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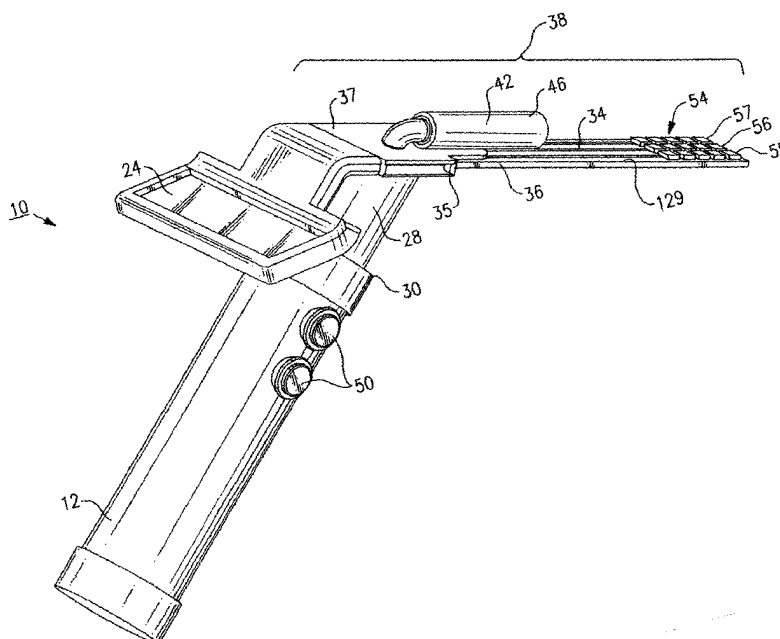
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(54) Title: CHEMICAL SENSING INSTRUMENT AND RELATED METHOD OF USE



(57) **Abstract:** An apparatus for determining the presence of at least one vapor or gas includes at least one externally supported chemical sensing element capable of producing an electrical change when at least one vapor is detected in an area of interest. The apparatus includes processing electronics for processing electrical changes generated by the chemical sensing element(s) into a resulting signal. The chemical sensing element(s) being externally disposed in substantially immediate contact with the area of interest provides direct feedback without requiring pumps or similar apparatus to draw a sample into a contained sample chamber.



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## **CHEMICAL SENSING INSTRUMENT AND RELATED METHOD OF USE**

### **FIELD OF THE INVENTION**

The invention is directed to the field of chemical sensing devices and, in particular to a portable hand-held instrument capable of detecting vapors or fluids which are indicative of, for example, a disease process.

### **5. BACKGROUND OF THE INVENTION**

Chemical sensing devices are commonly 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.

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

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. These devices further include means for inputting a portion of the atmosphere of a target area into the  
15 housing for evaluation by the chemical sensor(s). The above inputting step typically requires that a pump or other similar apparatus be employed in order to direct the atmospheric portion into the confines of the housing. Such devices are described, for example, in U.S. Patent No. 5,799,102 to Leong which determines the authenticity of a bank note, and U.S. Patent No. 5,675,070 to Gelperin in which an array of gas sensors are disposed in an interior testing  
20 chamber. The gas sensors of the array detect the levels of specified gases in a gas mixture and then produce a sensor pattern which can be analyzed.

### **SUMMARY OF THE INVENTION**

It is a primary object of the present invention to improve the state of the art of electronic chemical sensing or detection devices.

25 It is another primary object of the present invention to provide a portable chemical sensing device which is capable, for example, for medical applications by providing

noninvasive diagnosis of a patient(s) or industrial applications wherein the chemical sensing element is directly exposed to a target area.

Therefore and according to a preferred aspect of the present invention, there is provided an apparatus for determining the presence of a disease process, said apparatus  
5 comprising:

at least one chemical sensing element;

support means for supporting said at least one chemical sensing element, said at least one chemical sensing element including means for producing an electrical change when at least one vapor indicative of a disease is detected in an area of interest; and

10 at least one processor means for processing said electrical change generated by said at least one chemical sensing element into a resulting signal indicative of the presence of said disease, wherein said at least one chemical sensing element is disposed in substantial proximity with the area of interest.

Preferably, the support means includes a substrate onto which the chemical sensing  
15 element(s) are arranged and in which the substrate is externally disposed in relation to the instrument housing.

The portable chemical sensing apparatus can include illumination means, such as a light emitting diode, miniature arc lamp, optical fiber bundle, and the like to illuminate the target area of interest. A display, such as an LED, can also be provided, for example, as an  
20 attached feature or integrally provided with the device.

The apparatus can also include a number of additional sensors, such as temperature, humidity, and/or PH sensors, for determining environmental conditions of the target area and/or to calibrate the chemical sensors of the device. The intended target area can include, for example, a body cavity, such as the mouth, nose, eye, ear, vagina, anus, urinary tract, and  
25 the colon. Alternately, other anatomical areas, such as the skin, esophagus, stomach, peritoneum, thorax, sinus, prostate gland, blood vessels, pericardium, amniotic sac, colostomy lumen, and laparoscopic lumen can be examined, as can a varied plurality of different industrial environments, including but not limited to pressure vessels, nuclear reactors, military equipment, aircraft, and the like. In addition to the environmental sensors  
30 noted above, additional sensors can be added to measure other physical parameters including

blood oxygen saturation, sound, light, fluid currents, turbidity, viscosity, radioactivity, magnetic fields and electrical fields.

According to a preferred aspect, the substrate containing the chemical sensing element(s) includes a pair of parallel portions, each of which are inserted into the mouth of a patient. One of the parallel portions including at least one miniature chemical sensing element which can be placed into the oral cavity above the tongue with the remaining parallel portion having at least one temperature sensor which can be placed under the tongue.

According to another preferred aspect of the invention, the substrate can be removed from the instrument housing following use and be autoclaved. Alternately, the substrate and/or sensing element portions of the device can be designed for a single patient use.

The chemical sensing elements are capable of detecting trace amounts of specified analytes and produce an electrical change (such as voltage, impedance, conductance, inductance, capacitance, resistance, etc.), the device further including a microprocessor and processing electronics which determines the extent of any electrical change as determined by the chemical sensing array. The microprocessor is preferably equipped with processing algorithms and includes a look-up table(s) which is compared to processed data to determine the presence of a disease process based on the comparison. Alternately, a neural network can be utilized.

According to another preferred aspect of the present invention, there is provided a hand-held diagnostic instrument for determining the presence of a disease process, said instrument comprising:

a handle portion;

an instrument head mounted at one end of said handle portion, said instrument head including at least one exteriorly mounted chemical sensing element which is capable of detecting the presence of at least one vapor emitted by said disease and producing an electrical change when said at least one vapor is detected; and

processing means for processing said electrical change generated by said at least one chemical sensing element into a resulting signal indicative of the presence of said disease.

According to yet another preferred aspect of the present invention, there is provided a hand-held diagnostic instrument for determining the presence of a disease process, said instrument comprising:

a handle portion;

an instrument head mounted at one end of said handle portion, said instrument head including at least one externally mounted chemical sensing element which is capable of detecting the presence of at least one vapor emitted by a disease and producing an electrical change when said at least one vapor is detected;

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

at least one temperature sensor.

According to yet another preferred aspect of the invention, there is provided apparatus for determining the presence of at least one chemical substance, said apparatus comprising:

at least one chemical sensing element;

support means for supporting said at least one claimed sensing element, said at least one chemical sensing element including means for producing an electrical change when at least one vapor or fluid is detected in an area of interest; and

at least one processor for processing said electrical change generated by said at least one chemical sensing element into a resulting signal indicative of the presence of said at least one chemical substance, wherein said at least one chemical sensing element is disposed in substantially immediate proximity with said area of interest.

According to still another preferred aspect of the present invention, there is provided a method of determining the presence of a disease by determining the presence of at least one chemical component of an emitted vapor emitted from an area of interest, said at least one chemical component being indicative of said disease, said method including the steps of:

positioning at least one chemical sensing element in substantially direct contact with said area of interest, said at least one chemical sensing element being capable of generating an electrical change when said at least one chemical component is detected;

processing said electrical change into a resulting signal indicative of the presence of a disease; and

indicating the resulting signal.

The above described sensing instrument is advantageously designed to include features lending itself to portability and ease of use. The substrate portion(s) is relatively

inexpensive to manufacture and therefore can be designed either for extended or for one time use (e.g., disposable), the substrate being easily attached and removed from the instrument housing.

Another advantage of the present invention is that an electronic chemical sensing apparatus is provided which is extremely compact and can be used in a variety of different medical and/or industrial environments.

Yet another advantage of the present invention is that a chemical sensing device as described above provides rapid noninvasive diagnosis of a patient or an industrial area of interest.

Yet another advantage of the present invention is that at least the sensing portion of the described chemical sensing device can be releasably attached to a hand-held instrument housing wherein the sensing portion can also be disposable.

Yet another advantage of the device of the present invention is that illumination provided by the instrument permits viewing of a target for positioning of the sensing portion.

These and other objects, features, and advantages will become apparent upon reading the following Detailed Description which should be read in conjunction with the accompanying drawings.

#### **BRIEF DESCRIPTION OF THE DRAWINGS**

Fig. 1 is a front perspective view of a chemical sensing device made in accordance with a first embodiment of the invention;

Fig. 2 is a rear perspective view of the chemical sensing device of Fig. 1;

Fig. 3 is a block diagram relating the primary components of the chemical sensing device of Figs. 1 and 2;

Fig. 4 is a front perspective view of a chemical sensing device made in accordance with a second embodiment of the present invention;

Fig. 5 is a perspective view of a chemical sensing device made in accordance with a third embodiment of the present invention; and

Fig. 6 is a perspective view of a chemical sensing device made in accordance with a fourth embodiment of the present invention.

## DETAILED DESCRIPTION

The following description relates to certain embodiments of an electronic chemical sensing apparatus capable of sensing vapors and other fluids from a target area of interest which can be indicative, for example, of the presence of a disease process. Throughout the course of discussion terms such as “upper”, “lower”, “top”, “bottom”, “above”, “below”, “transverse” and “lateral”, among others, are used to provide a frame of reference in describing the accompanying drawings. These terms, however, should not be construed as being additionally limiting of the invention as defined by the following claims. Furthermore, several embodiments are shown of specific instruments used to carry out inspections either in the oral cavity (mouth) or in relation to the skin of a patient. It will be readily apparent, however, that the inventive concepts described herein are equally applicable, for example, to other medical and industrial applications.

Turning to Figs. 1-3, there is shown a diagnostic instrument 10 in accordance with a first embodiment of the invention. The diagnostic instrument 10 includes a compact hand-grippable instrument handle 12 including a substantially hollow interior (not shown) which is suitably sized for retaining a number of discrete components. These components, as more particularly depicted in Fig. 3, include a microcontroller 18 having suitable storage memory 21 as well as electronic processing circuitry 19 including an A/D converter 25 and timing and control circuitry 23 used in conjunction with a reference crystal (not shown) as is known. A plurality of batteries or other suitable power supply 20 are electrically connected to each of the above components for powering the instrument 10. Each of the above convert an incoming electrical signal generated from corresponding sensors found in the chemical sensing element array into a processed output signal. The microprocessor 18 includes a look-up table (not shown) which compares incoming signals to reference values in order to provide an analysis. Alternately, a neural network 27 can be included, such as those described in “Fundamentals of Neural Networks” by L. Fausett, Prentice Hall, 1994, incorporated herein in its entirety by reference. According to this specific embodiment, an LCD or other form of electronic display 24 is attached to the rear of the instrument handle 12 and electrically interconnected to the microcontroller 18 by means commonly known in the field and which require no further discussion.

The instrument handle 12 itself, according to this specific embodiment, is similar in design to certain hand-held instruments such as otoscopes manufactured by Welch Allyn, Inc., including a neck portion 28 which extends from the top 30 of the instrument handle. The neck portion 28 according to this embodiment retains the microprocessor 18 and the processing components 19. An elongated planar substrate 34 made from a biocompatible material such as composite, wood, ceramic, or plastic, among others, forms in effect, an instrument head 38 for the device. The elongated substrate 34 is sized and configured, according to this embodiment, in a fashion resembling that of a tongue depressor for reasons which will be apparent below. The proximal end 36 of the substrate 34 is releasably attached within a receiving portion 33 of a clamp 35 provided at the upper end of the neck portion 28. An illumination assembly 42 includes a bundle of optical fibers 44 disposed in a substantially light-tight housing 46 which is attached to an upper facing surface 37 of the clamp 35. The optical fiber bundle 44 includes a plurality of light transmitting ends which are connected to a light source, such as a miniature halogen lamp 50, shown schematically in Fig. 3 only, disposed either within the neck portion 28 or the interior of the housing 46. Alternately, the light source can be, for example, a miniature arc lamp or at least one light emitting diode. The miniature lamp 50 can otherwise be included within the light-tight handle, wherein the illumination assembly 42 is powered by the power source 20 and activated by a push button 50 located along the exterior of the handle 12. The output of the illumination assembly 42 can be controlled by a rheostat provided in relation to the neck portion of the instrument handle 12. Details relating to the rheostat are commercially known and do not require further discussion.

An array 54 of chemical sensors are attached, e.g., by epoxy, glass frit, adhesive, or other means to a distal end 39 of the elongated planar substrate 34. Alternately, the sensor array 54 can be provided as part of a plug-in electrical module (not shown) having connectors (not shown) which mount to a mating portion (not shown) of the distal end of the elongated substrate 34. The chemical sensor array 54 according to this embodiment are miniature polymer gas sensors manufactured by Cyrano Sciences, Inc of Pasadena, California, such as those described in U.S. Patent No. 5,571,401 to Lewis et al., U.S. Patent No. 5,882,497 to Persaud et al., U.S. Patent No. 6,033,601 to Persaud et al., U.S. Patent No. 6,093,308 to Lewis, and U.S. Patent 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, and others, can easily be substituted without significantly deviating from the inventive concepts of the invention.

5 Due to the overall sensitivity of the miniature polymer gas sensors of the array 54 utilized in this embodiment, at least one temperature sensor and/or humidity sensor and/or pH sensor 55, 56, 57, respectively, are also attached to the exterior surface of the substrate 34 at the distal tip 39 in the immediate vicinity of the chemical sensing array 54.

Referring to Figs. 1-3, and in operation, the distal end 39 of the elongated planar  
10 substrate 34 is inserted into a closed body cavity, such as the mouth of a patient (not shown), wherein the chemical sensor array 54 and each of the environmental sensors 55, 56, 57 are placed in substantially immediate proximity (that is, are directly exposed) to a target environment (i.e., atmosphere). Alternately, the temperature, humidity and pH sensors 55, 56, 57 can be disposed within the neck portion 28 or the interior of the handle 12. In the  
15 presence of certain analytes, certain of the chemical sensors of the array 54 will produce a change in an electrical characteristic, (such as transconductance, conductance, impedance, resonant frequency, voltage, inductance, capacitance, and resistance, etc.,) the sensors of the array each being connected through traces 129 to corresponding connectors 130 provided in the neck portion of the handle 12 to provide an electrical path to the microprocessor 18.

20 Upon depression of one of the pushbuttons 50 on the exterior of the housing 14, the illumination assembly 42 is activated and illumination is provided such that the device can be accurately positioned in substantially immediate proximity to the target environment.

According to the depicted embodiment, the sensing portion of the elongated substrate 34 is first uncovered and then positioned within the mouth of a patient (not shown). The  
25 elongated substrate 34, as noted above, is shaped similarly to a tongue depressor and can be used in a like manner. However, and unlike a tongue depressor, the sensing portion can be placed anywhere in the mouth, including positioning the sensing portion under the tongue or along the cheek. Under the tongue may in fact be a preferred location for the sensing portion of the present device in that 100 % relative humidity is invariably found in this location as  
30 opposed to other portions of the mouth interior which may be dry, introducing humidity as a variable condition which can significantly affect the response of the sensor array 54.

The exposed sensing array 54 upon sensing specific gases or vapors indicative, according to this embodiment, of the presence of a disease process, produces various electrical changes, as described, for example, in previously cross referenced U.S. Patents No. 5,571,401, 6,013,229 and 6,093,308. The resulting electrical signal is then transmitted along the traces 129 to the microprocessor 18 in which the signal is processed using the processing circuitry 19. Upon depression of a second pushbutton provided on the handle 12, the resulting signals are compared to a look-up table (not shown) stored into memory for evaluation. An outputted digital signal is then transmitted to the LCD 24 for display. The output signal contains an indication of the quality of the match between the transmitted sensor values and the look-up table. Depending on the processing electronics, the output signal displayed can include an indication of a specific disease or bacteria and/or a confidence level regarding the match between the sensor values and the look-up table.

Referring to Fig. 4, a disease diagnostic device 60 according to a second preferred embodiment of the present invention is herein described. Parts which are similar to those described in the first embodiment are herein labeled with same reference numerals for the sake of clarity.

The device 60 includes a compact hand-grippable handle 12 having an interior (not shown) for retaining a microprocessor 18 and signal processing electronics 19, including timing and control circuitry and an A/D converter, similar to that previously described and shown in Fig. 3, and provided in a neck portion 28 or otherwise within the interior of the handle 12. A power source 20, such as a set of batteries for powering the device, are also provided within the handle of the device 60. Alternately, the device 60 can include an AC adapter (not shown) or can be connected to any suitable power supply (not shown) in a manner commonly known.

An LCD or other suitable display 24 is attached or is integral to the rear of the instrument handle 12 and is electrically interconnected to the contained microprocessor 18, Fig. 3. As previously described, the neck portion 28 includes a clamp 35 having a receiving section 33 sized to releasably retain a proximal end 67 of an elongated planar substrate 66.

An illumination assembly 42 includes a light source 50, (not shown in Fig. 4, but similar to that previously shown schematically in Fig. 3) as well as a bundle of optical fibers 44 retained within a cylindrical light-tight housing 46, including an exit face on which the

fiber ends are circumferentially arranged. The elongated substrate 66 is preferably releasably attached at its proximal end 67 to the receiving portion 33 of the clamp 35, the substrate further including a pair of essentially parallel distal sensor sections 70, 74. According to this embodiment, an upper sensor section 70 retains a chemical sensor array 54 as well as at least one humidity sensor 56 while a lower sensor section 74 retains at least one temperature sensor 55. The temperature and humidity sensors 55, 56 can be used for compensating or calibrating the sensor array 54 of the device 60 as well as for obtaining diagnostic information.

In operation and similarly to that previously described, the distal end of the substrate 66 is placed into the mouth of a patient with the upper sensor section 70 being placed above the tongue (not shown) of a patient and the lower sensor section 74 being positioned under the tongue. The array 54 of chemical sensors are capable of detecting vapors indicative of certain diseases including those emanating from areas that communicate with the mouth, such as the lungs, stomach, sinuses, ears, and intestines, among others. As in the preceding, a pair of pushbuttons 50 control the operation of the device, including the illumination assembly 42 and the processing and display of processed data.

Alternate embodiments of hand-held diagnostic instruments made in accordance with the present invention are herein illustrated in Figs. 5 and 6. As in the preceding, similar parts are labeled with the same reference numerals for the sake of clarity.

As shown in Fig. 5, a third embodiment of a disease diagnostic instrument 100 includes a substrate 34 having opposing distal and proximal ends 39, 36. An array 54 of miniature chemical sensors, such as those previously described, are attached by adhesive, epoxy, glass frit, or other suitable means to the distal end 39 of an exterior facing surface of the substrate 34. According to this embodiment, the proximal end 36 of the elongated planar substrate 34 is retained within a receiving portion 33 of a clamp 35, in the manner previously described. The clamp 35 is interconnected to one end 108 of a tethered cable 104, the cable being tethered at an opposing end 109 to a portable instrument unit 110. The portable instrument unit 110 includes a unit housing 114 having a contained microprocessor (not shown, but similar to that described with regard to Fig. 3) which is powered by batteries (not shown) or any other suitable power supply and enabled through a number of pushbuttons 106 provided on the exterior of the housing. The housing 114 further includes an LCD or other

suitable display 112. Preferably, the described device 100 is light-weight as well as portable, such that it can be worn by the patient for use in long term monitoring.

In operation, the above device 100 can be used, as in the preceding examples to examine the oral cavity of a patient. The device is gripped at the clamp 35 by the user and the elongated substrate 34 is used in a manner similar to that of a tongue depressor with the distal end 39 thereof being placed in the mouth of the patient in a location which can include under the tongue, above the tongue, or along the cheek area. As such, the sensor array 54 is placed in substantially immediate proximity with a target area of interest.

Referring to Fig. 6, a disease diagnostic instrument 120 in accordance with a fourth embodiment includes a handle 12 having an interior (not shown) which is capable of receiving a set of batteries 20, Fig. 3, as well as an electronics package including a microcontroller 18, Fig. 3, which enables the operation of the salient features of the instrument in a manner similar to that previously described. The device of this embodiment, however, includes an instrument head 122 having a flexible conical distal section 124 made preferably from an elastomeric material such as silicone rubber and having an open end defining a cavity 128 into which the distal end 39 of a planar elongated substrate 34 extends, the substrate being made of a biocompatible material such as composite, wood, ceramic, plastic or other suitable material and having disposed thereon at least one chemical sensor, such as those previously referred to and incorporated U.S. Patents No. 5,571,401 et al. listed above.

In operation, the above described device 120 could be used over the mouth of a patient, or otherwise used to define a sample chamber over, for example, a section of human epidermis. The flexible conical section 124 is placed in contact with the skin, forming a seal wherein the chemical sensor array 54 is placed in substantial direct proximity with a target atmosphere to detect analytes given off by the skin. As previously described, the detection of specified vapor substances by the chemical sensor array 54 produces an electrical change(s) which is relayed through traces 129 provided in or along the length of the elongated substrate 34 to connectors 130 electrically linked to the microprocessor 18, Fig. 3. The signals are then processed and analyzed with the analysis data being displayed for the user.

Though the preceding devices have included provisions for humidity, temperature and pH sensors for the herein described medical applications, it should be readily apparent that

sensors for detecting other physical parameters, such as but not limited to sound level, turbidity, light sensing, fluid/air currents, turbidity, viscosity, radioactivity, magnetic fields, electrical fields, and electromagnetic fields including RF and B could also be contemplated.

#### PARTS LIST FOR FIGS. 1-6

|    |     |                              |
|----|-----|------------------------------|
| 5  | 10  | disease diagnostic device    |
|    | 12  | instrument handle            |
|    | 14  | interior                     |
|    | 18  | microprocessor               |
|    | 19  | electronic components        |
| 10 | 20  | batteries                    |
|    | 21  | memory                       |
|    | 23  | timing and control circuitry |
|    | 24  | display                      |
|    | 25  | A/D converter                |
| 15 | 27  | neural network               |
|    | 28  | neck portion                 |
|    | 30  | handle top                   |
|    | 33  | receiving portion            |
|    | 34  | elongated planar substrate   |
| 20 | 35  | clamp                        |
|    | 36  | proximal end                 |
|    | 37  | upper facing surface         |
|    | 38  | instrument head              |
|    | 39  | distal end                   |
| 25 | 42  | illumination assembly        |
|    | 44  | optical fibers               |
|    | 46  | housing                      |
|    | 50  | miniature lamp               |
|    | 54  | chemical sensor array        |
| 30 | 55  | temperature sensor           |
|    | 56  | humidity sensor              |
|    | 57  | pH sensor                    |
|    | 60  | device                       |
|    | 64  | instrument head              |
| 35 | 66  | substrate                    |
|    | 67  | proximal end                 |
|    | 70  | upper sensor portion         |
|    | 74  | lower sensor portion         |
|    | 100 | device                       |
| 40 | 104 | cable                        |
|    | 106 | push buttons                 |
|    | 108 | cable end                    |
|    | 109 | cable end                    |

- 110 instrument unit
- 112 display
- 114 unit housing
- 120 device
- 5 122 instrument head
- 124 conical distal section
- 128 cavity
- 129 traces
- 130 connectors

Though the preceding has been described according to certain preferred embodiments, it will be readily apparent that modifications and variations are possible within the intended scope of inventive concepts contained herein. For example, the externally disposed chemical sensors can be utilized in other medical instruments and for assessing various industrial targets, including but certainly not limited to nuclear reactors, aircraft, fire scenes, military equipment and pressure vessels.

**WE CLAIM:**

- 1 1. An apparatus for determining the presence of a disease process, said apparatus  
2 comprising:  
3 at least one chemical sensing element;  
4 support means for supporting said at least one chemical sensing element, said at least  
5 one chemical sensing element including means for producing an electrical change when at  
6 least one vapor or fluid indicative of a disease is detected in an area of interest; and  
7 at least one processor means for processing said electrical change generated by said at  
8 least one chemical sensing element into a resulting signal indicative of the presence of said  
9 disease, wherein said at least one chemical sensing element is disposed in substantially  
10 immediate proximity with said area of interest.
- 1 2. The apparatus of Claim 1, wherein said support means includes a substrate onto which  
2 said at least one chemical sensing element is arranged.
- 1 3. The apparatus of Claim 1, including a housing having an interior sized for receiving  
2 said at least one processor means, wherein said support means and said at least one chemical  
3 sensing element are disposed externally relative to said housing.
- 1 4. The apparatus of Claim 1, including illumination means for directing light to said area  
2 of interest.
- 1 5. The apparatus of Claim 4, wherein said illumination means includes at least one  
2 halogen bulb disposed in relation to said support means for illuminating the area of interest.
- 1 6. The apparatus of Claim 4, wherein said illumination means includes at least one light  
2 emitting diode.
- 1 7. The apparatus of Claim 4, wherein said illumination means includes an arc lamp.

- 1 8. The apparatus of Claim 4, wherein said illumination means includes a fiber optic  
2 bundle having a plurality of light emitting ends.
- 1 9. The apparatus of Claim 1, further including at least one temperature sensor for  
2 sensing temperature.
- 1 10. The apparatus of Claim 3, including at least one temperature sensor externally  
2 disposed relative to said housing.
- 1 11. The apparatus of Claim 10, wherein said at least one temperature sensor is disposed  
2 proximately to said at least one chemical sensing element.
- 1 12. The apparatus of Claim 1, including sealing means for creating a substantially  
2 enclosed volume encompassing said at least one chemical sensing element and said area of  
3 interest.
- 1 13. The apparatus of Claim 3, further including means for indicating said resulting signal.
- 1 14. The apparatus of Claim 13, wherein said indicating means is integral to said housing.
- 1 15. The apparatus of Claim 1, including at least one humidity sensor for sensing the  
2 humidity of said area of interest.
- 1 16. The apparatus of Claim 1, including at least one sensor for measuring a physical  
2 parameter, said physical parameter including at least one of temperature, humidity, pH,  
3 blood oxygen saturation, sound, light, fluid currents, turbidity, viscosity, radioactivity,  
4 magnetic fields and electrical fields.
- 1 17. The apparatus of Claim 16, wherein said processing means is connected to said at  
2 least one sensor and is responsive to output therefrom.



1 18. The apparatus of Claim 17, including indicator means for indicating output from said  
2 at least one processor means.

1 19. The apparatus of Claim 18, wherein said indicator means is integral to said housing.

1 20. The apparatus of Claim 1, wherein said at least one processor means includes data  
2 storage means for storing said resulting signal, and for storing at least one of instructions and  
3 protocols for said processor.

1 21. The apparatus of Claim 1, wherein said data storage means includes a look-up table  
2 having at least one table of known data for comparison to measured data from said at least  
3 one chemical sensor.

1 22. The apparatus of Claim 1, wherein said processing means includes an artificial neural  
2 net.

1 23. The apparatus of Claim 1, wherein said support means includes a first projecting  
2 section including at least one chemical sensing element and a second projecting section  
3 adjacent said first projecting section, said second projecting section including a temperature  
4 sensor.

1 24. The apparatus of Claim 1, wherein the area of interest to be examined includes at least  
2 one of the group consisting of the mouth, nose, colon, ear, urinary tract, vagina, throat,  
3 esophagus, stomach, thorax, eye, sinus, prostate gland, anus, blood vessels, pericardium,  
4 amniotic sac, colostomy lumen, laparoscopic lumen, and the skin.

1 25. The apparatus of Claim 12, wherein the area of interest is at least one of the group  
2 consisting of the mouth, nose, urinary tract, vagina, anus, ear, eye, colostomy lumen,  
3 laparoscopic lumen, and the skin.

1 26. The apparatus of Claim 23, wherein the area of interest is the mouth wherein said first  
2 projecting portion is inserted onto the tongue and said second projecting portion is inserted  
3 beneath the tongue.

1 27. The apparatus of Claim 1, wherein said support means includes at least one projecting  
2 portion which is insertable into the mouth of a patient, at least one projecting portion  
3 including said at least one chemical sensing element on a distal end thereof and in which at  
4 least one projecting portion having said at least one chemical sensing element can be placed  
5 under the tongue, over the tongue, and in proximity with the cheek of the patient.

1 28. The apparatus of Claim 1, wherein at least one of said projecting portion and said at  
2 least one chemical sensing element is disposable.

1 29. A hand-held diagnostic instrument for determining the presence of a disease process,  
2 said instrument comprising:

3 a handle;

4 support means mounted to said handle, said support means including at least one  
5 externally mounted chemical sensing element which is capable of detecting the presence of at  
6 least one fluid or vapor emitted by said disease and producing an electrical change when said  
7 at least one fluid or vapor is detected;

8 processing means for processing said electrical change generated by said at least one  
9 chemical sensing element into a resulting signal indicative of the presence of said disease.

1 30. The diagnostic instrument of Claim 29, including output means integral with said  
2 handle for outputting said resulting signal.

1 31. The diagnostic instrument of Claim 29, wherein said support means includes an  
2 elongated portion upon which at least one chemical sensing element is mounted.

1 32. The diagnostic instrument of Claim 31, including illumination means for directing  
2 light to an area of interest.

1 33. The diagnostic instrument of Claim 32, wherein said illumination means includes a  
2 halogen bulb.

1 34. The diagnostic instrument of Claim 32, wherein said illumination means includes at  
2 least one light emitting diode.

1 35. The diagnostic instrument of Claim 32, wherein said illumination means includes an  
2 arc lamp.

1 36. The diagnostic instrument of Claim 32, wherein said illumination means includes a  
2 fiber optic bundle extending along said support means, said bundle including a plurality of  
3 light emitting ends.

1 37. The diagnostic instrument of Claim 29, including at least one temperature sensor for  
2 sensing temperature.

1 38. The diagnostic instrument of Claim 37, wherein said at least one temperature sensor is  
2 exteriorly disposed relative to said handle.

1 39. The diagnostic instrument of Claim 37, wherein said at least one temperature sensor is  
2 disposed proximately relative to said at least one chemical sensing element.

1 40. The diagnostic instrument of Claim 29, including sealing means disposed exteriorly to  
2 said support means for creating a substantially enclosed volume encompassing said at least  
3 one chemical sensing element and a target area.

1 41. The diagnostic instrument of Claim 29, including indicator means for indicating at  
2 least one resulting signal.

1 42. The diagnostic instrument of Claim 41, wherein said indicator means is integral to  
2 said handle.

1 43. The diagnostic instrument of Claim 29, including at least one humidity sensor for  
2 sensing the humidity of an area of interest.

1 44. The diagnostic instrument of Claim 29, wherein a portion of said support means  
2 terminates at a chemical sensing portion containing said at least one chemical sensing  
3 element, said chemical sensing portion further including at least one sensor for sensing  
4 environmental conditions adjacent said at least one chemical sensor.

1 45. The diagnostic instrument of Claim 44, wherein said processing means is connected  
2 to at least one sensor, said sensor being capable of measuring at least one physical parameter,  
3 said physical parameter being from the group consisting of temperature, humidity, pH,  
4 turbidity, and blood oxygen saturation.

1 46. The diagnostic instrument of Claim 45, including indicating means for displaying  
2 output from said chemical sensing portion.

1 47. The diagnostic instrument of Claim 46, wherein said indicating means is integral to  
2 said handle.

1 48. The diagnostic instrument of Claim 29, including data storage means for storing said  
2 resulting signal, and for storing at least one of instructions and protocols for said processor.

1 49. The diagnostic instrument of Claim 29, wherein said processing means includes an  
2 artificial neural net.

1 50. The diagnostic instrument of Claim 48, wherein said data storage means includes a  
2 look up table having at least one table of known data for comparison to measured data.

1 51. The diagnostic instrument of Claim 29, including said at least one chemical sensing  
2 element interiorly disposed within said handle, said instrument further including means for  
3 directing an emitted vapor or fluid from the area of interest toward said at least one interiorly  
4 disposed chemical sensing element.

1 52. The diagnostic instrument of Claim 29, including a pair of extending portions, in  
2 which one of said extending portions includes said tongue depressor section and the  
3 remaining extending portion includes at least one chemical sensing element.

1 53. The diagnostic instrument of Claim 52, wherein at least one of said extending portions  
2 includes a temperature sensor.

1 54. The diagnostic instrument of Claim 29, including said at least one chemical sensing  
2 element internally disposed within said handle, at least one temperature sensor and means for  
3 directing an emitted vapor or fluid from the area of interest toward said at least one interiorly  
4 disposed chemical sensing element.

1 55. The diagnostic instrument of Claim 54, wherein at least one temperature sensor is  
2 disposed externally so as to be in substantial proximity with an area of interest.

1 56. The diagnostic instrument of Claim 54, wherein at least one temperature sensor is  
2 disposed within said handle.

1 57. The diagnostic instrument of Claim 54, including a first temperature sensor disposed  
2 externally relative to said handle so as to be in proximity with an area of interest and a second  
3 temperature sensor disposed within said handle.

1 58. The diagnostic instrument of Claim 54, wherein said support means includes a first  
2 extending portion having a temperature sensor mounted thereon and a second extending  
3 portion having at least one chemical sensing element.

1 59. The diagnostic instrument of Claim 58, wherein the area of interest is the mouth, one  
2 of said extending portions being a tongue depressor section.

1 60. The diagnostic instrument of Claim 54, including at least one humidity sensor.

1 61. The diagnostic instrument of Claim 29, including means for calibrating at least one of  
2 said chemical sensing element, a temperature sensor, a humidity sensor, and a pH sensor.

1 62. The diagnostic instrument of Claim 29, wherein the area of interest comprises at least  
2 one of the mouth, nose, colon, ear, urinary tract, vagina, throat, esophagus, stomach,  
3 periditoneum, thorax, eye socket, sinus, prostate gland, anus, blood vessels, pericardium,  
4 amniotic sac, colostomy lumen, laparoscopic lumen, and skin.

1 63. The diagnostic instrument of Claim 29, including sealing means for creating a  
2 substantially enclosed volume encompassing said at least one chemical sensing element and a  
3 selected portion from the group consisting of the skin, eye, mouth, vagina, urinary tract, nose,  
4 anus, ear, coloscopy lumen, and laparoscopic lumen.

1 64. The diagnostic instrument of Claim 29, wherein said support means includes an  
2 extending portion having an array of chemical sensing elements, said extending portion  
3 further including said processing means.

1 65. The diagnostic instrument system of Claim 65, wherein said extending portion is  
2 releasably attached to said instrument and is disposable.

3 66. The diagnostic instrument of Claim 29, wherein said support means includes at least  
4 one projecting portion which is insertable into the mouth of a patient, at least one projecting  
5 portion including said at least one chemical sensing element on a distal end thereof and in  
6 which at least one projecting portion having said at least one chemical sensing element can be  
7 placed under the tongue, over the tongue, and in proximity with the cheek of the patient.

1 67. A hand-held diagnostic instrument system for determining the presence of a disease  
2 process, said instrument comprising:

3 a handle;

4 an instrument head mounted to said handle, said instrument head including at least  
5 one externally mounted chemical sensing element which is capable of detecting the presence  
6 of at least one fluid or vapor emitted by a disease and producing an electrical change when  
7 said at least one fluid or vapor is detected;

8 processing means for processing said electrical change generated by said at least one  
9 chemical sensing element into a resulting signal indicative of the presence of said disease;

10 and

11 at least one temperature sensor.

1 68. The hand-held diagnostic instrument of Claim 67, including at least one humidity  
2 sensor for sensing the humidity of said area of interest.

1 69. The hand-held diagnostic instrument of Claim 67, wherein said at least one exteriorly  
2 disposed chemical sensing element can be placed in substantially immediate proximity with  
3 an area of interest containing said at least one fluid.

1 70. The hand-held diagnostic instrument of Claim 67, including a first extending portion  
2 having said at least one chemical sensing element mounted thereto and a second extending  
3 portion having a temperature sensor, said first and second portions being spaced from one  
4 another by a predetermined distance which allows the first extending portion to be placed on  
5 the tongue of the patient and the second extending portion to be placed beneath the tongue.

1 71. The hand-held diagnostic instrument of Claim 69, wherein the area of interest  
2 comprises at least one of the mouth, nose, colon, ear, urinary tract, vagina, throat, esophagus,  
3 stomach, periditoneum, thorax, eye socket, sinus, prostate gland, anus, blood vessels,  
4 pericardium, amniotic sac, colostomy lumen, laparoscopic lumen, and skin.

1 72. The hand-held diagnostic instrument of Claim 70, including a humidity sensor.

1 73. The hand-held diagnostic instrument of Claim 3, wherein said humidity sensor is  
2 disposed on one of said extending portions.

1 74. A method of determining the presence of a disease by determining the presence of at  
2 least one chemical component of an emitted vapor or fluid emitted from an area of interest,  
3 said at least one chemical component being indicative of said disease, said method including  
4 the steps of:

5 positioning at least one chemical sensing element in substantial proximity with said  
6 area of interest, said at least one chemical sensing element being capable of generating an  
7 electrical change when said at least one chemical component is detected;

8 processing said electrical change into a resulting signal indicative of the presence of a  
9 disease; and

10 indicating the resulting signal.

1 75. The method of Claim 74, further including the step of creating a substantially  
2 enclosed volume encompassing a target of interest after said positioning step.

1 76. The method of Claim 74, further including the step of displaying said resulting signal  
2 on an integral indicating means provided on an instrument housing.

1 77. The method of Claim 74, including the step of calibrating said at least one chemical  
2 sensing element prior to said detecting and processing steps.

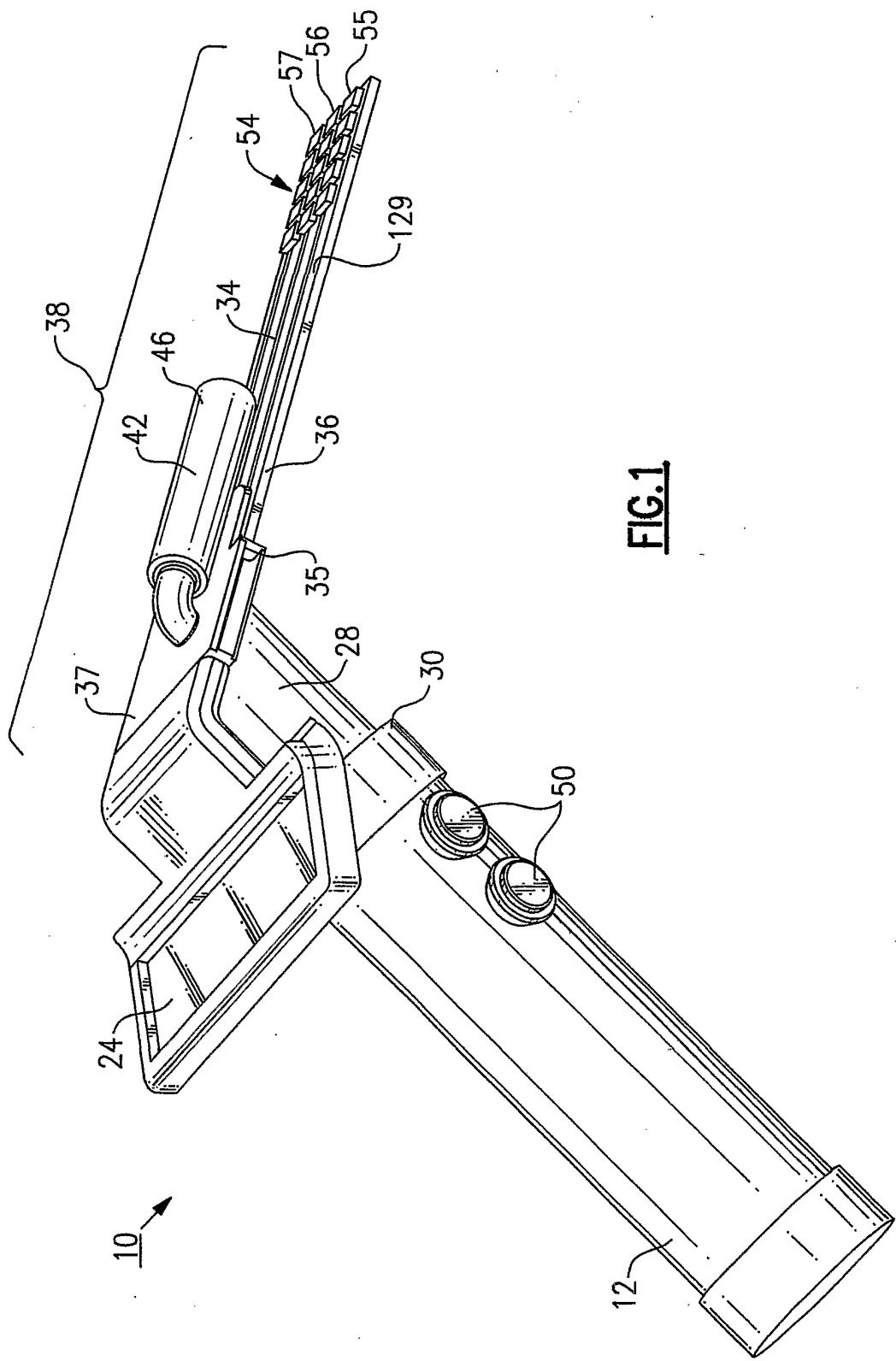
3 78. The method of Claim 74, wherein said support means includes at least one projecting  
4 portion, said at least one projecting portion including at least one chemical sensing element  
5 on a distal end thereof, said method including the steps of:

6 inserting said projecting portion into the mouth of a patient;

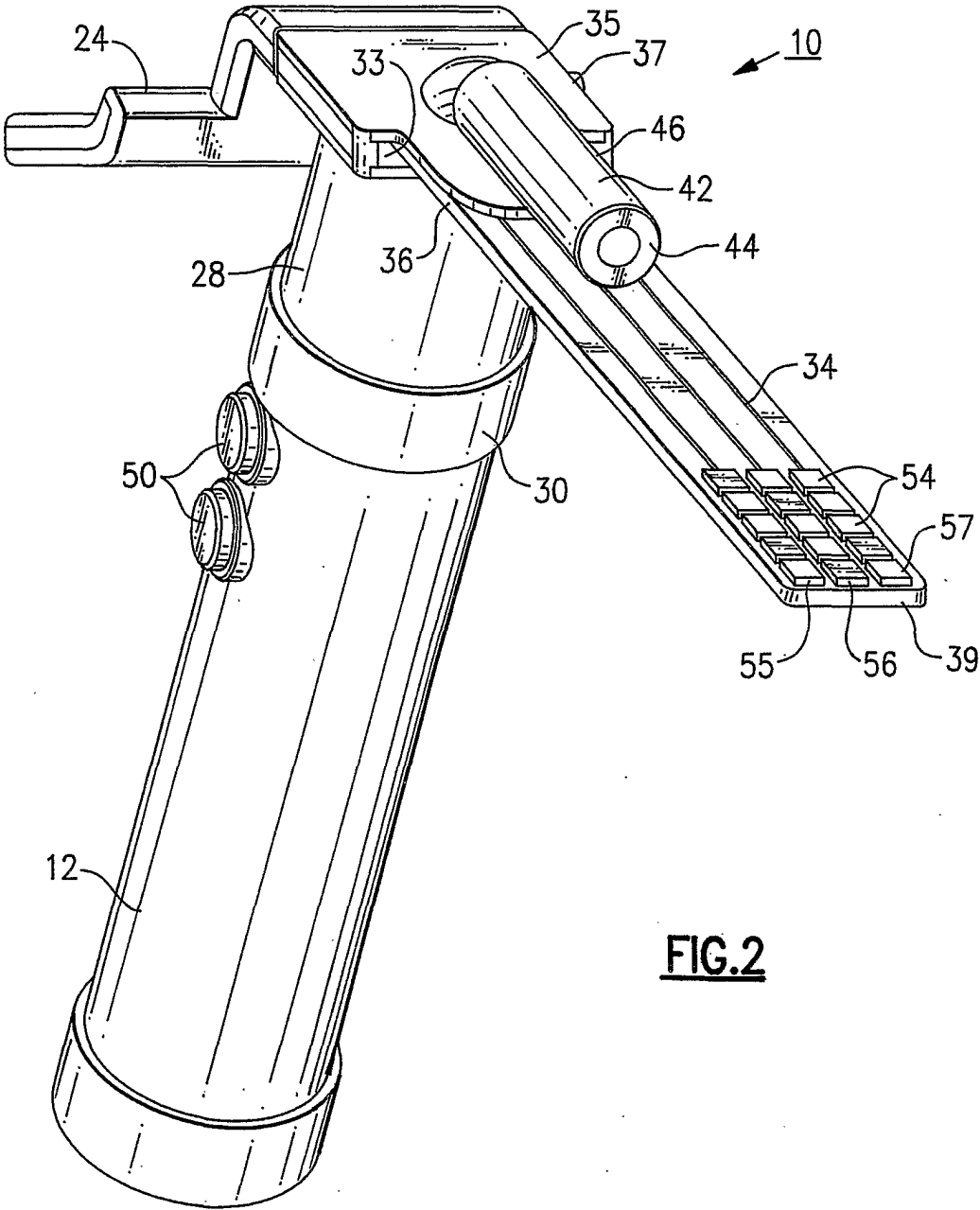
7 placing at least one projecting portion having said at least one chemical sensing  
8 element in a position including at least one of the group of under the tongue, over the tongue,  
9 and in proximity with the cheek of a patient.

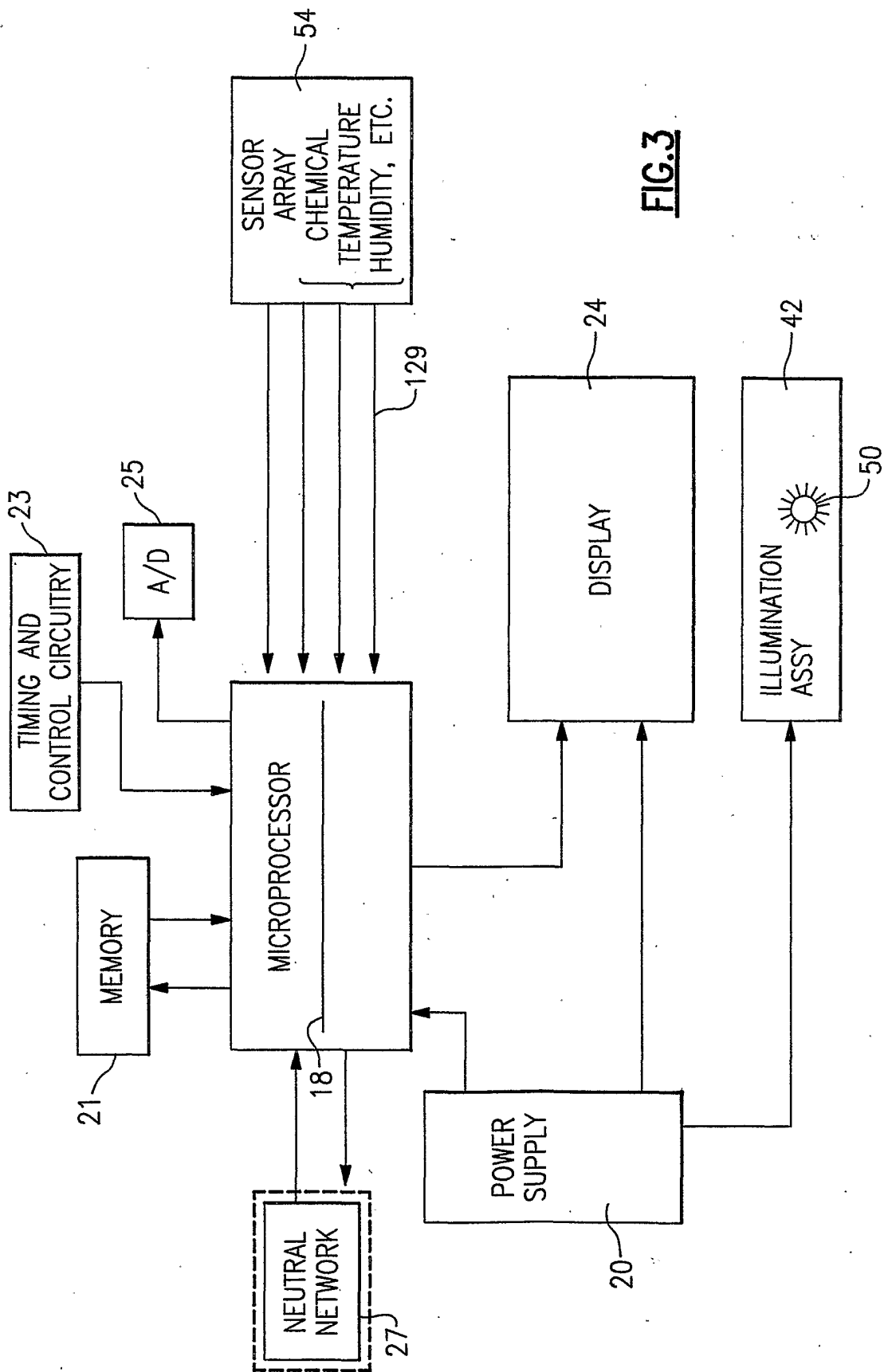


- 1 79. Apparatus for determining the presence of at least one chemical substance, said  
2 apparatus comprising:  
3 at least one chemical sensing element;  
4 support means for supporting said at least one chemical sensing element, said at least  
5 one chemical sensing element including means for producing an electrical change when at  
6 least one vapor or fluid is detected in an area of interest; and  
7 at least one processor for processing said electrical change generated by said at least  
8 one chemical sensing element into a resulting signal indicative of the presence of said at least  
9 one chemical substance, wherein said at least one chemical sensing element is disposed in  
10 substantially immediate proximity with said area of interest.
- 1 80. The apparatus of Claim 79, including sealing means for creating a substantially  
2 enclosed volume encompassing said at least one chemical sensor and an area of interest.
- 1 81. The apparatus of Claim 79, wherein the area of interest includes an industrial target.
- 1 82. The apparatus of Claim 81, wherein said industrial target includes at least one of the  
2 group consisting of pressure vessels, nuclear reactors, aircraft, wells, generators, vehicles, a  
3 fire site, airports, and military equipment.
- 1 83. The apparatus of Claim 79, including at least one sensor for measuring a physical  
2 parameter, said physical parameter consisting from one of the group consisting of at least one  
3 of temperature, humidity, pH, blood oxygen saturation, sound, light, fluid currents, turbidity,  
4 viscosity, radioactivity, magnetic fields and electrical fields.

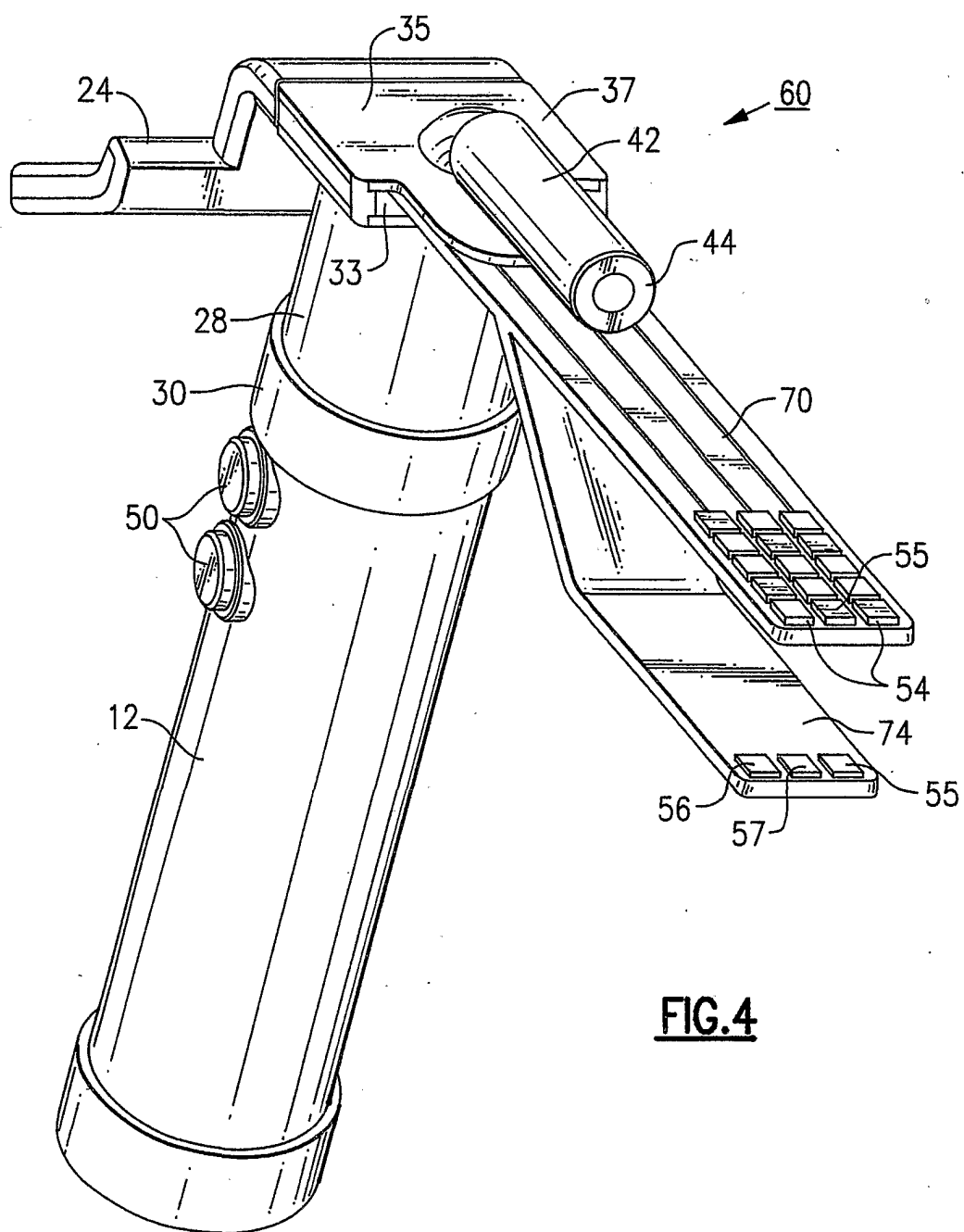


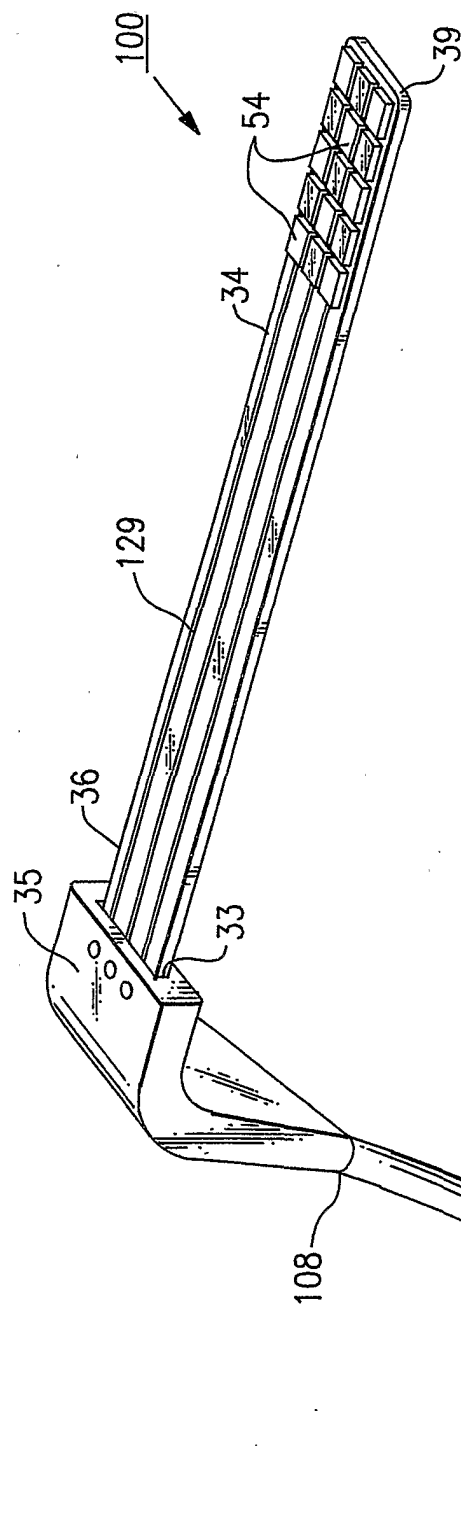
**FIG. 1**



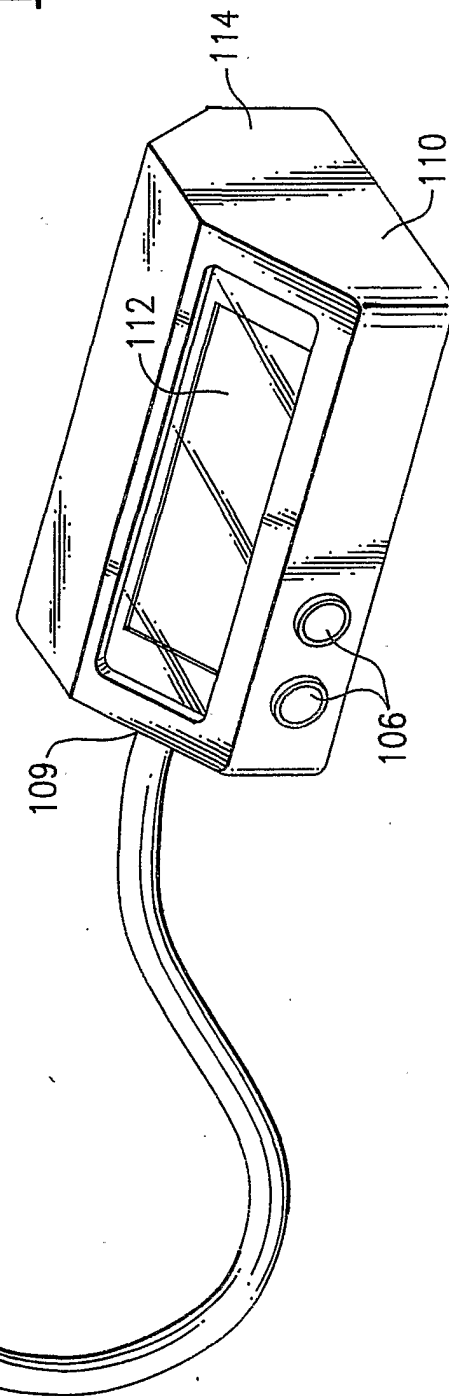


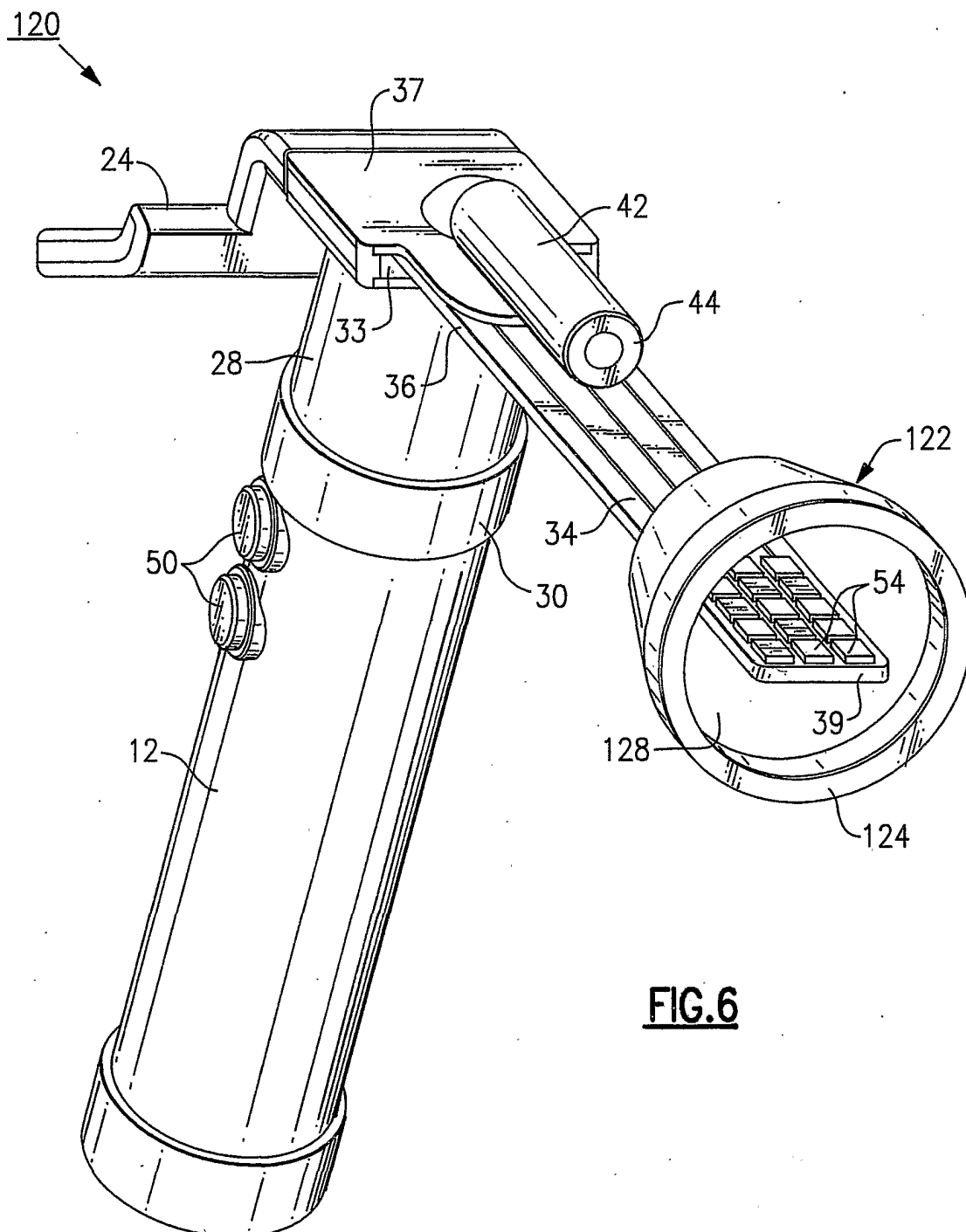
**FIG.3**





**FIG. 5**





**FIG.6**

|                |                                        |         |            |
|----------------|----------------------------------------|---------|------------|
| 专利名称(译)        | 化学传感仪器及相关使用方法                          |         |            |
| 公开(公告)号        | <a href="#">EP1408817A2</a>            | 公开(公告)日 | 2004-04-21 |
| 申请号            | EP2001972941                           | 申请日     | 2001-09-05 |
| [标]申请(专利权)人(译) | 伟伦公司                                   |         |            |
| 申请(专利权)人(译)    | 伟伦 , INC.                              |         |            |
| 当前申请(专利权)人(译)  | 伟伦 , INC.                              |         |            |
| [标]发明人         | NEWMAN RICHARD W<br>DANNA DOMINICK     |         |            |
| 发明人            | NEWMAN, RICHARD, W.<br>DANNA, DOMINICK |         |            |
| IPC分类号         | A61B5/083 G01N33/497 A61B5/00          |         |            |
| CPC分类号         | A61B5/083 G01N33/497                   |         |            |
| 优先权            | 09/663698 2000-09-15 US                |         |            |
| 外部链接           | <a href="#">Espacenet</a>              |         |            |

#### 摘要(译)

用于确定至少一种蒸汽或气体的存在的装置包括至少一个外部支撑的化学传感元件，当在感兴趣的区域中检测到至少一种蒸汽时，该化学传感元件能够产生电变化。该装置包括处理电子器件，用于处理由化学传感元件产生的电变化为结果信号。一个或多个外部设置在与感兴趣区域基本上直接接触的化学传感元件提供直接反馈，而不需要泵或类似装置将样品吸入所容纳的样品室。