

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
19 June 2008 (19.06.2008)

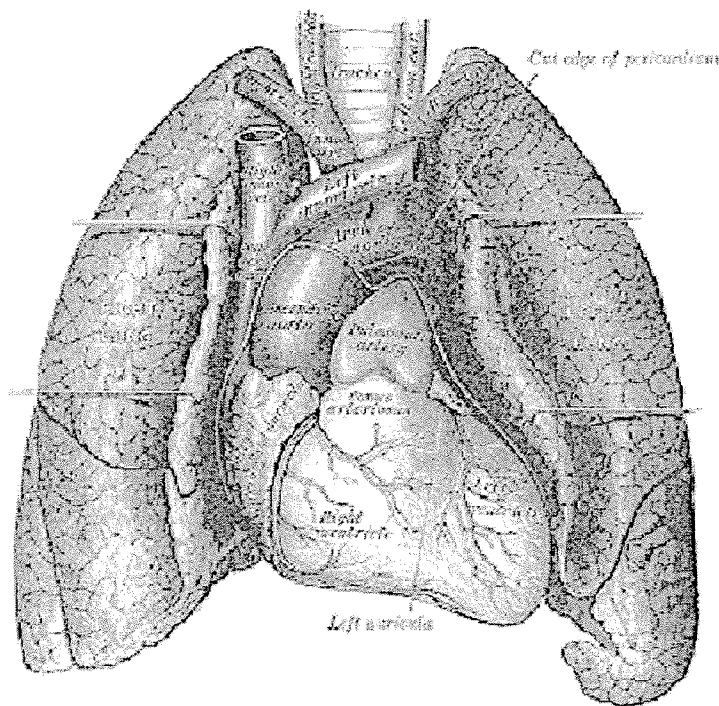
PCT

(10) International Publication Number
WO 2008/073560 A2

- (51) International Patent Classification:
A61B 8/14 (2006.01)
- (21) International Application Number:
PCT/US2007/080739
- (22) International Filing Date: 8 October 2007 (08.10.2007)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
60/828,614 6 October 2006 (06.10.2006) US
60/862,192 19 October 2006 (19.10.2006) US
60/862,190 19 October 2006 (19.10.2006) US
- (71) Applicant (for all designated States except US): **VE-RATHON INC.**; 21222 - 30th Drive SE Suite 120, Bothell, WA 98021 (US).
- (72) Inventors; and
- (75) Inventors/Applicants (for US only): **MCMORROW, Gerald** [US/US]; 6319 240th Way NE, Redmond, WA 98053 (US). **FILIPOVA-IVANOVA, Ekaterina** [US/US]; 11425 112th Place NE, Kirkland, WA 98033 (US).
- (74) Agent: **DOUGLAS, Christopher, T., L.**; Black Lowe & Graham PLLC, 701 Fifth Avenue, Suite 4800, Seattle, WA 98104 (US).
- (81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.
- (84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, MT, NL, PL,

[Continued on next page]

(54) Title: SYSTEMS AND METHODS FOR LUNG IMAGING, PNEUMOTHORAX DETECTION AND ENDOTRACHEAL TUBE INSERTION



(57) Abstract: An ultrasound system and method utilizing single dimensional, two dimensional, and three-dimensional ultrasound images for ascertaining or predicting normal and pathological lung states by determining the presence, the absence or intermediate degrees of lung sliding that is exhibited during respiratory cycles. An ultrasound system and method employing A-mode scanning to generate echogenic histogram patterns to discern whether a lung has an echogenic pattern indicative of a normal lung or that indicative of a pneumothorax or a haemothorax. The A-mode scanning may be of single scan-lines or multiple scan-lines. Multiple scan-lines may also be confined within a two-dimensional scanplane, an array of two-dimensional scanplanes, or as a three-dimensional distribution of scan-lines. A video laryngoscope having a blade-located camera and an optical calibrator connected with the camera to be configured to emit visible lines separating by a known distance onto the tracheal region in view of

the camera. An image of the tracheal region and lines may be conveyed to a video screen from which the dimension of the tracheal orifice may be estimated by comparing the orifice's diameter to the known separation distance of the two projected lines. Endotracheal tubes may be then selected having a size that may be slidably accommodated through the estimated tracheal orifice diameter.

WO 2008/073560 A2



PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM,
GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

- *without international search report and to be republished
upon receipt of that report*

**SYSTEMS AND METHODS FOR LUNG IMAGING, PNEUMOTHORAX
DETECTION AND ENDOTRACHEAL TUBE INSERTION**

PRIORITY CLAIM

[0001] This application claims priority to U.S. Provisional Patent Application Serial No. 60/828,614 filed October 6, 2006; U.S. Provisional Patent Application Serial No. 60/862,192 filed October 19, 2006; U.S. Provisional Patent Application Serial No. 60/862,190 filed October 19, 2006. This application also claims priority to U.S. Application Serial No. 11/285,743 filed November 21, 2005 and U.S. Application Serial No. 11/645,086 filed December 21, 2006. All of the foregoing applications are hereby incorporated by reference in their entirety as if fully set forth herein.

COPYRIGHT NOTICE

[0002] This disclosure is protected under United States and International Copyright Laws. © 2007 Verathon Inc. All Rights Reserved. A portion of the disclosure of this patent document contains material which is subject to copyright protection. The copyright owner has no objection to the facsimile reproduction by anyone of the patent document or the patent disclosure after formal publication by the USPTO, as it appears in the Patent and Trademark Office patent file or records, but otherwise reserves all copyright rights whatsoever.

FIELD OF THE INVENTION

[0003] This invention relates generally to ultrasound-based diagnostic systems and procedures utilized for lung imaging to determine lung status.

[0004] An embodiment of the invention relates generally to ultrasound-based diagnostic systems and procedures utilized for determining normal and injured lung conditions.

[0005] This invention relates generally to ultrasound-based diagnostic systems and procedures utilized for determining normal and injured lung conditions.

BACKGROUND OF THE INVENTION

[0006] The targeted organ for ultrasound imaging is the lungs. The lungs are essential organs of respiration. The substance of the lung is of a light, porous spongy texture that is able to float in water. The lungs, as shown in FIGURE 1, is contained within the thoracic cavity, are somewhat triangular in shape with their apex superior and base inferior. The lungs are separated from the abdominal cavity by the muscular diaphragm located at the base of the lung. They are divided into lobes with the right having three lobes and the left only two. The left lung is smaller in order to accommodate the heart.

[0007] Furthermore, the lungs are surrounded by a double-walled sac called the pleura (visceral and parietal pleura) and include a pleural fluid located between them to enable the lung to expand and contract without adhering to the sac walls. The pressure within the lungs is below the atmospheric pressure which allows the lungs to remain partially inflated at all times.

[0008] Tension Pneumothorax occurs due to the accumulation of air under pressure in the pleural space. This condition can occur without any prior lung conditions or diseases, but in most cases, a tension pneumothorax is a result from the rupture of the bleb (air-filled sac on the lung). Because of this, air escapes from the lungs and enters the chest cavity which causes the lung to collapse as shown in FIGURE 2. Furthermore, as air leaks out into the pleural space it causes increase in the intrapleural pressure which eventually increases to the point where it interferes with venous return, resulting in blood pooling in capacitance vessels with ensuing cardiovascular collapse and shock.

[0009] Tension pneumothorax is a life-threatening condition and can have a number of different causes. A penetrating trauma to the chest, lung infection, or recurrent prior pneumothorax may all lead to a tension pneumothorax. The most common etiology of

tension pneumothorax are either iatrogenic (induced inadvertently by medical treatment or procedure) or related to trauma (blunt or penetrating) which can result in a one-way valve being created at the point of rupture.

[0010] The diagnosis of pneumothorax in critically ill patients is problematic. The reason for that is that the bedside chest x-ray is not fully sensitive and the computed tomography (CT) which is considered the gold standard is not easy to perform in critically ill patients. On the other hand, ultrasound is harmless and inexpensive technique that is readily available even at the patient's bedside and in recent years, a number of signs have allowed the identification of pneumothorax with ultrasound.

[0011] When ultrasound is used as imaging modality, the normal "pleural line" is an image that is a result due to the reflection of US waves at the lung surface (as shown in FIGURE 3) and is characterized as "lung sliding" or "lung gliding". The lung sliding or gliding indicates that the visceral and parital pleura are sliding with respiratory acts. The sliding actions can be recognized during a B-mode in real time ultrasonography. In normal subjects, the lung pleura can be visualized between rib echogenic windows and is also used to observe for evidence of the to-and-fro "lung sliding".

[0012] Another characteristic that can aid in the detection of pneumothorax with ultrasound is the artifact called "comet-tail". "Comet-tail" artifacts are hyperechoic lines that originate from the pleural line and directed toward the depth as far as the background of the scan (as shown in FIGURE 4). In the absence of "lung sliding", "comet-tail artifact" becomes the second criterion in ruling out pneumothorax.

[0013] If either sign is absent, the "lung point" sign is searched in the images. The lung point is characterized by the fleeting appearance of a normal lung pattern (lung sliding or comet-tail artifact) and replaced by a pneumothorax pattern (absent lung sliding and absent comet tail artifact) in particular location of the chest wall. With the transducer fixed in

one spot, the sign is usually seen in the intercostal spaces of the anterior and lateral chest wall on inspiration as well as posteriorly (as shown in FIGURE 5).

[0014] A theoretical explanation of the “lung point”. Left: during expiration, the pneumothorax has a defined volume on CT. The probe is placed at a point that is slightly superior to the lung level with display of pneumothorax pattern. Right: during inspiration, the lung volume should slightly increase, therefore increasing the surface of the lung that is in contact with the wall. The probe should remain at the same location and thus display a fleeting pattern of lung (i.e. lung sliding).

[0015] The presence of one or both of these “lung sliding” and “comet-tail artifact” signs indicates that contact of the visceral pleura with the parietal pleura exists and so indicates the absence of pneumothorax. The need to observe either one or both of these signs is important because there are situations in which one or the other sign could indicate other abnormalities. For example, the absence of “lung sliding” could be indicative of patients with extensive pleural scarring or adult respiratory distress syndrome which will make the evaluation of pneumothorax more challenging. The same applies for the “comet-tail” artifacts. The presence of multiple and disseminated “comet-tail” artifacts could be indication of alveolar-interstitial syndrome”. Furthermore, subcutaneous shotgun pellets or subcutaneous emphysema could also cause “comet-tail” artifact signs; therefore caution must be exercised when evaluating trauma patients (as shown in FIGURE 6).

[0016] In summary, it has been shown from various researches that thoracic ultrasound can be used to detect pneumothorax with moderate accuracy. For example, based on the results from Soldati and et al, US sensitivity and specificity in diagnosing pneumothorax to be 98.2 % (95% CI: 90.4 to 99.9%) and 100% respectively, with positive predictive value of 100% and negative predictive value of 99.2% (95% CI: 95.8 to 99.8). Another example is Garofalo and et al. study results where the US sensitivity was 95.65%,

specificity of 100% and diagnostic accuracy of 98.91% with positive predictive value of 100% and negative predictive value of 98.57%⁶.

[0017] There is a need for and improved ultrasound-based systems and methods to accurately image the lungs for diagnosing lung pathological conditions indicative of pneumothorax and haemothorax.

[0018] Frank trauma to the lungs, for example as in stab and gunshot wounds, as shown in FIGURE 1, causes a pneumothorax or haemothorax condition wherein air and blood (arrows) flows and pools in thoracic cavity and displaces the lung tissue. Oftentimes the patients are not cognizant of or are unable to explain their physical condition. There is a need for a non-invasive way to rapidly diagnose of a pneumothorax or haemothorax condition so that medical personnel may perform triage and treatment procedures.

[0019] The insertion of endotracheal tubes can cause frank trauma to the tracheal orifice or trachea, especially when the endotracheal tube is larger than the tracheal orifice.

[0020] The GlideScope®, available from Verathon, Inc. of Redmond, Washington, USA is often used to see the trachea for tube insertion as shown in FIGURE 1.

[0021] The GlideScope® uses a camera to view the trachea – the size of the trachea is a function of range and viewing angle.

[0022] Range is a strong function described by the equations below:

$$S_o \downarrow \left(\begin{matrix} f \\ \end{matrix} \right) \uparrow S_i$$

$$\leftarrow \xrightarrow{d_o} \quad | \quad \leftarrow \xrightarrow{d_i}$$

$$\frac{l}{d_o} + \frac{l}{d_i} = \frac{l}{f}$$

$$\frac{S_i}{S_o} = \frac{d_i}{d_o} = M$$

[0023] Thus, in use, the Magnification factor (M) is inversely proportional to the distance of the object, d_o . Since this varies by some percentage, say 25%, it is a strong error in simply sizing the trachea from the image. Viewing angles: the apparent size of the trachea image is also an error:

$$\frac{d_i}{d_o} = \cos \Theta$$

[0024] Thus, for up to a 10 degree error (the maximum routinely expected), an error of 1.5% would occur – so we can ignore this small effect.

[0025] Both tubes and tracheas come in a variety of diameters. There is a need to decide what tube size should be used prior to insertion into the trachea would save trauma, time, and supplies.

BRIEF DESCRIPTION OF THE DRAWINGS

[0026] Embodiments of the present invention are described in detail below with reference to the following drawings.

[0027] FIGURE 1 depicts a schematic of a human lung showing lung structure in relation to the heart and trachea;

[0028] FIGURE 2 schematically depicts a cross section of the human lung under a tension pneumothorax pathological condition;

[0029] FIGURE 3 is an image obtained by a longitudinal ultrasound scan acquired along the anterior abdominal region showing the pleural line (arrow heads);

[0030] FIGURE 4 is an image obtained by an intercostal ultrasound scan showing the “comet-tail” artifact (two long vertical orientated streaks along the center of ultrasound wedge);

[0031] FIGURE 5 is a cross-sectional schematic delineating the “lung point”;

[0032] FIGURE 6 is an image obtained by a longitudinal ultrasound scan acquired along the intercostal space showing the generation of “comet-tail” artifacts arising from superficial layers that limit recognition of the pleural line and rib relief;

[0033] FIGURE 7 is a partial isometric of the thoracic region depicting acoustic windows (first look defined to be between the 3rd and 4th intercostal spaces to right of midline and second look defined to be near the clavicle to the right of midline) for placing ultrasound transceivers for image acquisition;

[0034] FIGURE 8 is a schematic of a decision tree for ascertaining the presence of a pneumothorax condition;

[0035] FIGURE 9A presents an ultrasound images obtained on Subject #1 with a 5-2 Mhz convex array transducer using the Sonosite 180 ultrasound transceiver device near the clavicle to the right of midline with Subject #1 in the supine position and presenting normal respiration during scanning;

[0036] FIGURES 9B present ultrasound images obtained on Subject #1 with a 5-2 Mhz convex array transducer using the Sonosite 180 ultrasound transceiver device between the 3rd and 4th intercostal spaces to right of midline with Subject #1 in the supine position and presenting normal respiration during scanning;

[0037] FIGURE 10A presents an ultrasound images obtained on Subject #1 with a 5-10 Mhz convex array transducer using the Sonosite 180 ultrasound transceiver device near the clavicle to the right of midline with Subject #1 in the supine position and presenting normal respiration during scanning;

[0038] FIGURES 10B present ultrasound images obtained on Subject #1 with a 5-10 Mhz convex array transducer using the Sonosite 180 ultrasound transceiver device between the 3rd and 4th intercostal spaces to right of midline with Subject #1 in the supine position and presenting normal respiration during scanning;

[0039] FIGURES 11A-D depicts a partial schematic and a partial isometric view of a transceiver, a scan cone comprising a rotational array of scan planes, and a scan plane of the array using a transceiver 10A having Doppler-speaker circuit 15;

[0040] FIGURE 12 depicts a partial schematic and partial isometric and side view of a transceiver, and a scan cone array comprised of 3D-distributed scan lines using a transceiver 10B having Doppler-speaker circuit 15;

[0041] FIGURE 13 depicts image acquisition in a series of translational acquired scan plane images using a transceiver 10C having Doppler-speaker circuit 15;

[0042] FIGURE 14 depicts image acquisition in a series of fan orientated acquired scan plane images using a transceiver 10D having Doppler-speaker circuit 15;

[0043] FIGURE 15 depicts an ultrasound transceiver housed in a communications cradle and the data being wirelessly uploaded;

[0044] FIGURE 16 depicts an ultrasound transceiver housed in a communications cradle where the data uploaded by electrical connection;

[0045] FIGURE 17 depicts acquisition between the 3rd and 4th intercostal spaces to right of midline;

[0046] FIGURE 18 depicts images showing the chest area in cross section of a patient being scanned by a transceiver and the data being wirelessly uploaded to a personal computer during initial targeting of a region of interest (ROI) of the lung between the 3rd and 4th intercostal spaces to right of midline;

[0047] FIGURE 19 is a schematic illustration and partial isometric view of a network connected lung imaging ultrasound system 100 in communication with ultrasound imaging systems 60A-D;

[0048] FIGURE 20 is a schematic illustration and partial isometric view of an Internet connected lung imaging ultrasound system 110 in communication with ultrasound imaging systems 60A-D;

[0049] FIGURES 21A-J present ultrasound images obtained on Subject #1 using the BVM 6500 transceiver device between the 3rd and 4th intercostal spaces to right of midline with subject #1 in the supine position and presenting normal respiration during scanning;

[0050] FIGURES 22A-J present ultrasound images obtained on Subject #1 using the BVM 6500 transceiver device near the clavicle to the right of midline with subject #1 in the supine position and presenting normal respiration during scanning;

[0051] FIGURE 23A presents an ultrasound images obtained on Subject #2 using a 5-2 Mhz convex array transducer using the Sonosite 180 ultrasound transceiver device near the clavicle to the right of midline with Subject #2 in the supine position and presenting normal respiration during scanning;

[0052] FIGURES 23B present ultrasound images obtained on Subject #2 using a 5-2 Mhz convex array transducer using the Sonosite 180 ultrasound transceiver device between the 3rd and 4th intercostal spaces to right of midline with Subject #2 in the supine position and presenting normal respiration during scanning;

[0053] FIGURE 24A presents an ultrasound images obtained on Subject #2 using a 5-10 Mhz convex array transducer using the Sonosite 180 ultrasound transceiver device near the clavicle to the right of midline with Subject #2 in the supine position and presenting normal respiration during scanning;

[0054] FIGURES 24B present ultrasound images obtained on Subject #2 using a 5-10 Mhz convex array transducer using the Sonosite 180 ultrasound transceiver device between the 3rd and 4th intercostal spaces to right of midline with Subject #2 in the supine position and presenting normal respiration during scanning; and

[0055] FIGURES 25A-J present ultrasound images obtained on Subject #2 using the BVM 6500 transceiver device between the 3rd and 4th intercostal spaces to right of midline with subject #2 in the supine position and presenting normal respiration during scanning.

[0056] FIGURE 101 is a partial isometric of the thoracic region depicting acoustic windows;

[0057] FIGURE 102 schematically depicts a cross section of the human lung under a tension pneumothorax pathological condition;

[0058] FIGURE 103 is a schematic illustration of a pneumothorax-haemothorax detection system scanning a normal lung;

[0059] FIGURE 104 presents a normal lung A-line histogram of echo strength plotted against time t or depth;

[0060] FIGURE 105 is a schematic illustration of the pneumothorax-haemothorax detection system scanning an injured lung;

[0061] FIGURE 106 presents an injured lung A-line histogram of echo strength plotted against time t or depth;

[0062] FIGURES 107A-D depicts a partial schematic and a partial isometric view of a transceiver, a scan cone comprising a rotational array of scan planes, and a scan plane of the array using a transceiver 10A having Doppler-speaker circuit 15;

[0063] FIGURE 108 depicts a partial schematic and partial isometric and side view of a transceiver, and a scan cone array comprised of 3D-distributed A-scan lines using a transceiver 10B having Doppler-speaker circuit 15;

[0064] FIGURE 109 is a schematic illustration and partial isometric view of a network connected lung imaging ultrasound system 100 in communication with ultrasound imaging systems 60A-D; and

[0065] FIGURE 110 is a schematic illustration and partial isometric view of an Internet connected lung imaging ultrasound system 110 in communication with ultrasound imaging systems 60A-D.

[0066] FIGURE 201 is a schematic depiction of a video laryngoscope system;

[0067] FIGURE 202 illustrates a video laryngoscope adjacent to two endotracheal tubes;

[0068] FIGURE 203 is a schematic illustration of a video laryngoscope having a blade mounted camera;

[0069] FIGURE 204 schematically illustrates an embodiment of an optical calibrator adjacent to a laryngoscope camera;

[0070] FIGURE 205 schematically illustrates in a plane view an image of two optical lines projected onto a tracheal region;

[0071] FIGURE 206 is a schematic illustration, not drawn to scale, of an alternate embodiment of a calibrated video laryngoscope system; and

[0072] FIGURE 207 pictographically presents an alternate embodiment of the calibrated video laryngoscope system.

DETAILED DESCRIPTION OF THE PARTICULAR EMBODIMENTS

[0073] Methods and systems to acquire an ultrasound lung images for determining lung pathological and non-pathological conditions are described. In general, the particular embodiments concern ultrasound systems and methods that generate and utilize single dimensional, two dimensional, and/or three-dimensional ultrasound images for ascertaining or predicting normal and pathological lung states by determining the presence, the absence or intermediate degrees of lung motion that is exhibited during respiratory cycles. Other particular embodiments include the absence or presence of lung motion and the degree of blood flow as determined by Doppler equipped ultrasound transceiver systems to diagnose the presence and severity of pneumothorax with or without the presence of vary degress of haemothorax.

[0074] FIGURES 5-25J relate to FIGURES 1-4 and illustrate particular system and method procedures to obtain single dimensional, two dimensional, and three-dimensional ultrasound images for ascertaining or predicting the normal and pathological lung states by

determining the presence, the absence, or intermediate degrees of lung motion in the form of lung sliding during respiratory cycles. The extent of lung sliding is used to determine whether a pneumothorax pathological state is indicated or a non-pathological (normal) state exists. Other particular embodiments include the absence or presence of lung motion and the degree of blood flow as determined by Doppler equipped ultrasound transceiver systems to diagnose the presence and severity of pneumothorax with or without the presence of vary degrees of haemothorax.

[0075] In one particular embodiment, a subject or patient is scanned using an ultrasound transceiver similar to the BladderScan[®] BVM6500 marketed by Diagnostic Ultrasound Incorporated of Redmond, Washington provides an ultrasound sound image in the form of a three-dimensional scan cone. Other embodiments include the BVM6500 having color Doppler abilities and/or the BVM further modified to have a Doppler–speaker circuit to assist in transceiver aiming. The 3D scan cone provides images of the ultrasound-probed region of interest (ROI) of the lung in the form of a rotational 2D scan plane array referred to as a V-mode[®] image or images. The V-mode[®] images may also be include wedge, translational arrays, and images made from 3-D randomly distributed scanlines.

[0076] Using either the BVM 6500 or the Sonosite 180 ultrasound transceivers, scans using radiofrequency ultrasound pulses are made for approximate four minutes at two anatomical sites that present a clear acoustical window, or unobstructed view, of the lung. Times other than four minutes may be used. The anatomical sites include a clavicle view and an inter-rib view as described below. After the scans, the transceiver displays a plurality of lung images along with any aiming information for the transceiver to enable the correct placement of the probe with respect to the lung. The aiming information allows the user to repeat the scans as needed to get a well-centered image and/or to complete the image acquisition of the lung.

[0077] Once the scans are complete, signals received from returning echoic pulses in the single, two, and/or three-dimensional scans are communicated directly to a dedicated computer or transmitted securely to a server computer coupled to a local or Internet-based network. In either the local computer or network connected computers, image processing algorithms executed by the upon the signals to analyze pixels within a 1D, 2D, or voxels of a 3D portion a 3D image to provide a plurality of lung images seen from each anatomical site.

[0078] The plurality of images from each anatomical site is used to analyze the presence of lung motion, especially lung motion associated with transitory lung sliding. In one particular embodiment, the detection of the fleeting or transitory states of lung sliding is advantageously established by use of the greater number of three dimensional images generated by the BVM ultrasound transceivers.

[0079] FIGURE 1 depicts a schematic of a human lung showing lung structure in relation to the heart and trachea.

[0080] FIGURE 2 schematically depicts a cross section of the human lung under a tension pneumothorax pathological condition. Tension pneumothorax can occur without any prior lung conditions or diseases, but commonly results from the rupture of a bleb. When the bleb ruptures air escapes from the lungs and enters the chest cavity (curved arrows, right lung) that causes the lung to collapse.

[0081] FIGURE 3 is an image obtained by a longitudinal ultrasound scan acquired along the anterior abdominal region showing the pleural line (arrow heads).

[0082] FIGURE 4 is an image obtained by an intercostal ultrasound scan showing the “comet-tail” artifact (two long vertical orientated streaks along the center of ultrasound wedge).

[0083] FIGURE 5 is a cross-sectional schematic delineating the “lung point”.

[0084] FIGURE 6 is an image obtained by a longitudinal ultrasound scan acquired along the intercostal space showing the generation of “comet-tail” artifacts arising from superficial layers that limit recognition of the pleural line and rib relief.

[0085] FIGURE 7 is a partial isometric of the thoracic region depicting acoustic windows (second acoustical window look defined to be between the 3rd and 4th intercostal spaces to right of midline first acoustical look defined to be near the clavicle to the right of midline) for placing ultrasound transceivers for image acquisition.

[0086] Good acoustic window for scanning the lungs for pneumothorax include performing longitudinal scans at a first acoustical window to rule out a pneumothorax, and a clavicle scan to evaluate the size and location of a pneumothorax.

[0087] Longitudinal scan of the anterior chest wall in the parasternal line on both sides between the third and fourth intercostal space with the patient in supine position (Fig 4).¹⁰

[0088] If pneumothorax is detected, assessment with transverse scans along the intercostal spaces from sternal to middle-axillary line can used to evaluate size and location (Fig.4).¹⁰

[0089] FIGURE 8 is a schematic of a decision tree for ascertaining the presence of a pneumothorax condition. The decision tree begins with observing whether anterior lung sliding is absent or present. If present, a pneumothorax pathological condition is unlikely, whereas if lung sliding is absent, the presence of B-line comet-lines artifacts is established. If the comet-line artifact is observed, or positive, then a pneumothorax pathological condition is unlikely. If negative for observable comet-line artifacts, then the presence of a lung point signs is established. If a lung point exists, a mild, moderate, or severe pneumothorax pathological condition is indicated. If a lung point doesn't exist, a suspected massive pneumothorax pathological condition is indicated. Accompanying mild to massive pneumothorax conditions may be a haemothorax pathological conditions wherein blood

surrounds the lungs in addition to the air from the pneumothorax. The presence pneumothorax and/or haemothorax occurs for patients on mechanical ventilators, patients having lung cancer, and respiratory wounds as caused by gun shots and knives.

[0090] If the pneumothorax condition exists, the patient, while in a supine position, will have air between the lung and the inner chest wall during all or part of the respiratory cycle. Thus, when a Doppler probe is positioned to transmit between the ribs at the highest point on the chest, a Doppler signal will be observable during the entire respiratory cycle. However, if there is an absence of this Doppler motion, a pneumothorax condition is highly likely. The region posterior to the rib cage should exhibit no ultrasound reflection due to air blocking the signal. The probe shall be held in place for 10 seconds or one respiratory cycle, whichever is longer. Poor transceiver contact or ultrasound blocking by the ribs will be indicated on the display by an arrow or icon. Both right and left lung are scanned by the transceiver.

[0091] If the haemothorax condition exists, the patient, while in a face-down position, will have blood between the lung and the inner chest wall during all or part of the respiratory cycle. Thus, when a Doppler ultrasound transceiver probe is positioned to transmit between the ribs at the lowest point on the chest, a Doppler signal should be present during the entire respiratory cycle. If there is an absence of this Doppler motion, haemothorax is highly likely. The region posterior to the rib cage should exhibit some ultrasound reflection, as there is no blocking of the signal. The operator will place the patient in a caudal positional and measure the lowest point on the ribcage. Each side of the ribcage is measured. A form wedge develops and is used to position the patient while allowing access with the ultrasound instrument. Both right and left lung are scanned by the transceiver.

[0092] Another particular embodiment of BVM 6500 is the DCD372 transceiver programmed to scan the intercostal space for the Doppler signals. Data files would be transmitted to directly to a personal computer or via a network as described in FIGURES 18-

20 below. Calculations and analytical results are displayed in output reports similar to those shown in the exemplary illustrations of FIGURES 9A-10B and 21A-25J below.

[0093] The output reports are configured to determine the presences of three lung physiological states—normal or non-pathological state, a pathological pneumothorax state, and a pathological haemothorax state. For determining the presence of pneumothorax the right side and left side color Doppler image of lung interface readings are obtained to establish a non-normal condition, or if normal, the image of the normal sliding action. An arrow is to point to the sliding section from a Doppler Velocity vs. time report. The Doppler Velocity vs. time report may use a graph of Doppler velocity at the interface vs. time for a period of 10 seconds or times other than 10 seconds. For determining the presence of haemothorax, the right side and left side color Doppler Image of lung interface readings are obtained to similar ascertain the presence of a non-normal condition, or if normal, the image of the normal sliding action. An arrow is to point to the sliding section from a Doppler Velocity vs. time report. The Doppler Velocity vs. time report shall consist of a graph of Doppler Velocity at the interface vs. time for a period of 10 seconds or times other than 10 seconds.

[0094] Scanning frequencies and ultrasound transceiver configurations are varied for the purposes of optimizing the detection of a pneumothorax by enhancing the abilities to detect lung motion or sliding during respiratory cycles. A 3.5 to 5 MHz convex array transducer or linear transducer can be use in detecting pneumothorax. However, a 5 MHz convex array transducer was preferred because it provides a good compromise between resolution and penetration. Furthermore, 5MHz convex array transducer will able to visualize the various horizontal and vertical artifacts that are mostly associated with normal lung US and simultaneously good penetration to the deeper layers. Moreover, a curved surface of the transducer will facilitate better for scanning between the intercostal spaces.

[0095] Scanning resolution was defined to be 4mm and the acoustic focus designed to visualize the pleural interface at approximately 4 cm depth. The transceiver depth of field was adjusted to approximately 5cm with a 10cm view window to optimize detection of the “comet-tail” artifact. Ultrasound penetration was set to approximately 7cm. Scanning times for a chest ultrasound examination for pneumothorax was approximately 4 minutes.

[0096] Two study subjects received the ultrasound exams using the BVM 6500 was and Sonosite 180 ultrasound instruments at acoustical windows 1 and 2. Ultrasound images were obtained using Sonosite 180 ultrasound machine with both 10-5 MHz linear array transducer and 5-2 MHz convex array transducer. Images were obtained on two subjects in longitudinal plane with the probe placement being between the 3rd and 4th intercostal space and near the clavicle.

[0097] FIGURE 9A presents an ultrasound images obtained on Subject #1 with a 5-2 Mhz convex array transducer using the Sonosite 180 ultrasound transceiver device near the clavicle to the right of midline with Subject #1 in the supine position and presenting normal respiration during scanning. The ribs, rib shadows, pleural line and comet-tail artifact are visible.

[0098] FIGURES 9B present ultrasound images obtained on Subject #1 with a 5-2 Mhz convex array transducer using the Sonosite 180 ultrasound transceiver device between the 3rd and 4th intercostal spaces to right of midline with Subject #1 in the supine position and presenting normal respiration during scanning. The ribs, rib shadows, pleural line and comet-tail artifact are visible.

[0099] FIGURE 10A presents an ultrasound images obtained on Subject #1 with a 5-10 Mhz convex array transducer using the Sonosite 180 ultrasound transceiver device near the clavicle to the right of midline with Subject #1 in the supine position and presenting normal respiration during scanning. The ribs, rib shadows, pleural line and comet-tail artifact are visible.

[00100] FIGURES 10B present ultrasound images obtained on Subject #1 with a 5-10 Mhz convex array transducer using the Sonosite 180 ultrasound transceiver device between the 3rd and 4th intercostal spaces to right of midline with Subject #1 in the supine position and presenting normal respiration during scanning. The ribs, rib shadows, pleural line and comet-tail artifact are visible.

[00101] FIGURES 11A-D depicts a partial schematic and partial isometric view of a transceiver, a scan cone array of scan planes, and a scan plane of the array.

[00102] FIGURE 11A depicts a transceiver 10A having an ultrasound transducer housing 18 and a transceiver dome 20 from which ultrasound energy emanates to probe a patient or subject. Information from ultrasound echoes returning from the probing ultrasound is presented on the display 14. The information may be alphanumeric, pictorial, and describe positional locations of a targeted organ or ROI.

[00103] FIGURE 11B is a graphical representation of a plurality of scan planes 42 that contain the probing ultrasound. The plurality of scan planes 42 defines a scan cone 40 in the form of a three-dimensional (3D) array having a substantially conical shape that projects outwardly from the dome 20 of the transceivers 10A.

[00104] The plurality of scan planes 42 are oriented about an axis 11 extending through the transceivers 10A. One or more, or alternately each of the scan planes 42 are positioned about the axis 11, which may be positioned at a predetermined angular position θ . The scan planes 42 are mutually spaced apart by angles θ_1 and θ_2 whose angular value may vary. That is, although the angles θ_1 and θ_2 to θ_n are depicted as approximately equal, the θ angles may have different values. Other scan cone configurations are possible. For example, a wedge-shaped scan cone, or other similar shapes may be generated by the transceiver 10A.

[00105] FIGURE 11C is a graphical representation of a scan plane 42. The scan plane 42 includes the peripheral scan lines 44 and 46, and an internal scan line 48

having a length r that extends outwardly from the transceivers 10A and between the scan lines 44 and 46. Thus, a selected point along the peripheral scan lines 44 and 46 and the internal scan line 48 may be defined with reference to the distance r and angular coordinate values ϕ and θ . The length r preferably extends to approximately 18 to 20 centimeters (cm), although other lengths are possible. Particular embodiments include approximately seventy-seven scan lines 48 that extend outwardly from the dome 20, although any number of scan lines may be used.

[00106] FIGURE 11D a graphical representation of a plurality of scan lines 48 emanating from the ultrasound transceiver forming a single scan plane 42 extending through a cross-section of portions of an internal bodily organ. The scan plane 42 is fan-shaped, bounded by peripheral scan lines 44 and 46, and has a semi-circular dome cutout 41. The number and location of the internal scan lines emanating from the transceivers 10A within a given scan plane 42 may be distributed at different positional coordinates about the axis line 11 as required to sufficiently visualize structures or images within the scan plane 42. As shown, four portions of an off-centered region-of-interest (ROI) are exhibited as irregular regions 49 of the internal organ. Three portions are viewable within the scan plane 42 in totality, and one is truncated by the peripheral scan line 44.

[00107] As described above, the angular movement of the transducer may be mechanically effected and/or it may be electronically or otherwise generated. In either case, the number of lines 48 and the length of the lines may vary, so that the tilt angle ϕ (FIGURE 11C) sweeps through angles approximately between -60° and $+60^\circ$ for a total arc of approximately 120° . In one particular embodiment, the transceiver 10A is configured to generate approximately about seventy-seven scan lines between the first limiting scan line 44 and a second limiting scan line 46. In another particular embodiment, each of the scan lines has a length of approximately about 18 to 20 centimeters (cm). The angular separation between adjacent scan lines 48 (FIGURE 11B) may be uniform or non-uniform. For

example, and in another particular embodiment, the angular separation ϕ_1 and ϕ_2 to ϕ_n (as shown in FIGURE 1B) may be about 1.5° . Alternately, and in another particular embodiment, the angular separation ϕ_1, ϕ_2, ϕ_n may be a sequence wherein adjacent angles are ordered to include angles of $1.5^\circ, 6.8^\circ, 15.5^\circ, 7.2^\circ$, and so on, where a 1.5° separation is between a first scan line and a second scan line, a 6.8° separation is between the second scan line and a third scan line, a 15.5° separation is between the third scan line and a fourth scan line, a 7.2° separation is between the fourth scan line and a fifth scan line, and so on. The angular separation between adjacent scan lines may also be a combination of uniform and non-uniform angular spacings, for example, a sequence of angles may be ordered to include $1.5^\circ, 1.5^\circ, 7.2^\circ, 14.3^\circ, 20.2^\circ, 8.0^\circ, 8.0^\circ, 8.0^\circ, 4.3^\circ, 7.8^\circ$, and so on.

[00108] FIGURE 12 depicts a partial schematic and partial isometric and side view of a transceiver 10B, and a scan cone array 30 comprised of 3D-distributed scan lines. Each of the scan lines have a length r that projects outwardly from the transceiver 10B. As illustrated the transceiver 10B emits 3D-distributed scan lines within the scan cone 30 that are one-dimensional ultrasound A-lines. Taken as an aggregate, these 3D-distributed A-lines define the conical shape of the scan cone 30. The ultrasound scan cone 30 extends outwardly from the dome 20 of the transceiver 10B and centered about the axis line 11 (FIGURE 11B). The 3D-distributed scan lines of the scan cone 30 include a plurality of internal and peripheral scan lines that are distributed within a volume defined by a perimeter of the scan cone 30. Accordingly, the peripheral scan lines 31A-31F define an outer surface of the scan cone 30, while the internal scan lines 34A-34C are distributed between the respective peripheral scan lines 31A-31F. Scan line 34B is generally collinear with the axis 11, and the scan cone 30 is generally and coaxially centered on the axis line 11.

[00109] The locations of the internal and peripheral scan lines may be further defined by an angular spacing from the center scan line 34B and between internal and peripheral scan lines. The angular spacing between scan line 34B and peripheral or internal

scan lines are designated by angle Φ and angular spacings between internal or peripheral scan lines are designated by angle \emptyset . The angles Φ_1 , Φ_2 , and Φ_3 respectively define the angular spacings from scan line 34B to scan lines 34A, 34C, and 31D. Similarly, angles \emptyset_1 , \emptyset_2 , and \emptyset_3 respectively define the angular spacing between scan line 31B and 31C, 31C and 34A, and 31D and 31E.

[00110] With continued reference to FIGURE 12, the plurality of peripheral scan lines 31A-E and the plurality of internal scan lines 34A-D are three dimensionally distributed A-lines (scan lines) that are not necessarily confined within a scan plane, but instead may sweep throughout the internal regions and along the periphery of the scan cone 30. Thus, a given point within the scan cone 30 may be identified by the coordinates r , Φ , and \emptyset whose values generally vary. The number and location of the internal scan lines 34A-D emanating from the transceiver 10B may thus be distributed within the scan cone 30 at different positional coordinates as required to sufficiently visualize structures or images within a region of interest (ROI) in a patient. The angular movement of the ultrasound transducer within the transceiver 10B may be mechanically effected, and/or it may be electronically generated. In any case, the number of lines and the length of the lines may be uniform or otherwise vary, so that angle Φ may sweep through angles approximately between -60° between scan line 34B and 31A, and $+60^\circ$ between scan line 34B and 31B. Thus, the angle Φ may include a total arc of approximately 120° . In one embodiment, the transceiver 10B is configured to generate a plurality of 3D-distributed scan lines within the scan cone 30 having a length r of approximately 18 to 20 centimeters (cm).

[00111] FIGURE 13 depicts image acquisition in a series of translational acquired scan plane images using a transceiver 10C having Doppler-speaker circuit 15.

[00112] FIGURE 14 depicts image acquisition in a series of fan orientated acquired scan plane images using a transceiver 10D having Doppler-speaker circuit 15.

[00113] FIGURE 15 depicts the transceiver 10A (FIGURE 1) removably positioned in a communications cradle 50A that is operable to communicate the data wirelessly uploaded to the computer or other microprocessor device (not shown). The data is uploaded securely to the computer or to a server via the computer where it is processed by lung imaging processes described below. The transceiver 10B may be similarly housed in the cradle 50A. In this wireless embodiment, the cradle 50A has circuitry that receives and converts the informational content of the scan cone 40 or scan cone 30 to a wireless signal 50A-2.

[00114] FIGURE 16 depicts the transceiver 10A removably positioned in a communications cradle 50B where the data is uploaded by an electrical connection 50B-2 to the computer or other microprocessor device (not shown). The data is uploaded securely to the computer or to a server via the computer where it is processed by lung imaging processes described below. The transceiver 10B may be similarly removably positioned in the cradle 50B. In this embodiment, the cradle 50B has circuitry that receives and converts the informational content of the scan cone 40 or the scan cone 30 to a non-wireless signal that is conveyed in conduit 50B-2 capable of transmitting electrical, light, or sound-based signals. A particular electrical embodiment of conduit 50B-2 may include a universal serial bus (USB) in signal communication with a microprocessor-based device.

[00115] FIGURE 17 depicts acquisition between the 3rd and 4th intercostal spaces to right of midline using the BVM 6500 transceiver devices 10A-D or the Sonosite 180 transceiver. Alternatively these device may acquine clavicle view at the second acoustic window.

[00116] FIGURE 18 illustrates system 60A for beginning of acquiring 1D, 2D, and/or 3D data sets acquired during 3D transthoracic procedures. The ultrasound energy from single scan plane or BVM 6500 devices equipped to scan in 1D, 2D, and/or 3D do so at a variety of ultrasound frequencies. The frequencies include 5-2 MHz and 5-10MHz as a

convex array transducer using a Sonosite 180 transceiver, or alternatively the BVM 6500 transceiver 10A-D, wherein a focused 3.7 MHz single element transducer is used that is steered mechanically to acquire a 120-degree scan cone 42.

[00117] As shown, the transceiver 10A-D and/or is placed at the first acoustical window with the scan head 20 aimed slightly between the 3rd and 4th intercostal space to the right of midline. Alternatively, the convex array transducer using a Sonosite 180 transceiver is placed at the first acoustical window for image acquisition. Similarly, the transceiver 10A-D and Sonosite 180 is placed at the second acoustical window defined as the near the clavicle to the right of midline. For reference, the heart is shown beneath the sternum and rib cage as in a dashed outline. After the 1D, 2D, and/or 3D data scans are complete, the display 16 on the devices 10A-D displays aiming information in the form of arrows, or alternatively, by sound maxima arising from Doppler shifts. A flashing arrow indicates to the user to point the device in the arrow's direction. The scan is repeated until the device displays only a solid arrow or no arrow. The display 16 on the device may also display the calculated ventricular or atrial chamber volumes at systole and/or diastole. The aforementioned aiming process is more fully described in U.S. Patent 6,884,217 to McMorro et al., which is incorporated by reference as if fully disclosed herein. Other methods and systems described below incorporate by reference U.S. Patents Nos. 4,926,871; 5,235,985; 6,569,097; 6,110,111; 6,676,605; 7,004,904; and 7,011,059 as if fully disclosed herein.

[00118] The transceiver 10A-D has circuitry that converts the informational content of the scan cones 40/30, translational array 70, or fan array 60 to wireless signal 25C-1 that may be in the form of visible light, invisible light (such as infrared light) or sound-based signals. As depicted, the data is wirelessly uploaded to the personal computer 52 during initial targeting of the heart or other cavity-containing ROI. In a particular embodiment of the transceiver 10A-D, a focused 3.7 MHz single element transducer is used that is steered mechanically to acquire a 120-degree scan cone 42. Wireless signals 25C-2

include echo information that is conveyed to and processed by the image processing algorithm in the personal computer device 52. On a display screen 54 coupled to the computer 52, a scan cone image 40B displays a centered view of the lung 56B.

[00119] The scan protocol for obtaining a ultrasound based lung images begins by placing the transceiver 10A-D or Sonosite 180 transceivers at the first and/or second acoustical window sites for image acquisition. First, second, or three-dimensional ultrasound data is collected upon pressing the scan button on the scanner. After the scan is complete, the display 14 on the device 10A-D displays aiming information in the form of arrows. A flashing arrow indicates to the user to point the device in the arrow's direction and rescan. The scan is repeated until the device displays only a solid arrow or no arrow. The display 16 on the device may also display the calculated blood pool volumes of an apparent haemothorax. The aforementioned aiming process is more fully described in U.S. Patent 6,884,217 to McMorrow et al., which is incorporated by reference as if fully disclosed herein.

[00120] FIGURE 19 is a schematic illustration and partial isometric view of a network connected ultrasound system 100 in communication with ultrasound imaging systems 60A-D. System 60B is a wired version of 60A. System 60C is a wireless cradle in communication with computer 52, and System 70 is a wired cradle in communication with computer 52. The system 100 includes one or more personal computer devices 52 that are coupled to a server 56 by a communications system 55. The devices 52 are, in turn, coupled to one or more ultrasound transceivers, for examples the systems 70A-70D. The server 56 may be operable to provide additional processing of ultrasound information, or it may be coupled to still other servers (not shown in FIGURE 18) and devices, for examples transceivers 10A or 10B equipped with snap on collars having an inertial reference system that may employ at least one accelerometer 22 to determine the translational component of

the location coordinates and at least one gyroscope 23 to determine the rotational component of the location coordinates.

[00121] FIGURE 20 is a schematic illustration and partial isometric view of an Internet connected ultrasound system 110 in communication with ultrasound imaging systems 60A-D. The Internet system 110 is coupled or otherwise in communication with the systems 60A-60D. The system 110 may also be in communication with the transceiver 10A or 10B having inertial reference capability as described above.

[00122] FIGURES 21A-J present ultrasound images obtained on Subject #1 using the BVM 6500 transceiver device between the 3rd and 4th intercostal spaces to right of midline with subject #1 in the supine position and presenting normal respiration during scanning. The prominence of the comet-tail artifacts vary with the 2D scanplanes within the 3D acquired images. Panels A-C and E-J show moderately penetrating comet tails, whereas panels D and I the comet-tails penetrate more deeply. Panels H and J are respective magnifications of the enclosed squares of panels G and I.

[00123] FIGURES 22A-J present ultrasound images obtained on Subject #1 using the BVM 6500 transceiver device near the clavicle to the right of midline with subject #1 in the supine position and presenting normal respiration during scanning. The prominence of the comet-tail artifacts vary with the 2D scanplanes within the 3D acquired images. Panel A the comet-tail deeply penetrates the scanplane, with only slight to moderate penetration in the remaining panels. Panels H and J are respective magnifications of the enclosed squares of panels G and I.

[00124] FIGURE 23A presents an ultrasound images obtained on Subject #2 using a 5-2 Mhz convex array transducer using the Sonosite 180 ultrasound transceiver device near the clavicle to the right of midline with Subject #2 in the supine position and presenting normal respiration during scanning. The ribs, rib shadows, pleural line and comet-tail artifact are visible.

[00125] FIGURES 23B present ultrasound images obtained on Subject #2 using a 5-2 Mhz convex array transducer using the Sonosite 180 ultrasound transceiver device between the 3rd and 4th intercostal spaces to right of midline with Subject #2 in the supine position and presenting normal respiration during scanning. The ribs, rib shadows, pleural line and comet-tail artifact are visible.

[00126] FIGURE 24A presents an ultrasound images obtained on Subject #2 using a 5-10 Mhz convex array transducer using the Sonosite 180 ultrasound transceiver device near the clavicle to the right of midline with Subject #2 in the supine position and presenting normal respiration during scanning. The ribs, rib shadows, pleural line and comet-tail artifact are visible.

[00127] FIGURES 24B present ultrasound images obtained on Subject #2 using a 5-10 Mhz convex array transducer using the Sonosite 180 ultrasound transceiver device between the 3rd and 4th intercostal spaces to right of midline with Subject #2 in the supine position and presenting normal respiration during scanning. The ribs, rib shadows, pleural line and comet-tail artifact are visible.

[00128] FIGURES 25A-J present ultrasound images obtained on Subject #2 using the BVM 6500 transceiver device between the 3rd and 4th intercostal spaces to right of midline with subject #2 in the supine position and presenting normal respiration during scanning. The prominence and number of the comet-tail artifacts vary with the 2D scanplanes within the 3D acquired images. Panels A-B and F-G show more than one comet-tail, each varying in intensity and depth. Panels H and J are respective magnifications of the enclosed squares of panels G and I.

[00129] Methods and systems to acquire an ultrasound lung echoic scan line data and images for determining blood accumulation in the thoracic cage. In general the ultrasound system and method employs A-mode scanning to generate echogenic histogram patterns to discern whether a lung has an echogenic pattern indicative of a normal lung or

that indicative of a pneumothorax or a haemothorax. The A-mode scanning may be of single scan-lines or multiple scan-lines. Multiple scan-lines may also be confined within a two-dimensional scanplane, an array of two-dimensional scanplanes, or as a three-dimensional distribution of scan-lines.

[00130] In one particular embodiment, a subject or patient is scanned using an A-line specific ultrasound transceiver for detection of lung interfaces. In another embodiment, a transceiver similar to the BladderScan[®] BVM6500 marketed by Diagnostic Ultrasound Incorporated of Redmond, Washington provides an ultrasound sound image in the form of a three-dimensional scan cone, the scan cone being comprised of scan planes having a plurality of A-line scanlines. Other embodiments include the BVM6500 having color Doppler abilities and/or the BVM further modified to have a Doppler–speaker circuit to assist in transceiver aiming. The 3D scan cone provides images of the ultrasound-probed region of interest (ROI) of the lung in the form of a rotational 2D scan plane array referred to as a V-mode[®] image or images. The V-mode[®] images may also be include wedge, translational arrays, and images made from 3-D randomly distributed scanlines as shown below.

[00131] Once the scans are complete, signals received from returning echoic pulses in the single, two, and/or three-dimensional scans may be communicated directly to a dedicated computer or transmitted securely to a server computer coupled to a local or Internet-based network. In either the local computer or network connected computers, image processing algorithms executed by the upon the signals to analyze A-line intensity patterns of echoes contained within a 1D scan line, a 2D plane collection of scan lines, or a portion of a 3D image having a series of defined planes, each plane having a set of scan lines, or a 3D image comprised of a randomly distributed series of A-line scan lines.

[00132] FIGURE 101 is a partial isometric of the thoracic region depicting acoustic windows (a first acoustical window look (“first look”) defined to be between the 3rd

and 4th intercostal spaces to right of midline and a second acoustical look (“second look”) defined to be near the clavicle to the right of midline) for placing ultrasound transceivers for image acquisition and/or A-line scanning. Other acoustical windows may be selected along the thoracic cage that provide a clear ultrasonic view of the lung in which an ultrasonic wave pulse sets 6 (see FIGURES 103, 105, 107A-108 below) in the form of single A-lines, plane confined plurality of A-lines, or randomly distributed 3D A-line scan lines are not blocked by ribs or other echo reflective structures.

[00133] FIGURE 102 schematically depicts a cross section of the human lung under a tension pneumothorax pathological condition. Tension pneumothorax can occur without any prior lung conditions or diseases, but commonly results from the rupture of a bleb or from frank trauma caused by a stab or bullet wound. Air and/or blood escapes, enters the chest cavity, accumulates and pools (curved arrows, right lung) that causes the lung to collapse or be compressed against the chest wall.

[00134] FIGURE 103 is a schematic illustration of a pneumothorax-haemothorax detection system scanning a normal lung. The pneumothorax-haemothorax detection system 1 comprises an ultrasound transceiver 2 in signal communication with a computer system 4 having a display (not shown). The ultrasound transceiver 2 may be an A-mode transceiver probe configured to deliver an ultrasonic wave pulse set 6 to the thoracic cavity and lung. As shown the wave pulse set 6 is shown as a series of horizontal bars that represents radiofrequency pulsed ultrasound that may be substantially confined to a linear pathway. The ultrasound may be radiofrequency pulsed in the wave pulse set 6 may with frequencies of approximately 2-10 MHz that may be substantially directed along a linear pathway. The wave pulse set 6 may also be configured as a plurality of scan lines confined to a scan plane (see FIGURE 107A-107D) or as a conic array of randomly distributed 3D scan lines (see FIGURE 108). The wave pulse set may be aimed between bones so that a clear

view of the lungs is obtained. Ultrasound echoes of the wave set 6 return to the transceiver 2. Signals from the echoes may be conveyed to the computer 4 for analysis and data processing.

[00135] FIGURE 104 presents a normal lung A-line histogram of echo strength plotted against time t or depth. The computer 4 includes a display that presents the normal lung A-line histogram. In this case, a single lung capacity interface may be seen at ≤ 4 cm.

[00136] FIGURE 105 is a schematic illustration of the pneumothorax-haemothorax detection system scanning an injured lung. The injured lung may be similar to that depicted in FIGURE 102 in which a penetrating knife or gunshot wound causes frank trauma and leaks air and/or blood into the thoracic cavity. In this case, the ultrasound wave pulse set 6 traverses through a blood pool (pictographically represented as an oval region of blood cells) that compresses the lung in a convex pattern away from the rib cage. Signals from the echoes may be conveyed to the computer 4 for analysis and data processing to determine the presence of an air (pneumothorax) and/or blood pool (haemothorax).

[00137] FIGURE 106 presents an injured lung A-line histogram of echo strength plotted against time t or depth. The computer 4 includes a display that presents the normal lung A-line histogram. In this case, two lung interfaces having strong echogenic spikes or maxima may be seen at ≤ 4 cm, the lung capacity interface, and ≥ 10 cm, a lung-blood interface, with a low echogenic basin of approximately 6 cm separating the lung capacity and lung-blood interfaces. The time or distance of the lung capacity interface, the lung-blood interface, the echogenic basin or low echogenic plateau between the interfaces may vary with the anatomical location of injury, the severity of the injury within the lung or thoracic cavity, and with the physical size of the subject undergoing examination. This low echogenic basin may represent an air cavity of a pneumothorax, a blood pooling of a haemothorax, or a combined cavity and pooling of a pneumothorax-haemothorax.

[00138] FIGURES 107A-D depicts a partial schematic and partial isometric view of a transceiver, a scan cone array of scan planes, and a scan plane of the array.

[00139] FIGURE 107A depicts a transceiver 10A having an ultrasound transducer housing 18 and a transceiver dome 20 from which ultrasound energy emanates to probe a patient or subject. Information from ultrasound echoes returning from the probing ultrasound may be presented on the display 16. The information may be alphanumeric, pictorial, and describe positional locations of a targeted organ or ROI. In alternate embodiments, the display 16 may also present the normal and injured lung histograms depicted in FIGURES 104 and 106.

[00140] FIGURE 107B is a graphical representation of a plurality of scan planes 42 that contain the probing ultrasound. The plurality of scan planes 42 defines a scan cone 40 in the form of a three-dimensional (3D) array having a substantially conical shape that projects outwardly from the dome 20 of the transceivers 10A.

[00141] The pluralities of scan planes 42 may be oriented about an axis 11 extending through the transceivers 10A. One or more, or alternately each of the scan planes 42 may be positioned about the axis 11, which may be positioned at a predetermined angular position θ . The scan planes 42 may be mutually spaced apart by angles θ_1 and θ_2 whose angular value may vary. That is, although the angles θ_1 and θ_2 to θ_n are depicted as approximately equal, the θ angles may have different values. Other scan cone configurations are possible. For example, a wedge-shaped scan cone, or other similar shapes may be generated by the transceiver 10A.

[00142] FIGURE 107C is a graphical representation of a scan plane 42. The scan plane 42 includes the peripheral scan lines 44 and 46, and an internal scan line 48 having a length r that extends outwardly from the transceivers 10A and between the scan lines 44 and 46. Thus, a selected point along the peripheral scan lines 44 and 46 and the internal scan line 48 may be defined with reference to the distance r and angular coordinate values ϕ and θ . The length r preferably extends to approximately 18 to 20 centimeters (cm), although other lengths are possible. Particular embodiments include approximately seventy-

seven scan lines 48 that extend outwardly from the dome 20, although any number of scan lines may be used.

[00143] FIGURE 107D a graphical representation of a plurality of scan lines 48 emanating from the ultrasound transceiver forming a single scan plane 42 extending through a cross-section of portions of an internal bodily organ. The scan plane 42 may be fan-shaped, bounded by peripheral scan lines 44 and 46, and has a semi-circular dome cutout 41. The number and location of the internal scan lines emanating from the transceivers 10A within a given scan plane 42 may be distributed at different positional coordinates about the axis line 11 as may be required to sufficiently visualize structures or images within the scan plane 42. As shown, four portions of an off-centered region-of-interest (ROI) are exhibited as irregular regions 49 of the internal organ. Three portions may be viewable within the scan plane 42 in totality, and one may be truncated by the peripheral scan line 44.

[00144] As described above, the angular movement of the transducer may be mechanically effected and/or it may be electronically or otherwise generated. In either case, the number of lines 48 and the length of the lines may vary, so that the tilt angle ϕ (FIGURE 111C) sweeps through angles approximately between -60° and $+60^\circ$ for a total arc of approximately 120° . In one particular embodiment, the transceiver 10A may be configured to generate approximately about seventy-seven scan lines between the first limiting scan line 44 and a second limiting scan line 46. In another particular embodiment, each of the scan lines has a length of approximately about 18 to 20 centimeters (cm). The angular separation between adjacent scan lines 48 (FIGURE 107B) may be uniform or non-uniform. For example, and in another particular embodiment, the angular separation ϕ_1 and ϕ_2 to ϕ_n (as shown in FIGURE 107B) may be about 1.5° . Alternately, and in another particular embodiment, the angular separation ϕ_1 , ϕ_2 , ϕ_n may be a sequence wherein adjacent angles may be ordered to include angles of 1.5° , 6.8° , 15.5° , 7.2° , and so on, where a 1.5° separation may be between a first scan line and a second scan line, a 6.8° separation may be between the

second scan line and a third scan line, a 15.5° separation may be between the third scan line and a fourth scan line, a 7.2° separation may be between the fourth scan line and a fifth scan line, and so on. The angular separation between adjacent scan lines may also be a combination of uniform and non-uniform angular spacings, for example, a sequence of angles may be ordered to include 1.5° , 1.5° , 1.5° , 7.2° , 14.3° , 20.2° , 8.0° , 8.0° , 8.0° , 4.3° , 7.8° , and so on.

[00145] FIGURE 108 depicts a partial schematic and partial isometric and side view of a transceiver 10B, and a scan cone array 30 comprised of 3D-distributed scan lines. Each of the scan lines have a length r that projects outwardly from the transceiver 10B. As illustrated the transceiver 10B emits 3D-distributed scan lines within the scan cone 30 that may be one-dimensional ultrasound A-lines. Taken as an aggregate, these 3D-distributed A-lines define the conical shape of the scan cone 30. The ultrasound scan cone 30 extends outwardly from the dome 20 of the transceiver 10B and centered about the axis line 11 (FIGURE 107B). The 3D-distributed scan lines of the scan cone 30 include a plurality of internal and peripheral scan lines that may be distributed within a volume defined by a perimeter of the scan cone 30. Accordingly, the peripheral scan lines 31A-31F define an outer surface of the scan cone 30, while the internal scan lines 34A-34C may be distributed between the respective peripheral scan lines 31A-31F. Scan line 34B may be generally collinear with the axis 11, and the scan cone 30 may be generally and coaxially centered on the axis line 11.

[00146] The locations of the internal and peripheral scan lines may be further defined by an angular spacing from the center scan line 34B and between internal and peripheral scan lines. The angular spacing between scan line 34B and peripheral or internal scan lines are designated by angle Φ and angular spacings between internal or peripheral scan lines are designated by angle \emptyset . The angles Φ_1 , Φ_2 , and Φ_3 respectively define the angular spacings from scan line 34B to scan lines 34A, 34C, and 31D. Similarly, angles \emptyset_1 , \emptyset_2 , and

Θ_3 respectively define the angular spacing between scan line 31B and 31C, 31C and 34A, and 31D and 31E.

[00147] With continued reference to FIGURE 108, the plurality of peripheral scan lines 31A-E and the plurality of internal scan lines 34A-D may be three dimensionally distributed A-lines (scan lines) that are not necessarily confined within a scan plane, but instead may sweep throughout the internal regions and along the periphery of the scan cone 30. Thus, a given point within the scan cone 30 may be identified by the coordinates r , Φ , and Θ whose values generally vary. The number and location of the internal scan lines 34A-D emanating from the transceiver 10B may thus be distributed within the scan cone 30 at different positional coordinates as may be required to sufficiently visualize structures or images within a region of interest (ROI) in a patient. The angular movement of the ultrasound transducer within the transceiver 10B may be mechanically effected, and/or it may be electronically generated. In any case, the number of lines and the length of the lines may be uniform or otherwise vary, so that angle Φ may sweep through angles approximately between -60° between scan line 34B and 31A, and $+60^\circ$ between scan line 34B and 31B. Thus, the angle Φ may include a total arc of approximately 120° . In one embodiment, the transceiver 10B may be configured to generate a plurality of 3D-distributed scan lines within the scan cone 30 having a length r of approximately 18 to 20 centimeters (cm).

[00148] FIGURE 109 illustrates system 60A for beginning of acquiring 1D, 2D, and/or 3D data sets acquired during 3D trans-thoracic procedures. The ultrasound energy from single scan plane or BVM 6500 devices equipped to scan in 1D, 2D, and/or 3D do so at a variety of ultrasound frequencies. As shown, the transceiver 10A-D and/or may be placed at the first acoustical window with the scan head 20 aimed slightly between the 3rd and 4th intercostal space to the right of midline. Alternatively, other acoustical windows may be used for A-line scanning and/or image acquisition such as the second acoustical window defined as the near the clavicle to the right of midline. For reference, the heart is shown

beneath the sternum and rib cage as in a dashed outline. After the 1D, 2D, and/or 3D data scans are complete, the display 16 on the devices 10A-D displays aiming information in the form of arrows, or alternatively, by sound maxima arising from Doppler shifts. A flashing arrow indicates to the user to point the device in the arrow's direction.

[00149] The transceiver 10A-D has circuitry that converts the informational content of the scan line echoes via a wireless signal 25C-1 that may be in the form of visible light, invisible light (such as infrared light) or sound-based signals. As depicted, the data may be wirelessly uploaded to the personal computer 52 during initial targeting of the heart or other cavity-containing ROI. In a particular embodiment of the transceiver 10A-D, a focused 3.7 MHz single element transducer may be used that may be steered mechanically to acquire a 120-degree scan cone 42. Wireless signals 25C-2 include echo information that may be conveyed to and processed by the image processing algorithm in the personal computer device 52. On a display screen 54 coupled to the computer 52, an injured lung histogram 56B is presented.

[00150] The scan protocol for obtaining a ultrasound based lung images begins by placing the transceiver 10A-D or dedicated A-line transceiver probe against the dermal region having a clear, acoustical view of the lung. Sonic coupling gel may be applied to the skin or alternatively a pad of sonic gel may be inserted between the transducer and the subject's skin to insure efficient conveyance of ultrasound energy to the subject and from the subject. First, second, or three-dimensional ultrasound data may be collected upon pressing the scan button on the scanner. After the scan is complete, the display 16 on the device 10A-D displays aiming information in the form of arrows. A flashing arrow indicates to the user to point the device in the arrow's direction and rescan. The scan may be repeated until the device displays only a solid arrow or no arrow. The display 16 on the device may also display the calculated blood pool volumes of an apparent haemothorax along with the normal or injured thoracic cavity echo histograms as representively illustrated in FIGURES 104 and

106. The aforementioned aiming process is more fully described in U.S. Patent 6,884,217 to McMorrow et al., which is incorporated by reference as if fully disclosed herein.

[00151] FIGURE 110 is a schematic illustration and partial isometric view of a network connected ultrasound system 100 in communication with ultrasound imaging systems 60A-D. System 60B is a wired version of 60A. System 60C may be a wireless cradle in communication with computer 52, and System 70 may be a wired cradle in communication with computer 52. The system 100 includes one or more personal computer devices 52 that may be coupled to a server 56 by a communications system 55. The devices 52 may be, in turn, coupled to one or more ultrasound transceivers, for examples the systems 70A-70D. The server 56 may be operable to provide additional processing of ultrasound information, or it may be coupled to still other servers (not shown in FIGURE 109) and devices, for examples transceivers 10A or 10B equipped with snap on collars having an inertial reference system that may employ at least one accelerometer 22 to determine the translational component of the location coordinates and at least one gyroscope 23 to determine the rotational component of the location coordinates. Displays on the computers 52 illustrate an injured lung histogram similar to that shown in FIGURE 106.

[00152] FIGURE 110 is a schematic illustration and partial isometric view of an Internet connected ultrasound system 110 in communication with ultrasound imaging systems 60A-D. The Internet system 110 may be coupled or otherwise in communication with the systems 60A-60D. The system 110 may also be in communication with the transceiver 10A or 10B having inertial reference capability as described above. Displays on the computers 52 illustrate an injured lung histogram similar to that shown in FIGURE 106.

[00153] System and methods of using a calibrated video laryngoscope to estimate the size of a tracheal orifice are described with reference to the figures below. The estimation may be achieved by the projection of two optical lines separated by a known distance onto a tracheal region from an optical calibrator mounted nearby a camera located

on the blade region of a video laryngoscope. Direct visualization or viewing images having the tracheal region and projected optical lines provide a basis for estimating tracheal opening dimensions in relation to the known distance separating the optical lines.

[00154] The calibrated video laryngoscope includes a blade-located camera and an optical calibrator connected with the camera. The calibrator may be configured to emit visible lines separating by a known distance onto the tracheal region in view of the camera. An image of the tracheal region and lines may be conveyed to a video screen from which the dimension of the tracheal orifice may be estimated by comparing the orifice's diameter to the known separation distance of the two projected lines. The video screen may be analog and connected with the calibrated video laryngoscope or the calibrated video laryngoscope may be connected to a computer system having a monitor in the form of, and not limited to, a cathode ray tube, flat screen display, or liquid crystal display. The endotracheal tubes may be then selected having a size that may be slidably accommodated through the estimated tracheal orifice diameter.

[00155] Embodiments of the calibrated video laryngoscope are described in detail below with reference to the following drawings.

[00156] FIGURE 201 is a schematic depiction of a video laryngoscope system 10. System 10 includes a video laryngoscope 12 in cabled communication 16 with a computer 14 having a screen 15 showing an image of a trachea. The trachea image shows a tracheal opening through which endotracheal tubes must be intubated.

[00157] FIGURE 202 illustrates a video laryngoscope 12 adjacent to two endotracheal tubes 17 and 19 having different diameters. As shown the system 10 does not have a means to allow a calibrated means by which selection of endotracheal tubes can be determined before intubation.

[00158] FIGURE 203 is a schematic illustration of a video laryngoscope 12 having a blade-mounted camera 20. The video laryngoscope 12 includes a handle member 12A and a blade member 12B on which the camera 20 may be mounted and/or embedded.

[00159] FIGURE 204 schematically illustrates an embodiment of an optical calibrator adjacent to a laryngoscope camera. A laser source 30 and a cylindrical lens 32 may be mounted on each side of the camera 20 (one laser source and lens shown). A laser line 36 may be projected from each laser source 30 to provide a pair of laser lines projected onto the a tracheal region in view of the camera 20 at a known distance from each other in all viewing planes. The laser source may include a light emitting diode (LED).

[00160] FIGURE 205 schematically illustrates in a plane view an image of two optical lines projected onto a tracheal region. Two laser lines, 36A and 36B, may be projected onto the tracheal region in view of the camera 20 and flank the tracheal opening by a distance d as captured on image 15. The distance d may be set from the geometrical distance between each laser source 30 and lens 32 that may be mounted on opposite sides of the camera 20. Alternatively, other distances besides d may be obtained, for example d_1 and d_2 depending on the mounted distances separating the lasers/lens 30/32 assemblies that may be mounted at distances other than opposite sides of the camera 20. The tracheal opening dimension may be then determined by ratio calculation of the trachea image diameter to the known image distance d between the laser lines. Software could be configured to identify the trachea in the image, identify the laser lines and compute the tracheal diameter and endotracheal tube size automatically.

[00161] FIGURE 206 is a schematic illustration, not drawn to scale, of an alternate embodiment of a calibrated video laryngoscope system 40. System 40 includes calibrated video laryngoscope 42 to which a camera 20 may be mounted to its blade section. On each side of the camera 20 may be a combination laser lens assembly 50A and 50B, from which laser lines 56A and 56B may be respectively projected onto the tracheal region with a

separation distance d spaced between the lines 56A, 56B. The calibrated video laryngoscope 42 may be in cabled communication 16 with the computer 14 and display 15. On display 15 is seen the tracheal region image having images of the lines 56A, 56B contained therein. Ratio and/or proportion calculation of the measured major and minor axes of the tracheal orifice or opening to that of the known distance d provides determination of the major and minor diameters of the orifice aperture. Endotracheal tube selection to be within the tracheal orifice major and/or minor diameters may be achieved before attempting intubation.

[00162] FIGURE 207 pictographically presents an alternate embodiment of a calibrated video laryngoscope system 70. Substantially similar to the calibrated video laryngoscope system 40, the system 70 may be handheld configured and includes a computer 74 with visual screen 75 that presents a tracheal image. The tracheal image may be obtained from a calibrated video laryngoscope 72 from which visual light lines 72A and 72B may be projected from a laser and lens assembly (not shown) similar to the laser lens assembly 50A and 50B of FIGURE 206. In the tracheal image on screen 75 are images of the laser light lines 72A, 72B from which the tracheal orifices major and minor diameters may be determined by ratio or proportional calculation using the known distance d separating the lines. The calibrated video laryngoscope 70 may be ideal to use in military arenas or by emergency medical teams active in other regions.

[00163] While the particular embodiments have been illustrated and described, many changes can be made without departing from the spirit and scope of the invention. For example, the projected light may be infrared that is made visible by the video monitors or displays. Accordingly, the scope of the invention is not limited by the disclosure of the preferred embodiment. Instead, the invention should be determined entirely by reference to the claims that follow.

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

1. A method of imaging a lung to determine a lung physiologic state comprising:
 - positioning an ultrasound transceiver exterior to a patient such that at least a portion of the lung is viewable by the transceiver at a first location and a second location;
 - transmitting radio frequency ultrasound pulses and receiving echoic pulses corresponding to the transmitted pulses echoed back from external and internal surface portions of the lung at the first and second locations;
 - processing signals associated with the echoic pulses to form a plurality of lung images from the first and second locations; and
 - detecting from the plurality of lung images a status of lung motion for predicting the lung physiological state.
2. The method of claim 1, wherein the status of lung motion includes lung sliding.
3. The method of claim 2, wherein the absence of lung sliding indicates the lung physiological state is a pathological condition.
4. The method of claim 3, wherein the pathological condition includes pleural scarring and adult respiratory distress syndrome.
5. The method of claim 3, wherein the absence of lung sliding and the appearance of an ultrasound comet tail artifact indicates that the pathological condition includes pneumothorax.
6. The method of claim 2, wherein the presence of lung sliding indicates that the lung physiological state is a non-pathological condition.

7. The method of claim 1, wherein the first location near the clavicle to the right of midline.
8. The method of claim 1, wherein the second location is between the third and fourth intercostal space to the right of midline.
9. A method of using ultrasound to detect a physiological condition in a lung comprising:
 - positioning an ultrasound transceiver against the dermas of a subject exterior to the thoracic cage such that at least a portion of the lung is viewable by the transceiver;
 - transmitting radio frequency ultrasound pulses and receiving echoic pulses from external and internal surface portions of the lung and surrounding structures;
 - processing signals associated with the echoic pulses to form a echo histogram;
 - and
 - examining the echo histogram to determine the numerical occurrence of an interface pattern, the echogenic strength of the interface pattern, the location of the interface pattern, and the location of a non-interface pattern.
10. The method of claim 9 wherein when the interface pattern includes two maxima having strong echogenic strengths separated by the non-interface pattern having low echogenic strengths, the physiologic state includes at least one of a pneumothorax and a haemothorax condition.
11. The method of claim 9 wherein when the interface pattern includes a single maxima followed by the non-interface pattern having low echogenic strengths, the physiologic state indicates a normal lung condition.

12. A method of using inserting an endotracheal tube comprising:
 - positioning a video laryngoscope into the buccal cavity of a subject to visualize a tracheal image, the video laryngoscope in signal communication with a computer system having a display the tracheal image and equipped with an optical calibrator;
 - transmitting two visible lines separated by a known distance from the optical calibrator onto the subject's tracheal region;
 - estimating a tracheal orifice dimension by the known distance; and
 - selecting the endotracheal tube having a size that is slidable through the tracheal orifice dimension.
13. The method of claim 12 wherein transmitting two visible lines includes lines defined by a laser source residing in the optical calibrator.
14. A system for inserting an endotracheal tube into a subject's trachea comprising:
 - a video laryngoscope configured to capture an image of the subject's tracheal region;
 - a display in signal communication with the video laryngoscope configured to present the image; and
 - an optical calibrator attached with the video laryngoscope,wherein a pair of visible lines separated by a known distance is projected onto the subject's tracheal region and is presented on the displayed image to provide a means to estimate a tracheal orifice dimension to provide a basis to select the endotracheal having a size amenable to sliding through the tracheal orifice.
15. The system of claim 14, wherein the optical calibrator is attached with the video laryngoscope.

16. The system of claim 14, wherein the two lines are derived from a laser source residing in the optical calibrator.

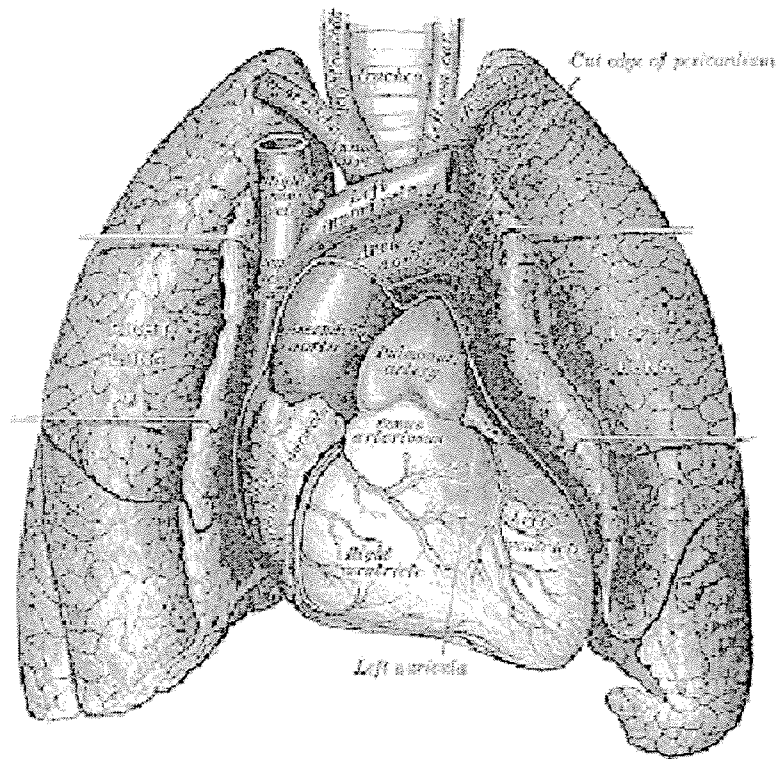


Fig. 1

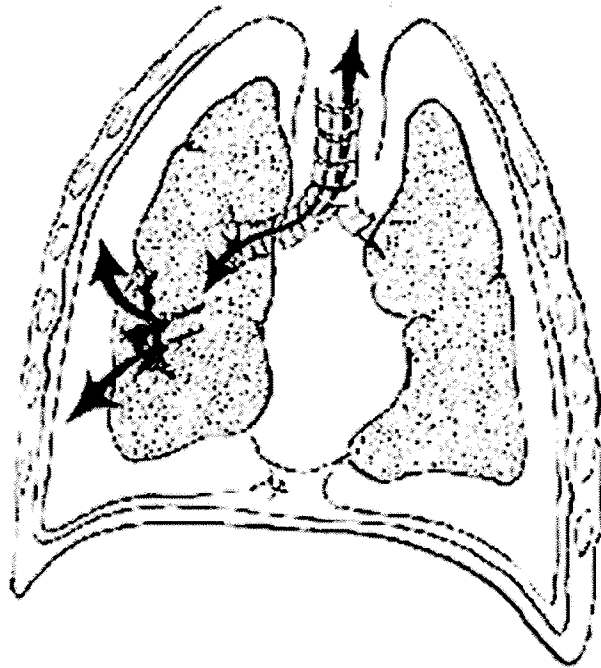


Fig. 2

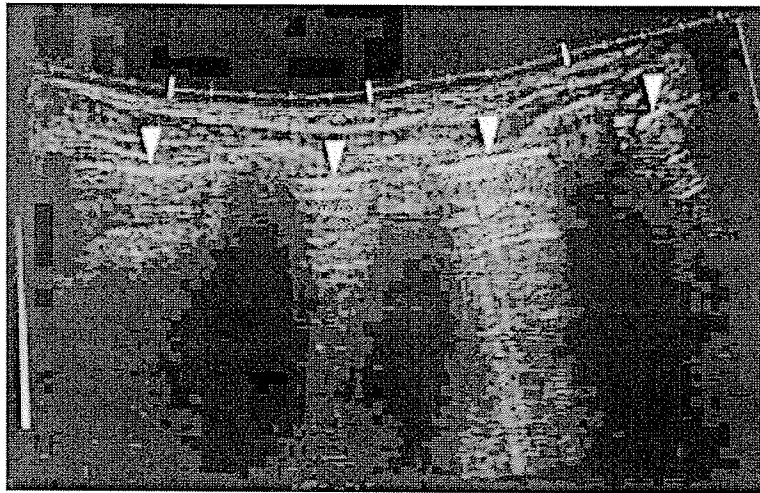


Fig. 3

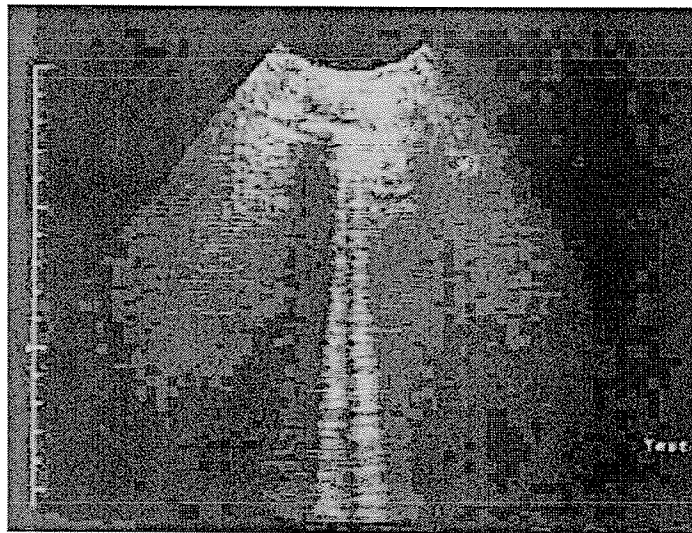


Fig. 4

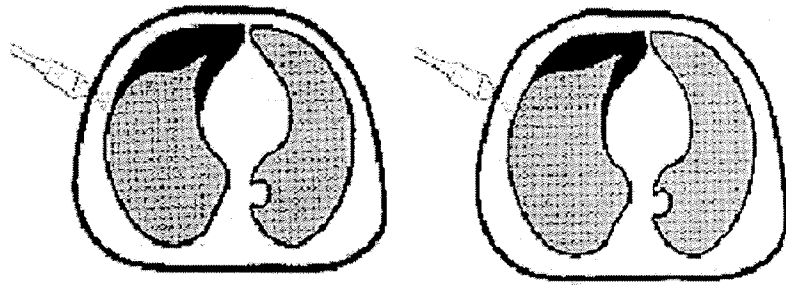


Fig. 5

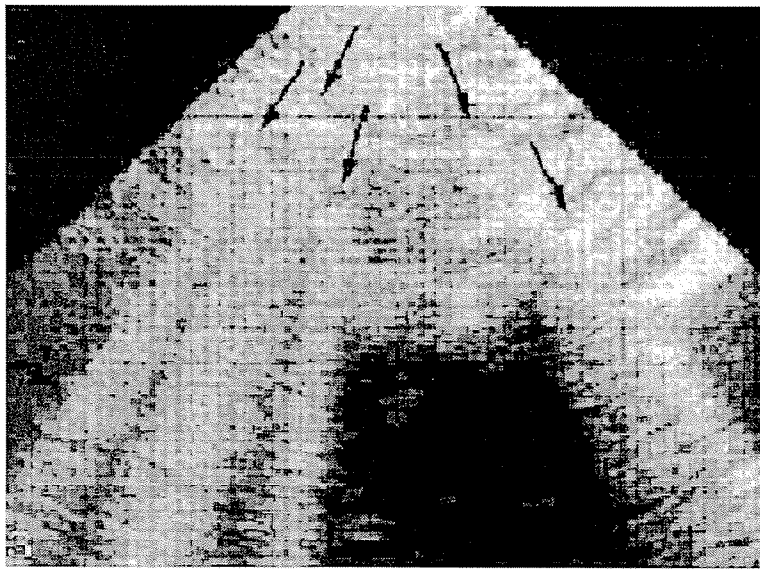


Fig. 6

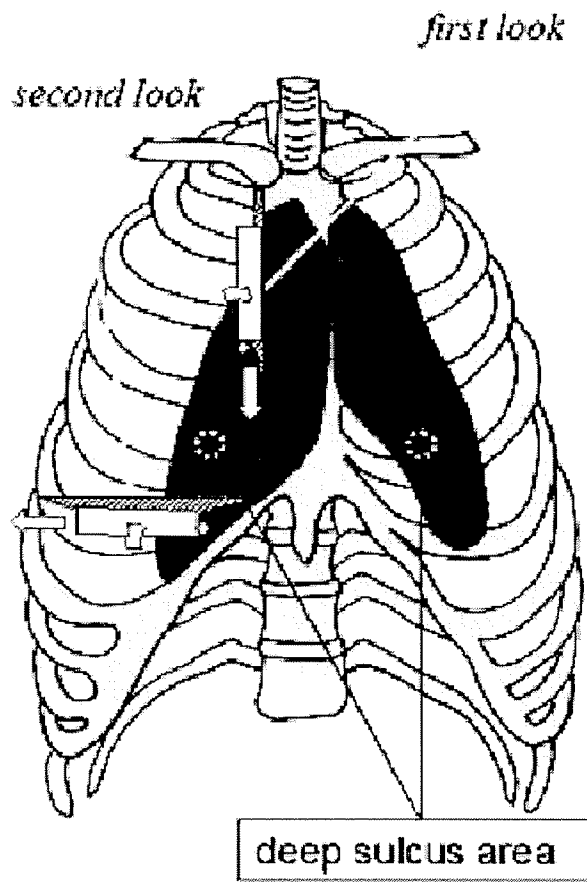


Fig. 7

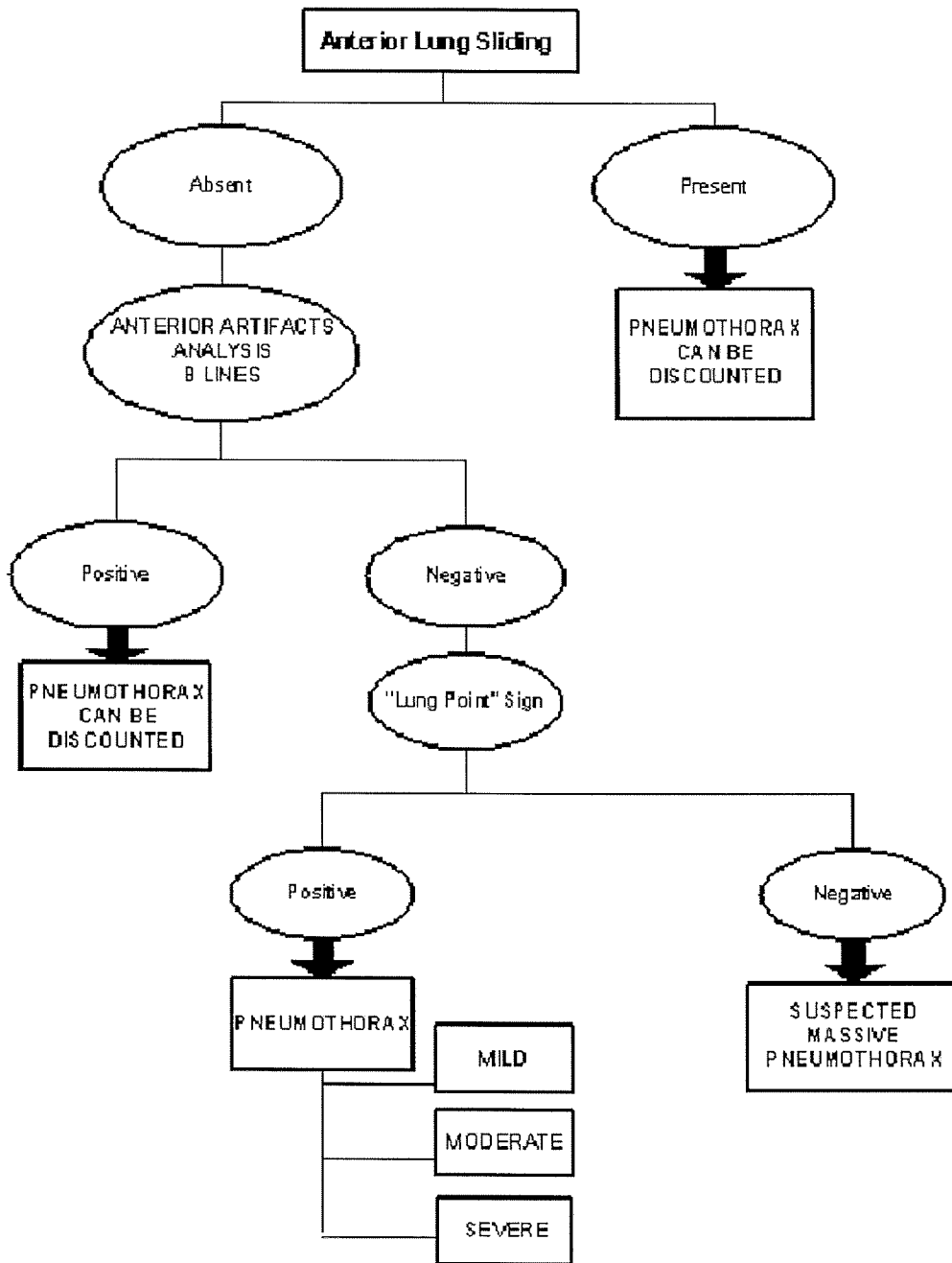
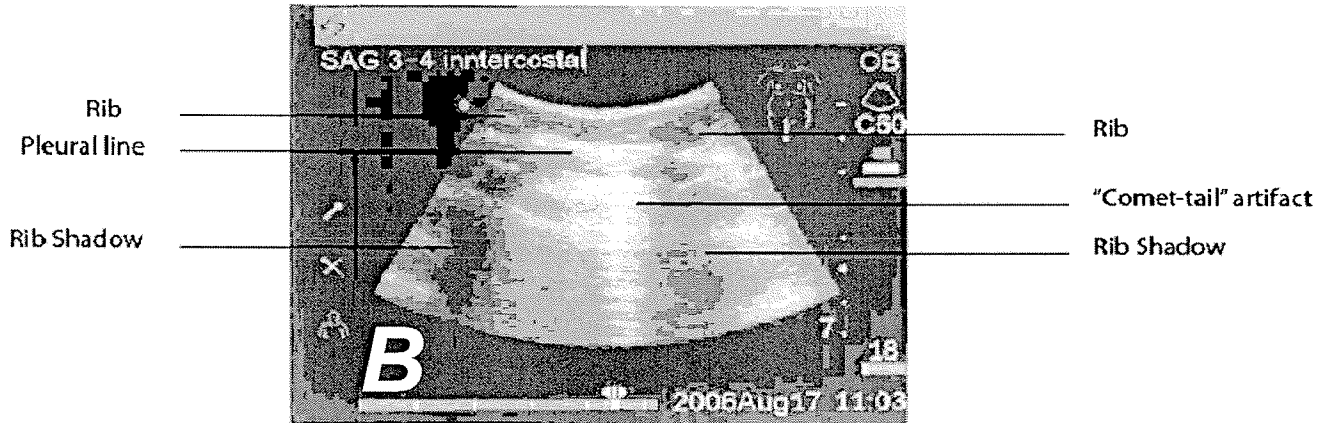


Fig. 8

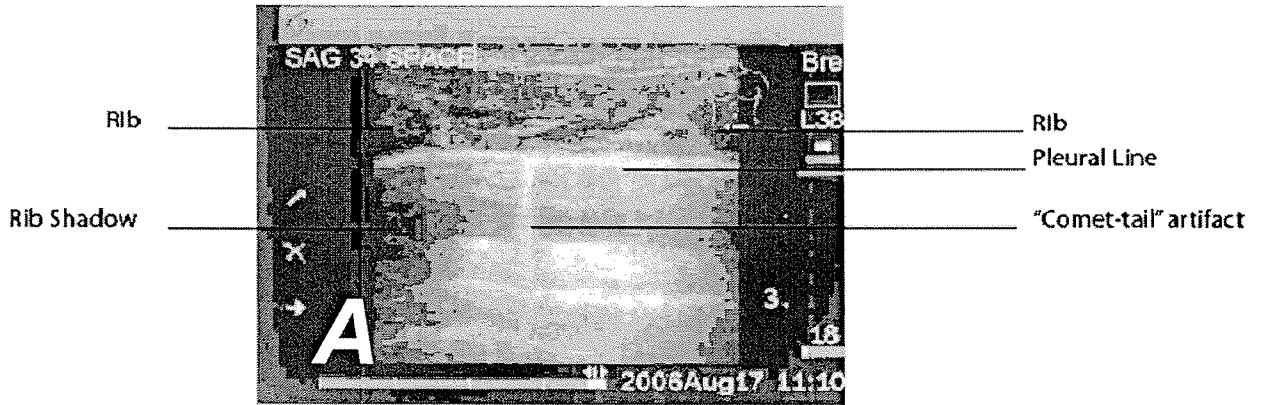


This image was taken near the clavicle to the right of midline. The pleural line is the bright echogenic (horizontal) line

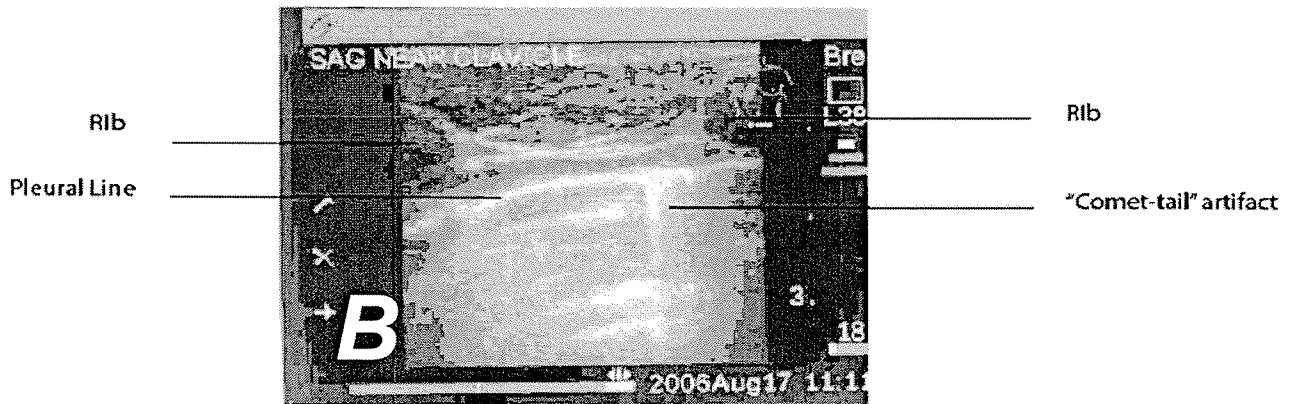


This image was taken between the 3rd and 4th intercostal space to the right of midline. The pleural line is the bright echogenic (horizontal) line.

Figs. 9A-B

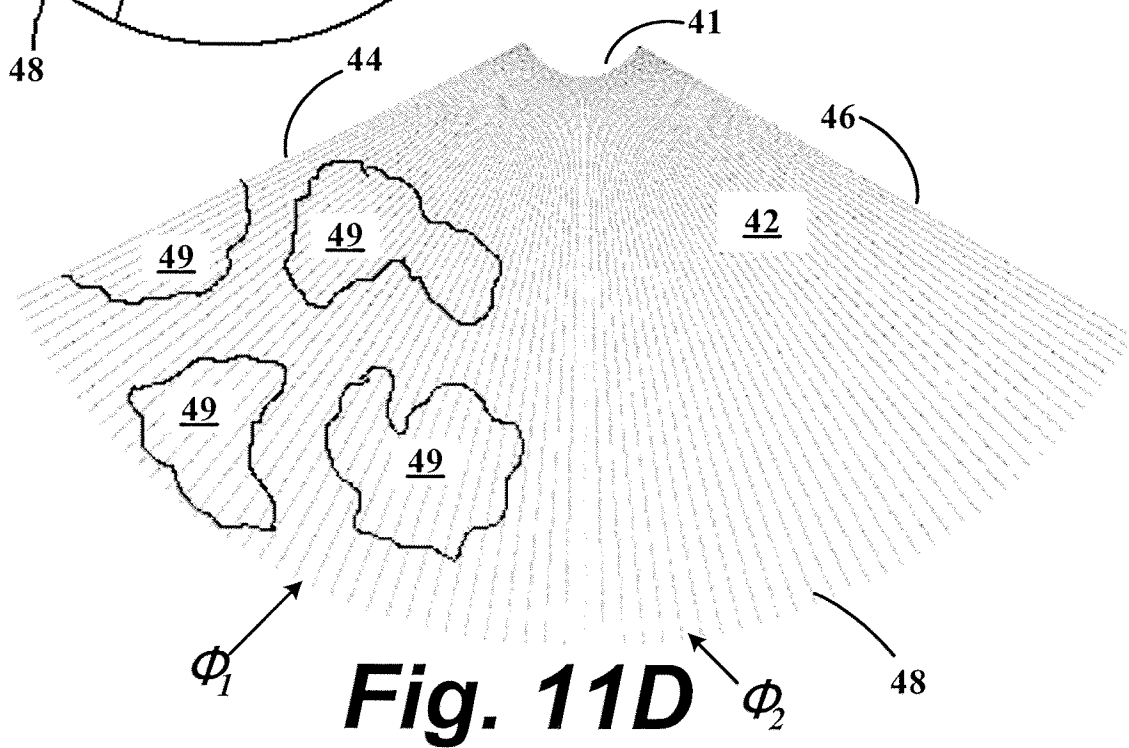
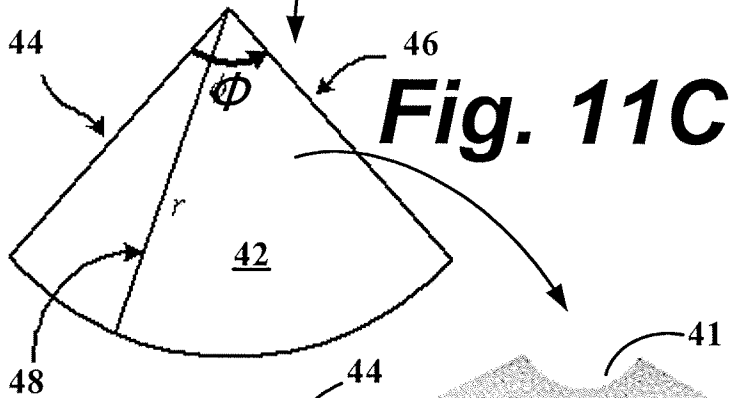
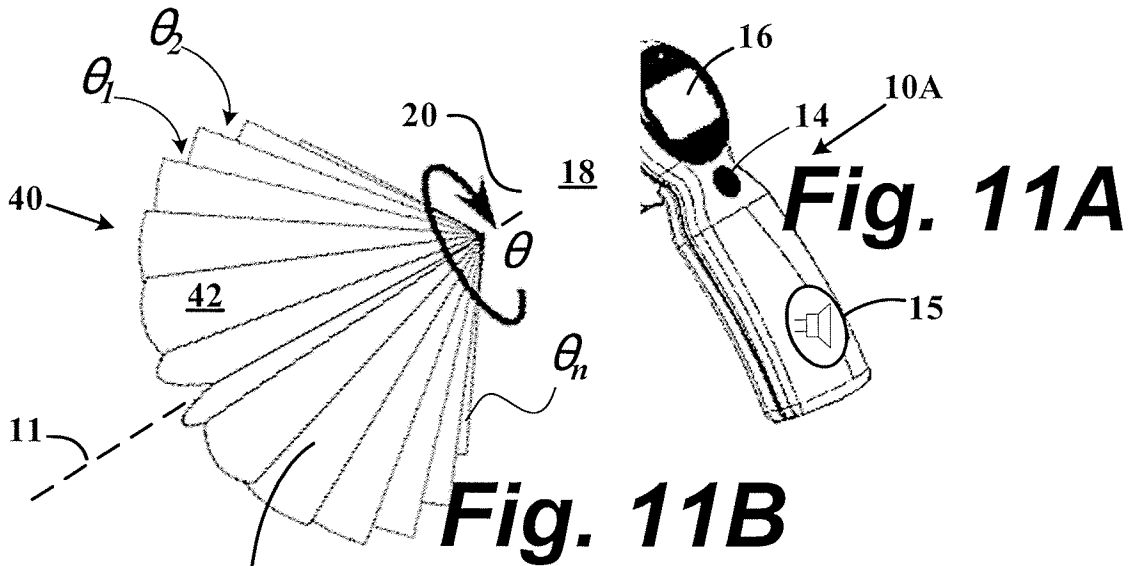


This image was taken between the 3rd and 4th intercostal space to the right of midline. The pleural line is the bright echogenic (horizontal) line.



This image was taken near the clavicle to the right of midline. The pleural line is the bright echogenic (horizontal) line.

Figs. 10A-B



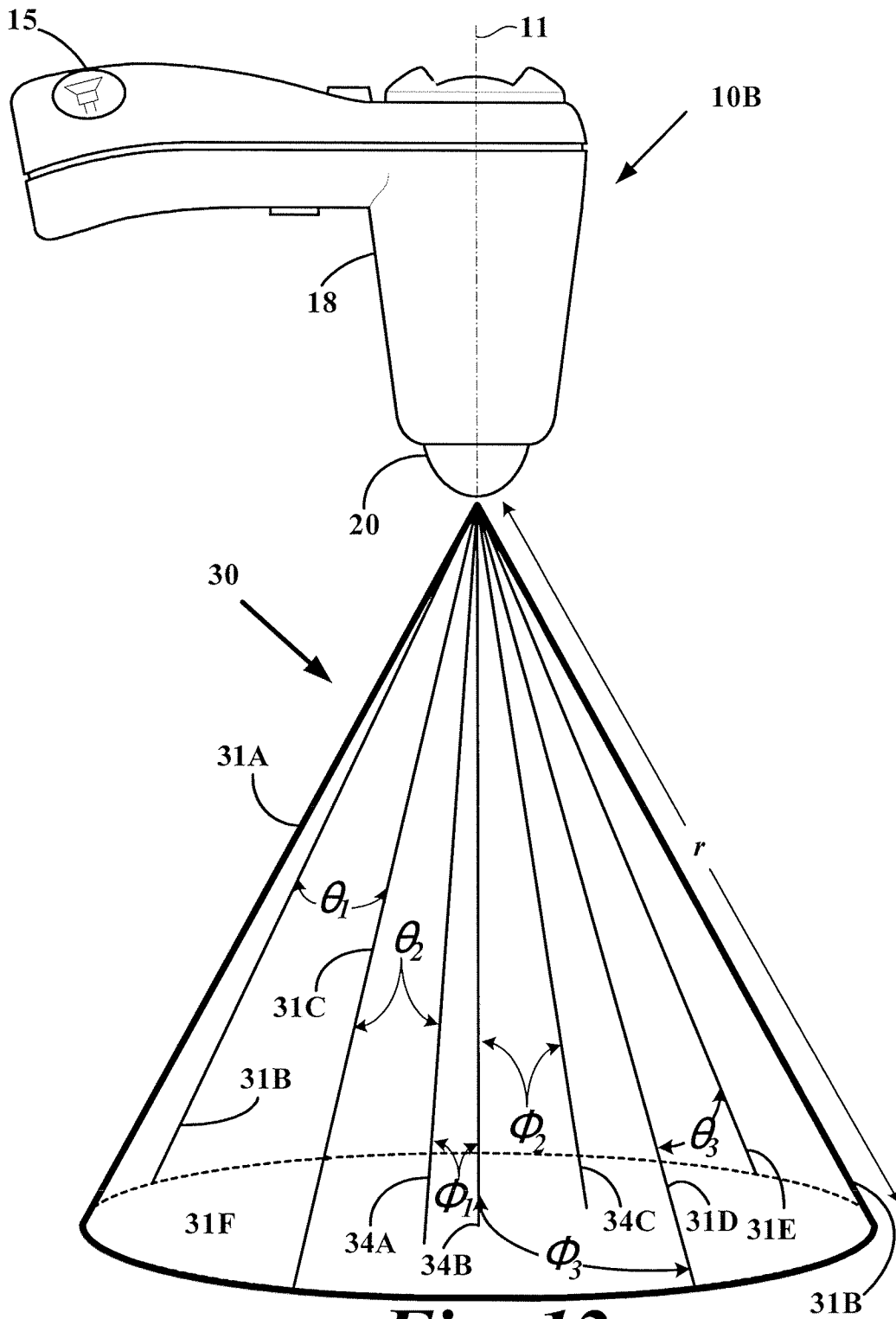


Fig. 12

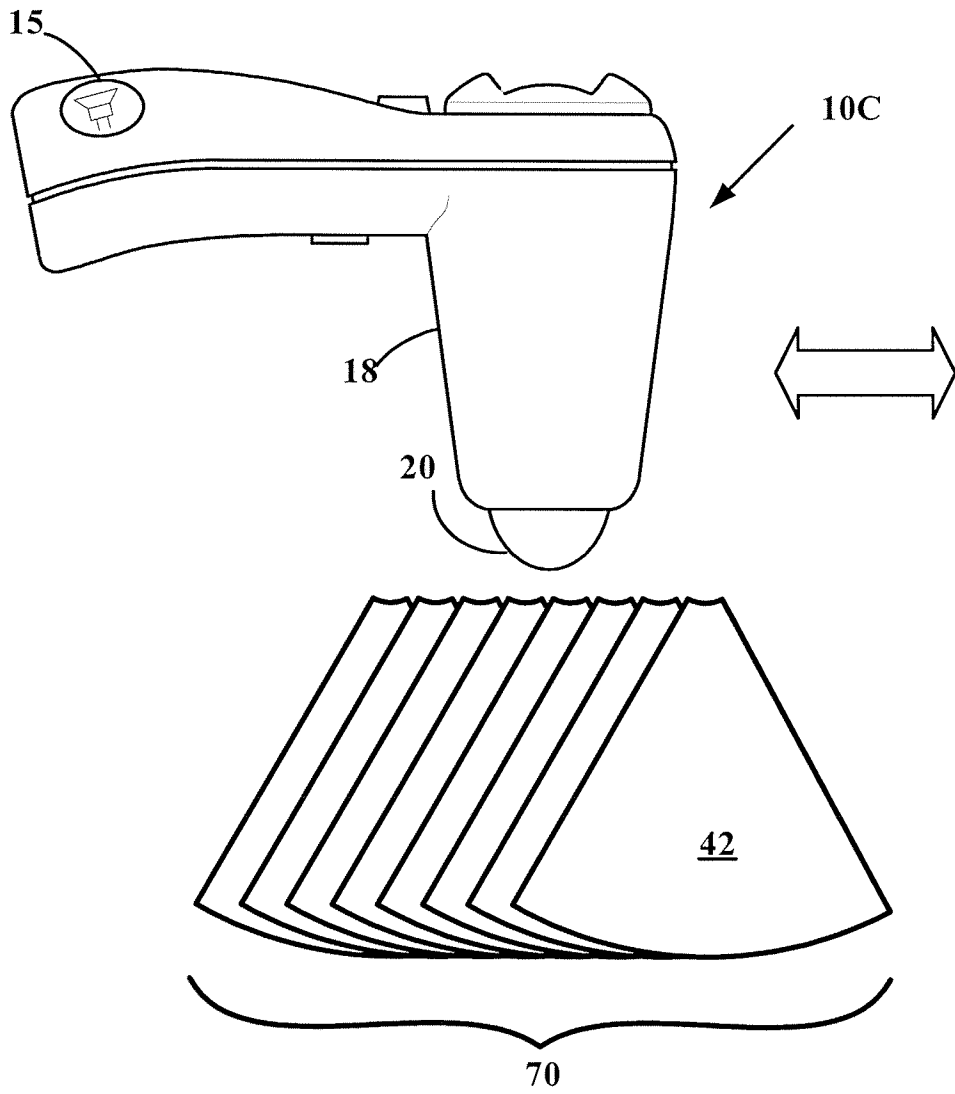


Fig. 13

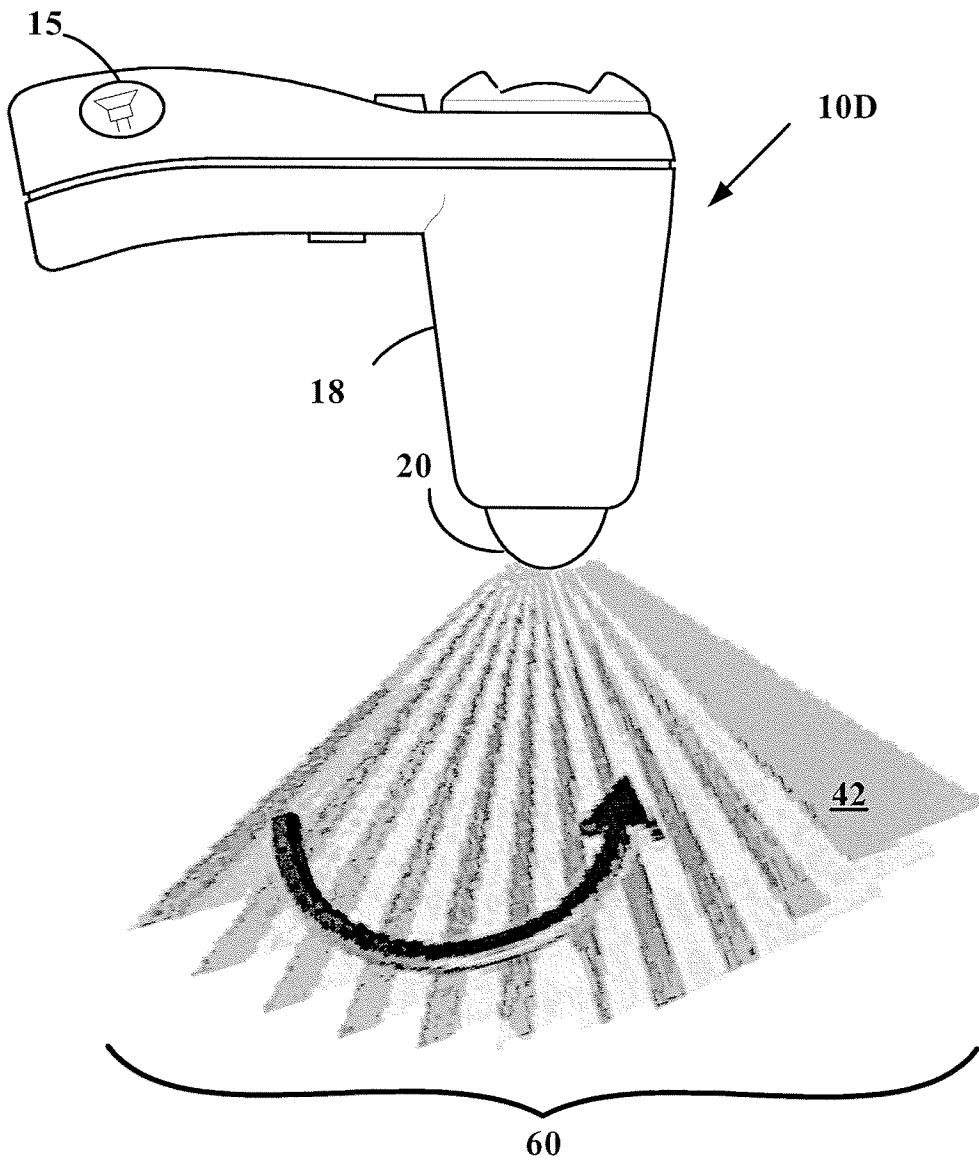


Fig. 14

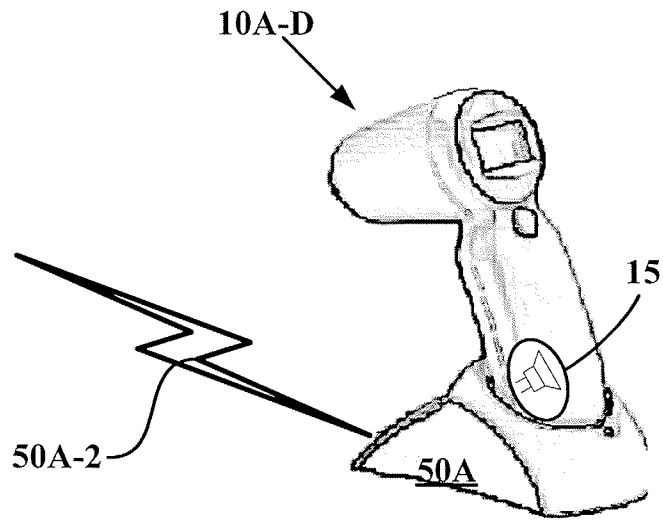


Fig. 15

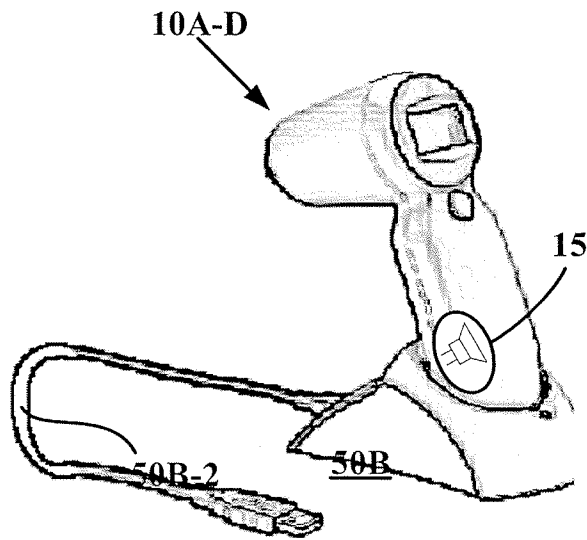


Fig. 16

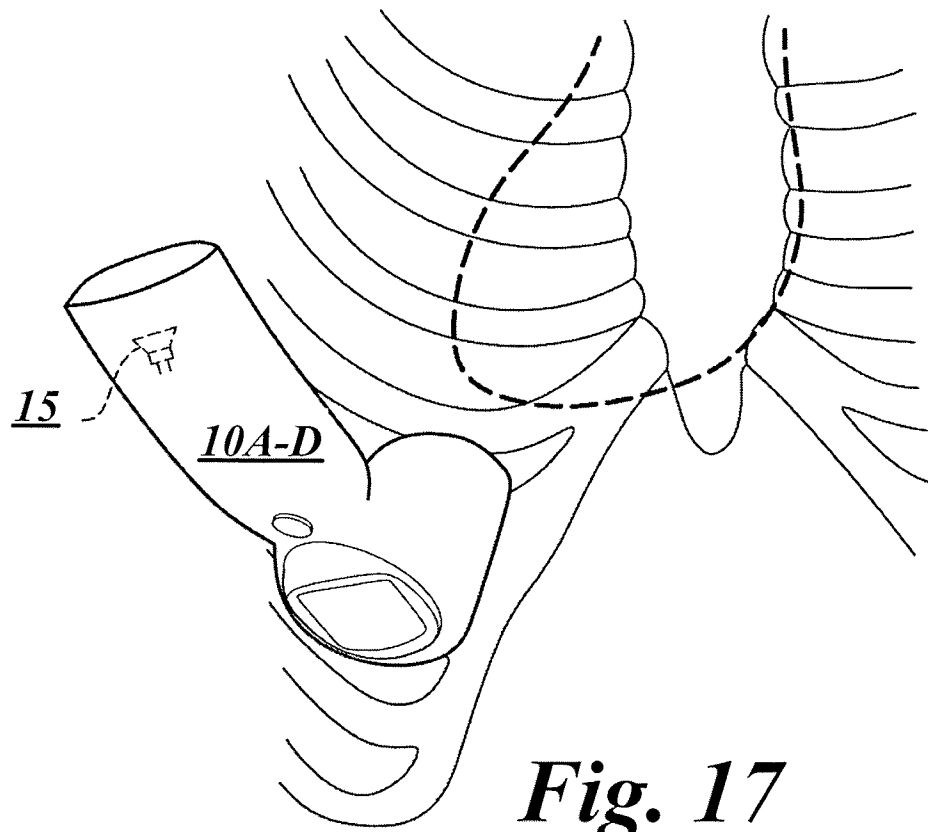


Fig. 17

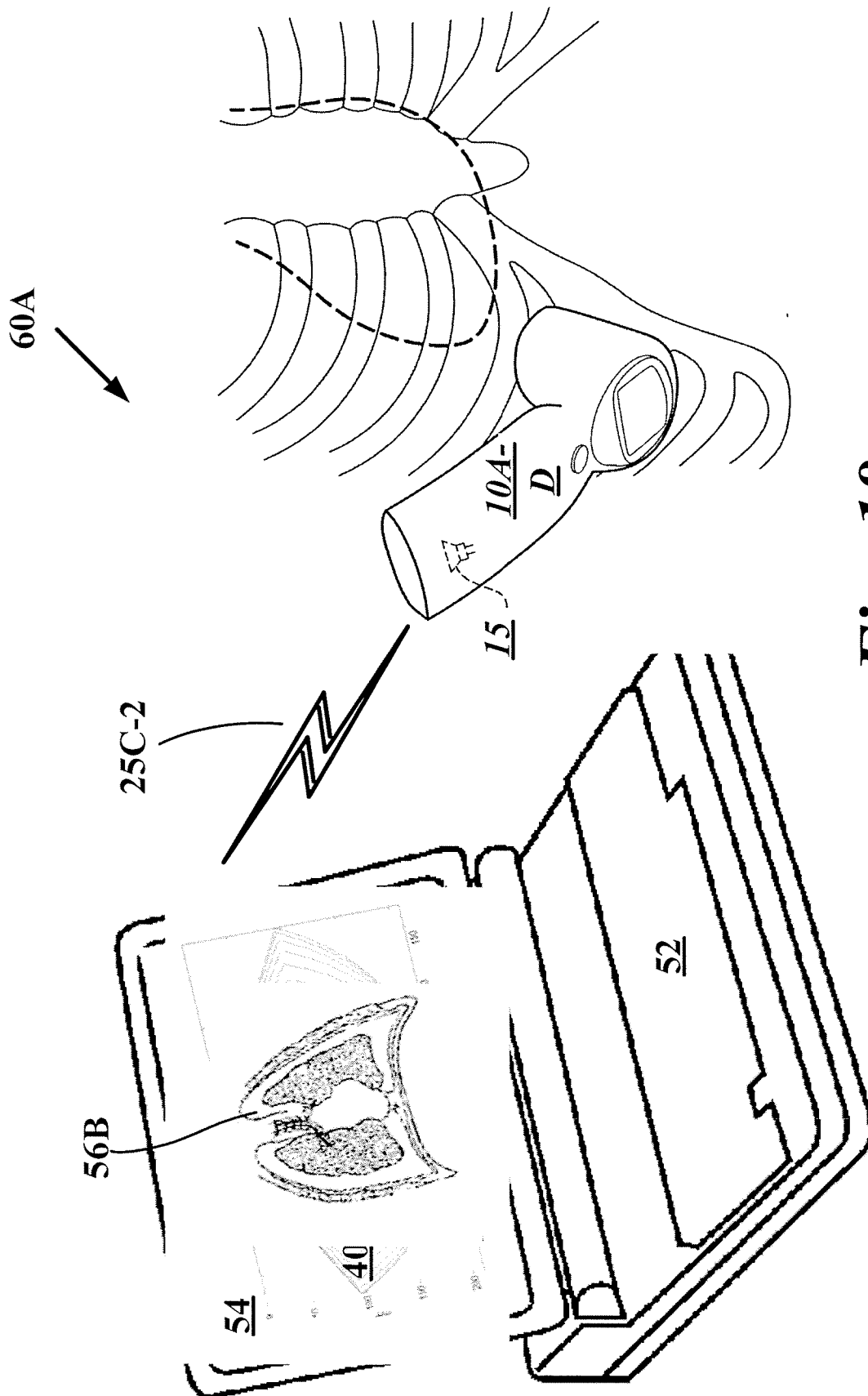


Fig. 18

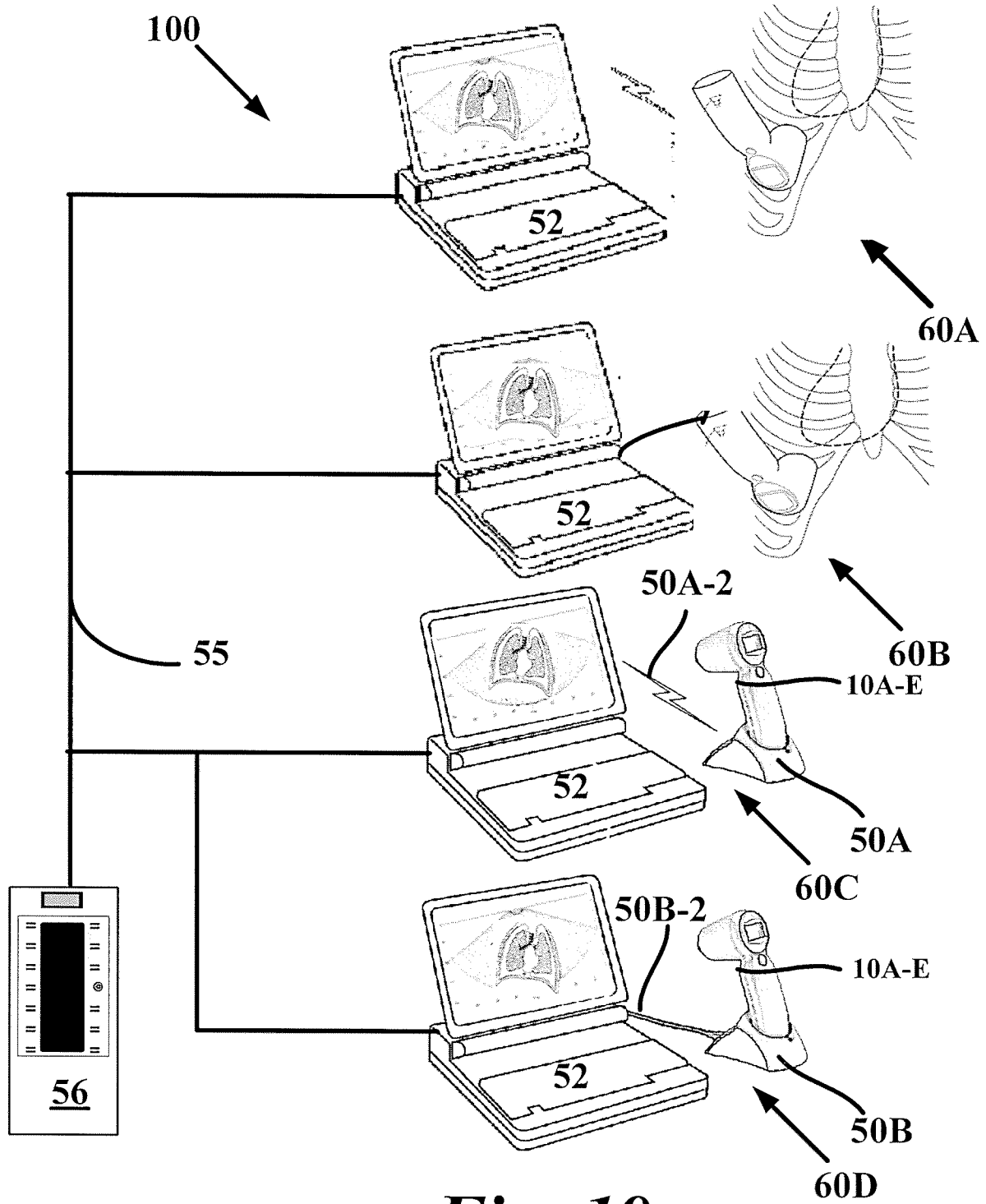


Fig. 19

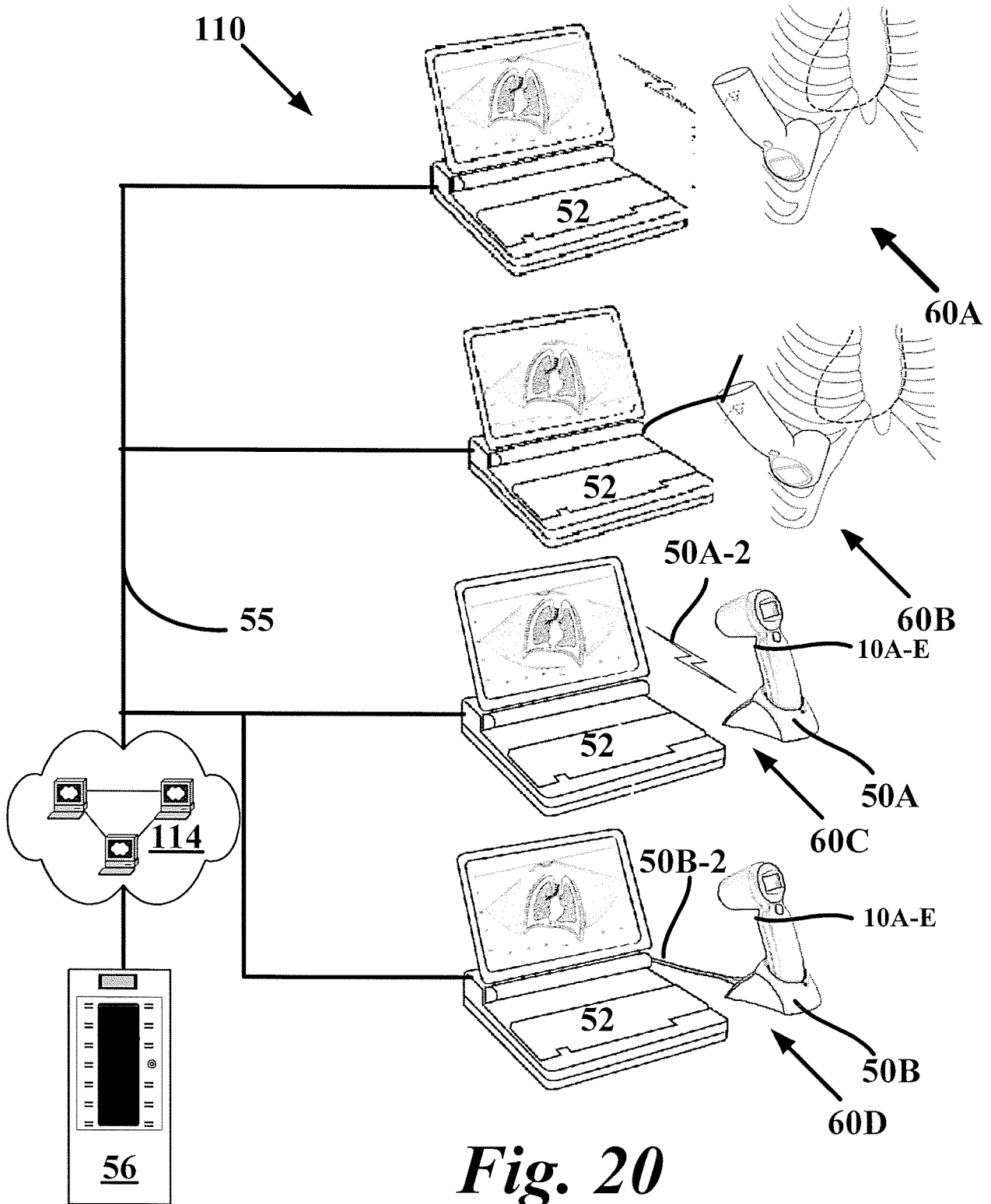
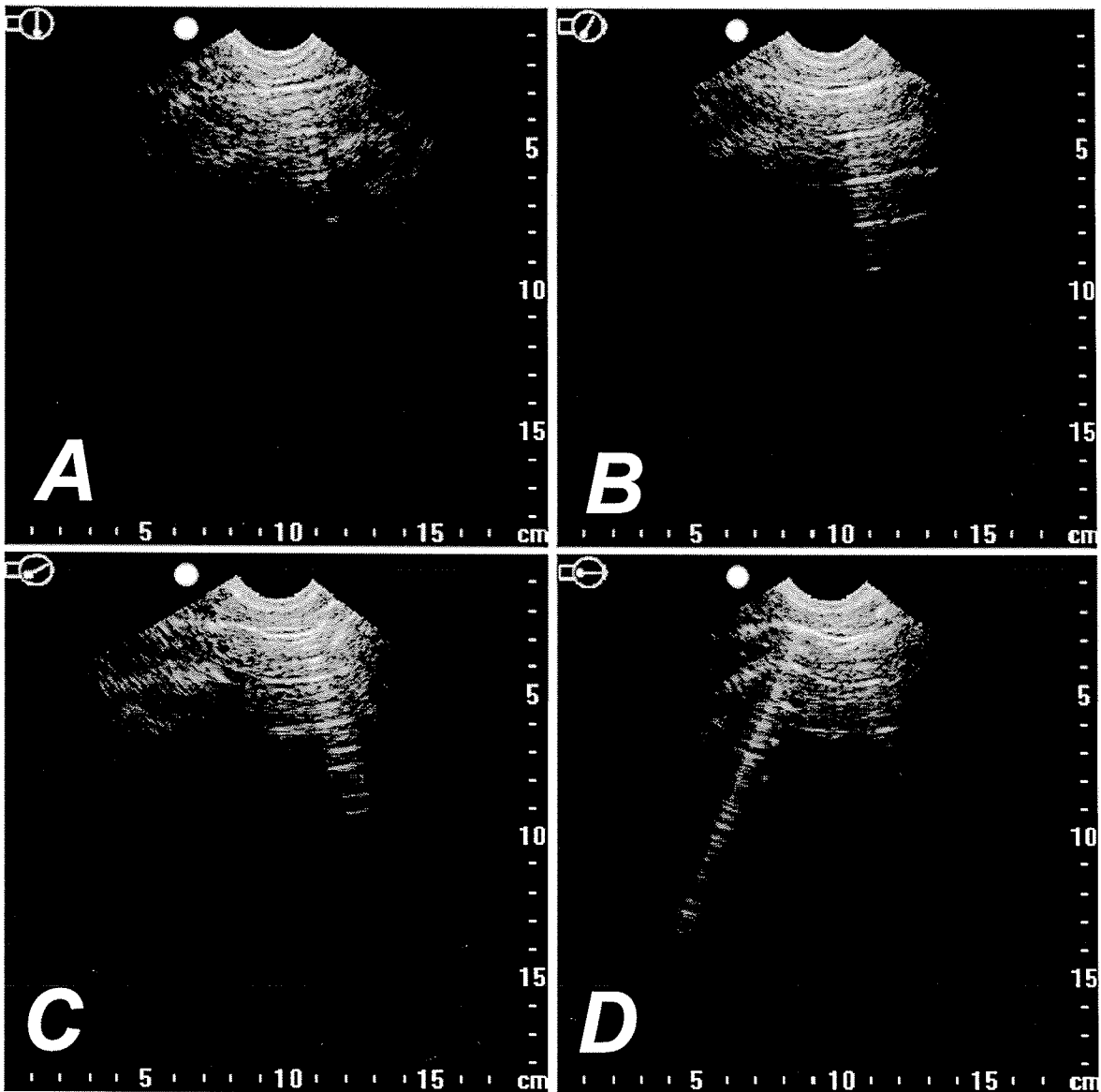


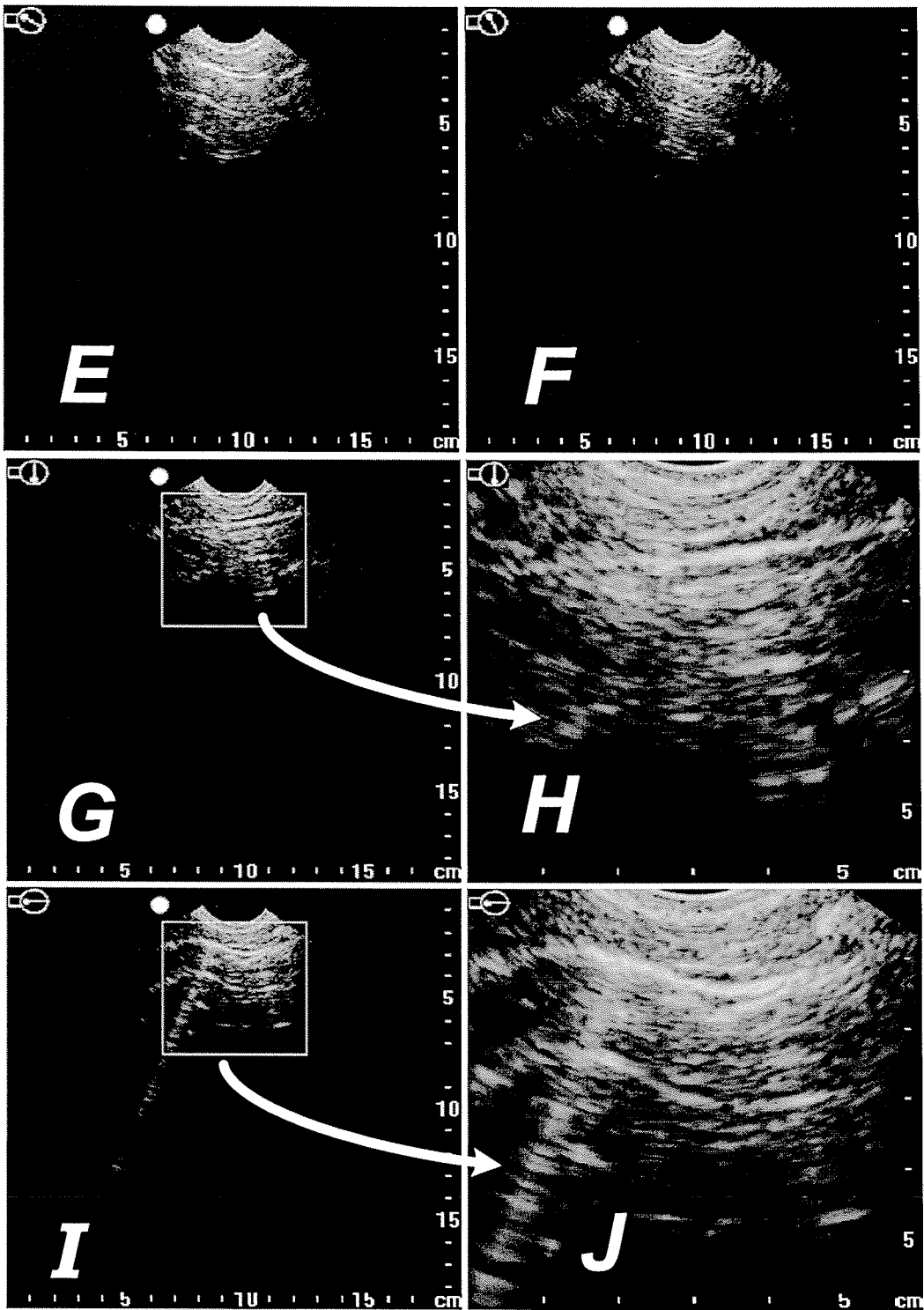
Fig. 20

Information	Measurements
Exam Date: Wednesday, August 16, 2006 11:12:00 AM	Urine Volume: 0 ml
Patient ID: 1	Surface Area: Not available.
Patient Name: 3-4 intercostal space	Wall Thickness: Not available.
Operator: ki	Ultrasound Estimated Bladder Weight: Not available.
Physician:	

Images



Figs. 21A-D



Figs. 21E-J

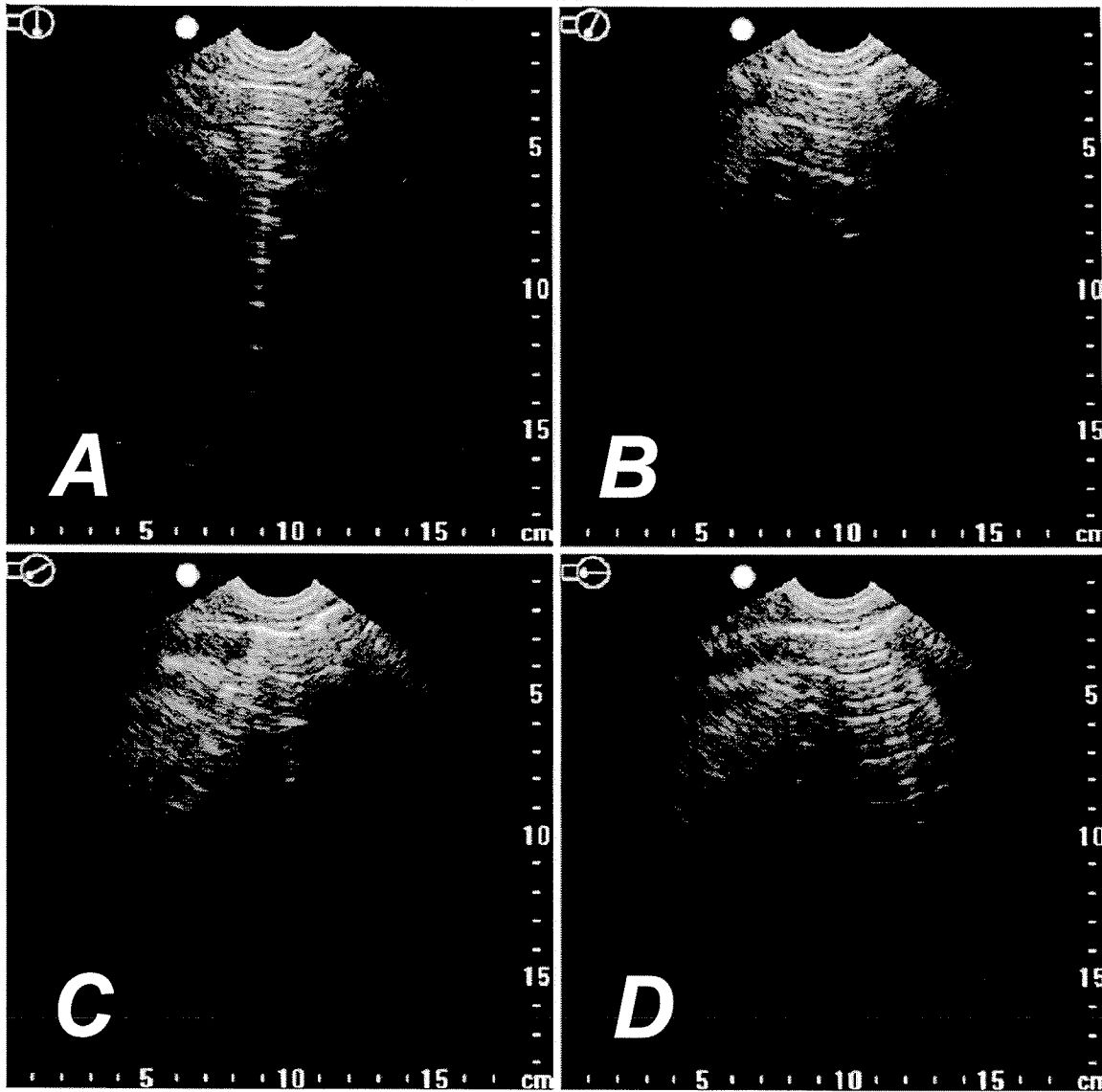
Information

Exam Date: Wednesday, August 16, 2006 11:23:00 AM
Patient ID: 1
Patient Name: near clavide
Operator: ki
Physician:

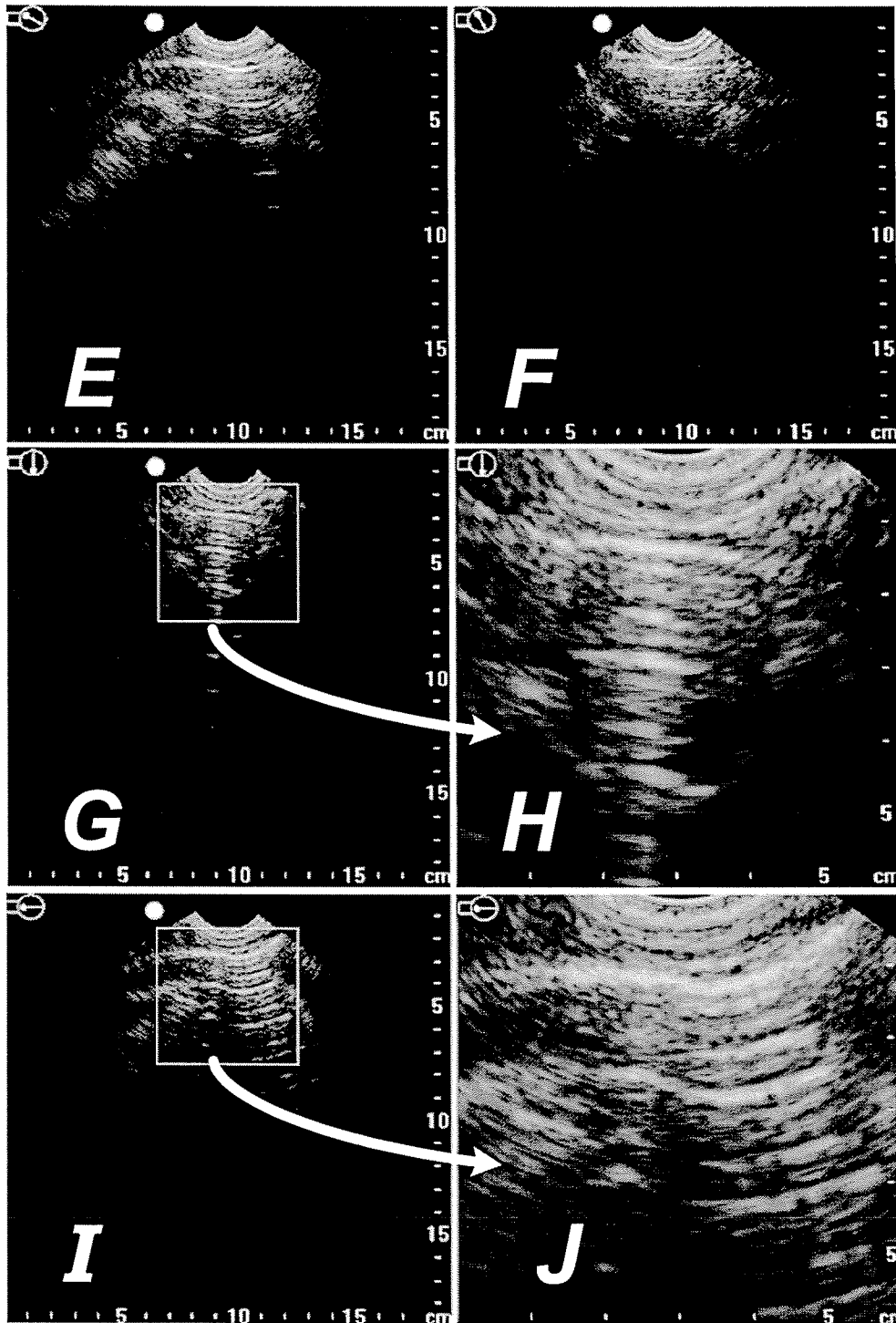
Measurements

Urine Volume: 0 ml
Surface Area: Not available.
Wall Thickness: Not available.
Ultrasound Estimated Bladder Weight: Not available.

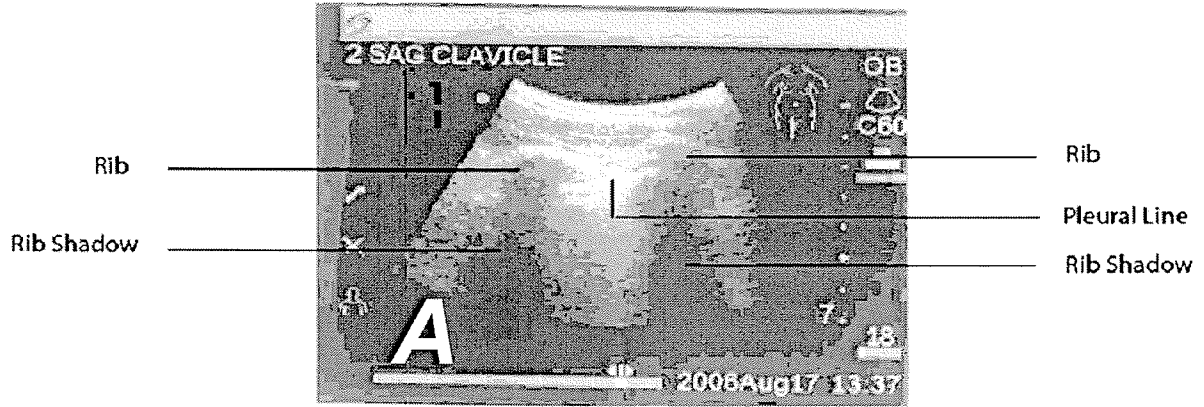
Images



Figs. 22A-D



Figs. 22E-J

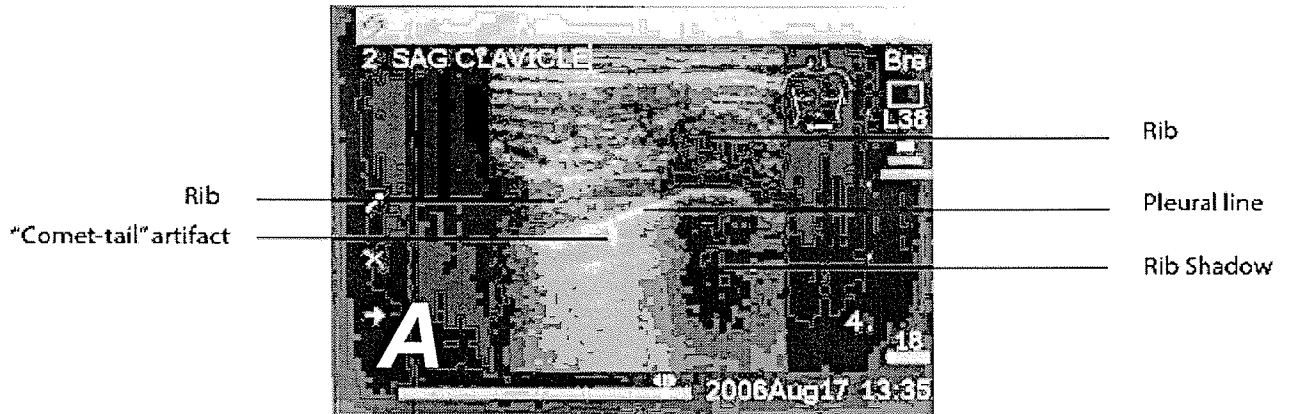


This image was taken near the clavicle to the right of midline. The pleural line is the bright echogenic (horizontal) line

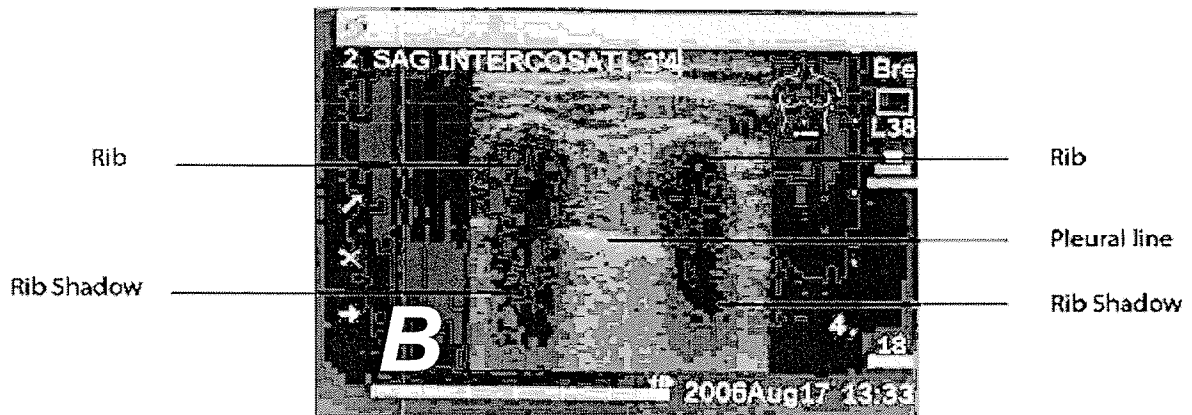


This image was taken between the 3rd and 4th intercostal space to the right of midline. The pleural line is the bright echogenic (horizontal) line.

Figs. 23A-B



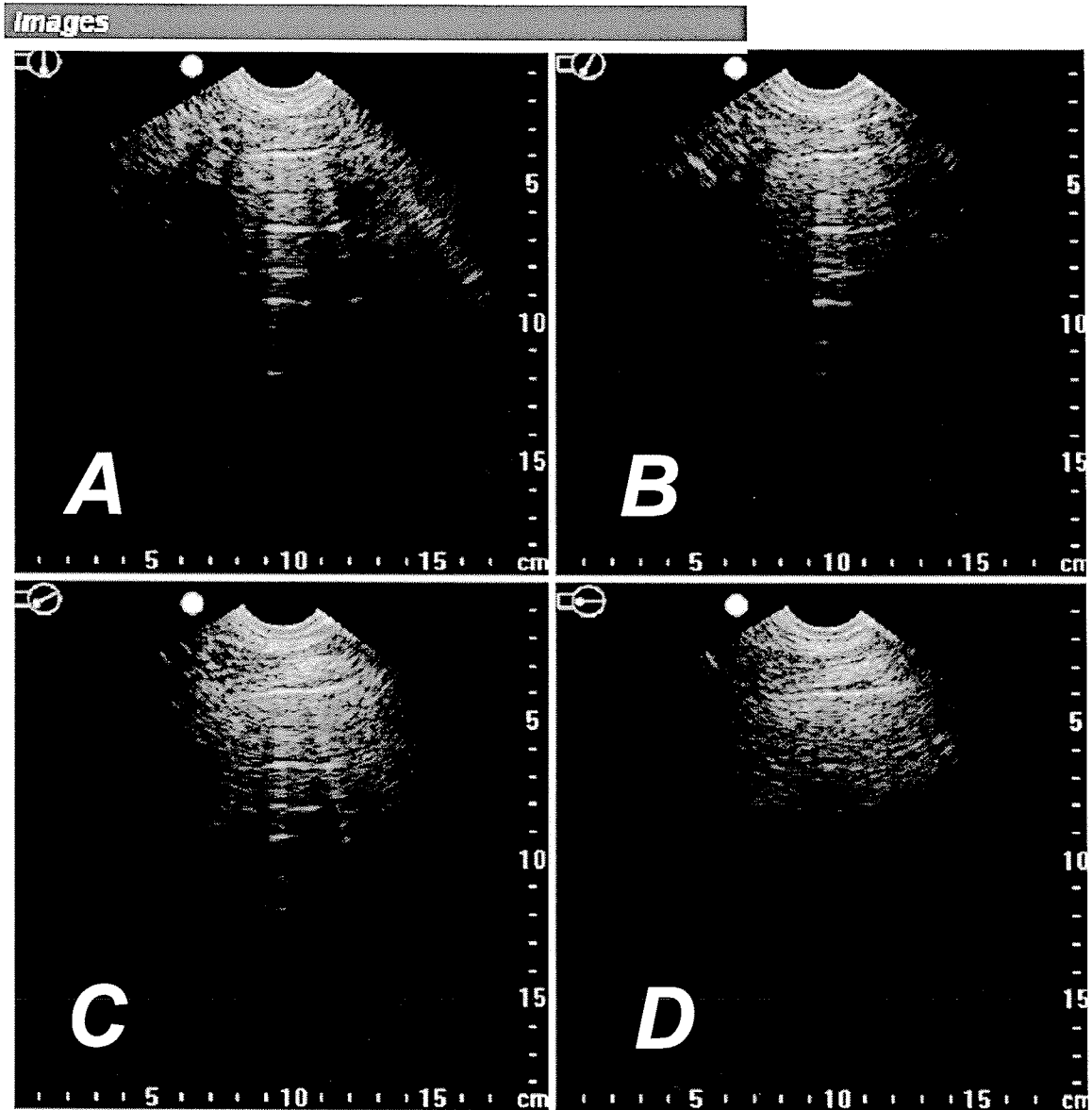
This image was taken near the clavicle to the right of midline. The pleural line is the bright echogenic (horizontal) line



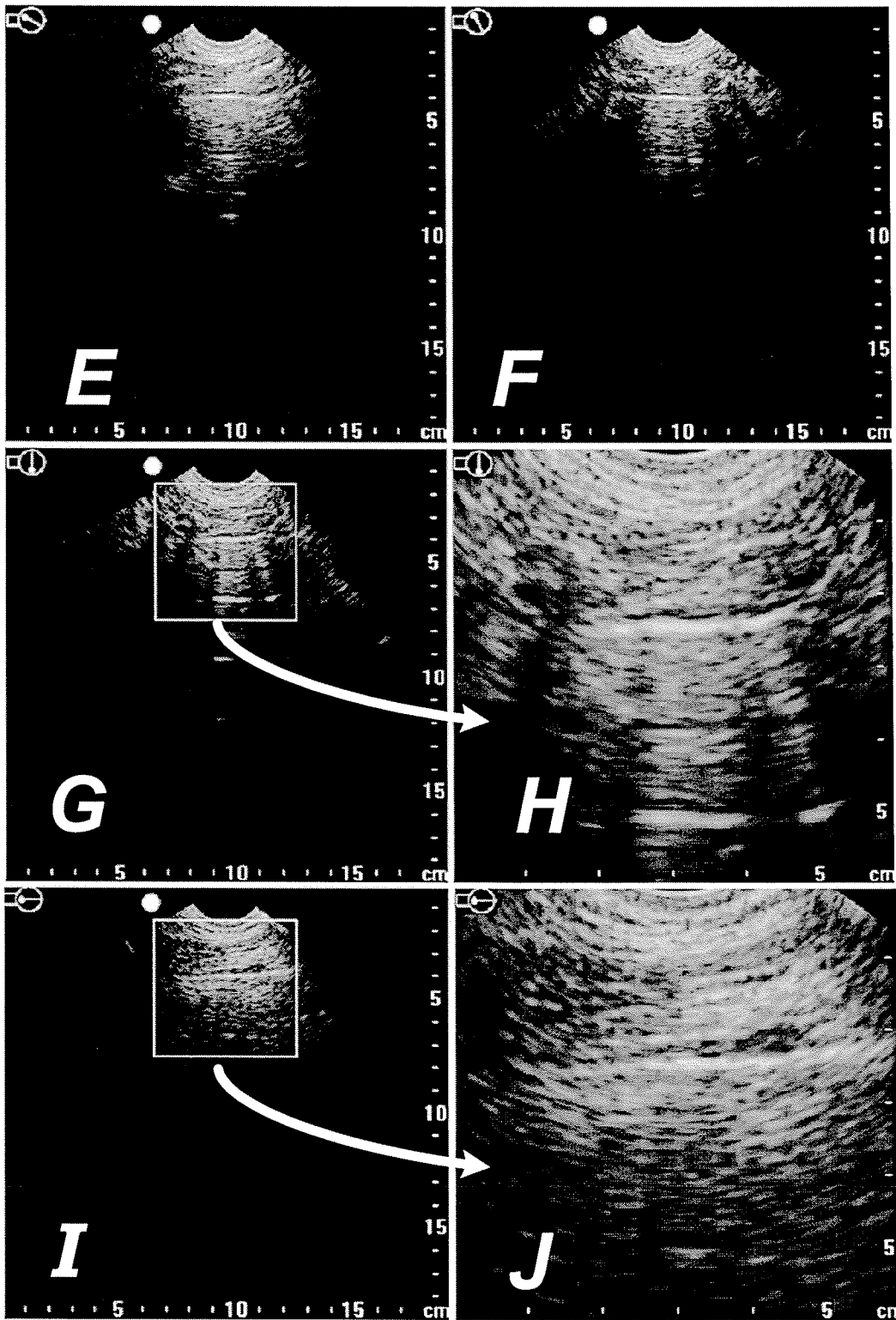
This image was taken between the 3rd and 4th intercostal space to the right of midline. The pleural line is the bright echogenic (horizontal) line.

Figs. 24A-B

Information	Measurements
Exam Date: Wednesday, August 16, 2006 1:39:00 PM	Urine Volume: 0 ml
Patient ID: 2	Surface Area: Not available.
Patient Name: sag intercostal space	Wall Thickness: Not available.
Operator: ki	Ultrasound Estimated Bladder Weight: Not available.
Physician:	



Figs. 25A-D



Figs. 25E-J

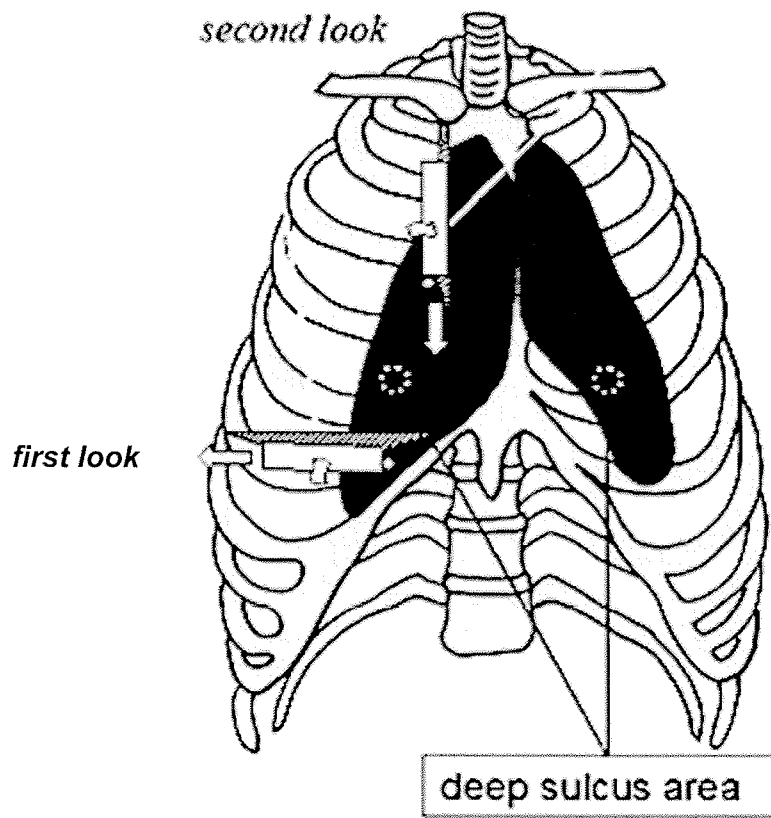


Fig. 101

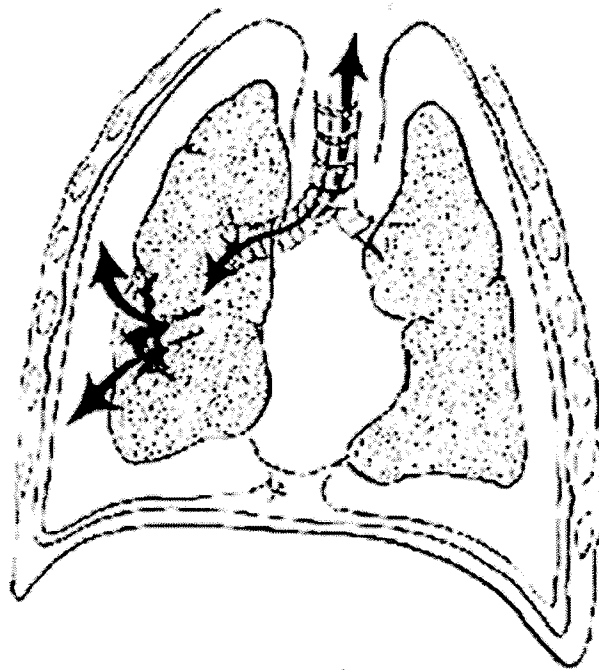
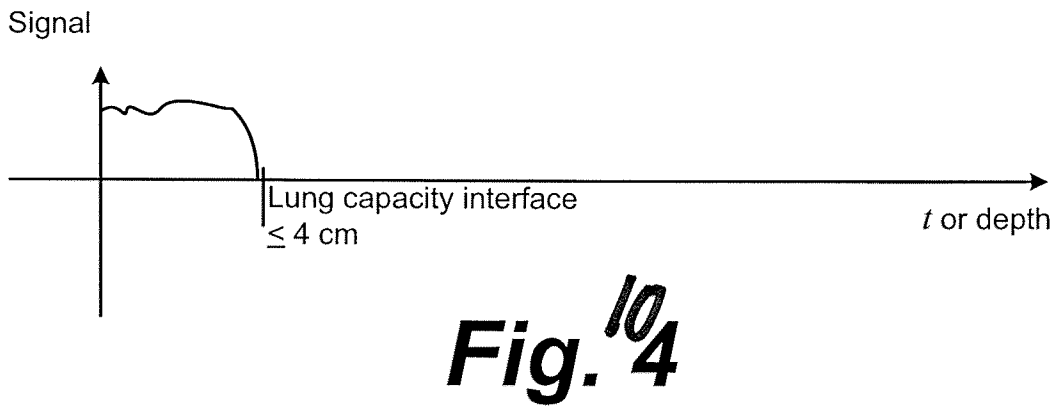
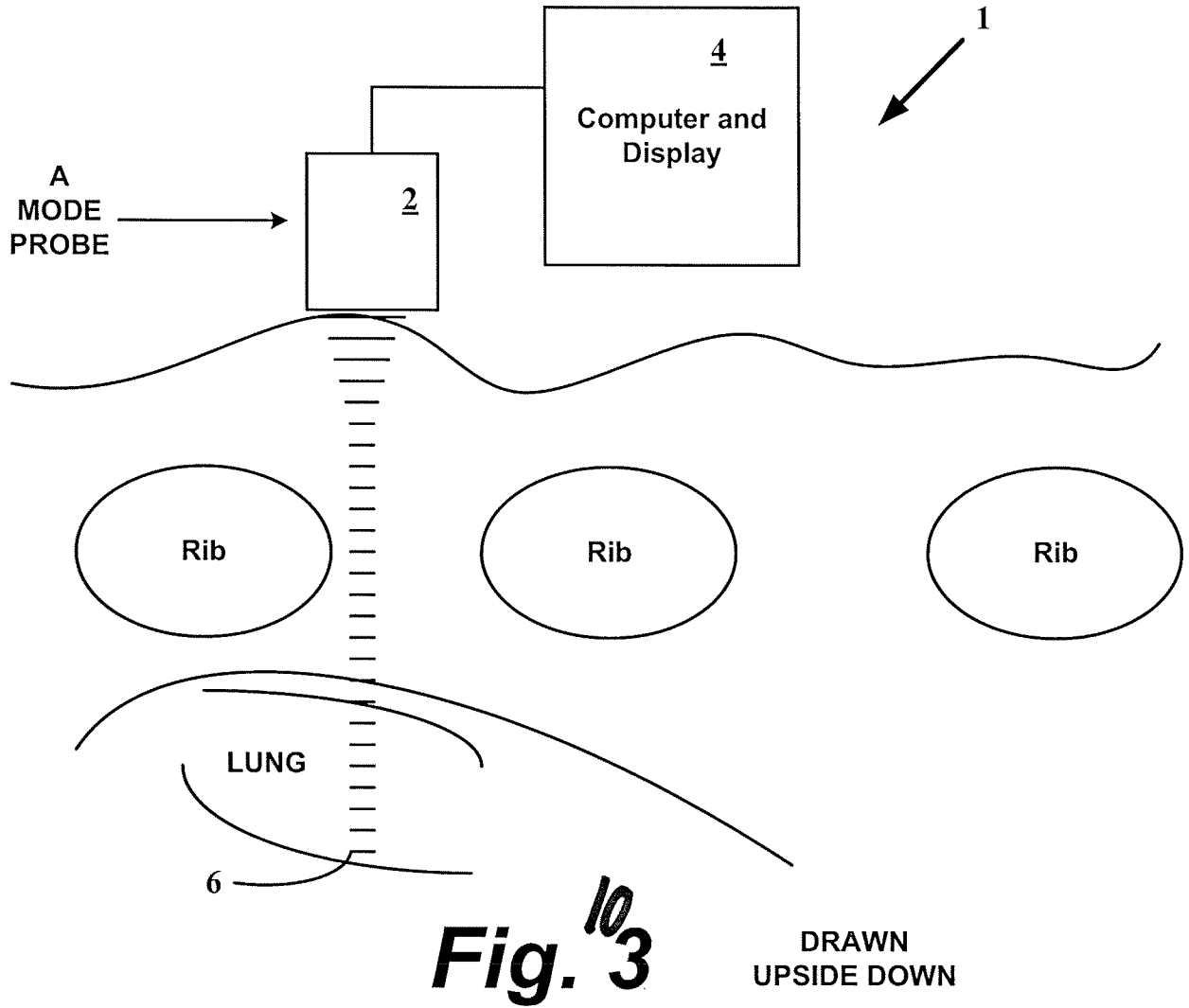


Fig. 102



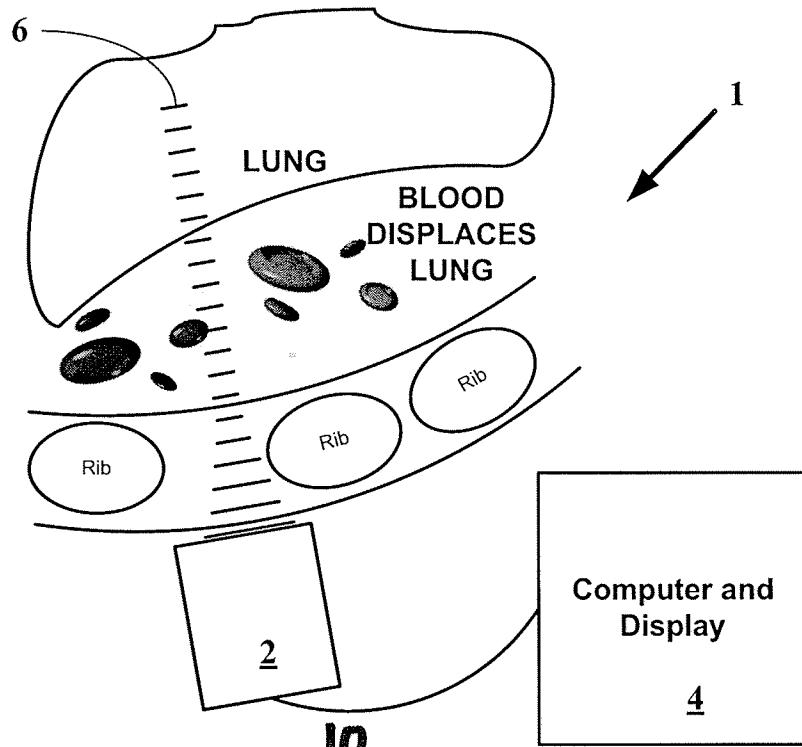


Fig. 10
5

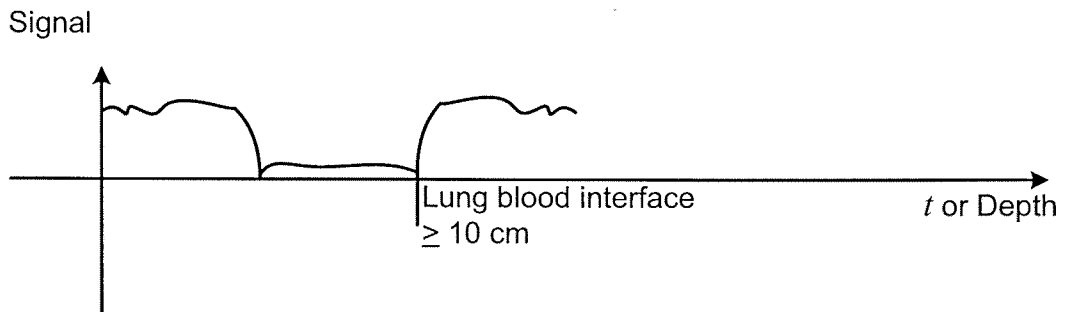
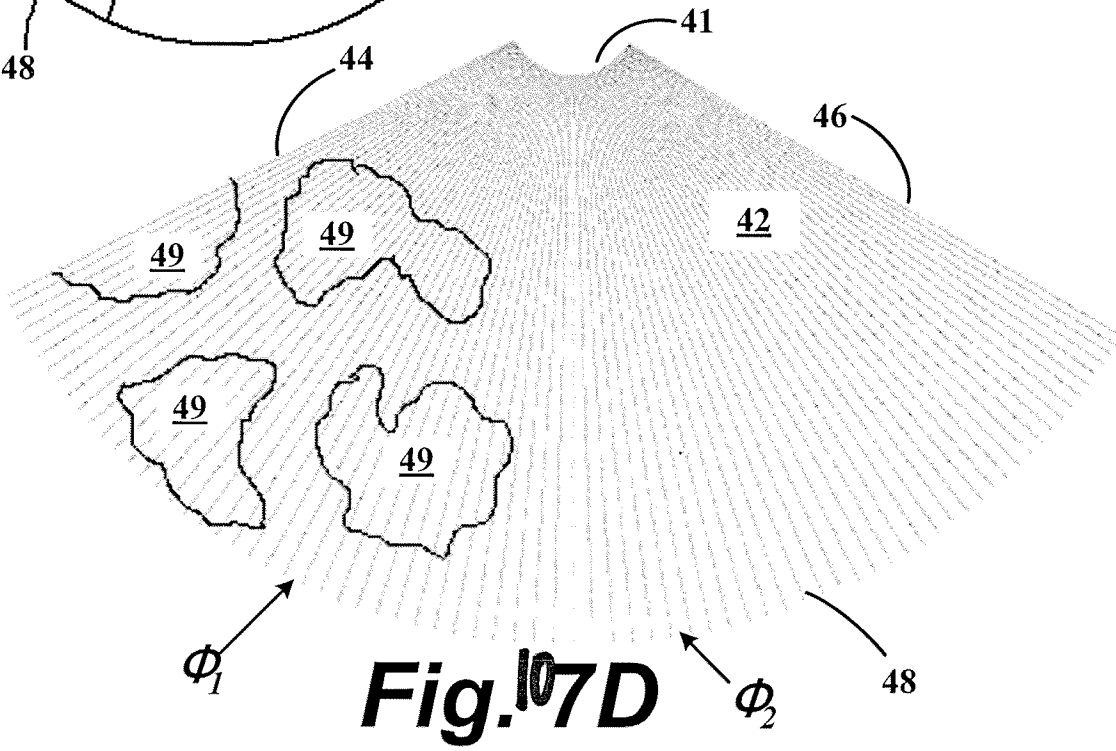
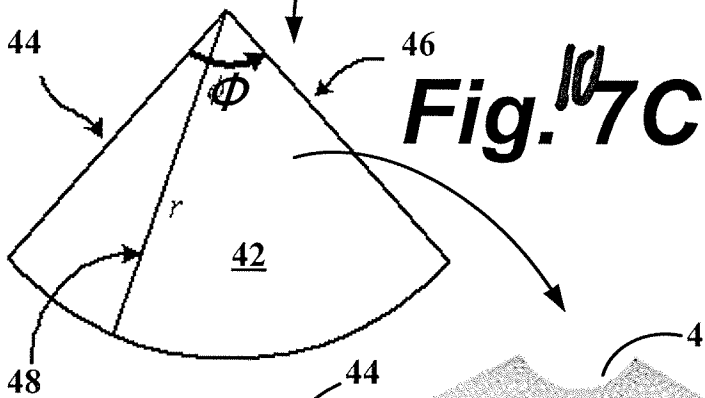
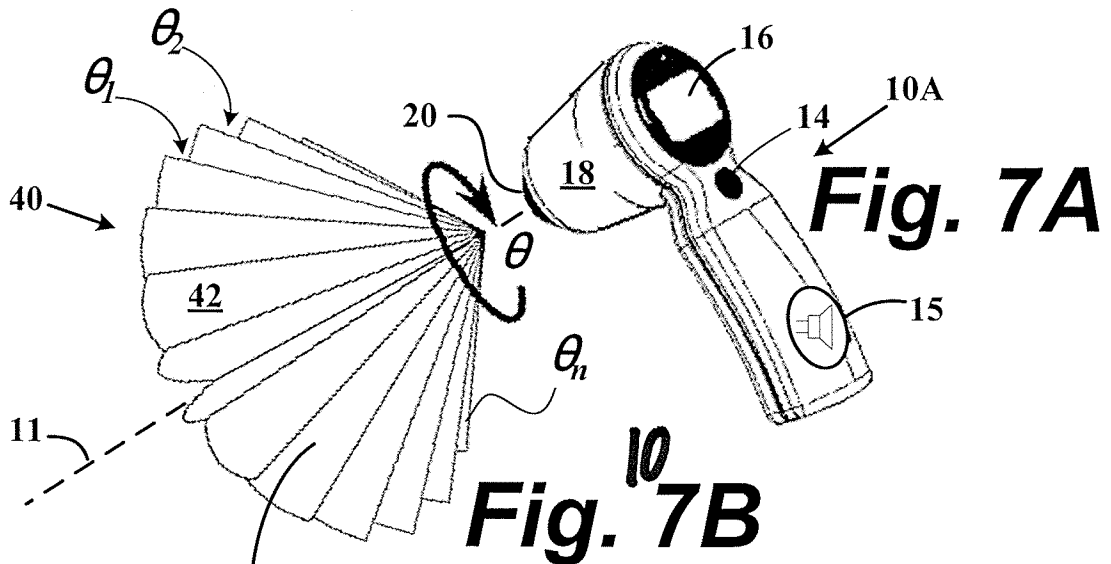


Fig. 10
6



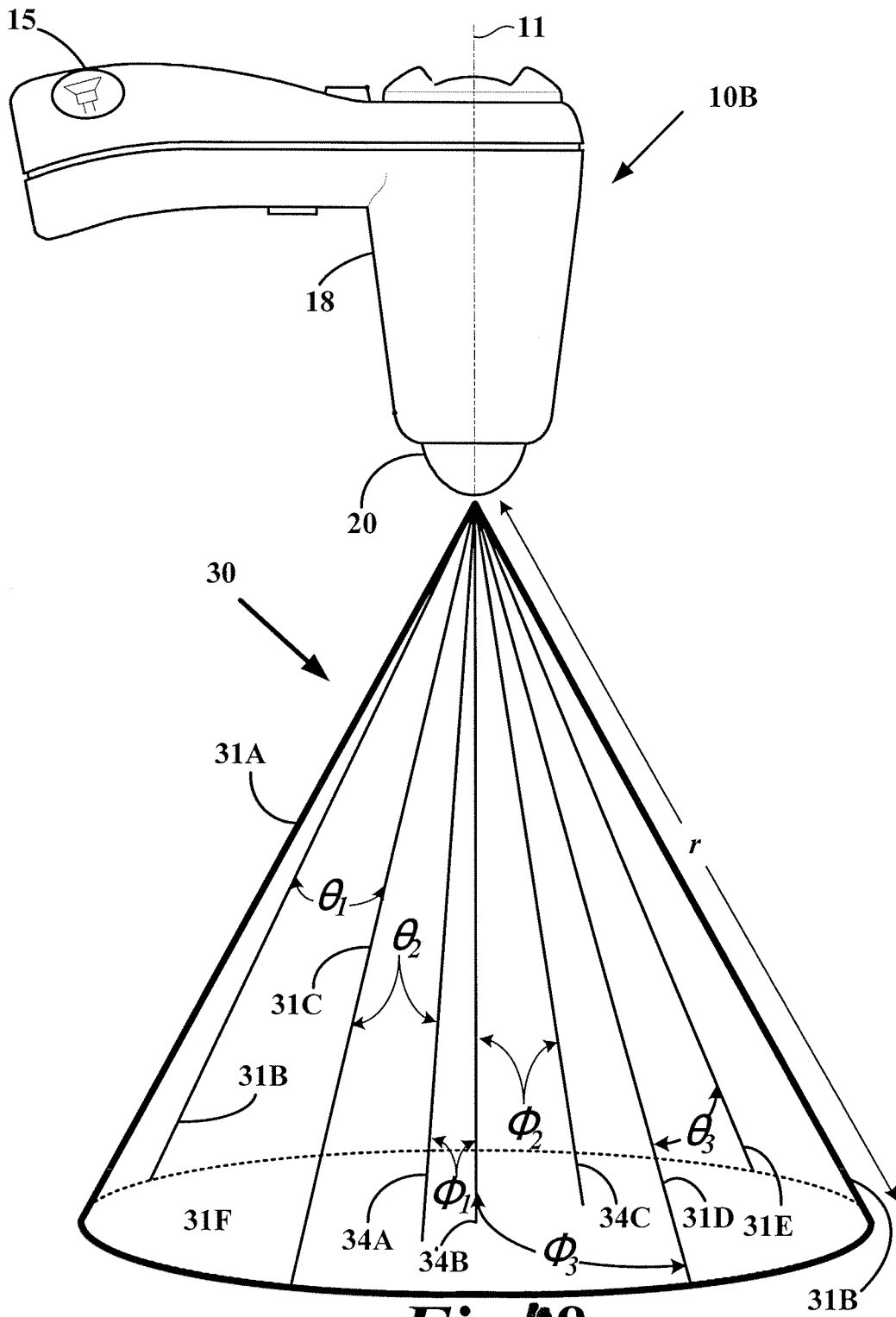


Fig.08

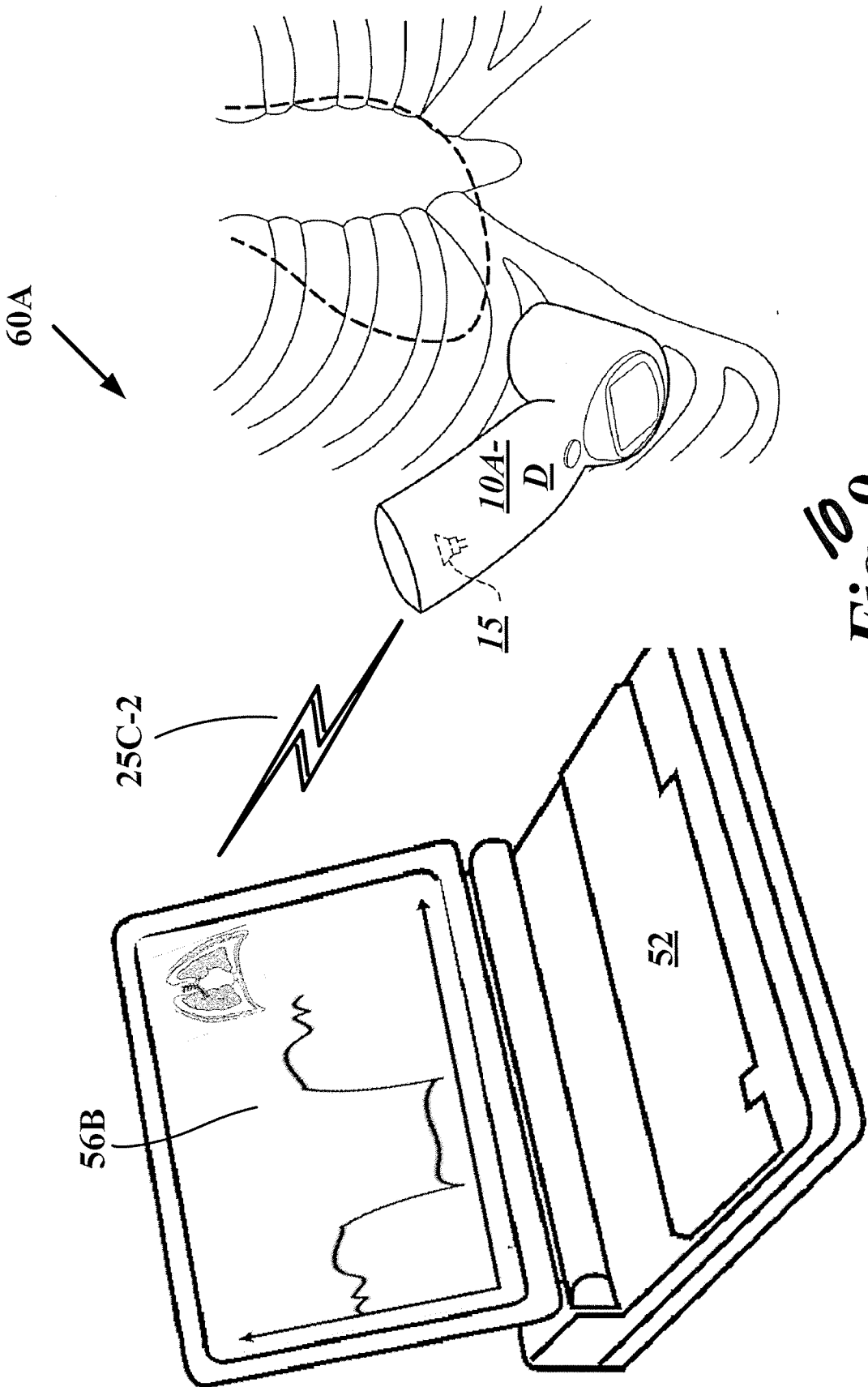


Fig. 9

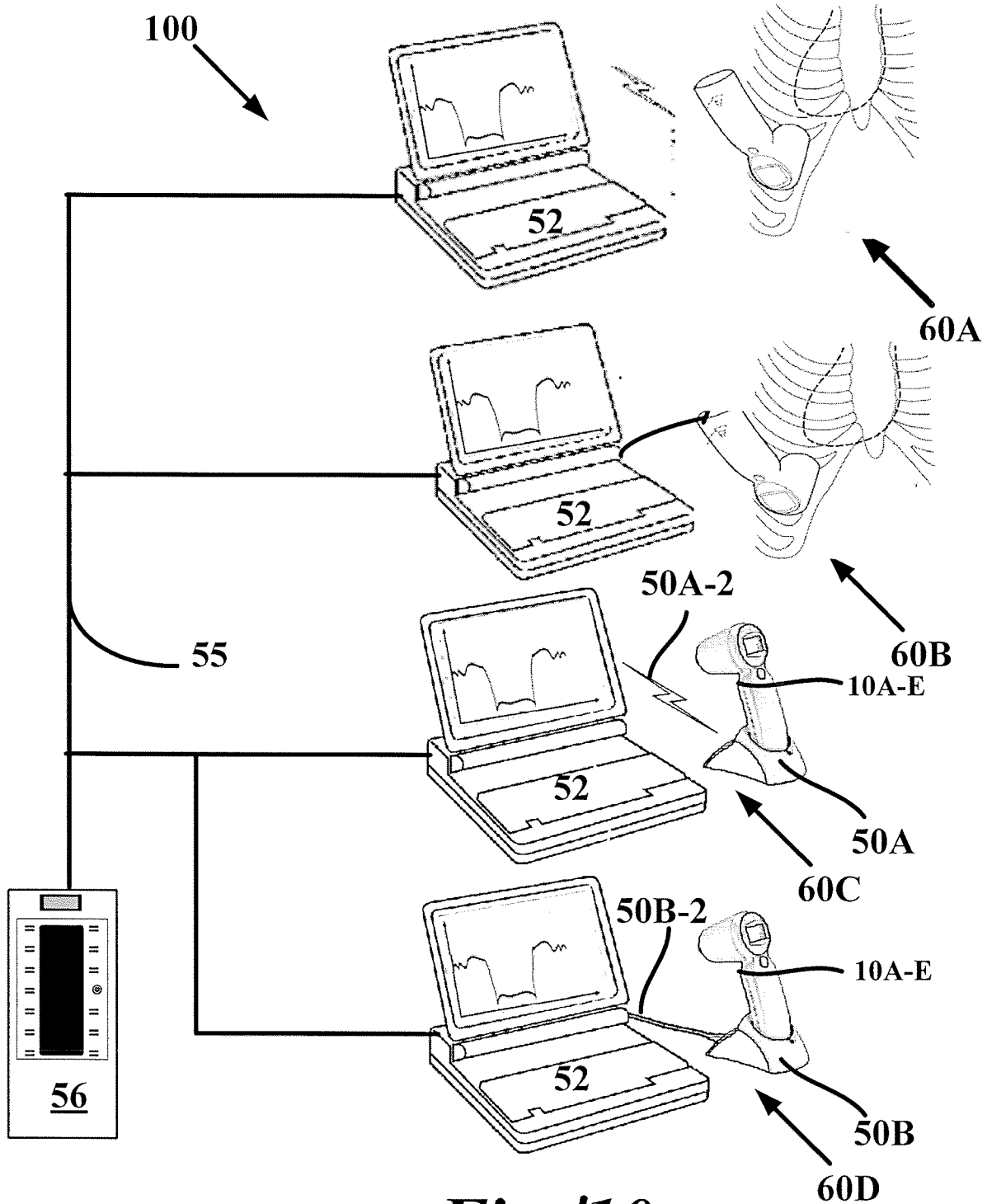


Fig. 10

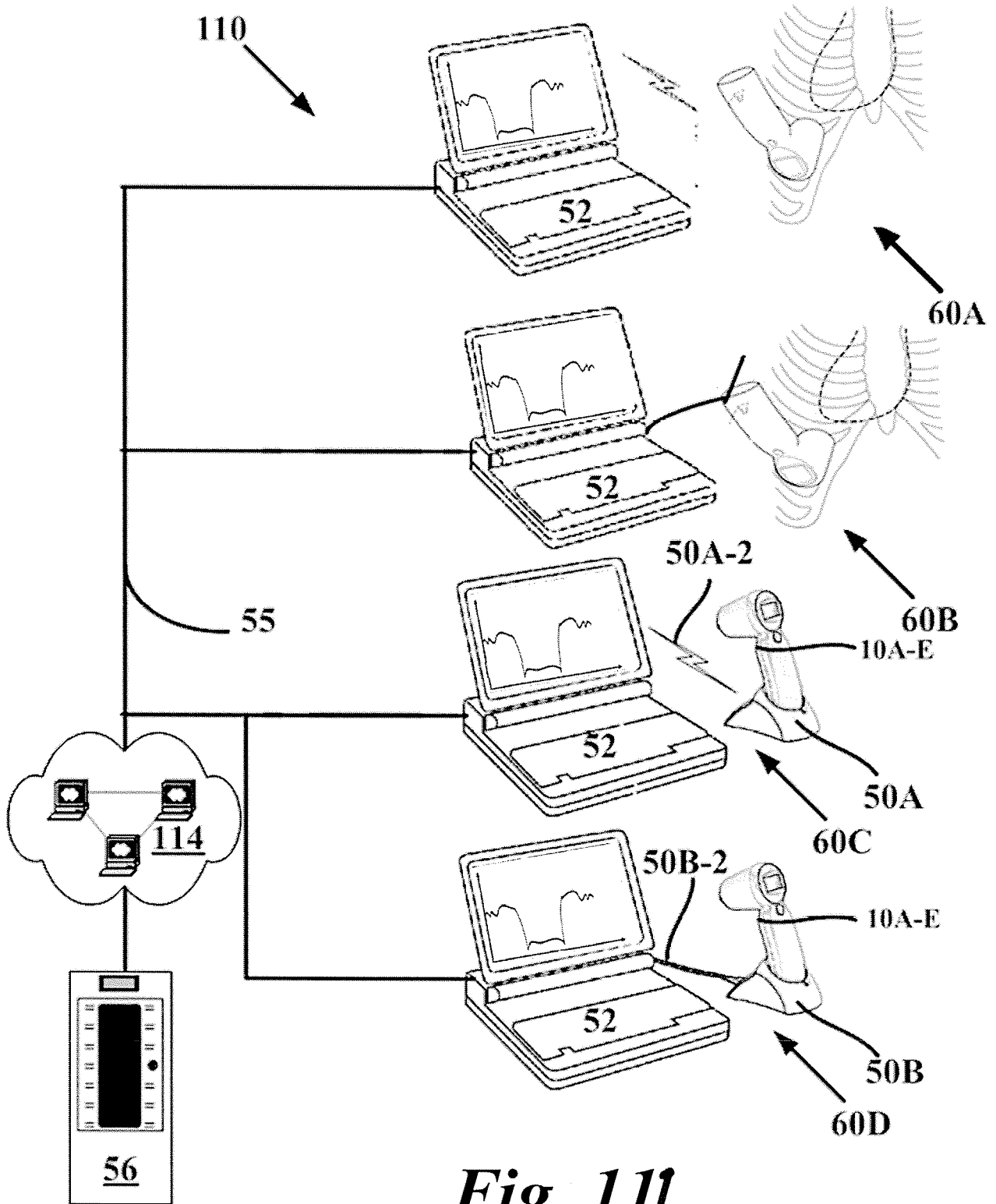


Fig. 11

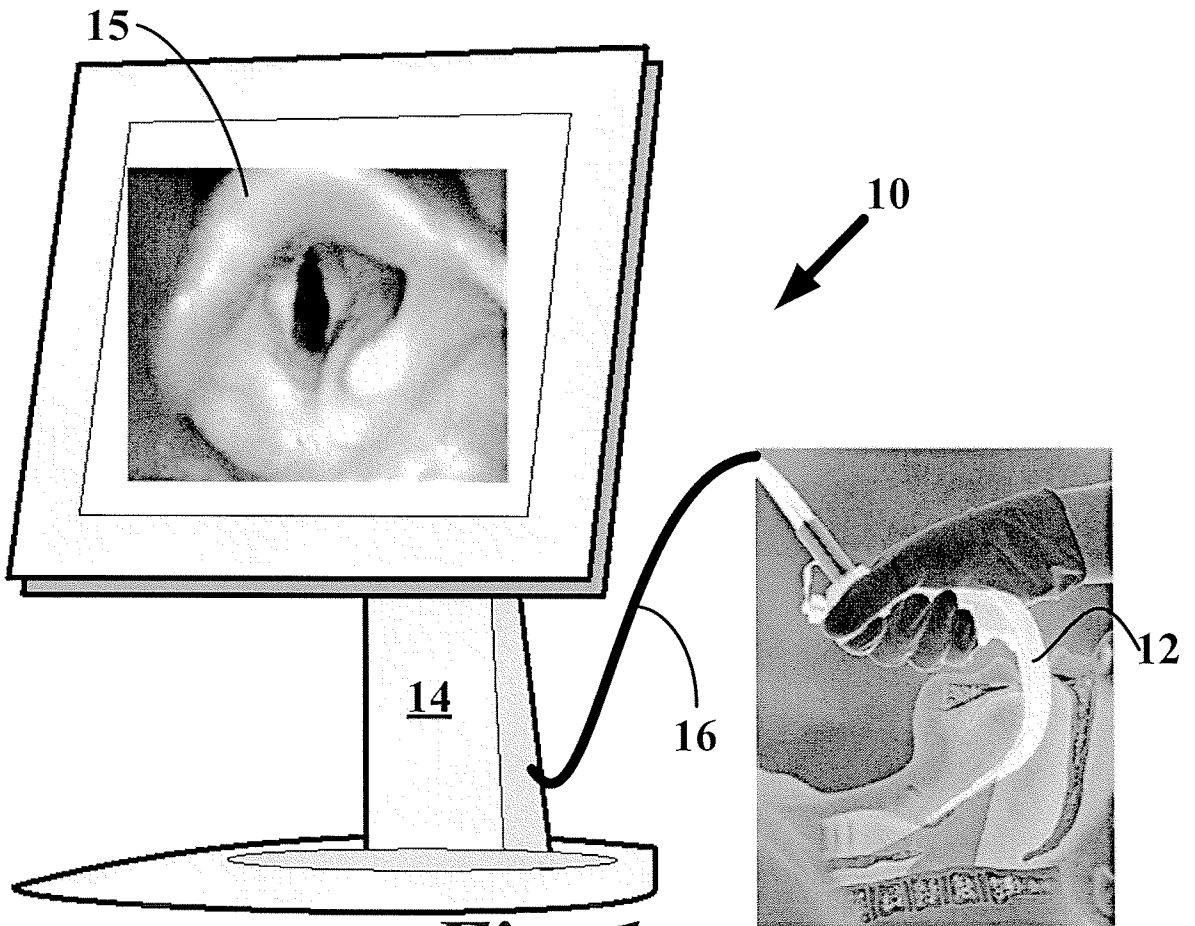


Fig. 1

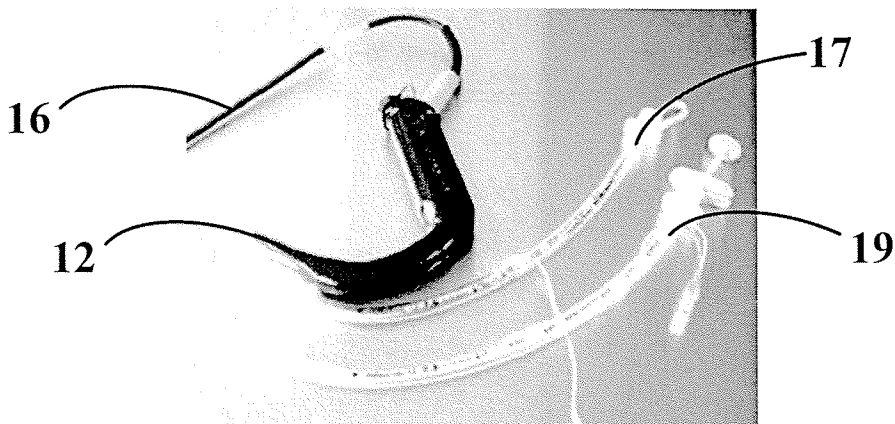


Fig. 202

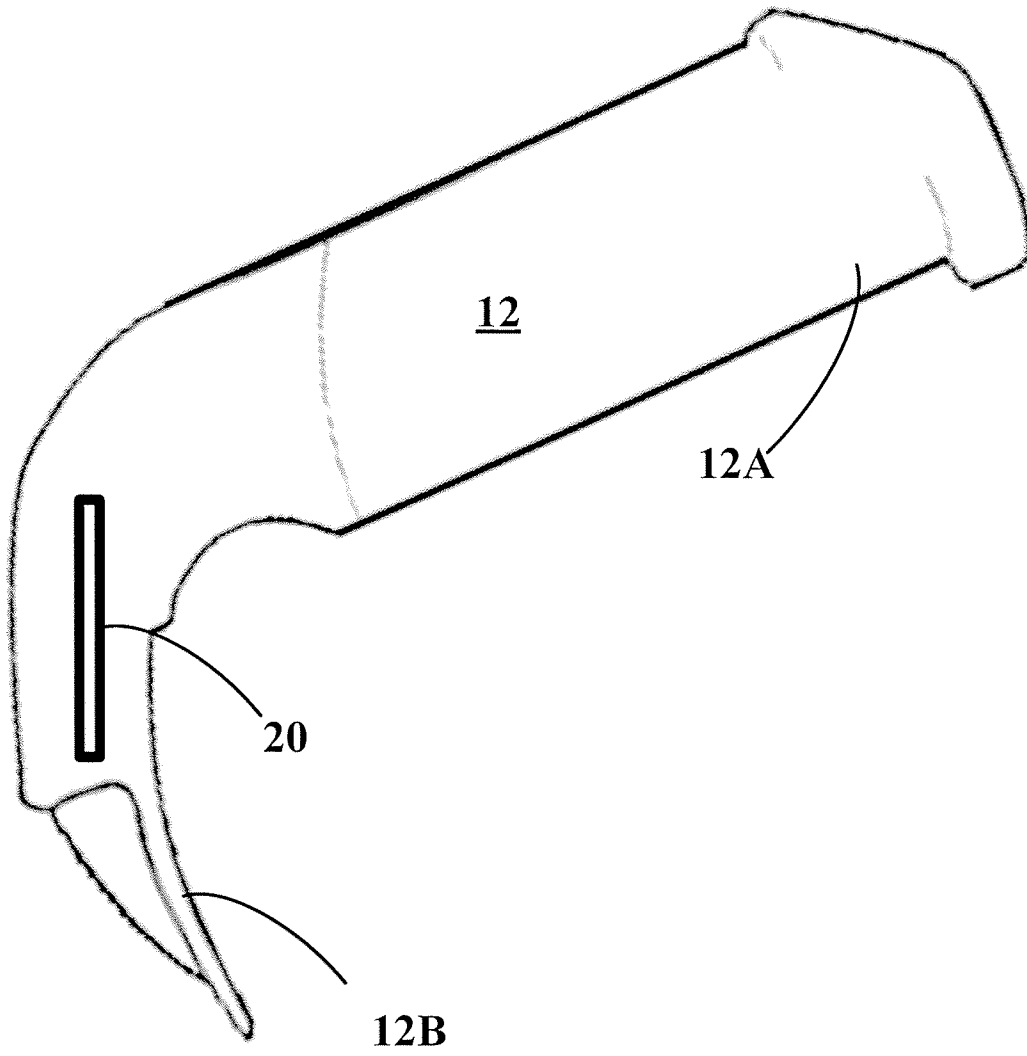


Fig. 20

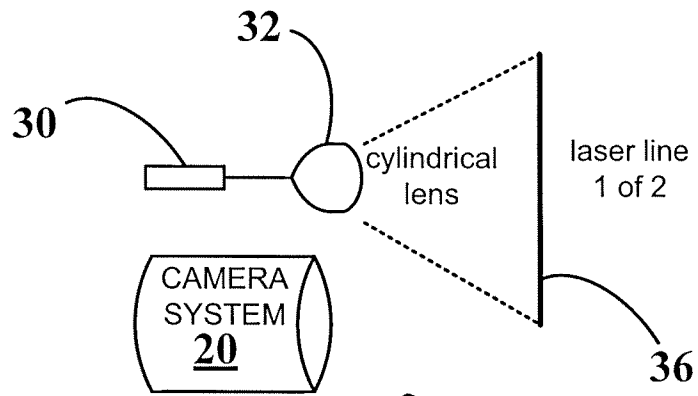


Fig. 20

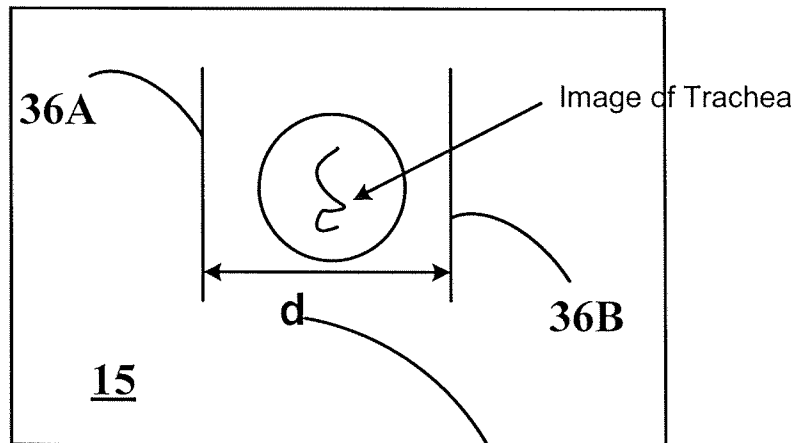
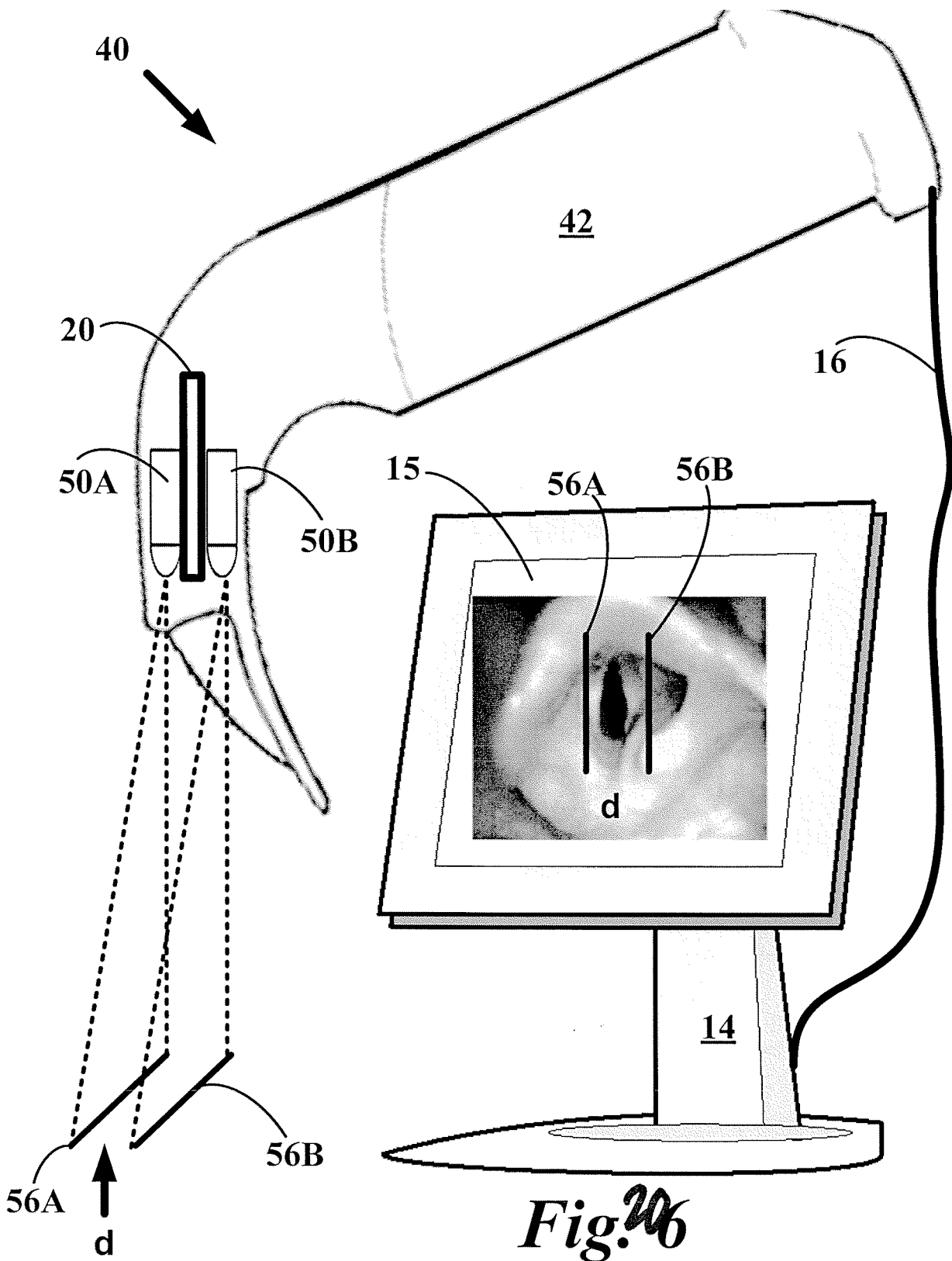


Fig. 20

Known geometry distance "d" from mounting



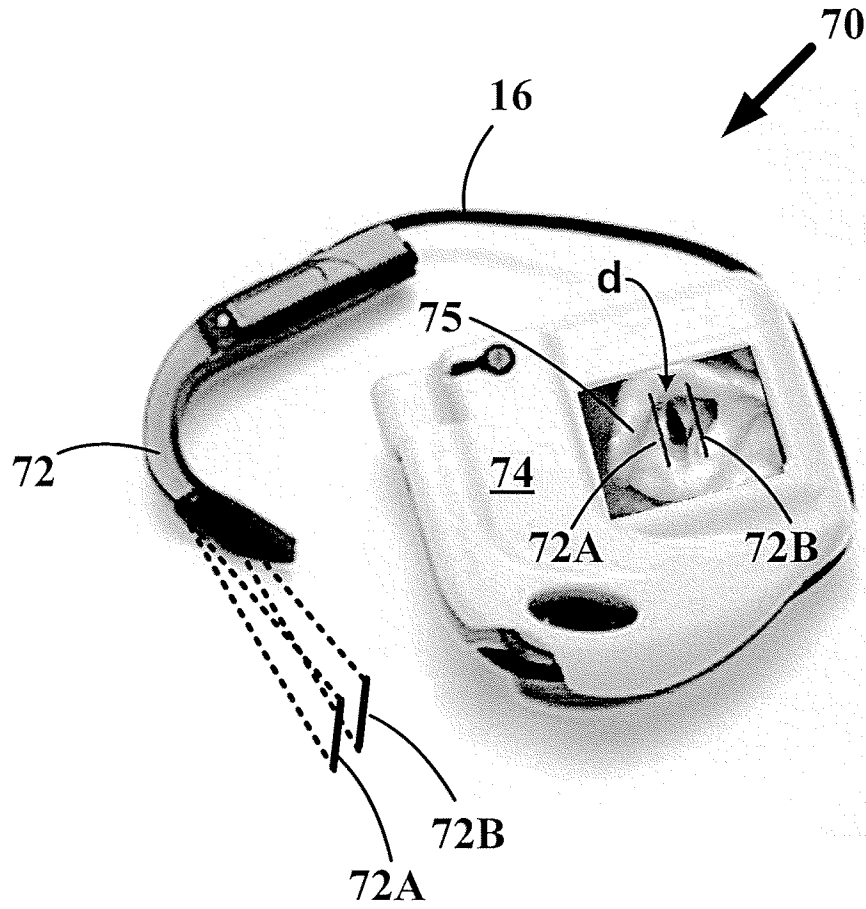


Fig. 20