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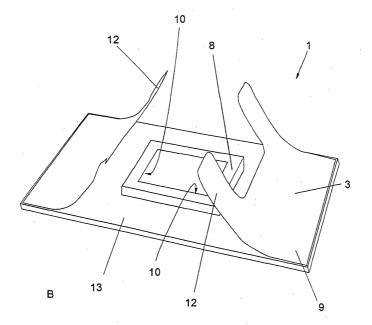
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## (54) Ultrasound coupling device

(57) An ultrasound coupling device for transmitting ultrasound waves from an ultrasound transducer to a test specimen, especially to a human or animal body, said coupling device comprising (a) a gel pad (2) for transmitting said ultrasound waves, (b) a support (3) having i) a transducer side (T), ii) a body side (B), and iii) an aperture

(11) through said transducer side and said body side of said support (3), (c) said support (3) being provided with an adhesive element (13) on said body side, and (d) said gel pad (2) being received within said aperture (11) such that said gel pad (2) contacts said human or animal body when said body side of said support contacts said human or animal body.



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### Description

[0001] The invention relates to an ultrasound coupling device for transmitting ultrasound waves from an ultrasound transducer to a human or animal body, wherein that coupling device comprises a solid gel pad for transmitting the ultrasound waves and a self-adhesive material for attaching the ultrasound transducer to the patient.

#### Background

[0002] Ultrasound is used in a variety of medical treatment methods. Especially, ultrasound is used to promote the healing of soft tissue injuries. Ultrasound is also used for monitoring a human or animal body, for example, for monitoring the velocity of a blood stream or the position of veins or arteries. Ultrasound is used for imaging the internal organs and systems of the body and for diagnosing abnormalities.

[0003] It is known, for example from US 2002/0049395 A1, to apply ultrasound to the thoracic cavity for cardiac rehabilitation over an extended treatment period. From US 5,458,140 it is also known that the application of ultrasound can enhance transdermal drug delivery. Both applications require fixing a transducer head to the body for a long time.

[0004] Ultrasound waves are produced with an ultrasound transducer head and transmitted to the human or animal body via an ultrasound couplant. The ultrasound couplant reduces reflection of the ultrasound waves and thus increases the amount of ultrasound wave energy that is coupled into the body.

[0005] To enhance the focusing of an ultrasound transducer head, gel pads are used as couplants that are made of acoustically inert material. In particular, gel pads are used in cases when an ultrasound beam needs to be focused close to the surface of the skin.

[0006] For long term therapy, existing devices may use a strap or other fixation device to fix the ultrasound transducer head and the gel pad to the human or animal body. It is a disadvantage that these methods/devices may hamper blood circulation. Additionally, many patients regard these kinds of methods/devices as uncomfortable. [0007] Thus, the invention relates to the problem of mitigating disadvantages in known ultrasound coupling devices.

#### SUMMARY OF THE INVENTION

[0008] One object of the invention is to develop an ultrasound coupling device which has a simple structure and is easy and inexpensive to manufacture. For long term applications the ultrasound coupling device must be removed frequently, for example to allow the patient to take a shower. Therefore, it is desirable to provide an inexpensive ultrasound coupling device that can be used as a disposable product.

[0009] The inventive coupling device can be adhered

to a patient's body, where the patient may be an animal or a human being, so that no bandage or strap is needed. Further, the blood circulation is not hampered and the ultrasound device according to the invention can be worn for a long time and in a comfortable way.

**[0010]** It is a further object of the invention to provide a tight and safe coupling between the ultrasound transducer and the patient's skin. The adhesive element holds the ultrasound coupling device in place and ensures a tight fit to the patient's skin. The gel pad is designed to precisely fit inside the cavity of the transducer in order to provide sufficient contact,

[0011] Yet another object of the invention is to provide more comfort for patients. As the ultrasound coupling device is flat, it can be worn under the clothes so that it is invisible to other persons. Further, the ultrasound coupling device has a low weight, which contributes to the wearing comfort. Due its simple construction, the ultrasound coupling device according to the invention can be manufactured as a throwaway product and can be changed regularly. This leads to an increased comfort for the patient.

[0012] In accomplishing the foregoing objects, there has been provided, according to the present invention, an ultrasound coupling device for transmitting ultrasound waves from an ultrasound transducer for a test specimen such as a human or animal body, the coupling device comprising a gel pad for transmitting the ultrasound waves that further comprises a support having a transducer side, a body side, and an aperture to the transducer side and the body side, the support being provided with an adhesive element on the body side, and the gel pad being received within the aperture such that the gel pad contacts the human or animal body if the body side of the support contacts the human or animal body.

[0013] In particular, a gel pad is a dimensionally stable body that contains or consists of a gel. The gel acts as a couplant, i.e. as a material that facilitates the transmission of ultrasonic energy from the transducer into the test specimen, especially into the human or animal body. Preferably, the gel pad is made from a gel that does not dry out when it is in contact with ambient air. Additionally, the gel is preferably not hygroscopic so that its consistency does not change during application. The gel may include a content of salts which is approximately equivalent to the content of salts in the human or animal skin so that no osmosis takes place when the gel pad is brought into contact with the skin.

[0014] The support may be any element that provides a stable connection between the skin of the human or animal body and the gel pad when the ultrasound coupling device is adhered to the human or animal body. The support may be made from plastics, rubber, latex, a woven textile, and a non-woven and may comprise reinforcing elements.

[0015] The adhesive element may have any shape. However, it is preferred that the adhesive element covers the entire or almost the entire body side of the support.

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This yields a strong and tight fit of the support to the skin of the human or animal body. It is preferred, but not necessary, that the adhesive element is homogeneous all over the body side of the support. It is possible that the support is provided with a plurality of adhesive elements, for example in form of concentric rings or polygons that encircle the aperture.

**[0016]** In a preferred embodiment, the gel pad has an edge and is encircled by a frame along this edge. This frame isolates the gel pad from ambient air and dirt. Further, this frame prevents liquid from the gel pad from leaking out and thus protects clothes of the patient from being contaminated with gel.

**[0017]** It is preferred that this frame is made of a foam. Foam is elastic, light-weight, easy to manufacture, and waterproof. Further, the foam can be used to soak in an adhesive in case this is needed. In a preferred embodiment this foam is a reticulated foam. The reticulated foam becomes integrated into the gel pad due to the pores inherent in the foam and thus provides a safe hold of the gel pad. The edges of the foam are adhered to the support so that the foam is securely fixed to the support. That way, the reticulated foam enables the attachment of the gel pad to the skin adhesive.

[0018] The adhesive element may be capable of securely fixing the ultrasound coupling device to the human or animal body. The adhesive element may be chosen such that it does not irritate the skin and provides for a sufficient adhesive force to couple the ultrasound transducer to a human or animal body for more than one day. [0019] Preferably, the support comprises a liner covering the adhesive element. The liner protects the adhesive element against dirt, grease, and humidity and thus preserves it against loss of adhesive force during storage.

[0020] It is preferred that the adhesive element is a pressure-sensitive film. Pressure-sensitive films combine strong adhesion to little weight and small thickness. [0021] In a preferred embodiment, the support is a flat patch. A flat patch is flexible and fits to uneven or curved parts of the human or animal body such as legs, arms, and so on.

**[0022]** Preferably, the flat patch has a width, a length, and a height, wherein the width or the length are at least ten times larger than the height. The width preferably exceeds six centimeters and the height is less than four millimeters.

**[0023]** It is preferred that the support comprises a fixing area on the transducer side that comprises a fastener which surrounds the aperture for fixing the ultrasound transducer. This fixing area preferably completely surrounds the aperture. This yields an especially strong connection between the ultrasound coupling device and the ultrasound transducer.

**[0024]** The fastener is preferably an adhesive that is located in cells of foam, especially in cells of the frame that surrounds the gel pad. This yields a simple construction which is easy to handle and to manufacture. Addi-

tionally, the support may include an additional strip of adhesive to further secure the transducer cable.

**[0025]** To provide for a save hold of the ultrasound coupling device on the human or animal body, the aperture is located close to a center of the support.

#### BRIEF DESCRIPTION OF THE DRAWINGS

**[0026]** The foregoing and other objects, aspect and advantages will be better understood from the following detailed description of a preferred embodiment of the invention with reference to the drawings, in which:

Figure 1 is a perspective view on the body side of an ultrasound coupling device according to the invention;

Figure 2 is a perspective view on the coupling device of Figure 1 with two parts of a liner partly peeled off;

Figure 3 is a perspective view on a transducer side of the ultrasound coupling device of Figures 1 and 2;

Figure 4 is a perspective view of the transducer side as shown in Figure 3 with a liner covering a fixing area for an ultrasound transducer being partly peeled of; and

Figures 5a, 5b and 5c are schematic views of the ultrasound coupling device according to Figures 1 to 4.

#### DETAILED DESCRIPTION OF THE DRAWINGS

**[0027]** Referring now to the drawings, and more particularly to Figure 1, there is shown a body side B of an ultrasound coupling device 1 comprising a gel pad 2 and a support 3. Gel pad 2 has a substantially rectangular cross-section and consists of a isotonic gel. As the gel is isotonic, it can be brought into contact with a skin of human or animal body without losing water to the skin or drawing water from the skin.

[0028] Support 3 may have a substantially rectangular shape and a height H. Gel pad 2 is located in the center of support 3. Long sides 4.1, 4.2 of support 3 are aligned with long sides 5.1, 5.2, respectively, of the gel pad 2. Accordingly, broadsides 6.1, 6.2 of the support 3 are aligned with broadsides 7.1, 7.2 of gel pad 2. Broadsides 6.1, 6.2 have a width U and long sides 5.1, 5.2 have a length L2.

**[0029]** Support 3 comprises a one-piece frame 8 which is made of a reticulated foam or generally of a open-celled foam. Frame 8 has a constant width w, and is irremovably fixed to a main body 9 of support 3, e.g. by a permanent adhesive. In an alternative embodiment, frame 8 has a circumferential groove that is received in a tongue-and-groove-like manner in main body 9.

[0030] Frame 8 has an inner edge 10 that surrounds

an aperture 11 of support 3. The gel pad 2 is received within the aperture 11 (so that gel pad 2 is completely surrounded by inner edge 10 of frame 8) and is thus fixed to support 3.

**[0031]** Gel pad 2 is flush with frame 8 and both protrude from main body 9. If support 3 is brought into contact with the human body, gel pad 2 and frame 8 come into close contact with the human body as well.

**[0032]** Referring now to Figure 2, it can be seen that main body 9 comprises a liner 12 covering an adhesive element in form of a pressure-sensitive film 13. Liner 12 covers the entire surface of pressure sensitive film 13 and can be peeled off to expose the adhesive surface. In the embodiment of Figure 1, liner 12 does not cover gel pad 2 or frame 8. In an alternative embodiment, liner 12 may also cover those components.

[0033] Figure 3 shows a transducer side T of support 3. Gel pad 2 protrudes from a main body surface 14 of a flat foam pad 16. Foam pad 16 has the same shape as pressure-sensitive film 13 to which it is fixed. On the transducer side T, frame 8 is covered by a frame liner 15 which can be peeled off.

**[0034]** In an alternative embodiment additional adhesive strips can be positioned on the surface 14 to further secure the transducer or cable/wire. An additional liner can be positioned on the surface of this additional adhesive strip.

**[0035]** As can be seen in Figure 4, the transducer side part of the frame 8 acts as a fixing area A for a transducer head (not shown). To fix the transducer head to the support 3, frame liner 15 is peeled off so that an adhesive 17 is exposed. The transducer head comprises a flange that may be fixed to fixing area A by the adhesive 17. The shape and size of the pad is determined by the design of the transducer. The transducer can be virtually any shape.

**[0036]** Figures 5a, 5b and 5c are to scale and show the ultrasound coupling device 1 of Figures 1 to 4. Figure 5a shows transducer side T, Figure 5b shows a sectional view, and Figure 5c shows body side B.

[0037] An ultrasound device is provided for transmitting ultrasound waves from an ultrasound transducer to a human or animal body. The ultrasound device may comprise the ultrasound coupling device 1 comprising the gel pad 2 for transmitting the ultrasound waves, the support 3 having the transducer side T, the body side B and the aperture 11 through the transducer side T and the body side B of the support 3, the support 3 being provided with the adhesive element 13 on the body side B, and the gel pad 2 being received within the aperture 11 such that the gel pad 2 contacts the human or animal body (not shown), when the body side B of the support 3 contacts the human or animal body; and an ultrasound transducer, the ultrasound transducer comprising a cavity with an ultrasound transducer head, the cavity having a sectional area, wherein the gel pad 2 is substantially shaped like said sectional area.

[0038] The ultrasound device may be provided in a

method for monitoring a human or animal body. The method for monitoring a human or animal body may comprise the steps of providing the ultrasound device, attaching the ultrasound device to the human or animal body, powering the ultrasound transducer to generate ultrasound waves, receiving reflected or scattered ultrasound waves, and calculating a graphical representation from the scattered ultrasound waves.

**[0039]** A method for treating a human or animal body may comprise the steps of providing the ultrasound device, attaching the ultrasound device to the human or animal body, and powering the ultrasound transducer to generate ultrasound waves to promote a healing process of the human or animal body tissue. The method may be used for treating and promoting healing of soft tissue. The method may also be used for monitoring the human or animal body. The, the method may comprise the step of calculating a graphical representation from received scattered ultrasound waves.

#### **Claims**

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- An ultrasound coupling device for transmitting ultrasound waves from an ultrasound transducer to a test specimen, especially to a human or animal body, the coupling device comprising
  - (a) a gel pad (2) for transmitting the ultrasound waves,
  - (b) a support (3) having
    - i) a transducer side (T),
    - ii) a body side (B), and
    - iii) an aperture (11) through the transducer side (T) and the body side (B) of support (3),
  - (c) the support (3) being provided with an adhesive element (13) on the body side (B), and (d) the gel pad (2) being received within the aperture (11) such that the gel pad (2) contacts the human or animal body when the body side (B) of the support (3) contacts the human or animal body.
- The ultrasound coupling device according to claim 1, the gel pad (2) having an edge (10), the gel pad (2) being encircled by a frame (8) alongside the edge (10).
- **3.** The ultrasound coupling device according to claim 2, the frame (10) comprising foam, in particular a reticulated foam.
- 4. The ultrasound coupling device according to any of claims 1 to 3, the adhesive element (13) being capable of securely fixing the ultrasound coupling device (1) to the human or animal body.

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**5.** The ultrasound coupling device according to any of claims 1 to 4, the support (3) comprising a liner (12) covering the adhesive element (13).

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- **6.** The ultrasound coupling device according to any of claims 1 to 5, the support (3) comprising a flat patch.
- 7. The ultrasound coupling device according to any of claims 1 to 6, the support (3) comprising a fixing area (A) on the transducer side (T), the fixing area (A) comprising a fastener (17) surrounding the aperture (11) for fixing the ultrasound transducer.
- **8.** The ultrasound coupling device according to claim 7, the fixing area (A) completely surrounding the aperture (11).
- The ultrasound coupling device according to any of claims 1 to 8, the fastener comprising an adhesive (17) capable of adhesively fixing the ultrasound transducer.
- **10.** The ultrasound coupling device according to claim 9, the adhesive (17) being located in cells of a foam, particularly the adhesive (17).
- **11.** The ultrasound coupling device according to any of claims 1 to 10, the aperture (11) being located close to a center of the support (3).
- **12.** An ultrasound device for transmitting ultrasound waves from an ultrasound transducer to a human or animal body, the ultrasound device comprising:
  - (a) an ultrasound coupling device (1) according to any of claims 1 to 10,
  - (b) an ultrasound transducer, the ultrasound transducer comprising a cavity with an ultrasound transducer head, the cavity having a sectional area, wherein the gel pad (2) is substantially shaped like the sectional area.
- 13. The ultrasound device according to claim 12,
  - (a) the support (3) comprising a fixing area (A) comprising a fastener (17) surrounding the aperture (11) for fixing the ultrasound transducer, (b) the gel pad (2) being substantially shaped like the sectional area and
  - (c) the fixing area (A) being attached to a flange of the ultrasound transducer.

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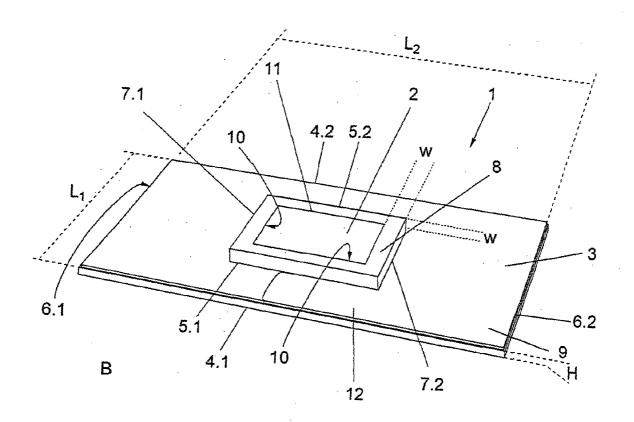


Fig. 1

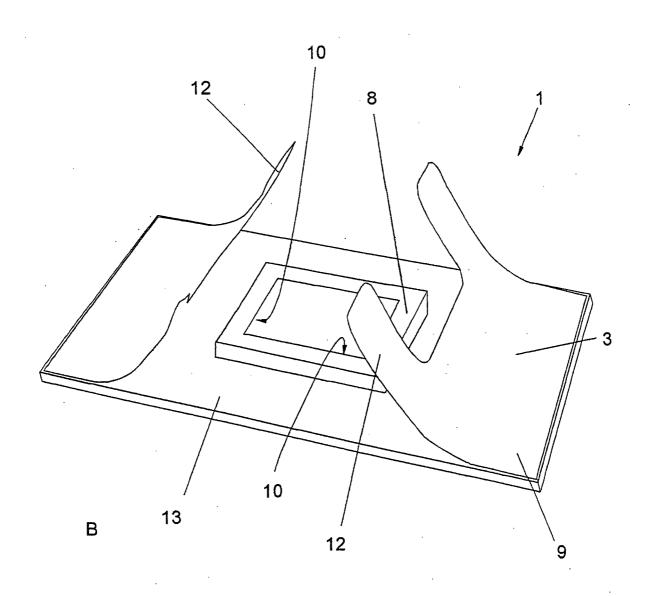


Fig. 2

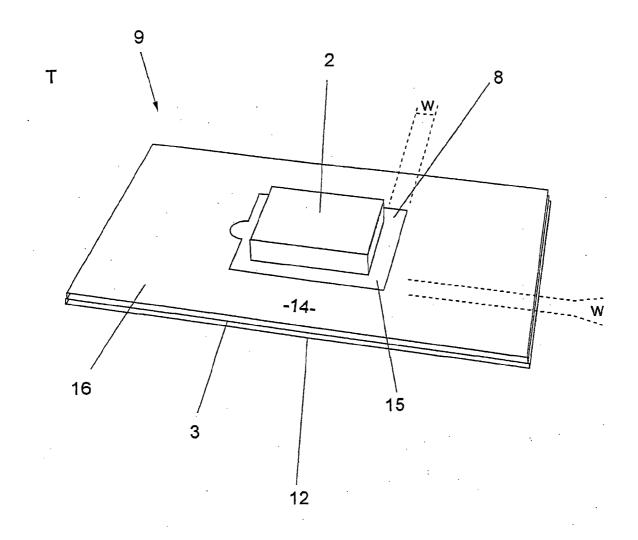


Fig. 3

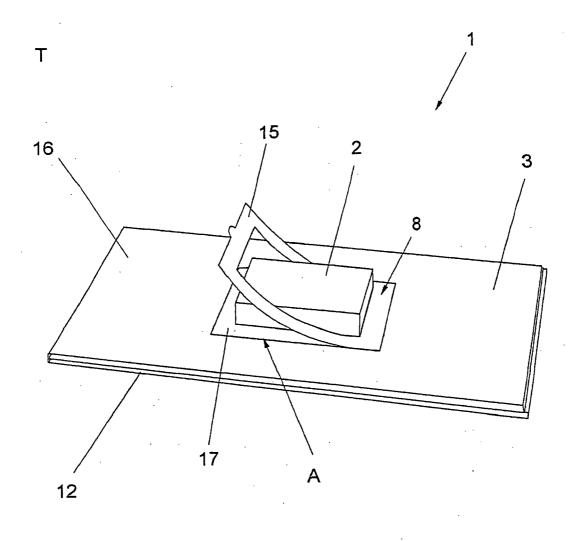
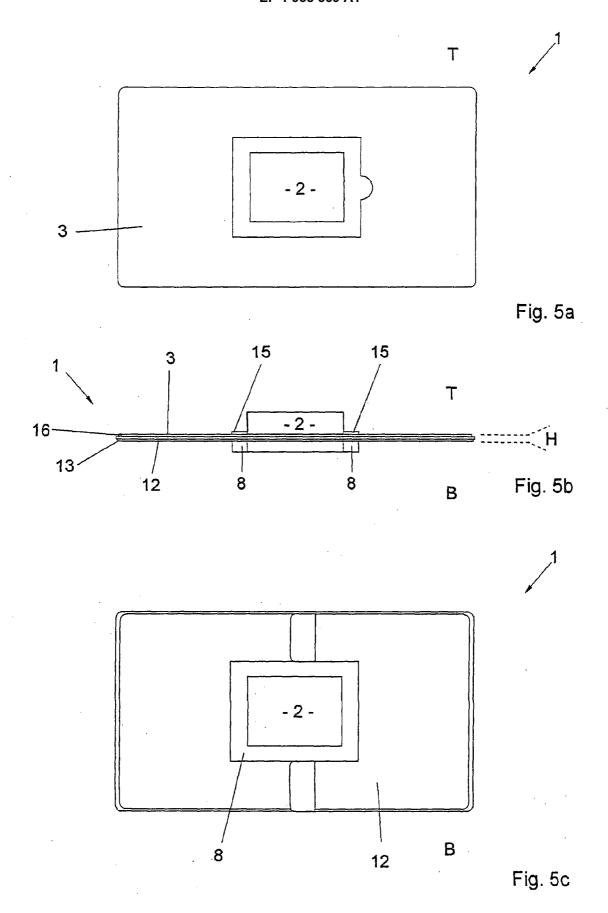


Fig. 4





## **EUROPEAN SEARCH REPORT**

**Application Number** EP 07 00 9102

i		ERED TO BE RELEVANT					
ategory	Citation of document with i of relevant pass	ndication, where appropriate, ages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)			
X	EP 0 800 788 A (LEC 15 October 1997 (19 * page 5, line 22 - * figures 1-4 *	997-10-15)	1-6,11	INV. A61B8/00			
X	US 2005/090725 A1 (28 April 2005 (2005 * paragraph [0060] * paragraph [0063] * paragraph [0064] * paragraph [0074] * paragraph [0077]	PAGE JOSEPH [US] ET AL) 5-04-28) * * * * *	1,7-13				
Х	US 2004/064051 A1 (AL) 1 April 2004 (2 * paragraph [0027] * paragraph [0029] * figures 6-8 *	(TALISH ROGER J [US] ET 2004-04-01) * *	1,5,6,11				
Α	US 2005/215901 A1 ( ET AL) 29 September * the whole documer	2005 (2005-09-29)	1-13	TECHNICAL FIELDS SEARCHED (IPC) A61B			
A	US 5 655 539 A (WAN 12 August 1997 (199 * the whole documen	97-08-12)	1-13				
	The present search report has	been drawn up for all claims					
	Place of search	Date of completion of the search		Examiner			
	The Hague	6 November 2007	Bat	aille, Frédéric			
X : parti Y : parti docu A : tech O : non	ATEGORY OF CITED DOCUMENTS icularly relevant if taken alone icularly relevant if combined with anot iment of the same category inological background written disclosure mediate document	L : document cited for	ument, but publis the application rother reasons	hed on, or			

## ANNEX TO THE EUROPEAN SEARCH REPORT ON EUROPEAN PATENT APPLICATION NO.

EP 07 00 9102

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

06-11-2007

Patent document cited in search report		Publication date		Patent family member(s)		Publication date
EP 0800788	Α	15-10-1997	NONE			
US 2005090725	A1	28-04-2005	NONE			
US 2004064051	A1	01-04-2004	AU CA EP JP WO	2003272651 2506649 1545707 2006501026 2004030762	A1 A1 T	23-04-200 15-04-200 29-06-200 12-01-200 15-04-200
US 2005215901	A1	29-09-2005	NONE			
US 5655539	Α	12-08-1997	EP JP WO	0959939 2000506749 9730750	T	01-12-199 06-06-200 28-08-199

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## EP 1 958 569 A1

#### REFERENCES CITED IN THE DESCRIPTION

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## Patent documents cited in the description

• US 20020049395 A1 [0003]

• US 5458140 A [0003]



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当前申请(专利权)人(译)	BUCHALTER , NEAL			
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## 摘要(译)

一种超声耦合装置,用于将超声波从超声换能器发射到测试样本,尤其是人体或动物体,所述耦合装置包括(a)用于发射所述超声波的凝胶垫(2),(b)支撑物(3)具有i)换能器侧(T),ii)主体侧(B),以及iii)穿过所述换能器侧和所述支撑件(3)的所述主体侧的孔(11),(c)所述支撑件(3)在所述体侧设置有粘合元件(13),和(d)所述凝胶垫(2)容纳在所述孔(11)内,使得所述凝胶垫(2)在所述人体或动物体接触时所述支撑的身体侧接触人体或动物体。

