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PROVISIONAL APPLICATION FOR PATENT COVER SHEET – Page 1 of 2

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

Express Mail Label No. _____

INVENTOR(S)		
Given Name (first and middle [if any])	Family Name or Surname	Residence (City and either State or Foreign Country)
Louis	Pace	San Carlos, CA

Additional inventors are being named on the _____ separately numbered sheets attached hereto.

TITLE OF THE INVENTION (500 characters max):

Analyte Sensor Devices, Connections, and Methods

Direct all correspondence to: **CORRESPONDENCE ADDRESS**

☒ The address corresponding to Customer Number:

30349

OR

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ENCLOSED APPLICATION PARTS (check all that apply)

☐ Application Data Sheet. See 37 CFR 1.76

☐ CD(s), Number of CDs _____

☒ Drawing(s) Number of Sheets **44**

☐ Other (specify) _____

☒ Specification (e.g. description of the invention) Number of Pages **25**

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METHOD OF PAYMENT OF THE FILING FEE AND APPLICATION SIZE FEE FOR THIS PROVISIONAL APPLICATION FOR PATENT

☐ Applicant claims small entity status. See 37 CFR 1.27.

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Abbott Diabetes v. Dexcom

IPR2024-00859

EXHIBIT 2010

PROVISIONAL APPLICATION COVER SHEET
Page 2 of 2

PTO/SB/16 (09-11)

Approved for use through 01/31/2014. OMB 0651-0032

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SIGNATURE /Seong-Kun Oh/ Date December 11, 2011

TYPED or PRINTED NAME Seong-Kun Oh REGISTRATION NO. 48,210
(if appropriate)

TELEPHONE 510.652.6418 Docket Number: TS-02-305P

ANALYTE SENSOR DEVICES, CONNECTIONS, AND METHODSFIELD OF THE DISCLOSURE

[0001] Aspects of the present disclosure relate to analyte sensor devices and to the preparation by a user handling separate loading and coordinated insertion devices. Other aspects of the present disclosure relate to analyte sensor elements and the sensor connection made with an on-body electronics unit to which the sensor is connected/coupled.

BACKGROUND

[0002] Diabetes Mellitus is an incurable chronic disease in which the body does not produce or properly utilize insulin. Insulin is a hormone produced by the pancreas that regulates blood sugar (glucose). In particular, when blood sugar levels rise, e.g., after a meal, insulin lowers the blood sugar levels by facilitating blood glucose to move from the blood into the body cells. Thus, when the pancreas does not produce sufficient insulin (a condition known as Type 1 Diabetes) or does not properly utilize insulin (a condition known as Type II Diabetes), the blood glucose remains in the blood resulting in hyperglycemia or abnormally high blood sugar levels.

[0003] The vast and uncontrolled fluctuations in blood glucose levels in people suffering from diabetes cause long-term, serious complications. Some of these complications include blindness, kidney failure, and nerve damage. Additionally, it is known that diabetes is a factor in accelerating cardiovascular diseases such as atherosclerosis (hardening of the arteries), leading to stroke, coronary heart disease, and other diseases. Accordingly, one important and universal strategy in managing diabetes is to control blood glucose levels.

[0004] One element of managing blood glucose levels is testing to monitor blood glucose levels. Conventional in vitro techniques, such as drawing blood samples, applying the blood to a test strip, and determining the blood glucose level using colorimetric, electrochemical, or photometric test meters may be employed. Another more recent technique for monitoring glucose levels is by using an in vivo glucose monitoring system, that continuously or automatically tests glucose, such as for example, the FreeStyle Navigator® Continuous Glucose Monitoring System, manufactured by Abbott Diabetes Care Inc.

- [0005] Unlike conventional blood glucose monitoring approaches, new analyte monitoring systems may employ an insertable or implantable sensor contacting interstitial fluid associated with a user for a period of time that detects and monitors glucose levels.
- [0006] Prior to use of a new sensor, a user inserts at least a portion of the sensor under his skin. Typically, an inserter assembly is employed to insert the sensor in the body of the user, with the sensor maintained in position by an on-body unit including electronics. For insertion, an introducer sharp – while engaged with the sensor – pierces the skin of the user and is removed from the body of the user leaving the sensor in place.
- [0007] To fully realize the advantages associated with such systems, applicator systems configured to handle insertion as well as associated storage and user interface issues include easy-to-use, reliable and minimize user hassle and pain. The present disclosure provides such solutions and additional or alternative advantages as referenced below and/or as may be appreciated by those with skill in the art upon review of the subject disclosure.

INCORPORATION BY REFERENCE

- [0008] Patents, applications and/or publications described herein, including the following patents, applications and/or publications are incorporated herein by reference for all purposes: U.S. Patent Nos. 4,545,382, 4,711,245, 5,262,035, 5,262,305, 5,264,104, 5,320,715, 5,356,786, 5,509,410, 5,543,326, 5,593,852, 5,601,435, 5,628,890, 5,820,551, 5,822,715, 5,899,855, 5,918,603, 6,071,391, 6,103,033, 6,120,676, 6,121,009, 6,134,461, 6,143,164, 6,144,837, 6,161,095, 6,175,752, 6,270,455, 6,284,478, 6,299,757, 6,338,790, 6,377,894, 6,461,496, 6,503,381, 6,514,460, 6,514,718, 6,540,891, 6,560,471, 6,579,690, 6,591,125, 6,592,745, 6,600,997, 6,605,200, 6,605,201, 6,616,819, 6,618,934, 6,650,471, 6,654,625, 6,676,816, 6,730,200, 6,736,957, 6,746,582, . 6,749,740, 6,764,581, 6,773,671, 6,881,551, 6,893,545, 6,932,892, 6,932,894, 6,942,518, 7,041,468, 7,167,818, 7,299,082, and 7,866,026, U.S. Patent Publication Nos. 2004/0186365, 2005/0182306, 2006/0025662, 2006/0091006, 2007/0056858, 2007/0068807, 2007/0095661, 2007/0108048, 2007/0199818, 2007/0227911, 2007/0233013, 2008/0066305, 2008/0081977, 2008/0102441, 2008/0148873, 2008/0161666, 2008/0267823, 2009/0054748, 2009/0294277, 2010/0213057, 2010/0081909, 2009/0247857, 2011/0106126, 2011/0082484, 2010/0326842, 2010/0198034, 2010/0324392, 2010/0230285, 2010/0313105, 2011/0213225, 2011/0021889, 2011/0193704, 2011/0190603,

and 2011/0191044, U.S. Patent Application Nos. 13/071,461, 13/071,487, and 13/071,497, and U.S. Provisional Application No. 61/325,260.

SUMMARY

- [0009] Certain embodiments concern the subject packaging and/or loading systems, applicators and elements of the on-body units themselves. The on-body units include electronics and mounting for a sensor held in a plug assembly. Certain embodiments also concern the connection of electrochemical analyte sensors to and/or within the associated on-body units. The approaches variously involve the use of unique sensor and unique ancillary element arrangements to facilitate assembly of separate on-body units and sensor assembly units that are kept apart until the user brings them together. Methods associated with such use also form part of the inventive subject matter.
- [0010] Certain sensor assembly embodiments are described that include an analyte sensor (e.g., a glucose sensor), and an applicator device to position at least a portion of such a device beneath a skin surface, as well as methods of positioning at least a portion of such a device and methods of analyte testing or monitoring. Further methods include the manner of preparing the applicator device. Namely, such acts associated with user assembly/mating the component parts of a monitoring system.
- [0011] Such a monitoring system includes an on-body unit mount typically adapted to adhere to a skin of a subject, an analyte sensor coupled to the on-body unit, and an insertion sharp having a longitudinal body including a longitudinal opening to receive at least a portion of the sensor body. The details of the sensor may vary. Exemplary chemistries and constructions are described in any of US Patent Nos. 5,593,852, 6,284,478, and 6,329,161, each incorporated by reference herein in its entirety. Exemplary form-factors or configurations (e.g., for associated use with an insertion “sharp”) are described in any of US Patent Nos. 6,175,752, 6,565,509, 6,134,461 and 6,990,366 and in US Publication No. 2010/0230285, each incorporated by reference herein in its entirety.
- [0012] Likewise, the details of the mount may vary. For instance, the mount may include electronics and other adaptation to communicate with a monitoring device. Various options for communication are described in detail in US Publication Nos. 2010/0198034 and

2011/0213225, the entirety of the applications hereby incorporated by reference, including cited and incorporated references.

[0013] In any case, certain embodiments of the disclosure may include sensor assemblies which include a sensor comprising a portion for operative contact with a fluid of the subject, an on body unit defining a distal surface adapted for attachment to the skin of a subject and housing a circuit coupled to the sensor for performing a function with the sensor. An applicator or insertion apparatus may include a sleeve or sheath defining a distal surface for placement on the skin of the subject, a knob or handle for user interface and various internal support, coupling, guide, grasping, stop and detent features as well as driver elements. A container may be provided to interface with the applicator for the purpose of loading either one of (or both) the sensor or mount into the applicator, readying the system for use.

[0014] The present disclosure includes the subject devices, kits in which they are included, and methods of use and manufacture. A number of aspects of such manufacture are discussed herein. Further details can be appreciated in reference to the figures and/or associated description.

BRIEF DESCRIPTION OF THE DRAWINGS

[0015] A detailed description of various aspects, features, and embodiments of the subject matter described herein is provided with reference to the accompanying drawings, which are briefly described below. The drawings are illustrative and may or may not be drawn to scale, with the possibility of some components and features being exaggerated for clarity. Similar components may be numbered identically or not. The drawings illustrate various aspects and features of the present subject matter and may illustrate one or more embodiment(s) or example(s) of the present subject matter in whole or in part.

[0016] Fig. 1 is a flowchart, indicating user activity in handling the subject devices;

[0017] Figs. 2A-2G illustrate such activity with additional detail;

[0018] Fig. 3 is an assembly view of an applicator or inserter;

[0019] Fig. 4 is an assembly view of a sensor container set or loader;

[0020] Figs. 5A and 5B are section views of the loader in Fig. 4;

[0021] Fig. 6 is an assembly view of an alternative container set or loader;

[0022] Fig. 7 is a section view of the assembly of Fig. 6;

- [0023] Figs. 8 is an assembly view of yet another sensor container set or loader;
- [0024] Figs. 9A and 9B are top and section views, respectively, of the container set assembly of Fig. 8 in stages of operation;
- [0025] Figs. 10A-10N variously illustrate the mechanics of preparing the applicator for use;
- [0026] Figs. 11A-11F illustrate the mechanics of applicator use;
- [0027] Figs. 12A-12D are perspectives illustrating another applicator/container set approach in which the container holds the on-body unit;
- [0028] Figs. 13A-13C variously illustrate use of the applicator in Figs. 12A-12D in connection with a locking-sleeve feature;
- [0029] Figs. 14A and 14B illustrate an applicator with a removable locking strip;
- [0030] Figs. 15A-15F variously illustrate use of the applicator in Figs. 14A and 14B;
- [0031] Figs. 16A and 16B are sectional and detail to views, respectively, of features of the container in Figs. 15A-15D;
- [0032] Figs. 17A and 17B are perspective assembly views illustrating alternative container configurations to that illustrated in Fig. 16A and 16B;
- [0033] Fig. 18 is a side-section view illustrating the features of the applicator and container sets variously shown in Figs. 15A-15F;
- [0034] Figs. 19A and 19B are perspective views of a sensor assembly incorporated in the system shown in Fig. 18;
- [0035] Figs. 20A and 20B are perspective views of the operation of a sensor assembly retention unit incorporated in the system shown in Fig. 18;
- [0036] Figs. 21A-21C are perspective section views illustrating sensor assembly receipt by the sensor mount and sharp withdrawal from the assembled complex;
- [0037] Fig. 22 is a perspective assembly view of advantageous sensor and sensor connector elements;
- [0038] Figs. 23A and 23B are perspective assembly and final-assembly views, respectively of the sensor components in Fig. 22;
- [0039] Figs. 24A and 24B are top and bottom perspective views, respectively of circuit board components to be used with the assembly shown in Figs. 23A and 23B;
- [0040] Figs. 25A and 25B are perspective views illustrating assembly of the subject components in stages;

- [0041] Fig. 26 is an assembly view of the on-body/sensor mount unit in Figs. 25A and 25B illustrating an advantageous seal element;
- [0042] Figs. 27A and 27B are section views further illustrating the seal element and its relation to the mount in Fig. 26;
- [0043] Figs 28A-F are perspective views of another advantageous sensor and sensor element arrangement;
- [0044] Figs. 29A and 29B are perspective view illustrating yet another advantageous sensor approach, with the sensor as originally produced and modified for use, respectively;
- [0045] Fig. 30 is a perspective view illustrating the sensor as configured in Fig. 29B in contact with a circuit board assembly;
- [0046] Fig. 31 is a side-section view showing a comparative approach, in a final on-body sensor assembly;
- [0047] Figs. 32 and 33 are perspective views of still other advantageous sensor configurations, these figures illustrating split-sensor approaches;
- [0048] Figs. 34A-34D are perspective views illustrating combination electrical connector and sensor isolator in yet another advantageous sensor arrangement;
- [0049] Figs. 35A and 35B are side assembly and section views, respectively, of the system shown in Figs. 34A-34D;
- [0050] Fig. 35C is an end-section view, with detail view, Fig. 34D, illustrating additional sensor features;
- [0051] Fig. 36 is a perspective assembly view illustrating a sensor connection approach related to that in Figs. 34A-34D for a single-sided sensor;
- [0052] Fig. 37 is a perspective partial assembly view illustrating a mount-and-socket interface for the sensor assembly employing the components in Fig. 36;
- [0053] Fig. 38 is a complete assembly view of that illustrated in Fig 37;
- [0054] Figs. 39A and 39B are perspective assembly and as-assembled views of a stacked non-directional sensor connect arrangement;
- [0055] Fig. 40 is a side partial-section views of the sensor in Fig. 39 received within an on-body unit;
- [0056] Figs. 41A and 41B are partial perspective assembly views of another stacked non-directional sensor connection arrangement;

- [0057] Fig. 41C is a section view of the complete assembly of the components variously illustrated in Figs. 41A and 41B;
- [0058] Fig. 42 is an assembly view of an advantageous radial arrangement sensor connector assembly;
- [0059] Figs. 43A and 43B are reversed perspective views of the mount-side sensor connection component for use with an assembly as shown in Fig. 42;
- [0060] Fig. 44 is a section view of the complete assembly of the components variously illustrated in Figs. 42, 43A and 43B;
- [0061] Figs. 45A and 45B are reversed assembly views of an alternative advantageous sensor connection assembly that can be used like that in Fig. 42;
- [0062] Figs. 46A and 46B are assembly and sectional views, respectively of a complete on-body unit employing the sensor and connection elements illustrated in Figs. 45A and 45B;
- [0063] Figs. 47A-47D are construction views of an on-body subassembly;
- [0064] Fig. 48 is a perspective view of a complete on-body electronics subassembly;
- [0065] Figs. 49A-49D illustrate the process of co-molding/overmolding the assembly in Fig. 48;
- [0066] Figs. 50A and 50B are assembly and sectional views of an alternative snap-together approach with the assembly in Fig. 48; and
- [0067] Figs. 51A-51B are assembly views illustrating adhesive backing application in producing a final on-body unit ready for use as shown in perspective-view Fig. 51C.

DETAILED DESCRIPTION

- [0068] Before the present disclosure is further described, it is to be understood that this disclosure is not limited to particular embodiments described, as such may, of course, vary. It is also to be understood that the terminology used herein is for the purpose of describing particular embodiments only, and is not intended to be limiting, since the scope of the present disclosure will be limited only by the appended claims.
- [0069] As will be apparent to those of skill in the art upon reading this disclosure, each of the individual embodiments described and illustrated herein has discrete components and features which may be readily separated from or combined with the features of any of the

other several embodiments without departing from the scope or spirit of the present disclosure.

[0070] Where a range of values is provided, it is understood that each intervening value, to the tenth of the unit of the lower limit unless the context clearly dictates otherwise, between the upper and lower limit of that range and any other stated or intervening value in that stated range, is encompassed within the disclosure. The upper and lower limits of these smaller ranges may independently be included in the smaller ranges, and are also encompassed within the disclosure, subject to any specifically excluded limit in the stated range. Where the stated range includes one or both of the limits, ranges excluding either or both of those included limits are also included in the disclosure.

[0071] Unless defined otherwise, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this disclosure belongs. Although any methods and materials similar or equivalent to those described herein can also be used in the practice or testing of the present disclosure, exemplary methods and materials are now described. All publications mentioned herein are incorporated herein by reference to disclose and describe the methods and/or materials in connection with which the publications are cited.

[0072] As used herein and in the appended claims, the singular forms “a,” “an,” and “the” include plural referents unless the context clearly dictates otherwise. It is further noted that the claims may be drafted to exclude any optional element. As such, this statement is intended to serve as antecedent basis for use of such exclusive terminology as “solely,” “only” and the like in connection with the recitation of claim elements, or use of a “negative” limitation.

[0073] The publications discussed herein are provided solely for their disclosure prior to the filing date of the present application. Nothing herein is to be construed as an admission that the present disclosure is not entitled to antedate such publication by virtue of prior disclosure. Further, the dates of publication provided may be different from the actual publication dates which may need to be independently confirmed.

[0074] Various exemplary embodiments of the disclosure are described below. Reference is made to these examples in a non-limiting sense. They are provided to illustrate more broadly applicable aspects of the present disclosure. Various changes may be made to the disclosure

described and equivalents may be substituted without departing from the true spirit and scope of the disclosure. In addition, many modifications may be made to adapt a particular situation, material, composition of matter, process, process act(s) or step(s) to the objective(s), spirit or scope of the present disclosure. All such modifications are intended to be within the scope of the claims made herein.

Insertor/Applicator and Loader Overview

[0075] Turning to Fig. 1, in certain embodiments, a user starts with the acts 10, 20 of unpacking each of the system “Loader” and “Applicator”. Next, in an assembly operation 30 the constituent components are merged or connected (these elements include the sensor plug, the on body unit and insertion sharp or needle), and the user unlocks the applicator (or removes a locking element). Then in an on body unit application operation 40, the applicator is driven to insert the sensor and apply the on-body unit to the skin. In a post application stage 50, use in monitoring occurs during wear followed by appropriate disposal.

[0076] A more detailed illustration of related activity is shown in Figs. 2A-2G in connection with a subject or user 60. In Fig. 2A, one of the highlighted application sites 62 on a user 60 is prepared. The application site may be shaved, simply cleaned with alcohol or otherwise prepared. Fig. 2B illustrates container set or loader 100 preparation, in removing cover 102 from casing 104. Fig. 2C illustrates applicator or inserter 200 preparation in separating cap 202 from inserter assembly 204. In Fig. 2D once alignment indicators “A” are aligned, assembly 30 is achieved by pushing the applicator firmly into the container. In Fig. 2E, inserter assembly 204 is placed on the application site and pushed down firmly to effect patch 212 application 40 as shown in Fig. 2F upon used insertion device removal from the application site. In one mode of operation 50, as illustrated in Fig. 2G, analyte levels detected by the sensor are transmitted over a wireless communication link “WL” to a reader device 400 (referred to alternatively as a "receiver unit" or "receiver device", or in some contexts, depending on the usage, as a "display unit," "handheld unit," or "meter"). Relevant information is presented on the unit display 402.

[0077] The applicator/inserter and container/loader shown in Figs. 2A-2F are illustrated in detail in Figs. 3 and 4, respectively. Other variations are described in detail below. These

may operate differently insofar as their internal workings, but may present no difference concerning user activity.

[0078] In reference to Fig. 3, applicator 200 comprises a cap 202 and inserter assembly 204. The top end of the cap (not shown) includes an opening. The opening (or openings) is capped by a TYVEK, or other suitable material, seal 206. Such provision allows for ethylene oxide (ETO) sterilization of the unit through the TYVEK when closed. Such closure may employ complimentary threadings 208, 208'. ETO sterilization is compatible with the electronics within the on-body unit 210, with its associated adhesive patch 212. Finally, a label 214 may be affixed to the inserter assembly 204, bearing pertinent information, such as expiration date, for example. As shown, the inserter assembly includes a handle cover 216 and translating sleeve or sheath 218.

[0079] In reference to Fig. 4, loader 100 includes a foil cover 102 and casing 104. Housed within the casing are a desiccant body 106 and table or platform 108. A sensor plug assembly 110 is snap-fit to an interface coupler 112 that is snap-fit to the table 108. With the cover sealed, the assembly may be subjected to gamma (e-beam) sterilization – an approach compatible with the chemistry of the sensor included in the sensor plug assembly.

[0080] Use of different sterilization approaches as referenced above speaks to the utility of the separate loader/applicator design. Still other advantages may exist, given different shelf-life attributes for the active (i.e., electronic, chemical, etc.) elements. In certain embodiments, all components may be sterilized using the same sterilization technique, such as, but not limited to ETO and e-beam sterilization described above.

[0081] Considerations include handling, regarding which the table or platform in the loader primarily serves as an anti-tampering feature. It is positioned to protect and assist in the retention of the sensor, sensor sharp and associated connector. Additionally, features of the loader casing can be employed to unlock a sleeve 218 safety feature of the inserter assembly.

[0082] Figs. 5A and 5B are section views of the loader of Fig. 4. As seen in Figs 5A and 5B, table 108 is surrounded by multiple locking features 120 (at least one is advantageously provided in this embodiment). Each of these includes a cantilevered arm 122 with a tongue 124 received in a slot or groove 126. So received, the table 108 is locked in place. When the arm(s) 122 are urged inward, in the direction represented by arrows A and A', from a concentric sleeve 218 riding over ramp(s) 130, the lock is released, and the table can “drop”

in direction B, thereby providing access to sensor assembly 110 which is otherwise isolated from being poked at or otherwise handled/accessed by a user. Detent ramp feature(s) 128 may be provided to hold the table/platform until depressed with force by a user. In addition, various key-and-way or slot-and-groove guidance features 132, as shown, may be provided to control such motion and ensure that it is linear (i.e., avoid table canting, binding, etc.)

[0083] In some embodiments the sleeve/ramp interface with associated locks relies only on detent features to maintain table position. So-configured, inadvertent handling of the sensor assembly could be avoided. Rather, the detent(s) can be tuned to require deliberate action to clear the table.

[0084] A related style of drop-table loader device 100' is illustrated in Figs. 6 and 7. Here, a collapsible armature or linkage 140 supports a tabletop 142. This member is integrally guided and spring-loaded by virtue of the "living hinge" design of the linkage. Alternatively, a coil spring could be employed along with guides for the table. A sleeve element of the inserter or the base of sensor mount unit 210 itself, can be used to translate the table top 142 to provide clearance for sensor element 110 access and pick-up by the applicator and incorporation as a complete on-body unit 300 (FIG. 11F).

[0085] Another approach to sensor storage and protection is illustrated in Fig. 8 with loader 100". Here, casing 104 is provided in connection with a support base 144. The support base receives sensor assembly 110 and a frame 146. The frame carries a door 148. As shown, the frame incorporates three channels 150 for receipt of frame legs 152 to serve as guidance. In its up/closed position shown in Fig. 9A, door 148 (not shown) protects the sensor assembly from contact from the user. Features interacting between the base and the frame may cause the door 148 to swing open as the frame 146 is moved down as shown in Fig 9B. Likewise, features of the frame may hold sensor assembly against the base until it is pushed down by user activity.

[0086] Similar to loader embodiment 100 shown in Figs. 5A and 5B, the frame in loader 100" may be locked in place and released by inserter sleeve introduction. A support ring 160 may lock against boss or tang 162 until the boss is urged inward by the action of an inserter sleeve along angled interface surface 164 of each leg 152. The legs may be biased outward with a preload or not. Fig. 9A illustrates the locked configuration, whereas Fig. 9B illustrates unlocked/translated relation of pieces.

[0087] Figs. 10A-10N illustrate the internal device mechanics of preparing the applicator for use with loader 100. Modification of such activity for use with the alternative loader embodiments (as-described above or others) can be appreciated in reference to the same by those with skill in the art. Figs. 10A and 10B show loader 100 and applicator 200 with their constituent parts, along with arrows indicating the manner of cover 102 and cap 202 removal, respectively. Upon peeling off foil cover 102, the table or platform 108 within is locked, thus protecting the sensor assembly 110 which includes sensor, plug and sharp. Likewise, upon removal of cap 202, the applicator is locked. Its distal sleeve 218 (not shown in Fig. 10B) cannot collapse into its housing (also referred to as or cover 216).

[0088] In Fig. 10C, inserter assembly 204 is set within loader 100. It is twisted and advanced until mechanical alignment features “M” engage, allowing the inserter to sit flat within the loader. Visual alignment indicators “A” assist or guide the user to quickly find the proper alignment position. Fig. 10D shows the elements with the mechanical alignment features engaged. Sleeve 218 passes over platform 108, with the platform nested inside the sleeve 218.

[0089] Cross-section views Figs. 10E and 10F illustrate the relationship of parts overviewed in Figs. 10C and 10D. When the inserter assembly is seated onto the platform 108 of the loader, platform 108 bends and displaces platform locking arms 122 inward as indicated by action arrows A and A' (Fig. 5A) to clear of locking grooves 126 of casing 104, thus unlocking the platform. At this point, the platform is held in place by ramps 128 providing a detent feature between the platform that can be overcome by further downward pressure to be applied by the user upon further depression of user interface cover 216.

[0090] Fig. 10G illustrates such further depression (inward, radial deflection urged by ramp 128) so that arms 122 are flexed further inward as illustrated by this next action arrow in detent zone or region 168. In Fig. 10H, once a distal ring 170 of the platform 108 is past the detent features, a relieve or undercut 172 provides increased clearance for the tongue(s) 124 to reduce sliding friction as the sleeve slides or telescopes further into the loader casing 104. Also, one or more flexible grasping arms 174 in contact with the sensor assembly 110, particularly through needle sharp head or boss 302, are moved from a stabilizing configuration in Fig. 10G to a freed state or configuration.

[0091] In Fig. 10I, as the inserter assembly is further advanced into the loader, locking tray/platform support(s) 180 contacts unlocking ring or standoff feature(s) 182. Displacement driven in contact zone 184 (provided by offset entities) bends supports 180 out of contact with ledge 188 of sensor mount holder 190 in lock section 192, thereby unlocking the inserter assembly to allow removal by the applicator from the loader.

[0092] When the platform bottoms-out in the loader casing as shown in Fig. 10J, the inserter sheath/sleeve is released and ready to move. While the support arm features are shown flexing outward to unlock, they can be oriented to flex radially inward to free the elements. The same may hold true for the various locking/unlocking features. However, the present arrangement offers critical advantages in terms of a coordinated whole providing an advantageous form factor and minimized loader casing size (a factor important to the user experience) in which the sensor mount is coaxially arranged. As to the carrier 190, it is advantageously designed with unique carrier arm features as detailed in, for example, US. Patent Application Serial No 13/071,461, the disclosure of which is incorporated herein by reference.

[0093] In Figs. 10K and 10L, follow-through from force in pushing past the sleeve locks permits engagement of the sensor sharp (via head or hub 302) within connection zone 250 by sharp holder 260 by tangs 262 supported by flexible arms 264 - collectively referred to as “jaws” 266. Referred to as such, or as grasping “finger” assemblies, they pass over and secure collect the sensor sharp, just as the sensor assembly 110 is secured within sensor mount 220 by snaps 270 to complete on-body unit 300 assembly as illustrated in Fig. 10L. As an alternative snap features 270, the sensor assembly 110 and sensor mount 220 may be connected by a light press fit or otherwise. However, the positive interaction and lock is an advantage. So too is the minimal force required to deflect fine locking features that spring back for engagement.

[0094] The connection features between the holder and inserter/sharp within the connection zone can be otherwise configured. Fig. 10L illustrates alternative connection arrangements. Instead of a basic set of spring jaws 266, an over-center snap design is provide that pinches more tightly onto the sharp hub when retraction force is applied. In the design, sharp holder 260' includes angled arms/legs 280 that pinch tighter to the sharp hub 302' as urged down and inward by cap 304 when pulled as indicated by the action arrows. Retention force is

limited only by material strength, because the self-energizing lock is not prone to slip between the pieces.

[0095] Returning the original connection zone arrangement 250 shown in Fig. 10M (which is slightly rotated from the view shown in Fig. 10L) when the sharp hub 302 and jaws 266 are engaged, so too are platform tongue(s) 124 engaged in undercut socket(s) or groove(s) 180 provided in the loader casing 104. This engagement between the platform 108 and the casing 104 marks the final position of the loader assembly 200' from which the loaded inserter assembly 204 is withdrawn, freed or retrieved to be used. A base 306 of the sharp hub may be included to limit hub insertion into the holder through interference with stop limit or shoulder 308.

[0096] Now, the inserter assembly (alternatively referred to as the applicator) is ready to "fire" as illustrated in Fig. 11A. As such, the inserter assembly 204 is ready to use as in act 40 described in connection with Fig. 2E. Here, the inserter/applicator has already been unlocked by interaction with the loader, and the sensor assembly is included in the sensor mount. A sensor extension 320 is housed within sheath end 330, just above the skin of the user. Rails 290 (optionally three of them) of an upper guide section 290 may be provided to control inserter cap motion relative to sleeve 218.

[0097] User force is applied to overcome or override detent arrangement 294 as shown in Fig. 11B, sheath 218 collapses into housing 216 driving the on body unit 300 (with associated parts) as indicated by the action arrow. An inner diameter of the upper guide section 292 of the sheath constrains the position of carrier arms 294 through the full stroke of the sensor/sharp insertion process. The retention between the stop surfaces 296 of carrier arms and complimentary faces 298 of the sharp holder 260 maintains the position of the members with return spring 252 fully energized.

[0098] In Fig. 11C, sensor 320 and sharp 330 have reached full insertion depth. In so doing, the carrier arms 294 clear the upper guide section 292 inner diameter. Then, the compressed force of the coil spring 252 drives angled stop surfaces 296 radially outward, releasing force to drive sharp holder/carrier 260 to pull the (slotted or otherwise configured) sharp body 330 out of the subject and off of the sensor 320 as indicated by the action arrow as indicated in Fig. 11D.

[0099] With the sharp/needle fully retracted as shown in Fig. 11E, the upper guide portion, with sleeve is set with a final locking feature 254. The spent inserter/applicator is removed from the insertion site, leaving behind the on-body unit 300, and with the sharp secured deep inside the inserter within a socket 256, inserter 204 now ready for disposal.

[00100] As for further details of the operation, certain ones may be appreciated in view of related approaches discussed below, others in review of the incorporated subject matter and still more appreciated by those with skill in the art based upon further review of the figures which depict actual hardware produced according to various aspects of the subject disclosure.

[00101] Turning to Figs. 12A-12D one alternative applicator/container set approach is now described. In Fig. 12A the loader container 500 holds the on body unit 550 whereas – above – the relationship between the sensor assembly and the on body unit were reversed. Upon aligning markers “M”, the applicator 600 is inserted in the loader. In Fig. 12B, the units are merged. In Fig. 12C, the parts are separated. Finally, in Fig. 12D the inserter/applicator 600 is unlocked and ready for use with the on body unit 550 with sensor assembly unit loaded therein.

[00102] Figs. 13A-13C variously illustrate use of the applicator in Figs. 12A-12D in connection with a locking-sleeve feature. Fig. 13A shows the sleeve locked. A visual indication (open window) is seen when ready for use as presented in Fig. 13B. Upon use, as shown in Fig. 13C, the unit is fully compressed/collapsed.

[00103] Figs. 14A and 14B illustrate an applicator with a removable locking strip. The strip includes a pull tab and adhesive or other locking member to keep it in place until removed and the system is ready for use.

[00104] Figs. 15A-15D illustrate preparation of the application in Figs. 14A and 14B for use. Fig. 15E shows the applicator loaded with the on-body unit and ready for sensor/sharp insertion with the locking strip removed. Fig. 15F illustrates the system after such action has been taken in transferring the on body unit from the inserter onto the skin of a user.

[00105] Figs. 16A and 16B are sectional and detail to views, respectively, of features of the container in Figs. 15A-15D. Specifically, the on body unit is shown with an adhesive patch and its backing. The backing is spiral cut and attached to a boss so that when the sensor mount/puck is transferred from its loader container, the peel-away backing is left behind. In this fashion, the adhesive backing remains covered and “fresh” until just before use.

[00106] As an alternative to the spiral peel-around approaches, Figs. 17A and 17B are perspective assembly views illustrating alternative container configurations for capturing separate peel-off “butterfly” wings or bilateral liner panels from the adhesive-backed patch. In each case, a two-part base is provided for gripping the peel-away cover pieces. Naturally, the base adapted to fit in the container cup/casing may be configured differently. In the version in Fig. 17A, traction/tread is provided to assist with grip. In the version in Fig. 17b, ramps are provided to assist in ease of liner handling. In another version the base may be a one-piece molding incorporating a living hinge in a “clamshell” arrangement. The liner piece(s) may be captured along a center line or at an offset location. However configured, the base may snap into place with complementary band and rib interface features associated with each of the base and cup, snaps or other features. As with other assemblies described herein, they may alternatively be press fit, ultrasonically welded or otherwise secured in place.

[00107] Fig. 18 is a side-section view illustrating the features of the applicator and container sets shown in Figs. 15A-15F. It includes many of the details described in connection with the alternative loading approach above. However, it is simplified in approach. Most notably, the loader includes no active/mobile components. Moreover, it offers advantages of not having to expose the adhesive on the patch – as convenient in the approach where the sensor mount is held within the applicator. Furthermore, the position for the on body unit provides a good “table” for sensor plug insertion. Still, the other approach has its advantages as well. Grasping or picking-up an on-body unit minimized in size can be difficult. By preloading the applicator with the on body unit, this handoff is avoided – by instead opting for the plug handoff. Also, the use of including a needle guard/sharp protector is avoided.

[00108] Figs. 19A and 19B show as sensor assembly in association with a needle guard. In use, its distal interface feature (barb) of the needle guard is captured by a complimentary split ring or other feature in the loader during the two-piece assembly. Then, when the inserter is separated from the loader, the guard stays with the loader. In certain embodiments, the guard may comprise polypropylene with a TPE insert to lightly secure the sharp/needle. Other materials may be selected.

[00109] Naturally, the same applies to the materials selected for construction of other elements. For example, the user interface casing may be made of polycarbonate or another material.

The sleeve, container, etc. may comprise acetyl (for reason of lubricity of sliding parts). Any number of the parts may be injected molded, thermoformed or otherwise produced.

[00110] Regarding the sensor plug handoff to the sensor mount, Figs. 20A and 20B illustrate a manner of holding a sensor plug boss to the element that will pick up the on-body electronics. Snap arm clip or snap to the plug lit and hold the plug within the inserter during shipping and handling. When the inserter and the loader are brought together, lever arm(s) contacts the on body unit, causing associated spring armature(s) or “spring arms” to twist and rotate the connection out of the way. A chamfer on the sensor plug/boss can help ensure alignment and proper actuation of the one or more (e.g., three) torqueing spring arm assemblies.

[00111] Figs. 21A-21C illustrate another handoff approach. In this, a plug gripper with a light snap fit grabs and orients the plug for assembly. After the plug assembly is firmly snapped into the sensor mount (puck), the plug gripper is retracted with force that overcomes its grip. Such an approach offers simplicity in reduction in the number of parts required (given that the snap features may be incorporated in the needle hub/boss). However, the approach also requires adequate clearance to facilitate such activity, as well a good control of the relative strength of the snap features.

Electrical Connections Details

[00112] The selection of various hardware options from the above will depend – at least in part – based on the sensor assembly configuration. Sensor assembly configuration – in turn – depends on the manner scheme selected for contact and or sealing. A number of advantageous options are presented in the next figures.

[00113] A first example is presented in Fig. 22. Here a sensor is provided with an elongate “tail” section. The distal portion of the tail is to be inserted through the skin surface. The proximal portion of the sensor includes a “flag” type connector region. Three carbon-doped (for conductivity) silicone electrical connector are provided to interface with the circuit connection pads of the sensor. A split “V” portion of each sensor receives the contact pads on the sensor. A flexible nubbin on the opposite side is provided for electrical contact with the circuit board incorporated in the sensor mount. When inserted in a housing, the sensor and the connector pads are advantageously sealed, encased or potted with an adhesive. Epoxy, a

UV cure or another type of dielectric (non-conductive) compound may be used. Generally, the compound selected is of such viscosity that it is able to flow around features and fully seal the “tail” sensor within its housing to avoid leakage along that path. Such an approach avoids contamination and/or current leakage due to fluid intrusion. Figs. 23A and 23B are perspective assembly and final-assembly views, respectively of the sensor components in Fig. 22.

[00114] Figs. 24A and 24B are top and bottom perspective views, respectively of circuit board components to be used with such an assembly. In each, a custom printed circuit board (PCB) is shown. It includes a battery with mount, application specific integrated circuit (ASIC), or other appropriate processing unit, and various other circuitry, including a thermocouple. On its face, the PCB includes a housing with snap features. On the reverse, heat stakes show the mode of attaching the housing.

[00115] The on-body unit is formed by over molding with a polymer “macromelt” (i.e., a thermoplastic hot-melt based on polyamide) or other compound and then affixing an adhesive patch with releasable liner thereto. A completed sensor assembly is provided once fitted with a complimentary sensor assembly, as illustrated in Figs. 25A and 25B.

[00116] Internal to such assembly, it may be desirable to include a seal or gasket as shown in assembly view Fig. 26. As shown in cross section, in Fig. 27A, and magnified in Fig 27B, the seal advantageously includes discrete ring/rim elements to compress and ensure sealing in critical areas, including around each circuit connection/nubbin.

[00117] Figs. 28A-28F illustrate another advantageous sensor and sensor mount or plug arrangement. It resembles the previous approach, but is configured with a curve imparted to the sensor connection “flag”. This permits package and sealing within in a roughly triangular envelope to shorten the length of the connector. Doing so results in a generally more compact sensor plug body and the ability to downsize all associated components. Yet, it does not significantly complicate manufacture.

[00118] More extensive sensor manipulation is contemplated in connection with the sensor approach illustrated in Figs. 29A and 29B. Here, a design is provided that eliminates a connection element and the need for separate spring contacts (be they metal or elastomeric as above). In addition, the approach offers the advantage of turning a two-sided sensor into a single-sided sensor after folding. The sensor shown in Fig. 29A has two contacts facing on

the split contact area and one contact obscured by the view. When folded and optionally clamped, glued or otherwise affixed in the orientation in Fig. 29B, all of the sensor contacts point down. Set within a housing (not shown) to restrain and/or seal the sensor, it is associated with connections on the PCB as shown in Fig. 30.

[00119] Such an approach in some embodiments includes a thinner on body unit relative to the variation shown in Fig. 31 (represented by height H). Here, a flag type sensor is shown in a housing with separate electrical connectors. The “stack height” in Fig. 31 includes these connectors as well as the housing. The approach shown in Fig. 30 enables eliminating the connector height above the sensor. Thus, elements are eliminated without losing functionality. Moreover, the elimination of parts reduce cost, and impedance (relative at least to the inclusion of elastomeric connectors as shown in Fig. 22, etc.) between the sensor and the PCB. Another useful aspect is allowing a two-sided sensor to connect to the PCB with no vias or holes in the sensor, thereby helping with sealing considerations and ease of electrical connection.

[00120] Figs. 32 and 33 illustrate other sensor configurations. In these, two-sided sensors are split and bent in opposite directions to orient the connections onto a single side or plane. As above, ease of sealed, electrical connection is facilitated. Moreover, overall sensor plug height can be reduced relative to other approaches. Any of conductive adhesives, conductive films and/or mechanical contacts may be used to electrically connect with the sensor contacts so arranged.

[00121] A significantly different clamshell arrangement for 2-sided sensor connection from that illustrated in Fig. 31 is shown in Figs. 34A-34D (further detailed in Figs. 35A-35D). As seen in Fig. 34A, a flexible one-piece seal is molded in silicone. Separate doped silicone conductive elements are set therein. The result is a generally malleable/flexible hybrid connection and sealing unit incorporating a living hinge joining two (as-shown) symmetrical sections. Alternatively, a two-piece design is possible. Yet, with the unitary design, the arrangement can be neatly secured using a single catch boss or post opposite the hinged section. The one-piece design also facilitates assembly as illustrated, in which the flexible connector is set in a rigid or semi-rigid housing with one side located on the post. Then a sensor is inserted, and folded over. Once folded, it is captured with the upper connector side or layer. The connector is illustrated as bilaterally symmetrical, however, it can be formed in

a direction-specific orientation because certain of the lower electrically conductive plugs are not necessary, only the one opposite the sensor via, which is used to contact the upper. In certain embodiments, all the contacts may be provided on a single side of the sensor.

[00122] In any case, with the sensor captured within the conductor/seal element, a sharp is then introduced, with its hub contacting the housing. Fig. 35A illustrates the insertion and Figs. 35B and 35C provide an overview of the relation of the needle/sharp to the sensor. In Fig. 35D further details of the sensor configuration are visible. Particularly, biasing features are shown that abut surfaces in order to center the sensor in its channel. The curved section of the sensor may overlie a corresponding surface to help limit sensor insertion depth. Sensor vertical placement is also controlled given its sandwiched relationship between the connector halves. As noted with respect to the other sensor assembly housings discussed herein, this one may also include various clip or snap features for its precise associations with the sensor mount or socket within the on-body unit.

[00123] A related arrangement to that described in connection with Figs. 34A-34D and 35A-35D is presented in Figs. 36-38. In Fig. 36, a single sided sensor (i.e. all contacts are provided on a single side of the sensor) is shown with a sharp for insertion in a housing. The housing includes an elastomeric (e.g., silicone) seal backing. Once such an assembly set is in a loader (or vice versa in an inserter), it is coupled to the electronics of an on-body unit, within a socket that includes a second elastomeric unit, this one with conductive plugs in the elastomer body, together set within a socket affixed to a PCB. Once the assembly is received, the on-body unit (complete over-mold and adhesive patch as shown in Fig. 38) is ready for use.

[00124] Notably, all of the connection/connector approached described above are “directional”. In other words, they require a selected alignment for fit between the sensor plug and the on-body unit. Other arrangements are advantageously non-directional.

[00125] The plug construction shown in Figs. 39A and 39B offers such an approach. Separate conductive (optionally metal) bands connect to sensor sections as shown in Fig. 39A. The assembled unite, with sharp in place is received in an on-body unit as illustrated in Fig. 40. Brush-type connectors reach to the individual levels. Such a sensor assembly can be inserted into the socket of the on-body unit in any radial orientation.

[00126] An “opposite” approach is illustrated in Figs. 41A-41C. Here, the connector (optionally conductive elastomeric) O-rings connect to stacked sensor conductors. The sensor-side conductors/connectors may be formed by rolling up a single-sided sensor or using the oppositely directed folding/rolling approach shown in connection with Fig. 30 – but oriented vertically. Other approaches may be utilized as well. In any case, the sensor-side connectors subtend less than 360 degrees while those associated the PCB provide a multi-level encircling relationship.

[00127] In contrast, the connections associated with the PCB in the next embodiment shown in Figs. 42-44 are laid out in concentric rings. The sensor contacts held within housing member utilize micro-spring wireform connections. These spring provide compliance as well as a discrete top loop, each oriented on a different radial track for connection. Very fine wire can be used in this regard, thus producing an easily miniaturized system.

[00128] Figs 45A and 45B illustrate another sensor housing side connection approach that can be employed with concentric on body unit side connection. As illustrated, a bent-over sensor with contacts positioned along different radial paths or arcs connect with conductive elastomeric plugs carried by two opposing discs. Two of the plugs are set on one disc, and a third – configured to pass through a sensor via – is set on the other. These elements are used in association with a system shown in assembly view, and as-assembled in Figs. 46A and 46B, respectively.

On-Body Unit Construction Details

[00129] Certain elements of the on-body electronics fabrication may apply to any or all of the above electrical connection configurations or schemes. Figs. 47A-47D provide construction views of an exemplary on-body subassembly.

[00130] A socket or mount is fit through vias in a PCB with other associated components including ASIC, thermistor/thermocouple, battery mount, etc. Once loaded as shown in Fig. 47C, the socket is heat staked in place. Once a battery is set in place, the unit is ready as shown in Fig. 48 for over-mold. As illustrated in Figs. 49A-49D, the PCB is first set in the mold. With the mold slide inserted and mold closed, macromelt is injected, encasing the PCB. The mold is opened and the near-final part ejected.

[00131] Alternatively, the on-body unit may comprise elements snap-fit (or welded/adhered) together as illustrated in the assembly view of Fig. 50A and as-assembled in Fig. 50B. When snap-fit, various interference or snap fit elements may be provided around the entirety (as in annular rims) of the device or as discrete snap-fit connectors (not shown). Notably, such an approach may benefit from additional O-ring sealing elements to avoid fluid intrusion. Alternatively, adhesive set at the snap junction(s) may be used to ensure good sealing – especially in connection with continuous annular snap-fit features.

[00132] However constructed, final assembly of the on-body unit involves adhesive patch installation. An exemplary approach is illustrated in Figs. 51A-51C. First, a double-sided adhesive patch has the inner liner removed. This is set over the on body unit body (with the temperature sensor folded to seat with a complimentary pocket) and adhered with a first window available for temperature sensing and second window for sensor assembly receipt. As such, it is ready for placement in an applicator/insertor upon removal of the outer release liner, or alternatively ready for placement in a loader unit with or without the outer liner in place, depending on the presence or absence of any liner-puller features provided therein.

[00133] Various other modifications and alterations in the structure and method of operation of the embodiments of the present disclosure will be apparent to those skilled in the art without departing from the scope and spirit of the present disclosure. Although the present disclosure has been described in connection with certain embodiments, it should be understood that the present disclosure as claimed should not be unduly limited to such embodiments. It is intended that the following claims define the scope of the present disclosure and that structures and methods within the scope of these claims and their equivalents be covered thereby.

CLAIMS

1. A system for preparing an on-body analyte sensor, the system comprising:
a casing containing a sensor assembly releasably held within the casing, and a movable platform protecting the sensor from touch; and
an inserter containing an on-body unit, the inserter including a sleeve adapted to fit within the container to release the platform, the inserter further adapted to retrieve the sensor assembly and fit it to the on-body unit.
2. A system for preparing an on-body analyte sensor, the system comprising:
a casing containing a an on-body unit releasably held within a housing and including an adhesive liner, the liner attached to the casing; and
an inserter containing a sensor assembly, the inserter adapted to retrieve the on-body unit and fit it to the sensor assembly.
3. An on-body analyte sensor applicator, the applicator comprising:
a user interface cover and a sleeve received within the cover,
the sleeve including a lock for remaining in an extended position, until interfaced with a loading container, whereby it is slidably received within the cover.
4. An on-body analyte sensor system, the system comprising:
an electrochemical sensor with contacts, the contacts secured in a rolled contact position for connection within the system.
5. An on-body analyte sensor system, the system comprising:
an electrochemical sensor with contacts, the contacts split and separated in oppositely directed orientations for connection within the system.
6. An on-body analyte sensor system, the system comprising:

an electrochemical sensor with contacts, the contacts arranged along an arcuate path for connection within the system.

7. An on-body analyte sensor system, the system comprising:
an electrochemical sensor with contacts, the contacts bent over and held between elastomeric members, wherein at least one of the elastomeric members includes conductive plugs.

ABSTRACT

Devices associated with on-body analyte sensor units are disclosed. These devices include any of packaging and/or loading systems, applicators and elements of the on-body sensor units themselves. Also, approaches to connecting electrochemical analyte sensors to and/or within associated on-body analyte sensor units are disclosed. The connector approaches variously involve the use unique sensor and ancillary element arrangement to facilitate assembly of separate mount and sensor elements that are kept apart until the end user brings them together.

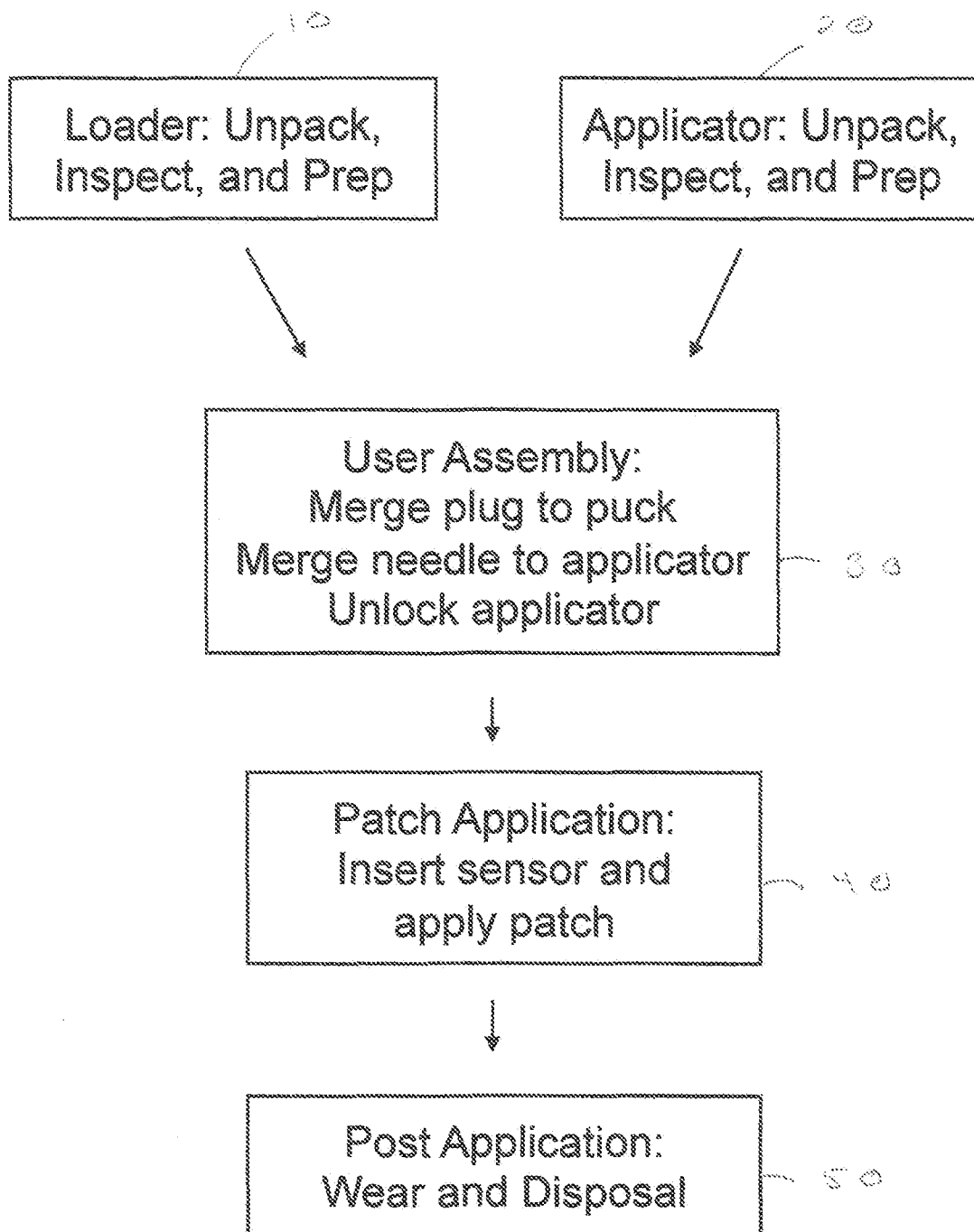


Fig. 1

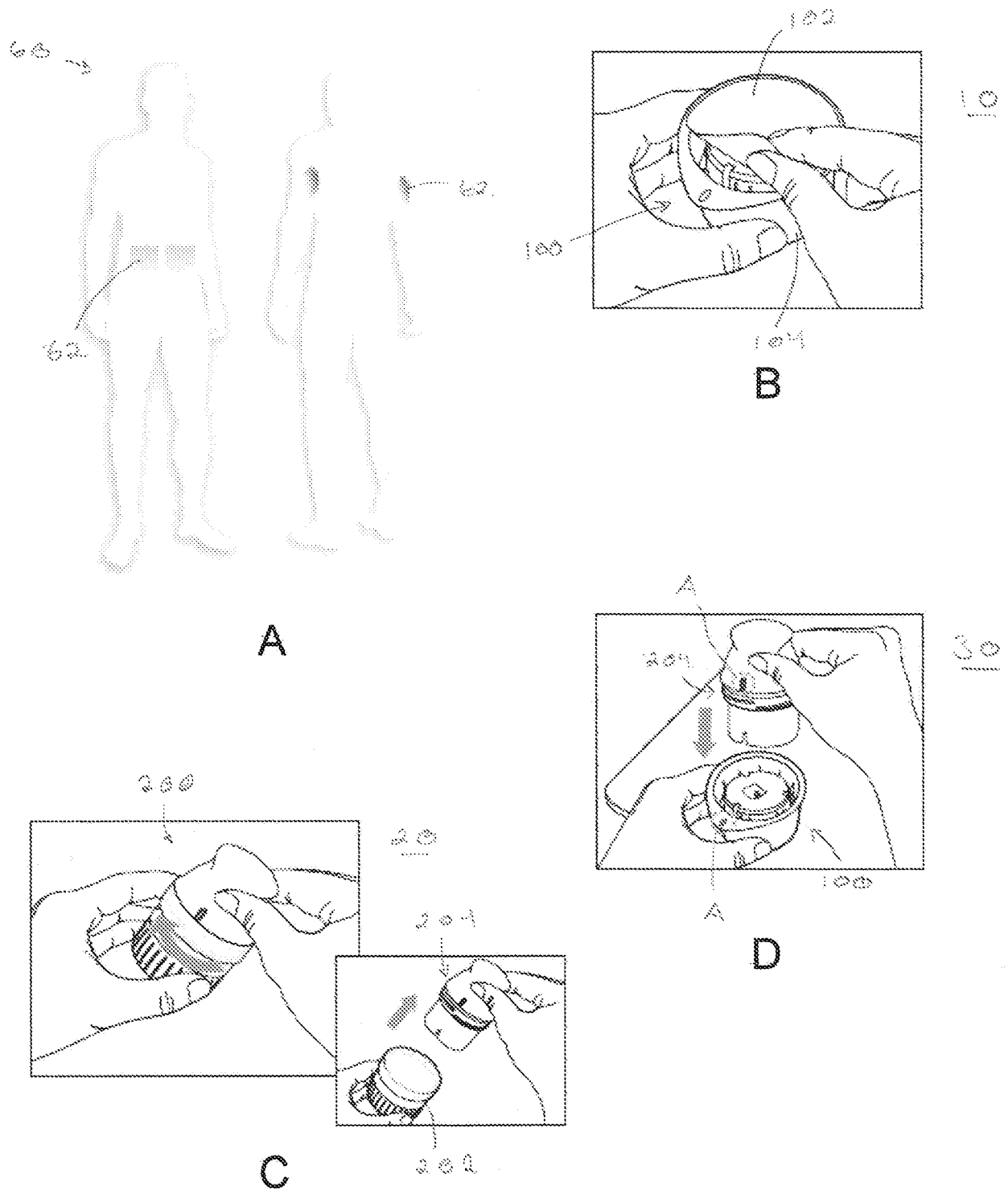


Fig. 2

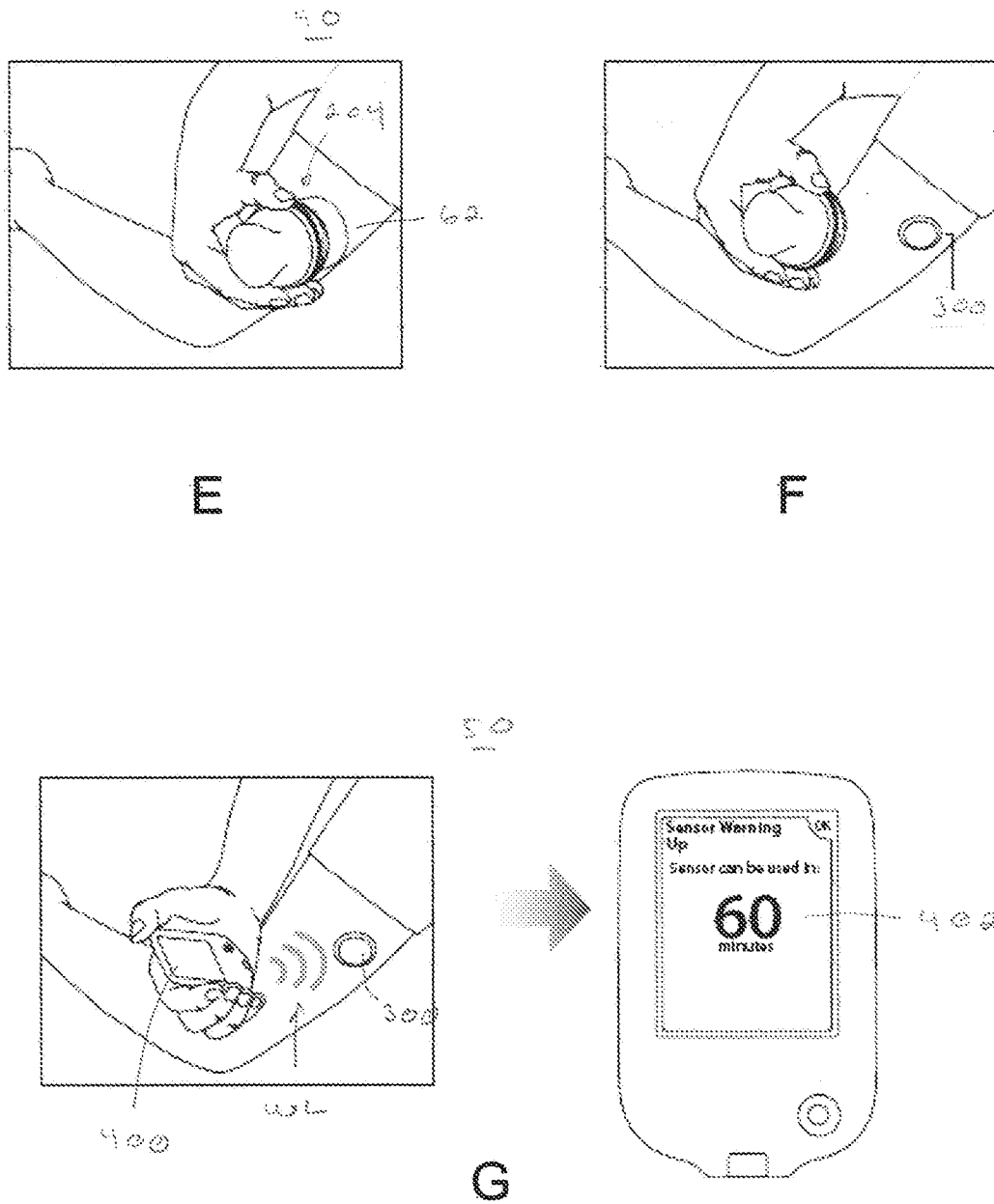


Fig. 2

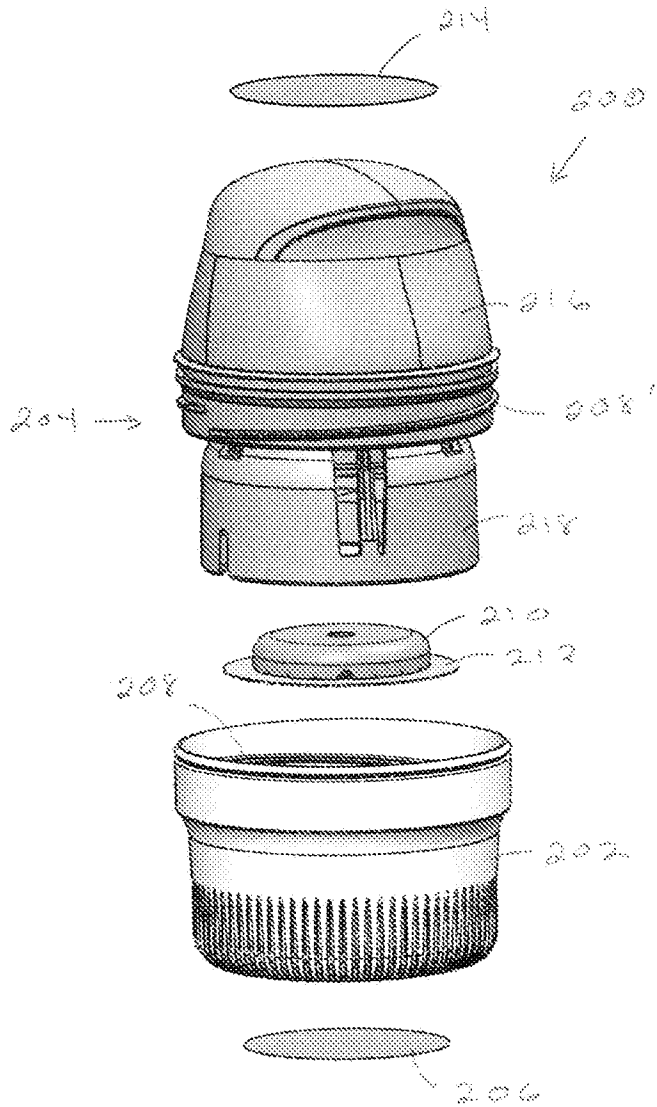


Fig. 3

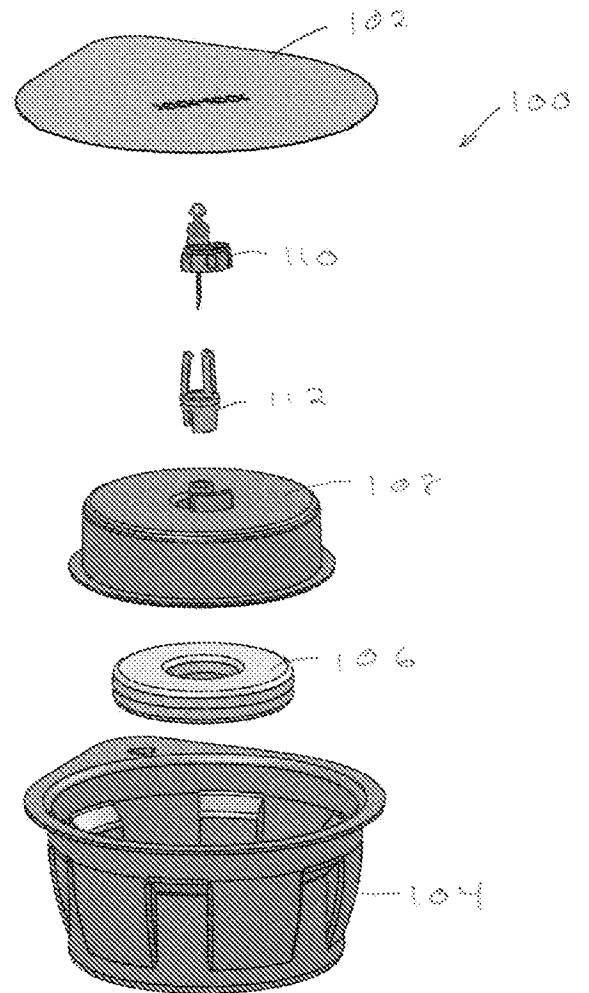


Fig. 4

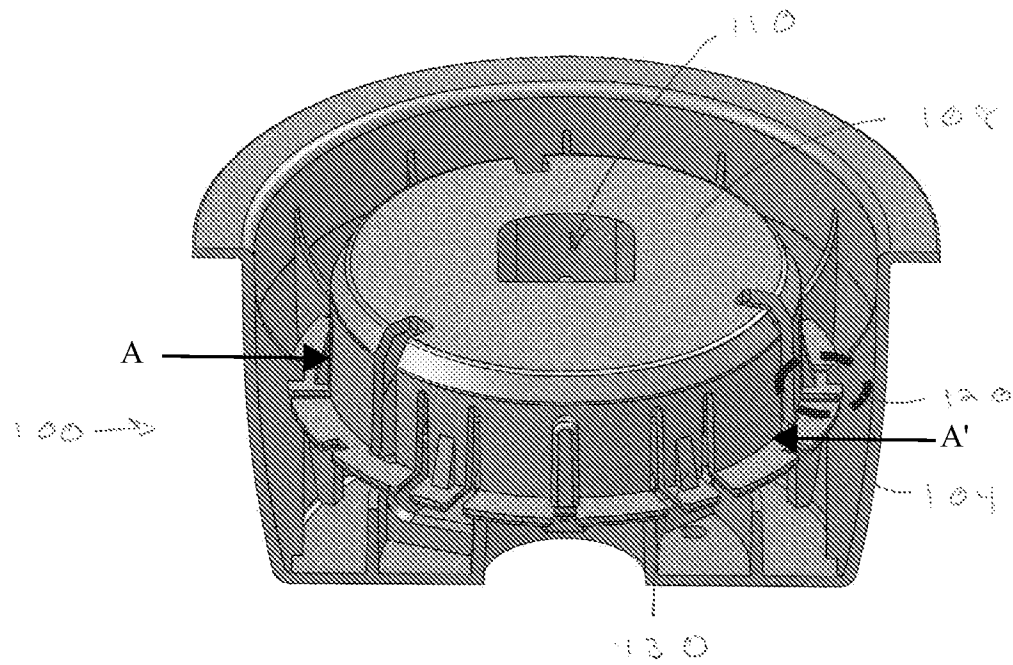


Fig. 5A

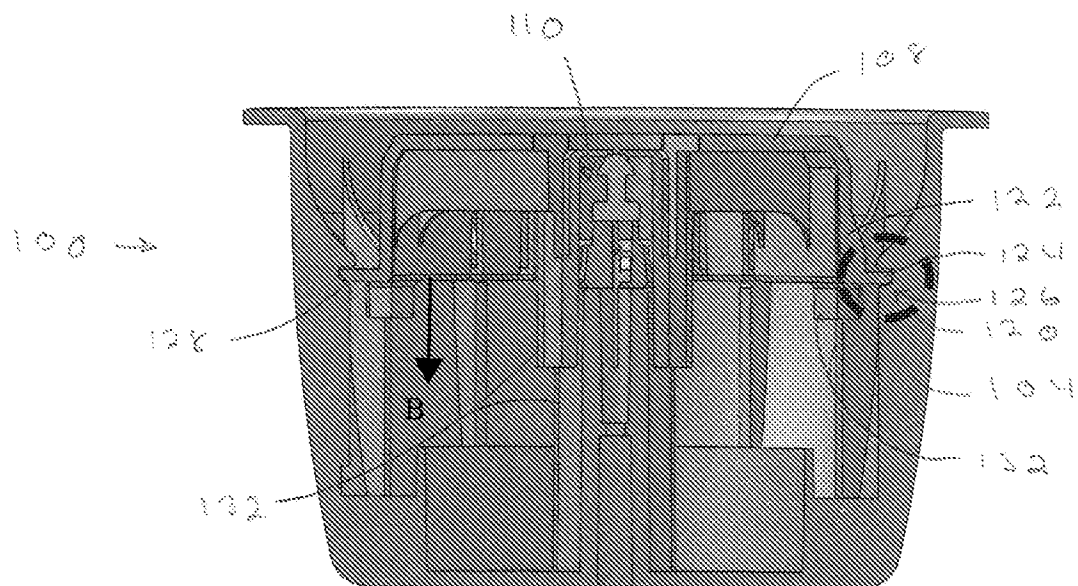


Fig. 5B

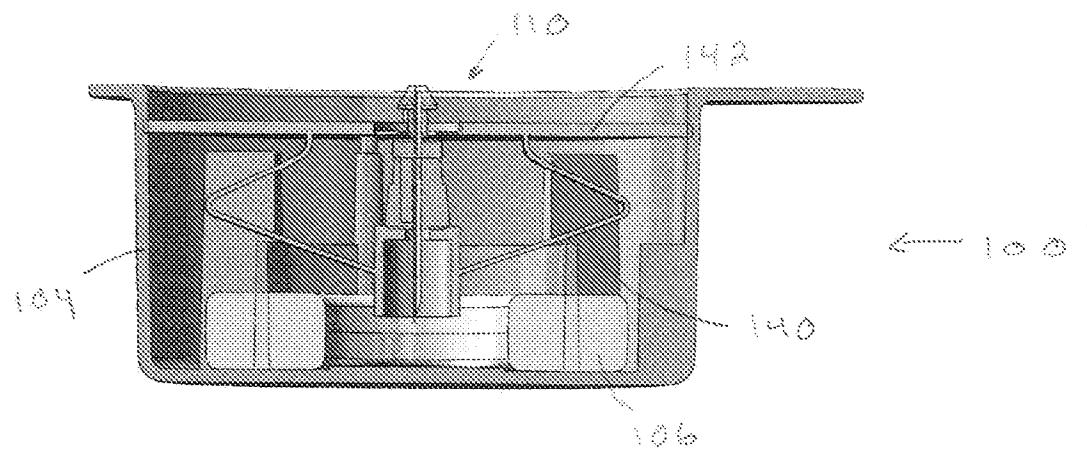


Fig. 7

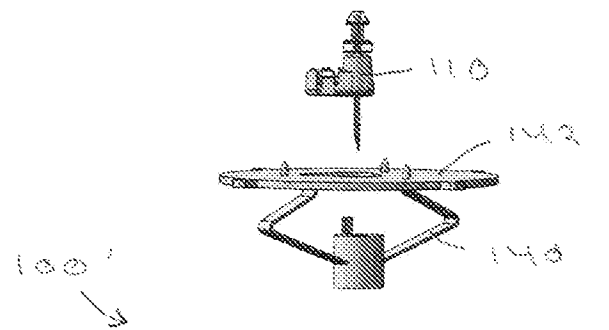
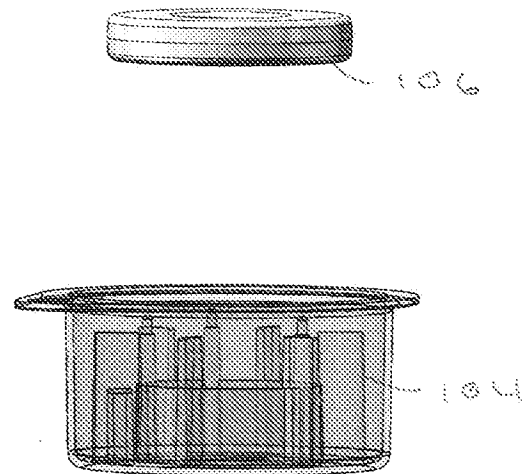


Fig. 6



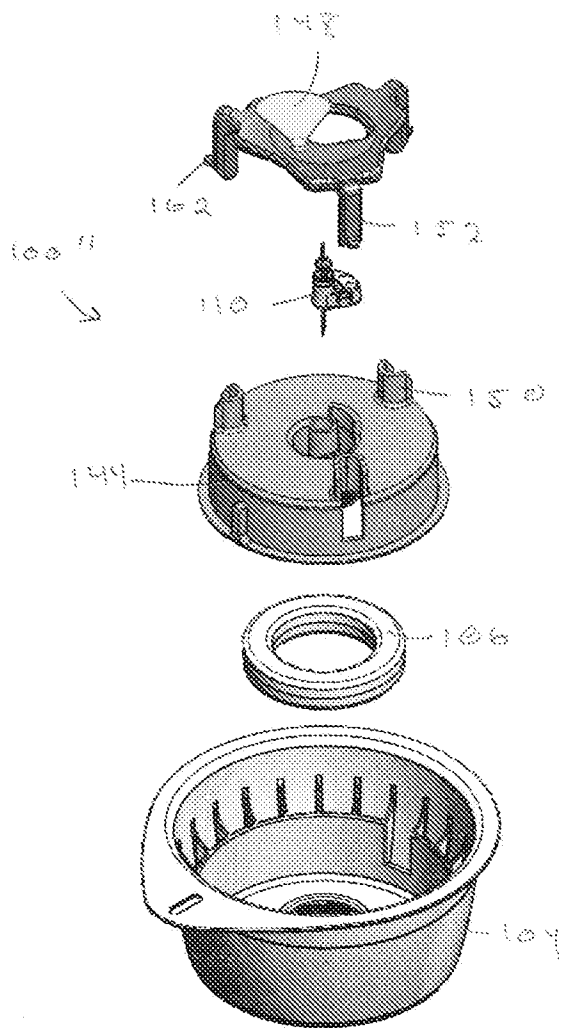


Fig. 8

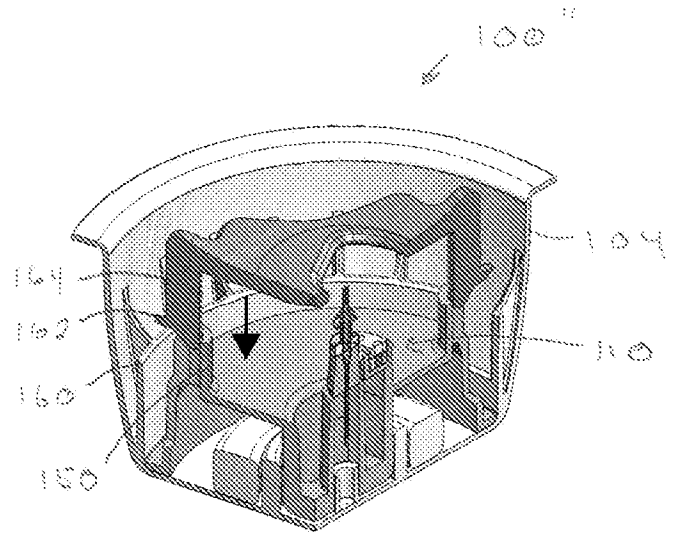


Fig. 9A

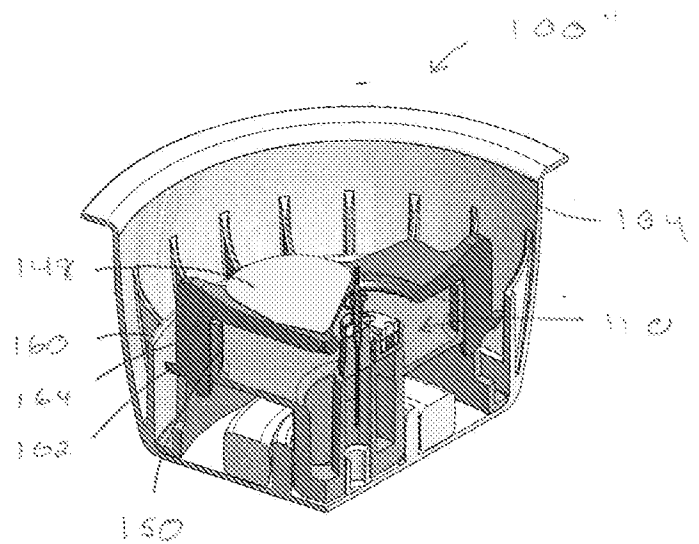


Fig. 9B

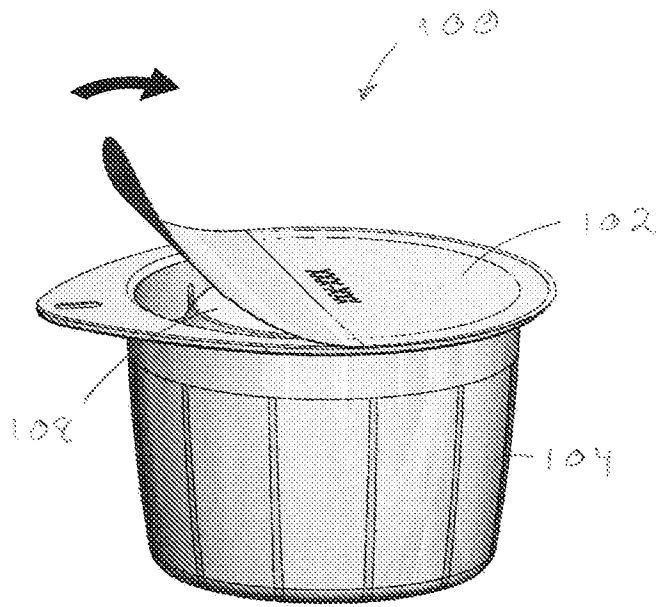


Fig. 10A

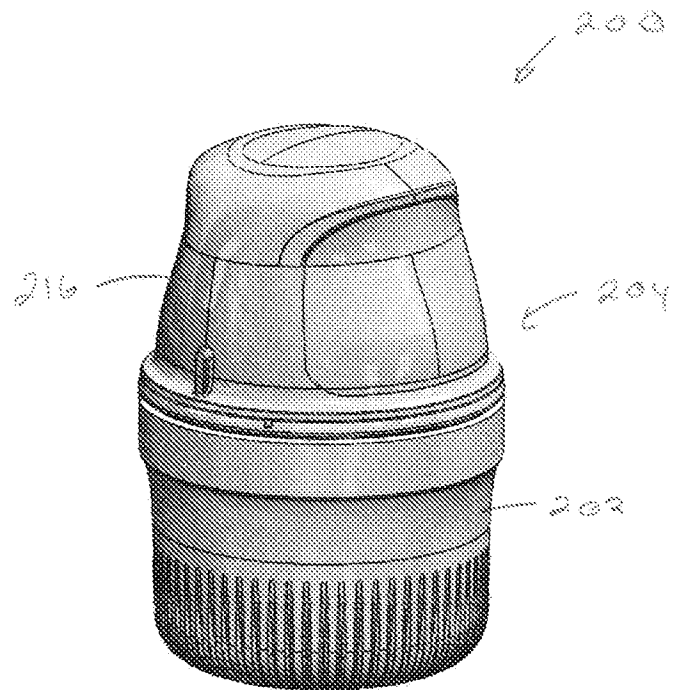


Fig. 10B



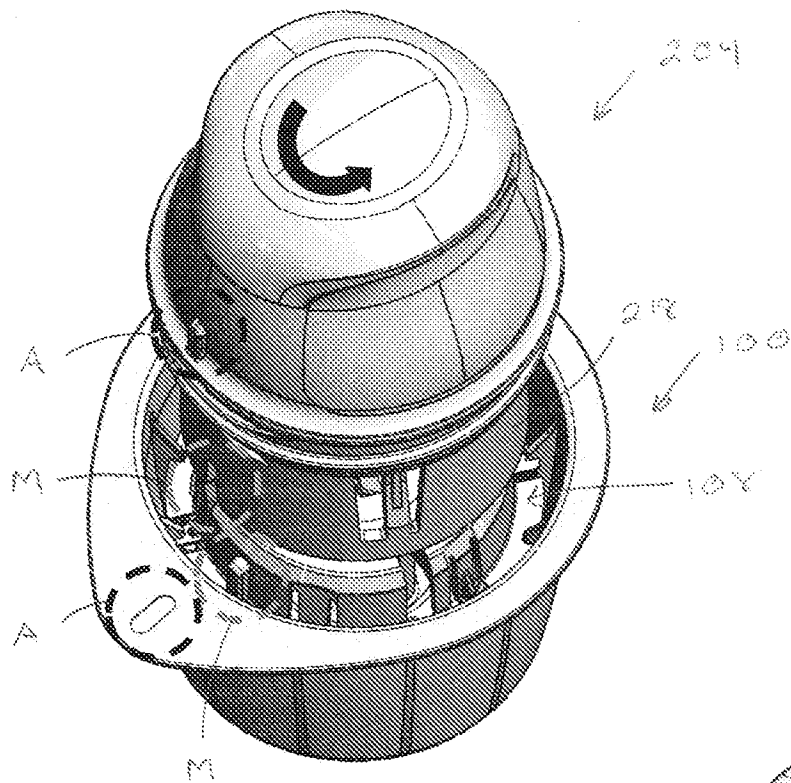
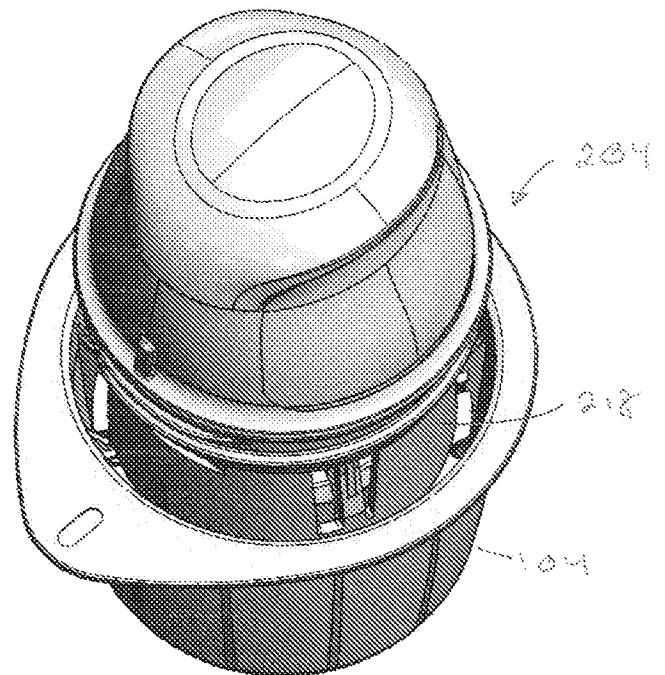


Fig. 10C

Fig. 10D



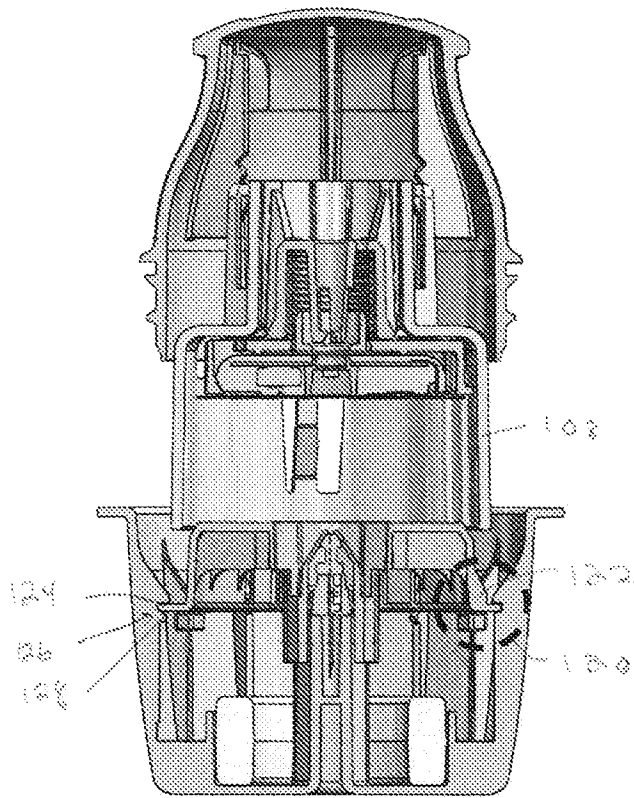


Fig. 10E

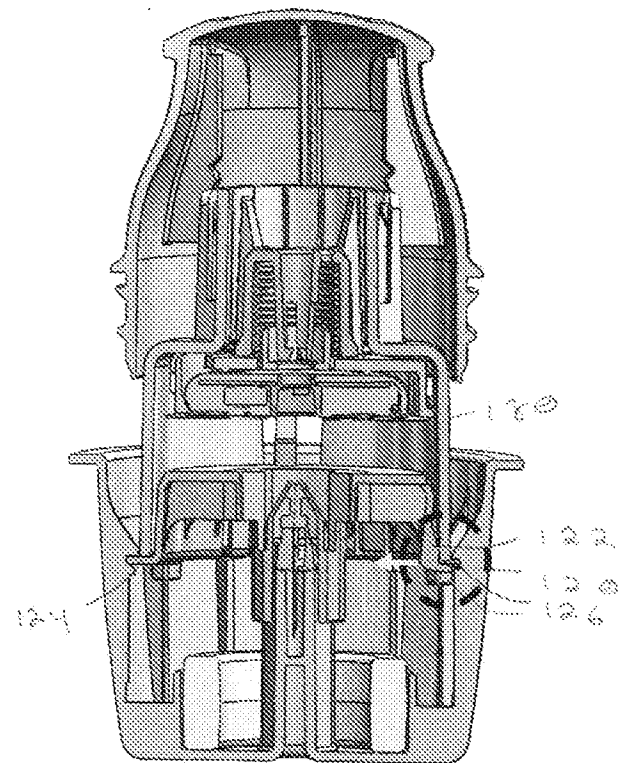


Fig. 10F

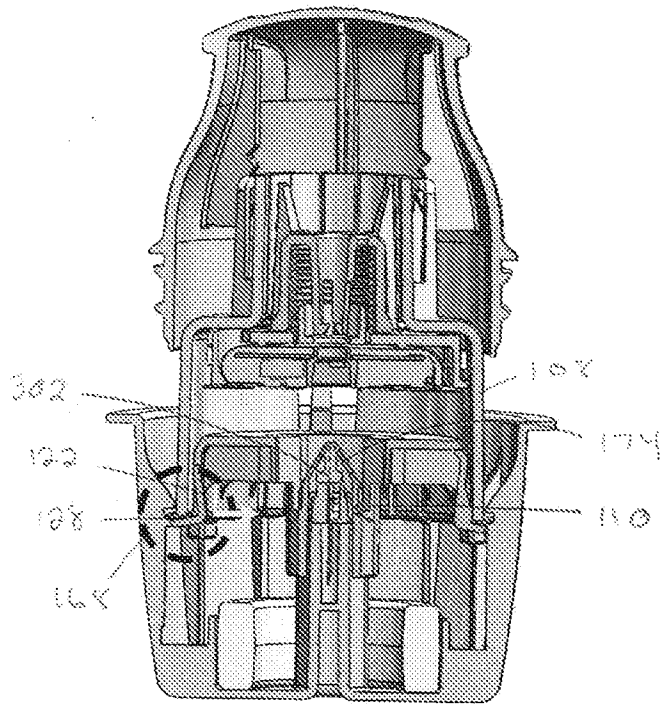
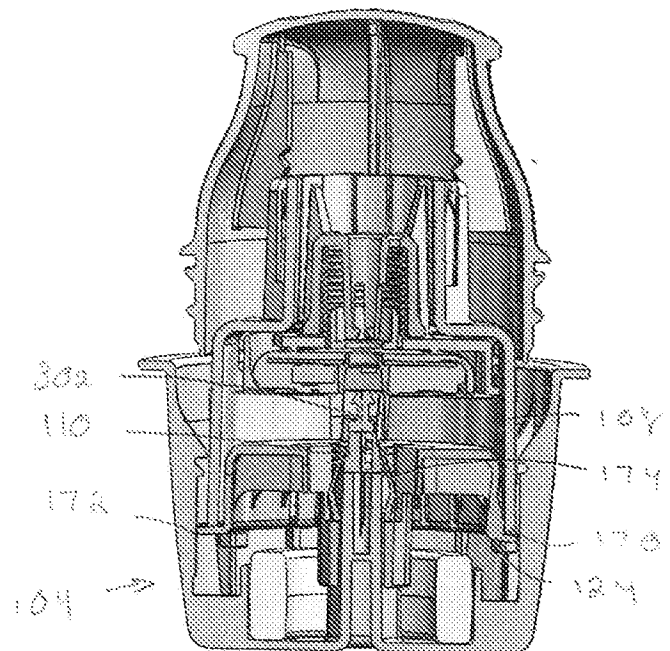


Fig. 10G

Fig. 10H



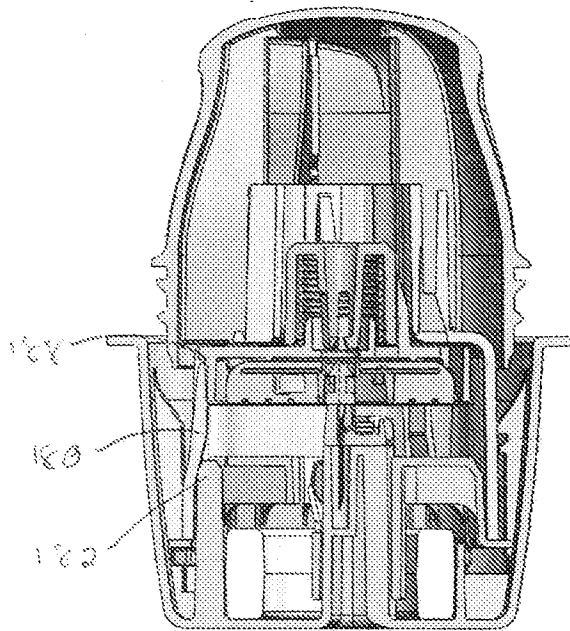
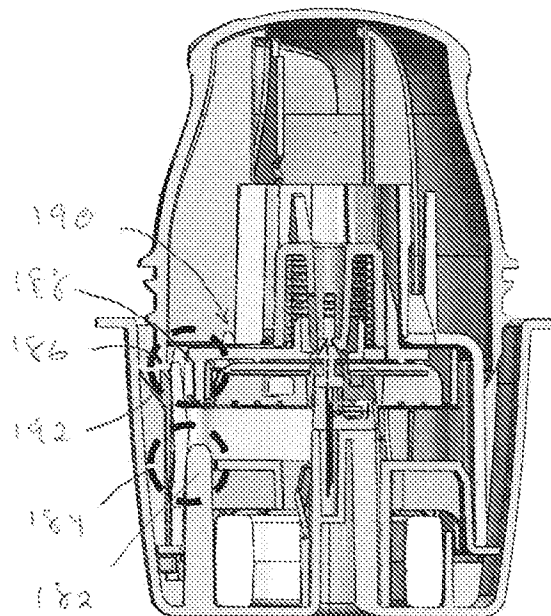


Fig. 10I

Fig. 10J



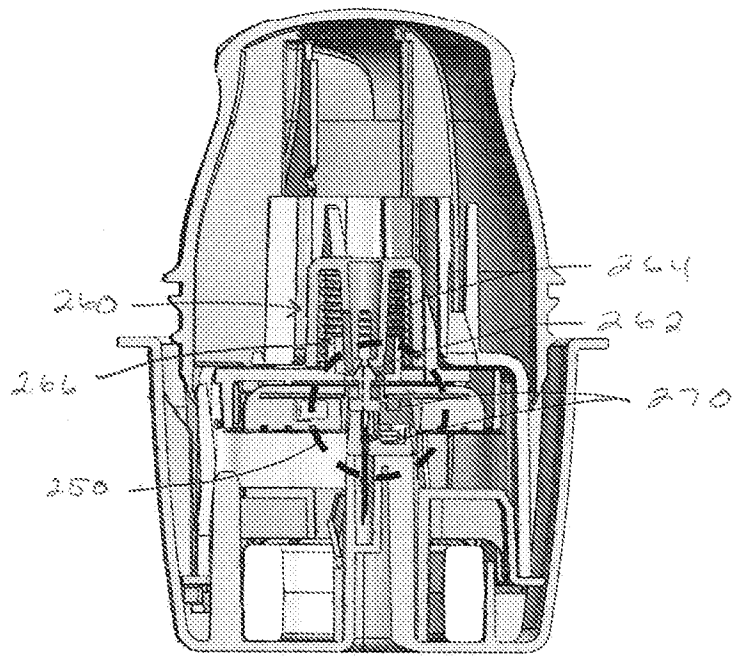


Fig. 10K

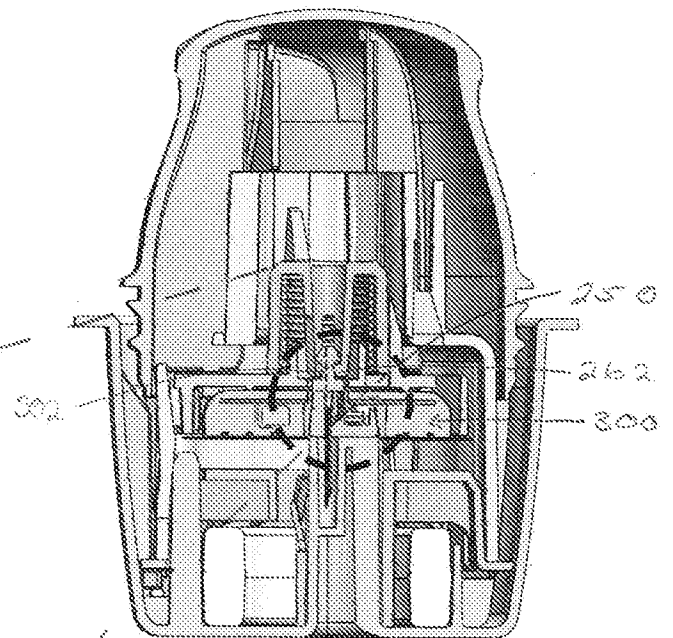
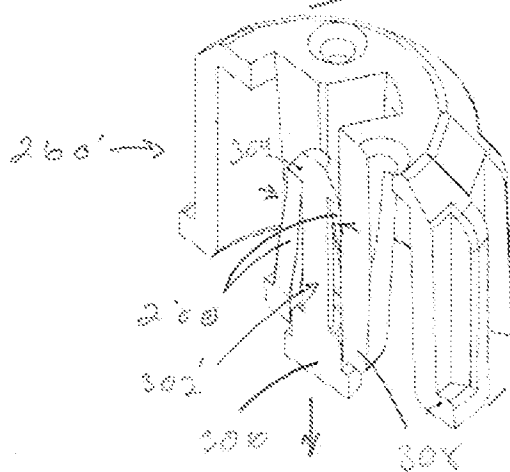


Fig. 10L



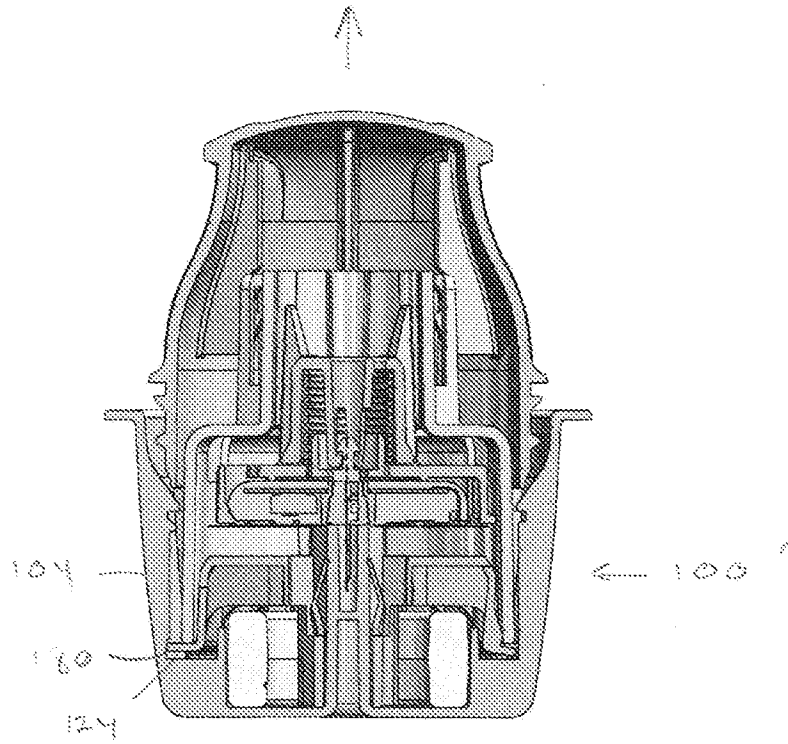


Fig. 10M

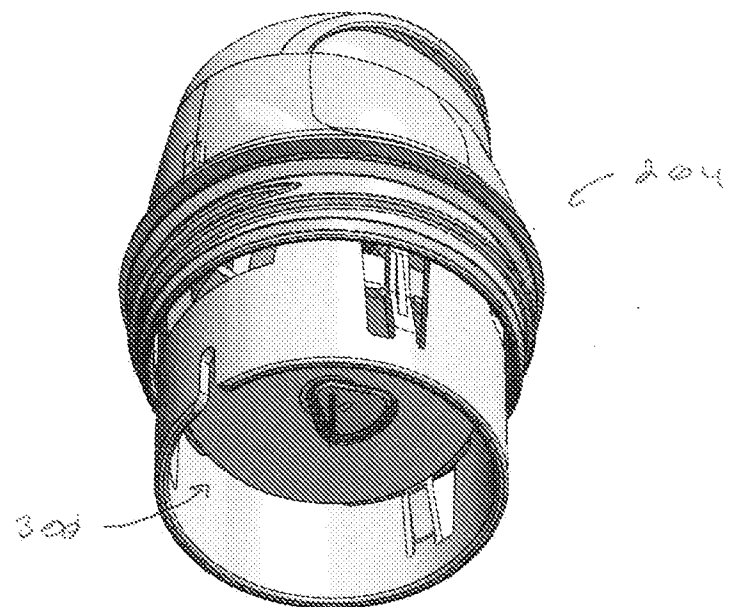


Fig. 10N

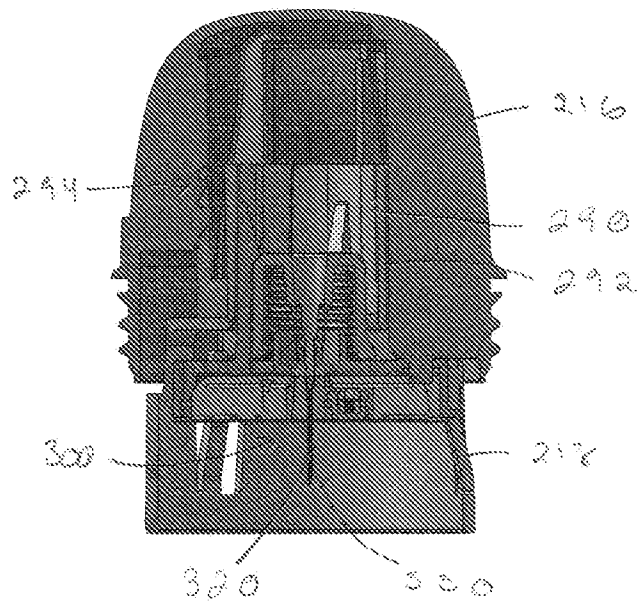


Fig. 11A

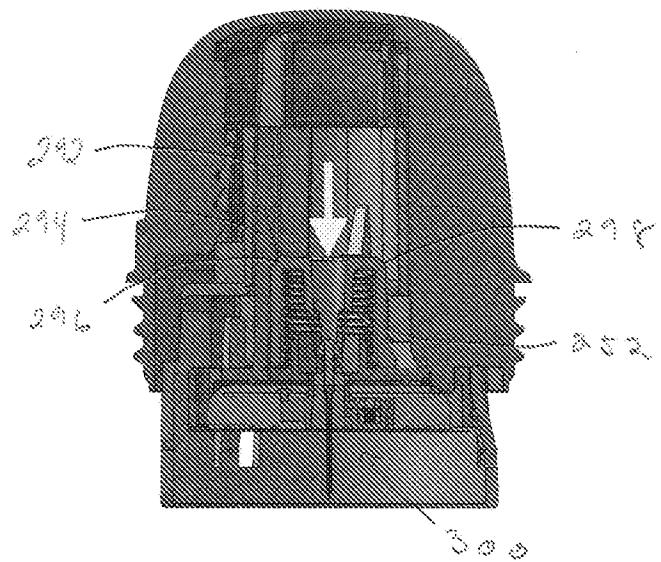


Fig. 11B

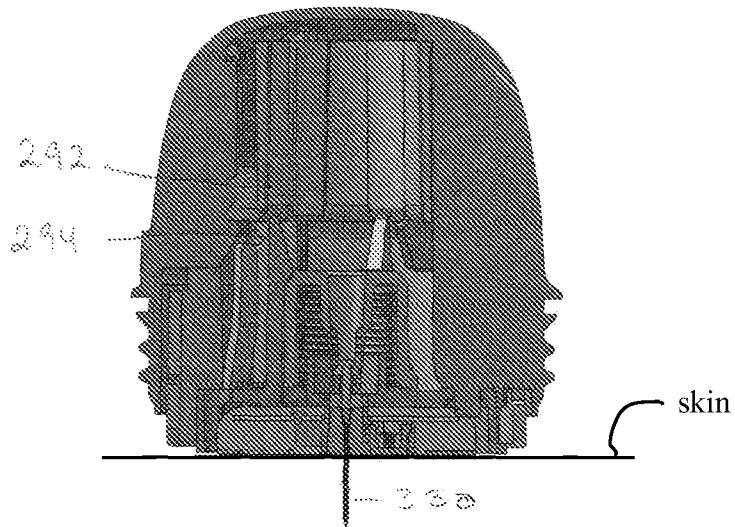


Fig. 11C

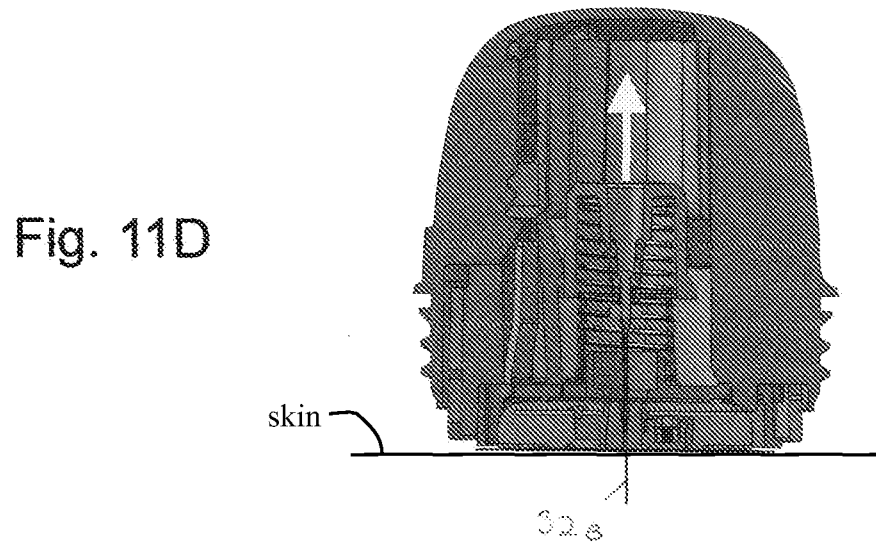


Fig. 11D

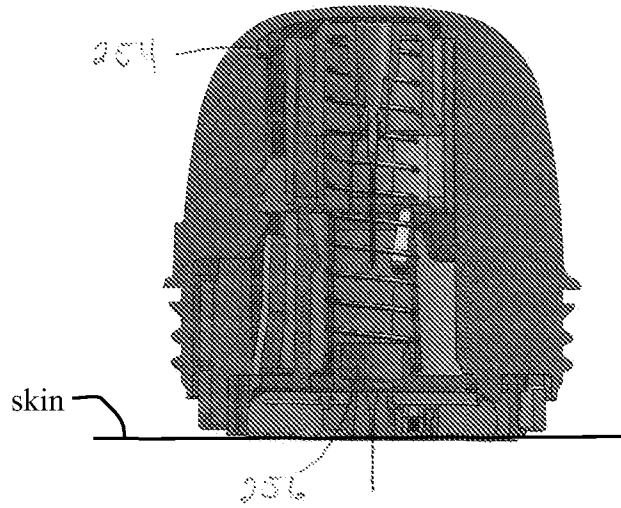
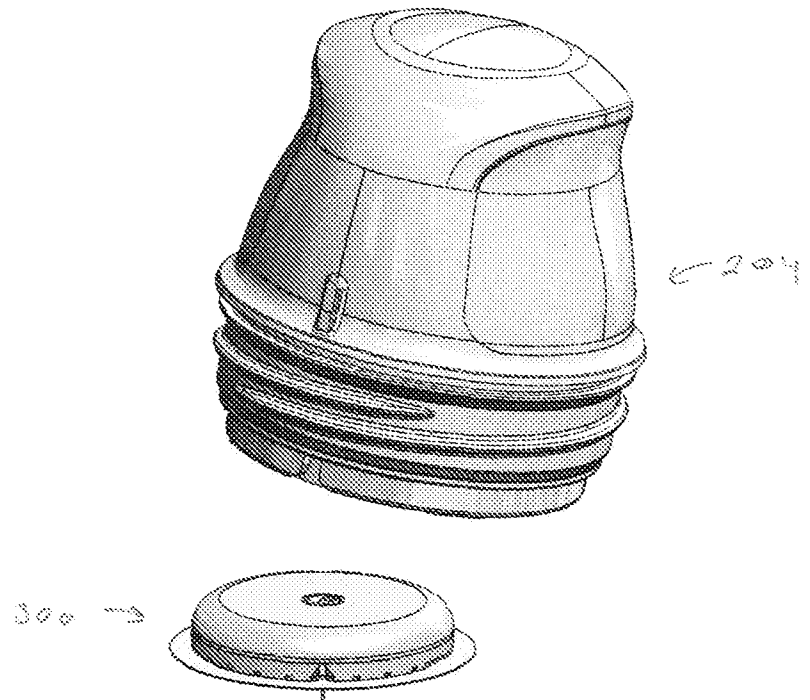


Fig. 11E

Fig. 11F



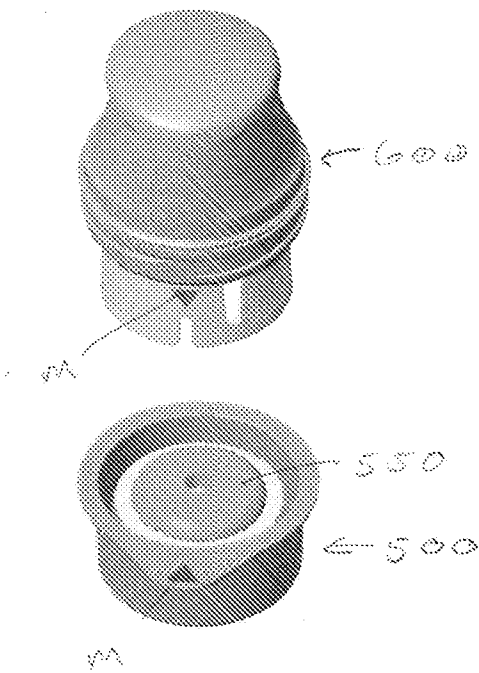


FIG. 12A

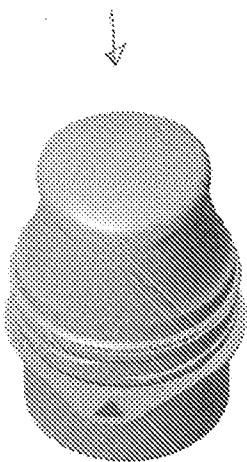


FIG. 12B

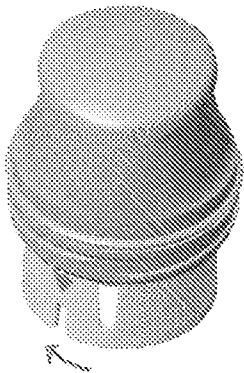


FIG. 12C

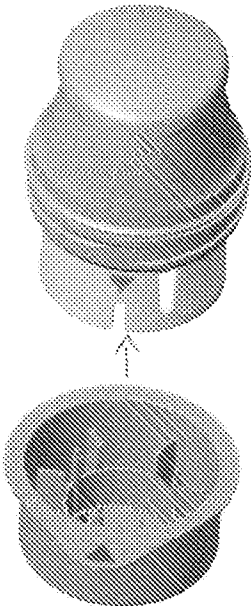


FIG. 12D

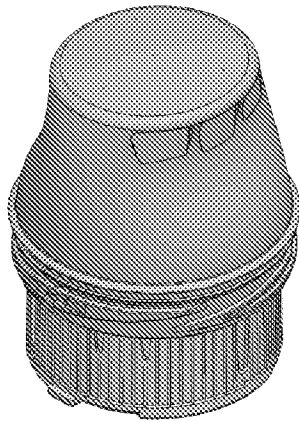


Fig. 13A

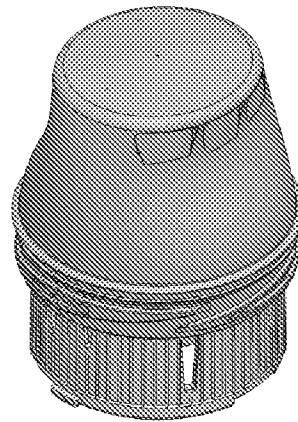


Fig. 13B

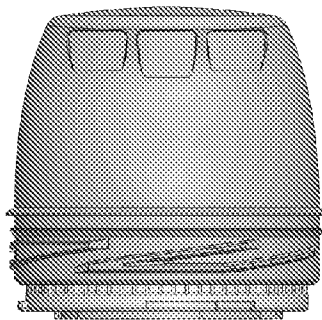


Fig. 13C

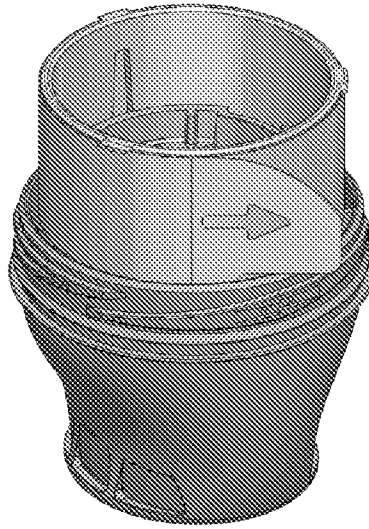


Fig. 14A

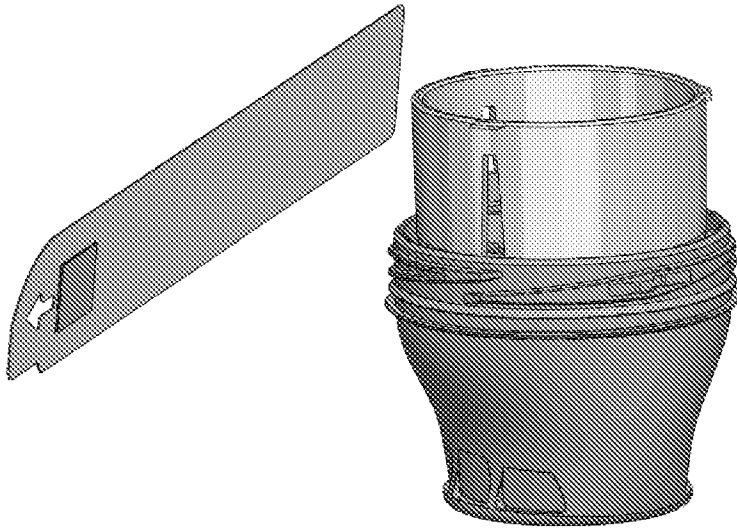


Fig. 14B

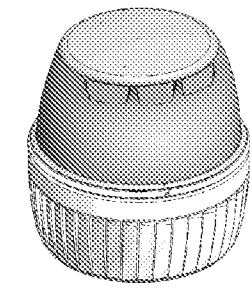


Fig. 15A

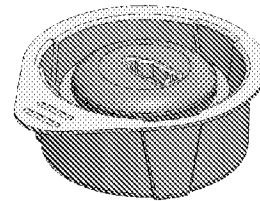
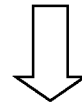
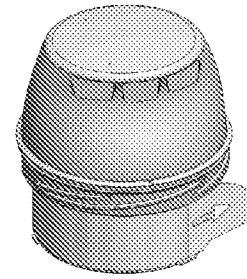
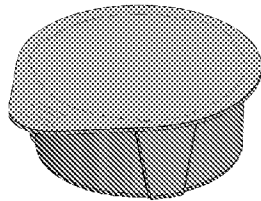


Fig. 15B

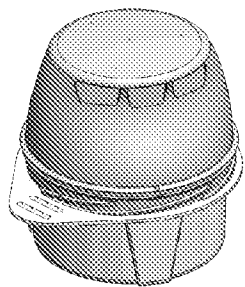


Fig. 15C

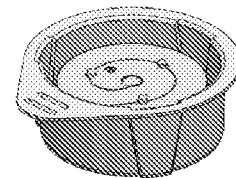
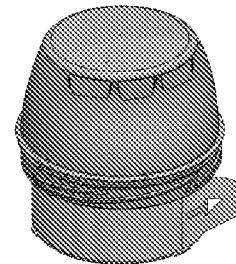


Fig. 15D

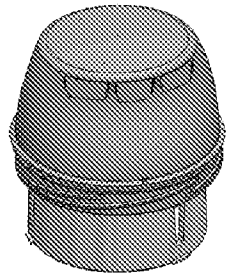


Fig. 15E

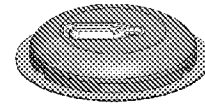


Fig. 15F

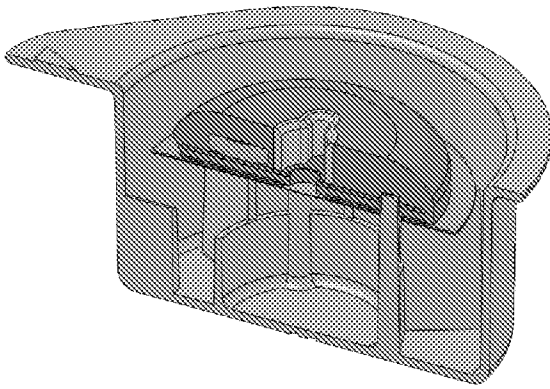


Fig. 16A

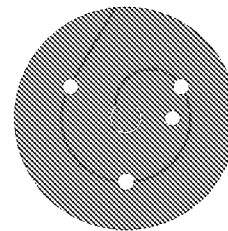


Fig. 16B

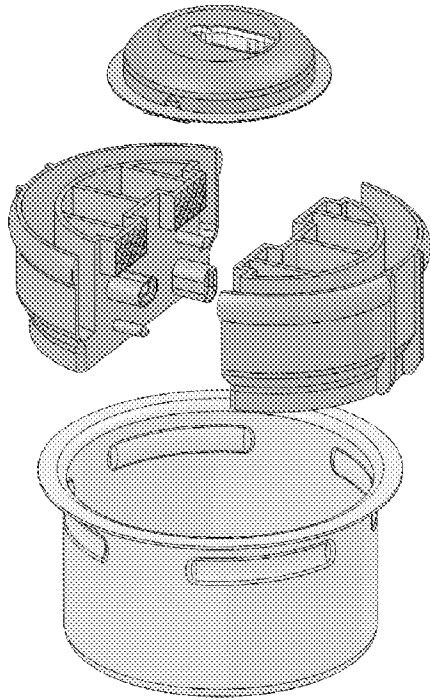


Fig. 17A

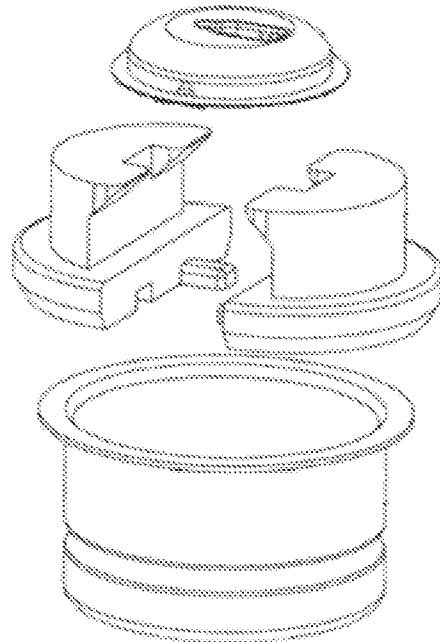


Fig. 17B

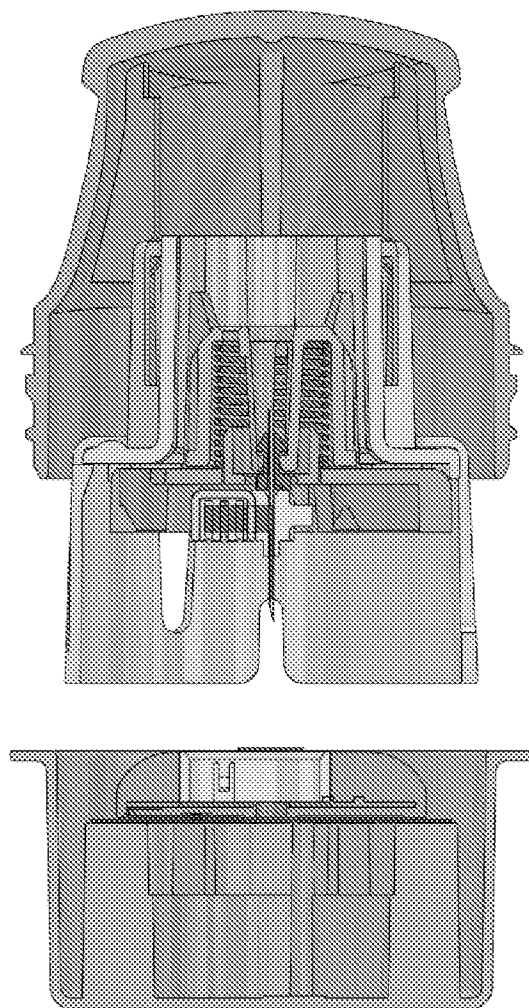


Fig. 18

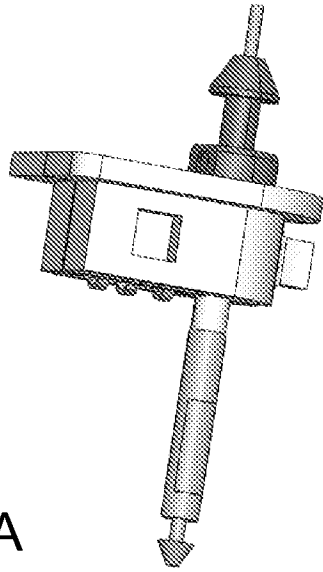


Fig. 19A

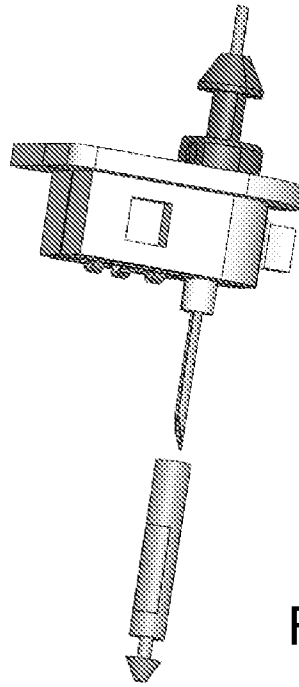


Fig. 19B

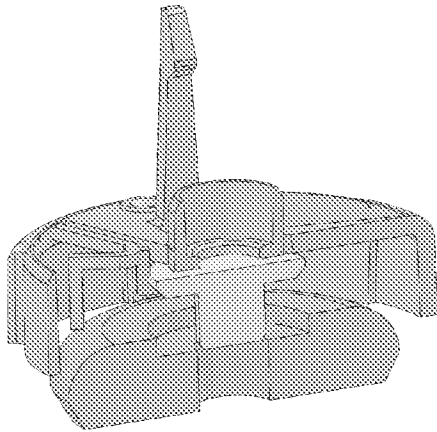


Fig. 20A

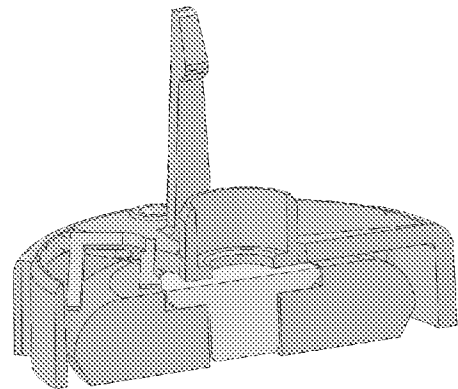


Fig. 20B

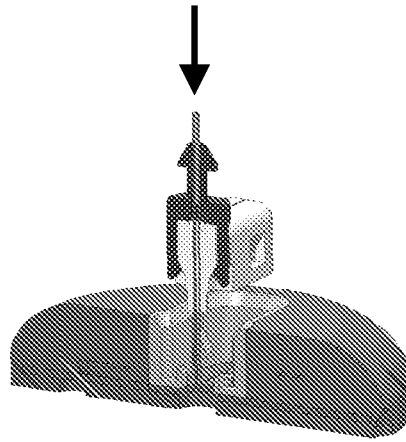


Fig. 21A

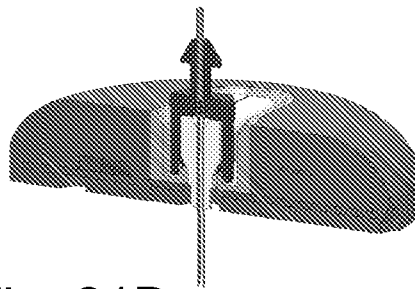


Fig. 21B

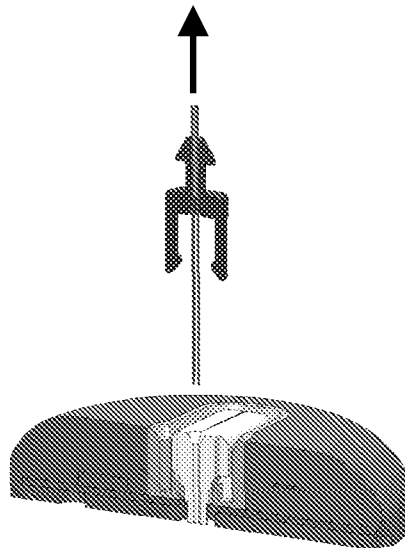


Fig. 21C

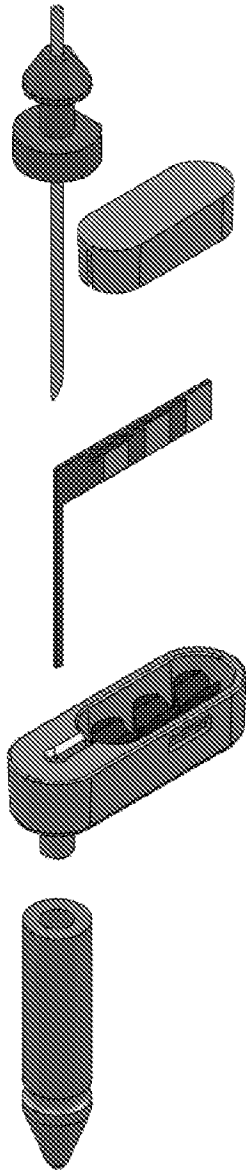


Fig. 23A

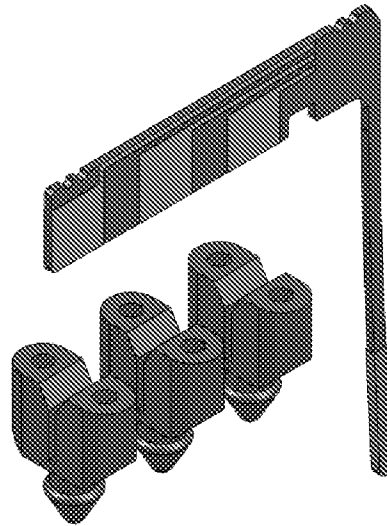


Fig. 22

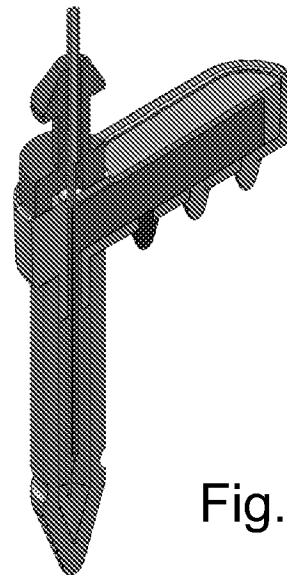


Fig. 23B

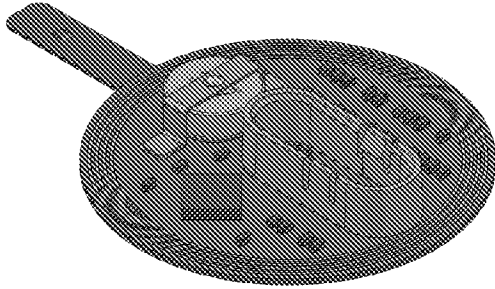


Fig. 24A

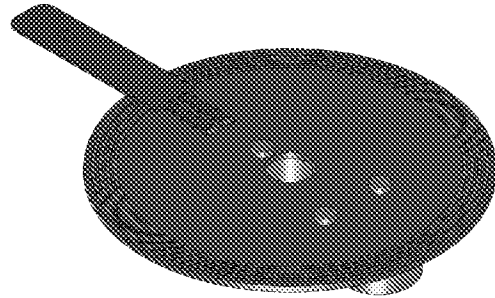


Fig. 24B

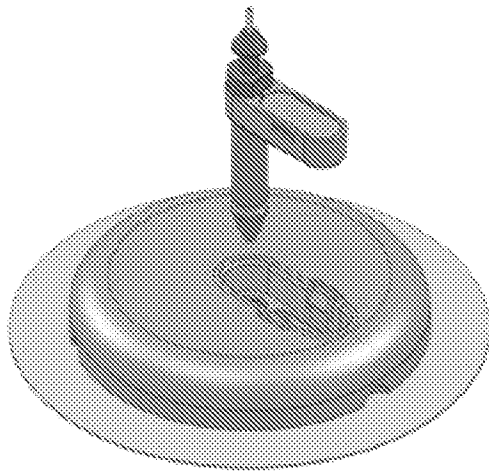


Fig. 25A

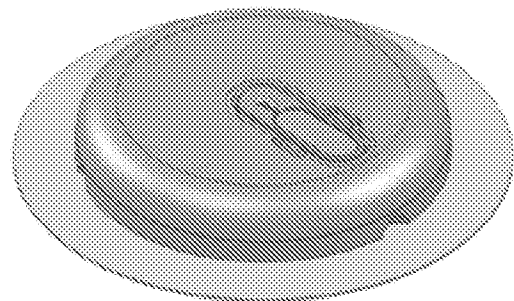


Fig. 25B

Fig. 26

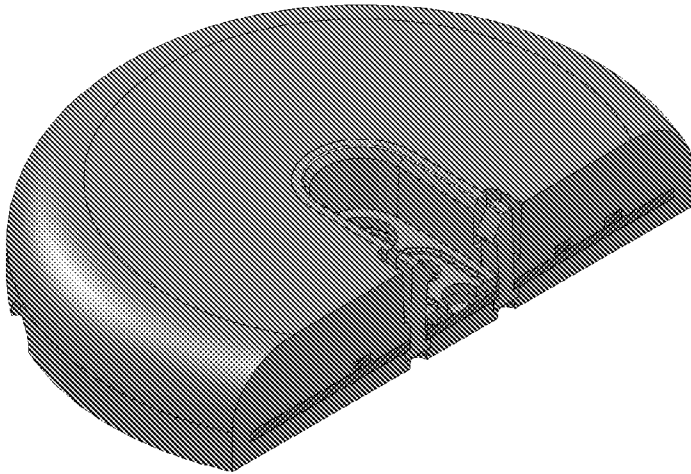
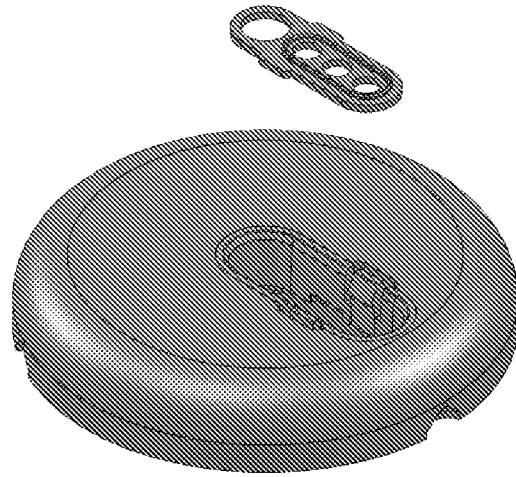


Fig. 27A

Fig. 27B

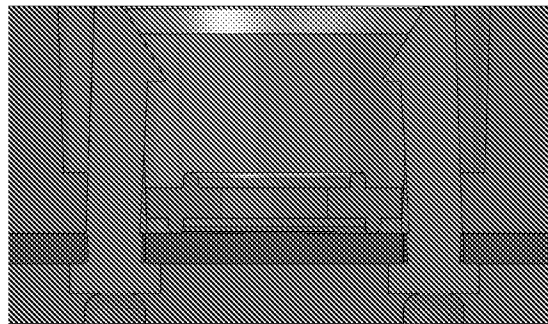




Fig. 28A



Fig. 28B



Fig. 28C

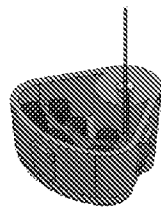
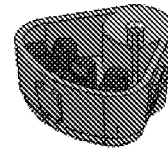


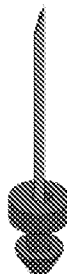
Fig. 28D



Fig. 28E



Fig. 28F



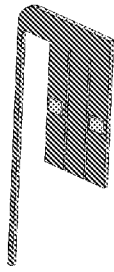


Fig. 29A

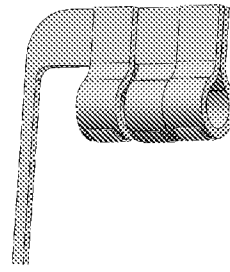


Fig. 29B

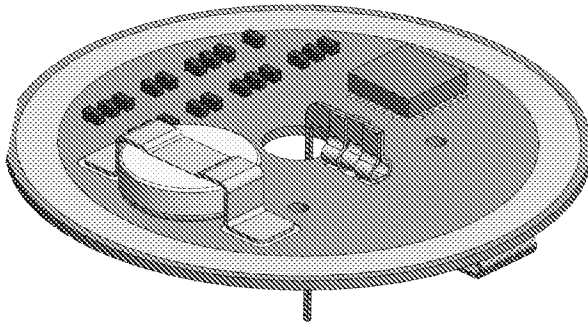


Fig. 30

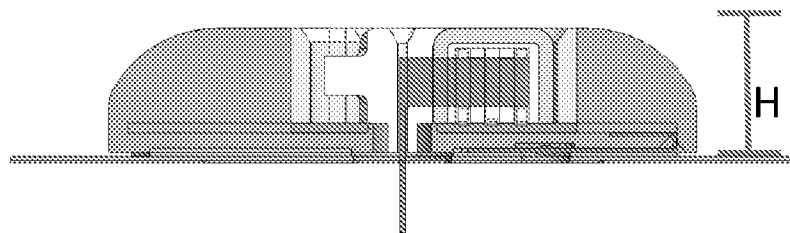


Fig. 31

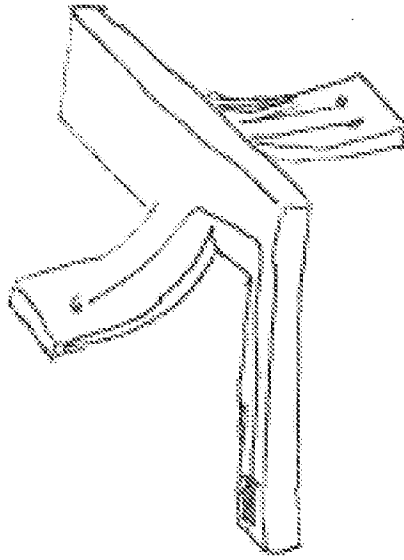


Fig. 32

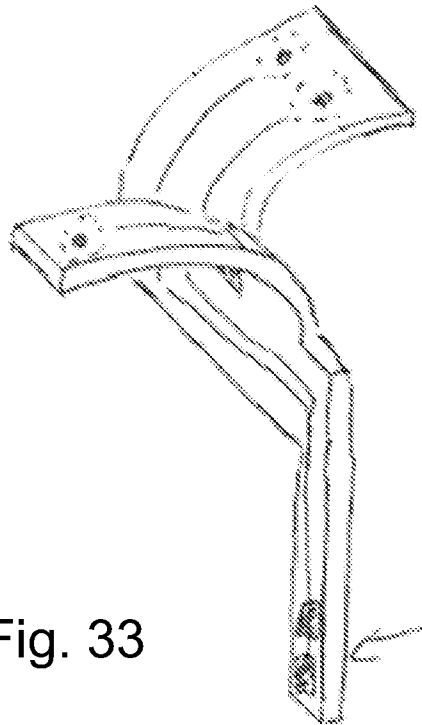


Fig. 33

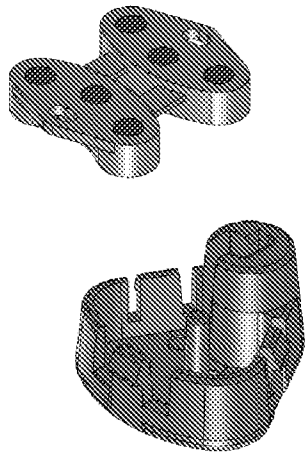


Fig. 34A

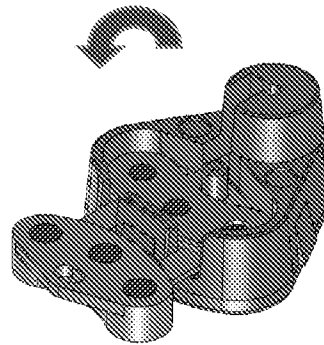


Fig. 34C

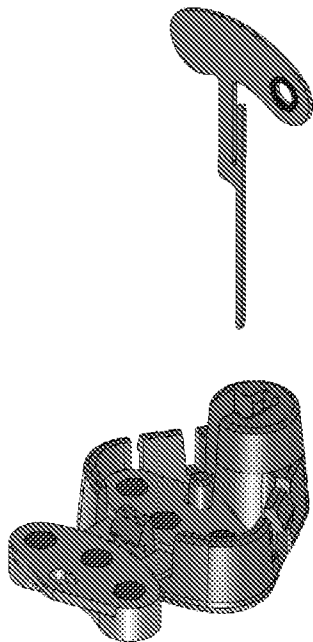


Fig. 34B

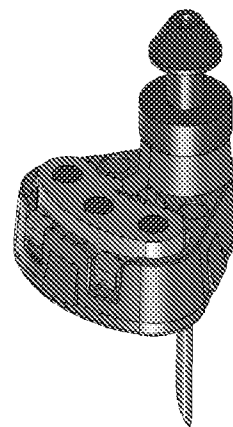


Fig. 34D

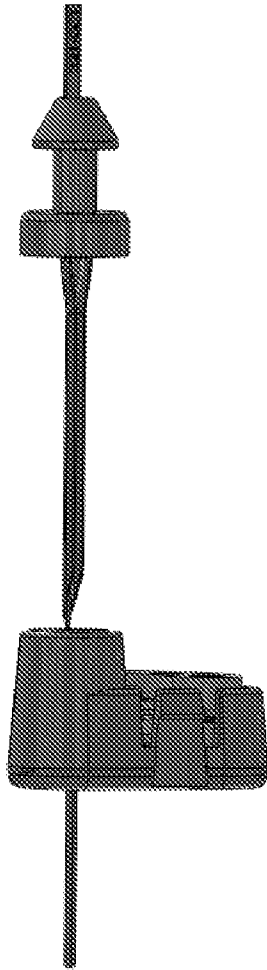


Fig. 35A

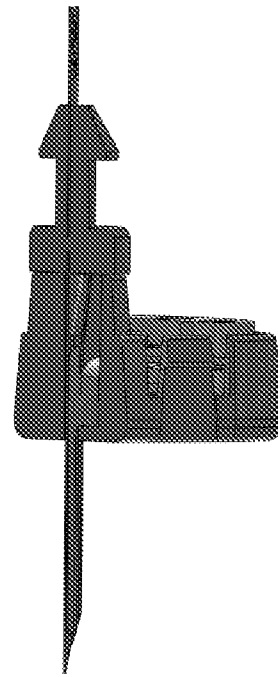


Fig. 35B

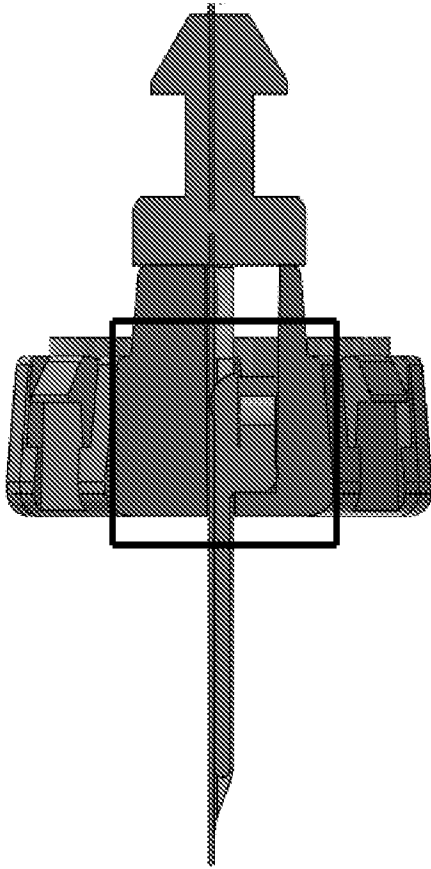
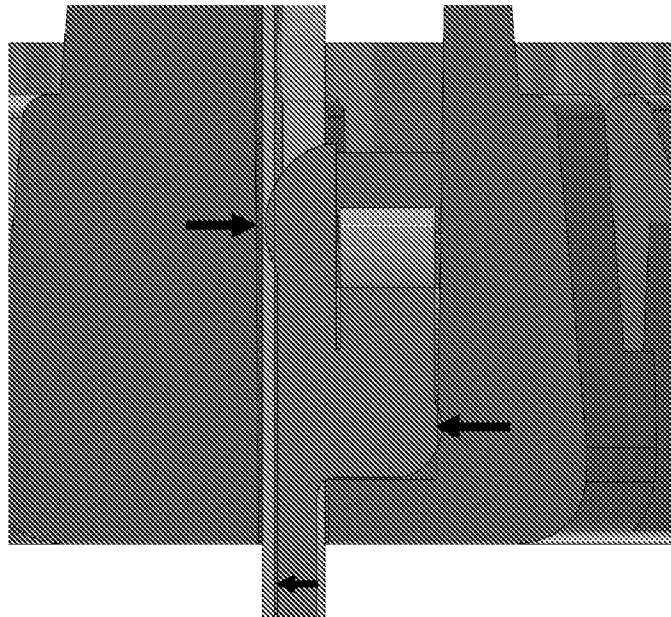


Fig. 35C

Fig. 35D



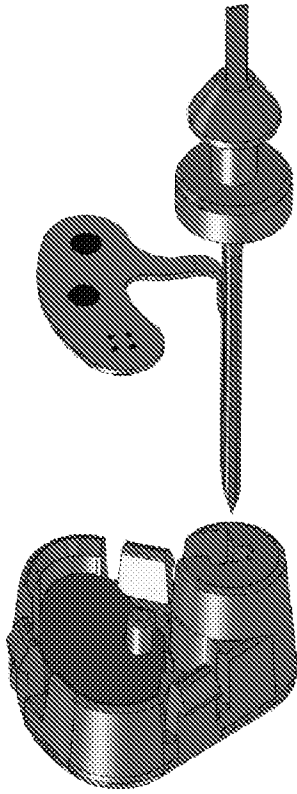


Fig. 36

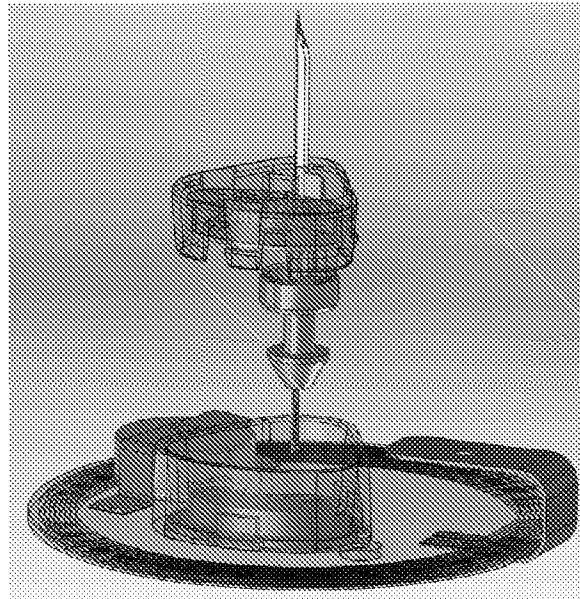


Fig. 37

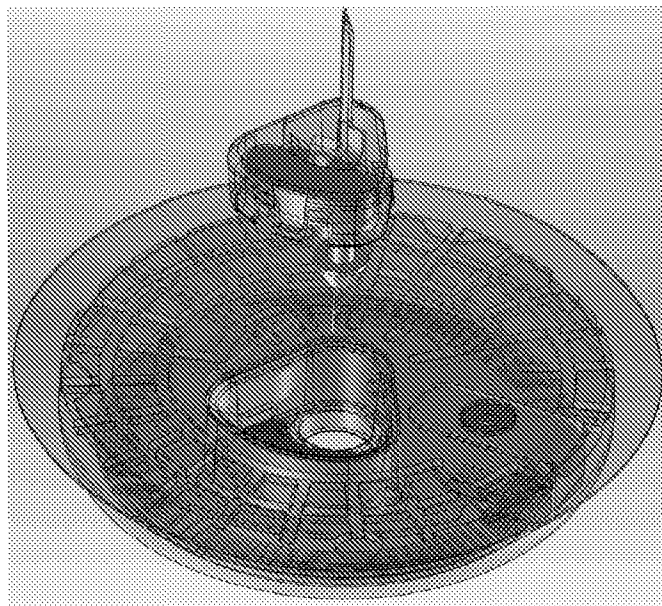


Fig. 38

Fig. 39A



Fig. 39B

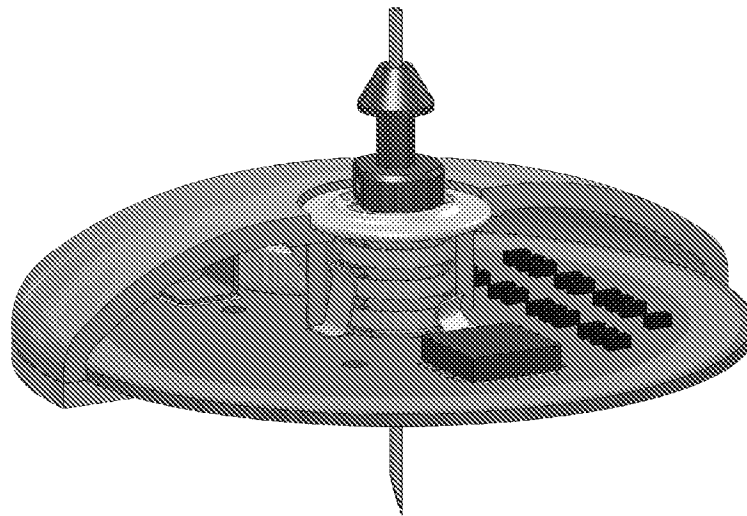
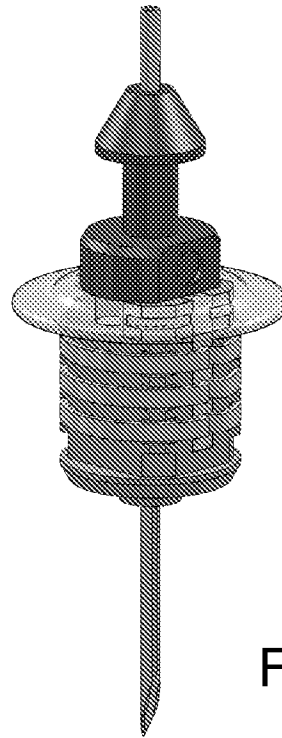


Fig. 40

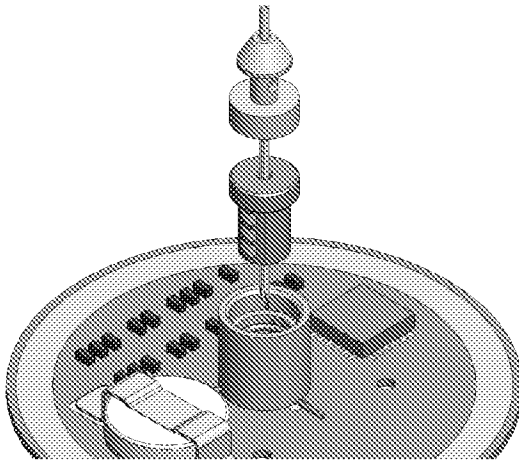


Fig. 41A

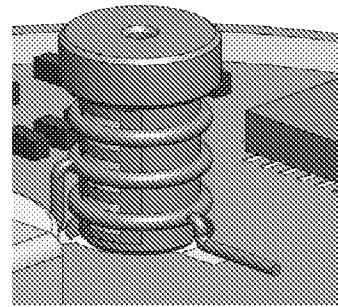


Fig. 41B

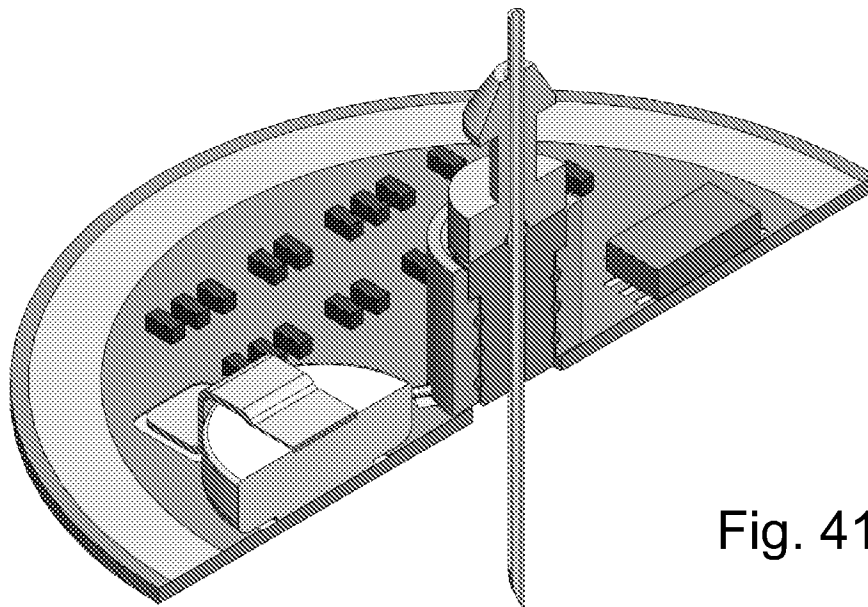


Fig. 41C

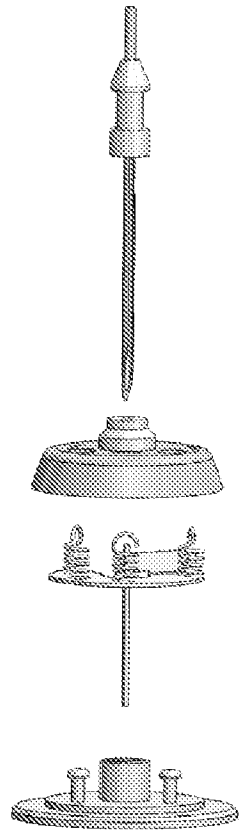


Fig. 42

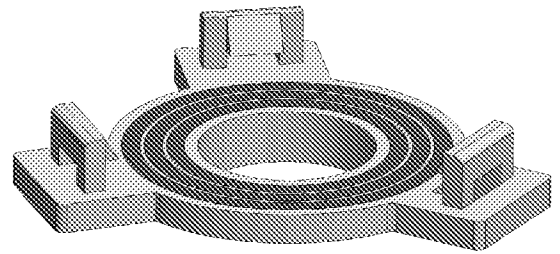


Fig. 43A

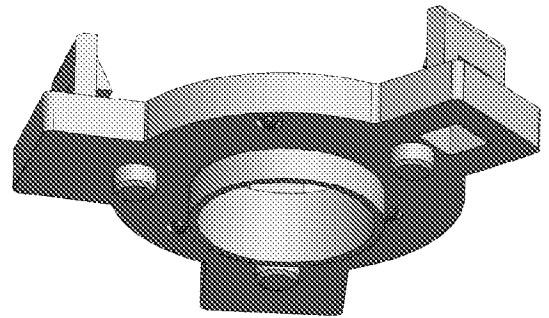


Fig. 43B

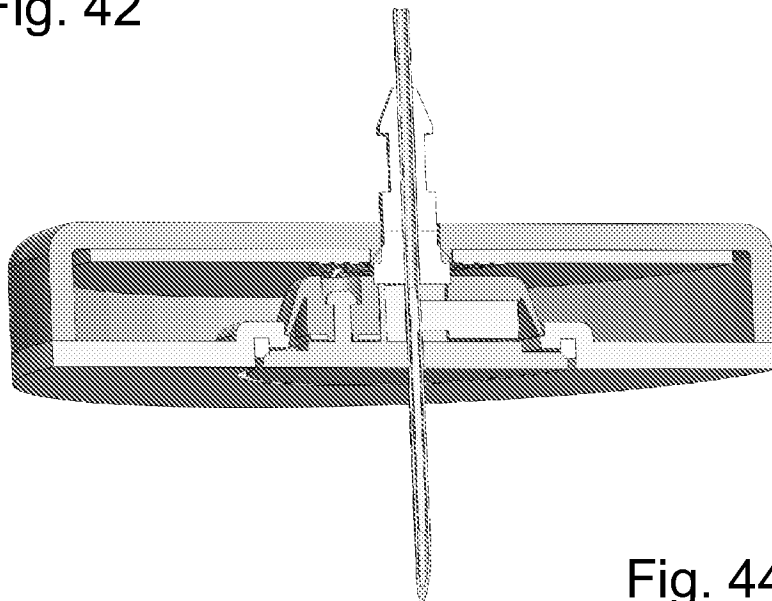


Fig. 44

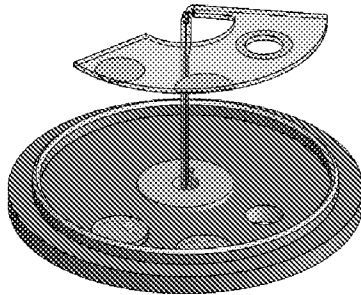
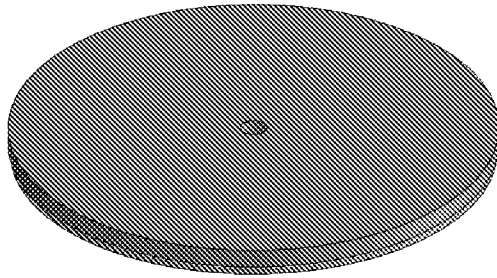
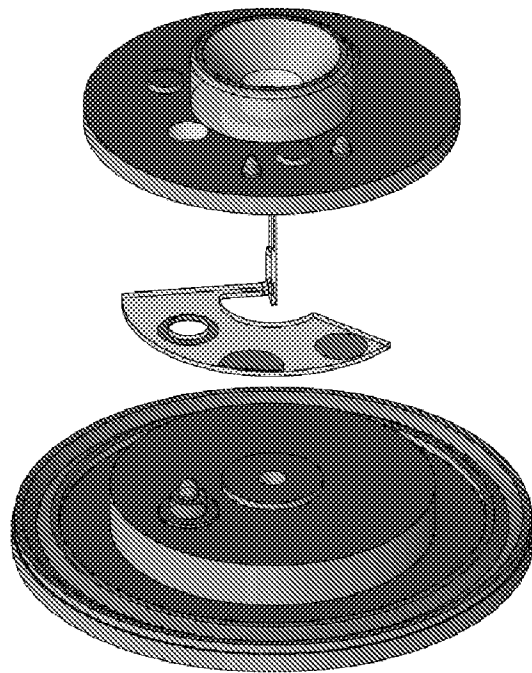


Fig. 45B

Fig. 45A



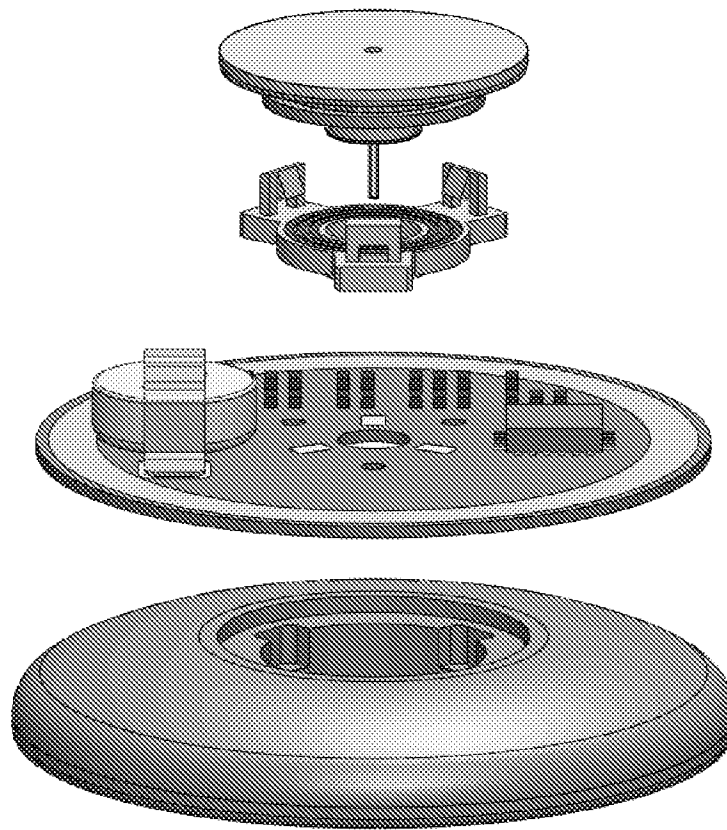


Fig. 46A

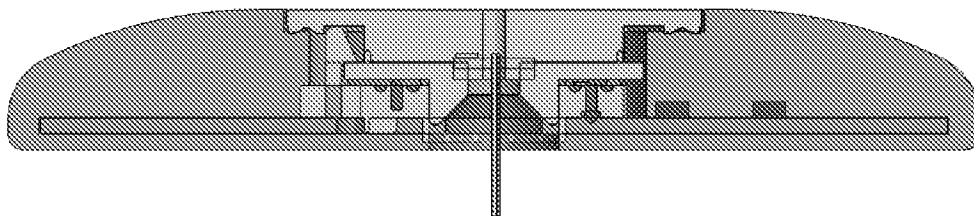


Fig. 46B

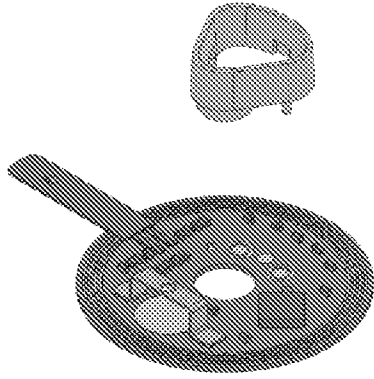


Fig. 47A

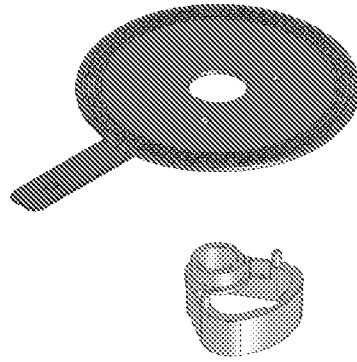


Fig. 47B

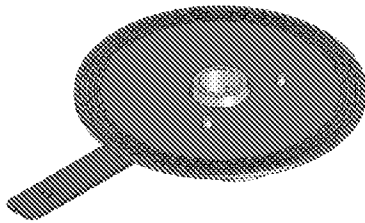


Fig. 47C

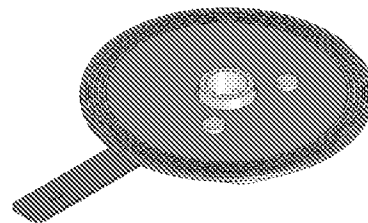


Fig. 47D

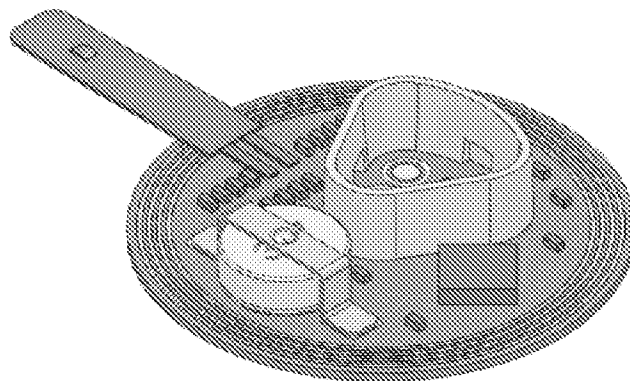


Fig. 48

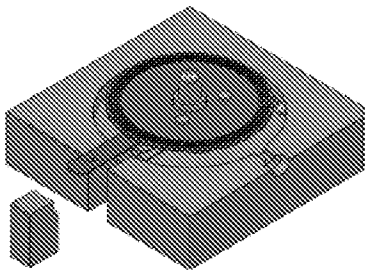
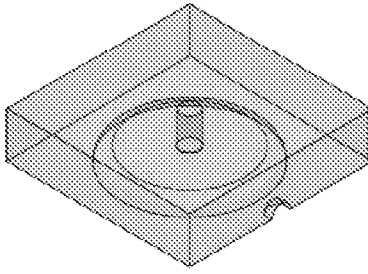


Fig. 49A

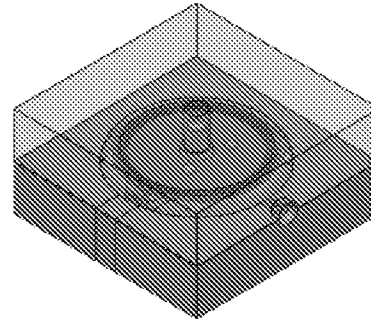


Fig. 49B

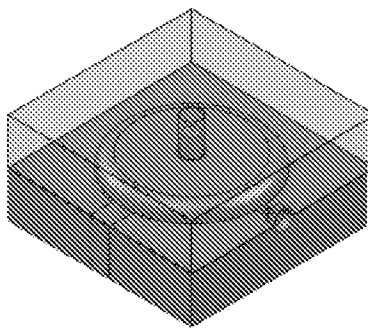
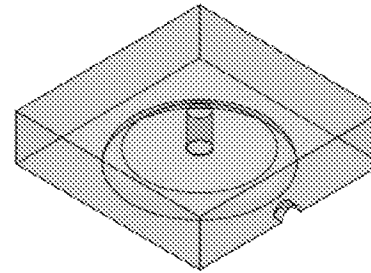


Fig. 49C

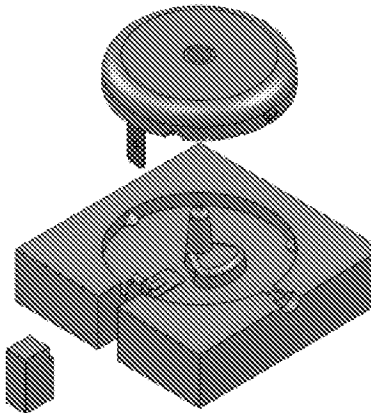


Fig. 49D

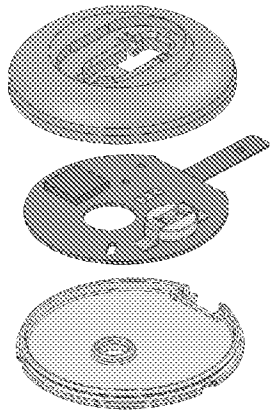


Fig. 50A

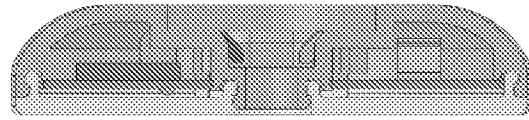


Fig. 50B

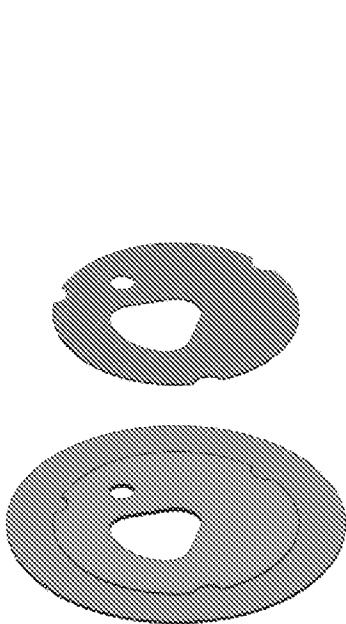


Fig. 51A

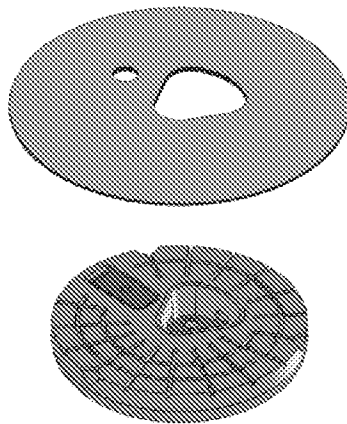


Fig. 51B

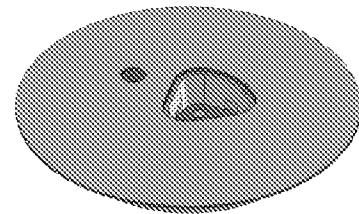


Fig. 51C

Electronic Patent Application Fee Transmittal

Application Number:

Filing Date:

Title of Invention:

Analyte Sensor Devices, Connections, and Methods

First Named Inventor/Applicant Name:

Louis Pace

Filer:

Seong-Kun Oh/Michael Chen

Attorney Docket Number:

TS-02-305P

Filed as Large Entity

Provisional Filing Fees

Description

Fee Code

Quantity

Amount

**Sub-Total in
USD(\$)**

Basic Filing:

Provisional application filing

1005

1

250

250

Pages:

Claims:

Miscellaneous-Filing:

Petition:

Patent-Appeals-and-Interference:

Post-Allowance-and-Post-Issuance:

Extension-of-Time:

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Miscellaneous:				
Total in USD (\$)				250

Electronic Acknowledgement Receipt

EFS ID:	11589251
Application Number:	61569287
International Application Number:	
Confirmation Number:	9053
Title of Invention:	Analyte Sensor Devices, Connections, and Methods
First Named Inventor/Applicant Name:	Louis Pace
Customer Number:	30349
Filer:	Seong-Kun Oh/Michael Chen
Filer Authorized By:	Seong-Kun Oh
Attorney Docket Number:	TS-02-305P
Receipt Date:	11-DEC-2011
Filing Date:	
Time Stamp:	23:47:21
Application Type:	Provisional

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	\$ 250
RAM confirmation Number	7740
Deposit Account	
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
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1	Provisional Cover Sheet (SB16)	TS-02-305P-Provisional-Cover-Sheet.pdf	41789 fa1af716572a92b4079fd978728f3069d5ef3686	no	2
Warnings:					
This is not a USPTO supplied Provisional Cover Sheet SB16 form.					
Information:					
2	Specification	TS-02-305P-Provisional-Application-as-filed.pdf	311230 1b186abb9c0791f3b1f4c1dfe81f11e87bc8d9f	no	25
Warnings:					
Information:					
3	Drawings-only black and white line drawings	TS-02-305P-Figures-as-filed.pdf	13816123 8c93d35b6c1c4f7dbcc0349ae5576dd289beaa23	no	44
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4	Fee Worksheet (SB06)	fee-info.pdf	28950 9c7756ee62d04c2cb22d7dc57008315c7e6272	no	2
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