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(54) **DEVISE HOLDER APPARATUS**

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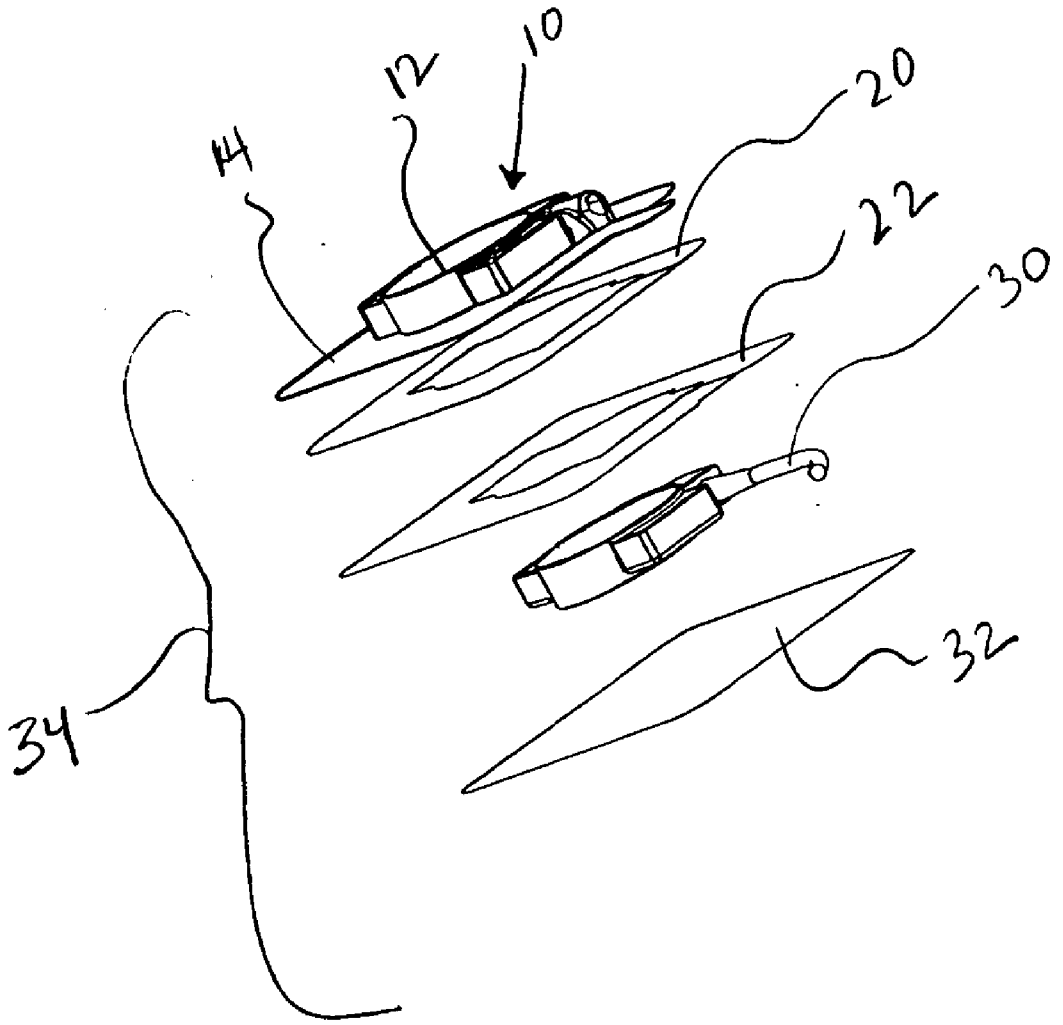
(57) **ABSTRACT**

In one aspect, a medical device holder apparatus may include a housing molded into a predetermined shape and size that accommodates the medical device. Also included is a flange attached to the housing. The flange has a surface attachment side in which an adhesive is disposed on and aids in attaching the flange to a surface. The flange is made from a pliable material capable of conforming to a surface and adapting to surface movement and flexing. In another aspect, the housing is comprised of a stretchable substrate conformable to the shape of the medical device. In another aspect, a medical device holder kit may include a medical device holder, similar to those described earlier. Also included is at least one coupling medium held between a surface and the device by the device holder.



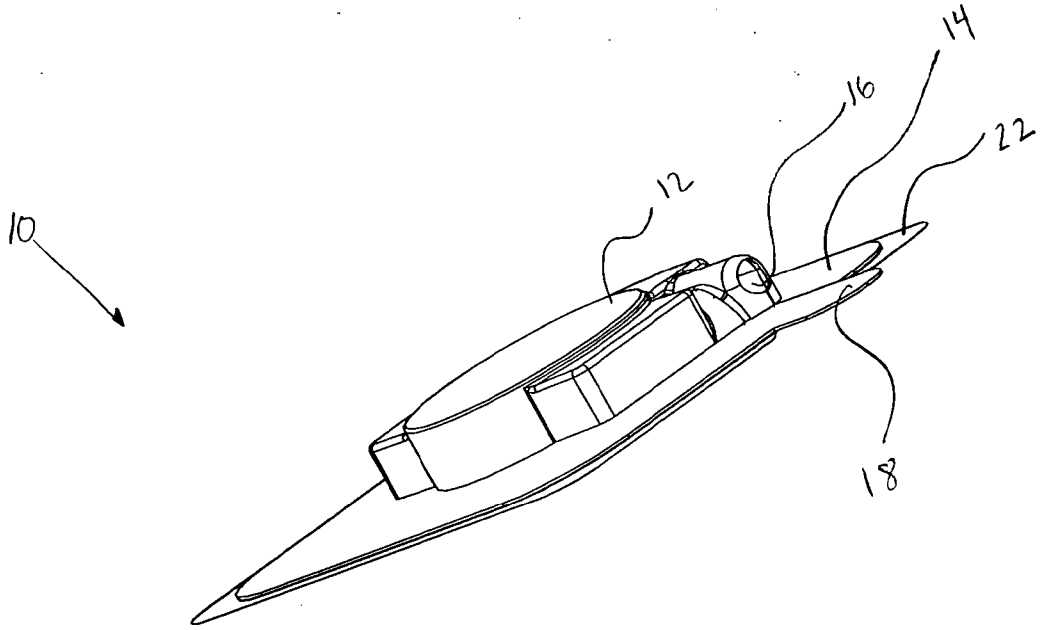


FIG. 1A

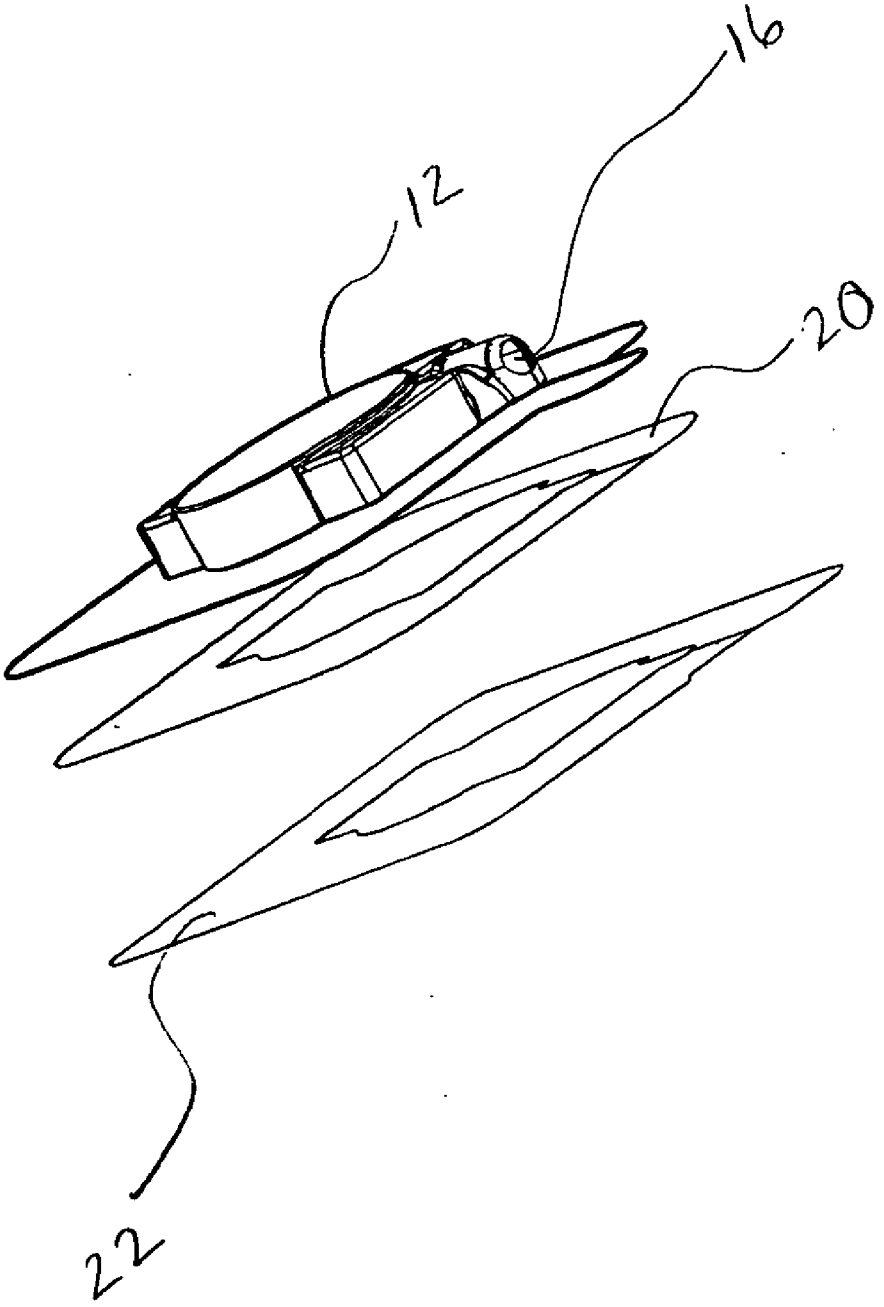


FIG. 1B

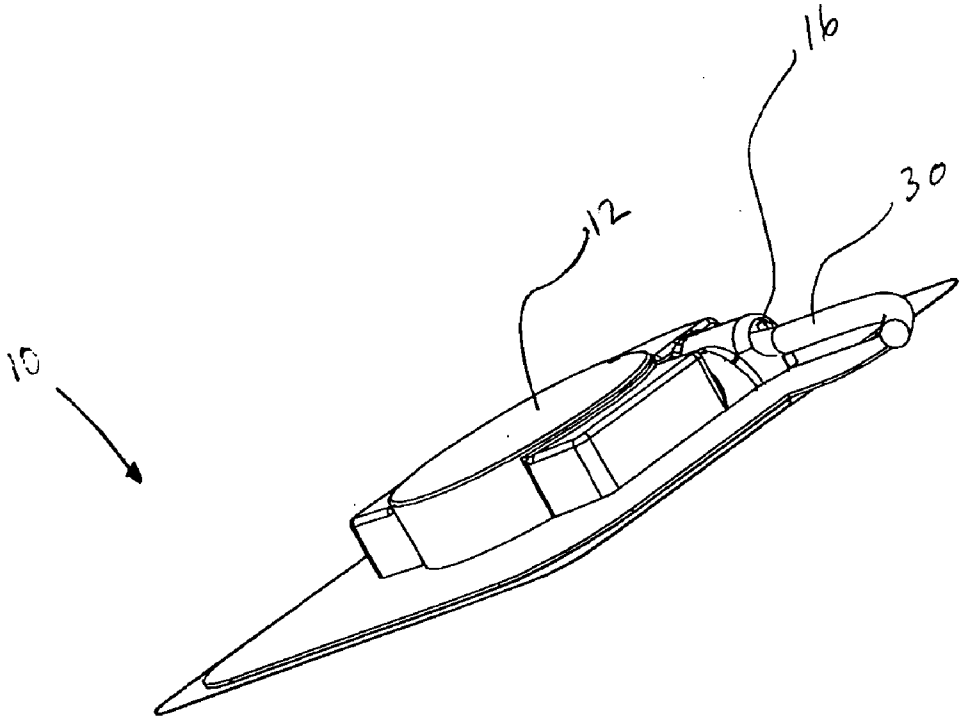


FIG. 2A

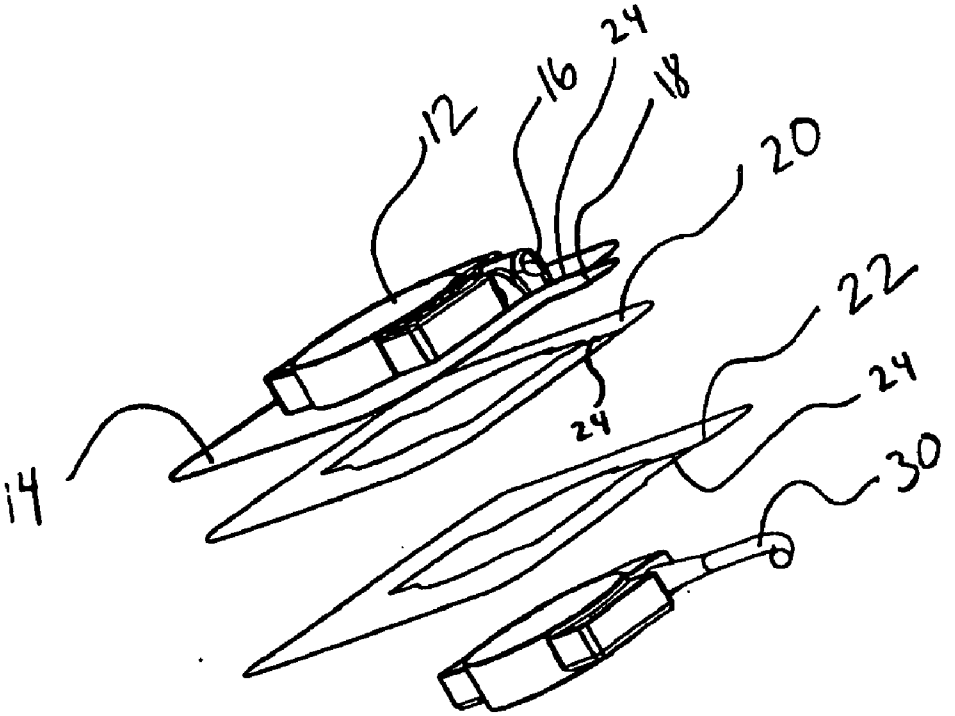


FIG. 2B

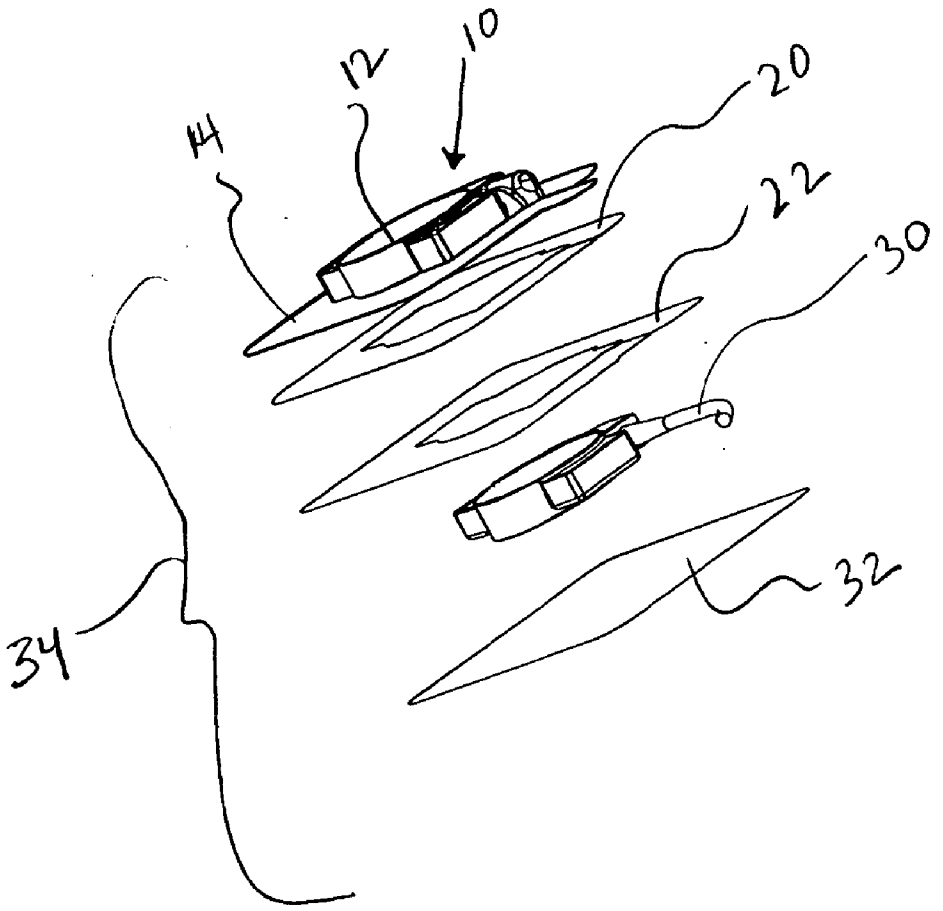


FIG. 3A

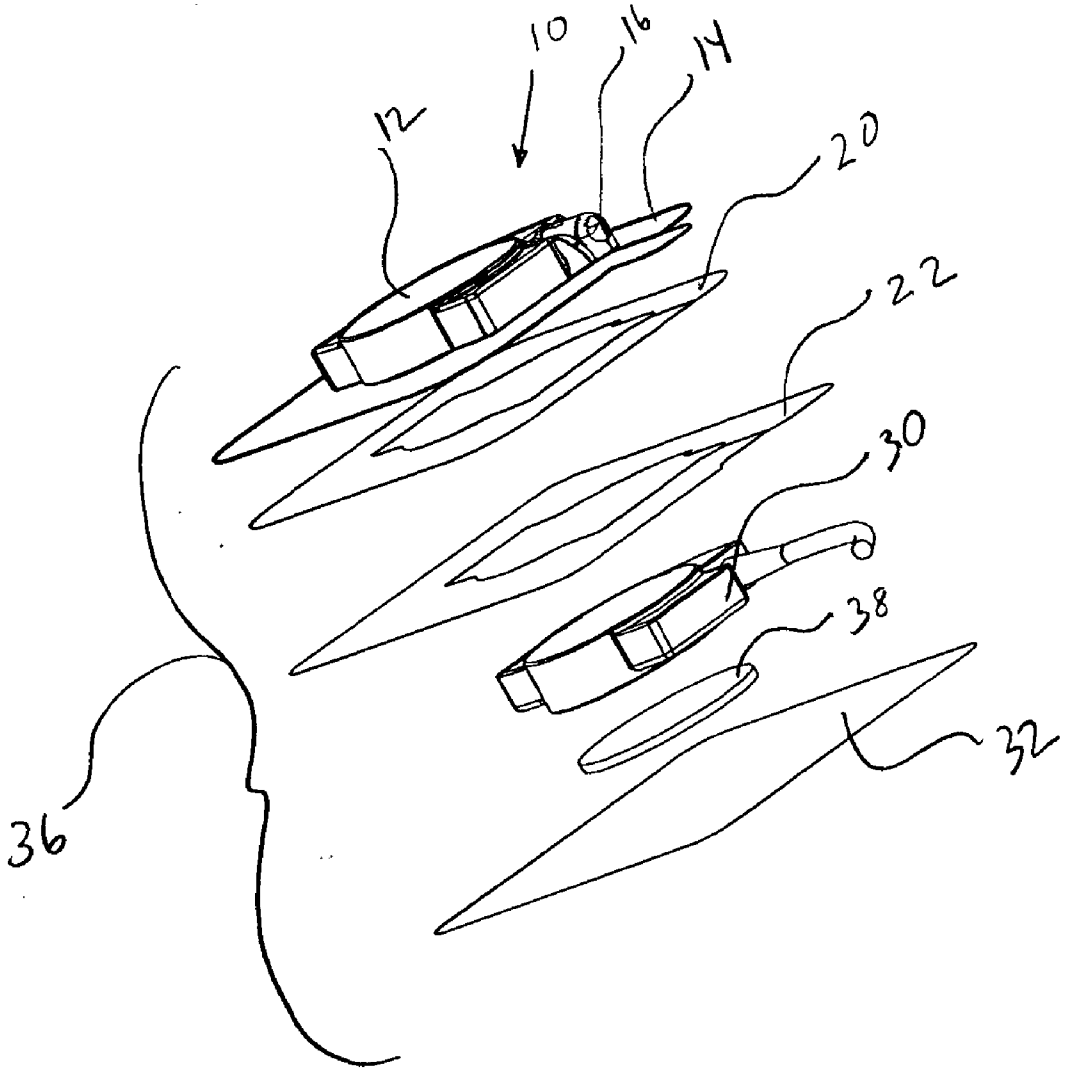


FIG. 3B

DEVISE HOLDER APPARATUS

RELATED APPLICATION

[0001] This application is a continuation in part of U.S. patent application Ser. No. 11/020,767, titled "DEVICE HOLDER APPARATUS" filed Dec. 23, 2004, the contents of which are hereby incorporated by reference herein.

BACKGROUND

[0002] The present disclosure relates to a device holder apparatus. Devices are often required to be close to a surface in which the device is intended to effect, detect or otherwise interact. Many devices are portable. Devices include electronic devices and non-electronic devices. Examples of electronic devices are medical devices, time keeping devices, cell phones, PDAs, organizers, music devices such as MP3 player and portable personal stereos, as well as other devices known in the art.

[0003] To keep the device close to the surface, oftentimes a holder is used. A holder is any apparatus capable of holding something. A holder can hold the entire device or part of the device.

SUMMARY OF THE INVENTION

[0004] The subject matter of the present disclosure may involve, in some cases, interrelated products, alternative solutions to a particular problem, and/or a plurality of different uses of a single system or article.

[0005] In accordance with one aspect of the present disclosure, the disclosure includes a device holder apparatus including a housing having a predetermined shape and size that accommodates the device. Also included is a flange attached to the housing. The flange has a surface attachment side which attaches to a surface.

[0006] Some aspects of this embodiment may include one of more of the following: Where the flange further includes an adhesive on the surface attachment side; where the adhesive is a hydrogel adhesive; where the device holder includes a release liner at least partially covering the adhesive on the adhesive side of the flange; where the housing includes an open portion and a closed portion; where the flange includes a tab of a predetermined size and shape; where the housing further includes at least one opening having a predetermined size; and where the flange further includes a slit extending through the flange to the housing.

[0007] In accordance with another aspect of the present disclosure, the disclosure includes a device holder apparatus including a housing having a shape and size complementary to the device, the housing having an open portion and a closed portion. Also included is a flange attached to the housing, the flange having an adhesive side, the adhesive side being on the same side as the open portion of the housing.

[0008] Some aspects of this embodiment may include one of more of the following: where the device holder further includes at least one opening having a predetermined size; where the flange of the device holder further includes a slit extending through the flange to the housing; where the device holder further includes an adhesive on the adhesive side of the flange; where the flange includes a tab having a predetermined size and shape; and where the device holder further include a release liner, the release liner at least partially covers the adhesive on the adhesive side of the flange.

[0009] In accordance with another aspect of the present disclosure, the disclosure includes a device holder kit. The kit includes a device holder and at least one coupling medium. Some aspects of this embodiment include one or more of the following: where the device holder includes a housing having a shape and size complementary to the device, the housing having an open portion and a closed portion, and a flange attached to the housing, the flange having an adhesive side, the adhesive side being on the same side as the open portion of the housing; where the device holder further includes at least one opening having a predetermined size; where the flange further includes a slit extending through the flange to the housing; where an adhesive is included on the adhesive side of the flange; where the flange further includes a tab having a predetermined size and shape; where the kit includes a release liner, the release liner at least partially covering the adhesive on the adhesive side of the flange; where the kit further includes a slip sheet; and where the coupling medium is at least one ultrasound gel pad.

[0010] In another aspect, a medical device holder apparatus for holding a medical device against skin is provided, the apparatus comprising a housing comprised of a first material, the housing molded into a shape that is complementary to the shape and size of the medical device, the housing defining at least one opening therein, a flange attached to the housing, the flange having a skin attachment side for attachment to the skin, and an adhesive disposed on the skin attachment side of the flange, wherein the flange comprises a second material that is different from the first material, the second material capable of conforming to the skin surface and adapting to movements and flexibility of the skin allowing the flange to remain in contact with the skin surface.

[0011] In another aspect, a medical device holder apparatus for holding a medical device against skin is provided, the apparatus comprising a housing and a flange attached to the housing, wherein the housing is comprised of a stretchable substrate conformable to the shape of the medical device, the housing having an open portion and a closed portion and the housing defining at least one opening therein, and wherein an adhesive is disposed on an adhesive side of the flange, whereby the adhesive side is on the same side as the open portion of the housing, and wherein the flange comprises a flexible, resilient, pliable material capable of conforming to the skin surface and adapting to movements and flexibility of the skin allowing the flange to remain in contact with the skin surface.

[0012] In another aspect, a method of fabricating a holder for a medical device where the medical device is to be maintained adjacent the patient's skin is provided, the method comprising molding a housing to substantially conform to the medical device, forming a flange designed to adhere to the patient's skin, and attaching the flange to the housing to form the holder.

[0013] In another aspect, a medical device holder kit is provided, the kit comprising a medical device holder capable of holding a medical device against skin, the device holder having a housing and a flange attached to the housing, wherein the housing is molded into a shape that is complementary to the shape and size of the device, the housing having an open portion and a closed portion, an adhesive is disposed on an adhesive side of the flange, whereby the adhesive side is on the same side as the open portion of the housing, and at least one coupling medium, wherein the coupling medium is held between the surface and the device by

the device holder through adherence of the adhesive side of the flange to the surface, and wherein the flange comprises a pliable material capable of conforming to the skin surface and adapting to movements and flexibility of the skin, thus allowing the flange to remain in contact with the skin surface

[0014] These aspects of the disclosure are not meant to be exclusive and other features, aspects, and advantages of the present invention will be readily apparent to those of ordinary skill in the art when read in conjunction with the appended claims and accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0015] These and other features and advantages of the present invention will be better understood by reading the following detailed description of preferred embodiments, taken together with the drawings wherein:

[0016] FIG. **1**A is a pictorial view of one embodiment of the present invention;

[0017] FIG. **1**B is an exploded pictorial view of the embodiment of the present invention shown in FIG. **1**A;

[0018] FIG. **2**A is a pictorial view of the embodiment shown in FIG. **1**A with a device inside the housing;

[0019] FIG. **2**B is an exploded pictorial view of the embodiment of the present invention shown in FIG. **2**A;

[0020] FIG. **3**A is a view of the embodiment shown in FIG. **2**B with the addition of the slip sheet, making it one embodiment of the kit; and

[0021] FIG. **3**B is a view of the embodiment shown in FIG. **3**A with the addition of the coupling medium.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

[0022] The present disclosure is a holder for a device. In one exemplary embodiment, the device is a medical device. However, in other embodiments, the device is any device where the ability of the device to attach to a surface is desired. The device holder of the present disclosure holds the device and allows the device, while held, to be attached to any surface. The device is either held leaving the device directly interfacing with the surface (open housing) or else the housing is closed (closed housing) and the device does not touch the surface directly. Thus, in the open embodiment of the present disclosure, the device is held securely against a surface by the holder in such a way that the device itself is actually in direct contact with the surface (open portion of housing faces the surface).

[0023] In some embodiments, in addition to the opening, a coupling medium can be placed between the device and the surface. The device holder holds both the device and the coupling medium in place, against the surface. The coupling medium can be any substance and does not require adhesive characteristics, since the device holder will hold the coupling medium as well as the device against the surface.

[0024] Referring first to FIG. **1**A, one embodiment of the present invention is shown. The device holder **10** includes a housing **12** and a flange **14**. As shown in FIG. **1**A, the housing **12** is shaped to complement the device. Thus, in one embodiment of the present invention, the housing is molded into a shape that is complementary to the device it is intended to hold. The housing **12** can be made from a variety of materials. For example, a molded substrate, flexible film or foam or any other material capable of cupping or holding the device. However, in other embodiments, the device holder **10** is not molded, but rather, is made from any material having a stretchable characteristic and therefore, inherently will conform generally to the shape of the device once the device is inserted into the housing **12**.

[0025] Referring now to FIG. **2**A, the housing **12** cups the device so as to hold the device **30** in a stable manor. The dimensions of the housing **12** vary depending on the device in which it is intended to hold. Thus, although in the exemplary embodiment of the present disclosure, the housing **12** is shaped so as to complement and hold an ultrasound device **30**, the invention is not limited to the ultrasound device **30**, but to any device, independent of shape or utility.

[0026] Referring back to FIG. **1**A, the device holder **10** includes a flange **14** surrounding the housing **12**. The flange **14** can have any dimensions and the dimensions will vary depending on the device that the device holder **10** is designed to hold. The flange **14** allows the device holder **10** to be attached to a surface (not shown). In one embodiment, the flange **14** includes an adhesive on the bottom side (see **20**, FIG. **1**B). That is, the adhesive is on the attachment side of the device holder **10**.

[0027] The disclosure is not limited to any type of adhesive. In the preferred embodiment, the adhesive is hydrogel. However, in other embodiments, and depending on the type of device and the type of surface in which the device holder will attach to, the adhesive varies. In alternate embodiments, the adhesive is acrylic or rubber based. The hydrogel is preferable for use with devices requiring repositioning on the surface. For example, in the exemplary embodiment, the device holder is shown to accommodate an ultrasound device. In this embodiment, the user of the ultrasound device likely will desire a device holder that attaches to the patient's skin and maintain its position and has the ability to change the position of the device on the patient's skin, and have the device holder maintain that new position. Therefore, in this embodiment, hydrogel is the most preferred adhesive. However, in other embodiments, other repositionable and non-repositionable adhesive systems such as acrylic or rubber-based are used depending on the application and device to be adhered.

[0028] In the preferred embodiment, the flange **14** includes a tab **18**. In some embodiments where the flange **14** includes an adhesive, the tab **18** does not include the adhesive. However, in other embodiments, the tab **18** includes an adhesive or else includes a substrate to "kill" its adhesive properties. In some embodiments, the release liner covers the tab **18** with an adhesive and is cut so that the release liner can be removed from the adhesive on the flange separately from the adhesive on the tab. Among other functions, the tab **18** facilitates the removal of the device from the housing **12**.

[0029] Still referring to FIG. **1**A, some embodiments of the housing **12** include at least one opening **16** of a predetermined size to accommodate external elements of the device, or to allow for user interaction with the device. The embodiment shown in FIG. **1**A shows one opening. In this embodiment, the opening accommodates a wire from the device. Referring to FIG. **2**A, the wire from the ultrasound device **30** is shown emerging from the housing **12** through the opening **16**. However, any element of any device can be accommodated by an opening **16**. In some embodiments, the housing **12** includes multiple openings. The number of opening **16** is dependent on the type of device being held in the device holder **10**. In some embodiments, the opening serves as a window to allow for manipulation of the device.

[0030] Referring back to FIG. **1**A, in embodiments using an adhesive, a release liner **22** covers the adhesive so that the adhesive maintains its cleanliness and adhesion qualities before the device holder **10** is used. The release liner **22** can have any desired dimensions, however, in the preferred embodiment, the release liner **22** covers the adhesive completely and is of a complimentary shape to the adhesive. In the preferred embodiment, the release liner **22** is any substrate coated with silicone or a fluoropolymer treatment. However, in other embodiments, the substrate is coated with any other treatment known and used in the art.

[0031] Referring now to FIG. **2**B, a slit **24** is included both in the adhesive **20** and the release liner **22**. In some embodiments, the slit **24** is not included in either the release liner **22** or the adhesive **20**, and in still other embodiments, the slit **24** is included in either the release liner **22** or the adhesive **20**. The slit **24** extends from the tab **18** into the housing **12**. In embodiments not including the tab **18**, the slit extends from the outside of the flange **14** to the housing **12**. In still other embodiments, the slit **24** is located anywhere on the flange **14**. The slit **24** functions to reduce the peel force necessary to remove the device holder from the surface to which it is attached. The slit **24** additionally aids in the removal of the release liner **22** from the adhesive **20**. Additionally, the slit **24** allows for better accommodation of wires and other external elements through the opening **16**.

[0032] Referring next to FIGS. **3**A and **3**B, one preferred embodiment of the kit embodiment of the present disclosure is shown **34**. The kit **34**, **36** includes the device holder **10**, including the housing **12** and the flange **14**. In embodiments including an adhesive, the adhesive **20** is also included, as well as the release liner **22**. Finally, in some embodiments, a slip sheet **32** is included. A device **30** is shown for illustration only, the device **30** is not included as part of the kit **34**, **36**.

[0033] Referring to FIGS. **3**A and **3**B, some embodiments of the present disclosure **34**, **36** include a slip sheet **32**. The slip sheet **32** can have any dimensions desired. The slip sheet **32** can be made from any material. In the preferred embodiment, the slip sheet **32** is slightly larger than the release liner **22** and is made of the same material as the release liner. When using an adhesive such as hydrogel, the adhesive has a tendency to migrate. The slip sheet **32** works to maintain the adhesive **20**, specifically, to prevent the adhesive from migrating and affixing to the packaging for the device holder.

[0034] Referring to FIG. **3**B, an embodiment of the kit **36** of the present disclosure is shown. In this embodiment, the kit **36** includes the device holder **10**, including the housing **12** and the flange **14**, the adhesive **20**, the release liner **22**, the slip sheet **32** and a coupling medium **38**. The coupling medium **38** can be any coupling medium that complements the device being held by the device holder **10**. In the exemplary embodiment, the device **30** is an ultrasound device, and the coupling medium **38** is an ultrasound gel pad. In other embodiments, more than one type of coupling medium **38** is included. In other exemplary embodiments, more than one ultrasound gel pad **38** is included.

[0035] Referring back to FIG. **1**B, the device holder includes an adhesive **20** in some embodiments. However, in other embodiments, the device holder does not include an adhesive. In these embodiments, the device holder can be fastened to the surface by any means known in the art.

[0036] Although in the preferred embodiment of the present invention, the invention is molded to the shape of the device that it will hold, other embodiments do not employ this method. By molding the shape of the housing, the device holder provides the preferred hold of the device. However, this could also be accomplished by using a stretchable or other conformable substrate or the housing could be shaped in such a way that it holds a variety of different devices. Thus, the housing can be any generic shape.

[0037] In the exemplary embodiments shown in FIGS. **1**A and **2**B and described above, the housing **12** and the flange **14** are one molded part from the same material. In other embodiments, however, the housing **12** and flange **14** can be fabricated from different materials and subsequently joined together to form the device holder.

[0038] It has been found when the housing and flange are made from a rigid material that the device may be too rigid and unable to conform to patient's skin surfaces. The rigid flange may lose contact with the skin when the patient moves or is moved and may be uncomfortable to the patient. It has also been determined that the entire device, including the housing and the flange, may be difficult to mold as one piece and that, despite common belief to the contrary, a two-piece device may actually be more cost effective even though it requires additional forming and adhering steps. As a result, a preferred set of embodiments includes a flange made of a material having sufficient flexibility such that the flange will adapt to movement and flexing of a surface upon which it is attached, while the housing can be made of a different material that may be transparent.

[0039] The flange may be made from any pliable and flexible material that will conform generally to the shape of the desired surface, such as a patient's skin. Because the material is able to adapt to movements and flexibility of the skin and muscle, the flange is more likely to remain in contact with the skin surface and likelihood of detachment is decreased. The flange (and/or adhesive) may be made of a material that is suitable for contact with human skin while the housing may be made from a broader range of materials.

[0040] The flange provides support for the adhesive. The flange can also be used to fasten the device holder to any surface, absent an adhesive. The flange can be any size to allow for a different amount of adhesive area available for attachment to the surface. In this way, any device of any weight or size can be held onto the surface. The flange may be made from either natural or synthetic flexible and resilient materials such as fabrics, polymers and/or copolymers. Examples include polyurethane, latex, natural rubber, nylon (polyamides), polyester, polyethylene, polypropylene, PVC, fluoroplastics, silicone, block copolymers, polyethers, composites and woven and non-woven fabrics. The flange material may be elastic and may, in some embodiments, have a Young's Modulus (GPa) of less than 1.0, less than 0.5, less than 0.2 or less than 0.1. In one set of embodiments the flange is made from a nonwoven fabric such as a spunlace. An example of this material is DuPont Spunlace Sontara®. The hardness of the flange material may be measured on the Shore A hardness scale and may be less than 100, less than 90, less than 70 or less than 50. The flange may be die cut from a sheet and need not be molded. Those skilled in the art will understand that any other material suitable for similar medical applications may also be used.

[0041] The housing may be made from any material capable of being molded to the shape of the device. However, in other embodiments, the housing may be made from a conformable substrate, the substrate having more rigidity than the flange material. The housing may be made from

either natural or synthetic materials such as polymers and/or copolymers and other materials suitable for use with medical applications. Examples include nylon (polyamides), polyimides, polycarbonate, polyester, polystyrene, polypropylene, ABS, PET, polyethylene, PVC, fluoroplastics, block copolymers, polyethers and composites thereof. These materials may be transparent so that an observer can look at readings or indicators on the device being held. The hardness of the housing material may be measured on the Shore A or Shore D scale and may be greater than 0, greater than 10, greater than 20 greater than 30 or greater than 50 on the D scale. Of course, softer moldable materials may also be used in other embodiments.

[0042] The flange may be joined to the housing by methods known to those of skill in the art including, for example, adhesives and ultrasonic welding. In some cases, one material may be overmolded onto the other material. For instance, the flange may be overmolded onto the housing. The housing may include a mini-flange that can be used in attaching the housing to the flange. The mini-flange may be arranged so that it is in substantially the same plane as is the flange. The flange can then be secured to the mini-flange by, for example, an adhesive, welding or by overmolding.

[0043] Referring again to FIG. **3**B, an exemplary embodiment of the present disclosure is shown. In this embodiment, an ultrasound device **30** is held by the device holder **10**. The ultrasound device **30** is placed into the housing **12** of the device holder **10**. A wire from the ultrasound device **30** is allowed through the opening **16**. The release liner **22** is then removed from the adhesive **20**, the ultrasound gel pad **38** is placed in the location desired, and the flange **14** is pressed onto the skin of a patient. Thus, the ultrasound device **30** is now touching the ultrasound gel pad **38**, and the device holder **10** is maintaining the ultrasound device **30** and ultrasound gel pad **38** in the desired location on the patient's skin. In the preferred embodiment, the adhesive **20** is a hydrogel. However, when desired, the device holder **10** is pulled from the skin, and the device holder **10** is moved to a new location on the patient. The flange **14** is then pressed onto the skin, the hydrogel, being reusable, securely fastens the ultrasound device **30** against the patient's skin in this second location. This can be repeated any number of times.

[0044] In other embodiments, the device is an insulin pump, a tocodynamometer, a fetal heart beat monitor, or any other medical device where it is desirable to maintain the device in a stable position, and at the same time, maintain the ability to move the device when desired. The present invention allows for attachment to the skin or any other surface, and then removal and re-attachment of the device to another location. In other embodiments, non-medical devices are used with the device holder. These include MP3 or other personal music players or personal stereos, cell phones, PDAs, smartphones such as BLACKBERRYS and any other device where the user desires the device to attach to a surface and/or their skin, and/or have the ability to remove the device when desired, and/or to change the location of the device easily.

[0045] While several embodiments of the present disclosure have been described and illustrated herein, those of ordinary skill in the art will readily envision a variety of other means and/or structures for performing the functions and/or obtaining the results and/or one or more of the advantages described herein, and each of such variations and/or modifications is deemed to be within the scope of the present disclosure. More generally, those skilled in the art will readily appreciate that all parameters, dimensions, materials, and configurations described herein are meant to be exemplary and that the actual parameters, dimensions, materials, and/or configurations will depend upon the specific application or applications for which the teachings of the present invention is/are used. Those skilled in the art will recognize, or be able to ascertain using no more than routine experimentation, many equivalents to the specific embodiments of the disclosure described herein. It is, therefore, to be understood that the foregoing embodiments are presented by way of example only and that, within the scope of the appended claims and equivalents thereto, the disclosure may be practiced otherwise than as specifically described and claimed. The present disclosure is directed to each individual feature, system, article, material, kit, and/or method described herein. In addition, any combination of two or more such features, systems, articles, materials, kits, and/or methods, if such features, systems, articles, materials, kits, and/or methods are not mutually inconsistent, is included within the scope of the present invention.

[0046] All definitions, as defined and used herein, should be understood to control over dictionary definitions, definitions in documents incorporated by reference, and/or ordinary meanings of the defined terms.

[0047] The indefinite articles "a" and "an," as used herein in the specification and in the claims, unless clearly indicated to the contrary, should be understood to mean "at least one."

[0048] The phrase "and/or," as used herein in the specification and in the claims, should be understood to mean "either or both" of the elements so conjoined, i.e., elements that are conjunctively present in some cases and disjunctively present in other cases. Other elements may optionally be present other than the elements specifically identified by the "and/or" clause, whether related or unrelated to those elements specifically identified, unless clearly indicated to the contrary.

[0049] All references, patents and patent applications and publications that are cited or referred to in this application are incorporated in their entirety herein by reference.

What is claimed is:

1. A medical device holder apparatus for holding a medical device against the skin of a patient, the holder having a predetermined shape and size, the apparatus comprising:

a housing comprised of a first material, the housing molded into a shape that is complementary to the shape and size of the medical device, the housing defining at least one opening therein;

a flange attached to the housing, the flange having a skin attachment side for attachment to the skin; and

an adhesive disposed on the skin attachment side of the flange, wherein the flange comprises a second material that is different from the first material, the second material capable of conforming to the skin surface and adapting to movements and flexibility of the skin allowing the flange to remain in contact with the skin surface.

2. The apparatus set forth in claim **1**, wherein the adhesive is a hydrogel adhesive.

3. The apparatus of claim **1** wherein the first material is capable of being injection or blow molded.

4. The apparatus of claim **1** wherein the housing is molded and the flange is cut from a sheet.

5. The apparatus set forth in claim **1**, wherein the flange further comprises a tab having a predetermined size and shape.

6. The apparatus set forth in claim **1**, wherein the flange further comprises a slit extending through the flange to the housing.

7. The apparatus set forth in claim **1**, wherein said adhesive is a repositionable adhesive.

8. The apparatus set forth in claim **1**, wherein the housing defines at least one hole of adequate dimension to provide for manipulation of controls on the device.

9. A medical device holder apparatus for holding a medical device against skin, the apparatus comprising:

a housing comprised of a stretchable substrate conformable to the shape of the medical device the housing having an open portion and a closed portion, and the housing defining at least one opening therein;

a flange attached to the housing, the flange having an adhesive side, the adhesive side being on the same side as the open portion of the housing; and

an adhesive disposed on the adhesive side of the flange, wherein the flange comprises a pliable material capable of conforming to the skin surface and adapting to movements and flexibility of the skin and muscle allowing the flange to remain in contact with the skin surface, and wherein the housing comprises a material that is different than the flange material.

10. The apparatus set forth in claim **9**, wherein the flange further comprises a tab having a predetermined size and shape.

11. The apparatus set forth in claim **9**, further comprising a release liner, the release liner at least partially covering the adhesive on the adhesive side of the flange.

12. The apparatus set forth in claim **9**, wherein the flange further comprises a slit extending through the flange to the housing.

13. The apparatus set forth in claim **9**, wherein the flange further comprises a repositionable adhesive.

14. The apparatus set forth in claim **9**, wherein the housing defines at least one hole of adequate dimension to provide for manipulation of controls on the device.

15. The apparatus of claim **9** wherein housing comprises a moldable thermopolymer and the flange comprises woven or non-woven fabric.

16. The apparatus of claim **1** wherein the flange is comprised of rubber, silicone, latex, polyurethane or fabric.

17. The apparatus of claim **1** wherein the housing is transparent.

18. The apparatus of claim **1** wherein the housing comprises a mini-flange constructed and arranged to be joined to the flange.

19. A method of fabricating a holder for a medical device where the medical device is to be maintained adjacent the patient's skin, the method comprising:

molding a housing to substantially conform to the medical device;

forming a flange designed to adhere to the patient's skin; and

attaching the flange to the housing to form the holder.

20. The method of claim **19** further comprising molding a mini-flange into the housing.

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