(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
25 July 2013 (25.07.2013)

WIPO | PCT

(10) International Publication Number
WO 2013/108198 A1

(51) International Patent Classification:
A61B 8/08 (2006.01) *A61B 19/00* (2006.01)
A61B 8/00 (2006.01) *G06T 7/00* (2006.01)

(21) International Application Number:
PCT/IB2013/050417

(22) International Filing Date:
17 January 2013 (17.01.2013)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/587,784 18 January 2012 (18.01.2012) US

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(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, 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, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, 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, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*

— *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))*

Published:

— *with international search report (Art. 21(3))*

(54) **Title**: ULTRASONIC GUIDANCE OF A NEEDLE PATH DURING BIOPSY

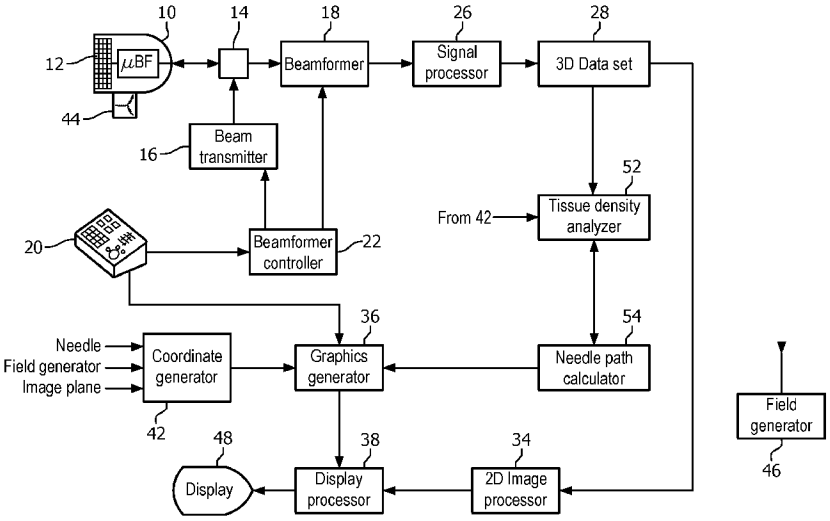

FIG. 1

(57) **Abstract**: An ultrasonic imaging system is described which visually assists biopsy needle insertion. The system produces pixel values of pixels along one or more paths of needle insertion. A tissue density analyzer is responsive to the pixel values to estimate tissue density along a path of needle insertion. A needle path calculator is responsive to the tissue density analyzer and proposes one or more favorable paths through imaged tissue for insertion of the biopsy needle. The system may be used in conjunction with a three dimensional navigation system which spatially locates the needle and ultrasound image plane in 3D space.

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ULTRASONIC GUIDANCE OF A NEEDLE PATH DURING BIOPSY

This invention relates to medical diagnostic imaging systems and, in particular, to diagnostic ultrasound systems which provide visual guidance of a needle during biopsy or other invasive procedure.

A biopsy is a medical procedure involving the removal of cells or tissues for examination. The procedure comprises the medical removal of tissue from a living subject to determine the presence or extent of a disease. The excised tissue is generally examined under a microscope by a pathologist, and can also be analyzed chemically for disease states. When an entire lump or suspicious area is removed, the procedure is called an excisional biopsy. When only a sample of tissue is removed with preservation of the histological architecture of the cells of the tissue, the procedure is called an incisional biopsy or core biopsy. When a sample of tissue or fluid is removed with a needle in such a way that cells are excised without preserving the histological architecture of the tissue cells, the procedure is called a needle aspiration biopsy.

In order to efficiently insert the needle directly to the target tissue it is preferable to perform the procedure with the assistance of diagnostic imaging such as ultrasound imaging. The clinician can locate the target tissue in the image, then insert the needle in line with the image plane. The clinician can then observe the needle as it is inserted and confidently guide the needle until the needle tip accesses the target tissue. A sample of the target tissue can then be aspirated or excised through the needle. For even greater ease and precision, the procedure can also use a surgical

navigation system such as the Philips PercuNav guidance system. The PercuNav system broadcasts a modulated magnetic field around and through the site of the procedure. Sensors are positioned on the needle and the ultrasound imaging probe so that the system can locate the position and orientation of the patient, the surgical site, the needle and the ultrasound image plane in three dimensional space. The PercuNav system can then aid in the more precise display of the needle and needle tip in the ultrasound image and its position and orientation with respect to the image plane. The clinician can indicate the target tissue on the ultrasound image and the PercuNav system will graphically indicate on the display the path to be followed by the needle to reach the target tissue.

However, difficulties in tumor targeting still exist as the ultrasound image plane and biopsy needle must remain coplanar throughout the procedure to display the actual needle tip position. Also, the Philips PercuNav system will not suggest a favorable path for insertion which provides the least resistance to insertion and avoids nearby sensitive organs. In many instances the needle will deflect and bend as it encounters stiff or dense tissue during insertion. As a result, biopsy procedural efficiency is hindered since needle pathway interpretation is often difficult, especially for needle insertions at large depths that can require multiple reinsertions. All the aforementioned difficulties result in additional time with multiple reinsertions of the biopsy needle with increased patient discomfort and morbidity. Accordingly it is desirable for the imaging system to predict the most favorable path for needle insertion so as to reduce

technique variability and unnecessary injury to the patient. This will lead to a shorter learning curve for biopsy procedures, reduce procedure time, avoid multiple biopsy needle insertions and enable consistent replicable biopsy procedures, thereby reducing discomfort to the patient and improving outcomes.

In accordance with the principles of the present invention, an ultrasonic imaging system is provided for guiding needle insertion procedures. An ultrasound probe images the target tissue for the procedure and the tissue through which the needle is inserted to access the target tissue. As the insertion begins, ultrasonic echo information of pixels along the projected insertion path is acquired and analyzed to determine local variations in tissue density along the projected path. If the analysis shows that a region of dense tissue will be encountered along the intended path, densities along other possible paths are acquired and analyzed and an alternative insertion path is presented for consideration by the clinician. The clinician can then choose an insertion path which is most effective for the procedure and most comfortable for the patient.

In the drawings:

FIGURE 1 illustrates in block diagram form an ultrasonic imaging system for needle guidance constructed in accordance with the principles of the present invention.

FIGURE 2 illustrates a column of pixels along the projected insertion path of a biopsy needle.

FIGURE 3 illustrates an ultrasound probe imaging target tissue and tissue through which the target is accessed in a body.

FIGURE 4 illustrates the positioning of a needle for a biopsy procedure and a projected path of insertion.

FIGURE 5 illustrates the imaging state of FIGURE 4 with an indication of tissue density along the projected path of insertion.

FIGURE 6 illustrates the imaging state of FIGURE 4 with a dense anatomical structure in the projected path of needle insertion.

FIGURE 7 illustrates the imaging state of FIGURE 6 with suggested alternative paths of insertion.

Referring first to FIGURE 1, an ultrasonic imaging system for assisting needle guidance is shown in block diagram form. an ultrasound probe 10 contains an array transducer 12 for scanning and imaging the region in front of the transducer. The transducer array can be a one-dimensional (1D) array for scanning a plane in front of the probe, but preferably the transducer is a two dimensional (2D) array transducer 12 which transmits electronically steered and focused beams over a volumetric region and receives single or multiple receive beams in response to each transmit beam. With the 2D array 12 the probe can scan an image plane and the tissue on either elevational side of the image plane. Groups of adjacent transducer elements of the array, referred to as "patches" or "subarrays," are integrally operated by a microbeamformer (μBF) in the probe 12, which performs partial beamforming of received echo signals and thereby reduces the number of conductors in the cable between the probe and the mainframe ultrasound system. Suitable two dimensional arrays are described in U.S. Patent 6,419,633 (Robinson et al.) and in U.S. Patent 6,368,281 (Solomon et al.) Microbeamformers are

described in U.S. Patents 5,997,479 (Savord et al.) and 6,013,032 (Savord). The transmit beam characteristics of the array are controlled by a beam transmitter 16, which causes the apodized aperture elements of the array to emit a focused beam of the desired breadth in a desired direction through a volumetric region of the body. Transmit pulses are coupled from a beam transmitter 16 to the elements of the array by means of a transmit/receive switch 14. The echo signals received by the array elements and partially beamformed by the microbeamformer in response to a transmit beam are coupled to a system beamformer 18, where the partially beamformed echo signals are processed to form fully beamformed single or multiple receive beams in response to a transmit beam. A suitable beamformer for this purpose is described in the aforementioned Savord '032 patent.

The receive beams formed by the beamformer 18 are coupled to a signal processor 12 which performs functions such as filtering and quadrature demodulation. The echo signals along the receive beams are detected and processed into a succession of pixels along each beam which are stored as a 3D data set 28. A B mode ultrasound image is generally formed by pixels in a range of grayscale values which are proportionate to the strength of received echo signals. Blood and very soft tissue will return relatively weak echo signals which produce relatively low grayscale values that are presented as darker shades in a B mode image. The blood in a blood vessel will be reproduced as a dark, almost black shade. But hard and dense substances such as hard cysts and dense tissue and specular reflectors will return relatively strong echo signals. The pixels of relatively high pixel values displayed from these

locations are displayed as bright, almost white pixels. Boundaries between different tissue types such as the boundaries of organs will also return strong echo signals which are displayed as bright pixels. Thus the values of the pixels are indicators of local tissue densities and organ boundaries.

The pixels of a plane of the scanned volume are coupled to a 2D image processor 34 where they are processed to form a two-dimensional ultrasound image of a scan plane of the volume. A technique for forming a 2D image from a 3D data set is commonly known and multi-planar reformatting (MPR). The MPR technique addresses the data values of image data which is in a common plane, which is then processed to form a 2D image of the selected plane. Alternatively, a plane of the scanned volume can be separately scanned in a time-interleaved manner as described in US Pat. 6,497,663 (Fraser et al.), which can result in a 2D display with a higher frame rate. A control panel 20 by which the clinician controls the operation of the ultrasound system includes a control by which the clinician selects and positions the plane of the MPR or scanned 2D image. The 2D image plane is generally aligned with the center of the two-dimensional array transducer, which advantageously means that regions on both sides of the image plane are scanned to produce pixel values in the image plane and on either side of it in the elevation dimension. However, a plane which is offset from the center of the transducer can also be used in accordance with the present invention, and the plane can be orthogonal to the transducer or tilted at a non-orthogonal angle to the transducer array. The processed 2D image is coupled to the display processor where it is overlaid with graphics

from a graphics generator 36, then displayed on the image display 48.

The ultrasound system described above can be used with a navigation system such as the PercuNav system, elements of which are shown in FIGURE 1. The PercuNav system has a field generator 46 which radiates an electromagnetic field permeating the site of the procedure and surrounding space. Sensors 44 are located on the probe 10, the biopsy needle (not shown) and the patient (not shown) which interact with the electromagnetic field and produce signals used to calculate the position and orientation of the 2D image plane of the probe, the biopsy needle and needle tip, and the patient. This calculation is done by a coordinate generator 42 of the PercuNav system, which is shown receiving signals from the needle and image plane and is also coupled to the field generator for field registration purposes. Coordinate information of the needle and image plane is coupled to the graphics generator 36 which produces needle path graphics in response thereto and in response to operator control signals from the control panel 20 as described below.

In accordance with the principles of the present invention, a tissue density analyzer 52 is provided which receives pixel data of the 3D Data Set 28. Using the coordinate information of the projected path of needle insertion from coordinate generator 42, the tissue density analyzer selects out and analyzes pixels along the projected needle path. These pixels can all be in the same plane such as the plane of the 2D image produced by the 2D image processor 34. Preferably the pixels are a three dimensional set of pixels (voxels) of the 3D Data Set as illustrated in FIGURE 2. This drawing illustrates

a 3 x 3 x N group of pixels where N is a number of pixels occupying some or all of the distance between the tip 62 of the needle 60 in the D direction. In this example the tip of the needle is aligned with the center column of this group of pixels which is in alignment with the projected path of the needle. This center column is surrounded in all directions by eight adjacent columns of pixels. Thus, each group of pixels in the x-y plane includes a center pixel on the projected needle path and pixels from the space surrounding the path. While a single column of pixels can be used, a three dimensional group is preferred as it samples the needle path and the pixel space around the path. In this example the tissue density analyzer 52 averages or sums the values of the nine pixels in each x-y plane and produces a value representing the tissue density at the distance D of the group along the needle path. For example, if there is dense, highly reflective anatomy at a given pixel plane, the value of the combined pixels of that location along the path will be relatively high, indicating a dense substance which may impede needle insertion. An organ boundary along the path will also generally return stronger echo signals. If a location comprises only soft tissue, the combined value will be relatively low, indicating less dense substance which should be easily penetrated by a needle. The sequence of density estimates thus calculated in the D direction is forwarded to a needle path calculator 54. The tissue density analyzer also performs this operation for possible needle paths adjacent to the projected needle path. For example the calculation can be performed on another group of pixels with the same y and D coordinates but with x incremented by three,

identifying a similar 3 x 3 x N group of pixels immediately adjacent to the first one. A sequence of density estimates is similarly calculated for this adjacent group of pixels. An adjacent but non-parallel group can be addressed by using incrementally different x coordinates along the D direction, which would provide a density estimate for a possible insertion path adjacent to but not parallel to the initial projected path. When the needle path calculator 54 receives the sequential density estimates for the projected path and several alternative adjacent paths, it can select the one that poses the least hazard and resistance to needle insertion. For example the needle path calculator can select the sequence of densities with the lowest peak density. Or, the needle path calculator can sum or average the sequential density values of each path and select the one with the lowest combined or average density. The coordinates of one or more alternative paths which have been identified as more favorable for needle insertion are then coupled to the graphics generator for indication on the displayed image.

A procedure conducted in accordance with the present invention can proceed as follows. The clinician hold an ultrasound imaging probe 30 by its handle 40 and places the distal end of the probe 32 which contains the transducer array in contact with the surface 80 of a body. With acoustic contact with the skin established the probe will image the interior of the body as illustrated by the 2D sector region 84 which is shown to contain the ultrasound image. The region of the body which is imaged contains target tissue 86 which is to be biopsied. The clinician manipulates a target icon control of

the control panel 20 to position a target graphic over the target tissue in the image as shown by the circle graphic 92 in FIGURE 4. The navigation system identifies the position of the circle graphic in the image 84 and, using the the coordinates of the position and orientation of the needle in the electromagnetic field, produces a graphic 90 on the ultrasound image which predicts the insertion path of the needle 60. As FIGURE 4 illustrates, the projected path of the needle 60 in this example is graphically identified by a line of dots 90 in line with the needle 60 and the target graphic 92. When the clinician continues to insert the needle in this orientation, the path of the needle will follow the line of dots 90 and reach the target tissue identified by the target graphic 90.

With the projected needle path now identified by the line of dots 90, the tissue density analyzer 52 can access the pixels along the projected path and analyze them to determine tissue density along the path. In the example of FIGURE 5 the needle path calculator has caused the sequence of density estimates along the path to be graphically displayed as a curve 94 in relation to a zero baseline. In this example the curve 94 shows the tissue density to be relatively low and substantially uniform from a shallow depth to the target tissue 86, where the solid mass of the target tissue has caused a noticeable increase of the density curve 94. The clinician may be satisfied with these characteristics of the tissue along the projected path of insertion and may then insert the needle along the line of dots 90 to biopsy the mass 86.

FIGURE 6 illustrates a different situation, in which there is a semi-solid mass 88 such as a cyst in

the needle insertion path. When the tissue density analyzer and the needle path calculator generate a curve for this insertion path, the curve 94 is seen to have a second peak 95 indicating the greater density in the path posed by the cyst 88. In this example the clinician decides that the insertion path proposed by the dots 90 is unacceptable and queries the system to propose a more desirable insertion path. The clinician actuates a control on the control panel 20 which causes the tissue density analyzer and needle path calculator to iteratively identify, analyze, and propose alternative insertion paths, as described above. In this example the needle path calculator has found and identified two alternative insertion paths which are graphically indicated by dashed lines 97 and 99 on the ultrasound image. The proposed insertion path 97 is tilted slightly to the left of the current insertion path 90, and the proposed insertion path 99 is located to the right of the current insertion path and accessed from the other side of the probe 30. When the clinician moves or reinserts the needle tip in line with one of these alternative insertion paths, the navigation system causes the line of dots 90 to move in line with the proposed path, and the density curve 94 will change and display density along the newly aligned path. The clinician can then choose the insertion path that is deemed to be most appropriate to perform the biopsy procedure.

While the above examples illustrate the display of a tissue density curve 94, the display of the curve can be omitted in a constructed embodiment. The system will then only show alternative insertion paths. Another possible implementation is to illustrate the tissue density along an insertion path

by a numeric value such as the average or peak or mean value of the sequence of density values. Yet another possibility is to omit the proposed insertion lines 97 and 99 and just show the density curve or value of the dotted insertion path in line with the needle as the needle is moved to various possible insertion positions. A clinician may also prefer to employ a needle guide to aid in guiding the needle insertion. As a needle is inserted, the system can monitor the path of insertion, compare it with a recommended insertion path, and advise the clinician as to whether the prescribe path is being followed or that the insertion is varying from the prescribed path. Other variations from the examples described above will be readily apparent to those skilled in the art.

WHAT IS CLAIMED IS:

1. An ultrasonic imaging system which visually guides the insertion of an invasive device such as a needle comprising:

an ultrasound probe having an array transducer for imaging a region of tissue containing target tissue and producing received signals;

an ultrasound system processing signals received by the ultrasound probe to produce a set of spatially identified pixels having pixel values proportionate to the received signals;

an image processor responsive to the pixel values which produces an ultrasound image;

a display which displays the ultrasound image;

a tissue density analyzer, responsive to the pixel values, which produces an estimate of tissue density along a path of invasive device insertion,

wherein the estimate of tissue density is displayed on the display.

2. The ultrasonic imaging system of Claim 1, further comprising a needle path calculator, responsive to the tissue density analyzer, which calculates a path of invasive device insertion,

wherein the calculated path of invasive device insertion is displayed in spatial registration with the ultrasound image.

3. The ultrasonic imaging system of Claim 1, wherein the estimate of tissue density is displayed as a curve of relative tissue density along a path of invasive device insertion.

4. The ultrasonic imaging system of Claim 1, wherein the estimate of tissue density is numerically displayed.

5. The ultrasonic imaging system of Claim 1, further comprising a spatial navigation system which identifies the position and orientation of a needle in relation to the target tissue,

wherein the navigation system is operable to identify a projected path of needle insertion in relation to the position and orientation of the needle,

wherein the projected path of needle insertion is displayed in spatial registration with the ultrasound image.

6. The ultrasonic imaging system of Claim 5, wherein the tissue density analyzer is operable to produce an estimate of tissue density along the projected path of needle insertion using the values of pixels in registration with the projected path.

7. The ultrasonic imaging system of Claim 1, wherein the ultrasound image further comprises a 2D ultrasound image; and

wherein the tissue density analyzer produces an estimate of tissue density using the values of pixels of the 2D ultrasound image.

8. The ultrasonic imaging system of Claim 1, wherein the array transducer further comprises a 2D array transducer used by the probe to scan a volumetric region of tissue;

wherein the volumetric region includes the plane of the 2D ultrasound image; and

wherein the tissue density analyzer produces an estimate of tissue density using a group of pixels representing a three dimensional region.

9. The ultrasonic imaging system of Claim 8, wherein some of the pixels of the group are coincident with the plane of the 2D ultrasound image.

10. The ultrasonic imaging system of Claim 8, wherein the tissue density analyzer produces a sequence of tissue density estimates along a path of needle insertion,

wherein each estimate is produced from a two dimensional array of pixels having at least two pixels in each of the dimensions.

11. The ultrasonic imaging system of Claim 2, wherein the tissue density analyzer is operable to produce estimates of tissue density along a plurality of possible paths of needle insertion,

wherein the needle path calculator is further operable to calculate a plurality of proposed paths of needle insertion,

wherein one of the proposed paths is displayed in spatial registration with the ultrasound image.

12. The ultrasonic imaging system of Claim 11, wherein a plurality of proposed paths are displayed in spatial registration with the ultrasound image.

13. The ultrasonic imaging system of Claim 1, further comprising a graphics generator which produces graphics for overlaid display with the ultrasound image,

wherein the graphics generator produces a

graphic indicating a path of needle insertion.

14. The ultrasonic imaging system of Claim 13, further comprising a user control which is actuated to indicate the location of a target tissue in the ultrasound image,

wherein the graphics generator is responsive to the user control to produce a target tissue graphic in registration with the ultrasound image.

15. The ultrasonic imaging system of Claim 13, further comprising a needle path calculator, responsive to the tissue density analyzer, which calculates a path of needle insertion,

wherein the graphics generator is responsive to the needle path calculator to produce a graphic representing a proposed path of needle insertion.

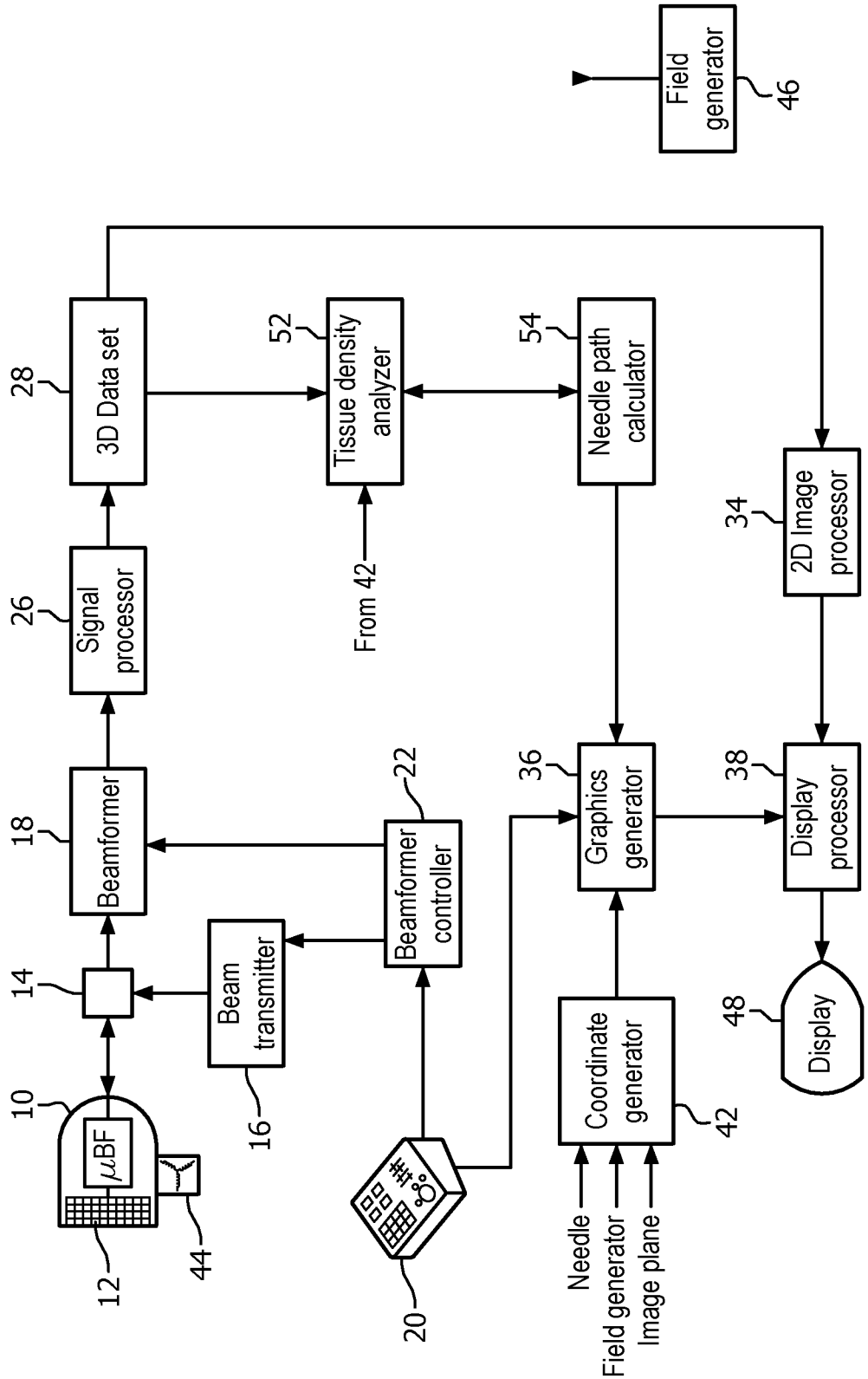
Field generator
46
28
3D Data set
52
Tissue density analyzer
54
Needle path calculator
34
2D Image processor
26
Signal processor
From 42
18
Beamformer
22
Beamformer controller
36
Graphics generator
38
Display processor
14
Beam transmitter
16
10
μBF
12
44
20
Coordinate generator
42
48
Display
Needle
Field generator
Image plane

FIG. 1

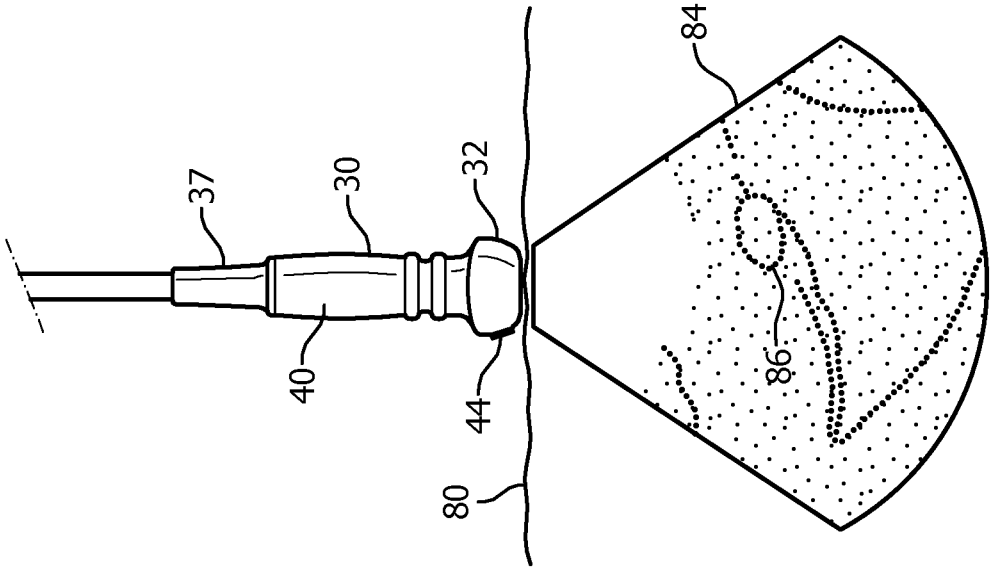

FIG. 3

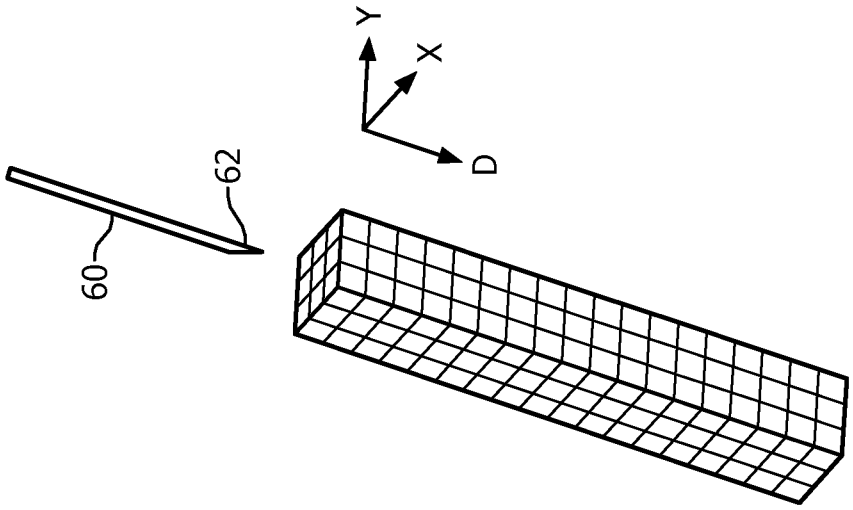

FIG. 2

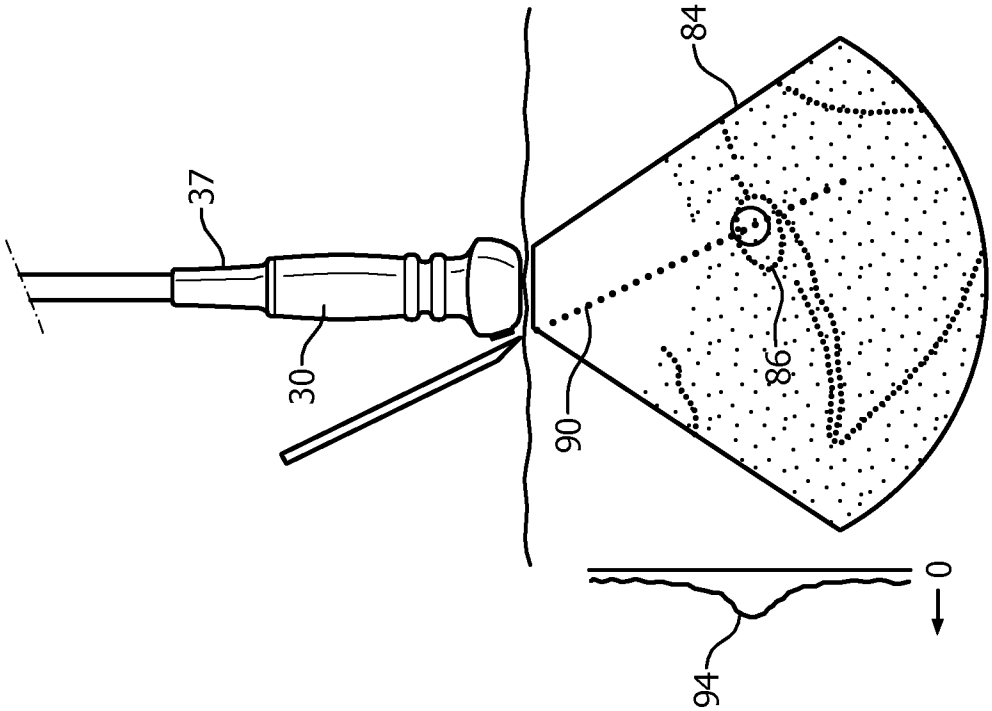

FIG. 5

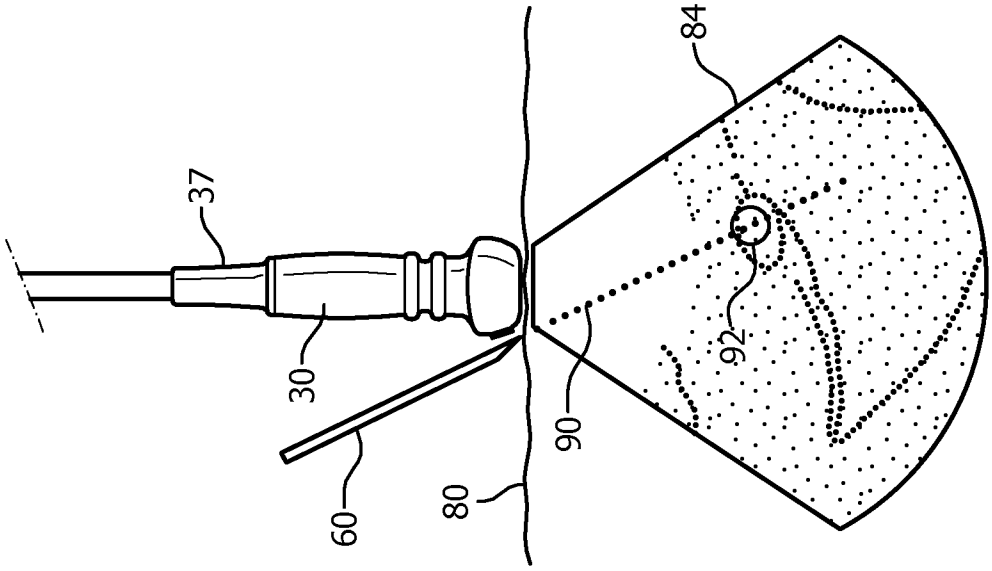

FIG. 4

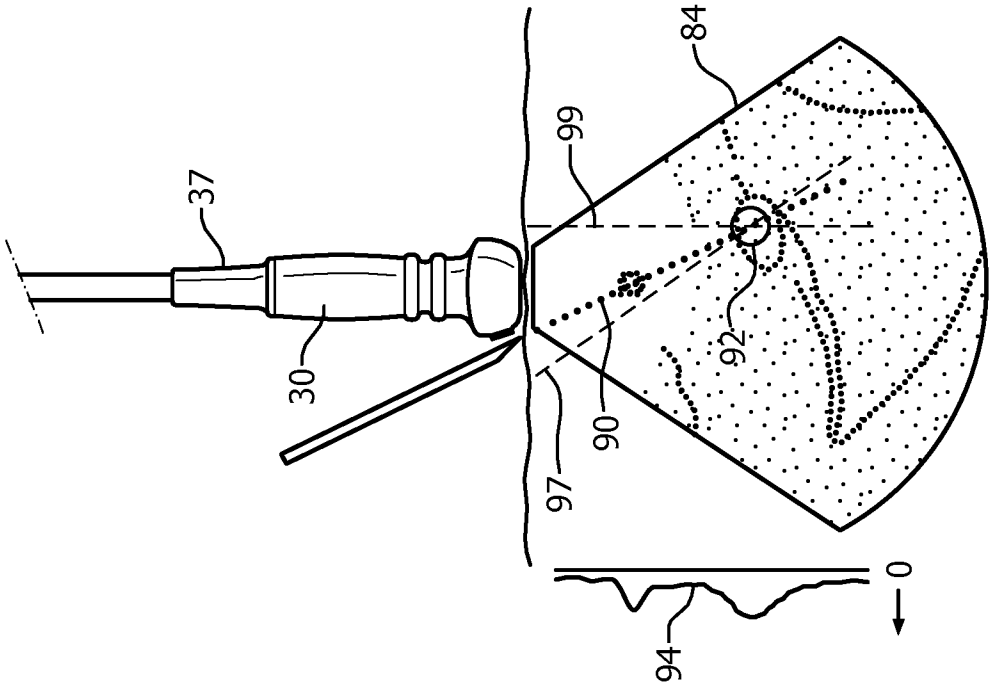

FIG. 7

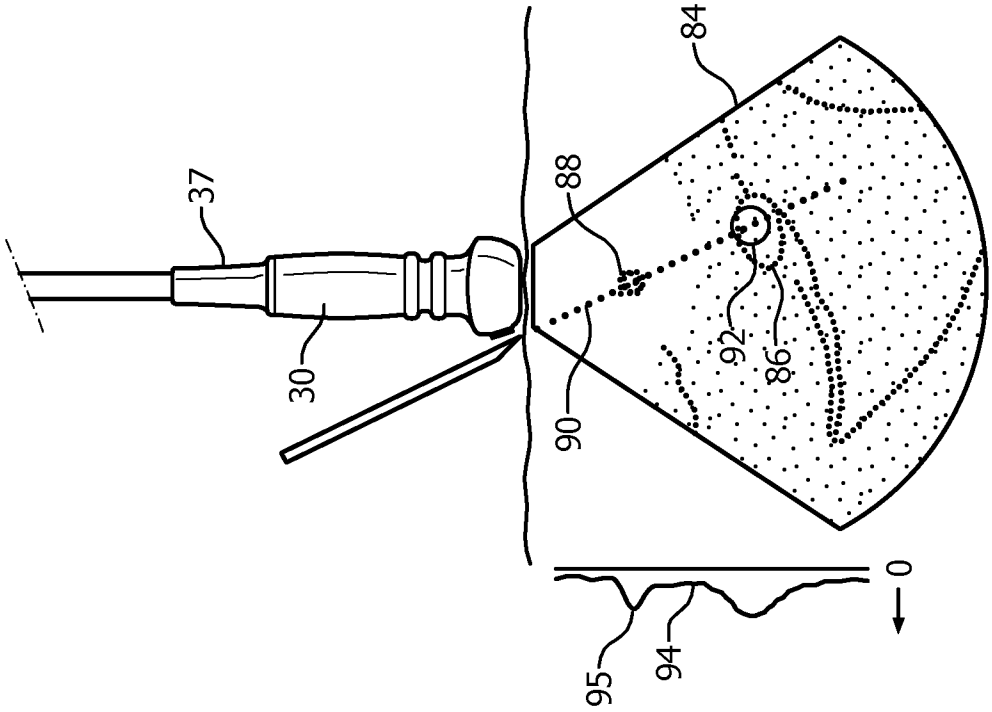

FIG. 6

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2013/050417

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B8/08 A61B8/00 A61B19/00 G06T7/00
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B G06T

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 1 649 818 A2 (ETHICON ENDO SURGERY INC [US]) 26 April 2006 (2006-04-26) abstract paragraph [0039] - paragraph [0048] paragraph [0070] - paragraph [0086] figures 1,3B,10-15	1-3,5,7, 11-15
X	WO 01/78607 A1 (LITTON SYSTEMS INC [US]) 25 October 2001 (2001-10-25) abstract page 6, line 5 - page 13, line 3 figures 1-2	1,2,4, 7-10,13

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

[X] See patent family annex.

* Special categories of cited documents :

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
8 April 2013	16/04/2013

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

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2013/050417

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2007/059452 A2 (SUNDAR SATISH [US]; SUBRAMANIAN THYAGARAJAN [US]) 24 May 2007 (2007-05-24) abstract page 9, line 3 - page 12, line 20 page 18, line 8 - page 19, line 27 figures 1-3 -----	1,2,5,8, 9,13,15

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
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专利名称(译)	活检期间针道的超声引导		
公开(公告)号	EP2804532A1	公开(公告)日	2014-11-26
申请号	EP2013710017	申请日	2013-01-17
[标]申请(专利权)人(译)	皇家飞利浦电子股份有限公司		
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IPC分类号	A61B8/08 A61B8/00 A61B19/00 G06T7/00 A61B10/00 A61B90/00		
CPC分类号	A61B8/0841 A61B8/0858 A61B8/463 A61B8/483 A61B8/5207 A61B10/0233 A61B90/11 A61B2034/107 A61B2090/378		
代理机构(译)	STEFFEN，THOMAS		
优先权	61/587784 2012-01-18 US		
其他公开文献	EP2804532B1		
外部链接	Espacenet		

摘要(译)

描述了一种超声成像系统，其在视觉上辅助活检针插入。该系统沿着一个或多个针插入路径产生像素的像素值。组织密度分析器响应于像素值以估计沿着针插入路径的组织密度。针路径计算器响应于组织密度分析器并且提出穿过成像组织的一个或多个有利路径以插入活检针。该系统可以与三维导航系统结合使用，该三维导航系统在3D空间中空间定位针和超声图像平面。