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[Continued on next page]

(54) **Title**: ULTRASOUND PROBE

(57) **Abstract**: An ultrasound probe (10) comprises a pair of one dimensional transducer modules (1, 2) arranged in-line but set apart from each other in a shallow "V" shape. This allows a wide gap for needle manipulation while maintaining the ability to compute a good acoustic image of the target area (4) on an ultrasound scan engine. The ultrasound image is a product of data from both the arrays. The probe (10) is shaped to allow ergonomic manipulation possibilities for the anaesthetist. The probe can be held in a "pencil-type" grip anywhere on the main body, or by pushing directly on the back of arrays. The shape of the probe, means it sits in position better on a patient than a conventional probe.

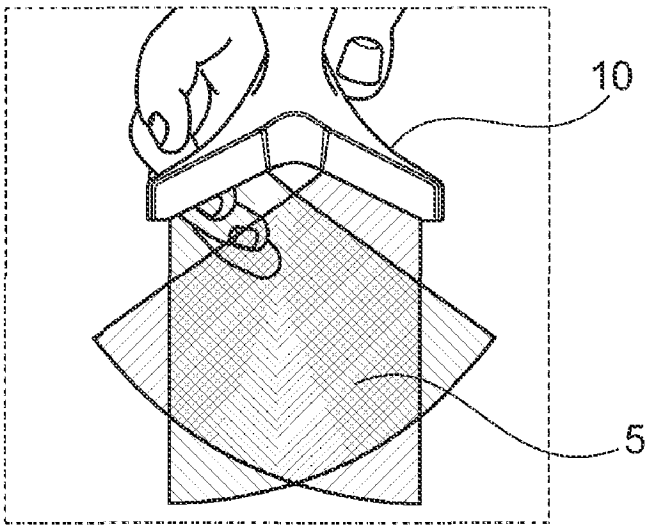

Fig. 2

WO 2013/030556 A1

Published:

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

Ultrasound Probe

FIELD OF THE INVENTION

The present invention relates to an ultrasound imaging probe for use in ultrasound guided interventional procedures including regional anaesthesia.

BACKGROUND OF THE INVENTION

Current techniques in ultrasound guided regional anaesthesia (UGRA) require an anaesthetist to position a needle tip adjacent to a nerve bundle and inject anaesthetic agent under the guidance of medical ultrasound imaging. In order to maintain a clearer image of the needle tip position the needle may be inserted 'in-plane' with the array.

In order to insert a needle in-plane, as directly to target as possible and avoiding passing the needle along and under the length of the array; previous inventions have involved taking a linear array and removing elements from the central section to create a gap for needle insertion.

This technique may create an unwanted gap in the ultrasound image over the area of greatest interest.

It also does not aid the visibility of the needle shaft or tip due to the angle of attack between the length of needle and acoustic beam.

Because of a necessity to minimise the gap in the acoustic image, the physical gap for the needle to pass though must also be kept to a minimum, and this reduces possible articulation in the gap with the probe in place.

Curved arrays may allow a more direct entry of the needle but are not generally available in a suitable frequency and for other reasons may not offer optimum imaging or other features.

Previous proposals such as those described in the publication by S. Cochran, G. a Corner, K.J. Kirk, D.I. a Lines, and M.J. Watson, "P5C-5 Design and Validation of an Ultrasound Array Optimised for Epidural Needle Guidance," 2007 IEEE Ultrasonics Symposium Proceedings, vol. 1, Oct. 2007, pp. 2255-2258; in US Patent 4408611 by S.Enjoji entitled "Probe for ultrasonic imaging apparatus"; and in US Patent 4029084 by R. Soldner entitled "Ultrasound applicator with guide slot for puncturing cannula" are essentially flat linear arrays with missing elements over the gap where the needle passes through.

Each probe functions as a normal linear (1D) array with a corresponding gap in the image. There is minimal overlap in the acoustic image from the two

blocks of elements as all elements exist on the same linear plane. The direction/plane of propagation of each block of elements is identical.

Other inventions (US Patent 4,475,553 by Yamaguchi et al.) have addressed the issues associated with the gap with extra laterally displaced imaging components; however this adds complication to the probe design and image reconstruction and still allows only minimal articulation in the gap.

US Patent 6423002 by J.A. Hossack, entitled "Intra-operative diagnostic ultrasound multiple-array transducer probe and optional surgical tool" and US Patent 7214191 by B. Stringer and G. Simmons entitled "Multiplanar ultrasonic vascular imaging device, system incorporating same, method of use and protective sheath," are probes where at least two individual blocks of elements are arranged onto the same 2D plane and lie perpendicular to each, i.e. in a T-shape. Each block of elements produces an individual image which can be viewed adjacent to each other or in pseudo (wrap-around) 3D, on-screen.

Again there is no significant overlap in imaging area. The direction of propagation of each block of elements is the same, while the two acoustic imaging fields lie on perpendicular planes.

A related US Patent 2005020919A by B.J. Stringer, G.A. Simmons, D.A. Christensen, S. Messerly, C.P. Ford, and R.W. Evensen entitled "Multiplanar

ultrasonic vascular sensor assembly, system and methods employing same, apparatus for movably affixing a sensor assembly to a body and associated methods," is the same as above, except that it has the addition of a single/double element angled towards the imaging field for doppler analysis.

The angled element is not an array. Although it is defined as comprising of at least one element, it has only one element in cross section along the plane of the adjacent array.

A publication by M. Delaide and G. Maes entitled "Design and Application of Low-Frequency Twin Side-by-Side Phased Array Transducers for Improved UT Capability on Cast Stainless Steel Components," *Proc. 2nd Int. Conf. on NDE in Relation to Structural Integrity for Nuclear and Pressurized Components, New Orleans May 2000,* describes the use of 2 x 2D arrays consisting of 4 x 2 elements positioned directly next to each other and angled inwards.

The main differences are:

1/ The arrays described are 2 dimensional, i.e. each is arranged in a grid of elements, in this case 2 x 4 elements with only 2 elements in lateral section.

2/ There is no gap between the edges of the adjacent arrays

3/ The probe is connected to a shaped waveguide for mounting to steel.

4/ The intended aim is to improve beam focusing rather than provide an overlapping visual image area.

It is an object of at least one aspect of the present invention to obviate or mitigate at least one or more of the aforementioned problems.

SUMMARY OF THE INVENTION

According to a first aspect of the present invention there is provided an ultrasound probe comprising a pair of transducer modules arranged in-line and spaced apart from each other to form a shallow "V" shape in a defined range of angles which correspond to ergonomic conformity to a patient's body surface at procedure specific locations such as to allow a full ultrasound image of a target depth through an ultrasound scan engine.

Preferably the ultrasound probe is shaped to conform to the body surface of the majority of patients over the areas of the neck, axilla, forearm, lower leg, chest wall, knee and other joints.

Preferably also the angle between each front plane of the twin arrays is angled between 110° and 140°, conforming to the respective part of the body being imaged.

The ultrasound probe preferably provides a gap for needle manipulation through the center of the two arrays of between 2mm and 15mm.

Preferably the ultrasound image is created through a recombination of waveform data obtained from the separate arrays by treating the twin angled arrays as one virtual array, using respective delays and angular realignment of the individual transmit and receive channels to create one continuous visual image.

More preferably the ultrasound image creation includes the application of beam steering and RF signal compounding to the arrays to produce an improved visual image.

Alternatively the recombination of waveform data is obtained from the separate arrays by capturing standard B-mode images from each array individually, rotating and positioning said images, using weighted pixel selection and overlapping visual gain mixing to create one cohesive image.

The arrays may be straight linear arrays or curved.

The ultrasound probe may be shaped to allow ergonomic manipulation possibilities for an operator.

A third array may be provided arranged perpendicular to the plane of the first pair, at a similar angle thereto and also in-plane with a needle entry area, which adds a concurrent 2D image to the combined image.

According to a second aspect of the present invention there is provided a method of carrying out ultrasound guided regional anaesthesia using an ultrasound probe in accordance with a first aspect of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

Embodiments of the present invention will now be described, by way of example only, with reference to the accompanying drawings in which:

Figure 1 is a representation of the layout and operating range of an ultrasound probe according to an embodiment of the present invention having flat arrays;

Figure 2 is a front view of an ultrasound probe similar to that of Fig 1 arranged to provide an expanded field of view;

Figure 3 is a corresponding view to Fig 1 illustrating the layout and operating range of an ultrasound probe having curved arrays;

Figure 4 is a perspective view from below of an ultrasound probe in accordance with the present invention;

Figure 5 is a front perspective view from above of the ultrasound probe of Fig 4;

Figure 6 is a perspective view from below of an alternative embodiment of an ultrasound probe in accordance with the present invention;

Figure 7 is a representation of the visual display resulting from use of an ultrasound probe as exemplified in Figs 1-5; and

Figure 8 is a representation of the visual display resulting from an ultrasound probe as exemplified in Figure 6.

BRIEF DESCRIPTION

Referring to the drawings an ultrasound probe 10 of the present invention comprises a pair of one dimensional transducer modules 1, 2, arranged in-line but set apart from each other in a shallow "V" shape.

This allows a wide gap for needle manipulation while maintaining the ability to compute a good acoustic image of the target area 4 on the ultrasound scan engine.

The ultrasound image is a product of data from both the arrays.

The concept can be applied to linear arrays as shown in Fig 1, or for a wider field of view 5, using expanded field of view algorithms as in Fig 2 or a pair of curved linear arrays 1a, 2a as in Fig3.

The probe 10 is shaped to allow ergonomic manipulation possibilities for the anaesthetist. The probe can be held in a 'pencil-type' grip anywhere on the main body, or by pushing directly on the back of arrays.

The shape of the probe, which can best be seen in Figs 2, 4 & 5 means it sits in position better on a patient than a conventional probe.

A further option is the addition of a third array 11 arranged perpendicular to the plane of the twin pair and in-plane with the needle entry 20 as shown in Fig 6; this gives a secondary in-plane view of the target area and needle point . The third array is set at a similar angle to the others.

In the case of the twin array, a visual display will be constructed using the data from both array modules, combined with scan engine processing to form one cohesive image 21 covering the extent of the acoustic beam width of the probe as can be seen in Fig 7.

With the triple array probe, a third array image 22 will be displayed side by side with the combined image 21 from the twin arrays as can be seen in Fig 8.

The image reconstruction for the combined view can be performed either through visual mixing of the independent images from each array or by forming one visual image through the interpretation of transmit and receive signals to represent one virtual curved or linear array.

The ultrasound probe of the current invention has a number of advantages.

In particular a pair of arrays are set apart and angled in a shallow 'V' shape with overlapping beam area providing an ultrasound image.

The conformal shape of the device provides a more stable 'platform' for an anaesthetist.

The probe does not provide a 'needle guide' as such and the anaesthetist is free to work within an extended gap.

Optionally the inclusion of a perpendicular third array, also angled enhances the probe.

The probe may incorporate 'sparse' array beam forming to utilise the full width of all available array elements despite the limitations of the maximum number of independent channels that current circuitry can handle.

Whilst specific embodiments of the present invention have been described above, it will be appreciated that departures from the described embodiments may still fall within the scope of the present invention.

Throughout the description and claims of this specification, the words "comprise" and "contain" and variations of them mean "including but not limited to", and they are not intended to (and do not) exclude other components, integers or steps.

Throughout the description and claims of this specification, the singular encompasses the plural unless the context otherwise requires. In particular, where the indefinite article is used, the specification is to be understood as contemplating plurality as well as singularity, unless the context requires otherwise.

Features, integers and characteristics described in conjunction with a particular aspect, embodiment or example of the invention are to be understood to be applicable to any other aspect, embodiment or example described herein unless incompatible therewith.

All of the features disclosed in this specification (including any accompanying claims, abstract and drawings), and/or all of the steps of any method or process so disclosed, may be combined in any combination, except combinations where at least some of such features and/or steps are mutually exclusive.

The invention is not restricted to the details of any foregoing embodiments.

The invention extends to any novel one, or any novel combination, of the features disclosed in this specification (including any accompanying claims, abstract and drawings), or to any novel one, or any novel combination, of the steps of any method or process so disclosed.

Claims

1. An ultrasound probe comprising a pair of transducer modules arranged in-line and spaced apart from each other to form a shallow "V" shape in a defined range of angles which correspond to ergonomic conformity to a patient's body surface at procedure specific locations such as to allow a full ultrasound image of a target depth through an ultrasound scan engine.

2. An ultrasound probe as claimed in claim 1 that is shaped to conform to the body surface of the majority of patients over the areas of the neck, axilla, forearm, lower leg, chest wall, knee and other joints.

3. An ultrasound probe as claimed in claims 1 and 2 where the angle between each front plane of the twin arrays is angled between 110° and 140°, conforming to the respective part of the body being imaged.

4. An ultrasound probe as claimed in claims 1 to 3 which preferably provides a gap for needle manipulation through the center of the two arrays of between 2mm and 15mm.

5. An ultrasound probe as claimed in Claim 4, wherein the recombination of waveform data is obtained from the separate arrays by treating the twin angled arrays as one virtual array, using respective delays and angular realignment of the individual transmit and receive channels to create one continuous visual image.

6. An ultrasound probe as claimed in Claim 5 which includes the application of beam steering and RF signal compounding to the arrays to produce an improved visual image.

7. An ultrasound probe as claimed in Claims 5 and 6, wherein the recombination of waveform data is obtained from the separate arrays by capturing standard B-mode images from each array individually, rotating and positioning said images, using weighted pixel selection and overlapping visual gain mixing to create one cohesive image.

8. An ultrasound probe as claimed in any one of the preceding Claims wherein the arrays may be straight linear arrays or curved.

9. An ultrasound probe as claimed in any one of the preceding Claims, wherein the probe is shaped to allow ergonomic manipulation possibilities for an operator.

10. An ultrasound probe as claimed in any one of the preceding Claims, wherein a third array may be provided arranged perpendicular to the plane of the first pair, at a similar angle thereto and also in-plane with a needle entry area, which adds a concurrent 2D image to the combined image.

11. A method of carrying out ultrasound guided interventional procedures using an ultrasound probe in accordance with any one of Claims 1-10.

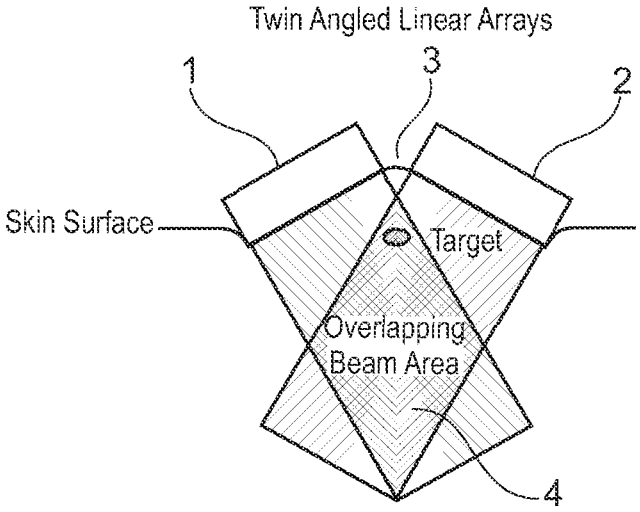

Fig. 1

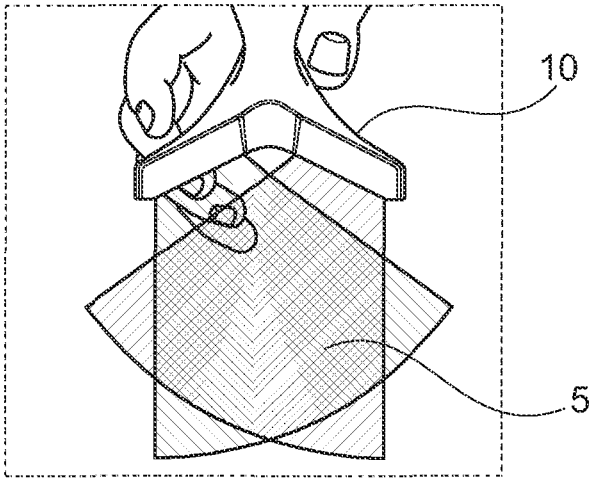

Fig. 2

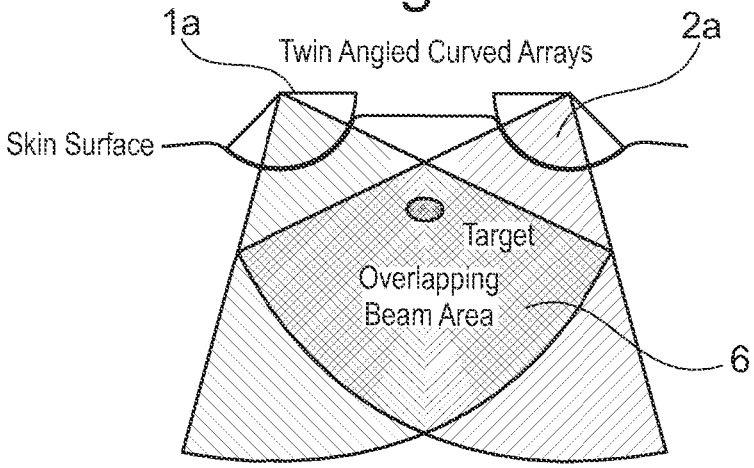

Fig. 3

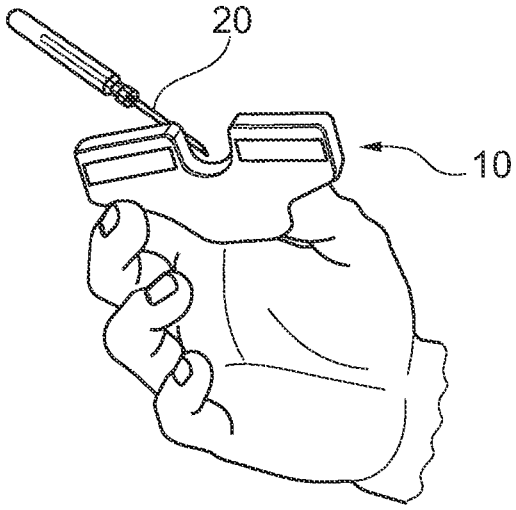

Fig. 4

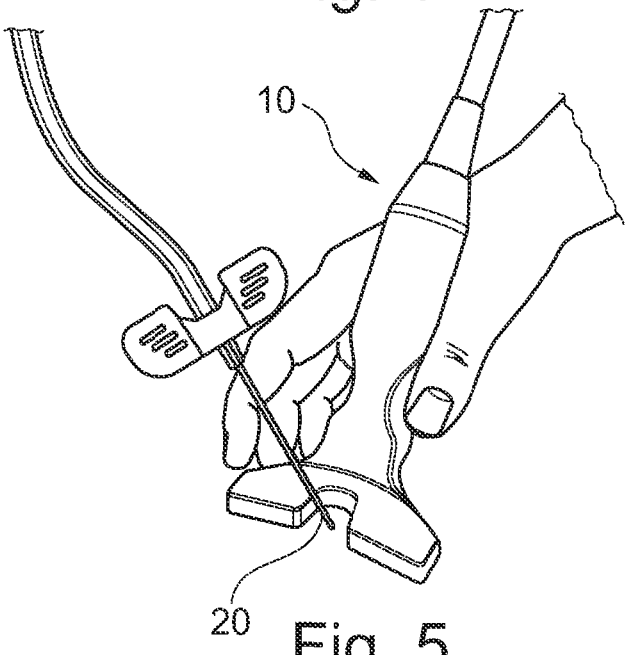

Fig. 5

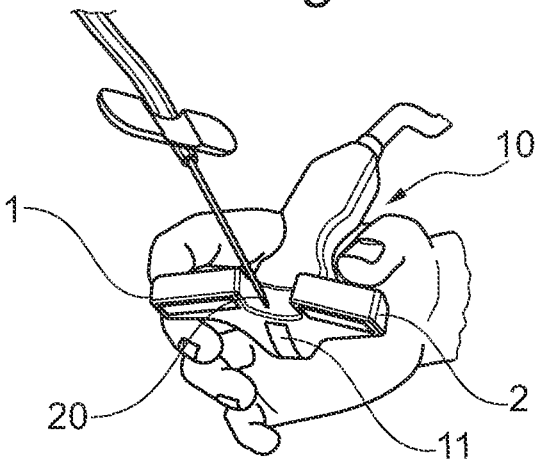

Fig. 6

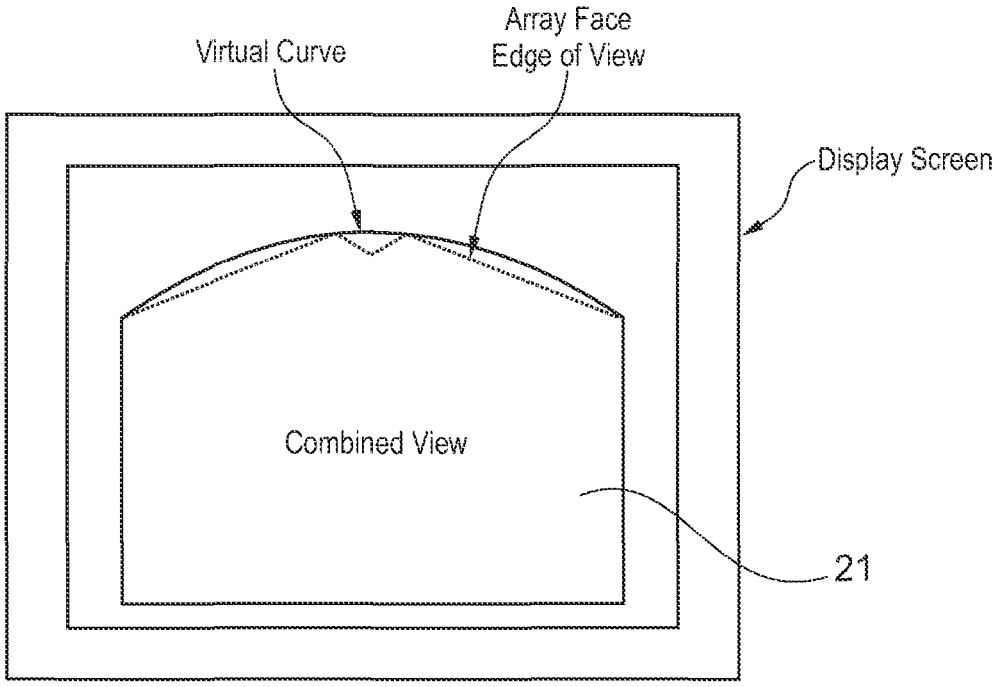
Virtual Curve
Array Face
Edge of View
Display Screen
Combined View
21

Fig. 7

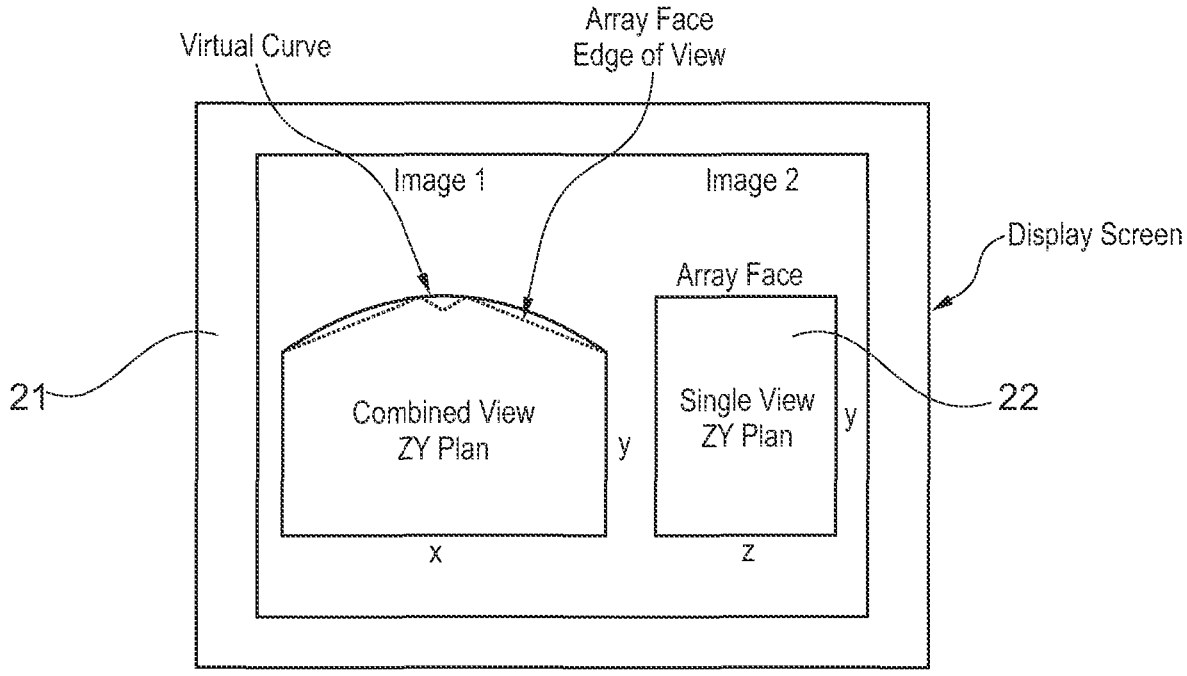
Virtual Curve
Array Face
Edge of View
Image 1
Image 2
Display Screen
Array Face
21
Combined View
ZY Plan
y
Single View
ZY Plan
y
22
x
z

Fig. 8

INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2012/052096

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B8/08 A61B17/34
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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2009/024034 A1 (MOREAU-GOBARD ROMAIN [US] ET AL) 22 January 2009 (2009-01-22) abstract paragraph [0020] - paragraph [0074] figures 1-3	1-10
X	US 2010/262013 A1 (SMITH DAVID M [US] ET AL) 14 October 2010 (2010-10-14) abstract paragraph [0096] - paragraph [0107] figures 9, 10	1-3,8-10
A	US 4 475 553 A (YAMAGUCHI KEIKI [JP] ET AL) 9 October 1984 (1984-10-09) cited in the application the whole document	1-6,8-10

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

[X] See patent family annex.

* Special categories of cited documents :

"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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
27 November 2012	04/12/2012

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

INTERNATIONAL SEARCH REPORT

International application No.
PCT/GB2012/052096

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 11
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [X] Claims Nos.: 11
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

see FURTHER INFORMATION sheet PCT/ISA/210

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2012/052096

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	GB 2 400 176 A (NORTH GLASGOW UNIVERSITY HOSPI [GB]; WATSON MALCOLM J [GB] NORTH GLASG) 6 October 2004 (2004-10-06) abstract page 23, line 27 - page 25, line 12 figures 15,16 -----	1-6,8,9

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/GB2012/052096

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2009024034 A1	22-01-2009	NONE	
US 2010262013 A1	14-10-2010	EP 2419023 A2	22-02-2012
		JP 2012523920 A	11-10-2012
		KR 20110137829 A	23-12-2011
		US 2010262013 A1	14-10-2010
		WO 2010120913 A2	21-10-2010
US 4475553 A	09-10-1984	NONE	
GB 2400176 A	06-10-2004	NONE	

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 11

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

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Continuation of Box II.2

Claims Nos.: 11

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guideline C-VI, 8.2), should the problems which led to the Article 17(2) declaration be overcome.

专利名称(译)	超声探头		
公开(公告)号	EP2747664A1	公开(公告)日	2014-07-02
申请号	EP2012753587	申请日	2012-08-24
[标]申请(专利权)人(译)	邓迪大学		
申请(专利权)人(译)	邓迪大学		
当前申请(专利权)人(译)	邓迪大学		
[标]发明人	COCHRAN SANDY HABESHAW RODERICK MCLEOD GRAEME CORNER GEORGE MARSH JONATHAN		
发明人	COCHRAN, SANDY HABESHAW, RODERICK MCLEOD, GRAEME CORNER, GEORGE MARSH, JONATHAN		
IPC分类号	A61B8/08 A61B17/34		
CPC分类号	A61B8/0841 A61B8/4455 A61B8/4477 A61B8/4483 A61B8/4488 A61B8/5253 A61B2017/3413		
代理机构(译)	HGF LIMITED		
优先权	2011014758 2011-08-26 GB 2011019005 2011-11-03 GB		
外部链接	Espacenet		

摘要(译)

超声探头（10）包括一对一维换能器模块（1,2），所述一维换能器模块（1,2）成直线布置，但是以浅“V”形状彼此分开设置。这允许针操作的宽间隙，同时保持在超声扫描引擎上计算目标区域（4）的良好声学图像的能力。超声图像是来自两个阵列的数据的产物。探针（10）成形为允许麻醉师的人体工程学操作可能性。探头可以固定在主体上任何位置的“铅笔型”手柄中，也可以直接推到阵列背面。探头的形状意味着它比传统探头更适合患者。