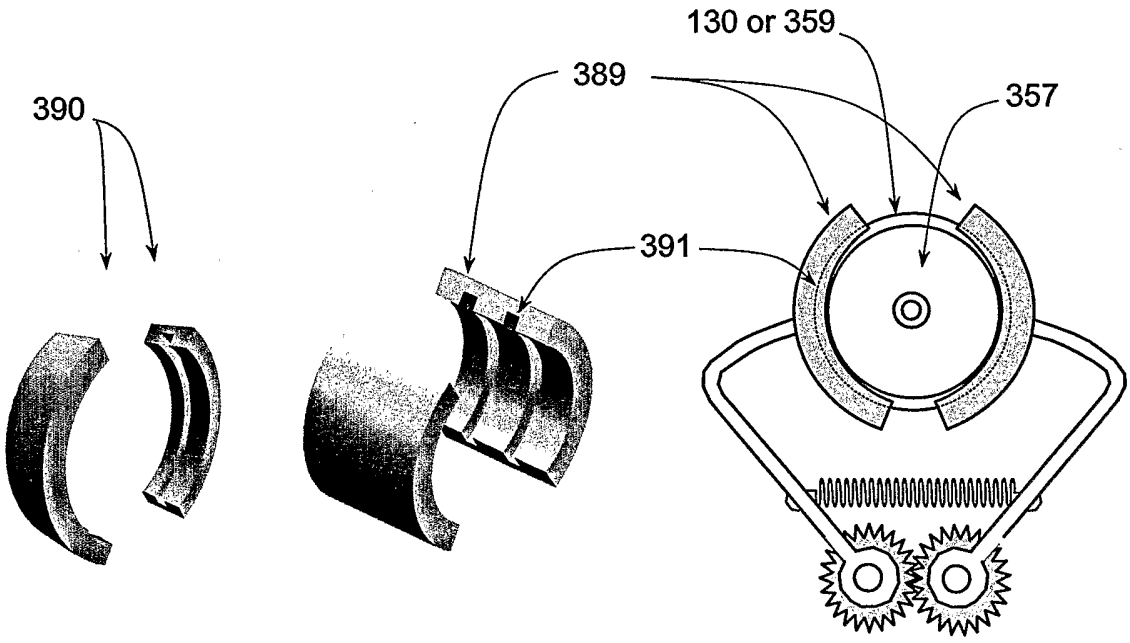


Figure 18(i)

Figure 18(j)

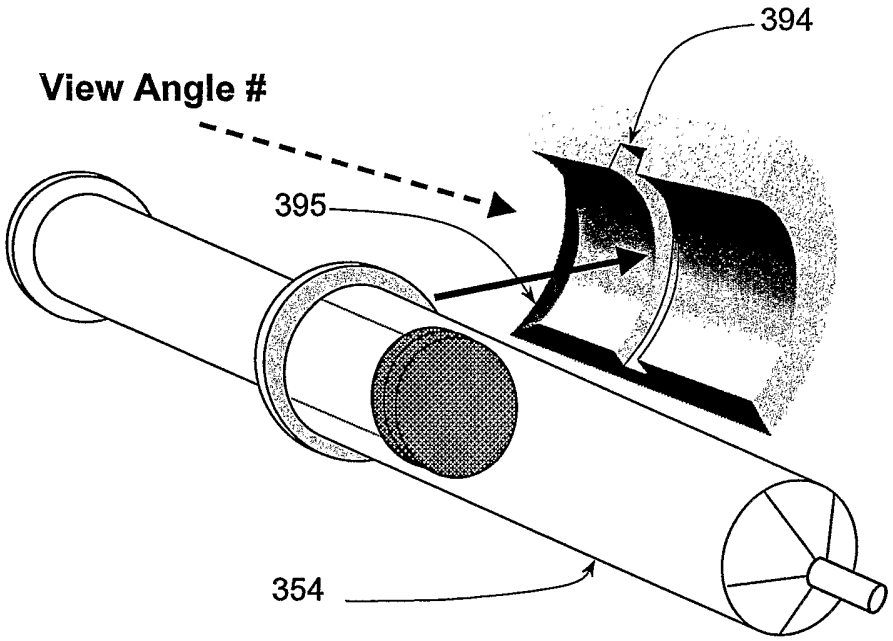


Figure 18(k)

393

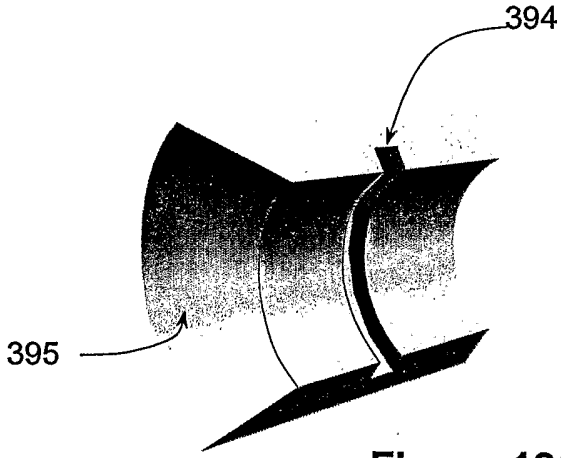
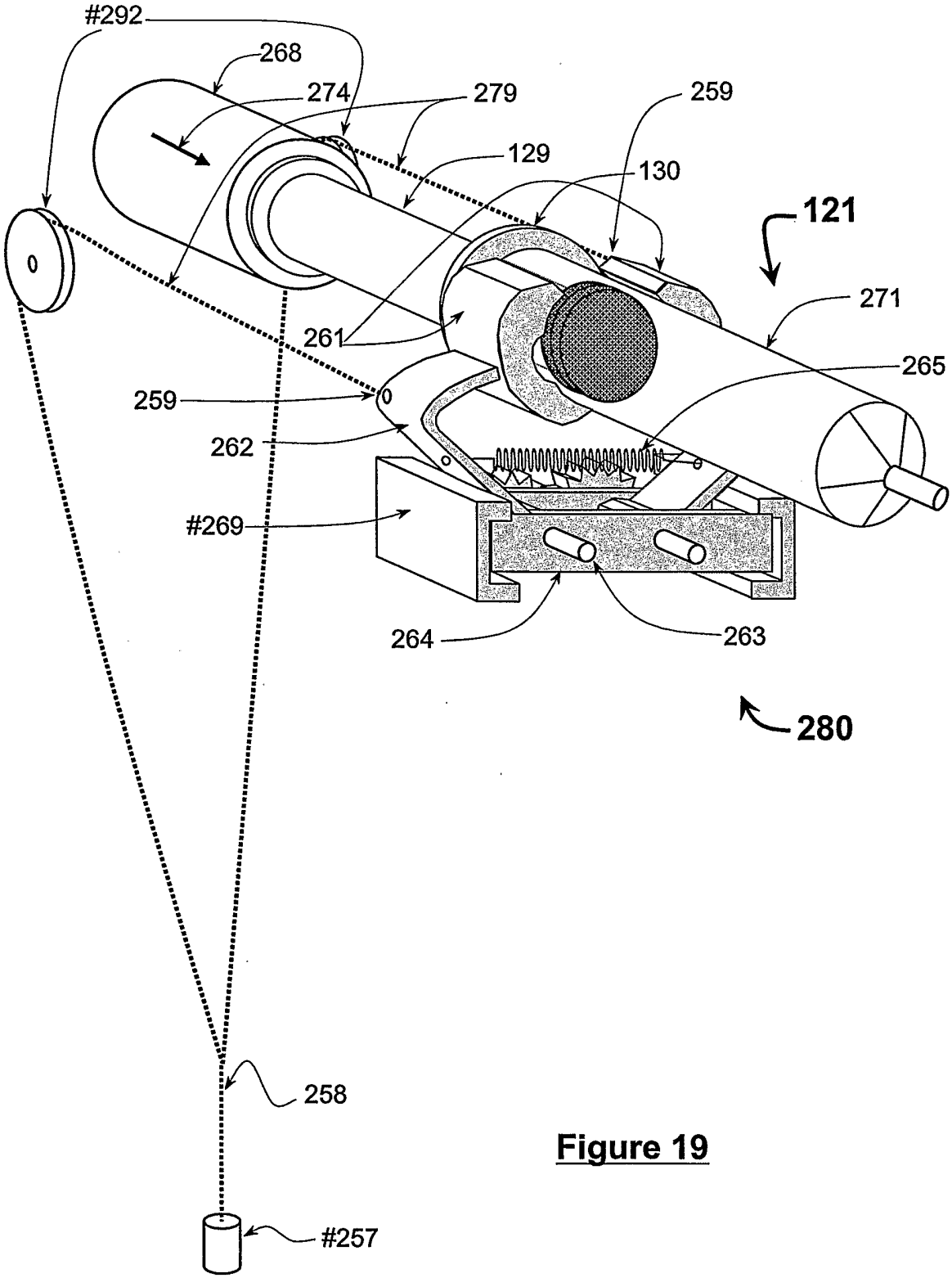


Figure 18(l)


#292
268
274
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121
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#269
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#257

Figure 19

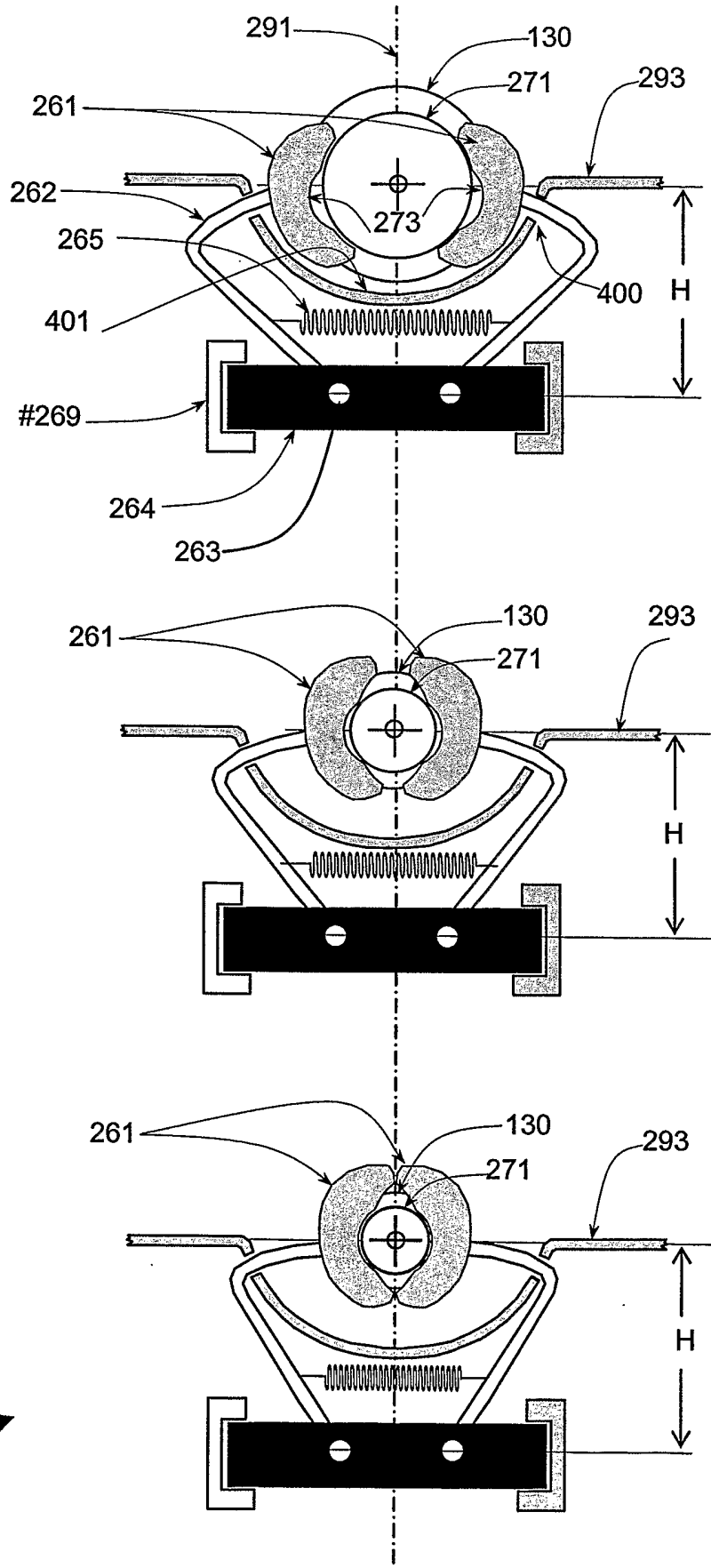


Figure 20 (a)

Figure 20 (b)

Figure 20 (c)

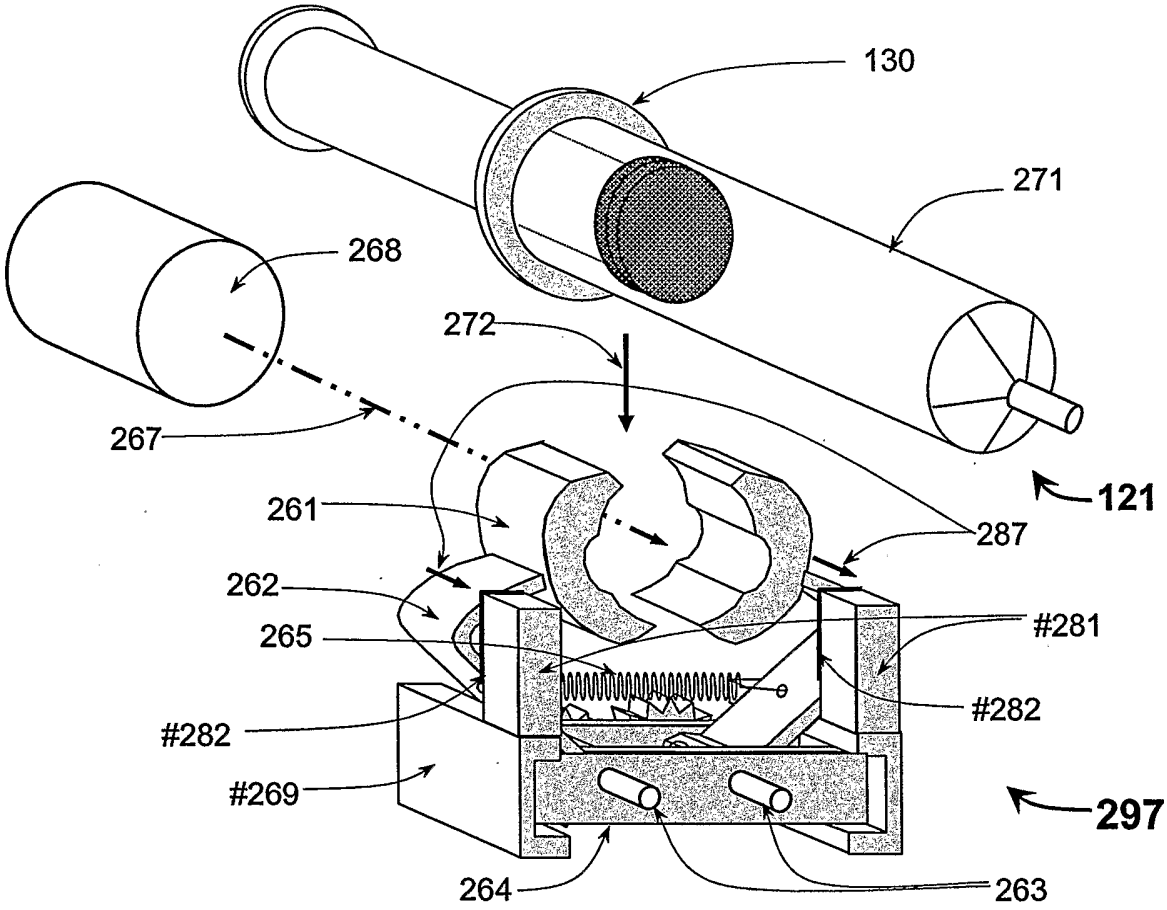


Figure 21 (a)

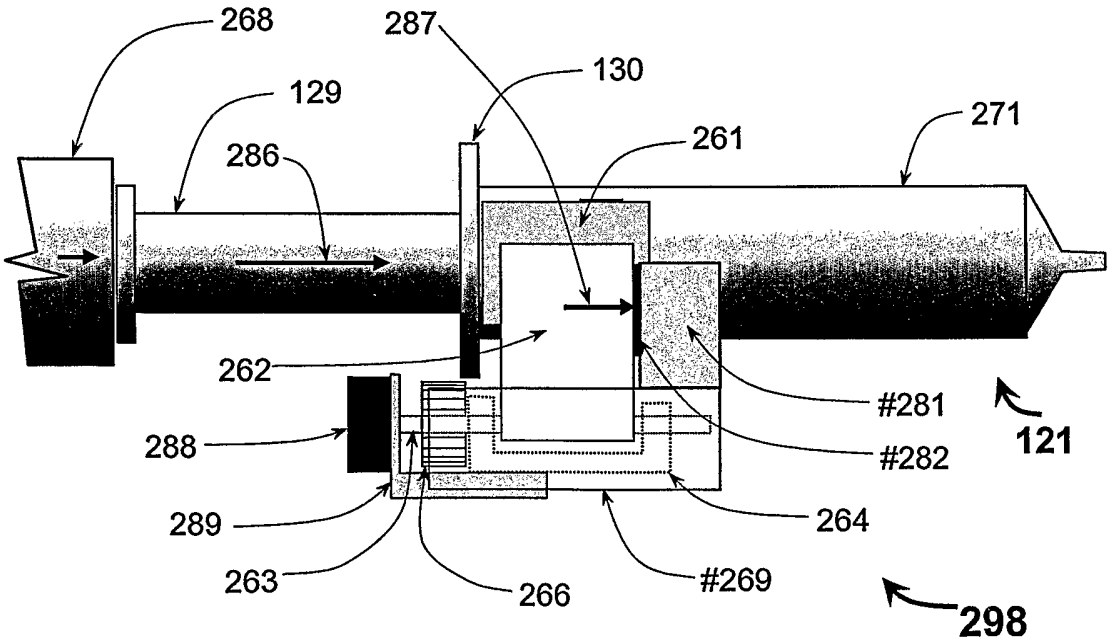


Figure 21 (b)

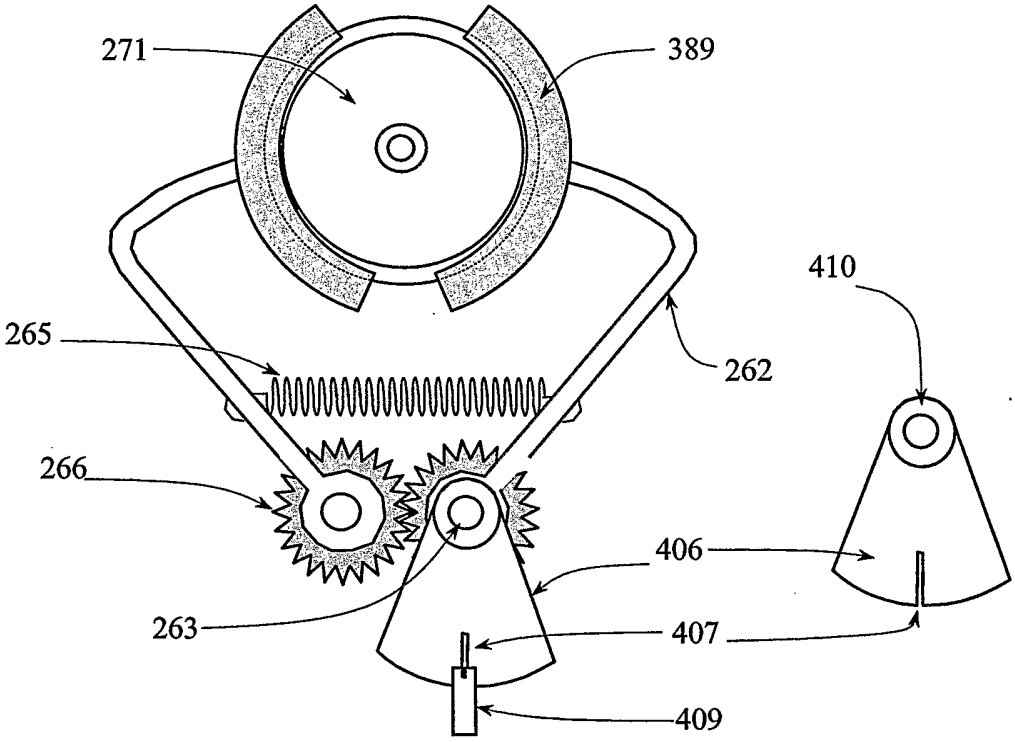


Figure 21(c)

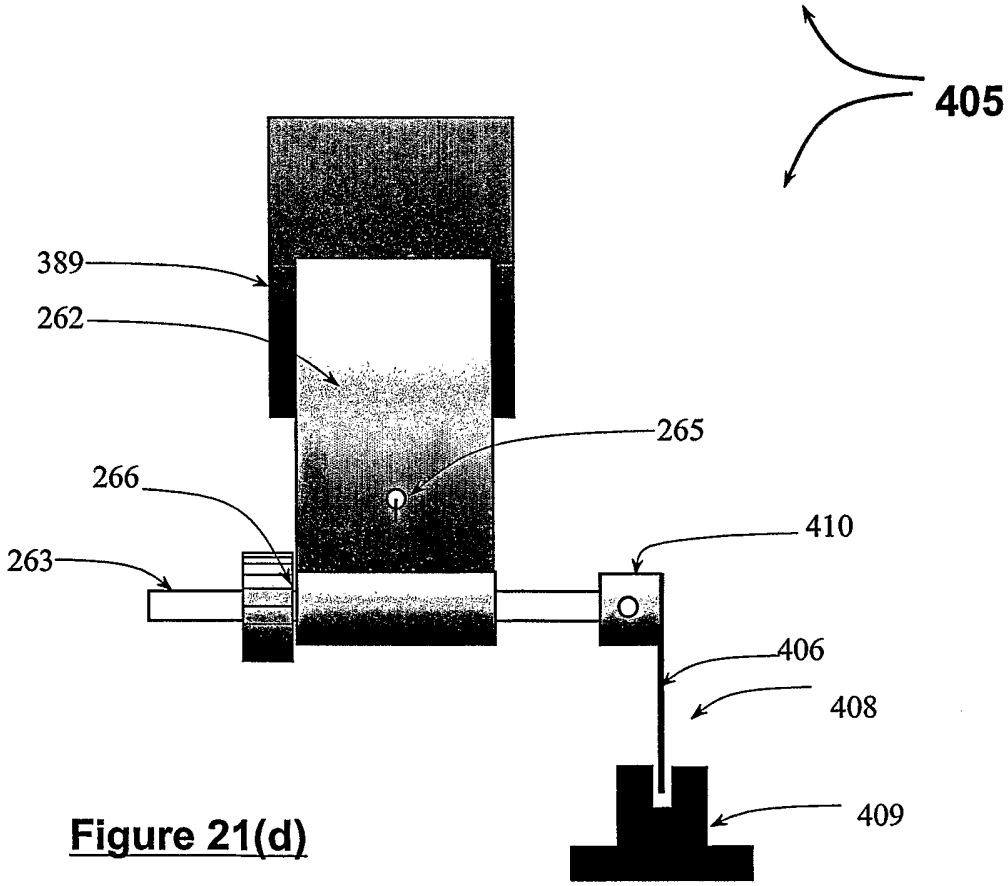
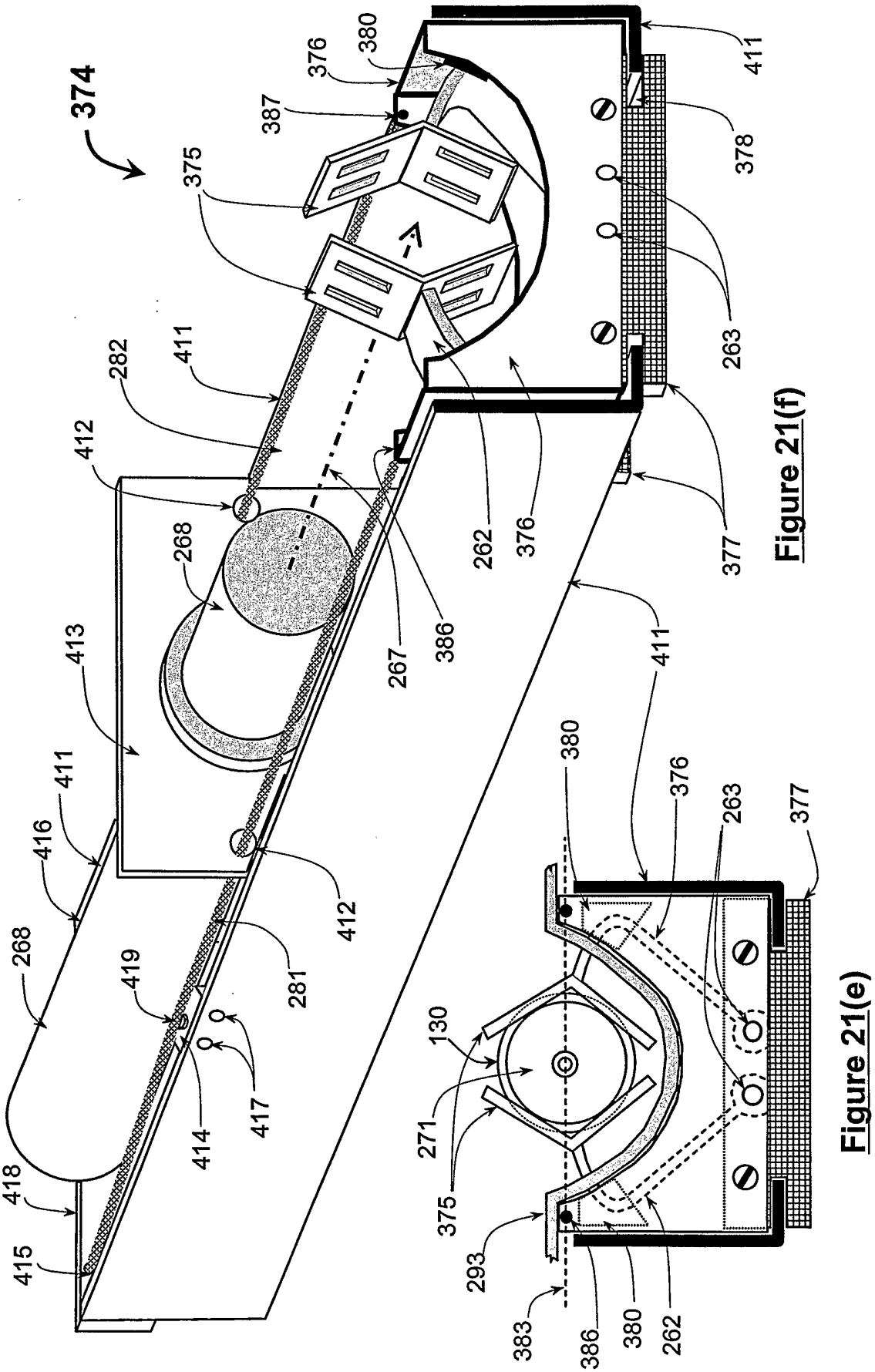


Figure 21(d)


374
375
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263
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268
262
377
267
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281
419
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417
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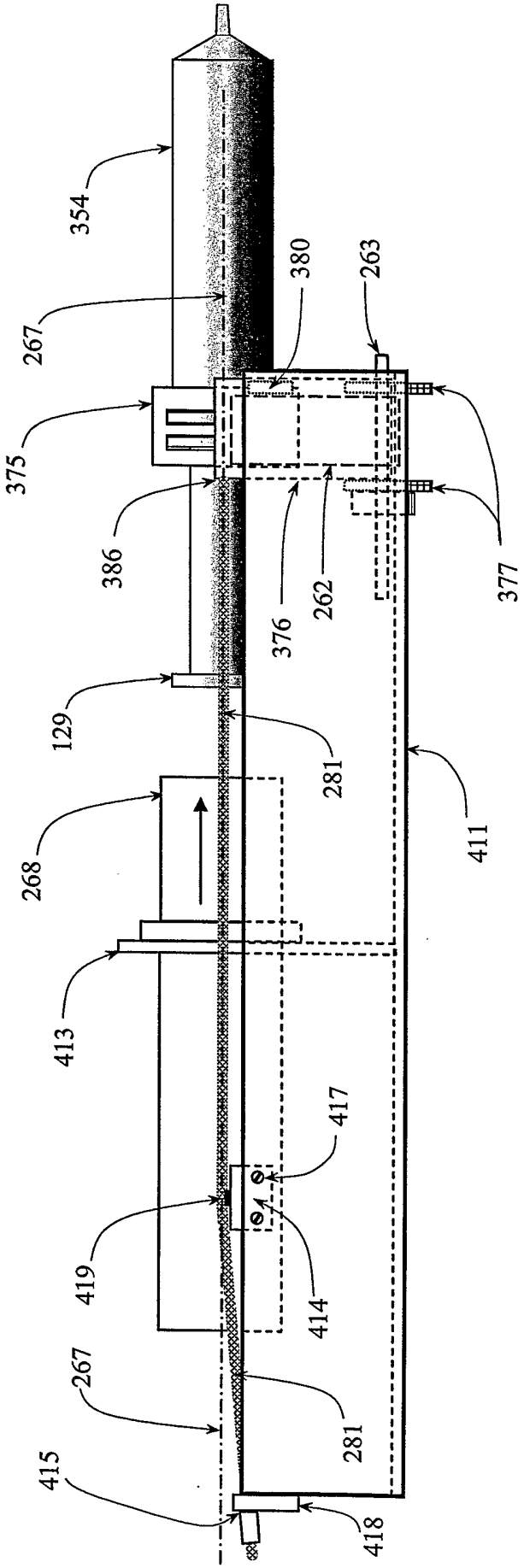
415
416
130
271
293
383
Figure 21(f)
Figure 21(e)


354
380
263
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377
129
281
411
268
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267
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418

Figure 21(g)

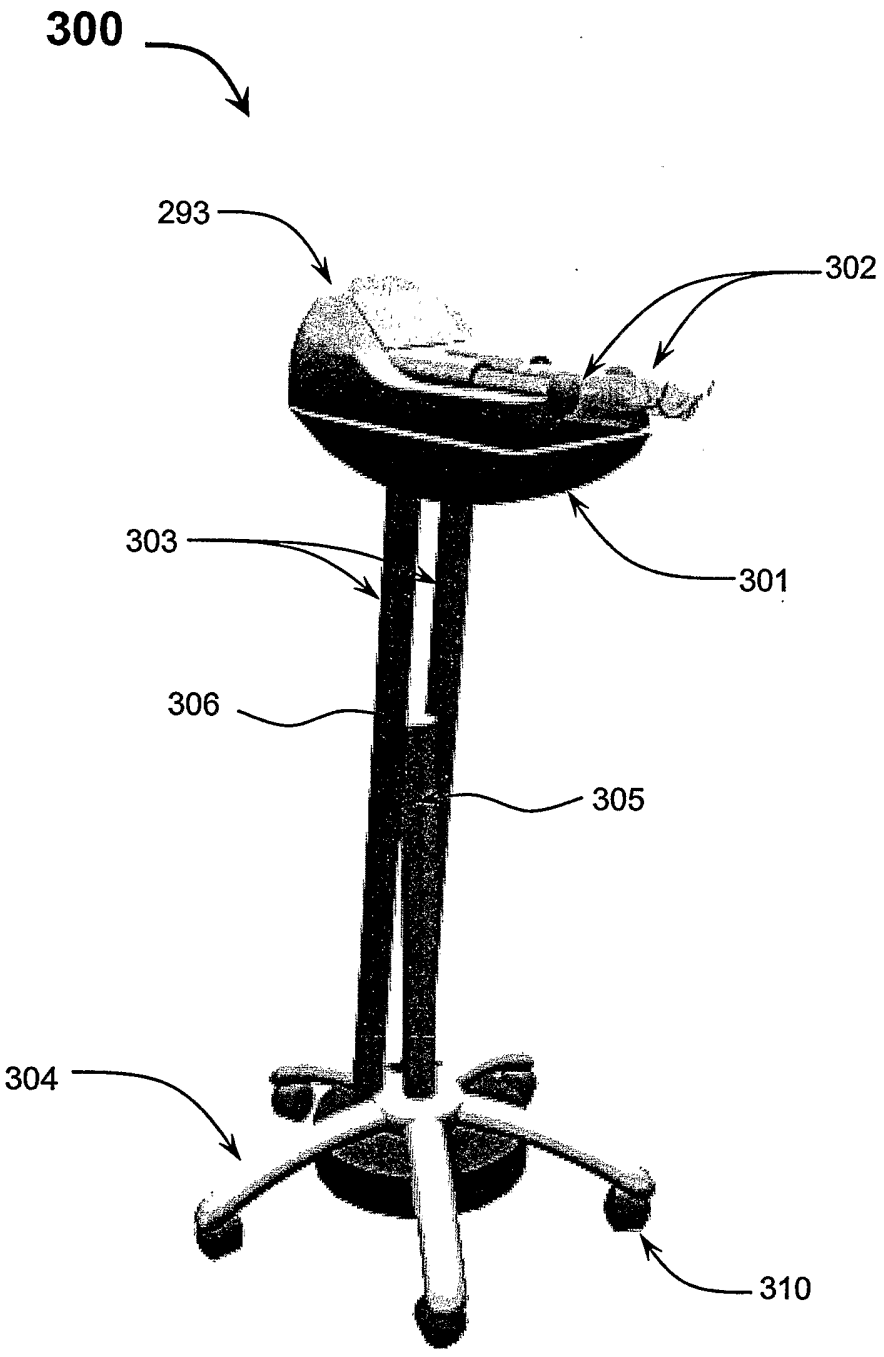

Fig 22.

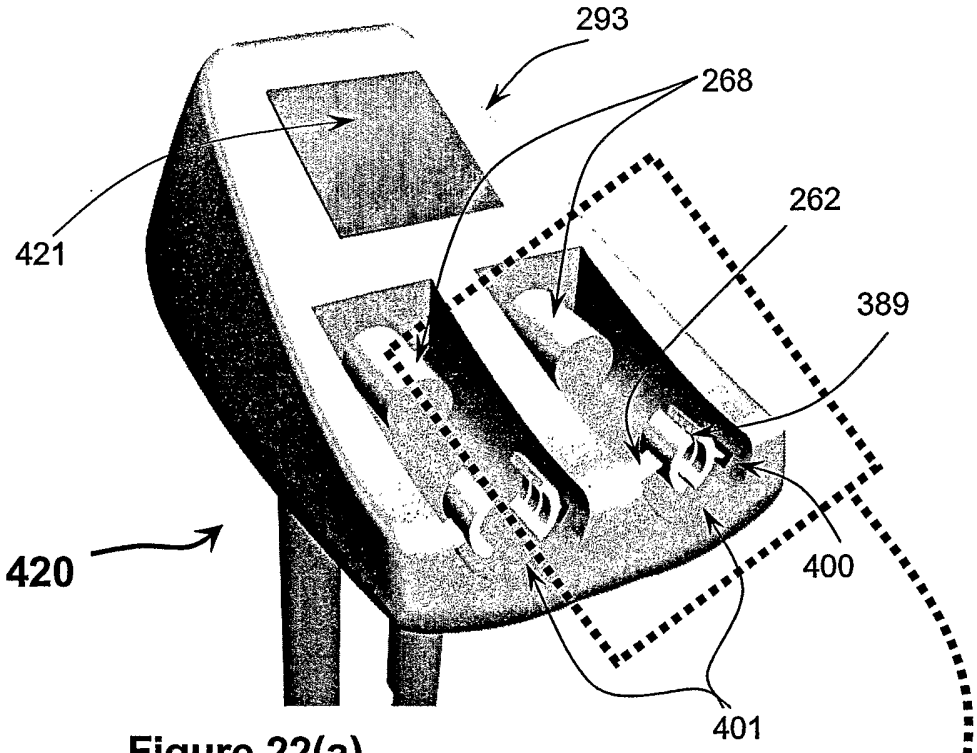

Figure 22(a)

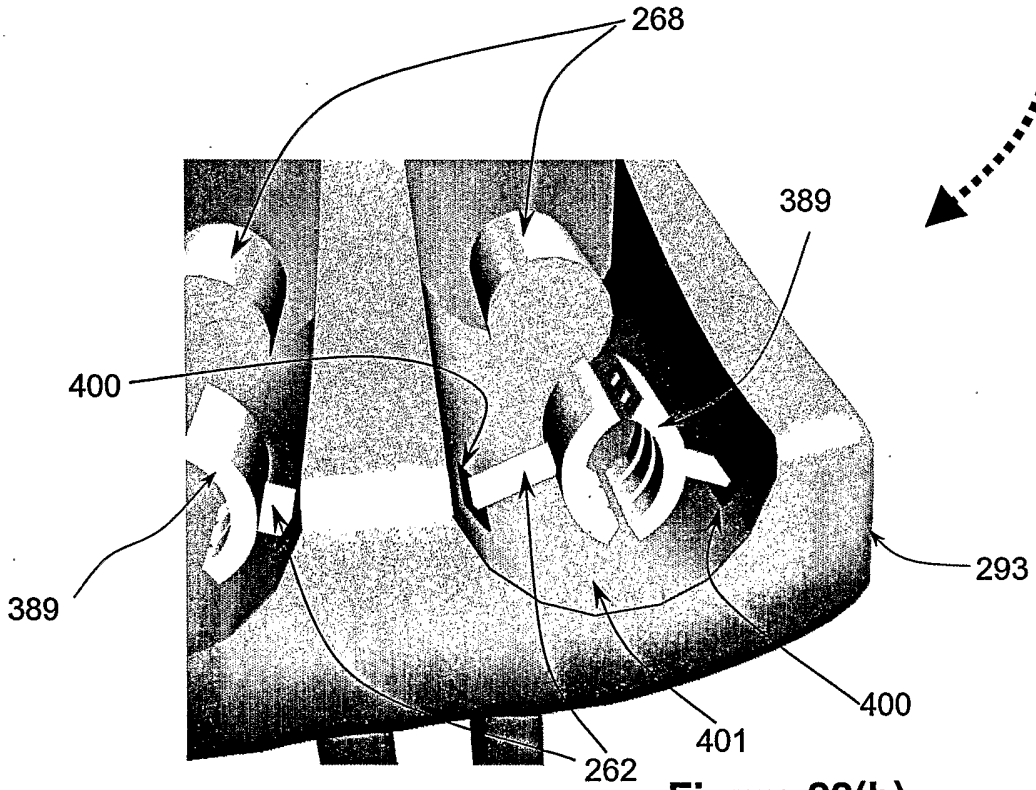

Figure 22(b)

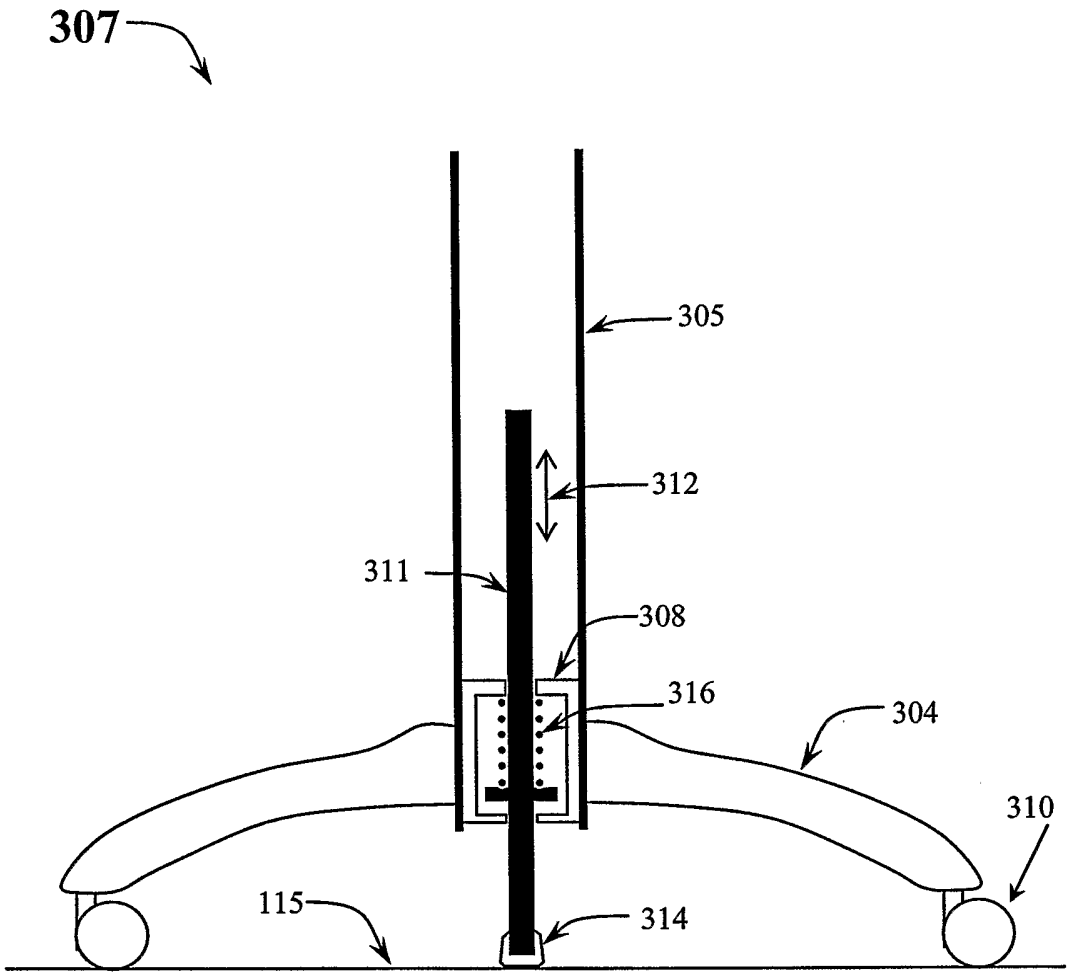

Fig 23

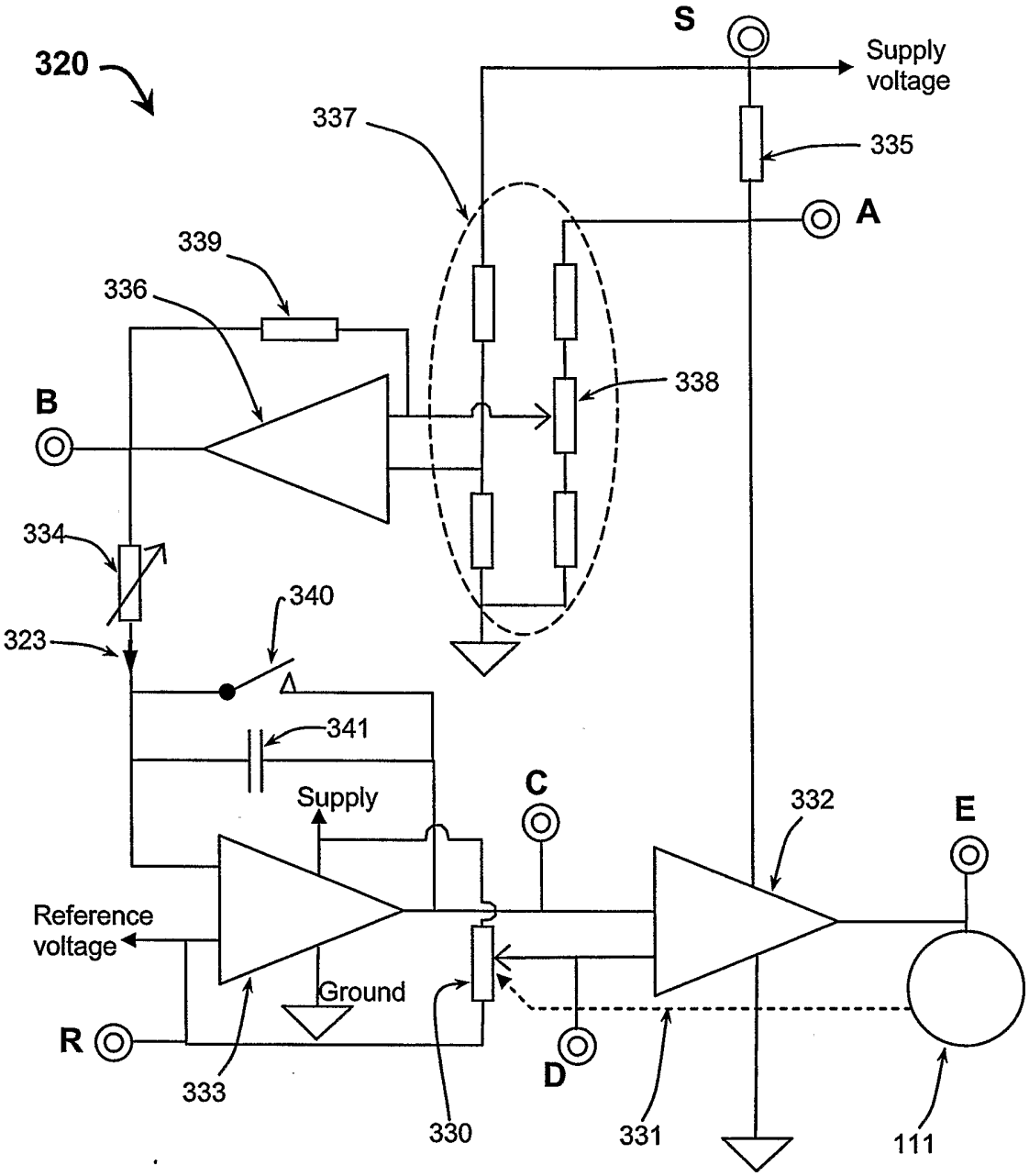
320
S
Supply voltage
337
335
A
339
336
338
B
334
340
323
341
Supply
C
332
E
Reference voltage
Ground
R
D
333
330
331
111

Fig 24.

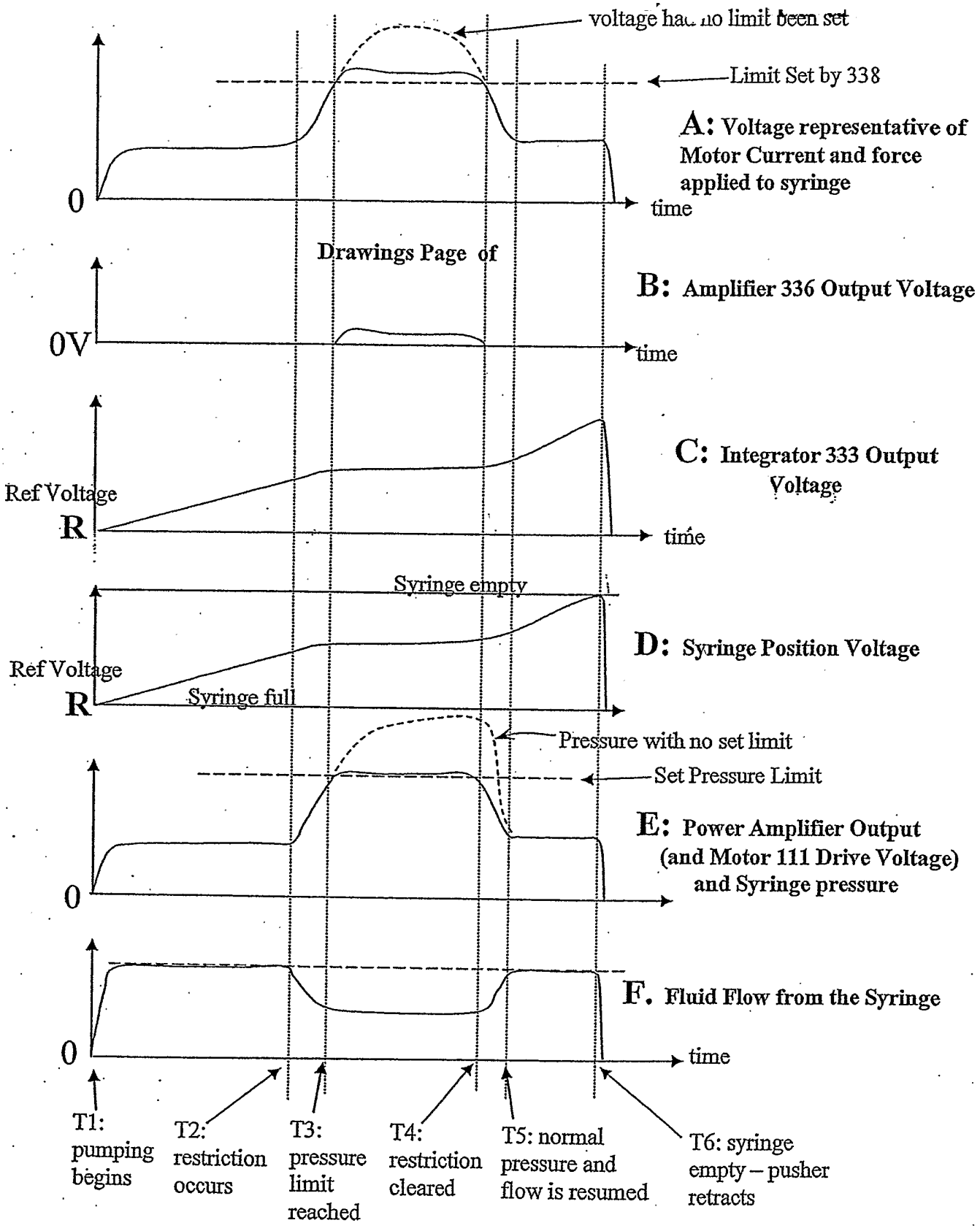
voltage has no limit been set
Limit Set by 338
A: Voltage representative of Motor Current and force applied to syringe
0
time
Drawings Page of
B: Amplifier 336 Output Voltage
0V
time
C: Integrator 333 Output Voltage
Ref Voltage
R
time
Syringe empty
D: Syringe Position Voltage
Ref Voltage
R
Syringe full
Pressure with no set limit
Set Pressure Limit
E: Power Amplifier Output (and Motor 111 Drive Voltage) and Syringe pressure
0
F. Fluid Flow from the Syringe
0
time
T1: pumping begins
T2: restriction occurs
T3: pressure limit reached
T4: restriction cleared
T5: normal pressure and flow is resumed
T6: syringe empty – pusher retracts

Fig 25.

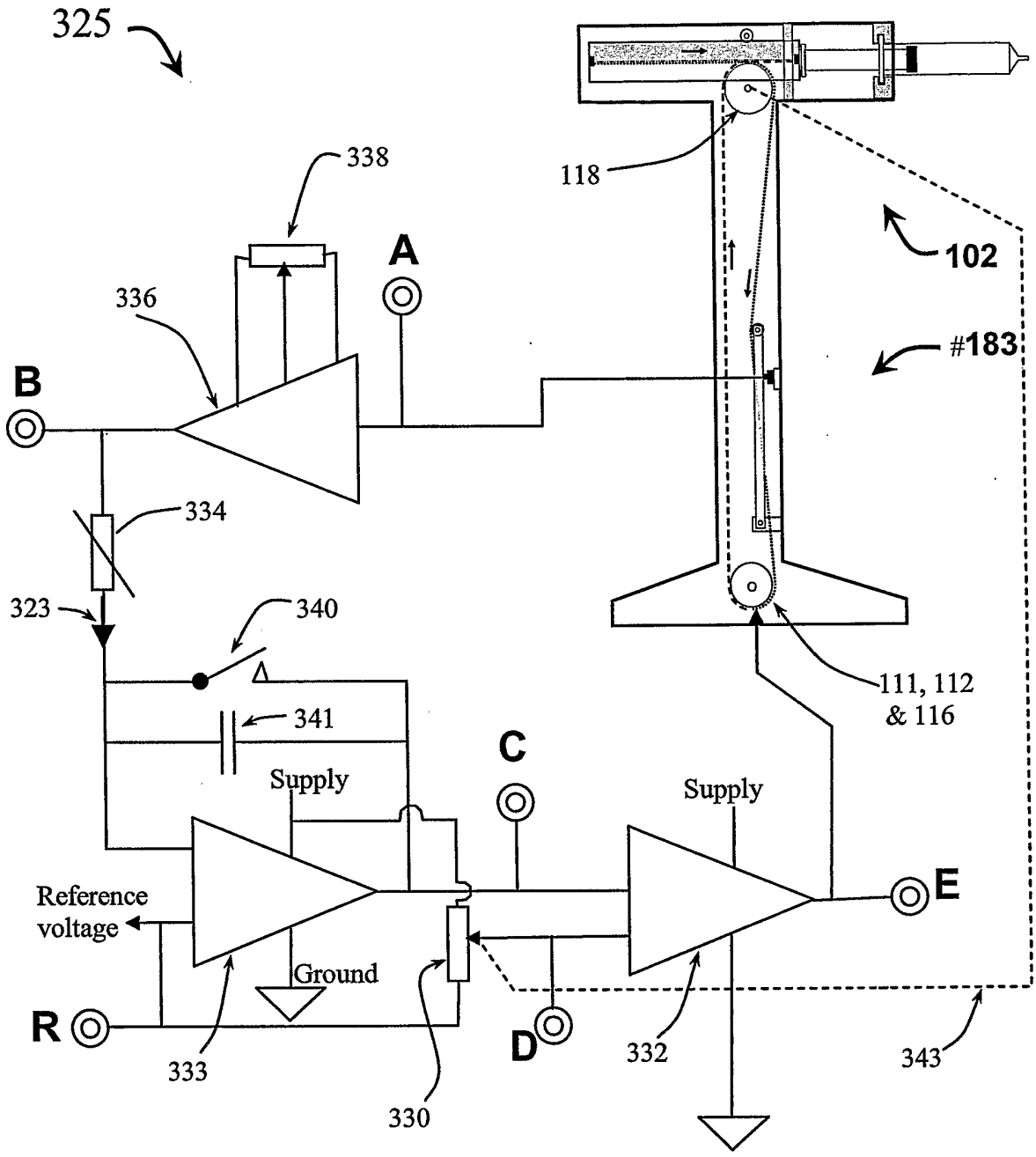
325
338
118
102
A
336
#183
B
334
323
340
111, 112
& 116
341
C
Supply
Supply
Reference
voltage
E
Ground
R
D
333
330
332
343

Fig 26.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2005/000583

A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl. [7]: A61M 5/145 A61B 6/00 G01R 33/28

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)

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 practicable, search terms used)
DWPI JAPIO: A61M A61B medical surgery surgical inject dispense squirt deliver syringe infuse drive motor power electric pump cable wire cord chain belt rope pulley wheel separate isolate space remote remove distant inject fluid interfere disrupt affect effect distort contrast media bubble base stand station platform

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
	WO 1997045749 A1 (BACKES) 4 December 1997	
X	Figure 2, abstract, page 6 line 25 to page 7 line 12	1-3, 7-21, 32-35, 41, 108
Y		4-6
	WO 2002/082113 A2 (MEDRAD, INC.) 17 October 2002	
X	Figures 1 and 2, page 8 paragraph 22 to page 9 paragraph 24	1-3, 7-21, 32-35, 41, 108
Y		4-6
	US 3880138 A (WOOTTEN et al) 29 April 1975	
A	Column 4 line 52 to column 5 line 41, figure 5	1, 108

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

Date of the actual completion of the international search	Date of mailing of the international search report
29 June 2005	4 JUL 2005
Name and mailing address of the ISA/AU	Authorized officer
AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	**MATTHEW FORWARD** Telephone No : (02) 6283 2606

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2005/000583

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4006736 A (KRANYS et al) 8 February 1977 Abstract and figure 28	1, 108
A	JP 5-84296 A (NEMOTO KIYOURINDOU KK) 6 April 1993 Abstract and figure 1	1. 108
A	US 5968015 A (YAMAMOTO) 19 October 1999 Figures	1, 108
A	WO 2001092907 A2 (MEDRAD, INC.) 6 December 2001 Figure 1	1, 108
Y	FR 2592307 A1 (GUEZ) 3 July 1987 Figures 3 and 7	4-6
Y	FR 2683140 A1 (DERIEN) 7 May 1993 Figure 1	4-6
P, A	WO 2004065544 A2 (AMNIS CORPORATION) 5 August 2004 Abstract	1, 108
P,A	JP 2004-162647 A (HOYUTEC KK) 10 June 2004 Abstract and figure 2	1, 108

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2005/000583

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

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

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

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

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

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

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

See Supplemental Box

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying 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.: **1 to 63 and 108**

Remark on Protest

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

☐ No protest accompanied the payment of additional search fees.

Supplemental Box
(To be used when the space in any of Boxes I to VIII is not sufficient)

Continuation of Box No: III

The international application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept. In coming to this conclusion the International Searching Authority has found that there are different inventions as follows:

1. Claims 1 to 63 and 108 define an injection unit with a head portion to receive a fluid container, a base housing a drive means and an elongate portion that supports the head and houses a cable drive transfer means between the drive and the injector. It is considered that an injection with these features comprises a first "special technical feature".

2. Claims 64 to 85 define a syringe holder having a base portion, two arms mounted to the base by hinges at a first end and having gripping element on the second end and biasing means to bias the arms into a holding position. It is considered that such a syringe holder for an injection unit comprises a second special technical feature.

3. Claims 86 to 96 recite a method of operating an injector unit by loading the unit with a container "containing the fluid to be injected, sensing a parameter associated with the container and controlling delivery of the fluid in response to the sensed parameter. It is considered that these method steps comprise the third special technical feature.

4. Claims 97 to 107 define an injector unit having a holder for holding and receiving a fluid container, an injecting means for applying a force to the container and a sensor for measuring the force applied by the injecting means to the holder. It is considered that an injector unit having these features comprises the fourth special technical feature.

Since the abovementioned groups of claims do not share any of the technical features identified, a "technical relationship" between the inventions, as defined in PCT rule 13.2 does not exist. Accordingly the international application does not relate to one invention or to a single inventive concept, a priori.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/AU2005/000583

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member					
WO	1997045749	DE	19621393				
WO	2002082113	US	2003050555				
US	3880138	DE	2410868	FR	2221157	JP	50026487
		US	3812843				
US	4006736	DE	2500851				
JP	5-84296	NO	FAMILY				
US	5968015	JP	10244002				
WO	2001092907	EP	1297351	US	6704592	US	2003058502
		US	2004030233				
WO	2004065544	US	2004174122	US	2004220472	WO	2004066675
JP	2004-162647	NO	FAMILY				
FR	2592307	NO	FAMILY				
FR	2683140	NO	FAMILY				

Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.

END OF ANNEX