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Newman et al.

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(54) **CONDITIONING APPARATUS FOR A CHEMICAL SENSING INSTRUMENT**

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(52) **U.S. Cl.** **600/309**; 600/345
(58) **Field of Search** 600/309, 345–349, 600/352–361, 365, 573, 576, 578, 579, 583; 606/181–183

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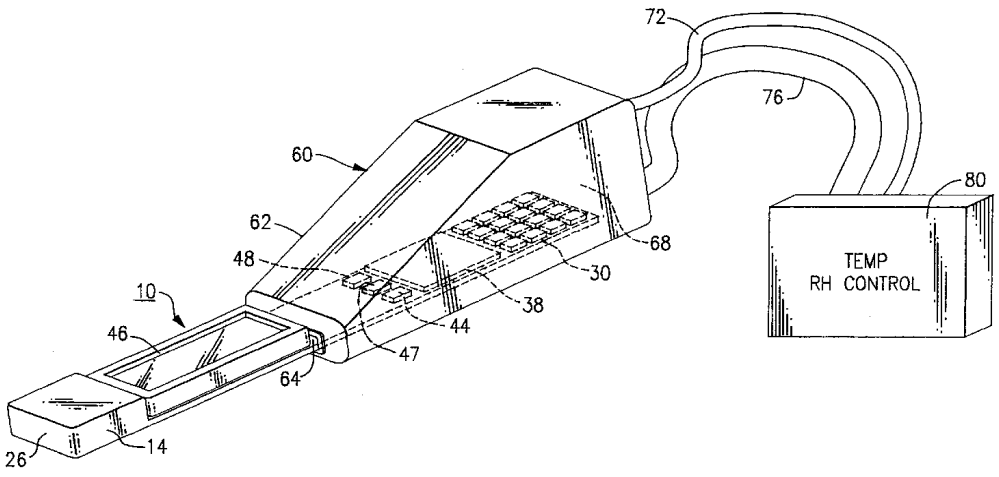
(74) *Attorney, Agent, or Firm*—Wall Marjama & Bilinski LLP

(57) **ABSTRACT**

A conditioning sleeve for a medical or an industrial diagnostic sensing instrument, in which the instrument has a support for supporting at least one chemical sensing element capable of detecting at least one chemical component of a fluid and producing an electrical signal when said at least one chemical component is detected. The sleeve includes an interior sized for enclosing at least a portion of the support including the at least one chemical sensing element and for producing environmental conditions within the sleeve interior which approximate those of an intended target area. Preferably, at least one heater or cooler and a humidifier approximate the environmental conditions of the target area in order to acclimate the sensing elements of the diagnostic instrument prior to actual use.

16 Claims, 4 Drawing Sheets



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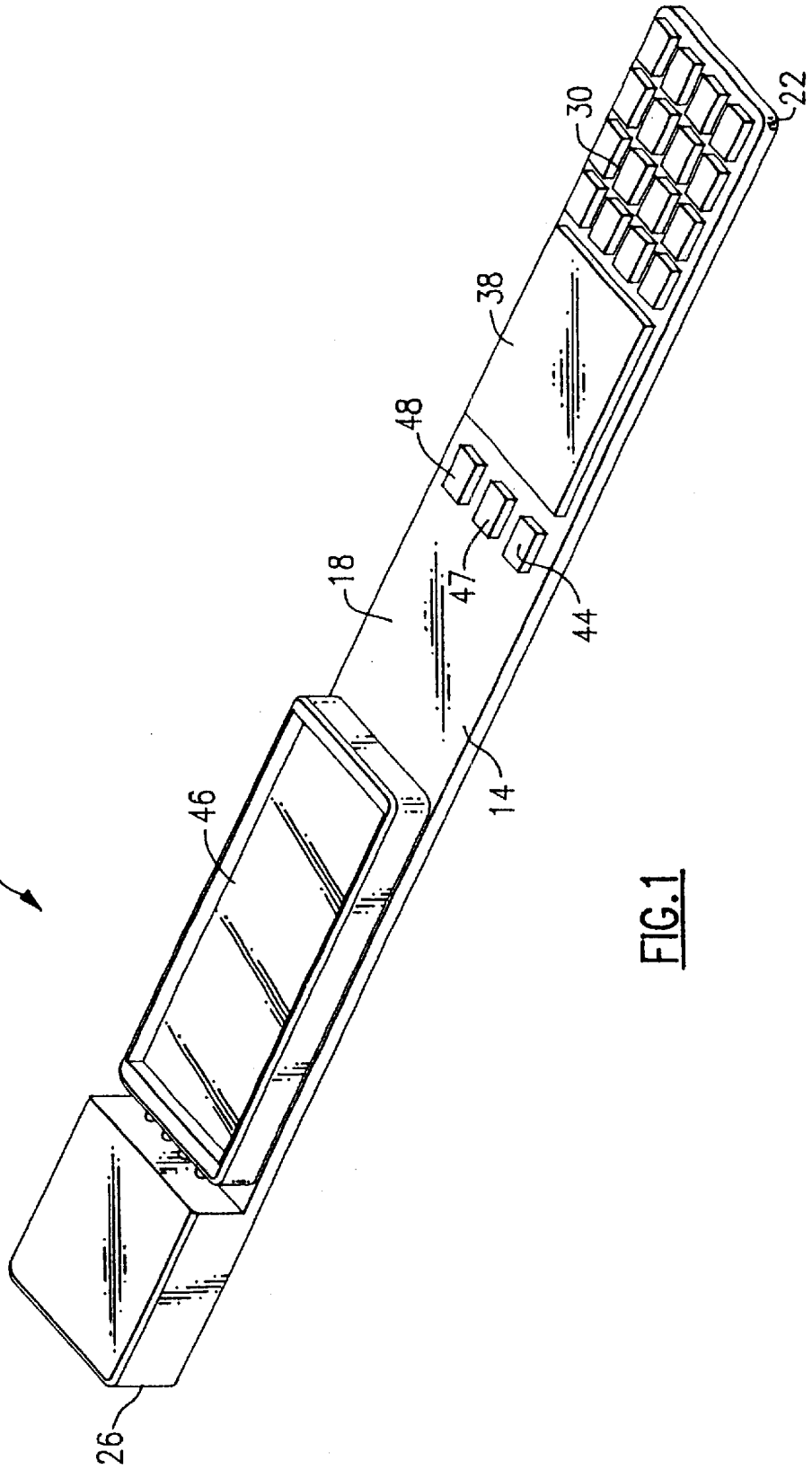

FIG.1

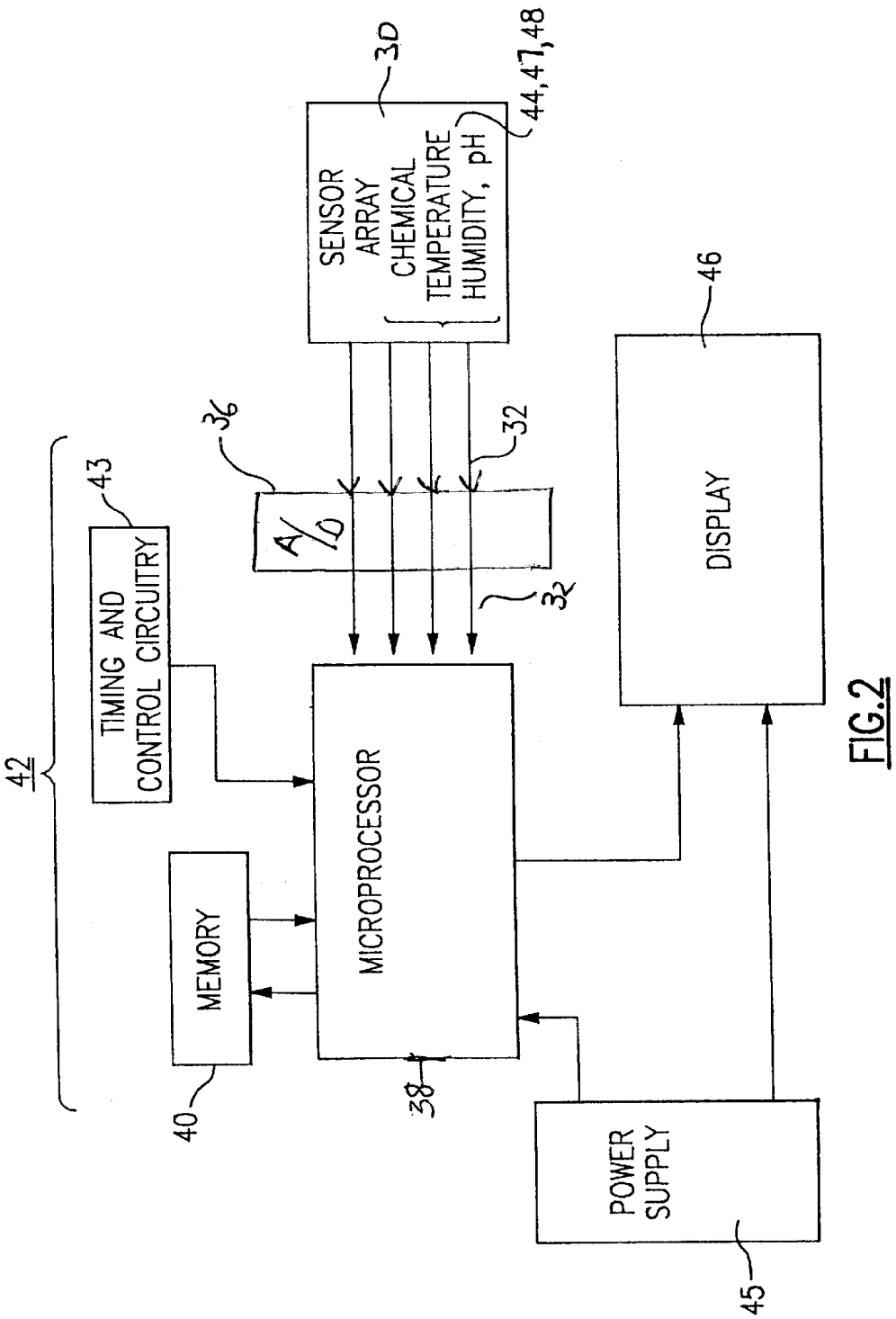
30
44,47,48
SENSOR ARRAY
CHEMICAL
TEMPERATURE
HUMIDITY, pH
46
DISPLAY
36
32
A/D
32
43
TIMING AND CONTROL CIRCUITRY
42
MICROPROCESSOR
MEMORY
40
38
POWER SUPPLY
45

FIG.2

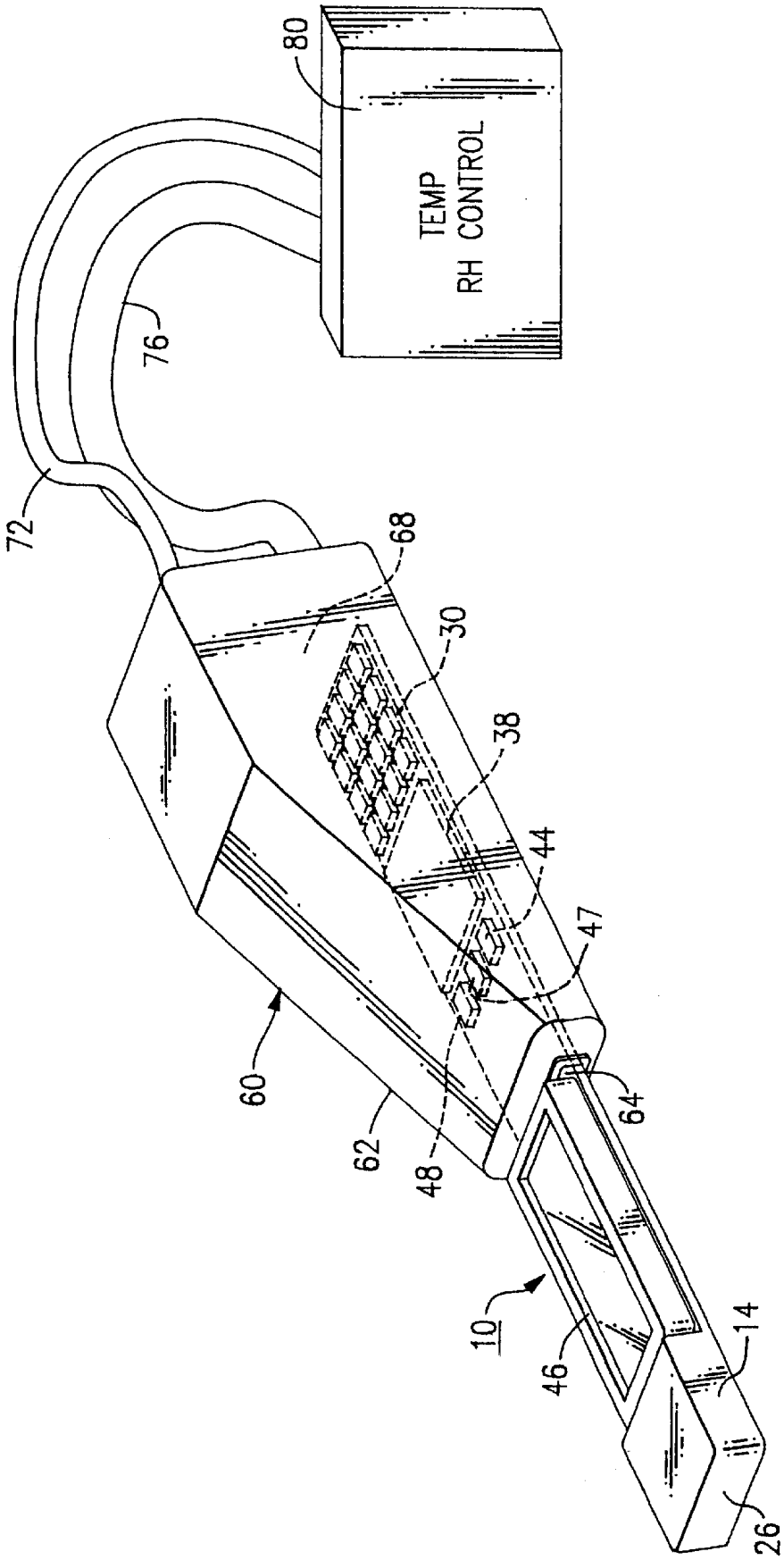

FIG.3

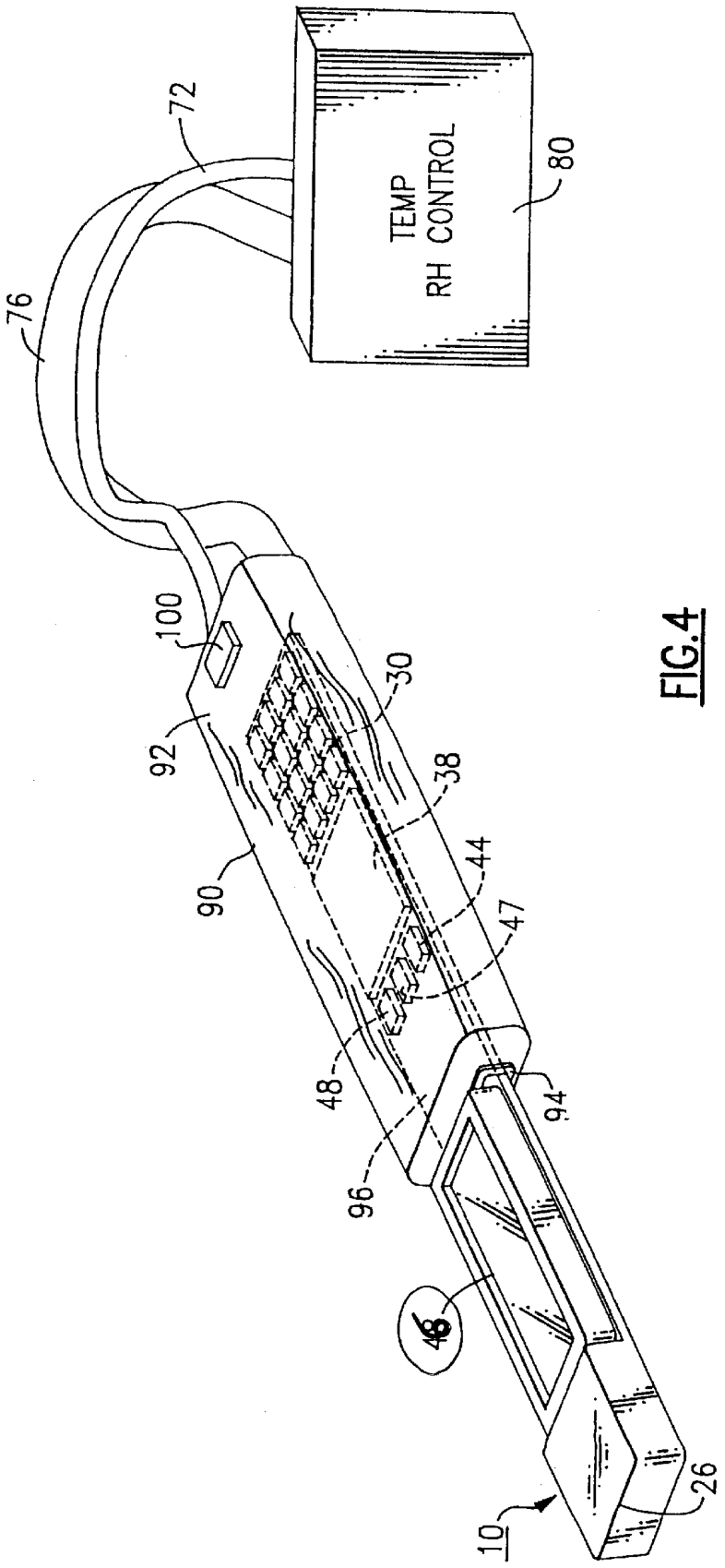

FIG.4

CONDITIONING APPARATUS FOR A CHEMICAL SENSING INSTRUMENT

FIELD OF THE INVENTION

The invention relates to the field of diagnostic fluid or vapor measurement and more particularly to a sleeve for conditioning a medical or industrial diagnostic chemical sensing instrument prior to use of the instrument.

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.

To date, there are very few known chemical sensing devices which are utilized for medical applications or purposes. In addition most known devices of this type, regardless of the field of use, require a housing which retains at least one chemical sensor. These devices further include means, such as a pump or other similar device, for inputting a portion of the atmosphere of an intended target area into the housing for evaluation by the chemical sensor(s). Such devices are 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 can detect the levels of specified gases in a gas mixture and then produce a sensor pattern which can subsequently be analyzed.

Among the problems encountered in using known electronic sensors, such as polymer gas sensors, as described by 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 Persaud et al, U.S. Pat. No. 6,013,229 to Lewis, and U.S. Pat. No. 6,093,308, to Lewis, among others, are those relating to stability. Utilizing these sensors in a medical environment; for example, to identify specific vapors indicative of a disease process by exposing the sensors to the interior of the mouth of a patient, could require that the sensors will be subjected to exposure of large changes in both temperature and humidity, as compared to those present in an ambient environment. Therefore and with present sensor technology, substantial and undesirable equalization time periods would be required.

SUMMARY OF THE INVENTION

A primary object of the present invention is to overcome the above noted deficiencies of the prior art.

Another primary object of the present invention is to provide a diagnostic testing or detecting device which can be environmentally calibrated prior to insertion into a target atmosphere in order to suitably and efficiently acclimate the device.

Therefore and according to a preferred aspect of the present invention, there is described a conditioning apparatus for a diagnostic instrument, said instrument comprising a support having at least one chemical sensing element capable of detecting at least one chemical component of a fluid and producing an electrical signal when said at least one chemical component is detected, said conditioning apparatus including:

a sleeve sized for enclosing at least a portion of said support including said at least one chemical sensing element; and

means for producing environmental conditions within said sleeve which approximate those of an intended target to be used by said diagnostic instrument.

Preferably, the sleeve includes at least one heating element which selectively heats or cools the interior of the sleeve to a predetermined temperature and/or a humidification chamber to pre-expose the chemical sensing element(s) to an environment approximately equivalent to that of the target atmosphere, such as the interior of the mouth or other suitable medical or industrial target.

According to another preferred aspect of the invention, a method is described for conditioning a diagnostic instrument, the instrument comprising a support for supporting at least one chemical sensing element capable of detecting at least one chemical component of a fluid, said method comprising the steps of:

placing a portion of said support including said at least one chemical sensing element into the interior of a sleeve;

conditioning said at least one chemical sensing element by providing an environment within the interior of said sleeve approximating that of a target;

removing said support from said sleeve; and

immediately positioning said support including said at least one chemical sensing element at the target.

Preferably, the target can be a medical and/or an industrial target.

An advantage of the present invention is that the environmental conditions of a target atmosphere can be applied to a chemical sensing element array prior to insertion therein, increasing the efficiency and also improving the reliability of the device.

A further advantage of the present invention is that a conditioning sleeve as described by the present invention can easily be attached and removed from a diagnostic sensing device which includes at least one chemical sensing element capable of detecting at least one chemical component of a fluid or fluids.

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

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a top perspective view of a diagnostic device including a plurality of electronic fluid sensing elements;

FIG. **2** is an electrical schematic diagram of the diagnostic device of FIG. **1**;

FIG. **3** is a sectional view of the diagnostic device of FIG. **1**, including a conditioning sleeve in accordance with a first embodiment of the invention; and

FIG. **4** is a perspective view of an electronic diagnostic device including a conditioning sleeve manufactured in accordance with a second embodiment of the present invention.

DETAILED DESCRIPTION

The following description relates to a preferred diagnostic chemical sensing apparatus having an environmental conditioning sleeve made in accordance with certain preferred embodiments. For purposes of the discussion which follows, "fluid" is defined as anyone of a liquid, gas or vapor. The description further includes a related method of pre-exposing at least one or a plurality of chemical sensing elements of the chemical sensing apparatus to environmental

conditions replicating those of a target environment, in which the target environment, such as an anatomical body cavity, e.g., the mouth of a patient, has environmental conditions that are considerably different than those found in ambient surroundings. It should be readily apparent, however, that other modifications and variations are possible within the spirit and scope of the inventive concepts described herein. In addition, certain terms are used throughout this discussion, such as "inner", "outer", "top", "bottom", "distal", "proximal", and the like which are used to provide a frame of reference with regard to the accompanying drawings. These terms, however, are not intended to be limiting of the present invention.

Referring to FIG. **1**, there is first depicted a diagnostic chemical sensing device **10** comprising an elongated substantially planar substrate **14**, made from any suitable biocompatible material such as composite, wood, ceramic or plastic, among others . The elongated substrate **14** according to the present embodiment has a shape and size which closely resembles that of a tongue depressor, for a specific application/use in conjunction with the mouth of a patient (not shown). Other shapes or geometries, however, can easily be imagined.

The elongated substrate **14** includes an exterior surface **18** as well as opposing distal and proximal ends **22**, **26**, respectively. A plurality or array **30** of chemical sensing elements are disposed on the exterior surface **18** of the elongated substrate **14** in the vicinity of the distal end **22**. According to the present embodiment, the chemical sensing elements of the array **30** are 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. 6,013,229 to Lewis, and U.S. Pat. No. 6,093,308, to Lewis, the entire contents of each which 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, catalytic gas sensors, quartz microbalance sensors, and others, can easily be substituted. Each of the sensing elements of the array **30** are capable of detecting a specific fluid, (e.g. gas, liquid or vapor), the presence of which produces an electrical change. The electrical change can be resistance, capacitance, transconductance, conductance, voltage, impedance, resonant frequency, or other perceivable electrical change.

The chemical sensing elements of the array **30** are attached e.g., by epoxy, glass frit, adhesive, or other means to the substrate **14**. Alternately, the sensing element array **30** can be provided as part of a plug-in electrical module (not shown) having connectors (not shown) at the distal end **22** of the elongated substrate **14**.

Referring to FIGS. **1** and **2**, a series of electrical traces **32** from each of the sensing elements of the array **30** are interconnected to provide an electrical path to a microprocessor **38**, having suitable store memory **40**, which according to this embodiment is also provided on the exterior surface **18** of the substrate **14**. Preferably, the microprocessor **38** includes certain processing electronics **42** including an A/D converter **36** and timing and control circuitry **43** used in conjunction with a reference crystal (not shown) as is known. Batteries (not shown in FIG. **1**) or other power supply **45** are electrically connected to each of the above components for powering the device **10**. Each of the above convert an electrical signal generated from the sensing elements of the array **30** into a processed output signal. The storage memory **40** of the microprocessor **38** according to this embodiment includes a look-up table (not shown) which compares incoming signals to reference values in order to provide an analysis. The results are outputted to a compact LCD **46** provided on the exterior surface **18** of the elongated substrate **14**. Alternately, an algorithm or other analytical means for providing a chemical analysis can be provided.

Still referring to FIGS. **1** and **2** and according to a typical procedure such as described in copending USSN 09/663,698, the device **10** is inserted, for example, by placing the distal end **22** of the elongated substrate **14** directly into the mouth (not shown) of a patient, with the array **30** of chemical sensing elements being positioned in substantial immediate proximity with a target environment. This environment can include that contained within the mouth itself and also can include those vapors which are present in the esophagus, stomach, throat, ear, nose, sinus, colon, urinary tract, peritoneum, vagina, lungs, and an in vivo portion of the skin etc. As noted previously, each of the sensing elements of the array **30** are manufactured so as to produce an electrical change when at least one chemical component of a particular fluid is detected. The electrical changes are then transmitted along the traces **32** to the microprocessor **38** where the processing electronics **42** compares the transmitted electrical signals with those of the stored lookup table and then displays the results of those chemical components present in the target environment.

Due to the overall sensitivity of the miniature sensing elements of the array **30** utilized in this embodiment, at least one temperature sensor and/or humidity sensor and/or pH sensor **44**, **47**, **48**, respectively, are also attached to the exterior surface **18** of the elongated substrate **14**. Signals from each of the sensors **44**, **47**, **48** are also transmitted to the microprocessor **38** for processing thereof.

Referring to FIG. **3**, there is shown a conditioning sleeve **60** made in accordance with a first preferred embodiment of the present invention and used with the described compact diagnostic device **10**. The conditioning sleeve **60** is defined by a sleeve housing **62**, made from tetrafluroethylene (teflon) or other suitable material which does not outgas or collect chemical components, and having a narrow input slot **64** that extends into an interior volume **68**, the slot being sized to receive the distal end **22** of the elongated substrate **14**. A pair of conduits **72**, **76** fluidly interconnect the interior volume **68** with a temperature/relative humidity controller **80**, which according to this embodiment provides warm moist air to the interior volume to replicate that of the intended target area (e.g., the mouth), which has a considerably higher temperature and relative humidity than ambient conditions. The controller **80** permits the temperature and relative humidity to be maintained specifically otherwise or in lieu of a control mechanism the temperature and humidity sensors **44**, **47**, of the device **10** can be utilized to monitor the conditions of the interior volume **68** until the temperature and humidity that the sensing element array **30** is exposed to approximates that of the intended target environment shown herein, though not specifically, it should be noted that the temperature/humidity controller **80** can also include a cooler element given that some conditioning of a sensing element array may involve acclimating the array to a cooler target environment.

Referring to FIG. **4**, a conditioning sleeve made in accordance with a second preferred embodiment is herein described. For the sake of clarity, similar part numbers are herein labeled with the same reference numerals. The sleeve **90** is also defined by a sleeve housing **92**, made from

tetrafluroethylene or other suitable material and having a narrow input slot **94** extending into an interior volume **96**, the slot again being sized to receive the distal end **22** of the elongated substrate **14** of the device **10**. In this instance, a heater element **100** is disposed within the interior volume **96** of the sleeve **90** wherein the sleeve is constructed to conform substantially to the shape of the substrate **14**. Similarly, the sensors **44**, **47** can be used to monitor the temperature and relative humidity of the interior volume **96** of the sleeve **90**, or these environmental conditions can be controlled using the controller **80** through conduits **72**,**76**.

PARTS LIST FOR FIGS. **1**–**4**

10 diagnostic device
14 substrate
18 exterior surface
22 distal end
26 proximal end
30 sensing element array
32 electrical traces
36 A/D converter
38 microprocessor
40 storage memory
42 processing electronics
43 timing and control circuitry
44 temperature sensor
45 power supply
46 display
47 humidity sensor
48 pH sensor
60 conditioning sleeve
62 sleeve housing
64 input slot
68 interior volume
72 conduit
76 conduit
80 heater/humidity controller
90 conditioning sleeve
92 sleeve housing
94 input slot
96 interior volume
100 heating element

We claim:

1. Conditioning apparatus for a diagnostic instrument, said instrument comprising a substrate having at least one chemical sensing element capable of detecting at least one chemical component of a fluid indicative of a condition of a target and producing an electrical signal when said at least one chemical component of a fluid is detected, said conditioning apparatus including:

a sleeve sized for enclosing at least a portion of said substrate including said at least one chemical sensing element; and

means for producing environmental conditions within said sleeve which approximate those of an intended target to be used by said diagnostic instrument.

2. Conditioning apparatus as recited in claim **1**, wherein said environmental conditions producing means includes means for at least one of heating and cooling the interior of said sleeve to at least one predetermined temperature.

3. Conditioning apparatus as recited in claim **1**, wherein said environmental conditions producing means includes means for humidifying the interior of said sleeve to at least one predetermined relative humidity.

4. Conditioning apparatus as recited in claim **1**, wherein said environmental conditions producing means includes at least one thermal conditioning element disposed within said sleeve.

5. Conditioning apparatus as recited in claim **1**, wherein said intended target is a medical target.

6. Conditioning apparatus as recited in claim **1**, wherein said intended target is an industrial target.

7. Conditioning apparatus as recited in claim **5**, wherein said medical target is a body cavity including at least one of those in the group consisting of the mouth, ear, nose, urinary tract, peritoneum, vagina, and colon.

8. Conditioning apparatus as recited in claim **5**, wherein said medical target is an in vivo portion of the skin of a patient.

9. Conditioning apparatus as recited in claim **5**, wherein said medical target is the lungs.

10. A method of conditioning a diagnostic instrument, said instrument comprising a substrate having at least one disposed chemical sensing element, said method comprising the steps of:

placing a portion of said substrate including said at least one chemical sensing element into a sleeve;

conditioning said at least one chemical sensing element by providing an environment within the interior of said sleeve approximating that of an intended target;

removing said substrate from said sleeve; and

positioning said at least one chemical sensing element in substantial direct proximity with said intended target.

11. A method as recited in claim **10**, wherein said conditioning step includes the steps of heating or cooling and humidifying the interior of said sleeve to condition said at least one chemical sensing element of said instrument from an ambient condition prior to using said instrument.

12. A method as recited in claim **11**, wherein said intended target is a medical target.

13. A method as recited in claim **12**, wherein said medical target is a body cavity selected from at least one of the group consisting of the ear, nose, sinus, mouth, urinary tract, peritoneum, vagina and colon.

14. A method as recited in claim **12**, wherein said medical target is the lungs.

15. A method as recited in claim **12** wherein said medical target is an in vivo portion of the skin.

16. A method as recited in claim **10**, wherein said intended target is an industrial area.

* * * * *

专利名称(译)	用于化学传感仪器的调节装置		
公开(公告)号	US6494833	公开(公告)日	2002-12-17
申请号	US09/884391	申请日	2001-06-19
[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 DANNA DOMINICK A		
发明人	NEWMAN, RICHARD W. DANNA, DOMINICK A.		
IPC分类号	A61B5/00		
CPC分类号	A61B5/145 A61B5/14539 A61B5/4283		
外部链接	Espacenet USPTO		

摘要(译)

一种用于医疗或工业诊断传感仪器的调节套管，其中所述仪器具有支撑件，所述支撑件用于支撑至少一个化学传感元件，所述化学传感元件能够检测流体的至少一种化学成分并在所述至少一种化学品时产生电信号检测到组件。所述套管包括内部，所述内部的尺寸适于封闭所述支撑件的至少一部分，所述支撑件包括所述至少一个化学传感元件并且用于在所述套管内部内产生接近预期目标区域的环境条件。优选地，至少一个加热器或冷却器和加湿器接近目标区域的环境条件，以便在实际使用之前使诊断仪器的传感元件适应环境。