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Wolf

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(54) **TRANSCUTANEOUS TELEMETRY OF CEREBROSPINAL FLUID SHUNT PROGRAMMABLE-VALVE PRESSURE USING NEAR-INFRARED (NIR) LIGHT**

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Related U.S. Application Data

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(51) **Int. Cl.**
A61M 5/00 (2006.01)
A61M 37/00 (2006.01)
F16K 31/02 (2006.01)

(52) **U.S. Cl.** **604/9**; 604/6.1; 251/129.11

(58) **Field of Classification Search** 604/8–10, 604/4.01–6.16; 251/129.11–129.22; 607/30–33, 607/59–65; 600/561, 651
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

3,672,252	A		6/1972	Summers
3,672,352	A	*	6/1972	Summers 600/476
4,387,715	A		6/1983	Hakim et al.
4,595,390	A		6/1986	Hakim et al.
4,660,568	A		4/1987	Cosman
4,677,982	A		7/1987	Llinas et al.
4,772,257	A	*	9/1988	Hakim et al. 604/9
4,787,886	A		11/1988	Cosman
4,807,662	A	*	2/1989	Verne 137/554
4,885,002	A		12/1989	Watanabe et al.
5,704,352	A		1/1998	Tremblay et al.
5,741,246	A		4/1998	Prescott
5,852,413	A	*	12/1998	Bacchi et al. 341/13
5,873,840	A		2/1999	Neff
5,928,182	A		7/1999	Kraus et al.
6,049,727	A		4/2000	Crothall
6,050,969	A		4/2000	Kraus
6,126,595	A		10/2000	Amano et al.
6,162,238	A		12/2000	Kaplan et al.

(Continued)

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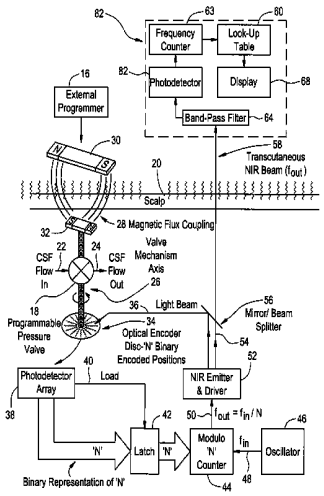
(57) **ABSTRACT**

An improvement for a programmable valve system of the type which is implanted in a medical patient and used to divert cerebrospinal fluid (CSF) from an intraventricular space of the patient to a terminus such as the patient peritoneal cavity. Such system includes means for establishing a flow path for the CSF to the terminus, which flow path includes a normally closed valve and means for adjusting the opening pressure of the valve in order to regulate the quantity of CSF diverted. The improvement enables an operator to be apprised of the actual opening pressure setting of the valve. A sensor is implantable at the patient and responds to the actual opening pressure setting, by generating an NIR telemetry signal indicative of the actual setting. This signal is transcutaneously transmitted through the skin of the patient to an external point. The telemetry signal is processed to produce observer intelligible data indicating the opening pressure setting of the valve.

14 Claims, 5 Drawing Sheets



U.S. PATENT DOCUMENTS

6,241,660	B1	6/2001	Dolle	
6,243,608	B1 *	6/2001	Pauly et al.	607/60
6,413,267	B1 *	7/2002	Dumoulin-White et al.	607/89
6,439,538	B1	8/2002	Ito	
6,533,733	B1 *	3/2003	Ericson et al.	600/561
2005/0010159	A1	1/2005	Reich et al.	
2005/0038371	A1	2/2005	Reich et al.	
2005/0085763	A1	4/2005	Ginggen et al.	
2005/0148925	A1	7/2005	Rottenberg et al.	

* cited by examiner

FIG. 1

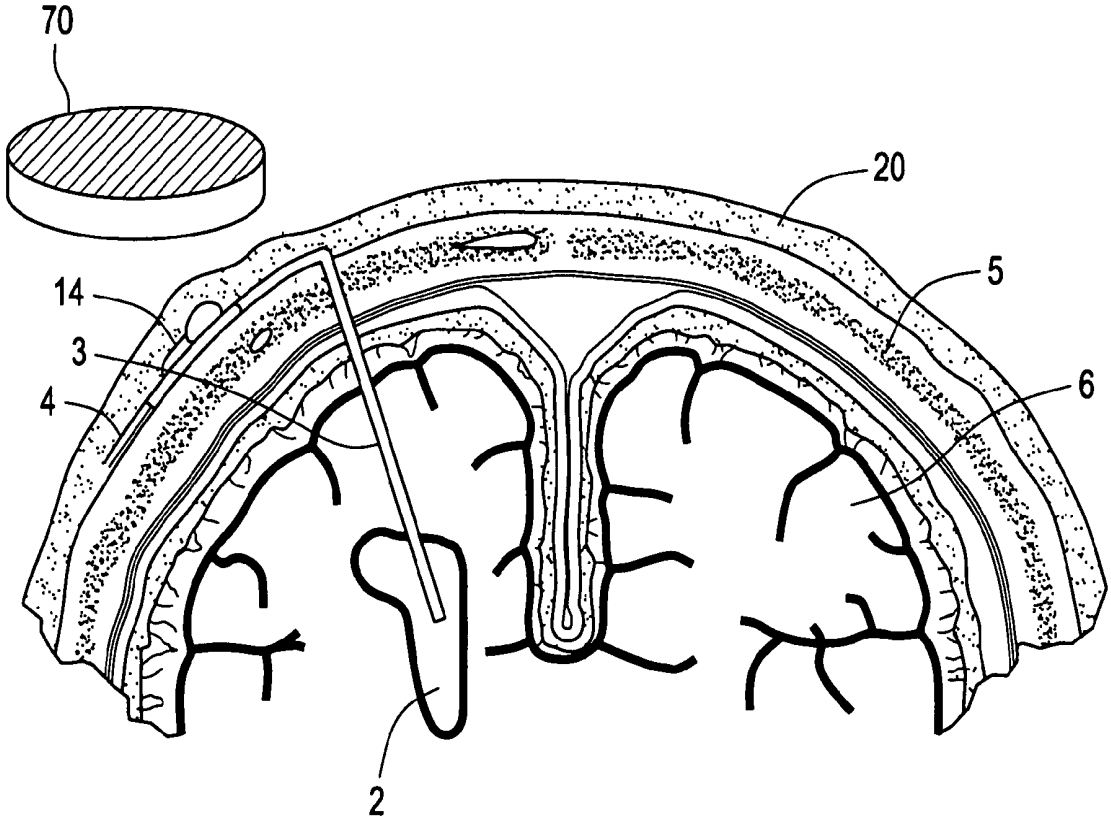
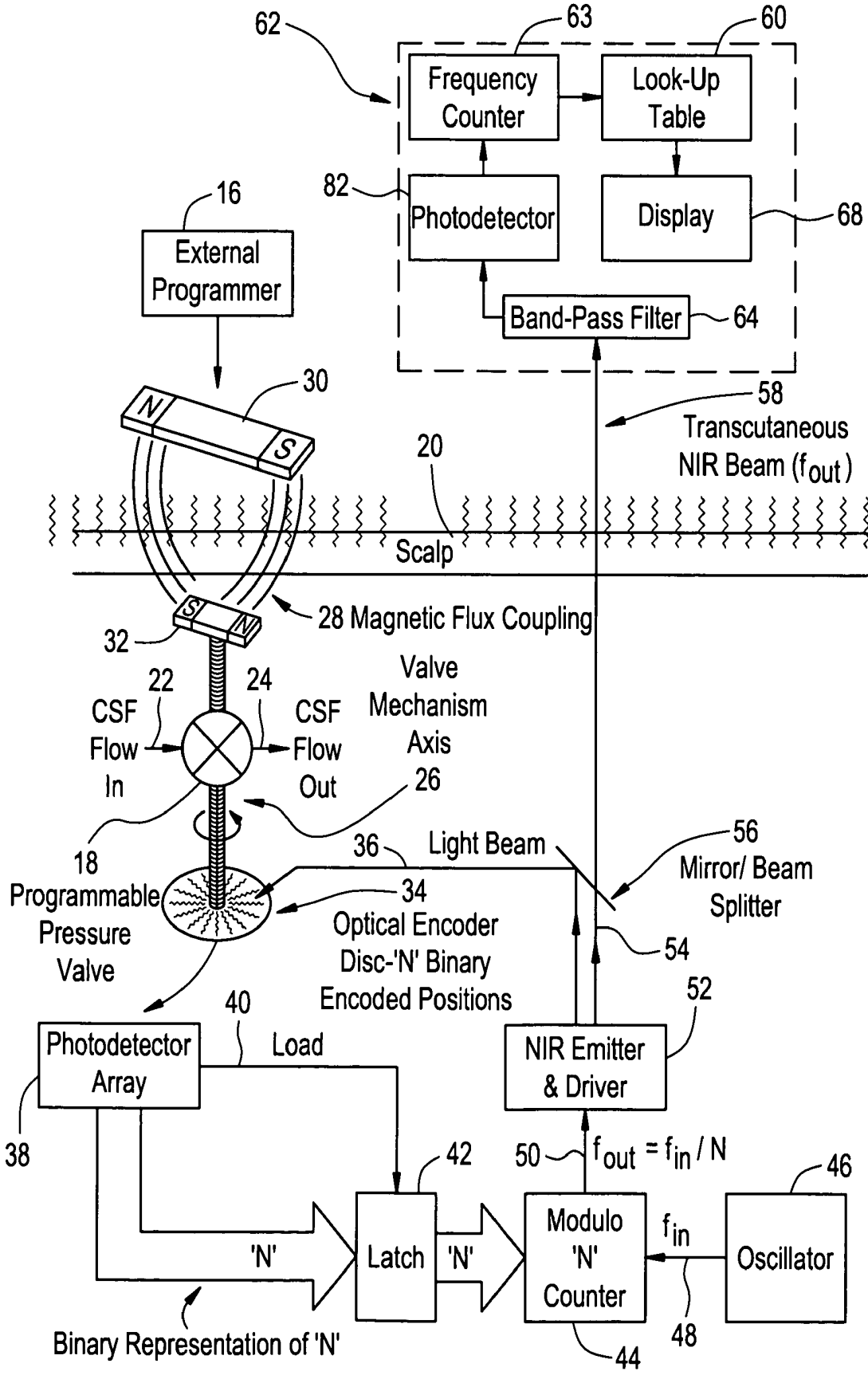


FIG. 2


62
63
60
Frequency Counter
Look-Up Table
82
Photodetector
Display
68
16
External Programmer
Band-Pass Filter
64
30
58
Transcutaneous NIR Beam (f_{out})
20
Scalp
28 Magnetic Flux Coupling
32
Valve Mechanism Axis
22
CSF Flow In
24
CSF Flow Out
26
18
Programmable Pressure Valve
36
Light Beam
56
Mirror/ Beam Splitter
34
Optical Encoder Disc-'N' Binary Encoded Positions
54
52
40
Load
Photodetector Array
NIR Emitter & Driver
38
42
50
$f_{out} = f_{in} / N$
46
'N'
Latch
'N'
Modulo 'N' Counter
f_{in}
Oscillator
48
Binary Representation of 'N'
44

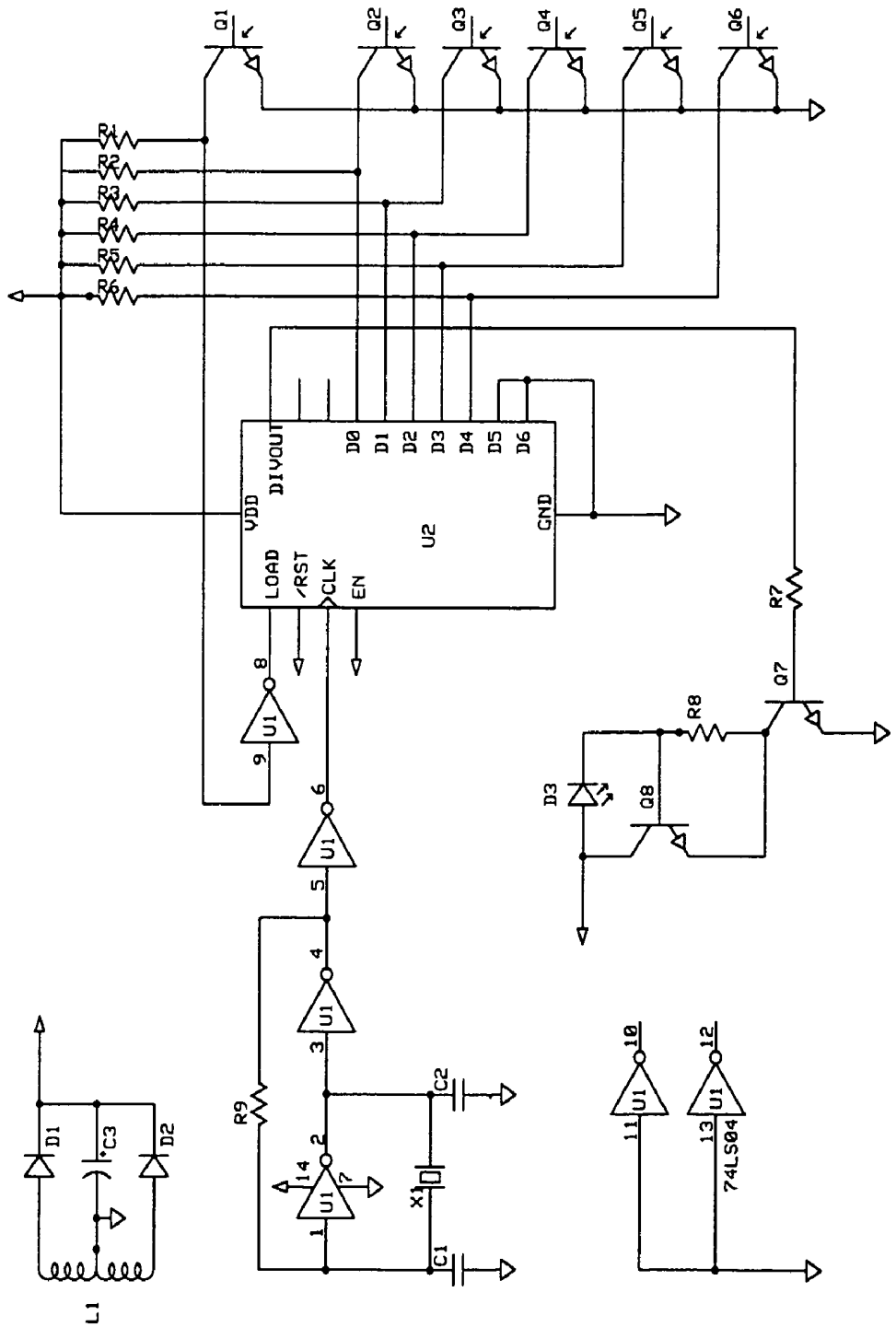
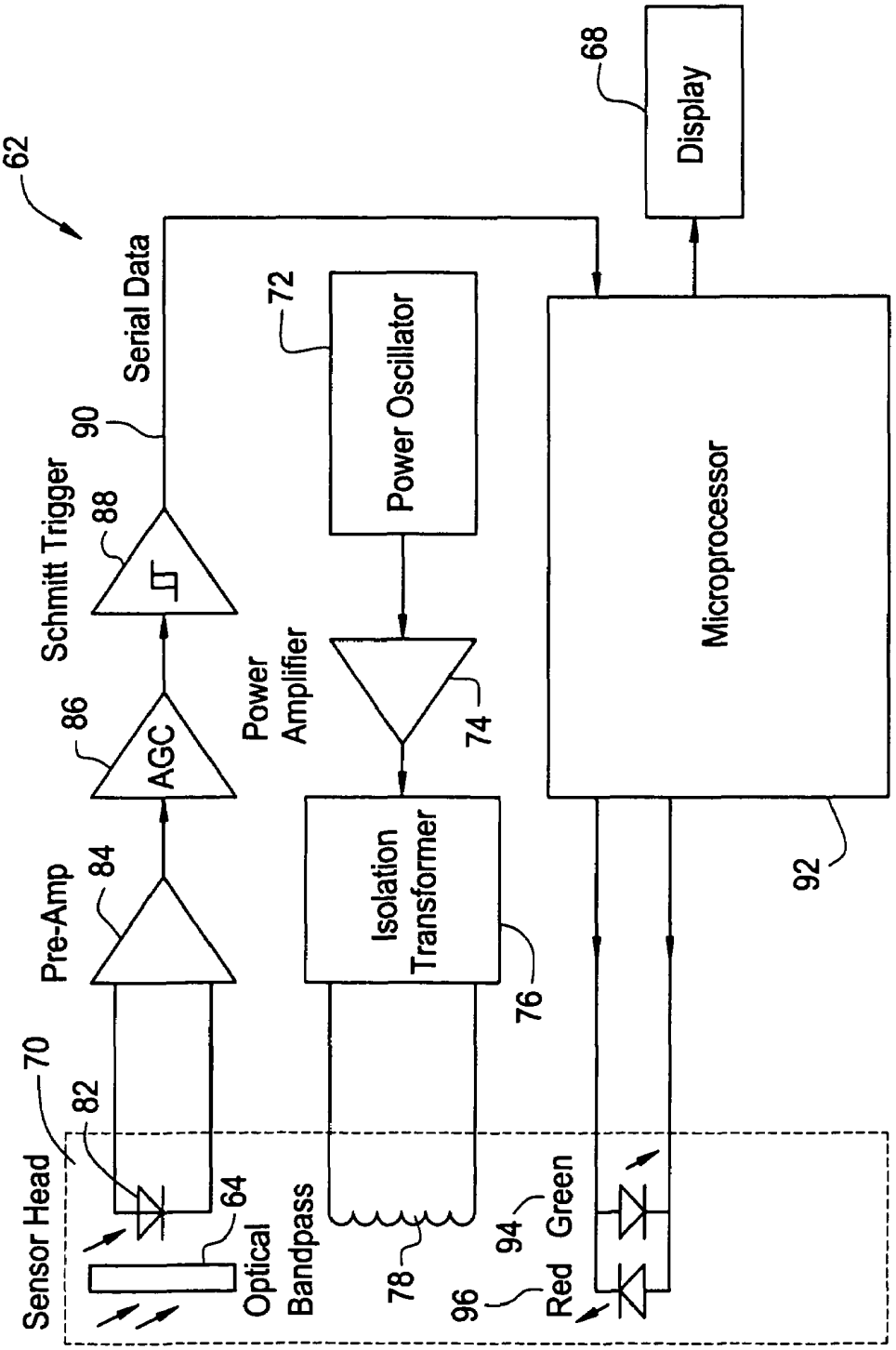

Q1
Q2
Q3
Q4
Q5
Q6
R1
R2
R3
R4
R5
R6
D0
D1
D2
D3
D4
D5
D6
DIVOUT
VDD
GND
LOAD
/RST
CLK
EN
U2
U1
R7
Q7
R8
Q8
D3
R9
C2
C1
X1
D1
C3
D2
L1
74LS04

FIG. 3

FIG. 4


62
68
Display
Serial Data
72
Power Oscillator
90
Schmitt Trigger
88
Power Amplifier
74
Microprocessor
86
AGC
84
Pre-Amp
Isolation Transformer
76
92
70
82
Sensor Head
64
Optical Bandpass
78
94
Green
96
Red

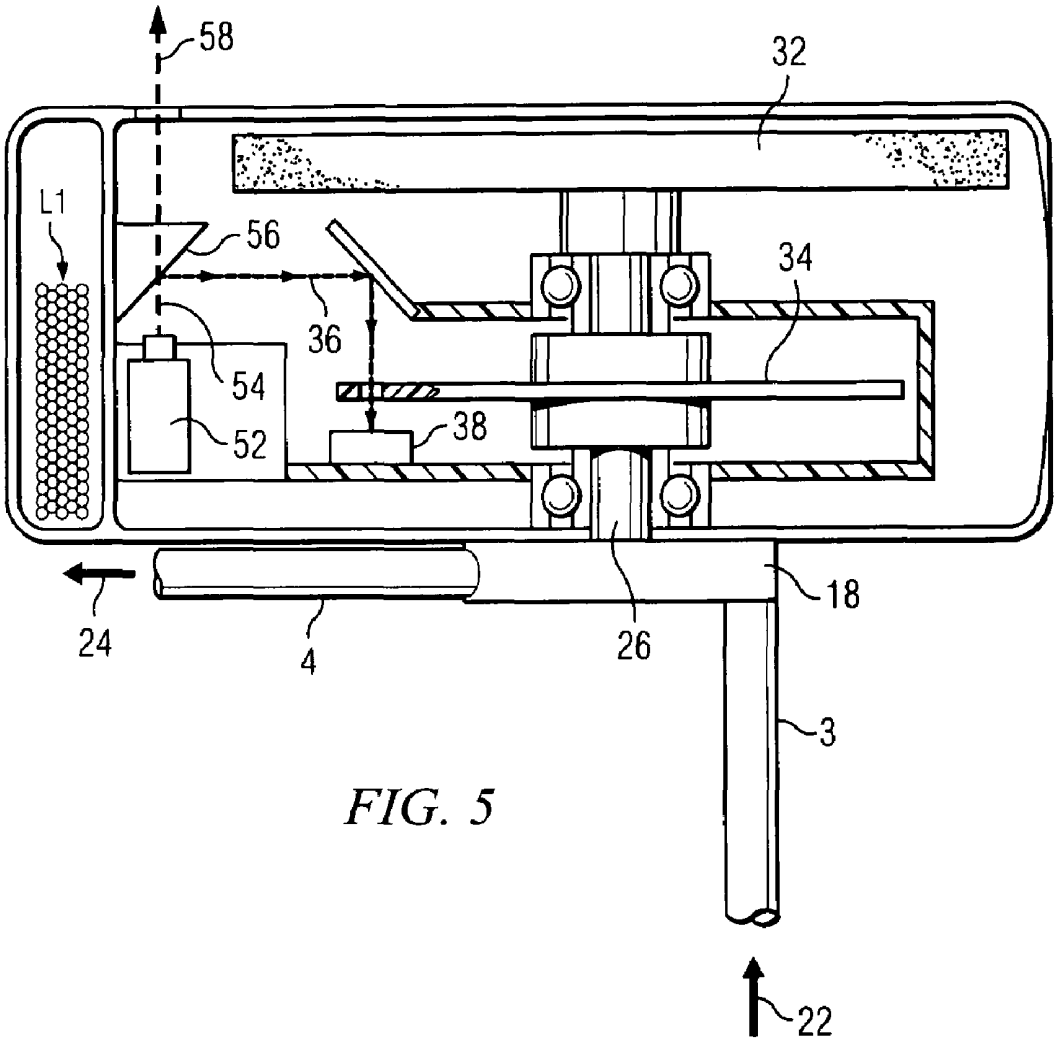


FIG. 5

TRANSCUTANEOUS TELEMETRY OF CEREBROSPINAL FLUID SHUNT PROGRAMMABLE-VALVE PRESSURE USING NEAR-INFRARED (NIR) LIGHT

RELATED APPLICATIONS

This application claims priority from U.S. Provisional Applications 60/547,691 filed Feb. 25, 2004; 60/577,807 filed Jun. 8, 2004; and 60/582,337 filed Jun. 23, 2004.

FIELD OF INVENTION

This invention relates generally to transcutaneous telemetry with an implantable biomedical device, and more specifically relates to a system which allows transcutaneous telemetry of a programmed valve opening pressure via near-infrared (NIR) light.

BACKGROUND OF THE INVENTION

Fluidic shunts are commonly employed for the diversion of cerebrospinal fluid from the cranial intraventricular space to a terminus such as the peritoneal cavity in the treatment of hydrocephalus. The quantity of cerebrospinal fluid (CSF) diverted by the shunt may be altered by adjusting the opening pressure of a normally closed integral valve. Several valve designs (e.g. Codman-Hakim® valve, Medtronic Strata® valve) allow transcutaneous adjustment, or programmability, of the opening pressure via a transcutaneously applied magnetic field.

The programmed valve pressure is dependent upon the position of the external programmer relative to the implanted valve. Because the valve is implanted beneath the skin, the exact orientation of the valve is not always apparent. Malpositioning of the programmer can introduce errors into the programming process and result in erroneous pressures being programmed. Therefore, it is desirable to be able to confirm the actual programmed pressure after reprogramming or as clinical conditions warrant. By "actual" programmed pressure is meant the de facto pressure which has been set for opening of the valve as opposed to the pressure which may be assumed to have been set as a result of the operator's manual adjustment.

While the Medtronic Strata® valve provides a transcutaneous means of magnetically indicating the valve pressure setting, the Codman-Hakim valve requires the use of an x-ray to determine the valve setting. The use of x-ray to determine valve pressure is undesirable as it is costly, time-consuming, and exposes the patient to ionizing radiation.

SUMMARY OF INVENTION

The invention disclosed herein provides an improvement pertinent to existing programmable valve systems which allows transcutaneous telemetry of programmed valve opening pressure via near-infrared (NIR) light. NIR light easily penetrates body tissues such as the scalp, and the light beam may be modulated to encode data for transcutaneous transmission. The actual valve pressure setting is determined by an attached cam. An optical disc coaxially mounted with the cam optically encodes the valve position and these data are transmitted extracorporally via NIR light.

Light in the near-infrared spectrum is easily transmitted through the skin and is detected by an external sensor head and associated electronics. Indefinite longevity and small size is attained in the implant by not incorporating a power source within the module. Instead, power is derived inductively through rectification of a transcutaneously-applied high-frequency alternating electromagnetic field which is generated by a power source within the external coupling module, in concept much like a conventional electrical transformer. The extracorporeal components of the system calculate the actual valve opening pressure setting.

The present invention overcomes the aforementioned disadvantages of existing technologies by providing a means for telemetric conveyance of physiological data via transcutaneous projection of a near infrared light beam. The use of this technique for telemetry of intracranial pressure and other applications is set forth in my co-pending U.S. patent application Ser. No. 11/065,428 filed Feb. 24, 2005. The entire disclosure of that application is hereby incorporated herein by reference.

The NIR spectrum is defined as 750-2500 nm. Choice of the preferred NIR wavelength for transcutaneous telemetry pursuant to the present invention is dependent upon the absorption coefficients of the intervening tissues. The absorption by melanosomes dominates over the visible and near-infrared spectra to about 1100 nm, above which free water begins to dominate. Absorption by the dermis decreased monotonically over the 700-1000 nm range. Whole blood has a minimum absorption at about 700 nm but remains low over the 700-1000 nm range. The nadir in the composite absorption spectrum therefore lies in the 800-1000 nm range.

The actual wavelength utilized is therefore dictated by the optimal spectral range (as above) and the availability of suitable semiconductor emitters. Several suitable wavelengths may include, but are not limited to: 760 nm, 765 nm, 780 nm, 785 nm, 790 nm, 800 nm, 805 nm, 808 nm, 810 nm, 820 nm, 830 nm, 840 nm, 850 nm, 870 nm, 880 nm, 900 nm, 904 nm, 905 nm, 915 nm, 920 nm, 940 nm, 950 nm, 970 nm, and 980 nm. Wavelengths outside this range may be used but will be subject to greater attenuation by the intervening tissues.

BRIEF DESCRIPTION OF DRAWINGS

The invention is diagrammatically illustrated, by way of Example, in the drawings appended hereto, in which:

FIG. **1** is a simplified longitudinal cross sectional diagram illustrating how the sensor may be implanted in a typical use with a patient;

FIG. **2** is a schematic diagram, partially in block form, illustrating an overall system in accordance with the invention;

FIG. **3** is an electrical schematic diagram of the valve pressure transducer and associated components; and

FIG. **4** is a schematic block diagram of the valve position sensor components which are external to the patient.

"FIG. **5** is a non-schematic diagram of the relationship and positioning of the optical encoder and magnetic flux coupling of the invention."

DESCRIPTION OF THE PREFERRED EMBODIMENT

The system of the present invention as shown in the simplified cross-sectional view of FIG. **1** includes an extracorporeal sensor head **70** which provides an interface to a human operator and which telemeters with an implanted component **14**. The latter is integrated into the shunt-valve housing, detects the actual valve setting, and telemeters these data to the extracorporeal sensor head **70**. The implanted component **14** may derive its power via inductive coupling from the extracorporeal sensor head **70**.

In a typical in vivo implementation a hollow ventricular catheter **3** is placed surgically into a cerebrospinal fluid (CSF) filled ventricle **2** of the brain **6** of the patient. The CSF is communicated via the ventricular catheter **3** to the implanted component **14** where its flow is controlled by controllable pressure valve **18** (FIG. **2**). The normally closed valve opening pressure setting is controlled by an attached cam which is mounted on a rotatable axis. An optical disc on that axis acts with other elements to encode the valve position, data for which is transmitted extracorporally through skin **20** via NIR light to sensor head **70**. Depending on valve position, the CSF may exit the implanted sensor **14** and passes, via distal catheter **4**, ultimately to the peritoneal cavity of the abdomen (not shown) or other appropriate point. The implanted sensor **14** is installed superficial to, or embedded within the skull **5**.

FIG. **2** depicts a schematic block diagram of a preferred embodiment of the ICP Valve transducer system. External programmer **16** is an extracorporeal device which is used to set the opening pressure of a programmable pressure valve **18** which is implanted beneath the skin (scalp) **20** of the patient. The opening pressure of normally closed valve **18** dictates the maximum pressure gradient between the cerebrospinal fluid compartment which is connected to inlet **22** to valve **18**, and the outflow for which is via outlet **24**. The valve **18** pressure setting is dependent upon the position of a cam which rotates around the valve's mechanical axis **26**.

The external programmer **16** is able to modify the rotational position of the valve **18** mechanical axis **26** via magnetic flux **28** coupling between an external magnet **30** and a magnet **32** fixedly attached to the mechanical axis **26** of the valve mechanism. The technology referenced by items **16** through **32** is described in the prior art.

In prior art valves exemplified by valve **18**, detents within the valve mechanism define specific rotational angles in which the valve mechanism axis **26** may remain in a static position. In the preferred embodiment of the current invention, an optical encoder disc **34** secured to axis **26** is an optically opaque disc with radially oriented perforations (or optically transparent windows) which encode binary numerals. Each specific static rotational angle which may be assumed by the valve mechanism axis **26** has a corresponding unique encoded binary numeral, n. An NIR light beam **36** transilluminates the optical encoder disc **34** such that the binary encoded numeral, n, may be detected by photodetector array **38**. In the preferred embodiment, these encoded numerals are arranged sequentially around the disc **34** ranging from 1 to 'N' where N is the total number of discrete static positions of the valve mechanism axis **26**. A valid encoded numeral, n, is detected by the photodetector array **38** only during transillumination of the encoder disc **34** by NIR light beam **36**. A "data valid" command is generated by logical OR of each of the bits of the binary encoded numeral, n, or by using a single separate photodetector with an additional optical window at each discrete static position of the valve mechanism axis **26**. The "data valid" signal provides a 'load' command **40** to a latch **42** which stores the encoded binary numeral, n.

The encoded binary numeral, n, is used as the divisor for a modulo-n counter **44**. A crystal oscillator **46** provides a stable reference frequency **48**, f_{in}, which is divided by the divisor ratio, n. Therefore, the output frequency **50**, f_{out}, is uniquely dependent upon the valve mechanism axis **26** position, and hence the pressure to valve **18**. The near infrared emitter **52** is driven at the output frequency **50**. The infrared beam **54** is passed through a beam-splitter mirror **56** such that a portion of the infrared light beam **36** is used to transilluminate the optical encoder disc **34**. The remainder of beam **54** travels through the skin **20** to become the transcutaneous NIR beam **58**. The transcutaneous beam **58** is detected by a photodetector **82** within sensor head and processing electronics **62** after passing through a narrow bandpass filter **64**. The narrow bandpass filter **64** excludes ambient light at wavelengths other than that expected from the NIR emitter **52**. The frequency of the photodetector **82** output is measured at **63** and is used to index a look-up table **60** which correlates the modulation frequency **50** with the actual valve pressure setting which is then displayed at **68**.

FIG. **3** illustrates representative electronic circuitry for the implant. A crystal oscillator composed of crystal X**1**, inverters U**1***a-c*, capacitors C**1**, C**2** and feedback resistor R**9**, provides a reference frequency to programmable divider U**2**. The reference frequency is divided by modulo-N and the output used to gate the VCSEL, D**3**, via transistor Q**7**. Transistor Q**8** and resistor R**8** act to regulate the maximum current through D**3**.

Light from the VCSEL is detected by an array of photodetectors Q**1**-Q**6**. During VCSEL illumination, the disc **34** (FIG. **2**) allows selective illumination of phototransistors Q**2**-Q**6**, thus providing a binary representation of the modulo-N. The light path from the VCSEL to Q**1** is never obstructed, despite the position of disc **34** so that Q**1** conducts each time the VCSEL illuminates. The output of Q**1** is fed to inverter U**1***d* which, in turn, asserts a positive-going 'load' signal to U**2** as the VCSEL illuminates. Upon assertion of the 'load' signal, the divider modulo-N data is latched on U**2** inputs D**0**-D**4**. A small capacitance, on the order of several picofarads, may be placed on the base of transistor Q**1** to allow Q**2**-Q**6** to stabilize prior to asserting the 'load' signal. A period of 2^N clock pulses may be necessary for the output frequency to stabilize.

FIG. **4** depicts a block diagram of the external circuitry which: 1) provides power to the implant; 2) detects the NIR emission from the implant; and, 3) converts the frequency data from the implant to a graphical representation of valve position.

Sensor head **70** is placed over the implant to deliver power and detect the optical output of the implant. A power oscillator **72** delivers a sinusoidal oscillating current with a nominal frequency of 200 kHz to a power amplifier **74** which buffers the current to an isolation transformer **76**. The isolation transformer **76** provides adequate galvanic isolation for a patient-connected device. The output from the isolation transformer is fed to the sensor head coil **78** which acts as the primary winding of a transformer to electromagnetically couple energy to the implant's secondary coil L**1** (FIG. **3**).

An optical bandpass filter **64** with center frequency equal to the emission frequency of the VCSEL, excludes ambient light from the photodetector **82**. Light from the implant VCSEL is transmitted through bandpass filter **64** and converted to an electrical current by photodetector **82**. This current is roughly a square wave with the same fundamental frequency as the VCSEL pulses. This signal is amplified by pre-amp **84** and automatic gain amplifier **86**, then converted to a digital signal by Schmitt trigger **88**. A serial data stream **90**, consisting of square-wave pulses, is fed to microprocessor **92** which measures the frequency of the aforementioned pulses. The frequency data is then used to index a look-up table **60** (FIG. **2**) through software programming; the result of which is a numerical indication of the valve pressure setting. The result is displayed for the user upon a digital or other graphical display **68**.

A bi-colored Light Emitting Diode, or LED, is also included in the sensor head **70** to aid positioning of the sensor head over the implant. In the default state, the red LED **96** is illuminated to indicate that the sensor head is not over the

implant. When the sensor head is properly aligned over the implant, the implant begins to receive power through the inductive coupling between coil **78** of the sensor head and L**1** of the implant. Once power is applied to the implant, the VCSEL begins to illuminate in synchrony with the programmable divider (U**2**) output. When the External device begins to detect the VCSEL, e.g. oscillations present on the 'serial data' output of Schmitt Trigger **88**, the microprocessor **92** turns off the red LED **96** and illuminates the green LED **94**.

While the present invention has been described in terms of specific embodiments thereof, it will be understood in view of the present disclosure, that numerous variations upon the invention are now enabled to those skilled in the art, which variations yet reside within the scope of the present teaching. Accordingly, the invention is to be broadly construed, and limited only by the scope and spirit of the claims now appended hereto.

The invention claimed is:

1. A system for regulating an internal programmable valve implanted in a medical patient comprising:

a subcutaneous case;

a valve in the case with access to an internal fluid;

a subcutaneous magnet connected to the valve;

a transcutaneous magnet;

a magnetic flux coupling between the subcutaneous magnet and the transcutaneous magnet;

an encoder disk within the case connected to the valve;

a near infrared optical source producing a near infrared source signal;

the near infrared source signal incident on the encoder disk;

an optical receiver in communication with the near infrared source signal and generating an angular position signal related to the angular position of the encoder disk;

a conversion circuit transforming the angular position signal into an encoded near infrared optical signal;

the conversion circuit comprising a reference signal generated by a frequency generator, and a frequency divider in communication with the reference signal and the angular position signal;

the near infrared optical source connected to the frequency divider and producing a transmitted near infrared optical signal;

the near infrared optical source further comprising a beam splitter in the path of the transmitted near infrared optical signal, the beam splitter being adapted to partition the transmitted near infrared optical signal into the near infrared optical source signal and a transcutaneous near infrared data signal; and

an inductive power coupling providing power to the near infrared optical source, the optical receiver and the conversion circuit.

2. The system of claim **1** wherein the encoder disk further comprises:

an optically opaque disk having an encoder pattern;

and wherein the near infrared optical source signal passes through the encoder pattern; and

wherein the optical receiver includes a first reference array adjacent the optically opaque disk adapted to receive the transmitted near infrared source signal through the encoder pattern.

3. The system of claim **1** wherein the encoder pattern contains a binary code.

4. The system of claim **1** wherein the encoder pattern is a set of transparent sections in the encoder disk.

5. The system of claim **1** wherein the encoder pattern is a set of radially oriented perforations.

6. The system of claim **1** wherein the first reference array generates a numerical signal.

7. The system of claim **1** wherein a logical OR operation is used on the numerical signal to generate a data valid signal.

8. The system of claim **1** wherein the encoder disk further comprises:

a reference pattern indicative of a valve position and wherein the near infrared optical source signal passes through the reference pattern; and

a second reference array, adjacent the reference pattern, adapted to receive the near infrared optical source signal through the reference pattern and generate a signal indicative of an angular position of the encoder disk.

9. The system of claim **8** wherein the second reference array generates a data valid signal for storing an encoded number indicative of the angular position of the encoder disk.

10. The system of claim **9** wherein the data valid signal is a binary number.

11. The system of claim **8** wherein the number of angular positions is a range between 0 and 255.

12. The system of claim **1** wherein the internal fluid is cerebral spinal fluid.

13. The system of claim **1** wherein the encoded near infrared optical signal is in a wavelength range of about 800 nm to about 1000 nm.

14. The system of claim **1** wherein the encoded near infrared optical signal is in the range of about 760 nm to about 980 nm.

* * * * *

专利名称(译)	使用近红外（NIR）光进行脑脊液经皮遥测分流可编程阀压力		
公开(公告)号	US7485105	公开(公告)日	2009-02-03
申请号	US11/067497	申请日	2005-02-25
[标]申请(专利权)人(译)	WOLF ERICHW		
申请(专利权)人(译)	WOLF ERICH W.		
当前申请(专利权)人(译)	WOLF ERICHW		
[标]发明人	WOLF ERICH W		
发明人	WOLF, ERICH W.		
IPC分类号	A61M5/00 A61M37/00 F16K31/02 A61B5/00 A61B5/03		
CPC分类号	A61B5/0017 A61B5/0031 A61B5/0086 A61B5/031 A61M27/006		
优先权	60/582337 2004-06-23 US 60/577807 2004-06-08 US 60/547691 2004-02-25 US		
其他公开文献	US20050187509A1		
外部链接	Espacenet USPTO		

摘要(译)

这种类型的可编程瓣膜系统的改进，其植入医疗患者体内并用于将脑脊液（CSF）从患者的心室内空间转移到诸如患者腹膜腔的末端。这种系统包括用于建立CSF到末端的流动路径的装置，该流动路径包括常闭阀和用于调节阀的开启压力以调节转向的CSF量的装置。该改进使操作员能够了解阀的实际开启压力设定。通过产生指示实际设置的NIR遥测信号，传感器可植入患者并响应实际开启压力设置。该信号经皮肤透过患者的皮肤传递到外部点。处理遥测信号以产生观察者可理解的数据，该数据指示阀的开启压力设定。