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(54) **GASTRIC RESTRICTION DEVICE DATA HANDLING DEVICES AND METHODS**

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(56) **References Cited**

U.S. PATENT DOCUMENTS

RE3,036	E	7/1868	Shunk
RE3,037	E	7/1868	Tucker
RE3,115	E	9/1868	Lewis
RE3,187	E	11/1868	Winchester
RE3,322	E	3/1869	Murch
236,373	A	1/1881	Spilman
322,388	A	7/1885	Lord
400,401	A	3/1889	Gutzkow
D23,637	S	9/1894	Casad et al.
D24,900	S	11/1895	Clemecet
D25,318	S	3/1896	Perky
D27,151	S	6/1897	Moulten
D29,715	S	11/1898	Wheeler
D29,745	S	11/1898	Bunker

(Continued)

FOREIGN PATENT DOCUMENTS

CA	1059035	7/1979
CA	1119469	3/1982

(Continued)

OTHER PUBLICATIONS

"Application Specific Integrated Circuits (ASICs)", Honeywell product information from website http://www.honeywell.com/sites/portal?smap=aerospace&page=Radiation-Hardened-Electronics3&theme=T18&catID=CE06BEF88-65F8-6A1E-4ED1-6A1EC1B7AE7A&id=HA0E380D3-C27B-9EBF-AAC8-9FAF8851256D&sel=1&sel4=1; 1 page.

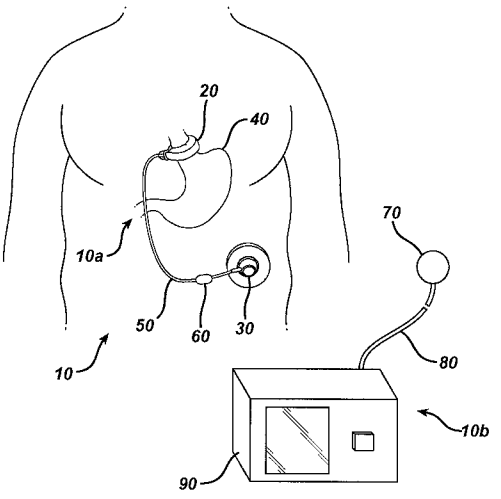
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(57) **ABSTRACT**

Methods and devices are provided for handling data in an implantable restriction system. In general, the methods and devices allow collection, analysis, storage, and transmission of pressure measurements. Pressure measurement data can be compressed before storing it. Additionally, not all pressure data need be recorded or retained, such as data substantially equaling a resting or nominal pressure of an implantable restriction device indicative of little to no pressure variation and data indicative of isolated, non-recurring events. Any pressure measurement data that is recorded can be transmitted to an external device using power telemetrically provided by the external device.

20 Claims, 15 Drawing Sheets



(56) **References Cited**

U.S. PATENT DOCUMENTS

D29,885	S	12/1898	Hughel et al.
D30,690	S	5/1899	Schwedtmann
D30,966	S	6/1899	Howe
D31,230	S	7/1899	Hogan
689,758	A	12/1901	Shaw
724,913	A	4/1903	Montgomery
899,477	A	9/1908	Williams
926,197	A	6/1909	Kim
953,875	A	4/1910	Waring
991,192	A	5/1911	Batttenfeld
1,087,988	A	2/1914	Sheldon
1,210,701	A	1/1917	Ryden
1,219,296	A	3/1917	Hahn
1,224,355	A	5/1917	Brown
1,263,914	A	4/1918	Martin
1,310,290	A	7/1919	Piechowicz
1,384,873	A	7/1921	Strickland
1,421,507	A	7/1922	Lindberg
1,551,525	A	8/1925	Hamer
1,560,973	A	11/1925	Cheron
1,620,633	A	3/1927	Colvin
1,623,403	A	4/1927	Friel
1,689,085	A	10/1928	Russell et al.
1,764,071	A	6/1930	Foulke
1,782,704	A	11/1930	Woodruff
1,807,107	A	5/1931	Sternberch
1,865,446	A	7/1932	Sears
1,882,338	A	10/1932	Reed et al.
1,924,781	A	8/1933	Gaiser
2,027,875	A	1/1936	Odend'hal
2,063,430	A	12/1936	Graser
2,099,160	A	11/1937	Charch
2,105,127	A	1/1938	Petrone
2,106,192	A	1/1938	Saville
2,143,429	A	1/1939	Auble
2,166,603	A	7/1939	Menzer
2,168,427	A	8/1939	McConkey
2,174,525	A	10/1939	Padernal
2,177,564	A	10/1939	Havill
2,178,463	A	10/1939	Bahnson
2,180,599	A	11/1939	Menasco
2,203,460	A	6/1940	Fieber
2,206,038	A	7/1940	Ford
2,216,374	A	10/1940	Martin
2,223,699	A	12/1940	Norgren
2,225,145	A	12/1940	Baumbach
2,225,880	A	12/1940	Montelius
2,261,060	A	10/1941	Giesler
2,261,355	A	11/1941	Flynn
2,295,539	A	9/1942	Beach
2,303,108	A	11/1942	Blackburn
2,303,502	A	12/1942	Rous
2,318,819	A	5/1943	Verson
2,327,407	A	8/1943	Edyvean
2,327,615	A	8/1943	Ankarlo
2,354,571	A	7/1944	Blain
2,426,392	A	8/1947	Fennema
2,426,817	A	9/1947	Charlton et al.
2,440,260	A	4/1948	Gall
2,442,573	A	6/1948	Stafford
2,453,217	A	11/1948	Gregg et al.
2,455,859	A	12/1948	Foley
2,477,922	A	8/1949	Emery et al.
2,478,876	A	8/1949	Nelson
2,482,392	A	9/1949	Whitaker
2,494,881	A	1/1950	Kost
2,509,210	A	5/1950	Clark
2,509,673	A	5/1950	Church
2,511,765	A	6/1950	Bradbury
2,520,056	A	8/1950	Pozun
2,521,976	A	9/1950	Hays
2,533,924	A	12/1950	Foley
2,538,259	A	1/1951	Merriman
2,581,479	A	1/1952	Grashman
2,600,324	A	6/1952	Rappaport
2,606,003	A	8/1952	McNeill
2,615,940	A	10/1952	Williams
2,632,447	A	3/1953	Dobes
2,639,342	A	5/1953	Cope
2,640,119	A	5/1953	Bradford, Jr.
2,641,742	A	6/1953	Wolfe
2,651,304	A	9/1953	Browner
2,665,577	A	1/1954	Sanowskis
2,673,999	A	4/1954	Shey
2,676,609	A	4/1954	Pfarrer
2,684,118	A	7/1954	Osmun
2,689,611	A	9/1954	Martinson
2,697,435	A	12/1954	Ray
2,723,323	A	11/1955	Niemi
2,734,992	A	2/1956	Elliot et al.
2,740,007	A	3/1956	Amelang
2,740,853	A	4/1956	Hatman, Jr.
2,742,323	A	4/1956	Shey
2,747,332	A	5/1956	Morehouse
2,753,876	A	7/1956	Kurt
2,756,883	A	7/1956	Schreck
2,756,983	A	7/1956	Furcini
2,761,603	A	9/1956	Fairchild
2,773,312	A	12/1956	Peck
2,783,728	A	3/1957	Hoffmann
2,787,875	A	4/1957	Johnson
2,793,379	A	5/1957	Moore
2,795,460	A	6/1957	Bletcher
2,804,514	A	8/1957	Peters
2,822,113	A	2/1958	Joiner, Jr.
2,831,478	A	4/1958	Uddenberg et al.
2,864,393	A	12/1958	Drake
2,865,541	A	12/1958	Hicks
2,870,024	A	1/1959	Martin
2,883,995	A	4/1959	Bialous et al.
2,886,355	A	5/1959	Wurzel
2,895,215	A	7/1959	Neher et al.
2,899,493	A	8/1959	Levine
2,902,861	A	9/1959	Frost et al.
2,923,531	A	2/1960	Bauer et al.
2,924,263	A	2/1960	Landis
2,924,432	A	2/1960	Arps et al.
2,930,170	A	3/1960	Holsman et al.
2,938,592	A	5/1960	Charske et al.
2,941,338	A	6/1960	Santschi
2,943,682	A	7/1960	Ingram, Jr. et al.
2,958,781	A	11/1960	Marchal et al.
2,961,479	A	11/1960	Bertling
2,976,355	A	3/1961	Levine
2,976,686	A	3/1961	Stelzer
2,977,876	A	4/1961	Meyers
2,986,715	A	5/1961	Church et al.
2,989,019	A	6/1961	Van Sciver, II
3,010,692	A	11/1961	Jentoft
3,013,234	A	12/1961	Bourns
3,018,791	A	1/1962	Knox
3,034,356	A	5/1962	Bieganski
3,040,800	A	6/1962	Hartley
3,054,618	A	9/1962	Abrams et al.
3,060,262	A	10/1962	Hoer
3,070,373	A	12/1962	Mathews et al.
3,082,414	A	3/1963	Papaminas
3,085,577	A	4/1963	Berman et al.
3,096,410	A	7/1963	Anderson
3,099,262	A	7/1963	Bigliano
3,125,028	A	3/1964	Rohde
3,126,029	A	3/1964	Englesson
3,129,072	A	4/1964	Cook et al.
3,135,914	A	6/1964	Callan et al.
3,144,017	A	8/1964	Muth
3,151,258	A	9/1964	Sonderegger et al.
3,153,460	A	10/1964	Raskin
3,161,051	A	12/1964	Perry, Jr.
3,167,044	A	1/1965	Henrickson
3,171,549	A	3/1965	Orloff
3,172,700	A	3/1965	Haas
3,173,269	A	3/1965	Imbertson
3,182,494	A	5/1965	Beatty et al.
3,187,181	A	6/1965	Keller

(56) **References Cited**

U.S. PATENT DOCUMENTS

3,187,745 A 6/1965 Baum et al.
3,190,388 A 6/1965 Moser et al.
3,205,547 A 9/1965 Riekse
3,208,255 A 9/1965 Burk
3,209,570 A 10/1965 Hills
3,221,468 A 12/1965 Casey
3,228,703 A 1/1966 Wilson
3,229,684 A 1/1966 Nagumo et al.
3,236,088 A 2/1966 Moller
3,238,624 A 3/1966 McCabe
3,240,510 A 3/1966 Spouge
3,245,642 A 4/1966 Dicke
3,255,568 A 6/1966 Martin et al.
3,260,091 A 7/1966 Shaw, Jr.
3,265,822 A 8/1966 Moulten
3,266,487 A 8/1966 Watkins et al.
3,273,447 A 9/1966 Frank
3,283,352 A 11/1966 Hu
3,290,919 A 12/1966 Malinak et al.
3,292,493 A 12/1966 Franklin
3,292,888 A 12/1966 Fischer
3,294,988 A 12/1966 Packard
3,299,603 A 1/1967 Shaw
3,299,882 A 1/1967 Masino
3,301,514 A 1/1967 Sugaya
3,302,457 A 2/1967 Mayes
3,306,384 A 2/1967 Ross
3,313,314 A 4/1967 Burke et al.
3,316,935 A 5/1967 Kaiser et al.
3,320,750 A 5/1967 Haise et al.
3,321,035 A 5/1967 Tarpley
3,332,788 A 7/1967 Barnby
3,334,510 A 8/1967 Hallesy
3,339,401 A 9/1967 Peters
3,340,868 A 9/1967 Darling
3,347,162 A 10/1967 Braznell
3,350,944 A 11/1967 De Michele
3,353,364 A 11/1967 Blanding et al.
3,353,481 A 11/1967 Antonucci
3,356,334 A 12/1967 Scaramucci
3,356,510 A 12/1967 Barnby
3,357,218 A 12/1967 Mitchell
3,357,461 A 12/1967 Friendship
3,359,741 A 12/1967 Nelson
3,361,300 A 1/1968 Kaplan
3,364,929 A 1/1968 Ide et al.
3,365,684 A 1/1968 Stemke
3,378,456 A 4/1968 Roberts
3,380,445 A 4/1968 Frasier
3,380,649 A 4/1968 Roberts
3,385,022 A 5/1968 Anderson
3,389,355 A 6/1968 Schroeder, Jr.
3,393,612 A 7/1968 Gorgens et al.
3,396,561 A 8/1968 Day
3,399,667 A 9/1968 Nishimoto et al.
3,400,734 A 9/1968 Rosenberg
3,403,237 A 9/1968 Wysong
3,409,924 A 11/1968 Slama
3,411,347 A 11/1968 Wirth et al.
3,417,476 A 12/1968 Martens
3,420,325 A 1/1969 McAlister et al.
3,422,324 A 1/1969 Webb
3,426,165 A 2/1969 Beaman
3,438,391 A 4/1969 Yocum
3,443,608 A 5/1969 Copping et al.
3,445,335 A 5/1969 Gluntz
3,447,281 A 6/1969 Bufford et al.
3,450,153 A 6/1969 Hildebrandt et al.
3,453,546 A 7/1969 Fryer
3,453,848 A 7/1969 Williamson
3,456,134 A 7/1969 Ko
3,457,909 A 7/1969 Laird
3,460,557 A 8/1969 Gallant
3,463,338 A 8/1969 Schneider
3,469,818 A 9/1969 Cowan
3,470,725 A 10/1969 Brown et al.
3,472,230 A 10/1969 Fogarty
3,478,344 A 11/1969 Schwitzgebel et al.
3,482,449 A 12/1969 Werner
3,482,816 A 12/1969 Arnold
3,487,959 A 1/1970 Pearne et al.
3,491,842 A 1/1970 Delacour et al.
3,492,638 A 1/1970 Lane
3,502,829 A 3/1970 Reynolds
3,503,116 A 3/1970 Strack
3,504,664 A 4/1970 Haddad
3,505,808 A 4/1970 Eschle
3,509,754 A 5/1970 Massingill, et al.
3,512,517 A 5/1970 Kadish et al.
3,514,919 A 6/1970 Ashton et al.
3,516,220 A 6/1970 Buford et al.
3,517,553 A 6/1970 Williams et al.
3,527,226 A 9/1970 Hakin et al.
3,529,908 A 9/1970 Smith
3,530,449 A 9/1970 Anderson
3,533,403 A 10/1970 Woodson
3,534,728 A 10/1970 Barrows
3,534,872 A 10/1970 Roth et al.
3,535,914 A 10/1970 Veith et al.
3,539,009 A 11/1970 Kudlaty
3,543,744 A 12/1970 LePar
3,545,275 A 12/1970 Harrison et al.
3,550,583 A 12/1970 Chiku
3,550,847 A 12/1970 Scott
3,563,094 A 2/1971 Rieschel
3,563,245 A 2/1971 McLean et al.
3,566,083 A 2/1971 McMillin
3,566,875 A 3/1971 Stoehr
3,568,367 A 3/1971 Myers
3,568,636 A 3/1971 Lockwood
3,576,554 A 4/1971 Temps, Jr. et al.
3,580,082 A 5/1971 Strack
3,581,402 A 6/1971 London et al.
3,583,387 A 6/1971 Garner et al.
3,587,204 A 6/1971 George
3,590,809 A 7/1971 London
3,590,818 A 7/1971 Lemole
3,590,992 A 7/1971 Soderstrom
3,592,183 A 7/1971 Watkins et al.
3,594,519 A 7/1971 Schmidlin
3,602,885 A 8/1971 Grajeda
3,610,016 A 10/1971 Bultman
3,610,851 A 10/1971 Krupski
3,611,811 A 10/1971 Lissau
3,614,926 A 10/1971 Brechtel
3,614,955 A 10/1971 Mirowski et al.
3,619,742 A 11/1971 Rud, Jr.
3,623,371 A 11/1971 Jullien-Davin
3,624,854 A 12/1971 Strong
3,630,242 A 12/1971 Schieser et al.
3,631,847 A 1/1972 Hobbs, II
3,633,881 A 1/1972 Yurdin
3,635,061 A 1/1972 Rydell et al.
3,635,074 A 1/1972 Moos et al.
3,638,496 A 2/1972 King
3,644,883 A 2/1972 Borman et al.
3,648,687 A 3/1972 Ramsey, III
3,651,289 A 3/1972 Nagashima
3,651,405 A 3/1972 Whitney et al.
3,653,671 A 4/1972 Shipes
3,659,615 A 5/1972 Enger
3,677,685 A 7/1972 Aoki
3,686,958 A 8/1972 Porter et al.
3,688,568 A 9/1972 Karper et al.
3,701,392 A 10/1972 Wirth et al.
3,702,677 A 11/1972 Heffington
3,703,099 A 11/1972 Rouse et al.
3,712,138 A 1/1973 Alinari et al.
3,713,124 A 1/1973 Durland et al.
3,719,524 A 3/1973 Ripley et al.
3,721,412 A 3/1973 Kindorf
3,723,247 A 3/1973 Leine et al.
3,724,000 A 4/1973 Eakman
3,727,463 A 4/1973 Intraub

(56) **References Cited**

U.S. PATENT DOCUMENTS

3,727,616 A 4/1973 Lenzkes
3,730,174 A 5/1973 Madison
3,730,560 A 5/1973 Abildgaard et al.
3,731,679 A 5/1973 Wilhelmson et al.
3,731,681 A 5/1973 Blackshear et al.
3,732,731 A 5/1973 Fussell, Jr.
3,735,040 A 5/1973 Punt et al.
3,736,930 A 6/1973 Georgi
3,738,356 A 6/1973 Workman
3,740,921 A 6/1973 Meyer et al.
3,746,111 A 7/1973 Berthiaume et al.
3,748,678 A 7/1973 Ballou
3,749,098 A 7/1973 De Bennetot et al.
3,749,422 A 7/1973 Abildgaard et al.
3,749,423 A 7/1973 Abildgaard et al.
3,750,194 A 8/1973 Summers
3,757,770 A 9/1973 Brayshaw et al.
3,759,095 A 9/1973 Short, Jr. et al.
3,760,638 A 9/1973 Lawson et al.
3,763,960 A 10/1973 John et al.
3,765,142 A 10/1973 Lindquist et al.
3,765,494 A 10/1973 Kielman, Jr.
3,769,156 A 10/1973 Brecy et al.
3,769,830 A 11/1973 Porter et al.
3,774,243 A 11/1973 Ng et al.
3,776,333 A 12/1973 Mathauser
3,778,051 A 12/1973 Allen et al.
3,780,578 A 12/1973 Sellman et al.
3,781,902 A 12/1973 Shim et al.
3,783,585 A 1/1974 Hoyland et al.
3,789,667 A 2/1974 Porter et al.
3,796,095 A 3/1974 Fussell, Jr.
3,807,219 A 4/1974 Wallskog
3,811,429 A 5/1974 Fletcher et al.
3,815,722 A 6/1974 Sessoms
3,818,765 A 6/1974 Eriksen et al.
3,820,400 A 6/1974 Russo
3,820,795 A 6/1974 Taylor
3,823,610 A 7/1974 Fussell, Jr.
3,825,065 A 7/1974 Lloyd et al.
3,825,963 A 7/1974 Abildgaard et al.
3,825,964 A 7/1974 Groswith, III et al.
3,828,672 A 8/1974 Gazzola et al.
3,828,766 A 8/1974 Krasnow
3,831,588 A 8/1974 Rindner
3,831,942 A 8/1974 Del Mar
3,833,238 A 9/1974 Liard et al.
3,834,167 A 9/1974 Tabor
3,834,739 A 9/1974 Abildgaard et al.
3,835,523 A 9/1974 Stansfield et al.
3,839,708 A 10/1974 Bredesen et al.
3,842,483 A 10/1974 Cramer
3,842,668 A 10/1974 Lippke et al.
3,845,664 A 11/1974 Perry, Jr.
3,845,751 A 11/1974 Runstetler
3,845,757 A 11/1974 Weyer
3,847,434 A 11/1974 Weman et al.
3,850,208 A 11/1974 Hamilton
3,853,117 A 12/1974 Murr
3,854,469 A 12/1974 Giori et al.
3,855,902 A 12/1974 Kirst et al.
3,857,399 A 12/1974 Zacouto et al.
3,857,452 A 12/1974 Hartman
3,857,745 A 12/1974 Grausch et al.
3,858,581 A 1/1975 Kamen
3,863,622 A 2/1975 Buuck
3,863,933 A 2/1975 Tredway
3,867,950 A 2/1975 Fischell
3,868,008 A 2/1975 Brumbaugh
3,868,679 A 2/1975 Arneson
3,871,599 A 3/1975 Takada et al.
3,872,285 A 3/1975 Shum et al.
3,874,388 A 4/1975 King et al.
3,876,980 A 4/1975 Haemmig et al.
3,878,908 A 4/1975 Andersson et al.
3,881,528 A 5/1975 Mackenzie
3,893,111 A 7/1975 Cotter
3,893,451 A 7/1975 Durand et al.
3,895,681 A 7/1975 Griffin et al.
3,899,862 A 8/1975 Muys et al.
3,904,234 A 9/1975 Hill et al.
3,908,334 A 9/1975 Rychiger
3,908,461 A 9/1975 Turpen
3,908,721 A 9/1975 McGahey et al.
3,910,087 A 10/1975 Jones
3,912,168 A 10/1975 Mullins et al.
3,912,304 A 10/1975 Abildgaard et al.
3,918,286 A 11/1975 Whitehead
3,918,291 A 11/1975 Pauly et al.
3,920,965 A 11/1975 Sohrwardy et al.
3,921,682 A 11/1975 McGahey et al.
3,922,951 A 12/1975 Linsinger
3,923,060 A 12/1975 Ellinwood, Jr.
3,924,635 A 12/1975 Hakim
3,928,980 A 12/1975 Ganzinotti
3,929,175 A 12/1975 Coone
3,930,682 A 1/1976 Booth
3,930,852 A 1/1976 Tanaka et al.
3,936,028 A 2/1976 Norton et al.
3,940,122 A 2/1976 Janzen et al.
3,940,630 A 2/1976 Bergonz
3,942,299 A 3/1976 Bory et al.
3,942,382 A 3/1976 Hok et al.
3,942,516 A 3/1976 Glynn et al.
3,942,536 A 3/1976 Mirowski et al.
3,943,915 A 3/1976 Severson
3,945,704 A 3/1976 Kraus et al.
3,946,613 A 3/1976 Silver
3,946,615 A 3/1976 Hluchan
3,946,724 A 3/1976 La Balme et al.
3,948,141 A 4/1976 Shinjo et al.
3,949,388 A 4/1976 Fuller
3,953,289 A 4/1976 Costes
3,954,271 A 5/1976 Tredway, Sr.
3,958,558 A 5/1976 Dunphy et al.
3,961,425 A 6/1976 Swanson et al.
3,961,646 A 6/1976 Schon et al.
3,962,895 A 6/1976 Rydell et al.
3,962,921 A 6/1976 Lips
3,963,019 A 6/1976 Quandt
3,964,485 A 6/1976 Neumeier
3,964,770 A 6/1976 Abildgaard et al.
3,967,737 A 7/1976 Peralta et al.
3,968,473 A 7/1976 Patton et al.
3,968,694 A 7/1976 Clark
3,972,320 A 8/1976 Kalman
3,973,753 A 8/1976 Wheeler
3,973,858 A 8/1976 Poisson et al.
3,974,655 A 8/1976 Halpern et al.
3,974,865 A 8/1976 Fenton et al.
3,977,391 A 8/1976 Fleischmann
3,980,871 A 9/1976 Lindstrom et al.
3,982,571 A 9/1976 Fenton et al.
3,983,948 A 10/1976 Jeter
3,985,133 A 10/1976 Jenkins et al.
3,987,860 A 10/1976 Jabsen
3,989,005 A 11/1976 Bowler, Jr. et al.
3,991,749 A 11/1976 Zent
3,992,948 A 11/1976 D'Antonio et al.
3,993,149 A 11/1976 Harvey
3,996,927 A 12/1976 Frank
3,996,962 A 12/1976 Sutherland
4,003,141 A 1/1977 Le Roy
4,005,282 A 1/1977 Jennings
4,005,593 A 2/1977 Goldberg
4,006,735 A 2/1977 Hittman et al.
4,009,375 A 2/1977 White et al.
4,009,591 A 3/1977 Hester
4,010,449 A 3/1977 Faggin et al.
4,014,319 A 3/1977 Favre et al.
4,014,321 A 3/1977 March
4,016,764 A 4/1977 Rice
4,017,329 A 4/1977 Larson
4,018,134 A 4/1977 Linsinger et al.

(56) **References Cited**

U.S. PATENT DOCUMENTS

4,022,190 A 5/1977 Meyer
4,024,864 A 5/1977 Davies et al.
4,025,912 A 5/1977 Rice
4,026,276 A 5/1977 Chubbuck
4,027,661 A 6/1977 Lyon et al.
4,031,899 A 6/1977 Renirie et al.
4,036,775 A 7/1977 Trautvetter et al.
4,039,069 A 8/1977 Kwan et al.
4,041,954 A 8/1977 Ohara et al.
4,042,504 A 8/1977 Drori et al.
4,045,345 A 8/1977 Drori et al.
4,047,851 A 9/1977 Bender
4,048,494 A 9/1977 Liesting et al.
4,048,879 A 9/1977 Cox
4,049,004 A 9/1977 Walters
4,051,338 A 9/1977 Harris, III
4,052,991 A 10/1977 Zacouto et al.
4,055,074 A 10/1977 Thimons et al.
4,055,175 A 10/1977 Clemens et al.
4,056,854 A 11/1977 Boretos et al.
4,058,007 A 11/1977 Exner et al.
4,062,351 A 12/1977 Hastwell et al.
4,062,354 A 12/1977 Taylor et al.
4,062,360 A 12/1977 Bentley
4,063,439 A 12/1977 Besson et al.
4,064,882 A 12/1977 Johnson et al.
4,070,239 A 1/1978 Bevilacqua
4,072,047 A 2/1978 Reismuller et al.
4,073,292 A 2/1978 Edelman
4,075,099 A 2/1978 Pelton et al.
4,075,602 A 2/1978 Clothier
4,077,072 A 3/1978 Dezura et al.
4,077,394 A 3/1978 McCurdy
4,077,405 A 3/1978 Haerten et al.
4,077,882 A 3/1978 Gangemi
4,078,620 A 3/1978 Westlake et al.
4,080,653 A 3/1978 Barnes, Jr. et al.
4,084,752 A 4/1978 Hagiwara et al.
4,086,488 A 4/1978 Hill
4,087,568 A 5/1978 Fay et al.
4,088,417 A 5/1978 Kosmowski
4,089,329 A 5/1978 Couvillon, Jr. et al.
4,090,802 A 5/1978 Bilz et al.
4,092,719 A 5/1978 Salmon et al.
4,092,925 A 6/1978 Fromson
4,096,866 A 6/1978 Fischell
4,098,293 A 7/1978 Kramer et al.
4,103,496 A 8/1978 Colamussi et al.
4,106,370 A 8/1978 Kraus et al.
4,107,689 A 8/1978 Jellinek
4,107,995 A 8/1978 Ligman et al.
4,108,148 A 8/1978 Cannon, III
4,108,575 A 8/1978 Schal et al.
4,109,148 A 8/1978 Jaulmes et al.
4,109,518 A 8/1978 Dooley et al.
4,109,644 A 8/1978 Kojima
4,111,056 A 9/1978 Mastromatteo
4,111,629 A 9/1978 Nussbaumer
4,114,424 A 9/1978 Johnson
4,114,606 A 9/1978 Seylar
4,120,097 A 10/1978 Jeter
4,120,134 A 10/1978 Scholle
4,121,635 A 10/1978 Hansel
4,123,310 A 10/1978 Varon et al.
4,124,023 A 11/1978 Fleischmann et al.
4,127,110 A 11/1978 Bullara
4,130,169 A 12/1978 Denison
4,131,596 A 12/1978 Allen
4,133,355 A 1/1979 Mayer
4,133,367 A 1/1979 Abell
4,140,131 A 2/1979 Dutcher et al.
4,141,348 A 2/1979 Hittman
4,141,349 A 2/1979 Ory et al.
4,143,661 A 3/1979 LaForge et al.
4,146,029 A 3/1979 Ellinwood, Jr.
4,147,161 A 4/1979 Ikebe et al.
4,148,096 A 4/1979 Haas et al.
4,149,423 A 4/1979 Frosch et al.
4,151,823 A 5/1979 Grosse et al.
4,153,085 A 5/1979 Adams
4,156,422 A 5/1979 Hildebrandt et al.
4,160,448 A 7/1979 Jackson
4,160,971 A 7/1979 Jones et al.
4,166,469 A 9/1979 Littleford
4,167,304 A 9/1979 Gelbke
4,167,952 A 9/1979 Reinicke
4,168,567 A 9/1979 Leguy et al.
4,170,280 A 10/1979 Schwarz
4,171,218 A 10/1979 Hoshino et al.
4,183,124 A 1/1980 Hoffman
4,183,247 A 1/1980 Allen et al.
4,185,641 A 1/1980 Minior et al.
4,186,287 A 1/1980 Scott
4,186,749 A 2/1980 Fryer
4,186,751 A 2/1980 Fleischmann
4,190,057 A 2/1980 Hill et al.
4,191,004 A 3/1980 Gmuer et al.
4,191,187 A 3/1980 Wright et al.
4,192,192 A 3/1980 Schnell
4,193,397 A 3/1980 Tucker et al.
4,204,547 A 5/1980 Allocca
4,206,755 A 6/1980 Klein et al.
4,206,761 A 6/1980 Cosman
4,206,762 A 6/1980 Cosman
4,207,903 A 6/1980 O'Neill
4,212,074 A 7/1980 Kuno et al.
4,217,221 A 8/1980 Masso
4,217,588 A 8/1980 Freeny, Jr.
4,220,189 A 9/1980 Marquez
4,221,219 A 9/1980 Tucker
4,221,523 A 9/1980 Eberle
4,223,837 A 9/1980 Gubbiotti et al.
4,226,124 A 10/1980 Kersten et al.
4,226,229 A 10/1980 Eckhart et al.
4,227,533 A 10/1980 Godfrey
4,231,376 A 11/1980 Lyon et al.
4,232,682 A 11/1980 Veth
4,237,900 A 12/1980 Schulman et al.
4,241,247 A 12/1980 Byrne et al.
4,241,870 A 12/1980 Marcus
4,245,593 A 1/1981 Stein
4,246,877 A 1/1981 Kennedy
4,247,850 A 1/1981 Marcus
4,248,238 A 2/1981 Joseph et al.
4,248,241 A 2/1981 Tacchi
4,256,094 A 3/1981 Kapp et al.
4,256,118 A 3/1981 Nagel et al.
4,262,343 A 4/1981 Claycomb
4,262,632 A 4/1981 Hanton et al.
4,265,241 A 5/1981 Portner et al.
4,265,252 A 5/1981 Chubbuck et al.
4,271,018 A 6/1981 Drori
4,273,070 A 6/1981 Hoefelmayr et al.
4,274,444 A 6/1981 Ruyak
4,275,600 A 6/1981 Turner et al.
4,275,913 A 6/1981 Marcus
4,278,540 A 7/1981 Drori et al.
4,280,036 A 7/1981 Fukatsu et al.
4,280,775 A 7/1981 Wood
4,281,666 A 8/1981 Cosman
4,281,667 A 8/1981 Cosman
4,284,073 A 8/1981 Krause et al.
4,285,770 A 8/1981 Chi et al.
4,291,699 A 9/1981 Geddes et al.
4,295,963 A 10/1981 Drori et al.
4,297,927 A 11/1981 Kuroda et al.
4,303,075 A 12/1981 Heilman et al.
4,305,402 A 12/1981 Katims
4,312,374 A 1/1982 Drori
4,314,480 A 2/1982 Becker
4,316,693 A 2/1982 Baxter et al.
4,325,387 A 4/1982 Helfer
4,327,804 A 5/1982 Reed
4,328,654 A 5/1982 Van Ginkel et al.

(56) **References Cited**

U.S. PATENT DOCUMENTS

4,332,254 A 6/1982 Lundquist
4,339,831 A 7/1982 Johnson
4,342,218 A 8/1982 Fox
4,342,308 A 8/1982 Trick
4,346,604 A 8/1982 Snook et al.
4,347,851 A 9/1982 Jundanian
4,350,647 A 9/1982 de la Cruz
4,350,970 A 9/1982 von Tomkewitsch et al.
4,351,037 A 9/1982 Scherbatskoy
4,351,116 A 9/1982 Scott, Jr.
4,356,486 A 10/1982 Mount
4,360,010 A 11/1982 Finney
4,360,277 A 11/1982 Daniel et al.
4,361,153 A 11/1982 Slocum et al.
4,363,236 A 12/1982 Meyers
4,364,276 A 12/1982 Shimazoe et al.
4,365,425 A 12/1982 Gotchel
4,368,937 A 1/1983 Palombo et al.
4,369,013 A 1/1983 Abildgaard et al.
4,373,527 A 2/1983 Fischell
4,376,523 A 3/1983 Goyen et al.
4,378,809 A 4/1983 Cosman
4,380,427 A 4/1983 Hehl et al.
4,385,636 A 5/1983 Cosman
4,386,422 A 5/1983 Mumby et al.
4,387,907 A 6/1983 Hiestand et al.
4,392,368 A 7/1983 Folkesson et al.
4,393,899 A 7/1983 Tsuji et al.
4,393,951 A 7/1983 Horst-Rudolf et al.
4,395,232 A 7/1983 Koch
4,395,258 A 7/1983 Wang et al.
4,395,916 A 8/1983 Martin
4,398,983 A 8/1983 Suzuki et al.
4,399,705 A 8/1983 Weiger et al.
4,399,707 A 8/1983 Wamstad
4,399,809 A 8/1983 Baro et al.
4,399,821 A 8/1983 Bowers
4,403,984 A 9/1983 Ash et al.
4,404,968 A 9/1983 Evans, Sr.
4,404,974 A 9/1983 Titus
4,405,318 A 9/1983 Whitney et al.
4,407,125 A 10/1983 Parsons et al.
4,407,271 A 10/1983 Schiff
4,407,296 A 10/1983 Anderson
4,407,326 A 10/1983 Wilhelm
4,408,597 A 10/1983 Tenney, Jr.
4,408,615 A 10/1983 Grossman
4,415,071 A 11/1983 Butler et al.
4,416,282 A 11/1983 Saulson et al.
4,418,899 A 12/1983 Zimmermann et al.
4,419,393 A 12/1983 Hanson et al.
4,421,505 A 12/1983 Schwartz
4,424,720 A 1/1984 Bucchianeri
4,428,228 A 1/1984 Banzhaf et al.
4,428,365 A 1/1984 Hakky et al.
4,430,899 A 2/1984 Wessel et al.
4,431,009 A 2/1984 Marino, Jr. et al.
4,431,365 A 2/1984 Sturtz, Jr.
4,432,363 A 2/1984 Kakegawa et al.
4,435,173 A 3/1984 Siposs et al.
4,439,186 A 3/1984 Kuhl et al.
4,441,491 A 4/1984 Evans, Sr.
4,441,501 A 4/1984 Parent
4,444,194 A 4/1984 Burcham
4,444,498 A 4/1984 Heinemann
4,445,385 A 5/1984 Endo
4,446,711 A 5/1984 Valente
4,447,224 A 5/1984 DeCant, Jr. et al.
4,449,493 A 5/1984 Kopec et al.
4,450,811 A 5/1984 Ichikawa et al.
4,451,033 A 5/1984 Nestegard
4,453,537 A 6/1984 Spitzer
4,453,578 A 6/1984 Wilder
4,460,835 A 7/1984 Masuoka et al.
4,464,170 A 8/1984 Clemens et al.
4,465,015 A 8/1984 Osta et al.
4,465,474 A 8/1984 Mardorf et al.
4,466,290 A 8/1984 Frick
4,468,172 A 8/1984 Dixon et al.
4,468,762 A 8/1984 Jurgens et al.
4,469,365 A 9/1984 Marcus et al.
4,471,182 A 9/1984 Wielgos et al.
4,471,786 A 9/1984 Inagaki et al.
4,473,067 A 9/1984 Schiff
4,473,078 A 9/1984 Angel
4,476,721 A 10/1984 Hochreuther et al.
4,478,213 A 10/1984 Redding
4,478,538 A 10/1984 Kakino et al.
4,483,196 A 11/1984 Kurtz et al.
4,484,135 A 11/1984 Ishihara et al.
4,485,813 A 12/1984 Anderson et al.
4,489,916 A 12/1984 Stevens
4,492,632 A 1/1985 Mattson
4,494,411 A 1/1985 Koschke et al.
4,494,950 A 1/1985 Fischell
4,497,176 A 2/1985 Rubin et al.
4,497,201 A 2/1985 Allen et al.
4,499,394 A 2/1985 Koal
4,499,691 A 2/1985 Karazim et al.
4,499,750 A 2/1985 Gerber et al.
4,503,678 A 3/1985 Wimbush
4,511,974 A 4/1985 Nakane et al.
4,513,295 A 4/1985 Jones et al.
4,515,004 A 5/1985 Jaenson
4,515,750 A 5/1985 Pardini et al.
4,516,866 A 5/1985 Yamauchi et al.
4,518,637 A 5/1985 Takeda et al.
4,519,401 A 5/1985 Ko et al.
4,520,443 A 5/1985 Yuki et al.
4,522,213 A 6/1985 Wallroth et al.
4,527,568 A 7/1985 Rickards et al.
4,529,401 A 7/1985 Leslie et al.
4,531,526 A 7/1985 Genest
4,531,936 A 7/1985 Gordon
4,536,000 A 8/1985 Rohm et al.
4,537,005 A 8/1985 Hoyland et al.
4,537,129 A 8/1985 Heinemann et al.
4,538,616 A 9/1985 Rogoff
4,540,404 A 9/1985 Wolvek
4,542,461 A 9/1985 Eldridge et al.
4,544,369 A 10/1985 Skakoon et al.
4,545,185 A 10/1985 Chikatani et al.
4,546,524 A 10/1985 Kreft
4,548,209 A 10/1985 Wielders et al.
4,552,150 A 11/1985 Zacouto et al.
4,553,226 A 11/1985 Scherbatskoy
4,556,063 A 12/1985 Thompson et al.
4,557,269 A 12/1985 Reynolds et al.
4,557,332 A 12/1985 Denison et al.
4,559,815 A 12/1985 Needham et al.
4,560,979 A 12/1985 Rosskopf et al.
4,561,442 A 12/1985 Vollmann et al.
4,562,751 A 1/1986 Nason et al.
4,563,175 A 1/1986 LaFond
4,565,116 A 1/1986 Hehl et al.
4,566,456 A 1/1986 Koning et al.
4,569,623 A 2/1986 Goldmann
4,570,351 A 2/1986 Szanto et al.
4,571,161 A 2/1986 Leblanc et al.
4,571,995 A 2/1986 Timme
4,573,835 A 3/1986 Eckardt et al.
4,574,792 A 3/1986 Trick
4,576,181 A 3/1986 Wallace et al.
4,576,183 A 3/1986 Plicchi et al.
4,577,512 A 3/1986 Lowenheck et al.
4,581,018 A 4/1986 Jassawalla et al.
4,581,915 A 4/1986 Haulsee et al.
4,587,840 A 5/1986 Dobler et al.
4,589,805 A 5/1986 Duffner et al.
4,592,339 A 6/1986 Kuzmak et al.
4,592,340 A 6/1986 Boyles
4,593,703 A 6/1986 Cosman
4,595,228 A 6/1986 Chu
4,596,563 A 6/1986 Pande

(56) **References Cited**

U.S. PATENT DOCUMENTS

4,599,943 A 7/1986 Kobler et al.
4,600,855 A 7/1986 Strachan et al.
4,602,541 A 7/1986 Benzinger et al.
4,604,089 A 8/1986 Santangelo et al.
4,605,354 A 8/1986 Daly
4,606,419 A 8/1986 Perini
4,606,478 A 8/1986 Hack et al.
4,610,256 A 9/1986 Wallace
4,614,137 A 9/1986 Jones
4,617,016 A 10/1986 Blomberg et al.
4,618,861 A 10/1986 Gettens et al.
4,620,807 A 11/1986 Polit
4,621,331 A 11/1986 Iwata
4,622,871 A 11/1986 Van Sickle et al.
4,626,462 A 12/1986 Kober et al.
4,633,304 A 12/1986 Nagasaki et al.
4,633,878 A 1/1987 Bombardieri et al.
4,635,182 A 1/1987 Hintz
4,637,736 A 1/1987 Andeen et al.
4,638,665 A 1/1987 Benson et al.
4,644,246 A 2/1987 Knapen et al.
4,646,553 A 3/1987 Tufte et al.
4,648,363 A 3/1987 Kronich
4,648,406 A 3/1987 Miller
4,658,358 A 4/1987 Leach et al.
4,658,760 A 4/1987 Zebuhr
4,660,568 A 4/1987 Cosman
4,665,511 A 5/1987 Rodney et al.
4,665,896 A 5/1987 LaForge et al.
4,669,484 A 6/1987 Masters
4,672,974 A 6/1987 Lee
4,674,457 A 6/1987 Berger et al.
4,674,546 A 6/1987 Fournier et al.
4,678,408 A 7/1987 Nason et al.
4,681,559 A 7/1987 Hooven
4,683,850 A 8/1987 Bauder et al.
4,685,463 A 8/1987 Williams
4,685,469 A 8/1987 Keller et al.
4,685,903 A 8/1987 Cable et al.
4,686,987 A 8/1987 Salo et al.
4,687,530 A 8/1987 Berscheid et al.
4,689,979 A 9/1987 Otsuka et al.
4,691,694 A 9/1987 Boyd et al.
4,691,710 A 9/1987 Dickens et al.
4,693,253 A 9/1987 Adams
4,695,237 A 9/1987 Inaba et al.
4,696,189 A 9/1987 Hochreuther et al.
4,697,574 A 10/1987 Karcher et al.
4,698,038 A 10/1987 Key et al.
4,700,497 A 10/1987 Sato et al.
4,700,610 A 10/1987 Bauer et al.
4,701,143 A 10/1987 Key et al.
4,703,756 A 11/1987 Gough et al.
4,705,507 A 11/1987 Boyles
4,706,948 A 11/1987 Kroecher et al.
4,712,562 A 12/1987 Ohayon et al.
4,718,425 A 1/1988 Tanaka et al.
4,722,348 A 2/1988 Ligtenberg et al.
4,724,806 A 2/1988 Hartwig
4,724,830 A 2/1988 Fischell
4,725,826 A 2/1988 Hunter
4,728,479 A 3/1988 Merkovsky
4,729,517 A 3/1988 Krokor et al.
4,730,188 A 3/1988 Milheiser
4,730,420 A 3/1988 Stratmann et al.
4,730,619 A 3/1988 Koning et al.
4,731,058 A 3/1988 Doan
4,735,205 A 4/1988 Chachques et al.
4,738,267 A 4/1988 Lazorthes et al.
4,738,268 A 4/1988 Kipnis
4,741,345 A 5/1988 Matthews et al.
4,741,732 A 5/1988 Crankshaw et al.
4,743,129 A 5/1988 Keryhuel et al.
4,745,541 A 5/1988 Vaniglia et al.
4,746,830 A 5/1988 Holland
4,750,495 A 6/1988 Moore et al.
4,752,115 A 6/1988 Murray, Jr. et al.
4,752,658 A 6/1988 Mack
4,757,463 A 7/1988 Ballou et al.
4,759,386 A 7/1988 Grouw, III
4,763,649 A 8/1988 Merrick
4,765,001 A 8/1988 Smith
4,767,406 A 8/1988 Wadham et al.
4,769,001 A 9/1988 Prince
4,772,896 A 9/1988 Nakatsu et al.
4,773,401 A 9/1988 Citak et al.
4,774,950 A 10/1988 Cohen
4,774,955 A 10/1988 Jones
4,777,953 A 10/1988 Ash et al.
4,779,626 A 10/1988 Peel et al.
4,781,192 A 11/1988 Demer
4,782,826 A 11/1988 Fogarty
4,783,106 A 11/1988 Nutter
4,788,847 A 12/1988 Sterghos
4,791,318 A 12/1988 Lewis et al.
4,794,803 A 1/1989 Osterhout et al.
4,796,641 A 1/1989 Mills et al.
4,798,211 A 1/1989 Goor et al.
4,798,227 A 1/1989 Goodwin
4,799,491 A 1/1989 Eckerle
4,799,625 A 1/1989 Weaver, Jr. et al.
4,802,488 A 2/1989 Eckerle
4,803,987 A 2/1989 Calfee et al.
4,804,368 A 2/1989 Skakoon et al.
4,807,321 A 2/1989 Grasselli et al.
4,808,167 A 2/1989 Mann et al.
4,812,823 A 3/1989 Dickerson
4,819,656 A 4/1989 Spector
4,820,265 A 4/1989 DeSatnick et al.
4,820,953 A 4/1989 Saubolle et al.
4,821,167 A 4/1989 Wiebe
4,821,723 A 4/1989 Baker, Jr. et al.
4,823,779 A 4/1989 Daly et al.
4,830,006 A 5/1989 Haluska et al.
4,832,034 A 5/1989 Pizziconi et al.
4,833,384 A 5/1989 Munro et al.
4,834,731 A 5/1989 Nowak et al.
4,838,857 A 6/1989 Strowe et al.
4,840,068 A 6/1989 Mayhew, Jr.
4,840,350 A 6/1989 Cook et al.
4,844,002 A 7/1989 Yasui et al.
4,846,153 A 7/1989 Berci
4,846,191 A 7/1989 Brockway et al.
4,846,664 A 7/1989 Hehl
4,854,328 A 8/1989 Pollack
4,863,470 A 9/1989 Carter
4,865,587 A 9/1989 Walling
4,867,160 A 9/1989 Schaldach
4,867,498 A 9/1989 Delphia et al.
4,867,618 A 9/1989 Brohammer
4,869,252 A 9/1989 Gilli
4,870,258 A 9/1989 Mochizuki et al.
4,871,351 A 10/1989 Feingold
4,872,483 A 10/1989 Shah
4,872,869 A 10/1989 Johns
4,873,677 A 10/1989 Sakamoto et al.
4,875,483 A 10/1989 Vollmann et al.
4,880,004 A 11/1989 Baker, Jr. et al.
4,882,678 A 11/1989 Hollis et al.
4,886,392 A 12/1989 Iio et al.
4,895,151 A 1/1990 Grevis et al.
4,896,594 A 1/1990 Baur et al.
4,898,158 A 2/1990 Daly et al.
4,898,578 A 2/1990 Rubalcaba, Jr.
4,899,751 A 2/1990 Cohen
4,899,752 A 2/1990 Cohen
4,902,277 A 2/1990 Mathies et al.
4,903,701 A 2/1990 Moore et al.
4,909,678 A 3/1990 Kakimoto et al.
4,913,147 A 4/1990 Fahlstrom et al.
4,919,143 A 4/1990 Ayers
4,924,872 A 5/1990 Frank
4,926,903 A 5/1990 Kawai et al.
4,932,406 A 6/1990 Berkovits

(56) **References Cited**

U.S. PATENT DOCUMENTS

4,934,369 A 6/1990 Maxwell
4,936,304 A 6/1990 Kresh et al.
4,940,037 A 7/1990 Eckert et al.
4,941,718 A 7/1990 Alexander, III et al.
4,942,004 A 7/1990 Catanzaro
4,944,050 A 7/1990 Shames et al.
4,944,298 A 7/1990 Sholder
4,944,307 A 7/1990 Hon et al.
4,945,761 A 8/1990 Lessi et al.
4,949,724 A 8/1990 Mahutte et al.
4,952,205 A 8/1990 Mauerer et al.
4,952,928 A 8/1990 Carroll et al.
4,953,563 A 9/1990 Kaiser et al.
4,954,677 A 9/1990 Alberter et al.
4,958,630 A 9/1990 Rosenbluth et al.
4,958,645 A 9/1990 Cadell et al.
4,960,424 A 10/1990 Grooters
4,960,966 A 10/1990 Evans et al.
4,967,585 A 11/1990 Grimaldo
4,967,761 A 11/1990 Nathanielsz
4,970,823 A 11/1990 Chen et al.
4,971,251 A 11/1990 Dobrick et al.
4,977,896 A 12/1990 Robinson et al.
4,978,335 A 12/1990 Arthur, III
4,978,338 A 12/1990 Melsky et al.
4,979,730 A 12/1990 Holbrook et al.
4,980,671 A 12/1990 McCurdy
4,981,141 A 1/1991 Segalowitz
4,981,173 A 1/1991 Perkins et al.
4,981,426 A 1/1991 Aoki et al.
4,987,897 A 1/1991 Funke et al.
4,988,337 A 1/1991 Ito et al.
4,992,794 A 2/1991 Brouwers et al.
4,997,556 A 3/1991 Yano et al.
5,001,528 A 3/1991 Bahraman
5,003,807 A 4/1991 Terrell et al.
5,003,975 A 4/1991 Hafelfinger et al.
5,003,976 A 4/1991 Alt et al.
5,004,472 A 4/1991 Wallace
5,004,873 A 4/1991 Schnut
5,005,574 A 4/1991 Fearnot et al.
5,005,586 A 4/1991 Lahr
5,006,844 A 4/1991 Ohta et al.
5,007,401 A 4/1991 Grohn et al.
5,007,430 A 4/1991 Dardik
5,007,919 A 4/1991 Silva et al.
5,009,662 A 4/1991 Wallace et al.
5,010,893 A 4/1991 Sholder
5,012,286 A 4/1991 Kawano et al.
5,012,411 A * 4/1991 Policastro et al. 600/485
5,012,810 A 5/1991 Strand et al.
5,013,292 A 5/1991 Lemay et al.
5,014,040 A 5/1991 Weaver et al.
5,019,032 A 5/1991 Robertson
5,019,041 A 5/1991 Robinson et al.
5,020,845 A 6/1991 Falcoff et al.
5,021,046 A 6/1991 Wallace
5,022,395 A 6/1991 Russie
5,024,965 A 6/1991 Chang et al.
5,026,180 A 6/1991 Tajima et al.
5,026,360 A 6/1991 Johnsen et al.
5,028,918 A 7/1991 Giles et al.
5,032,822 A 7/1991 Sweet
5,036,869 A 8/1991 Inahara
5,038,800 A 8/1991 Oba
5,041,086 A 8/1991 Koenig et al.
5,041,826 A 8/1991 Milheiser
5,042,503 A 8/1991 Torok et al.
5,044,770 A 9/1991 Haghkar
5,046,661 A 9/1991 Kimura et al.
5,048,060 A 9/1991 Arai et al.
5,050,922 A 9/1991 Falcoff
5,052,910 A 10/1991 Hehl et al.
5,053,008 A 10/1991 Bajaj
5,057,078 A 10/1991 Foote et al.
5,058,583 A 10/1991 Geddes et al.
5,061,239 A 10/1991 Shiels
5,062,052 A 10/1991 Sparer et al.
5,062,053 A 10/1991 Shirai et al.
5,062,559 A 11/1991 Falcoff
5,064,974 A 11/1991 Vigneau et al.
5,067,960 A 11/1991 Grandjean et al.
5,068,779 A 11/1991 Sullivan et al.
5,069,680 A 12/1991 Grandjean et al.
5,077,102 A 12/1991 Chong
5,077,870 A 1/1992 Melbye et al.
5,078,139 A 1/1992 Strand et al.
5,082,006 A 1/1992 Jonasson
5,083,563 A 1/1992 Collins
5,084,699 A 1/1992 DeMichele
5,085,224 A 2/1992 Galen et al.
5,085,258 A 2/1992 Fink, Jr. et al.
5,089,673 A 2/1992 Strzodka et al.
5,089,979 A 2/1992 McEachern et al.
5,095,309 A 3/1992 Troyk et al.
5,096,271 A 3/1992 Portman
5,097,831 A 3/1992 Lekholm
5,098,384 A 3/1992 Abrams
5,103,832 A 4/1992 Jackson
5,105,810 A 4/1992 Collins et al.
5,107,850 A 4/1992 Olive
5,112,344 A 5/1992 Petros et al.
5,113,859 A 5/1992 Funke et al.
5,113,869 A 5/1992 Nappholz et al.
5,115,676 A 5/1992 Lee
5,117,825 A 6/1992 Grevious
5,121,777 A 6/1992 Leininger et al.
5,127,451 A 7/1992 Fink, Jr. et al.
5,129,394 A 7/1992 Mehra
5,129,806 A 7/1992 Hehl
5,131,145 A 7/1992 Badoureaux et al.
5,131,388 A 7/1992 Pless et al.
5,133,358 A 7/1992 Gustafson et al.
5,135,488 A 8/1992 Foote et al.
5,139,484 A 8/1992 Hazon et al.
5,144,949 A 9/1992 Olson
5,148,580 A 9/1992 Dyckow et al.
5,148,695 A 9/1992 Ellis
5,152,770 A 10/1992 Bengmark et al.
5,152,776 A 10/1992 Pinchuk
5,154,170 A 10/1992 Bennett et al.
5,154,171 A 10/1992 Chirife et al.
5,154,693 A 10/1992 East et al.
5,156,972 A 10/1992 Issachar et al.
5,158,078 A 10/1992 Bennett et al.
5,163,429 A 11/1992 Cohen
5,167,615 A 12/1992 East et al.
5,168,757 A 12/1992 Rabenau et al.
5,168,982 A 12/1992 Hakanen et al.
5,171,299 A 12/1992 Heitzmann et al.
5,173,873 A 12/1992 Wu et al.
5,174,286 A 12/1992 Chirife et al.
5,174,291 A 12/1992 Schoonen et al.
5,176,502 A 1/1993 Sanderson et al.
5,178,197 A 1/1993 Healy
5,181,423 A 1/1993 Philipps et al.
5,181,517 A 1/1993 Hickey
5,184,132 A 2/1993 Baird
5,184,614 A 2/1993 Collins et al.
5,184,619 A 2/1993 Austin
5,185,535 A 2/1993 Farb et al.
5,186,224 A 2/1993 Schirmacher
5,188,106 A 2/1993 Nappholz et al.
5,188,604 A 2/1993 Orth
5,192,314 A 3/1993 Daskalakis
5,195,362 A 3/1993 Eason
5,197,322 A 3/1993 Indravudh
5,199,427 A 4/1993 Strickland
5,199,428 A 4/1993 Obel et al.
5,201,753 A 4/1993 Lampropoulos et al.
5,204,670 A 4/1993 Stinton
5,207,429 A 5/1993 Walmsley et al.
5,209,223 A 5/1993 McGorry et al.
5,209,732 A 5/1993 Lampropoulos et al.

(56) **References Cited**

U.S. PATENT DOCUMENTS

5,211,129 A 5/1993 Taylor et al.
5,211,161 A 5/1993 Stef et al.
5,212,476 A 5/1993 Maloney
5,213,331 A 5/1993 Avanzini
5,215,523 A 6/1993 Williams et al.
5,218,343 A 6/1993 Stobbe et al.
5,218,957 A 6/1993 Strickland
5,226,429 A 7/1993 Kuzmak
5,226,604 A 7/1993 Seiffert et al.
5,230,694 A 7/1993 Rosenblum
5,233,985 A 8/1993 Hudrlik
5,235,326 A 8/1993 Beigel et al.
5,244,269 A 9/1993 Harriehausen et al.
5,244,461 A 9/1993 Derlien et al.
5,246,008 A 9/1993 Mueller et al.
5,249,858 A 10/1993 Nusser
5,250,020 A 10/1993 Bley
5,254,096 A 10/1993 Rondelet et al.
5,256,157 A 10/1993 Samiotes et al.
5,263,244 A 11/1993 Centa et al.
5,263,981 A 11/1993 Polyak et al.
5,267,940 A 12/1993 Moulder
5,267,942 A 12/1993 Saperston
5,269,891 A 12/1993 Colin et al.
5,271,395 A 12/1993 Wahlstrand et al.
5,274,859 A 1/1994 Redman et al.
5,280,789 A 1/1994 Potts
5,282,839 A 2/1994 Roline et al.
5,282,840 A 2/1994 Hudrlik
5,291,894 A 3/1994 Nagy et al.
5,292,219 A 3/1994 Merin et al.
5,295,967 A 3/1994 Rondelet et al.
5,298,022 A 3/1994 Bernardi
5,298,884 A 3/1994 Gilmore et al.
5,300,093 A 4/1994 Koestner et al.
5,300,120 A 4/1994 Knapp et al.
5,304,112 A 4/1994 Mrklas et al.
5,305,923 A 4/1994 Kirschner et al.
5,312,443 A 5/1994 Adams et al.
5,312,452 A 5/1994 Salo
5,312,453 A 5/1994 Shelton et al.
5,313,953 A 5/1994 Yomtov et al.
5,314,451 A 5/1994 Mulier
5,314,457 A 5/1994 Jeutter et al.
5,324,315 A 6/1994 Grevious
5,325,834 A 7/1994 Ballheimer et al.
5,326,249 A 7/1994 Weissfloch et al.
5,328,460 A 7/1994 Lord et al.
5,330,511 A 7/1994 Boute et al.
5,337,750 A 8/1994 Walloch
5,341,430 A 8/1994 Aulia et al.
5,342,401 A 8/1994 Spano et al.
5,342,406 A 8/1994 Thompson
5,344,388 A 9/1994 Maxwell et al.
5,347,476 A 9/1994 McBean, Sr.
5,348,210 A 9/1994 Linzell et al.
5,348,536 A 9/1994 Young et al.
5,350,413 A 9/1994 Miller et al.
5,352,180 A 10/1994 Candelon et al.
5,353,622 A 10/1994 Theener
5,353,800 A 10/1994 Pohndorf et al.
5,354,200 A 10/1994 Klein et al.
5,354,316 A 10/1994 Keimel
5,354,319 A 10/1994 Wyborny et al.
5,360,407 A 11/1994 Leonard et al.
5,365,462 A 11/1994 McBean, Sr.
5,365,619 A 11/1994 Solomon
5,365,985 A 11/1994 Todd et al.
5,368,040 A 11/1994 Carney
5,370,665 A 12/1994 Hudrlik
5,373,852 A 12/1994 Harrison et al.
5,375,073 A 12/1994 McBean
5,377,128 A 12/1994 McBean
5,378,231 A 1/1995 Johnson et al.
5,382,232 A 1/1995 Hague et al.
5,383,915 A 1/1995 Adams
5,388,578 A 2/1995 Yomtov et al.
5,388,586 A 2/1995 Lee et al.
5,388,831 A 2/1995 Quadri et al.
5,394,909 A 3/1995 Mitchell et al.
5,402,944 A 4/1995 Pape et al.
5,406,957 A 4/1995 Tansey
5,409,009 A 4/1995 Olson
5,411,031 A 5/1995 Yomtov
5,411,551 A 5/1995 Winston et al.
5,411,552 A 5/1995 Andersen et al.
5,416,372 A 5/1995 Ljungstroem et al.
5,417,226 A 5/1995 Juma
5,417,717 A 5/1995 Salo et al.
5,425,362 A 6/1995 Siker et al.
5,431,171 A 7/1995 Harrison et al.
5,431,694 A 7/1995 Snaper et al.
5,433,694 A 7/1995 Lim et al.
5,437,605 A 8/1995 Helmy et al.
5,443,215 A 8/1995 Fackler
5,447,519 A 9/1995 Peterson
5,449,368 A 9/1995 Kuzmak
5,456,690 A 10/1995 Duong-Van
5,461,390 A 10/1995 Hoshen
5,464,435 A 11/1995 Neumann
5,467,627 A 11/1995 Smith et al.
5,474,226 A 12/1995 Joseph
5,479,818 A 1/1996 Walter et al.
5,482,049 A 1/1996 Addiss et al.
5,487,760 A 1/1996 Villafana
5,493,738 A 2/1996 Sanderson et al.
5,494,036 A 2/1996 Uber, III et al.
5,494,193 A 2/1996 Kirschner et al.
5,504,474 A 4/1996 Libman et al.
5,505,916 A 4/1996 Berry, Jr.
5,507,412 A 4/1996 Ebert et al.
5,507,737 A 4/1996 Palmskog et al.
5,507,785 A 4/1996 Deno
5,509,888 A 4/1996 Miller
5,509,891 A 4/1996 DeRidder
5,513,945 A 5/1996 Hartmann et al.
5,514,103 A 5/1996 Srisathapat et al.
5,518,504 A 5/1996 Polyak
5,520,606 A 5/1996 Schoolman et al.
5,523,740 A 6/1996 Burgmann et al.
5,534,018 A 7/1996 Wahlstrand et al.
5,535,752 A 7/1996 Halperin et al.
5,538,005 A 7/1996 Harrison et al.
5,541,857 A 7/1996 Walter et al.
5,545,140 A 8/1996 Conero et al.
5,545,151 A 8/1996 O'Connor et al.
5,545,186 A 8/1996 Olson et al.
5,545,214 A 8/1996 Stevens
5,547,470 A 8/1996 Johnson et al.
5,551,427 A 9/1996 Altman
5,551,439 A 9/1996 Hickey
5,554,185 A 9/1996 Block et al.
5,558,644 A 9/1996 Boyd et al.
5,564,434 A 10/1996 Halperin et al.
5,575,770 A 11/1996 Melsky et al.
5,584,803 A 12/1996 Stevens et al.
5,586,629 A 12/1996 Shoberg et al.
5,593,430 A 1/1997 Renger
5,594,665 A 1/1997 Walter et al.
5,596,986 A 1/1997 Goldfarb
5,597,284 A 1/1997 Weltlich et al.
5,610,083 A 3/1997 Chan et al.
5,611,768 A 3/1997 Tutrone, Jr.
5,612,497 A 3/1997 Walter et al.
5,615,671 A 4/1997 Schoonen et al.
5,619,991 A 4/1997 Sloane
5,625,946 A 5/1997 Wildeson et al.
5,626,623 A 5/1997 Kieval et al.
5,626,630 A 5/1997 Markowitz et al.
5,630,836 A 5/1997 Prem et al.
5,634,255 A 6/1997 Bishop et al.
5,637,083 A 6/1997 Bertrand et al.
5,643,207 A 7/1997 Rise
5,645,116 A 7/1997 McDonald

(56) **References Cited**

U.S. PATENT DOCUMENTS

5,650,766 A 7/1997 Burgmann et al.
5,673,585 A 10/1997 Bishop et al.
5,676,690 A 10/1997 Noren et al.
5,681,285 A 10/1997 Ford et al.
5,686,831 A 11/1997 Vandervalk et al.
5,687,734 A 11/1997 Dempsey et al.
5,693,076 A 12/1997 Kaemmerer
5,702,368 A 12/1997 Stevens et al.
5,702,427 A 12/1997 Ecker et al.
5,702,431 A 12/1997 Wang et al.
5,704,352 A 1/1998 Tremblay et al.
5,715,786 A 2/1998 Seiberth et al.
5,715,837 A 2/1998 Chen
5,720,436 A 2/1998 Buschor et al.
5,730,101 A 3/1998 Aupperle et al.
5,732,710 A 3/1998 Rabinovich et al.
5,733,313 A 3/1998 Barreras, Sr. et al.
5,738,652 A 4/1998 Boyd et al.
5,742,233 A 4/1998 Hoffman et al.
5,743,267 A 4/1998 Nikolic et al.
5,749,369 A 5/1998 Rabinovich et al.
5,749,909 A 5/1998 Schroeppel et al.
5,755,687 A 5/1998 Donlon
5,755,748 A 5/1998 Borza et al.
5,765,568 A 6/1998 Sweezer, Jr. et al.
5,769,812 A 6/1998 Stevens et al.
5,771,903 A 6/1998 Jakobsson
5,782,774 A 7/1998 Shmulewitz
5,787,520 A 8/1998 Dunbar
5,791,344 A 8/1998 Schulman et al.
5,792,094 A 8/1998 Stevens et al.
5,792,179 A 8/1998 Sideris
5,795,325 A 8/1998 Valley et al.
5,796,827 A 8/1998 Coppersmith et al.
5,800,375 A 9/1998 Sweezer et al.
5,807,265 A 9/1998 Itoigawa et al.
5,807,336 A 9/1998 Russo et al.
5,810,015 A 9/1998 Flaherty
5,810,757 A 9/1998 Sweezer, Jr. et al.
5,814,016 A 9/1998 Valley et al.
5,817,093 A 10/1998 Williamson, IV et al.
5,833,603 A 11/1998 Kovacs et al.
5,836,300 A 11/1998 Mault
5,836,886 A 11/1998 Itoigawa et al.
5,836,982 A * 11/1998 Muhlenberg et al. 607/9
5,840,081 A 11/1998 Andersen et al.
5,849,225 A 12/1998 Ebina et al.
5,855,597 A 1/1999 Jayaraman et al.
5,855,601 A 1/1999 Bessler et al.
5,860,938 A 1/1999 Lafontaine et al.
5,861,018 A 1/1999 Feierbach
5,863,366 A 1/1999 Snow
5,868,702 A 2/1999 Stevens et al.
5,873,837 A 2/1999 Lieber et al.
5,875,953 A 3/1999 Shioya et al.
5,879,499 A 3/1999 Corvi
5,881,919 A 3/1999 Womac et al.
5,885,238 A 3/1999 Stevens et al.
5,887,475 A 3/1999 Muldner
5,899,927 A 5/1999 Ecker et al.
5,908,392 A * 6/1999 Wilson et al. 600/509
5,916,179 A 6/1999 Sharrock
5,916,237 A 6/1999 Schu
5,935,078 A 8/1999 Feierbach
5,938,669 A * 8/1999 Klaiber et al. 606/157
5,951,487 A 9/1999 Brehmeier-Flick et al.
5,957,861 A 9/1999 Combs et al.
5,967,986 A 10/1999 Cimochowski et al.
5,971,934 A 10/1999 Scherer et al.
5,974,873 A 11/1999 Nelson et al.
5,978,985 A 11/1999 Thurman
5,995,874 A 11/1999 Borza
6,015,386 A 1/2000 Kensey et al.
6,015,387 A 1/2000 Schwartz et al.
6,019,729 A 2/2000 Itoigawa et al.
6,024,704 A * 2/2000 Meador et al. 600/486
6,030,413 A 2/2000 Lazarus
6,035,461 A 3/2000 Nguyen
6,047,214 A * 4/2000 Mueller et al. 607/61
6,053,873 A 4/2000 Govari et al.
6,056,723 A 5/2000 Donlon
6,058,330 A 5/2000 Borza et al.
6,059,757 A 5/2000 Macoviak et al.
6,067,474 A 5/2000 Schulman et al.
6,067,991 A 5/2000 Forsell et al.
6,076,016 A 6/2000 Feierbach
6,083,174 A 7/2000 Brehmeier-Flick et al.
6,090,096 A 7/2000 St. Goar et al.
6,102,678 A 8/2000 Peclat et al.
6,102,856 A 8/2000 Groff et al.
6,102,922 A 8/2000 Jakobsson et al.
6,106,477 A 8/2000 Miesel et al.
6,106,551 A 8/2000 Crossett et al.
6,110,145 A 8/2000 Macoviak
6,113,553 A 9/2000 Chubbuck
6,131,664 A 10/2000 Sonnier
6,135,945 A 10/2000 Sultan
6,159,156 A 12/2000 Van Bockel et al.
6,162,180 A 12/2000 Miesel et al.
6,162,245 A 12/2000 Jayaraman
6,168,614 B1 1/2001 Andersen et al.
6,234,745 B1 5/2001 Pugh et al.
6,240,316 B1 5/2001 Richmond et al.
6,240,318 B1 5/2001 Phillips
6,245,102 B1 6/2001 Jayaraman
6,248,080 B1 6/2001 Miesel et al.
6,251,093 B1 6/2001 Valley et al.
6,269,819 B1 8/2001 Oz et al.
6,277,078 B1 8/2001 Porat et al.
6,292,697 B1 9/2001 Roberts
6,309,350 B1 10/2001 VanTassel et al.
6,315,769 B1 11/2001 Peer et al.
6,319,208 B1 11/2001 Abita et al.
6,328,699 B1 12/2001 Eigler et al.
6,338,735 B1 1/2002 Stevens
6,357,438 B1 3/2002 Hansen
6,360,122 B1 3/2002 Fischell et al.
6,360,822 B1 3/2002 Robertson et al.
6,366,817 B1 4/2002 Kung
6,379,308 B1 4/2002 Brockway et al.
6,379,380 B1 4/2002 Satz
6,398,752 B1 6/2002 Sweezer, Jr. et al.
6,409,674 B1 6/2002 Brockway et al.
6,423,031 B1 7/2002 Donlon
6,430,444 B1 8/2002 Borza et al.
6,431,175 B1 8/2002 Penner et al.
6,432,040 B1 8/2002 Meah
6,443,887 B1 9/2002 Derus et al.
6,443,893 B1 9/2002 Schnakenberg et al.
6,450,173 B1 9/2002 Forsell et al.
6,450,946 B1 9/2002 Forsell et al.
6,453,907 B1 9/2002 Forsell et al.
6,454,698 B1 9/2002 Forsell et al.
6,454,699 B1 9/2002 Forsell et al.
6,454,700 B1 9/2002 Forsell et al.
6,454,701 B1 9/2002 Forsell et al.
6,461,292 B1 10/2002 Forsell et al.
6,461,293 B1 10/2002 Forsell et al.
6,463,329 B1 10/2002 Goedeke
6,463,935 B1 10/2002 Forsell et al.
6,464,628 B1 10/2002 Forsell et al.
6,470,212 B1 10/2002 Weijand et al.
6,470,892 B1 10/2002 Forsell et al.
6,471,635 B1 10/2002 Forsell et al.
6,475,136 B1 11/2002 Forsell et al.
6,475,170 B1 11/2002 Doron et al.
6,482,145 B1 11/2002 Forsell
6,482,171 B1 11/2002 Corvi et al.
6,482,177 B1 11/2002 Leinders
6,486,588 B2 11/2002 Doron et al.
6,503,189 B1 1/2003 Forsell et al.
6,504,286 B1 1/2003 Porat et al.
6,531,739 B2 3/2003 Cable et al.
6,533,719 B2 3/2003 Kuyava et al.

(56) **References Cited**

U.S. PATENT DOCUMENTS

6,533,733 B1 3/2003 Ericson et al.
6,542,350 B1 4/2003 Rogers
6,558,321 B1 5/2003 Burd et al.
6,558,994 B2 5/2003 Cha et al.
6,573,563 B2 6/2003 Lee et al.
6,582,462 B1 6/2003 Andersen et al.
6,599,250 B2 7/2003 Webb et al.
6,605,112 B1 8/2003 Moll et al.
6,629,534 B1 10/2003 Dell et al.
6,640,137 B2 10/2003 MacDonald
6,641,610 B2 11/2003 Wolf et al.
6,645,143 B2 11/2003 VanTassel et al.
6,673,109 B2 1/2004 Cox
6,678,561 B2 1/2004 Forsell et al.
6,682,480 B1 1/2004 Habib et al.
6,682,503 B1 1/2004 Fariss et al.
6,682,559 B2 1/2004 Myers et al.
6,695,866 B1 2/2004 Kuehn et al.
6,709,385 B2 3/2004 Forsell et al.
6,718,200 B2 4/2004 Marmaropoulos et al.
6,719,787 B2 4/2004 Cox
6,719,788 B2 4/2004 Cox
6,719,789 B2 4/2004 Cox
6,731,976 B2 5/2004 Penn et al.
6,733,525 B2 5/2004 Pease et al.
6,736,846 B2 5/2004 Cox
6,752,813 B2 6/2004 Goldfarb et al.
6,796,942 B1 9/2004 Kreiner et al.
6,822,343 B2 11/2004 Estevez
6,851,628 B1 2/2005 Garrison et al.
6,855,115 B2 2/2005 Fonseca et al.
6,889,772 B2 5/2005 Buytaert et al.
6,890,300 B2 5/2005 Lloyd et al.
6,896,651 B2 5/2005 Gross et al.
6,896,690 B1 5/2005 Lambrecht et al.
6,913,600 B2 7/2005 Valley et al.
6,915,165 B2 7/2005 Forsell et al.
6,926,246 B2 8/2005 Ginggen et al.
6,929,653 B2 8/2005 Strecter
6,932,792 B1 8/2005 St. Goar et al.
6,951,229 B2 10/2005 Garrison et al.
6,951,571 B1 10/2005 Srivastava
6,953,429 B2 10/2005 Forsell et al.
6,961,619 B2 11/2005 Casey
6,970,742 B2 11/2005 Mann et al.
6,979,350 B2 12/2005 Moll et al.
6,985,078 B2 1/2006 Suzuki et al.
6,989,027 B2 1/2006 Allen et al.
7,011,095 B2 3/2006 Wolf et al.
7,011,624 B2 3/2006 Forsell et al.
7,017,583 B2 3/2006 Forsell et al.
7,018,406 B2 3/2006 Seguin et al.
7,021,402 B2 4/2006 Beato et al.
7,025,727 B2 4/2006 Brockway et al.
7,044,920 B2 5/2006 Letort et al.
7,060,080 B2 6/2006 Bachmann et al.
7,081,683 B2 7/2006 Ariav et al.
7,109,933 B2 9/2006 Ito et al.
7,131,447 B2 11/2006 Sterman et al.
7,131,945 B2 11/2006 Fink et al.
7,134,580 B2 11/2006 Garrison et al.
7,144,400 B2 12/2006 Byrum et al.
7,147,640 B2 12/2006 Huebner et al.
7,153,262 B2 12/2006 Stivoric et al.
7,187,978 B2 3/2007 Malek et al.
7,225,032 B2 5/2007 Schmeling et al.
7,257,438 B2 8/2007 Kinast
7,285,090 B2 10/2007 Stivoric et al.
2001/0011543 A1 8/2001 Forsell
2001/0041823 A1 11/2001 Snyder et al.
2002/0049394 A1 4/2002 Roy et al.
2002/0120200 A1 8/2002 Brockway et al.
2002/0138009 A1 9/2002 Brockway et al.
2002/0177782 A1 11/2002 Penner
2002/0193668 A1* 12/2002 Munneke et al. 600/300
2003/0009201 A1 1/2003 Forsell
2003/0030893 A1 2/2003 Cornelius et al.
2003/0032857 A1 2/2003 Forsell
2003/0037591 A1 2/2003 Ashton et al.
2003/0045775 A1 3/2003 Forsell
2003/0066536 A1 4/2003 Forsell
2003/0088148 A1 5/2003 Forsell
2003/0092962 A1 5/2003 Forsell
2003/0093117 A1 5/2003 Saadat
2003/0100929 A1 5/2003 Forsell
2003/0105385 A1 6/2003 Forsell
2003/0109771 A1 6/2003 Forsell
2003/0114729 A1 6/2003 Forsell
2003/0125605 A1 7/2003 Forsell
2003/0125768 A1 7/2003 Peter
2003/0135089 A1 7/2003 Forsell
2003/0135090 A1 7/2003 Forsell
2003/0136417 A1 7/2003 Fonseca et al.
2003/0144648 A1 7/2003 Forsell
2003/0163079 A1 8/2003 Burnett
2003/0216666 A1 11/2003 Ericson et al.
2004/0054352 A1 3/2004 Adams et al.
2004/0113790 A1 6/2004 Hamel et al.
2004/0133092 A1 7/2004 Kain
2004/0147969 A1 7/2004 Mann et al.
2004/0172087 A1 9/2004 Forsell
2004/0186396 A1 9/2004 Roy et al.
2004/0225462 A1* 11/2004 Renken et al. 702/94
2004/0254537 A1 12/2004 Conlon et al.
2005/0015014 A1 1/2005 Fonseca et al.
2005/0025979 A1 2/2005 Sandt et al.
2005/0027175 A1 2/2005 Yang
2005/0032511 A1* 2/2005 Malone et al. 455/420
2005/0038328 A1 2/2005 Stoehrer et al.
2005/0061079 A1 3/2005 Schulman
2005/0102026 A1 5/2005 Turner et al.
2005/0159789 A1 7/2005 Brockway et al.
2005/0165317 A1 7/2005 Turner et al.
2005/0182330 A1 8/2005 Brockway et al.
2005/0187482 A1 8/2005 O'Brien et al.
2005/0187488 A1 8/2005 Wolf
2005/0192642 A1 9/2005 Forsell
2005/0240155 A1 10/2005 Conlon
2005/0240156 A1 10/2005 Conlon
2005/0250979 A1 11/2005 Coe
2005/0267406 A1 12/2005 Hassler
2005/0267500 A1 12/2005 Hassler et al.
2005/0272968 A1 12/2005 Byrum et al.
2005/0277960 A1 12/2005 Hassler et al.
2005/0277974 A1 12/2005 Hassler et al.
2005/0288604 A1 12/2005 Eigler et al.
2005/0288720 A1 12/2005 Ross et al.
2005/0288721 A1 12/2005 Girouard et al.
2005/0288739 A1 12/2005 Hassler et al.
2005/0288740 A1 12/2005 Hassler et al.
2005/0288741 A1 12/2005 Hassler et al.
2005/0288742 A1 12/2005 Giordano et al.
2006/0002035 A1 1/2006 Gao et al.
2006/0010090 A1 1/2006 Brockway et al.
2006/0020224 A1 1/2006 Geiger
2006/0020305 A1 1/2006 Desai et al.
2006/0035446 A1 2/2006 Chang et al.
2006/0047205 A1 3/2006 Ludomirsky et al.
2006/0049714 A1 3/2006 Liu et al.
2006/0058627 A1 3/2006 Flaherty et al.
2006/0064134 A1 3/2006 Mazar et al.
2006/0085051 A1 4/2006 Fritsch
2006/0089571 A1 4/2006 Gertner
2006/0094966 A1 5/2006 Brockway et al.
2006/0100531 A1 5/2006 Moser
2006/0113187 A1 6/2006 Deng et al.
2006/0122285 A1 6/2006 Falloon et al.
2006/0122863 A1 6/2006 Gottesman et al.
2006/0142635 A1 6/2006 Forsell
2006/0149124 A1 7/2006 Forsell
2006/0149324 A1 7/2006 Mann et al.
2006/0149327 A1 7/2006 Hedberg et al.
2006/0157701 A1 7/2006 Bauer et al.
2006/0161186 A1 7/2006 Hassler et al.

(56) **References Cited**

U.S. PATENT DOCUMENTS

2006/0173238	A1	8/2006	Starkebaum	
2006/0178617	A1	8/2006	Adams et al.	
2006/0178695	A1	8/2006	Decant et al.	
2006/0183967	A1	8/2006	Lechner	
2006/0184206	A1	8/2006	Baker et al.	
2006/0189887	A1	8/2006	Hassler et al.	
2006/0189888	A1	8/2006	Hassler et al.	
2006/0189889	A1	8/2006	Gertner	
2006/0199997	A1	9/2006	Hassler et al.	
2006/0211912	A1	9/2006	Dlugos et al.	
2006/0211913	A1	9/2006	Dlugos et al.	
2006/0211914	A1	9/2006	Hassler et al.	
2006/0217668	A1	9/2006	Schulze et al.	
2006/0217673	A1	9/2006	Schulze et al.	
2006/0235310	A1	10/2006	O'Brien et al.	
2006/0235439	A1	10/2006	Molitor et al.	
2006/0235448	A1	10/2006	Roslin et al.	
2006/0244914	A1	11/2006	Cech et al.	
2006/0247682	A1	11/2006	Gerber et al.	
2006/0247719	A1	11/2006	Maschino et al.	
2006/0247721	A1	11/2006	Machino	
2006/0247722	A1	11/2006	Maschino et al.	
2006/0247723	A1	11/2006	Gerber et al.	
2006/0247724	A1	11/2006	Gerber et al.	
2006/0247725	A1	11/2006	Gerber et al.	
2006/0252982	A1	11/2006	Hassler et al.	
2006/0293625	A1	12/2006	Hunt et al.	
2006/0293626	A1	12/2006	Byrum et al.	
2006/0293627	A1	12/2006	Byrum et al.	
2007/0010790	A1	1/2007	Byrum et al.	
2007/0027356	A1	2/2007	Ortiz	
2007/0027493	A1	2/2007	Ben-Haim et al.	
2007/0067206	A1	3/2007	Haggerty et al.	
2007/0070906	A1	3/2007	Thakur	
2007/0072452	A1	3/2007	Inagaki et al.	
2007/0081304	A1	4/2007	Takeguchi	
2007/0156013	A1*	7/2007	Birk	600/37
2007/0161958	A1	7/2007	Glenn	
2007/0167672	A1	7/2007	Dlugos et al.	
2007/0173881	A1	7/2007	Birk et al.	
2007/0179583	A1	8/2007	Goetzinger et al.	
2007/0208313	A1	9/2007	Conlon et al.	
2007/0225781	A1	9/2007	Saadat et al.	
2007/0255335	A1*	11/2007	Herbert et al.	607/40
2008/0009680	A1	1/2008	Hassler	

FOREIGN PATENT DOCUMENTS

CA	1275135		10/1990
CA	1277885		12/1990
CA	1317482		5/1993
CA	2082015		5/1993
CA	1327191		2/1994
CA	2119101		9/1994
CA	2305998		4/1999
CN	1059035		2/1992
CN	1119469		3/1996
CN	1241003		1/2000
EA	4581		6/2004
EP	125387	B1	11/1984
EP	417171		3/1991
EP	508141		10/1992
EP	568730		11/1993
EP	605302		7/1994
EP	660482		6/1995
EP	714017		5/1996
EP	769340		4/1997
EP	846475		6/1998
EP	848780		6/1998
EP	876808		11/1998
EP	888079		1/1999
EP	914059		5/1999
EP	981293		3/2000
EP	997680		5/2000
EP	1003021		5/2000
EP	1022983		8/2000
EP	1050265		11/2000
EP	1 115329		7/2001
EP	1119314		8/2001
EP	1128871		9/2001
EP	1202674		5/2002
EP	1213991		6/2002
EP	1253877		11/2002
EP	1253879		11/2002
EP	1253880		11/2002
EP	1253881		11/2002
EP	1253883		11/2002
EP	1253888		11/2002
EP	1255511		11/2002
EP	1255513		11/2002
EP	1255514		11/2002
EP	1263355		12/2002
EP	1263357		12/2002
EP	1284691		2/2003
EP	1374758		1/2004
EP	1488735		12/2004
EP	1500411		1/2005
EP	1510306		3/2005
EP	1518514		3/2005
EP	1545303		6/2005
EP	1547549		6/2005
EP	1563814		8/2005
EP	1568338		8/2005
EP	1582175		10/2005
EP	1582176		10/2005
EP	1584303		10/2005
EP	1586283		10/2005
EP	1591086		11/2005
EP	1593359		11/2005
EP	1598030		11/2005
EP	1609440		12/2005
EP	1674033		6/2006
EP	1736123		12/2006
EP	1799119		6/2007
EP	1832252	A2	9/2007
GB	2355937		5/2001
JP	2001-243698	A	9/2001
JP	2004-528104	A	9/2004
JP	2004-290548	A	10/2004
JP	2007-275583	A	10/2007
WO	WO-8911244		11/1989
WO	WO-8911701		11/1989
WO	WO-9004368		5/1990
WO	WO-9511057		4/1995
WO	WO-9715351		5/1997
WO	WO-9733513		9/1997
WO	WO-9833554		8/1998
WO	WO-9835610		8/1998
WO	WO-9901063		1/1999
WO	WO-9918850		4/1999
WO	WO-0004945		2/2000
WO	WO-0033738		6/2000
WO	WO-0072899		12/2000
WO	WO-014487		1/2001
WO	WO-0112075		2/2001
WO	WO-0112076		2/2001
WO	WO-0112077		2/2001
WO	WO-0112078		2/2001
WO	WO-0121066		3/2001
WO	WO-0136014		5/2001
WO	WO-0145485		6/2001
WO	WO-0145486		6/2001
WO	WO-0147431		7/2001
WO	WO-0147432		7/2001
WO	WO-0147433		7/2001
WO	WO-0147434		7/2001
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WO	WO-0147440		7/2001
WO	WO-0147575		7/2001
WO	WO-0148451		7/2001
WO	WO-0149245		7/2001
WO	WO-0150832		7/2001
WO	WO-0150833		7/2001

(56) **References Cited**

FOREIGN PATENT DOCUMENTS

WO	WO-0154626	8/2001
WO	WO-0158388	8/2001
WO	WO-0158390	8/2001
WO	WO-0158391	8/2001
WO	WO-0158393	8/2001
WO	WO-0160453	8/2001
WO	WO-0181890	11/2001
WO	WO-0200118	1/2002
WO	WO-0215769	2/2002
WO	WO-0226161	4/2002
WO	WO-02053228	7/2002
WO	WO-02055126	7/2002
WO	WO-02058551	8/2002
WO	WO-02065894	8/2002
WO	WO-02076289	10/2002
WO	WO-02082984	10/2002
WO	WO-02089655	11/2002
WO	WO-02090894	11/2002
WO	WO-02100481	12/2002
WO	WO-03002192	1/2003
WO	WO-03002193	1/2003
WO	WO-03020182	3/2003
WO	WO-03061467	7/2003
WO	WO-03061504	7/2003
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WO	WO-2004014456	2/2004
WO	WO-2004019773	3/2004
WO	WO-2004058101	7/2004
WO	WO-2004066879	8/2004
WO	WO-2004110263	12/2004
WO	WO-2005000206	1/2005
WO	WO-2005007075	1/2005
WO	WO-2005107583	11/2005
WO	WO-2006001851	1/2006
WO	WO-2006035446	4/2006
WO	WO-2006113187	10/2006
WO	WO-2006122285	11/2006
WO	WO 2006133735 A1 *	12/2006
WO	WO-2007067206	6/2007
WO	WO-2007070906	6/2007
WO	WO-2007072452	6/2007
WO	WO-2007081304	7/2007
WO	WO-2007104356	9/2007

OTHER PUBLICATIONS

"Rad Hard Aerospace Components Products", Honeywell product and service information from website http://www.honeywell.com/sites/portal?smap=aerospace&page=Radiation-Hardened-Electronics3&theme=T6&catID=C815147E4-8786-29FE-49EB-C21C8790AA99&id=H0166BA51-5344-E57E-5C37-C6333EA43F61&sel=1; 1 page.

"Radiation Hardened Electronics and Radiation Technology", Honeywell product and service information from website http://www.honeywell.com/sites/portal?smap=aerospace&page=Radiation-Hardened-Electronics&theme=T4; 2 pages.

Kirchner, G., "Honeywell and Synopsys: Concept-to-Parts Solutions for Next Generation Rad-Hard ASICs", in online magazine Compiler, http://www.synopsys.com/news/pubs/compiler/artlead_redasic-apr05.html, Apr. 2005, 5 pages.

P.A. Neukomm and H. Kundig, "Passive Wireless Actuator Control and Sensor Signal Transmission," Sensors and Actuators, A21-A23 (1990) 258-262.

Partial European Search Report, Application No. 09250214.5, Mailed Jul. 6, 2009, 7 pages.

Japanese Office Action for Application No. 2009-015101, issued Apr. 9, 2013. 3 pages.

* cited by examiner

FIG. 1A

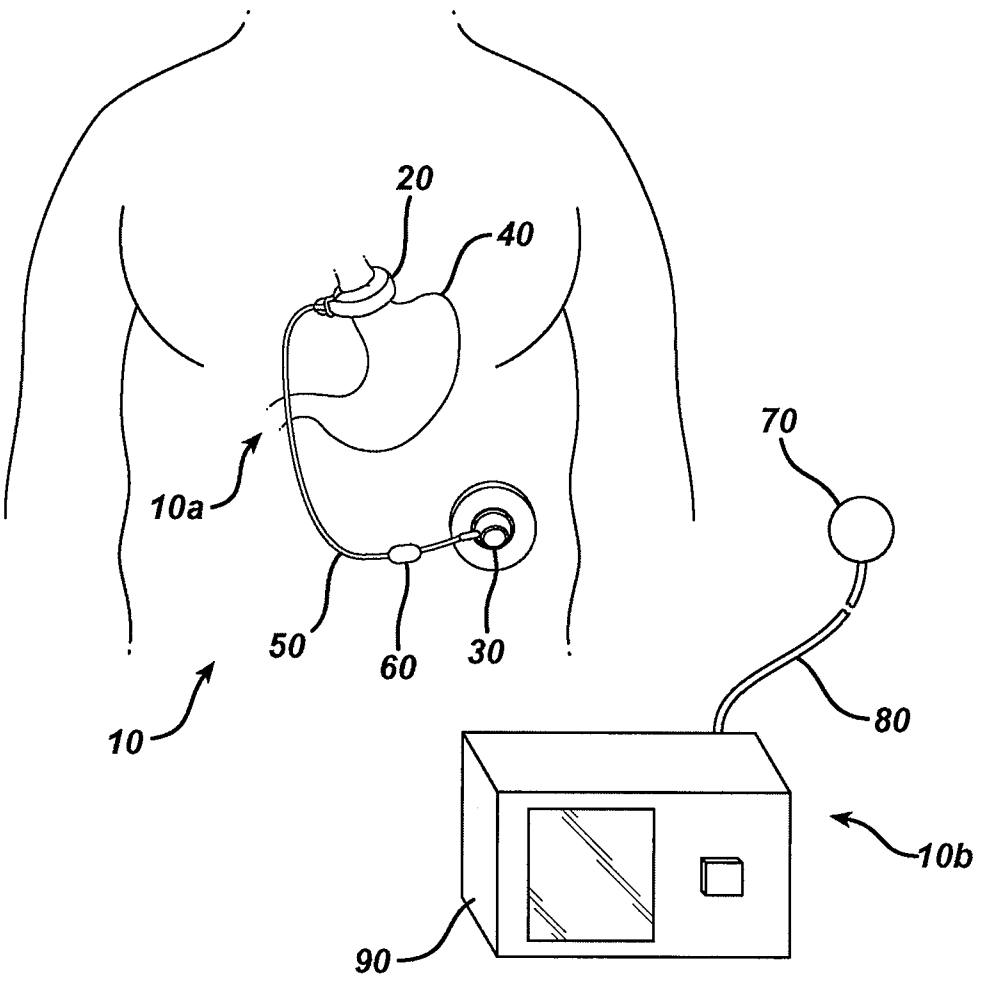


FIG. 1B

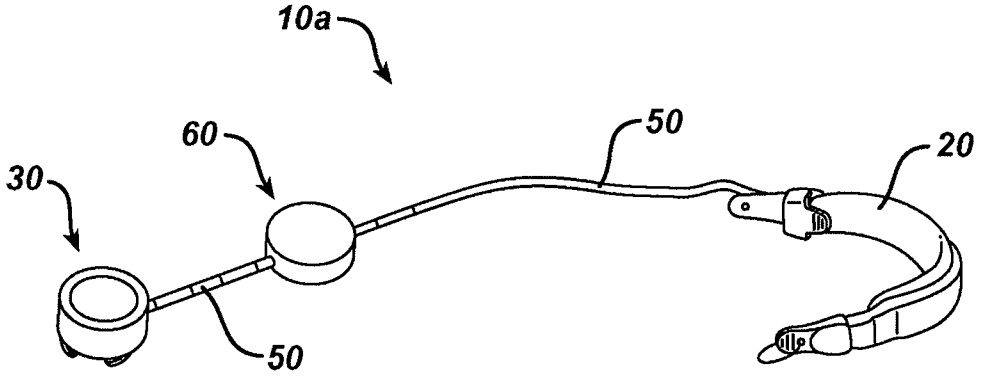


FIG. 2A

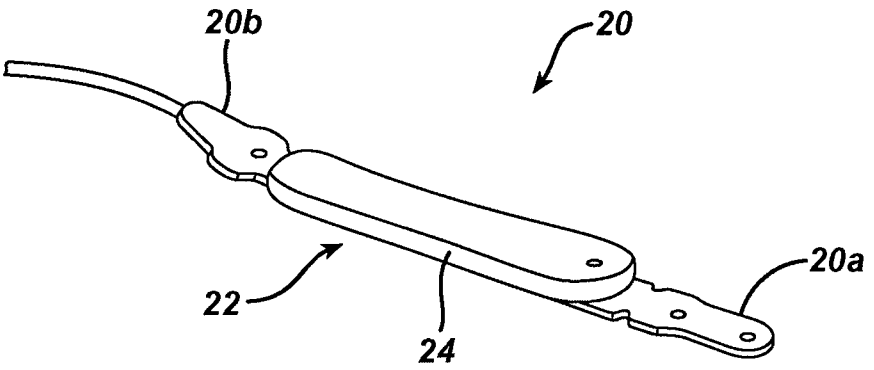


FIG. 2B

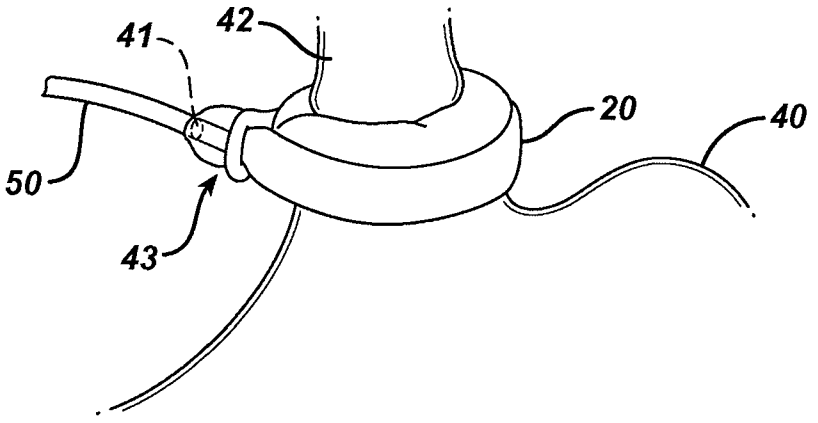


FIG. 3

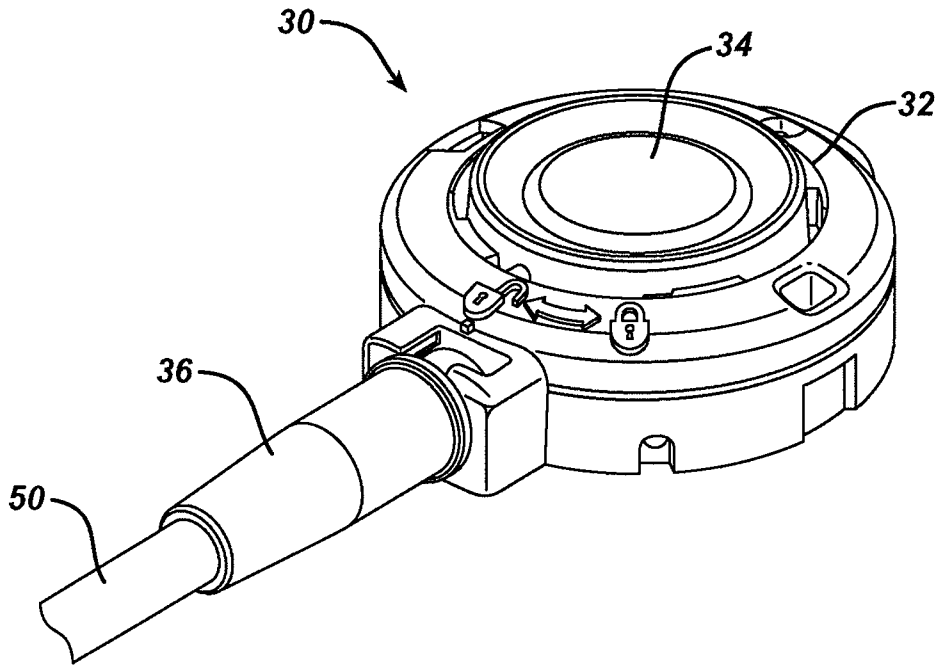


FIG. 4

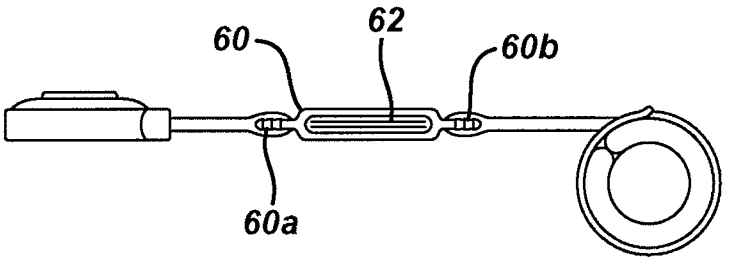


FIG. 5

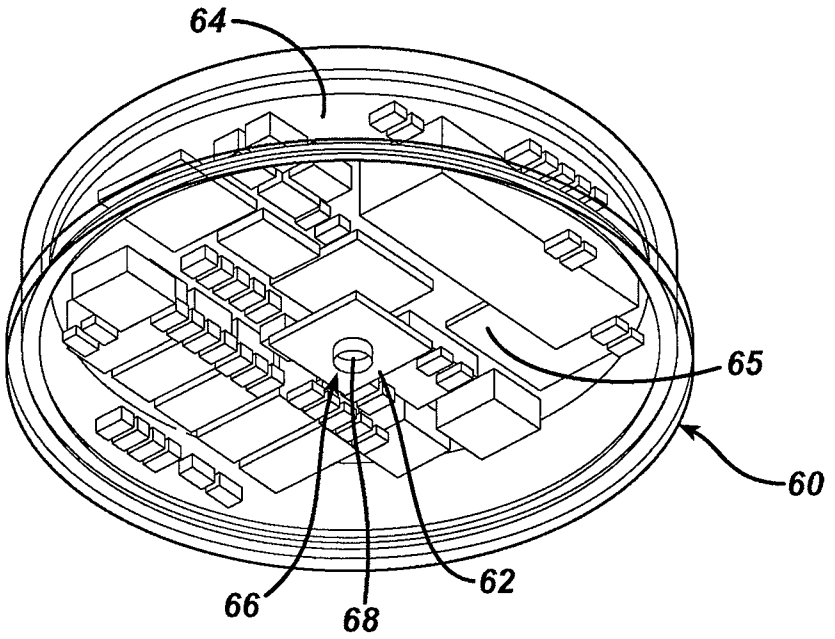


FIG. 6

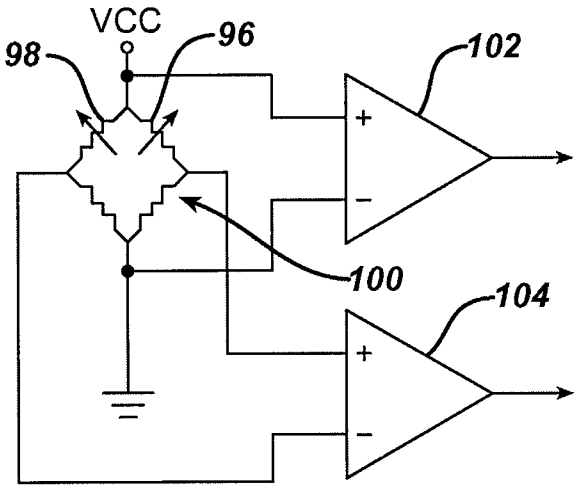


FIG. 7

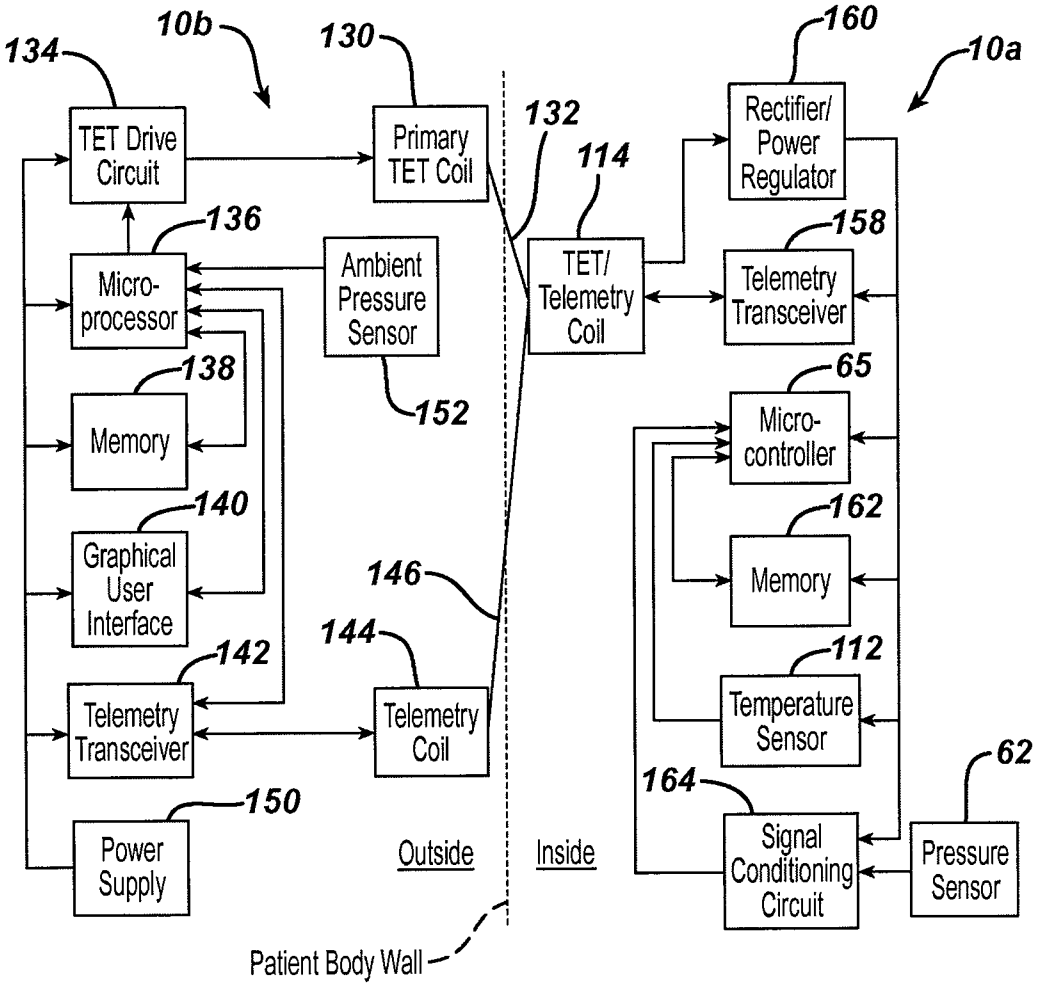

10b
134
130
160
10a
TET Drive Circuit
Primary TET Coil
132
114
Rectifier/ Power Regulator
136
158
Micro-processor
Ambient Pressure Sensor
TET/ Telemetry Coil
Telemetry Transceiver
138
65
152
Memory
Micro-controller
140
162
Graphical User Interface
146
Memory
144
112
142
Telemetry Transceiver
Telemetry Coil
Temperature Sensor
62
164
150
Power Supply
Outside
Inside
Signal Conditioning Circuit
Pressure Sensor
Patient Body Wall

FIG. 8

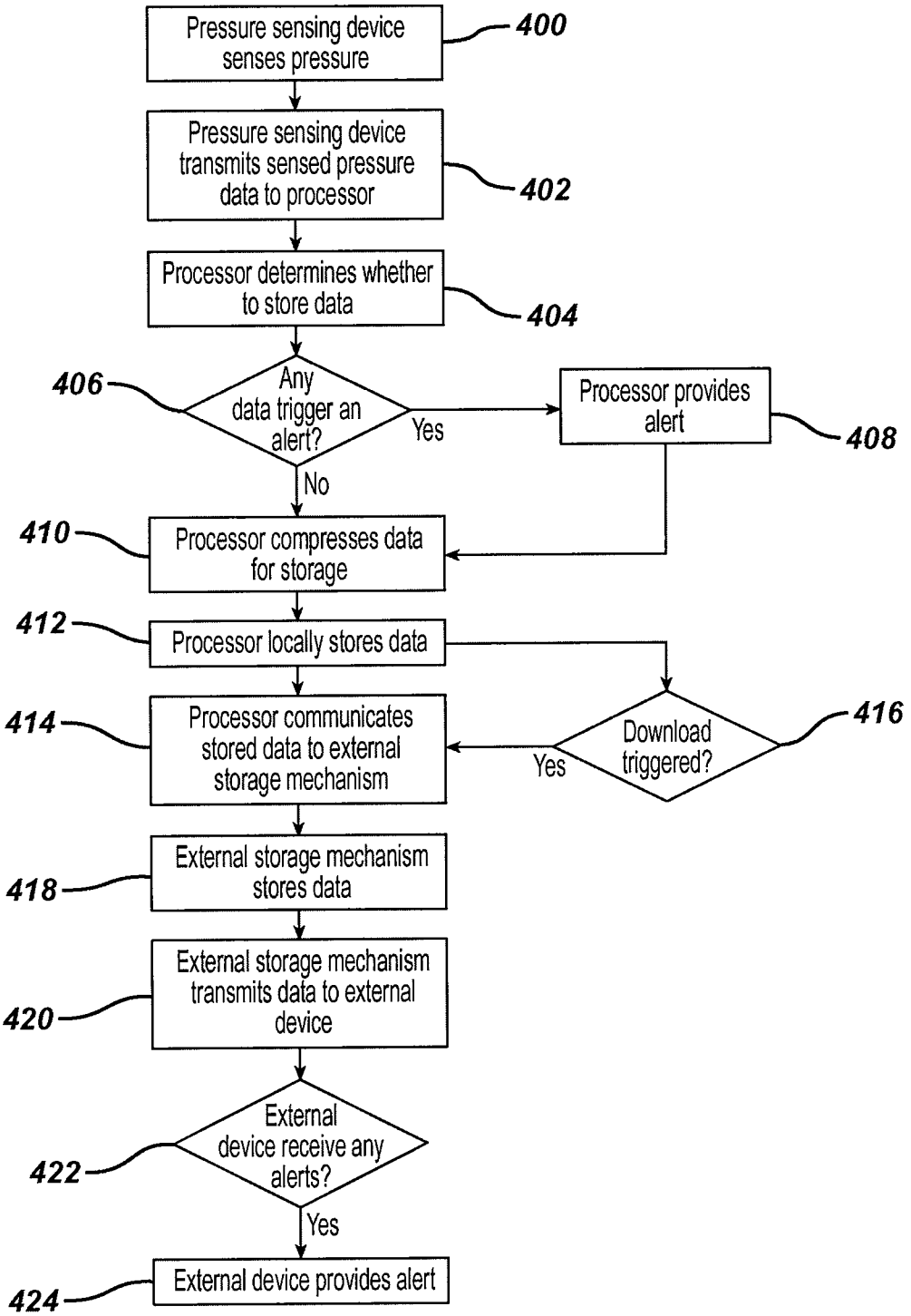

Pressure sensing device senses pressure
400
Pressure sensing device transmits sensed pressure data to processor
402
Processor determines whether to store data
404
406
Any data trigger an alert?
Yes
Processor provides alert
408
No
410
Processor compresses data for storage
412
Processor locally stores data
414
Processor communicates stored data to external storage mechanism
Download triggered?
416
Yes
418
External storage mechanism stores data
420
External storage mechanism transmits data to external device
422
External device receive any alerts?
Yes
424
External device provides alert

FIG. 9

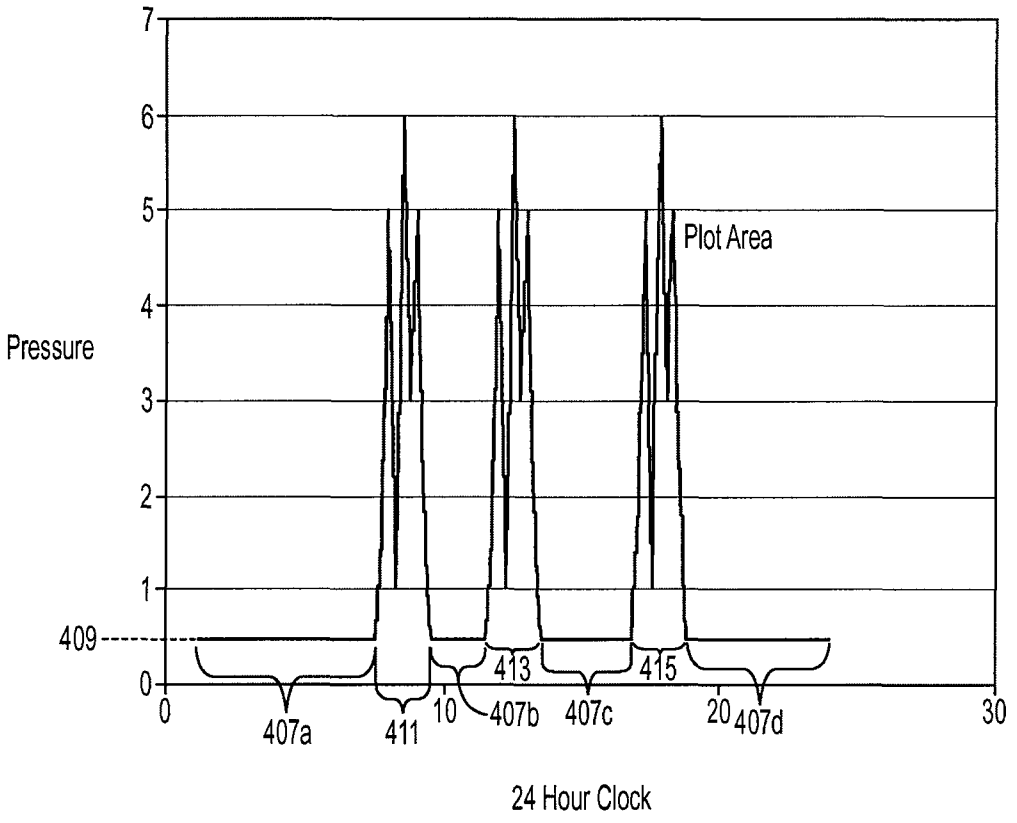

7
6
5
4
3
2
1
0
Pressure
409
Plot Area
413
415
0
10
20
30
407a
411
407b
407c
407d
24 Hour Clock

FIG. 10

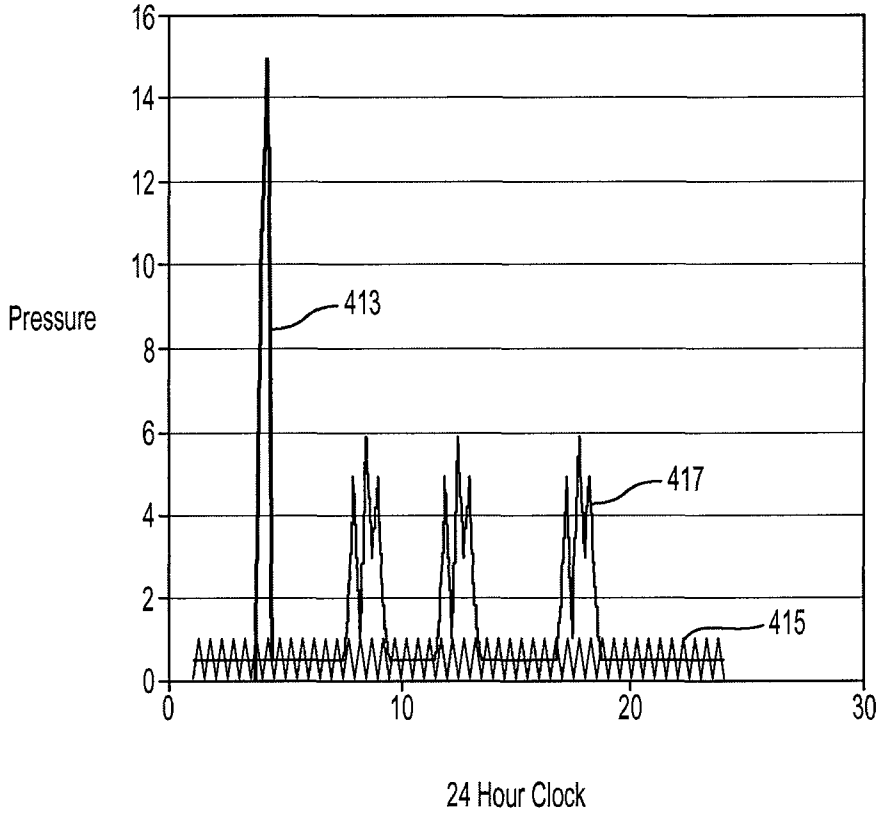


FIG. 11

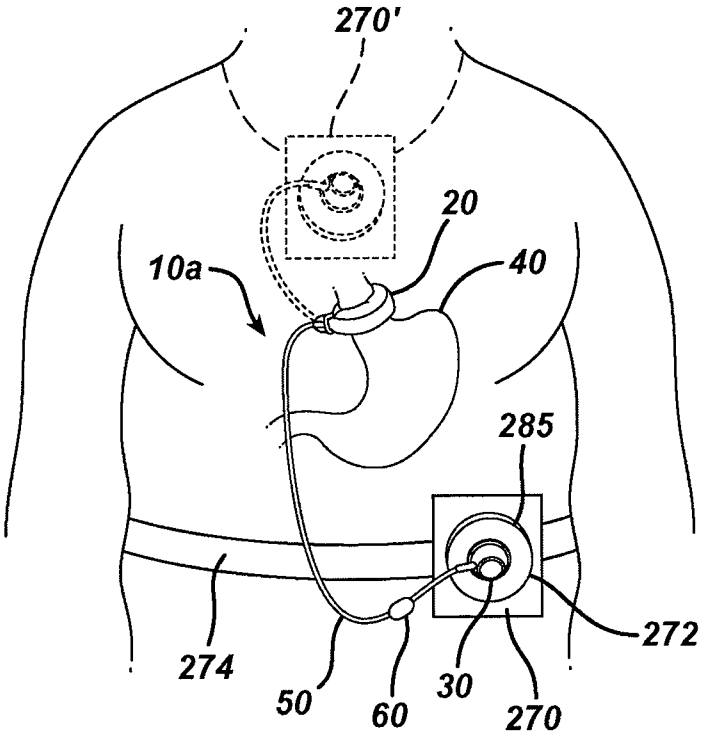

270'
20
10a
40
285
272
274
50
60
30
270

FIG. 12

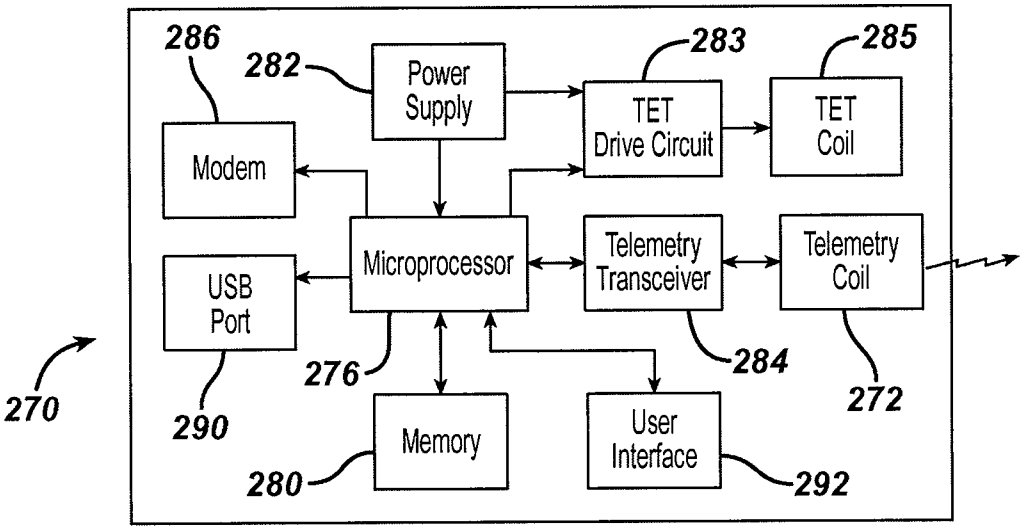

286
282
Power Supply
283
TET Drive Circuit
285
TET Coil
Modem
Microprocessor
Telemetry Transceiver
Telemetry Coil
USB Port
276
284
272
270
290
Memory
User Interface
280
292

FIG. 13

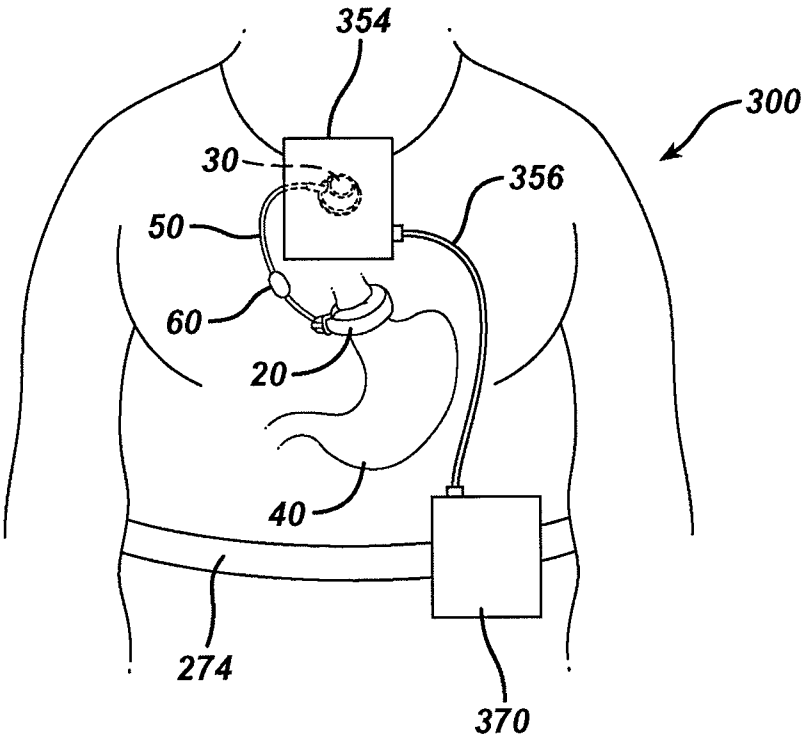
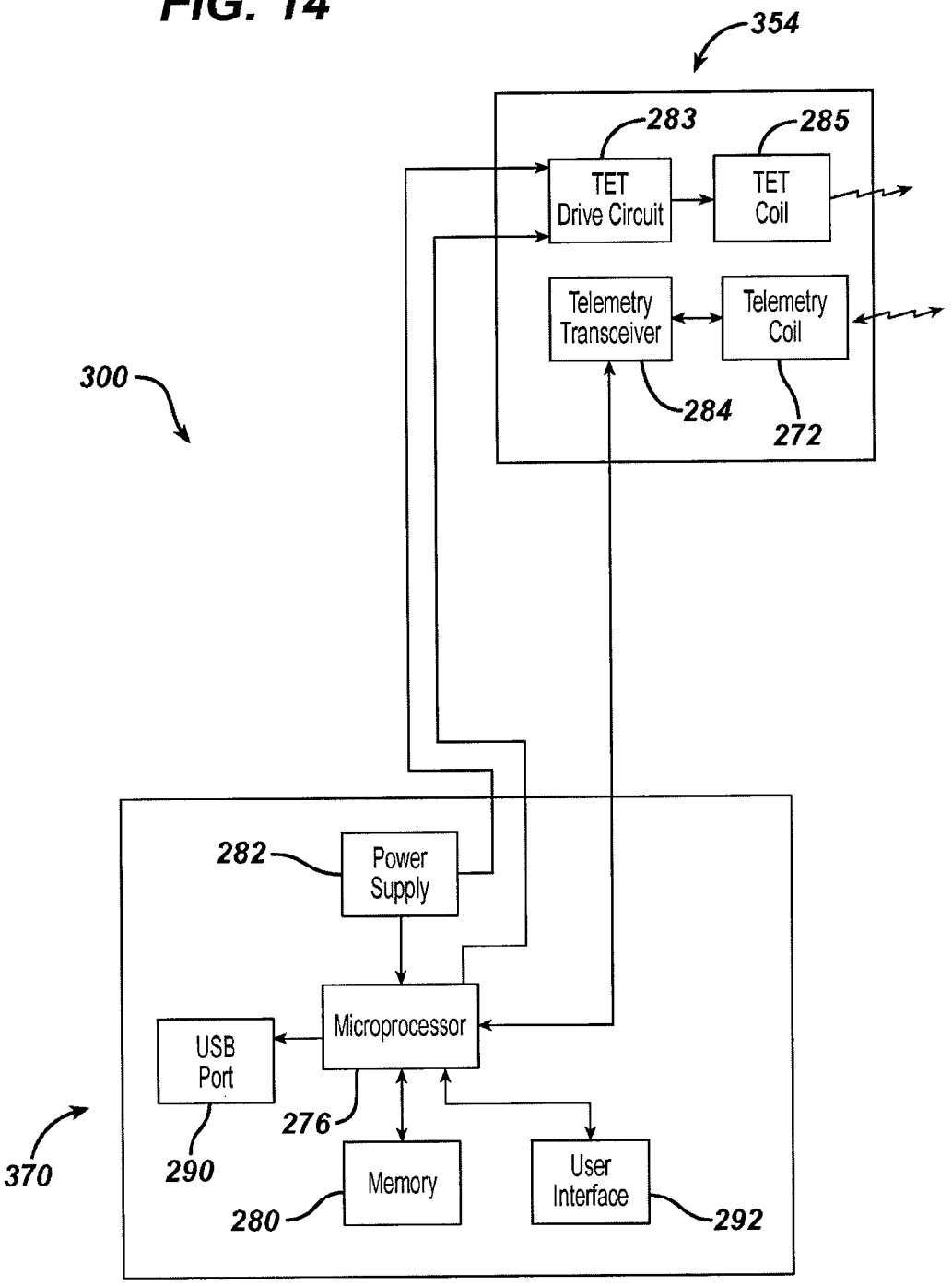


FIG. 14


354
283
285
TET Drive Circuit
TET Coil
Telemetry Transceiver
Telemetry Coil
284
272
300
282
Power Supply
Microprocessor
USB Port
276
290
370
Memory
280
User Interface
292

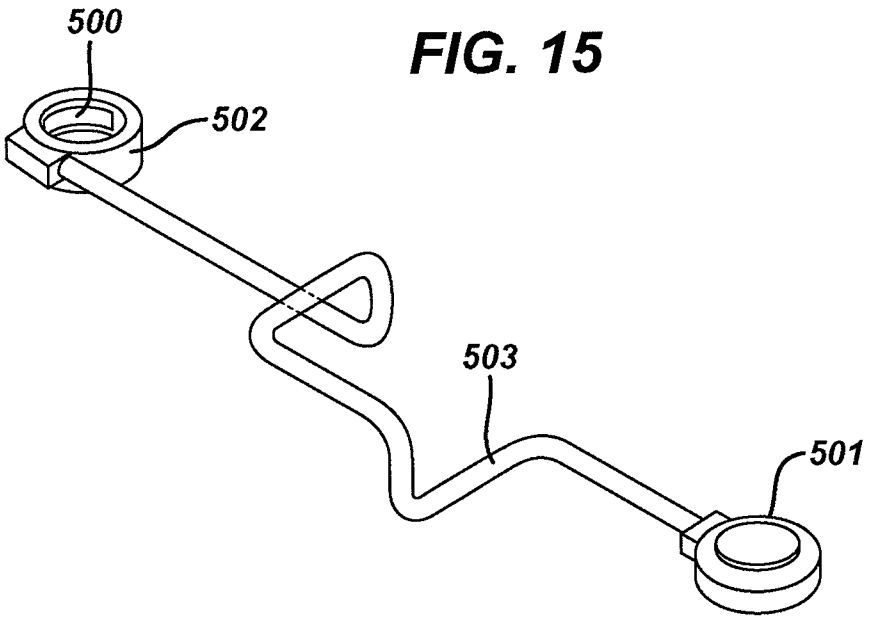


FIG. 15

FIG. 16

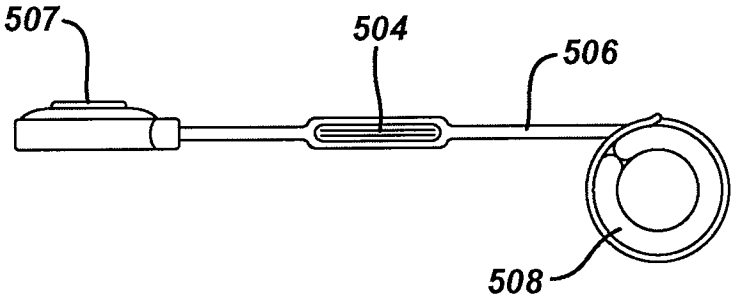


FIG. 17

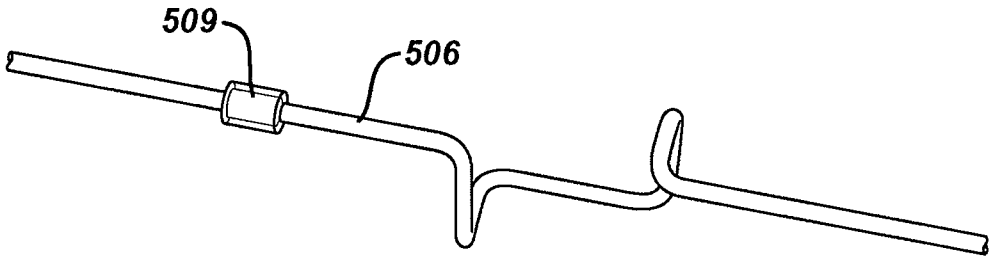
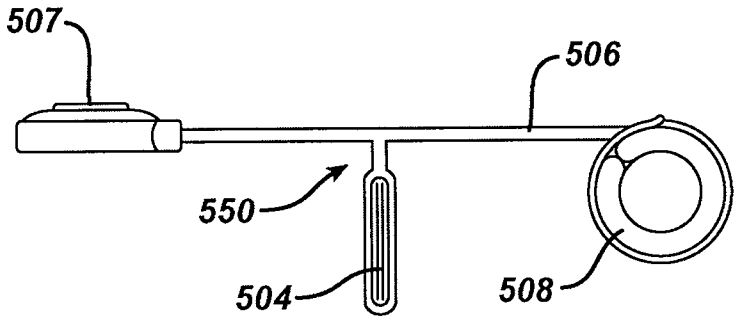


FIG. 18



GASTRIC RESTRICTION DEVICE DATA HANDLING DEVICES AND METHODS

FIELD OF THE INVENTION

The present invention relates to devices and methods for handling data related to implantable restriction devices.

BACKGROUND OF THE INVENTION

Obesity is becoming a growing concern, particularly in the United States, as the number of obese people continues to increase and more is learned about the negative health effects of obesity. Morbid obesity, in which a person is 100 pounds or more over ideal body weight, in particular poses significant risks for severe health problems. Accordingly, a great deal of attention is being focused on treating obese patients. One method of treating morbid obesity has been to place a restriction device, such as an elongated band, about the upper portion of the stomach. Gastric bands have typically comprised a fluid-filled elastomeric balloon with fixed endpoints that encircles the stomach just inferior to the esophageal-gastric junction to form a small gastric pouch above the band and a reduced stoma opening in the stomach. When fluid is infused into the balloon, the band expands against the stomach creating a food intake restriction or stoma in the stomach. To decrease this restriction, fluid is removed from the band. The effect of the band is to reduce the available stomach volume and thus the amount of food that can be consumed before becoming "full."

Food restriction devices have also comprised mechanically adjusted bands that similarly encircle the upper portion of the stomach. These bands include any number of resilient materials or gearing devices, as well as drive members, for adjusting the bands. Additionally, gastric bands have been developed that include both hydraulic and mechanical drive elements. An example of such an adjustable gastric band is disclosed in U.S. Pat. No. 6,067,991, entitled "Mechanical Food Intake Restriction Device" which issued on May 30, 2000, and is incorporated herein by reference. It is also known to restrict the available food volume in the stomach cavity by implanting an inflatable elastomeric balloon within the stomach cavity itself. The balloon is filled with a fluid to expand against the stomach walls and, thereby, decrease the available food volume within the stomach.

With each of the above-described food restriction devices, safe, effective treatment requires that the device be regularly monitored and adjusted to vary the degree of restriction applied to the stomach. With banding devices, the gastric pouch above the band will substantially increase in size following the initial implantation. Accordingly, the stoma opening in the stomach must initially be made large enough to enable the patient to receive adequate nutrition while the stomach adapts to the banding device. As the gastric pouch increases in size, the band may be adjusted to vary the stoma size. In addition, it is desirable to vary the stoma size in order to accommodate changes in the patient's body or treatment regime, or in a more urgent case, to relieve an obstruction or severe esophageal dilatation. Traditionally, adjusting a hydraulic gastric band required a scheduled clinician visit during which a Huber needle and syringe were used to penetrate the patient's skin and add or remove fluid from the balloon via an injection port. More recently, implantable pumps have been developed which enable non-invasive adjustments of the band. An external programmer communicates with the implanted pump using telemetry to control the pump. During a scheduled visit, a physician places a hand-held portion of the programmer near the gastric implant and transmits power and command signals to the implant. The implant in turn adjusts the fluid levels in the band and transmits a response command to the programmer.

During these gastric band adjustments, it has been difficult to determine how the adjustment is proceeding, and whether the adjustment will have the intended effect. In an attempt to determine the efficacy of an adjustment, some physicians have utilized fluoroscopy with a Barium swallow as the adjustment is being performed. However, fluoroscopy is both expensive and undesirable due to the radiation doses incurred by both the physician and patient. Other physicians have instructed the patient to drink a glass of water during or after the adjustment to determine whether the water can pass through the adjusted stoma. This method, however, only assures that the patient is not obstructing, and does not provide any information about the efficacy of the adjustment. Oftentimes, a physician may simply adopt a "try as you go" method based upon their prior experience, and the results of an adjustment may not be discovered until hours or days later, when the patient experiences a complete obstruction to the stomach cavity, or the band induces erosion of the stomach tissue due to excessive interface pressures against the band.

Additionally, it can be advantageous to acquire data indicating the pressure in a gastric band before, during, and/or after pressure adjustment for adjustment, diagnostic, monitoring, or other purposes. It can be further advantageous to store such pressure data and/or communicate it to an external location. However, data storage space can be limited, and power to communicate data can be resource-intensive.

Accordingly, methods and devices are provided for use with a gastric restriction device, and in particular for handling data gathered in relation to a gastric restriction device.

SUMMARY OF THE INVENTION

The present invention generally provides devices and methods for handling data related to implantable restriction devices. In one embodiment, a restriction system for forming a restriction in a patient is provided that includes an implantable restriction device that can form a restriction in a patient and an implantable sensing device in communication with the implantable restriction device. The implantable sensing device can sense a parameter related to the implantable restriction device and communicate a selected portion of data to an external device considering a variation of data from a nominal parameter value related to the implantable restriction device. The parameter can include at least one of, for example, pulse count, pulse width, and amplitude. In some embodiments, the selected portion of data is compressed prior to communication of the selected portion of data to the external device.

The sensing device can be implemented in a variety of ways. For example, the sensing device can communicate data to the external device when the external device telemetrically provides at least some power to the sensing device. As another example, the sensing device can discard data that substantially equals a nominal value. For yet another example, the sensing device can communicate a selected portion of data based on whether the data includes a value within a defined range of values. As still another example, the sensing device can compare data with a nominal value. For another example, the sensing device can store the selected portion of data prior to communication of the selected portion of data to the external device.

In another embodiment, a restriction system for forming a restriction in a patient includes an implantable restriction

device that can form a restriction in a patient, an implantable pressure sensing device in communication with the implantable restriction device that can sense a pressure within the implantable restriction device, and a processor (which can be included in the implantable pressure sensing device) that can determine whether to store any of the sensed pressure data prior to communicating any of the sensed pressure data to an external reading device. The processor, in some embodiments, can have a download of stored data to the external reading device triggered when the external reading device is moved in proximity of the implantable pressure sensing device. In some embodiments, the system can also include an external storage mechanism that can store sensed pressure data, communicate stored pressure data to an external device, and, optionally, be removably attached to the patient.

In other aspects, a method of forming a restriction in a patient is provided. The method includes using an implantable pressure sensing device to obtain pressure data related to a pressure within an implantable restriction device that can form a restriction in a patient, storing at least a portion of obtained pressure data at the implantable pressure sensing device, and triggering a download of stored pressure data when an external device is moved in proximity of the implantable pressure sensing device. The obtained pressure data stored at the implantable pressure sensing device can include pressure values that exceed a nominal pressure within the implantable restriction device. In some embodiments, the method can also include compressing at least a portion of obtained pressure data prior to storing the at least a portion of the obtained pressure data at the implantable pressure sensing device. The compression can be performed using at least one compression technique, such as storing difference values, using a quantization table, using run-length coding, and using Huffman coding.

In another embodiment, a method of forming a restriction in a patient includes obtaining pressure data related to a pressure within an implantable restriction device that can form a restriction in a patient. In some embodiments, obtaining pressure data includes reducing a rate of pressure data gathering during a determined period. The method further includes determining a portion of the pressure data to retain prior to communicating pressure data to an external reading device. Determining a portion of the pressure data to retain can include determining if any of the obtained pressure data includes a value within a defined range of pressure values, determining to retain any of the obtained pressure data that exceeds a nominal pressure within the implantable restriction device, and/or processing the obtained pressure data using a pressure sensing device (e.g., a processor) coupled to the implantable restriction device and configured to obtain the pressure data. An alert for communication to the external reading device can be generated if any of the obtained pressure data includes a value that exceeds a threshold pressure value. In some embodiments, the method also includes storing only the portion of the pressure data determined to be retained prior to communicating pressure data to the external reading device. In still other embodiments, the method also includes compressing the portion of the pressure data determined to be retained prior to storing the portion of the pressure data determined to be retained.

In yet another embodiment, a method of forming a restriction in a patient includes using an implantable pressure sensing device to obtain pressure data related to a pressure within an implantable restriction device that can form a restriction in a patient, storing the obtained pressure data at the implantable pressure sensing device, and compressing the obtained pressure data prior to storing the obtained pressure data. The obtained pressure data can be compressed using at least one compression technique, such as storing difference values, using a quantization table, using run-length coding, and using Huffman coding. The method can also include communicating at least a portion of the compressed and stored pressure data from the pressure sensing device to an external device.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will be more fully understood from the following detailed description taken in conjunction with the accompanying drawings, in which:

FIG. **1**A is a schematic diagram of an embodiment of a food intake restriction system;

FIG. **1**B is a perspective view of an embodiment of an implantable portion of the food intake restriction system of FIG. **1**A;

FIG. **2**A is a perspective view of the food intake restriction device of FIG. **1**A;

FIG. **2**B is a schematic diagram of the food intake restriction device of FIG. **2**A applied about the gastro-esophageal junction of a patient;

FIG. **3** is a perspective view of an embodiment of the injection port housing of FIG. **1**A;

FIG. **4** is a perspective view of an embodiment of the sensor housing of FIG. **1**A;

FIG. **5** illustrates an embodiment of the sensor housing of FIG. **1**A;

FIG. **6** is a schematic of an embodiment of a variable resistance circuit for the pressure sensor of FIG. **5**;

FIG. **7** is a block diagram showing an embodiment of internal and external components of the food intake restriction device of FIG. **1**A;

FIG. **8** is a flow diagram showing an embodiment of a data handling protocol for the food intake restriction device of FIG. **1**A;

FIG. **9** is a graphical representation of a pressure measurement from the pressure sensor of FIG. **5**;

FIG. **10** is a graphical representation of another pressure measurement from the pressure sensor of FIG. **5**;

FIG. **11** is a schematic diagram of an embodiment of a data logger for recording pressure measurements related to the food intake restriction device of FIG. **1**A;

FIG. **12** is a block diagram showing an embodiment of components of the data logger of FIG. **11**;

FIG. **13** is a schematic diagram of an embodiment of a data logging system for recording pressure measurements related to the food intake restriction device of FIG. **1**A;

FIG. **14** is a is a block diagram showing an embodiment of components of the data logging system of FIG. **13**;

FIG. **15** is a perspective view of an embodiment of a gastric band system with a pressure sensor positioned along a catheter;

FIG. **16** is a schematic view of an embodiment of a gastric band system with a pressure sensor positioned within a catheter;

FIG. **17** is a perspective view of another embodiment of a gastric band system with a pressure sensor positioned along a catheter; and

FIG. **18** is a schematic view of an embodiment of a gastric band system with a "T"-shaped pressure sensor and catheter configuration.

DETAILED DESCRIPTION OF THE INVENTION

Certain exemplary embodiments will now be described to provide an overall understanding of the principles of the

structure, function, manufacture, and use of the devices and methods disclosed herein. One or more examples of these embodiments are illustrated in the accompanying drawings. Those skilled in the art will understand that the devices and methods specifically described herein and illustrated in the accompanying drawings are non-limiting exemplary embodiments and that the scope of the present invention is defined solely by the claims. The features illustrated or described in connection with one exemplary embodiment may be combined with the features of other embodiments. Such modifications and variations are intended to be included within the scope of the present invention.

The present invention generally provides devices and methods for handling data related to implantable restriction devices. In general, the devices and methods allow collection, analysis, storage, and transmission of measurements related to any parameter related to implantable restriction devices, such as pressure, pulse count, pulse width, and amplitude. While the methods and devices discussed herein can relate to any sensed data parameter, in an exemplary embodiment, the measurements relate to pressure. Pressure measurements can help accurately evaluate the performance of and determine any advisable pressure adjustments of an implantable restriction device, but not all collected pressure data may be helpful in making such evaluations and determinations. Furthermore, handling pressure measurement data can drain power resources of an implantable restriction system and can use costly, physically bulky, and electronically large data storage space. Pressure measurement data can be compressed before storing it, thereby using less storage space, time, power, and/or bandwidth for communication than for the corresponding, uncompressed data. Pressure measurement data can also be compressed prior to communication. The data can be compressed and directly transmitted, or the compressed data stored in memory can be recalled and communicated wirelessly when interrogated. Additionally, not all pressure data need be recorded or retained. Not recording or retaining all pressure data, such as data substantially equaling a resting or nominal pressure of the implantable restriction device indicative of little to no pressure variation and data indicative of isolated, non-recurring events, can save storage space for potentially more analytically valuable pressure measurement data and reduce the amount of physical and/or electronic storage space used for pressure measurements. Any pressure measurement data that is recorded can be transmitted to an external device using power telemetrically provided or inductively coupled by the external device, thereby reducing or eliminating power supply resources local to the storage location of recorded data.

While the present invention can be used with a variety of restriction systems known in the art, FIG. **1**A illustrates one exemplary embodiment of a food intake restriction system **10** in use in a patient. As shown, the system **10** generally includes an implantable portion **10***a* and an external portion **10***b*. FIG. **1**B illustrates the implantable portion **10***a* outside of a patient. As shown, the implantable portion **10***a* includes an adjustable gastric band **20** that is configured to be positioned around the upper portion of a patient's stomach **40**, and an injection port housing **30** that is fluidly coupled to the adjustable gastric band **20**, e.g., via a catheter **50**. The injection port **30** is adapted to allow fluid to be introduced into and removed from the gastric band **20** to thereby adjust the size of the band **20** and thus the pressure applied to the stomach **40**. The injection port **30** can thus be implanted at a location within the body that is accessible through tissue. Typically, injection ports are positioned in the lateral subcostal region of the patient's abdomen under the skin and layers of fatty tissue. Surgeons also typically implant injection ports on the sternum of the patient.

The internal portion **10***a* can also include a sensing or measuring device that is in fluid communication with the closed fluid circuit in the implantable portion **10***a*. In one embodiment, the sensing device is a pressure sensing device configured to measure the fluid pressure of the closed fluid circuit. While the pressure measuring device can have various configurations and it can be positioned anywhere along the internal portion **10***a*, including within the injection port **30** and as described further below, in the illustrated embodiment the pressure measuring device is in the form of a pressure sensor that is disposed within a sensor housing **60** positioned adjacent to the injection port **30**. The catheter **50** can include a first portion that is coupled between the gastric band **20** and the pressure sensor housing **60**, and a second portion that is coupled between the pressure sensor housing **60** and the injection port **30**. While it is understood that the sensing device can be configured to obtain data relating to one or more relevant parameters, generally it will be described herein in a context of a pressure sensing device.

In addition to sensing pressure of fluid within the internal portion **10***a* as described herein, pressure of fluid within the esophagus and/or the stomach **40** can also be sensed using any suitable device, such as an endoscopic manometer. By way of non-limiting example, such fluid pressure measurements can be compared against measured pressure of fluid within the internal portion **10***a* before, during, and/or after adjustment of pressure within the internal portion **10***a*. Other suitable uses for measured pressure within the esophagus and/or the stomach **40** will be appreciated by those skilled in the art.

As further shown in FIG. **1**A, the external portion **10***b* generally includes a data reading device **70** that is configured to be positioned on the skin surface above the sensor housing **60** (which can be implanted beneath thick tissue, e.g., over 10 cm thick) to non-invasively communicate with the sensor housing **60** and thereby obtain data (e.g., pressure) measurements. The data reading device **70** can optionally be electrically coupled (wirelessly or wired, as in this embodiment via an electrical cable assembly **80**) to a control box **90** that can display the pressure measurements and/or other data obtained from the data reading device **70**. While shown in this example as located local to the patient, the control box **90** can be at a location local to or remote from the patient, as explained further below.

FIG. **2**A shows the gastric band **20** in more detail. While the gastric band **20** can have a variety of configurations, and various gastric bands currently known in the art can be used with the present invention, in the illustrated embodiment the gastric band **20** has a generally elongate shape with a support structure **22** having first and second opposite ends **20***a*, **20***b* that can be formed in a loop such that the ends are secured to each other. Various mating techniques can be used to secure the ends **20***a*, **20***b* to one another. In the illustrated embodiment, the ends **20***a*, **20***b* are in the form of straps that mate together, with one laying on top of the other. In another embodiment, illustrated, for example, in FIGS. **1**B and **2**B, a support structure at one end of the gastric band **20** can include an opening through which the other end of the gastric band **20** can feed through to secure the ends to one another. The gastric band **20** can also include a variable volume member, such as an inflatable balloon **24**, that is disposed or formed on one side of the support structure **22** and that is configured to be positioned adjacent to tissue. The balloon **24** can expand or

contract against the outer wall of the stomach to form an adjustable stoma for controllably restricting food intake into the stomach.

A person skilled in the art will appreciate that the gastric band can have a variety of other configurations. Moreover, the various methods and devices disclosed herein have equal applicability to other types of implantable bands. For example, bands are used for the treatment of fecal incontinence, as described in U.S. Pat. No. 6,461,292 which is hereby incorporated by reference. Bands can also be used to treat urinary incontinence, as described in U.S. Publication No. 2003/0105385 which is hereby incorporated by reference. Bands can also be used to treat heartburn and/or acid reflux, as disclosed in U.S. Pat. No. 6,470,892 which is hereby incorporated by reference. Bands can also be used to treat impotence, as described in U.S. Publication No. 2003/0114729 which is hereby incorporated by reference.

FIG. **2**B shows the adjustable gastric band **20** applied about the gastro-esophageal junction of a patient. As shown, the band **20** at least substantially encloses the upper portion of the stomach **40** near the junction with the patient's esophagus **42**. After the band **20** is implanted, preferably in the deflated configuration wherein the band **20** contains little or no fluid, the band **20** can be inflated, e.g., using saline, to decrease the size of the stoma opening. A person skilled in the art will appreciate that various techniques, including mechanical and electrical techniques, can be used to adjust the band **20**. FIG. **2**B also shows an alternate location of a pressure sensor **41**, disposed in a buckle **43** of the band **20**.

The fluid injection port **30** can also have a variety of configurations. In the embodiment shown in FIG. **3**, the injection port **30** has a generally cylindrical housing with a distal or bottom surface and a perimeter wall extending proximally from the bottom surface and defining a proximal opening **32**. The proximal opening **32** can include a needle-penetrable septum **34** extending there across and providing access to a fluid reservoir (not visible in FIG. **3**) formed within the housing. The septum **34** is preferably placed in a proximal enough position such that the depth of the reservoir is sufficient enough to expose the open tip of a needle, such as a Huber needle, so that fluid transfer can take place. The septum **34** is preferably arranged so that it will self seal after being punctured by a needle and the needle is withdrawn. As further shown in FIG. **3**, the port **30** can further include a catheter tube connection member **36** that is in fluid communication with the reservoir and that is configured to couple to a catheter (e.g., the catheter **50**). A person skilled in the art will appreciate that the housing can be made from any number of materials, including stainless steel, titanium, or polymeric materials, and the septum **34** can likewise be made from any number of materials, including silicone.

The reading device **70** can also have a variety of configurations, and one exemplary pressure reading device is disclosed in more detail in commonly-owned U.S. Publication No. 2006/0189888 and U.S. Publication No. 2006/0199997, which are hereby incorporated by reference. In general, the data reading device **70** can non-invasively measure the pressure of the fluid within the implanted portion **10***a* even when the pressure sensing device is implanted beneath thick (at least over 10 cm) subcutaneous fat tissue. The physician can hold the reading device **70** against the patient's skin near the location of the sensor housing **60**, and/or other pressure sensing device location(s), and observe the pressure reading on a display on the control box **90**. The data reading device **70** can also be removably attached to the patient, as discussed further below, such as during a prolonged examination, using straps, adhesives, and other well-known methods. The data reading device **70** can operate through conventional cloth or paper surgical drapes, and can also include a disposal cover (not shown) that may be replaced for each patient.

As indicated above, the system **10** can also include a pressure measuring device in communication with the closed fluid circuit and configured to measure pressure (e.g., fluid pressure) which corresponds to the amount of restriction applied by the adjustable gastric band **20** to the patient's stomach **40**. Measuring the pressure enables a person (e.g., a physician, a nurse, a patient, etc.) to evaluate the efficacy and functionality of the restriction created by a band adjustment. In the illustrated embodiment, as shown in FIG. **4**, the pressure measuring device is in the form of a pressure sensor **62** disposed within the sensor housing **60**. The pressure measuring device can, however, be disposed anywhere within the closed hydraulic circuit of the implantable portion, and various exemplary locations and configurations are disclosed in more detail in commonly-owned U.S. Publication No. 2006/0211913 entitled "Non-Invasive Pressure Measurement In a Fluid Adjustable Restrictive Device," filed on Mar. 7, 2006, and hereby incorporated by reference. In general, the illustrated sensor housing **60** includes an inlet **60***a* and an outlet **60***b* that are in fluid communication with the fluid in the implantable portion **10***a*. An already-implanted catheter **50** can be retrofitted with the sensor housing **60**, such as by severing the catheter **50** and inserting barbed connectors (or any other connectors, such as clamps, clips, adhesives, welding, etc.) into the severed ends of the catheter **50**. The sensor **62** can be disposed within the housing **60** and be configured to respond to fluid pressure changes within the hydraulic circuit and convert the pressure changes into a usable form of data.

Various pressure sensors known in the art can be used as the pressure sensor **62**, such as a wireless pressure sensor provided by CardioMEMS, Inc. of Atlanta, Ga., though a suitable MEMS pressure sensor may be obtained from any other source, including but not limited to Integrated Sensing Systems, Inc. (ISSYS) of Ypsilanti, Mich. and Remon Medical Technologies, Inc. of Waltham, Mass. One exemplary MEMS pressure sensor is described in U.S. Pat. No. 6,855,115, the disclosure of which is incorporated by reference herein for illustrative purposes only. It will also be appreciated by a person skilled in the art that suitable pressure sensors can include, but are not limited to, capacitive, piezoresistive, silicon strain gauge, or ultrasonic (acoustic) pressure sensors, as well as various other devices capable of measuring pressure.

One embodiment of a configuration of the sensor housing **60** having the sensor **62** disposed within it is shown in FIG. **5**. The sensor housing **60** in this example includes a motherboard that can serve as a hermetic container to prevent fluid from contacting any elements disposed within the sensor housing **60**, except as discussed for the sensor **62**. The sensor housing **60** can be made from any biocompatible material appropriate for use in a body, such as a polymer, biocompatible metal, and other similar types of material. Furthermore, the sensor housing **60** can be made from any one or more of transparent (as shown in FIG. **5**), opaque, semi-opaque, and radio-opaque materials. A circuit board **64** including, among other elements, a microcontroller **65** (e.g., a processor), can also be disposed within the housing **60** to help process and communicate pressure measurements gathered by the sensor **62**, and also possibly other data related to the band **20**. As further discussed below, the circuit board **64** can also include a transcutaneous energy transfer (TET)/telemetry coil and a capacitor. Optionally, a temperature sensor can be integrated into the circuit board **64**. The microcontroller **65**, the TET/telemetry coil, the capacitor, and/or the temperature sensor can be in communication via the circuit board **64** or via any

other suitable component(s). The TET/telemetry coil and capacitor can collectively form a tuned tank circuit for receiving power from the external portion **10***b*, and transmitting pressure measurements to a pressure reading device, e.g., the reading device **70**. Moreover, to the extent that a telemetry component associated with the pressure sensor **62** is unable to reach a telemetry device external to the patient without some assistance, such assistance can be provided by any suitable number of relays (not shown) or other devices.

Fluid can enter the sensor housing **60** through an opening **66** located anywhere on the housing's surface (here, its bottom surface) and come into contact with a pressure sensing surface **68** of the sensor **62**. The sensor **62** is typically hermetically sealed to the motherboard such that fluid entering the opening **66** cannot infiltrate and affect operation of the sensor **62** except at the pressure sensing surface **68**. The sensor **62** can measure the pressure of fluid coming into contact with the pressure sensing surface **68** as fluid flows in and out of the opening **66**. For example, the pressure sensing surface **68** can include a diaphragm having a deformable surface such that when fluid flows through the opening **66**, the fluid impacts the surface of the diaphragm, causing the surface to mechanically displace. The mechanical displacement of the diaphragm can be converted to an electrical signal by a variable resistance circuit including a pair of variable resistance, silicon strain gauges. One strain gauge can be attached to a center portion of diaphragm to measure the displacement of the diaphragm, while the second, matched strain gauge can be attached near the outer edge of diaphragm. The strain gauges can be attached to the diaphragm with adhesives or can be diffused into the diaphragm structure. As fluid pressure within band **20** fluctuates, the surface of the diaphragm can deform up or down, thereby producing a resistance change in the center strain gauge.

One embodiment of a variable resistance circuit for the sensor **62** is shown in FIG. **6**. The circuit includes first and second strain gauges **96**, **98** that form the top two resistance elements of a half-compensated, Wheatstone bridge circuit **100**. As the first strain gauge **96** reacts to the mechanical displacements of the sensor's diaphragm, the changing resistance of the first gauge **96** changes the potential across the top portion of the bridge circuit **100**. The second strain gauge **98** is matched to the first strain gauge **96** and athermalizes the Wheatstone bridge circuit **100**. First and second differential amplifiers **102**, **104** are connected to the bridge circuit **100** to measure the change in potential within the bridge circuit **100** due to the variable resistance strain gauges **96**, **98**. In particular, the first differential amplifier **102** measures the voltage across the entire bridge circuit **100**, while the second differential amplifier **104** measures the differential voltage across the strain gauge half of bridge circuit **100**. The greater the differential between the strain gauge voltages, for a fixed voltage across the bridge, the greater the pressure difference. Output signals from the differential amplifiers **102**, **104** can be applied to the microcontroller **65** integrated into the circuit board **64**, and the microcontroller **65** can transmit the measured pressure data to a device external to the patient. If desired, a fully compensated Wheatstone bridge circuit can also be used to increase the sensitivity and accuracy of the pressure sensor **62**. In a fully compensated bridge circuit, four strain gauges are attached to the surface of diaphragm rather than only two strain gauges.

FIG. **7** illustrates one embodiment of components included in the internal and external portions **10***a*, **10***b* of the food intake restriction system **10**. As shown in FIG. **7**, the external portion **10***b* includes a primary TET coil **130** for transmitting a power signal **132** to the internal portion **10***a*. A telemetry coil **144** is also included for transmitting data signals to the internal portion **10***a*. The primary TET coil **130** and the telemetry coil **144** combine to form an antenna, e.g., the reading device **70**. The external portion **10***b*, e.g., the control box **90**, includes a TET drive circuit **134** for controlling the application of power to the primary TET coil **130**. The TET drive circuit **134** is controlled by a microprocessor **136** having an associated memory **138**. A graphical user interface **140** is connected to the microprocessor **136** for inputting patient information and displaying and/or printing data and physician instructions. Through the user interface **140**, a user such as the patient or a clinician can transmit an adjustment request to the physician and also enter reasons for the request. Additionally, the user interface **140** can enable the patient to read and respond to instructions from the physician and/or pressure measurement alerts, as discussed further below.

The external portion **10***b* also includes a primary telemetry transceiver **142** for transmitting interrogation commands to and receiving response data, including sensed pressure data, from the implanted microcontroller **65**. The primary transceiver **142** is electrically connected to the microprocessor **136** for inputting and receiving command and data signals. The primary transceiver **142** drives the telemetry coil **144** to resonate at a selected RF communication frequency. The resonating circuit can generate a downlink alternating magnetic field **146** that transmits command data to the microcontroller **65**. Alternatively, the transceiver **142** can receive telemetry signals transmitted from a secondary TET/telemetry coil **114** in the internal portion **10***a*. The received data can be stored in the memory **138** associated with the microprocessor **136**. A power supply **150** can supply energy to the control box **90** in order to power element(s) in the internal portion **10***a*. An ambient pressure sensor **152** is connected to microprocessor **136**. The microprocessor **136** can use a signal from the ambient pressure sensor **152** to adjust the received pressure measurements for variations in atmospheric pressure due to, for example, variations in barometric conditions or altitude, in order to increase the accuracy of pressure measurements.

FIG. **7** also illustrates components of the internal portion **10***a*, which in this embodiment are included in the sensor housing **60** (e.g., on the circuit board **64**). As shown in FIG. **7**, the secondary TET/telemetry coil **114** receives the power/communication signal **132** from the external antenna. The secondary coil **114** forms a tuned tank circuit that is inductively coupled with either the primary TET coil **130** to power the implant or the primary telemetry coil **144** to receive and transmit data. A telemetry transceiver **158** controls data exchange with the secondary coil **114**. Additionally, the internal portion **10***a* includes a rectifier/power regulator **160**, the microcontroller **65**, a memory **162** associated with the microcontroller **65**, a temperature sensor **112**, the pressure sensor **62**, and a signal conditioning circuit **164**. The implanted components can transmit pressure measurements (with or without adjustments due to temperature, etc.) from the sensor **62** to the control box **90** via the antenna (the primary TET coil **130** and the telemetry coil **144**). Pressure measurements can be stored in the memory **138**, adjusted for ambient pressure, shown on a display on the control box **90**, and/or transmitted, possibly in real time, to a remote monitoring station at a location remote from the patient.

As illustrated in a process shown in FIG. **8**, the sensor housing **60** can generally sense pressure within the gastric band **20**, locally store the sensed pressure data (e.g., at the memory **162**), and communicate at least a portion of the sensed pressure data to an external device such as the control box **90** via the reading device **70**. While the pressure sensor **62** can communicate all pressure data it senses to the reading

device **70**, communicating only a selected portion of the pressure data (e.g., a portion less than the entirety of the sensed pressure data) can use less power, require less physical and/or electronic storage space in the sensor housing **60**, and/or reduce costs.

While the process shown in FIG. **8** is discussed with relation to the elements included in FIGS. **1A-7**, a person skilled in the art will appreciate that the process can be modified to include more or fewer elements, reorganized or not, and can be performed in the system **10** or in another, similar system having other, similar elements. For example, the microcontroller **65** processes instructions in this embodiment, but any processor configured to process instructions for a system (e.g., a central processing unit, a microprocessor, a digital signal processing unit, application specific integrated circuits (ASICs), a state machine, an analog computer, an optical or photonic computer, logic circuitry, etc.) can be used. Furthermore, the sensor **62** in this illustrated embodiment measures fluid pressure, but any sensed pressure data related to the band **20** can be handled as discussed herein.

In use, the sensor housing **60** can sense **400** a pressure of fluid disposed within the band **20** using the sensor **62**. The sensor **62** can transmit measured signals to the signal conditioning circuit **164**, which can amplify the signals before the signal conditioning circuit **164** transmits **402** the measured pressure data to the microcontroller **65**. Alternatively, in some embodiments, the sensor **62** can directly transmit signals to the microcontroller **65**. In this embodiment, the pressure sensor **62** provides pressure data at an update rate of approximately 20 Hz. Such a rate can provide a telemetry/TET mode cycle completion at approximately every 50 ms. For example, the TET/telemetry coil **114** can provide TET for the sensor housing **60** for approximately 45 ms to power the sensor housing **60** and then provide telemetry of pressure data for approximately 5 ms. Of course, any other switching topology can be used. It will also be appreciated that switching between TET and telemetry may be unnecessary. For example, the sensor housing **60** can be active, such that TET is not required. As another example, a second coil (not shown) can be added to the sensor housing **60**, with one of the coils in the sensor housing **60** being dedicated to TET and the other to telemetry. Still other alternatives and variations will be apparent to those of ordinary skill in the art.

Having received sensed pressure data, the microcontroller **65** can determine **404** whether to store **412** the data, e.g., in the memory **162**. Any type of memory can be used for the memory **162**, including but not limited to one or more of volatile (e.g., SRAM, etc.), non-volatile (e.g., flash, hard drive, etc.), or other memory. Determining whether to store the data allows the microcontroller **65** to analyze the data and potentially discard at least a portion of the data before storing it, thereby using less of the storage space available in the memory **162**. The microcontroller **65** can, however, be configured to store **412** all sensed pressure data and thus may not make such a determination and instead proceed to evaluating **406** whether any of the data triggers an alert, as further discussed below. (In such a configuration, it may be more power efficient to store raw (unprocessed) data from the pressure sensor **62** and process the raw data via an external reading device.) Furthermore, the memory **162** can be used to store pre-selected information or pre-selected types of information. For example, the memory **162** can store maximum, minimum, and/or baseline, pressure measurements, pressure profiles, pressure trends, fluoroscopic images or video of a patient swallowing, and/or any other information. Other information suitable for storing in the memory **162** will be appreciated by those skilled in the art.

The microcontroller **65** can analyze the data in a variety of ways in determining whether to store it. Typically, the microcontroller **65** analyzes a sequence of pressure data values measured over a period of time rather than analyzing every discrete pressure measurement, thereby allowing analysis of pressure trends over time and saving processing resources by not necessarily having to continually analyze incoming data. The microcontroller **65** can, however, evaluate individual pressure data measurements (and/or a range of data) for invalid data and determine to discard any invalid data. Generally, in determining whether to store data, the microcontroller **65** considers a variation of pressure data from a nominal pressure, or resting pressure, within the band **20**. The nominal pressure is typically programmed into the microcontroller **65** by a physician based on historical band performance in the patient or, particularly for recently implanted bands, in a typical patient. If the measured pressure data exceeds the nominal pressure, then the data indicates pressure variation in the system **10** and hence likely includes potentially beneficial information for analytical, diagnostic, and/or other purposes. If the pressure data substantially equals the nominal pressure, then the data is not likely indicative of a potentially significant event for analysis purposes, e.g., a change in band pressure due to patient activity such as eating or drinking. The microcontroller **65** can discard any such substantially nominal data. Discarding data can include not storing the data or storing a representation of the data, e.g., storing a specific set of digits (e.g., "888," "999," "000," etc.) or one or more alphabetic characters. Different representations of data can be used to indicate measurement of a different types of data, e.g., substantially nominal data, data outside a defined pressure range, etc. Although, in some embodiments, the microcontroller **65** can store **412** even nominal pressure data in the memory **162** to maintain a complete historical record of pressure measurements. Furthermore, the microcontroller **65** can store **412** all sensed pressure data it receives in the memory **162** and subsequently determine whether to keep or discard it, e.g., store all data and analyze it every "X" minutes and/or upon signal from an external device.

FIGS. **9** and **10** show example sequences of pressure data that the microcontroller **65** can receive from the sensor **62**. In each of FIGS. **9** and **10**, a plot shows sensed pressure data versus time for a twenty-four hour period. The plot in FIG. **9** includes four periods **407***a*, **407***b*, **407***c*, **407***d* of substantially nominal pressure at a nominal pressure level **409**. The nominal pressure level **409** shown in the plot is an example only; the nominal pressure value can be any value or range of values. Furthermore, the nominal pressure value for a patient can change over time, e.g., as the patient loses weight. The microcontroller **65** can compare the pressure data from this twenty-four hour period with the nominal pressure **409** and determine to discard data from the nominal pressure periods **407***a*, **407***b*, **407***c*, **407***d* (e.g., never store it in the memory **162** or delete it from the memory **162**) and only store **412** the remaining, selected portion of pressure data. In some instances, the microcontroller **65** can determine to discard pressure data that exceeds the nominal pressure **409**. For example, the microcontroller **65** can discard pressure data except for data obtained during two of three meals the patient ate during the day, e.g., discard pressure data measured during the four periods **407***a*, **407***b*, **407***c*, **407***d* and during a breakfast period **411** and store **412** the remaining, selected pressure data, corresponding to lunch and dinner periods **413**, **415**. Pressure data can be determined to be related to a particular meal based on one or more factors considered by the micro-

controller **65**, such as a combination of a time of day when the sensor **62** measured the data and a duration of pressure values above the nominal level **409**.

The microcontroller **65** can also determine to discard pressure data related to one or more physiologic events, as illustrated in FIG. **10**. Non-limiting examples of physiologic events include supra events (e.g., coughing, vomiting, wretching, etc.) and normal events (heartbeats, breathing, talking, etc.). Physiologic events can result in measured pressure data that significantly differs from an expected level in magnitude, duration, occurrence (e.g., an unexpected time of day, such as midnight), and/or frequency from established patterns of patient eating. The microcontroller **65** can determine to retain pressure data by analyzing the data for such a significant difference, such as by determining if any of the obtained pressure data includes a value above a pre-programmed threshold value typically not exceeded except in response to a physiologic event. The microcontroller **65** can also or instead determine if any of the obtained pressure data includes a value within a defined range of pressure values. Depending on the defined range, which can in some embodiments be defined at an upper and/or lower limit by an immediately preceding pressure data value or by pressure values corresponding to a particular time of day, the microcontroller **65** can determine to discard data within the range (e.g., if the range reflects pressure readings of an expected frequency and magnitude caused by a normal event) or to retain data within the range (e.g., if the range includes any positive pressure values up to a threshold value typically not exceeded except by a physiologic event). As an example, the plot in FIG. **10** includes pressure data **413** indicative of a supraphysiologic event, pressure data **415** indicative of a normal event, and actual band pressure data **417**. The microcontroller **65** can discard the event data **413** and the normal event data **415** using one or more programmed algorithms as described above.

The microcontroller **65** can also determine **406** whether any data triggers an alert. If the microcontroller **65** determines that any pressure data falls outside a defined range of pressure values and/or is more or less than a threshold value, then the microcontroller **65** can provide **408** an alert to a physician, the patient, and/or to any number of other people because such outlying pressure data can indicate a possible problem such as band leakage, band over-tightening, recurrent wretching, band slippage, erosion, etc. The microcontroller **65** can provide the alert by, for example, communicating a signal to an external device (e.g., the control box **90**) indicating the potentially problematic sensed pressure data and triggering notice of the alert. An alert can include any one or more of the following: an e-mail, a phone call, a text message, an audible signal, a mechanical vibration, a light or other visual display, a tactile display, a message displayed on an external device, or any other type of alert. Different alert patterns (e.g., varying audio signals, varying vibration patterns, etc.) can be used to signify different conditions. Two or more alerts can be provided to multiple people under similar conditions, although alerts may not be provided simultaneously to multiple people or be provided to anyone at all. The conditions for and/or the type of an alert can also vary relative to the recipient of the alert. For example, with respect to alerts for physicians or other medical personnel, such alerts may be limited to those provided upon a supra event indicating that some component of the internal portion **10***a* has structurally failed (e.g., a kink in catheter **50**, a leak in the band **20**, etc.). With respect to alerts for patients, such alerts may be limited to patient activity such as those provided upon an indication that the patient is eating too much, eating too quickly, or if the patient's bite sizes are too big. A variety of other conditions under which alerts can be directed to a physician, a patient, and/or another person will be understood by those skilled in the art. Other suitable processes for detecting alert triggers, as well as ways in which the alerts can be provided and the timing of providing the alerts (e.g., immediately, on a regular schedule such as every day or every hour, after detection of a certain milestone or pattern of data, etc.), will be appreciated by those skilled in the art.

The microcontroller **65** can optionally compress **410** data prior to storing **412** data in the memory **162**. Such compression can reduce the amount of memory space required to store data in the internal portion **10***a* (and subsequently in the external portion **10***b*), reduce the number of microcontroller accesses to the memory **162** (thereby saving power), reduce the amount of time and/or power required to communicate data from the sensor housing **60** to an external device, and allow more data to be locally stored prior to communicating the data to an external device. While pressure data is shown in FIG. **8** as being compressed following a determination of a selected portion of data to store in the memory **162**, if any, the microcontroller **65** can compress data before making such a determination. For example, as mentioned above, the microcontroller **65** can store **412** pressure data prior to making such a determination (possibly subsequently retrieving the data for analysis). As another example, the microcontroller **65** may not be configured to perform such determining analysis and may store **412** all data for communication to an external device.

The microcontroller **65** can compress data using any one or more lossless and/or lossy compression techniques. Non-limiting examples of lossless compression techniques include recording difference values (instead of absolute values), reducing the sensor's data sampling rate (which can include reducing the sensor's data sampling rate to zero) during a determined period (e.g., a period of quiescent pressure, after a certain period of data-gathering time, etc.), run-length coding, Huffman coding, and other types of lossless compression. Non-limiting examples of lossy compression includes using a quantization table (e.g., sparse quantization) and other types of lossy compression. Storing difference values instead of absolute values can be effective compression if, typically at the beginning of pressure measuring and at regular intervals, the microcontroller **65** stores an absolute value in the memory **162** that can serve as a baseline in reconstructing the originally sensed data. Sensed pressure values are often near the values of their neighbors, so differences from a baseline are often likely to be small, if not zero. The microcontroller **65** can compress difference values for storage using a compression technique, such as encoding difference values into the shortest code symbols in Huffman coding.

Data stored in the memory **162** can be communicated **414** to an external device. In some embodiments, the microcontroller **65** continually communicates **414** data (via the telemetry transceiver **158** and the secondary coil **114**), and the data is only received when an appropriate receiving device, such as the antenna (the primary TET coil **130** and the telemetry coil **144**), moves into sufficient proximity of it. In some embodiments, a download of data from the memory **162** can be triggered **416** when an external device (e.g., the reading device **70**) telemetrically provides power to the sensor housing, e.g., when the external device is moved in proximity of the sensor housing **60**. The external device can be mobile (e.g., a wand or hand-held unit that can be waved or otherwise placed in proximity of the sensor housing **60**) or stationary (e.g., a bedside, desk-mounted, or car-mounted box that the patient can move near). Telemetrically providing power to the

sensor housing **60** can save power in the internal portion **10***a* because download communication power is supplied by the external portion **10***b*.

The external device can be configured to store **418** data received from the sensor housing **60**. The external device can be further configured communicate **420** the data to another external device, such as a base unit at a location remote from the patient. The external device (typically, the control box **90** or other device having a capability to display or otherwise provide an alert) can detect **422** if the internal portion **10**a communicated a signal indicating an alert and provide **424** an alert as appropriate (e.g., displaying a warning notice, sending an e-mail message, etc.).

As mentioned above, a pressure history (e.g., pressure data gathered by the sensor **62**) can be uploaded to the control box **90** (and/or other units located local or remote to the patient) to allow a person to physically evaluate and/or the control box **90** to electronically evaluate the patient's treatment and/or performance of elements included in the internal portion **10***a* over a designated time period. FIG. **11** illustrates an embodiment of an external device, a data logger **270**, that can be used as an external storage mechanism to store pressure measurements over a period of time. The data logger **270** can function as a removably attached data reading device **70**, mentioned above. In this example, the data logger **270** includes a wearable pack external to the patient worn on a belt **274** and positioned over or within communication range of the region under which the sensor housing **60** is implanted within the patient. Alternatively, the data logger **270** can be worn about the patient's neck, as shown by a device **270'**, such as when the injection port **30** is implanted on the patient's sternum and the port **30** includes the pressure sensing device. In another embodiment, the data logger **270** is also implanted within the patient.

As shown in FIG. **11**, the data logger **270** includes a TET coil **285** and a telemetry coil **272** which can be worn by the patient so as to lie adjacent to the internal portion **10***a*. The TET coil **285** can provide power to the implant, while the telemetry coil **272** can interrogate the implant and can receive data signals, including pressure measurements, through the secondary telemetry coil **114** in the implanted portion **10***a*. In another embodiment, the TET coil **285** and the telemetry coil **272** can be consolidated into a single coil and alternate between TET and telemetry functions at any suitable rate for any suitable durations.

The pressure within the band **20** can be repeatedly sensed and transmitted to the data logger **270** at an update rate sufficient to measure peristaltic pulses against the band **20**. Typically, this update rate is in the range of 10-20 pressure measurements per second, but any update range can be used. The data logger **270** is typically worn during waking periods to record pressure variations during the patient's meals and daily routines. At the end of the day, or another set time period, the data logger **270** can be removed and recorded pressure data downloaded to the external memory **138**. The pressure history can be uploaded from the memory **138** to a remote unit over one or more communication links during a subsequent communication session. Alternatively, pressure data can be directly uploaded from the data logger **270** to a remote unit using one or more communication links. A communication link can include any single or combination of two or more data transmission media including web-based systems utilizing high-speed cable or dial-up connections, public telephone lines, wireless RF networks, Bluetooth, ultrawideband (UWB), satellite, T1 lines or any other type of communication media suitable for transmitting data between remote locations. The data logger **270** can be configured to dock into another device, e.g., a docking station, that is configured to receive data communication from the data logger **270** and transmit the received data to a remote unit.

FIG. **12** shows the data logger **270** in greater detail. As shown in FIG. **12**, the data logger **270** includes a microprocessor **276** for controlling telemetry communications with the internal portion **10***a*. The microprocessor **276** is connected to a memory **280** for, at least, storing pressure measurements from the internal portion **10***a*. In this embodiment, the memory **280** includes forty MB of Non-Volatile EEPROM or FLASH memory and is configured to store about one hundred hours of time stamped pressure data, but any other type of storage can be used, and the memory **280** can store any amount of and any type of data. By way of non-limiting example, any other type of volatile memory or any type of non-volatile memory can be used, including but not limited to flash memory, hard drive memory, etc. While the data logger **270** in this example is operational, pressure can be read and stored in the memory **280** at a designated data rate controlled by the microprocessor **276**.

The microprocessor **276** can be energized by a power supply **282**. In one embodiment, the power supply **282** includes a rechargeable cell (not shown), such as a rechargeable battery. In some embodiments, the rechargeable cell is removable and can be recharged using a recharging unit and replaced with another rechargeable cell while the spent cell is recharging. In other embodiments, the rechargeable cell can be recharged by plugging a recharging adapter into the data logger **270** and a wall unit. In yet another embodiment, the rechargeable cell can be recharged wirelessly by a wireless recharging unit. In still another embodiment, the power supply **282** includes an ultra capacitor, which can also be recharged. Of course, any other type of power supply can be used.

To record pressure, the microprocessor **276** can initially transmit a power signal to the internal portion **10***a* via a TET drive circuit **283** and the TET coil **285**. After transmitting the power signal, the microprocessor **276** can transmit an interrogation signal to the internal portion **10***a* via a telemetry transceiver **284** and the telemetry coil **272**. The interrogation signal can be intercepted by the telemetry coil **114** and transmitted to the microcontroller **65**. The microcontroller **65** can send a responsive, optionally-temperature-adjusted pressure reading from the sensor **62** via the transceiver **158** and the secondary telemetry coil **114**. The pressure reading can be received through the telemetry coil **272** and directed by the transceiver **284** to the microprocessor **276**. The microprocessor **276** can store the pressure measurement and initiate the next interrogation request. If applicable, the microprocessor **276** can also respond to an alert identified by the microcontroller **65**, such as with a visual alert (e.g., flashing a light on the data logger **270**, displaying a message on a user interface **292**, etc.) and/or with an audible alert. The user interface **292** can include any number and types of features, including but not limited to a speaker, an LED, an LCD display, an on/off switch, etc. In some embodiments, the user interface **292** is configured to provide only output to the patient and does not permit the patient to provide input to the data logger **270**. The user interface **292** thus includes an LED, which when lit shows that the power supply **282** is sufficiently charged and another, differently colored LED to show when the power supply **282** needs to be recharged, although such power indicators can be shown using any type and any combination of indicators such as one light that illuminates upon low power charge, an audible alert, an email alert, etc. In other embodiments, the user interface **292** can allow the patient to provide input to the data logger **270** and can accordingly include any suitable components and features.

When finished measuring and recording pressure, the data logger **270** can be removed from the patient and/or from the belt **274** and the recorded pressure data downloaded to the control box **90** (and/or to any other external device). The data logger **270** can include a modem **286** for transmitting sensed pressure data directly to a remote base unit using a communication link. For example, the patient can connect the modem **286** to a telephone line (or other communication link), dial the physician's modem (if necessary), and select a "send" button on the user interface **292**. Once connected, the microprocessor **276** can transmit stored pressure history through the phone line to a microprocessor included in the remote unit. Alternatively, the data logger **270** can include a USB port **290** for connecting the logger **270** to the control box **90**. The logger USB port **290** can be connected to a USB port included on the control box **90** and the "send" switch activated to download pressure data to the memory **138** in the control box **90**. After pressure data is downloaded, the logger **270** can be turned off through the user interface **292** or reset and placed back on the patient and/or the belt **274** for continued pressure measurement.

An alternate embodiment of a data logging system **300** is shown in FIG. **13**. In this example, the data logging system **300** includes a coil head **354** and a data logger **370**. The coil head **354** and the data logger **370** are in communication via a detachable cable **356**. Any one or more suitable alternative communication links can be used in the place of the cable **356**, including but not limited to a wireless transmitter/receiver system. In the illustrated embodiment, the coil head **354** is worn around the neck of the patient and is positioned generally over the injection port **30** and within communication range of the sensor housing **60**. The data logger **370** is worn on the belt **274** about the patient's waist. Of course, these respective locations are merely exemplary, and either or both the coil head **354** and the data logger **370** can be positioned elsewhere. By way of non-limiting example, when the injection port **30** is implanted in the patient's abdomen, the coil head **354** can be worn on the belt **274**. The coil head **354** and the data logger **370** are represented as simple blocks in FIG. **13** for illustrative purposes only, and either of the coil head **354** or the data logger **370** can be provided in a variety of shapes, sizes, and configurations.

Exemplary components of the data logging system **300** are shown in FIG. **14**. As shown, the data logger **370** includes the microprocessor **276**, the memory **280**, the power supply **282**, the USB port **290**, and the user interface **292**. The coil head **354** includes the TET drive circuit **283**, the telemetry transceiver **284**, the TET coil **285**, and the telemetry coil **272**. The TET drive circuit **283** is configured to receive power from the power supply **282** via the cable **356**. The TET drive circuit **283** is further configured to receive signals from the microprocessor **276** via the cable **356**. The telemetry transceiver **284** is configured to receive signals from the microprocessor **276** and transmit signals to the microprocessor **276**, via the cable **356**. In another embodiment, the telemetry transceiver **284** is configured to only transmit signals to the microprocessor **276**. The above discussion of such components with reference to FIG. **12** can also be applied to the components shown in FIG. **14**. In the embodiment illustrated in FIG. **14**, the coil head **354** and the data logger **370** can be viewed as a separation of components including the data logger **270** (described above) into two physically separate units. It will be appreciated by a person skilled in the art that any of the components shown in FIG. **14**, as well as their relationships, functions, etc., can be varied in any suitable way.

In the present example, the coil head **354** is configured similar to and functions in a manner similar to the antenna (the primary TET coil **130** and the telemetry coil **144**) described above. The TET coil **285** of coil head **354** is configured to provide power to the injection port **30**. Of course, to the extent that any other devices (e.g., a pump, etc.) are implanted in the patient that are configured to receive power from the TET coil **285**, the TET coil **285** can also provide power to such devices. Power provided by the TET coil **285** can be provided to the TET coil **285** by and regulated by the TET drive circuit **285**, which can itself receive power from the power supply **282** via the cable **356**. Such power provided to the TET drive circuit **283** can be regulated by the microprocessor **276** via the cable **356**. In addition, or in the alternative, the microprocessor **276** can regulate the manner in which the TET drive circuit **285** provides power to the TET coil **285**. While the present example contemplates the use of RF signaling through the TET coil **285**, any other type of powering technique, as well as alternative power communicators, can be used. Other suitable configurations and relationships between these components, as well as alternative ways in which they may operate, will be appreciated by those skilled in the art.

The telemetry coil **272** of the coil head **354** is configured to receive signals from the coil **114**, including signals indicative of the pressure within the implanted band system (e.g., pressure of fluid within the injection port **30**, within the catheter **50**, and/or within the adjustable band **20**, pressure obtained using the pressure sensor **62**, etc.) and signals indicative of temperature. The telemetry coil **272** can also receive any other type of signal representing any other type of information from any other source. Signals received by the telemetry coil **272** can be communicated to the telemetry transceiver **284**, which can communicate such signals to the microprocessor **276** via the cable **356**. The telemetry transceiver **284** can perform any appropriate translation or processing of signals received from the telemetry coil **272** before communicating signals to the microprocessor **276**. Other suitable configurations and relationships between these components, as well as alternative ways in which they may operate, will be appreciated by those skilled in the art. It will also be appreciated that components may be combined. By way of non-limiting example, the TET coil **285** and the telemetry coil **272** can be consolidated into a single coil and alternate between TET and telemetry functions at any suitable rate for any suitable durations. In addition, while the present example contemplates the use of RF signaling through the telemetry coil **272**, it will be appreciated that any other type of communication technique (e.g., ultrasonic, magnetic, RF, light, inductive, etc.) can be used alone or in any combination, as well as alternative communicators other than a coil, can be used. Furthermore, different data handling can be more beneficial to a given communication technique, and given a particular communication technique, appropriate data handling can be selected.

In one exemplary use, the patient wears the coil head **354** and the data logger **370** throughout the day to record pressure measurements in the memory **280**. At night, the patient can decouple the data logger **370** from the coil head **354** and couple the data logger **370** with a docking station, e.g., the control box **90**. While the data logger **370** and the control box **90** are coupled, the control box **90** can transmit data received from the data logger **370** to a remote unit. To the extent that the power supply **282** includes a rechargeable cell, the control box **90** can recharge the cell while the data logger **370** is coupled with the control box **90**. However, a patient need not necessarily decouple the data logger **370** from the coil head **354** in order to couple the data logger **370** with the control box **90**. Moreover, pressure measurements can be recorded in the

memory **280** during the night in addition to or as an alternative to recording such measurements during the day, and pressure measurements can be recorded twenty-four hours a day. In that way, timing of pressure measurement taking and recordation need not be limited to the daytime only.

As described above, the data logger **370** can receive, store, and communicate data relating to pressure within the restriction system. However, the data logger **370** can receive, store, and/or communicate a variety of other types of data. By way of non-limiting example, the data logger **370** can also receive, process, store, and/or communicate data relating to temperature, EKG measurements, eating frequency of the patient, the size of meals eaten by the patient, the amount of walking done by the patient, etc. It will therefore be appreciated by those skilled in the art that the data logger **370** can be configured to process received data to create additional data for communicating to the control box **90**. For example, the data logger **370** can process pressure data obtained via the coil head **354** to create data indicative of the eating frequency of the patient. It will also be appreciated by those skilled in the art that the data logger **370** can include additional components to obtain non-pressure data. For example, the data logger **370** can include a pedometer or accelerometer (not shown) to obtain data relating to the amount of walking done by the patient. Data obtained by such additional components can be stored in the memory **280** and communicated to the control box **90** in a manner similar to pressure data. The data logger **370** can also include components for obtaining data to be factored in with internal pressure measurements to account for effects of various conditions on the pressure. For example, the data logger **370** can include a barometer for measuring atmospheric pressure. In some embodiments, the data logger **370** includes an inclinometer or similar device to determine the angle at which the patient is oriented (e.g., standing, lying down, etc.), which can be factored into pressure data to account for hydrostatic pressure effects caused by a patient's orientation. Alternatively, an inclinometer or other device for obtaining non-pressure data can be physically separate from the data logger **370** (e.g., implanted). Still other types of data, ways in which such data may be obtained, and ways in which such data may be used will be appreciated by those skilled in the art.

It will also be appreciated by those skilled in the art that one or more embodiments described herein can enable health care providers or others to use pressure data as a feedback mechanism to identify, train, and/or prescribe dietary advice to a patient. Such a feedback mechanism can provide data or otherwise be used in multiple ways. For example, pressure feedback can be obtained when a patient swallows a particular food portion, and based on such pressure feedback, the patient can be advised or taught to eat smaller portions, larger portions, or portions equal to the portion tested. Of course, a food portion so prescribed can be tested by evaluating pressure feedback obtained when the patient swallows the prescribed food portion, such that a food portion prescription may be refined through reiteration. As another example, a patient can test desired foods for appropriateness based on pressure feedback together with portion size and/or based on any other parameters. It will also be appreciated by those skilled in the art that continuous pressure data monitoring can be used locally and/or remotely to enable portion size monitoring, food consistency monitoring (e.g., liquids vs. solids), eating frequency, and/or other patient activities.

While embodiments described above include the use of the pressure sensor **62** within the sensor housing **60** removably joined to the catheter **50**, a pressure sensor can be located elsewhere within a patient. For example, the pressure sensor **62** could be included in the port housing **30**. In another embodiment, shown in FIG. **15**, a pressure sensor **500** can be located within a gastric band **502**, such as in an inflatable portion of gastric band **502**. To the extent that the gastric band **502** includes a resilient portion and a non-resilient portion, the pressure sensor **500** can be secured to either or neither of the resilient portion or non-resilient portion. In any case, the pressure sensor **500** can sense and communicate fluid pressure within the gastric band **502** before, during, and after fluid is added to or withdrawn from gastric band **502** via an injection port **501** and a catheter **503**. The pressure sensor **500** can be used when a pump (not shown) or any other device is used to adjust pressure within the gastric band **502**.

Alternatively, as shown in FIG. **16**, a pressure sensor **504** can be located within a catheter **506** positioned between a gastric band **508** and a port **507**, pump, reservoir, or other device in fluid communication with the catheter **506**. As another variation, an example of which is shown in FIG. **17**, a pressure sensor **509** can be fixedly secured in-line with a catheter **506**, while not residing within catheter **506**.

Yet another variation is shown in FIG. **18**, which illustrates a catheter **506** having a "T"-shaped intersection **550**. A pressure sensor **504** is disposed in the arm of the "T"-shaped intersection **550** that is perpendicular to the catheter **506** and is in fluid communication with the catheter **506**. In one embodiment, the "T"-shaped intersection **550** is integrally formed with the catheter **506** (as shown). In another embodiment, the "T"-shaped intersection **550** is a separate component joined to the catheter **506** (e.g., using barbed connectors, etc.). Other suitable ways in which the "T"-shaped intersection **550** can be provided will be appreciated by those skilled in the art. Similarly, other ways in which a pressure sensor **504** can be provided within, in-line with, or adjacent to the catheter **506** will be appreciated by those skilled in the art.

In yet another embodiment (not depicted), a pressure sensor can be located at the interface of an injection port and a catheter, and/or at the interface of a gastric band and a catheter. Still other suitable locations for a pressure sensor will be appreciated by those skilled in the art, including but not limited to any location in or adjacent to the fluid path of a gastric band system. In addition, a pressure sensor can be positioned within (e.g., against an inner wall of) a gastric band, a catheter, and a buckle, or alternatively, a portion of such band, catheter, and buckle can include a protrusion extending outwardly therefrom to house at least a portion of the corresponding pressure sensor. Other suitable configurations for housing a pressure sensor within or adjacent to a band, catheter, or buckle will be appreciated by those skilled in the art.

In another embodiment, a plurality of pressure sensors can be used. For example, a gastric band system can include a pressure sensor within a gastric band in addition to a pressure sensor within a catheter that is in fluid communication with the gastric band. Such a plurality of pressure sensors can provide an indication of how well fluid pressure is distributed among components of a gastric band system. Such a plurality of pressure sensors can also provide greater accuracy in pressure readings, reduce the likelihood of catheter obstruction (e.g., pinching) affecting pressure reading, reduce effects of hydrostatic pressure changes from patient movement, and/or provide one or more other results. Any system that includes a plurality of pressure sensors can include a pressure sensor in a port housing and/or a pressure sensor external to the patient (e.g., a pressure sensor in a syringe or in a pressure sensor portion coupled with a syringe), in addition to any of the implanted pressure sensors described above. Furthermore, a device such as an internal or external inclinometer (or a substitute therefor) may be used to determine the angle at which

the patient and/or the internal portion is oriented (e.g., standing, lying down, etc.), which may be factored into pressure data sensed by one or more sensors to account for hydrostatic pressure effects caused by a patient's orientation. Such a factor (or any other factor) may be accounted for prior to or in conjunction with the rendering of a pressure reading.

A person skilled in the art will appreciate that the present invention has application in conventional endoscopic and open surgical instrumentation as well application in robotic-assisted surgery.

The devices disclosed herein can be designed to be disposed of after a single use, or they can be designed to be used multiple times. In either case, however, the device can be reconditioned for reuse after at least one use. Reconditioning can include any combination of the steps of disassembly of the device, followed by cleaning or replacement of particular pieces, and subsequent reassembly. In particular, the device can be disassembled, and any number of the particular pieces or parts of the device can be selectively replaced or removed in any combination. Upon cleaning and/or replacement of particular parts, the device can be reassembled for subsequent use either at a reconditioning facility, or by a surgical team immediately prior to a surgical procedure. Those skilled in the art will appreciate that reconditioning of a device can utilize a variety of techniques for disassembly, cleaning/replacement, and reassembly. Use of such techniques, and the resulting reconditioned device, are all within the scope of the present application.

Preferably, the invention described herein will be processed before surgery. First, a new or used instrument is obtained and if necessary cleaned. The instrument can then be sterilized. In one sterilization technique, the instrument is placed in a closed and sealed container, such as a plastic or TYVEK bag. The container and instrument are then placed in a field of radiation that can penetrate the container, such as gamma radiation, x-rays, or high-energy electrons. The radiation kills bacteria on the instrument and in the container. The sterilized instrument can then be stored in the sterile container. The sealed container keeps the instrument sterile until it is opened in the medical facility.

It is preferred that device is sterilized. This can be done by any number of ways known to those skilled in the art including beta or gamma radiation, ethylene oxide, steam.

One skilled in the art will appreciate further features and advantages of the invention based on the above-described embodiments. Accordingly, the invention is not to be limited by what has been particularly shown and described, except as indicated by the appended claims. All publications and references cited herein are expressly incorporated herein by reference in their entirety.

The invention claimed is:

1. A method of forming a restriction in a patient, comprising:

using an implantable pressure sensing device to obtain pressure data over a period of time related to a pressure within an implantable restriction device configured to form a restriction in a patient;

determining a portion of the obtained pressure data which corresponds to a time within the period of time when a meal was consumed by the patient based on at least one of a time of day the pressure data was obtained and a duration of the obtained pressure data being above a nominal pressure level;

storing at least a portion of the obtained pressure data at the implantable pressure sensing device;

in response to a signal from an external device, downloading at least a portion of the stored data to the external device;

telemetrically providing power to the implantable pressure sensing device from the external device by moving the external device in proximity of the implantable pressure sensing device, wherein telemetrically providing power triggers a download of the portion of the stored data to the external device; and

discarding pressure data obtained during the period of time that does not correspond to the time within the period of time when the meal was consumed such that the discarded data is not downloaded to the external device.

2. The method of claim **1**, further comprising compressing at least a portion of obtained pressure data prior to storing the at least a portion of the obtained pressure data at the implantable pressure sensing device.

3. The method of claim **2**, wherein the compressing includes using at least one compression technique selected from the group consisting of: storing difference values, storing values, using a quantization table, using run-length coding, and using Huffman coding.

4. The method of claim **1**, wherein the obtained pressure data stored at the implantable pressure sensing device includes pressure values that exceed a nominal pressure within the implantable restriction device.

5. The method of claim **1**, wherein the implantable pressure sensing device cannot download the stored pressure data without being supplied the power from the external device.

6. The method of claim **1**, wherein the implantable pressure sensing device lacks an implantable power source to supply power for the download of the stored pressure data.

7. The method of claim **1**, wherein storing at least a portion of obtained pressure data comprises storing all the obtained pressure data.

8. A method of forming a restriction in a patient, comprising: obtaining pressure data related to a pressure within an implantable restriction device configured to form a restriction in a patient;

determining a portion of the obtained pressure data to retain prior to communicating pressure data to an external reading device, the determining comprising comparing the obtained pressure data with a pre-programmed pressure chosen by a user and indicating a nominal pressure within the implantable restriction device;

storing in an implantable memory the obtained pressure data that exceeds the pre-programmed pressure;

communicating the portion of the obtained pressure data stored in the memory to the external reading device;

determining to retain pressure data obtained during the pre-determined time of day and determining to not retain pressure data obtained outside the pre-determined time of day;

storing in the implantable memory any of the pressure data obtained during the pre-determined time of day; and

communicating the stored pressure data obtained during the pre-determined time of day.

9. The method of claim **8**, wherein the pre-programmed pressure is a defined range of pressure values, and determining a portion of the pressure data to retain comprises determining if any of the obtained pressure data includes a value within the defined range of pressure values and determining to store the obtained pressure data in the implantable memory based on whether the obtained pressure data falls within the range.

10. The method of claim 8, further comprising generating an alert for communication to the external reading device if any of the obtained pressure data includes a value that exceeds a threshold pressure value.

11. The method of claim 8, wherein storing in the implantable memory only the obtained pressure data that exceeds the pre-programmed pressure comprises storing the portion of the pressure data determined to be retained prior to communicating the portion of the obtained pressure data to the external reading device.

12. The method of claim 11, further comprising compressing the portion of the pressure data determined to be retained prior to storing the portion of the pressure data determined to be retained.

13. The method of claim 8, wherein obtaining pressure data includes reducing a rate of pressure data gathering during a determined period.

14. The method of claim 8, wherein determining a portion of the pressure data to retain includes processing the obtained pressure data using a pressure sensing device coupled to the implantable restriction device and configured to obtain the pressure data.

15. The method of claim 14, wherein processing the obtained pressure data includes using a processor in electronic communication with the pressure sensing device.

16. The method of claim 8, wherein the pre-programmed pressure is based on at least one of a historical performance of the implantable restriction device in the patient and a performance of the implantable restriction device in a typical patient.

17. A method of forming a restriction in a patient, comprising: using an implantable pressure sensing device to obtain pressure data over a period of time related to a pressure within an implantable restriction device configured to form a restriction in a patient;

storing at the implantable pressure sensing device an absolute value of the obtained pressure data at a start of the period of time;

storing at the implantable pressure sensing device difference values of the obtained pressure data relative to the absolute value for a remainder of the period of time after the start;

determining a portion of the obtained pressure data which corresponds to a time within the period of time when a meal was consumed by the patient based on at least one of a time of day the pressure data was obtained and a duration of the obtained pressure data being above a nominal pressure level; and

discarding pressure data obtained during the period of time that does not correspond to the time within the period of time when the meal was consumed such that the discarded data is not downloaded to an external device.

18. The method of claim 17, further comprising compressing at least one of the absolute value and the difference values prior to storage of the at least one of the absolute value and the difference values, wherein the compressing includes using at least one compression technique selected from the group consisting of: using quantization table, using run-length coding, and using Huffman coding.

19. The method of claim 17, further comprising communicating the stored absolute value and difference values from the pressure sensing device to the external device.

20. The method of claim 17, further comprising using the implantable pressure sensing device to obtain pressure data over a second, subsequent period of time related to the pressure within the implantable restriction device;

storing at the implantable pressure sensing device an absolute value of the obtained pressure data at a start of the second period of time; and

storing difference values of the obtained pressure data for a remainder of the second period of time after the start of the second period of time.

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