



(11) **EP 1 960 032 B9**

(12) **CORRECTED EUROPEAN PATENT SPECIFICATION**

(15) Correction information:
Corrected version no 1 (W1 B1)
Corrections, see
Description Paragraph(s) 3, 5-10

(51) Int Cl.:
A61M 37/00 (2006.01)

(86) International application number:
PCT/US2006/033909

(48) Corrigendum issued on:
07.09.2011 Bulletin 2011/36

(87) International publication number:
WO 2007/037900 (05.04.2007 Gazette 2007/14)

(45) Date of publication and mention
of the grant of the patent:
15.12.2010 Bulletin 2010/50

(21) Application number: **06790101.7**

(22) Date of filing: **30.08.2006**

(54) **SURGICAL CASSETTE FOR INTRAOCULAR PRESSURE CONTROL**
CHIRURGISCHE KASSETTE FÜR DIE INTRAOKULARE DRUCKKONTROLLE
CASSETTE CHIRURGICALE DE MESURE DE LA TENSION INTRAOCULAIRE

(84) Designated Contracting States:
AT BE BG CH CY CZ DE DK EE ES FI FR GB GR
HU IE IS IT LI LT LU LV MC NL PL PT RO SE SI
SK TR

(30) Priority: **28.09.2005 US 237568**

(43) Date of publication of application:
27.08.2008 Bulletin 2008/35

(60) Divisional application:
10194426.2 / 2 286 851

(73) Proprietor: **Alcon, Inc.**
6331 Hünenberg (CH)

(72) Inventors:
• **NAZARIFAR, Nader**
Laguna Niguel, CA 92677 (US)
• **HOPKINS, Mark A.**
Mission Viejo
California 92691 (US)

- **GAO, Shawn X.**
Irvine
California 92620 (US)
- **REED, Frederick M.**
Cypress
California 90630 (US)
- **HUCULAK, John C.**
Mission Viejo
California 92692 (US)
- **THOMAS, Roger D.**
Tustin
California 92782 (US)

(74) Representative: **Moore, Barry et al**
Hanna Moore & Curley
13 Lower Lad Lane
Dublin 2 (IE)

(56) References cited:
WO-A-91/17112 **WO-A-94/27659**
WO-A-03/079927 **US-A- 5 047 009**
US-A1- 2002 019 607 **US-A1- 2003 208 155**
US-A1- 2004 116 911 **US-A1- 2004 204 679**
US-A1- 2005 065 462 **US-B1- 6 485 451**

EP 1 960 032 B9

Note: Within nine months of the publication of the mention of the grant of the European patent in the European Patent Bulletin, any person may give notice to the European Patent Office of opposition to that patent, in accordance with the Implementing Regulations. Notice of opposition shall not be deemed to have been filed until the opposition fee has been paid. (Art. 99(1) European Patent Convention).

DescriptionField of the Invention

[0001] The present invention generally pertains to microsurgical systems and more particularly to controlling intraocular pressure in ophthalmic surgery.

Description of the Related Art

[0002] During small incision surgery, and particularly during ophthalmic surgery, small probes are inserted into the operative site to cut, remove, or otherwise manipulate tissue. During these surgical procedures, fluid is typically infused into the eye, and the infusion fluid and tissue are aspirated from the surgical site.

[0003] Maintaining an optimum intraocular pressure during ophthalmic surgery is currently problematic. When no aspiration is occurring, the pressure in the eye becomes the pressure of the fluid being infused into the eye. This pressure is typically referred to as the "dead head pressure". However, when aspiration is applied, the intraocular pressure drops dramatically from the dead head pressure due to all the pressure losses in the aspiration circuit associated with aspiration flow. Therefore, ophthalmic surgeons currently tolerate higher than desired dead head pressures to compensate for occasions when aspiration would otherwise lower the intraocular pressure to soft-eye conditions. Clinically, such overpressurizing of the eye is not ideal.

[0004] US 2004204679 (A1) describes a disposable trumpet valve tube cassette assembly, as well as, a surgical irrigation instrument that includes a probe assembly, a pump, a removable pump cartridge, and a socket. The probe assembly provides passage of fluids for irrigating the body interior and for evacuating matter from the body interior.

[0005] US 6485451 (B1) describes a body cavity irrigation system includes a housing having at least one interior chamber which is connectable to a faucet or other continuous fluid supply which delivers liquid under pressure through an inlet port.

[0006] WO 03079927 (A2) describes a method and system for continuous infusion of a dense fluid (e.g., a perfluorocarbon) during performance of a vitrectomy procedure. A vitrectomy cutter device is used to remove vitreous humor from the posterior chamber of the eye and a continuous flow of the dense fluid is infused in the posterior chamber concurrently with the removal of the vitreous through the vitrectomy cutter device.

[0007] WO 9117112 (A1) describes an irrigation system and method for delivering a selected one of multiple solutions to a treatment site. The invention solves the technical problem of being able to positively verify the type of solution being administered. The invention solves these problems by providing a plurality of solution reservoirs having a quantity of a solution, a selector valve coupling a handpiece to each of the solutions and a pump

causing the solutions to flow to the handpiece.

[0008] US 2003208155 (A1) describes automated control of aural irrigation by utilizing a process controller in connection with an irrigation supply unit and irrigation delivery unit. Sensors situated in the irrigation supply unit and irrigation delivery unit provide data feedback to the process controller enabling essentially instantaneous and precise control of operational parameters.

[0009] WO 9427659 (A1) describes a method comprising placing a flexible bag containing a biological liquid in an enclosure sealed by a cover. The flexible bag is connected to a cavity in the human body through a tube (8) that passes through the cover by means of a sealing gasket. In order to supply the biological liquid under an adjustable pressure to the cavity, the enclosure is connected to a source of pressurized air by means of an adjustable valve and a pressure regulator, so that the pressure of the liquid contained in the cavity remains constant, independently of the flow-rate in the outlet pipe.

[0010] Accordingly, a need continues to exist for improved apparatus for controlling intraocular pressure during ophthalmic surgery.

Summary of the Invention

[0011] Accordingly there is provided a surgical cassette as detailed in claim 1. Advantageous embodiments are provided in the dependent claims.

Brief Description of the Drawings

[0012] For a more complete understanding of the present invention, and for further objects and advantages thereof, reference is made to the following description taken in conjunction with the accompanying drawings, in which:

Figure 1 is a schematic diagram illustrating infusion control in an ophthalmic microsurgical system;

Figure 2 is a schematic diagram illustrating infusion control and irrigation control in an ophthalmic microsurgical system;

Figure 3 is a front, perspective view of a preferred surgical cassette for use in the ophthalmic microsurgical system of Figures 1 and 2; and

Figure 4 is a front, perspective, partially fragmentary view of a dual infusion chamber of the surgical cassette of Figure 3.

Detailed Description of the Preferred Embodiments

[0013] The preferred embodiments of the present invention and their advantages are best understood by referring to Figures 1-4 of the drawings, like numerals being used for like and corresponding parts of the various drawings. As shown in Figure 1, ophthalmic microsurgical system 10 includes a pressure cuff 12; an infusion source 14; a dual infusion chamber 16 having a chamber 16a

and a chamber 16b; fluid level sensors 18 and 20; a flow sensor 22; filters 24 and 26; a surgical device 29; a computer or microprocessor 28; gas manifolds 30 and 32; a pressurized gas source 34; proportional solenoid valves 36, 38, and 40; "on/off" solenoid valves 42, 44, 46, 48, 50, 52, 54; actuators 56, 58, 60, and 62; and pressure transducers 64, 66, and 68. Dual infusion chamber 16; fluid level sensors 18 and 20; portions of infusion fluid lines 70, 72, 74, 76, 78, and 80; and portions of gas lines 84 and 86 are disposed in a surgical cassette 27. Infusion source 14; dual infusion chamber 16; flow sensor 22; filters 24 and 26; and surgical device 29 are fluidly coupled via infusion fluid lines 70-80. Infusion source 14, dual infusion chamber 16, gas manifolds 30 and 32; pressurized gas source 34; and actuators 56, 58, 60, and 62 are fluidly coupled via gas lines 82, 84, 86, 88, 90, 92, 94, and 96. Infusion source 14; fluid level sensors 18-20; flow sensor 22; microprocessor 28; proportional solenoid valves 36-40; on/off solenoid valves 42-54; actuators 56-62; and pressure transducers 64-68 are electrically coupled via interfaces 100, 102, 104, 106, 108, 110, 112, 114, 116, 118, 120, 122, 124, 126, 128, 130, and 132.

[0014] Infusion source 14 is preferably a flexible infusion source. As shown best in Figures 3-4, dual infusion chamber 16 is preferably formed on a rear surface 27a of surgical cassette 27. Surgical cassette 27 preferably also has a top surface 27b and a bottom surface 27c. Chambers 16a and 16b are preferably separated by a divider 16c, and chambers 16a and 16b are not fluidly coupled. Dual infusion chamber 16 preferably also has an upper surface 16d and a lower surface 16e. As shown best in Figures 1-2, chamber 16b has an opening 226 disposed on or near lower surface 16e for fluid line 74, and chamber 16a has an opening 228 disposed on or near lower surface 16e for fluid line 72. As used in the context of the preceding sentence, "near" preferably means closer to lower surface 16e than to a transverse plane passing through a midpoint between lower surface 16e and upper surface 16d, and "near" more preferably means closer to lower surface 16e than to a transverse plane passing through a point one quarter of the distance from lower surface 16e and three quarters of the distance from upper surface 16d. Fluid level sensors 18 and 20 may be any suitable device for measuring the level of fluid in infusion chambers 16a and 16b, respectively. Fluid level sensors 18 and 20 are preferably capable of measuring the level of fluid in infusion chambers 16a and 16b in a continuous manner. Flow sensor 22 may be any suitable device for measuring the flow rate of fluid within fluid line 80. Flow sensor 22 is preferably a non-invasive flow sensor. Filters 24 and 26 are hydrophobic microbacterial filters. A preferred filter is the Versapor® membrane filter (0.8 micron) available from Pall Corporation of East Hills, New York. Microprocessor 28 is capable of implementing feedback control, and preferably PID control. Surgical device 29 may be any suitable device for providing surgical irrigating fluid to the eye but is preferably an infusion cannula, an irrigation handpiece, or and

irrigation/aspiration handpiece. The portions of fluid lines 70-80 disposed in surgical cassette 27, and the portions of gas lines 84-46 disposed in surgical cassette 27, may be any suitable line, tubing, or manifold for transporting a fluid but are preferably manifolds integrally molded into surgical cassette 27.

[0015] In operation, fluid lines 70, 72, and 74; chambers 16a and 16b; fluid lines 76, 78, and 80; and surgical device 29 are all primed with a surgical irrigating fluid 140 by pressurizing infusion source 14. Surgical irrigating fluid 140 may be any surgical irrigating fluid suitable for ophthalmic use, such as, by way of example, BSS PLUS® intraocular irrigating solution available from Alcon Laboratories, Inc.

[0016] The pressurizing of infusion source 14 is preferably performed by pressure cuff 12. More specifically, microprocessor 28 sends a control signal to open solenoid valve 42 via interface 106 and to close solenoid valves 44 and 46 via interfaces 108 and 110, respectively. Microprocessor 28 also sends a control signal to open proportional solenoid valve 40 via interface 104 so that manifold 30 supplies the appropriate amount of pressurized air to actuate pressure cuff 12. Pressure transducer 68 senses the pressure within gas line 82 and provides a corresponding signal to microprocessor 28 via interface 126. Solenoid valves 48-54 are initially open so that manifold 32 provides pressurized air to actuate actuators 56-62 to close fluid lines 72-78. Microprocessor 28 sends control signals to close solenoid valves 48-54 via interfaces 114-120. The closing of solenoid valves 48-54 actuates actuators 56-62 to open fluid lines 72-78. After all chambers and fluid lines are primed, microprocessor 28 closes actuators 56-62 and thus fluid lines 72-78. Alternatively, the pressuring of infusion source 14 may be performed solely via gravity.

[0017] After priming, a user then provides a desired intraocular pressure to microprocessor 28 via an input 134. Input 134 may be any suitable input device but is preferably a touch screen display or physical knob. Chamber 16b is preferably the initial active infusion chamber. Microprocessor 28 sends appropriate control signals to open solenoid valve 44 and to open proportional solenoid valve 36 (via interface 100) to provide an appropriate level of pressurized air to chamber 16b. Pressure transducer 64 senses the pressure within gas line 84 and provides a corresponding signal to microprocessor 28 via interface 124. Microprocessor 28 also sends an appropriate control signal to open actuator 60 and thus fluid line 78. Chamber 16b supplies pressurized fluid 140 to the eye via fluid lines 78 and 80 and surgical device 29. Flow sensor 22 measures the flow rate of fluid 140 and provides a corresponding signal to microprocessor 28 via interface 132. Microprocessor 28 calculates a predicted intraocular pressure using the signal from flow sensor 22 and empirically determined impedance information of microsurgical system 10. Microprocessor 28 then sends an appropriate feedback control signal to proportional solenoid valve 36 to maintain the predicted in-

traocular pressure at or near the desired intraocular pressure during all portions of the surgery.

[0018] Fluid level sensor 20 continuously monitors the decrease in the level of fluid 140 in chamber 16b during surgery and provides a corresponding signal to microprocessor 28 via interface 130. Microprocessor 28 performs adjustments to the air pressure provided to chamber 16b to accommodate for the difference in fluid head height as the level of fluid 140 decreases. When the level of fluid 140 in chamber 16b reaches a bottom limit level, microprocessor 28 closes solenoid valve 44 and actuator 60 and opens solenoid valve 46 and actuators 58 and 62. Chamber 16a is now the active infusion chamber. Microprocessor 28 sends an appropriate control signal to proportional solenoid valve 38 via interface 102 to provide an appropriate level of pressurized air to chamber 16a. Pressure transducer 66 senses the pressure within gas line 86 and provides a corresponding signal to microprocessor 28 via interface 122. Chamber 16a supplies pressurized fluid 140 to the eye via fluid lines 76 and 80 and surgical device 29. Flow sensor 22 measures the flow rate of fluid 140 and provides a corresponding signal to microprocessor 28 via interface 132. Microprocessor 28 calculates the predicted intraocular pressure as described above and the sends an appropriate feedback signal to proportional solenoid valve 38 to maintain the predicted intraocular pressure at or near the desired intraocular pressure during all portions of the surgery. Microprocessor 28 closes actuator 58 and fluid line 74 once chamber 16b is refilled with fluid 140.

[0019] Fluid level sensor 18 continuously monitors the decrease in the level of fluid 140 in chamber 16a during surgery and provides a corresponding signal to microprocessor 28 via interface 128. Microprocessor 28 performs adjustments to the air pressure provided to chamber 16a to accommodate for the difference in fluid head height as the level of fluid 140 decreases. When the level of fluid 140 in chamber 16a reaches a bottom limit level, microprocessor 28 switches chamber 16b to active infusion, makes chamber 16a inactive, and refills chamber 16a with fluid 140 via fluid line 72. This cycling between chambers 16b and 16a continues throughout the surgery.

[0020] Infusion source 14 is preferably monitored via a fluid level sensor (not shown) capable of providing a signal to microprocessor 28 via interface 112 when source 14 reaches a near empty limit. Chambers 16a and 16b also preferably each have a volume that enable infusion source 14 to be exchanged, when near empty, without interrupting the surgical procedure. More specifically, chambers 16a and 16b preferably each have a volume of about 30 cc. Such volume allows about two minutes for a near empty infusion source 14 to be exchanged during conditions of maximum flow (e.g. core vitrectomy). In addition, since fluid lines 72 and 74 are fluidly coupled to chambers 16a and 16b, respectively, at or near lower surface 16e, once infusion source 14 is exchanged all air bubbles within fluid lines 70, 72, and 74 will be automatically "scrubbed out" as the inactive

chamber 16a or 16b refills, without the need for re-priming.

[0021] In the case of failure of either of chambers 16a or 16b, microprocessor 28 can preferably continue surgery with only one active chamber. In the case of failure of both chambers 16a and 16b, microprocessor 28 can preferably continue surgery using only infusion source 14.

[0022] Figure 2 shows a modified ophthalmic microsurgical system 10a. Microsurgical system 10a is similar to microsurgical system 10 except that it has an irrigation system in addition to the infusion system described above for system 10. More specifically, system 10a is identical to system 10 except that system 10a also includes an irrigation source 200; fluid lines 202 and 206; gas lines 208 and 216; solenoid valves 210 and 218; actuators 214 and 222; electrical interfaces 212 and 220; and a surgical device 224. As shown in Figure 2, irrigation source 200 is pressurized solely by gravity. The portions of fluid lines 202 and 206 disposed in surgical cassette 27, and the portions of gas lines 208 and 216 disposed in surgical cassette 27, may be any suitable line, tubing, or manifold for transporting a fluid but are preferably manifolds integrally molded into surgical cassette 27. As will be appreciated by one of ordinary skill in the art, microsurgical system 10a allows surgical irrigating fluid 140 to be delivered to surgical device 29 via fluid line 80 (infusion), and surgical irrigating fluid 140 to be delivered to surgical device 224 via fluid line 206 (irrigation), independently. Microprocessor 28 can calculate flow information for fluid 140 within fluid line 206 by continuously monitoring the volumetric change of fluid inside chamber 16b, as indicated by fluid sensor 20.

[0023] From the above, it may be appreciated that the present invention provides an improved method of controlling intraocular pressure with a microsurgical system. The present invention is illustrated herein by example, and various modifications may be made by a person of ordinary skill in the art. For example, while the present invention is described above relative to controlling intraocular pressure in an ophthalmic microsurgical system, it is also applicable to controlling pressure within the operative tissue during other types of microsurgery.

[0024] It is believed that the operation and construction of the present invention will be apparent from the foregoing description. While the apparatus and methods shown or described above have been characterized as being preferred, various changes and modifications may be made therein without departing from the scope of the invention as defined in the following claims

Claims

1. An ophthalmic surgical cassette (27), comprising:
 - a dual infusion chamber (16), said dual infusion chamber having a first chamber (16a) not fluidly

coupled to a second chamber (16b);
 a first fluid line (72) fluidly coupled to said first chamber for providing an irrigating fluid (140) to said first chamber;
 a second fluid line (76) fluidly coupled to said first chamber for providing said irrigating fluid to a surgical device (29);
 a third fluid line (74) fluidly coupled to said second chamber for providing said irrigating fluid to said second chamber; and
 a fourth fluid line (78) fluidly coupled to said second chamber for providing said irrigating fluid to said surgical device;
 said dual infusion chamber, said first fluid line, said second fluid line, said third fluid line, and said fourth fluid line being disposed within an interior of said surgical cassette.

2. The surgical cassette of claim 1 wherein said first chamber and said second chamber are separated by a divider (16c).
3. The surgical cassette of claim 1 further comprising a fifth fluid line (202) fluidly coupled to one of said first chamber or said second chamber for providing said irrigating fluid to said one of said first chamber or said second chamber.
4. The surgical cassette of claim 3 further comprising a sixth fluid line (206) fluidly coupled to said one of said first chamber or said second chamber for providing said irrigating fluid to a second surgical device (224).

Patentansprüche

1. Ophthalmische chirurgische Kassette (27), mit:

einer Doppel-Infusionskammer (16), wobei die Doppel-Infusionskammer eine erste Kammer (16a) hat, die nicht fluidisch mit einer zweiten Kammer (16b) gekoppelt ist;
 einer ersten Fluidleitung (72), die fluidisch mit der ersten Kammer gekoppelt ist, um ein Irrigationsfluid (140) zur ersten Kammer zu liefern;
 einer zweiten Fluidleitung (76), die fluidisch mit der ersten Kammer gekoppelt ist, um das Irrigationsfluid zu einem chirurgischen Gerät (29) zu liefern;
 einer dritten Fluidleitung (74), die fluidisch mit der zweiten Kammer gekoppelt ist, um das Irrigationsfluid zur zweiten Kammer zu liefern; und
 einer vierten Fluidleitung (78), die fluidisch mit der zweiten Kammer gekoppelt ist, um das Irrigationsfluid zu dem chirurgischen Gerät zu liefern;
 wobei die Doppel-Infusionskammer, die erste

Fluidleitung, die zweite Fluidleitung, die dritte Fluidleitung und die vierte Fluidleitung im Innern der chirurgischen Kassette angeordnet sind.

2. Chirurgische Kassette nach Anspruch 1, bei der die erste und zweite Kammer durch eine Trennwand (16c) getrennt sind.
3. Chirurgische Kassette nach Anspruch 1, die ferner eine fünfte Fluidleitung (202) aufweist, die fluidisch entweder mit der ersten oder der zweiten Kammer gekoppelt ist, um das Irrigationsfluid an die erste oder die zweite Kammer zu liefern.
4. Chirurgische Kassette nach Anspruch 3, die ferner eine sechste Fluidleitung (206) aufweist, die fluidisch entweder mit der ersten oder der zweiten Kammer gekoppelt ist, um das Irrigationsfluid an ein zweites chirurgisches Gerät (224) zu liefern.

Revendications

1. Cassette chirurgicale ophtalmique (27), comprenant :

une chambre de perfusion double (16), ladite chambre de perfusion double ayant une première chambre (16a) couplée de manière non fluïdique à une seconde chambre (16b) ;
 une première conduite de liquide (72) couplée de manière fluïdique à ladite première chambre pour amener un liquide d'irrigation (140) à ladite première chambre ;
 une deuxième conduite de liquide (76) couplée de manière fluïdique à ladite première chambre pour amener ledit liquide d'irrigation au dispositif chirurgical (29) ;
 une troisième conduite de liquide (74) couplée de manière fluïdique à ladite seconde chambre pour amener ledit liquide d'irrigation à ladite seconde chambre ; et
 une quatrième conduite de liquide (78) couplée de manière fluïdique à ladite seconde chambre pour amener ledit liquide d'irrigation audit dispositif chirurgical ;
 ladite chambre de perfusion double, ladite première conduite de liquide, ladite deuxième conduite de liquide, ladite troisième conduite de liquide, et ladite quatrième conduite de liquide étant disposées à l'intérieur de ladite cassette chirurgicale.

2. Cassette chirurgicale selon la revendication 1, dans laquelle ladite première chambre et ladite seconde chambre sont séparées par une cloison (16c).
3. Cassette chirurgicale selon la revendication 1, com-

prenant en outre une cinquième conduite de liquide (202), couplée de manière fluidique à une chambre parmi ladite première chambre et ladite seconde chambre pour amener ledit liquide d'irrigation à ladite chambre parmi ladite première chambre et ladite seconde chambre. 5

4. Cassette chirurgicale selon la revendication 3, comprenant en outre une sixième conduite de liquide (206) couplée de manière fluidique à ladite chambre parmi ladite première chambre et ladite seconde chambre pour amener ledit liquide d'irrigation au second dispositif chirurgical (224). 10

15

20

25

30

35

40

45

50

55

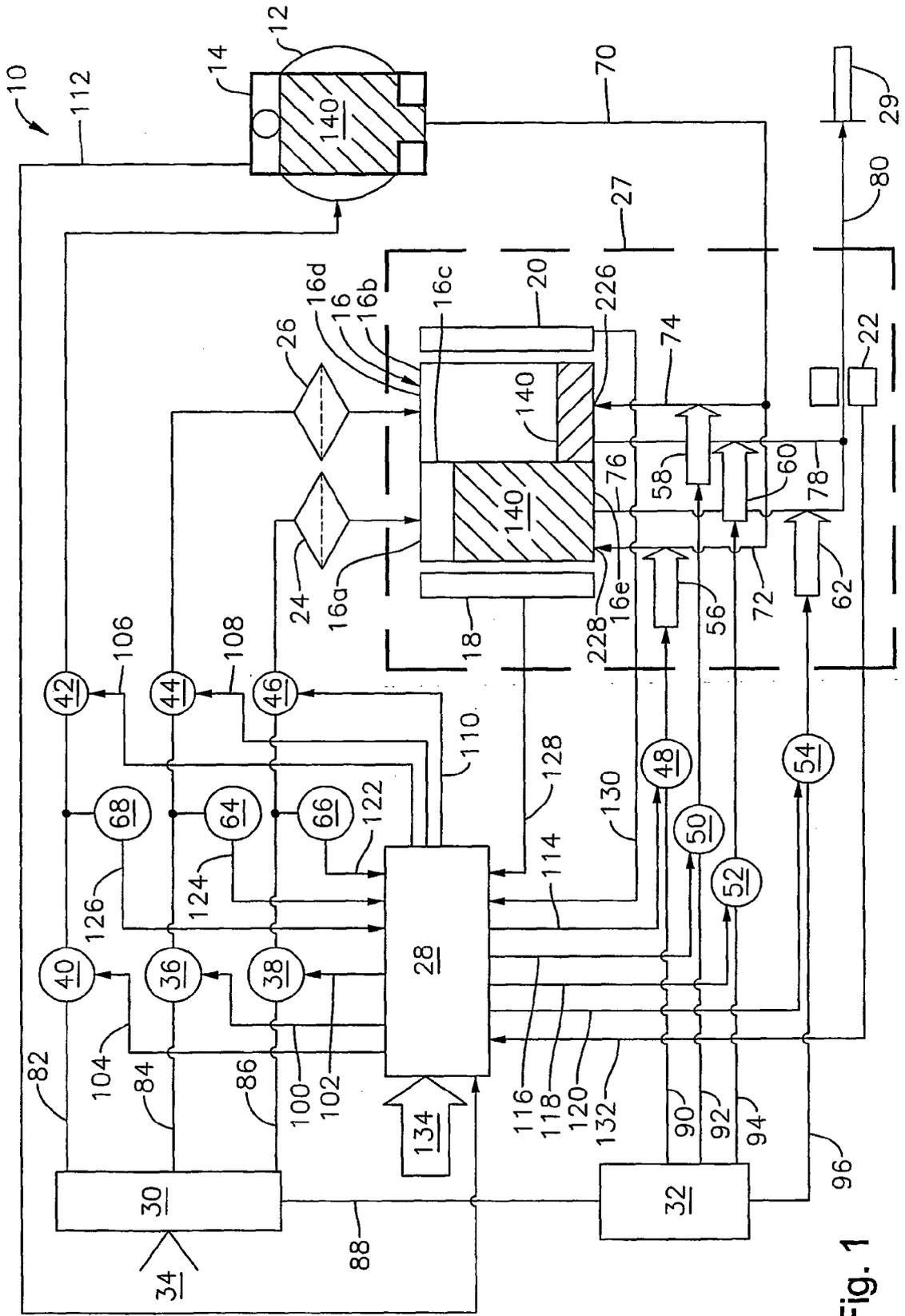


Fig. 1

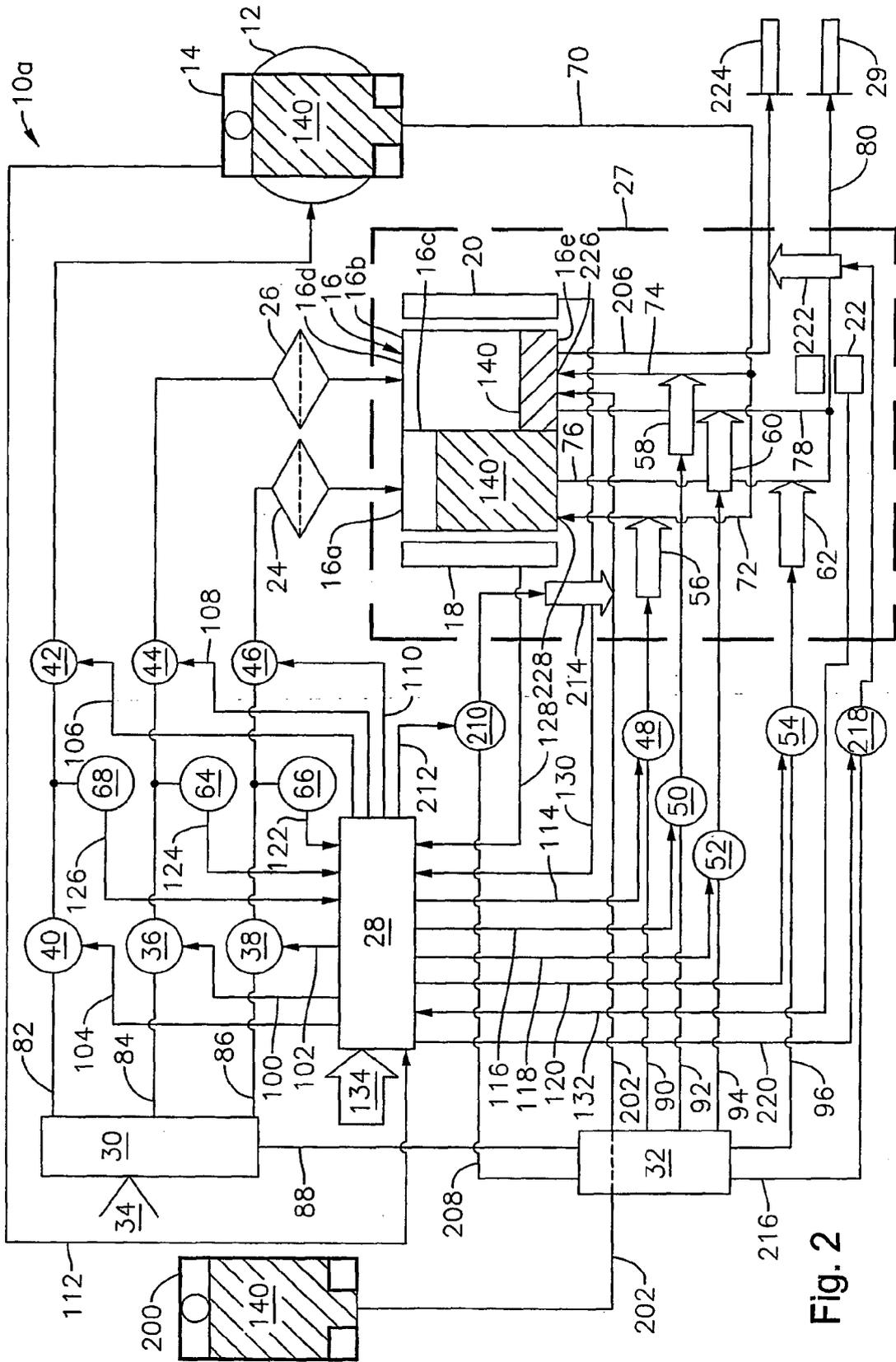


Fig. 2

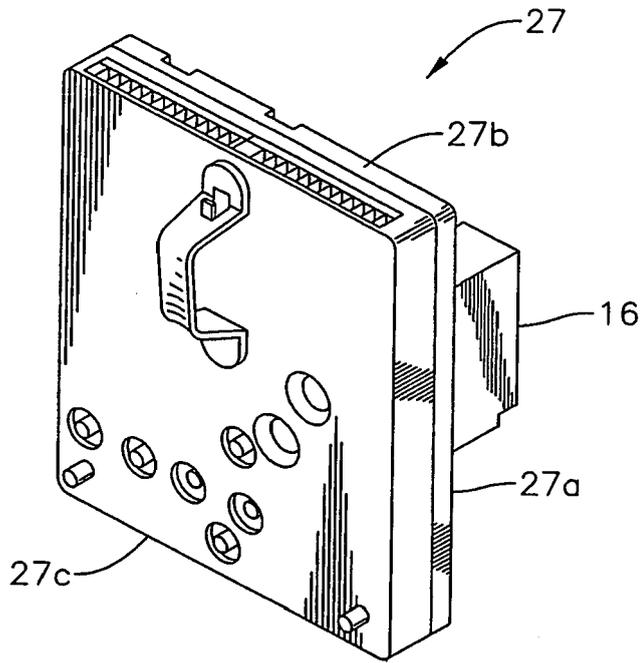
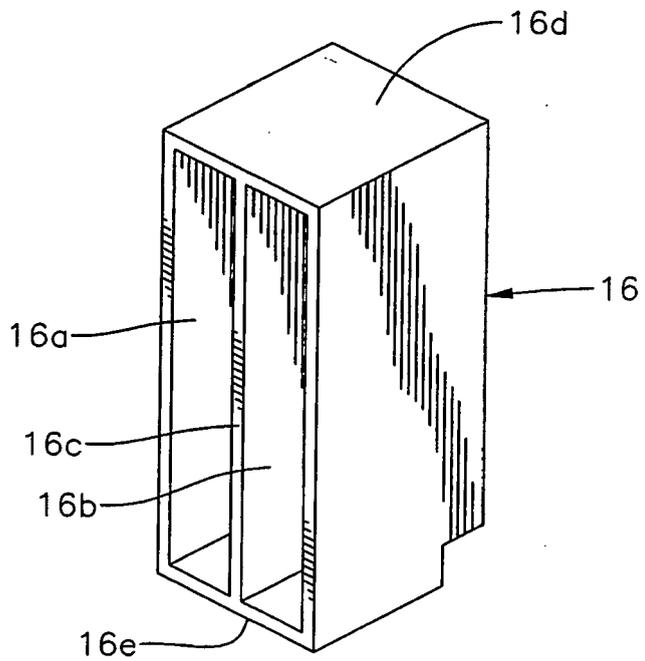


Fig. 3

Fig. 4



REFERENCES CITED IN THE DESCRIPTION

This list of references cited by the applicant is for the reader's convenience only. It does not form part of the European patent document. Even though great care has been taken in compiling the references, errors or omissions cannot be excluded and the EPO disclaims all liability in this regard.

Patent documents cited in the description

- US 2004204679 A1 [0004]
- US 6485451 B1 [0005]
- WO 03079927 A2 [0006]
- WO 9117112 A1 [0007]
- US 2003208155 A1 [0008]
- WO 9427659 A1 [0009]