



US00RE46007E

(19) **United States**
(12) **Reissued Patent**
Banik et al.

(10) **Patent Number:** **US RE46,007 E**
(45) **Date of Reissued Patent:** ***May 24, 2016**

(54) **AUTOMATED CONTROL OF IRRIGATION AND ASPIRATION IN A SINGLE-USE ENDOSCOPE**

(56) **References Cited**

U.S. PATENT DOCUMENTS

(71) Applicant: **Boston Scientific Scimed, Inc.**, Maple Grove, MN (US)

3,266,059	A	8/1966	Stelle
3,470,876	A	10/1969	Barchilon
3,572,325	A	3/1971	Bazell
3,581,738	A	6/1971	Moore
4,108,211	A	8/1978	Tanaka
4,286,585	A	9/1981	Ogawa
4,294,162	A	10/1981	Fowler

(Continued)

(72) Inventors: **Michael S. Banik**, Bolton, MA (US);
Lucien Alfred Couvillon, Concord, MA (US); **Anh Nguyen**, Woburn, MA (US);
William H. Stahley, Andover, MA (US)

FOREIGN PATENT DOCUMENTS

(73) Assignee: **Boston Scientific Scimed, Inc.**, Maple Grove, MN (US)

DE	198 00 765	A1	4/1999
EP	0 075 153	B1	3/1983

(Continued)

(*) Notice: This patent is subject to a terminal disclaimer.

(21) Appl. No.: **14/628,972**

Primary Examiner — Beverly M Flanagan

(22) Filed: **Feb. 23, 2015**

(74) *Attorney, Agent, or Firm* — Bookoff McAndrews, PLLC

Related U.S. Patent Documents

Reissue of:

(64) Patent No.: **8,435,172**
Issued: **May 7, 2013**
Appl. No.: **12/330,470**
Filed: **Dec. 8, 2008**

U.S. Applications:

(63) Continuation of application No. 10/955,901, filed on Sep. 30, 2004, now Pat. No. 7,479,106.

(51) **Int. Cl.**
A61B 1/12 (2006.01)
A61B 1/00 (2006.01)

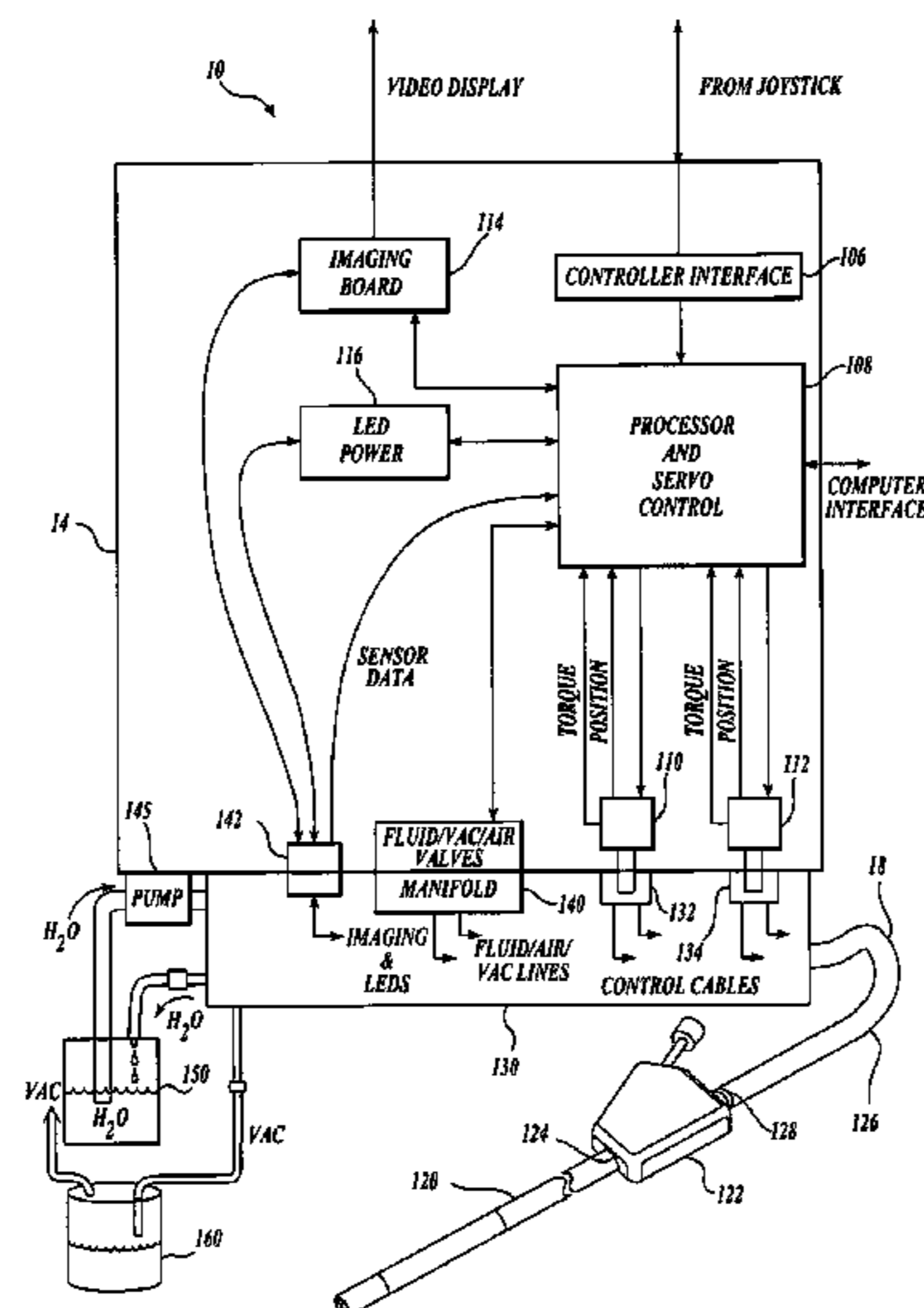
(52) **U.S. Cl.**
CPC **A61B 1/00068** (2013.01); **A61B 1/12** (2013.01)

(58) **Field of Classification Search**
USPC 600/101-183
See application file for complete search history.

(57) **ABSTRACT**

The present invention is an integrated and automated irrigation and aspiration system for use in an endoscopic imaging system. The system provides for the automated cleaning of poorly prepared patients during a colonoscopy procedure as well as automated cleaning of an imaging system of an endoscope. The invention analyzes images obtained from an image sensor to detect the presence of an obstructed field of view, whereupon a wash routine is initiated to remove the obstruction. The wash routine may be adjusted in accordance with environmental conditions within the patient that are sensed by one or more sensors within the endoscope. In another embodiment, insufflation is automatically controlled to inflate a patient's colon as a function of one or more sensor readings obtained from one or more environmental sensor(s) on the endoscope.

20 Claims, 4 Drawing Sheets



(56)

References Cited

U.S. PATENT DOCUMENTS

4,311,134 A	1/1982	Mitsui	4,844,071 A	7/1989	Chen
4,315,309 A	2/1982	Coli	4,845,553 A	7/1989	Konomura
4,351,323 A	9/1982	Ouchi	4,845,555 A	7/1989	Yabe
4,425,113 A	1/1984	Bilstad	4,847,694 A	7/1989	Nishihara
4,432,349 A	2/1984	Oshiro	4,853,772 A	8/1989	Kikuchi
4,471,766 A	9/1984	Terayama	4,860,731 A	8/1989	Matsuura
4,473,841 A	9/1984	Murakoshi	4,867,546 A	9/1989	Nishioka
4,488,039 A	12/1984	Sato	4,868,647 A	9/1989	Uehara
4,491,865 A	1/1985	Danna	4,869,237 A	9/1989	Eino
4,493,537 A	1/1985	Nakahashi	4,873,965 A	10/1989	Danieli
4,495,134 A	1/1985	Ouchi	4,875,468 A	10/1989	Krauter
4,499,895 A	2/1985	Takayama	4,877,314 A	10/1989	Kanamori
4,503,842 A	3/1985	Takayama	4,882,623 A	11/1989	Uchikubo
4,513,235 A	4/1985	Acklam	4,884,134 A	11/1989	Tsuji
4,515,444 A	5/1985	Prescott	4,885,634 A	12/1989	Yabe
4,516,063 A	5/1985	Kaye	4,890,159 A	12/1989	Ogiu
4,519,391 A	5/1985	Murakoshi	4,894,715 A	1/1990	Uchikubo
4,552,130 A	11/1985	Kinoshita	4,895,431 A	1/1990	Tsujiuchi
4,559,928 A	12/1985	Takayama	4,897,789 A	1/1990	King
4,566,437 A	1/1986	Yamaguchi	4,899,731 A	2/1990	Takayama
4,573,450 A	3/1986	Arakawa	4,899,732 A	2/1990	Cohen
4,580,210 A	4/1986	Nordstrom	4,899,787 A	2/1990	Ouchi
4,586,923 A	5/1986	Gould	4,905,666 A	3/1990	Fukuda
4,615,330 A	10/1986	Nagasaki	4,916,533 A	4/1990	Gillies
4,616,630 A	10/1986	Arakawa	4,918,521 A	4/1990	Yabe
4,617,915 A	10/1986	Arakawa	4,919,112 A	4/1990	Siegmund
4,618,884 A	10/1986	Nagasaki	4,919,114 A	4/1990	Miyazaki
4,621,618 A	11/1986	Omagari	4,920,980 A	5/1990	Jackowski
4,622,584 A	11/1986	Nagasaki	4,928,172 A	5/1990	Uehara
4,625,714 A	12/1986	Toyota	4,931,867 A	6/1990	Kikuchi
4,631,582 A	12/1986	Nagasaki	4,941,454 A	7/1990	Wood
4,633,303 A	12/1986	Nagasaki	4,941,456 A	7/1990	Wood
4,633,304 A	12/1986	Nagasaki	4,951,134 A	8/1990	Nakasima
4,643,170 A	2/1987	Miyazaki	4,951,135 A	8/1990	Sasagawa
4,646,723 A	3/1987	Arakawa	4,952,040 A	8/1990	Igarashi
4,649,904 A	3/1987	Krauter	4,960,127 A	10/1990	Noce
4,651,202 A	3/1987	Arakawa	4,961,110 A	10/1990	Nakamura
4,652,093 A	3/1987	Stephen	4,967,269 A	10/1990	Sasagawa
4,652,916 A	3/1987	Suzaki	4,971,034 A	11/1990	Doi
4,654,701 A	3/1987	Yabe	4,973,311 A	11/1990	Iwakoshi
RE32,421 E	5/1987	Hattori	4,979,497 A	12/1990	Matsuura
4,662,725 A	5/1987	Nishioka	4,982,725 A	1/1991	Hibino
4,663,657 A	5/1987	Nagasaki	4,984,878 A	1/1991	Miyano
4,667,655 A	5/1987	Ogiu	4,986,642 A	1/1991	Yokota
4,674,844 A	6/1987	Nishioka	4,987,884 A	1/1991	Nishioka
4,686,963 A	8/1987	Cohen	4,989,075 A	1/1991	Ito
4,697,210 A	9/1987	Toyota	4,989,581 A	2/1991	Tamburrino
4,700,693 A	10/1987	Lia	4,996,974 A	3/1991	Ciarlei
4,714,075 A	12/1987	Krauter	4,996,975 A	3/1991	Nakamura
4,716,457 A	12/1987	Matsuo	5,001,556 A	3/1991	Nakamura
4,719,508 A	1/1988	Sasaki	5,005,558 A	4/1991	Aomori
4,727,417 A	2/1988	Kanno	5,005,957 A	4/1991	Kanamori
4,727,418 A	2/1988	Kato	5,007,408 A	4/1991	Ieoka
4,745,470 A	5/1988	Yabe	5,018,509 A	5/1991	Suzuki
4,745,471 A	5/1988	Takamura	5,019,056 A	5/1991	Lee
4,746,974 A	5/1988	Matsuo	5,022,382 A	6/1991	Ohshoji
4,748,970 A	6/1988	Nakajima	5,029,016 A	7/1991	Hiyama
4,755,029 A	7/1988	Okabe	5,034,888 A	7/1991	Uehara
4,762,119 A	8/1988	Allred, III	5,040,069 A	8/1991	Matsumoto
4,765,312 A	8/1988	Sasa	RE33,689 E	9/1991	Nishioka
4,766,489 A	8/1988	Kato	5,045,935 A	9/1991	Kikuchi
4,787,369 A	11/1988	Allred, III	5,049,989 A	9/1991	Tsuji
4,790,294 A	12/1988	Allred, III	5,050,584 A	9/1991	Matsuura
4,794,913 A	1/1989	Shimonaka	5,050,974 A	9/1991	Takasugi
4,796,607 A	1/1989	Allred, III	5,056,503 A	10/1991	Nagasaki
4,800,869 A	1/1989	Nakajima	5,061,994 A	10/1991	Takahashi
4,805,596 A	2/1989	Hatori	5,068,719 A	11/1991	Tsuji
4,806,011 A	2/1989	Bettinger	5,074,861 A	12/1991	Schneider
4,819,065 A	4/1989	Eino	5,081,524 A	1/1992	Tsuruoka
4,819,077 A	4/1989	Kikuchi	5,087,989 A	2/1992	Igarashi
4,821,116 A	4/1989	Nagasaki	5,110,645 A	5/1992	Matsumoto
4,824,225 A	4/1989	Nishioka	5,111,281 A	5/1992	Sekiguchi
4,831,437 A	5/1989	Nishioka	5,111,306 A	5/1992	Kanno
4,836,187 A *	6/1989	Iwakoshi et al. 600/157	5,111,804 A	5/1992	Funakoshi
4,844,052 A	7/1989	Iwakoshi	5,113,254 A	5/1992	Kanno
			5,119,238 A	6/1992	Igarashi
			5,131,393 A	7/1992	Ishiguro
			5,137,013 A	8/1992	Chiba
			5,140,265 A	8/1992	Sakiyama

(56)

References Cited

U.S. PATENT DOCUMENTS

5,159,446 A	10/1992	Hibino	5,674,182 A	10/1997	Suzuki
5,170,774 A	12/1992	Heckele	5,674,197 A	10/1997	van Muiden
5,170,775 A	12/1992	Tagami	5,685,823 A	11/1997	Ito
5,172,225 A	12/1992	Takahashi	5,685,825 A	11/1997	Takase
5,174,293 A	12/1992	Hagiwara	5,691,853 A	11/1997	Miyano
5,176,629 A	1/1993	Kullas	5,695,450 A	12/1997	Yabe
5,188,111 A	2/1993	Yates	5,698,866 A	12/1997	Doiron
5,191,878 A	3/1993	Iida	5,702,349 A	12/1997	Morizumi
5,198,931 A	3/1993	Igarashi	5,702,754 A	12/1997	Zhong
5,201,908 A	4/1993	Jones	5,703,724 A	12/1997	Miyano
5,208,702 A	5/1993	Shiraiwa	5,704,371 A	1/1998	Shepard
5,209,220 A	5/1993	Hiyama	5,704,896 A	1/1998	Fukunishi
5,225,958 A	7/1993	Nakamura	5,708,482 A	1/1998	Takahashi
5,228,356 A	7/1993	Chuang	5,721,566 A	2/1998	Rosenberg
5,243,416 A	9/1993	Nakazawa	5,724,068 A	3/1998	Sanchez
5,243,967 A	9/1993	Hibino	5,728,045 A	3/1998	Komi
5,257,628 A	11/1993	Ishiguro	5,730,702 A	3/1998	Tanaka
5,271,381 A	12/1993	Ailinger	5,739,811 A	4/1998	Rosenberg
RE34,504 E	1/1994	Uehara	5,740,801 A	4/1998	Branson
5,279,542 A	1/1994	Wilk	5,746,696 A	5/1998	Kondo
5,291,010 A	3/1994	Tsuji	5,764,809 A	6/1998	Nomami
5,299,559 A	4/1994	Bruce	5,767,839 A	6/1998	Rosenberg
5,311,858 A	5/1994	Adair	5,779,686 A	7/1998	Sato
5,325,845 A	7/1994	Adair	5,781,172 A	7/1998	Engel
5,331,551 A	7/1994	Tsuruoka	5,788,714 A	8/1998	Ouchi
5,342,299 A	8/1994	Snoke	5,789,047 A	8/1998	Sasaki
5,347,987 A	9/1994	Feldstein	5,793,539 A	8/1998	Konno
5,347,989 A	9/1994	Monroe	5,805,140 A	9/1998	Rosenberg
5,374,953 A	12/1994	Sasaki	5,810,715 A	9/1998	Moriyama
5,379,757 A	1/1995	Hiyama	5,812,983 A	9/1998	Kumagai
5,381,782 A	1/1995	DeLaRama	5,819,736 A	10/1998	Avny
5,390,662 A	2/1995	Okada	5,820,591 A	10/1998	Thompson
5,400,769 A	3/1995	Tanii	5,821,466 A	10/1998	Clark
5,402,768 A	4/1995	Adair	5,821,920 A	10/1998	Rosenberg
5,402,769 A	4/1995	Tsuji	5,823,948 A	10/1998	Ross, Jr.
5,409,485 A	4/1995	Suda	5,827,176 A	10/1998	Tanaka
5,412,478 A	5/1995	Ishihara	5,827,186 A	10/1998	Chen
5,418,649 A	5/1995	Igarashi	5,827,190 A	10/1998	Palcic
5,420,644 A	5/1995	Watanabe	5,828,197 A	10/1998	Martin
5,429,596 A	7/1995	Arias	5,828,363 A	10/1998	Yaniger
5,431,645 A	7/1995	Smith	5,830,124 A	11/1998	Suzuki
5,434,615 A	7/1995	Matumoto	5,830,128 A	11/1998	Tanaka
5,436,640 A	7/1995	Reeves	5,836,869 A	11/1998	Kudo
5,436,767 A	7/1995	Suzuki	5,837,023 A	11/1998	Koike
5,440,341 A	8/1995	Suzuki	5,840,014 A	11/1998	Miyano
5,464,007 A	11/1995	Krauter	5,841,126 A	11/1998	Fossum
5,469,840 A	11/1995	Tanii	5,842,971 A	12/1998	Yoon
5,473,235 A	12/1995	Lance	5,843,000 A	12/1998	Nishioka
5,482,029 A	1/1996	Sekiguchi	5,846,183 A	12/1998	Chilcoat
5,484,407 A	1/1996	Osypka	5,855,560 A	1/1999	Idaomi
5,485,316 A	1/1996	Mori	5,857,963 A	1/1999	Pelchy
5,492,131 A	2/1996	Galel	5,865,724 A	2/1999	Palmer
5,496,260 A	3/1996	Krauter	5,868,664 A	2/1999	Speier
5,515,449 A	5/1996	Tsuruoka	5,868,666 A	2/1999	Okada
5,518,501 A	5/1996	Oneda	5,873,816 A	2/1999	Kagawa
5,518,502 A	5/1996	Kaplan	5,873,866 A	2/1999	Kondo
5,543,831 A	8/1996	Tsuji	5,876,326 A	3/1999	Takamura
5,549,546 A *	8/1996	Schneider et al. 604/26	5,876,331 A	3/1999	Wu
5,569,158 A	10/1996	Suzuki	5,876,373 A	3/1999	Giba
5,569,159 A	10/1996	Anderson	5,876,427 A	3/1999	Chen
5,586,262 A	12/1996	Komatsu	5,877,819 A	3/1999	Branson
5,589,854 A	12/1996	Tsai	5,879,284 A	3/1999	Tsujita
5,591,202 A	1/1997	Slater	5,880,714 A	3/1999	Rosenberg
5,608,451 A	3/1997	Konno	5,882,293 A	3/1999	Ouchi
5,609,563 A	3/1997	Suzuki	5,882,339 A	3/1999	Beiser
5,619,380 A	4/1997	Ogasawara	5,889,670 A	3/1999	Schuler
5,622,528 A	4/1997	Hamano	5,889,672 A	3/1999	Schuler
5,631,695 A	5/1997	Nakamura	5,892,630 A	4/1999	Broome
5,633,203 A	5/1997	Adair	5,895,350 A	4/1999	Hori
5,643,203 A	7/1997	Beiser	5,897,507 A	4/1999	Kortenbach
5,643,302 A	7/1997	Beiser	5,897,525 A	4/1999	Dey
5,645,075 A	7/1997	Palmer	5,907,487 A	5/1999	Rosenberg
5,647,840 A	7/1997	D'Amelio	5,923,018 A	7/1999	Kameda
5,658,238 A	8/1997	Suzuki	5,928,136 A	7/1999	Barry
5,667,477 A	9/1997	Segawa	5,929,607 A	7/1999	Rosenberg
			5,929,846 A	7/1999	Rosenberg
			5,929,900 A	7/1999	Yamanaka
			5,929,901 A	7/1999	Adair
			5,931,833 A	8/1999	Silverstein

(56)

References Cited

U.S. PATENT DOCUMENTS

5,933,809	A	8/1999	Hunt	6,221,070	B1	4/2001	Tu
5,935,085	A	8/1999	Welsh	6,238,799	B1	5/2001	Opolski
5,936,778	A	8/1999	Miyano	6,241,668	B1	6/2001	Herzog
5,941,817	A	8/1999	Crawford	6,260,994	B1	7/2001	Matsumoto
5,950,168	A	9/1999	Simborg	6,261,226	B1	7/2001	McKenna
5,951,462	A	9/1999	Yamanaka	6,272,470	B1	8/2001	Teshima
5,956,416	A	9/1999	Tsuruoka	6,275,255	B1	8/2001	Adair
5,956,689	A	9/1999	Everhart, III	6,282,442	B1	8/2001	DeStefano
5,956,690	A	9/1999	Haggerson	6,283,960	B1	9/2001	Ashley
5,959,613	A	9/1999	Rosenberg	6,295,082	B1	9/2001	Dowdy
5,976,070	A	11/1999	Ono	6,299,625	B1	10/2001	Bacher
5,976,074	A	11/1999	Moriyama	6,309,347	B1	10/2001	Takahashi
5,980,454	A	11/1999	Broome	6,310,642	B1	10/2001	Adair
5,980,468	A	11/1999	Zimmon	6,319,196	B1	11/2001	Minami
5,986,693	A	11/1999	Adair	6,319,197	B1	11/2001	Tsuji
5,991,729	A	11/1999	Barry	6,334,844	B1	1/2002	Akiba
5,991,730	A	11/1999	Lubin	6,346,075	B1	2/2002	Arai
5,999,168	A	12/1999	Rosenberg	6,354,992	B1	3/2002	Kato
6,002,425	A	12/1999	Yamanaka	6,366,799	B1	4/2002	Acker
6,007,482	A	12/1999	Madni	6,381,029	B1	4/2002	Tipirneni
6,007,531	A	12/1999	Snoke	6,398,724	B1	6/2002	May
6,014,630	A	1/2000	Jeacock	6,413,207	B1	7/2002	Minami
6,015,088	A	1/2000	Parker	6,421,078	B1	7/2002	Akai
6,017,322	A	1/2000	Snoke	6,425,535	B1	7/2002	Akiba
6,020,875	A	2/2000	Moore	6,425,858	B1	7/2002	Minami
6,020,876	A	2/2000	Rosenberg	6,436,032	B1	8/2002	Eto
6,026,363	A	2/2000	Shepard	6,441,845	B1	8/2002	Matsumoto
6,030,360	A	2/2000	Biggs	6,447,444	B1	9/2002	Avni
6,032,120	A	2/2000	Rock	6,449,006	B1	9/2002	Shipp
6,039,728	A	3/2000	Berlien	6,453,190	B1	9/2002	Acker
6,043,839	A	3/2000	Adair	6,454,162	B1	9/2002	Teller
6,050,718	A	4/2000	Schena	6,459,447	B1	10/2002	Okada
6,057,828	A	5/2000	Rosenberg	6,468,204	B2	10/2002	Sendai
6,059,719	A	5/2000	Yamamoto	6,475,141	B2	11/2002	Abe
6,061,004	A	5/2000	Rosenberg	6,478,730	B1	11/2002	Bala
6,066,090	A	5/2000	Yoon	6,489,987	B1	12/2002	Higuchi
6,067,077	A	5/2000	Martin	6,496,827	B2	12/2002	Kozam
6,071,248	A	6/2000	Zimmon	6,498,948	B1	12/2002	Ozawa
6,075,555	A	6/2000	Street	6,503,193	B1	1/2003	Iwasaki
6,078,308	A	6/2000	Rosenberg	6,520,908	B1	2/2003	Ikeda
6,078,353	A	6/2000	Yamanaka	6,524,234	B2	2/2003	Ouchi
6,078,876	A	6/2000	Rosenberg	6,530,882	B1	3/2003	Farkas
6,080,104	A	6/2000	Ozawa	6,533,722	B2	3/2003	Nakashima
6,081,809	A	6/2000	Kumagai	6,540,669	B2	4/2003	Abe
6,083,152	A	7/2000	Strong	6,544,194	B1	4/2003	Kortenbach
6,083,170	A	7/2000	Ben-Haim	6,545,703	B1	4/2003	Takahashi
6,095,971	A	8/2000	Takahashi	6,551,239	B2	4/2003	Renner
6,099,465	A	8/2000	Inoue	6,558,317	B2	5/2003	Takahashi
6,100,874	A	8/2000	Schena	6,561,971	B1	5/2003	Akiba
6,104,382	A	8/2000	Martin	6,565,507	B2	5/2003	Kamata
6,120,435	A	9/2000	Eino	6,574,629	B1	6/2003	Cooke, Jr. et al.
6,125,337	A	9/2000	Rosenberg	6,589,162	B2	7/2003	Nakashima
6,128,006	A	10/2000	Rosenberg	6,595,913	B2	7/2003	Takahashi
6,132,369	A	10/2000	Takahashi	6,597,390	B1	7/2003	Higuchi
6,134,056	A	10/2000	Nakamura	6,599,239	B2	7/2003	Hayakawa
6,134,506	A	10/2000	Rosenberg	6,602,186	B1	8/2003	Sugimoto
6,135,946	A	10/2000	Konen	6,605,035	B2	8/2003	Ando
6,139,508	A	10/2000	Simpson	6,609,135	B1	8/2003	Omori
6,141,037	A	10/2000	Upton	6,611,846	B1	8/2003	Stoodley
6,142,956	A	11/2000	Kortenbach	6,614,969	B2	9/2003	Eichelberger
6,146,355	A	11/2000	Biggs	6,616,601	B2	9/2003	Hayakawa
6,149,607	A	11/2000	Simpson	6,623,424	B2	9/2003	Hayakawa
6,152,877	A	11/2000	Masters	6,638,214	B2	10/2003	Akiba
6,154,198	A	11/2000	Rosenberg	6,638,215	B2	10/2003	Kobayashi
6,154,248	A	11/2000	Ozawa	6,641,528	B2	11/2003	Torii
6,155,988	A	12/2000	Peters	6,641,553	B1*	11/2003	Chee et al. 604/68
6,181,481	B1	1/2001	Yamamoto	6,651,669	B1	11/2003	Burnside
6,184,922	B1	2/2001	Saito	6,656,110	B1	12/2003	Irion
6,193,714	B1	2/2001	McGaffigan	6,656,112	B2	12/2003	Miyanaga
6,195,592	B1	2/2001	Schuler et al.	6,659,940	B2	12/2003	Adler
6,203,493	B1	3/2001	Ben-Haim	6,663,561	B2	12/2003	Sugimoto
6,206,824	B1	3/2001	Ohara	6,669,629	B2	12/2003	Matsui
6,211,904	B1	4/2001	Adair	6,673,012	B2	1/2004	Fujii
6,216,104	B1	4/2001	Moshfeghi	6,677,984	B2	1/2004	Kobayashi
6,219,091	B1	4/2001	Yamanaka	6,678,397	B1	1/2004	Ohmori
				6,682,479	B1	1/2004	Takahashi
				6,685,631	B2	2/2004	Minami
				6,686,949	B2	2/2004	Kobayashi
				6,690,409	B1	2/2004	Takahashi

(56)

References Cited

U.S. PATENT DOCUMENTS

6,690,963 B2	2/2004	Ben-Haim	6,923,818 B2	8/2005	Muramatsu
6,692,431 B2	2/2004	Kazakevich	6,928,490 B1	8/2005	Bucholz
6,697,101 B1	2/2004	Takahashi	6,930,706 B2	8/2005	Kobayashi
6,699,181 B2	3/2004	Wako	6,932,761 B2	8/2005	Maeda
6,702,737 B2	3/2004	Hino	6,934,093 B2	8/2005	Kislev
6,711,426 B2	3/2004	Benaron	6,934,575 B2	8/2005	Ferre
6,715,068 B1	3/2004	Abe	6,943,663 B2	9/2005	Wang
6,716,162 B2	4/2004	Hakamata	6,943,821 B2	9/2005	Abe
6,728,599 B2	4/2004	Wright	6,943,822 B2	9/2005	Iida
6,730,018 B2	5/2004	Takase	6,943,946 B2	9/2005	Fiete
6,736,773 B2	5/2004	Wendlandt	6,943,959 B2	9/2005	Homma
6,743,240 B2	6/2004	Smith	6,943,966 B2	9/2005	Konno
6,749,559 B1	6/2004	Kraas	6,944,031 B2	9/2005	Takami
6,749,560 B1	6/2004	Konstorum	6,949,068 B2	9/2005	Taniguchi
6,749,561 B2	6/2004	Kazakevich	6,950,248 B2	9/2005	Rudischhauser
6,753,905 B1	6/2004	Okada	6,950,691 B2	9/2005	Uchikubo
6,758,806 B2	7/2004	Kamrava	6,954,311 B2	10/2005	Amanai
6,758,807 B2	7/2004	Minami	6,955,671 B2	10/2005	Uchikubo
6,758,842 B2	7/2004	Irion	6,956,703 B2	10/2005	Saito
6,774,947 B2	8/2004	Muto	6,961,187 B2	11/2005	Amanai
6,778,208 B2	8/2004	Takeshige	6,962,564 B2	11/2005	Hickle
6,780,151 B2	8/2004	Grabover	6,963,175 B2	11/2005	Archenhold
6,785,410 B2	8/2004	Vining	6,964,662 B2	11/2005	Kidooka
6,785,414 B1	8/2004	McStravick, III	6,967,673 B2	11/2005	Ozawa
6,785,593 B2	8/2004	Wang	6,974,466 B2	12/2005	Ahmed
6,796,938 B2	9/2004	Sendai	6,975,968 B2	12/2005	Nakamitsu
6,796,939 B1	9/2004	Konomura	6,976,954 B2	12/2005	Takahashi
6,798,533 B2	9/2004	Tipirneni	6,977,053 B2	12/2005	Mukasa
6,800,056 B2	10/2004	Tartaglia	6,977,670 B2	12/2005	Takahashi
6,800,057 B2	10/2004	Tsujita	6,980,227 B2	12/2005	Iida
6,808,491 B2	10/2004	Kortenbach	6,980,921 B2	12/2005	Anderson
6,824,539 B2	11/2004	Novak	6,981,945 B1	1/2006	Sarvazyan
6,824,548 B2	11/2004	Smith	6,982,740 B2	1/2006	Adair
6,829,003 B2	12/2004	Takami	6,984,206 B2	1/2006	Kumei
6,830,545 B2	12/2004	Bendall	6,985,183 B2	1/2006	Jan
6,832,990 B2	12/2004	Kortenbach	6,986,686 B2	1/2006	Shibata
6,840,932 B2	1/2005	Lang	6,994,668 B2	2/2006	Miyano
6,842,196 B1	1/2005	Swift	6,994,704 B2	2/2006	Qin
6,846,286 B2	1/2005	Hashiyama	7,001,330 B2	2/2006	Kobayashi
6,847,933 B1	1/2005	Hastings	7,008,376 B2	3/2006	Ikeda
6,849,043 B2	2/2005	Kondo	7,335,159 B2*	2/2008	Banik et al. 600/156
6,850,794 B2	2/2005	Shahidi	2001/0039370 A1	11/2001	Takahashi
6,855,109 B2	2/2005	Obata	2001/0049491 A1	12/2001	Shimada
6,858,004 B1	2/2005	Ozawa	2002/0017515 A1	2/2002	Obata
6,858,014 B2	2/2005	Damarati	2002/0028984 A1	3/2002	Hayakawa
6,860,849 B2	3/2005	Matsushita	2002/0055669 A1	5/2002	Konno
6,863,650 B1	3/2005	Irion	2002/0080248 A1	6/2002	Adair
6,863,661 B2	3/2005	Carrillo, Jr.	2002/0087048 A1	7/2002	Brock
6,868,195 B2	3/2005	Fujita	2002/0087166 A1	7/2002	Brock
6,871,086 B2	3/2005	Nevo	2002/0095175 A1	7/2002	Brock
6,873,352 B2	3/2005	Mochida	2002/0128633 A1	9/2002	Brock
6,876,380 B2	4/2005	Abe	2002/0193662 A1	12/2002	Belson
6,879,339 B2	4/2005	Ozawa	2002/0193664 A1	12/2002	Ross
6,881,188 B2	4/2005	Furuya	2003/0032863 A1	2/2003	Kazakevich
6,882,785 B2	4/2005	Eichelberger	2003/0065250 A1	4/2003	Chiel
6,887,195 B1	5/2005	Pilvisto	2003/0069474 A1	4/2003	Couvillon, Jr.
6,890,294 B2	5/2005	Niwa	2003/0069897 A1	4/2003	Roy
6,892,090 B2	5/2005	Verard	2003/0149338 A1	8/2003	Francois
6,892,112 B2	5/2005	Wang	2003/0181905 A1	9/2003	Long
6,895,268 B1	5/2005	Rahn	2003/0216617 A1	11/2003	Hirakui
6,898,086 B2	5/2005	Takami	2004/0049097 A1	3/2004	Miyake
6,899,673 B2	5/2005	Ogura	2004/0054258 A1	3/2004	Maeda
6,899,674 B2	5/2005	Viebach	2004/0073083 A1	4/2004	Ikeda
6,899,705 B2	5/2005	Niemeyer	2004/0073084 A1	4/2004	Maeda
6,900,829 B1	5/2005	Ozawa	2004/0073085 A1	4/2004	Ikeda
6,902,527 B1	6/2005	Doguchi	2004/0143159 A1	7/2004	Wendlandt
6,902,529 B2	6/2005	Onishi	2004/0147809 A1	7/2004	Kazakevich
6,903,761 B1	6/2005	Abe	2004/0167379 A1	8/2004	Akiba
6,903,883 B2	6/2005	Amanai	2004/0204671 A1	10/2004	Stubbs
6,905,057 B2	6/2005	Swayze	2004/0220452 A1	11/2004	Shalman
6,905,462 B1	6/2005	Homma	2004/0249247 A1	12/2004	Iddan
6,908,427 B2	6/2005	Fleener	2004/0257608 A1	12/2004	Tipirneni
6,908,429 B2	6/2005	Heimberger	2005/0192476 A1	9/2005	Homan
6,911,916 B1	6/2005	Wang	2005/0197861 A1	9/2005	Omori
6,916,286 B2	7/2005	Kazakevich	2005/0200698 A1	9/2005	Amling
			2005/0203341 A1	9/2005	Welker
			2005/0203418 A1	9/2005	Yamada
			2005/0205958 A1	9/2005	Taniguchi
			2005/0207645 A1	9/2005	Nishimura

(56)

References Cited

FOREIGN PATENT DOCUMENTS

U.S. PATENT DOCUMENTS

2005/0209509 A1 9/2005 Belson
 2005/0225872 A1 10/2005 Uzawa
 2005/0226508 A1 10/2005 Gotohda
 2005/0228221 A1 10/2005 Hirakawa
 2005/0228222 A1 10/2005 Furumi
 2005/0228227 A1 10/2005 Weber
 2005/0228697 A1 10/2005 Funahashi
 2005/0231591 A1 10/2005 Abe
 2005/0234507 A1 10/2005 Geske
 2005/0243169 A1 11/2005 Ono
 2005/0247081 A1 11/2005 Sakata
 2005/0250983 A1 11/2005 Tremaglio
 2005/0251112 A1 11/2005 Danitz
 2005/0251998 A1 11/2005 Bar-Or
 2005/0253044 A1 11/2005 Kuriyama
 2005/0256370 A1 11/2005 Fujita
 2005/0256373 A1 11/2005 Bar-Or
 2005/0256377 A1 11/2005 Deppmeier
 2005/0256424 A1 11/2005 Zimmon
 2005/0264687 A1 12/2005 Murayama
 2005/0267417 A1 12/2005 Secrest
 2005/0271340 A1 12/2005 Weisberg
 2005/0272978 A1 12/2005 Brunnen
 2005/0273085 A1 12/2005 Hinman
 2005/0288545 A1 12/2005 Matsumoto
 2005/0288553 A1 12/2005 Sugimoto
 2006/0015008 A1 1/2006 Kennedy

EP 0 278 217 A1 8/1988
 EP 0 437 229 A1 7/1991
 EP 0 689 851 A1 1/1996
 EP 0 728 487 B1 8/1996
 EP 1 300 883 A2 4/2003
 JP 58-78635 A 5/1983
 JP 05-31071 A 2/1993
 JP 05-091972 A 4/1993
 JP 06-105800 4/1994
 JP 06-254048 A 9/1994
 JP 07-008441 A 1/1995
 JP 10-113330 A 5/1998
 JP 10-286221 A 10/1998
 JP 11-216113 A 8/1999
 JP 2001 128933 A 5/2001
 JP 3219521 B2 8/2001
 JP 2002 078675 A 3/2002
 JP 2002-102152 A 4/2002
 JP 2002-177197 A 6/2002
 JP 2002-185873 A 6/2002
 JP 2002-253481 A 9/2002
 JP 3372273 B2 11/2002
 JP 2003-075113 A 3/2003
 JP 2002 007134 7/2003
 JP 2002 007134 A 7/2003
 JP 3482238 B2 10/2003
 WO 93/13704 A1 7/1993
 WO 2004/016310 A2 2/2004
 WO 2005/023082 A2 3/2005

* cited by examiner

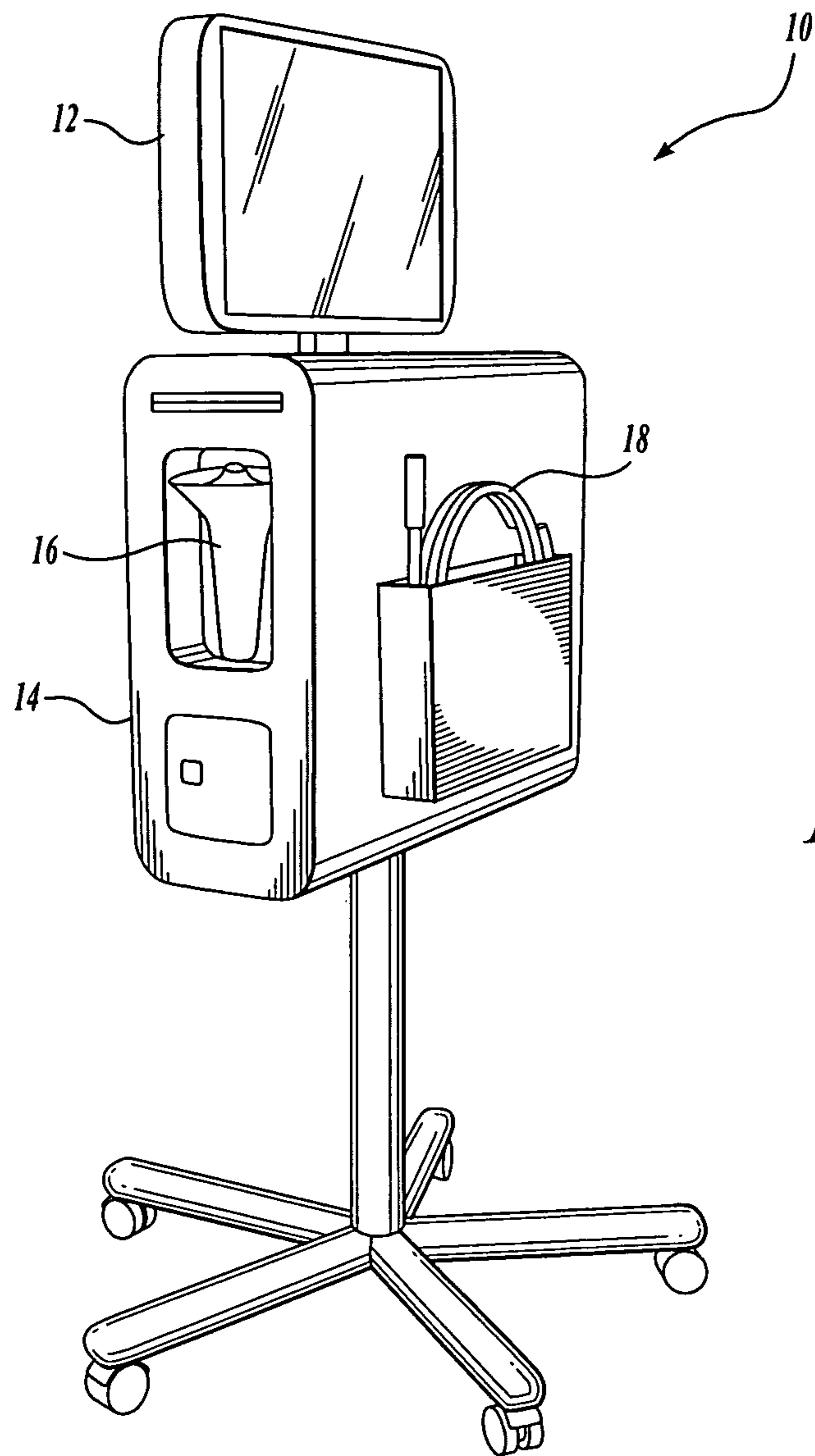
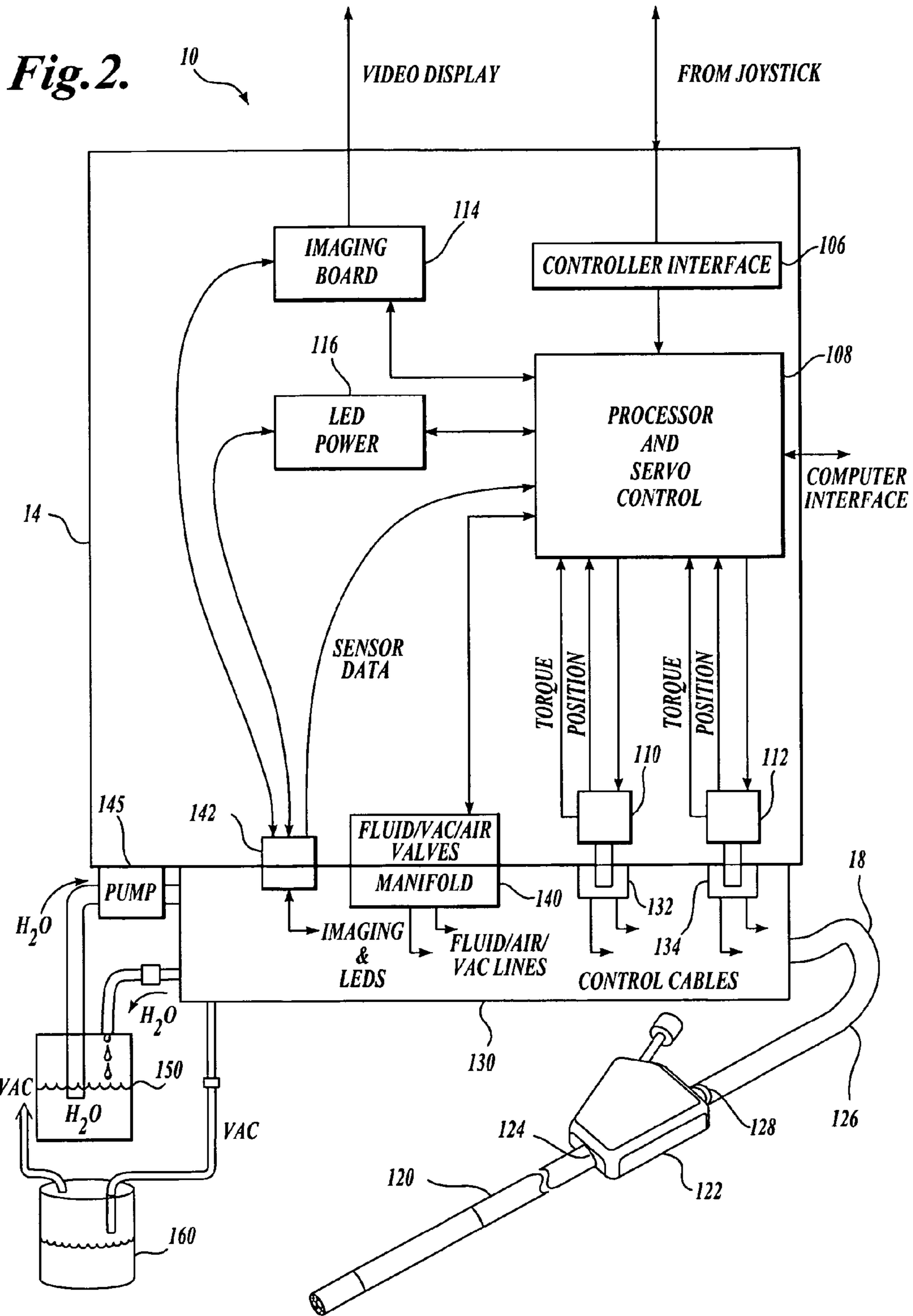


Fig. 1.



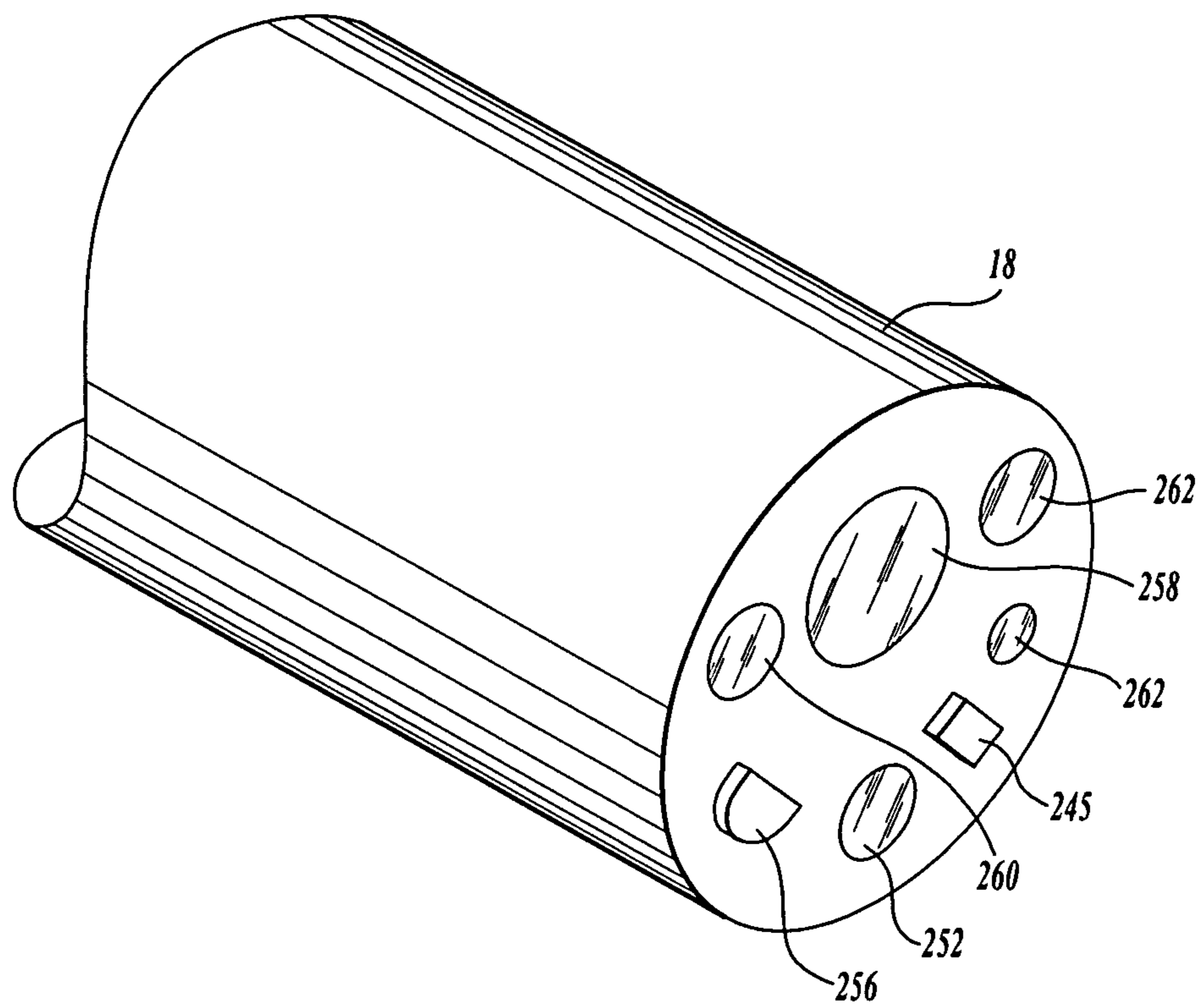
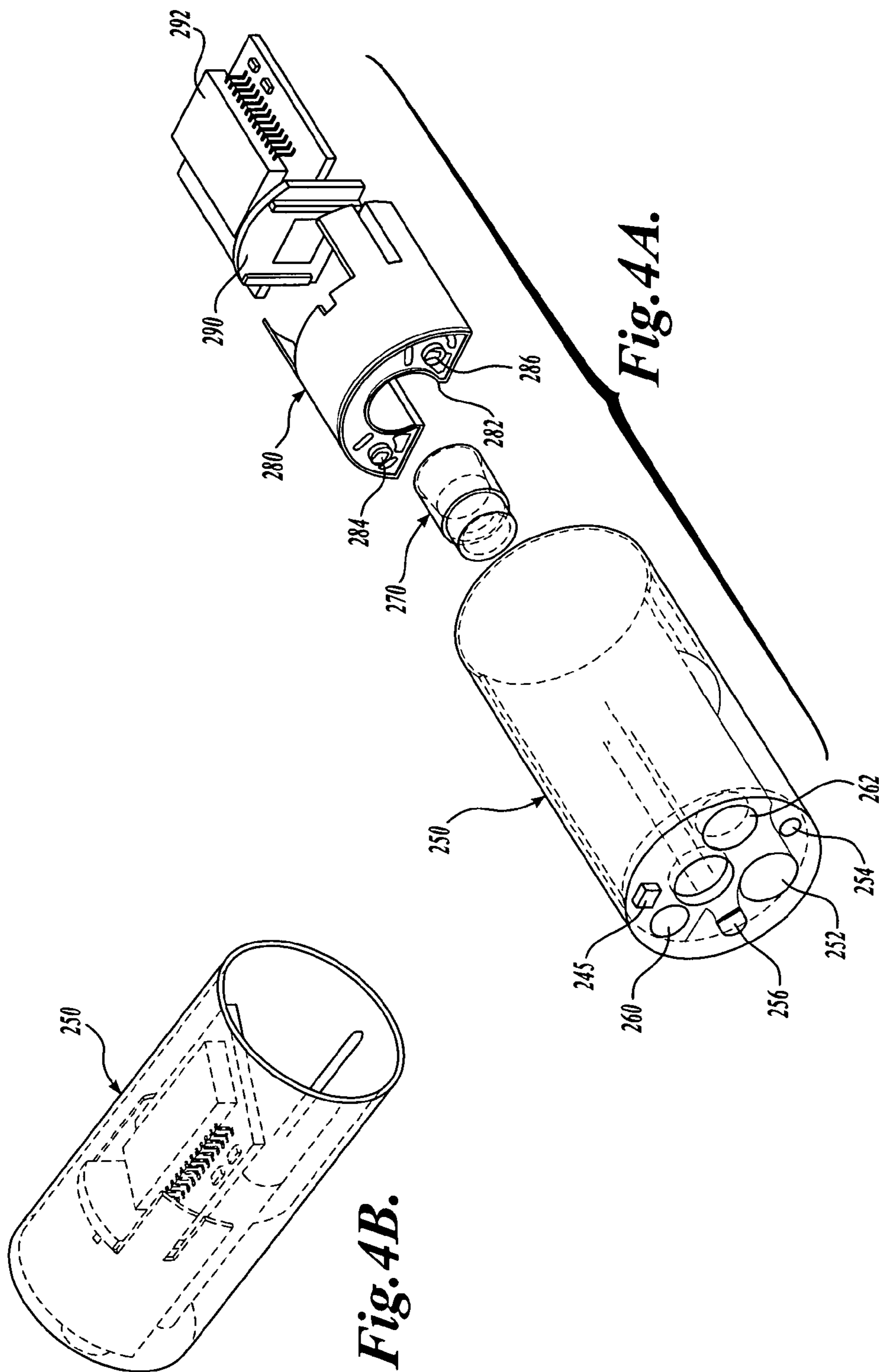


Fig. 3.



**AUTOMATED CONTROL OF IRRIGATION
AND ASPIRATION IN A SINGLE-USE
ENDOSCOPE**

Matter enclosed in heavy brackets [] appears in the original patent but forms no part of this reissue specification; matter printed in italics indicates the additions made by reissue; a claim printed with strikethrough indicates that the claim was canceled, disclaimed, or held invalid by a prior post-patent action or proceeding.

CROSS-REFERENCE TO RELATED
APPLICATION

This application is a reissue application of U.S. Pat. No. 8,435,172, which issued from U.S. patent application Ser. No. 12/330,470, filed Dec. 8, 2008, which is a continuation of U.S. patent application Ser. No. 10/955,901, filed Sep. 30, 2004, now U.S. Pat. No. 7,479,106, the disclosure of which is expressly incorporated herein by reference.

FIELD OF THE INVENTION

The present invention relates to an endoscope system. In particular, it relates to an integrated and automated irrigation and aspiration system for use in an endoscope system.

BACKGROUND OF THE INVENTION

Endoscopes have been used for many years in the medical field to look within a selected region of a patient's body or to perform surgical, therapeutic, diagnostic, or other medical procedures under direct visualization. A conventional endoscope generally contains several components including illuminating means such as light-emitting diodes or fiber optic light guides connected to a proximal source of light, an imaging means such as a miniature video camera or a fiber optic image guide, and a working channel. These components are positioned within an endoscope sheathing tube. Flexible or steerable endoscopes also incorporate an elongated flexible shaft and an articulating distal tip to facilitate navigation through the internal curvature of a body cavity or channel.

Colonoscopy is a medical procedure in which a flexible endoscope, or colonoscope, is inserted into a patient's colon for diagnostic examination and/or surgical treatment of the colon. A standard colonoscope is typically 135-185 cm in length and 12-13 mm in diameter. Colonoscopes generally include a fiber optic imaging bundle, illumination fibers, one or two instrument channels that may also be used for insufflation or irrigation, and a suction channel that extends the length of the colonoscope to facilitate removal of occlusions such as mucus, plaque, fecal matter, or other material that can obstruct the physician's view or interfere with the endoscopic procedure. The colonoscope is inserted via the patient's anus and is advanced through the colon, allowing direct visual examination of the colon, the ileocecal valve, and portions of the terminal ileum. Approximately six million colonoscopies are performed each year.

In order to examine a patient's anatomy during a colonoscopy, it is essential to have a clear field of view. Currently, about 20% of colon polyps are undetected due to low visibility, which can arise from inadequate lens cleaning. Poor colon preparation is also a cause of reduced visibility in the colon. Presently, about 10% of all patients are non-compliant with preparatory procedures and approximately 4% of all patients are unable to complete the exam due to an excess of stool in

the colon. The remaining 6% of all cases are considered marginal, and the colonoscopy may still be performed if the colon is evacuated as a part of the procedure. Conventionally, the colons of marginal cases are cleared by repeatedly administering several small (60 cc) fluid flushes through an endoscope's working channel by means of an ancillary apparatus that employs a low-volume wash and suction. The waste is then removed through the suction channel in the endoscope. However, this tedious and inefficient process is limited by the amount of stool that can be removed with each flush. The process also causes a loss of productivity due to the added time required to evacuate the colon. Therefore, there is a need for a system and method of efficiently cleaning poorly prepared colons.

One example of a colon irrigation method for colonoscopy is described in U.S. Pat. No. 5,279,542, entitled "Colon Irrigation Method." The '542 patent describes an irrigation instrument for use in evacuating the colon prior to endoscopic surgery. The instrument consists of an elongate tube with a plurality of longitudinally and circumferentially spaced apertures along its entire length. A pressurized source of irrigation fluid is connected to the tube for feeding fluid through the channel and out through the apertures with an essentially uniform radial distribution. The tube is thin enough to fit down the biopsy channel of an endoscope. The invention essentially provides an improved method for providing irrigating fluid to a distal end of an endoscope or to a surgical site.

Although the apparatus and method of the colon irrigation method described in the '542 patent provides a means of irrigation for colonoscopy and other endoscopic procedures, the device is an accessory to standard endoscopes that uses the working channel of the endoscope. As such, the apparatus requires labor-intensive assembly on an as-needed basis. Furthermore, it is up to the physician to determine the amount of cleaning that is required and to control the apparatus such that the patient is sufficiently prepped for an examination. This reduces the time that the physician has to perform the actual examination.

Given these problems, there is a need for a system that can automatically prepare poorly prepped patients for an endoscopic examination with minimal physician supervision. In addition, the system should operate based on the patient's individual physical anatomy and detected level of cleanliness so that a desired field of view is created in which an examination is conducted.

SUMMARY OF THE INVENTION

To address the foregoing deficiencies in the prior art, the present invention is an endoscopic system that provides automated irrigation and aspiration of patients undergoing colonoscopy. The endoscopic examination system according to the present invention includes an endoscope with a source of illuminative light and an image sensor to produce images of a patient's colon. An image processor is coupled to receive image signals from the image sensor. The image processor or a computer automatically analyzes the images obtained from the image sensor to determine if irrigation and aspiration is required to provide a clear field of view. If so, the computer operates one or more control valves that supply the insufflation, irrigation, and aspiration to the patient.

In one embodiment, the endoscope may include one or more sensors that sense environmental conditions within the patient's colon such that the amount, rate, or composition of the cleaning solution delivered can be adjusted to the patient's individual anatomy and level of preparation. In one embodi-

ment, the level of insufflation and aspiration are automatically adjusted to provide a desired field of view in the region of the distal tip of the endoscope.

BRIEF DESCRIPTION OF THE DRAWINGS

The foregoing aspects and many of the attendant advantages of this invention will become more readily appreciated as the same become better understood by reference to the following detailed description, when taken in conjunction with the accompanying drawings, wherein:

FIG. 1 illustrates a single-use endoscopic imaging system in accordance with one embodiment of the present invention;

FIG. 2 is a functional block diagram that shows the interrelationship of the major components of a single-use endoscopic imaging system shown in FIG. 1;

FIG. 3 illustrates a distal end of a single-use imaging endoscope in accordance with an embodiment of the present invention; and

FIGS. 4A and 4B illustrate an imaging sensor and heat exchanger positioned at the distal end of the endoscope in accordance with an embodiment of the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

As indicated above, the present invention is an endoscopic examination system that provides integrated and automated irrigation and aspiration for prepping poorly prepared patients for examination. The system is integral to the overall endoscope architecture. Further, the physical hardware implementation of the endoscope improves upon previous means of irrigation by the use of an automated mechanism that administers one or more colon irrigation modalities depending on an analysis of the patient's anatomy or level of preparation. Although the present invention is described with respect to its use within the colon, it will be appreciated that the invention can be used in any body cavity that can be expanded and/or prepared for examination or surgery.

FIG. 1 illustrates the major components of an exemplary single-use endoscopic imaging system 10. The components of the system 10 include a display 12, a user input device 16, and a single-use imaging endoscope 18, all of which are functionally connected to a control cabinet 14 that executes application software (not shown) residing therein. Display 12 is any special-purpose or conventional computer display device, such as a computer monitor, that outputs graphical images and/or text to a user. Single-use imaging endoscope 18 is a single-use flexible tube that contains one or more lumens for the purpose of performing endoscopic procedures and facilitating the insertion and extraction of fluids, gases, and/or medical devices into and out of the body. Single-use endoscope 18 further contains a digital imaging system (not shown) comprised of, in one example, an image sensor such as a CMOS imager, optical lenses such as plastic optics, a light source such as a number of LEDs, and an articulating tip that enables steering of the endoscope in a desired direction.

Control cabinet 14 is a special-purpose electronic and electromechanical apparatus that processes and manages all system functions, and includes a network-enabled image-processing CPU, a physical connection to the single-use endoscope 18, an optional dock for the user interface 16, and valves that control the delivery of gas/water to the endoscope and a vacuum line that removes the air/gas and debris, etc., from the patient. User input device 16 is a hand-held device, either wired to the control cabinet 14 or wireless, that accepts inputs from a human operator via standard push buttons,

joysticks, or other activation devices either singularly or in combination to control the operation of single-use endoscopic imaging system 10.

Operation of single-use endoscopic imaging system 10 is as follows: the system is initiated and operated upon command by means of user input device 16, causing the application software executed by a processor within the control cabinet 14 to activate the appropriate hardware to perform surgical, therapeutic, diagnostic, or other medical procedures and to deliver insufflation and/or suction to the lumen(s) of single-use endoscope 18. Display 12 provides live endoscopic video images and visual feedback of control parameters to the physician or operator so that an examination of the patient can be completed. Upon termination of the examination, the endoscope 18 is disconnected from the control cabinet and disposed of.

FIG. 2 is a functional block diagram of single-use endoscopic imaging system 10 that shows the operational interrelationship of the major hardware and software elements of the system. A complete description of the control cabinet 14 and other components is set forth in U.S. patent application Ser. No. 10/811,781, filed Mar. 29, 2004, and U.S. patent application Ser. No. 10/956,007, entitled VIDEO ENDOSCOPE, filed concurrently herewith) and herein incorporated by reference. The single-use endoscopic imaging system 10 includes the control cabinet 14 that operates to control the orientation and functions of a single-use imaging endoscope 18. The control cabinet 14 includes a controller interface 106 that receives commands from the user input device 16 such as a joystick, that is used by a physician or their assistant to control the operation of the single-use endoscope 18. Commands from the joystick are supplied to a programmable processor such as a digital signal processor that controls the overall operation of the imaging system and a servo control unit 108. The processor and servo control unit 108 control the operation of a pair of servo motors 110, 112 that in turn drive control cables within the single-use endoscope 18. The orientation of the distal tip is controlled in response to directional signals received from the user input device as well as feedback signals obtained from sensors that measure the position and torque of each of the servo motors 110, 112.

In one embodiment of the invention, the processor and servo control unit 108 implement a position-to-rate control that varies the speed at which the distal tip is moved as a function of the position of the directional switch on the user input device 16. However, other control algorithms such as position-to-position or position-to-force (i.e., acceleration) could also be implemented.

The control cabinet 14 also includes an imaging board 114 that produces images from the signals that are received from the image sensor at the distal end of the single-use endoscope 18. The imaging board 114 deserializes the digital video signals from the CMOS imager sensor and performs the necessary algorithms such as demosaicing, gain control and white balance to produce a quality color image. The gain control of the system is implemented by adjusting the intensity of the illumination (current supplied to a number of LEDs) and adjusting the RGB gains of the CMOS imager. The imaging board 114 also includes isolation circuitry to prevent a patient from becoming shocked in the event of an electrical failure on the imaging board 114 or within the control cabinet 14 as well as circuitry for transmitting control signals to the image sensor and for receiving image signals from the image sensor. In one embodiment of the invention, the imaging board 114 is provided on a standard PC circuit

5

board to allow individual endoscopes to be tested with a personal computer and without the need for an additional control cabinet **14**.

In the embodiment shown in FIG. 2, the single-use endoscope **18** has a distal shaft portion **120** that is connected to a breakout box **122** with a swivel connection **124**. The breakout box **122** provides access to a working channel in the distal portion of the endoscope. In addition, the proximal portion **126** of the shaft is connected to the breakout box **122** with a second swivel connection **128**. The swivel connections **124**, **128** allow the distal and proximal ends of the endoscope to rotate with respect to the breakout box **122** and without twisting the breakout box **122** in the hands of the physician or their assistant.

In the embodiment shown, the single-use endoscope **18** is connected to the control cabinet **14** with a connector **130**. Within the connector **130** are a pair of spools **132**, **134** that are engageable with the driveshafts of the servo motors **110**, **112**. Each spool **132**, **134** drives a pair of control cables that are wound in opposite directions. One pair of control cables drives the distal tip of the endoscope in the up and down direction, while the other pair of control cables drives the distal tip of the endoscope in the left and right direction. In an alternate embodiment, the endoscope may include a manual handle having control knobs that selectively tension or release the control cables to move the distal tip and one or more buttons that activate functions of the endoscope.

The connector **130** also includes a manifold **140** that controls the supply of irrigation fluid, air and vacuum to various tubes or lumens within the endoscope **18**. In addition, the connector **130** includes an electrical connector **142** that mates with the corresponding electrical connector on the control cabinet **14**. The connector **142** transfers signals to and from the image sensor as well as power to the illumination LEDs and allows connection to a thermal sensor at the distal end of the endoscope. In addition, the connector **142** carries signals from one or more remotely located environmental sensors as will be described below. Water or another irrigation liquid is supplied to the endoscope with a pump **145**. The pump **145** is preferably a peristaltic pump that moves the water through a flexible tube that extends into the proximal connector **130**. Peristaltic pumps are preferred because the pump components do not need to come into contact with the water or other fluids within the endoscope and it allows the wetted component to be single-use. A water or other irrigation liquid reservoir **150** is connected to the pump **145** and supplies water to cool the illumination LEDs as well as to irrigate the patient. The water supplied to cool the LEDs is returned to the reservoir **150** in a closed loop. Waste water or other debris are removed from the patient with a vacuum line that empties into a collection bottle **160**. Control of the vacuum to the collection bottle **160** is provided at the manifold **140** within the proximal connector **130**. A gas source provides insufflation by delivering an inert gas such as carbon dioxide, nitrogen, air, etc., to the lumen(s) of single-use endoscope **18** via the manifold **140**.

The processor and control unit **108** executes application software, including a GUI software application, a system control software application, and a network software application that reside on a computer readable medium such as a hard disc drive, CD-ROM, DVD, etc., or in a solid state memory. GUI software application is well known to those skilled in the art, and provides the physician or operator with live endoscopic video or still images and, optionally, with visual, audible, or haptic control and feedback on display **12** using user input device **16**. System control software application is the central control program of application software that

6

receives input from sensors, such as from the one or more environmental sensors at the distal end of the endoscope as described below, as well as from the input device **16**. System control software application provides system control for the functions necessary to operate single-use endoscope system **10**. The network software application operates a network connection to allow the endoscopic imaging system **10** to be connected to a local area network and/or the Internet.

As set forth in the 10/811,781 application, the manifold **140** supplies insufflation gas, water and vacuum to one or more lumens of single-use endoscope **18**. The manifold is preferably constructed as a series of passages that are formed between sheets of a thermoplastic material. Water, air, and vacuum are applied to inputs of the manifold and selectively delivered to outputs that are in turn connected to lumens within the endoscope **18** by pinch valves on the control cabinet **14** that open or close the passages in the manifold. The passages are preferably formed by rf welding the sheets of thermoplastic into the desired pattern of the passages.

In accordance with FIG. 2, the basic process of insufflation and exsufflation using single-use endoscopic imaging system **10** is as follows:

During operation, live endoscopic video images are provided on display **12** by the GUI software application, which processes information from the imaging board **114**, and the single-use endoscope **18**. Prior to operation, insufflation is initiated upon operator command by means of the user input device **16**, or according to a pre-programmed routine. As a result, system control software application activates the manifold **140** by means of the pinch valves on the control cabinet **14**. Upon advancing single-use endoscope **18**, images are produced by the image sensor at the distal tip of the endoscope and analyzed by the image processor **114** and/or the processor and servo control unit **108** to determine if either irrigation or insufflation is required. If insufflation is required, an insufflation gas is channeled through a lumen of single-use endoscope **18** and into the patient. In one embodiment of the invention, the gas delivery lumen terminates at directional port **256**, that directs the insufflation gas and/or irrigation liquid over a lens **270** of the imaging sensor, as shown in FIG. 3. As the distal tip of single-use endoscope **18** is advanced into the colon during the endoscopic procedure, further areas of the colon are insufflated, bringing new examination regions into view.

As shown in FIG. 3, the distal end of the single-use endoscope **18** includes a distal cap **250** having a number of openings on its front face. The openings include an opening to a working channel **252** and an opening **254** for a low pressure lavage lumen, whereby a stream of liquid can be delivered through the endoscope to remove debris or obstructions from the patient. A lens wash and insufflation port includes the integrated directional port or flush cap **256** that directs water across the lens of an image sensor and delivers the insufflation gas to expand the lumen in which the endoscope is inserted. Offset from the longitudinal axis of the endoscope is a lens port **258** that is surrounded by a pair of windows or lenses **260** and **262** that cover the illumination sources. One or more environmental sensors **245** are also disposed on or adjacent the front face of the distal cap **250** to detect environmental conditions within the body cavity of the patient. Signals from the one or more environmental sensors are transmitted back to the processor and servo control unit **108** through the electrical connector **142**. Suitable environmental sensors **245** include, but are not limited to, pressure, temperature, pH sensors to measure conditions in the patient adjacent the distal tip. In addition, sensors such as laser distance sensor or ultrasonic

probes can be used to measure the size of the area or thickness of the colon wall surrounding the endoscope.

As best shown in FIG. 4A, the imaging assembly at the distal end of the endoscope also includes a heat exchanger **280**. The heat exchanger **280** comprises a semi-circular section having a concave recess **282** into which a cylindrical lens assembly **270** is fitted. The concave recess **282** holds the position of the lens assembly **270** in directions perpendicular to the longitudinal axis of endoscope, thereby only permitting the lens assembly **270** to move along the longitudinal axis of the endoscope. Once the lens assembly is positioned such that it is focused on an image sensor **290** that is secured to a rear surface of the heat exchanger **280**, the lens assembly is fixed in the heat exchanger with an adhesive. A pair of LEDs **282**, **284** are bonded to a circuit board that is affixed in the heat exchanger such that a channel is formed behind the circuit board for the passage of a fluid or gas to cool the LEDs. A circuit board or flex circuit **292** containing circuitry to transmit and receive signals to and from the control cabinet is secured behind the image sensor **290** and to the rear surface of the heat exchanger **280**. With the lens assembly **270**, the LEDs **280**, **282**, the image sensor **290**, and associated circuitry **292** secured in the heat exchanger **280**, the heat exchanger assembly can be fitted within the distal cap **250** to complete the imaging assembly.

As discussed, the images obtained from the image sensor are analyzed by an image analysis program to determine when cleaning of the imaging system or the colon itself is desired. In addition, measurements of the colon cavity obtained from the one or more environmental sensors may be combined with image information as analyzed by the image analysis program to control the supply of irrigation and aspiration when a cleaning cycle is required.

The basic process of irrigation and aspiration for the purpose of prepping a poorly prepared patient during a colonoscopy procedure using the endoscopic imaging system **100** is as follows.

The GUI software application displays the live video or still images produced by the imaging board **114** on the display **110**. In addition, an image analysis program that is executed by a processor on the imaging board **114** or the processor and servo control unit **108** analyzes the image signals to determine if it is necessary to employ a wash routine in the patient or to clean the lens of the endoscope **18**. If the image analysis program determines that a lens cleaning or wash routine should be initiated, the control software application activates one or more valves controlling the manifold to deliver an irrigation liquid and vacuum aspiration to the endoscope. The modality of the washing routine supplied can be determined based on an analysis of the images produced as well as volumetric, environmental or other measurements obtained by the one or more environmental sensors **245** at the distal end of the endoscope.

To determine if the field of view of the single-use endoscope **18** is clear or obstructed, the image analysis program analyzes images of the patient's body for the presence of obstructing matter within the area of view or on the surface of imaging optics. For example, the image analysis program determines if the position of an obstruction changes with a change in probe position. If an obstruction remains in the same place within an image despite moving the endoscope, then the system control software initiates a blast of cleaning solution over the surface of the imaging lens. However, if the image appears to indicate that the patient has not been properly prepped, then the system control software proceeds to initiate one or more cleaning or washing routines.

In one embodiment of the invention, the presence of obstructing material in the field of view is detected by the image analysis program on the basis of the color or spectral reflectance of the tissue being observed. Healthy colon tissue is typically characterized by white or pinkish tissue. Therefore, the image analysis program searches an image to determine the number of pixels in the image that display the desired tissue color. If the image contains too many dark or other colored pixels, the presence of obstructing material is presumed. Of course, it will be appreciated that the color of healthy, clean tissue can vary from patient to patient. Therefore, the physician may be prompted to direct the probe at a known portion of healthy, clean tissue to calibrate the image analysis program prior to beginning the colonoscopy.

In performing the washing routine, the system control software may take into consideration measurements obtained from the one or more environmental sensors **245** included in the single-use endoscope **18**. For example, measurements of the size of the colon cavity, thickness of the colon wall, pressure within the colon, or other factors such as temperature, pH, etc. can be obtained from the one or more environmental sensors **245** and used to adjust the volume or rate of delivery and/or aspiration of liquid supplied or the composition of the washing liquid can be adjusted based on the measurements obtained. Similarly, the environmental sensor **245** positioned along the length of the endoscope can measure the depth of insertion of the distal tip of the endoscope.

With the endoscopic imaging system **10**, any obstructions that interfere with the endoscopic procedure are automatically detected. Washing or lens cleaning routines are initiated upon command by the system control software or may be initiated by an operator command received via user interface **16**. Wash routines may include, for example, a continuous spray, a pulsating jet, and a large bolus wash. Sequential mixtures of fluids or gases can be augmented with aeration and/or additives. Additives are added into the irrigant solution, either singularly or in combination, upon operator command using user interface **16** or as directed by preprogrammed wash routines or based on an analysis of signals produced from the image sensor and/or the one or more environmental sensors **245**. New wash routines may be downloaded through network connection by means of network software application. Alternatively, a user may also manually define new irrigant mixes and/or wash routines by recording a series of operator commands on user interface **16**.

After irrigation, the resulting maceration is aspirated under control of the system control software application, which activates the manifold **140**. The manifold **140** applies vacuum through a working or aspiration channel of the single-use endoscope **18**. At any time, the physician or their assistant may manually interrupt the wash routine or aspiration.

The endoscopic imaging system of the present invention also determines if the body cavity is properly inflated. Such a determination is made by measuring the pressure and/or analyzing images obtained from the image sensor. If the body cavity is not properly inflated, insufflation gas is delivered to the patient in a manner that is adjusted for environmental conditions in the patient. As with the washing mode, the insufflation gas can be delivered in accordance with the detected pressure in the body cavity, the size of the cavity, or until the image signals produced by the image sensor indicate that the colon is inflated to produce a desired field of view. Furthermore, the insufflation gas can be adjusted in accordance with the sensed thickness of the colon wall or other parameters that assure that insufflation gas is not delivered too quickly so as to cause discomfort or potential injury to the patient. By automatically controlling the insufflation of the

colon at the region of the distal tip a desired field of view is provided and inadvertent collapse of the colon is prevented. Furthermore, the physician can concentrate on performing the procedure without having to manually control insufflation.

As will be appreciated, the automated irrigation and aspiration features of the present invention reduce the need for the physician to actively control the preparation of poorly prepared patients for examination. Because obstructions and poor fields of view are automatically detected and cleared, the physician can concentrate on performing the required procedure. Furthermore, the evacuation wash routines may be tailored to a patient's individual condition as detected by the image analysis program and one or more sensors 122.

While the preferred embodiment of the invention has been illustrated and described, it will be appreciated that various changes can be made therein without departing from the scope of the invention. For example, although the present invention is described with respect to single use, disposable endoscopes, it will be appreciated that the present invention is also applicable to non-disposable, reusable endoscopes as well. It is therefore intended that the scope of the invention be determined from the following claims and equivalents thereof.

The embodiments of the invention in which an exclusive property or privilege is claimed are defined as follows:

1. A system for automatically controlling the delivery of [insufflation gas] *gas or liquid to a patient*, the system comprising:

[a control cabinet including] a processor [and one or more valves] configured to control the delivery of [insufflation] *gas or liquid* to [a] *the patient*; and

an [endoscope removably connected to the control cabinet and] *elongate member* including a pressure sensor and an image sensor at *or adjacent* a distal end of the [endoscope] *elongate member*;

wherein the processor is configured to obtain *an image [signals] signal* from the image sensor and *a pressure [readings] reading* from the pressure sensor and automatically control [insufflation] *gas or liquid* delivered to the patient as a function of the image [signals] *signal* and the pressure [readings] *reading*.

2. The system of claim 1, wherein the delivery of [insufflation] *gas* is controlled to maintain a predefined field of view in the image [signals] *signal* produced by the image sensor.

3. The system of claim 1, further comprising a sensor configured to determine a size of an inflated body cavity, and wherein the processor is configured to control the delivery of [insufflation] *gas* to maintain a predetermined inflated cavity size.

4. The system of claim 1, wherein the processor is configured to control the delivery of [insufflation] *gas* to maintain a predetermined pressure in a body cavity.

5. The system of claim 1, further comprising a sensor configured to detect a thickness of a tissue wall surrounding the [endoscope] *elongate member*, and wherein the processor is configured to control the delivery of [insufflation] *gas* as a function of the wall thickness detected.

[6. The system of claim 1, wherein the endoscope is dispensable.]

7. A system for automatically controlling the delivery of [insufflation gas] *fluid*, the system comprising:

a control [cabinet] *unit* including a processor [and at least one valve] configured to control the delivery of [insufflation gas] *fluid*; and

an endoscope removably connected to the control [cabinet] *unit* and including a pressure sensor and an image sensor at *or adjacent* a distal end of the endoscope;

wherein the processor is configured to receive *an image [signals] signal* from the image sensor and *a pressure [readings] reading* from the pressure sensor and automatically control the delivery of [insufflation gas] *fluid* as a function of the image [signals] *signal* and the pressure [readings] *reading* by controlling actuation of the at least one valve] *reading*.

8. The system of claim 7, wherein the processor is configured to control the delivery of [insufflation gas] *fluid* to maintain a predefined view produced by the image sensor.

9. The system of claim 7, wherein the processor is configured to control the delivery of [insufflation gas] *fluid* to maintain a predetermined pressure in the body cavity and to maintain a predefined view produced by the image sensor.

10. The system of claim 7, wherein the control [cabinet] *unit* includes a manifold configured to supply [insufflation] *at least one of gas, [a] liquid, and aspiration* to the endoscope.

11. The system of claim 10, [wherein the] *further including* at least one valve *that* is configured to control the supply of [insufflation] *at least one of gas, [the] liquid, and aspiration* from the manifold.

[12. The system of claim 11, wherein the endoscope is removably coupled to the manifold.]

13. A system for automatically controlling the delivery of [insufflation] *gas or liquid*, the system comprising:

a control [cabinet] *unit* including a processor and at least one valve configured to control the delivery of [insufflation] *gas or liquid*; and

an endoscope removably connected to the control [cabinet] *unit* and including a pressure sensor configured to determine a pressure in a body cavity and an image sensor;

wherein the processor is configured to receive *an image [signals] signal* from the image sensor and *a pressure [readings] reading* from the pressure sensor and automatically control the delivery of [insufflation] *gas or liquid* as a function of the image [signals] *signal* and the pressure [readings] *reading* to maintain a predetermined pressure in the body cavity by controlling actuation of the at least one valve.

14. The system of claim 13, wherein the processor is configured to control the delivery of [insufflation] *gas or liquid* to maintain the predetermined pressure in the body cavity and to maintain a predefined view produced by the image sensor.

15. The system of claim 13, wherein the control [cabinet] *unit* includes a manifold configured to supply [insufflation] *gas, [a] liquid, and aspiration* to the endoscope.

16. The system of claim 15, wherein the at least one valve is configured to control the supply of [insufflation] *gas, [the] liquid, and aspiration* from the manifold, *wherein the endoscope is removably coupled to the manifold*.

[17. The system of claim 16, wherein the endoscope is removably coupled to the manifold.]

18. *The system of claim 1, wherein the elongate member is an endoscope.*

19. *The system of claim 18, wherein a control cabinet includes the processor and one or more valves configured to control the delivery of gas or liquid to the patient, and wherein the endoscope is removably connected to the control cabinet.*

20. *The system of claim 19, wherein the processor is configured to obtain image signals from the image sensor and pressure readings from the pressure sensor and automatically control gas or liquid delivered to the patient as a function of the image signals and the pressure readings.*

21. The system of claim 7, wherein the control unit is a control cabinet that further includes at least one valve, and the processor is configured to control the delivery of fluid by controlling actuation of the at least one valve.

22. The system of claim 21, wherein the processor is configured to receive image signals from the image sensor and pressure readings from the pressure sensor and automatically control fluid delivered to the patient as a function of the image signals and the pressure readings. 5

23. The system of claim 13, wherein the control unit is a control cabinet, and wherein the processor is configured to obtain image signals from the image sensor and pressure readings from the pressure sensor and automatically control gas or liquid delivered to the patient as a function of the image signals and the pressure readings. 10 15

* * * * *