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(54) **INTRA-NEEDLE ULTRASOUND SYSTEM AND ITS METHOD OF USE FOR ANALYSIS, TRACKING, AND DISPLAY OF PLEURA IN MILLIMETER SCALE RESOLUTION**

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A61B 17/34	(2006.01)

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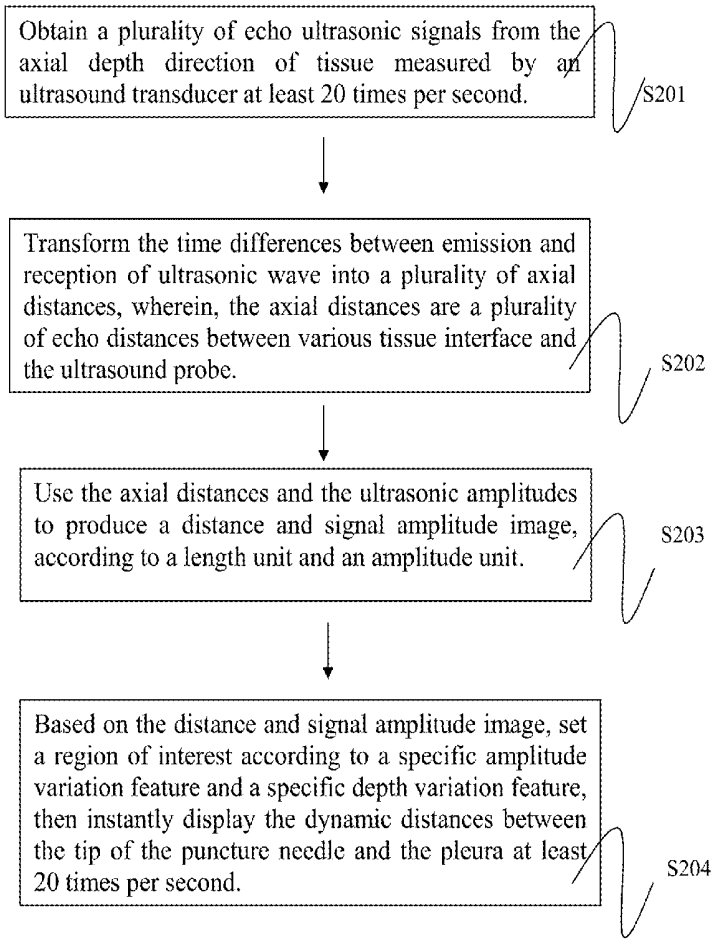
(57) **ABSTRACT**

The invention provides an intra-needle ultrasound system and its method of use for analysis, tracking, and display of pleura in millimeter-scale resolution. This method includes the following steps: Assembling the puncture needle and intra-needle ultrasound transducer, which can generate and receive ultrasound waves at the needle tip. To transform the axial ultrasonic signal into a figure, that can help to identify different anatomic structures according to the corresponding feature of ultrasonic RF (Radio Frequency) signal, and to set the region of interest according to corresponding RF feature of amplitude and depth. This invention can indicate the distance between the ultrasound needle tip and pleura in a real-time fashion, and to identify the best position for anesthetic injection in the paravertebral block (PVB) and the intercostals nerve block (ICNB). The system can also help to avoid damage to the pleura and lung during the nerve block procedure.



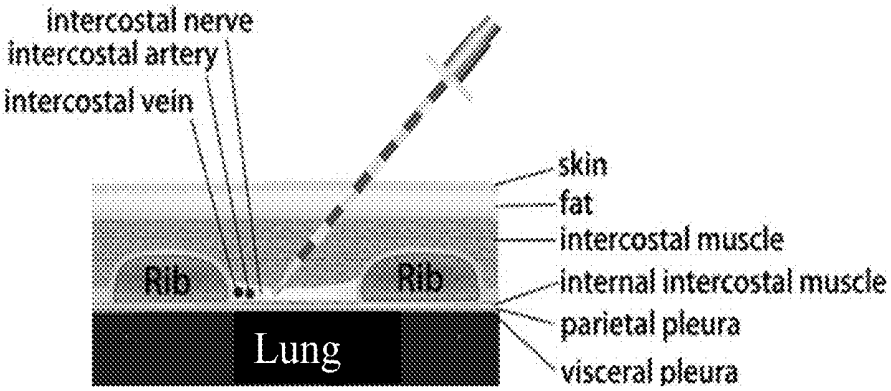

intercostal nerve
intercostal artery
intercostal vein
skin
fat
intercostal muscle
internal intercostal muscle
parietal pleura
visceral pleura
Rib
Rib
Lung

Fig. 1A

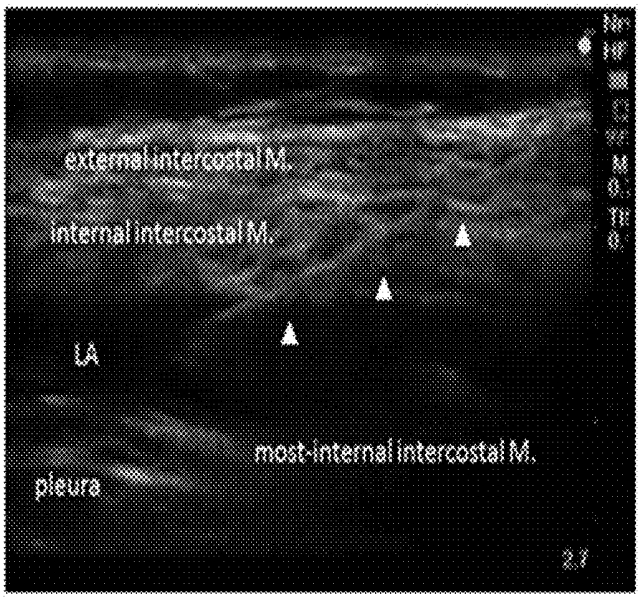

external intercostal M.
internal intercostal M.
LA
most-internal intercostal M.
pleura

Fig. 1B

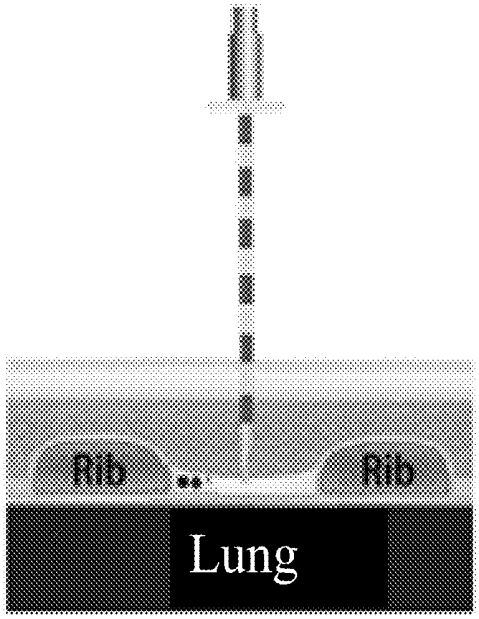


Fig.1C

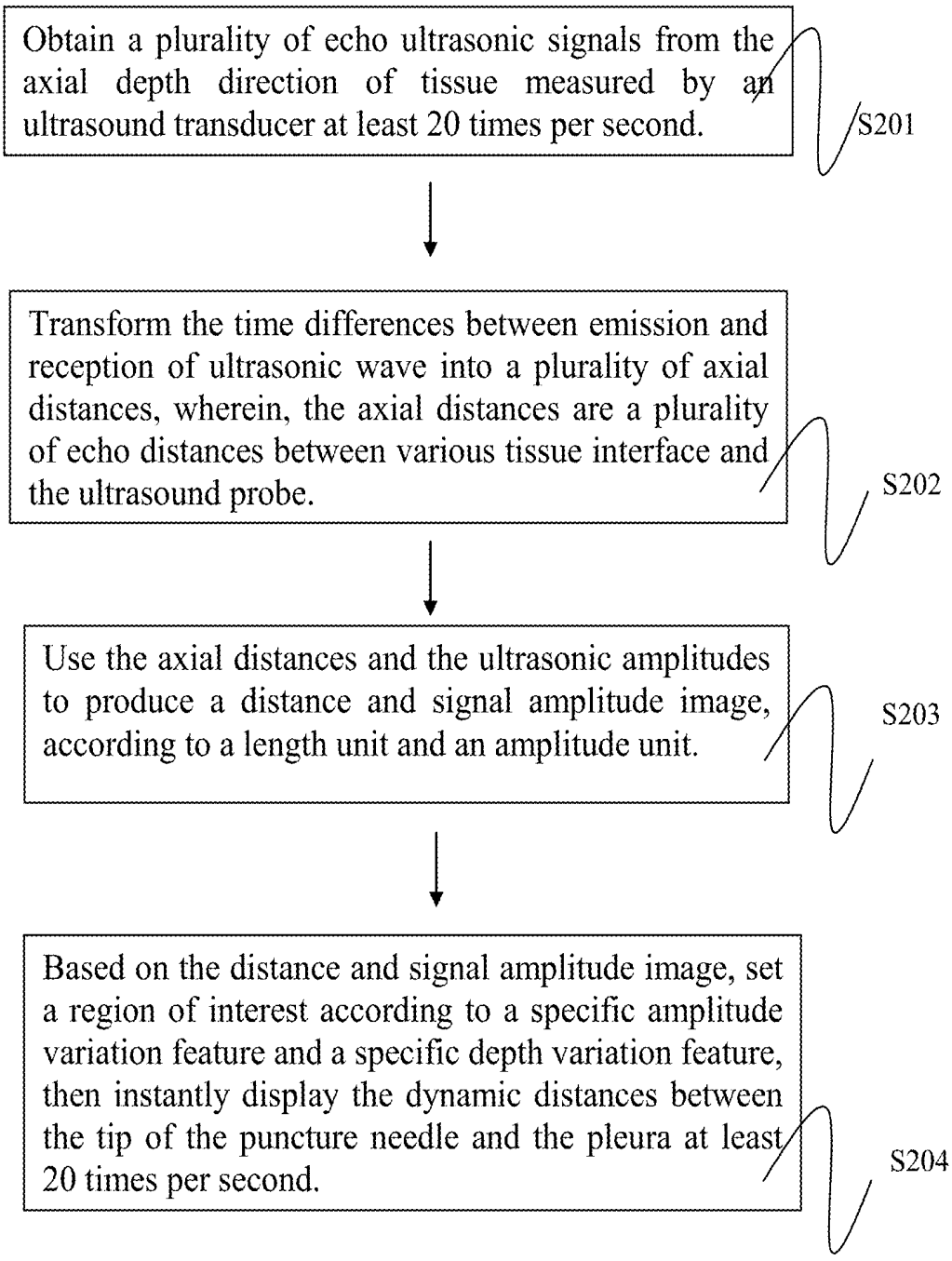

Obtain a plurality of echo ultrasonic signals from the axial depth direction of tissue measured by an ultrasound transducer at least 20 times per second.
S201
Transform the time differences between emission and reception of ultrasonic wave into a plurality of axial distances, wherein, the axial distances are a plurality of echo distances between various tissue interface and the ultrasound probe.
S202
Use the axial distances and the ultrasonic amplitudes to produce a distance and signal amplitude image, according to a length unit and an amplitude unit.
S203
Based on the distance and signal amplitude image, set a region of interest according to a specific amplitude variation feature and a specific depth variation feature, then instantly display the dynamic distances between the tip of the puncture needle and the pleura at least 20 times per second.
S204

Fig. 2

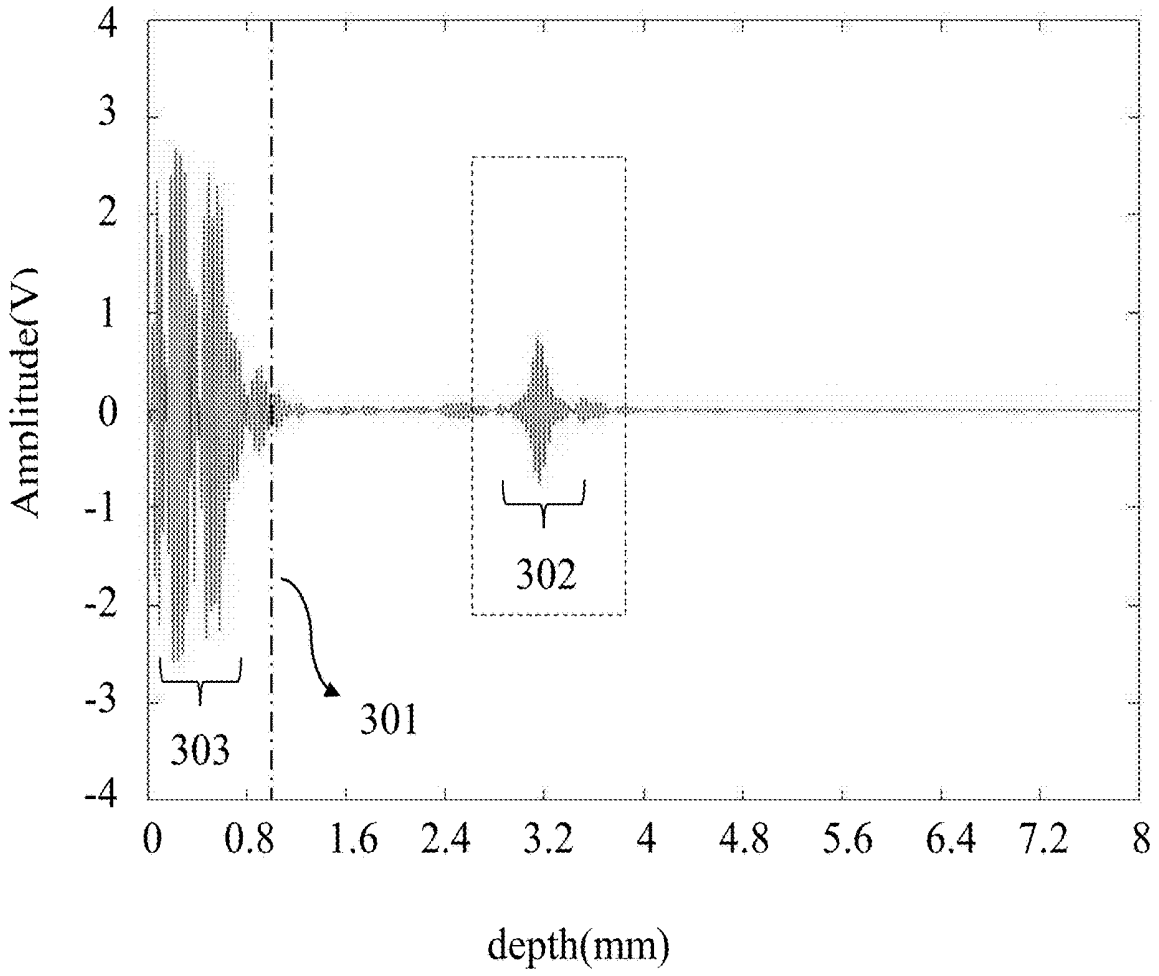

4
3
2
1
0
-1
-2
-3
-4
Amplitude(V)
0
0.8
1.6
2.4
3.2
4
4.8
5.6
6.4
7.2
8
depth(mm)
302
301
303

Fig. 3

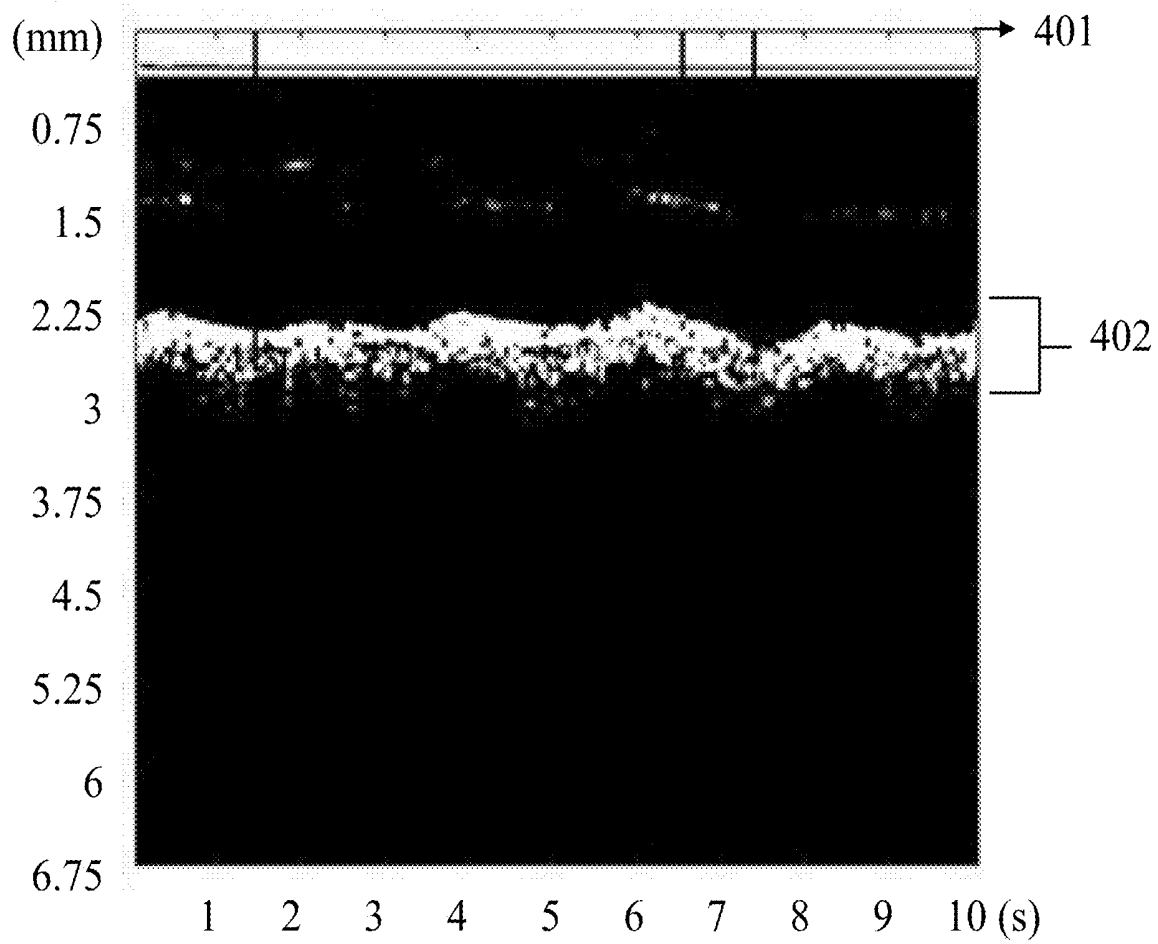


Fig. 4

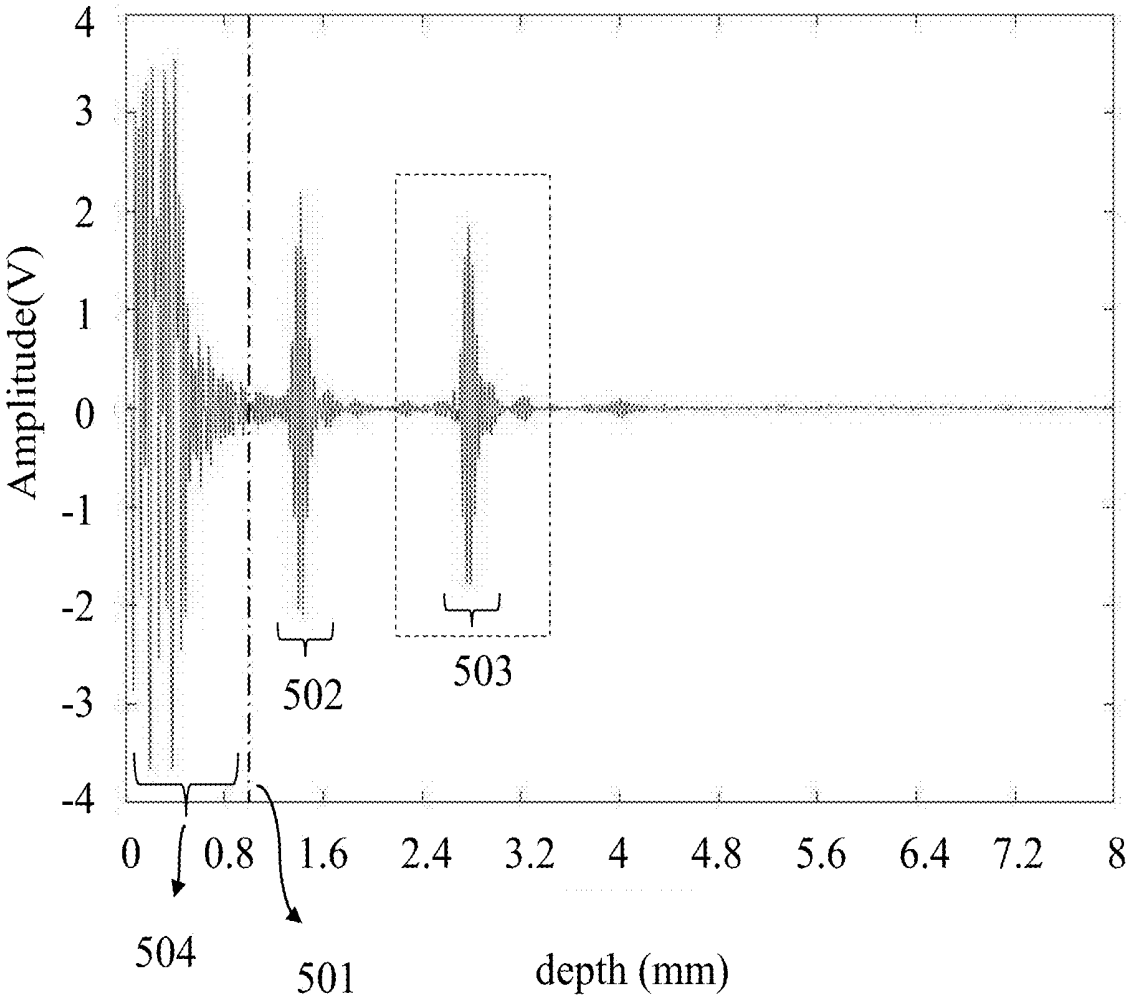

4
3
2
1
0
-1
-2
-3
-4
Amplitude(V)
0
0.8
1.6
2.4
3.2
4
4.8
5.6
6.4
7.2
8
depth (mm)
501
502
503
504

Fig. 5

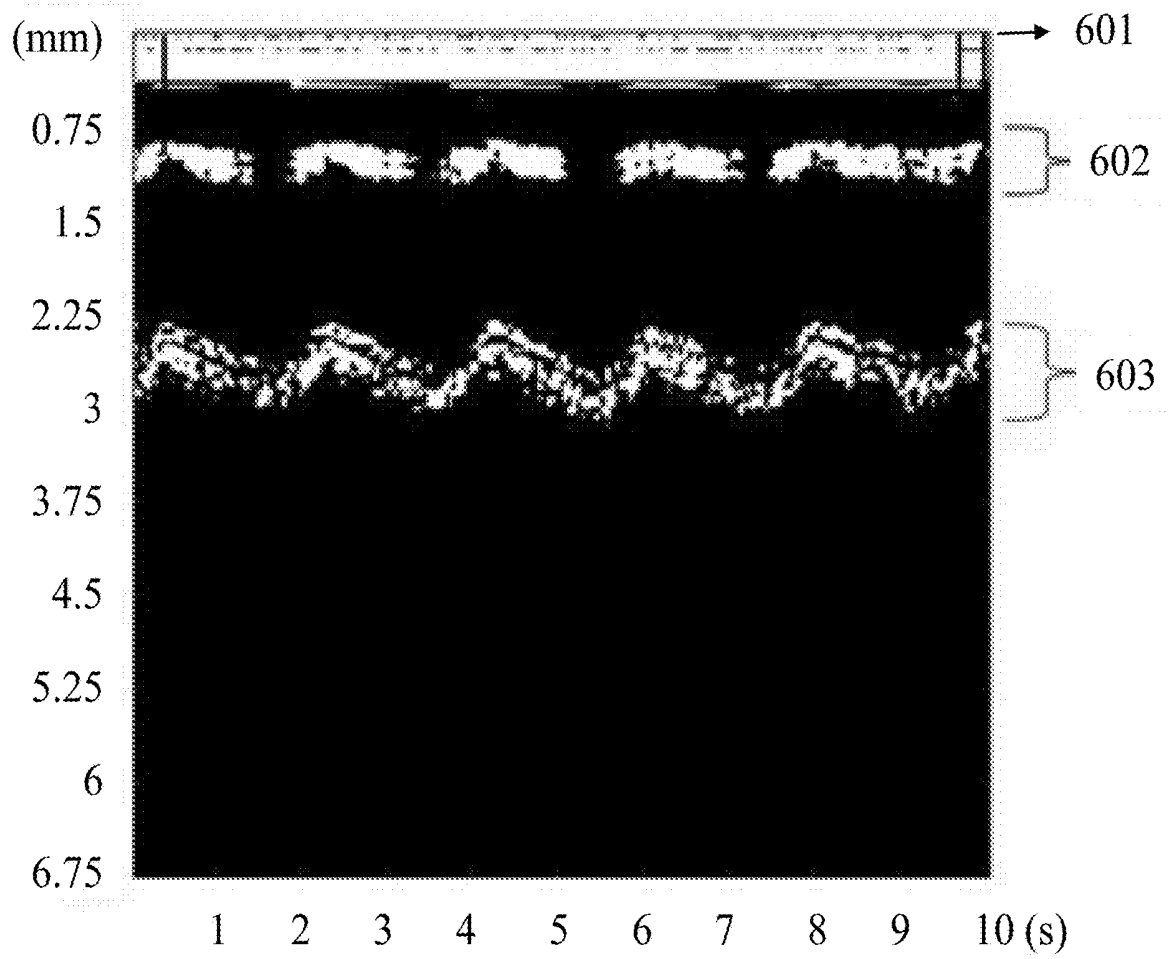


Fig. 6

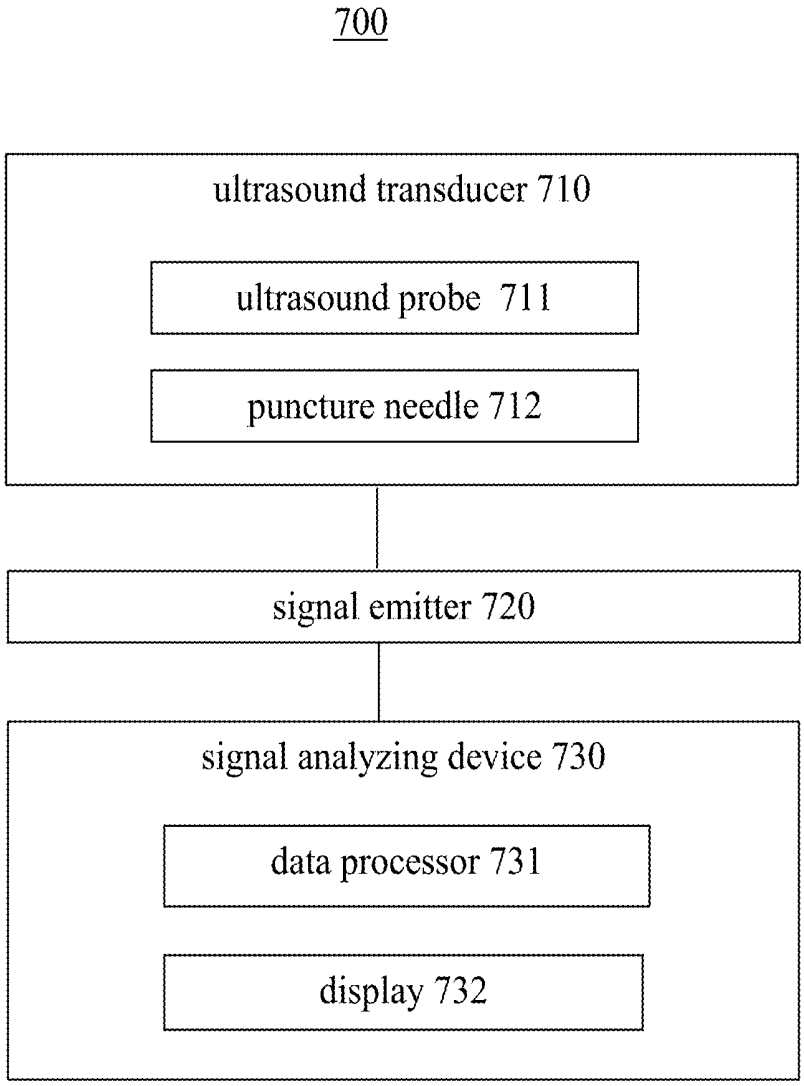

700
ultrasound transducer 710
ultrasound probe 711
puncture needle 712
signal emitter 720
signal analyzing device 730
data processor 731
display 732

Fig.7

INTRA-NEEDLE ULTRASOUND SYSTEM AND ITS METHOD OF USE FOR ANALYSIS, TRACKING, AND DISPLAY OF PLEURA IN MILLIMETER SCALE RESOLUTION

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This non-provisional application claims priority under 35 U.S.C. § 119 on Patent Application No. TW 108100218 filed in Taiwan, Republic of China Jan. 3, 2019, the entire contents of which are hereby incorporated by reference in its entirety.

FIELD OF THE INVENTION

[0002] The invention provides an ultrasound system and its method of use for analysis, tracking, and display of pleura in millimeter-scale resolution. Particularly, it is used in Paravertebral Block (PVB) and Intercostals Nerve Block (ICNB) to identify the pleura of a signal feature from ultrasound, and detect the distance between the puncture needle tip and the pleura. It can also help to avoid damage to the lung during the nerve block procedure.

BACKGROUND OF INVENTION

[0003] In the present, the main technique for peripheral nerve block in the thoracic region is to inject local anesthetics to block nerve roots of thoracic spine or to infiltrate the spaces with nerves, to achieve pain relief.

[0004] Over the past ten years, ultrasonic technology is widely used in the area of anesthesiology and has greatly enhanced the effectiveness and success rate of regional anesthetics. Particularly, in the case of the paravertebral block (PVB) and the intercostal nerve block (ICNB). In the present, the medical professionals will perform PVB and ICNB procedures under the guidance of the B-mode (Brightness Mode) ultrasonic image. However, the B-mode image cannot: (1) locate the tip of the puncture needle precisely (2) measure the distances between the tip of the puncture needle and the pleura. Therefore, even with ultrasound guidance, the above operations are still facing considerable risks such as accidental pleural puncture or pneumothorax.

[0005] The present invention combines a puncture needle and an intra-needle ultrasonic transducer to provide an identification of anatomical structures. It provides a real-time ultrasonic signal during puncture and enhances safety by objectively identifying the lung and surrounding tissues.

SUMMARY OF THE INVENTION

[0006] The paravertebral block (PVB) and the intercostal nerve block (ICNB) can provide an excellent analgesic effect. However, at present, it has potential risks. With the existence of several important organs in the chest area, it is a challenge to ensure absolute effectiveness and safety. Therefore, the present invention: (1) Using ultrasound needle probe. The needle-shaped ultrasound probe is placed in the inner side of the puncture needle. The ultrasound probe can measure the distance precisely in real-time with the 0.2 mm axial-resolution, and provide warning function. (2) In previous research, the discovery of the flickering pleura signal in respiratory movement in A-mode (amplitude mode) has not been reported. (3) Base on the A-mode signal, setting a region of interest, analyzing and identifying the flickering pleura signal in respiratory movement with de-correlation value, or FFT spectrum or time-frequency spectrum. And then display and track the dynamic distances between the tip of the puncture needle and the pleura in real-time.

[0007] The main object of the present invention is to provide a method and system that can identify the axial depth of puncture by analyzing the characteristics of breath movement and the ultrasonic echo signals, particularly echo signals from the pleura, so as to provide assistance for the puncture needle to reach a target depth accurately.

[0008] Furthermore, with the use of external ultrasonic depth measurement, the most common implementation of the above-mentioned anesthesia at present is an oblique downward puncture. Referring to FIG. **1**A, the puncture needle goes into the intercostal nerve region with an angle between the needle and the skin; referring to FIG.**1**B, as in the oblique downward puncture, the external ultrasonic depth measurement is not parallel to the movement direction of the puncture needle, it is difficult to judge and determine the relation between the length of needle thrust and the actual depth, and the needle tip and its distance from the pleura cannot be easily observed. This may increase the risk of the operation. The present invention further discloses another method of needle puncture. See FIG. **1**C, the needle is punctured with an orthogonal or nearly perpendicular angle against the skin before going into the region of intercostal nerve. Thus, the depth of needle thrust equals the actual depth.

[0009] As such, the present invention provides a combined method for analyzing, identifying, tracking and ranging pleura breath signal in millimeter-scale resolution, which include: (a) obtaining a plurality of echo ultrasonic signals from the axial depth direction of tissue measured by an ultrasound probe at least 20 times per second, wherein, each echo ultrasonic signal includes an ultrasonic amplitude and a time difference between emission and reception of ultrasonic wave; (b) transforming the time differences between emission and reception of ultrasonic wave into a plurality of axial distances, wherein, the axial distances are a plurality of echo distances between various tissue interface and the ultrasound probe; (c) using the axial distances and the ultrasonic amplitudes to produce a distance and signal amplitude image according to a length unit and an amplitude unit; and (d) based on the distance and signal amplitude image, setting a region of interest according to a specific amplitude variation feature and a specific depth variation feature, then displaying the dynamic distances between the tip of the puncture needle and the pleura at least 20 times per second.

[0010] Furthermore, the present invention provides a combined system for analyzing, identifying, tracking, ranging and displaying of pleura in millimeter-scale resolution, which includes: an ultrasound transducer, a signal emitter and a signal analyzing device with a wired or wireless connection to the ultrasound transducer.

[0011] Said ultrasound transducer has an ultrasound probe and a puncture needle, wherein, said ultrasound probe is placed in the inner side of the puncture needle, emitting, through a signal emitter, ultrasonic impulse waves at least 20 times per second. (For example: 50 times per second)

[0012] Said signal emitter, to obtain a plurality of echo ultrasonic signals from the axial depth of tissue puncture by the ultrasound probe, wherein, each echo ultrasonic signal

includes an ultrasonic amplitude and a time difference between emission and reception of the ultrasonic wave.

[0013] Said signal analyzing device includes: a data processor, connected to the signal receiver, to transform the time differences between emission and reception of the ultrasonic wave into a plurality of axial distances. The axial distances are a plurality of echo distances between various tissue interface and the ultrasound probe, then, according to a length unit and an amplitude unit, a distance and signal amplitude image is produced; and a display, connected to the data processor, to display the distance and signal amplitude image, and to set a region of interest according to a specific amplitude variation feature and a specific depth variation feature, then to instantly display and track the dynamic distances between the tip of the puncture needle and the pleura in real time.

[0014] The term "pleura" as used in the present invention refers to consisting of the visceral pleura and the parietal pleura.

[0015] The term " signal " relative position as used in the present invention is the sequence listed below [ultrasonic noise] (**303**, **504**), [puncture needle tip] (**301**, **501**)-[ultrasound probe] (**401**-**601**)-[innermost intercostal muscle] (**502**-**602**)and [pleura] (**302**, **402**, **503**, **603**), and the pleura signal that is a useful benchmark for measuring to identify the best position for anesthetic injection.

[0016] In order to realize the above-mentioned and other objects, one or more embodiments of the present invention are disclosed and illustrated below. Other features and advantages of the present invention are detailed in the embodiments and claims.

BRIEF DESCRIPTION OF THE DRAWINGS

[0017] FIG. **1**A is an embodiment of oblique downward puncture(in-plane).

[0018] FIG. **1**B is an ultrasonic signal diagram of the oblique downward puncture to the schematic diagram.

[0019] FIG. **1**C is an embodiment of orthogonal downward puncture.

[0020] FIG. **2** is a step-by-step process chart of the present invention.

[0021] FIG. **3** is an image showing the distance between the ultrasound probe and the pleura as well as the signal amplitude obtained from PVB by the method of the present invention.

[0022] FIG. **4** is a time-varying image of the distance between the ultrasound probe and the pleura and the signal amplitude obtained from PVB by the method of the present invention (ultrasonic M-mode image).

[0023] FIG. **5** is an image showing the distance between the ultrasound probe and the pleura as well as the signal amplitude obtained from ICNB by the method of the present invention.

[0024] FIG. **6** is a time-varying image of the distance between the ultrasound probe and the pleura and the signal amplitude obtained from ICNB by the method of the present invention (ultrasonic M-mode image).

[0025] FIG. **7** is a component relationship diagram of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

[0026] The embodiments of the present invention are illustrated in FIGS. **2** to **7**.

[0027] The present invention provides a combined method for analyzing, identifying, tracking, and ranging pleura breath signal in millimeter-scale resolution. See FIG. **2**, its steps include: (a) obtaining a plurality of echo ultrasonic signals of the axial depth of tissue puncture by an ultrasound probe at least 20 times per second, wherein, each echo ultrasonic signal includes an ultrasonic amplitude and a time difference between emission and reception of ultrasonic wave S**201**; (b) transforming the time differences between emission and reception of ultrasonic wave into a plurality of axial distances, wherein, the axial distances are echo distances between various tissue interface and the ultrasound probe S**202**; (c) using the axial distances and the ultrasonic amplitudes to produce a distance and signal amplitude image S**203** according to a length unit and an amplitude unit; and (d) based on the distance and signal amplitude image, setting a region of interest according to a specific amplitude variation feature and a specific depth variation feature, then instant displaying and tracking the dynamic distances between the tip of the puncture needle and the pleura in real time S**204**.

[0028] Preferably, the steps of the method to measure the distance of the target object further include: (e) within an operation period, repeating the operational steps (a) to (c), using different axial depths to obtain a plurality of distance and signal amplitude images; (f) based on the distance and signal amplitude images, obtaining a distance and signal time-varying image according to the operation period; and (g) based on the distance and signal time-varying image, setting a region of interest according to the amplitude variation feature, the depth variation feature and a cyclic variation feature, then displaying the dynamic distances between the tip of the puncture needle and the pleura. Preferably, the cyclic variation feature is a signal amplitude variant or a signal frequency variant. In one embodiment, the cyclic variation feature is related to the breath, and the two variants can be analyzed using de-correlation value or FFT spectrum or time-frequency spectrum.

[0029] In one preferred embodiment, the tissue puncture refers to a region, the paravertebral region, which is formed by the superior costotransverse ligament, pleura, and the transverse processes of the vertebrae. The needle ultrasound probe measures the distance between the tip of the puncture needle and the pleura in real time during the breathing. FIG. **3** is a distance and signal amplitude image obtained from PVB by the ultrasound probe of the present invention. It shows the puncture depths at intervals from the puncture needle tip **301** to the pleura **302**; furthermore, referring to FIG. **4**, a time-varying image of the depths and signals obtained from PVB by the ultrasound probe of the present invention, the pleura **402** has cyclic ups and downs along with the breath.

[0030] In one preferred embodiment, the tissue puncture refers to a region from an intercostal space to the pleura. The needle ultrasound probe measures the distance among the tip of the puncture needle, the innermost intercostal muscle (IiM)**502** and the pleura in real time during the breathing. FIG. **5** is a distance and signal amplitude image obtained from the intercostal nerve block (ICNB) by the ultrasound probe of the present invention. It shows the puncture depths

at intervals from the puncture needle tip **501** to the innermost intercostal muscle (IiM) **502** and the pleura **503**; furthermore, referring to FIG. **6**, a time-varying image of the depths and signals obtained from intercostal nerve block (ICNB) by the probe of the present invention, the pleura **603** has cyclic ups and downs along with the breath.

[0031] Preferably, the steps of the method further include: when the distance between the pleura and the tip of the puncture needle is closer than a preset distance, a warning signal is produced which is not limited to being expressed in the form of light, sound or symbols.

[0032] The implementation steps of the combined method of the present invention can further be written into a software program. The software program can be saved in record media to be identified and decoded by any micro-processing unit, or in any object or device containing the above record media. With no limit to the form, the above object can be a hard disk, floppy disk, CD-ROM, ZIP, MO, IC chip, RAM, or any object containing the above record media available to those skilled in the art. Referring to FIG. **7**, the present invention provides a combined system **700** for analyzing, identifying, tracking, ranging and displaying of pleura in millimeter-scale resolution, which includes: an ultrasound transducer **710**, a signal emitter **720** and a signal analyzing device **730**, with a wired or wireless connection to the ultrasound transducer **720**.

[0033] Said ultrasound transducer **710** has an ultrasound probe **711** and a puncture needle **712**, wherein, said ultrasound probe **711** is placed on the inner side from the puncture needle **712**, emitting, through a signal emitter, ultrasonic impulse waves at least 20 times per second(For example: 50 times per second). Preferably, the frequency of the ultrasonic impulse wave is 5-40 MHz, and the amplitude is 50-100V.

[0034] In one embodiment, the end face of the ultrasound probe **711** is a plane, and the tube end of the puncture needle **712** is a relatively inclined plane; or, the end face of the ultrasound probe **711** and the tube end of the puncture needle **712** are aligned to the same inclined plane, and the same plane is an inclined plane with an included angle of 20 to 50 degrees. Said signal emitter **720**, to obtain a plurality of echo ultrasonic signals of the axial depth of tissue puncture by the ultrasound transducer **710**, wherein, each echo ultrasonic signal includes an ultrasonic amplitude and a time difference between emission and reception of ultrasonic wave.

[0035] Said signal analyzing device **730** includes: a signal processor **731**, to transform the time differences between emission and reception of the ultrasonic wave into a plurality of axial distances. The axial distances are a plurality of echo distances between various tissue interface and the ultrasound probe, and, according to a length unit and an amplitude unit, a distance and signal amplitude image is produced; and a display **732**, connected to the data processor **731**, to display the distance and signal amplitude image, and to set a region of interest according to a specific amplitude variation feature and a specific depth variation feature, then to instantly display and track the dynamic distances between the tip of the puncture needle **712** and the pleura in real time. Preferably, the data processor **731** to obtain the plurality of distance and signal amplitude images based on different axial depths, and, based on the distance and signal amplitude images, to output a distance and signal time-varying image according to the operation period; and the display **732** displays the distance and signal time-varying image, and set the region of interest according to the amplitude variation feature, the depth variation feature and a cyclic variation feature, and display the distances between the pleura and the tip of the puncture needle **712**.

[0036] The features disclosed in the present invention can be realized in any form of combination, and can be substituted by any alternatives with the same, equal or similar objects. Therefore, unless otherwise indicated, each feature disclosed is just an embodiment of one type of an equivalent or similar feature.

1. A combined method for analyzing, identifying, tracking, ranging and displaying pleura breath signal in millimeter-scale resolution, with its steps including:

(a) obtaining a plurality of echo ultrasonic signals from the axial depth direction of tissue measured by an ultrasound probe, wherein, each echo ultrasonic signal includes an ultrasonic amplitude and a time difference between emission and reception of ultrasonic wave;

(b) transforming the time differences between emission and reception of ultrasonic wave into a plurality of axial distances, the axial distances are a plurality of echo distances between various tissue interface and the needle tip of the ultrasound probe;

(c) using the axial distances and the ultrasonic amplitudes to produce a distance and signal amplitude image according to a length unit and an amplitude unit; and

(d) based on the distance and signal amplitude image, setting a region of interest according to a specific amplitude variation feature and a specific depth variation feature, then instantly displaying and tracking the dynamic distances between the tip of the puncture needle and the pleura.

2. The method defined in claim **1**, with its steps further including:

(e) within an operation period, repeating the operational steps (a) to (c), using different axial depths to obtain a plurality of distance and signal amplitude images;

(f) based on the distance and signal amplitude images, obtaining a distance and signal time-varying image according to the operation period; and

(g) based on the distance and signal time-varying image, setting a region of interest according to the amplitude variation feature, the depth variation feature and a cyclic variation feature, then displaying the dynamic distances between the pleura and the tip of the ultrasound probe at least 20 times per second.

3. The method defined in claim **1**, wherein said the tissue puncture refers to a region, the paravertebral region, which is formed by the superior costotransverse ligament, pleura, and the transverse processes of the vertebrae; the needle ultrasound transducer measures the distance between the tip of the puncture needle and the pleura in real time during the breathing.

4. The method defined in claim **1**, wherein said the tissue puncture refers to a region from an intercostal space to the pleura; the needle ultrasound transducer measures the distance among the tip of the puncture needle, the innermost intercostal muscle (IiM) and the pleura in real time during the breathing.

5. The method defined in claim **1**, wherein its steps further including: when the distance between the pleura and the tip of the puncture needle is shorter than a preset distance, a warning signal is produced.

6. A combined system for analyzing, identifying, tracking, ranging and displaying of pleura in millimeter-scale resolution, including:

an ultrasound transducer, having an ultrasound probe and a puncture needle, wherein, said ultrasound probe is placed in the inner side of the puncture needle, emitting, through a signal emitter;

a signal emitter, to obtain a plurality of echo ultrasonic signals from the axial depth direction of tissue measured based on an ultrasound probe, wherein, each echo ultrasonic signal includes an ultrasonic amplitude and a time difference between emission and reception of ultrasonic wave; and

a signal analyzing device, with a wired or wireless connection to the ultrasound probe, including:

a data processor, to transform the time differences between emission and reception of the ultrasonic wave into a plurality of axial distances; the axial distances are a plurality of echo distances between various tissue interface and the ultrasound probe, then, according to a length unit and an amplitude unit, a distance and signal amplitude image is produced; and

a display, connected to the data processor, to display the distance and signal amplitude image, and to set a region of interest according to a specific amplitude variation feature and a specific depth variation feature, then to instantly display and track the dynamic distances between the-tip of the puncture needle and the pleura in real time.

7. The system defined in claim **6**, wherein the end face of the ultrasound probe is a plane, and the tube end of the puncture needle is a relatively inclined plane.

8. The system defined in claim **6**, wherein the end face of the ultrasound probe and the tube end of the puncture needle are aligned to the same inclined plane, and the same plane is an inclined plane with an included angle of 20 to 50 degrees.

9. The system defined in claim **6**, which further includes:

an ultrasound transducer, wherein signal emitter ultrasonic impulse waves at least 20 times per second;

a data processor, to obtain the plurality of distance and signal amplitude images based on different axial depths, and, based on the distance and signal amplitude images, to output a distance and signal time-varying image according to the operation period; and

a display, to display the distance and signal time-varying image, and, according to the amplitude variation feature, the depth variation feature and a cyclic variation feature, set the region of interest, and to display the dynamic distances between the pleura and the tip of the puncture needle.

* * * * *

专利名称(译)	针内超声系统及其在毫米级分辨率下用于胸膜的分析,跟踪和显示的方法		
公开(公告)号	US20200214678A1	公开(公告)日	2020-07-09
申请号	US16/699277	申请日	2019-11-29
[标]申请(专利权)人(译)	国立阳明大学 台北荣民总医院		
申请(专利权)人(译)	国立阳明大学 台北荣总		
当前申请(专利权)人(译)	国立阳明大学 台北荣总		
[标]发明人	CHIANG HUIHUA TING CHIEN KUN LIAO SHU WEI YANG CHIA WEI		
发明人	CHIANG, HUIHUA TING, CHIEN-KUN LIAO, SHU-WEI SU, FU-WEI YANG, CHING-FANG YANG, CHIA-WEI		
IPC分类号	A61B8/08 A61B8/00 G06T7/00 A61B17/34		
CPC分类号	A61B2017/3413 A61B8/461 A61B8/0841 G06T7/0012 A61B8/54 A61B8/4483 G06T2207/10132 A61B8/5207 A61B17/3403 G06T2207/30061		
优先权	108100218 2019-01-03 TW		
外部链接	USPTO		

摘要(译)

本发明提供了一种针内超声系统及其用于以毫米级分辨率分析,追踪和显示胸膜的方法。 该方法包括以下步骤:组装穿刺针和针内超声换能器,它们可以在针尖产生和接收超声波。 将轴向超声信号转化为图形,可以根据超声RF(射频)信号的相应特征来识别不同的解剖结构,并根据幅度和深度的相应RF特征来设置感兴趣区域。 本发明可以实时指示超声针尖与胸膜之间的距离,并确定在椎旁阻滞(PVB)和肋间神经阻滞(ICNB)中进行麻醉注射的最佳位置。 该系统还可以帮助避免在神经阻滞过程中损坏胸膜和肺。