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(54) **An implantable medical device having pressure sensors control**

Implantierbare medizinische Vorrichtung mit Drucksensorenkontrolle

Dispositif medical implantable avec des capteurs de pression pour controle

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(73) Proprietor: **Codman & Shurtleff, Inc.**
Raynham,
Massachusetts 02767-0350 (US)

(72) Inventor: **Rosenberg, Meir**
Newton, MA 02459 (US)

(74) Representative: **Mercer, Christopher Paul et al**
Carpmaels & Ransford LLP
One Southampton Row
London
WC1B 5HA (GB)

(56) References cited:
EP-A- 0 982 048
EP-A- 1 050 264
WO-A-01/21066
US-A1- 2002 156 464
US-B1- 6 237 398

EP 1 491 137 B1

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Description

1. Background of the Invention

[0001] The present invention relates to an implantable shunt having pressure sensors for diagnosing the performance of an implanted shunt by non-invasive techniques, such as telemetry.

2. Description of the Related Art

[0002] The present invention relates to an intracranial shunt that incorporates pressure sensors for measuring the pressure within the device and includes a device for communicating that information to an external device by telemetry.

[0003] Hydrocephalous is a condition in which the body, for any one of a variety of reasons, is unable to relieve itself of excess cerebral spinal fluid (CSF) collected in the ventricles of the brain. The excess collection of CSF in the ventricular space results in an increase in both epidural and intradural pressures. This, in turn, causes a number of adverse physiological effects, including compression of brain tissue, impairment of blood flow in the brain tissue, and impairment of the brain's normal metabolism. Treatment of a hydrocephalous condition frequently involves relieving the abnormally accumulated fluid volume with a shunt valve. The shunt valve is implanted in the body and, therefore, it is difficult to non-invasively verify the valve's performance.

[0004] A programmable valve, such as, for example, the CODMAN HAKIM Programmable Valve®, which is commercially available from Codman & Shurliff, Inc. of Raynharn, MA, or the programmable shunt valve disclosed in U.S. Patent Nos. 4,595,390, 4,615,691, 4772,257, and 5,928,182 are commonly referred to as the Hakim programmable valve. The Hakim valve described in these patents is a differential pressure valve with very precise opening pressures determined by the force exerted on a ruby ball in a ruby seat. The pressure at which the valve opens can be adjusted non-invasively by the clinician by means of an externally applied rotating magnetic field. The valve opening pressure is adjusted by varying the spring tension exerted on the ruby ball. Applying an external magnetic field to energize the soft magnet stator components of the valve initiates the adjustment cycle. The magnetic field causes the rotor to rotate about a central axis. As the stator polarity is cycled, the rotor (cam) moves to different positions to align with the stator. These components perform together as a stepping motor. The spring rides along the cam; as the cam rotates clockwise or counter-clockwise, the spring tension increases or decreases, respectively Hakim programmable shunt valves utilize current practice that requires an x-ray to be taken after each valve adjustment to verify the new setting. The use of additional energy means to conventionally determine valve position, however, can often lead to undesirable complications. For instance, when magnetic fields are used for verifying valve position, metallic equipment within the clinical environment often interferes with the accuracy of information obtained through the use of these magnetic force, leading to inaccurate roadings.

[0005] US publication no. 2002/0156464 discloses an implantable infusion pump having a refillable infusate reservoir in fluid communication with a delivery site via a flow path. The infusion device includes a sensing device, positioned relative to the flow path, to provide data regarding a flow rate along the flow path.

[0006] European publication no. EP 1050264 discloses an implantable biosensor system for monitoring and optionally alleviating a physiological condition in a patient and includes at least one sensor for sensing at least one parameter of as physiological condition.

[0007] Thus, there is a need in the art for a device that permits the surgeon to non- invasively verify the performance of the shunt valve. There is a further need in the art for a device that permits the surgeon to non- invasively verify the valve setting so that repeated exposure of the patent to magnetic or radiation energy is reduced or eliminated.

[0008] During use, shunt valves occasionally malfunction, but the reason for malfunction is not immediately known to the surgeon. One example of failure of the shunt valve could be occlusion of the drainage apertures within the ventricular catheter, thereby preventing fluid from entering into the valve housing mechanism. Another source of shunt failure could be a malfunction of the valve mechanism itself, or a blockage of the distal apertures in the drainage catheter. However, currently the only way for a medical professional to determine the source of failure is by using invasive medical techniques. Thus, there is a need in the art for a device which permits the surgeon to non-invasively determine the source of the shunt failure.

[0009] Therefore, it is an object of the present invention to provide such a device and a method for diagnosing the performance of an implanted medical device and to verity its valve setting.

Summary of the Invention

[0010] These and other objects of the present invention are achieved with an implantable shunt as set forth in either of the accompanying independent claims 1 or 12 and/or with a method as set forth in any one of the accompanying independent claims 24, 26.

[0011] Further, preferred aspects of the invention are set out in the accompanying dependent claims.

Brief Description of the Drawing Figures

[0012] Further features and other objects and advantages of this invention will become clear from the following detailed description made with reference to the accompanying drawings illustrating in a schematic and non-

limiting way an implantable shunt having pressure sensors for diagnosing the performance of an implanted shunt according to the invention and in which:

Figure 1 is a side view of an implantable shunt system in accordance with the present invention;
Figure 2 is a perspective view of the implantable shunt system shown in Figure 1;
Figure 3 is a partial top sectional view of the shunt shown in Figure 1;
Figure 4 is a schematic showing the communications between the pressure sensors and the CPU;
Figure 5 is a partial top sectional view of the shunt system in accordance with another example, and
Figure 6 is a side view of the shunt system shown in Figure 5.

Detailed Description of the Currently Referred Exemplary Embodiment:

[0013] Referring now to Figures 1-4, an implantable shunt system (10) in accordance with the present invention, is illustrated. Device (10) includes a housing (12), and a valve mechanism (14) disposed within housing (12). Valve (14) is preferably an Hakim-type programmable valve, as is known in the art. See, for example, U.S. Patent No. 5,928,182 to Kraus et al. Of course, other pressure relief valves may be utilized within housing (12), as desired by the user. As illustrated in Figure 4, a first pressure sensor (16) is disposed within housing (12) and downstream of valve (14). A second pressure sensor (18) is disposed within housing (12) upstream of valve (14). A central processing unit ("CPU") (20) is disposed within housing (12) and is electrically connected to the first pressure sensor (16) by line (22) and to second pressure sensor (18) by line (24). In practice, pressure sensors (16), (18) and CPU (20) may lie on a common ceramic substrate or PC board (26), with lines (22), (24) also lying upon PC board (26). CPU (20) preferably includes an antenna (28) for wireless communicating with an external device by telemetry in a manner known to those skilled in the art. CPU (20) includes a processor for calculating the differential pressure between the first pressure sensor (16) and the second pressure sensor (18).

[0014] A first catheter (38) is fluidly connected to housing (12). First catheter (38) is preferably a ventricular catheter, which can be placed within the ventricles of the brain to drain excess fluid therefrom. Catheter (38) includes a plurality of drainage apertures (42). Cerebral spinal fluid is preferably received within apertures (42) and is drained therefrom when the pressure difference between the ventricles and the drainage site (peritoneum or right atrium) exceeds the differential pressure set by valve (14). Disposed within first catheter (38), preferably distally with respect to apertures (32), is a third pressure sensor (40). Third pressure sensor (40) is electrically connected to CPU (20) by line (44). Line (44) is illustrated schematically in Figure 3 as being external to the catheter, but, in practice, line (44) will preferably run internally or within catheter (38) directly to PC board (26) and eventually to the CPU (20). Similarly, a drainage catheter (30) is fluidly connected to housing (12) to drain fluid from the ventricles to another portion of the body, in a manner known in the art. A fourth pressure sensor (34) is disposed within drainage catheter (30), preferably distally with respect to the plurality of drainage apertures (32). Fourth pressure sensor (34) is electrically connected to CPU (20) by line (36). As with line (44), line (36) is also preferably disposed within or internally within catheter (30) and is electrically connected to PC board (26) and eventually to CPU (20).

[0015] CPU (20) can measure the differential pressure or absolute pressure of any pressure sensor (16), (18), (34), (40). This information, which is preferably communicated to an external device by telemetry may be used by a medical professional to determine if the shunt is working properly or not. For example, if the differential pressure between third pressure sensor (40) and second pressure sensor (18) is high, [meaning that the pressure detected by sensor (40) is relatively high, whereas the pressure detected by sensor (18) is relatively low], then the operator will know that there is a blockage within first catheter (38). Similarly, based on the pressures measured by sensors (18) and (16) immediately both upstream and downstream of the valve (14), one can determine if the valve is malfunctioning. For example, if valve (14) is set to open at 0.980 kPa (100 mm water), and the differential pressure across the valve is higher than 0.980 kPa (100 mm water) (i.e., the valve set pressure), then this is an indication that the valve may not be operating properly. When the measured pressure exceeds the valve set pressure, this is an indication of a potential valve failure. In another example, if the pressure sensed from all four pressure sensors is relatively high, it is an indication that the drainage catheter (30) is blocked and no fluid is getting out of or being drained from this catheter (30). Finally, if the differential pressure between sensor (16) and fourth pressure sensor (34) is relatively low, then one will know that the distal catheter is working properly. However, if this differential pressure is relatively high, then one can deduce that there may be an occlusion in the drainage catheter (30) somewhere between these two sensors (16, 34).

[0016] Referring now to Figures 5 and 6, example is illustrated. In this example, many of the elements are identical to the embodiment shown in Figures 1-4 and described above. Thus, for the sake of brevity in the disclosure, only those elements that differ will be described. In this example a membrane (50), which forms a barrier between one side of valve (14) and the other side, acts as a differential pressure sensor and replaces, first pressure sensor (16) and second pressure sensor (18). As illustrated in Figure 6, the lower surface of membrane (50) is exposed to fluid pressure upstream of the valve by a fluid conduit (52), whereas the upper surface of membrane (50) is exposed to fluid pressure downstream

of the valve. Of course, the terms "upper" and "lower" are used herein with reference to the drawing figures to ease the description of the present invention, and are not intended to limit the scope of the present invention. In use, the portion of the housing described as upper, may in fact be lower, and vice versa.

[0017] Membrane (50) is electrically connected to CPU (20) by line (54). Line (54) is illustrated schematically in Figure 6 as being external to the shunt housing, but, in practice, line (54) will preferably run internally atop of the PC board (26) within the shunt housing directly to the CPU (20). One skilled in the art will recognize that membrane (50) can be of conventional design, such as, for example, the ones disclosed in U.S. Patent Nos. 5,431,057 and 5,633,594. Based upon the position of membrane (50), the differential pressure across the valve can be determined. Thus, one can determine if the valve is malfunctioning based upon the signal received from membrane (50). For example, if valve (14) is set to open at 100 mm water, and the differential pressure across the valve is higher than 0.980 kPa (100 mm water) (i.e., the valve set pressure), then this is an indication that the valve may not be operating properly. When the measured pressure exceeds the valve set pressure, this is an indication of a potential valve failure.

[0018] In the above described embodiment and the example, the sensors have been described as communicating directly with an internal CPU (20). However, each sensor could communicate to an external device by telemetry. The external device would then perform the function of CPU (20). Alternatively, the CPU may transmit the individual pressure reading from each sensor and the external receiver may perform the necessary calculations.

[0019] Thus, a method for diagnosing the performance of an implanted shunt in accordance with the present invention includes comparing the pressure measured by the first pressure sensor to the pressure measured by the second pressure sensor or comparing the pressure measured by any one of the first, second, third or fourth pressure sensors to any one of the other of the first, second, third or fourth pressure sensors and wirelessly communicating these compared pressures to an external device. Alternatively, the CPU may wirelessly communicate the absolute value of the pressure measured by any one of the first, second, third or fourth pressure sensors to the external device. The CPU and sensors are preferably non- invasively powered by the external device using RF telemetry. However, the CPU and sensors may be non-invasively powered using optical or acoustical methods. The sensors could also directly communicate with the external device using acoustic waves, thereby eliminating the need of the CPU. Such sensors are currently available from Remon Medical Technologies, Ltd, 7 Halamish St, Caesaria Industrial Park, 38900, Israel. Alternatively, as one skilled in the art will recognize, the CPU and sensors may communicate with an external device using RF or optics. An example of an optical signal and energy transmission device is disclosed in Optical Signal and Energy Transmission for a Retina Implant, by M. Gross et al. and published in BMEW- EMBS 1st Joint conference, 1999, Atlanta, USA.

[0020] Having described the presently preferred exemplary embodiment of an implantable shunt having pressure sensors for diagnosing the performance of the medical device in accordance with the present invention, it is believed that other modifications, variations and changes will be suggested to those skilled in the art in view of the teachings set forth herein. It is, therefore, to be understood that all such modifications, variations, and changes are believed to fall within the scope of the present invention as defined by the appended claims.

Claims

1. An implantable shunt (10) comprising:

   a housing (12);
   a valve (14) disposed within said housing;
   a first pressure sensor (16) disposed within said housing and upstream of said valve;
   a second pressure sensor (18) disposed within said housing and downstream of said valve;
   a first catheter (38) fluidly connected to said housing (12), and a third pressure sensor (40) disposed within said first catheter; and
   an internal CPU operatively connected to said first pressure sensor (16), said second pressure sensor (18) and said third pressure sensor and configured for comparing a pressure measured by the first pressure sensor to a pressure measured by the second pressure sensor and comparing a pressure measured by the third pressure sensor to one of the pressure measured by the first pressure sensor and second pressure sensor.

2. The shunt according to claim 1, wherein said CPU (20) is disposed within said housing (12).

3. The shunt according to any of claims 1 to 2, wherein the CPU (20) is electrically connected to said first pressure sensor (16), said second pressure sensor (18) and said third pressure sensor (40).

4. The shunt according to any of claims 1 to 3, wherein the CPU (20) includes an antenna (28) for wirelessly communicating with an external device.

5. The shunt according to claims 1 to 4, wherein the CPU (20) includes a processor for calculating a differential pressure between the first pressure sensor (16) and the second pressure sensor (18) and between the third pressure sensor (40) and at least one of the first pressure sensor (16) and the second pres-

sure sensor (18).

6. The shunt according to claims 1 to 5, wherein said first catheter (38) is fluidly connected to said housing (12) upstream of said valve (14).

7. The shunt according to claims 1 to 6, further comprising a second catheter (30) fluidly connected to said housing (12), and a fourth pressure sensor (34) disposed within said second catheter.

8. The shunt according to claim 7, wherein said fourth pressure sensor (34) is electrically connected to said CPU (20).

9. The shunt according to claim 7 or claim 8, wherein said second catheter (30) is fluidly connected to said housing (12) downstream of said valve (14).

10. The shunt according to claims 7 to 9, wherein the processor is also for calculating a differential pressure between the fourth pressure sensor (34) and at least one of the first pressure sensor (16), the second pressure sensor (18) and the third pressure sensor (40).

11. The shunt according to any preceding claim, wherein the CPU (20) is non-invasively powered using RF, acoustics, or optics.

12. A system comprising an implantable shunt (10) comprising:

a housing (12);
a valve (14) disposed within said housing;
a first pressure sensor (16) disposed within said housing and upstream of said valve;
a second pressure sensor (18) disposed within said housing and downstream of said valve;
a first catheter (38) fluidly connected to said housing (12), and a third pressure sensor (40) disposed within said first catheter; and
an external device operatively connectable to said first pressure sensor (16), said second pressure sensor (18) and said third pressure sensor and configured for comparing a pressure detected by the first pressure sensor to a pressure detected by the second pressure sensor and comparing a pressure detected by the third pressure sensor to one of the pressure detected by the first and second pressure sensor.

13. The system of claim 12, wherein the shunt further comprises
a CPU (20) being operatively connected to said first pressure sensor (16),said second pressure sensor (18) and said third pressure sensor.

14. The system of claim 13, wherein said CPU (20) is disposed within said housing (12).

15. The system according to any of claims 13 to 14, wherein the CPU (20) is electrically connected to said first pressure sensor (16), said second pressure sensor (18) and said third pressure sensor (40).

16. The system according to any of claims 13 to 15, wherein the CPU (20) includes an antenna (28) for wirelessly communicating with the external device.

17. The shunt according to claim 13 to 16, wherein the CPU (20) includes a processor for calculating a differential pressure between the first pressure sensor (16) and the second pressure sensor (18 and between the third pressure sensor (40) and at least one of the first pressure sensor (16) and the second pressure sensor (18)).

18. The system according to any of claims 1 to 17, wherein said first catheter (38) is fluidly connected to said housing (12) upstream of said valve (14).

19. The system according to claims 12 to 18, wherein the shunt further comprises a second catheter (30) fluidly connected to said housing (12), and a fourth pressure sensor (34) disposed within said second catheter.

20. The system according to claim 19, wherein said fourth pressure sensor (34) is electrically connected to said CPU (20).

21. The shunt according to claim 19 or 20, wherein said second catheter (30) is fluidly connected to said housing (12) downstream of said valve (14).

22. The shunt according to any of claim 19 to 21, wherein the processor is also for calculating a differential pressure between the fourth pressure sensor (34) and at least one of the first pressure sensor (16), the second pressure sensor (18) and the third pressure sensor (40).

23. The shunt according to any of claims 13 to 22, wherein the CPU (20) is non-invasively powered using RF, acoustics, or optics.

24. A method for diagnosing the performance of an implanted shunt (10), wherein the implanted shunt has:

a housing (12);
a valve (14) disposed within said housing;
a first pressure sensor (16) disposed within said housing (12) and upstream of said valve (14);
a second pressure sensor (18) disposed within said housing (12) and downstream of said valve

(14);
a CPU (20) disposed within said housing (12) and being operatively connected to said first pressure sensor (16) and said second pressure sensor (18); and
a first catheter (38) fluidly connected to said housing (12), and a third pressure sensor (40) disposed within said first catheter,
the method comprising the steps of:

comparing the pressure measured by the first pressure sensor (16) to the pressure measured by the second pressure sensor (18);
comparing the pressure measured by the third pressure sensor (40) to one of the pressure measured by the first pressure sensor (16) and second pressure sensor (18); and;
wirelessly communicating the compared pressures to an external device.

25. The method according to claim 24, wherein the shunt (10) further comprises a second catheter (30) fluidly connected to said housing (12), and fourth pressure sensor (34) disposed within said second catheter, said method further comprising the step of:

comparing the pressure measured by the fourth pressure sensor (34) to one of the pressure measured by the first pressure sensor (16), the second pressure sensor (18) and third pressure sensor (40).

26. A method for diagnosing the performance of an implanted shunt (10), wherein the implanted shunt has:

a housing (12);
a valve (14) disposed within said housing;
a first pressure sensor (16) disposed within said housing (12) and upstream of said valve (14); and
a second pressure sensor (18) disposed within said housing (12) and downstream of said valve (14);
a first catheter (38) fluidly connected to said housing (12), and a third pressure sensor (40) disposed within said first catheter;

the method comprising the steps of:

wirelessly communicating a signal representative of the pressure detected by the first pressure sensor (16) to an external device;
wirelessly communicating a signal representative of the pressure detected by the second pressure sensor (18) to an external device;
wirelessly communicating a signal representative of the pressure detected by the third pressure sensor (40) to an external device;
comparing the pressure detected by the first pressure sensor (16) to the pressure detected by the second pressure sensor (18) with the external device; and
comparing the pressure detected by the third pressure sensor (40) to any of the pressure detected by the first pressure sensor (16) or pressure detected by the second pressure sensor (18) with the external device.

Patentansprüche

1. Implantierbarer Shunt (10), umfassend:

ein Gehäuse (12);
ein in dem Gehäuse angeordnetes Ventil (14);
einen in dem Gehäuse und stromaufwärts von dem Ventil angeordneten ersten Drucksensor (16);
einen in dem Gehäuse und stromabwärts von dem Ventil angeordneten zweiten Drucksensor (18);
einen ersten Katheter (38) in Fluidverbindung mit dem Gehäuse (12) und einen in dem ersten Katheter angeordneten dritten Drucksensor (40); und
einen internen Hauptprozessor in Wirkverbindung mit dem ersten Drucksensor (16), dem zweiten Drucksensor (18) und dem dritten Drucksensor und der zum Vergleichen eines von dem ersten Drucksensor gemessenen Drucks mit einem von dem zweiten Drucksensor gemessenen Druck und zum Vergleichen eines von dem dritten Drucksensor gemessenen Drucks mit einem der von dem ersten Drucksensor und dem zweiten Drucksensor gemessenen Drücke ausgelegt ist.

2. Shunt nach Anspruch 1, worin der Hauptprozessor (20) in dem Gehäuse (12) angeordnet ist.

3. Shunt nach einem der Ansprüche 1 bis 2, worin der Hauptprozessor (20) elektrisch mit dem ersten Drucksensor (16), dem zweiten Drucksensor (18) und dem dritten Drucksensor (40) verbunden ist.

4. Shunt nach einem der Ansprüche 1 bis 3, worin der Hauptprozessor (20) eine Antenne (28) für drahtlose Kommunikation mit einer externen Vorrichtung aufweist.

5. Shunt nach Ansprüchen 1 bis 4, worin der Hauptprozessor (20) einen Prozessor zur Berechnung eines Differentialdrucks zwischen dem ersten Drucksensor (16) und dem zweiten Drucksensor (18) und zwischen dem dritten Drucksensor (40) und zumin-

dest dem ersten Drucksensor (16) oder zumindest dem zweiten Drucksensor (18) aufweist.

6. Shunt nach Ansprüchen 1 bis 5, worin der erste Katheter (38) mit dem Gehäuse (12) stromaufwärts von dem Ventil (14) in Fluidverbindung steht.

7. Shunt nach Ansprüchen 1 bis 6, ferner umfassend einen zweiten Katheter (30) in Fluidverbindung mit dem Gehäuse (12) und einen in dem zweiten Katheter angeordneten vierten Katheter (34).

8. Shunt nach Anspruch 7, worin der vierte Drucksensor (34) elektrisch mit dem Hauptprozessor (20) verbunden ist.

9. Shunt nach Anspruch 7 oder Anspruch 8, worin der zweite Katheter (30) mit dem Gehäuse (12) stromabwärts von dem Ventil (14) in Fluidverbindung steht.

10. Shunt nach Ansprüchen 7 bis 9, worin der Prozessor auch zur Berechnung eines Differentialdrucks zwischen dem vierten Drucksensor (34) und zumindest dem ersten Drucksensor (16), zumindest dem zweiten Drucksensor (18) oder zumindest dem dritten Drucksensor (40) bestimmt ist.

11. Shunt nach einem der vorhergehenden Ansprüche, worin der Hauptprozessor (20) mittels HF, Akustik oder Optik nicht-invasiv angetrieben wird.

12. System, umfassend
einen implantierbaren Shunt (10), umfassend:

ein Gehäuse (12);
ein in dem Gehäuse angeordnetes Ventil (14);
einen in dem Gehäuse und stromaufwärts von dem Ventil angeordneten ersten Drucksensor (16);
einen in dem Gehäuse und stromabwärts von dem Ventil angeordneten zweiten Drucksensor (18);
einen ersten Katheter (38) in Fluidverbindung mit dem Gehäuse (12) und einen in dem ersten Katheter angeordneten dritten Drucksensor (40); und
eine externe Vorrichtung, die in Wirkverbindung mit dem ersten Drucksensor (16), dem zweiten Drucksensor (18) und dem dritten Drucksensor gebracht werden kann und zum Vergleichen eines von dem ersten Drucksensor gemessenen Drucks mit einem von dem zweiten Drucksensor gemessenen Druck und zum Vergleichen eines von dem dritten Drucksensor gemessenen Drucks mit einem der von dem ersten Drucksensor und dem zweiten Drucksensor gemessenen Drücke ausgelegt ist.

13. System nach Anspruch 12, worin der Shunt ferner Folgendes umfasst:

einen Hauptprozessor (20) in Wirkverbindung mit dem ersten Drucksensor (16), dem zweiten Drucksensor (18) und dem dritten Drucksensor.

14. System nach Anspruch 13, worin der Hauptprozessor (20) in dem Gehäuse (12) angeordnet ist.

15. System nach einem der Ansprüche 13 bis 14, worin der Hauptprozessor (20) elektrisch mit dem ersten Drucksensor (16), dem zweiten Drucksensor (18) und dem dritten Drucksensor (40) verbunden ist.

16. System nach einem der Ansprüche 13 bis 15, worin der Hauptprozessor (20) eine Antenne (28) für drahtlose Kommunikation mit der externen Vorrichtung aufweist.

17. System nach Ansprüchen 13 bis 16, worin der Hauptprozessor (20) einen Prozessor zur Berechnung eines Differentialdrucks zwischen dem ersten Drucksensor (16) und dem zweiten Drucksensor (18) und zwischen dem dritten Drucksensor (40) und zumindest dem ersten Drucksensor (16) oder zumindest dem zweiten Drucksensor (18) aufweist.

18. System nach Ansprüchen 12 bis 17, worin der erste Katheter (38) mit dem Gehäuse (12) stromaufwärts von dem Ventil (14) in Fluidverbindung steht.

19. System nach Ansprüchen 12 bis 18, worin der Shunt ferner einen zweiten Katheter (30) in Fluidverbindung mit dem Gehäuse (12) und einen in dem zweiten Katheter angeordneten vierten Katheter (34) umfasst.

20. System nach Anspruch 19, worin der vierte Drucksensor (34) elektrisch mit dem Hauptprozessor (20) verbunden ist.

21. Shunt nach Anspruch 19 oder 20, worin der zweite Katheter (30) mit dem Gehäuse (12) stromabwärts von dem Ventil (14) in Fluidverbindung steht.

22. Shunt nach einem der Ansprüche 19 bis 21, worin der Prozessor auch zur Berechnung eines Differentialdrucks zwischen dem vierten Drucksensor (34) und zumindest dem ersten Drucksensor (16), zumindest dem zweiten Drucksensor (18) oder zumindest dem dritten Drucksensor (40) bestimmt ist.

23. Shunt nach einem der Ansprüche 13 bis 22, worin der Hauptprozessor (20) mittels HF, Akustik oder Optik nicht-invasiv angetrieben wird.

24. Verfahren zur Diagnose der Leistung eines implan-

tierten Shunts (10), worin der implantierte Shunt Folgendes aufweist:

ein Gehäuse (12);
ein in dem Gehäuse angeordnetes Ventil (14);
einen in dem Gehäuse (12) und stromaufwärts von dem Ventil (14) angeordneten ersten Drucksensor (16);
einen in dem Gehäuse (12) und stromabwärts von dem Ventil (14) angeordneten zweiten Drucksensor (18);
einen in dem Gehäuse (12) angeordneten Hauptprozessor (20) in Wirkverbindung mit dem ersten Drucksensor (16) und dem zweiten Drucksensor (18); und
einen ersten Katheter (38) in Fluidverbindung mit dem Gehäuse (12) und einen in dem ersten Katheter angeordneten dritten Drucksensor (40),
worin das Verfahren die folgenden Schritte umfasst:

Vergleichen des von dem ersten Drucksensor (16) gemessenen Drucks mit dem von dem zweiten Drucksensor (18) gemessenen Druck;
Vergleichen des von dem dritten Drucksensor (40) gemessenen Drucks mit einem der von dem ersten Drucksensor (16) und dem zweiten Drucksensor (18) gemessenen Drücke;
und
drahtlose Mitteilung der verglichenen Drükke an eine externe Vorrichtung.

25. Verfahren nach Anspruch 24, worin der Shunt (10) ferner einen zweiten Katheter (30) in Fluidverbindung mit dem Gehäuse (12) und einen in dem zweiten Katheter angeordneten vierten Drucksensor (34) umfasst, wobei das Verfahren ferner den folgenden Schritt umfasst:

Vergleichen des von dem vierten Drucksensor (34) gemessenen Drucks mit dem von dem ersten Drucksensor (16), dem zweiten Drucksensor (18) oder dem dritten Drucksensor (40) gemessenen Druck.

26. Verfahren zur Diagnose der Leistung eines implantierten Shunts (10), worin der implantierte Shunt Folgendes aufweist:

ein Gehäuse (12);
ein in dem Gehäuse angeordnetes Ventil (14);
einen in dem Gehäuse (12) und stromaufwärts von dem Ventil (14) angeordneten ersten Drucksensor (16);
einen in dem Gehäuse (12) und stromabwärts von dem Ventil (14) angeordneten zweiten Drucksensor (18);
einen ersten Katheter (38) in Fluidverbindung mit dem Gehäuse (12) und einen in dem ersten Katheter angeordneten dritten Drucksensor (40),
wobei das Verfahren die folgenden Schritte umfasst:

drahtlose Mitteilung eines Signals, das für den von dem ersten Drucksensor (16) nachgewiesenen Druck repräsentativ ist, an eine externe Vorrichtung;
drahtlose Mitteilung eines Signals, das für den von dem zweiten Drucksensor (18) nachgewiesenen Druck repräsentativ ist, an eine externe Vorrichtung;
drahtlose Mitteilung eines Signals, das für den von dem dritten Drucksensor (40) nachgewiesenen Druck repräsentativ ist, an eine externe Vorrichtung;
Vergleichen des von dem ersten Drucksensor (16) gemessenen Drucks mit dem von dem zweiten Drucksensor (18) gemessenen Druck mittels der externen Vorrichtung;
und
Vergleichen des von dem dritten Drucksensor (40) gemessenen Drucks mit einem beliebigen der von dem ersten Drucksensor (16) oder dem zweiten Drucksensor (18) gemessenen Drücke mittels der externen Vorrichtung.

Revendications

1. Élément de dérivation de type shunt (10) implantable comprenant :

un carter (12) ;
une valve (14) disposée à l'intérieur dudit carter ;
un premier capteur de pression (16) disposé à l'intérieur dudit carter et placé en amont de ladite valve ;
un second capteur de pression (18) disposé à l'intérieur dudit carter et placé en aval de ladite valve ;
un premier cathéter (38) relié sur le plan fluide audit carter (12) et un troisième capteur de pression (40) disposé à l'intérieur dudit premier cathéter ; et
un CPU interne relié en fonctionnement audit premier capteur de pression (16), audit second capteur de pression (18) et audit troisième capteur de pression et configuré pour comparer une pression mesurée par le premier capteur de pression à une pression mesurée par le second capteur de pression et pour comparer une pres-

sion mesurée par le troisième capteur de pression à une pression parmi la pression mesurée par le premier capteur de pression et par le second capteur de pression.

2. Élément de dérivation de type shunt selon la revendication 1, dans lequel ledit CPU (20) est disposé à l'intérieur dudit carter (12).

3. Élément de dérivation de type shunt selon l'une quelconque des revendications 1 à 2, dans lequel le CPU (20) est relié sur le plan électrique audit premier capteur de pression (16), audit second capteur de pression (18) et audit troisième capteur de pression (40).

4. Élément de dérivation de type shunt selon l'une quelconque des revendications 1 à 3, dans lequel le CPU (20) comprend une antenne (28) servant à communiquer sans fil avec un dispositif externe.

5. Élément de dérivation de type shunt selon les revendications 1 à 4, dans lequel le CPU (20) comprend un processeur permettant de calculer une pression différentielle entre le premier capteur de pression (16) et le second capteur de pression (18) et entre le troisième capteur de pression (40) et au moins un capteur parmi le premier capteur de pression (16) et le second capteur de pression (18).

6. Élément de dérivation de type shunt selon les revendications 1 à 5, dans lequel ledit premier cathéter (38) est relié sur le plan fluide audit carter (12) en amont de ladite valve (14).

7. Élément de dérivation de type shunt selon les revendications 1 à 6, comprenant en outre un second cathéter (30) relié sur le plan fluide audit carter (12), et un quatrième capteur de pression (34) disposé à l'intérieur dudit second cathéter.

8. Élément de dérivation de type shunt selon la revendication 7, dans lequel ledit quatrième capteur de pression (34) est relié sur le plan électrique audit CPU (20).

9. Élément de dérivation de type shunt selon la revendication 7 ou la revendication 8, dans lequel ledit second cathéter (30) est relié sur le plan fluide audit carter (12) en aval de ladite valve (14).

10. Élément de dérivation de type shunt selon les revendications 7 à 9, dans lequel le processeur sert également à calculer une pression différentielle entre le quatrième capteur de pression (34) et au moins un capteur parmi le premier capteur de pression (16), le second capteur de pression (18) et le troisième capteur de pression (40).

11. Élément de dérivation de type shunt selon l'une quelconque des revendications précédentes, dans lequel le CPU (20) est alimenté en courant de façon non invasive par le biais de RF, d'un système acoustique ou optique.

12. Système comprenant :

un élément de dérivation de type shunt implantable (10) comprenant :

un carter (12) ;
une valve (14) disposée à l'intérieur dudit carter ;
un premier capteur de pression (16) disposé à l'intérieur dudit carter et placé en amont de ladite valve ;
un second capteur de pression (18) disposé à l'intérieur dudit carter et placé en aval de ladite valve ;
un premier cathéter (38) relié sur le plan fluide audit carter (12), et un troisième capteur de pression (40) disposé à l'intérieur dudit premier cathéter ; et
un dispositif externe pouvant être relié en fonctionnement audit premier capteur de pression (16), audit second capteur de pression (18) et audit troisième capteur de pression et configuré pour comparer une pression détectée par le premier capteur de pression à une pression détectée par le second capteur de pression et pour comparer une pression détectée par le troisième capteur de pression à une pression parmi la pression détectée par le premier et le second capteur de pression.

13. Système selon la revendication 12, dans lequel l'élément de dérivation de type shunt comprend en outre un CPU (20) relié en fonctionnement audit premier capteur de pression (16), audit second capteur de pression (18) et audit troisième capteur de pression.

14. Système selon la revendication 13, dans lequel ledit CPU (20) est disposé à l'intérieur dudit carter (12).

15. Système selon l'une quelconque des revendications 13 à 14, dans lequel le CPU (20) est relié sur le plan électrique audit premier capteur de pression (16), audit second capteur de pression (18) et audit troisième capteur de pression (40).

16. Système selon l'une quelconque des revendications 13 à 15, dans lequel le CPU (20) comprend une antenne (28) servant à communiquer sans fil avec le dispositif externe.

17. Élément de dérivation de type shunt selon les reven-

dications 13 à 16, dans lequel le CPU (20) comprend un processeur permettant de calculer une pression différentielle entre le premier capteur de pression (16) et le second capteur de pression (18) et entre le troisième capteur de pression (40) et au moins un capteur parmi le premier capteur de pression (16) et le second capteur de pression (18).

18. Système selon l'une quelconque des revendications 12 à 17, dans lequel ledit premier cathéter (38) est relié sur le plan fluide audit carter (12) placé en amont de ladite valve (14).

19. Système selon les revendications 12 à 18, dans lequel l'élément de dérivation de type shunt comprend en outre un second cathéter (30) relié sur le plan fluide audit carter (12), et un quatrième capteur de pression (34) disposé à l'intérieur dudit second cathéter.

20. Système selon la revendication 19, dans lequel ledit quatrième capteur de pression (34) est relié sur le plan électrique audit CPU (20).

21. Élément de dérivation de type shunt selon la revendication 19 ou 20, dans lequel ledit second cathéter (30) est relié sur le plan fluide audit carter (12) placé en aval de ladite valve (14).

22. Élément de dérivation de type shunt selon l'une quelconque des revendications 19 à 21, dans lequel le processeur sert également à calculer une pression différentielle entre le quatrième capteur de pression (34) et au moins un capteur parmi le premier capteur de pression (16), le second capteur de pression (18) et le troisième capteur de pression (40).

23. Élément de dérivation de type shunt selon l'une quelconque des revendications 13 à 22, dans lequel le CPU (20) est alimenté en courant de façon non invasive par le biais de RF, d'un système acoustique ou optique.

24. Procédé de diagnostic de la performance d'un élément de dérivation de type shunt (10) implanté, dans lequel l'élément de dérivation de type shunt implanté comprend :

un carter (12) ;
une valve (14) disposée à l'intérieur dudit carter ;
un premier capteur de pression (16) disposé à l'intérieur dudit carter (12) et placé en amont de ladite valve (14) ;
un second capteur de pression (18) disposé à l'intérieur dudit carter (12) et placé en aval de ladite valve (14) ;
un CPU (20) disposé à l'intérieur dudit carter (12) et relié en fonctionnement audit premier capteur de pression (16) et audit second capteur de pression (18) ; et
un premier cathéter (38) relié sur le plan fluide audit carter (12), et un troisième capteur de pression (40) disposé à l'intérieur dudit premier cathéter ;
le procédé comprenant les étapes consistant à :

comparer la pression mesurée par le premier capteur de pression (16) à la pression mesurée par le second capteur de pression (18) ;
comparer la pression mesurée par le troisième capteur de pression (40) à une pression parmi la pression mesurée par le premier capteur de pression (16) et le second capteur de pression (18) ; et
communiquer sans fil les pressions comparées à un dispositif externe.

25. Procédé selon la revendication 24, dans lequel l'élément de dérivation de type shunt (10) comprend en outre un second cathéter (30) relié sur le plan fluide audit carter (12), et un quatrième capteur de pression (34) disposé à l'intérieur dudit second cathéter, ledit procédé comprenant en outre l'étape de :

comparaison de la pression mesurée par le quatrième capteur de pression (34) à une pression parmi la pression mesurée par le premier capteur de pression (16), le second capteur de pression (18) et le troisième capteur de pression (40).

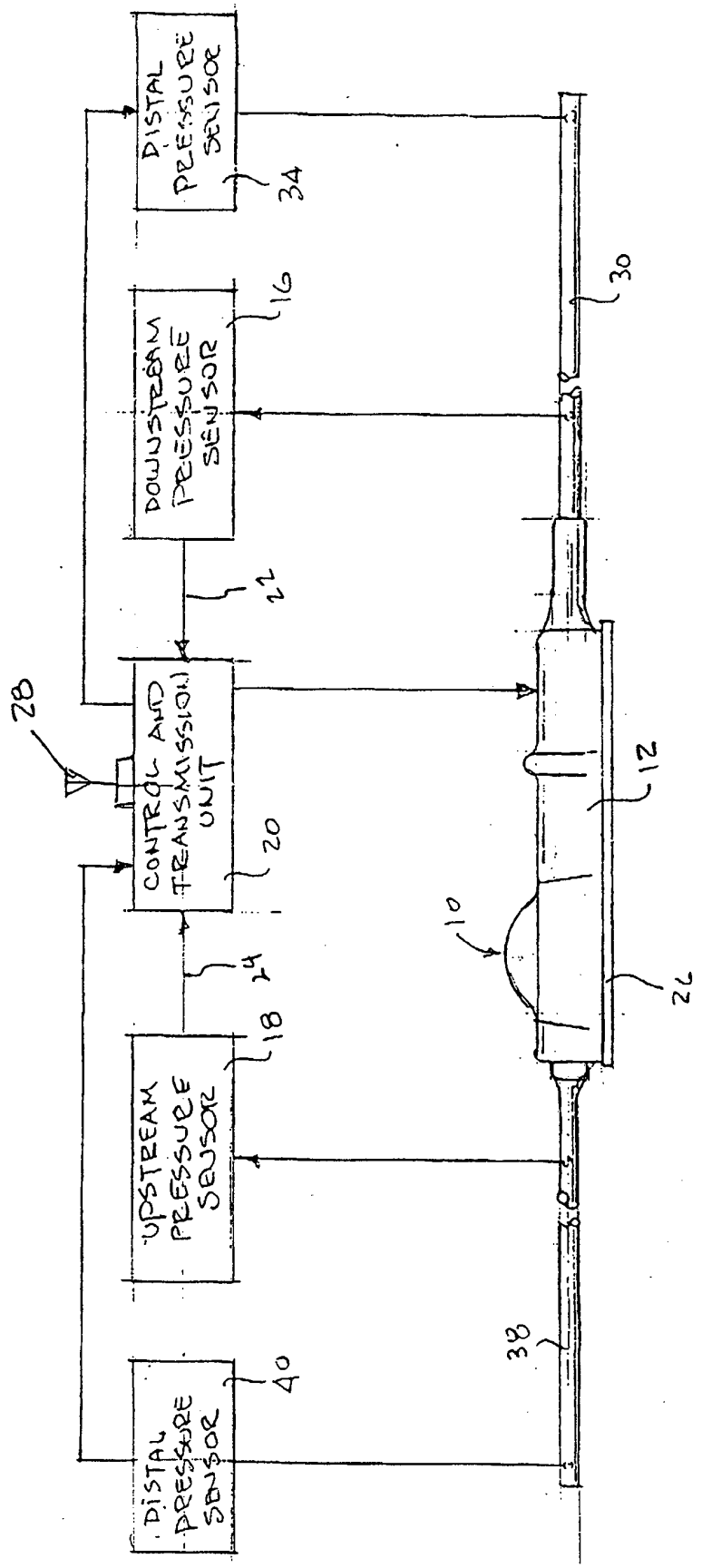
26. Procédé de diagnostic de la performance d'un élément de dérivation de type shunt (10) implanté, dans lequel l'élément de dérivation de type shunt implanté comprend :

un carter (12) ;
une valve (14) disposée à l'intérieur dudit carter ;
un premier capteur de pression (16) disposé à l'intérieur dudit carter (12) et placé en amont de ladite valve (14) ; et
un second capteur de pression (18) disposé à l'intérieur dudit carter (12) et placé en aval de ladite valve (14) ;
un premier cathéter (38) relié sur le plan fluide audit carter (12) et un troisième capteur de pression (40) disposé à l'intérieur dudit premier cathéter ;
le procédé comprenant les étapes consistant à :

communiquer sans fil un signal représentatif de la pression détectée par le premier capteur de pression (16) à un dispositif externe ;
communiquer sans fil un signal représenta-

tif de la pression détectée par le second capteur de pression (18) à un dispositif externe ;
communiquer sans fil un signal représentatif de la pression détectée par le troisième capteur de pression (40) à un dispositif externe ;
comparer la pression détectée par le premier capteur de pression (16) à la pression détectée par le second capteur de pression (18) à l'aide du dispositif externe ; et
comparer la pression détectée par le troisième capteur de pression (40) à n'importe quelle pression parmi la pression détectée par le premier capteur de pression (16) ou la pression détectée par le second capteur de pression (18) à l'aide du dispositif externe.

FIG. 1


DISTAL PRESSURE SENSOR
34
DOWNSTREAM PRESSURE SENSOR
16
30
22
28
CONTROL AND TRANSMISSION UNIT
20
12
10
24
18
UPSTREAM PRESSURE SENSOR
26
38
40
DISTAL PRESSURE SENSOR

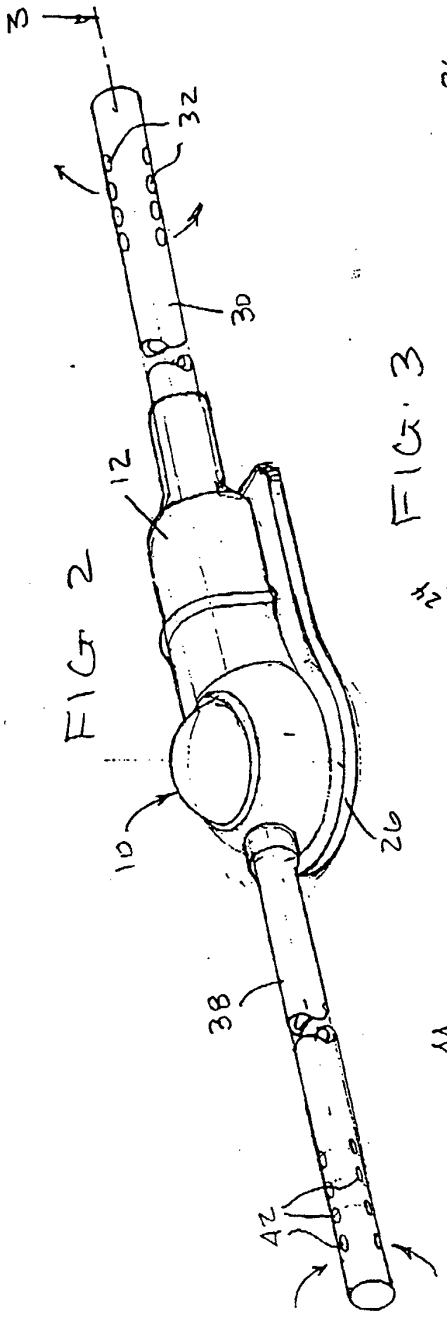


FIG 2

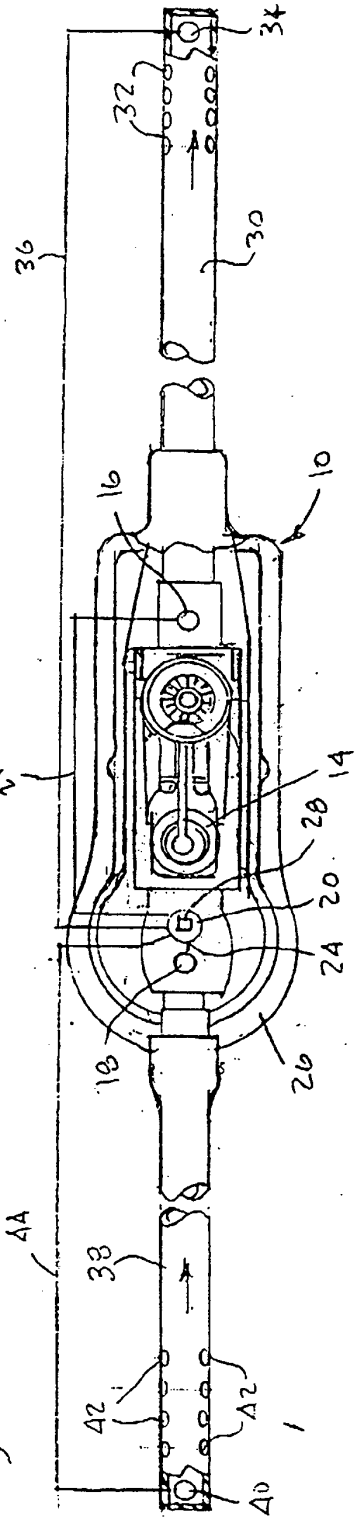


FIG. 3

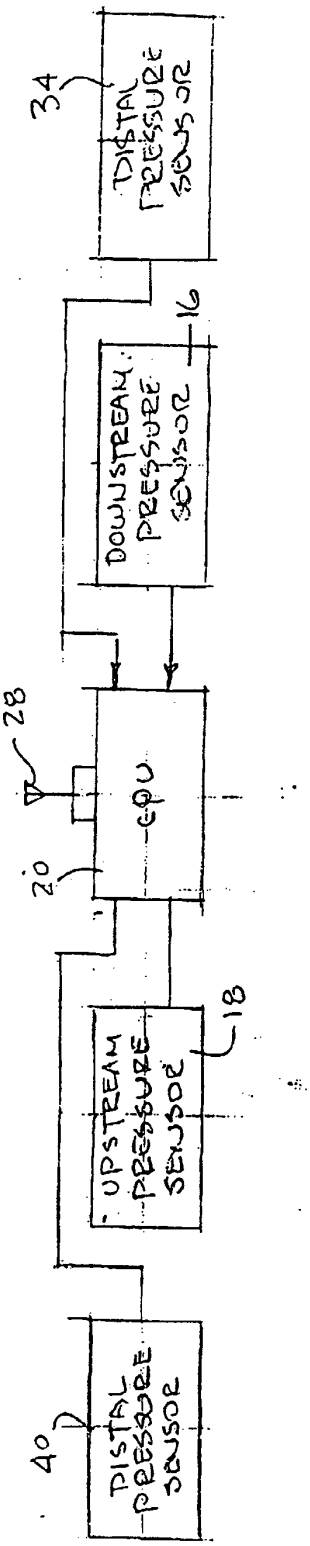


FIG. 4

FIG. 5

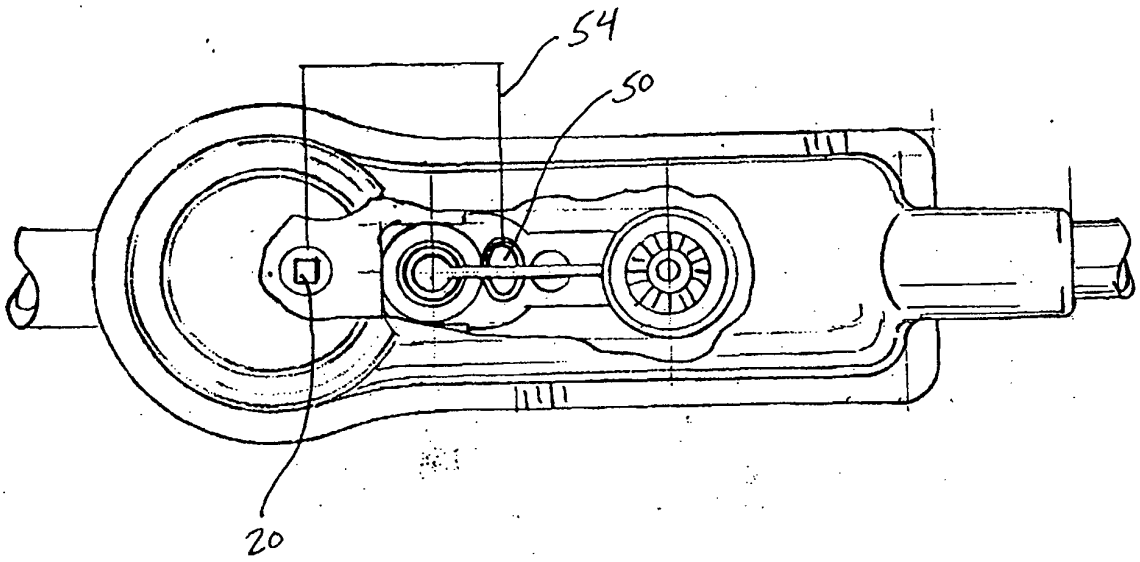
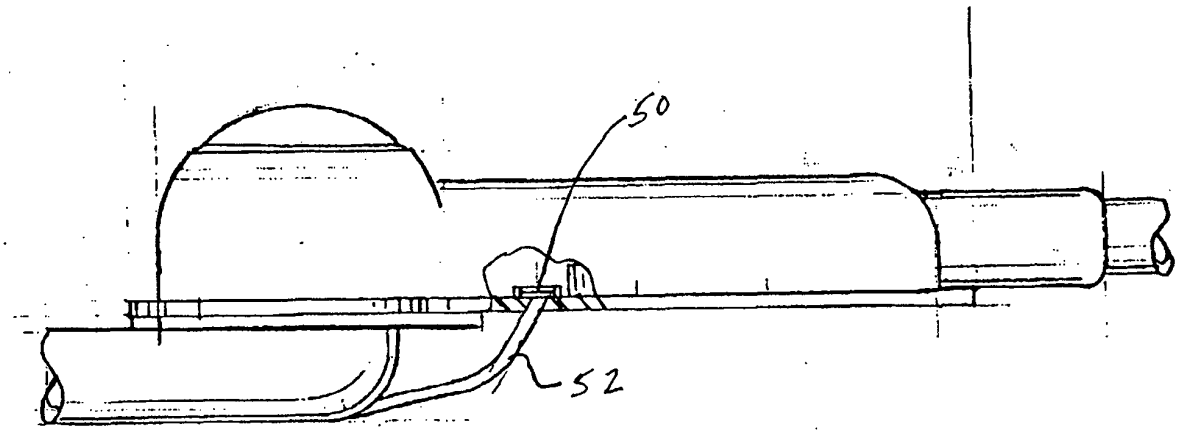


FIG. 6



REFERENCES CITED IN THE DESCRIPTION

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Patent documents cited in the description

- US 4595390 A **[0004]**
- US 4615691 A **[0004]**
- US 4772257 A **[0004]**
- US 5928182 A **[0004] [0013]**
- US 20020156464 A **[0005]**
- EP 1050264 A **[0006]**
- US 5431057 A **[0017]**
- US 5633594 A **[0017]**

Non-patent literature cited in the description

- **M. GROSS et al.** Optical Signal and Energy Transmission for a Retina Implant. *BMEW-EMBS 1st Joint conference,* 1999 **[0019]**

专利名称(译)	一种具有压力传感器控制的可植入医疗设备		
公开(公告)号	EP1491137B1	公开(公告)日	2013-09-18
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当前申请(专利权)人(译)	DePuy公司SYNTHES产品有限责任公司		
[标]发明人	ROSENBERG MEIR		
发明人	ROSENBERG, MEIR		
IPC分类号	A61B5/03 A61M27/00 A61B5/0215 A61B5/00 A61M1/00		
CPC分类号	A61M27/006 A61B5/0031 A61B5/031		
代理机构(译)	MERCER，CHRISTOPHER PAUL		
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其他公开文献	EP1491137A3 EP1491137A2		
外部链接	Espacenet		

摘要(译)

一种可植入医疗装置，包括壳体，设置在壳体内的阀，设置在壳体上游的第一压力传感器和设置在阀下游的壳体内的第二压力传感器。 CPU布置在壳体内并且电连接到第一压力传感器和第二压力传感器。为了将测量的压力信息传送到外部装置，CPU将由第一压力传感器测量的压力与由第二压力传感器测量的压力进行比较，并将这些比较的压力无线地传送到外部装置。或者，CPU可以将由第一压力传感器和第二压力传感器测量的压力的绝对值无线地传送到外部设备。另外，CPU和传感器可以使用光学或声学方法非侵入性地供电。