

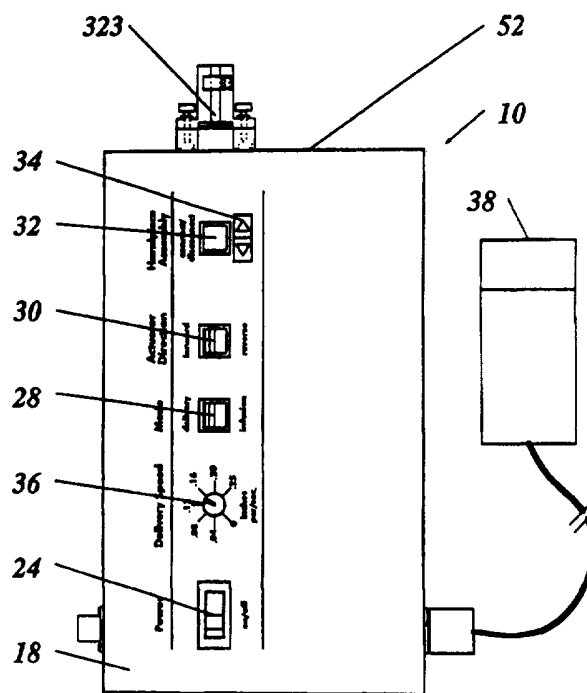


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(54) Title: MEDICAL LINEAR ACTUATOR FOR SURGICAL DELIVERY, MANIPULATION, AND EXTRACTION**(57) Abstract**

This invention is a linear actuator assembly (10) for operating a plurality of surgical tools. The actuator (40) can provide motive power to the surgical tools which are attachable to a hand-piece (100) associated with the actuator assembly and may be foot pedal (38) operated. In a preferred embodiment, the actuator is electromechanically driven (10) and microprocessor-controlled (22). Embodiments of the device may be used for surgeries, such as but not limited to, retinal surgery, biopsies, and stent removal.



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MEDICAL LINEAR ACTUATOR FOR SURGICAL DELIVERY,
MANIPULATION, AND EXTRACTION

BACKGROUND OF THE INVENTION

5 The present invention relates in general to surgical instruments and surgical techniques. More particularly, the present invention is directed to a linear actuator for a multifunctional surgical tool for delivery of grafts, drugs, devices, and for irrigation/aspiration of various parts of the
10 body; as well as surgical manipulation and extraction.

 There is a need for a device to deliver, extract, and implant medical devices, drugs, tissue, etc. to various parts of the body. Such a device must be capable of delivering an implant in a target site in the body in a controlled,
15 calibrated fashion where necessary. There is a need for implantation of neural and other living tissue, an increasing number of surgical devices, and drugs. In addition, existing implants frequently require treatment involving manipulation and extraction procedures. By way of non-limiting example, a
20 significant number of patients receive vascular prosthetics, e.g. stents, which are provided by way of a catheter. It is desirable that vascular prosthetics and grafts be expressed from the catheter in a controlled and calibrated fashion. Further, there is a need to alter the position of such
25 prosthetic devices in the body or to extract these devices. Likewise, there is a need to deliver, manipulate, and extract other medical and therapeutic devices.

 Many self powered surgical tools have been developed which are capable of performing the previously mentioned
30 tasks. Most of these tools have pneumatic drive means. U.S. Patent No. 5,019,035 issued to Missirlian et al. discloses one such device. Missirlian describes a pneumatically operated

microsurgical cutting instrument. A spring biased inner cutting member moves in a first direction relative to a stationary cutting member in response to the applied air pressure. A spring returns the inner cutting member to its original position. This system, like all pneumatic systems suffers from an inherent hysteresis in the system. This hysteresis limits the control that the operator has over the implement thereby complicating delicate procedures. Also, pneumatic systems tend to impart a "jerky" movement to the implement further affecting the precision and accuracy with which the tool can be effectively used. Finally, the pneumatic systems can be subject to leaky and clogged supply/vacuum lines which can affect performance.

U.S. Pat. No. 4,837,857 issued to Scheller et al. discloses a foot pedal assembly which can be used for remotely controlling a variety of microsurgical instruments. The system employs pneumatic drive means and is thereby subject to the aforementioned drawbacks.

SUMMARY OF THE INVENTION

Among the several objects and features of the present invention may be noted the provision of a microprocessor controlled drive means adaptable for use with a plurality of functional attachments including, but not limited to, cutting tools, grasping tools, and tools useful for implantation of various devices, tissues, grafts, and drugs into the body.

Generally, the microprocessor controlled drive means comprises a source of motive power, a linear actuator, and a microprocessor to selectively apply power to the linear actuator. The microprocessor can control the direction, speed, length of travel, and duration that power is applied to the linear actuator.

The linear actuator of the present invention provides previously unobtainable levels of accuracy and precision in the controlled surgical delivery and manipulation of materials and devices, particularly in surgery beneath and around the retina, other parts of the eye, and in remote portions of blood vessels from the surgical delivery incision.

The linear actuator may be a cable or thin tubular plunger disposed within a second tubular body and capable of relative axial movement therein. In alternative embodiments, the plunger may be actuated manually, by a spring loaded foot pedal assembly, or by a foot pedal operated ratchet wheel assembly.

Other objects and features of the invention will be in part apparent and in part pointed out hereinafter with reference to the following description of non-limiting embodiments.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a top elevation view of a housing for a source of motive power for the surgical instrument.

Fig. 2 is a top plan view of the interior components of Fig. 1.

Figs. 3(a)-(e) are schematics of the control circuitry used to selectively supply power to the surgical instrument.

Fig. 4 is a partial sectional view of a handpiece cable assembly including fittings for the linear actuator, infusion line, and the fiber optic cable.

Fig. 5 is a perspective view of a functional attachment to the linear actuator of the present invention for containing an implant for implantation or for extraction of a material.

Fig. 6(a) is a sectional view of a functional attachment to the linear actuator of the present invention including

grasping members which are outwardly biased.

Fig. 6(b) is a sectional view of a functional attachment to the linear actuator of the present invention including grasping forceps which can be inwardly biased.

5 Figs. 6(c) and 6(d) are views of a stent having an inner lip capable of engagement with the grasping members illustrated in Fig. 6(a).

Fig. 7 is a sectional view of a handpiece cable assembly which can be operably connected to a source of motive power.

10 Fig. 8 is a perspective view of an alternative hand actuated embodiment of the surgical instrument.

Fig. 9 is a partially exploded perspective view of Fig. 8.

DETAILED DESCRIPTION

15 Referring now to Figures 1 and 2, a top view of a preferred embodiment of a microprocessor controlled electromechanical drive assembly 10 is shown. The assembly 10 includes stepper motors 12 and 14 (Figure 2) which are contained within a housing 16. It should be noted that while
20 an electromechanical drive is a preferred means for providing motive power, a mechanical drive mechanism obtains power from the energy stored in a spring or like mechanism may also be used. Attached to the housing 16 is a front panel 18 and a source of fluid pressure or suction in the form of a syringe
25 20, the fluid pressure or suction being controlled by stepper motor 14. The housing 16 can also contain a light source for illuminating a fiber optic filament as will be discussed later. A laser source could also be provided.

Both of the stepper motors 12 and 14 are controlled by
30 a microprocessor 22. A plurality of switches and terminals are disposed on the front panel 18 to allow the operator to select the various functions and modes of operation used with the

various functional attachments.

Power is selectively applied to the assembly 10 by power switch 24. DC power is supplied to the microprocessor by the transformer/rectifier assembly 26. The mode switch 28 allows
5 the operator to alternate between actuation of the plunger 29 and the syringe 20. The plunger 29 is alternated between delivery and retraction by switch 30 which, depending on the position of the mode switch 28, also alternates the fluid pressure source, syringe 20, between infusion and aspiration.
10 Thus in the embodiment of Figs. 1 and 2, delivery or retraction of the plunger 29 is mutually exclusive of infusion or aspiration. In an alternative embodiment, infusion/aspiration can be performed simultaneously with delivery/retraction of the plunger 29. In either embodiment,
15 separate conduits and associated drive means can be used to apply infusion and aspiration simultaneously to a functional attachment.

Pushbutton switch 32 controls the connecting and disconnecting of a functional attachment to device 10, with
20 the connect status being indicated by LEDs 34. The delivery speed of the plunger 29 is infinitely variable over a range of speeds by speed control 36. The range of speeds is variable depending upon the exact procedure being performed and the associated functional attachment. The speed range can be
25 altered if necessary to operate certain functional attachments. Actuation of the plunger 29 is controlled by footswitch 38 which may be a commercially available footswitch such as a model produced under the trademark Linemaster®. The footswitch 38 will operate the plunger 29 or the syringe 20
30 in the selected direction and speed as long as it is depressed.

The assembly 10 includes an actuator 40 for advancing and

retracting the plunger 29 which is connected to motor 12 via screw drive 42 and has solenoid controlled locking mechanisms 44 and 46. Locking mechanism 44 locks onto the connector 48 of sheath 50 and locking mechanism 46 locks onto the plunger 29. The connector 48 is adapted to be secured within terminal 52 when mechanism 44 locks onto annular recess 54 of the connector 48 (Fig. 4). The connector 48 has an axial bore 56 for slidably receiving the plunger 29. The sheath 50 is secured within the connector bore 56 by an adhesive, by frictional engagement, or is integrally attached. The opposite end of the sheath 50 is secured to a functional attachment. Thus, when locking mechanisms 44 and 46 are locked onto the connector 48 and plunger 29 respectively, movement of the actuator 40 causes movement of the plunger 29 within axial bore 56 and sheath 50 as the connector and sheath are held stationary relative to the actuator. Locking mechanism 46 moves with the actuator 40 along slide member 58.

Referring again to Fig. 2, the actuator travel 40 is limited by limit switches 60 and 62. The limit switches are actuated by transversely extending arm 64 and serve to physically limit the travel of the actuator 40 as well as interrupt the supply of power to stepper motor 12.

In a preferred embodiment, the syringe 20 is releasably mounted in syringe support 66. The support 66 includes a rectangular clamp 68 having a groove therein which is sized for holding the syringe 20. The clamp 68 has a threaded aperture extending therethrough, the aperture corresponding to an aperture in the support 66, both apertures aligned for receiving a screw 70 for tightening the clamp 68 onto the syringe 20. A recess 72 formed in the support is adapted to hold the annular flange 74 of the syringe 20 thereby preventing axial movement of the syringe. The syringe actuator

76 has a similar recess 78 for retaining the annular lip 80 at the tip of the syringe piston rod enabling the actuator to move the piston 82 to effect infusion or aspiration.

The syringe 20 is filled with infusion fluid from a second syringe 84 via 3-way stopcock 86. The stopcock 86 is positioned to allow fluid flow from second syringe 84 to syringe 20 at startup. The stopcock 86 is then repositioned to allow fluid flow or suction through infusion/aspiration terminal 87 to the infusion line 88.

The travel of actuator 76 is limited by actuator arm 77 and limit switches 90 and 92 in the same manner as actuator 40. It should be noted that the limit switches can be repositioned to adjust the travel of the actuators 40 and 76.

It should be noted that a pump, fluid reservoir, and a fluid collection container (not shown) may be used to apply fluid flow or aspiration to infusion line 88. A pump such as a peristaltic pump would provide suitable control of flow, and the infusion line 88 or other suitable conduit could be inserted into the pump drive mechanism. Such a pump could have the motor inside the housing of device 10, and have the pump and tubing connection external to the housing.

Referring now to Fig. 3, the microprocessor 22 circuitry is shown. Microcontroller U3 is the main control unit for the microprocessor 22. An Intel(R) 8031 may be used for U3. Microcontroller U3 is controlled in accordance with the following program.

U1 is a data latch which is used to latch data coming from U3 and may be a 74HC245 integrated circuit. U2 is also a data latch and may be a 74HC373 IC. U4 are 74HC08 Quad two input AND gates which are used as temporary data stores. U5 is a 74ALS156 decoder which outputs control signals from the controller U3 for control of the other ICs. U7 is a RAM which

stores data such as speed control for access as needed by the controller U3. An MCM6164-55C 64K RAM may be used for U7. U13 are 74HC32 Quad two input OR gates. U8 is programmed to perform as 3 eight bit ports. Port A and Port B are used as
5 inputs. Port C is used as an output. The inputs are from the panel switches or the limit switches in the control box. The outputs are indicators such as LEDs 311. U8 may be a 8255 IC and is controlled by U3.

U9 and U11 are UCN5804B microcontrollers and are used to
10 drive the stepper motors 12 and 14. U9 and U11 respond to control signals from U3.

U12 is a ADC0808CCJA 8 bit A/D converter used to convert the input voltage from the footswitch to a digital format that the controller recognizes. U10 is a 74HC74 flip-flop which
15 divides the clock pulse by 2 since U12 cannot convert data as fast as U3.

U14 is a 7407 hex buffer that responds to control signals from U3 to turn on the relays which activate the solenoids which operate locking mechanisms 44 and 46.

20 Thus, a drive means for a linear actuator which is capable of being operably connected to a functional attachment has been described.

A functional attachment capable of implantation of grafts, tissues, or drugs; as well as irrigation, aspiration
25 or removal of tissue includes a handpiece cable assembly as is shown in Fig. 4. The handpiece cable assembly can be operatively connected to the microprocessor controlled drive assembly 10 and can be used for a retinal transplant procedure as described in copending U.S. patent application entitled
30 "METHOD FOR TRANSPLANTATION OF PLANAR IMPLANTS AND SURGICAL INSTRUMENT THEREFOR" filed on even date herewith which is herein incorporated by reference.

Referring now to Fig. 5, the handpiece cable assembly includes a handpiece 100 which is sectional and which has a delivery cannula 102 within which plunger 29 is axially movable to express the graft, drug, material, or device to be
5 implanted. The handpiece 100 also includes an infusion lumen 104 which can be connected to infusion tube 88 for providing a source of infusion fluid or aspiration, as well as a fiber optic cable 106 which can be connected to a source of illumination for providing illumination at the site of
10 implantation. Alternatively, a laser source can be connected to fiber optic cable 106 for, e.g., cauterizing blood vessels.

The sheath 50 is connected to the delivery cannula 102 to allow for passage of the plunger 29 into the delivery cannula for expressing the desired implant from the tubular
15 tip 114 of the cannula.

In operation, the handpiece cable assembly is set up for the implantation of the graft by manually inserting the plunger 29 into and through the connector 48 and sheath 50 until the plunger enters a first section of the handpiece 100
20 and abuts the inner end wall 112 of the calibration cap 112 as shown in Fig. 4. The calibration cap 110 is adapted for detachable locking engagement with the first section of the handpiece 100 and is used to preset the initial position of the plunger 29 within the handpiece 100 when the actuator 40
25 is in the fully retracted position. Thus, the travel of the plunger 29 within the handpiece 100 extends from the preset position to a position of maximum extension within the delivery cannula 102 as determined by the spacing of the limit switches 60 and 62 as has been previously explained. The
30 plunger 29 is made long enough so that an excess length of the plunger 29 protrudes from the connector 48 when the plunger abuts wall 112. The excess length of the plunger 29 is long

enough to ensure proper engagement with the locking mechanism 46, but not so long as to prevent full insertion of the connector 48 into the terminal 52. To attach the handpiece assembly to the drive the connect/disconnect switch 32 is depressed thereby deactivating locking mechanisms 44 and 46 and returning the actuator 40 to the fully retracted position as shown in Fig. 2. The plunger 29 and connector 48 can then be inserted into terminal 52. It should be noted that for most procedures the limit switches 60 and 62 do not allow the plunger 29 to travel beyond the opening 114 of the tubular tip of the delivery cannula 102. When connector 48 is fully inserted into terminal 52 a switch (not shown) activates mechanisms 44 and 46 to lock onto annular recess 54 and plunger 29 respectively. Speed control 36 is then set to the desired speed. The foot pedal 38 can then be used to control extension or retraction of the plunger 29 as desired by setting the panel switches to the appropriate positions.

The infusion/aspiration assembly is set up by attaching syringes 20 and 84 to the infusion/aspiration terminal 87 with the syringe clamp 68 being firmly attached to the syringe 20 so as to prevent axial movement of the syringe 20. The syringe 20 is then loaded with infusion fluid from syringe 84 via stopcock 86 by setting the panel switches in the aspiration mode and depressing the foot pedal 38. The stopcock 86 is then repositioned to allow infusion fluid to flow through infusion line 88. Fluid pressure or suction can then be applied to infusion line 88 via microprocessor controlled stepper motor 14 by operating foot pedal 38 with the panel switches in the appropriate positions. It should be noted that a multilumen cannula can be attached to infusion line 88 to aspirate tissue from the subretinal space or other locations, followed by the implant of drugs, grafts, or devices.

The assembly can be adapted to provide accurately controlled motive power to a wide variety of functional attachments. Modification of the hardware or software may be required in order to operate certain functional attachments.

5 Another functional attachment capable of being operably connected to the drive assembly is shown in Fig. 6(a). This attachment requires the connection of a straight cannula 120 to the handpiece 100 which is sufficiently strong that it does not tear under the outward pressure exerted by retraction of
10 outwardly biased members 122 into cannula 120. This may require reinforcement of tip 121, particularly in instances where cannula 120 is made sufficiently flexible to follow the contours of a blood vessel or other lumen into which it has been inserted. This attachment can be used as a stent
15 retriever and has a pair of outwardly biased grasping members 122 having hook-like ends 124. The opposite ends of the grasping members 122 are attached to the plunger 29 by a connector (not shown) which allows for simultaneous delivery or retraction of the grasping members. When fully retracted,
20 the grasping members 122, and ends 124, do not expand radially beyond the outer dimensions of the cannula 120 allowing for smooth progression of the device through blood vessels or other lumens. When advanced, the grasping members 122 extend outwardly as shown so that the ends 124 can be used to grasp
25 the stent or other device for removal. (Examples of stents can be seen in U.S. Pat. No. 4,580,568 issued to Gianturco, U.S. Pat. No. 4,733,665 issued to Palmezz, and U.S. 5,135,536, issued to Hillstead.) A stent 125 is illustrated in Fig. 6(c), and includes inner flexing lip 127 for engagement with ends
30 124. Inner flexing lip 127 is designed to lie against the inner surface of stent 125 when inserted so that blood flow biases lip 127 against the inner stent wall to create a smooth

surface.

Although two members 122 are shown, additional members may be connected to plunger 29 and be biased radially outward to ensure a better grip and manipulation of the stent. The
5 blood vessel may be dilated in front of stent 125, for example at position 129 with a balloon dilatation catheter 131 to permit use of the cannula and grasping elements of the device shown in 6(a) to be inserted through a lumen passing through the balloon dilatation catheter into the stent 125, and
10 permitting retraction of the stent 125 into the lumen of the balloon dilatation catheter.

A forceps-like grasping attachment is shown in Fig. 6(b). This attachment may be used for removal of tissues or devices, or for the manipulation of various devices within the body,
15 and is attached to the drive assembly 10 in the same manner as the attachment of Fig.6(a). The attachment has grasping members 126 which are biased outwardly to open upon advancement of the plunger 29 and to close upon retraction thus allowing the attachment to be used as a miniature
20 forceps.

In one embodiment, the forceps can be inserted through a retinotomy to perform a choroidal biopsy; the members 126 (which can be two or more in number) may also be rotatably connected to plunger 29, and means for rotating members 126
25 in order to ensure a cleaner incision, or a better cutting and tearing action. A cauterization device (e.g. electrocauterization probe) can be included to reduce bleeding following the excision of tissue to biopsied and its retraction within cannula 120.

30 The device can be used for insertion into a lumen of a balloon dilatation catheter for removal of a pre-shrunken (e.g., thermally cooled) stent, or may be used to both

radially contract and extract a vascular stent. The cannula 120 in both attachments can be provided with an infusion/aspiration lumen which can be used for irrigation/aspiration at the surgical site.

5 It should be noted that the devices in Figures 5 and 6 can be effectively employed by making only small surgical incisions.

A handpiece cable assembly 250 having a handpiece 251 which can be functionally attached to a source of motive power is shown in Fig. 7. The handpiece cable assembly 250 includes a delivery cannula 252 which is secured to hollow frusto-conical connector 254 by an adhesive. The main body of the assembly 250 has an inner member 256 and an outer member 258. The inner member 256 has a frusto-conical portion 260
15 projecting from one end and a threaded cylindrical post 262 projecting from the opposite end. Connector 254 is adapted for frictional engagement with projecting portion 260 and may be further secured thereto by an adhesive. Outer member 258 has a contoured outer surface 264 to facilitate manipulation of the delivery cannula. A central aperture 266 in the outer
20 member is threaded to enable threaded engagement with post 262 and is inwardly sloped at one end to form a camming surface 268. The post 262 has an aperture 270 adapted to receive a vice member 272 which has an exterior camming surface thereby forming a pin vice assembly comprised of threaded post 262,
25 outer member 258, and vice member 272. Thus, axial movement of the syringe tube 222 within the handpiece 251 is restricted by tightening the pin vice assembly, which causes vice member 272 to compress syringe tube 222 and sheath 224.

30 If desired infusion/aspiration can be manually effected by securing an infusion/aspiration lumen (not shown) to the exterior of the delivery cannula 252 by using an adhesive, the

infusion lumen having an opening proximate the opening at the tip 274 of the delivery cannula, the infusion/aspiration lumen being connected to a syringe 276 as shown in Fig. 8.

In another embodiment, plunger 29 may be actuated by a foot pedal operated ratchet assembly (not shown). The ratchet assembly includes two foot pedals, one for delivery, the other for retraction, or a single foot pedal having a directional switch, which reverses the direction of movement of the plunger in response to one up/down cycle of the foot pedal. The travel per foot pedal cycle can also be adjusted. The plunger 29 will move with each depression of the foot pedal until it reaches its limit of travel, the distance traveled by a single depression being adjustable by the spacings of gear teeth on the ratchet assembly as is well known. Such a ratchet drive assembly may be included with the device 10 as a backup source of motive power.

Manual delivery and retraction of a linear actuator can be accomplished with an alternative embodiment as shown in Figures 11 and 12. In this embodiment the attachment 500 comprises a cylindrical aluminum housing 302 having a delivery cannula 304 attached thereto. A plunger 306 is actuated by thumbswitch 308 which slides in track 310. An actuator 312 is connected to thumbswitch 308 as can be seen in Figure 12. Actuator 312 is connected to plunger 306 by rod 314 which projects into and through bore 316 in luer connector 317 and is inserted into an aperture 318 at one end of plunger 306 where it is secured therein by an adhesive. Luer connector 317 is connected to the housing 302 and therefore is held stationary relative to rod 314, actuator 312 and plunger 306. The travel of plunger 306 is limited by set screw 320 which screws into bore 322 and projects into the path of actuator 312. A plurality of bores such as bore 322 can be provided to

adjustably limit the travel of actuator 312 and therefor the plunger 306. Grooves 324 and 326 are provided to hold infusion conduits 328 and 330 in place. Infusion fluid or aspiration can be provided to the infusion conduits 328 and 330 by a
5 syringe.

The delivery cannula 304 is connected to a hollow frusto-conical connector 332 which is secured to housing 302 and has a bore 334 into which the delivery cannula 304 is secured by an adhesive. Conduits 328 and 330 can also be secured to the
10 exterior surfaces of connector 332 and delivery cannula 304 as shown to provide aspiration/infusion at the tip of the delivery cannula. Advancing or retracting the thumbswitch causes advancing or retraction of the plunger 306 within the delivery cannula 304. For further information on the preferred
15 uses and applications of the present invention, reference may be made to copending U.S. patent applications 08/322,735, 08/057,144, 08/033,105, and the application entitled "METHOD FOR PREPARATION AND TRANSPLANTATION OF PLANAR IMPLANTS AND SURGICAL INSTRUMENTS THEREFOR", filed on even date herewith.

20 Of course, two or more of the features described with respect to the alternate embodiments could be combined, as necessitated by the particular circumstances.

As various changes could be made in the above surgical instruments, compositions of matter and methods without
25 departing from the scope of the invention, it is intended that all matter contained in the above description or shown in the accompanying drawings shall be interpreted as illustrative and not in a limiting sense.

What is claimed is:

1. A device for surgical delivery, manipulation, and extraction of surgical material and devices comprising:
 - a source of motive power;
 - 5 a cannula;
 - a plunger partially disposed within said cannula having first and second end portions, said first end portion connected to said source of motive power, the power source capable of selectively imparting linear reciprocating motion to said plunger;
 - 10 whereby a plurality of functional attachments can be operably connected to said second end portion one at a time to deliver, manipulate, cut, or extract in accordance with the reciprocating motion of said plunger.
 - 15
2. The device of claim 1 where said source of motive power is microprocessor controlled.
- 20 3. The device of claim 1 including means to limit the speed and travel of said plunger.
4. The device of claim 1 including means to provide at least one of the following: a source of infusion fluid to said surgical tools, a source of aspiration to said surgical tools, and a source of illumination to said surgical tools.
- 25
5. The device of claim 4 wherein said source of infusion fluid and said source of aspiration are microprocessor controlled.
- 30
6. The device of claim 1 wherein said source of motive power is selected from the group consisting of a manually operated

ratchet assembly, and an electromechanical drive.

7. The device of claim 1, further comprising a functional attachment comprising at least two members extending from said
5 second end portion of said plunger, the distal ends of said members being biased radially outward and capable of reciprocating radial movement in response to reciprocating linear movement of said plunger, said members extending radially outward upon at least partially extension of said
10 members from the distal end of said cannula.

8. The device of claim 7, wherein said members are adapted for cutting tissue upon at least partial linear retraction of said members into the distal end of said cannula from a
15 relatively more extended position.

9. The device of claim 7, wherein said members are adapted for grasping a stent disposed within a blood vessel upon at least partial linear extension of said members from the distal
20 end of said cannula.

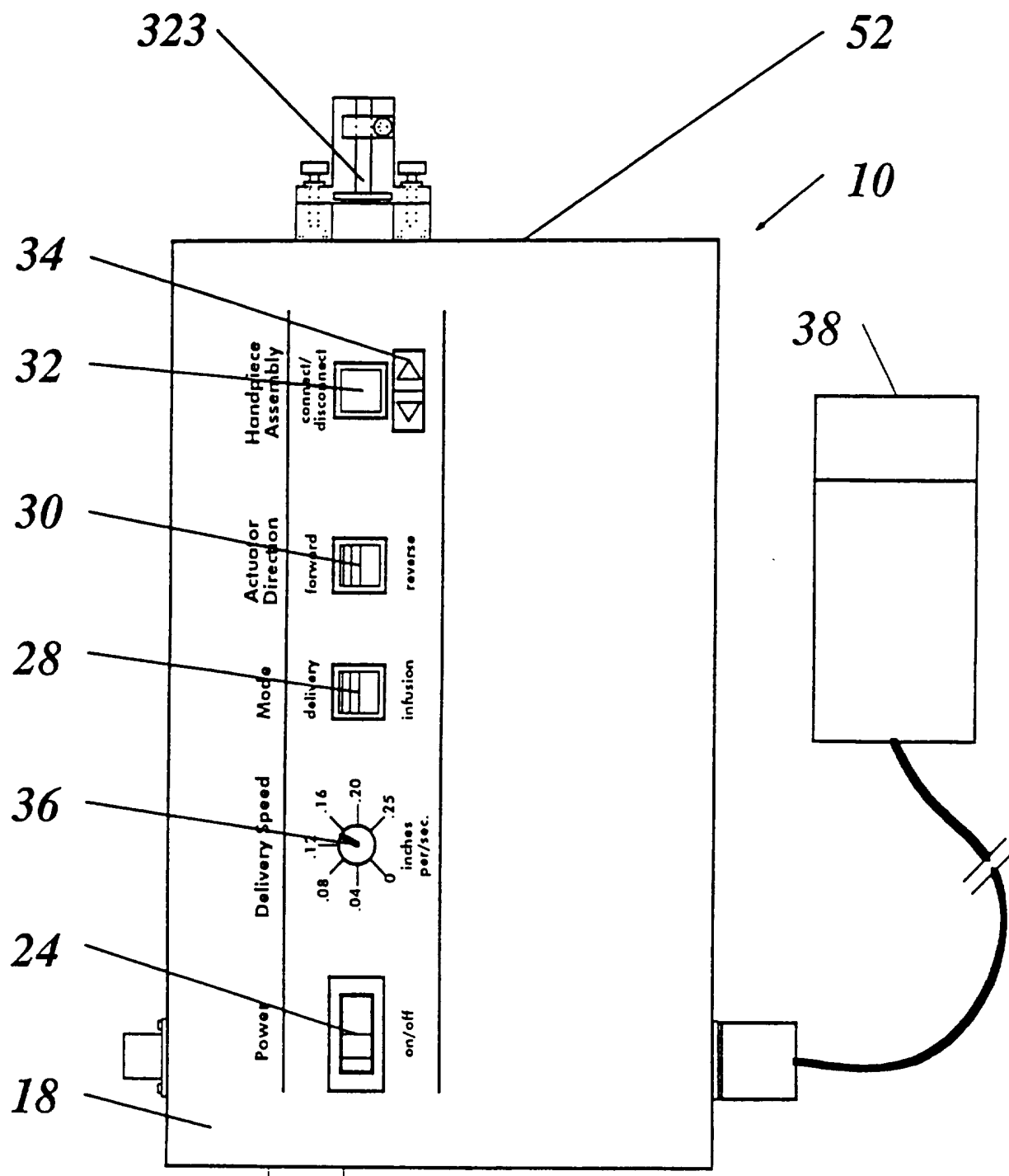


FIG. 1

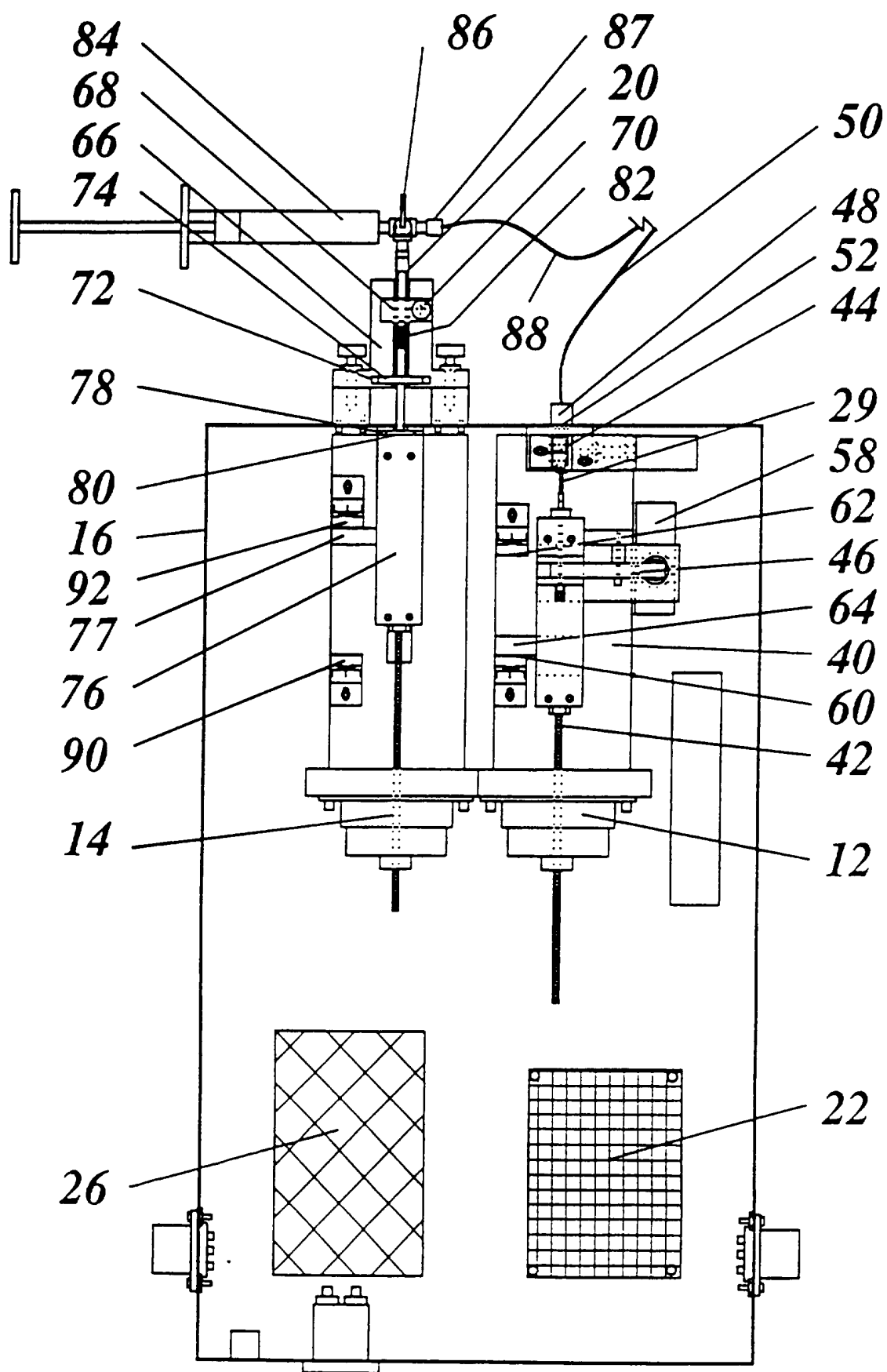


FIG. 2

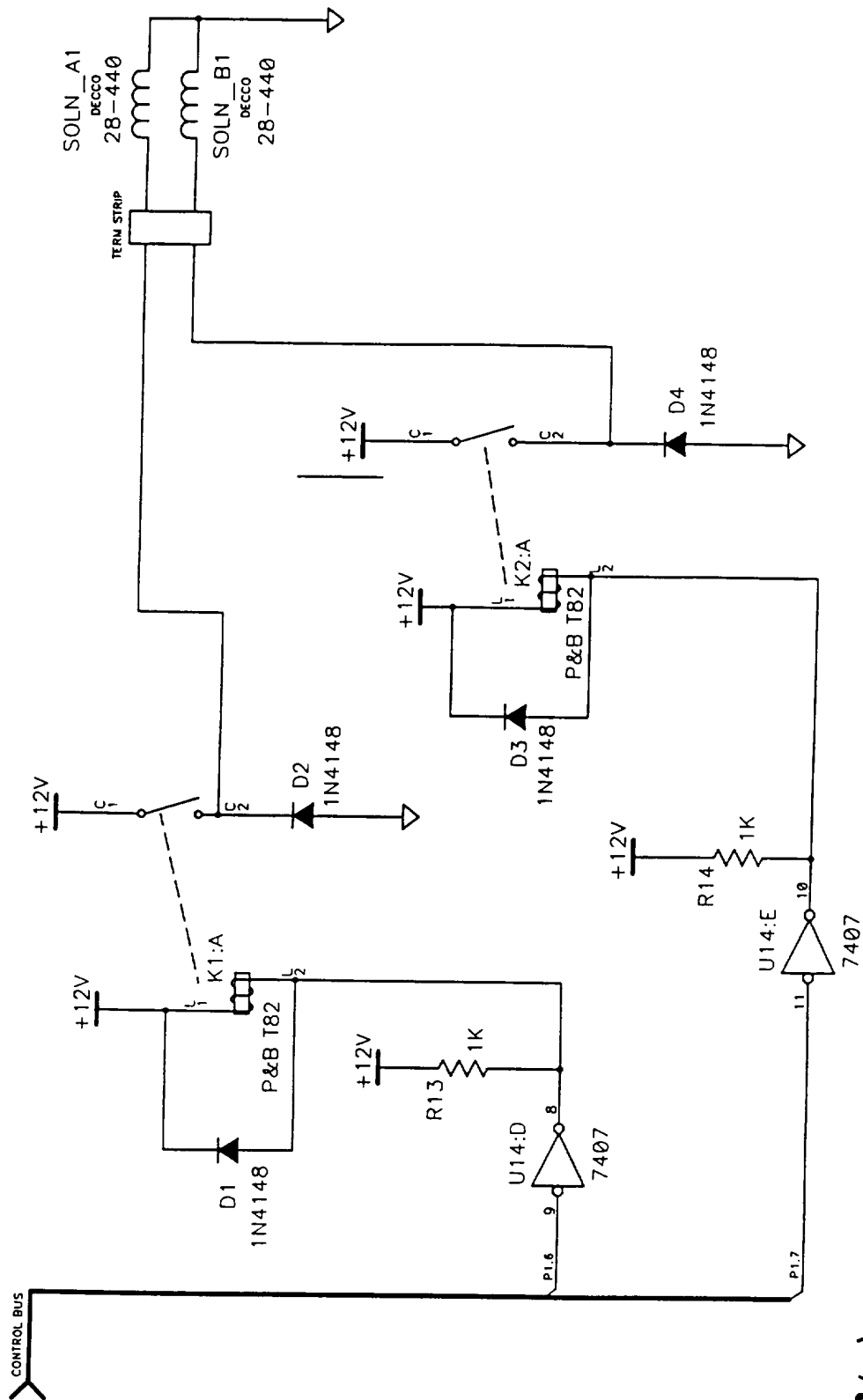


FIG. 3(a)

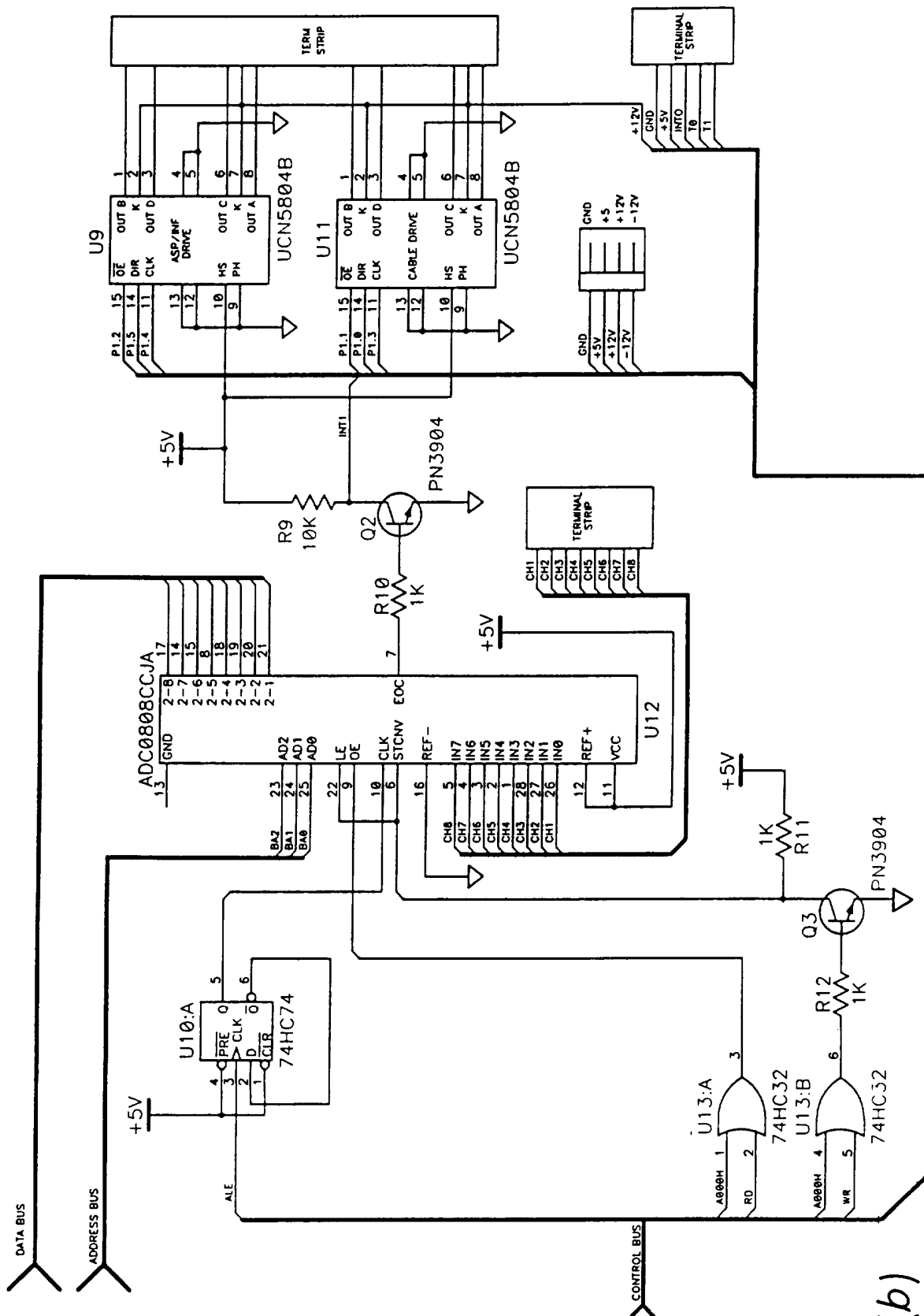


FIG. 3(b)

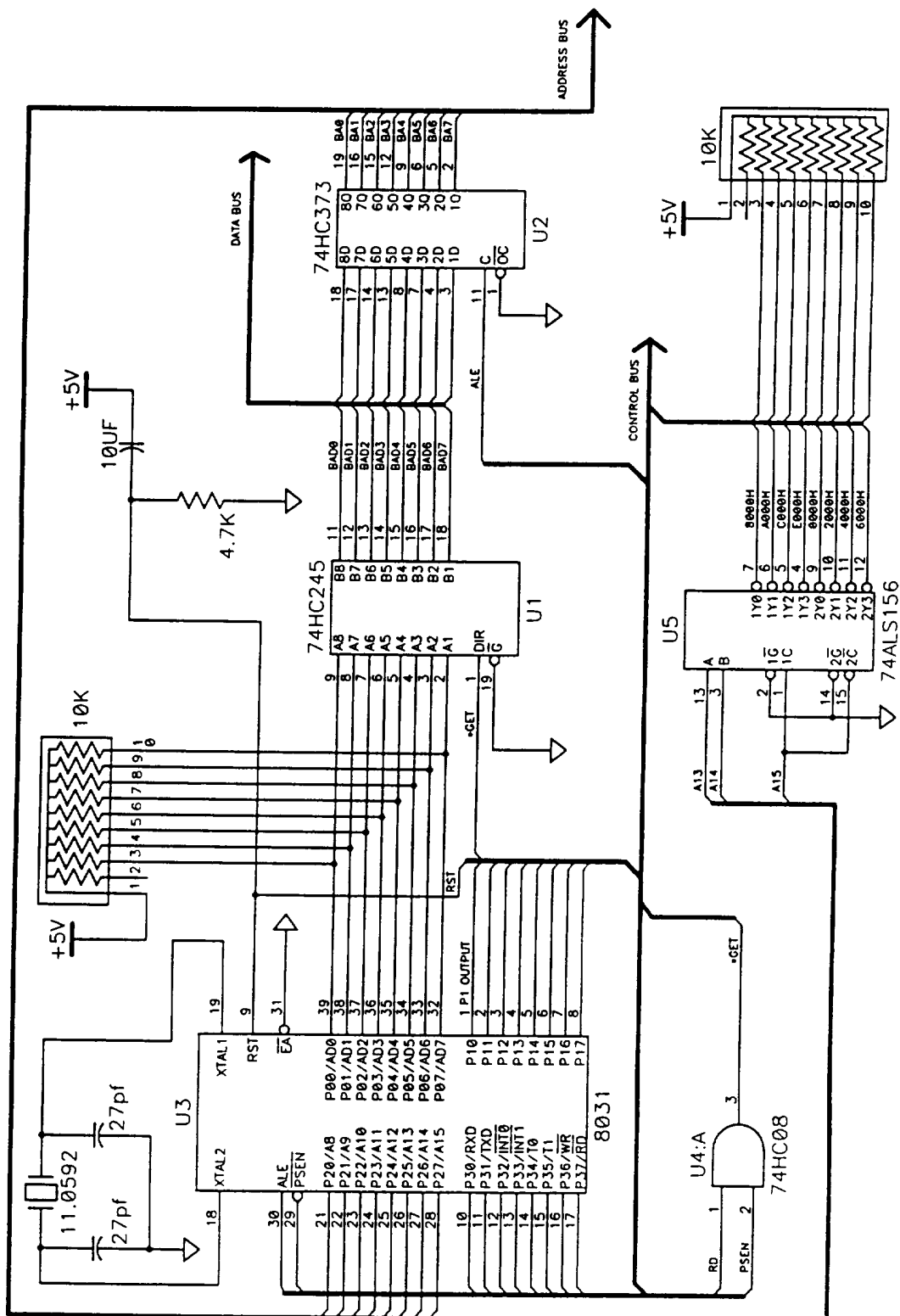


FIG. 3(c)

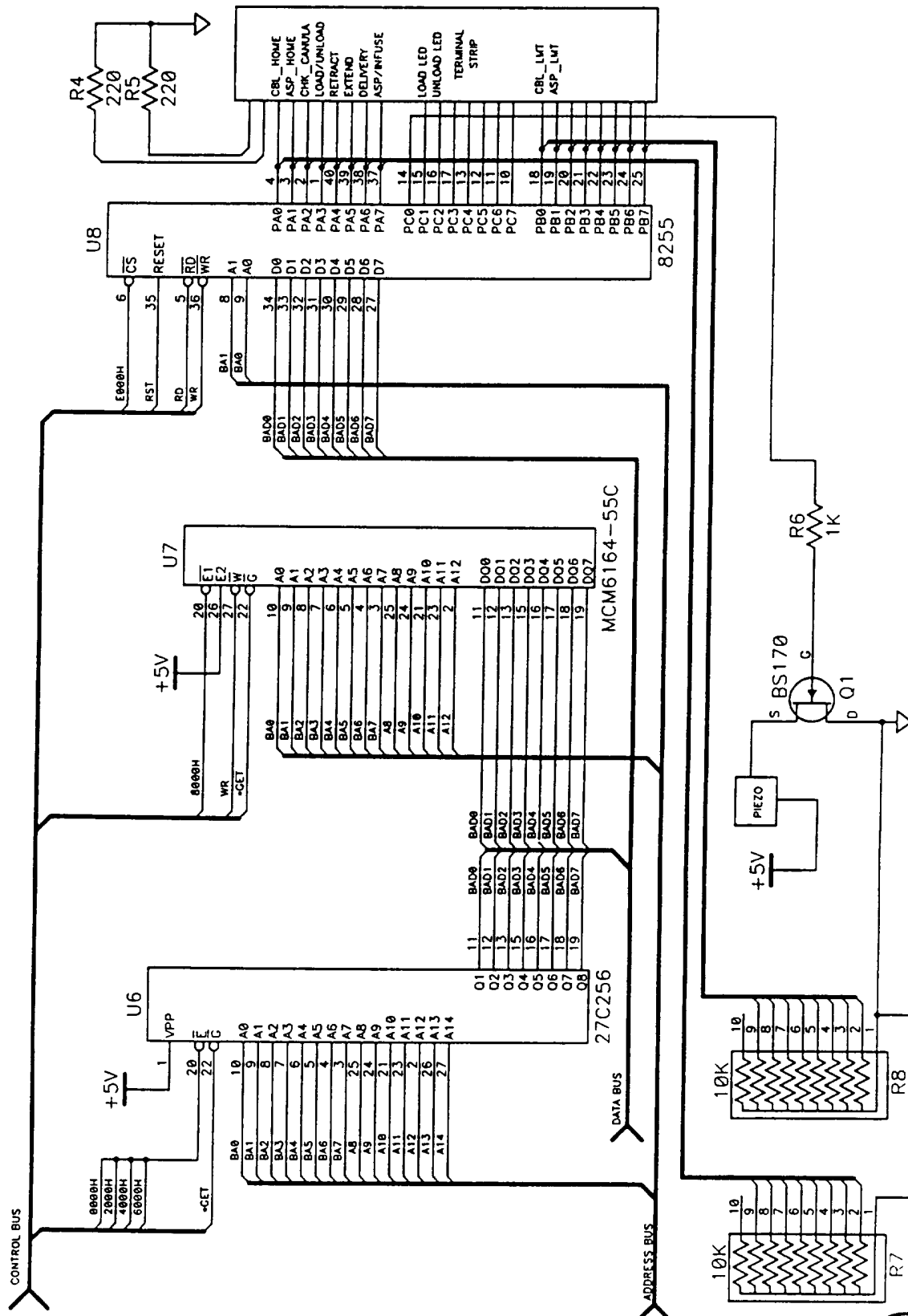


FIG. 3(d)

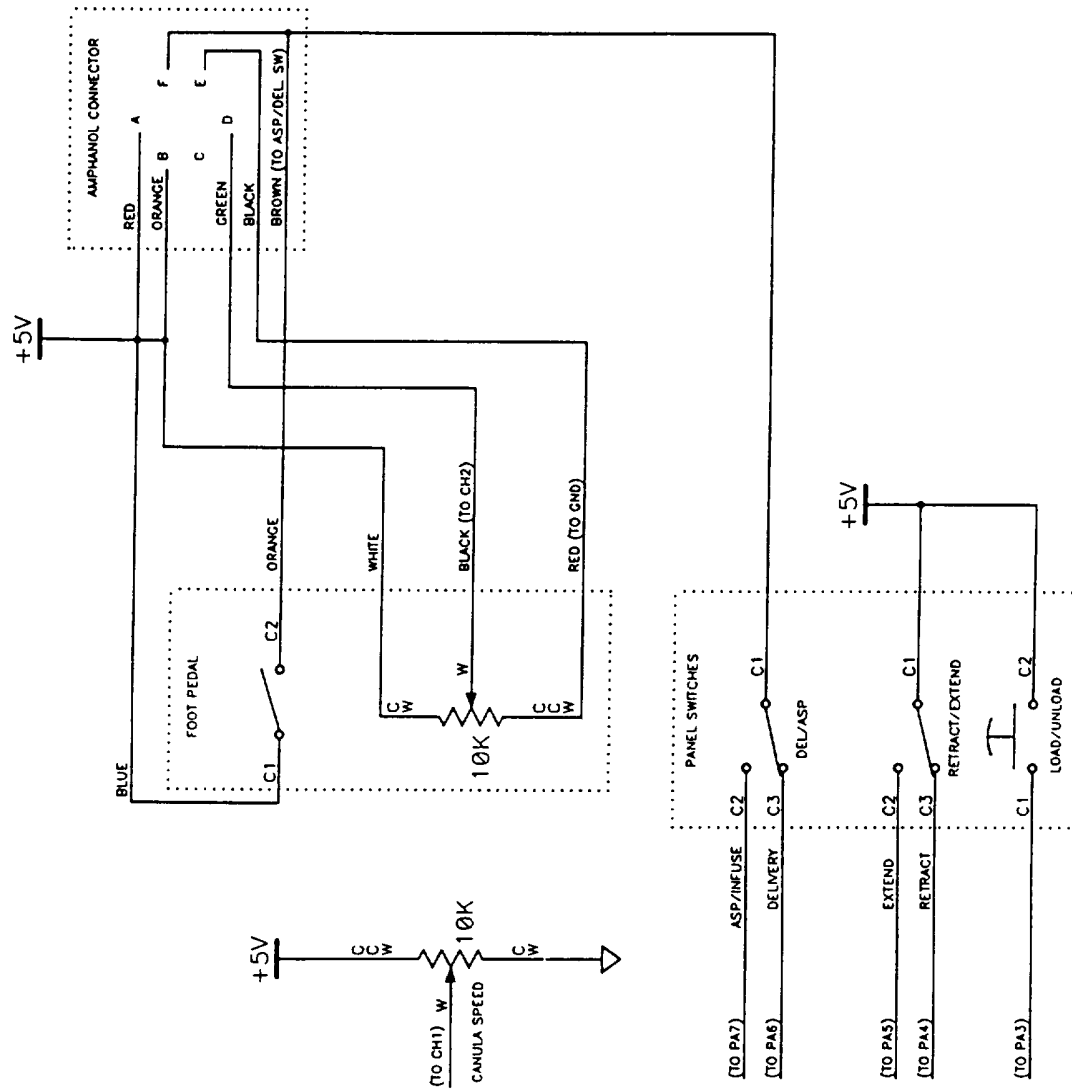


FIG. 3(e)

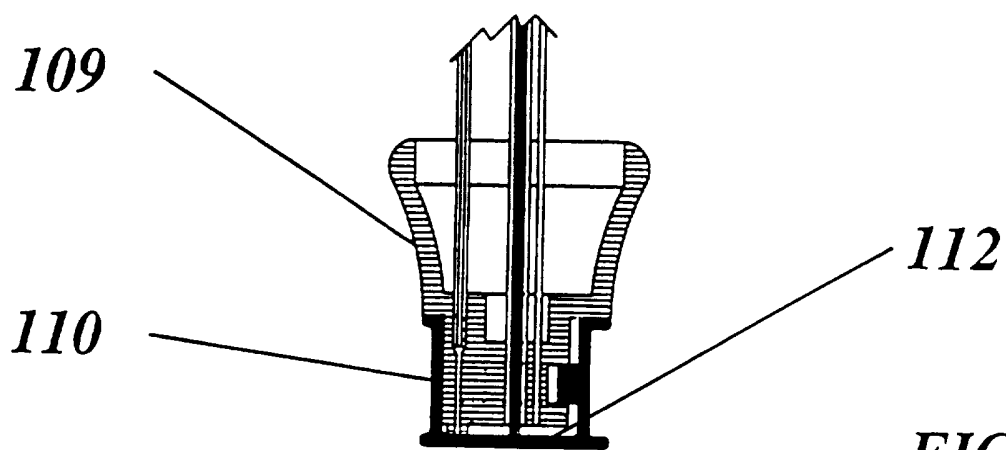
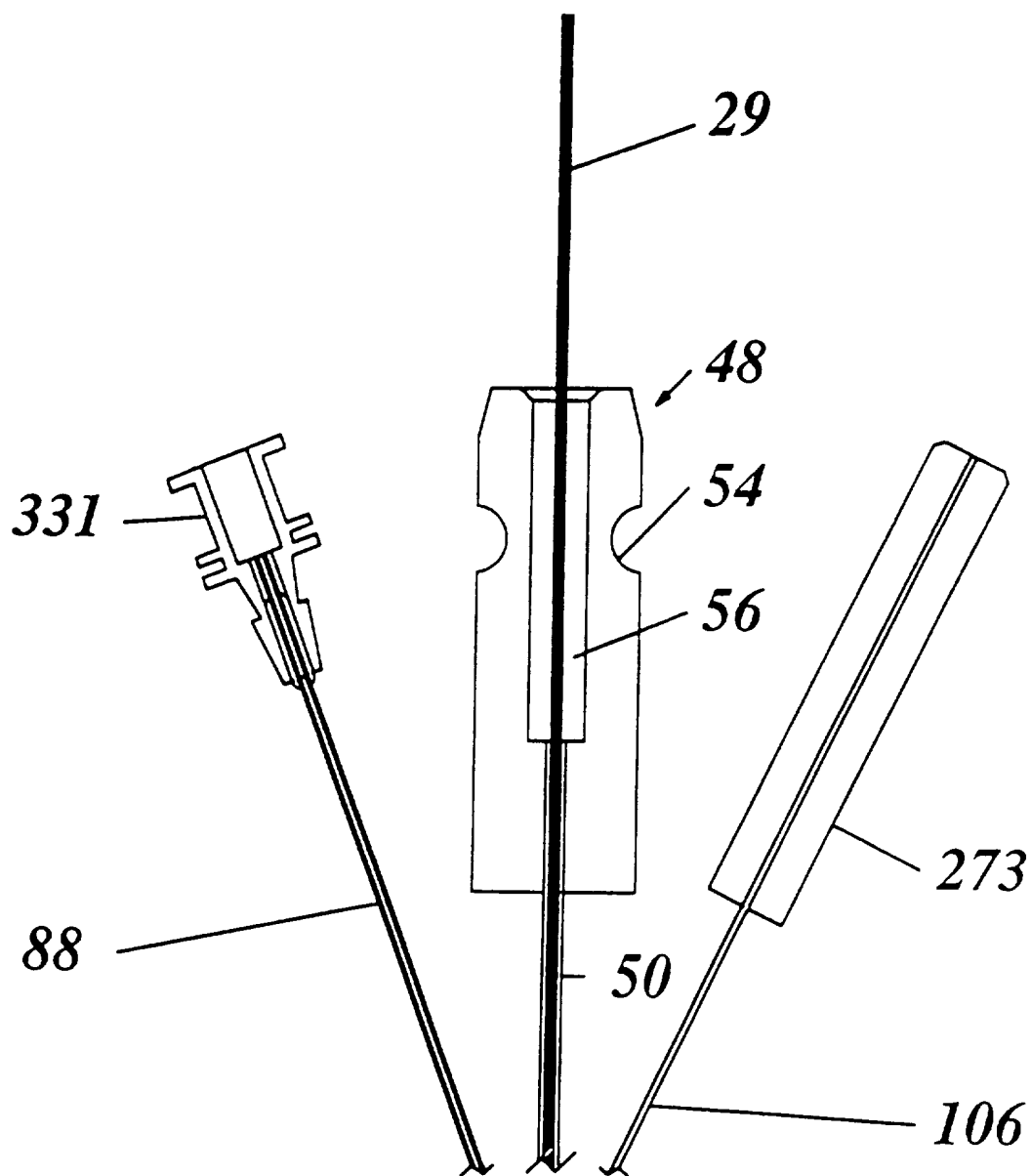
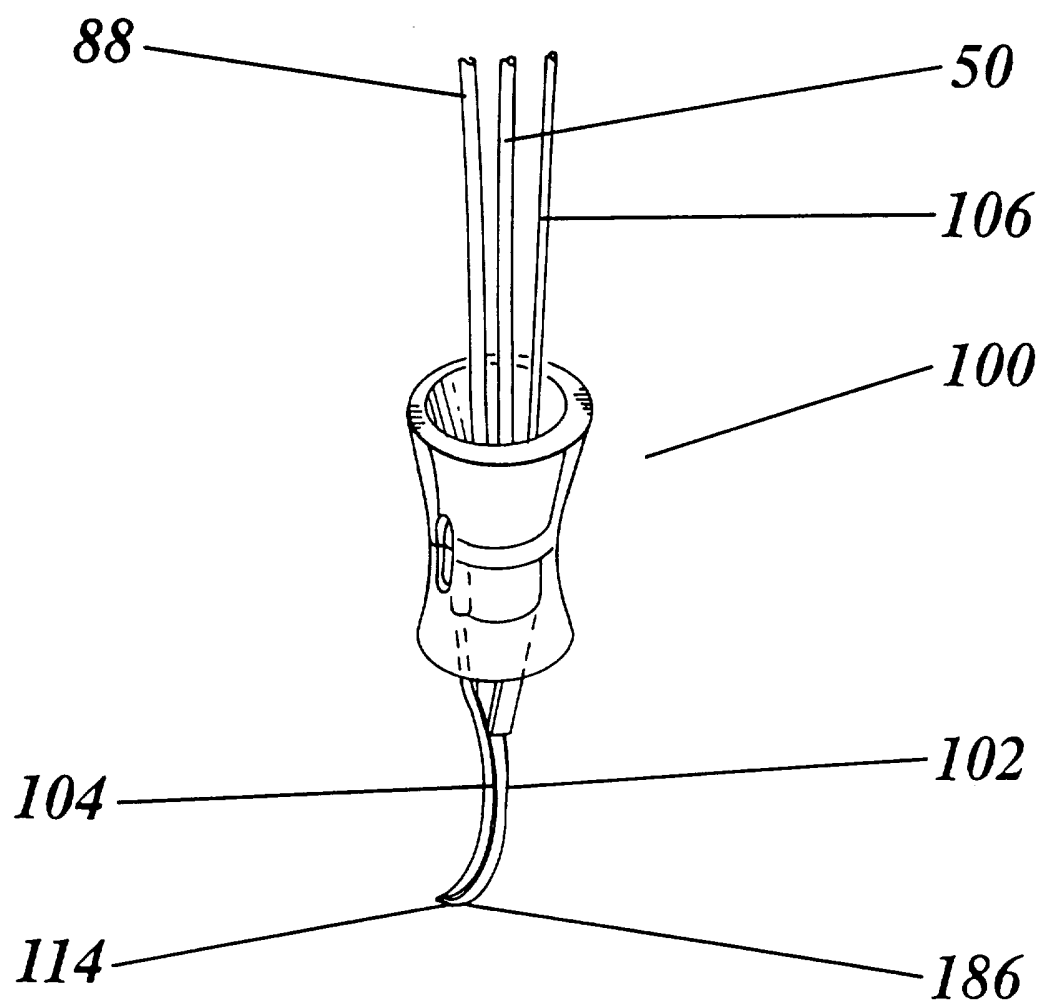


FIG. 4

**FIG. 5**

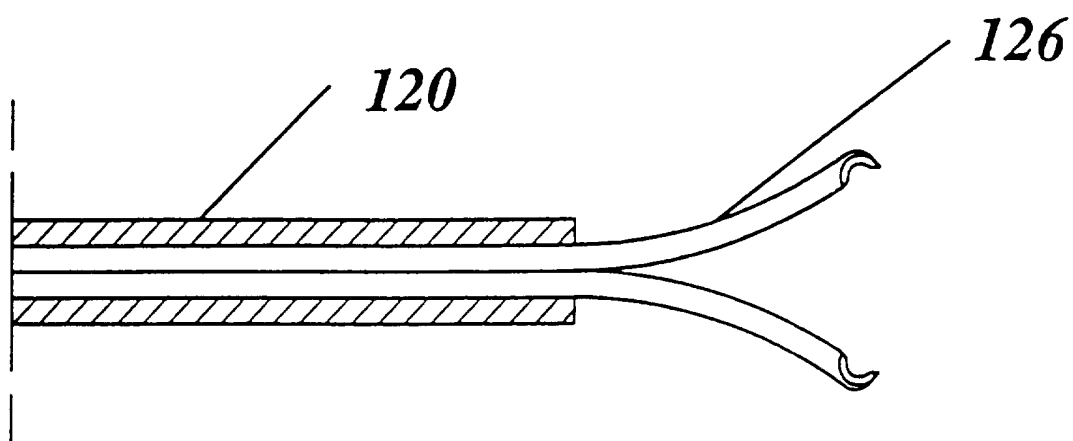


FIG. 6b

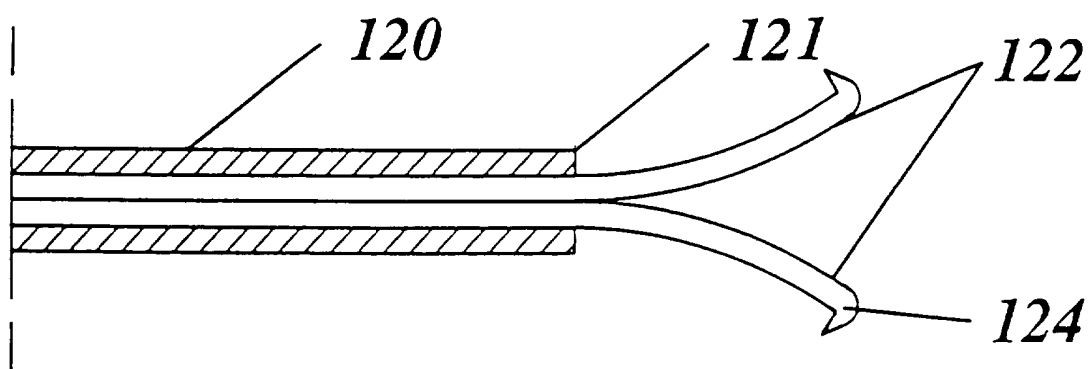
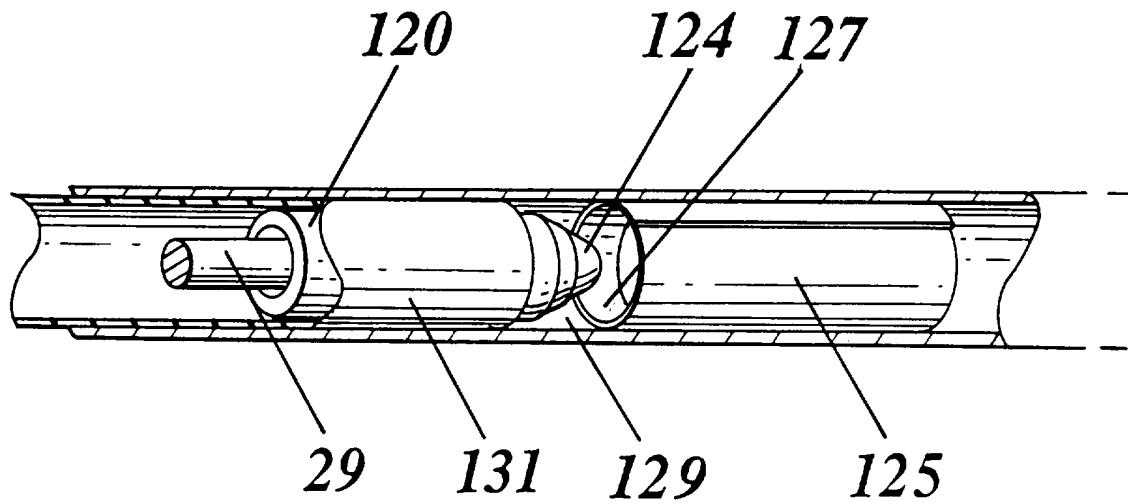
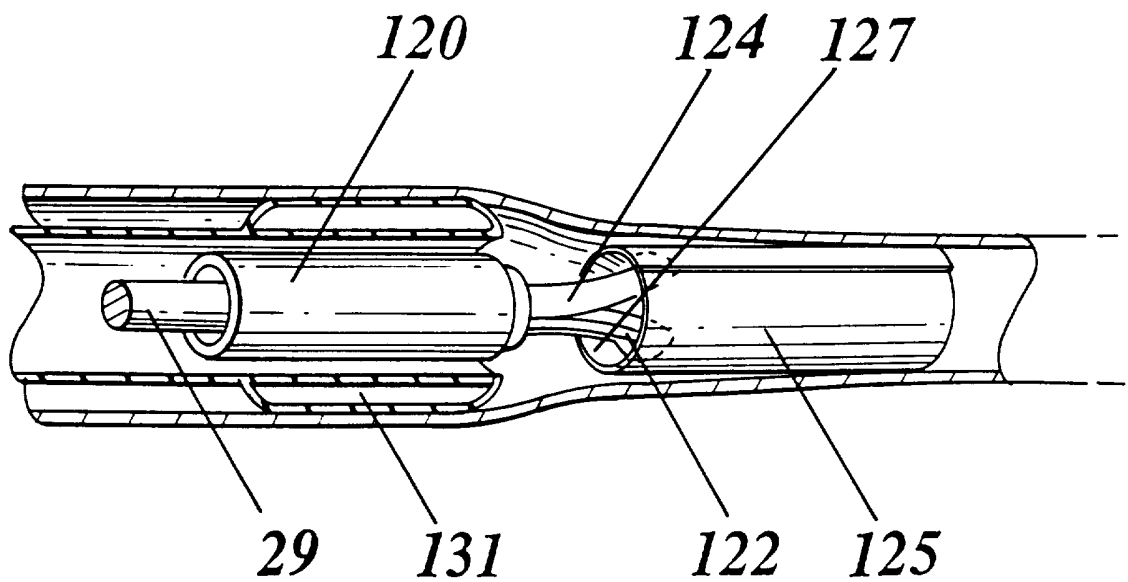


FIG. 6a

FIG. 6c*FIG. 6d*

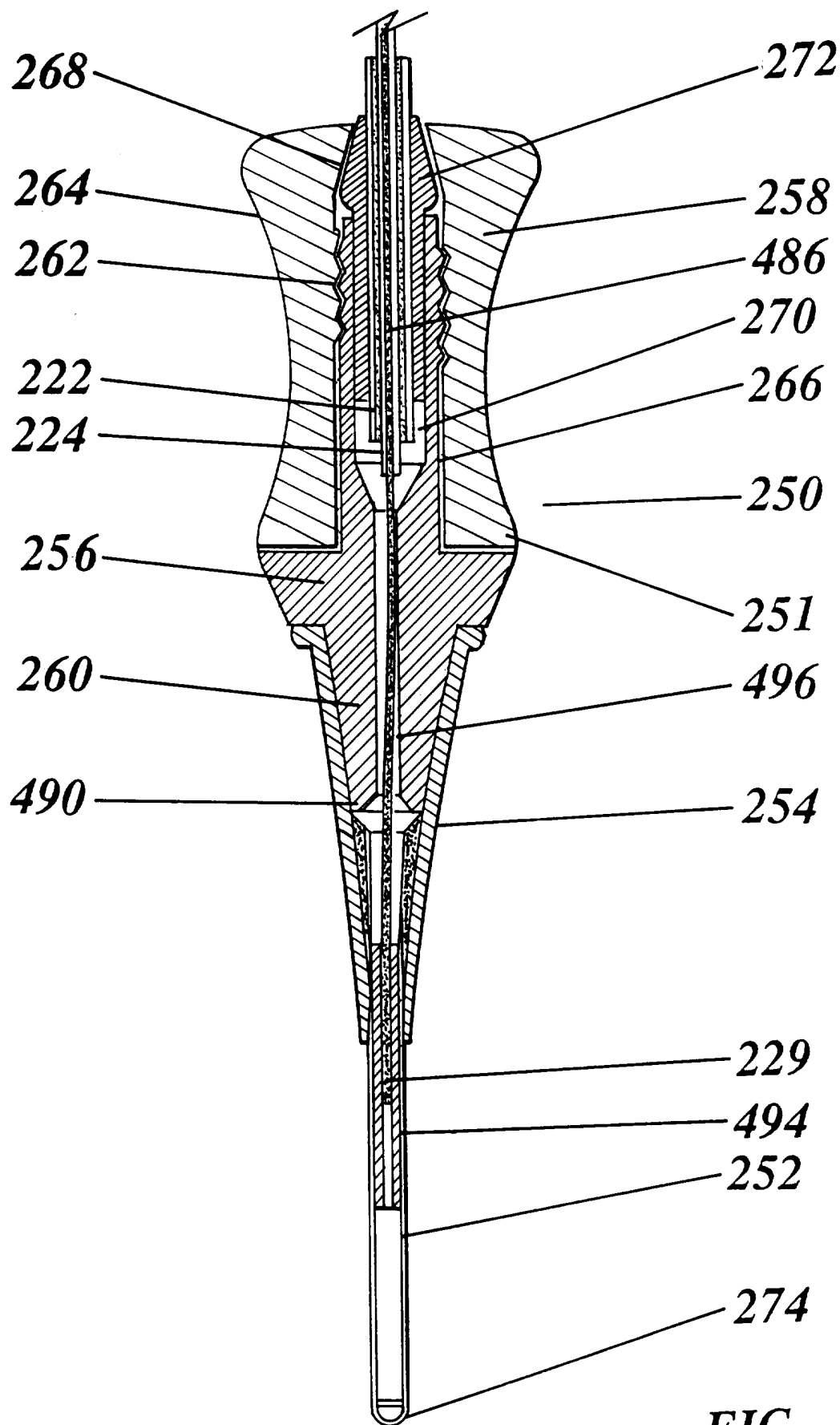


FIG. 7

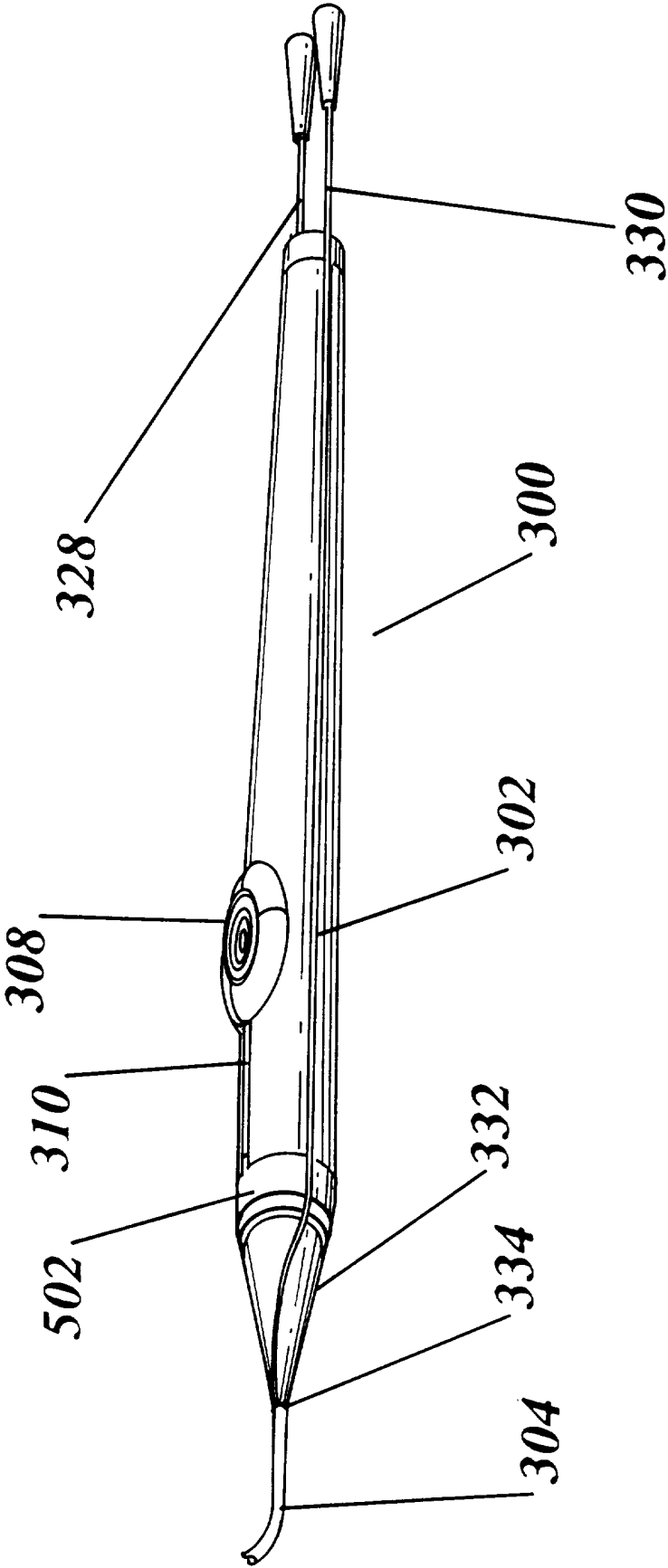
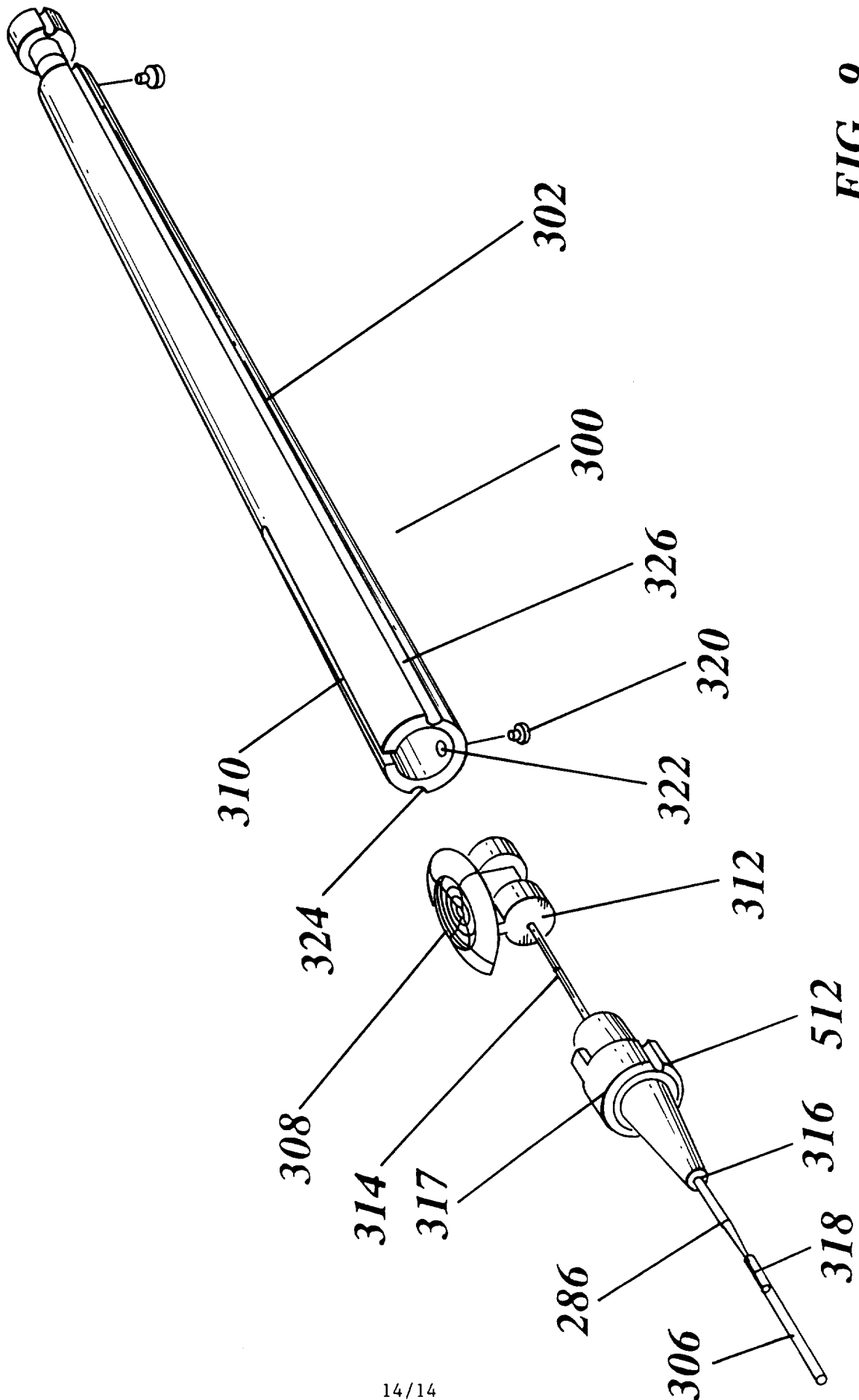


FIG. 8

FIG. 9



INTERNATIONAL SEARCH REPORT

International application No.
PCT/US96/02270

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) : A61F 11/00

US CL : 606/108

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)

U.S. : 606/108,1,127,167-185

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)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US, A, 4,428,748 (PEYMAN ET AL.) 31 January 1984, see Fig. 1, and column 3 lines 19-61.	1-6
X	DE, A, 3632 786 (GRIESAT W) 31 March 1988, see Figs. 1-3.	1, 7-9
X	EP, A, 428 998 (SCHNEPP-PESCH) 29 May 1991, see Fig. 1.	1, 3
X, P	US, A, 5,409,478 (GERRY ET AL.) 25 April 1995, see Fig. 2.	1, 3, 6

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

* Special categories of cited documents:	*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
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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	

Date of the actual completion of the international search

21 JUNE 1996

Date of mailing of the international search report

19 JUL 1996

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