Abstract: An improved patient monitoring system is described herein. In particular, the present invention provides an improved system, method, and kit for positioning and removably mounting, often repeatedly, a monitor transducer on a patient, for example, an external fetal monitor used during pregnancy and childbirth labor. The improved system avoids many of the disadvantages of conventional monitoring systems in that it maintains transducer position during patient movement, allows the position of the transducer to be changed without repositioning the patient, allows for simple and expeditious adjustment so as to maximize signal quality without causing patient discomfort, eliminates the need for a belt circumferentially disposed about the patient's abdomen, and can be applied to a wide array of body types, including patients having round abdomens. The system, method, and kit of the present invention is not only both efficient and effective but also economical.
SYSTEM, METHOD, AND KIT FOR POSITIONING A MONITOR TRANSUDER ON A PATIENT

Priority
This application claims the benefit of provisional application 60/682,298 filed May 18, 2005, the contents of which are hereby incorporated by reference in its entirety.

Technical Field Of The Invention
The present invention relates to an improved patient monitoring system and method. More particularly, the present invention relates to a system, method and kit for positioning and removably mounting one or more monitor transducers on a patient, for example, an external fetal monitor system used during pregnancy and childbirth labor.

Background Of The Invention
Fetal monitoring is a valuable tool for monitoring and assessing fetal status and labor progress during pregnancy and childbirth. While there are various types of monitors, all monitor the same signals and assess fetal well-being by measuring parameters such as fetal heart rate and observing the effect of maternal influences, such as labor contractions, on the baby’s heart rate. In the modern hospital environment of today, monitoring is most often done electronically.

There are two types of electronic monitoring methods: internal and external. Internal monitoring involves affixing a transducer to the baby’s scalp to monitor heart rate, and an intrauterine pressure catheter to monitor contractions. Internal monitoring can only be used after the cervix is dilated at least two centimeters. Because of this, internal monitoring cannot be used during preterm or early labor and is generally used only after signs of fetal distress are observed through an external monitoring method.

The conventional external electronic fetal monitor is a two-belt ultrasound device that is strapped about the mother’s abdomen. One belt holds a listening device (e.g., an acoustic signal transducer) in place while the other belt holds the contraction monitor (e.g., a pressure signal transducer). The nurse or midwife frequently must
adjust the belts to get the best readings from each device. The response of the baby’s heartbeat to uterine contractions is used to determine the baby’s health and well-being. For example, a deceleration or drop in fetal heart rate following a contraction may indicate that the baby is not getting enough oxygen, an early sign of possible fetal distress. One or both of the transducers may be used intermittently or continuously during labor. Frequently the transducers are used intermittently during early labor and continuously during later stages of labor. In addition, mothers hospitalized for preterm labor and pregnancy complications often must wear the external fetal monitor continuously for extended periods.

The present method for external fetal monitoring, using circumferential belts to position the heart rate and uterine contraction transducers, has several distinct disadvantages. For example, the belts limit the mobility of the mother since movement by the mother frequently causes the positions of the belts and transducers to shift, thereby causing the loss of one or both of the signals. The loss of the fetal heartbeat signal due to movement of the transducer may cause an alarm on the monitor to sound requiring the attention of a clinician and causing anxiety to the mother. Often the mother must remain relatively motionless, in a more or less prone position, a circumstance that both increases patient discomfort and slows the progress of labor. Each time a transducer is dislodged by patient movement, a nurse or other clinician must hunt around with the transducer to find a “sweet spot” in which a clear signal is obtained and adjust the associated belt to keep the transducer in this position. This happens frequently during labor. Also, as the baby often changes position, the transducer location must also be changed to obtain a suitable signal. This repositioning of the transducer requires an associated repositioning of the appropriate belt, an operation which frequently causes discomfort for the mother.

If the monitor is being used intermittently, it is necessary to apply and remove the associated belts from the mother, again causing discomfort. In addition, some patients have a shape which does not allow transducers to be reliably positioned on their abdominal region using the current belt system. Accordingly, there is a need for an improved system and method for positioning and retaining monitoring transducers on a patient. The present invention addresses that need.
Summary Of The Invention

It is an object of the present invention to provide a system, method, and kit for positioning and removable mounting a monitor transducer on a patient.

It is a further object of the present invention to provide a system, method, and kit wherein the transducer position is maintained during patient movement.

It is a further object of the present invention to provide a system, method, and kit that allows the position of the transducer to be changed without repositioning the patient.

It is a further object of the present invention to provide a system, method, and kit that allows for simple and expeditious adjustment so as to maximize signal quality without causing patient discomfort.

It is a further object of the present invention to provide a system, method, and kit that eliminates the need for a belt circumferentially disposed about the patient’s abdomen.

It is a further object of the present invention to provide a system, method, and kit that can be applied to a wide array of body types, including patients having round abdomens.

It is a further object of the present invention to provide a system, method, and kit that is both efficient and effective yet also economical.

Accordingly, the present invention provides an external fetal monitoring system comprising:

(a) two or more anchor strips, each of which include a layer of adhesive material disposed on one side and one or more fasteners disposed on the opposite side;

(b) one or more elastomeric straps, each of which include one or more fastener receivers disposed at either end, wherein the fasteners and fastener receivers mate to form a fastener pair; and

(c) one or more monitor transducers, each of which include retaining features on one side thereof, the retaining features allowing said one or more transducers to be affixed to said one or more elastomeric straps.

In one embodiment, transducer(s) are slidably affixed to the elastomeric strap(s). Alternatively, each transducer may be held in place by first and second strap
“halves” or “portions”, wherein one end of a strap portion is attached to the transducer and the other end is attached to the anchor strip.

In a preferred embodiment, the transducers include a pressure signal transducer and an acoustic signal transducer, such as a sonic or ultrasonic transducer.

In a further preferred embodiment, the fastener pair is selected from mating hook and loop fabric, hooks and eyes, buttons and button holes, and snaps.

The present invention further provides a method for positioning at least one monitor transducer on a patient by means of the above described system. In a preferred embodiment, the method comprises the steps of:

(a) attaching the two or more anchor strips in a more or less vertical and laterally spaced fashion to a patient’s abdomen;

(b) mounting the one or more monitor transducers to the one or more elastomeric straps;

(c) extending the one or more elastomeric straps in a relatively horizontal fashion across the patient’s abdomen and attaching either end of the straps to the anchor strips by means of the mating fasteners and fastener receivers; and

(d) positioning the one or more transducers so that it measures a desired parameter.

In a further preferred embodiment, the desired parameters to be measured include fetal heartbeat and intrauterine contraction frequency, strength and duration.

The present invention further provides a kit for external fetal monitoring comprising:

(a) one or more pairs of anchor strips, each of which include a layer of adhesive material disposed on one side and one or more fasteners disposed on the opposite side;

(b) one or more elastomeric straps, each of which include one or more fastener receivers disposed at either end, wherein the fasteners and fastener receivers mate to form a fastener pair; and

(c) one or more monitor transducers, each of which include retaining features on one side thereof, the retaining features allowing said one or more transducers to be slidably affixed to said one or more elastomeric straps.
These and other objects and features of the invention will become more fully apparent when the following detailed description is read in conjunction with the accompanying figures and examples. However, it is to be understood that both the foregoing summary of the invention and the following detailed description are of illustrative and preferred embodiments, and are not restrictive of the invention or other alternate embodiments of the invention.

**Brief Description Of The Drawings**

Figure 1 is a side elevational view of a prior art means for mounting transducers on a pregnant patient during a prenatal diagnostic procedure (e.g., a non-stress test) or during preterm, early or active labor.

Figure 2 is a side elevational view of a mounting system constructed in accordance with the principles of this invention for mounting a pair of transducers to a patient’s abdomen, for example to a pregnant patient during a prenatal diagnostic procedure or labor.

Figure 3 is a plan view of the objects of Figure 2.

Figure 4 is a plan view of an anchor strip for use with the system of Figure 2.

Figure 5 is a perspective view of the objects of Figure 4.

Figure 6 is a side elevational sectional view of the object of Figure 4 at location A – A of Figure 4.

Figure 7 is a side elevational view of a lateral strap of the system of Figure 2.

**Detailed Description Of The Preferred Embodiments**

The embodiments described herein are merely intended to illustrate the principles of the invention. Those skilled in the art will recognize that variations and modifications may be made to the embodiments without changing the principles of the invention herein disclosed. Accordingly, the accompanying figures, described in detail below, that depict aspects of the invention are in no way intended to limit the scope of the present invention.

As used herein, the noted directional terms relate to a human body in a standing position. For instance, “up” refers to in the direction of the head, “down” refers to in the direction of the feet. Herein, the “vertical” direction is parallel to the axis of the body and the “horizontal” direction is parallel to the floor. “Lateral” refers
to the direction extending away from the center of the body whereas “medial” refers to a direction extending toward the center of the body.

The present invention contemplates the use of one or more “transducers”. The transducer may be any device that converts one parameter, such as sound, temperature, pressure, light, or other signals, into an electronic signal. Exemplary transducers include, but are not limited to, piezoelectric crystals, microphones, photoelectric cell, and the like. In the context of external fetal monitoring, a first transducer measures an acoustic signal (e.g., the baby’s heartbeat) while a second transducer measures a pressure signal (e.g., an intrauterine contraction). While the preferred embodiments utilize sonic and ultrasonic transducers, other measuring mechanisms are contemplated.

Referring now to the figures, Figure 1 shows a prior art method of positioning and retaining monitoring transducers to the body of a pregnant woman, for example during routine or emergency assessments and childbirth labor. A first transducer 1 is retained on the body of the woman by a first circumferential belt 2. A second transducer 3 is retained on the body of the patient by a second circumferential belt 4. Transducers 1 and 3 are positioned so as to maximize signal strength, the signals being the fetal heartbeat and uterine contractions. Discomfort during pregnancy and labor results in frequent movement of the patient, which, in turn, necessitates frequent repositioning of the belts and/or transducers. Because belts 2 and 4 are circumferential, movement by the patient frequently causes movement of the belts and/or dislodging of the transducers from their positions.

Referring now to Figures 2 and 3 showing a mounting system 10 for transducers constructed in accordance with the principles of this invention, first anchor strip 100 and second anchor strip 200 are positioned more or less vertically on lateral sides of the abdomen, and first transverse strap 300 and second transverse strap 400 extend between anchor strips 100 and 200. First transducer 12 is removably affixed to first lateral strap 300, and second transducer 14 is removably affixed to second lateral strap 400.

Referring now to Figures 4 through 6, anchor strip 100 of length 102 has a medial edge 104 and a lateral edge 106 which forms a plurality of laterally extending, elongated portions (e.g., tabs) 108 of length 110 spaced distance 112 apart. When strip 100 is applied to an abdominal wall, elongated portions 108 wrap adapt to the curvature of the wall laterally so as to provide both increased patient comfort and
increased holding strength, particularly when the strip is subjected to a lateral force as frequently occurs during routine use. Length 102 is preferably an integral multiple of distance 112. For instance, if distance 112 is one inch, length 102 is preferably an integral multiple thereof such as, for example, five inches, six inches or seven inches. As best seen in Figure 6, anchor strip 100 has a first layer 114, formed of a compliant material such as polymeric foam, a second layer 116 formed of an adhesive material suitable for application to the skin in medical applications, and a third layer 118 having a lower surface which is permanently joined to layer 114 and an upper surface having a plurality of hook-shaped protrusions 120 suitable for removably fastening to a pile fabric so as to form a hook and loop fastener pair. Lateral anchor strip 200 is identical in construction to medial anchor strip 100.

Referring now to Figure 7, first lateral strap 300 is made from an elastomeric material and has a top surface 302 and a bottom surface 304. Retaining features 306 on the back of first transducer 12 retain the transducer on strap 300 yet allow for slidable movement of the transducer along the length of said strap. Strap 300 has on its bottom surface 304 first region 306 and second region 308 in which a pile material is bonded to surface 304. The pile material is suitable for forming a hook and loop fastener pair with protrusions 120 of layer 118 of anchor strips 100 and 200.

The reverse orientation, wherein the lateral strap is provided with the hook protrusions and the anchor strip is provided with the pile material, is also contemplated. Other fastening means for removably affixing lateral straps 300 and 400 to anchor strips 100 and 200 are also contemplated. For instance, hooks which engage the fabric of the elastomeric strap per se rather than a pile material affixed thereto, may be mounted to the anchor strips or vice versa. Alternatively, such hooks may engage a plurality of eyelets in the fabric of the elastomeric strap. In other embodiments, buttons and/or snaps may be used.

In use, first anchor strip 100 and second anchor strip 200 are applied to the abdominal wall, laterally opposed and more or less vertically. First transducer 12 is removably mounted to first lateral strap 300. Transducer 12 is positioned on the abdomen of the patient in a location which gives an acceptable signal to the monitoring system. While maintaining the transducer location, first end 320 of strap 300 is removably affixed to first anchor strip 100, the pile of first region 306 of bottom surface 304 of strip 300 and hooked protrusions 120 of third layer 118 of anchor strip 100 forming a fastener pair. Second end 322 of strip 300 is removably
affixed to second anchor strip 200 in the same manner as end 320, an initial tension being applied to strip 200 prior to fastening so as to ensure acceptable compressive force between transducer 12 and the patient's abdominal wall. Second transducer 14 is positioned and retained on the patient in the manner as transducer 12 using second lateral strip 400.

If repositioning of a transducer is required, the ends of the appropriate lateral strap are removed from the anchor strips and the transducer is repositioned and affixed in the manner previously described.

During use, the elastomeric straps can be rapidly adjusted, removed and reapplied as needed. For example, their placement and the amount of initial tension can be adjusted to maximize patient comfort. In addition, one or more of the anchor strips can be removed and reapplied as needed. For example, it may be necessary to replace one or more of the anchor strips, for instance during prolonged labor. In such circumstances, fresh (unused) anchor strips can be applied and the previously used lateral strips and transducers may be mounted in the manner previously described.

Another aspect of the present invention is a low-cost kit for mounting transducers to a patient during labor, the kit containing multiple lateral straps and multiple pairs of anchor strip assemblies, all components of the kit being fabricated from economic materials such that they may be discarded after use.

In the embodiment previously herein described, transducers 12 and 14 are slidably positioned on straps 300 and 400 respectively. In other embodiments, strap 300 or strap 400 or both are formed so has to have a first portion and a second portion, each portion having a first end removably attachable to a transducer, and a second end attachable to an anchor strip as previously herein described.

While the present invention is described in terms of two anchor strips, two traverse straps and two transducers, it will be readily apparent to those skilled in the art that multiple strips, straps, and transducers may be combined as needed, particularly when the pregnancy involves multiple fetuses.

The disclosure of each publication, patent or patent application mentioned in this specification is specifically incorporated by reference herein in its entirety.

The invention has been illustrated by reference to specific examples and preferred embodiments. However, it should be understood that the invention is intended not to be limited by the foregoing description, but to be defined by the appended claims and their equivalents.
What is claimed:

1. An external fetal monitoring system comprising:
   a. two or more anchor strips, each of which include a layer of adhesive
      material disposed on one side and one or more fasteners disposed on
      the opposite side;
   b. one or more elastomeric straps, each of which include one or more
      fastener receivers disposed at either end, wherein said fasteners and
      fastener receivers mate to form a fastener pair; and
   c. one or more monitor transducers, each of which include retaining
      features on one side thereof, said retaining features allowing said one
      or more transducers to be affixed to said one or more elastomeric
      straps.

2. The system of claim 1, wherein said one or more transducers are slidably
   affixed to said one or more elastomeric straps.

3. The system of claim 1, wherein said one or more elastomeric straps are
   comprised of a first portion and a second portion, each portion having a first
   end for attachment to a transducer and a second end for attachment to an
   anchor strip.

4. The system of claim 1, wherein said fastener and said fastener receiver mate to
   form a hook and loop fastener pair.

5. The system of claim 1, wherein said fastener comprises a plurality of hooked
   protrusions and said fastener receiver comprises a plurality of eyes or a pile
   fabric pad.

6. The system of claim 1, wherein said fastener comprises a button and said
   fastener receiver comprises a button hole.

7. The system of claim 1, wherein said fastener and said fastener receiver
   comprise snaps.

8. The system of claim 1, wherein said one or more anchor strips comprise a
   medial edge and a lateral edge, wherein said lateral edge comprises a plurality
   of elongated, laterally extending tabs.

9. The system of claim 1, wherein said one or more anchor strips are formed
   from a compliant material.

10. The system of claim 9, wherein said complaint material is polymeric foam.
11. The system of claim 1, wherein said elastomeric strap comprises a fabric belt.
12. The system of claim 1, wherein said monitor transducer comprises a sonic or ultrasonic transducer.
13. The system of claim 1, wherein said monitor transducers comprise an acoustic signal transducer and a pressure signal transducer.
14. A method for positioning at least one monitor transducer on a patient comprising the steps of:
   a. attaching two or more anchor strips, each of which include a layer of adhesive material disposed on one side and one or more fasteners disposed on the opposite side, in a more or less vertical and laterally spaced fashion, to a patient’s abdomen;
   b. providing one or more elastomeric straps, each of which include one or more fastener receivers disposed at either end and one or more monitor transducers mounted thereon;
   c. extending said one or more elastomeric straps in a relatively horizontal fashion across the patient’s abdomen and attaching either end of said straps to said anchor strips by means of said mating fasteners and fastener receivers; and
   d. positioning said one or more transducers so that it measures a desired parameter.
15. The system of claim 14, wherein said one or more transducers are slidably affixed to said one or more elastomeric straps.
16. The system of claim 14, wherein said one or more elastomeric straps are comprised of a first portion and a second portion, each portion having a first end for attachment to a transducer and a second end for attachment to an anchor strip.
17. The method of claim 14, further including the step of adjusting said one or more transducers without detaching said elastomeric straps from said anchor strips.
18. The method of claim 14, wherein said one or more transducers comprise an acoustic signal monitor and a pressure signal monitor.
19. The method of claim 14, wherein the desired parameter comprises fetal heartbeat.
20. The method of claim 14, wherein the desired parameter comprises intrauterine contractions.

21. A kit for external fetal monitoring comprising:
   a. one or more pairs of anchor strips, each of which include a layer of adhesive material disposed on one side and one or more fasteners disposed on the opposite side;
   b. one or more elastomeric straps, each of which include one or more fastener receivers disposed at either end, wherein said fasteners and fastener receivers mate to form a fastener pair; and
   c. one or more monitor transducers, each of which include retaining features on one side thereof, said retaining features allowing said one or more transducers to be slidably affixed to said one or more elastomeric straps.