US 20030100819A1

(19) United States

(12) Patent Application Publication (10) Pub. No.: US 2003/0100819 A1

Newman et al. (43) Pub. Date: May 29, 2003

(54) HAND-HELD CHEMICAL SENSING INSTRUMENT

(75) Inventors: **Richard W. Newman**, Auburn, NY (US); **Dominick Danna**, Syracuse, NY (US)

Correspondence Address:
WALL MARJAMA & BILINSKI
101 SOUTH SALINA STREET
SUITE 400
SYRACUSE, NY 13202 (US)

(73) Assignee: **Welch Allyn, Inc.**

(21) Appl. No.: **09/995,390**

(22) Filed: **Nov. 28, 2001**

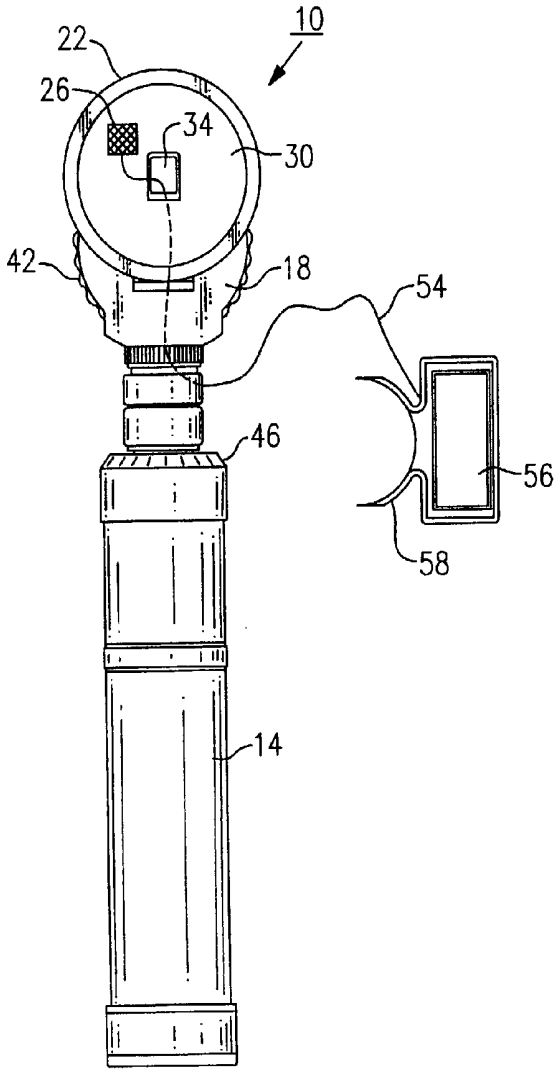
Publication Classification

(51) **Int. Cl.**[7] **A61B 5/00**

(52) **U.S. Cl.** **600/300**

(57) **ABSTRACT**

A hand-held medical or industrial diagnostic instrument includes at least one chemical sensing element capable of detecting at least one fluid emitted by a disease and producing an electrical or optical change when said at least one fluid is detected. The instrument further includes a processor having resident circuitry for processing the electrical change generated by said at least one chemical sensing element into a resulting output signal indicative of the disease(s). The at least one chemical sensing element is preferably supported in substantial direct proximity with a target area to be tested.



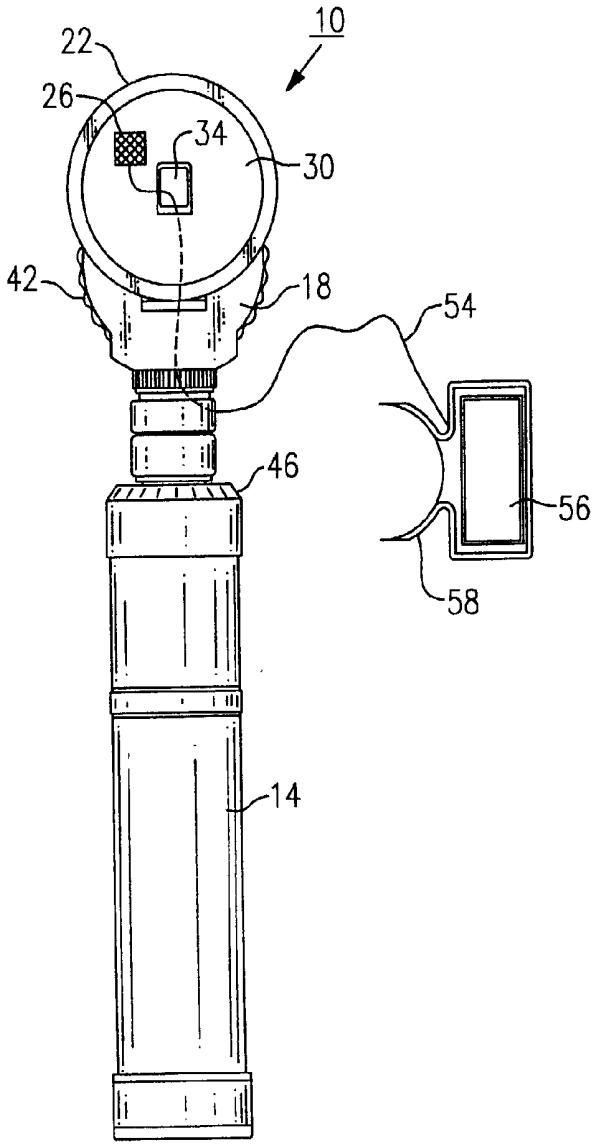


FIG.1

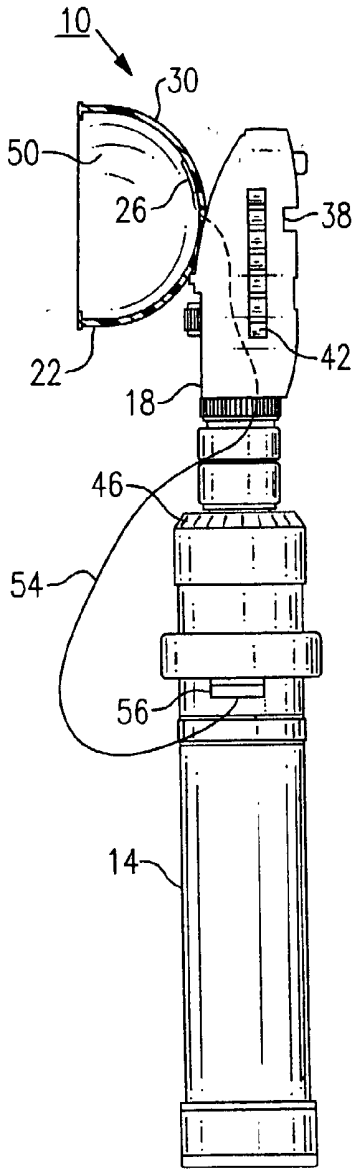


FIG.2

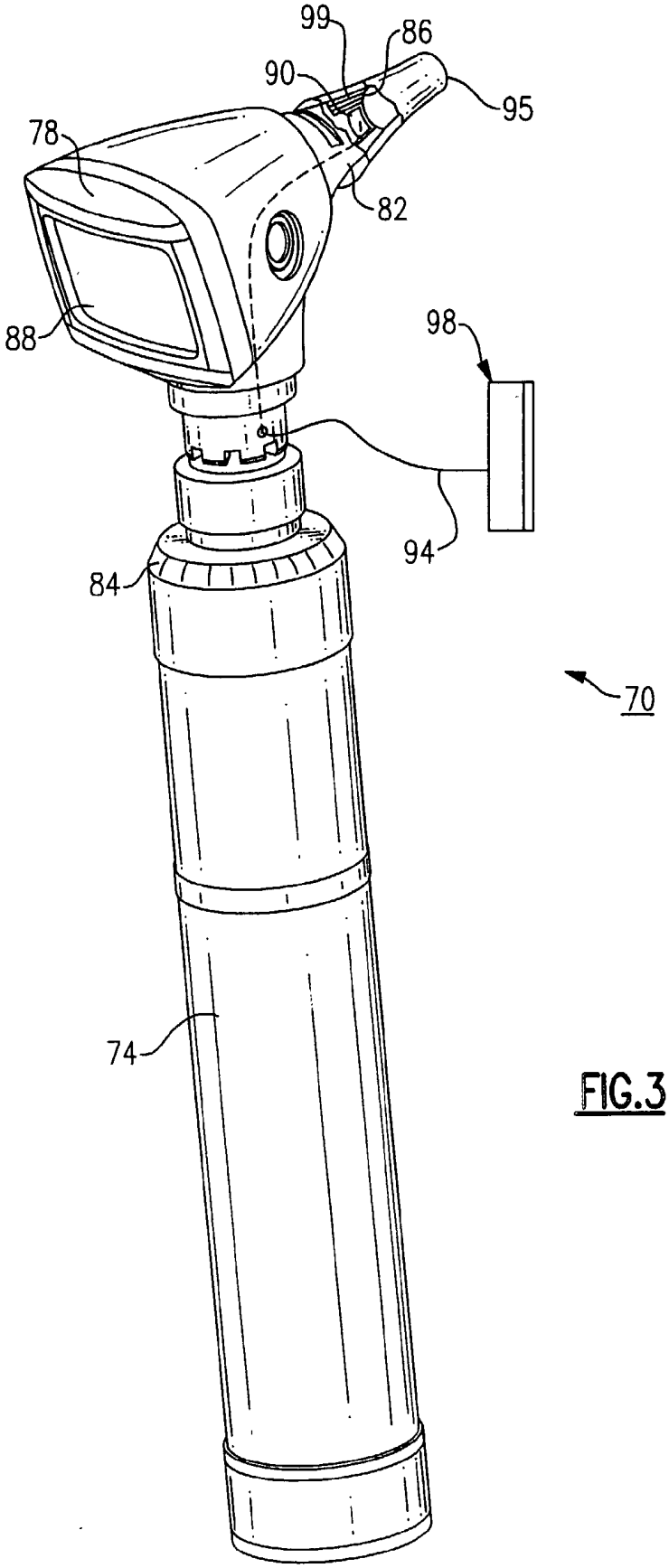


FIG.3

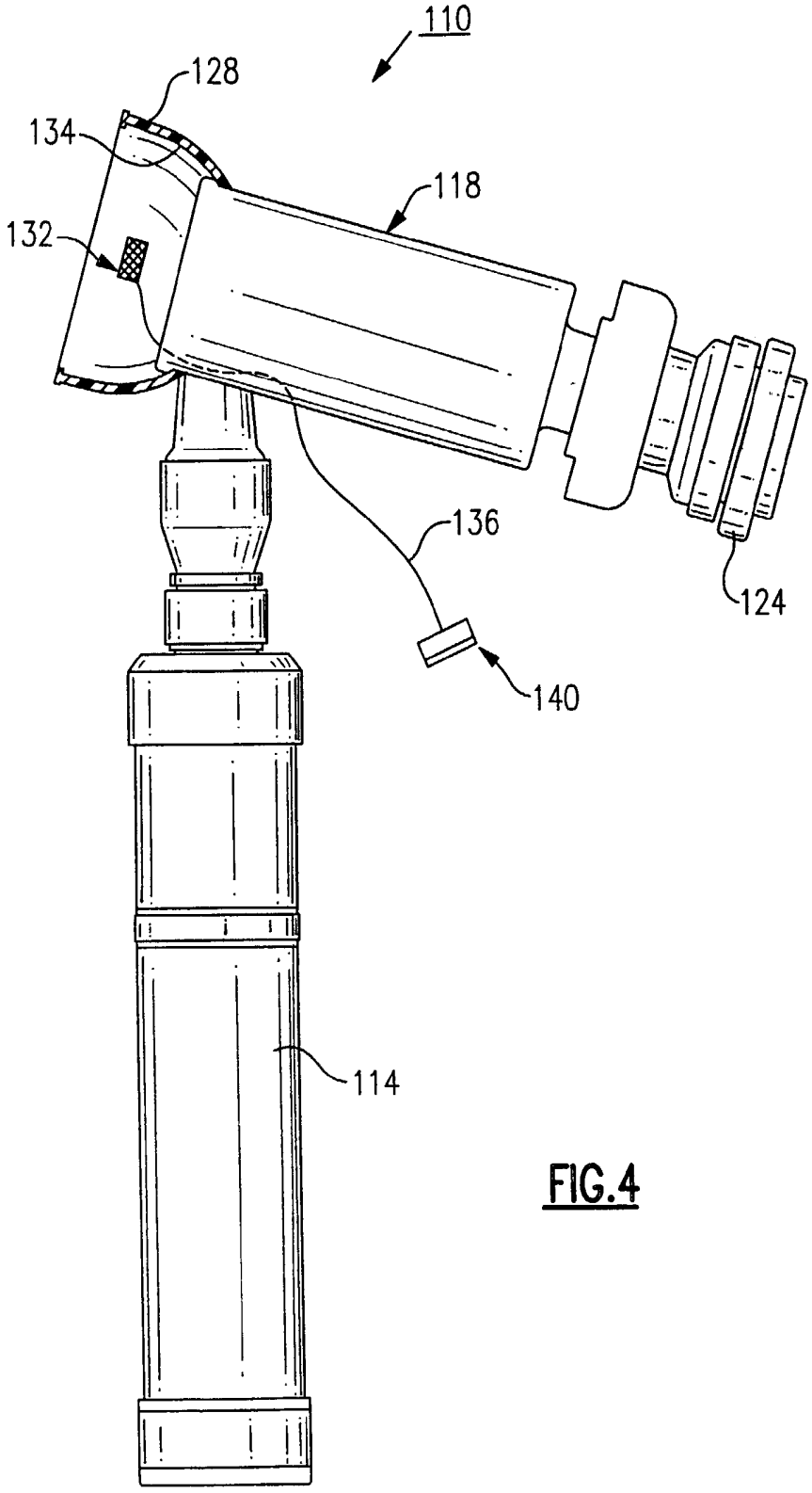


FIG.4

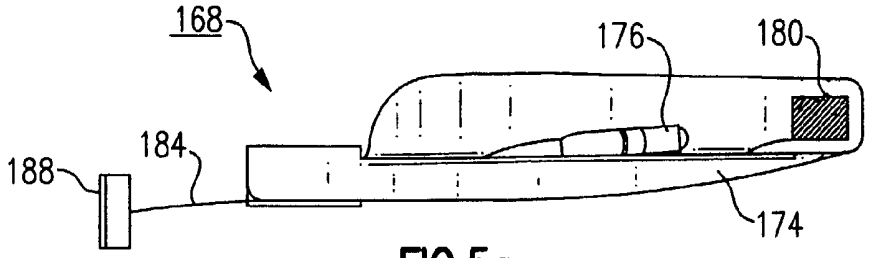


FIG.5a

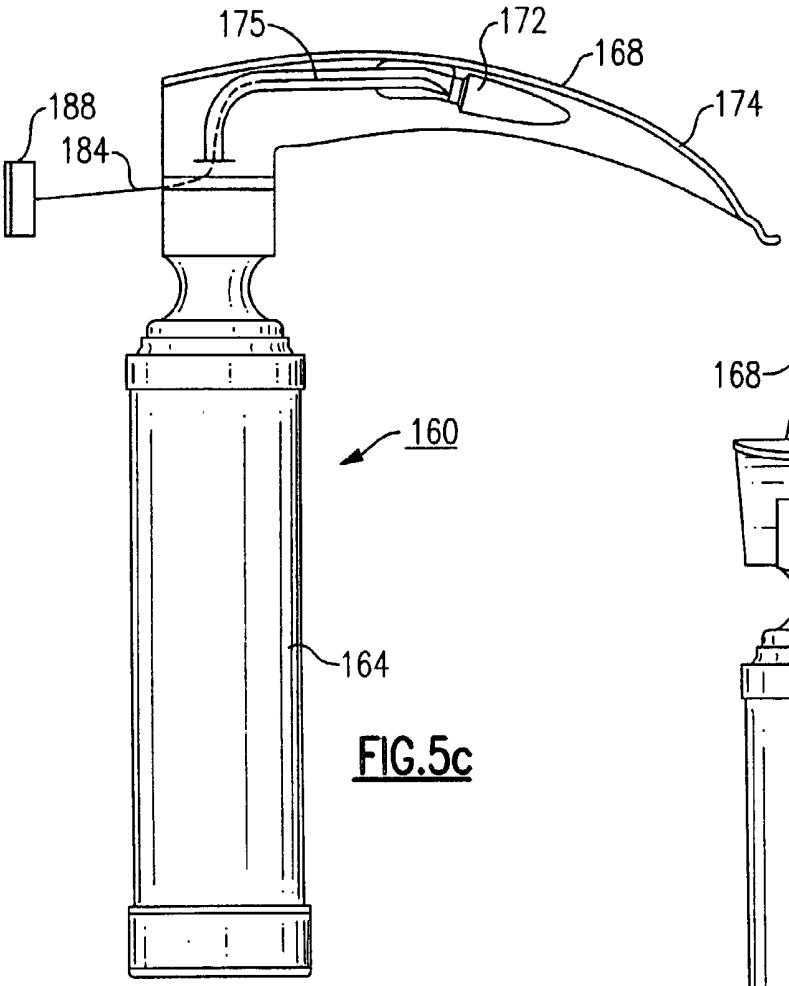


FIG.5c

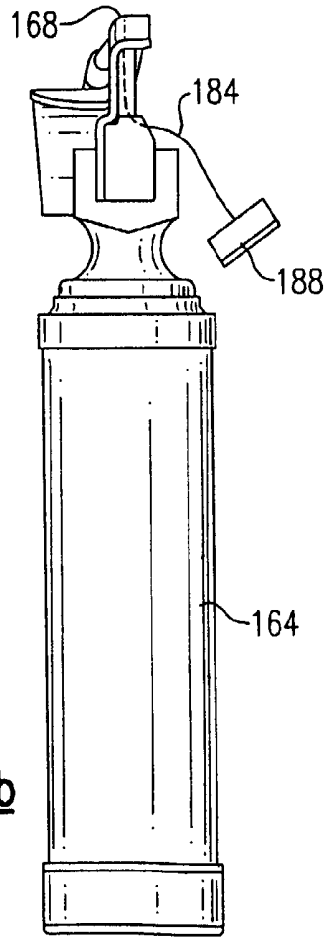


FIG.5b

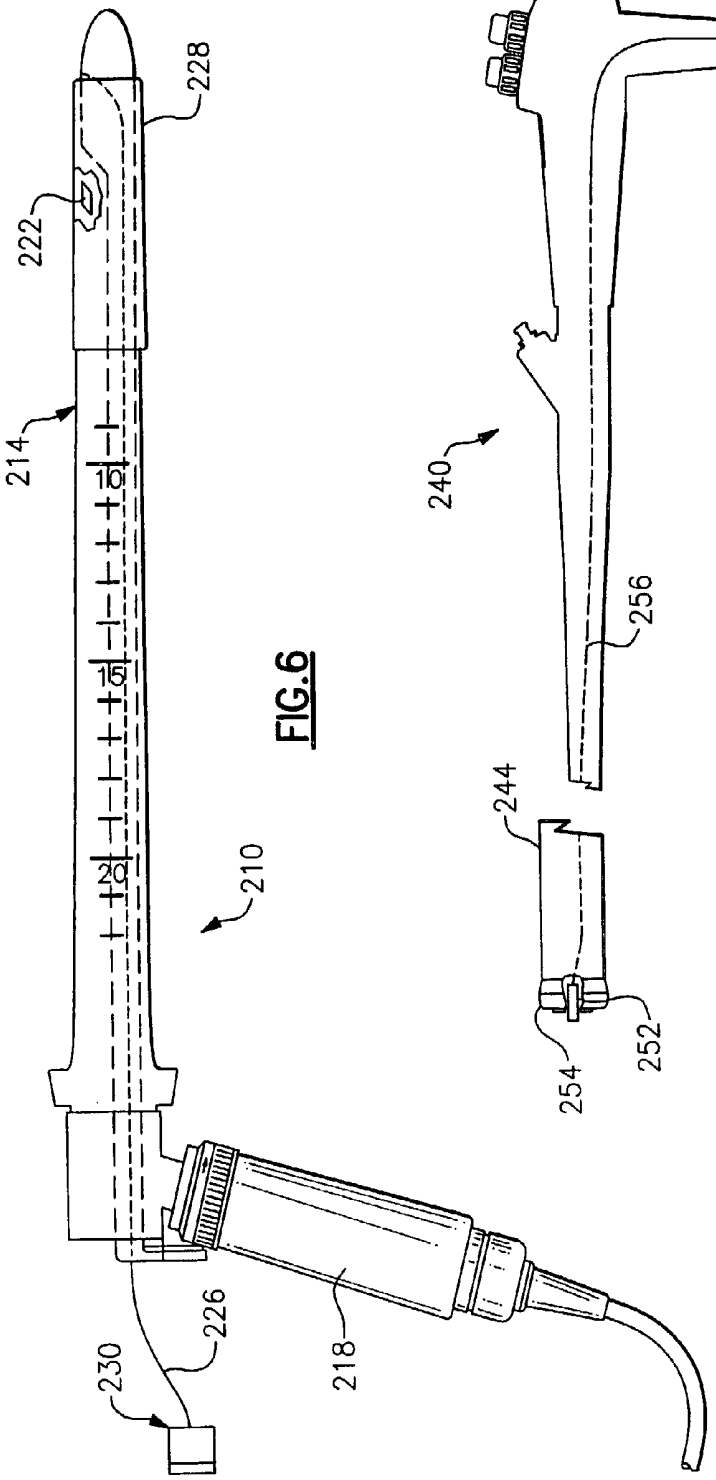


FIG.6

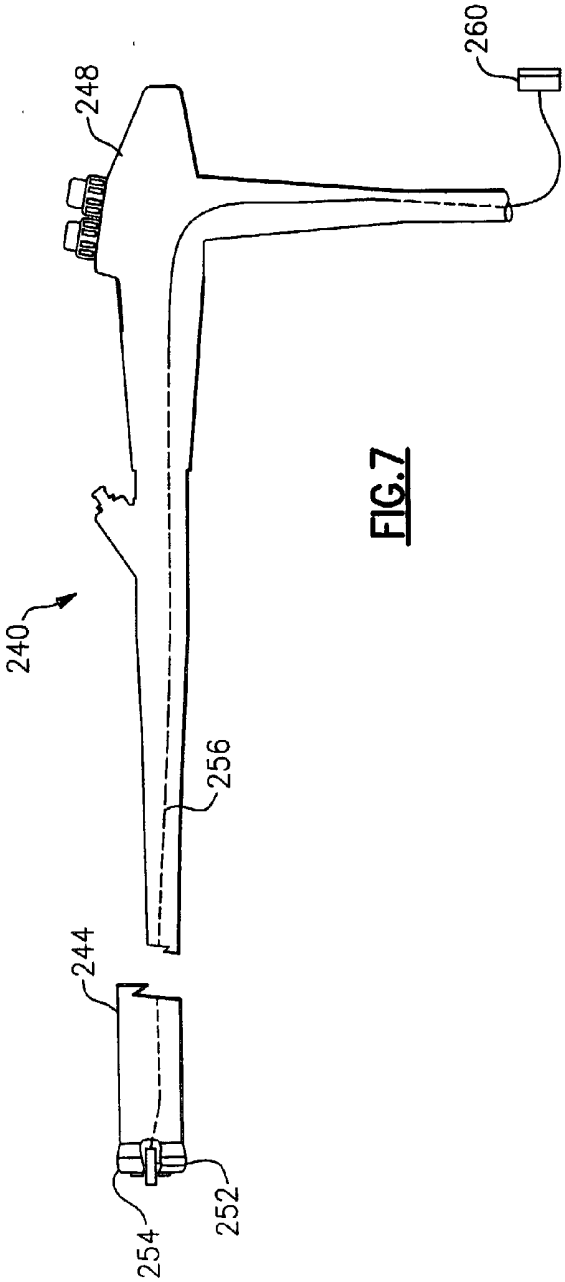


FIG.7

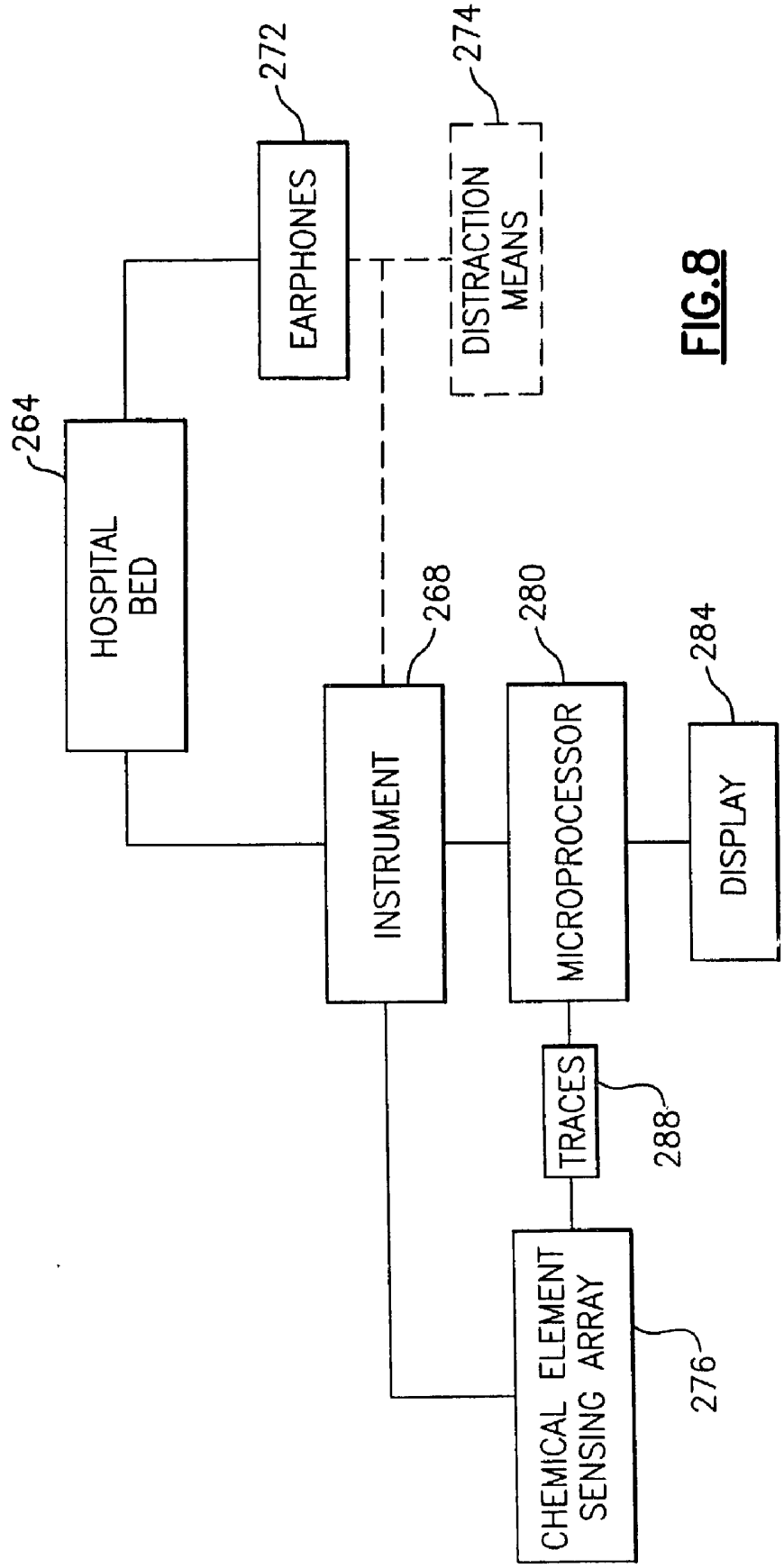

272
274
EARPHONES
DISTRACTION MEANS
264
HOSPITAL BED
268
280
284
INSTRUMENT
MICROPROCESSOR
DISPLAY
TRACES
288
CHEMICAL ELEMENT SENSING ARRAY
276

FIG.8

HAND-HELD CHEMICAL SENSING INSTRUMENT

FIELD OF THE INVENTION

[0001] The invention relates to the field of diagnostic instruments, and more particularly to a hand-held diagnostic instrument having at least one electronic chemical sensing element which can be used for medical and/or industrial purposes.

BACKGROUND OF THE INVENTION

[0002] Chemical sensing devices are repletely well known for detecting the presence of certain vapors, such as carbon monoxide and/or carbon dioxide, in either an industrial or home environment. Likewise, further applications of chemical sensing technology are found in the food processing industry.

[0003] To date, however, there are very few known devices which utilize chemical sensors for medical applications.

[0004] In addition, most known chemical sensing devices, including each of those referred to above, typically require a housing which retains at least one chemical sensor in a testing chamber. These devices further include means, such as a pump or other similar mechanism, for inputting a portion of the atmosphere of a target area into the housing for evaluation by the chemical sensor(s). An example of such a device is described at length in U.S. Pat. No. 6,234,006 to Sunshine et al. The testing chamber is internally disposed relative to a device housing. Another example found commercially is the Breath Alert Breath Checker manufactured by the Tanika Corporation. Such devices are also described, for example, in U.S. Pat. No. 5,799,102 to Leong which determines the authenticity of a bank note, and U.S. Pat. No. 5,675,070 to Gelperin in which an array of gas sensors are disposed in an interior testing chamber. The gas sensors of the array detect predetermined levels of specified components in a fluid mixture and then produce a sensor pattern which can subsequently be analyzed.

SUMMARY OF THE INVENTION

[0005] It is a primary object of the present invention to overcome the above-noted deficiencies in the prior art.

[0006] It is another primary object of the present invention to provide a compact diagnostic instrument which is capable of detecting a hazardous condition in a target environment.

[0007] It is yet another primary object of the present invention to provide at least one hand-held medical diagnostic instrument which is capable of detecting the presence of a fluid indicative of a disease or a disease process.

[0008] Therefore and according to a preferred aspect of the present invention, there is provided a hand-held medical diagnostic instrument comprising:

[0009] at least one chemical sensing element capable of detecting at least one fluid emitted by a disease and producing an electrical or an optical change when said at least one fluid is detected;

[0010] processing means for processing said electrical or optical change generated by said at least one chemical sensing element into a resulting signal indicative of said disease; and

[0011] supporting means for supporting said at least one chemical sensing element in substantial proximity with a target area to be tested.

[0012] The instrument can be any medical diagnostic instrument; for example, a skin surface microscope, an otoscope, an ophthalmoscope, or other similar device, for example, a vaginal scope. According to a preferred embodiment, the instrument includes an instrument head having means for defining a substantially enclosed volume which encompasses at least one chemical sensing element and a medical target area such as an in vivo portion of skin, the eye, nose, vagina, anus, throat and/or other similar area of a patient.

[0013] The instrument can also be an endoscope, such as a colonoscope, or a borescope with the target area being an anatomical body cavity or an industrial target such as a chemical fire or pressure vessel, among others.

[0014] A preferred form of medical diagnosis can be performed by using miniature chemical sensing elements in conjunction with a hand-held medical diagnostic instrument for detecting the presence of at least one fluid which is indicative of a specified disease of interest. For example, at least one chemical sensing element can be disposed on the blade of a laryngoscope in order to detect the presence of strep throat without requiring a culture from a patient as is required by known apparatus in the field. Similarly, the presence of ketones or acetone as detected by at least one chemical sensing element of the herein described instrument could provide a preliminary indication of diabetes. Moreover, the instrument can include processing means for determining the relative concentration of at least one specific fluid present in a target environment. In addition, a display or other indicating means can be provided to indicate the presence of a disease or other hazardous condition.

[0015] The supporting means, for example, can include at least one substrate upon which the at least one chemical sensing element or element array can be disposed. Preferably, an array of chemical sensing elements are disposed upon the supporting substrate which can be positioned in substantial direct contact with the target area. The chemical sensing element arrays and/or the supporting means can also be disposable.

[0016] The output of the chemical sensing elements is an electrical or an optical signal when a specific fluid is detected. The generated electrical signal can be transmitted using conventional conductive carriers to a local processing device which provides a comparison between the transmitted signal and a signature indicative of a disease. Alternately, the signal generated by the chemical sensing element(s) can be communicated using IR, RF, or other wireless techniques to a remote diagnostic center or database containing additional processing capability.

[0017] According to another preferred aspect of the invention, there is provided a method for detecting the presence of a disease or disease process, said method including the steps of: incorporating at least one chemical sensing element in conjunction with a medical diagnostic instrument, said chemical sensing element being capable of producing an electrical or optical signal when a fluid indicative of said

disease or disease process is detected; and disposing said medical diagnostic instrument and said chemical sensing element in substantial direct proximity with a medical target.

[0018] Preferably, the method includes the steps of incorporating at least one chemical sensing element into at least one of a hysteroscope and a colposcope and positioning the at least one chemical sensing element in substantial direct proximity with the cervix of a patient for determining the presence of at least one of endometreosis and cancer.

[0019] Alternately, the method includes the steps of incorporating at least one chemical sensing element capable of detecting the presence of at least one fluid indicative of a disease in a colonoscope, and positioning said colonoscope in substantial direct proximity with the colon for detecting the presence of at least one of ulcerative colitis and cancer.

[0020] An advantage of the present invention is that the presence of a disease, for example, such as strep throat or diabetes, can be determined non-invasively and more expeditiously than by any known means.

[0021] A further advantage of the present invention is that the instrument can detect the presence of the hazardous condition without requiring the use of pumps or other apparatus given that the sensor is in substantially direct contact with the target area.

[0022] Still another advantage is that the supporting means and/or the chemical sensing element can be disposable and therefore available for single patient use.

[0023] These and other objects, features, and advantages will be readily apparent from the following Detailed Description which should be read in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0024] **FIG. 1** is a front elevational view of a hand-held medical diagnostic instrument made in accordance with a first embodiment of the present invention;

[0025] **FIG. 2** is a side elevational view of the instrument depicted in **FIG. 1**;

[0026] **FIG. 3** is a side view, partly in section, of a medical diagnostic instrument made in accordance with a second embodiment of the invention;

[0027] **FIG. 4** is a side view, partly in section, of a medical diagnostic instrument made in accordance with a third embodiment of the present invention;

[0028] FIGS. **5**(*a*), (*b*) are frontal and side elevational views of a medical diagnostic instrument made in accordance with a fourth embodiment of the present invention;

[0029] **FIG. 5**(*c*) is a top view of a laryngeal blade assembly of the medical diagnostic instrument depicted in FIGS. **5**(*a*) and (*b*);

[0030] **FIG. 6** is a side view of a medical diagnostic instrument made in accordance with a fifth embodiment of the present invention;

[0031] **FIG. 7** is a side view of a diagnostic instrument made in accordance with a sixth embodiment of the present invention; and

[0032] **FIG. 8** is a schematic view of a hand-held medical instrument according to the present invention as used in connection with a hospital bed.

DETAILED DESCRIPTION

[0033] The following discussion relates to several embodiments of medical diagnostic instruments incorporating an electronic sensing apparatus. Throughout the discussion which follows, several terms such as "upper", "lower", "top", "bottom" and "lateral", among others, are used to provide a frame of reference with regard to the accompanying drawings. These terms, however, should not be interpreted as limiting of the inventive concepts described herein. Furthermore, it will also be readily apparent that the herein described concepts are equally applicable outside of the medical field. That is, similar instruments can be created including the concepts herein described which are useful for industrial uses, such as determining the nature of certain chemical fires, determining the presence of certain volatile compounds in a building or structure, and/or a myriad of other potential applications. In addition and for definitional purposes, "fluid" is intended herein to mean any liquid, gas, or vapor. In addition, the term "disease" is also used repletely throughout the discussion. By "disease", it is intended to cover both diseases which are found in a particular medical target area, such as conjunctivitis in the eye, otitis in the ear, strep throat in the ear and throat, etc. The term is also intended to cover the detection of fluids, for example, the detection of ketones which are indicative of the presence of a systemic disease or disease process.

[0034] Referring to **FIGS. 1 and 2**, there is shown a hand-held medical diagnostic instrument made in accordance with a first embodiment of the present invention. The instrument according to this embodiment is an ophthalmoscope **10** used for examining the eyes of a patient which includes a cylindrical handle **14** which can be gripped by the hand of a user as well as an instrument head **18** which is attached to the top of the handle.

[0035] The instrument head **18** of the herein described ophthalmoscope **10** includes a horizontal viewing passage therethrough with an aperture **34** on its front or distal side that is brought close to a patient's eye (not shown) and a smaller aperture **38** on its rear or proximal side into which the physician looks. A scalloped edge of a lens wheel **42** is accessible on opposite lateral sides of the instrument head **18** which permits registry with the aperture **38**. The lens wheel **42** contains a plurality of lenses (not shown) arranged circumferentially, as is conventionally known, each lens having a different focal length. A light source (not shown), such as a halogen or other miniature bulb, is provided in the body of the cylindrical handle **18** as well as a power source, such as batteries for powering same. The output of the light source is preferably adjusted by a rheostat **46** which is provided on a neck portion of the handle **14**. Additional details relating to the standard features and operation of the ophthalmoscope **10** are provided, for example, in U.S. Pat. Nos. 3,978,850, 4,643,546, and 4,998,818, the entire contents of which are herein incorporated by reference.

[0036] A semi-spherical enclosure **22** which can be attached by known means to the distal side of the instrument head **18** (or integrally provided therewith) retains an array **26** of chemical sensing elements that are attached by con-

ventional means by epoxy, glass frit, adhesive, or other means. Alternately, the array **26** can also be detachably mounted such as through the use of hook and loop fasteners (not shown) or other commonly known means. The sensing elements of the array **26** are attached to a supporting substrate which is attached along an interior surface of the enclosure **22**. The chemical sensing element array **26** according to this embodiment consists of a plurality of miniature polymer gas sensors such as those manufactured by Cyrano Sciences, Inc of Pasadena, Calif., or as described in U.S. Pat. No. 5,571,401 to Lewis et al., U.S. Pat. No. 5,882,497 to Persaud et al., U.S. Pat. No. 6,033,601 to Persuad et al., U.S. Pat. No. 6,093,308 to Lewis, and U.S. Pat. No. 6,013,229 to Lewis, the entire contents of each are herein incorporated by reference. It will be readily apparent, however, that other known chemical sensing elements such as organic gas sensors, conductive composites, metal oxide field effect transistors, surface acoustic wave (SAW) sensors, piezoelectric sensors, metal oxide sensors, and others, can easily be substituted without significantly deviating from the inventive concepts of the invention. Each of the chemical sensing elements of the array **26** are capable of detecting a specific fluid (e.g., gas, liquid, or vapor), the presence of which produces an electrical change. Chemical reactions on the sensors can also cause changes which can be subsequently detected by optical means. These miniature optical chemical sensors, for example, those manufactured by Illumina, Inc., of San Diego Calif., are also within the ambit of the present invention.

[**0037**] Due to the overall sensitivity of the miniature polymer gas sensors of the chemical sensing element array **26** utilized in this embodiment, at least one temperature sensor and/or humidity sensor and/or pH sensor (not shown) are also preferably attached in a conventional manner either to the interior surface of the semi-spherical enclosure **22** or otherwise in the immediate vicinity of the chemical sensing element array **26**. The semi-spherical enclosure **22**, when brought into direct, intimate contact with the patient, defines a substantially sealed and enclosed volume or head space **50** which in effect creates a test chamber, the chamber including the chemical sensing element array **26** and the target atmosphere. It should be further noted that though enclosure **22** is substantially semi-spherical, other suitable shapes or geometries capable of defining a head space can be utilized. As further described below, the semi-spherical enclosure can also be used to produce a head space for interrogating a number of different anatomical target areas, including body cavities such as the vagina, nose, throat, anus or an in vivo potion of skin.

[**0038**] In operation, the ophthalmoscope **10** is used in the conventional way to examine the eye using the lens wheel **42** and contained light source. The semi-spherical enclosure **22** includes a rear opening to allow optical access to the distal side aperture **34**, the enclosure further providing a substantially sealed area about the eye (not shown) as previously noted. As noted above, and the presence of certain analytes (fluids), for example, those which might be representative of conjunctivis or other disease, certain of the chemical sensing elements of the array **26** will produce a change in an electrical or optical characteristic (such as resistance, transconductance, conductance, impedance, resonant frequency, voltage, inductance, capacitance, or other perceivable electrical or optical parameter), the sensing elements of the array each being connected through traces (not shown) provided along the supporting substrate to corresponding electrical conductors **54** to provide an electrical path to an attached microprocessor **56** or alternately to a display (not shown).

[**0039**] The microprocessor **56** includes suitable memory as well as processing circuitry which analyzes the electrical signals generated by the chemical sensing element array **26**, the herein described microprocessor including a snap-on clip **58** to attach same to the cylindrical handle **14** of the ophthalmoscope **10**. Preferably, the microprocessor **56** includes certain integrated processing electronics including an analog-digital (A/D) converter as well as resident control and timing circuitry which is used in conjunction with a reference crystal in order to detect the amount of electrical change by each of the sensing elements of the array **26** for processing, such as comparing to a stored look-up table and then outputting the results to an LCD or other suitable display. The microprocessor **56** can further include a set of internal lithium batteries (not shown) for powering the processor and the chemical sensing element array **26**, or each can be powered by the batteries (not shown) which are already contained within the instrument handle **14**. Each of the above features are described in greater detail in commonly owned U.S. Ser. No. 09/663,698 to Newman et al., the entire contents of which are herein incorporated by reference.

[**0040**] The microprocessor **56** preferably includes sufficient memory for storing the values of the electrical signals generated by the chemical sensing element array **26**. According to an alternate embodiment, the instrument can include a transmitting antenna and receiver. These features are described in greater detail in U.S. Ser. No. 09/884,224, which is also herein incorporated by reference in its entirety. In this manner, a remotely generated signal can cause wireless (RF, IR, etc.,) transmission of the electrical signal values stored by the memory of the microprocessor **56** for downloading to a local and/or remote processing unit (not shown) having greater processing capability.

[**0041**] Referring to **FIG. 3**, there is shown a diagnostic instrument made in accordance with a second embodiment of the present invention. In this instance, the diagnostic instrument is an otoscope **70** which is used for examining the outer ear. Like the preceding, the present instrument includes a hand-grippable instrument handle **74** as well as an instrument head **78** which is attached in a known manner to the top of the instrument handle. The instrument head **78** of the herein-described otoscope **70** includes a frustoconical insertion or speculum portion **82** which is sized to be fitted a predetermined distance into the ear canal (not shown) of a patient and further includes a distal or front tip opening **86** and may include a tip **95** enclosing the ear canal. A magnifying eyepiece **88** is provided on the opposite rear or proximal side of the instrument head **78**, the head possibly further including an enclosed optical system (not shown), such as an objective or relay lens assembly, used to transmit light reflected from the ear through the distal tip opening **86** and to the eyepiece **88**. As in the preceding, a halogen or other miniature bulb (not shown) contained within the instrument handle **74** is used to illuminate the target. Preferably, the output of the light source is preferably controlled by a rheostat **84** provided on the upper portion of the instrument handle **74**. The illumination output is directed, for example, using a series of optical transmitting fibers **99**

that extend into the interior of the insertion portion **82** and encircle the distal tip opening **86**. Alternately, white LEDs (not shown) or other light sources can be utilized, the choice of light source not being an essential part of the present invention. In each instance, power is supplied to the light source through batteries (not shown) which are retained within the handle **74** of the instrument **70**. The standard features of the herein described otoscope **70** and operation thereof can be found, for example in U.S. Pat. Nos. 3,992,158 and 5,919,130, the entire contents of each herein being incorporated by reference.

[**0042**] For purposes of this invention and still referring to **FIG. 3, a** chemical sensing element array **90** is attached, detachably or otherwise, to an interior surface of the frusto-conical insertion portion **82** or the tip **95**, preferably adjacent the distal tip opening **86**. As in the preceding, the chemical sensing element array **90** according to this embodiment are miniature polymer gas sensors manufactured by Cyrano Sciences, Inc of Pasadena, Calif., such as those described in previously incorporated U.S. Pat. Nos. 5,571,401, 5,882,497, 6,033,601, 6,093,308, and 6,013,229. As previously noted, however, it will be readily apparent that other known chemical sensing elements, such as organic gas sensors, conductive composites, metal oxide field effect transistors, surface acoustic wave sensors, piezoelectric sensors, metal oxide sensors, optical chemical sensors and others, can easily be substituted without significantly deviating from the inventive concepts of the invention.

[**0043**] The chemical sensing element array **90** is preferably disposed on a supporting substrate, such as that described in previously incorporated U.S. Ser. Nos. 09/663,698 and 09/884,224, wherein a series of traces (not shown in **FIG. 3**) which extend from each of the individual chemical sensing elements through the interior of the insertion portion **82** and the handle **74** along corresponding electrical conductors **94** to a microprocessor **98** which can be connected to the instrument handle **74**, such as using the exemplary clip-like attachment previously shown in **FIGS. 1 and 2**. The sensing element array **90**, as well as the microprocessor **98** which includes the processing circuitry described previously and also as described in incorporated U.S. Ser. No. 09/884,224 can be powered using the batteries (not shown) contained within the handle **74**, or alternately through dedicated batteries (not shown) provided with the microprocessor **98**.

[**0044**] In use, the otoscope **70** is used in a conventional manner to examine the ear (not shown) of a patient by placing the distal part of the insertion portion **82** into the ear of the patient and by directing light from the contained light source through the distal tip opening **86**. The image received through the magnifying eyepiece **88** is then inspected by the physician to detect, for example, the presence of infection. In addition, the chemical sensing element array **90** is also exposed directly to the atmosphere of the outer ear and in the presence of certain analytes, for example, those which might be representative of otitis or other malady including upper respiratory infections such as strep throat. As a result, certain of the chemical sensing elements of the array **90** will produce a change in an electrical and/or optical characteristic, (such as transconductance, conductance, impedance, resonant frequency, voltage, inductance, capacitance, and resistance, etc.,) the sensing elements of the array each being connected through traces (not shown) provided along the supporting substrate to the corresponding electrical conductors **94** to provide an electrical path to the attached microprocessor **98**. The microprocessor **98** includes processing circuitry which analyzes the electrical signals generated by the chemical sensing element array **90**. As in the preceding, a transmitter (not shown) could permit wired or wireless transmission of stored electrical signal values from the microprocessor **98**, such as to a remote processing unit (not shown).

[**0045**] Referring to **FIG. 4**, there is shown a diagnostic instrument made in accordance with a third embodiment of the present invention. In this instance, the instrument is a skin surface microscope **110** which includes an instrument head **118** attached to a hand-grippable handle **114**, the instrument head having a distal side (not shown) and a proximal side which includes an eyepiece **124**. The interior of the instrument head **118** includes an optical system which magnifies a corresponding image of a target which is brought to the eyepiece **124**. As in the preceding, a light source (not shown) and batteries (not shown) are contained within the instrument handle **114** for illuminating a target of interest, in this instance, an in vivo section of skin. Details relating to the specific features of a skin surface microscope are provided, for example, in previously incorporated U.S. Pat. No. 3,978,850.

[**0046**] Still referring to **FIG. 4, a** semi-spherical enclosure **128** is attached to the distal side of the instrument head **118**, the enclosure including a chemical sensing element array **132**, similar to those previously described above. The sensing element array **132** is attached such as by glass frit, epoxy, or other means to a supporting substrate which is attached fixedly or detachably by conventional means to an interior surface **134** of the enclosure **128**. The sensing element array **132** includes a plurality of polymeric, organic or other fluid sensing elements, such as those described above, each of the sensing elements including traces provided on the substrate which permit electrical or optical signals to be carried along electrical or optical conductors **136** to an attached microprocessor **140** having suitable memory and processing circuitry for processing the generated electrical signals, as described below, and in incorporated U.S. Ser. No. 09/884,224.

[**0047**] In operation, the presently described skin surface microscope **110** is used in its intended conventional manner by placing the semi-spherical enclosure **128** over and in direct intimate contact with a target of interest and viewing same as illuminated by the contained light source (not shown) through the eyepiece **124** of the instrument head **118** to examine an in vivo portion of skin and to detect the occurrence of moles, lesions, warts, skin cancers, psoriasis, allergic reactions such as rashes, and the like. In addition, and without detracting from this original use, the chemical sensing element array **132** can be used to detect the presence of at least one fluid in the vicinity of the in vivo skin portion (not shown) which is indicative of a disease, such as diabetes. As in the preceding, the detection of a specific vapor produces an electrical or optical change in at least one chemical sensing element, this change(s) being transmitted to the microprocessor **140** having suitable memory for storing the signal value.

[**0048**] According to the present embodiment, the microprocessor **140** contains sufficient processing circuitry and a

look up table to compare the sensor pattern of the array **132** in order to indicate the presence of a disease process. Alternately and as described above, the stored electrical signal values could be transmitted by known wire or wireless (IR, RF) technologies to a local or remote processing unit (not shown). The instrument **110** can further include an LCD (not shown) or other means to indicate a result.

[**0049**] Referring to FIGS. **5**(*a*)-**5**(*c*), there is shown a medical diagnostic instrument made in accordance with a fourth embodiment of the present invention. In this instance, the instrument is a laryngoscope **160** which is generally used to displace the tongue and to inspect the throat/larynx of a patient preferably before introducing tracheal tubes and the like for intubation. The laryngoscope **160** includes a hand-grippable cylindrical handle **164**, similar to that previously described, as well as a releasable blade assembly **168** which is attached to the top of the handle. An exemplary blade assembly is described in commonly assigned U.S. Pat. Nos. 6,013,026 and 6,213,927, the entire contents of each are herein incorporated by reference.

[**0050**] According to this embodiment, the laryngeal blade assembly **168** includes a laryngeal blade **174**, sometimes referred to as a spatula, which is an elongated member made from a biocompatible material, such as stainless steel, which is sized to examine the larnyx. A tube with wires **175** extends from the handle **164** terminating at a halogen bulb **176** which extends from a distal opening in a receiving pocket **172**. This particular design of instrument is not critical to the present invention; that is, other laryngoscopes include a halogen bulb disposed within the handle and a plurality of optical fibers extending into the hollow light pipe **175** in order to transmit the light from the bulb to the distal tip of the laryngeal blade **174**.

[**0051**] Still referring to FIGS. **5**(*a*)-**5**(*c*), an array **180** of chemical sensing elements, such as the polymeric gas sensing elements which have been previously described above, is attached by known means to a supporting substrate which is mounted to a distal end of the laryngeal blade **172**.

[**0052**] Like the previous embodiments, the array **180** of chemical sensing elements includes a set of traces provided on the supporting substrate which are connected to electrical conductors **184** extending to a microprocessor **188**. As in the preceding, the microprocessor **188** contains suitable memory for storing electrical signal values generated by the array as well as processing circuitry, such as described in previously incorporated U.S. Ser. No. 09/884,224, for analyzing the generated signals.

[**0053**] As in each of the preceding examples, the herein described instrument **160** can be used in the conventional manner to inspect the larynx, the distal end of the blade **172** extending into the throat of a patient permitting, for example, the detection of certain fluids given off which are indicative of upper respiratory infections such as strep throat or other fluids such as ketones or acetone indicative of diabetes, or cancer.

[**0054**] Alternately an in lieu of a laryngoscope blade, a tongue blade or depressor can be used to similarly interrogate the throat of a patient. Such a tongue depressor design is described in copending U.S. Ser. No. 09/884,224, previously incorporated, in its entirety.

[**0055**] Referring to **FIGS. 6 and 7**, medical diagnostic instruments are depicted which are made in accordance with respective fifth and sixth embodiments of the present invention, each incorporating at least one chemical (fluid) sensing element. In these examples, the instruments are a medical endoscope, such as a rigid sigmoidoscope **210**, shown in **FIG. 6**, which is used to inspect the sigmoid-colon and a flexible endoscope **240**, such as a colonoscope that is shown in **FIG. 7**.

[**0056**] Referring to **FIG. 6**, the sigmoidoscope **210** includes an elongated insertion portion **214** which is connected to a handle section **218** such as described in, for example, U.S. Pat. No. 4,353,358 to Emerson et al., among others. The insertion portion **214** is a cylindrical stainless steel or plastic tube which is shaped and sized for fitting into the rectum and including therein an illumination system which permits visualization by the physician either through an eyepiece or through video endoscopy. Details relating to the general operation and features of the sigmoidoscope **210** are found in the above U.S. Pat. No. 4,353,358 which is herein incorporated by reference in its entirety.

[**0057**] According to the present embodiment, a chemical sensing element array **222** is attached by known means to a distal end **228** of the insertion portion **214**. As in the preceding, the array includes a plurality of polymeric, organic, or other type of miniature fluid sensing elements which in the presence of certain analytes will change an electrical characteristic. Examples of such sensors are provided in the preceding embodiments. The sensing elements are provided on a supporting substrate (not shown) made from a biocompatible material and including a set of traces which are connected to a set of electrical conductors **226** extending to a microprocessor **230**. The microprocessor **230** contains memory and processing circuitry as described in each of the preceding embodiments and as further described in previously incorporated U.S. Ser. No. 09/884,224. Likewise, wired or wireless interconnection with a remote or local processing unit having additional capability is also contemplated, though not shown in **FIG. 6**.

[**0058**] As in the preceding, the instrument **210** can be used in its intended manner by the physician for examination purposes, with additional capability being provided by the attached array **222** which can be used to detect the specific fluids present in the examined environment, indicative of disease, for example, ulcerative colitis, diverticulitis, cancer, and ilitis among others.

[**0059**] Referring to **FIG. 7, a** flexible endoscope or borescope **240** is shown which is constructed similarly to the endoscope of **FIG. 6**; that is, including an insertion portion **244** and a control section **248**. A chemical sensing element array **252**, similar to that shown in **FIG. 6**, is attached by conventional means to a distal end **254** of the insertion portion **244**, the array being electrically connected through a series of conductors **256** to a microprocessor **260**. The instrument shown is a colonoscope though it should be readily apparent that other medical endoscopes, such as the group consisting of laparoscopes, laryngoscopes, hysteroscopes, gastroscopes, otoscopes, laparoscopes, colposcopes, arthoscopes, vaginal scopes, esosphogoscopes, anoscopes, angioscopes, thoraxoscopes, and cystoscopes can also be utilized.

[**0060**] A number of different medical diagnosis procedures can be performed using certain of the above noted instruments. For example, at least one of ulcerative colitis

and cancer can be diagnosed using at least one chemical sensing element or elements capable of detecting the presence of at least one vapor indicative of a disease and mounting the element(s) in the manner described above in a colonoscope.

[0061] Similarly, the presence of endometreosis or cancer or pre-cancer in the cervix can also be detected by incorporating at least one chemical sensing element or an array of such elements, such as those described herein, in conjunction with at least one of a hysteroscope and a colposcope and positioning the chemical sensing element(s) in substantial direct proximity with the cervix of a patient. The herein described endoscope can further include an isolating enclosure similar to 22 to allow build-up of concentration of fluids in the target environment.

[0062] As noted, industrial borescopes include designs similar to that illustrated in **FIG. 7** which can be used for inspection purposes. It is contemplated that this apparatus can also be configured to include sensing arrays such as described herein which can be added to permit detection of specific vapors or other fluids.

[0063] Referring to **FIG. 8**, there is shown a schematic view to better describe the overall versatility of the above invention.

[0064] In this instance, a hand-held medical instrument (a sphygmomanometer **268** used to measure mean arterial blood pressure) includes a chemical sensing element array **276** which is releasably or fixedly attached to the interior side of an inflatable blood pressure sleeve. The instrument **268**, including the chemical sensing element array **276**, a microprocessor **280** and a display **284** is attached, either directly or in close proximity to a hospital bed, shown schematically as **264**.

[0065] The chemical sensing element array **276** includes at least one chemical sensing element of detecting a specific fluid through an electrical or optical change. This change is transmitted through traces **288** to the microprocessor **280** which contains appropriate processing circuitry. If the specific fluid, indicative of a disease or disease process is detected, then an appropriate signal is sent to the display **284**.

[0066] According to this embodiment, a set of earphones **272** are provided. These earphones **272** can be used to distract the patient during measurement. Alternate distracting means, shown in phantom as **274**, can also be contemplated, for example, an audio, video or other distraction can be provided. In addition, the earphones **272** cover the ears and thereby can produce an enclosed headspace in a similar manner to the semi-spherical enclosed volume **50**, **FIG. 2**, for use with a device (not shown) such as previously described for determining the presence of fluid indicative of a disease within the ear. However, because the ear volume is relatively small, it may take considerable time to build up a measurable concentration of fluid within the headspace. Therefore, the earphones **272** can be also be used to distract the patient (not shown) during measurements.

[0067] It should also be apparent that the instrument could wirelessly transmit the electrical or optical change/signal to a remote processor unit (not shown).

PARTS LIST FOR FIGS. **1-8**

[0068] 10 ophthalmoscope

[0069] 14 handle

[0070] 18 instrument head

[0071] 22 enclosure

[0072] 26 chemical sensing element array

[0073] 30 interior surface

[0074] 34 aperture

[0075] 38 aperture

[0076] 42 lens wheel

[0077] 46 rheostat

[0078] 50 enclosed volume

[0079] 54 conductors

[0080] 56 microprocessor

[0081] 58 clip

[0082] 70 otoscope

[0083] 74 handle

[0084] 78 instrument head

[0085] 82 frusto-conical insertion portion

[0086] 84 rheostat

[0087] 86 distal tip opening

[0088] 88 magnifying eyepiece

[0089] 90 chemical sensing element array

[0090] 94 electrical conductors

[0091] 95 tip

[0092] 98 microprocessor

[0093] 99 optically transmitting fibers

[0094] 110 skin surface microscope

[0095] 114 handle

[0096] 118 instrument head

[0097] 124 eyepiece

[0098] 128 enclosure

[0099] 132 chemical sensing element array

[0100] 134 interior surface

[0101] 136 conductors

[0102] 140 microprocessor

[0103] 160 laryngoscope

[0104] 164 handle

[0105] 168 laryngeal blade assembly

[0106] 172 receiving pocket

[0107] 174 blade

[0108] 175 tube with wires

[0109] 176 bulb

[0110] 180 chemical sensing element array

[0111] 184 electrical conductors

[0112] 188 microprocessor

[0113] 210 sigmoidoscope

[0114] 214 insertion portion

[0115] 218 handle portion

[0116] 222 chemical sensing element array

[0117] 226 conductors

[0118] 228 distal end

[0119] 230 microprocessor

[0120] 240 endoscope

[0121] 244 insertion portion

[0122] 248 control section

[0123] 252 chemical sensing element array

[0124] 254 distal end

[0125] 256 conductors

[0126] 260 microprocessor

[0127] 264 hospital bed

[0128] 268 instrument (sphygmomanometer)

[0129] 272 earphones

[0130] 274 distracting means

[0131] 276 chemical sensing element array

[0132] 280 microprocessor

[0133] 284 display

[0134] It should be apparent that other variations and modifications can be realized within the intended scope of the present invention in addition to the embodiments described herein.

We claim:

1. A hand-held medical diagnostic instrument comprising:

at least one chemical sensing element capable of detecting at least one fluid emitted by a disease and producing an electrical or optical change when said at least one fluid is detected; and

processing means for processing said electrical change generated by said at least one chemical sensing element into a resulting output signal indicative of said disease; and

supporting means for supporting said at least one chemical sensing element in substantial proximity with an area to be tested.

2. An instrument as recited in claim 1, including indicating means for indicating when said at least one fluid is detected.

3. An instrument as recited in claim 2, wherein said indicating means is a display.

4. An instrument as recited in claim 1, wherein said instrument is a skin surface microscope.

5. An instrument as recited in claim 4, including means for creating a substantially enclosed volume encompassing at least one chemical sensing element and an in vivo portion of skin serving as a target area.

6. An instrument as recited in claim 5, wherein said instrument can interrogate a medical target area selected from the group consisting of at least one of the ear, mouth, eyes, vagina, anus, urinary tract, nose, throat and an invivo portion of skin using said means for creating a substantially enclosed volume.

7. An instrument as recited in claim 1, wherein said instrument is an ophthalmoscope.

8. An instrument as recited in claim 7, wherein said at least one chemical sensing element is capable of detecting conjunctivitis.

9. An instrument as recited in claim 7, including means for creating a substantially enclosed volume encompassing at least one chemical sensing element and an eye of a patient.

10. An instrument as recited in claim 1, wherein said instrument is an endoscope and said area of interest is a body cavity.

11. An instrument as recited in claim 10, wherein said instrument is selected from the group consisting essentially of colonoscopes, laryngoscopes, hysteroscopes, gastroscopes, otoscopes, laparoscopes, colposcopes, arthoscopes, vaginal scopes, esosphogoscopes, anoscopes, angioscopes, thoraxoscopes, and cystoscopes.

12. An instrument as recited in claim 1, wherein said instrument is capable of detecting the presence of strep throat in a patient without requiring a culture therefrom.

13. An instrument as recited in claim 1, wherein said supporting means includes a substrate upon which said at least one chemical sensing element is disposed, said substrate being sized to be positioned in the mouth or throat of a patient, wherein said at least one chemical sensor is capable of detecting the presence of diabetes.

14. An instrument as recited in claim 13, wherein said at least one chemical sensing element is capable of detecting the presence of at least one of ketones and acetone, said processing means being capable of calculating the concentration thereof as detected by said at least one chemical sensing element.

15. An instrument as recited in claim 14, including indicating means for indicating the concentration of said at least one of ketones and acetone.

16. An instrument as recited in claim 1, including indicating means for indicating the concentration of said at least one of ketones and acetone.

17. An instrument as recited in claim 15, wherein said indicating means includes a display connected to said processing means.

18. An instrument as recited in claim 1, wherein said indicating means includes a display connected to said processing means.

19. An instrument as recited in claim 1, wherein said instrument is a sphygmomanometer including a cuff mounted onto the limb of a patient and in which said at least one chemical sensing element is mounted on said cuff such that chemicals emitted by and through the skin of a patient can be detected.

20. An instrument as recited in claim 1, including means for installing said instrument in at least close proximity to a hospital bed.

21. An instrument as recited in claim 20, wherein said instrument is capable of interrogating a medical target from the group consisting of at least on of the ear, mouth, eyes, vagina, anus, urinary tract, nose, throat, and an invivo portion of skin.

22. An instrument as recited in claim 1, wherein said instrument is a sphygmomanometer.

23. An instrument as recited in claim 1, including distracting means for distracting a patient when the device is being used.

24. An instrument as recited in claim 23, wherein said distracting means includes a set of earphones.

25. An instrument as recited in claim 1, wherein said instrument is an industrial borescope.

26. An instrument as recited in claim 1, wherein at least one of said supporting means and said at least one chemical sensing element is disposable.

27. An instrument as recited in claim 1, including means for transmitting signals from said at least one chemical sensing element to a remote processing unit.

28. An instrument as recited in claim 27, wherein said transmitting means includes a wireless link between said at least one chemical sensing element and said remote processing unit.

29. An instrument as recited in claim 1, wherein said instrument is battery powered.

30. A method for detecting the presence of a disease or disease process, said method including the steps of:

incorporating at least one chemical sensing element in conjunction with a medical diagnostic instrument, said chemical sensing element being capable of producing an electrical or optical signal when a fluid indicative of said disease or disease process is detected; and

disposing said medical diagnostic instrument and said chemical sensing element in substantial direct proximity with a medical target.

31. A method as recited in claim 30, including the additional steps of:

incorporating at least one chemical sensing element in conjunction with at least one of a hysteroscope and a colposcope; and

positioning said at least one chemical sensing element in substantial direct proximity with the cervix of a patient, for detecting the presence of at least one of endometreosis and cancer.

32. A method as recited in claim 30, comprising the additional steps of:

incorporating at least one chemical sensing element capable of detecting the presence of at least one fluid indicative of a disease in at least one of a colonoscope, a gastroscope and a laparoscope; and

positioning said at least one chemical sensing element in substantial direct contact with the sigmoid-colon of a patient for detecting the presence of at least one of ulcerative colitis and cancer.

33. A method as recited in claim 30, including the additional steps of:

disposing at least one chemical sensing element onto at least one of a laryngoscope blade and a tongue depressor; and

positioning said one of said laryngeal blade and tongue depressor including said at least one chemical sensing element within the throat of a patient for detecting the presence of at least one of diabetes, upper respiratory infections and cancer.

34. A method as recited in claim 30, including the additional steps of:

disposing at least one chemical sensing element in conjunction with an otoscope; and

positioning said at least one chemical sensing element into the ear of a patient for detecting the presence of at least one of otitis and upper respiratory infections.

* * * * *

专利名称(译)	手持式化学传感仪		
公开(公告)号	US20030100819A1	公开(公告)日	2003-05-29
申请号	US09/995390	申请日	2001-11-28
[标]申请(专利权)人(译)	伟伦公司		
申请(专利权)人(译)	伟伦，INC.		
[标]发明人	NEWMAN RICHARD W DANNA DOMINICK		
发明人	NEWMAN, RICHARD W. DANNA, DOMINICK		
IPC分类号	A61B1/227 A61B1/267 A61B1/31 A61B3/12 A61B5/00 A61B5/021 A61B5/103		
CPC分类号	A61B1/00052 A61B1/0008 A61B1/227 A61B1/267 A61B1/31 A61B3/1208 A61B2560/0443 A61B5/0088 A61B5/021 A61B5/145 A61B5/411 A61B5/444 A61B5/0002		
外部链接	Espacenet USPTO		

摘要(译)

一种手持式医疗或工业诊断仪器，包括至少一个化学传感元件，其能够检测由疾病发出的至少一种流体，并且当检测到所述至少一种流体时产生电或光学变化。该仪器还包括具有驻留电路的处理器，该驻留电路用于将由所述至少一个化学传感元件产生的电变化处理成指示疾病的结果输出信号。优选地，至少一个化学传感元件基本上直接接近待测试的目标区域。