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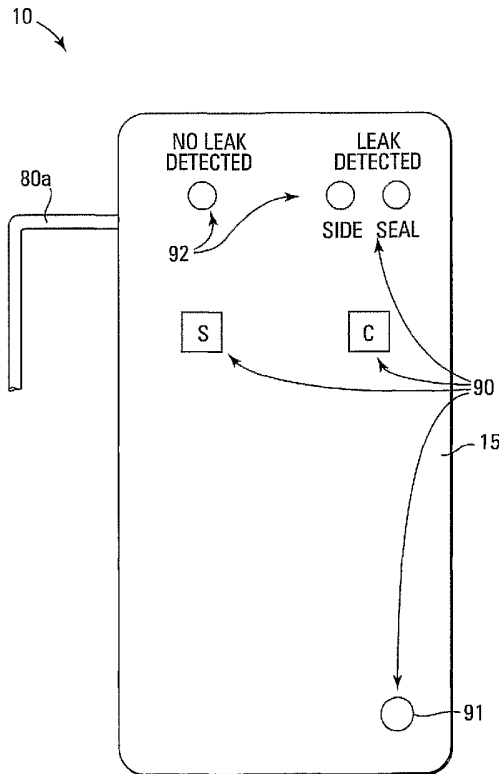
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[Continued on next page]

(54) Title: DETECTING AND REPORTING THE LOCATION OF A LEAK IN HERMETICALLY SEALED PACKAGING



(57) Abstract: An instrument for detecting and reporting the location of a leak in thin-walled hermetically sealed packaging as between a seal leak and a sidewall leak. The instrument includes a needle, a vacuum pump, a means for creating at least two different steady-state  $\Delta P$  values across the packaging, a mass flow rate sensor, at least one pressure sensor, a device for generating a perceptible signal, and a processor. The instrument is operative for sensing the external pressure outside the packaging's retention chamber, sensing the internal pressure within the packaging's retention chamber and transmitting an internal pressure signal, sensing the mass flow rate of gas pulled from the packaging's retention chamber, calculating a first ratio of mass flow rate to  $\Delta P$  at a first  $\Delta P$  and a second ratio of mass flow rate to  $\Delta P$  at a second  $\Delta P$ , calculating a variation between the first ratio and the second ratio, and generating a first perceptible signal indicating that the packaging contains a sidewall leak when the variation is equal to or greater than a threshold value and generate a second perceptible signal indicating that the packaging contains a seal leak when the variation is less than the threshold value.

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**DETECTING AND REPORTING THE LOCATION  
OF A LEAK IN HERMETICALLY SEALED PACKAGING**

**FIELD OF INVENTION**

[0001] The invention relates to instruments and techniques for detecting leaks in hermetically sealed packaging.

**BACKGROUND**

[0002] Products susceptible to spoilage, such as processed foods, nuts and sliced fruits and vegetables, are often placed in hermetically sealed packaging which has been flushed with an inert gas, such as nitrogen or argon, to achieve an oxygen concentration within the packaging of less than about 3% and thereby prolong the shelf-life of the product. Such packaging is commonly known as controlled atmosphere packaging (CAP) or modified atmosphere packaging (MAP).

[0003] Leaks in the packaging can significantly reduce the anticipated shelf life, resulting in undesired spoilage. Hence, proper quality control efforts for CAP/MAP typically involve at least periodic testing of packaging to determine if the packaging has any leaks.

[0004] A variety of instruments and methods are known for detecting leaks in hermetically sealed packaging. Leak detection typically involves the creation of a pressure differential between the pressure inside the packaging (internal pressure) and the pressure outside the packaging (external pressure) - such as by compressing the packaging or pulling a vacuum in the atmosphere surrounding the packaging, followed by the detection of any change in a given variable which could be correlated to the presence of a leak in the packaging. Specific examples include submersion of packaging into a liquid and detecting any liquid within the packaging (United States Patent No. 6,763,702 issued to Allen Chien et al.), squeezing packaging and detecting any pressure decay (United States Patent No. 6,427,524 issued to Frank Raspante et al.), squeezing packaging and detecting any volume decay (United States Patent No. 5,533,385 issued to William Frievalt) and placing packaging within a vacuum chamber and detecting any loss of vacuum (United States Patent. No. 5,150,605 issued to Edwin Simpson).

[0005] Leaks in hermetically sealed packaging typically result from (i) the presence of a pinhole in the packaging material created during manufacture of the packaging material or puncturing of the packaging during the form, fill and/or seal process (commonly known as a sidewall leak), or (ii) the presence of a channel through a seal in the packaging created by inadequate sealing of the filled packaging (commonly known as seal leaks). In the event leaks are detected in an unacceptable number of packages, the first step in correcting the problem is to identify whether the leaks are predominantly seal leaks or sidewall leaks.

[0006] While the instruments and techniques described above are generally effective for detecting leaks in hermetically sealed packaging, none are capable of detecting the presence of a leak and reliably reporting the location of the leak as between a seal leak and a sidewall leak.

#### SUMMARY OF THE INVENTION

[0007] A first aspect of the invention is an instrument for detecting and reporting the location of a leak in thin-walled hermetically sealed packaging as between a seal leak and a sidewall leak. The instrument includes (A) a needle having a lumen, (B) a vacuum pump, (C) a means for creating at least two different steady-state  $\Delta P$  values across the packaging as between a first  $\Delta P$  value and a second  $\Delta P$  value, (D) a mass flow rate sensor, (E) at least one pressure sensor, (F) a device for generating a perceptible signal, and (G) a processor. The needle is operable for perforating the hermetically sealed packaging so as to place the lumen of the needle in fluid communication with a retention chamber defined by the packaging. The vacuum pump is in fluid communication with the lumen defined by the needle for evacuating gaseous content from the hermetically sealed packaging to form an evacuated retention chamber exhibiting an internal steady-state pressure, whereby a steady-state pressure differential ( $\Delta P$ ) exists across the packaging as between an external steady-state pressure outside the retention chamber and the internal steady-state pressure within the retention chamber. The mass flow rate sensor is in sealed fluid communication with the lumen defined by the needle for sensing a first mass flow rate pulled through the lumen from the evacuated retention chamber by the vacuum pump at the first  $\Delta P$ , sensing a second mass flow rate pulled through the lumen from the evacuated retention chamber by the vacuum pump at the second  $\Delta P$ , and transmitting corresponding mass flow rate signals. The pressure sensor is operative for (i) sensing the external pressure outside the retention chamber and transmitting an external pressure signal, and (ii) sensing the internal

pressure within the retention chamber and transmitting an internal pressure signal. The processor is interconnected and programmed to (i) receive the mass flow rate signals, (ii) receive the external pressure signal, (iii) receive the internal pressure signal, (iv) calculate a first ratio of mass flow rate to  $\Delta P$  at the first  $\Delta P$  and a second ratio of mass flow rate to  $\Delta P$  at the second  $\Delta P$ , (v) calculate a variation between the first ratio and the second ratio, and (vi) generate a first perceptible signal indicating that the packaging contains a sidewall leak when the variation is equal to or greater than a threshold value and generate a second perceptible signal indicating that the packaging contains a seal leak when the variation is less than the threshold value.

**[0008]** A second aspect of the invention is a computerized method for detecting and reporting the location of a leak in thin-walled hermetically sealed packaging as between a seal leak and a sidewall leak. The method comprises the steps of (A) perforating the hermetically sealed packaging so as to place a lumen in fluid communication with a retention chamber defined by the packaging, (B) evacuating a gaseous content from the retention chamber through the lumen so as to form an evacuated retention chamber exhibiting an internal steady-state pressure, whereby a first steady-state pressure differential ( $\Delta P$ ) exists across the packaging as between an external steady-state pressure outside the retention chamber and the internal steady-state pressure within the retention chamber, (D) sensing an external pressure of a gas outside the evacuated retention chamber at the first  $\Delta P$ , (E) sensing an internal pressure within the evacuated retention chamber at the first  $\Delta P$ , (F) sensing a first mass flow rate through the lumen from the evacuated retention chamber at the first  $\Delta P$ , (F) repeating at least one of (D) and (E) along with (F) at the second  $\Delta P$ , (G) calculating a first ratio of mass flow rate to  $\Delta P$  at the first  $\Delta P$  and a second ratio of mass flow rate to  $\Delta P$  at the second  $\Delta P$ , (H) calculating a variation between the first ratio and the second ratio, and (I) generating a first perceptible signal indicating that the packaging contains a sidewall leak when the variation is equal to or greater than a threshold value and generate a second perceptible signal indicating that the packaging contains a seal leak when the variation is less than the threshold value.

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

**[0009]** Figure 1 is a front view of one embodiment of the invention depicted with an evacuated thin-walled flexible packaging.

[0010] Figure 2 is a front view of the invention shown in FIG 1 with the cover of the housing removed to facilitate viewing of the internal components.

[0011] Figure 3 is an enlarged cross-sectional side view of the distal end of the needle shown in FIG 1.

[0012] Figure 4 is an enlarged top view of one corner of a hermetically sealed packaging with a hole through the seal.

[0013] Figure 5 is an enlarged cross-sectional side view of one end of a hermetically sealed packaging with a hole through the packaging wall.

**DETAILED DESCRIPTION OF THE INVENTION  
INCLUDING A BEST MODE**

*Nomenclature*

- 10 Instrument
- 15 Housing
- 16 Inlet Port Through the Housing
- 17 Outlet Port Through the Housing
- 18 Access Port Through the Housing
- 20 Needle
- 21 Distal End of Needle
- 29 Lumen of Needle
- 31 First Pressure Sensor
- 32 Second Pressure Sensor
- 40 Vacuum Pump (Variable Speed)
- 50 Mass Flow Rate Sensor
- 60 Processor
- 65 Memory
- 70 Collective Reference to Leads 70a, 70b, 70c and 70d.
- 70a Lead from the First Pressure Sensor to the Processor
- 70b Lead from the Second Pressure Sensor to the Processor

- 70c Lead from the Vacuum Pump to the Processor
- 70d Lead from the Mass Flow Rate Sensor to the Processor
- 71 Leads from the Processor to the Battery
- 80 Collective Reference to Tubing 80a, 80b and 80c
- 80a Length of Tubing Interconnecting the Needle and the First Pressure Sensor
- 80b Length of Tubing Interconnecting the First Pressure Sensor and the Vacuum Pump
- 80c Length of Tubing Interconnecting the Vacuum Pump and the Mass Flow Rate Sensor
- 81 Length of Tubing from the Mass Flow Rate Sensor to the Exit Port through the Housing
- 82 Length of Tubing from the Second Pressure Sensor to the Access Port through the Housing
- 90 User Interface Components
- 91 Power Button
- 92 Display Device
- 100 Packaging
- 100a Thickness of Packaging Wall
- 101 Solids Content of Packaging
- 102 Gaseous Content of Packaging
- 109 Retention Chamber Defined by Packaging
- 110 Packaging Seal
- 110a Length of Packaging Seal
- 120 Hole in Packaging
- 200 Septum
- 300 Battery
- $r_{\text{seal}}$  Radius of Hole Through Seal
- $r_{\text{side}}$  Radius of Hole Through Sidewall
- C Clear Button
- S Start Button

### ***Definitions***

[0014] As utilized herein, including the claims, the phrase “*thin-walled*” means a wall having a thickness of less than about 0.1 mm.

[0015] As utilized herein, including the claims, *Poiseuille's Law* refers to the mathematical equation set forth below which was developed by the French physician Jean Poiseuille to describe the rate of flow of a fluid through a tube based upon the diameter, length and pressure drop along the tube.

$$R = [(\pi)(r^4)(\Delta P)] / (8\mu L)$$

Where: R = rate of flow  
 r = inside radius of the pipe  
 $\Delta P = P_1 - P_2$  wherein  
 $P_1$  = pressure at one end of the pipe  
 $P_2$  = pressure at the other end of the pipe  
 $\mu$  = viscosity of the fluid flowing through the pipe  
 L = length of the pipe

Poiseuille's Law can be meaningfully adapted to describe the rate of flow of a fluid through a hole in packaging by equating each of the variables in the equation as set forth below.

R = rate of flow through the hole  
 r = radius of the hole  
 $P_1$  = pressure outside the packaging  
 $P_2$  = pressure inside the packaging  
 $\mu$  = viscosity of the fluid flowing into the packaging through the hole  
 L = length of the hole, wherein L is either  
 $L_{\text{seal}}$  = length of a hole through a seal in the packaging  
 $L_{\text{side}}$  = length of a hole through a sidewall in the packaging

### *Underlying Discovery*

[0016] The invention disclosed herein is based upon the discovery that Poiseuille's Law can accurately and consistently describe the rate of flow through a seal leak in thin-walled packaging **100**, but does not accurately and consistently describe the rate of flow through a sidewall leak in thin-walled packaging **100**. Without intending to be limited to a specific theory, it is believed

that Poiseuille's Law does not accurately and consistently describes the rate of flow through a sidewall leak in thin-walled packaging **100** as such flow tends to be nonlaminar in nature.

[0017] For any given packaging **100** having a leak, the radius "r" of the hole **109** through the packaging **100** and the length "L" of the hole **109** through the packaging will be unknown, but a constant unknown. Hence for a given package **100** Poiseuille's Law can be represented as  $R = (\Delta P)(K)$  wherein  $K = [(\pi)(r^4)] / (8\mu L)$ . This equation can be rewritten as  $R / \Delta P = K$ . We have discovered that since this equation accurately describes the rate of flow through a seal leak in thin-walled packaging **100**, the ratio of R to  $\Delta P$  will remain substantially constant at different  $\Delta P$ s for seal leaks. We have also discovered that since this equation does not accurately describe the rate of flow through a sidewall leak in thin-walled packaging **100**, the ratio of R to  $\Delta P$  tends to vary substantially at different  $\Delta P$ s for sidewall leaks.

[0018] The specific extent to which the ratio of R to  $\Delta P$  varies at different  $\Delta P$ s for sidewall leaks can be readily determined by those skilled in the art through routine experimentation. This value - as a fixed value or a variable value dependent upon such variables as the actual thickness of the packaging sidewall or the value of  $\Delta P$  - can be employed as a threshold value for determining whether a ratio of R to  $\Delta P$  at different  $\Delta P$ s are sufficiently similar to indicate a seal leak or sufficiently dissimilar to indicate a sidewall leak.

### *Structure*

[0019] As shown in FIGs 1 and 2, a first aspect of the invention is an instrument **10** for detecting and reporting the location of a leak in thin-walled hermetically sealed packaging **100** as between a seal leak and a sidewall leak.

[0020] The instrument **10** can be effectively employed with a wide variety of thin-walled hermetically sealed packaging **100** ranging from fairly rigid packaging such as thin-walled polyvinyl chloride tubes, through semi-flexible packaging such as wax-coated cartons and thin-walled polyethylene bottles, to flexible packaging such as bags made from polyethylene terephthalate (*i.e.*, MYLAR®) or polyethylene films.

[0021] Referring to FIGs 1 and 2, the first aspect of the instrument **10** includes a needle **20**, a first pressure sensor **31**, a second pressure sensor **32**, a vacuum pump **40**, a mass flow rate sensor **50**, and a processor **60**. Appropriate tubing **80a**, **80b**, and **80c** (hereinafter collectively referenced as tubing **80**) sequentially interconnect the needle **20**, first pressure sensor **31**, vacuum pump **40**, and mass flow rate sensor **50**, respectively. Appropriate electrical leads **70a**, **70b**, **70c** and **70d** (hereinafter collectively referenced as electrical leads **70**) electrically connect the processor **60** to the first pressure sensor **31**, the second pressure sensor **32**, the vacuum pump **40**, and the mass flow rate sensor **50**, respectively.

[0022] As shown in FIG. 3, the needle **20** is configured and arranged with a lumen **29** and a sharp pointed distal end **21** effective for piercing a sidewall (unnumbered) of the packaging **100**. A septum **200** is preferably adhered to the sidewall of the packaging **100** - especially when the packaging **100** is highly flexible - prior to piercing of the packaging **100** with the needle **20** in order to maintain a hermetic seal around the needle **20**.

[0023] Referring to FIG. 2, a vacuum pump **40** is sealingly connected to the lumen **29** of the needle **20** by tubing **80**. Once the needle **20** has been inserted through packaging **100**, operation of the vacuum pump **40** is effective for evacuating the gaseous content **102** from the retention chamber **109** defined by the packaging **100** through the lumen **29** of the needle **20** and creating a vacuum within the retention chamber **109**.

[0024] Substantially any type of vacuum pump **40** is suitable for use in the instrument **10**, with selection dependent primarily upon choice of power source (*i.e.*, battery or electrical power lines), desired level of portability (*i.e.*, hand-held or desk-top), and intended use (*i.e.*, testing of large volume or small volume packaging). For most applications, a vacuum pump **40** with a maximum gas volumetric flow rate of about 250 to 1,000 cm<sup>3</sup>/minute and capable of pulling a maximum vacuum of about 1-15 lb/in<sup>2</sup>, preferably 4-8 lb/in<sup>2</sup>, using standard consumer batteries (*e.g.*, AAA, AA, A, C, D or 9-volt batteries) will be sufficient.

[0025] Referring to FIG. 2, a first pressure sensor **31** is employed between the needle **20** and the vacuum pump **40** for measuring and reporting the pressure within the evacuated retention chamber **109**. The internal pressure sensed by the first pressure sensor **31** after the gaseous content **102** has been evacuated from the retention chamber **109** and a steady state vacuum has been established within the retention chamber **109** is the value "P<sub>2</sub>" utilized to calculate  $\Delta P$ .

[0026] Referring again to FIG. 2, a second pressure sensor 32 is employed to measure and report the atmospheric pressure surrounding the outside of the packaging 100. The external pressure sensed by the second pressure sensor 32 is the value “ $P_1$ ” utilized to calculate  $\Delta P$ .

[0027] A cost-effective alternative to employing the second pressure sensor 32 is to utilize the first pressure sensor 31 to sense both the internal  $P_2$  and external  $P_1$  pressures by taking a pressure reading with the first pressure sensor 31 while the lumen 29 defined by the needle 20 is still in fluid communication with the surrounding environment (*i.e.*, before the needle 20 is inserted into the packaging 100).

[0028] The instrument 10 must include some means for creating at least two different steady-state  $\Delta P$  values (*i.e.*,  $P_1 - P_2$ ) across the packaging as between a first  $\Delta P$  value and a second  $\Delta P$  value. A variety of devices or systems may be employed to create two different steady-state  $\Delta P$  values including specifically, but not exclusively (i) placing the packaging 100 within a pressure chamber (not shown) and selectively changing the external pressure  $P_1$ , (ii) employing two different vacuum pumps 40 effective for creating different internal pressures  $P_2$  within the packaging 100 and a three-way valve (not shown) effective for selectively placing one of the pumps 40 in fluid communication with the lumen 29 in a first mode and placing the other pump 40 in fluid communication with the lumen 29 in a second mode, (iii) incorporating a restriction valve (not shown) between the needle 20 and the vacuum pump 40 which is effective for selectively providing essentially unrestricted fluid flow through the valve in a first mode and restricted fluid flow through the valve in a second mode, (iv) incorporating a three-way valve (not shown) between the needle 20 and the vacuum pump 40 which can be selectively opened and closed to the introduction of ambient air into the tubing 80 (provided the additional mass flow introduced into the tubing 80 when the valve is open can be accurately determined and subtracted from the mass flow rate measured by the mass flow rate sensor 50), etc. Other systems and devices for achieving a selective change in  $\Delta P$  across the packaging 100 would be known and understood by those of skill in the art and are also encompassed within the scope of this invention.

[0029] Referring to FIG 2, one method for achieving two different steady-state  $\Delta P$  values across the packaging 100 as between a first  $\Delta P$  value and a second  $\Delta P$  value is to employ a variable speed vacuum pump 40 with the speed controlled by the processor 60.

[0030] As shown in FIG. 2, a mass flow rate sensor **50** is positioned downstream from the vacuum pump **40** for measuring the mass flow rate pulled from the evacuated retention chamber **109** by the vacuum pump **40**. The mass flow rate sensor **50** may alternatively be positioned upstream from the vacuum pump **40**. The mass flow rate of interest is the mass flow rate measured after the gaseous content **102** has been evacuated from the retention chamber **109** and a steady state vacuum has been established within the retention chamber **109**. The mass flow rate measured at this stage is the value of "R" utilized in determining the ratio of R to  $\Delta P$ .

[0031] Suitable gas mass flow rate sensors **50** for use in the instrument **10** are available from a number of sources, including MKS Instruments of Wilmington, Massachusetts.

[0032] Referring to FIG. 2, the first pressure sensor **31**, second pressure sensor **32**, vacuum pump **40**, and mass flow rate sensor **50** are operably interconnected to a microcontroller or processor **60** by appropriate leads **70** for controlling operation of the various components, and receiving and processing the data signals generated by the various sensors. The processor **60** is connected to a suitable power source, such as a battery **300**, by electrical leads **71**. These components, along with the associated electrical leads **70**, tubing **80** and a power source such as a battery **300**, are preferably retained within a single housing **15** which is equipped with (i) an inlet port **16** configured and arranged to attach to a length of tubing **80a** in order to place the needle **20** into fluid communication with the components retained within the housing **15**, (ii) an outlet port **17** attached by a length of tubing **81** to the mass flow rate sensor **50** for venting gas pumped from the retention chamber **109** by the vacuum pump **40**, and (iii) an access port **18** attached by a length of tubing **82** to the second pressure sensor **32** for placing the second pressure sensor **32** into sensible contact with the surrounding atmosphere.

[0033] Referring to FIG. 1, the front face (unnumbered) of the housing **15** includes the necessary and appropriate user interface components **90** including (i) a power ON/OFF switch **91**, and (ii) a device for generating a perceptible signal **92** indicating that the packaging **100** contains no detectable leak, a seal leak or a sidewall leak, such as a speaker (not shown), an LCD screen (not shown), a plurality of labeled or color coded lights as shown in FIG 2, etc. The display device **92** is operably interconnected to the microcontroller or processor **60**.

[0034] As shown in FIG. 2, the microcontroller or processor **60** includes associated memory **65** for storing data values received from the various sensors **31**, **32** and **50**.

[0035] The microcontroller or processor **60** is programmed to (1) operate at a first mode (*e.g.*, operation of a variable speed vacuum pump **40** at a first speed) effective to create a first steady-state  $\Delta P$  value and receive data values at the first  $\Delta P$  for (i) the pressure outside the packaging **100** from the second pressure sensor **32** - which will be utilized as the value " $P_1$ " to determined the value of the first  $\Delta P$ , (ii) the pressure inside the packaging **100** from the first pressure sensor **31** - which will be utilized as the value " $P_2$ " to determine the value of the first  $\Delta P$ , and (iii) the mass flow rate through the hole **120** from the mass flow rate sensor **50** - which will be utilized as the value " $R$ " in calculating a first ratio of mass flow rate to  $\Delta P$  at the first  $\Delta P$ , (2) operate at a second mode (*e.g.*, operation of a variable speed vacuum pump **40** at a second speed) effective to create a second steady-state  $\Delta P$  value and receive data values at the second  $\Delta P$  for (i) the pressure outside the packaging **100** from the second pressure sensor **32** - which will be utilized as the value " $P_1$ " to determined the value of the second  $\Delta P$ , (ii) the pressure inside the packaging **100** from the first pressure sensor **31** - which will be utilized as the value " $P_2$ " to determine the value of the second  $\Delta P$ , and (iii) the mass flow rate through the hole **120** from the mass flow rate sensor **50** - which will be utilized as the value " $R$ " in calculating a second ratio of mass flow rate to  $\Delta P$  at the second  $\Delta P$ . After receiving these values, the microcontroller or processor **60** then either (A) generates a perceptible signal indicating NO LEAK DETECTED when the value of  $R$  - at the first  $\Delta P$  and/or second  $\Delta P$  as appropriate - is less than a predetermined threshold value for  $R$ , or (B) proceeds to determine whether the detected leak is a seal leak or a sidewall leak when the value of  $R$  is greater than or equal to the predetermined threshold value for  $R$ . The microcontroller or processor **60** determines whether the detected leak is a seal leak or a sidewall leak by (i) calculating a first ratio of mass flow rate to  $\Delta P$  at the first  $\Delta P$ , (ii) calculating a second ratio of mass flow rate to  $\Delta P$  at the second  $\Delta P$ , (iii) calculating a variation between the first ratio and the second ratio, and (iv) comparing the calculated variation to a threshold value for the variation. The microcontroller or processor **60** generates a first perceptible signal indicating that the packaging contains a SIDEWALL LEAK when the variation is equal to or greater than the variation threshold value, and generates a second perceptible signal indicating that the packaging contains a SEAL LEAK when the variation is less than the variation threshold value.

[0036] The instrument **10** may be constructed as a portable or desktop unit.

*Use*

[0037] A unit of packaging **100** having a solids content **101** and a gaseous content **102** is selected for analysis. The power switch **91** is depressed to activate the instrument **10** and the START button **S** is depressed. The instrument **10** may optionally direct the user to insert the needle **20** into the test packaging **100**.

[0038] A septum **200** is optionally adhered to the outer surface (unnumbered) of the packaging **100**. The septum **200** and packaging **100** are perforated by the distal end **21** of the needle **20** a sufficient distance to place the lumen **29** into fluid communication with the retention chamber **109** defined by the packaging **100**. The needle **20** is then left in the inserted position for the balance of the procedure.

[0039] The user then initiates analysis by again pressing the START button **S**. The vacuum pump **40** is activated to evacuate the gaseous content **102** from the retention chamber **109** defined by the packaging **100** and pull a vacuum. The processor **60** causes whatever means is employed for creating different steady-state  $\Delta P$  values across the packaging **100** (*i.e.*, a variable speed vacuum pump **40**) to operate in a first mode which will create a first  $\Delta P$  across the packaging **100**. The first pressure sensor **31**, second pressure sensor **32**, and mass flow rate sensor **50** are activated to sense the internal pressure " $P_2$ ", external pressure " $P_1$ " and mass flow rate " $R$ " through the tubing **80** at the first steady-state  $\Delta P$ . These values are transmitted to the processor **60**.

[0040] After receiving these values the processor **60** compares the value of  $R$  with a threshold value for  $R$  and in the event the actual value for  $R$  is less than the threshold value for  $R$ , generates a perceptible signal indicating NO LEAK DETECTED and discontinues the balance of the testing procedure.

[0041] In the event the actual value for  $R$  is greater than or equal to the threshold value for  $R$ , the processor **60** then causes whatever means is employed for creating different steady-state  $\Delta P$  values across the packaging **100** to operate in a second mode which will create a second  $\Delta P$  across the packaging **100**. The first pressure sensor **31**, second pressure sensor **32**, and mass flow rate sensor **50** are again activated to sense the internal pressure " $P_2$ ", external pressure " $P_1$ "

and mass flow rate "R" through the tubing **80** at the second steady-state  $\Delta P$ . These values are also transmitted to the processor **60**. It is noted that in circumstances where the external pressure  $P_1$  is not likely to change during the testing procedure, the external pressure  $P_1$  need not be sensed and transmitted a second time.

[0042] The processor **60** then utilizes the set of transmitted values for  $P_1$ ,  $P_2$  and R at each  $\Delta P$  to determine whether the detected leak is a seal leak or a sidewall leak by (i) calculating a first ratio of mass flow rate to  $\Delta P$  at the first  $\Delta P$ , (ii) calculating a second ratio of mass flow rate to  $\Delta P$  at the second  $\Delta P$ , (iii) calculating a variation between the first ratio and the second ratio, and (iv) comparing the calculated variation to a threshold value for the variation. The microcontroller or processor **60** generates a first perceptible signal indicating that the packaging **100** contains a SIDEWALL LEAK when the variation is equal to or greater than the variation threshold value, and generates a second perceptible signal indicating that the packaging **100** contains a SEAL LEAK when the variation is less than the variation threshold value.

[0043] It is noted that in the event the packaging **100** has multiple holes **120** through the packaging sidewall or multiple holes **120** through the packaging seal **110**, the instrument **10** remains effective for accurately reporting the presence of a leak and the location of the leak as between a seal leak or a sidewall leak. However, in the relatively rare event that the packaging **100** has at least one hole **120** through the sidewall and at least one hole through the seal **110**, the existence of a leak will be reported but the location of only one leak will be reported.

[0044] The testing procedure can then be repeated by pressing the CLEAR button **C** followed by pressing the START button **S**.

I claim:

1. An instrument comprising:
  - (a) a needle having a lumen operable for perforating a hermetically sealed packaging so as to place the lumen of the needle in fluid communication with a retention chamber defined by the packaging;
  - (b) a vacuum pump in fluid communication with the lumen defined by the needle effective for evacuating gaseous content from the hermetically sealed packaging to form an evacuated retention chamber exhibiting an internal steady-state pressure, whereby a steady-state pressure differential ( $\Delta P$ ) exists across the packaging as between an external steady-state pressure outside the retention chamber and the internal steady-state pressure within the retention chamber;
  - (c) a means for creating at least two different steady-state  $\Delta P$  values across the packaging as between a first  $\Delta P$  value and a second  $\Delta P$  value;
  - (d) a mass flow rate sensor in sealed fluid communication with the lumen defined by the needle for sensing a first mass flow rate pulled through the lumen from the evacuated retention chamber by the vacuum pump at the first  $\Delta P$ , sensing a second mass flow rate pulled through the lumen from the evacuated retention chamber by the vacuum pump at the second  $\Delta P$ , and transmitting corresponding mass flow rate signals;
  - (e) at least one pressure sensor operative for (i) sensing the external pressure outside the retention chamber and transmitting an external pressure signal, and (ii) sensing the internal pressure within the retention chamber and transmitting an internal pressure signal;
  - (f) a device for generating a perceptible signal; and
  - (g) a processor interconnected and programmed to (i) receive the mass flow rate signals, (ii) receive the external pressure signal, (iii) receive the internal pressure signal, (iv) calculate a first ratio of mass flow rate to  $\Delta P$  at the first  $\Delta P$  and a second ratio of mass flow rate to  $\Delta P$  at the second  $\Delta P$ , (v) calculate a variation between the first ratio and the second ratio, and (vi) generate a first perceptible signal indicating that the packaging contains a sidewall leak when the variation is equal to or greater than a threshold value and generate a second perceptible signal indicating that the packaging contains a seal leak when the variation is less than the threshold value.

2. A method comprising the steps of:
- (a) perforating a hermetically sealed packaging so as to place a lumen in fluid communication with a retention chamber defined by the packaging;
  - (b) evacuating a gaseous content from the retention chamber through the lumen so as to form an evacuated retention chamber exhibiting an internal steady-state pressure, whereby a first steady-state pressure differential ( $\Delta P$ ) exists across the packaging as between an external steady-state pressure outside the retention chamber and the internal steady-state pressure within the retention chamber;
  - (c) sensing an external pressure of a gas outside the evacuated retention chamber at the first  $\Delta P$ ;
  - (d) sensing an internal pressure within the evacuated retention chamber at the first  $\Delta P$ ;
  - (e) sensing a first mass flow rate through the lumen from the evacuated retention chamber at the first  $\Delta P$ ;
  - (f) repeating at least one of (c) and (d) along with (e) at the second  $\Delta P$ ;
  - (g) calculating a first ratio of mass flow rate to  $\Delta P$  at the first  $\Delta P$  and a second ratio of mass flow rate to  $\Delta P$  at the second  $\Delta P$ ;
  - (h) calculating a variation between the first ratio and the second ratio; and
  - (i) generating a first perceptible signal indicating that the packaging contains a sidewall leak when the variation is equal to or greater than a threshold value and generate a second perceptible signal indicating that the packaging contains a seal leak when the variation is less than the threshold value.

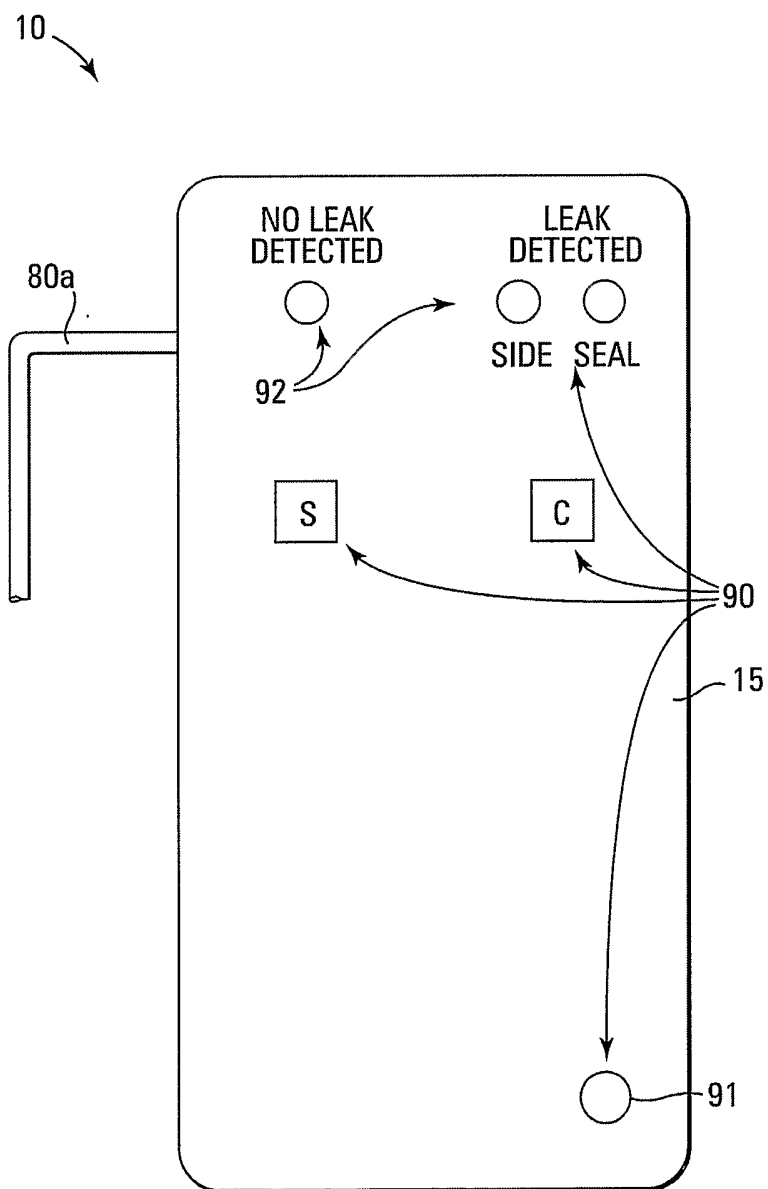


Fig. 1

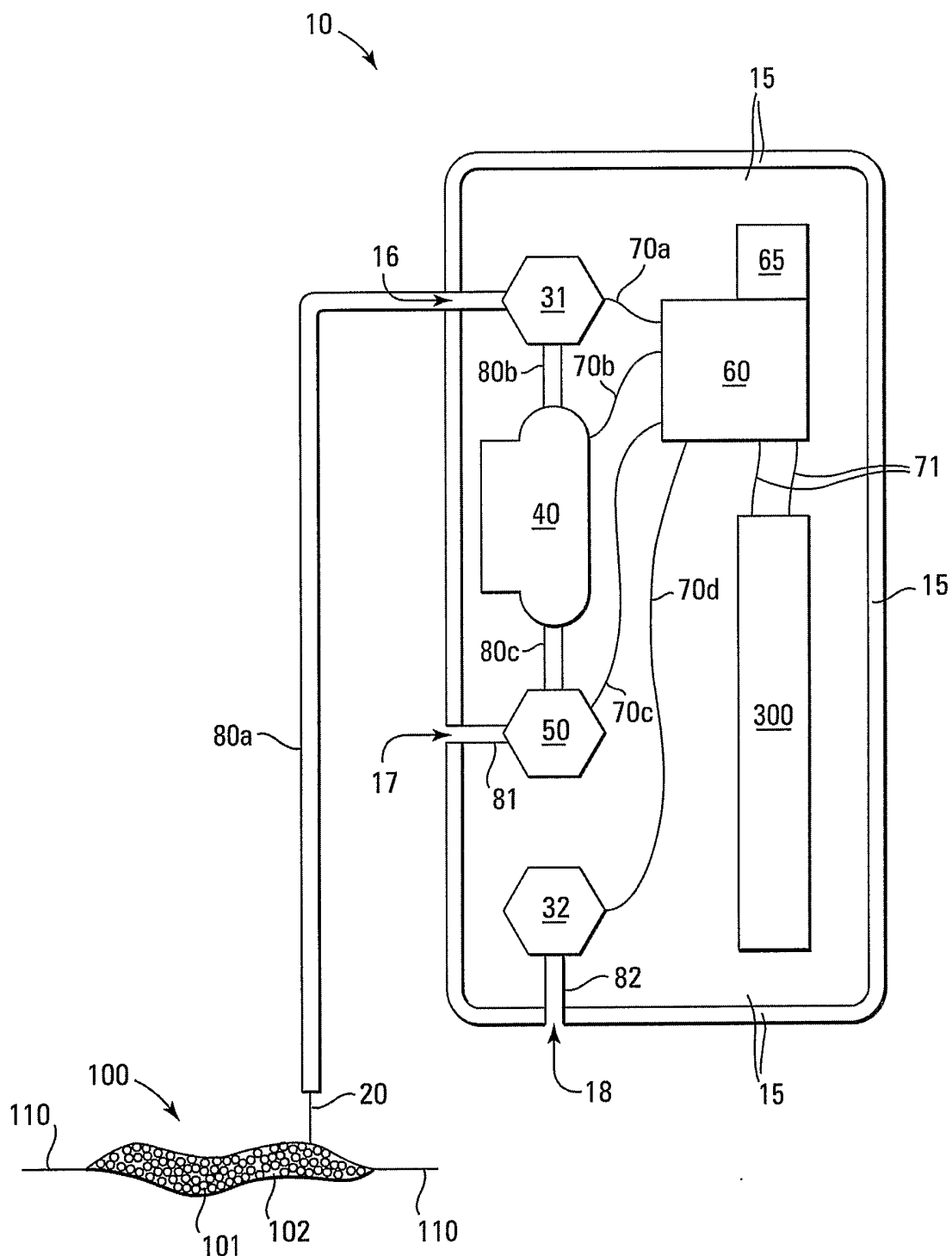
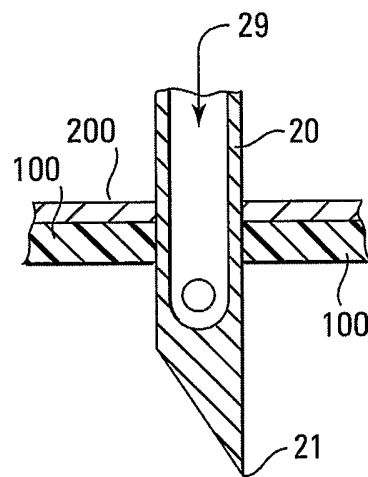


Fig. 2



*Fig. 3*

