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— *as to the identity of the inventor (Rule 4.17(i))*
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(54) Title: CROSS-PLANE ULTRASOUND IMAGING SYSTEM FOR COMBINED IN-PLANE AND OUT-OF-PLANE INSTRUMENT GUIDANCE

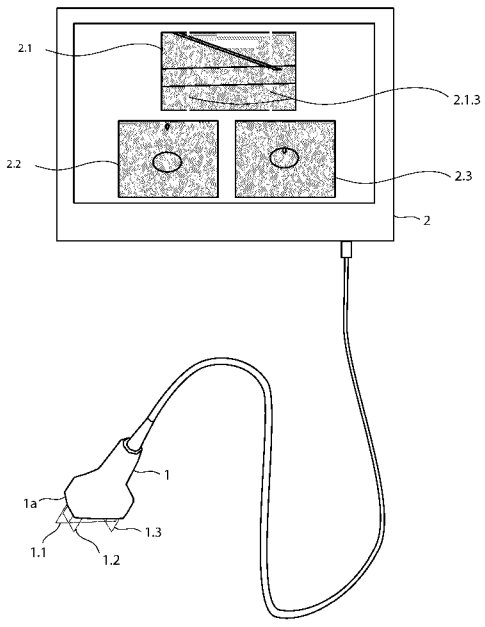


Fig. 4

(57) Abstract: The present invention relates to an ultrasound imaging system (12) that simultaneously creates and displays images from two or more intersecting planes in real time. The system includes an ultrasound probe head (1) and a console (2). The probe head (1) has a transducer field or a combination of at least two transducer arrays to generate two or more imaging planes. The console can address the electronic signal (to emit ultrasound waves) to different transducer arrays or to combinations of transducers in the same probe and thus generate corresponding images from different imaging planes which the console can display simultaneously. The invention as well relates to a method that combines in-plane and out-of- plane instrument guidance.

Cross-plane ultrasound imaging system for combined in-plane and out-of-plane instrument guidance

The present invention relates to the field of ultrasound imaging devices. More particularly, the invention relates to the field of medical ultrasound devices.

There are different types of ultrasound systems and techniques applied in medicine. Over the last decade, the use of ultrasound imaging systems has become increasingly important in anesthesia and intensive care medicine. Especially in anesthesia, ultrasound imaging is used to survey the introduction of needles or catheters into the human body. Ultrasound has improved patients' security by such manner that several national associations of anesthesists have included ultrasound-guided puncture of e.g. veins for central venous ports into guidelines. Usually, ultrasound systems are employed which generate a high-resolution single-plane image. To survey the introduction of a needle into the body, the needle can be displayed as a whole (i.e. the longitudinal axis of the needle lies within the imaging plane: "in-plane"-technique) or partly (i.e. the needle only intersects with the imaging plane: out-of-plane-technique). The target structure, e.g. a vessel or a peripheric nerve, is usually displayed either along its course (longitudinal section) or at right angle to it (oblique section) by placing the ultrasound probe in a corresponding position. Both techniques (in-plane or out-of-plane) have advantages and disadvantages. Out-of-plane scanning allows considerable freedom for manoeuvring a needle but has the disadvantage of showing only a small section of the needle while the location of the needlepoint can often at most be assumed. In-plane scanning allows surveillance of the whole needle which can be guided accurately within the scanning plane, though alignment of the needle with the scanning plane can prove difficult given the small width of the scanning plane (about 1mm). Several inventions aimed to improve the alignment of a needle with the scanning plane: mechanical needle guides (which certainly limit free manoeuvring of the needle), laser projection of an axis to align the needle with, electromagnetic detection of the needle and automatically adjusting the imaging plane to it, and many more.

However, when using a standard equipment (single-plane linear-array imaging) it can be necessary to switch between the in-plane and the out-of-plane technique by turning the probe around its longitudinal axis.

Thus, based on the above, the problem to be solved by the present invention is to provide an improved ultrasound imaging device and a corresponding method.

This problem is solved by an ultrasound imaging device having the features of claim 1 as well as by a method having the features of claim 12. Preferred embodiments of the

respective aspect of the present invention are stated in the corresponding sub claims or are described below.

According to claim 1, an ultrasound imaging device is disclosed, comprising

- an ultrasound probe head having a face side for butting against a sample to be scanned by the ultrasound imaging device, and

- a plurality of ultrasound transducers, wherein each ultrasound transducer is configured to transmit an ultrasound wave in a direction normal to said face side and to receive incoming ultrasound waves.

According to the present invention, said ultrasound transducers form at least a first linear array of ultrasound transducers, which first array extends along a first direction as well as a second linear array of ultrasound transducers, which second array extends along a second direction, wherein said at least two linear arrays intersect at a right angle, and wherein the ultrasound probe is configured to generate ultrasound signals using said first array of ultrasound transducers for scanning said sample along a first plane spanned by said first direction and said normal, and wherein the ultrasound probe is configured to generate ultrasound signals using said second array of ultrasound transducers for scanning said sample along a second plane spanned by the second direction and said normal, so that said two planes intersect at a right angle.

Particularly, the present invention allows for combined in-plane and out-of-plane technique. Especially the in-plane alignment of the probe with a needle is facilitated because the oblique section of the needle and its position relatively to the longitudinal plane can easily be followed in the corresponding out-of-plane image. The combination of two orthogonally intersecting imaging planes enables three-dimensional understanding of the target structure the way oblique-sectional views in engineering drawings help define and understand three-dimensional objects with two-dimensional media. Vessels and nerves are especially apt to be depicted in two intersecting planes because of their linear structure (instead e.g. organs, which are rather amorphous structures, are better depicted by multitudes of parallel layers). Unlike former inventions that introduced biplane or multiplane ultrasound probes for three-dimensional guidance of instruments (e.g. EP 0955010A1, US 2013/0225984A1, US006099474A) the present invention allows to observe needle and target structure in orthogonally intersecting imaging planes as in the above mentioned engineering drawings. Unlike former inventions that introduced biplane or multiplane ultrasound probes but with fixed instrument paths (e.g. EP 0955010A1, WO 2014/001963A1) the present invention allows to independently manoeuvre probe and needle.

According to a preferred embodiment of the present invention, each ultrasound transducer comprises a piezo crystal for generating and receiving ultrasound waves.

Further, according to a preferred embodiment of the present invention, the ultrasound probe is configured to trigger said two linear arrays of ultrasound transducers in an alternate fashion, wherein each linear array transmits an ultrasound signal and receives a back-scattered ultrasound signal before the other array transmits an ultrasound signal and receives a back-scattered ultrasound signal from the sample.

Further, according to a preferred embodiment of the present invention, the ultrasound probe head comprises a circumferential lateral wall, wherein light sources are arranged on said lateral wall for indicating the linear array that is currently transmitting or receiving an ultrasound signal.

Further, according to a preferred embodiment of the present invention, the ultrasound probe head comprises a 2D array of ultrasound transducers wherein said two linear arrays are comprised by said 2D array, and wherein the probe head is configured to select a linear array comprised by the 2D array as said first linear array and another linear array comprised by the 2D array as said second linear array.

Particularly, said ultrasound probe head is configured to trigger a plurality of linear arrays of ultrasound transducers comprised by the 2D array (particularly two or three linear arrays) in an alternating fashion so that each of said linear array transmits an ultrasound signal and receives a back-scattered ultrasound signal before the next linear array transmits its ultrasound signal, wherein each of said linear arrays transmits an ultrasound signal that scans the sample along an associated plane.

Particularly, in case of triggering three linear arrays, the planes scanned by the second and third linear array extend parallel to each other and spaced apart from each other, wherein the plane scanned by the first linear array extends perpendicular to the planes scanned by the second and third linear array and cuts the planes scanned by the second and third linear array.

Further, according to a preferred embodiment of the present invention, the imaging device comprises a console having a display that is configured to simultaneously display a first digital image rendered using the back-scattered ultrasound signals received by the first linear array and a second digital image rendered using the back-scattered ultrasound signals received by the second linear array.

Furthermore, the present invention relates to a method for imaging an elongated object, particularly a needle, that extends along a longitudinal axis and has been inserted into a sample, wherein the method uses an ultrasound imaging device according to one of the preceding claims, and wherein the ultrasound probe head is relatively moved with respect to said elongated object (i.e. probe and/or elongated object may be moved) such that the longitudinal axis of the elongated object lies in the first plane scanned by the ultrasound probe head and such that a cross section of the elongated object lies in the second plane scanned by the second linear array.

Further features, advantages and embodiments of the present invention shall be described with reference to the figures below, wherein

Figure 1 illustrates ultrasound guided punction of the jugular vein as a typical application of the crossplane ultrasound probe.

Figure 2 shows the ultrasound probe head scanning two intersecting imaging planes and the console with a simplified illustration of the two corresponding ultrasound images.

Figure 3 shows two configurations of the ultrasound probe head which allow for ultrasound imaging as illustrated in Figure 2.

Figure 4 shows the ultrasound probe head scanning three intersecting imaging planes and the console with a simplified illustration of the three corresponding ultrasound images.

Figure 5 shows a configuration of the ultrasound probe head which allows for ultrasound imaging as illustrated in Figure 4.

Figure 6 shows a configuration of the ultrasound probe head which has control buttons to move one of the imaging planes.

Particularly, the present invention provides an ultrasound imaging device 12 that introduces simultaneous multiplane ultrasound imaging of orthogonally intersecting imaging planes 1.1, 1.2 allowing for simultaneous in-plane and out-of-plane guidance of instruments such as needles or catheters. The technical requirements of the invention are partly new and partly well known. In the following, only those structures, circuits or techniques are shown in detail that contribute to the technical improvement specific to the invention. It should be appreciated that while the invention is primarily described with reference to ultrasound-guided punction of a vessel, the imaging system 12 is designed to be used for other ultrasound-guided punctions like e.g. of peripheric nerves. As well, the invention should not

necessarily be limited to imaging devices for ultrasound-guided punctions or for medical purposes at all.

In the following description, numerous specific details are set forth to provide a thorough understanding of the invention. However, it is understood that the invention may be practiced without these specific details.

Figures 1 and 2 illustrate ultrasound guided punction of the jugular vein – a typical application of the crossplane ultrasound probe head 1. A physician is introducing a needle into a patients neck in order to place it within the jugular vein 2.1.2. The physician is holding the ultrasound probe head 1 in his left hand while manoeuvring the needle 2.1.1 with his right hand. The ultrasound probe head 1 is shown in oblique projection with dotted lines representing the image planes. The ultrasound echoes scanned by the ultrasound probe head 1 are transformed into images by a console 2 and simultaneously displayed on it.

Figure 2 shows the ultrasound probe head 1 scanning two intersecting imaging planes 1.1 and 1.2 and the console 2 with a simplified illustration of the two corresponding ultrasound images 2.1 and 2.2. The ultrasound probe is shown in oblique projection with the dotted rhomboids representing the imaging planes 1.1 and 1.2. The console 2 is shown in front projection with the two ultrasound images, while the left image 2.1 is corresponding to the longitudinal imaging plane 1.1 and the right image 2.2 is corresponding to the oblique imaging plane 1.2. A needle being introduced as shown in Figure 1 and lying within the longitudinal imaging plane would appear on both ultrasound images, as well in longitudinal section 2.1.1 as in cross section 2.2.1. The target structure, a vein, appears on the left image in longitudinal section 2.1.2 and on the right image in oblique section 2.2.2. A dotted line 2.1.3 displayed on the left image 2.1 marks the position of the cross imaging plane in relation to the longitudinal imaging plane. By matching the needles cross section with the dotted line (by moving either the needle or the probe), the physician can easily align the needle with the longitudinal imaging plane.

Figure 3 shows two configurations of the ultrasound probe 1 which allow for ultrasound imaging as illustrated in Figure 2.

The ultrasound probe 1 in the upper part of Fig. 3 has a 2D-matrix of ultrasound transducers 1b that can be activated separately. By activating groups of transducers that comprise linear arrays 100, 200, the ultrasound probe head 1 scans a longitudinal section (at t=0,00sec) and an oblique section (at t=0,01sec). The two arrays 100, 200 are activated alternately, with one of the two arrays activated i.e. each 1/100 second (or any time interval that allows for transmitting and back-scattering an ultrasound-signal with one array) and the ultrasound

probe head 1 thus generates two intersecting images. The ultrasound probe head has light diodes 1.4 that indicate the position of the selected linear array 100, 200 within the matrix 1b.

The ultrasound probe 1 in the lower part of Fig. 3 has two linear arrays 100, 200 of ultrasound transducers 1b that can be activated separately the same way the two selected arrays 100, 200 of the above-described ultrasound probe 1 are activated and thus generate two intersecting ultrasound images.

Figure 4 shows the ultrasound probe head 1 scanning three intersecting imaging planes (1.1, 1.2 and 1.3) and the console 2 with a simplified illustration of the three corresponding ultrasound images 2.1, 2.2 and 2.3. The ultrasound probe head 1 is shown in oblique projection with the dotted rhomboids representing the three imaging planes 1.1, 1.2 and 1.3. The console 2 is shown in front projection with the three ultrasound images, while the upper image 2.1 is corresponding to the longitudinal imaging plane 1.1 and the lower images 2.2 and 2.3 are corresponding to the two oblique imaging planes 1.2 and 1.3. A needle being introduced as shown in Figure 1 and lying within the longitudinal imaging plane would appear on the three ultrasound images, as well in longitudinal section 2.1 as in the two cross sections 2.2. and 2.3. Two dotted lines 2.1.3 displayed on the upper image 2.1 mark the position of the cross imaging planes in relation to the longitudinal imaging plane. This configuration of the ultrasound probe allows for the most accurate alignment of the needle: by matching both of the needles cross sections with the dotted lines (by moving either the needle or the probe), the needle will be necessarily aligned with the longitudinal plane along its full length.

Figure 5 shows a configuration of the ultrasound probe 1 which allows for ultrasound imaging as illustrated in Figure 4.

The ultrasound probe 1 has a 2D-matrix of ultrasound transducers 1b that can be activated separately. By activating groups of transducers 1b that comprise linear arrays 100, 200, 300, the ultrasound probe head 1 scans a longitudinal section (e.g. at t=0,00sec) and two oblique sections (e.g. at t=0,01sec and t=0,02sec). The three linear arrays 100, 200, 300 are activated alternately, with one of the three arrays activated i.e. each 1/100 second (or any time interval that allows for transmitting and back-scattering an ultrasound-signal with one array) and the ultrasound probe thus generates three intersecting images. The ultrasound probe head has light diodes 1.4 that indicate the position of the selected array within the matrix.

Figure 6 shows a configuration of the ultrasound probe head 1 which allows for ultrasound imaging as illustrated in Figure 2.

In contrast to the ultrasound probe described in reference to Figure 3 (upper part) the ultrasound probe 1 shown in Fig. 6 has control buttons 1.5 to move one of the imaging planes. The ultrasound probe head 1 has light diodes 1.4 that indicate the position of the selected array 100, 200 within the matrix 1b.

Claims

1. An ultrasound imaging device (12), comprising:

- an ultrasound probe head (1) having a face side (1a) for butting against a sample to be scanned by the ultrasound imaging device, and

- a plurality of ultrasound transducers (1b), wherein each ultrasound transducer is configured to transmit an ultrasound wave in a direction of a normal (N) to said face side (1a) and to receive incoming ultrasound waves,

characterized in that

said ultrasound transducers (1b) form at least a first linear array (100) of ultrasound transducers, which first linear array extends along a first direction (D) as well as a second linear array (200) of ultrasound transducers, which second linear array (200) extends along a second direction (D'), wherein said at least two linear arrays (100, 200) intersect at a right angle, and wherein the ultrasound probe head (1) is configured to generate ultrasound signals using said first linear array (100) of ultrasound transducers for scanning said sample along a first plane (1.1) spanned by said first direction (D) and said normal (N), and wherein the ultrasound probe head (1) is configured to generate ultrasound signals using said second linear array (200) of ultrasound transducers for scanning said sample along a second plane (1.2) spanned by the second direction (D') and said normal (N), so that said two planes (1.1, 1.2) intersect at a right angle.

2. The ultrasound imaging device according to claim 1, characterized in that each ultrasound transducer (1b) comprises a piezo crystal for generating and receiving ultrasound waves.

3. The ultrasound imaging device, characterized in that the ultrasound imaging device (12) is configured to trigger said two linear arrays (100, 200) of ultrasound transducers (1b) in an alternate fashion, wherein each linear array (100, 200) transmits an ultrasound signal and receives a back-scattered ultrasound signal before the other linear array (100, 200) transmits an ultrasound signal and receives a back-scattered ultrasound signal from the sample.

4. The ultrasound imaging device according to one of the preceding claims, characterized in that the ultrasound probe head (1) comprises a circumferential lateral wall (10), wherein light sources (1.4) are arranged on said lateral wall (10) for

indicating the linear array (100, 200) that is currently transmitting or receiving an ultrasound signal.

5. The ultrasound imaging device according to one of the preceding claims, characterized in that said ultrasound transducers (1b) form a third linear array (300) of ultrasound transducers, which third linear array (300) extends along a third direction (D''), wherein said third linear array (300) intersects at a right angle with the first linear array (100) and runs parallel to the second linear array (200), and wherein the ultrasound probe head (1) is configured to generate ultrasound signals using said third linear array (300) of ultrasound transducers for scanning said sample along a third plane (1.3) spanned by said third direction (D'') and said normal (N), wherein the third plane (1.3) runs parallel to the second plane (1.2) and intersects the first plane (1.1) at a right angle, and wherein particularly the ultrasound imaging device (12) is configured to trigger said three linear arrays (100, 200, 300) of ultrasound transducers (1b) in an alternate fashion, wherein each linear array (100, 200, 300) transmits an ultrasound signal and receives a back-scattered ultrasound signal before the other linear arrays (100, 200, 300) transmit an ultrasound signal and receive a back-scattered ultrasound signal from the sample.

6. The ultrasound imaging device according to one of the preceding claims, characterized in that the ultrasound probe head (1) comprises a 2D array of ultrasound transducers (1b), wherein said two linear arrays (100, 200) are comprised by said 2D array, and wherein the ultrasound probe head (1) is configured to select a linear array comprised by the 2D array as said first linear array (100) and another linear array comprised by the 2D array as said second linear array (200).

7. The ultrasound imaging device according to claims 5 and 6, characterized in that said third linear array (300) is comprised by said 2D array (1b), and wherein the ultrasound probe head (1) is configured to select a linear array comprised by the 2D array as said third linear array (300).

8. The ultrasound imaging device according to one of the preceding claims, characterized in that the ultrasound imaging device (12) comprises a console (2) having a display (2.1, 2.2) that is configured to simultaneously display a first digital image (2.1) rendered using the back-scattered ultrasound signals received by the first linear array (100) and a second digital image (2.2) rendered using the back-scattered ultrasound signals received by the second linear array (200).

11. The ultrasound imaging device according to claims 7 and 8, characterized in that the display (2.1, 2.2, 2.3) is configured to simultaneously display also a third digital image

(2.3) rendered using the back-scattered ultrasound signals received by the third linear array (300).

12. Method for imaging an elongated object (2.1.1), particularly a needle, that extends along a longitudinal axis and has been inserted into a sample, wherein the method uses an ultrasound imaging device (12) according to one of the preceding claims, and wherein the ultrasound probe head (1) is relatively moved with respect to said elongated object (2.1.1) such that the longitudinal axis of the elongated object (2.1.1) lies in the first plane (1.1) scanned by the ultrasound probe head (1) and such that a cross section (2.2.1) of the elongated object (2.1.1) lies in the second plane (1.2) scanned by the ultrasound probe head (1).

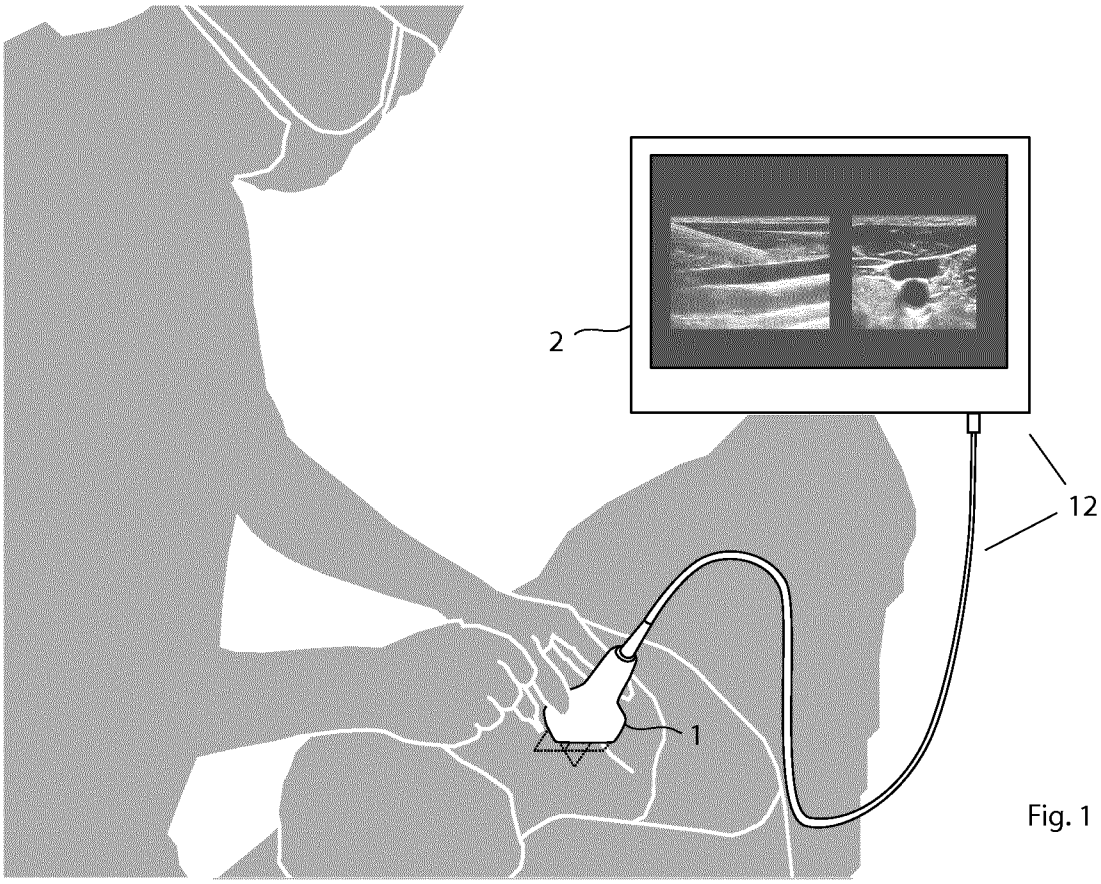


Fig. 1

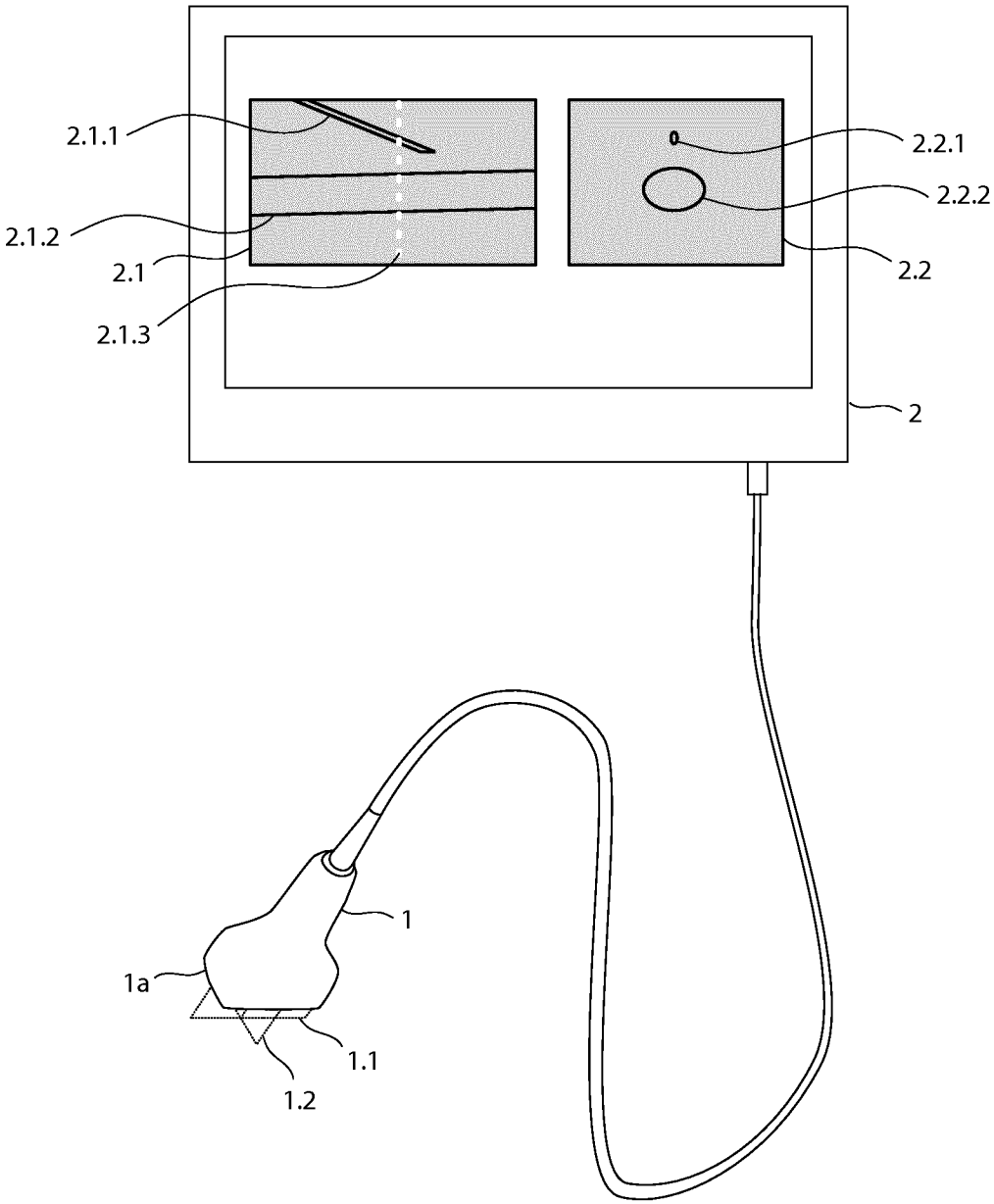


Fig. 2

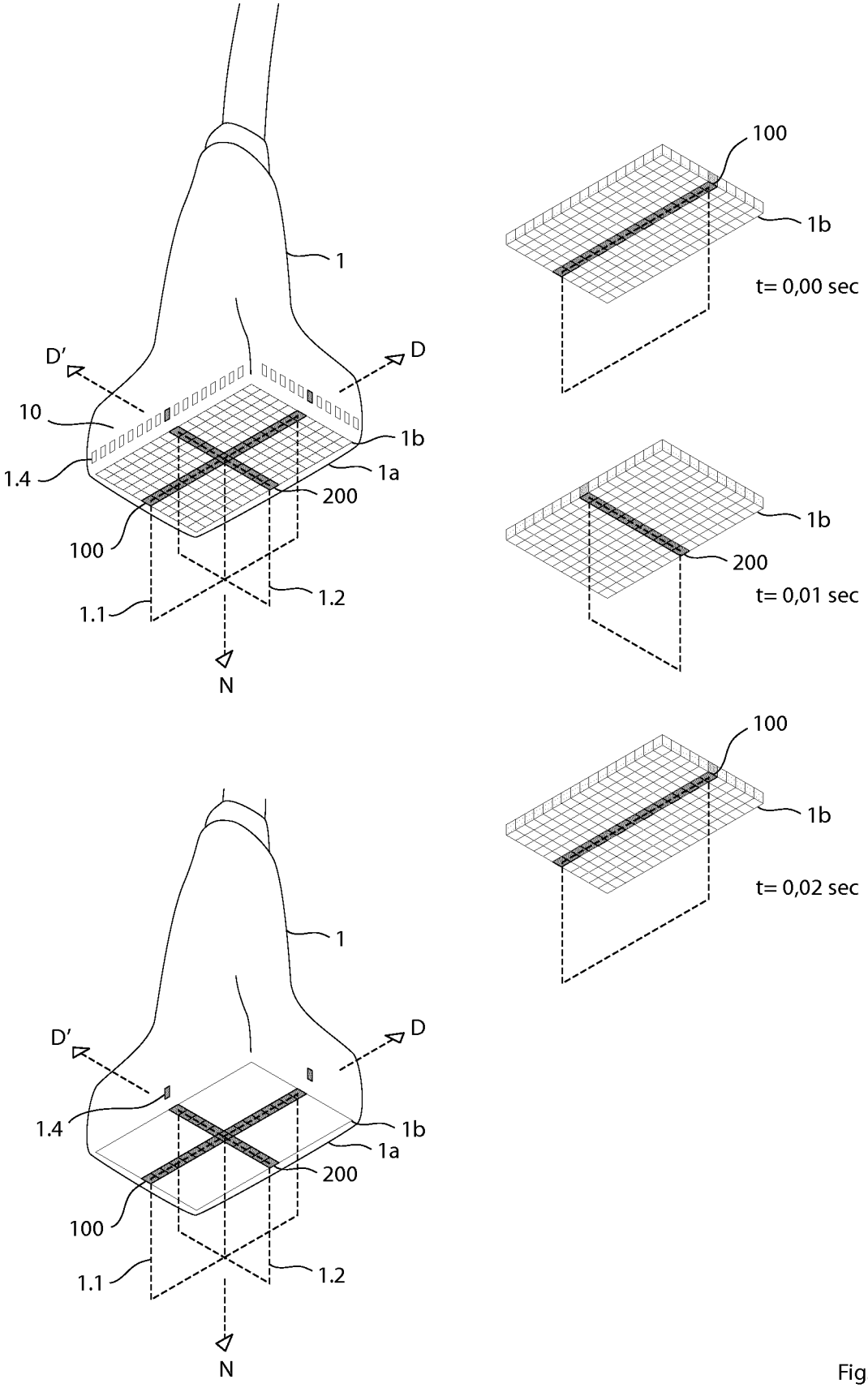

1
D'
D
10
1b
1.4
1a
200
100
1.1
1.2
N
100
1b
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1b
200
t= 0,01 sec
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Fig. 3

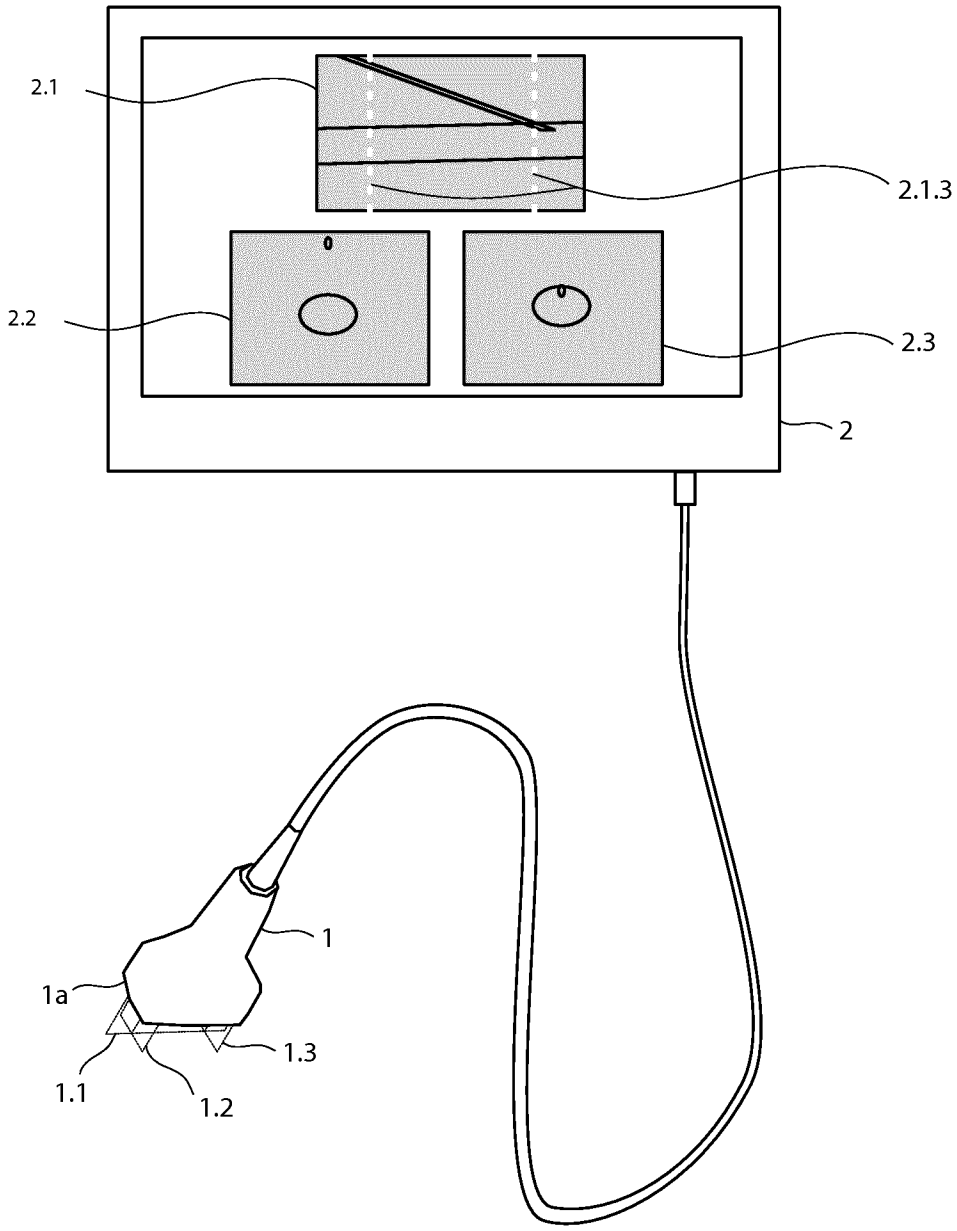


Fig. 4

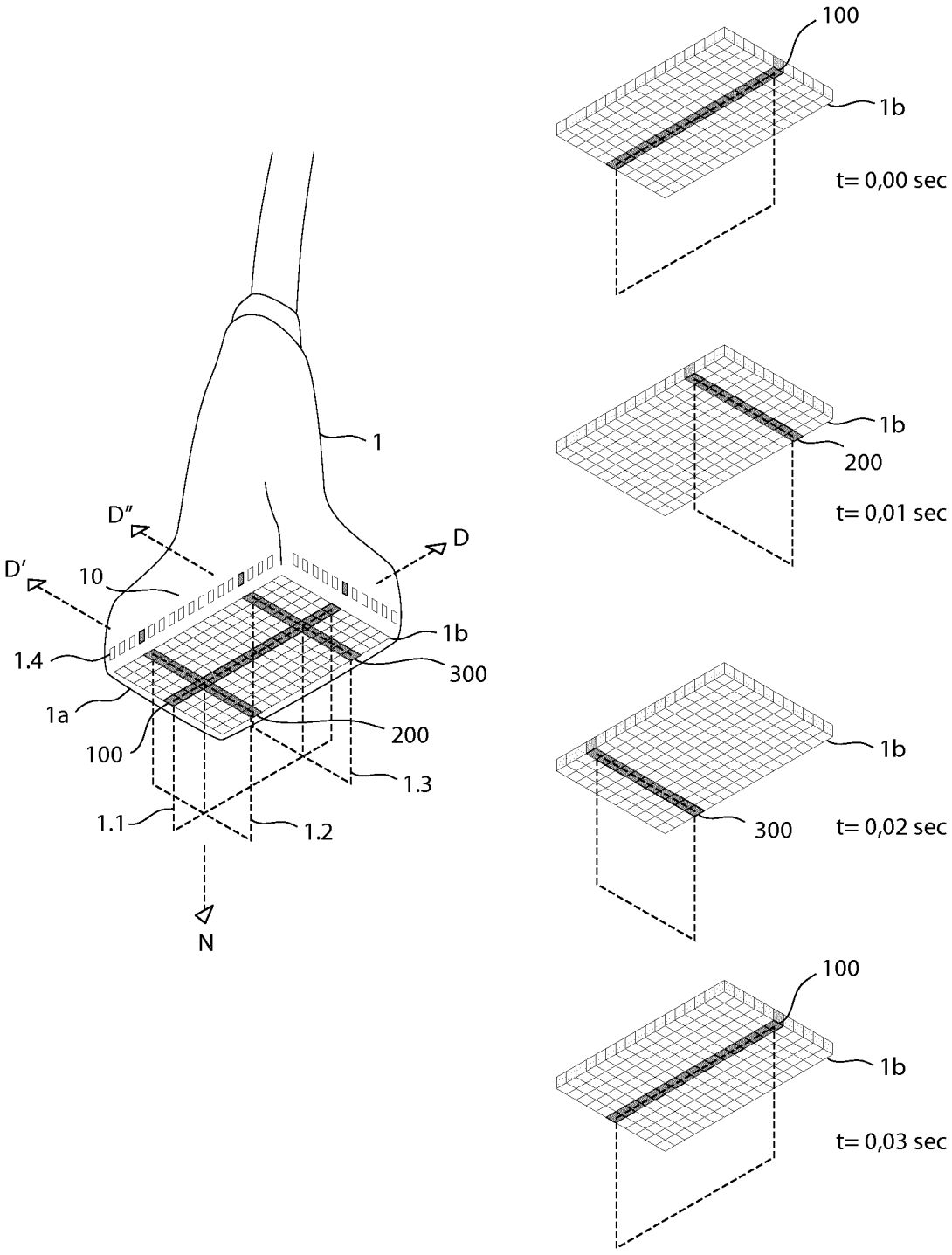

1
D"
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D'
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1.3
1.1
1.2
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1b
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Fig. 5

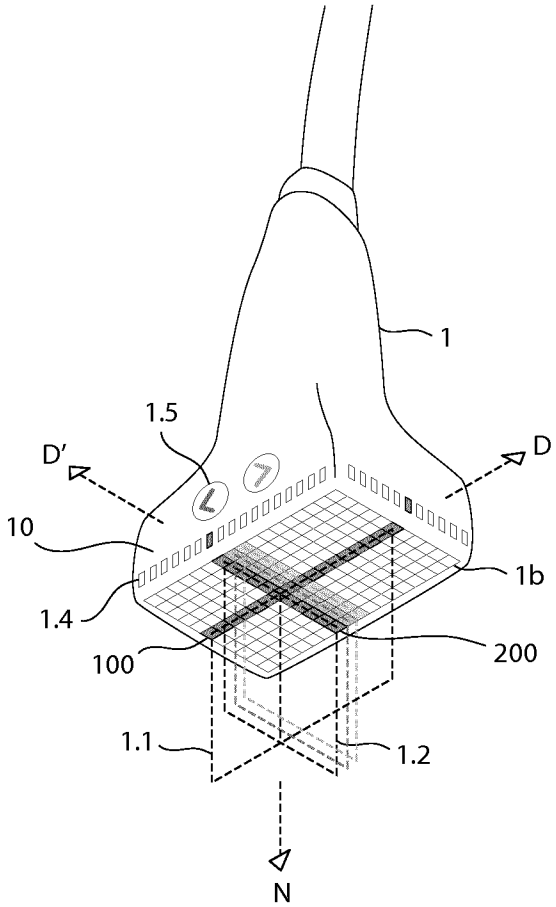


Fig. 6

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	**FOR FURTHER ACTION**	see Form PCT/ISA/220 as well as, where applicable, item 5 below.
kho101wo		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/EP2018/069695	19 July 2018 (19-07-2018)	21 July 2017 (21-07-2017)
Applicant		
KHONSARI, Sassan		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 3 sheets.

[X] It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**
   a. With regard to the **language,** the international search was carried out on the basis of:
      [X] the international application in the language in which it was filed
      [ ] a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))
   b. [ ] This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6*bis*(a)).
   c. [ ] With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. [ ] **Certain claims were found unsearchable** (See Box No. II)

3. [ ] **Unity of invention is lacking** (see Box No III)

4. With regard to the **title,**
   [X] the text is approved as submitted by the applicant
   [ ] the text has been established by this Authority to read as follows:

5. With regard to the **abstract,**
   [X] the text is approved as submitted by the applicant
   [ ] the text has been established, according to Rule 38.2, by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority

6. With regard to the **drawings,**
   a. the figure of the **drawings** to be published with the abstract is Figure No. 4
      [ ] as suggested by the applicant
      [X] as selected by this Authority, because the applicant failed to suggest a figure
      [ ] as selected by this Authority, because this figure better characterizes the invention
   b. [ ] none of the figures is to be published with the abstract

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2018/069695

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B8/00 A61B8/08 A61B8/14
ADD.

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

B. FIELDS SEARCHED

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

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2012/028896 A1 (BK MEDICAL APS [DK]; BAGGE JAN PETER [DK]) 8 March 2012 (2012-03-08)	1-3,8,10
Y	page 3, lines 17-26 page 4, lines 6-7 page 8, lines 7-14 figures 1,3-5	4-7,9

Y	WO 2010/125505 A1 (KONINKL PHILIPS ELECTRONICS NV [NL]; ROBINSON ANDREW L [US]) 4 November 2010 (2010-11-04) page 6, lines 20-24 page 11, lines 27-30 claim 1 figure 5	5-7,9

Y	WO 2016/083985 A1 (KONINKL PHILIPS NV [NL]) 2 June 2016 (2016-06-02) page 6, lines 30-35	4

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

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