(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 2 147 636 B1

(12) **EUROPEAN PATENT SPECIFICATION**

(45) Date of publication and mention of the grant of the patent:
30.11.2016 Bulletin 2016/48

(51) Int Cl.:
A61B 8/08 *(2006.01)* *A61B 90/00* *(2016.01)*

(21) Application number: **09165926.8**

(22) Date of filing: **20.07.2009**

(54) **Device and method for guiding surgical tools by ultrasonic imaging**

Vorrichtung und Verfahren zum Führen von chirurgischen Werkzeugen durch Ultraschallbildgebung

Dispositif et procédé pour le guidage d'outils chirurgicaux par imagerie ultrasonique

(84) Designated Contracting States:
AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HR HU IE IS IT LI LT LU LV MC MK MT NL NO PL PT RO SE SI SK SM TR

(30) Priority: **24.07.2008 IT GE20080064**

(43) Date of publication of application:
27.01.2010 Bulletin 2010/04

(73) Proprietor: **Esaote S.p.A.**
16152 Genova (IT)

(72) Inventors:
- **De Beni, Stefano**
16123, Genova (IT)
- **Macciò, Marco**
16145, Genova (IT)

(74) Representative: **Karaghiosoff, Giorgio Alessandro**
Studio Karaghiosoff e Frizzi S.r.l.
Via F. Baracca 1R 4° piano
17100 Savona (IT)

(56) References cited:
WO-A-2005/039391 **WO-A-2006/067676**

Printed by Jouve, 75001 PARIS (FR)

Description

[0001] The invention relates to a device and a method for guiding surgical tools by ultrasonic imaging.

[0002] The device and method of the invention are particularly applicable to ultrasonically guided minimally invasive surgery and are especially aimed at avoiding the use of the known biopsy kits. The main applications are in the surgical field (biopsy, infiltrations, ablations, etc.). In the past, minimally invasive surgery mainly relied on CT imaging, followed by free-hand needle introduction based on the previously acquired images.

[0003] The advent of ultrasonic imaging machines and biopsy kits allowing biopsy needles to be imaged as they were inserted in the tissue did not solve all the needle guiding problems. In many cases, CT imaging is still used because certain types of diseases cannot be imaged by ultrasound (lungs, bones), wherefore the ultrasonically guided biopsy kit is of no effective help.

[0004] Nonetheless, there undoubtedly exists the need for a needle insertion supporting tool allowing to evaluate beforehand the path of the needle, and hence its position relative to the probe plane and its path before actual insertion, because such tool would provide remarkable help, as well as technological advantage.

[0005] Also, there currently exist neurosurgery navigation systems as well as other virtual navigation systems combined with ultrasonic imaging methods. Nevertheless, these systems require an image of a pre-acquired volume, i.e. acquired prior to the surgical procedure, to be always associated with the surgical tool or ultrasonic probe.

[0006] Document WO2006/067676, discloses a method for visualizing the position of an interventional device involving the acquisition of images of an area of interest from an object displaying multiple planes that intersect. The intersection defines the position of the interventional device and the planes that identify the position of the interventional device are displayed as bounding planes. These bounding planes are displayed in a multi-dimensional display, where each plane is only rendered up to where it intersects another plane. Thanks to this only relevant portions of the data are displayed, thereby increasing the readability of the displayed image.

[0007] From the above document it is clear that at least a 3D image of the intervention area is acquired prior of carrying out the intervention and the intervention tool tracking and imaging. The orientation and the position of the tool is determined by the tracking data. The tracking system is registered with the acquired and stored 3D image data and the tracking data are used to determine the bounding planes and the image information along these bounding planes from the previously acquired 3D image data. It is important to consider that in this case volumetric (3D image data of the patient is acquired only once prior of the carrying out of the intervention, so that the determination of the interventional tool in the following intervention due to the tracking data is referred to the volumetric image data which has been acquired at an earlier instant. Considering patient movements and also natural movements of the tissues due to heart beats, breathing, etc. the reliability of the information about the relative position of the tool relatively to the a target object is relatively low.

[0008] Document WO2005/039391, seems to have considered this problem and suggests a way of solving the above problem. A method is disclosed for assisting a user in guiding a medical instrument to a subsurface target site in a patient. The method generates at least one intraoperative ultrasonic image. The method indicates a target site on the ultrasonic image and determines 3-D coordinates of the target site in a reference coordinate system. The method tracks the position of the instrument in the coordinate system, projects onto a display device a view field as seen from the position with respect to the tool in the reference system and projects onto the displayed view field indicia of the target site corresponding to the position. By observing the indicia the user can guide the instrument toward the target site by moving the instrument so that the indicia are placed or held in a given state in the displayed filed of view.

[0009] The above disclosed method requires an endoscope for determining the images of the target site. It further requires means for acquiring a pre-interventional 3D image which is the reference image, means for acquiring ultrasound images, an interventional tool, means for tracking the ultrasound probe, the endoscope and the interventional tool and means for registering the data from the pre-interventional volumetric image with the endoscopic image, with the ultrasound image data and with the tracking data.

[0010] The system is complex and in order to generate images corresponding to the views of a human user as placed on the tip of the tool and looking in direction of view corresponding to a certain tool orientation, the endoscopic image is needed. Furthermore this image is a video image and not an ultrasound image which could help to see what is behind a certain surface. The ultrasound images displayed are along planes which comprise also the interventional tool image. The computational burden is considerable since the computation shall provide for registering video images of the endoscope, tracking data of the interventional tool and of the endoscope and of the ultrasound probe and the pre-intervention volumetric images and has to continuously generate images which are recalculated based on the new position of the tool and of the target.

[0011] Each of the above methods require a pre-interventional volumetric image acquisition, which image data are used for determining the relative position of the tool to the anatomy of the interventional district and to a certain target site and cannot thus considered pure real-time methods, since a high influence in the image showing the relative position of target site and tool is given by this fact and the position inaccuracy due to systemic physiological tissue movements is still given to a high rate.

[0012] The invention has the object of providing a device and a method for guiding surgical tools by ultrasonic imaging which, using simple and inexpensive arrangements, can obviate the limitations of current surgical tool guiding and/or virtual navigation systems, while providing a better, easier and more intuitive control of the tool, with higher accuracy and in a substantially real-time mode, without involving any hardware extension image quality degradation or excessively longer scanning and processing times.

[0013] The invention fulfils the above object by providing a device as defined in claim 1.

[0014] Claims 2 and 3 define further aspects of the invention.

[0015] It is important to notice that the acquisition of the volumetric (3-D) ultrasound images is made at the same time, i.e. contemporary to the tracking of the probe and of the tool and to the registration of the tracking coordinates with the coordinates of the said volumetric images, so that the images shown on the 2D image planes is a real-time image, which time delay relatively to the effective one is limited to the time needed for the computation. Computational burden and computational times are dramatically low relatively to prior art systems particularly due to the fact that only ultrasound data are used for generating some sort of endoscopic images which are non video (i.e. surface images) and that the registration step can be carried out at the beginning of the session only once and eventually may be repeated at certain time intervals.

[0016] No endoscopic or video device is needed further to the ultrasound probe and to the tracking means.

[0017] As it will appear also from the following description using a 3-D probe reduces further the computational burden because the probe may be held at a fixed position and the tracking data to be determined are only the ones of the interventional tool.

[0018] Claims 4 to 9 define further aspects of the invention.

[0019] Referring to the units that compose the device of the present invention, either one of the two following solutions can be used for detecting the relative position of the probe and the tool.

[0020] In a first embodiment, the means for determining the position and orientation of the tool and particularly the biopsy needle, i.e. the characteristic axis thereof, are the 3D imaging system itself, i.e., in this special case, the means for acquiring the sequence of 3D ultrasonic images. The detected volumetric images also include the image of the tool when the latter is within the field of view, and this image of the tool is used to determine, thanks to the markers, the position and orientation of the tool, i.e. its characteristic axis, relative to the 3D image and hence the position and orientation of the tool in the anatomic region being imaged.

[0021] This technique is not limited to the ultrasonic imaging use. It can be also applied to X-ray or CT imaging. In this case the ring would be displaced instead of the patient table, and the CT images would display both the diseased tissue and the tool, i.e. the biopsy needle.

[0022] It is noted that the invention is limited to ultrasound imaging techniques.

[0023] In the second embodiment, a tracking system is used for detecting the position and orientation of the probe and the tool, particularly the characteristic axis thereof. The tracking system allows the positions of the probe and tool, e.g. a needle, to be related to each other, to define the cut plane in the tool path. Several different tracking systems are current available, of either electromagnetic or optical type. The remarkable advantage of an electromagnetic system consists in that it has very small markers, consisting of micro-receivers that may be also placed at the tip of the needle. A tracking system adapted for use with a needle is the one sold by Ascension Technology with the trade name PCIBird.

[0024] These micro-receivers are used in combination with the transmitter to define the position of the probe and the needle on space and to determine the cut plane. Advantageously, two micro-receivers are associated with the needle at the tip and the rear, to accommodate any bending. Such bending would create curved surfaces formed by the volume 4D.

[0025] Concerning the tools for which the method and device of the invention are particularly suitable, these may be of the minimally invasive type, such as infiltration syringes, biopsy tools, thermoablation needles, HIFU rays. A possible method for standardizing all needle families consists in providing a custom "spindle" equipped with a receiver to be used as an insertion tool designed to be fitted with the special needle for the required procedure.

[0026] The probe, particularly of volumetric type, may be either convex or linear and will be advantageously able to generate a 3D image of the required size. The minimum volume rate required to obtain effects is 4 volumes/sec.

[0027] A volumetric probe may be as disclosed in EP 1 681 019 and in EP 1 167 996 by the applicant hereof.

[0028] The invention also relates to a method as defined in claim 12.

[0029] Particularly relevant for the present invention is the fact that steps a) to c) are contemporary and carried out in real time.

[0030] So each 3-D image is a real time ultrasound image and the position and orientation of the tool is also real-time and related to the a corresponding 3-D image. Thus also the steps and the results of the said steps indicated above with d) to h) are essentially carried out in real-time, if considering vary short computational times. Thus the 2-D image displayed and corresponding to a certain plane as defined in steps g) to h) is practically a real-time image. The time shift between the effective position of the tool in the real world and the one determined by the method being infinitesimal and corresponding to the time needed by the system to carry out the computational steps.

[0031] As additional information, said image may also include indications about the dimensions of the tool in a direction perpendicular to said functional characteristic axis.

[0032] Claims 13 and 14 define further aspects of the invention.

[0033] In this case the 2D image plane may be perpendicular to the direction or characteristic axis of the tool.

[0034] Claim 16 defines a further aspect of the invention.

[0035] In order to determine the position and orientation of the tool with reference to an axis and particularly to the characteristic or working axis thereof, one position detection and identification marker has to be placed on the tool in a predetermined position relative to the tool shape.

[0036] Claim 17 defines a further aspect of the invention.

[0037] As mentioned above in greater detail, several different systems may be used for determining the position and orientation of the tool relative to the image volume.

[0038] One solution consists in using the tool image that appears in the acquired volumetric images.

[0039] The second solution, which has also been described above, includes a tracking system which uses sensors or transponders on the tool and the ultrasonic probe to determine their position and orientation relative to a reference coordinate system predetermined by the tracking system itself.

[0040] Claims 21 and 22 define further aspects of the invention.

[0041] Considering the above characteristics of the method of the invention, such method is thus based on the concept of using the image planes generated by a volumetric probe to drive an tool, such as a needle, using a tracking system, for optimized selection of both the position of the needle relative to the probe and the image plane to be associated with the needle. In this case, the image plane of the probe may not be coplanar with the image plane of the needle.

[0042] In other words, the volumetric probe is used to generate a real-time 4D volume. The mutual positions of the probe and the needle are defined using the tracking system. These relative position coordinates are used to generate a plane to be associated with the needle, by cutting off the acquired volumes according to the needle position. A real-time image is thus obtained, which is associated with the needle. The volumetric probe is only used as a data generator, whereas the needle is used both for the percutaneous procedure and as a probe. Thus, by simply moving the needle, the user can display the target and easily select the type of insertion.

[0043] Claim 19 defines a further aspect of the invention.

[0044] Images may be also possibly displayed according to different image planes, intersecting the volumetric image with different inclinations and at different points.

[0045] In at least one of the images, the position of the tool is indicated by a symbol which is well differentiated from the image of the target area.

[0046] The above description clearly shows the advantages and differences of the method and device of the present invention as compared with standard neurosurgery navigators. In prior art navigation and guide systems, the surgical tool or the ultrasound probe is associated with an image obtained from a pre-acquired volume and not a real-time image associated with the needle.

[0047] Conversely, the present invention uses a real-time imaging source, to associate the position of the tool and the image of its path. On the other hand, the tracking system may be the imaging source itself, with the tool and its position and orientation in the imaging volume being identified in real time.

[0048] The characteristics of the invention and the advantages derived therefrom will appear more clearly from the following description of a non limiting embodiment, illustrated in the annexed drawings, in which:

Figure 1 is a schematic block diagram of the structure of a system of the invention, in which said system is provided in combination with a biopsy needle.

Figure 2 shows a tissue image of the present invention corresponding to the central frame of the succession of frames that cover the acquisition volume of a volumetric probe.

Figure 3 shows an image of the same acquired volume, with the image plane being oriented relative to the characteristic working axis of the needle, and particularly parallel to the needle axis.

Figure 4 shows a schematic icon representing the relative positions and orientations of the needle and the probe.

[0049] A system for guiding surgical tools by real-time ultrasonic imaging is very schematically shown in Figure 1.

[0050] Numeral 8 designates an ultrasonic scan probe which is connected to a probe control unit for ultrasonic imaging and particularly for generating volumetric ultrasound images. A variety of volumetric ultrasound imaging methods are known. According to a known method, the probe is provided in combination with a tracking system which detects the position, orientation and displacement of the probe. A succession of ultrasound images is acquired as the probe is moved, said images being grouped into a 3D image composed of the various 2D images acquired at different probe positions along the displacement path, which positions are detected by the tracking system. Thus, the 2D images can be arranged in relative order to form a 3D image.

[0051] Tracking systems are known and widely used for the purpose of acquiring a 3D ultrasound image. An example of tracking system is the system sold by Ascension Technology with the trade name PCI Bird which is incorporated in a currently available product, sold by the owner hereof with the name of "Virtual Navigator".

[0052] In the scheme of Figure 1, the tracking system is represented by the coordinate system designated by numeral 1. The tracking system actually defines the various positions of the probe 8 with reference to a predetermined initial reference point and is thus the operating unit that defines a reference system describing the probe displacement space.

[0053] In principle, there is no limitation as for the type of probe to be used, provided that it can cover a slice area large enough to contain the image to be acquired. Nonetheless, as shown in Figure 1, advantages are achieved from using a volumetric probe. A volumetric probe may be as disclosed in EP 1 681 019 and in EP 1 167 996 by the owner hereof.

[0054] Thus, when the size of the subject to be imaged by ultrasound allows to do so, the probe is not required to be manually displaced by the operating personnel or a specially dedicated device. In other cases, the volumetric probe can be displaced less often and to few different positions, in which it can be held during automatic acquisition of the volumetric image that the probe can generate without being displaced.

[0055] In this case, the tracking system 1 is only used to define the different probe position/s in the space described by the reference system generated or defined by the tracking system 1 itself.

[0056] The tracking systems require at least one detector to be mounted to the element whose displacement or position is to be monitored, which marker/detector, with reference to the tracking system used herein, is a transponder. A transmitter-receiver unit can detect the marking transponder and determine the probe position. The marker means associated with the probe 8 are designated by numeral 3.

[0057] Numeral 6 designates the volumetric image acquired by the volumetric probe 8.

[0058] Numeral 2 designates a surgical tool and particularly a needle or similar elongate, rod-like element. These tools may include, for example, biopsy needles, cannulas for insertion of a variety of devices, thermoablation needles or the like.

[0059] The needle or rod-like element has a characteristic functional axis, and in this case this axis is the axis of the needle which coincides with the insertion axis. Different types of tools may have different characteristic functional axes. For example, in the case of a surgical knife, the characteristic working axis may be the cutting edge of its blade. The characteristic functional axis of a particular type of tool can be determined in an intuitive and simple manner.

[0060] The needle 2 may carry a single sensor or marking transponder, which is sufficient to determine the position of the tool and its orientation, particularly with reference to the characteristic working or functional axis of said needle which, as mentioned above, is the central longitudinal axis of the needle.

[0061] However, according to the improvement of the figures, the tool, i.e. the needle 2 carries two or more sensors or marking transponders, designated by numerals 3, 4. This improvement allows detection of any needle bending, which can be thus accounted for while operating the system.

[0062] Therefore, in the case of the needle 2 of the figures, two transponders are located at a certain distance from each other, coincident with the needle axis, and can be used to determine the needle orientation with particular reference to the insertion direction, as well as any deformation, particularly bending or curving of the needle. When a transponder is mounted directly to the tip or at a predetermined distance therefrom, the position of the needle tip can be determined upon insertion into the body under examination.

[0063] The sensor or transponder at the tip of the needle 2, here the transponder 4, shall not necessarily be placed at the tip but, as mentioned above, it may be located at a predetermined known distance from the tip. In this case, once the position of the transponder 4 has been detected, the position of the tip may be determined by a simple arithmetic operation.

[0064] Numeral 7 designates a cutting plane of the 3D image that has a predetermined inclination relative to the characteristic functional axis, i.e. the longitudinal central axis, i.e. the direction of insertion of the needle 2.

[0065] A 2D image of the object is generated along said cutting plane, using the image data of the 3D image.

[0066] This process consists in determining the subset of voxels of the 3D image that falls within the predetermined cutting plane 7, to generate a 2D image. This may occur in a known manner, as disclosed for instance in the above mentioned patent applications by the applicant hereof, and particularly in EP 1 167 996.

[0067] Processing occurs in a control and processing unit typically incorporated in ultrasonic imaging apparatus, which substantially consists of a processing unit that stores and executes special ultrasound apparatus control programs for transmitting and receiving ultrasound signals, for focusing the ultrasound signals transmitted by the probe and the ultrasound signals received by the probe upon reflection of the transmitted signals, for converting the received signals into image data and for generating and displaying images on a monitor, as well as for monitoring the execution of other operations that depend on the ultrasound signal acquisition and processing mode being used. The processing unit also controls the tracking system, which may be provided as software or dedicated hardware controlled by said software.

[0068] In Figure 1, the processing unit is designated by its functional blocks only, which are generally used to execute the operations of the present invention. Thus, the block 11 generally includes all hardware and software units required for 3D imaging (see also EP 1 681 019 and EP 1 167 996). Thanks to the tracking system, the 3D image is assigned a well-defined position in a reference Cartesian system, which is defined by the tracking system that detects the position of the probe 8. The tracking system simultaneously detects the position of the needle or other tool 2 and the orientation of the characteristic functional axis of such tool 2 with reference to the same reference system defined by the tracking system. This will provide well-defined relative positions between the volumetric image and the position and orientation of the tool 2, i.e. the characteristic functional axis thereof.

[0069] In these conditions, a cutting plane may be defined in the 3D or volumetric image generated by the probe 8, which plane has a predetermined inclination relative to the characteristic functional axis of the tool 2.

[0070] Multiple cutting planes may be also defined, having predetermined and different positions and orientations relative to said characteristic functional axis of the tool 2.

[0071] Particularly, referring to the needle, a cutting plane may be defined, which is oriented perpendicular to the characteristic functional axis of the tool 2 and is at a predetermined distance from the internal or front end tip, with reference to the direction of insertion of the needle. In this case, the image generated along said cutting plane and reconstructed from the volumetric image data, i.e. the voxels that fall within such cutting plane will be as viewed by an observer situated at the tip of the needle and looking towards the longitudinal axis of the needle in the direction of insertion of the latter.

[0072] Alternatively to or in combination with the above, images may be also generated along different cutting planes.

[0073] A possible additional cutting plane might be the plane that contains the longitudinal axis of the needle 2, with the path of the needle into the body under examination being thus visible.

[0074] The images obtained along the various cutting planes may be displayed in succession, i.e. alternate to each other or in side-by-side or simultaneous arrangement.

[0075] This condition is shown by the functional blocks 13 and 14, which designate all hardware and software units required to define the above mentioned cutting planes and generate images along said cutting plane, as well as simultaneously or alternately display them using display drivers 14 on the display 15.

[0076] The use of a volumetric probe 8 allows the above process to be accomplished in a very short time, wherefore imaging may be deemed to occur in real time.

[0077] Figure 2 shows the central 2D image of a volumetric image obtained using a volumetric probe as disclosed in EP 1 681 019 and EP 1 167 996 respectively.

[0078] Figure 3 shows a 2D image along a plane parallel to the axis of the needle 2, containing an indication of the target 20 to be reached and treated by the needle and the trajectory of the needle 21, i.e. an image as viewed from the needle, and not from the probe. The trajectory of the needle 21 is indicated in the form of a channel delimited by longitudinal dash lines. These lines are parallel to the needle axis and their spacing is at least equal to the external diameter of the needle 2.

[0079] As clearly shown herein, in this case the needle guiding function does not rely on an image of the needle in the body from the point of view of the probe position, but on the needle trajectory that is indicated in the 2D image that corresponds to the image of one of the cutting planes containing the longitudinal axis of the needle.

[0080] The image of Figure 2 may also contain indications about the incidence point of the longitudinal axis of the needle and the 2D image plane and possibly the cross-section of the needle, using the 2D image plane as a cutting plane.

[0081] Alternative to or in combination with the above, the cutting plane of the 3D image, i.e. the 2D image may be a plane parallel to the longitudinal axis of the needle, but situated at a predetermined distance from such axis.

[0082] According to an improvement, a traditional image of the body being examined and the needle may be also displayed in either alternate or simultaneous, side-by-side arrangement.

[0083] In yet another improvement, as shown by way of example in Figure 4, in order to visually check the position of the needle 2 or tool relative to the probe, i.e. to the central longitudinal plane parallel to the long side of the array of electroacoustic transducers of the probe 8 which, in the case of volumetric probes, is parallel to the axis of oscillation of the array of transducers, a schematic image may be displayed in which the probe, said plane, the tool and the predetermined cutting plane/s are indicated in their proper relative positions as detected by the tracking system. By this arrangement, the user may simply ascertain proper operation of the system at a glance.

[0084] The schematic icon image may be displayed at the same time as the ultrasound images, side by side with or in a separate window, partially overlapping one or more of the ultrasound images being displayed. If one or more ultrasound images are displayed, each for a cutting plane having a predetermined position and a predetermined orientation, i.e. a predetermined inclination relative to the axis of the needle 2, i.e. the characteristic functional axis of the tool, then a corresponding schematic icon image may be displayed for each of said images, in which the probe and the tool, as well as the corresponding cutting plane, are in the relative positions corresponding to the ultrasound image.

[0085] Referring to the above system and method, a variant of the needle tracking means may be provided for determining the position and orientation of the needle relative to the acquired volumetric images.

[0086] According to such variant, the position and orientation of the tool relative to the volumetric images may be determined using the needle image appearing in such volumetric images, instead of providing an external tracking system that detects both the position and orientation of the tool and the position and orientation of ultrasound probe. Once more, the provision of a position identification and indication marker having a predetermined position relative to the shape and size of the tool, particularly the needle, allows the tool to be located within the 3D image, wherefore a cutting plane may be defined in the 3D image, which has predetermined orientation and position relative to the tool, along which cutting plane a 2D image is generated whose pixels are the voxels of the imaging volume which fall within said cutting plane. Therefore, regardless of the means that are used for determining the position and orientation of the tool and/or the characteristic axis thereof, the next steps are the same as in the example in which an external system is used for tracking the position and orientation of the tool and the position and orientation of the ultrasound probe. It shall be obviously noted that the term cutting plane is indented to also mean a thin slice, i.e. a volume delimited by two parallel cutting planes very close to each other within the resolution of the ultrasonic imaging system. This interpretation will be well understood by those skilled in the art, who are perfectly aware that any reference to a 2D image will relate to an image of an area having a predetermined volume, which is formed of a thin slice crossing the subject under examination.

[0087] It has to be noticed that ultrasound 3-D images and probe and tool tracking are carried out at the same time and in real-time. This means that while inserting and displacing the interventional tool the probe acquires a sequence of 3D (three dimensional or volumetric) images of the zone in which the probe is present. Thus to a certain instant a specific 3D-image is associated and to it a specific tracking data for the tool and of the probe are also univocally associated. This image data and the corresponding tracking data of the tool and eventually of the probe are used for constructing by computation the image or images along one or more specific 2D planes (two dimensional planes) having a predetermined orientation in the space defined by the corresponding 3D image and relatively to the tool tip and orientation. So the 2D image or images shown are essentially real time images. The time shift between the effective tool position in the real world and the one as determined by the acquired image and tracking data is limited to the time needed for the acquisition of the image and tracking data and for computing the said data in order to generate the 2D image or images. These times are relatively short so that the inaccuracy is infinitesimal and can be disregarded. Furthermore it has also to be considered that in the above kind of intervention the tool is normally displaced very carefully and at very low speed and often also step by step, so that the already infinitesimal time shift can be disregarded completely for no having any significant practical effect.

[0088] Concerning the system and method of the present invention, a remarkable advantage has to be noted as compared with prior art systems and methods.

[0089] A true real-time guiding method and system is provided which can furnish a special kind of endoscopic view which is not limited to a video (surface) image, but which goes beyond the visible surfaces and allows the user to efficiently and precisely guide the tool by having a visual and spontaneous feedback of the manipulation of the tool.

[0090] With the invention, the body can be penetrated by the tool, i.e. the needle, from the side opposite the one with the ultrasound probe. In clinical terms, this means that while at present the ultrasound scanning window and the needle access must be located in a well-defined area of the body under examination, possibly providing the best results in terms of both imaging and tool, i.e. needle, insertion, the invention allows simultaneous selection of the best ultrasound scanning window and the best access, because these conditions are independent of each other.

Claims

1. A device for guiding surgical tools (2) by ultrasonic imaging, which device comprises:

a) means (8) for acquiring in real time a time sequence of 3D ultrasonic images of a target area;

b) means for determining and/or tracking, at the same time as step a) and in real time, the position and orientation of a surgical tool (2) and means for defining the position or direction of a characteristic axis of the tool (2) corresponding to the detected position and orientation of the tool (2) ;

c) means for determining in real time the position of a working or functional end of the tool (2) along said direction of said characteristic axis;

d) means for determining in real time the relative position in space of each real time 3D image (6) and the direction of the characteristic axis of the tool (2) corresponding to each real time 3D image (6) ;

e) means for generating, for one or more of the real time 3D images (6) acquired in a time sequence, a real time 2D image (7) defined by an image plane that intersects the corresponding real time 3D image (6) of said time sequence, which real time 2D image plane has a predetermined inclination relative to the direction of the characteristic axis of the tool (2) determined in real time and a predetermined distance from the working end of the tool with reference to the orientation and position of the tool upon acquisition of the corresponding real time 3D image (6), said real time 2D image being generated using the image data of the corresponding real time 3D image of the time sequence of real time 3D images;

g) the inclination of said real time 2D image plane (7) relative to the direction of the characteristic

axis of the tool (2) determined in real time, and the distance of said 2D image plane relative to the working end of the tool (2) being such that the image generated in the 2D image plane corresponds at least approximately to a vision of the target area from the point of view of an observer situated at or near a part of the tool (2) or said characteristic axis of the tool;
h) the image generated along said plane (7) including indications of the position of the target to be treated by said tool (2) and/or the position of the characteristic axis of said tool in said image and the dimensions of the tool in a direction perpendicular to said characteristic axis.

2. A device as claimed in claim 1, **characterized in that** the inclination of said 2D image plane relative to the direction of the characteristic axis of the tool (2), and the distance of said 2D image plane (7) relative to the working end of the tool (2) are such that the image generated in the 2D image plane (7) corresponds at least approximately to a vision of the target area from the point of view of an observer situated at said working end of the tool (2), and whose direction of view is coincident with or parallel to the direction of the characteristic axis of the tool (2), whereas said real time 2D image includes indications of the position of the target to be treated by said tool and/or the point of coincidence of the characteristic axis of the tool with said 2D image plane and possibly also with the section of the tool along said plane.

3. A device as claimed in claim 1, **characterized in that** the 2D plane is parallel to the characteristic axis of the tool (2) and possibly coincident therewith so that the image along said cutting plane (7) substantially corresponds to the image that a user would see in a direction of view perpendicular to said characteristic axis of the tool, whereas the position of the characteristic axis of the tool (2) is indicated in said image by two lines parallel to said axis and situated at a distance from each other at least corresponding to the tool size perpendicular to said characteristic axis, and the position of the target to be treated by said tool is also indicated.

4. A device as claimed in one or more of the preceding claims, **characterized in that** the tool (2) is a rod or needle-like element and the direction of the characteristic axis is the longitudinal axis of said rod or needle or a direction or axis parallel to said longitudinal axis, whereas the working end is the rod or needle insertion end into the target area.

5. A device as claimed in one or more of the preceding claims, **characterized in that** a marker (3, 4) is associated with the tool (2), for identifying and detecting the position and orientation of the tool or the characteristic axis thereof, which marker cooperates with detection means of a system for determining and/or tracking the position and orientation of the tool relative to a predetermined reference system.

6. A device as claimed in one or more of the preceding claims, **characterized in that** at least two or more identification and detection markers (3, 4) are associated with the tool (2), and are located at a certain distance from each other along said direction of said characteristic axis or along an axis parallel to said characteristic axis, which markers (3, 4) cooperate with detection means of a system (1) for determining and/or tracking the position and orientation of the tool (2) relative to a predetermined reference system.

7. A device as claimed in one or more of the preceding claims, **characterized in that** it comprises a monitor (16) and means for displaying images on said monitor, which means allow simultaneous, side-by-side or alternate display of images of the target area defined by at least one image plane coincident or parallel to the direction of the characteristic axis of the tool (2) and by at least one image plane having the predetermined inclination relative to the direction of the characteristic axis of the tool (2) and the predetermined distance from the working end of the tool.

8. A device as claimed in one or more of the preceding claims, **characterized in that** the sequence of real time 3D images (6) is acquired by an ultrasonic probe (8), whereas the position in space of the acquired image relative to a reference system is determined in real time by probe position and displacement detection systems.

9. A device as claimed in one or more of the preceding claims, **characterized in that** a volumetric probe (8) is used for acquiring the sequence of real time 3D images (6).

10. A device as claimed in one or more of the preceding claims, **characterized in that** it comprises means (12) for detecting or tracking in real time the position and orientation of the tool (2) or the characteristic axis thereof, with reference to real time 3D images (6) that determine said position and said orientation from the tool images appearing in the sequence of the real time 3D images of the area being scanned.

11. A device as claimed in one or more of the preceding claims 1 to 9, **characterized in that** it comprises external means for tracking the position and orientation of the tool (2) and/or the characteristic axis of

the latter and the ultrasound probe (8), which means define a reference coordinate system and, in such system, the relative positions and orientations of the tool (2) and the ultrasound probe (8).

12. A method for guiding surgical tools by ultrasonic imaging, comprising the steps of:

a) acquiring in real time a time sequence of 3D ultrasonic images of a target area;
b) defining a direction of a characteristic axis for the tool (2);
c) defining the position of a working or functional end of the tool (2) along said direction of said characteristic axis;
d) determining in real time the relative position in space of each of the real time 3D images (6) of the time sequence of real time images and the direction of the characteristic axis of the tool for each of said real time 3D images;
e) defining, for one or more of the real time 3D imaged acquired in the time sequence, a plane (7) of a real time 2D image which intersects the corresponding real time 3D image (6) and has a predetermined inclination relative to the direction of the characteristic axis of the tool (2) determined in real time and a predetermined distance from the working end of the tool with reference to the orientation and position of the tool (2) upon acquisition of the corresponding real time 3D image (6) ;
f) using the data of the corresponding real time 3D image (6) of the sequence of real time 3D images to generate an image along said 2D image plane;
g) the inclination of said 2D image plane relative to the direction of the characteristic axis of the tool (2) determined in real time, and the distance of said 2D image plane relative to the working end of the tool being such that the image generated in the 2D image plane corresponds at least approximately to a vision of the target (20) area from the point of view of an observer situated at or near a part of the tool (2) or said characteristic axis of the tool; and
h) the image generated along said plane (7) including indications of the position of the target (20) to be treated by said tool and/or the position of the characteristic axis of said tool (2) in said image and the dimensions of the tool (2) in a direction perpendicular to said characteristic axis.

13. A method as claimed in claim 12, **characterized in that** the inclination of said 2D image plane relative to the direction or the characteristic axis of the tool (2), and the distance of said 2D image plane relative to the working end of the tool are such that the image generated in the 2D image plane (7) corresponds at least approximately to a vision of the target (20) area from the point of view of an observer situated at said working end of the tool (2), and whose direction of view is coincident with or parallel to the direction of the characteristic axis of the tool.

14. A method as claimed in claim 12 and 13, **characterized in that** the tool (2) is a rod or needle-like element and the direction of the characteristic axis is the longitudinal axis of said rod or needle or a direction or axis parallel to said longitudinal axis, whereas the working end is the rod or needle insertion end into the target area.

15. A method as claimed in claim 14, **characterized in that** the 2D image plane is perpendicular to the direction of the characteristic axis of the tool (2), whereas said real time 2D image includes an indication of the position of the target (20) to be treated by said tool and/or the point of coincidence of the characteristic axis of the tool (2) with said plane of the real time 2D image and possibly also the section of the tool along said plane (7).

16. A method as claimed in claim 12 or 14, **characterized in that** the 2D image plane is parallel to the direction of the characteristic axis of the tool (2) and possibly coincident with said characteristic axis so that the image along said cutting plane substantially corresponds to the image that a user would see in a direction of view perpendicular to said characteristic axis of the tool (2), whereas the position of the characteristic axis of the tool is indicated in said image by two lines parallel to said axis and situated at a distance from each other at least corresponding to the tool size perpendicular to said characteristic axis, and the position of the target to be treated by said tool is also indicated.

17. A method as claimed in one or more of the preceding claims 12 to 16, **characterized in that** a marker (3, 4) is associated with the tool (2), for identifying and detecting the position and orientation of the tool (2) or the characteristic axis thereof, which marker (3, 4) cooperates with detection means of a system (1) for determining and/or tracking the position and orientation of the tool relative to a predetermined reference system.

18. A method as claimed in one or more of the preceding claims 12 to 16, **characterized in that** at least two or more identification and detection markers (3, 4) are associated with the tool (2), and are located at a certain distance from each other along said direction or said characteristic axis or along an axis parallel to said characteristic axis, which markers cooperate with detection means of a system for determining and/or tracking the position and orientation of the tool relative to a predetermined reference system.

19. A method as claimed in one or more of the preceding claims, **characterized in that** it provides simultaneous, side-by-side or alternate display of real time images of the target area as defined by at least one image plane coincident or parallel to the direction of the characteristic axis of the tool and by
at least one image plane having the predetermined inclination relative to the direction of the characteristic axis of the tool and the predetermined distance from the working end of the tool.

20. A method as claimed in claim 19, **characterized in that** in at least one of the real time images, the position of the tool (2) is indicated by a symbol which is well differentiated from the image of the target area (20).

21. A method as claimed in one or more of the preceding claims 12 to 20, **characterized in that** the sequence of real time 3D images is acquired by an ultrasonic probe (8), whereas the position in space of the acquired image relative to a reference system is determined by probe position and displacement detection systems.

22. A method as claimed in one or more of the preceding claims 12 to 21, **characterized in that** a volumetric probe (8) is used for acquiring the sequence of real time 3D images.

23. A method as claimed in one or more of the preceding claims 12 to 22, **characterized in that** the system for detecting or tracking the position and orientation of the tool or the characteristic axis thereof with reference to the real time 3D images consists in the image of the tool that appears in the sequence of the real time 3D images of the area being scanned.

24. A method as claimed in one or more of the preceding claims 12 to 22, **characterized in that** it comprises external means for tracking the position and orientation of the tool and/or the characteristic axis of the latter and the ultrasound probe, which means define a reference coordinate system and, in such system, the relative positions and orientations of the tool and the ultrasound probe.

Patentansprüche

1. Vorrichtung zum Führen von chirurgischen Werkzeugen (2) durch Ultraschall-Bilderfassung, wobei die Vorrichtung umfasst:

a) Mittel (8) zum Erfassen in real time eine Zeitsequenz von 3D-Ultraschallbildern eines Zielgebietes;
b) Mittel zum Bestimmen und/oder Verfolgen, gleichzeitig als Schritt a) und in real time die Position oder die Ausrichtung eines chirurgischen Werkzeugs (2) und Mittel für die Bestimmung der Position oder der Ausrichtung einer charakteristischen Achse des Werkzeugs (2);
c) Mittel zur Bestimmung in real time der Position eines arbeitenden oder funktionellen Endes des Werkzeuges (2) entlang der besagten Richtung der besagten charakteristischen Achse;
d) Mittel zur Bestimmung in real time der relativen Position im Raum jedes real time-3D-Bildes (6) und der Richtung der charakteristischen Achse des Werkzeugs (2) welche jedem real time-3D-Bild (6) entspricht;
e) Mittel zum Erzeugen, für eine oder mehrere der real time-3D-Bilder (6), die in einer Zeitfolge erfasst worden sind, ein real time-2D-Bild (7), das durch eine Bildebene definiert ist die das entsprechende real time-3D-Bild (6) der Zeitfolge schneidet, welches real time-2D-Bildebene eine vorbestimmte Neigung gegenüber der Richtung der charakteristischen Achse des Werkzeuges (2), die in real time bestimmt wird, und einem vorbestimmten Abstand vom Arbeitsende des Werkzeuges mit Bezug auf die Ausrichtung und Position des Werkzeugs bei Erfassung des entsprechenden real time-3D-Bildes (6) aufweist, wobei das real time-2D-Bild erzeugt wird indem die Bilddaten der entsprechenden real time-3D-Bild der Zeitfolge von real time-3D-Bildern benutzt wird;
g) die Neigung des real time Bildes (7) gegenüber der Richtung der charakteristische Achse des Werkzeuges (2) welche in real time bestimmt ist und der Abstand dieser Ebene des 2D-Bildes relativ zum Arbeitsende des Werkzeuges (2) ist der Art dass das Bild, das in der 2D-Bildebene erzeugt wird zumindest annähernd einer Vision des Zielgebietes aus der Sicht eines Beobachters der an oder in der Nähe eines Teils des Werkzeugs (2) oder der charakteristischen Achse des Werkzeugs angeordnet ist, entspricht
h) das entlang der Ebene (7) erzeugte Bild enthält Angaben der Position des Zielobjektes welche mit diesem Werkzeug (2) behandelt werden soll und/oder der Position von der charakteristischen Achse des Werkzeuges in besagten Bild und die Abmessungen des Werkzeuges in einer Richtung senkrecht zur charakteristischen Achse.

2. Vorrichtung nach Anspruch 1, **dadurch gekennzeichnet dass** die Neigung der 2D-Bildebene bezüglich der Richtung der charakteristischen Achse des Werkzeugs (2) und der Abstand des 2D-Bildebene (7) sind so bemessen dass das Bild welches in der 2D-Bildebeme (7) erzeugt wird zumindest annähernd einer Sicht des Zielgebietes aus der Sicht eines Beobachters der sich an dem Arbeitsende des Werkzeugs (2) befindet und dessen Sichtrichtung mit der charakteristischen Achse des Werkzeugs zusammenfällt oder zu dieser parallel ist, während das real time-2D-Bild Anzeigen über der Position des Zielobjektes, welches mit diesem Werkzeug behandelt werden muss, und/oder der Punkt der Koinzidenz der charakteristischen Achse des Werkzeuges mit der 2D-Bildebene und möglicherweise auch der Querschnitt des Werkzeugs entlang dieser Ebene enthaelt.

3. Vorrichtung nach Anspruch 1, **dadurch gekennzeichnet, dass** die 2D-Ebene parallel zur charakteristische Achse des Werkzeuges (2) und gegebenenfalls mit dieser koinzident ist, so dass das Bild längs dieser Schnittebene (7) im Wesentlichen mit dem Bild, das ein Benutzer sehen würde in einer Blickrichtung senkrecht zu der charakteristischen Achse des Werkzeuges (2), während die Position der charakteristischen Achse des Werkzeuges (2) ist in dem Bild durch zwei parallel zu dieser Achse verlaufende Linien welche in einem Abstand zueinander stehen der mindestens der Werkzeugabmessungen senkrecht zu dieser charakteristische Achse entspricht und die Position des mit dem Werkzeug zu behandelnden Zielobjektes ist ebenfalls angezeigt.

4. Vorrichtung nach einem oder mehreren der vorhergehenden Ansprüche, **dadurch gekennzeichnet, dass** das Werkzeug (2) ein stab- oder nadelartiges Element ist und die Richtung der charakteristischen Achse ist die Längsachse dieses Stabes oder dieser Nadel oder eine Richtung oder Achse parallel zur Längsachse, während das Arbeitsende des Stabes oder der Nadel ist das Einführungsende in den Zielbereich.

5. Vorrichtung nach einem oder mehreren der vorhergehenden Ansprüche **dadurch gekennzeichnet, dass** eine Markierung (3, 4) dem Werkzeug (2) zugeordnet ist zum Identifizieren und Erfassen der Position und Ausrichtung des Werkzeuges oder dessen charakteristischen Achse, welche Markierung mit Erfassungsmitteln kooperiert eines Systems für die Bestimmung und/oder zum Verfolgen der Position und der Ausrichtung des Werkzeuges relativ zu einem vorbestimmten Bezugssystem.

6. Vorrichtung nach einem oder mehreren der vorhergehenden Ansprüche **dadurch gekennzeichnet, dass** mindestens zwei oder mehr Identifikations- und Erkennungs-markierungen (3, 4) sind dem Werkzeug (2) zugeordnet welche mit bestimmten Abstände voneinander entlang der charakteristischen Achse oder entlang einer zur charakteristischen Achse parallelen Achse positioniert sind, welche Markierungen (3, 4) mit Erfassungsmittel kooperieren eines Systems (1) zur Bestimmung oder zur Verfolgung der Position und der Ausrichtung des Werkzeuges (2) bezüglich einen bestimmten Bezugsystem

7. Vorrichtung nach einem oder mehreren der vorhergehenden Ansprüche, **dadurch gekennzeichnet, dass** die Vorrichtung einen Bildschirm (16) und Mittel zum Anzeigen von Bildern auf diesen Bildschirm aufweist, welche Mittel eine gleichzeitige anzeige der Bilder Seite an Seite oder eine alternative Anzeige von Bildern des Zielbereich, welche Bilder durch mindestens eine Bildebene definiert sind die koinzident oder parallel zur Richtung der charakteristische Achse des Werkzeuges (2) und durch mindestens eine Bildebene mit der vorbestimmten Neigung gegenüber der Richtung der charakteristischen Achse des Werkzeuges (2) und dem vorbestimmten Abstand vom Arbeitsende des Werkzeuges.

8. Vorrichtung nach einem oder mehreren der vorhergehenden Ansprüche **dadurch gekennzeichnet, dass** die Sequenz von real time-3D-Bildern (6) wird von einer Ultraschallsonde (8) erfasst, während die Position im Raum des erfassten Bildes relativ zu einem Bezugssystem ist in real time bestimmt durch ein System zur Erfassung der Lage und der Verschiebung der Sonde.

9. Vorrichtung nach einem oder mehreren der vorhergehenden Ansprüche **dadurch gekennzeichnet, dass** eine volumetrische Sonde (8) zum Erfassen der Sequenz von real time-3D-Bilder (6) verwendet wird.

10. Vorrichtung nach einem oder mehreren der vorhergehenden Ansprüche **dadurch gekennzeichnet, dass** Mittel (12) zum Erfassen oder Verfolgen in real time der Position und Lage des Werkzeuges (2) bzw der charakteristischen Achse aufweist, mit Bezug auf real time-3D-Bilder (6) welche diese Position diese Ausrichtung aus den Werkzeugbildern welche in der Folge der real time-3D-Bilder des abgetasteten Bereichs bestimmen.

11. Vorrichtung nach einem oder mehreren der vorhergehenden Ansprüche 1 bis 9, **dadurch gekennzeichnet, dass** diese externe Mittel zum Verfolgen der Position und Ausrichtung des Werkzeugs (2) und/oder der charakteristischen Achse desselben und der Ultraschallsonde, welche Mittel einen Bezugkoordinatensystem definieren und in diesem System die relativen Positionen und Ausrichtungen des Werkzeuges (2) und der Ultraschallsonde (8).

12. Verfahren zum Führen von chirurgischen Werkzeugen durch Ultraschallbilderfassung umfassend die Schritte:

a) Erfassen in real time eine Zeitfolge von 3D Ultraschallbilder eines Zielgebietes;
b) Definieren eine Richtung einer Charakteristische Achse des Werkzeuges (2);
c) Festlegung der Position eines arbeitenden oder funktionalen Endes des Werkzeugs (2) entlang der Richtung der charakteristischen Achse;
d) Bestimmen in real time der relativen Position im Raum von jedem der real time-3D-Bilder (6) der Zeitfolge von real time Bildern und der Ausrichtung der Werkzeugachse für jeden dieser real time-3D-Bilder;
e) Definieren, für eine oder mehrere der real time-3D-Bilder die in der Zeitsequenz erfasst worden sind, eine Ebene (7) eines real time-2D-Bildes, welches das entsprechende real time-3D-Bidung (6) schneidet und eine vorbestimmte Neigung relativ zu der Richtung der charakteristischen Achse des Werkzeuges (2) aufweist welche in real time und in einem bestimmten Abstand vom Arbeitsende des Werkzeugs bestimmt ist mit Bezug zur Ausrichtung und Position des Werkzeugs (2) bei Erfassung des entsprechenden real time-3D-Bildes (6).
f) Benutzung der Daten des entsprechenden real time-3D-Bildes (6) der Folge solcher real time-3D-Bilder um ein Bild entlang dieser 2D-Bildebene;
g) Die Neigung dieser 2D-Bildebene bezüglich der Richtung der charakteristischen Achse des Werkzeuges (2) ist in real time bestimmt und der Abstand dieser 2D-Bildebene bezüglich des Arbeitsende des Werkzeugs ist so bemessen, dass das Bild welches in der 2D-Bildeben generiert wird zumindest annährend zur Sicht des Zielbereichs (20) aus der Sicht eines Beobachters welcher auf oder in der Nähe des Werkzeugs (2) oder dieser charakteristischen Achse des Werkzeugs steht entspricht; und
h) das Bild welches entlang dieser Eben (7) erzeugt wird enthaelt Angaben über die Position des Zieles (20) welches mit diesem Werkzeug behandelt werden soll und/oder die Position der charakteristischen Achse dieses Werkzeugs (2) in diesem Bild und über die Ausmaßen des Werkzeuges (2) in einer Richtung die senkrecht zu dieser charakteristischen Achse ist.

13. Verfahren nach Anspruch 12, **dadurch gekennzeichnet, dass** die Neigung dieser 2D-Bildebene bezüglich der Richtung oder der charakteristischen Achse des Werkzeugs (2) und der Abstand dieser 2D-Bildebene bezüglich des Arbeitsende des Werkzeugs sind so bemessen dass das Bild welches erzeugt wird in dieser 2D-Bildebene, entspricht zumindest annährend der Sicht des Zielbereiches (20) aus der Sicht eines Beobachters der am Arbeitsende des Werkzeugs (2) steht und dessen Blickrichtung koinzident oder parallel zur Ausrichtung der charakteristischen Achse des Werkzeugs ist.

14. Verfahren nach Anspruch 12 und 13, **dadurch gekennzeichnet, dass** das Werkzeug (2) ein Stab- oder Nadel-artiges Element ist und dass die Richtung der charakteristischen Achse die Langsachse dieses Stabes oder dieser Nadel ist oder eine zu dieser Längsachse parallelen Achse, während das Arbeitsende des Stabes oder der Nadel die Einführungspitze im Zielbereich ist.

15. Verfahren nach Anspruch 14, **dadurch gekennzeichnet, dass** die 2D-Bildeben senkrecht zur Richtung der charakteristischen Achse des Werkzeugs (2) ist, während dieses real time 2D-Bild eine Angabe über die Position des zu behandelnden Zieles (20) mit diesem Werkzeug und/oder der Koinzidenzpunkt der charakteristischen Achse des Werkzeugs (2) mit dieser Ebene des real time-2D-Bildes und möglicherweise auch der Schnitt des Werkzeuges entlang dieser Ebene (7).

16. Verfahren nach Anspruch 12 oder 14, **dadurch gekennzeichnet, dass** die 2D-Bildebene parallel zur Richtung der charakteristischen Achse des Werkzeugs (2) ist und möglicherweise koinzident mit dieser charakteristischen Achse, so dass das Bild entlang dieser Schnittebene im Wesentlichen dem Bild entspricht welcher ein Benutzer sehen würde in einer Blickrichtung senkrecht zu dieser charakteristischen Achse des Werkzeugs (2), während die Position der charakteristischen Achse des Werkzeugs ist in diesem Bild angegeben mit zwei zu dieser Achse parallelen Linien und mit einem Abstand zueinander welches zumindest den Werkzeugs Abmessungen senkrecht zu dieser charakteristischen Achse entspricht, und die Position des mit diesem Werkzeug zu behandelnden Ziels ist auch angegeben.

17. Verfahren nach einen oder mehreren der vorangehenden Anspruche 12 zu 16, **dadurch gekennzeichnet, dass** eine Markierung (3, 4) dem Werkzeug (2) zugeordnet ist zum Identifizieren und Erfassen der Position und Ausrichtung des Werkzeuges oder dessen charakteristischen Achse, welche Markierung (3, 4) mit Erfassungsmitteln kooperiert eines Systems (1) für die Bestimmung und/oder zum Verfolgen der Position und der Ausrichtung des Werkzeuges relativ zu einem vorbestimmten Bezugssystem.

18. Verfahren nach einen oder mehreren der vorangehenden Anspruche 12 zu 16, **dadurch gekennzeichnet, dass** mindestens zwei oder mehr Identifikations- und Erkennungs-markierungen (3, 4) sind dem Werkzeug (2) zugeordnet welche mit bestimmten Abstände voneinander entlang der charakteristischen Achse oder entlang einer zur charakteristischen Achse parallelen Achse positioniert sind, welche Markierungen (3, 4) mit Erfassungsmittel kooperieren eines Systems (1) zur Bestimmung oder zur Verfolgung der Position und der Ausrichtung des Werkzeuges (2) bezüglich einen bestimmten Bezugsystem.

19. Verfahren nach einen oder mehreren der vorangehenden Anspruche, **dadurch gekennzeichnet, dass** eine gleichzeitige anzeige der Bilder Seite an Seite oder eine alternative Anzeige von Bildern des Zielbereich, vorgesehen ist welche Bilder durch mindestens eine Bildebene definiert sind die koinzident oder parallel zur Richtung der charakteristische Achse des Werkzeuges und durch mindestens eine Bildebene mit der vorbestimmten Neigung gegenüber der Richtung der charakteristischen Achse des Werkzeuges und dem vorbestimmten Abstand vom Arbeitsende des Werkzeuges.

20. Verfahren nach Anspruch 19, **dadurch gekennzeichnet, dass** in zumindest einem der real time Bilder die Position des Werkzeugs (2) mit einem Symbol angezeigt ist welches gut unterscheidbar vom Bild des Zielbereiches (20) ist.

21. Verfahren nach einen oder mehreren der vorangehenden Anspruche 12 zu 20, **dadurch gekennzeichnet, dass** die Folge der real time-3D-Bilder wird erfasst mit Hilfe einer Ultraschallsonde (8), während die Lage in Raum des erfassten Bildes bezüglich eines Bezugsystem durch ein System zur Erfassung der Lage und der Bewegung der Sonde bestimmt ist.

22. Verfahren nach einen oder mehreren der vorangehenden Anspruche 12 zu 21, **dadurch gekennzeichnet, dass** für die Erfassung der Folge der real time-3D-Bilder eine volumetrische Sonde (8) benutzt wird.

23. Verfahren nach einen oder mehreren der vorangehenden Anspruche 12 zu 22, **dadurch gekennzeichnet, dass** das System zum Erfassen oder Verfolgen der Position und Richtung des Werkzeuges bzw. der charakteristischen Achse desselben mit Bezug auf real time-3D-Bilder besteht im Bild des Werkzeugs welches in der Folge der real time-3D-Bilder des abgetasteten Gebietes erscheint.

24. Verfahren nach einen oder mehreren der vorangehenden Anspruche 12 zu 22, **dadurch gekennzeichnet, dass** externe Mittel zum Verfolgen der Position und Ausrichtung des Werkzeugs (2) und/oder der charakteristischen Achse desselben und der Ultraschallsonde vorhanden sind, welche Mittel einen Bezugkoordinatensystem definieren und in diesem System die relativen Positionen und Ausrichtungen des Werkzeuges (2) und der Ultraschallsonde (8).

Revendications

1. Dispositif pour le guidage d'outils chirurgicaux (2) par imagerie échographique, ce dispositif comprenant:

a) des moyens (8) pour acquérir en temps réel une séquence temporelle d'images échographiques 3D d'une région cible ;
b) des moyens pour déterminer et/ou suivre, en même temps que l'étape a) et en temps réel, la position et l'orientation d'un outil chirurgical (2) et des moyens pour définir la position ou la direction d'un axe caractéristique de l'outil (2) correspondant à la position et à l'orientation détectées de l'outil (2) ;
c) des moyens pour déterminer en temps réel la position d'une extrémité de travail ou fonctionnelle de l'outil (2) dans ladite direction dudit axe caractéristique ;
d) des moyens pour déterminer en temps réel la position relative dans l'espace de chaque image 3D en temps réel (6) et la direction de l'axe caractéristique de l'outil (2) correspondant à chaque image 3D en temps réel (6) ;
e) des moyens pour générer, pour une ou plusieurs des images 3D en temps réel (6) acquises dans une séquence temporelle, une image 2D en temps réel (7) définie par un plan d'image intersectant l'image 3D en temps réel correspondante (6) de ladite séquence temporelle, ce plan d'image 2D en temps réel ayant une inclinaison prédéterminée par rapport à la direction de l'axe caractéristique de l'outil (2) déterminée en temps réel, et une distance prédéterminée de l'extrémité de travail de l'outil par rapport à l'orientation et à la position de l'outil dès l'acquisition de l'image 3D en temps réel correspondante (6), ladite image 2D en temps réel étant générée à partir des données d'image de l'image 3D en temps réel correspondante de la séquence temporelle d'images 3D en temps réel ;
g) l'inclinaison dudit plan d'image 2D en temps réel (7) par rapport à la direction de l'axe caractéristique de l'outil (2) déterminée en temps réel, et la distance dudit plan d'image 2D par rapport à l'extrémité de travail de l'outil (2) étant telles

que l’image générée dans le plan d’image 2D corresponde au moins approximativement à une vision de la région cible du point de vue d’un observateur situé au niveau ou près d’une partie de l’outil (2) ou dudit axe caractéristique de l’outil ;

h) l’image générée sur ledit plan (7) comportant des indications relatives à la position du cible à traiter par ledit outil (2) et/ou à la position de l’axe caractéristique dudit outil dans ladite image est aux dimensions de l’outil dans une direction perpendiculaire audit axe caractéristique.

2. Dispositif selon la revendication 1, **caractérisé en ce que** l’inclinaison dudit plan d’image 2D par rapport à la direction de l’axe caractéristique de l’outil (2) et la distance dudit plan d’image 2D (7) par rapport à l’extrémité de travail de l’outil (2) sont telles que l’image généré dans le plan d’image 2D (7) corresponde au moins approximativement à une vision de la région cible du point de vue d’un observateur situé au niveau de ladite extrémité de travail de l’outil (2), dont la direction de vue coïncide avec ou soit parallèle à la direction de l’axe caractéristique de l’outil (2), alors que ladite image 2D en temps réel comporte des indications relatives à la position du cible à traiter par ledit outil et/ou le point de coïncidence de l’axe caractéristique de l’outil avec ledit plan d’image 2D et éventuellement aussi avec la section de l’outil le long dudit plan.

3. Dispositif selon la revendication 1, **caractérisé en ce que** le plan 2D est parallèle à l’axe caractéristique de l’outil (2) et éventuellement coïncide avec celui-ci, de manière que l’image le long dudit plan de coupe (7) corresponde sensiblement à l’image qu’un utilisateur verrait dans une direction de vue perpendiculaire audit axe caractéristique de l’outil, alors que la position de l’axe caractéristique de l’outil (2) est indiquée dans ladite image par deux lignes parallèles audit axe et situées à une distance entre elles au moins correspondant à la dimension de l’outil perpendiculaire audit axe caractéristique, et la position du cible à traiter par ledit outil est aussi indiquée.

4. Dispositif selon une ou plusieurs des revendications précédentes, **caractérisé en ce que** l’outil (2) est en forme de tige ou d’aiguille et la direction de l’axe caractéristique est l’axe longitudinal de ladite tige ou aiguille ou une direction ou un axe parallèle audit axe longitudinal, alors que l’extrémité de travail est l’extrémité d’insertion de la tige ou aiguille dans la région cible.

5. Dispositif selon une ou plusieurs des revendications précédentes, **caractérisé en ce qu’**un marqueur (3, 4) est associé à l’outil (2), pour identifier et détecter la position et l’orientation de l’outil ou l’axe caractéristique de celui-ci, ce marqueur coopérant avec des moyens détecteurs d’un système pour déterminer et/ou suivre la position et l’orientation de l’outil par rapport à un système de référence prédéterminée.

6. Dispositif selon une ou plusieurs des revendications précédentes, **caractérisé en ce qu’**au moins deux ou plusieurs marqueurs d’identification et de détection (3, 4) sont associés à l’outil (2), et sont situés à une certaine distance l’un de l’autre dans ladite direction dudit axe caractéristique ou le long d’un axe parallèle audit axe caractéristique, ces marqueurs (3, 4) coopérant avec des moyens détecteurs d’un système (1) pour déterminer et/ou suivre la position et l’orientation de l’outil (2) par rapport à un système de référence prédéterminé.

7. Dispositif selon une ou plusieurs des revendications précédentes, **caractérisé en ce qu’**il comprend un moniteur (16) et des moyens d’affichage d’images sur ledit moniteur, ces moyens permettant un affichage simultané et côte à côte ou alterné d’images de la région cible définies par au moins un plan d’image coïncidant avec ou parallèle à la direction de l’axe caractéristique de l’outil (2) et par au moins un plan d’image ayant l’inclinaison prédéterminée par rapport à la direction de l’axe caractéristique de l’outil (2) et la distance prédéterminée de l’extrémité de travail de l’outil.

8. Dispositif selon une ou plusieurs des revendications précédentes, **caractérisé en ce que** la séquence d’images 3D en temps réel (6) est acquise par une sonde échographique (8), alors que la position dans l’espace de l’image acquise par rapport au système de référence est déterminée en temps réel par des systèmes de détection de la position et du déplacement de la sonde.

9. Dispositif selon une ou plusieurs des revendications précédentes, **caractérisé en ce qu’**une sonde volumétrique (8) est utilisée pour acquérir la séquence d’images 3D en temps réel (6).

10. Dispositif selon une ou plusieurs des revendications précédentes, **caractérisé en ce qu’**il comprend des moyens (12) pour détecter ou suivre en temps réel la position et l’orientation de l’outil (2) ou l’axe caractéristique de celui-ci, par rapport à des images 3D en temps réel (6), qui déterminent ladite position et ladite orientation à partir des images de l’outil apparaissant dans la séquence des images 3D en temps réel de la région balayée.

11. Dispositif selon une ou plusieurs des revendications précédentes 1 à 9, **caractérisé en ce qu’**il comprend des moyens externes de poursuite de la position et de l’orientation de l’outil (2) et/ou de l’axe caractéristique de celui-ci et de la sonde échographique (8), ce moyen définissant un système de coordonnées de référence et, dans ledit système, les positions et les orientations relatives de l'outil (2) et de la sonde échographique (8).

12. Procédé de guidage d'outils chirurgicaux par imagerie échographique, comportant les étapes suivantes :

a) acquérir en temps réel une séquence temporelle d'images échographiques 3D d'une région cible ;
b) définir une direction d'un axe caractéristique pour l'outil (2) ;
c) définir la position d'une extrémité de travail ou fonctionnelle de l'outil (2) dans ladite direction dudit axe caractéristique ;
d) déterminer en temps réel la position relative dans l'espace desdites images 3D en temps réel (6) de la séquence temporelle d'image en temps réel et la direction de l'axe caractéristique de l'outil pour chacune desdites images 3D en temps réel ;
e) définir, pour une ou plusieurs des images 3D en temps réel (6) acquises dans la séquence temporelle, un plan (7) d'une image 2D en temps réel intersectant l'image 3D en temps réel correspondante (6) et ayant une inclinaison prédéterminée par rapport à la direction de l'axe caractéristique de l'outil (2) déterminée en temps réel, et une distance prédéterminée de l'extrémité de travail de l'outil par rapport à l'orientation et à la position de l'outil (2) dès l'acquisition de l'image 3D en temps réel correspondante (6) ;
f) utiliser les données de l'image 3D en temps réel correspondante (6) de la séquence d'images 3D en temps réel pour générer une image le long dudit plan d'image 2D ;
g) l'inclinaison dudit plan d'image 2D par rapport à la direction de l'axe caractéristique de l'outil (2) déterminée en temps réel, et la distance dudit plan d'image 2D par rapport à l'extrémité de travail de l'outil étant telles que l'image générée dans le plan d'image 2D corresponde au moins approximativement à une vision de la région cible (20) du point de vue d'un observateur situé au niveau ou près d'une partie de l'outil (2) ou dudit axe caractéristique de l'outil ; et
h) l'image générée sur ledit plan (7) comportant des indications relatives à la position du cible à traiter par ledit outil (2) et/ou à la position de l'axe caractéristique dudit outil dans ladite image est aux dimensions de l'outil dans une direction perpendiculaire audit axe caractéristique.

13. Procédé selon la revendication 12, **caractérisé en ce que** l'inclinaison dudit plan d'image 2D par rapport à la direction de l'axe caractéristique de l'outil (2), et la distance dudit plan d'image 2D par rapport à l'extrémité de travail de l'outil sont telles que l'image générée dans le plan d'image 2D corresponde au moins approximativement à une vision de la région cible (20) du point de vue d'un observateur situé au niveau de ladite extrémité de travail de l'outil (2), et dont la direction de vue coïncide avec ou est parallèle à la direction de l'axe caractéristique de l'outil.

14. Procédé selon les revendications 12 et 13, **caractérisé en ce que** l'outil (2) est en forme de tige ou d'aiguille et la direction de l'axe caractéristique est l'axe longitudinal de ladite tige ou aiguille ou une direction ou un axe parallèle audit axe longitudinal, alors que l'extrémité de travail est l'extrémité d'insertion de la tige ou aiguille dans la région cible.

15. Procédé selon la revendication 14, **caractérisé en ce que** le plan d'image 2D est perpendiculaire à la direction de l'axe caractéristique de l'outil (2), alors que ladite image 2D en temps réel comporte une indication relative à la position du cible (20) à traiter par ledit outil et/ou le point de coïncidence de l'axe caractéristique de l'outil (2) avec ledit plan d'image 2D en temps réel et éventuellement aussi avec la section de l'outil le long dudit plan (7).

16. Procédé selon la revendication 12 ou 14, **caractérisé en ce que** le plan d'image 2D est parallèle à la direction de l'axe caractéristique de l'outil (2) et éventuellement coïncide avec ledit axe caractéristique, de manière que l'image le long dudit plan de coupe corresponde sensiblement à l'image qu'un utilisateur verrait dans une direction de vue perpendiculaire audit axe caractéristique de l'outil (2), alors que la position de l'axe caractéristique de l'outil est indiquée dans ladite image par deux lignes parallèles audit axe et situées à une distance entre elles au moins correspondant à la dimension de l'outil perpendiculaire audit axe caractéristique, et la position du cible à traiter par ledit outil est aussi indiquée.

17. Procédé selon une ou plusieurs des revendications précédentes 12 à 16, **caractérisé en ce qu'**un marqueur (3, 4) est associé à l'outil (2), pour identifier et détecter la position et l'orientation de l'outil (2) ou l'axe caractéristique de celui-ci, ce marqueur (3, 4) coopérant avec des moyens détecteurs d'un système (1) pour déterminer et/ou suivre la position et l'orientation de l'outil par rapport à un système de référence prédéterminé.

18. Procédé selon une ou plusieurs des revendications précédentes 12 à 16, **caractérisé en ce qu'**au moins deux ou plusieurs marqueurs d'identification et de détection (3, 4) sont associés à l'outil (2), et sont situés à une certaine distance l'un de l'autre dans ladite direction ou ledit axe caractéristique ou le long d'un axe parallèle audit axe caractéristique, ces marqueurs coopérant avec des moyens détecteurs d'un système pour déterminer et/ou suivre la position et l'orientation de l'outil par rapport à un système de référence prédéterminé.

19. Procédé selon une ou plusieurs des revendications précédentes, **caractérisé en ce qu'**il comporte l'affichage simultané, côte à côte ou alterné d'images en temps réel de la région cible, définies par au moins un plan d'image coïncidant avec ou parallèle à la direction de
l'axe caractéristique de l'outil et par au moins un plan d'image ayant l'inclinaison prédéterminée par rapport à la direction de l'axe caractéristique de l'outil et la distance prédéterminée de l'extrémité de travail de l'outil.

20. Procédé selon la revendication 19, **caractérisé en ce que**, dans au moins une des images en temps réel, la position de l'outil (2) est indiquée par un symbole qui est bien différencié par rapport à l'image de la région cible (20).

21. Procédé selon une ou plusieurs des revendications précédentes 12 à 20, **caractérisé en ce que** la séquence d'images 3D en temps réel est acquise par une sonde échographique (8), alors que la position dans l'espace de l'image acquise par rapport au système de référence est déterminée par des systèmes de détection de la position et du déplacement de la sonde.

22. Procédé selon une ou plusieurs des revendications précédentes 12 à 21, **caractérisé en ce qu'**une sonde volumétrique (8) est utilisée pour acquérir la séquence d'images 3D en temps réel.

23. Procédé selon une ou plusieurs des revendications précédentes 12 à 22, **caractérisé en ce que** le système pour détecter ou suivre la position et l'orientation de l'outil ou l'axe caractéristique de celui-ci, par rapport à des images 3D en temps réel constitué de l'image de l'outil apparaissant dans la séquence des images 3D en temps réel de la région balayée.

24. Procédé selon une ou plusieurs des revendications précédentes 12 à 22, **caractérisé en ce qu'**il comprend des moyens externes de poursuite de la position et de l'orientation de l'outil et/ou de l'axe caractéristique de celui-ci et de la sonde échographique, ce moyen définissant un système de coordonnées de référence et, dans ledit système, les positions et les orientations relatives de l'outil et de la sonde échographique.

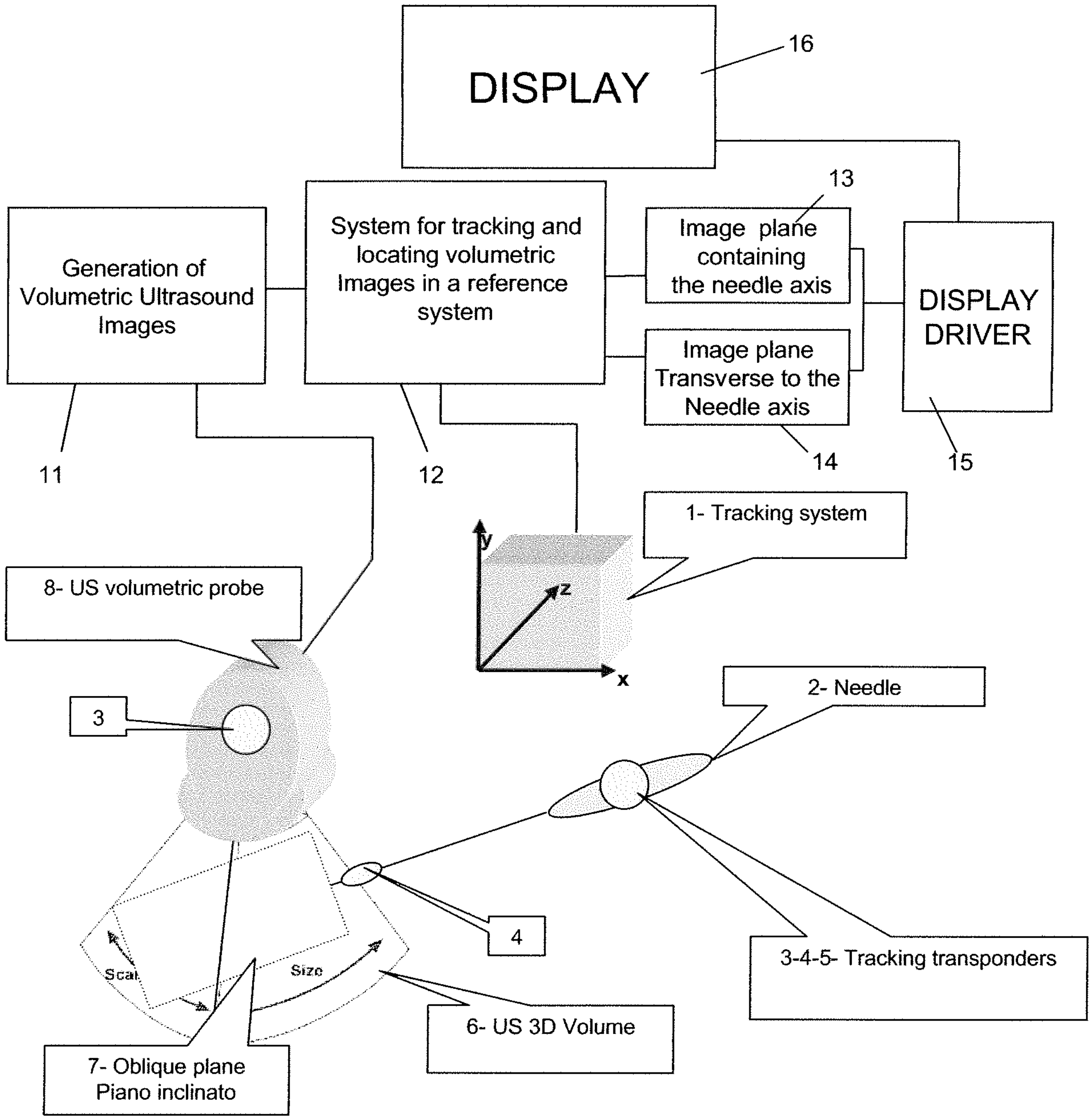
DISPLAY
16
13
System for tracking and locating volumetric Images in a reference system
Image plane containing the needle axis
Generation of Volumetric Ultrasound Images
DISPLAY DRIVER
Image plane Transverse to the Needle axis
11
12
14
15
1- Tracking system
y
z
x
8- US volumetric probe
2- Needle
3
4
3-4-5- Tracking transponders
6- US 3D Volume
7- Oblique plane Piano inclinato
Size

Fig. 1

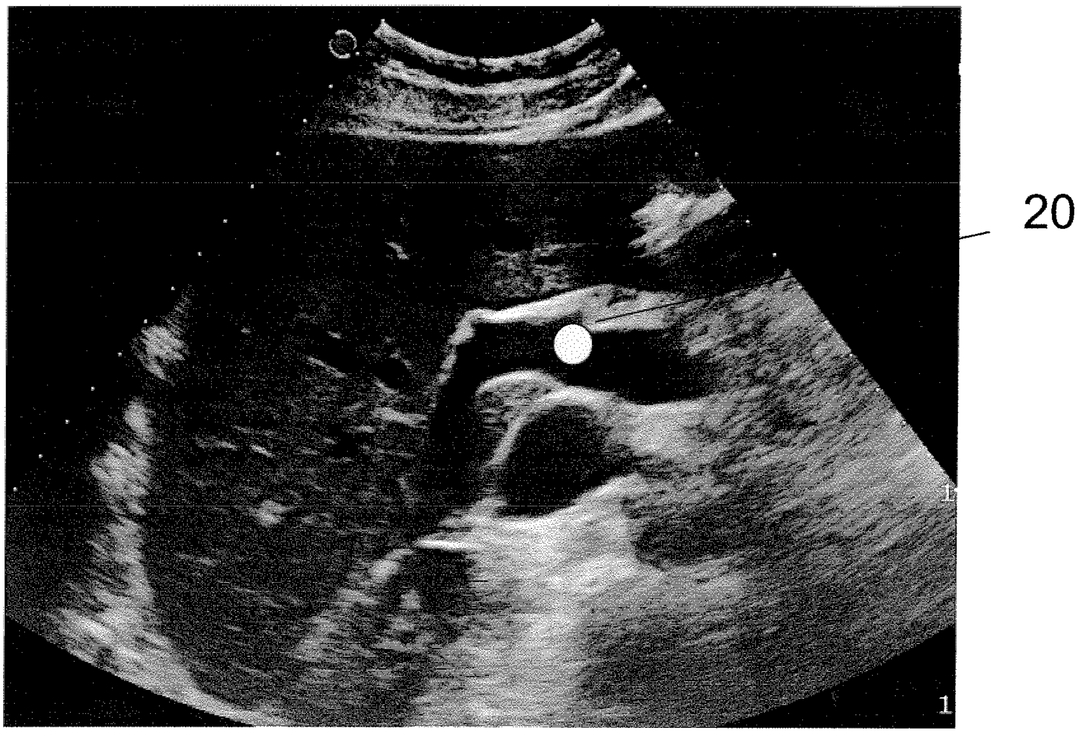

Fig. 2

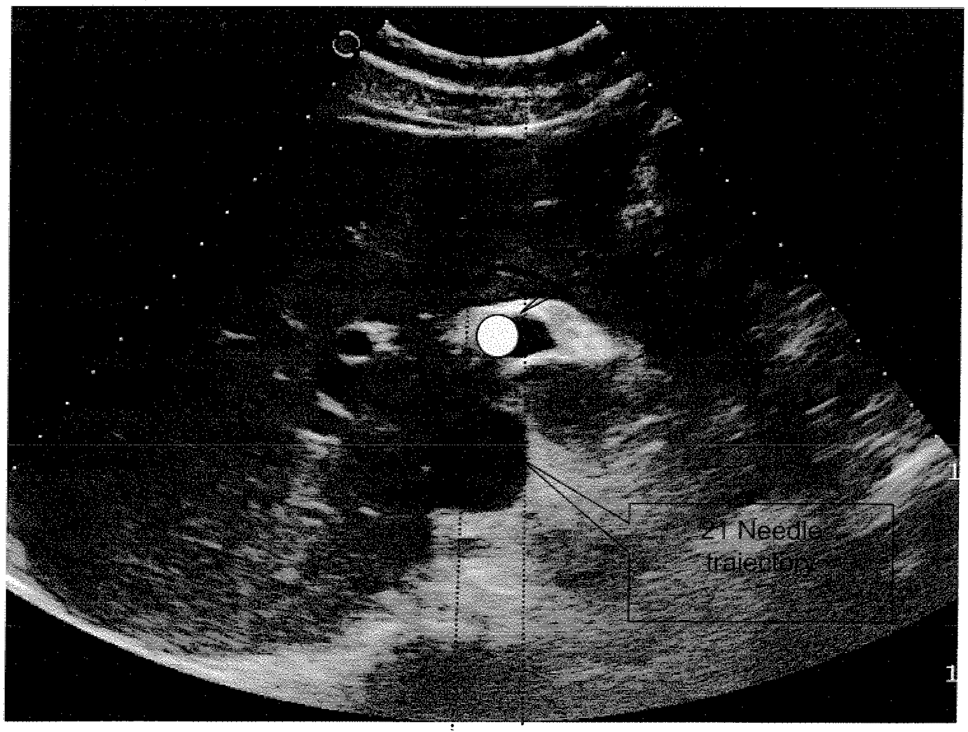

Fig. 3

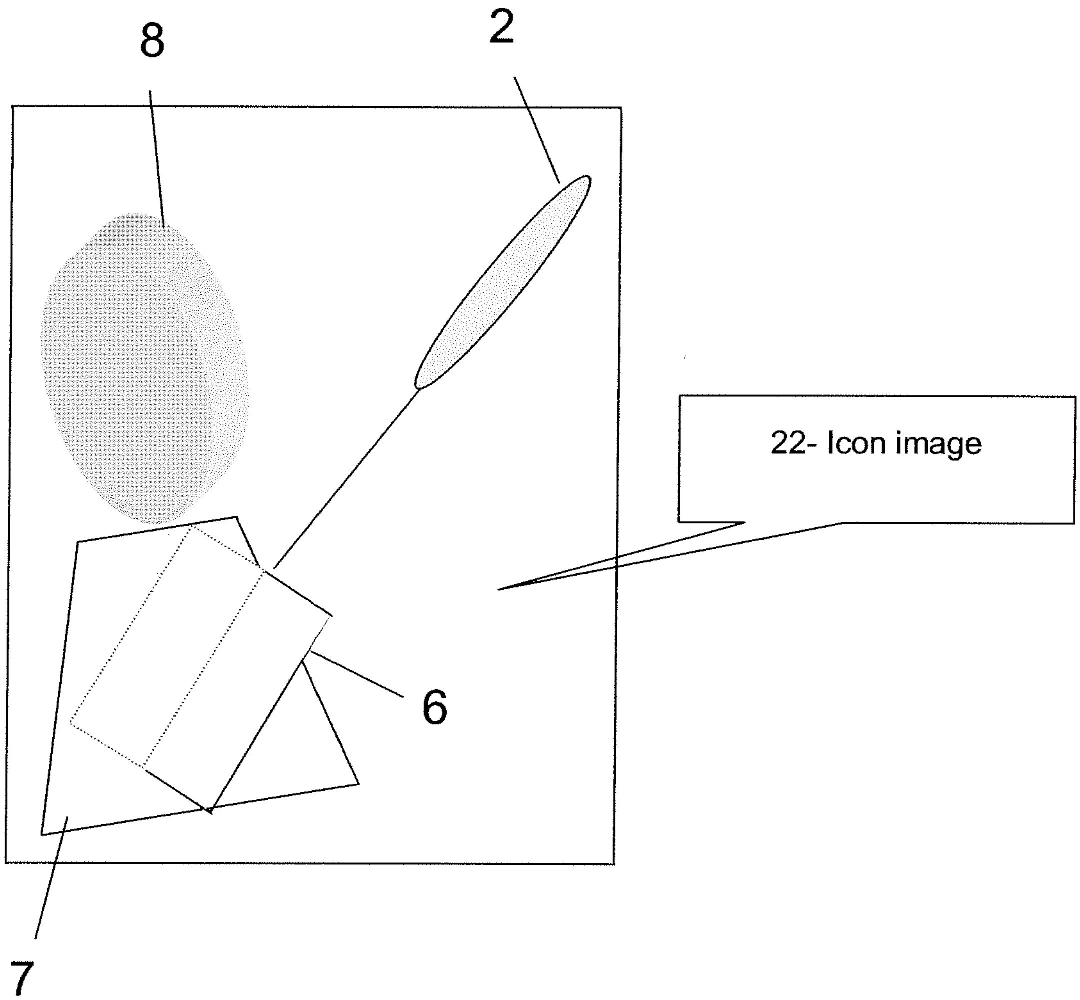

Fig. 4

REFERENCES CITED IN THE DESCRIPTION

This list of references cited by the applicant is for the reader's convenience only. It does not form part of the European patent document. Even though great care has been taken in compiling the references, errors or omissions cannot be excluded and the EPO disclaims all liability in this regard.

Patent documents cited in the description

- WO 2006067676 A **[0006]**
- WO 2005039391 A **[0008]**
- EP 1681019 A **[0027] [0053] [0068] [0077]**
- EP 1167996 A **[0027] [0053] [0066] [0068] [0077]**

专利名称(译)	用于通过超声成像引导手术工具的装置和方法		
公开(公告)号	EP2147636B1	公开(公告)日	2016-11-30
申请号	EP2009165926	申请日	2009-07-20
[标]申请(专利权)人(译)	百胜集团		
申请(专利权)人(译)	ESAOTE S.P.A.		
当前申请(专利权)人(译)	ESAOTE S.P.A.		
[标]发明人	DE BENI STEFANO MACCIO MARCO		
发明人	DE BENI, STEFANO MACCIÒ, MARCO		
IPC分类号	A61B8/08 A61B90/00		
CPC分类号	A61B8/0833 A61B8/0841 A61B8/4245 A61B8/4254 A61B8/483 A61B34/20 A61B2090/364		
优先权	102008901647593 2008-07-24 IT		
其他公开文献	EP2147636A1		
外部链接	Espacenet		

摘要(译)

一种通过超声成像引导手术工具的装置。从3D图像，生成对应于来自工具尖端的视图的2D图像。

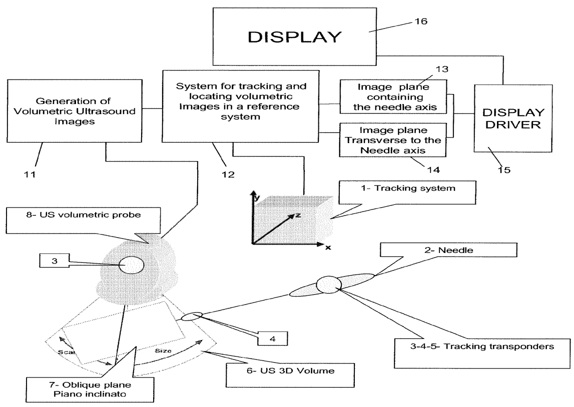

Fig. 1