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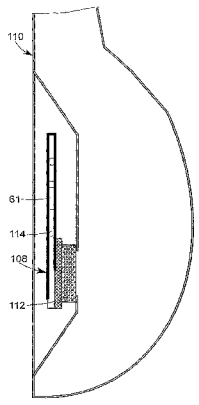
(54) **Title:** POINT OF CARE PHYSIOLOGIC PARAMETER DETECTION SYSTEM



(57) **Abstract:** Point of care sample preparation and test devices for in situ testing for the presence of physiologic parameters of interest based on analysis of excretions. Various embodiments of sample preparation and test devices for detecting the presence of markers consistent with infection or colonized pathogens reduce reliance on healthcare professionals ordering lab tests for such infections or pathogens by providing passive testing that resides in excretion collection devices already associated with patient care. Visual indicia activated upon the presence of predetermined markers within collected excretions alert the healthcare provider to potential infection. The indicia may be coded so as to be interpreted only by trained individuals.

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POINT OF CARE PHYSIOLOGIC PARAMETER DETECTION SYSTEM

Field of the Disclosure

[0001] This disclosure relates generally to the field of detection of physiologic parameters within humans and animals. More specifically, the disclosure relates to apparatus and methods associated with sensors embedded within point of care collection, sampling and diversion apparatus for detecting specific physiologic parameters contained in human or animal effluent, such as fecal output. These apparatus and methods are congruent with collection and diversion systems used to sample and collect physiologic specimens.

Background of the Disclosure

[0002] Historically, human and animal physiologic diagnostics have primarily relied on invasive sampling techniques such as the sampling of serum, blood or excised tissue through the use of needles, trocars, and surgical excision. Most of the traditional sampling techniques are designed for examination of a specimen away from the point of care (POC) in a lab or other non-POC environment. The current sampling methodologies almost always involve an active decision followed by a specific intervention by a healthcare professional as well as often a lab or examination technician. In general, an active decision must be made to obtain and process the specimen, even if it is readily available. An inquiry is often initiated only after clinical suspicion is raised in a patient or cohort for a possible explanation of a clinical situation or to rule out some asyptomatic condition.

[0003] For example, the common stool guaiac test for occult blood involves taking a smear of feces directly from the rectum or from a fecal collection device. The smear is placed on a special card and then a reagent is deposited to perform the test. This test can be performed at the point of care (POC) and results are nearly immediate. More

elaborate tests for infectious agents or colonized pathogens such as Clostridium difficile or A. baumannii in human or animal stool require sending a properly obtained and handled specimen to the laboratory to be processed. This may require batch processing and results could take days. Both examples require an active decision be made to test for the desired physiologic parameter. That decision often requires clinical acumen or specific protocols for sampling for identified at-risk populations. Lab testing and detection of disease causing microorganisms in human fecal specimens is not commercially available today by some rapid diagnostic techniques.

[0004] Generally fecal organisms or their toxins are identified by laboratory techniques only. The most common technique is culturing. An example of a commercially available Clostridium difficile test kit is the latex agglutination lab diagnostic test kit by Meridian Meritec. This test kit requires the transfer of a specimen from a fresh or frozen stool sample to a test card. A reagent mixture is then added and within 20 minutes a result is obtained. This type of kit has many drawbacks, the least of which is the continued exposure of the specimen collector and laboratory worker to the specimen.

[0005] There has been much work on test methods that improve the time and accuracy of physiologic parameter testing. For example, DNA testing and other photo reactive equipment have increased the speed of the laboratory work involved in many testing techniques.

[0006] The traditional physiologic specimen collection and analysis methods have several disadvantages even with the above-mentioned improvements. Namely, that a decision to initiate screening for a desired physiologic parameter is required before the detection process and intervention can begin, lab or other non-POC testing lead-time is often lengthy, lab testing often requires individual samples for each test to be packaged

by one individual and delivered by currier to a lab, lab processing often requires multiple test kits and reagents to be stocked, and processing error could confuse lab test results with another subject. Thus, lab testing often requires complex systems to decrease errors.

[0007] Thus, there is a need in the art for an apparatus and method of point of care physiologic sampling that both limits the time for decision-making, collection and analysis of the samples. It is desired that a system be real time monitoring without the requirement of a repetitive decision or action by a health care provider. Another advantage over current methodologies would be a closed system whereby no exposure to the physiologic matter by the health care provider or the lab technician would occur.

Advantages

[0008] The methods and apparatus of the present disclosure have several advantages over the art described, including but not limited to: There is no dependency on a conscious decision to screen for a physiologic parameter, because the screening for the parameter is passively performed during routine use of a collection device; the disclosed methods and apparatus allow for more timely implementation of precautions and treatments; The disclosed methods and apparatus drastically reduce testing lead-time; The disclosed methods and apparatus may be conducted at the point of care using visual verification from a line of sight sensor; all components of the test are embedded in a routinely used diversion/collection device and discarded with the device; the disclosed methods and apparatus avoid handling of potentially infectious specimens or biohazard materials, thereby reducing exposure of healthcare professionals and patients or surrounding persons or animals to the samples; the disclosed methods and apparatus pose a reduced risk of patient identity confusion or cross-contamination of samples; and the disclosed methods and apparatus allow for clear results that are immediately reported

to the health care provider without any additional human intervention once the patient is connected to the collection system.

Summary of the Disclosure

[0009] The methods and apparatus of the present disclosure include a novel method of providing point of care (POC) capability for detecting human or animal physiologic parameters, such as infection or the colonization of pathogens in feces, using sensors integrated with a system specifically designed to collect physiologic output or integrated within sampling devices. One embodiment of the invention works in conjunction with a system designed to divert and contain the human fecal stream. The methods and apparatus disclosed herein apply existing visual sensor indicators to detect specific pathogens in stool by means of a stool sample port on a bowel management catheter, or integrated onto the inner panel of an effluent collection device in close proximity to a human, such as a stool collection bag that may be part of the fecal diversion/collection system or a stand alone collector for fecal incontinence or for ostomy appliances. In other embodiments the sensor may be embedded in any human effluent container, or sampling device such as a specimen cup or a syringe. In these embodiments, the sensors alert the caregiver to the presence of a specific pathogen or group of pathogens found in the effluent of the patient in a passive manner. The communication of the presence of the pathogen may be conducted through multiple embodiments of communication systems such as visual, remote, electronic, digital, audio, or other equivalent communication means. Appropriate treatment or changes in patient protocol may then be initiated based upon the detection of a particular pathogen thereby expediting the change in treatment for the patient that otherwise may have been delayed or not conducted.

[0010] In certain preferred embodiments hereof, the present disclosure incorporates the fecal collection and preparation steps with an assay itself inside a fecal collection bag. This combination eliminates multiple sample preparation and assay manipulation steps present in other tests. As a result of these changes the fecal assay is easier to carry out and no additional parts or equipment are needed. For example, a separate sample collection device is not required. Further, a separate filter membrane and centrifugation step is not required. Furthermore, no additional fluid addition steps are required.

[0011] The methods and devices of these preferred embodiments of present disclosure include the following advantages:

[0012] The methods and devices eliminate or reduce the complexity associated with prior art assay methods and, as a result:

[0013] • Reduce the complexity of testing fecal samples for the healthcare provider by reducing the number of steps required to execute the test

[0014] • Allow for more timely implementation of precautions and treatments as testing lead time is drastically reduced and conducted at the point of care

[0015] • All components required for the test are embedded within the collection bag and discarded with the bag. For example, a separate sample collection device is not required. Further, a separate filter membrane and centrifugation step is not required. Nor are separate fluid addition steps required.

[0016] • Eliminate handling of potentially infectious specimens or biohazard material by the healthcare provider or lab technician, i.e., sample is collected and tested within collection bag.

[0017] • Lower the cost of detecting physiologic parameters present in fecal samples.

[0018] • Reduce the risk of patient identity confusion.

[0019] • Provide test results directly to principal caregiver with no intermediary required.

[0020] Additionally, using the embodiments of the present disclosure, the decision to test for a physiologic parameter is not required because the parameter is automatically obtained during routine use of a collection bag, rather than based on clinical suspicion or hospital protocol.

[0021] The embodiments of the disclosure allow for more timely implementation of precautions and treatments as testing lead time is drastically reduced and conducted at the point of care using visual verification from line of sight sensor.

[0022] All components required for the test are embedded within the collection bag and discarded with the bag. For example, a separate sample collection device is not required. Further, a separate filter membrane and centrifugation step is not required. Furthermore, no separate fluid addition steps are required.

[0023] The embodiments disclosed eliminate handling of potentially infectious specimens or biohazard material by the healthcare provider or lab technician.

[0024] The disclosed embodiments also allow for clear results that are immediately reported to the healthcare provider without any additional human intervention once a patient is connected to the collection system.

[0025] In addition, the disclosed embodiments lowers the cost of detecting physiologic parameters present in fecal samples.

[0026] In a preferred embodiment, the fecal sample test device of the present disclosure is disposed in the collection bag of a bowel management system, such as the bowel management system disclosed in U.S. Patent No. 5,561,216 or U.S. Patent Application No. 10/225,820, which are incorporated herein by reference (except to the

extent those documents incorporate by reference other documents), in such a manner that fecal matter inside the collection bag will come in contact with the fecal sample test device. An advantage of this embodiment is that the device is incorporated within a closed system thereby protecting the healthcare provider, the patient and the healthcare environment from exposure to the fecal matter being analyzed.

[0027] The method of this embodiment of the disclosure comprises the steps of: A) collecting a patient's fecal output within a collection bag; B) presenting a fecal sample to the device C) preparing the fecal sample for the assay; D) contacting the sample to the assay such that the physiologic parameter present in the sample is transferred to the assay; and E) detecting the presence of the physiologic parameter by said assay. (Steps A and E can be performed in an order differing from the order in which they are listed here).

[0028] In one example of a preferred embodiment, the fecal sample test device is placed along the inside face of the collection bag. The device comprises; A) a sample collection element; B) a sample preparation element; and C) a sample assay element.

[0029] The **sample collection element** of the device is comprised of the formed front and rear panels of the collection bag. In this case, the collection bag is a sample reservoir and as the bag fills, the sample is presented to the device.

[0030] The **sample preparation element** of the device comprises a particulate filter used to capture fecal debris and other interfering substances, and an extraction reagent used to extract the analyte from the fecal sample. The porosity of the filter can be chosen based on optimal separation of test analyte from interfering fecal substances during operation of the device. Porous plastic, plastic membrane, glass fiber and the like, having the ability to filter to at least 100 microns, are suitable for the filter. Those skilled in the art will be able to determine acceptable filters for these purposes. Suitable

extraction reagents include aqueous solution with any variety of salts including sodium chloride, sodium phosphate, ethylene diamine tetra acetic acid (EDTA) salts or others. The extraction reagent may contain a preservative to maintain the integrity of the sample and minimize degradation. This preservative serves to inhibit proteolytic properties of enzyme materials that can cause destruction of the antibodies being tested with the device. Types of preservatives include enzyme inhibitors, anti-bacterial agents, bacteriostatic molecules such as sodium azide and thimerosal, and anti-fungal compounds among others. The extraction reagent may also include a detergent material to facilitate analyte release. Examples of detergents include: deoxycholate, Tween-20, triton X-100, and sodium docedyl sulfate. Alternatively, the device may contain a non-fluid containing extraction reagent also known as a dry extraction reagent. The advantages of a dried extraction reagent are ease of storage and handling. Those skilled in the art will appreciate there are many possible agents capable of being used as extraction reagents. The combinations and concentrations of any agents used as part of the sample preparation process will be optimized for the pre-selected physiologic parameters being detected.

[0031] The sample preparation element of the device of various embodiments of this disclosure utilizes both positive and negative pressures to collect, partition and concentrate analytes of interest from bowel contents before presenting the fecal specimen to the assay. Specifically, in one preferred embodiment, compression of the device housing creates a positive pressure within the device which in turn expels a fixed volume of air from inside the device. Release of the housing creates a vacuum which in turn draws a fixed volume of sample into the device.

[0032] Alternately, manipulation of the device such as compression, can initiate a chemical reaction to produce gas expansion which will assist in sample collection, filtration and analyte extraction prior to analysis.

[0033] In further alternate embodiments, hydrostatic pressure, exerted by the collection of effluent within the collection bag, is utilized to partition and concentrate analytes of interest from bowel contents before presenting the fecal specimen to the assay. Specifically, the collection bag is shaped in such a manner so that an increase in the effluent volume within the bag results in an increase in hydrostatic pressure which assists in the filtering and extraction of the analyte prior to analysis.

[0034] The **sample assay element** of the device is an immunoassay which comprises a porous strip containing immunoreagents for detecting a preselected physiologic parameter. In the preferred embodiments, the assay element of the fecal sample collection and test device is an immunoassay. However, the means of fecal sample preparation presented in this disclosure could be applied to detection technologies other than immunoassays such as: another antibody-type test, an electronic sensing device, a photosensitive element, a combination of electrical and mechanical elements such as Micro-Electro Mechanical System (MEMS), a nanoparticle element capable of detecting target proteins and / or nucleic acids, or a micro extraction element capable of extracting and analyzing gaseous or aerosolized compounds from a headspace above the effluent.

Brief Description of the Several Views of the Drawing

[0035] Fig. 1 is a perspective view of a fecal collection bag with a wafer style sensor module attached in accordance with an embodiment of the present disclosure;

[0036] Fig. 2 is a plan view of the wafer-style sensor module;

[0037] Fig. 3 is a cross sectional view of the wafer-style sensor module;

[0038] Fig. 4 is a plan view of a multiple visual indicator module;

[0039] Fig. 5 is a plan view of a single view indicator module;

[0040] Fig. 6 is a perspective view of a specimen bowl equipped with a strip style sensor of the present disclosure;

[0041] Fig. 7 is a plan view of a strip style sensor;

[0042] Fig. 8 is a plan view of a sampling syringe with a strip style sensor module attached in accordance with an embodiment of the present disclosure;

[0043] Fig. 9 is a plan view of the strip style sensor module attached to the barrel of a syringe, which is partially broken away;

[0044] Fig. 10 is a cross sectional end view of a syringe, broken away, with a strip sensor attached thereto;

[0045] Fig. 11 is a bottom view of a syringe with a strip sensor attached thereto;

[0046] Fig. 12 is a cross section view of a syringe-mounted strip sensor module;

[0047] Fig. 13 is a perspective view of a fecal collection bag with a strip style sensor module positioned along an edge of a front bag panel;

[0048] Fig. 14 is a front perspective view of a sample preparation and test device of an additional embodiment of the present disclosure, housed within a compressible tube integrated into a collection bag, wherein a filter serves both as a filter and a support for a dried extraction reagent embedded in the filter;

[0049] Fig. 15 is a front perspective view of a sample preparation and test device of an additional embodiment of the present disclosure, housed within a compressible tube integrated into a collection bag, and wherein the filter is in contact with an absorbent material embedded with a dried extraction reagent;

[0050] Fig. 16 is a front perspective view of a sample preparation and test device of an additional embodiment of the present disclosure, housed within a compressible tube

integrated into a collection bag, and wherein the filter is in contact with an absorbent material embedded with a dried extraction reagent in the form of a tablet;

[0051] Fig. 17 is a front perspective view of a sample preparation and test device of an additional embodiment of the present disclosure, housed within a compressible tube integrated into a collection bag, and wherein the filter is in contact with an absorbent material embedded with a dried extraction reagent in the form of crystals;

[0052] Fig. 18 is a cross sectional view of a sample preparation and test device of an additional embodiment of the present disclosure, attached within an appendage of a collection bag, and wherein the filter serves both as a filter and as a support for a dried buffer;

[0053] Fig. 19 is a plan view of the wall of an appendage of the collection bag of Fig. 18 to which the test device is attached, taken from a position within the collection bag;

[0054] Fig. 20 is a cross sectional view of a sample preparation and test device of an additional embodiment of the present disclosure, attached within an appendage of a collection bag, and wherein the filter is in contact with an absorbent material embedded with dried extraction reagent;

[0055] Fig. 21 is a plan view of the wall of an appendage of the collection bag of Fig. 20 to which the test device is attached, taken from a position within the collection bag;

[0056] Fig. 22 is a front perspective view of a sample preparation and test device of an additional embodiment of the present disclosure, housed within a compressible tube integrated into a collection bag, and wherein, upon the collection bag reaching a sufficient volume, the compressible tube is squeezed so as to blow out an end plug associated with the compressible tube, thereby expelling the air inside the device and breaking open an ampoule containing a liquid extraction reagent, which reagent saturates the filter;

[0057] Fig. 23 is a front perspective view of a sample preparation and test device of an additional embodiment of the present disclosure, housed within a tube similar to a syringe barrel, integrated into a collection bag. The filter serves both as a filter and a support for the dried extraction reagent. A spring activated plunger is provided within the tube, and the tube includes a series of openings which act as intake ports;

[0058] Fig. 24 is a front perspective view of a sample preparation and test device of an additional embodiment of the present disclosure, housed within a tube similar to a syringe barrel, integrated into a collection bag. The filter is in contact with an absorbent material embedded with a dried extraction reagent. A spring activated plunger is provided within the tube, and the tube includes a series of openings which act as intake ports;

[0059] Fig. 25 is a front perspective view of a sample preparation and test device of an additional embodiment of the present disclosure, is a stand alone device which can access the fecal sample via an access port either in the collection bag or the catheter portion of the bowel management system;

[0060] Fig. 26 is a cross-sectional view of a sample preparation and test device of an additional embodiment of the present disclosure, integrated into a collection bag, wherein hydrodynamic pressure is utilized to push a sample across the filter;

[0061] Fig. 27 is a plan view of the wall of the collection bag of Fig. 26 to which the test device is attached, taken from a position within the collection bag;

[0062] Fig. 28 is a cross-sectional view of a sample preparation and test device of an additional embodiment of the present disclosure, wherein the filter element is separate from the analyte extraction element;

[0063] Fig. 29 is a plan view of the wall of the collection bag of Fig. 28 to which the test device is attached, taken from a position within the collection bag;

[0064] Fig. 30 is a cross-sectional view of a sample preparation and test device of an additional embodiment of the present disclosure, integrated into a collection bag, wherein hydrostatic pressure is utilized to push a sample across the filter, and the filter is in contact with a separate porous membrane embedded with a dried extraction reagent;

[0065] Fig. 31 is a plan view of the wall of the collection bag of Fig. 30 to which the test device is attached, taken from a position within the collection bag;

[0066] Fig. 32 is a cross-sectional view of a sample preparation and test device of an additional embodiment of the present disclosure, integrated into a collection bag, wherein hydrostatic pressure is utilized to push a sample across the filter, and the analyte is transferred from the filter to the porous membrane and from the porous membrane to the immunoassay via droplets;

[0067] Fig. 33 is a plan view of the wall of the collection bag of Fig. 32 to which the test device is attached, taken from a position within the collection bag;

[0068] Fig. 34 is a cross-sectional view of a sample preparation and test device of an additional embodiment of the present disclosure, integrated into a collection bag, wherein hydrostatic pressure is utilized to push a sample across the filter, wherein a mixing compartment is open to the inside of the collection bag and contains the dried extraction reagent in crystal form, and the sample preparation element of the device is comprised of at least two compartments, with the filter located in one compartment being in proximity to a dried extraction reagent located in a second compartment;

[0069] Fig. 35 is a cross-sectional view of a sample preparation and test device of an additional embodiment of the present disclosure, integrated into a collection bag, wherein hydrostatic pressure is utilized to push a sample across the filter, and the sample preparation element of the device is comprised of at least two compartments, with the filter located in one compartment being in proximity to a dried extraction reagent

located in a second compartment, and wherein the analyte is transferred from the filter to the immunoassay via droplets; and

[0070] Fig. 36 is a perspective view of an exemplary sample preparation and test device of the present disclosure.

Detailed Description of the Preferred Embodiments

[0071] With reference to Figure 1, one embodiment shows a wafer style sensor module 4 attached to a waste collection bag 2 at a point where the module 4 can come into contact with the matter contained in the bag 2. An advantage of this embodiment is that the system is closed, i.e. there is no exposure to the matter being sampled in the bag 2 by a health care provider.

[0072] The module 4 may be of any size or shape suitable to effectively house the required physiologic parameter detection elements and is manufactured such that the module has an inner and outer surface. An inner surface of the module 4 is disposed within the collection bag 2 such that it is in fluid communication with the contents of the collection bag 2, and an outer surface may be external to the collection bag 2.

[0073] Figure 2 shows the sensor module 4 in more detail with a sensor array 8. The module 4 can contain a sensor array 8 in order to house multiple physiologic parameter detection devices, or the module 4 can be configured to contain only one physiologic parameter detection device.

[0074] Figure 3 demonstrates a cross section of a wafer style sensor module 4. The module 4 comprises a sampling filter 16 on the inside surface of the module. Preferably, the sampling filter 16 is capable of filtering at least to the 100-micron level. In a middle section of the module 4 is a chamber 18 that receives the filtered effluent as it comes through the filter 16 and exposes the effluent to a reagent disc 12 and a detector 14. The detector 14 may be constructed of a fabric embedded with the reagent.

[0075] One embodiment of the detector 14 comprises a monoclonal or polyclonal antibody unique to a specific colonized pathogen. Alternatively, the detector 14 could be an electronic sensing device. The module 4 contains visual indicators 10 that are exposed to the outside surface of the module 4, allowing a health care professional to view the indicator.

[0076] The basic operation of the sensor includes a sample entering the filter 16 wherein the sample is filtered of particulates and then travels via capillary action into the detector 14 where a reagent or other detection mechanism is applied to the sample and an outcome is communicated to the visual indicators 10.

[0077] Figure 4 shows a view of the visual indicator 10 wherein multiple specific markers 10 are indicated. The physiologic parameter can be colonized pathogens, proteins, enzymes or any detectible chemical or physiologic parameter in the sample. By using a specific coding system, the visual indicator 10 can be coded so as to require interpretation, such as by a trained healthcare provider, so that a non-health care professional cannot determine the outcome. Figure 5 shows an example of a single physiologic parameter visual indicator module.

[0078] Figure 6 shows a strip-style sensor module 22 mounted in a specimen container 24. The sensor module 22 functions similarly to the wafer sensor module in the waste collection bag shown in Figure 1. One advantage of the strip sensor module is that it could be placed in any sample container such as cups, bowls, trays, or tubes that are designed to hold effluent and allows the effluent to flow into the filter intake of the sensor module.

[0079] Figure 7 shows a detailed perspective view of the indicator side of a strip style sensor module at 26. The strip sensor module 26 contains visual indicators 28 that are similar to the visual indicators on the wafer sensor module shown in Figure 2. Similar

to the wafer sensor module 4, the strip sensor module 26 can be of any size necessary to accommodate the filter and detection sub-assemblies. The strip style sensor module 26 also may contain detection mechanisms and corresponding indicators for multiple physiologic parameters. The ability of the strip sensor module 26 to be placed into various specimen collection containers would allow point of care sensing for various physiologic effluents such as blood, plasma, urine and the like in addition to fecal matter.

[0080] Figure 8 shows a strip style sensor module 32 embedded within a syringe 30. The placement of the sensor module directly in the syringe 30 allows for point of care sensor application in a common sampling tool, the syringe. Figure 9 shows the strip sensor module 32 in closer detail toward a proximal end of the syringe 30. The strip sensor module 32 is located proximally in the syringe 30 such that it requires only a small sample of effluent in order to expose the sensor module 32 to the sample.

[0081] Figure 10 shows a cross section of the proximal end of the syringe 30 and a cross section of the strip sensor module 32. As can be seen in this figure, the strip sensor module 32 is embedded in a wall of the syringe 30 such that an inside edge of the module 32 is flush with, and in fluid communication with, the inside of the barrel 34 of the syringe 30.

[0082] Figure 11 shows a perspective end view of the syringe 30 with the strip sensor module 32. This embodiment demonstrates that the strip sensor module 32 does not significantly alter the circumference of the syringe barrel 34. This characteristic is preferred, however, a strip sensor module that significantly altered the circumference, size or shape of the syringe 30 would not necessarily impact the function of the strip sensor module 32 or the syringe 30.

[0083] Figure 12 shows a detailed cross section of a strip sensor module 32 with a filter 38 capable of filtering to at least 100 microns, a chamber 37 wherein the filtered effluent passes, via capillary action, into at least one reagent disc 41 that contains the reagent to be mixed with the effluent, a detector module 43 that may be a fabric embedded with a detector or other sensing electronic mechanism such as a photosensitive element, and at least one visual indicator 42.

[0084] Figure 13 shows an alternate embodiment wherein a strip style sensor 40 is placed along a face edge of a collection bag 42. The strip sensor 40 is mounted in a vertical manner with multiple detectors and indicators 46 such that multiple readings may be taken as the level of effluent rises in the collection bag 42.

Additional Preferred Embodiments – Simplified Fecal Specimen Preparation and Analysis

[0085] In a preferred embodiment, the filter element and analyte extraction elements are combined. The filter serves both as a filter and a support for the dried extraction reagent. In this embodiment, as the sample passes through the filter, it mixes with the extraction reagent.

[0086] In another preferred embodiment, the filter element is separate from the analyte extraction element. In this embodiment, as the sample passes through the filter and communicates with the absorbent membrane, a sample / extraction reagent mixture is formed.

[0087] In the embodiment shown in Fig. 14, the sample preparation and test device 50 is a one-step activated device housed within a compressible tube 52 which is integrated into a collection bag (not shown) so as to be seen by the healthcare provider. The filter 56 and analyte extraction elements are combined, and are in direct contact with the immunoassay. The filter 56 serves both as a filter and a support for the dried extraction reagent. Once the stool in the collection bag has reached a sufficient volume to be in

contact with the sample preparation and test device 50, the compressible tube 52 is squeezed once so as to blow out an end plug 58 of the compressible tube 52 and expel the air inside the sample preparation and test device 50. The end plug 58 keeps the stool from contacting the immunoassay and initiating the test prematurely.

[0088] When the compressible tube 52 is released, a vacuum is created which draws a fixed volume of sample through the filter 56 where it mixes with the extraction reagent forming an analyte solution. The analyte is transferred to the immunoassay test strip 60 through an absorbent membrane 54 via capillary action. The immunoassay test strip 60 is encapsulated in a material that is impervious to moisture, such as a mylar laminate 61, in order to ensure unilateral flow and to prevent premature activation or fouling of the immunoassay.

[0089] In the embodiment shown in Figs. 15, the sample preparation and test device 50 is a one-step activated device housed within a compressible tube 52 which is integrated into the collection bag (not shown) so as to be seen by the healthcare provider. The filter 56 and analyte extraction elements are in direct contact with the immunoassay. The filter 56 is in contact with an absorbent membrane 54 embedded with dried extraction reagent. Once the stool in the collection bag has reached a sufficient volume to be in contact with the sample preparation and test device 50, the compressible tube 52 is squeezed once so as to blow out the end plug 58 and expel the air inside the sample preparation and test device 50. When the compressible tube 52 is released, a vacuum is created which draws a fixed volume of sample through the filter. The filtered sample then contacts the absorbent material with the extraction reagent forming an analyte solution. The analyte is transferred to the immunoassay test strip 60 through the absorbent membrane 54 via capillary action. The immunoassay test strip 60 is encapsulated in a material that is impervious to moisture, such as a mylar laminate 61,

in order to ensure unilateral flow and to prevent premature activation or fouling of the immunoassay.

[0090] In the embodiment shown in Fig. 16, the sample preparation and test device 50 is a one-step activated device housed within a compressible tube 52 which is integrated into a collection bag (not shown) so as to be seen by the healthcare provider. The filter 56 and analyte extraction elements are in direct contact with the immunoassay. The filter 56 is in contact with a dried extraction reagent in the form of a tablet 62. Once the stool in the collection bag has reached a sufficient volume to be in contact with the sample preparation and test device 50, the tube is squeezed once so as to blow out the end plug 58 of the compressible tube 52 and expel the air inside the sample preparation and test device 50. When the compressible tube 52 is released, a vacuum is created which draws a fixed volume of sample through the filter. The filtered sample then contacts the tablet 62, mixing with the extraction agent forming an analyte solution. The immunoassay test strip 60 is encapsulated in a material that is impervious to moisture, such as a mylar laminate 61, in order to ensure unilateral flow and to prevent premature activation or fouling of the immunoassay.

[0091] In the embodiment shown in Fig. 17, the sample preparation and test device 50 is a one-step activated device housed within a compressible tube 52 which is integrated into the collection bag (not shown) so as to be seen by the healthcare provider. The filter 56 and analyte extraction elements are in direct contact with the immunoassay. The filter is in contact with a dried extraction reagent in the form of crystals 64. Once the stool in the collection bag has reached a sufficient volume to be in contact with the sample preparation and test device 50, the compressible tube 52 is squeezed once so as to blow out an end plug 58 of the compressible tube 52 and expel the air inside the device. When the compressible tube 52 is released, a vacuum is created which draws a

fixed volume of sample through the filter 56. The filtered sample then mixes with the extraction reagent crystals 64 forming an analyte solution. The analyte is transferred to the immunoassay test strip 60 through an absorbent membrane 54 via capillary action. The immunoassay test strip 60 is encapsulated in a material that is impervious to moisture, such as a mylar laminate 61, in order to ensure unilateral flow and to prevent premature activation or fouling of the immunoassay.

[0092] In the embodiment shown in Figs. 18-19, the sample preparation and test device 66 is a one-step activated device attached within an appendage 68 of the collection bag (not shown) so as to be seen by a healthcare provider. The filter 70 and analyte extraction elements are in direct contact with the immunoassay. Similar to the embodiment shown in Figure 14, the filter 70 serves both as a filter and a support for the dried buffer. Once the stool in the collection bag has reached a sufficient volume, the appendage 68 can be folded down so as to allow the stool to contact the sample preparation and test device 66. Hydrodynamic pressure pushes the sample across the filter 70 where it mixes with the extraction reagent forming an analyte solution. The analyte is transferred to the immunoassay test strip 60 through an absorbent membrane 54 via capillary action. As in embodiments described above, the immunoassay test strip 60 is encapsulated in a material that is impervious to moisture, such as a mylar laminate 61, in order to ensure unilateral flow and to prevent premature activation or fouling of the immunoassay.

[0093] In the embodiment shown in Figs. 20-21, the sample preparation and test device 66 is a one-step activated device attached within an appendage 68 of the collection bag (not shown) so as to be seen by a healthcare provider. Similar to the embodiment shown in Fig. 16, the filter 70 is separate from the analyte extraction element. The filter 70 and analyte extraction elements are in direct contact with the

immunoassay. As in the embodiment shown in Fig. 16, the filter 70 is in contact with an absorbent membrane 54 embedded with dried extraction reagent (as opposed to the filter being embedded with dried extraction reagent, as in the previous embodiment). Once the stool in the collection bag has reached a sufficient volume, the appendage 68 can be folded down so as to allow the stool to contact the device. Hydrodynamic pressure pushes the sample across the filter 70. The filtered sample then contacts the absorbent membrane 54 with the extraction reagent forming an analyte solution. The analyte is transferred to the immunoassay test strip 60 through the absorbent membrane 54 via capillary action. The immunoassay test strip 60 is encapsulated in a material that is impervious to moisture, such as a mylar laminate 61, in order to prevent premature activation or fouling of the immunoassay.

[0094] In the embodiment shown in Fig. 22, the sample preparation and test device 72 is a one-step activated device housed within a compressible tube 74 which is integrated into the collection bag (not shown) so as to be seen by the healthcare provider. The filter 76 and extraction elements do not directly contact the immunoassay. Once the collection bag has reached a sufficient volume, the compressible tube 74 is squeezed so as to blow out an end plug 78 associated with the compressible tube 74, expel the air inside the device and break open an ampoule 80 containing liquid extraction reagent, allowing the liquid extraction reagent to saturate the filter 76. When the compressible tube 74 is released, a vacuum is created which draws a fixed volume of sample / extraction reagent mixture back across the filter 76. The analyte is transferred to the immunoassay test strip 82 through an absorbent membrane via capillary action. The immunoassay test strip 82 is encapsulated in a material that is impervious to moisture, such as a mylar laminate 61, in order to ensure unilateral flow and to prevent premature activation or fouling of the immunoassay.

[0095] In the embodiment shown in Fig. 23, the sample preparation and test device 72 is a one-step activated device housed within a tube 84 similar to a syringe barrel which is integrated into the collection bag (not shown) so as to be seen by the healthcare provider. The filter 86 and analyte extraction elements are in direct contact with the immunoassay. The filter 86 serves both as a filter and a support for the dried extraction reagent. Within the tube 84 is a plunger 88 activated by a spring 90. The syringe barrel-type tube 84 has a series of openings 92 which act as intake ports. Once the stool in the collection bag has reached a sufficient volume to be in contact with the sample preparation and test device 72, the plunger 88 is retracted thereby compressing the spring 90 and drawing a fixed volume of sample into the syringe barrel-type tube 84 through openings 92. As the plunger 88 is released, the restoring force of the spring 90 pushes the sample across the filter 86 where it mixes with the extraction reagent forming an analyte solution. The analyte is transferred to the immunoassay test strip 82 through an absorbent membrane 54 via capillary action. The immunoassay test strip 82 is encapsulated in a material that is impervious to moisture, such as a mylar laminate 61, in order to ensure unilateral flow and to prevent premature activation or fouling of the immunoassay.

[0096] In the embodiment shown in Fig. 24, the sample preparation and test device 72 is a one-step activated device housed within a tube 84 similar to a syringe barrel which is integrated into the collection bag (not shown) so as to be seen by the healthcare provider. The filter 86 and analyte extraction elements are in direct contact with the immunoassay. The filter 86 is in contact with an absorbent material embedded with dried extraction reagent (as opposed to the filter being embedded with dried extraction reagent, as in the previous embodiment). Within the tube 84 is a plunger 88 activated by a spring 90. The tube has a series of openings 92 which act as intake ports. Once the

stool in the collection bag has reached a sufficient volume to be in contact with the device, the plunger 88 is retracted thereby compressing the spring 90 and drawing a fixed volume of sample into the syringe barrel-type tube 84 through openings 92. As the plunger 88 is released, the restoring force of the spring 90 pushes the sample across the filter 86. The filtered sample then contacts the absorbent material with the extraction reagent forming an analyte solution. The analyte is transferred to the immunoassay test strip 82 through an absorbent membrane via capillary action. The immunoassay test strip 82 is encapsulated in a material that is impervious to moisture, such as a mylar laminate 61, in order to ensure unilateral flow and to prevent premature activation or fouling of the immunoassay.

[0097] In the embodiment shown in Fig. 25, the sample preparation and test device 94 is a one-step activated device which is not integrated into the collection bag. Rather, it is a stand alone device which can access the fecal sample via an access port either in the collection bag or the catheter portion of a bowel management system such as the bowel management system disclosed in U.S. Patent No. 5,561,216 or U.S. Patent Application No. 10/225,820. The device 94 takes the form of a hand-held syringe 96. Within the barrel 98 of the syringe 96 is a plunger 100 incorporating an immunoassay test strip 102 and a filter 104. Also, in the tip of the barrel 98 is a one-way valve 106 which allows sample to enter the barrel for testing but precludes the sample from leaking out.

[0098] The filter 104 serves both as a filter and a support for the dried extraction reagent. A sample is taken by inserting the sample preparation and test device 94 into the sample access port and retracting the plunger 100 to its locked position, i.e. a position at which the plunger is locked in place by the plunger lock 105. A vacuum is created which draws a fixed volume of sample through the filter where it mixes with the

extraction reagent forming an analyte solution. The analyte is transferred to the immunoassay test strip 102 via capillary action.

[0099] A particularly preferred method of the present disclosure includes: A) collecting a patient's fecal output within a collection bag; B) presenting a fecal sample to a sample preparation and test device; C) preparing the fecal sample for an assay; D) contacting the sample to the assay such that a physiologic parameter present in the sample is transferred to the assay; and E) detecting the presence of the physiologic parameter by said assay.

Additional Preferred Embodiments – Automatic Fecal Specimen Preparation and Analysis

[00100] Turning now to Figs. 26-35, additional embodiments are illustrated in which the sample preparation element of the fecal sample collection and test device utilizes hydrostatic pressure, exerted by the collection of effluent within a collection bag, to isolate and concentrate analytes of interest from bowel contents before presenting the fecal specimen to the assay. Specifically, the collection bag is shaped in such a manner so that an increase in the effluent volume within the bag results in an increase in hydrostatic pressure which assists in the filtering and extraction of the analyte prior to analysis. Alternately, the device can utilize a chemical reaction to produce gas expansion which will assist in the filtering and extraction of the analyte prior to analysis.

[00101] **A)** In the embodiments shown in Figs. 26-29, the filter serves both as a filter and a support for the dried extraction reagent. As the sample passes through the filter, it mixes with the extraction reagent. The analyte is transferred from the filter to the immunoassay test strip through an absorbent membrane via capillary action (Figs. 28-29). Alternatively, the analyte is transferred from the filter to the immunoassay via droplets (Figs. 30-31).

[00102] **B)** In the embodiments shown in Figs. 30-33, the filter is in contact with a separate porous membrane embedded with a dried extraction reagent. The sample passes through the filter into the porous membrane embedded with the dried extraction reagent. As the absorbent membrane saturates, it transfers the analyte to the immunoassay strip via capillary action (Figs. 30-31). Alternatively, the analyte is transferred from the filter to the porous membrane and from the porous membrane to the immunoassay via droplets (Figs. 32-33).

[00103] **C)** In the preferred embodiments shown in Figs. 34-35, the sample preparation element of the device is comprised of at least two compartments. The filter (located in one compartment) is in proximity to a dried extraction reagent in the form of a dissolvable tablet or crystals (located in a second compartment). In this case, the sample first contacts the dried extraction reagent. Next, the sample/extraction reagent mixture passes through the filter. The analyte is transferred to the immunoassay test strip via capillary action (Fig. 34). Alternatively, the analyte is transferred from the filter to the immunoassay via droplets (Fig. 35).

[00104] Referring now to Figures 26-35, six physical embodiments in accordance with the present invention are provided.

[00105] In the embodiment shown in Figs. 26-27, a sample preparation and test device 108 is a passively activated device attached to the inside of a collection bag 110 so as to be seen by a healthcare provider. A filter 112 serves both as a filter and a support for a dried extraction reagent. As the collection bag 110 fills with stool, hydrostatic pressure pushes the sample across the filter where it mixes with the extraction reagent, forming an analyte solution. The analyte is transferred to an immunoassay test strip 114 through an absorbent membrane 54. As the absorbent membrane saturates, it transfers the analyte to the immunoassay test strip 114. The immunoassay test strip 114 is at least

partially encapsulated in a material that is impervious to moisture, such as a mylar laminate 61, in order to ensure unilateral flow and to prevent premature activation or fouling of the immunoassay.

[00106] In the embodiment shown in Figs. 28-29, the sample preparation and test device 108 is a passively activated device attached to the inside of the collection bag 110 so as to be seen by the healthcare provider. The filter 112 serves both as a filter and a support for the dried extraction reagent. As the collection bag 110 fills with stool, hydrostatic pressure pushes the sample across the filter where it mixes with the extraction reagent, forming an analyte solution. As the filter 112 becomes saturated, analyte droplets collect on the filter 112 and contact an immunoassay test strip 114. The immunoassay test strip 114 is at least partially encapsulated in a material that is impervious to moisture, such as a mylar laminate 61, in order to ensure unilateral flow and to prevent premature activation or fouling of the immunoassay.

[00107] In the embodiment shown in Figs. 30-31, the sample preparation and test device 108 is a passively activated device attached to the inside of the collection bag 110 so as to be seen by the healthcare provider. The filter 112 is in proximity to a separate absorbent membrane 54 embedded with a dried extraction reagent. As the collection bag 110 fills with stool, hydrostatic pressure pushes the sample across the filter 112. The filtered sample passes through the filter 112 into the absorbent membrane 54 embedded with the dried extraction reagent, forming an analyte solution. As the absorbent membrane 54 saturates, it transfers the analyte to an immunoassay test strip 114. The immunoassay test strip 114 is at least partially encapsulated in a material that is impervious to moisture, such as a mylar laminate 61, in order to prevent premature activation or fouling of the immunoassay.

[00108] In the embodiment shown in Figs. 32-33, the sample preparation and test device 108 is a passively activated device attached to the inside of the collection bag 110 so as to be seen by the healthcare provider. The filter 112 is in proximity to a separate absorbent membrane 54 embedded with a dried extraction reagent. As the collection bag 110 fills with stool, hydrostatic pressure pushes the sample across the filter. As the filter 112 becomes saturated, filtered sample droplets collect on the filter 112 where they wet an absorbent membrane 54 embedded with the dried extraction reagent, forming an analyte solution. As the absorbent membrane 54 saturates, analyte droplets collect on the opposite end and contact the immunoassay test strip 114. The immunoassay test strip 114 is at least partially encapsulated in a material that is impervious to moisture, such as a mylar laminate 61, in order to prevent premature activation or fouling of the immunoassay.

[00109] In the embodiment shown in Fig. 34, the sample preparation and test device 108 is a passively activated device attached to the inside of the collection bag 110 so as to be seen by the healthcare provider and is comprised of two compartments 116, 118. The mixing compartment 116, or sample preparation compartment, is open to the inside of the collection bag 110 and contains the dried extraction reagent in crystal form. As the collection bag 110 fills with stool, the sample enters the compartment and mixes with the extraction reagent, forming a sample / reagent solution. As the collection bag 110 continues to fill, hydrostatic pressure pushes the solution across the filter 112 into the second compartment 118, which also might be termed a test compartment or a sample analysis compartment, where it contacts the immunoassay test strip 114. The immunoassay test strip 114 is at least partially encapsulated in a material that is impervious to moisture, such as a mylar laminate 61, in order to prevent premature activation or fouling of the immunoassay.

[00110] In the embodiment shown in Fig. 35, the sample preparation and test device 108 is a passively activated device attached to the inside of the collection bag 110 so as to be seen by the healthcare provider and is comprised of two compartments 120, 122. The first compartment 120, a mixing compartment, is open to the inside of the collection bag and contains the dried extraction reagent 121 in crystal form. As the collection bag 110 fills with stool, the sample enters the first compartment 120, which is a mixing compartment or sample preparation compartment, and mixes with the extraction reagent, forming a sample / reagent solution. As the collection bag 110 continues to fill, hydrostatic pressure pushes the solution across the filter 112, into the second compartment 122, a sample analysis compartment or test compartment, where it contacts the immunoassay test strip 114. The immunoassay test strip 114 is at least partially encapsulated in a material that is impervious to moisture, such as a mylar laminate 61, in order to prevent premature activation or fouling of the immunoassay.

[00111] Referring now to Fig. 36, a sample preparation and test device 120 for the detection of pathogens, such as A. Baumannii, may include a filter 122 made of a porous fabric material, such as a 100 micron debris filter, a reagent 124, a reagent support insert 126, a sanitary spent reactants reservoir 128, and a sensor strip 130.

[00112] The various implementations of sample preparation and test devices disclosed herein may be programmed for detecting markers consistent with the presence of particular colonized pathogens in the following manner: By a minimum number of one or more known colonized pathogens of the type to be detected first contacting and reconstituting the colloidal gold reagent polyclonal or monoclonal antibodies dried onto a porous fabric material such as a 20-micron filter disc, which complete the reaction and generate a visible signal indicating detection.

[00113] As various modifications could be made to the exemplary embodiments, as described above with reference to the corresponding illustrations, without departing from the scope of the present disclosure, it is intended that all matter contained in the foregoing description and shown in the accompanying drawings shall be interpreted as illustrative rather than limiting. Thus, the breadth and scope of the present disclosure should not be limited by any of the above-described exemplary embodiments, but should be defined only in accordance with the following claims appended hereto and their equivalents.

What is claimed is:

1. A point of care physiologic parameter sensing system comprising:

a sensor module embedded in a fecal matter collection device wherein said sensor module provides an indication when a specific physiologic parameter is detected in the fecal matter.

2. The sensing system of claim 1, wherein the fecal matter collection device is a collection bag.

3. The sensing system of claim 1, wherein the indication is coded so as to require interpretation.

4. Device of claim 1 where a dried analyte extraction reagent lies upon or is embedded within a filter which is in proximity to or in direct fluid communication with an assay.

5. A method of testing human fecal matter for the presence of specific physiologic parameters comprising:

(a) collecting fecal matter in an effluent collection device in close proximity to a human;

(b) presenting a sample of the collected fecal matter to a testing area;

(c) preparing the sample of the collected fecal matter for presentation to an assay;

(d) contacting the prepared sample of the collected fecal matter to the assay, whereby a physiologic parameter present in the sample is transferred to the assay;

(e) detecting the presence of a physiologic parameter by the assay; and

(f) providing a visual indication of the presence or non-presence of the physiologic parameter.

6. A collection bag with a device for testing fecal matter in the collection bag for the presence of a physiologic parameter, comprising:

(a) a sample collection element;

(b) a sample preparation element, including a filter and an extraction reagent; and

(c) a sample assay element.

7. The collection bag and test device of claim 6, wherein the filter filters to at least as small as 100 microns.

8. The collection bag and test device of claim 6, wherein the filter includes at least one of porous plastic, plastic membrane, or glass fiber.

9. The collection bag and test device of claim 6, wherein the extraction reagent includes a salt.

10. The collection bag and test device of claim 9, wherein the salt includes at least one of sodium choride, sodium phosphate, or ethylene diamine tetra acetic acid (EDTA) salts.

11. The collection bag and test device of claim 6, wherein the extraction reagent includes a preservative.

12. The collection bag and test device of claim 11, wherein the preservative includes at least one of enzyme inhibitors, anti-bacterial agents, bateriostatic molecules, or anti-fungal compounds.

13. Thc collection bag and test device of claim 6, wherein the extraction reagent includes a detergent.

14. The collection bag and test device of claim 13, wherein the detergent includes at least one of deoxycholate, Tween-20, triton X-100, or docedyl sulfate.

15. The collection bag and test device of claim 6, including a dry extraction reagent.

16. A device embedded in a fecal matter collection system wherein said device automatically collects, prepares and analyzes the fecal matter and provides an indication to a health care provider when a specific physiologic parameter is present in the fecal matter.

17. The device of claim 16 wherein a dried analyte extraction reagent lies upon an absorbent membrane which is in proximity to an assay.

18. The device of claim 16 wherein a dried analyte extraction reagent is embedded within an absorbent membrane which is in proximity to an assay.

19. The device of claim 16 wherein a dried analyte extraction reagent lies upon an absorbent membrane which is in direct fluid communication with an assay.

20. The device of claim 16 wherein a dried analyte extraction reagent is embedded within an absorbent membrane which is in direct fluid communication with an assay.

21. The device of claim 16 comprising at least one sample preparation compartment physically partitioned from at least one sample analysis compartment.

22. The device of claim 21, wherein sample filtration occurs within the sample preparation compartment.

23. The device of claim 21, wherein analyte extraction occurs within the sample preparation compartment.

24. The device of claim 16, wherein positive pressures created by the collection of effluent within the collection bag are utilized to facilitate sample filtration and analyte extraction prior to analysis.

25. The device of claim 16, wherein a chemical reaction is utilized to produce gas expansion to assist in sample filtration and analyte extraction prior to analysis.

FIG. 1

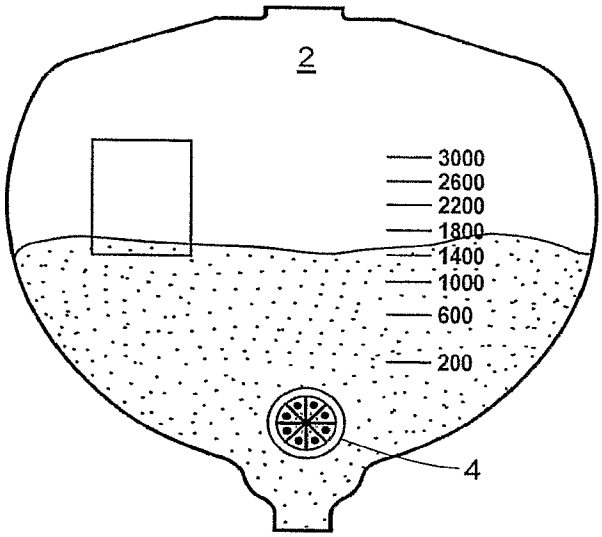


FIG. 2

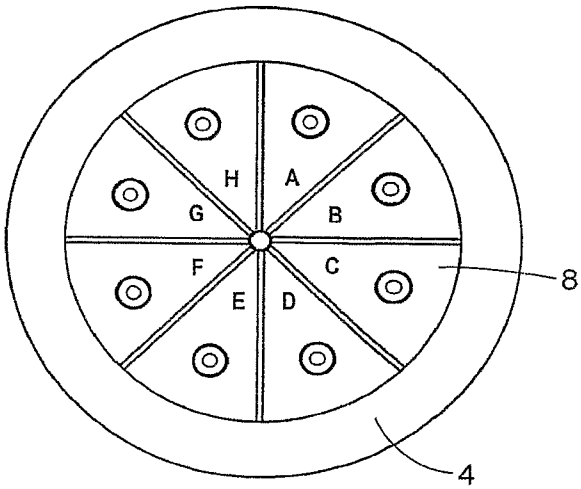


FIG. 3

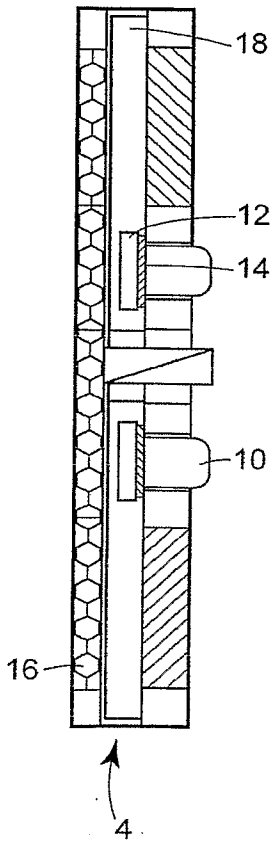


FIG. 4

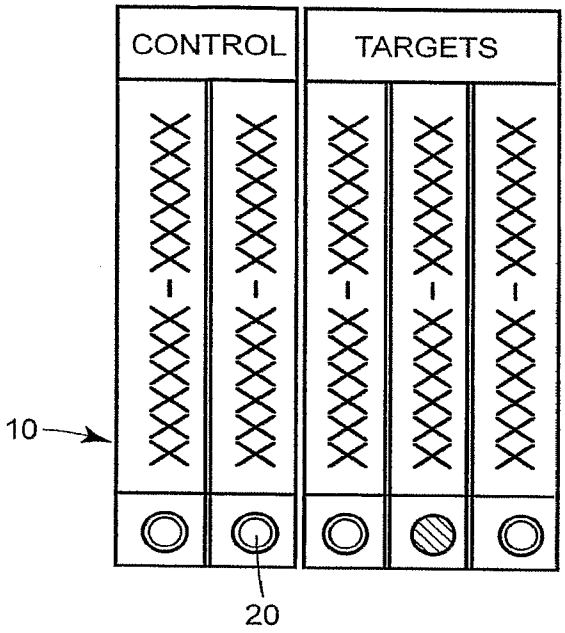


FIG. 5

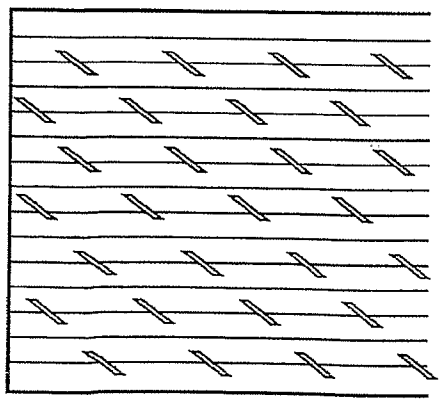


FIG. 6

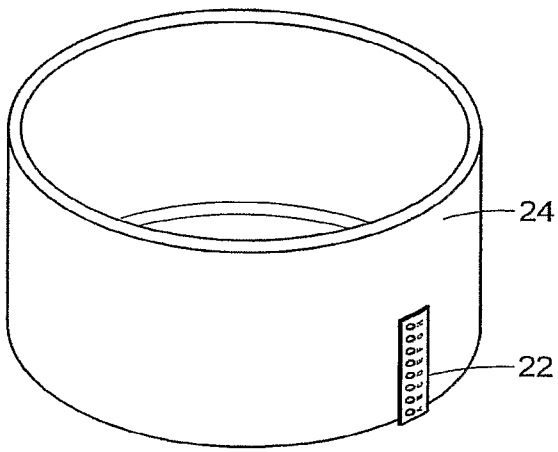


FIG. 7

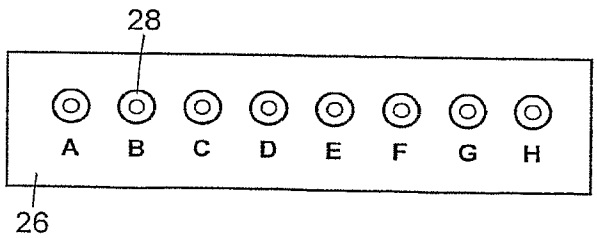


FIG. 8

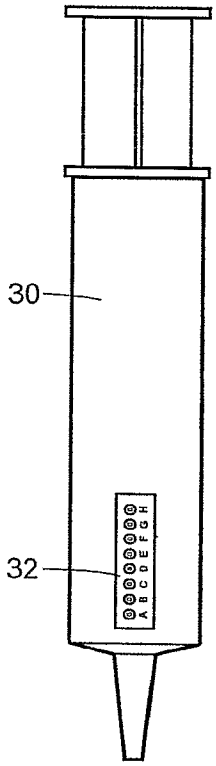


FIG. 9

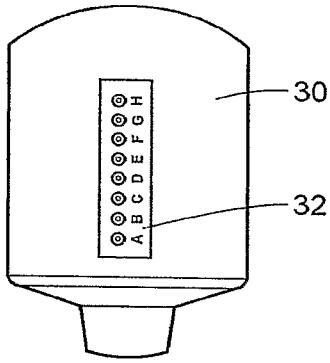


FIG. 11

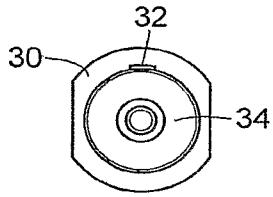


FIG. 12

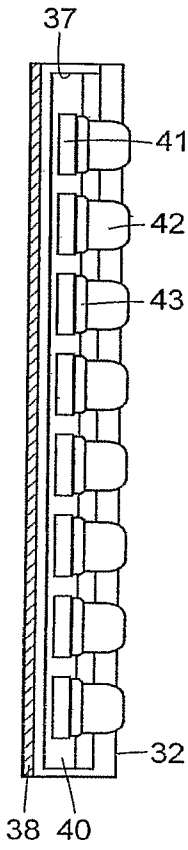


FIG. 10

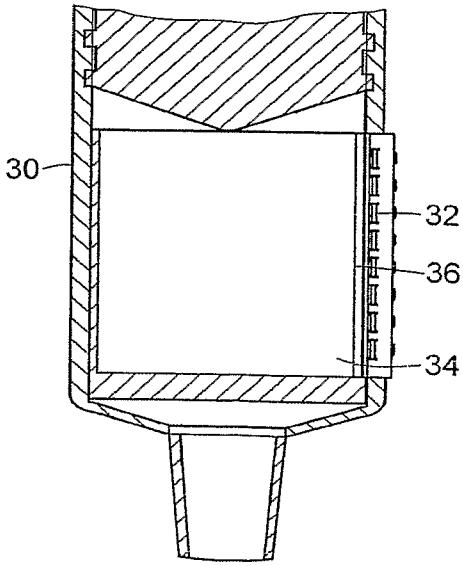


FIG. 13

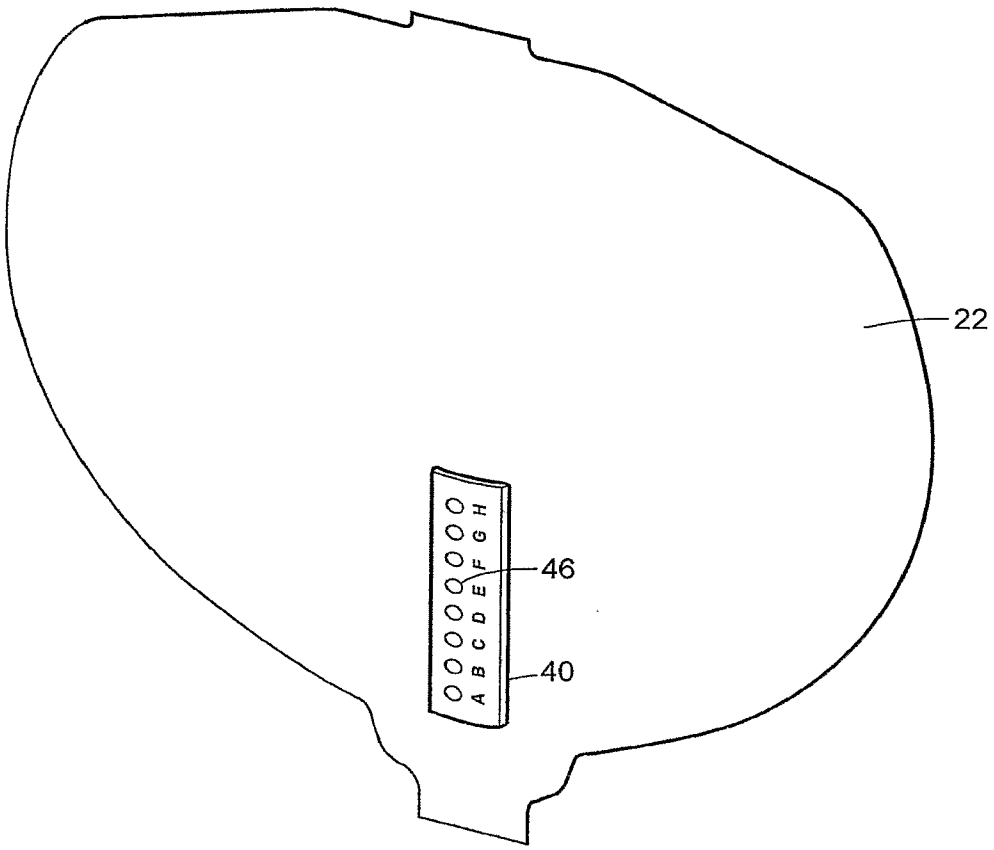


FIG. 14

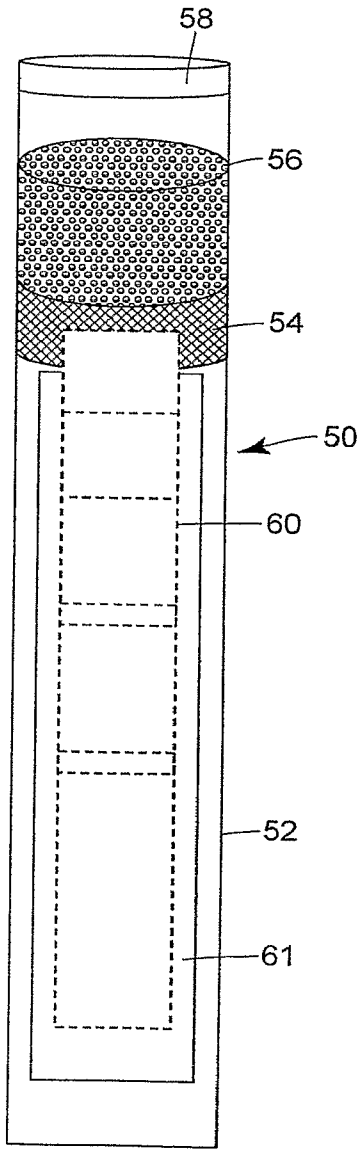


FIG. 15

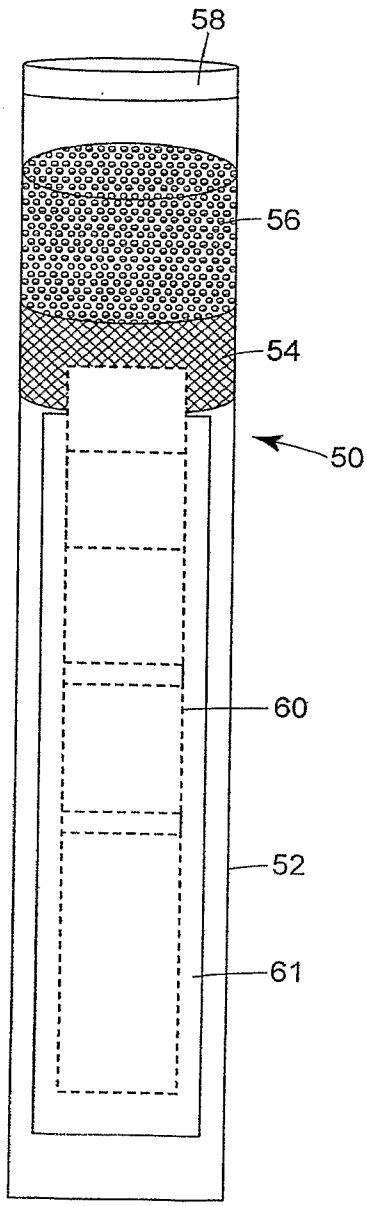


FIG. 16

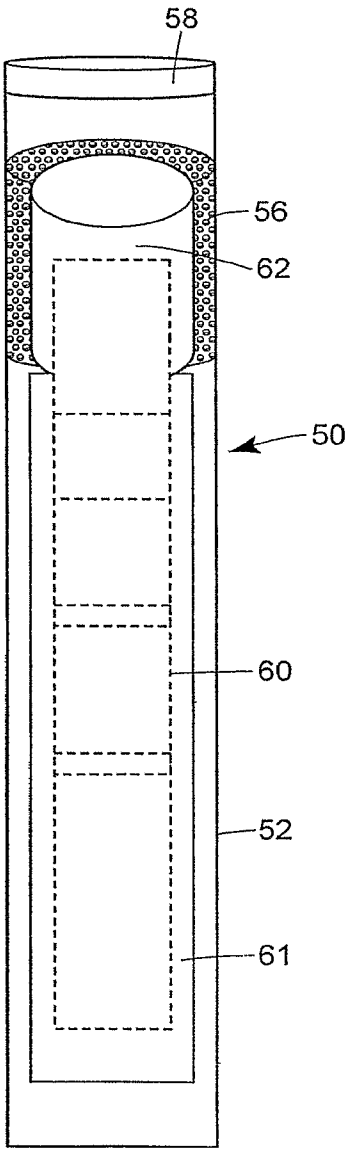


FIG. 17

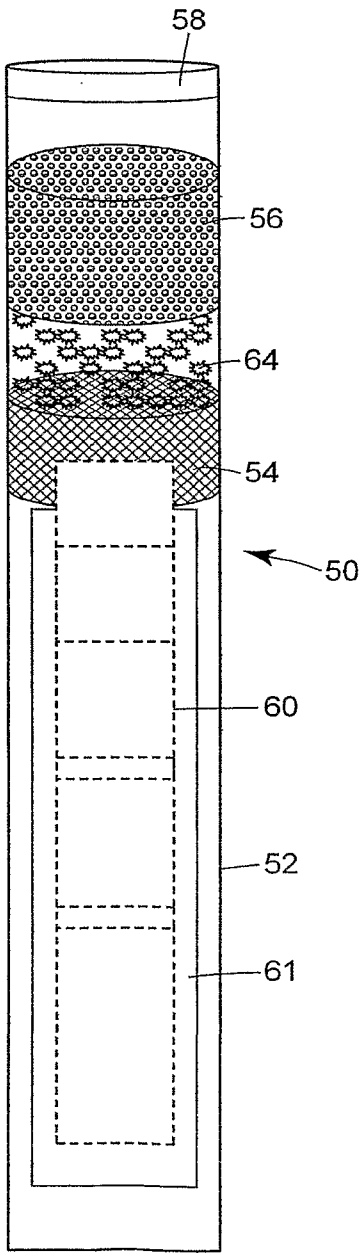


FIG. 18

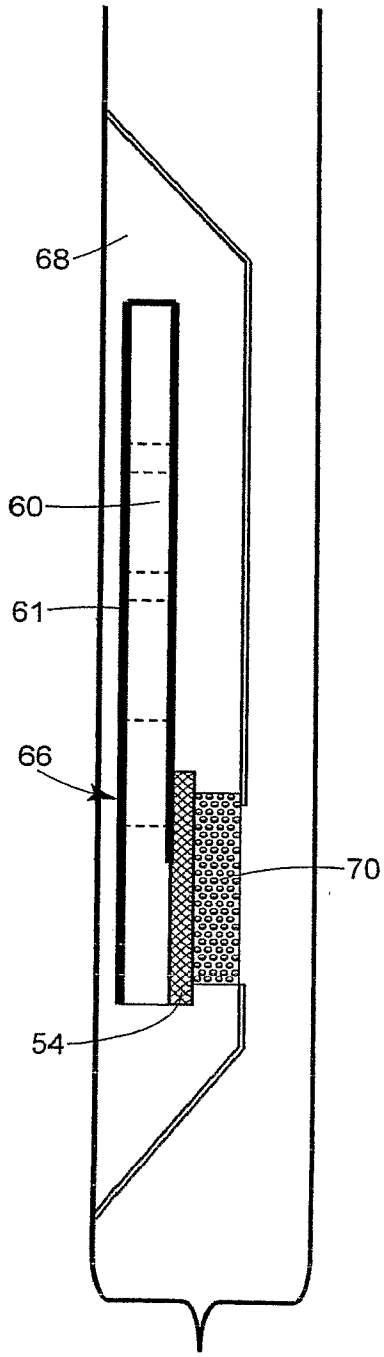


FIG. 19

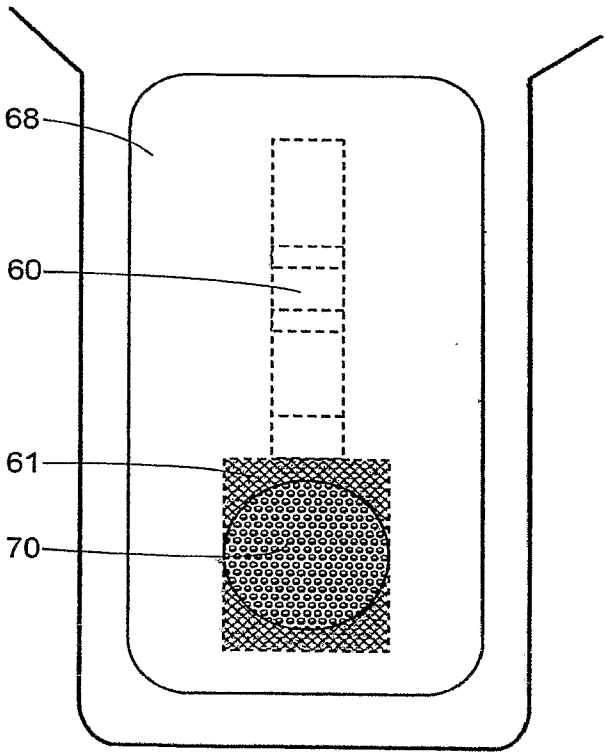


FIG. 20

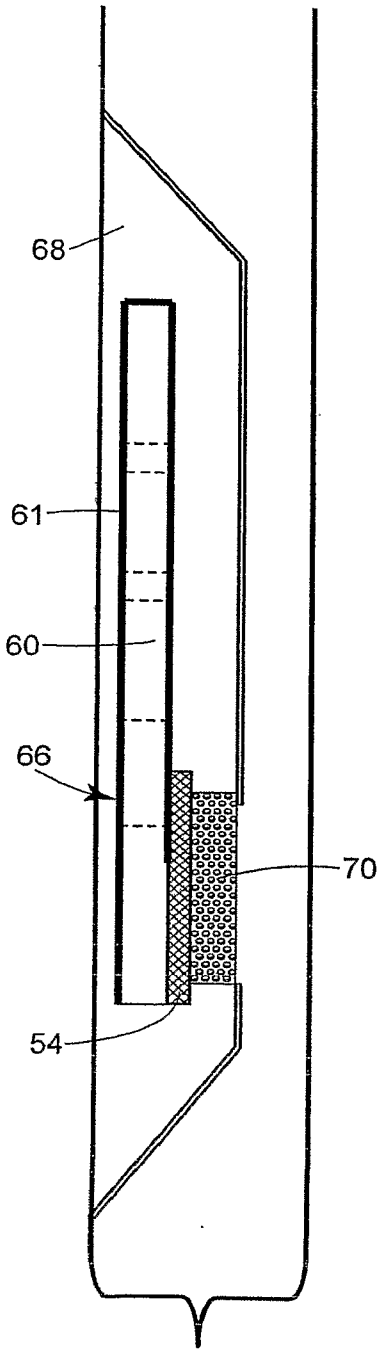


FIG. 21

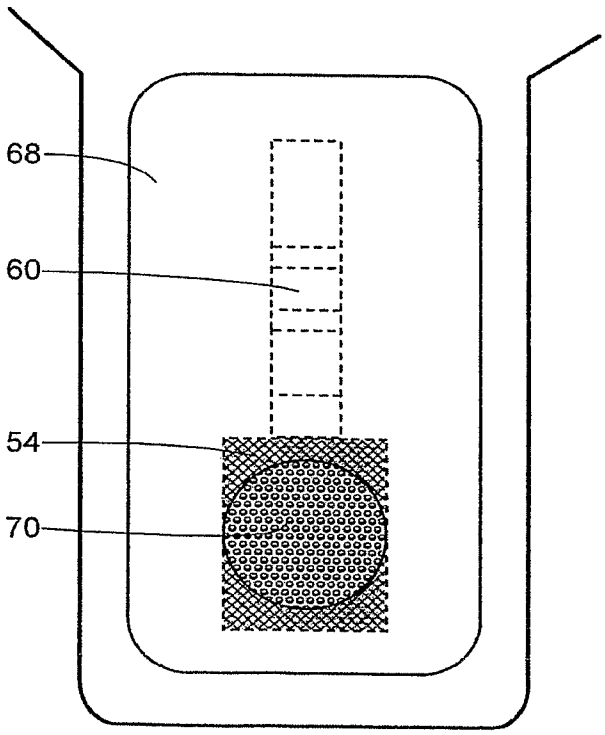


FIG. 22

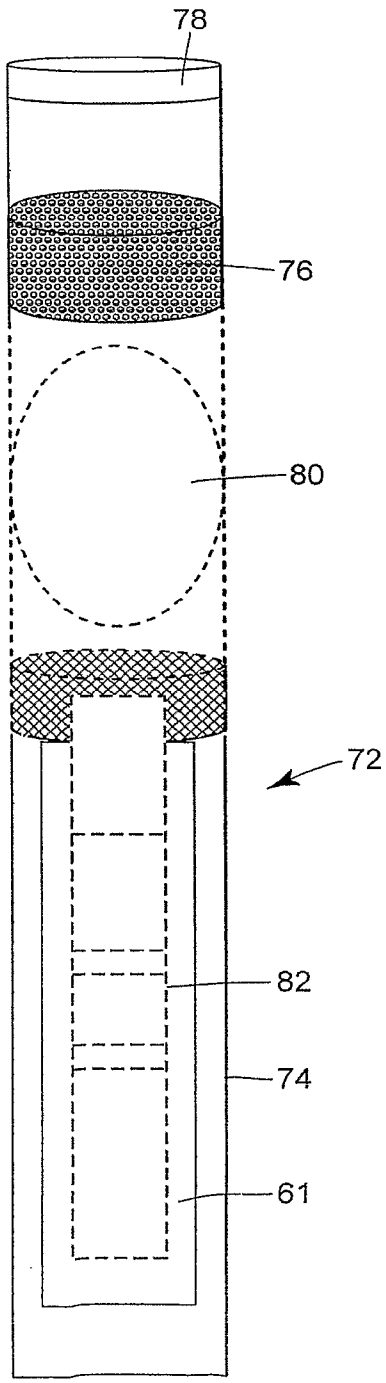


FIG. 23

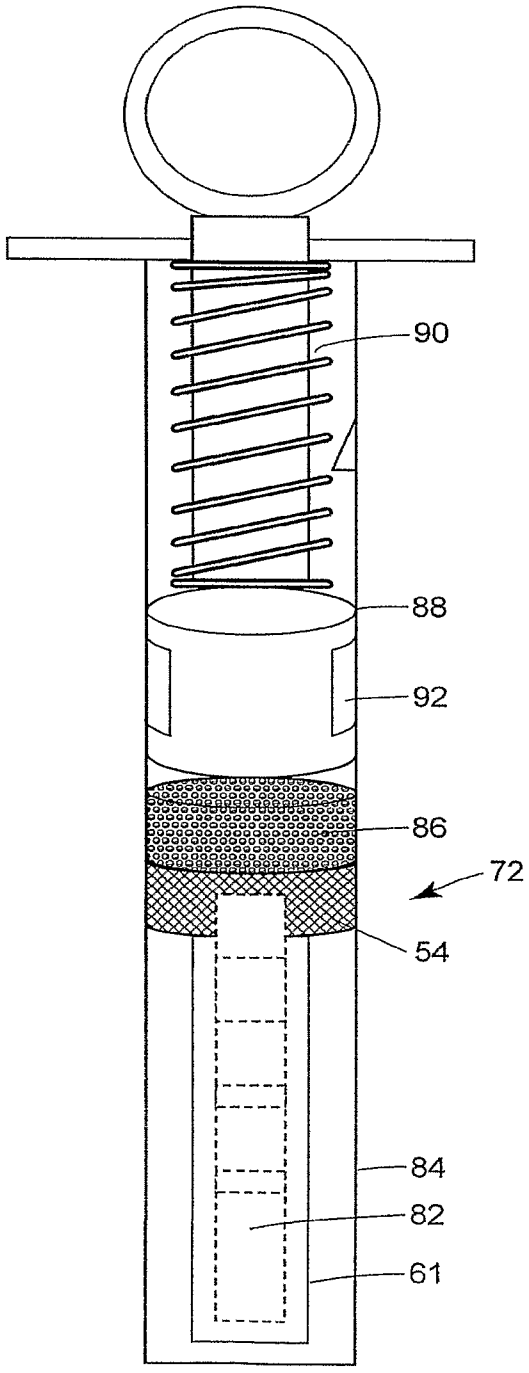


FIG. 24

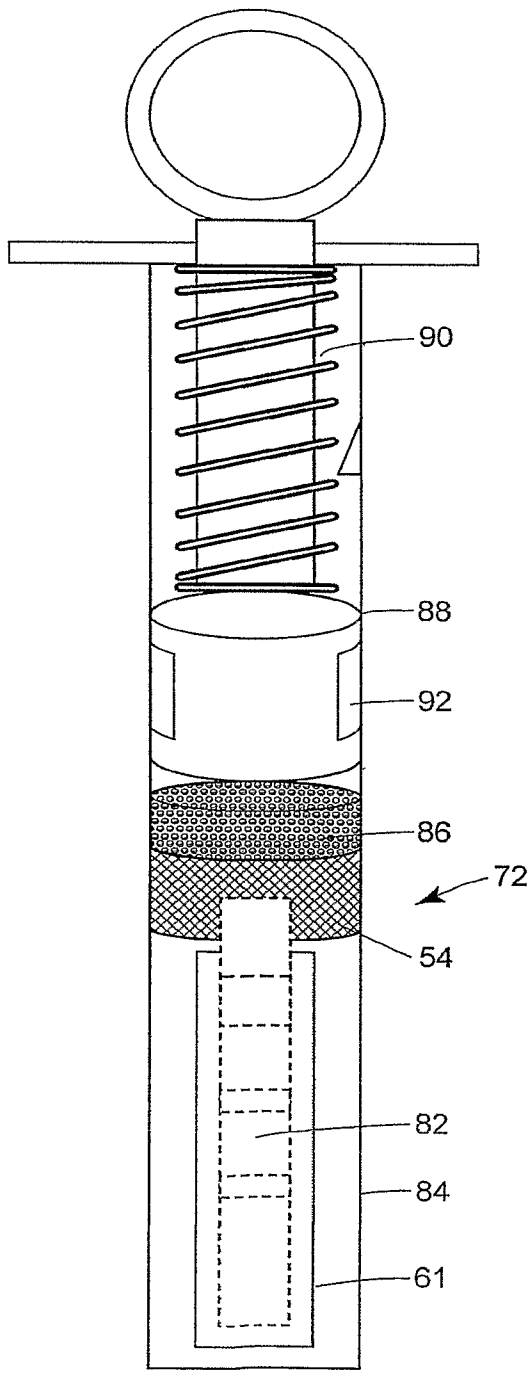


FIG. 25

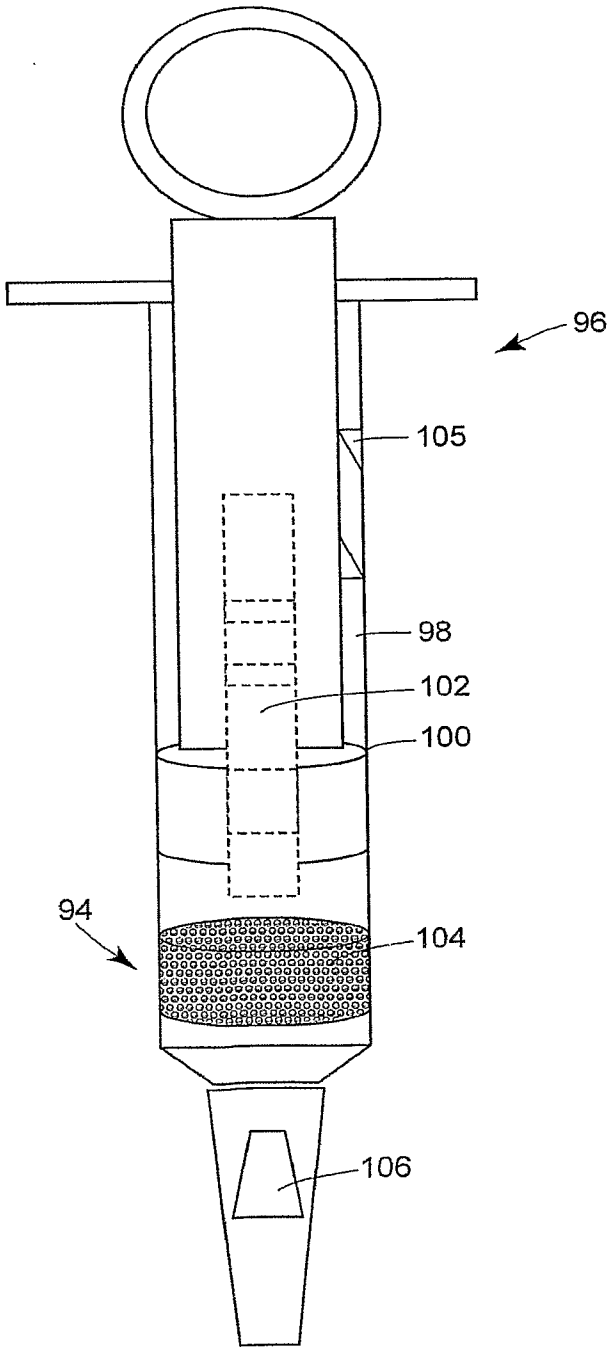


FIG. 26

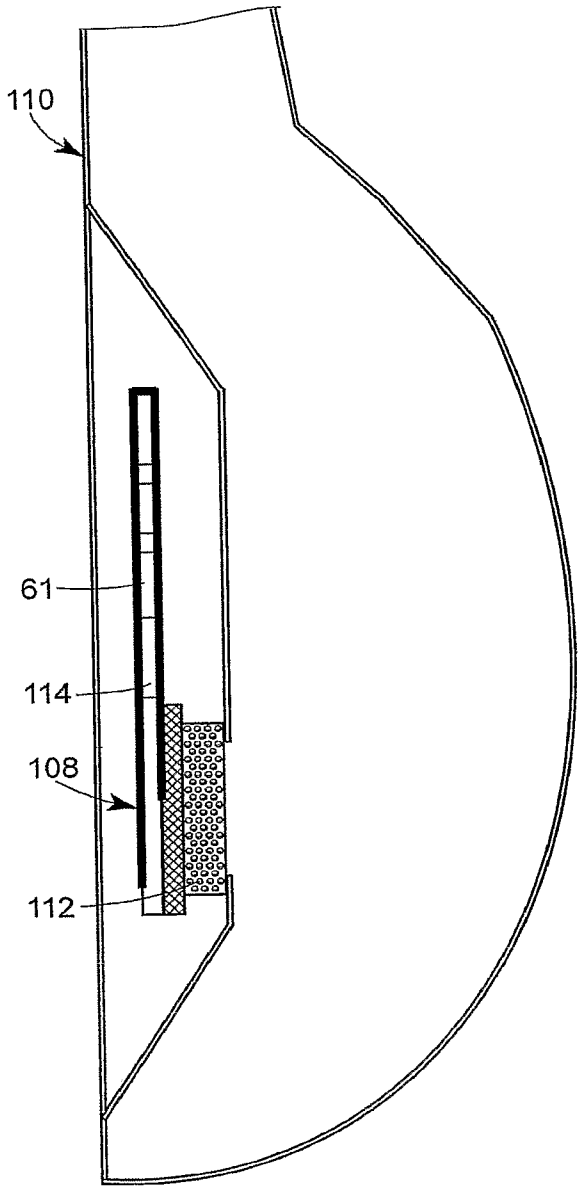


FIG. 27

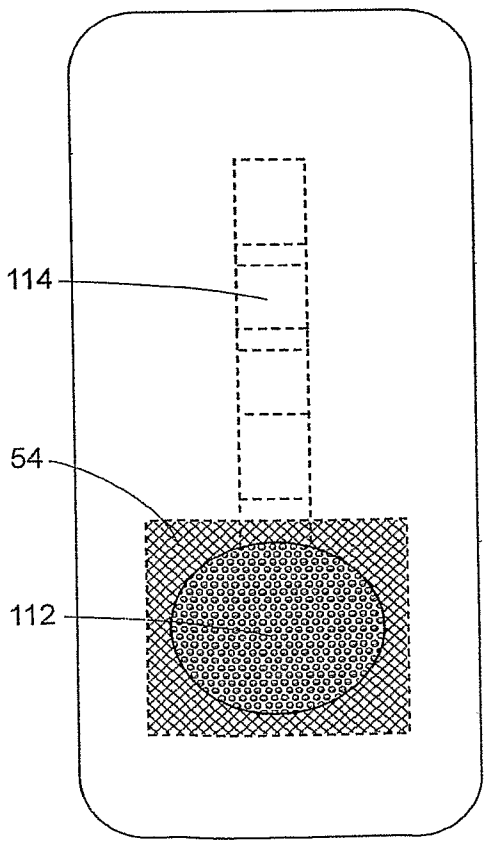


FIG. 28

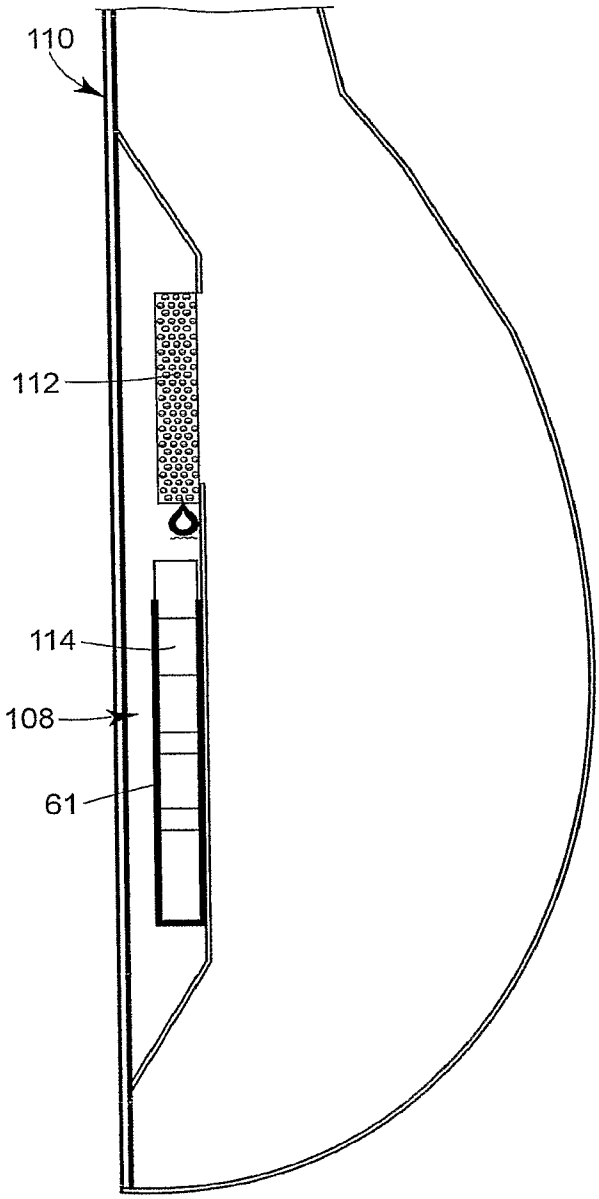


FIG. 29

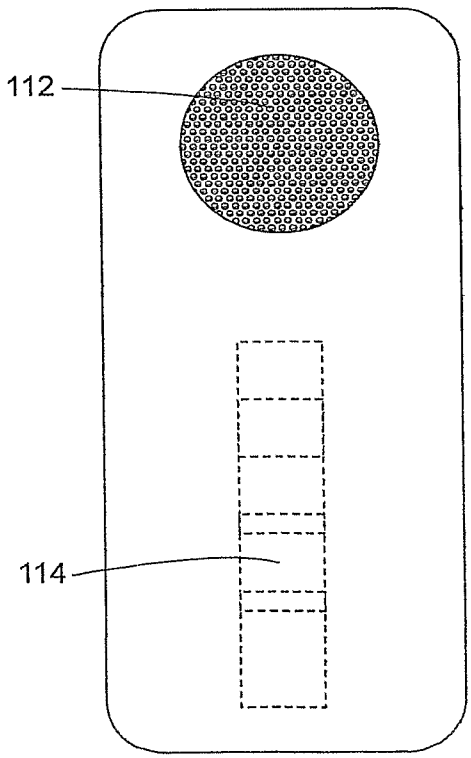


FIG. 30

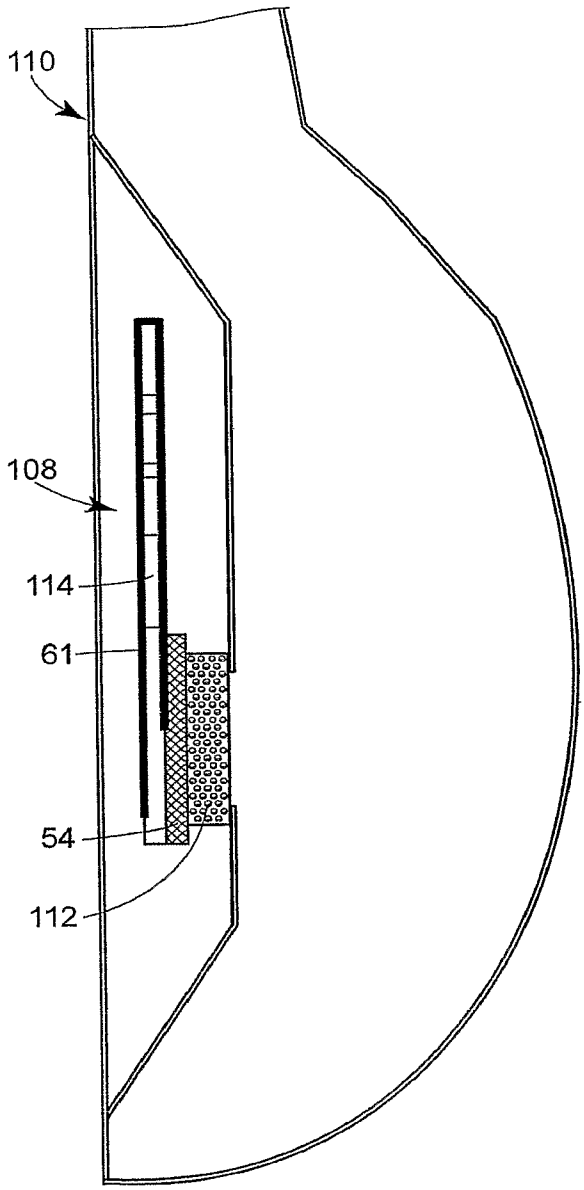


FIG. 31

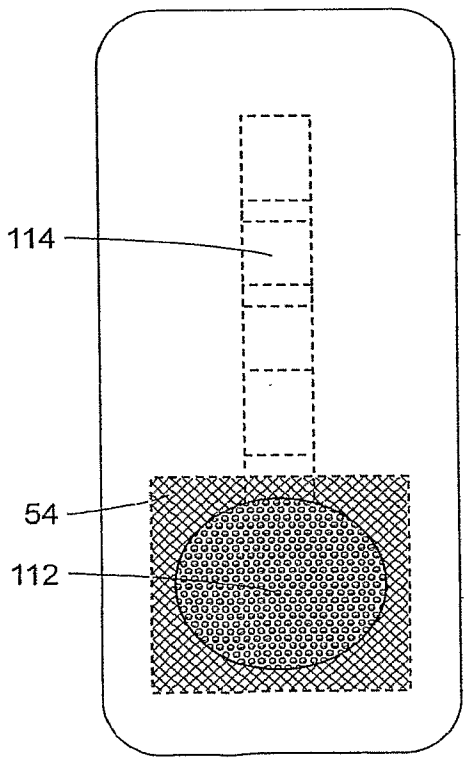


FIG. 32

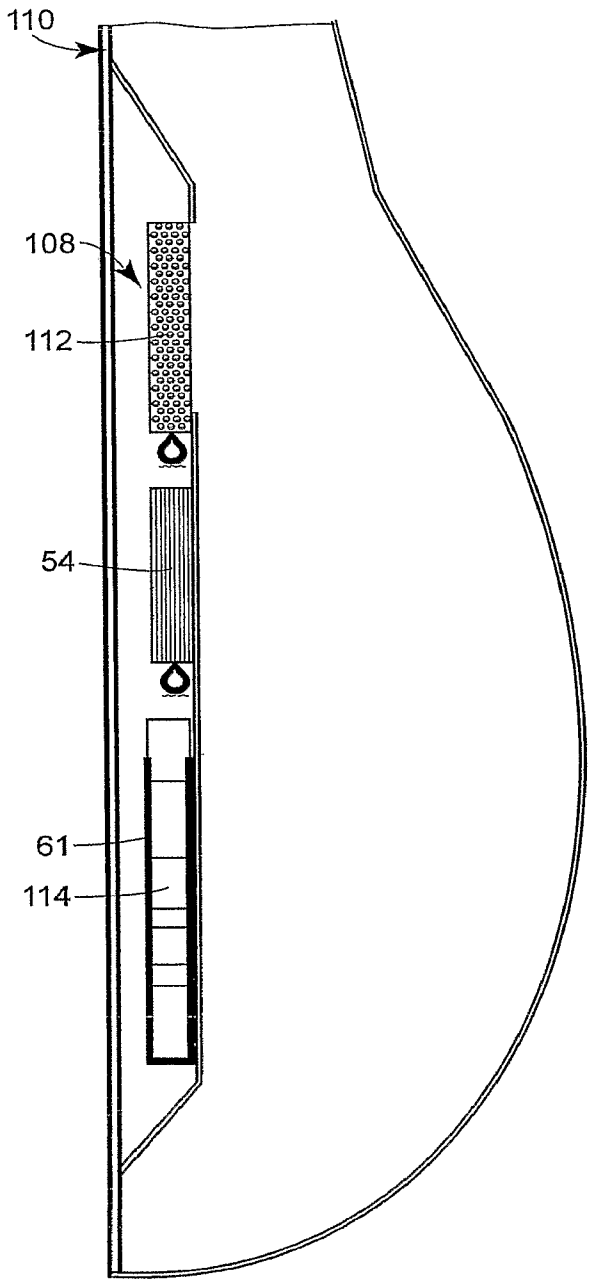


FIG. 33

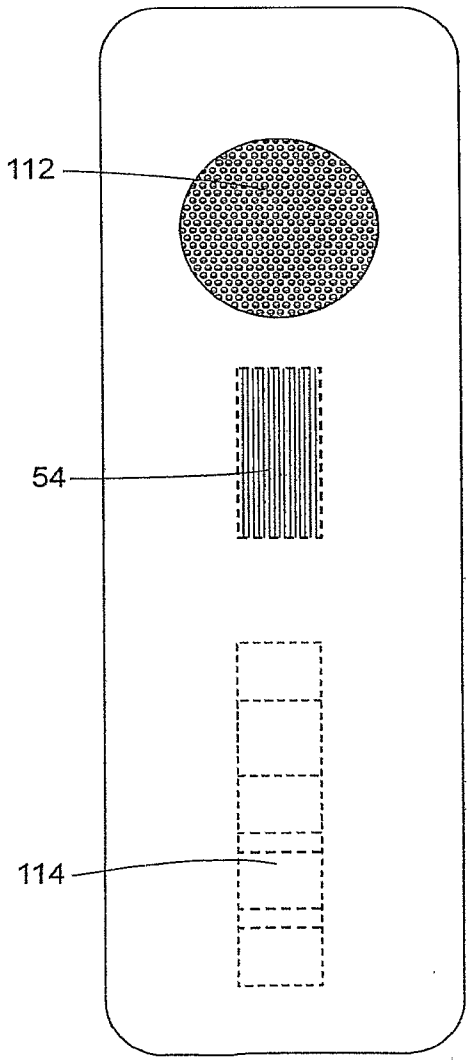


FIG. 34

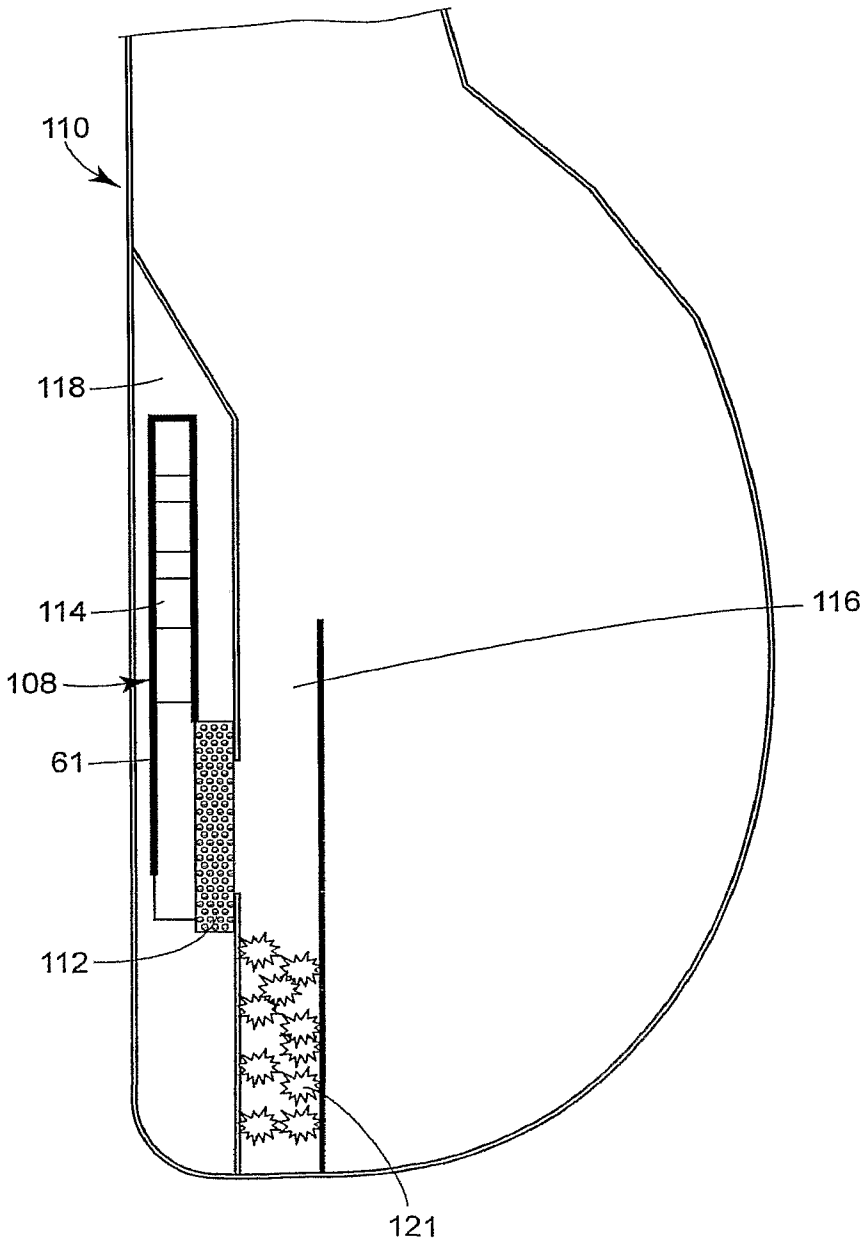


FIG. 35

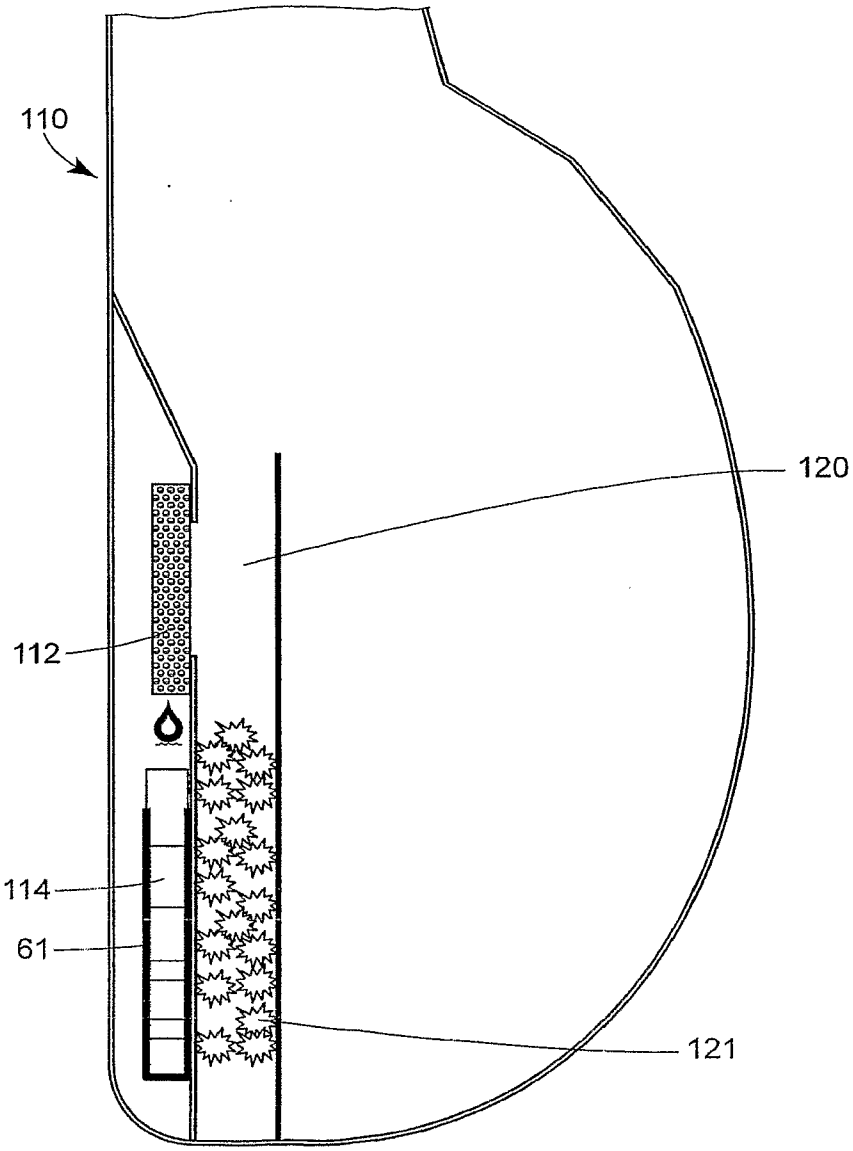
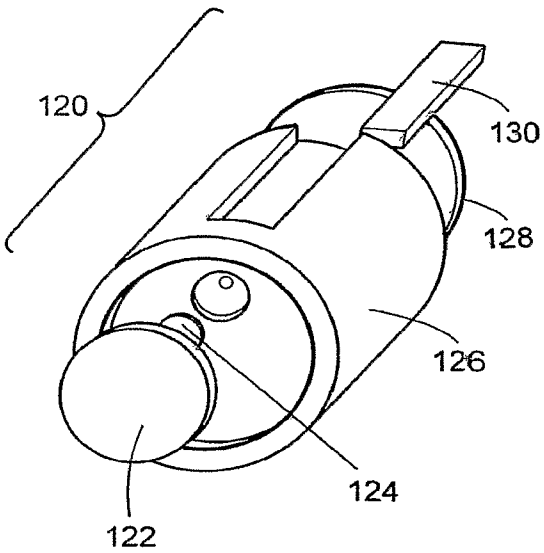


FIG. 36



INTERNATIONAL SEARCH REPORT

International application No
PCT/US2006/062564

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B10/00 G01N33/558 G01N33/569

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 G01N

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, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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X Y	WO 86/00704 A (INT HEALTH SERVICES INC [US]) 30 January 1986 (1986-01-30) pages 6,7,22; figure 4A pages 13-15	1-3, 5-14,16, 21-24 4,15, 17-20
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Y	WO 97/23781 A (UNIVERSAL HEALTHWATCH INC [US]; CHILDS MARY ANN [US]; CHOWDURY MOHAMME) 3 July 1997 (1997-07-03) pages 10-18; figures 1-5	4,15, 17-20

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

[X] See patent family annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
30 April 2007	09/05/2007

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, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	HERBERHOLD, C

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INTERNATIONAL SEARCH REPORT

International application No
PCT/US2006/062564

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E	EP 1 736 777 A (PORVAIR FILTRATION GROUP LTD [GB]) 27 December 2006 (2006-12-27) abstract; figure 2	1,3-5, 16,18,20
A	US 2005/277203 A1 (NISKANEN AIMO [FI]) 15 December 2005 (2005-12-15) abstract	4

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Information on patent family members

International application No
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