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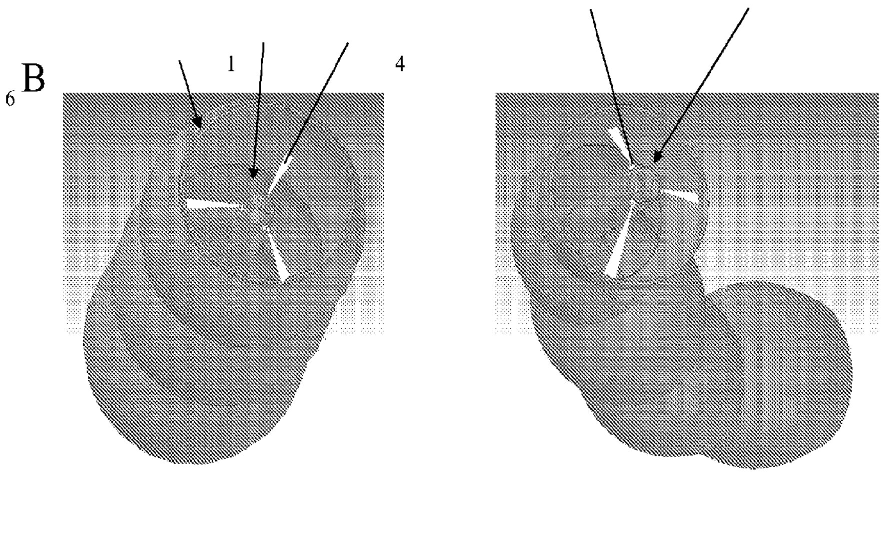

FIGURE 2

(57) Abstract: Provided in various embodiments are endoscopy systems adapted to detect the position of the distal end of the endoscope with respect to the surrounding anatomical structure under examination. Said endoscopy systems may also be adapted to automatically move or maintain the distal end at a pre-determined position with respect to the anatomical structure.

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AUTOMATICALLY ADJUSTABLE ENDOSCOPES

CROSS REFERENCE TO RELATED APPLICATION

[0001] This application claims priority to and any other benefit of US 61/165,295, filed March 31, 2009, the entirety of which is incorporated by reference.

FIELD

[0002] In various embodiments, the invention relates to endoscopes and endoscopy systems and methods.

BACKGROUND

[0003] Endoscopy is a medical procedure that permits a clinician to access remote organs and tissues in a minimally invasive manner for diagnostic and surgical purposes. Endoscopy is performed with an endoscope, a medical device that can pass through anatomical structures in the body of an animal, thereby providing a clinician access to the interior surfaces of the structures for visual inspection, imaging, biopsy, manipulation, and other diagnostic and surgical procedures. A variety of different endoscope designs have been developed and adapted for use in the context of accessing and visualizing particular anatomical structures, such as the gastrointestinal tract (eg., colonoscopes and sigmoidoscopes), the respiratory tract (eg., rhinoscopes and bronchoscopes), the abdominal or pelvic cavity (eg., laparascopes), the joint (eg., arthroscopes), and the reproductive system (eg., hysteroscopes and falloscopes).

[0004] Irrespective of the type of structures targeted, endoscopes typically comprise a rigid or flexible body, an illumination means (eg., light or light delivery system), and an imaging means (eg. lens system or camera), all of which are in communication with equipment that controls the functions of the device and allows for image visualization and capture. Endoscopes can generally be categorized as dependent or independent, with the dependent-type typically having a tubular body and long cables for the purpose of operations, and biopsy or other medical tools at the distal end; and the independent-type typically having a cylindrical body and no attachments for ease of navigation.

[0005] Independent-type endoscopes (also called capsule type endoscopes) are typically characterized as being either passive or active, wherein the passive-type do not have actuators and are dependent upon peristalsis for mobility, and wherein the active-type have externally controlled actuators for mobility. A passive independent-type endoscope is typically used in a mouth-to-anus method in which the capsule is swallowed and natural bowel movements are relied upon to move the endoscope through the digestive tract. An active independent-type endoscope typically utilizes shape memory alloys (SMAs) or magnets for controlling the movement of a capsule through the digestive tract.

[0006] In contrast, dependent-type endoscopes are typically characterized as having actuators attached at or near the distal end of the scope for locomotion, so that a clinician does not have to rely solely on pushing or pulling the shaft of the endoscope for advancement or retraction. Instead, the clinician controls actuators, such as SMAs, pneumatic/hydraulic actuators, or motors, to navigate the endoscope. A variety of dependent-type endoscopes have been described in the art. For example, *see* Koji Ikuta, et al., "Shape memory alloy servo actuator system with electric resistance feedback and application for active endoscope," *Proceedings of the 1988 IEEE International Conference on Robotics and Automation*, pp. 427-430, 1988 (applying shape memory alloys and servo motors to active endoscope and showing mechanical compliance by passing the minimum radius of curvature of a sigmoid colon on a two-dimensional plane); A. Menciassi, et al., "Robotic Solution and Mechanisms for a Semi-Autonomous Endoscope," *Intl. Conference on Intelligent Robotics and Systems*, pp. 1379-1384, EPFL, Lausanne, Switzerland, October 2002 (semi-autonomous, self-propelled colonoscopy device without external forces such as pushing and pulling by endoscopist); Wan Sing Ng, et al., "Development of a robotic colonoscope," *Digestive Endoscopy, (2000)*, 12, 00.131-135, 1999 (robotic colonoscope having a graphical user interface program to allow users to control two direct current motors for motion and monitor its motion); Joel Burdick, et al., "The Development of a Robotic Endoscope," *Proceedings of the 1991 IEEE International Conference on Robotics and Automation*, pp. 2582-2591, 1999 (robotic endoscope for gastrointestinal diagnosis and therapy); H.D. Hoeg, et al., "Biomedical Model of the Small Intestine as Required for the Design and Operation of a Robotic Endoscope," *Proceedings of the 2000 IEEE International Conference on Robotics and Automation*, pp. 1599-1606 San Francisco, CA April 2000 (discussing the locomotion of a robotic endoscope in the human small intestine and analytical models for the body's blood flow auto regulation mechanism); and Elizabeth V. Mangan, et al., "Development of a Peristaltic Endoscope," *IEEE International Conference on Robotics and Automation*, Washington DC, pp. 347-352, May 2002 (peristaltic endoscope that successfully moved both forward and backward within a transparent acrylic tube).

[0007] Many types of endoscopes are known in the art. Among the most commonly used are sigmoidoscopes and colonoscopes, which are dependent-type endoscopes. Sigmoidoscopes may be flexible or rigid and enable a physician to examine the rectum and sigmoid colon in a sigmoidoscopy procedure. Sigmoidoscopes are useful in diagnosis of colon disorders, such as inflammatory bowel disease, bowel obstruction, polyps, and cancer in the descending colon and rectum. Sigmoidoscopy can also determine the cause of blood, mucus, or pus in the stool and confirm findings of another test by taking a biopsy. Similar to sigmoidoscopes are colonoscopes, which are flexible endoscopes used in a colonoscopy procedure in which the entire length of the colon can be examined for tumors or polyps, or to identify the source of gastrointestinal bleeding, although there are other diagnostic and therapeutic uses as well.

[0008] As used herein, the term "colonoscope" is meant to refer to colonoscopes and sigmoidoscopes, and the term "colonoscopy" is meant to refer to colonoscopy and sigmoidoscopy. Colonoscopes and colonoscopy are discussed more particularly herein to illustrate known endoscopes, needs in the art, and embodiments of the present invention. However, one of skill in the art will understand that the invention is applicable to endoscopes and endoscopy procedures having similar requirements for positioning and steering through an anatomical structure, and that nothing herein shall be construed as limiting the invention to colonoscopes and colonoscopy.

[0009] A typical colonoscope has an elongated, flexible body, and is controlled at the proximal end with a handle mechanism for controlling the scope's movement and its various functions. The typical scope also includes a mechanism, often associated with the handle, for steering the distal end using wires running through the interior of the elongated, flexible body. In conducting colonoscopies, the clinician inserts the distal end of the scope through the patient's rectum and navigates the device through the length of the colon under examination, starting with the sigmoid colon, and passing as needed through the descending colon, the transverse colon and the ascending colon. Once the ascending colon has been navigated, inspection of the cecum typically completes a full colonoscopy procedure.

[0010] The stiffness required to support the tools in the scope makes it difficult to navigate the twisted path of the colon and difficulties in navigation are frequently encountered, such as coiling of the colonoscope within the colon. Thus, during colonoscopy procedures, the clinician often must navigate the scope with a variety of pushing and twisting maneuvers, including advancing and withdrawing the scope from the colon and pushing and otherwise manipulating the patient's abdomen and position. These manipulations can result in prolonged procedure time and substantial pain and discomfort for the patient. There is also risk of more serious complications, such as perforation of the colon wall.

[0011] Some complications during colonoscopy can occur due to the distal end of the colonoscope. When the clinician pushes and advances the colonoscope, he or she attempts to avoid contact between the distal end and the inside wall of the colon by rotating the stem of the colonoscope or manipulating it during maneuvers while simultaneously scrutinizing the inside of the colon through an imaging means. Despite such efforts, when the clinician advances and navigates inside a colon, it is difficult to avoid making contact between the distal end and the colon wall.

[0012] Another potential complication is that a clinician can have difficulty finding the intestine lumen, especially while advancing the colonoscope. In part, this can be due to the complicated shapes of the colon, closed intestine lumen, or simply losing sense of direction in the colon. Often clinicians lose their sense of direction due to the severe maneuvering of the distal end involed in the search for polyps or other possible diseases. This loss of direction can increase the time of the operation and cause the need for more medicine for anesthesia, which leads to increased costs and risk associated with the procedure.

[0013] In view of the foregoing, there is an evident need for endoscopes, including but not limited to colonoscopes, that aid navigation through the target anatomical structures and that minimize contact between the distal end of the scope and surrounding tissue of such structures.

SUMMARY

[0014] Embodiments of the present invention meet such needs by providing an endoscopy system that can automatically reduce direct contact between the distal end of an endoscope and surrounding tissue of the target anatomical structures, thereby reducing the potential for mechanical trauma. The provided endoscopy system can also allow a clinician to maintain orientation of the distal end of the endoscope and sense of direction through an anatomical structure when performing an endoscopy procedure, thereby allowing for reduced surgery time, anesthesia needs of the patient, and cost of the procedure.

[0015] In various embodiments, endoscopy systems according to the invention comprise an adjustable endoscope with various combinations of sensors, actuators, and a control system that are in communication with each other. Such endoscopy systems are dynamic in that the sensors, actuators, and control system may be engaged so as to allow for automation of scope positioning when desired, and may also be disengaged so as to allow for conventional control of scope positioning by a clinician. The described endoscopy systems may also cooperate with a variety of conventional endoscopes to provide additional clinician-selected functionality.

[0016] These and additional embodiments will become apparent in the course of the following detailed description.

BRIEF DESCRIPTION OF THE DRAWINGS

[0017] A more complete appreciation of the invention and the many embodiments thereof will be readily obtained as the same becomes better understood by reference to the following detailed description when considered in connection with the accompanying drawings, wherein:

[0018] **Figure 1** illustrates various embodiments of one example of a colonoscopy system; and

[0019] **Figure 2** illustrates embodiments of one example of **A**, the distal end of a colonoscope; **B**, the distal end within a straight and curved sections of a colon.

DETAILED DESCRIPTION

[0020] The present invention will now be described with occasional reference to the specific embodiments. This invention may, however, be embodied in different forms and should not be construed as limited to the embodiments set forth herein. Rather, these embodiments are provided so that this disclosure will be thorough and complete, and will fully convey the scope of the invention to those skilled in the art.

[0021] Unless otherwise defined, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this invention belongs. The terminology used in the description of the invention herein is for describing particular embodiments only and is not intended to be limiting of the invention. As used in the description of the invention and the appended claims, the singular forms “a,” “an,” and “the” are intended to include the plural forms as well, unless the context clearly indicates otherwise.

[0022] As used herein, the term "actuator" is intended to refer to a means for moving or controlling movement of a mechanism or device.

[0023] The term "anatomical structure," as used herein, is intended to refer to an organ, cavity, or passage of the body, or subparts thereof, that may be examined by an endoscope.

[0024] As used herein, the term "clinician" is intended to refer to a health professional, such as a physician, nurse, or technician, that is involved in administering an endoscopy procedure to a patient.

[0025] The term "control system," as used herein, is intended to refer to a means for managing, commanding, directing, or regulating the operation of sensors, actuators, or other aspects of a provided endoscopy system. A control system may comprise logic or sequential control, feedback or linear control, fuzzy logic control, or combinations thereof.

[0026] As used herein, the term "endoscope" is intended to refer to an instrument used to examine the interior tissues of an organ or cavity of the body, including but not limited to, the gastrointestinal tract, the respiratory tract, the abdominal or pelvic cavity, joints, and the reproductive system.

[0027] The term "sensor," as used herein, is intended to refer to a means for detecting, measuring, or otherwise determining a physical quantity and converting it into a form that can be read by an instrument or observer. Examples of sensors include, but are not limited to, optical sensors, temperature sensors, magnetic sensors, mechanical sensors, acoustic sensors, and MEMs sensors. Some sensors merely receive a signal, whereas other sensors emit and receive signals.

[0028] Unless otherwise indicated, all numbers expressing quantities, properties, conditions, and so forth as used in the specification and claims are to be understood as being modified in all instances by the term “about.” Additionally, the disclosure of any ranges in the specification and claims are to be understood as including the range itself and also anything subsumed therein, as well as endpoints. Unless otherwise indicated, the numerical properties set forth in the specification and claims are approximations that may vary depending on the desired properties sought to be obtained in embodiments of the present invention. Notwithstanding that numerical ranges and parameters setting forth the broad scope of the invention are approximations, the numerical values set forth in the specific examples are reported as precisely as possible. Any numerical values, however, inherently contain certain errors necessarily resulting from error found in their respective measurements.

[0029] When an endoscopy procedure is performed with a conventional endoscope, a clinician must advance the shaft of the scope through an anatomical structure and maneuver its distal end through the often complicated shapes of the structure. In doing so, a clinician can lose directional sense or have difficulty advancing the scope, which can prolong a procedure and increase discomfort and costs for the patient. In order to navigate through the anatomical structure, a clinician must push and advance the shaft and distal end of a convention endoscope, and in doing so, often cannot prevent the distal end of the scope from making contact with tissue of the structure. Thus, during a procedure with a conventional endoscope, mechanical trauma to the structure can occur from the shaft and the distal end of the endoscope. For example, in a colonoscopy procedure, the distal end of a conventional colonoscope is inserted through the anus and after passing the rectum, the first curve of the sigmoid colon is encountered. The scope is then navigated through the sigmoid colon and remaining length of the colon by pushing and advancing the shaft and distal end. Due in part to the complex shape of the colon, the clinician can lose directional sense of the intestine lumen. Moreover, the pushing and advancing maneuvers required can result in the shaft causing trauma near the junction of the rectum and the sigmoid colon or in the sigmoid colon, and the distal end can cause mechanical trauma to the colon wall.

[0030] To overcome such difficulties, elements of the provided endoscopy system can be engaged to automatically aid a clinician in maintaining directional sense and avoid unintentional contact of the distal end with tissue of a structure. In some embodiments, such elements may also be disengaged so as to allow for conventional control of distal end positioning by a clinician.

[0031] In various embodiments, the provided endoscopy systems comprise (i) an endoscope comprising a shaft having a distal end for insertion into an anatomical structure of a subject's body and a proximal end that remains substantially outside of the body; (ii) one or more sensors in communication with the distal end; (iii) one or more actuators in communication with the distal end; and (iv) a control system in communication with at least one of the one or more sensors and at least one of the one or more actuators; wherein the control system is configured to receive from the one or more sensors data corresponding to distance between the distal end and surrounding tissue of the anatomical structure, and based upon the data received, direct the one or more actuators to move the distal end such that it is maintained at a pre-determined position with respect to the surrounding tissue.

[0032] In various embodiments, the provided endoscopy system may also comprise (i) one or more secondary sensors not in communication with the distal end, each secondary sensor independently attached to the shaft between the distal and proximal ends; (ii) one or more secondary actuators not in communication with the distal end; each secondary actuator independently attached to the shaft between the distal and proximal ends; or (iii) combinations thereof. The secondary sensors may be of the same type as those in communication with the distal end, be of some alternative type, or combinations thereof. Similarly, the secondary actuators may be of the same type as those in communication with the distal end, be of some alternative type, or combinations thereof. In some embodiments, the provided endoscopy system may also comprise a control system in communication with (i) at least one of the one or more secondary sensors, (ii) at least one of the one or more secondary actuators, or (iii) combinations thereof. Said control system may have, but is not required to have, the same components as the controller that is configured to control movement of the distal end in response to sensor data.

[0033] In some embodiments, the provided endoscopy system is a colonoscopy system that can reduce unintended contact between the distal end of a colonoscope with the colon wall and allow a clinician to maintain orientation of the distal end of the colonoscope within, and sense of direction through, the intestine lumen when performing a colonoscopy procedure.

Sensors

[0034] In the various embodiments, the provided endoscopes comprise one or more sensors that are in communication with the distal end of the endoscope and that can detect its position in relation to an anatomical structure. Sensors generate data corresponding to the distance between themselves and the surrounding tissue of the structure and relay the data to a control system. For example, a colonoscope may comprise sensors that can detect the position of the distal end of the scope in relation to the colon wall as the scope is advanced through or manipulated in the colon by a clinician. According to some embodiments, sensors may be positioned at or proximate to the distal end of the endoscope. According to other embodiments, sensors may be positioned at a different location on the endoscope and collect information about positioning of the distal end by remote means, such as through fiber optic cables. For example, a sensor may be attached at or near the proximal end of the shaft of an endoscope, wherein the sensor is also attached to a first end of a fiber optic cable that runs through an interior cavity of the shaft and attaches at its second end at or near the distal end.

Thus, the fiber optic cable can relay a signal between the remote sensor and the distal end.

[0035] Whether located at or near the distal end or remotely, the sensors relay information about the position of the distal end to the control system, which in turn can direct function of actuators. Actuators are in communication with the sensors through the control system and mechanically communicate with the distal end to direct its movement such that the tip maintains a controlled distance from tissue of an anatomical structure, such as the colon wall. Sensors can detect distance of the distal end from the tissue, and positioning by the actuators may be controlled by the control system for the directions of up, down, right, and left, and various combinations thereof.

[0036] Sensors used with the provided endoscopy system may be of one type or may be used in combination with other types of suitable sensors, all of which may be attached to or integrated with the endoscope in various configurations. Examples of suitable sensors include, but are not limited to, infra-red sensors. In some embodiments, sensors may be attached to or integrated with the distal end, wherein the emitting direction of the signal is selected from perpendicular to the shaft, parallel to the shaft, or perpendicular to the distal face of the distal end. Thus, the signal may be emitted in a direction of from 0° to 180° to the shaft. For example, infra-red sensors may be attached to or integrated with the distal end such that the emitted infra-red signal may be in a direction selected from orthogonal to the endoscope's stem or shaft, toward the distal face of the distal end, or a combination thereof.

[0037] If conventionally-sized sensors are not small enough to be accommodated in the distal end of a conventional endoscope, the size of the tip can be increased. An alternative to installing such sensors without sacrificing the size of the tip is to use fiber optic cables that may be run through the shaft of the endoscope. Accordingly, in some embodiments, sensors may be attached to or integrated with the endoscope base and the signal is carried by fiber optic cables to the distal end, wherein attachment or integration of the fiber optic cables at the distal end may be such that the emitting direction of the signal is selected from perpendicular to the shaft, parallel to the shaft, or perpendicular to the distal face of the distal end. Thus, the signal may be emitted from the fiber optic cables in a direction of from 0° to 180° to the shaft. For example, infra-red sensors may be attached to or integrated with the proximal end and fiber optic cables attached to or integrated with the distal end such that the signal travels through the fiber optic cables between the proximal infra-red sensors and the distal end.

[0038] Regardless of how configured, when the sensor is an infra-red sensor and the emitting direction of the signal is solely toward the distal face of the distal end, the overall percentage of infra-red reception will be lowered, thereby degrading accuracy and response time of the actuators. Thus, in some embodiments, it is contemplated that the infra-red signal may be emitted in a direction of from about 45° to about 135° to the shaft. For example, the direction of emission may be from 45°-55°, 55°-65°, 65°-75°, 75°-85°, 85°-95°, 95°-105°, 105°-115°, 115°-125°, and 125°-135°.

[0039] The range of suitable infra-red sensors for use with the provided endoscopes can be determined by the dimensions of the anatomical structure in which the scope is to be used. For example, the range of infra-red sensors used in conjunction with a colonoscope can be determined by the dimensions of a sigmoid colon, which has an average width of 3.5 to 4.2 centimeters.

[0040] In some embodiments, the provided endoscopes comprise one or more infra-red sensors suitably arranged to detect an anatomical structure and allow for measurement of the distance between it and the distal end. In some embodiments, each infra-red sensor has signal-emitting and signal-receiving elements. It will be understood by one of skill in the art that positioning of the sensors and cables at or with respect to the distal end can be configured in a variety of ways. For example, a colonoscope of the invention may have three sensors at or proximate to the end of the distal end for detection of the colon wall, each sensor positioned around the circumference of the distal end at 120° or other suitable angle from a neighboring sensor. Alternatively, a colonoscope may have sensors at the endoscope base and ends of three fiber optic cables positioned at or proximate to the end of the distal end, each cable end positioned around the circumference of the distal end at 120° or other suitable angle from a neighboring cable end. In another example, a colonoscope of the invention may have four sensors at or proximate to the end of the distal end for detection of the colon wall, each sensor positioned around the circumference of the distal end at 90° or other suitable angle from a neighboring sensor. Alternatively, a colonoscope may have sensors at the endoscope base and ends of four fiber optic cables positioned at or proximate to the distal end, each cable end positioned around the circumference of the distal end at 90° or other suitable angle from a neighboring cable end.

[0041] In some embodiments, each sensor can be located directly above tendons that are attached to the distal end, said tendons being connected internally to one or more knobs on the endoscope that allow for positioning of the distal end. In some embodiments, one or more actuators are also connected to such one or more knobs. For example, four sensors can be located directly above tendons, said sensors forming right angles to each other. In such configuration, two of the sensors may be assigned to left-right sensing and the other two sensors assigned for up-down sensing; wherein movement of the distal end is achieved via the tendons with up-down motion governed by the distance measured through the two up-down sensors and right-left motion governed by the distance measured through the two right-left sensors.

Actuators

[0042] In the various embodiments, the provided endoscopes comprise actuators that are in communication with the endoscope and can position the distal end of the scope. The positioning of the distal end by the actuators may be controlled to be in relation to an anatomical structure such that the distance between each portion of the tip and the anatomical structure becomes approximately the same within an allowable tolerance. Such actuators are also in communication with the sensors via the control system. For example, a provided colonoscope may comprise sensors that can detect the position of the distal end of the scope in relation to the colon wall, as well as actuators that can position or reposition the distal end in relation to the colon wall as the scope is advanced through or manipulated in the colon by a clinician.

[0043] Actuators suitable for use with the inventive endoscopy system may be selected from a variety of actuators and may be attached to or integrated with the endoscope in a manner allowing for mechanical control of the distal end of the scope. In some embodiments, suitable actuators may be selected from pneumatic/hydraulic actuators, shape memory alloys, magnetic actuators, electric motors, and combinations thereof.

[0044] A variety of pneumatic/hydraulic actuators have been described in the art for use with endoscopes. For example, *see* A. Menciassi, et al., "Robotic Solution and Mechanisms for a Semi-Autonomous Endoscope," *Intl. Conference on Intelligent Robotics and Systems*, pp. 1379-1384, EPFL, Lausanne, Switzerland, October 2002 (combined inchworm and sliding clamper propulsion using pneumatic mechanisms such as a vacuum generator, on-off valves, and manual pressure regulator to make elongation and retraction phases for the movement of an endoscope); Wan Sing Ng, et al., "Development of a robotic colonoscope," *Digestive Endoscopy, (2000)*, 12, 00.131-135, 1999 (rubber bellow actuators push capsule-type endoscope against the colon wall and cause self-propulsion without helping of external forces; wherein pressurized air and vacuum are introduced to inflate and collapse the base of the bellow actuator); Joel Burdick, et al., "The Development of a Robotic Endoscope," *Proceedings of the 1991 IEEE International Conference on Robotics and Automation*, pp. 2582-2591, 1999 (locomotion by using the components of traction and extensor segments; wherein hydraulic power actuation locally increases the diameter of the traction segments, extensor segments expand and contract along the local axial direction, and specific sequences of gripping and stretching cause the net displacement of a robotic endoscope); H.D. Hoeg, et al., "Biomedical Model of the Small Intestine as Required for the Design and Operation of a Robotic Endoscope," *Proceedings of the 2000 IEEE International Conference on Robotics and Automation*, pp. 1599-1606 San Francisco, CA April 2000 (locomotion by using the components of traction and extensor segments, wherein endoscope size is reduced to fit into a human small intestine); and Elizabeth V. Mangan, et al., "Development of a Peristaltic Endoscope," *IEEE International Conference on Robotics and Automation*, Washington DC, pp. 347-352, May 2002 (three serial pneumatic actuators in series to cause peristaltic locomotion). Any pneumatic/hydraulic actuator suitable for use with the provided endoscopy system may be used alone, in combination with other pneumatic/hydraulic actuators, or in combination with other types of actuators.

[0045] A variety of shape memory alloys (SMAs) have also been described in the art for use with endoscopes. For example, *see* Koji Ikuta, et al., "Shape memory alloy servo actuator system with electric resistance feedback and application for active endoscope," *Proceedings of the 1988 IEEE International Conference on Robotics and Automation*, pp. 427-430, 1988 (antagonistic type SMA actuator with electric resistance feedback); A. Menciassi, et al., "Robotic Solution and Mechanisms for a Semi-Autonomous Endoscope," *Intl. Conference on Intelligent Robotics and Systems*, pp. 1379-1384, EPFL, Lausanne, Switzerland, October 2002 (SMA springs installed at the central bellow to elongate and retract the entire body, and a distal end with a silicon bellow and SMA springs for enhanced visualization and performance); TS. Kim et al., "Fusion of Biomedical Microcapsule Endoscope and Microsystem Technology," *The 13th International Conference on Solid-State Sensors, Acuators and Microsystems*, pp. 9-14, Seoul, Korea, June 2006 (actuator with a PEEK structure, a leg, and an actuation means; wherein SMA wires and pulley are connected in the PEEK structure, and the leg is connected to the pulley; and wherein Pulse Width Modulation technique is used for a homogeneous heating of the wires and activation of SMA wires to rotate the leg and advance the body); and BK. Kim et al., "Design and Fabrication of a Locomotive Mechanism for Capsule-Type Endoscopes Using Shape Memory Alloys (SMAs)," *IEEE/ASME Transactions on Mechatronics*, pp. 77-86, Vol. 10, No. 1, February 2005 (two-way linear actuators as bi-directional linear actuators, wherein the actuators comprise SMA springs, clampers, and a capsule body). Any shape memory alloy actuator suitable for use with the provided endoscopy system may be used alone, in combination with other SMAs, or in combination with other types of actuators.

[0046] A variety of magnetic actuators have been described in the art for use with endoscopes. For example, *see* M. Sendoh, et al., "Fabrication of Magnetic Actuator for Use in a Capsule Endoscope," *IEEE Transactions on Magnetics*, Vol. 39, No. 5, pp. 3232-3234, September 2003 (magnetic actuator for a capsule-type endoscope); and Sturges et al., "AA Flexible, Tendon-Controlled Device for Endoscopy," *The International Journal of Robotics Research*, Vol. 12, No. 2, pp. 121-131, April 1993 (means of guiding an endoscope to reduce patient's pain by introducing controllable stiffness--alternating stiffening and relaxation--of the anatomical access guide and an alternate sliding motion of an endoscope). Any magnetic actuator suitable for use with the provided endoscopy system may be used alone, in combination with other magnetic actuators, or in combination with other types of actuators.

[0047] A variety of AC and DC electric motors are known in the art for use with endoscopes, including but not limited to servo motors, brushless DC motors, brush-type DC motors, stepper motors, and DC motors with encoders. Any electric motor actuator suitable for use with the provided endoscopy system may be used alone, in combination with other electric motor actuators, or in combination with other types of actuators. In some embodiments, electric motors may be attached to tendons that are in mechanical communication with the distal end, thereby allowing for mechanical communication between the motor and the distal end. For example, a colonoscope of the provided invention may comprise DC servo motors at its base that push or pull attached tendons, wherein said tendons are also attached to a knob on the scope that is in mechanical communication with the distal end. Movement of the distal end can thereby be controlled by the servo motors until the distance between each side of the distal end and the colon wall becomes approximately the same within the tolerance.

Control System

[0048] In the various embodiments, the provided endoscopes comprise a control system that communicates electronically with, directs, and coordinates the action of the sensors and the actuators. In operation, the control system enables real time adjustment of the position of the distal end of the endoscope via the actuators in response to the detected location of the scope tip by the sensors. Thus, the sensors act as input components and the actuators as output components.

[0049] In various embodiments, the control system comprises a logic component and one or more components selected from power sources, drivers processors, and analog/digital converters. To make the system independent and portable, an embedded system comprising sensors and actuators controlled by a micro-controller can be utilized. An embedded control system may be configured on one board. For example, a Programmable Intelligent Controller (PIC) micro-controller, which contains an internal Analog to Digital Converter (ADC) for the sensors may be utilized. Some of the advantages of using PIC are that a company can supply the system for a moderate price, developers can use different kinds of computer languages (eg., C or assembly language) in real-time processing for their convenience, and because of the simplicity of the processor board, the control element can be very stable and relatively maintenance-free. Additionally, firmware can be easily upgraded.

[0050] In some embodiments, the sensitivity of the sensor and response time of the actuator may be related to the advancing speed of an endoscope shaft. Thus, the provided endoscopy system may also include an image processing module or other sensor system capable of recognizing the speed of the shaft and adjusting sensor sensitivity and actuator response time. For example, the response time of servo motors utilized by a colonoscopy system of the invention may be directly related to the advancing speed of a shaft through a colon, and thus, such system may include an image processing module to recognize the speed of the shaft as it moves through the colon and adjust the response time of the distal end accordingly.

[0051] In some embodiments, the provided endoscopy systems may also allow for selectable sensitivity of the distal end motion, wherein a clinician can select the sensitivity of the tip movement and a washout algorithm can be utilized to maximize the movement of the tip to the zero reference position for the maximum availability of the next motion.

[0052] According to some embodiments, each motion (i.e., up, down, right, and left, and combinations thereof) of the distal end of a provided endoscope is governed by one or more infra-red sensors and one or more decoupled servo motors. For example, in a colonoscope of the invention, maintenance of the position of the distal end in the center of the colon when the colonoscope is stationary or moving may be governed by one or more infra-red sensors and one or more decoupled servo motors. Since sensitivity of the sensors in the detection of distal end motion may be dependent upon the advancing speed of the colonoscope, an additional sensor system could be utilized to measure the advancing speed of the colonoscope. Alternatively, the sensitivity of the distal end motion can be adapted by having the clinician select the sensitivity so that he or she can comfortably perform the procedure.

[0053] It will be appreciated to one of skill in the art that the components of the provided endoscopy systems may vary, and that sensors, actuators, control systems, and other components may be attached to or integrated with an endoscope of the invention in numerous configurations. Moreover, it will be appreciated that a variety of suitable sensors, actuators, and control systems may be selected for use with an endoscope of the invention. Additionally, it will be appreciated that conventional endoscopes may also be combined with suitable sensors, actuators, and control systems to provide an endoscope having various embodiments of the invention.

[0054] In the various embodiments, the general principle of operation of a provided endoscopy system is that the distal end of the endoscope maintains the same distance from tissue of an anatomical structure with respect to the directions of up, down, right, left, or combinations thereof within the structure. According to some examples, the distal end of the endoscope can be manually manipulated by knobs (eg., knobs positioned at the base of the scope), wherein each knob is internally connected to a push-pull mechanism comprising at least one pair of tendons (eg., steel tendons) and wherein such tendons are also connected to actuators, the activation of which also manipulates the tip. According to some examples, two sets of tendons may be orthogonally positioned with respect to each other so that the distal end can make left-right and up-down motions in response to manipulation of the corresponding knobs, actuators, or combination thereof. A diagonal motion of the tip may be achieved by the combined manipulation of the various knobs, actuators, or combinations thereof. Rotation of the tip can also be achieved by turning the base of the endoscope. According to some examples, infra-red sensors (or other sensors) detect the tissue of the structure and measure the distance between portions of the tip (for example, upper, lower, right, and left, and combinations thereof) and the tissue. If the distance between each portion of the tip and the tissue is different, a servo motor (or other actuator) attached to the tendons automatically pushes or pulls the tendons to control the same distance. Each sensor and corresponding actuator may be decoupled and work independently so that the positioning response of the distal end approximates real-time.

[0055] Referring to **Figure 1**, embodiments of one example of a provided colonoscopy system are illustrated, wherein the depicted system has at least three components: sensors, actuators, and an embedded control system. The dashed lines represent the mechanical attachment of the sensors and the actuators to the colonoscope. According to this example, the system includes three infra-red sensors and two DC servo motors mechanically connected to the colonoscope. However, it is also contemplated that alternative numbers, types, and configurations of sensors and actuators would be suitable. For example, four infra-red sensors and two DC servo motors may be mechanically connected to the colonoscope.

[0056] As shown, the system also comprises an embedded control system configured on one board. This allows for control of the infra-red sensors as input sources and actuators as output sources to make a closed loop control system. The control system comprises a microprocessor and an analog/digital converter. Any microprocessor, analog/digital converter, or combination thereof suitable for the application may be used. For example, an 8 bit microprocessor, a 10 bit analog/digital converter, or combinations thereof may be suitable for use with the provided colonoscope. The control system and DC servo motors may be housed in one enclosure (not shown) remote from the endoscope, and may include a power source, such as an AC power supply or battery packs for portability (not shown).

[0057] Referring to **Figure 2**, embodiments of one example of a provided endoscopy system are illustrated, wherein the depicted system comprises at three infra-red sensors at or proximate to the distal end. As shown in **A**, the system has three infra-red sensors **1** (two visible) located on the shaft **2** proximate to the distal face **3** of the distal end **4**. Each sensor **1** has signal-emitting and signal-receiving elements (not labeled) and is positioned around the circumference of the shaft **2** at approximately 120° from the neighboring sensor **1**. As illustrated in **B**, the distal end **4** may maneuver through straight sections of an anatomical structure **5** while maintaining a central position within the structure **5** such that contact between the distal end **3** and the structure **5** is avoided. As illustrated, the sensors **1** emit and receive a signal **6** detecting the distance between the distal end **4** and the structure **5**; the signal **6** is transmitted to the control system (not shown); and the control system directs response of the actuators (not shown) to move the distal end **4** to, or maintain its location at, the central position. As also illustrated in **B**, the provided system also allows for maneuvering of the distal end **4** through curved sections of an anatomical structure **5** while maintaining the distal end **4** in the central position.

EXAMPLES

[0058] The present invention will be better understood by reference to the following examples which are offered by way of illustration not limitation.

EXAMPLE 1

Automatic Avoidance of Direct Contact With Colon Tissue

[0059] An endoscopy system of the invention may be designed to automatically avoid direct contact between the distal end of the scope and the surrounding anatomical structure. To achieve this, the system includes sensory elements, control elements, and actuator elements.

[0060] One example of such a system is a colonoscope comprising four infra-red sensors positioned around the circumference of the distal end of the colonoscope, wherein each sensor comprises signal-emitting and signal-receiving elements and is located 90° from its neighboring sensor. To manually control the distal end, the colonoscope has two knobs located at its base, with each knob internally connected to the distal end by one set of steel tendons. The two sets of tendons are orthogonally positioned with respect to each other so that the distal end can make left-right and up-down motions. To automate control of the distal end, attached to each knob by steel tendons, and to the proximal end of the scope, is a DC servo motor that can push or pull the tendons attached to the knob and thus control the distal end movement.

[0061] To coordinate and control the sensors and actuators, the system also has an embedded control system comprising a DC servo motor driver, an infra-red sensor driver, a microprocessor, and an analog/digital converter. Each DC servo motor is linked by the control system to two infra-red sensors such that two sensors are assigned to left-right motion control, and the other two are assigned to up-down motion control. The infra-red sensors detect the inside colon wall and measure the distance between each portion of the distal end (i.e., up, down, left, right, and combinations thereof) and the colon wall. If the distance between a portion of the distal end and the colon wall is different, the relevant servo motor pushes or pulls the corresponding tendons attached to the relevant knob to control the tip until that tip portion becomes approximately the same distance (within tolerance) from the colon wall as the other portions.

[0062] The system automatically responds to the distal end's placement within the colon to avoid it making contact with the colon wall. Since each servo motor and corresponding pair of infra-red sensors are decoupled and work independently, the positioning response approximates real-time. The automation of sensing and positioning may also be selectively disengaged to allow for manual control of the distal end by the clinician via the knobs.

EXAMPLE 2

Automatic Detection of the Colon Lumen

[0063] A colonoscopy system may also be designed to automatically detect the colon lumen. To achieve this, the system includes sensory elements, control elements, and actuator elements.

[0064] Three infra-red sensors are positioned around the circumference of the distal end of a colonoscope, wherein each is located 120° from its neighboring sensor. The distal end is connected internally by two sets of steel tendons to two knobs located at the scope base, with each knob connected to one set of steel tendons. The two sets of tendons are orthogonally positioned with respect to each other so that the tip can make left-right and up-down motions. Two DC servo motors are attached to the base of the scope, with each attached to one of the knobs by steel tendons. Each DC servo motor can push or pull the tendons attached to the knob and thus control the distal end positioned within the colon.

[0065] To coordinate and control the sensors and actuators, the system also has an embedded control system comprising a DC servo motor driver, an infra-red sensor driver, a microprocessor, and an analog/digital converter. Each DC servo motor is linked by the control system to the infra-red sensors. The infra-red sensors detect the inside colon wall and measure the distance between each portion of the tip and the colon wall. If the distance between a portion of the distal end and the colon wall is different, the relevant servo motor pushes or pulls the corresponding tendons attached to the relevant knob to control the tip until that tip portion becomes approximately the same distance (within tolerance) from the colon wall as the other portions. Thus, the colon wall is automatically detected, and by an approximately real-time response, the distal end is automatically positioned to be in the lumen.

[0066] The present invention should not be considered limited to the specific examples described herein, but rather should be understood to cover all aspects of the invention. Various modifications, equivalent processes, as well as numerous structures and devices to which the present invention may be applicable will be readily apparent to those of skill in the art. Those skilled in the art will understand that various changes may be made without departing from the scope of the invention, which is not to be considered limited to what is described in the specification.

CLAIMS

What is claimed is:

1. An endoscopy system, comprising:

an endoscope comprising a shaft having a distal end for insertion into an anatomical structure of a subject's body and a proximal end that remains substantially outside of the subject's body;

one or more sensors in communication with the distal end;

one or more actuators in communication with the distal end;

a control system in communication with at least one of the one or more sensors and at least one of the one or more actuators, the control system comprising one or more sensor drivers, one or more actuator drivers, and one or more processors;

wherein the control system is configured to receive data from the one or more sensors, the data corresponding to distance between the distal end and surrounding anatomical structure, and based upon the data received, direct the one or more actuators to move the distal end such that it is at a pre-determined position with respect to the surrounding anatomical structure.

2. An endoscopy system of claim 1, wherein the one or more sensors are infra-red sensors, each sensor comprising signal-receiving and signal-emitting elements.

3. An endoscopy system of claim 1, wherein the one or more actuators are selected from pneumatic actuators, hydraulic actuators, shape memory alloys, magnetic actuators, electric motors, and combinations thereof.

4. An endoscopy system of claim 1, wherein the control system is an embedded system comprising a programmable intelligence microcontroller and an infra-red sensor driver.

5. An endoscopy system of claim 4, comprising at least three infra-red sensors.

6. An endoscopy system of claim 5, comprising at least two DC servo motors and a DC servo motor driver.

7. An endoscopy system of claim 1, comprising:

(i) one or more secondary sensors not in communication with the distal end, each secondary sensor independently attached to the shaft between the distal and proximal ends;

(ii) one or more secondary actuators not in communication with the distal end; each secondary actuator independently attached to the shaft between the distal and proximal ends;

(iii) one or more secondary sensors and one or more secondary actuators not in communication with the distal end, each secondary sensor and each secondary actuator independently attached to the shaft between the distal and proximal ends.

8. A endoscopy system according to claim 7, wherein at least one of the one or more secondary sensors is configured to emit a signal in a direction selected from orthogonal to the shaft, parallel to the shaft, or combinations thereof

9. An endoscopy system according to claim 7, wherein at least one of the one or more secondary sensors is attached at or proximate to the proximal end of the shaft and to a first end of a fiber optic cable; and wherein each fiber optic cable comprises a second end that is attached to the shaft between the distal and proximal ends and is configured to emit a signal in a direction selected from orthogonal to the shaft, parallel to the shaft, or combinations thereof.

10. A endoscopy system according to claim 7, comprising a control system in communication with (i) at least one of the one or more secondary sensors, (ii) at least one of the one or more secondary actuators, or (iii) at least one of the one or more secondary sensors and at least one of the one or more secondary actuators.

11. A colonoscopy system of claim 1.

12. An endoscopy system, comprising:

an endoscope comprising a shaft having a distal end for insertion into an anatomical structure

of a subject's body and a proximal end that remains substantially outside of the subject's body;

one or more infra-red sensors in communication with the distal end;

one or more actuators in communication with the distal end, the one or more actuators

selected from pneumatic actuators, hydraulic actuators, shape memory alloys, magnetic actuators, electric motors, and combinations thereof;

a control system in communication with at least one of the one or more infra-red sensors and at least one of the one or more actuators, the control system comprising an infra-red sensor driver, a programmable intelligence microcontroller, and an actuator driver;

wherein the control system is configured to receive data from the one or more infra-red sensors, the data corresponding to distance between the distal end and surrounding tissue of the anatomical structure, and based upon the data received, direct the one or more actuators to move the distal end such that it is at a pre-determined position with respect to the surrounding anatomical structure.

13. An endoscopy system of claim 12, wherein the one or more infra-red sensors are attached at or proximate to the distal end and are configured to emit a signal in a direction selected from orthogonal to the shaft, parallel to the shaft, perpendicular to the distal end, or combinations thereof.

14. An endoscopy system of claim 13, comprising three infra-red sensors, each circumferentially positioned around the shaft at 120° from a neighboring sensor.

15. An endoscopy system of claim 13, comprising four infra-red sensors, each circumferentially positioned around the shaft at 90° from a neighboring sensor.

16. An endoscopy system of claim 12, wherein each of the infra-red sensors is attached at or proximate to the proximal end of the shaft and to a first end of a fiber optic cable; and wherein each fiber optic cable comprises a second end that is attached at or proximate to the distal end of the shaft and is configured to emit a signal in a direction selected from orthogonal to the shaft, parallel to the shaft, perpendicular to the distal end, or combinations thereof.

17. An endoscopy system of claim 16, comprising three infra-red sensors and three fiber optic cables, the second end of each fiber optic cable circumferentially positioned around the shaft at 120° from a neighboring second end.

18. An endoscopy system of claim 16, comprising four infra-red sensors and four fiber optic cables, the second end of each fiber optic cable circumferentially positioned around the shaft at 90° from a neighboring second end.

19. A colonoscopy system, comprising:

a colonoscope comprising a shaft having a distal end for insertion into a subject's colon and a proximal end that remains substantially outside of the subject's body;

one or more infra-red sensors in communication with the distal end;

one or more DC servo motors in communication with the distal end;

a control system in communication with at least one of the one or more infra-red sensors and at least one of the one or more DC servo motors, the control system comprising an infra-red sensor driver, a programmable intelligence microcontroller, and a DC servo motor driver;

wherein the control system is configured to receive data from the one or more infra-red sensors, the data corresponding to distance between the distal end and surrounding colon wall, and based upon the data received, direct the one or more DC servo motors to move the distal end such that it is at a pre-determined position with respect to the colon wall.

20. A colonoscopy system of claim 19, wherein each DC servo motor is in mechanical communication with at least one pair of tendons, each pair of tendons in mechanical communication with the distal end and configured to provide a pushing force, pulling force, or combination thereof at the distal end.

21. A colonoscopy system of claim 20, comprising a first DC servo motor in communication with a first pair of tendons configured to provide movement of the distal end in a first plane, and a second DC servo motor in communication with a second pair of tendons configured to provide movement of the distal end in a second plane.

22. An colonoscopy system of claim 21, wherein the configuration of motors and tendons allows for automated control of movement of the distal end by the control system.

23. A colonoscopy system, comprising:

a colonoscope comprising a shaft having a distal end for insertion into a subject's colon and a proximal end that remains substantially outside of the subject's body;

three or more infra-red sensors in communication with the distal end;

two or more DC servo motors in communication with the distal end;

a control system in communication with at least three of the three or more sensors and at least two of the two or more DC servo motors, the control system comprising an infra-red sensor driver, a programmable intelligence microcontroller, and a DC servo motor driver;

a first pair of tendons comprising first ends in mechanical communication with the distal end

and second ends in mechanical communication with at least the first of the two or more DC servo motors, the first pair of tendons housed within the shaft and configured to provide a pushing force, pulling force, or combination thereof at the distal end to cause movement in a first plane;

a second pair of tendons comprising first ends in mechanical communication with the distal

end and second ends in mechanical communication with at least the second of the two or more DC servo motors, the first pair of tendons housed within the shaft and configured to provide a pushing force, pulling force, or combination thereof at the distal end to cause movement in a second plane;

wherein the control system is configured to receive data from the three or more infra-red sensors data corresponding to distance between the distal end and surrounding colon wall, and based upon the data received, direct the two or more DC servo motors to actuate the first and second pair of tendons to move the distal end such that it is at a pre-determined position with respect to the colon wall.

24. A colonoscopy system of claim 23, wherein each of the infra-red sensors is attached at or proximate to the proximal end of the shaft and to a first end of a fiber optic cable; and wherein each fiber optic cable comprises a second end that is attached at or proximate to the distal end of the shaft and is configured to emit a signal in a direction selected from orthogonal to the shaft, parallel to the shaft, perpendicular to the distal end, or combinations thereof.

25. A colonoscopy system of claim 24, comprising three infra-red sensors and three fiber optic cables, the second end of each fiber optic cable circumferentially positioned around the shaft at 120° from a neighboring second end.

26. A colonoscopy system of claim 24, comprising four infra-red sensors and four fiber optic cables, the second end of each fiber optic cable circumferentially positioned around the shaft at 90° from a neighboring second end.

27. An colonoscopy system of claim 23, wherein each of the infra-red sensors are attached at or proximate to the distal end and are configured to emit a signal in a direction selected from orthogonal to the shaft, parallel to the shaft, perpendicular to the distal end, or combinations thereof.

28. An colonoscopy system of claim 27, comprising three infra-red sensors, each circumferentially positioned around the shaft at 120° from a neighboring sensor.

29. An colonoscopy system of claim 27, comprising four infra-red sensors, each circumferentially positioned around the shaft at 90° from a neighboring sensor.

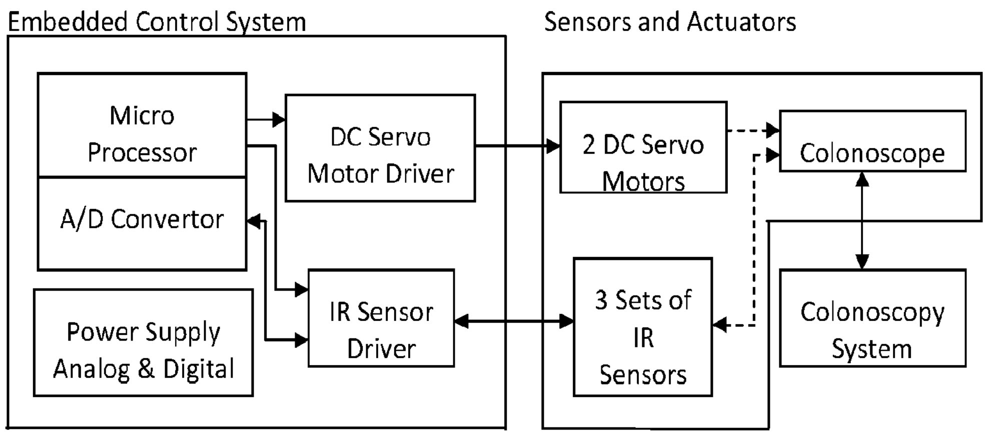
Embedded Control System
Sensors and Actuators
Micro Processor
A/D Convertor
DC Servo Motor Driver
IR Sensor Driver
Power Supply Analog & Digital
2 DC Servo Motors
3 Sets of IR Sensors
Colonoscope
Colonoscopy System

FIGURE 1

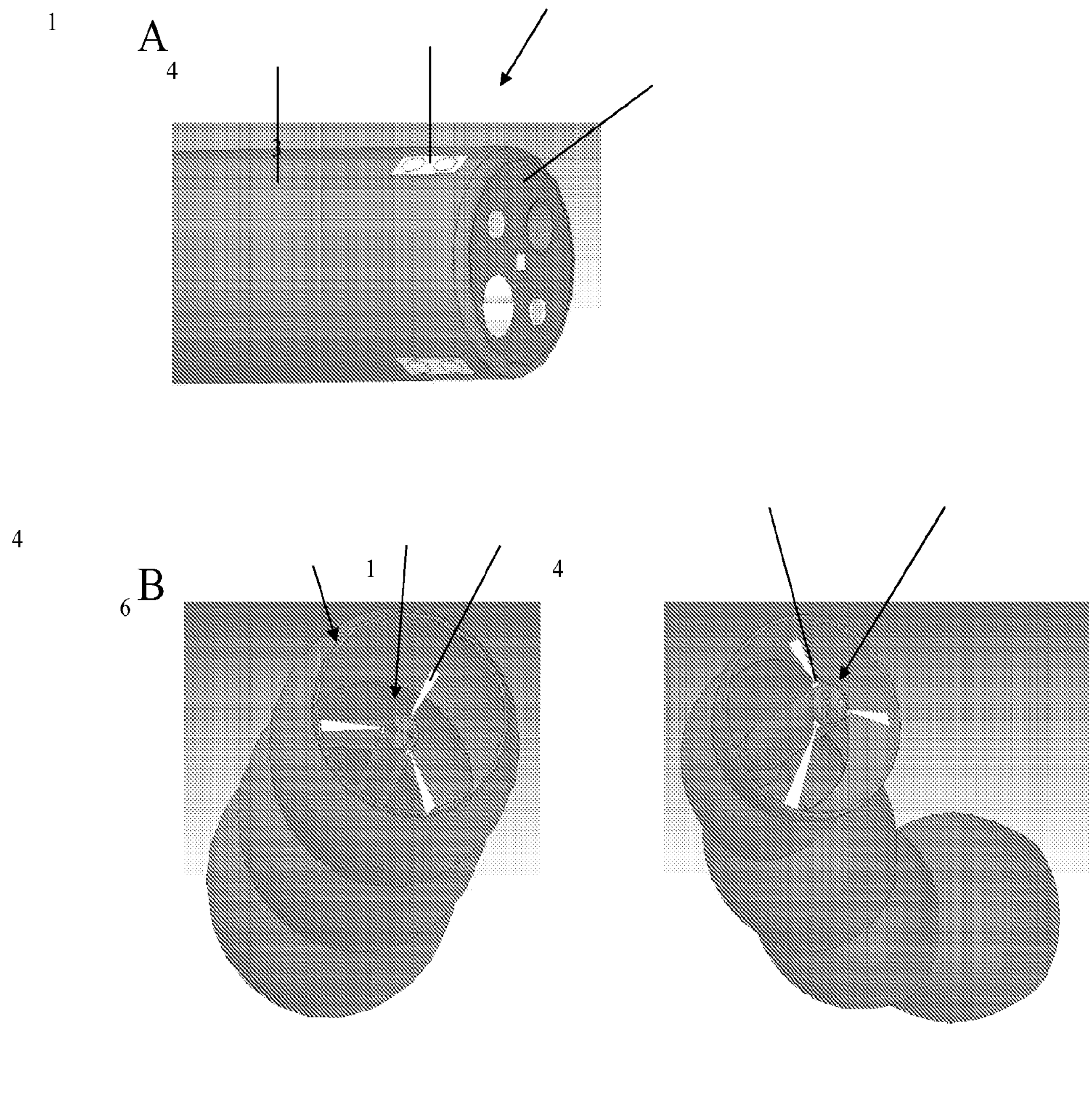

FIGURE 2

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 10/29466

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61B 1/01 (2010.01)
USPC - 600/146
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
USPC: 600/146

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
USPC: 600/101, 109, 114, 118, 139, 145, 146, 149 (keyword limited; terms below)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
DIALOGWEB(databases 652,654); Google
Search Terms Used: endoscop?, colonoscop?, infrared, flexible, automatic, distance, measur?, calculat?, wall, lumen, sensor, camera, imag?, fiber, optic, space, robot?, computer?, control?, mov?, navigat?, manipulat?

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	US 4,292,961 A (KAWASHIMA) 06 October 1981 (06.10.1981) fig 1, 2, col 2, ln 4-11, col 3, ln 23-27, col 3, ln 46-47, col 3, ln 48-62, col 4, ln 9-15	1, 3, 11 2, 4-10, 12-29
Y	US 2008/0045792 A1 (SHIMIZU et al) 21 February 2008 (21.02.2008) para [0192]	2, 4-6, 9, 12-29
Y	US 2007/0135803 A1 (BELSON) 14 June 2007 (14.06.2007) para [0219]-[0220], [0529]	7-10, 16-18, 24-26
Y	US 6,036,637 A (KUDO) 14 March 2000 (14.03.2000) col 34, ln 60-65	19-29

☐ Further documents are listed in the continuation of Box C. ☐

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
09 June 2010 (09.06.2010)	22 JUN 2010

Name and mailing address of the ISA/US	Authorized officer:
Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774