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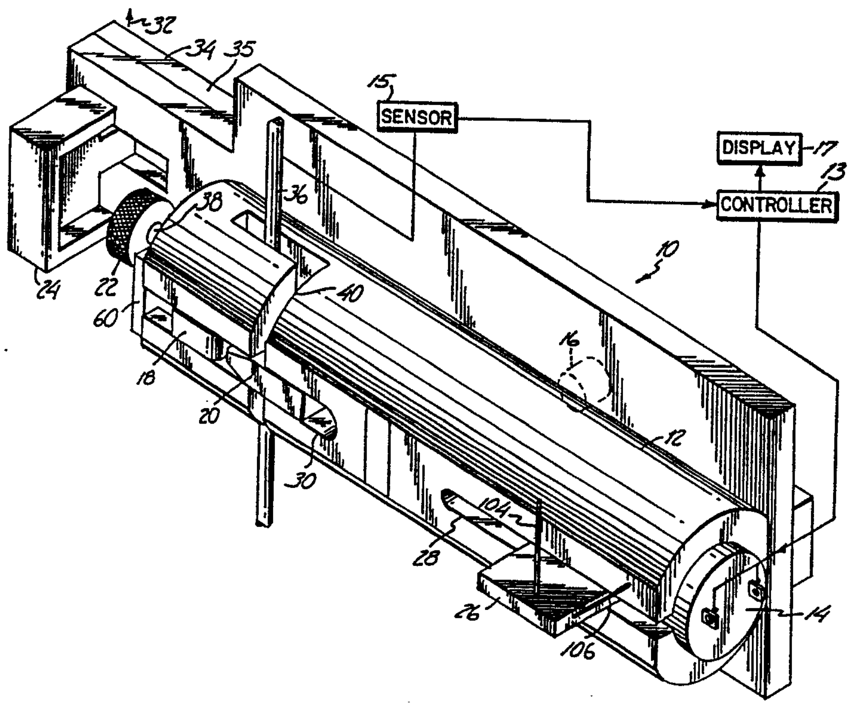

(57) Abstract

The present invention relates to an automatic clamp for controlling flow rate of IV fluid in an infusion device. The invention includes a first clamping member (18) which is operably coupled to the clamp housing (12). The housing includes a second clamping member (20). Activation of the clamp motor (14) causes variable restriction of the IV tube between first clamping member (18) and second clamping member (20).

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AUTOMATIC IV CLAMP

INCORPORATION BY REFERENCE

The following patent application is hereby incorporated by reference:

The Archibald U.S. utility patent application serial no. 07/458,286 for SPRING POWERED FLOW RATE IV CONTROLLER filed December 28, 1989.

BACKGROUND OF THE INVENTION

The present invention relates to an intravenous (IV) infusion device. More particularly, the present invention relates to an automatic clamp for controlling flow rate of IV fluid in an infusion device.

Infusion devices are used to deliver (IV) fluids to patients. A typical infusion device includes a fluid source or reservoir, a drip chamber and an IV tube set. Fluid drips from the reservoir through the drip chamber into the IV tube. The rate at which the fluid drips from the fluid reservoir is proportional to the flow rate of the fluid through the IV tube.

Physicians often require IV fluid to be delivered to patients at a certain rate. Therefore, it is necessary to control the flow rate of the IV fluid through the IV tube.

In the past, flow rate controllers were developed which used electromechanical devices to apply a pinching force to the IV tube. By pinching the IV tube, the flow of IV fluid through the IV tube was restricted and the flow rate was controlled. The degree of flow restriction varied based on a feedback system.

However, typical IV tubes are formed of a material having a certain resilience. Most of the pinching force required to restrict flow of IV fluid through the IV tube is needed to overcome the resilience of the IV tube. Therefore, an IV controller requires a large amount of electrical energy to drive the electromechanical pinching device. This is especially true where the pinching device is used with a standard set of IV tubes because of the stiffness of the IV tubes. For an IV controller of this type to be provided with an adequate amount of electrical energy, it must either by connected to an AC source or have a large battery. In either case, this type of IV device is not a practical device to be used with ambulatory patients.

For these reasons, there have been several attempts to provide the medical community with an IV control device that is small and that contains its own power source. One example is the Danby U.S. Patent No. 4,533,350 which utilizes a battery for control power. In order to keep the power requirements of the controller low, a special IV tube set having a special control valve is used. The special IV tube set is designed to decrease the amount of pinching force required to restrict flow in the IV tube in order to achieve a corresponding decrease in the power requirements of the controller.

Similarly, the Krumme U.S. Patent No. 4,645,489 illustrates an attempt to provide a small IV control device with self-contained energy requirements. The device in Krumme uses a shaped memory alloy driven by electrical energy to provide the pinching force. However, as with Danby, the Krumme patent requires a special IV tube set to reduce the required pinching force.

Because of the special IV tube sets required in both the Danby and Krumme patents, the cost of the IV device is higher than it would be if a standard IV tube set were used. Additionally, this extra cost is recurring each time the device is used since a new IV tube set is required for each infusion.

Another technique for controlling the flow of fluid in an IV tube involves a simple mechanical clamp. The flow rate through the IV tube is initially set by an attending medical person observing the drip rate in the drip chamber. The clamp is adjusted to maintain a set flow rate. Periodically, the attending medical person returns to the IV set, monitors the flow rate and adjusts the mechanical clamp. There is no automatic feedback system for variably controlling the clamp to adjust the flow rate to compensate for deviations caused by varying environmental conditions such as hydrostatic pressure or venous pressure. Hence, the technique is inefficient because of the time required by the attending medical person to periodically monitor and adjust the mechanical clamp. In addition, this technique requires the attending medical person to make an accurate determination of the flow rate each time the mechanical clamp is adjusted. Therefore, errors are likely.

Spring power has been used in the past to propel the IV fluid from the reservoir. For example, the Brown U.S. Patent No. 4,741,736 teaches a programmable infusion pump which has a constant force spring to force the fluid from the reservoir. However, flow restriction is controlled by a mechanical screw clamp which is not automatically variable.

Other spring power propulsion devices are taught by the Muller U.S. Patent No. 3,384,080; the Hargest U.S. Patent No. 3,647,117; the Hill U.S. Patent No. 3,670,926 and the Sealfon U.S. Patent No. 4,447,232.

All of these devices teach the use of spring driven pumps to force the IV fluid from the reservoir.

SUMMARY OF THE INVENTION

The present invention provides an IV flow rate controller with low power requirements. Therefore, the controller is compact and can be supplied with power by a small source.

The present invention includes a clamp motor coupled to a clamp housing. A first clamping member is operably coupled to the clamp housing and is manually adjustable. A second clamping member is also coupled to the clamp housing. The first and second clamping members are suitable for placement of an IV tube between them. Activation of the clamp motor causes variable restriction of the IV tube between the first clamping member and the second clamping member. A spring abuts the second clamping member and a spring stop and has a spring force variably applied to the IV tube through the second clamping member as the first clamping member is manually adjusted. The spring force and the tube resilience are substantially in equilibrium when a desired flow rate is manually set.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is an isometric view of an automatic IV clamp of the present invention.

FIG. 2 is an exploded view of a portion of the automatic IV clamp shown in FIG. 1.

FIG. 2A is a top view of the portion of the automatic IV clamp shown in FIG. 2.

FIG. 3 is a side sectional view of a differential motor coupling suitable for use with the present invention.

FIG. 4 is a view showing a guard and cable assembly of the automatic IV clamp of the present invention.

FIG. 5 is a top view showing the guard and cable assembly shown in FIG. 4.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

1. Overview

FIG. 1 is an isometric view of automatic IV clamp 10, controller 13, flow sensor 15 and display 17. IV clamp 10 includes clamp housing 12, clamp motor 14, coupling lock 16, first clamping member 18, second clamping member 20, manual adjustment knob 22 and adjustment guard 24. Motor 14 is slidably coupled within clamp housing 12 and is rigidly coupled to plate 26. Plate 26 is slidably mounted within housing 12 and slides along slot 28 in housing 12.

Second clamping member 20 is coupled to motor 14 via a differential coupling mechanism described in detail later in the specification. Coupling lock 16 is also coupled to the differential coupling mechanism and is slidable within clamp housing 12. Coupling lock 16 slides in a slot similar to slot 28.

First clamping member 18 is also slidable within clamp housing 12. Second clamping member 20, along with first clamping member 18, slides within slot 30 of clamp housing 12 and a corresponding slot (not shown) opposite slot 30 in clamp housing 12. First clamping member 18 is also coupled to manual adjustment knob 22.

Adjustment guard 24 is pivotally coupled, along axis 32, to side plate 34. Mounting plate 35 is coupled to side plate 34. Adjustment guard 24 will be described in greater detail later in the specification.

Automatic clamp 10 is operated in substantially three steps. First, an IV tube 36 is inserted into clamp 10 between first and second clamping members 18 and 20. Next, clamp 10 is manually adjusted by an operator to set a desired flow rate of IV fluid through IV tube 36. Then, controller 13 controls activation of motor 14 to control restriction of IV tube 36 by manipulating second clamping member 20. Controller 13 controls motor 14 based on the desired flow rate manually set and the flow rate through IV tube 36 which is sensed by flow sensor 15. In this preferred embodiment, flow sensor 15 is an optical sensor such as that described in U.S. utility patent application serial no. 07/458,286 to Archibald which is incorporated by reference.

To prepare clamp 10 for insertion of IV tube 36, an operator raises adjustment guard 24 from its guarding position (the position shown in FIG. 1) to an adjustment position by pivoting it, up away from adjustment knob 22, about axis 32. The operator then rotates adjustment knob 22 clockwise. Adjustment knob 22 is coupled to housing 12 via threaded shaft 38. Threaded shaft 38 cooperates with a threaded bore in adjustment block 60, which is attached to housing 12, and abuts first clamping member 18. Therefore, rotation of adjustment knob 22 clockwise causes first clamping member 18 to move toward second clamping member 20. By continuing to rotate adjustment knob 22 clockwise, both first and second clamping members 18 and 20 slide along slot 30 toward transverse insertion slot 40 located in clamp housing 12. When adjustment knob 22 is rotated far enough that the plane of intersection of first and second clamping members 18 and 20 is positioned within insertion slot 40, clamp 10 is in the tube insertion position and is ready for insertion of IV tube 36.

As second clamping member 20 slides along slot 30, motor 14 which is coupled to second clamping member 20, also slides back, away from manual adjustment knob 22 along slot 28. Controller 13 senses when first and second clamping members 18 and 20 are moved to the tube insertion position. This signifies to controller 13 that clamp 10 is in a set-up mode and, in order to save energy, controller 13 de-energizes flow sensor 15 and turns itself off.

Once tube 36 is inserted in slot 40, between first and second clamping members 18 and 20, the operator then begins rotating adjustment knob 22 counterclockwise. This causes adjustment knob 22 to move back, away from housing 12. First clamping member 18 slides back along slot 30 with threaded shaft 38. As first clamping member 18 slides back along slot 30, IV tube 36 becomes less restricted and a passage opens through the tubule of IV tube 36. Hence, flow of the IV fluid through IV tube 36 begins.

Controller 13 senses movement of first and second clamping members 18 and 20 out of the tube insertion position. Upon sensing this movement, controller 13 turns itself back on and re-activates flow sensor 15. As the IV fluid begins flowing through IV tube 36, controller 13 displays the flow rate sensed by flow sensor 15 at display 17.

The operator continues to rotate adjustment knob 22 counterclockwise, increasing the size of the passage through IV tube 36 and thereby increasing the flow of IV fluid through IV tube 36, until a desired flow rate is displayed at display 17. Then, the operator moves his or her hand from knob 22 and guard 24 pivots back automatically about pivot axis 32 into its guarding position down over adjustment knob 22. Guard 24, when in the guarding position, helps prevent accidental bumping or repositioning of adjustment knob 22 once the desired flow rate has been set by the operator.

The movement of guard 24 up away from adjustment knob 22 into the adjustment position is sensed by controller 13. This causes controller 13 to operate in a manual mode where it waits for a desired flow rate to be set by the operator. Controller 13 also senses movement of adjustment guard 24 back into the guarding position. Upon sensing movement of guard 24 back into the guarding position, controller 13 stores the current flow rate of IV fluid through IV tube 36 as the desired flow rate. In other words, movement of guard 24 back into the guarding position indicates that the operator has manually adjusted restriction of IV tube 36 to achieve a desired flow rate displayed at display 17. Controller 13 then enters an automatic mode. In the automatic mode, controller 13 controls motor 14 based on the flow rate sensed by flow sensor 15 as well as the desired flow rate set by the operator.

If flow sensor 15 senses a flow rate in IV tube 36 which is below the desired flow rate manually set by the operator, controller 13 activates motor 14 to reposition second clamping member 20 along slot 30 in order to decrease the restriction of IV tube 36 and, consequently, increase the flow of IV fluid through IV tube 36. On the other hand, if flow sensor 15 senses a flow rate which is greater than the desired flow rate set by the operator, controller 13 activates motor 14 to reposition second clamping member 20 along slot 30 to increase restriction of IV tube 36 and, hence, decrease the flow rate of the IV fluid through IV tube 36.

It should be noted that, in this preferred embodiment, a cover plate 33 (shown in FIG. 4), similar to plate 34, is coupled to housing 12 opposite plate 34. The only differences between plates 33 and 34 are that cover plate 33 only extends to adjustment block 60, contains a slot corresponding to slot 40 for tube insertion, and contains a slot corresponding to slot 28 for movement of plate 26.

2. Clamping Mechanism 11

a. The Clamp

FIG. 2 is an exploded view of clamping mechanism 11 of clamp 10 with housing 12 removed. FIG. 2A is a top view of clamping mechanism 11 shown in FIG. 2. FIG. 2 and FIG. 2A show that motor 14 is coupled to second clamping member 20 by several elements including drive shaft 68 (shown in phantom in FIG. 2A), differential coupler 42, and clamp shaft 46. Motor 14 is coupled by drive shaft 68 to differential coupler 42. Clamp shaft 46 has a threaded end 48 which protrudes through clearance hole 44 in spring block 56. Clamp shaft 46 also has tongue 50 which is inserted within and pivotally coupled to second clamping member 20 at pivot point 52.

Second clamping member 20 also cooperates with clamp spring 54. Clamp spring 54 engages spring block 56, which is rigidly attached to housing 12. Clamp spring 54 also engages spring recess 58 in second clamping member 20.

Adjustment block 60 is rigidly attached to housing 12 and is provided with a threaded bore 62.

Threaded bore 62 cooperates with threaded shaft 38 which is coupled to adjustment knob 22. Therefore, rotation of adjustment knob 22 causes threaded shaft 38 to move through threaded bore 62.

b. Adjustment for tube insertion

Rotation of adjustment knob 22 in the clockwise direction (the direction indicated by arrow 63) causes threaded shaft 38 to engage first clamping member 18 which, in turn, abuts second clamping member 20. Continued rotation of adjustment knob 22 in a clockwise direction causes both clamping members 18 and 20, as well as clamp shaft 46, differential coupler block 42, coupling lock 16, and motor 14, to slide with respect to housing 12.

Since spring block 56 is rigidly attached to housing 12, clamp spring 54 is compressed as second clamping member 20 slides toward spring block 56. Continued compression of clamp spring 54 causes greater and greater pressure to be exerted by second clamping member 20 against first clamping member 18. When first and second clamping members, 18 and 20 respectively, are moved to the IV tube insertion position, the pressure exerted by second clamping member 20 against first clamping member 18, due to the compression of clamp spring 54, is great enough to overcome the resilience of IV tube 36 and close off IV tube 36 completely. This is a fail-safe technique which substantially eliminates any unwanted fluid flow of IV fluid through IV tube 36 immediately after it is inserted in clamp 10.

Perfect alignment of clamping members 18 and 20 within housing 12 is difficult to achieve and maintain. For example, during insertion of IV tube 36, clamping members 18 and 20 may become misaligned or skewed in the manner shown in FIG. 2A. (This misalignment of clamping members 18 and 20 is normally very slight, but has been greatly exaggerated in FIG. 2A for clarity.) Therefore, tongue 50 of clamp shaft 46 is pivotally coupled within slot 51 of second clamping member 20 at pivot point 52. Because of the fit between slot 51 and tongue 50, second clamping member 20 is only capable of very limited pivoting with respect to clamp shaft 46 and housing 12. This small amount of pivoting, however, allows IV tube 36 to be inserted between clamping members 18 and 20 when clamping members 18 and 20 are moved to the tube insertion position.

c. Setting an initial flow rate

Once IV tube 36 is inserted and the operator wishes to set a desired initial flow rate, the operator begins rotating adjustment knob 22 in a counterclockwise direction. The cooperation of threaded shaft 38 with threaded bore 62 as well as the spring force exerted on second clamping member 20 by clamp spring 54 causes first and second clamping members 18 and 20 to slide away from spring block 56 within housing 12. Movement of second clamping member 20 away from spring block 56 also causes motor 14 and differential coupler 42 to slide toward spring block 56 within clamp housing 12.

As adjustment knob 22 is rotated in a counterclockwise direction, and as first and second clamping members 18 and 20 move away from spring block 56, the restriction force exerted by clamp spring 54 on IV tube 36 diminishes. At some point, the resilience of IV tube 36 begins to offset the compression force exerted by spring 54 resulting in an opening through the portion of the tubule of IV tube 36 clamped between first and second clamping members 18 and 20. As the operator continues to rotate adjustment knob 22, the size of the opening through IV tube 36 increases. This causes increased fluid flow of the IV fluid through IV tube 36.

Flow sensor 15 senses the increased flow and controller 13 displays the flow rate at display 17. When the flow rate reaches a desired point, the operator stops rotating adjustment knob 22, guard 24 rotates back into the guarding position shown in FIG. 1, and differential coupler 42 is locked in a fixed position with respect to clamp housing 12. Controller 13 senses movement of guard 24 into its guarding position and enters an automatic mode controlling activation of motor 14 based on the flow rate sensed and the desired flow rate set by the operator.

d. Differential Coupler 42

FIG. 3 is an enlarged sectional view showing the arrangement of differential coupler 42 with respect motor 14 and shaft 46. Coupling lock 16 is rigidly coupled to differential coupler 42. Differential coupler 42 has a threaded bore 64 which cooperates with threaded shaft 66. Threaded shaft 66 is rigidly attached to drive shaft 68 of motor 14. Threaded shaft 66 is also rigidly attached to an extended threaded bore 70. Threaded bore 70 cooperates with threaded end 48 of clamp shaft 46.

When guard 24 pivots into its guarding position, coupling lock 16 is locked in position with respect to housing 12. (This will be described in greater detail later in the specification). This, in turn, locks differential coupler 42 in position with respect to housing 12.

It can be seen that when the operator rotates adjustment knob 22 sufficiently to achieve the desired initial flow rate, the resilience of IV tube 36 is precisely in equilibrium with the clamping force exerted by clamp spring 54. If the operator were to rotate adjustment knob 22 in a clockwise direction, the clamping force exerted by compression spring 54 would become greater and greater until it eventually overcame the resilience of tube 36 and clamped it completely closed. On the other hand, if the operator continued to rotate adjustment knob 22 in a counterclockwise direction, the clamping force of clamp spring 54 would continue to decrease and the resilience of IV tube 36 would eventually overcome the clamping force, thereby fully opening the tubule of IV tube 36 for maximum IV fluid flow.

3. Operation

When controller 13 determines that the flow rate through IV tube 36 must be increased, controller 13 activates motor 14 to rotate drive shaft 68 in the clockwise direction (the direction indicated by arrow 72). This, in turn, causes rotation of threaded shaft 66 in the clockwise direction. Cooperation between threaded shaft 66 and threaded bore 64 causes threaded shaft 66 to move in the direction indicated by arrow 74 within threaded bore 64.

Rotation of threaded shaft 66 also causes rotation of extending threaded bore 70 in the clockwise direction. Cooperation of threaded bore 70 with threaded end 48 of clamp shaft 46 causes clamp shaft 46 to move in the direction indicated by arrow 76, with respect to threaded bore 70. In this preferred embodiment, the differential between the pitch of the threads in threaded bore 64 and the pitch of the threads in threaded bore 70 cause a net movement of clamp shaft 46 in the direction indicated by arrow 76 with respect to differential coupler 42 and housing 12. This effectively decreases the shaft length of clamp shaft 46 between coupler 42 and second clamping member 20. Hence, the second clamping member 20 is drawn towards spring block 56. This decreases the restrictive force of second clamping member 20 against IV tube 36 allowing the fluid passage through IV tube 36 to become larger and the flow rate of the IV fluid through IV tube 36 to become greater.

When controller 13 determines that the flow rate of the IV fluid through IV tube 36 should be decreased, based on the flow rate sensed by sensor 15 and the desired initial flow rate manually set by the operator, controller 13 activates motor 14 to rotate drive shaft 68 in the counterclockwise direction (the direction indicated by arrow 78). This causes essentially the opposite reaction caused by rotation of shaft 68 in the direction indicated by arrow 72. Hence, the effective length of clamp shaft 46 is increased and the pinching force on IV tube 36 is increased. This results in a decrease in the flow rate of IV fluid through IV tube 36.

In this preferred embodiment, the threads in threaded bore 64 have a pitch of 36 and the threads in threaded bore 70 have a pitch of 32. Therefore, when drive shaft 68 is rotated a quarter turn in the direction indicated by arrow 72, clamp shaft 46 moves in the direction indicated by arrow 76 a distance of .000868 inches with respect to coupler 42 and housing 12. It should be noted, that differential coupler 42 could be replaced with any suitable gear box or positioning mechanism.

It should also be noted that the automatic clamp of the present invention takes advantage of the resilience of IV tube 36. Therefore, only a very small amount of force is required by motor 14 to reposition second clamping member 20 with respect to first clamping member 18 during control of the flow rate of IV fluid through IV tube 36 in the automatic mode.

For example, once the operator has set the initial flow rate through IV tube 36 by setting the initial positions of first and second clamping members 18 and 20 with respect to one another, coupling lock 16, and, as a result, coupler 42 are locked in position with respect to housing 12. At that point, the resilience of IV tube 36 is substantially balanced with the clamping force exerted on second clamping member 20 by clamp spring 54. Therefore, any adjustment in the flow rate by motor 14 requires only the marginal amount of force required to shift that balance.

In this preferred embodiment, the clamping force exerted by clamp spring 54 is exerted at a rate of 5 pounds per inch of compression. Therefore, if the adjustment by motor 14 requires movement of second clamping member 20 a distance of .0005 inches and, prior to the adjustment, the resilience of IV tube 36 and the clamping force of clamp spring 54 are in perfect balance (as would be the case after the operator has set the initial flow rate) then motor 14 is only required to supply

$$(0.0005 \text{ in}) \times (5 \text{ lb. per in}) = .00025 \text{ lb} \qquad \text{(Eq. 1)}$$

This is a very small amount of force relative to that required to offset the entire clamping force of spring 54 or the entire resilience of IV tube 36.

4. Cable Assembly 80

FIG. 4 shows a top view of IV clamp 10 shown in FIG. 1. A cable assembly, shown generally at 80, includes slide 82, cable assembly spring 84, spring block 86, cable 88 and cable lock block 90. Slide 82 is slidably coupled to plate 34 in notch 94. Spring 84 abuts block 86 and slide 82. Cable 88 is attached to slide 82 through bore 96. Cable 88 is also wrapped around coupling lock 16 and attached to cable lock block 90.

When the operator wishes to adjust the initial flow rate, or change the existing flow rate, by manipulating adjustment knob 22, the operator first pivots adjustment guard 24 along arc 92 about pivot 32. As adjustment guard 24 pivots along arc 92, it cooperates with side 82 forcing slide 82 to slide within notch 94 and compress spring 84 against spring block 86.

Therefore, as slide 82 slides toward spring block 86, slack occurs in cable 88, cable 88 loosens around coupling lock 16, and coupling lock 16 is free to slide within slot 98 in plate 34 and housing 12. Since coupling lock 16 is rigidly attached to differential coupler 42, when guard 24 is pivoted into the adjustment position, coupler 42, motor 14, clamp shaft 46 and second clamping member 20 are all free to slide within housing 12.

When the operator is through making adjustments to adjustment knob 22, the operator releases knob 22 and guard 24 automatically pivots (is urged) back into the guarding position, shown in FIG. 4, under the force of spring 84. Spring 84 then urges slide 82 back into the position shown in FIG. 4. As slide 82 moves away from spring block 86 towards the position shown in FIG. 4, cable 88 tightens around coupling lock 16 thereby holding it in position with respect to housing 12. This allows motor 14 to effect differential repositioning of second clamping member 20 with respect to first clamping member 18 as described earlier.

As just described, automatic IV clamp 10 operates in the manual mode when the operator is setting or adjusting a desired flow rate and automatically goes into the automatic mode when the operator has finished setting a new flow rate. The switching between modes is all done automatically without requiring the operator to depress any buttons or enter any data.

FIG. 5 is a side view of automatic IV clamp 10. Adjustment knob 22 is shown in phantom. Probe 100 is attached to slide 82 and probe contact 102 is attached to plate 34 and controller 13. Also, FIGS. 1 and 4 show probe 104 coupled to motor plate 26, and probe contact 106 coupled to either housing 12, or cover plate 33 (shown in FIG. 4), as well as plate 34 and controller 13.

As guard 24 is pivoted into the adjustment position, slide 82 slides towards spring block 86 and probe 100 contacts probe contact 102. Controller 13 detects the contact between probe 100 and probe contact 102 and interprets the contact as a command to enter the manual mode. In the manual mode, controller 13 stops controlling activation of motor 14 and allows the operator to manipulate adjustment knob 22 and set a desired initial flow rate or a new flow rate through IV tube 36.

To insert or remove IV tube 36, the operator adjusts knob 22 to move first and second clamping members 18 and 20 to the insertion position. This causes coupling lock 16 as well motor plate 26 to slide along slots 98 and 28, respectfully. When clamping members 18 and 20 are moved to the insertion position, probe 104 makes contact with probe contact 106. Controller 13 detects the contact between probe 104 and probe contact 106 and enters an idle mode. In the idle mode, the controller can perform any desired tasks. In this preferred embodiment, the controller re-initializes clamp 10 and de-activates the flow sensor and shuts itself off to save energy.

Re-initialization can be accomplished in several ways. In this preferred embodiment, controller 13 accumulates total adjustments made during the previous automatic control mode. Based on these adjustments, controller 13 activates motor 14 to re-center coupler 42. Controller 13 effectively resets the initial relationship between threaded end 48 and bore 70 as well as between threaded shaft 66 and bore 64. This repositioning can be done either in the idle mode or the manual mode.

Once the operator has inserted IV tube 36 and begins to set the initial flow rate by rotating adjustment knob 22, probe 104 breaks contact with probe contact 106. Controller 13 senses this, re-activates itself and flow sensor 15 and displays the flow rate at display 17. However, since guard 24 is still in the adjustment position, probe 100 is still in contact with probe contact 102. Therefore, controller 13, although no longer in the idle mode, is still in the manual mode waiting for the operator to set an initial flow rate.

Once the operator sets the initial flow rate, the guard 24 automatically pivots back into its guarding position. This causes cable 88 to tighten around coupling lock 16 thereby holding it in place with respect to housing 12. Also, as guard 24 pivots into its guarding position, slide 82 is urged back away from slide block 86 and probe 100 breaks contact with probe contact 102. Controller 13 senses this and stores the current flow rate (i.e., the flow rate through IV tube 36 when contact between probe 100 and probe contact 102 is broken) as the desired flow rate. Controller 13 then controls activation of motor 14 based on the desired flow rate and the flow rate sensed by flow sensor 15.

CONCLUSION

Automatic IV clamp 10 of the present invention substantially reduces power requirements over prior art clamps. By using the resiliency of IV tube 36, the pinching force required to be exerted by motor 14 is only the marginal force needed to offset the balance between clamp spring 54 and the resiliency of IV tube 36 which is achieved when the operator sets the desired flow rate. This requires less energy than overcoming the entire resiliency of IV tube 36 and, therefore, saves energy.

The slidable arrangement of motor 14 with respect to clamp housing 12 could be replaced by a fixed motor and, for example, a rigidly fixable telescoping drive shaft. To take advantage of the resilience of tube 36 and clamp spring 54, motor 14 must simply be coupled to second clamping member 20 so substantially no pinching force is exerted by motor 14 during manual adjustment of clamp 10.

In addition, cable assembly 80 could be replaced by a rigid assembly or any other suitable locking technique for locking motor 14 with respect to clamp housing 12.

Also, automatic IV clamp 10 of the present invention uses probes 100 and 104 in conjunction with probe contacts 102 and 106 to operate controller 13. This eliminates the need for the operator to enter any numbers or commands of any type using a keypad or data entry apparatus of any kind. All that is required of the operator is movement of adjustment guard 24 into the adjustment position, rotation of knob 22 to move the first and second clamping members to the insertion position, insertion of tube 36 and adjustment of the desired flow rate by watching display 17 and rotating knob 22. Then, once the operator has set the desired flow rate and removes his or her hand from knob 22, guard 24 automatically pivots into the guarding position, and the controller automatically controls the IV flow rate through IV tube 36 by dithering around the initial flow rate set by the operator. By eliminating the requirement for any keypad or set buttons, use of IV clamp 10 is made efficient and the opportunity for human error is decreased.

Although the present invention has been described with reference to preferred embodiments, workers skilled in the art will recognize that changes may be made in form and detail without departing from the spirit and scope of the invention.

WHAT IS CLAIMED IS:

1. An apparatus for controlling restriction of an intravenous (IV) tube, having a tube resiliency, in an infusion device to control flow rate of IV fluid in the IV tube, the apparatus comprising:

a clamp housing;

a pair of clamping members operably coupled to the clamp housing and suitable for arrangement in an insertion position for placement of the IV tube between the pair of clamping members;

a spring operably coupled to at least one of the pair of clamping members and having a spring force urging at least one of the pair of clamping members toward the other of the pair of clamping members; and

manual adjustment means, operably coupled to at least one of the pair of clamping members, for manually positioning said one of the pair of clamping members to set a desired flow rate.

2. The apparatus of claim 1 wherein the spring force is applied to the IV tube through the one of the pair of clamping members operably coupled to the spring, the spring force capable of overcoming the tube resiliency when the pair of clamping members are in the tube insertion position causing substantially complete restriction of flow in the IV tube.

3. The apparatus of claim 2 wherein the spring force is variably applied to the IV tube during manual

positioning of the one of the pair of clamping members operably coupled to the manual adjustment means.

4. The apparatus of claim 3 and further comprising:

a clamp motor operably coupled to the clamp housing, activation of the clamp motor causing the restriction of the IV tube between the pair of clamping members to vary.

5. The apparatus of claim 4 and further comprising:

a controller, coupled to the clamp motor, for controlling activation of the clamp motor to control restriction of the IV tube.

6. The apparatus of claim 5 and further comprising:

an insertion sensor, coupled to the controller, the insertion sensor sensing when the pair of clamping members are arranged in the tube insertion position and providing an insertion signal to the controller.

7. The apparatus of claim 6 wherein the controller controls the clamp motor in an insertion mode upon receiving the insertion signal.

8. The apparatus of claim 7 wherein the controller re-initializes the apparatus during the insertion mode.

9. The apparatus of claim 8 wherein the controller deactivates itself after re-initializing the apparatus during the insertion mode.

10. The apparatus of claim 1 wherein the pair of clamping members comprises:

a first clamping member coupled to the clamp housing and the manual adjustment means; and

a second clamping member, the first and second clamping members being suited for placement of the IV tube between them.

11. The apparatus of claim 10 wherein the spring is operably coupled to the second clamping member and the clamp housing, the spring having a spring force variably applied to the IV tube through the second clamping member as a function of the manual adjustment of the first clamping member, the spring force and the tube resiliency being substantially in equilibrium when the desired flow rate is manually set.

12. The apparatus of claim 11 and further comprising:

a clamp motor; and

adjustment coupling means for operably coupling the clamp motor to the second clamping member so the clamp motor exerts substantially no clamping force on the second clamping member during manual adjustment of the first clamping member.

13. An apparatus for clamping an intravenous (IV) tube, having a tube resilience, in an infusion device to control flow rate of IV fluid in the IV tube, the apparatus comprising:

a drop detector for detecting the flow rate of the IV fluid in the IV tube;

a pair of clamping members positionable in an insertion position for placement of the IV tube between the pair of clamping members;

bias means operably coupled to at least one of the pair of clamping members and having a spring force urging at least one of the pair of clamping members toward the other of the pair of clamping members;

manual adjustment means coupled to at least one of the pair of clamping members for manually positioning said one of the pair of clamping members to set a desired flow rate, the spring force and the tube resilience being substantially in equilibrium when the desired flow rate is set; and

a controller, coupled to the drop detector and at least one of the pair of clamping members, for controlling clamping of the IV tube between the clamping members based on the flow rate detected and the desired flow rate, the controller controlling the drop detector to intermittently detect the flow rate.

14. The apparatus of claim 13 wherein the drop detector comprises:

a photosensitive transistor positioned to generate a drop signal representative of drops of IV fluid, the controller controlling the photosensitive transistor to operate in an active region.

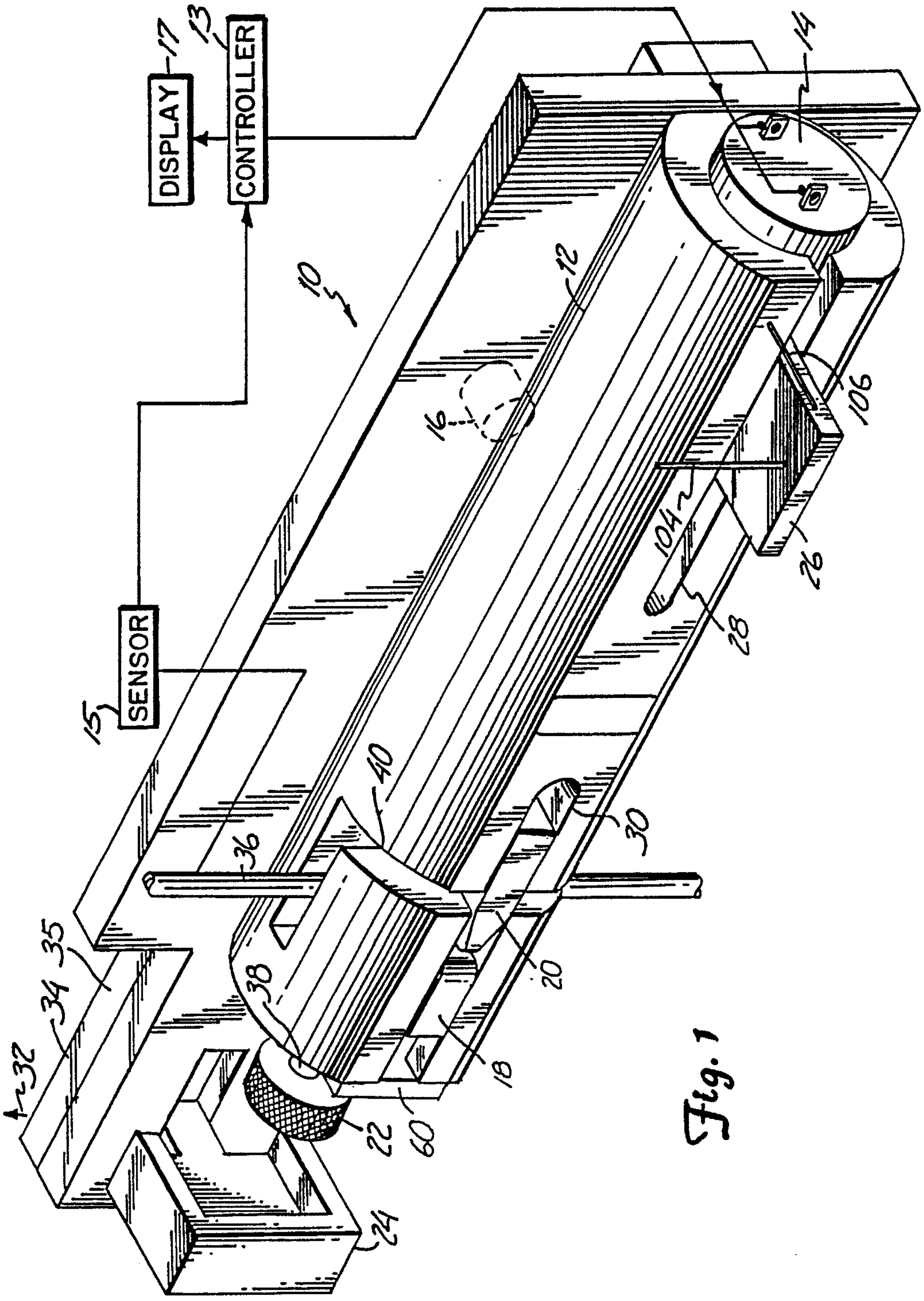
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Fig. 1

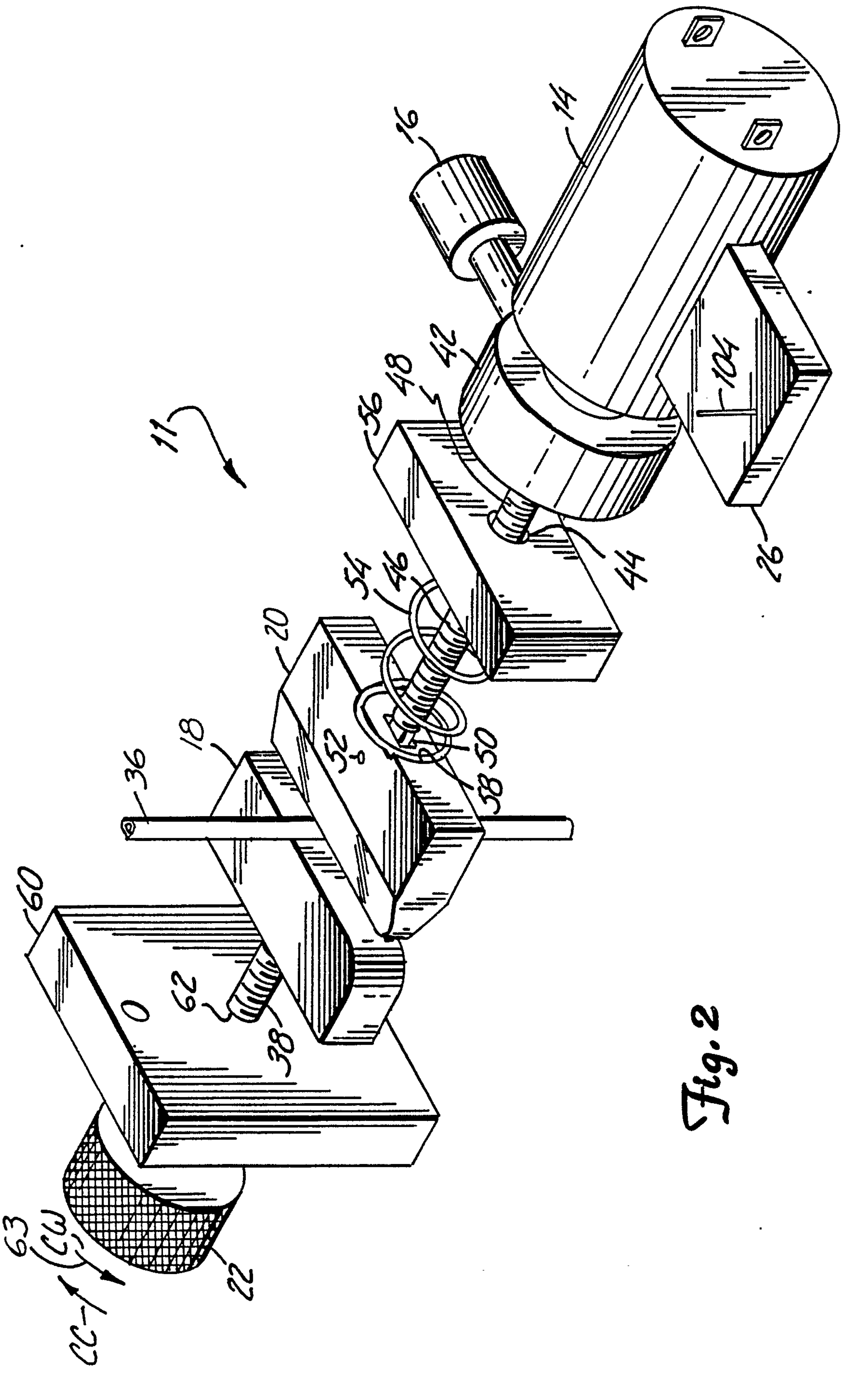
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Fig. 2

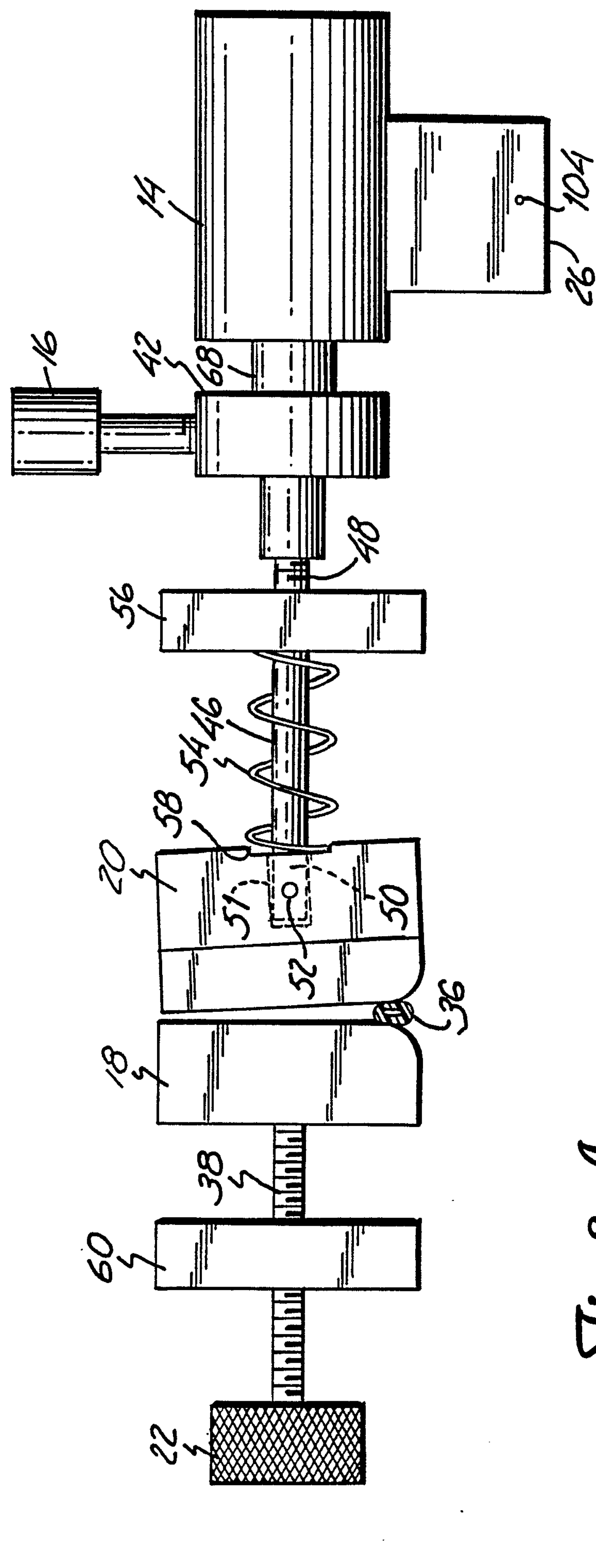

Fig. 2A

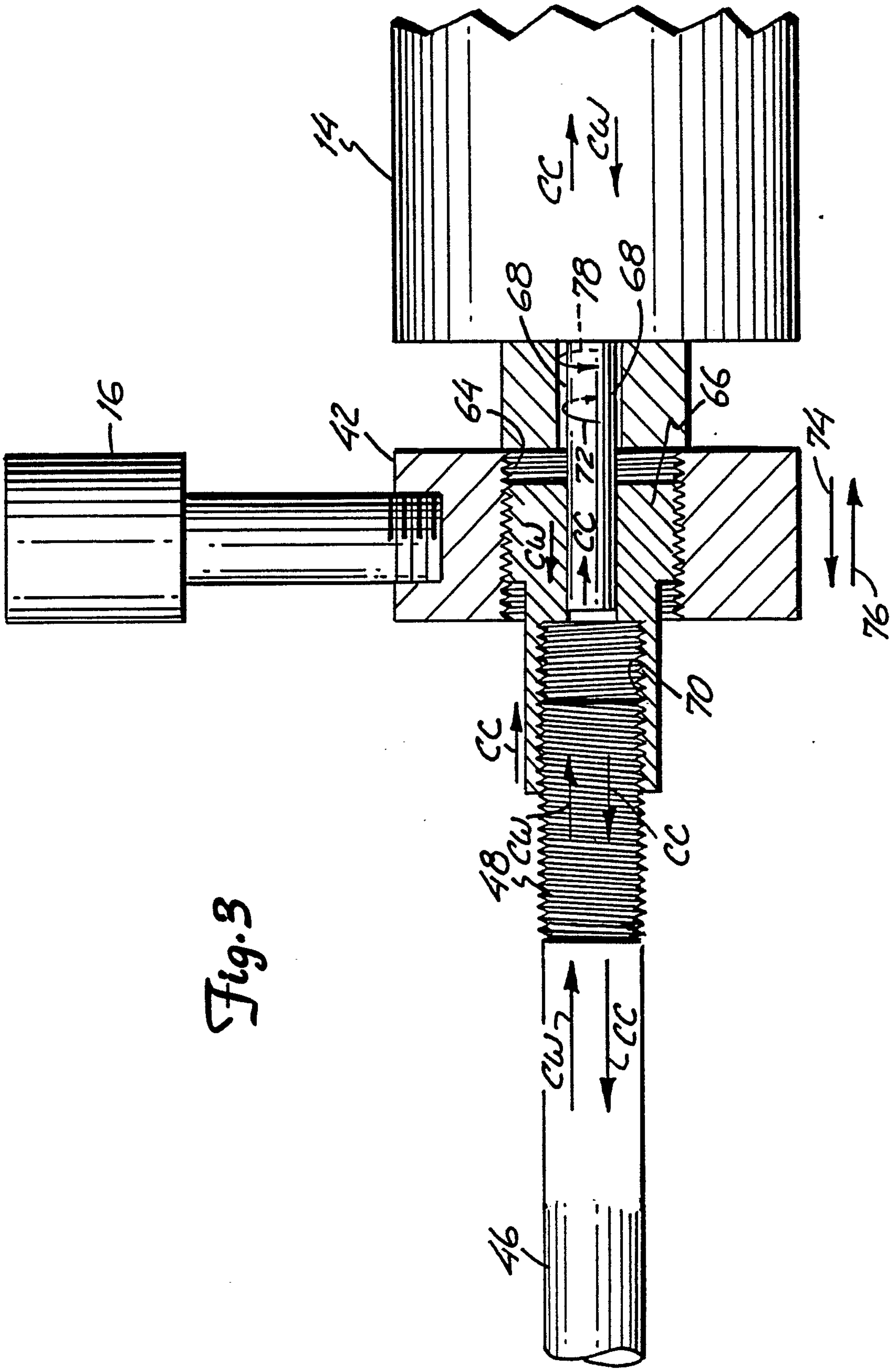

Fig.3

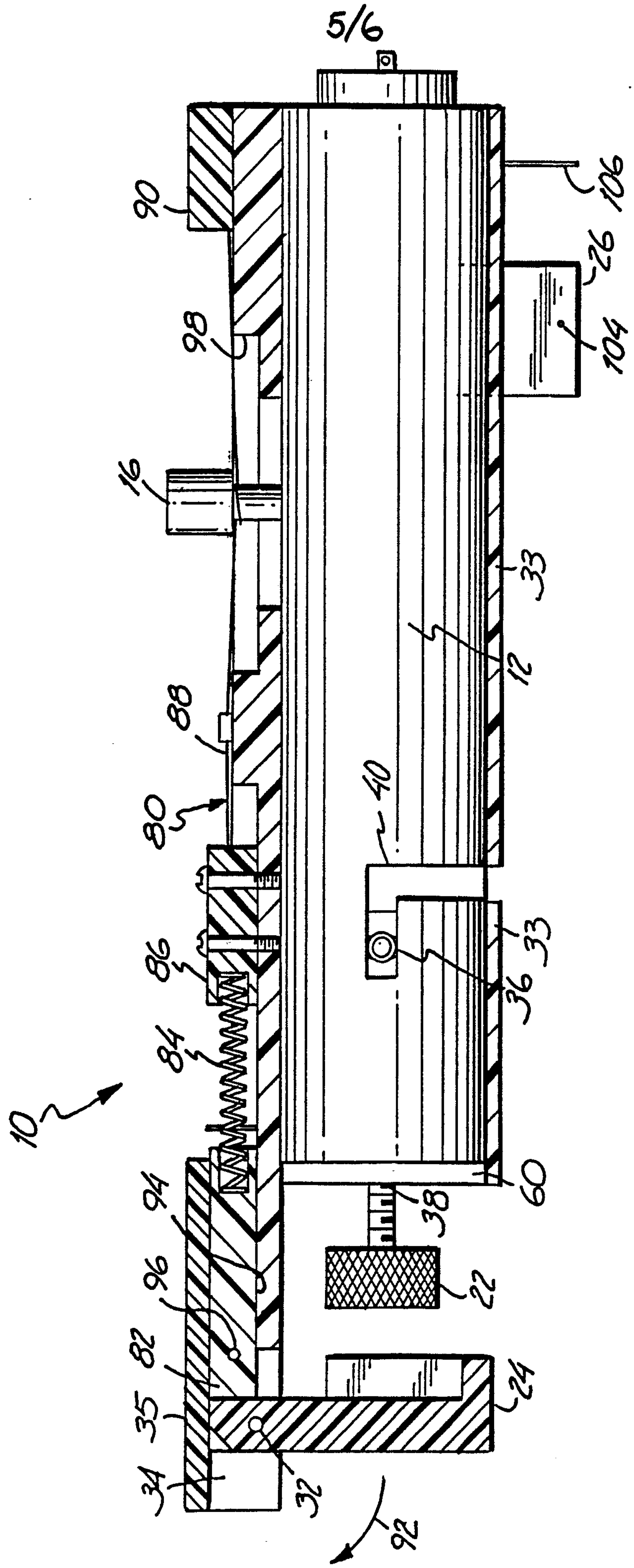
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Fig. 4

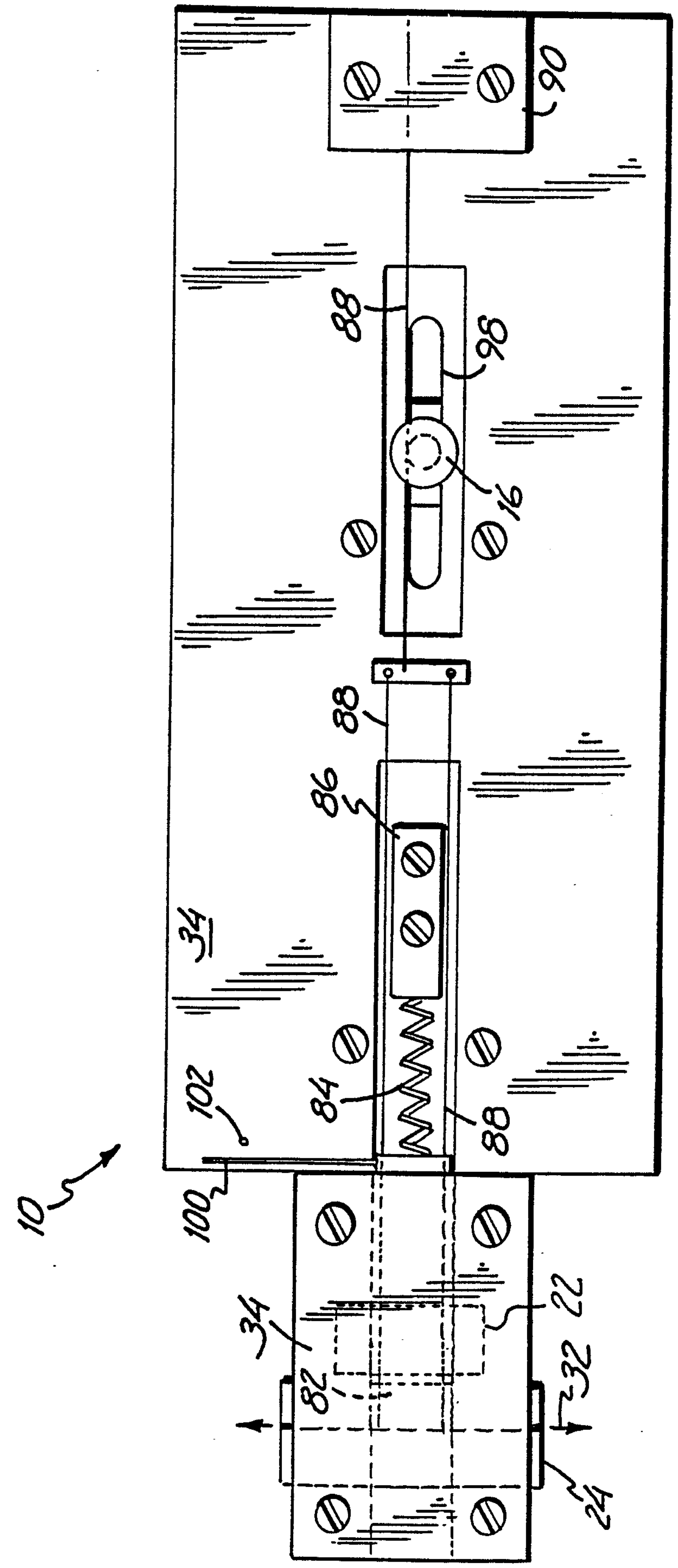

Fig. 5

INTERNATIONAL SEARCH REPORT

International Application No PCT/US91/01309

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all)

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC(5) A61M 5/00
US CL 604/850

II. FIELDS SEARCHED

Minimum Documentation Searched

Classification System	Classification Symbols
US	604/253,81,250

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched

III. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of Document, with indication, where appropriate, of the relevant passages	Relevant to Claim No
A	US, A, 4,236,880 (ARCHIBALD) 02 DECEMBER 1980	1-13
A	US, A, 4,277,226 (ARCHIBALD) 07 JULY 1981	1-13
A	US,A , RE 32,294 (KNOTE) 25 NOVEMBER 1986	1-13
A	US, A, 4,714,463 (ARCHIBALD) 22 DECEMBER 1987	1-13
A	US, A, 4,725,269 (DANBY) 16 FEBRUARY 1988	1-13
A	US, A, 4,827,970 (SUGISAKI) 09 MAY 1989	1-13
A	US, A, 4,872,813 (GORTON) 10 OCTOBER 1989	1-13
A	US, A, 4,919,596 (SLATE) 24 APRIL 1990	1-13
A	US, A, 4,919,649 (TIMOTHY) 24 APRIL 1990	1-13

* Special categories of cited documents:

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

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

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

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

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

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

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

"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

IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
18 APRIL 1991	18 JUL 1991
International Searching Authority	**Signature of Authorized Officer**
ISA/US	André Robinson P. KUBEL

Form PCT/ISA/210 (second sheet) (May 1986)

DC 6-28-91

FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

V. [X] OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE [1]

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

1. [ ] Claim numbers because they relate to subject matter [1] not required to be searched by this Authority, namely:

2. [X] Claim numbers 13 , 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 [1], specifically:

Missing page 25; Claim 13 incomplete

3. [ ] Claim numbers__________, because they are dependent claims not drafted in accordance with the second and third sentences of PCT Rule 6.4(a).

VI. [ ] OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING [2]

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

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims of the international application.
2. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the international application for which fees were paid, specifically claims:
3. [ ] 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 claim numbers:
4. [ ] As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additional fee.

Remark on Protest

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

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