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(54) **NON-ADHESIVE OXIMETER SENSOR FOR SENSITIVE SKIN**

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A61B 5/00 (2006.01)

(52) **U.S. Cl.** **600/344**; 600/310; 600/323

(58) **Field of Classification Search** 600/309–310, 600/322–323, 344
See application file for complete search history.

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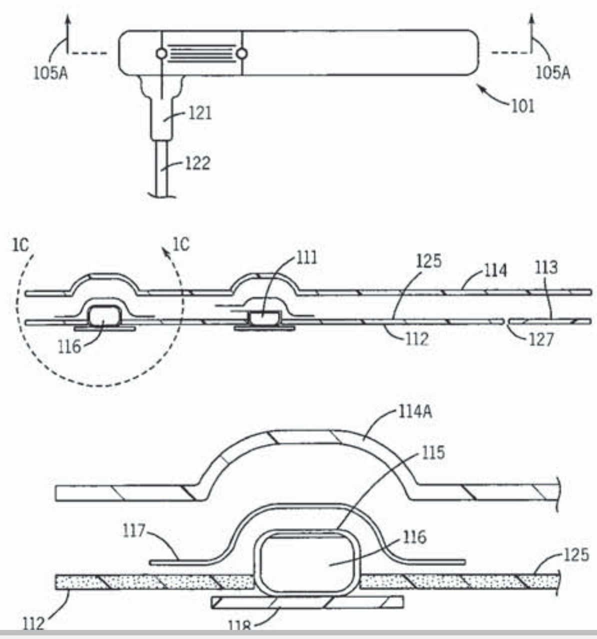
(57) **ABSTRACT**

The present invention provides non-adhesive oximeter sensors for patients with sensitive skin. Sensors of the present invention include a light emitting diode (LED) and a photodetector. The LED and the photodetector may be covered by a reflective mask and a faraday shield. Sensors of the present invention have a non-adhesive laminated layer. The non-adhesive layer contacts, but does not stick to, the patient's skin. When the sensor is removed from the patient, the non-adhesive layer does not tear or irritate the patient's skin. The non-adhesive layer preferably has a large static coefficient of friction. Sensors of the present invention can also have hook-and-loop layers. The sensor can be attached to the patient's body by wrapping the sensor around the patient and engaging the hook layer to the loop layer.

71 Claims, 2 Drawing Sheets



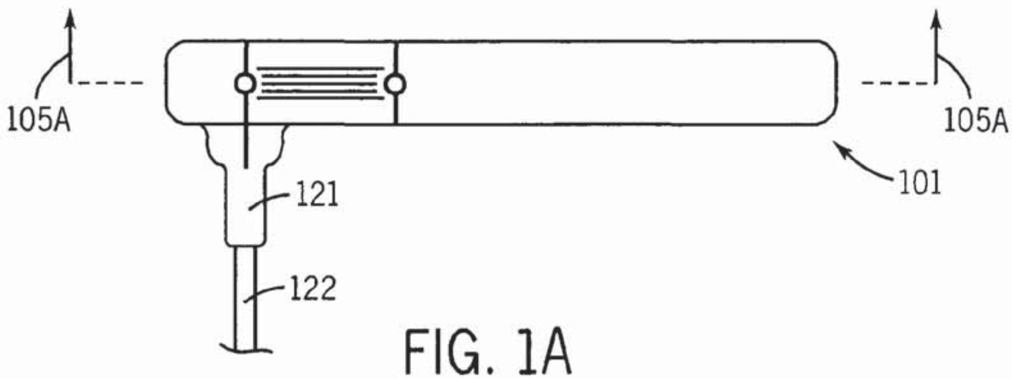


FIG. 1A

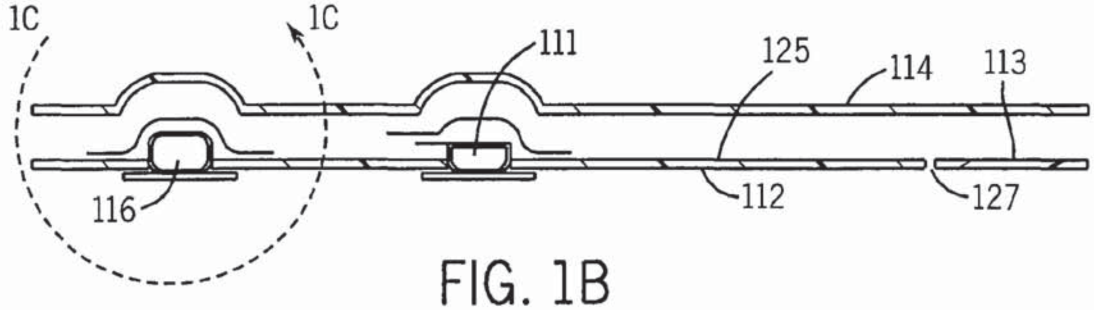


FIG. 1B

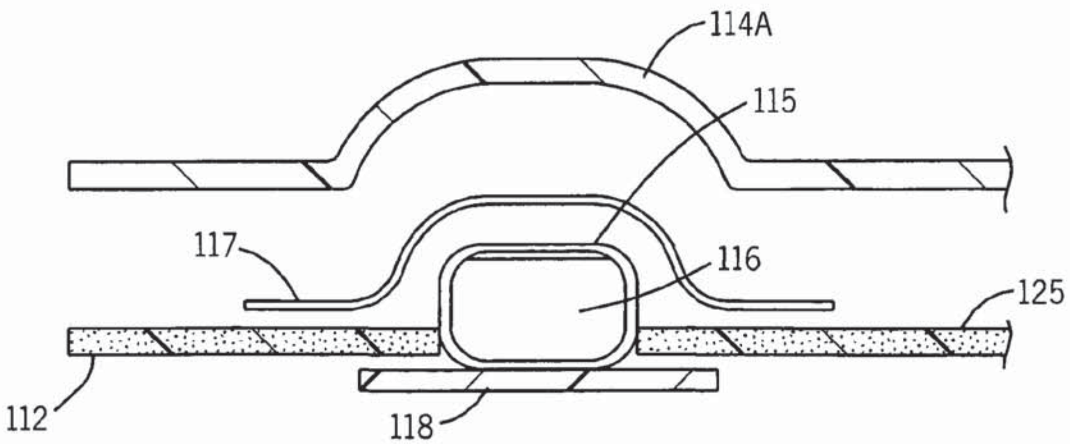


FIG. 1C

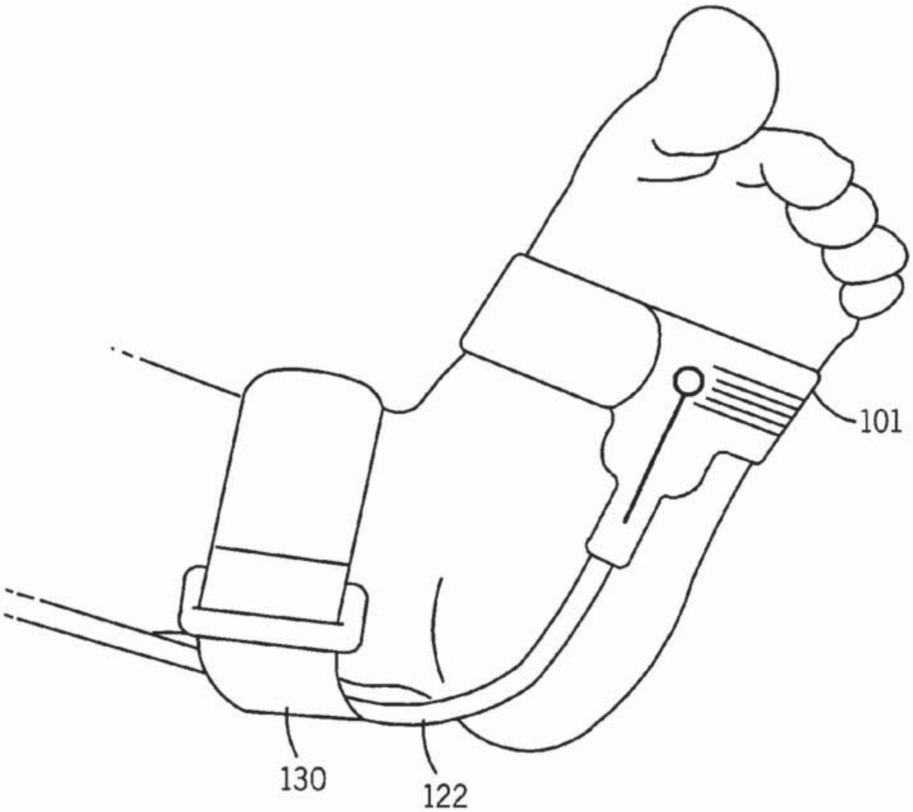


FIG. 2

NON-ADHESIVE OXIMETER SENSOR FOR SENSITIVE SKIN

BACKGROUND OF THE INVENTION

The present application relates to non-adhesive oximeter sensors, and more particularly to non-adhesive oximeter sensors for patients with sensitive skin.

Non-invasive monitoring of a patient's pulse is common in medical practice. One type of pulse oximeter monitor incorporates one or more light-emitting-diodes (LEDs) to shine through an area of tissue containing large amounts of blood. The light source is mounted to well-perfused tissue, such as a fingertip. Light is emitted and shines through the tissue. The amount of light passing through the tissue is measured using a photodetector.

Changes between the light emitted by the light source and the light received by the photodetector are caused by changes in the optical absorption of the light by the blood perfusing through the monitored tissue. The LEDs can emit either broad-spectrum visual light or narrow bandwidth light in the red or infrared wavelengths.

The absorption of certain wavelengths is related to the oxygen saturation level of hemoglobin in the blood perfusing the tissue. The variations in light absorption caused by change in oxygen saturations make possible direct measurement of the arterial oxygen content.

One type of prior art oximeter sensor is the STAT-WRAP™ sensor E542 by Epic Medical Equipment Services of Plano, Tex. The STAT-WRAP™ sensor has a non-adhesive foam outer layer that contacts a patient's skin. The foam layer is a thick, bulky layer relative to the overall thickness of the sensor. The foam layer has a static coefficient of friction of about 1.43.

The STAT-WRAP™ sensor also has hook-and-loop layers that engage each other. The hook layer is a separate layer that is stitched to an end of the sensor.

Other prior art oximeter sensors have an outer adhesive layer. The adhesive layer is a sticky material that bonds temporarily to the skin like a band-aid. The adhesive holds the oximeter sensor on the skin of the patient so that it does not move or fall off, while measurements are being taken.

Some patients (e.g., neonates) have sensitive skin that may tear or become irritated when adhesive material is applied to the skin and later removed. It would therefore be desirable to provide an oximeter sensor that remains attached to a patient's skin without using adhesive material, while avoiding the bulk of prior-art non-adhesive sensors. It would further be desirable to accomplish these two features in a manner that the sensor can be sterilized and produced economically.

BRIEF SUMMARY OF THE INVENTION

The present invention provides non-adhesive oximeter sensors for patients with sensitive or fragile skin. Sensors of the present invention include a light emitting diode (LED) and a photodetector. The LED light shines light through a patient's tissue. The light from the LED is detected by the photodetector. The LED and photodetector may be covered by transparent windows. The LED and the photodetector may also be covered by a reflective mask and a Faraday electromagnetic shield.

Sensors of the present invention have a laminated non-adhesive layer. The non-adhesive layer contacts, but does not stick to, the patient's skin. When the sensor is removed irritate the patient's skin. Therefore, the non-adhesive layer protects sensitive skin. In one embodiment, the non-adhesive layer is a polyvinyl chloride foam material. The non-adhesive layer preferably has a large static coefficient of friction to help keep the sensor motionless relative to the patient.

Sensors of the present invention also include one or more laminated layers that hold the sensor unit on the patient's body. These layers may include hook and loop layers. The sensor can be attached to the patient's body by wrapping the sensor around the patient and engaging the hook layer to the loop layer.

Sensors of the present invention may include a strengthening layer that lies between the other laminated layers. Furthermore, sensors of the present invention may include light-blocking features to minimize or eliminate ambient light interference and LED light from reaching the photodetector without passing through blood-perfused tissues (shunting).

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1**A illustrates a plan view of an exemplary embodiment of a non-adhesive oximeter sensor in accordance with the present invention;

FIG. **1**B illustrates a cross-sectional view of the sensor of FIG. **1**A taken along line **105**A—**105**A;

FIG. **1**C illustrates a detailed view of a portion of FIG. **1**B designated by the circle **1**C; and

FIG. **2** illustrates how an embodiment of the non-adhesive oximeter sensor of the present invention can be placed on a patient's foot.

DETAILED DESCRIPTION OF THE INVENTION

Oximeter sensor **101** shown in FIGS. **1**A, B, and C is an embodiment of the present invention. A top down view of oximeter sensor **101** is shown in FIG. **1**A. A cross sectional view of oximeter sensor **101** along a plane **105**A is shown in FIG. **1**B. The cross sectional view shows the laminated layers of sensor **101**. FIG. **1**C illustrates an expanded view of a portion of the cross sectional view.

Oximeter sensor **101** has one or more light emitting diodes (LED) **111** and a photodetector **116** as shown in FIG. **1**. LED **111** emits light that shines through a patient's tissue. The light from LED **111** is sensed by photodetector **116**. Photodetector **116** produces a signal in response to the detected light. The signal is decoded by an oximeter monitor (not shown) to calculate the patient's blood oxygen saturation. LED **111** and photodetector **116** are connected to the oximeter monitor through wires that feed through cable **122**.

Sensor **101** has a polyurethane window **118** below photodetector **116**. Sensor **101** also has a polyurethane window below LED **111**. The polyurethane windows are transparent. Light from LED **111** can pass unobstructed through the polyurethane windows to photodetector **116**.

As shown in exploded view in FIG. **1**C, photodetector **116**, is surrounded by a reflective mask **117**. Reflective mask **117** reflects light from LED **111** (that has passed through patient tissue and exited near the photodetector) back toward photodetector **116** like a mirror.

Reflective mask **117** increases the amount of LED light that the photodetector **116** receives from the patient's tissue, while assisting in blocking ambient light and LED light that

111 toward the patient's tissue. The reflective masks may comprise polyester or polypropylene with a reflective metal surface.

Photodetector **116** is also covered with a Faraday shield **115**. Faraday shield **115** protects photodetector **116** from electromagnetic fields in the environment. Shield **115** reduces electromagnetic interference that may introduce noise into the output signal of photodetector **116**.

Sensor **101** has laminated layers including layer **112** and hook-and-loop layers **113** and **114** shown in FIG. **1**. Loop layer **114** has, for example, small loops of threads. Hook layer **113** has, for example, small hooks that engage with the loops in loop layer **114**.

Hook layer **113** and loop layer **114** are used to attach sensor **101** to a patient. Hooks in hook layer **113** engage with the loops in loop layer **114**. Once engaged, the hook-and-loop layers remain attached to each other, until they are pulled apart. The end user can engage and disengage hook layer **113** from loop layer **114** multiple times in order to open or close the fastener. One portion of layer **114** cannot attach to another portion of layer **114**.

In one embodiment of the present invention, hook and loop layers **113** and **114** are VELCRO layers. In this embodiment, layer **114** comprises a VELCRO loop, and layer **113** comprises a VELCRO hook.

Loop layer **114** has a first raised portion **114**A that provides room for the thickness of photodetector **116**. Loop **114** also has a second raised portion that provides room for LED **111**.

Sensor **101** also has a bottom laminated layer **112** as shown in FIG. **1**. Layer **112** is a non-adhesive layer. Layer **112** is preferably made of a material that has a soft, smooth, non-skid surface. Layer **112** may, for example, comprise polyvinyl chloride (PVC) foam. One type of PVC that may be used with the present invention is 3M-9777L PVC foam manufactured by 3M Co. Layer **112** may also comprise other types of soft, non-adhesive material.

Bottom layer **112** is an outer layer of the sensor that contacts the patient's skin. Layer **112** comprises a non-adhesive material that does not adhere or stick to the patient's skin. Because layer **112** comprises a soft, non-adhesive material, it does not tear or irritate sensitive or fragile skin when sensor **101** is removed from the patient.

Layer **112** preferably comprises a material that has a relatively large static coefficient of friction. A material with a large static coefficient of friction helps to keep sensor **101** motionless relative to the skin as a patient moves. In sensors of the present invention, it is important to maximize the friction between the sensor and the skin, without the use of adhesives. Adhesives can damage fragile skin, and one objective of the present invention is to keep the sensor on the patient without slippage, but without the use of an adhesive.

According to the present invention, the static coefficient of friction of a material is tested using the following procedure. Attach a protractor to a vertical wall with the center in line with the edge of a table. Set up a stop block at the edge of the table to act as a pivot point for a glass plate. Place the glass plate flat on the table with one edge along the edge of the table, up against the stop block. Place a test sample of the material on the glass plate (or other reference materials, such as skin). Lift the free edge of the glass plate until the test sample just starts to slip. Record angle at which slippage first occurred. This angle is the angle of repose. Then calculate the coefficient of friction, which is the tangent of the angle of repose.

in the STAT-WRAP™ sensor. The 3M-9777L PVC foam measured using the above-described measuring technique resulted in a value of static coefficient of friction of infinity with respect to glass. The 3M-9777L PVC foam actually stayed on the glass test plate even after achieving a 90 degree angle of repose.

The 3M-9777L PVC material almost exhibits slight adhesive properties, surface tension forces, or static cling forces. Therefore, PVC foam is a very good choice of material for layer **112** in consideration of the preferred non-slip characteristics. Using skin as a reference material instead of glass, the 3M-9777L PVC foam exhibits a static coefficient of friction of greater than 5, such as 5.7.

The PVC material almost exhibits slight adhesive properties, surface tension forces, or static cling forces. Therefore, PVC foam is a very good choice of material for layer **112** in consideration of the preferred non-slip characteristics.

Materials other than PVC foam can be used for layer **112**. The static coefficient of friction for layer **112** is preferably greater than 10. Most preferably, layer **112** has a static coefficient of friction that is greater than 100.

Layer **112** is preferably light in color to enhance the amplitude of the light signals received by photodetector **116**. For example, layer **112** may be white, off-white, or cream colored. Alternatively, layer **112** may be dark in color to decrease the amount of ambient and shunted light that reaches the photodetector, at an expense of the amount of detected LED light signals.

Layer **112** is preferably a thin layer, as shown in the cross sectional views in FIG. **1**. By selecting a narrow thickness for layer **112**, sensor **101** is less bulky. Because sensor **101** is thin, it is more flexible, and it can be easily conformed around a patient's body part. FIG. **2** illustrates an example of how sensor **101** can be placed around a patient's foot.

Sensor **101** may include an additional laminated layer. The additional laminated layer is a strengthening film (not shown) that lies between laminated layers **114** and **112**. In one embodiment, hook layer **113** is attached to the strengthening film. In this embodiment, hook **113** is an integral part of one of the laminated layers that makes up the body of sensor **101**. Hook portion **113** is not attached to layer **112**. The foam layer **112** is discontinued at point **127** in FIG. **1**, and hook portion **113** begins to the right of **127**. In other embodiments, hook layer **113** is an integral part of bottom layer **112** or top layer **114**.

In one embodiment of the present invention, the inner side **125** of layer **112** is covered with a laminated opaque film. The opaque film blocks ambient light that may interfere with photodetector **116**. The opaque film may comprise polyethylene. The opaque film may be black or some other dark color that helps block ambient light and reduces shunted light. Dark in color is understood here to be of a nature with little reflectance of the wavelengths of light sensed by the sensor's photodetector.

Non-adhesive layer **112** is preferably long enough to wrap all the way around the patient's finger, toe, ear, or other portion of the body. Non-adhesive layer **112** is the only portion of sensor **101** that directly contacts the patient's skin. This feature of the present invention eliminates damage to the patient's skin that can be caused by adhesive portions of a sensor.

Once sensor **101** has been wrapped snuggly around the patient's finger, toe, or other body part, hook **113** is engaged with loop layer **114**. Layer **114** is facing outward relative to

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