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(71) Applicant *(for DE only)*: **ROCHE DIAGNOSTICS GMBH** [DE/DE]; Sandhofer Strasse 116, 68305 Mannheim (DE).

(71) Applicant *(for all designated States except DE, US)*: **F. HOFFMANN-LA ROCHE AG** [CH/CH]; Grenzacher Strasse 124, CH-4070 Basel (CH).

(72) Inventor: **ROE, Steven, N.**; 21 Hillbarn Court, San Mateo, CA 94403 (US).

(74) Agent: **STÖßEL, Matthias**; Herzog Fiesser & Partner, Patentanwälte, Dudenstrasse 46, 68167 Mannheim (DE).

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(54) **Title**: HANDHELD MEDICAL DIAGNOSTIC DEVICES HOUSING LANCET STRUCTURES

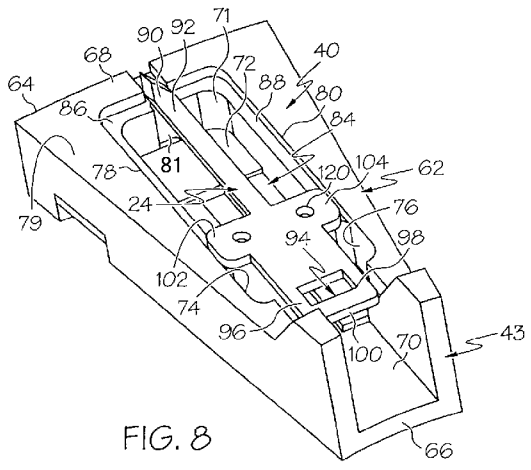


FIG. 8

(57) **Abstract**: A lancet housing assembly (30; 400; 430; 452; 00; 600) includes a housing structure comprising multiple lancet compartments (40; 405; 444; 458; 505; 605). At least one of the lancet compartments includes an outer facing side (64) and an inner facing side. (66) An opening (68) is located at the outer facing side (64) that is arranged and configured to align with a lancet port (20) of a medical diagnostic device (10). A lancet structure (24; 406; 432; 450; 506; 606) is located in the at least one lancet compartment and comprises a skin penetrating end (90; 408; 434; 462; 508; 608) and a blood transport portion (92; 410; 464; 510; 610). The lancet structure has (i) an initial configuration where the lancet structure is supported to align the skin penetrating end with the opening to allow the skin penetrating end to extend through the opening and (ii) a retracted configuration where the skin penetrating end moves to a position within the lancet compartment offset from the opening to prevent the lancet structure from extending through the opening.

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HANDHELD MEDICAL DIAGNOSTIC DEVICES HOUSING LANCET STRUCTURES

Technical Field

[0001] The present disclosure relates generally to handheld medical devices, and in particular, to a handheld medical diagnostic device that can reduce steps needed to measure concentrations of biologically significant components of bodily fluids.

Background

[0002] Portable handheld medical diagnostic devices are often employed to measure concentrations of biologically significant components of bodily fluids, such as, for example, glucose concentration in blood. The portable handheld medical diagnostic devices and their accessories may work together to measure the amount of glucose in blood and be used to monitor blood glucose in one's home, healthcare facility or other location, for example, by persons having diabetes or by a healthcare professional.

[0003] For people with diabetes, regular testing of blood glucose level can be an important part of diabetes management. Thus, it is desirable to provide medical diagnostic devices that are portable and easy to use. Various medical diagnostic devices have been introduced for testing blood sugar that are portable. However, there continues to be a need for improved portability and ease of use for medical diagnostic devices.

[0004] Often times, self-monitoring of blood glucose may require the patient to first load a lancet into a lancer and a separate test strip into a blood glucose meter. The lancer and lancet are then used to prick the finger and a small drop of blood is squeezed to the surface. The sample port on the strip is brought into contact with the blood and the sample may be transported to the reaction zone on the strip via capillary action. This can be a labor-intensive, uncomfortable

process that requires multiple steps and devices. Patients may need to repeat this process several times a day.

Summary

[0005] In one embodiment, a lancet housing assembly includes multiple lancets for use in a portable handheld medical diagnostic device for sampling bodily fluids from a skin site of a patient. The lancet housing assembly includes a housing structure comprising multiple lancet compartments. At least one of the lancet compartments includes an outer facing side and an inner facing side. An opening is located at the outer facing side that is arranged and configured to align with a lancet port of the medical diagnostic device. A lancet structure is located in the at least one lancet compartment and comprises a skin penetrating end and a blood transport portion adjacent the skin penetrating end. The lancet structure has (i) an initial configuration where the lancet structure is supported to align the skin penetrating end with the opening to allow the skin penetrating end to extend through the opening and (ii) a retracted configuration where the skin penetrating end moves to a position within the lancet compartment offset from the opening to prevent the lancet structure from extending through the opening.

[0006] In another embodiment, a portable handheld medical diagnostic device for sampling bodily fluids includes a protective enclosure and a measurement system including a controller facilitating a physiologic measurement. A display device is connected to the measurement system that displays information related to the physiologic measurement. A lancet housing assembly comprises a housing structure comprising multiple lancet compartments. At least one of the lancet compartments includes an outer facing side, an inner facing side and an opening located at the outer facing side that is arranged and configured to align with a lancet port of the medical diagnostic device. A lancet structure is located in the at least one lancet compartment and comprises a skin penetrating end and a blood transport portion adjacent the skin penetrating end. The lancet structure has (i) an initial configuration where the lancet structure is supported to align the skin penetrating end with the opening to allow the skin penetrating end to extend through the opening and (ii) a retracted configuration where the skin penetrating end moves to a position within the lancet compartment offset from the opening to prevent the lancet structure from extending through the opening.

[0007] In another embodiment, a method of controlling movement of one or more lancet structures provided within a lancet housing assembly in a portable handheld medical diagnostic device for sampling bodily fluids from a skin site of a patient is provided. The method includes locating a lancet structure in at least one lancet compartment of the lancet housing assembly comprising a skin penetrating end and a blood transport portion adjacent the skin penetrating end. The lancet structure is provided with an initial configuration within the lancet compartment where the lancet structure is supported to align the skin penetrating end with a port in the medical diagnostic device to allow the skin penetrating end to extend through the port. The lancet structure is provided with a retracted configuration within the lancet compartment where the skin penetrating end moves to a position within the lancet compartment offset from the port to prevent the lancet structure from extending through the port.

[0008] Unless otherwise stated, the expressions "skin piercing end" and "skin penetrating end" are synonymously used in this application. Unless otherwise stated, the expressions "inner facing side" and "inner end" are synonymously used in this application with regard to a lancet compartment. Unless otherwise stated, the expressions "outer facing side" and "outer end" are synonymously used in this application with regard to a lancet compartment. Unless otherwise stated, the expressions "protective enclosure" and "housing structure" are synonymously used in this application with regard to a portable, handheld medical diagnostic device. Unless otherwise stated, the expressions "blood transport portion" and "blood transfer portion" are synonymously used in this application. Unless otherwise stated, the expressions "spring-driven motor assembly" and "clockwork spring drive assembly" are synonymously used in this application. Unless otherwise stated, the expressions "rotatable element" and "thumb wheel" are synonymously used in this application.

[0009] These and other advantages and features of the various embodiments of the invention disclosed herein, will be made more apparent from the description, drawings and claims that follow.

[0010] Summarizing the ideas of the present invention, the following items are preferred:

[0011] Item 1: A lancet housing assembly comprising multiple lancets for use in a portable handheld medical diagnostic device for sampling bodily fluids from a skin site of a patient, the lancet housing assembly comprising:

a housing structure comprising multiple lancet compartments, at least one of the lancet compartments comprising

an outer facing side;

an inner facing side;

an opening located at the outer facing side that is arranged and configured to align with a lancet port of the medical diagnostic device; and

a lancet structure located in the at least one lancet compartment and comprising a skin penetrating end and a blood transport portion adjacent the skin penetrating end, the lancet structure having (i) an initial configuration where the lancet structure is supported to align the skin penetrating end with the opening to allow the skin penetrating end to extend through the opening and (ii) a retracted configuration where the skin penetrating end moves to a position within the lancet compartment offset from the opening to prevent the lancet structure from extending through the opening.

[0012] Item 2: The lancet housing assembly of item 1, wherein the skin penetrating end of the lancet structure is supported on a bottom surface of the opening at the outer facing side with the lancet structure in the initial configuration.

[0013] Item 3: The lancet housing assembly of item 1 further comprising a reagent material offset vertically from the opening at the outer face and within the housing structure.

[0014] Item 4: The lancet housing assembly of item 1 further comprising one or more lancet guide rails that extend along one or more of sidewalls of the at least one lancet compartment between the outer facing side and the inner facing side.

[0015] Item 5: The lancet housing assembly of item 4, wherein the lancet structure includes rail riding structure providing a support surface that supports the lancet structure upon the one or more lancet guide rails with the lancet structure in the initial configuration.

[0016] Item 6: The lancet housing assembly of item 5 further comprising one or more drop down slots formed in the one or more of the sidewalls, the rail riding structure located to align with the one or more drop down slots such that the skin penetrating end moves to the position within the lancet compartment offset from the opening in the retracted configuration.

[0017] Item 7: The lancet housing assembly of item 1 further comprising a biasing mechanism that provides a biasing force against the lancet structure such that the skin penetrating end moves to the position within the lancet compartment offset from the opening in the retracted configuration.

[0018] Item 8: A portable handheld medical diagnostic device for sampling bodily fluids, comprising:

a protective enclosure;

a measurement system including a controller facilitating a physiologic measurement;

a display device connected to the measurement system that displays information related to the physiologic measurement;

a lancet housing assembly comprising a housing structure comprising multiple lancet compartments, at least one of the lancet compartments comprising

an outer facing side;

an inner facing side;

an opening located at the outer facing side that is arranged and configured to align with a lancet port of the medical diagnostic device; and

a lancet structure located in the at least one lancet compartment and comprising a skin penetrating end and a blood transport portion adjacent the skin penetrating end, the lancet structure having (i) an initial configuration where the lancet structure is supported to align the skin penetrating end with the opening to allow the skin penetrating end to extend through the opening and (ii) a retracted configuration where the skin penetrating end moves to a position within the lancet compartment offset from the opening to prevent the lancet structure from extending through the opening.

[0019] Item 9: The medical diagnostic device of item 8, wherein the skin penetrating end of the lancet structure is supported on a bottom surface of the opening at the outer facing side with the lancet structure in the initial configuration.

[0020] Item 10: The medical diagnostic device of item 8 further comprising a reagent material offset vertically from the opening at the outer face and within the housing structure.

[0021] Item 11: The medical diagnostic device of item 8 further comprising one or more lancet guide rails that extend along one or more of the sidewalls between the outer facing side and the inner facing side.

[0022] Item 12: The medical diagnostic device of item 11, wherein the lancet structure includes rail riding structure providing a support surface that supports the lancet structure upon the one or more lancet guide rails with the lancet structure in the initial configuration.

[0023] Item 13: The medical diagnostic device of item 12 further comprising one or more drop down slots formed in the one or more of the sidewalls, the rail riding structure located to align with the one or more drop down slots such that the skin penetrating end moves to the position within the lancet compartment offset from the opening in the retracted configuration.

[0024] Item 14: The medical diagnostic device of item 8 further comprising a biasing mechanism that provides a biasing force against the lancet structure such that the skin penetrating end moves to the position within the lancet compartment offset from the opening in the retracted configuration.

[0025] Item 15: The medical diagnostic device of item 8 further comprising a motor operatively connected to the lancet structure.

[0026] Item 16: A method of controlling movement of one or more lancet structures provided within a lancet housing assembly in a portable handheld medical diagnostic device for sampling bodily fluids from a skin site of a patient, the method comprising:

locating a lancet structure in at least one lancet compartment of the lancet housing assembly comprising a skin penetrating end and a blood transport portion adjacent the skin penetrating end;

providing the lancet structure with an initial configuration within the lancet compartment where the lancet structure is supported to align the skin penetrating end with a port in the medical diagnostic device to allow the skin penetrating end to extend through the port; and

providing the lancet structure with a retracted configuration within the lancet compartment where the skin penetrating end moves to a position within the lancet compartment offset from the port to prevent the lancet structure from extending through the port.

[0027] Item 17: The method of item 16 comprising supporting the skin penetrating end of the lancet structure on a bottom surface at the port with the lancet structure in the initial configuration.

[0028] Item 18: The method of item 16 further comprising providing a reagent material offset vertically from the port at the outer face and within the lancet compartment.

[0029] Item 19: The method of item 16 further comprising providing a biasing force against the lancet structure using a biasing mechanism such that the skin penetrating end moves to the position within the lancet compartment offset from the port in the retracted configuration.

[0030] Item 20: The method of item 16 further comprising connecting a motor to the lancet structure.

Brief description of the Drawings

[0031] The following detailed description of the exemplary embodiments of the present invention can be best understood when read in conjunction with the following drawings, where like structure is indicated with like reference numerals, and in which:

[0032] FIG. 1 is a perspective view of an embodiment of a portable handheld medical diagnostic device;

[0033] FIG. 2 is a schematic representation of the portable handheld medical diagnostic device of FIG. 1;

[0034] FIG. 3 is another perspective view of the portable handheld medical diagnostic device of FIG. 1 with an embodiment of a lancet housing assembly exposed;

[0035] FIG. 4 is a perspective view of the lancet housing assembly of FIG. 3 in isolation;

[0036] FIG. 5 is an exploded perspective view of the lancet housing assembly of FIG. 3;

[0037] FIG. 6 is another exploded perspective view of the lancet housing assembly of FIG. 3;

[0038] FIG. 7 is an embodiment of a lancet compartment for use with the lancet housing assembly of FIG. 3 without a lancet structure;

[0039] FIG. 8 illustrates the lancet compartment of FIG. 7 with an embodiment of a lancet structure;

[0040] FIG. 9 illustrates the lancet compartment of FIG. 7 with the lancet structure in operation;

[0041] FIG. 10 illustrates the lancet compartment of FIG. 7 with the lancet structure in operation;

[0042] FIG. 11 illustrates the lancet compartment of FIG. 7 with the lancet structure in operation;

[0043] FIG. 12 illustrates the lancet compartment of FIG. 7 with the lancet structure in operation;

[0044] FIG. 13 illustrates the portable handheld medical diagnostic device of FIG. 1 with a portion of the housing removed;

[0045] FIG. 14 is an exploded view of an embodiment of a spring-drive motor for use in the portable handheld medical diagnostic device of FIG. 1;

[0046] FIG. 15 is a top view of an embodiment of a slidable cam housing assembly for use with the spring-drive motor of FIG. 14;

[0047] FIG. 16 illustrates the slidable cam housing assembly of FIG. 15 in operation with the spring-drive motor of FIG. 14;

[0048] FIG. 17 illustrates the slidable cam housing assembly of FIG. 15 in operation with the spring-drive motor of FIG. 14;

[0049] FIG. 18 illustrates the slidable cam housing assembly of FIG. 15 in operation with the spring-drive motor of FIG. 14;

[0050] FIG. 19 illustrates the slidable cam housing assembly of FIG. 15 in operation with the spring-drive motor of FIG. 14;

[0051] FIG. 20 illustrates the slidable cam housing assembly of FIG. 15 in operation with the spring-drive motor of FIG. 14;

[0052] FIG. 21 illustrates the slidable cam housing assembly of FIG. 15 in operation with the spring-drive motor of FIG. 14 and an embodiment of a speed control mechanism;

[0053] FIG. 22 illustrates components of the speed control mechanism of FIG. 21 in isolation;

[0054] FIG. 23 illustrates an example of a velocity control profile using the speed control mechanism of FIG. 21;

[0055] FIG. 24 illustrates another embodiment of a lancet housing assembly;

[0056] FIG. 25 illustrates another embodiment of a lancet housing assembly;

[0057] FIG. 26 illustrates another embodiment of lancet housing assembly;

[0058] FIG. 27 illustrates the lancet housing assembly of FIG. 26 in operation;

[0059] FIG. 28 illustrates the lancet housing assembly of FIG. 26 in operation;

[0060] FIG. 29 illustrates another embodiment of lancet housing assembly;

[0061] FIG. 30 illustrates the lancet housing assembly of FIG. 29 in operation;

[0062] FIG. 31 illustrates the lancet housing assembly of FIG. 29 in operation;

[0063] FIG. 32 illustrates the lancet housing assembly of FIG. 29 in operation;

[0064] FIG. 33 illustrates the lancet housing assembly of FIG. 29 in operation;

[0065] FIG. 34 illustrates the lancet housing assembly of FIG. 29 in operation;

[0066] FIG. 35 illustrates the lancet housing assembly of FIG. 29 in operation;

[0067] FIG. 36 illustrates the lancet housing assembly of FIG. 29 in operation;

[0068] FIG. 37 illustrates the lancet housing assembly of FIG. 29 in operation;

[0069] FIG. 38 illustrates the lancet housing assembly of FIG. 29 in operation;

[0070] FIG. 39 illustrates the lancet housing assembly of FIG. 29 in operation;

[0071] FIG. 40 illustrates another embodiment of lancet housing assembly;

[0072] FIG. 41 illustrates the lancet housing assembly of FIG. 40 in operation;

[0073] FIG. 42 illustrates the lancet housing assembly of FIG. 40 in operation;

[0074] FIG. 43 illustrates the lancet housing assembly of FIG. 40 in operation;

[0075] FIG. 44 illustrates the lancet housing assembly of FIG. 40 in operation;

[0076] FIG. 45 illustrates the lancet housing assembly of FIG. 40 in operation;

[0077] FIG. 46 illustrates the lancet housing assembly of FIG. 40 in operation; and

[0078] FIG. 47 illustrates the lancet housing assembly of FIG. 40 in operation.

Detailed Description

[0079] The following description of the preferred embodiment is merely exemplary in nature and is in no way intended to limit the invention or its application or uses.

[0080] Embodiments described herein generally relate to handheld medical diagnostic devices that are used to acquire and measure concentrations of biologically significant components of bodily fluids. In particular, the handheld medical diagnostic device may be used to acquire a blood sample and measure a blood glucose level of the sample. As will be described below, the medical diagnostic device may include a motor-driven lancet structure inside the medical diagnostic device, which can be used to generate a prick wound in a body part. The lancet structure can also be used to take up blood emerging from the prick wound using capillary action and deliver the blood to a reagent material. A measuring system located in the medical diagnostic device may be used to determine a blood glucose concentration value of the acquired blood.

[0081] Referring to FIG. 1, a portable, handheld medical diagnostic device 10 with a display device 12 behind a transparent, protective lens 13 includes a protective enclosure, generally indicated by element 14 that protects electronics and other mechanical components therein. The protective enclosure 14 is somewhat rectangular in shape, however, any other suitable shapes may be used for the protective enclosure, such as circular shapes, etc. The display device 12 may be any suitable display device used in a portable, handheld electronic device, such as, for example, but not limited to LCD display devices, LED display devices, OLED display devices, and other types of display devices which may be heretofore developed. Further, display device 12 may be any other variety of indicators, including, but not limited to a series of lights and/or other types of light devices as opposed to a single integrated display screen. In the illustrated

embodiment, the display device 12 includes an electronic paper component such as an electrophoretic display, which may be an information display that forms visible images by rearranging charged pigment particles using an electric field. The display device 12 may be used for electronically displaying graphics, text, and other elements to a user. In some embodiments, the display device 12 may be a touch-screen user interface that is used with the tip of a finger of the user and/or a stylus or other touching device to select elements from the screen, to draw figures, and to enter text with a character recognition program running on the device 10. In some embodiments, the medical diagnostic device 10 may also include other types of output devices such as for example, sound devices, vibration devices, etc.

[0082] The medical diagnostic device 10 further includes a user interface (generally referred to as element 17), which may include buttons 15, 16 and 18. The buttons 15, 16 and 18 may be used by an operator, for example, to view memory of the medical diagnostic device 10, adjust settings of the device and scroll through test results. The buttons 15, 16 and 18 may be manually actuated, such as by pressing the buttons. The buttons 15, 16 and 18 may comprise touch sensors (e.g., resistive or capacitive touch sensors, surface acoustic wave sensors, infrared LED, photodetectors, piezoelectric transducers, etc.) that can be actuated by placing and/or pressing a tip of the finger within the button areas. In these embodiments, the buttons 15, 16 and 18 may not move. Instead, the buttons 15, 16 and 18 may be indicated visually to identify where to place the finger. In other embodiments utilizing touch sensors, the buttons 15, 16 and 18 may move, for example, to bring the finger or touching device into close proximity to the touch sensor. In some embodiments, the medical diagnostic device 10 may provide other button or input types such as an OK button and/or joy stick/track ball, which a user may utilize to navigate through a software drive menu provided on the display device 12. Additional buttons may be used as shortcut buttons, for example, to call up a certain program on the medical diagnostic device 10, as a method of scrolling, to select items from a list, or to provide any function that the software designer of the device may assign to the button or set of buttons. Each button size, layout, location, and function may vary for each manufacturer and model of the medical diagnostic device 10.

[0083] A lancet port 20 is located at a bottom 22 of the medical diagnostic device 10. The lancet port 20 provides an opening through which the lancet structure can extend outwardly from the protective enclosure 14. The lancet structure may extend outwardly from the lancet port 20 to make an incision at a skin site of the patient and produce an amount of bodily fluid from the skin site of the patient. In one embodiment, the medical diagnostic device 10 is an *in vitro* diagnostic device that is used to test blood and other body fluids and tissues to obtain information for the diagnosis, prevention and treatment of a disease. The medical diagnostic device 10 may be a self-testing blood glucose meter for people with diabetes. In one embodiment, the medical diagnostic device 10 is a handheld reagent-based blood glucose meter, which measures glucose concentration by observing some aspect of a chemical reaction between a reagent and the glucose in a fluid sample. The reagent may be a chemical compound that is known to react with glucose in a predictable manner, enabling the monitor to determine the concentration of glucose in the sample. For example, the medical diagnostic device 10 may be configured to measure a voltage or a current generated by the reaction between the glucose and the reagent in one embodiment, electrical resistance in another embodiment, as well as a color change of the reagent in still another embodiment.

[0084] In some embodiments, the medical diagnostic device 10 is a mechanically-driven device where the protective enclosure 14 includes a winding assembly (not shown) that is operated using telescoping housing portions 25 and 27. FIG. 1 illustrates the telescoping housing portions 25 and 27 in their initial, uncocked positions. As will be described in greater detail below, the housing portions 25 and 27 may be moved relative to each other manually to place a lancet actuator assembly (not shown) in a wound, triggerable configuration. The lancet actuator assembly may be used to drive a lancet structure through the lancet port 20 to make an incision at a skin site of the patient and produce an amount of bodily fluid that can then be carried from the skin site of the patient. In some embodiments, the housing portion 27 includes a cartridge housing 29 with a removable door 31 for holding a lancet housing assembly (not shown) that includes multiple lancet structures. In other embodiments, the door 31 may be hinged to the housing portion 27, such that it can be rotated relative to the housing portion 27 to permit access to the cartridge housing 29 for removing or loading the lancet housing assembly. An indicator device 33 may be provided that provides the patient with information regarding the number of

unused lancet structures available in the lancet housing assembly. In this embodiment, the indicator device 33 includes a window 35 in the removable door 31 that allows viewing of numbers provided on the lancet housing assembly as the lancet housing assembly is indexed within the cartridge housing 29.

[0085] Referring to FIG. 2, a simplified, schematic view of the medical diagnostic device 10 includes a number of features that allow for improved comfort and ease of use for a patient. In general, the medical diagnostic device 10 may include a lancet housing assembly 30 in the form of a cartridge or disk that is used to house multiple lancet structures 24 for use in the medical diagnostic device 10, a lancet actuator assembly 28 for extending and/or retracting the lancet structures 24 and a speed control mechanism 36 that engages the lancet actuator assembly 28 for adjusting the speed at which the lancet structure 24 is extended and/or retracted by the lancet actuator assembly 28. A depth adjustment mechanism 37 may also be provided that allows for adjustment of a penetration depth of the lancet structure 24 before extending the lancet structure 24.

[0086] A measurement system 32 may be provided that measures glucose concentration in a blood sample delivered to a test material 39, for example, using an optical device 34 in one embodiment for detecting a color change in a reagent or other suitable device in other embodiments, such as electrical contacts if measuring a change in an electrical characteristic/property of the reagent. The test material 39 may be employed to hold the reagent and to host the reaction between the glucose and the reagent mentioned above. In one embodiment, the test material 39 and the optical device 34 may be located such that the reaction between the glucose and the reagent may be read electronically in order for the measurement system 32 to determine the concentration of glucose in the sample and display the results to a user using the display device 12. These embodiments enable both health care professionals and patients to perform reliable decentralized testing in hospitals, clinics, offices or patients' homes.

[0087] Referring to FIGS. 3-6, in some embodiments, multiple lancet structures are housed in the lancet housing assembly in the form of a disk 30 that includes multiple lancet compartments 40 (FIG. 5) arranged in a radial fashion about a central axis 42. The disk 30 may

have an outer protective housing (not shown) formed of any one or more suitable materials, such as plastics, foils, metals, and the like. Materials with sterile moisture barriers may be used to provide lancet compartments 40 with protected environments. In some embodiments, such as the one illustrated, the disk 30 may be formed by a center hub 48 and a disk component 51 that is configured to rotate relative to the center hub 48. In some embodiments, the disk component 51 includes an upper disk member 41 and a lower disk member 43 that is connected to the upper disk member 41. Any suitable connection may be used between the upper and lower disk members 41 and 43, such as laser welding, snap fit, press fit, adhesives, fasteners, and the likes.

[0088] As depicted in the exploded view of FIG. 5, the center hub 48 may be provided within a central bore 50 of the disk 30 such that it may rotate relative to the disk component 51. In one embodiment, the center hub 48 may be provided such that it may snap fit into place within the central bore 50 of the disk 30. For example, the center hub 48 may include fastening structures 47 in the form of hook-like projections that engage a bottom surface 73 of the disk component 51. Although the center hub 48 may be mounted rotatably within the central bore 50 of the disk 30 such that it may be removably retained therein, such as via the snap fit arrangement depicted in FIG. 5, or via a fastener(s) in another embodiment which provides a nut or clip (not shown) which engages a threaded or shaped end (not shown) of the center hub 48 adjacent the bottom surface 73, in other embodiments the center hub 48 may be provided rotatably therein but also retained permanently therein, such as via laser welding in another embodiment which provides a deformed free end (not shown) of the center hub 48 that flairs outwardly about the bottom surface 73. The center hub 48 may have a non-circular or irregular-shaped (e.g., D-shaped) key or opening 75 that allows for automatic alignment of the disk 30 in only one or more orientations for insertion into a disk compartment 52 of the medical diagnostic device 10. For example, in the illustrated embodiment, the D-shaped key may allow for automatic alignment of the disk 30 in only one orientation for insertion into the disk compartment 52.

[0089] In addition to FIG. 5, FIG. 6 also illustrates an exploded view of the disk 30 including the upper disk member 41 and the lower disk member 43 of the disk component 51 and the center hub 48. The upper disk member 41 includes a top surface 49 and a bottom surface 56 opposite the top surface 49. Numbered indicia 53 (FIG. 5) may be printed, molded, etched,

machined, etc. onto the top surface 49 for providing the user an indication of the number of unused lancet structures 24 are remaining or have been used. The numbered indicia 53 may be viewed through the window 35 of the removable door 31 (FIG. 1). Notches 55 extend inwardly from the top surface 49 of the upper disk member 41. The notches 55 are spaced angularly from adjacent notches 55 and are located substantially equidistant from the center of the upper disk member 41. The notches 55 may each be associated with a respective lancet compartment 40 and provide engagement structure for preventing over rotation of the disk 30 relative to the center hub 48.

[0090] The center hub 48 may include rotation limiting structure 54 that cooperates with rotation limiting structure (e.g., the notches 55) of the upper disk member 41. The center hub 48 may include arm members 57 and 59, each having a downward protruding projection 61 and 63 that is sized and arranged to be removably received by the notches 55 as the upper disk member 41 rotates relative to the center hub 48. The projections 61 and 63 may each include a relatively vertically oriented side 65 and a relatively angled side 67 that is at an angle to the vertical. The vertically oriented side 65 can inhibit rotation of the upper disk member 41 relative to the center hub 48 while the angled side 67 allows rotation of the upper disk member 41 relative to the center hub 48 in the opposite direction. The arm members 57 and 59 may be formed of a somewhat flexible material to allow the arm members 57 and 59 to resiliently bend so that the projections 61 and 63 may move out of one notch 55 and be received by an adjacent notch 55 for locking the upper disk member 41 in an angular relationship relative to the center hub 48. Cooperating end stops 58 and 69 may also be provided to prevent rotation of the upper disk member 41 relative to the center hub 48 once the end stops 58 and 69 engage.

[0091] The lower disk member 43 includes a top surface 79, a bottom surface 73 opposite the top surface 79, an outer facing side 64 and an inner facing side 66. The lancet compartments 40 extend in a generally radial direction from the inner facing side 66 to the outer facing side 64. The lancet compartments 40 may be equally spaced an angular distance apart from one another and about the periphery of the lower disk member 43. As will be described in greater detail below, each lancet compartment 40 may include a lancet structure 24 that can extend through an opening 68 in each lancet compartment 40 and through the lancet port 20 of the medical

diagnostic device 10. Extending downwardly from the bottom surface 73 of the lower disk member 43 are indexing pins 77. The indexing pins 77 may be used to rotate the disk component 51 relative to the center hub 48, for example, after each operation of the lancet structures 24.

[0092] Referring to FIGS. 7 and 8, an exemplary empty lancet compartment 40 and a lancet compartment 40 with an unused lancet structure 24 are shown, respectively. Referring first to FIG. 7, the lancet compartment 40 is formed, in part, by a compartment section 62 of the lower disk member 43. The upper disk member 41 is removed in FIGS. 7 and 8 for clarity. The compartment section 62 includes the outer facing side 64 and the inner facing side 66. The opening 68 is located at the outer facing side 64 that can align with the lancet port 20 located at the bottom 22 of the medical diagnostic device 10 (FIG. 1). Sidewalls 78 and 80 extend between the outer facing side 64 and the inner facing side 66. A clearance floor 70 extends from an inner wall 71 at the outer facing side 64 within the lancet compartment 40 to the inner facing side 66 and forms a lowermost floor of the lancet compartment 40. Adjacent the inner wall 71 of the lancet compartment 40 is a reagent material 72, which is located on the clearance floor 70 and within the lancet compartment 40. The reagent material 72 may be a test strip such as electrochemical type test strips, colorimetric or optical type test strips, etc. to name a few.

[0093] Drop down slots 74 and 76 are located in sidewalls 78 and 80 and extend vertically from the top surface 79 of the compartment section 62 to a lancet floor 84. Another drop down slot 81 is located in the inner wall 71 and extends vertically from the opening 68 to the reagent material 72. The lancet floor 84 extends along the clearance floor 70, in a raised relationship thereto, from the reagent material 72 back toward the inner facing side 66 and within the drop down slots 74 and 76. In some embodiments, the lancet floor 84 may be formed by a pair of strips 85 and 87 that extend along their respective sidewall 78 and 80 and spaced-apart from each other thereby exposing part of the clearance floor 70 therebetween. In some embodiments, the lancet floor 84 and the clearance floor 70 may both be part of the same floor structure. The lancet floor 84 provides clearance between the clearance floor 70 and the lancet structure 24 when the lancet structure is dropped down against the reagent material 72 and seated against the lancet floor 84. Lancet guide rails 86 and 88 extend along the sidewalls 78 and 80 and recessed

vertically below the top surface 79 of the compartment section 62. In some embodiments, the lancet guide rails 86 and 88 extend substantially parallel to the lancet floor 84 and/or clearance floor 70 from the drop down slots 74 and 76 to the opening 68 with the drop down slot 81 intersecting the lancet guide rails 86 and 88 at the inner wall 71 and the drop down slots 74 and 76 intersecting the guide rails 86 and 88, respectively, at the sidewalls 78 and 80.

[0094] Referring to FIG. 8, the lancet compartment 40 is illustrated with a lancet structure 24. The lancet structure 24, in this exemplary embodiment, includes a skin penetrating end 90 and a blood transport portion 92 adjacent the skin penetrating end 90. In some embodiments, the blood transport portion 92 may include one or more capillary structures that facilitate movement of the bodily fluid away from the skin penetrating end to the blood transport portion 92. The skin penetrating end 90, when extended through the opening 68, is shaped and sized to penetrate the patient's skin at a skin location in order to provide an amount of blood. The blood transport portion 92 can receive the amount of blood from the skin penetrating end 90 and be used to carry the amount of blood away from the skin location.

[0095] A drive member connecting structure 94 is located at an end 96 that is opposite the skin penetrating end 90. In this embodiment, the drive member connecting structure 94 is a closed opening 98 having a rear ledge 100 that is used to engage the drive member 95 (e.g., in the form of a drive hook). Rail riding structure in the form of outwardly extending wings 102 and 104 are located between the drive connecting structure 94 and the blood transport portion 92. The wings 102 and 104 extend outwardly in the widthwise direction to ride along the lancet guide rails 86 and 88 when extending and retracting the lancet structure 24.

[0096] Referring to FIG. 9, a cross-section of the lancet compartment 40 is illustrated in an assembled configuration with the upper disk member 41 connected to the lower disk member 43 thereby providing the lancet compartment 40 therebetween. The drive member 95 extends into the lancet compartment 40 and is illustrated releasably engaged with the drive member connecting structure 94 of the lancet structure 24. The skin penetrating end 90 of the lancet structure 24 is illustrated as resting on a bottom surface 106 of the opening 68 while the wings (only wing 102 is partially shown) rest on the lancet guide rails (only guide rail 86 is partially

shown).

[0097] A biasing mechanism 108 (e.g., a flat spring) extends into the lancet compartment 40, toward the lancet floor 84 and engages a surface 110 of the lancet structure 24. The biasing mechanism 108 may be connected at opposite ends 112 and 114 to a ceiling 116 of the upper disk member 41. A projection 118 formed in the biasing mechanism 108 may be provided that mates with a corresponding detent 120 of the lancet structure 24 (FIG. 8). In another embodiment, the lancet structure 24 may include the projection 118 and the biasing mechanism 108 may include the detent 120. Any other suitable mating arrangement can be used, such as opposing ramp structures. This mating arrangement can provide added resistance to unintended movement of the of the skin penetrating end 90 of the lancet structure 24 through the opening 68.

[0098] Referring to FIG. 10, the lancet structure 24 may be extended through the opening 68 in the direction of arrow 122 using the drive member 95 that is connected to the drive member connecting structure 94. As can be seen by FIGS. 9 and 10, the biasing mechanism 108 may include a slot 124 that is formed along a length of the biasing mechanism 108, between the ends 112 and 114. The slot 124 may be sized to receive a hook portion 126 of the drive member 95 and to allow movement of the drive member 95 through the slot 124 and toward the opening 68. In some embodiments, the hook portion 126 of the drive member 95 is received within the slot 124 such that the biasing mechanism 108 maintains contact with the lancet structure 24 as the lancet structure 24 is being driven toward the opening 68. As the lancet structure 24 is driven toward the opening 68, the outwardly extending wings 102 and 104 ride along the lancet guide rails 86 and 88 of the sidewalls 78 and 80.

[0099] Referring to FIG. 11, the lancet structure 24 may be retracted from the opening 68 in the direction of arrow 128 using the drive member 95. The hook portion 126 of the drive member 95 may be received within the slot 124 such that the biasing mechanism 108 maintains contact with the lancet structure 24 as the lancet structure 24 is being driven away from the opening 68. As shown in FIG. 11, once the outwardly extending wings 102 and 104 that ride along the lancet guide rails 86 and 88 of the sidewalls 78 and 80 align with the drop down slots 74 and 76, and the skin penetrating end 90 aligns with or moves beyond the drop down slot 81,

the biasing mechanism 108 forces the lancet structure 24 in a direction substantially transverse to the retract direction 128, toward the lancet floor 84 and the reagent material 72. Thus, the biasing mechanism 108 can be used to automatically deliver the lancet structure 24 to the reagent material 72 as the lancet structure 24 is retracted by the drive member 95.

[00100] Referring to FIG. 12, the lancet structure 24 is illustrated fully retracted and directed toward the reagent material 72. In this position, the skin penetrating end 90 and the blood transport portion 92 of the lancet structure 24 are offset from the opening 68 (i.e., out of alignment with the opening 68) and in contact with the reagent material 72 such that blood can be transferred to the reagent material 72. In addition to delivering the lancet structure 24 to the reagent material 72, the offset arrangement of the skin penetrating end 90 out-of-alignment with the opening 68 can also inhibit unintended extension of the skin penetrating end 90 through the opening 68 by the drive member 95, which no longer can engage and extend the lancet structure 24. In particular, in the illustrated embodiment should the drive member 95 once again move towards the opening 68 of the lancet compartment 40 containing a used lancet structure 24, the drive member 95 will pass over the lancet structure 24 due to the offset arrangement also placing the drive member connecting structure 94 of the lancet structure 24 out-of-alignment with drive member 95. Accordingly, the biasing mechanism 108 providing the lancet structure 24 in the offset arrangement after the transfer of blood from the blood transport portion 92 of the lancet structure 24 to the reagent material 72, provides a convenient fail safe.

[00101] Referring to FIG. 13, the drive member 95 including the hook portion 126 is operatively connected to the lancet actuator assembly 28, which is used to extend and retract the drive member 95. The drive member 95 is connected to a hook arm 130. The hook arm 130 can slide along a pair of guide rails 132 and 134, which are used to accurately guide the drive member 95 toward extended and retracted positions. The guide rails 132 and 134 are fixedly connected to the housing portion 27 by an anchor 136. The hook arm 130 is connected to a follower arm 138 by an adjustable linkage 140. The follower arm 138 is driven in opposite directions (represented by arrows 142) by a clockwork spring drive assembly 144, which, in turn, moves the hook arm 130 and drive member 95 between their extended and retracted positions.

[00102] A rack member 146 is used to wind the clockwork spring drive assembly 144 and includes a rack portion 148 and a disk indexing portion 150. The rack portion 148 includes a first bar 152 having teeth 154 along its length and a second bar 156 having no teeth that is spaced from the first bar 152 by a slot 158. The teeth 154 are meshed with teeth 160 of a cam gear 162 having arms 164 and 166 that can engage a spring wheel assembly 168 (e.g., when rotating in only one direction, such as clockwise) for rotating the spring wheel assembly 168.

[00103] The rack member 146 may also include an indexing component 147 that is used to engage the indexing pins 77 of the disk 30. The indexing component 147 may include a pin engagement structure 149 including a ramp portion 151. As the rack member 146 is moved backward, the ramp portion 151 may engage one of the indexing pins 77, forcing the disk component 51 to rotate relative to the center hub 48.

[00104] The rack member 146 is connected to a slidable cam housing assembly 170 (e.g., using a pair of pins 172 and 174 or any other suitable connection). The slidable cam housing assembly 170 is connected to the telescoping housing portion 25 (e.g., using fasteners 175) such that movement of the telescoping housing portion 25 relative to the telescoping portion 27 moves the rack member 146 relative to the clockwork spring drive assembly 144. As can be appreciated from FIG. 13 and from the description below, movement of the rack member 146 in the direction of arrow 176 causes the cam gear 162 to rotate in the counterclockwise direction. Rotating counterclockwise, the cam gear 162 may not engage the spring wheel assembly 168 and may rotate relative thereto. Thus, moving the telescoping portion 27 outwardly in the direction of arrow 176 places the rack member 146 in a preload or pre-primed position that is ready to wind or prime the clockwork spring drive assembly 144 during its return stroke. Movement of the rack member 146 in a direction opposite arrow 176 causes the cam gear 162 to rotate in the clockwise direction. Rotating clockwise, the cam gear 162 engages the spring wheel assembly 168 thereby rotating the spring wheel assembly 168 in the clockwise direction, which can wind the clockwork spring drive assembly 144, as will be described in greater detail below.

[00105] FIG. 14 illustrates an exploded view of the exemplary clockwork spring drive assembly 144 in isolation. The clockwork spring drive assembly 144 includes the cam gear 162

and the spring wheel assembly 168. The spring wheel assembly 168 includes a spring wheel 180, a torsion spring 182, a cover plate 184 and a roller wheel 186. The spring 182 connects the spring wheel 180 to the roller wheel 186 with the cover plate 184 providing a smooth, relatively low friction surface between the spring 182 and the roller wheel 186. At an inner end 188, the spring 182 is connected to the roller wheel 186, while at an outer end 190, the spring 182 is connected to the spring wheel 180. Rotation of the spring wheel 180 relative to the roller wheel 186 about a pivot axle 187 causes the spring 182 to wind thereby increasing the stored energy in the spring 182.

[00106] The roller wheel 186 includes a face cam portion 192 including a groove 196 that is provided at a face 198 of the roller wheel 186. The groove 196 provides a track that is followed by the follower arm 138 (FIG. 13) such that the follower arm 138 is moved a fixed distance between extended and retracted positions as the roller wheel 186 rotates. A follower pin 200 is provided at an opposite face 202 of the roller wheel 186. Rotation of the roller wheel 186 (and thus movement of the follower arm) is controlled through interaction between the follower pin 200 and a cam track portion of the slidable cam housing assembly 170.

[00107] Referring to FIG. 15, the slidable cam housing assembly 170 is depicted in isolation and includes a first side member 204, a second side member 206 and an end member 208 that extends between the first and second side members 204 and 206 thereby forming a somewhat U-shape. At each first and second side member 204 and 206 is a respective slidable rail 207, 209 that, in the illustrated embodiment, have a U-shaped groove 210 for slidably receiving a rail 212 of the housing portion 27 (FIG. 13) thereby forming a slide/rail assembly. The end member 208 includes the pins 172 and 174 for connecting the rack member 146 thereto and spring housing structures 214, 216 and 218, each for receiving a coil spring.

[00108] A track portion 220 extends outwardly from the end member 208 and generally between the first and second side members 204 and 206. The track portion 220 is formed by a pair of track support members 222 and 224 that are cantilevered at one end 226 and 228 to the end member 208 and extend outwardly to a joined free end 330. A slot 332 extends along a length of the track portion 220 that is sized to receive the pivot axle 187 of the clockwork spring

drive assembly 144 such that the slidable cam housing assembly 170 can slide by the pivot axle 187. Carried by each of the track support members 222 and 224 is a respective elongated guide track element 225 and 227 that extends upwardly from top surfaces 229 and 231 of each track support member 222 and 224. The guide track elements 225 and 227 are used to control winding and releasing of the clockwork spring drive assembly 144 by controlling (i.e., allowing and disallowing) rotation of the roller wheel 186.

[00109] FIGS. 16-20 illustrate a priming and firing sequence utilizing the clockwork spring drive assembly 144 and the slidable cam housing assembly 170. The roller wheel 186 is shown somewhat transparent such that the follower pin 200 can be seen as it interacts with the track portion 220 and the guide track elements 225 and 227. FIG. 16 illustrates the roller wheel 186 and the slidable cam housing assembly 170 in a start position with the follower pin 200 biased clockwise against a wall portion 334 of the guide track element 225 by the spring 182. In this position, the slidable cam housing assembly 170 can be pulled in the direction of arrow 336 relative to the clockwork spring drive assembly 144 through the connection of the slidable cam housing assembly 170 with the housing portion 25 and due to the clockwork spring drive assembly 144 being rotatably connected to the housing portion 27. FIG. 17 illustrates the slidable cam housing assembly 170 in a fully pre-primed position with the follower pin 200 biased against a wall portion 338 of the guide track element 227. As indicated above, movement of slidable cam housing assembly 170 and the rack member 146 connected thereto (FIG. 13) in the direction of arrow 336 causes the cam gear 162 to rotate in the counterclockwise direction. Rotating counterclockwise, the cam gear 162 may not engage the spring wheel assembly 168 and may rotate relative thereto without winding the spring 182. However, the spring 182 may be preloaded an amount such that the follower pin 200 moves against the guide track element 225, over an edge 340 of the guide track element 225 and to the wall portion 338 of the guide track element 227 in the fully pre-primed position.

[00110] Referring now to FIG. 18, the slidable cam housing assembly 170 may be pushed in the direction of arrow 342 toward a wound, triggerable position (or primed position) once placed in the fully pre-primed position with the follower pin between the guide track elements 225 and 227. As the slidable cam housing assembly 170 is pushed in the direction of arrow 342, the

movement of slidable cam housing assembly 170 and the rack member 146 connected thereto (FIG. 13) in the direction of arrow 342 causes the cam gear 162 to rotate in the clockwise direction. Rotating clockwise, the cam gear 162 engages the spring wheel assembly 168 thereby rotating the spring wheel assembly 168 and winding the spring 182. The guide track element 227 prevents rotation of the roller wheel 186, which allows the spring 182 to wind relative to the roller wheel 186 as the spring wheel assembly 168 rotates.

[00111] The follower pin 200 follows along the guide track element 227 until the follower pin 200 reaches an opening 344. The follower pin 200 may then be rotated into the opening 344 due to the bias force provided on the roller wheel 186 by the spring 182. With the follower pin 200 in this position, the slidable cam housing assembly 170 is in a primed, safety-ready position. Biasing members 346, 348 and 350 (e.g., coil springs) may be provided that provide a slight spring back force once the slidable cam housing assembly 170 in the primed, safety-ready position shown by FIG. 18. The slight spring back force causes the slidable cam housing assembly 170 to move a relatively short distance in the pull direction of arrow 336, which allows the follower pin 200 to rotate around an edge 352 of the guide track element 227 and into the wound, triggerable position illustrated by FIG. 19.

[00112] Once the follower pin 200 is in the wound, triggerable position of FIG. 19, the medical diagnostic device 10 is ready to fire the lancet structure 24 through the lancet port 20. Triggering the medical diagnostic device 10 may be accomplished by placing the finger or other body part on the lancet port 20, pushing the housing portion 25 toward the housing portion 27 and overcoming the bias provided by the biasing members 346, 348 and 350. Referring to FIG. 20, the roller wheel 186 rotates due to the bias provided by the spring 182 once the follower pin 200 moves beyond a release point 354 provided by the guide track element 227. Rotation of the roller wheel 186 causes the lancet structure 24 to extend outwardly from the lancet port 20 and retract back into the lancet port 20.

[00113] In some embodiments, a velocity profile of the lancet structure 24 when being extended and retracted using the clockwork spring drive assembly 144 may be controlled such that the velocity profile is asymmetric during the extending and retracting phases. Such control

can affect impact, retraction velocity and dwell time of the skin penetrating end 90 of the lancet structure 24.

[00114] Referring again to FIG. 13 and also to FIG. 21, the speed control mechanism 36 may be a gearbox and includes a housing 356 including a top wall 358, a bottom wall 360 and sidewalls 362. Located at least partially in the housing are gears 364, 366, 368 and 370. Referring also to FIG. 22, the gear 364 is an engagement gear and engages the clockwork spring drive assembly 144 as the roller wheel 186 rotates. In one embodiment, the roller wheel 186 includes an eccentric ring member 372 (e.g., formed of rubber or plastic) that increases the diameter of the roller wheel 186 at a particular location at the periphery of the roller wheel 186. As the roller wheel 186 rotates during the return stroke of the lancet structure 24, the eccentric ring member 372 engages the gear 364 thereby rotating the gear 364 and slowing the roller wheel 186. As the gear 364 rotates, it causes the gears 366, 368 and 370 to rotate. Gear 370 includes a flywheel 374 with weights 376 that are selected to mechanically slow the roller wheel 186 a selected amount. In some embodiments, the gear ratio provided by the gears 364, 366, 368 and 370 may be about 18:1 and the mass of the flywheel 374 may be less than one gram, such as about 0.67 gram.

[00115] Referring to FIG. 23, an exemplary velocity over time profile of the lancet structure 24 is illustrated. As can be seen, portion A shows relatively rapid acceleration of the lancet structure 24 as the skin penetrating end 90 approaches and penetrates a skin site. Portion B shows relatively slow deceleration of the lancet structure 24 as the skin penetrating end exits the skin site. In some embodiments, a ratio of time during the extending phase to time during the retracting phase is at least about 1:25. Deceleration is adjustable by, for example, adding mass to the flywheel 374 and/or by changing the gear ratio.

[00116] Referring again to FIG. 13, as noted above, the medical diagnostic device 10 may further include the depth adjustment mechanism 37. The depth adjustment mechanism 37 may include a thumb wheel 355 that is adjustably connected to the adjustable linkage 140 at a pivot location P_1. Rotation of the thumb wheel 355 causes movement of an end 357 of the adjustable linkage 140, which, in turn, causes the adjustable linkage to pivot about pivot location P_2 and

adjusts the start position of the hook portion 126 of the drive member 95. Movement of the hook portion 126 of the drive member 95 toward the lancet port 20 can increase the penetration depth of the skin penetrating end 90 of the lancet structure 24 due to the fixed stroke length of the follower arm 138 and roller wheel 186. Movement of the hook portion 126 of the drive member 95 away from the lancet port 20 can decrease the penetration depth of the skin penetrating end 90 of the lancet structure 24. As one exemplary embodiment, the penetration depth (e.g., the distance the skin penetrating end 90 extends beyond the lancet port 20) may be adjustable from about 0.8 mm to about 2.3 mm. Additionally, because the follower arm 138 is connected to the adjustable linkage 140 (e.g., at slot 381) for extending and retracting the drive member 95, the adjustable linkage 140 may act to amplify movement of the drive member 95 relative to movement of the follower arm 138. In some embodiments, the adjustable linkage 140 provides a multiplier of 1.8:1 ratio of the drive member 95 to the follower arm 138.

[00117] Referring now to FIG. 24, an alternative embodiment of a lancet housing assembly 400 (e.g., in the form of a disk) includes an upper disk member 402 and a lower disk member 404 defining a lancet compartment 405. A lancet structure 406 includes a skin penetrating end 408, a blood transfer portion 410 and engagement structure 412 for engaging a drive member 414. Similar to the embodiments described above, the lancet structure 406 includes a laterally extending wing 416 that can ride along a side rail 418 extending along a side wall 420 of the lancet compartment 405. In this embodiment, the side rail 418 includes a step 422 that causes the lancet structure 406 to move (i.e., snap down) toward a lancet floor 424, release the driver member and bring the skin penetrating end 408 in contact with a reagent material 426. In the illustrated embodiment, the step 422 is substantially parallel to vertical (i.e., perpendicular to the side rail 418), however, the step may be at other angles to vertical.

[00118] Referring to FIG. 25, another embodiment of a lancet housing assembly 430 may utilize a curvature of a lancet structure 432 to bring a skin penetrating end 434 of the lancet structure 432 in contact with a reagent material 436. In this embodiment, the lancet structure 432 includes a laterally extending wing 438 that can ride along a curved side rail 440 extending along a side wall 442 of the lancet compartment 444. When the skin penetrating end 434 is pulled by the opening 446, the curvature of the lancet structure 432 causes the skin penetrating end 434 to

come into contact with the reagent material 436.

[00119] Referring to FIGS. 26-28, movement of a lancet structure 450 may have a lateral or sideways component (i.e., angular movement toward an adjacent lancet compartment). A lancet housing assembly 452 (e.g., in the form of a disk) includes an upper disk member 454 and a lower disk member 456 defining the lancet compartment 458. The lancet structure 450 includes a skin penetrating end 462, a blood transfer portion 464 and engagement structure 466 for engaging a drive member. Similar to the embodiments described above, the lancet structure 450 includes a laterally extending wing 468 that can ride along a side rail 470 extending along a side wall 472 of the lancet compartment 458. In this embodiment, the opening 474 includes a horizontal wall component 476 that forces the skin penetrating end 462 laterally toward an adjacent lancet compartment to bring the lancet structure 450 into contact with an reagent material 478.

[00120] FIGS. 29-41 illustrate another embodiment of a lancet housing assembly 500 including an upper disk member 502 and a lower disk member 504 defining a lancet compartment 505. A lancet structure 506 includes a skin penetrating end 508, a blood transfer portion 510 and engagement structure 512 for engaging a drive member 514. Referring first to FIG. 29, securing structure 516 is provided for securing the lancet structure 506 within the lancet compartment 505. The securing structure 516 allows some force to be placed on the lancet structure 506 during engagement of the drive member 514 therewith without longitudinal displacement of the lancet structure 506. Yet, the securing structure 516 may allow for longitudinal displacement of the lancet structure 506 in response to a force above a preselected threshold force.

[00121] The securing structure 516 may include spring elements 518 and 520 that extend outwardly from the extended axis of the lancet structure 506. The spring elements 518 and 520 may each be received within a respective notch 522 and 524, which are sized to receive the spring elements 518 and 520. The locking strength of the securing structure 516 can be selected using the spring strength of the spring elements 518 and 520 and the exit angle of the notches 522 and 524. In this embodiment, the exit angles of the notches 522 and 524 are less than about

90 degrees.

[00122] FIG. 30 illustrates a starting position including the drive member 514 with the lancet structure 506 engaged with the securing structure 516. Wing structures 526 and 528 may be provided (FIG. 29) that rest upon support structures 530 to space the lancet structure 506 from a reagent material 532. The drive member 514 may be inserted into the lancet compartment 505 and pushed forwards, in a manner similar to that described above. In some embodiments, the drive member 514 is subjected to an upward spring force F (e.g., using a spring), which also is shown by FIG. 31.

[00123] In FIG. 31, the drive member 514 includes a guide projection 534 having a rounded outer periphery and extending upwardly from the hook portion 536. The guide projection 534 may engage a downwardly extending cam surface 538 to force the hook portion 536 downward to position the hook portion 536 for engagement with engagement structure 540 of the lancet structure 506. Referring to FIG. 32, as the guide projection 534 moves past the cam surface 538, the hook portion 536 raises due to the bias F and engages the engagement structure 540 of the lancet structure 506.

[00124] In FIG. 33, the spring elements 518 and 520 (FIG. 29) may free from the notches 522 and 524 and at FIG. 34, a landing member 542 may engage the cam surface 538 to limit upward movement of the hook portion 536. At FIGS. 35 and 36, an incision may be made by moving the skin penetrating end 508 through the opening 544 followed by decelerated return movement, in a fashion similar to that described above.

[00125] Referring to FIG. 37, at the end of the return movement of the lancet structure 506, the bias force F acts on the lancet structure 506 thereby tensioning the lancet structure 506. With the wing structures 526 and 528 (FIG. 29) resting upon support structures 530, a gap remains between the lancet structure 506 and the reagent material 532 as shown by FIG. 37. Referring to FIG. 38, with further return movement of the drive member 514, the wing structures 526 and 528 (FIG. 29) disengage the support structures 530 and the skin penetrating end 508 contacts the reagent material 532. The bias force F facilitates contact between the skin penetrating end 508

and the reagent material 532 such that a liquid contact takes place. Upon further return of the drive member 514, the guide projection 534 engages the cam surface 538 forcing the hook portion 536 to disengage the lancet structure 506 as shown by FIG. 38. Referring to FIG. 39, ribs 546 may be provided to maintain spring tension within the lancet structure 506.

[00126] FIGS. 40-47 illustrate another embodiment of a lancet housing assembly 600 including an upper disk member 602 and a lower disk member 604 defining a lancet compartment 605. A lancet structure 606 includes a skin penetrating end 608, a blood transfer portion 610 and engagement structure 612 for engaging a drive member 614. Referring first to FIG. 40, an initial position of the lancet structure 606 and the drive member 614 is illustrated. In this embodiment, the lancet structure 606 includes an outwardly extending spring finger 616 that extends upwardly at portion 618 and longitudinally at portion 620. A bend 622 connects the upwardly extending portion 618 and longitudinally extending portion 620. The longitudinally extending portion 620 includes a hump-shaped portion 624 that is received within a notch 626 thereby providing securing structure for the lancet structure 606 within the lancet compartment 605.

[00127] The lancet structure 606 includes engagement structure 612 that is used to engage the lancet structure 606 with a hook portion 630 of the drive member 614. In the illustrated initial position, the engagement structure 612 rests on a decline guide ramp or rail 632 that is used to support the lancet structure 606 during its extending and retracting phases. The skin penetrating end 608 of the lancet structure 606 rests on a support surface 634 at opening 636 through which the skin penetrating end 608 extends.

[00128] Referring to FIG. 41, during a priming and firing sequence, the drive member 614 enters the lancet compartment 605 and a guide projection 638 engages an incline ramp surface 640, which forces the hook portion 630 upward as the drive member 614 enters the lancet compartment 605. Referring to FIG. 42, as the drive member 614 continues to move toward the opening 636, the guide projection 638 engages a decline ramp surface 642 and the hook portion 630 travels downward and engages the engagement structure 612 of the lancet structure 606. Referring to FIG. 43, the hook portion 630 continues to travel down the decline ramp surface 642

thereby fully engaging the engagement structure 612 and extending the skin penetrating end 608 of the lancet structure 606 through the opening 636. As can be seen by FIGS. 42 and 43, the hump-shaped portion 624 is forced out of the notch 626 by deflecting the spring finger 616 upon application of a sufficient force by the drive member 614. The amount of force needed to release the hump-shaped portion 624 from the notch 626 can be selected based on the spring force and the shapes of the notch 626 and hump-shaped portion 624. In some embodiments, the hump-shaped portion 624 continues to contact an upper wall surface 644 thereby biasing the lancet structure 606 in a downward direction as the skin penetrating end 608 is extended. FIG. 44 illustrates the lancet structure 606 fully extended.

[00129] Referring to FIG. 45, during retraction, the skin penetrating end 608 of the lancet structure 606 is pulled back into the lancet compartment 605. The pulling force applied by the drive member 614 is sufficient to pull the hump-shaped portion 624 past the notch 626 to allow the skin penetrating end 608 to clear the support surface 634 at the opening 636 and fall downward toward a reagent material 650 to transfer an amount of bodily fluid to the reagent material. Unhooking of the engagement structure 612 occurs as the lancet structure falls toward the reagent material 650 and the guide projection 638 moves up the ramp surface 642. FIGS. 46 and 47 illustrate the lancet structure 606 in its final, released state with the lancet structure 606 in contact with the reagent material 650 and the skin penetrating end 608 offset from the opening 636.

[00130] The above-described medical diagnostic devices include a number of features that allow for improved comfort and ease of use for a patient. In general, the medical diagnostic devices may include a lancet housing assembly in the form of a cartridge or disk that is used to house multiple lancet structures for use in the medical diagnostic devices, a lancet actuator assembly for extending and retracting the lancet structures and a speed control mechanism that engages the lancet actuator assembly for adjusting the speed at which the lancet structure is extended and/or retracted by the lancet actuator assembly. A depth adjustment mechanism may also be provided that allows for adjustment of an initial position of the lancet structure prior to its use, which can adjust the penetration depth of the lancet structure during use.

[00131] The above description and drawings are only to be considered illustrative of exemplary embodiments, which achieve the features and advantages of the present invention. Modification and substitutions to specific process steps, system, and setup can be made without departing from the spirit and scope of the present invention. Accordingly, the invention is not to be considered as being limited by the foregoing description and drawings, but is only limited by the scope of the appended claims.

Reference numerals

10	device	47	fastening structures
12	display device	48	center hub
13	lens	49	top surface
14	protective enclosure/element	50	central bore
15	button	51	disk component
16	button	52	disk compartment
17	user interface/element	53	numbered indicia
18	button	54	rotation limiting structure
20	lancet port	55	notch
22	bottom	56	bottom surface
24	lancet structure	57	arm member
25	housing portion	58	end stop
27	housing portion/telescoping portion	59	arm member
		61	projection
28	lancet actuator assembly	62	compartment section
29	cartridge housing	63	downward protruding projection
30	lancet housing assembly/disk	64	outer facing side
31	door	65	vertically oriented side
32	measurement system	66	inner facing side
33	indicator device	67	angled side
34	optical device	68	opening
35	window	69	end stop
36	speed control mechanism	70	clearance floor
37	depth adjustment mechanism	71	inner wall
39	test material	72	reagent material
40	lancet compartment	73	bottom surface
41	upper disk member	74	drop down slot
42	central axis	75	opening
43	lower disk member		

76	drop down slot
77	indexing pins
78	sidewall
79	top surface
80	sidewall
81	drop down slot
84	lancet floor
85	strips
86	guide rail
87	strips
88	guide rail
90	skin penetrating end
92	blood transport portion
94	connecting structure
95	drive member
96	end
98	closed opening
100	rear ledge
102	wing
104	wing
106	bottom surface
108	biasing mechanism
110	surface
112	end
114	end
116	ceiling
118	projection
120	detent
122	arrow
124	slot
126	hook portion
128	arrow/retract direction
130	hook arm
132	guide rail
134	guide rail
136	anchor
138	follower arm
140	adjustable linkage
142	arrows
144	clockwork spring drive assembly
146	rack member
147	indexing component
148	rack portion
149	pin engagement structure
150	disk indexing portion
151	ramp portion
152	first bar
154	teeth
156	second bar
158	slot
160	teeth
162	cam gear
164	arm
166	arm
168	spring wheel assembly
170	cam housing assembly
172	pin
174	pin
175	fasteners
176	arrow
180	spring wheel
182	spring

184	cover plate
186	roller wheel
187	pivot axle
188	inner end
190	outer end
192	face cam portion
196	groove
198	face
200	follower pin
202	opposite face
204	first side member
206	second side member
207	rail
208	end member
209	rail
210	U-shaped groove
212	rail
214	spring housing structures
216	spring housing structures
218	spring housing structures
220	track portion
222	track support member
224	track support member
225	guide track element
226	end
227	guide track element
228	end
229	top surface
330	joined free end
231	top surface
332	slot
334	wall portion
336	arrow
338	wall portion
340	edge
342	arrow
344	opening
346	biasing member
348	biasing member
350	biasing member
352	edge
354	release point
355	thumb wheel
356	housing
357	end
358	top wall
360	bottom wall
362	sidewalls
364	gear
366	gear
368	gear
370	gear
372	eccentric ring member
374	flywheel
376	weights
381	slot
400	housing assembly
402	upper disk member
404	lower disk member
405	lancet compartment
406	lancet structure
408	skin penetrating end

410	blood transport portion
412	engagement structure
414	drive member
416	laterally extending wing
418	side rail
420	side wall
422	step
424	lancet floor
426	reagent material
430	housing assembly
432	lancet structure
434	skin penetrating end
436	reagent material
438	extending wing
440	curved side rail
442	side wall
444	lancet compartment
446	opening
450	lancet structure
452	lancet housing assembly
454	upper disk member
456	lower disk member
458	lancet compartment
462	skin penetrating end
464	blood transport portion
466	engagement structure
468	laterally extending wing
470	side rail
472	side wall
474	opening
476	horizontal wall component
478	reagent material
500	lancet housing assembly
502	upper disk member
504	lower disk member
505	lancet compartment
506	lancet structure
508	skin penetrating end
510	blood transport portion
512	engagement structure
514	drive member
516	securing structure
518	spring element
520	spring element
522	notch
524	notch
526	wing structure
528	wing structure
530	support structures
532	reagent material
534	guide projection
536	hook portion
538	cam surface
540	engagement structure
542	landing member
544	opening
546	ribs
600	lancet housing assembly
602	upper disk member
604	lower disk member
605	lancet compartment

606 lancet structure
608 skin penetrating end
610 blood transport portion
612 engagement structure
614 drive member
616 spring finger
618 portion
620 portion
622 bend
624 hump-shaped portion
626 notch
630 hook portion
632 rail
634 support surface
636 opening
638 guide projection
640 incline ramp surface
642 ramp surface
644 upper wall surface
650 reagent material
P1 pivot location
P2 pivot location

[00132] What is claimed is:

Claims

1. A lancet housing assembly (30; 400; 430; 452; 00; 600) comprising multiple lancets for use in a portable handheld medical diagnostic (10) device for sampling bodily fluids from a skin site of a patient, the lancet housing assembly (30; 400; 430; 452; 00; 600) comprising:

a housing structure (14) comprising multiple lancet compartments (40; 405; 444; 458; 505; 605), at least one of the lancet compartments (40; 405; 444; 458; 505; 605) comprising

an outer facing side (64);

an inner facing side (66);

an opening (68) located at the outer facing side (64) that is arranged and configured to align with a lancet port (20) of the medical diagnostic device (10); and

a lancet structure (24; 406; 432; 450; 506; 606) located in the at least one lancet compartment (40; 405; 444; 458; 505; 605) and comprising a skin penetrating end (90; 408; 434; 462; 508; 608) and a blood transport portion (92; 410; 464; 510; 610) adjacent the skin penetrating end (90; 408; 434; 462; 508; 608), the lancet structure (24; 406; 432; 450; 506; 606) having (i) an initial configuration where the lancet structure (24; 406; 432; 450; 506; 606) is supported to align the skin penetrating end (90; 408; 434; 462; 508; 608) with the opening (68) to allow the skin penetrating end (90; 408; 434; 462; 508; 608) to extend through the opening (68) and (ii) a retracted configuration where the skin penetrating end (90; 408; 434; 462; 508; 608) is adapted to move to a position within the lancet compartment (40; 405; 444; 458; 505; 605) offset from the opening (68) to prevent the lancet structure (24; 406; 432; 450; 506; 606) from extending through the opening (68).

2. The lancet housing assembly (30; 400; 430; 452; 00; 600) of claim 1, wherein the skin penetrating end (90; 408; 434; 462; 508; 608) of the lancet structure (24; 406; 432; 450; 506; 606) is supported on a bottom surface (106) of the opening (68) at the outer facing side (64) with the lancet structure (24; 406; 432; 450; 506; 606) in the initial configuration.

3. The lancet housing assembly (30; 400; 430; 452; 00; 600) of claim 1 further comprising a reagent material (72) offset vertically from the opening (68) at the outer facing side (64) and within the housing structure (14).

4. The lancet housing assembly (30; 400; 430; 452; 00; 600) of any preceding claim further comprising one or more lancet guide rails (86, 88) that extend along one or more of sidewalls (78, 80) of the at least one lancet compartment (40; 405; 444; 458; 505; 605) between the outer facing side (64) and the inner facing side (66).

5. The lancet housing assembly (30; 400; 430; 452; 00; 600) of claim 4, wherein the lancet structure (24; 406; 432; 450; 506; 606) includes rail riding structure (102, 104) providing a support surface (634) that is adapted to support the lancet structure (24; 406; 432; 450; 506; 606) upon the one or more lancet guide rails (86, 88) with the lancet structure (24; 406; 432; 450; 506; 606) in the initial configuration.

6. The lancet housing assembly (30; 400; 430; 452; 00; 600) of claim 5 further comprising one or more drop down slots (74, 76) formed in the one or more of the sidewalls (78, 80), the rail riding structure (102, 104) located to align with the one or more drop down slots (74, 76) such that the skin penetrating end (90; 408; 434; 462; 508; 608) is adapted to move to the position within the lancet compartment (40; 405; 444; 458; 505; 605) offset from the opening (68) in the retracted configuration.

7. The lancet housing assembly (30; 400; 430; 452; 00; 600) of any preceding claim further comprising a biasing mechanism (108) that is adapted to provide a biasing force against the lancet structure (24; 406; 432; 450; 506; 606) such that the skin penetrating end (90; 408; 434; 462; 508; 608) is adapted to move to the position within the lancet compartment (40; 405; 444; 458; 505; 605) offset from the opening (68) in the retracted configuration.

8. A portable handheld medical diagnostic device (10) for sampling bodily fluids, comprising:

a protective enclosure (14);

a measurement system (32) including a controller facilitating a physiologic measurement;

a display device (12) connected to the measurement system that is adapted to display information related to the physiologic measurement;

a lancet housing assembly (30; 400; 430; 452; 00; 600) comprising a housing structure comprising multiple lancet compartments (40; 405; 444; 458; 505; 605), at least one of the lancet compartments (40; 405; 444; 458; 505; 605) comprising

an outer facing side (64);

an inner facing side (66);

an opening (68) located at the outer facing side (64) that is arranged and configured to align with a lancet port (20) of the medical diagnostic device (10); and

a lancet structure (24; 406; 432; 450; 506; 606) located in the at least one lancet compartment (40; 405; 444; 458; 505; 605) and comprising a skin penetrating end (90; 408; 434; 462; 508; 608) and a blood transport portion (92; 410; 464; 510; 610) adjacent the skin penetrating end (90; 408; 434; 462; 508; 608), the lancet structure (24; 406; 432; 450; 506; 606) having (i) an initial configuration where the lancet structure (24; 406; 432; 450; 506; 606) is supported to align the skin penetrating end (90; 408; 434; 462; 508; 608) with the opening (68) to allow the skin penetrating end (90; 408; 434; 462; 508; 608) to extend through the opening (68) and (ii) a retracted configuration where the skin penetrating end (90; 408; 434; 462; 508; 608) is adapted to move to a position within the lancet compartment (40; 405; 444; 458; 505; 605) offset from the opening (68) to prevent the lancet structure (24; 406; 432; 450; 506; 606) from extending through the opening (68).

9. The medical diagnostic device (10) of claim 8, wherein the skin penetrating end (90; 408; 434; 462; 508; 608) of the lancet structure (24; 406; 432; 450; 506; 606) is supported on a bottom surface (106) of the opening (68) at the outer facing side (64) with the lancet structure (24; 406; 432; 450; 506; 606) in the initial configuration.

10. The medical diagnostic device (10) of claim 8 or 9 further comprising a reagent material (72) offset vertically from the opening (68) at the outer facing side (64) and within the housing structure.

11. The medical diagnostic device (10) of any one of claim 8 to 10 further comprising one or more lancet guide rails (86, 88) that extend along one or more of the sidewalls (78, 80) between the outer facing side (64) and the inner facing side (66).

12. The medical diagnostic device (10) of claim 11, wherein the lancet structure (24; 406; 432; 450; 506; 606) includes rail riding structure (102, 104) providing a support surface (634) that is adapted to support the lancet structure (24; 406; 432; 450; 506; 606) upon the one or more lancet guide rails (86, 88) with the lancet structure (24; 406; 432; 450; 506; 606) in the initial configuration.

13. The medical diagnostic device (10) of claim 12 further comprising one or more drop down slots (74, 76) formed in the one or more of the sidewalls (78, 80), the rail riding structure (102, 104) located to align with the one or more drop down slots (74, 76) such that the skin penetrating end (90; 408; 434; 462; 508; 608) is adapted to move to the position within the lancet compartment (40; 405; 444; 458; 505; 605) offset from the opening (68) in the retracted configuration.

14. The medical diagnostic device (10) of any one of claims 8 to 13 further comprising a biasing mechanism (108) that is adapted to provide a biasing force against the lancet structure (24; 406; 432; 450; 506; 606) such that the skin penetrating end (90; 408; 434; 462; 508; 608) is adapted to move to the position within the lancet compartment (40; 405; 444; 458; 505; 605) offset from the opening (68) in the retracted configuration.

15. The medical diagnostic device (10) of claim 8 further comprising a motor operatively connected to the lancet structure (24; 406; 432; 450; 506; 606).

16. A method of controlling movement of one or more lancet structures (24; 406; 432; 450; 506; 606) provided within a lancet housing assembly (30; 400; 430; 452; 00; 600) in a portable handheld medical diagnostic device (10) for sampling bodily fluids from a skin site of a patient, the method comprising:

locating a lancet structure (24; 406; 432; 450; 506; 606) in at least one lancet compartment (40; 405; 444; 458; 505; 605) of the lancet housing assembly (30; 400; 430; 452; 00; 600) comprising a skin penetrating end (90; 408; 434; 462; 508; 608) and a blood transport portion (92; 410; 464; 510; 610) adjacent the skin penetrating end (90; 408; 434; 462; 508; 608);

providing the lancet structure (24; 406; 432; 450; 506; 606) with an initial configuration within the lancet compartment (40; 405; 444; 458; 505; 605) where the lancet structure (24; 406; 432; 450; 506; 606) is supported to align the skin penetrating end (90; 408; 434; 462; 508; 608) with a lancet port (20) in the medical diagnostic device (10) to allow the skin penetrating end (90; 408; 434; 462; 508; 608) to extend through the lancet port (20); and

providing the lancet structure (24; 406; 432; 450; 506; 606) with a retracted configuration within the lancet compartment (40; 405; 444; 458; 505; 605) where the skin penetrating end (90; 408; 434; 462; 508; 608) moves to a position within the lancet compartment (40; 405; 444; 458; 505; 605) offset from the lancet port (20) to prevent the lancet structure (24; 406; 432; 450; 506; 606) from extending through the lancet port (20).

17. The method of claim 16 comprising supporting the skin penetrating end (90; 408; 434; 462; 508; 608) of the lancet structure (24; 406; 432; 450; 506; 606) on a bottom surface (106) at the port (20) with the lancet structure (24; 406; 432; 450; 506; 606) in the initial configuration.

18. The method of claim 16 or 17 further comprising providing a reagent material (72) offset vertically from the port (20) at the outer face and within the lancet compartment (40; 405; 444; 458; 505; 605).

19. The method of any one of claims 16 to 18 further comprising providing a biasing force against the lancet structure (24; 406; 432; 450; 506; 606) using a biasing mechanism (108) such that the skin penetrating end (90; 408; 434; 462; 508; 608) moves to the position within the lancet compartment (40; 405; 444; 458; 505; 605) offset from the port in the retracted configuration.

20. The method of any one of claims 16 to 19 further comprising connecting a motor to the lancet structure (24; 406; 432; 450; 506; 606).

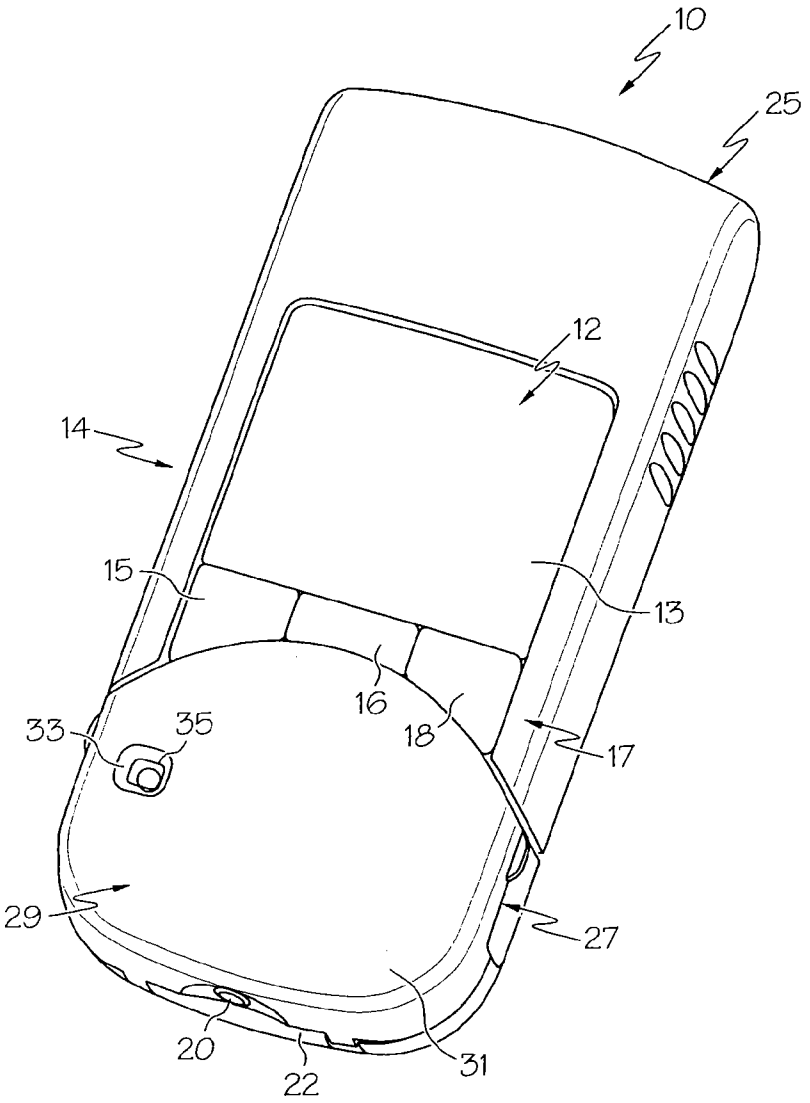


FIG. 1

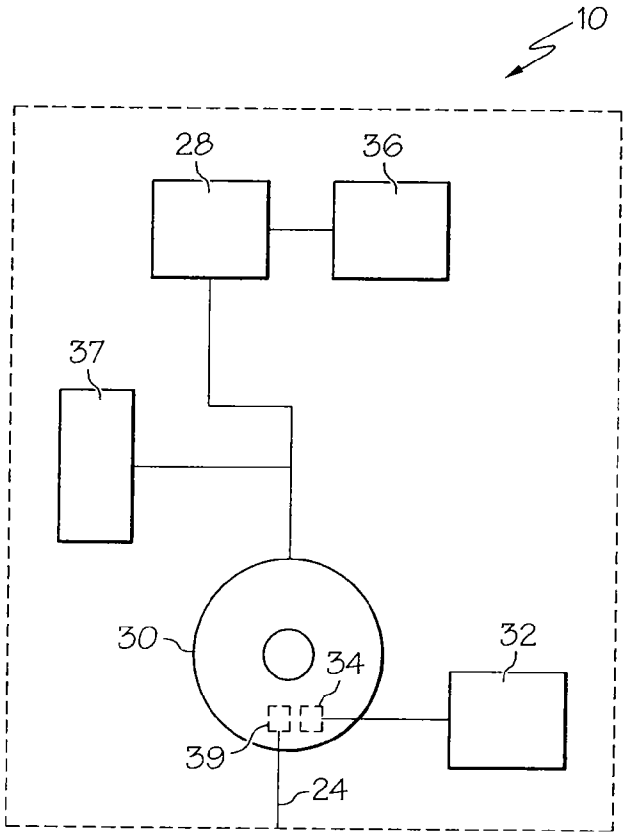


FIG. 2

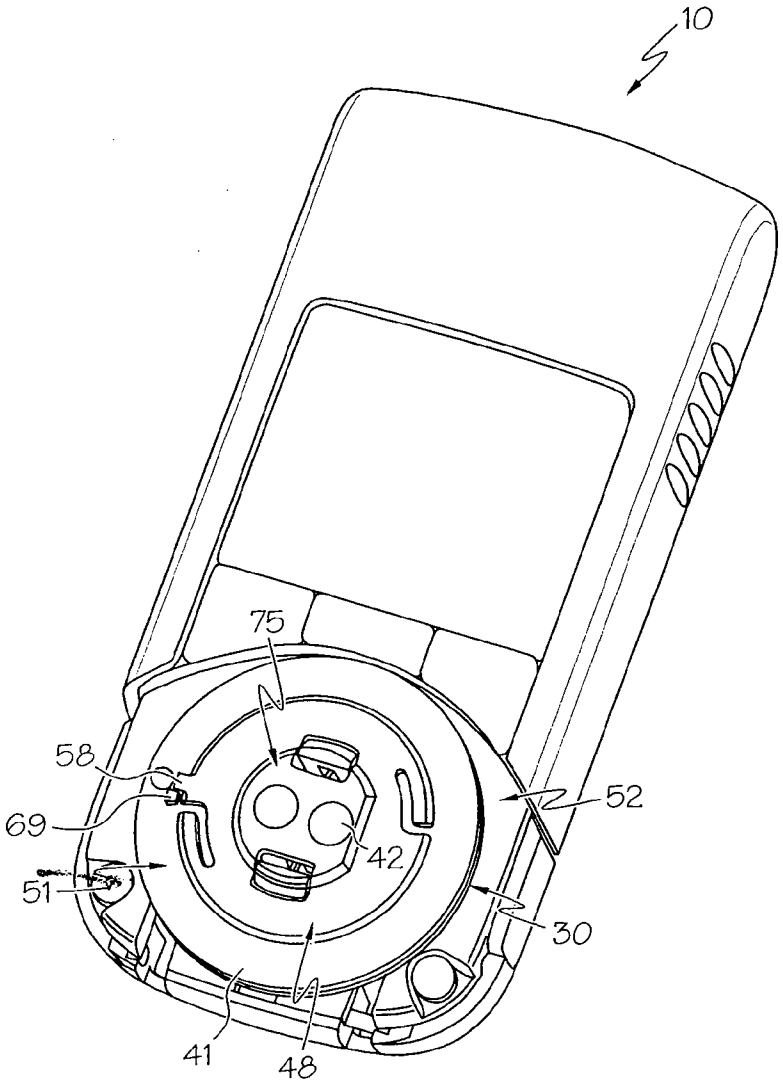


FIG. 3

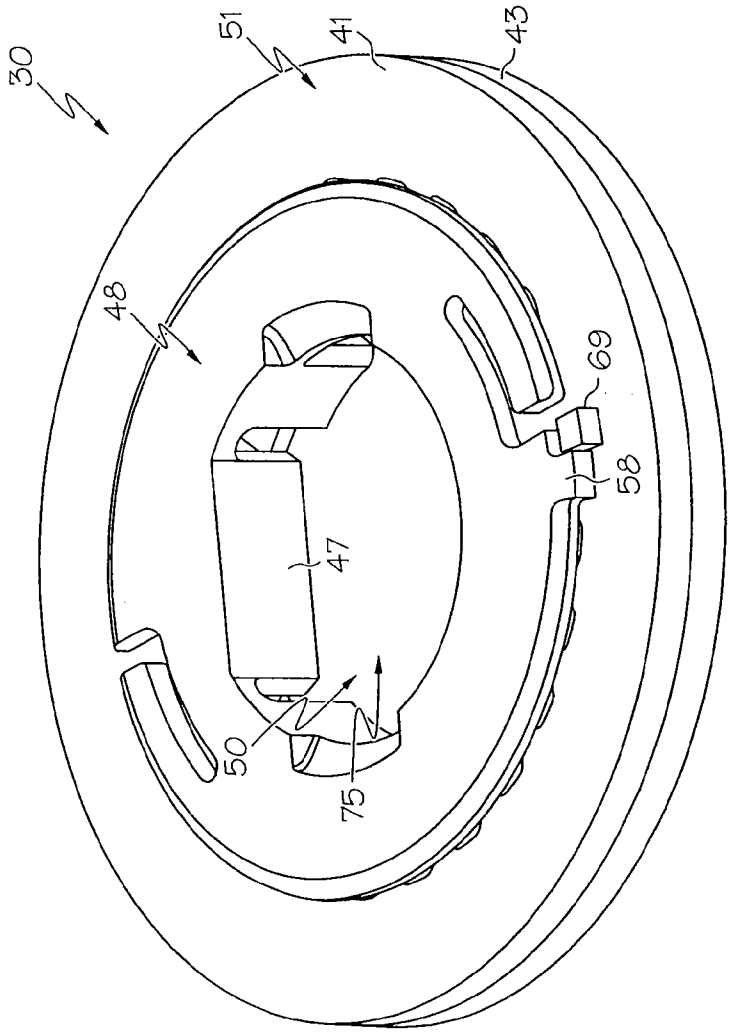


FIG. 4

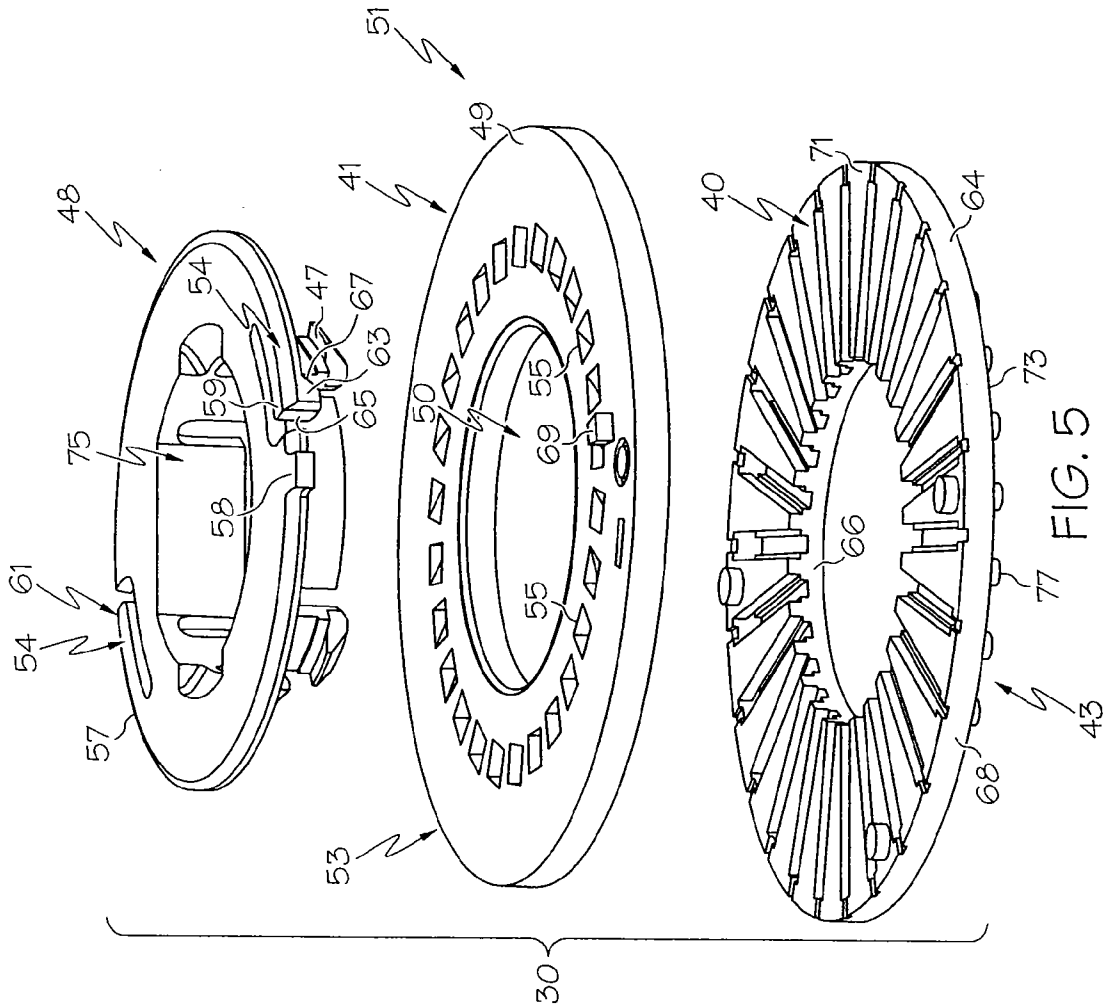

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FIG. 5

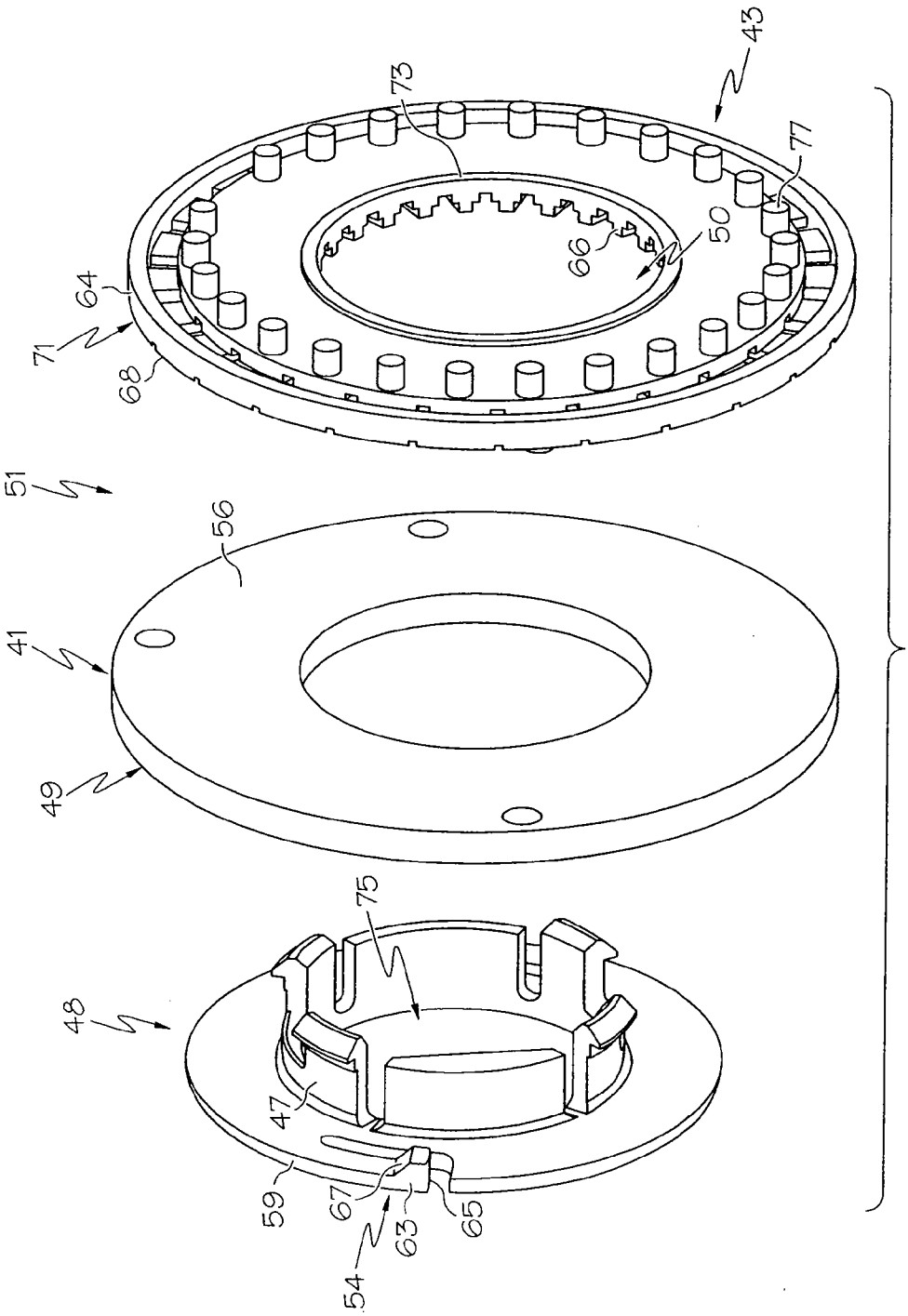


FIG. 6

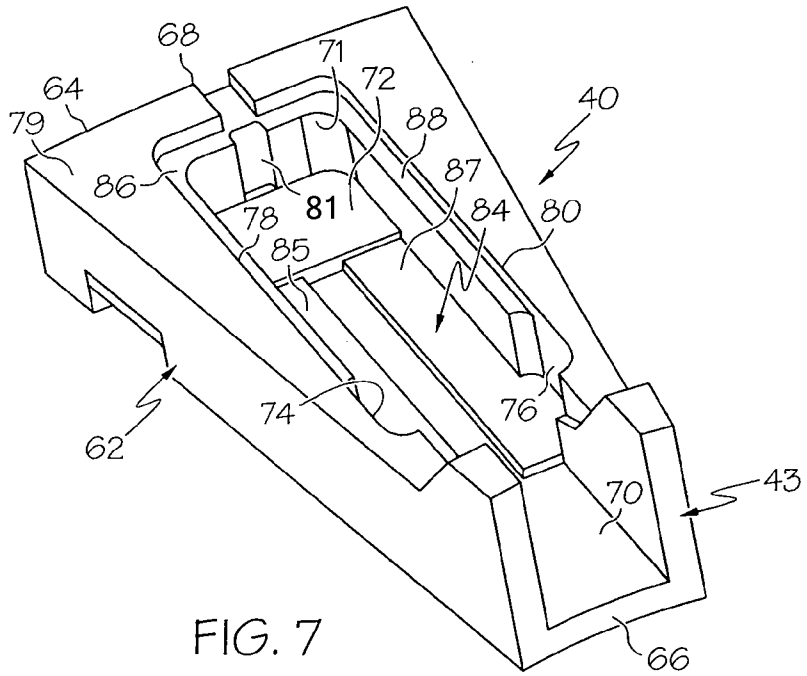

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FIG. 7

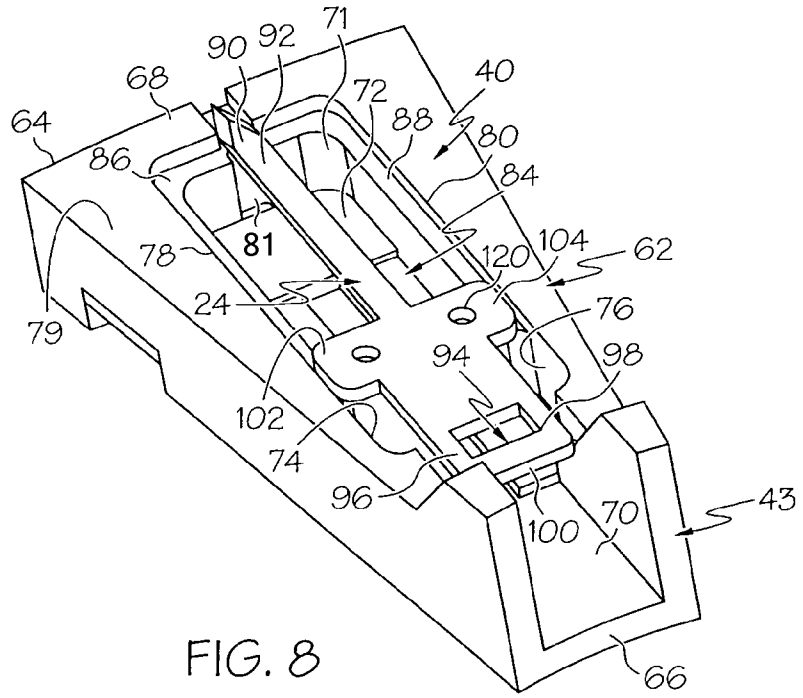

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FIG. 8

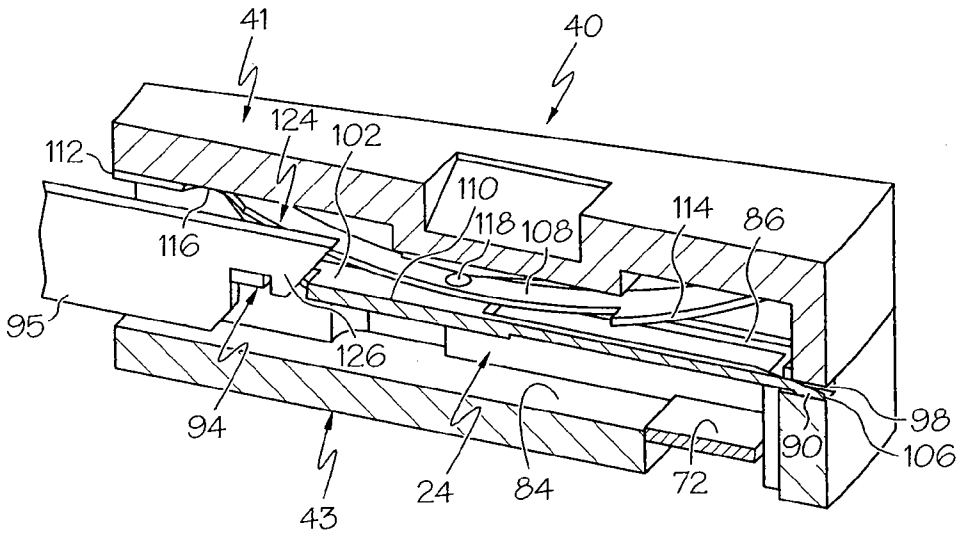

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FIG. 9

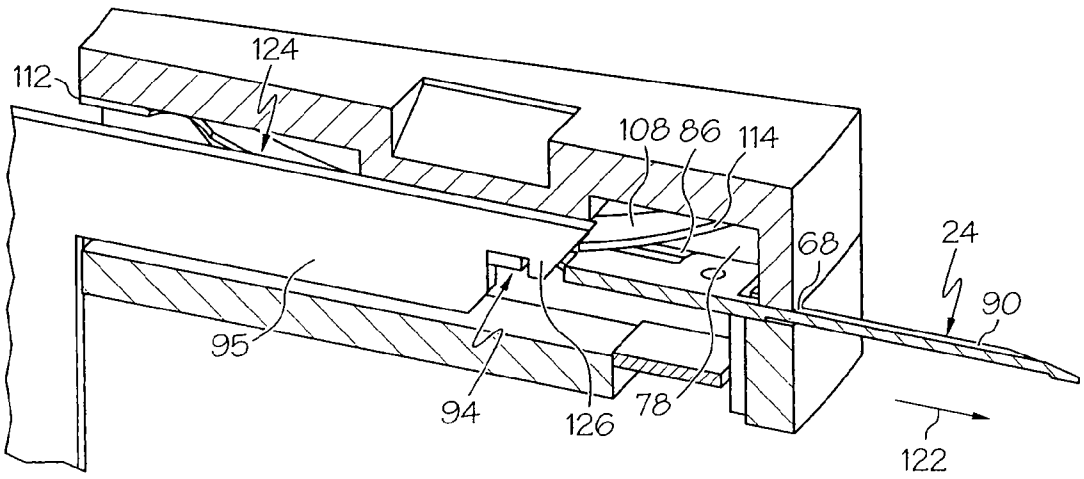

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FIG. 10

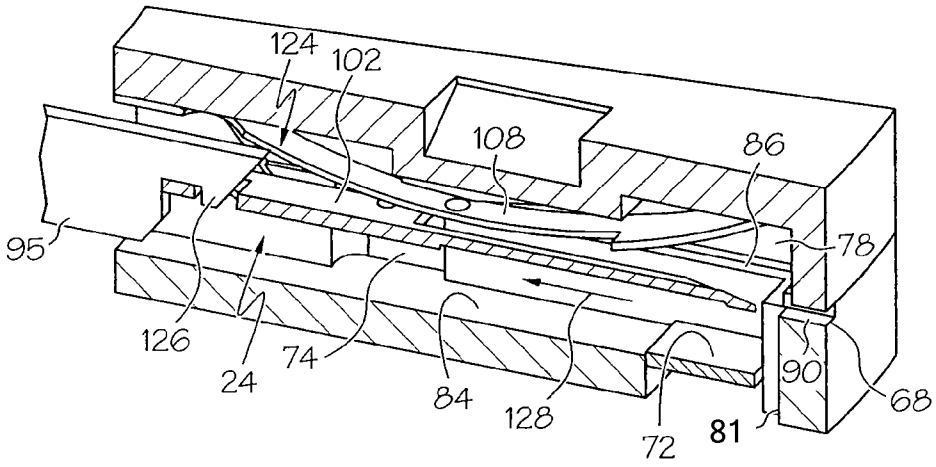

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FIG. 11

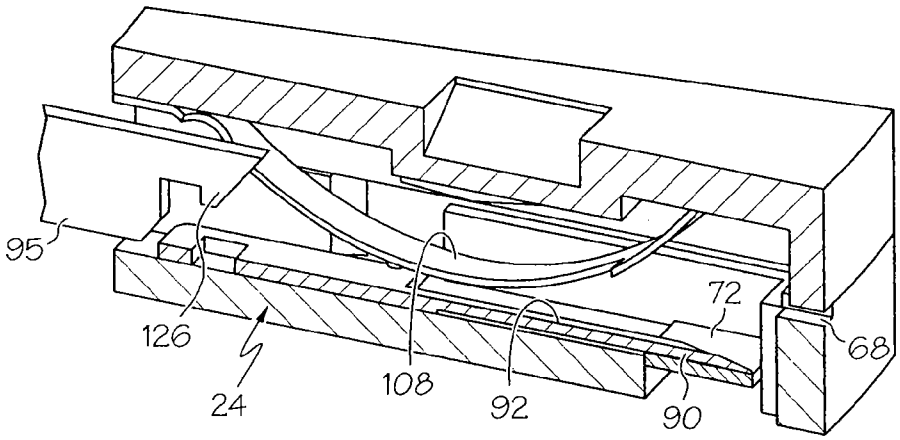

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FIG. 12

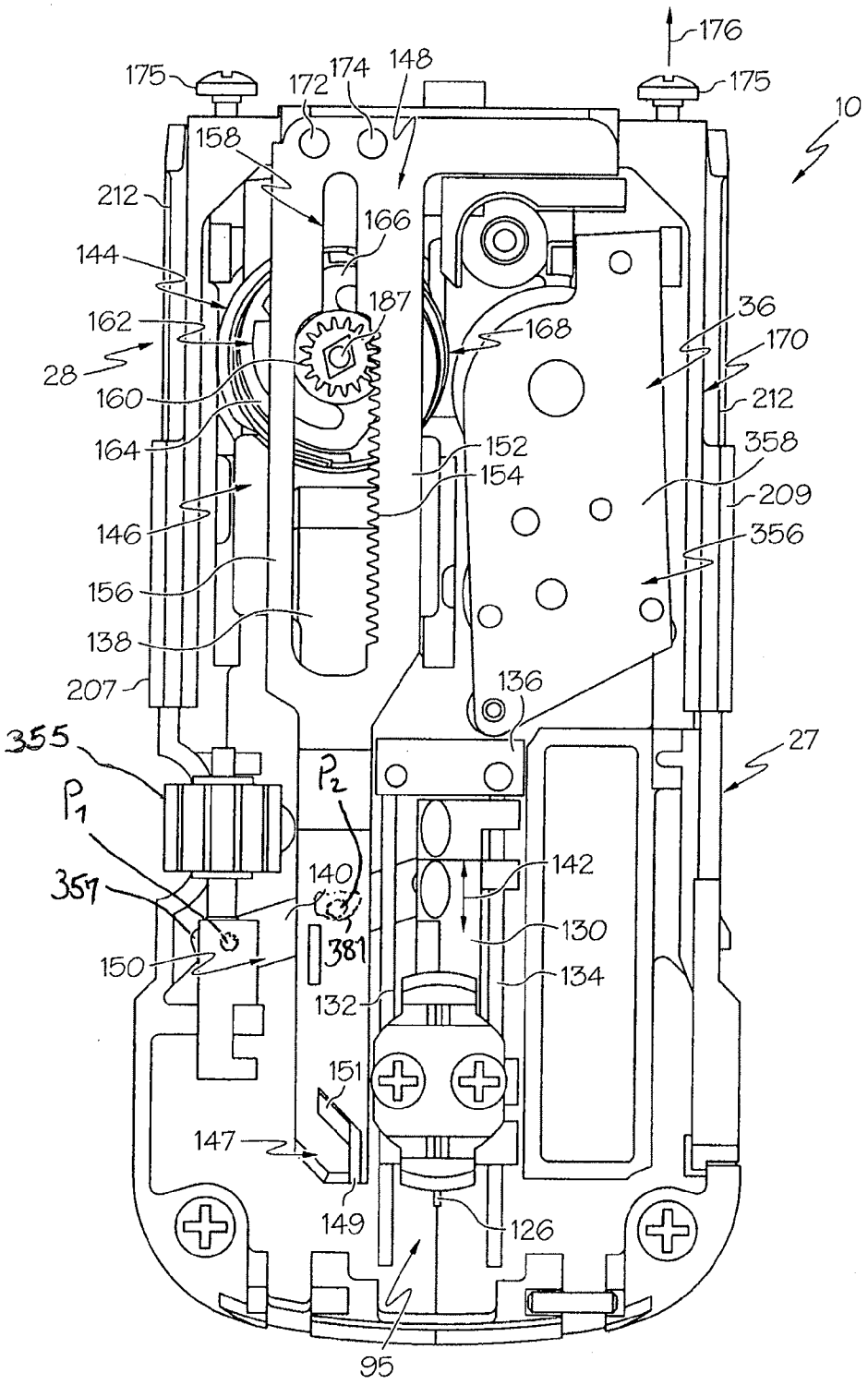

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FIG. 13

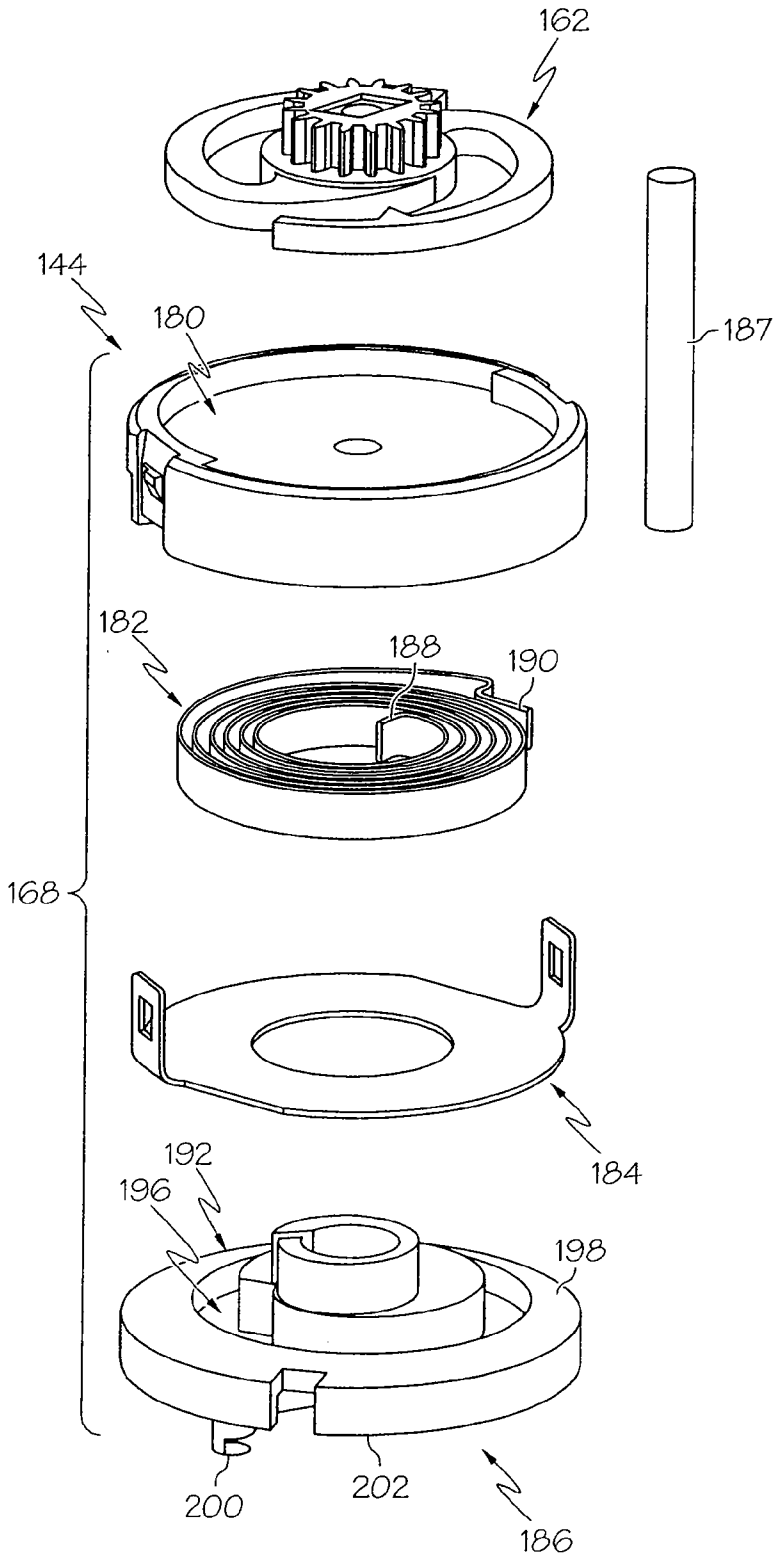


FIG. 14

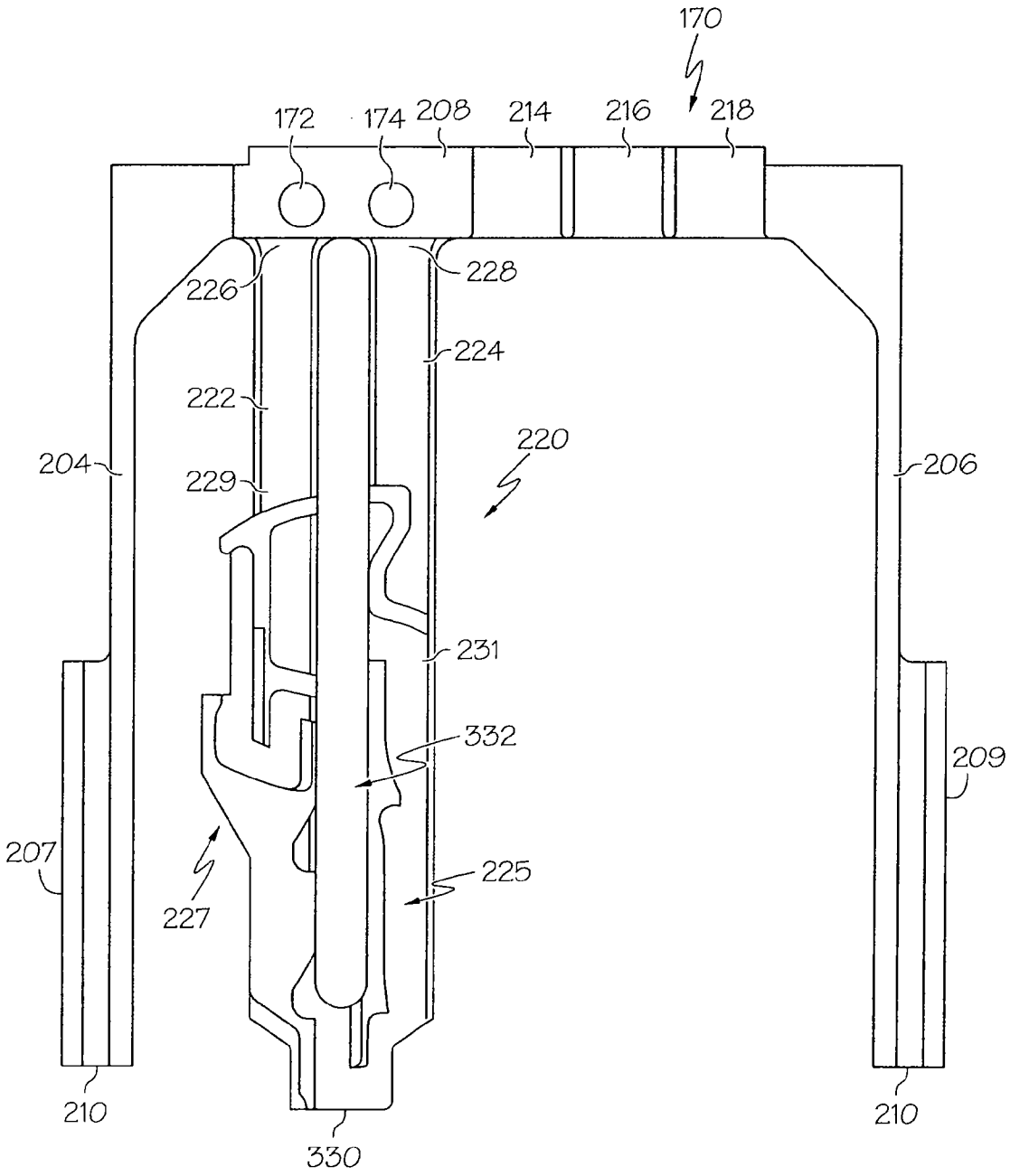

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FIG. 15

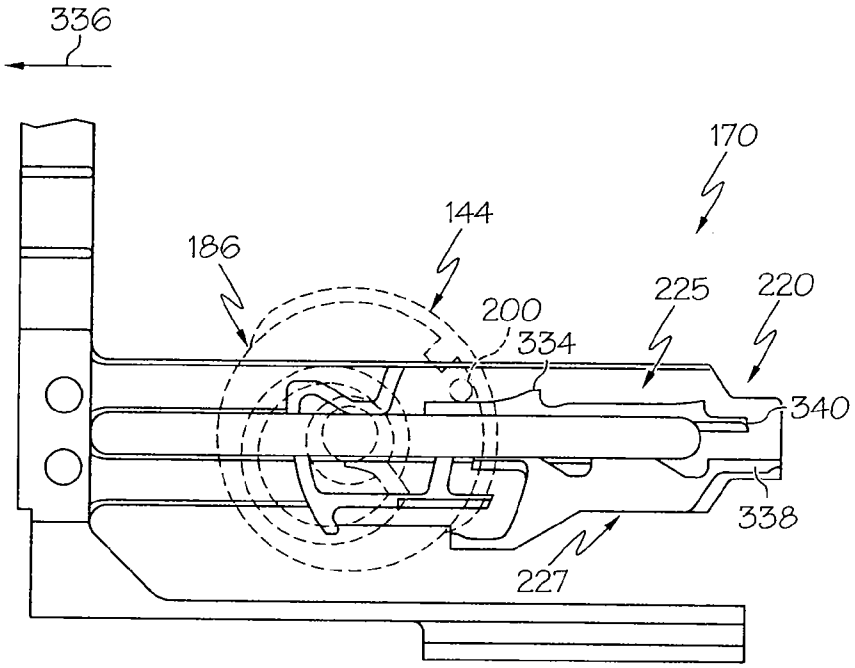

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FIG. 16

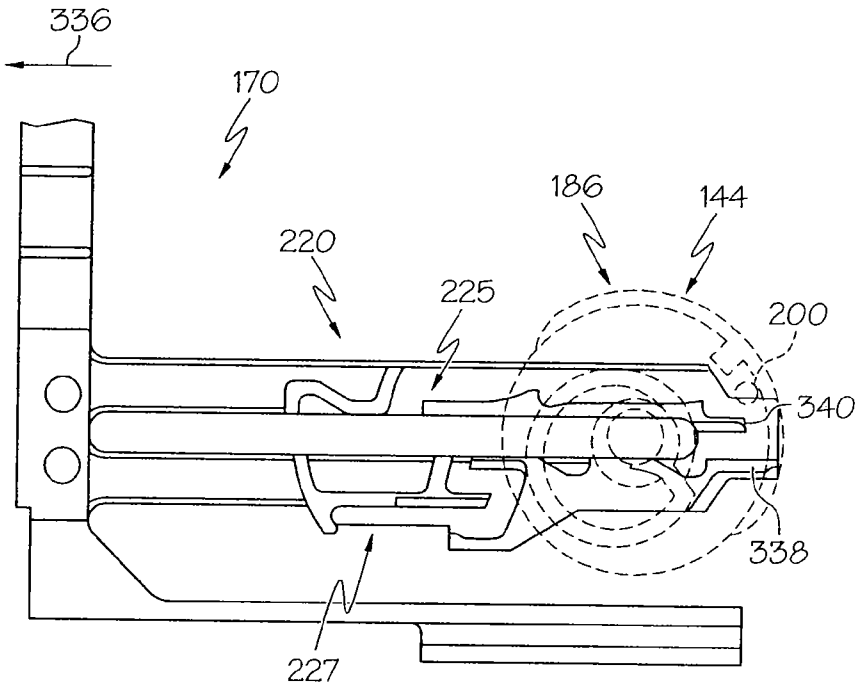

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FIG. 17

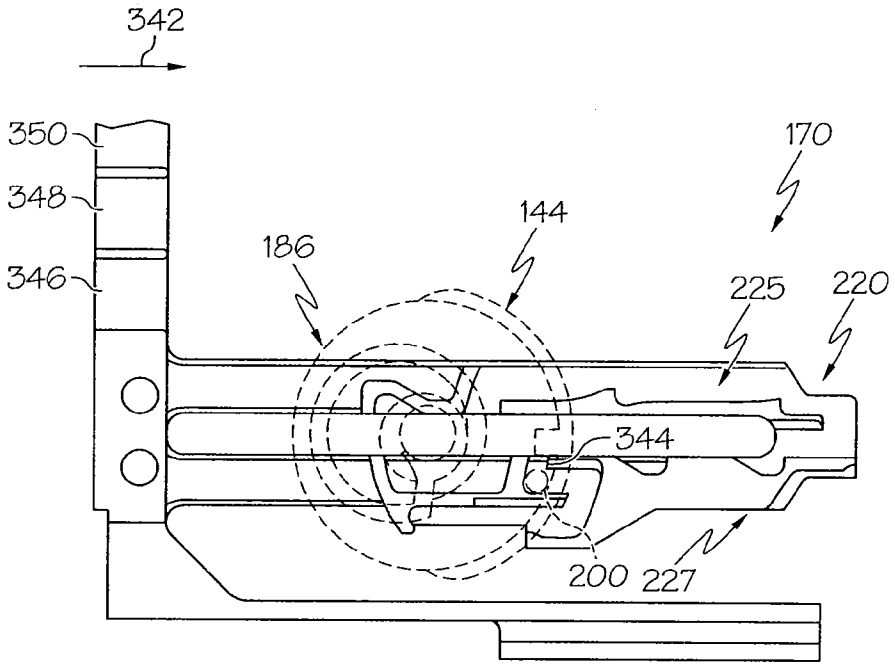

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FIG. 18

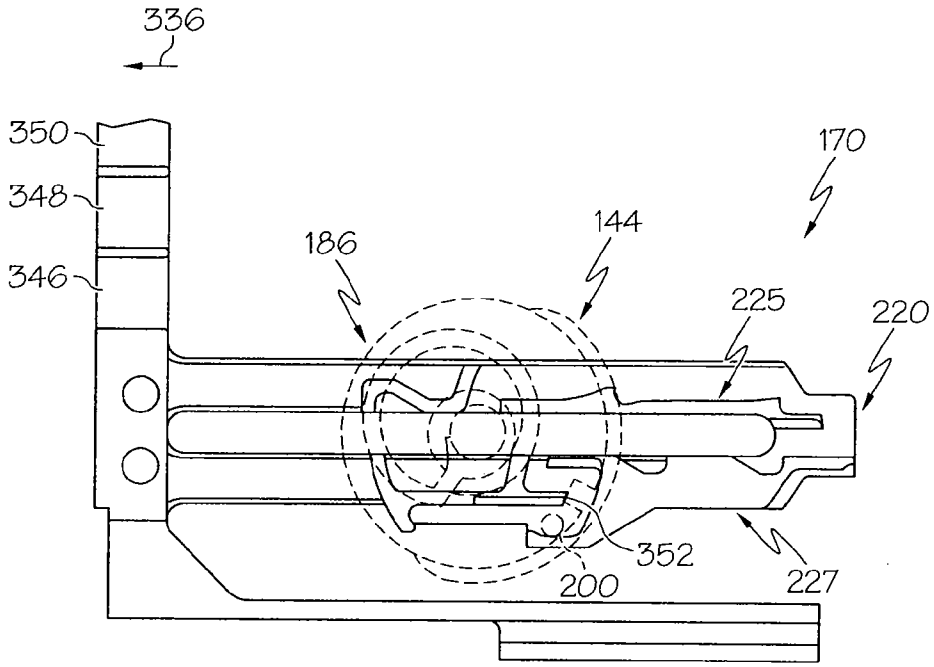

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FIG. 19

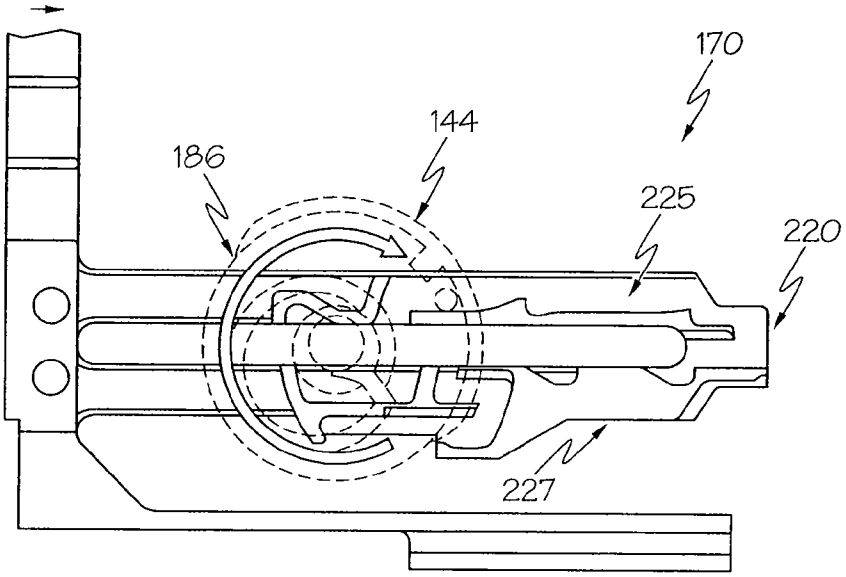

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FIG. 20

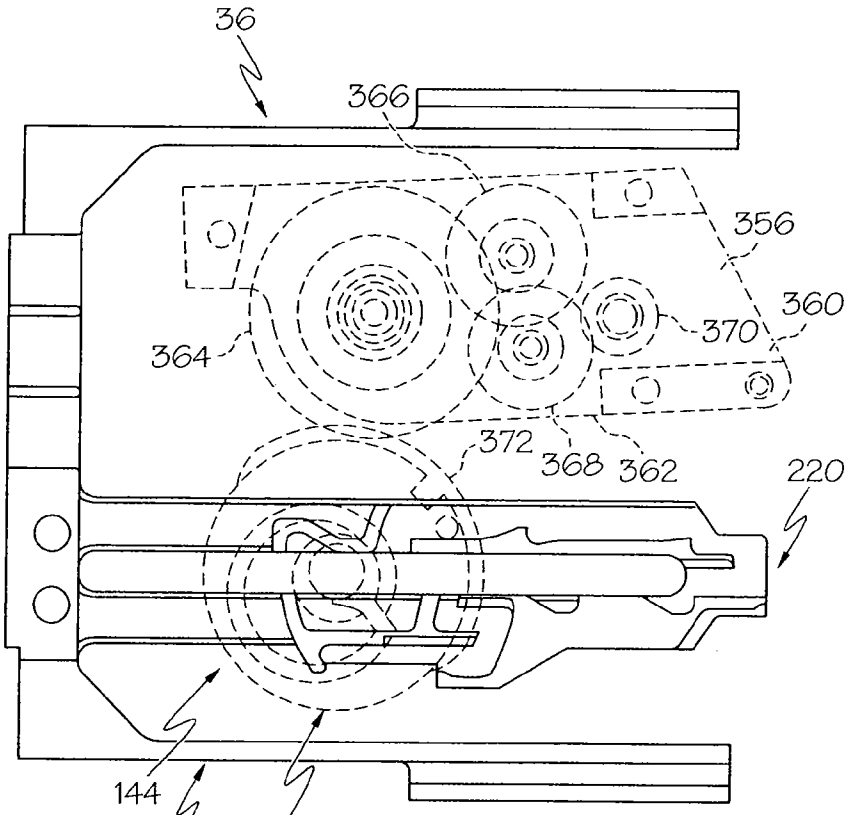

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FIG. 21

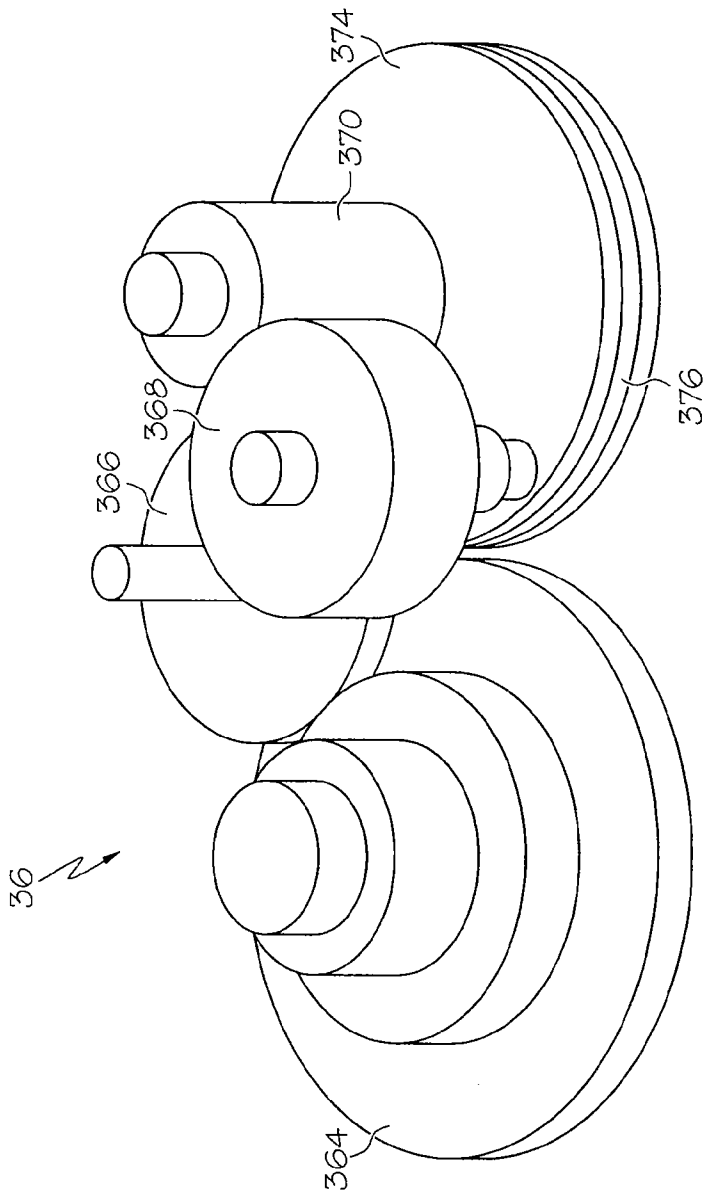


FIG. 22

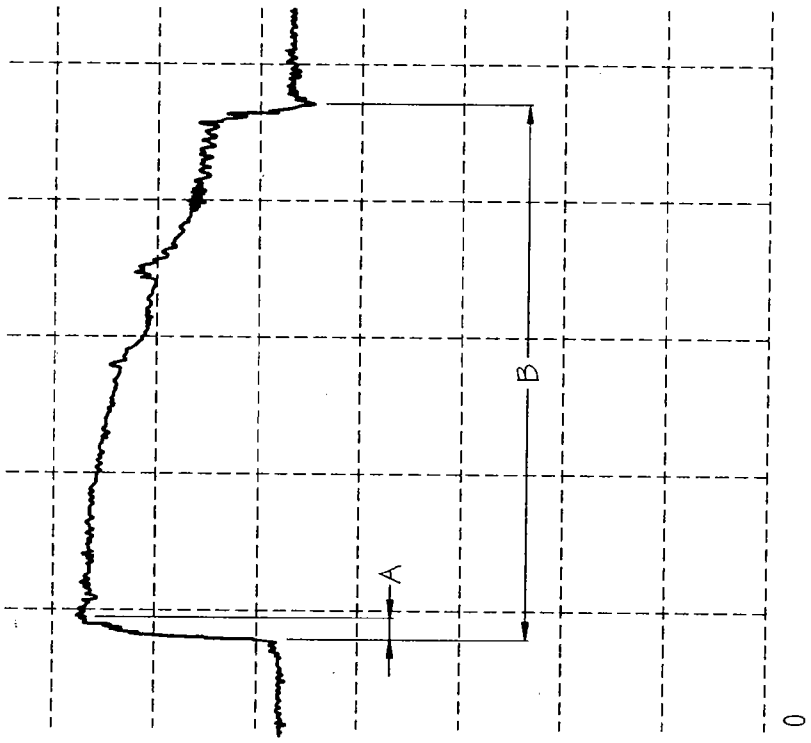


FIG. 23

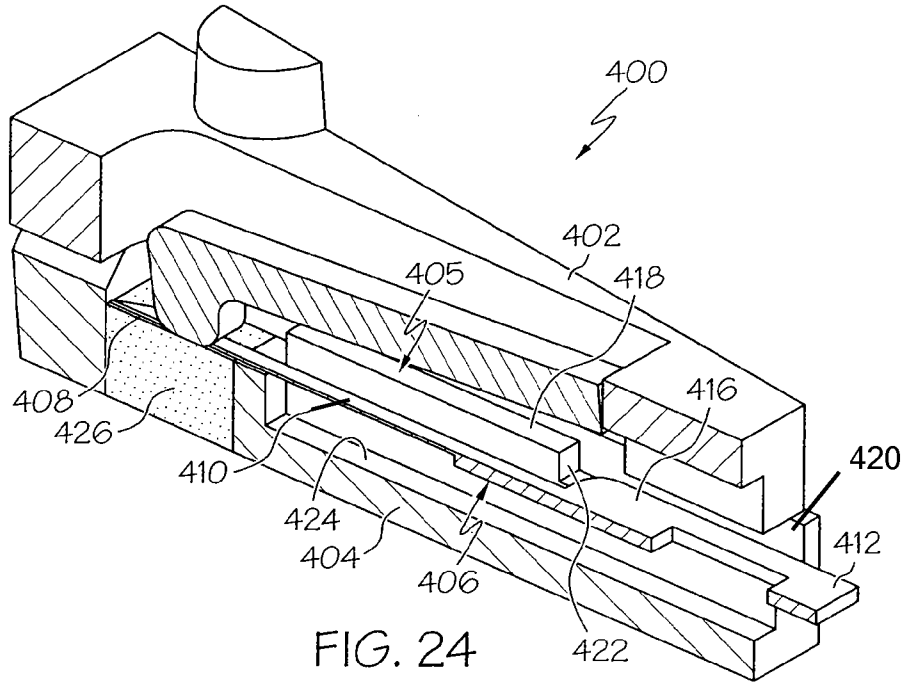

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FIG. 24

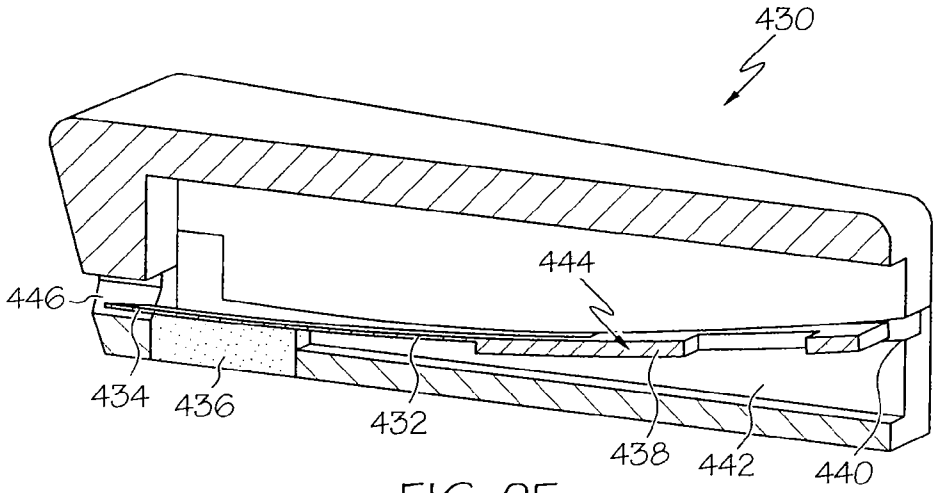

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FIG. 25

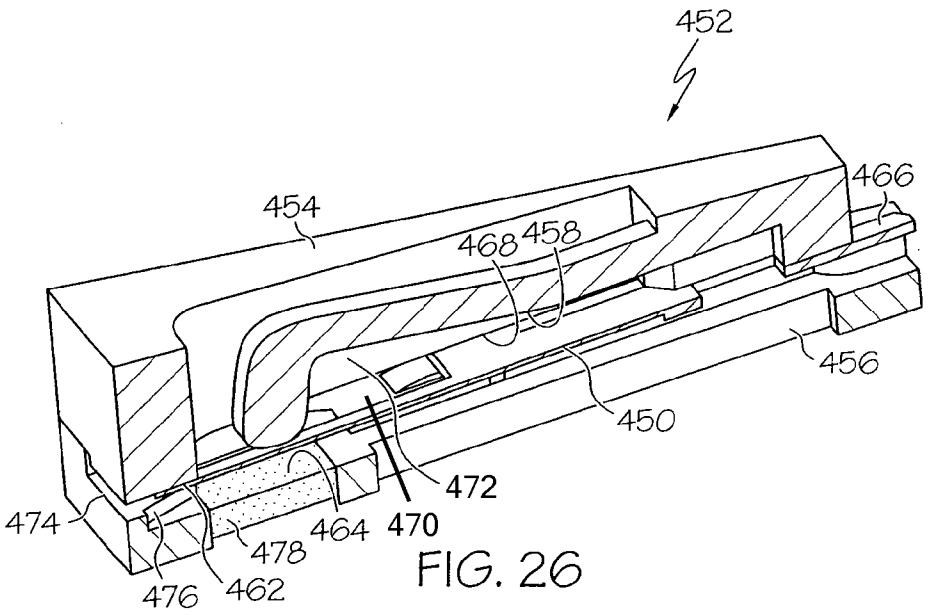

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FIG. 26

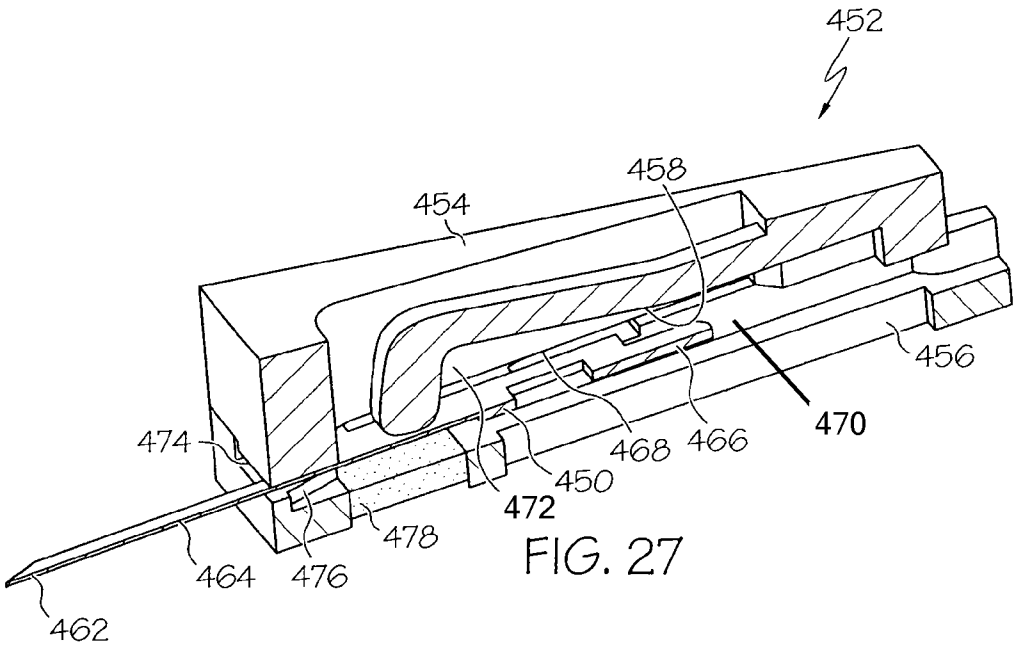

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FIG. 27

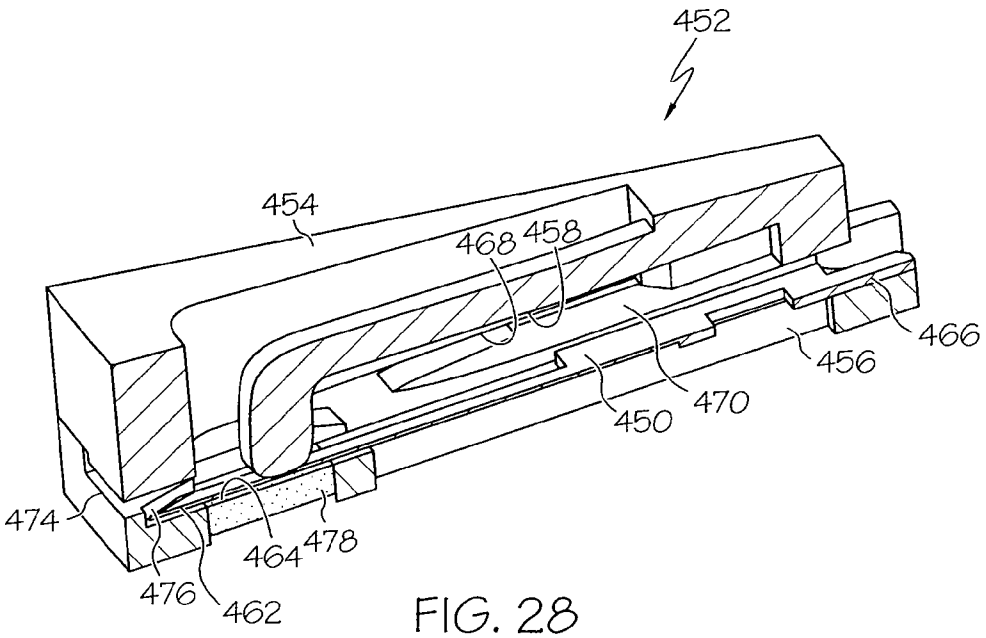


FIG. 28

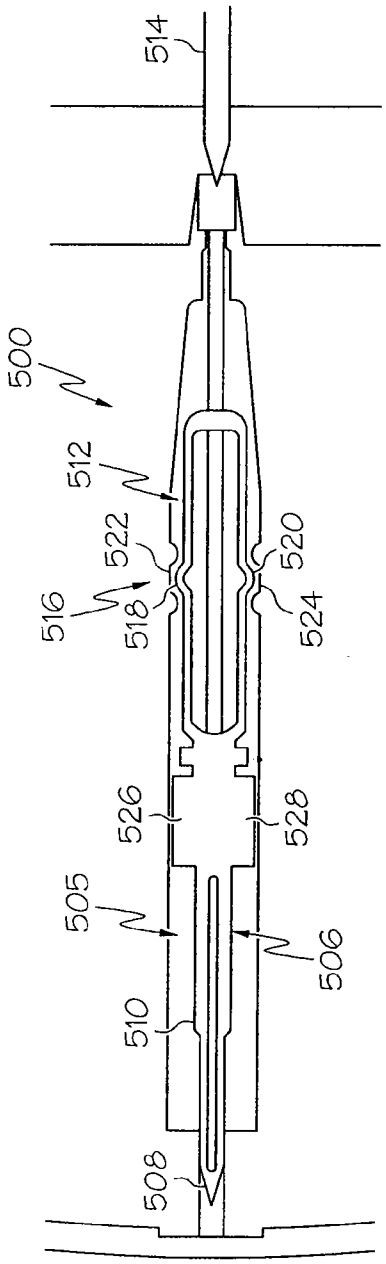

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FIG. 29

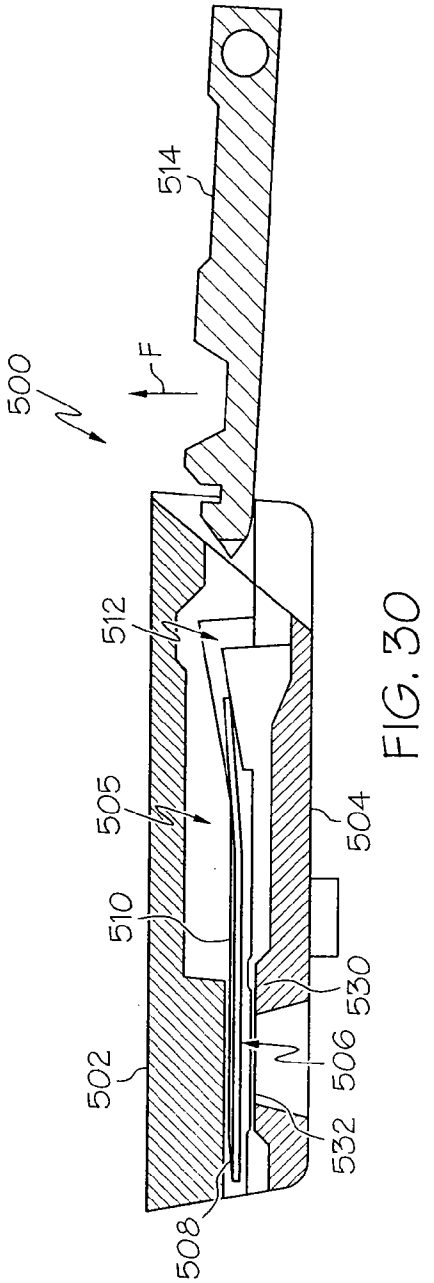

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FIG. 30

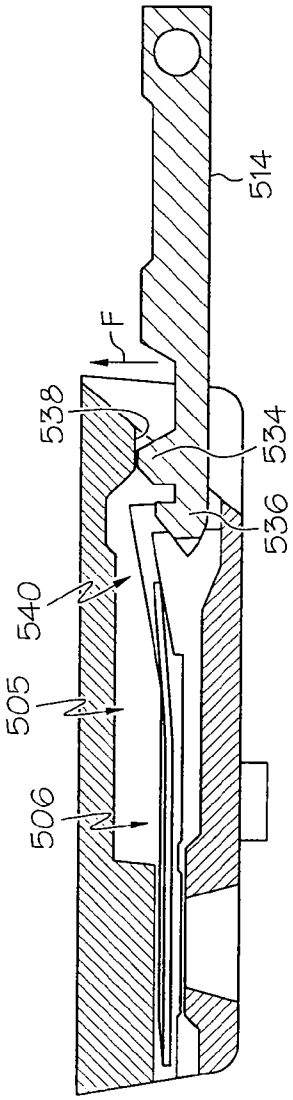


FIG. 31

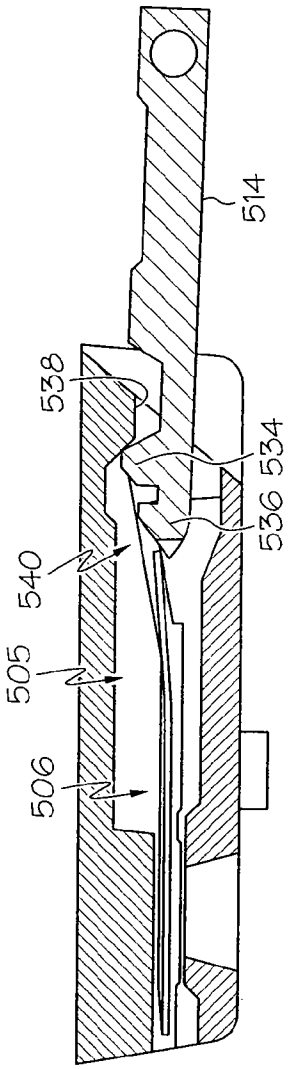


FIG. 32

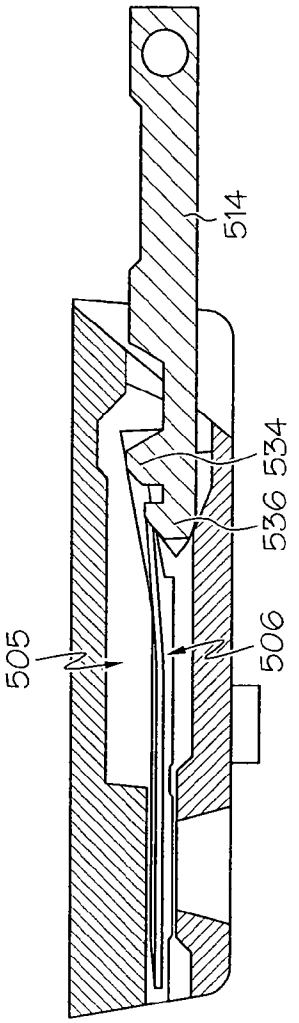


FIG. 33

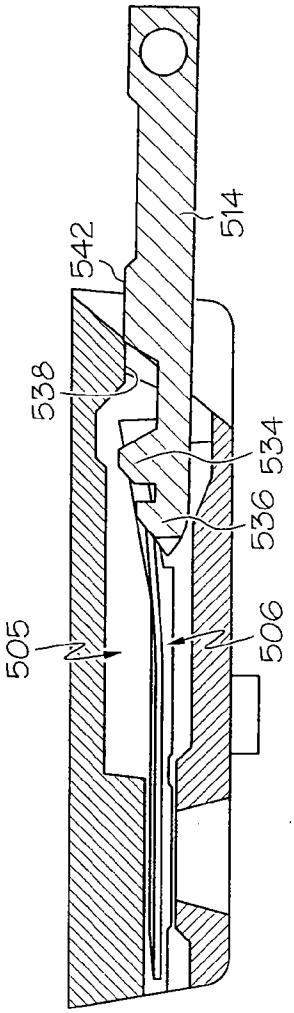


FIG. 34

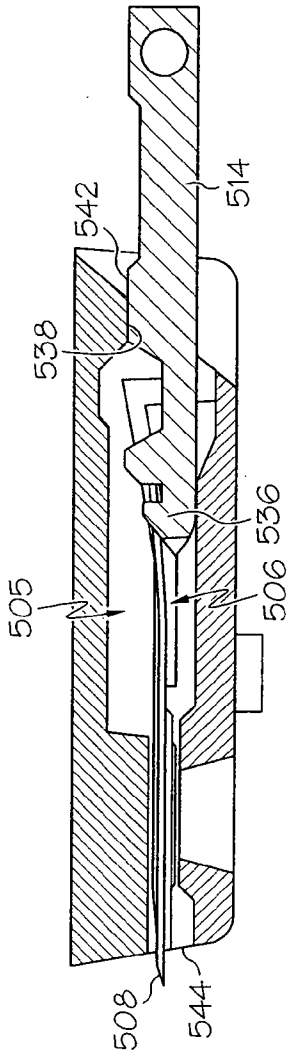


FIG. 35

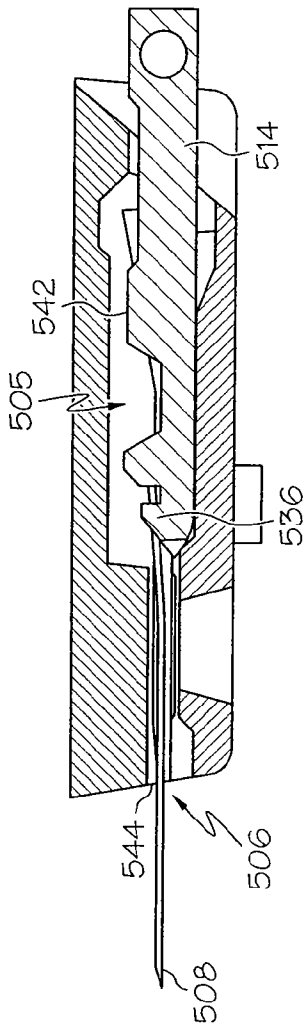


FIG. 36

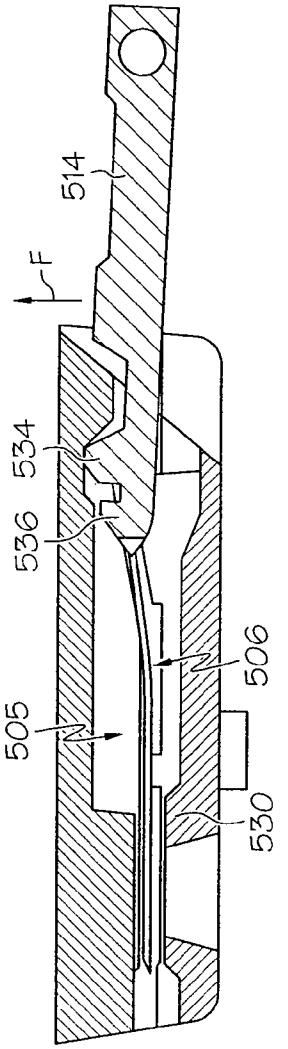

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FIG. 37

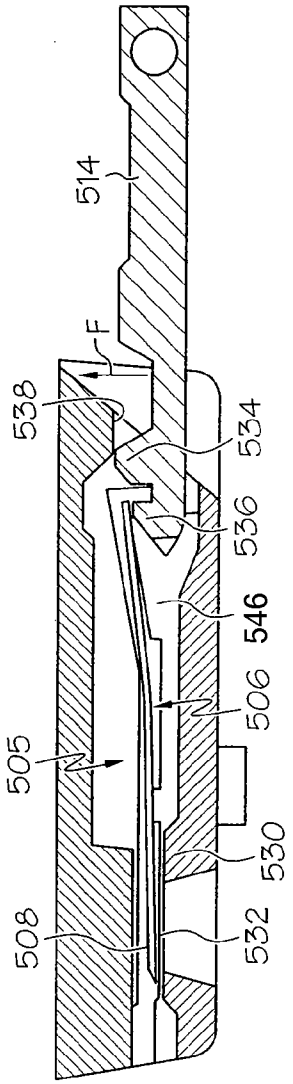

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FIG. 38

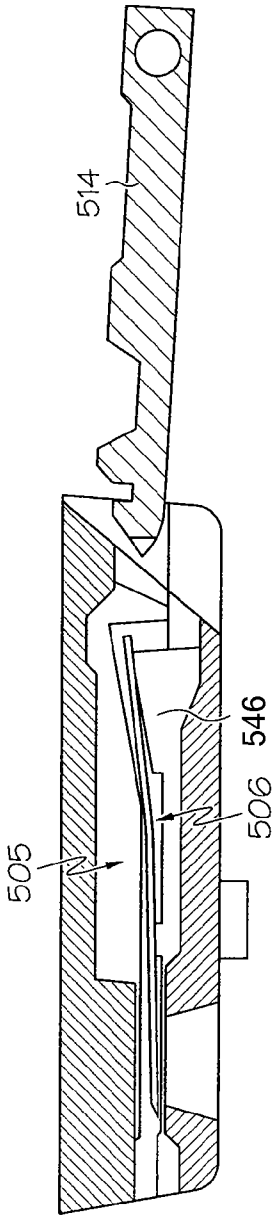


FIG. 39

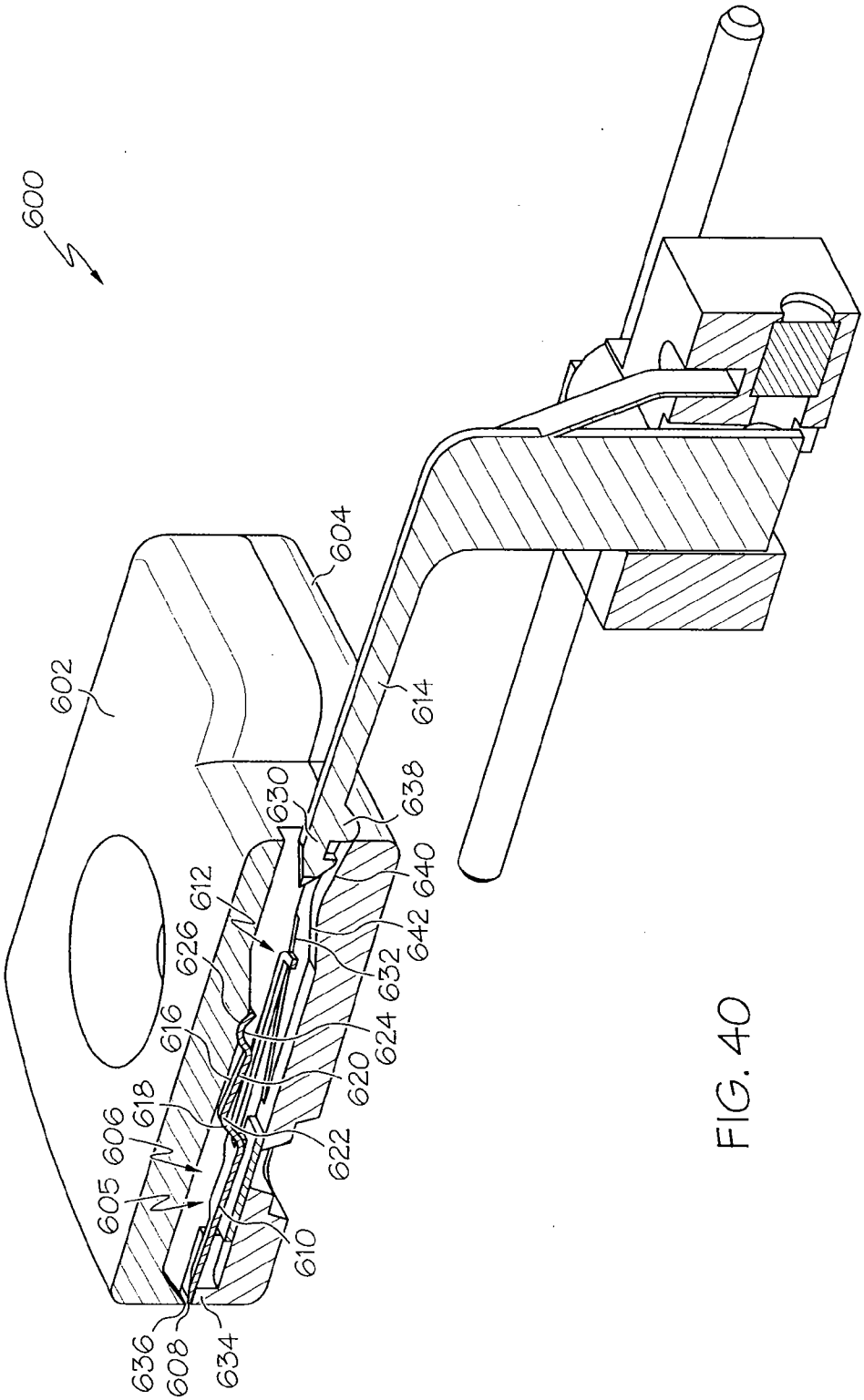

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FIG. 40

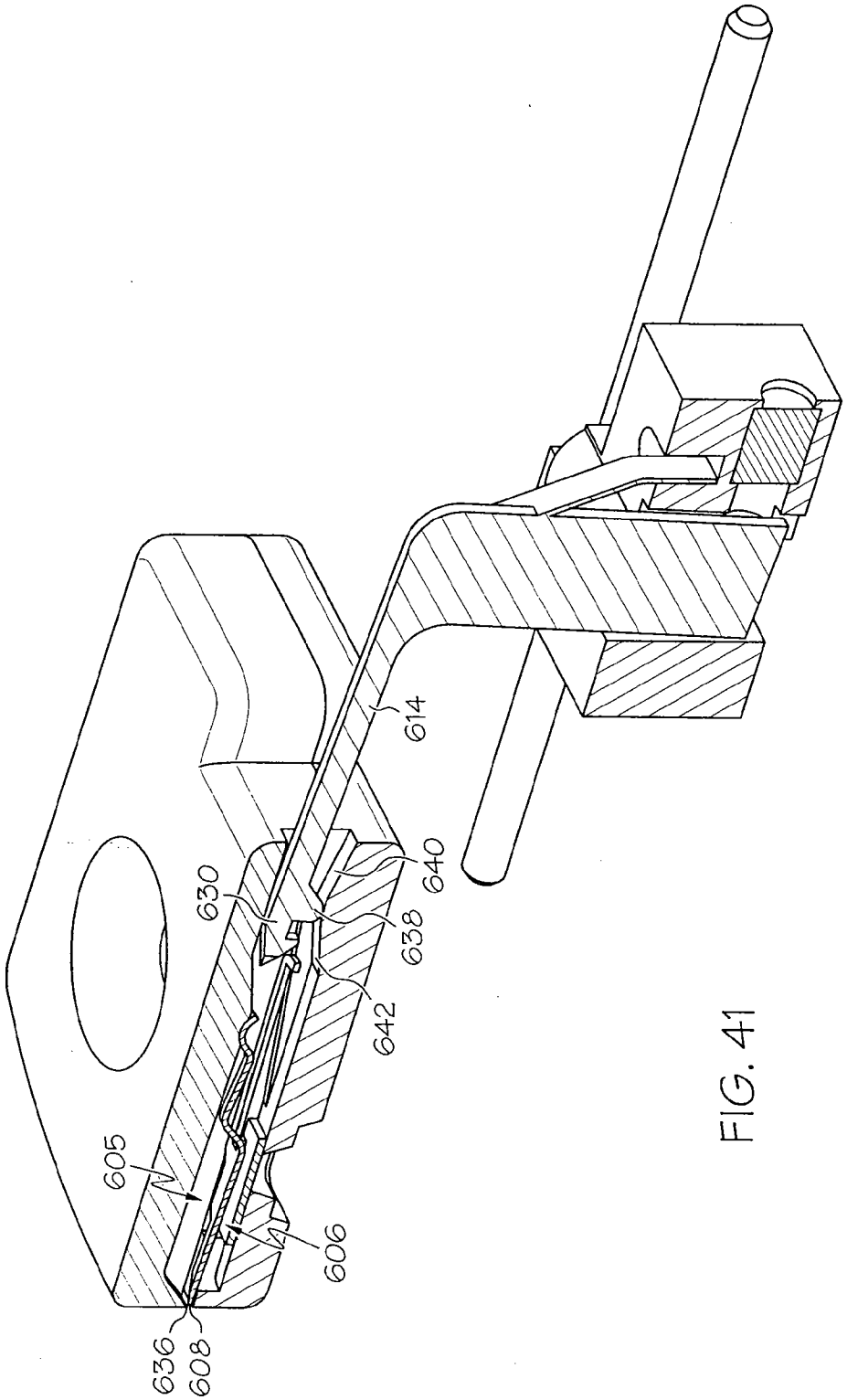


FIG. 41

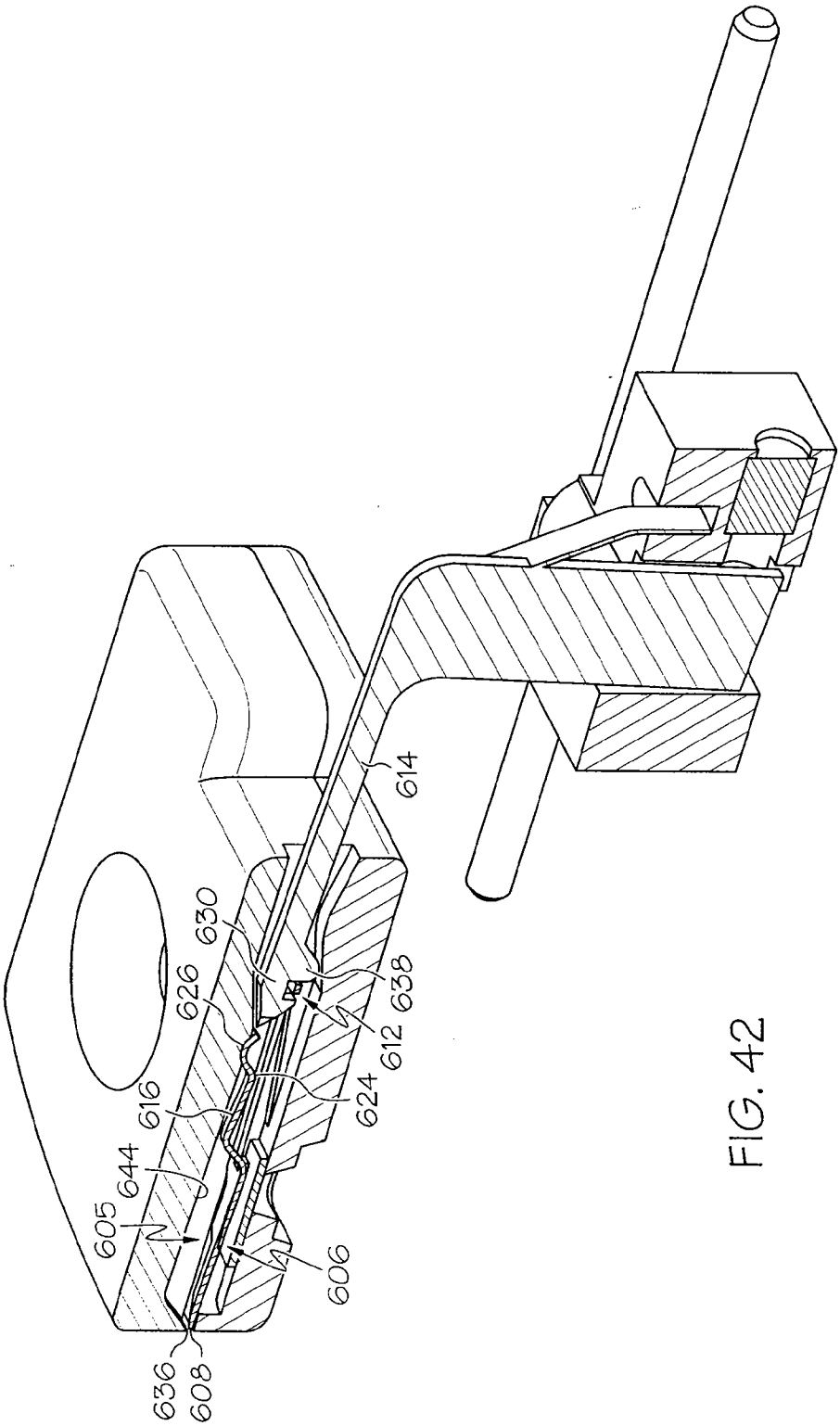


FIG. 42

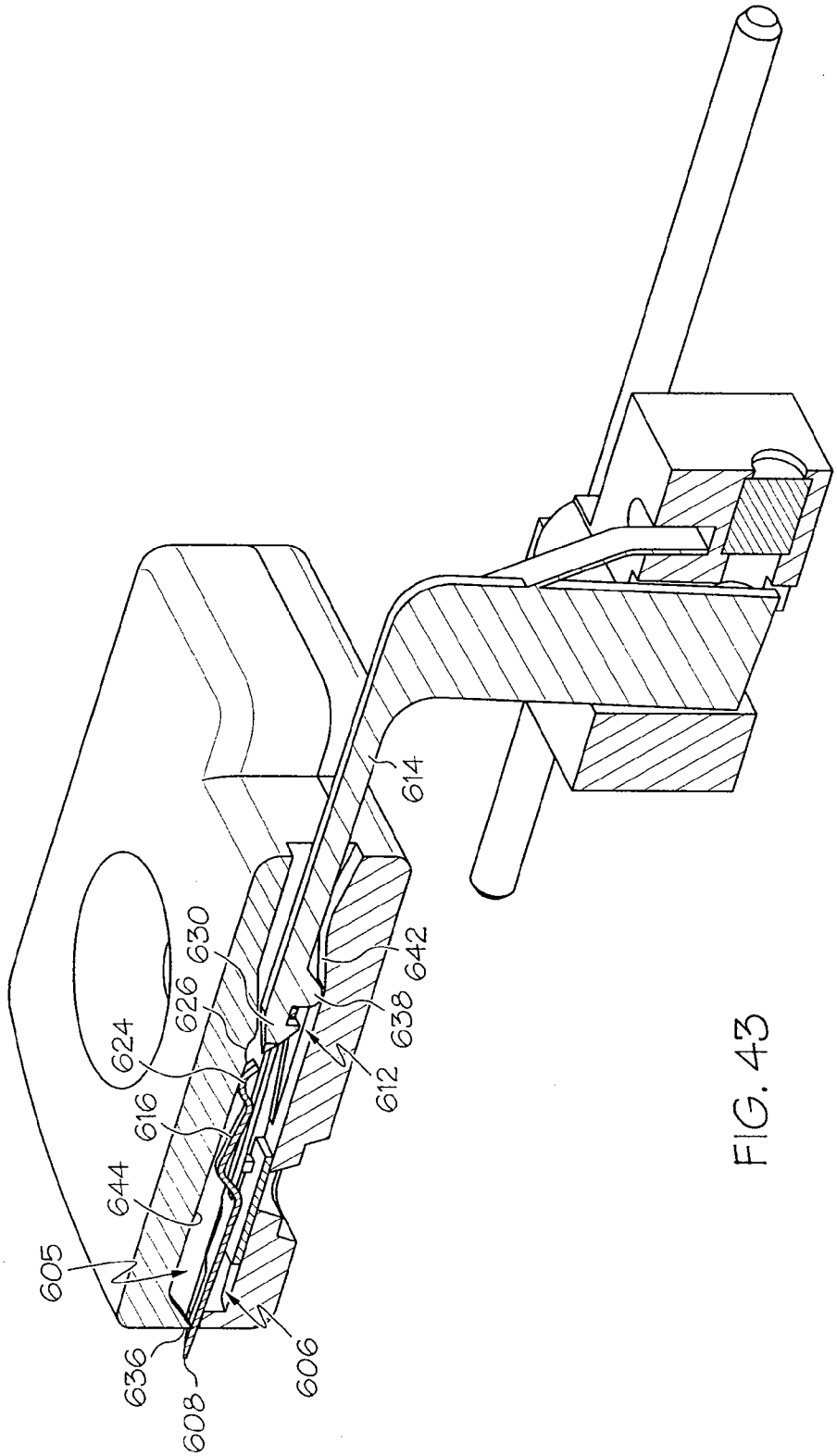


FIG. 43

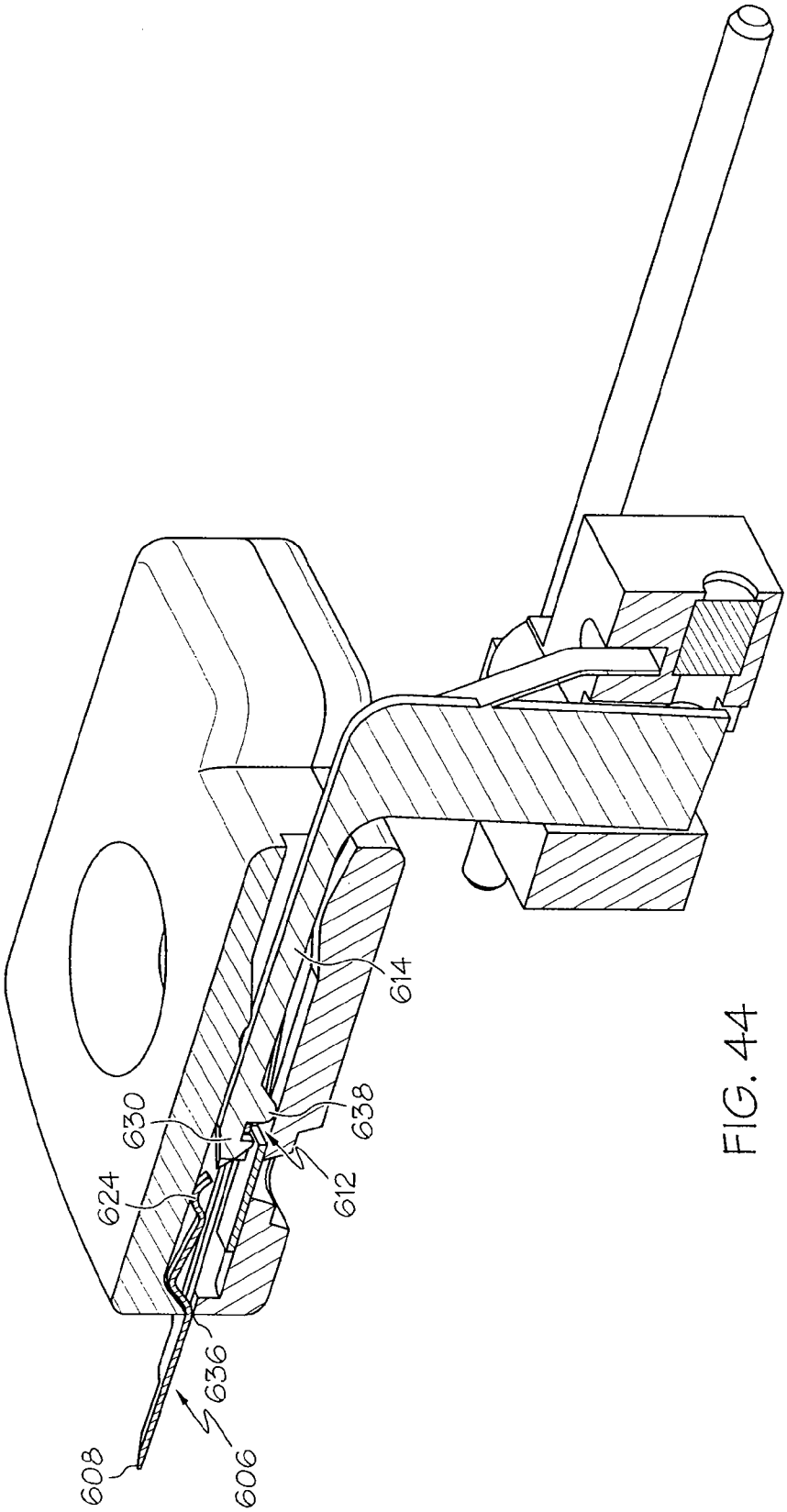


FIG. 44

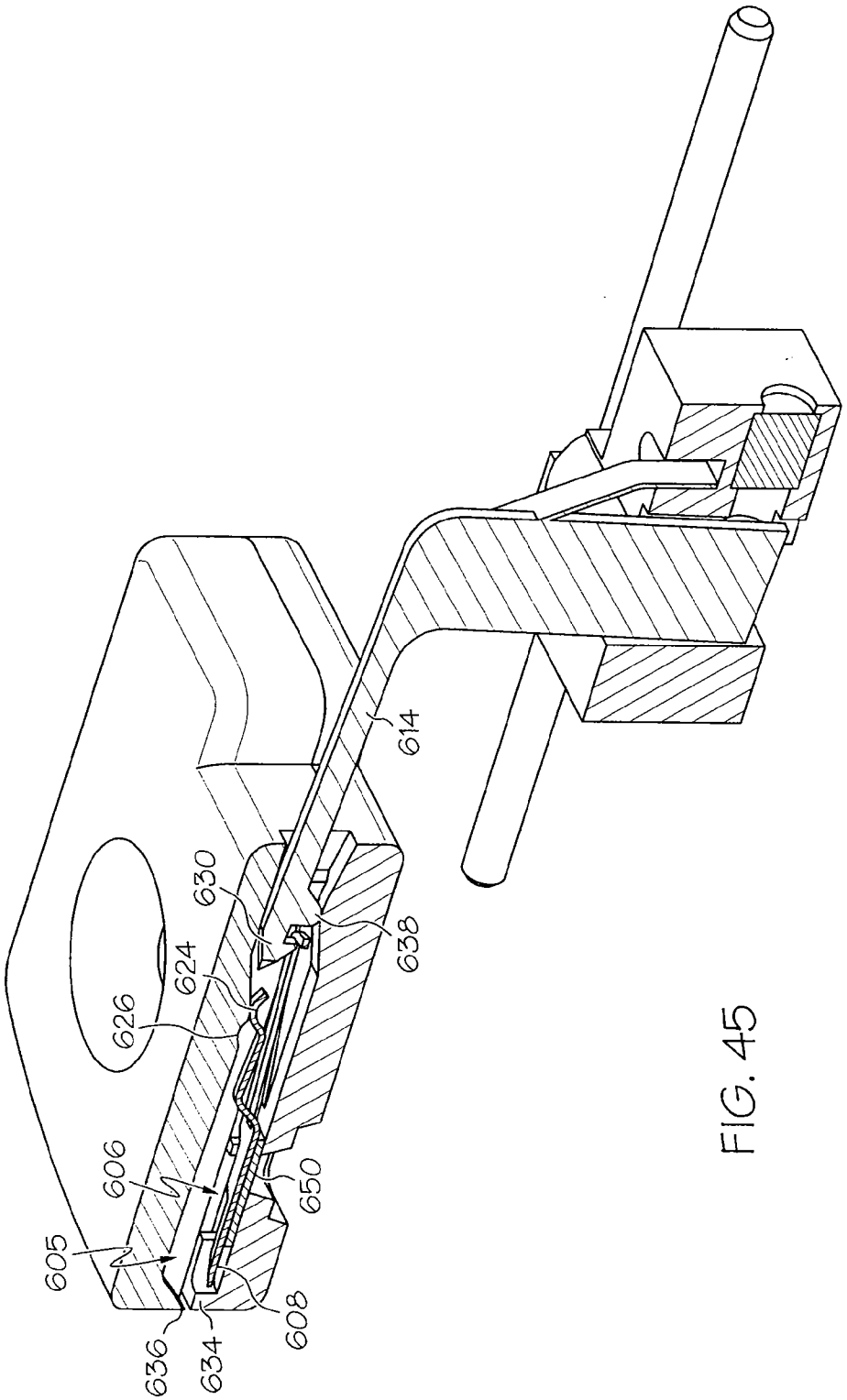


FIG. 45

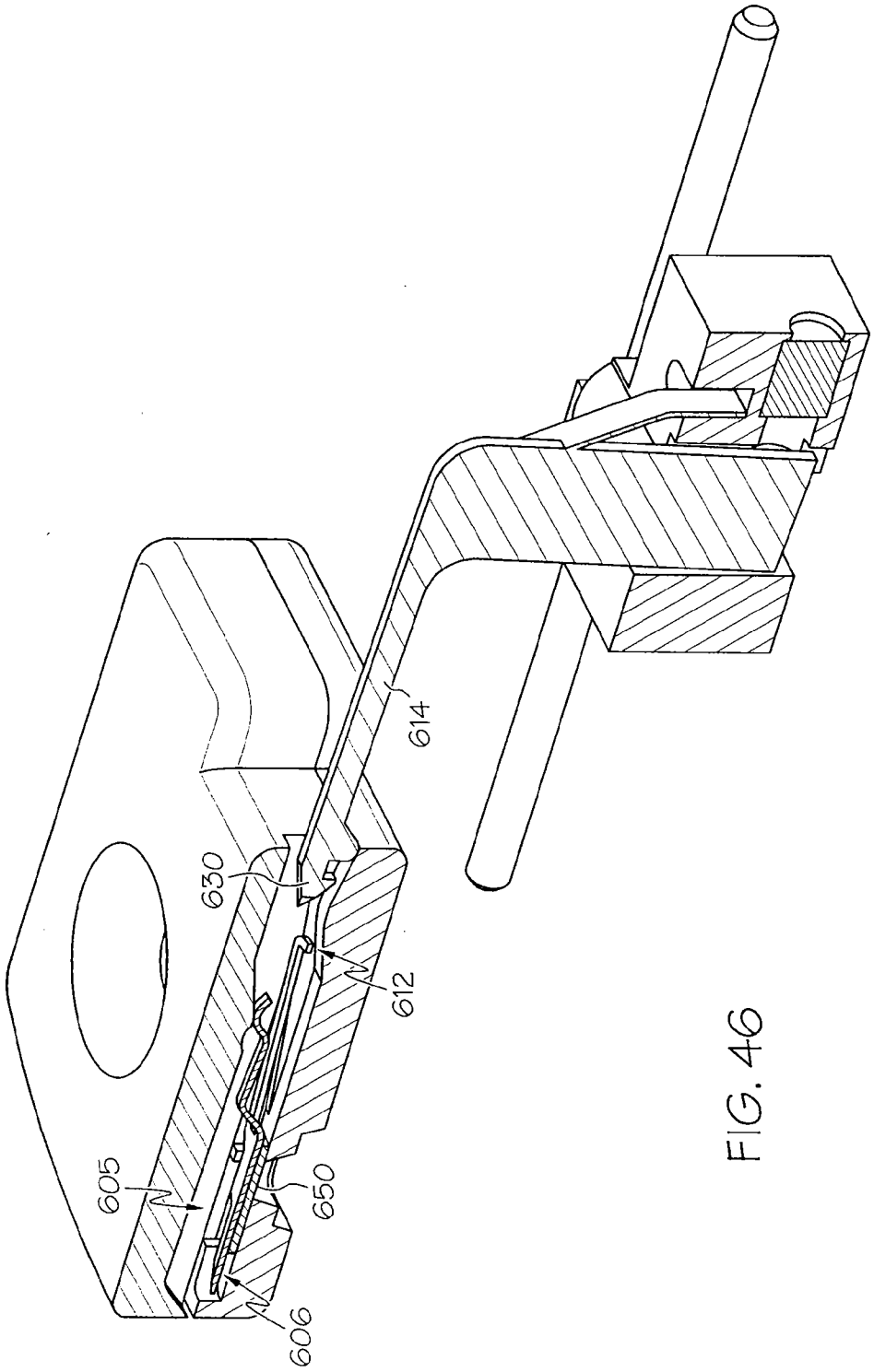


FIG. 46

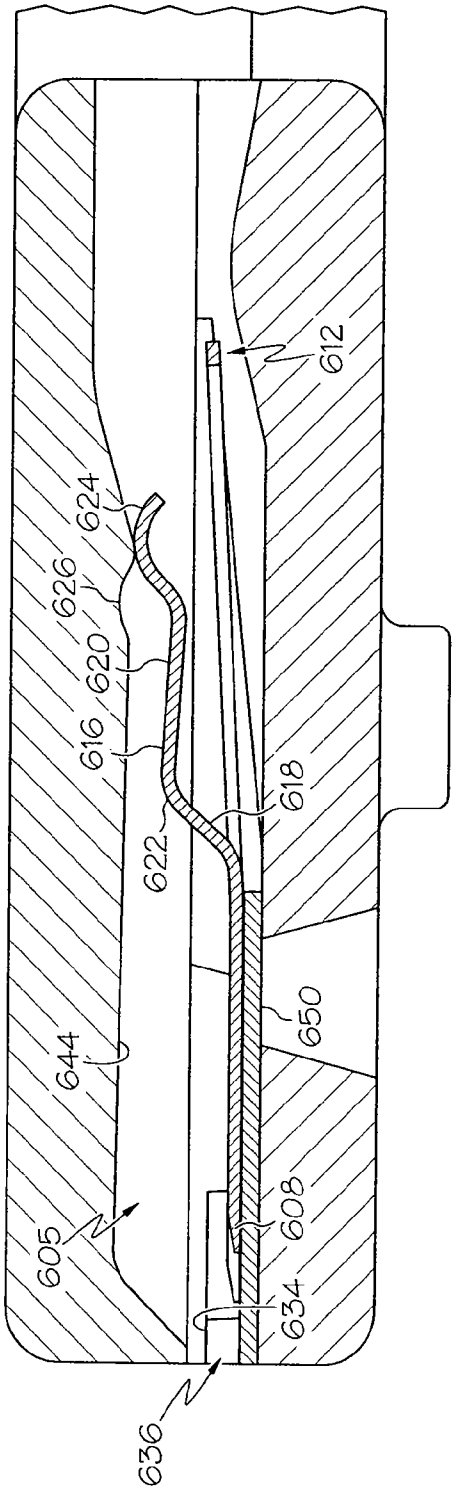


FIG. 47

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2011/072884

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B5/151 A61B5/15
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 2 226 007 A1 (ROCHE DIAGNOSTICS GMBH [DE]; HOFFMANN LA ROCHE [CH]) 8 September 2010 (2010-09-08) paragraphs [0067], [0071], [0076], [0077], [0094] - [0096] figures	1-5, 7-12, 14-20
X	US 2010/174211 A1 (FREY STEPHAN-MICHAEL [DE] ET AL) 8 July 2010 (2010-07-08) paragraphs [0154] - [0174], [0183] figures 33-47,49A,49B,66-69	1-20
A	EP 2 042 098 A1 (ROCHE DIAGNOSTICS GMBH [DE]; HOFFMANN LA ROCHE [CH]) 1 April 2009 (2009-04-01) paragraphs [0031] - [0036] figures 8-13	1-20

-/--

[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

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"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

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"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
16 February 2012	24/02/2012

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Schultz, Ottmar

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Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2011/072884

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X,P	WO 2011/044971 A2 (ROCHE DIAGNOSTICS GMBH [DE]; HOFFMANN LA ROCHE [CH]; LIST HANS [DE]; F) 21 April 2011 (2011-04-21) page 21, line 13 - page 22, line 12 figures -----	1-5, 7-12, 14-20

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP2011/072884

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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