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(71) Applicant (for all designated States except US): **KONINKLIJKE PHILIPS ELECTRONICS, N.V.** [NL/NL];
Groenewoudseweg 1, NL-5621 BA Eindhoven (NL).

(72) Inventors; and

(75) Inventors/Applicants (for US only): **RAJU, Balasundara** [IN/US]; P.O. Box 3001, 345 Scarborough Road,

Briarcliff Manor, NY 10510-8001 (US). **HALL, Christopher** [GB/US]; P.O. Box 3001, 345 Scarborough Road, Briarcliff Manor, NY 10510-8001 (US). **CHIN, Chien Ting** [CA/US]; P.O. Box 3001, 345 Scarborough Road, Briarcliff Manor, NY 10510-8001 (US). **SHI, William T.** [US/US]; P.O. Box 3001, 345 Scarborough Road, Briarcliff Manor, NY 10510-8001 (US).

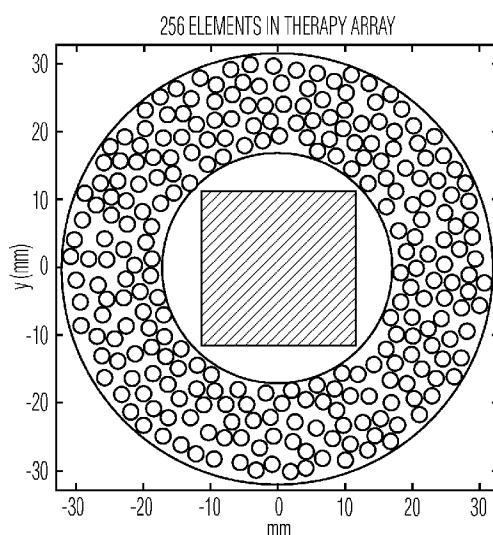
(74) Agent: **DAMEN, Daniel, M.**; Philips Intellectual Property & Standards, High Tech Campus 44, P.O. Box 220, NL-5600 AE Eindhoven (NL).

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(54) Title: APPARATUS FOR 3D ULTRASOUND IMAGING AND THERAPY



(57) Abstract: An apparatus for application of three-dimensional ultrasound imaging and therapy comprising a two-dimensional ultrasound imaging array of transducer elements having an image signal transmitter and receiver that forms, steers and selectively focuses ultrasound beams to a three-dimensional moving or stationary spatial volume; one or more two-dimensional ultrasound therapy arrays of transducer elements, each array having a therapy signal transmitter that forms, steers and selectively focuses and delivers ultrasound therapy to the volume; wherein the location of the array of imaging and therapy transducer elements are known relative to one another; and a controller that controls the image transmitter and receiver to provide three-dimensional images of the volume and simultaneously independently controls each of the one or more therapy transmitters to deliver therapy to the volume. Also disclosed is a method of delivering ultrasound therapy to a biological tissue in a three-dimensional moving or stationary spatial volume utilizing the apparatus.

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Declarations under Rule 4.17:

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

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

Published:

- *with international search report*
- *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

APPARATUS FOR 3D ULTRASOUND IMAGING AND THERAPY**Cross Reference to Related Cases**

Applicants claim the benefit of Provisional Application Serial No. 60/867,464, filed November 28, 2006.

5 The invention relates to an apparatus containing two separate two-dimensional (2D) ultrasound array transducers, one for providing three-dimensional (3D) images, and the other for generating therapy beams that can be electronically steered in three dimensions; and the use of the apparatus in delivering ultrasound mediated therapy such as localized gene delivery, drug delivery, sonothrombolysis, tissue ablation etc.

10 Ultrasound has many therapeutic applications such as tissue ablation, drug delivery, hyperthermia, clot dissolution, etc. Single element therapy transducers are limited by a fixed focal length, and depend on mechanical translation to treat different regions of the body. In order to steer the therapy beam to different locations in the body, electronically phased array transducers may be employed. Simultaneous imaging of tissues during therapy
15 makes it possible to plan and monitor the treatment.

One example of a combined therapy and imaging system is described by US patent Nock et al (US6,716,188). This patent describes a system for drug delivery enhancement and imaging comprising a transducer having only one linear array of elements.

20 US patent 5,558,092 (Unger et al) discloses one example of a combined ultrasound imaging and therapy system with separate transducers on the same substrate. Several transducer configurations are proposed including one that has a 2D matrix of elements for both the imaging and therapy that are operated in a multiplexed manner such that a sequential linear set of elements are activated.

25 US patent 6,428,477 (Mason) assigned to Philips, describes a fully steerable two-dimensional ultrasound array that delivers therapy by steering and selective focusing of beams. Same transducer is used for both therapy and imaging.

US patent 6,719,694 describes ultrasound transducers that perform both therapy and imaging. A quality factor circuit changes the bandwidth of the transducer such that high bandwidth operation is used in imaging.

30 US patent 6,500,121 describes an ultrasonic therapy system having a single transducer that performs imaging, therapy, and temperature monitoring, where the single transducer can be operated to provide imaging or therapy in a 3D manner.

The method of Unger et al uses multiplexed linear elements (US5,558,092). The therapy array is not configured to perform 3D steering of the beam and only provides shallow operation near the skin surface. Moreover, the same substrate is used for both the imaging and therapy arrays. This leads to the possibility of cross talk between the two arrays especially since the therapy array commonly utilizes higher power levels. Also, imaging array is fixed and cannot be swapped with other imaging probes for the same therapy array. Using the same substrate for both the arrays leads to less optimal use of the piezo material, since therapy arrays might benefit from being made of piezocomposite materials where arbitrary elements size and shapes can be made.

The method of Mason (US6,428,477), Weng (US6,719,694) and Slayton et al (6,500,121) uses the same transducer for imaging and therapy. However, therapy and imaging have different requirements since the focusing capabilities and frequency requirements are different. It is often difficult to optimize the transducer for both the applications. For example, ultrasound imaging typically employs frequencies greater than 2 MHz, whereas therapy employs frequencies less than two MHz. For small animal studies, even higher frequencies such as 15 MHz are preferred for imaging. The small aperture sizes of imaging transducers are insufficient to achieve focusing gains needed for therapy that usually requires much larger transducers. Moreover the imaging array has regularly spaced elements and if used for therapy would require a large number of elements in order to accommodate the requirement to avoid grating lobes.

However, as discussed above, problems still persist with these systems and methodology in ultrasound imaging and therapy, particularly for biological tissue in a spatial volume which may be in motion, which are overcome by the apparatus and methodology disclosed herein.

According to this invention, herein disclosed is an apparatus containing two separate two-dimensional (2D) ultrasound array transducers, one for providing three-dimensional (3D) images, and the other for generating therapy beams that can be electronically steered in three dimensions; and the use of the apparatus in delivering ultrasound mediated therapy such as localized gene delivery, drug delivery, sonothrombolysis, tissue ablation.

Specifically, it is an object of the invention to provide an apparatus for application of three-dimensional ultrasound imaging and therapy comprising:

a two-dimensional ultrasound imaging array of transducer elements having an image signal transmitter and receiver that forms, steers and selectively focuses ultrasound beams to a three-dimensional moving or stationary spatial volume;

one or more two-dimensional ultrasound therapy arrays of transducer elements,
5 each array having a therapy signal transmitter that forms, steers and selectively focuses and delivers ultrasound therapy to the volume; wherein the location of the array of imaging and therapy transducer elements are known relative to one another; and

a controller that controls the image transmitter and receiver to provide three-dimensional images of the volume and simultaneously independently controls each of the
10 one or more therapy transmitters to deliver therapy to the volume.

Another object of the invention is to provide an apparatus further comprising each of the imaging and therapy transducer arrays having a plurality of ultrasound elements that are individually controllable in amplitude, phase and frequency of operation.

Another object of the invention is to provide an apparatus further comprising the
15 controller correlating the imaged volume with the therapy transducer array so that the therapy is delivered to the volume.

Another object of the invention is to provide an apparatus further comprising the therapy transducer array located in a two-dimensional annular space between two concentric circles and the imaging transducer array located within the two-dimensional
20 space of the inner circle.

Another object of the invention is to provide an apparatus further comprising the therapy transducer array fixedly attached to a side of the imaging transducer array.

Another object of the invention is to provide an apparatus further comprising a plurality of therapy transducer arrays located in a two-dimensional annular space between
25 two concentric circles and the imaging transducer array located within the two-dimensional space of the inner circle, wherein each of the plurality of therapy arrays is capable of providing therapy in different spatial volumes, different therapy regimens including different ultrasound wave frequencies and different tissue penetration depths.

Another object of the invention is to provide a method of delivering ultrasound
30 therapy to a biological tissue in a three-dimensional moving or stationary spatial volume comprising:

imaging the volume utilizing an apparatus for application of three-dimensional ultrasound imaging and therapy, the apparatus comprising:

a two-dimensional ultrasound imaging array of transducer elements having an image signal transmitter and receiver that forms, steers and selectively focuses ultrasound beams to a three-dimensional moving or stationary spatial volume;

one or more two-dimensional ultrasound therapy arrays of transducer elements,
5 each array having a therapy signal transmitter that forms, steers and selectively focuses and delivers ultrasound therapy to the volume; wherein the location of the array of imaging and therapy transducer elements are known relative to one another; and

a controller that controls the image transmitter and receiver to provide three-dimensional images of the volume and simultaneously independently controls each of the
10 one or more therapy transmitters to deliver therapy to the volume;
delivering the therapy to the tissue utilizing the apparatus.

Another object of the invention is to provide a method further comprising each of the imaging and therapy transducer arrays having a plurality of ultrasound elements that are individually controllable in amplitude, phase and frequency of operation.

15 Another object of the invention is to provide a method further comprising the controller co-registering the imaged volume with the therapy transducer array so that the therapy is delivered to the volume.

Another object of the invention is to provide a method further comprising the therapy transducer array located in a two-dimensional annular space between two
20 concentric circles and the imaging transducer array located within the two-dimensional space of the inner circle.

Another object of the invention is to provide a method further comprising the therapy transducer array fixedly attached to a side of the imaging transducer array.

Another object of the invention is to provide a method further comprising a plurality
25 of therapy transducer arrays located in a two-dimensional annular space between two concentric circles and the imaging transducer array located within the two-dimensional space of the inner circle, wherein each of the plurality of therapy arrays is capable of providing therapy in different spatial volumes, different therapy regimens including different ultrasound wave frequencies and different tissue penetration depths.

30 Another object of the invention is to provide a method further comprising delivering ultrasound therapy to a biological tissue selected from the group consisting of brain lesions, uterine fibroids, liver tumor, breast tumor, other tumors of the mammalian body and blood clots.

These and other aspects of the invention are explained in more detail with reference to the following embodiments and with reference to the figures.

Figure 1 depicts an embodiment of the apparatus having a combined 2D therapy and 2D imaging array or probe. The imaging array in the shape of a square is placed at the center of the annular hole and the therapy array having numerous elements shown as circles are in the annulus surrounding the imaging array.

In any non-invasive therapy application, planning, guidance, and monitoring are critical. This invention provides three important benefits to these goals: fast real-time three dimensional interrogation of the 3D spatial volume surrounding the target biological tissue, accurate and precise correlation or co-registration of the ultrasound therapy or treatment beam's) to the ultrasound 3D imaging information and near-real-time adjustment of both the size and shape of the 3D spatial volume target zone containing the biological tissue of interest and the path of the treatment beam's). For example, in the treatment of the heart, the movement of the target tissue may be complicated and irregular due to respiration motion and arrhythmia. The imaging array can image in real time this motion, then the therapy array can be programmed to deliver the therapeutic ultrasound with temporal gating and/or spatial steering so that the treatment zone coincides with the target volume.

According to the invention herein, the apparatus contains two separate 2D ultrasound array transducers, one for providing 3D images, and the other for providing therapy beam that is electronically steerable in three dimensions; the individual elements of both arrays are distributed along two dimensions, and are individually controllable in amplitude, phase, and frequency of operation. The elements of both the imaging and therapy arrays could be distributed in a random or irregular manner over the surface. The two arrays can use separate beam formers for steering and focusing. The two arrays allow the 3D images and therapy beams to be registered or correlated with respect to each other.

In one embodiment, the therapy array consists of a 2D spherical annulus. The hole in the annulus provides space for the imaging array. The elements of the therapy array are circular in shape and randomly distributed throughout the array. Figure 1 shows the therapeutic array with the imaging array at the center. This embodiment provides a simple implementation for the registration of the therapy probe in the space of the image provided by the imaging array. The imaging probe could be any matrix transducer such as the X3-1 transducers sold by Philips.

In another embodiment, the 2D imaging array is attached to the side of the therapy array and fixed with respect to it. The two arrays are rigidly fixed with respect to each other and hence the registration information is known a priori.

In another embodiment, an arrangement of several therapy arrays is used with one
5 imaging transducer. The different 2D therapy arrays could be located around the imaging array in a circular fashion. Each array may provide treatment in different spatial regions or different treatment regimens such as frequencies and penetration depth. The imaging array would provide a wide field of view for planning purpose. One or more of the therapy arrays would be turned on to activate the therapy based on spatial location and depth of the
10 treatment region, available acoustic window and other factors.

The controller that controls and co-registers the ultrasound therapy delivery with 3D images provided by the ultrasound image transmitter and receiver can include one or more computers or processors. The beam forming and steering electronics controlled by the controller are conventional and can be operated according to computer programs known to
15 one skilled in the art. The therapy system consists of an array of piezo-electric, piezo-composite, crystal, or ceramic elements capable of generating either a high, low duty cycle or a lower, longer duty cycle pressure field. The transducer elements are excited by a voltage supplied by a high power amplifier and generated by either an arbitrary wave or a single frequency source. The timing of these signals is controlled by either programmable
20 trigger circuitry or a therapeutic beam former. The commencement and cessation of therapy pressure field can be controlled through programmable triggers, controlled externally, or from a derived trigger event from the 2D imaging array (e.g. when the desired tissue volume is within a specific spatial location). The entire system consisting of both therapeutic and imaging arrays and corresponding electronic circuitry (amplifiers, power
25 supplies, signals sources, beam formers, trigger circuitry) is controlled by a external controller, usually a personal computer. This external controller is the master controller of most timing events, user interaction, and integration of the imaging and therapy probe.

Ultrasound therapy is an emerging application and business opportunity. Currently ultrasound therapy is used routinely in cancer treatment in China; in the USA it is approved
30 by the FDA for the treatment of uterine fibroid and in trials for prostate cancer and benign prostate hyperplasia; and in Europe clinical trials are on-going.

The invention can be used in many application areas for delivering ultrasound therapy, for example in treating hyperthermia, high intensity focused ultrasound (HIFU),

and microbubble/nanoparticle-mediated therapy. The last application area exploits acoustically induced bioeffects to enhance and control localized gene and drug delivery, such as delivery of high intensity ultrasound beams to cause previously injected microspheres containing a drug substance to burst at the tissue site releasing the drug substance; and other applications in the field of ultrasound mediated molecular medicine. This area also includes the use of ultrasound to enhance the efficacy of thrombolytic agents used in an acute setting following an atherosclerotic event. The application can also be used where ultrasound is used for clot dissolution for stroke or DVT patients.

The invention can be used in any areas where focused ultrasound may provide therapeutic effects. Typical examples include brain lesions, uterine fibroids, liver tumor, breast tumor and other tumors of the mammalian body and blood clots. In the cardiac setting, novel applications are being developed to protect the heart prior to or subsequent to a myocardial infarction.

While the present invention has been described with respect to specific embodiments thereof, it will be recognized by those of ordinary skill in the art that many modifications, enhancements, and/or changes can be achieved without departing from the spirit and scope of the invention. Therefore, it is manifestly intended that the invention be limited only by the scope of the claims and equivalents thereof.

CLAIMS

1. An apparatus for application of three-dimensional ultrasound imaging and therapy comprising:

a two-dimensional ultrasound imaging array of transducer elements having an image signal transmitter and receiver that forms, steers and selectively focuses ultrasound beams to a three-dimensional moving or stationary spatial volume;

one or more two-dimensional ultrasound therapy arrays of transducer elements, each array having a therapy signal transmitter that forms, steers and selectively focuses and delivers ultrasound therapy to the volume; wherein the location of the array of imaging and therapy transducer elements are known relative to one another; and

a controller that controls the image transmitter and receiver to provide three-dimensional images of the volume and simultaneously independently controls each of the one or more therapy transmitters to deliver therapy to the volume.

2. The apparatus of claim 1 further comprising each of the imaging and therapy transducer arrays having a plurality of ultrasound elements that are individually controllable in amplitude, phase and frequency of operation.

3. The apparatus of claim 1 further comprising the controller co-registering the imaged volume with the therapy transducer array so that the therapy is delivered to the volume.

4. The apparatus of claim 1 further comprising the therapy transducer array located in a two-dimensional annular space between two concentric circles and the imaging transducer array located within the two-dimensional space of the inner circle.

5. The apparatus of claim 1 further comprising the therapy transducer array fixedly attached to a side of the imaging transducer array.

6. The apparatus of claim 1 further comprising a plurality of therapy transducer arrays located in a two-dimensional annular space between two concentric circles and the imaging transducer array located within the two-dimensional space of the inner circle, wherein each of the plurality of therapy arrays is capable of providing therapy in different spatial

volumes, different therapy regimens including different ultrasound wave frequencies and different tissue penetration depths.

7. A method of delivering ultrasound therapy to a biological tissue in a three-dimensional moving or stationary spatial volume comprising:

imaging the volume utilizing an apparatus for application of three-dimensional ultrasound imaging and therapy, the apparatus comprising:

a two-dimensional ultrasound imaging array of transducer elements having an image signal transmitter and receiver that forms, steers and selectively focuses ultrasound beams to a three-dimensional moving or stationary spatial volume;

one or more two-dimensional ultrasound therapy arrays of transducer elements, each array having a therapy signal transmitter that forms, steers and selectively focuses and delivers ultrasound therapy to the volume; wherein the location of the array of imaging and therapy transducer elements are known relative to one another; and

a controller that controls the image transmitter and receiver to provide three-dimensional images of the volume and simultaneously independently controls each of the one or more therapy transmitters to deliver therapy to the volume;

delivering the therapy to the tissue utilizing the apparatus.

8. The method of claim 7 further comprising each of the imaging and therapy transducer arrays having a plurality of ultrasound elements that are individually controllable in amplitude, phase and frequency of operation.

9. The method of claim 7 further comprising the controller co-registering the imaged volume with the therapy transducer array so that the therapy is delivered to the specified volume.

10. The method of claim 7 further comprising the therapy transducer array located in a two-dimensional annular space between two concentric circles and the imaging transducer array located within the two-dimensional space of the inner circle.

11. The method of claim 7 further comprising the therapy transducer array fixedly attached to a side of the imaging transducer array.

12. The method of claim 7 further comprising a plurality of therapy transducer arrays located in a two-dimensional annular space between two concentric circles and the imaging transducer array located within the two-dimensional space of the inner circle, wherein each of the plurality of therapy arrays is capable of providing therapy in different spatial volumes, different therapy regimens including different ultrasound wave frequencies and different tissue penetration depths.

13. The method of claim 7 further comprising delivering ultrasound therapy to a biological tissue selected from the group consisting of brain lesions, uterine fibroids, liver tumor, breast tumor, other tumors of the mammalian body and blood clots.

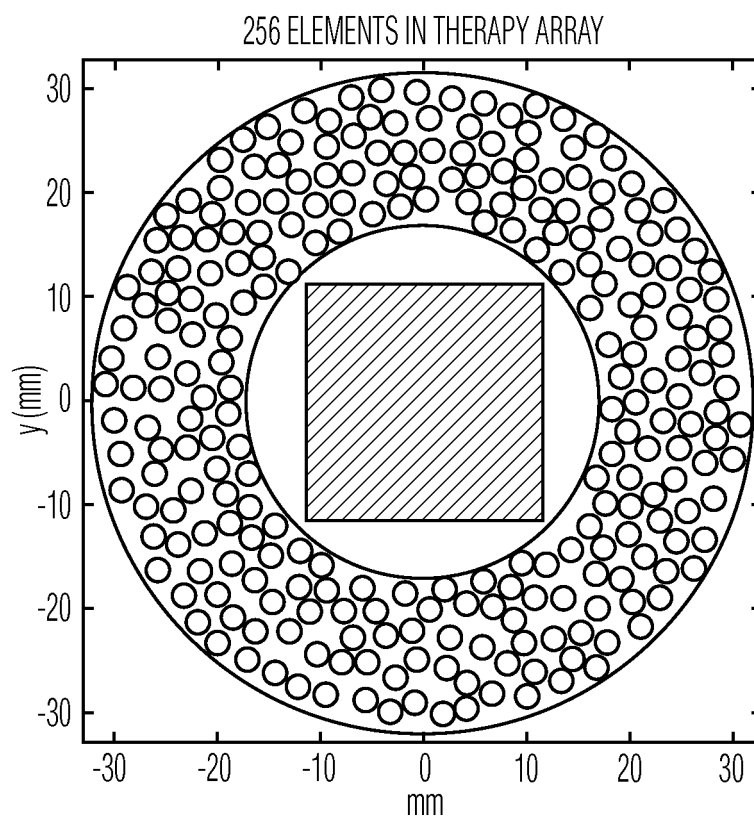


FIG. 1

INTERNATIONAL SEARCH REPORT

International application No

PCT/IB2007/054507

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61B8/08 A61M37/00 A61N7/02 B06B1/06
 ADD. A61N7/00

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 A61M A61N B06B

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 practical, 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.
P,X	US 2007/073135 A1 (LEE WARREN [US] ET AL) 29 March 2007 (2007-03-29)	1,3-5
P,Y	abstract	2
P,A	paragraph [0050] - paragraph [0081] figures 5-8,13	6
Y	US 6 425 867 B1 (VAEZY SHAHRAM [US] ET AL) 30 July 2002 (2002-07-30) abstract	1-5
A	column 8, line 35 - column 17, line 41 column 20, line 21 - column 23, line 67 figures 1-3,21	6
Y	US 6 428 477 B1 (MASON MARTIN K [US]) 6 August 2002 (2002-08-06) cited in the application	1-5
A	column 4, line 33 - column 10, line 23 figures 3,4	6
	-/--	

☒ 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 document 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.
- *G* document member of the same patent family

Date of the actual completion of the international search

4 April 2008

Date of mailing of the international search report

23/04/2008

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2
 NL - 2280 HV Rijswijk
 Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
 Fax: (+31-70) 340-3016

Authorized officer

Artikis, T

INTERNATIONAL SEARCH REPORT

International application No

PCT/IB2007/054507

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 2006/042201 A (GUIDED THERAPY SYSTEMS L L C [US]; BARTHE PETER G [US]; SLAYTON MICHAEL) 20 April 2006 (2006-04-20)	1,3-5
A	the whole document	2,6
A	WO 99/22652 A (UNIV WASHINGTON [US]) 14 May 1999 (1999-05-14) abstract page 17, paragraph 3 - page 26, paragraph 3 figures 8A-E,12	1-6
A	US 5 391 140 A (SCHAETZLE ULRICH [DE] ET AL) 21 February 1995 (1995-02-21) abstract column 6, line 26 - column 7, line 60 figure 2	1-6

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IB2007/054507

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. ☒ Claims Nos.: 7-13
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 or therapy
2. ☐ Claims Nos.:
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:
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 allsearchable 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 reportcovers 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

Information on patent family members

International application No

PCT/IB2007/054507

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2007073135 A1	29-03-2007	NONE	
US 6425867 B1	30-07-2002	US 2003028111 A1	06-02-2003
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专利名称(译)	用于3D超声成像和治疗的装置		
公开(公告)号	EP2091438A1	公开(公告)日	2009-08-26
申请号	EP2007826995	申请日	2007-11-06
[标]申请(专利权)人(译)	皇家飞利浦电子股份有限公司		
申请(专利权)人(译)	皇家飞利浦电子N.V.		
当前申请(专利权)人(译)	皇家飞利浦电子N.V.		
[标]发明人	RAJU BALASUNDARA HALL CHRISTOPHER CHIN CHIEN TING SHI WILLIAM T		
发明人	RAJU, BALASUNDARA HALL, CHRISTOPHER CHIN, CHIEN TING SHI, WILLIAM T.		
IPC分类号	A61B8/08 A61M37/00 A61N7/02 B06B1/06 A61N7/00		
CPC分类号	A61B8/08 A61B8/0808 A61B8/0833 A61B8/4483 A61B8/463 A61B8/483 A61B2090/378 A61M37/0092 A61N7/02 B06B1/0625 B06B1/0637		
优先权	60/887640 2007-02-01 US 60/867464 2006-11-28 US		
其他公开文献	EP2091438B1		
外部链接	Espacenet		

摘要(译)

一种用于三维超声成像和治疗的应用的装置，包括具有图像信号发射器和接收器的换能器元件的二维超声成像阵列，所述图像信号发射器和接收器形成，操纵并选择性地使超声波束聚焦到三维移动或静止空间体积；换能器元件的一个或多个二维超声治疗阵列，每个阵列具有治疗信号发射器，其形成，操纵并选择性地聚焦并向该体积递送超声治疗；其中成像和治疗换能器元件阵列的位置相对于彼此是已知的；控制器控制图像发送器和接收器以提供体积的三维图像，并同时独立地控制一个或多个治疗发射器中的每一个以向该体积递送治疗。还公开了一种利用该装置将超声治疗传递到三维移动或静止空间体积中的生物组织的方法。