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(54) Title: SKIN ABRADER

(57) Abstract: The present invention relates to devices, methods, and systems for abrading the skin in preparation for attachment of an electrode. In some embodiments, the invention may provide for a simple, low-cost device 120 with a flat, abrading surface that removes the topmost layer of the skin without causing undue injury.

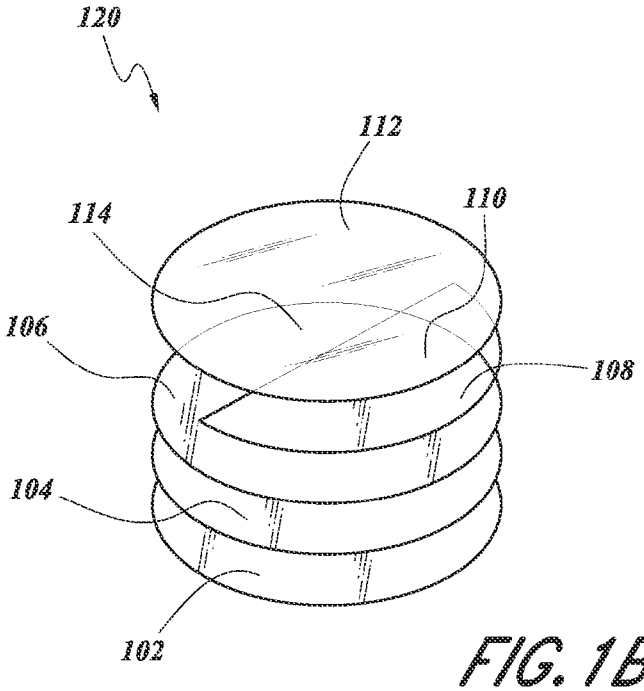


FIG. 1B

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SKIN ABRADER

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of U.S. Provisional Application No. 61/809,817, filed April 8, 2013, entitled SKIN ABRADER. The contents of the aforementioned application are hereby incorporated by reference in their entirety as if fully set forth herein. The benefit of priority to the foregoing application is claimed under the appropriate legal basis, including, without limitation, under 35 U.S.C. §119(e).

BACKGROUND OF THE INVENTION

Field of the Invention

[0002] This application describes embodiments of apparatuses, methods, and systems for the abrasion of skin in preparation for application of an electrode for detection of cardiac and other low level electrical signals generated within the human body, allowing for improved short term and long-term adhesion and improved conductance through skin, resulting in better signal quality of recorded data.

Description of the Related Art

[0003] Skin contact electrodes are used extensively for detecting and transforming potentials generated within the body into electrical signals which may be monitored for a variety of functions, such as the preparation of electrocardiograms and electroencephalograms. Many disposable electrode assemblies and similar devices utilize an electrode together with an adhesive for holding the electrode in position on the skin. For the best electrical contact with mammalian skin, it is desirable to remove hair and a portion of the epidermis, as well as surface oils. Typically, the process involves removal of hair by shaving or other depilatory method. Next, the skin is abraded for the removal of the dry layers of stratum corneum, followed by cleaning and defatting of the skin using an alcohol wipe. The skin abrasion process exposes more conductive layers of skin to improve electric connection, promoting better transmission of a cleaner signal.

[0004] As mentioned previously, electrodes may contain an adhesive to keep the electrode in contact with the skin. The outer layers of the stratum corneum are typically the driest and nearest to being sloughed off by the body. Removing these cells

prior to electrode placement allows the adhesive to come into newer, more anchored layers of the skin, promoting longer adhesion performance. With sensing applications that require longer-term wear periods, sufficient removal of skin takes on greater importance. The development of a long-term recording ECG patch has further created a need for a tool that is effective in thoroughly removing the stratum corneum layers, to allow for patch adhesion for periods up to and beyond 14 days.

[0005] As critical as the skin abrasion process is for good signal conduction and long term adhesion, it is a process that is often incomplete in practice. This is largely due to the limitations of existing abrasion tools in combination with the limited time and attention typically given to the abrasion process. Certain abrasion tools, resembling woven polymer sponges, have a coarse texture. Though the sensation of abrasion is heightened for the patient, the contours of the tool's surface are more conducive to creating scratches in the skin than evenly removing the outer stratum corneum layer. Other products, such as pumice-impregnated alcohol wipes, do an adequate job of abrading the skin without causing unwanted injury to the skin, however significant pressure and attention is required for an effective outcome. In combining the skin abrasion and cleaning step into a single tool, these instruments are easily confused for alcohol wipes intended for just cleaning, and the pressure required for abrasion is not achieved.

[0006] Because of the limitations of existing skin abrasion tools, there is need for a simple, one-piece, disposable and low-cost tool that can effectively abrade the skin while being easy to manipulate and that minimizes the amount of attention that must be given to this part of the prep process.

SUMMARY OF THE INVENTION

[0007] Embodiments of the present invention relate to skin abrasion devices. In one embodiment, a skin abrasion device comprises: a flat abrasive surface with a rounded shape and a holding layer to facilitate handling the device while applying even pressure to the skin. The device can be used in advance of skin-surface application of electrodes or devices that contain electrodes for sensing biopotentials such as an ECG. In some embodiments, the skin abrasion tool enables even and thorough removal of the top layer of stratum corneum without causing injury to the skin in the form of scratches or gouges, regardless of the experience level of the user.

[0008] In one embodiment, a dermal preparation device for preparation of the stratum corneum of a patient for long term adhesion of an electrode to the patient, comprises:

a support layer having an upper surface, a lower surface, a major axis extending through a geometrical center of the support layer and along the longest dimension of the support layer;

an abrasive adhered to the lower surface;

a handle secured to the upper layer; and

wherein the handle is formed by bonding a first portion of a handle layer to the support layer, and folding a second portion of the handle layer to form the handle.

[0009] In some embodiments, the support layer of the dermal preparation device is approximately circular, and the major axis is a diameter of the circle. In certain embodiments, the major axis is no more than about 2.5 inches long. In further embodiments, the is no more than about 2.0 inches long. Certain embodiments may cal for the dermal preparation device to further comprise an atraumatic edge. In some embodiments, the atraumatic peripheral edge comprises a rounded surface formed by inclining a peripheral edge of the device away from a plane defined by the lower surface, in the direction of the upper surface. In further embodiments, the support layer is sufficiently flexible that when pressed against a dermal surface using the handle, the lower surface will deform into a convex surface against the dermal surface. In some embodiments, the handle is bonded to the support layer along a bond which extends at least about 50 % of the maximum dimension of the support, along the axis of the bond. In certain embodiments, the handle is bonded to the support layer along a bond which extends at least about 85 % of the maximum dimension of the support, along the axis of the bond. In further embodiments, the handle is bonded directly to the support layer. . In certain embodiments, the handle is bonded to the support layer by a bond which covers at least about 15% of the total area of the upper surface of the support layer. In certain embodiments, the handle is bonded to the support layer by a bond which covers at least about 35% of the total area of the upper surface of the support layer. In some embodiments, the abrasive comprises a grit ranging from about 36-66 μm.

[0010] In further embodiments, in a dermal preparation device as described above where the handle is bonded to the support layer along a bond which extends at least about 50 % of the maximum dimension of the support along the axis of the bond, the axis

of the bond is substantially parallel to the major axis. In some embodiments, a transdermal electrode and surface preparation kit, comprises at least one transdermal electrode configured for adhesive attachment to a patient's skin, and at least one dermal preparation device as described above.

[0011] In some embodiments, a dermal preparation device for preparation of the stratum corneum of a patient for long term adhesion of an electrode to the patient, comprises:

an abrasive surface;

an inner layer; and,

a holding layer further comprising a gripping portion.

[0012] In certain embodiments, a method of abrading the skin of patient via a dermal preparation device in preparation for the long term adhesion of an electrode, comprises:

placing the dermal preparation device on the skin;

grasping a gripping portion of the dermal abrasion device;

applying pressure to the skin through the dermal abrasion device; and

moving the device in a manner to remove a desirable amount of skin.

[0013] In some embodiments, the method may comprise preparing the skin for application of the dermal preparation device. Certain embodiments may call for the method to further comprise adhering a physiological monitoring device that comprises an electrode. In embodiments of the method, a physiological parameter may be measured with the physiological monitoring device. In embodiments, the desirable amount of skin comprises an amount of skin configured to improve the signal quality of the physiological monitoring device.

BRIEF DESCRIPTION OF THE DRAWINGS

[0014] Figs. 1A-B illustrate different views of embodiments of a skin abrasion device.

[0015] Figs. 2A-E illustrate different views and photographs of embodiments of a skin abrasion device.

[0016] Fig. 3 illustrates an embodiment of a sheet for use in manufacturing a skin abrasion device.

[0017] Fig. 4 illustrates an additional embodiment of a skin abrasion device.

[0018] Fig. 5 illustrates a method for the manufacture of skin abrasion devices.

[0019] Fig. 6 illustrates an additional method for the manufacture of a skin abrasion device.

[0020] Figs. 7A-B illustrate embodiments of packaging for a skin abrasion device.

[0021] Fig. 8 illustrates an additional embodiment of packaging for a skin abrasion device.

[0022] Fig. 9 illustrates an embodiment of a kit containing skin abrasion devices.

[0023] Fig. 10 illustrates an embodiment of a kit containing materials related to prepping the surface of the skin for electrode placement.

DETAILED DESCRIPTION

[0024] Embodiments disclosed herein relate to apparatuses and methods directed towards the use and manufacture of skin abrasion devices.

[0025] Figure 1A illustrates an embodiment of a skin abrasion device 100 comprising an abrasive layer 102 with an abrasive surface 103, an adhesive layer 104, an inner sheet 106, a partial adhesive layer 108, and a holding layer 110 further comprising a gripping portion 112. The skin abrasion device 100 may be flexible and can be further configured to remove at least a portion of the stratum corneum. An advantage of ensuring properties of flexibility and resilience in the abrasion device is the ability to conform against the curvature and contours of the body where electrodes would be placed, while maintaining a relatively even plane such that the pressure applied to the skin during abrasion can be substantially uniformly distributed across the surface as best as practicable.

[0026] It will be understood by one skilled in the art that the geometric shapes of the peripheral edge of the skin abrasion device described herein are non-limiting. The embodiments of the skin abrasion device described herein are applicable to a wide variety of geometric shapes.

[0027] In some embodiments, the abrasive layer 102 can comprise a material sheet such as medical grade or equivalent sandpaper, where a range of grit sizes can be used depending upon the level of abrasion or gentleness desired as well as the type of skin

that is being abraded. In some embodiments, the average diameter of the grit may range in size from about 16-93 microns (μm). For example, the grit can have an average diameter ranging from: about 20-90 μm, about 25-85 μm, about 30-80 μm, about 35-75 μm, about 40-70 μm, about 45-65 μm, or about 50-60 μm. Preferably, Grit diameters in the range of 36-66 μm can provide a level of abrasion that is effective with minimal pressure and a perception of minimal roughness by the subject being abraded.

[0028] In some embodiments, the abrasive surface 103 may be a surface that is embedded with or bonded to abrasive material, such as polymeric or mineral particles, or one that is textured through material properties or a manufacturing process.

[0029] Preferably, the abrasive surface 103 is biocompatible. In one embodiment, the abrasive surface 103 may comprise a biocompatible mineral such as silicon carbide. Another embodiment may be a biologically inert polymer that is formed or molded to have an abrasive texture, such as hook and loop fasteners. Further embodiments include the use of aluminum oxide, alumina-zirconia, chromium oxide, ceramic aluminum oxide or any other appropriately abrasive material.

[0030] In some embodiments, the abrasive surface 103 may comprise commercially available abrasive surfaces such as 426U Abrasive, available from 3M Innovative Properties Company. Further abrasive surfaces may also include those described in US 6,136,008, SKIN ABRASION DEVICE FOR BIOMEDICAL ELECTRODE, filed March 19, 1998 and hereby incorporated by reference. For example, as described in US 6,136,008, an abrasive surface can comprise: a polymeric geometrically structured surface abrasive which minimizes and preferably avoids any use of mineral particle content, making the assembly of a skin abrasion device in a high-speed, low-cost biomedical electrode manufacturing facility possible under GMP/QSR conditions; and a predetermined pattern of geometrically structured surface abrasive, which permits assured, engineered surfaces for consistent abrading properties on a specific type of mammalian skin or a specific mammal, in order to achieve reduced skin impedance without undue damage or pain to the patient. Using these parameters, it is possible to engineer a geometrically structured surface abrasive based upon the tooling used to produce such surface.

[0031] As further described in US 6,136,008, a portion of an abrasive surface can be engineered from a variety of polymeric materials. Non-limiting examples of such polymers include (meth)acrylates such as triacrylates prepared from one or more monomers such as trimethyolpropane triacrylate and triacrylate of trishydroxyethyl

isocyanate. Additives can be added to such an abrasive surface and can include pigments, dyes, plasticizers, anti-oxidants, and fillers as desired by those skilled in the art.

[0032] The embodiments described herein may further include the use of open-coat abrasives or perforations, in order to minimize the collection of abraded skin that may reduce the effectiveness of the abrasive during the time of use.

[0033] In certain preferable embodiments, the material properties of the selected abrasive material sheet used in the abrasive layer 102 contribute to the flexibility and structural resilience of the abrasive device. In some embodiments, the abrasive surface 102 can be laminated to the inner sheet 106 via an adhesive layer 104. Adhesive layer 104 can comprise any suitable adhesive material, for example a double-sided rubber adhesive such as 300LSE manufactured by 3M Innovative Properties Company. In some embodiments, adhesive layer 104 is a glue or other adhesive material sheet or substance.

[0034] In certain embodiments, the inner sheet 106 can be a flexible sheet or film, preferably constructed from a polymer such as polythethylene terephthalate. In other embodiments, the inner sheet 106 can comprise any suitable polymer, for example polyethylenes, polypropylenes, polyesters, vinyl esters, other flexible polymer films. The thickness of the inner sheet 106 can range from about 0.002 inches to 0.015 inches. For example, the thickness of the inner sheet 106 can range from: about 0.003-0.014 inches, about 0.004-0.013 inches, about 0.005-0.012 inches, about 0.006-0.011 inches, about 0.007-0.010 inches, or about 0.008-.009 inches. The use of a flexible polymer film advantageously contributes to the flexibility and structural resilience of the skin abrasion device.

[0035] In certain embodiments, the thickness of the inner sheet 106 is desirably selected to complement the material properties of the abrasive layer. For example, if the abrasive layer is particularly thick, then a thinner inner sheet layer may be more desirable.

[0036] Another advantage of laminating the inner sheet 106 to the abrasive surface 102 is the minimization of creases that can form on the abrasive surface, as certain abrasive materials can be prone to crease-forming due to bending. Such creasing can produce sharp corners which may scratch or break the skin, increasing the likelihood of skin irritation or sensitization to electrode materials.

[0037] In some embodiments, the inner sheet 106 is attached to an adhesive layer 108 that covers less than 100% of an upper surface of the inner sheet 106. The

partial adhesive layer 108 can be comprised of any suitable adhesive material, for example a double-sided rubber adhesive such as 300LSE manufactured by 3M Innovative Properties Company. In other embodiments, the adhesive layer 108 is a type of glue or other adhesive substance. In some embodiments, the adhesive layer 108 can cover a portion of the inner sheet 106 ranging from approximately 5% to 100% of inner sheet 106. For example, the portion of inner sheet 106 covered by adhesive layer 108 can be at least about 10%, at least about 15%, at least about 20%, at least about 25%, at least about 30%, at least about 35%, at least about 40%, at least about 45%, at least about 50%, at least about 55%, at least about 60%, at least about 65%, at least about 70%, at least about 75%, at least about 80%, at least about 90%, or about 100% of the total top area of the inner sheet 106. In certain embodiments, the adhesive layer 108 covers no more than about 60% or no more than about 50% of the area of the inner shet 106. In alternative embodiments, the inner sheet 106 can comprise multiple thinner sheets laminated together.

[0038] In some embodiments, the holding layer 110 can be attached to the inner sheet 106 via an adhesive layer 108. The adhesive layer 108 can be attached to only a portion of the holding layer 110. As will be described in greater detail below, the portion of the holding layer 110 that is not attached to the adhesive layer 108 functions as the gripping portion 112, which can be a tab, handle, or other protrusion. The gripping portion 112 can be grasped between the fingers of a user to control the movement and applied pressure of the skin abrasion device.

[0039] In some embodiments, the portion of the holding layer 110 attached to the adhesive layer 108 can be at least about 1%, at least about 5%, at least about 10%, at least about 15%, at least about 20%, at least about 25%, at least about 30%, at least about 35%, at least about 40%, at least about 45%, at least about 50%, at least about 55%, at least about 60%, at least about 65%, at least about 70%, at least about 75%, at least about 80%, at least about 90%, or about 100% of the total area of the holding layer 110. In certain embodiments, the portion of the holding layer 110 that is attached to the inner sheet 106 by adhesive layer 108 is no more than about 70%, about 60%, or about 50% of the area of the holding layer 110.

[0040] In certain embodiments, the holding layer 110 can be a flexible sheet or film, preferably constructed from a polymer such as polythethylene terephthalate. In other embodiments, the holding layer 110 can comprise any suitable polymer, for example polyethylenes, polypropylenes, polyesters, vinyl esters, or other flexible polymer

films. The thickness of the holding layer can range from about 0.001-0.010 inches. For example, the thickness of the holding layer 110 can range from: about 0.002-.009 inches, about 0.003-0.008 inches, about 0.004-0.007 inches, or about 0.005-0.006 inches.

[0041] In some embodiments, the holding layer 110 can be printed to include text instructions, diagrams, images, or other labeling that facilitates use of the device for certain applications, or that aid in correct selection of the device as applicable to cases in which multiple abrasion devices are provided to the user. For example, a visual indicium such as a number symbol or color code may be provided on the holding layer, or visible through the holding layer, indicative of a particular coarseness of the abrasive layer 102. In certain embodiments, a plurality of abrasion devices may be provided, each having two unique abrasive characteristics and unique corresponding indicium.

[0042] In some embodiments, the abrasive layer is not comprised of a separate layer, but rather, the bottom layer of the abrasive device is comprised of grit as described above, directly adhered to the inner sheet 106 via an adhesive.

[0043] Figure 1B illustrates an embodiment of a skin abrasion device with a circular peripheral shape 120. In some embodiments, the abrasive device 120 may be rounded, circular, oval, or otherwise curved. With a rounded shape, the abrasive device remains free of the types of angled or straight edges that can scratch, cut, or break the skin of the subject during the abrasion process when the device is moved back and forth with application of pressure. The abrasive device 120 may be made into further shapes without sharp or jagged edges unconfined to the aforementioned shapes. Similar to Figure 1A, In some embodiments, the portion of the holding layer 110 attached to the adhesive layer 108 can be at least about 1%, at least about 5%, at least about 10%, at least about 15%, at least about 20%, at least about 25%, at least about 30%, at least about 35%, at least about 40%, at least about 45%, at least about 50%, at least about 55%, at least about 60%, at least about 65%, at least about 70%, at least about 75%, at least about 80%, at least about 90%, or about 100% of the total area of the holding layer 110. In certain embodiments, the portion of the holding layer 110 that is attached to the inner sheet 106 by adhesive layer 108 is no more than about 70%, about 60%, or about 50% of the area of the holding layer 110.

[0044] In some embodiments, the abrasive device comprises a major axis 114 comprising the longest dimension that extends across the geometric center of the device in a plane parallel to the plane of the abrasive device. The length of the major axis 114 can range from about 0.5-3.0 inches. For example, the length of the major axis can range

from: about 0.75-2.75 inches, about 1.0-2.5 inches, about 1.25-2.25 inches, or about 1.5-2.0 inches. In a preferred embodiment, the length of the major axis is 1.625 inches.

[0045] Figures 2A-F illustrate different views of an embodiment of an abrasive device, similar to the device described in Figure 1B, wherein a holding feature such as the gripping portion 112 of the holding layer 110 can be pinched between the fingers 122 and used to abrade the skin 124. The gripping portion, which may be embodied as a tab, handle, or other protrusion, serves to facilitate secure holding of the abrasion device while minimizing contact between the abrasion device's user and the skin of the subject being abraded. The gripping portion also enables the clinician or wielder of the abrasion device to apply even pressure to the center of the abrasion device rather than uneven pressure to one edge, as may be the case if a flat piece of abrasive material were held without a holding feature. In a preferred embodiment, the gripping portion 112 of holding layer 110 extends across at least approximately half of the abrasive device as defined by the major axis 114. In some embodiments, the gripping portion 112 has the approximate shape of a half-circle. Preferably, the flat edge of the half-circle gripping portion 112 can extend across the entirety of major axis 114. However, in some embodiments, the flat edge of the gripping portion 112 extends along only a portion of the major axis 114. For example, the flat edge can extend across: at least about 10%, at least about 20%, at least about 30%, at least about 40%, at least about 50%, at least about 60%, at least about 70%, at least about 80%, at least about 90%, or about 100%. Further, it will be understood that the gripping portion 112 is not limited to a flat edge aligning with the major axis 114. In some embodiments, the flat edge of the gripping portion may be located parallel to the major axis between the major axis and the edge of the abrasive device. In other embodiments, the flat edge of the gripping portion may be perpendicular to the major axis 114. As will be understood by those skilled in the art, in still other embodiments, the shape of the gripping portion may be rectangular, circular, or further shapes other than a half-circle.

[0046] Figure 3 illustrates a sheet 130 for use in one method of manufacturing the abrasion device as described above, comprising disc cut-outs 136, partial adhesion layer 134, and unadhered sections of holding layer 132. In some embodiments, a method of producing the skin abrasion device comprises: laminating the aforementioned abrasive surface with a backing material, or multiple materials, for structural support and flexibility; attaching material that is used as a holding feature; and, cutting the material to a desired shape. Within the aspect of manufacturing, the use of an abrasive film or sheet

130 facilitates the use of scalable and inexpensive converting methods for laminating to other necessary materials. In one embodiment of this process, as illustrated in Figure 3, two abrasive discs 136 can be made as mirror images within the same 2-up die strike. This approach could be repeated in a pattern in both x and y dimensions, utilizing either a flat steel-rule die or a rotary die for large-scale production.

[0047] In some embodiments, the abrasion device comprises a topmost support layer and a handle. In certain embodiments, the handle can be attached to the support layer via two or more attachment points. Preferably, the two or more attachment points can be spaced apart for further stability. In some embodiments, the attachment points for the handle can be located in any location across the top surface of the abrasion device.

[0048] Figure 4 illustrates an embodiment of an abrasive device similar to the embodiments described in Figures 1-2 that is formed to have a slight upwardly concave shape, particularly at the edges, forming an atraumatic periphery 214. The abrasion device can have a rounded profile in plan view. In further embodiments, the abrasion device may have a rectangular, oval, or other shape in plan view. As with Figures 1-2, the abrasive device can comprise an abrasive layer 202, an adhesive layer 204, an inner sheet 206, a partial adhesive layer 208, and a holding layer 210 comprising a gripping portion 212. The atraumatic periphery 214 concaves upwardly and presents a convex curve along the peripheral lower edge which would reduce the risk of contact between skin and the potentially sharp edges of the abrasive device, further eliminating potential for inadvertent scratching or gouges in the skin. In some embodiments, the annular atraumatic surface can be formed by molding or thermoforming operations or by cold stamping the device or support layer from a sheet stack. An atraumatic periphery can alternatively be formed by tapering the thickness of the abrasion device towards the edges or by using lower stiffness materials to construct an annular peripheral zone on the device.

[0049] As similarly described above in relation to Figure 1, the thickness of inner layer 206 can be varied, generally between about .001-.015. A thicker inner layer 206 beyond about .01 may lead to decreased flexibility in the abrasive device; however, depending upon the construction material, a thicker inner layer can allow for greater ease in curving the edges of the device.

[0050] Figure 5 illustrates an embodiment of a method 300 for creating the concave shape of the abrasive device of Figure 4 through a cutting method using cutters

306 applied against a softer surface 304, causing the abrasive device 302 to take a curved edge 308. Figure 6 illustrates an embodiment where preparation of the concave shape can be achieved through more deliberate forming methods 400 after the material is cut. In some embodiments, the material could be cut against an explicitly concave surface 404, imparting that shape when the cut force is applied.

[0051] The shape and form of the abrasion device is conducive to flat and user-friendly packaging. Figure 7A illustrates an embodiment of a mechanism for packaging the abrasion device 500 via a half-moon slit 502, where the tab or handle 504 of the abrasion device is presented on top of the slit 502. Figure 7B illustrates an embodiment of a mechanism for packaging the abrasion device 500 where the tab or handle 504 may extend in a direction away from the half-moon slit 502. In some embodiments, the tab or handle 504 may extend in an opposite direction, directly away from the half-moon slit 502. In certain embodiments, the tab or handle can extend in a direction perpendicular to the half-moon slit 502. It will be understood by one of skill in the art that the slit may be of any shape suitable for holding the abrasion device, for example an angular slit. The abrasion device may also be held by more than one slit, such as two slits, three slits, or more than three slits. The half-moon slit may be a slit extending through an arc of at least about 120° and preferably at least about 160°, or 180°, and may have a substantially constant radius or a curve conforming to a portion of an oval or ellipse.

[0052] Figure 8 illustrates another packaging embodiment where the abrasion device is placed in a rectangular slot 506, which can secure the abrasion device through friction against the packaging surface, and presents a handle above or below the slot. Both of these embodiments described in Figures 7 and 8 allow the user to grip the abrasion device from the included tab or handle 504 and remove the device from the packaging without changing grip.

[0053] As described above, the abrasion device allows for versatility in its packaging. In one packaging embodiment, the abrasion device may be individually packaged and provided in multiple unit packaging 600. Alternately, many abrasion devices may be provided loose, in a box of multiple quantities 602. Figure 9 illustrates a kit embodiment, in which a single, or multiple abrasion devices are provided for use with a single electrode or other physiological monitoring product.

[0054] In a kitted embodiment 700, the abrasion device's flat form factor allows for packaging within instructions along with other skin preparation materials, such as razors and alcohol wipes. Figure 10 illustrates one embodiment of such a kit, a Zio Patch kitted assembly 704, which contains the monitor, shaving tool, abrading tool, and cleaning wipe(s) 702 packaged together within the application instructions booklet. Instructions 706 In another embodiment of the abrasion device included within a kit, multiple abrasion devices of varying coarseness could be provided for sequential steps of abrasion, such as a coarse abrasion device for the first pass, and a finer grit abrasion device for the final pass. In another embodiment of the abrasion device included within a kit in which multiple abrasion devices of varying coarseness could be provided for sequential steps of abrasion, the different abrasion devices could vary in size and shape so as to be distinguishable within the kit.

[0055] In certain embodiments, the handle contains cut-outs (semi-circular, triangular, rectangular, or any suitable shape) along its edge, giving the user a feature that helps peel the handle up from the main body of the device if it has not been folded up.

[0056] In some embodiments, the kit 700 may further include instructions for the use of the abrasion device in combination with a monitoring device. For example, the kit may include instructions 706 such as how to enroll in an online website related to the abrasion device. Further instructions may include advising a user as to properly planning for the placement of the physiological monitoring device, including shaving, abrading the skin, cleaning the skin, removal of the device, and proper application of the physiological monitoring device.

WHAT IS CLAIMED IS:

1. A dermal preparation device for preparation of the stratum corneum of a patient for adhesion of an electrode to the patient, comprising:

a support layer having an upper surface, a lower surface, a major axis extending through a geometrical center of the support layer and along the longest dimension of the support layer;

an abrasive adhered to the lower surface;

a handle secured to the upper layer; and

wherein the handle is formed by bonding a first portion of a handle layer to the support layer, and folding a second portion of the handle layer to form the handle.

2. A dermal preparation device as in Claim 1, wherein the support layer is approximately circular, and the major axis is a diameter of the circle.

3. A dermal preparation device as in Claim 1, wherein the major axis is no more than about 2.5 inches long.

4. A dermal preparation device as in Claim 1, wherein the major axis is no more than about 2.0 inches long.

5. A dermal preparation device as in Claim 1, further comprising an atraumatic peripheral edge.

6. A dermal preparation device as in Claim 5, wherein the atraumatic peripheral edge comprises a rounded surface formed by inclining a peripheral edge of the device away from a plane defined by the lower surface, in the direction of the upper surface.

7. A dermal preparation device as in Claim 1, wherein the support layer is sufficiently flexible that when pressed against a dermal surface using the handle, the lower surface will deform into a convex surface against the dermal surface.

8. A dermal preparation device as in Claim 1, wherein the handle is bonded to the support layer along a bond which extends at least about 50 % of the maximum dimension of the support, along the axis of the bond.

9. A dermal preparation device as in Claim 1, wherein the handle is bonded to the support layer along a bond which extends at least about 85 % of the maximum dimension of the support, along the axis of the bond.

10. A dermal preparation device as in Claim 1, wherein the handle is bonded to the support layer by a bond which covers at least about 15% of the total area of the upper surface of the support layer.

11. A dermal preparation device as in Claim 1, wherein the handle is bonded to the support layer by a bond which covers at least about 35% of the total area of the upper surface of the support layer.

12. A dermal preparation device as in Claim 1, wherein the abrasive comprises a grit with diameters ranging from about 36-66 μm.

13. A dermal preparation device as in Claim 8, wherein the axis of the bond is substantially parallel to the major axis.

14. A transdermal electrode and surface preparation kit, comprising at least one transdermal electrode configured for adhesive attachment to a patient's skin, and at least one dermal preparation device as in Claim 1.

15. A dermal preparation device for preparation of the stratum corneum of a patient for adhesion of an electrode to the patient, comprising:

an abrasive surface;

an inner layer; and,

a holding layer further comprising a gripping portion.

16. A method of abrading the skin of patient via a dermal preparation device in preparation for adhesion of an electrode, comprising:

placing a dermal preparation device on the skin;

grasping a gripping portion of the dermal abrasion device;

applying pressure to the skin through the dermal abrasion device; and

moving the device in a manner to remove a desirable amount of skin.

17. The method of claim 16, further comprising preparing the skin for application of the dermal preparation device.

18. The method of claim 16, further comprising adhering a physiological monitoring device comprising an electrode.

19. The method of claim 18, further comprising measuring a physiological parameter with the physiological monitoring device.

20. The method of claim 19, wherein a desirable amount of skin comprises an amount of skin configured to improve the signal quality of the physiological monitoring device.

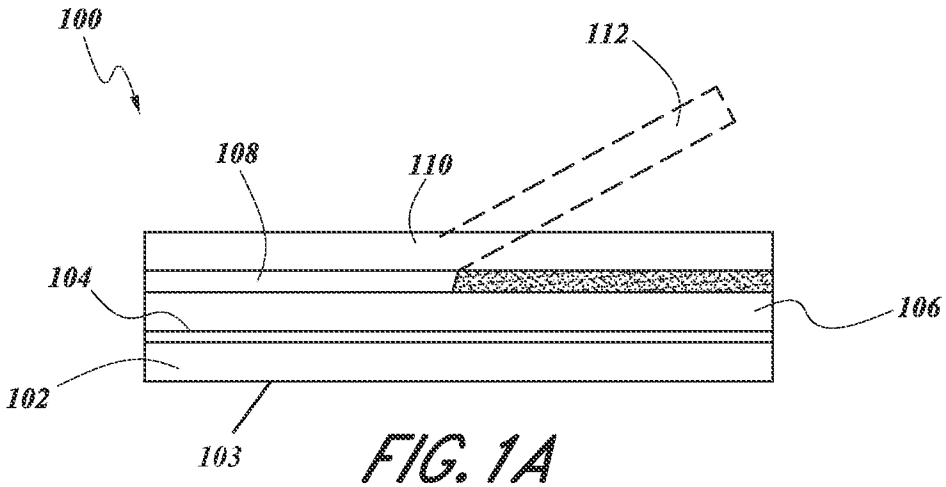


FIG. 1A

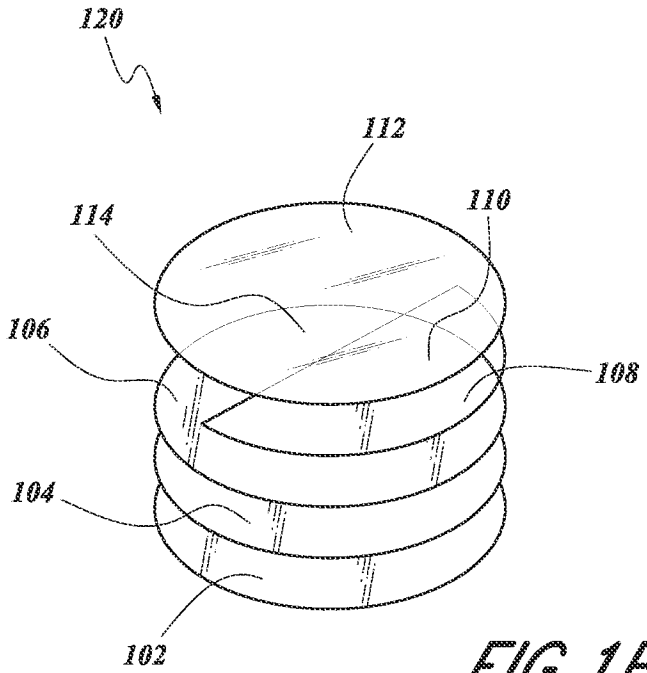


FIG. 1B

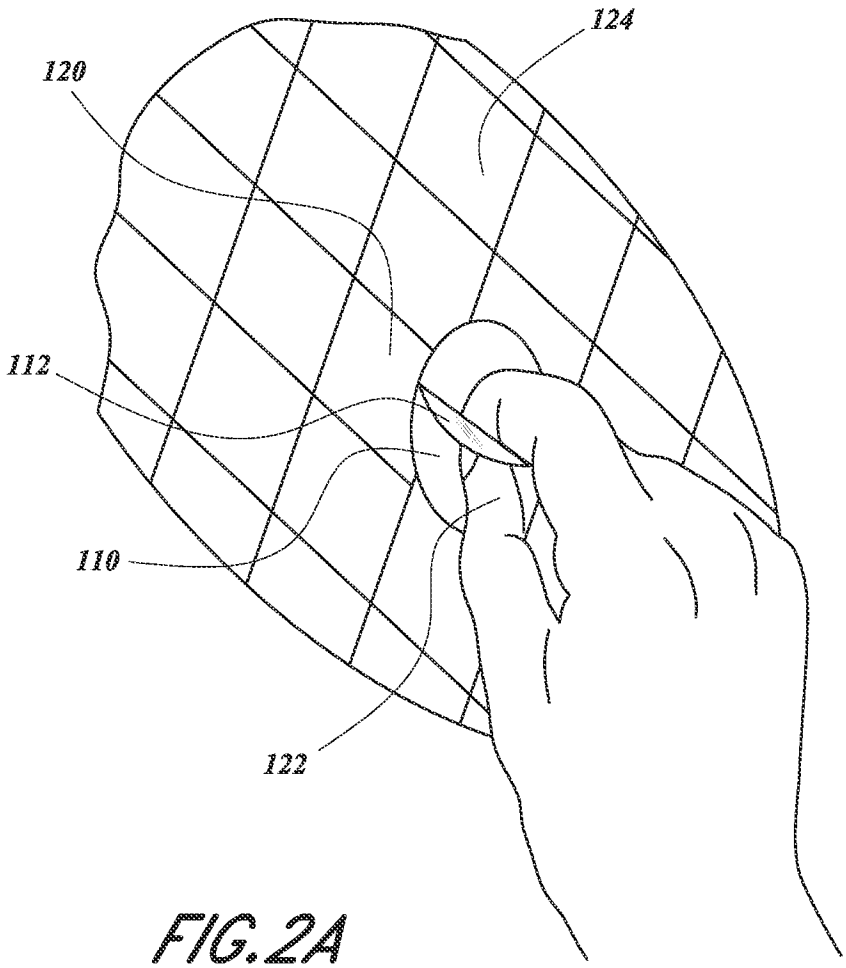


FIG. 2A

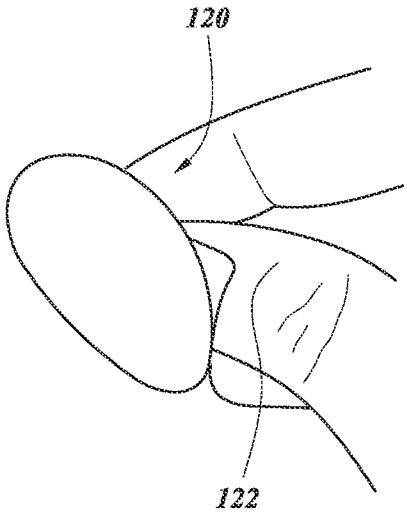


FIG.2B

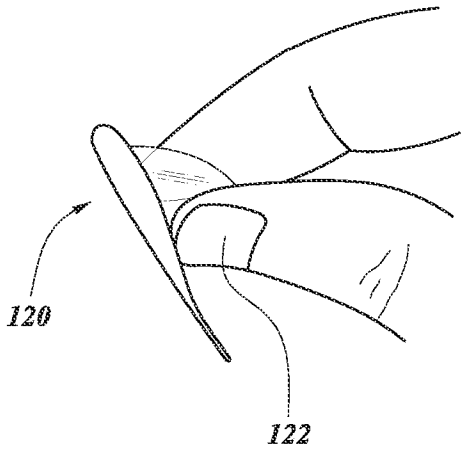


FIG.2C

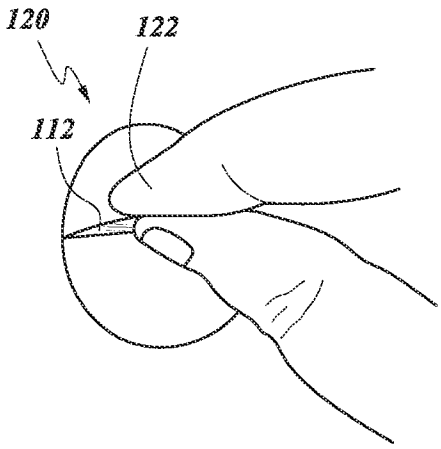


FIG.2D

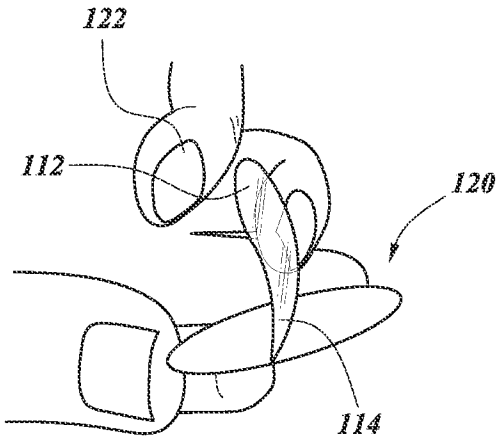


FIG.2E

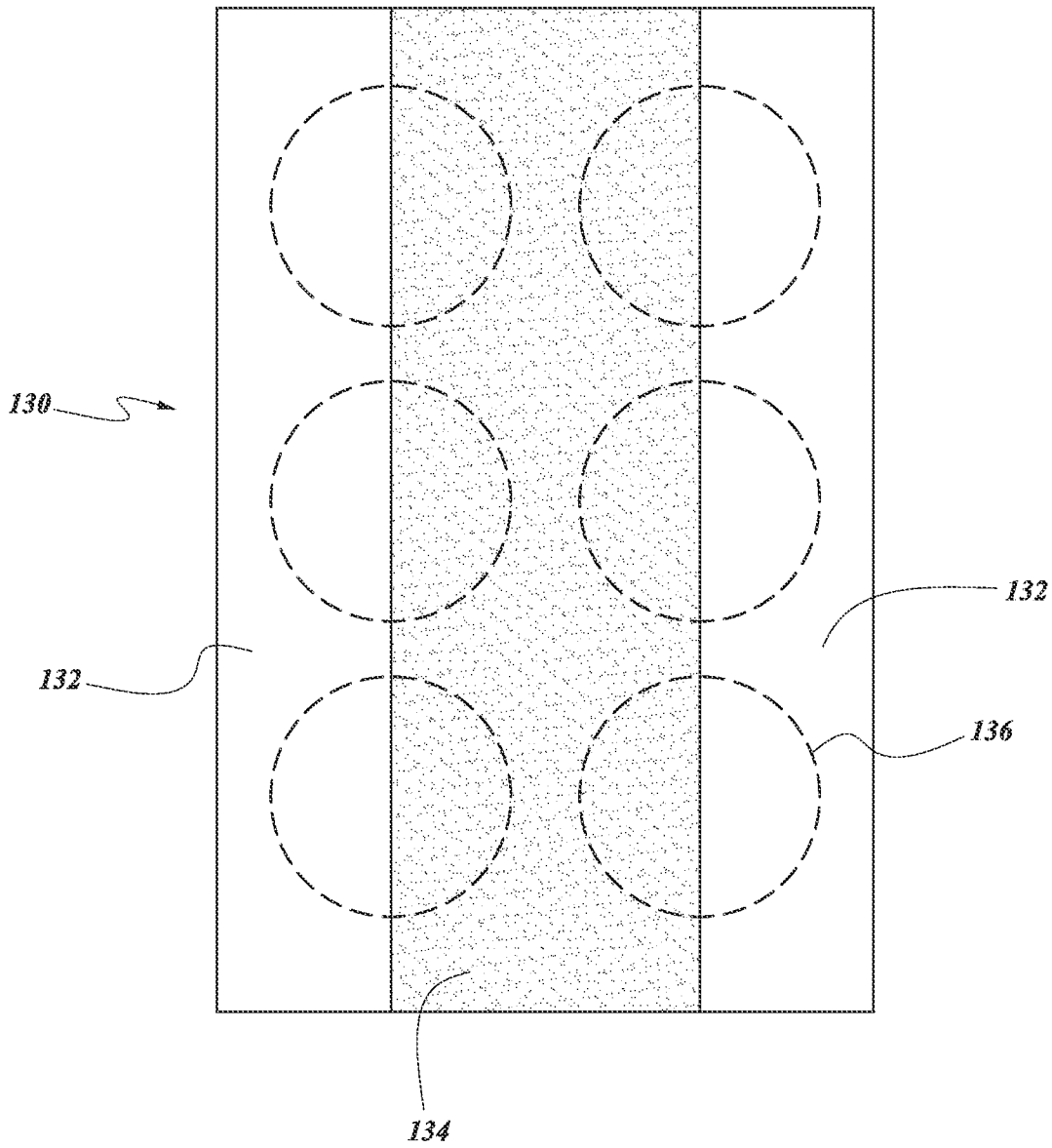


FIG. 3

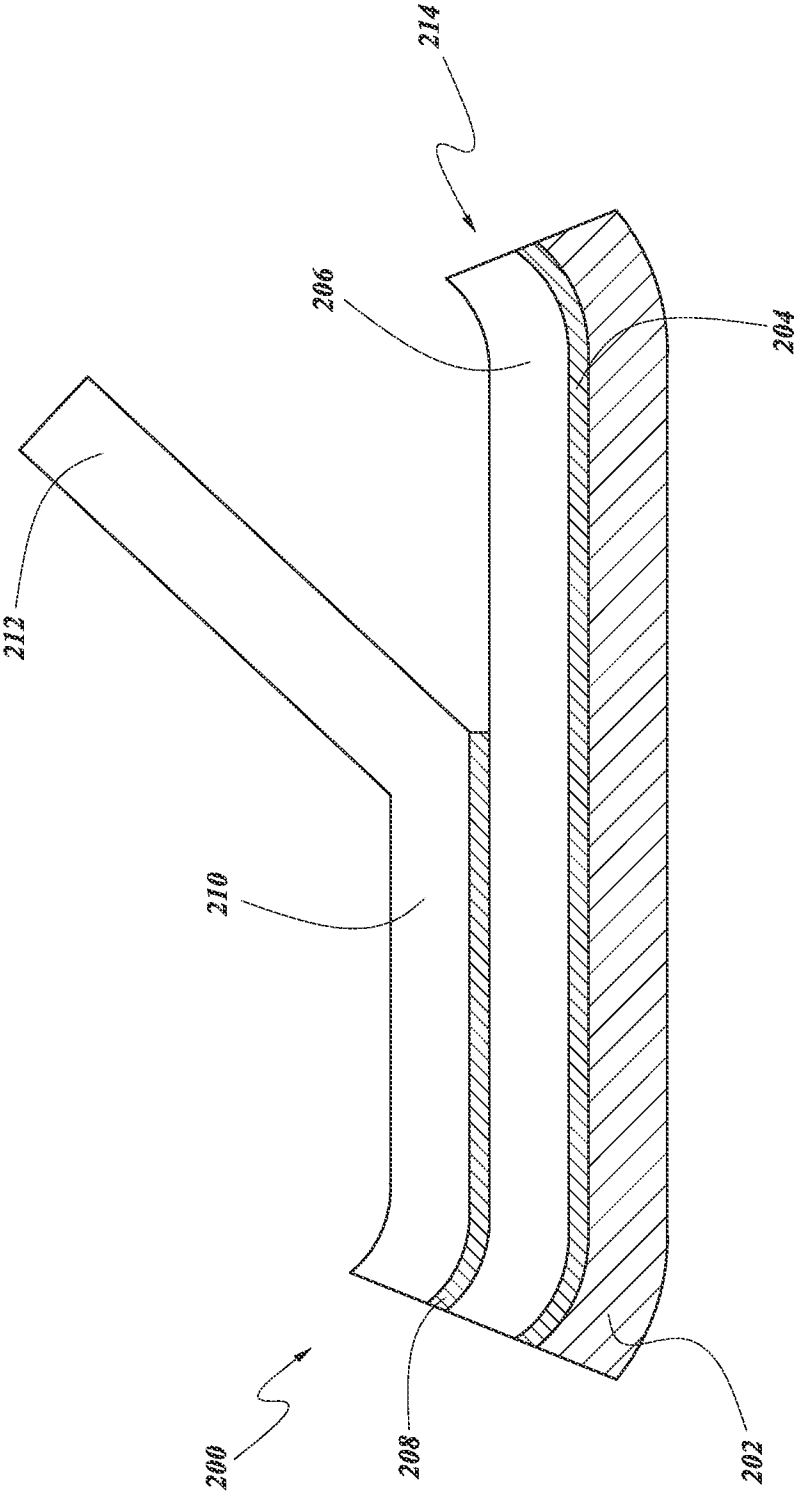


FIG. 4

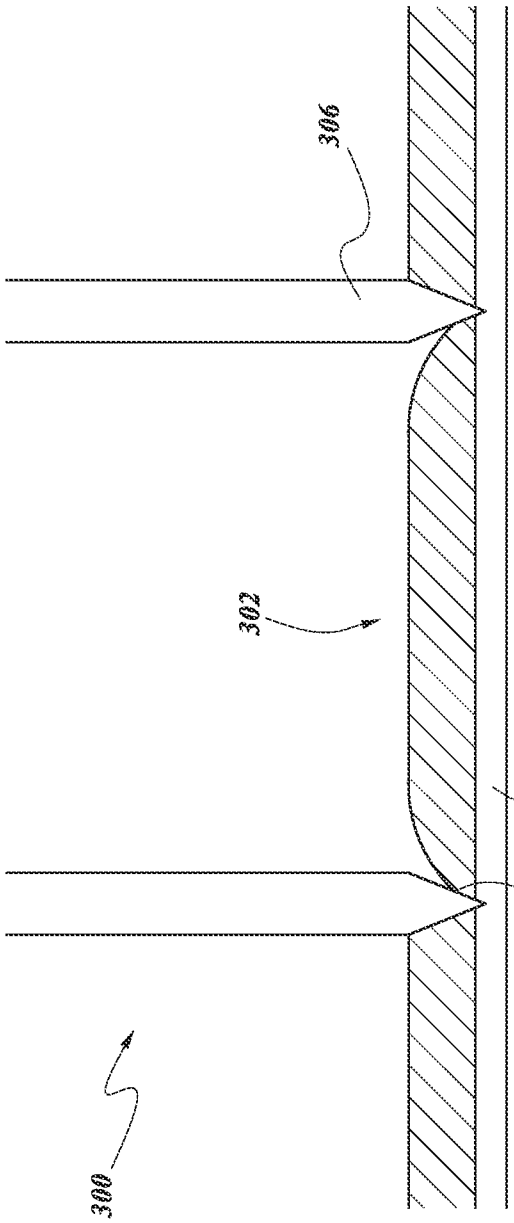


FIG. 5

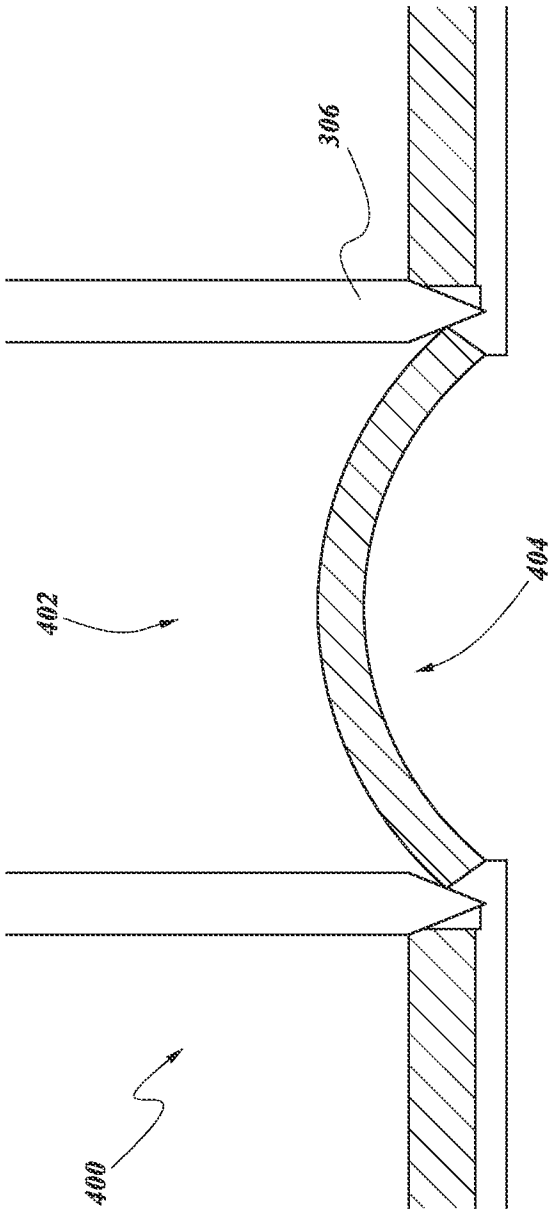


FIG. 6

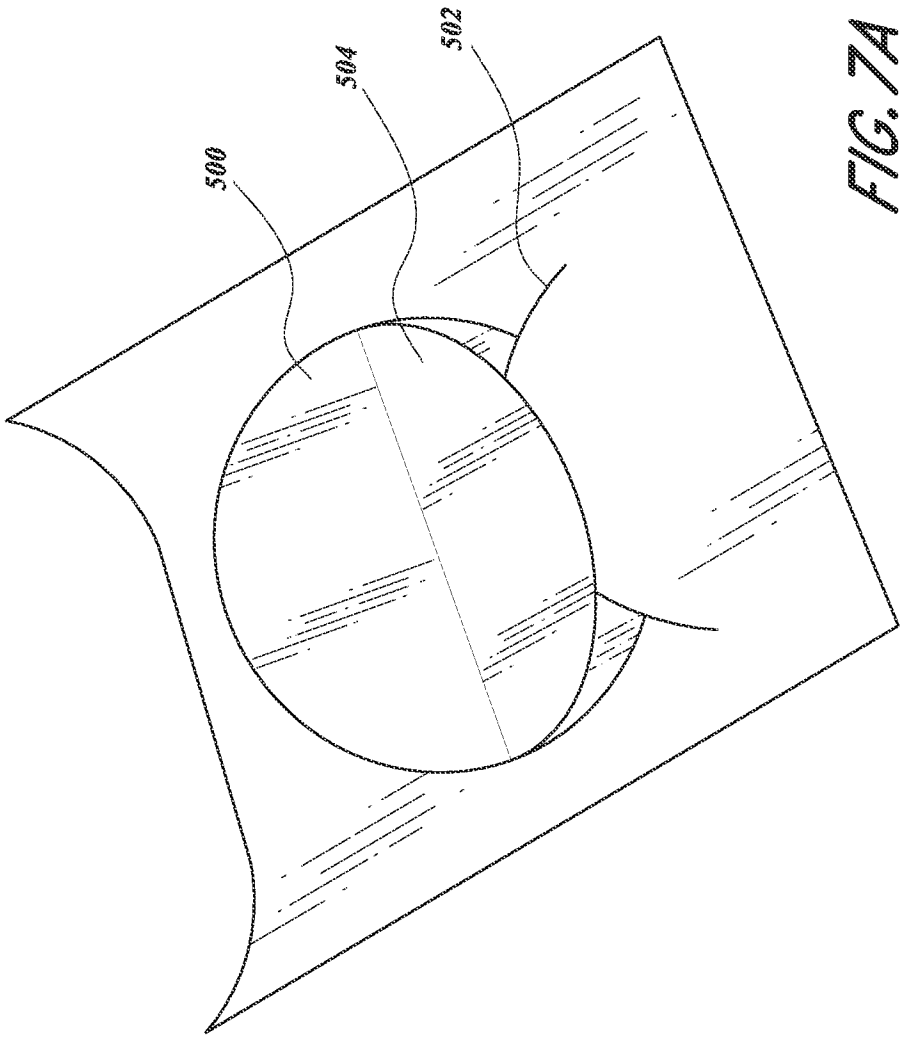


FIG. 7A

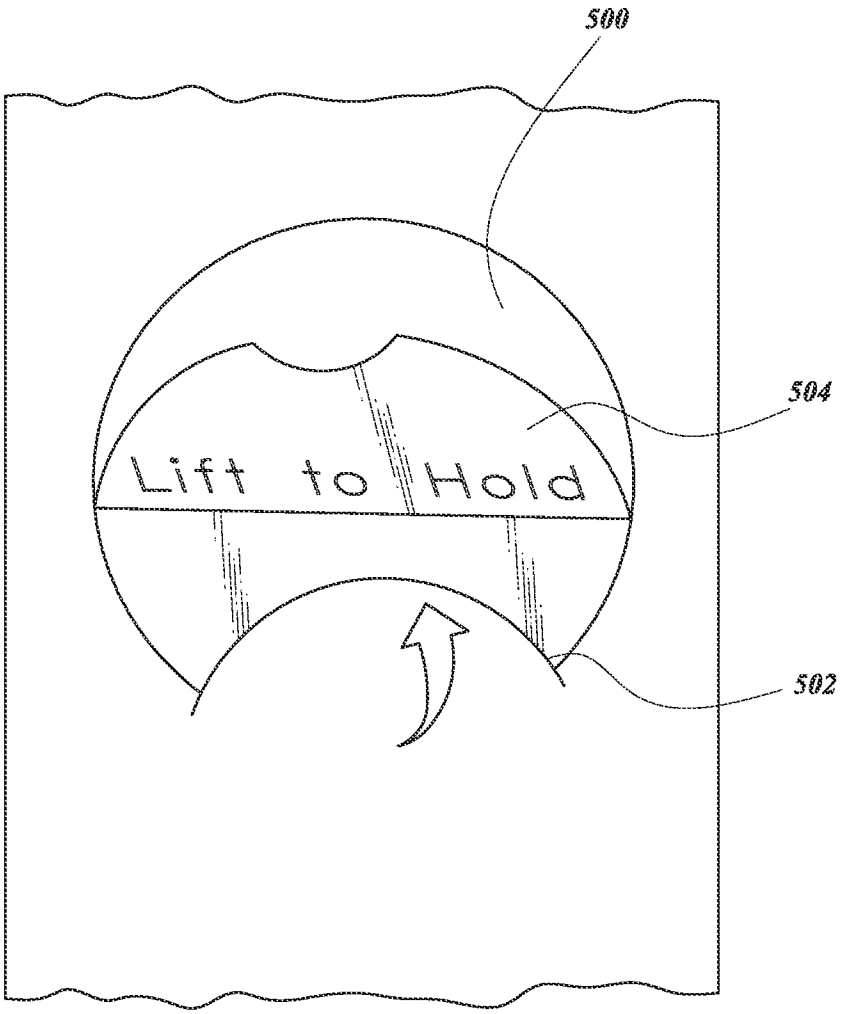


FIG. 7B

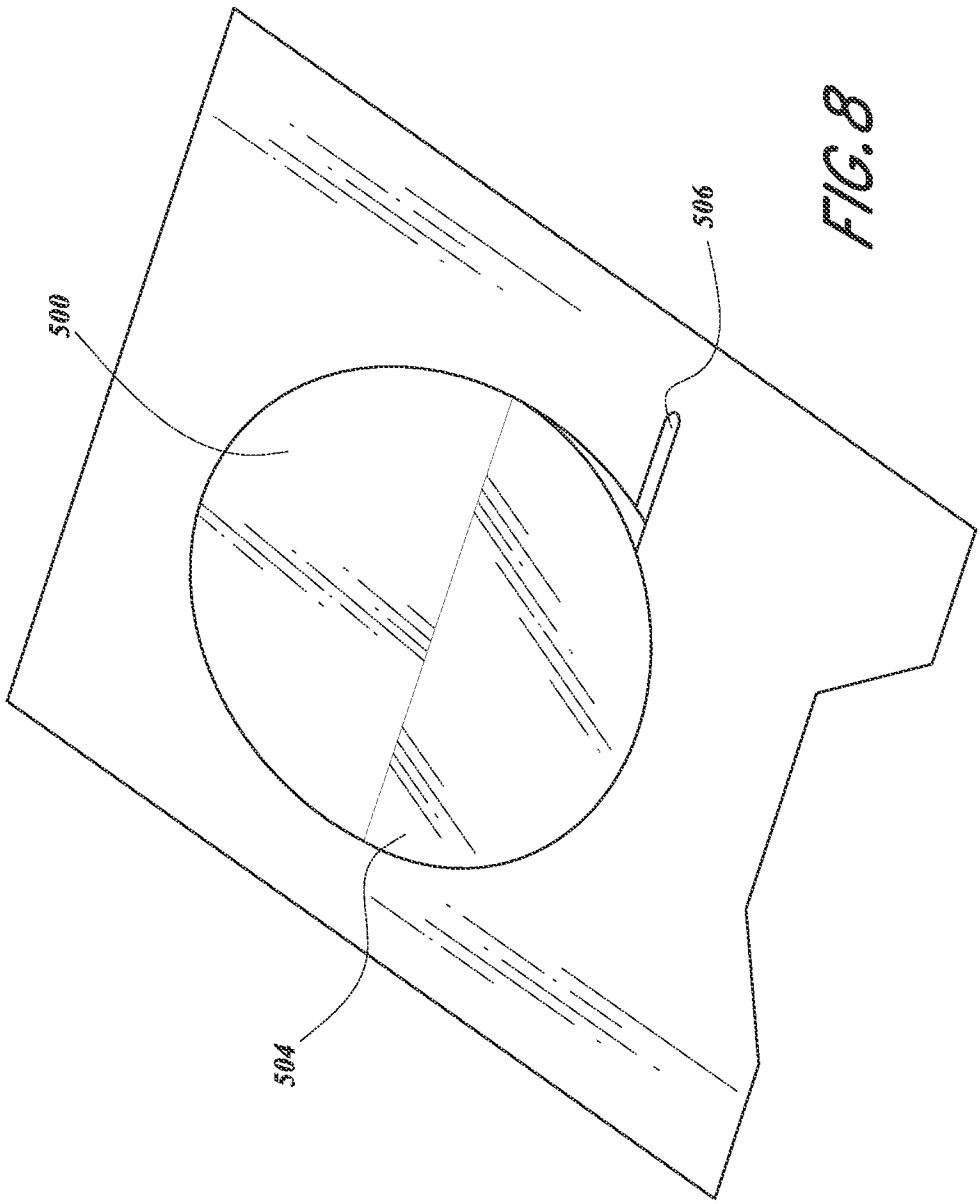


FIG. 8

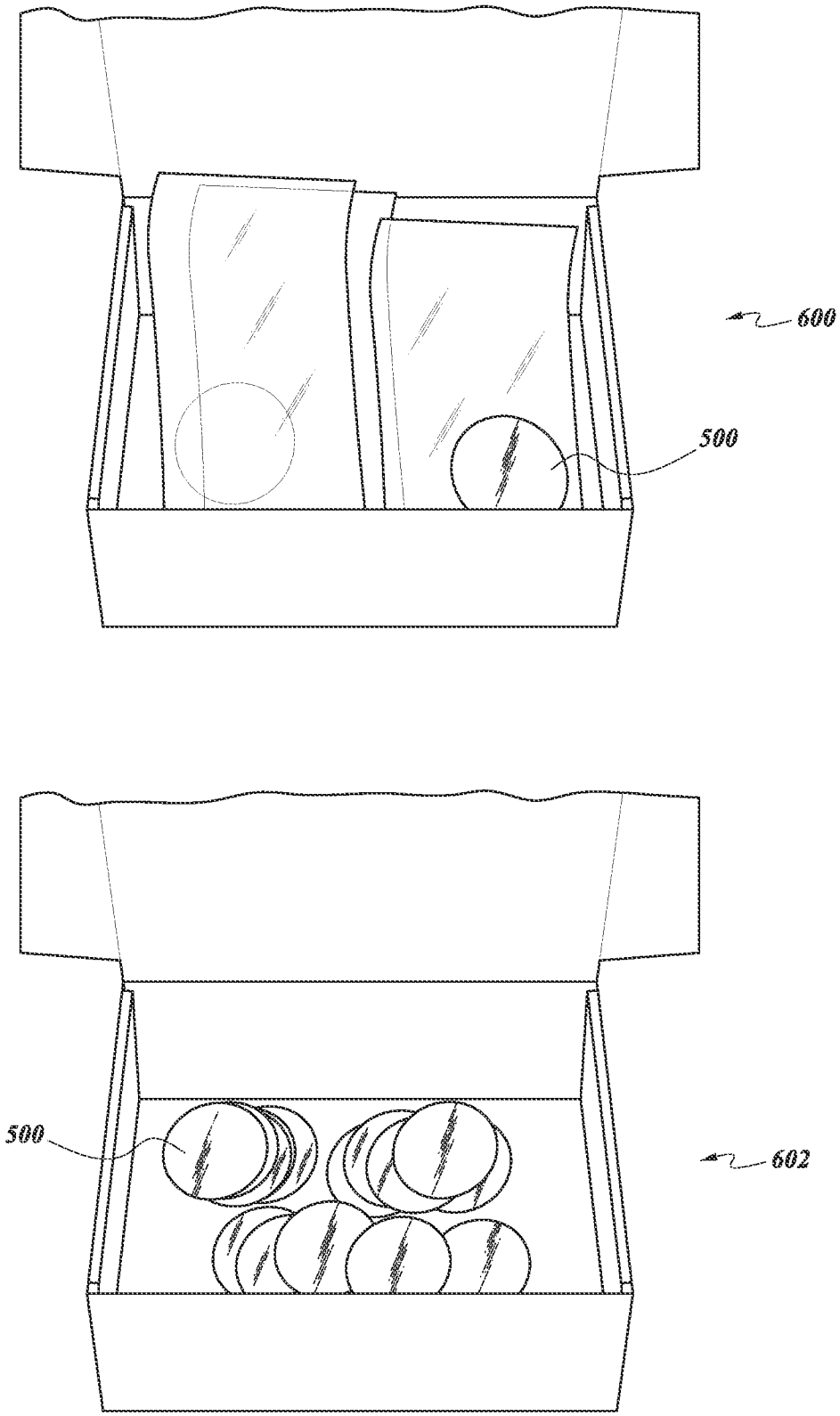


FIG. 9

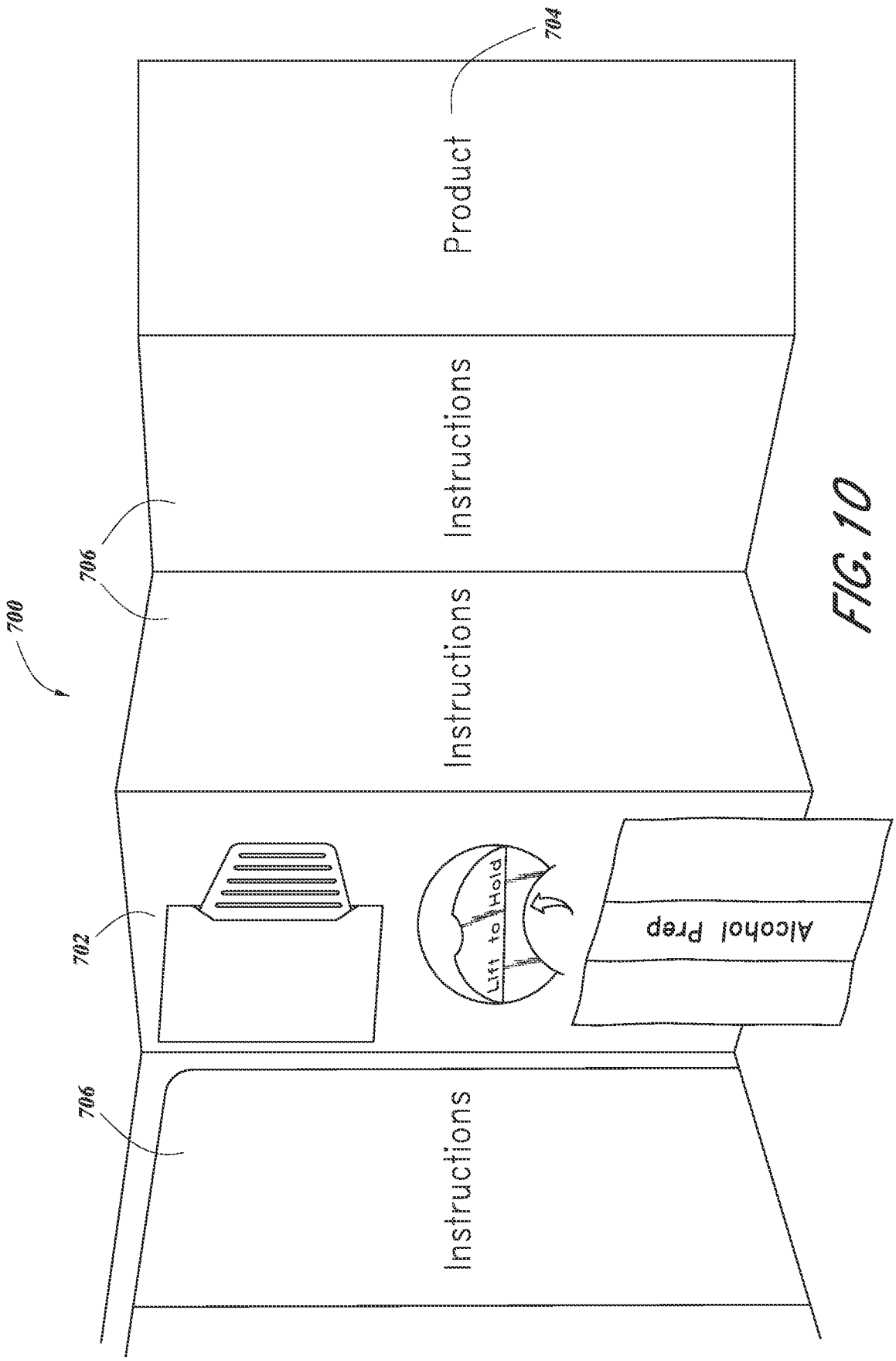

700
702
704
706
706
706
Product
Instructions
Instructions
Instructions
Lift to Hold
Alcohol Prep

FIG. 10

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2014/033064

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61B 17/00 (2014.01)
CPC - A61B 17/00 (2014.07)
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(8) - A61B 17/00, 17/20; A61M 35/00 (2014.01)
CPC - A61B 17/00, 17/20; A61M 35/00 (2014.07)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
USPC - 132/76.4, 76.5; 600/386, 391, 392; 604/289, 290; 606/131

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
Orbit, Google Patents, Google

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X -- Y	US 4,202,139 A (HONG et al) 13 May 1980 (13.05.1980) entire document	1-5, 7-13, 15 ---------- 6, 14
X -- Y	US 4,274,429 A (TAM et al) 23 June 1981 (23.06.1981) entire document	16, 18-20 ---------- 17
Y	US 4,459,987 A (PANGBURN) 17 July 1984 (17.07.1984) entire document	6
Y	WO 2011/149755 A1 (BIBIAN et al) 01 December 2011 (01.12.2011) entire document	14
Y	US 6,711,427 B1 (KETELHOHN) 23 March 2004 (23.03.2004) entire document	17
A	US 8,406,843 B2 (TIEGS et al) 26 March 2013 (26.03.2013) entire document	1-20

☐ Further documents are listed in the continuation of Box C. ☐

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
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"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
02 September 2014	23 SEP 2014
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774