

US007596403B2

(12) **United States Patent
Horn**

(10) **Patent No.:** **US 7,596,403 B2**
(45) **Date of Patent:** **Sep. 29, 2009**

(54) **SYSTEM AND METHOD FOR DETERMINING
PATH LENGTHS THROUGH A BODY LUMEN**

5,109,870 A 5/1992 Silny et al.
5,187,572 A 2/1993 Nakamura et al.
5,211,165 A 5/1993 Dumoulin et al.
5,267,033 A 11/1993 Hoshino
5,279,607 A 1/1994 Schentag et al.

(75) Inventor: **Eli Horn**, Kiryat Motzkin (IL)

(73) Assignee: **Given Imaging Ltd.**, Yoqneam (IL)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 379 days.

(Continued)

(21) Appl. No.: **10/879,053**

FOREIGN PATENT DOCUMENTS

(22) Filed: **Jun. 30, 2004**

DE 34 40 177 6/1986

(65) **Prior Publication Data**

US 2006/0036166 A1 Feb. 16, 2006

(Continued)

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

OTHER PUBLICATIONS

(52) **U.S. Cl.** **600/424; 600/117; 600/476**

U.S. Appl. No. 09/807,892, filed Jun. 6, 2001, Meron et al.

(58) **Field of Classification Search** **600/407,**
600/424, 117; 128/899

(Continued)

See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

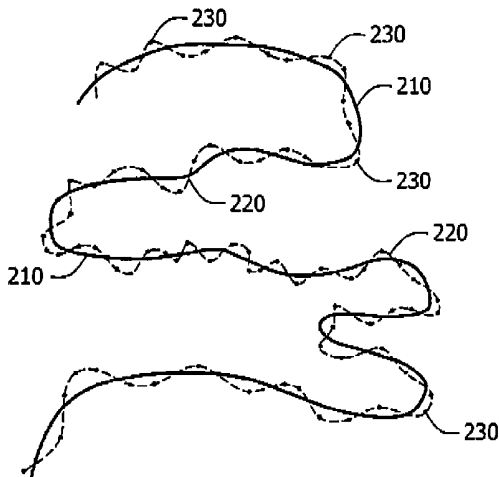
3,460,528 A * 8/1969 Carney 600/424
3,683,890 A 8/1972 Beal
3,971,362 A 7/1976 Pope et al.
4,178,735 A 12/1979 Jackson
4,239,040 A 12/1980 Hosoya et al.
4,262,632 A 4/1981 Hanton et al.
4,278,077 A 7/1981 Mizumoto
4,439,197 A 3/1984 Honda et al.
4,507,115 A * 3/1985 Kambara et al. 604/135
4,646,724 A 3/1987 Sato et al.
4,689,621 A 8/1987 Kleinberg
4,803,992 A 2/1989 Lemelson
4,819,620 A 4/1989 Okutsu
4,844,076 A * 7/1989 Lesho et al. 600/302
4,936,823 A 6/1990 Colvin et al.
4,940,997 A 7/1990 Hamlin et al.
5,042,486 A 8/1991 Pfeiler et al.
5,081,041 A 1/1992 Yafuso et al.

Primary Examiner—Eric F Winakur
Assistant Examiner—Helene Bor
(74) *Attorney, Agent, or Firm*—Pearl Cohen Zedek Latzer, LLP

(57) **ABSTRACT**

A system and method for determining the path length through a body lumen, for example to a specified location, is described. A location detection system may identify the location in space of an in-vivo device over time. A path-length detection unit may use data from the location detection system to determine a path traveled by an in-vivo device. A site of interest along that path may be identified. The distance of the site of interest from at least one end point of a body lumen may be determined.

20 Claims, 3 Drawing Sheets



U.S. PATENT DOCUMENTS

5,330,427	A	7/1994	Weissenburger		
5,368,027	A	11/1994	Lubbers et al.		
5,377,678	A *	1/1995	Dumoulin et al.	600/424	
5,395,366	A	3/1995	D'Andrea et al.		
5,398,670	A	3/1995	Ortiz et al.		
5,429,132	A	7/1995	Guy et al.		
5,479,935	A	1/1996	Essen-Moller		
5,495,114	A	2/1996	Adair		
5,549,109	A	8/1996	Samson et al.		
5,558,640	A	9/1996	Pfeiler et al.		
5,604,531	A	2/1997	Iddan et al.		
5,671,739	A *	9/1997	Darrow et al.	600/424	
5,697,384	A	12/1997	Miyawaki et al.		
5,730,129	A *	3/1998	Darrow et al.	600/407	
5,782,765	A *	7/1998	Jonkman	600/424	
5,800,350	A	9/1998	Coppelson et al.		
5,819,736	A	10/1998	Avny et al.		
5,837,196	A	11/1998	Pinkel et al.		
5,913,820	A	6/1999	Bladen et al.		
5,929,901	A	7/1999	Adair et al.		
5,936,406	A *	8/1999	Pothast	324/318	
5,946,813	A *	9/1999	Nachbaur et al.	33/357	
5,986,693	A	11/1999	Adair et al.		
5,993,378	A	11/1999	Lemelson		
6,043,839	A	3/2000	Adair et al.		
6,082,366	A *	7/2000	Andra et al.	128/899	
6,099,482	A	8/2000	Brune et al.		
6,149,581	A	11/2000	Klingenstein		
6,174,291	B1	1/2001	McMahon		
6,285,897	B1	4/2001	Kilcoyne et al.		
6,228,048	B1	5/2001	Robbins		
6,230,038	B1 *	5/2001	von Gutfeld et al.	600/409	
6,233,476	B1	5/2001	Strommer et al.		
6,240,312	B1 *	5/2001	Alfano et al.	600/476	
6,304,766	B1 *	10/2001	Colvin, Jr.	600/317	
6,324,418	B1	11/2001	Crowley et al.		
6,330,464	B1 *	12/2001	Colvin et al.	600/316	
6,369,812	B1	4/2002	Lyriboz et al.		
6,385,482	B1 *	5/2002	Boksberger et al.	600/424	
6,395,562	B1	5/2002	Hammock et al.		
6,428,469	B1	8/2002	Iddan et al.		
6,473,635	B1 *	10/2002	Rasche	600/428	
6,475,145	B1	11/2002	Baylor		
6,488,694	B1	12/2002	Lau et al.		
6,618,612	B1 *	9/2003	Acker et al.	600/424	
6,632,175	B1	10/2003	Marshall		
6,692,430	B2	2/2004	Adler		
6,709,387	B1	3/2004	Glukhovsky et al.		
6,741,882	B2 *	5/2004	Schaffter et al.	600/424	
6,757,557	B1 *	6/2004	Bladen et al.	600/424	
6,804,547	B2 *	10/2004	Pelzer et al.	600/424	
6,813,512	B2 *	11/2004	Aldefeld et al.	600/410	
6,871,086	B2 *	3/2005	Nevo et al.	600/424	
6,904,308	B2 *	6/2005	Frisch et al.	600/424	
6,923,768	B2 *	8/2005	Camus et al.	600/463	
6,944,316	B2	9/2005	Glukhovsky et al.		
6,947,787	B2 *	9/2005	Webler	600/434	
6,950,690	B1 *	9/2005	Meron et al.	600/424	
6,992,477	B2 *	1/2006	Govari	324/207.13	
6,996,432	B2 *	2/2006	Ostrovsky et al.	600/424	
7,010,338	B2 *	3/2006	Ritter et al.	600/424	
7,076,284	B2 *	7/2006	Segawa et al.	600/424	
2001/0017649	A1	8/2001	Yaron		
2001/0025135	A1	9/2001	Naito et al.		
2001/0035902	A1	11/2001	Iddan et al.		
2002/0015952	A1	2/2002	Anderson et al.		
2002/0042562	A1 *	4/2002	Meron et al.	600/361	
2002/0099310	A1 *	7/2002	Kimchy et al.	600/587	
2002/0103417	A1	8/2002	Gazdzinski		
2002/0109774	A1 *	8/2002	Meron et al.	348/74	
2002/0146368	A1	10/2002	Meron et al.		
2002/0158976	A1	10/2002	Vni et al.		
2002/0173718	A1	11/2002	Frisch et al.		
2002/0177779	A1	11/2002	Adler et al.		
2002/0198470	A1 *	12/2002	Imran et al.	600/587	
2003/0018280	A1	1/2003	Lewkowicz et al.		
2003/0020810	A1	1/2003	Takizawa et al.		
2003/0023150	A1	1/2003	Yokoi et al.		
2003/0114742	A1	1/2003	Lewkowicz et al.		
2003/0028078	A1	2/2003	Glukhovsky		
2003/0045790	A1	3/2003	Lewkowicz et al.		
2003/0167000	A1	9/2003	Mullick et al.		
2003/0171648	A1	9/2003	Yokoi et al.		
2003/0171649	A1	9/2003	Yokoi et al.		
2003/0171652	A1	9/2003	Yokoi et al.		
2003/0195415	A1	10/2003	Iddan		
2003/0208107	A1	11/2003	Refael		
2003/0214579	A1	11/2003	Iddan		
2003/0214580	A1	11/2003	Iddan		
2003/0216622	A1	11/2003	Meron et al.		
2004/0027459	A1	2/2004	Segawa et al.		
2005/0065441	A1 *	3/2005	Glukhovsky	600/476	

FOREIGN PATENT DOCUMENTS

FR	2 688 997	10/1993
IL	126727	8/1999
IL	143259	5/2001
IL	143258	4/2002
JP	4144533	5/1992
JP	6114037	4/1994
JP	6285044	10/1994
JP	7111985	5/1995
JP	7289504	11/1995
JP	2000342522	12/2000
JP	2001091860	4/2001
JP	2001095755	4/2001
JP	2001095756	4/2001
JP	2001104241	4/2001
JP	2001104242	4/2001
JP	2001104243	4/2001
JP	2001104244	4/2001
JP	2001104287	4/2001
JP	2001112709	4/2001
JP	2001112710	4/2001
JP	2001112740	4/2001
JP	2001137182	5/2001
JP	2001224554	8/2001
JP	2001231744	8/2001
JP	2001245844	9/2001
JP	2002010990	1/2002
JP	2000342524	6/2002
JP	2000342525	6/2002
WO	WO 99/32028	7/1999
WO	WO 01/10294	2/2001
WO	WO 01/50941	7/2001
WO	WO 01/69213	9/2001
WO	WO 02/055126	7/2002
WO	WO 02/055984	7/2002
WO	WO 02/067593	8/2002
WO	WO 02/094337	11/2002
WO	WO 02/102223	12/2002
WO	WO 03/003706	1/2003
WO	WO 03/011103	2/2003
WO	WO 2004/028336	4/2004
WO	WO 2004/035106	4/2004

OTHER PUBLICATIONS

U.S. Appl. No. 10/200,548, filed Jul. 23, 2002, Glukhovsky et al.
U.S. Appl. No. 10/724,109, filed Dec. 1, 2003, Glukhovsky et al.
U.S. Appl. No. 10/166,025, filed Jun. 11, 2002, Lewkowicz et al.
U.S. Appl. No. 10/213,345, filed Aug. 7, 2002, Glukhovsky.
U.S. Appl. No. 60/297,761, filed Jun. 14, 2001, Lewkowicz et al.
U.S. Appl. No. 60/299,178, filed Jun. 20, 2001, Glukhovsky et al.

- BBC News Online—Pill camera to 'broadcast from the gut', Feb. 21, 2000, www.news.bbc.co.uk, printed Oct. 22, 2002.
- Evaluation of the heidelberg pH capsule: Method of Tubeless Gastric Analysis, Yarbrough, III et al., *The American Journal Of Surgery*, vol. 117, Feb. 1969, pp. 185-192.
- "In Pursuit of the Ultimate Lamp", Craford et al., *Scientific American*, Feb. 2001.
- International Search Report for PCT/IL99/0554 dated Apr. 4, 2000.
- International Search Report of PCT/IL02/00391, dated May 19, 2003.
- Katgraber F, Glenewinkel, F, Fischler S, *Int J. Legal Med* 1998; 111(3) 154-6.
- Manual of Photogrammetry, Thompson (Ed.), Third Edition, vol. Two, Copyright 1944, 1952, 1966 by the American Society of Photogrammetry.
- "New Smart Plastic has Good Memory"—Turke, European Medical Device Manufacturer, devicelink.com.
- PCT Search Report International Application No. PCT/IL02/00386 International Filing Date: May 19, 2002.
- "Robots for the Future"—Shin-ichi, et al. <http://jin.jcic.or.jp/nip-ponaia13/sp05.html>. printed Nov. 29, 2001.
- Rowell, Nancy D., Endoscopes Go Wireless, *Biophotonics in Action, Photonics Spectra*, pp. 60-62, Mar. 2001.
- Supplementary Partial European Search Report, Mar. 19, 2004.
- Video Camera to "TAKE"—RF System Lab, Dec. 25, 2001.
- Wang, et al., "Integrated Micro-Instrumentation for Dynamic Monitoring of the Gastro-Intestinal Tract", Presented at IEEE Instrumentation and Measurement Technology Conference, May 2002, Anchorage, Ak, USA, www.see.ed.ac.uk/Naa.publications.html.
- "Wellesley Company Sends Body Montiors into Space"—Crum, *Boston Business Journal*, 1998.
- www.jason.net/tinycam.htm, © 2001, printed Dec. 19, 2001.
- www.middleeasthealthmag.com/article2.htm—Review proves the value of computers, © 2001, printed Nov. 29, 2001.
- www.pedinc.com Personal electronic devices, © 1997.
- www.rfnorkia.com—NORIKA3, printed on Jan. 1, 2002.
- * cited by examiner

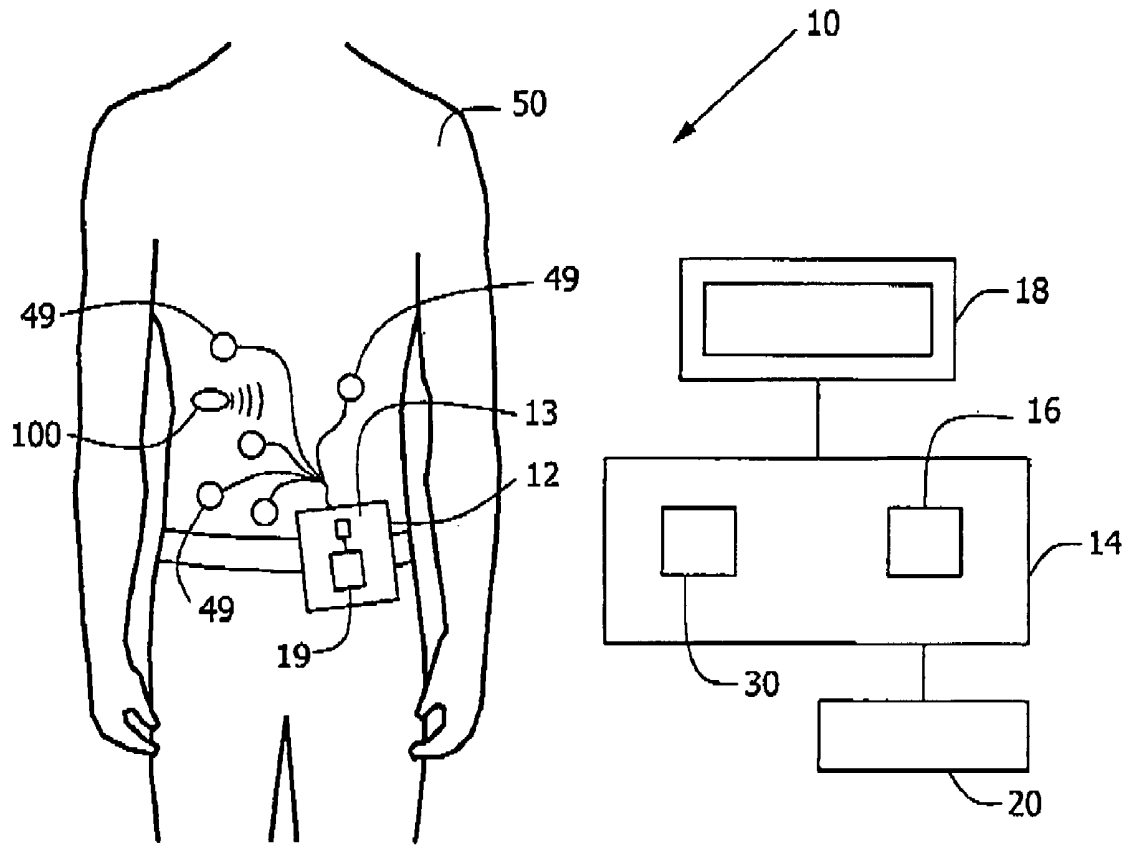


Fig. 1

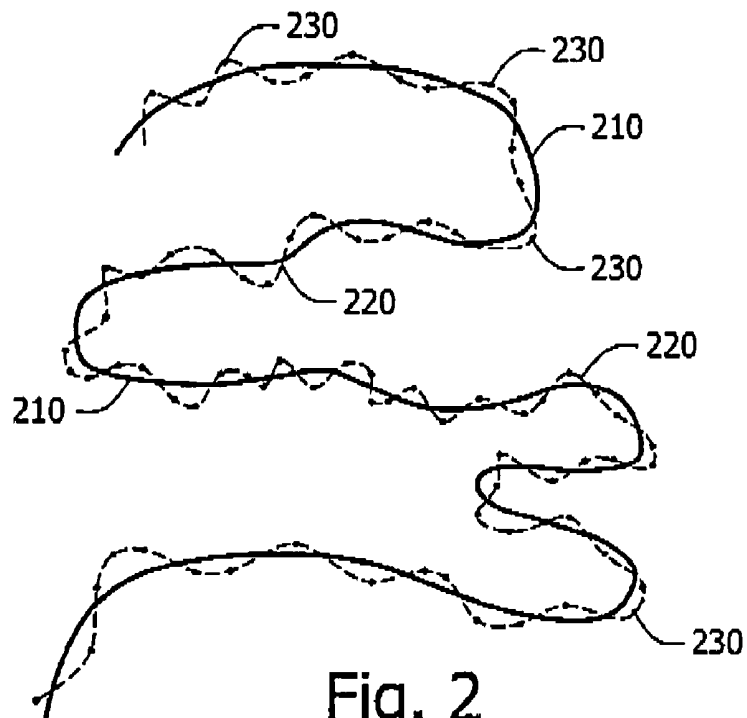


Fig. 2

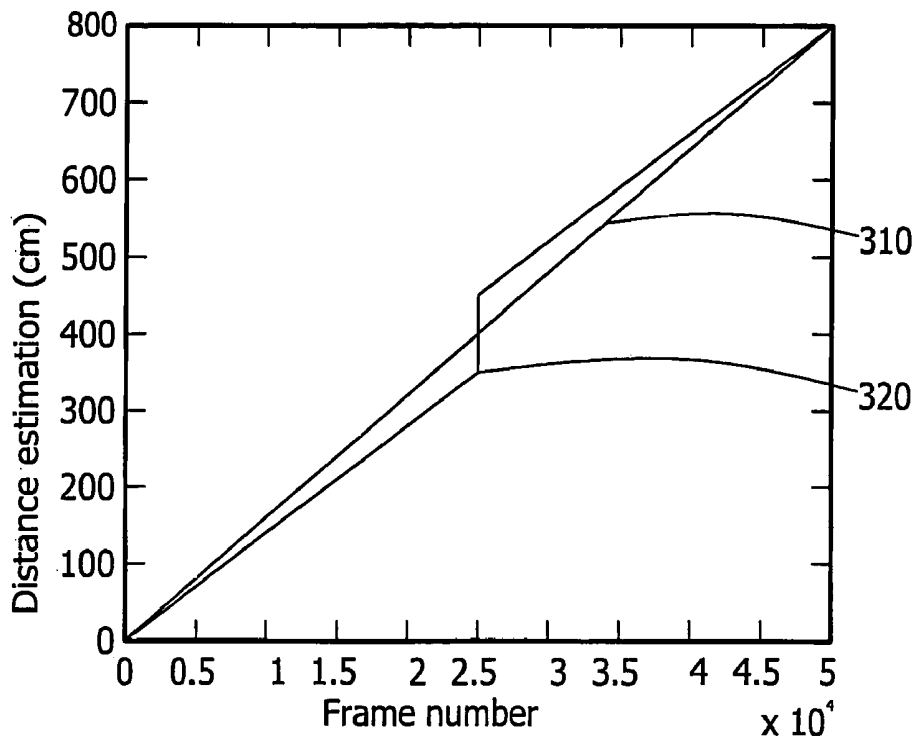


Fig. 3

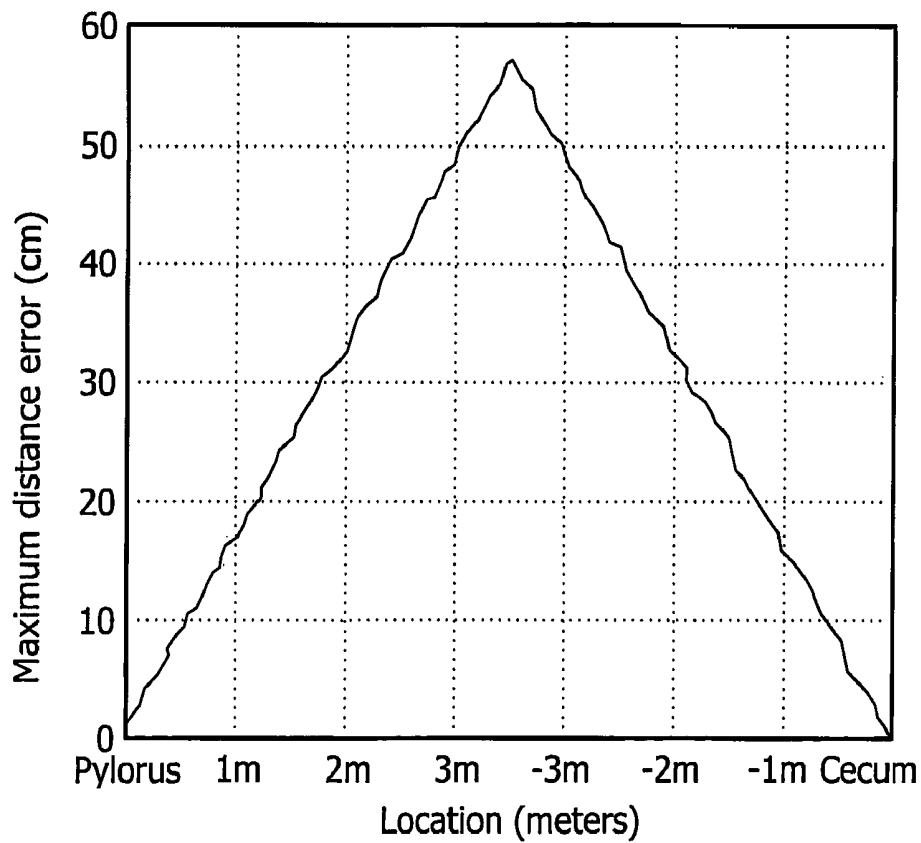


Fig. 4

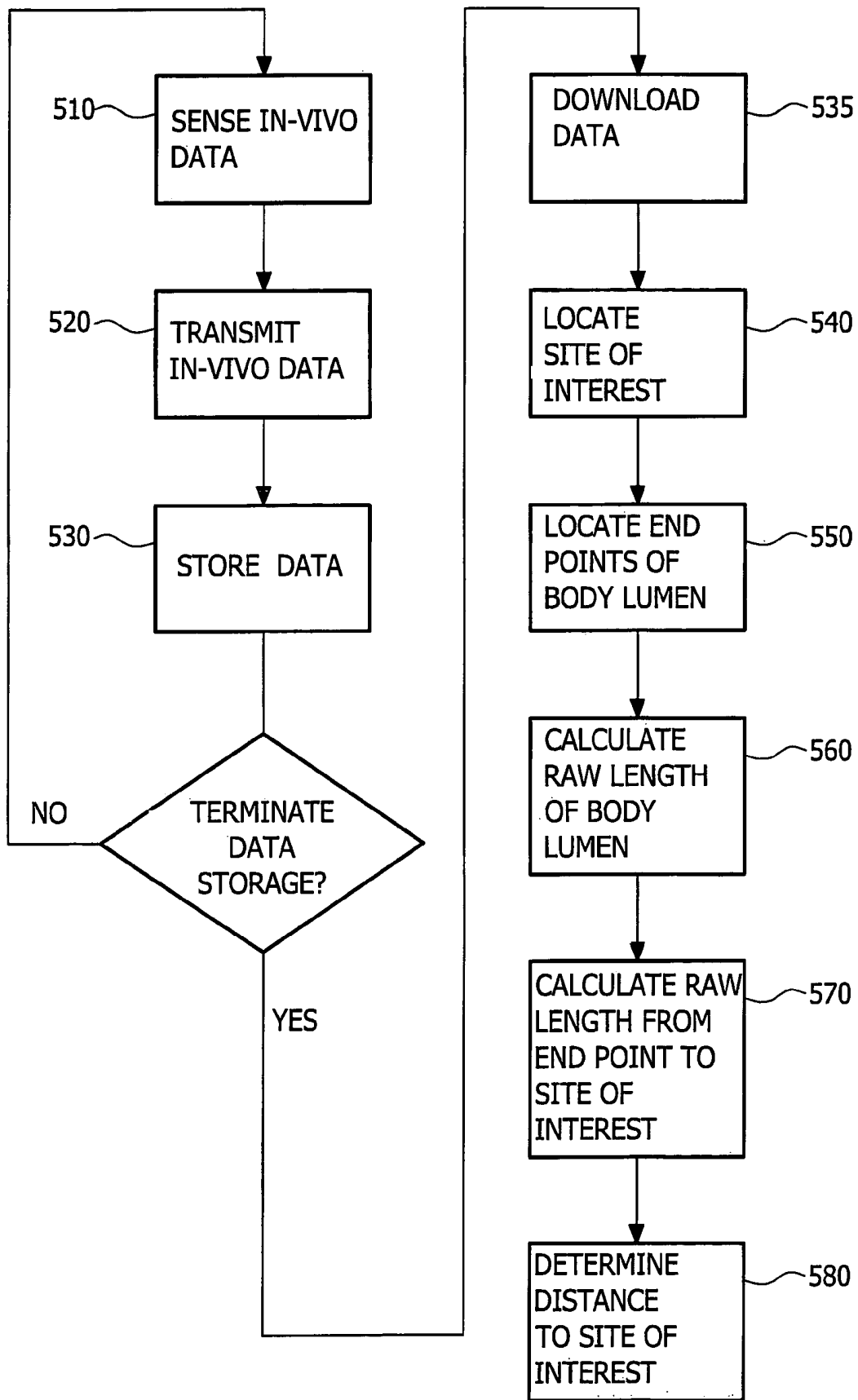


Fig. 5

SYSTEM AND METHOD FOR DETERMINING PATH LENGTHS THROUGH A BODY LUMEN

FIELD OF THE INVENTION

The present invention relates to an in-vivo device traveling through a body lumen, and in particular to a system and method to determine the path length or distance through a body lumen to a specified location.

BACKGROUND OF THE INVENTION

The gastrointestinal (GI) tract may typically be a convoluted long tube that folds many times to fit inside the abdomen, proceeding through the esophagus, stomach, small intestine, and large intestine. Autonomous in-vivo devices, for example, ingestible devices that may move through the GI tract, and that may collect data and transmit the data to a receiver system, are known in the art. Such devices may be used to examine areas that may otherwise be difficult to access with non-autonomous devices such as for example, endoscopes, colonoscopes, gastroscopes, enteroscopes, laproscopies, catheters, etc.

During examination of a patient with an autonomous device, a physician may identify one or more sites of interest. A physician may want to revisit the sites of interest using, for example, an alternate device (e.g. endoscope, colonoscope, a second autonomous device etc). Revisiting may be for more examining, sensing, diagnosing, treating, surgery, etc. In some instances, a physician may attempt to revisit a site of interest with a non-autonomous device only to discover that the site of interest is beyond the range that the non-autonomous device can penetrate. In other instances, an attempt to revisit the site of interest may be carried out with more than one alternate device before succeeding in locating the site of interest. This may lead to unnecessary discomfort, cost, and potential risk to the patient.

SUMMARY OF THE INVENTION

Various embodiments of the present invention provide a system and method for determining path length through a body lumen, for example path length or distance to a specified location. In some embodiments of the present invention a raw path length of the in-vivo device traveling to a specified location along a body lumen may be compared to a raw path length of the in-vivo device traveling through the entire body lumen. The ratio between the two path lengths together with a pre-selected body lumen length may be used to determine a true path length through a body lumen to a specified location. Typically the system of the present invention may include an in-vivo device, a location detection system and a path-length detection unit. Other configurations may be used.

BRIEF DESCRIPTION OF THE DRAWINGS

The subject matter regarded as the invention is particularly pointed out and distinctly claimed in the concluding portion of the specification. The invention, however, both as to organization and method of operation, together with objects, features and advantages thereof, may best be understood by reference to the following detailed description when read with the accompanied drawings in which:

FIG. 1 is a schematic illustration of an in-vivo system according to an embodiment of the present invention;

FIG. 2 is a schematic illustration of a simulated body lumen and a superimposed estimated path through measured location points according to an embodiment of the present invention;

FIG. 3 is an estimated maximum error distribution resulting from using an estimated value of the total length of a body lumen, according to an embodiment of the present invention;

FIG. 4 is a simulated maximum distance error as a function of location along a small intestine according to an embodiment of the present invention; and

FIG. 5 is a flow chart describing a method for determining distance through a body lumen according to some embodiment of the present invention.

It will be appreciated that for simplicity and clarity of illustration, elements shown in the figures have not necessarily been drawn to scale. For example, the dimensions of some of the elements may be exaggerated relative to other elements for clarity. Further, where considered appropriate, reference numerals may be repeated among the figures to indicate corresponding or analogous elements.

DETAILED DESCRIPTION OF THE INVENTION

In the following description, various aspects of the present invention will be described. For purposes of explanation, specific configurations and details are set forth in order to provide a thorough understanding of the present invention. However, it will also be apparent to one skilled in the art that the present invention may be practiced without the specific details presented herein. Furthermore, well-known features may be omitted or simplified in order not to obscure the present invention.

Embodiments of the system, and method of the present invention may typically be used in conjunction with an in-vivo sensing device and system such as described in embodiments in U.S. Pat. No. 5,604,531 to Iddan et al. and/or in International Application number WO 01/65995 entitled "A Device And System For In-Vivo Imaging", published on 13 Sep. 2001, both of which are assigned to the common assignee of the present invention and both of which are hereby incorporated by reference. Other embodiments of the system and method of the present invention may be used in conjunction with an in-vivo device and system such as is described in embodiments in International Application number WO/03005877, entitled "Device and method for examining a body lumen", published on Jan. 23, 2003, which is assigned to the common assignee of the present invention and is hereby incorporated in its entirety by reference. Alternate embodiments of the system and method of the present invention may be used with other devices, e.g. non-imaging and/or non-in-vivo devices.

Embodiments of the in-vivo device that may be used together with the system and method of the present invention may typically be autonomous and may typically be self-contained. For example, the in-vivo device may be a capsule or another unit where all the components may be substantially contained within a container or shell, and where the in-vivo device may not require any wires or cables to, for example, receive power or transmit information. The in-vivo device may communicate with an external receiving and display system to provide display of data, control, or other functions. For example, power may be provided by an internal battery or a wireless receiving system. Other embodiments may have other configurations and capabilities. For example, components may be distributed over multiple sites or units. Control information may be received from an external source.

Embodiments of the present invention may typically include a location detection system for locating the device in vivo, for example, as is described in embodiments of U.S. patent application Publication No. US20020173718, published on Nov. 21, 2001 and entitled “Array System and Method for Locating an In Vivo Signal Source”, which is hereby fully incorporated by reference. It is noted that in other embodiments of the invention, other location detecting methods may be used. For example, in one embodiment of the present invention, location information may be determined by, for example, including one or more transmitting antennas in an in vivo device, to transmit data using various frequencies, and/or by detecting the location of the in vivo device using components of quasi-static magnetic field(s)—a magnetic method. In some embodiments, methods such as those using ultrasound transceivers or monitors that include, for example, three magnetic coils that receive and transmit positional signals relative to an external constant magnetic field may be used. In yet other embodiments, GPS-like system may be used; for example, a system using transmission from three or more stations. Typically, in some embodiments of the present invention, an array of antennas or sensors may be placed on or close to the abdomen to enable tracking of the in vivo device. Of course, other components or sets of components may be used in accordance with embodiments of the invention.

In one embodiment, a set of locations of the in-vivo device may be determined, and from these locations a distance or path length may be determined. The locations may be determined from the data that is sensed by the device—for example, a radio signal including image or other data may be analyzed for location.

Reference is now made to FIG. 1 showing an in-vivo system 10 according to an embodiment of the present invention. In-vivo system 10 may include an in-vivo device 100, an external recorder 12, a processing unit 14, a display unit 18, and a user input unit 20. In-vivo device 100 may be any suitable traceable or trackable in-vivo device. In some embodiments of the present invention, device 100 may typically be, for example, an in-vivo imaging device, for example as is described in embodiments in U.S. Pat. No. 5,604,531 and/or in International Application number WO 01/65995, that may transmit signals, for example, images through for example an RF channel. Transmitted signals may, for example, be picked-up by an array of antennas 49 that may be, for example, positioned and/or worn on a patient’s body 50. Recorder 12 may typically be a portable wearable receiving and recording device and may include a signal pick up system, for example, antenna array 49.

Recorder 12 may, for example, receive signals from antennas 49 and store them, for example, temporarily in for example, a portable storage unit 19. Recorder 12 may include a location detection system 13 that may in one embodiment of the invention utilize, for example, a triangulation method to determine the location of in-vivo device 100 relative to the antenna array 49. The triangulation method may be based, for example, on the difference in signal strength picked up from the transmitting in-vivo device by the various antennas in antenna array 49. Typically, the location detection system 13 and method may be similar to that described in U.S. patent application Publication No. US20020173718. Other suitable location detection systems may be used. In other embodiments of the present invention, location detection system 13 may be wholly or partially integral to data processor 14.

Location data obtained from the location detection system 13 as well as signals or data transmitted by in-vivo device 100 may be, in one embodiment of the invention, for example,

downloaded to processor 14 for post-processing, and storage in, for example, storage unit 16. In other embodiments, device 100 may be or include another transmitting device other than an imaging device, for example, an in-vivo device with an RFID tag, or device 100 may be, for example, a non-transmitting in-vivo devices for example a marker, or other traceable, trackable or locatable devices.

A physician or other operator may, for example, use an in-vivo sensing system 10 to, for example, examine, diagnose, check for strictures, treat, and/or perform surgery on a patient. For example, an in-vivo sensing device 100 may, for example, capture images as it travels through the GI tract and transmit them to a recorder 12 external to the body. An external recorder 12 may store the transmitted images as well as other data, for example location data indicating the position in space of the transmitting device. In one embodiment, location data may be determined from sensed data. For example, sensed data such as image data or pressure data may be transmitted, and from the transmissions (e.g., via triangulation) location data may be determined. In other embodiments, the sensed data itself may be analyzed for location data, such as by determining from a set of images distance traveled between images.

After reviewing the transmitted data, for example the images and/or image stream, a physician may identify a site that may be of interest, for example, a location where an in vivo device captured an image(s) indicating, for example, a pathological area in the GI tract that may need further diagnosis, examination, or treatment. In some embodiments of the present invention, a site of interest may be other than a site where pathology may have been identified, a site of interest may be any specified location. In other embodiments, the in-vivo sensing device may include other sensors besides or in addition to image sensors, for example, temperature sensor, pH sensors, blood sensors, etc. and the specified location may be determined based on reviewing data other than image data. In other embodiments of the invention, the in vivo device may be other than a sensing device, or have other functions in addition to sensing, for example, medicine delivery, treatment, or biopsy.

Following examination and/or treatment with an in-vivo autonomous device, a physician may want to revisit one or more sites or location points of interest using an alternate device (e.g. endoscope, colonoscope, gastroscope, enteroscope, laparoscope, and another autonomous in-vivo device, etc). It may be helpful for the physician to know how deep into the body lumen the device may need to be inserted in order to reach the location point of interest. This may aid in choosing a procedure, and/or equipment for revisiting. Pre-knowledge of the path length, may help the physician reach the location point of interest more quickly so as to shorten the procedure time (e.g. examination, diagnostic, or treatment) and in that reduce the patient’s discomfort. In an alternate embodiment, this information may help a physician decide if it is at all possible to reach the location point of interest with alternate devices. For example, there may be some areas, for example, in the small intestine that may not be reachable with for example with an endoscope, or colonoscope, etc. Surgical intervention may be necessary in some circumstances. In some embodiments of the present invention, prior knowledge of the path length to the site may help avoid unsuccessful attempts to approach a site that may not be possible to access. Path length information may be used for other applications. Further, path length other than to a specific or selected location may be obtained using embodiments of the present

invention; for example, path length to arbitrary or multiple points, path length after certain times; times to certain path lengths, etc.

Location detection system, such as location detection system **13**, may be useful for indicating the location of a transmitting device in space, the motility, as well as the speed at given period of time. However, for body lumens that may be convoluted, it may be difficult to deduce how far through a body lumen a device advanced to reach a location point of interest from knowledge of its instantaneous position in space. In addition, it may be difficult to use an instantaneous location in space to locate a site of interest at a later time, since some body lumens may not be stationary over time. An instantaneous location of a site of interest within a body lumen may change over time and thus it may be difficult to predict its location with respect to the shifting body lumen when revisiting the site.

Typically, processor **14** may also include or be associated with a path-length detection unit **30**, to for example, to determine the path length through a body lumen, for example up to a specified location, or in another manner. Data obtained from the location detection system **13**, as well as other data, may be used as input to path-length detection unit **30**. Other data to be used as input to the path-length detection unit **30** may, for example, include user input data **20** or data from other features of system **10**. Path-length detection unit **30** may in some embodiments include one or more software units within processor **14**.

Path-length detection unit **30** may typically in some embodiments of the present invention, involve post-processing location data obtained from location detection system **13** and, for example, downloaded from recorder **12**. In some embodiments of the present invention, the path-length detection unit **30** may be a stand-alone unit, may be integral to data processor **14** with storage unit **16**, and/or integral to data recorder **12**. The path-length detection unit **30** may typically include processing and storing capability. In some embodiments of the present invention, the path-length detection unit **30** may include input systems for a user, as well as display systems for displaying to the user, for example, display unit **18**. Path-length detection unit **30** may, in other embodiments of the present invention, be partially or entirely integral to recorder **12**, and may, for example, not receive user input. Processor **14** may typically be a personal computer but may be any suitable unit for processing and/or storing data. Signals, data, and location related data may for example, be displayed on display unit **18**.

Reference is now made to FIG. **2** showing a simulated body lumen path **210** (solid line) that an in-vivo device may be, for example, traveling in and a set of example location points **230**, obtained from a location detection system **13** along the simulated path. An estimated path may be drawn by interpolating between consecutive points to obtain, for example, the estimated path **220** (dashed line). The raw path length may be determined, for example, by integrating the distances between consecutive points using known methods. Small errors may exist when estimating the location data. Errors may be due to, for example, random noise or from the device **100** shifting its orientation in-vivo. When estimating the raw path length through, for example, path **220**, the small errors in estimating location may accumulate into large errors in estimating a length of a path especially for long paths such as for example, the path of the small intestine, or other paths in the GI tract, or other body lumens. Calculating the path traveled by an in-vivo device using, for example, the estimated path **220** may, for example, lead to a path much longer than the true path. Smoothing may be used to reduce the error however

since the true path may in itself be torturous and unpredictable, it may be difficult to smooth the curve with good precision.

Typically, in some embodiments of the invention, it may be possible to assume that the noise level of the output signal from location detection system **13** may be substantially similar along the entire path through which the in-vivo device travels. As such, a relative path length (L_R) represented by the ratio between raw path length to a location point of interest (L) and the raw total path length though the entire body lumen (L_T) may be used to estimate more accurately the path length to a location point of interest without the need of separating, or otherwise eliminating the noise from the signal. In one embodiment, the ratio may be described by the following relationship:

$$L_R = L/L_T$$

Other formulas may be used. In one embodiment, a set of calculated paths, such as a calculated total path length in a lumen and a calculated length to a specified point or target or targets, may be determined. The known or estimated total lumen length may be determined, and a ratio between the known or estimated length and the calculated total length may be determined. This ratio may be applied to the calculated path length of the device to the specified point or points, to determine a more accurate estimated path length or distance to the point or points.

When the in-vivo device may be closer to an existing end point of a body lumen it may be useful for a user to know the relative distance from the existing end point since that may be the direction through which the site may be revisited. As such the following relationship may be used:

$$L_R = L/L_T; L \leq L_T/2$$

$$L_R = (L_T - L)/L_T; L > L_T/2$$

Other formulas may be used. For a clearer indication of the path length from an end point of a body lumen, a pre-selected overall length of the body lumen may be used. For example, the small intestine may be known to be on average 6 to 8 meters long. In one example, 7 meters may be used as a pre-selected value for the length of the small intestine. Using this estimation, the actual path length (L_A) may be expressed by the following equations:

$$L_A = 7 * L/L_T; L \leq L_T/2$$

$$L_A = 7 * (L_T - L)/L_T; L > L_T/2$$

Other formulas may be used.

Reference is now made to FIG. **3** showing an estimated error distribution resulting from using a pre-selected value (as opposed to a true value) of the length of a body lumen, and assuming no error due to location detection (the location detection error is not taken into account in this figure), according to one embodiment of the present invention; other values and curves may be used. The horizontal axis may mark the number of frames, for an in-vivo device transmitting image frames to an external recorder **12** at, for example, a given frequency. The vertical axis may mark the path length traveled through a body lumen determined by location points calculated from transmission signals of each image frame. Curve **310** may represent the true distance traveled. Curve **320** may represent the estimated distance determined, for example, by the method described herein.

As may be seen by the curves in FIG. **3**, the greatest discrepancy between the true path length (**310**) and estimated path length (**320**) through a body lumen may be near the

middle of the body lumen path while the smallest discrepancy between the true (310) and estimated (320) path length through body lumen may be near each of the end points of the body lumen. In some embodiments of the present invention, it may be desirable to estimate the distance through the small intestine so that a site of interest may be revisited for example by an enteroscope and/or a colonoscope. Enteroscopes, for example, may only be able to penetrate, for example, approximately a half a meter beyond the top entrance to the small intestine, for example, the pylorus. Colonoscopes, for example, may only be able to penetrate, for example, a few centimeters beyond the cecum and into the small intestine. As such accuracy near the end points may be of greater importance than accuracy for example half way along the small intestine.

Reference is now made to FIG. 4 showing an exemplary simulated maximum distance error as a function of distance along a small intestine, according to one embodiment of the present invention; other functions may be used, and other lumens may be examined. In this exemplary simulation, the pylorus may be marked as the entrance of the small intestine and the cecum may be marked as the point of exit of the small intestine. The location detection error in this graph may be modeled, for example, as a Rayleigh distribution with, for example, the average distance error of 3.5 cm that may, in some embodiments of the invention, be a typical location detection error. In other embodiments of the present invention, other models and error levels may be used. In this exemplary model, as may be seen by the graph in FIG. 4, the error of the path length through the body lumen may be in the order of magnitude of 10 cm at a distance of 0.5 meter from an end point (entrance and/or exit) of the small intestine marked by the cecum and pylorus respectively. As such, a physician may have indication if a site detected by an autonomous in-vivo device may be revisited by an alternate device and from which direction.

When an in-vivo device may travel through more than one lumen or portion of lumen in its course, for example, esophagus, stomach, and small intestine, it may be useful to be able to locate the end point of the lumen of interest, for example, the small intestine and measure the path length from that end point of that lumen. Various methods may be used for this purpose. For example, pH measurement may be used to detect a change in pH when entering and/or exiting the stomach. A pressure sensor may be used to indicate when device 100 was released from, for example, the small intestine into the roomier large intestine. In one embodiment of the present invention, a pressure indicator may be used to detect, for example, the rhythmic peristaltic pressure that may be typical in the small intestine. In some embodiments of the present invention, other methods involving post-processing of images may be used to identify mucosa and/or tissue that may, for example, be typically found in a specific body lumen. In other embodiments, for example, a specific color scheme that may typically be found in a specific body lumen may be used to identify the end points through a body lumen. In yet other embodiments, a physician or medical technician may identify through image or other data, the end points of a body lumen and use, for example, user input unit 20 to input that information to path-length detection unit 30.

Reference is now made to FIG. 5 showing a flow chart describing a method for determining a path length through a body lumen up to a specified location, according to one embodiment of the present invention. In block 510 an in-vivo device may sense data or a condition from within a body lumen. In some embodiments of the invention, the sensed data may be image data, for example, image data captured

within the body lumen of the GI tract. Other data may be sensed instead of or in addition to image data, for example, temperature, pressure, motility, etc.

Data captured or collected may be, for example, transmitted (block 520). In other embodiments pure location data (e.g., via a carrier signal or other signal) may be transmitted; further, transmission need not occur. For example, externally generated signals (e.g., X-rays, ultrasound signals) may be used to determine location data. In other embodiments of the present invention, a signal other than the data sensed may be transmitted to indicate a specified condition was met, for example, a signal to indicate that an in-vivo device may be caught behind a stricture, or other conditions. The data transmitted may be picked up by one or more pick up devices, for example one or more antennas 49. The transmitted data and the data pertaining to the location of the in-vivo device (obtained by location detection system 13) may be, for example, stored in recorder 12 (block 530). Typically, the process of sensing (block 510), transmitting (block 520), and storing (block 530) may continue for predetermined time period until all relevant data may be assumed to have been collected and stored. Other methods of determining a suitable time for termination of data collection and storage may be used.

In block 535, sensed data and location data may be downloaded to, for example, data processor 14. According to some embodiments no downloading may be required. In other embodiments of the present invention, transmitted data may be directed (by wire or wireless connection) to processing unit 14 in real time. A user may review data transmitted from an in-vivo device, for example, a stream of images. When reviewing the data, the user may mark one or more images that may be of interest, for example, may show pathology. The image or images of interest may be marked with any suitable user input means 20, for example, keyboard, computer mouse, touch-sensitive screen, and/or other suitable means. Data from the location detection system may be used to determine the location of a site of interest, for example a site where the marked images were captured in-vivo (block 540). In one embodiment of the present invention, a user may mark, for example, images that indicate the entrance and exit points of the body lumen containing the image of interest. In other embodiments, marking need not be used, and path length data may be generated independent of specific or requested points.

Data from the location detection system may be used to determine the location of the end points of the body lumen (block 550). In other embodiments of the present invention, the end points of the body lumen may be located without user input, for example, by methods described herein. In other embodiments of the present invention, the end points may be recognized by for example, a change of color, visible texture, measured pH, measured pressure, etc. In other embodiments of the present invention, the end points may be recognized by using a tissue color bar as may be described in embodiments described in U.S. provisional application 60/507,508, entitled, "Device, System And Method For Presentation Of In-Vivo Data," which is hereby incorporated by reference in its entirety. Other methods of determining end points of body lumens may be implemented.

In block 560 the data pertaining to the location of the in-vivo device may be processed to determine the raw path length through the body lumen from the entrance to the exit point (L_T). In block 570 the raw path length from the determined entrance point of the body lumen to the location point of interest (L) may be calculated. In block 580 the actual path length (L_A) may be determined based on raw path lengths L_T and L , and a pre-selected length of the overall length of the

body lumen. In other embodiments of the present invention, the actual path length (L_A) may be based on other suitable input data besides or in addition to the input data described herein. For example, path lengths L_T and L may be pre-processed before calculating their ratio for determining the actual path length. Typically, the path-length detection unit **30** may perform tasks described in blocks **560** through blocks **580**. In other embodiments of the present invention, the tasks described in blocks **560** to **580** may be shared by more than one unit or component in system **10**, for example the tasks may be shared by location detection system **13**. A health professional may use the information obtained on the path length to, to help him decide how to proceed with diagnosis or treatment of a patient.

Other steps and series of steps may be used.

While the invention has been described with respect to a limited number of embodiments, it will be appreciated that many variations, modifications and other applications of the invention may be made. Embodiments of the present invention may include other apparatuses for performing the operations herein. Such apparatuses may integrate the elements discussed, or may comprise alternative components to carry out the same purpose. It will be appreciated by persons skilled in the art that the appended claims are intended to cover all such modifications and changes as fall within the true spirit of the invention.

The invention claimed is:

1. A computer-implemented method for determining a relative path length traveled to a specific location through a body lumen by an in vivo device, the method comprising the steps:

determining, using a processing unit, a raw path length value of the in vivo device through the body lumen to the specific location based upon location data of the in vivo device;

determining a total raw lumen length value based upon location data of the in vivo device;

calculating, using the processing unit, a relative path length value using a ratio between the raw path length value and the raw total lumen length value; and

providing the relative path length value to a user for use by said user in examination, diagnosis or treatment of said body lumen.

2. The method according to claim **1** comprising capturing images of the body lumen as the in vivo device travels through the body lumen.

3. The method according to claim **1** comprising sensing the body lumen as the in vivo device travels through the body lumen.

4. The method according to claim **1** comprising sensing pH, pressure or temperature of the body lumen.

5. The method according to claim **2**, comprising obtaining the location data of the in vivo device based on the captured images.

6. The method according to claim **1**, comprising obtaining the location data of the in vivo device based on data sensed by the in vivo device.

7. The method according to claim **2** comprising transmitting the captured images to an external receiving system.

8. The method according to claim **1** wherein the body lumen is the gastrointestinal tract.

9. The method according to claim **1** wherein the in vivo device is a swallowable capsule.

10. The method according to claim **1**, comprising obtaining the location data of the in vivo device based on triangulation of the signal strength received by antennas of the an external receiving system.

11. The method according to claim **1** further comprising: post-processing images sent from the in vivo device to identify end points of a portion of a body lumen traveled by the in vivo device; and

providing indication to the user if a point of interest may be revisited by an alternate device.

12. The method according to claim **11** wherein post-processing images is performed by identifying a color scheme of the images corresponding to a specific body lumen portion.

13. The method according to claim **11** further comprising providing indication to the user from which direction the point of interest may be revisited by the alternative device.

14. The method according to claim **10** further comprising providing a relative distance from a near exit point of a body lumen portion.

15. The method according to claim **10** wherein a portion of a body lumen is selected from the group consisting of: esophagus, stomach, and small intestine.

16. The method according to claim **10** wherein an end point of a portion of a body lumen is selected from the group consisting of: pylorus and cecum.

17. The method according to claim **10** wherein providing indication to the user comprises suggesting a method selected from the group consisting of:

endoscopy, colonoscopy, gastroscopy, enteroscopy, laparoscopy and surgical intervention.

18. The method according to claim **1** further comprising: pre-selecting an overall length of the body lumen value; and

calculating an actual path length value using said relative path length value and the overall length of the body lumen value.

19. The method according to claim **18** further comprising providing the corrected path length value to a user.

20. The method according to claim **18** wherein the overall length of the body lumen value is between 6 to 8 meters.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 7,596,403 B2
APPLICATION NO. : 10/879053
DATED : September 29, 2009
INVENTOR(S) : Eli Horn

Page 1 of 1

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

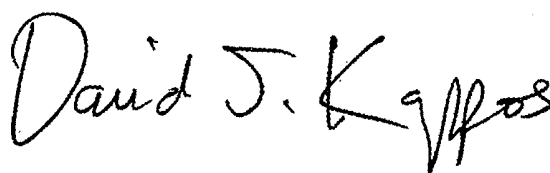
On the Title Page:

The first or sole Notice should read --

Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 564 days.

Signed and Sealed this

Twenty-eighth Day of September, 2010

A handwritten signature in black ink that reads "David J. Kappos". The signature is written in a cursive style with a large, stylized 'D' and 'K'.

David J. Kappos
Director of the United States Patent and Trademark Office

专利名称(译)	用于确定通过体腔的路径长度的系统和方法		
公开(公告)号	US7596403	公开(公告)日	2009-09-29
申请号	US10/879053	申请日	2004-06-30
[标]申请(专利权)人(译)	HORN ELI		
申请(专利权)人(译)	HORN ELI		
当前申请(专利权)人(译)	基文影像有限公司.		
[标]发明人	HORN ELI		
发明人	HORN, ELI		
IPC分类号	A61B1/00		
CPC分类号	A61B1/00156 A61B1/04 A61B5/064 A61B5/061 A61B1/041		
其他公开文献	US20060036166A1		
外部链接	Espacenet	USPTO	

摘要(译)

描述了用于确定通过体腔的路径长度(例如,到指定位置)的系统和方法。位置检测系统可以随时间识别体内装置的空间位置。路径长度检测单元可以使用来自位置检测系统的数据来确定体内装置行进的路径。可以识别沿着该路径的感兴趣的站点。可以确定感兴趣部位距体腔的至少一个端点的距离。

