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(71) Applicant: BAXTER INTERNATIONAL INC. [US/US]; One Baxter Parkway, DF3-3E, Deerfield, IL 60015 (US).

(72) Inventors: KUHN, David; 650 Garfield Avenue, Lake Bluff, IL 60044 (US). CARTWRIGHT, Jason; 1144 Weeping Willow Lane, Libertyville, IL 60048 (US). CHIM, Ed; 188 Monteith Court, Vernon Hills, IL 60061 (US). JENSEN, Jan; 4821 Blossom Court, Waukegan, IL 60087 (US). PRISCO, Michael; 833 Samantha Circle, Geneva, IL 60134 (US). RIPLEY, Jerry; P.O. Box 715, McHenry, IL 60051 (US).

(74) Agents: REAGEN, Joseph et al.; Baxter Healthcare Corporation, One Baxter Parkway, DF3-3E, Deerfield, IL 60015 (US).

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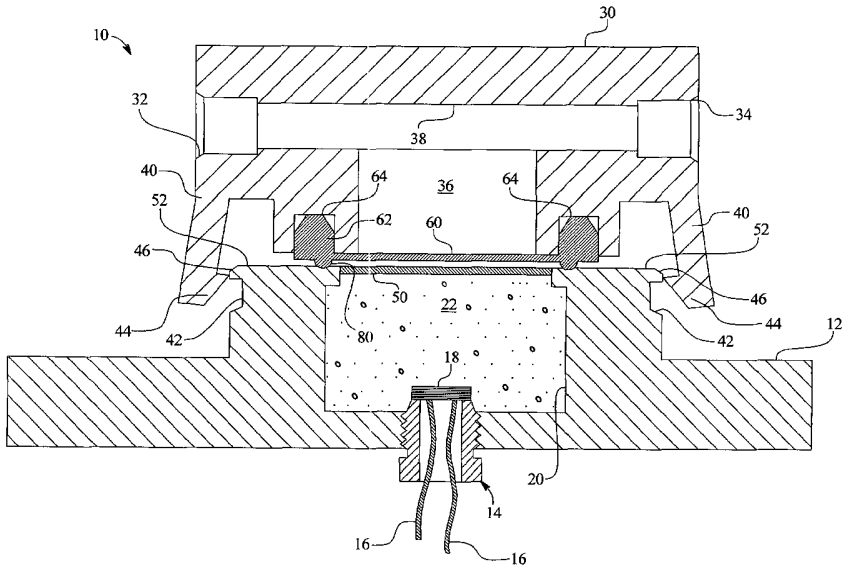

(57) Abstract: The present invention lessens the amount of air entering between mating membranes of a pressure sensor. The pressure sensor of the present invention includes a transducer portion and separate patient or medical fluid transfer portion or dome. The transducer portion is reusable and the dome is disposable. The dome defines a fluid flow chamber that is bounded on one side by a dome membrane. Likewise, the transducer is mounted inside a housing, wherein the housing defines a surface that holds a transducer membrane. The two membranes mate when the dome is fitted onto the transducer housing. The pressure sensor enhances the seal between the mated membranes by creating higher localized contact stresses. The pressure sensor also reduces the amount of gas that permeates from the fluid chamber across the dome membrane and between the interface by making the dome membrane from a material having a low vapor transmission.

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SPECIFICATION

TITLE OF INVENTION

"APPARATUS AND METHOD FOR SEALING PRESSURE SENSOR MEMBRANES"

BACKGROUND OF THE INVENTION

The present invention relates generally to medical treatments. More specifically, the present invention relates to pressure sensing devices for medical fluids.

Due to disease, insult or injury, a person may require the infusion of a medical fluid. It is known to infuse blood, medicaments, nutrients, replacement solutions, dialysis fluids and other liquids into a patient. It is also known to remove fluid from a patient, for example, during dialysis. Dialysis is used to treat renal system failure, including kidney failure and reduced kidney function.

Renal failure causes several physiological effects. The balance of water, minerals and the excretion of daily metabolic load is no longer possible in renal failure. During renal failure, toxic end products of nitrogen metabolism (urea, creatinine, uric acid, and others) can accumulate in blood and tissues. Dialysis removes waste, toxins and excess water from the body that would otherwise have been removed by normal functioning kidneys.

Hemodialysis and peritoneal dialysis are two types of dialysis therapies commonly used to treat loss of kidney function. Hemodialysis ("HD") treatment utilizes the patient's blood to remove waste, toxins and excess water from the patient. The patient is connected to an HD machine and the patient's blood is pumped through the machine. Catheters are inserted into the patient's veins and arteries to connect the blood flow to and from the HD machine. As blood passes through a dialyzer in the HD machine, the dialyzer removes the waste, toxins and excess water from the patient's blood and returns the blood to infuse back into the patient.

Peritoneal dialysis ("PD") utilizes a dialysis solution or "dialysate", which is infused into a patient's peritoneal cavity. The dialysate contacts the patient's peritoneal membrane in the peritoneal cavity. Waste, toxins and excess water pass from the patient's bloodstream through the peritoneal membrane and into the dialysate.

The transfer of waste, toxins, and water from the bloodstream into the dialysate occurs due to diffusion and osmosis, i.e., an osmotic gradient occurs across the membrane. The spent dialysate drains from the patient's peritoneal cavity and removes the waste, toxins and excess water from the patient. This cycle is repeated on a semi-continuous or continuous basis. There are manual PD techniques, known as Continuous Ambulatory Peritoneal Dialysis ("CAPD"). There are also Automated Peritoneal Dialysis techniques ("APD").

In each type of dialysis treatment, it is critical to know the pressure of the fluid that is being transported to or from the patient. Moreover, in any type of blood transfusion, saline transfusion, or any other type of fluid infusion or flow to or from a patient's body, it is important to know and control the pressure of fluid entering and leaving a patient's body.

Fluid pressure, generally, is sensed using a transducer or strain gauge. Medical fluid transducers have included strain gauges made from a silicon chip. Some medical fluid pressure transducers employ a mechanical linkage to transmit pressure from the fluid to the strain gauge. Many medical transducers, however, have abandoned the mechanical linkage in favor of a hydraulic pressure coupling medium comprised of a silicone elastomer, or "silicone gels". In use, the gel is positioned between the medical fluid (that is sensed for pressure) and the transducer chip, wherein the gel conveys a hydraulic pressure signal to the integral sensing diaphragm of the transducer chip. At the same time, the gel isolates the chip electrically from the medical fluid.

In one type of medical transducer, the entire transducer assembly, including the chip, is discarded after a single use, since the internal components cannot be adequately cleaned for resterilization or reuse. Disposable transducer designs employing semiconductor strain gauge sensors and gel coupling media are desirable because they are rugged and accurate. Further, the disposable transducers do not require attachment of a separate disposable dome as do reusable types of medical pressure transducers.

Regardless of the advantages of the completely disposable medical pressure transducers, manufacturing costs for the pre-calibrated semiconductor chip and associated wiring of these types of transducers remain high. Moreover, the electronics, which could otherwise be reused, are thrown away with the rest of the unit. This is

wasteful and costly. Indeed, because the waste contains electronics, it is more costly to dispose.

Accordingly, a pressure sensor that enables the valuable electronics of the transducer to be reused and allows the inexpensive sterile portion for the transfer of the medical fluid to be discarded is desirable. Such pressure sensors exist and typically have a dome portion, which defines a fluid lumen for the medical fluid, and a transducer portion, housing the electronics. The hurdle presented by these types of sensors is in trying to accurately transfer pressure fluctuations in the dome to like fluctuations in the transducer.

In many systems, the medical fluid carrying dome employs a first membrane and the transducer employs a second membrane. The two membranes abut one another and attempt to transmit medical fluid pressure fluctuations through to the strain gauge. One problem with these sensors that employ a membrane to membrane seal is in attempting to maintain the seal along the length of the membranes. A slight amount of air entering even a small part of the interface between the two membranes can falsify readings.

A similar problem exists with materials that have been used for the membranes. In particular, dome membranes can be susceptible to gas diffusion. Certain materials, such as ethylene propylene diene methylene ("EPDM"), have relatively high vapor transmission properties, enabling gas to diffuse from the dome, through the dome membrane, and into the interface between the membranes.

A need therefore exists for a medical fluid pressure sensor having a reusable transducer, a disposable medical fluid dome and an improved and repeatable seal between abutting membranes.

SUMMARY OF THE INVENTION

The present invention relates to medical fluid pressure sensors. More specifically, the present invention provides an apparatus that reduces the amount of air that enters between mating membranes of a pressure sensor. The pressure sensor of the present invention includes a transducer portion and separate patient or medical fluid transfer portion (referred to herein as a "dome" or a "body"). The transducer portion is reusable and the dome is disposable. The dome defines a fluid flow

chamber that is bounded on one side by a dome membrane. Likewise, the transducer is mounted inside a housing, wherein the housing defines a surface that holds a transducer membrane.

The transducer can be any type of strain gauge known to those of skill in the art. In an embodiment, the sensor includes a silicone force sensing chip. The transducer membrane in an embodiment is silicone. The dome can hold and allow the transportation of many types of medical fluids such as blood, saline, dialysate (spent or clean), infiltrate, etc. The pressure sensor can likewise be used with many medical treatments, including but not limited to HD, PD, hemofiltration, and any other type of blood transfusion, intravenous transfusion, etc. Accordingly, the pressure sensor can be used with many types of medical devices including dialysis devices. In an embodiment, the reusable transducer housing mounts to the medical or dialysis device, wherein the dome or body removably couples to the housing.

The two membranes mate when the dome is fitted onto the transducer housing. The dome body and transducer housing include mating devices that enable the dome to removably couple to the housing. The pressure sensor enhances the seal between the mated membranes by creating higher localized contact forces or stresses. The pressure sensor also reduces the amount of gas that permeates from the fluid chamber across the dome membrane by making the dome membrane from a material having a low vapor transmission property.

In an embodiment the increased contact forces or stresses are provided by a sealing member or O-ring integral to the dome membrane. The integral sealing member or O-ring of the dome membrane compresses to help prevent air from leaking between the dome and transducer membranes, which mate when the housing and dome are mated. The integral O-ring can have various cross-sectional shapes and in an embodiment is at least partly circular in cross-section. The dome membrane in an embodiment also includes an integral mounting ring that pressure fits into the dome.

In another embodiment, the increased contact forces or stresses are provided by a sealing member or O-ring integral to the dome membrane in combination with a groove defined by the surface of the transducer housing. The surface of the transducer housing surrounds the transducer membrane. In an embodiment, this surface is metal, for example, stainless steel. The integral O-ring of the dome membrane compresses

into the groove of the transducer housing when the housing and dome are mated. At the same time, the dome and transducer membranes are mated.

In a further embodiment, the increased contact forces or stresses are provided by a separate O-ring. Here, the O-ring compresses between the dome membrane and the surface of the transducer housing. Like the above embodiment, the surface of the transducer housing surrounds the transducer membrane and defines a groove into which the separate O-ring seats. The separate O-ring compresses into the groove of the transducer housing when the housing and dome are mated. At the same time, the dome and transducer membranes become mated.

In another embodiment, the O-ring compresses between the surface of the transducer housing and a surface of the dome. Here, either one of the surfaces of the transducer housing or the dome defines a groove into which the separate O-ring seats. The separate O-ring compresses into the groove of the transducer or dome surfaces when the housing and dome are mated. At the same time, the dome and transducer membranes become mated.

In yet another embodiment, the increased contact forces or stresses are provided by a raised portion of the surface of the transducer housing, which surrounds the transducer membrane. In an embodiment, this raised portion is metal, for example, stainless steel. The raised portion of the transducer housing compresses into the dome membrane when the housing and dome are mated. At the same time, the dome and transducer membranes become mated.

In any of the above-described embodiments for the increased contact forces, the dome membrane, in one preferred embodiment, is made of a material having a low gas permeability. That is, the dome membrane material has low vapor transmission properties. In an embodiment, the dome membrane includes butyl rubber, which is generally understood to have one of the lowest gas (especially air) permeabilities of all similar materials and is consequently one of the best rubber sealants. In another embodiment, the dome membrane includes a plurality of members or layers. One of the layers is of a material having a low gas permeability, such as a metal foil, a sputter coating of metal or a layer of saran or mylar. The other layer or layers include a flexible and expandable material, such as EPDM, silicone, polyurethane and any combination thereof.

It is therefore an advantage of the present invention to provide a pressure sensor having a reusable transducer.

Another advantage of the present invention is to provide a pressure sensor having a disposable medical or patient fluid transfer portion.

Moreover, an advantage of the present invention is to provide an accurate pressure sensor.

Still another advantage of the present invention is to provide a low cost pressure sensor.

A further advantage of the present invention is to provide a pressure sensor having a relatively gas impermeable membrane.

Yet another advantage of the present invention is to provide a pressure sensor having an additional relatively gas impermeable membrane layer.

Yet a further advantage of the present invention is to provide a pressure sensor having a localized area of high contact force.

Still further, an advantage of the present invention is to provide a pressure sensor having an integral O-ring.

Additionally, it is an advantage of the present invention to provide a pressure sensor having a separate O-ring.

Further still, it is an advantage of the present invention to provide an improved medical infusion device that employs the pressure sensor of the present invention.

Still another advantage of the present invention is to provide an improved dialysis device that employs the pressure sensor of the present invention.

Yet another advantage of the present invention is to provide an improved method of sealing membranes in a medical fluid infusion device.

Additional features and advantages of the present invention are described in, and will be apparent from, the following Detailed Description of the Invention and the Figures.

BRIEF DESCRIPTION OF THE FIGURES

Fig. 1A is a sectioned elevation view of one embodiment of the pressure sensor of the present invention having an integral O-ring that is just about to be compressed.

Fig. 1B is the sectioned elevation view of Fig. 1A, wherein the O-ring has been compressed and the pressure sensor is fully sealed.

Fig. 2 is a sectioned elevation view of one embodiment of a dome membrane of the present invention having an additional low gas permeability layer.

Fig. 3 is a sectioned elevation view of another embodiment of the pressure sensor of the present invention having an integral O-ring and a mating groove.

Fig. 4 is a sectioned elevation view of another embodiment of the pressure sensor of the present invention having a separate O-ring and a mating groove.

Fig. 5 is a sectioned elevation view of a further embodiment of the pressure sensor of the present invention having a separate O-ring and a mating groove.

Fig. 6 is a sectioned elevation view of yet another embodiment of the pressure sensor of the present invention having a raised contact force increasing portion.

Fig. 7 is a sectioned view of still another embodiment of the pressure sensor of the present invention, wherein the dome body includes a localized contact extension.

Fig. 8 illustrates various different cross-sectional shapes that the sealing member of the present invention can assume.

DETAILED DESCRIPTION OF THE INVENTION

The present invention provides a pressure sensor and a membrane therefore that helps to prevent air from entering between the membrane and a second membrane when the two membranes are mated. The membranes each belong to a separate component of the pressure sensor, namely, a fluid transfer portion (referred to herein as a "dome" or "body") and a pressure sensing portion (referred to herein as the "transducer housing"). The pressure sensor of the present invention can be used with a variety of fluid transfusion treatments. The pressure sensor is adaptable for use with patient fluids, such as blood, urine, etc. The pressure sensor is adaptable for use with medical fluids, such as saline, dialysate (spent or clean), infiltrate, etc. The pressure sensor can likewise be used with many medical treatments, including but not limited to HD, PD (including CAPD and APD), hemofiltration, and any other type of blood transfusion, intravenous transfusion, etc.

Referring now to the figures, and in particular to Fig. 1A, one embodiment of a pressure sensor 10 is illustrated. Pressure sensor 10 includes a reusable portion or housing 12. The housing 12 can be a separate housing that mounts to a panel or enclosure of a medical device, for example, a dialysis device or machine. The housing 12 is alternatively integral to the housing or enclosure of the medical device or dialysis machine.

The housing 12 holds or supports a transducer 14. In the illustrated embodiment, the transducer 14 threads to the housing 12. The transducer 14 alternatively removably mounts to the housing via fasteners, etc., or permanently mounts to the housing, for example, via a weld.

The transducer 14 includes a number of electrical conductors 16, for example two, three or four conductors, which convey electrical signals to and from a transducer chip 18. The electrical conductors 16 are insulated so that the electrical signals can convey away from the transducer housing 14 to a pressure monitor (elsewhere on the medical or dialysis machine or to a remote device) without risk of shocks, shorts or signal distortion. The chip 18 in an embodiment is a silicone force sensing chip. The housing 12, into which the transducer 14 and chip 18 mount is, in an embodiment, stainless steel.

The transducer housing 12 defines a chamber 20, which in an embodiment holds a pressure transmitting and an electrically and biologically isolating gel, hydraulic fluid or other type of pressure transmission material 22. In an embodiment the pressure transmission material 22 includes silicone. Regardless of the type of pressure transmission material 22 used, the material 22 is responsive to negative or positive pressure signals from the medical fluid flowing through the dome or body. The material 22 transmits the positive or negative pressure signals to the transducer chip 18. In an embodiment, the transducer chip 18 includes a pressure sensing surface, which is exposed to the pressure transmission material 22. Also, in an embodiment, the chip 18 includes on-chip circuitry for predetermined gain and temperature compensation.

A disposable body or dome 30 removably mounts to the transducer housing 12. The disposable body or dome 30 is detached from the reusable transducer housing 12 usually after a single use. The dome 30 defines an inlet fluid port 32, an outlet fluid

port 34 and a fluid chamber 36. The illustrated embodiment defines a generally "T" shaped inlet/outlet, wherein the chamber 36 forms the leg of the "T". The dome 30 or body can otherwise define angled or "V" shaped inlets and outlets and/or a contoured chamber. One such dome is disclosed in published PCT application WO 99/37983, entitled, "Connecting Element for Connecting a Transducer With a Sealed Fluid System", the teachings of which are incorporated herein by reference. PCT application WO 99/37983 discloses a dome ceiling, similar to the ceiling 38 of the present invention, which is curved and has a central portion that slopes downward towards the chamber 36 and the membranes.

The body 30 can be constructed from any inert, biologically safe material, such as an inert plastic, for example, a polycarbonate. In an embodiment, the body 30 is clear or transparent. The inlet port 32 and outlet port 34 can include any suitable medical industry interface for connecting to a tube connector or directly to medical fluid tubes. The ports can individually or collectively include a conical packing seat.

The dome or body 30 releasably engages the transducer housing 12. In an embodiment, the body 30 includes a series of tabs 40 that frictionally engage a mating ring 42 defined by the housing 12. When a user presses the body 30 onto the housing 12, the tabs 40 bend slightly outward so that tips 44 of the tabs 40 slide over a rib 46 partially defining the ring 42. Eventually the tips 44 extend far enough over the housing 12, wherein the tips 44 snap into the ring 42. Each of Figs. 1 and 3 to 6 show the body 30 as it is just about to fully engage the housing 12 (with the tops 44 shown figuratively overlapping the rib 46). The body 30 disengages from the housing 12 in the opposite manner, wherein the tabs 40 again bend outwardly, so that the tips 44 slide back over the rib 46 and away from the ring 42.

Both the housing 12 and the body 30 of the pressure sensor 10 include a flexible membrane. The housing 12 includes a membrane 50 disposed over and defining a bounding surface of the chamber 20. The membrane 50 is positioned substantially flush along the top surface (e.g., stainless steel surface) 52 of the housing 12. The transducer membrane 50 is, in an embodiment, silicone of approximately .1 to .5 mm thickness. Other materials and thicknesses may be used for the transducer membrane 50.

The transducer membrane 50 contacts the dome membrane 60 when the dome 30 and the housing 12 have been mated together. The contacting membranes 50 and 60 enable positive and negative pressure fluctuations of medical or patient fluid in the chamber 36 of the body 30 to be transmitted to the transmission material 22 and to the chip 18. In past pressure sensors, the interface between the contacting membranes 50 and 60 has become corrupted with gas leaking into the interface through the sides of the membranes 50 and 60 and from the medical or patient fluid though a relatively gas permeable dome membrane. The present invention seeks to address both these problems.

First, the dome membrane 60 is made from a substantially gas impermeable material. In a preferred embodiment, the dome membrane 60 is made from butyl rubber or from a blended rubber using butyl, such as halobutyl rubber. Butyl is generally known to have very good sealing properties and have a very low gas permeability rate. Butyl also has relatively good tear strength, chemical resistance, environmental resistance (including resistance to ozone attack) and is relatively easy to manufacture. The membrane 60 material can be made using a high state of cure (i.e., crosslink density), wherein the crosslinking reduces the rate of permeation.

Butyl rubber, with respect to air at standard temperature and pressure, is approximately thirty-five times less permeable than ethylene propylene diene methylene ("EPDM"), a known membrane material. Butyl rubber is approximately eighteen times less permeable than natural rubber. Other materials, besides butyl, which have low vapor permeability or transmission rates, and which alone or in combination with butyl rubber or with each other, can be used in the present invention, include neoprene (about 7.5 times less permeable than EPDM), polyurethane (about 6.7 times less permeable than EPDM), Buna-N (Nitrile) (about 7.5 times less permeable than EPDM), Alcryn® (about 25 times less permeable than EPDM), Hypalon® (about 13.5 times less permeable than EPDM), Vamac® (about 19 times less permeable than EPDM), and Viton® (about 19 times less permeable than EPDM).

The membrane 60 also defines a sealing rib 62 that press fits inside of an annular ring 64 defined by the body 30. In an embodiment, sealing rib 62 has an inner radius slightly less than the inner radius of the annular ring 64, so that the membrane 60 has to stretch to fit the rib 62 inside of the ring 64. The sealing rib 62 and the thin

portion of the membrane (that engages at least a portion of the membrane 50) are made of the same material in an embodiment, but may be of different materials in other embodiments. The thin, sealing portion of the membrane 60 is, in an embodiment, approximately .4mm thick.

Fig. 1B illustrates the pressure sensor 10 of Fig. 1A, which is now fully sealed. The dome or body 30 is now ready to receive a medical fluid. The dome membrane 60 is flush against the transducer membrane 50. That is, the dome membrane 60 sealingly engages the transducer membrane 50. When the dome membrane 60 moves due to either a positive or negative pressure fluctuation of medical fluid in chamber 36, the transducer membrane 50 follows or moves along with the dome membrane 60. The transducer membrane 50 in turn imparts a positive or negative force on the transmission material 22, which activates the chip 18 of the transducer 14.

Referring now to Fig. 2, another embodiment for making a low vapor permeable dome membrane 70 is illustrated. The dome membrane 70 includes the sealing rib 62 described above. The dome membrane 70 also includes a low vapor transmission layer 72. The low vapor transmission layer 72 can be a layer of metal foil, a sputter coating of metal, saran, mylar and any combination thereof. In another embodiment, the low vapor transmission layer 72 includes butyl rubber, one of the other low vapor transmission materials described above or a film such as SiO2 glass film and EvOH barrier film. In a further embodiment, a low vapor transmission filler is used, such as a reinforcing or lamellar type, which has a plate-like structure that lengthens the diffusion pathway and reduces the rate of permeation.

The low vapor transmission layer 72 in an embodiment is co-extruded with the rest of the membrane 70, so that the layer 72 resides within outer layers 74 of a flexible material, which may also have a low or high vapor transmission rate. The outer layers 74 can include any type of flexible material, for example, EPDM, silicone, polyurethane or any combination of these. In another embodiment, the low permeability layer 72 is bonded to the flexible layer 74 via a suitable adhesive or heat sealing technique.

The low permeability membranes 60 and 70 tend to prevent gas entrained in the medical or patient fluid in the chamber 36 of the dome 30, or present when no medical/patient fluid resides in the chamber 36, from permeating across the dome

membrane 60 or 70. Either of the dome membranes 60 and 70 can be used in the embodiments for creating local areas of high contact force, which are about to be presented in Figs. 1 and 3 to 6. The increased contact forces act to keep gas from entering between the sides of the dome membrane 60 or 70 and the transducer membrane 50.

Figs. 1A and 1B illustrate one embodiment, wherein the increased contact forces or stresses are provided by an O-ring or sealing member 80, which is formed integrally to the dome membrane 60 or 70. The integral O-ring 80 of the dome membrane 60 or 70 compresses to the top surface (e.g., stainless steel surface) 52 of the housing 12 to help prevent air from leaking between the sides of the dome membrane 60 or 70 and the transducer membrane 50. The integral O-ring 80 compresses enough so that the dome membrane 60 or 70 contacts and seals to the transducer membrane 50. The integral O-ring 80 is co-extruded or co-molded with the remainder of the dome membrane 60 and with at least part of the dome membrane 70.

Referring now to Fig. 3, in another embodiment, the increased contact forces or stresses are provided by the integral O-ring 80 in combination with a groove 82 defined by the surface 52 of the transducer housing 12. The groove 82 is formed to fit the cross-sectional shape of the O-ring 80. The surface 52 of the transducer housing 12 surrounds the transducer membrane 50 and is metal, for example, stainless steel. The integral O-ring 80 of the dome membrane compresses into the groove 82 of the transducer housing 12 when the housing and dome are mated, so as to allow the dome membrane 60 or 70 and transducer membrane 50 to contact and seal to each other.

Referring now to Fig. 4, in a further embodiment, the increased contact forces or stresses are provided by a separate O-ring or sealing member 90. In an embodiment, the O-ring 90 compresses between the dome membrane 60 or 70 and the surface 52 of the transducer housing 12. Here, like the above embodiment, the surface 52 of the transducer housing 12 surrounds the transducer membrane 50 and defines a groove 92 into which the separate O-ring 90 seats. The separate O-ring 90 compresses into the groove 92 of the transducer housing 12 when the housing and dome are mated, so as to allow the dome membrane 60 or 70 and transducer membrane 50 to contact and seal to each other. The separate O-ring 90 can have any of the cross-sectional shapes described below, wherein the groove 92 has a similar shape. The groove 92 in

an embodiment also serves to provide a storage place for the separate O-ring 90, during packaging, shipping and set-up. The O-ring 90 therefore slightly pressure fits into the groove 92.

Referring now to Fig. 5, in another embodiment, the O-ring or sealing member 90 compresses between the surface 52 of the transducer housing 12 and a surface 94 of the body 30. Here, either one of the surfaces 52 or 94 of the transducer housing 12 or the dome 30, respectively, defines a groove 92 (in surface 52 shown previously in Fig. 4) or 96 (in surface 94) into which the separate O-ring 90 seats and is stored during packaging, shipping and set-up. The separate O-ring 90 compresses into the groove 92 or 96 of the transducer or dome surfaces 52 or 94, respectively when the housing and dome are mated, so as to allow the dome membrane 60 or 70 and transducer membrane 50 to contact and seal to each other. The separate O-ring 90 can have any of the cross-sectional shapes described below, wherein the groove 92 or 96 has a similar shape.

Referring now to Fig. 6, in yet another embodiment, the increased contact forces or stresses are provided by a raised portion 98 of the surface 52 of the transducer housing 52, which surrounds the transducer membrane 50. In an embodiment, the raised portion 98 is metal, for example, stainless steel. The raised portion 98 of the transducer housing 12 compresses into the dome membrane 60 or 70 at a point where the membrane 60 or 70 is backed up by the sealing rib 62, i.e., where the membrane 60 or 70 has enough material to accept the raised portion 98. The raised portion 98, like the O-rings, can have a variety of cross-sectional shapes, such as rectangular, trapezoidal, circular, etc. The raised portion 98 compresses into the dome membrane 60 or 70 when the housing 12 and dome 30 are mated, so as to allow the dome membrane 60 or 70 and transducer membrane 50 to contact and seal to each other.

Referring now to Fig. 7, yet another embodiment places a raised portion on the dome or body 30 rather than the transducer housing 12 as in Fig. 6. Here, the increased contact forces or stresses are provided by an extension 99 of the surface 101 of the dome 30, which surrounds the transducer membrane 50. In an embodiment, the extension 99 is made of the same material as the dome 30, for example, plastic. The extension 99 of the transducer housing 12 compresses into the dome membrane 60 or

70 at a point where the membrane 60 or 70 is backed up by the sealing rib 62, i.e., where the membrane 60 or 70 has enough material to accept the extension 99.

The extension 99, like the O-rings, can have a variety of cross-sectional shapes, such as rectangular, trapezoidal, circular, etc. As illustrated, the extension 99 compresses into the dome membrane 60 or 70 when the housing 12 and dome 30 are mated, so as to allow the dome membrane 60 or 70 and transducer membrane 50 to contact and seal to each other. Further, the annular ring 64 presses on the sealing rib 62 so that the membrane 60 or 70 also seals generally to the surface 52 of the transducer housing 12.

Referring now to Fig. 8, any of the sealing members disclosed herein, such as the integral O-ring 80 or the separate O-ring 90, can have at least a partially circular cross-sectional shape as illustrated in Figs. 1 and 3 to 6. Alternatively, the sealing members can have various partial or full cross-sectional shapes, such as those shapes commonly associated with a delta-ring 102, D-ring 104, T-ring 106, square-ring 108, lobed-ring 110, cored-ring 112, hollow-ring 114 and K-ring 116.

It should be understood that various changes and modifications to the presently preferred embodiments described herein will be apparent to those skilled in the art. Such changes and modifications can be made without departing from the spirit and scope of the present invention and without diminishing its intended advantages. It is therefore intended that such changes and modifications be covered by the appended claims.

CLAIMS

The invention is claimed as follows:

1. A fluid pressure sensor comprising:

a housing having a first membrane;

a transducer positioned inside the housing;

a body including a fluid inlet and a fluid outlet removably coupled to the housing; and

a second membrane provided with the body that contacts at least a portion of the first membrane when the body is coupled to the housing, the second membrane including an integral sealing member.

2. The fluid pressure sensor of Claim 1, wherein the second membrane includes a mounting ring that pressure fits into the body.

3. The fluid pressure sensor of Claim 1, wherein the second membrane includes a material selected from the group consisting of butyl rubber, neoprene, polyurethane, Buna-N, saran, mylar, a sputter coating of metal, a metal film and any combination thereof.

4. The fluid pressure sensor of Claim 1, wherein the second membrane includes a first member and a second member, the second member having a lower gas permeability than the first member.

5. The fluid pressure sensor of Claim 1, wherein the integral sealing member compresses to a surface of the housing that surrounds the first membrane.

6. The fluid pressure sensor of Claim 1, wherein the sealing member is selected from the group consisting of: an O-ring, a delta-ring, a D-ring, a T-ring, a square-ring, a lobed-ring, a cored-ring, a hollow-ring and a K-ring.

7. A fluid pressure sensor comprising:

a housing having a first membrane;

a transducer positioned inside the housing;

a body including a fluid inlet and a fluid outlet removably coupled to the housing;

a second membrane provided with the body that contacts at least a portion of the first membrane when the body is coupled to the housing; and

an apparatus that creates a localized contact force between the second membrane and a surface of the housing surrounding the first membrane.

8. The fluid pressure sensor of Claim 7, wherein the second membrane includes a material selected from the group consisting of butyl rubber, neoprene, polyurethane, Buna-N, saran, mylar, a sputter coating of metal, a metal film and any combination thereof.

9. The fluid pressure sensor of Claim 7, wherein the apparatus includes a groove in the surface of the housing and a sealing member integral to the second membrane that compresses into the groove.

10. The fluid pressure sensor of Claim 9, wherein the surface of the housing defining the groove is metal.

11. The fluid pressure sensor of Claim 7, wherein the apparatus includes a groove in the surface of the housing and a separate sealing member compressed between the second membrane and the groove.

12. The fluid pressure sensor of Claim 11, wherein the separate sealing member pressure fits into the groove when the housing and the body are separated.

13. The fluid pressure sensor of Claim 7, wherein the apparatus includes a raised portion extending from the surface of the housing contacting the second membrane.

14. The fluid pressure sensor of Claim 13, wherein the surface and the raised portion are metal.

15. The fluid pressure sensor of Claim 7, wherein the apparatus includes a raised portion extending from a surface of the body.

16. A fluid pressure sensor comprising:

a housing having a first surface and a first membrane;

a transducer positioned inside the housing;

a body including a second surface, a fluid inlet and a fluid outlet removably coupled to the housing; and

a second membrane provided with the body that contacts at least a portion of the first membrane when the body is coupled to the housing; and

a sealing member positioned between the first surface and the second surfaces.

17. The fluid pressure sensor of Claim 16, wherein one of the first and second surfaces defines a groove that houses the sealing member.

18. The fluid pressure sensor of Claim 16, wherein the second membrane includes a material selected from the group consisting of butyl rubber, neoprene, polyurethane, Buna-N, saran, mylar, a sputter coating of metal, a metal film and any combination thereof.

19. A fluid pressure sensor comprising:

a housing having a first membrane;

a transducer positioned inside the housing;

a body including a fluid inlet and a fluid outlet removably coupled to the housing; and

a second membrane provided with the body that contacts at least a portion of the first membrane when the body is coupled to the housing, the second membrane constructed at least partly of a material that is at least five times less permeable to air at standard temperature and pressure than ethylene propylene diene methylene ("EPDM").

20. The fluid pressure sensor of Claim 19, wherein the material includes butyl rubber.

21. A fluid pressure sensor comprising:

a housing having a surface surrounding a first membrane;

a transducer positioned inside the housing;

a body including a fluid inlet and a fluid outlet and having a means for removably coupling to the housing; and

a second membrane provided with the body that contacts at least a portion of the first membrane when the body is coupled to the housing, the second membrane including a first material and a second material having a lower gas permeability than the first material.

22. The fluid pressure sensor of Claim 21, wherein the second material is bonded to first material.

23. The fluid pressure sensor of Claim 21, wherein the first material is selected from the group consisting of: ethylene propylene diene methylene (EPDM), silicone, polyurethane and any combination thereof.

24. The fluid pressure sensor of Claim 21, wherein the second member includes a material selected from the group consisting of: metal foil, a sputter coating of metal, saran, mylar, SiO2 glass film, EvOH barrier film and any combination thereof.

25. A medical infusion device comprising:

an enclosure; and

a pressure sensor mounted to the enclosure, the pressure sensor including

a housing having a first membrane,

a transducer positioned inside the housing,

a body including a fluid inlet and a fluid outlet removably coupled to the housing,

a second membrane provided with the body that contacts at least a portion of the first membrane when the body is coupled to the housing, and

an apparatus that creates a localized contact force between the second membrane and a surface of the housing surrounding the first membrane.

26. The medical infusion device of Claim 25, wherein the housing is mounted to the enclosure.

27. A dialysis device comprising:

an enclosure; and

a pressure sensor mounted to the enclosure, the pressure sensor including

a housing having a first membrane;

a transducer positioned inside the housing;

a body including a fluid inlet and a fluid outlet removably coupled to the housing, and

a second membrane provided with the body that contacts at least a portion of the first membrane when the body is coupled to the housing, the second membrane constructed at least partly of a material that is at least five times less permeable to air at standard temperature and pressure than ethylene propylene diene methylene ("EPDM").

28. The dialysis device of Claim 27, wherein the pressure sensor monitors pressure of a fluid selected from the group consisting of: blood, dialysate, infusate, saline and any combination thereof.

29. A method of disallowing air from entering contacting membranes of a medical device comprising:

forming a seal between the membranes that includes a localized contact force between one of the membranes and a surface surrounding the other membrane.

30. The method of Claim 29, wherein one of the membranes is made at least in part of butyl rubber.

31. The method of Claim 29, which includes using a compressible member to provide the localized contact force.

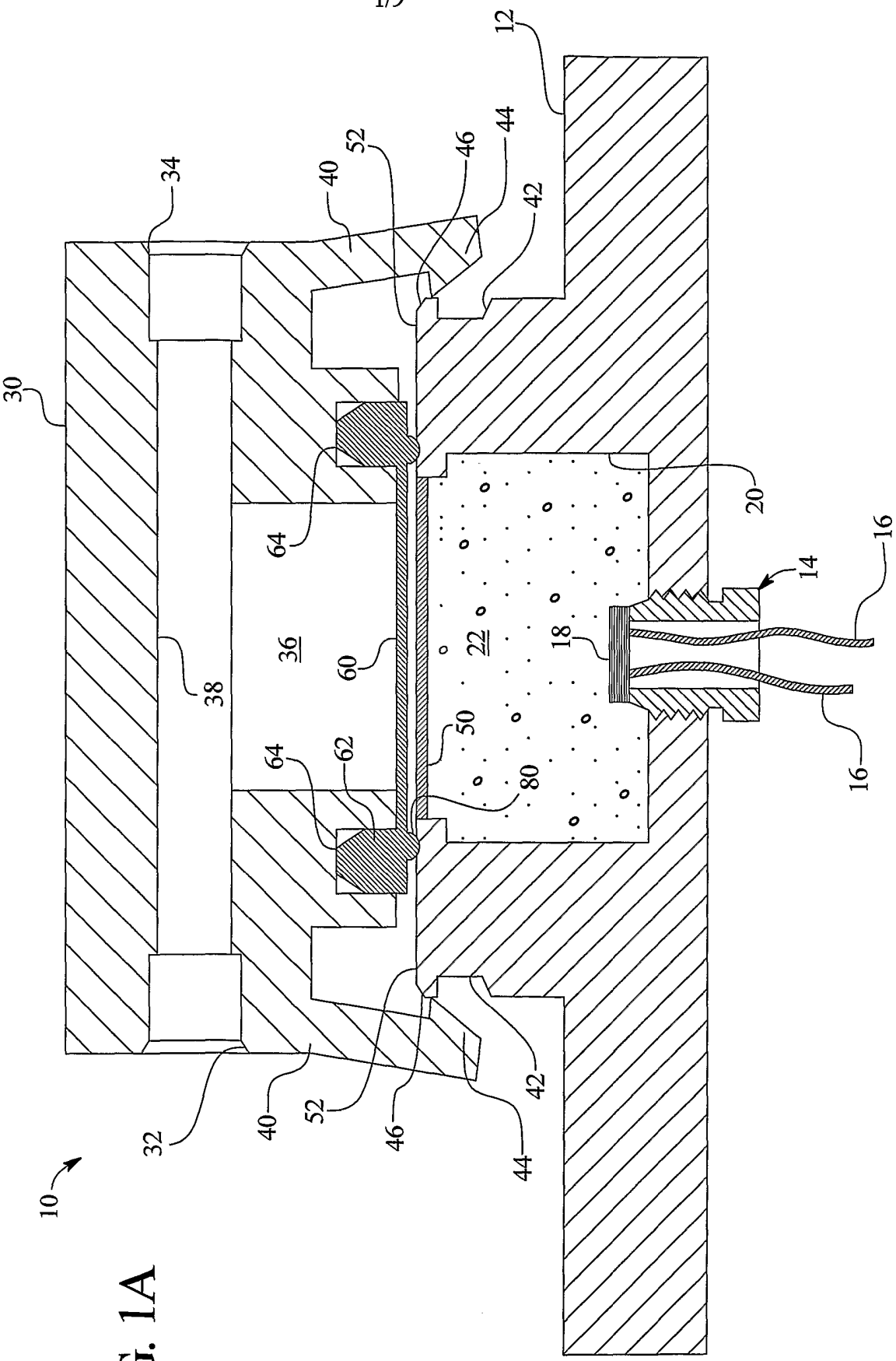
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FIG. 1A

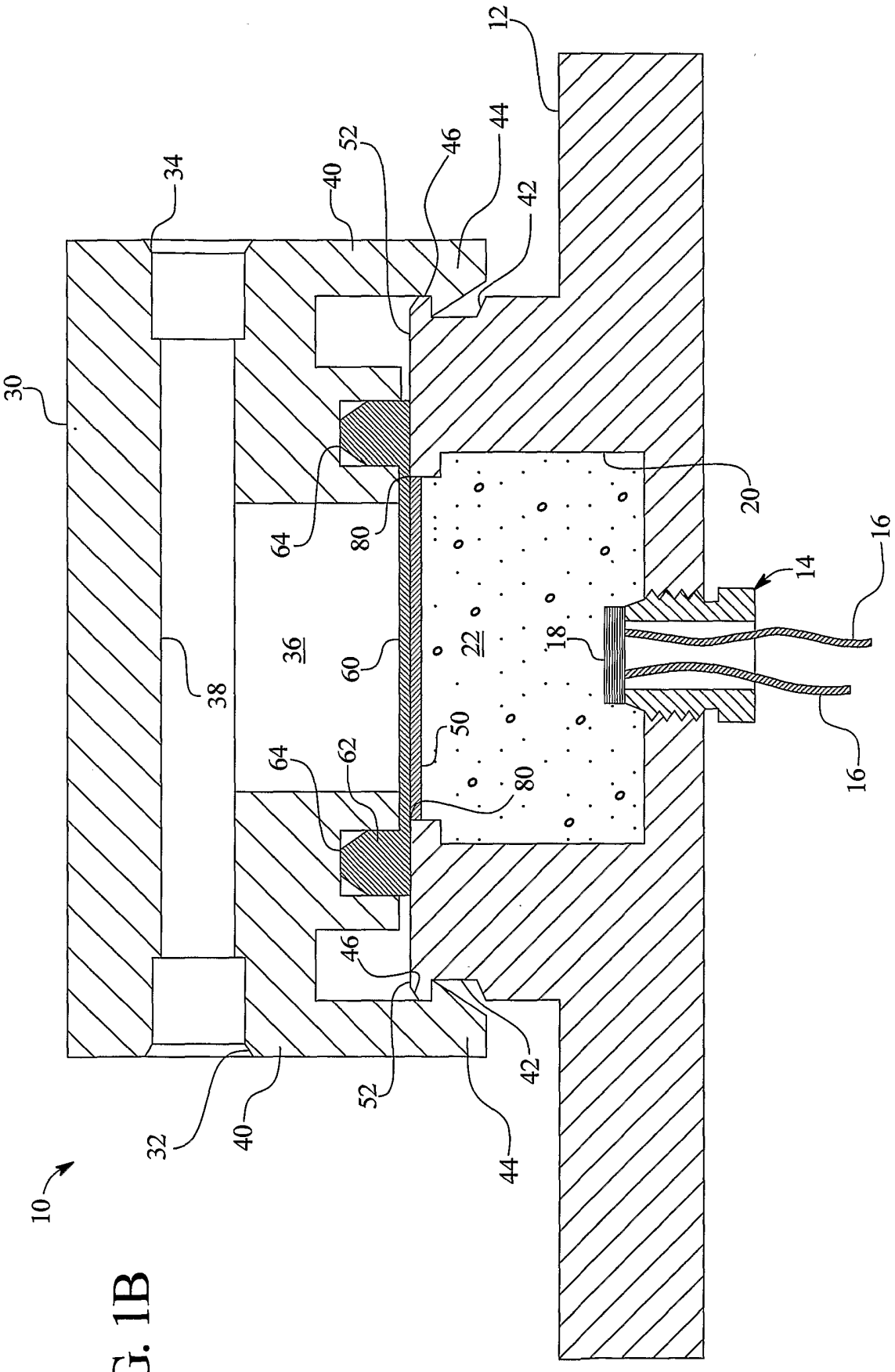
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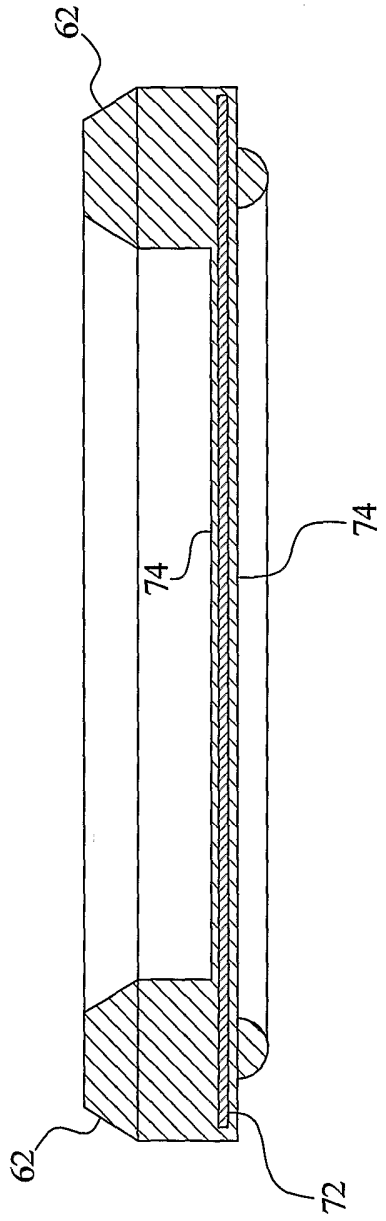
FIG. 1B

FIG. 2



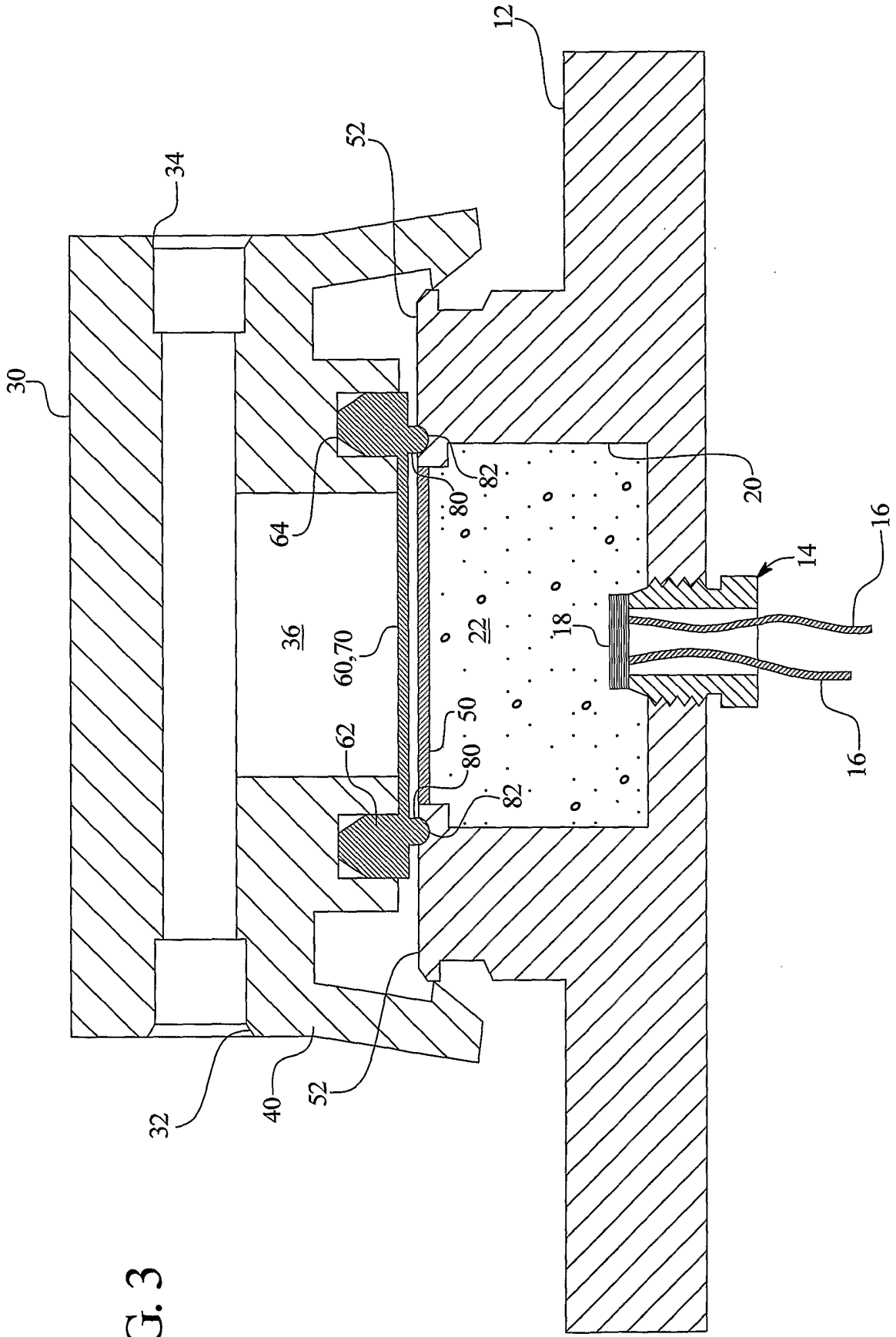


FIG. 3

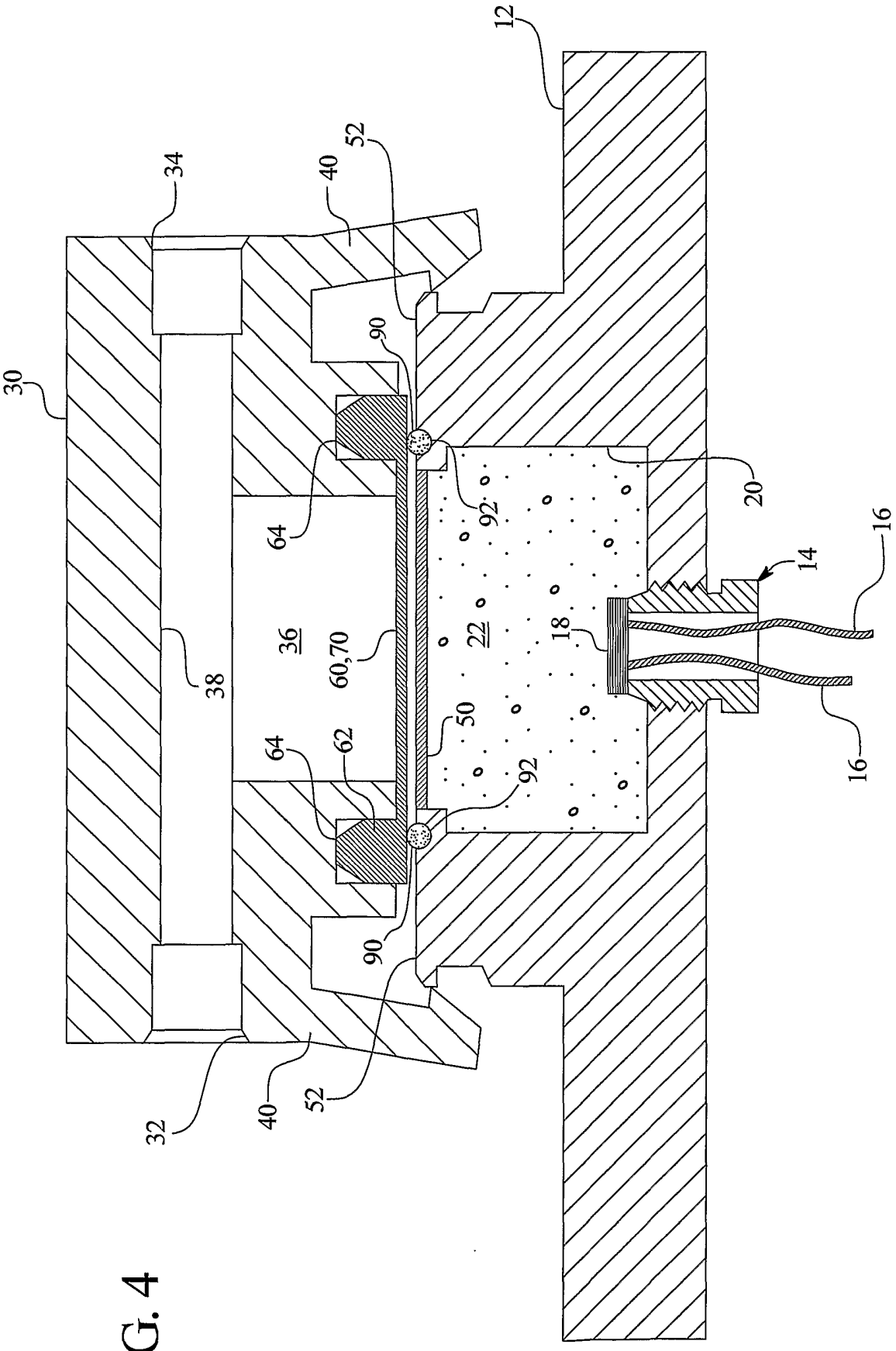

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FIG. 4

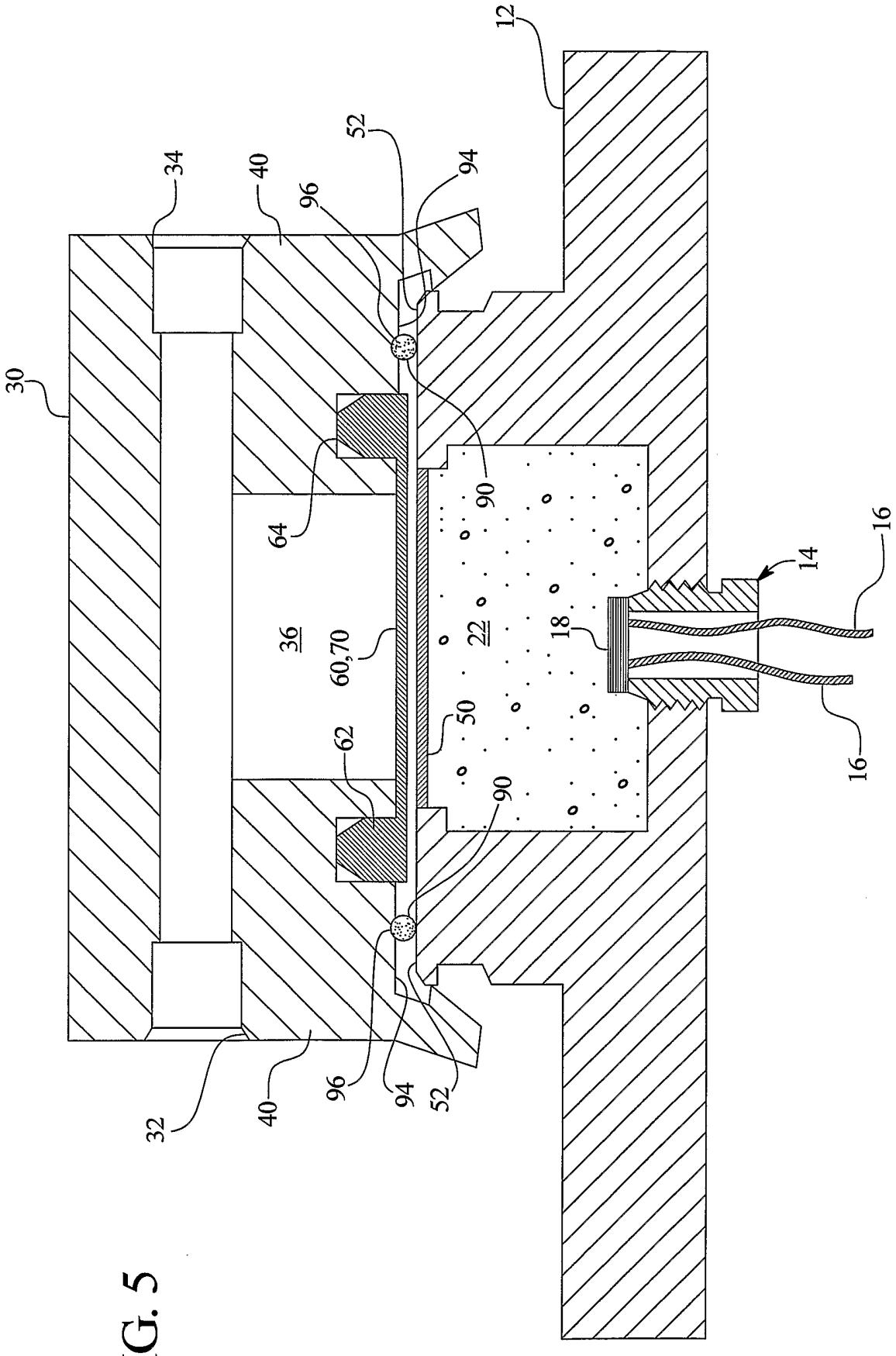
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FIG. 5

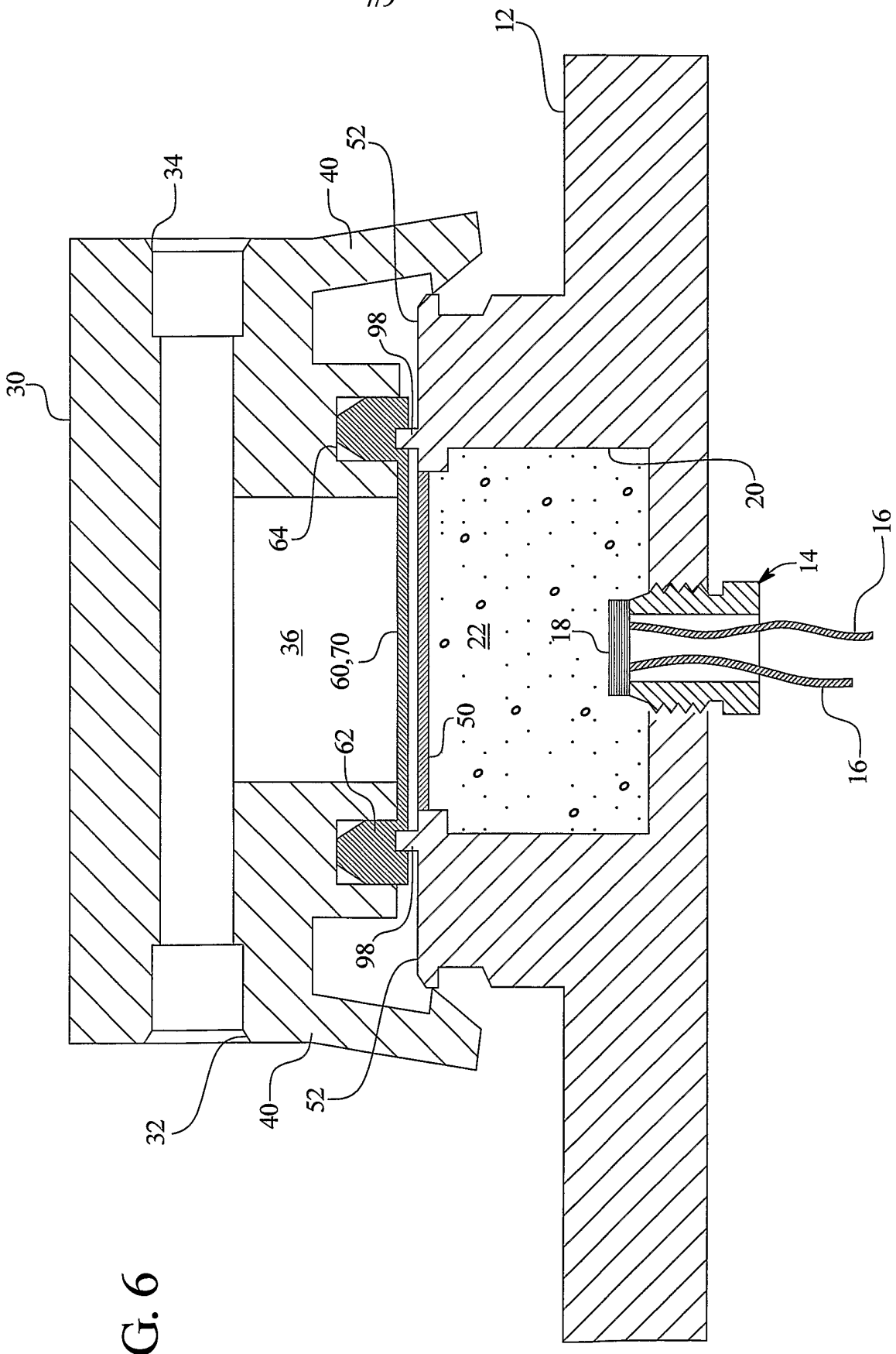

FIG. 6

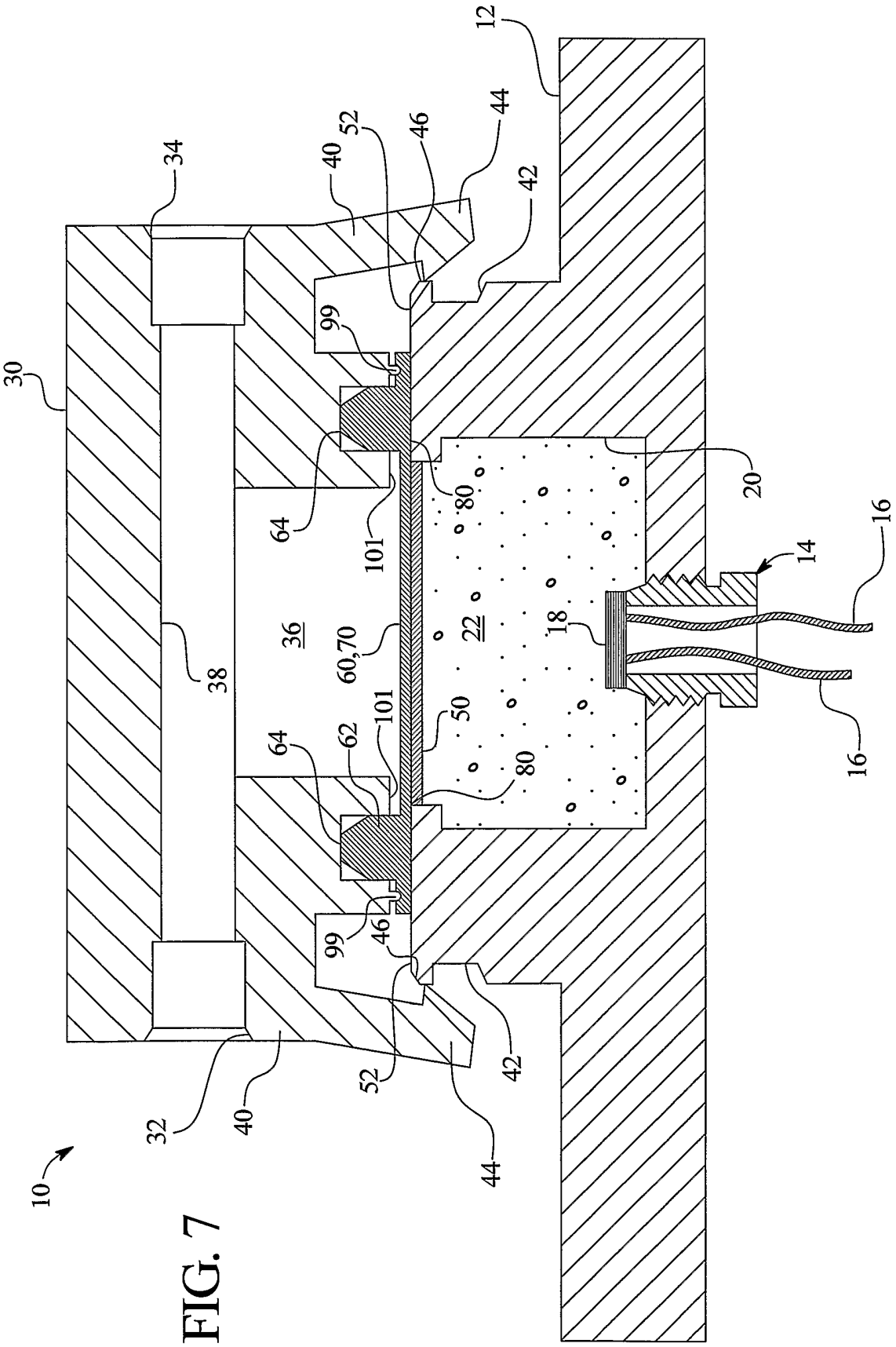
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FIG. 7

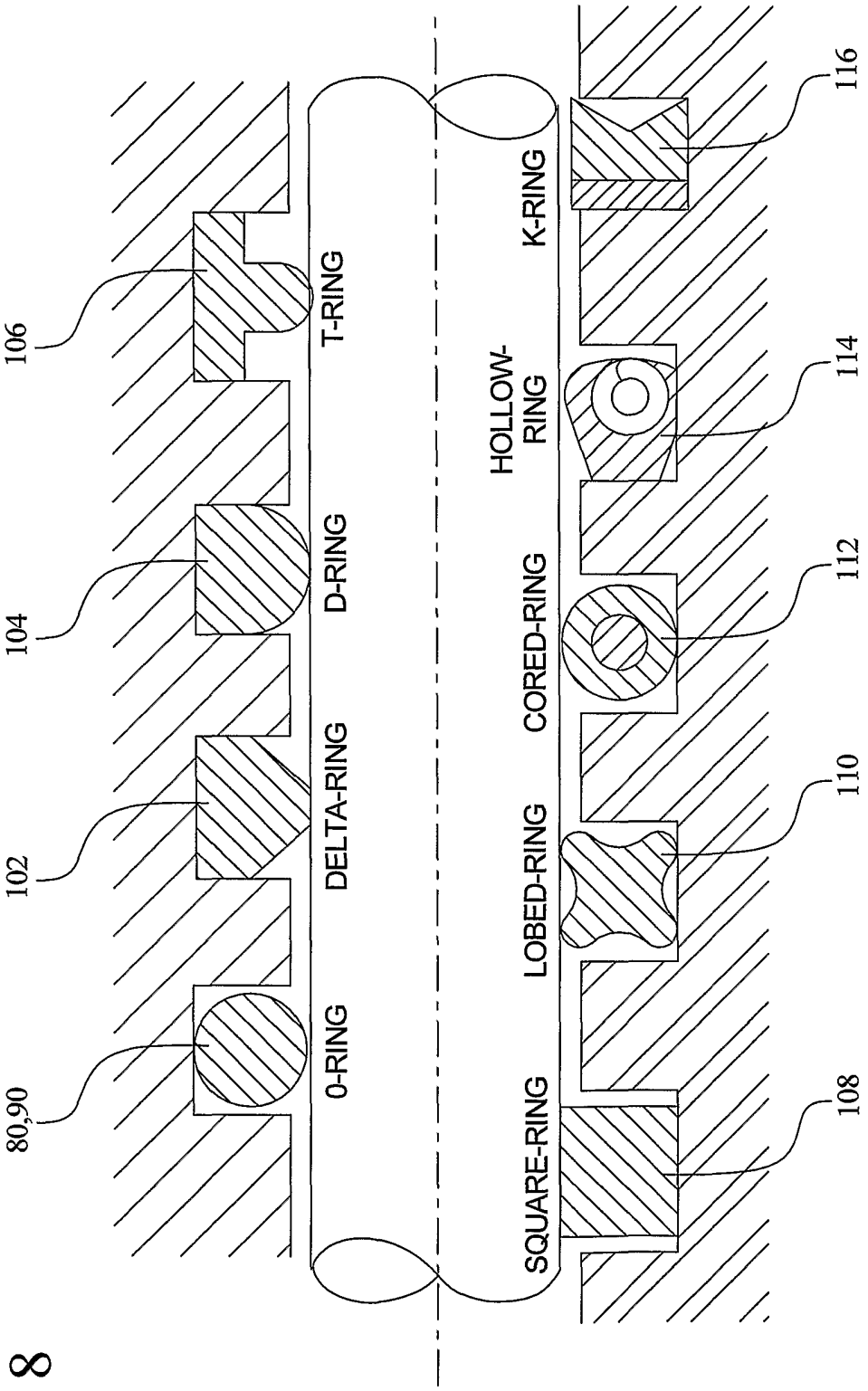
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FIG. 8

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 03/12815

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 G01L19/00 G01L9/00 A61M1/36

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)
IPC 7 G01L A61B A61M

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DE 100 32 616 A (MHM HARZBECHER MEDIZINTECHNIK) 24 January 2002 (2002-01-24) the whole document	1-6,29, 30
A	US 4 610 256 A (WALLACE) 9 September 1986 (1986-09-09) abstract; figures 1,2	1-6
A	US 5 614 677 A (PIEPER ET AL.) 25 March 1997 (1997-03-25) abstract column 4, line 57 -column 5, line 12; figure 1	1-6
A	US 4 920 972 A (FRANK ET AL.) 1 May 1990 (1990-05-01) abstract; figures 1-3	1-6

-/--

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

[X] Patent family members are listed in annex.

° Special categories of cited documents :

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

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
5 August 2003	11/08/2003

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

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 03/12815

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 993 395 A (SHULZE) 30 November 1999 (1999-11-30)	
A	US 5 483 994 A (MAURER) 16 January 1996 (1996-01-16)	

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 03/12815

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

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

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

2. ☒ Claims Nos.: 7-28
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
see FURTHER INFORMATION sheet PCT/ISA/210

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

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

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

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

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

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

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

Remark on Protest

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

☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.2

Claims Nos.: 7-28

The present application contains eight independant claims (Claims 1,7,16,21,25,27,29) differing from one to another and/or in the wording used to define such technical content, and including within their scope an extremely large number of possible devices.
The large number and also the wording of the independant claims presently on file renders it difficult, if not impossible, to determine the matter for which protection is sought.
As a result the present application fails to comply with the clarity and conciseness requirements of Article 6 PCT (see also Rule 6.1(a) PCT) to such an extent that a meaningful search is impossible over the scope of all claims.
Consequently, the search has been carried out for those parts of the application which do appear to be clear (and concise), namely independant claim 1 with dependant claims 2-6 together with the related independant method claim 29 with the dependant claims 30,31.

No formal objection concerning lack of unity has been raised at this point because of the above-mentioned clarity objection. However, it could be that several of the independant & dependant claims define inventions which are not linked so as to form a single inventive concept (Rule 13.1 of the PCT) and the applicant's view is thus drawn to this point.

The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US 03/12815

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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