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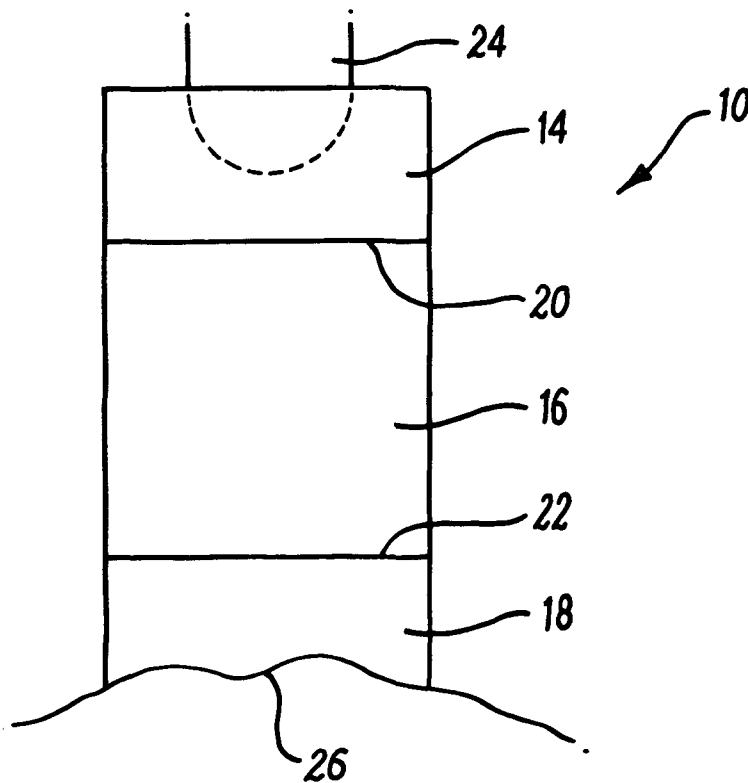
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(54) Title: APPARATUS FOR COUPLING AN ULTRASOUND PROBE TO AN OBJECT



(57) Abstract: Improved coupling apparatus (10) for coupling an ultrasound probe (24) to an object (26) is described. The apparatus (10) is particularly suitable for use within medical devices. The coupling apparatus (10) comprising first (14) and second (18) deformable coupler located on separate sides of an intermediate layer (16). Employing the first coupler (14) allows the apparatus (10) to be coupled to the probe (24) while the second coupler (18) provides a means for coupling the apparatus (10) to the object (26). The intermediate layer (16) acoustically connects the first (14) and second couplers (18) while providing structural strength for the apparatus (10). Optionally a sheath or cover (157) may be incorporated within the coupling apparatus (141) so as to improve the hygiene and sterile nature of the device.

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1 Apparatus for Coupling an Ultrasound Probe to an Object

2

3 This invention relates to an apparatus for coupling an  
4 ultrasound probe to an object. The apparatus is suitable  
5 for use in medical devices and other related fields  
6 although it is not restricted to use in those fields.

7

8 Ultrasound probes are well known and well used in  
9 medicine. For example, ultrasound imaging is used to  
10 provide expectant mothers with images of the foetus, to  
11 measure the blood flow in veins and arteries and when a  
12 medical practitioner wishes to inspect an internal cavity  
13 of a patient.

14

15 In most cases, the apparatus and techniques are very  
16 similar to those shown in Figures 1 and 2. Figure 1  
17 shows a system 1 comprising an ultrasound probe 3, having  
18 a probe head 5 which contains an ultrasound transducer 10  
19 acoustically coupled to the head 5. Outside the probe a  
20 gel 7 is applied to the outer surface of the head 5 or to  
21 an object 9 to provide a coupling or contact between the  
22 probe head 5 and the object 9.

1 The gel, typically an aqueous gel, is applied either to  
2 the surface of the object 9 or to the probe head 5 in  
3 order to ensure effective acoustic coupling between the  
4 probe head 5 and the surface of the object 9. The gel is  
5 therefore required to provide a constant contact between  
6 the head 5 and the surface 9.

7

8 It is often the case that the probe 5 will be moved  
9 around over a significant area across the object 9 in  
10 order to obtain an image. Consequently, a large amount  
11 of gel is smeared across the surface of the object 9  
12 which, in the case of a human, may be the abdomen, arm,  
13 leg or the like; this is unpleasant, messy and time  
14 consuming. In addition, the application of the gel is  
15 far from an exact science. It is often the case that the  
16 gel must be reapplied in order to obtain a good  
17 ultrasound signal.

18

19 Figure 2 shows a second example of the current use of an  
20 ultrasound probe. In this case, the system 11 shows  
21 probe 13 with a head 15 and gel 17 positioned between the  
22 probe head 15 and the object 19 which is a surface in a  
23 body cavity 21. In order to keep the ultrasound probe  
24 clean it is necessary to retain the probe within a sheath  
25 23. It is common for such sheaths to interfere with the  
26 ultrasound signal because they are not acoustically  
27 matched to the probe or gel. This, in turn, affects the  
28 quality of the image produced by the ultrasound probe.

29

30 Single layer gel pads are known to be used as coupling  
31 pads. However, these pads are prone to allow air into  
32 the path of the ultrasound signal which causes a  
33 degradation of the signal and hence the image.

1

2 It is therefore an object of an aspect of the present  
3 invention to provide a coupling apparatus for coupling an  
4 ultrasound probe to an object that obviates, or at least  
5 mitigates, one or more of the above described problems  
6 experienced by the coupling apparatus known in the art.

7

### 8 **Summary of Invention**

9 In accordance with a first aspect of the invention there  
10 is provided a coupling apparatus for coupling an  
11 ultrasound probe to an object, the coupling apparatus  
12 comprising:

13 a first coupler connectable to the probe;

14 a second coupler connectable to the object; and

15 an intermediate layer for acoustically connecting the  
16 first coupler and the second coupler, the intermediate  
17 layer being further adapted to provide structural  
18 strength to the apparatus,

19 wherein, the first coupler and the second coupler are  
20 adapted for direct acoustic coupling with the respective  
21 probe and object.

22

23 Preferably, the first coupler and the second coupler are  
24 made of a pliable material such that when in contact with  
25 the probe and/or object, the respective first coupler and  
26 second coupler deform to fit the shape of the probe and  
27 object, respectively.

28

29 Preferably, the first coupler and the second coupler  
30 exude an acoustic coupling liquid when in operative  
31 contact with the respective probe and object.

32

1 Preferably, the first coupler is shaped to accommodate  
2 the probe.

3

4 Preferably, the first coupler is made from a material  
5 that undergoes syneresis.

6

7 Preferably, the first coupler is semi-solid.

8

9 Preferably, the first coupler is a gel.

10

11 Preferably, the first coupler is a hydro-gel.

12

13 Preferably, the first coupler is a polyvinyl alcohol  
14 hydro-gel.

15

16 Preferably, the first coupler has a composition with less  
17 than six weight percentage of polyvinyl alcohol in water.

18

19 Preferably, the second coupler is made from a material  
20 that undergoes syneresis.

21

22 Preferably, the second coupler is a gel.

23

24 Preferably, the second coupler is a hydro-gel.

25

26 Preferably, the second coupler is a polyvinyl alcohol  
27 hydro-gel.

28

29 Preferably, the second coupler has a composition of less  
30 than six weight percentage polyvinyl alcohol.

31

1 Preferably, the intermediate layer has a similar, or  
2 identical, acoustic impedance to the first coupler and  
3 the second coupler.

4

5 Preferably, the intermediate layer has a higher density  
6 than the first coupler or the second coupler.

7

8 Preferably, the intermediate layer is a gel.

9

10 Preferably, the intermediate layer is a hydro-gel.

11

12 Preferably, the intermediate layer is a polyvinyl alcohol  
13 hydro-gel.

14

15 Preferably, the intermediate layer is a polyvinyl alcohol  
16 hydro-gel having a percentage composition of polyvinyl  
17 alcohol greater than six weight percentage.

18

19 Preferably, the intermediate layer is acoustically  
20 coupled to the first coupler and the second coupler.

21

22 Preferably, the acoustic coupling is achieved via a  
23 junction layer.

24

25 Preferably, the junction layer is defined by a discrete  
26 layer.

27

28 Optionally, the junction layer is defined by a transition  
29 layer of varying density.

30

31 Optionally, the transition layer is characterised by an  
32 increased density towards the intermediate layer.

33

1 Preferably, the coupler is formed in a single piece.

2

3 Optionally, the coupler is formed in three discrete  
4 layers.

5

6 Optionally, the discrete layers are bonded together.

7

8 Optionally, the discrete layers are bonded together using  
9 a heating and cooling cycle.

10

11 Preferably, the apparatus of the present invention is  
12 provided with a sterile cover for use in-vivo.

13

14 The cover is used to prevent the probe being  
15 contaminated, particularly when used in vivo.

16

17 Preferably, the cover is a sheath.

18

19 Preferably, the cover is integrally formed with the  
20 apparatus of the present invention.

21

22 Preferably, the cover is integrally formed with the  
23 intermediate layer of the present invention.

24

25 Optionally, the cover is connectable to the apparatus of  
26 the present invention.

27

28 Optionally, the cover is connectable by means of a  
29 channel.

30

31 Preferably, the channel is in the intermediate layer.

32

1 Preferably, the apparatus of the present invention  
2 further comprises a frame adapted to support the cover.

3

4 In accordance with a second aspect of the present  
5 invention there is provided a method for making a  
6 coupling apparatus for coupling an ultrasound probe to an  
7 object, the method comprising the steps of:

8 1) applying a heating and cooling cycle to a first  
9 mixture in order to form a first hydro-gel of a  
10 first density;

11 2) adding a second mixture to the first formed  
12 hydro-gel and applying a heating and cooling  
13 cycle to the second mixture so as to form a  
14 second hydro-gel having a second density, wherein  
15 the second density is higher than the first  
16 density; and

17 3) adding a third mixture to the second hydro-gel  
18 and applying a heating and cooling cycle to form  
19 a third hydro-gel of a third density, wherein the  
20 third density is lower than the second density.

21

22 Following the above method results in the formation of a  
23 bonded structure comprising three layers of lower and  
24 higher density hydro-gels.

25

26 Most preferably the third density is selected so as to be  
27 equal to the first density.

28

29 Preferably the first hydro-gel is a polyvinyl alcohol  
30 hydro-gel. Preferably the first hydro-gel has a  
31 composition of less than six weight percentage polyvinyl  
32 alcohol in water.

33

1 Preferably the third hydro-gel is a polyvinyl alcohol  
2 hydro-gel. Preferably the third hydro-gel has a  
3 composition of less than six weight percentage polyvinyl  
4 alcohol in water.

5

6 Preferably the second hydro-gel is a polyvinyl alcohol  
7 hydro-gel. Preferably the second hydro-gel has a  
8 composition of greater than six weight percentage  
9 polyvinyl alcohol in water.

10

11 In accordance with a third aspect of the present  
12 invention there is provided a method for making a  
13 coupling apparatus for coupling an ultrasound probe to an  
14 object, the method comprising the steps of:

- 15 1) applying a heating and cooling cycle to a first  
16 mixture in order to form a intermediate hydro-gel  
17 layer having a first density;
- 18 2) adding a second mixture to a first side of the  
19 intermediate hydro-gel layer and applying a  
20 heating and cooling cycle to the second mixture  
21 so as to form a first hydro-gel layer having a  
22 lower density than the intermediate hydro-gel  
23 layer; and
- 24 3) adding a third mixture to a second side of the  
25 intermediate hydro-gel layer and applying a  
26 heating and cooling cycle to third mixture so as  
27 to form a second hydro-gel layer having a lower  
28 density than the intermediate hydro-gel layer.

29

30 Optionally the second and third steps are carried out  
31 simultaneously.

32

33

1 **Brief Description of Drawings**

2 Aspects and advantages of the present invention will  
3 become apparent upon reading the following detailed  
4 description and upon reference to the following Figures  
5 in which:

6

7 Figure 1 is an illustration of a prior art ultrasound  
8 probe arrangement in use;

9

10 Figure 2 is an illustration of another prior art probe  
11 arrangement in use;

12

13 Figures 3A and 3B show a first embodiment of the coupling  
14 apparatus in accordance with an aspect of the present  
15 invention;

16

17 Figure 4 is an illustration of a second embodiment of the  
18 coupling apparatus in accordance with an aspect of the  
19 present invention;

20

21 Figure 5 is an illustration of a third embodiment of the  
22 coupling apparatus in accordance with an aspect of the  
23 present invention;

24

25 Figure 6 is a graph showing the variation in  
26 concentration of a polyvinyl alcohol hydro-gel in the  
27 example of the present invention shown in Figure 4;

28

29 Figure 7 is an illustration of a further embodiment of  
30 the coupling apparatus in accordance with an aspect of  
31 the present invention;

32

1 Figure 8 is an illustration of a further embodiment of  
2 the coupling apparatus in accordance with an aspect of  
3 the present invention;

4

5 Figure 9 is an illustration of a further embodiment of  
6 the coupling apparatus in accordance with an aspect of  
7 the present invention;

8

9 Figure 10 is an illustration of a further embodiment of  
10 the coupling apparatus in accordance with an aspect of  
11 the present invention incorporating a frame and sheath;  
12 and

13

14 Figure 11A is a side view of another embodiment of the  
15 coupling apparatus in accordance with an aspect of the  
16 present invention incorporating a frame and sheath,  
17 Figure 11B is a cross sectional view along lines A-A' of  
18 Figure 11A and Figure 11C is a cross sectional view of  
19 part of the illustration of Figure 11A, in order to show  
20 the manner in which the sheath is embedded into the  
21 intermediate layer.

22

### 23 **Specific Description**

24 Figures 3A and 3B illustrate a first embodiment of the  
25 invention 10 having a first coupler 14 an intermediate  
26 layer 16 and a second coupler 18. Junction layers 20 and  
27 22 illustrate the position at which the layers are  
28 joined.

29

30 In this example of the present invention, the first and  
31 second couplers 14 and 18 provide a means for directly  
32 coupling an ultrasound probe to the apparatus 10 and the  
33 apparatus to a body without requiring the application of

1 a coupling gel to the body 26 or the probe 24. In this  
2 example the direct coupling is provided by selecting a  
3 pliable material of the first 14 and/or second coupler 18  
4 such that the material deforms around the probe 24 and/or  
5 body 26. The coupler therefore fits around or conforms  
6 to the shape of the probe 24 and/or body 26 to provide  
7 good acoustic coupling. In this example, the probe 24 is  
8 pressed into the first coupler 14, and the second coupler  
9 18 is pressed against the body 26.

10

11 Figure 4 shows a second embodiment 31 of an apparatus in  
12 accordance with an aspect of the present invention  
13 similar to that of Figure 3 which is used to couple an  
14 ultrasound probe 33 to an object 49. The apparatus  
15 comprises a first coupler 35, an intermediate layer 37  
16 and a second coupler 39. There are two interfaces, 41  
17 and 43, positioned between the first coupler 35 and the  
18 intermediate layer 37 and between the intermediate layer  
19 37 and the second coupler 39, respectively.

20

21 In this example the entire arrangement of the first and  
22 second couplers, 35 and 39, along with intermediate layer  
23 37 are made from a hydro-gel. In addition, in this  
24 example, the density (as measured by the weight percent  
25 of polyvinyl alcohol (PVA)) of the first coupler 35 and  
26 the second coupler 39 are substantially identical. The  
27 density of the intermediate layer 37 is higher than that  
28 of the first coupler 35 and the second coupler 39. The  
29 intermediate layer 37 is designed to be a harder and more  
30 resilient structure in order to provide mechanical  
31 strength to the overall structure.

32

1 Couplers 35 and 39 are designed to be pliable such that  
2 they deform on contact with the probe 33 or body 49,  
3 respectively, and conform to the shape of the probe 33 or  
4 body 49.

5

6 The apparatus 31 may be designed to be disposable after a  
7 single use.

8

9 Figure 5 shows a third embodiment of an aspect of the  
10 present invention 51. In this embodiment, a probe 53 is  
11 positioned near or at a first coupler 55 which is  
12 connected to an intermediate layer 57 and to a second  
13 coupler 59. Liquid layers 65 and 67 are formed between  
14 the probe 53 and the object 69.

15

16 Couplers 55 and 59 are designed to exude a liquid when in  
17 operative contact with the probe 53 and the object 69,  
18 respectively. The purpose of the liquid is to provide a  
19 physical coupling between the probe 53 and first coupler  
20 55 and between the object 69 and second coupler 59. The  
21 purpose of this coupling liquid is to remove the need for  
22 applying a gel to the object surface.

23

24 The couplers 55 and 59 have composition that readily  
25 allows a liquid 65, 67, in this example water, to be  
26 exuded onto the probe 53 and object 69. The process by  
27 which a liquid is exuded in this manner is known as  
28 syneresis and the extent to which, or the amount of,  
29 liquid that is exuded is dependant upon the density of  
30 the gel.

31

32 In one respect the couplers 55 and 57 can be viewed as  
33 liquid reservoirs where the liquid 65, 67 is held in a

1 semi-fixed state and which can be released from the  
2 reservoir during operative contact with a probe 53 and  
3 object 69. The presence of the layers of liquid 65, 67  
4 provide a good coupling and because the gel contains a  
5 significant amount of liquid the coupling is maintained  
6 when the probe apparatus is moved across the object  
7 surface, because liquid is continuously exuded during  
8 use.

9

10 In this example the interfaces 61 and 63 between the  
11 first coupler 55 and intermediate layer 57 and the  
12 intermediate layer 57 and second coupler 59 are not  
13 discrete. This means there is a change in density as  
14 measured by a change in the weight percentage of PVA in  
15 the hydro-gel across the layer. It is believed that this  
16 type of structure is likely to occur where the apparatus  
17 is formed using the heating/cooling cycled described  
18 below.

19

20 Arrow 58 shows the distance through the apparatus and a  
21 graph of density 75 as measured by weight percentage of  
22 the hydro-gel against distance D 73 is shown in Figure 6.  
23 The graph clearly shows the change in density across the  
24 interface layers 61 and 63.

25

26 As outlined above, the apparatus of the present invention  
27 can be made using PVA hydro-gels in the following manner.  
28 A first mixture containing a lower concentration of PVA  
29 is added to a container where it is first frozen and then  
30 thawed until a hydro-gel is formed in the bottom of a  
31 container (usually the container is shaped like a  
32 column).

33

1 A second mixture containing a higher concentration of PVA  
2 is added to the container where it is first frozen and  
3 then thawed until a hydro-gel is formed on top of the  
4 first formed hydro-gel. During the freezing and thawing  
5 process the second, higher density, hydro-gel fuses,  
6 bonds or mixes with the first formed hydro-gel to form a  
7 continuous hydro-gel with an area of higher concentration  
8 and an area of lower concentration of PVA.

9

10 Thereafter, a third mixture is added to the container.  
11 This third mixture contains a lower concentration of PVA  
12 similar or identical to the concentration of the PVA in  
13 the first mixture. Once again, a freezing and thaw cycle  
14 is performed until a hydro-gel is formed from the  
15 mixture. As with the first and second mixtures this  
16 third mixture, upon formation of a hydro-gel is fused,  
17 bonded or mixed with the second hydro-gel to form a  
18 larger, continuous hydro-gel with a lower density similar  
19 to the density of the first hydro-gel.

20

21 In an alternative embodiment the coupling apparatus of  
22 the present invention can be made by initially carrying  
23 out the second step so as to form the high density  
24 intermediate hydro-gel layer. Thereafter the first and  
25 second steps can be carried out in order to form the  
26 lower density hydro-gel layers on different sides of the  
27 intermediate layer. It will be appreciated that the  
28 first and second steps may be carried out simultaneously  
29 in order to speed up the production process.

30

31 Figure 7 shows a further embodiment of the present  
32 invention. In this example a probe 83 is coupled to an  
33 object 95 via a coupling apparatus 81 in accordance with

1 an aspect of the present invention. The coupling  
2 apparatus 81 can be seen to comprises: a first coupler  
3 87, an intermediate layer 89 and a second coupler 91.  
4 The first 87 and second 91 couplers are pliable and  
5 deform when a probe 83 is pressed against it or where it  
6 is pressed against a body 95. It should be noted that  
7 the embodiment of Figure 7 has an elongated shaped and a  
8 triangular or prism shaped second coupler 91.

9

10 Figure 8 shows another embodiment 101 of an aspect of the  
11 present invention in which the intermediate layer 109 is  
12 triangular or prism shaped and the first coupler 107 and  
13 the second coupler 111 comprise the layers of hydro-gel  
14 adapted to exude a liquid, 105 and 113, upon operative  
15 contact with a probe 103 and object 114, respectively.

16

17 Figure 9 shows a further embodiment 121 of an aspect of  
18 the present invention. In this embodiment the apparatus  
19 has a substantially rectangular cross section with the  
20 intermediate layer 129 forming the major part of the  
21 apparatus. The couplers 127 and 131 are relatively small  
22 when compared to the intermediate layer 129. In this  
23 case the apparatus 121 is designed to maximise the  
24 mechanical strength and structural properties that are  
25 provided by the intermediate layer 129, whilst providing  
26 a suitable amount of lower concentration hydro-gel in the  
27 couplers 127 and 131 to provide liquid layers 125 and 133  
28 upon operative contact with a probe 123 and object 135.

29

30 Figure 10 shows another embodiment 141 of an aspect of  
31 the present invention in which the probe 143 is adapted  
32 for use in vivo by the addition of a sheath or cover 157.  
33 Figure 10 shows a probe 143, liquid layer 145, first

1 coupler 147, intermediate layer 149, second coupler 151,  
2 liquid layer 153 and object 155. In addition, a sheath  
3 157 is arranged around the probe so as to enclose the  
4 probe when in use. A frame 159 is also included to space  
5 the sheath 157 from the probe 143. The sheath 157 is  
6 attached to the intermediate layer 149. This attachment  
7 may be via an elasticated collar 156 or the like that  
8 forms a tight fit around the intermediate layer 149. In  
9 addition, the intermediate layer may be provided with a  
10 circumferential channel which is adapted to accept a  
11 leading portion of the sheath 157. In this way the edge  
12 of the sheath 157 can fit into the channel thereby  
13 improving the fit between the channel and the sheath 157.

14

15 Figures 11A to 11C show a further embodiment 171 of an  
16 aspect of the present invention. Figure 11A shows the  
17 probe 173, a frame 174, a liquid layer 175, a first  
18 coupler 177, an intermediate layer 179, a second coupler  
19 181, a liquid layer 183 and an object 185. In this  
20 embodiment of the present invention the sheath 187 is  
21 integrally formed with the intermediate layer 179 during  
22 manufacture of the apparatus 171. The position of the  
23 embedded portion 189 of the sheath 187 is clearly shown  
24 in relation to the outer surfaces 191 and 193 of the  
25 intermediate layer 179 and the sheath 187, respectively,  
26 within Figures 11B and 11C. In addition, Figure 11A also  
27 show the outer surface 193 of the sheath 187 as it  
28 extends backwards towards the probe 173.

29

30 In this embodiment of an aspect of the present invention  
31 the integrated sheath 187 provides a ready made hygienic  
32 and sterile sheath which, as with the previous  
33 embodiment, that does not present any part of the sheath

1 157 or 187 to the path of the ultrasound as it goes from  
2 the probe, 143 or 173, to the object, 155 or 185. In  
3 addition, the embodiment of Figures 11A to 11C provides a  
4 sturdy and secure fixing for the sheath 187. Once the  
5 sheath, 157 or 187, and probe, 143 or 173, have been used  
6 the sheath, 157 or 187, and coupler apparatus, 141 or  
7 171, may be disposed of hygienically. In this way, there  
8 is little or no prospect of contamination of the  
9 expensive ultrasound probe, 143 or 173.

10

11 The above described apparatus provides an improved means  
12 for coupling an ultrasound probe to an object and  
13 particularly a medical ultrasound probe to a patient.  
14 This is achieved without the need to deploy layers of gel  
15 to the object or patient or to employ hydro-gel pads.  
16 Since the described apparatus comprises a multi layered  
17 hydro-gel structure it provides an elegant and cost  
18 effective solution for improving the coupling of  
19 ultrasound to an object. In some or the above described  
20 embodiments, a sheath is employed that provides for a  
21 cost effective disposable device thus significantly  
22 reducing the risk of cross contamination between  
23 patients.

24

25 The foregoing description of the invention has been  
26 presented for purposes of illustration and description  
27 and is not intended to be exhaustive or to limit the  
28 invention to the precise form enclosed. The described  
29 embodiments were chosen and described in order to best  
30 explain the principles of the invention and its practical  
31 application to thereby enable others skilled in the art  
32 to best utilise the invention in various embodiments and  
33 with various modifications as are suited to the

1 particular use contemplated. Therefore, further  
2 modifications or improvements may be incorporated without  
3 departing from the scope of the invention as defined by  
4 the appended claims.

1 Claims

2

3 1) A coupling apparatus for coupling an ultrasound probe  
4 to an object, the coupling apparatus comprising:  
5 a first coupler connectable to the probe;  
6 a second coupler connectable to the object; and  
7 an intermediate layer for acoustically connecting the  
8 first coupler and the second coupler, the  
9 intermediate layer being further adapted to provide  
10 structural strength to the apparatus,  
11 wherein, the first coupler and the second coupler are  
12 adapted for direct acoustic coupling with the  
13 respective probe and object.

14

15 2) A coupling apparatus as claimed in claim 1 wherein  
16 the first coupler is made of a pliable material such  
17 that when in contact with the probe the first coupler  
18 deforms to fit the shape of the probe.

19

20 3) A coupling apparatus as claimed in either of claims 1  
21 or 2 wherein the second coupler is made of a pliable  
22 material such that when in contact with the object  
23 the second coupler deforms to fit the shape of the  
24 object.

25

26 4) A coupling apparatus as claimed in any of the  
27 preceding claims wherein the first coupler exudes an  
28 acoustic coupling liquid when in operative contact  
29 with the probe.

30

31 5) A coupling apparatus as claimed in any of the  
32 preceding claims wherein the second coupler exudes an

1 acoustic coupling liquid when in operative contact  
2 with the object.

3

4 6) A coupling apparatus as claimed in any of the  
5 preceding claims wherein the first coupler is shaped  
6 to accommodate the probe.

7

8 7) A coupling apparatus as claimed in any of the  
9 preceding claims wherein the first coupler is made  
10 from a material that undergoes syneresis.

11

12 8) A coupling apparatus as claimed in any of the  
13 preceding claims wherein the first coupler is semi-  
14 solid.

15

16 9) A coupling apparatus as claimed in any of the  
17 preceding claims wherein the first coupler is a gel.

18

19 10) A coupling apparatus as claimed in claim 9 wherein  
20 the gel is a hydro-gel.

21

22 11) A coupling apparatus as claimed in claim 10 wherein  
23 the hydro-gel is a polyvinyl alcohol hydro-gel.

24

25 12) A coupling apparatus as claimed in Claim 11 wherein  
26 the hydro-gel has a composition with less than six  
27 weight percentage of polyvinyl alcohol.

28

29 13) A coupling apparatus as claimed in any of the  
30 preceding claims wherein the second coupler is made  
31 from a material that undergoes syneresis.

32

- 1 14) A coupling apparatus as claimed in any of the  
2 preceding claims wherein the second coupler is a gel.  
3
- 4 15) A coupling apparatus as claimed in claim 14 wherein  
5 the gel is a hydro-gel.  
6
- 7 16) A coupling apparatus as claimed in claim 15 wherein  
8 the hydro-gel is a polyvinyl alcohol hydro-gel.  
9
- 10 17) A coupling apparatus as claimed in claim 16 wherein  
11 the hydro-gel has a composition of less than six  
12 weight percentage of polyvinyl alcohol.  
13
- 14 18) A coupling apparatus as claimed in any of the  
15 preceding claims wherein the intermediate layer has a  
16 similar, or identical, acoustic impedance to the  
17 first coupler and second coupler.  
18
- 19 19) A coupling apparatus as claimed in any of the  
20 preceding claims wherein the intermediate layer has a  
21 higher density than the first coupler or the second  
22 coupler.  
23
- 24 20) A coupling apparatus as claimed in any of the  
25 preceding claims wherein the intermediate layer is a  
26 gel.  
27
- 28 21) A coupling apparatus as claimed in claim 20 wherein  
29 the gel is a hydro-gel.  
30
- 31 22) A coupling apparatus as claimed in claim 21 wherein  
32 the hydro-gel is a polyvinyl alcohol hydro-gel.  
33

1 23) A coupling apparatus as claimed in claim 22 wherein  
2 the hydro-gel has a composition with greater than six  
3 weight percentage of polyvinyl alcohol.

4

5 24) A coupling apparatus as claimed in any of the  
6 preceding claims wherein the intermediate layer is  
7 acoustically coupled to the first coupler and the  
8 second coupler.

9

10 25) A coupling apparatus as claimed in claim 24 wherein  
11 the acoustic coupling is achieved via a junction  
12 layer.

13

14 26) A coupling apparatus as claimed in claim 25 wherein  
15 the junction layer is defined by a discrete layer.

16

17 27) A coupling apparatus as claimed in claim 25 wherein  
18 the junction layer is defined by a transition layer  
19 of varying density.

20

21 28) A coupling apparatus as claimed in claim 27 wherein  
22 the transition layer is characterised by an increased  
23 density towards the intermediate layer.

24

25 29) A coupling apparatus as claimed in any of the  
26 preceding claims wherein the coupler is formed in a  
27 single piece.

28

29 30) A coupling apparatus as claimed in any of claims 1 to  
30 28 wherein the coupler is formed in three discrete  
31 layers.

32

1 31) A coupling apparatus as claimed in claim 30 wherein  
2 the discrete layers are bonded together.

3

4 32) A coupling apparatus as claimed in claim 31 wherein  
5 the discrete layers are bonded together using a  
6 heating and cooling cycle.

7

8 33) A coupling apparatus as claimed in any of the  
9 preceding claims wherein the coupling apparatus  
10 further comprises a sterile cover for use in-vivo.

11

12 34) A coupling apparatus as claimed in claim 33 wherein  
13 the cover is a sheath.

14

15 35) A coupling apparatus as claimed in either of claims  
16 33 or 34 wherein the cover is integrally formed with  
17 the coupling apparatus.

18

19 36) A coupling apparatus as claimed in claim 35 wherein  
20 the cover is integrally formed with the intermediate  
21 layer.

22

23 37) A coupling apparatus as claimed in either of claim 33  
24 or 34 wherein the cover is connectable to the  
25 coupling apparatus.

26

27 38) A coupling apparatus as claimed in claim 37 wherein  
28 the cover is connectable by means of a channel.

29

30 39) A coupling apparatus as claimed in claim 38 wherein  
31 the channel is in the intermediate layer.

32

1 40) A coupling apparatus as claimed in any of claims 33  
2 to 39 wherein the coupling apparatus further  
3 comprises a frame adapted to support the cover.  
4

5 41) A method for making a coupling apparatus for coupling  
6 an ultrasound probe to an object, the method  
7 comprising the steps of:

8 4) applying a heating and cooling cycle to a first  
9 mixture in order to form a first hydro-gel of a  
10 first density;

11 5) adding a second mixture to the first formed  
12 hydro-gel and applying a heating and cooling  
13 cycle to the second mixture so as to form a  
14 second hydro-gel having a second density, wherein  
15 the second density is higher than the first  
16 density and

17 6) adding a third mixture and applying a heating and  
18 cooling cycle to form a third hydro-gel of a  
19 third density, wherein the third density is lower  
20 than the second density.  
21

22 42) A method for making a coupling apparatus as claimed  
23 in claim 41 wherein the third density is selected so  
24 as to be equal to the first density.  
25

26 43) A method for making a coupling apparatus as claimed  
27 in either of claims 41 or 42 wherein the first hydro-  
28 gel is a polyvinyl alcohol hydro-gel.  
29

30 44) A method for making a coupling apparatus as claimed  
31 in claim 43 wherein the first hydro-gel has a  
32 composition of less than six weight percentage  
33 polyvinyl alcohol.

1

2 45) A method for making a coupling apparatus as claimed  
3 in any of claims 41 to 44 wherein the third hydro-gel  
4 is a polyvinyl alcohol hydro-gel.

5

6 46) A method for making a coupling apparatus as claimed  
7 in claim 45 wherein the third hydro-gel has a  
8 composition of less than six weight percentage  
9 polyvinyl alcohol.

10

11 47) A method for making a coupling apparatus as claimed  
12 in any of claims 41 to 46 wherein the second hydro-  
13 gel is a polyvinyl alcohol hydro-gel.

14

15 48) A method for making a coupling apparatus as claimed  
16 in claim 47 wherein the second hydro-gel has a  
17 composition of greater than six weight percentage  
18 polyvinyl alcohol.

19

20 49) A method for making a coupling apparatus for coupling  
21 an ultrasound probe to an object, the method  
22 comprising the steps of:

23 4) applying a heating and cooling cycle to a first  
24 mixture in order to form a intermediate hydro-gel  
25 layer having a first density;

26 5) adding a second mixture to a first side of the  
27 intermediate hydro-gel layer and applying a  
28 heating and cooling cycle to the second mixture  
29 so as to form a first hydro-gel layer having a  
30 lower density than the intermediate hydro-gel  
31 layer; and

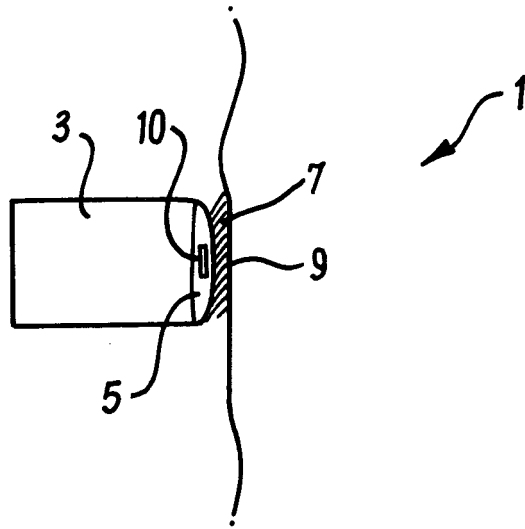
32 6) adding a third mixture to a second side of the  
33 intermediate hydro-gel layer and applying a

1 heating and cooling cycle to third mixture so as  
2 to form a second hydro-gel layer having a lower  
3 density than the intermediate hydro-gel layer.

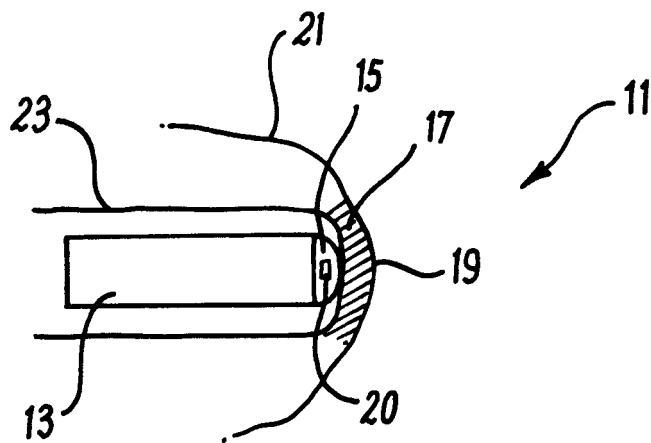
4

5 50) A method for making a coupling apparatus as claimed  
6 in claim 49 wherein the second and third steps are  
7 carried out simultaneously.

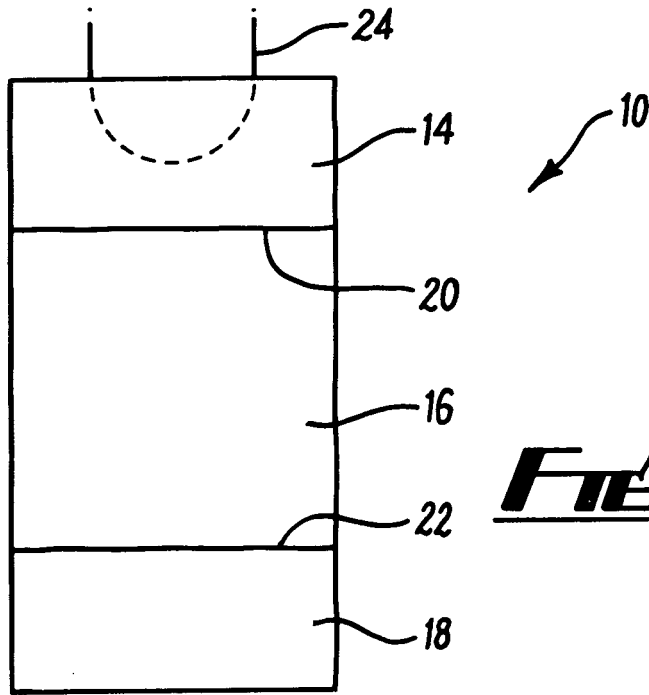
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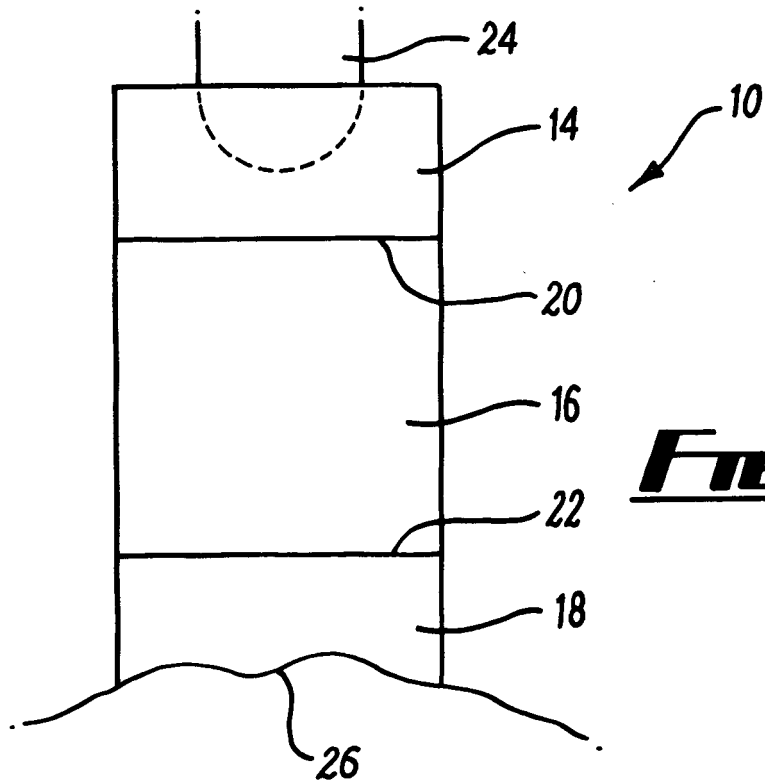
**FIG. 1**  
(Prior Art)



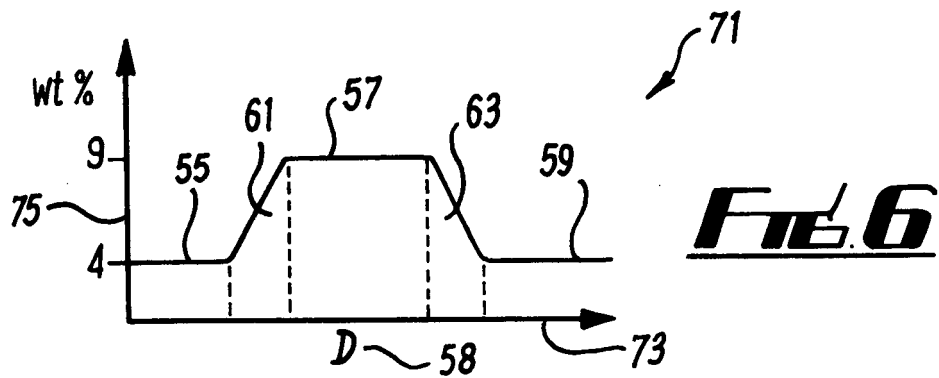
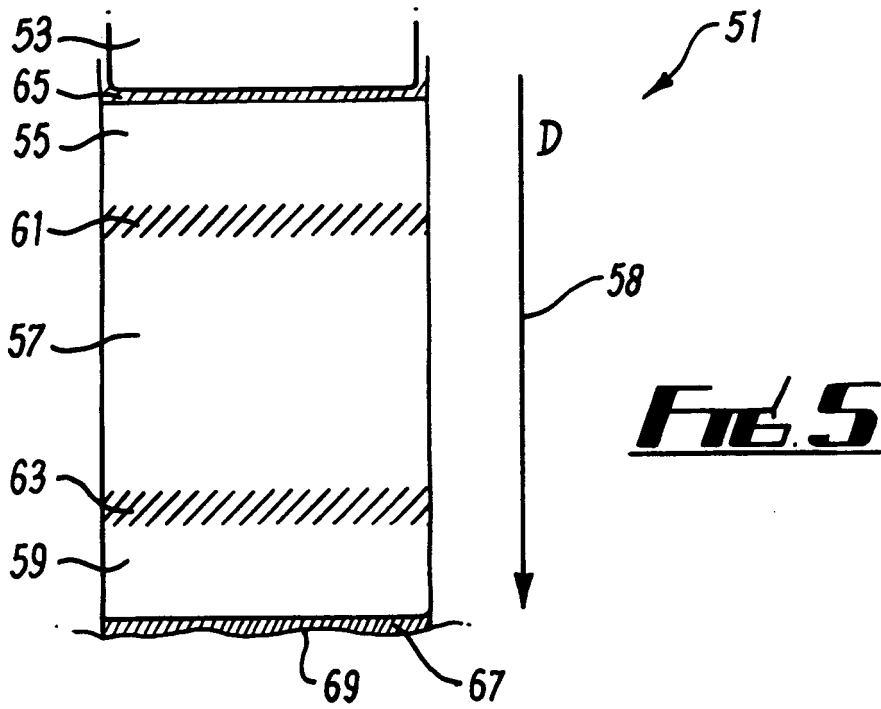
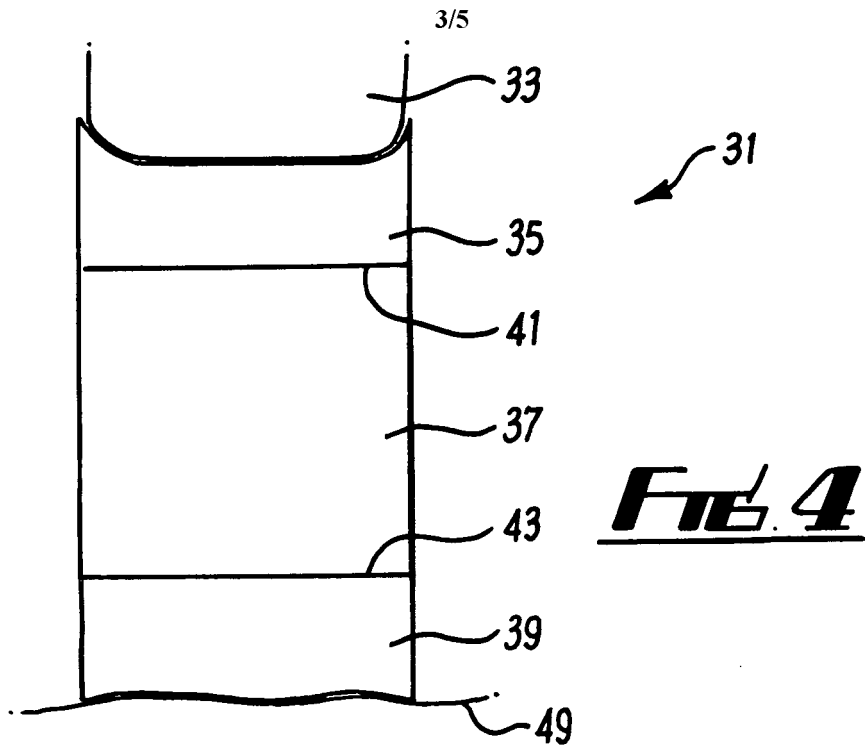
**FIG. 2**  
(Prior Art)

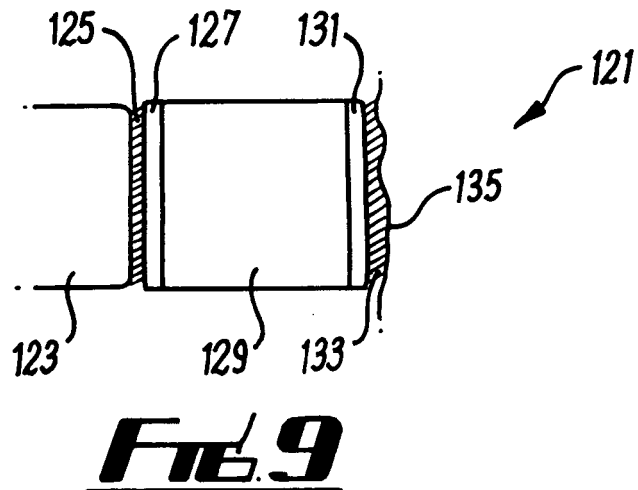
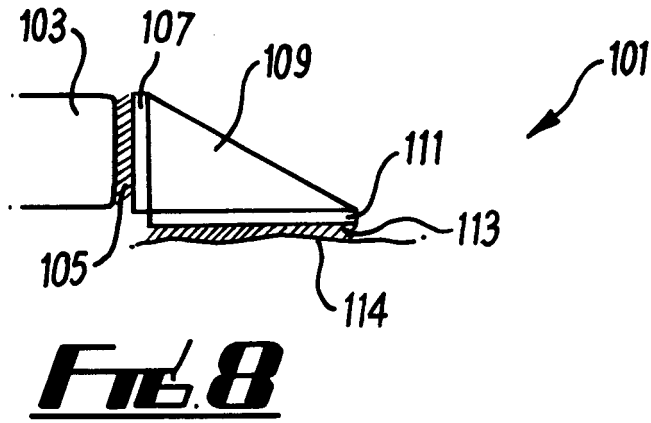
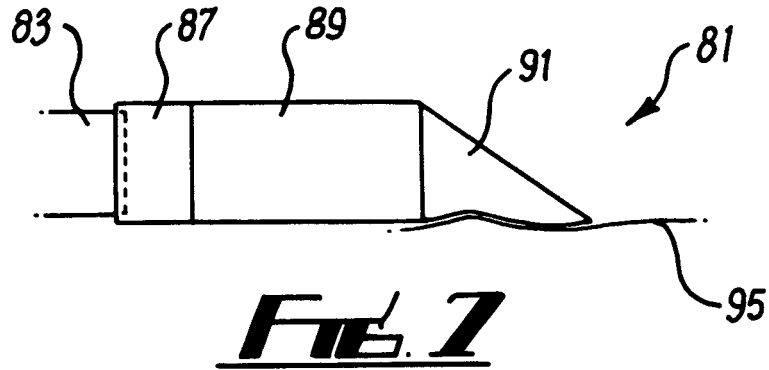


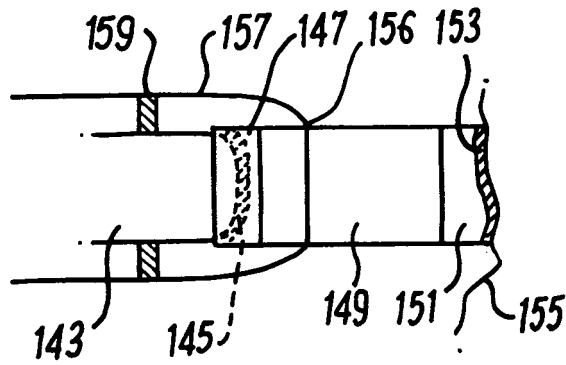
**FIG. 3A**



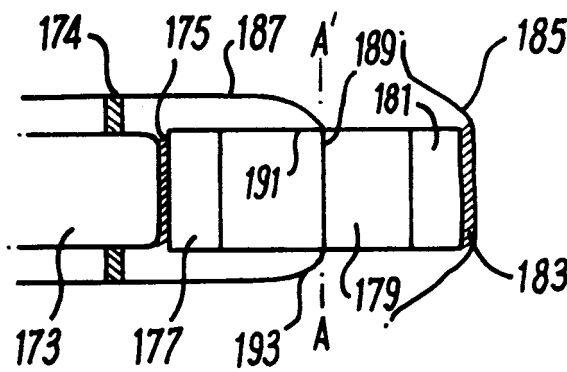
**FIG. 3B**



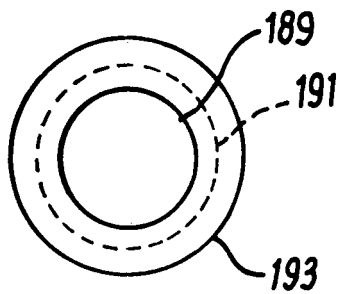




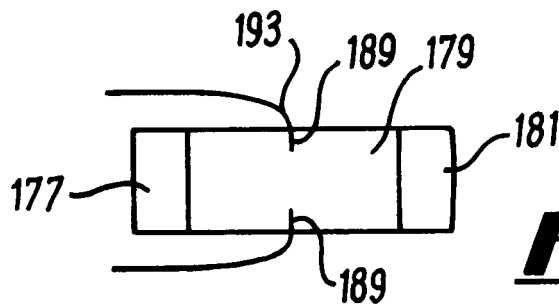
**FIG. 10**



**FIG. 11A**



**FIG. 11B**



**FIG. 11c**

## INTERNATIONAL SEARCH REPORT

International application No  
PCT/GB2007/003712A. CLASSIFICATION OF SUBJECT MATTER  
INV. A61B8/00 G01N29/28 G10K11/02

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 G01N G10K

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.
X	DE 37 02 179 A1 (BAUER JOHANN) 11 August 1988 (1988-08-11)	1-3, 6-10, 13-15, 24-26, 30-32
Y	abstract  column 2, line 2 - column 6, line 30 figure 2	11, 12, 16, 17
Y	----- WO 90/01902 A (FUJITSU LTD [JP]) 8 March 1990 (1990-03-08)	11, 12, 16, 17
A	the whole document  ----- -/--	41-50

 Further documents are listed in the continuation of Box C. See patent family annex.

## \* Special categories of cited documents :

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Date of the actual completion of the international search

13 February 2008

Date of mailing of the international search report

25/02/2008

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Authorized officer

ARTIKIS, T

## INTERNATIONAL SEARCH REPORT

International application No

PCT/GB2007/003712

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2003/195420 A1 (MENDLEIN JOHN D [CA] ET AL) 16 October 2003 (2003-10-16)  paragraph [0127] - paragraph [0177] figures 1,2,5	1-3,9, 14,24, 30, 33-38,40
X	US 5 394 877 A (ORR JOSEPH A [US] ET AL) 7 March 1995 (1995-03-07)  abstract column 5, line 21 - column 7, line 26 figures 2,3	1,3,6,9, 10,14, 15,18, 19,24, 25,29
X	WO 97/31364 A (ABBOTT LAB [US]) 28 August 1997 (1997-08-28) abstract column 7, line 24 - column 10, line 19 figure 8	1-6,18, 24-26,30

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No PCT/GB2007/003712
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Patent document cited in search report	Publication date	Patent family member(s)	Publication date												
DE 3702179	A1	11-08-1988	NONE												
WO 9001902	A	08-03-1990	<table style="width: 100%; border: none;"> <tr> <td style="width: 25%;">DE</td> <td style="width: 25%;">68923448 D1</td> <td style="width: 50%;">17-08-1995</td> </tr> <tr> <td>DE</td> <td>68923448 T2</td> <td>07-12-1995</td> </tr> <tr> <td>EP</td> <td>0413028 A1</td> <td>20-02-1991</td> </tr> <tr> <td>US</td> <td>5265614 A</td> <td>30-11-1993</td> </tr> </table>	DE	68923448 D1	17-08-1995	DE	68923448 T2	07-12-1995	EP	0413028 A1	20-02-1991	US	5265614 A	30-11-1993
DE	68923448 D1	17-08-1995													
DE	68923448 T2	07-12-1995													
EP	0413028 A1	20-02-1991													
US	5265614 A	30-11-1993													
US 2003195420	A1	16-10-2003	US 2006020210 A1 26-01-2006												
US 5394877	A	07-03-1995	NONE												
WO 9731364	A	28-08-1997	<table style="width: 100%; border: none;"> <tr> <td style="width: 25%;">CA</td> <td style="width: 25%;">2246322 A1</td> <td style="width: 50%;">28-08-1997</td> </tr> <tr> <td>EP</td> <td>0883876 A1</td> <td>16-12-1998</td> </tr> <tr> <td>JP</td> <td>2000505333 T</td> <td>09-05-2000</td> </tr> </table>	CA	2246322 A1	28-08-1997	EP	0883876 A1	16-12-1998	JP	2000505333 T	09-05-2000			
CA	2246322 A1	28-08-1997													
EP	0883876 A1	16-12-1998													
JP	2000505333 T	09-05-2000													

专利名称(译)	用于将超声探头耦合到物体的装置		
公开(公告)号	<a href="#">EP2094162A1</a>	公开(公告)日	2009-09-02
申请号	EP2007823969	申请日	2007-10-01
[标]申请(专利权)人(译)	大格拉斯哥卫生局		
申请(专利权)人(译)	大格拉斯哥卫生局		
当前申请(专利权)人(译)	大格拉斯哥卫生局		
[标]发明人	ELEJALDE NAIARA WATSON MALCOLM JOHN CORNER GEORGE A		
发明人	ELEJALDE, NAIARA WATSON, MALCOLM, JOHN CORNER, GEORGE, A.		
IPC分类号	A61B8/00 G01N29/28 G10K11/02		
CPC分类号	A61B8/4422 A61B8/4281 G10K11/02		
代理机构(译)	WALKER , STEPHEN		
优先权	2006019322 2006-09-30 GB		
外部链接	<a href="#">Espacenet</a>		

#### 摘要(译)

描述了用于将超声探头 ( 24 ) 耦合到物体 ( 26 ) 的改进的耦合装置 ( 10 )。装置 ( 10 ) 特别适用于医疗装置。耦合装置 ( 10 ) 包括位于中间层 ( 16 ) 的不同侧面上的第一 ( 14 ) 和第二 ( 18 ) 可变形耦合器。采用第一耦合器 ( 14 ) 允许装置 ( 10 ) 耦合到探针 ( 24 )，而第二耦合器 ( 18 ) 提供用于将装置 ( 10 ) 耦合到物体 ( 26 ) 的装置。中间层 ( 16 ) 在声学上连接第一 ( 14 ) 和第二耦合器 ( 18 )，同时为装置 ( 10 ) 提供结构强度。可选地，护套或盖子 ( 157 ) 可以结合在联接装置 ( 141 ) 内，以便改善装置的卫生和无菌性质。