

Sensor device, monitor and sensor assembly

Field of the invention

[0001] The present invention relates to a physiological sensor device. More particularly, although not exclusively, the invention relates to an electrophysiological sensor device. The sensor device may be of the kind which is worn on the body, most preferably torso-worn. One intended application is pregnancy monitoring. However, the invention may have many other applications for physiological monitoring.

[0002] This application claims priority from Australian provisional patent application 2023903483, filed in our name, the contents of which are incorporated herein by reference.

Background of the invention

[0003] Continuous monitoring of electrophysiological information via torso-worn sensors is an attractive modality which allows the freedom of patient movement within both the clinical and home healthcare environments. Previous designs for torso-worn electrophysiological measurement devices have utilised a range of approaches for connecting with sensor arrays placed on the skin. These designs have included:

- 1) Consumable sensor patches with a rigid connector which magnetically attaches to a rigid non-moving measurement device; and
- 2) Integrated sensor/device constructions which require shipment back to the manufacturer for refurbishing between uses.

[0004] These approaches however involve design complexity which entail high consumable manufacturing or refurbishment costs and thus limit their utility for widespread, low-cost clinical use. Particularly in the domain of pregnancy monitoring there is a need for comfortable, low-cost torso-worn electrophysiological sensors for more convenient monitoring of maternal and fetal activities.

[0005] The object of the present invention is to meet the above need or at least provide the public with a useful choice over known sensors.

[0006] Reference to any prior art in the specification is not an acknowledgment or suggestion that this prior art forms part of the common general knowledge in any jurisdiction or that this prior art could reasonably be expected to be understood, regarded as relevant, and/or combined with other pieces of prior art by a skilled person in the art.

Summary of the invention

Wearable sensor with folding portion

[0007] In accordance with a first aspect of the present invention, there is provided, a wearable sensor for sensing physiological characteristics of a subject, including:

a strip portion having a first side;

one or more electrodes to obtain signals indicative of physiological characteristics, each of the one or more electrodes having a contact face on the first side of the strip portion;

one or more electrical connector contact portions, each of the one or more electrical connector contact portions having an electrical contact face on the first side of the strip portion; and

one or more conductive paths from the one or more electrodes to the connector contact portions,

wherein the strip portion defines a fold portion which is foldable, such that in the folded configuration of the strip portion, the electrical contact faces of the electrical connector contact portions are disposed on a side of the wearable sensor which is opposite to the side of the wearable sensor on which the electrode(s) are disposed.

[0008] In accordance with another aspect of the present invention, there is provided, a wearable sensor for sensing physiological characteristics of a subject, including:

a strip portion having a first side;

one or more electrodes to obtain signals indicative of physiological characteristics, each of the one or more electrodes having a contact face on the first side of the strip portion;

one or more electrical connector contact portions, each of the one or more electrical connector contact portions having an electrical contact face on the first side of the strip portion; and

one or more conductive paths from the one or more electrodes to the electrical connector contact portions,

wherein the strip portion defines a fold portion which is folded such that the electrical contact face(s) of the electrical connector contact portions are disposed on a side of the wearable sensor which is opposite to the side of the wearable sensor on which the one or more electrodes are disposed.

[0009] The electrical contact face(s) of the one or more electrical connector contact portions may be exposed (for the purpose of making electrical contact) on the side of the wearable sensor opposite to that side on which the one or more electrodes are disposed, or alternatively, the electrical contact face(s) of the one or more electrical connector contact portions may have a removable cover. The removable cover may provide protection for the electrical contact face(s) of the one or more electrical connector contact portions until the wearable sensor is ready for use. Accordingly, the electrical contact face(s) of the one or more electrical connector contact portions are configured to be readily accessible and electrically connected to a monitoring device.

[0010] The strip portion may comprise a flexible strip portion.

[0011] The one or more electrodes may be printed onto a substrate, preferably a flexible substrate. For example, the substrate may be comprised of thermoplastic polyurethane (TPU) or polyethylene terephthalate (PET). Preferably the substrate is comprised of compressible material such as TPU.

[0012] The electrodes may be printed from materials as one or more stacks on the substrate. Likewise, the one or more connector contact portions may be printed onto the substrate. Similarly, the one or more conductive paths may be printed onto the substrate. Preferably, the electrode(s), the connector contact portion(s) and the conductive path(s) are integrated and disposed on the first side of the strip portion. This avoids the need for vias to route the conductive path(s) through the strip portion to the other side, which increases manufacturing complexity. Preferably, the or each electrode, the associated connector contact portion and the conductive path therebetween are integrated into a single stack of printed materials. The substrate and the electrically conductive printed layers may define the strip portion, along with one or more other printed or applied layers such as one or more shielding layer(s), one or more dielectric layer(s) and one or more adhesive layer(s).

[0013] The portion of the strip portion which is foldable may be defined by a fold portion. The fold portion may be relatively less flexible compared to one or more other portions of the strip portion. This relative rigidity may be simply effected by the folding of the strip portion, thereby doubling the layers. In the fold portion of the strip portion, there may be a contacts region and an overlaid region, with the contacts region overlaying the overlaid region upon folding. The contacts region and the overlaid region may be commensurate in size. The contacts region and the overlaid region may be commensurate in shape. The contacts region may be superimposed over the overlaid region once folded. The wearable sensor may comprise the fold portion being pre-folded.

[0014] The fold portion of the strip portion could also be less flexible compared to one or more other portions of the strip portion as a result of one or more stiffening layers disposed on the substrate to confer less flexibility to the fold portion. Such layer(s) may be a printed layer(s). The stiffening layer(s) could be disposed on the contacts region or the overlaid region or both. The combination of doubling and printed layers may lead to this relative rigidity of the fold portion.

[0015] A crease or region of increased flexibility compared to the fold portion may be provided to facilitate folding. Preferably, this is comprised of the stiffening layer(s) being absent in that region. In other words, the contacts region and the overlaid region are relatively stiffer than a hinge region extending therebetween. The contacts region and the

overlaid region preferably have spaced edges. In one or both of the contacts region and the overlaid region, the spaced edge may contain an indent. The hinge region may be connected at the indent. The hinge region may be of reduced length compared to the length of the spaced edges. The indent(s) facilitates folding or bending of the hinge region along an axis oriented substantially parallel with the spaced edges, with the axis positioned midway across the width. In this way, the contacts region and the overlaid region may overlay each other in a manner whereby the hinged region doesn't project beyond the spaced edge of one or both of the contacts region and the overlaid region.

[0016] Adhesive may be provided on the fold portion to retain the fold portion in the folded configuration. The fold portion may be factory configured or alternatively could be folded immediately prior to use.

[0017] The fold portion may include alignment features. Alignment features of the wearable sensor may be mutually cooperable with alignment features of a monitoring device (otherwise referred to as a "monitor"). For instance, one or more apertures may be provided on the wearable sensor for receipt of corresponding projections in the monitoring device.

[0018] The wearable sensor may be comprised of one or more arms extending from a central region, such as the fold portion. Each of the arms may include one or some of the electrode(s). Alternatively only a subset of the arms may include electrode(s). For instance, there may be first and second arm portions which each include electrode(s), while a third arm portion is provided for stability of securement. For instance, the first arm portion may be an extension of the fold portion. For instance, the contacts region and the overlaid region may be arranged in series with the first arm portion. A plurality of the sensors may be disposed on or integrated with the first arm portion. In use, the first arm portion is intended to extend transversely across the torso of a subject. In a pregnancy application, the first arm portion is intended to traverse the torso above the enlarged abdomen (baby bump) of the pregnant woman.

[0019] The first arm portion may include skin adhesive to aid securement of the first arm portion to the body of the subject. Preferably, the skin adhesive is arranged to surround the contact face of each electrode. Skin adhesive may be arranged in an annulus around

each electrode. The skin adhesive around the electrodes may be provided on a foam pad configured in a substantially annulus shape.

[0020] The wearable sensor may have a contiguous adhesive layer which integrates the adhesive layer required for adhering the arms to the subject, as well as securing together the two portions of the fold portion. Alternatively, the adhesive layer may be discontinuous, with discrete portions of adhesive arranged in discrete regions. For example, each of the arms may have a discrete portion of adhesive, with the adhesive on the fold portion discrete from the portions of adhesive on the arms.

[0021] The second arm portion may be provided with an elbow such that an upper arm portion of the second arm portion extends substantially orthogonal to the first arm portion and a lower arm portion of the second arm portion extends substantially parallel to the first arm portion. The second arm portion may be connected to the fold portion, preferably the overlaid portion.

[0022] In use, the lower arm portion of the second arm portion is disposed to extend substantially parallel to the first arm portion across the torso of a subject. In a pregnancy application, the lower arm portion is intended to traverse the torso below the enlarged abdomen (baby bump) of the pregnant woman. A plurality of the electrodes may be disposed on or integrated with the second arm portion.

[0023] As all be appreciated, the conductive paths from each of the electrode(s), traverse towards the contact portions. Depending upon the layout of the conductive paths, the conductive paths from the first arm portion and the second arm portion may converge in the fold portion. Preferably, these conductive parts converge in the overlaid portion. Since the conductive paths will be required to fold in the folding operation of the fold portion, it is preferable that the conductive paths are comprised of a flexible material, such as a conductive flexible ink, more preferably a conductive flexible silver ink. It is also preferred that the conductive parts are comprised of a material which is foldable without degradation of its electrically conductive properties in a manner that would affect obtaining a suitable measurement.

[0024] The conductive flexible ink should be selected such that its adhesive properties are compatible with the selected substrate.

[0025] The second arm portion may include skin adhesive to aid securement of the second arm portion to the body of the subject. Preferably, the skin adhesive is arranged to surround the contact face of each electrode. Skin adhesive may be arranged in an annulus around each electrode. The skin adhesive around the electrodes may be provided on a foam pad configured in a substantially annulus shape.

[0026] The third arm portion is preferably oriented transversely to the first arm portion, and most preferably, orthogonal to the first arm portion. This orientation of the third arm portion helps carry the weight of the monitoring device, when in use. The third arm portion may be aligned with the upper arm portion. Preferably, the third arm portion is aligned with the upper arm portion on opposite sides of the fold portion.

[0027] Preferably, the third arm portion does not include any electrodes. The majority of the surface area of the third arm portion may comprise a layer of skin adhesive to adhere to the torso of the subject.

[0028] While the foregoing describes the third arm portion aligned with the upper arm portion on opposite sides of the overlaid portion, other configurations are also possible. For example, the third arm portion and the overlaid portion could be offset in the blank (unfolded) configuration of the wearable sensor since the contacts region overlays the overlaid region in the folded configuration of the wearable sensor and thus the third arm portion and the upper arm portion will come to align in any case. It is also possible for the third arm portion to be contiguous with the upper arm portion, with the fold portion juxtaposed to the aligned and joined third arm portion and upper arm portion.

[0029] Suitably, there is a respective path from each of the one or more sensors to a respective connector contact portion.

[0030] The fold portion of the wearable sensor may incorporate compressible material to aid with sealing at the monitor. For instance, where the fold portion incorporates the substrate, the compressibility is afforded by the compressible substrate.

[0031] Any of the features described below in connection with other aspects of the invention may be applied to this aspect of the invention.

Wearable assembly – thin profile of second housing portion

[0032] In accordance with a second aspect of the present invention, there is provided, a wearable sensor assembly for sensing physiological characteristics of a subject including:

a wearable sensor including a flexible strip portion, the wearable sensor provided with one or more electrodes to obtain signals indicative of physiological characteristics, and one or more connector contact portions;

a monitor including:

a housing including first and second housing portions which are relatively movable, the housing being adapted to clamp at least a portion of the flexible strip portion between the first and second housing portions in a closed position thereof;

one or more monitor contact portions provided on the first housing portion for electrical connection with the connector contact portions to receive signals therefrom;

a seal to seal the electrical connection between the monitor contact portions and the connector contact portions in the closed position of the housing; and

wherein the second housing portion is thinner in profile than the first housing portion, and the wearable sensor assembly is configured to be worn with the second housing portion closer to the subject than the first housing portion.

[0033] In use, it is proposed that the second housing portion is disposed adjacent the subject's skin. Used in this way, it places the clamped portion of the wearable sensor closer to the subject's skin, spaced only by the thickness of the second housing portion. This results in the wearable sensor assembly being more wearable in terms of comfort and reduced tendency to detach from the subject.

[0034] As will be appreciated, the electrodes will be oriented towards the subject's skin on a first side of the flexible strip portion. Accordingly, it is necessary to route the conductive path through to the connector contact portion(s) which are positioned to face the first housing portion and make contact with the monitor contact portion(s). Accordingly, the connector contact portion(s) will be on the opposite side of the wearable sensor to the electrodes in order to face the monitor contact portions on the first housing

portion. Vias formed in the flexible strip portion may be provided to route the conductive path to the opposite side of the strip portion. However, in a preferred form of the invention, the electrodes, the conductive path and the electrodes are printed onto the first side of flexible strip portion, with the flexible strip portion being foldable to position the connector contact portions to mate with the monitor contact portions. Any of the features described above in connection with the first aspect may be applied to this second aspect of invention.

[0035] The monitor may include a hinged connection between the first and second housing portions. As such, the monitor may have a clam shell construction. However, other constructions are feasible such as the first and second housing portions being able to twist or swivel relative to each other, such that the second housing portion is able to swing aside to expose the monitor contact portions on the first housing portion and closable to clamp the flexible strip portion therebetween and effect the seal.

[0036] Another possible construction is for the first and second housing portions to slide relative to each other, with the sliding track designed to clamp the flexible strip portion therebetween in the closed position and effect the seal.

[0037] The monitor may be round in profile, although other shapes are feasible. The monitor may be in the shape of a hamburger bun, with each of the first and second housing portions being convex.

[0038] It is preferred that substantially all of the electronics for the monitor are housed within the first housing portion. The first housing portion may comprise a compartment in which the electronics are sealed. This enables the second housing portion to be of lower i.e. thinner profile than the first housing portion, given the substantial or total absence of electronics in the second housing portion.

[0039] The wearable sensor is preferably separable from the monitor. For example, the wearable sensor may be a single use device and discarded after each use. On the other hand, the monitor may be a reusable device. Accordingly, after use, the wearable sensor is preferably removed and discarded and replaced by another wearable sensor. The wearable sensor may include adhesive, provided on the flexible strip portion. Preferably, the adhesive is on the same side of the flexible strip portion as the one or more electrodes.

[0040] Alignment features may be provided to facilitate correct positioning of the wearable sensor in relation to the monitor, for assembly therewith. Suitably, the electrodes should be disposed such that they face the subject's skin and the connector contact portions should be disposed for electrical connection to the monitor contact portions. Alignment features include:

- a recess provided in the first housing portion and/or the second housing portion commensurate with the shape of the accommodated portion of the wearable sensor to correctly position the wearable sensor. Since the wearable sensor could be in the form as described above in connection with the first aspect, the part of the wearable sensor accommodated within the housing may be in a T-shape. Accordingly, the recess provided in the housing could be commensurately in the form of a corresponding T-shape. Preferably, the shape of the accommodated portion and the corresponding recess is asymmetrical to preclude incorrect placement of the wearable sensor within the housing.
- Corresponding projections and recesses/apertures on the wearable sensor and the housing. Since the wearable sensor includes a flexible strip portion, it is preferred that the projections are provided on the housing and the recesses or apertures are provided on the wearable sensor. In a preferred form of the invention, projections are arranged on one of the first housing portion or the second housing portion, with corresponding recesses provided on the other of the first housing portion and the second housing portion. Alternatively, there may be projections on both the first housing portion and the second housing portion, with corresponding recesses provided on the first housing portion and the second housing portion. Preferably, there is an asymmetric arrangement of the projections and recesses/apertures to preclude incorrect placement of the wearable sensor within the housing.
- The housing may include an on/off switch in the form of a button. Suitably, the button is provided on the first housing portion. The button has a similar effect to the corresponding projections and recesses/apertures described in the above paragraph and may collectively function therewith as asymmetric alignment features.

[0041] The seal may surround the monitor contact portions and the connector contact portions. For example, the seal may be in the form of an O-ring, gasket, over-molded elastomeric polymer or other suitable sealing mechanism. In a most preferred form of the invention, the O-ring is accommodated in the first housing portion and seals against the wearable sensor upon closure of the housing.

[0042] Additionally or alternatively, the wearable sensor may incorporate sealing material. For example, the strip portion of the wearable sensor may include compressible material. Preferably, the accommodated or clamped portion of the wearable sensor includes compressible material. For example, the fold portion of the wearable sensor may incorporate compressible material.

[0043] The monitor may be provided with a closure to hold closed the first and second housing portions to hold or clamp the wearable sensor in position and effect the seal around the electrical connection. The closure may be in the form of a mechanical closure such as a latch or catch. Alternatively, the closure may be in the form of a magnetic closure including one or more magnetic components. Preferably, the magnetic closure is arranged to apply a compressive force to the seal. For example, if the electrical connection is such that the contacts are linearly arranged along a longitudinal axis then preferably the compressive force applied to the seal is applied along the longitudinal axis. In a most preferred form of the invention, the magnetic closure includes a bar including magnetic, ferrous, or other magnetised or magnetisable material provided on the second housing portion, the bar being substantially aligned with the longitudinal axis. Cooperable magnets, ferrous components or other magnetised or magnetisable material (as appropriate to provide magnetic attraction to bar) may be provided on the first housing portion and arranged along the longitudinal axis on either side of the electrical connection. Accordingly, a substantially evenly distributed compressive force will be applied to the seal.

[0044] The wearable sensor may be comprised of one or more arms extending from a central region, the central region being adapted to be captured or clamped between the first and second housing portions. Where the wearable sensor is in the form described above in connection with the first aspect of the invention, the fold portion may be adapted

to be captured between the first and second housing portions. However, other arrangements of the wearable sensor are possible, without a fold portion.

[0045] The wearable sensor assembly may be provided in kit form.

[0046] Any of the features described above or below in connection with other aspects of the invention may be applied to this aspect of the invention.

Wearable sensor – multi arms

[0047] In accordance with a third aspect of the present invention, there is provided, a wearable sensor including:

a flexible strip portion provided with one or more electrodes to obtain signals indicative of physiological characteristics, and one or more connector contact portions, wherein the flexible strip portion is configured with:

two arms extending from a central region, wherein the one or more electrodes are positioned on the two arms, the two arms having at least portions thereof which extend substantially parallel to each other; and

a third arm extending from the central region, wherein the third arm extends substantially orthogonal to the portions of the two arms which extend parallel.

[0048] Preferably the third arm has a substantial surface area with skin adhesive. In a preferred form of the invention, the surface area of the third arm is substantially covered with skin adhesive. It is preferred that a monitor is mounted to the wearable sensor in the vicinity of the central region. Accordingly, the third arm having a substantial surface area with skin adhesive helps to secure the monitor and the overall assembly. Other portions of the flexible strip portion may be provided with skin adhesive. For example, the electrodes may be surrounded by adhesive, most preferably arranged in a foam annulus or a foam annulus with a radial slot.

[0049] Preferably, the electrodes are positioned on the portions of the two arms which extend substantially parallel to each other.

[0050] The third arm may be aligned with a portion of the second arm. The central region may include the fold portion as described above in connection with earlier aspects.

[0051] Any of the features described above or below in connection with other aspects of the invention may be applied to this aspect of the invention.

Monitor *per se*

[0052] In accordance with a fourth aspect of the present invention, there is provided, a monitor for receiving signals from a wearable sensor strip, the monitor including:

electronic components for processing of the received signals;

a housing including first and second housing portions which are relatively movable, the housing being adapted to clamp at least a portion of the wearable sensor strip between the first and second housing portions in a closed configuration of the housing;

one or more monitor contact portions provided on the first housing portion for electrical connection with the wearable sensor strip to receive the signals;

a seal to seal the electrical connection between the monitor contact portions and the wearable sensor strip; and

wherein at least the majority of the electronic components are housed in the first housing portion and the second housing portion is thinner in profile than the first housing portion.

[0053] The first housing portion may comprise a compartment in which the electronic components are sealed. All of the electronic components may be housed in the first housing portion. This configuration with the electronic components provided in the first housing portion enables the second housing portion to be of lower i.e. thinner profile than the first housing portion. Preferably the monitor is configured to receive physiological signals from a subject via the sensor strip, in which case, preferably the monitor is configured to orient the second housing portion closer to the subject than the first housing portion.

[0054] A closure may be provided to hold the first and second housing portions in the closed configuration. The closure may be in the form of a magnetic closure including one or more magnetic components. Preferably, the magnetic closure is arranged to apply a compressive force to the seal. For example, if the electrical connection is such that the monitor contact portions are linearly arranged along a longitudinal axis then preferably the compressive force applied to the seal by the first and second housing portions is applied along the longitudinal axis. In a most preferred form of the invention, the magnetic closure includes a bar provided on the second housing portion, with cooperative or components in the first housing portion, as described above in connection with the above aspect of the invention.

[0055] Any of the features described above or below in connection with other aspects of the invention may be applied to this aspect of the invention.

Method of fabricating

[0056] In accordance with yet another aspect of the present invention, there is provided, a method of fabricating a wearable sensor, the wearable sensor including:

a strip portion having a first side;

one or more electrodes to obtain signals indicative of physiological characteristics, each of the one or more electrodes having a contact face on the first side of the strip portion;

one or more electrical connector contact portions, each of the one or more electrical connector contact portions having an electrical contact face on the first side of the strip portion; and

one or more conductive paths from the one or more electrodes to the electrical connector contact portions, the method including:

folding the strip portion such that in the folded configuration, the electrical connector contact portions are disposed on a side of the wearable sensor which is opposite to the side of the wearable sensor on which the electrodes are disposed, the electrical connector contact portions being exposed or having a removable cover..

[0057] The electrical connector contact portions may be exposed (for the purpose of electrical contact) on the side of the wearable sensor opposite to that side on which the one or more electrodes are disposed, or alternatively, the electrical connector contact portions may have a removable cover. The removable cover may provide protection for the electrical connector contact portions until the wearable sensor is ready for use. Accordingly, the electrical connector contact portions are configured to be accessed and electrically connected to a monitoring device.

[0058] Preferably, the method of fabricating includes applying adhesive to hold the strip portion in the folded configuration.

[0059] Additionally, the strip portion may include alignment features which serve to ensure alignment in the folding process and also alignment of the folded wearable sensor with a monitoring device. The fabricating process may include using a jig to locate the alignment features during folding.

[0060] Preferably another aspect of the present invention provides a method of assembling a monitor assembly, the method including:

fabricating the wearable sensor as set out above; and

installing the wearable sensor in a monitor which includes:

a housing including first and second housing portions which are relatively movable, the housing being adapted to clamp at least a portion of the flexible strip portion between the first and second housing portions in a closed position thereof;

one or more monitor contact portions provided on the first housing portion for electrical connection with the connector contact portions to receive signals therefrom;

wherein the wearable sensor is installed such that the connector contact portions face the monitor contact portions.

[0061] Any of the features described above in connection with other aspects of the invention may be applied to this aspect of the invention.

[0062] As used herein, except where the context requires otherwise, the term "comprise" and variations of the term, such as "comprising", "comprises" and "comprised", are not intended to exclude further additives, components, integers or steps.

[0063] Likewise, the term "contain" and variations of the term such as "containing", are not intended to be construed exclusively as excluding further additives, components or integers.

[0064] It must be noted that as used herein and in the appended claims, the singular forms "a", "an" and "the" include plural reference unless the context clearly dictates otherwise. Thus, for example, a reference to "a contaminant" may include a plurality of contaminants or a reference to "at least one contaminant" may include one or more contaminants, and so forth.

[0065] The term "and/or" can mean "and" or "or" depending on context.

[0066] The term "(s)" following a noun contemplates the singular or plural form, or both.

[0067] It will be understood that the invention(s) disclosed and defined in this specification extends to all alternative combinations of two or more of the individual features mentioned or evident from the text or drawings. All of these different combinations constitute various alternative aspects of the invention.

[0068] Further aspects of the present invention and further embodiments of the aspects described in the preceding paragraphs will become apparent from the following description, given by way of example and with reference to the accompanying drawings.

Brief description of the drawings

[0069] In order that the invention may be more fully understood, one preferred embodiment will now be described by way of example, with reference to the figure(s) in which:

[0070] Figure 1 is a plan view of a wearable sensor in accordance with a first preferred embodiment of the present invention, the wearable sensor shown in the flat blank configuration;

[0071] Figure 2 is a plan view of the wearable sensor of Figure 1, the wearable sensor shown in the folded configuration;

[0072] Figure 3 is a diagram illustrating the material layers of wearable sensor of the type shown in Figure 1, the wearable sensor being a shielded wearable sensor;

[0073] Figure 4 is a diagram illustrating the material layers of a wearable sensor of the type shown in Figure 1, the wearable sensor of being an unshielded wearable sensor;

[0074] Figure 5A and Figure 5B are plan views of an adhesive disc to adhere the monitor shown in Figures 9 onwards, to the subject;

[0075] Figure 6 is a diagram illustrating the material layers of the adhesive disc shown in Figures 5A and 5B;

[0076] Figure 7 is a diagrammatic view illustrating the layers in the fold portion of the wearable sensor shown in Figure 1, the wearable sensor being a shielded wearable sensor;

[0077] Figure 8 is a diagrammatic view illustrating the placement of sections B, C, D, E, F of the wearable sensor as detailed in Figure 3 and Figure 4;

[0078] Figure 9 is a perspective view of a monitor according to a preferred embodiment of the present invention, the monitor being shown in the open configuration;

[0079] Figure 10 is a perspective view of the monitor shown in Figure 9, except with the monitor shown in the closed configuration;

[0080] Figure 11A is a side elevation of the monitor shown in Figure 9;

[0081] Figure 11B is a cross-sectional view through A-A of Figure 11A;

[0082] Figure 12A is a side elevation of the monitor shown in Figure 9;

[0083] Figure 12B is a cross-sectional view through B-B of Figure 12A;

[0084] Figure 13 is an exploded view of the wearable sensor of Figure 1, together with the monitor of Figure 9, forming a wearable sensor assembly;

[0085] Figure 14 is a perspective view of the wearable sensor assembly of Figure 13, with the monitor shown in the open configuration;

[0086] Figure 15 is a perspective view of the wearable sensor assembly of Figure 13, with the monitor shown in the closed configuration;

[0087] Figure 16 is a perspective view of the wearable sensor assembly of Figure 13 installed on the subject;

[0088] Figure 17 is an alternative embodiment of the monitor

[0089] Figure 18 is a plan view of another embodiment of the wearable sensor, the wearable sensor shown in the folded configuration and including additional iconography and arrows; and

[0090] Figure 19 is a perspective view of a monitor of a wearable sensor assembly according to another preferred embodiment, shown in the open configuration.

Detailed description of the embodiments

Wearable sensor

[0091] The wearable sensor 10 illustrated in Figure 1 is formed of a flexible strip material 12, the constitution of which will be described in connection with subsequent figures. The strip material 12 has a first side 14 shown in Figure 1 (facing out of the page) and a second opposite side 16 (facing into the page as shown in Figure 2).

[0092] The wearable sensor 10 has seven electrodes 18 as shown. However, this number is merely preferred and the sensor 10 may be provided with any reasonable number of electrodes, depending upon the physiological characteristics to be sensed by the wearable sensor 10.

[0093] The wearable sensor 10 is shown in the unfolded flat “blank” form in Figure 1, prior to being folded into the configuration shown in Figure 2. The wearable sensor 10 has a central region 20 from which three arms (otherwise referred to in the specification as “arm portions”) emanate. The first of these arms is first arm 22. The first arm 22 is a straight arm and is provided with four of the seven electrodes 18. The first arm 22 is of

constant width along its length. However, a constant width is merely preferred and each arm may vary in width depending on the application.

[0094] The second arm 24 is a crooked or bent arm having an elbow 26 which divides the second arm 24 into an upper arm portion 28 and a lower arm portion 30. In the flat blank form of the wearable sensor 10, the lower arm portion 30 extends substantially parallel to the first arm 22. As shown in Figure 1, the lower arm portion 30 lies beneath the first arm 22. This is also true in the in-use configuration illustrated in Figure 16. The extent of the lower arm portion 30 is somewhat commensurate in length with the length of the first arm 22, although the lower arm portion 30 is somewhat shorter in reach than the first arm 22. The lower arm portion 30 could be of substantially equal length and/or reach to the first arm 22.

[0095] The upper arm portion 28 extends substantially orthogonally to the first arm 22 and is contiguous with radiused elbow 26. The lower arm portion 30 is also contiguous with the radiused elbow 26. The second arm 24 is of constant width along its length.

[0096] Both the first and second arms 22, 24 extend from a central region 20. This central region 20 is comprised of a fold portion 20 which is made up of two portions including a contacts region 32 and an overlaid region 34.

[0097] The contacts region 32 includes a number of electrical connector contact portions 36 which are arranged linearly along a first longitudinal axis. There is a respective electrical connector contact portion 36 for each of the electrodes 18. Additionally, there is an electrical connector contact portion 36 for the shield, the purpose of which will be explained later. Additional electrical connector contact portions may also be provided for other purposes. For instance, in other embodiments, multiple shield contacts may be provided.

[0098] The connector contact portions 36 are connected to respective electrodes 18 via respective conductive paths 39. The connector contact portions 36, the electrodes 18 and the conductive paths 39 are contiguous (for each electrode/path/contact set 39) and are laid down during a printing process onto a flexible substrate 40. The flexible substrate 40 and the printed electroconductive layers 39, the dielectric layers 37 and optional shield

layer 41 define the flexible strip material 12, along with other layers as discussed in connection with Figures 3 – 7.

[0099] The flexible substrate 40 may be comprised of TPU material, although other flexible polymer materials may alternatively be used. The flexible substrate 40 is preferably relatively non-extensible. Significant extensibility would corrupt the printed electroconductive layers 39 and is therefore seen as undesirable (unless the printed electroconductive layers also have the feature of extensibility). Elasticity of the substrate (meaning the material's ability to return to its original state after attempting to stretch it), is desirable.

[0100] The wearable sensor 10 is shown in Figure 1 with the first side 14 of the flexible strip material 12 facing out of the page. This first side 14 is the side which makes contact with the skin of the subject, given that the electrodes 18 are printed so as to be exposed from the first side 14. Additionally, given the printing process, the electrical connector contacts 36 will also be on the first side 14 of the flexible strip material 12. As will be appreciated in connection with the subsequent discussion of the monitor (see Figures 9 onwards), it is desirable for the connector contacts 36 to be disposed to face away from the subject's skin. Accordingly, the fold portion 20 of the flexible strip material 12 enables the connector contacts 36 to be oriented to face away from the subject's skin. Specifically, the contacts region 32 is folded over the overlaid region 34. From the perspective of Figure 1, the contacts region 32 is folded into the page so that the contacts region 32 will substantially, if not completely overlay the overlaid region 34.

[0101] In this respect, see Figure 2 where the flexible strip material 12 has been flipped over so that the first side 14 is now facing into the page and the second opposite side 16 is facing out of the page. In Figure 2, it can be seen that the contacts region 32 with the connector contacts 36 is now facing out of the page. Accordingly, with the first side 14 making contact with the subject's skin, the contacts region 32 and the contacts 36 will be facing away from the subject's skin.

[0102] From Figure 1 and Figure 2, it can be seen that the configuration of the fold portion 20 affords folding between the contacts region 32 and the overlaid region 34. To facilitate this, the flexible strip material has a flexible hinge portion 42 which is reduced in

length, compared to the length of the contacts region 32 and the overlaid region 34 (length is up/down in the context of Figure 1). Additionally, where the contacts region 32 and the overlaid region 34 has been provided with one or more stiffening layers, then the flexible hinge portion 42 made be absent any stiffening layers. Furthermore, the flexible hinge portion 42 could be creased or other features employed to enhance folding. However the flexible hinge portion 42 need not be of reduced length.

[0103] Reverting to Figure 1, it can be seen that the overlaid region 34 is substantially commensurate in size and shape with the contacts region 32. Accordingly, the contacts region 32 is superimposed upon the overlaid region 34 when the flexible strip material 12 is in the folded configuration. Additionally, from Figure 2, it can be seen that the fold portion 20 in the folded configuration has a T-shape. Accordingly, each of the contacts region 32 and the overlaid region 34 are of a T-shape. In the flat blank configuration of Figure 1, the contacts region 32 and the overlaid region 34 are substantially mirror images of each other, along an axis extending through the flexible hinge portion 42. As shown, the T-bar of the T-shape of each of the contacts region 32 and the overlaid region 34 are adjacent.

[0104] Additionally, it can be seen from Figure 1 that the fold portion 20 is also provided with small apertures 44 and large apertures 46. There are two small apertures 44 on the contacts region 32 and two small apertures 44 on the overlaid region 34. Each of the two small apertures 44 on the contacts region 32 is superimposed on a respective one of the two small apertures 44 on the overlaid region 34 when the fold portion 20 is folded. Thus, in the folded configuration as shown in Figure 2, the small apertures 44 on the contacts region 32 and the overlaid region 34 are aligned and appear as two apertures only.

[0105] There is one large aperture 46 on the contacts region 32 and one large aperture 46 on the overlaid region 34. When the contacts region 32 is folded over the overlaid region 34, the large aperture 46 on the contacts region 32 becomes superimposed over the large aperture 46 on the overlaid region 34. Accordingly, in the folded configuration shown in Figure 2, only one large aperture 46 is apparent.

[0106] The apertures 44, 46 serve as alignment features when assembled with the monitor as will be explained in connection with Figures 9 onwards. Additionally, the

alignment pin holes in the sensor 10 are integral to the manufacturing process. A jig having protrusions resembling the protrusions of the monitor is used to hold the sensor 10 prior to folding. Once folded, the jig protrusions receive the small apertures 44 on both the contacts region 32 and the overlaid region 34 to ensure that the connector contacts 36 are in the correct position relative to the remainder of the wearable sensor 10 for correct alignment with the monitor contacts 96.

[0107] Referring still to Figure 1, each electrode 18 is covered by a hydrogel layer 48. Furthermore, each electrode 18 is surrounded by an annulus 50. The annulus 50 is comprised of foam material with a skin adhesive, suitably medical grade skin adhesive. The skin adhesive is outermost of the foam material, for contact with the subject's skin, to assist with adhering the wearable sensor 10 to the subject. Additionally, adhesive is provided to adhere the foam annulus 50 to the substrate 40 or layers applied to the substrate, such as the dielectric layer 37, as per Figure 3 or 4. This adhesive may be the same or different as the skin adhesive.

[0108] The first arm 22 is provided with a first removable protective liner 52 having a tab 54 to aid removal. When the protective liner 52 is removed, the skin adhesive on the first arm 22 is exposed to enable the first arm 22 to be applied to the subject's skin.

[0109] Similarly, the second arm 24 is also provided with a second removable protective liner 56, having a tab 58 to aid removal. When the protective liner 56 is removed, the skin adhesive on the second arm 24 is exposed to enable the second arm 24 to be applied to the subject's skin.

[0110] The wearable sensor 10 also includes a third arm 60. The third arm 60 is substantially shorter than the first arm 22 and the second arm 24. The third arm 60 is of substantially constant width. The third arm 60 can be regarded as an extension of the second arm 24, on the other side of the fold portion 20 and is of the same width as the second arm 24. The third arm 60 extends substantially orthogonally to the first arm 22. Accordingly, the third arm 60 extends in the upward direction in the in-use configuration.

[0111] The third arm 60 is also provided with a third removable protective liner 66, having a tab 68 to aid removal. When the protective liner 66 is removed, the skin adhesive

provided on the third arm 60 is exposed to enable the third arm 60 to be applied to the subject's skin.

[0112] All of the arms 22, 24, 60 preferably have rounded ends.

[0113] Figure 16 illustrates the in use configuration of the wearable sensor 10, in a pregnancy application. As can be seen, the first arm 22 extends transversely across the torso of the subject 62 and is positioned at a relatively upward location relative to the abdominal extension (baby bump) 64. The crooked second arm 24 extends downwardly on one side of the abdominal extension and then curves around so that the lower arm portion 30 extends transversely across the torso of the subject 62 and is positioned at a relatively lower location relative to the abdominal extension 64.

[0114] Additionally, Figure 7 is a diagram illustrating the layers making up the fold portion 20 in the unfolded configuration (middle of the page), while the right-hand side of the page is a diagram illustrating the layers making up the fold portion 20 in the folded configuration. The legend is provided on the left-hand side of Figure 7.

[0115] The left-hand side of Figure 8 is a diagram illustrating various different regions of the flat blank form of the wearable sensor 10.

[0116] The right-hand side of Figure 8 illustrates the fold portion 20 in the folded configuration. Further information of the layers making up the sections B, C, D, E, F shown in Figure 8 are shown in Figure 3 for the wearable sensor being a shielded wearable sensor, and Figure 4 for the wearable sensor being an unshielded wearable sensor.

[0117] The wearable sensor 10 illustrated in Figures 3, 4, 7, 8 has the same overall form illustrated and described in connection with Figures 1 and 2. The embodiment of Figure 3 includes a shielded layer whereas the embodiment of Figure 4 omits the shielded layer.

[0118] The wearable sensor has a contiguous substrate 40 extending across the entire wearable sensor 10 and defines the backbone of the first, second and third arms 22, 24, 60 and the fold portion 20. As per Figures 3 and 4, the substrate is a TPU substrate in both the shielded and unshielded versions. The Substrate could be thermoplastic polyurethane (TPU) or polyethylene terephthalate (PET).

[0119] The layers are progressively built up on the substrate 40. Initially, the shielded version as set out in Figure 3 and Figure 8 will be explained. The conductive paths 39 are printed onto the substrate and are made up of a number of layers. The first layer printed onto the substrate 40 is a carbon shield layer. The carbon shield layer can be found in the skin adhesive foam area “C”, the no skin adhesive foam area “D” and the fold portion “E” and the skin adhesive no foam area “F”. The shield layer could be silver, or carbon, or a silver/carbon mixture. The carbon layer travels under the conductive paths and then beyond by an additional amount. This can be seen in Figure 1 where the shield layer 41 is larger than the conductive paths, but does not extend to the entire substrate.

[0120] The second layer printed onto the substrate 40 is a first dielectric layer. The dielectric layer can be found in the areas C, D, E, and F. The dielectric layer should be larger than both the conductive and shield layers such that these layers do not touch one another or the subject's body. The dielectric layer can touch the subject's body. But the dielectric layer does not extend across the entire substrate.

[0121] The third printed layer onto the substrate 40 is a silver layer. The silver layer is extended across the areas C, D and E, but not F. Furthermore, the silver layer is found at the electrode 18, which is area “B”. The silver layer is confined to the regions where the conductive paths are visible in Figure 1.

[0122] The fourth printed layer is silver chloride which is found only at the electrode 18 (area B). The fifth printed layer is a second dielectric layer onto the areas C, D, E and F. The sixth layer applied to the substrate is adhesive at areas C and F.

[0123] It is typically known that printing silver inks on flexible substrates are likely to be weakened by bending. However by careful choice of the material stack and avoiding repeated bending of the substrate, a tight bend radius can be obtained which does not significantly impact conductivity. One method of achieving this is by using a flexible silver ink printed onto a thermoplastic polyurethane substrate, separated by one or more stiffener layers made from polyethylene terephthalate. As can be seen from Figure 1, the overlaid region 34 and the contacts region 32 have spaced edges adjacent to each other separated by a hinge 42. The spaced edge of the overlaid region 34 includes an outer edge and an indent 43 providing an indented edge. The indent 43 lies adjacent the hinge

42. Stiffener material is provided for the contacts region 32 and the overlaid region 34 but not the hinge 42. Accordingly, the hinge 42 bends along an axis oriented along its length, with the axis positioned at an intermediate location across the width, approximately midway across the width. In this way, the hinge axis will be aligned with the outer edge of the overlaid region or inset within the indent 43. Thereby the vulnerable conductive paths 39 along the hinge 42 are less vulnerable to damage during installation in the monitor since they are not exposed beyond the outside edge of the overlaid region 34. See for instance the folded configuration shown in Figure 2.

[0124] As shown in Figure 8, a foam annulus 50 is applied to area C, about the electrode 18. See also Figure 3.

[0125] Hydrogel 48 is applied to the electrode 18 (area B).

[0126] As already discussed above, the protective liner 52, 56, 66 is present at areas B, C and F is also depicted in Figure 3.

[0127] The unshielded version set out in Figure 4 is made in a similar manner, except with the omission of the carbon layer and the first dielectric layer.

[0128] Figure 7 contains more detail about the constitution of the fold portion 20. Printed onto the first side of the substrate is the carbon shield layer, followed by the first dielectric layer, the silver layer which makes up the conductive path 39 and the connector contacts 36, and the second dielectric layer. (See the stack in the middle part of the diagram.)

[0129] Applied to the opposite side of the substrate 40 is a first adhesive layer. A stiffener is applied to the first adhesive layer. Accordingly, the first adhesive layer is required on both regions 32, 34 of the fold portion 20. A second adhesive layer is applied onto the stiffener 70. The purpose of the second adhesive layer is to adhere the stiffener back onto itself. Accordingly, the second adhesive layer need only be applied to either the contacts region 32 or the overlaid region 34.

[0130] The stiffener 70 may be an applied layer or alternatively could be in the form of a discrete piece or pieces which is applied to the first adhesive layer. For instance the discrete pieces may be laser cut before application. As can be seen from Figure 2, the stiffener pieces on the overlaid region 34 and the contacts region 32 define the overall

shape of the fold portion. The stiffener pieces are therefore two T-shaped portions arranged symmetrically to each other, with an axis of symmetry along the hinge portion 42.

[0131] The right-hand side of Figure 7 shows the material stack once the contacts region 32 has been folded over and overlaid on top of the overlaid region 34. The folding may occur in the manufacturing process. Accordingly, a protective liner is not required over the second adhesive layer if the folding takes place immediately. However, it is possible that the folding operation could be conducted by the end user or medical professional, in which case an additional protective liner would be required over the second adhesive layer.

[0132] The fold portion 20 of the unshielded embodiment is similarly constructed, with the carbon layer and the first dielectric layer omitted. Figure 4 provides more information about the various layers making up the fold portion 20 in the unshielded embodiment (see area E).

Monitor

[0133] Figures 9 to 12 show the wearable monitor 72. The wearable monitor 72 has a housing including a first housing portion 74 and a second housing portion 76. The first housing portion 74 and the second housing portion 76 are hingeably interconnected by means of a passive hinge 78. When the housing is closed, the second housing portion 76 is superimposed over the first housing portion 74.

[0134] The housing is circular in plan, as can be seen from Figure 12. Both of the first housing portion 74 and the second housing portion 76 have a convex or domed outer periphery 82, 80 respectively, with substantially flat inner sides 84, 86 respectively. The substantially flat inner sides 84, 86 face each other in the closed configuration of the housing. Accordingly, the overall shape of the housing in the closed configuration appears like a round hamburger bun.

[0135] As can be seen from Figure 11, the second housing portion 76 has a thinner profile than the first housing portion 74. In other words, the thickness of the second housing portion 76 from the domed outer periphery 80 to the substantially flat inner side

86, is less than the thickness of the first housing portion from the domed outer periphery 82 to the substantially flat inner side 84.

[0136] As can be seen from Figure 9, the housing contains various alignment features which cooperate with alignment features provided by the wearable sensor 10. Firstly, two spaced small projections 88 are provided on the substantially flat inner side 84 of the first housing portion 74. These are received by two small recesses 90 provided in the substantially flat inner side 86 of the second housing portion 76. The two small projections 88 seat into the two small recesses 90 when the housing is in the closed configuration. The two small projections/recesses 88/90 cooperate with the two small apertures 44 provided in the fold portion 20 of the wearable sensor 10.

[0137] The substantially flat inner side 84 of the first housing portion 74 is provided with an actuator (on/off button) 92. The actuator 92 projects out of the face of the substantially flat inner side 84 and is received in a recess 94 provided in the substantially flat inner side 86 of the second housing portion 76. Accordingly, the actuator 92 seats within the recess 94 in the closed configuration of the housing. The actuator 92 and recess 94 are cooperable with the large recess 46 provided in the wearable sensor 10.

[0138] It can be understood that the alignment features 88, 90, 92 and 94 are asymmetrical. Accordingly, the operator/subject/hospital staff member cannot inadvertently place the wearable sensor 10 in the wrong configuration relative to the monitor 72, e.g. upside down. The alignment features 88, 90, 92 and 94 ensure the correct placement of the wearable sensor 10 to ensure that the connector contacts 36 align with the monitor contacts 96 and the connector contacts 36 are facing the monitor contacts 96 for electrical contact.

[0139] Additionally, it can be seen that the substantially flat side inner 84 of the first housing portion 74 has a shallow T-shaped recess 98. The T-shaped recess 98 is commensurate in shape with the T-shape of the fold portion 20. This enables the operator/subject/hospital staff member to seat the fold portion 20 into the housing for correct placement of the wearable sensor to ensure electrical contact between the contacts 36, 96.

[0140] As previously explained, the connector contacts 36 are a spaced linear array along a longitudinal axis. Likewise, the monitor contacts 96 are spaced in a linear array along a longitudinal axis. The spacing between the contacts of both sets 36 and 96 is equidistant.

[0141] The first housing portion 74 includes an O-ring 100. The O-ring 100 is not circular but elongated in the same direction as the longitudinal axis of the monitor contacts 96. Accordingly, the O-ring 100 is in an oval or oblong shape surrounding the monitor contacts 96. The O-ring 100 may be seated within an oval or oblong-shaped trench provided on the substantially flat inner side 84 of the first housing portion 74. When the second housing portion 96 is closed, the substantially flat surface 86 of the second housing portion compresses the O-ring 100.

[0142] A catch or latch may be provided to hold the housing in the closed configuration. A magnetic catch is provided in the form of a magnetic or ferrous bar, or a bar made of other magnetised or magnetisable material 102 as shown in Figure 11B. The bar 102 magnetically engages with two spaced catch portions 104 as shown in Figure 12B. The two spaced catch portions 104 each include magnetic or ferrous material or any other magnetised or magnetisable material. For instance, if the bar 102 is magnetic than the two spaced catch portions 104 need only be of a material attracted to the magnet, such as iron.

[0143] The bar 102 is oriented to lie within the second housing portion 76 beyond the small recesses 94 in the direction extending away from the hinge 78. The bar 102 has a lengthwise direction which extends substantially parallel to the longitudinal axis of the monitor contacts 96 and the hinge axis of the hinge 78. The spaced catch portions 104 are positioned at each end of the O-ring 100, beyond the O-ring 100, along the longitudinal axis of the monitor contacts. Accordingly, the spaced catch portions 104 are aligned with the bar 102. In this way, the magnetic attraction between the bar 102 and the catch portions 104 will apply a force to hold closed the second housing portion 76, with the force being substantially equally distributed along the longitudinal axis between the two spaced catch portions 104. The O-ring 100 provides a seal between the substantially flat inner side 84 of the first housing portion 74 and the facing side of the fold portion 20 with the connector contacts 36. Accordingly, both sets of contacts 36, 96

are sealed within the O-ring 100. This seal protects against the ingress of liquid or dust. The seal is particularly required in pregnancy applications since pregnant women may take showers to relieve the pain symptoms. The wearable sensor assembly can be worn in the shower. The force applied by the magnetic attraction of the bar 102 and the two spaced catch portions 104 ensures that the substantially flat inner side 86 of the second housing portion 76 will be held against the fold portion 20 which in turn ensures that the fold portion is fully engaged with the O-ring 100 to provide an effective seal around the monitor contacts 96 and the connector contacts 36.

Installation

[0144] Figures 13 to 16 illustrate the assembly of the wearable sensor 10 with the wearable monitor 72. Firstly, the second housing portion 76 is opened to the position illustrated in Figure 13. The wearable sensor 10 is placed over the first housing portion 74. The wearable sensor 10 has already been folded. The fold portion 20 which has a T-shape is placed such that it is received in the commensurately shaped recess 98 in the first housing portion 74, as shown in Figure 14. As will be appreciated, the small apertures 44 receive the small projections 88 and the large recess 46 receives the actuator 92. Because the alignment features 44, 88, 46, 92 are asymmetrical, the wearable sensor 10 can only be placed in the orientation with the connector contacts 36 placed face down (from the viewpoint of Figure 14), facing the monitor contacts 96.

[0145] The closed configuration of the housing and the fully assembled wearable assembly is illustrated in Figure 15. As will be appreciated from the foregoing description, the connector contacts of the wearable sensor 10 are positioned face down relative to the substrate 40 (from the viewpoint of Figure 15). However, the remainder of the conductive layer, including the conductive paths 39 and the electrodes 18, as present on the first and second arms 22, 24 will be face up relative to the substrate 40 (from the viewpoint of Figure 15).

[0146] In Figures 13 – 16, the first side of the wearable sensor 10 is facing upwards. It is the first side of the wearable sensor 10 which is to be placed against the subject's skin. Accordingly, the wearable sensor assembly can be attached to the subject 62 such that the relatively thinner profiled second housing portion 76 is closest to the subject 62. Since

the arms 22, 24, 60 of the wearable sensor 10 extend from the monitor 72 and attach to the subject's skin, there will be a relatively short distance for the arms to leave the housing and attached to the subject's skin. Accordingly, by having substantially all, if not all of the electronics (not shown) in the first housing portion 74 and/or substantially none or absolutely none of the electronics in the second housing portion 76, the second housing portion 76 can be made relatively thinner in profile. This configuration having the second housing portion 76 against the subject's skin means that there is less strain on the arms 22, 24, 60 tending to detach the adhesive on the arms 22, 24, 60 from the subject's skin. The electronics are provided in a single compartment of the first housing portion 74 which is sealed.

[0147] Because the monitor contacts 96 are required in the first housing portion 74, in order for the connector contacts 36 to interface with the monitor contacts 96, the fold portion 20 configures the connector contacts 36 on the opposite side of the flexible strip material 12, once the fold portion 20 has been folded. By this ingenious solution, the connector contacts 36 can be placed on the desired side of the flexible strip material, without the complexity of making vias in the flexible strip material 12.

[0148] In order to position the sensor assembly onto the subject, the protective liners 52, 56 and 66 are removed from their respective arms. Additionally, the protective liners surrounding the electrodes are also removed. The sensor assembly is then positioned as shown in Figure 16.

[0149] The wearable sensor 10 is intended to be a single use device, whereas the monitor 72 is intended to be reusable. Accordingly, once use of the assembly has occurred, the housing is opened and the wearable sensor 10 is removed and discarded. The monitor 72 may be subjected to suitable infection control measures, as determined by the hospital, following which, the monitor 72 may be reused by inserting another wearable sensor 10.

[0150] The electronics in the monitor 72 could be as described in connection with our earlier patent application PCT WO2021243420A1 filed by Kali Healthcare Pty Ltd, the disclosure of which is incorporated herein by reference. However, other electronics could

be used instead. While the present disclosure is in relation to pregnancy monitoring, other physiological characteristics could be monitored.

[0151] Figure 17 illustrates an alternative embodiment to the monitor 72'. In this version, the second housing portion 76 is slidable relative to the first housing portion 74, to open the housing. In other respects, the monitor 72' is the same as monitor 72. In this embodiment, like reference numerals are used to indicate like parts, except with the addition of the prime symbol (') to indicate the change.

[0152] Figure 18 is a slight variation to the embodiment of Figure 2. The flexible substrate 40' contains indicia and arrows to indicate the placement of the wearable sensor 10' on the subject. For instance, the third arm 60 contains indicia 122 representative of a head plus an arrow indicate that the third arm 60 of the wearable sensor 10' should be uppermost towards the head of the subject. The first arm 22 contains indicia 124 representative of a torso plus an arrow to indicate where the first arm 22 of the wearable sensor 10' should be positioned relative to the torso and umbilicus (naval). Likewise, the second arm 24 also contains indicia 126 and 127 representative of a torso plus an arrow to indicate where the second arm 24 of the wearable sensor 10' should be positioned relative to the torso and umbilicus.

[0153] Pin-style contacts are described in connection with the above embodiments. However, in a variant illustrated in Figure 19, individual pogo pin style connectors 128 could be used. This may enable the catch portions 104 to be set closer together. The pogo pin style connector is a common type of engineering connector and serves to show that we intend different types of electrical connectors may be used in the product.

[0154] The foregoing describes only some embodiments of the present invention and modifications may be made thereto without departing from the scope of the invention. For example, a variant of the device uses only two sensor arms 22, 24 and omits the third sensor arm 60. Instead, an adhesive disc may be placed under the monitor 72 i.e. on the skin facing side of the second housing portion 76. The adhesive disc is shown in Figure 5A and 5B and includes a foam disc 110 in the shape of an annulus. Alternatively the annulus may be slotted 111 as shown for better dispersion of sweat etc. The foam disc 110 is provided with adhesive on both sides with two protective liners 112, 113 arranged

against respective adhesive layers. The protective liners 112, 113 may have tabs 114, 115 to aid removal. Further information concerning the material layers of the adhesive disc is provided in Figure 6.

Advantages

[0155] At least the preferred embodiment of the present invention provides an assembly with simple and cost-effective mating between torso-worn electrophysiological sensors 10 and a waterproof electronic measurement device (monitor 72). This assembly not only reduces the manufacturing cost of the consumable sensors 10 but also simplifies operational aspects of the design in sealing the sensor 10 and measurement device 72 from liquid and dust ingress, making continuous torso-worn monitoring more accessible and commercially attractive.

Definitions

[0156] It will be understood that when an element is referred to as being "on", "attached" to, "connected" to, "coupled" with, "contacting", etc, another element, it can be directly on, attached to, connected to, coupled with, or contacting the other element or intervening elements may also be present. In contrast, when an element is referred to as being, for example, "directly on", "directly attached" to, "directly connected" to, "directly coupled" with, "directly contacting", etc, another element, there are no intervening elements present. It will also be appreciated by those skilled in the art that references to a structure or feature that is disposed "adjacent" another feature may have portions that overlap or underlie the adjacent feature.

[0157] Spatially relative terms, such as "under," "below," "lower," "over," "upper" and the like, may be used herein for ease of description to describe one element or feature's relationship to another element(s) or feature(s) as illustrated in the figures. It will be understood that the spatially relative terms are intended to encompass different orientations of the device in use or operation in addition to the orientation depicted in the figures. For example, if the device in the figures is inverted, elements described as "under" or "beneath" other elements or features would then be oriented "over" the other elements or features. Thus, the exemplary term "under" can encompass both an orientation of "over" and "under." The device may be otherwise oriented (rotated 90

degrees or at other orientations) and the spatially relative descriptors used herein interpreted accordingly. Similarly, the terms "upwardly," "downwardly," "vertical," "horizontal" and the like are used herein for the purpose of explanation only unless specifically indicated otherwise.

[0158] It will be understood that, although the terms "first," "second," etc. may be used herein to describe various elements, components, regions, layers and/or sections, these elements, components, regions, layers and/or sections should not be limited by these terms. These terms are only used to distinguish one element, component, region, layer or section from another element, component, region, layer or section. Thus, a "first" element, component, region, layer or section discussed below could also be termed a "second" element, component, region, layer or section without departing from the teachings of the present invention. The sequence of operations (or steps) is not limited to the order presented in the claims or figures unless specifically indicated otherwise or the context indicates otherwise.

[0159] Herein, the terms "individual", "subject" or "patient" can be used interchangeably with each other. The terms "individual", "subject" or "patient" refer to an animal that is treatable by the device and/or method, respectively, including but not limited to, for example, dogs, cats, horses, sheep, pigs, cows, and the like, as well as human, non-human primates. Unless otherwise specified, the "individual", "subject" or "patient" may include both male and female genders. Further, it also includes a subject, preferably a human, suitable for receiving treatment with a device and/or method of the present invention.

CLAIMS

1. A wearable sensor for sensing physiological characteristics of a subject, including:

a strip portion having a first side;

one or more electrodes to obtain signals indicative of physiological characteristics, each of the one or more electrodes having a contact face on the first side of the strip portion and configured for electrical contact with a monitoring device;

one or more electrical connector contact portions, each of the one or more electrical connector contact portions having an electrical contact face on the first side of the strip portion; and

one or more conductive paths from the one or more electrodes to the electrical connector contact portions,

wherein the strip portion defines a fold portion which is folded or foldable, such that in the folded configuration of the strip portion, the electrical contact face(s) of the one or more electrical connector contact portions are disposed on a side of the wearable sensor which is opposite to the side of the wearable sensor on which the one or more electrodes are disposed.

2. The wearable sensor as claimed in claim 1, wherein the one or more electrodes, the one or more electrical connector contact portions and the one or more conductive paths are printed from materials as one or more stacks on a substrate.

3. The wearable sensor as claimed in claim 1, wherein the one or more electrodes, the one or more electrical connector contact portions and the one or more conductive paths are integrated and disposed on the first side of the strip portion.

4. The wearable sensor as claimed in claim 3, wherein the one or more electrodes, the one or more electrical connector contact portions and the one or more conductive paths are integrated into a single stack of printed materials.

5. The wearable sensor as claimed in any one of the preceding claims, wherein the fold portion is defined by a contacts region and an overlaid region, with the contacts

region overlaying the overlaid region in the folded configuration, the contacts region and the overlaid region being relatively stiffer than a hinge region extending therebetween.

6. The wearable sensor as claimed in any one of the preceding claims, wherein the wearable sensor includes first and second arm portions extending from the fold portion and including the one or more electrodes, wherein the conductive paths from each of the one or more electrodes traverse towards the electrical connector contact portions.

7. The wearable sensor as claimed in any one of the preceding claims, wherein the fold portion of the wearable sensor incorporates compressible material.

8. A wearable sensor assembly for sensing physiological characteristics of a subject including:

- a wearable sensor including a flexible strip portion, the wearable sensor provided with one or more electrodes to obtain signals indicative of physiological characteristics of the subject, and one or more connector contact portions;

- a monitor including:

- a housing including first and second housing portions which are relatively movable, the housing being adapted to accommodate or clamp at least a portion of the wearable sensor between the first and second housing portions in a closed position of the housing;

- one or more monitor contact portions provided on the first housing portion for electrical connection with the connector contact portions to receive signals therefrom;

- a seal to seal the electrical connection between the monitor contact portions and the connector contact portions in the closed position of the housing; and

- wherein the second housing portion is thinner in profile than the first housing portion, and the wearable sensor assembly is configured to be worn with the second housing portion closer to the subject than the first housing portion.

9. The wearable sensor assembly as claimed in claim 8, wherein the one or more electrodes and the one or more connector contact portions are printed onto a first side of the flexible strip portion, with the flexible strip portion being folded or foldable to position the connector contact portions to mate with the monitor contact portions.

10. The wearable sensor assembly as claimed in claim 8 or 9, wherein substantially all of the electronics for the monitor are housed within the first housing portion.

11. The wearable sensor assembly as claimed in any one of claims 8 to 10, wherein the wearable sensor is separable from the monitor.

12. The wearable sensor assembly as claimed in any one of claims 8 to 11, further including alignment features to align the wearable sensor in relation to the monitor, wherein the alignment features include any one or more of the following features:

a recess provided in the first housing portion and/or the second housing portion, said recess being commensurate with the shape of the portion of the wearable sensor which is clamped or accommodated within the housing, to correctly position the wearable sensor;

corresponding projections and recesses/apertures on the wearable sensor and the housing, such as an asymmetric arrangement of the projections and recesses/apertures; and

the housing including an on/off switch in the form of a projecting button which is cooperable with a recess/aperture provided in the wearable sensor.

13. The wearable sensor assembly as claimed in any one of claims 8 to 12, wherein the portion of the wearable sensor which is clamped or accommodated within the housing includes compressible material and a closure is provided to apply a compressive force to the compressible material.

14. The wearable sensor assembly as claimed in any one of claims 8 to 13, wherein the wearable sensor is comprised of one or more arm portions extending from

a central region, the central region being adapted to be clamped or accommodated between the first and second housing portions.

15. The wearable sensor assembly as claimed in any one of claims 8 to 14, wherein the wearable sensor assembly is provided in kit form.

16. A wearable sensor including:

a flexible strip portion provided with one or more electrodes to obtain signals indicative of physiological characteristics, and one or more connector contact portions, wherein the flexible strip portion is configured with:

two arm portions extending from a central region, wherein the one or more electrodes are positioned on the two arm portions, the two arm portions having at least portions thereof which extend substantially parallel to each other; and

a third arm portion extending from the central region, wherein the third arm portion extends substantially orthogonal to the portions of the two arm portions which extend parallel.

17. The wearable sensor as claimed in claim 16, wherein the third arm portion is substantially covered with skin adhesive.

18. A monitor for receiving signals from a wearable sensor strip, the monitor including:

electronic components for processing of the received signals;

a housing including first and second housing portions which are relatively movable, the housing being adapted to clamp or accommodate at least a portion of the wearable sensor strip between the first and second housing portions in a closed configuration of the housing;

one or more monitor contact portions provided on the first housing portion for electrical connection with the wearable sensor strip to receive the signals;

a seal to seal the electrical connection between the monitor contact portions and the wearable sensor strip; and

wherein at least the majority of the electronic components are housed in the first housing portion and the second housing portion is thinner in profile than the first housing portion.

19. The monitor as claimed in claim 18, wherein the monitor contact portions are linearly arranged along a longitudinal axis, the monitor further including a closure provided to hold the first and second housing portions in the closed configuration and arranged to apply a compressive force to the seal along the longitudinal axis.

20. A method of fabricating a wearable sensor, the wearable sensor including:

a strip portion having a first side;

one or more electrodes to obtain signals indicative of physiological characteristics, each of the one or more electrodes having a contact face on the first side of the strip portion;

one or more electrical connector contact portions, each of the one or more electrical connector contact portions having an electrical contact face on the first side of the strip portion; and

one or more conductive paths from the one or more electrodes to the electrical connector contact portions, the method including:

folding the strip portion such that in the folded configuration, the electrical connector contact portions are disposed on a side of the wearable sensor which is opposite to the side of the wearable sensor on which the electrodes are disposed, the electrical contact face(s) of the one or more electrical connector contact portions being exposed or having a removable cover.

21. The wearable sensor as claimed in claim 2, wherein the substrate is a thermoplastic polyurethane and the one or more electrodes, the one or more electrical connector contact portions and the one or more conductive paths are printed in flexible silver ink onto the substrate.