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(54) **Title:** SYSTEMS AND METHODS FOR REAL-TIME REPORTS RELATING TO ESOPHAGEAL MEASUREMENTS

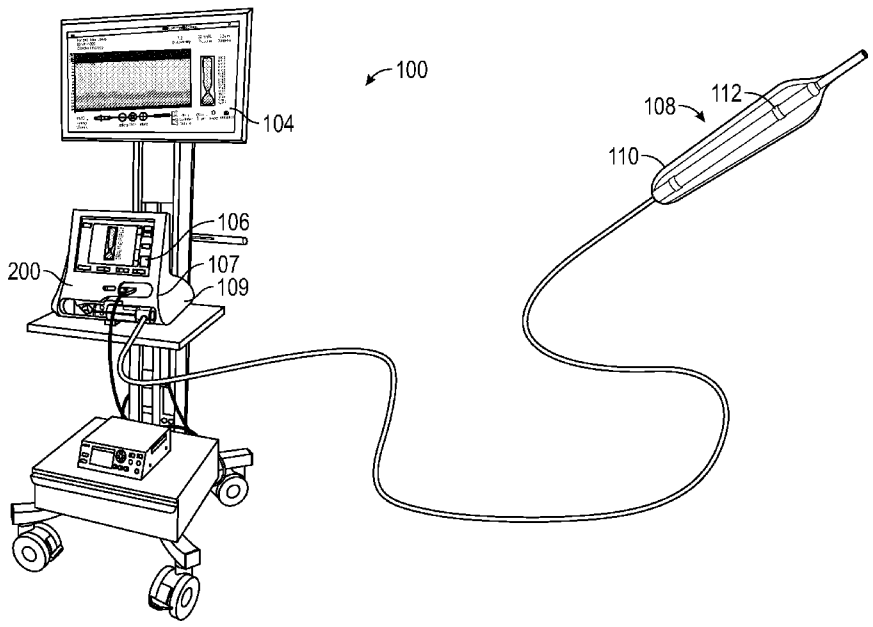


FIG. 1

(57) **Abstract:** A method for annotating an image stream in real-time during a procedure to assess motility function of a patient's body lumen, includes: receiving pressure measurements from a catheter positioned in a body lumen of a patient; generating real-time image data of the body lumen based on the received pressure measurements; generating a stream of images based on the generated real-time image data; displaying in real-time the stream of images on a display; receiving, via a user interface, an annotation from a user corresponding to one or more images of the stream of images; storing the annotation, associating the stored annotation with the one or more images of the stream of images as one or more annotated images; and displaying, on the display, a report including the received pressure measurements, and at least one of the one or more annotated images.

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SYSTEMS AND METHODS FOR REAL-TIME REPORTS RELATING TO ESOPHAGEAL MEASUREMENTS

CROSS-REFERENCE TO RELATED APPLICATION

[0001] The present application claims the benefit of and priority to U.S. Provisional Patent Application Serial No. 63/073,067, filed on September 1, 2020, the entire content of which being hereby incorporated by reference.

FIELD

[0002] This disclosure relates generally to surgical systems, and more particularly, to systems and methods for creating real-time reports during a procedure to assess motility function of a patient's body lumen.

BACKGROUND

[0003] The esophagus is a tubular organ that carries food and liquid from the throat to the stomach. Accurate measurements of physiological parameters of the esophagus under realistic swallowing conditions are valuable in diagnosing esophageal diseases such as achalasia, dysphagia, diffuse esophageal spasm, ineffective esophageal motility, and hypertensive lower esophageal sphincter (LES). When a person with a healthy esophagus swallows, circular muscles in the esophagus contract. The contractions begin at the upper end of the esophagus and propagate downwardly toward the lower esophageal sphincter (LES). The function of the peristaltic muscle contractions, i.e., to propel food and drinks through the esophagus to the stomach, is sometimes called the motility function, but is also often referred to as peristalsis.

[0004] Esophageal manometry, in particular, is a test used to assess pressure and motor function of the esophagus, allowing physicians to evaluate how well the muscles in the esophagus work to transport liquids or food from the mouth into the stomach. Snapshots are captured during a procedure, and a report is written at the end of the day in the clinician's office. Time separating the procedure from the report makes the preparing of the report less efficient as imaging may need to be reviewed all over again. Thus, a continuing need exists for creating a report in real-time during a manometry procedure to assess motility function of a patient's esophagus or other body lumen.

SUMMARY

[0005] In accordance with the disclosure, a method for annotating an image stream in real-time during a procedure to assess motility function of a patient's body lumen, includes receiving pressure measurements from a catheter positioned in a body lumen of a patient, generating real-time image data of the body lumen based on the received pressure measurements, generating a stream of images based on the generated real-time image data, displaying the stream of images in real-time on a display, receiving, via a user interface, an annotation from a user corresponding to one or more images of the stream of images, storing the annotation, associating the stored annotation with the one or more images of the stream of images as one or more annotated images, and displaying, on the display, a report including the received pressure measurements and at least one of the one or more annotated images.

[0006] In an aspect, the method may further include inflating a balloon disposed on the catheter within the body lumen to a predetermined inflation volume. The pressure measurements may be received in response to inflation of the balloon.

[0007] In another aspect, the method may further include displaying the inflation volume on the report.

[0008] In an aspect, the method may further include displaying, for each of the one or more annotated images, at least one thumbnail image of the annotated image.

[0009] In another aspect, the one or more annotated images may include a diameter measurement of the body lumen.

[0010] In yet another aspect, the body lumen may include a pharynx, an esophagus, a proximal gut, an anus, and/or a rectum.

[0011] In still yet another aspect, the method may further include receiving, via the user interface, an input that causes an image of the stream of images to be captured and an annotation window to be displayed for receiving the annotation from the user corresponding to the captured image.

[0012] In still yet another aspect, an annotation window includes a predetermined set of annotations.

[0013] In still yet another aspect, the user interface may include a touch screen, a microphone, a keyboard, and/or a mouse.

[0014] In another aspect, storing the annotation may include storing the annotation in a database or storing the annotation as metadata in the one and/or more images of the stream of images.

[0015] In accordance with aspects of the disclosure, a manometry system includes a manometric balloon catheter configured to capture real-time diameter measurements in a body lumen of a patient, a user interface, a display, a processor, and a memory. The memory includes instructions stored thereon, which when executed by the processor, cause the manometry system to: receive pressure measurements from the manometric balloon catheter positioned in a body lumen of a patient; generate real-time image data of the body lumen based on the received pressure measurements; generate a stream of images based on the generated real-time image data, display in real-time, on the display, the generated stream of images; receive, via the user interface, an annotation from a user corresponding to one or more images of the stream of images; store the annotation, associate the stored annotation with the one or more images of the stream of images as one or more annotated images; and display, on the display, a report including the received pressure measurements and at least one of the one or more annotated images.

[0016] In an aspect, the instructions, when executed by the processor, may further cause the manometry system to inflate a balloon disposed on the balloon catheter within the body lumen to a predetermined volume. The pressure measurements may be received in response to inflation of the balloon.

[0017] In another aspect, the instructions, when executed by the processor, may further cause the manometry system to display an inflation volume on the report.

[0018] In yet another aspect, the instructions, when executed by the processor, may further cause the manometry system to display, for each of the one or more annotated images, at least one thumbnail image of the annotated image.

[0019] In still yet another aspect, the one or more annotated images may include a diameter measurement of the body lumen.

[0020] In another aspect, the body lumen may include a pharynx, an esophagus, a proximal gut, an anus, and/or a rectum.

[0021] In yet another aspect, the instructions, when executed by the processor, may further cause the manometry system to receive, via the user interface, an input that causes an image of the

stream of images to be captured and an annotation window to be displayed for receiving the annotation from the user corresponding to the captured image.

[0022] In still yet another aspect, the annotation window includes a predetermined set of annotations selectable by the user.

[0023] In still yet another aspect, the user interface may include a touch screen, a microphone, a keyboard, and/or a mouse.

[0024] In accordance with other aspects of the disclosure, a non-transitory computer-readable storage medium stores a program for causing a processor to execute a method for annotating an image stream in real-time during a procedure to assess motility function of a patient's body lumen. The method includes: receiving pressure measurements from a catheter positioned in a body lumen of a patient; generating real-time image data of the body lumen based on the received pressure measurements; generating a stream of images based on the received real-time image data; displaying in real-time, on a display, the generated stream of images; receiving, via a user interface, an annotation from a user corresponding to one or more images of the stream of images; storing the annotation; associating the stored annotation with the one or more images of the stream of images as one or more annotated images; and displaying, on the display, a report including the received pressure measurements and at least one of the one or more annotated images.

BRIEF DESCRIPTION OF DRAWINGS

[0025] Various aspects of the disclosure are described herein with reference to the drawings wherein:

[0026] FIG. 1 is an illustration of a manometry system in accordance with the disclosure;

[0027] FIG. 2 is a block diagram of a controller provided in accordance with the disclosure and configured for use with the manometry system of FIG. 1;

[0028] FIG. 3 is an illustration of an interface showing an image captured by the manometry system of FIG.1 in accordance with the disclosure;

[0029] FIG. 4 is an illustration of an annotation entry screen configured for use with the manometry system of FIG.1 in accordance with the disclosure;

[0030] FIG. 5 is an illustration of a report generated by the manometry system of FIG.1 in accordance with the disclosure; and

[0031] FIG. 6 is a flow diagram of a method for real-time annotation and report generation in

accordance with the disclosure.

DETAILED DESCRIPTION

[0032] The disclosed system and method will now be described in detail with reference to the drawings in which like reference numerals designate identical or corresponding elements in each of the several views. However, it is to be understood that the aspects of the disclosure are merely exemplary of the disclosure and may be embodied in various forms. Well-known functions or constructions are not described in detail to avoid obscuring the disclosure in unnecessary detail. Therefore, specific structural and functional details disclosed herein are not to be interpreted as limiting, but merely as a basis for the claims and as a representative basis for teaching one skilled in the art to variously employ the disclosure in virtually any appropriately detailed structure. In addition, directional terms such as front, rear, upper, lower, top, bottom, distal, proximal, and similar terms are used to assist in understanding the description and are not intended to limit the disclosure.

[0033] This disclosure relates generally to surgical systems, and more particularly, to systems and methods for creating real-time reports during a procedure to assess motility function of a patient's body lumen.

[0034] Esophageal manometry, in particular, is a test used to assess pressure and motor function of the esophagus, allowing physicians to evaluate how well the muscles in the esophagus work to transport liquids or food from the mouth into the stomach. To perform this test, the manometry system operates in conjunction with a manometric catheter probe placed in the esophagus of a patient to record pressure and/or impedance data over a period of time using various sensors placed on the catheter. The data is analyzed using analysis software to evaluate causes of and help diagnose conditions such as gastric reflux, difficulty swallowing, functional chest pain, achalasia, and hiatal hernia.

[0035] The disclosed manometry system obtains high resolution and/or three-dimensional (3D) mapping of pressure levels within the tubular organs of the human gastrointestinal tract and, optionally, pressure with impedance levels within the tubular organs of the human upper gastrointestinal tract which may include the pharynx, esophagus, proximal gut (stomach/duodenum), anus, and rectum. The manometry system is used in a medical clinical setting to acquire the pressure and impedance levels and store the corresponding data for visualization and analysis using the software.

[0036] FIG. 1 illustrates a manometry system 100 according to this disclosure. The manometry system 100 generally includes a controller 200, a display 104, a touch screen display 106, and a balloon catheter 108. The controller 200 (FIG. 2) is configured to execute software for data acquisition and analysis. Various balloon catheter configurations may be used depending on the application (esophageal/anorectal manometry), size, and catheter diameter. The manometry system 100 may include a microphone 109 configured for voice command entry.

[0037] The manometry system 100 enables evaluation of the motor functions of an esophagus and/or other body lumen. The manometry system 100 provides useful information to support diagnosis of conditions like dysphagia, achalasia, and hiatal hernia. By precisely quantifying the contractions of the esophagus and its sphincters, this procedure helps provide a more complete esophageal pressure profile of the patient.

[0038] Esophageal pressure measurement, or manometry, can be used to assess motility function of the esophagus and bolus transit dynamics in the esophagus. The balloon catheter 108 generally includes one or more sensors 112 (e.g., pressure sensors) disposed along the length of the balloon catheter 108 and configured to circumferentially sense pressure during a procedure. The one or more sensors 112 are and in communication with the controller 200 and encapsulated in a balloon 110, which is configured to be inflated during a procedure. During a procedure, the balloon catheter 108 is inserted into the esophagus, typically reaching the lower esophageal sphincter (LES) and extending into the stomach of a patient, with the pressure sensors positioned at the LES and at a plurality of other points along the length of the esophagus, for example at specific, predetermined distances above the LES. The LES is a muscle that separates the esophagus from the stomach and acts like a valve that normally stays tightly closed to prevent contents in the stomach from backing up into the esophagus.

[0039] During a procedure, the patient swallows a specific amount of water (or other bolus) with the balloon catheter 108 placed in the esophagus. The manometry system 100 inflates the balloon 110 to a specific volume (e.g., 30 mL) and records pressure measurements from the sensors 112 to create, for display, real-time images depicting pressure measurements along the length of the body lumen (e.g., esophagus). In this way, the pressure at the sensors 112 can be measured and used as an indication of the magnitude and sequence of the peristaltic contractions within the body lumen. In addition, because the positions of the sensors 112 are known, the velocity of the peristaltic motion can also be ascertained from the location of the peak pressure, or onset of

pressure rise, at each location as a function of time. The measurement may be repeated a number of times to obtain a set of pressure and velocity values, a statistical analysis of which may be used for diagnostic purposes. High-resolution manometry, in particular, involves the collection of data with a catheter having closely spaced sensors 112. Such high-resolution data enables spatiotemporal contour plots visualization of contractile pressure physiology.

[0040] In various aspects, the balloon catheter 108 may include other sensors, such as impedance sensors. High-resolution impedance measurements provide for spatiotemporal plotting of bolus movement. Electrical impedance at a plurality of points in the esophagus can be used to detect and monitor the movement of a bolus through the esophagus. A bolus of water or food will cause the esophagus to have a different electrical impedance than that of a non-filled esophagus, such that a detected change in impedance in the esophagus is indicative of the presence of a bolus. With this in mind, the balloon catheter 108 positioned in the esophagus with a plurality of impedance sensors disposed along its length can be used to detect and monitor bolus transit, e.g., the movement of a bolus through the esophagus.

[0041] FIG. 2 illustrates the controller 200, in accordance with the disclosure, which includes a processor 220 that is connected to a computer-readable storage medium or a memory 230. The computer-readable storage medium or memory 230 may be a volatile type memory, *e.g.*, RAM, or a non-volatile type memory, *e.g.*, flash media, disk media, *etc.* In various aspects of the disclosure, the processor 220 may be any type of processor such as, without limitation, a digital signal processor, a microprocessor, an ASIC, a graphics processing unit (GPU), a field-programmable gate array (FPGA), or a central processing unit (CPU). In certain aspects of the disclosure, network inference may also be accomplished in systems that have weights implemented as memristors, chemically, or other inference calculations, as opposed to processors.

[0042] In aspects of the disclosure, the memory 230 can be random access memory, read-only memory, magnetic disk memory, solid-state memory, optical disc memory, and/or another type of memory. In some aspects of the disclosure, the memory 230 can be separate from the controller 200 and can communicate with the processor 220 through communication buses of a circuit board and/or through communication cables such as serial ATA cables or other types of cables. The memory 230 includes computer-readable instructions that are executable by the processor 220 to operate the controller 200. The memory 230 may include volatile (e.g., RAM) and non-volatile storage configured to store data, including software instructions for operating the manometry

system 100. In other aspects of the disclosure, the controller 200 may include a network interface 240 to communicate with other computers or to a server. A database 210 and/or a storage device may be used for storing data.

[0043] FIG. 3 shows an illustration of an interface 300 displaying a real-time 3D image generated by the manometry system of FIG. 1 based on the pressure measurements received from the sensors 112 disposed on the balloon catheter 108. The interface 300 generally includes a first image window 304 which displays a real-time 3D image depicting the pressure along the balloon catheter 108 as measured at the sensors 112, a second image window 302 which displays in real-time a two-dimensional (2-D) representation of the real-time 3D image as pressure measured at each of the sensors 112 over time (e.g., the real-time 3D image flattened and displayed over time). The 2-D image displayed in the second image window 302 may continuously or periodically scroll horizontally (e.g., from right to left) as time elapses during the procedure. The 2-D image displayed in the second image window 302 may simultaneously display one or more 2-D images in chronological order. The interface 300 also includes a capture image control 310 configured for capturing a real-time image and generating an annotation window 400 (FIG. 4) for receiving an annotation associated with the generated real-time image provided by the clinician, controls for inflating or deflating the balloon 308, an indication of the inflation setting 306, a timer 312, an indication of the measured pressure 320 of the body lumen (e.g., the esophagus), an indication of the diameter of the body lumen 318, and patient identification data 316. As shown in FIG. 3, the first image window 304 and the second image window 302 may be vertically aligned such that each of the pressure measurements shown in one image window align vertically with the corresponding pressure measurements shown in the other image window. For example, and with reference to FIG. 3, a sensor referenced as "13" in the second image window 302 vertically aligns with the same sensor referenced as "13" in the first image window 304 such that the pressure sensed at sensor "13" can be viewed by the clinician side-by-side in the 3D and 2D representations of the pressure measurements received from the balloon catheter 108. In various aspects, the sensors may include electrodes in electrical communication with the controller 200.

[0044] The capture image control 310 may include a soft button on the touch screen 106 (FIG. 1), a hardware button 107, and/or may be voice-activated using speech recognition. In aspects, the capture image control 310 may be clicked via a mouse and/or a touch control. In aspects, activation of the capture image control 310 captures an image from the real-time 3D image and opens an

annotation window 400 (FIG. 4) for the creation of an annotation associated with the captured image.

[0045] FIG. 4 shows an annotation window 400 of the interface of FIG. 3. The annotation window 400 enables the clinician to provide an annotation and to associate the provided annotation with a particular image or images captured by the manometry system of FIG. 1. For example, annotation window 400 may include a pop-up window with a plurality of radio buttons that provide for the selection of a predetermined set of annotations 402. This would allow for fast data entry by the clinician during a procedure. The annotation may include, for example, text (e.g., "weak contraction") and/or graphics (e.g., an arrow pointing to a specific portion of the captured image). The term, clinician, includes doctor, surgeon, nurse, medical assistant, or any user of the manometry system involved in performing, monitoring, and/or supervising a procedure in connection with the manometry system. The annotation window 400 may include radio buttons for the selection of one or more predetermined annotations 402, for example, including, but not limited to, weak contraction, strong contraction, no contraction, high pressure and/or repetitive retrograde contraction (RAC). The predetermined annotations 402 may include other examples, such as "further review." In aspects, the clinician may use the annotation window 400 (or an additional annotation window) to provide an annotation that is not included in the provided predetermined annotations 402. For example, the clinician may utilize the controller 200 to manually enter text in lieu of or in addition to providing a predetermined annotation 402.

[0046] A clinician may view and edit an annotation. Typically, the clinician first selects the annotation by, for example, using a pointing device to indicate the annotation in the annotation window. Annotations or annotation summaries may appear in areas other an annotation window. The full text or representation of the annotation appears or is otherwise displayed or output, and the clinician may, for example, read or edit the text, for example, in a pop-up window. The clinician may see an enlarged view of the image or set of images included in the annotation. If the annotation includes a set of images, the clinician may view the set of images as a moving image.

[0047] In other aspects, annotations may be created in conjunction with or based on an analysis performed by the controller 200. For example, the system may be configured to use image recognition on the image, determine whether the image includes, for example, but not limited to weak contraction, strong contraction, no contraction, high pressure, and/or RAC, and annotate the captured image accordingly. For example, in a system where images captured by a balloon catheter

108 are analyzed for low motility, an annotation may automatically be created when such conditions are detected. Thus, the clinician may access a set of bookmarks that refer the clinician to the portions of the moving image where such conditions exist.

[0048] In aspects, speech recognition may include capturing a verbal command by the clinician using a microphone of the manometry system 100, analyzing the voice for speech recognition based on feature extraction, and generating an annotation based on the recognized command. In aspects, the analyzing the voice for speech recognition may be based for example, a Hidden Markov Model (HMM). For example, the clinician may say, "annotate, strong contraction." The manometry system 100 would recognize the command and capture a still image from the moving image, create an annotation including "strong contraction," and associate the created annotation with the captured still image.

[0049] In aspects, the annotation window 400 may display a summary of previously provided annotations stored in memory 230. In aspects, the annotation window 400 may include the captured image and/or a thumbnail 404 of the captured image. For example, each annotation may include at least one image, the elapsed time for the image, and a title. In the annotation window 400, each image may be displayed in reduced form (e.g., thumbnail 404). In other aspects, other information may be displayed, and information may be displayed in other sets of windows, and need not be displayed in the same window as the displayed image.

[0050] FIG. 5 shows an illustration of a report 500 generated by the manometry system 100 of FIG.1 using the captured images and the associated annotations in accordance with the disclosure. Typically, after a procedure, a clinician may generate a report 500 to compare images and associated annotations. The report 500 generally includes one or more inflation setting(s) 502 of the balloon catheter 108, a first image 504 which includes the captured real-time 3D image, a second image 506 including a still portion of the captured image, patient data 516, and a diagnosis 508. The report 500 may include additional data such as the mean diameter of the body lumen as measured by the manometry system 100, distensibility, RAC presence, RRC presence, and/or max/min diameter of the body lumen. In aspects, the clinician may add more data to each of the measurements when reviewing the report 500.

[0051] The flow diagram of FIG. 6 shows a computer-implemented method 600 for real-time annotation and report generation in connection with the use of the manometry system 100 of FIG.1. In various aspects, the images created by the manometry system 100 using sensor measurements

from the balloon catheter 108 may include a body lumen (e.g., the pharynx, esophagus, proximal gut, anus, and/or rectum.) as detailed above. Persons skilled in the art will appreciate that one or more operations of the method 600 may be performed in a different order, repeated, and/or omitted without departing from the scope of the disclosure. In some methods in accordance with this disclosure, some or all of the operations in the illustrated method 600 can operate using a balloon catheter, and the controller 200 (see FIG. 2). Other variations are contemplated to be within the scope of the disclosure. The operations of FIG. 6 will be described with respect to a computing device, *e.g.*, controller 200 of manometry system 100 (FIG. 2) for analyzing medical images captured in vivo via a manometry procedure, or any other suitable computing system device or location thereof including a remotely-disposed computing device. It will be understood that the illustrated operations are applicable to other systems and components thereof as well. Esophageal pressure measurements may be used as an example; however, the disclosed methods may apply to other body lumen pressure measurements.

[0052] Initially, at step 602, the operation includes receiving pressure measurements from a catheter positioned in a body lumen of a patient. For example, during a procedure using the manometry system 100, a patient swallows a specific amount of water with the balloon catheter 108 placed in the patient's esophagus. Once positioned within the esophagus, the balloon 110 of the balloon catheter 108 (FIG. 1) is inflated to a specific volume (e.g., 30 mL), which may be set by a clinician, e.g., using interface 300 (FIG. 3). In aspects, the balloon 110 of the balloon catheter 108 (FIG. 1) may be inflated to a volume of about 30-70 mL in about 10 mL steps, for example, by using the controls for inflating or deflating the balloon 308 of interface 300 (FIG. 3).

[0053] At step 604, the operation includes generating real-time image data based on the pressure measurements received at step 602. For example, the pressure along the length of the body lumen is measured at the sensors 112 (FIG.1), and real-time image data is generated based on the pressure measurements received by the controller 200 from the sensors 112 (FIG. 1).

[0054] At step 606, the operation includes generating a stream of images based on the real-time image data generated in step 604. At step 608, the operation includes displaying, on a display 104, the generated stream of images in real-time. For example, the pressure measured at the sensors 112 (FIG.1) (e.g., esophageal pressure) is processed by the controller 200 and used to generate the real-time image data in real-time, which in turn, are processed by the controller 200 to generate and store the real-time stream of images. For example, the display 104 (FIG.1) may display the

first image window 304 (FIG. 3), which displays a real-time 3D image depicting the pressure along the balloon catheter 108 as measured at the sensors 112 (FIG. 1).

[0055] Typically, after about thirty to sixty seconds of uninterrupted pressure data, the clinician may want to capture a still image from the stream of real-time images for generating an annotation and associating the annotation with the captured still image. In aspects, the manometry system 100 may prompt the clinician to capture a still image from the stream of real-time images and/or the clinician may, at any point during a procedure, choose to capture a still image without being prompted by the manometry system 100. At step 610, the operation includes receiving, as input, one or more annotations from the clinician corresponding to one or more images of the stream of images. For example, the clinician may activate the capture image control 310 (FIG. 3) via the interface 300, which causes a still image from the stream of real-time images to be captured and opens an annotation window 400 (FIG. 4) for the creation of an annotation associated with the captured still image. The operation may include storing the annotation in a database 210 (FIG. 2) along with the captured still image with which it is associated. In aspects, the annotation may be stored as metadata in the captured still image with which it is associated. In various aspects, the capture image control 310 may include a soft button on the touch screen (FIG. 1) 106, a hardware button 107, and/or may be voice-activated using speech recognition. In aspects, the capture image control 310 may be clicked via a mouse and/or a touch control. In aspects, the captured image includes an esophageal diameter measurement.

[0056] At step 612, the operation includes associating the stored annotation with the one or more still images captured from the stream of real-time images as one or more annotated images. For example, the clinician may capture a still image at a balloon catheter inflation volume of 40 mL and annotate the captured image as "RAC." The operation would associate the captured image with the RAC annotation and store this annotation as metadata in the captured image with which it is associated.

[0057] At step 614, the operation includes displaying a report corresponding to the received pressure measurements and one or more captured still images either annotated or not annotated. In aspects, the operation may include on the displayed report the annotation corresponding to an inflation volume. For example, the report may include captured images and associated annotations at each of a plurality of balloon catheter inflation volumes in the range of about 30-70 mL in about 10 mL steps. In aspects, the operation may further include displaying for each annotated image at

least one thumbnail image of the annotated image.

[0058] At step 616, the operation may increment the predetermined volume to a second predetermined volume, for example, from approximately 30 mL to approximately 40 mL, and returning to step 602, receive pressure measurements from the balloon catheter 108 with the balloon 110 inflated to the new volume, e.g., approximately 40 mL. For example, the balloon catheter 108 (FIG. 1) may be inflated to about 30-70 mL in about 10 mL steps, and images may be captured and annotated at each 10 mL step. The above ranges and step sizes are intended only to illustrate example step sizes, the actual steps and step sizes may vary based on the procedure being performed.

[0059] From the foregoing and with reference to the various figure drawings, those skilled in the art will appreciate that certain modifications can also be made to the present disclosure without departing from the scope of the same. While several embodiments of the disclosure have been shown in the drawings, it is not intended that the disclosure be limited thereto, as it is intended that the disclosure be as broad in scope as the art will allow and that the specification be read likewise. Therefore, the above description should not be construed as limiting, but merely as exemplifications of particular embodiments. Those skilled in the art will envision other modifications within the scope and spirit of the claims appended hereto.

WHAT IS CLAIMED IS:

1. A computer-implemented method for annotating an image stream in real-time during a procedure to assess motility function of a patient's body lumen, comprising:

receiving pressure measurements from a catheter positioned in a body lumen of a patient;

generating real-time image data of the body lumen based on the received pressure measurements;

generating a stream of images based on the generated real-time image data;

displaying in real-time, on a display, the generated stream of images;

receiving, via a user interface, an annotation from a user corresponding to one or more images of the stream of images;

storing the annotation;

associating the stored annotation with the one or more images of the stream of images as one or more annotated images; and

displaying, on the display, a report including the received pressure measurements and at least one of the one or more annotated images.

2. The computer-implemented method of claim 1, further comprising inflating a balloon disposed on the catheter within the body lumen to a predetermined inflation volume, wherein the pressure measurements are received in response to inflation of the balloon.

3. The computer-implemented method of claim 2, further comprising displaying the inflation volume on the report.

4. The computer-implemented method of claim 1, further comprising displaying, for each of the one or more annotated images, at least one thumbnail image of the annotated image.

5. The computer-implemented method of claim 1, wherein the one or more annotated images include a diameter measurement of the body lumen.

6. The computer-implemented method of claim 1, wherein the body lumen includes at least one of a pharynx, an esophagus, a proximal gut, an anus, or a rectum.

7. The computer-implemented method of claim 1, further comprising receiving, via the user interface, an input that causes an image of the stream of images to be captured and an annotation window to be displayed for receiving the annotation from the user corresponding to the captured image.

8. The computer-implemented method of claim 7, wherein the annotation window includes a predetermined set of annotations selectable by the user.

9. The computer-implemented method of claim 1, wherein the user interface includes at least one of a touch screen, a microphone, a keyboard, or a mouse.

10. The computer-implemented method of claim 1, wherein storing the annotation includes at least one of storing the annotation in a database or storing the annotation as metadata in the one or more images of the stream of images.

11. A manometry system, comprising:

a manometric balloon catheter configured to capture real-time diameter measurements in a body lumen of a patient;

a user interface;

a display;

a processor; and

a memory, including instructions stored thereon, which when executed by the processor, cause the manometry system to:

receive pressure measurements from the manometric balloon catheter positioned in the body lumen;

generate real-time image data of the body lumen based on the received pressure measurements;

generate a stream of images based on the generated real-time image data;

display in real-time, on the display, the generated stream of images;

receive, via the user interface, an annotation from a user corresponding to one or more images of the stream of images;

store the annotation;

associate the stored annotation with the one or more images of the stream of images as one or more annotated images; and

display, on the display, a report including the received pressure measurements and at least one of the one or more annotated images.

12. The manometry system of claim 11, wherein the instructions, when executed by the processor, further cause the manometry system to inflate a balloon disposed on the balloon catheter within the body lumen to a predetermined volume, wherein the pressure measurements are received in response to inflation of the balloon.

13. The manometry system of claim 12, wherein the instructions, when executed by the processor, further cause the manometry system to display an inflation volume on the report.

14. The manometry system of claim 11, wherein the instructions, when executed by the processor, further cause the manometry system to display, for each of the one or more annotated images, at least one thumbnail image of the annotated image.

15. The manometry system of claim 11, wherein the one or more annotated images include a diameter measurement of the body lumen.

16. The manometry system of claim 11, wherein the body lumen includes at least one of a pharynx, an esophagus, a proximal gut, an anus, or a rectum.

17. The manometry system of claim 16, wherein the instructions, when executed by the processor, further cause the manometry system to receive, via the user interface, an input that causes an image of the stream of images to be captured and an annotation window to be displayed for receiving the annotation from the user corresponding to the captured image.

18. The manometry system of claim 17, wherein the annotation window includes a predetermined set of annotations selectable by the user.

19. The manometry system of claim 11, wherein the user interface includes at least one of a touch screen, a microphone, a keyboard, or a mouse.

20. A non-transitory computer-readable storage medium storing a program for causing a processor to execute a computer-implemented method for annotating an image stream in real-time during a procedure to assess motility function of a patient's body lumen, the computer-implemented method comprising:

receiving pressure measurements from a catheter positioned in a body lumen of a patient;

generating real-time image data of the body lumen based on the received pressure measurements;

generating a stream of images based on the generated real-time image data;

displaying in real-time, on a display, the generated stream of images;

receiving, via a user interface, an annotation from a user corresponding to one or more images of the stream of images;

storing the annotation;

associating the stored annotation with the one or more images of the stream of images as one or more annotated images; and

displaying, on the display, a report including the received pressure measurements and at least one of the one or more annotated images.

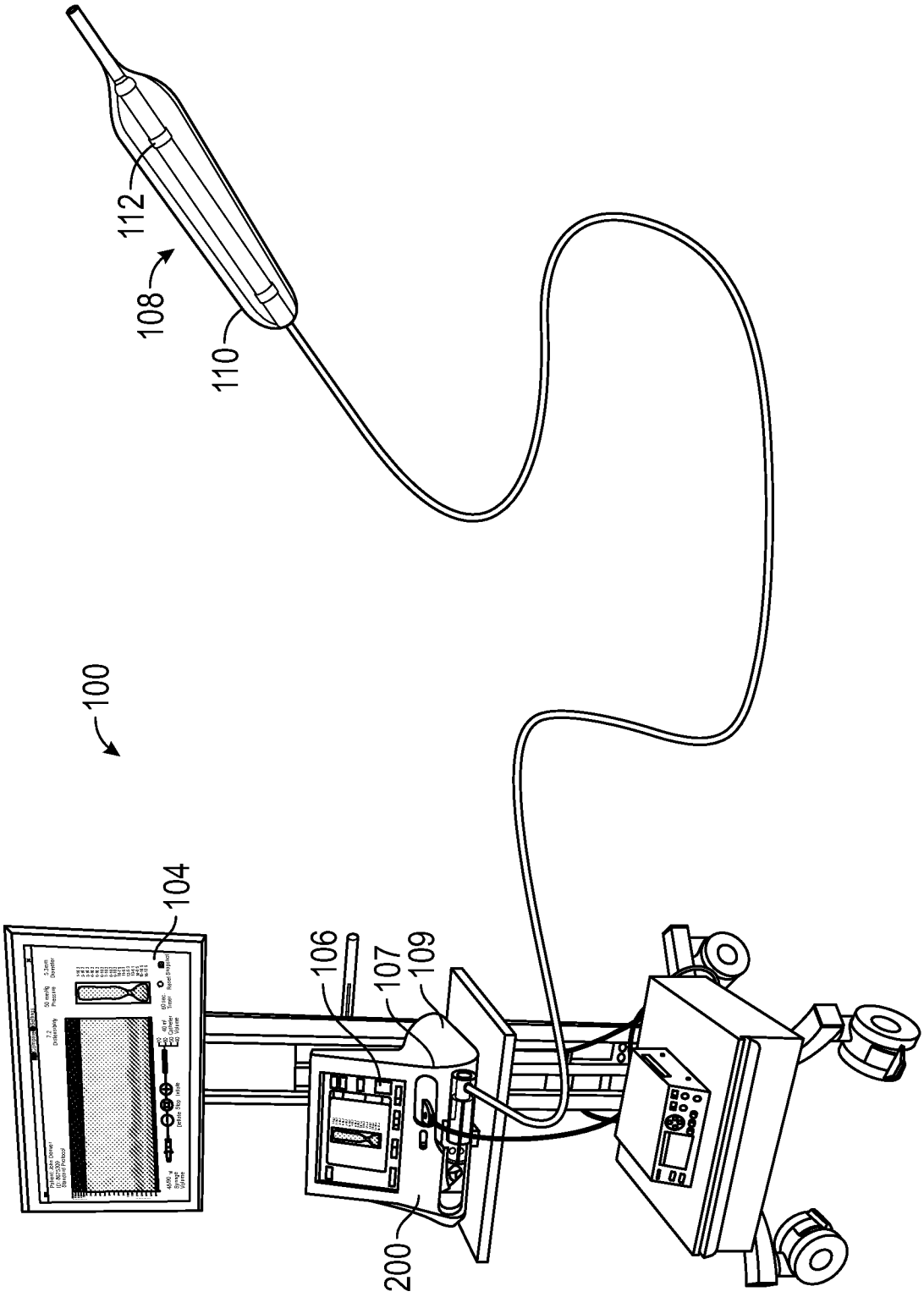


FIG. 1

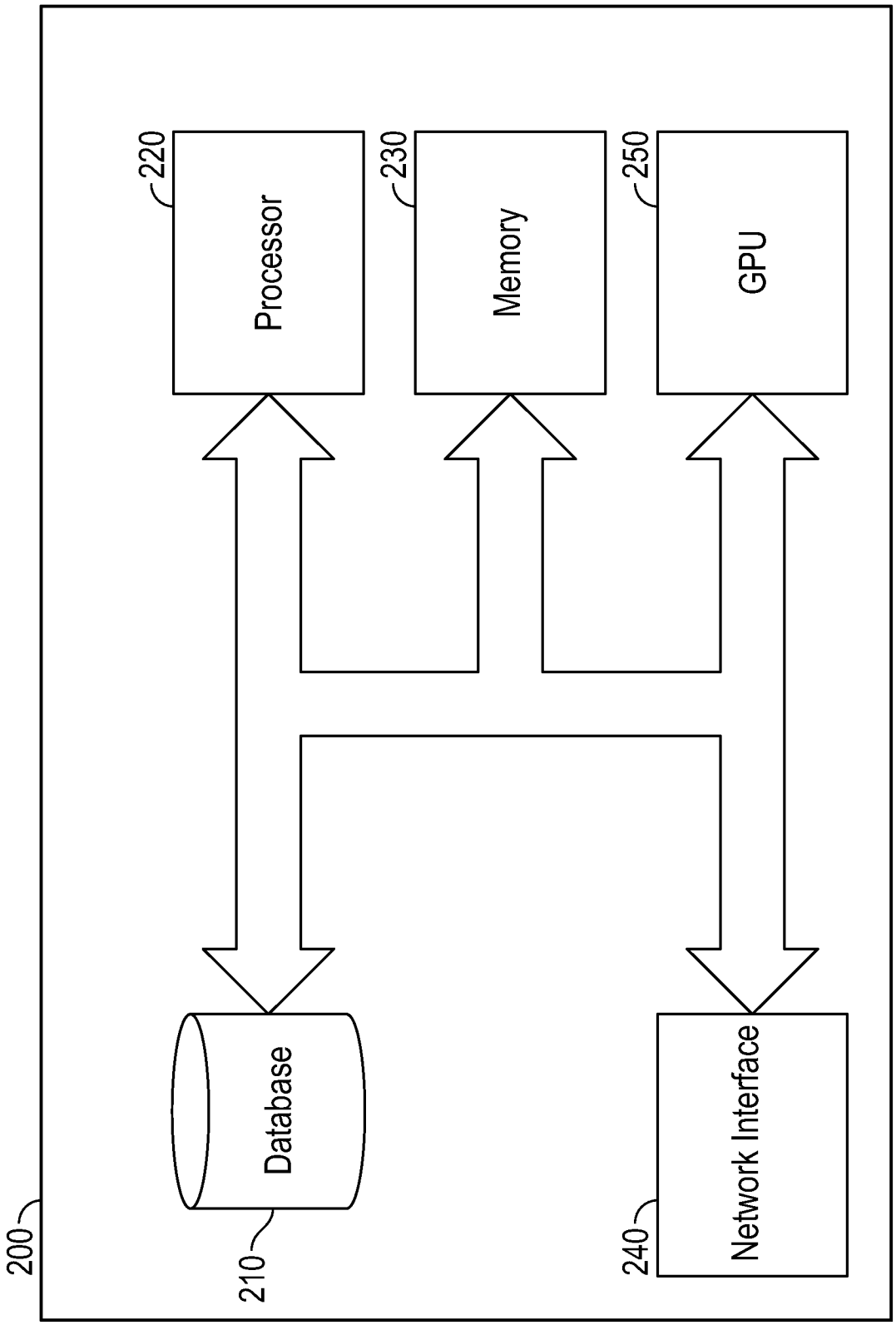

200
210
Database
240
Network Interface
220
Processor
230
Memory
250
GPU

FIG. 2

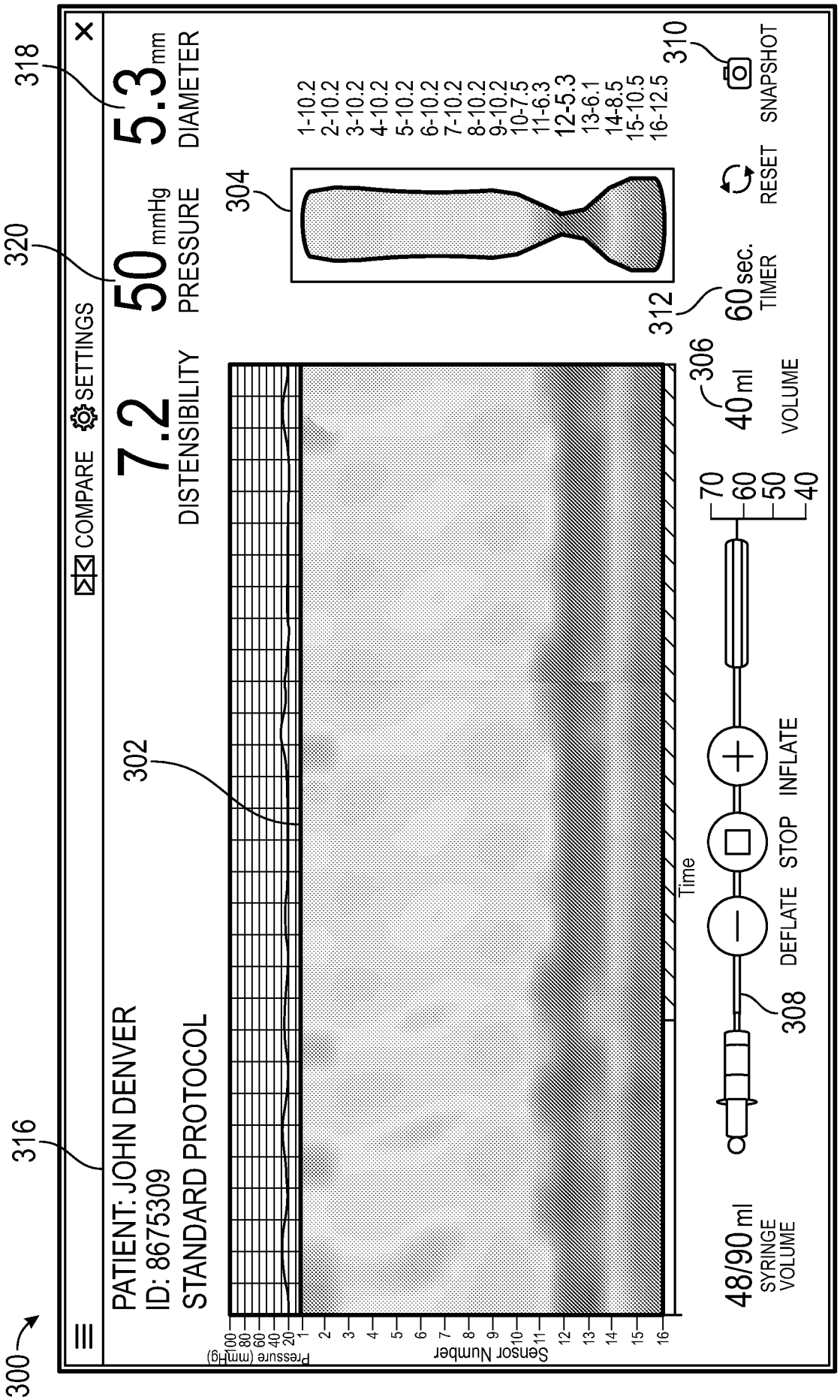

300
316
318
320
302
304
306
308
310
312
PATIENT: JOHN DENVER
ID: 8675309
STANDARD PROTOCOL
COMPARE
SETTINGS
7.2
DISTENSIBILITY
50 mmHg
PRESSURE
5.3 mm
DIAMETER
1-10.2
2-10.2
3-10.2
4-10.2
5-10.2
6-10.2
7-10.2
8-10.2
9-10.2
10-7.5
11-6.3
12-5.3
13-6.1
14-8.5
15-10.5
16-12.5
RESET
SNAPSHOT
60 sec.
TIMER
40 ml
VOLUME
70
60
50
40
DEFLATE
STOP
INFLATE
48/90 ml
SYRINGE VOLUME
Time
Sensor Number
Pressure (mmHg)

FIG. 3

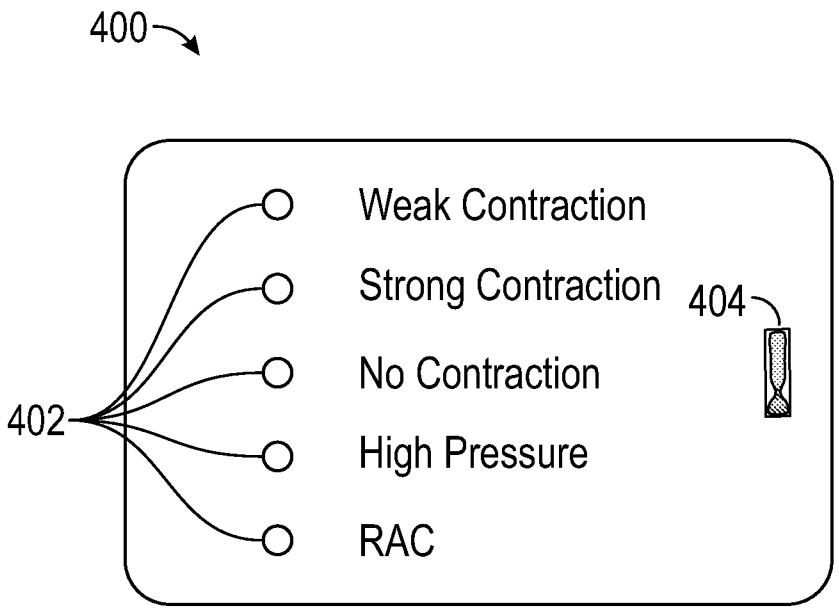

400
Weak Contraction
Strong Contraction
No Contraction
High Pressure
RAC
402
404

FIG. 4

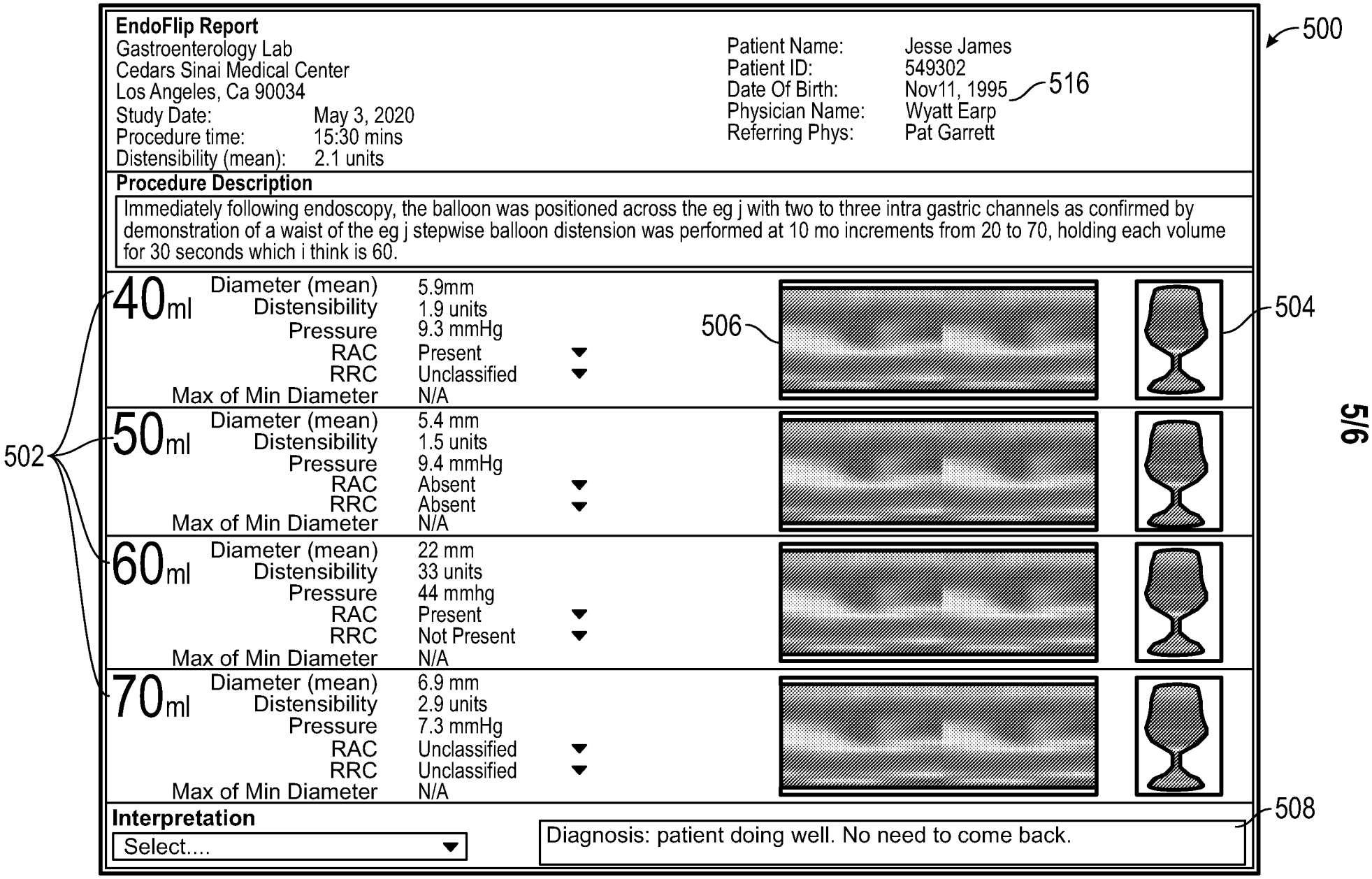

EndoFlip Report
Gastroenterology Lab
Cedars Sinai Medical Center
Los Angeles, Ca 90034
Study Date: May 3, 2020
Procedure time: 15:30 mins
Distensibility (mean): 2.1 units
Patient Name: Jesse James
Patient ID: 549302
Date Of Birth: Nov11, 1995
Physician Name: Wyatt Earp
Referring Phys: Pat Garrett
500
516
Procedure Description
Immediately following endoscopy, the balloon was positioned across the eg j with two to three intra gastric channels as confirmed by demonstration of a waist of the eg j stepwise balloon distension was performed at 10 mo increments from 20 to 70, holding each volume for 30 seconds which i think is 60.
502
40ml
Diameter (mean) 5.9mm
Distensibility 1.9 units
Pressure 9.3 mmHg
RAC Present
RRC Unclassified
Max of Min Diameter N/A
50ml
Diameter (mean) 5.4 mm
Distensibility 1.5 units
Pressure 9.4 mmHg
RAC Absent
RRC Absent
Max of Min Diameter N/A
60ml
Diameter (mean) 22 mm
Distensibility 33 units
Pressure 44 mmhg
RAC Present
RRC Not Present
Max of Min Diameter N/A
70ml
Diameter (mean) 6.9 mm
Distensibility 2.9 units
Pressure 7.3 mmHg
RAC Unclassified
RRC Unclassified
Max of Min Diameter N/A
506
504
Interpretation
Select....
Diagnosis: patient doing well. No need to come back.
508

FIG. 5

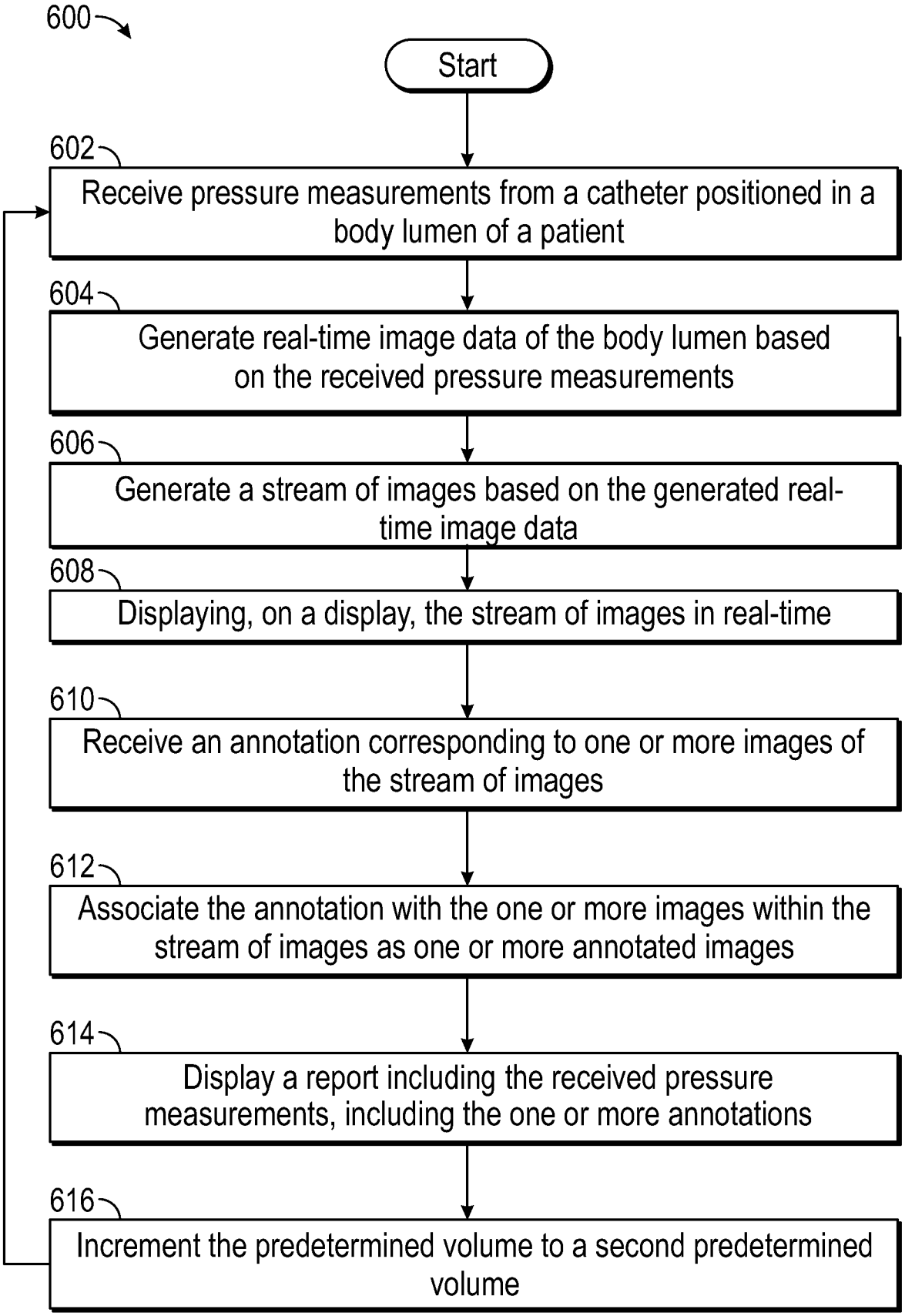

600
Start
602
Receive pressure measurements from a catheter positioned in a body lumen of a patient
604
Generate real-time image data of the body lumen based on the received pressure measurements
606
Generate a stream of images based on the generated real-time image data
608
Displaying, on a display, the stream of images in real-time
610
Receive an annotation corresponding to one or more images of the stream of images
612
Associate the annotation with the one or more images within the stream of images as one or more annotated images
614
Display a report including the received pressure measurements, including the one or more annotations
616
Increment the predetermined volume to a second predetermined volume

FIG. 6

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2021/048411

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B5/03 A61B5/00
ADD.

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)
A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	HIRANO IKUO ET AL: "Functional Lumen Imaging Probe for the Management of Esophageal Disorders: Expert Review From the Clinical Practice Updates Committee of the AGA Institute", CLINICAL GASTROENTEROLOGY AND HEPATOLOGY, vol. 15, no. 3, 1 March 2017 (2017-03-01), pages 325-334, XP055876773, AMSTERDAM, NL ISSN: 1542-3565, DOI: 10.1016/j.cgh.2016.10.022 Retrieved from the Internet: URL:https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5757507/pdf/nihms912964.pdf> p. 3, chapter: "Data analysis", second paragraph figures 1, 2 ----- -/--	1,2, 4-12, 14-20

[x] Further documents are listed in the continuation of Box C.

[x] See patent family annex.

* 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
10 January 2022	19/01/2022

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Worms, Georg

1

Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2021/048411

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	CARLSON DUSTIN A ED - MARTIN JOHN: "Evaluation of esophageal motility during endoscopy with the functional luminal imaging probe", TECHNIQUES IN GASTROINTESTINAL ENDOSCOPY, W.B. SAUNDERS, AMSTERDAM, NL, vol. 20, no. 3, 29 July 2018 (2018-07-29), pages 107-113, XP085487937, ISSN: 1096-2883, DOI: 10.1016/J.TGIE.2018.07.004 p. 107, chapter 2 figure 1 p. 108, right column	1-3, 5-13, 15-20
X	US 2018/008156 A1 (PANDOLFINO JOHN ERIK [US] ET AL) 11 January 2018 (2018-01-11) paragraphs [0040], [0044], [0046], [0047], [0049], [0053], [0078], [0079], [0085] figures 1, 3, 6, 7	1-20
A	Crospon Ltd.: "EndoFLIP System; Functional Lumen Imaging Probe; EF-100 User Manual", , 1 January 2016 (2016-01-01), XP055877257, Retrieved from the Internet: URL:https://www.medwrench.com/documents/view/10318/medtronic-crospon-endoflip-instructions-for-use-pdf page 22 figure 14	1-20

1

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2021/048411

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2018008156 A1	11-01-2018	CA 2975603 A1	11-08-2016
		US 2018008156 A1	11-01-2018
		WO 2016126701 A1	11-08-2016