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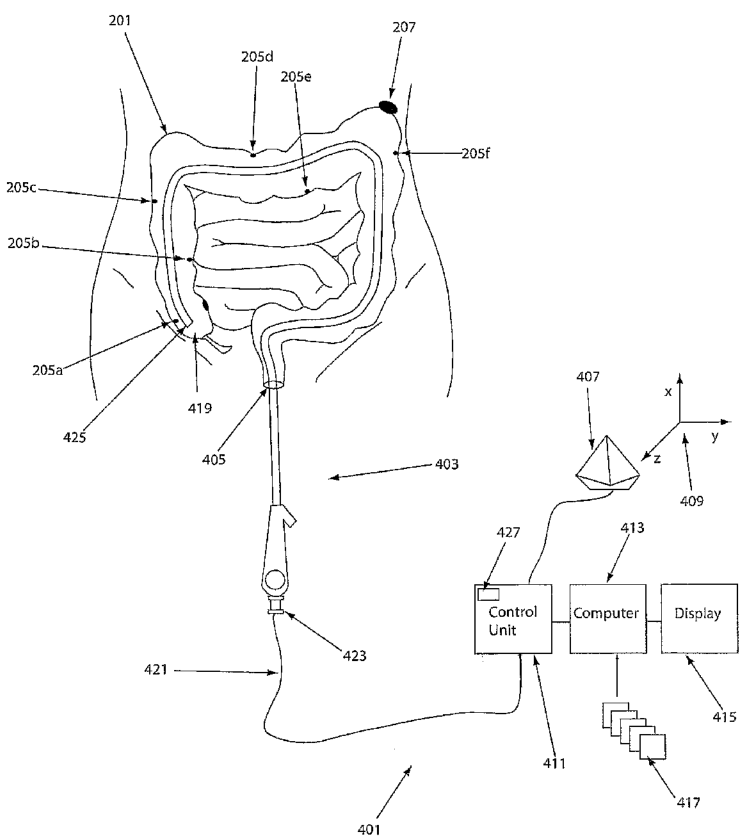
(54) **Title:** SYSTEM, METHOD AND DEVICES FOR NAVIGATED FLEXIBLE ENDOSCOPY



(57) **Abstract:** The invention provides a method and system for performing an image-guided endoscopic medical procedure. The invention may include registering image-space coordinates of a path of a medical instrument within the anatomy of a patient to patient-space coordinates of the path of the medical instrument within the anatomy of the patient. In some embodiments, the image space coordinates of the path of the medical instrument may be predicted coordinates such as, for example, a calculated centerline through a conduit-like organ, or a calculated "most likely path" of the medical instrument within the anatomy of the patient. In other embodiments, the path of the medical instrument may be an actual path determined using intra-operative images of the patient's anatomy with the medical instrument inserted therein. The registered instrument may then be navigated to one or more items of interest for performance of the endoscopic medical procedure.

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SYSTEM, METHOD, AND DEVICES FOR NAVIGATED FLEXIBLE ENDOSCOPY

REFERENCE TO RELATED APPLICATIONS

[001] This application claims priority to U.S. Provisional Patent Application No. 60/710,657, filed August 24, 2005, which is hereby incorporated by reference herein in its entirety.

FIELD OF THE INVENTION

[002] The present invention relates to methods and apparatus for assisting navigated flexible endoscopy.

BACKGROUND

[003] During exploratory endoscopic procedures such as colonoscopy, bronchoscopy, endoscopic retrograde cholangiopancreatography (ECRP) or other endoscopic procedures, it is desirable to locate any lesions or other areas that are of interest such as, for example, precancerous changes, bleeding sites, polyps, nodules, or other areas of interest. Traditional endoscopic examination consists entirely of an optical examination of the conduit or area of interest within the anatomy of the patient. More recently, virtual examination has become more popular. In virtual endoscopy, computerized tomography (CT), magnetic resonance (MR), ultrasound, or other diagnostic imaging methods are first used to locate a suspect lesion either with or without the assistance of a computer algorithm (e.g., "CAD" or computer assisted diagnosis). Lesion candidates are then inspected optically and treated or biopsied as deemed appropriate by the physician.

[004] During optical endoscopic examination, it is important to locate all flagged suspicious regions (e.g., lesions or other areas of interest) and examine them. In practice, this can be difficult because there is no way to easily register image-based data regarding suspect lesions to the patient space (e.g., the real world location of the suspected lesions). Often the length of the endoscope from the insertion point into the patient is the only indication of the location of suspect lesions. Typically this indication is extremely crude, averaging 10 centimeters (cm) or more of error. In arborized tissues, such as, the bronchial pathways of the lungs, physicians frequently become disoriented and enter a branch other than the desired one.

[005] The invention is designed to assist in the optical localization of suspect lesions or other areas of interest that are initially detected using virtual colonoscopy or other virtual endoscopy. This invention enables the physician performing the examination to more efficiently locate suspicious lesion candidates from imaging scans, such as CT, MR, ultrasound, or other imaging scans. Once the position of the candidate lesion or other area of

interest is determined from the imaging scan (either manually, computer assisted, or through the use of a fully automated CAD software) the (x, y, z) location of the candidate will be recorded in image (i.e. CT space) or in some other convenient form. The system then enables these locations to be indicated to the physician during a conventional optical endoscopic exam, increasing the likelihood that he will be able to locate and inspect them. The invention further enables the shape of a flexible endoscope or other instrument to be determined without the use of additional imaging.

SUMMARY OF THE INVENTION

[006] In one embodiment, the invention provides a system and method for performing and/or assisting in image-guided medical endoscopic medical procedures. In one embodiment, the system of the invention may comprise a control unit, a control application, a tracked medical instrument, a position sensing system, a display device, and/or other elements.

[007] In one embodiment, the control unit may include one or more special purpose or general purpose computers and/or processors cable of responding to and executing instructions in a defined manner. The control unit may include, be associated with, and/or be in communication with a memory device that stores any data necessary for the performing the features or functions of the invention such as, for example, image data, position data, orientation data, coordinate data, transformation matrices, and/or other data. The control unit may also include, run, and/or support a control application comprising one or more software modules for directing and performing one or more data reception, transmission, data processing, and/or other data manipulation operations according to the features and functions of the invention. Other software modules may also be utilized with the system of the invention.

[008] In one embodiment, the tracked medical instrument may include an endoscope equipped with at least one working channel, optics for viewing the anatomy present at the distal tip of the endoscope, one or more trackable sensor elements, and/or other elements. The position and/or orientation of the one or more sensor elements may be determined/monitored by the position sensing system. The position sensing system may be in communication with the control unit and may provide sampled position coordinates and orientation information of the one or more sensor elements to the control unit. An example of the position sensing system is an electromagnetic position sensing system used with electromagnetic sensor elements.

[009] In some embodiments, the tracked medical instrument may include an untracked endoscope or other instrument used in conjunction with a tracked catheter, tracked guidewire, tracked treatment device, and/or other tracked instrument. In some embodiments, the tracked medical instrument may be a tracked endoscope. In some embodiments, the system of the invention may not include an endoscope, but may include one or more tracked devices that do not include the optics typically associated with an endoscope.

[010] The system of the invention may also include a display device that displays images used in the system and methods of the invention such as, pre-operative images of the anatomy of a patient (including one or more items of interest), intra-operative images of the anatomy of the patient (including an inserted medical instrument and the one or more items of interest), real-time or near-real-time images displaying motion of the tracked instrument relative to the one or more items of interest within the anatomy of the patient, and/or other images or data.

[011] In one embodiment, the invention provides a method for performing and/or assisting with an image-guided medical procedure, wherein a path of the tracked medical instrument in image space is registered to the path of the medical instrument in patient space. The path of the medical instrument in image space may be obtained from one or more pre-operative images and/or one or more intra-operative images of the anatomy of the patient. The path of the medical instrument in patient space may be obtained using a position sensing system and one or more sensor elements located on the medical instrument itself or on a separate tracked instrument. The patient space data is then registered to the image space data to produce a registration matrix relating the patient space to the image space. This registration matrix may be used to display the location and movement of the medical instrument on the one or more pre or intra-operative images so as to navigate to the one or more items of interest within the anatomy of the patient.

[012] In one embodiment, the method of the invention includes obtaining one or more pre-operative images of a portion of the anatomy of a patient, wherein the portion of the anatomy of the patient includes the one or more items of interest. For example, if the medical procedure was a colonoscopy for the investigation of one or more colonic lesions, the one or more pre-operative images may be taken of the colon and/or digestive tract of the patient. The pre-operative images may comprise image data obtained using, x-rays, computerized tomography (CT), magnetic resonance (MR), positron emission tomography (PET), ultrasound, and/or other imaging modalities.

[013] In one embodiment, the pre-operative image data is then examined to determine the locations of candidate lesions or other items or points of interest in the patient's anatomy. In one embodiment, these locations are expressed in the coordinate system of the pre-operative imaging modality (i.e. the "pre-operative image space"). As such, the location of all lesions or items of interest is expressed in terms of a frame of reference intrinsic to the pre-operative image-gathering device.

[014] In some embodiments, this examination may be performed by a physician, technician, or other individual. In other embodiments, the examination may be partially assisted by diagnostic software modules (e.g., one or more modules comprising the control application). In still other embodiments, this examination may be completely automated using one or more software modules or applications.

[015] In one embodiment, such as, when the anatomy involved in the medical procedure includes a channel-like organ or region (e.g., the colon, bronchial system, or other channel-like region) the centerline of a path through the anatomy/organ may calculated. For example, if the anatomy on which the procedure is performed is the patient's colon, the centerline may be calculated and represented by a locus of points that form a path defining the approximate centerline of the colon. Because these coordinates are derived from the one or more pre-operative images, these coordinates are expressed relative to the pre-operative image space.

[016] In one embodiment, a skeleton or "graph" of a pathway to the organ may also be determined. This may be particularly useful if the conduit/organ in which the items of interest are located is arborized (e.g., bronchial passages). The graph represents a map from start to target (e.g., a lesion or other item of interest) along the centerline of any branches in the organ (e.g., the bronchi of a lung) indicating the direct path to the target, including all turns.

[017] In another embodiment, rather than a calculated centerline, the "most likely path" of the passage of a flexible endoscope or other flexible instrument is calculated using the one or more pre-operative images. The coordinates of a plurality of points defining this "most likely path" are determined in the pre-operative image space. In some instances, the most likely path of an endoscope may include points that intersect the walls of any conduit-like anatomy in the anatomical region (e.g., the endoscope may collide with the walls of the colon), rather than points that follow a centerline path through the anatomy. Using mathematical predictive techniques, this "most likely path" of an endoscope/instrument can be calculated. In some embodiments, determination of the most likely path uses a predictive collision detection system that predicts the endoscope locations touching the walls of

channel-like anatomy such as, for example, at locations with sharp curvature (e.g., the junction between the ascending-transverse and transverse-descending colon). In some embodiments, this predicted path may also be measured, as discussed below.

[018] In one embodiment, the medical procedure may begin, usually by insertion of the medical instrument. For example, if the medical procedure included a colonoscopy, the medical procedure may include insertion of a colonoscope or other endoscope into the colon of the patient. The medical instrument may be inserted into the anatomy of interest in a manner known in the art. In some embodiments, this can be done by inserting the instrument into natural or artificially created orifice of the patient.

[019] In some embodiments, wherein the endoscope and/or other medical instrument is visible to an imaging modality, intra-operative images of the anatomy of the patient may be taken with the endoscope inserted. The intra-operative imaging may be used to precisely determine the location of the path of the endoscope and/or other instrument following insertion. For example, in one embodiment, the path of the endoscope can be obtained using two or more fluoroscopic shots taken at different angles, a CT scan, ultrasound images, or other images taken following insertion of the endoscope. This intra-operative imaging may also be used to determine the location of the lesions or other areas of interest relative to the inserted endoscope.

[020] In general, the intra-operative images may be obtained in a new coordinate system/frame of reference (i.e., "intra-operative image space"). In some embodiments, as discussed herein, the path of the endoscope determined using the intra-operative images may be matched or registered with the coordinate system of the pre-operative images on which the candidate lesions, or other items of interest have been annotated, and on which the predicted path of the endoscope (e.g., centerline path or most likely path) has been calculated.

[021] The centerline path and/or the most likely path of the endoscope calculated in the pre-operative image space may differ from the actual path taken by the inserted endoscope. As such, the intra-operative images provide the "true path" of the endoscope. The true path of endoscope becomes available once the intra-operative imaging is performed and analyzed. Registering the intra-operative image data with the pre-operative image data provides a more accurate set of image space data regarding the path of the endoscope and provides a richer set of data regarding other features of the anatomy of the patient.

[022] In some embodiments, it may be desirable to determine the contortions that the endoscope or other instrument has undergone without the use of images. For example, a colonoscope frequently undergoes loops and other deformations that affect a medical

procedure being performed with the colonocsope. Normally, it is difficult to determine these deformations without imaging. If a tracked elongated member is dragged through a channel of the endoscope or other instrument, the locus of points gathered as the position of sensor elements in the tracked member are sampled prescribe a shape that is the same as the shape of the endoscope or other instrument. This information may be used to assist in the medical procedure. In some embodiments, only a single sensor element attached to a slidable elongated member (e.g., a guidewire) is needed to determine this shape. In some embodiments, multiple sensor elements may be fixed to or moved along the endoscope or other instrument to determine its path. In some embodiments, motion may be compensated for by using a dynamic reference device such as, for example, a skin motion tracker, an internally-placed catheter, or other dynamic referencing device. Motion may also be compensated for using a gating device such as, for example, an ECG (electroencephalogram), a respiratory gating device, or other gating device.

[023] To conduct or assist image-guided surgery, it is desirable to register or match the coordinate system of the position sensing system to the coordinate system belonging to the pre-operative image space, intra-operative image space, or a co-registered combination of the pre and intra-operative images. One way of facilitating this is by acquiring a plurality of points in position sensor space or "patient space" (i.e., the coordinate system/frame of reference intrinsic to the position sensing system) and mathematically matching them to the same points in image space.

[024] This may be done by first obtaining patient space data regarding the endoscope or other instrument within the anatomy of the patient. This patient space data may be obtained using the position sensing system and the one or more sensor elements located on the endoscope or other medical instrument.

[025] The position sensing system is associated with its own coordinate system (i.e., a frame of reference intrinsic to the position sensing system). The position sensing system is capable of determining the position and orientation of one or more sensor elements attached to an instrument (e.g., the endoscope or another instrument) and relaying that information to the control unit.

[026] Acquisition of data in patient space can be performed by dragging a tracked endoscope or other instrument back through the anatomy of the patient (e.g., dragging it back through the colon) or a tracked instrument back through the working channel of the endoscope (or the working channel of a catheter or other instrument inserted into the patient's anatomy) while the position sensing system gathers/samples data points regarding the

position and/or orientation of the sensor elements on the tracked instrument in the frame of reference/coordinate system of the position sensing system. This technique may be labeled a "dragback" technique. More information regarding the use of this technique and other information relevant to registration, dynamic referencing, and other image guided surgery techniques can be found in U.S. Patent Application No. 11/059,336 (U.S. Patent Publication No. 20050182319), which is hereby incorporated by reference herein in its entirety.

[027] In some embodiments, instead of, or in addition to, using the dragback method described above for obtaining data points in patient space, individual identifiable locations in the anatomy of the patient are sampled by touching or indicating them with the tracked instrument or endoscope. In some embodiments, a tracked instrument may be temporarily secured in the endoscope and sensor element positions sampled (i.e., not dragged through the endoscope). In some embodiments, a tracked ultrasound device may be used to indicate points.

[028] In one embodiment, registration of the patient space data to the image space data may involve only image space data acquired pre-operatively. For example, in one embodiment, the patient space path of the endoscope acquired using a tracked instrument and the position sensing system may be registered to pre-operative image space data relating to the "assumed" path of the endoscope (i.e. based on the centerline path or the "most likely path" calculated using the pre-operative images).

[029] In some embodiments, however, the patient space data may be registered to the intra-operative image space data. For example, the image space path of the endoscope registered to the patient space data may be based on the directly measured path of the inserted endoscope observed in the intra-operative images (e.g., the "true path"). Directly measured or true paths may require a method expressing the coordinates of this path in the same frame of reference as the candidate lesions (e.g., the above-discussed co-registration of the pre-operative images to the intra-operative images). In these embodiments, a separate registration must be performed to match the pre-operative images to the intra-operative images before the combined image data is registered to the patient space data. In one embodiment, this is done by using 2D-3D or 3D-3D co-registration techniques.

[030] Once at least two representations of the endoscope's path have been determined (i.e. in image space [pre-operative and/or intra-operative] and in patient space), they may be "matched" or "registered". The two paths may be matched using an iterative closest points (ICP), piecewise ICP, or similar algorithm. This enables a registration matrix (or sequence of registration matrices) to be generated. In some embodiments, the registration takes the form

of a rigid transformation matrix. In some embodiments, the registration uses an affine transformation. In some embodiments, several matrices are used at different places. In some embodiments, weighted combinations of matrices are used. In some embodiments, complex matrices embodying deformable transformations are used.

[031] In some embodiments, registration may be accomplished using techniques other than or in addition to the dragback technique described above. For example, in one embodiment, a "landmark-based" method may be used that includes the identification of "fiducials" present in both pre-operative images and identified during the examination by, for example, touching them with a tracked instrument or imaging them with a tracked calibrated ultrasound transducer to determine their location in patient space. If at least 3 such points are co-located, a registration can be performed using techniques such as the ICP above or simpler methods such as singular valued decomposition. In some embodiments, the fiducials can be naturally occurring landmarks, such as polyps, and in other embodiments, they can be artificial landmarks such as small balls, surgical staples, specially placed needles, or other elements that may be visible in both the pre-operative images and intra-operative images. Other registration methods may also be used.

[032] In some embodiments, the endoscope or other elongated instrument may be equipped with additional sensor elements that can act as dynamic referencing or tracking sensors, either with multiple sensor elements placed along the scope or one or two sensor elements located at the most distal end of the scope. These track gross patient movement or the motion of the field generator of the position sensor system as long as the endoscope or other elongated instrument remains stationary.

[033] In some embodiments, dynamic references (i.e., sensor elements) can be placed into additional catheters, guidewires, or instrument placed elsewhere in/on the patient that are not affected by the exam. The purpose of these sensor elements is to account for patient movement, including that occurring from respiration, or other patient movement.

[034] Once registration has been performed, the invention may include a navigation step in which the endoscope or other instrument equipped with sensor elements is tracked by the position sensing system. As the endoscope is moved through the anatomy to inspect its interior, the position of the endoscope or tracked instrument may be sampled in the reference frame of the position sensing system. The locations and orientations determined by the position sensing system are sent to the control unit, which creates a real-time or near real-time display of the motion of the tracked instrument relative to the lesions or other points of interest as identified in the image space. The display is enabled by the transformation matrix

produced by the registration. This display is used, for example, for image-guided navigation of the endoscope in an attempt to locate suspect lesions or other items of interest using the optics of the endoscope.

[035] In some embodiments, the only information required may be the shape of the endoscope or other instrument. This may be acquired without having to explicitly perform a registration step.

[036] In some embodiments, whenever one of the flagged locations (i.e., lesions or other items of interest) is in the proximity of the tracked portion of the endoscope or other instrument, the physician may be notified or he or she will be able to determine from the images that he or she is in proximity of the suspect lesion and can look for it.

[037] In some embodiments, the lesions or other items of interest can then be treated, destroyed, biopsied, or otherwise treated, if detected. This treatment may be enabled by treatment-oriented instruments, that may be tracked themselves, and which may be inserted through the working channel of the endoscope that has been navigated to a lesion or other item of interest.

[038] In some embodiments, the sensor elements on a trackable guidewire act simply as a distance measurement device to determine the location of the endoscope relative to a known location. In this embodiment, the relative location of all suspect lesions are calculated relative to each other and landmarks within the anatomy. As each is examined, the location is stored and the distance to the next location of interest is calculated. In this way, the system is self-correcting at each identified location along the path of the endoscope as it is removed. This method may not require registration to be performed prior to use.

[039] For example, during a "virtual colonoscopy," suspect lesions may be flagged (on the preoperative images) by the physician or computer program, and their locations calculated in the frame of reference of the images.

[040] During the intervention, the colonoscope is inserted into the colon and a reference point is identified (for example, the ileocecal sphincter or appendiceal orifice). The path length of each of the suspect lesions is identified relative to this location along the centerline of the colon. For a first lesion, the path is the length of the distance along the centerline of the colon between the reference point (e.g., the appeniceal orifice) and the first suspect lesion. Likewise, the path length of a second lesion is the length of the distance along the centerline between the reference point (e.g., the appeniceal orifice) and the second suspect lesion. Thus by dragging the endoscope back and calculating the distance traversed by the sensor attached to the endoscope, the location of the next suspect lesion can be determined.

[041] Once the first lesion is encountered, the locations of the next lesions may be calculated relative to it. For example, the second suspect lesion can be estimated to be located a distance from the first lesion (or equivalently a distance from the appeniceal orifice). In general it may be more accurate to estimate measure the inter-lesion distances, rather than the distance between the start point and each lesion.

[042] In one embodiment, the physician indicates each lesion as it is encountered and in one embodiment, the lesions and landmarks are weighted according to their distance from the reference point.

[043] In one embodiment, these measured distances are augmented using shape information regarding the endoscope or other instrument, as may be determined using a path determination method such as those described herein. This shape information may be helpful in more accurately determining the location of an area of interest.

[044] These and other objects, features, and advantages of the invention will be apparent through the detailed description of the preferred embodiments and the drawings attached hereto. It is also to be understood that both the foregoing general description and the following detailed description are exemplary and not restrictive of the scope of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

[045] FIG. 1 illustrates an example of a process for assisting an image-guided endoscopic procedure, according to an embodiment of the invention.

[046] FIG. 2 illustrates an example of a pre-operative image of a portion of an anatomy of a patient, according to an embodiment of the invention.

[047] FIG. 3 illustrates an example of the "most likely path" of an endoscope through a conduit, according to an embodiment of the invention.

[048] FIG. 4A illustrates an example of a system for image-guided endoscopy used in the anatomy of a patient, according to an embodiment of the invention.

[049] FIG. 4B illustrates an example of a tracked elongated instrument within an endoscope used in the anatomy of a patient, according to an embodiment of the invention.

[050] FIGS. 5A and 5B illustrate an example of a steerable catheter, according to an embodiment of the invention.

[051] FIG. 6 illustrates an example a process for registration-free navigation during an endoscopic procedure, according to an embodiment of the invention.

[052] FIG. 7 illustrates an example of an image of a portion of the anatomy of a patient, according to an embodiment of the invention.

DETAILED DESCRIPTION

[053] In one embodiment, the invention provides method for assisting an image-guided endoscopic procedure. FIG. 1 illustrates a process 100, an example of a method for assisting an image-guided endoscopic medical procedure. In an operation 101, a conventional virtual endoscopic data set may be acquired prior to commencement of the medical procedure using existing standard protocols such as, for example, those described in A. K. Hara et al., *Reducing Data Size and Radiation Dose for CT Colonography*, 168 American Journal of Roentgenology 1181-1184 (1997), which is hereby incorporated by reference herein in its entirety.

[054] The virtual endoscopic data set may comprise image data obtained using x-rays, computerized tomography (CT), magnetic resonance (MR), positron emission tomography (PET), ultrasound, and/or other imaging modalities. In some embodiments, the pre-operative imaging may be performed with the patient in same position as the endoscopic procedure. In some embodiments the endoscopic procedure occurs in the same room as the pre-operative imaging.

[055] In an operation 103, the pre-operative image data may then by examined by a physician, technician, or other individual. In some embodiments, this examination may include the assistance of computer assisted diagnostic software such as, for example, that described in Ronald M. Summers et al., *Colonic Polyps: Complementary Role of Computer-aided Detection in CT Colonography*, 225 Radiology 391-399 (2002), which is hereby incorporated by reference herein in its entirety. In some embodiments, this examination may be completely automated using one or more software modules or applications.

[056] During the examination of operation 103, the locations of candidate lesions or other items or points of interest in the patient's anatomy are determined. In one embodiment, these locations are expressed in the coordinate system of the pre-operative images (i.e. "pre-operative image space"). As such, the location of all lesions or items of interest is expressed in terms of a frame of reference intrinsic to the pre-operative image-gathering device.

[057] FIG. 2 illustrates an example image 200 of a part of an anatomy of a patient, including colon 201 and small intestine 203. Identified candidate lesions are indicated as 205a, 205b, 205c, 205d, 205e, and 205f. A region of interest is indicated as 207. All identified lesions, regions, or other points or items of interest are expressed in terms of a coordinate system 209 that is a frame of reference intrinsic to the image gathering device used to produce image 200.

[058] In an operation 105, a predicted path of a flexible endoscope or other instrument through the anatomy of the patient wherein the one or more points of interest reside is determined. For example, in one embodiment, the centerline of a path through the patient's anatomy is obtained. For instance, if the anatomy on which the procedure is performed is a channel-like organ or region (e.g. the colon, bronchial system, or other channel-like region), the predicted path of a flexible endoscope may comprise a locus of points that form a path defining the approximate centerline of the organ. The coordinates of these points are determined in the pre-operative image space. Image 200 of FIG. 2 illustrates calculated centerline 211 through colon 201.

[059] In another embodiment, rather than a calculated centerline, the predicted path of the endoscope comprises a "most likely path" of the passage of a flexible endoscope that is charted on the pre-operative images. The coordinates of a plurality of points defining this "most likely path" are determined in the pre-operative image space. In some instances, the most likely path of an endoscope may include points that intersect or collide with the walls of the patient's anatomy, rather than points that follow a centerline path through the anatomy. Using mathematical predictive techniques, this "most likely path" of an endoscope can be assumed. In some embodiments, determination of the most likely path uses a predictive collision detection system that predicts an endoscope location that touches the walls of channel-like anatomy at locations with sharp curvature such as, for example, the junction between the ascending-transverse and transverse-descending colon.

[060] FIG. 3 illustrates a portion of colon 201, wherein a predicted "most likely path" of an endoscope is indicated as path 301. An endoscope 303 is shown along part of most likely path 301. Endoscope 303, as illustrated, collides with the wall of colon 201 at location 305. Rather than follow the path of centerline 211, endoscope 303 is most likely to follow path 301.

[061] In some embodiments, during operations 103 and/or 105, one or more anatomical points of interest may also be noted and their coordinates in pre-operative image space may be determined. For example, as illustrated in image 200 of FIG. 2, if the anatomy of the patient upon which the medical procedure is being performed includes colon 201, the location of ileocecal sphincter 213, appendiceal orifice 215, or other anatomical points of interest may be noted and/or their positions in the image space may be determined.

[062] In one embodiment of the invention, the patient undergoes an optical endoscopic examination or other medical procedure using traditional endoscopic techniques and/or instruments augmented with one or more sensor elements, as described herein.

[063] FIG. 4A illustrates a portion of the anatomy of a patient, including colon 201, and a system 401 for performing an image guided medical procedure. FIG. 4A illustrates candidate lesions 205a-205f and region of interest 207. Flexible endoscope 403, which is part of system 401, is shown inserted into colon 201 via orifice 405. One of ordinary skill in the art will recognize that, while the figures illustrate the invention as used in colonoscopy, these applications are illustrative only, and applications of the systems and methods described herein on other parts of the anatomy of a patient are within the scope of the invention, including those with additional, modified, and/or alternate system components. As such, flexible endoscope 403 may comprise a colonoscope, a bronchoscope, a ventricularscope, a cystoscope, a arthroscope, a duodenoscope, a colposcope, a hysteroscope, a laparoscope; a laryngoscope, a sigmoidoscope, a gastroscope, or other instrument.

[064] According to one embodiment of the invention, a position sensing system 407 is used during the endoscopic medical procedure. As such, position sensing system 407 may be located near, on, or in the patient. Position sensing system 407 is associated with its own coordinate system 409 (i.e., a frame of reference intrinsic to position sensing system 407). Position sensing system 407 is capable of determining the position and orientation of a sensor element attached to an instrument (e.g., endoscope 403) and relaying that information to an attached control unit 411. Control unit 411 may in turn be connected to a computer system 413 onto which pre-operative images, intra-operative images, other images, coordinates of the candidate lesions, centerline path points, most likely path points, regions of interest, and/or other data 417 is loaded. Computer system 413 may be associated with a display device 415, input devices (not shown), and/or other devices.

[065] In one embodiment, control unit 411 may be attached directly (e.g., via a wired connection) to a sensor element embedded in endoscope 403 or other tracked instrument. In other embodiments, control unit 411 may be in communication with the sensor element via a wireless connection. In one embodiment, the sensor element may comprise an electromagnetic sensor coil. In these embodiments position-sensing system 407 may comprise an electromagnetic position sensing system that is capable of determining the position and orientation of the electromagnetic sensor coil and/or other electromagnetic sensor coils. Other types of position sensing systems may be used.

[066] Referring back to FIG. 1, in an operation 107, the medical procedure may begin by introducing an instrument into the anatomy of the patient. For example, operation 107 may include inserting endoscope 403 into colon 201 in a manner known in the art. In some

embodiments, this can be done by inserting endoscope 403 into natural or artificially created orifice of the patient (e.g. orifice 405).

[067] In some types of standard endoscopy as known in the art, the medical procedure may include fully inserting endoscope 403 into the anatomy of interest of the patient and then slowly withdrawing it from the anatomy while observing optically in all directions. For example, in the case of colonoscopy, endoscope 403 may be fully inserted, e.g., to caecum 419 and then withdrawn while optically observing the interior of colon 201.

[068] In some embodiments, once the endoscope is fully inserted in the organ (or inserted to a desired depth), a guidewire, catheter, biopsy device, diagnostic tool or other elongated instrument 421, may be placed inside endoscope 403's working channel 423. In some embodiments, the distal end of elongated instrument 421 is moved through working channel 423 of endoscope 403 to or beyond a distal end 425 of endoscope 403. In some embodiments, elongated instrument 421 may be placed beside the optical portion of endoscope 403.

[069] In one embodiment, such as those illustrated in FIG. 4B, elongated instrument 421 may be equipped with at least one sensor element 429, which enables the determination of the position and/or the orientation (in the frame of reference 409 of position sensing system 407) of a specific part of elongated instrument 421 and therefore the part of endoscope 403 in which the specific part of elongated instrument 421 resides. In one embodiment, sensor element 429 may be placed at the tip of elongated instrument 421. For more information regarding instruments equipped with sensor elements and other information relevant to the invention, see U.S. Patent Application No. 11/471,604, entitled "System, Method and Apparatus for Navigated Therapy and Diagnosis, which is hereby incorporated by reference herein in its entirety.

[070] In some embodiments, one or more sensor elements may be embedded in or attached to endoscope 403 itself. Sensor elements embedded directly in endoscope 403 enable direct determination of the position and orientation of the tip (i.e., distal end 425) of endoscope (when at least one sensor element is located at or near the tip of the endoscope) and potentially many points along endoscope 403 (when multiple sensor elements are located along a portion of the endoscope), and thus its "shape" within the anatomy of the patient, in the frame of reference of position sensing system 407. Sensor elements in endoscope 403 may be used instead of, or in addition to, an elongated instrument 421 with one or more sensor elements included therein.

[071] In one embodiment, endoscope 403 is a flexible endoscope. For example, endoscope 403 may comprise a colonoscope or other endoscope designed to examine the digestive system. As discussed herein, other types of endoscopes may be used. In some embodiments, endoscope 403 can be replaced by an elongated member such as a catheter that contains a working channel.

[072] In some embodiments, wherein endoscope 403 and/or elongated instrument 421 is visible to an imaging modality, supplementary or "intra-operative" images of the anatomy of the patient may be taken in an operation 109, with endoscope 403 inserted. The imaging modality used may be considered a "secondary" or "intra-operative" imaging modality relative to the imaging modality used to acquire the pre-operative images, which may be considered a "primary" or pre-operative imaging modality. In some embodiments, the primary and secondary imaging modalities may be the same or similar. In some embodiments, because the relative position of the patient and the imaging modality used in imaging may differ from pre-operative imaging and intra-operative imaging, the coordinate systems of the pre-operative images and the intra-operative images may differ, even when the imaging modalities are the same.

[073] In some embodiments, as more complex imaging modalities (e.g., CT or MR scans) may be difficult or unwieldy to use during the endoscopic procedure, x-ray, fluoroscopic ultrasound, or other easier to use imaging devices may be used for intra-operative imaging. However, CT, MR, or other complex imaging may be used, nonetheless.

[074] The intra-operative imaging may be used to precisely determine the location of the actual path of endoscope 403 following insertion. For example, in one embodiment, the actual path of endoscope 403 can be obtained using two or more fluoroscopic shots taken at different angles, a CT scan, or other images taken following insertion of endoscope 403. This intra-operative imaging may also be used to determine the location of the lesions 205a-205f or other areas of interest relative to the inserted endoscope.

[075] In general, the intra-operative images may be obtained in a new coordinate system belonging to the secondary imaging modality (e.g., in a frame of reference relative to the secondary imaging modality). The actual path of endoscope 403 determined using the intra-operative images may, in one embodiment, be matched or registered to coordinate system 209 of the pre-operative images on which the candidate lesions 205a-205f or other items of interest have been annotated. For example, in one embodiment, centerline path 211 calculated above for endoscope 403 may differ from the actual path taken by inserted

endoscope 403 (i.e., the "true path" of the endoscope). The true path of endoscope 403 becomes available once the intra-operative imaging is performed and analyzed.

[076] In some embodiments it is desirable to register or match the coordinate system of position sensing system 407 to one or more of the coordinate system belonging to the primary imaging modality (e.g., coordinate system 209) and/or the coordinate system belonging to the secondary imaging modality (not illustrated). One way of facilitating this is by acquiring a plurality of points in position sensor space (i.e., coordinate system 409 – the frame of reference intrinsic to position sensing system 407) and mathematically matching them to the same points in image space of the pre-operative images (i.e., coordinate system 209 – the frame of reference of the primary imaging modality). As such, in an operation 111, data regarding a plurality of points in position sensor space may be obtained using one or more sensor elements and position sensing system 407.

[077] Acquisition of data in position sensor space can be performed by obtaining the path of endoscope 403 by, for example, sampling sensor elements placed in endoscope 403 using position sensing system 407 to determine the path of endoscope 409. Another method may involve dragging a tracked endoscope (e.g., endoscope 409) back through the anatomy of the patient (e.g., dragging it back through colon 201) or elongated instrument 421 back through working channel 423 of endoscope 403 (or the working channel of a catheter or other instrument inserted into the patient's anatomy) while position sensing system 407 gathers data points regarding the position and/or orientation of the sensor elements on the tracked instrument in coordinate system 409 of position sensing system 407. While the frame of reference/coordinate system of position sensing system 407 is referred to above as "position sensor space," this frame of reference/coordinate system may also be referred to as the "patient space." The collected data points in patient space may be used is used to register the patient space to the pre-operative image space of the primary imaging modality (pre-operative images), the intra-operative image space of the secondary imaging modality (intra-operative images), or both.

[078] In some embodiments, instead of, or in addition to, using the dragback method described above for obtaining data points in patient space, individual identifiable locations in the anatomy of the patient are sampled by touching or indicating them with the tracked instrument or endoscope. In some embodiments, a tracked instrument may be temporarily secured in endoscope 403 and not dragged through working channel 423 of endoscope 403. In some embodiments the tracked portion of the tracked instrument is placed near the distal tip 425 of endoscope 403.

[079] In some embodiments, it may be desirable to determine the contortions that endoscope 421 has undergone without the use of images. For example, a colonoscope frequently undergoes loops and other deformations that affect a medical procedure being performed using the colonocsope. Normally, it is difficult to determine these deformations without imaging. If a tracked elongated member is dragged through working channel 423 of endoscope 403, the locus of points gathered as the position of sensor elements in the tracked member are sampled prescribe a shape that is the same as the shape of endoscope 403 within the anatomy of the patient. This information may be used to assist in the medical procedure. In some embodiments, only a single sensor element attached to a slidable elongated member (e.g., a guidewire) is needed to determine this shape. In some embodiments, multiple sensor elements may be fixed or moved along endoscope 403 to determine its path. In some embodiments, motion may be compensated for by using a dynamic reference device such as, for example, a skin motion tracker, an internally-placed catheter, or other dynamic referencing device. Motion may also be compensated for using a gating device such as, for example, an ECG (electroencephalogram), a respiratory gating device, or other gating device.

[080] In an operation 113, the image space path of inserted endoscope 403 is resolved. As before, it is assumed that registration can be performed using an elongated member or other instrument and a distinction need not be made between endoscope 403 and elongated member 421 or other tracked instrument inserted within the anatomy of the patient. In one embodiment, the image space path of endoscope 403 may be "assumed" or "predicted" (i.e. based on centerline path 211 or the "most likely path" 301 calculated using the pre-operative images that were also used to identify the candidate lesions). This assumed image space path of the endoscope may be used, but lacks a direct measure of the endoscope in situ. In other embodiments, the image space path of the endoscope may be based on the actual path of the inserted endoscope observed in the intra-operative images. This "directly measured" path may require a method expressing the coordinates of this path in the same frame of reference as the candidate lesions (e.g., registering the pre-operative images to the intra-operative images).

[081] In an operation 115, the resolved image space path of endoscope 403 and the patient space path of endoscope 403 may be registered. The two paths may be matched using an iterative closest points (ICP), piecewise ICP, or similar algorithm. This enables a registration matrix (or sequence of registration matrices) to be generated. For additional information regarding registration techniques and other information relevant to the invention, see U.S. Patent Application No. 11/059,336 (U.S. Patent Publication No. 20050182319),

which is hereby incorporated by reference herein in its entirety. In some embodiments, the start and end points of the centerline locus of points may be adjusted so that the centerline points correspond better to the sampled path.

[082] In some embodiments, registration may be accomplished using other techniques as well, including the identification of "fiducials" present in both preoperative images and identified during the examination by for example touching them with a tracked instrument to determine their location in position sensor space. If at least 3 such points are co-located, a registration can be performed using techniques such as the ICP above or simpler methods such as singular valued decomposition. In some embodiments, the fiducials can be naturally occurring landmarks, such as polyps, and in other embodiments, they can be artificial landmarks such as small balls, surgical staples, specially placed needles, or other elements that may be visible in both the pre-operative images and during optical examination with the endoscope. In some embodiments, the dragback method described above may be used together with the landmark based registration or other registration methods.

[083] In some embodiments, the registration takes the form of a rigid transformation matrix. In some embodiments, the registration uses an affine transformation. In some embodiments, several matrices are used at different places. In some embodiments, weighted combinations of matrices are used.

[084] If two representations of the endoscope's path from two different coordinate systems are to resolve the image space path of endoscope 403 (e.g., an assumed path calculated using pre-operative image data and the actual path observed from the intra-operative images), the two representations themselves must first be "matched" or "registered." This registration may utilize 2D-3D or 3D-3D co-registration techniques.

[085] In some embodiments, endoscope 403 or other elongated instrument may be equipped with additional sensor elements that can act as dynamic referencing or tracking sensors, either with multiple sensor elements placed along the length of endoscope 403 or sensor elements located at the most distal end (e.g., distal end 425) of endoscope 403. These will track gross patient movement or movement the filed generator or other portion of position sensing system 207 motion as long as endoscope 403 remains stationary.

[086] In some embodiments, dynamic references (i.e., sensor elements) can be placed into additional catheters, guidewires, or instruments placed elsewhere in/on the patient that are not affected by the exam. The purpose of these sensor elements is to account for patient movement, including that occurring from respiration, or other patient movement.

[087] In some embodiments the dynamic reference may be externally applied in the form of a skin patch or skin reference in which trackable entities have been embedded. Information regarding skin patch devices that can be used as dynamic references or for other purposes in the context of the invention can be found in U.S. Patent Application No. 11/271,899 (U.S. Patent Publication No. 20060173269), entitled "Integrated Skin-Mounted Multifunction Device For Use in Image-Guided Surgery," which is hereby incorporated by reference herein in its entirety.

[088] In some embodiments the dynamic reference may be internally applied using needles, catheters, guidewires, or other instruments. In some embodiments, if, for example, skin patch fiducials or internal fiducials are applied to the patient anatomy prior to obtaining the pre-operative images, the fiducials may be used as a "start point" for registration calculations that may ordinarily take an extended amount of time to perform without a reasonable guess of the correct transformation matrix. This is accomplished by the skin patch, fiducials, or other registration objects having features that are visible in the preoperative scan, where the locations of these features are known relative to any sensor elements used for dynamic referencing. Such features can take the form of pathways (i.e. 2D or 3D shapes made from continuous paths or shapes of an imagable material) or as fiducial clusters.

[089] In some embodiments, the skin patch reference (if used) may contain applied directional markings (e.g. printed on the surface of the skin patch reference). These directional markings may point, for example, toward the patient's left, right, head, and/or toe. The positioning of these marks is used as a patient-centric reference system. The patient-centric reference system is used to reorient a display of the patient's anatomy being explored so as to assist the hand-eye coordination of the surgeon such that the tools moved on the display move according to the expectations of the surgeon. In some forms of the display, displayed tools may move in a non-intuitive way unless the display is rotated into the patient-centric coordinate system.

[090] In an operation 117, once registration has been performed, the invention may include a display and navigation step in which endoscope 403 is tracked in an attempt to locate the suspect lesions with the assistance of the position sensor. In one embodiment, this is facilitated by "parking" a tracked instrument (e.g., elongated instrument 421) at the end of endoscope 403's working channel (once any drag-back sampling or other registration sampling that is required has been performed). In one embodiment, endoscope 403 itself may also be tracked using sensor elements attached to or integrated into endoscope 403, as

described herein. In one embodiment, an instrument can be inserted into the working channel 423 of endoscope 403, and thus made to assume the shape of working channel 423. This instrument is then made to become rigid in the shape of endoscope 403 (e.g., through tensioning of a cable such as, for example, that used in a "Greenberg Arm," or other methods known in the art) and endoscope 403 is slid, along the instrument, retracing the known path of the rigid path. Alternatively, this type of instrument can be placed into the anatomy prior to the registration and used as a guide for insertion of endoscope 403.

[091] As endoscope 403 and/or tracked instrument 421 (if used as the means to track the endoscope) is moved through the anatomy to inspect its interior, the position of endoscope 403 and/or tracked instrument 421 may be sampled in the reference frame of position sensing system 407. The locations and orientations determined by position sensing system 407 are converted for the display of the patient's anatomy by applying the registration transformation(s). The location of endoscope 403 may then be indicated on the display. In some embodiments, the display may be based on one or both of the pre-operative or intra-operative images of the patient's anatomy. Displays may include, for example, multiplanar reformats, oblique reformatted views, 3D views, 3D perspective views, simplified graphical "cockpit" style views, simplified maps, or other views. Whenever one of the flagged locations (i.e., lesions or other items of interest) is in the proximity of the tracked portion of endoscope 403 or other instrument, the physician may be notified or he or she will be able to determine from the images that he or she is in proximity of the suspect lesion and can look for it.

[092] In an operation 119, one or more of lesions 205a-205f or other items of interest can then be destroyed, biopsied, or otherwise treated, if detected. In one embodiment, tracked elongated instrument 421 (if used in addition to endoscope 403) can be removed from working channel 423 of endoscope 403, and a biopsy, resection, or other treatment or detection device can be introduced into working channel 423 of endoscope 403 (as the suspect will likely be directly visible). Once investigated or treated, the tracked elongated instrument 421 can be reintroduced into working channel 423 of endoscope 403 and again parked at the end of endoscope 403. In some embodiments, there may be enough space for both tracked elongated instrument 421 and the treatment instrument. In some embodiments, the treatment instrument itself may be tracked.

[093] In some embodiments, a tracked treatment instrument may be introduced percutaneously or through an organ wall to perform a biopsy, treatment, resection, or other treatment. In this way, for example, an ablation or biopsy can be performed using a second

instrument. The second instrument can be operable either with visual guidance or it can be positioned completely using the electromagnetic guidance described herein. In some embodiments, an imaging device such as a tracked endoscopic ultrasound can be inserted into endoscope 403 to provide additional views. By facilitating percutaneous treatment, candidate lesions on the exterior of an organ being investigated can be accessed, which may not be normally visible internally.

[094] In some embodiments, a device containing trackable sensor elements is not used in conjunction with the endoscope. Instead, the device is used "blind", or for registration only. For example, a steerable catheter might be inserted into colon 201. FIGS. 5A and 5B illustrate an example of a steerable catheter 500 that may be used according to one embodiment of the invention. Steerable catheter 500 may include a deflectable portion 501 with a steerable tip 503. In some embodiments, steerable catheter 500 may include a handle 505 with at least one deflection control knob or other deflection control device 507. The shaft of steerable catheter 500 may include multiple lumens populated by different devices, including a magnetic sensor element 509 with associated lead-wires 511 that exits catheter 500 and is connected to a control unit, in some embodiments.

[095] Section A-A details an embodiment of catheter 500 shown in cross-section. The elongated body of steerable catheter 500 may comprise a tube 513, which may be formed of any relatively soft elastomeric material 515 (e.g., braid reinforced Fluorinated Ethylene Propylene [FEP or Teflon®], polytetrafluoroethylene [PTFE], polyether block amides such as, for example, Pebax® or other material, some of which may be reinforced or include features to render them visible in the imaging modality). Lumens within the tube may include one or more steering wire channels such as channels 517 or 519, a working channel 521, and a channel 523 for a magnetic sensor element (e.g., element 509).

[096] Other "blind" devices may include needles with tip tracking, graspers, steerable forceps, or other elements. When used, the "blind" device is positioned to targets within the anatomy entirely using position sensing system 407 and the display.

[097] In some embodiments, the invention provides for registration-free navigation of an endoscope. In registration–free navigation, sensor elements on a tracked guidewire or other tracked device act simply as a distance measurement device to determine the location of an endoscope relative to a known location. In this embodiment, the relative location of all suspect lesions are calculated relative to each other and landmarks within the anatomy. As each is examined, the location is stored and the distance to the next location of interest is calculated. In this way, the system is self-correcting at each identified location along the path

of the endoscope as it is removed. This method may not require registration to be performed prior to use.

[098] FIG. 6 illustrates a process 600, an example of a process for registration-free navigation. In an operation 601, pre-operative images of the anatomy of interest (e.g., colon 201) may be obtained. FIG. 7 an example wherein suspect lesions 701a-701f may be flagged on pre-operative images of colon 201 during a "virtual colonoscopy." This flagging/identification may take place in an operation 603 an may be performed by physician, a computer program, or both. The flagging/identification of operation 603 may include calculating the locations of the flagged suspect lesions 701a-701f in a coordinate system 703, which is a frame of reference intrinsic to the pre-operative images.

[099] In an operation 605, the endoscope is inserted into colon 201. In an operation 607, a reference point 705 within colon 201 is identified (for example, the ileocecal sphincter or appendiceal orifice). In an operation 609, the path length of each of the suspect lesions 701a-701f is identified relative to reference point 705 location along centerline 211 of colon 201. For example, for a lesion 701a, path 707a is the length of the distance along centerline 211 between reference point 705 (e.g., the appeniceal orifice) and suspect lesion 701a. Likewise, path 709 is the length of the distance along centerline 211 between reference point 705 (e.g., the appeniceal orifice) and suspect lesion 701b. Thus by dragging the endoscope back and calculating the distance traversed by the sensor attached to the endoscope, the location of the each next suspect lesion can be determined.

[0100] In one embodiment, once the first lesion (i.e., 701a) is encountered, the locations of the next lesions (i.e., 701b-701f) may be calculated relative to it. For example, suspect lesion 701b can be estimated to be located a distance 707b from suspect lesion 701a (or equivalently a distance 709 from reference point 705). In general it may be more accurate to estimate the inter-lesion distances (i.e. 707c, 707d, 707e, 707f), rather than the distance between reference point 705 each successive lesion.

[0101] In one embodiment, the physician indicates each lesion 701 as it is encountered and in one embodiment, the lesions 707 and other landmarks are weighted according to their distance from reference point 705. As each lesion is encountered, the expected distance to the next lesions is known from the pre-operative images, since an estimate of that distance is available from the images. Once the first lesion 701a or reference point 705 is located, the endoscope is positioned at the next location (e.g., the next lesion – 701b) according to the distance determined from the pre-operative images (distance 707b from lesion 701a or distance 709 from reference point 705). The distance that the endoscope is moved from one

lesion to the next is obtained from the sensor elements in the endoscope. By measuring the distance that the endoscope or a tracked instrument in the endoscope moved from a first lesion to a second lesion, the location of the second lesion can therefore be estimated from the pre-operative image estimates without the need for registration.

[0102] In one embodiment, these measured distances are augmented using shape information regarding the endoscope or other instrument, as may be determined using a path determination method such as those described herein. This shape information may be helpful in more accurately determining the location of an area of interest. In one embodiment, the suspect lesions can be used to perform a registration. As each lesion is encountered, its position is sampled using a tracked instrument and used to calculate a transformation matrix. In some embodiments, only the nearest candidate lesions to the immediate endoscope location can be used to calculate a local registration, since they are most representative of the local anatomy.

[0103] In one embodiment, at least one of the one or more points of interest (e.g., location of lesions, polyps, or other points of interest) within the anatomy of the patient that are identified in image space, may be sampled in patient space and used for registration of patient space coordinates to image space coordinates. The locations of these points of interest may be used bootstrap the registration, thereby enabling the system of the invention to display the location of subsequent points of interest not used in the registration (e.g., obtain position/location of a first few lesions/polyps for registration, after which it becomes "automatic" to locate other lesions/polyps due to the fact that the registration has been performed). As such, the system will automatically display the location of a tracked medical instrument relative to the items of interest whose location has been sampled as well as the items of interest whose location has not been sampled. In one embodiment, the points of interest used to register patient space to image space may be weighted relative to any points of interest whose location is not sampled and used in a registration.

[0104] In one embodiment, the invention provides a system for performing and/or assisting in image-guided medical endoscopic medical procedures. FIG 4 illustrates a system 401, which is an example of a system for performing and/or assisting in image-guided medical endoscopic medical procedures. In one embodiment, system 401 may comprise control unit 411, a control application 427, a tracked medical instrument (e.g., endoscope 403), position sensing system 407, display device 415, and/or other elements.

[0105] In one embodiment, control unit 411 may be operatively connected to or include one or more special purpose or general purpose computers 413 and/or other devices having

processors cable of responding to and executing instructions in a defined manner. Control unit 411 and/or computer system 413 may include, be associated with, and/or be in operative communication with a memory device that stores any data necessary for the performing the features or functions of the invention such as, for example, image data, position data, orientation data, coordinate data, transformation matrices, and/or other data (e.g., data 417). Control unit 411 and/or computer system 413 may also include, run, and/or support control application 427 comprising one or more software modules for directing and performing one or more data reception, transmission, data processing, and/or other data manipulation operations according to the features and functions of the invention. Other software modules supporting or enabling the various features and functions of the invention may be used.

[0106] In some embodiments, the tracked medical instrument may include endoscope 403 that is equipped with at least one working channel, optics for viewing the anatomy present at the distal tip of the endoscope, one or more trackable sensor elements, and/or other elements. The position and/or orientation of the one or more sensor elements may be determined/monitored by position sensing system 407. Position sensing system 407 may be in communication with control unit 411 and/or computer system 413 and may provide sampled position coordinates and orientation information of the one or more sensor elements to control unit 411 and/or computer system 413. An example of position sensing system 407 includes an electromagnetic position sensing system used with electromagnetic sensor elements.

[0107] In some embodiments, the tracked medical instrument may include an untracked endoscope or other instrument used in conjunction with a tracked catheter, tracked guidewire, tracked treatment device, and/or other tracked instrument (e.g., elongated instrument 421). In some embodiments, system 401 may not include an endoscope, but may include one or more tracked devices that do not include the optics typically associated with an endoscope.

[0108] The system of the invention may also include display device 415 that displays images used in the system and methods of the invention such as, pre-operative images of the anatomy of a patient (including one or more items of interest), intra-operative images of the anatomy of the patient (including an inserted medical instrument and the one or more items of interest), real-time or near-real-time images displaying motion of the tracked instrument relative to the one or more items of interest within the anatomy of the patient, and/or other images or data. In some embodiments, display device 415 may include a computer monitor, a television monitor, a touch screen, a cathode-ray tube, an LCD display device, and/or other display device.

[0109] In some embodiments, system 401 may include other elements (e.g., input/output ports, additional devices, additional modules/software). Those having skill in the art will appreciate that the invention described herein may work with various system configurations. Accordingly, more or less of the aforementioned system components may be used and/or combined in various embodiments. Accordingly, more or less of the aforementioned operations of the methods and processes of the invention may be used, and/or may be performed in varying orders. As would also be appreciated, the functionalities described herein may be implemented in various combinations of hardware and/or firmware, in addition to, or instead of, software.

[0110] Other embodiments, uses and advantages of the invention will be apparent to those skilled in the art from consideration of the specification and practice of the invention disclosed herein. The specification should be considered exemplary only, and the scope of the invention is accordingly intended to be limited only by the following claims.

CLAIMS

I claim:

1. A method for assisting an image-guided medical procedure relating to one or more items of interest within an anatomy of a patient, the method comprising:

receiving one or more preoperative images of the anatomy of the patient;

determining image-space coordinates of the one or more items of interest in a frame of reference of the one or more preoperative images;

determining pre-operative image-space coordinates of a predicted path of a medical instrument within the anatomy of the patient in the frame of reference of the one or more preoperative images;

obtaining patient-space coordinates of an actual path of the medical instrument within the anatomy of the patient in a frame of reference of a position sensing system associated with one or more sensor elements within the anatomy of the patient;

registering the pre-operative image space coordinates of the predicted path of the medical instrument with the patient space coordinates of the actual path of the medical instrument to produce at least one transformation matrix relating the frame of reference of the one or more pre-operative images to the frame of reference of the position sensing system; and

creating a display indicating relative locations of the medical instrument and the one or more items of interest using the at least one transformation matrix.

2. The method of claim 1, wherein the pre-operative image space coordinates of the predicted path of the medical instrument are obtained by assuming a calculated centerline of a conduit within the anatomy of the patient.

3. The method of claim 1, wherein the pre-operative image space coordinates of the predicted path of the medical instrument are obtained by calculating a most-likely path of the endoscope based on assumed collisions with interior walls of a conduit within the anatomy of the patient.

4. The method of claim 1, wherein determining image-space coordinates of the one or more items of interest further comprises using one or more of a computer program and a human operator.

5. The method of claim 1, wherein the one or more items of interest include one or more of a lesion, a polyp, a preoperatively applied fiducial marking, a known tumor, a suspected tumor, a mass, an organ, an osteophyte, a billiary stone, an identifiable hard tissue

structures, an identifiable soft tissue structure, an orifice, a junction, a sphincter, a branch point, a tissue transition, a foreign body, and a necrotic zone.

6. The method of claim 1, wherein the medical instrument comprises an endoscope.

7. The method of claim 6, wherein the endoscope further comprises one of a colonoscope, a bronchoscope, a ventricularscope, a cystoscope, a arthroscope, a duodenoscope, a colposcope, a hysteroscope, a laparoscope; a laryngoscope, a sigmoidoscope, or a gastroscope.

8. The method of claim 6, where the endoscope comprises a flexible endoscope.

9. The method of claim 1, wherein the position sensing system comprises one of one an electromagnetic position sensing system, a fiber-optic position sensing system, a GPS positioning system, or an optical position sensing system.

10. The method of claim 1, wherein the one or more sensor elements comprises one of one or more electromagnetic sensor coils, one or more fiber-optic sensor elements, and one or more optical sensor elements.

11. The method of claim 1, wherein registering the pre-operative image space coordinates of the predicted path of the medical instrument with the patient space coordinates of the actual path of the medical instrument further comprises using one or more of a drag-back registration, a point to point registration, a combined registration, and a surface registration.

12. The method of claim 1, wherein registering the pre-operative image space coordinates of the predicted path of the medical instrument with the patient space coordinates of the actual path of the medical instrument further comprises matching, using a mathematical algorithm, the pre-operative image-space coordinates of the predicted path of the instrument with the patient-space coordinates of the actual path of the medical instrument.

13. The method of claim 12, wherein the mathematical algorithm is an iterative closest points (ICP) algorithm.

14. The method of claim 1, wherein the patient-space coordinates are obtained by sampling the position of the one or more sensor elements located on the instrument while the instrument is moved within the anatomy of the patient.

15. The method of claim 1, further comprising:

receiving one or more intra-operative images of the anatomy of the patient;

determining intra-operative image-space coordinates of an actual path of a medical instrument within the anatomy of the patient in the frame of reference of the one or more intra-operative images; and

registering the pre-operative image-space coordinates of the predicted path of the medical instrument with the intra-operative image space coordinates of the actual path of the medical instrument to produce combined image-space coordinates of a path of the medical instrument within the anatomy of the patient,

wherein registering the pre-operative image space coordinates of the predicted path of the medical instrument with the patient space coordinates of the actual path of the medical instrument further comprises matching, using a mathematical algorithm, the combined image-space coordinates of the path of the medical instrument with the patient-space coordinates of the actual path of the medical instrument, and wherein the at least one transformation matrix relates a combined frame of reference of both the one or more pre-operative images and the one or more intra-operative images to the frame of reference of the position sensing system.

16. The method of claim 15, wherein registering the pre-operative image-space coordinates of the predicted path of the medical instrument with the intra-operative image space coordinates of the actual path of the medical instrument comprises one of a 2D-3D or 3D-3D registration.

17. The method of claim 1, wherein the display includes one or more of multi-planar reformats, oblique reformatted views, 3D views, 3D perspective views, simplified graphical cockpit-style views, targeting displays, and simplified maps.

18. The method of claim 1, wherein registering the pre-operative image space coordinates of the predicted path of the medical instrument with the patient space coordinates of the actual path of the medical instrument further comprises using an externally placed device is used to begin the registration and to dynamically reference the anatomy of the patient.

19. The method of claim 18, wherein the externally placed device includes marks to indicate placement in a cranial-caudal and anterior-posterior to facilitate manipulation of instruments.

20. A method for assisting an image-guided medical procedure relating to a plurality of items of interest within an anatomy of a patient, the method comprising:

receiving one or more preoperative images of the anatomy of the patient;

determining pre-operative image-space coordinates of the one or more items of interest in a frame of reference of the one or more preoperative images;

obtaining patient-space coordinates of the actual path of the medical instrument within the anatomy of the patient in a frame of reference of a position sensing system associated with one or more sensor elements within the anatomy of the patient;

creating a display indicating relative locations of the medical instrument and the one or more items of interest;

measuring, in the frame of reference of the position sensing system, a sensor distance traversed by the medical instrument from a first item of the plurality of items of interest within the anatomy of the patient to a second item of the plurality of items of interest within the anatomy of the patient.

measuring, in the frame of reference of the one or more preoperative images, an image distance between the first item and the second item;

providing an indication when the sensor distance and the image distance differ by less than a predetermined amount.

21. The method of claim 20, wherein the sensor distance is measured by assuming a centerline of a conduit within the anatomy of the patient between the first item and the second item within the anatomy of the patient.

22. A system for assisting an image-guided medical procedure relating one or more points of interest within an anatomy of a patient, the system comprising:

a memory device that receives one or more preoperative images of the anatomy of the patient;

a tracked instrument that includes one or more sensor elements associated with a position sensing system, wherein the tracked instrument provides patient space coordinates of the path of the tracked instrument within the anatomy of the patient in a frame of reference of the position sensing system;

a control application that determines image-space coordinates of the one or more items of interest in a frame of reference of the one or more preoperative images and that determines pre-operative image-space coordinates of a predicted path of the tracked instrument within the anatomy of the patient in the frame of reference of the one or more preoperative images;

wherein the control application registers the pre-operative image space coordinates of the predicted path of the tracked instrument with the patient space coordinates of the path of the tracked instrument to produce at least one transformation matrix relating the frame of reference of the one or more preoperative images to the frame of reference of the position sensing system; and a display module that creates a display indicating the relative locations of the instrument and the one or more points of interest using the at least one transformation matrix.

23. A method of determining the shape of a flexible endoscope inserted into a portion of an anatomy of a patient, comprising:

inserting the flexible endoscope into the portion of the anatomy of the patient, wherein the endoscope includes at least one working channel;

inserting a tracked elongated member into the working channel of the flexible endoscope, wherein the tracked elongated member is equipped with at least one sensor element whose position and orientation is tracked by a position sensing system;

recording a locus of positions of the at least one sensor elements as the tracked elongated member is moved within the working channel of the flexible endoscope;

determining the path of the flexible endoscope inserted into the portion of the anatomy of the patient using the locus of positions.

24. The method of claim 24, wherein motion of the portion of the anatomy of the patient is measured and accounted for using one or more of a cardiac gating device, a respiratory gating device, an externally placed motion tracking device, and in internally placed motion tracking device.

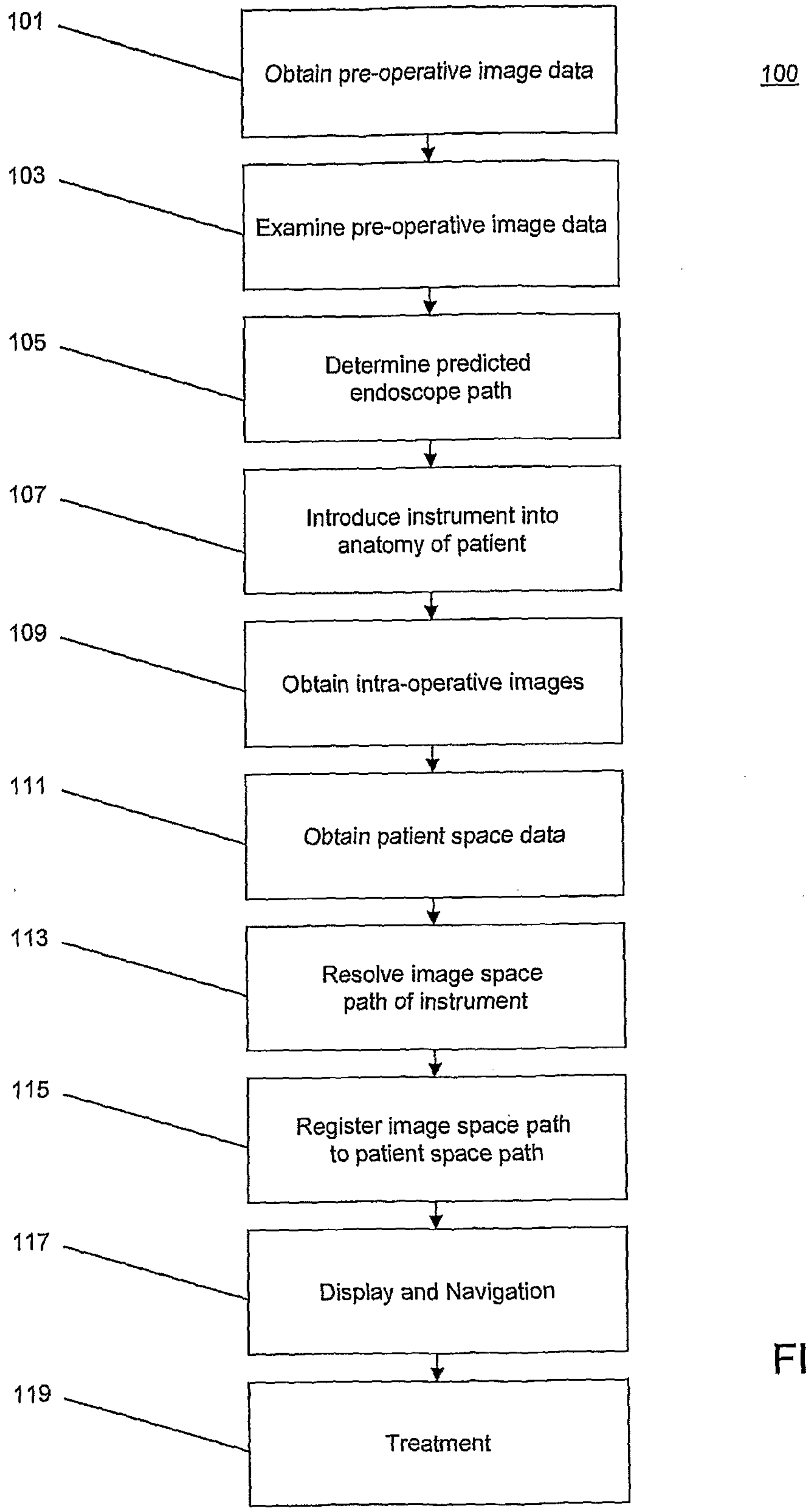

101
Obtain pre-operative image data
100
103
Examine pre-operative image data
105
Determine predicted endoscope path
107
Introduce instrument into anatomy of patient
109
Obtain intra-operative images
111
Obtain patient space data
113
Resolve image space path of instrument
115
Register image space path to patient space path
117
Display and Navigation
119
Treatment

FIG. 1

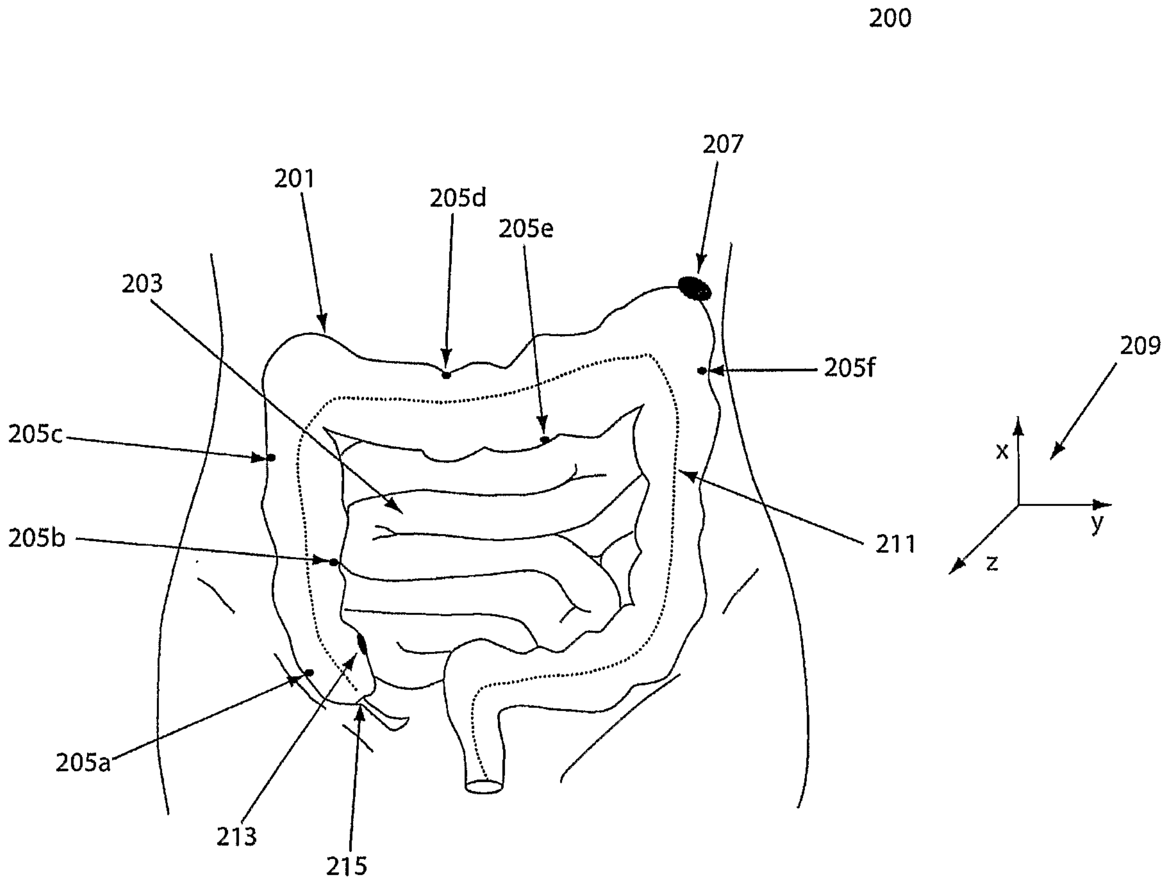

200
207
201
205d
205e
203
209
205f
205c
x
y
z
211
205b
205a
213
215

Fig. 2

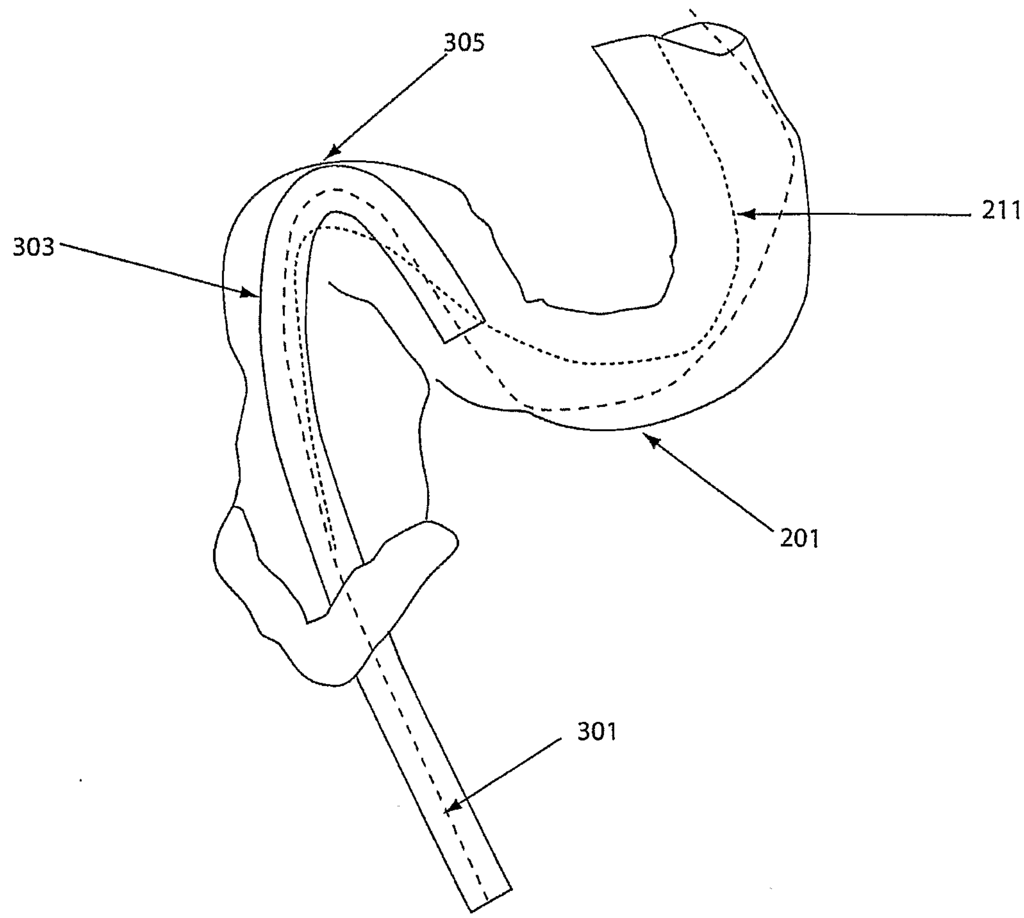


Fig. 3

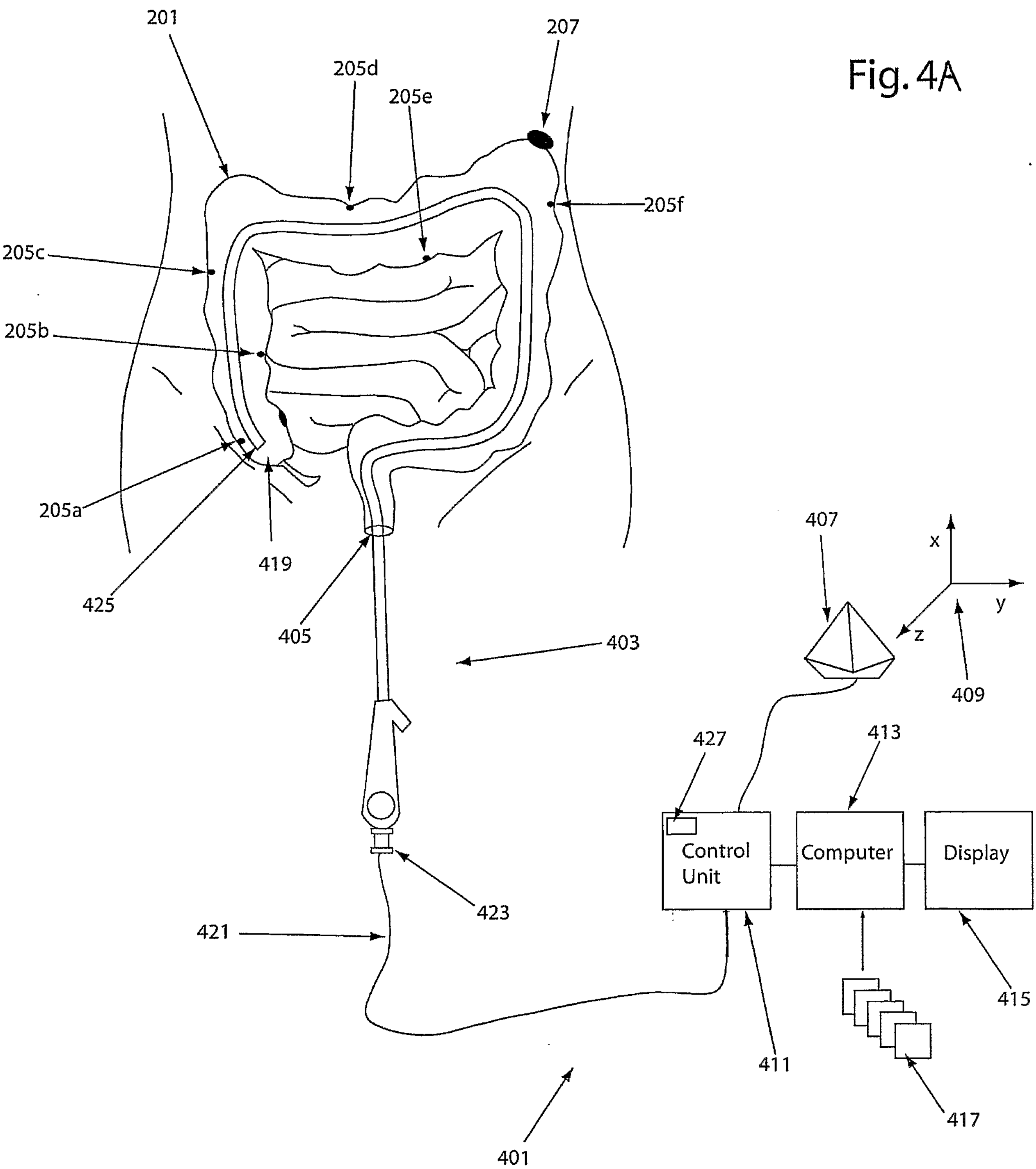

201
207
205d
205e
205f
205c
205b
205a
419
425
405
403
407
x
y
z
409
427
413
Control Unit
Computer
Display
423
421
411
415
417
401

Fig. 4A

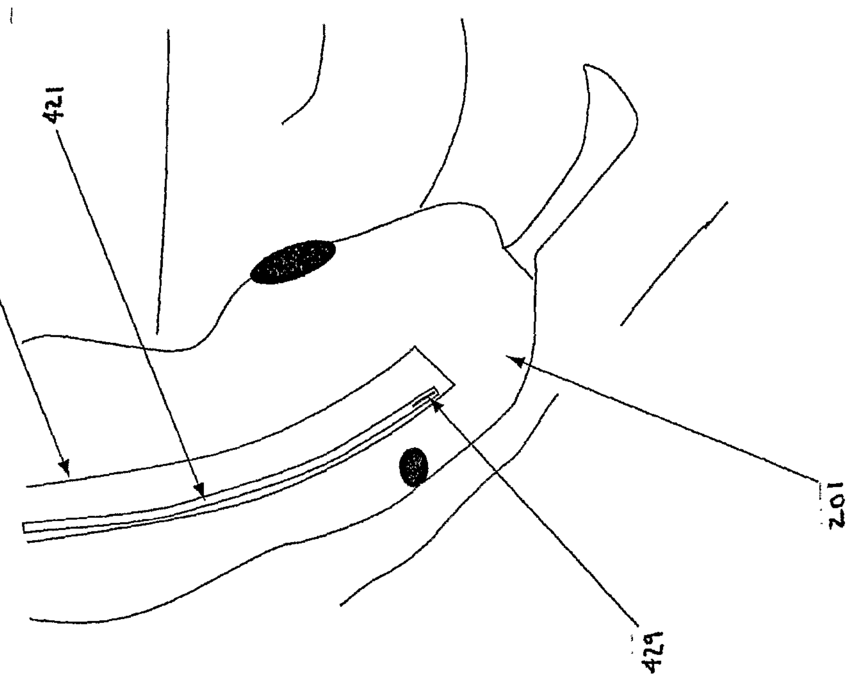


Fig 4B

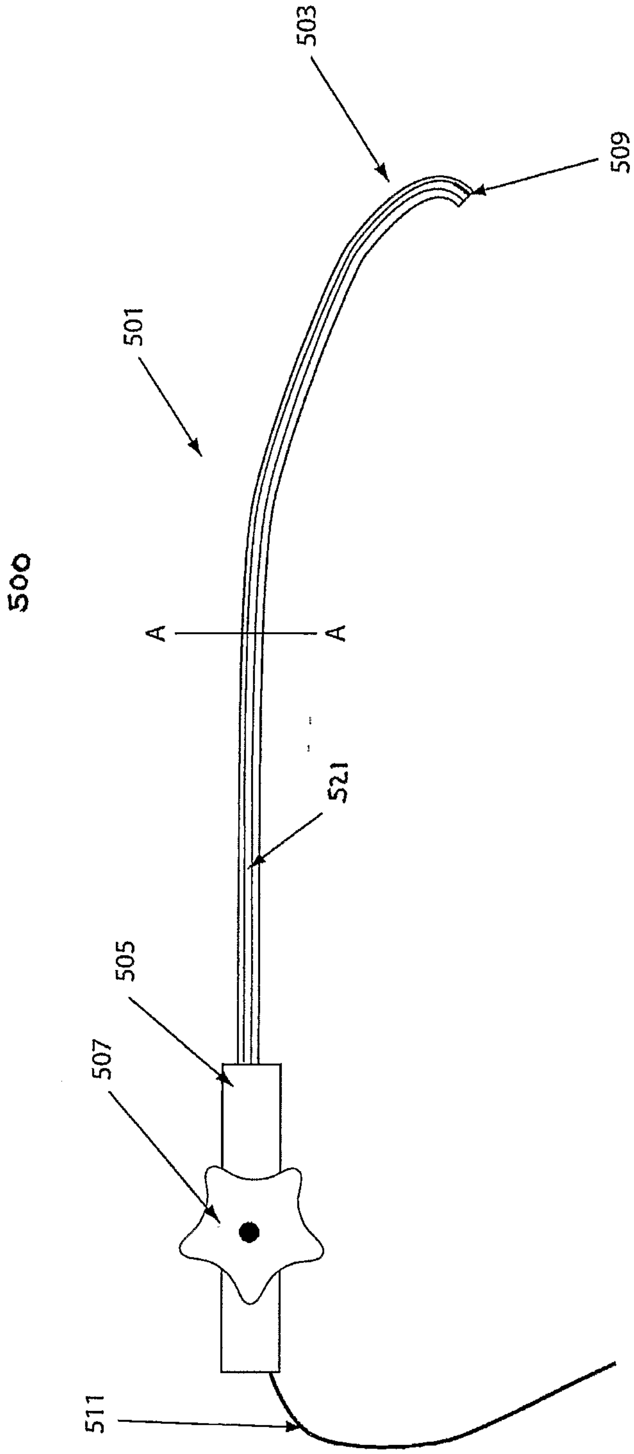
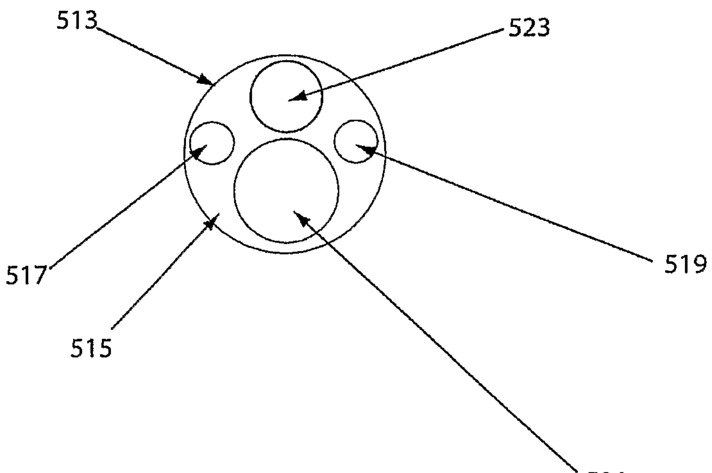


Fig 5A

500



Sec A-A

Fig 5B

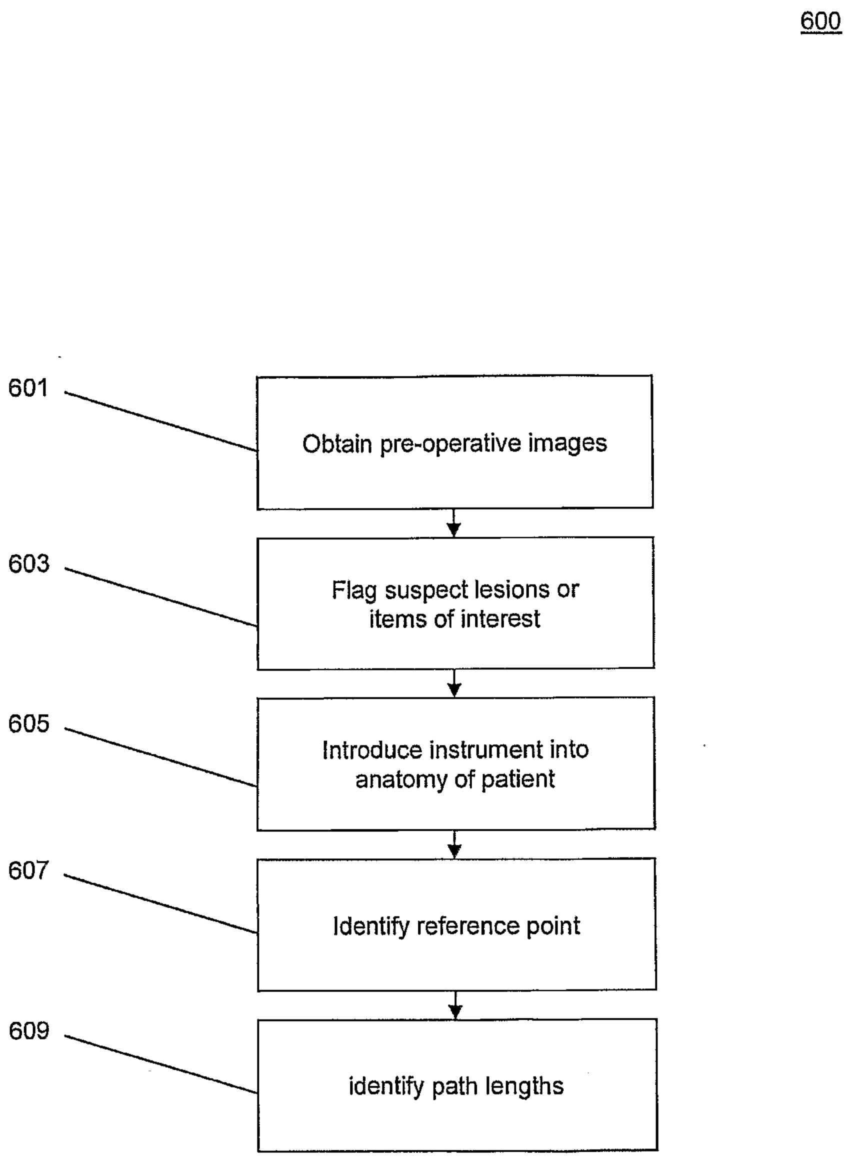

600
601
Obtain pre-operative images
603
Flag suspect lesions or items of interest
605
Introduce instrument into anatomy of patient
607
Identify reference point
609
identify path lengths

FIG. 6

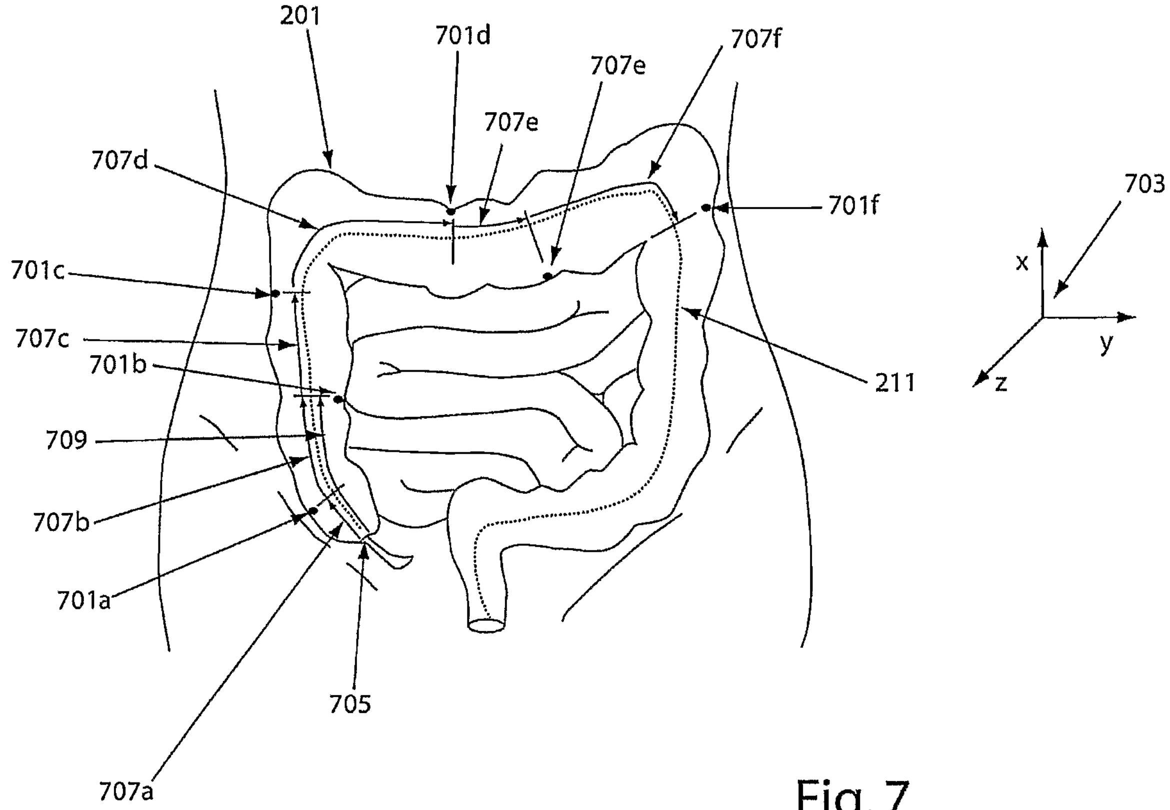

201
701d
707f
707e
707e
707d
701f
703
701c
x
707c
y
701b
211
z
709
707b
701a
705
707a

Fig. 7

专利名称(译)	用于导航柔性内窥镜检查的系统，方法和设备		
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[标]发明人	GLOSSOP NEIL DAVID		
发明人	GLOSSOP, NEIL, DAVID		
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其他公开文献	EP1924197A4 EP1924197B1		
外部链接	[Espacenet](#)		

摘要(译)

本发明提供了一种用于执行图像引导的内窥镜医疗程序的方法和系统。本发明可以包括将患者的解剖结构内的医疗器械的路径的图像空间坐标登记到患者的解剖结构内的医疗器械的路径的患者 - 空间坐标。在一些实施例中，医疗器械的路径的图像空间坐标可以是预测的坐标，例如，通过导管样器官计算的中心线，或者解剖学内的医疗器械的计算的“最可能的路径”。病人在其他实施例中，医疗器械的路径可以是使用插入其中的医疗器械的患者解剖结构的术中图像确定的实际路径。然后可以将注册的仪器导航到一个或多个感兴趣的项目以执行内窥镜医疗程序。