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EP 0262976 A2 **WO 2004/030762 A1**
US 5058592 A **US 4556066 A**
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(54) Abstract Title: **Transducer holder for maintaining signal-receiving contact with a patient's body**

(57) A transducer holder 20 comprising a base 22 adherently attachable to a patient's skin 12 and a retainer 24 attached or attachable to the base 22 to hold the transducer 36 in signal-receiving contact with the body. The base 22 may have one or more apertures (26, fig 2). The aperture may be open for use with an acoustic gel or closed by a barrier film. Alternatively the base 22 itself may receive signals. The base 22 may be adhesively attached to the patient's skin 12or held by suction. The retainer 24 may be in the form of one or more bands 30 or a membrane including an opening for inserting or removing the transducer 36. A method of using the transducer holder 20 is claimed. The holder may assist in monitoring a mother and baby during labour without the need for body straps.

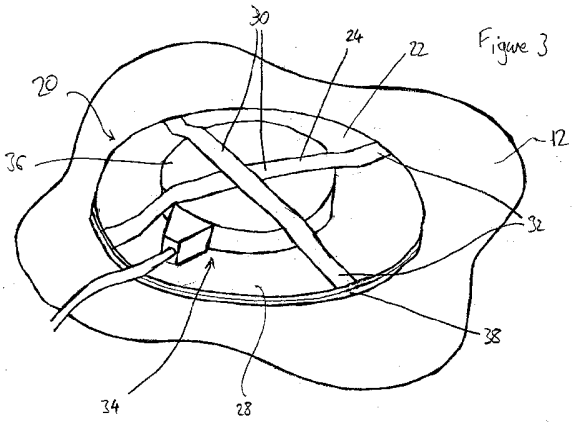

Figure 3

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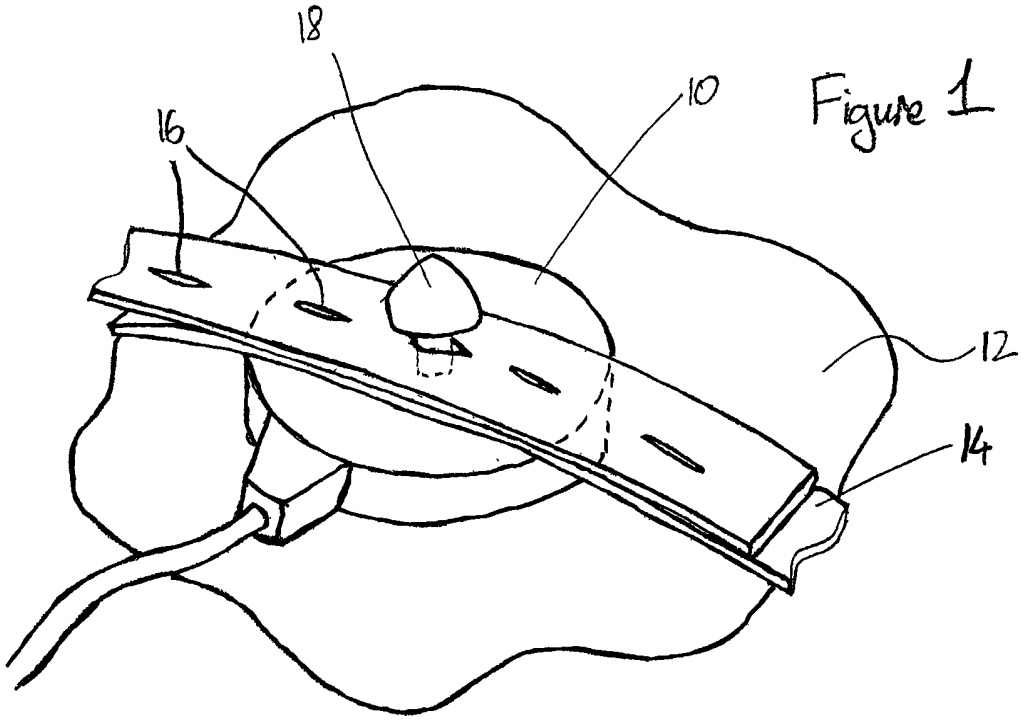
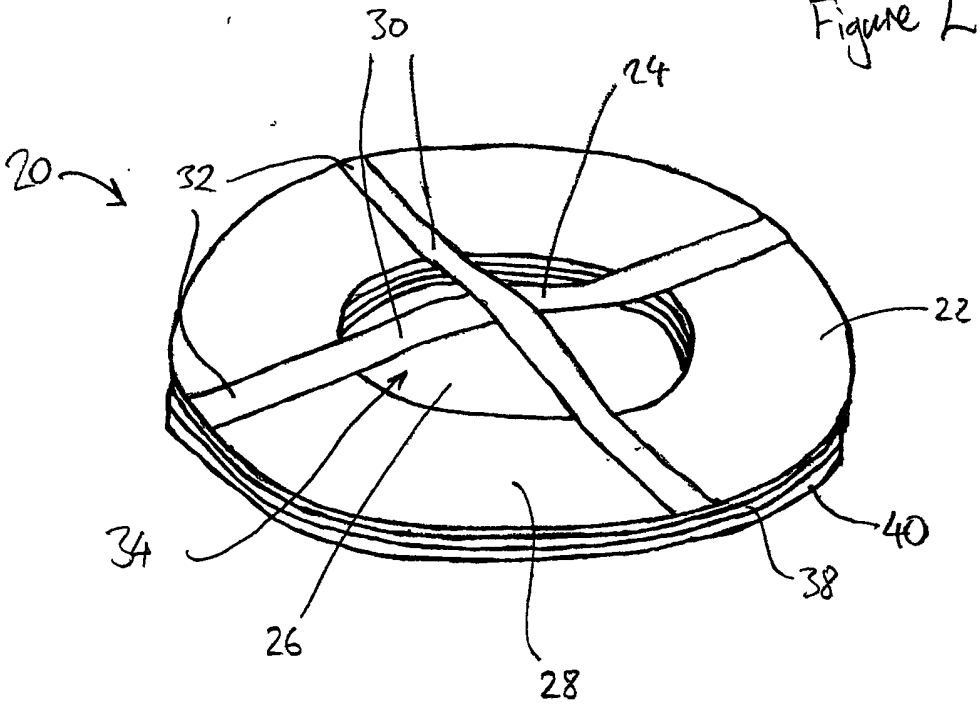


Figure 1

Figure 2



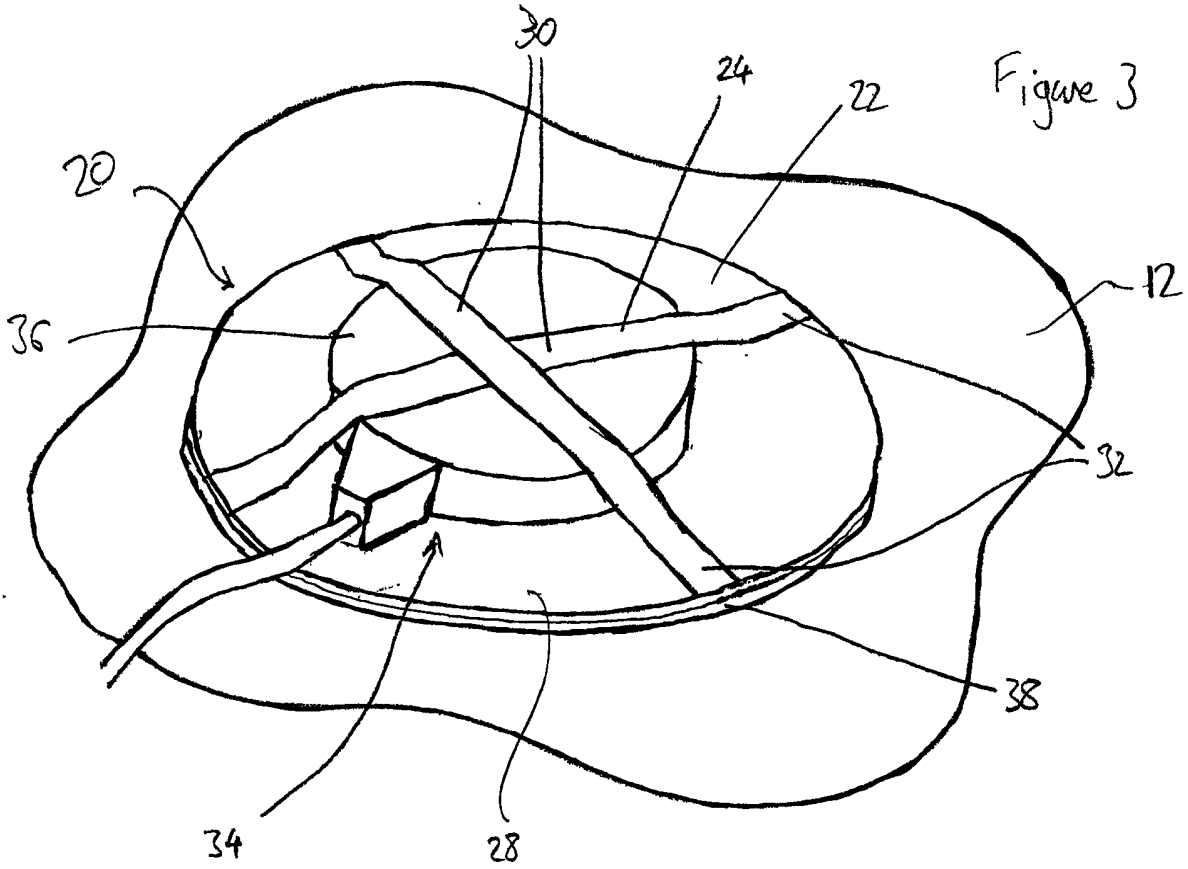


Figure 3

Figure 4

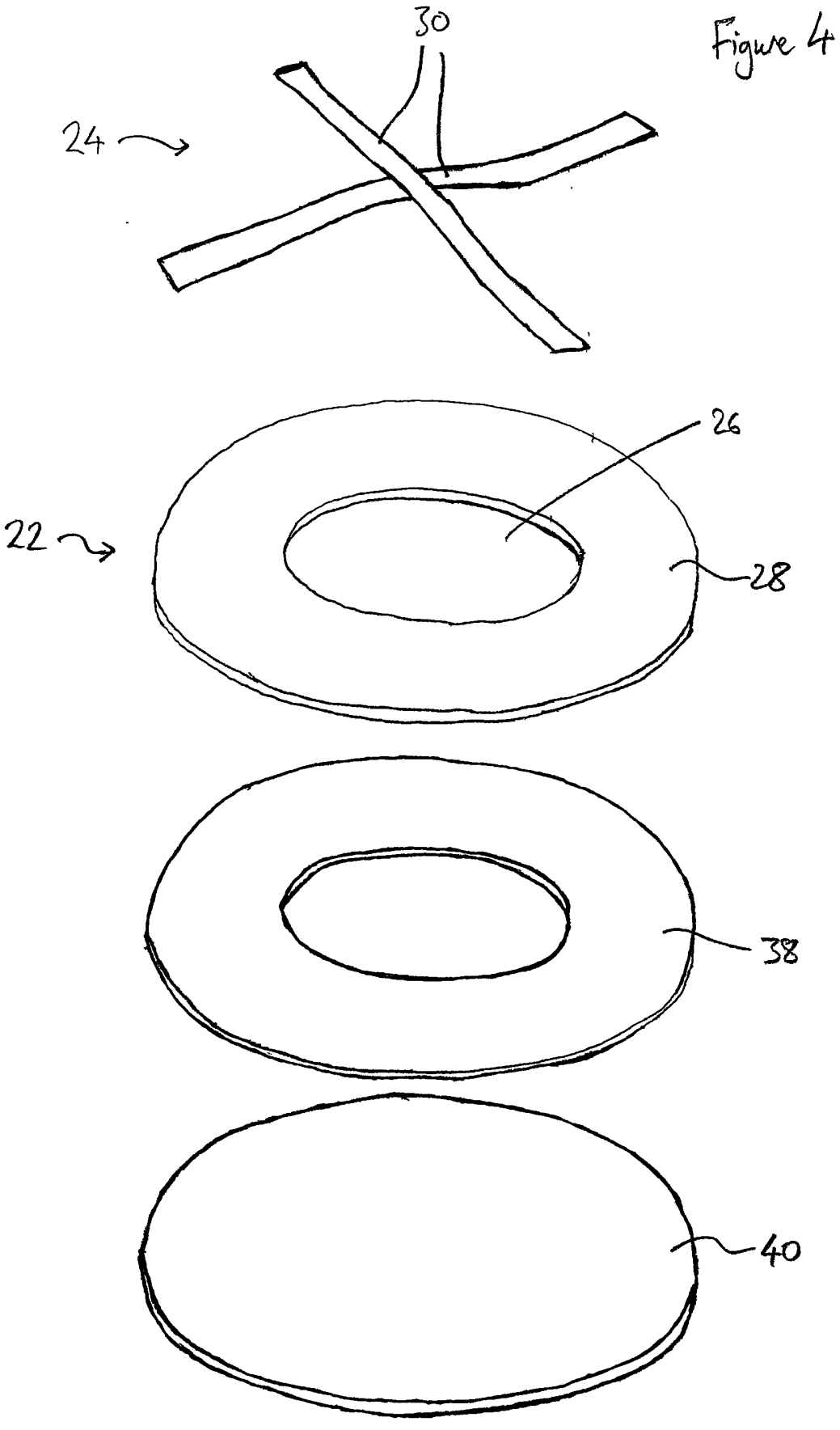


Figure 5

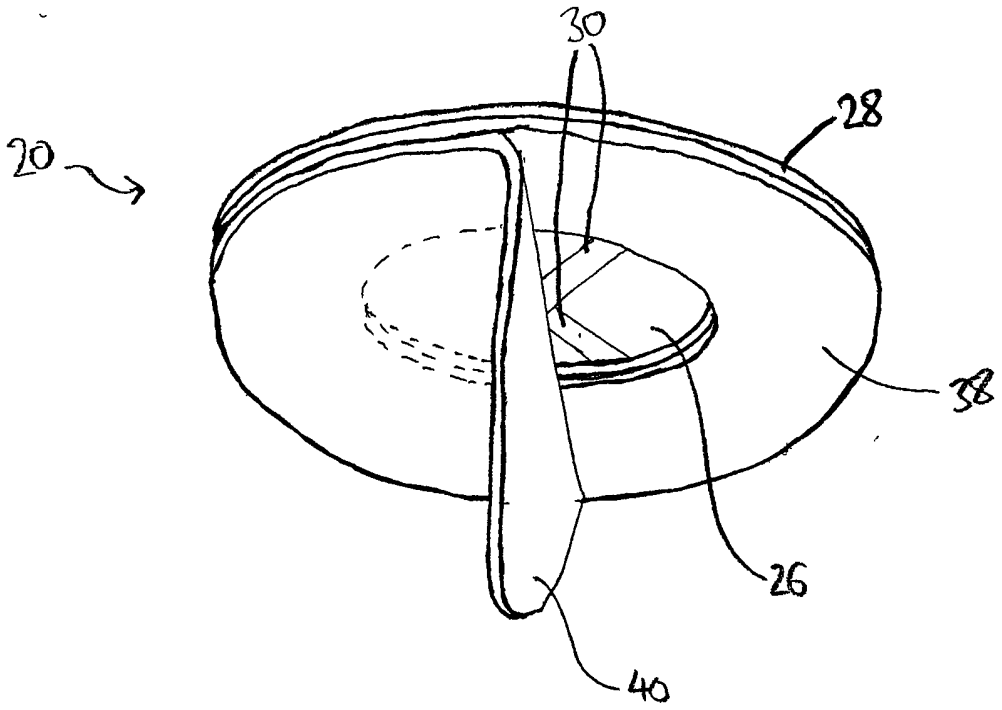
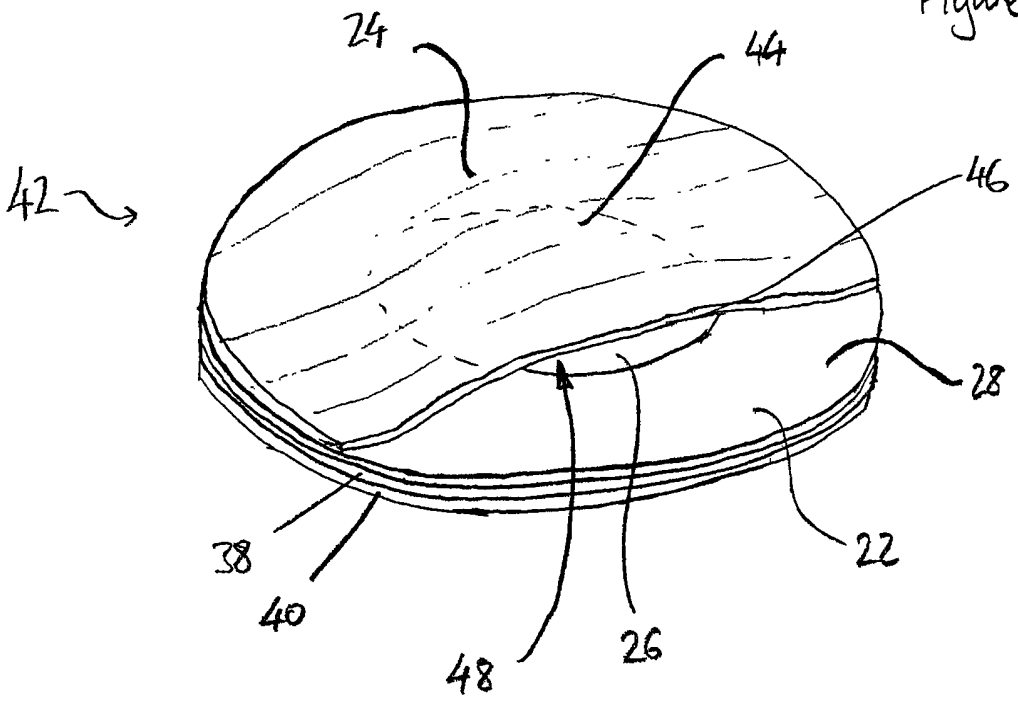


Figure 6



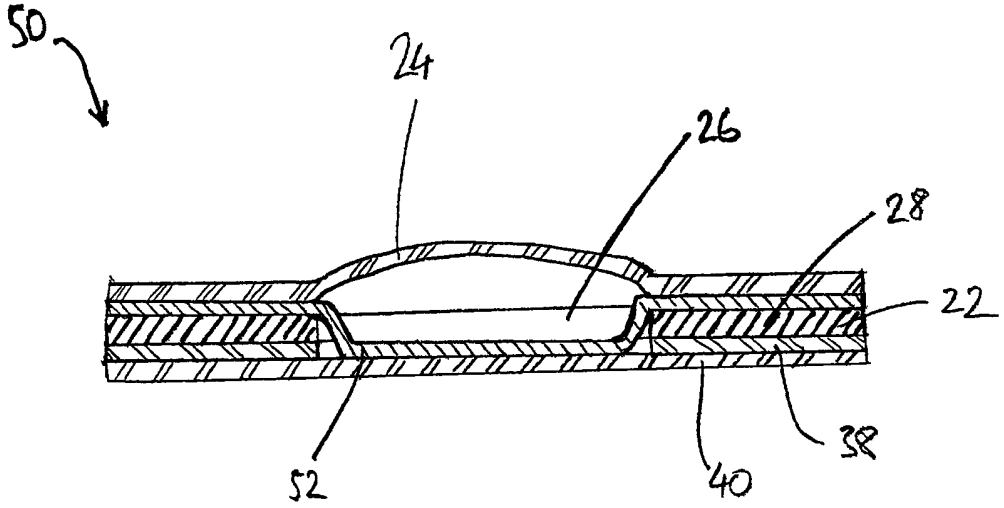


Figure 7

IMPROVEMENTS IN OR RELATING TO TRANSDUCER ATTACHMENTS

This invention relates to monitoring of patients during medical procedures, for example monitoring a mother and baby during labour. In particular, the invention relates to a transducer holder.

In medical practice, it is often desirable to monitor events occurring inside a patient's body. For example, it is common practice to monitor the fetal heartbeat during labour. Interpretation of the fetal heartbeat can give a skilled practitioner an indication of developing problems in time to take remedial action.

A fetus must obtain enough oxygen from the mother's blood, via the placenta and umbilical cord, at all times during labour. However, many factors can cause the oxygen supply to be disrupted. For example, the umbilical cord can become wrapped around the fetus or be compressed, or the mother's blood pressure can fall, diminishing the oxygen supply to the placenta. If the fetus cannot obtain enough oxygen, there is a high risk of damage to the brain, central nervous system and organs of the fetus. The longer the oxygen starvation goes on, the more likely it is that severe damage will occur. Eventually, the fetus will die.

A normal fetal heart rate is a good indicator that the fetus is extracting enough oxygen; conversely, abnormal variations in the heart rate can indicate that the fetus is

being deprived of oxygen. By continuous monitoring of the fetal heart rate, an early indication of oxygen deprivation can be obtained which can allow immediate treatment and resolution of the problem, for example by performing an emergency Caesarian section or by assisting delivery with forceps or a vacuum extractor, before the fetus is harmed.

Continuous monitoring of the fetal heartbeat is especially important when epidural anaesthesia is administered, since the mother's blood pressure may drop during the procedure and lead to fetal distress as described above.

In the worst case, continuous monitoring provides a record of the state of the baby during labour, and such a record can be useful if problems cannot be avoided and litigation ensues.

The mother's uterine contractions can also be continuously monitored. This is usually done in conjunction with fetal heart rate monitoring because the fetal heart rate usually slows down during a contraction and speeds up again after the contraction. By simultaneously monitoring the contractions and the fetal heart rate, fluctuations in this normal pattern can be identified and can be indicative of fetal distress. In addition, contraction monitoring can be used as a guide to those helping the mother through labour, who may, for example, encourage a pattern of breathing or pushing

complementary to the contractions. Also, in some cases, contraction monitoring can reveal that contractions are occurring even though the mother is unaware of them.

A known apparatus for performing fetal heart rate monitoring comprises a transducer, connected by a signal cable to a monitoring device. One or more such transducers may be held to the mother's abdomen.

Two main types of transducer are used in fetal heart rate monitoring, namely active transducers which emit ultrasound and detect a response by way of reflection, and passive transducers which do not emit ultrasound but simply detect sounds made by the fetal heart.

In an active transducer, a low-energy ultrasound beam is directed from the transducer towards the fetal heart. The ultrasound beam is reflected from the fetal heart, and the reflected beam is modified in amplitude and phase by the beating of the fetal heart. The reflected beam is detected by the transducer, which converts the reflected ultrasound beam into an output signal. The output signal is transmitted through the signal cable to the monitoring device, in which the output signal is interpreted and converted into a suitable visual or audio indication of the fetal heart rate. Fetal movement can also be detected by this kind of ultrasonic transducer.

A passive transducer is adapted to detect vibrations induced by the fetal heartbeat that are transmitted from the womb through the mother's body to her skin. The transducer produces an output signal which is transmitted through the signal cable to the monitoring device in which, again, the output signal is interpreted and converted into a suitable visual or audio indication.

Uterine contractions are typically monitored using a pressure-sensing transducer, which has a pick-up button disposed on one face. The pick-up button is held against the mother's abdomen, and communicates with a piezoelectric strain gauge within the transducer. Movements of the mother's abdomen, such as those caused by uterine contractions, are detected by the strain gauge and converted to an electrical signal which is transmitted through a signal cable to a monitoring device. The monitoring device interprets the signal and converts it into a suitable audio or visual indication of the frequency, duration and strength of the uterine contractions.

In the remainder of this specification, the invention will be described in the context of fetal heart rate monitoring. However, the invention could equally be used with a uterine contraction transducer or any transducer with a similar shape, including transducers that communicate wirelessly with the monitoring device. Indeed, the invention has benefit in patient monitoring in medical fields other than obstetrics.

Typically, a transducer for fetal heart rate monitoring is substantially disc-shaped, with a diameter of around 8 cm and a thickness of around 1 cm. One face of the disc is adapted for acoustic contact with the mother's abdomen.

In use, one face of the transducer is held in contact with the patient's skin. The transducer must be held securely to the patient's body, since good acoustic contact must be maintained between the transducer face and the patient's skin. A layer of acoustic gel may be used between the transducer face and the skin to improve the acoustic contact. Secure location of the transducer is a challenge because the patient will wish to move around, and perhaps be required to roll onto her side, during labour.

One known means for holding a transducer against a patient's skin is shown in Figure 1 of the accompanying drawings. The transducer 10 is held against the patient's skin 12 by a strap 14 provided with a row of slits 16. The row of slits 16 extends along the length of the strap 14 along its central longitudinal axis. The strap 14 is typically made from a textile, such as cotton, and may be elastic or non-elastic. In use, the strap 14 is passed around the patient's body so that the two end regions of the strap 14 cross over one another and overlap. The strap 14 is pulled tightly to put it under tension. A stud 18, provided on the exposed face of the transducer 10 opposed to the face held against the patient, locates in two aligned slits 16, one from each end region of the strap 14. The strap 14 is thereby held in tension. The tension in the strap 14

pushes the transducer 10 against the patient's body, hence maintaining the necessary acoustic contact between the transducer 10 and the skin 12.

If more than one transducer is being used – as will be the case when fetal heart rate and the mother's contractions are being monitored simultaneously – more than one strap must also be used.

There are several disadvantages with this known transducer holding means. To provide the force required to hold the transducer on the patient's skin and maintain acoustic contact, the strap must be pulled tightly around the patient's abdomen. This can cause the patient considerable discomfort, which is particularly undesirable during a traumatic experience such as childbirth. Moreover, the or each strap hampers access to the patient's abdomen and back, hindering comforting and soothing actions such as massaging or rubbing. More seriously, straps are incompatible with the administration of epidural anaesthesia, as will now be explained.

Epidural anaesthesia is often administered for pain relief during labour, and requires the patient to roll from her back onto her side and to lie still for an extended period for administration of the anaesthetic into the spine. One or more straps around the abdomen will prevent access to the required area of the spine and must therefore be removed for the duration of the procedure. Consequently, it is common practice for the transducer to be held against the mother's abdomen by a medical practitioner

while epidural anaesthesia is administered, inconveniently requiring the removal and subsequent re-fitting of the or each strap and occupying a member of medical staff to hold the transducer in position. For example, a highly-skilled midwife might typically be occupied for half an hour or more in performing this task and be unable to perform other duties. This represents a considerable waste of both human and financial resources.

The strap is so cumbersome that it can hamper the mother's mobility, which is dangerous since immobility can cause a decrease in the blood supply and, hence, the oxygen supply to the fetus, thereby increasing the risk of complications. In addition, immobility can slow down labour and increase the pain and discomfort of the mother. For these reasons, the mother is encouraged to move as much as possible.

When the mother does move, the strap can come loose or be displaced. If the strap slips, acoustic contact between the transducer and the patient may be lost, interrupting monitoring and therefore putting the fetus at risk. In addition, such a failure is inconvenient and time consuming, and can also cause further discomfort and distress to the mother.

Furthermore, and in discordance with currently preferred medical practice, transducer straps are usually re-usable. Because of the woven textile construction of the strap and the nature of childbirth, the strap tends to become soiled with blood and other

bodily fluids. Even if the strap is washed and disinfected between patients, it can act as a potential source of cross-infection. Similarly, the transducers themselves must be re-used since they are costly to manufacture, and consequently also pose a risk of cross-infection between patients. Often, transducers cannot be cleaned well enough to remove all potential sources of contamination. For example, they cannot be autoclaved to kill bacteria, and in some cases they are not watertight and therefore cannot be immersed in disinfectant.

It is an aim of the present invention to provide a means for holding a transducer on a patient's skin that alleviates or overcomes the abovementioned difficulties.

Against this background, the invention resides in a transducer holder for holding a transducer in signal-receiving contact with a patient's body, the holder comprising: a base adherently attachable to the patient's skin; and a retainer attached or attachable to the base; wherein, in use, the retainer holds the transducer in signal-receiving contact with the patient's body and retains the transducer in the holder.

Throughout this specification, references to adherently attachable encompass adhesively attachable and attachable by suction.

The base may have an aperture for enabling said signal-receiving contact. The aperture may, for example, be circular. It is preferably disposed centrally with respect

to the base. The aperture may be defined by a border, and the border may be ring-shaped. More than one aperture may be provided.

The aperture may be open to permit direct signal-receiving contact between the transducer and the patient's skin in use, optionally through a layer of acoustic gel. Alternatively, the aperture is closed by a barrier film through which signal-receiving contact may be effected, again optionally through one or more layers of acoustic gel. The barrier film reduces the risk of cross-infection by preventing the transducer from touching the patient's skin, in use.

If the aperture is defined by a border, the barrier film may be attached to the border. The barrier film may, for example, be attached to an upper surface of the border, facing away from the patient's skin in use. In this case, the barrier film may be dished, having a raised periphery overlying the border and a depressed centre to lie against the patient's skin in use. Alternatively, the barrier film could be attached to an undersurface of the border, facing toward the patient's skin in use.

Optionally, the base is adapted to permit said signal-receiving contact through the base, in which case the base may be uninterrupted by any apertures.

The base may, for example, be a disc, and the base may be flexible. Conveniently, the base has self-supporting stiffness to allow easy handling of the holder.

Advantageously, the base is adhesively attachable to the patient's skin. Preferably, the base has an adhesive undersurface, facing toward the patient's skin in use. The undersurface of the base may be coated with an adhesive layer. If the base has an aperture defined by a border, the adhesive layer is suitably applied to the underside of the border. Where the aperture is bridged by a barrier film, the adhesive layer may also be applied to the barrier film. In all such arrangements, a backing layer may be attached to the adhesive undersurface of the base, the backing layer being removable to expose the adhesive undersurface. This allows the holder to be conveniently packaged and handled.

The base may be attachable by suction to the patient's skin, as an alternative to the base being adhesively attachable.

Preferably, the retainer is resiliently extensible to provide location and retention forces. The holder may include an insertion opening through which the transducer can be introduced to and removed from the holder.

The insertion opening may be defined by the retainer. For example, the retainer may be defined by one or more bands that, in use, extend over the transducer held by the holder, in which case the periphery of the insertion opening is defined by a band. Alternatively, the retainer may be defined by a membrane having free edges defining

the periphery of the insertion opening. The free edges may be in the body of the membrane. For example, the free edges may be defined by a cut or slit through the membrane.

The insertion opening may alternatively be defined by the base. For example, the insertion opening may be an aperture in the base.

The insertion opening could instead be defined partially by the retainer and partially by the base. For example, the retainer could be defined by one or more bands that, in use, extend over the transducer held by the holder, in which case the periphery of the insertion opening is defined partially by a band. Alternatively, the retainer could be defined by a membrane having a free edge partially defining the periphery of the insertion opening, in which case the free edge may be at the periphery of the membrane.

The retainer may comprise one or more bands that, in use, extend over the transducer held by the holder. Preferably, the or each band is substantially straight in plan view. Advantageously, the or each band has a convex cross section rising from the base from the ends of the band toward its centre. The or each band may extend over an aperture in the base.

The retainer may comprise two or more bands that, optionally, intersect. If the base is a disc, the bands may intersect at the diametric centre of the base. Preferably, the bands are attached or attachable to the base at attachment points, although it is also possible for the or each band to be integral with the base. The attachment points may be equi-angularly spaced around the base. Alternatively, the bands may be parallel to one another.

Instead of bands, the retainer may comprise a membrane that, in use, extends over the transducer held by the holder. The membrane may have a convex cross section rising from the base from the edges of the membrane toward its centre. The membrane may be attached or attachable to the base around a major portion of its periphery, a minor unattached peripheral portion of the membrane having a free edge. Preferably, the membrane is part-circular and the free edge defines a chord of the circle. Alternatively, the membrane may be attached or attachable to the base around the whole of its periphery.

The invention extends to the combination of a transducer held by the transducer holder as previously described. The base of the holder may have an aperture wider than the face of the transducer that is to be in signal-receiving contact with the patient's body. Alternatively, the holder may have an aperture narrower than the face of the transducer that is to be in signal-receiving contact with the patient's body. Preferably, the retainer is extended elastically to accommodate the transducer.

The inventive concept also embraces a method for holding a transducer in signal-receiving contact with a patient's body, the method comprising: adherently attaching a transducer holder to the patient's skin; and removably attaching the transducer to the holder so that the transducer is in signal-receiving contact with the patient's body.

Also within the inventive concept is a method for holding a transducer in signal-receiving contact with a patient's body, the method comprising: removably attaching a transducer to a transducer holder; and then adherently attaching the transducer holder to the patient's skin so that the transducer is in signal-receiving contact with the patient's body.

In either of the methods described above, the holder may be adhesively attached to the skin. For example, the holder may be attached to the skin by applying an adhesive undersurface of the holder to the skin. Furthermore, either method may include removing a backing layer to expose the adhesive undersurface before the holder is attached to the skin. The methods may include applying an adhesive to the undersurface of the holder before attaching the holder to the skin. Alternatively, the holder may be attached to the patient's skin by first applying an adhesive to an area of the patient's skin, and then applying the holder to the adhesive.

The holder may be attached to the patient's skin by suction, as an alternative to adhesively attaching the holder to the skin.

In all of these methods, a layer of acoustic gel may be applied to at least one of the patient's skin, the transducer holder, and the transducer.

The methods of the invention may further comprise removing the transducer from the holder, leaving the holder attached to the patient's skin. For example, a plurality of holders may be attached to the patient's skin at different locations and, following removal of the transducer from one holder of the plurality, that transducer may be attached to another holder of the plurality.

A holder may be removed from the patient's skin and relocated to another location on the patient's skin. The transducer may be retained in the holder during said relocation.

The transducer is preferably attached to the holder by insertion through an insertion opening. In that case, the transducer may be removed from the holder through the insertion opening. Preferably, the insertion opening deforms resiliently to allow the transducer to pass during said insertion or removal, such that insertion or removal overcomes resilient resistance.

Because the transducer holder of the invention is attached to the patient only in the location where the measurement is required, the present invention affords the patient significantly less disturbance, discomfort and distress than other means for holding a transducer, for example, the strap of Figure 1. A particular benefit is that epidural anaesthesia may be administered while a transducer remains in its holder, because access to the patient's spine is unrestricted.

In general, the transducer holder and transducer may be fitted to the patient at the beginning of the procedure and left in place throughout. Alternatively, the transducer holder may be left in place while the transducer is removed, for example if the patient is to be moved. The transducer can then be easily re-inserted into the transducer holder with the minimum of discomfort to the patient. Similarly, two or more transducer holders could be attached to the abdomen in a plurality of locations at the start of a procedure, and transducers may be fitted to the transducer holders only when required during the procedure, or one transducer could be moved around the abdomen between a plurality of pre-applied holders. Moreover, the transducer could be inserted or removed from the transducer holder before or after the transducer holder is attached to the patient's skin.

The transducer holder of the invention is particularly suitable to be manufactured from low-cost, readily available materials such as polymer sheets or films and is simple in construction. Consequently, the holder can be manufactured cheaply and is

suitable for once-only, disposable use, avoiding the risks of cross-infection as well as the inconvenience and expense of cleaning and disinfecting associated with re-use of medical devices.

Reference has already been made to Figure 1, which is a perspective drawing of a fetal heart rate transducer in use with a known strap-type transducer holding means in position on a patient. The present invention will now be described, by way of example only, with reference to the remaining drawings, in which:

Figure 2 is a perspective drawing of a transducer holder according to a first embodiment of the present invention;

Figure 3 is a perspective drawing of the transducer holder of Figure 2, in use holding a transducer in a desired position on a patient's abdomen;

Figure 4 is an exploded drawing of the transducer holder of Figure 2;

Figure 5 is a perspective drawing showing the underside of the transducer holder of Figure 2;

Figure 6 is a perspective drawing of a transducer holder according to a second embodiment of the present invention; and

Figure 7 is a sectional drawing of a third embodiment of the present invention.

Referring firstly to Figures 2 to 4, in a first embodiment of the present invention there is provided a transducer holder 20, comprising a base 22 and an elastic retainer 24. The base 22 is a flexible disc with a circular aperture 26 in its centre defining an annular ring 28. The aperture 26 is dimensioned to receive the face of a transducer. In use, the base 22 is adhesively attached to a patient's body at a desired location. The elastic retainer 24 extends over the aperture 26 to hold a transducer both within the holder 20 and with respect to a patient to whom the holder 20 is attached.

Whilst the base 22 is flexible to conform to a patient's body contours, it is advantageous for the base 22 to have some self-supporting stiffness so that the holder 20 can easily be removed from packaging and applied to the patient's skin 12 without curling up, wrinkling or otherwise unhelpfully deforming.

In this embodiment, the elastic retainer 24 comprises two elastic strips or bands 30. The bands 30 are attached to the ring 28 at attachment points 32 at or close to the ends of the bands 30. The attachment points 32 are equi-angularly spaced around the aperture 26. The bands 30 therefore run diametrically across the base 22 from one side of the ring 28 over the aperture 26 to the opposite side of the ring 28 and intersect orthogonally at the diametric centre of the base 22 and the aperture 26.

The bands 30 are generally straight when viewed in plan but when viewed from the side, the bands 30 curve upwardly moving inwardly from the ring 28 to the diametric centre of the base 22. A cross-section along one of the bands 30 is a shallow hump shape. This aids insertion of a transducer as will now be described.

The ring 28, the bands 30, and particularly the gaps between adjacent attachment points 32, define insertion openings 34 through which a transducer 36 can be passed to lie under, and be restrained by, the intersecting bands 30. In that position, when the transducer 36 is centrally disposed with respect to the base 22, the transducer 36 is received within the aperture 26 where it is held in acoustic contact with the patient's body.

Each insertion opening 34 is shaped and dimensioned so that, when the transducer 36 is passed through an insertion opening 34 into the space between the bands 30 and the base 22, the bands 30 hold the transducer 36 both within the holder 20 and with respect to the patient to whom the holder 20 is attached. More specifically, the gaps between adjacent attachment points 32 and the length of the bands 30 are such that the bands 30 must deform elastically to admit the transducer 36. The transducer 36 is thereby held resiliently within the embrace of the bands 30. The holding force of the bands 30 is sufficient that the transducer 36 is held within the holder 20 under the normal conditions of use, for example when the patient moves. However, the

transducer 36 can easily be removed from the holder 20 through the insertion opening 34 when required by manipulating and stretching the bands 30, or simply by pulling the transducer 36 out through the insertion opening 34 against the resilience of the bands 30.

As shown most clearly in Figure 5, the bottom surface of the ring 28 is provided with an adhesive layer 38 which may be coated or otherwise applied to the ring 28. The adhesive layer is itself annular, substantially of the same size as the ring 28.

The adhesive material of the adhesive layer 38 is of a known type suitable for effecting a strong but non-permanent bond with the patient's skin. For example, a suitable adhesive is hydrocolloid adhesive supplied by Coloplast Ltd.

The transducer holder 20 is provided with a removable backing layer 40 shown partially removed in Figure 5, which covers the adhesive layer 38 to prevent the adhesive drying out or sticking to anything else before use, such as to packaging during storage. A tab (not shown) may project beyond the general periphery of the backing layer 40 to ease its removal.

When required for use on a patient, the backing layer 40 is peeled off the adhesive layer 38 and the transducer holder 20 is applied to the patient's skin 12 in the desired location. The adhesive layer 38 adheres to the skin 12 and keeps the holder 20 in

position on the patient. The transducer 36 is then inserted through an insertion opening 34, so that its face is pressed through the aperture 26 against the patient's abdomen. As the bands 30 must deform elastically in order to accommodate the transducer 36, the elastic restoring forces of the bands 30 provide a net force acting on the transducer 36 in the direction of the patient's abdomen. This net force pushes the face of the transducer 36 against the patient's abdomen to maintain acoustic contact. By a combination of the adhesive layer 38 and the elastic retainer 24 defined by the bands 30, the transducer 36 is held firmly in place against the patient's body, even if the patient moves or rolls over.

In describing a second embodiment of the present invention, the transducer holder 42 shown in Figure 6, like numerals will be used for like parts. In this embodiment, the elastic retainer 24 is a resiliently-stretchable polymeric membrane 44. The provision of a membrane 44 is advantageous in that it covers the transducer in use and so protects the transducer from soiling.

The membrane 44 is attached to the ring 28 around most of its periphery and is part-circular, terminating in an unattached free edge 46 that is a chord of the circle. In plan view, the free edge 46 is disposed slightly outside the aperture 26 in the ring 28. Otherwise, the membrane 44 is of substantially the same diameter as the ring 28, or at least wider than the aperture 26 so as to provide for attachment to the ring 28.

It will be appreciated that the membrane 44 and the base 22 therefore define a pocket that receives a transducer in use. The transducer is introduced through an insertion opening 48 defined between the free edge 46 of the membrane 44 and the ring 28. Like the bands 30 of the first embodiment, the membrane 44 defines a shallow hump in cross-section to ease insertion of the transducer. The membrane 44 is therefore slightly wider in its unattached state than when attached to the ring 28.

The dimensions of the membrane 44 and the insertion opening 48 are such that the membrane 44 must deform elastically to accommodate a transducer within the space between the membrane 44 and the base 22. The elastic restoring forces exerted by the membrane 44 cause a net force to act on the transducer, pushing it against the patient's abdomen through the aperture 26 of the base 22. The restoring forces also retain the transducer within the holder 42 under the normal conditions of use, for example when the patient moves. However, the transducer can be removed from the holder 42 through the insertion opening 48 when required, simply by pulling out the transducer against the resilience of the membrane 44.

In a third embodiment of the present invention, shown in Figure 7, a transducer holder 50 that is otherwise similar to the first and second embodiments further comprises a barrier film 52 which extends across the aperture 26 of the base 22. The barrier film 52 is attached to the top surface of the ring 28 and, as illustrated, is dished by the thickness of the ring 28 to lie against the patient's skin when the backing layer

40 has been peeled off and the adhesive layer 38 has been applied to the skin. The barrier film 52 is advantageous in that it prevents direct contact between the transducer and the patient and therefore helps to keep the transducer clean. It also reduces the risk to the patient of cross-infection from a soiled transducer.

Acoustic contact between the face of the transducer and the patient's skin is maintained through the barrier film by the action of the elastic restoring forces of the retainer acting on the transducer as previously described.

If desired, in any embodiment of the invention, acoustic contact can be further improved by applying a layer of acoustic gel between the transducer and the skin or between the transducer and the barrier film, if present. For example the transducer holder may be supplied with the upper surface of the barrier film pre-coated with acoustic gel. Moreover, acoustic gel may also be applied between the barrier film, if present, and the skin.

Because the transducer holder of the invention is simple in construction and can be easily manufactured from cheap materials, it can be produced at low cost and is suitable for disposable, once-only use.

It will be apparent to the reader that several modifications are possible within the scope of the present invention. For example, the aperture in the base may be larger

than, smaller than, or the same diameter as, the face of the transducer. Also, as some transducers have more than one sensor or transmitter on their face, it is possible to provide more than one aperture in the base.

It will be appreciated that the elastic retainer could comprise any arrangement appropriate for providing the necessary force on the transducer. If the elastic retainer comprises elastic bands in accordance with the first embodiment of the invention, any number of elastic bands in any geometrical arrangement could be provided. For example, a single wider band could be provided, delivering two insertion openings, one to each side of the band. Two or more bands could be arranged parallel to one another as chords, defining insertion openings between the bands and/or outside the bands. Alternatively, more than two bands could be disposed across diameters of the base at suitable mutual orientations, for example at equiangular intervals. It is also possible for two or more bands to be oriented other than in equi-angular disposition. A combination of diametric and other chordal bands could also be provided.

The insertion opening could be provided in any convenient way. For example, in the second embodiment of the invention, the insertion opening could be a slit or hole in the membrane, in which case the membrane could be completely circular such that the entire perimeter of the membrane could be attached to the base. Also, the transducer could be introduced to the transducer holder through the aperture in the

base, in which case the insertion opening could be designed to allow passage of the connecting lead, if present.

Advantageously, the adhesive of the adhesive layer can be re-adhered to the skin after removal, so that the transducer holder can be removed and re-applied as necessary. Other adherent arrangements are possible within the broadest concepts of the invention. For example, the adhesive layer and backing layer may be omitted and an alternative means of affixing the transducer holder to the patient's skin may be provided, for example double-sided tape or a separately applied adhesive. Furthermore, the transducer holder could be attached to the patient's skin by suction, for example by shaping the base to act as a suction cup.

Alternative embodiments of the barrier film lie within the scope of the present invention. For example, the barrier film may be attached to the bottom surface of the ring. Alternatively, a barrier between the patient and the transducer may be provided by eliminating the aperture of the base so that the material of the base itself forms the barrier. That is to say, the base can be a simple acoustically-transparent disc rather than being defined by a ring around an aperture. Moreover, the adhesive layer may or may not extend across all or part of the underside of the barrier film.

The transducer holder could be of any size and shape appropriate for accommodating any design of transducer. Therefore, whilst having particular advantages in the field

of obstetrics, the present invention is not limited to any specific design of transducer, and could be used in many different medical procedures.

For these and other reasons, reference should be made to the accompanying claims rather than to the foregoing specific description in interpreting the scope of the invention.

CLAIMS

1. A transducer holder for holding a transducer in signal-receiving contact with a patient's body, the holder comprising:

a base adherently attachable to the patient's skin; and

a retainer attached or attachable to the base;

wherein, in use, the retainer holds the transducer in signal-receiving contact with the patient's body and retains the transducer in the holder.

2. The transducer holder of Claim 1, wherein the base has an aperture for enabling said signal-receiving contact.

3. The transducer holder of Claim 2, wherein the aperture is circular.

4. The transducer holder of Claim 2 or Claim 3, wherein the aperture is disposed centrally with respect to the base.

5. The transducer holder of any of Claims 2 to 4, wherein the aperture is defined by a border.

6. The transducer holder of Claim 5, wherein the border is ring-shaped.

7. The transducer holder of any of Claims 2 to 6, wherein the base has more than one aperture.

8. The transducer holder of any of Claims 2 to 7, wherein the aperture is open to permit direct signal-receiving contact between the transducer and the patient's skin in use, optionally through a layer of acoustic gel.

9. The transducer holder of any of Claims 2 to 7, wherein the aperture is closed by a barrier film through which signal-receiving contact may be effected.

10. The transducer holder of Claim 9, wherein the aperture is defined by a border and the barrier film is attached to the border.

11. The transducer holder of Claim 10, wherein the barrier film is attached to an upper surface of the border, facing away from the patient's skin in use.

12. The transducer holder of Claim 11, wherein the barrier film is dished, having a raised periphery overlying the border and a depressed centre to lie against the patient's skin in use.

13. The transducer holder of Claim 10, wherein the barrier film is attached to an undersurface of the border, facing toward the patient's skin in use.

14. The transducer holder of any preceding claim, wherein the base is adapted to permit said signal-receiving contact through the base.

15. The transducer holder of Claim 14 when dependent upon Claim 1, wherein the base is uninterrupted by any apertures.

16. The transducer holder of any preceding claim, wherein the base is a disc.

17. The transducer holder of any preceding claim, wherein the base is flexible.

18. The transducer holder of any preceding claim, wherein the base has self-supporting stiffness.

19. The transducer holder of any preceding claim, wherein the base is adhesively attachable to the patient's skin.

20. The transducer holder of Claim 19, wherein the base has an adhesive undersurface, facing toward the patient's skin in use.

21. The transducer holder of Claim 20, wherein the undersurface of the base is coated with an adhesive layer.

22. The transducer holder of Claim 21, wherein the base has an aperture defined by a border and the adhesive layer is applied to the underside of the border.

23. The transducer holder of Claim 22, wherein the aperture is bridged by a barrier film and the adhesive layer is also applied to the barrier film.

24. The transducer holder of any of Claims 20 to 23, wherein a backing layer is attached to the adhesive undersurface of the base, the backing layer being removable to expose the adhesive undersurface.

25. The transducer holder of any of Claims 1 to 18, wherein the base is attachable to the patient's skin by suction.

26. The transducer holder of any preceding claim, wherein the retainer is resiliently extensible.

27. The transducer holder of any preceding claim, wherein the holder includes an insertion opening through which the transducer may be introduced to and removed from the holder.

28. The transducer holder of Claim 27, wherein the insertion opening is defined by the retainer.

29. The transducer holder of Claim 28, wherein the retainer is defined by one or more bands that, in use, extend over the transducer held by the holder and the periphery of the insertion opening is defined by a band.

30. The transducer holder of Claim 28, wherein the retainer is defined by a membrane having free edges defining the periphery of the insertion opening.

31. The transducer holder of Claim 30, wherein the free edges are in the body of the membrane.

32. The transducer holder of Claim 31, wherein the free edges are defined by a cut through the membrane.

33. The transducer holder of Claim 27, wherein the insertion opening is defined by the base.

34. The transducer holder of Claim 33, wherein the insertion opening is an aperture in the base.

35. The transducer holder of Claim 27, wherein the insertion opening is defined partially by the retainer and partially by the base.

36. The transducer holder of Claim 35, wherein the retainer is defined by one or more bands that, in use, extend over the transducer held by the holder and the periphery of the insertion opening is defined partially by a band.

37. The transducer holder of Claim 35, wherein the retainer is defined by a membrane having a free edge partially defining the periphery of the insertion opening.

38. The transducer holder of Claim 37, wherein the free edge is at the periphery of the membrane.

39. The transducer holder of any of Claims 1 to 29 or 33 to 36, wherein the retainer comprises one or more bands that, in use, extend over the transducer held by the holder.

40. The transducer holder of Claim 39, wherein the or each band is substantially straight in plan view.

41. The transducer holder of Claim 39 or Claim 40, wherein the or each band has a convex cross section rising from the base from the ends of the band toward its centre.

42. The transducer holder of any of Claims 39 to 41, wherein the or each band extends over an aperture in the base.

43. The transducer holder any of Claims 39 to 42, wherein the retainer comprises two or more bands.

44. The transducer holder of Claim 43, wherein the bands intersect one another.

45. The transducer holder of Claim 44, wherein the base is a disc and the bands intersect at the diametric centre of the base.

46. The transducer holder of any of Claims 43 to 45, wherein the bands are attached or attachable to the base at attachment points.

47. The transducer holder of Claim 46, wherein the attachment points are equi-angularly spaced around the base.

48. The transducer holder of Claim 43, wherein the bands are parallel to one another.

49. The transducer holder of any of Claims 1 to 28, 30 to 35, 37 or 38, wherein the retainer comprises a membrane that, in use, extends over the transducer held by the holder.

50. The transducer holder of Claim 49, wherein the membrane has a convex cross section rising from the base from the edges of the membrane toward its centre.

51. The transducer holder of Claim 49 or Claim 50, wherein the membrane is attached or attachable to the base around a major portion of its periphery, a minor unattached peripheral portion of the membrane having a free edge.

52. The transducer holder of Claim 51, wherein the membrane is part-circular and the free edge defines a chord of the circle.

53. The transducer holder of Claim 49 or Claim 50, wherein the membrane is attached or attachable to the base around the whole of its periphery.

54. In combination, a transducer held by the transducer holder of any preceding claim.

55. The combination of Claim 54, when the holder is as defined in any of Claims 1 to 53 except Claim 15, wherein the base of the holder has an aperture wider than the face of the transducer that is to be in signal-receiving contact with the patient's body.

56. The combination of Claim 54, when the holder is as defined in any of Claims 1 to 53 except Claim 15, wherein the base of the holder has an aperture narrower than the face of the transducer that is to be in signal-receiving contact with the patient's body.

57. The combination of any of Claims 54 to 56, wherein the retainer is extended elastically to accommodate the transducer.

58. A method for holding a transducer in signal-receiving contact with a patient's body, the method comprising:

adherently attaching a transducer holder to the patient's skin; and

removably attaching the transducer to the holder so that the transducer is in signal-receiving contact with the patient's body.

59. A method for holding a transducer in signal-receiving contact with a patient's body, the method comprising:

removably attaching a transducer to a transducer holder; and

adherently attaching the transducer holder to the patient's skin so that the transducer is in signal-receiving contact with the patient's body.

60. The method of Claim 58 or Claim 59, wherein the holder is adhesively attached to the patient's skin.

61. The method of Claim 60, wherein the holder is attached to the skin by applying an adhesive undersurface of the holder to the skin.

62. The method of Claim 61, further comprising removing a backing layer to expose the adhesive undersurface before the holder is attached to the skin.

63. The method of any of Claims 60 to 62, further comprising applying an adhesive to the undersurface of the holder before attaching the holder to the skin.

64. The method of Claim 60, wherein the holder is attached to the patient's skin by first applying an adhesive to an area of the patient's skin, and then applying the holder to the adhesive.

65. The method of Claim 58 or Claim 59, wherein the holder is attached to the patient's skin by suction.

66. The method of any of Claims 58 to 65, comprising applying a layer of acoustic gel to at least one of the patient's skin, the transducer holder, and the transducer.

67. The method of any of Claims 58 to 66, further comprising removing the transducer from the holder, leaving the holder attached to the patient's skin.

68. The method of Claim 67, comprising attaching a plurality of holders to the patient's skin at different locations and following removal of the transducer from one holder of the plurality, attaching that transducer to another holder of the plurality.

69. The method of any of Claims 58 to 68, comprising removing a holder from the patient's skin and relocating the holder to another location on the patient's skin.

70. The method of Claim 69, wherein the transducer is retained in the holder during said relocation.

71. The method of any of Claims 58 to 70, wherein the transducer is attached to the holder by insertion through an insertion opening.

72. The method of Claim 71, wherein the transducer is removed from the holder through the insertion opening.

73. The method of Claim 71 or Claim 72 wherein the insertion opening deforms resiliently to allow the transducer to pass during said insertion or removal.

74. A transducer holder, substantially as hereinbefore described with reference to, or as illustrated in, any of Figures 2 to 7 of the accompanying drawings.

75. The combination of a transducer held by a transducer holder, substantially as hereinbefore described with reference to, or as illustrated in, Figure 3 of the accompanying drawings.

76. A method for holding a transducer in signal-receiving contact with a patient's body, substantially as hereinbefore described with reference to, or as illustrated in, any of Figures 2, 3, 5, 6 or 7 of the accompanying drawings.

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Application No: GB0604093.5 **Examiner:** Stephanie Parry

Claims searched: 1 to 76 **Date of search:** 28 June 2006

Patents Act 1977: Search Report under Section 17

Documents considered to be relevant:

Category	Relevant to claims	Identity of document and passage or figure of particular relevance
X	1-6, 8, 16-22, 24, 26, 54, 55	US 4556066 A (SEMROW) Figs, col 1 line 57 to col 2 line 30
X	1-5, 9, 10, 14, 15, 17-21, 24, 27, 28, 54, 58, 60-62, 66, 67	WO 2004/030762 A1 (TALISH) Figs, page 2 line 30 to page 3 line14, page 6 lines 9-24
X	1-6, 8, 16, 18-22, 54	EP 1265223 A2 (CHANDRARATNA) Figs, paragraph 0011
X	1-6, 8, 16-22, 24, 26-28, 54, 55	US 5058592 A (WHISLER) Figs, col 2 lines 5-34
X	1-6, 9-13, 16-22, 24, 26-28, 54, 58, 60-62, 67	EP 0262976 A2 (HON) Figs, col 4 lines 7-40, col 8 lines 1-10
X	1-6, 8, 16-22, 24, 27, 28, 54, 58, 66	EP 0331348 A1 (HON) Figs, col 2 lines 13-30, col 5 lines 24-44
X	1-6, 16-18, 25-28, 54, 59, 65	US 4355643 A (LAUGHLIN) Figs, col 2 lines 6-18

Categories:

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application

Field of Search:

Search of GB, EP, WO & US patent documents classified in the following areas of the UKC^{X} :

A5R; H4J

Worldwide search of patent documents classified in the following areas of the IPC

A61B; G10K

The following online and other databases have been used in the preparation of this search report

EPODOC, WPI